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ATTD 2018 Invited Speaker Abstracts

001

OPENING CEREMONY

ATTD8-0442

BEYOND A1C: CONSENSUS ON CGM OUTCOMES

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Recently several panels of physicians, researchers, regulators and individuals with diabetes who are experts in continuous glucose monitoring (CGM) technologies addressed the issue how to move beyond the HbA1c measurement as the sole marker of glycemic control. Although HbA1c has proved extremely valuable in for patient management, is a valuable measure of population health and remains a validated indicator of glycation as a risk factor for complications, it is not as helpful for personalized diabetes management. The recently published ATTD consensus recommendations represent the current understanding of how CGM results can affect outcomes. CGM, either from real-time use (rtCGM) or intermittently-viewed continuous glucose monitoring (iCGM), address many of the limitations inherent in HbA1c testing and SMBG. The reliable identification of hypoglycemia is just as important as the measurement of time in range (70–180 mg/dl [3.9–10.0 mmol/L]) in clinical trials. Quantifying the duration and extent of glycemic excursions and glycemic variability (by Coefficient of Variation, which defines stable glucose levels as CV <36%) provides another parameter for assessing glucose control. In clinical practice, the advanced metrics of assessing continuous glucose data are appropriate as outcome parameters that complement HbA1c for a wide range of patients with diabetes and should be considered for use to help them improve glycemic control provided that appropriate educational and technical support is available. CGM is also a robust research tool, and CGM data should be recognized by governing bodies as a valuable and meaningful endpoint to be used in clinical trials of new drugs and devices for diabetes treatment.

002

GLUCOSE METRICX: BEYOND HBA1C

ATTD8-0439

GLYCATION GAP: DOES IT EXIST?

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Clinicians are frequently confronted with discrepancies between glucose values as noted by patients in their diaries and HbA1c values. Also in the CGM era, such discrepancies are still seen. A number of explanations can co-exist. One of these is the glycation gap, the variation in HbA1c that can be seen between patients with identical mean glucose values. Whether this is more than a mathematical phenomenon has been debated extensively over the years. More recently, the glycation gap has been proposed as a possible explanation for the ACCORD findings. All this will be put in perspective in this talk.

003

NEXT GENERATION SOLUTIONS

ATTD8-0446

DEALING WITH PATIENT AND DEVICE UNCERTAINTY IN THE ARTIFICIAL PANCREAS: MULTI-ZONES, ADAPTATION, AND TRUST INDICES

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There have been well over 100 closed-loop clinical trials for the artificial pancreas (AP), in one form or another, over the last decade. Commercial devices have also begun to emerge in the last year. Yet, in many respects, we have only scratched the surface on algorithms for the AP as most of the current studies focus on fairly traditional implementations of fuzzy logic, PID, or MPC control systems. In this talk I will highlight recent algorithm engineering results, including preliminary clinical data, on the next wave of algorithms that address the intrinsic uncertainty in the patient-device feedback loop. These include extensions of our successful zone MPC design to address multiple distinct zones and trust indices.

004

NEXT GENERATION SOLUTIONS

ATTD8-0447

NEXT GENERATION AUTOMATED INSULIN DELIVERY: ON-BODY ECOSYSTEM FOR AUTOMATED INSULIN DELIVERY IN TYPE 1 DIABETES

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Fully automated glucose management technologies for type 1 diabetes (T1D) require advanced sensing and decision-support to function safely, intelligently, and efficiently. Recent academic studies as well as early commercial devices have shown to be safe and effective in managing glucose across different challenges and in outpatient settings.

New developments in wearable and embedded technology, big data, fog and edge computing, wireless networks and cloud computing, provide a unique opportunity to enhance automation, manage therapeutic strategies and improve quality of care in people with T1D by exploiting real-time medical information from a vast collection of sensors: the medical internet-of-things (mIoT). In this talk I will highlight recent developments to enable on-Body Ecosystem including a new platform to support the clinical investigation of mIoT, results of fully embedded control design on a chip and strategies to integrate mIoT in diabetes research and clinical studies.

005

DEBATE: PUMP V. SENSOR – WHAT IS MORE IMPORTANT

ATTD8-0438

SENSORS

H. De Vries[1]

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Drs Leelarathna and DeVries will debate on the pro's and cons of insulin pump therapy in the age of continuous glucose monitoring. Continuous glucose monitoring seems to establish itself as the standard of care. What, if any, is the role of insulin pumps nowadays?

006

CLOSING THE LOOP - NIH-FUNDED AP RESEARCH EFFORTS

ATTD8-0452

THE INTERNATIONAL DIABETES CLOSED-LOOP (IDCL) TRIAL

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The iDCL Trial is supported by NIH/NIDDK grant UC4 DK 108483. This project includes three parallel protocols testing different hardware implementations of the inControl closed-loop algorithm originally developed at the University of Virginia and then refined by TypeZero Technologies, Inc. A fourth protocol is planned for 2018 to test a control algorithm developed at Harvard University. The objectives of the iDCL Trial are to:

1. Establish the artificial pancreas as a clinically accepted treatment for type 1 diabetes that is superior to the current sensor-augmented pump (SAP) therapy;
2. Establish that contemporary smart phones provide accessible and user-friendly AP platform that facilitates technology proliferation and gives physicians and patients the freedom to select optimal treatment;
3. Generate data able to satisfy safety and efficacy requirements by regulatory agencies regarding the clinical testing of artificial pancreas device systems in the target population of people with type 1 diabetes.

The iDCL Trial runs in 7 research sites in the U.S. and 3 sites in Europe coordinated by the Jaeb Center for Health Research. iDCL Protocol 1 is a trial of mobile closed-loop control using a smart phone to run the control algorithm and communicate with subcutaneous continuous glucose monitor (CGM) and an insulin pump. Protocol 2 uses a mobile system as well, but the CGM is expected to be an implantable device. Protocol 3 is testing a hardware configuration in which the control algorithm is embedded in the insulin pump. First data from the active protocols will be presented.

007

BIOTECHNOLOGY AND DIABETES

ATTD8-0443

POST-TRANSPLANT DIABETES IN CHILDREN AND ADOLESCENTS

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POST-TRANSPLANT DIABETES IN ADOLESCENTS

Post-transplant diabetes (PTDM) is an increasingly recognized and common consequence of solid organ transplantation, present in the majority in the immediate post-operative period and persisting as ''permanent'' diabetes in about 12%–15% of transplant recipients. The immediate precipitating factors are the immunosuppressive agents; the calcineurin inhibitors cyclosporine and tacrolimus, the molecular target of Rapamycin (mTOR) inhibitors sirolimus and everolimus, and high dose steroids. Together, these agents combine to exert toxic effects on beta cells, induce hypomagnesemia, impair insulin secretion, and induce insulin resistance, magnified by the inflammatory stressors of surgery. In addition, a family history and identified SNPs associated with T1DM, T2DM, and MODY suggest a genetic predisposition in those who go on to permanent DM after the acute high doses of immuno-suppressive drugs used to manage rejection are reduced. The criteria applied to diagnose DM are based on glucose concentrations as defined by the American Diabetes Association and/or the International Diabetes Federation; HbA1c measurements should not be used to diagnose PTDM because they are unreliable in the post-operative patient receiving blood products. PTDM may interfere with post-operative healing and recovery and predisposes the patient to infections, particularly HCV and CMV viral infections. Sepsis is more likely in those with poorly controlled PTDM. The source of the donor organ also influences the subsequent development of PTDM; e.g. cadaveric kidney organs, related or unrelated to the recipient, are more likely to be associated with PTDM than organs from living donors, and this has been attributed to higher levels of pro-inflammatory cytokines in the organs of deceased donors. Some studies suggest that PTDM is associated with reduced graft survival, as well as increased mortality in older subjects.

Treatment in the immediate post-operative period should be based on insulin; intravenous infusion provides the most convenient means to titrate insulin requirement to caloric intake and existing glucose concentration and may be added to parenteral

nutrition. Transitioning to insulin pump therapy with CGM represents the next phase. Oral agents are not recommended as their absorption may be impaired post-operatively, and metabolism of the drug may be altered by the degree of functioning kidney or liver. When renal or hepatic function has stabilized, the GLP1 agonists or DPP-4 inhibitors are preferred since their action is glucose dependent and avoids potential side effects of hypoglycemia. Oral agents such as Meglitinide, short-acting sulfonylureas and Metformin may be considered if renal function as determined by GFR is stable; SGLT2 inhibitors are not approved for use in adolescents and have undesirable side effects including monilial skin infections. Permanent DM in such post-transplant subjects requires careful monitoring of metabolic control and potential effects of ongoing anti-rejection medications on organ function and development of microvascular complications such as nephropathy and retinopathy.

In summary, PTDM represents a relatively common problem in those receiving solid organ transplants, with unique features of etiology, impact of the transplanted organ on DM, of DM on the transplanted organ, and special considerations in the choice of treatments and monitoring requirements. Inclusion of diabetes specialists in the management team improves likelihood of better outcomes.

008

NUTRITION AND FOOD TECHNOLOGIES

ATTD8-0433

PERSONALIZED MEDICINE APPROACHES FOR TREATMENT OF DIABETES BASED ON GUT MICROBIOTA

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Accumulating evidence supports a causal role for the human gut microbiome in obesity, diabetes, metabolic disorders, cardiovascular disease, and numerous other conditions, including cancer. Here, I will present our research on the role of the human microbiome in health and disease, aimed at developing personalized medicine approaches that combine human genetics, microbiome, and nutrition.

In one project, we set out to understand personal variation in the glycemic response to food, tackling the subject of personalization of human nutrition, a poorly studied topic that is critical for human health and to billions of people predisposed to, or suffering from, obesity, T2D and related co-morbidities. We assembled a 1,000 person cohort and measured blood glucose response to >50,000 meals, lifestyle, medical and food frequency questionnaires, blood tests, genetics, and gut microbiome. We showed that blood glucose responses to meals greatly vary between people even when consuming identical foods; devised the first algorithm for accurately predicting personalized glucose responses to food based on clinical and microbiome data; and showed that personalized diets based on our algorithm successfully balanced blood glucose levels in prediabetic individuals. These results suggest that personalized diets may successfully modify elevated postprandial blood glucose and its metabolic consequences.

I will also present our studies of the mechanisms driving recurrent post-dieting obesity in which we identified an intestinal microbiome signature that persists after successful dieting of obese mice. This microbiome signature contributes to faster weight regain and metabolic aberrations upon re-exposure to obesity-promoting conditions and transmits the accelerated weight regain phenotype upon inter-animal transfer. These results thus highlight a possible microbiome contribution to accelerated post-dieting weight regain, and suggest that microbiome-targeting approaches may help to diagnose and treat this common disorder.

Finally, we studied the relative contribution of host genetics and environmental factors in shaping human gut microbiome composition. To this end, we examined genotype and microbiome data in over 1,000 healthy individuals from several distinct ancestral origins who share a relatively common environment, and demonstrated that the gut microbiome is not significantly associated with genetic ancestry. In contrast, we find significant similarities in the microbiome composition of genetically unrelated individuals who share a household, and show that over 20% of the gut microbiome variance can be explained via environmental factors related to diet, drugs and anthropometric measurements. We define the term biome-explainability as the variance of a host phenotype explained by the microbiome after accounting for the contribution of human genetics. Consistent with our finding that microbiome and host genetics are largely independent, we find significant biome-explainability levels of 24%–36% for several human traits and disease risk factors. We also successfully replicated our results in an independent Dutch cohort. Overall, our results suggest that human microbiome composition is dominated by environmental factors rather than by host genetics.

009

MAJOR OUTCOME STUDIES: THE HypoDE STUDY

ATTD8-0437

INDEPENDENT COMMENTARY

H. De Vries[1]

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Dr DeVries will give an independent commentary on the HypoDE study design, execution, results and their implication for clinical practice.

010

CLINICAL DECISION SUPPORT SYSTEMS (ADVISORS)

ATTD8-0453

DECISION SUPPORT SYSTEMS

B. Kovatchev[1]

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In this presentation we discuss decision support systems (DSS) based on self-monitoring of blood glucose (SMBG), or on continuous glucose monitoring (CGM). These expert systems are designed to provide actionable information to physicians and/or patients with diabetes.

A general rule is that the density of the data determines the treatment options recommended by the DSS. For example, SMBG data could provide information that enables insulin dosing advice, risk stratification, long-term glycemic pattern recognition, or estimated HbA1c (eA1c). Because CGM data are time series reflecting a person's metabolic system's dynamics,

CGM expands these treatment options further, with prediction of events (e.g. hypo- or hyperglycemia), real-time trends, alerts, and warnings, real-time monitoring, or automated closed-loop control. The common framework of SMBG- and CGM-based DSS is a set of algorithms that are deployed to estimate the metabolic state of a person from available data, taking into account the data density.

We illustrate this concept by reviewing a DSS originally developed at the University of Virginia and further refined by TypeZero Technologies, Inc. This DSS uses CGM data to track actionable risk over time and to deliver feedback through modules implemented on mobile devices, including: (1) Exercise Advice; (2) Sleep Advice; (3) Smart Bolus Calculator; (4) Hypoglycemia Prediction; (5) Estimated HbA1c (eA1c), and (6) *In Silico* Therapy Optimization. Data from ongoing NIH-supported trial are presented to illustrate the ability of the DSS to improve the glycemic control of insulin pen users with type 1 diabetes.

011

ISPAD SESSION: CHALLENGES WITH DIABETES TECHNOLOGY IN PEDIATRICS

ATTD8-0448

DIABETES TECHNOLOGY IN ADOLESCENTS AND YOUNG ADULTS

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Teenage years and the transition to adulthood are difficult phases of human life due to rapid physical development and deep emotional change that occur during that period. Managing a demanding chronic disease such as diabetes adds additional burdens and complexity to lives of adolescents and young adults with diabetes. It is not surprising that HbA1c levels are notably worse among 13 to 25-year olds with only 14% meeting the recommended target HbA1c level as compared to other age groups. Consequently, adolescents and young adults are identified as one of the most challenging patients within the diabetes population.

The path to improve diabetes management for this challenging, high-risk group of patients has never been simple, however the brainchild of technology revolution, the diabetes technology, has become a strong contender to confront the obstacles by becoming an ally for people with diabetes and their clinicians. From continuous glucose monitors and automated insulin delivery systems to smart phone applications, the integration of diabetes technology to daily management of diabetes has been tangible and continuously evolving. There is a growing body of evidence supporting the favorable impact of diabetes technology on diabetes management and indicating that there is still room for improvement.

The presentation will be centered on the successes and limitations of diabetes technology in managing adolescents and young adults with diabetes. New and advanced diabetes technology systems on the horizon to transform diabetes management and unlock opportunities will be summarized with an emphasis on innovative methods to break the vicious cycle of poor treatment compliance and poor glycemic control in adolescents and young adults with diabetes.

012

ISPAD SESSION: CHALLENGES WITH DIABETES TECHNOLOGY IN PEDIATRICS

ATTD8-0457

DIABETES TECHNOLOGY IN DEVELOPING COUNTRIES

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The concept of developing countries varies depending on the source and sometimes is translated as ''less developed country'' or ''underdeveloped country''. Criticism for using this term is that it assumes the desire to develop following the traditional western model. The most used index to define it is the Human Development Index (HDI) (1). Independently of the political debate, this term is accepted as referring to sovereign states that are categorized into Medium or High HDI, meaning that they are not in the extremes of Low or Very High HDI. Brazil, China, and India, among others, are some examples of this idea of ''developing countries''.

Characteristics that can be similar between these major ''developing countries'' are related to their extensive territories, their vast population, and high GDP. Also, there are internal cultural and economic discrepancies and social and health inequities. Due to all these characteristics, and to those depending on political and governmental decisions, it is not possible to delineate a pattern of general technologic evolution of a developing country. Even the evaluation focused only on diabetes technology also brings forward many inequalities, due to geographic, economic and politic disparities. In this context, the growth of technology is erratic and dependent on particularities of societies and governments.

Technology in all these countries still has room to increase. In Brazil, a recent nationwide survey with 2961 patients showed that only 1.2% of type 1-diabetes patients using insulin infusion systems in tertiary hospitals. This number is probably smaller for the whole population of patients with type 1 diabetes, since those hospitals have diabetes specialists and would probably be the places for public patients to get access to the newest technologies (2).

Limitations to the increase in the use of new technologies in diabetes are related to many aspects, mainly health care system, social and educational issues and medical knowledge and experience.

Each country has its characteristics regarding the organization of health care system. In Brazil, there is a clear division of attendance of patients with diabetes in three major areas – public, insured and private patients. The majority of patients is on public services, without resources to obtain medication and other required diabetes material (strips, meters, needles, syringes, pens, etc.) and receives NPH and Regular insulin from the government for free. Insulin analogs and pumps may be obtained only via administrative or judicial processes. Insured and private patients are usually from a better economic background and have more resources to acquire better treatment.

Social and educational challenges include unstructured families, unprepared schools, and difficulties in understanding basic concepts and putting into practice multiple daily injections, frequent monitoring and calculations. Families coming from better educational and economic levels have a better level of education and these aspects reflect on HbA1c outcomes (3), which is also true when considering only children and adolescents (4).

The unfamiliarity of healthcare professionals with new technologies is also a barrier to its use. In a survey during the Brazilian Congress of Pediatric Endocrinology in 2013, where the majority of the doctors were specialists and shared professional time between public and private attendance, 63.6% of the 316 respondents had no patients on pumps, 21.7% had one patient and only 14.8% had 2 or more patients on pumps (5). One of the reasons detected was the lack of previous experience and knowledge to initiate and manage technical aspects of the systems.

The conclusion is that developing countries have to overcome many barriers to increase the use of health technology in general, diabetes-related technology specifically.

Diabetologists and pediatric diabetologists are fundamental in this process, to get and spread knowledge and information about new treatments, products and services, and their impact on diabetes management. In accordance with these ideas, it is key that they get deeper into diabetes technology, looking after information, participating in clinical protocols, advisory boards, and international congresses, paving the way to bring technology closer to the regular clinician that attends the patients. In this matter, Brazil is a good example, the last decade being full of novelties. There was an increase in information exchange, culminating in the first ATTD out of Europe, the ATTD Latin America in Rio in 2012 and the creation of a Department of Technology by the Brazilian Diabetes Society in 2014, for the first time. Following these steps, in 2015 the first International Symposium of Diabetes Technology in Brazil was organized, followed by the second one in 2017, consolidating the necessity and the interest on new technologies to improve diabetes treatment in the country. These kinds of initiatives are happening all over the world, and assistance of non-profit diabetes societies, like IDF and ISPAD is essential.

Technology is also important for these developing countries because it can be used to fight obstacles and to mitigate costs. Even with difficulties, the creativity and tenacity of a few diabetologists are leading to the creation of facilitators, like telemedicine, bolus calculators, in-patient insulin dose calculator and diabetic ketoacidosis apps, which are accessible and helps spread good practices more easily (6,7).

Parallel efforts have taken parent associations and medical societies to press the government and insurance companies to accelerate the access to technology for a greater number of patients, grounded on evidence-based data.

The balance between the socio-economic limitations and the increase in technology remains a big challenge for the majority of the countries, but probably more prevailing for ''developing countries.'' From their point of view, it is imperative that diabetes technology evolution considers lowering costs and being clinically meaningful, so the equation of information plus access can reach to better long-time control and quality of life.

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013

DIABETES INDIA SYMPOSIUM

ATTD8-0456

USE OF INSULIN PUMP THERAPY IN INDIA - THE CHANGING PERSPECTIVE

M. Chawla[1], *P. Chawla*[1], *M. Kothari*[1], *F. Shaikh*[1]

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Insulin pump therapy in the management of hyperglycaemia has been used for more than three decades globally and more than a decade in India.

Available since 2013, insulin pumps have benefitted more than 10,000 diabetic individuals and the acceptance rate is fast growing. A number of studies and guidelines have been published and pump therapy is also starting to gain reimbursement from many government bodies and government undertakings.

The current availability and pricing of insulin pumps and consumables are as follows:-

i) Non-sensor augmented pumps eg. Paradigm 715 (~2,640$)
ii) Sensor augmented pumps eg. Minimed 640G (~8,750$), Paradigm Veo (~6,250$) and Paradigm 722 (~3,580$) with the predictive alerts/low glucose suspend algorithm.
iii) Infusion Set (~60$/month)
iv) Reservoir (~23$/month)
v) Glucose sensor (~55$/sensor)

There are ongoing efforts to raise Insulin Pump therapy awareness at the level of the medical practitioners and general population by means of providing - structured learning programs, clinical insights and indications for insulin pump therapy in practice.

The usage is divided as follows, most with T1DM (60% vs 40% T2DM), males (60% vs. 40% females), in the age group of 13–30 years of age (35% vs 25% <12 years and between 30–60 years 25% vs 15% >60 years). The average insulin infusion set use is for 4.5 days. The adoption rate is maximum in West India 37%, next in the South with 33%, North 25% and the rest in the East.

014

DIABETES INDIA SYMPOSIUM

ATTD8-0455

SMBG AND VIRTUAL CONSULTATION DTMS (R): 20 YEARS' EXPERIENCE

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SMBG AND VIRTUAL CONSULTATION VIA DTMS®: 20 YEARS' EXPERIENCE

Benefits of a structured Self-Monitoring of Blood Glucose (SMBG) Program on improving glycemic control has been well-documented by many studies in individuals with diabetes. Data obtained from SMBG can help clinicians to take appropriate treatment decisions. It also allows the patients to more clearly understand the impact of their daily routine on their glycaemic status, thus making them more informed as well as motivated towards a judicious diabetes management. However, such benefits of SMBG can only be gained with a collaborative effort from both the patients and the clinicians alike in terms of obtaining SMBG data, analysing and interpreting them to make appropriate decisions on medications, diet and lifestyle choices.

In 1990's, in India, glucose meters were not popular. Procuring a glucose meter was considered too expensive, the results were inaccurate and of no benefit not only among patients but also among physicians. It was in the second half of the 1990s, the benefits of intensive glucose management in type 2 diabetes from the landmark clinical trial UKPDS began throwing new light into the science of diabetes. It was quite evident that patients despite the practice of blood glucose monitoring are not able to achieve the targets when the possibilities of a complementing technology were thought of.

The major gaps in diabetes management have always been lack of awareness on prevention of complications, suboptimal dosages prescribed to avoid fatal hypoglycemia, non-adherence to drugs, wrong timing of medications, wrong injection techniques, non-compliance to diet and exercise advice. In usual diabetes practice, patients were making physical visits to the hospital either once in three to five months or whenever they developed severe symptoms due to the disease or its complications. The minority of patients religiously maintaining an SMBG diary definitely demonstrated slight improvement but still continued to have either persistent hyperglycemia or life-threatening hypoglycemia.

In 1997, 'Jothydev's Diabetes Research Centre (JDC)' introduced a new concept in diabetes care, a structured SMBG program integrated with Electronic Medical Records, telephone and internet – ''Diabetes Tele Management System'', DTMS®, as a cost-effective tool to achieve and sustain all major and minor targets in a comprehensive diabetes therapy protocol. That was an era when the technologies such as computer, internet etc. were just gaining popularity and our main intention of implementing DTMS® was to educate and empower the enrolled patients at periodic intervals via virtual visits for an indefinite period.

DTMS® allows individualization of therapeutic goals with the aid of its five components: 1) Customized software which includes Electronic Medical Records with different user interfaces, 2) Decision support system provided by the multidisciplinary diabetes care team (consisting of well-trained physicians, diabetes educators, dieticians, nurses, pharmacists, and psychologists), 3) Telecommunication with the help of telephones, emails, and internet using a secure website, 4) Telemedicine enabled customized empowerment, education, and troubleshooting, and 5) Ensuring multidrug compliance by linking DTMS® with diabetes pharmacy.

Patient enrolled with DTMS® report blood glucose values, that is, fasting, 2 hrs after breakfast, lunch, and dinner and 3 am whenever necessary, through the telephone/email/secure websiteand the DTMS® team titrates the dosages of the medications based on the individualized targets. Education modules on insulin injection technique, diet, exercise, use of a glucometer, hypoglycemia, and compliance to medications are also administered to the patient during every teleconsultation customized to the patient-specific characteristics. The above-mentioned components gradually evolved over the years when the team gained more experience. DTMS® thus precludes frequent physical visits to the hospital, saving the time and money spent in travelling, waiting, consulting the physician and dietician, and the number of working hours/days which would have otherwise been lost.

The primary barrier to optimal glycemic control is the possible risk of hypoglycemia. However, patients enrolled with DTMS® have been found to achieve treatment goals with only lesser instances of hypoglycemia. Frequent telemedicine follow-ups based on SMBG enable slow and steady titration of drug doses, reducing the risk of hypoglycemia. Sustained glycemic goals further translate to the prevention of vascular complications among these patients. Due to the phenomenal developments in technologies in the past one decade, DTMS® has gone through several upgradations to match with the changing requirements.

Though there are several telemedicine programs in existence, DTMS® stands unique due to individualization of therapeutic goals based on the various parameters of the patient. Blood glucose, HbA1c, blood pressure, and LDL targets are reviewed and reassessed once in every 3–6 months for each patient. Any diabetes patient can avail the DTMS® program as the minimal requirement is a land phone/cell phone. The patient can save time and money, staying at the comfort of their home or office. In an earlier study, which analysed the cost-effectiveness of DTMS® in 1000 T2DM patients, there was a statistically significant reduction in the glycemic and non-glycemic parameters with no reported hypoglycemia in 84% of the patients.

Despite the multiple benefits of this system, there exist many challenges for running this program such as communication errors, inefficiency to respond to questions, unavailability of the physician to attend the phone, etc. which has been resolved to a significant extent through rigorous and continuous training and supervision of the multidisciplinary team. Many a time, patients also tend to approach telemedicine facility as the first resort for myriad problems. However, after the initial period of intensive follow-up, most of the patients develop sufficient disease awareness and management skills and require only lesser follow-ups in the long run. The scalability of the facility to the ever-increasing patient population, as well as, across multiple centers is another challenge. The effort required to successfully set up the DTMS® infrastructure and operational facilities to be available round the clock is also a major limitation.

Studies have shown that it is the aggressive treatment regimens adopted, as well as, the real-time, frequent communication with medical professionals through DTMS®, that brings in improved clinical outcomes. While only 3–4% of the diabetes patients in India achieve all the treatment targets, the success rate of DTMS® is a phenomenal 86%. With the adoption of artificial intelligence and a further improvised version, DTMS® carries the potential to evolve as a cost-effective solution to the day to day challenges of diabetes management.

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015

DIABETES INDIA SYMPOSIUM

ATTD8-0441

CGM & AGP - HOW TO REAP ITS BENEFIT FROM BUSY CLINICS IN INDIA?

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Context

India is a country to 68 million diabetics representing wide varieties of patients across its geography with varied cultures. This provides the scope of experiencing any drug or device across a large population with different cultural backgrounds, different environments, different food/lifestyle habits, different genetic constitution and different glycemic profiles. Indians are proven to have a special Asian-Indian phenotype that is more prone to diabetes with more visceral adiposity. Moreover, food habits defined by larger carbohydrate load of the meal make the further push towards such lifestyle diseases. Various estimates including the IDF have predicted India to show an exponential rise in diabetes burden by 2030. Recently concluded studies have shown the shift of diabetes from urban to rural areas within India in context with the speed of rising diabetes burden. All these factors showcase increasing need for advanced technologies and treatment options for diabetes treatment in India.

Glucose Monitoring in DM in India

Evidence speaks that glucose monitoring in diabetes is critical to manage glycemic levels and reduce glycemic variability.

Despite of the disease burden, India still faces inertia in adopting glucose monitoring as an integral part of diabetes management. Self-monitoring of blood glucose (SMBG) that dates to 1960's era is yet in nascent stages of utilization. In a country-wide epidemiology study, it has been observed that only 11% of diagnosed diabetes population in India practices SMBG. While we are moving fast towards digitalization, the acceptance of technology in this field remains restricted.

Amongst the newer advancements available are more accurate auto-calibrated glucometers with biosensors and the technique of continuous glucose monitoring (CGM).

Concept of CGM & AGP

In studies, SMBG captures blood glucose levels only at tested times and has been found to miss the ability to detect hypoglycemic episodes about 60% of the times due to its periodic testing. On the other hand, HbA1c, which is considered as the standard tool today only provides an average of glucose control not giving any information on highs or lows experienced by a diabetic patient. To reveal the complete picture of a patient's glycemic profile, the technology of continuous glucose monitoring was developed. CGM is an effective way to record the fluctuations in glucose levels in the diabetes patients throughout the day. It reads glucose levels in interstitial fluid every 10 seconds and records the same every 5 minutes via a tiny sensor inserted just beneath the skin.

As a limitation of each innovation gives scope for further discovery, the constant calibration of the CGMS posed a restraint on the wide usage of CGMS. This gave opportunity to Flash glucose monitoring (FGM) to enter the glucose monitoring space in diabetes – named such due to its ability to provide glucose data on demand instantly. This is one step further advancement where due to factory calibration, device does not require any manual calibrations and records data for up to 14 days – essentially ruling out all finger pricks that were to be used with CGMs. So far, this is the longest period available for sensor wear for any CGM.

Over and above the application of automated Ambulatory Glucose Profile (AGP) reporting system to FGM made it very convenient for both doctors as well as patients with diabetes to understand their diurnal fluctuations. AGP provides both graphic and quantitative characterizations of diurnal glucose patterns making it possible to identify previously undetectable abnormalities in glucose metabolism. First developed by Dr Roger Mazze, while AGP was initially applied to represent episodic SMBG in 1987, it's adoption by FGM is a breakthrough in diabetes for the various clinical benefits it offers in both Type 1 and 2 diabetes.

Rationale for CGM/AGP in India

Science is constantly evolving and more dynamic is the field of diabetes. As guidelines suggest, diabetes treating physicians must intend attaining optimal blood glucose control avoiding hypoglycemia, knowing its deleterious effects on diabetes morbidity & mortality. Focus is largely shifting from a single parameter in control to more time spent in range for the diabetes patient to battle complications and expect a better quality of life while dealing with this lifestyle disease.

As a country, we are moving towards a stronger economy with improving paying capacity. The health awareness quotient also has seen a decent rise in the current days with advent of pedometers and fitness bands.

In the light of above, glucose monitoring must be seen as an integral part of diabetes management. As outlined earlier, CGM has potential to highlight diurnal fluctuations and thereby enable better glucose control in the patients with diabetes. With India having substantial contribution in disease burden of the globe, economy taking a hit due to costs spent in diabetes management due to lack of timely care, there is definite need for cost-effective approaches such as CGMs to improve overall diabetes outcomes for India.

AGP enables the day to day assessment of glycemic status of the patient – the hypoglycemias, the hyperglycemias, the time spent in range for the patient, and even the impact of food or any activity such as exercise on the glucose levels. This is aligned with the tech-savvy population of India that believes in empowerment towards self-care. AGP using professional or personal (Freestyle Libre Pro & Libre respectively) can

facilitate multiple benefits such as lifestyle modification, therapy optimization, and more-over cost-saving. If understood and applied correctly, this can be a very significant tool to cause paradigm shift in the history of diabetes management in India.

Strategy for Adoption in India

Currently AGP seems to be underutilized in India due to several factors. The diabetes explosion overwhelms the number of diabetes treating physicians. Doctor-patient ratio in India is down to 1:1700 as estimated by the world health organization (WHO). Hence limited time available for the doctors to spend per patient. Our approach to have the technology leveraged to the core must be multi-targeted basis the above factors.

Firstly, education of HCPs across country, on the technology of FGM/CGM and the technique of interpretation and clinical co-relation is extremely crucial. Innovative educational models should be largely driven by the industry partners of the field.

Considering people wanting to take charge of their disease control, patient awareness becomes key to have the utilization of this tool for their betterment. This may also reduce the pressure on the HCP and time spent by them to counsel and convince the ideal patients for AGP/CGM.

My own clinical experience:

We have designed an even more cost effective and time effective method for the use of AGP in our regular patients. After the application of AGP we ask the patient to come back to the clinic on the 6^{th}–10^{th} and 14^{th} day. On the day of application the patient is properly educated on all aspects of diabetes self management life physical activity, diet and treatment advised. On the 6^{th} day the patient is asked to visit our clinic and the glycemic variability is analyzed and the importance of lifestyle modification reinstated. On the 10^{th} day, again the data is analyzed and if necessary the therapy is titrated according the statistics from the AGP data. The same is repeated on the 14^{th} day. If the patient is from a distant place the patient is asked to visit the clinic only on the 7^{th} and 14^{th} day with the above method, sometimes only on the 14^{th} day for very exceptional cases.

We found out that by doing so, the next 2 to 3 consecutive HbA1c of the patient were always within the target range without application of the next FGM device. The constraint of application of a second FGM device is the patient reluctance to apply; lack of understanding for the importance of the device despite educating the patient, also cost for a few patients.

Conclusion: Looking at longer period outcomes, government initiatives should be proposed to include this cost-effective tool as standard of care before formulating treatment of any patient with diabetes.

Finally, the medical & paramedical framework in India needs restructuring to support the busy clinics to be able to prioritize time spent with each patient through appropriately trained and designated channels. This points towards centers of excellence that have adequately trained staff to ensure meeting all needs and queries of patients off-loading the burden from the busy doctors to concentrate on team-work in holistically treating the patients with diabetes.

Additionally, the insights provided by AGP/CGM may change the disease representation at follow-ups and probably lower the complication burden and thereby the overall disease morbidity leading to less time spent on obtaining health care.

In the longer run, with the personal version of the FGM (Freestyle Libre), patients may lead much more quality lives being empowered enough to manage their health and enabled to make more informed decisions about their diabetes.

016

DIABETES TECHNOLOGY FOR TYPE 2 DIABETES

ATTD8-0451

INSULIN PUMP AND CGM

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Many patients with type 2 diabetes struggle to achieve adequate glucose control despite escalation of therapy including complex insulin regimens with multiple daily injections. Until 2014, pump therapy was used mostly for treating type 1 diabetes but scarcely in type 2 diabetes patients. Few randomized studies compared pump therapy to multiple daily insulin injections and their results were conflicting and suggested that pump therapy may be beneficial in a subgroup of patients with the most severe type 2 diabetes condition. Retrospective observational studies also suggested that pump therapy may be beneficial in advanced type 2 diabetes and that insulin needs remained constant on pump therapy. The randomized multicenter OPT2MISE study which included 331 patients treated with high dose multiple daily insulin injections and having poor glycemic control has demonstrated a significant HbA1c reduction without hypoglycemia increase after 6 months of intensive pump therapy, when compared with multiple injections. Weight gain was moderate and insulin needs were reduced by 20% on pump therapy. A french observational study including 161 type 2 diabetes patients with the same characteristics demonstrated the durability of pump therapy efficacy which was maintained during a 5-year follow up. In both studies, psycho-cognitive functions and age were not limiting factors precluding pump efficacy, and pump therapy gave a metabolic benefit in the classic type 2 diabetes patient but also in the latent autoimmune diabetes in adult (LADA) and in patients with the most advanced beta cell failure. In summary, pump therapy may be considered a valuable option in type 2 diabetes strategy for insulin therapy intensification. Continuous glucose monitoring (CGM) may be utilized in type 2 diabetes patients for different purposes : as a diagnostic tool, the professional blinded CGM may help understanding the glycemic profile in patients failing to reach the glycemic targets, in order to determine the respective influence of the fasting and postprandial components of overall hyperglycemia and choose antihyperglycemic agents targeting the former and/or the later component. Personal CGM may be used by patients with intensified insulin therapy including multiple daily injections and insulin pump therapy in order to finely tune their insulin regimen and therefore optimize glucose control.

017

DIABETES TECHNOLOGY FOR TYPE 2 DIABETES

ATTD8-0444

ARTIFICIAL PANCREAS

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Experience of closed-loop insulin delivery in patients with type 2 diabetes (T2D) has been quite limited so far. However,

whereas between-day variability of glucose levels is less present in T2D than in T1D patients, some specificities of insulin therapy in T2D can support some interest in considering algorithm-driven insulin delivery. Insulin resistance, interferences between endogenous insulin action and action from exogenous insulin, trend for defective skills in adjustment of insulin doses based upon measured glucose values leading to conservative attitude promote assistance of patients in managing insulin therapy. A feasibility trial in hospital has been reported by the Cambridge group in insulin-naïve patients. The observed benefit of closed-loop insulin delivery was a reduction of time spent in hyperglycemia, mostly overnight. This result was associated with higher plasma insulin levels which might have some deleterious effects on body weight on long-term. Investigations are needed to assess whether closed-loop has similar benefits without increased insulin delivery in insulin-treated patients with type 2 diabetes. A more recent assessment of a fully-automated closed-loop insulin infusion without meal bolus has been conducted by the same group in T2D inpatients against standard hospital management of insulin delivery. It showed increased percent time spent in a near-normal range thanks to a reduction of time spent in hyperglycemia as well as less glucose variability, with no increase of percent time spent in hypoglycemia and similar insulin doses. The combination of a lower average glucose level with no increase of hypoglycemia is of interest, especially for patients with a previous or recent history of cardiovascular events. Whether such results could be sustainable on longer term in outpatients with T2D need to be investigated.

018

PUMPS, SENSORS & FGM – WHERE DO WE GO?

ATTD8-0450

REVIEW OF FLASH GLUCOSE MONITORING – BENEFITS VS CAPILLARY AND VS CGM

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Flash glucose monitoring (FGM) with the Freestyle Libre™ system is currently widely available in Europe and North America. Glucose recordings and information about glucose trend and rate of change are transferred from the sensor to a reader or to a mobile app when the user actively scans the sensor; otherwise the data are automatically captured every 15 min on the sensor. The device is factory-calibrated and needs no calibration against capillary blood glucose measurements during the up to 14 day wear-time. In head-to-head comparisons, the accuracy of the system was similar to or better than other CGM-based glucose sensors, and the device has been approved for non-adjunctive use. Accordingly, the recordings can be used for making therapy-adjustments without confirmatory blood glucose measurements. In randomized, controlled trials (RCTs) comparing FGM and self-monitoring of blood glucose (SMBG), the use of FGM has been shown to markedly increase the frequency of self-testing, resulting in reduced exposure to hypoglycemia, increased time-in-range, decreased glucose variability and improvements in various patient-reported quality of life aspects. Safety concerns have mainly been related to skin reactions, affecting about 5–10% of the users. In non-randomized studies, the feasibility of FGM has been demonstrated in pediatric cohorts (above four years of age) and in pregnancy. In addition, real-world data have revealed a clear relationship between scanning frequency and glycemic control (HbA1c), and prevention of hypoglycemia, in FGM users. It is concluded that FGM offers great potentials as a replacement of conventional SMBG in the self-management of glycemic control. RCTs comparing the effectiveness of FGM and CGM in various diabetes cohorts are lacking, and are greatly warranted to facilitate clinical recommendations of different glucose monitoring systems.

019

PUMPS, SENSORS & FGM – WHERE DO WE GO?

ATTD8-0454

INSULIN PUMP TREATMENT IN TYPE 2 DIABETES: IMPACT ON INSULIN RESISTANCE AND RELATED METABOLIC PARAMETERS

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Previously, it was suggested that the continuous subcutaneous insulin infusion (CSII) is a promising therapy for the growing number of patients with type 2 diabetes (T2D) showing the failure to achieve optimal metabolic control on previous insulin treatment, which was finally documented in the OpT2mize trial. Moreover, it has been shown that the lower doses of insulin by CSII vs multiple daily injections (MDI) were able to achieve good metabolic control, measured by HbA1c, fasting and post-prandial glucose and less glucose variability, suggesting that CSII provides better basal insulin delivery.

Few focused studies and meta-analyses, until now, have assessed the changes of insulin secretion and insulin sensitivity during the CSII treatment in T2D. Some of the studies with short-term insulin treatment suggested improvements both in insulin sensitivity and beta cell function. In contrast, other studies, including ours, could not demonstrate the significant improvements in insulin sensitivity in the whole group of treated patients. However, we detected a significant improvement in the subgroup of highly insulin resistant subjects, which was consistent with the previous data in the obese T2D diabetes patients. The results imply that the selection criteria for the use of CSII in T2D should include the estimation of insulin resistance, which can be significantly improved in the highly insulin resistant patients with the use of this treatment approach.

020

PRACTICAL CLOSED LOOP THERAPY: EDUCATION AND IMPLEMENTATION

ATTD8-0445

TRAIN THE TRAINER: WHAT DO CLINICIANS NEED TO UNDERSTAND ABOUT CL TECHNOLOGY?

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Diabetes educators and clinicians caring for patients that use Closed Loop (CL) technology must understand each component of the system, the insulin pump, the glucose sensor and the software with the control algorithm (may be integrated into the insulin pump or on a separate device). Thus a step-by-step

approach should be used to guide the patient into the system. In addition to knowledge about insulin pump treatment, the most important requirement is establishing best practices regarding realtime glucose sensor use (rtCGM). Indeed psychological research shows that patients with experience in rtCGM reported higher satisfaction with and higher overall acceptance of CL therapy. Depending on the underlying algorithm the CL adjusts insulin dosing based on this information and administers the calculated amount of insulin by basal rate adjustment, additional insulin bolus deliveries or in case of bi-hormonal approaches achieving counter-regulatory responses with glucagon or other hormones. Even if the system automatically doses insulin a basic knowledge of the functioning of the respective system is the prerequisite for proper education. The educators must enable the patient to detect any malfunction in time and avoid the feeling of data overload with such a system. This education has to be balanced not to compromise the trust in the system as too much patient interference by responding too quickly to imminent hypoglycemia or hyperglycemia instead of ''Letting the algorithm do the work'' is counterproductive. This trust into the CL can often only be achieved through a detailed analysis of the data together with the patient.

021

TURKISH DIABETES TECHNOLOGY GROUP: GLYCEMIC VARIATION IN DIABETES CONTROL

ATTD8-0449

NEW SHORT AND LONG ACTING INSULIN ANALOGUES AND GLYCEMIC VARIABILITY

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Rediscovering the First Miracle Drug: New Short and Long Acting Insulin Analogs and Glycemic Variability

Insulin has been named as the ''Miracle Drug'' after its discovery in 1921 and transformed diabetes mellitus from a death sentence in to a chronic disease with a demanding treatment regimen. Over the course of decades, scientists searched for methods to mimic physiologic insulin action for an ultimate goal of achieving ideal glycemic control. The quest for ideal insulin treatment led to the development of new insulin formulations that are categorized by differences in onset and duration of action, concentration, and route of delivery.

The ultra-long acting basal insulins and basal insulins with little or no peak effect, and with a near-continuous level of blood glucose-lowering action with no intra-patient variability at a given dose have been the latest additions to the basal insulin group. On the other end of the spectrum, the ultra-rapid acting insulin research has become a hot topic once the essential and undeniable need for faster acting insulins to achieve target postmeal blood glucose control became apparent. While there is ongoing research in this field, few insulin formulations with faster absorption and action have been FDA approved for clinical management of diabetes.

As the diabetes technology revolution shapes how we manage diabetes, a wealth of breakthroughs emerge to improve insulin delivery, for monitoring blood glucose and to detect blood glucose patterns. The glycemic variability has become an important measure of diabetes treatment success highlighting the importance of intensive insulin treatment and underlining the key role of insulin formulations with improved pharmacokinetics and pharmacodynamics to achieve this goal.

The results of ultra-long and ultra-rapid acting insulin clinical trials and findings from research studies regarding innovative insulin formulations and methods to deliver insulin in conjunction with up-and-coming diabetes technology tools will be reviewed during the presentation.

022

SURGICAL AND PHARMACEUTICAL SOLUTIONS FOR OBESE PEOPLE WITH TYPE 2 DIABETES

ATTD8-0435

THE DOWNSIDE TO METABOLIC (BARIATRIC) SURGERY

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Metabolic surgery, one of the great medical advances of the 20th Century, has produced outcomes previously considered impossible: full and durable remission of type 2 diabetes with prevention of the co-morbidities and a reduction in mortality by 78%, similar improvements in hypertension, dyslipidemias, severe obesity, NASH, GERD, and polycystic ovary syndrome as well as reduction of the prevalence of solid cancers by over 70%.

This advance, however, similar to other medical breakthroughs, has also brought a series of challenges:

- Metabolic and long-term surgical complications: malnutrition, internal hernias, excess skin, rapid absorption of alcohol, bone absorption
- Emotional and mental health changes: alterations in body image, social relationships and sexuality; improved cognition and need to reset social status
- Economic concerns: access, health care costs, especially with the increased demands for hip and knee replacements now that these patients are more active

This presentation will review these issues and assess the current adaptations by society, providers, carriers, industry and legislators.

ATTD 2018 Oral Abstracts

023

Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0244

THE PERFORMANCE OF A NOVEL SMARTPHONE-BASE HBA1C MEASUREMENT

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Background and Aims: By measuring HbA1c, doctors get an overall view of the average blood sugar levels over the last months. Due to the clinical need, more and more point-of-care devices is trying to test HbA1c. PixoTest is a smartphone based in vitro diagnosis platform, which had already published the result of blood glucose, now can check HbA1c. PixoTest utilizes the screen of smartphones as the light source and the camera as the detector to check the color change of the test strips.

Method: Total 60 subjects were collected in China Medical University Beigang Hospital. Each subject underwent 2 tests in 3 lots of PixoTest HbA1c test. Sample is subsequently checked for both the hematocrit and A1c concentration using Sysmex SF Analyzer and Roche Cobas c111 analyzer, respectively. Results within 10% bias of the reference value should be more than 95% of the tests and considered in compliance with criteria.

Results: The total number of tests is 360, 120 tests in each lot. The range of HbA1c is 4.9% to 15%. For 1st lot, 117 of 120 (98%) tests were in 10% bias of the reference value. For the 2nd lot, 119 of 120 (99%) tests were in 10% bias. for the 3rd lot, 117 of 120 (98%) tests were in 10% bias. Therefore 353 of 360 values (98%) are within the system accuracy criteria 95%. The correlation coefficient is $y = -0.2 + 1.02x$, $R = 0.99$.

Conclusion: The smartphone based PixoTest HBA1c test demonstrate accurate results which comply to the criteria and is consider a novel mobile solution for HBA1c.

024

Artificial Pancreas

ATTD8-0051

ADD-ON THERAPY WITH DAPAGLIFLOZIN IMPROVES FULL CLOSED LOOP POST PRANDIAL GLYCAEMIC CONTROL IN TYPE 1 DIABETIC YOUNG ADULTS – THE DAPADREAM

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Background and Aims: Dapagliflozin (DAPA) as an SGLT2-Inhibitor is currently discussed as adjunct therapy in type1 diabetes.

The DreaMed Substance Administration System with fuzzy logic closed loop algorithm is proven to be safe and effective in hybrid closed loop settings, in full closed loop (FCL) settings postprandial time is always a phase of high glucose excursions. The aim of the present trial is to investigate the effect of DAPA on glucose levels after an unannounced meal under FCL conditions.

Method: Eligible patients (T1DM, SII, non-severe obese) were admitted for 24 hours of FCL in this monocentric, double-blind, randomized, placebo-controlled cross-over trial on two occasions. They received 10 mg DAPA or placebo twice. Two mixed meal tests were performed. Glucose control was achieved by DreaMed FCL. Primary outcome was ''Time in Range 70-180 mg/dl'' (TIR).

Table 1:

Variable ITT(N=15)	DAPA	Placebo	p
Primary			
Time within 70-180 mg/dl [%]			
24 h	68.40 (60.68, 70.66)	50.35 (45.56, 56.16)	<0.001
7 am-7 pm	41.67 (33.23, 47.22)	18.75 (14.04, 29.83)	<0.001
11 pm-7 am	100.00 (93.17, 100.00)	90.63 (77.27, 100.00)	0.123
Secondary			
Time below 70 mg/dl [%]	1.39 (0, 4.11)	0 (0, 2.53)	0.064
Time above 180 mg/dl [%]	29.17 (26.39, 36.84)	45.49 (42.45, 54.21)	<0.001
Mean Glucose Levels [mg/dl]	154.20 (144.74, 174.55)	186.61 (172.53, 201.03)	0.001
TDD [U]	27.75 (22.44, 34.29)	39.36 (28.65, 43.78)	<0.001
Bolus Insulin [U]	9.65 (8.13, 12.46)	16.00 (13.41, 19.16)	<0.001
Basal Insulin [U]	17.33 (14.50, 21.78)	22.51 (15.38, 27.14)	0.008
Urinary glucose excretion [mg/24h]	149331±42057	48520 ± 22618	<0.001

Results: Participants were 15 young adults (9 female) with mean [IQRange] of age 19 [18–20], HbA1c 8.3 % [7.1-10.4]. TIR with DAPA increased significantly overall and during postprandial phase, urinary glucose excretion raised threefold (Table). Time above 180 mg/dl was significantly decreased no increase below 70 mg/dl and no serious ketosis was observed.

Conclusion: Young adults with T1D took effort from DAPA combined with FCL. Average TIR was increased by 2.8 hours compared to placebo despite two unannounced meals. Bolus and basal insulin was reduced in FCL. SGTL2 inhibition appears to be a safe and effective adjunction in FCL.

025

Artificial Pancreas

ATTD8-0087

FIRST CLINICAL TRIALS IN LATIN AMERICA: THE ARG ALGORITHM WITHOUT CHO COUNTING

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Background and Aims: This trial evaluated an Artificial Pancreas with the new Automatic Regulation of Glucose (ARG) algorithm for the first time in Latin America. The algorithm was designed by a research team in Argentina from ITBA, UNQ, and UNLP.

Method: Five subjects with T1DM participated in this study. Each patient wore a DEXCOM G4 CGM and a Roche Accu-Check Combo CSII during an open-loop (OL) period at home, and the same hardware connected to a Diabetes Assistant (DiAs) cellphone at Hospital. In this last case, the ARG algorithm was loaded in the DiAs cellphone to perform the closed-loop (CL) test. For comparison, both periods had a duration of 36 hrs. The OL procedure was performed with the usual basal-bolus method. The CL procedure did not require CHO counting for any of the five meals.

Results: For the total 36 hr period, the CL results were: average glycaemia 88.6% in [70–250] mg/dl; 74.7% in [70–180] mg/dl; 5.8% <70 mg/dl and 0.8% <50 mg/dl, with LBGI = 2.3 and HBGI = 4.9. After a parameter tuning period, and considering the last 15hr, the results significantly improved: 94.7% in [70–250] mg/dl; 82.6% in [70–180] mg/dl; 4.1% <70 mg/dl and 0.2% <50 mg/dl, with LBGI = 1.8 and HBGI = 2.8. The last night results were even better. No severe or nocturnal hypoglycemia occurred. No serious adverse events were reported.

Conclusion: The novel ARG algorithm provided a good performance in its first clinical trial, particularly when comparing OL vs. CL results. Once the initial algorithm tuning was achieved, the results become significantly better. This algorithm shows promising results and further tests will be performed with unannounced meals.

026

Artificial Pancreas

ATTD8-0109

PROLOG: A RANDOMIZED CLINICAL TRIAL TO ASSESS THE EFFICACY OF PREDICTIVE LOW GLUCOSE SUSPEND VERSUS SENSOR-AUGMENTED PUMP THERAPY IN THE MANAGEMENT OF TYPE 1 DIABETES

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Background and Aims: Hypoglycemia is a major concern for patients with type 1 diabetes. With sensor-augmented pump therapy (SAP), there is the opportunity to reduce the occurrence or degree of hypoglycemia by decreasing insulin delivery when hypoglycemia is predicted.

Method: A multi-center randomized crossover trial is being conducted in the United States in which participants with type 1 diabetes, age >6 years old, use a predictive low glucose suspend (PLGS) algorithm on a Tandem Diabetes Care ambulatory insulin infusion pump with integrated Dexcom G5 CGM (t:slim X2 with Basal-IQ Technology) during one 3-week period and SAP (same pump and CGM without PLGS algorithm) during the other 3-week period. The planned sample size is 90.

Results: The primary outcome is percentage of CGM sensor glucose values <70 mg/dL compared between treatment arms using a repeated measures regression model. Additional outcomes include other CGM metrics of hypoglycemia, hyperglycemia, mean glucose, time in range, DKA, and severe hypoglycemia.

Conclusion: The study will be completed in January 2018 and final results will be presented.

027

Artificial Pancreas

ATTD8-0116

PERFORMANCE OF OMNIPOD PERSONALIZED MODEL PREDICTIVE CONTROL ALGORITHM WITH SPECIFIC MEAL CHALLENGES IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: To assess the safety and performance of the Omnipod hybrid closed-loop (HCL) personalized model predictive control (MPC) algorithm using an investigational device in adults with type 1 diabetes with specific meal challenges including missed meal bolus, 130% overbolus and use of extended bolus with high-fat meals.

Method: The study consisted of a 7-day, outpatient, open-loop phase, followed by a supervised, 54-hour HCL phase conducted in a hotel setting. Subjects aged 18–65 y with type 1 diabetes and A1C 6.0–10.0% were eligible. Endpoints included mean glucose, percentage time <70, 70–180 and ≥250 mg/dL. Meal challenge outcomes included glycemic response over 4 hours to missed lunch bolus and 130% breakfast bolus compared to 100% bolus for identical meals, respectively. Response to a 50% pre-dinner bolus with remaining 50% bolus extended over 4 hours compared to 100% pre-dinner bolus was also assessed.

Results: Patients' (n = 12) baseline characteristics were (mean±SD): age 35.4 ± 14.2y, diabetes duration 16.5 ± 9.3, A1C 7.7 ± 0.9% and TDD 0.58 ± 0.19 U/kg. Outcomes over the 54-hour HCL phase overall were mean glucose: 153.4 ± 15.3 mg/dL, percentage time <70 mg/dL: 0.6 ± 0.9, 70–180 mg/dL: 76.1 ± 8.0, ≥250 mg/dL: 4.5 ± 3.6. Meal challenges comparisons to 100% bolus are presented in the Table.

Parameter	Breakfast		Lunch		Dinner - High Fat	
Bolus type	100% Bolus	130% Bolus	100% Bolus	No Bolus	100% Bolus	Extended Bolus
Pre-meal bolus amount, U	5.2 ± 2.1	6.7 ± 2.7	5.2 ± 2.6	-	6.7 ± 3.8	3.2 ± 1.6
MPC insulin delivered during 4h post-prandial period	4.1 ± 1.7	3.8 ± 1.7	3.5 ± 1.8	6.5 ± 2.2	3.7 ± 2.0	5.9 ±2.5
Preprandial glucose, mg/dL	125.8 ± 12.7	130.7 ± 13.5	119.3 ± 41.6	126.2 ± 17.4	140.8 ± 36.6	117.5 ± 22.3
Peak postprandial glucose, mg/dL	242.1 ± 63.8	221.9 ± 44.4	188.7 ± 39.6	244.8 ± 42.5	192.0 ± 43.9	209.7 ± 41.8
Peak glucose excursion, mg/dL	116.3 ± 61.2	91.3 ± 44.0	69.5 ± 39.5	118.7 ± 45.9	51.3 ± 45.6	92.2 ± 39.7
Time to peak glucose, min	108.8 ± 37.2	120.0 ± 50.8	116.4 ± 84.3	118.8 ± 48.2	126.3 ± 101.4	170.8 ± 40.3
Minimum glucose during 4h post-prandial period, mg/dL	118.5 ± 20.0	111.8 ± 31.8	96.6 ± 30.0	118.2 ± 17.7	107.2 ± 36.4	109.1 ± 23.5
Average 4h post-prandial glucose, mg/dL	182.3 ± 37.6	169.9 ± 32.9	140.4 ± 31.3	191.8 ± 32.0	145.3 ± 34.2	163.7 ± 23.6

Conclusion: The Omnipod personalized MPC algorithm performed well and was safe during day and night use in response to high fat meals and bolus challenges in adults with type 1 diabetes. Glycemic outcomes to extended- and missed- and over-boluses indicated responsiveness of the algorithm to maintain within target ranges.

028

Artificial Pancreas

ATTD8-0235

THE STABLE GLUCAGON ANALOG DASIGLUCAGON IS WELL-TOLERATED AND AS EFFECTIVE AS RECOMBINANT HUMAN GLUCAGON WHEN DELIVERED BY THE BIONIC PANCREAS IN RESPONSE TO INSULIN EXCESS

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Background and Aims: Chemical instability of commercially available recombinant glucagon formulations after reconstitution has been a barrier to commercialization of the dual hormonal artificial pancreas systems. Dasiglucagon is a glucagon analog that is stable in an aqueous formulation, making it suitable for pump use. We compared dasiglucagon to freshly reconstituted recombinant human glucagon (Eli Lilly) in the dual hormonal bionic pancreas (DHBP) in 12 adults with T1DM in a randomized, two-period crossover trial.

Method: Ten subjects completed both periods and contributed to efficacy analyses. Each 8-hour study period stress-tested the anti-hypoglycemic action of the DHBP under conditions that increased the need for glucagon by starting with fasted participants and giving them extra insulin (up to 2X normal basal rate, full bolus for lunch) via a separate pump without informing the DHBP. Structured exercise started 3 hours after lunch. The primary endpoint was safety and tolerability. Key secondary endpoints addressed glycemic regulation.

Results: Adverse events were mild or moderate in intensity and were similar between groups; the most frequent besides hypoglycemia was nausea. No subjects developed antibodies against either drug. No infusion set occlusions occurred. There were no significant differences in percentage of time below 60 mg/dL (13 ± 17% vs 20 ± 15%; p = 0.25) or percentage of time in the 70-180 mg/dL range (71 ± 24% vs 62 ± 16%; p = 0.34) between dasiglucagon and recombinant glucagon. The delivered dose over 8 hours and the number of carbohydrate interventions were also comparable.

Conclusion: In sum, dasiglucagon delivered by the DHBP was well tolerated and provided anti-hypoglycemic action similar to recombinant human glucagon under challenging conditions.

029

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0376

THE I-HART CGM STUDY: EIGHT-WEEK HEAD-ON-HEAD COMPARISON OF GLYCAEMIC VARIABILITY BETWEEN FLASH AND CONTINUOUS GLUCOSE MONITORING SYSTEMS IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: The I-HART CGM Study is the first head-to-head glucose monitoring study designed to assess impact of flash and continuous glucose monitoring (CGM) in highest risk patients with type 1 diabetes mellitus (T1DM). In this analysis, we present the impact of CGM and flash on glycaemic variability (GV) measures.

Method: Forty participants with highest risk diabetes (Gold Score ≥4 or recent severe hypoglycaemia using insulin injections) were recruited to this randomised, parallel group trial. Following two weeks of blinded CGM (DexcomG4), participants were randomised to CGM (DexcomG5; n = 20) and flash (Freestyle Libre; n = 20) for 8-weeks. GV measures were compared between baseline and 8-weeks for both groups using EasyGV

v9.0, including lability index (LI), mean absolute glucose change (MAG), continuous overlapping net glycemic action (CONGA1), J-Index, mean of daily differences (MODD) as well as the glycaemic risk assessment in diabetes equation (GRADE).

Results: At the 8-week end-point, analysis of between-group differences demonstrate significant reduction in several GV-indices in favour of CGM compared to flash (see table). In terms of glucose distribution measures, statistically significant between-group differences were observed within LI and MAG ($p < 0.001$), as well as MODD ($p = 0.05$), whereas flash was associated with improved CONGA1 (mean change −1.91, $P < 0.01$). For measures of risk and quality of glycemic control, CGM improved J-Index, LBGI and GRADE %hypo.

Glycaemic Variability	Baseline mean (± SD) [n=40]	Mean change from baseline to end-point (± SD)		
		CGM Dexcom [n=19]	Flash Libre [n=20]	p-value
Mean	8.85 (± 1.79)	-0.49 (± 1.7)	-0.71 (± 1.2)	0.58
Stdev	3.97 (± 1.05)	-0.70 (± 0.9)	-0.26 (± 1.0)	0.07
CONGA1	8.10 (± 1.77)	-0.82 (± 1.6)	-1.91 (± 1.1)	0.005
LI	6.91 (± 2.78)	-0.25 (± 3.8)	12.36 (± 9.8)	<0.001
JINDEX	55.61 (± 23.49)	-10.49 (± 21.0)	-8.37 (± 17.0)	<0.001
LBGI	8.47 (± 3.64)	-3.59 (± 2.3)	1.18 (± 2.8)	<0.001
HBGI	12.17 (± 5.92)	-3.13 (± 5.3)	-2.24 (± 4.4)	0.44
GRADE	8.39 (± 3.97)	-2.01 (± 3.7)	-1.60 (± 2.5)	0.65
GRADE - %Hypo	18.93 (± 13.18)	-8.23 (± 10.5)	6.48 (± 12.7)	0.01
GRADE - %Eugly	4.84 (± 2.26)	2.93 (± 3.2)	1.61 (± 2.2)	0.62
GRADE - %Hyper	76.23 (± 14.01)	5.30 (± 11.9)	-8.09 (± 12.7)	0.05
MODD	4.16 (± 1.19)	-0.55 (± 1.2)	0.04 (± 1.2)	0.05
MAGE	8.42 (± 2.12)	-1.12 (± 2.3)	0.51 (± 2.3)	0.40
ADDR	32.76 (± 12.47)	-4.09 (± 15.0)	4.01 (± 12.6)	0.01
MVALUE	20.38 (± 10.54)	-8.32 (± 9.0)	-1.40 (± 8.0)	0.005
MAG	2.66 (± 0.54)	0.34 (± 0.8)	4.24 (± 1.2)	<0.0001

Conclusion: Real-time CGM shows greater beneficial impact on most GV-indices compared with flash in adults with T1DM at highest risk of hypoglycaemia. Addressing glucose variability in this cohort is important to minimize the risk of glucose extremes, including severe hypoglycaemia.

030

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0265

THE EFFECT OF CONTINUOUS GLUCOSE MONITORING USE ON GLUCOSE VARIABILITY IN PRESCHOOLERS WITH TYPE 1 DIABETES

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Background and Aims: Glucose variability (GV) is potentially associated with damage to developing brain in children with type 1 diabetes (T1D). Regular continuous glucose monitoring (CGM) use reduces GV in older children. The evidence on CGM efficacy in preschool children is limited and inconsistent. The objective of this study was to evaluate the efficacy of CGM on GV in preschoolers with T1D.

Method: We analyzed data from the national registry for preschoolers (up to seven years of age, including) with T1D using CGM. We compared HbA1c, average glucose level and measures of glucose variability (standard deviation (SD) and coefficient of variation (CV) between periods when CGM was used and periods when CGM was not used (SMBG data). We performed and additional analysis for frequent CGM use (more than 5 days/week). Data are presented as median (IQR).

Results: Forty preschoolers with T1D (age 6.8 (4.9–8.7) years) were included into analysis (214 reports with, and 250 without CGM use for the estimated observational period of 53.5 and 62.5 patient/years, respectively). Both CV ($p = 0.021$) and SD ($p < 0.001$) were significantly reduced with CGM use (Figure 1). There was no change in HbA1c and average glucose levels. Frequent CGM use lowered HbA1c level for 0.4% ($p = 0.047$).

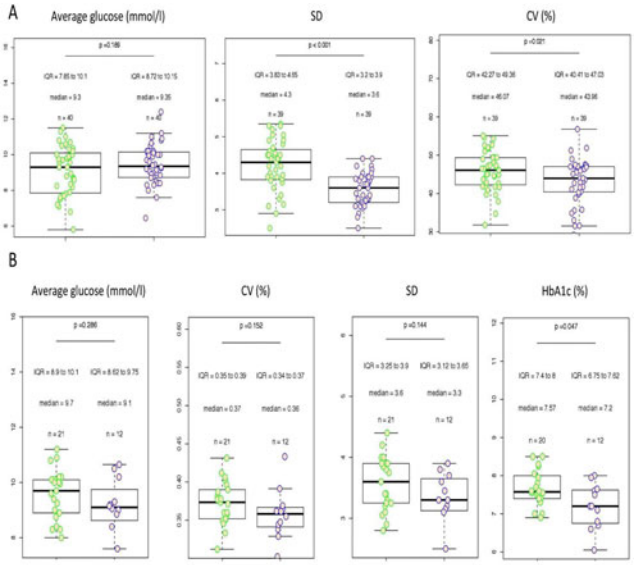

Figure 1. Comparisons between CGM (purple) and non-CGM (green) periods (A) and between frequent (purple) and non-frequent (green) CGM use periods (B). CV – Coefficient of variation. SD – Standard deviation

Conclusion: Data from the present study indicate benefit from CGM use on GV in preschoolers with T1D, especially when used frequently. This may prevent the detrimental effect of GV on developing brain.

031

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0139

CONTINUOUS GLUCOSE MONITORING OVER A 6-DAY PERIOD IN INSULIN-TREATED PATIENTS WITH TYPE 2 DIABETES ON HAEMODIALYSIS AT SAN JOSE HOSPITAL (BOGOTA)

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Background and Aims: To determine glucose behaviour using continuous glucose monitoring (CGM) in insulin-treated patients with type 2 diabetes on haemodialysis (HD) at San José Hospital - Fresenius Medical Care Renal Unit.

Method: Longitudinal descriptive study conducted between April and August 2016, including insulin-treated patients with type 2 diabetes and renal failure on haemodialysis. The variables measured included severe or asymptomatic hypoglicaemia, hyperglicaemia, blood sugar variability, demographic characteristics and paraclinical variables.

Results: Overall, 25 patients were included and 72% of them were males. Glycosylated haemoglobin (HbA1c) levels were 8.35% (± 2.34). CGM showed high variability, with the data showing a 67.7% trend towards hyperglicaemia, and alowering of tissue glucose during HD. There were 52 hypoglycaemic episodes detected, with a higher frequency during the days without dialysis and during the day. There was a lower ratio of hypoglicaemic episodes with the use of insulin Glargine.

Conclusion: CGM in diabetic patients on HD detected high blood sugar variability, hyperglycaemia predominantly during non-dialysis days, and a higher number of hypoglycaemic episodes when compared with blood glucose measurements.

032

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0035

RELATIONSHIP BETWEEN ADMISSION BLOOD GLUCOSE VARIABILITY AND PROGNOSIS OF ACUTE MYOCARDIAL INFARCTION PATIENTS WITH TYPE 2 DIABETES MELLITUS IN INTENSIVE CARE UNIT

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Background and Aims: Background: glucose variability (GV) is an important component of dysglycemia and might play an important role in the pathogenesis of atherosclerosis suggesting that it could be an independent risk factor for cardiovascular complications in diabetic patients.

Aims: To study the relationship between admission glucose variability and its effect on acute myocardial infarction diabetic patients admitted to the ICU.

Method: Patients and methods: Our prospective study was conducted on selected total number of 35 type –2 diabetic patients admitted to the ICU with acute anterior STEMI, all of them were on conservative anti- ischemic medical therapy (no PCI or intervention), and current casual anti-diabetic drugs, all patients were equipped with a CGMS (Medtronic MiniMed;) device and monitored for 3–5 consecutive days after admission for detection of glucose variability which was determined by Mean Amplitude of Glycemic Excursion (MAGE). They were classified mainly according to their outcome into 2 groups: Group (I):12 diabetic patients complicated by MACE during their ICU observation time. Group (II): 23 non complicated diabetic patients.

	Complications	N	Mean	Std. Deviation	t	P
Age	Complicated	12	57.5000	7.17952	1.553	0.08
	Not	23	54.4783	5.61548		
DM duration	Complicated	12	12.5000	2.61116	1.317	0.197
	Not	23	10.8261	3.96177		
WT	Complicated	12	89.5000	4.21038	2.104	0.04*
	Not	23	75.7391	4.51480		
Height	Complicated	12	174.2500	3.86417	-0.072	0.943
	Not	23	174.3478	3.76115		
BMI	Complicated	12	28.8130	0.84601	-7.215	0.00**
	Not	23	26.3250	1.17560		

(*):significant, (**):highly significant

Table (1): Demographic data distribution among studied groups:

Results: There was significant statistical association between Adm BG and the occurrence of complications (p = 0.036). Moreover, there was highly significant statistical association between MAGE which is the sole marker of glucose variability and occurrence of complications (p = 0.00). The increased level of MAGE (≥124 mg/dl) can be considered as highly significant predictor of complications.

Conclusion: Elevated admission MAGE can predict the risk of MACE in AMI patients with DM more than admission blood glucose level and HBA1c in the ICU.

	Complications	N	Mean	Std. Deviation	t	P
Adm BG	Complicated	12	386.0000	23.58736	2.186	0.036*
	Not	23	343.8261	64.23724		
HBA1c	Complicated	12	11.8000	.92540	2.498	0.018*
	Not	23	10.2174	2.07882		
Hs CRP	Complicated	12	29.7750	4.08904	2.185	0.037*
	Not	23	25.4087	3.33547		
troponin	Complicated	12	38.7500	8.30252	2.747	0.003*
	Not	23	25.6957	7.21624		
T chol	Complicated	12	241.9500	52.33484	2.403	0.018*
	Not	23	187.2174	41.28499		
TG	Complicated	12	186.0435	21.41044	-1.442	0.159
	Not	23	172.5214	34.51745		
LDL c	Complicated	12	161.7500	16.94443	0.722	0.475
	Not	23	156.2609	23.23637		
HDL c	Complicated	12	39.0000	3.04512	-1.738	0.092
	Not	23	41.2652	3.93268		
Creat	Complicated	12	.9250	.25981	-0.452	0.654
	Not	23	.9609	.20167		
Peak BG	Complicated	12	299.5000	99.77110	1.223	0.230
	Not	23	261.6087	79.83832		
Nadir BG	Complicated	12	63.0000	32.24339	0.288	0.775
	Not	23	61.6087	21.26401		
MAGE	Complicated	12	196.9167	30.26086	7.312	0.00**
	Not	23	120.9565	28.52029		
Killip	Complicated	12	2.2500	.45227	13.443	0.00**
	Not	23	1.0000	.00000		
TIMI	Complicated	12	5.5000	.52223	17.719	0.00**
	Not	23	3.0870	.28810		

(*) significant, (**) highly significant

Table (3): Comparison of studied groups as regards lab parameters:

			MAGE		Total	X^2	P
			<124	>124			
killip	1.00	Count	21	2	23	23.3	0.00**
		% within MAGE	95.5%	15.4%	65.7%		
	2.00	Count	1	8	9		
		% within MAGE	4.5%	61.5%	25.7%		
	3.00	Count	0	3	3		
		% within MAGE	0.0%	23.1%	8.6%		
TIMI	3.00	Count	19	2	21	23.6	0.00**
		% within MAGE	86.4%	15.4%	60.0%		
	4.00	Count	2	0	2		
		% within MAGE	9.1%	0.0%	5.7%		
	5.00	Count	1	5	6		
		% within MAGE	4.5%	38.5%	17.1%		
	6.00	Count	0	6	6		
		% within MAGE	0.0%	46.2%	17.1%		
Total		Count	22	13	35		
		% within MAGE	100.0 %	100.0 %	100.0 %		

(**) highly significant

Table (7): Comparison and correlation between the predictive cut off value of the MAGE (124mg/dl) and Killip and TIMI risk score.

033

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0080

A NOVEL KINETIC MODEL DEMONSTRATES IMPORTANT INDIVIDUAL KINETIC CONSTANT THAT AFFECTS COMPLEX RELATIONSHIP BETWEEN STEADY BLOOD GLUCOSE AND HBA1C FOR PEOPLE WITH DIABETES

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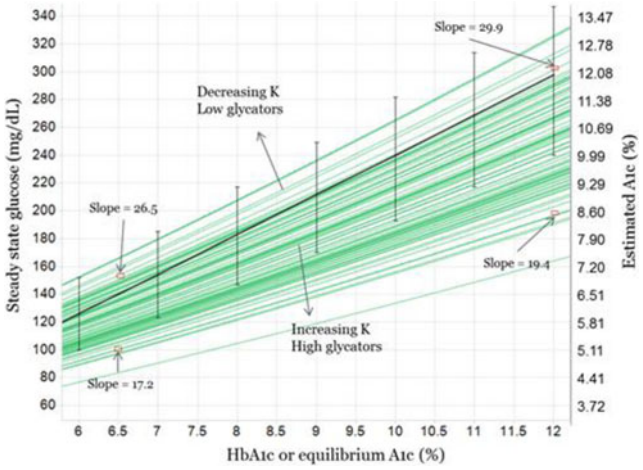
Background and Aims: HbA1c should depend upon red blood cells (RBCs) generation, elimination, and glycation. A novel kinetic model is introduced incorporating these three processes and is examined for the relationship between average glucose and HbA1c.

Method: HbA1c can be determined by glucose history, the glycation rate constant, and the RBC elimination (or generation) rate constant. The concept of equilibrium HbA1c is introduced. The relationship between constant glucose level and equilibrium A1c is: K*G/(1+K*G)

Where G is the constant glucose level, and K is the ratio of RBC glycation and elimination rate constants.

Results: The model was applied to the experimental data from 90 type 1 and type 2 subjects in 2 previous studies. The individual RBC glycation and elimination rate constants, as well as K were determined, which all varied substantially. The accepted conversion of average glucose to HbA1c is shown in Figure 1 (black lines) compared with the individual relationships (green curves) at equilibrium A1c derived from the model. These individual curves, which correspond to individual K values, represent the agreement of the average glucose to laboratory HbA1c under the condition of their average being stable for days-to-weeks.



Conclusion: A novel kinetic model that includes the irreversible processes of RBC generation, elimination and glycation elucidates the impact of individual parameters on the relationship between glucose levels and HbA1c and can inform individualized clinical care regarding targets for HbA1c and average glucose. Understanding the underlying glycation and regeneration kinetic constants can help making safer adjustment on individual glucose target to avoid hypoglycemic and hyperglycemic damages.

034

Clinical Decision Support Systems/Advisors

ATTD8-0373

NON-LINEAR RELATIONSHIPS BETWEEN FEAR OF HYPOGLYCEMIA AND ACTUAL RISK FOR SEVERE HYPOGLYCEMIA IN PARENTS OF ADOLESCENTS WITH TYPE 1 DIABETES: CLINICAL IMPLICATIONS

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Background and Aims: In adults with type 1 diabetes (T1D), mismatches exist between fear of hypoglycemia (FoH) and actual risk for severe hypoglycemia (SH), i.e. those at low SH risk can have high FoH and vice versa. This phenomenon has not been investigated in parents of adolescents with T1D.

Method: This study examined relationships between FoH and SH risk in Australian parents (N = 382) of youth (10–19 years) with T1D completing a national online survey. Parental FoH scores in the lowest/highest tertiles were categorized as low/high. Children's SH Risk was categorized as low (no episodes past year)/high (≥2 episodes past year).

Results: Table 1 shows the distribution of parents across categories of FoH/SH Risk. There was no difference in the number of SH episodes between the Low FoH/High SH Risk and those in the High FoH/High SH Risk group (5.1 ± 4.9 vs 5.8 ± 4.0, p = ns). 28% of parents were in the High FoH/Low SH Risk group, with elevated scores on other measures of anxiety and emotional distress ($p = 0.0001$), suggesting a general predisposition toward anxiety. Parents in both High FoH groups were more likely to report maintaining higher BG in their children to avoid hypoglycemia ($p = 0.000$).

Table 1. Parent distribution Across Levels (Low/High) of FoH and SH Risk

	FoH Level	
SH Risk	Low FoH	High FoH
Low	46.1% (n=176)	27.7% (n=106)
High	8.4% (n=32)	17.8% (n=68)

Conclusion: Thus, parents of adolescents with T1D may have inappropriately low or high FOH relative to their child's actual SH risk, which can affect diabetes management. These findings warrant further scientific and clinical attention.

035

Clinical Decision Support Systems/Advisors

ATTD8-0207

MODELING INTER-DAY VARIABILITY OF INSULIN SENSITIVITY IN TYPE 1 DIABETIC SUBJECTS FROM 1 MONTH OUTPATIENT ARTIFICIAL PANCREAS DATA

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Background and Aims: Diurnal variability of insulin sensitivity (S_I) has been recently assessed in subjects with type 1 diabetes (T1D), showing the existence of different patterns describing intra-day variations of S_I (Hinshaw et al., Diabetes 2013). However, inter-day variability of S_I has not been properly assessed yet. Here we aim to estimate and model the variability in S_I patterns from 1-month closed-loop study data in T1D subjects in free-living conditions.

Method: A validated index of S_I (Schiavon et al., Diabetes Care 2014), estimated for each recorded meal from continuous glucose monitoring (CGM) sensor and insulin pump data, has been used to obtain the intra-day S_I variations in 20 T1D subjects wearing an artificial pancreas 24/7 for 1 month under free-living conditions. Each pattern of S_I has been classified based on the S_I values measured during the day. A Markov chain model was developed to capture subject's day-to-day S_I variations and validated against data.

Results: Despite a non-negligible intra-subject variability of S_I daily pattern, results show the existence of patient-specific trends in S_I. A Markov chain transition matrix has been generated for each subject, describing his/her S_I pattern evolution during the 1-month period.

Conclusion: S_I was estimated in 20 T1D subjects using 1-month CGM and insulin pump data. To be conclusive on the extent of such variability the model needs to be tested in a larger cohort. The availability of a stochastic model of S_I daily pattern may improve in silico testing of T1D treatments in the long term, e.g. adaptive artificial pancreas.

036

Clinical Decision Support Systems/Advisors

ATTD8-0238

AUGMENTING CLINICAL DECISION SUPPORT FOR DIABETES CARE IN SOUTH ASIA WITH PATIENT JOURNEY CLINICAL AND LIFESTYLE DATA BY USING WELLTHY DIABETES APP

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[4]North Delhi Diabetes Centre, Diabetes, New Delhi, India
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[6]Dia Care - Diabetes Care & Hormone Clinic, Diabetes, Ahmedabad, India
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[9]Wellthy Therapeutics Pvt Ltd, Product & Clinical Innovation, Mumbai, India

Table I : Distribution of Clinical and Lifestyle Data self-reported using Wellthy Diabetes App

Variables	Total Instances of Data Captured. N (%)	Participants Self-Reporting at least 1 Reading N (%)
Meals	***6791 (100%)***	***129 (100%)***
Breakfast	2533 (37.29%)	100 (77.51%)
Lunch	2449 (36.06%)	100 (77.51%)
Dinner	1809 (26.63%)	91 (70.54%)
Blood Glucose	***1127 (100%)***	***107 (83%)***
Fasting	536 (47.55%)	96 (74.41%)
Post-Prandial	360 (31.94%)	78 (58.91%)
Random	231 (20.49%)	50 (38.75%)
Weight	***572 (100%)***	***115 (89%)***
Physical Activity	***36,456 (100%)***	***113 (87.59%)***
Sensor Tracked	21,873 (59.99%)	96 (74.41%)
Self Reported	14,583 (40.01%)	88 (68.21%)
Total	**44,976**	

Background and Aims: Ongoing Diabetes Care is often limited to episodic clinical data at the time of consultation. Our study aimed at demonstrating the role of a digital therapeutic, Wellthy Diabetes, in augmenting clinical and lifestyle decision-making in real-world beyond consultation visits.

Method: Wellthy Diabetes Smartphone App (WD) was developed in scientific collaboration with the Research Society for Study of Diabetes India (RSSDI). This study reports data from participants of an AI-Augmented lifestyle modification program for people with T2DM using WD. Patients self-reported data on meals, blood glucose, physical activity, and weight. Physical activity time was also tracked using sensor data on the mobile phone.

Results: 44,976 diabetes-related clinical and lifestyle data points along with 144,695 minutes of physical activity were captured from 129 participants over 15,042 user days. The mean duration of a participant on the app during this study was 116.60 days during which on average 348 clinical and lifestyle data points were tracked per participant at a mean of 2.98 data points per participant per day. Meals, blood sugar, weight and activity were reported by a mean of 52.64, 8.73, 4.43, 1121 instances respectively by the participants (Table-I)

Conclusion: We conclude that our study demonstrates that WD engages participants with T2DM through digital technology to extensively self-report patient journey clinical and lifestyle data in-between consultations, which augments clinical decision-making during consultations and allows for better implementation of evidence based guidelines in practice to further personalize care.

037

Clinical Decision Support Systems/Advisors

ATTD8-0161

IN SILICO HEAD-TO-HEAD COMPARISON OF INSULIN GLARGINE 300 U/ML AND INSULIN DEGLUDEC IN TYPE 1 DIABETES

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Background and Aims: Second generation long-acting insulin analogs glargine 300 U/mL (Gla-300) and degludec (Deg) both provide novel basal insulin therapies for the treatment of type 1 diabetes (T1D). Both offer a flatter pharmacokinetic profile than the currently used long-acting insulins, thus improving glycemic control while reducing hypoglycemic events. This work aims to evaluate in silico the benefit of both basal insulins on 24-hr glucose profiles.

Method: The UVA/Padova T1D simulator describes the intra-/inter-day variability of glucose-insulin dynamics and thus provides a robust bench-test for assessing glucose control for basal insulin therapies. Pharmacokinetic models describing subcutaneous absorption of Gla-300 and Deg have been developed based on T1D clinical data and incorporated into the most recent version of the simulator. One hundred in silico T1D subjects received a basal insulin dose (Gla-300 or Deg) for 12 weeks (8 weeks up-titration, 4 weeks stable dosing) by morning or evening administration in a basal-bolus regimen. The virtual patients were up-titrated to their individual dose exploring various titration rules.

Results: Simulated 24-hour blood glucose profiles were used to calculate various endpoints for both basal insulin treatments (e.g. %time in glucose target [70–180] mg/dL, T_t; %time below 70 mg/dL, T_b). The simulations show no statistically significant difference for Gla-300 vs. Deg in the main endpoints.

Conclusion: This work suggests comparable glucose control using either Gla-300 or Deg and may provide guidance for clinical trials design intended to compare second generation basal insulin analogs.

038

Closed-loop System and Algorithm

ATTD8-0119

REAL-WORLD USE OF THE MINIMED™ 670G HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: In September 2016, the FDA approved the MiniMed™ 670G hybrid closed-loop (HCL) system for type 1 diabetes. The 3-month study phase of the MiniMed™ 670G HCL pivotal trial demonstrated significantly improved HbA1c levels, increased time in target level (71–180 mg/dL), and reduced time within hypoglycemic and hyperglycemic ranges, for both adolescents and adults, versus baseline run-in. During the trial, the Guardian™ Sensor 3 glucose sensor had an overall grouped-cohort accuracy of 10.3 ± 9.0% (3710 paired points). Data from the *MiniMed™ 670G Commercial Launch* were analyzed retrospectively to determine the early real-world performance of this HCL therapy for diabetes management.

Method: MiniMed™ 670G system data voluntarily uploaded to CareLink™ Personal software, from March 2017 to August 2017 (n = 3031), were de-identified, analyzed, and compared with data from the pivotal trial (n = 124). Analyses included data with >7 days of sensor wear.

Results: For the *Commercial Launch*, overall average time in Auto Mode was 85%, sensor glucose (SG) was 151.7 mg/dL (8.4 mmol/L), SD of SG was 48.3 mg/dL (2.7mmol/L), and time in range was 73.3%; for the pivotal, it was 88%, 150.8 mg/dL (8.4 mmol/L), 45.6 mg/dL (2.5 mmol/L), and 72.2%. The table

Table 1. Longitudinal metric data during the MiniMed™ 670G *Commercial Launch*

	Initial Manual Mode	1st 30 Calendar Days†	2nd 30 Calendar Days†	3rd 30 Calendar Days†	4th 30 Calendar Days†
Patients	3026	2690	659	366	191
Sensor days	26472	44867	14093	8175	3250
% Days in Auto Mode	NA	88.4%	86.0%	85.9%	86.7%
% Time in Auto Mode per patient (median)	NA	85.7% (91.6%)	79.0% (87.5%)	78.7% (87.9%)	79.8% (87.2%)
SG, mg/dL (mmol/L)	159.6 ± 52.3 (8.9 ± 2.9)	151.6 ± 48.2 (8.4 ± 2.7)	151.2 ± 48.9 (8.4 ± 2.7)	150.5 ± 47.9 (8.4 ± 2.7)	147.8 ± 46.8 (8.2 ± 2.6)
Percentage of time in sensor glucose ranges, mg/dL (mmol/L)					
≤50 (≤2.8)	0.5%	0.4%	0.4%	0.4%	0.4%
≤70 (≤3.8)	3.0%	2.3%	2.7%	2.5%	2.6%
71-180 (3.9-10)	**64.7%**	**72.9%**	**72.4%**	**73.1%**	**74.9%**
>180 (>10)	31.8%	24.2%	24.4%	23.9%	22.0%
>250 (>13.9)	8.2%	5.0%	5.2%	4.7%	3.9%
Overall sensor data from March 2017 to August 2017					
MARD, %	10.4				
MARD day 1, %	12.7				
20/20 agreement	87.7				
Sensor life, days	6.2				
Sensor use, %	88.6				
Calibrations per day	3.6				

†From Auto Mode start.
All values are shown as averages or mean ± SD, unless indicated otherwise.
The Initial Manual Mode period was 1 week in duration.
5 patients did not have sensor data for the Manual Mode period.
Overall sensor data: Total sensor days = 93301, Total sensor count = 13607.

shows longitudinal system use and glycemic control metrics for the *Commercial Launch* from the initial Manual Mode period to the 4th 30 calendar-day period, after Auto Mode start.

Conclusion: These early real-world findings from the MiniMed™ 670G HCL system demonstrate that the results are similar to those reported in the 3-month pivotal trial, and sustained over the time of the observation to date.

039

Closed-loop System and Algorithm

ATTD8-0405

GLYCEMIC OUTCOMES DURING MINIMED™ 670G SYSTEM USE IN CHILDREN WITH T1D

B. Buckingham[1], D. Shulman[2], G. Forlenza[3], B. Bode[4], O. Pinhas-Hamiel[5], M. Wood[6], K. Kaiserman[7], D. Liljenquist[8], T. Bailey[9], J. Shin[10], S. Huang[10], T. Cordero[11], S. Lee[11], F. Kaufman[11]

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Background and Aims: In-home use of the MiniMed™ 670G hybrid closed-loop (HCL) system for 3 months by T1D patients aged ≥14 years significantly improved glycated hemoglobin (HbA1c) and percentage of time in target range from baseline. This study evaluated the same in-home system for safety and glycemic outcomes in patients 7–13 years old.

Method: Data from children (N = 105, aged 7-13 years, mean age of 10.8 ± 1.8 years) with T1D who completed 2-weeks of baseline data in Manual Mode followed by a 3-month study phase with HCL control enabled (Auto Mode) were analyzed. Overall (24-hour) and overnight (10:00 pm–7:00 am) sensor glucose (SG) and HbA1c from run-in and study phase were compared. The study was followed by an optional continued access program (CAP).

Results: Once enabled, Auto Mode was used a median 80.6% (IQR, 70.0–87.7%) of the time. The table shows a significantly greater percentage of SG values in target range (70–180 mg/dL [3.9–10 mmol/L]) during the 24-hour day and overnight periods, during the study phase versus run-in. There was also a significant decrease in HbA1c (7.9 ± 0.8% [58.5 ± 14.8 mmol/mol] to 7.5 ± 0.6% [58.4 ± 16.9 mmol/mol], P < 0.001). SG variability (coefficient of variation) decreased from 39.6% to 38.5% (P = 0.0095). During the study phase, there were no episodes of severe hypoglycemia or DKA, and no serious device-related AEs during a total 15,353 patient-days. At study end, all except 3 entered the CAP.

Table. Overall (24-hour) and overnight (10:00pm-7:00am) glycemic outcomes during in-home use of the MiniMed™ 670G system in children.

	Overall (24-hour day)			Overnight (10:00pm-7:00am)		
Category	Baseline Run-in	Study	p-value	Baseline Run-in	Study	p-value
SG						
mg/dL	168.6±21.6 (168.0)	161.7±12.4 (161.9)	<0.001*	166.0±26.4 (162.7)	155.0±12.6 (153.1)	<0.001
mmol/L	9.4±1.2 (9.3)	9.0±0.7 (9.0)		9.2±1.5 (9.0)	8.6±0.7 (8.5)	
Percentage of time in glucose range, mg/dL (mmol/L)						
>180 (>10)	39.1±12.8 (38.4)	32.0±7.7 (32.4)	<0.001	38.5±16.7 (37.6)	26.7±9.0 (25.7)	<0.001
70-180 (3.9-10)	56.2±11.4 (55.9)	65.0±7.7 (64.6)	<0.001	56.6±15.3 (57.5)	70.9±9.4 (72.0)	<0.001*
≤70 (≤3.9)	4.7±3.8 (3.5)	3.0±1.6 (2.9)	<0.001*	4.9±5.2 (3.3)	2.4±1.6 (1.9)	<0.001*
≤50 (≤2.8)	0.8±1.2 (0.5)	0.5±0.5 (0.4)	0.0012*	1.0±1.6 (0.3)	0.5±0.6 (0.3)	0.0125*

All data values are shown as mean±SD (median)
The run-in phase duration was 2 weeks and the study phase was duration was 3 months.
Paired t-test determined p-values
*Wilcoxon Signed Rank test

Conclusion: The in-home use of the MiniMed™ 670G system in children with T1D, similar to that observed in adolescents and adults, was safe and associated with improved glycemic metrics.

040

Closed-loop System and Algorithm

ATTD8-0406

EVALUATION OF THE MINIMED™ 670G SYSTEM PREDICTIVE LOW GLUCOSE MANAGEMENT FEATURE IN CHILDREN

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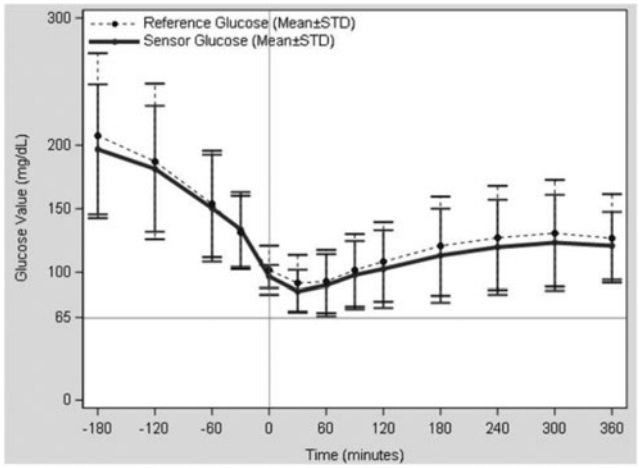
Background and Aims: Activation of ''suspend before low'' in the Predictive Low Glucose Management (PLGM) algorithm can stop insulin delivery when sensor glucose (SG) is predicted to reach or fall below a preset low glucose limit, and later, automatically resume basal insulin delivery. The present study evaluated the PLGM ''suspend before low'' feature of the MiniMed™ 670G hybrid closed-loop (HCL) system in children.



Mean reference and sensor glucose levels are shown over time (Time = 0 indicates automated insulin suspension), during the PLGM "suspend before low" evaluation of the MiniMed™ 670G hybrid closed-loop system. PLGM "suspend before low" activations were triggered when glucose events of ≤65 mg/dL (≤3.6 mmol/L) were predicted to occur within 30 minutes.

Method: Participants (N = 105, aged 7–13 years) with T1D were enrolled in the MiniMed™ 670G HCL system pivotal trial that included a 2-week run-in phase, followed by a 3-month study phase. During the run-in, all participants underwent an overnight PLGM evaluation with the low limit set to 65 mg/dl (3.6 mmol/L), and had YSI or SMBG reference measurements every 5 minutes if <70 mg/dL (<3.9 mmol/L); 15 minutes if 70–80 mg/dL (3.9–4.4 mmol/L); and 30 minutes if >80 mg/dl. Treatment was given for reference values ≤50 mg/dL (≤2.8 mmol/L).

Results: Of the 105 experiments, there were 79 during which PLGM was activated; 80% (63/79) did not reach ≤65mg/dL. The figure shows reference and SG values, over the 6-hour overnight observation period for PLGM evaluation. The mean insulin suspension duration was 85.6 ± 32.4 minutes. Four hours post-insulin resumption, reference glucose was 129.9 ± 41.9mg/dL (7.2 ± 2.3 mmol/L) indicating glucose stabilization. For the 26 experiments in which PLGM was not activated, none involved reference glucose ≤65 mg/dl suggesting the algorithm functioned as designed.

Conclusion: The PLGM ''suspend before low'' feature in the MiniMed™ 670G system was activated before all hypoglycemic events, and did not involve rebound hyperglycemia, in children with T1D.

Table 1:

		Standard HCL (control) N = 6	HCL with enhancements (intervention) N = 6
Demographics$^{\phi}$	HbA1c	8.7 ± 0.8	8.4 ± 0.9
	Age	15 ± 1.3	15 ± 1.2
	Gender	M3:F3	M4:F2
Glycaemia (%time sensor glucose)$^{\phi}$	<2.8mmol/L	0.32 ± 0.30	0.23 ± 0.14
	<3.3mmol/L	0.32 ± 0.30	0.23 ± 0.14
	<3.9mmol/L	3.29 ± 1.83	2.15 ± 0.97
	3.9 – 10mmol/L	75.9 ± 8.55	74.5 ± 8.27
	>10mmol/L	20.8 ± 8.26	23.3 ± 8.09
	>13.9mmol/L	5.3 ± 4.64	6.4 ± 2.48
	Mean SG mmol/L	8.05 ± 0.73	8.21 ± 0.56
Performance	% time in SmartGuard auto mode	97%	99%
	Sensor MARD	10.9%	7.76%
	auto mode exits (episodes per person per day)	0.3	0.14
Usability	Satisfaction	83% satisfied or extremely satisfied	100% satisfied or extremely satisfied

ϕ = mean ± SD

041

Closed-loop System and Algorithm

ATTD8-0348

PERFORMANCE OF MEDTRONIC HYBRID CLOSED LOOP ITERATIONS, RESULTS FROM A RANDOMIZED TRIAL IN ADOLESCENTS WITH TYPE 1 DIABETES

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Background and Aims: This study investigates the performance of an iteration of the Medtronic hybrid closed loop (HCL) algorithm which utilizes sensor glucose values non adjunctively for bolus advice, recognises sustained hyperglycaemia and suggests insulin bolus correction, and includes more accommodative SmartGuard™ auto mode parameters that aim to improve function and usability.

Method: Adolescents aged 13–17 years with type 1 diabetes >1 year, HbA1c 7.0–10%, currently using CSII, were recruited and randomized to the control Medtronic standard HCL algorithm, or to the intervention Medtronic HCL with enhancements. Participants attended a 7 day and night non-structured camp setting. HCL challenges included a high fat meal, exercise, and an unannounced carbohydrate rich meal. Outcome measures included time in target glucose range, % time in SmartGuard™ auto mode, auto mode exits, and user satisfaction.

Results: Outcome measures are reported in table 1. There were no episodes of severe hypoglycaemia or ketosis.

Conclusion: Feasibility of the enhanced HCL algorithm was demonstrated with a high proportion of time spent in SmartGuard™ auto mode and target glucose range. The iterative changes resulted in less SmartGuard™ auto mode exits without compromising glycaemic control. Participants reported high levels of satisfaction with both algorithms

042

Closed-loop System and Algorithm

ATTD8-0458

FULLY CLOSED-LOOP 24 HOURS GLUCOSE CONTROL WITH DREAMED GLUCOSITTER USING FASTER-ACTING INSULIN ASPART IN YOUNG ADULTS WITH TYPE 1 DIABETES

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Background and Aims: The objective was to evaluate the safety and the efficacy of fully closed-loop insulin delivery with DreaMed Glucositter in young adults with type 1 diabetes (T1D) comparing faster-acting and regular insulin aspart during day and night with unannounced afternoon physical activity and all meals.

Methods: In a two-arm, randomized, double-blinded, crossover clinical trial 20 young-adults on insulin pump therapy (11 females, mean age 21.3 ± 2.3 years, HbA1c 7.5 ± 0.5 %) performed 26-h hospitalization on two occassions with unannanounced afternoon exercise (40 min 55/80% VO2max with integrated high-intensity sprints) and unannanounced and uncovered meals (35 grams carbohydrates for snack and 50–80 grams for main meals) with either faster-acting or regular insulin aspart.

Results: Results are presented as medians (IQR). Proportion of time within the target glucose range 70–180 mg/dl (3.9–10 mmol/l) for the overnight period was 83.9% (74.0–91.7) for faster-acting and 88.0% (81.0–100) for regular insulin aspart, p = 0.227. Proportion of time in hypoglycemia was 0.0% for both groups for all thresholds (below 70 mg/dl (3.9) mmol/l, below 60 mg/dl (3.3 mmol/l, and 50 mg/dl (2.8 mmol/l). Faster-acting (compared to regular) insulin aspart provided modestly greater glucose-lowering effect: ΔAUC0–1h after breakfast was −3782 mmol/l × min, p = 0.033, ΔAUC0–5h after dinner was −1158 mmol/l × min, p = 0.033.

Conclusions: Fully closed-loop glucose control using either faster-acting or regular insulin aspart was safe and provides a mean to achieve near-normal glucose concentrations in young adults with type 1 diabetes.

Clinicaltrial.gov: NCT03212950

043

Closed-loop System and Algorithm

ATTD8-0071

MINIMED™ 670G SYSTEM ADAPTATION EFFECTIVENESS – RESULTS FROM THE PIVOTAL TRIAL

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Background and Aims: The Medtronic MiniMed™ 670G system for type 1 diabetes (T1D) includes a personalized adaptation once per day at midnight, using 6 full days of sensor-integrated pump history to calculate key parameters (control gain and insulin delivery limits) of the algorithm. In certain conditions, the adaptation cannot be fully achieved, and partial adaptation occurs using only the total daily insulin delivered (TDD). Grosman, et al (J Diabetes Sci Technol 2016;10:708-13) previously reported improved mean sensor glucose (SG) values with an Android-based experimental system with full (158 ± 49 mg/dL) versus partial adaptation (137 ± 37 mg/dL).

Method: Data from the 3-month MiniMed™ 670G pivotal trial (n = 124) was used to re-estimate the frequency and outcome of full versus partial adaptation, after the algorithm was improved to minimize partial adaptation days.

Results: A full 10901 subject-days were evaluated. In 99% of days, a full adaptation was achieved; only 91 days had partial adaptation.

Days with full adaptation were significantly more effective. Mean SG was 158 ± 48 and 147 ± 44 mg/dL (P < 0.001), and % time between 70–180 mg/dL was 67.64% and 75.65% (P < 0.001), with partial versus full adaptation, respectively.

There was no significant difference in % SG <70 mg/dL, 2.15% and 2.48% (P = 0.39), with partial versus full adaptation, respectively.

Conclusion: These results emphasize the flexibility of the MiniMed™ 670G algorithm that allows for partial adaptation when full adaptation is not possible. However, as expected full adaptation allows for the maximal positive effect of the hybrid closed-loop system in minimizing hypo and hyperglycemia.

044

Glucose Sensors

ATTD8-0155

LONGEVITY OF AN IMPLANTABLE CGM SYSTEM DURING A 180 DAY STUDY

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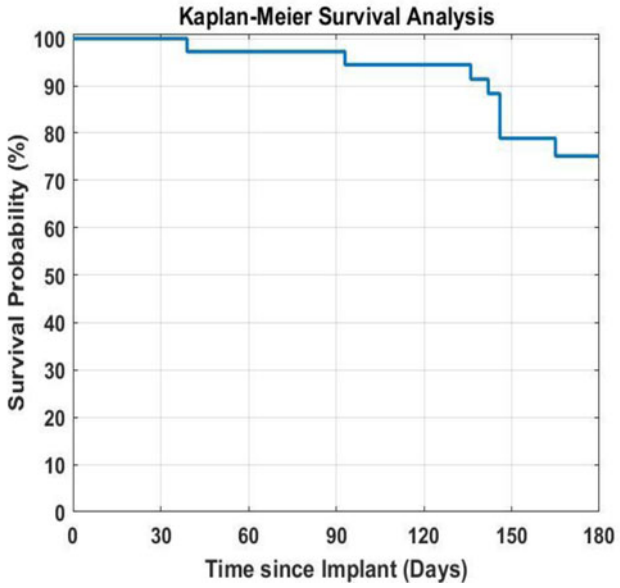
Background and Aims: The implantable Eversense® CGM System (Senseonics, Maryland USA), which has an anti-inflammatory dexamethasone ring located at the mid-section of the sensor length, has been previously introduced with a 90-day sensor duration. A new sensor configuration, Eversense® XL co-locates the dexamethasone ring directly adjacent to the glucose-indicating region above the LED and photodetectors and was recently approved with an extended duration up to 180 days. The current study investigated the longevity of the new Eversense XL over 180-days.

Method: 36 participants with Type 1 diabetes were enrolled in a prospective, unblinded, single-arm, single-center 180-day study. Sensors were inserted in the upper arm and assessed every 30 days for sensor longevity, safety and efficacy. An interim analysis of second-generation sensor longevity was performed using the Kaplan-Meier method to estimate the probability of sensor survival through 180 days.

Results: Subjects included 30 pediatric patients and 6 adult patients (12 to 51 years of age, mean 17 ± 9.2 years), 13 female/

Figure – Kaplan Meier Survival Analysis for Sensor Longevity



23 male, with mean BMI of 22 ± 4. At the interim analysis, 25 sensors had either completed the 180-day follow-up without a replacement alarm or had undergone device removal prior to day 180. At post-implant days 90, 120, 150, and 180, the estimated probabilities of sensor survival were 97%, 94%, 79%, and 75%, respectively (Figure).

Conclusion: The Eversense CGM using a new sensor configuration demonstrates 75% survivability through 180 days of sensor wear.

045

Glucose Sensors

ATTD8-0239

NEXT GENERATION DEXCOM SENSOR WITH BAYESIAN ALGORITHM GOES TOWARDS A CALIBRATION-FREE SCENARIO

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Background and Aims: Dexcom continuous glucose monitoring (CGM) devices currently in the market need to be calibrated twice/day exploiting self-monitoring of blood glucose references. Recently, we developed and validated an online Bayesian calibration algorithm able to reduce the frequency of calibrations up to one every four days without worsening sensor accuracy on Dexcom G4 Platinum data. Here, we assess performance of our algorithm on a next-generation Dexcom CGM sensor prototype.

Method: The new Bayesian calibration algorithm is applied to 48 raw signals acquired with a next-generation Dexcom CGM sensor prototype for a 10-day period. By simulating an online setting, we tested progressively less-calibration scenarios, until zero. Accuracy of the calibrated glycemic profiles is evaluated by comparison with blood glucose references via absolute relative difference (ARD) using a cross-validation approach for prior knowledge derivation. We then assessed the algorithm ability to generalize by deriving prior knowledge from a different dataset (55 sensors belonging to a different lot).

Results: In the cross-validation approach, median ARD over all matched-pairs for the different scenarios is 7.5% (one-per-day calibration), 7.3% (one-every-two-days calibration), 7.8% (one-every-four-days calibration) and 9.3% (zero calibrations). Accuracy of the zero-calibration scenario worsens of only 1% when using prior knowledge derived from a different lot of sensors.

Conclusion: The new Bayesian calibration algorithm well performs on CGM data acquired by a next-generation Dexcom sensor prototype, outperforming the current commercial CGM devices, independently from the frequency of calibrations. Moreover, accuracy remains stable when including more variability in sensor-to-sensor characteristics, allowing moving towards a calibration-free scenario.

046

Glucose Sensors

ATTD8-0092

SENSOR-AUGMENTED PUMP WITH PREDICTIVE LOW GLUCOSE SUSPEND FUNCTION: IMPACT ON GLYCAEMIC CONTROL IN ADULTS AND CHILDREN

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Background and Aims: To evaluate the effect of sensor-augmented pump with predictive low-glucose suspend function (SAP-PLGS) on glycaemic control and frequency of hypoglycaemia.

Method: All the patients with type 1 diabetes treated with MiniMed 640G® pump with ''suspend before-low'' function at 3 referral hospitals in Spain were retrospectively evaluated. Baseline HbA1c, HbA1c at 3, 6, 12, 18 and 24 months and SAP-PLGS downloads at baseline and last follow-up visit were analysed.

Results: 162 patients had at least 3 months of follow-up, median follow-up: 12 months [6–18], age: 32 ± 17 years, 28% <18 years-old, 62% female. The main indication for SAP-PLGS was frequent hypoglycaemia (57%, n = 92), 29% of the patients had a history of severe hypoglycaemia. Baseline HbA1c dropped from 7.2 ± 0.8% to 7.1 ± 0.7% at 12 months ($p = 0.029$, n = 100), with no significant differences at 3, 6, 18 and 24 months. Percentage of patients with HbA1c in range increased from 56% to 59% at the last follow-up visit; percentage of SMBG values <70 mg/dl decreased from 10 ± 7% to 6 ± 5%, with no changes in values <54 mg/dl, >180 mg/dl or >250 mg/dl; number of SMBG per day decreased from 7.4 ± 3.2 to 6.6 ± 2.7; bolus insulin increased from 52 ± 14% to 54 ± 13% (all $p < 0.01$). Sensor use was 6.0 ± 0.8 days/week. Sensor values were compared in the group of patients using CGM before SAP-PLGS (n = 54, median

	Baseline	End of follow-up	p
Hba1c (%)	7.0 ± 0.7	7.1 ± 0.8	0.640
Time < 54 mg/dl (%)	1.2 ± 1.6	0.8 ± 0.9	**0.035**
Time < 70 mg/dl (%)	4.5 ± 3.6	3.1 ± 2.3	**0.001**
Time > 180 mg/dl (%)	30 ± 14	44 ± 74	0.144
Time > 250 mg/dl (%)	6.8 ± 6.4	8.1 ± 7.5	0.160
Mean sensor glucose (mg/dl)	147 ± 29	156 ± 22	**0.034**
SD of sensor glucose (mg/dl)	54 ± 12	53 ± 13	0.579
Sensor use (days per week)	5.6 ± 1.1	5.9 ± 0.9	0.059

n=54. Data are expressed as mean ± standard deviation.

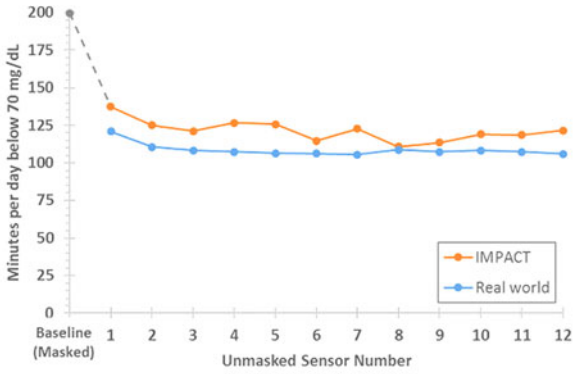

Figure 1 Comparison of longitudinal outcomes between clinical trial and real-world use of the FreeStyle Libre system for individuals at risk for hypoglycaemia.

follow-up: 12 months) (Table 1). Patient satisfaction was high in 73% of patients (n = 80).

Conclusion: Sensor-augmented insulin pump with predictive low glucose suspension reduces time in hypoglycaemia, without worsening glycaemic control, in children and adults in a real-world clinical setting.

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Glucose Sensors

ATTD8-0345

COMPARISON OF FLASH GLUCOSE MONITORING USAGE PATTERNS AND GLYCAEMIC OUTCOMES IN THE REAL-WORLD WITH THOSE OBSERVED IN A RANDOMIZED CONTROLLED TRIAL

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Background and Aims: Flash Glucose Monitoring (Freestyle Libre™ system) use was assessed in the IMPACT study for glycaemic outcomes and scanning patterns over 6 months. Here, we compare real-world data with data from IMPACT in a similar population of individuals with well controlled diabetes.

Method: De-identified glucose data from 4793 users over 6 months (12 sensors) were investigated. Only individuals with an Estimated HbA1c ≤ 7.5% during Sensor 1 wear were included. A comparison of time spent in hypoglycaemia (<70 mg/dL) and time spent in serious hypoglycaemia (54 mg/dL or lower) in consecutive 2 week periods over 6 months was made between real-world and IMPACT data. A comparison of overall scanning frequencies was also made.

Results: Comparing time spent in hypoglycaemia, a reduction of 11% was seen from Sensor 1 to Sensor 12 (from 137 min/day to 122 min/day, p = 0.039) in IMPACT and 12% in real-world data (from 121 min/day to 106 min/day, p < 0.001). A reduction in time spent in serious hypoglycaemia of 13% was seen from Sensor 1 to Sensor 12 (from 55 min/day to 48 min/day, p = 0.112) in IMPACT data and 10% in real-world data (from 48 min/day to 43 min/day, p < 0.001). Overall average scan rates of 15 scans/day were observed in IMPACT and 14 scans/day in real-world data.

Conclusion: Freestyle Libre use in the real world demonstrates similar usage patterns and improvements in hypoglycaemia that were observed in clinical trials in individuals with well controlled diabetes.

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Glucose Sensors

ATTD8-0320

ACCURACY AND PRECISION EVALUATION OF FLASH GLUCOSE MONITORING SENSORS IN DIFFERENT SITES: THE ABDOMEN AND UPPER THIGH COMPARED TO THE UPPER ARM (OUT OF SIGHT)

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Background and Aims: To compare accuracy and precision of FreeStyle® Libre™ (FSL) flash glucose monitoring sensors (Abbott Diabetes Care, Alameda, CA) placed on the upper arm, abdomen and upper thigh.

Method: Twenty-two well controlled (median HbA_{1c} 7.2%; IQR 6.9–7.4) adults with long-standing type 1 diabetes on multiple daily injections (18/22) or insulin pump (4/22) and median BMI of 24.9 kg/m^2 (IQR 23.0–25.6) were included. Three FSL sensors were simultaneously inserted for 14 days on the back of upper arm, abdomen and upper thigh. FSL measurements were compared to capillary blood glucose (BG) measurements (median 6.8/day; IQR 6.3–7.0) obtained with the built-in FSL BG meter.

Results: Overall mean absolute relative difference (MARD) was 11.9%, 18.7% and 12.3% for arm, abdomen (p < 0.0005 vs.

arm) and thigh (p = 0.5 vs. arm) respectively. In hypoglycaemic range (≤70 mg/dL), sensors performed worse in every position with MARD of 22.7%, 22.5% and 21.1% respectively. Overall precision absolute relative difference (PARD) was markedly lower for thigh vs. arm (10.9%) compared to abdomen vs. arm (20.9%). Clarke error grid analysis for arm and thigh were comparable (zone A: 84.70% vs. 84.41%; zone B: 12.76% vs. 13.48%, p = 0.5), while less accuracy was seen for the abdomen (zone A: 69.19%; zone B: 28.31%, p = 0.01). Sensors on the thigh were more often lost (nine times by seven patients) than those on arm or abdomen (two times by two patients).

Conclusion: Accuracy and precision of FSL sensors placed on the upper thigh are comparable to the upper arm but sensor loss was higher, whereas the abdomen performed unacceptably poor.

049

Glucose Sensors

ATTD8-0079

IMPACT OF NATIONAL REIMBURSEMENT STATUS ON REAL WORLD FLASH GLUCOSE MONITORING USE AND GLYCEMIC CONTROL MEASURES

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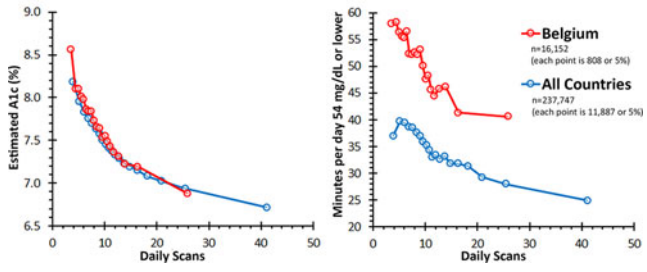
Background and Aims: Flash glucose monitoring (FreeStyle Libre™) has been available fully reimbursed since introduction in Belgium, allowing evaluation of use patterns and associations with glucose control measures. The FreeStyle Libre system is a sensor-based glucose monitor, and when connected to the PC-based software with an active internet connection, the reader's 90-day memory is de-identified and uploaded to a database.

Method: For analysis, sensors were required to have at least 120 hours of operation, and all sensors were grouped per reader, resulting in 237,747 readers with 1,569,588 sensors, of which 16,152 readers with 147,976 sensors were from Belgium. Twenty equally-sized groups by scan rate were analyzed overall and for only Belgium.

Results: Overall, users performed an average (SD) of 13.2 (8.9) scans per day (median:11.1, interquartile range: 8.0–15.5), compared to Belgian users averaging (SD) 9.6 (5.3) scans per day (median:8.8, interquartile range: 6.2–11.4). For Belgian users, estimated HbA1c decreased (p < 0.001) as scan rate increased, from 8.6% to 6.9% from the lowest (mean 3.5 scans/day) to highest (mean 25.8 scans/day) groups, while simultaneously time at 54 mg/dL or below decreased by 30% (all p < 0.001). Time above 180 mg/dL decreased from 12.0 to 6.8 h/day (43% decrease, p < 0.001), and time in range 70-180 mg/dL increased from 10.1 to 15.4 h/day (52% increase, p < 0.001).

Conclusion: In real-world use when access to flash glucose monitoring is fully reimbursed, similar patterns were observed of higher rates of scanning associated with improved glucose measures, including decreased mean glucose, decreased time in hyper- and hypoglycemia, and increased time in range.

Figure 1. Association between frequency of flash glucose monitoring scans and glucose control measures during real-world usage.



050

Glucose Sensors

ATTD8-0018

REVISITING THE RELATIONSHIPS BETWEEN MEASURES OF GLYCAEMIC CONTROL AND HYPOGLYCAEMIA IN CONTINUOUS GLUCOSE MONITORING DATASETS

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Background and Aims: The Diabetes Control and Complication Trial (DCCT) identified an inverse relationship between HbA_{1c} and severe hypoglycaemia. We investigate the relationship between hypoglycaemia and HbA_{1c} in a large type 1 diabetes cohort on multiple daily injection or insulin pump therapy using blinded continuous glucose monitoring (CGM) data. The impact of unblinded CGM on these relationships and how these relationships differ with biochemical definitions of hypoglycaemia have also been assessed.

Method: CGM data were obtained from the *JDRF* CGM randomised control trial. Baseline blinded-CGM data were used to assess time in hypoglycaemia in all individuals. Endpoint data from the CGM intervention group were used to assess the impact of CGM. Percentage time below 3.9 mmol/L, 3.3 mmol/L, 3.0 mmol/L and 2.8 mmol/L were calculated and quadratic regression plots drawn. Relationships were analysed visually and analysis of variance was used to assess relationships between glycaemia and time below threshold.

Results: J-shaped relationships were observed for all biochemical hypoglycaemia thresholds with the lowest hypoglycaemia risk occurring at HbA_{1c} values between 8.1–8.6% (65-70 mmol/mol). Real-time CGM flattened the relationships for 3.3 mmol/L, 3.0 mmol/L and 2.8 mmol/L and analysis of variance confirmed the loss of relationship for the 3.3 mmol/L threshold using CGM.

Conclusion: The relationship between hypoglycaemia and HbA_{1c} in a type 1 diabetes population is J-shaped. Lower HbA_{1c} values are still associated with increased hypoglycaemia risk, although the magnitude of risk depends on biochemical threshold. Real-time CGM abolishes this relationship below 3.3mmol/L. CGM may dissociate biochemically significant hypoglycaemia from HbA_{1c}.

051

Glucose Sensors

ATTD8-0142

SUSTAINED IMPROVEMENT IN GLYCAEMIC CONTROL FOLLOWING FLASH GLUCOSE MONITORING: A WORLDWIDE OBSERVATIONAL ANALYSIS

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Background and Aims: Flash Glucose Monitoring (Freestyle Libre™ system) in clinical trials shows significant improvement in glycaemic markers during initial days of sensor use followed by further gradual, sustained improvement over several months. In the absence of glucose data before sensor use, our aim was to evaluate Libre in real life settings for gradual and sustained improvement in glycaemia using a longitudinal observational study.

Method: De-identified glucose data from 6802 users over 6 months (12 sensors) were investigated. The population was divided into tertiles of low, medium and high risk groups defined by time in hyperglycaemia (>180 mg/dl), hypoglycaemia (<70 mg/dl) and serious hypoglycaemia (<55 mg/dl) during 1st sensor use. Each group was further sub-divided into tertiles of lower, medium and higher scanning frequency. Glycaemic parameters of the 1st and 12th sensor were compared.

Results: Comparing the 1st and 12th sensors, individuals in high risk tertile for hyperglycaemia showed reduced time >180 mg/dl (mean±SD) from 12.7 ± 2.8 to 11.3 ± 4.0 h/day in higher scanners ($p < 0.0001$) with a limited effect in lower frequency scanners (from 13.4 ± 3.0 to 12.8 ± 4.3h; $p = 0.002$). Higher and lower frequency scanners in high risk tertile for hypoglycaemia showed reduced time <70 mg/dl (from 194 ± 86 to 156 ± 116 min; $p < 0.0001$ and 199 ± 95 to 151 ± 105 min; $p < 0.0001$, respectively). Time <55 mg/dL was also reduced in higher and lower frequency scanners (87 ± 60 to 64 ± 70 min and 94 ± 66 to 71 ± 70 min, respectively; $p < 0.0001$ for both).

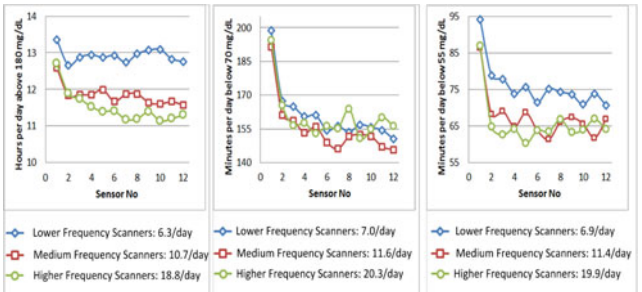

Figure 1 Hyperglycaemia and Hypoglycaemia outcomes over time (represented by sensor number) for individuals with high initial risk of hyperglycemia (left), hypoglycemia (middle) or serious hypoglycemia (right). The legend shows mean scanning frequency (scans/day) for each of the sub-groups.

Conclusion: Similar to clinical trials, Freestyle Libre system use in real life settings is associated with sustained improvement in time spent in hyperglycaemia, hypoglycaemia and serious hypoglycaemia, with an enhanced benefit for frequent scanners.

052

Glucose Sensors

ATTD8-0346

THE IMPACT OF SWITCHING FROM FLASH GLUCOSE MONITORING TO REAL-TIME CGM ON HYPOGLYCAEMIA IN ADULTS WITH TYPE 1 DIABETES AND IMPAIRED AWARENESS OF HYPOGLYCAEMIA

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Background and Aims: The I-HART-CGM study showed that real-time continuous glucose monitoring (RT-CGM, Dexcom G5) has greater beneficial impact on hypoglycaemia than intermittent flash glucose monitoring (flash, Abbott Freestyle Libre) in adults with type 1 diabetes (T1D) and impaired awareness of hypoglycaemia (IAH). We then aimed to evaluate the impact of continuing RT-CGM or switching from flash to RT-CGM for another 8 weeks.

Method: Prospective randomized parallel group study. After two-week run in with blinded CGM participants were randomized to either RT-CGM or flash for 8 weeks. All participants were then given the option to continue with RT-CGM for another 8 weeks. Glycaemic outcomes at 8 weeks are compared to the 16-week endpoint.

Results: 40 adults with T1D on intensified multiple daily insulin injections and IAH were included (40% female, median (IQR) age 49.5 (37.5–63.5) years, diabetes duration 30.0 (21.0–36.5) years, HbA1c 56 (48–63) mmol/mol and Gold Score 5 (4–5)) of which 36 completed the final 8-week intervention. There was significant reduction in percentage time in hypoglycaemia (<3.0 mmol/l) in the flash group after switching to RT-CGM (5.0 (3.7–8.6) vs 0.8 (0.4–1.9), $p = 0.0001$) and no change was observed in the RT-CGM group that continued with RT-CGM (1.3 (0.4–2.8) vs 1.3 (0.8–2.5), $p = 0.82$). Significant difference in reduction between the groups ($D = -4.2$, $p < 0.0001$) was observed (Table 1).

Conclusion: Our data suggest that switching from flash to RT-CGM has a significant beneficial impact on hypoglycaemia outcomes and that continued use of RT-CGM maintains hypoglycaemia benefit in this high-risk population.

	RT-CGM group n=16			Flash glucose monitoring group n=20			Median change from baseline		
% time in defined glucose range	At 8 weeks	Endpoint at 16 weeks	p	At 8 weeks	Endpoint at 16 weeks	p	RT-CGM group	FGM group	p
<2.8mmol/L	0.8 (0.2 – 1.7)	0.9 (0.3 – 1.5)	0.82	3.8 (3.0 – 6.4)	0.5 (0.2 – 1.4)	**<0.001**	0.1	- 3.3	**<0.001**
<3.0mmol/L	1.3 (0.4 – 2.8)	1.3 (0.8 – 2.5)	0.82	5.0 (3.7 – 8.6)	0.8 (0.4 - 1.9)	**<0.001**	0.0	- 4.2	**<0.001**
<3.3mmol/L	2.3 (0.9 – 4.4)	2.1 (1.4 – 4.4)	0.73	6.8 (4.8 - 11.7)	1.5 (0.7 - 2.8)	**<0.001**	- 0.2	- 5.3	**<0.001**
<3.5mmol/L	3.1 (1.5 – 5.9)	3.3 (2.2 – 6.7)	0.77	8.2 (6.0 – 13.2)	2.1 (1.2 – 4.0)	**<0.001**	0.2	- 7.1	**<0.001**
<3.9mmol/L	6.2 (3.1 – 8.7)	5.4 (3.9 - 9.7)	0.86	11.0 (8.2 -17.0)	3.9 (2.4 -6.7)	**<0.001**	- 0.8	- 7.1	**<0.001**
>7.8mmol/L	49.0 (43.9 – 56.8)	45.6 (40.4 – 63.5)	0.99	47.1 (37.4 – 53.5)	50.2 (44.7 – 57.8)	**0.007**	-3.4	3.1	**0.02**
>10mmol/L	26.7 (17.5 – 36.1)	28.8 (15.8 – 46.3)	0.82	28.0 (18.0 – 32.1)	27.8 (23.0 – 34.3)	**0.02**	2.1	-0.2	0.18
>15mmol/L	4.2 (1.2 – 8.8)	4.8 (1.4 – 9.1)	0.71	2.6 (1.2 – 5.1)	2.7 (2.3 – 5.0)	0.09	0.6	0.1	0.36
3.9-7.8 mmol/L	43.7 (38.1 – 47.8)	43.1 (32.1 - 54.0)	0.69	40.4 (34.7 – 45.3)	42.9 (34.9 – 49.8)	0.68	-0.6	2.5	0.81
3.9-10 mmol/L	65.9 (54.1 – 74.8)	64.9 (49.2 – 73.9)	0.64	60.0 (54.5 – 67.8)	67.4 (56.3 – 72.4)	**0.02**	-1.0	7.4	**0.04**
Other outcomes									
Low Blood Glucose Index	4.8 (2.8 – 6.3)	4.6 (3.8 – 5.9)	0.69	9.1 (7.2 – 10.7)	4.1 (3.0 – 4.9)	**<0.001**	-0.2	-5.0	**<0.001**
Gold score	5.0 (3.0 – 5.0)	4.5 (3.0 – 6.0)	0.82	5.0 (3.5 – 6.0)	4.5 (3.0 – 5.5)	**0.04**	-0.5	-0.5	0.46
HbA1c mmol/mol	54.0 (46.0 – 62.0)	51.5 (47.0 – 58.0)	0.87	51.0 (48.5 – 59)	52.0 (49.5 – 60.5)	0.07	- 2.5	1.0	0.49

Table 1: Change in glucose outcomes and Gold scores from 8 weeks to endpoint at 16 weeks with RT-CGM. Results are expressed as median (IQR). P values of <0.05 are significant.

053

Glucose Sensors

ATTD8-0117

CHARACTERIZATION OF THE ERRORS BETWEEN SMBG AND A FLASH GLUCOSE MONITOR IN THE FIRST DAY OF USE

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Background and Aims: Freestyle Libre (FL) is a factory calibrated Flash Glucose Monitor providing point measurements of glucose whenever the user scans the sensor. This study investigated some offset and lag issues seen in the first day of wear of the Libre.

Method: 39 subjects with DM1 wore FL for one week. One day after the sensor was inserted, a comparison session with frequent measurements from a Self Monitoring Blood Glucose (SMBG) meter was performed. Glucose excursions were generated by meals and insulin injections. The Mean Absolute Relative Deviation (MARD), bias and lag between the FL and SMBG measurements were computed.

Results: The individual session MARDs ranged from 4% to 26% with a mean MARD of 12.3% and standard deviation of 5.4%. Five patients had a MARD ≥20%. The estimated biases range from −1.9 to 1.4 mmol/L, and lags range from 1 to 24 minutes. The bias is the main reason for poor MARDs. Bias correction results in a max per-patient MARD of 17%, and a mean MARD of 9%. None of the factors body mass index, blood pressure medication, other medication, diabetes duration or gender could explain the bias or lag.

Conclusion: The Freestyle Libre has some signal errors in the first day of wear that is relevant for normal users of the systems and researchers using data from the Freestyle Libre. The errors can be characterized as a combination of bias and lag errors. All cases of MARD ≥20% can be eliminated by bias correction.

054

Glucose Sensors

ATTD8-0354

TIME SPENT IN THE LOW GLYCEMIC RANGE: DIFFERENCES BETWEEN AND WITHIN CONTINUOUS GLUCOSE MONITORING SYSTEMS

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Background and Aims: The effect of continuous glucose monitoring (CGM) on glycemic control is often assessed by analysis of time spent within certain glycemic ranges. This analysis focused on time spent in the low glycemic range as reported by different CGM systems.

Method: Data from 20 subjects who each wore 2 Dexcom® G5 (DG5) systems and 2 FreeStyle® Libre (FL) systems in parallel for 14 days were used to calculate time spent at glucose values <70 mg/dL. For each of the four 14-day data sets in a subject, CGM readings were linearly interpolated to 1-minute intervals. Percentage of time spent <70 mg/dL was calculated by dividing the number of interpolated values <70 mg/dL by the total duration of the experiment. Additionally, paired absolute differences between percentages from the same model of CGM system within a subject were calculated.

Results: On average, 5.6% of DG5 and 7.4% of FL values were <70 mg/dL, corresponding to 81 and 106 min per day, respectively. Within the same subject, the median paired absolute difference between percentages was 0.6% (≙9 min) for DG5 and 3.0% (≙43 min) for FL, ranging from 0.0% to 1.8% (≙0 to 26 min) and from 0.0% to 23.4% (≙0 to 337 min), respectively.

Conclusion: In this analysis, time apparently spent in the low glycemic range varied not only between the two models of CGM system, but also among different systems of the same model. If time within specific glycemic ranges is calculated from CGM values, it may be influenced by the specific CGM system used.

055

Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0074

INTERVENTION INCLUDING PERSONALIZED CARBOHYDRATE RESTRICTION BY LOW CARBOHYDRATE HIGH FAT DIET USING DIGITAL INTERVENTION TO REDUCE HB1AC LEVEL, MEDICATION & WEIGHT IN T2DM PATIENTS

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Background and Aims: To evaluate intervention of personalized carbohydrate restriction by incorporating Low Carbohydrate High Fat Diet as part of a comprehensive training for T2D patients using mobile phone digital intervention and its efficacy in reducing HB1AC level and improving weight.

Method: This study was a non-randomized outpatient intervention focused on adults with Type 2 Diabetes. Patients enrolled in the trial were provided intensive dietary (low carb high fat diet) and lifestyle training, digital recording of blood sugars, food intake, physical activity and weight. Hb1Ac and other bio markers were recorded baseline and after the 12-week study. Ketones levels were checked after every 15 days. Continuous monitoring of data was done by AI, health coaches and doctor and any inconsistency was appropriately responded and reported to doctors.

Results: Adults (N = 112 with mean age of 48, F = 44; M = 68) were enrolled for trial and 98 people completed it. Baseline average Hb1Ac was 8.6% (SD: 0.65%). After the study, the average baseline Hb1Ac was reduced by 1.3% (SD: 0.68%). The average weight loss was 7.7 kg (SD: 2 kg), with reduction in medication dependence by 59%. People were able to understand the diet plan and record data on the app easily.

Conclusion: The initial results indicate that digital intervention program incorporating personalized carbohydrate restriction

leading to nutritional ketosis, data monitoring and AI can help in improving quality of life of T2DM patients by reducing Hb1AC level, reducing weight and lowering medication dependence. A similar program can be launched in mass to help patients and physicians achieve better results.

056

Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0026

INSIGHTS FROM BIG DATA (2): BENEFITS OF SELF-GUIDED RETROSPECTIVE REVIEW OF CONTINUOUS GLUCOSE MONITORING REPORTS

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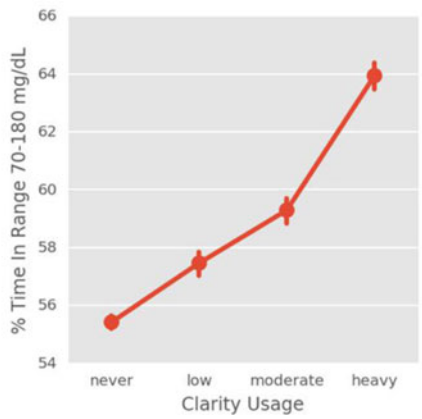
Background and Aims: Retrospective analysis of continuous glucose monitoring (CGM) data can help patients identify and formulate strategies to improve their diabetes management. The analysis can be independent (self-guided) or with expert guidance of specialist clinician(s). We examined the extent of CGM usage and exposure to hypoglycemia among users of Clarity® software (Dexcom, Inc., San Diego, CA).

Method: Clarity is a web-based and mobile app that stores and displays CGM data that highlight glucose patterns, trends, and statistics in standardized reports. Patients who upload their data can view reports at their discretion. We included data from a convenience sample of 50,000 users of the Dexcom G5 Mobile CGM system who uploaded data in August, 2017. Time in range was calculated as the percentage of SG values between 70 and 180 mg/dL.

Results: The distribution of Clarity login frequencies is shown in the Table, and the relationship between login frequency and mean (±SE) time in range is shown in the Figure. Most patients never reviewed their Clarity reports. Patients who logged in more frequently had higher percentages of SG values in the target range, with correspondingly lower percentages indicative of hypoglycemia and hyperglycemia.

Conclusion: Improvements in time in range were strongly correlated with the frequency that patients logged in to access their stored data and review their Clarity reports. Self-guided retrospective review of CGM data may help patients improve their diabetes management skills.

Login Frequency (per month)	0 ("never")	1 ("low")	2-3 ("moderate")	4+ ("heavy")
N (%)	29248 (58%)	7829 (16%)	6558 (13%)	6365 (13%)
% Time In Range (Mean ± SD)	55.4 ± 19.4	57.4 ± 18.8	59.2 ± 18.3	63.9 ± 18.0



057

Insulin Pumps

ATTD8-0094

IMPACT OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION ON DIABETES RELATED COMPLICATIONS AND ASSOCIATED COSTS IN TYPE 2 DIABETES PATIENTS IN FINLAND

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Background and Aims: To assess the reduction of complications and costs with continuous subcutaneous insulin infusion (CSII) versus multiple daily injections (MDI) in uncontrolled type 2 diabetic patients (T2D) in Finland.

Method: The Core Diabetes Model was used to calculate the diabetes-related complications incidence and associated costs (treatment, complications and productivity costs) for both treatments. The population characteristics, the reduction of HbA1c, and insulin dose were based on the Opt2mise study (Reznik et al., Lancet 2014). For a baseline HbA1c of 9.0%, the reduction in HbA1c was −1.1% for CSII versus −0.4% for MDI. Costs were

Table 1. Time alive and free of complications (in years).

	CSII	MDI	Delta
Background Retinopathy	14.38	13.18	1.2
Proliferative Retinopathy	19.03	18.17	0.86
Microalbuminuria	12.4	11.27	1.13
Gross Proteinuria	17.06	15.87	1.19
End Stage Renal Disease	20.19	19.31	0.88
1st Ulcer	19.98	19.29	0.69
Amputation	20.32	19.63	0.69
Neuropathy	8.59	7.43	1.16
Peripheral Vascular Disease	17.59	16.89	0.7
Congestive Heart Failure	20.03	19.36	0.67
Angina	18.87	18.28	0.59
Myocardial Infarction	18.62	17.96	0.66
Stroke	19.71	19.01	0.7
Cataract	16.73	16.05	0.68
Macular Edema	16.04	14.84	1.2
Severe Vision Loss	18.23	17.27	0.96

specific to Finland and expressed in 2017 euros. The main analysis was conducted from a societal perspective over a lifetime horizon with costs and health results discounted at 3%.

Results: Over lifetime, diabetes-related complications with CSII were delayed by 0.9 years with notably a delay in myocardial infarction, amputation, end-stage renal disease and severe vision loss by 0.66; 0.69; 0.88 and 0.96 years respectively (table 1). CSII was associated with improvements in quality-adjusted life years by 0.318 and €15'206 higher total costs, versus MDI. In the short term (year 5), the reduction in complications incidence associated with eye diseases, renal diseases, ulcer/amputation and cardiovascular diseases were −24%, −28%, −17% and −5%, respectively, in favor of CSII. This equates to complication cost reduction of 16.5% over 5 years.

Conclusion: Improvements in HbA1c with CSII versus MDI, may offer important reductions in diabetes-related complications and associated costs in a Finnish setting for uncontrolled T2D.

058

Insulin Pumps

ATTD8-0130

GLYCO-METABOLIC CONTROL, INFLAMMATION MARKERS AND CARDIOVASCULAR OUTCOMES IN DIABETIC PATIENTS ON INSULIN PUMP OR MULTIPLE DAILY INJECTION

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Background and Aims: Studies regarding the effects of continuous subcutaneous insulin infusion (CSII) regarding cardiovascular complications are lacking. We performed a study aimed to evaluate if the positive effects recorded on glycemic control with CSII were maintained on the long term compared to multi-daily injections (MDI). The secondary objective was to evaluate if there is a reduction of type and number of cardiovascular events (CV) in CSII group compared to MDI group after 8 years of observation.

Method: This retrospective, observational trial evaluated 104 diabetic patients with prior treatment with MDI initiating CSII therapy compared to 109 diabetic patients continuing MDI.

Results: After 8 years the glycemic control including HbA_{1c}, FPG, and PPG improved with both CSII, and MDI compared to baseline, however, data with CSII were lower than those recorded with MDI. More patients in the group treated with MDI had a higher rate of hypoglycemia, and a higher rate of hyperglycemia. After 8 years, patients treated with CSII showed a decrease of TC, Tg, and LDL-C, and an increase of HDL-C compared to baseline. In group to group comparison, TC, and LDL-C were lower, and HDL-C was higher in CSII group compared to MDI. During the 8 years, there was a reduction of the CV events with CSII, compared to MDI, and in particular there was a reduction of atrial fibrillation, premature ventricular contractions, acute coronary infarction, angina pectoris, and peripheral vascular ischemia.

Conclusion: Despite the higher costs, CSII treatment seems to reduce the rates of cardiovascular events compared to MDI therapy.

059

Insulin Pumps

ATTD8-0357

THE EFFECT OF INSULIN PUMP THERAPY ON GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS – A PROSPECTIVE STUDY

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Background and Aims: Continuous subcutaneous insulin infusion (CSII) has been less evaluated in type 2 diabetes (T2D). It may be offered as an alternative treatment to patients with poor glycaemic control despite high-dose insulin requirements administered through multiple daily injections (MDI).

The purpose of the study was to evaluate the use of CSII in patients with T2D who have not achieved sufficient glycemic control on MDI regimen

Method: In this multi-center prospective, observational, 26-week study, 18 insulin-pump-naive T2D patients [age 57 ± 10 years, HbA1c 9.0 ± 1.0%, body weight 93.1 ± 18.1 kg, total daily insulin dose 99 ± 65 U, mean±SD] treated at baseline with MDI therapy with or without oral antidiabetic agents discontinued all diabetes medications except metformin and initiated CSII.

The primary endpoint was to evaluate the difference in average HbA1c between baseline and 6 months.

Results: Glycemic control improved significantly after 26 weeks to HbA1c 7.6 ± 0.7% (−1.5 ± 1.2%, $p < 0.001$) At week 26, the mean daily basal, bolus, and total insulin doses were 40 ± 36, 56 ± 40, and 93 ± 22 U (1.2 U/kg), respectively, and 90% of patients were treated with two basal rates. The body weight changed from 93.1 ± 18.1 to 92.2 ± 17.8 kg, $p = 0.831$. Hypoglycemic event frequency reduced for −2.1% (95%CI, −6.0 to −0.25; $P = 0.04$). Moreover, no severe hypoglycemia was detected during the study follow-up. There were no diabetes-related serious adverse events.

Conclusion: CSII improved glycemic control, reduced the number of hypoglycemic episodes without weight gain, and was well tolerated for the whole study period. Furthermore, this therapeutic approach was accompanied with lower daily insulin requirements.

060

Insulin Pumps

ATTD8-0067

AIM FOR THE BEST - INSULIN PUMPS COMMENCED AT DIAGNOSIS

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Background and Aims: Families always remember the first words spoken to them with the onset of Type 1 Diabetes. These words and the education received, colour the next 30 years of diabetes care.

It is clear that the diabetes control in the first year also predicts the long-term level of control.

We propose that starting a pump at diagnosis and offering pens as back up provides the best outcome with the least education time, less anxiety and lower HbA1c.

Previously shown in a respective study, 38 subjects in the early pump group (EPG) (age 12.6 + 4.9yr, 23 male) and 37 in the later pump group (LPG) (age 13.1 + 4.1yr, 19 male).

Method: Haemoglobin A1c (HbA1c), rate of severe hypoglycaemia, and diabetic ketoacidosis (DKA) were collected retrospectively over a 48-month period. Eligible subjects and/or their parents completed both a Pediatric and Pediatric Diabetes-specific Quality of Life Inventory.

Results: HbA1c measurements were lower in the EPG (6.8%;51 mmol/mol) compared to the LPG (7.9%; 63 mmol/mol), across the 48 month of the study ($P < 0.0001$). There was no significant difference in the rate (per patient years) of severe hypoglycaemia (0.02;0.07) $p = 0.075$ between the groups. There were no significant difference in QOL between the groups with both having high satisfaction rates.

Conclusion: Initiation of IPT at diagnosis of type 1 diabetes in children resulted in consistently lower HbA1c with no apparent change in hypoglycaemia, DKA, or QOL.

Given these dramatic outcomes we propose this is the gold standard approach in the care of children with Type 1 Diabetes from diagnosis.

061

New Insulin Analogues

ATTD8-0209

ONSET 1: EFFICACY AND SAFETY OF MEALTIME FAST-ACTING INSULIN ASPART VERSUS INSULIN ASPART AFTER 52 WEEKS

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Background and Aims: onset 1 was a randomised trial evaluating fast-acting insulin aspart (FA) in adults with type 1 diabetes (T1D) over 52 weeks in two 26-week periods.

Method: Subjects were administered double-blind mealtime FA, insulin aspart (IAsp) or open-label post-meal FA, each with insulin detemir, for 26 weeks. Subjects on mealtime FA (n = 381) and IAsp (n = 380) continued to the additional 26-week period assessing long-term safety and efficacy.

Results: After 52 weeks, HbA_{1c} change from baseline (−0.08% [FA] vs. +0.01% [IAsp]) showed significant estimated treatment difference (ETD) [95% confidence interval (CI)] favouring FA (−0.10% [−0.19;−0.00]). Change from baseline in 1-h postprandial plasma glucose (PPG) increment after a standardised meal test significantly favoured FA (ETD: −0.91 mmol/L [−1.40;−0.43]); a similar trend was seen in change from baseline in 2-h PPG increment (ETD: −0.42 mmol/L [−1.11;0.27]). Mean 7-9-7-point self-measured plasma glucose profiles significantly favoured FA (ETD: −0.23 mmol/L [−0.46;−0.00]). Median total insulin dose was 0.77 U/kg (FA) vs. 0.83 U/kg (IAsp). No difference was observed for body-weight change (ETD: 0.13 kg [−0.38;0.65]). After 52 weeks, adverse events were similar between FA and IAsp, and as expected for IAsp. Severe or blood glucose-confirmed hypoglycaemia rates (plasma glucose <3.1 mmol/L) were similar with FA versus IAsp (estimated ratio: 1.01 [0.88;1.15]).

Conclusion: No long-term safety issues were identified with FA. Approaching a profile closer to physiology with FA achieves lower PPG and HbA_{1c} in T1D compared with IAsp.

062

New Insulin Analogues

ATTD8-0440

EFFICACY AND SAFETY OF INSULIN GLARGINE-300 U/ML VS INSULIN DEGLUDEC-100 U/ML IN INSULIN-NAIVE ADULTS WITH T2DM: FIRST HEAD-TO-HEAD RANDOMISED CLINICAL TRIAL

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Background and Aims: Insulin glargine 300 U/mL (Gla-300) and insulin degludec 100 U/mL (IDeg 100) have similar efficacy on glycaemic control versus insulin glargine 100 U/mL (Gla-100) in type 2 diabetes (T2DM), with lower frequencies of hypoglycaemia. However, direct head-to-head clinical comparisons of Gla-300 versus IDeg-100 have not been reported. This study aimed to evaluate the efficacy and safety of Gla-300 and IDeg-100 in insulin-naïve T2DM. Baseline characteristics are focussed on here.

Method: In this 24-week multinational, multicentre, open-label, two-arm, parallel-group trial (NCT02738151), insulin-naïve adults with T2DM inadequately controlled with oral anti-hyperglycaemic drugs (OAD) with/without glucagon-like peptide-1 receptor agonists (GLP-1 RAs) were randomised 1:1 to receive Gla 300 or IDeg-100, administered once-daily during the evening. The primary endpoint was HbA1c change from baseline to week 24. Secondary endpoints included incidence and event rates of hypoglycaemia categories, insulin dose change, blood glucose level change, and adverse events.

Table: Baseline characteristics

Randomised population			
Baseline characteristics	**Gla-300 (N=466)**	**IDeg-100 (N=463)**	**Total (N=929)**
Age, years	60.6 ± 9.6	60.5 ± 9.8	60.5 ± 9.7
Gender (%), (male/female)	53/47	54/46	54/46
BMI, kg/m²	31.7 ± 4.3	31.3 ± 4.4	31.5 ± 4.4
Known T2DM duration, years	10.5 ± 6.1	10.7 ± 6.5	10.6 ± 6.3
Number of prior non-insulin anti-hyperglycaemic agents used (%)			
0	0.0	0.2	0.1
1	15.0	14.0	14.5
2	38.4	40.4	39.4
>2	46.6	45.4	46.0
Prior non-insulin anti-hyperglycaemic treatment (%)			
Metformin	91.8	91.1	91.5
Sulphonylureas	64.6	66.7	65.7
DDP-4 inhibitors	26.0	22.9	24.4
SGLT-2 inhibitors	13.3	13.4	13.3
GLP-1 RA	9.9	14.0	11.9
Thiazolidinediones	4.5	5.2	4.8
Glinides	2.6	1.9	2.3
Alpha-glucosidase inhibitors	1.9	1.5	1.7
Other	0.2	0.2	0.2
Intention-to-treat population			
Baseline characteristics	**Gla-300 (N=462)**	**IDeg-100 (N=462)**	**Total (N=924)**
HbA_{1c}, %	8.7 ± 0.8	8.6 ± 0.8	NA
FPG, mmol/L	10.6 ± 2.7	10.1 ± 2.9	NA

Data are presented as mean ± SD, unless otherwise stated
DDP-4, dipeptidyl peptidase-4; GLP-1 RA, glucagon-like peptide-1 receptor agonist; NA, not assessed; SD, standard deviation; SGLT-2, sodium-glucose co-transporter-2; T2DM, type 2 diabetes

Results: In total, 929 participants from 16 countries were randomised to Gla-300 or IDeg-100; 94% of participants completed the 24-week treatment period. Baseline characteristics were similar between the treatment groups (Table). Both groups titrated insulin effectively; overall, 47% of participants reached target HbA1c <7.0 %. No specific safety concerns were reported.

Conclusion: This head-to-head trial is the first to directly assess similarities and/or differences in the efficacy and safety of Gla-300 and IDeg-100, in insulin-naïve adults with uncontrolled, long-standing T2DM on OAD with/without GLP-1 RAs. Demographics were typical of this population, and well balanced between treatment arms. Approximately half achieved target HbA1c, indicating effective insulin titration.

Study sponsored by Sanofi: NCT02738151

Conflict of interest statement:

(Potential conflict of interest can involve: grants, honorarium, shares, paid positions on advisory boards, etc.)

063

New Insulin Analogues

ATTD8-0331

DEVICE-SUPPORTED VS ROUTINE (INVESTIGATOR-RECOMMENDED) TITRATION OF INSULIN GLARGINE 300 U/ML (GLA-300) IN TYPE 2 DIABETES (T2DM): EFFICACY AND TREATMENT SATISFACTION

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Background and Aims: Evaluate efficacy and treatment satisfaction of device-supported versus routine titration of Gla-300 using MyStar DoseCoach™ (MSDC), a combined titration device/blood glucose meter.

Method: In a randomized, parallel-group, multicenter, treat-to-target trial (AUTOMATIX), insulin-pretreated or -naïve people with T2DM were titrated to a fasting self-monitored plasma glucose (FSMPG) target of 90–130 mg/dL. Primary endpoint: percentage of participants achieving target FSMPG at week 16 without severe hypoglycemia. Secondary endpoints included time to first achieve FSMPG target and participant-reported outcomes (PROs) including ease of use (1 = difficult to 7 = easy), and diabetes treatment satisfaction questionnaire (DTSQ; 0 = low to 36 = high).

Results: Participants were randomized to device-supported (n = 75) or routine titration (n = 76). Although not significant (p = 0.262), more participants achieved the primary endpoint using device-supported (45.9%) versus routine titration (36.8%) and median time (weeks) to first achieve FSMPG target was shorter (device-supported: 10.0 [95%CI: 8.0, 10.0]; routine: 13.0

[6.0, 16.0]). Cumulative incidence of FSMPG target achievement at week 16 was 0.8 (95%CI: 0.67, 0.87) versus 0.6 (0.54, 0.75), respectively.

LS mean change in DTSQ score was 4.46 (SE: 0.60) and 2.90 (0.61) for routine and device-supported titration, respectively (LS mean difference −1.57 [95%CI: −3.28, 0.15]). MSDC had high scores for ease of dose titration (mean [SD]: 6.23 [1.36]), selection (6.11 [1.36]), calculation (6.07 [1.40]) and adjustment (6.24 [1.30]). For 80.3% of MSDC users, healthcare professionals considered MSDC the most convenient titration method.

Conclusion: Device-supported self-titration enabled achievement of the primary endpoint with a trend towards a shorter median time to first achieve FSMPG target, without adversely affecting PROs.

Sponsor: Sanofi (NCT02585674)

064

New Insulin Analogues

ATTD8-0099

BIOCHAPERONE LISPRO, AN ULTRA-RAPID INSULIN LISPRO FORMULATION, IMPROVES POST-PRANDIAL BLOOD GLUCOSE CONTROL IN A 14-DAY MULTIPLE DAILY INSULIN INJECTIONS STUDY IN SUBJECTS WITH T1DM

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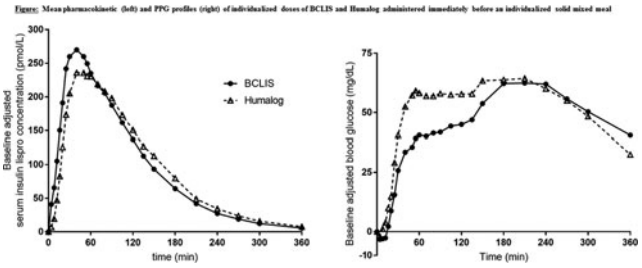
Background and Aims: BioChaperone Lispro (BCLIS) is an ultra-rapid insulin lispro formulation.

Method: This clinical trial was a double blind, randomized, cross-over study in 36 participants with T1DM treated with multiple daily subcutaneous insulin injections (MDI) [mean±SD age: 45 ± 12 yrs; BMI: 24.3 ± 2.6 kg/m^2; HbA1c: 7.2 ± 0.7%] to investigate safety and post-prandial blood glucose (PPG) control with BCLIS and Humalog®. During two 14-day outpatient periods, participants used BCLIS or Humalog® as prandial insulin injected immediately before meals. The PK/PD profile of BCLIS over time was assessed using individualized solid mixed meal tests (MMTs) at the beginning and at the end of each 14-day period. Additional MMTs were performed to assess the effect of the timing of injection relative to the meal (at meal start, 15 minutes before or 15 minutes after meal start).

Results: BCLIS showed similar overall safety and tolerability to Humalog® with 12% less hypoglycemic episodes in the outpatient period. No injection site reactions were observed. Pharmacokinetic evaluations indicated a faster-in and faster-out profile with BCLIS (Figure), with significant reduction of early- and late-time-to-half-maximal insulin lispro blood concentrations by −29% ($p < 0.0001$) and −12% ($p < 0.05$) respectively with similar exposure (0-last) to lispro. The accelerated profile of BCLIS was sustained after 14 days. In MMTs, BCLIS significantly reduced 0-2h PPG by 31% vs. Humalog® when injected at meal start ($\Delta AUC_{BG\_0\text{-}2h}$, $p = 0.02$). PPG control was comparable between BCLIS injected 15 minutes after meal and Humalog® injected at meal start.



Conclusion: BCLIS was well-tolerated and safe over 14 days of MDI and significantly improved PPG versus Humalog®.

065

New Insulin Analogues

ATTD8-0177

1,5-ANHYDROGLUCITOL CORRELATES WITH POSTPRANDIAL GLUCOSE IN SUBJECTS WITH TYPE 1 DIABETES IRRESPECTIVE OF HBA1C RESPONDER STATUS

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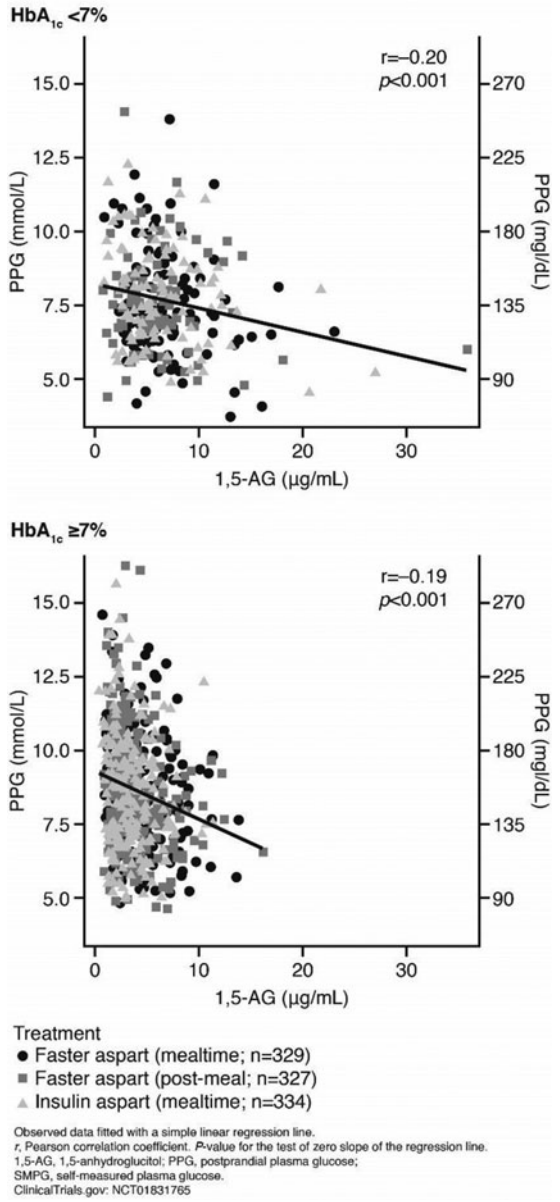
Background and Aims: Serum 1,5-anhydroglucitol (1,5-AG) decreases during periods of hyperglycaemia (>180 mg/dL) and reflects postprandial plasma glucose (PPG) control over the previous 1–2 weeks. The extent to which 1,5-AG reflects PPG control may also depend on overall glycaemic control.

Method: This was assessed in a *post hoc* analysis of onset 1, a 26-week, randomised, phase 3 trial in subjects with type 1 diabetes evaluating mealtime (MT) fast-acting insulin aspart (faster aspart), 20 min post-meal (PT) faster aspart and MT insulin aspart (IAsp), each with insulin detemir. Subjects (n = 990) were pooled to examine the correlation between absolute values of 1,5-AG and 2-h PPG from 7-9-7-point self-measured plasma glucose profiles at week 26 according to HbA_{1c} (<7% or ≥7%) at week 26.

Results: HbA_{1c} was reduced in all treatment arms. Primary endpoint in onset 1 was HbA_{1c} change from baseline (est. treatment difference [ETD] [95% CI]: MT faster aspart versus IAsp −0.15% [−0.23;−0.07]; PT faster aspart versus IAsp 0.04% [−0.04;0.12]). Glycaemic differences were reflected in 1,5-AG change from baseline (ETD [95% CI]: MT faster aspart versus IAsp 0.50 μg/mL [0.24;0.76]; PT faster aspart versus IAsp −0.16 μg/mL [−0.42;0.10]). 1,5-AG correlated with 2-h PPG, in subjects with HbA_{1c} <7% and HbA_{1c} ≥7% (Figure).

Conclusion: These results are consistent with the usefulness of 1,5-AG as a marker of short-term glycaemic control, irrespective of HbA_{1c} responder status.

Figure. Correlation between absolute values of 1,5-AG and 2-h PPG (SMPG) at week 26 by HbA_{1c} responder status



Observed data fitted with a simple linear regression line.
r, Pearson correlation coefficient. *P*-value for the test of zero slope of the regression line.
1,5-AG, 1,5-anhydroglucitol; PPG, postprandial plasma glucose;
SMPG, self-measured plasma glucose.
ClinicalTrials.gov: NCT01831765

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New Insulin Analogues

ATTD8-0091

A NOVEL FORMULATION OF INSULIN LISPRO CONTAINING CITRATE AND TREPROSTINIL SHOWS FASTER ABSORPTION AND IMPROVED POSTPRANDIAL GLUCOSE EXCURSIONS VS. HUMALOG IN PATIENTS WITH T1DM

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Background and Aims: LY900014 (LY) is a novel formulation containing locally-acting excipients to accelerate insulin lispro absorption with the goal of providing an ultra-rapid prandial insulin. This abstract focuses on the first part of a 2-part, 6-period cross-over study evaluating pharmacokinetic and pharmacodynamic differences between LY and insulin lispro (Humalog®, HL).

Method: Thirty T1DM patients were randomized to receive individualized subcutaneous doses of LY or HL administered at the start of a mixed-meal tolerance test. Prior to the test, blood glucose was stabilized at 126 mg/dL.

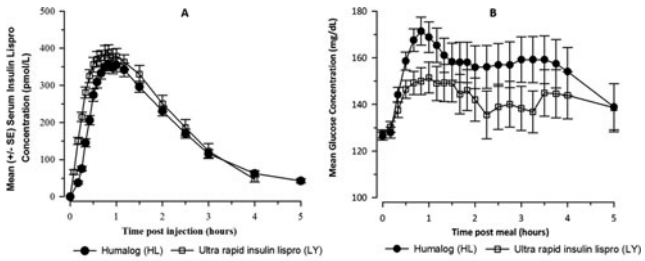

Figure 1. Ultra rapid insulin lispro and Humalog. A. Mean serum insulin concentration over time. B. Mean postprandial glucose over time.

Results: Patients treated with LY had accelerated early insulin lispro absorption compared to HL (Figure 1). LY reduced the time to early half-maximal drug concentration by 36.5% ($p < 0.0001$) and the insulin lispro area under the concentration curve versus time (AUC) from 0 to 30 min post dose increased by 123% ($p < 0.0001$) compared to HL. The 90% CI of the ratio (LY:HL) for the maximum observed drug concentration and AUC(0-∞) remained within bioequivalence criteria. The total glucose excursion over the 5-hour test-meal was significantly reduced by 44% for LY vs. HL.

No differences were observed between LY and HL in local tolerability or the number or severity of hypoglycemic events.

Conclusion: These results support continued development of LY as an ultra-rapid prandial insulin for patients with T1DM.

067

New Insulin Analogues

ATTD8-0460

EFFICACY AND SAFETY OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION OF FASTER ASPART COMPARED WITH INSULIN ASPART IN TYPE 1 DIABETES

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Background and Aims: onset 5, a double-blind, treat-to-target trial, evaluated the efficacy and safety of fast-acting insulin aspart (faster aspart) in continuous subcutaneous insulin infusion (CSII).

Methods: Following a 4-week run-in on pre-trial insulin, subjects (n = 472) with type 1 diabetes (T1D) were randomised to 16 weeks of treatment with CSII to either faster aspart (n = 236) or insulin aspart (IAsp, n = 236). All available information regardless of treatment discontinuation was used for the evaluation of effect.

Results: Non-inferiority of faster aspart to IAsp for the change from baseline in HbA1c (primary endpoint) using a prespecified margin of 0.4% was confirmed. Mean HbA1c changed from 7.5% at baseline to 7.4% (faster aspart) and 7.3% (IAsp) with an estimated treatment difference (ETD) of 0.09% [95% CI: 0.01;0.17] (1.0 mmol/mol [95% CI: 0.14;1.87]). Faster aspart was superior to IAsp in 1-h postprandial plasma glucose (PPG) increment after a standardised meal test (78 g carbs) with statistically significant reductions also at 30 min and 2 h (Figure). The improvement in PPG was also reflected in the mean 1-h interstitial glucose increment after all meals (ETD [95% CI] −0.21 mmol/L [−0.31;−0.11], −7.69 mg/dL [−12.15;−3.23]). There was no statistically significant difference in the overall rate of severe or confirmed hypoglycaemia (plasma glucose <3.1 mmol/L [56 mg/dL]). A numerical imbalance in severe hypoglycaemic episodes between faster aspart and IAsp was seen in the treatment (21 vs. 7) and run-in period (4 vs. 0).

Conclusion: Faster aspart provides an effective and safe option for CSII treatment in subjects with T1D.

068

New Insulin Analogues

ATTD8-0098

EVALUATION OF EARLY POSTPRANDIAL SUPPRESSION OF ENDOGENOUS GLUCOSE PRODUCTION WITH FASTER ASPART VERSUS INSULIN ASPART

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Background and Aims: Fast-acting insulin aspart (faster aspart) is insulin aspart (IAsp) in a new formulation with added excipients providing faster early absorption and improved postprandial glucose (PPG) control. This randomised, double-blind, crossover trial investigated mechanisms behind the lower PPG seen with faster aspart versus IAsp.

Method: Subjects with T1D (n = 40; HbA_{1c} 7.3 ± 0.7%) received identical doses of faster aspart and IAsp (individualised by subject; 0.06–0.28 U/kg subcutaneously) at the start of a standardised mixed meal (75 g carbohydrate labelled with [1-^{13}C] glucose). PPG turnover was assessed by the triple-tracer meal method using continuous, variable [6-^{3}H] glucose and [6,6-$^{2}H_2$] glucose infusion.

Results: Early insulin exposure was greater for faster aspart versus IAsp ($AUC_{IAsp,0–30min}$ treatment ratio [95% CI] 1.93 [1.59;2.34]; $AUC_{IAsp,0–1h}$ 1.32 [1.18;1.48], both $p < 0.001$), leading to smaller PPG increment at 1 h (ΔPG_{1h} treatment difference [95% CI] −10.6 [−21.5;0.3] mg/dL, $p = 0.055$). The smaller ΔPG_{1h} with faster aspart was due to greater suppression of endogenous glucose production ($EGP_{suppression,0–30min}$ 1.96 [1.13;4.43], $p = 0.017$; $EGP_{suppression,0–1h}$ 1.12 [1.01;1.25], $p = 0.040$) and higher glucose disappearance ($\Delta AUC_{Rd,0–1h}$ 1.23 [1.05;1.45]; $p = 0.012$) with faster aspart versus IAsp during the first hour post-dose. Suppression of free fatty acid levels was greater for faster aspart versus IAsp ($AOC_{FFA,0–1h}$ 1.36 [1.01;1.88], $p = 0.042$).

Conclusion: Faster aspart provides improved PPG control versus IAsp partly through earlier and greater EGP suppression.

069

New Insulin Analogues

ATTD8-0334

TAKE CONTROL: EFFICACY AND SAFETY OF PATIENT- VERSUS PHYSICIAN-MANAGED TITRATION OF INSULIN GLARGINE 300 U/ML (GLA-300) IN PATIENTS WITH UNCONTROLLED TYPE 2 DIABETES

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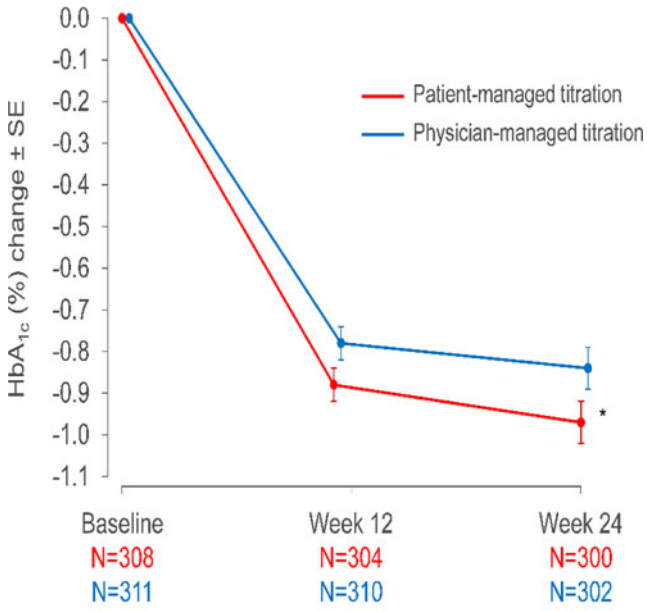
Background and Aims: Patients with T2DM require effective insulin titration to achieve recommended HbA_{1c} targets. However, most patients do not achieve HbA_{1c} goals in clinical practice, owing to several patient- and physician-related barriers. This study evaluated whether the new generation basal insulin Gla-300 empowered patients to self-titrate effectively.

Method: This 24-week, multicenter, randomized, open-label, parallel-group study compared the efficacy and safety of a simple Gla-300 titration algorithm (fasting self-monitored plasma glucose [SMPG] >130 mg/dL, +3 U; <80 mg/dL, −3 U), when managed by patients versus physicians, in patients with T2DM insufficiently controlled on their previous regimen. Participants (N = 631) from 10 EU countries were equally randomized to each group.

Results: Mean baseline characteristics, including age, BMI and HbA_{1c}, were similar in both groups. The least squares mean difference between patient- and physician-managed groups in HbA_{1c} change from baseline (Figure) was –0.13 % (95% CI: –0.2619 to –0.0004), demonstrating non-inferiority and statistically significant superiority for the patient-managed group. The proportion of patients achieving a fasting SMPG of 80–130 mg/dL without confirmed (<54 mg/dL) or severe hypoglycemia was 67% in the patient-managed and 58% in the physician-managed group (p = 0.0187). Similar proportions of patients in both groups (7.4% vs 7.9%) experienced confirmed (<54 mg/dL) or severe hypoglycemia. Severe hypoglycemia was reported in 0.6% and 0.3% of patients in patient-managed and physician-managed groups, respectively.



Baseline HbA_{1c} was 8.40 % and 8.42 % in the patient-managed and physician-managed groups, respectively. At week 24, HbA_{1c} was 7.42 % and 7.56 % in the patient-managed and physician-managed titration groups, respectively.

*Non-inferiority p-value <0.0001; superiority p-value=0.0247

LS, least squares; SE, standard error

Conclusion: In T2DM, use of Gla-300 in a simple titration regimen managed by the patient resulted in improved glycemic control without increased hypoglycemia, compared with physician-managed titration.

Study sponsored by Sanofi (EudraCT: 2015-001626-42)

070

New Medications for Treatment of Diabetes

ATTD8-0159

MECHANISMS FOR OSTEOCALCIN-IMPROVED INSULIN RESISTANCE

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Background and Aims: Recent studies have shown that osteocalcin, a protein synthetized by osteoblasts, acts as a hormone that has positive effects on insulin secretion and sensitivity. However, very little is known about the molecular pathways involving osteocalcin and glucose metabolism. The present study aimed to investigate the mechanisms of action of osteocalcin on insulin resistance in obese mice.

Method: Mice were divided in control lean mice, untreated obese mice and obese mice treated continuously with uncarboxylated osteocalcin (uOC) for 28 days.

Results: uOC-treated obese mice showed improvement of whole-body insulin resistance accompanied by increased glucose transporter (GLUT) 4 protein expression and its mRNA in white adipose tissue (WAT). Of note, uOC greatly reduced macrophage infiltration and fibrosis in WAT, and reduced mRNA expression of proinflammatory cytokines. Surprisingly, WAT was found to express the gene that encodes for osteocalcin (*Bglap*), which has thought to be expressed exclusively by osteoblasts. Moreover, *Bglap* expression is reduced in obese mice and uOC treatment markedly increased its own expression in WAT of obese mice. Finally, obese mice had lower circulating levels of uOC and, in femur, increased expression of genes that encodes for osteotesticular protein tyrosine phosphatase and osteoprotegerin, both genes involved in bone insulin resistance. Interestingly, uOC treatment reduced the expression of these genes in femur.

Conclusion: Our findings demonstrate that uOC treatment improves insulin resistance in obese mice by improving insulin resistance and inflammation in WAT, and improving insulin resistance in bones.

Funding: FAPESP 2013/18841-1, 2014/10007-5, 2015/01576-9, 12/04831-1

071

New Medications for Treatment of Diabetes

ATTD8-0068

CGM MAY SERVE AS A "GOLD STANDARD" TOOL, CONFIRMING METABOLIC RECOVERY AND RESTORATION OF FUNCTIONAL ABILITY AND SECRETION OF ENDOGENOUS INSULIN IN T2DM PATIENTS

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Background and Aims: Remission in T2DM patients is no longer a myth. Recent studies show it can be achieved quickly as therapeutic objectives shift from Blood Glucose (BG) normalization to metabolic purposes (BMI reduction).

Method: 18 uncontrolled T2DM patients initially treated by insulin combined with Metformin and other oral antidiabetic medications were recruited. CGM recordings were done before metabolic (Gravicentric) intervention and immediately after complete insulin discontinuation. Mean age was 58.8 ± 10.6 years with diabetes duration of 14.4 ± 8.4 years, while the duration of insulin therapy was 7.5 ± 6.9 years. Since intervention was aimed at weight reduction, Liraglutide was started in all patients. In five patients SGLT2i were also added.

Results: BMI and HBA1C were reduced from 34.1 ± 5.6 to 29.0 ± 4.1, p = 0.005 and 8.5 ± 1.3 to 6.9 ± 0.6%, p = 0.0002 respectively. This produced a dramatic improvement in metabolic state and facilitated insulin discontinuation. CGM recordings showed a highly significant reduction in CV (coefficient of variability), from 27.0 ± 8.0% to 20.0 ± 6.0%, p = 0.004; MAGE, from 82.9 ± 30.6 to 64.8 ± 23.4 mg%, p = 0.002; Standard Deviation, from 48.6 ± 18.4mg% to 31.5 ± 11.3 mg%, p < 0.001. Significant reduction was observed in other parameters, like CONGA; LI; JINDEX; LBGI; HBGI; GRADE; MODD; MVALUE; MAG. Hypoglycemia indexes remained unchanged. Strong positive correlation was shown between CV and MAGE.

Conclusion: In T2DM patients, metabolic recovery and insulin weaning were accompanied by a dramatic reduction in all parameters reflecting glucose variability, with no changes in hypoglycemia indexes. CV appears to be easily accessible and most informative for confirming metabolic recovery in T2DM persons, thus making CGM a ''gold standard'' tool.

072

New Medications for Treatment of Diabetes

ATTD8-0083

MODERATE EXERCISE DOES NOT IMPAIR THE EFFECT OF GLUCAGON IN INSULIN PUMP TREATED INDIVIDUALS WITH TYPE 1 DIABETES: A RANDOMIZED CROSSOVER STUDY

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Background and Aims: To compare the plasma glucose increase after a subcutaneous injection of 200 μg glucagon after 45 minutes of cycling versus resting. Furthermore to compare the glucose response to 200 μg glucagon given before versus after 45 min of cycling.

Method: Fourteen insulin pump-treated individuals with type 1 diabetes completed three visits in a randomized placebo-controlled single-blinded crossover study (HbA1c 53 mmol/mol (7.0 %), mean age 45 years, BMI 26 kg/m^2, diabetes duration 26 years). On each visit, participants consumed a breakfast (40 g carbohydrate) two hours prior to 45 minutes of cycling or resting. A subcutaneous 200 μg glucagon injection was either given after cycling, after resting or before cycling.

Results: Mean plasma glucose increase was higher when glucagon was given after cycling compared with after resting, 2.6 ± 1.7 versus 1.8 ± 2.0 mmol/l ((P = 0.02). Five hypoglycaemia events (plasma glucose ≤3.9) occurred during cycling when glucagon was given before cycling and four events when glucagon was given after cycling. Mean decrease in plasma glucose during cycling when glucagon was given before versus after exercise was 0.9 ± 2.8 versus 3.1 ± 2.8 mmol/l (P = 0.0017).

Conclusion: Moderate cycling for 45 minutes does not impair the glucose response to glucagon. Mini-dose glucagon can be used to treat hypoglycaemia after cycling and the plasma glucose fall during cycling can be diminished by a pre-exercise injection of 200 μg glucagon.

073

New Medications for Treatment of Diabetes

ATTD8-0162

ARACHIDONIC ACID PREVENTS DIABETES MELLITUS

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Background and Aims: In both type 1 and type 2 diabetes mellitus, increased production of pro-inflammatory cytokines and reactive oxygen species (ROS) occurs that induce apoptosis of β cells and cause peripheral insulin resistance respectively though the degree of their increased production is higher in type 1 and less in type 2 diabetes mellitus. Hence, methods designed to suppress inflammatory events may be of benefit in diabetes mellitus.

Method: We performed in vitro and in vivo studies to identify possible endogenous anti-diabetic molecules with emphasis on low molecular weight lipid moieties.

Results: Studies showed that plasma concentrations of arachidonic acid (AA) and lipoxin A_4 (LXA_4) are low in alloxan-induced type 1 diabetes mellitus in experimental animals and patients with type 2 diabetes mellitus. In vitro studies revealed that AA and LXA4 can prevent alloxan and streptozotocin-induced cytotoxicity to pancreatic beta cells. Both alloxan and streptozotocin-induced type 1 and type 2 diabetes mellitus could be prevented by arachidonic acid and LXA4 by suppressing production of inflammatory cytokines, expression of NF-kB and preserved beta cell function.

Conclusion: Our studies revealed that AA and LXA4 can prevent both type 1 and type 2 diabetes mellitus and thus, may function as endogenous anti-diabetic molecules.

ATTD 2018 E-Poster Discussion Abstracts

074

Artificial Pancreas

ATTD8-0157

PERSONALIZED DATA-DRIVEN VERIFICATION AND SYNTHESIS FOR ARTIFICIAL PANCREAS CONTROLLERS

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Background and Aims: People with T1D exhibit a vary in the physiological characteristics, such as hormonal fluctuations, which affect their glucose-insulin physiology. At the same time, control algorithms for the artificial pancreas can be tuned using numerous parameters that affect the correctness and performance of the closed-loop system.

We present a data-driven approach to modeling blood glucose values of people with T1D and use these models to simulate closed-loop systems and test controllers over a range of scenarios. This approach is demonstrated using data from an outpatient clinical trial of a predictive low glucose pump shutoff involving night-time CGM and insulin data for nearly 30 patients with 90 sessions/patient. Next, the resulting models are used for in-silico verification and parameter tuning for a PID-based algorithm proposed by Steil et al.

Method: Whereas existing approaches use deterministic models, we propose non-deterministic relational models that predict a range of possible glucose values rather than a single point. These models capture important glucose trends as well as

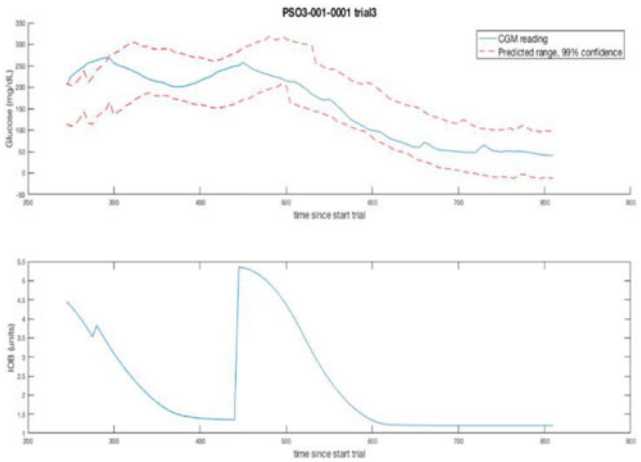

Figure 1: Example of model predictions using our non-deterministic approach (dashed red) and actual patient blood glucose (solid blue) for a test patient. Model shown predicting onto data which was not used for training fit. Note our model is able to catch of observed dynamics.

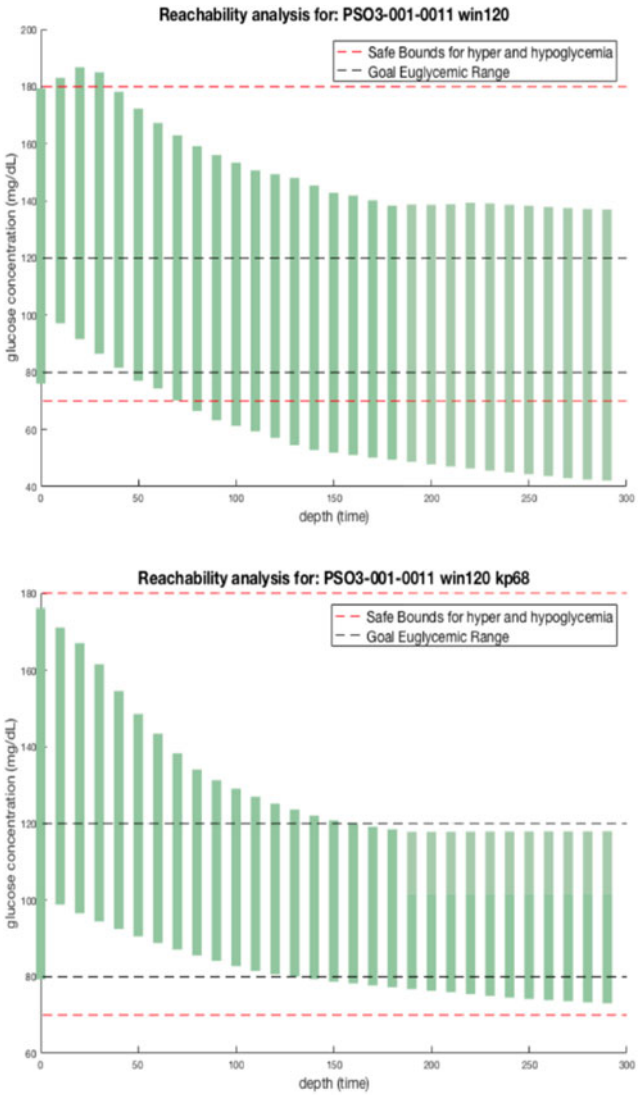

Figure 2: Example Reachability a sample patient pre (top), and post (bottom), parameter re-tuning. Our tuning method is able to prescribe improved controller settings for patients where out-of-the-box setting would result in poor control.

uncertainty in predictions arising from uncontrollable externalities such as CGM noise (Fig1).

Treating these equations as constraints, and coupling them with a PID control scheme, we predict all possible behaviors of the closed-loop system over a time horizon using integer linear optimization solvers. Next, we demonstrate improvements in control achieved using this approach with patient data gathered from a previously conducted outpatient clinical study. (Fig2)

Results:

Conclusion: We use nondeterministic data-driven models to simulate, verify, and tune the performance of new control algorithms to perform personalized, pre-clinical evaluation for closed loop systems.

075

Artificial Pancreas

ATTD8-0183

KIDSAP - HOME USE OF THE ARTIFICIAL PANCREAS IN VERY YOUNG CHILDREN WITH TYPE 1 DIABETES: THE PILOT STUDY

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[11]Medical University of Vienna, Department of Pediatrics, Vienna, Austria

Background and Aims: The multinational KidsAP project assesses the ability of closed-loop insulin delivery to improve glucose control in children with type 1 diabetes aged 1 to 7 years. KidsAP pilot study evaluates the feasibility of closed-loop in home settings and the potential benefit of diluted insulin use during closed-loop operation given the low insulin amounts needed in this population.

Method: The pilot study adopts an open-label, multi-centre, multinational, randomised, two-period crossover design contrasting closed-loop using diluted insulin U20 and closed-loop using standard insulin U100. The order of the two 3-week intervention periods is random. FlorenceM hybrid closed-loop system is used during both arms. Up to 30 children aged 1 to 7 years with type-1 diabetes will be recruited at 7 European diabetes centres. Primary outcome is time spent in target (3.9 and 10.0 mmol/l). Secondary outcomes include mean glucose, time spent with glucose levels in hypo- and hyperglycaemia.

Results: Recruitment started in August 2017. Through September 2017, 3 participants were enrolled. One randomised participant (5 years, female, HbA1c 47 mmol/mol, total daily insulin dose 12 U/day) completed the first arm (U100) during which her percentage of time in target was 71%, mean glucose was 8.0 mmol/l, time spent in significant hypoglycaemia (<3.0 mmol/l) was 1.8% (see Figure 1).

Conclusion: The study will assess feasibility of home use of closed-loop in very young children and will provide insights into safety, utility and user-acceptance of closed-loop in this age group, and will determine the role of diluted insulin during closed-loop use.

076

Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0275

DOES PREDICTED LOW SUSPEND PUMP TREATMENT IMPROVE CONTROL AND QUALITY OF SLEEP IN CHILDREN WITH TYPE 1 DIABETES AND THEIR CAREGIVER? THE QUEST STUDY

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Background and Aims: Fear of nocturnal hypoglycemia amongst parents of children with Type 1 diabetes (T1D) leads frequently to chronic sleep disturbances for parents as well as for their children.

Aim: Comparison of sensor augmented pump (SAP) treatment with predictive low glucose suspend to the use of insulin pump with independent continuous glucose measurement (CGM) on the impact on time in glucose target, effect on sleep and quality of life in children with T1D.

Method: In this open-label, single-centre, crossover study subjects with type 1 diabetes (7–14 years) are randomized to treatment with sensor augmented pump (640G Medtronic ®) or treatment with insulin pump and independent CGM (Freestyle libre ®) for 5 weeks. After washout period they cross over to the other study arm. The week before and in the last week of treatment subjects and their caregiver wear a sleep monitor (Actigraph ®) and complete a sleep diary.

Main outcome: Between arm difference in percentage of time in glucose target during the final 6 days of each arm, measured by a blinded CGM.

Secondary outcomes: Comparison of quantity and quality of sleep as well as quality of life perception of the subjects and their caregiver in the two different treatments.

Results: Recruitment started in February 2017. 36 patients are planned to be included. Study completion: in January 2018.

Conclusion: This study evaluates a potential impact of SAP on time in glucose target, sleep quality, quantity and quality of life perception in patients with T1DM and their primary caregivers, when compared with pump treatment with continuous monitoring.

077

Clinical Decision Support Systems/Advisors

ATTD8-0361

BLOOD GLUCOSE TESTING FREQUENCY CORRELATES TO A1C REDUCTION AFTER 3 MONTHS OF INSULIN TITRATION UTILIZING DIABETES THERAPY MANAGEMENT SOFTWARE

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Background and Aims: Effective basal bolus insulin therapy requires dose titration to identify the right doses for each individual patient. Self-monitoring of blood glucose (SMBG) provides the requisite data to make dose titration successful. The intention of our study was to compare A1C improvement in two groups: a group that SMBG less vs. a group that SMBG more than half of the prescribed 4 times/day.

Method: This retrospective study evaluated 68 patients with type 1 and type 2 diabetes mellitus, who had their basal and bolus insulin doses adjusted by a healthcare professional that utilized Glucommander, diabetes therapy management software (DTMS), to analyze blood glucose data and calculate each dose titration of their basal and nutritional insulin. We compared the A1C reduction at three months of patient who SMBG <2 times/day to those that SMBG ≥2 times/day.

Results: The 27 patients that tested <2 times/day had a starting A1C of 10.4%, tested 1.1 times/day and had a 1.5% A1C reduction. The 41 patients that tested ≥2 times/day had a starting A1C of 10.5%, tested 3.1 times/day and had a 3.0% A1C reduction.

Conclusion: The use of DTMS for the titration of basal bolus insulin therapy has been shown to be effective; however, more frequent SMBG renders the DTMS even more effective. For patients reluctant to SMBG 2 or more times daily, the use of continuous glucose monitoring during the time of titration may be an effective alternative to fingerstick SMBG in order to better inform a DTMS decision support tool.

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Clinical Decision Support Systems/Advisors

ATTD8-0103

ESTIMATION OF THE ECONOMIC IMPACT DERIVING FROM BETTER MANAGEMENT OF GLYCEMIC CONTROL IN ADULTS WITH TYPE 1 DIABETES IN THE UK SETTING

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Background and Aims: Over 90% of diabetes cost is related to complications, most of which in turn are related to elevated glycated hemoglobin (HbA1c). The aim of this analysis is to estimate the potential savings associated with instituting better glycemic control in adults with Type 1 diabetes (T1D) in the UK setting.

Method: An interactive probabilistic model using published risk curves based on DCCT data was developed to project incidence and progression of diabetes-related complications associated with different HbA1c levels over a 5-year time horizon in T1D. Associated costs of diabetic ketoacidosis, severe hypoglycemia, microvascular and macrovascular complications as well as costs associated with loss of productivity were derived from published literature and used to estimate the economic impact of complications in the UK setting. Based on UK National Diabetes Audit data, the T1D population with HbA1c≥8.5% (123125 patients) was modelled.

Results: Over 5 years the estimated total costs of complications was about £799 million, translating into £6496 cost per patient.

A treatment strategy able to bring the overall population to target (HbA1c≤7%) would lead to potential total savings of about £687 million in complications avoided over 5 years, corresponding to £5585 saved per patient.

Conclusion: Implementation of strategies aimed to reduce HbA1c in T1D in the UK has the potential to drive a significant reduction in complications costs. This estimate may give strategic insights to the NHS to identify the level of resources that should be dedicated to reducing diabetes complications in the future.

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Clinical Decision Support Systems/Advisors

ATTD8-0292

MAXIMUM FAT OXIDATION DURING EXERCISE IS LOWER IN ADOLESCENTS WITH DIABETES MELLITUS TYPE 1

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Background and Aims: Maximization of fat oxidation during exercise may bring health benefits, help control weight, and reduce the dependence of glucose as a source of energy. Compare the maximum fat oxidation rates (FATMAX) and analyze its association with cardiorespiratory fitness can help to emphasize the exercise prescription for patients with type 1 diabetes mellitus (T1DM).

Method: The study included 22 adolescents of both sexes, aged 11–17 years. After clinical and anthropometric evaluation, the subjects were allocated to either a T1DM group (DMG; n = 10) or a control group (CG; n = 12). Cardiorespiratory fitness was determined with the maximum oxygen consumption (VO_{2}-max) during a submaximal aerobic test on a cycle ergometer using the Balke protocol. FATMAX values were calculated by ventilatory exchange ratio during exercise and were based on Lusk's table.

Results: Adolescents with T1DM showed similar cardiorespiratory fitness, however lower FATMAX ($p < 0.01$) and $\%VO_{2FATMAX}$ ($p = 0.001$) when compared with controls.

Table 1. General characteristics of the groups

	DMG (n=10)	CG (n=12)	*p*
HbA1c	9.39 (±1.25)	-	-
Sex (M/F)	(5/4)	(4/8)	0.503
Tanner (4/5)	(1/9)	(2/10)	0.509
Age (years)	13.80 (±1.90)	12.78 (±1.39)	0.163
BM (kg)†	53.88 (±14.62)	57.39 (±8.33)	0.100
Height (m)	1.59 (±0.14)	1.61 (±0.10)	0.767
BMI z-score	0.39 (±0.84)	0.81 (±0.85)	0.258
VO_2max (L/min)	2.09 (±0.54)	1.87 (±0.50)	0.345
R_{FATMAX}†	0.81 (±0.005)	0.80 (±0.008)	0.100
FATMAX† (Kcal/min)	3.36 (±0.51)	5.33 (±1.73)	0.01*
$\%VO_{2Fatmax}$	35 (±11)	60 (±12)	0.001**

DMG = group with type 1 diabetes mellitus; CG = control group; BM = body mass; BMI z-score = body mass index z-score; VO_2max = maximum oxygen consumption; R_{FATMAX} = ventilatory exchange ratio at the FATMAX point; FATMAX = maximal fat oxidation; $\%VO_{2FATMAX}$ = percentage of maximum oxygen consumption at the Fatmax point; p<0.05; (*); p<0.01 (**)

FATMAX values was inversely correlated with serum glycosylated hemoglobin (HbA1c) levels (r = –0.77) and directly with BMI z-scores (r = 0.76), while $\%VO_{2FATMAX}$ results correlated with age (r = 0.81), BMI z-scores (r = 0.65) and VO_2max (r = 0.81). On multiple linear regression, HbA1c values explained 54% (adjusted $r^2 = 0.54$, $p = 0.009$) and BMI z-scores explained 3.1% (adjusted $r^2 = -0.031$, $p = 0.009$) of the variation in FATMAX in the DMG.

Conclusion: These results suggest lower fat oxidation and higher use of glucose as an energy substrate during exercise and worse control in T1DM. Therefore, results may contribute to the prescription of physical exercises and help choose the appropriate intensity of exercise to prevent hypoglycemia in T1DM.

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Clinical Decision Support Systems/Advisors

ATTD8-0188

UTILITY OF A MULTI-MODEL BOT ENABLED AND DOCTOR LED INTERVENTION FOR DIABETES MANAGEMENT - CLINICIAN AND PATIENT PERSPECTIVES

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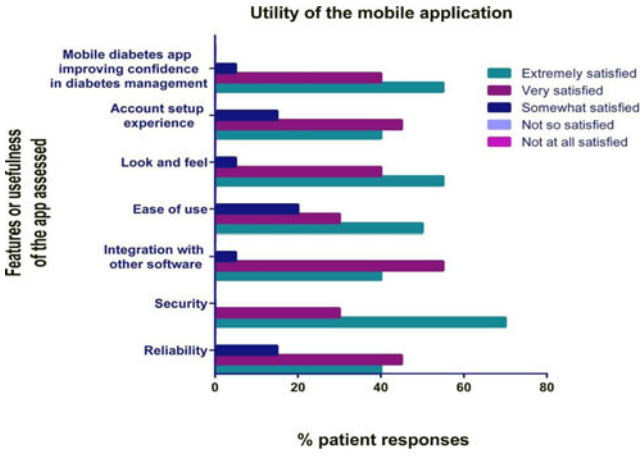
Background and Aims: Diabetes self-management and education is the cornerstone of any diabetes care plan. To aid this, many mobile phone based platforms are available now-a-days to enable patient-centered healthcare. We tried to assess the utility of a multi model BOT enabled diabetes care platform (LifeInControl) integrated with hospital EMR and monitoring devices to improve the prospects of diabetes management.

Patient's perspectives	Clinician's perspectives
• Enables a convenient mode to be in real-time contact with their healthcare team • Boosts their confidence in managing diabetes with the feeling that a coach is available round the clock to guide them in different aspects of diabetes management like medications, diet, activity etc. • The graphs and trends generated by the software based on logged in data enables patients to better understand the close relationship between diet, medications, activities etc. making them more informed regarding a wise management of their disease • Personalized care plans provided by the healthcare team based on the routinely logged in diet, activity and other relevant details motivates them to be more compliant towards their diabetes care plan • Patients especially those with a tight daily schedule, find it very much convenient to track their disease as well as manage it efficiently at the comfort of their daily routine	• Enabled a convenient mode for regularly following up the patients • Software generated graphs and trends helps to gain more insights into a patient's health status • Increases patient engagement towards diabetes management • Personalized diet and activity plans when followed up regularly helps to improve patient compliance towards clinician's diabetes care plan • Use of mobile app highly improves the overall productivity and has been found to be a highly cost effective as well as a time saving option

Method: As a pilot study, 30 smartphone using T2D patients were randomly selected (mean age = 56.41 ± 12.21, T2D duration = 11.11 ± 6.57y, males = 66%, % of patients on OHAs+insulin = 85.18), and LifeInControl app was installed in their phones. Patients were briefed regarding the app. They remained in real time contact with our healthcare team through the app and obtained appropriate health advices. After 4 weeks, the utility of the mobile app and the perceptions regarding the same were assessed among our patients and clinicians.

Results: The platform enabled to seamlessly connect doctors, patients and diabetes coaches and thereby allowed patients to manage their disease in real time through medication dose titrations, lifestyle modifications etc. Net Promoter Score® for the app was found to be 75 (willingness to recommend the app to others). 85% reported that they will continue app use.

Conclusion: The multiple model BOT enabled platform with machine learning capabilities under study enables real time and automated two way communication and integration with EMR



and monitoring devices overcoming the major challenges in diabetes. It ensures continuing customized education and enhance adherence to medications and lifestyles.

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Clinical Decision Support Systems/Advisors

ATTD8-0163

OPTIMIZING GLYCEMIC CONTROL – IS EDUCATION THE KEY?

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Background and Aims: The aim of this study was to check the impact of self-analysis and modification of treatment on glycemic control in T1D pediatric patients.

Method: 61 T1D patients (34 Males), aged 3.3–17.9 years ($x = 12.4 \pm 4.6$) were enrolled into the study. 33 patients (group 1) regularly attend ''Children with Diabetes Association'' meetings, where they received Contour Plus Link meters and attended a lecture on managing glucose and pump data with CareLink software. The remaining 28 patients (group 2) received meters and a short information about CareLink during a visit in the Clinic. Pumps were downloaded and HbA1c was checked twice: while issuing meters (visit 1, V1) and 3 months later (visit 2, V2).

Results: HbA1c in group 1 was $6.93 \pm 0.87\%$ (5.5–9.0%) on V1 and $6.75 \pm 0.75\%$ (5.6–8.2%) on V2 ($p > 0{,}05$). HbA1c in group 2 was $7.48 \pm 1.17\%$ (5.9–9.8%) on V1 and $7.6 \pm 0.86\%$ (6.7–9.5%) on V2 ($p > 0.05$). HbA1c was lower on both visits in group 1 ($p = 0.039$ and $p = 0.02$, respectively). HbA1c changed by $(-)0.02 \pm 0.63\%$ ((-)1.7–1.0) in group 1 and $(-)0.27 \pm 1.17\%$ ((-)2.6–1.6) in group 2 ($p > 0.05$). Comparable number of patients in both groups improved their glycemic control (11/31 vs. 9/19, $p > 0.05$).

Conclusion: Although the change in HbA1c was not significant, it has to be emphasized that 1/3 of patients improved their glycemic control. Easy access to treatment data analyzing tools may help people manage their diabetes more effectively by making better informed decisions. Moreover, lower HbA1c in group 1 proves that any additional education may be beneficial.

082

Closed-loop System and Algorithm

ATTD8-0284

THE EFFECT OF INSULIN DELIVERY SPEED ON POSTPRANDIAL GLUCOSE RESPONSES AT BREAKFAST FOLLOWING OVERNIGHT CLOSED LOOP

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Background and Aims: The Medtronic MiniMed® 670G hybrid closed-loop system has two bolus speeds: Quick bolus (1 unit in 4 seconds), and Standard bolus (1 unit in 40 seconds). Our objective was to investigate postprandial breakfast glycaemia pre and post changing the insulin delivery speed.

Table-1			
	Tmax (min)	$T_{1/2}$ max (min)	Max Glucose (mg/dl)
Standard	79±31	37±27	79±30
Quick	84±26	43±18	90±32
Difference	5±21	6±31	11±28
	p=0.5	p=0.54	p=0.21

Method: Retrospective analysis of data from adolescents ($n = 8$) and pediatric ($n = 6$) patients participating in the Medtronic® 670G extension study. Records were selected for analysis if: insulin was delivered preprandially with stable sensor values (<0.3 mg/dl-min), under 150 mg/dL in the hour before breakfast, and there were no boluses in the subsequent 3 hours.

Results: For each subject, 2 to 18 weeks of data were reviewed (1,700 daily reports) to identify a total of 52 mornings (Standard $n = 27$, Quick $n = 25$) meeting our criteria for inclusion with at least one pair of mornings for each subject. There was no statistical difference in time to maximum glucose (t_{max}) or time to half maximum glucose ($t_{1/2max}$) comparing the Standard vs. Quick bolus speeds. To augment comparability, meals were matched for carbs consumed (mean difference 1.3 grams between pairs) and insulin delivered (mean difference 0.07 units between pairs). A paired t-test on 11 paired meals again showed no statistically significant differences between the two bolus speeds (Table-1).

Conclusion: In an outpatient setting with uncontrolled meals, the rate of insulin delivery did not have an impact on postprandial glucose pharmacodynamics. Future, larger studies with controlled meals are warranted to assess if the Quick bolus has any benefit.

083

Closed-loop System and Algorithm

ATTD8-0133

A NOVEL CLOSE-LOOP CONTROL PERFORMANCE MONITORING METHOD BASED ON TEMPORAL FEATURES FOR ARTIFICIAL PANCREAS

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Background and Aims: To make glucose levels within normal region, people with T1DM depend on exogenous insulin delivery calculated by various close-loop control algorithms. Generally, control performance is assessed by quantifying the frequency of hyper/hypo glycemic events without considering the factor of frequent controller regulation. The objective here is to propose an alternative control performance assessment method which can be implemented realtime.

Method: A novel control performance monitoring strategy is designed based on cointegration analysis and slow feature analysis (CA-SFA). It is based on the following consideration that once controller regulates insulin delivery in a different fashion, the process dynamics will be unusual. Two types of temporal information are extracted including temporal equilibrium features and

temporal slow features. Two statistics are designed to quantify how fast the glucose changes and realtime monitor changes of process dynamics resulting from the controller regulation.

Results: The novel strategy was applied to ten subjects generated using the UVa/Padova metabolic simulator with close-loop control. The models are developed with seven samples as the modeling dimension and two-day close-loop data sampled with 5 min which was then tested for another five-day data. It was found that although the glucose level stays well within the normal region, the controller may work differently, revealing different performance. The monitoring strategy can accurately detect the regulation of controller with 90% sensitivity and 5% false alarms.

Conclusion: It provides an alternative solution of glucose control performance assessment by using temporal information. A combination of the proposed method and conventional one can provide more complete control performance assessment.

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Devices Focused on Diabetic Preventions

ATTD8-0191

ACCU-CHEK® VIEW: A DIGITAL PREVENTION-PROGRAM SUPPORTING WEIGHT REDUCTION FOR ADULTS WITH METABOLIC SYNDROME IMPLEMENTED IN PHYSICIANS' OFFICES IN GERMANY

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Background and Aims: Fighting the epidemic of type 2 diabetes will advance by addressing the underlying concern of the metabolic-syndrome (MS). Obesity and unhealthy lifestyle were identified as major contributors to developing MS which is frequently perceived as a social problem but not a medical condition. Key is the involvement of healthcare professionals (HCP) to leverage an evidence-based medical perspective in weight-reduction.

Method: The observational pilot study enrolled 166 MS patients in a one-year weight reduction program. 109 joined the digital prevention-program (DPP) employing Accu-Chek® View a web and app interface between HCP and patients, goal setting and personalized feedback functionality. 57 joined a usual care program (UC) with routine visits in the practices. The goal was to achieve 5% weight reduction from baseline.

Statistical analysis for comparison need to account for time in study and were largely based on time to event methods (5% weight loss) adjusting for relevant covariates in Cox-regression.

Results: DPP participants had higher BMI at baseline than UC (32.2 vs 30.0, $p = 0.02$). Cox-regression for time-to-5% adjusting for sex, age and baseline BMI revealed for DPP a 5.8-fold better chance than UC to achieve the reduction. After one year under DPP about 45% may be expected, for UC 15%. Achievers in the DPP group at study end reduced weight by 8.4kg (8.3%) and BMI improved by 2.9 points. DPP non-achievers did not gain weight.

Conclusion: Results show a high potential of digital programs to reduce the risk of diabetes by lifestyle intervention sustained by a coaching approach.

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Glucose Sensors

ATTD8-0112

ARTIFACT SUPPRESSION ALGORITHM IN A SECOND-GENERATION LONG TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM

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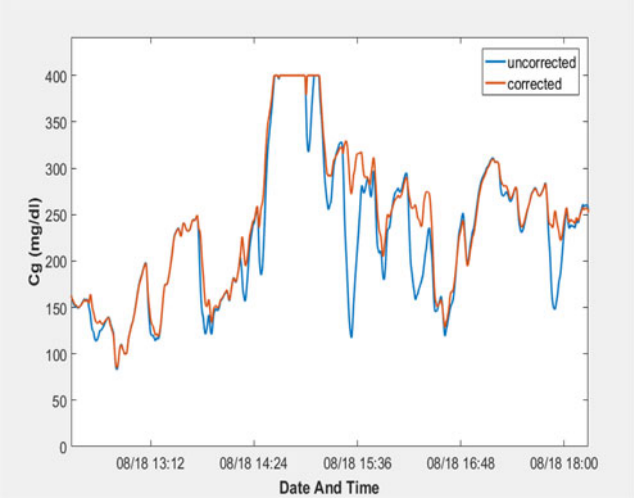
Background and Aims: Feasibility of a second generation long-term, fully-implanted (no skin-attached elements) CGM system (the GlySens® Eclipse® ICGM® System) has been documented, with additional studies ongoing. The aim of this study was to evaluate the effectiveness of a real-time artifact suppression algorithm for reduction of non-physiological artifacts in sensor-generated glycemic profiles.

Method: Four adult participants were implanted with the GlySens Model 100 ICGM Sensor subcutaneously in the lower abdomen during a minor outpatient surgical procedure utilizing local anesthesia and optional light sedation. Participants self-monitor blood glucose four times per day and simultaneously wear a Dexcom G5 CGM. Meter-stored fingerstick and G5 CGM values are downloaded weekly during clinic visits. In addition, monthly clinic visits, including meal-based glucose excursions with YSI plasma glucose measurements, provide additional paired values. Participant interviews include standardized survey questionnaires to assess tolerance of the device. Algorithm effectiveness is assessed by examining reduction in spurious, non-physiological artifacts from the measured glycemic profiles.

Results: There have been no significant adverse events associated with the sensor implantations. Simulations indicated that the proposed real-time artifact suppression algorithm should significantly reduce the impact on the glucose signal from spurious, non-physiologic artifacts, and as shown below, artifacts are seen to be significantly suppressed in profiles from the human-implanted sensors.

Conclusion: Real-time artifact suppression algorithms implemented in the second-generation ICGM System demonstrate an advance in sensor signal performance that may enhance overall



accuracy. Additional studies are underway to further evaluate the performance and accuracy of the system in adult populations.

086

Glucose Sensors

ATTD8-0152

USABILITY, SAFETY, AND BENEFITS OF MULTIPLE SENSOR USE OF A LONG-TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background and Aims: Continuous glucose monitoring (CGM) over prolonged period can be linked to hypoglycemia prevention. The Eversense® CGM System consists of an implanted fluorescence-based glucose sensor that lasts up to 90 days, a wearable smart transmitter, and a mobile app to display real-time glucose readings. The first generation Eversense system is commercially available in Europe. This abstract presents user adherence, adverse events, and glucose variability results of multiple sensor use from the EU registry database.

Method: A group of 50 persons with diabetes (PWDs) who had three cycles of sensor use or are currently on their 3rd sensor (up to 270 days) between September 2016 and September 2017 were included in this analysis. For each individual sensor use, the percent wear time, number of device or procedure related adverse events (AEs), the average glucose, and percent time in ranges were tabulated.

Results: A total of ~13,500 sensor wear days were analyzed. High user adherence was observed in all sensor use cases. Five AEs were reported during the 1st sensor use and 2 were reported during the 2nd and 3rd sensor use, respectively. While average glucose between sensor use remained similar, numerical reduction in percent time in both hypoglycemia and severe hypoglycemia was observed.

Conclusion: The Eversense CGM system exhibits high usability, remains safe for up to 270 days, and numerically reduces patients' time in (severe) hypoglycemia.

	1st Sensor Use	2nd Sensor Use	3rd Sensor Use
Percent Wear Time (%)	86.7 (SD 15.5)	88.6 (9.8)	85.0 (13.6)
Total Number of AEs (Number of PWDs)	5 (4)	2 (1)	2 (2)
Average Glucose (mg/dL)	162.6 (22.8)	165.1 (23.7)	165.2 (25.9)
Percent Time in Hypoglycemia (<70 mg/dL) (%)	5.1 (5.1)	4.4 (2.7)	4.0 (3.1)
Percent Time in Target (70-180 mg/dL) (%)	36.3 (14.8)	37.4 (15.2)	37.0 (16.3)
Percent Time in Hyperglycemia (>180 mg/dL) (%)	58.6 (15.1)	58.2 (14.4)	59.0 (15.5)
Percent Time in Severe Hypoglycemia (<54 mg/dL) (%)	1.7 (3.1)	1.2 (1.1)	1.1 (1.2)

087

Glucose Sensors

ATTD8-0258

BENEFICIAL EFFECTS OF FLASH GLUCOSE MONITORING ON HBA1C AND TREATMENT SATISFACTION PERSISTS AFTER 2 YEARS OF USAGE - A REAL LIFE CLINICAL FOLLOW-UP STUDY

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Background and Aims: Flash glucose monitoring (FGM) has improved metabolic control and treatment satisfaction in people with 1 diabetes. Whether these beneficial effects persist or dimes as time to goes by is unknown. This study evaluates long-term effects on HbA_{1c} and treatment satisfaction in people with type 1 diabetes after introduction of FGM.

Method: Patients with type 1 diabetes received FGM if their individual metabolic goal was unmet or if problems with glucose fluctuations or repeated hypoglycemia occurred. HbA_{1c} was measured at baseline and 3, 12 and 24 months thereafter. A DTSQs questionnaire was completed before FGM initiation and a DTSQs follow-up questionnaire twelve months later.

Results: 171 patients were introduced to FGM until September 2015. At the 2-year follow-up 76% were still users, 8.2% stopped due to skin reactions, 7.6% changed to a CGM-system, 7.6% did not want to continue and 1.8% had died. Baseline HbA_{1c} among continuers were 73.5 ± 17.2 (36/141 (min/max) mmol/mol. Compared to baseline Hba_{1c} was -7.6 ± 8.7 (–44/11) mmol/mol after three months, -8.2 ± 10.4 (–34/20) mmol/mol after 12 months and -10.1 ± 12.2 (–52/55) mmol/mol after 2 years. Self-estimated treatment satisfaction after 1 year was 2.43 (+3 to –3) and rating for continued FGM use was 2.8. Unacceptable high blood glucose was less often present (–0.7) as were unacceptable low blood glucose levels (–0.3).

Conclusion: Use of FGM adds clinical significant advantages to individuals with 1 diabetes in terms of HbA_{1c} reduction and improved self-estimated treatment satisfaction. The beneficial effect of FGM seems to persist at least in a two-year perspective.

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Glucose Sensors

ATTD8-0178

ROUTINE USE OF SENSOR AUGMENTED PUMP COMPARED WITH INSULIN PUMP THERAPY IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: To analyse the routine use characteristics and its efficacy of CSII (Continuous subcutaneous insulin infusion) with or without continuous glucose monitoring (SAP) in type 1 diabetic patients (T1D).

Method: Retrospective observational cross-sectional study collecting routine use data from T1D patients between January-December 2016. CSII and SAP users were matched in relation 3:1 paired by diabetes duration and gender. Patients used Paradigm Veo or 640G (Medtronic-Minimedâ) devices with linked blood glucose meter.

Results: One-hundred-sixty subjects with T1D were included, 40 using SAP and 120 CSII therapy (aged 46.74 ± 12.02 years, 45% women, diabetes duration 28.72 ± 9.34 years, 10.18 ± 4.68 years on CSII, HbA_{1C} 7.63 ± 0.83%).

Those in SAP therapy used the sensor 64.3% of time. They performed less self-monitoring blood glucose/day (3.3 ± 1.9

vs.4.4 ± 2.0;p<0.01), more boluses/day (6.2 ± 3.6 vs. 4.7 ± 1.6; p = 0.034), more basal insulin segment/day (6.53 ± 2.1 vs. 5.85 ± 1.5;p = 0.03) and suspended the pump during more time (97.3 ± 93.4 vs. 9.6 ± 20.1 minutes/day;p<0.001).

SAP group had a lower mean blood glucose (150.8 ± 31.9 vs. 162.9 ± 30.1 mg/dL;p = 0.034) with less % of lectures >180mg/dl (30.43 ± 18.95 vs. 37.21 ± 16.14;p = 0.031) without differences in % of lectures <70mg/dl. There was a trend towards of lower HbA_{1C} in those using SAP therapy (7.42 ± 0.74 vs.7.7 ± 0.85 %;p = 0.068).

There were no differences in total daily insulin dose, basal/bolus ratio, number of bolus wizard (BW), basal patterns per day or BW glucose targets.

Conclusion: In real world clinical practice, SAP therapy is associated with a significant improvement in glucose profile in T1D patients in comparison with CSII. More frequent self-adjustments of therapy with SAP may have contributed to these effects.

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Glucose Sensors

ATTD8-0208

ANALYSIS OF ENHANCED PREDICTION ALGORITHMS FOR TIME LAG COMPENSATION IN CGM SYSTEMS

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Background and Aims: The goal of prediction in CGM systems is to compensate the time lag between the glucose level in the blood (BG) and the glucose level in the interstitial fluid (IG). Additionally, data-processing performed on raw current signals can introduce additional time-lags. Since the overall time delay based on these factors is of the order of magnitude of about 10 minutes, short-term prediction models are used to deal with this phenomenon in order to increase the overall precision of CGM systems with respect to the reference device.

Method¤	Prediction·horizon,·min¤	MARD,%¤
No·prediction¤	0¤	9.09¤
SOA¤	8¤	7.80¤
CWT¤	8¤	7.69¤
GARX(2)¤	12¤	7.69¤
GARX(4)¤	12¤	7.70¤
GARX(11)¤	12¤	7.70¤
GNARX(2)¤	10¤	7.86¤
GNARX(4)¤	10¤	7.86¤
PSARX(2)¤	16¤	7.72¤
PSARX(4)¤	19¤	7.88¤
PNARX(2)¤	15¤	8.29¤
PNARX(4)¤	15¤	8.61¤

Tab. 1

Method: The available data of clinical studies consists of 176 records. Each record contains data of one patient measured over a period of 7 days. In our analysis we compared the performance of a sensor equipped with different prediction algorithms. The following linear and nonlinear prediction models have been considered in this analysis: default built-in two-compartment model of the manufacturer's state of the art (SOA) algorithm, a two-compartment model with the derivative calculated by continuous wavelet transform (CWT), global and patient-specific autoregressive linear (GARX, PSARX) and nonlinear (GNARX, PNARX) models of different orders.

Results: The results displaying the performance of the considered methods in terms of MARD are presented in Table 1.

Conclusion: It can be concluded that the global ARX model of order 2, GARX(2), and the CWT-based two-compartment model perform best in terms of MARD. The higher order linear as well as nonlinear models do not lead to any significant performance improvements. There is also no improvement for the patient-specific models.

090

Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0182

THE NECESSITY OF USING MIXED METHODS FOR ASSESSMENT OF MHEALTH INTERVENTIONS: APPLICATION IN THE "FULL FLOW OF DATA-SHARING" PROJECT

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Background and Aims: Research typically assesses ''what'' a clinical intervention impacts, e.g. change in HbA1c. However, the current mobile health (mHealth) movement advocates for better understanding of ''how'' to best use new tools in self-management and ''why'' associated elements trigger positive health changes. We propose a mixed method approach for such interventions based on experience gained from our previous studies [1–3] with a new set of measures.

Method: A) Previous studies evaluated an mHealth self-management smartphone application (Diabetes Diary) for Type 2 Diabetes patients. We reviewed and identified positive and negative qualities of these studies.

B) To improve upon previous studies, additional and alternative measures and methods were identified through courses, lectures and literature searches in Pubmed and Google Scholar.

Results: A) Review of previous studies revealed: 1) too few measures of app-impact; 2) that users recorded data inconsistently; 3) the need for secure and efficient infrastructure for mHealth data-capture and 4) the potential benefit of analyzing app usage-logs.

B) We expect the following measures will improve mHealth intervention evaluation: questionnaires reflecting health competence, behaviour change, motivation, as well as usage-logs and registered-data within the apps (see Figure 1). Figure 1 illustrates

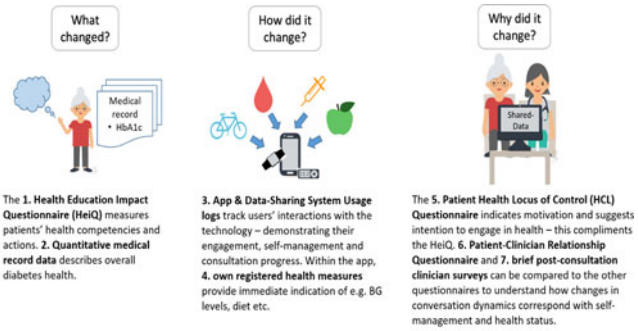

Figure 1: Framework for choosing measures (1-7) for evaluating what, how and why an mHealth data-sharing system impacts patients and clinicians.

that the chosen measures better explain what, why and how an mHealth data-sharing intervention impacts diabetes self-management and treatment.

Conclusion: mHealth intervention assessment should not be limited to clinical measures. Measures that reflect patients' engagement, e.g. usage logs, health competence and health beliefs should be added to better understand why and how self-management and health status are affected by mHealth interventions.

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091

Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0324

MOBILE APPLICATION "EUGLYCA" IN MANAGEMENT OF DIABETES MELLITUS TYPE 1 IN CHILDREN AND ADOLESCENTS

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Background and Aims: We developed <<Euglyca>>, a mobile application which calculate the amount of carbohydrates and lipids that a patient consumes during a meal and by taking into consideration eight more parameters calculates the required bolus dose of insulin. Aim of this study is to evaluate the efficacy of this application on patient's glycemic control and satisfaction.

Method: 80 children and adolescents with T1DM were randomly assigned in two groups. 40 of them used the application and the rest were controls. At the baseline, three months and 6 months later, Glycosilated Hamoglobin (Hba1c) levels were determined and amount of hypoglycemias, hyperglycemias and normoglycemias were calculated. In addition, Diabetes Treatment Satisfaction (DTSQ) was used to assess patient's satisfaction.

Results: In the target group HbA1c dropped from 7.8 ± 0.75 at baseline to 7.05 ± 0.59 in 3 months and 6.9 ± 0.61 in 6 months. In the control group HbA1c rose from 7.5 ± 0.91 to 7.8 ± 0.83 and 7.9 ± 0.8 at the same period. At the baseline there was no statistically significant difference ($p = 0.279$), while at 3 and 6 months there was, $p = 0.011$ and $p < 0.001$ respectively.

In the target group Normoglycemias increased from $48.3\% \pm 10.9$ at baseline to $62.3\% \pm 10.2$ in 3 months and 58.3 ± 10.1 in 6 months ($p < 0.05$). At the same period, hyperglycemias decreased from $38.7\% \pm 11.2$ to $28.5\% \pm 8.9$ and $30.5\% \pm 11.1$ respectively ($p < 0.05$).

In the control group Normoglycemias fell from $52.3\% \pm 11.8$ to $48.4\% \pm 12$ and $46.8\% \pm 13.3$ while hyperglycemias rose from $37.4\% \pm 12.6$ to $39.3\% \pm 13.1$ and $41.3\% \pm 13.7$.

Improvement in patient's satisfaction is noted in the target group.

Conclusion: ''Euglyca'' improves the glycemic control and satisfaction of children and adolescents with T1DM.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0396

RESULTS OF THE MULTI-CENTRIC STUDY RENACED DIABETES TIPO 1 IN MEXICO

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Background and Aims: Information regarding type 1 diabetes (T1D) patients follow-up in Mexico is limited. An online-system, RENACED DT1, registers longitudinal T1D data in Mexico.

Method: Descriptive analysis of 894 T1D patients registered on RENACED DT1, in 17 Mexican States, until 10/8/2017.

Results: Fifty percent patients were diagnosed in last 10 years, 59% women and 41% men. Average age at diagnosis was 12.5 years old (yo), being men 2 years younger than women (11.78 vs. 13.02, $p = 0.0289$). At the time of analysis, 860 patients remain active, with a ratio women:men of 1.5. Their average age was 24.6 yo, being women significantly ($p = 0.0268$) older than men (25.4 vs. 23.4); 12% have family history of T1D and 57.5% of T2D. Mean BMI was 22.3 Kg/m2 and mean HbA1c was 8.5%. Thirty-eight percent of patients performs SMBG ≥4 times/day, 23% uses insulin-pump and 66% MDI. Performing SMBG ≥4 times/day, results in lower HbA1c (8.08; CI95% 7.9–8.3) than monitoring less (8.7; CI 95% 8.4–8.9; $p < 0.05$). Lower HbA1c (<0.05) was observed in CGM users (8.0; CI 95% 7.5–8.5 vs. 8.8; CI 95% 8.5–9.0). A total of 20.9% and 12.1% of patients had HbA1c<7% and 7<7.5%, respectively. The presence of mild/moderate hypoglycemia was high at 74.6%, severe hypoglycemia, 26.3%, and chronic complications, 12.2%.

Conclusion: The percentage of T1D patients in Mexico that reach the HbA1c target is low (20.9 % <7% and 33% <7.5%), but similar to that described in the literature. Improved glucose monitoring technology, insulin delivery systems and adjunctive therapy are necessary to improve glycemic control in T1D patients.

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Insulin Pumps

ATTD8-0409

EFFICACY AND SAFETY OF SENSOR-AUGMENTED INSULIN PUMP THERAPY WITH LOW-GLUCOSE SUSPEND FEATURE IN OLDER ADULTS

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Background and Aims: Life expectancy is increasing worldwide, it is therefore essential to maintain functionality, improve quality of life and decrease incidence of complications. We evaluated efficacy and safety of sensor augmented insulin pump therapy (SAP) in older adults.

Method: Before and after study. Patients with Type 1 and 2 diabetes mellitus (DM) with preserved basic functionality by Barthel index and clinically, evaluating capability of self-administration of insulin, carbohydrate counting and smartphone usage. Participants with adequate social network support and who had been using SAP for at least 3 months were included. Data was analyzed from a cohort of SAP users recruited from 2008 to 2014 at Diabetic Clinic of Hospital Universitario San Ignacio in Bogotá, Colombia, a tertiary level referral center. Efficacy was assessed with A1C and safety by frequency of hypoglycemia. There were also addressed body mass index, number of hospitalizations, severe hypoglycemia episodes and self-rated health (SRH).

Results: 50 patients were included, 26 were younger adults and 24 older adults (≥60 years), mean age was 38 and 69.7 years-of-age for younger and older adults respectively. 58.3% of older adults had Type 2 DM and after SAP, number of hospitalizations (12.85% vs 33%), severe hypoglycemia (66.67% vs. 0%) and A1c (9.06 ± 1.69 vs. 7.27 ± 0.87) significantly decreased and a significant improvement of SPH was found (46.08 ± 24.30 vs. 82.69 ± 18.86) ($p < 0.05$). No statistically significant differences were found in A1C comparing older and younger adults.

Conclusion: Integrated systems in older adults led to a significant decrease in A1c and severe hypoglycemia episodes.

094

New Insulin Analogues

ATTD8-0420

HYPOGLYCEMIA RISK ASSOCIATED WITH BASAL INSULIN USE IN TYPE 2 DIABETES (T2DM): THE LIGHTNING STUDY

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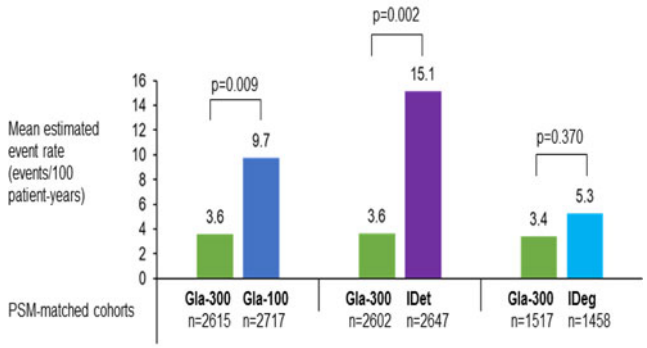
Background and Aims: The Lightning study aims to utilize real-world electronic health record data, representative of the general population and real-life practice, to assess hypoglycemia rates in patients with type 2 diabetes (T2DM) prescribed first-(glargine 100 U/mL [Gla-100], detemir [IDet]) or second-generation (degludec [IDeg], glargine 300 U/mL [Gla-300]) basal insulin (BI) analogs.

Method: We collected data for BI treatments between April 1, 2015 and December 31, 2016. This preliminary analysis

Figure: Estimated rates of severe hypoglycemia



Severe hypoglycemia was defined as any hypoglycemic event (identified by ICD 9/10 codes or plasma glucose levels) related to an inpatient or emergency department encounter. HbA_{1c} reduction for each comparison was: Gla-300 vs Gla-100, 0.59 % vs 0.56 %; Gla-300 vs IDet, 0.59 % vs 0.50 %; Gla-300 vs IDeg, 0.80 % vs 0.89 %.
ICD, International Classification of Diseases; PSM, propensity score matching

focuses on patients switching BIs, to validate findings from previous real-world Gla-300 studies. Propensity score matching (PSM) for variables including BI start date, diabetes duration, patient demographics, comorbidities and baseline HbA_{1c} ensured similar baseline characteristics between treatment groups, minimizing potential confounders. Period of BI use was the unit of analysis. Main endpoints: severe hypoglycemia event rate and HbA_{1c} change from baseline to 76–180 days follow-up.

Results: Severe hypoglycemia rates were significantly lower in patients switching from any BI to Gla-300 vs those switching to Gla-100 ($p = 0.009$) or IDet ($p = 0.002$), and comparable vs those switching to IDeg ($p = 0.370$) (Figure). Between-treatment difference in HbA_{1c} reduction was ≤0.09 % for all comparisons.

Conclusion: Findings from the Lightning study PSM analysis indicate significantly lower rates of severe hypoglycemia for Gla-300 vs first-generation BIs and comparable rates vs IDeg, without compromising HbA_{1c} reduction, in patients with T2DM switching from any previous BI. These results are consistent with previous randomized controlled trials and other real-world analyses of Gla-300. Further analyses are planned to correlate the different incidence of severe hypoglycemia with clinical and economic outcomes.

Study supported by Sanofi.

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New Medications for Treatment of Diabetes

ATTD8-0110

EFFICACY ON METABOLIC PARAMETERS, MGFR AND SAFETY FROM THE ADMINISTRATION OF IDEGLIRA IN A REAL-LIFE SETTING IN POORLY CONTROLLED PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: To investigate clinical outcomes in a real-world population with long-standing, poorly controlled type 2 diabetes mellitus (T2DM) after switching from oral drugs, GLP-1RA or/and insulin to IDegLira [a combination of insulin degludec (IDeg) and liraglutide (Lira)].

Method: The present study was a prospective, open-label, single-center observational follow-up, of 35 patients, 42.9% men, mean age 63.9 ± 9.7 years, and mean duration of DM 15.8 ± 8.5 years. All patients before Ideg/lira were on treatment with metformin, DPP-4Inh., sulfonyloureas, SGLT-2Inh., GLP-1 RAs or/and insulin. After the initiation and additionally to Ideg/lira, all patients were on metformin and in a few cases on fast insulin analogs. Patients were on treatment with Ideg/lira for at least 3 months. Information about glycemic control, total IDegLira dose, weight, mGFR and blood pressure, along with any adverse events, was collected from medical records and patient reports during clinic visits.

Results: Mean HbA_{1c} improved (8.9 ± 1.6% vs 7.3 ± 0.7%, $p < 0.001$) with concomitant weight loss (97.4 ± 18.4 vs 94.4 ± 18.4 Kg, $p < 0.001$). There was a decrease in mean systolic (135.6 ± 19.4 vs 130.7 ± 16.4 mmHg, $p < 0.05$) but not to mean diastolic blood pressure with IDegLira. Mean dose of IDegLira was 35.9 ± 13.8 U/24h. MGFR did not change significantly (74.7 ± 17.4 vs 72.6 ± 22.8 ml/min/1.73m^2). There were no episodes of severe hypoglycemia during treatment with IDegLira.

Conclusion: Switching to IDegLira, mostly from regimens using insulin in conjunction with oral antidiabetics in a real-world population of patients with type 2 diabetes, resulted in improved glycemic control with a lower systolic blood pressure and weight loss.

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New Technologies for Treating Obesity and Preventing Related Diabetes

ATTD8-0176

IMPROVEMENT OF METABOLIC CONTROL AND DIABETES MANAGEMENT IN INSULIN-TREATED PATIENTS RESULTS IN SUBSTANTIAL COST SAVINGS FOR THE GERMAN HEALTH SYSTEM

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Background and Aims: Self-monitoring of blood glucose (SMBG) using the ColourSure™ Technology to visualize target range showed improvement of metabolic control and overall diabetes self-management in insulin-treated patients. This economic analysis aims to identify cost savings for the German Health System resulting from an HbA1c reduction due to the utilization of user-friendly glucose meters.

Method: Patient data from a recently published observational study on SMBG were used for risk evaluations using the UKPDS risk engine. These values were integrated in an economic analysis regarding costs of myocardial infarctions (MI) related to diabetes for the German Health System. Based on an earlier assessment we combined these calculations with a 10 % reduction of severe hypoglycemic episodes. In the current study, 0% severe hypoglycemic episodes were observed.

Results: An HbA1c reduction of 0.69% over six month was associated with a 3% decrease of MI in 10 years. In our model this decrease led to cost savings of €4.90 per patient-year. Considering 2.3 million insulin-treated patients in Germany this 3% reduction of MI could result in annual savings of €11.27 million. Combining this with a 10% reduction in hypoglycemic events, the cost savings would increase to €30.61 per patient-year or €70.4 million for 2.3 million insulin-treated patients in Germany.

Conclusion: The improvement of metabolic control and diabetes self-management which was achieved with the ColourSure™ Technology has the potential to generate substantial cost savings for the German Health system underlining the importance of user-friendly methods for SMBG.

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Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0423

THE CRITERIA FOR EVALUATING AND SELECTING MOBILE APPLICATION FOR DIABETES CARE

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Background and Aims: Since 1552 B.C., the diabetes is considered as deadly disease. If it is not controlled in time, it will be very fatal. Most of the healthcare institutions are using ordinary software for diagnosis and reporting purposes for diabetes mellitus (DM). Now, this is the age of Information Technology, the diagnosis and reporting are better represent and easily manage at the finger tips access. In this paper, the aim of our study was to evaluate and select the suitable existing mobile application using specific criteria which will help us to diagnose, maintain, control and monitor the DM level.

Method: It is quite difficult and cumbersome to identify and select a tool that is appropriate for a this project. There are many deliberations and considerations that need to be dealt with while selecting a diabetes application existing on Mobile technology. We selected some specific apps and evaluate the features to utilize for diagnosing Md.

Results: e find staisfactory result which to use these tools (mobile apps) which we submit of full paper.

Conclusion: Regardless of the process methodology, however, this is certain that the odds of choosing the corrects mobile application for monitoring and controlling DM will be greatly enhanced if the app's selection process and tactics completely align with the healthcare institutional strategic goals and objectives.

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Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0326

SKIN AUTOFLUORESCENCE IN TYPE 1 DIABETIC AND NON-DIABETIC SUBJECTS: A 8-DECADE CROSS-SECTIONAL STUDY

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Background and Aims: Skin autofluoresence (SAF), which correlates with tissue Advanced Glycation End-Products, reflects prior long-term glycemia and is associated with concurrent and future chronic diabetes complications. There is a lack of data related to SAF in Type 1 diabetes (T1D) and non-diabetic subjects across a wide age-range.

Method: In a cross-sectional study SAF was measured non-invasively in T1D subjects ($n = 269$, including $n = 83$ with vascular complications (CX+), T1D duration between 6 month and 70 years) and non-diabetic ($n = 114$) subjects (CON), all between 9 and 73 y.o. SAF was related to age, diabetes duration, smoking and concurrent T1D complication status and HbA1c. Data analysed included age associated changes in SAF with T1D and its CX and SAF determinants).

Results: SAF increased linearly with age in T1D ($r = 0.77$; $p < 0.0001$) and CON ($r = 0.78$; $p < 0.0001$), and at higher rates in T1D (slope: 0.029 vs. 0.022 in CON; $p = 0.004$), including in subjects with ($r = 0.76$; $p < 0.0001$) and without complications ($r = 0.78$; $p < 0.0001$). Mean (SEM) age-adjusted SAF was higher in T1D subjects with vs. without complications (1.78 (0.04) vs. 1.64 (0.03) vs. CON 1.46 (0.03), all $p < 0.003$. Age-adjusted SAF was higher in smokers and recent ex-smokers than in non-smokers and long-past smokers (1.80 (0.06) vs. 1.57 (0.02); $p = 0.0004$). Determinants of SAF were age, gender, presence of diabetes, smoking status, renal function, HbA1c and BMI.

Conclusion: SAF increases with age in T1D and non-diabetic subjects, and at faster rates in diabetes, particularly in the presence of complications and with smoking. Results support accelerated aging in T1D. SAF may be used to assess diabetes complication status and risk.

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Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0327

IN TYPE 1 DIABETES CORNEAL NERVE STRUCTURE ASSESSED BY CONFOCAL MICROSCOPY CORRELATES WITH NON-INVASIVE MEASURES OF SKIN AUTOFLOURESCENCE AND RETINAL VESSEL CALIBRE

A. Januszewski[1,2], *A. Al-Alosi*[1], *R. McGrath*[3], *E. Scott*[1,3], *G. Fulcher*[3], *A. Jenkins*[1,2]

Table 1. CCM measures, retinal AVR and skin AFL (unadjusted) in T1D vs. CON and in CX- vs. CX+.

	CON	All T1D	T1D CX-	T1D CX+
N	10	33	20	13
NFD - Nerve Fibre Density (fibre per mm^2)	25.6±5.5	**16.8±7.3 †**	**19.5±6.5 †**	**12.3±6.5 ‡ †**
NBD - Nerve Branch Density (branch per mm^2)	23.2±10.2	20.2±13.7	24.0±12.0	**14.0±14.4 ‡**
NFL - Nerve Fibre Length (mm/mm^2)	14.6±2.5	**11.6±4.0 †**	13.1±3.4	**9.2±3.9 ‡ †**
ECD - Endothelial Cells Density (cells/mm^2)	5463±736	**4581±813 †**	**4547±911 †**	4637±652
CRAE - Central Retinal Arteriolar Equivalents	32.7±3.7	30.1±5.9	31.8±5.6	27.9±5.7
CRVE - Central Retinal Venular Equivalents	53.4±5.9	47.3±9.2	48.4±10.0	45.7±8.1
AVR - Arterio-Venous Ratio	0.62±0.10	0.64±0.06	0.66±0.06	**0.61±0.06 ‡**
Skin AutoFluorescence (AU)	1.67±0.44	**2.30±0.76 †**	2.17±0.70	**2.50±0.83 †**

† - p<0.05 vs. CON, ‡ - p<0.05 vs. CX-

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Background and Aims: Non-invasive tools for early detection of diabetic complications (including neuropathy) may be of use in clinical practice. Corneal confocal microscopy (CCM) measures have not been related to other non-invasive measures of tissue health which are associated with and predictive of chronic diabetes complications. Aims were to determine if CCM nerve measures (1) differ between non-diabetic and T1D subjects, and by T1D complication (CX) status; and (2) correlate with retinal vascular parameters and SAF.

Method: Cross-sectional study: T1D subjects; mean ± SD age 44 ± 17 yrs; T1D duration 22 ± 14 yrs and healthy controls (CON). Quantification: CCM HRT-3 (Heidelberg Engineering, Germany); Skin AGE Reader (Diagnoptics, The Netherlands); Retinal images by CR-2 camera (Canon, Japan); grading Vampire software (University of Dundee, Scotland).

Results: NFD and NFL differences for CON vs. T1D and T1DCX- vs. T1DCX+ remained significant after adjustment for age and T1D duration respectively. In T1D SAF correlated inversely with NFD ($r=-0.48$; $p=0.006$), NBD ($r=-0.48$; $p=0.006$) and NFL ($r=-0.54$; $p=0.002$). CRAE and CRVE correlated with NFD ($r=0.49$; $p=0.005$, $r=0.41$; $p=0.02$), NBD ($r=0.41$; $p=0.02$, $r=0.43$; $p=0.01$) and NFL ($r=0.47$; $p=0.007$, $r=0.41$; $p=0.02$). In T1D CX- AVR and in CX+ CRAE correlated with NFL ($r=-0.54$, $r=0.02$, $r=0.56$; $p=0.04$ respectively). CRAE and CRVE correlated with SAF ($r=-0.52$; $p=0.002$ and $r=-0.40$; $p=0.02$ respectively).

Conclusion: Corneal nerve measures and SAF are worse in T1D and in T1D CX+ vs. T1D CX-, whilst retinal calibre measures do not differ significantly. Some CCM measures are inversely correlated with SAF and retinal vessel calibre. Such clinically applicable tools may facilitate diabetes monitoring.

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Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0054

NEUROLOGICAL DEVELOPMENT IN INFANTS BORN TO MOTHERS WITH GESTATIONAL DIABETES

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Background and Aims: Gestational diabetes (GD) can lead to a number of negative consequences, including the impact on neurological development of children.

The aim. To compare the impact of GD on sensory motor development in children.

Method: 28 infants born to mothers with GD, treated by insulin, were involved in evaluation of sensory motor development (Piaget's method) at the age of 6 months. There were investigating the elementary forms of behavior of infants (motor, sensor, emotional, vocal reactions, interactions with objects).

Results: In 27 children (96.5%) motor reactions corresponded to a reference level for an age, only 1 child (3.5%) was in a zone of mild severity reduction. In the sensory sphere 57% were classified in the group of normal values. An easy degree of reduction was diagnosed in 18%, with an average severity of disorders in 25% cases. In group of emotional reactions 82% of children were assigned to the normal response group; 14.5% had mild disorders, and 3.5% had a moderate emotional disorder. In the vocal reactions 21.5% had a delay in voice development, while the rest (78.5%) had normal development. In interaction with objects only 21.5% of children were assigned to the normal age group of development, 64% had mild disorders, and 14.5% showed an average severity of the disorder.

Conclusion: The deviations of the sensory motor development were represented by disturbances in the sensory sphere and interaction with objects; To a lesser extent - the development of emotional and voice spheres. The smallest deviations were identified in the motor sphere.

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ATTD8-0195

CURRENT USE OF SENSOR-AUGMENTED INSULIN PUMPS (SAP) IN ROUTINE CARE IN GERMANY AND AUSTRIA: DATA FROM THE DIABETES PROSPECTIVE FOLLOW-UP (DPV) REGISTRY

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Background and Aims: The Austrian/German diabetes registry includes 117957 patients with type-1 diabetes, 465 institutions (hospitals, rehab units and private practices) do contribute. 35788 patients used insulin pumps (mean age 20.8 years, 46.9% male). Among pump patients, 8981 subjects (25.1 %) simultaneously used subcutaneous glucose monitoring (rtCGM or FGM).

MethodResults: Average age of this group was 16.8 years, 48.9 % were male. 31.8 % of these patients reported use of bolus calculator, 3.8 a low glucose suspend (LGS) and an additional 3.4 % used predicted low glucose suspend (PLGS). Patients with LGS / PLGS were slightly younger (15.7/10.4 years), while metabolic control (HbA1c) was comparable (7.5/7.5 compared to 7.6 % in SAP patients). In contrast, rate of severe hypoglycemia (definition: help required) was lower in LGS (11.7 events per 100 patient-years) or PLGS (12.8 events) compared to patients with SAP (16.4 events per 100 patient-years.

Conclusion: In summary, the combination of insulin delivery by CSII and glucose monitoring systems (sensor-augmented insulin pump - SAP) is used by increasing numbers of type-1 patients in the real world. In this registry, the use of automatic suspension of basal rate infusion during (LGS) or before (PLGS) hypoglycemia is associated with lower rates of reported severe hypoglycemia, while HbA1c-values are comparable. LGS and PLGS are predominantly used in younger subjects.

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ATTD8-0296

CONTENTS OF ADIPOKINES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: To determine content of adipokines in patients with type 2diabetes mellitus (DM) and obesity.

Method: 57 patients with type 2 DM were examined (mean age 57.6 ± 1.1 years, mean duration of disease 7.9 ± 0.6 years. All patients received standard glucose-lowering therapy. They were divided into the following groups according to their degree of obesity: grade I obesity (n = 15), grade II obesity (n = 17), grade III obesity (n = 25). All patients were determined contents of adiponectin, resistin and leptin levels in serum.

Results: It is shown that the average level of adiponectin and leptin in obese patients with grade I obesity was 8.5 ± 0.67 mg/ml and 55,3 ± 12.9 ng/ml, respectively; in patients with grade II obesity – 10.97 ± 1.2 mg/ml and 63.7 ± 12.3 ng/ml, respectively; in patients with grade III obesity – 9.86 ± 0.6 mg/ml and 83.3 ± 4.21 ng/ml, respectively. Averaged level of resistin in patients with grade I, II and III was above the normal range (12.7 ± 2.1ng/ml, 14.5 ± 3.0 ng/ml and 13,1 ± 0,85 ng/ml, respectively).

Conclusion: Studies in patients with type 2 DM with different grade of obesity showed a decrease in serum adiponectin levels, elevated content of leptin and resistin.

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Advanced Medical Technologies to Be Used in Hospitals

ATTD8-0243

DIFFERENCES IN DIABETES TECHNOLOGY REIMBURSEMENT FOR DIABETIC CHILDREN: THE SWEET PERSPECTIVE

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Background and Aims: Frequent use of modern diabetes technologies increases the chance for optimal Type 1 diabetes (T1D) control. Limited reimbursement influences the access to these modalities for patients with T1D and could cause worsening of their prognosis. We aimed to describe the situation on reimbursement of insulins, glucometers, insulin pumps (CSII) and continuous glucose monitoring (CGM) devices for diabetic children in countries participating in the SWEET Project (www.sweet-project.org), and to compare data from EU countries with our previous study from 2010.

Method: The study was running between March and August 2017. First, we approached diabetes technology companies with a survey mapping the reimbursement of insulins and diabetic devices. The data gained from them were then validated by members of the SWEET consortium (one respondent per country).

Results: We gained data from 37 countries (9/37 non-European). In Europe, insulins are mostly fully covered. Heterogeneity was observed in the reimbursement of strips for glucometers (from 100 strips/month to no-limit). CSII is well available in 19/28 European countries, five countries reported significant quota or obstacles for CSII prescription, and in four countries there is no CSII reimbursement. CGM is at least partially reimbursed in 17/28 European countries. The situations in non-European countries vary according to the GDP and health care system. Comparison with 2010 showed a slowly increasing availability of CSII (2 countries) and better access to CGM across the EU.

Conclusion: Although innovative technology is available, a large proportion of children with T1D do not profit from it due to a limited reimbursement.

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ATTD8-0145

FIRST DIGITAL DIABETES CAMP IN VOJVODINA

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Background and Aims: Pediatric education camp - implementation and aplication of modern technologies, in order to support participants to make independent and confident decisions in diabetes management.

Method: 15 participants with Diabetes type I, have been observed during 6 days. 8 of them are on the CSII (Medtronic pump) and 7 are on the MDII. All of them have finished basic education at The Insitute, at different time, due to various periods of time since they have diabetes.

Participants had used Accu-chek Performa meters to monitor their glycemia and define therapy. Parents and Clinical Endocrinologist double-checked them using the Continuous monitoring of Accu-chek Connect Diabetes Management System, that provide them all relevant data: BG, Uhc, insulin, physical activity…

During all the time at the camp, medical team was alert and involved in partcipants' actions.

Results: Modern technologies have positively influenced the camp participants, primarily in the field of motivation, which consequently had an impact on active participation, in a sense of individual decision making through all aspects of diabetes management. Better insight in their glucose values, increased motivation of our participants and their confidence in all area of diabetes control.

Conclusion: Parents and Endocrinologists were satisfied how participants used modern technologies to optimise BG control.

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Artificial Pancreas

ATTD8-0082

INTRAPERITONEAL GLUCOSE SENSING IN PIGS; INVESTIGATING POTENTIAL SPATIAL DIFFERENCES IN GLUCOSE DYNAMICS

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Background and Aims: Fast, accurate and reliable glucose sensing is crucial for a well-functioning artificial pancreas (AP). Studies have identified the peritoneal cavity as a promising site for early glucose sensing in an AP, as the site is expected to provide a more responsive, stable and protected environment compared to the subcutaneous (SC) tissue.

The main aim of this study was to investigate potential spatial differences in glucose dynamics within the peritoneal cavity, using commercially available amperometric glucose sensors.

Method: Seven anaesthetised, non-diabetic pigs (31 to 42 kg) were implanted with four glucose sensors (Abbott Freestyle Libre Flash), one in each quadrant of the peritoneal cavity as viewed in the frontal plane, and two SC sensors, of the same type, placed on the external abdominal wall. Meal glucose excursions were simulated by 30 minute intravenous glucose infusions, aiming at glucose excursions of at least 4 mmol/l. Frequent blood and intraperitoneal (IP) fluid samples were drawn and analysed in a blood gas analyzer (Radiometer ABL 725, Radiometer

Medical ApS, Brønshøj, Denmark) for comparison and for calibration of the sensors.

Results: Intravenous glucose infusions gave a rise in glucose measured by both SC and IP sensors. The glucose dynamics seems to be faster IP compared to SC. We were unable to identify major differences in glucose dynamics between the four different quadrants of the peritoneal cavity.

Conclusion: The preliminary results of this study do not indicate major differences in glucose dynamics between the four quadrants of the abdominal cavity. Further analyses of the data will be presented.

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Artificial Pancreas

ATTD8-0337

THE INTERNATIONAL DIABETES CLOSED LOOP (IDCL) TRIAL: RESULTS FROM THE TRAINING STUDY AND DESIGN OF THE MULTI-CENTER PROTOCOL 1

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Background and Aims: The iDCL Training Study is a 10-site (3 in Europe, 7 in the U.S.) protocol intended for clinical staff to gain experience with the inControl artificial pancreas (AP) system, and to assess the 24/7 in-home usability of different system components prior to initiating larger studies.

Method: NCT number: NCT02844517, IDE G160097. Major eligibility criteria: age 14-75years, type 1 diabetes treated with insulin >1 year, HbA1c <10.5%, pump use >6 mos. Forty-three subjects were enrolled, with 40 having completed the main 2-week home use phase to date. System configurations: inControl AP software platform, Dexcom G4 or G5 CGM, Roche Spirit Combo or Tandem t:AP pump.

Results: While the AP system was active, glycemic control was similar regardless of which sensor or insulin pump was used. However, there was a difference between the radio connectivity of the two pumps with peripheral devices (91% Roche; 66% Tandem). Table 1 summarizes the glycemic outcomes pooled across all hardware configurations.

Conclusion: The Training Study met its objective and the inControl system achieved good glycemic control with little time spent in hypoglycemia. Based on Training Study results and on technology developments, we designed three large-scale clinical protocols. Protocol 1 (NCT02985866, IDE G160181) is a 3-month parallel group RCT randomizing N = 126 at 7 U.S. sites to AP vs. sensor-augmented pump therapy. Eligibility criteria are the same as the Training Study. Co-primary outcomes include: (1) superiority in CGM-measured time below 70 mg/dL, and (2) non-inferiority in CGM-measured time above 180 mg/dL over 3 months.

*iDCL Study Group: Stacey Anderson, Boris Kovatchev, Sue Brown, Ananda Basu, John Lum, Lori Laffel, Jordan Pinsker, Carol Levy, David Lam, Yogish Kudva, Paul Wadwa, Gregory Forlenza, Bruce Buckingham, David Maahs, Simone Del Favero, Eric Renard, Claudio Cobelli, J Hans DeVries, Eyal Dassau, Frank Douyle, and Danlela Bruttomesso.

Table 1. CGM metrics during closed-loop mode system use (N = 40 subjects)

Metric	Overall	Daytime	Nighttime
Mean glucose	152	155	150
Coefficient of variation (median)	33%	34%	28%
% below 50 mg/dL (median)	0%	0%	0%
% below 60 mg/dL (median)	1%	1%	0%
% below 70 mg/dL (median)	2%	2%	1%
Low BG index (median)	0.5	0.6	0.3
Mean percent in range 70-180 mg/dL	73%	70%	76%
High BG index (median)	5.2	5.3	4.0
% above 180 mg/dL (median)	24%	26%	18%
% above 250 mg/dL (median)	3%	4%	2%
% above 300 mg/dL (median)	1%	1%	0%

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Artificial Pancreas

ATTD8-0302

ACCEPTANCE OF THE ARTIFICIAL PANCREAS: COMPARING THE EFFECT OF TECHNOLOGY READINESS, PRODUCT CHARACTERISTICS AND SOCIAL INFLUENCE BETWEEN INVITED AND SELF-SELECTED RESPONDENTS

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Background and Aims: Human factors that may affect acceptance of artificial pancreas (AP) systems have been investigated in small sample sizes of highly motivated, self-selected persons with type 1 diabetes (T1DM) with a focus on product characteristics. We investigated the impact of technology readiness and social influence on AP acceptance in a larger sample, including both self-selected and invited respondents with T1DM.

Method: A reliable and valid online survey was developed based on established questionnaires. Intention to use the AP was chosen as measure of AP acceptance. T1DM patients who signed up themselves for scientific research into AP represented the self-selected group, while patients treated at a teaching hospital represented the invited group. Questionnaire values were compared using independent t-tests and regression analyses.

Results: The survey was completed by 425 self-selected and 109 invited persons. Intention to use the AP was high in both groups, but was significantly higher among self-selected respondents. In both groups, intention to use the AP was most strongly influenced by product compatibility followed by product complexity, technology readiness and product usefulness among invited respondents; and followed by product usefulness and technology readiness among self-selected respondents.

Conclusion: Product characteristics have a larger impact on AP acceptance than technology readiness, while social influence does not seem to impact AP acceptance. As the (strength of) influencing factors differ between self-selected and invited

persons, researchers and product developers should be cautious when relying on self-selected persons with T1DM in the design, development, and testing of AP systems.

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Artificial Pancreas

ATTD8-0371

THE INTERNATIONAL DIABETES CLOSED LOOP (IDCL) TRIAL: PLANNED PIVOTAL TRIALS OF CLOSED LOOP CONTROL ON AN EMBEDDED SYSTEM AND A MOBILE SYSTEM

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Background and Aims: A series of planned studies will allow for the initiation of two pivotal trials of closed loop control utilizing an embedded version of an artificial pancreas (AP) on an insulin pump, and a mobile version with an implantable sensor, respectively.

Method: Both pivotal trials will be multi-center randomizing participants 2:1 to AP vs sensor-augmented pump for 3 months. Major eligibility criteria are age 14–75 years with Type 1 Diabetes treated with current insulin pump use. Co-primary outcomes include: (1) superiority in CGM-measured time below 70 mg/dL, and (2) non-inferiority in CGM-measured time above 180 mg/dL.

Embedded System:

Participants: N = 147 subjects recruited at 7 U.S. sites: University of Virginia (UVA), Harvard, Mt Sinai School of Medicine, Mayo Clinic, Barbara Davis Diabetes Center, Stanford, Sansum Diabetes Center. Following the main trial, all eligible experimental and control participants will continue with a 3-month extension phase.

System Configuration: Dexcom G6 CGM and Tandem t:slim X2 insulin pump with Control-IQ Technology. Control-IQ is an embedded in the pump version of the inControl AP system developed by TypeZero Technologies under license from UVA.

Mobile System:

Participants: Approximately 72 participants recruited at 3 European sites: Academic Medical Center Amsterdam, CHRU Montpellier, University of Padova.

System Configuration: Senseonics Eversense implantable CGM and Roche Insight insulin pump with closed-loop running on a modified smartphone with inControl user interface and closed-loop algorithm.

Results:

Conclusion: Both trials will be coordinated by the Jaeb Center for Health Research and are expected to begin enrollment in early 2018.

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Artificial Pancreas

ATTD8-0328

OPEN ARTIFICIAL PANCREAS SYSTEM REDUCED HYPOGLYCEMIA AND IMPROVED GLYCEMIC CONTROL IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Artificial pancreas combines continuous glucose monitoring (CGM) with insulin pump by using a control algorithm to direct insulin delivery. Although several control algorithms are developed, the control algorithms are beyond reach of most of diabetes patients in need. The Open Artificial Pancreas System project (openAPS) is an open control algorithm for artificial pancreas, which is widely available to worldwide type 1 diabetes. Here, we present several interesting clinical experiences using openAPS.

Method: Twenty type 1 diabetes patients using openAPS, CGM (Dexcom G4®), and insulin pump (Sooil, Dana R®) were studied. Normal glycemic range was set as 80 ~ 180 mg/dl.

Results: Mean age was 11.9 ± 6.9 years and 10 patients were male. Median openAPS duration was 180 (30–240) days. By using openAPS, CGM analysis showed significant decrease in A1C (6.8 ± 1.0% to 6.3 ± 0.7%, $p < 0.001$), increase in percent time in normal glycemic range (70.1 ± 16.4% to 83.3 ± 10.1%, $p < 0.001$), decrease in percent time in high glycemic range (24.7 ± 16.5% to 13.3 ± 9.4%, $p < 0.001$) and decrease in percent time in low glycemic range (5.1 ± 3.3% to 3.4 ± 2.3%, $p = 0.004$), respectively. There was no significant side effect due to openAPS.

Conclusion: Open artificial pancreas system reduced hypoglycemia and improved glycemic control in patients with type 1 diabetes.

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Artificial Pancreas

ATTD8-0367

HISTOLOGY OF SUBCUTANEOUS TISSUE SURROUNDING COMMERCIAL STAINLESS STEEL AND TEFLON CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) SETS IN AMBULATORY SWINE

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Background and Aims: Patients managing their Type 1 Diabetes with an insulin pump are required to insert a new continuous subcutaneous insulin infusion (CSII) set every 2–3 days to ensure safe and effective glycemic control. A pilot study was performed to better understand the tissue response of commercial CSII sets with Teflon catheters (Inset) versus sets with stainless steel needles (Contact Detach) when implanted in soft adipose tissue of ambulatory swine for up to 7 days.

Method: CSII sets with Teflon catheters and steel needles were implanted within abdominal subcutaneous tissue of swine for 7 days, 5 days, 3 days, 8 hours, and 10 minutes prior to surgical excision. Insulin lispro (U-10) was continuously infused through the catheters (5uL/hr.) using insulin pumps during wear time. CSII sets and the surrounding tissue were excised and immediately frozen. Tissue histology surrounding each catheter was analyzed using H&E and Trichrome stains.

Results: Catheter insertions initiated an acute inflammatory response and a layer of inflammatory tissue formed around the cannula, becoming thicker, denser, and more continuous over time. Tissue damage and local inflammation were more extensive in specimens with steel needles when compared to Teflon catheters.

Conclusion: Though steel needles were less susceptible to kinking and occlusions, they elicited a more severe tissue response surrounding the insertion site, which may interfere with insulin diffusion and absorption into the circulation. Results from this study provide information pertaining to bio-compatibility and the acute inflammatory response that may cause insulin absorption variability and help guide the development of more effective insulin infusion catheters.

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Artificial Pancreas

ATTD8-0084

INTRAPERITONEAL, SUBCUTANEOUS AND INTRAVENOUS GLUCAGON DELIVERY IN RATS: EFFECT ON GLUCOSE LEVELS

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Background and Aims: Glucagon is primarily used as an emergency treatment of hypoglycaemia in DM1 patients. Recently, it has also been incorporated in the dual-hormone artificial pancreas (AP) in order to prevent hypoglycaemia and keep glucose levels within a narrow range. So far glucagon has only been studied in AP with a double subcutaneous (SC) approach.

We investigated the glucose rising effect of glucagon administrated intraperitoneally (IP), and compared it to SC and intravenous (IV) administration.

Method: 20 Sprague Dawley rats were used. 15 rats received IP, SC injections of glucagon and a placebo IP injection. 5 rats received IV, SC and IP injections of glucagon. A blood gas analyser (ABL 725, Radiometer Medical ApS, Denmark) was used for frequent blood glucose (BG) measurements.

Results: Compared to placebo, a significant increase in mean delta BG could be seen in the IP treated rats already after 4 minutes ($p = 0.009$), whereas significant increase were seen in SC and IV treated rats after 8 minutes ($p = 0.002$ and $p < 0.001$, respectively).

When comparing IP and SC administration, mean delta BG in IP administration was higher after 4 minutes ($p = 0.019$) and lower after 40 and 50 minutes ($p = 0.005$, $p = 0.011$), as compared to delta blood glucose during SC administration.

Maximum glucose response occurred sooner after IP compared to SC delivery (25 minutes vs 35 minutes, $p = 0.003$).

Conclusion: Glucagon administered IP gives a faster glucose response compared to SC administered glucagon. These results favor the IP route of glucagon administration in a dual-hormone AP.

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Artificial Pancreas

ATTD8-0017

MODELING EATING BEHAVIOR OF ADULTS WITH TYPE 1 DIABETES

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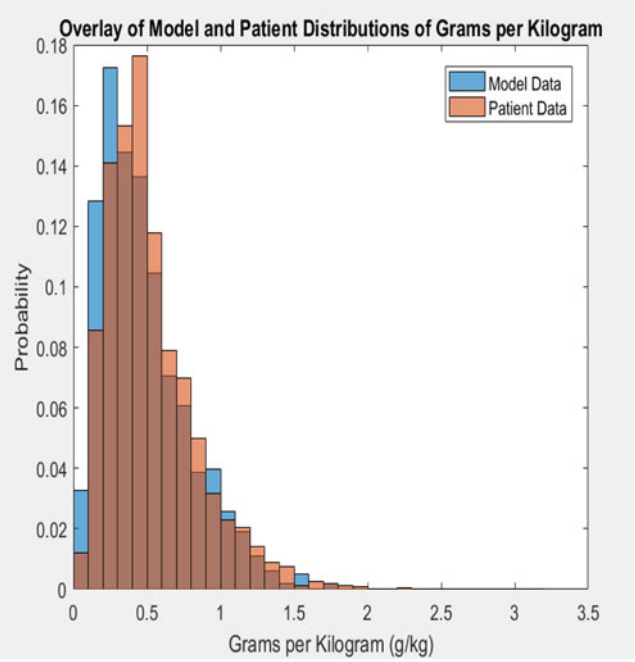
Background and Aims: To develop a model of eating behaviors of adults that can accurately replicate meal times and sizes for use in *in silico* studies in the UVA-Padova T1DM Simulator.

Method: Phase 1 data from grant RO1-DK-085623 (see clinicaltrial.gov, NCT01434030) were used, this data included CGM readings and meal diaries from 53 patients (21 Male, 32 Female). The time and size of a meal is modeled as the state of a Markov chain. The probabilities for relative meal times and sizes were estimated as empirical frequencies based on this data. The size and time of the last meal were used in specified intervals to predict the next meal time. This predicted next time was used in conjunction with the size of last meal to predict the relative size of the next meal. To test the accuracy of this model, 500 1-day trials were conducted and compared to Phase 1 subject data using a two-sample Kolmogorov–Smirnov test.

Results: After 500 1-day trials of the Markov chains, the distribution of the meal sizes (in grams per kilogram) and times of meals created by the Markov chains was consistent with the Phase 1 distributions of meal sizes (g/kg) ($p < 0.001$) and times of meals ($p < 0.001$). The resulting model has been incorporated into the UVA-Padova T1DM Simulator.

Conclusion: The proposed model accurately replicates adult meal behavior and provides a new behavioral component to the UVA-Padova T1DM Simulator. The model will provide a realistic testbed for adaptive technologies such as closed-loop systems and other forms of decision support.



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Artificial Pancreas

ATTD8-0257

MEASURING TRADE-OFFS: PATIENT'S REPORTS REGARDING PROS VERSUS CONS WHEN CONSIDERING AN AUTOMATED INSULIN DELIVERY SYSTEM

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Background and Aims: To examine perceived trade-offs when using an automated insulin delivery system. Perceptions of children, teens, and adults with type 1 diabetes and parents/partners were assessed.

Method: Verbatim transcripts of focus groups and individual interviews from the INSPIRE Study, examining psychosocial aspects of automated insulin delivery systems, were analyzed using content analysis. Coders reviewed data for 'trade-offs,' the perceived negative aspects or tasks the individual is willing to accept to achieve a perceived benefit.

Results: Coders reached saturation of themes after coding 98 of the 136 transcripts. Analysis revealed 6 key trade-offs: 1) For improved glycemic outcomes, participants would increase time managing the system, wear multiple devices, and continue typical daily diabetes tasks; 2) For decreased daily management burden, participants would increase system management time, change sites frequently, and wear multiple devices; 3) For improved health, participants would pay for the system, increase system management time, and wear multiple devices; 4) For accurate management of diabetes, participants would pay for the system; 5) For improved sleep (for patients/family members), participants would increase system management time; 6) For a reduction in mental burden, participants would wear multiple devices, increase system management time, and pay for the system.

Conclusion: An increase in management time was consistently chosen as a trade-off for potential system benefits. Awareness of stakeholder perceived trade-offs may provide insight into the potential uptake and continued use of these systems. Attention to these tradeoffs with provision of realistic expectations may improve adoption for new and emerging technologies.

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Artificial Pancreas

ATTD8-0330

TITLE- "MICRONEEDLE - A CLOSED LOOP HYPOXIA SENSITIVE INTRADERMAL INSULIN DELIVERY SYSTEM FOR THE MANAGEMENT OF DIABETES."

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Background and Aims: A glucose-responsive ''closed-loop'' insulin delivery system mimicking the function of pancreatic cells has tremendous potential to improve quality of life and health in diabetics. Here, we report a novel glucose responsive insulin delivery device using painless microneedle-array patch (''smart insulin patch'') containing glucose responsive vesicles containing insulin and enzyme glucose oxidase. Instead of injecting a needle full of insulin, a hormone that body uses to process the sugar in food when needed the patch would be worn constantly and inject the wear it when needed. An artificial pancreas-like, closed-loop, glucose-responsive insulin delivery system that is able to secrete insulin in response to elevated blood glucose would be desirable. This described work will be the demonstration of a synthetic glucose-responsive device using a hypoxia activater for regulation of insulin release. Thus this novel glucose responsive insulin delivery device may hold a promise in avoiding hyperglycemia and hypoglycemia if translated for human therapy.

Method:

1. Preparation of Glucose responsive vesicles containing insulin and glucose
2. Preparation of Microneedle- A Biomedical engineering approach
3. *In vitro* Assay
4. *In vivo* Assay

Results: Thus this combination may explore and give a new approach towards insulin loaded dissolving microneedle promoting free insulin in faster and controlled manner (An effective alternative to parental and oral delivery of insulin).

Conclusion: This smart insulin patch with its novel trigger mechanism may guide the development of a useful drug delivery platform for treating using artificial vesicles, the behaviours of which can be ''intelligently'' activated and self-regulated by the variation of physiological signals.

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Artificial Pancreas

ATTD8-0181

PATIENT AND CAREGIVER FEEDBACK ON THE FIRST GENERATION ARTIFICIAL PANCREAS IN INDIA

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Background and Aims: Automating insulin delivery is impossible with conventional insulin injections, and hence elimination of hypoglycemia is a major challenge in T1D and brittle T2D. Here we share our clinical experience on using the first generation Artificial Pancreas (AP) which suspends insulin and almost eliminates hypoglycemia (Predictive Low Glucose Suspend-PLGS).

Method: A brief survey was conducted among our T1D and T2D patients (n = 15) and our clinicians(n = 4) to access utility of MiniMed 640G® system.

Results:

Merits	Demerits
- Enhances confidence in managing diabetes with minimal fear of hypoglycemia.	- 3 patients found application of sensor and pairing with AP difficult and cumbersome.
- The integrated glucose meter functions as a remote for more accurate, convenient and comfortable bolus dosing without disrupting privacy and automatically calibrates the sensor.	- AP functions as ordinary insulin pump in the absence of sensor.
- Those previously on Veo appreciated insulin suspension well ahead of hypo events.	- 52% were addicted to sensor so much so that they could not wait for next sensor application due to intense fear of severe hypoglycemia.
- Personal software allows patients and healthcare team to get a better glycaemic picture.	- Patients desired to have a single insertion site for AP device and sensor.
	- Device and the sensor being bulky, and revealing, few patients changed the insertion sites to thighs to overcome the same.

Conclusion: 640G is phenomenally different from earlier devices. Even though cost of device is prohibitively high, for those truly deserving, it is certainly a lifesaving option if judiciously used.

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Artificial Pancreas

ATTD8-0362

CLOSING THE LOOP FOR DIABETES: EXTENDING CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) IN VIVO

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Background and Aims: Although insulin regulation of blood glucose (BG) levels is the mainstay of diabetic management, minimal effort has been directed towards evaluating the CSII biological interface at insulin infusion sites. Progress has been hindered by the lack of cellular and animal models that could enhance the insulin infusion performance. To fill this gap, we have modified the murine air pouch (MAP) model to investigate the impact of CSII-induced infusion site tissue reactions on insulin-based regulation of BG levels.

Method: Cellular toxicity of insulin, diluents and insulin fibrils was determined using standard cell culture technology. Local inflammation at the MAP site was induced by injecting insulin, diluents and insulin fibrils, as well as an irritant (thioglycolate) or inflammatory cells. CSII in MAP was conducted for up to 7 days including BG determinations. The extent of tissue toxicity and inflammation were assessed using MAP lavage and FACS analysis of cell numbers and populations. Using MAP, the effect of local inflammation on BG levels was evaluated with respect to various inflammatory cell populations' outcomes.

Results: We determined that commercial insulin and its excipients as well as fibrils were cell and tissue toxic. Inflammation in the MAP was characterized by an influx of polymorphonuclear leukocytes and monocytes/macrophages. Our studies further demonstrated that direct injection of irritants or inflammatory cells inhibited insulin's ability to lower BG *in vivo*.

Conclusion: These studies demonstrate that insulin and related products are cell and tissue toxic, resulting in tissue inflammation and reduced effectiveness of insulin-mediated BG regulation *in vivo*.

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Artificial Pancreas

ATTD8-0113

PERFORMANCE OF OMNIPOD PERSONALIZED MODEL PREDICTIVE CONTROL ALGORITHM WITH MODERATE INTENSITY EXERCISE AND VARIABLE SETPOINTS IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: To assess the safety and performance of the Omnipod hybrid closed-loop (HCL) personalized model predictive control (MPC) algorithm using an investigational device in adults with type 1 diabetes performing moderate intensity exercise.

Method: The study consisted of a 7-day, outpatient, open-loop phase, followed by a supervised, 54-hour HCL phase conducted in a hotel setting. Subjects aged 18–65y with type 1 diabetes and A1C 6.0–10.0% were eligible. Endpoints included mean glucose, percentage time <70, 70–140, 70–180, >180 and >250 mg/dL. Two 45 minutes sessions of moderate intensity exercise were performed in the afternoon on Days 1 and 2. On Day 1 the initial HCL setpoint of 110 mg/dL was increased to 130 mg/dL pre-lunch, increased to 150 mg/dL 90 min pre-exercise and then decreased to 130 mg/dL post-exercise. On Day 2 the setpoint was increased from 110 mg/dL pre-breakfast to 130 mg/dL pre-lunch with a temporary basal rate of 50% set 90 min pre-exercise. The standard basal rate was resumed post-exercise. On both days the setpoint was lowered to 120 mg/dL at 2100h.

Results: Glycemic outcomes for the HCL phase overall and exercise challenges are summarized in Table A and B. Overall mean glucose was 136.0 ± 14.3 mg/dL with 85.1 ± 9.3% time in range 70–180 mg/dL.

Table A. Overall Glycemic Outcomes

Glycemic outcomes	Overall (54-hr)	Day (07:00-23:00)	Night (23:00-7:00)
Mean glucose (mg/dL)	136.0 ± 14.3	139.0 ± 12.6	129.3 ± 23.4
Standard deviation (mg/dL)	41.5	45.3	30.0
Percentage time (mg/dL)			
<70	1.4 ± 1.3	2.1 ± 1.9	0
70-140	60.3 ± 16.5	56.1 ± 13.2	69.4 ± 32.7
70-180	85.1 ± 9.3	81.3 ± 8.7	93.4 ± 14.2
>180	13.5 ± 9.5	16.6 ± 8.6	6.6 ± 14.2
≥250	1.8 ± 2.4	2.5 ± 3.3	0.1 ± 0.3

Table B. Exercise Challenge

Mean Glucose, mg/dL	Day 1	Day 2
Pre-exercise, over 60 min	139.1 ± 60.2	133.8 ± 26.3
During exercise, over 45 min	135.7 ± 27.6	129.5 ± 26.6
Post-exercise, over 60 min	99.3 ± 19.3	122.6 ± 34.9

Conclusion: The Omnipod personalized MPC algorithm performed well and was safe during day and night use in response to moderate intensity exercise with variable setpoints in adults with type 1 diabetes.

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Artificial Pancreas

ATTD8-0347

PRELIMINARY RESULT OF AN EMBEDDED MODEL CONTROLLER FOR INSULIN INFUSION IN TYPE 1 DIABETIC PATIENTS

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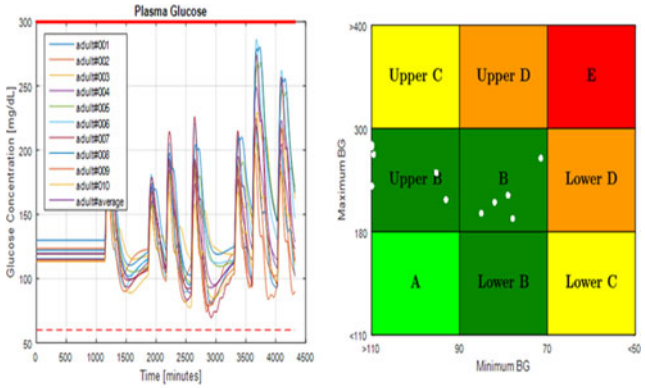
[3]*Universidad Nacional de La Plata, Electrotécnia, La Plata, Argentina*

Background and Aims: Control algorithms for artificial pancreas based on a control oriented model of the blood glucose variation with respect to the subcutaneous injected insulin must be adjusted according to each patient and usually have several parameters that should be identified.

Method: This work presents the preliminary results of a control algorithm for artificial pancreas using the EMC design methodology [1], extracting a linear and time-invariant model of the linear parameter-variant (LPV) model presented in [2], and augmenting it by a proper disturbance dynamics designed to handle the uncertainties. This so-called embedded model (EM) has only two parameters and no delay, which is a remarkable novelty with respect to previous works, where more complex models have been successfully used in clinical trials [2].

Results: Preliminary results are satisfactory and were validated using the same in-silico patient population as in [2]. The control system works even in the virtual patient excluded in the original LPV model exhibiting good performance (see figure).



Results of the proposed EMC controller for all the adult population of the Uva/Padova Simulator. Left: Blood Glucose Trace. Right: CVGA Plot B-zone 100%

Conclusion: The EMC controller was able to regulate the blood glucose for all in-silico patients with a unique and novel EM for all of them. This performance is susceptible to be improved in future works since others EM based on the original non-linear dynamics model can be implemented.

[1] Canuto, Enrico. Embedded Model Control: outline of the theory. ISA transactions 46.3 (2007):363-377.

[2] Sánchez-Peña, R., et al. Artificial Pancreas: First Clinical Trials in Argentina, 20th IFAC WorldCongress, 2017.

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Artificial Pancreas

ATTD8-0293

TENSOR PRODUCT-BASED ROBUST CONTROL OF DIABETES

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Background and Aims: Modern advanced control algorithms have proven their importance in artificial pancreas development. However, due to neglected dynamics robustness is still a challenge. On one hand, personalization demands the use of more accurate and complex patient models tuned on patients' own data, while robust control focuses less on the quality of the control, but much more on the safety characteristics.

Our aim is further development of the robust control algorithm developed by the Hungarian Artificial Pancreas Working Group (MAP).

Method: We transformed the available patient models into linear parameter varying (LPV) form by determining the control region using Tensor Product (TP) transformation, then Linear Matrix Inequality (LMI) based robust controller is designed on the same concept presented at previous ATTD conferences. The efficiency of the algorithm is tested on real data of 203 weeks of 89 T1DM patients from the MAP's insulin pump centers (aged 6–52 years).

Results: Hypoglycaemia is completely avoided and hyperglycaemia is reduced more than 70% compared to the real datasets. These safety features have been proven for large meal scenarios, or irregular and inexactly determined (±20 g CHO) meal scenarios as well. However, initial condition identification is crucial for the algorithm.

Conclusion: Results proved quality performance of the robust controller even in extreme conditions. The robust controller can handle patient variability as well. Further steps plan the use of general observers (e.g. Kalman-filter) to estimate the states of the model and use of machine learning algorithms for initial condition identification, but for increasing robustness against disturbance effects as well.

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Artificial Pancreas

ATTD8-0270

SMARTPHONE AND WATCH BASED ACTIVITY PREDICTION FOR THE ARTIFICIAL PANCREAS

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Background and Aims: Requiring manual announcements for Artificial Pancreas devices is a burden and often unreliable, especially with adolescents and teenagers. This requirement can be mitigated by anticipating activities. This work uses smartwatch, phone, and population level data to predict future activity.

Method: We use the gyroscope, accelerometer, and heart-rate sensor on a smartwatch along with the accelerometer and GPS on a smartphone to track patient activity. The sensor readings are fed into Recurrent Neural Networks (RNN) that classify each minute of sensor readings as null (inactive device), eating, exercising, sleeping, or other. Locally Weighted Regression (LWR) is implemented to predict future activity, since it can readily adapt to patient history and incorporate announcements.

Results: The RNN for gyroscope data is trained on 35,770 samples and validated on 7,750 samples. Using lab-like data containing only eating, sleep and exercise data, 79% accuracy is achieved. Classification specificity is 73%. Training on all 5 activity types, 57% accuracy is achieved. Confusion is primarily between null and sleep; eating and other. 77% specificity is achieved for exercise samples. The LWR prediction algorithm is trained on 120,000 samples and validated with 6,363 samples. Comparing against two algorithms providing constant predictions based on prior probabilities and the current activity respectively, the LWR algorithm reduces error by 74%/71%/64% for 1/2/3-hour predictions.

Conclusion: We will integrate this probabilistic activity prediction into our multiple model probabilistic predictive controller (MMPPC) algorithm to better mitigate post-prandial hyperglycemia and exercise-induced hypoglycemia, allowing patients with Type-1 diabetes to live more normal lives.

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Artificial Pancreas

ATTD8-0233

FACTORS ASSOCIATED WITH HYPERGLYCEMIC EXCURSIONS AMONG YOUNG ADULTS WITH TYPE 1 DIABETES

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Background and Aims: This study explored differences in glycemic variability (GV) among young adults with T1DM by age of onset (childhood [<12 years]; or teenager/adults [≥12 years]); and HbA1c. We also compared weekdays (WD) and weekends (WE) as all subjects were employed/students and tended to have different lifestyle habits on WD compared to WE.

Method: Subjects wore continuous glucose monitors (DEXCOM G4® or Medtronic Guardian®) for up to 6 days including WD/WE. GV measures were calculated using the Easy GV version 9.0 software. T-tests were conducted to examine differences among variables.

Results: There were 38 subjects with T1DM: female (65.8%); age (25.0 ± 5.5 years); Caucasian (86.8%); with onset of T1DM: childhood (55.3%); duration of T1DM (12.0 ± 8.4 years); HbA1c (7.8 ± 1.2%); and BMI (26.2 ± 3.9 kg/m^2). There were significant differences in the *high blood glucose index* (HBGI) between WD and WE (10.02 ± 5.43. vs. 13.02 ± 8.41; t = 2.63, $p = 0.01$); childhood and teenager/adults onset of T1DM (14.12 ± 5.53 vs. 8.90 ± 6.01; t = 2.76, $p < 0.01$); and HbA1c <8% or ≥8% (8.71 ± 5.55 vs. 15.20 ± 5.30; t = −3.68, $p < 0.01$).

Conclusion: Those with childhood onset T1DM and HbA1c ≥ 8% were at greater risk for hyperglycemic excursions. All subjects had greater risk for these excursions on WE compared to WD. This suggests that along with optimizing glucose control, people with T1DM need to be cognizant as to how weekend activities place them at greater risk for hyperglycemic excursions.

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Artificial Pancreas

ATTD8-0290

IDENTIFICATION OF A CONTROL-RELEVANT GLUCOSE MODEL OF TYPE 1 DIABETIC (T1DM) PATIENTS WITH PHYSIOLOGICAL MEANING FOR CLOSED-LOOP STRATEGIES IN ARTIFICIAL PANCREAS

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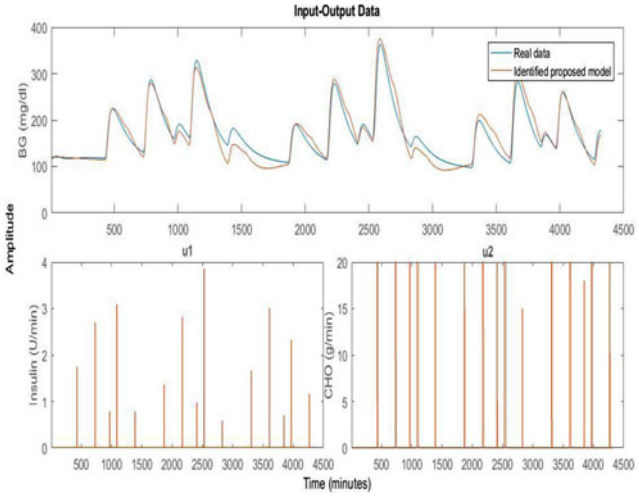
Background and Aims: Minimal models are usually used in the design of control strategies in the so-called device 'artificial pancreas' (AP). Simple black-box minimal models have been obtained from experimental data, but they have limited representation of a T1DM physiology. Also, some gray-box models based on physiological knowledge and real data have been proposed but with equilibria characterizations far from being realistic. Recently, a new model with realistic equilibria was developed in [1], which also permits an explicit computation of the tools of the functional insulin therapy (FIT) - IOB, DIA, and



others. A further improvement of that is done here, which shows better characteristic from both, real patient physiological description and control relevance point of view.

Method: An identification study with three control-relevant models was performed: the two ones presented in [1, 2], respectively, and the one proposed here. The data used was the standard one for T1DM patients: CGM measurements, basal and bolus insulin, and count of carbohydrates, collected for 3 days, from 60 real patients and 33 virtual patients from the UVA/Padova Simulator. The Gauss-Newton identification method was used.

Results: The new model shows significant increments of model-FIT. The model-FIT mean was 50% for real patients and 70% for virtual patients.

Conclusion: The proposed model here allows to describe better the interaction blood glucose, insulin, and absorption of meals than the models already reported in the literature. Advantages of this model are the realistic equilibriums and the computation of the FIT tools.

[1] N. Magdaleine, IEEE TBME, 2015.
[2] Y. Ruan, IEEE TBME, 2017.

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Artificial Pancreas

ATTD8-0167

HYPOGLYCAEMIA OCCURENCE AND RECOVERY DURING HOME USE OF CLOSED-LOOP INSULIN DELIVERY AND SENSOR-AUGMENTED PUMP THERAPY IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Hypoglycaemia limits tight glucose control even during closed-loop (CL) insulin delivery. We assessed glucose excursion and insulin delivery around hypoglycaemia to increase understanding of hypoglycaemia occurrence and recovery during CL.

Method: We retrospectively analysed CGM and insulin delivery from 60 adults with type 1 diabetes who were randomly assigned to receive 4-week day-and-night CL followed by sensor-augmented pump therapy (SAP), or vice versa. We identified hypoglycaemic episodes (CGM <3.0 mmol/l for at least 10 min without any insulin bolus given 60 min prior to hypoglycaemia) and evaluated CGM excursions and basal insulin infusion rates from −60min to 120min relative to hypoglycaemia.

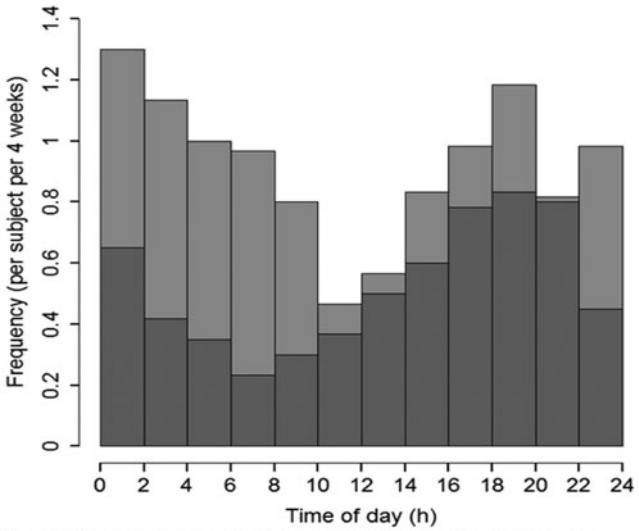

Figure 1. Histogram of the frequency of hypoglycaemia events during closed-loop insulin delivery (dark grey bars) and sensor-augmented insulin pump therapy (light grey bars).

Results: We detected 377 hypoglycaemic episodes during CL versus 662 during SAP. Figure 1 shows reduced hypoglycaemia events during the CL period compared to the SAP period with a predominant reduction overnight. Figure 2 presents CGM values prior and post-hypoglycaemia. The CGM slope prior to hypoglycaemia was steeper ($P < 0.01$) during CL than during SAP, and insulin delivery was reduced ($P < 0.01$). During the daytime, the participants recovered from hypoglycaemia faster when treated by CL compared to SAP. At 120 min post-hypoglycaemia, CGM values were higher during CL compared to SAP ($P < 0.05$).

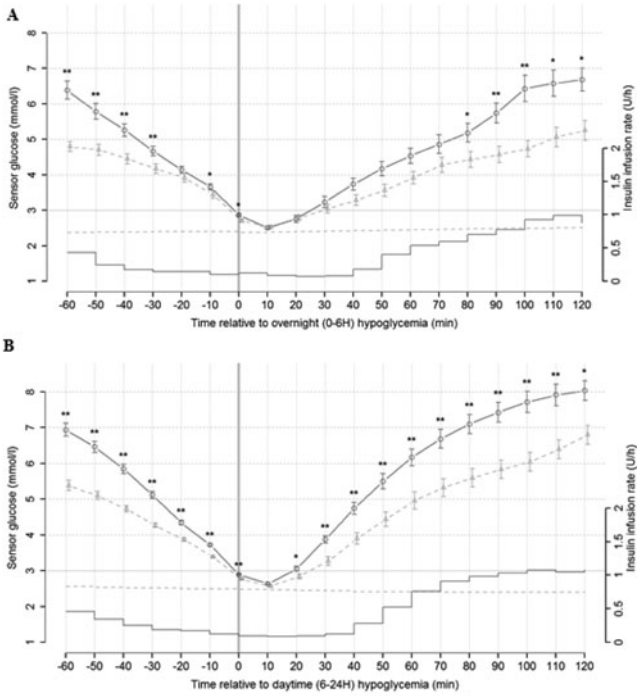

Figure 2. Sensor glucose values (mean ± SEM, N=60, *P < 0.05, **P < 0.01) from -60 min to 120 min relative to the start time of hypoglycaemia (vertical bar) with hypoglycaemic episodes obtained during closed-loop insulin delivery (solid lines with error bars) and during sensor-augmented pump therapy (dashed lines with error bars). Solid lines without error bars represent mean basal insulin infusion rates during closed-loop insulin delivery and dashed lines without error bars are insulin infusion during sensor-augmented pump therapy. Panel A shows glycaemic and insulin infusion data during the overnight period (0-6h00) and panel B shows the daytime period (6h00-24h00).

Conclusion: Closed-loop reduces the risk of hypoglycaemia when CGM is not decreasing rapidly particularly overnight with a swift recovery from hypoglycaemia during the daytime, but leads to higher 2-hour post-hypoglycaemia glucose levels.

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Artificial Pancreas

ATTD8-0251

WITHDRAWAL OF REMOTE REAL-TIME TELEMETRIC MONITORING INCREASES HYPOGLYCEMIA DURING USUAL CARE BUT NOT DURING AUTOMATED GLUCOSE MANAGEMENT WITH AN INSULIN-ONLY OR BIHORMONAL BIONIC PANCREAS

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Background and Aims: In previous adult outpatient studies of the bionic pancreas (BP), remote telemetric monitoring for hypoglycemia (monitoring) was performed in all arms, including the usual care (UC) arms. When continuous glucose monitoring glucose (CGMG) remained <50 mg/dl for ≥15 minutes study staff would contact the participant. This study aimed to evaluate the safety of eliminating monitoring from the BP and UC arms.

Method: We compared the BP with the lowest glucose targets that we have tested (bihormonal at 100 mg/dl [BH100] and insulin-only at 110 mg/dl [IO110]) with UC (insulin pump therapy or sensor-augmented pump therapy), each with and without monitoring for 7 days, in a random-order, six-week, crossover study, in 23 adult subjects with T1DM. The primary outcome was percentage of time spent hypoglycemic (CGMG <60 mg/dl).

Results: There was more hypoglycemia without monitoring vs. with monitoring in the two UC arms (1.95 vs. 1.32%, p = 0.02). However, there was no difference in hypoglycemia without monitoring vs. with monitoring in the two BH100 (0.99 vs. 1.05%, p = 0.82) and two IO110 (1.66 vs. 1.55%, p = 0.74) arms. Without monitoring, hypoglycemia was reduced in BH100 vs. UC (0.99 vs. 1.95%, p = 0.02) and was comparable in IO110 vs. UC (1.66 vs. 1.95%, p = 0.47). The mean CGMG was significantly lower in all BP vs. UC arms. There were no mean CGMG differences between the two BH100, two IO110, and two UC arms.

Conclusion: We conclude that monitoring had no effect on hypoglycemia with the BP and can be safely omitted from future BP studies. Funding: The Helmsley Charitable Trust.

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Artificial Pancreas

ATTD8-0277

CAN AN AUTOMATED CLOSED LOOP SYSTEM IMPROVE OUTCOME IN ADOLESCENTS WITH POORLY CONTROLLED TYPE 1 DIABETES? THE SPIDIMAN 02 STUDY

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Background and Aims: Good metabolic control during adolescent years has a permanent impact on the prevalence of micro-and macroangiopathy in young adults.

Aims to evaluate efficacy, safety and acceptability of the automated closed-loop glucose control (CL) 24/7 over 28 days in comparison with continuous subcutaneous insulin infusion in home setting in poorly controlled type 1 diabetes adolescents.

Design: open-label, single-centre, randomised, cross over study

Method: Subjects with type 1 diabetes (12–18 years, duration >6 months, on insulin pump ≥6 months, HbA1c ≥ 8, 0% ≥ 3 months) are randomized to CL treatment (CLFD2A : Florence D2A) with Model Predictive Control (MPC) algorithm or to their usual treatment with insulin pump and continuous glucose measurement (CGM). After 4 weeks they will switch to the other treatment. Before and during the last treatment week, subjects wear a sleep monitor (Actigraph) to record sleep data.

Primary endpoint: Percentage of time spent in target (3.9–10 mmol/l)

Additional endpoints: Comparison of 7 days sleep data (quantity and quality) as well as quality of life perception of the subjects and one of their caregivers To what extend this impacts on family responsibility is evaluated by questionnaire.

Results: Recruitment started in July 2017. Twelve patients will be randomized with completion in March 2018.

Conclusion: This study will evaluate whether automated closed loop treatment can improve control and quality of sleep. as well as the acceptance of parents to allow adolescents to take his/her responsibility in diabetes management.

Funding: EU Framework 7 Programme, grant 305343

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Artificial Pancreas

ATTD8-0168

BIOCHAPERONE TECHNOLOGY ENABLES RHGLUCAGON AQUEOUS FORMULATION FOR USE IN RESCUE AND DUAL HORMONES ARTIFICIAL PANCREAS (DHAP)

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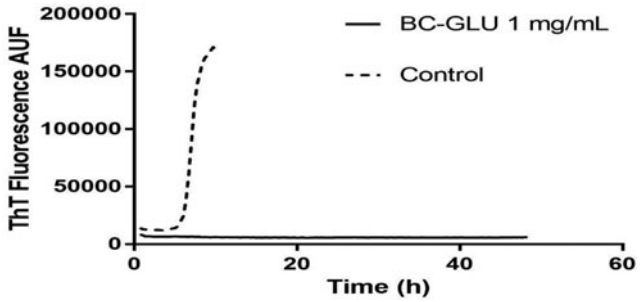
Background and Aims: Human glucagon is an emergency drug used to rescue people with diabetes from severe hypoglycemia. DHAP is designed to better mimic normal physiology by automatically infusing both insulin and glucagon as required. However, due to the poor solubility and stability of glucagon in solution, no commercial ready-to-use liquid formulation is available for rescue and for pump use in DHAP.



Method: BioChaperone® mixed with glucagon (BC-GLU) was evaluated for physical stability in a range of techniques: Thioflavine T (ThT) fibrillation assay, flow imaging microscopy (MFI) and light scattering, while chemical stability was followed by RP-HPLC.

Results: BioChaperone® and glucagon form a highly anionic reversible molecular complex enabling a ready-to-use, aqueous formulation of glucagon at 1 or 2 mg/mL at physiological pH. The BC-GLU formulation is a clear solution, essentially free of aggregates for at least 6 weeks at 37°C and in long term storage conditions, as assessed by visual inspection, MFI, and light scattering. In-use stability in pumps was confirmed by the same methods for at least 2 weeks at 37°C.

By ThT, no glucagon fibril formation in BC-GLU formulations was detected (figure).

By RP-HPLC, the level of degradation products was 4% after 2 weeks at 37°C and 4% after 12 months at 4°C. To address prolonged pump use, the addition of m-cresol as preservative to BC-GLU formulation was found not to impact its stability and to comply with EP and USP effectiveness criteria.

Conclusion: In conclusion, BC-GLU aqueous formulation has a physical and chemical stability profile suitable for both rescue and DHAP applications.

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Artificial Pancreas

ATTD8-0106

A NOVEL ADAPTIVE ARTIFICIAL PANCREAS USING REINFORCEMENT LEARNING AND ITERATIVE LEARNING CONTROL: AN IN SILICO VALIDATION

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Background and Aims: An Artificial Pancreas (AP) is a wearable, automated insulin infusion system, capable of providing blood glucose control in people with diabetes. Complex environmental and individualized factors, such as variability on meal times, meal portion sizes, physical exercise and hormonal changes make the goal of glucose regulation for current APs severely challenging.

Method: This work proposes a novel adaptive closed loop system for the effective blood glucose control on all main types of diabetes (i.e. Type 1, Type 2) and Prediabetes, under realistic inter and intra-day variability. The proposed adaptive controller is designed as an Indirect Learning Type Controller and involves a closed-loop controller (i.e. Bio-inspired Artificial Pancreas), a predictive insulin infusion module and a novel online adaptation module based on a combination of Reinforcement Learning and Iterative Learning Control.

TABLE 1. POPULATION RESULTS OF ALL THE COMPARED METHODS
(NA: Non-Adaptive, R2R: Toffanin's R2R Control Approach, A: Proposed Adaptive Controller)

	BG mean (mg/dl)	% in Target Range	% in Hypo Range	% in Hyper Range	LBGI
Type 1 Adults	NA: 146±21 R2R: 140±10 A: 136±4	NA: 69.8±8 R2R: 78.4±5 A: 88.6±3.3	NA: 5.1±9.1 R2R: 2.6±4.5 A: 0.2±0.4	NA: 25.1±9.9 R2R: 19.1±5.6 A: 11.2±3	NA: 1.18±2.01 R2R: 0.76±1.3 A: 0.13±0.16
Type 1 Children	NA: 154±25 R2R: 140±9 A: 145±6	NA: 62.9±12 R2R: 67.2±8.7 A: 78±4.9	NA: 6.7±15.2 R2R: 7.3±6.3 A: 0.6±0.4	NA: 30.3±7.2 R2R: 25.5±5.8 A: 21.4±5	NA: 0.54±0.43 R2R: 1.53±0.9 A: 0.26±0.17
Type 1 Adolescents	NA: 155±18 R2R: 150±5 A: 141±9	NA: 65.3±10.1 R2R: 67.9±7 A: 77.1±12.2	NA: 3.9±5.2 R2R: 2±2.6 A: 1.6±3.1	NA: 30.7±11.1 R2R: 30±4.6 A: 21.3±9.6	NA: 0.65±0.83 R2R: 0.6±0.51 A: 0.53±0.71
Type 2 Adults	NA: 140±30 R2R: 138±28 A: 129±9	NA: 75.4±17.9 R2R: 76.2±17.1 A: 86.5±8.3	NA: 2.6±5.1 R2R: 2.4±4.8 A: 0.7±0.7	NA: 22±19 R2R: 21.4±18.2 A: 12.8±8	NA: 0.65±0.83 R2R: 0.63±0.79 A: 0.56±0.26
Prediabetic Adults	NA: 86±22 R2R: 90±20 A: 115±20	NA: 78±14.2 R2R: 82.5±12.9 A: 100±0.1	NA: 21.1±15.3 R2R: 16.6±13.7 A: 0±0	NA: 0.9±2.7 R2R: 0.9±2.7 A: 0±0.1	NA: 3.28±1.51 R2R: 3.13±1.46 A: 0.21±0.27
p-values (A vs NA)	< 0.005				
p-values (A vs R2R)	< 0.005				

Results: We conduct two-month *in silico* studies on the latest version of the FDA-accepted DMMS.R simulator (Epsilon Group), involving Type Diabetic 1 Adults, Children and Adolescents (n = 11 for each group), Type 2 Diabetic Adults (n = 10) and Prediabetic Adults (n = 10), under real-life variability scenarios. We compare the performance of our adaptive controller against a non-adaptive controller and a state-of-art approach from the literature (Toffanin et al., 2017). Table 1 shows the mean population results of the blood glucose value, percentages of time spent in target, hypoglycemic and hyperglycemic ranges and the low blood glucose index (LBGI).

Conclusion: The proposed adaptive controller outperforms the compared methods and has the potential to improve glycemic control in a Type 1 diabetes, Type 2 diabetes and prediabetes populations.

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Artificial Pancreas

ATTD8-0175

CLOSED-LOOP FROM ONSET IN CHILDHOOD TYPE-1 DIABETES (CLOUD): A RANDOMISED CONTROLLED TRIAL TO ASSESS THE EFFECT OF CLOSED-LOOP INSULIN DELIVERY ON RESIDUAL BETA-CELL FUNCTION

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Background and Aims: Retention of beta-cell function in type 1 diabetes (T1D) is associated with reductions in short and long-term complications. The impact of continued intensive metabolic control on beta-cell function using closed-loop insulin delivery following diagnosis is unknown. The CLOuD study aims to assess the effectiveness of hybrid closed-loop initiated at T1D diagnosis on the preservation of beta-cell function compared to standard MDI therapy.

Method: CLOuD adopts an open-label, multi-centre, randomised, single-period, two-arm parallel group study design, and aims to recruit 96 randomised participants over 2 years. Eligible patients (youths with type 1 aged 10 to 16 years) are approached at 5 UK sites within 2 weeks of diagnosis. In closed-loop participants, the FlorenceM hybrid closed-loop system is initiated within 6 weeks of diagnoses and applied over a 2-year period. The primary outcome is meal stimulated C-peptide AUC during mixed-meal-tolerance-test at 12 months post diagnosis. Secondary outcomes include residual beta-cell function at 6 and 24 months, glycaemic control and insulin requirements. Participants' and their families' cognitive, emotional, behavioural characteristics and response to trial participation will be evaluated; a cost-utility analysis will be performed.

Results: Recruitment started in January 2017. Between January and September 2017, 21 participants were recruited, of whom 10 were randomised to closed-loop intervention. Over this period, there were no dropouts, and none of the subjects starting closed-loop had discontinued treatment.

Conclusion: Preliminary findings suggest that starting closed-loop shortly after diagnosis of T1D is feasible. CLOuD study will generate evidence about safety, efficacy, utility, user-acceptance and cost-effectiveness of closed-loop in new onset diabetes.

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Artificial Pancreas

ATTD8-0358

A NOVEL PARSIMONIOUS MODEL OF THE GLUCOSE/INSULIN SYSTEM DURING A MIXED MEAL IN PATIENTS WITH TYPE 1 DIABETES ON SENSOR AUGMENTED INSULIN PUMP THERAPY.

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Background and Aims: We published a novel parsimonious minimal model (GLUKINSLOOP2.0) of the plasma glucose/insulin (PG/I) system in type 1 diabetes (T1DM) patients on I pump therapy during a mixed meal (MMT). G(CGM), estimated by continuous monitoring in the interstitial fluid, not PG, is the available information in T1DM patients on sensor augmented pump (SAP) therapy and the input for wearable artificial pancreas. We test, in T1DM patients on SAP, during a MMT, whether GLUKINSLOOP 2.0 can reconstruct CGM dynamics and provides similar numerical values of the parameters governing the PG/I and the CGM/I systems.

Method: GLUKINSLOOP2.0 was used to describe the dynamics of either plasma G or CGM and of plasma I during a MMT (polenta+parmesan cheese: 292 Kcal) in 10 (7M/3F) C-peptide negative T1DM patients on SAP (age = 39.9 ± 3.9years; BMI = 23.3 ± 0.71kg/m^2; HbA1c = 7.8 ± 0.19%), who underwent a standard euglycemic I clamp on a separate day for modeling purposes.

Results: The time courses of PG and of CGM during the MMT were similar (p = 0.05). GLUKINSLOOP2.0 provided a similar performance, as assessed by weighted residuals and by the Akaike's criterion, in describing either PG or CGM dynamics. The numerical values of the parameters governing the PG/I and the CGM/I systems were similar: I sensitivity was 0.63 ± 0.19 vs 0.74 ± 0.12ml · min-1pmol · l-1(p = 0.76), G effectiveness was 8.88 ± 3.40 vs 6.97 ± 3.78 ml · min-1(p = 0.60), G mean transit time from meal ingestion to the appearance as PG or CGM signal was 113 ± 7.0 vs 146 ± 25.8 min (p = 0.24) in the PG/I and CGM/I system, respectively.

Conclusion: In T1DM patients on SAP, GLUKINSLOOP2.0 performs well in describing the CGM/I system and may be a useful tool to refine closed-loop control of subcutaneous I delivery systems.

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Artificial Pancreas

ATTD8-0180

OVERTREATMENT OF HYPOGLYCAEMIA IN ADULTS WITH TYPE 1 DIABETES DOES NOT APPEAR TO DETERIORATE GLYCAEMIC CONTROL DURING CLOSED-LOOP INSULIN DELIVERY

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Background and Aims: It is currently unclear whether overtreatment of hypoglycaemia worsens glycaemic control in type 1 diabetes during closed-loop (CL) insulin delivery.

Method: We retrospectively assessed overtreatment of hypoglycaemia using continuous glucose monitoring (CGM) data collected in 60 adults with type 1 diabetes who underwent 4-week day-and-night CL and 4-week of sensor-augmented insulin pump therapy (SAP) in random order under free-living home settings. We defined overtreatment if at least one CGM value was above 10 mmol/l within 60 min of the onset of hypoglycaemia (CGM <3.5 mmol/l for at least 10 min). For each participant, we calculated the frequency of hypoglycaemia, the frequency of overtreatment and the proportion of hypoglycaemic episodes with overtreatment. Correlation coefficients were used to assess the relationships between the frequency and the proportion of overtreatment of hypoglycaemia and participants' demographic characteristics and glycaemic outcomes.

Results: Mean(SD) frequency of hypoglycaemia was 3.2(2.0) episodes per participant-week during CL, and was lower than 5.0(4.2) episodes during SAP ($P < 0.01$). Overtreatment was infrequent and comparable between treatments ($P > 0.05$) (CL: frequency 0.04[0, 0.05] episodes per participant-week, proportion 2.0[0, 2.1]% of all episodes; SAP: frequency 0.03[0, 0.05], proportion 1.0[0, 1.3]%; median [IQR]). No relationship was found between participants' baseline HbA1c levels and the frequency and proportion of overtreatment of hypoglycaemia ($P > 0.05$).

Conclusion: The frequency and the proportion of overtreatment of hypoglycaemia are low during closed-loop insulin delivery and sensor-augmented pump therapy. Overtreatment of hypoglycaemia does not seem to be associated with deteriorated glycaemic control in adults with type 1 diabetes.

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Artificial Pancreas

ATTD8-0374

THE IMPACT OF SHORT-TERM ARTIFICIAL PANCREAS USE ON DAILY PHYSICAL ACTIVITY LEVELS IN INDIVIDUALS WITH TYPE 1 DIABETES: PILOT STUDY RESULTS:

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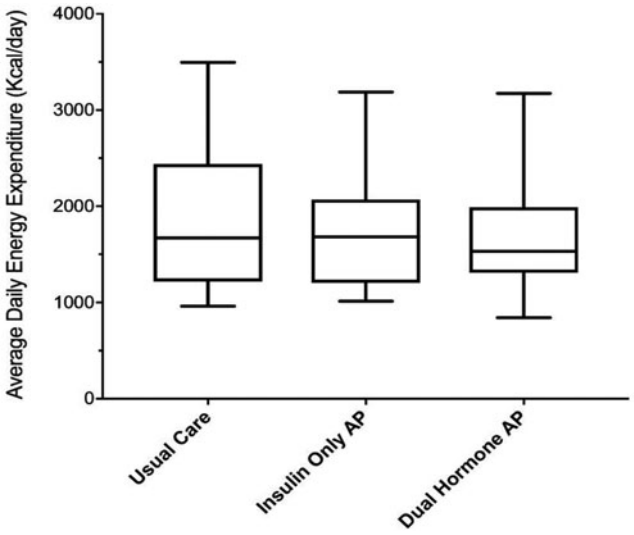
Background and Aims: Artificial pancreas (AP) systems improve glucose control while reducing the daily burden of living with type 1 diabetes (T1D). People with T1D often avoid physical activity due to a fear of hypoglycemia and thus daily energy expenditure (EE) is often suboptimal. While emerging AP systems may improve glucose control, it is unclear whether daily EE is impacted.

This pilot study aims to determine the feasibility in measuring EE in adults with T1D during an AP study.

Method: Twenty-three participants (17 females) with T1D (age 38 ± 14 yrs, mean±SD) participated in each of the following treatment arms for 2-weeks during a 6-week random-order crossover study: usual care, insulin-only AP, and dual-hormone (insulin and glucagon) AP while wearing an activity monitor (ActiGraph) on their wrist. Patients were instructed to exercise freely. Data were analyzed using a two-factor ANOVA on subjects with complete datasets for daily EE as measured by ActiGraph (n = 15).



Results: Participants were reasonably active throughout the study period, expending 1,794 ± 677 kcals/day. There was no main effect on daily EE between any of the conditions over the duration of this short-term study ($p = 0.46$). Factors that contributed to the incomplete datasets (n = 8) included battery/equipment failure, water damage, and/or possible user non-compliance.

Conclusion: Wrist-worn accelerometers also have a tendency to over-report step count (data not shown) and therefore, the location of wear may need to be modified in future studies (i.e. worn at the hip). Future studies will need to implement longer interventions with aims to improve overall compliance and feasibility.

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Artificial Pancreas

ATTD8-0131

CONCURRENT MONITORING OF STATIC AND TEMPORAL INFORMATION WITH SLOW FEATURE ANYLYSIS FOR GLUCOSE SENSOR FAILURE DETECTION

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Background and Aims: One of the critical problems for continuous glucose monitoring is safe operation which however may not be guaranteed because of sensor failures. The purpose here is to propose a feasible sensor failure detection method which can identify the inaccuracy of sensor observation in time to avoid false therapy.

Method: A novel sensor failure detection strategy is designed based on slow feature analysis (SFA) considering both static and temporal information. The models are developed using glucose samples of 35 mins. Four monitoring statistics are designed including fast and slow as well as static and dynamic aspects. It can

concurrently monitor glucose status deviations and process dynamics anomalies which is different from the classical statistics.

Results: The novel strategy was initially evaluated for thirty subjects generated using the UVa/Padova metabolic simulator with 5 min as sampling interval. One-day normal data was considered for model design and another four-day data for testing. Two major types of sensor failures are considered in this study: spike and transient loss of sensitivity. The monitoring strategy accurately detected the two glucose measurement disturbances with a 90% success rate and less than 10% false positives. Besides, the proposed method also worked well on two groups of de-identified ambulatory clinical data retrieved from the Diabetes Research in Children Network (DirecNet) website, reporting 80% sensitivity and 15% false alarms.

Conclusion: Therefore, the concurrent use of static and temporal information can remove unnecessary alarms and convey useful information for sensor failure detection, which provides a feasible solution for further development of artificial pancreas.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0246

IGT AND T2D SUBJECTS AUTOMATICALLY CLASSIFIED USING A SELECTION OF CGM-BASED GLYCEMIC VARIABILITY INDICES

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Background and Aims: Glycemic Variability (GV) indices are compact metrics useful for characterizing the dynamic properties of CGM-acquired glucose concentration profiles. However, there is still no consensus on how to use the plethora of indices proposed in the literature due, partly, to the high degree of correlation between them. With the aim of investigating whether a suitable subset of literature CGM-based GV indices can be used for classification of subjects, we consider the problem of automatically identifying subjects affected by IGT and T2D on the basis of their often similar CGM profiles and some basic clinical information by means of a machine learning approach.

Method: The dataset includes 62 subjects, 37 affected by IGT and 25 affected by T2D. Subjects were monitored with the iPro CGM system (Medtronic MiniMed, Inc., Northridge, CA) for six days (Botnia study, Finland, EU FP7 Mosaic project). A linear Support Vector Machine model is used to classify subjects affected by IGT and T2D using a minimal subset of 17 GV indices and four basic parameters (sex, age, BMI, waist circumference) selected by an expert diabetologist on the basis of their interpretability and significance in clinical practice.

Results: An easily interpretable machine learning technique and a clinically-sound set of indices allow to distinguish subjects affected by IGT/T2D with 82.3% accuracy. Expert-knowledge-driven feature selection increases classification performance by $\sim$30%.

Conclusion: CGM-based GV indices and basic parameters can be used to quite accurately distinguish the subtle differences between IGT and T2D glucose recordings, by relying only on metrics trusted by an expert clinician.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0150

GLYCEMIC RESULTS PREDICTABILITY IN TYPE 2 DIABETIC PATIENTS SWITCHING FROM FAILING INSULIN MULTI-INJECTIONS PATTERN TO INSULIN PUMP

F. Travert[1], S. Clavel[2], D. Huet[3], E. Ghanassia[4], O. Dupuy[3], K. Krompa[5], J.P. Le Berre[6], N. Vigier-Simmore[7], J.P. Courrèges[7], N. Bastide[8]

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Background and Aims: Despite insulin multi-injections pattern optimization, failure in glycemic control may lead to consider insulin pump treatment in type 2 diabetic (T2D) patients. Is it possible to predict the evolution of glycemic control, weight and insulin needs when starting an insulin pump treatment?

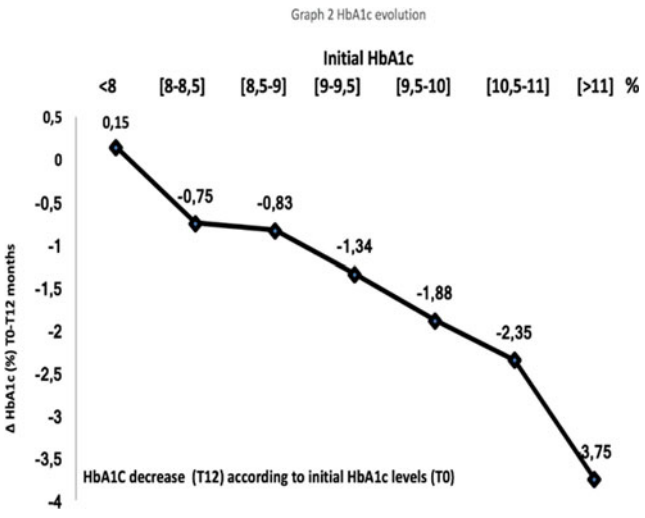
Method: 92 T2D patients, failing to achieve glycemic control in spite of a multi-injections optimization, started an ambulatory insulin pump treatment and are evaluated one year later (T12). The evolution (ΔT0-T12) of HbA1c, weight and insulin needs (U/kg/d) were analyzed according to initial values to detect a potential predictibility.

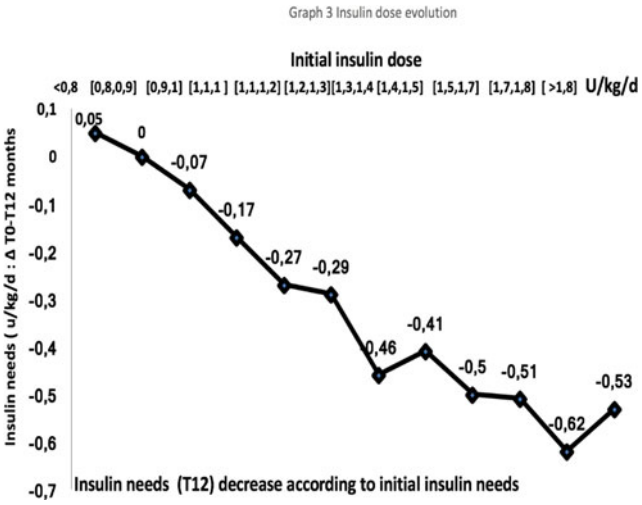
Results: HbA1c

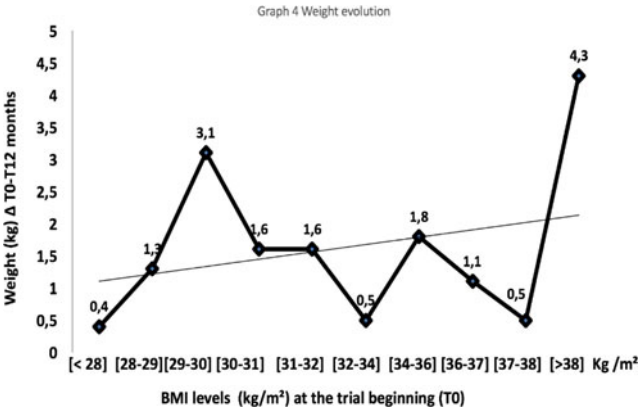
In the total population HbA1c dropped by -1.55 ± 1.53%. HbA1c values were divided into 7 homogenic groups to illustrate potential correlation between initial value and evolution (Graph 2). The analysis set a linear correlation between initial value and evolution according to the equation: HbA1c ΔT0-T12 = –0,806*HbA1c(T0).

Insulin dose

Same analysis was run for insulin needs according to initial value (Graph3). It revealed a linear correlation between T0-T12 evolution and initial value according to the equation : Insulin dose ΔT0-T12 = –0,524*insulin dose T0.







Weight

Weight gain (kg) was analyzed according to BMI before insulin pump, divided in 8 groups, every 2kg/m^2 (Graph4). The T0-T12 evolution analysis showed heterogenic values, not very different except for BMI >38kg/m^2 (solid weight gain: +4.3kg).

Conclusion: The majority of enrolled patients followed a similar HbA1c and insulin needs evolution: the higher the initial value, the lower it was after 1 year through a linear correlation. On the contrary, weight evolution was variable and heterogenic, more visible for initial BMI >38kg/m^2.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0069

HEALTH STATUS AND GLYCAEMIC CONTROL IN GERIATRIC PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: Up to 25% of people older than 70 years suffer from type-2-diabetes. Diabetes guidelines emphasize the need to individualize glycaemic goals and to simplify treatment strategies with the main focus on avoiding hypoglycaemia in geriatric patients. The aim of this study was to assess glycaemic control in patients with type-2-diabetes in geriatric care facilities based on the individual health status.

Method: 170 medical records of geriatric patients with type-2-diabetes in 4 geriatric care facilities (64.7% female, age 80 ± 9 years, HbA1c 51 ± 16 mmol/mol, BMI 27.9 ± 5.8 kg/m2) were retrospectively assessed. Based on the individual health status, patients were allocated to three groups (healthy n = 27, complex n = 86, poor n = 57).

Results: The overall blood glucose (BG) value was highest in the poor health group with 10.4 ± 2.6 mmol/l (poor) vs. 9.3 ± 2.3 mmol/l (complex) vs. 8.3 ± 1.9 mmol/l (healthy). 1.6% (poor) vs. 2.8% (complex) vs. 1.4% (healthy) of all BG values were below 90 mg/dl. 37.2% (poor) vs. 23.4% (complex) vs. 18.5% (healthy) received insulin as the main diabetes therapy, but only 14.3% (poor) vs. 30% (complex) vs. 40% (healthy) were treated with basal insulin.

Conclusion: Overall BG values were higher in the poor and complex group. There were few low BG values in all groups. Although recommended by international guidelines basal insulin therapy with its low complexity and low hypoglycaemic risk is still underused, especially in the poor-health group. Therefore the individualization of diabetes therapy is an issue, which could be solved in part by implementing electronical decision-support-systems considering geriatric needs.

Supported by: Research Studio Austria ''GlucoTab'' (FFG, project 844737).

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0151

WEIGHT INFLUENCE OF FUTURE EFFICACY OF AN INSULIN PUMP TREATMENT IN TYPE 2 DIABETIC PATIENTS IN METABOLIC FAILURE WITH OPTIMIZED INSULIN MULTI-INJECTIONS PATTERN

D. Huet[1], S. Clavel[2], F. Travert[3], E. Ghanassia[4], O. Dupuy[1], K. Krompa[3], J.F. Thuan[5], J.M. Andrieu[6], J.P. Courrèges[5], N. Bastide[7]

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Background and Aims: Can weight influence metabolic results with an insulin pump in type 2 diabetic (T2D) patients with multi-injections metabolic failure?

Method: 92 T2D patients with multi-injections pattern (3.4/injections/d – 1.23U/kg/j) didn't achieve glycemic control (HbA1c≥ 8% - average : 9.5%) and start ambulatory insulin pump (AIP) treatment for a probing period of 12 months. Among them, we extracted 2 groups (Group1: BMI ≤30kg/m^2;N = 21; average: 28.5kg/m^2 – Group2: BMI ≥35 kg/m^2;N = 29; average 37.8kg/m^2).

Results: The global improvement of HbA1c (Δ T0/T12) was −1.55 ± 1.52 % (p < 0.001) and 56,5% of the patients with HbA1C ≤8%. HbA1c dropped respectively by −1.6 ± 1.62% and −1.57 ± 2.75 in groups 1 et 2 (NS). The proportion of patients with HbA1c≤8% evolved (T0-T12): 19%/67% (Group1); 3%/52% (Group2) – p = 0,008. No severe hypoglycemia was reported in both groups.

Global weight gain was +1,5kg, not significantly different in both groups: +1.5kg vs +1.7kg. Whereas specific T0-T12 evolution (Group1/Group2): weight loss:28.6/21.4% and weight gain >3%: 38.1 vs 43 % was not significant.

Global reduction in insulin needs with AIP was 20%. Its evolution (T0/T12/ΔT0-T12/%) was : Group1: 1.26/0.99 U/kg/j/-0.27U/kg/j/-20.5% - p = 0.0008 and Group2: 1.31/ 0.97U/kg/j/ −0.33U/kg/j/ −21.2% ; p = 0.0005), not significantly different between both groups.

Conclusion: For both overweighted or severely obese T2D patients, AIP treatment didn't lead to significantly different metabolic results in terms of glycemic control, weight evolution or insulin needs. AIP treatment maintain its benefits even in case of severe obesity.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0360

I RESIST' : WEIGHT EVOLUTION WITH AMBULATORY INSULIN PUMP (AIP) IN TYPE 2 DIABETIC (T2D) PATIENTS SHOWING MULTI-INJECTIONS OPTIMIZATION FAILURE.

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Background and Aims: Glycemic optimization usually leads to increase in weight in T2D patients with insulin. We evaluated weight evolution with AIP in T2D patients showing high doses multi-injections optimization failure.

Method: We run a multicentric observational trial on 92 T2D patients (diagnosed for 16 ± 8 yrs, average age 60 ± 9.6 yrs, sex ratio M/F : 1.56, average BMI: 33.6 ± 4.0kg/m^2) with multi-injections (n = 3.6 ± 1.1) failure (average HbA1c : 9.52 ± 1.47%), who benefited from an AIP.

Results: After 1 year under AIP, weight increase was mild (+1.3 ± 5.3kg) while HbA1c dropped (1.55/–16.3%), and insulin needs decreased (–0.25U/kg/d/-20%). Weight evolution was very heterogenic ([−17.8;+15kg]): 21 (27.3%) lost weight ([−15.5 ; −1.0%]), 9 (11.7%) stayed stable, 46 (59.7%) put on weight (30 ≥ 3% et 18 ≥ 5%).

We compared stable and/or weight decreasing patients (N = 30) with ≥3% weight increase patients (N = 30) at T_0 on HbA1c, weight, BMI, initial insulin dose. None of the criteria were significantly different: HbA1c : 9.61 ± 1.47-9.75 ± 1.72% ; weight: 93.7 ± 14.4-93.9 ± 16.2kg ; BMI : 32.8 ± 3.6-33.4 ± 4.3 kg/m^2; insulin dose: 1.19 ± 0.31-1.26 ± 0.46 U/kg/d.

Weight evolution was evaluated in 3 groups according to BMI (kg/m^2) at T_0 [overweight (≤30), obesity (>30 ≤ 35), severe obesity (>35)] : BMI (28.4 ± 1.2;32.1 ± 1.4;37.8 ± 1.8 kg/m^2)-p<0.0001. There was no difference between the 3 groups weight evolution: +1.7 ± 5.7;+0.8 ± 4.1;+1.6 ± 6.1 kg-NS.

Reduction in insulin doses with AIP (terciles : [−1.3;-0.4] ; [−0.3;-0.2] ; [−0.1;0.7]) has no influence on weight evolution: +0.7 ± 7.3;+1.1 ± 3.1;+2.5 ± 4.9-NS.

Conclusion: Weight increase with AIP, switching from multi-injections, appeared mild (+1.3kg) according to the drop in HbA1c and heterogenic weight evolution. There is no proved influence of initial weight or 1-year insulin dose reduction on total insulin dose.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0387

RANDOMISED CONTROL TRIAL OF 2 GROUPS OF DIABETES PATIENTS COMPARING GLUCOSE CONTROL AFTER CORONARY BYPASS BY GLUCOSE MONITORING ALONE OR ASSOCIATED WITH CONTINUOUS GLUCOSE MONITORING

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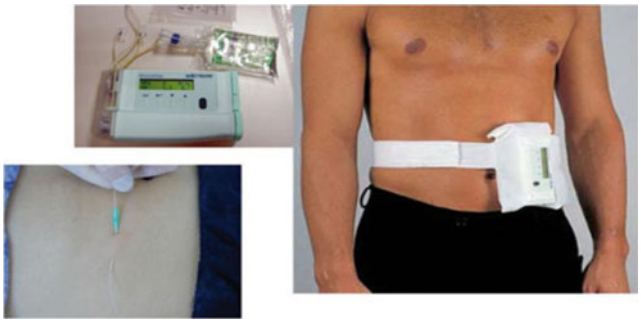
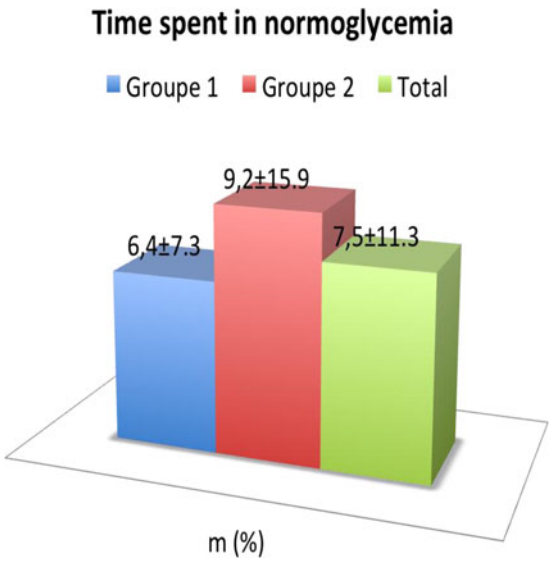
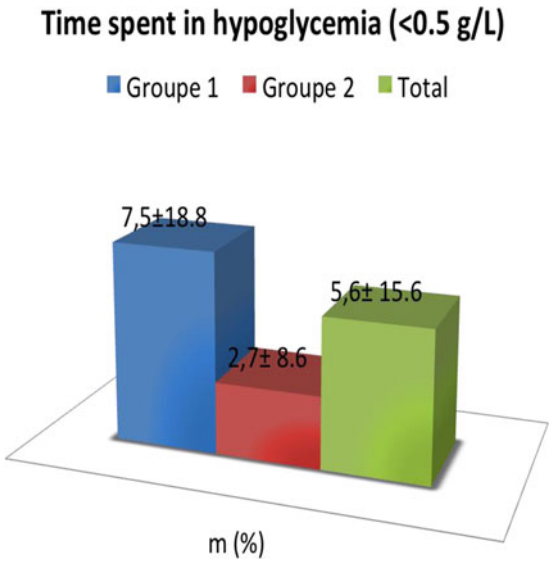
Background and Aims: In intensive care, stress is a hyperglycemic factor regardless of whether a patient is diabetic or not. Strict glucose control has resulted in decreased mortality. Seeing as capillary blood glucose measurement (CBGM) is imprecise and intermittent, we decided to compare the efficiency of glycemic control under CBGM alone or associated with real-time continuous glucose monitoring (RT-CGMS), in diabetic patients following coronary bypass surgery.

Method: Randomised control prospective trial of 2 groups of patients; group 1: CBGM alone and group 2: CBGM associated with RT-CGMS (Glucoday, Menarini), a sensor implanted in the interstitial fluid directly following surgery for a period of 48h. The main criterion was time spent in normoglycemia (0.8–1.1 g/L).

Results: 45 patients (24 in group 1, 21 in group 2) were included: 37 men and 8 women of 67.1 ± 9.3 years old; 8 of type 1 diabetes and 37 of type 2. HbA1C 7.14 ± 0.87% and upon entry glycemia 1.45 ± 0.47 g/L.(<0.5 g/L) was significantly bettered in group 2 (2.7 vs. 7.5%) as well as for time spent in normoglycemia (9.2 vs. 6.4%).







Conclusion: This study enabled us to see that RT-GMS allowed for an improvement of times spent in hypoglycemia and normoglycemia for patients in surgical intensive care. Larger randomised control trials along with insulin therapy adaptation algorithm are necessary to properly establish the efficiency of CGMS in intensive care.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0325

COULD THE SENSOR-AUGMENTED PUMP DETERMINE A BETTER BETA CELLS RESERVE IN TIME OR ARE THERE OTHER INTERFERING FACTORS?

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Background and Aims: There's no unanimous consent that the use of sensor augmented pump (SAP) right after the diagnosis of diabetes will lead to a better preservation of insulin reserve and metabolic control in later years. In our study we compared 3 group of 15 prepubertal children:

1) SAP within one month after the diagnosis of diabetes; 2) pump and self-monitoring glycemic control (SMBG) - at least 5 daily measures - 3) MDI with SMBG.

Method: We considered C-peptide, HbA1c and GAD antibodies levels at the onset and 18 months later. Then the kids with SMBG were provided with glucose monitoring flash system for two weeks. We compared C-peptide, insulin dose (U/Kg/day), percentage of blood sugar levels outside the desired range (90-130 mg/dl) and anti GAD levels.

Results: We found no significant differences between the three groups in terms of C-peptide levels, glycated and anti GAD, but a far better average percentage of therapeutic range BG levels in children with SAP. However, if we evaluate the data considering the C-peptide levels and anti GAD at the onset of diabetes, those with higher levels of C-peptide and lower levels of anti GAD maintain a more insulin reserve over time and make less insulin, tending to have lower percentage of BG out of range.

Conclusion: What we observed can inspire research with the implication of more patients.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0390

EFFICACY AND SAFETY OF BASAL BOLUS INSULIN REGIMEN IN A COHORT OF TYPE 2 DIABETES PATIENTS HOSPITALIZED IN GENERAL WARD ASSESSED BY CONTINUOUS GLUCOSE MONITORING

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Background and Aims: Basal – bolus insulin regimen (BBIR) is recommended for patients with T2D hospitalized in general ward. Hypoglycemia with this therapy is low, but it is the main barrier in its implementation.

Objective: to assess efficacy and safety of BBIR using Continuous Glucose Monitoring (CGM) and determine the risk factors associated with hypoglycemia.

Method: Observational prospective cohort study with T2D patients treated with BBIR in general ward following 2017 American Diabetes Association guidelines. Time in range, hypoglycemia (< 70 mg/dl, <54 mg/dl), SD (standard

deviation) and Coefficient of variation (CV%) were measured with CGM.

Results: 38 patients were included. Baseline A1C was 9.26 ± 2.62%, mean blood glucose at admission was 254 ± 11 mg/dl. Time in range increased from 72.1% to 89.4% at the end of the study. The event rate <70 mg/dl was 0.032 events/patient. Factors related with hypoglycemia (<70 mg/dl) were BMI (body mass index), mean glucose, SD and CV%. Per 1 unit of decrease in BMI and Per each 10 mg/dl of decrease of the mean glucose there was an increase in the incidence of hypoglycemia of 0.17 (p = 0.021) and 0.11 (p = 0.026) events, respectively. An increase of 10 units on the SD and CV%, increased the incidence of hypoglycemia on 0.45 (p = 0.012) and 0.74 (p = 0.015) events, respectively.

Conclusion: BBIR in hospitalized patients with T2D is effective with low incidence of hypoglycemia. Increase of SD and CV%, as well as decrease in mean glucose and BMI were associated with events <70 mg/dl.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0055

FREQUENCY OF METABOLIC SYNDROME IN TYPE 2 DIABETES MELLITUS IN MEDICAL DIABETIC CENTRE -MEDANI-GEZIRA STATE-SUDAN-FEBRUARY 2015-2016

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Background and Aims: Metabolic syndrome is a disorder of energy utilization and storage, diagnosed by a co-occurrence of three out of five of the following medical conditions: abdominal (central) obesity, elevated blood pressure, elevated fasting plasma glucose, high serum triglycerides, and low high-density cholesterol levels. This study was to review the prevalence of the metabolic syndrome in Sudanese type 2 diabetes mellitus.

Method: The study included 80 Sudanese patients; half of them with type 2 diabetes mellitus and the rest are non-diabetics. Cases and controls blood pressure, abdominal circumference and body mass index were reported. Venous blood samples were taken from all after at least 10 hours fasting for determination of serum level of cholesterol, triglycerides, high density lipoprotein and low density lipoprotein. Glucose level and HbA1c were also measured. Cases and controls were compared in all measures above looking for the differences. The metabolic syndrome was diagnosed according to criteria of national cholesterol education program

Results: in cases fasting blood glucose, waist circumference, serum triglyceride, high density lipoprotein, blood pressure, total cholesterol were found to be 87.5% (35 cases),130% (52 cases), 50 % (20 cases), 64.5% (28 cases), 62.5%(25 cases), 42.5% (17 cases)respectively. In control group, fasting blood glucose 100% (40 cases), waist circumference 70% (27 cases) , serum triglyceride, high density lipoprotein ,blood pressure, total cholesterol…….. were found to be 40% (16 cases), …. respectively.

Conclusion: The frequency of the metabolic syndrome was found significantly high, especially in women between 40 to 60 years.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0132

MODEL OF STRUCTURED GROUP EDUCATION IN DIABETES EDUCATIONAL CENTERS DEMONSTRATED SIGNIFICANT IMPROVEMENT IN DIABETES CONTROL

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Background and Aims: Integration of structured group education is part of diabetes care management. Aim was to assess effect of model Project of Structured Diabetes Group Education on diabetes control across diabetes educational centers.

Method: Schedule included 8 structured educational lessons realized with the passage of 14 days for a group of 6–12 Type 2 diabetics on insulin. Educational teams were instructed in uniform methodology. Patients performed structured selfmonitoring of blood glucose. Selected metabolic parameters were measured before as well as after the course and within the interval of 3 and 6 months.

Results: Project was implemented in 9 educational centers countrywide during 2016. Overall 62 subjects were included (63.3 ± 8.2yrs, 53% of men, BMI 32.9 ± 6.7kg/m^2). Regarding metabolic parameters, fasting plasma glucose decreased from 8.8 ± 2.8mmol/l initially to 7.9 ± 2.5(p = 0.008) after 3 months and 7.7 ± 2.1(p = 0.0002) after 6 months, respectivelly. HbA_{1c} decreased from 70.0 ± 16.2mmol/mol initially to 63.7 ± 12.6 (p = 0.0001) after 3 months and 63.1 ± 12.6(p = 0.0001) after 6 months. Frequency of subjects with HbA1c<60 mmol/mol improved significantly from 26% to 42%(p < 0.01) after 3 and 45%(p < 0.01) after 6 months. Reduction of body weight on average was 0.8kg(p = 0.004) after 3 months and 0.9kg (p = 0.005) after 6 months. Systolic blood pressure decreased from 140 ± 18 mmHg to 135 ± 14 mmHg(p = 0.047) after 6 months. No significant changes were observed in diastolic blood pressure and serum lipids. Homogeneity of outcomes of HbA_{1c} decrease and body weight among educational centers was statistically verified.

Conclusion: Project demonstrated true possibility of its introduction in diabetes educational centers and showed significant improvement of diabetes control. Its continuation is one of the tasks in National diabetes programme.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0429

EVOLUTION OF GLUCOSE MONITORING: CHOOSING THE RIGHT SYSTEM TO OPTIMIZE PATIENT EXPERIENCE

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Background and Aims: Continuous Glucose Monitoring (CGM) has evolved as a key component of diabetes care with improved accuracy and ease of use.

Integration of data management and cloud connectivity has further improved the analysis ability of clinicians. Despite this CGM remains under-utilized and many patients discontinue use within the first year. CGM improvement in glucose control correlates with adherence. Access and reimbursement for both Flash Glucose Monitoring devices (FGM) and CGM has increased. Understanding of the features, benefits and limitations of each system may assist in choosing the optimum device for each patient thus improving patient experience as well as adherence.

Method

Results: The four systems currently approved for use all measure interstitial glucose, differences in type of measurement duration, form, fit and function provide clear differentiation.

	Eversense	Dexcom G5	Medtronic Gardian	Abbott Libre
Type	CGM	CGM	CGM	FGM
Sensor Duration	180 days	7 days	6 days	14 days
Measurement	Non-enzymatic	Enzymatic	Enzymatic	Enzymatic
Sensor position	Subcutaneous	Transcutaneous	Transcutaneous	Transcutaneous
Alarms	Yes, on body and display	Yes, display	Yes, display	none
Predictive Alerts	Yes	No	Yes	No
Display	Smartphone, watch	Receiver, smartphone, watch	Integrated with pump	Reader device
Adhesive	Silicone	Acrylate	Acrylate	Acrylate

Conclusion: Proper selection of the FGM or CGM device is imperative. Patients requiring intensive management including those with hypoglycemic unawareness may benefit from CGM while FGM may be sufficient for others. Patients may migrate from one type of device to another depending upon their lifestyle and level of control desired. Future studies will help identify the best match to improve patient adherence.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0382

EFFECT OF DATA GAPS IN CONTINUOUS GLUCOSE MONITORING TRACINGS ON THE ACCURACY OF THE GLUCOSE VARIABILITY ANALYSIS

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P-values	1h data gaps	2h data gaps	4h data gaps	6h data gaps	8h data gaps
CV*	0.9295	0.7557	0.2289	0.0040	0.0000
SD*	0.9447	0.8405	0.3238	0.0310	0.0000
IQR**	0.8971	0.7825	0.2762	0.0311	0.0000
MAG**	0.7648	0.3511	0.0000	0.0000	0.0000
MAGE**	0.9537	0.9518	0.7191	0.3224	0.0254
Mean**	0.9914	0.9509	0.9028	0.8828	0.6467

Table. CV: coefficient of variation, SD: standard deviation, IQR: interquartile range, MAG: mean absolute glucose, MAGE: mean amplitude of glycemic excursions. * T-test used in metrics data that comes from a normal distribution. ** Mann-Whitney U-test used in nonparametric metrics data.

Background and Aims: Data gaps are commonly presented in continuous glucose monitoring (CGM) systems due to communication failures, inappropriate use of the device, or many others reasons. However, such data gaps may affect the analysis of glucose variability obtaining misleading results in the metrics calculation.

Method: In this work, a first analysis of consecutive data gaps and glucose variability was performed based on CGM data from diabetic patients, implementing a number of artificial gaps randomly in order to measure their effect on several glucose variability metrics (GVM). A two-sample t-test and a Mann-Whitney U-test were performed in order to compare the resulting variability metrics based on CGM data without vs with daily gaps of 1, 2, 4, 6 and 8 hours linearly interpolated.

Results: The metrics of CV, SD, MAGE, MAG, IQR, and Mean were assessed on 374 original CGM data days without gaps in total. Data from the first two metrics showed a normal distribution according to Kolmogorov-Smirnov test and F-test. The rest of the metrics were assessed as nonparametric variables. The following table shows the p-value obtained with the corresponding comparison statistical test for each data gaps duration. Results show that data gaps affect the reliability of variability metrics at different daily duration of data gaps.

Conclusion: The relationship between data gaps duration in CGM tracings and reliability of several GVM was assessed. Results suggest that several GVM suffer a lack of reliability when consecutive daily data gaps equal to or greater than 4 hours duration appear in CGM data.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0298

FAMILY REACTION TO CHILDREN WITH DIABETES MELLITUS

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Background and Aims: Diabetes, as one of the most common metabolic disorders, can have adverse effects on the child, the family and the community. How families behave in dealing with

diabetes can play an important role in controlling and treating diabetes. The purpose of this study is to identify different family responses to diabetes in the face of childhood.

Method: In this descriptive-analytical study, 103 children aged 7–15 years old with type 1 diabetes who were admitted to the Isfahan Diabetes Clinic were selected. A questionnaire describing the characteristics of the research units and the questionnaire of the child's family reaction questionnaire was used to collect the data. Data were analyzed by SPSS software version 20.

Results: The findings showed that 62.4% of families showed an acceptance response, 15.5% of the rejection response and 22.1% of the excessive support response. There was a significant relationship between family response and age, parental education and duration of diabetes. Also, inappropriate reactions lead to poorer blood glucose control.

Conclusion: According to the results of the research, and the relationship between family type and diabetes control, it is suggested that increasing the level of awareness of parents about the process of diabetes will show a good and desirable response to their child's illness, which will lead to improved care levels and control diabetes, especially in children.

Keyword: diabetes, children, family reaction

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0377

GLUCOSE VARIABILITY AND GLUCOSE STATUS INVESTIGATED IN RELATION WITH CARDIO-METABOLIC RISK FACTORS IN TYPE 2 DIABETES

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Background and Aims: Glucose variability is one of newest parameters of glucose control, is correlated with oxidative stress in type 2 diabetes and its influence is yet to be determined. This study investigated the relation between cardiometabolic risk factors(CMRF)and glucose parameters evaluated by continuous glucose monitoring(CGM)in persons with type 2 diabetes.

Method: 30 persons with T2D(8 women/22 men, insulin-treated-14/oral-treatment-16, mean diabetes duration-11.43years, mean age-56.59years) were assessed by CGM.CMRF:body weight, BMI, waist circumference, physical activity, smoking, alcohol consumption, lipid profile (total cholesterol (T-col), HDLc, tryglycerides (TG), LDLc), blood pressure (systolic–SBP, diastolic-DBP), personal and family history of CVD, family history of diabetes. Glucose parameters:glycated haemoglobin A1c(A1C), glucose variability (GV), mean amplitude of glucose excursions (MAGE), number of glucose values (time), area under the curve(AUC, glucose exposure), mean glucose values (glucose amplitude) on domains–hypoglycemic (<70mg/dl), intermediate (70–180mg/dl), hyperglycemic (>180 mg/dl), optimal(90–130mg/dl).

Results: Body weight was inversely correlated with GV and MAGE. Persons with SPB >130 mmHg had lower percent of hypoglycemic values and hypoglycemic exposure, higher total glucose exposure, higher diurnal and nocturnal glucose exposure and higher glucose amplitude(mean).TG values were directly correlated with diurnal glucose exposure and inversely related to nocturnal AUC.HDLc was directly correlated with the magnitude of intermediate glucose exposure(70-180 mg/dl). Persons with family history of diabetes had higher time spent and total glucose exposure to hypoglycemia. Persons with family history of CVD had lower A1C values. The other assessed data were not significant, even if the direct relation between worse metabolic control and hyperglycemic exposure was close to statistical significance.

Conclusion: SBP was lower in persons with higher hypoglycemic exposure and was directly correlated with total glucose status. TG and HDLc were also directly correlated with total glucose status. Awareness of familial cardiovascular risk factors was associated with better glucose control with a higher exposure to hypoglycemia.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0381

SHORT-TERM GLUCOSE VARIABILITY CHANGE IN TYPE 2 DIABETES ASSESSED BY CONTINUOUS GLUCOSE MONITORING

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Background and Aims: Glucose status is the main determinant factor for diabetes evolution on short-term and long-term periods. Glucose fluctuations are related to oxidative stress in a higher extent than sustained hyperglycemia in type 2 diabetes. This study evaluated prospectively the relation between glucose variability (GV-standard deviation of glucose values), mean amplitude of glucose excursions (MAGE) and glycated haemoglobin (A1c), anthropometric parameters, gender, diabetes treatment in persons with type 2 diabetes assessed by continuous glucose monitoring (CGM).

Method: 30 persons with type 2 diabetes (8 women/22 men, median age 64(39–69) years, mean diabetes duration 14(0–17)years, insulin therapy-14/, oral therapy-16)performed blinded CGM for 3 days. 10 of the insulin treated subjects performed a second CGM after 3 months. Assessed parameters: A1C, body weight, body mass index–BMI, waist circumference, glucose variability (GV - standard deviation of glucose values), mean amplitude of glucose excursions (MAGE), number of glucose values (time), area under the curve (AUC, glucose exposure), mean glucose values (glucose amplitude) on domains–hypoglycemic (<70mg/dl), intermediate (70–180mg/dl), hyperglycemic (>180 mg/dl), optimal (90–130mg/dl).

Results: GV and MAGE were significantly higher in insulin treated persons and women at the first visit. A1C was higher in women and in insulin treated persons. GV and MAGE were directly correlated with A1C initially and after 3 months. GV and MAGE were inversely correlated with body weight initially and after 3 months. GV and MAGE were directly related to hyperglycemic exposure, and inversely related to normoglycemic exposure. A1C, GV and MAGE decreased after three months, possibly due to specific treatment adjustments based on continuous glucose monitoring.

Conclusion: Short-term glucose fluctuations were directly related to long-term glucose status (A1C), and hyperglycemic exposure, while inversely related to parameters of normoglycemia, and body weight.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0379

INFLUENCE OF AMBIENT TEMPERATURE ON GLYCAEMIC BEHAVIOUR IN TYPE 1 DIABETES PATIENTS

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Background and Aims: Environmental factors impact Type 1 Diabetes glycaemic patterns. In this work, the impact of the ambient temperature on glycaemia and glycaemic variability is assessed.

Method: CGM data were obtained from the JDRF CGM randomised control trial. 26-week intervention and 26-weeks follow up data were used (n = 252). Meteorological data were acquired from the National Centers for Environmental Information (NCEI). Glucose variability (GV) measures were calculated including glycaemic mean, standard deviation (SD), mean amplitude of glucose excursions (MAGE), low and high blood glucose index (LBGI, HBGI), and times in ranges. Kruskal Wallis test and post-hoc analysis was performed to assess monthly variability to determine the significance of ambient temperature.

Results: Glycaemic mean was affected by the temperature ($p = 0.0003$), and an increasing trend was observed with increasing temperatures. There was a statistical difference between the glycemic mean at the highest temperature (30°C, 164.3 (141.7-183.3)mg/dL) compared to that at low temperature levels (5°C, 153.0 (136.2–65.5)mg/dL). SD and MAGE were also influenced by temperature ($p = 0.0011$ and $p = 0.0030$, respectively). Glucose risk indexes were statistically different across the temperature range ($p = 0.0434$ and $p = 0.0005$, LBGI and HBGI, respectively), with stronger associations observed in HBGI. In addition, temperature had an impact on the time in range and time under 70mg/mL ($p = 0.0003$ and $p = 0.0285$).

Conclusion: Ambient temperature levels significantly affect glycemic profiles and variability in T1D patients. This factor should be taken into account during clinical practice, in education and decision support, and in automatic insulin delivery algorithms.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0075

CLINICAL FACTORS ASSOCIATED WITH DAILY AND DAY-TO-DAY GLUCOSE VARIABILITY DETERMINED BY CONTINUOUS GLUCOSE MONITORING AND THE GLUCAGON STIMULATION TEST IN TYPE 2 DIABETES PATIENTS

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Background and Aims: We studied the clinical factors associated with daily and day-to-day of glucose variability as determined by continuous glucose monitoring (CGM) and the glucagon stimulation test.

Method: We performed a cross-sectional analysis of type 2 diabetes (T2D; insulin-treated, n = 80; not insulin-treated, n = 115) patients who underwent over 72 h of continuous glucose monitoring between October 2013 and April 2017 at Showa University Hospital. Correlations of clinical factors with the mean amplitude of glycemic excursions (MAGE) and mean of daily differences (MODD) in CGM were analyzed by multiple regression.

Results: In insulin-treated T2D, MAGE and MODD were both correlated with age, fasting plasma glucose (FPG), and haemoglobin A1c (HbA1c) and inversely correlated with ΔCPR, and MODD was correlated with duration. In T2D without insulin therapy, MAGE and MODD were both correlated with age, FPG, and HbA1c, MAGE was correlated with TG and LDL-C, and MODD was correlated with duration. In insulin-treated T2D, MAGE and MODD were both correlated with FPG and inversely correlated with ΔCPR in multiple linear regression analysis. In T2D without insulin therapy, MAGE and MODD were both correlated with HbA1c and MODD was correlated with age and diastolic blood pressure in multiple linear regression analysis. In T2D with or without of insulin, MAGE and MODD were both correlated with the use of sulfonylurea (SU).

Conclusion: Insulin secretion is related to glucose variability in insulin-treated T2D. Poor glycemic control greatly contributes to glucose variability in T2D. SU administration increases daily glucose variability in T2D with or without insulin therapy.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0134

PERSONALIZED PHARMACOKINETIC MODELING OF WHOLE BODY GLUCOSE METABOLISM BASED ON CONTINIOUS GLUCOSE MONITORING FOR THE PURPOSE OF INSULIN THERAPY ADJUSTMENT

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Background and Aims: One of the ways to describe complex biological systems it is using mechanical models which are built with system of differential equations. The pharmacokinetic/pharmakodynamic modeling (PKPD) is one of the prevalent ways to create a such model.

The aim of this paper is to construct a mathematical model that takes into account the main physiological parameters of blood glucose regulation, in order to identify them for individual patients according to the CGM data.

Method: The mathematical model of PKPD is elaborated for the purposes of the present research. The model is comprised of 6 differential equations which govern dynamics variations of glucose's concentration, insulin as well as counterintuitive factors in blood.

The method of continuous glucose monitoring (CGM) was used for obtaining a continues glycemic curve (CGG): individual data of 7 patients with type I diabetes were recorded during several days. Then, the parameters of glucose metabolism of every patient were calculated on the basis of the data received during the first day of monitoring. The results were used to predict the value of CGG during the next day.

Results: Finally, based on the built model, the values of the physiological parameters of the glucose metabolism were obtained. The curve of glycemia calculated with these parameters is quite similar to the experimental level of glycemia, obtained as a result of CGM.

Conclusion: These results might be used to predict the results of treatment and early correction of insulin therapy in patients with type I diabetes, which should be investigated in the next stage.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0268

PERFORMANCE EVALUATION OF A NEW NON-INVASIVE GLUCOSE MONITORING DEVICE IN DIFFERENT PATIENT SUBTYPES DURING STANDARDIZED MEAL EXPERIMENTS

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Background and Aims: Patients with insulin-treated diabetes mellitus have to perform regular blood glucose self-testing, which is consdered to be the most painful procedure during daily routine. This study was undertaken to evaluate the meal-related performance of TensorTip CoG, a non-invasive glucose monitoring device (NI-CoG, CNOGA Medical, Israel) with an additional built-in invasive glucose meter (Inv-CoG) in different patient populations during a standardized meal experiment

Method: The study was performed in 15 healthy volunteers (HV: age, gender, HbA1c), 6 type 1 patients (T1D: age, gender, HbA1c), and 15 type 2 patients (T2D: age, gender, HbA1c). The participants ingested a standardized meal and capillary blood glucose was assessed with Inv-CoG, YSI Stat 2300 plus, and Ascensia Contour Next, at time-points −30, 0, 15, 30, 45, 60, 75, 90, 120, 150, and 180 min. Tissue glucose was predicted by NI-CoG. Mean Absolute (Relative) Difference (MA(R)D) was calculated and a consensus error grid analysis (CGA) was performed in comparison to YSI.

Results: Similar results were obtained with each individual device in all three study cohorts. MARD (for values ≥100 mg/dL) with NI-CoG was determined to be 11% (HV), 13% (T1D), and 14% (T2D), respectively (NI-CoG MAD: 20mg/dL/19mg/dL/20mg/dL, Inv-Cog: MARD: 8%/8%/8% and MAD: 12mg/dL, 13mg/dL/14mgdL, Contour: MARD: 4%/4%/4% and MAD: 4mg/dL/3mg/dL/5mgdL). All data pairs were seen in CGA zones A + B with all devices (NI-CoG: 96% +4%, Inv-CoG: 100% +0%, Contour: 100% +0%).

Conclusion: The non-invasive TensorTip device was shown to reliably track meal related glucose excursions in all three patient populations with a similar and acceptable performance as compared to common invasive methods.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0363

SYSTEM ACCURACY ASSESSMENT OF THE COG DEVICE - A COMBINED INVASIVE AND NON-INVASIVE GLUCOMETER

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Background and Aims: The pain associated with pricking the fingertip for blood glucose self-testing is considered to be a major burden in diabetes treatment. This study was performed to evaluate the system accuracy of the invasive TensorTip device component in accordance with ISO15187:2015 requirements, and to explore the accuracy of the non-invasive tissue glucose prediction.

Method: One hundred samples were obtained from patients with type 1 and type 2 diabetes and healthy volunteers (43 female, 57 male; age: 53 ± 16 yrs.), with glucose distribution as requested by the ISO guideline. Three strip lots were tested twice by healthcare professionals, with the YSI Stat 2300 plus reference method, and the non-invasive device component (NI-CoG). Mean Absolute (Relative) Difference (MARD) was calculated and a consensus error grid analysis (CEG) was performed.

Results: The ISO system accuracy criteria was met by 589/600 of the data points (98.2 %) and by each strip lot separately. All values (100 %) were within CEG-zone A and total MARD was calculated to be 7.1 %. Ten of the 90 data pairs obtained by NI-CoG were excluded rejected due to incomplete prior calibration. ISO criteria were met by 80 % of the remaining data pairs (CEG: 100 % in A, MARD: 12.4 %).

Conclusion: The invasive component of the CoG device was shown to be in full compliance with current ISO15197 criteria. Good results were also obtained with the NI-CoG tissue glucose prediction. This non-invasive technology would be suitable for frequent pain-free glucose monitoring in a vast majority of people with diabetes.

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Blood Glucose Monitoring and Glycemic Control in the Hospitals

ATTD8-0052

PERFORMANCE OF A NEW REAL-TIME CONTINUOUS GLUCOSE MONITORING SYSTEM: A MULTICENTER PILOT STUDY

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Background and Aims: The present study aimed to investigate the performance of a new real-time continuous glucose monitoring (CGM) system.

Method: Interstitial glucose levels were monitored for 7 days in 63 patients with type 1 or type 2 diabetes using the Medtrum A6 TouchCare® CGM System. Venous blood was collected as reference values on a randomized day of the wear period.

Results: Among 1,678 paired sensor–reference values, 90.5% (95% confidence interval 89.1–91.9%) were within ±20%/20 mg/dL of the reference values, with a mean absolute relative difference of 9.1% ± 8.7% (95% confidence interval 8.9–9.2%). The percentages of paired sensor–reference values falling within zone A and B of the Clarke error grid analysis (EGA) and the type 1 diabetes consensus EGA were 99.1% and 99.8%. Continuous EGA showed that the percentages of accurate readings, benign errors, and erroneous readings were 89.9%, 6.3% and 3.8%, respectively. Surveillance EGA showed that 90.6%, 9.2%, and 0.2% of sensor–reference values with no, slight and lower moderate risk, respectively. The mean absolute relative difference was 16.6%, and 96.0% of the sensor values fell within zones A and B of the consensus EGA for hypoglycemia. More than 85% of sensor values were within ±20%/20 mg/dL of reference values, the mean absolute relative difference was <11%, and >99.5% of the sensor values fell in zones A and B of the consensus EGA.

Conclusion: The Medtrum real-time CGM system was numerically and clinically accurate over a large glucose range across 7 days of wear.

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Clinical Decision Support Systems/Advisors

ATTD8-0344

EXPERIENCE FROM USING A DYNAMIC STUDY MANAGEMENT SERVICE FOR AN MHEALTH DIABETES TYPE 2 RCT

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Background and Aims: Clinical trial performance is often delayed, especially so when incorporating mobile health (mHealth). In response, dynamic study-management platform was developed to improve study efficiency. The intervention spanned 6 months for each participant, and the RCT spanned 10 months (January–November 2017). The system is acknowledged by Datatilsynet and REK (ref. 2013/1906/REK sør-øst B), for use in the ''Tailoring Type 2 Diabetes Self-Management'' project, a cross-over RCT variant involving two groups assigned to use either a standard or tailored version of the Diabetes Diary self-management app. We report experiences and main administrative findings from the trial.

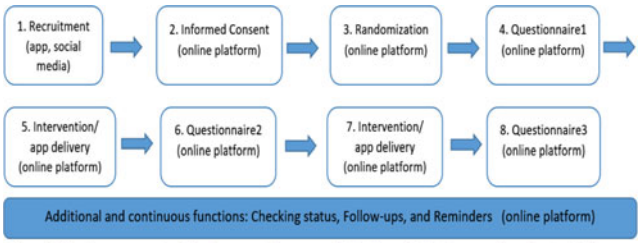

Figure 1. Visual representation of the elements in the proposed eHealth and mHealth research evaluation platform. The functions were designed by using the following technologies and systems: LimeSurvey [2], Piwik [3], Django [4].

Method: Amount of time that a study manager spent using the platform[1] to complete each task per stage (see Figure 1) of the RCT was approximated.

Results: Recruitment spanned 11 weeks. The study manager spent the following amount of time on each task per participant: Informed consent delivery and collection (2-minutes); Randomization (1-minute); Delivery of the Initial questionnaire (1-minute); App administration (4-minutes); Mid-study questionnaire (1-minute); and Final questionnaire (1-minutes). Minutes spent logging into the system, checking participant status, sending questionnaire reminders, etc. approximately tripled these times – totaling 30-minutes per user. Time spent on data-gathering and analysis are being processed.

Conclusion: The most time consuming functionalities were the creation of the study elements: questionnaire, app-related materials, recruitment texts, administrative project documents and webpage, etc. We demonstrated the potential of efficiently managing a study involving mHealth technologies using the presented platform. Final results, as well as times that participants spent per study task, will be reported in coming venues and publications.

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Clinical Decision Support Systems/Advisors

ATTD8-0210

PERSONALIZATION OF INSULIN BOLUS CORRECTION ACCORDING TO GLUCOSE CONCENTRATION RATE OF CHANGE

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Background and Aims: The recent FDA approval of non-adjunctive use of continuous glucose monitoring (CGM) in T1D therapy set new research horizons in developing algorithms that exploit CGM information, including glucose rate of change (ROC), for therapy optimization. So far, some empirical rules were proposed to correct insulin boluses according to the glucose ROC that, however, are not personalized at the patient level. The aim of this work is to investigate the use of neural networks (NNs) in personalizing the ROC-based insulin bolus correction.

Method: The model of (Vettoretti et. al, IEEE TBME, 2017), which expanded the UVa/Padova T1D model by adding models of CGM sensor and patient behavior, was used to simulate 100 virtual adults in 9-h single-meal scenarios with different preprandial blood glucose (BG) and ROC conditions. For each scenario, different meal bolus corrections were simulated. Then, a NN was trained to estimate the optimal bolus correction in each subject for each scenario, i.e., that obtaining the best glycemic outcomes in terms of BG risk index (RI). The NN input data include information on the meal scenario (e.g., preprandial BG and ROC) and patient's parameters (e.g., carb-ratio and correction factor).

Results: In an independent test set, the use of the NN to personalize the ROC-based bolus correction allows, on average, to improve glycemic control with lower RI compared to the standard bolus calculation.

Conclusion: Preliminary results show the potential benefit of using NN to personalize the insulin therapy. Future work will focus on studying the NN architecture and investigating the factors affecting its performance.

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Clinical Decision Support Systems/Advisors

ATTD8-0266

BURDEN OF SEVERE HYPOGLICEMIA AND KETOACIDOSIS IN PATIENTS WITH TYPE 1 DIABETES MELLITUS: MORBIDITY, MORTALITY AND COSTS

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Background and Aims: Hypoglycemia (HYPO) and Diabetes Ketoacidosis (DKA) are the two most serious metabolic complications of Type-1 diabetes (T1DM). Increasing the risk of death, in addition to other vascular complications, they place a very heavy burden on health care systems. Using data from administrative databases, we aimed to assess mortality risk and burden of severe HYPO and DKA, in T1DM patients, compared to those without acute events.

Method: Records were obtained for T1DM patients (N = 33,774) using DENALI (years 2000–2010) a data warehouse matching with probabilistic record-linkage data of about 10.000.000 individuals in Lombardy. HYPO and DKA events were defined using ICD-9-CM codes. Direct costs were estimated.

Results: A total of 958 patients in DKA group and 363 patients in HYPO group were compared with 32,453 patients with T1DM (without events). Patients with HYPO had an older mean age and a greater number of comorbidities, than other groups. HYPO and DKA patients reported a statistically significant higher risk of death when compared to T1DM patients without event. 5-year survival probability of HYPO was lower than DKA and T1DM patients without acute event ($p < 0.05$). Costs observed for HYPO patients during the years before and after the acute event were up to 50% higher than those observed in DKA and no-acute event patients' groups (e.g. about €11,400 vs €10,200 vs €6,000 during the first year).

Conclusion: HYPO accounted for significant morbidity, hospitalizations and mortality among T1DM patients and contributed significantly to the high costs of diabetes care more than patients with DKA or without acute event.

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Clinical Decision Support Systems/Advisors

ATTD8-0436

COMPUTERIZED INSULIN DOSE ADJUSTMENT FOR CLINICIAN SUPPORT IN THE TREATMENT OF INSULIN-REQUIRING DIABETIC PATIENTS

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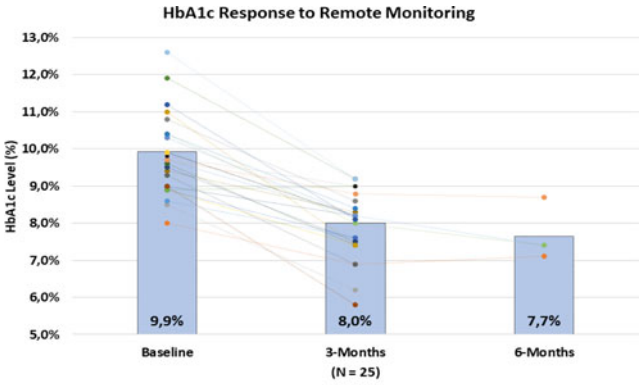
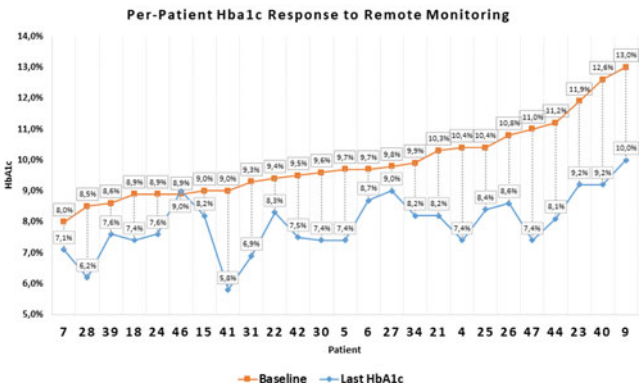
Initiating insulin therapy and subsequent intensification is difficult for primary care physicians. This is evidenced by a 3–7 year lag period before insulin is started in patients who have failed oral anti-diabetes drugs at which time the baseline HbA1c level averages 9.3%. Less than 50% of patients with HbA1c levels >8.0% are even started on insulin. A key barrier for appropriate insulin treatment is time: physicians have only 8–15 minutes for each patient visit and then only see them ~ every 3 months. We computerized these principles into insulin dose adjustment algorithms. The system captures patient's glucose





meter readings downloaded to a computer (or via smartphone) containing the Mellitus Health program. Within 15 seconds, a report is generated containing: a) a scatterplot of glucose values; b) glucose values organized into pre- and post-prandial values by meal; c) values' analysis; and d) insulin dose recommendations the physician can accept, modify or ignore. Reports are generated in specified intervals and sent to the patient's physician (or staff), who contact the patient with any dose adjustments. The remote glucose monitoring approach is currently being evaluated in patients who had been previously taking insulin for at least 6 months with baseline HbA1c levels ≥8.0%. Preliminary results in 25 patients reveal a 1.9% decrease in HbA1c levels from 9.9% to 8.0% over 3 months. These algorithms will facilitate insulin treatment by saving the PCP time, improving the patient's diabetes control, and reducing the need for patient visits.

Graphs and images

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Clinical Decision Support Systems/Advisors

ATTD8-0434

THE RELATIONSHIP BETWEEN TYPE 2 DIABETES PATIENTS AND DEPRESSION

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Background: Type 2 diabetes is one of the most common chronic diseases worldwide, which its frequency becomes increases every year, especially within developed countries. One of the most significant consequences of type 2 diabetes is the development of depression disease.

Purpose: This quantitative research aimed at examining the correlation between five main variables, which are connected to type 2 diabetes, and levels of depression: age, education level, socio-economic level, perception of the disease and performance of physical activity.

Methods: 91 participants with type 2 diabetes participated and required to fulfill 2 questionnaires; (1) Sociodemographic questionnaire, (2) Beck Depression Inventory (BDI) questionnaire. Questionnaires data were analyses using descriptive statistics as well as pearson and spearman correlations.

Results: Findings show that there is a correlation between the perception of the disease and depression ($r = 0.439$, $p < 0.05$) and socio-economic level and depression ($r = -0.267$, $p < 0.05$). No significant correlation was found between the performance of physical activity, age, education level and depression ($p > 0,05$).

Conclusions: Type 2 diabetes patients are exposed to many lifestyle changes that affect their well-being and impair their daily routine. There is a need to promote programs that will help the medical team to recognize depressive symptoms and create treatment management that will address it. The socioeconomic status has a great impact on coping with the disease and future studies must examine the weaker segments of the population that tend to develop depression symptoms.

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Clinical Decision Support Systems/Advisors

ATTD8-0205

LATENT AUTOIMMUNE DIABETES OF THE ADULTS (LADA) - WOULD YOU MISS IT?

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Background and Aims: Latent autoimmune diabetes of the adult (LADA) is a terminology which is used to describe people with type 2 diabetes mellitus (T2DM) and pancreatic autoantibodies. Typically they have preserved beta cell function which gradually declines, requiring insulin treatment.

Method: We present a series of three cases of LADA with positive islet cell or GAD 65 antibodies.

Results: Median age at diagnosis was 55 (patients were diagnosed at 73, 52, and 55 years respectively.) All patients tested positive for anti-GAD 65 antibodies at diagnosis, with just one testing positive for anti-islet cell antibodies in addition.

This patient has a particularly severe phenotype with multiple admissions for diabetic ketoacidosis and long term complications of diabetes including pre-proliferative retinopathy.

All three patients are currently on insulin therapy and well controlled. They had a poor response to oral hypoglycaemic in the initial stages. The prevalence of LADA is around 10% of T2DM patients in the UK .Complete β-cell failure occurs after 12 years. There is short lived response to oral hypoglycaemic agents and high incidence of association with other autoimmune diseases.

In this cases series it can be noted that antibody status may confer the severity of disease phenotype as well as predisposition to other autoimmune disease.

Conclusion: Estimated prevalence of LADA is likely under diagnosed.

Vigilance with antibody testing will be key in the swift identification of cases reaching to a correct diagnosis. If not sure of diagnosis starting these patients on insulin while waiting for antibodies result is suggested approach.

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Clinical Decision Support Systems/Advisors

ATTD8-0224

INFORMATION IS POWER: USING REAL TIME DATA TO TRACK BLOOD GLUCOSE TRENDS OF CELLNOVO CSII SYSTEM USERS

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Background and Aims: The Cellnovo system is the first mobile diabetes management system, providing connectivity and real-time tracking of data. Data is collected and collated to provide a rich seam of clinical information which affords users and their health care professional (HCPs) individual blood glucose (BG) trends. This review highlights some of the data captured.

Method: Blood glucose (BG) level data from 193 patients (each with >200 days and >600 measurements) at month 1 and final month of use, were mined and compared with other studies. Mean BG level and variability, the number of hypo/hyperglycaemic episodes, and percentage of BG readings outside users recommended range were analysed.

Results:

- In 65.6% (n = 127) of patients, hypoglycaemic episodes fell by between 1 & 51 episodes

- Hyperglycaemic episodes fell by between 1 & 79 episodes in 50.8% (n = 98) of patients
- 15.5% (n = 30) showed a significant ($p < 0.05$) decrease in average blood glucose levels between time points
- BG Variability as expressed by the standard deviation of measured values, decreased for 40.4% (n = 78) and of these, 52.6% (n = 41) decreased by 10-52 mg/dL

Conclusion: The preliminary results from our cohort of Cellnovo users indicates a decrease in the number of hypoglycaemic and hyperglycaemic episodes, which has been demonstrated in a previous study[1].

Data available from Cellnovo System users can be mined and analysed to indicate efficacy and identify patients' needs in managing diabetes.

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Clinical Decision Support Systems/Advisors

ATTD8-0431

EFFECT OF QUALITY OF FAT AND PROTEIN ON POST PRANDIAL BLOOD GLUCOSE LEVEL

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Background: It is known that the elevation of postprandial glucose (PG) level after the digestion of fat and protein rich food cannot be controlled by carbohydrate counting (CC). Some reports focused on the additional insulin for dietary proteins and lipids. FPU method was proposed by Pańkowska E. Few studies have examined the influence on postprandial blood glucose given by the difference in type of dietary lipid and protein.

Aim: To see the influence of dietary protein and fat types on postprandial blood glucose.

Method: In type 1 diabetes patients, postprandial glucose profile was analyzed by CGM or FGM after eating various kinds of test foods

Results: The PG profile was stable after taking Sushi dishes (high carbo, low fat and protein) without additional insulin to CC. The PG profiles were variable among the subjects after taking grilled meat dishes and carbonara spaghetti (high fat and protein) with additional insulin according to FPU to CC. Boiled Chicken meat and boiled Puffer (100% protein) elevated PG. On the other hand, 300g boiled Squid and boiled Whitebait did not elevate PG level. The olive oil and canola oil itself did not too.

Discussion and conclusion: Additional insulin was not needed for high carbohydrate foods such as Sushi dish. Insulin dose calculated by FPU method for high fat and high protein food, sometimes induced hypoglycemia several hours after meals. Furthermore, this study showed that there were differences among the influences on PG profile was greatly dependent on the type of protein.

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Clinical Decision Support Systems/Advisors

ATTD8-0417

THE MEDIATING EFFECT OF MEDICATION ADHERENCE ON THE RELATIONSHIP OF PERCEIVED STRESS TO QUALITY OF LIFE IN ADULTS AT RISK FOR METABOLIC SYNDROME WITH DIABETES

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Background and Aims: Although perceived stress decreases quality of life (QoL), there is lack of studies on the role of medication adherence in relation to stress and QoL in adults taking medication for metabolic syndrome. This study examined the mediating role of medication adherence on the relationship between stress and QoL.

Method: This study was part of an ongoing clinical trial using Mobile Short Message of 79 adults taking medication. Participants completed a series of questionnaires on Morisky Medication Adherence, Perceived Stress, and WHOQoL Scales. Multiple regression analysis and Sobel test were used to examine the mediating role of medication adherence on the relationship between stress and QoL.

Results: The average age was about 53 years old and 61.5% of patients were women. The prevalence of high, moderate, and poor medication adherence were 24%, 49.4%, and 26.6%, respectively with mean (SD) of 6.59 (0.23). Medication adherence was significantly predicted both stress and QoL (all ps < .001). Medication adherence was significantly predictive of QoL ($p < .05$). Inclusion of medication adherence in the model non-significantly decreased the slope for stress as a predictor of QoL. The Sobel test confirmed that medication adherence completely mediated on stress and QoL ($p < .05$).

Conclusion: This study concludes that direct and indirect effects of medication adherence on the relationship between stress and QoL in adults taking medication. This mediating role has an important implication as interventions designed to increase medication adherence may be more effective than those that target stress management alone to improve QoL.

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ATTD8-0229

GLUCOSE FORECASTING USING A PHYSIOLOGICAL MODEL AND STATE ESTIMATION

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Background and Aims: In diabetes management, glucose forecasting algorithms have been proven to be an effective solution for reducing the risk of hypo- and hyperglycaemia events when combined with glucose alarms and/or low-insulin suspension systems. Therefore, an accurate forecasting algorithm is desired.

Method: This work presents a novel glucose forecasting algorithm which employs a composite physiological model, including a minimal model of glucose-insulin dynamics, an insulin absorption model and a meal absorption model. To enhance forecasting accuracy, the glucose absorption state is estimated using a validated state estimation technique. Insulin sensitivity, insulin absorption time-to-peak and glucose absorption time-to-peak parameters are individualised, while the rest of model parameters are fixed to mean population values. Furthermore, the algorithm considers the meal composition and the physical activities reported by the user. The proposed algorithm has been validated *in silico* using the UVa-Padova simulator and compared against a state-of-art glucose forecasting algorithm referred to as latent variable with exogenous input (LVX).

Results: *In silico* results on a virtual adult population ($n = 10$) over one-week scenario and 30-min forecasting horizon showed superior forecasting accuracy (RMSE) when compared against the LVX algorithm (11.6 ± 1.3 mg/dL vs. 10.7 ± 1.6 mg/dL, $p < 0.05$).

Conclusion: The proposed forecasting algorithm provides good accuracy and has the potential to reduce hypo- and hyperglycaemia events in a type 1 diabetes population. The presented technique is currently being clinically tested as part of a safety layer for an insulin decision support system within the framework of the H2020 PEPPER project.

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Clinical Decision Support Systems/Advisors

ATTD8-0351

COST EFFICIENCY DIABETIC FOOT INFECTION TREATMENT BY SHORT PROBABILIST ANTIBIOTHERAPY COMBINED WITH SELECTIVE DRAINAGE GUIDED BY CT SCAN AND 3D ANGIOGRAPHY

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Background and Aims: New and unconventional approach was used to treat diabetic foot infections (D.F.I).

Since 2016 a systematic 3D angiography approach of diabetic foot vascular exploration was practiced.

We noticed that vascular inflammation matched with CT scan soft tissu infection, even in atherosclerotic patients.

Excision of all infected tissues through selected 3D approach was decided.

Method: 102 patients were referred since october 2013 to june 2017 for D.F.I with or without osteomyelitis.

We selected 18 of them, patients without osteomyelitis, classified PEDIS 3 or 4 and IDSA mild or severe.

Bacteriological retriaval was Gram +32 %, Gram – 68%, MRB in 18% of total.

CRP range was 62- 230, WBC count range was 10 200 – 21 500.

Combined selected surgical drainage and 3D angiography of inferior limb allowed accurate opening and drainage of deep fascia infection

Protocol :

Imaging

- CT scan identified air or fluid concentration in foot
- 3D foot angiography was performed through femoral punction

Antiobiotic

- IV Amoxicilin – clavulanic acid and gentamicyn. Used as probabilist antibiotherapy, vancomycin was used in 3 cases

Surgery

- Excisions followed the tendons, deep in the fascia plantar sole, were multiple in 8 cases
- Endovascular revascularisation was practiced if necessary

Results: We had an amputation free cohort in these selected patients without osteomyelitis.

Length of stay was 7 to 28 days.

Cicatrisation was achieved in of 6 to 11 weeks.

Regularisation of CRP was achieved in a range of 4 to 8 days.

Conclusion: High cost efficiency was achieved by low cost and short term antibiotic treatment, foot revascularisation had to be effective.

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Clinical Decision Support Systems/Advisors

ATTD8-0459

HOW DO WE ADJUST INSULIN DOSING FOR PATIENTS WITH TYPE 1 DIABETES USING SENSOR AUGMENTED PUMP? – VARIATIONS AMONG COUNTRIES AND PHYSICIANS

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Objective: To evaluate various attitudes of physicians treating patients with Diabetes type 1 on how to change insulin pump settings based on continuous glucose monitoring and compare them to automated recommendations.

Research Design and Methods: 25 physicians from different centers in Europe & Israel and one from South-America participated in the study. Each physician was asked to adjust insulin

dosing based on uploaded CareLink Pro® data of 15 patients (aged 16.2 ± 4.3 y, A1c 8.3 ± 0.9%) included sensor, glucometer and insulin pump data from a three weeks period. The physicians' recommendations for changes to the patients' pump settings in the basal rate, carbohydrate-ratio (CR) and correction- factor (CF) plans were compared between the physicians, among centers as well as between the physicians and the automated algorithm DreaMed Advisor Pro of DreaMed-Diabetes. Study endpoints were the percentage of comparison points where there was full, partial or no agreement on the direction of changes in the treatment plan.

Results: Full agreement between physicians on the direction of insulin adjustments of the basal, CR and CF plans were 41 ± 9%, 45 ± 11% and 45.5 ± 13% and significant similar results of 41.5 ± 8%, 48 ± 11% and 43.5 ± 11% respectively between the physicians and the Advisor Pro. Complete disagreement between physicians was found to be 12 ± 7%, 9.5 ± 7% and 10 ± 8% for the basal, CR and CF plan respectively and significant similar results between the physicians and the Advisor Pro.

Conclusions: There was a diversity in the insulin dose recommendations made by different experienced physicians even when they were from the same center. The automated advice of the DreaMed Advisor did not differ significantly from the advice given by the expert physicians in the direction and magnitude of the insulin dosing.

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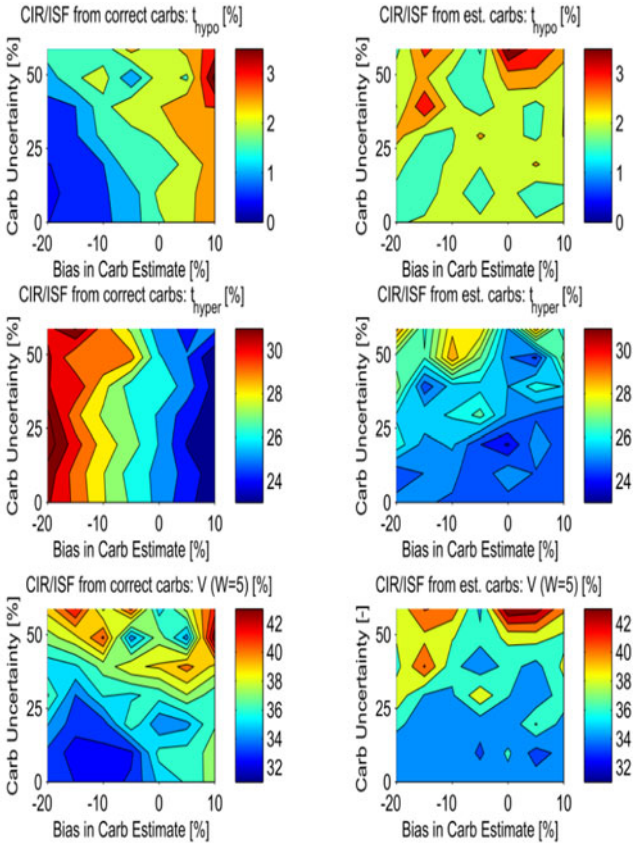
Clinical Decision Support Systems/Advisors

ATTD8-0213

EFFECT OF CARBOHYDRATE COUNTING ERRORS ON GLYCEMIC CONTROL – A HYBRID IN SILICO STUDY



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Background and Aims: Many T1DM patients have difficulties to correctly estimate meal carbohydrates. These estimates are used for calculating meal boluses, but there is a lack of data on how estimation errors affect glycemic control.

Method: 6 days of data of a recent clinical trial with 37 patients are used for identifying carbohydrate-to-insulin-ratios (CIRs) and insulin-sensitivity-factors (ISFs) based on a previously published method, either using the correct carbohydrate amount or an estimated amount, affected by some random estimation error. On the 7th day the identified CIRs and ISFs are used to calculate the insulin doses based on estimated carbohydrate amounts, including estimation errors. A deviation based method is used to simulate the effect of carbohydrate counting errors on glycemic control. In the simulations a whole range of values is tested regarding estimation bias (between −20% and +10%) and uncertainty of estimation (between 0% and 60%).

Results: The figures show the time in hypoglycemia (t_{hypo}) and hyperglycemia (t_{hyper}) and the value of a combined cost function ($V = 0.05 * t_{hypo} + 0.01 * t_{hyper}$). The left ones correspond to the case of CIRs and ISFs identified using the correct carbohydrate amounts, whereas for the right ones CIRs and ISFs identified based on the estimated carb amount are used, affected by the same bias and uncertainty that is afterwards used in the simulations.

Conclusion: Uncertainty in carb estimates always leads to inferior glycemic control, whereas an estimation bias hardly affects the results since it is usually implicitly included in the CIRs and ISFs used by the patients.

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Clinical Decision Support Systems/Advisors

ATTD8-0105

TIME-SERIES ANALYSIS OF HBA1C USING RECURRENT NEURAL NETWORKS STRATIFIES FOR 1-YEAR MORTALITY IN TYPE 1 AND TYPE 2 DIABETES, INDEPENDENT OF AGE AND VARIABILITY

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Background and Aims: To assess association between time-series sequence of HbA1c values over a 5-year period and all-cause 1-year mortality.

Method: HbA1c and mortality data for all individuals with T1D or T2D in our region were identified from 2008–2013. T1D and T2D were analysed separately. Inclusion required diagnosis prior to 2008. An HbA1c sequence was generated using 2-month time bins. Missing values were imputed by carrying last value forward. Age and HbA1c coefficient of variation (CV) were calculated. A recurrent neural network (with an embedding layer, and a 128-node LSTM (Long Short-Term Memory) layer) was trained on 80% of HbA1c data, taking 1-year mortality as the dependent variable. A survival analysis was performed on individuals within the test-set (20%) - comparing those with a predicted probability of death (within 1 year) above the median probability value vs those below, with age and HbA1c CV as covariables.

Results: T1DM - 6620 individuals. 1324 individuals in test set. 18 deaths within 1 year. HR for mortality for those with a predicted probability of death above median 5.58 (95% CI 1.25-24.9) p = 0.02

T2DM - 34060 individuals. 6816 individuals in test set. 318 deaths within 1 year. HR for mortality for those with a predicted probability of death above median 1.94 (95% CI 1.52–2.49) p = <0.001

Conclusion: Time-series analysis allows information to be captured from the sequence of numerical values, as well as from the values themselves. The use of Time-series analytical approach appears to add additional information over summary metrics of HbA1c when stratifying for outcome.

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Clinical Decision Support Systems/Advisors

ATTD8-0316

PARALLEL TIME-SERIES ANALYSIS OF HBA1C, SYSTOLIC BP AND BMI USING RECURRENT NEURAL NETWORKS STRATIFIES FOR 1-YEAR MORTALITY IN T2D, INDEPENDENT OF AGE AND PARAMETER VARIABILITY

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Background and Aims: To assess association between time-series sequence of HbA1c, SBP and BMI values over a 5-year period and all-cause 1-year mortality.

Method: HbA1c, SBP, BMI (analysis parameters) and mortality data for all individuals with T2D in our region were identified from 2008-2013. Inclusion required diagnosis prior to 2008. Sequences of all parameters was generated using 2-month time bins. Missing values were imputed by carrying last value forward. Age and coefficient of variation (CV) of all parameters were calculated. A recurrent neural network (with 2 LSTM (Long Short-Term Memory) layers) was trained on 80% of parameter time-series data, taking 1-year mortality as the dependent variable. A survival analysis was performed on individuals within the test-set (20%) - comparing those with a predicted probability of death (within 1 year) above the median probability value vs those below, with age, HbA1c CV, SBP CV and BMI CV as covariables.

Results: 33456 individuals with T2D diagnosed prior to 2008 were included, with 6691 individuals in test set. 279 deaths occurred within 1 year. ROC curve AUC for predicting mortality 0.86. On survival analysis, HR for mortality for those with a predicted probability of death above median value was 4.34 (95% CI 2.95 - 6.38) p = <0.001, when age HbA1c CV, SBP CV and BMI CV included as covariates.

Conclusion: Multi-parameter time-series analysis allows information to be captured from both the sequence of values and their interaction over time, as well as from the numerical values themselves, and in this analysis is an independent stratifier for mortality.

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Clinical Decision Support Systems/Advisors

ATTD8-0120

USE OF FLASH GLUCOSE MONITORING FOR NON ADJUNCTIVE USE IN TYPE DIABETIC SUBJECTS USING CARBO COUNTING TECHNIQUE

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Background and Aims: Over the past 5 years, there has been substantial improvement in glucose monitoring and its non-adjunctive use.

Method: We evaluated nonadjunctive insulin dosing in 28 Type 1 Diabetes subjects (T1DM), on carbo-counting willing to use Libre flash monitoring system for 6 months. They measured 14 days before each visit, pre-meal glucose values with finger-stick and Libre at the same time. Fourteen subjects were asked to take therapeutic decisions after scan results if pre-meal glucose value 80-250 mg/dl and trend arrow not rapidly upward or downward.

Results: Population age was (M±SD) 38 ± 8,7, diabetes duration 15,3 ± 9,06. For statistical analisys we used ANOVA for repeated measures. There was any difference regarding HbA1c and number of hypoglycemic events, Time spent in hypoglicemia was reduced in all Libre users after six months (177,1 ± 84,62 min vs 141,7 ± 67,7 min p < 0.0001) with an addictional little effect in finger-sticking subjects (p < 0.0001). In Libre users variability <10th percentile was reduced at 6 months (p = 0.028) but not in subjects on carbo-counting based on SMBG. Post meal glucose area under the curve was not significantly lower in those who used finger-stick test.

Conclusion: In our real world experience T1DM subjects using Libre flash monitoring system were able to rely on results of their scans for carbo-counting, for management of hypoglicemic events and for insulin dosing. We need more information on Libre use at the outer boundaries of glucose values (glucose values <80 mg/dl pre-meal or >250 mg/dl rapidly changing).

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Clinical Decision Support Systems/Advisors

ATTD8-0355

EFFECTIVENESS OF A DIGITAL THERAPEUTIC FOR IMPROVING OUTCOMES IN SOUTH ASIANS LIVING WITH TYPE-2 DIABETES - RESULTS FROM AN ONGOING REAL WORLD PILOT TRIAL

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Background and Aims: Health Insurers in South Asia are challenged by lack of a clinically effective lifestyle intervention that can be delivered at scale to their insured populations. This

study reports results for a subset of participants (who completed the intervention at the time of submitting this abstract) of a real-world pilot of Wellthy Diabetes™ (WD), a digital therapeutic for people living with type-2 diabetes, in collaboration with an insurance provider with the aim to validate WD as a diabetes management and risk reduction tool.

Method: A 16 week lifestyle modification program was delivered through WD to adult subjects with type 2 diabetes. The program included skill development through structured DSME content developed along the guidelines of AADE7 and Artificial Intelligence(AI) powered real time 24x7 coaching and feedback on self-reported blood glucose, weight, physical activity and meals. Participants were supported by a personal diabetes coach throughout the study.

Results: For the 39 participants (mean age: 50.5 yrs & 62% males) mean pre and post-intervention A1c were 8.31% (95% CI:7.85-8.78) and 7.7% (95%CI: 7.28–8.12) respectively. A mean reduction of 0.61% A1c (95%CI:0.26-0.96, $p = 0.001$) was reported post intervention with 62% ($n = 24$) of participants reducing A1c with a mean reduction of −1.17% A1c (95% CI: 0.75–1.60).

Conclusion: This study demonstrates Wellthy Diabetes as a clinically effective intervention for health insurers in South Asia to improve health outcomes and reduce risk for people with type-2 diabetes.

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Clinical Decision Support Systems/Advisors

ATTD8-0081

EFFECT OF AUTOMATED BOLUS CALCULATION ON GLYCAEMIC VARIABILITY AND RELATION WITH PSYCHOLOGICAL PROBLEMS

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Background and Aims: Reducing (meal time) glucose swings and reducing complications in diabetes patients is typically done by adjusting insulin dosage based on the carbohydrate intake and individual parameters. The main purpose of this study is to test whether education in carbohydrate counting and automation of the bolus calculation offers psychosocial and glycaemic benefits.

Method: This was a 16-week, single center, single arm study. Inclusion criteria were an age >18; Diabetes Mellitus type 1 or 2 for at least 12 months; treated with multiple daily injections and an HbA1c between 48–86 mmol/mol. After administering baseline questionnaires, patient were scheduled to receive training in both carbohydrate counting and in the use of the blood glucose monitor and automated bolus calculator. After 16 weeks the follow-up questionnaires were administered and the HbA1c was determined.

Results: In total 23 patients were included of which 12 Type I and 5 Type II patients completed the study, participants were 54 ± 14 years old with an average diabetes duration of 17 ± 14 years. After 16 weeks, the HbA1c lowered 5 mmol/mol ($p < 0.05$) and the low blood glucose index (LBGI) was reduced by 0.4 ($p < 0.05$)). In addition participants showed a decreased depression score of 5 points ($p = 0.01$) while the questioners scores for sleep quality, diabetes related stress, fear of hypoglycaemia, confidence in diabetes selfcare and cognitive failure remained unchanged.

Conclusion: The study seems to indicate that education in carbohydrate counting together with a bolus calculator could lead to improvements in HbA1, LBGI and depressive symptoms.

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Clinical Decision Support Systems/Advisors

ATTD8-0352

PREDICTION OF HYPERGLYCAEMIA AND HYPOGLYCAEMIA EVENTS USING LONGITUDINAL DATA

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Background and Aims: Glucose forecasting algorithms have been proven effective to prevent hypo- and hyperglycaemia events. However, most algorithms rely on Continuous Glucose Monitoring (CGM). This work studies the use of sequential data to predict hypo- and hyperglycaemia events without the need of CGM.

Method: This work proposes prediction of hypo- and hyperglycaemia using meal information: bolus (B), pre-prandial blood glucose (BG), carbohydrates (CHO) and type of meal (breakfast, lunch, dinner).

The method consists of using a k-nearest neighbour algorithm to retrieve similar sequences of meals to then predict if it will convey a hypo- or hyperglycaemia event according to the outcome (a previous hypo- or hyperglycaemia event or not) of the retrieved sequences.

Results: The proposed method has been *in-silico* tested with 10 virtual adults with 500-days simulation with UVA/Padova simulator. It is compared with the prediction of hypo- and hyperglycaemia considering meal information but not sequences of meals, called one-shot. The following tables show the results with the average and standard deviation over ten folds using cross-validation, where TPR is the true positive rate and FPR the false positive rate.

Conclusion: The proposed method achieves an acceptable accuracy given the limited information it uses, with TPR over 80%. Moreover, it is capable to significantly improve the

Table 1. Accuracy, TPR and FPR at predicting hypo- and hyperglycaemia

Glucose state	Type of meal	One shot			Sequences		
		Accuracy	TPR	FPR	Accuracy	TPR	FPR
Hypo	BF	0.7525 ± 0.0045	0.7758	0.2707	0.8100 ± 0.0049	0.8555	0.2354
Hypo	Lunch	0.7365 ± 0.0041	0.7296	0.2566	0.7731 ± 0.0060	0.7350	0.1887
Hypo	Dinner	0.7619 ± 0.0106	0.7413	0.2175	0.8309 ± 0.0044	0.8878	0.2261
Hyper	BF	0.7807 ± 0.0057	0.7789	0.2177	0.8364 ± 0.0077	0.8258	0.1530
Hyper	Lunch	0.7280 ± 0.0066	0.8132	0.3572	0.8324 ± 0.0044	0.7994	0.1345
Hyper	Dinner	0.6409 ± 0.0063	0.6947	0.4129	0.7389 ± 0.0060	0.7652	0.2874

Table 2. Accuracy, TPR and FPR at predicting hypo- and hyperglycaemia without using meal type information

	One shot			Sequences		
	Accuracy	TPR	FPR	Accuracy	TPR	FPR
Hypo	0.6814 ± 0.0039	0.7451	0.2549	0.7029 ± 0.0045	0.7186	0.3128
Hypo	0.6872 ± 0.0033	0.7070	0.2930	0.6703 ± 0.0061	0.6642	0.3237

prediction accuracy respect to the one-shot, achieving TPR over 80%. However, no improvement is detected when the retrieved sequences are forced to end with the same type of meal than the target due to intra-day variability.

This work has been funded with H2020 project No 689810 (PEPPER).

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Clinical Decision Support Systems/Advisors

ATTD8-0269

USE OF GOCAP TO EVALUATE APPROPRIATENESS OF BOLUS INSULIN DOSING TO ACHIEVE TARGET GLUCOSE LEVELS IN PATIENTS ON BASAL BOLUS REGIMEN

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Background and Aims: In patients on basal bolus regimen using multiple daily injections (MDI), the impact of timing and amount of bolus doses on post-prandial BG is not known. Clinicians are then required to make changes in insulin prescription based only on blood glucose (BG) data.

Method: We used insulin pen caps (Gocap), that record insulin injection data via bluetooth, to evaluate the impact of bolus insulin dosing on 3-hour post-injection BG levels in two groups of patients: younger (18–35 years) and older (age >65 years).

Results: We evaluated 24 patients on MDI (12 in each group). We assessed the adequacy of timing and dose of bolus insulin by tracking if each dose resulted in glucose levels below target (<50, or 70 mg/dl), at target (70–150 mg/dl in younger; 70–180 mg/dl in older), or above target (150 mg/dl in younger; 180 mg/dl in older). The table shows data stratified by age group. On an average, out of 1,343 doses, 701 doses (52%) resulted in glucose levels above target, 521 doses (39%) resulted in glucose levels at target, and 121 doses (9%) resulted in glucose levels below target.

Conclusion: This data from Gocap may help clinicians to educate patients, and adjust bolus insulin dosing and/or insulin-carbohydrate ratio to improve glycemic control in patients on MDI.

Younger Cohort (N=12, T1D=12)	End BG <50 mg/dL	End BG 50-70 mg/dL	End BG 70-150 mg/dL	End BG >150 mg/dL
Start BG <70 mg/dL (N=58)	0	4 (6.9%)	28 (48.3%)	26 (44.8%)
Start BG 70-150 mg/dL (N=287)	2 (0.7%)	27 (9.4%)	154 (53.7%)	104 (36.2%)
Start BG >150 mg/dL (N=422)	7 (1.6%)	38 (9.0%)	136 (32.3%)	241 (57.1%)
Older Cohort (N=12, T1D=9)	End BG <50 mg/dL	End BG 50-70 mg/dL	End BG 70-180 mg/dL	End BG >180 mg/dL
Start BG <70 mg/dL (N=13)	0	0	11 (84.6%)	2 (15.4%)
Start BG 70-180 mg/dL (N=247)	2 (0.8%)	24 (9.7%)	115 (46.6%)	106 (42.9%)
Start BG >180 mg/dL (N=316)	3 (0.9%)	14 (4.4%)	77 (24.4%)	222 (70.3%)

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Clinical Decision Support Systems/Advisors

ATTD8-0272

USE OF MOBILE-BASED TECHNOLOGIES IMPROVE DIABETES SELF-MANAGEMENT BEHAVIOR

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Background and Aims: The goal of this study was to evaluate whether a clinical intervention incorporating flash glucose monitoring (Abbott FreeStyle Libre) together with real-time contextual prompts from a smartphone app and web-based nutrition education could lead to improvement in diabetes self-management behavior.

Method: CGM-naïve T1D subjects with an A1c 7.0–9.0% used a FreeStyle Libre system that communicated with the ''Sugar Sleuth'' app for 14 weeks. Subjects were instructed to periodically ''scan'' the sensor to see their glucose readings. Following a glycemic excursion, the app prompted them to enter the suspected cause, including food and insulin information. Participants completed an online nutrition education module focused on the impact of food on postprandial glucose control. At baseline and the conclusion of the study, 24-hour dietary recalls were performed using the Nutrition Data System for Research program from the University of Minnesota.

Results: A total of 30 T1D subjects participated in the study. Baseline characteristics: mean A1c 8.0 ± 0.6%, mean age 57 ± 14, 52% female, mean duration of diabetes 32 ± 16 years. Participants used either multiple daily injections (57%) or insulin pumps (43%). Over the 14 weeks A1c improved by 0.45 ± 0.37% ($P < 0.0001$). Changes in insulin doses did not account for this improvement, therefore further investigation is underway to identify meaningful changes in disease management behavior.

Conclusion: This is the first time to our knowledge that a clinical intervention that incorporates contextual feedback on continuous post prandial glucose fluctuations promoted changes in self-management behavior and improved glucose control.

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Clinical Decision Support Systems/Advisors

ATTD8-0276

MOBILE DIABETES MANAGEMENT APP SIGNIFICANTLY REDUCES LOW AND HIGH BLOOD GLUCOSE RISKS REGARDLESS OF ITS FREQUENCY OF USE

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Background and Aims: The goal of this work is to analyze the effect of the frequency of use of a diabetes management application (app) on glycemic control. This study will analyze

the impact on Low Blood Glucose Index (LBGI) and High Blood Glucose Index (HBGI).

Method: 2056 T1D users of the *Social Diabetes app* were analyzed. Inclusion criteria: engagement (logging ≥5 days/month for ≥6 months). The cohort was split into two groups according to the intensity of app engagement: Group A: low engagement group (between 5 and 10 logging per month for ≥6 months); group B: high engagement group (logging ≥60 times/month for ≥6 months.

From each group the highest quartile regarding LBGI and HBGI at baseline, t1, was selected (n = 74 for group A, n = 440 for group B). Changes in HBGI and LBGI at month 6 (t2) were analysed.

Results: Baseline LBGI results for groups A and B were 5.2 ± 3.9 and 4.4 ± 2.3, dropping at t2 to 3.4 ± 3.3 and 3.4 ± 1.9 respectively. A reduction in mean of 53% ($p < 0.001$) and 29% ($p < 0.001$) respectively.

Baseline HBGI results for groups A and B were 12.6 ± 4.3 and 10.6 ± 4.03, dropping at t2 to 9.0 ± 6.5 and 8.6 ± 4.7 respectively. A reduction in mean of 40% ($p < 0.001$) and 23% ($p < 0.001$) respectively.

Conclusion: Significant reduction of LBGI and HBGI has been found in all groups regardless of the frequency of use of the app. LBGI and HBGI indices of both groups tend to have similar values after 6 months of use of the app.

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Clinical Decision Support Systems/Advisors

ATTD8-0329

THE PREGNANCY OUTCOMES OF LOW CARBOHYDRATE DIETS IN JAPANESE WOMEN WITH GESTATIONAL DIABETES

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Background and Aims: Nutrition therapy is an integral part of gestational diabetes mellitus (GDM) management. Diet is the cornerstone treatment of patients with GDM, but its role in maternal and newborn outcomes has been scarcely studied. The purpose of this study was to evaluate the pregnancy outcomes of low carbohydrate diets in Japanese women with GDM.

Method: The study group comprised 337 Japanese women who had been newly diagnosed with GDM via a 75-g oral glucose tolerance test. The women chose either a low carbohydrate diet with 40–50 % of energy supply coming from carbohydrates (n = 322) or balanced diet (n = 15). The date collected included maternal characteristics, delivery characteristics, neonatal characteristics. All statistical analyses were performed using the statistical software, SPSS Version 21 for Windows.

Results: The median of the percentage of kilocalories from carbohydrate was significantly lower in the low carbohydrate diet group compared to that of the balanced diet group ($p < 0.01$). Pre-pregnancy BMI and glucose concentrations before implementation of the diet regimen did not differ between the groups. No differences were found in the obstetric and perinatal outcomes between the two groups.

Conclusion: Our results suggest that the low carbohydrate diets were not associated with perinatal abnormalities. The low carbohydrate diets are effective and safe. A diet with a carbohydrate limitation may be recommended as part of the nutritional management of pregnant women with GDM.

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Clinical Decision Support Systems/Advisors

ATTD8-0090

INSILICO STUDY EXAMINING INITIATION OF INSULIN GLARGINE U100 IN VIRTUAL SUBJECTS WITH T2DM

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Background and Aims: This insilico study examined the effectiveness of dose titration rules (TRs) for initiating insulin glargine U100 in patients with T2DM via a webtool.

Method: One hundred virtual T2DM subjects received initial dosing of insulin glargine 0.2 U/kg body weight to reach steady state insulin-on-board, then submitted fasting glucose measures (FBG) to the webtool daily and received dose recommendations for 4 months. The TRs titrated glargine doses to achieve a target BG range of 90–130 mg/dL (TR2), or 110-150 mg/dL (TR3). After reaching a stable dose (SD), (no adjustment for 10 days), and the target ranges (5 consecutive days with FBG in target), subjects experienced 2 consecutive days of exercise, illness and overeating to determine if the TRs maintained BGs in target. Efficacy measures included Time-to-target change in mean BG and HBGI, and number of hypoglycemia events.

Results: Three subjects experienced BG <70 mg/dL on the initial dose of weight-based insulin. Mean days to SD was 14 ± 18 (TR2) and 6 ± 12 (TR3); 98 and 96 subjects reached target range for TR2 and TR3 respectively, with an average time to target of 19 ± 18 days (TR2) and 14 ± 12 days (TR3). mean glucose was reduced from 186 mg/dL to 158 (TR2) and 168 mg/dL (TR3); HBGI was reduced from 9.7% to 5.7% (TR2) and 6.9% (TR3). Exercise, illness and overeating resulted in minimal dosing adjustments and no over-adjustment.

Conclusion: The webtool was effective in achieving BG targets without hypoglycemia in 2 weeks in virtual T2DM subjects and only minimal dose adjustments were observed related to the interventions.

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Clinical Decision Support Systems/Advisors

ATTD8-0009

IMPROVING THE AWARENESS OF THE HYPOGLYCEMIA ELECTRONIC ORDER SET AMONG PRIMARY PRACTITIONERS

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Background and Aims: The evaluation of pediatric hypoglycemia requires obtaining a time- sensitive critical blood

sample collected during the hypoglycemia episode to evaluate different hormonal axes.

Our aim was to increase the awareness of an electronic order set to evaluate hypoglycemia among primary practitioners in our children's hospital with resultant improvement in the efficiency of collecting the correct orders.

Method: We created a survey that was distributed to physicians. This survey used a scale of 1 to 10 to assess the baseline likelihood of initiating a work up for hypoglycemia before the pediatric endocrine consultation with 1 being the least likely and 10 being most likely.

We then reviewed the electronic order set demonstrating hormonal testing needed to be collected prior to correcting the hypoglycemia and demonstrated step-by-step screenshots on how to find and order the hypoglycemia order set.

We then repeated the survey after this teaching session to assess the practitioners' likelihood to start the hypoglycemia evaluation prior to the pediatric endocrinology consultation.

Results: The group had 31 physicians. Only four of them were aware of the electronic order set.

Baseline characteristics: The group's average likelihood to initiate the evaluation of hypoglycemia prior to obtaining a consultation was 6.2 on the 1 to 10 scale.

Following the teaching session: The group's average likelihood to initiate the evaluation of hypoglycemia prior to consultation was up to 8.7.

Conclusion: Physicians awareness of the availability of electronic order sets to obtain critical blood samples for hypoglycemia can increase their confidence in its management and improve the quality of care.

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Clinical Decision Support Systems/Advisors

ATTD8-0011

USING HEMOGLOBIN A1C AS AN INDICATOR OF PEDIATRIC DIABETES TRANSITION OF CARE BETWEEN INPATIENT AND OUTPATIENT SETTINGS

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Background and Aims: The Hemoglobin A1c (HbA1c) test is the most commonly used measurements in the assessment of diabetes glycemic control reflecting the average glycemic control over past 3 months and predict the occurrence of diabetes related complications.

The pediatric diabetes transition of care program was implemented at UT Physicians (UTP) to provide the continuum of care between the inpatient and outpatient settings. We evaluated the impact of the pediatric diabetes transition of care using HbA1c results.

Method: Pre and post study was conducted among diabetes ketoacidosis (DKA) patients. HbA1c level during hospitalization was compared with those at the outpatient follow-up visits.

Results: A total of 102 pediatric patients with type 1 and type 2 diabetes were followed through their hospital admission with DKA to their follow up clinic visits. Out of 102 patients, more than 99% had an age-adjusted high risk HbA1c in the hospital. This number went down to 91.1% at the first follow-up outpatient visit and 65.7% within 6 months of hospital discharge.

Conclusion: Under the transition of care, there was a significant improvement in HbA1c level. Testing HbA1c as an indicator of diabetes control and progression can provide an immediate feedback to the patient, family and physician regarding diabetes care. Comparing the HbA1c levels between inpatient and outpatient settings is a simple concept to educate the family about the improvement of diabetes control.

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Closed-loop System and Algorithm

ATTD8-0366

AUTOMATIC CONTROL OF BLOOD GLUCOSE LEVELS BY MODULATING RELEASE RATES OF INSULIN GLARGINE FROM ITS SUBCUTANEOUS INJECTION SITE

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Background and Aims: Real time control of basal insulin delivery is a key component in closed loop systems and therefore such systems are limited to patients on insulin infusion therapy.

Insulin Glargine is a frequently used basal insulin. Glargine is intended for once or twice daily injections into the SC tissue where it forms a drug depot from which it is slowly released to the circulation.

The aim of this study is to test the InsuTec system intended for automatic control of blood glucose levels by modulating the release rate of insulin Glargine from it's SC depot.

Method: Type I diabetic subjects were admitted and injected their usual Insulin Glargine dose. The InsuTec device, attached to the skin over the injection site, applies cooling or heating to decrease or increase the Glargine release rates following controller decisions based on CGM readings. Each subject completed two procedures, test and control.

Results: 12 type I subjects were included in this feasibility study. Overall, in the test arm patients spent more time in the target range (86% vs 76% n.s.). A sub analysis including only studies where low or high glucose levels were predicted in both test and control arms showed that patients on the test arm spent much more time in the target range (92% vs 66% $P < 0.05$).

Conclusion: The results indicate that the use of the insuTec system can reduce the risk of hyper and hypo glycemic events. A larger study in home settings is needed to further evaluate the potential of this system.

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Closed-loop System and Algorithm

ATTD8-0141

EXPLORATORY ANALYSIS FOR SELECTED PATIENTS WITH DAWN PHENOMENON DURING THE MINIMED™ 670G HYBRID CLOSED-LOOP PIVOTAL TRIAL

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Table. Overall average basal insulin, SG, and variability; and percentage of SG values across ranges during the 12:00am-6:00am, 12:00am-3:00am, and 3:00am-6:00am periods of the run-in and study phases, for individuals experiencing the dawn phenomenon in the MiniMed™ 670G Hybrid Closed Loop system pivotal trial.

		Overall Insulin and SG Averages and Variability				Percentage of SG values across ranges, mg/dL (mmol/L)		
		Basal insulin, units	SD Basal insulin, units	SG, mg/dL	SD SG, mg/dL	≤70 (≤3.8)	>70 – 180 (>3.9 – 10)	>180 (>10)
12:00am-6:00am	Run-in	0.08 (0.07, 0.05-0.09)	0.01 (0.01, 0.00-0.01)	8.2 (8.1, 7.3 - 8.9)	2.9 (3.1, 2.4 - 3.3)	6.4 (5.5, 2.8-8.9)	67.9 (69.5, 58.8-79.6)	25.7 (25.7, 14.4-34.9)
	Study	0.09 (0.07, 0.06-0.10)	0.06 (0.05, 0.04-0.07)	8.0 (8.0, 7.5 - 8.5)	2.6 (2.6, 2.2 - 2.9)	3.3 (2.7, 1.6-4.4)	77.3 (78.1, 72.9-85.1)	19.4 (19.1, 11.6-24.9)
	Change	0.01 (0.00, -0.00-0.01)	0.05 (0.04, 0.03-0.06)	-0.2 (-0.2, -0.7 - 0.5)	-0.3 (-0.4, -0.6 - 0.1)	-3.1 (-2.0, -5.6-0.0)	9.3 (9.0, 1.1-18.4)	-6.3 (-5.5, -14.7-2.5)
	p-value	0.00512*	<0.001*	0.14148	<0.001	<0.001*	<0.001	<0.001
12:00am-3:00am	Run-in	0.08 (0.06, 0.05-0.09)	0.00 (0.00, 0.00-0.00)	8.1 (8.0, 7.3 - 8.8)	2.9 (3.0, 2.4 - 3.4)	7.5 (6.3, 3.2-10.4)	66.8 (67.0, 58.5-77.4)	25.7 (25.5, 14.8-34.8)
	Study	0.09 (0.08, 0.05-0.10)	0.07 (0.05, 0.04-0.07)	8.2 (8.2, 7.7 - 9.0)	2.8 (2.7, 2.4 - 3.2)	4.0 (3.2, 1.9-5.4)	72.8 (74.3,65.3-80.3)	23.2 (22.0, 15.7-32.0)
	Change	0.01 (0.01, -0.00-0.02)	0.06 (0.05, 0.04-0.07)	0.1 (0.1, -0.6 - 1.0)	-0.2 (-0.2, -0.5 - 0.2)	-3.4 (-1.8, -7.9-0.5)	6.0 (4.4, -4.0-14.9)	-2.5 (-0.4, -12.3-6.6)
	p-value	<0.001*	<0.001*	0.32529	0.01487	<0.001*	<0.001	0.059
3:00am-6:00am	Run-in	0.08 (0.07, 0.06-0.10)	0.01 (0.00, 0.00-0.01)	8.3 (8.3, 7.4 - 9.0)	2.8 (2.8, 2.3 - 3.3)	5.2 (4.3, 1.5-8.2)	69.1 (69.1, 60.7-81.5)	25.7 (25.5, 13.5-33.1)
	Study	0.09 (0.07, 0.06-0.10)	0.06 (0.05, 0.04-0.06)	7.6 (7.8, 7.3 - 8.2)	2.4 (2.3, 1.9 - 2.6)	2.5 (1.8, 0.8-3.6)	81.9 (83.7, 76.3-89.6)	15.6 (14.1, 7.4-22.2)
	Change	0.00 (-0.00, -0.01-0.01)	0.05 (0.04, 0.03-0.06)	-0.4 (-0.4, -1.1- 0.3)	-0.5 (-0.5, -0.8 - -0.1)	-2.8 (-2.0, -5.4-0.6)	12.8 (12.4, 3.0-20.5)	-10.1 (-8.6, -17.7--1.1)
	p-value	0.81704*	<0.001*	<0.001	<0.001	<0.001*	<0.001	<0.001

All values are shown as mean (median, 25th percentile - 75th percentile).
*=Wilcoxon signed rank test.

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Background and Aims: Three-month use of the MiniMed™ 670G system reduced HbA1c and increased time in target range during 24-hour and night-time periods, in adults and adolescents with T1D. Due to marked variability in glucose and hyperglycemia, from night-time to early morning (i.e., dawn phenomenon, DP) in some individuals, the ability of the MiniMed™ 670G system to manage DP-related glycemia was investigated.

Method: A DP subject was identified when one of three criteria was met 25% of the time during the run-in phase: 1) Higher average SG of 10mg/dL (0.6mmol/L) during 3:00 am–6:00 am; 2) Increased basal rate of 10% during 3:00 am–6:00 am; 3) Increased basal rate of 0.5 unit during 3:00 am–6:00 am versus that during 12:00–3:00 am. The percentage of sensor glucose (SG) values in low, within-target (>70–180 mg/dL [>3.9–10 mmol/L]), and high ranges; and insulin variability from 12:00 am–6:00 am, 12:00 am–3:00 am, and 3:00 am–6:00 am of the run-in and study phases were analyzed.

Results: Eighty-two of 124 subjects experienced DP. Run-in basal insulin usage was significantly increased in DP versus Non-DP from 12:00–3:00 am ($p = 0.0338$). DP-subjects time within target for 12:00 am–6:00 am, 12:00 am–3:00 am, and 3:00 am–6:00 am improved from 67.9% to 77.3%, 66.8% to 72.8, and 69.1% to 81.9%, respectively. SG improved most during 3:00–6:00 am (8.3 ± 1.3mmol/L to 7.8 ± 0.7mmol/L); insulin delivery changed most during 12:00–3:00 am (0.09 to 0.01unit). The table shows results for all subjects meeting DP criteria.

Conclusion: DP subjects displayed improved overnight-to-early morning glycemic control during the HCL pivotal trial supporting use of the MiniMed™ 670G system in the management of marked glycemic variability in these patients.

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Closed-loop System and Algorithm

ATTD8-0308

STUDY DESIGN OF RANDOMIZED, ADAPTIVE TRIAL IN ADULT AND PEDIATRIC PATIENTS WITH TYPE 1 DIABETES USING HYBRID CLOSED LOOP VERSUS CONTROL (CSII, MDI OR SAP)

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Background and Aims: To report the design of a prospective randomized trial in patients with T1D that compares outcomes with use of the MiniMed™ 670G HCL insulin delivery system versus outcomes of other therapy use (CSII, MDI, or SAP).

Method: This is a 6-month randomized adaptive study in subjects (aged 2-80 years) with T1D, with multiple-cohorts (CSII, MDI, and SAP) and a 6-month continuation period with HCL. After blinded CGM at baseline run-in, participants will be randomized to use the MiniMed™ 670G system or remain on their current therapy. The co-primary effectiveness endpoints are change in HbA1c among Group 1(Baseline HbA1c >8%) and time in hypoglycemic range among Group 2(Baseline A1c ≤ 8%). If superiority is established, key secondary endpoints including time in range among Group 1 and change in HbA1c among Group 2 will be evaluated with non-inferiority tests. Safety endpoints include diabetic ketoacidosis (DKA), severe hypoglycemia, severe hyperglycemia, serious adverse events (SAEs), and unanticipated adverse device effects (UADEs). A Data Safety Monitoring Board will review safety data throughout the study and interim analysis will be performed for primary effectiveness endpoints by cohort (CSII, MDI, or SAP) to allow for adjustment in sample size. The study will enroll approximately 1120 subjects at over 70 centers.

Results: As of October 25, 2017, 73 subjects were enrolled in the first cohort, CSII.

Conclusion: This study will assess the safety and effectiveness of the MiniMed™ 670G HCL insulin delivery system, compared to CSII, MDI, or SAP control.

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Closed-loop System and Algorithm

ATTD8-0154

DOES A HYBRID-CLOSED LOOP SYSTEM REDUCE OVERNIGHT ALARMS IN PATIENTS WITH TYPE 1 DIABETES?

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Background and Aims: It is unknown how the use of hybrid closed-loop will affect sleep. This retrospective review was done to assess overnight alarms.

Method: Twenty-seven subjects, 5 to 20 years, with type 1 for >2 years and HbA_{1c} <10% were recruited to Medtronic™ 670G pump studies at Stanford. There was a 2-week run-in period (open-loop) before starting on hybrid closed-loop for 3 months.

	Average # of events/night		
	Open Loop	Closed Loop	P-Value
Total number of alarm events	2.33±1.07	1.7±0.70	**0.03**
Number of alarm events WITHOUT intervention	1.35±0.72	1.25±0.50	0.56
Number of alarm events WITH intervention	0.98±0.66	0.54±0.35	**0.003**
Alarms due to hypoglycemia	0.79±0.66	0.22±0.32	**<0.001**
Alarms due to hyperglycemia	0.65±0.72	0.37±0.36	0.08
Sensor Alarms	0.83±0.66	0.90±0.51	0.99
Pump alarms	0.05±0.10	0.34±0.34	**<0.001**
Interventions without alarm	0.60±0.52	0.39±0.29	0.07

Information on overnight alarms from the system and interactions with the system (meter readings and insulin boluses) were collected for one week in open-loop and for one week a month after initiation of closed-loop. Sleep was defined as the time between midnight and the first morning insulin bolus. Alarm events were defined by 30 minutes separating alarms.

Results: Overall the closed-loop system decreased the number of alarm events by 27%, and the number of events requiring an intervention by 45%; predominately due to a 73% reduction in hypoglycemic alarm events, but there was also a 43% reduction in hyperglycemic events and a 35% reduction in interventions without an alarm (meter test or insulin bolus). There was, however, an 85% increase in pump alarms in closed-loop (mainly for exiting auto-mode, and minimal insulin delivery). Subjects were able to adjust their sensor hyper and hypo alarms, and between the two periods of analysis 88% made changes to their settings (65% of these changes could lower alarm frequency and 35% could increase alarm frequency). (table)

Conclusion: Hybrid closed loop is associated with a significant decrease in overall nocturnal alarm events and alarms requiring intervention.

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Closed-loop System and Algorithm

ATTD8-0343

HYPOGLYCEMIA PREVENTION IN CLOSED-LOOP GLYCEMIC CONTROL VIA CONSTRAINTS IN THE GLUCOSE SLOPE

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Background and Aims: Within the development of closed-loop glucose controllers one of the major risks is the insulin induced hypoglycemia that can be produced due to controller overreaction.

Here a supervisory methodology is proposed for the prevention of hypoglycemia, which differs from previous work (Revert et al., IEEE TBME 2013) by considering a limitation on the controlled variable or output of the system.

Method: The GSAFE (Glucose-based Safety Auxiliary Feedback Element) is a security layer based on the Sliding Mode Reference Conditioning technique. By means of a reduced-order glucose estimator, the GSAFE modifies the reference of the main controller to regulate the slope with which the glucose decreases, thereby limiting the insulin delivered by the controller as it can be seen in the illustrative figure below. The proposed technique can be applied to any control algorithm, both PID and MPC.

Results: The algorithm was tested in a platform based on the UVa/Padova T1D Simulator (3-meals scenario with varying insulin sensitivity) with the controller given in Palerm CMPB 2011. Preliminary results show that the amount of hypoglycemic events and time spent in hypoglycemia were considerably reduced when applying the GSAFE, even for aggressive controller configurations. In particular, low glucose values were avoided in the late postpandrial period.

Conclusion: The promising in-silico results obtained with the novel GSAFE methodology allow considering it as a potential safety layer for hypoglycemia prevention in the next clinical trials in Argentina, after the first and successful trial carried out in June 2017 without carbohydrates counting.

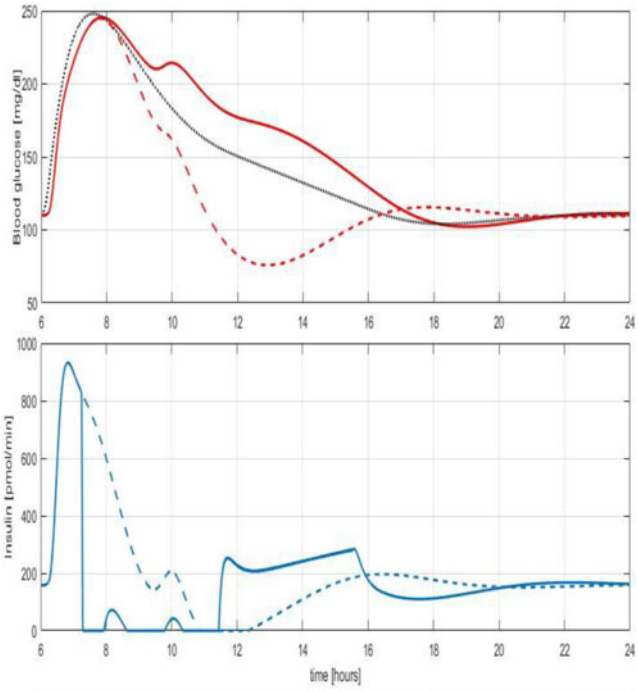

Figure: GSAFE operation over the controller given in Palerm CMPB 2011. Upper panel: blood glucose level with (solid line) and without (dashed line) GSAFE and estimated glucose (dotted line). Below: insulin delivered by the closed-loop controller with (solid line) and without GSAFE (dashed line).

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Closed-loop System and Algorithm

ATTD8-0240

REAL-WORLD ASSESSMENT OF FORMER MDI PATIENTS' EXPERIENCE ON THE MEDTRONIC MINIMED™ 670G HYBRID CLOSED-LOOP SYSTEM

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Background and Aims: The real-world experience of patients transitioning from Multiple Daily Injections (MDI) therapy to the Medtronic MiniMed™ 670G system, the world's first hybrid closed-loop diabetes management system was assessed. These patients were part of a Customer Training Phase (CTP), wherein a limited number were exposed to the product before commercial launch.

Method: 47 former MDI patients on the system completed an online Medtronic-developed survey that evaluated their product and training experience, and satisfaction with the product overall. This abstract represents results from the patients using the system for 8 weeks.

Results: Most patients reported that the system met/exceeded expectations with respect to overall health (98%), perceived better A1C (98%), improved blood glucose control (96%), more time in range (96%), overall system expectations (91%), and fewer lows (91%). Patients felt confident in their ability to use the system (91%), and trusted that the SmartGuard™ Auto Mode feature could help manage their glucose levels (85%).

After 8 weeks of system use, all participants using the system expressed having a positive experience in various dimensions of living with diabetes: treating lows and symptoms (83%), not affected by limited energy levels (81%), reduced concerned

about long term complications (79%), and reduced burden around food restrictions (>70%).

Conclusion: Results indicate that former MDI patients had high satisfaction with the Medtronic MiniMed^{TM}670G system and their training. This suggests that patients can transition successfully from MDI to hybrid closed-loop therapy.

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Closed-loop System and Algorithm

ATTD8-0241

SLIDING MODE REFERENCE CONDITIONING DUAL HORMONE COORDINATED GLUCOSE CONTROL

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Background and Aims: A dual hormone closed-loop system for automatic insulin and glucagon delivery has the potential to improve glycaemic control in type 1 diabetes patients, reducing the risk of hypo- and hyperglycaemia. In this work, we present a novel sliding mode reference conditioning (SMRC) coordinated dual hormone artificial pancreas system.

Method: Insulin-glucagon coordination was based on the Habituating Control strategy (HC) to which a SMRC external loop was added to account for insulin-on-board (IOB) limitation. Single hormone (SH) and dual hormone (DH) SMRC controllers were compared. An *in silico* study using an FDA-accepted type 1 simulator enhanced with additional variability and exercise was performed to evaluate the proposed coordinated control strategy compared to its single hormone counterpart. Two 1-day scenarios were simulated: scenario (1), without exercise; scenario (2), with exercise.

Results: In scenario (1), time in hypoglycaemia for the DH controller was 0.44% vs. 2.76% in the SH configuration. Time in euglycaemia was 96.65% in DH vs. 95.33% in SH. However, the total insulin delivered was slightly greater in the DH one (46.07U vs 47.22U) but not statistically significant ($p > 0.05$). Regarding scenario (2), time in hypoglycaemia was even more significantly reduced in DH compared to SH (1.52% vs. 5.15%). Moreover, time in range for DH configuration was 93.53% vs. 92.53% in the SH. Total glucagon delivery was 0.2352mg in the scenario (1) and 0.3220mg in scenario (2).

Conclusion: The coordination strategy proposed achieves a reduction of hypoglycaemia and improves the time in range with the same total insulin delivery as SH.

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Closed-loop System and Algorithm

ATTD8-0219

PERSONALISED ADAPTIVE BASAL-BOLUS ALGORITHM USING SMBG/CGM DATA

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	Blood Glucose	% in range 70-180 mg/dL	% < 70 mg/dL	% > 180 mg/dL	TDI
A. Adults					
ABBA_CGM	136.76±16.73	90.61±12.46	0.15±0.28	9.25±12.5	43.29±11.06
ABBA_SMBG	139.26±18.49	89.09±14.82	0.1±0.3	10.81±14.86	42.71±10.3
p-value	0.0640	0.0949	0.5711	0.0952	0.1280
B. Adolescents					
ABBA_CGM	143.5±10.48	81.07±9.49	1.12±2.65	17.82±9.02	31.45±6.49
ABBA_SMBG	139.81±13.76	82.5±11.97	1.45±2.92	16.04±12.1	31.95±6.89
p-value	0.3394	0.2973	0.6407	0.3431	0.3231
C. Children					
ABBA_CGM	145.58±13.53	82.25±10.19	0.57±1.06	17.18±9.46	15.95±4.07
ABBA_SMBG	143.79±7.57	83.9±6.92	0.4±0.61	15.7±6.41	16.09±3.81
p-value	0.5102	0.4614	0.4471	0.4851	0.4547

α=0.05

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Background and Aims: Most individuals with Type 1 diabetes (T1D) employ either devices for self-monitoring of blood glucose (SMBG) or continuous glucose monitors (CGMs) to measure glucose concentrations. The aim of this study is to introduce an algorithmic approach for estimating the basal and bolus insulin to be delivered by a pump, in a personalised and adaptive manner, independent of the glucose monitoring devices used.

Method: The proposed adaptive basal-bolus algorithm (ABBA) is based on reinforcement learning (RL), a type of artificial intelligence (AI) algorithm, to optimise the insulin to be delivered to individuals with T1D, independently of the their glucose monitoring device. The ABBA uses glucose information from the same day to output the basal rate and three CIRs - for breakfast, lunch and dinner - for the next day. The algorithm was evaluated *in silico* with FDA approved UVa/Padova T1DM Simulator v3.2 with 33 virtual subjects. The total simulation duration was 98 days, with the last 7 days for evaluation. The scenario involved three main meals and one bedtime snack per day, along with different variabilities for insulin sensitivity, mealtime and carbohydrate amount. Furthermore, uncertainty was introduced to simulate the error when the patient estimates the meal's carbohydrate content. Both variabilities and uncertainty follow uniform distributions.

Results: The proposed system achieves comparable performances for CGM and SMBG input signals, without affecting the total daily insulin dose.

Conclusion: The implementation of the system will offer diabetic patients the possibility of personalised adaptive insulin administration and glucose control, independently of the glucose monitoring device used.

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Closed-loop System and Algorithm

ATTD8-0216

A NEW APPROACH IN ZONE MODEL PREDICTIVE CONTROL FOR TYPE 1 DIABETES TO BE TESTED IN COLOMBIA

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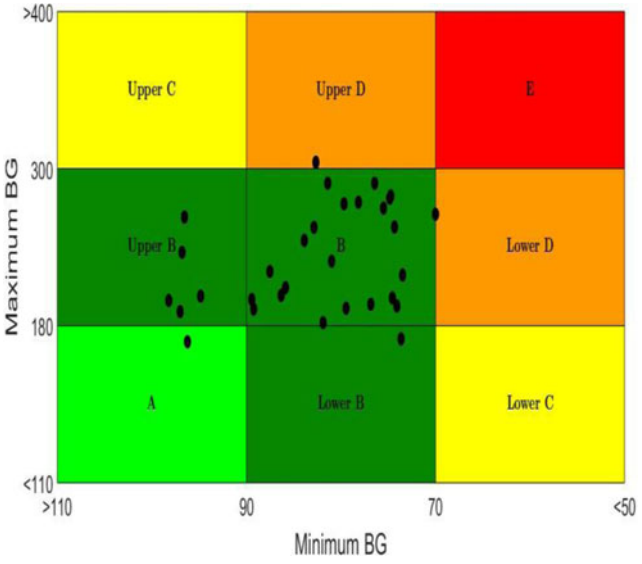

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Background and Aims: Nowadays, model predictive control (MPC) has been the most developed strategy for the artificial pancreas. However, the proposed strategies are developed based on linearizations without physiological meaning and do not guarantee the achievement of glucose targets. Here, a zone mpc (ZMPC) using a slack variable is proposed based on a simple model but with a physiological interpretation.

Method: The ZMPC is evaluated using 33 virtual patients from the UVA/Padova simulator. The virtual protocol considers a simulation of 2 days and 3 meals per day without meal announcement. The protocol starts at midnight with a 140 mg/dl glucose value. 50 g, 80 g, and 60 g meals are given at 7 h, 14 h and 20 h, respectively and repeated the next day. The total simulation time is 55 h. The performance is compared to previous results through statistical and control variability grid analysis.

Results: The figure shows the performance of the proposed ZMPC. 88.74 % of CGM sensor readings remain inside [70 - 180] mg/dl, against the 77.7 % reported in [1]. The proposed strategy has 1 case of hypoglycemia and 1 of hyperglycemia, while zero cases of hypoglycemia and 7 cases of hyperglycemia are reported in [1].

Conclusion: The strategy results show better performance than others registered in literature. This ZMPC algorithm will be under clinical evaluation in 2018. This trial will be the first one in Colombia.

[1] K. van Heusden and *et al.*, Control-relevant models for glucose control using a priori patient characteristics, IEEE transactions on biomedical engineering, 59(7): 1839–1849, 2012.

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Closed-loop System and Algorithm

ATTD8-0064

MINIMED™ 670G PIVOTAL TRIAL: TIMING OF MEAL BOLUS PLAYS A CRITICAL ROLE IN POSTPRANDIAL GLUCOSE CONTROL

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Table 1: The timing of meal bolus may have contributed to glucose levels during the postprandial (up to 5 hrs post-meal) period. The rate of change (ROC) columns labeled Stable (ROC <0.5 mg/dL/min); Rising (ROC >1 mg/dL/min); and Fast Rising (ROC >2 mg/dL/min) indicate the sensor glucose trend at the time of meal bolus. The table represents Auto Mode data only.

Items	Stable (ROC <0.5 mg/dL/min)	Rising (ROC >1 mg/dL/min)	Fast Rising (ROC >2 mg/dL/min)
Assumption	Bolus delivered prior to meal consumption	Bolus delivered after/during meal commencement	Bolus delivered after/during meal commencement
Number of meal events	3,580	403	98
Average carb-to-insulin ratio, grams/unit	9.5 ± 3.7	8.8 ± 3.2†	8.3 ± 3.2‡
Average postprandial SG peak, mg/dL	187 ± 40	201 ± 40†	214 ± 44‡
Average postprandial SG AUC >180 mg/dL, min × mg/dL	1,284 ± 2,841	1,829 ± 3,185†	2,588 ± 3,727‡
Average postprandial SG time >180 mg/dL, min	42 ± 60	57 ± 67†	68 ± 71‡

All values, except 'Number of meal events', are shown as mean ± SD.
† *Indicates significance in p-value, between Stable (ROC <0.5 mg/dL/min) and Rising (ROC >1 mg/dL/min) groups.*
‡ *Indicates significance in p-value, between Stable (ROC <0.5 mg/dL/min) and Rising (ROC >2 mg/dL/min) groups.*

Background: The Auto Mode feature of the Medtronic MiniMed™ hybrid closed-loop system automatically adjusts basal insulin delivery every 5min based on sensor glucose (SG) values. Patients are required to calibrate the sensor, enter meal carbohydrate estimates, and notify the system of exercise. The pivotal trial data of the system were analyzed to study the effect of meal bolus timing on postprandial SG levels.

Method: The study protocol comprised a 2-week Manual Mode run-in phase followed by a 3-month in-home Auto Mode study phase. There were 124 type 1 diabetes patients (aged 14–75yrs) who participated in the 10-center trial. A total of 4,011 meal events during the study phase were divided into 3 groups based on the rate of change (ROC) of SG at meal-bolus time: A Stable SG Group (ROC <0.5 mg/dL/min) indicating bolus delivered before meal consumption; a Rising SG Group (ROC >1 mg/dL/min) and a Fast Rising SG Group (ROC >2 mg/dL/min). For both latter groups, bolus delivery during or after meal consumption was assumed.

Results: The table lists data from the three groups. For the 'Stable Profile', postprandial SG-peak, AUC >180 mg/dL, and time spent >180 mg/dL were significantly lower than those in the other two groups. This occurred despite the more aggressive mean carb-to-insulin ratios in the two Rising SG Groups.

Conclusion: These postprandial data demonstrate that meal bolus timing has a significant effect on the postprandial glycemic outcome. Initiating MiniMed™ 670G system meal bolus delivery prior to meal consumption remains the recommendation during Auto Mode.

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Closed-loop System and Algorithm

ATTD8-0231

MODELING GLUCOSE REGULATION IN POSTPRANDIAL INTERMITTENT HIGH INTENSITY EXERCISE WITH T2DM PATIENTS

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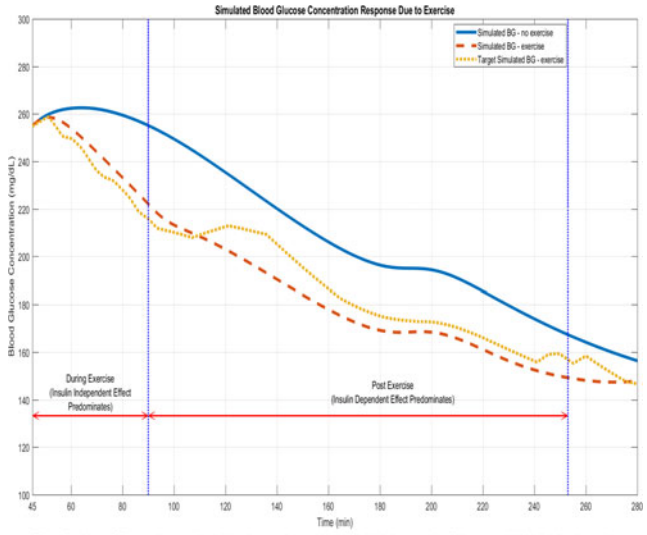

Figure 1 Blood glucose (BG) concentration curves with: simulated values, assuming no exercise (blue); simulated values, assuming a 45-minute postprandial high intensity intermittent exercise session, applying our model for insulin independent and dependent utilization effects (red); values targeted by our modeling process, based on published data (yellow).

Background and Aims: We attempted to create a mathematical model representative of exercise's acute effects in type 2 diabetic people, in a way that supports integration into the metabolic model defined by Dalla Man. This effort was limited to modeling effects during and within a few hours following a single postprandial, intermittent, high intensity session.

Method: We examined data from publications describing exercise's effects on glucose regulation, primarily those involving high intensity exercise in type 2 subjects. We attempted to reproduce observed glucose responses by modeling the underlying causes, shown in the literature to be changes in endogenous glucose production (EGP) and glucose utilization. Interpreting the data in the context of Dalla Man's model allowed us to distinguish portions of glucose utilization due to insulin dependent vs. independent effects. Using analytical techniques and optimization methods within the Diabetes Mellitus Metabolic Simulator (DMMS.R, The Epsilon Group), we established time profiles, spanning several hours, for variations in model parameters governing EGP and both utilization types.

Results: Simulations with the DMMS.R showed that when exercise begins 45 minutes after a meal, modeling the two utilization effects was sufficient to match the exercise-induced glucose concentration impact over time, as seen in the literature, with an RMS error of 7.3mg/dL and correlation $R > 0.98$.

Conclusion: An exercise model, spanning a few hours, of the glucose response to postprandial intermittent high intensity exercise, has been defined and incorporated into a simulator based on Dalla Man's metabolic model. More investigation involving EGP effects would be useful in defining a more general, longer term model.

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Devices Focused on Diabetic Preventions

ATTD8-0404

ASSOCIATION BETWEEN VISCERAL FAT AND FINISH DIABETES RISK SCORE (FINDRISC) IN SONS AND DAUGHTERS OF PATIENTS WITH T2DM TREATED AT DIABETES CARE CENTRE IN INDIA

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Background and Aims: Visceral fat mass has stronger associations with diabetes and pre-diabetes. The FINish Diabetes RIsk SCore (FINDRISC) helps in identifying the 10-year risk of developing diabetes and pre-diabetes. It is our hypothesis that Visceral Fat (VF) has strong correlation with FINDRISC along with its obesity parameters such as body mass index (BMI) and waist circumference.

Aim is to analyse the correlation between VF and FINDRISC in subjects with diabetic parents who were treated at a diabetes care centre and its contribution in prediction of pre-diabetes and diabetes.

Method: The study is an ongoing prospective analysis of 222 subjects over a one year period. VF by BIOELECTRICAL IMPEDANCE ANALYSIS and FINDRISC was determined. Subjects were divided into two risk groups; low-slightly elevated (<7–11) vs. moderate-high (12–>17) according to FINDRISC and association between variables was measured.

Results: When subjects were categorized according to FINDRISC, those at higher risk (>12) had higher values for components that add points to the score such as blood pressure ($p < 0.0001$), VF ($p < 0.0001$), age ($p = 0.010$), BMI ($p < 0.0001$) and waist circumference ($p < 0.0001$).

Pearsons correlation analysis showed significant correlation between FINDRISC was observed with BMI ($r = 0.590$; $p < 0.0001$), waist circumference ($r = 0.585$; $p < 0.0001$) and VF ($r = 0.567$; $p < 0.0001$).

Conclusion: In subjects with diabetic parents, visceral fat is significantly associated with an increase in FINDRISC. Early detection of high risk population for pre-diabetes or T2DM using BIOELECTRICAL IMPEDANCE ANALYSIS for VF in combination with FINDRISC is a promising mode of preventive diabetes medicine. Timely lifestyle interventions along with counselling will empower high risk individuals for self-management.

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Devices Focused on Diabetic Preventions

ATTD8-0197

SERUM IRAP: A NOVEL BIOMARKER FOR THE DIAGNOSIS OF INSULIN-RESISTANCE

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Background and Aims: Insulin resistance (IR) is estimated to affect more than half of the adult population worldwide. Type 2 diabetes (T2D), which usually follows in the absence of treatment, affects more than 400 million people worldwide and represents more than 15 % of the health budget in industrialized countries. Nevertheless, the majority of individuals affected by IR and ≥20 % of those affected by T2D are not diagnosed.

There is indeed no simple and reliable test for the diagnosis or screening of IR.

The aim of this project was to develop such a test.

Method: We developed a sandwich ELISA, using two monoclonal antibodies and recombinant human IRAP, for the quantitative determination of a novel circulating biomarker of IR, IRAP. IRAP (Insulin-Regulated AminoPeptidase) is translocated together with GLUT4 to the plasma membrane in response to insulin and its extracellular domain is subsequently cleaved and secreted in the bloodstream. In T2D, IRAP translocation in response to insulin is strongly decreased.

Results: Our patented sandwich ELISA is highly sensitive (10 ng/ml; reference range: 101.4 ± 15.9 μg/ml), specific, robust

and cost-effective. Results of various pilots studies indicate a close correlation of IRAP with insulinemia and glycemia in eumetabolic but a complete discordance in T2D.

Conclusion: IRAP is the first direct marker of insulin sensitivity and its quantitative determination should allow the screening of populations at risk for IR and T2D, i.e. around one billion individuals in the industrialized countries alone. IRAP should be of particular interest for the screening of overweight children, adolescents and pregnant women.

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Devices Focused on Diabetic Preventions

ATTD8-0211

EFFECTS OF BETA CELL FUNCTION RELATED GENETIC VARIANTS ON PREDICTING DETERIORATION OF GLUCOSE TOLERANCE IN A 9-YEAR PROSPECTIVE COHORT STUDY IN THE CHINESE

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Background and Aims: The relative contribution of beta cell function and insulin sensitivity in the pathogenesis of type 2 diabetes (T2D) are not fully understood. We investigated the role of genetic variants of beta cell function in deterioration of glucose tolerance, from a 9-year prospective cohort in the Chinese population.

Method: We first genotyped 89 T2D susceptible loci in an established cross-sectional Chinese population (N = 6822), and then we selected the 40 SNPs associated with T2D in the Chinese ($P < 0.05$). Of 40 SNPs, 12 were correlated with pancreatic beta cell function indicated by Stumvoll 1st or 2nd phase insulin secretion or HOMA-beta indices in individuals with normal glucose tolerance (NGT). Then, an Insulin Secretion genetic risk score model (IS-GRS) was constructed to assess its predicting effects on incidence rate of T2D and impaired glucose regulation (IGR) in a 9-year prospective cohort (N = 2495), including 2192 NGT and 303 IGR patients at baseline through Logistic, Cox and multiple linear regression tests.

Results: During 9-year follow-up, 260 and 326 developed T2D and IGR, respectively. IS-GRS predicted incidence of T2D and IGR in the logistic regression (OR 1.236, 95% CI 1.094–1.395, $P = 0.0006$) as well as in the Cox model (HR 1.038, 95% CI 1.002, 1.078, $P = 0.0410$) after adjusting for covariates. In addition, IS-GRS was significantly associated with change in beta cell function during follow-up ($P = 0.0259$, $P = 0.0083$ for Stumvoll 1st and Stumvoll 2nd index, respectively).

Conclusion: IS-GRS could predict deterioration of glucose tolerance in the Chinese. Chinese population are susceptible to T2D due to their poor beta cell function.

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Devices Focused on Diabetic Preventions

ATTD8-0414

A SELF-ADMINISTERED HOME OGTT TEST KIT - COMPARISON TO LABORATORY BASED OGTT USING VENOUS PLASMA AND THE YSI 2300 REFERENCE ANALYSER

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Background and Aims: A new Home OGTT test kit uses fingerprick blood samples to perform a 2 hour OGTT procedure and record test data for subsequent analysis. The procedure is self-administered conveniently at home. Test data captured by the disposable OGTT device can be sent using a smartphone to a cloud-based server for analysis, with results sent to the healthcare professional for interpretation.

Aims: To establish correlation of Home OGTT with corresponding venous plasma samples measured by a YSI 2300 laboratory reference analyser.

Method: Women aged 18 to 47 years underwent a standard 2 hour OGTT procedure using a 75 gram glucose load. Corresponding fingerprick capillary blood and venous plasma samples were taken. Capillary blood was added to the OGTT device and venous plasma analysed within 5 minutes using a laboratory YSI analyser.

Results: Data from the first 31 participants were used to establish the required fasting adjustment*. Adjusted fasting samples and 2 hour unadjusted samples from the Home OGTT showed correlations (R2) of 0.96 with the reference analyser. Fasting bias was −0.091 mmol/l and 2 hour bias −0.12 mmol/l. Further data will be presented for the full sample set.

*In other studies fasting capillary samples provide lower glucose values than venous plasma. For Home OGTT an adjustment of 20% is applied to the fasting samples.

Conclusion: Home OGTT using capillary blood shows excellent correlation and low bias compared to laboratory YSI venous plasma. Ease of use and patient acceptability have been demonstrated in previous studies. Home OGTT offers an accurate and convenient alternative to clinic-based OGTT.

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Devices Focused on Diabetic Preventions

ATTD8-0121

ANTIOXIDANT STATUS AND RISK OF GESTATIONAL DIABETES MELLITUS : A CASE-CONTROL STUDY

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Introduction: Gestational diabetes mellitus (GDM) is described as glucose intolerance diagnosed during pregnancy. Increased oxidative stress has implicated in diabetic problems. The relationship between gestational diabetes mellitus [GDM] and oxidative stress is not well known, and the importance of the oxidant/antioxidant equilibrium in the clinical evolution and its complications require elucidation The aim of the current study was to compare antioxidant capacity and antioxidant nutrient intake between women with GDM and healthy pregnant women.

Method: Demographic data were collected using interview technique and dietary intakes by using a semi-quantitative Food Frequency Questionnaire. Total antioxidant capacity (TAC) of serum was assessed by (ELISA) method. Statistical Analysis was done by SPSS 20.

Results: The results showed that TAC concentration of serum in women with GDM was significantly lower than in healthy

pregnant women (2.3 ± 0.7 vs. 3.7 ± 0.1 μmol/L, p < 0.001). Intakes of vitamin E (11.8 + 3.1 vs. 16.2 + 3.1 mg, p < 0.001), selenium (81 ± 26 vs.95 ± 36 μg, p < 0.05) and zinc (7.4 ± 1.9 vs. 9.1 ± 1.7 mg, p < 0.001) were significantly lower in women with GDM as compared to healthy pregnant women. In contrast, the groups showed no significant differences about vitamin C, β-carotene, selenium, fruit, and vegetable intake.

Conclusion: Our findings showed that antioxidant capacity is lower in women with GDM, possibly related to lower intakes of vitamin E and zinc. These results suggest that promotion in antioxidative status in pregnancy, may have considerable effect in GDM prevention.

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Devices Focused on Diabetic Preventions

ATTD8-0295

THE INFLUENCE OF HEALTH BELIEF MODEL COMPONENT ON SELF EFFICACY AMONG PATIENTS WITH TYPE 2 DIABETES

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Background: increasing of the number of patients with diabetes in the world has become the disease the world's largest epidemic. The patient's self-efficacy is a key element in the prevention and treatment of diabetes. This study aimed to assessing the Influence of Health Belief Model component on Self Efficacy among patients with type 2 diabetes.

Methods: This study was a cross sectional on which 80 persons referee to Iranian Diabetes Association in 2013–2014 were selected by convenience non-randomly method. Instrument of data gathering was a two part one included demographic variables (9 items) and self-administered diabetes assessment based on HBM (51 items). Data was analyzed with SPSS software version 18 using independent t-test, ANOVA and person correlation coefficient. Significant level was set at 0.05.

Results: Mean and SD of participant age was 55.16 ± 8.89 years. Mean and SD of perceived threat and cues to action were the most and the least on (60.42 ± 31.08) and (49.64 ± 18.76) respectively. Self-Efficacy had significant relation with perceived threat, cues to action and perceived benefits and barriers. Perceived barriers among various structures had the greatest impact on patients' self-efficacy.

Conclusion: Based on the results in this study perceived barriers who had their effectiveness overshadows that. So Health Education and promotion interventions to Improving patient's perceive about barriers and Enhance their ability to solve problems leads to improving self-esteem and self-worth is suggested as a necessary step toward Self Efficacy promotion.

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Devices Focused on Diabetic Preventions

ATTD8-0217

EFFECTS OF INSULIN RESISTANCE RELATED GENETIC VARIANTS ON PREDICTING GLUCOSE DETERIORATION IN A CHINESE 9 YEAR PROSPECTIVE COHORT STUDY

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Background and Aims: The relative contribution of beta cell function and insulin resistance in the pathogenesis of type 2 diabetes (T2D) are not fully understood. We investigated the role of genetic variants of insulin resistance in predicting glucose deterioration in a Chinese 9-year prospective study.

Method: We first validated 89 loci associated with T2D in a Chinese case-control study (N = 3410 for cases and 3412 for controls), and selected 40 SNPs ($P < 0.05$) to assess their association with insulin resistance in controls. 6 SNPs were associated with insulin resistance indicated by GUTT-ISI or HOMA-ISI. Then, we constructed an insulin resistance genetic risk score model (IR-GRS) consisting of the alleles negatively correlated with insulin sensitivity and evaluated its predicting effects on incidence of T2D and impaired glucose regulation (IGR) in a Chinese 9-year prospective study (N = 2495, including 2192 normal glucose tolerance [NGT] and 303 IGR individuals at baseline). Logistic, Cox and multiple linear regression tests were performed.

Results: 6 SNPs were correlated with insulin resistance indicated by GUTT-ISI or HOMA-ISI index. During 9-year follow-up, 260 individuals developed T2D and 326 developed IGR, respectively. IR-GRS could not predict incidence of T2D and IGR in the logistic regression (OR = 1.004, $P = 0.9466$) and in the Cox model (HR = 1.068, $P = 0.2750$) after adjusting for age, sex, body mass index (BMI) at baseline. In addition, IR-GRS could not predict change in insulin sensitivity during follow-up ($P = 0.5387$ and $P = 0.5148$ for GUTT-ISI and HOMA-ISI index, respectively).

Conclusion: IR-GRS could not predict glucose deterioration in the Chinese. Chinese population susceptible to T2D may not due to insulin resistance.

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Glucose Sensors

ATTD8-0410

IMPACT OF EXTENDING THE USE LIFE AND NOT CALIBRATING AS REQUIRED ON ACCURACY OF CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background and Aims: Continuous glucose monitoring (CGM) systems are designed to report glucose results over a claimed use life of the sensor and typically require finger-stick calibrations to achieve claimed accuracy. This study evaluated the impact of performing the calibration only at the start-up and extending the use life beyond the product label-indicated 7-days on the accuracy of Dexcom G4® Platinum CGM system with 505 software (G4 system).

Method: A total of 46 subjects wore two G4 sensors and one FreeStyle Libre™ sensor. One of the G4 sensors was calibrated per instructions for use while the other was only calibrated at start-up using FreeStyle Libre built-in blood glucose meter. At the end of the indicated use life of 7 days, the G4 sensors were reinitiated and continued to be worn for additional 7 days with the same calibration scheme as that of the previous 7-days of wear. Subjects performed 8 capillary blood glucose (SMBG) measurements per day which served as reference for accuracy evaluation.

Table: Accuracy parameters of CGM systems under different use conditions

Sensor	Calibration	Sensor Wear Days	Mean Bias(%)	MARD (%)	% Within 20mg/dL/20%,	N
FreeStyle Libre	n/a	1-14	-1.0	11.9	84.9	3392
G4 Platinum	Per label	1-7	-1.8	11.0	88.1	2169
		8-14	-6.8	13.2	81.2	2192
	At Start up only	1-7	12.4	18.9	67.6	2082
		8-14	-14.8	20.2	57.0	2121

Results: Table below shows the accuracy parameters of G4 systems and FreeStyle Libre under different use conditions when compared to SMBG reference.

Conclusion: When the CGM system is not calibrated as required or is used beyond the indicated use life, the accuracy is significantly compromised. Therefore, it is vital for the patients to understand the importance of using CGM systems within the manufacturers specifications.

Funding: The study was funded by Abbott Diabetes Care, USA.

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Glucose Sensors

ATTD8-0076

PERFORMANCE OF A NON-INVASIVE GLUCOSE MONITORING DEVICE: ACCURACY AND PRECISION

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Background and Aims: GlucoTrack® is a non-invasive glucose monitoring device for home-use that tracks glucose-related physiological changes by measuring acoustic impedance, electromagnetic impedance and heat capacity of the earlobe tissue. This study evaluated the accuracy and precision of GlucoTrack.

Method: Device accuracy was assessed in 37 people with type 2 diabetes. Seven paired invasive-GlucoTrack measurements were obtained from each subject. Clinical accuracy was assessed using Consensus error grid for type 2 and numerical accuracy was assessed using absolute relative difference (ARD). Sensor-to-sensor precision was evaluated using precision absolute relative difference (PARD) calculated on 20 people performing simultaneous measurements using two devices placed on each earlobe. Measurement precision was evaluated in 20 people undergoing 1 to 7 sequences of 4 to 11 invasive-GlucoTrack measurements performed with 10-minutes intervals under stable glycemic conditions ($\sim$3 hours postprandial). The coefficient of variation (CV) of sequential measurements was calculated.

Results: 99.6% of 257 measurements were in the clinically acceptable A and B zones of the Consensus error grid, with 90.3% of the measurements in zone A. Mean and median ARD were 17.2% and 12.9%, respectively. 841 pairs of measurements obtained from two devices worn in parallel revealed a mean PARD of 7.92% $\pm$ 0.64%, which was comparable across postprandial periods and glucose concentrations. Mean CV of 86 sequences consisting of 538 measurements was 7.61% $\pm$ 0.91%.

Conclusion: The results indicate that GlucoTrack is highly accurate and consistent. Specifically, sensor-to-sensor precision is comparable to that of continuous glucose monitoring systems and there is only a minimal difference between repeated measurements using the same device.

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Glucose Sensors

ATTD8-0215

FEASIBILITY AND PRELIMINARY RESULTS OF AN AMBUTATORY EDUCATIONAL PROGRAM FOR THE USE OF FSL IN 359 INSULIN-TREATED PATIENTS

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Background and Aims: In France, reimbursement for the FSL system was implemented on 1st June 2017. In order to respect the legislation, diabetologists of our unit had to set up an educational program quickly with precise endpoints to reach for patients; if not, these diabetic patients could not continue with FSL.

Method: We first built an ambulatory educational program based on the French position statement concerning the practical implementation, educational and interpretation guidelines. We developed a five-individual or collective session (10/12 subjects) program over a maximal duration of 9 months with dual teaching: Nurses and Doctors. We asked our Finance Department for authorization to employ an additional nurse, given the excess activity due to this new legislation and taking account increased takings for the hospital.

Results: We rapidly obtained authorization to employ an additional nurse, who started effective work at the end of June 2017. We enrolled 359 insulin-treated patients at the 30th of September. Only 5 subjects didn't reach criteria for reimbursement or indication. The next table describes the results with the number, type of sessions and patients who had already participated. One diabetic patient dropped out the program.

Conclusion: We demonstrated that the ambulatory educational program for FSL is feasible in trained teams used to such developments and with the involvement of diabetology units. The number of patients taking part illustrates the major impact of this new, useful technology and the need for continual evaluation in diabetic disease.

Type of session	Individual **Educational review**	Collective 1 **first steps**	Collective 2 **go further with FSL**	Collective 3 **become an expert**	Individual **evaluation**
Caregivers	Nurse	2 nurses	Nurse/Doctor	Nurse	Doctor
N=359	226	163	96	0	0

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Glucose Sensors

ATTD8-0189

PARENTS' ATTITUDES TO CONTINUOUS GLUCOSE MONITORING AT A NON-REIMBURSED SETTING

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Background and Aims: Continuous glucose monitoring (CGM) is an emerging technology helping to improve metabolic control, quality of life of patients with diabetes and their families, and reduces the time spent in hypoglycemia.

Aim: To evaluate benefits of CGM and assess parents' attitudes to it in non reumbursed settings.

Method: A short questionnaire was sent out to the pediatric patients with diabetes from 5 clinics and outpatient facilities in the country. A total of 110 (23.5%) families returned filled-in questionnaires

Results: In total 88 mothers, 19 fathers, 1 grandmother and 1 patient answered, mean age 39.7 ± 6.6y, 57.2% of all with University degree. Mean age of the children was 11.2 ± 3.9y., 54% boys, mean T1D duration 4.03 ± 6.1y; 82.7% of all are on insulin analogs;75.4% on MDI and 53.8% are on CSII. According to the type of therapy, 96.3% of CSII and 66% of MDI patients use CGM; and 68 used CGM at least once (45 use CGM continuously). According to parents, most common reasons for CGM usage are: optimizing insulin therapy (80.8%), reducing glucose variability (60.3%), remote kids surveillance (58.8%), reducing hypoglycemia (55.9%), increased independence of the child (45.5%), better HbA1c (42.6%) and less Dawn phenomenon (38.2%). The most frequent sensor is FreeStyle Libre (66.2%), followed by Dexcom G4 (20.6%), EnLite (8.8%), and iPro2 (4.4%). Mean HbA1c in sensor augmented CSII, MDI with sensor and MDI without sensor were as follows: 7.46 ± 1.1%, 6.77 ± 2.3%, and 7.95 ± 2.6%.

Conclusion: CGM is well accepted and widely prevalent among well-controlled children with T1D at an entirely non-reimbursed setting.

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Glucose Sensors

ATTD8-0222

ACCURACY AND PRECISION OF CONTINUOUS GLUCOSE MONITORING BEFORE, DURING, AND AFTER AEROBIC AND RESISTANCE EXERCISE IN SUBJECTS WITH TYPE 1 DIABETES

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Background and Aims: This study assessed the influence of aerobic and resistance exercise in accuracy and precision of the

Table 1 - Median Absolute Relative Difference (MARD) before, during and after aerobic and resistance exercise sessions. P0 to P5 represent 1-h duration periods of analysis. P0 starts 1-h before the beginning of exercise.

MARD (%)

	Aerobic	Resistance	p-value*
P0	9.5 (4.7 - 13.9) n = 112	15.5 (6.5 - 26.4) n = 76	<0.01
P1 (Exercise)	16.5 (7.6 - 23.5) n = 108	16.8 (7.9 - 24.5) n = 86	0.876
P2	9.3 (5.4 - 16.3) n = 108	12.7 (4.9 - 20.3) n = 88	0.129
P3	11.6 (6.5 - 17.5) n = 108	14.3 (4.8 - 26.5) n = 88	<0.05
P4	11.3 (6.2 - 16.0) n = 108	14.3 (7.9 - 19.7) n = 89	<0.05
P5	12.9 (4.7 - 18.8) n = 108	12.3 (5.7 - 18.8) n = 88	0.694
p-value*	Aerobic	Resistance	
P0 vs P1	<0.001	0.9933	
P1 vs P2	<0.001	0.0626	
P1 vs P3	<0.01	0.7981	
P1 vs P4	<0.001	0.1712	
P1 vs P5	<0.05	<0.05	
P0 vs P5	0.0598	<0.05	

*two-sided Wilcoxon rank sum test.
Results presented as the median (IQR).

Table 2- Precision Absolute Relative Difference (PARD) before, during and after aerobic and resistance exercise sessions. P0 to P5 represent 1-h duration periods of analysis. P0 starts 1-h before the beginning of exercise.

PARD (%)

	Aerobic	Resistance	p-value*
P0	5.7 (2.2 - 9.1) n = 780	9.2 (5.7 - 11.1) n = 420	<0.001
P1 (Exercise)	9.7 (2.5 - 16.2) n = 757	10.3 (5.4 - 14.0) n = 522	0.128
P2	4.8 (1.5 - 10.0) n = 720	9.6 (6.2 - 13.4) n = 540	<0.001
P3	5.8 (2.8 - 12.5) n = 720	8.1 (3.4 - 12.3) n = 535	<0.001
P4	6.3 (2.1 - 9.6) n = 720	7.9 (6.1 - 16.0) n = 540	<0.001
P5	5.2 (2.6 - 10.1) n = 702	8.0 (5.6 - 11.2) n = 517	<0.001
p-value*	Aerobic	Resistance	
P0 vs P1	<0.001	0.1378	
P1 vs P2	<0.001	0.9652	
P1 vs P3	<0.001	<0.001	
P1 vs P4	<0.001	0.5844	
P1 vs P5	<0.001	<0.05	
P0 vs P5	0.5744	<0.05	

* two-sided Wilcoxon rank sum test.
Results presented as the median (IQR).

Medtronic Enlite2 sensor before, during, and after physical activity.

Method: A total of six adults were enrolled. Each subject underwent three aerobic and three resistance exercise tests. The day before, patients inserted two CGM sensors at home. In aerobic sessions, participants performed 3 sets of 15-min cicloergometer at 60% of VO_{2max} with 5-min rest between them. Anaerobic sessions were composed by five sets of eight repetitions of four different exercises at 70% of the maximum capacity with 90 seconds rest between sets. Plasma glucose levels (YSI 2300 STAT Plus) were used as reference to compute the median absolute relative difference (MARD).

Results: Due to hardware failure, some sensors were excluded. A total of 56 sensors were analyzed (31 aerobic, 25 resistance). Results are presented in Table 1 and Table 2. For aerobic exercise, a significant increase in MARD was observed after the beginning of exercise. Besides that, PARD during exercise was significantly higher when compared to other periods. In the resistance sessions, no difference was observed in MARD before and during exercise. Accuracy improved in the first hour after both types of exercise.

Conclusion: Our results indicate that aerobic exercise has more influence in accuracy and precision than resistance exercise. However, the significant difference in MARD and PARD between the types of exercise at baseline is a hurdle to attest which type of exercise interfere more on CGM.

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Glucose Sensors

ATTD8-0250

HEAD TO HEAD ACCURACY COMPARISON BETWEEN TWO INTERSTITIAL GLUCOSE SENSORS

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Background and Aims: Continuous glucose monitoring improves glycaemic control in diabetes. Aim of the study was to compare the accuracy of two interstitial glucose sensors.

Method: The study involved subjects with type 1 diabetes who simultaneously wore the FreeStyle Libre, (Abbott, Alameda, CA) and the Dexcom G5 Mobile, (Dexcom, San Diego, CA) sensors for two consecutive weeks, with the Dexcom G5 replaced after one week. During week 1 patients were admitted to a clinical research center (CRC) to receive breakfast with delayed and increased insulin bolus in order to induce glucose excursions. At CRC, venous glucose was monitored every 15 min for 6 hours by YSI, every 5 minutes during hypoglycemia. At home patients were requested to perform 4 fingerstick glucose measurements daily.

Results: 21 patients (10 F, mean age 39.0 ± 13.8 years, mean diabetes duration 23.3 ± 11.7 years) were enrolled. During homestay the median 25^th −75^th percentile] absolute relative difference (ARD) over all matched-pairs was 12.3[5.6–21.4]% for the Libre and 9.8[4.7–18.0]% for the Dexcom G5 ($p < 0.001$). Median ARD increased during hypoglycemia with both systems (13.7[7.4–23.9]% for Libre, 14.0[7.7–23.2]% for Dexcom G5, p non significant) and decreased during hyperglycemia (10.2[4.5–16.8]% for Libre, 8.4[4.3–13.9]% for G5, $p = 0.007$). At CRC, during breakfast, the Dexcom G5 showed overall smaller median ARD, 10.7[4.8–19.8]% vs 14.7[7.3–27.4]% than Libre ($p < 0.001$). Libre showed slightly lower , not significant, median ARD in hypoglycemia.

Conclusion: Dexcom G5 Mobile was more accurate than Libre in outpatient settings and in CRC during rapid glycaemic excursions. In the hypoglycemic range both systems were less accurate.

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Glucose Sensors

ATTD8-0264

A NEW METHOD TO EVALUATE ANALYTIC PERFORMANCE OF CGM DEVICES

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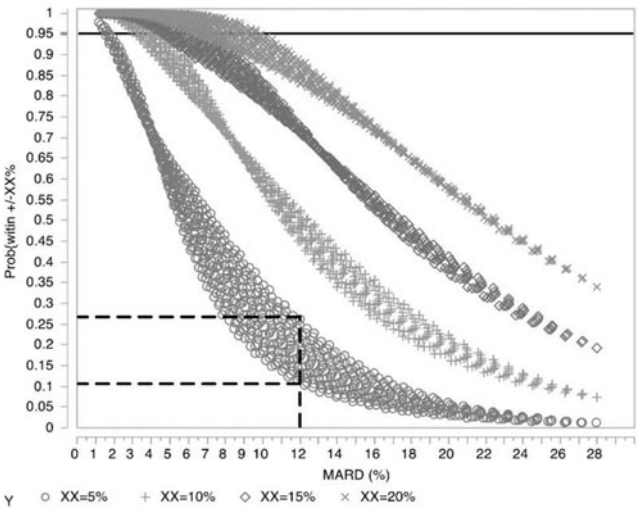
Background and Aims: The mean absolute relative difference (MARD) between CGM and reference method glucose measurements (RMGM) is commonly used to describe analytic performance of CGMs, but quantitative analysis demonstrates that it may be insufficient to characterize CGMs performance. Here we examine a new methodology for assessing CGM analytical performance.

Method: A more complete characterization of CGM performance can be obtained by computing the absolute relative difference (ARD) of each CGM and RMGM pair, for each subject/sensor combination. While MARD is easily computed by taking the average, one may empirically construct the distribution of ARD and fit it to known parametric probability distributions. Data from 30 T1D subjects over a month (NCT01835964) were used to construct such histograms.

Results: Only the Gamma distributions family passed goodness-of-fit tests for all subject/sensor combinations, out of 7 parametric distributions. This model and its parameters, shape and scale, easily provide the expected MARD, and the probability that CGM and RMGM would be within pre-specified bounds. Figure 1 shows various probabilities plotted against MARD, for shape 0.8 to 3.5, and scale 1.5 to 8.0 (756 combinations), highlighting that similar MARDs (from 1.2% to 28%) may mask different error characteristics: e.g. MARD = 12% may correspond to CGM within 5% of RMGM anywhere between 10% to 25% of the time.

Figure 1. Probability of Errors within ±XX% by MARD



Conclusion: The error probability calculation facilitated by the gamma distribution model may be a valuable tool for assessing CGM analytic performance.

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Glucose Sensors

ATTD8-0043

IMPROVED QUALITY OF LIFE METRICS AFTER USING REAL-TIME CONTINUOUS GLUCOSE MONITORING WITH REMOTE MONITORING IN YOUNG CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: Real-time continuous glucose monitoring (RT CGM) improves glycaemic control in people with Type 1 diabetes (T1D), but little is known about the impact of RT CGM use in children and their families on diabetes burden. This study aimed to explore the effect of RT CGM on psychosocial factors in children and their caregivers.

Method: RT CGM-naive children (age 2–12years) with T1D along with their parents participated in a randomized, crossover study. They participated in two 3-month periods using conventional blood glucose monitoring (control) or the Dexcom G5® Mobile CGM system and remote monitoring (intervention) and completed validated psychosocial questionnaires before and after each period. The primary outcome was the parental fear of hypoglycaemia score assessed by the hypoglycaemia fear survey (HFS). Data were analyzed using a mixed model approach including a random effect for individual and treatment, period and sequence as fixed effects.

Results: 47 of 50 randomised children and their parents completed the study. The children's (mean±SD) age was 9.6± 1.8 years, diabetes duration 4 ± 2.5 years and HbA1c 7.6 ± 0.7%. FOH scores were lower while the child was using the RT CGM and remote monitoring: unadjusted total scores (mean±SD) were 53.0 ± 14.9 (control) vs 44.4 ± 15.8 (intervention), least squared mean difference – 8.5,p <0.001. Furthermore, parental health-related quality of life and family functioning, stress, anxiety and sleep improved significantly. There was no change in the child FOH score. Mean HbA1c was 7.8 ± 0.7% after each period, p = 0.426.

Conclusion: RT CGM and remote monitoring improves multiple measures of quality of life, reduces family stress and importantly parental sleep.

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Glucose Sensors

ATTD8-0111

PATIENT TOLERANCE OF A LONG TERM FULLY-IMPLANTED CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: Abundant evidence exists to support CGM as a standard of care in type 1 diabetes management, with glycaemic benefits directly related to duration of device wear. All current CGM technology however requires regular patient interaction with external, body worn components; this can impact adoption or result in intermittent use (e.g. Tanenbaum et al. Diabetes Care 2017,40:181–187). In this study, attitudes of users were assessed regarding a new long-term, fully implanted CGM designed to address these impediments.

Method: Clinical evaluation of a long-term, fully implanted (nothing worn on the skin) continuous glucose monitoring system (the Eclipse® ICGM® System) is currently underway at St. Vincent's Hospital Fitzroy, Melbourne, AUS (CTN-02048-1) in four adult participants with type 1 diabetes. Each participant received one sensor implanted subcutaneously in a lower abdominal quadrant during a minor outpatient procedure utilizing local anesthesia and optional conscious sedation. An 18-question standardized questionnaire was administered at pre-specified intervals to assess device tolerance, yielding an ''acceptance index'' (AI) (−2 = strong negative, 0 = indifferent, +2 = unaware).

Results: Results from all subjects' AI scores are (mean ± SD): 1-day following implant 0.5 ± 0.7, 7-days 0.8 ± 0.7, 14-days 0.8 ± 1.1, 1 month 1.0 ± 0.9 and 2 months 1.2 ± 0.7. No significant adverse events occurred associated with the sensor implantations.

Conclusion: Consistent with previous clinical experience, participant responses suggest robust tolerance and acceptance of the Eclipse ICGM System. Additional studies are underway to validate device performance and assess changes in attitude over time.

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Glucose Sensors

ATTD8-0187

COMPARISON OF MINIMAL MONITORING FREQUENCY USING TWO GLUCOSE MONITORING SYSTEMS

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Background and Aims: Glucose monitoring is essential for people with T1DM. Sensor-based glucose monitoring (''sensor'') systems have found increasing use, in addition to strip-based blood glucose monitoring (''BGM'') systems. A new sensor system was recently assessed relative to BGM-based care, in a 6-month RCT (NCT02232698) enrolling 328 participants. Those in the sensor-based care checked between 5.5 to 38.5 times daily. An in-silico analysis complementing this RCT, where

participants only check 4 times daily (pre-meal and pre-bedtime), is of interest.

Method: 100 virtual T1DM subjects were enrolled in 420-day, parallel sensor-based and BGM-based study arms, using the UVA/Padova T1DM Simulation platform. The sensor is modeled using clinical study data, while the BGM is modeled to have 95% points within 15mg/dL/15%. Only 4 daily real-time glucose readings are available to the patients in either study arm. All simulations incorporate mixed meal effect, carbohydrate counting errors, variable meal timing/duration, and fluctuations in day-to-day insulin sensitivity.

Results: There is no significant difference in hypoglycemia risk (0.27% ± 0.56% vs 0.25% ± 0.55% in BG ≤55mg/dl), time in range (40.6% ± 23.5% vs 41.0% ± 23.3% in 70<BG ≤180mg/dl), and hyperglycemia risk (22.9% ± 22.8% vs 22.4% ± 22.5% in BG >240mg/dl) between the two study arms.

Conclusion: In a parallel-universe simulation setting where realistic variations in meal intake, carbohydrate counting, and variable insulin sensitivity are repeated across study arms, checking glucose with the sensor-based system even less frequently than found in a real-world RCT presents similar hypoglycemia risk, time in range, and hyperglycemia risk relative to BGM-based care.

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Glucose Sensors

ATTD8-0153

DYNAMIC LAG COMPENSATION REDUCES OVERALL SYSTEM LAG TIME AND IMPROVES ACCURACY OF A LONG TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background and Aims: Interstitial fluid glucose (ISF) to blood glucose (BG) lag is an inherent characteristic of continuous glucose monitoring (CGM) systems. Lag time can vary by individual, sensor, and duration of sensor use. This analysis compares the performance of a long term implantable sensor using fixed lag compensation against dynamic lag compensation for ISF to BG conversion.

Method: An innovative dynamic lag compensation method was evaluated on data collected from 82 subjects on the Eversense® CGM sensor over a 90 day period in the PRECISE II U.S. pivotal study.

The fixed lag method utilizes fixed lag parameters of a two-compartment model for different periods throughout the sensor life. The dynamic lag method builds on that and uses the fixed lag values as the initial lag condition. At each calibration point the two lag parameters—the diffusion time from BG to ISF and the consumption rate of glucose in the interstitial space—are calibrated using a weighted SMBG history. Those updated values are used to calculate BG glucose from ISF glucose until the next calibration.

Results: Dynamically updating lag parameters reduced the overall sensor lag time from 10.7 to 8.1 minutes, a 24% reduction in lag. Additionally, MARD against YSI over a 90-day period improved from 8.8% to 8.5% and 15/15% agreement to YSI improved from 85.7% to 86.8%.

Conclusion: Dynamically updating lag parameters not only reduces overall sensor lag but also improves sensor accuracy over 90 days.

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Glucose Sensors

ATTD8-0143

USE OF CONTINUOUS GLUCOSE MONITORING (CGM) TRENDS TO PREVENT HYPOGLYCAEMIA DURING EXERCISE IN YOUNG CHILDREN WITH TYPE 1 DIABETES

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Background and Aims: This study investigates the use of a carbohydrate (CHO) intake algorithm based on CGM trends during physical activity.

Method: Children with T1D diagnosed for >1 year, aged 8-12 years, with a HbA1c of <10% were recruited into a randomized crossover study. They attended two similar mornings of fun-based physical activity and adhered to either a CHO intake algorithm based on CGM trends (intervention) or to standard exercise guidelines (consumption of 0.5gCHO/kg/h when glucose <8mmol/l) (control). Outcome measures included percentage time spent in sensor glucose ranges and events such as interruptions in exercise, CHO intake and symptomatic hypoglycaemia. CGM data were analyzed using a mixed model approach. A generalized linear mixed model with a Poisson distribution was used for events.

Results: 14 children (5:9;M:F) aged 10.5 ± 1.4years (mean±SD), diabetes duration 4.8 ± 2.7years and HbA1c of 7.7 ± 0.6% completed the study. There was no difference in percentage time in range (3.9–10mmol/l), least squared mean difference was 2.1%, p = 0.735. Similarly, there was no difference in percentage time spent low or high. Symptomatic hypoglycaemia occurred in 2 participants during control and intervention. Mean CHO intake/kg/h was similar in both groups, 0.3 ± 0.2g/kg/h. However, the intervention algorithm resulted in fewer CHO intake events (mean±SE) 2.4 ± 0.4 vs 0.9 ± 0.2 times/day,(p = 0.003), and exercise interruptions 7.2 ± 0.7 vs 1.4 ± 0.3 times/day, p <0.001 compared to control.

Conclusion: Using a carbohydrate intake algorithm based on CGM trends resulted in fewer CHO intake events and fewer interruptions to exercise. Use of this algorithm may reduce the burden of diabetes management with potential to facilitate activity in young people with T1D.

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Glucose Sensors

ATTD8-0138

EVALUATION OF A PERCUTANEOUS OPTICAL FIBRE GLUCOSE SENSOR (FIBERSENSE) ACROSS THE GLYCEMIC RANGE WITH RAPID GLUCOSE EXCURSIONS USING THE GLUCOSE CLAMP

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Background and Aims: FiberSense is a real-time continuous glucose monitoring (CGM) system with a percutaneous fibre optic glucose sensor. We aimed to evaluate the accuracy of the FiberSense system across the glycemic range and with rapid glucose excursions during a glucose clamp.

Method: 10 healthy subjects wore 2 FiberSense sensors, one in the abdomen and the upper arm respectively and one Dexcom G4 Platinum CGM sensor. Blood glucose was maintained hypoglycemic (45mg/dl), hyperglycemic (250mg/dl) and then euglycemic (90 mg/dl) plateaus each for twenty minutes using intravenous insulin and 20% dextrose. Blood glucose increased or decreased rapidly at a rate of 2 to 4mg/dl/min during transition periods between each glucose plateau. FiberSense readings were compared against arterialized blood glucose measured with the YSI glucose analyzer.

Results: In the full glycemic range, the mean absolute relative difference (MARD) was 21.4% (n = 166) and 27.0% (n = 206) for FiberSense worn on the abdomen and upper arm respectively as compared to 29.4% (n = 189) with Dexcom. Consensus Error Grid (CEG) analysis yielded 99.4% and 96.1% of paired FiberSense measurements in zones A and B from the abdomen and upper arm respectively. During rapid descent in blood glucose (mean rate of change −3.05 mg/dl/min), the MARD was 18.8% (n = 50) and 23.7% (n = 62) for FiberSense worn on the abdomen and upper arm respectively, as compared to 40.6% (n = 74) with Dexcom.

Conclusion: The FiberSense system is comparable in accuracy to existing commercial enzyme-based CGM systems across the glycemic range. Further studies are under way to evaluate the system for extended home use in diabetes patients.

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Glucose Sensors

ATTD8-0288

AVOIDANCE OF GLUCOSE EXCURSIONS BY THE GUARDIAN CONNECT CGM SYSTEM - REAL-WORLD DATA

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Background and Aims: The Guardian™ Connect continuous glucose monitoring (CGM) system allows users to view sensor glucose data directly on the smartphone. The system also includes predictive glucose alerts notifying users 10-60 minutes before a predicted low or high glucose excursion. We evaluated the real-world rates of alerts and outcomes of users on the Guardian Connect system from January 2, 2017.

Method: We identified 2,541 people with ≥5 days of sensor data in the CareLinkTM database. Excursions were defined as ≥3 consecutive sensor values beyond the preset threshold (range from high [2.8-22.2 mmol /L] and low [2.2-21.6 mmol /L]). The window of evaluation for excursion start times was 60 minutes following the alert. The time to excursion resolution measure described the duration of the excursion and was segmented [avoided, ≤20 min, 20–60 min, >60 min].

Table. Changes of Glycemic Parameters over System Use MiniMed Guardian Connect: Alert Response

		Alert Type	High SG Predictive Alert	Low SG Predictive Alert	High SG Alert	Low SG Alert
Time to Excursion Resolution		Total Alert Count	119265	217710	402130	255591
	Avoided	Excursion Count	68286	146222	NA	NA
		% of total	57%	67%	NA	NA
	0-20 min	Excursion Count	10180	29860	372641	235877
		% of total	9%	14%	93%	92%
	20-60 min	Excursion Count	15567	30674	12201	14006
		% of total	13%	14%	3%	6%
	> 60 min	Excursion Count	25232	10954	17288	5708
		% of total	21%	5%	4%	2%

SG, sensor glucose;

Results: The results are shown in the Table as the percentage of each alert resulting in an excursion and segmented per excursion duration. Mean settings for high and low alert thresholds were 11.9 +/–2.7 mmol/L and 4.0+/–0.5 mmol/L, respectively. The mean alert frequency was 2.9/day, 1.8/day, 0.9/day, 1.6/day for high, low, predicted high and predicted low, respectively. Users who received predictive alerts avoided 60% of low events and 39% of high events following each alert.

Conclusion: Guardian Connect CGM system users who enabled predictive alerts avoided more than half of predicted low and high events. Predictive alerts are a useful tool for users to act to keep sensor glucose levels within their target ranges.

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Glucose Sensors

ATTD8-0147

FLASH GLUCOSE MONITORING INDICATES THAT THE SOMOGYI EFFECT IS AN INFREQUENT CAUSE OF EARLY MORNING HYPERGLYCAEMIA

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Background and Aims: The Somogyi effect (SE) is considered to be a cause of early morning hyperglycaemia (EMH). When suspected, the nocturnal insulin dose is reduced, to avoid nocturnal hypoglycaemia (NH). We aimed to describe the natural history of NH in patients with type 1 diabetes on multiple daily insulin injections, and describe the causes leading to EMH in patients using Freestyle Libre®(FL).

Method: We retrospectively reviewed data from 28 consecutive patients who used FL for at least 14 days. SE was defined as EMH (≥160 mg/dl) without carbohydrate intake following NH (<70 mg/dl). Potential causes of EMH (hypoglycaemia overcorrection, high sensor glucose value at bedtime, dawn effect,

insufficient dose of basal insulin, SE or nocturnal food intake) were registered.

Results: Median age was 43 (IQR 34–56) years, 20/28 were female. Median HbA1c was 7.2% (6.5–8.1%). 601 nights were evaluated, with 129 episodes (21%) of NH. The lowest sensor glucose presented when patients arose in the morning in 44/129 (34%) episodes. Following NH, EMH ocurred in 19 episodes (14%), all explained by nocturnal carbohydrate intake, none by SE. 167/601 (27%) nights were followed by EMH. The causes were: 90/167 (53%) with sensor hyperglycaemia (≥150 mg/dl) at bedtime, 20 (12%) had insufficient basal insulin, 7 (4%) had dawn effect, 31 (19%) ate carbohydrates and 19 (11%) due to NH overcorrection.

Conclusion: We found no cases of EMH due to the Somogyi effect. Over half of EMH episodes were secondary to pre-bedtime hyperglycaemia. Thus, correcting pre-bedtime hyperglycaemia could have a significant impact on overall glycaemic control.

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Glucose Sensors

ATTD8-0028

DIFFERENCES BETWEEN HIGH AND LOW HYPOGLYCAEMIA RISK POPULATIONS USING CONTINUOUS GLUCOSE MONITORING DATASETS

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Background and Aims: Little is known about differences in glycaemic patterns in subjects with type 1 diabetes (T1D) with high or low hypoglycaemia risk. We investigated the differences between these two T1D cohorts using CGM data.

Method: Two-weeks of blinded-CGM data from the *REPLACE-BG (N = 119, low hypoglycaemia risk)* and *I-HART-CGM (N = 40, high hypoglycaemia risk)* trials were used to assess time in target (70-180mg/dl), hypoglycaemia (<54mg/dl, <70mg/dl) and hyperglycaemia (>180mg/dl). Other outcomes included measures of glycaemic variability and risk (standard deviation (SD), coefficient of variation (CV), mean amplitude of glucose excursions (MAGE), low-blood glucose index (LBGI) and high-blood glucose index (HBGI)). Depending on data distribution an unpaired t-test or Mann Whitney U-test was performed for between group comparisons. A multilinear regression analysis was performed to evaluate which variables were independently associated with a higher time in hypoglycaemia or LBGI.

	REPLACE BG NAÏVE	I HART CGM	P value
N	119	40	
Age (y)	42.0 (30-53.5)	49.5 (38.8-63.3)	<0.001
T1D duration (y)	22.8 ± 11.3	29.4 ± 12.3	<0.002
Gender (% F)	50	40	N.S
HbA_{1c} (%)	7.0 (6.7-7.4)	7.3 (6.6-7.8)	0.07; N.S.
Mean CGM (mg/dl)	165 (150-176)	160 (140-176)	0.07; N.S.
Time 70-180 (%)	60.4 ± 12.7	54.2 ± 15.5	<0.02
Time 54-180 (%)	63.1 ± 13.3	59.8 ± 16.5	N.S.
Time <70mg/dl (%)	3.6 (1.9-4.8)	11.1 (6.8-14.3)	<0.0001
Time <54mg/dl (%)	0.9 (0.3-1.1)	5.5 (2.1-7.6)	<0.0001
Time >180mg/dl (%)	36.0 ± 13.4	35.0 ± 17.0	N.S.
SD (mg/dl)	63.0 ± 12.0	72.2 ± 19.2	<0.0001
CV	0.38 (0.35-0.41)	0.45 (0.41-0.50)	<0.0001
MAGE	124.9 ± 24.0	145.9 ± 41.1	<0.001
LBGI	0.96 (0.57-1.23)	2.76 (1.69-3.70)	<0.0001
HBGI	8.37 (5.81-10.06)	8.95 (5.05-11.22)	N.S.

Results: Participants in the high risk hypoglycaemia group were older (49.5(38.8-63.3) vs. 42.0(30–53.5)years; $p < 0.001$) and with longer T1D duration (29.4 + 12.3 vs. 22.8 + 11.3years; $p < 0.002$). CGM data showed higher time in hypoglycaemia, higher risk of hypoglycaemia and higher glycaemic variability in the high risk group (see Table). The multilinear regression analysis showed that HbA_{1c} and being at high risk of hypoglycaemia *(I HART CGM cohort)* were independently associated with both time <54 mg/dl and LBGI.

Conclusion: Glucose profiles and variability are different in T1D participants at high risk of hypoglycemia compared to low-risk participants. CGM could be useful to estimate risk of hypoglycemia and introduce preventive approaches in clinical practice.

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Glucose Sensors

ATTD8-0428

FACTORS ASSOCIATED WITH HYPOGLYCEMIA IN PATIENTS WITH TYPE 2 DIABETES AND HIGH RISK OF HYPOGLYMEMIA

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Background and Aims: To determine the clinical variables and indices of glycemic variability evaluated by continuous glucose monitoring (CGM) associated with hypoglycemia in a group of patients with type 2 diabetes and a history of hypoglycemia.

Method: Observational study with retrospective analysis of the data. We included patients seen at the San Ignacio University Hospital (Bogotá, Colombia) with a diagnosis of type 2 diabetes and a history of hypoglycemia as an indication of CGM. We evaluated demographic variables, Hb1Ac, previous antidiabetic therapy, complications of diabetes, glomerular filtration rate and all the measures used to evaluate glycemic variability by MCG. Hypoglycemia was defined when the interstitial glucose was less than or equal to 54mg/dL for at least 20 minutes. Bivariate analysis was performed and then a logistic regression model for data analysis.

Results: A total of 166 patients were included. 52 patients presented hypoglycemia (31.3%). The demographic variables, complications of diabetes and pharmacological management were not associated with the presence of hypoglycemia (<70mg/dL). The percentage of the coefficient of variation (CV%) was associated with hypoglycemia ($p < 0.000$). In the adjusted multivariate model, the best predictor of hypoglycemia was the percentage of the CV (OR 1.31 IC95% 1.20 – 1.44), with a cut-off point of CV% above 33%.

Conclusion: In this study, no significant association was found between the clinical variables and hypoglycemia; the only associated variable was the CV%, this makes evident the importance of carrying out CGM in patients with a history of hypoglycemia.

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Glucose Sensors

ATTD8-0228

A WIRELESS, MINIATURIZED, FULLY-INTEGRATED CONTINUOUS GLUCOSE MONITORING PLATFORM FOR ACCESSIBLE AND USER-FRIENDLY DIABETES MANAGEMENT

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Background and Aims: IMS has developed world's first fully-integrated, miniaturized (smaller than 1/3rd of a rice grain), completely wireless glucose sensor with 10x lower projected cost and 20x longer expected lifetime compared to existing CGM systems, to make glucose sensing accessible and hassle free. The small size and wireless nature results in reduced inflammation and encapsulation and hence increased sensor lifetime and less frequent calibration.

Method: This sensor is implanted few mm under the skin , measures glucose from the interstitial fluid using an integrated electrochemical sensor and relays the real-time data wirelessly to the patient and a cloud database (accessible by caregivers, doctors) via a wearable wireless transmitter and a smart reader. This becomes possible by integrating advanced microelectronics, RF technology, nanotechnology and electrochemistry. The innovative design and manufacturing makes this device extremely low-cost, its wireless nature makes it easy to use, and its miniaturized size makes it suitable for injection and reduces foreign body response resulting in minimal lag in readings and long useful life compared to existing CGM sensors. Our patent protected nano-patterned sensor improves sensitivity ten fold making it possible to detect hypoglycemia accurately.

Results: We have built a fully-functioning prototype and have successfully demonstrated (i) >1 year of in-vitro lifetime, (ii) extensive biocompatibility and efficacy in animal models (MARD of 12%), and (iii) preliminary human feasibility using this system.

Conclusion: IMS sensor provides a simple and accurate interface for glucose sensing making it attractive for diabetes management using ''artificial pancreas''. This system holds the promise to transform the future of diabetes care.

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Glucose Sensors

ATTD8-0033

DIFFERENT CGM EFECTTS OF GLP-1 RECEPTOR AGONIST: LIRAGLUTIDE VS. LIXISENATIDE

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Background and Aims: To analyze effects of glucagon-like peptide 1 (GLP-1) receptor agonist (Liraglutide or Lixisenatide) in different continuous glucose monitoring (CGM) variables in obese type 2 diabetes mellitus (T2DM) patients.

Method: Prospective observational study with patients assigned (1:1) to be treated with Liraglutide or Lixisenatide during 24 weeks. Rest of antidiabetic treatments were adjusted through free medical decision. Basal and final retrospective CGM datas were obtained from blind retrospective CGMS Gold (Medtronic Inc.).

Results: One-hundred patients were enrolled and treated with Liraglutide (50) or Lixisenatide (50). Mean age was 56.4 yr. (range 29–74 yr.), T2DM duration of 8.7 ± 6.9 yr. and body mass index of 38.2 ± 5.9 Kg/m^2. Both treatment groups showed similar improvement in glycated haemoglobin A1c (HbA_{1c}) and body weight. Only Liraglutide patients experimented a reduction in high glucose excursion frequency (−4.5 events/CGM registry; CI 95% −8.6, −0.5; $P = 0.03$) and area under the curve (AUC) >180 mg/dL (−31.4 mg/dL/day; CI 95% −52.1, −10.7; $P = 0.005$). Moreover, glycemic variability, expressed as SD of 24-hours mean interstitial glucose, improved only among Liraglutide treated patients (DMC −8 mg/dL, CI 95% −15, −1; $P = 0.029$). Nevertheless, Lixisenatide group showed a decrement in the AUC <70 mg/dL (DMC −0.1 mg/dL/day; CI 95% −0.3, −0.1; $P = 0.033$).

Conclusion: GLP-1 receptor agonists, Liraglutide and Lixisenatide, produced different glycemic effects registered through CGM system despite major classic clinical results (HbA_{1c} and weight).

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Glucose Sensors

ATTD8-0372

HYPOGLYCAEMIA FEAR IN ADULTS WITH TYPE 1 DIABETES AT HIGH RISK OF HYPOGLYCAEMIA: THE IMPACT OF SWITCHING FROM FLASH GLUCOSE MONITORING TO CONTINOUOS GLUCOSE MONITORING

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Background and Aims: The initial 8-week I-HART-CGM study suggested that continuous glucose monitoring (CGM, Dexcom G5) has a greater benefit compared to flash glucose monitoring (flash, Freestyle Libre) in reducing fear of hypoglycaemia in type 1 diabetes (T1DM). We aim to evaluate the impact of switching the flash cohort to CGM and extending its use in the CGM cohort.

Method: Adults with T1DM on a multiple dose insulin injection regimen with a Gold score of ^{3} 4 or recent severe hypoglycaemia were randomised as part of a prospective parallel group study to flash or CGM for 8 weeks. At 8 weeks, participants were either switched to CGM or continued on it for another 8 weeks. The Gold score, PAID and HFS-II questionnaires were used to assess hypoglycaemia awareness, diabetes related emotional distress and fear of hypoglycaemia respectively.

Results: 40 participants were included (40% female, median (IQR) age of 49.6 (37.5–63.5) years) of which 36 completed the final 8 weeks of CGM (Flash n = 20, CGM n = 16). At the 16-week endpoint there was significant reduction in the HFS-II-worry sub-score (31.7 vs 26.9, p = 0.04) and Gold score (4.65 vs 4.20, p = 0.04) when participants switched from flash to CGM. Extended use of CGM showed no further change in worry or hypoglycaemia awareness. No significant difference was observed in PAID score in either cohort.

Conclusion: Our data suggest that switching from flash to CGM reduces worry associated with hypoglycaemia fear. Interestingly the Gold score fell significantly, but remained above 4.

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Glucose Sensors

ATTD8-0230

COST-EFFECTIVENESS OF REAL-TIME CONTINUOUS GLUCOSE MONITORING (RT-CGM) COMPARED WITH SMBG IN TYPE 1 DIABETES (T1DM) ADULTS USING MULTIPLE DAILY INJECTIONS (MDI) FROM THE ITALIAN PERSPECTIVE

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Background and Aims: To evaluate the cost effectiveness of Dexcom G5®Mobile real-time CGM compared with self-monitoring of blood glucose (SMBG) alone in T1DM adults using multiple daily injections (MDI) from the Italian perspective.

Method: The IMS CORE Diabetes Model (v.9.0) was used to assess a long-term (50 years) cost effectiveness of real-time CGM (Dexcom G5 Mobile) compared with SMBG alone for a cohort of adults with poorly-controlled T1DM. Treatment effects and baseline characteristics of patients were derived from the recently published DIAMOND randomized controlled trial; all other assumptions and costs were sourced from published research. The accuracy and clinical effectiveness of the G5 Mobile is the same as the US-version G4® Platinum used in the DIAMOND trial. Base-case assumptions included **a)** baseline HbA1c of 8.6%; **b)** HbA1c reduction of −1.0% for rtCGM versus −0.4% for SMBG; **c)** dis-utilities of −0.0142 for non-severe hypoglycemic events (NSHEs) and severe hypoglycemic events (SHEs) not requiring medical intervention and −0.047 for SHEs requiring medical resources. Treatment costs and outcomes were discounted at 3% per year.

Results: The base-case incremental cost-effectiveness ratio (ICER) for G5 Mobile vs. SMBG was €18,409 per Quality Adjusted Life Year (QALY). Sensitivity analyses showed base-case results were most sensitive to changes in %-reduction in hypoglycemic events, and dis-utility associated with hypoglycemic events. Base-case results were minimally impacted by changes in baseline HbA1c, baseline utility of patients, and changes in discount rate.

Conclusion: This analysis demonstrates acceptable long-term cost-effectiveness of G5 Mobile rtCGM compared with SMBG in T1DM adults using multiple daily injections from the Italian perspective.

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Glucose Sensors

ATTD8-0370

CORRELATION BETWEEN FREQUENCY OF FLASH GLUCOSE MONITORING SCANS AND HEMOGLOBIN A1C LEVELS: A REAL LIFE STUDY

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Background and Aims: The association between low frequency of self-monitoring of blood glucose (SMBG) and high hemoglobin A1c level (HbA1c) in patients with type 1 diabetes mellitus (T1D) is already known, but the optimal frequency of SMBG is not clearly defined. Flash glucose monitoring (FGM) is an emerging technology that allows the patient to measure interstitial glucose concentration more frequently than SMBG.

Method: We collected data from 85 adults T1D patients using FGM technology in real life for at least 28 days. Demographic and clinical characteristics (sex, age, sex, diabetes duration, CSII or MDI therapy) were taken; we downloaded data to the Abbott Freestyle Libre Software, that provides the number of daily FGM scans and estimates HbA1c level based on continuous glucose profile readings. The association between median FGM scan frequency and the estimated HbA1c was analyzed using linear regression and Kruskal-Wallis test.

Results: Linear regression analysis between HbA1c and median FGM scan frequency showed a negative correlation with $r = -0.43$ ($p = 0.001$). Moreover, a significant correlation between median FGM scan number and HbA1c levels was found until ''10-15 scans'' group ($p = 0.04$), with no further benefits in the ''above 15 scans'' groups ($p = 0.43$).

Conclusion: In T1D patients using FGM in real life the benefits of a frequent glucose monitoring is confirmed, with a maximum benefit in term of HbA1c reduction at 15 scans daily, a number of glucose measurements that would unlikely be sustained with SMBG.

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Glucose Sensors

ATTD8-0088

CONTINUOUS GLUCOSE MONITORING SYSTEM AND PREDICTION OF PREGNANCY OUTCOMES IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS: A PROSPECTIVE COHORT STUDY

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Background and Aims: Gestational diabetes mellitus (GDM) is associated with an increase of maternal-fetal complications. Continuous glucose monitoring system (CGMS) detects parameters of glycemic variability through which it could be predicted the appearance of maternal-fetal complications.

Method: Women with GDM at 26–32 gestational weeks were allocated a 6-day CGM system (Ipro™2) right after diagnosis in an observational prospective study. It was analyzed:

- CGMS: mean glucose and standard deviation (SD), mean amplitude of glycemic excursions (MAGE), mean of daily differences (MOOD), continuous overlapping net glycemic action (CONGA). Expressed: mg/dL.
- Maternal and neonatal outcomes.

Results: n = 52. Maternal age 30 ± 2.42 years (>35 years = 40.3%), family history of diabetes 57.7%, prepregnancy BMI 26.1 ± 4.62 kg/m^2 (>30 kg/m^2 = 23.1%), weigh gain 7.6 ± 5.19 kg, HbA1c 4.9%, insulin treatment 32.7%.

- CGMS: mean 98.02, DS 19.66, MAGE 44.22 ± 13.16, MODD 19.44 ± 5.74, CONGA 86.19 ± 8.56.
- Maternal and neonatal outcomes: Caesarean 32.7%, gestational age at delivery 39 week, macrosomia 9.6%, large for gestational age (LGA) 21.2%, small for gestational age 5.8%, neonatal hypoglycemia 25%, neonatal hyperbilirubinemia 7.7% and need for supplemental oxygen in the neonatal 5.8%.
- Multivariable binary logistic regression: MAGE was an independent factor for LGA (Odds ratio 1.075; 95% confidence interval 1.007-1.148; p value 0.031). It was not found another independent risk factor for maternal or neonatal outcomes.

Conclusion: There is a correlation between MAGE at diagnosis of GDM and LGA. The use of CGMS could identify patients with more risk of maternal-fetal complications. These patients should have a close surveillance in order to prevent complications. However, further studies with a larger number of patients are required.

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Glucose Sensors

ATTD8-0402

CLINICAL FEASIBILITY AND HOME USE STUDY OF A PERCUTANEOUS OPTICAL FIBER GLUCOSE SENSOR

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Background and Aims: Current real-time continuous glucose monitoring systems (CGM) exhibit a rather short lifetime of up to 7 days. We present data of a novel CGM (FiberSense) with improved duration of action and accuracy, based on a fluorescent biosensor placed on the tip of an optical fiber.

Method: FiberSense was inserted in the subcutaneous upper arm tissue of six patients and worn under home use condition for 29 days. Patients were blinded to FiberSense readings. During 6 in-clinic measurement sessions of 4–6 h each, FiberSense readings were compared to capillary blood glucose measured by a laboratory method. In parallel, a commercial CGM system was placed at the abdomen. The commercial system was replaced weekly. Blood glucose was altered by administration of insulin and carbohydrates. During home use patients took at least 4 to 5 SMBG readings daily. Fluorescence was measured using a miniaturized photometer. Two-point calibration as well as one-point calibration was applied. Skin was evaluated according to the Draize scale.

Results: FiberSense was clinically well tolerated for up to 29 days without complications or signs of inflammation. Comfort was comparable to the commercial CGM system. The pooled data exhibit a MARD of 10,6% (7,9% hypo range <76mg/dL; two point calibration) compared to 12,4% (11,4%) for the commercial CGM system used at the same measurement times. MARD changed only marginally over the course of the trial.

Conclusion: The present study proves the capability of FiberSense to replace current CGM systems, with the possibility to extend the duration of action to up to 29 days.

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Glucose Sensors

ATTD8-0340

LONG-TERM CONTINUOUS GLUCOSE MONITORING IMPROVED GLYCAEMIC CONTROL AND VARIABILITY IN PATIENTS WITH TYPE 1 DIABETES IN REAL-LIFE STUDY

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Background and Aims: Previous studies showed that continuous glucose monitoring (CGM) is an effective method for the improvement of diabetes control. From 2016, long-term CGM is reimbursed by health insurances in the Czech Republic. Our aim was to evaluate the effect of long-term (CGM) on glycaemic control in patients with type 1 diabetes (T1D) in retrospective, observational and real-life study.

Method: Twenty-eight consecutive T1D subjects (40.7 ± 11.7 years old, 54% women, 24.4 ± 12.7 years of diabetes duration) mainly on insulin pump therapy (96%) indicated to long-term CGM were assessed in our study. Indications for long-term CGM were unsatisfactory glycaemic control (57%) or protection against recurrent disabling hypoglycaemia (43%). The glycaemic control was evaluated by glycosylated hemoglobin (HbA1c), average glyceamia and glycaemic variability (standard deviation - SD) before and at least 6 months from the beginning of long-term CGM. All patients underwent standard education.

Results: There was a significant reduction of HbA1c during long-term CGM (8.5 ± 1.8% before vs. 7.5 ± 1.2% after at least 6 months; p = 0.02). In addition, decrease of glycaemic variability was seen during long-term CGM (SD 3.4 ± 0.9 vs 2.7 ± 0.7; p = 0.002). Average glycaemia was lower during long-term CGM in comparison with initial data, but this difference was only on the level of trend (9.3 ± 2 vs. 8.4 ± 1.7 mmol/l; p = 0.08).

Conclusion: Long-term CGM led to improvement of diabetes control evaluated by HbA1c and glycaemic variability in T1D patients in real-life study.

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Glucose Sensors

ATTD8-0101

SENSOR AUGMENTED PUMP THERAPY IN TYPE 1 DIABETIC PATIENTS WITH SEVERE AND / OR UNAWARENESS HYPOGLYCEMIC EVENTS. RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Aims: Patients with type 1 diabetes mellitus (DM) on treatment with continuous subcutaneous insulin infusion (CSII) who suffer severe and/or unawareness hypoglycemic events (HE), are given the continuous glucose monitoring (CGM) among their initial treatment with the aim of reducing severe HE and improving the metabolic control of the disease.

Aims: To determine if treatment with CSII and CGM decreases the number of severe HE and allows better metabolic control.

Method: Six-month retrospective observational study. A sample of 15 patients on treatment with CSII and CGM were included. We evaluated the metabolic control evolution (% HbA1c), mean glucose and standard deviation (mg/dL), mild HE (% in a month), severe HE (episodies in 6 months), capillary blood glucose measurements (number in a month) and total insulin dose (IU/day).

Results: Significant differences ($p < 0.05$) were found for three variables: severe HE (16 vs 1), $p = 0.001$, mild HE (7.04 ± 5.47) vs (3.92 ± 3.14), $p = 0.005$ and standard deviation (73.67 ± 14.30) vs (64.80 ± 11.13) $p = 0{,}031$.

Conclusion: Continuous subcutaneous insulin infusion and continuous glucose monitoring decreased the number of severe and mild hypoglycemic events, and improved the metabolic control of patients with type 1 diabetes mellitus suffering from severe and/or unawareness hypoglycemic events significantly. Therefore, continuous glucose monitoring is considered a recommended therapy for this patient profile.

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Glucose Sensors

ATTD8-0255

MINIATURIZATION OF AN OSMOTIC PRESSURE-BASED GLUCOSE SENSOR BY MEANS OF NANOSENSING TECHNOLOGY

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Background and Aims: The Sencell Glucose ensor (Lifecare, Norway) uses osmotic pressure differences between a reagent chamber containing an active fluid with ConA and dextrane and the interstitial fluid, to determine interstitial glucose concentrations. Successful proof of concept studies have been performed in pigs with wired prototypes (2 x 1.5 x. 0.6 cm^3). Substantial miniaturization of the measurement chamber and addition of wireless data and energy transfer are the next development steps.

Method: To achieve miniaturization to the planned size of $2 \times 3 \times 6\,mm^3$, cantilever-based very sensitive pressure transducers will be employed. These nano strain-sensors are composed of a carbon matrix in which nanogranular metals are being embedded and have a size of 20 x 50 nm^2. These nanosensors will be 3D-printed on the bottom of the pressure chamber. The employed ConA/dextrane system becomes more viscous upon upconcentration and will be replaced by a complex with similar fluidic properties even at high concentrations. Wireless power induction and data transfer requirements can be established by commercially available microelectronic components.

Results: The nanosensors have been shown to be very robust and with stable signal performance (< 1 % drift over 6 months). The printing process can be uesed in highly reliable mass production procedures (CV between sensors <0.01 %). A laboratory experimental working station will be developped to compare nanosensor performance with piezo resistive of-the-shelf sensors.

Conclusion: When miniaturized to the desired small size, the Sencell device is expected to provide higher convenience than needle sensors and a pronounced longevity (> 6 months).

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Glucose Sensors

ATTD8-0365

NON-ADJUNCTIVE FLASH GLUCOSE MONITORING USE DURING SUMMER CAMP IN CHILDREN WITH TYPE 1 DIABETES – THE FREE-SUMMER STUDY

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Background and Aims: FreeStyle Libre™, a factory-calibrated sensor for flash glucose monitoring (FGM), is accurate and safe in children with type 1 diabetes (T1D). There are no published data on FGM effectiveness as a replacement for self-monitoring of blood glucose (SMBG) in this population. The aim of this study was to evaluate the non-adjunctive use of FGM in children with T1D during two weeks in a summer camp.

Method: In this double-blinded clinical trial we randomized 45 participants (25 females), aged 6-15 years (mean±SD: age

Table 1. Glycemic control of children with type 1 diabetes

	Partecipants (n= 45)			Partecipants with HbA1c>7% (n=29)		
	SMBG (n= 20)	FGM (n=25)	P-value	SMBG (n= 13)	FGM (n=16)	P-value
Time within Range 3.9 – 10.0 mmol/l (%)	50.8 ± 13.75	50 ± 11.25	0.64	10.5 ± 1.7	12.2 ± 2.4	0.05
Time < 3 mmol/L (%)	1.4 ± 2.2	1.3 ± 1.7	0.98	1.0 ± 1.9	1.5 ± 1.6	0.35
Time > 10 mmol/L (%)	44.7 ± 15.8	45.2 ± 12.5	0.89	53.0 ± 8.0	43.9 ± 11.6	0.03

Table 2. The percentage of FGM results within and outside the range ± 2 mmol/l of SMBG.

	Number	%
Results outside range ± 2 mmol/L (36 mg/dL)		
All	491	17.6
< 4.4 mmol/L (80 mg/dL)	249	8.9
Result within range ± 2 mmol/L (36 mg/dL)	2297	82.4
Total	2788	100

11.1 ± 2.6y, HbA1c 7.4 ± 0.7%): 25 in the FGM group were blinded for the SMBG and insulin dosing was FGM based, whereas 20 in the control group were blinded for FGM and performed SMBG based insulin dosing. The primary outcome was between-group difference (FGM vs. SMBG) in time in range 3.9-10 mmol/l (TIR).

Results: TIR (3.9–10 mmol/l) was not different between the groups (Table 1). In participants with suboptimal metabolic control (HbA1c>7%) we observed a significant reduction in time spent above 10 mmol/L ($P < 0.05$) and an improvement in TIR ($P = 0.05$) in the FMG group. No severe hypoglycemic events or serious adverse events occurred.

Overall MARD between FGM and SMBG was 18.3%, with median ARD of 8. Consensus error grid analysis demonstrated 82.2% of results in zone A and 95.2% of results in zones A+B. Additional results are shown in Table 2.

Conclusion: The non-adjunctive use of FGM was as safe and effective as SMBG, and reduced time spent in hyperglycemia in a sub-population with suboptimal glycemic control of children with T1D.

Trial registration: NCT03182842.

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Glucose Sensors

ATTD8-0140

CGM USE WITH OR WITHOUT REMOTE MONITORING DURING PREGNANCIES ASSOCIATED WITH TYPE 1 DIABETES (T1D)

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Background and Aims: Sharing CGM data with family and friends may affect pregnancy outcomes.

Method: Women with T1D were stratified prospectively (n = 40) to: (1) CGM Alone: women without Apple devices or (2) CGM Share (DexCom, San Diego, CA): women with iPhone and followers with data viewing devices, and retrospectively (n = 8) to: (3) no CGM. Analyses include 28 prospective and 8 retrospective pregnancies. Data from subjects who withdrew or miscarried were excluded. Longitudinal mixed models were used for change in outcomes over time.

Results: Baseline characteristics between groups differed for smoking and insulin pump use (Figure 1A), though pump use was similar during pregnancy. CGM Alone users had significantly higher mean total daily doses of insulin than other groups (Alone 0.95 ± 0.03 vs Share 0.79 ± 0.03 vs no CGM 0.77 ± 0.05 units/kg/day, $p = 0.0017$). Maternal weight change over time was higher among CGM Share than no CGM (1.27 ± 0.48 kg difference,

Figure 1A: Baseline Characteristics and Hypoglycemia Fear Changes over Time

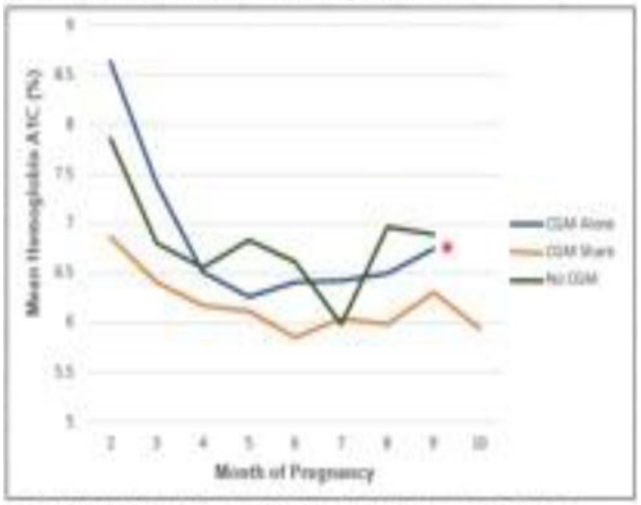
Baseline Characteristics:	CGM Alone		CGM Share		No CGM	
Number of Subjects	13		15		8	
Age (years)[a]	24.4 (21.2, 30.3)		28.9 (26.7, 31.0)		27.6 (20.7, 29.5)	
Diabetes duration (years)[a]	11.6 (6.8, 17.0)		18.0 (10.0, 21.0)		9 (2.0, 15.5)	
Body mass index (kg/m^2)[a]	25.8 (24.6, 28.5)		24.7 (24.2, 31.4)		26.8 (22.6, 33.5)	
Past cigarette use, n (%)[b]	8 (67)		3 (20)		2 (29)	
Method of insulin delivery, n (%)[b,c]	Baseline	F/U	Baseline	F/U	Baseline	F/U
Multiple daily injections (MDI)	7 (54)	4 (31)	2 (13)	0 (0)	4 (57)	2 (25)
Insulin pump therapy	6 (46)	9 (69)	13 (87)	15 (100)	3 (43)	6 (75)
Basal insulin (units)[a]	32.5 (20.0, 54.0)		23.1 (18.6, 30.0)		25.8 (20.8, 30.0)	
Bolus insulin (units)[a]	24.1 (15.5, 31.9)		19.7 (14.3, 28.3)		20.6 (18.1, 25.5)	
Preconception Hemoglobin A1C (%)[a]	8.1 (7.2, 9.0)		7.1 (6.3, 8.4)		7.2 (5.5, 8.4)	
Changes in Hypoglycemia Fear Survey Scores over Time:	**CGM Alone**		**CGM Share**			
1st Trimester (n)	13		15			
Behavior Score (mean ± SD)[d]	28.8 ± 5.8		27.9 ± 3.9			
Worry Score (mean ± SD)[e,f]	45.1 ± 14.8		34.0 ± 7.2			
2nd Trimester (n)	13		14			
Behavior Score (mean ± SD)[d]	28.2 ± 6.9		28.9 ± 4.5			
Worry Score (mean ± SD)[e,f]	37.5 ± 12.5		34.6 ± 9.7			
3rd Trimester (n)	10		10			
Behavior Score (mean ± SD)[d]	28.6 ± 6.6		28.2 ± 4.1			
Worry Score (mean ± SD)[e,f]	43.4 ± 19		37.4 ± 7.8			

Abbreviation: F/U, follow-up.
[a] Median (25th %ile, 75th %ile); [b] P-value<0.05; [c] Three women on CGM Alone, two on CGM Share, and three on no CGM changed MDI to pump therapy during pregnancy (p=0.07); [d] p=0.48 over time; [e] p=0.03 over time; [f] p=0.04 for total score (behavior and worry) over time.

$p < 0.0001$ after adjusting for preconception weight). The change in A1C differed between groups over time ($p = 0.0042$, Figure 1B). Worry and total scores were significantly higher in CGM Alone users on the Hypoglycemia Fear Survey (Figure 1A). CGM Share spent less time >180 mg/dL (17.2% Alone vs 14.6% Share in 1st trimester, 20.1% Alone vs 15.5% Share in 2nd trimester, 15% Alone vs 13.6% Share in 3rd trimester, $p = 0.0411$). Gestational age at delivery and neonatal hypoxemia were significantly less favorable in CGM Alone (Figure 1C).

Conclusion: CGM Share use improves glucose control with lower insulin use and improves neonatal hypoxemia. Larger studies are needed to determine if other pregnancy outcomes are affected.

Figure 1B: Mean Hemoglobin A1C Over Time



*p=0.0042 difference in changes in A1C over time between groups after adjusting for preconception A1C

Figure 1C: Maternal and Fetal Outcomes

Outcome	CGM Alone	CGM Share
Median CGM Ranges in Time:		
1st trimester <65 mg/dL (%)	7.5	7.3
1st trimester 65-140 mg/dL (%)[a]	52.8	59.3
1st trimester >140 mg/dL (%)	38.2	35.3
2nd trimester <65 mg/dL (%)	4.5	5.3
2nd trimester 65-140 mg/dL (%)[a]	50.7	56.6
2nd trimester >140 mg/dL (%)	46.1	37.2
3rd trimester <65 mg/dL (%)	3.8	4.5
3rd trimester 65-140 mg/dL (%)[a]	54.9	62.3
3rd trimester >140 mg/dL (%)	41.6	34.4
Gestational age (weeks)[bc]	36.7 (34.2, 37.2)	37.6 (36.6, 38.1)
Birth weight (grams)[c]	3,420 (2,538, 3,943)	3,610 (3,221, 3,988)
<37 weeks gestation, n (%)	7 (54)	4 (27)
Cesarean section, n (%)	8 (62)	13 (87)
Preeclampsia, n (%)	4 (31)	4 (27)
LGA, n (%)[c]	5 (39)	7 (47)
Macrosomia, n (%)[d]	0 (0)	3 (20)
Neonatal hypoglycemia, n (%)	7 (58)	11 (73)
Neonatal jaundice, n (%)	8 (67)	5 (33)
Neonatal hypoxemia, n (%)[b]	6 (46)	1 (7)
NICU admission, n (%)	5 (39)	7 (47)

Abbreviations: LGA, large-for-gestational age; NICU, neonatal intensive care unit.

[a] p=0.058 over time; [b] p<0.05; [c] median (25th %ile, 75th%ile); [d] estimated fetal weight >90th percentile; [d] fetal weight >4 kilograms.

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Glucose Sensors

ATTD8-0261

A QUALITATIVE EVALUATION OF 'REAL-WORLD' EXPERIENCES WITH AND PERCEPTIONS OF CONTINUOUS GLUCOSE MONITORING (CGM) TECHNOLOGY

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Background and Aims: Clinical evidence indicates that CGM use contributes to improved glucose control and reduced hypoglycemia, yet uptake of these devices in Canada remains low. The aim of this qualitative study was to develop an in-depth 'real-world' understanding of the role of CGM (used in conjunction with insulin pump) in T1D management and to illuminate barriers to device uptake, from various stakeholder perspectives.

Method: Qualitative interviews were conducted with 29 participants across five stakeholder groups: patients, parents, clinical experts, decision-makers and payers. Analysis entailed coding interview transcripts for common themes and patterns, and constant comparison was used to examine differences and similarities within and across stakeholder groups.

Results: Three themes were identified: *the complex and unending work of diabetes management*, *benefits and burdens of CGM,* and *barriers and facilitators* to adoption. The challenges inherent in the *work* of diabetes management provided a catalyst for CGM uptake. Participants across stakeholder groups explained that CGM provided important information that enhanced predictability, improved daily diabetes management, reduced psychological burden, and improved quality of life. However, participants explained that CGM was not without its shortcomings (information overload, device accuracy, alarm fatigue, discomfort) nor was it believed that CGM was well-suited for every patient with T1D. Cost and lack of reimbursement for CGM were further cited as barriers to uptake. This was seen as an important health equity issue, requiring attention and intervention.

Conclusion: Establishing medically-supported criteria to identify those most likely to benefit from CGM was seen as a clinically reasonable, economically feasible, and equitable approach to reimbursement.

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Glucose Sensors

ATTD8-0285

LONG TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DEMONSTRATES BENEFITS IN GLYCEMIC CONTROL WITH WEAR COMPLIANCE

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Background and Aims: The Eversense® CGM System (Senseonics Inc. MD, USA) consists of long term implantable glucose sensor, a smart transmitter and a mobile app to display real-time glucose readings every 5 minutes. The sensor glucose reading was calculated on the wearable smart transmitter and sent to the smartphone via Bluetooth low energy.

Method: A group of 51 people with diabetes who initiated use of the Eversense CGM system in May 2017 were followed over the 90-day sensor life period to analyze the group's glycemic status. The primary status indicator utilized were time in target between 70–180mg/dl, percentage of time in low glucose below 70mg/dl, and percentage of time in very low below 54mg/dl. Users were segregated into two groups; one group with wear compliance of 85% and above and the other group with wear compliance less than 85%. The data was gathered by Eversense Data management system (DMS), a cloud based platform that provides historical storage and diabetes management reports to share with caregivers and HCP.

Results: Users observed an increase in glycemic control and reduced time in severe hypoglycemia when wear compliance is above 85%.

Wear compliance	Low (54 – 70mg/dl)	High (>180 mg/dl)	In Target (70-180mg/dl)	Very low (<54mg/dl)	Average glucose value in mg/dl
Greater than 85% (n = 29)	2.6%	29.0%	67.7%	0.77%	153
Less than 85% (n = 22)	4.2%	32.2%	62%	1.72%	156

Conclusion: Benefits of Eversense CGM in optimization of diabetes control is more prominent in users who are compliant with the system.

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Glucose Sensors

ATTD8-0212

NEW CALIBRATION ALGORITHM LEADS TO ROBUST CGM PERFORMANCE WITH REDUCED NUMBER OF CALIBRATION MEASUREMENTS

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Background and Aims: Since CGM sensors tend to change their behavior over time, frequent calibrations (usually twice a day) using SMBG samples are required. We discuss here the newly proposed JKU calibration algorithm able to reduce the total number of calibrations over a sensor lifetime.

Method: In the available data of clinical studies consisting of 176 records, patients performed the first calibration measurement three hours after insertion, the second one two hours afterwards, and subsequently two measurements every day (one in the morning and one in the evening) over a period of 7 days. Based on this basic setup the impact of reducing the number of calibration measurements has been studied. We compared the newly developed JKU algorithm with the manufacturer's state of the art (SOA) algorithm, and with an algorithm from the literature based on a Bayesian Framework (BF) and specifically devoted to calibration with less SMBG measurements.

Results: From the results presented in Fig.1, one can see that the SOA algorithm cannot be used with less calibration points without a loss of performance. However, the other two algorithms, BF and JKU calibration, are more robust towards the reduction of calibration measurements. Moreover, for the JKU calibration a comparable quality can be reached with different calibration schedules (see the MARD distribution over different schedules in Fig. 2).

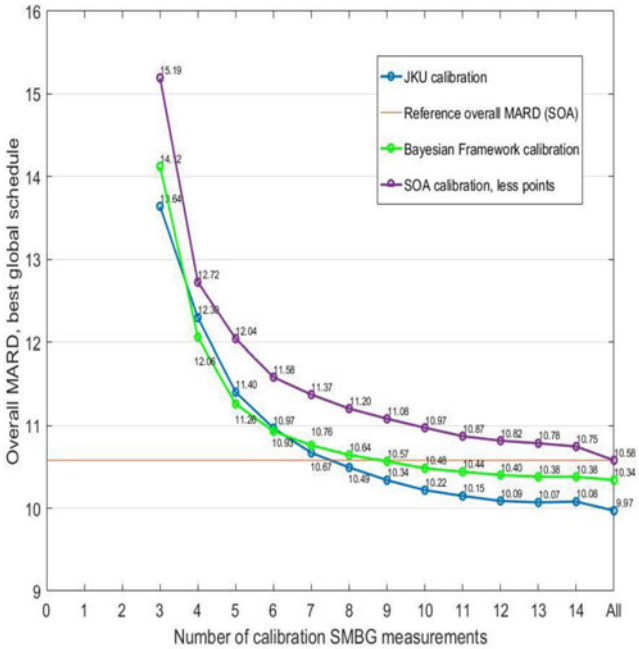

Fig. 1

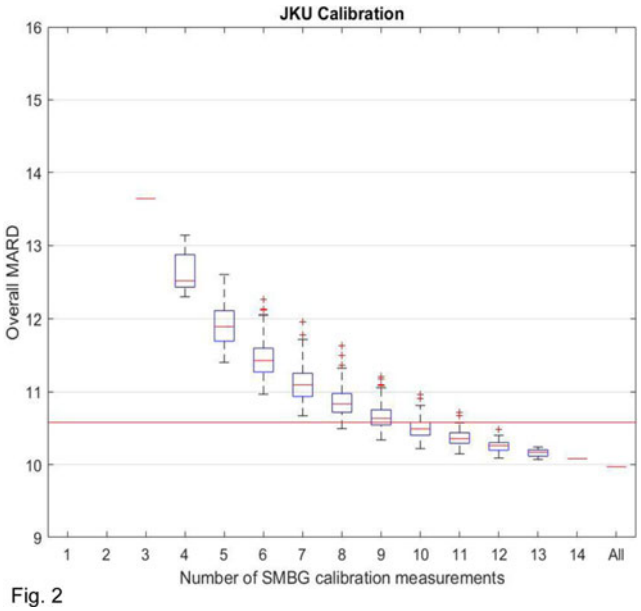

Fig. 2

Conclusion: The new calibration method can achieve the performance (in terms of MARD) of the manufacturer's algorithm by using approximately half of the calibrations and is robust with respect to calibration schedules.

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Glucose Sensors

ATTD8-0280

FLOW-CHART TO PREVENT HYPOGLYCEMIA AND HYPERGLYCEMIA IN ADOLESCENTS WITH TYPE 1 DIABETES USING STANDALONE CONTINUOUS GLUCOSE MONITORING WITH PREDICTIVE ALARMS: REAL LIFE VALIDATION.

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Background and Aims: Predictive alarms (PA) have been integrated in CGM (Guardian Connect™, Medtronic), to warn patients that within a pre-set time-frame a hypoglycemia or hyperglycemia will be reached. The efficacy of a specific-designed

Sensor value	Trend	Action	SMBG	Immediate action	Follow-up
<70 mg/dl* (<3.9 mmol/l)	ALL but ↑	Check SMBG	<70 mg/dl* (<3.9 mmol/l)	Sugar 0.3 gr/kg (max 15 gr)	If still symptomatic after 15 min could be repeated
70-180 mg/dl (3.9-10 mmol/l)	Predictive low (settled 30 min before)	Check SMBG	70-180 mg/dl (3.9-10 mmol/l)	Sugar 0.1 gr/kg (max 5 gr) If exercise tink of 0.2-0.3 gr/kg (max 15 gr)	
180-250 mg/dl (10-13.9 mmol/l)	No arrow or ↑	Check SMBG	180-250 mg/dl (10-13.9 mmol/l)	No action	
180-250 mg/dl (10-13.9 mmol/l)	↑↑ or ↑↑↑	See below	180-250 mg/dl (10-13.9 mmol/l)	See below	
>250 mg/dl (>13.9 mmol/l)	ALL but ↓	Check SMBG only if needed	>250 mg/dl (>13.9 mmol/l)	• If meal <2h just wait • If meal >2h correction bolus • If exercise, check ketones • If ketones <0.6 mmol/l correction bolus reduced 20% • If ketones >0.6 mmol/l NO exercise and correction bolus	Check glucose value after 1 h If no improvement, wait at least 2 h for another correction bolus

SMBG = self monitoring blood glucose
*or higher values if symptoms

flow-charts to limit hypo and hyper in adolescents with T1D using MDI plus Guardian Connect, under free-living conditions, has been evaluated.

Method: PA system safety and efficacy in 33 adolescents with T1D were evaluated by analyzing CareLink data either during a 3-day camp, or after 4 days back home. Mean BGs, mean SGs, %time spent in hypo (<3.9 mmol/l), %time spent in hyper (>10 mmol/l), have been analyzed. No severe hypo or DKA observed.

Results: We analyzed 32/33 patients because of missing sensor data (mean age 15.7 ± 1.5 years, diabetes duration 8 ± 4 years, HbA1c 7.8 ± 1.2%). The average BG was 10.3 ± 1.4 mmol/l, while average SG level was 10.1 ± 1.3 mmol/l, with higher values at home than at camp (10.0 ± 1.4 vs 10.4 ± 1.5, p = **0.000**), as well as %time in hyper (27.1 ± 14.9% vs 33.4 ± 16.3, p = **0.000**), but not in hypo (0.5 ± 0.8% vs 0.4 ± 0.7, p = **0.033**). After one month since camp, 100% of adolescents were still using glucose sensor daily (70-100% of the time).

Conclusion: PA system in adolescents with T1D was safe and effective. The use of the flow-charts contributed to reduce both hypo and hyper. Correcting BG before it reaches a hypo with 5 gr (instead of 15 gr) is effective to prevent hypo and limit hyperglycemic excursion. We confirm all adolescents are still using the system 1 month after the camp, as we demonstrated previously for 640G.

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Glucose Sensors

ATTD8-0408

CLINICAL ASSESSMENT OF THE MARD OF A BLOOD GLUCOSE TEST-STRIP OVER A SEVEN-YEAR PERIOD

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Background and Aims: Mean Absolute Relative Difference (MARD) is commonly referenced as a quantitative indicator of the accuracy of Continuous Glucose Monitoring (CGM) systems. In contrast, the accuracy of Blood Glucose Monitoring (BGM) systems is typically reported as per requirements of ISO 15197, in which the percentage of blood glucose (BG) values within a given range of the reference value is determined. This study evaluates the MARD performance of a substantial clinical data-set (80,258 individual data-points) for the OneTouch Verio® BGM system over a 7.5-year surveillance period.

Method: The data-set gathered over 7.5-years, represent routinely selected batches of manufacturer's test-strip product. Tests were performed at 3 hospital-based clinic sites by trained staff, drawing fresh capillary blood from patients with diabetes, with meter results compared against the reference system.

Results: MARD was calculated by strip batch (n = 671 unique batches) yielding values of 3.68-6.43% (±1.96 standard deviations from the all-batch mean MARD value of 5.05%). Mean MARD performance by year of manufacture ranged from 4.67-5.42%. The overall MARD for all data-points (n = 80,258) was also 5.05%.

Conclusion: The consistency of the MARD data over the 7.5-year surveillance period provides patients with confidence in the accuracy of this BGM system when transitioning from one strip batch to another. Mean MARD, by batch, and overall MARD across all strips tested, indicates the accuracy of the product within the clinic setting and compares favourably against alternative BG management technologies. Percent MARD should not be confused with percent accuracy as defined by the ISO 15197 standard, they are not interchangeable measures.

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Glucose Sensors

ATTD8-0146

SUSTAINED REDUCTIONS IN SEVERE HYPOGLYCAEMIA WITH CONTINUOUS GLUCOSE MONITORING: REAL LIFE CLINICAL EXPERIENCE

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Background and Aims: NICE guidelines recommend CGM for adults with type 1 diabetes (T1D) with problematic hypoglycaemia despite optimised, specialist medical management. Randomised controlled trials have shown CGM to be effective at improving glycaemic control and reducing the frequency of hypoglycaemia. We evaluated the effect of CGM therapy over time on HbA_{1c}, severe hypoglycaemia (SH) and hypoglycaemia awareness, in a cohort of adult patients with T1D.

Method: We conducted a retrospective case-note audit on adults with T1D treated with CGM at two teaching hospitals. Inclusion criteria were T1D and use of CGM for at least 12 months, with data on HBA_{1c}, SH and awareness status measured by Gold score. We excluded those using CGM in pregnancy.

Results: 75 were included in analysis, 61% were female, mean age was 46.7 ± 12.8 years with mean duration of diabetes 31.8 ± 13.9 years. The median (IQR) duration of follow-up was 46 months (24-65). Mean SH rate dropped from 7.69 ± 33.74 pre-CGM to 0.95 ± 4.1 (p < 0.001) after 1 year, with benefit sustained for up to 7 years (0.08 ± 0.29). No significant deterioration in HbA1c (7.94 ± 1.15[baseline] vs 7.35 ± 0.67[year 7]) or Gold

score (5.12 ± 2.09[baseline] vs 5.71 ± 1.49[year 7]) was observed over the duration of follow up.

Conclusion: These are the first data showing sustained benefits out to 7 years of CGM in significantly reducing SH rates, without deterioration of glucose control. However, there was no restoration of hypoglycaemia awareness, implying long-term dependence on this technology.

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Glucose Sensors

ATTD8-0149

CGM DATA AGGREGATION LIMITING LOSS OF VARIABILITY INFORMATION

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Background and Aims: CGM data is commonly aggregated by 1) calculating a 24hr average giving the average glucose value correlating well with HbA1c, or 2) calculating a point-by-point average value from midnight to midnight (PBP) yielding a 24hr (24h) curve of the ''average'' diurnal pattern. 2) tends to give flatter graphs than what is observed from the individual profiles, and we aimed here to explain why as well as developing a more individual representative methodology.

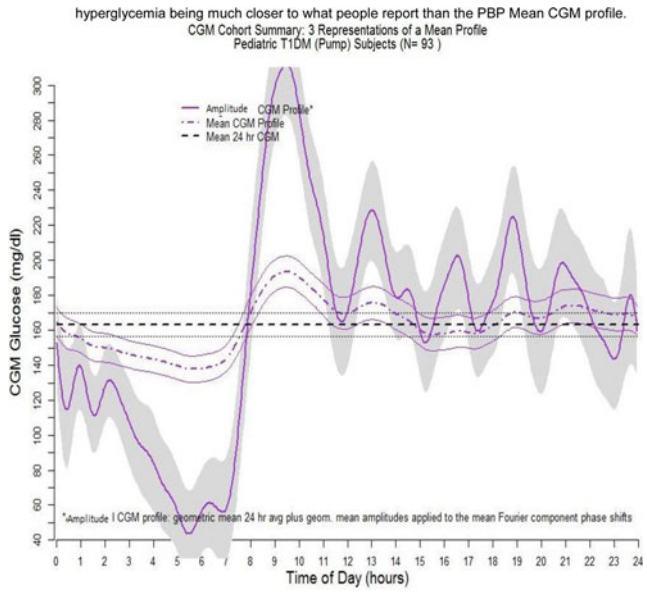
Method: We used Fourier transformation (FT) to a) derive a new aggregation method more visually representative of the raw data, and b) explain what information is lost when calculating the point-by-point average curve.

Results: A curve equivalent to the PBP 24h curve can be derived from FT data averaging the coefficients μ, C and S for each cycle (average sign and lower cases not available in editor):

$f(t) \approx \mu + (1/\mathrm{sqrt}(12)) \Sigma j = 1,\ k\ (Cj*\cos(2\pi jt/24)) + Sj*\sin(2\pi jt/24))$.

With D curves for aggregation, $(1/D)\Sigma i = 1$, $D\ Cij^2 - (Cj^2) =$ variance of Cj's; similarly for the Sj's.

Thus, the average squared amplitude $= (1/D)\Sigma 1 = 1, D(Aij^2) =$ $(1/D)\Sigma 1 = 1,\ D(Cij^2 + Sij^2) = (var(Cij's) + Cj^2) + (var(Sij's) + Sj^2) > (Cj^2 + Sj^2)$.



The graph illustrates the results of the 3 methods of deriving a CGM average curve of 93 adolescent CSII treated T1DM patients. Note the late night relative hypoglycemia and the apparent post breakfast hyperglycemia being much closer to what people report than the PBP Mean CGM profile.

Conclusion: The data aggregating in the PBP 24h curve underestimates the amplitude of variability by an amount related to the variance. Aggregating by the amplitudes eliminates this underestimation and leads the aggregate 24h profiles to more closely resemble the raw data.

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Glucose Sensors

ATTD8-0287

CARELINK ANALYSIS FOR REAL-WORLD NON-ADJUNCTIVE CGM INSIGHTS

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Background and Aims: Current Medtronic CGM systems require a self-monitored blood glucose (SMBG) meter to support diabetes treatment decisions. Patients and healthcare providers widely report that sensor glucose (SG) readings are frequently relied on for treatment decisions (non-adjunctive use). Non-adjunctive use of SG allows for fewer SMBG measures per day, reducing diabetes management burden, while also indicating a level of trust in the CGM system. CareLink™ data was analyzed to assess real-world glucose results for patients applying non-adjunctive use of a Medtronic CGM system.

Method: Data uploaded by MiniMed™ Veo pump users between January 1, 2015-July 12, 2016 were analyzed to determine the frequency of non-adjunctive vs. adjunctive use and the frequency of post-bolus hypo- (nadir) and hyperglycemia (peak) over the following 4 hours was compared. Manually-entered values that were identical to the preceding SG value were assumed to be non-adjunctive

11,367 users were identified as having used both an SMBG and SG value for 1 or more bolus calculations.

Results: Over 9.4 million bolus events were evaluated. 6.6% of all boluses meeting the defined criteria for non-adjunctive bolus, with results presented in the table below.

Conclusion: It was presumed that a manually-entered BG value that was identical to the SG, indicated non-adjunctive use of CGM for that reading. However, it is possible that this might have over or underestimated the true percentage of SG values used non-adjunctively. The frequency and severity of hypo- and hyperglycemia is lower with non-adjunctive vs. adjunctive bolusing but it is unclear at this time if this is clinically significant.

Threshold	Frequency of Hypo/Hyper		p-value
	SMBG Bolus	SG Bolus	
<50 mg/dL	2.0%	1.8%	<0.001
<60 mg/dL	5.7%	5.3%	<0.001
<70 mg/dL	12.1%	11.9%	<0.001
>180 mg/dL	42.1%	37.2%	<0.001

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Glucose Sensors

ATTD8-0144

NON-INVASIVE BLOOD GLUCOSE ESTIMATION FROM THE NEAR INFRA-RED (NIR) ABSORBANCE SPECTRUM

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[2]*Diacon Hospital, Diabetologist, Bangalore, India*
[3]*Diacon Hospital, Head of Clinical Research, Bangalore, India*

Background and Aims: Monitoring of capillary blood glucose (CBG) is integral to diabetes care. It involves the finger to be pricked to obtain the CBG. The aim of this study was to compare the NIR absorbance spectrum obtained from the fingertip with glucometer values. The method proposed in this paper is a cost-effective technique that eliminates the finger prick.

Method: This was a cross-sectional study of 500 patients with Diabetes Mellitus attending the outpatient at a diabetes center in Bangalore. The CBG glucose, i.e. fasting and two-hour post-prandial blood sugar measurements with a finger prick were collected from the subjects. AccuCheck-Active was used to measure the CBG. The absorbance spectrum was acquired from the finger tip for these subjects simultaneously. The spectrum values in the NIR range from 900 nm to 1700 nm were chosen as the input for the model. The input spectrum was used as the feature to train the models.

Results: When the blood glucose prediction model was built for the blood glucose range up to 250 mg/dL and applied on the test dataset; 93.97% of the results were within ±15% accuracy for the blood glucose values above 100 mg/dL. Parkes Error Grid for the results are shown in the figure. No results fall in Zone D&E.

Conclusion: The results of the proposed method is close to compliant with the ISO 15197:2013 for the data used for the study. Future work involves collecting more data covering the entire blood glucose range covering various variabilities and improve the algorithm.

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Glucose Sensors

ATTD8-0421

USING REAL-TIME CONTINUOUS GLUCOSE MONITORING: FEEDBACK FROM ADULTS PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: Since 2017 health insurance in CzR partially covers consumables for RT-CGM (sensors and transmitters) for T1D adult patients who measure glycemia min. 4x/day and fulfil at least one of the following conditions: *high glycemic variability, frequent or severe hypoglycemia, hypoglycemia unawareness, gravidity, protection of graft*. The aim was to identify how many patients interested in CGM fulfil the criteria and how they are content with the sensor.

Method: 47 patients with T1D with CGM experience filled a form stating interest in CGM, Gold score, DDS2, self-management of diabetes. After 7-days use of Enlite, Medtronic sensor completed the Glucose Monitoring Satisfaction Survey (GMSS-total score, four subscales).

Results: Interest in using CGM indicated 36/47 (77%) patients, out of them 17 (47%) measures <4x/day and 18 (50%) indicated CGM as the main factor to improve their diabetes. The motivated patients showed statistically higher Glucose monitoring satisfaction (GMS) total score 59, 7 ± 6, 9 (p = 0,027).

When compared the interested group with the one without interest, the former showed higher variability of glycemia with average SD 3,2 (p = 0.07), higher openness to using sensor (p = 0,048) and lower emotional burden (p = 0,039).

Only 11/36 (30%) of those interested in CGM fulfil the requirements for insurance coverage. Those without interest indicated similar rate (3/11 ∼ 27%).

Conclusion: Using CGM is suitable for any patient with T1D interested in CGM. The fact of not including indication *A1C above target* among the conditions for health insurance coverage disqualifies motivated patients that do not fulfil any other condition. Education in self-monitoring advantages is still needed.

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Glucose Sensors

ATTD8-0271

THE TYPE 1 DIABETES PATIENT DECISION MODEL REPRODUCES THE GLYCEMIC OUTCOMES OF THE REPLACE-BG TRIAL

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Background and Aims: The type 1 diabetes (T1D) patient decision model (Vettoretti et al., IEEE TBME, 2017) can simulate the glucose dynamics of T1D patients on insulin pump therapy using self-monitoring of blood glucose and/or continuous glucose monitoring (CGM) devices. The model accounts for the variability of CGM accuracy over one week of sensor wear. Here, the aim is to compare the model predictions vs data of the REPLACE-BG trial, where adjunctive and nonadjunctive CGM use were tested over 26 weeks, to determine if the model can simulate realistic in-silico trials.

Method: The T1D patient decision model was modified to implement the REPLACE-BG trial protocol with adjunctive and nonadjunctive CGM use. One-week glucose profiles were simulated in 100 virtual adults with adjunctive and nonadjunctive CGM treatments. Then, time spent in eu/hyper/hypo-glycemia [%] were calculated for both simulated data and a subset of real data obtained randomly extracting one week per subject. This comparison was repeated for 100 different random selections of study weeks.

Results: With adjunctive CGM treatment, median time in eu/hyper/hypo-glycemia were 63.93%, 32.36% and 3.03%, respectively, in simulation, on average 63.87%, 31.96% and 3.38%, respectively, in real data. In both simulated and real data, nonadjunctive CGM use allowed reducing time in hypoglycemia (1.63% in simulation, on average 2.91% in real data) with a slight increase of time in hyperglycemia (33.35% in simulation, on average 34.28% in real data).

Conclusion: Results suggest that the T1D patient decision model is able to realistically reproduce the outcome of trials based on both adjunctive and nonadjunctive CGM use.

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Glucose Sensors

ATTD8-0353

CRITICAL-DEPTH RAMAN SPECTROSCOPY ENABLES HOME-USE NON-INVASIVE GLUCOSE MONITORING

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Background and Aims: One of the most ambitious endeavors in the field of diabetes technology is non-invasive glucose sensing. In the past decades, a number of different technologies have been assessed, but none of these have found its entry into general clinical use. We report on the development of a table-top confocal Raman spectrometer that can be used in the home of diabetic subjects and can be operated for extended periods of time without any supervision or regular calibration. The system is based on measurement of glucose levels at a 'critical depth' in the skin, specifically in the interstitial fluid located below the stratum corneum but above the underlying adipose tissue layer. The region chosen for routine glucose measurements was the base of the thumb (the thenar). In a small clinical study, 35 diabetic subjects analyzed their interstitial fluid glucose for a period of 60 days using the new critical-depth Raman (CD-Raman) method. Levels were correlated to reference capillary blood glucose values using a standard finger-stick and test strip product. The calibration of the CD-Raman system was maintained for >10 days. Measurement performance for glucose levels present at, or below, a depth of $\sim 250\mu$m below the skin surface was comparable to that reported for currently available invasive continuous glucose monitors. In summary, using the CD-Raman technology we have demonstrated the first successful use of a non-invasive glucose monitor in the home.

Method
Results
Conclusion:

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Glucose Sensors

ATTD8-0422

MINIMALLY INVASIVE AUTONOMOUS BLOOD GLUCOSE MONITORING SMART-SHOE: HUMAN WHOLE BLOOD VOLUME COLLECTION AND GLUCOSE TESTING

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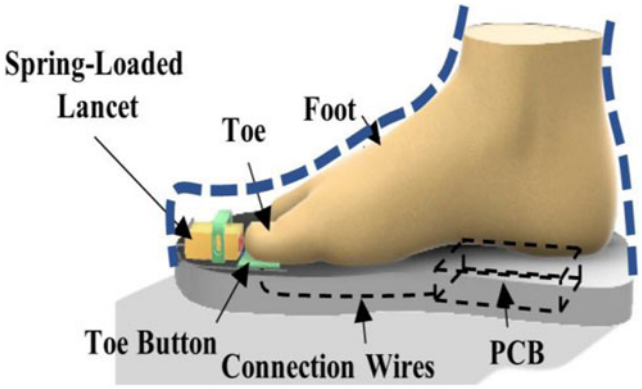

Figure 1. Schematic structure of the eTac (above) and its actual prototype implementation (below)

Background and Aims: To replace stationary whole blood tests with autonomous, automatic, painless and wearable microsystem device, and to illustrate its utilization as an alternative to finger-pricking blood glucose tests for diabetics.

Method: An autonomous, wearable ''smart shoe'' device for autonomous blood collection, the eTac, was designed, implemented and tested on humans. Two volunteers consented to be fitted with the eTac shoe prototype (Figure 1). They began walking soon after the integrated microcontroller activated a skin-lancing mechanism to penetrate the wearers' toe. The extracted whole blood was collected and weighed after ten and twenty steps, then converted to its volume using a factor of 1g/ml. In additional utilization tests, the blood was collected directly into an integrated standard glucose testing strip. Blood glucose concentration measurement was obtained using the custom-designed electronics embedded in the ''smart shoe'' sole and was wirelessly transmitted to a smartphone. Each volume-collecting and glucose-testing experiment was repeated four times per volunteer.

Results: Average collected blood volume was 17.1+/-12.5 μl after ten steps and 20.2+/-13.7μl after twenty steps, always exceeding the 1.2 μl minimum volume requirement for a commercial glucose-testing strip. The extracted whole blood sample was successfully collected without human intervention and the resulting blood glucose measurements were accurate within a 15% margin of error compared to baseline standard finger-pricking tests.

Conclusion: The eTac's actuator mechanism reliably harnessed natural forces produced by human walking to drive a lancet that created a small skin pricking at the toe, facilitating the collection of whole blood samples suitable for various in-situ blood tests, including glucose concentration measurements.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0305

A FHIR-BASED DATA FLOW ENABLING PATIENTS WITH DIABETES TO SHARE SELF-COLLECTED DATA WITH THE NORWEGIAN NATIONAL HEALTHCARE SYSTEMS AND ELECTRONIC HEALTH RECORD SYSTEMS

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Background and Aims: There is no system permitting to share data directly between patient-selected mobile health (mHealth) tools and electronic health records systems (EHRs) [1]. We describe a standard and open approach for this, allowing patients to share their self-collected data from mHealth tools, with Norwegian EHRs, using Norwegian National Services.

Method: The design of the data flow is based upon one-year of workshops with patients, clinicians, Norwegian EHR vendors and members of the Norwegian Directorate for E-health, who are responsible for Norwegian national healthcare infrastructure (NNHI).

Results: A step-based data flow was designed, which relies on FHIR standards enabling patients to send self-collected data to Norwegian EHRs through the NNHI. The flow relies on schemas, which contains metadata of the patients, raw health data from patients' tools, and summary reports generated from a context-sensitive-based data analysis system. Schemas are first filled by patients or their tools automatically, and then sent to the NNHI, which forward it to the relevant EHR system. This design also enables communication from EHRs to patients (see Figure 1).

Conclusion: Sharing patients' self-collected health data with EHRs requires solutions to interoperability issues, especially when various systems use different standards. However, use of such a National Service as 'middleware', could potentially enable data sharing between patients and EHRs, while allowing actors to choose the tools and services that suit them best. This system will be tested during the FullFlow study in early 2018 using diabetes as the use case, followed by report of results and experiences as the study progresses.

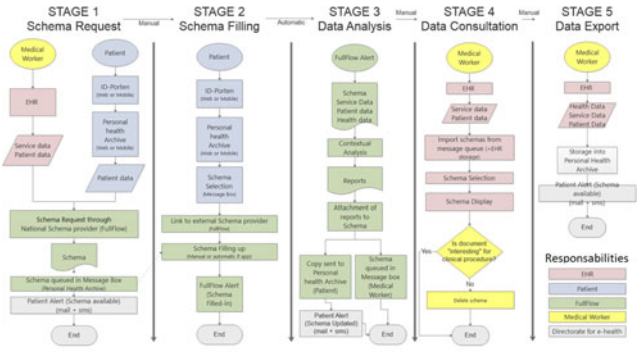

Figure 1. Illustration of the data flow system allowing patients' self-collected data to be shared with EHRs.

Reference

1. Giordanengo, A., et al., Systems integrating self-collected health data by patients into EHRs and medical system: a State-of-the-art review. Proceedings from Scandinavian Conference on Health Informatics. Linköping Electronic Conference Proceedings, Linköping, Sweden: Linköping University Electronic Press, 2017.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0247

A SMART MOBILE APPLICATION THAT INFORMS FAMILY, AND EMERGENCY ASSISTANCE ABOUT AN OCCURRENCE OF POSSIBLE DIABETIC COMA CONDITION IN A TYPE 1 DIABETES PATIENT

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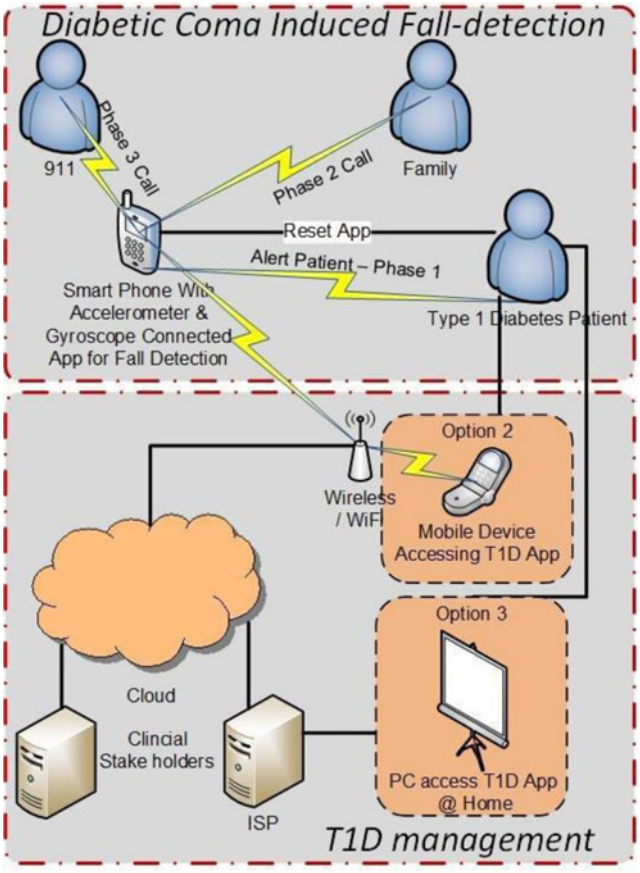
Background and Aims: Type 1 diabetes has to be thoroughly managed, beginning early in life, to avoid long term complications in the eyes, kidneys, cardiovascular, and cognitive systems and to extend the quality of life into later years. Type 1 diabetes costs $14.4



billion in medical costs and lost income in US alone, hence the urgency to mitigate the situation at the earliest. Diabetes management guidelines recommend very strict protocols for glycemic control to avoid the potential combination of hypoglycemia with dehydration and exhaustion, which can result in diabetic ketoacidosis and eventually diabetic coma. This research study applies a combination of information technology tools, such as mobile devices and wireless connectivity, for effective management of type 1 diabetes.

Method: To design and test a prototype through an observation based research in controlled conditions to calibrate and find the efficiency of the application in differentiating an actual fall to the floor, simulating a diabetic coma condition.

Results: An automated mobile software application monitors and sent the relevant information about the patient and inform the concerned authorities and stakeholders about patients' critical conditions in a progressive manner to avoid false positives. The application used a combination of accelerometer and gyroscope data that fed into a smart analytical tool for informing the patient, family and clinical support by calling/messaging in a progressive and intelligent manner.

Conclusion: The prototype performed with reasonable accuracy and was tested with a dummy and real person. The next phase will focus on testing with patient groups to identify practical difficulties.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0339

IDENTIFICATION OF FACTORS CONTRIBUTING TO FAILURE OF AMBULATORY NEGATIVE PRESSURE WOUND THERAPY IN PATIENTS WITH DIABETIC FOOT

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Background and Aims: Indication criteria of negative pressure wound therapy (NPWT) based on patient and wound characteristics are not clear verified. The aim of our study was to assess the effect of ambulatory NPWT on diabetic foot healing and identify factors contributing to failure of this method.

Method: 60 patients with NPWT on ambulatory basis and were enrolled in the present study. The success of NPWT was defined as a complete wound healing during 6 months follow-up; the unsuccess as a premature termination of NPWT, non- healing, major amputation or intolerance of the treatment by patient during 6 month follow-up. In all patients, factors which could influence wound healing were evaluated. Uni- and multivariate analyses were used to identification of factors contributing to failure of ambulatory NPWT.

Results: The median length of NPWT was 23 days (7–98). During follow-up period, 47/60 (78.3%) patients were completely healed after ambulatory NPWT, in 13/60 (21.7%) patients was not NPWT successful. In univariate analysis, the unsuccess of NPWT was influenced especially by poor diabetes control (HbA_{1C} in unsuccess vs. success; 77.2 ± 19 vs. 62.5 ± 18.6 mmol/mol; p = 0.01). Logistic regression showed that HbA_{1C} (OR 1.05; 95% CI 1.01-1.09; p = 0.01), haemodialysis (18; 1.6-208.3; p = 0.02) and exposed bone (7.8; 1.3–48.1; p = 0.03) were significant factors for failure of ambulatory NPWT, other followed factors were not significant.

Conclusion: Ambulatory NPWT was effective in majority of patients, but poor diabetes control, haemodialysis or exposed bone in the wound may contribute to the failure of this method.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0278

BEYOND GLUCOSE: HEALTHCARE PROFESSIONAL (HCP) PERCEPTIONS OF THE VALUE OF CAPTURING INSULIN DOSE DATA TO SUPPORT DIABETES MANAGEMENT. A TARGETED LITERATURE REVIEW

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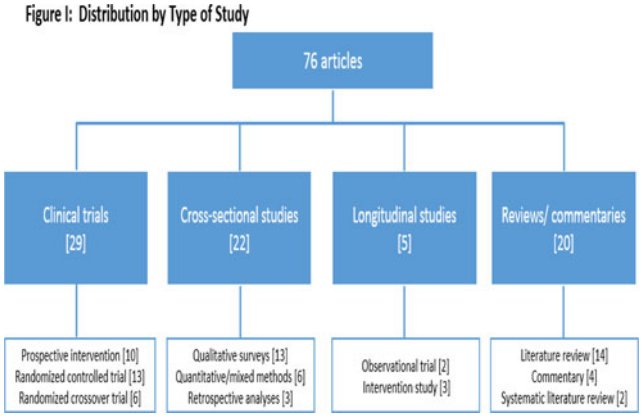
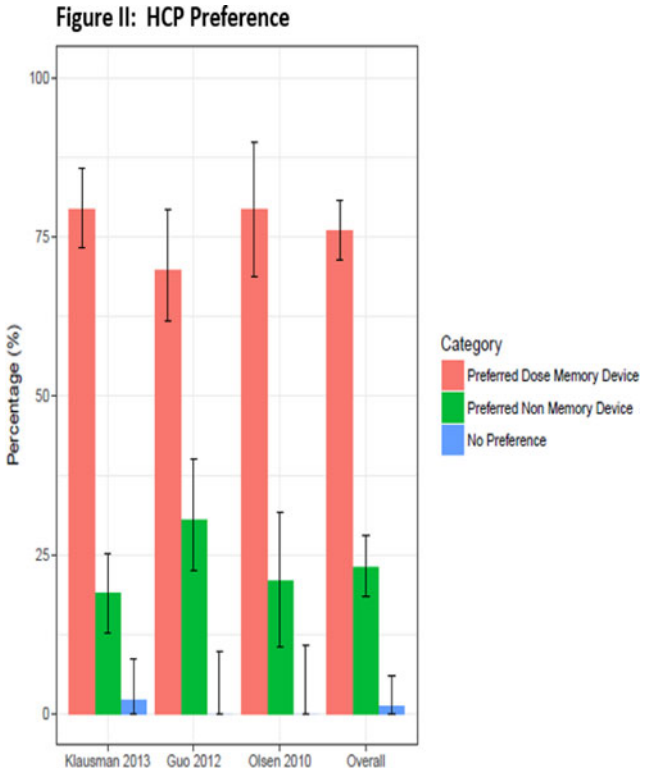
Background and Aims: Access to data on the dose and timing of an insulin injection is thought to be valuable in diabetes care. However, in clinical practice insulin dose data is often incomplete and/or inaccurate, which becomes a barrier to optimizing glycemic control. The objective was to explore HCP perceptions around the value of electronic capturing of the dose and timing of insulin administration for diabetes care.

Method: A search of PubMed and diabetes conference databases identified articles from 2007–2017 that evaluated HCP perceptions on having insulin dose data. Clinical practice guidelines were also reviewed.

Results: Database searches yielded 1,671 abstracts from which 76 articles met the inclusion criteria. Devices with insulin dose memory function (insulin pumps [15% of articles], memory insulin pens [11%], devices enabled with bolus calculators or dose titration [9%], and Bluetooth-enabled insulin pens [3%]) were perceived to be valuable to HCPs in improving adherence and assisting with clinical decision-making, specifically with determining safe and

Figure I: Distribution by Type of Study





appropriate dose adjustments. HCPs preferred insulin pens with memory function over those without (227/300 [76%], 95% CI: 71–81%) and reported greater confidence in patients' ability to manage daily injections (207/252 [82%], 95% CI: 78–87%). Features of memory function most important to HCPs were confirmation of patient dose administration and having access to dose amount and dose timing. No existing national or international clinical guidelines currently recommend capturing insulin dose information.

Conclusion: Despite evidence suggesting that HCPs perceive value in receiving information on insulin dosing, at present, clinical guidelines do not explicitly recommend capturing insulin data.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0185

STEPWISE TREATMENT CONCEPT PROPOSED FOR AN MHEALTH ENABLED DIABETES INTERVENTION

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Background and Aims: Mobile health (mHealth) tools allow people to more individually set the pace and focus of their disease self-management. However, research studies and clinical practice struggle to adapt due to the rapid development of technology. The developed system for use in our intervention dynamically presents diabetes Type 1 and Type 2 patient-gathered data from mHealth devices during clinical consultations.

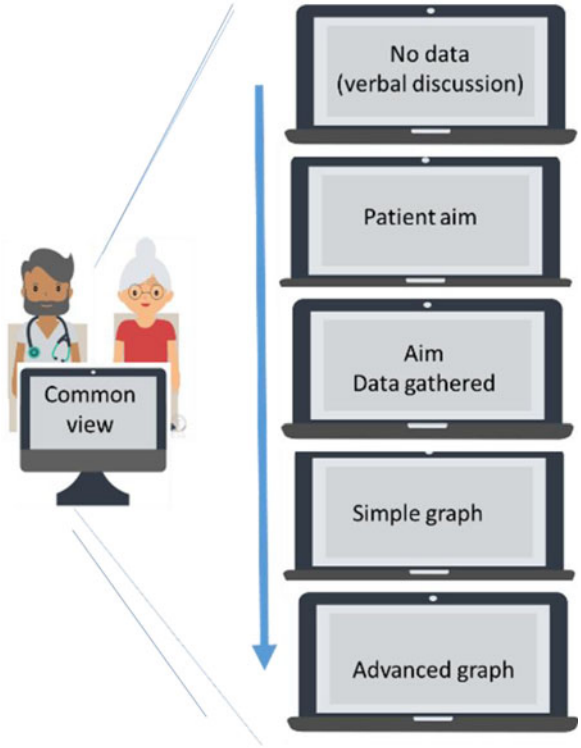

Figure 1. Illustration of the stepwise intervention concept and flow.

Method: The design and functionalities of the system are based upon workshops and studies involving patients and clinicians [1, 2]. Feedback suggests that in order for such a system to provide actionable treatment support, it must display the data based on the individual's knowledge, background and situation, and must also have the possibility to evolve with the individual's capacity to self-manage.

Results: Through several workshops and analysis of related mHealth interventions, a common data-sharing platform was designed to best utilize data from the patients' own mHealth devices. The design combines ''stepwise treatment'' and ''experiential learning'' concepts – enabling patients and clinicians to set self-management and treatment goals together, with or without patient-gathered data. With each incremental use, the system displays updated patient-generated data and goals, from simple graphs to more advanced clinical calculations, e.g. insulin sensitivity, thereby reflecting each patient's progress and capacity to self-manage (see Figure 1).

Conclusion: For a complex illness like diabetes, we cannot expect patients to change quickly. Therefore, by basing the pace of treatment on patients' own self-management capabilities, it has been suggested by stakeholder feedback that such a system could enable more collaborative and practical diabetes management.

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2. Bradway M, G.A., Blixgård H, Giordanengo A, Årsand E, *SYSTEM FOR ENABLING CLINICIANS TO RELATE TO A MOBILE HEALTH APP: PRELIMINARY RESULTS OF THE NORWEGIAN TRIAL IN THE EU FL-STAR PROJECT,* in *9th International Conference of Advanced Technologies & Treatments for Diabetes.* 2016, Diabetes Technology & Therapeutics: Milan, Italy. p. A-1–A-140.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0397

INSULIN RESISTANCE ASSOCIATED CHARACTERISTICS IN T1D PATIENTS 20 YEARS AND OLDER IN MEXICO. RESULTS FROM THE MULTI-CENTRIC STUDY RENACED DIABETES TIPO 1

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Background and Aims: Information regarding the prevalence of some insulin resistance (IR) associated characteristics in type 1 diabetes (T1D) patients during adulthood, in Mexico, is limited. We studied adult patients registered in RENACED DT1.

Method: The gold standard to measure IR is the hyperinsulinemic euglycemic clamp, usually done in a clinical research center. Clinical surrogates of IR include body weight, BMI, waist circumference, hypertension, HDL, triglycerides, and insulin dose. We analyzed the presence of these characteristics in 486 T1D patients ≥20 years-old registered on RENACED DT1, until 10/8/2017.

Results: Sixty-two percent of patients were women, 37.6% men, with a mean age of 32.8 years-old. Average diagnosis age was 16 years, 52% have family history of T2D. Mean BMI was 24.8 Kg/m2 (n = 412), 29% were overweight and 11% were obese. 12.5% had diagnosed hypertension. 21.9% had triglyceride levels ≥150 mg/dl and 19.1% had HDL levels <40 mg/dl. Mean HbA1c was 8.5% (n = 377). Regarding insulin dose, 13% of the patients use 1.0 < 1.5 U/kg/day, and 1.3% use ≥1.5 U/kg/day. Only 40% of patients with HbA1c ≥9.0% exercised vs 67% of patients with <7.0% (<0.0001). Thirteen percent of patients are on metformin therapy, those have lower HbA1c levels, but the difference was not significant (8.18 vs. 8.55).

Conclusion: A large proportion (40%) of adult patients living with T1D in Mexico are overweight or obese, and have some associated features associated with IR. Adjunctive therapies are needed to help improve glycemic control and reduce IR, and therefore reduce cardiovascular risk.

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ATTD8-0282

SOFTWARE TOOL FOR GLUCOSE VARIABILITY ANALYSIS FROM CONTINUOUS GLUCOSE MONITORING DATA

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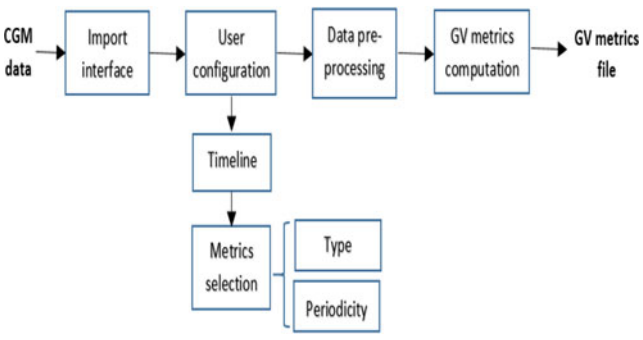
Background and Aims: In the last decade, multiple studies have shown the association between glucose variability (GV) and hypoglycemia. In this regard, different GV metrics and software tools



for GV calculation have been proposed. However, besides that there is no consensus on the implementation of some commonly metrics, generating different results, GV analysis is continuously demanding additional software features and data processing than usual.

Method: Continuous glucose monitoring (CGM) data are imported using a software prepared in MATLAB®, and then pre-processed to discard monitoring days with consecutive losses greater than 50 samples; fewer losses are linearly interpolated. CGM data can be organized by calendar days (00:00 to 23:59 hours) or user defined. Finally, a GV metrics selection is performed and computed.

Results: This tool has been used in several glucose variability studies showing a good performance and acceptance by physician users. The GV metrics included were: SD, CV, Mean, M-value, MAGE (average of MAGEup and MAGEdown, MAGE_day using SD diary and MAGE_total using SD of total registry), MAG, J-Index, IQR, MODD, CONGA (n = 1, 2 and 4 hours), LBGI, HBGI, ADDR. In addition, metrics such as area under the curve and percentage of time in hyperglycemia and hypoglycemia, and the hyperglycemia and hypoglycemia event count of a minimum duration defined by user can also be calculated. Results are exported as an Excel file, grouping the metrics by day and global computations.

Conclusion: A new and easy to use software tool, including a pre-processing method and flexible features, was developed in order to perform GV analysis.

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ATTD8-0267

TELE-MONITORING OF TYPE 1 PEDIATRIC DIABETES PATIENTS BY USE OF AN OPTIMIZED CGM DASHBOARD: EXPERIENCES FROM PATIENTS AND HEALTH CARE PROFESSIONALS

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Background and Aims: Interpretation of CGM data is difficult and time consuming for both patients and health care professionals (HCP). We want to report experiences of patients, parents and HCPs on bi-weekly tele-consultations and its effect on metabolic regulation and time burden.

Method: CGM data from 47 T1DM patients (3-18 years) on a Guardian Connect were automatically uploaded in the patient health records of the hospital between April and October 2017. Our Interpret-Dia dashboard visualized: Automatic ranking of patients according to calculated HbA1C, calculated HbA1C trend, trends in metabolic control over time, and alarms to the HCP in case of data loss. Bi-weekly, or more frequently in case of metabolic dysregulation, patients were contacted by phone.

Results: Parents and patients highly appreciated tele-consultations, felt their diabetes control improved, and would appreciate ongoing tele-consultations in case of metabolic instable periods. By using the dashboard, the amount of time HCPs spent analyzing CGM data averaged to about 2 minutes per patient. After 6 months, a decrease in HbA1C was noticed in 64% of patients with a HbA1C > 7.5% at start (from 8.3 to 7.6%). The other 36% was not therapy compliant. Patients with HbA1C < 7.5% at start, stayed in range. Analysis on AUC and time in hypo is in progress.

Conclusion: Regular remote analysis of CGM data by their medical team was very well accepted by patients and parents, and improved metabolic outcome in therapy compliant patients with poor metabolic control. Implementation of our dashboard improves the time spent in interpretation of CGM results.

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ATTD8-0254

EXTENDED GLUCOSE MONITORING THROUGH THE USE OF GROUP-BASED INTERNET OF THINGS MINI DISPLAYS

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Background and Aims: Social media, mobile technology and Internet of Things (IoT) have enabled new ways of interacting between people with diabetes. In this project, we have explored the potential of using group-based IoT mini displays to improve glucose monitoring.

Method: We have developed a system for group-based IoT-enabled mini displays that enables extended glucose monitoring of people with diabetes. The system is developed on the Android mobile platform, using Android SDK. The display is a Waveshare 2.9 inch e-Paper Module, controlled by microcontroller Wemos D1 mini Pro, using the Arduino SDK. The backend API server is a collection of microservices all written in Golang using the Gin framework.

Results: The system displays general messages (text, images), sent by users or their sensors, on a number of mini-displays that might be located anywhere. However, we expect that most of them will be located in people's homes or in their professional surroundings. The IoT devices are small, low-cost, and low-energy devices that can run for a long time without the need of recharging the batteries. These are only used for displaying information posted by the user herself or the user's group(s). The information is sent from each user's mobile self-management tool for diabetes.

Conclusion: The IoT mini displays, in combination with self-management tools, represent a new form of motivational technology (persuasive technology) that can be used by different groups of people with diabetes to motivate each other to be optimal regulated or to simply get continues status updates and reminders on diabetes-related health parameters.

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ATTD8-0380

ASSOCIATION ANALYSIS OF THE COMMON GENETIC VARIANT OF PPARG GENE WITH TYPE 2 DIABETES MELLITUS

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Background and Aims: Type 2 diabetes mellitus is characterized by chronic hyperglycemia associated with insulin resistance and relative insulin deficiency. Peroxisome proliferator activated receptor gamma (PPARG) is a nuclear hormone receptor of the ligand-dependent transcription factor with a key role in adipocyte differentiation, and glucose homeostasis; and It is one of the main candidate genes that are implicated in T2DM.

Method: This case-control study included 149 type 2 diabetic patients and 96 healthy individuals, Genotyping of PPARG common polymorphism (rs1801282) were determined by PCR and sequencing.

Results: The frequencies of CG and GG genotypes of PPARG polymorphism among diabetic and non-diabetic groups were 12.75% vs 18.75% respectively for CG and zero vs 1.04% respectively for GG ($p = 0.17$). Allelic analysis showed no difference of G allele between diabetic (6.37%) and non-diabetic subjects (10.42%) respectively ($p = 0.11$). The odds ratio for G allele was 0.58 which was not statistically significant ($p = 0.11$).

Although presence of PPARG polymorphism slightly decreased the odds of developing ophthalmic complications, the observed association was not statistically significant. In addition, presence of this polymorphism caused 27% increase in the risk of renal complication, but this association was not significant.

Conclusion: It seems that PPARG polymorphism was not associated with diabetes mellitus and its renal and ophthalmic complications. Longitudinal studies with larger sample sizes are suggested to show the exact effect of this polymorphism on developing diabetes mellitus.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0086

INTEGRATED PERSONALIZED DIABETES MANAGEMENT (IPDM) IN PATIENTS WITH INSULIN-TREATED T2DM: RESULTS OF THE PDM-PROVALUE STUDY PROGRAM

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Background and Aims: Patients with Type-2 Diabetes mellitus (T2D) do not achieve their treatment goals. The PDM-ProValue study program assessed whether a structured intervention program (''integrated personalized diabetes management'', iPDM) improves glycemic control and other parameters among insulin-treated patients with T2D.

Method: The PDM-ProValue study program was conducted as 12-month, prospective, controlled, cluster-randomized studies to determine if iPDM improves glycemic control and other clinical and patient reported outcomes. Visits in the iPDM study arm included a structured diabetes management process including visualisation of the analysis results to support treatment adaptions and shared decision making. 101 medical practices were randomized in the iPDM arm ($n = 53$) and in the control (CNL) group ($n = 48$).

Results: Patients were highly comparable at baseline: $n = 907$; gender (male) iPDM 60.5% vs. CG 55.9%; age: 65 ± 11 y (mean±SD) vs. 65 ± 10 y; duration of diabetes: 14 ± 9 y vs. 14 ± 8 y; BMI: 33.8 ± 6.1 kg/sqm vs. 34.0 ± 6.1 kg/sqm; baseline HbA1c: 8.5 ± 1.1% vs. 8.4 ± 1.0%; insulin therapy regimen MDI/basal/other: iPDM 61.1%/28.6%/10.2% vs. CG 61.7%/28.5%/9.9%.

After 12 months, improvement in glycemic control vs. baseline (= HbA1c reduction) was higher for patients in the iPDM study arm (0.5%, $p < 0.0001$) compared to those in CNL (0.3%, $p < 0.0001$; between-group difference = 0.2%, $p < 0.05$). Most of the reduction in HbA1c occurred after 3 months and remained stable thereafter.

Conclusion: Results of the PDM-ProValue study program document the considerable potential of iPDM. Structured guidance for physicians and patients based on a low-threshold digital solution represents a diagnostic measure which resulted in significant improvements in glycemic control.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0273

IMPROVING EDUCATION OF MEDICAL STUDENTS BY INVOLVING A TELEMEDICAL SYSTEM FOR DIABETES INTO LECTURES

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Background and Aims: Modern diabetes-related technologies are rarely involved in the teaching plan of medical students. Giving them an insight into current technologies, including innovative use initiated by the patients themselves, together with

the pronciples of the disease itself can deepen their knowledge in this area.

Method: Medical students of the Charles University in Prague who were attending a new voluntary course called ''Advanced Technologies in Diabetes'' had a possibility to play a role as both a patient and a clinician, using modern technologies for diabetes care. The students were working with the Diani telemedicine system that collects data automatically and in real-time from the Diabetes Diary mobile app, an activity tracker, a smartwatch and a CGM.

When playing the role as a patient the students were using the Diabetes Diary, whereas playing the role as a clinician they got access to anonymous patient's data through the Diani system. They were able to monitor the patient in real-time and see results as different actions were chosen.

Results: Three of the subscribed medical students (n = 28) who delivered their database from the Diary made 260 registrations. For the monitoring part, 4 T1D patients were involved, 15 accesses to the Diani web application by the students were detected and 3 messages were send to the patients. 77% of the students evaluated the practical part as very suitable to be involved into the lectures.

Conclusion: Making medical students familiar with the modern technologies in diabetes care can increase both their understanding and the acceptance in their later real practice.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0291

MORE INFORMATION MAY NOT MEAN BETTER DECISIONS: COMPARING THE UTILITY OF CAUSAL INFORMATION FOR BG MANAGEMENT DECISIONS AMONG INDIVIDUALS WITH T2D AND WITHOUT DIABETES

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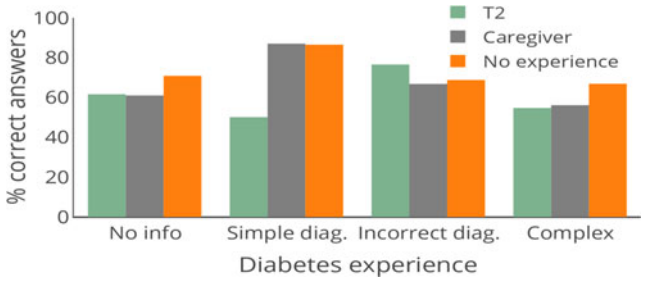
Background and Aims: Day-to-day management of blood glucose (BG) is challenging, due to the many factors such as activity and stress that affect BG. Now that some factors can be measured continuously, causal inference algorithms may provide personalized information on how these affect a specific individual's BG. We aim to determine whether such information actually leads to better decisions.



Method: We conduct large-scale online experiments through Amazon Mechanical Turk. Participants are presented with the case study of an individual recently diagnosed with T2D and his doctor's recommendations, and asked a multiple choice question about the best way to modify his current lifestyle. The question is presented four ways: no extra information, simple causal diagram, incorrect diagram, and complex diagram. The goal is testing the ability to use causal information to make a behavioral decision.

Results: Data was collected from 1178 individuals in the U.S. aged 18–64, with 52 T2D, and 98 caregivers of someone with diabetes. We find that individuals with T2D performed best in the incorrect information condition while in all other conditions, caregivers and those without diabetes made more accurate decisions (see figure). When they have prior experience, individuals have the difficult task of integrating causal information with their existing mental models. Those with less prior experience, may take the presented information at face value.

Conclusion: While individuals with T2D were able to recognize and ignore incorrect information, even simple causal information led to worse decisions. Significantly more work is needed to determine how to highlight relevant information at the time of decision.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0085

INTEGRATED PERSONALIZED DIABETES MANAGEMENT (IPDM) IMPROVES SATISFACTION OF PATIENTS WITH INSULIN-TREATED TYPE 2 DIABETES AND THEIR PHYSICIANS: RESULTS FROM THE PDM-PROVALUE STUDY PROGRAM

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Background and Aims: Integrated Personalized diabetes management (iPDM) is supposed to support improvement of glycemic control by bringing together the health care physician and the patient in the therapeutic decision making. It contains the use of structured SMBG, data management software and patient-physician collaboration into a formal, iterative, 6-step structured intervention program. We present the data of satisfaction of patients and physicians with iPDM and patient adherence.

Method: The PDM-ProValue study program comprised 12-month, controlled, cluster-randomized studies. 907 patients with insulin-treated Type-2 Diabetes were enrolled. Patients treatment satisfaction was assessed with the Diabetes Treatment Satisfaction Questionnaire (DTSQc), physician satisfaction with the Diabetes Physician Satisfaction Questionnaire (DPSQ).

Results: Patients were highly comparable at baseline. After 12 months iPDM showed greater improvement in treatment satisfaction (DTSQc: 12.2 vs. 10.4, delta = 1.78, p = 0.004) and similary the mean DTSQs was higher in iPDM (31.1) compared to control (CNL) group (30.0, delta = 0.924, p = 0.02). Also, physician satisfaction was higher in iPDM compared to CNL: General assessment of the current diabetes therapy in iPDM improved in mean by 9.73 vs. 4.87 in CG (delta = 4.87, p < 0.0001). Percentage of patients with enhanced therapy adherence was greater in the iPDM group than in CNL (Odds Ratio* = 2.34; p = 0.0015).

Conclusion: These results document the considerable benefit of an iPDM approach. Providing structured guidance together with a low-threshold digital solution resulted in significant improvements in patients and physicians treatment satisfaction and better adherence. Its implementation may help to overcome unsatisfactory glycemic control and improve clinical inertia.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0237

THE "ACTIVE AGEING" APP: PRELIMINARY USABILITY EVALUATION OF A MOBILE APPLICATION FOR DIABETES SELF-MANAGEMENT

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Background and Aims: Few mobile applications for diabetes care support incorporate educational functions and reminders for adherence to therapy, self-management and healthy lifestyle and fewer are tested for usability. We tested the mobile application ''Active Ageing'' in a pilot study in seniors (age >63 years) with type 2 diabetes (T2D) and women with gestational diabetes (GDM).

Method: An application, structured according to cognitive-argumentative model of verbal communication, with empowering text messages was developed by the Catholic University in Milan. Patients were recruited at the San Raffaele Hospital in Milan between 01/01/2017 and 31/08/2017, and invited to use the application to store and share data about glucose (SMBG) and weight and complete the System Usability Scale (SUS).

Results: Nineteen out of 116 T2D patients (16.4%) (median age 69 (65-73) years) and 12 out of 12 GDM patients (100%) (median age 37 (34-40) years) accepted to participate. After a median of 11 weeks of use (7-15), 7 T2D and 10 GDM patients completed the SUS (median score 77.5 (75-97.5) and 92.5 (87.5-95) respectively, p = 0.22). T2D patients performed 72% of SMBG measurements and 60% of weight measurements, GDM patients performed 53.5% of SMBG and 29% of weight measurements.

Conclusion: The application is usable, although a minority of patients with T2D >63 years are willing to use the App. Younger GDM patients are more likely to use the app, but less compliant to SMBG or weight measurements. Tailoring an App and targeting it to the right patient population may improve the use of technology to empower patients.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0108

A DEEP LEARNING PLATFORM FOR DIABETES BIG DATA ANALYSIS

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Background and Aims: Deep learning has been proven to achieve state-of-art performance in modelling complex behaviour and the prediction accuracy. The extensive data collected in hospitals opens the door to such powerful machine learning technology to improve healthcare management. So far, few artificial intelligence (AI) tools have enabled non-experts in data science to analyse clinical data intuitively. This work aims at building a bridge to link this demand.

Method: We develop a deep-learning platform for biomedical data analysis, and demonstrate its applicability using a diabetes dataset. All components are built using open-source software libraries, including popular TensorFlow (by @google), TensorLayer and TensorDB (by @Imperial College London). It provides healthcare professionals with an easy-to-use system to manage the heterogeneous clinical data with non-relational databases (e.g. MongoDB). With little specification, medical and clinical scientists with minimal expertise in data science can build their own deep learning models, and the system can train, update and deploy deep learning models autonomously. We have tested the platform by processing the *Pima Indians Diabetes Dataset* in a problem of predicting diabetes in a population of 700 subjects. A 10-fold cross-validation model validation technique was used for this purpose.

Results: On the platform, a plainest 2-layer neuron network was constructed within 10 minutes. It achieved an accuracy of 78.6% in identifying diabetes patients, ranking 3rd amongst the existing 45 published methods.

Conclusion: A user-friendly deep learning platform for clinical big data analysis was developed. It was tested in a diabetes dataset and achieved acceptable results when compared with published methods.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0341

WEARABLE SYSTEM TO HELP PATIENTS, CAREGIVERS AND PHYSICIANS WITH DIABETES MONITORING

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Background and Aims: Keeping 24h proper track of their disease is not an easy task for diabetics. The dose of insulin required varies depending on the carbohydrates being consumed, physical activity and metabolism of each person, and it is important to consider what patient did in previous shots and be able to analyze dosage trends for preventive purposes. On the other hand, it is really very hard to keep consciousness of a routine task to be performed every 2-3 hours along lifetime, and, as in any other chronic illnesses, very often the patient may forget to take insulin (which also causes the risk for double insulin injection). This also becomes of great importance for people in charge of diabetics when very young or very old to keep full control of their disease, and for which miss-treatment can be more dangerous.

The wearable (Insulclock®) is a small electronic device easily plugged to any brand of insulin pen devices to help track date, time and dosage of the last injection, type of insulin used and temperature. Insulclock has an alarm system with visual and sound alerts to prevent insulin omissions and mistiming. Via Bluetooth and smart-phone technology, information is stored and readily available for data analysis by patients, caregivers and healthcare professionals.

The wearable's (Insulclock®) real time memory and alert system are likely to improve treatment adherence, patient's satisfaction, and quality of life measures, which may improve glycemic control in insulin treated patients. Insulclock is being tested in several clinical trials to demonstrate it.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0160

COMPARISON OF CLINICAL CHARACTERISTICS OF A DIABETES TELEHEALTH SERVICE WITH SPECIALIST FACE-TO-FACE OUTPATIENTS: A CROSS-SECTIONAL SURVEY

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Background and Aims: Increasing incidence and prevalence of diabetes are a major strain on health-care resources. Telehealth can improve traditional care delivery and equitable distribution of health-care services with cost-efficiencies. This is relevant for overcoming geographical barriers in a country like Australia. This study aimed to compare the clinical characteristics of patients attending a tertiary hospital (Princess Alexandra Hospital, Brisbane, Australia) diabetes telehealth service (DTS) with specialist face-to-face diabetes outpatient service (DOS).

Method: A cross-sectional survey was undertaken as part of the well-established Australian National Diabetes Audit in May 2016 (focussed on patient education and self-management practices) and May 2017 (focussed on clinical management practices). Corresponding data from the two surveys were combined and analysed.

Results: 284 and 62 diabetes patients were surveyed in the DOS and DTS groups respectively. In the DOS group, 179 (63.0%) were type 2 diabetes (T2DM) and 98 (34.5%) were type 1 diabetes (T1DM). 44 (71.0%) DTS patients had T2DM and 15 (24.2%) were T1DM. There was no statistical difference between groups (DOS Vs DTS) in HbA1c, when analysed for T2DM (8.2%-66 mmol/mol Vs 8.7%-72 mmol/mol) and T1DM (8.3%-67 mmol/mol Vs 9.0%-95 mmol/mol); in the proportion of patients achieving HbA1c less than 8%(64mmol/mol); and in the proportion of diabetes treatment methods. Among T2DM patients, there was a statistically significant higher proportion of indigenous patients in DTS group(31.8% Vs 1.1%). Initial visits were higher in DTS group.

Conclusion: This analysis reveals similar clinical outcomes in glycaemic management among T1DM and T2DM patients in both DOS and DTS groups. As the DTS delivers services in regional Queensland, Australia, it provides a valuable service to patients in underserved areas.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0225

SMARTPHONE-BASED URINE STRIP ANALYSIS

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Background and Aims: People with diabetes commonly use urine strips to monitor and control their ketone and glucose levels. The strips are coated with chemicals that react with the compounds present in urine. The user has to dip the strip in urine so that the chemicals can react and cause the strip pads to change color. These colors are then compared by eye with the reference colors provided by the strip manufacturer, to give the corresponding index. However, this can become quite challenging - depending on the lighting conditions or the visual acuity of the user, especially for the elderly or people with eye disorders, and this can result in wrong estimations.

Method: The proposed mobile point-of-care (mPOC) application uses a smartphone, in order to produce an automatic and accurate estimation of the indexes. The user needs to place the urine strip on a specially designed reference card and then take a picture with their phone. The algorithm then precisely locates the urine strip and the rectangular pads by detecting keypoints and matching them to a reference. A color correction step follows, that relies on a support vector regressor (SVR), to estimate and invert any existing color distortion caused by

the different lighting conditions and camera characteristics. Finally, the concentrations are estimated by comparing the colors of the pads with the reference colours provided by the manufacturer.

Conclusion: The proposed application will assist people with diabetes, by offering a more accurate, automatic and portable method for monitoring glucose and ketone levels on a day-to-day basis.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0356

GOCARB ACCURACY ON CARBOHYDRATE ESTIMATION VERSUS VISUAL ESTIMATIONS BY DIETITIANS

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Background and Aims: Carbohydrate (CHO) intake plays a vital role in diabetic patients' glucose control and well-being. A system based on the use of AI and computer vision was recently introduced to estimate the meal's CHO content, using two images of the meal on a plate. The objective of the study is to compare the accuracy of GoCARB in estimating CHO with the visual estimations of six dietitians.

Method: The GoCARB system was used to estimate the CHO content of 54 meals on plates. The meals were served in the restaurants of Bern University Hospital. They corresponded to typical Central European meals, and each contained three different food items. Each item was weighed using household scales and ground truth (GT) was estimated using the meals' exact food items, as appear in the USDA food composition database for standard reference and the Swiss food composition database. One to three CHO estimations for each meal were carried out by GoCARB. A total of 222 images was given to six dietitians from Switzerland, Germany and Austria. The dietitians were asked to visually estimate the CHO content of each meal's food item.

Results: GoCARB and dietitians achieved comparable accuracies (Table), independent of the database used to calculate the GT, while the use of the local nutrient database seems to improve the CHO estimation of GoCARB.

Conclusion: The GoCARB system may offer diabetic patients the option of an easy, accurate and almost real-time estimation of the CHO content of meals on plates and thus help to enhance and improve diabetes management.

Table. Comparison of the accuracy in CHO estimation of the GoCARB system with the six dietitians

Ground truth using	Absolute error (grams) Mean (SD)	
	Dietitians	GoCARB
USDA food composition database	15.23 (10.18)	15.24 (9.89)
Swiss food composition database	14.21 (9.57)	12.56 (8.49)

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0279

GAMIFICATION TO INCENTIVIZE MHEALTH DIABETES MANAGEMENT

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Background and Aims: One essential practice for diabetics is registering diabetes related values, which, is a burden. MyDiabetes is a mobile application that helps type I diabetics with their daily records (glycaemia, carbohydrates, insulin, exercise, etc.). To incentivize patients' recordkeeping, we use gamification techniques, rewarding the insertion of new data with virtual badges.

Method: People feel motivated by different types of challenges. Considering this, we implemented different objectives and rewards. Our main gamification concept is badges. Completing a ''mission'' results in unlocking a badge. There are 68 badges to unlock.

Every new record entered is rewarded with points. These, when reaching a certain threshold, increase the user's virtual level. Advanced levels carry more challenging objectives and rewards. Different records encompass more points, based on an expected registers numbers.

Another concept is anonymous ranking. The stored data allows the inference of how well managed the user is among other users.

Results: Our survey, with the collaboration of the S. João's Hospital, gathered fourteen patients (ages between 21 and 54). These volunteers interacted with two mobile devices, one with the gamification implementation and the other without, to compare them. The reaction to the gamification component was positive:

only one patient didn't feel motivated to use the application;

78% showed interest in using the mobile application as their main management control device;

71% felt compelled by badges;

77% would like to access the anonymous ranking system.

Conclusion: The reactions obtained show promise. We are still testing the effects of gamification on the number and the consistency of daily records.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0289

BLOOD GLUCOSE IMPROVES AMONG PEOPLE 'AT RISK' USING ONE DROP | PREMIUM OR PLUS ON IPHONE AND APPLE WATCH

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Background and Aims: The One Drop diabetes app lets people track self-care/health data, get data-driven insights, set goals, monitor progress, receive and give support, view tips/recipes, etc. With a subscription, a live Certified Diabetes Educator ('Expert') sends in-app messages to educate, strategize, and answer questions. The Chrome blood glucose (BG) meter uploads objective BG readings via Bluetooth. Among people with type diabetes (T2D) and lab A1c ≥7.5% using the app on iPhone/Watch with an 'Expert', but not 'Chrome,' there was a −35 mg/dL (estimated [eA1c] −1.2%) 12-week improvement. We tested objective BG changes among people 'at risk' using One Drop on iPhone/Watch, an 'Expert' and 'Chrome.'

Method: We queried One Drop's database for people meeting criteria. Mixed models assessed 1st- to 12th-week change in average BG, percentage of high and in-range BGs by diabetes type (T1D vs. T2D).

Results: The sample (N = 34) was 77% male, 62% T2D with 8.5 ± 7.6 years since being diagnosed. The 12th-week average BG was −48 mg/dL lower (eA1c −1.6%) than the 1st week (227 vs. 179 mg/dL; $p < .01$), percentage of high BGs was −26% lower ($p < .01$) and in-range BGs +25% higher ($p < .05$). There was no interaction by diabetes type.

Conclusion: Objective blood glucose improved among people with diabetes and a One Drop | Premium or Plus subscription using the Apple Watch app. People with a subscription and Watch app may have more resources, support, and/or motivation than someone not paying for these services/devices. However, to date, self-reported and objective blood glucose improvements in two separate samples are consistent.

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ATTD8-0297

TYPE 1 DIABETES EXPERIENCE SIMULATOR APP

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Background and Aims: One challenge clinicians face when treating people living with type 1 diabetes (T1D) is the difficulty to understand the burden associated with self-management.

The aim of the Type 1 Diabetes Experience Simulator (T1DES) is to simulate the experience of living with T1D for people with normal glucose tolerance and, in particular, for healthcare professionals. The application has been developed in collaboration with INPUT Patient Advocacy, the UK diabetes technology advocacy charity.

Method: T1DES consists of a smartphone application developed in Android which includes a validated T1D simulator incorporating realistic intra-day variability. T1DES provides a set of graphical user interfaces (GUI) that allow the user to visualize glucose levels emulating continuous glucose monitoring (CGM) or self-monitoring blood glucose therapy. In CGM mode, T1DES alerts the user about low and high glucose events. The GUI also allows the user to manually input information about meals and exercise taken. Then, the user has to estimate the insulin doses needed to control glucose levels. Finally, T1DES incorporates a bolus calculator to assist to the calculation of insulin doses.

Results: Software specifications were gathered through focus groups organized by INPUT with people with T1D. The App went through several iterations before achieving a satisfactory result.

Conclusion: A functional user-friendly smartphone application aiming to partially emulate the experience of living with diabetes has been developed.

T1DES will be evaluated by a group of people with normal glucose tolerance over a prolonged period of time (e.g. 1 month). Semi-structured usability and quality of life questionnaire will be employed for this purpose.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0047

INTERPRETING SENSOR AUGMENTED PUMP IN TYPE 1 DIABETES: A 5-STEP APPROACH PROTOCOL USING CARELINK THERAPY SOFTWARE

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Background and Aims: The goal of this study was assess the usability and satisfaction of implementing a 5-step approach protocol in interpreting Sensor Augmented Pump by physicians.

Method: We have developed a 5-step approach protocol in interpreting SAP using CareLink. The main analysis is based on the Therapy Management Dashboard, where five segments are allocated: (1) basic statistics; (2) glucose and insulin overlay; (3) postprandial period; (4) basal/bolus insulin; (5) suspends and sensor. Every segment is analyzed with correlation through others with step by step confirmation of possible change (previosly noted on insulin settings page based on rationale/physiological insulin use).

Physicians used a 5-step approach protocol on a monthly basis for 3 months to analyze 14 days data and to manage SAP patients. Surveys were conducted in which the physicians rated their feedback related to acceptability of the protocol on a 5-point Likert scale.

Results: A total number of 34 patients with 128 downloads were analyzed. Mean age was 15.3 ± 7.7 years, BMI was 21.3 ± 2.1, A1C was 7.9 ± 1.6%. Surveys completed by physicians indicated a 5-step approach protocol to be more efficient, time saving, and structured compared to their current processes. A1C was decreased by 0.6 ± 0.3% in the following 3 months.

Conclusion: Our results indicate that a 5-step approach protocol of interpreting the data from SAP is simple and efficient. At the same time, it is time saving and useful tool for physicians to manage patients on insulin pump.

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ATTD8-0126

INITIATION OF CONTINUOUS SUBCUTANEOUS INSULIN INFUSION USING COMPUTERIZED PROGRAM IN QATAR: A PILOT STUDY

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Background and Aims: The aim of this study is to evaluate the effectiveness of unified computerized program for initiation of CSII in T1D patients in Qatar.

Method: We have analyzed 34 T1D patients (M 17; F 17, age 9.4 ± 3.6 years with diabetes duration 3.8 ± 2.6 years) who started CSII (Medtronic 722, Medtronic Veo and Minimed 640g, (Medtronic, Northridge, USA)) from January 2017 to June 2017. CSII settings were performed using a specific computerized program (in-house built), which calculates basal rates, bolus wizard and sensor settings. Physicians were asked to enter personal data (age, HbA1c, basal/bolus insulin dose, wake up and school time) for each patient and to review the generated settings before initiation of CSII. CSII characteristics and HbA1c were evaluated in the following three months.

Results: Most of the patients (28 from 34) were using Minimed 640G. All patients were using bolus wizard on regular basis with bolus ratio of 58.4 ± 6.7%. Insulin dose significantly increased from 0.58 ± 0.21 to 0.72 ± 0.22 u/kg/d ($p < 0.05$). Most of the patients (31 from 34) have two insulin-to-carbohydrate-ratio of 18.2 ± 8.6 gr for breakfast/snack (6am-12pm) and 23.4 ± 9.3 gr for the rest of the day; two insulin sensitivity factor of 138 ± 77mg/dl (10pm-6am) and 124 ± 72 mg/dl for the rest of the day. HbA1c significantly decreased ($p < 0.05$) by 1.5 % (from 9.6 to 8.1%) in the following 3 months.

Conclusion: Our study shows that unified computerized program for CSII initiation may improve glucose control in type 1 diabetes patients. The study should be performed on larger population and longer duration to confirm our results.

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ATTD8-0426

DIGITAL HEALTH FOR DIABETES – A GOOD IDEA WHOSE TIME HAS COME

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Background and Aims: Individuals with diabetes are burdened by complex medication regimens and challenged by the need for lifestyle and behavioral change. Health care providers are charged with delivering high quality care to greater number of patients with less time. Digital health tools hold the promise of both coaching users into optimizing diabetes self-management and supporting clinicians with decision support. Recent data suggests that self-monitored blood glucose may have little benefit for most patients with T2 diabetes. This is likely due to the data not being collected and used optimally or not being available in a digestible format to support health care teams.

Method: In 2014, WellDoc launched the first FDA-cleared platform for diabetes coaching and provider clinical decision support. The platform provides resources and intelligent messaging to users that support diabetes self-management and problem-solving in an automated fashion. Glucose data as well as behavioral/lifestyle information is collected in a non-burdensome manner. These patient generated data are used to deliver tailored, individualized, and contextual insights to users. These data are also distilled into a summary report that is sent to health care providers.

Results: Both randomized, controlled, prospective studies as well as post-marketing data demonstrate a high degree of user engagement, efficient provider implementations, and significant improvement in glycemic outcomes.

Conclusion: The question now is not whether the healthcare system should use digital tools or not, but rather which tools and how should they be implemented to best enhance the interaction between patients and providers and improve health outcomes.

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ATTD8-0430

METHOD OF IMPLEMENTATION INFLUENCES USER ENGAGEMENT WITH DIABETES DIGITAL HEALTH TOOL

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Background and Aims: Digital health tools not only should be effective in clinical trials, but should be implemented into the healthcare ecosystem without adding undue burden. We hypothesized that different models of implementation may be associated with differences in engagement.

Method: In the first model, users received a prescription for BlueStar from their healthcare providers. In the second model, certified diabetes educators provided BlueStar to their patients. In the third model, BlueStar was distributed via a direct-to-patient email from a large, national health plan for Medicare enrollees. The user data was collected electronically and de-identified according to WellDoc's data policies.

Results: 3,141 users were identified as part of the provider prescription model. Of note, 30.7% of users did not enter their diabetes medications into the system. 95 users were identified in the educator-driven model. Again, a significant minority (25.3%) did not enter their diabetes medications. In the health plan model, of the 11,000 enrollees who were invited to participate by email, 161 individuals activated accounts. Interestingly 67% of these users engaged with BlueStar via the web, not on mobile devices.

Conclusion: In the provider and educator models, individuals were provided BlueStar during face-to-face visits. Though engagement with the system was good, a significant minority of users still did not enter their medications into the system. In the health plan driven model, only a small proportion of targeted individuals activated their accounts. In conclusion, since important differences in user engagement were found based on implementation model, implementation strategies should be considered when deploying digital health solutions.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0412

DEVELOPMENT AND VALIDATION OF A PATTERN RECOGNITION ENGINE FOR VISUALIZATION OF GLYCEMIC PATTERNS

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Background and Aims: Innovative technologies supporting healthcare professionals (HCPs) and patients in the review of self-monitoring blood glucose (SMBG) data may facilitate clinical and educational approach to diabetes management.

MyStar Connect® (MSC) is a diabetes data management software that helps deliver insights to HCPs to review and adjust diabetes therapy.

Filtering mechanisms are needed to visualise data efficiently.

We are developing a pattern recognition engine (PRE) for visualizing glycemic patterns: hypoglycemia, hyperglycemia, and glycemic variability.

Method: Glycemic values derived from SMBG performed by 182 insulin-and non insulin treated patients during 3 months will be independently evaluated by three assessors, experts in the interpretation and use of SMBG data. Hyperglycemic, hypoglycemic and variability patterns identified by each assessor will be compared to those identified by PRE. In case of discrepancy in the identification of patterns, an independent assessor, using pre-defined criteria, will establish whether the pattern is present. The rate of agreement between each assessor and PRE will be evaluated, and expressed as the percentage of patterns identified by both the assessor and PRE. False-positive and false-negative rates in the identification of patterns by PRE, and the rate of concordance between the different assessors will be assessed. The analyses will be conducted separately for hyperglycemic, hypoglycemic and variability patterns.

ResultsConclusion: If PRE proves to be superior to subjective evaluation of clinicians in pattern identification, the implementation of PRE will represent a useful tool to guide treatment decisions and educate patients, thus minimizing the risk of hypoglycemia, hyperglycemia and excessive blood glucose fluctuations.

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Informatics in the Service of Medicine; Telemedicine, Software and other Technologies

ATTD8-0060

INSIGHTS FROM BIG DATA (1): VIEWING OF REAL-TIME CONTINUOUS GLUCOSE MONITORING DATA AND ITS IMPACT ON TIME IN RANGE

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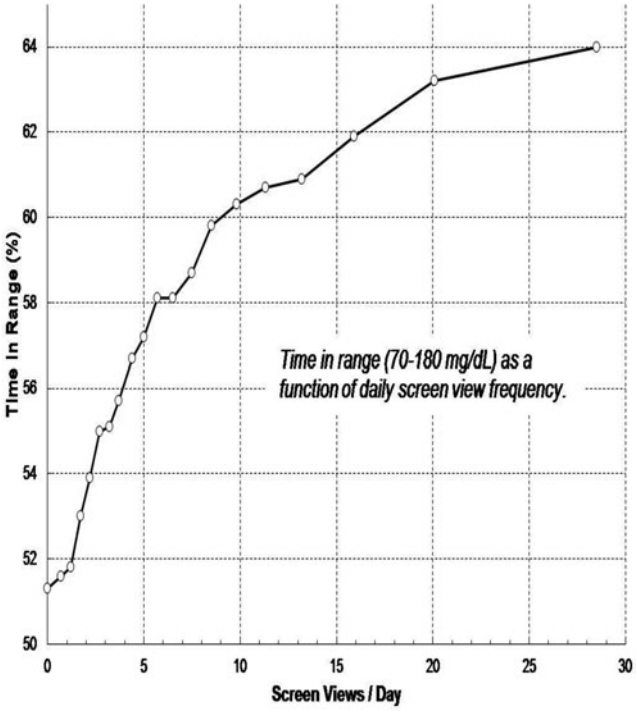

Background and Aims: Real-time awareness of glucose levels can inform short-term diabetes management decisions that minimize hypoglycemia and hyperglycemia. Users of continuous glucose monitoring (CGM) systems can actively check glucose levels and trends with a display device throughout the day. We examined the relationship between display device activations (screen views, SV) and glycemia.

Method: The Dexcom Mobile App allows users to view current and up to 24 hours of historical data from the Dexcom G5 Mobile CGM System. After a user's consent, it also uploads glucose concentration and app usage to a database, where it was available for retrospective analysis. The data represent a convenience sample of 50,000 anonymized users who employed an iPhone as their display device and spontaneously uploaded data in August 2017. Time in range (TIR) is the percentage of sensor glucose values from 70–180 mg/dL. App usage was expressed as SV/day, and the TIR for each of 20 equally-sized rank-ordered groups was calculated. Multiple SVs within any 10-minute interval were counted as a single SV.

Results: Mean SV frequency was 9.1/day (median [IQR], 5.7 [2.7-11.3]), but varied significantly among patients. The Figure shows mean TIR values compared to mean SV frequency for each quantile of 2500 users. Higher SV frequencies were strongly associated with greater TIR, even between groups that viewed their screens at the highest frequencies.

Conclusion: Increased frequency of user interactions with real-time CGM display devices may favorably influence short-term diabetes management decisions.

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Insulin Pumps

ATTD8-0169

THE COMPARISON OF DIFFERENT BASAL RATE PROFILES IN INSULIN PUMP THERAPY IN MOSCOW REGION CLINICAL PRACTICE

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Background and Aims: Nowadays continuous subcutaneous insulin infusion (CSII) has become more accessible in routine clinical practice. There are different basal rate profiles that can be used when initiating insulin pump therapy. The aim of this study was to compare two basal rate profiles during the first two days after the start of insulin pump therapy in order to evaluate which of them is safer in use.

Method: Data obtained from 407 patients with T1DM (92,1%) and T2DM (7,9%) with mean age of 33,1 ± 10,5 years and disease duration of 13,3 ± 9,3 years was analyzed. 160 of them started with circadian basal rate profile according to Renner's scale and 247 patients used flat basal rate when switching on CSII. Changes in blood glucose levels were evaluated using CGM values.

Results: We haven't found any variations in hypoglycemia frequency in first two days between patients starting insulin pump therapy with circadian basal rate as well as with flat basal rate. The average glucose AUC values below the goal according to CGM in first two days also had no differences: 0.006 [0-0.059] and 0.005 [0-0.02] respectively, p = 0.094.

Conclusion: During this study we have compared two basal rate profiles in patients during the first two days after starting insulin pump therapy. And while basal rate profiles in CSII should be individually adapted, there is no significant difference between basal rate profiles at the start of it.

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Insulin Pumps

ATTD8-0172

INSULIN PUMP THERAPY AS A PART OF HIGH-TECHNOLOGY MEDICAL CARE IN MOSCOW REGION ROUTINE CLINICAL PRACTICE

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Background and Aims: Insulin pump therapy is a progressive method of treatment of both patients with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) who needs insulin. The aim of this study was to evaluate the efficacy of the long-term use of the insulin pump therapy in Moscow Region routine clinical practice.

Method: 32 patients with T1DM (93,8%) and T2DM (6,3%) with mean age of 31 ± 9,9 years and disease duration of 15,7 ± 7,9 years were followed up during a year after switching on an insulin pump. The levels of HbA1c, total daily insulin dose, and the number of weekly hypoglycemia were analyzed.

Results: According to the data obtained the 12-month use of insulin pump leads to the total daily insulin dose decline from 51,5 [40,0-69,0] to 39,0 [30,0-50,0] units (p = 0,002). Besides that, the level of HbA1c significantly decreases from 7,9 % [6,9-8,9] to 6,9 % [6,3-8,2] (p = 0,008). The number of hypoglycemia lowers from 2,2 ± 1,8 to 1,4 ± 2,1 per week (p = 0,024).

Conclusion: This study shows the efficacy of the long-term use of CSII that can be proved by the decrease in HbA1c level, number of hypoglycemia, and total daily insulin dose. Besides the obvious benefits mentioned above, this method gives an opportunity for patients as well as for health officials to master modern medical technologies.

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Insulin Pumps

ATTD8-0104

ESTIMATION OF ECONOMIC IMPACT ASSOCIATED WITH CSII TREATMENT IN ADULT TYPE 1 DIABETES IN UK, ACCORDING TO NICE GUIDANCE

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Background and Aims: The aim of this analysis is to estimate health economic benefits associated with continuous subcutaneous insulin infusion (CSII) treatment in adults with Type 1 diabetes (T1D), used according to NICE guidance in the UK setting.

Method: An interactive probabilistic model using published risk curves based on DCCT data was used to project incidence and progression of diabetes-related complications associated with different HbA1c levels over a 5-year time horizon in T1D. CSII efficacy was derived from published meta-analysis (Pickup et al. 2008). Complications costs and associated loss of productivity costs were derived from published literature. Based on UK National Diabetes Audit data eligible patients meeting NICE criteria for CSII (HbA1c ≥8.5% or disabling hypoglycemia) were modeled (171875 patients).

Results: Over 5 years CSII therapy improved HbA1c over MDI (from −0.82% for those at HbA1c 8.5% to −1.86% for those at HbA1c 10.5%) potentially leading to 43% and 76% relative reduction in micro/macrovascular complications and acute complications respectively. Over 5 years, £3664 per patient would be saved on complications avoided.

The additional 5 years CSII investment over MDI (£8938 per patient) was partially offset by savings from reduced complications and associated loss of productivity, leading to a total CSII extra cost of £821 per patient over 5 years.

Conclusion: Implementation of CSII therapy as per NICE guidance in T1D in the UK has the potential to drive a significant reduction in complications, leading to important cost savings for the NHS over a 5-year horizon.

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Insulin Pumps

ATTD8-0114

EFFICACY OF SENSOR-AUGMENTED PUMP THERAPY WITH PREDICTIVE INSULIN SUSPENSION IN PATIENTS WITH DIABETES MELLITUS TYPE 1

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Background and Aims: To investigate the effect on metabolic control before and after using sensor-augmented pump therapy with predictive insulin suspension technology control in patients with diabetes type 1 (DM1) previous treated with other types of pumps or MDI. A sensor-augmented insulin pump (SAP) using the MiniMed 640G system with SmartGuard technology allows an automatic close of insulin delivery based on prediction of low glucose levels.

Method: Thirteen patients with DM1 who were at least three months on Minimed 640G system with Smart Guard (Medtronic) therapy, (female = 7, mean age = 44,7 ± 12.4 years, BMI = 23.7 ± 4.2 Kg/m^2, mean DM duration = 27,7 ± 7,8 years). HbA1C, anthropometric measurements and medical history before and after using the Minimed 640G system, were recorded. Additionally, the insulin pump's data of the last month were downloaded using the software Carelink Pro and Personal-Medtronic.

Results: The glycemic control after using the 640G system was significantly better compared to before using it (mean HbA1C = 6.54 ± 0.4 vs 7.36 ± 0.8, $\rho = 0.002$). The mean glycemic variability percentage between 70-180 mg/dl was 75.8%, while over 180mg/dl and under 70mg/dl were 21.09% and 3.18% respectively. There was a difference of the total daily dose (TDD) before and after using the system (mean TDD = 43.2 ± 20.1 vs 37.1 ± 17.9 respectively, p = 0.051). Finally, there was no significant change on the body weight (72.9 ± 19.6 vs 70.3 ± 18, p = 0.071).

Conclusion: In patients with DM1, the use of sensor-augmented pump therapy with predictive insulin suspension technology, optimize glycemic control and spending most of their daytime in the glucose target range without weight gain.

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Insulin Pumps

ATTD8-0089

THE USABILITY OF A HYBRID CLOSED LOOP INSULIN DELIVERY SYSTEM: A TANDEM T: SLIM X2 INSULIN PUMP FORMATIVE STUDY

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Background and Aims: INTRODUCTION: Hybrid closed loop (HCL) insulin delivery systems are being developed and used to minimize fluctuations in blood glucose levels associated with insulin therapy in people with diabetes. Usability of these systems is critical for their effectiveness.

Objective: To assess the usability of a touch-screen, wearable insulin pump with an operating system that automatically adjusted insulin delivery based on a) continuous glucose monitor (CGM) readings and b) user input that informed the pump of food intake and activity levels.

Method: RESEARCH DESIGN: 10 adult participants with experience using CGM and insulin pumps completed the study. After a 10 minute orientation to the system, the participants were given real-life scenarios as context for simulated use tasks and knowledge tests. Tasks and tests were designed to assess the ease of use of a Tandem t:slim X2 pump designed with a prototype HCL insulin delivery system. Ease of Use scores were collected after simulated use tasks, and a Systems Usability Scale (SUS) was administered at the end of each session.

Results: The average SUS score of 84 indicated high user satisfaction (typical scores are 65–75), as did the average Ease of Use score of 4.5 (with 5-Very Easy). In simulated use, participants scored an average of a 93% task completion rate.

Conclusion: The findings indicate that the Tandem t:slim X2 insulin pump with a hybrid closed loop (HCL) insulin delivery system was intuitive and easy to use after minimal training.

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Insulin Pumps

ATTD8-0336

IS LIVING A DOLCE VITA WITH DIABETES POSSIBLE? - -METABOLIC CONTROL AND QUALITY OF LIFE IN PATIENTS TREATED WITH 640G SYSTEM

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Background and Aims: The aim of the study was to assess the diabetic control and the quality of life (QoL) in patients suffering from diabetes type 1 (DM1) after introducing the therapy with personal 640G system.

Method: We included 26 girls and 18 boys with DM1 (mean HbA1C 7.61%; SD = 1.81), median age 9.32 years old and diabetes duration min. 12 months (median 48). They were divided into 3 age groups: I (3–6y/o), II (7-10), III (11–19). After observation period (median 10 months) of 640G therapy we analysed downloaded data from last 30 days. The QoL was assessed using two surveys: PedsQLTM 3.0 Diabetes and the authorial survey measuring satisfaction of therapy.

Results: Mean HbA1C improved from 7.61% to 6.71% on 640G. In all age groups time within glucose target was lowered by higher basal insulin dose (p < 0,05). The youngest patients had the lowest mean blood glucose (139 mg/dl) and the highest glucose variability (62.50 mg/dl). The II group had the highest sensor wearing time and lowest HbA1C (6.46%). In the III group highest HbA1C before 640G therapy (8.46%) reduced most (7.44%) with the lowest time of suspension before low (110 min/day). QoL improved due to reduction of hypoglycemia fear and less problems with pricking fingers. The authorial srv showed reduction of hypoglycemia episodes and greater involvement of children in DM control.

Conclusion: 640G improves metabolic control, especially in patients with higher HbA1C, and protect from hypoglycemia. Surveys' results confirm that 640G improves perceived QoL which allows to assume better compliance.

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Insulin Pumps

ATTD8-0364

COMPARISON OF TWO BOLUS STRATEGIES FOR A HIGH FAT WITH HIGH CARBOHYDRATE MEAL IN T1D PATIENTS ON CSII.

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Background and Aims: Management of foods high on carbohydrates and fat requires modifying bolus. We studied the postprandial control of two bolus: Split Super Bolus (SSB) and Augmented Dual Wave (ADW), in subjects with T1D on pump therapy.

Method: Subjects were assigned to receive SSB (calculated for 140% of the carbohydrates on T-0' and 40% booster at T-120') before eating pizza (standard amount of carbohydrates and fat), and capillary glycemia (CG) was measured every 30 minutes for 5 hours. On a separate date, they were assigned to receive ADW (calculated for 180% of the carbohydrates, distributed half on time-0 and half over 2 hours) and repeated the procedure. Objective: proportion of CG between 70–180 mg/dL. Secondary objectives: means of CG every 30 minutes and number of corrections of hypoglycemia and hyperglycemia. Non-parametric tests were used.

Results: 17 subjects participated, with mean A1c 7.05%, with a total of 34 events analyzed, 17 SSB and 17 ADW. No significant differences were found between the carbohydrates of the previous meal, CG on T-0' or insulin doses administered. 76 % of CG resulted between 70–180 mg/dL in both groups, with a non significant trend for more hypoglycemia in SSB (10.5% vs. 7.5%, p = 0.44). CG on T-120' and T-310' were similar for SSB and ADW, with no significant differences. More subjects required corrections of hypoglycemia in SSB (17 vs. 7), but it was not significant (p = 0.44). No severe hypoglycemia occurred.

Conclusion: Both bolus strategies get appropriate postprandial control, with a trend for lower risk of hypoglycemia for ADW.

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Insulin Pumps

ATTD8-0166

INTENSIVE TREATMENT WITH CONTINUOUS SUBCUTANEOUS INSULINE INFUSION IN TYPE 1 DIABETES: EDUCATIONAL THERAPY ROLE IN METABOLIC CONTROL OPTIMIZATION

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Background and Aims: DMT1 patients need a specific chronic care model. CSII has advanced functions (bolus wizard, temporary basal, combined bolus) and CGM can be linked. A successful therapy comes by compliance, personal motivation, ability and, when using CSII, an appropriate use of technology. OBJECTIVE: to value CSII educational therapy role in short and intermediate control optimization.

Method: 192 patients with CSII take part in an educational follow up. Three areas were valued: knowledge and use of advanced functions, ability in changing infusion set and diabetes management. Use of CGM is investigated. HbA1c was valued at the first meeting, after 3-4 and then 6-9 months.

Results: bolus wizard and CHO counting are used by 74,5%, combined bolus by 57%, temporary basal by 56%. When using these functions, patients gets better A1c (p < 0,05). The relationship between the number of functions used and A1c is relevant (p0,01). The more being used, the more probability to find A1c<7,5 raises. (p < 0,05). After 6–9 months values raise again. There's no difference between CGM users and non users. Who starts CGM improve in the short and intermediate time. In non-functions users, improvement is not durable.

Conclusion: the efficacy of educational therapy for advanced functions is relevant in HbA1c improvement in patients who have bad technologic abilities, but needs regular reeducation; in these patients CSII therapy must be revalued. Starting CGM is useful for everyone, especially for those who can't get good A1c values even if they are able to use CSII. At last, using CGM needs periodic re-evaluations to preserve its efficacy.

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Insulin Pumps

ATTD8-0263

LIPODYSTROPHY, A COMPLICATION OF INSULIN THERAPY: COMPARISON BETWEEN MDI AND CSII

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Background and Aims: Lipodystrophy in particular lipohypertrophy (LH) is the most common local complication of insulin injection therapy. The insulin absorption in these areas is significantly delayed. LH is associated with increased injected doses of insulin. Data about the prevalence of lipodystrophy during CSII are limited.

Method: 115 patients were included. 60 in MDI and 55 in CSII. Anthropometric parameters were collected, along with data about glycemic control. The presence of LH was evaluated with a specific physical examination. A comparison of lipodystrophic and healthy patients was performed for both therapeutic methods

Results: The prevalence of LH in MDI and CSII was 42% and 47%. LH is associated with significantly higher values of HbA1c (1% difference in MDI, 1.4% for SCII), higher incidence of hypoglycemia and increased glucose variability. LH is significantly associated with mistakes in injection technique. Patients with LH consume more insulin. The comparison does not reveal significant differences in HbA1c (7.5 vs 7.4%, p = 0.269), or in complications. Logistic regression recognized the three factors most related to lipohypertrophy: mistakes in injection technique, insulin dose and BMI.

Conclusion: The prevalence of lipohypertrophy in CSII and MDI patients is substantially equal. The effects of LH on glycemic control are important with both methods. The increased insulin consumption in patients with LH is related to health care costs: for only 51 patients the extra charge is about 17,000 € every year for the insulin. LH is a problem for MDI and CSII, which need further investigation.

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ATTD8-0342

CSII IN T2DM: "REAL LIFE" DATA FROM A MULTICENTRIC RETROSPECTIVE ANALYSIS

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Background and Aims: Aim of this study was to analyze the main clinical parameters of metabolic control and efficacy of CSII in patients with type 2 diabetes from a ''real life'' survey in the light of the results from the OpT2mise trial

Method: Data were collected from 50 type 2 diabetic patients (T2DM) in 7 Italian diabetes centers; they included age, BMI, disease and therapy description, HbA1c , total daily insulin dose (TDD), before CSII start and at last follow up visit.

Results: At CSII start : age was 58.1 ± 9.5 yrs , diabetes duration 17.1 ± 9.1 yrs, MDI duration (4.5 ± 5,1 yrs). Mean CSII duration was 5.98 ± 4.5 yrs. Clinical data starting CSII and at final observation were: Hba1c,% (9.1 ± 1.7, 7.8 ± 1.2; $p < 0.00001$), TDD, IU/day (76.8 ± 37.3, 60.5 ± 27,1; $p < 0.001$), BMI, kg/m^2 (31.1 ± 6.2, 30.6 ± 6.2, ns). 7 patients suspended CSII (3 for inability, 1 moved in another city, 1 for inefficacy of CSII and 1 for repeated infections in the site of cannula insertion), 2 patients were lost to follow-up and 2 died from causes non directly related to diabetes.

Conclusion: Our real life experience confirms the numbers emerging from the OpT2mise study: in particular Hba1c and TDD reduction after CSII treatment in T2DM (average observation of 6 years). These data add strength to the ones at present available considering the observation conducted in different centers and outside a clinical trial.

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Insulin Pumps

ATTD8-0388

INSULIN GENE (INS) MUTATION IN OFFSPRING UNRAVELING THE TRUE ETIOLOGY OF PATERNAL DIABETES MELLITUS (DM) SOME 20 YEARS LATER

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Background and Aims: The index case is a 9-week–old Caucasian female who presented with the chief concerns of failure to thrive, decreased activity, fever and vomiting. Further evaluation revealed a distressed, under-nourished infant with a blood glucose of 672 mg/dl, bicarbonate of 15 mg/dl and no ketonemia. Hemoglobin A1c was 15.1%. She was ICA, GAD-65 and insulin antibody negative. The family history was notable for type 1 DM in her 21-year-old father, diagnosed at 11 months of age. He has been managed with various subcutaneous insulin regimens.

During her 2-week-inpatient stay the patient required IV fluids and insulin drip and transitioned to subcutaneous insulin injections (NPH and diluted insulin lispro). Subsequent to discharge from the hospital, high blood sugars and insulin requirement persisted. At 4-1/2 months of age genetic studies revealed insulin gene mutation (INS: heterogeneous, missense: C.287 G>A;p.Cys98Tyr), confirming the diagnosis of neonatal diabetes. She was started on an insulin pump with a linked continuous glucose monitor at 7 months into the diagnosis of DM. She is currently 4 years old, with unremarkable physical growth and cognitive development.

This patient's younger paternal half brother, presented with hyperglycemia and was diagnosed with DM at 10 months of age. The father and half brother were also found to have the same mutation.

This case is important to point to variability in clinical phenotype in the same kindred with identical insulin gene mutation. Efficient use of new technologies contribute positively to the care of patients with neonatal diabetes.

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Insulin Pumps

ATTD8-0314

CSII MANAGEMENT IN AN INFANT WITH DEND SYNDROME

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Background and Aims: Some *KCNJ11* gene mutations result in DEND syndrome (Developmental delay, Epilepsy, Neonatal Diabetes). The diabetes management of the mutations with severe seizures and insensitivity to glibenclamide is troublesome.

Method and Results: A boy with NDM (38 wk,2340 gr) was referred to our center at 7th day of life age. At diagnosis, glucose and insulin levels were 202 mg/dl and 0.5 mIU/ml, respectively and insulin treatment was started. The parents were non-consanguineous. First genetic report showed no mutation in ABCC8 and KCNJ11 genes. Infantile spasms were noticed when the patient was switched from MDI to CSII at 4 months of age. The electroencephalogram was showed hypsarrythmia and suppression bursts. The seizures were refractory to several antiepileptics and his neurological condition deteriorated slowly. The patient had unpredictable hypo-hyperglycemia due to contractions and swallowing/feeding problems. During this period, the CSII overcame dysglycemia but the contractions due to seizures and physiotherapy caused frequent infusion blockage. Massage or set change was performed to cope with this problem, Glibenclamide (max 2 mg/kg/d) was administered at 10 months of age, since a known KCNJ11 gene mutation (c.497G>T) was detected at NGS. However, he didn't respond the sulphonylurea.

Conclusion: CSII is the most physiologic way for a good metabolic control in diabetes. However, CSII in diabetic patients with neurologic problems can be quite troublesome.

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ATTD8-0384

BENEFITS OF INSULIN PUMP THERAPY OVER MULTIPLE DAILY INJECTIONS FOR PREGNANT WOMEN WITH TYPE 1 DIABETES AND THEIR OFFSPRING: 20 YEAR EXPERIENCE IN ONE CENTRE

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Background and Aims: Our clinic has seen 130 pregnant women with type 1 diabetes since 1998. All were offered CSII rather than MDI for pregnancy. We compared outcomes according to treatment modality.

Method: We collected data on HbA1c before, during and after pregnancy; intra-partum maternal glucose; hypoglycaemia severity; fetal growth; neonatal morbidity; and maternal weight gain and insulin requirements.

Results: 70 women used CSII, 16 switching from MDI; 60 used MDI alone. HbA1c was significantly better in CSII users preconceptually (7.5 ± 1.4 vs 8.3 ± 1.9%) and in the first trimester (7.0 ± 1.1 vs 7.7 ± 1.6%), with no significant difference during later pregnancy. CSII users reported significantly less severe hypoglycaemia.

CSII use had no impact on fetal growth or birth weight. 28% of CSII users had a vaginal delivery compared to 18% of MDI users.

There was a reduction in frequency of neonatal hypoglycaemia (blood glucose <2.0 mmol/l), with 32% of the CSII group affected compared to 69% of the MDI group. There were no other differences in neonatal outcomes. There was significantly less weight gain (12.3 ± 5.3 vs 15.0 ± 4.58 kg), lower insulin requirement (insulin dose increase x 1.5 ± 0.5 vs 2.5 ± 1.7) and better post-partum HbA1c (7.6 ± 1.2 vs 8.4 ± 1.7%) for women using CSII.

Conclusion: Compared to MDI, CSII use in pregnant women with type 1 diabetes can achieve better glycaemic control, particularly preconceptually, in early pregnancy and post-partum; less severe hypoglycaemia; reduced maternal weight gain; and reduced frequency of neonatal hypoglycaemia.

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Insulin Pumps

ATTD8-0214

REAL WORLD EXPERIENCE OF LONG-TERM GLYCAEMIC CONTROL WITH INSULIN PUMP AMONG ADULTS WITH TYPE 1 DIABETES

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Background and Aims: Insulin pump (CSII) is commonly regarded as the most advanced device to replace insulin in patients with type 1 diabetes. The aim of this study was to evaluate the long-term glycaemic outcome in a routine clinical setting in adults with type 1 diabetes.

Method: Patients initiating CSII by the year 2011 in a single diabetes clinic (University Hospital) were included. Every subject was followed for 6 years, 3 years before the introduction of CSII and 3 years thereafter. Reasons for CSII selection as well as for discontinuation were evaluated.

Results: A total of 189 patients were included (76 men, 113 women). Initially the mean age was 33.1 (SD 8.9) yrs and the duration of diabetes 18.9 (11.6) yrs. During the follow-up 25 patients discontinued (13%) CSII. Reasons for initiating CSII included poor glucose control (38.1%) and lability (30.2%). Reasons for discontinuation (mean use 2.6 yrs) were deteriorating glucose control, tendency to ketoacidosis and personal wishes. CSII therapy led to improved glycaemic control (HbA_{1c} 9.20 % to 8.48%, $p < 0.01$). Daily insulin dose decreased by 24% (61.6 IU to 46.3 IU, $p < 0.01$). Patients with highest initial HbA_{1c} and labile diabetes gained most of CSII. Weight-gain was about 2 kg during the first year of CSII, but it stabilized thereafter. Twenty percent of the patients had technical difficulties with CSII.

Conclusion: CSII improves glucose control in a routine clinical setting. Even after careful selection a significant number of patients discontinues CSII therapy during the first years.

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Insulin Pumps

ATTD8-0318

FREQUENCY AND REASONS FOR CSII DISCONTINUATION IN CHILDREN AND YOUNG PATIENTS WITH T1DM

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Background and Aims: There has been a considerable increase in the use of CSII in the Russian Federation in recent 10 years with substantial benefits for glycemic control. However, despite the advantages and effectiveness, some patients discontinue insulin pump. Objectives of the study were to estimate CSII discontinuation rate and associated reasons.

Method: We survived 395 T1DM patients aged 2–25 years with duration of CSII for >6 months to investigate reasons and CSII discontinuation rate. Data were collected through CSII register of ''Endocrinology Research Center'' and cross-sectional analysis (telephone call).

Results: At the time of the study mean duration of CSII was 2,6 ± 1,8 years. Forty seven (11,9%) patients refused CSII corresponded to 4,6 cases per 100 patient-years. The mean duration of CSII at the time of the discontinuation was 1.6 ± 1.3 years, and HbA1c 9,1 ± 1,7%. The reasons for discontinuing CSII in 46.8% of cases was the inconvenience of use (hassle of constantly wearing an external device, inconvenience during the summer time or physical exercises etc.), in 23.4% - cost of supplies (no supply free of charge), in 21.3% - frequent complications (occlusions, kinking, DKA, infusion site problems etc.), in 6.4% - lack of effect (no improvement or deterioration of HbA1c), in 4.3% - poor adherence to the treatment by child/adolescent. In 8.5% of cases there were other reasons (weight gain, absence of a CSII specialist at the place of residence or others reasons).

Conclusion: Many young patients refuse CSII. This highlights the need for efforts to increase efficiency and overcome barriers to using and wearing devices.

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Insulin Pumps

ATTD8-0281

ASSESSMENT OF INFUSION SET SURVIVAL OF THE NEWLY DEVELOPED LANTERN CATHETER IN TYPE 1 DIABETES BY GLUCOSE CLAMP TECHNIQUE (A PILOT STUDY)

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Background and Aims: Modern insulin therapy aims to establish glycemic control without relevant hypoglycemia. Physiologic insulin secretion can best be mimicked by insulin pump therapy (CSII). The catheter-tissue interface is the bottle neck of CSII. Currently infusion sets shall be changed every 2–3 days to avoid lipohypertrophy, fluctuations in insulin absorption and occlusion. Patients would prefer an extended wear time if stable insulin absorption could be achieved.

Method: The novel catheter featuring Lantern Technology shall allow more stable insulin delivery via slots in the shaft of the Teflon cannula even if kinking or clotting occurs. It is expected that due to the specifications of the Lantern catheter insulin delivery is more stable over an extended wear time as compared to a conventional catheter. The aim of the present study is to investigate clinical performance of the Lantern catheter in 12 patients with type 1 diabetes using CSII over a period of up to 7 days.

Results: In this pilot study (Oct 2017–Dec 2017), a combined study design consisting of inpatient (euglycemic clamp) and outpatient phases (insulin pump therapy over 7 days) is chosen in order to allow assessment of performance and survival time of the Lantern catheter. During the clamp visit, pharmacodynamics and pharmacokinetic properties will be assessed over time and will be compared to baseline data obtained with a Teflon catheter. During the home phase, blood glucose monitoring will be performed.

Conclusion: It is expected that the novel Lantern catheter provides stable insulin delivery over an extended wear-time of 7 days.

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Insulin Pumps

ATTD8-0137

THE EFFECTS OF SUBCUTANEOUS INSULIN INFUSION VERSUS MULTIPLE INSULIN INJECTIONS ON GLUCOSE VARIABILITY IN YOUNG ADULTS WITH TYPE 1 DIABETES: THE METRO STUDY

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Background and Aims: Type 1 diabetic patients have high instability of daily glucose levels. The aim of this study was to evaluate the long-term effects of continuous subcutaneous insulin infusion (CSII) therapy, as compared with multiple daily injections of insulin (MDI), on glucose variability, in young type 1 diabetic patients transitioned to the adult diabetes care.

Method: Patients aged 18–30 years and considered eligible for insulin pump therapy were included in the study. Ninety-eight patients who started CSII therapy and 125 who remained in MDI completed a 2-year follow-up. Glucose variability was assessed with continuous glucose monitoring using blood glucose standard deviation (BGSD), mean amplitude of glycemic excursions (MAGE), continuous overlapping net glycemic action (CONGA-2h), low blood glucose index, high blood glucose index, daily risk range.

Results: MAGE and BGSD decreased in both groups, with an adjusted differences of –0.74 mmol/L (95% confidence interval [CI] –1.22 to –0.26, P = 0.003) and –0.3 (–0.52 to –0.1, P = 0.005) favoring the pump-therapy group. No significant differences between groups in the other variability indexes were observed. HbA1c decreased in both groups without significant difference (0.05, –0.26, 0.35, P = 0.77); fasting glucose, insulin dose and overall hypoglycemia (daily, nocturnal, and severe) decreased more in patients with CSII, as compared with those with MDI.

Conclusion: Among young adult with type 1 diabetes transitioning from the pediatric care, the use of CSII is associated with lower glucose variability, fasting glycemia and overall hypoglycemic events than MDI during a 2-year period of follow-up.

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Insulin Pumps

ATTD8-0368

MEDICAL PARAMETERS IN CONTINUOUS SUBCUTANEOS INSULIN INFUSION THERAPY

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Background and Aims: To evaluate the variation of medical parameters in patients with type 1 diabetes on CSII therapy.

Method: We gathered a sample of 85 patients on CSII therapy, 52.9% female, with a mean age of 37.4 ± 12.2 years, an average CSII utilization of 6.1 ± 2.79 years, a mean BMI of 25.1 ± 4.0 kg/m2, and a mean A1c of 7.7 ± 1.0 %, and we collected several treatment parametric values, namely, insulin sensitivity factor (ISF), carbohydrates/insulin ratio (CH/R) and daily total insulin dosage.

Results: In this sample we found a mean ISF of 40.5 ± 13.7, a mean CH/R of 1.07 ± 0.38, a mean total insulin dosage of 45.2 ± 17.6 and an average number of basal insulin infusion rates of 8.1 ± 2.6. We also found a significant statistical correlation between the CSII therapy duration and A1c (r = 0.25; p = 0.03) and ISF (r = –0.36; p = 0.001). Moreover the number of basal insulin infusion rates appears to have a significant correlation with age (r = 0.26; p = 0.01) and with the total insulin dosage (r = –0.64; p <= 0.001).

Conclusion: The number of basal insulin infusion rates appears to increase with age across the CSII therapy. Patients with more time on CSII utilization tend to have higher A1c. In this sample we found some interesting medical factors regarding A1c and ISF.

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Insulin Pumps

ATTD8-0046

A 10-YEAR FOLLOW UP IN TYPE 1 DIABETES PATIENTS ON CONTINUOUS SUBCUTANEOUS INSULIN INFUSION

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Background and Aims: The aim of this study is to evaluate the results of 10 years follow up in type 1 diabetes patients on Continuous Subcutaneous Insulin Infusion (CSII) at our center.

Method: We have retrospectively analyzed 162 Type 1 Diabetes patients using CSII from October 2004 until October 2014. Data was collected through the electronic medical record system, cross-sectional analysis and CSII reports generated by Carelink Therapy Management Software (Medtronic, Northridge, USA).

Results: All patients were treated with CSII more than 3.5 years. Patients were analyzed in three age groups: 12–18; 19–24 and >25 years. More than 50% of patients achieved HbA1c <7.0% and more than 70% of patients achieved HbA1c <7.5%. HbA1c level significantly changed (−1.1%) from baseline in all groups ($P < 0.05$). Basal ratio was 36% in younger age (< 16 years old) and showed trend of increasing with age and longer diabetes duration (up to 48%). Younger patients used bolus wizard on regular basis (more than 75%), which was significantly higher than other age groups ($P < 0.05$). Insulin dose was 0.98 U/kg/d in age group 12-18 years old, which was significantly higher than other two age groups ($P < 0.05$).

Conclusion: Our study shows improved glucose control in long-term CSII users. A reduction of HbA1c levels by −1.1% was maintained during the study period.

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ATTD8-0048

INSULIN PUMP CHARACTERISTICS IN TYPE 1 DIABETES PATIENTS WITH OPTIMAL GLUCOSE CONTROL

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Background and Aims: To describe Continuous Subcutaneous Insulin Infusion (CSII) characteristics in young people with Type 1 Diabetes (T1D) with optimal glucose control and to describe possible simple CSII settings.

Method: The retrospective study enrolled CSII patients (age 18–25 years) with T1D treated at our Center from January to December 2016. From total cohort of 124 patients, 93 patients meet the criteria: HbA1c<7.5% and at least 3 visits in the last year. Patients were grouped by age 12–18 (adolescents) and 19–25 years (young adults) and data was collected through the electronic medical record system and CSII characteristics were obtained from 8 weeks reports prior to Hba1c, generated by Carelink Therapy Management Software (Medtronic, Northridge, USA).

Results: Significant difference in basal insulin was found between groups. Adolescents had five basal rates, less insulin early morning (03–07h) and slight decrease of afternoon basal rate (13–19h), comparing with young adults with four basal rates, more insulin early morning (03–07h) and no decrease of afternoon basal rate (13–19h). Insulin to Carbohydrate Ratio was 8–12gr in adolescents and 8.5–10gr in young adults. Insulin Sensitivity factor was higher in adolescents (2.0–3.0 mmol/l) comparing with young adults (2.0–2.4 mmol/l).

Conclusion: Optimal glucose control is achievable in real life conditions among T1D patients on CSII therapy. Bolus wizard, frequent bolusing, multiple basal segments, and close follow up can be determinants for better control. Simple CSII settings as a tool, derived from our data may help clinicians to fine tune T1D patients and achieve optimal glucose control.

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Insulin Pumps

ATTD8-0127

CONTINUOUS SUBCUTANEOUS INSULIN INFUSION CHARACTERISTICS AND SUSPEND BEFORE LOW IN TYPE 1 DIABETES PATIENTS USING MINIMED 640G IN QATAR

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Background and Aims: To describe Continuous Subcutaneous Insulin Infusion (CSII) characteristics and predictive low glucose suspend (PLGS) feature in type 1 diabetes (T1D) patients using Minimed 640g (Medtronic, Northridge, USA) in routine clinical settings in Qatar.

Method: We have analyzed 28 T1D patients (M 11; F 16, age 9.7 ± 3.2 years with diabetes duration 4.4 ± 2.6 years) who started Minimed 640g, using standardized protocol from January 2017 to June 2017. CSII characteristics, PLGS and HbA1c were evaluated three months after the initiation.

Results: Insulin dose significantly increased from 0.59 ± 0.23 to 0.72 ± 0.23 u/kg/d ($p < 0.05$). Bolus wizard settings were as follows insulin-to-carbohydrate-ratio 20.1 ± 9.3 gr; insulin sensitivity factor of 128 ± 68 mg/dl; target range from 92 ± 9.8 to 138 ± 14.8 mg/dl; active insulin time 3.8 ± 0.8 hours. PLGS feature (at 62 ± 9 mg/dl) was set in all patients and showed 2.1 ± 0.8 events and 92 ± 35 min/patient/day. HbA1c significantly decreased ($p < 0.05$) by 1.6 % (from 9.7 ± 1.3 to 8.1 ± 0.8%) in the following 3 months.

Conclusion: Our results show that Minimed 640g may improve glucose control in T1D patients. PLGS is common and should be used to prevent hypoglycemia. The study should be performed on larger population and longer duration to confirm the results.

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Insulin Pumps

ATTD8-0202

THE IMPACT OF SENSOR-AUGMENTED INSULIN PUMP (SAP) THERAPY ON QUALITY OF LIFE (QOL) IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES (T1D) AND THEIR PARENTS

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Background and Aims: Ensuring QoL while maintaining a good glycemic control is an important challenge in T1D

treatment. Aim of this study was to evaluate the impact of SAP therapy on QoL in children and adolescents with T1D and their parents.

Method: 125 patients (T1D duration ≥1 year;) were recruited in the study. Twenty-one out of 125 (16.8%) were on SAP by at least 1 year (11.7 ± 3.5 yrs old; T1D duration = 6.6 ± 3.5 yrs) while others were on MDI by T1D onset (12.5 ± 3.5 yrs old; T1D duration = 5.4 ± 3.5 yrs). Patients and parents filled in the PedsQLTM 3.0 Diabetes Module including diabetes symptoms, treatment barriers, treatment adherence, worry, and communication scales.

Results: Patients in the SAP group reported a higher score in the ''hypoglycemic'' item of worry scale ($p = 0.035$) than the MDI group. Mothers in the SAP group, respect to MDI group ones, reported a lower score in both the ''injection pain'' item of treatment barriers scale ($p = 0.023$) and the ''difficulty to control glycemia'' item in treatment adherence scale ($p = 0.009$). HbA1c ($p = 0.001$) and fasting plasma glucose ($p = 0.044$) values were significantly lower in SAP group than in MDI.

Conclusion: SAP seems to reduce the fear of hypoglycemia in children and adolescents with T1D and this could be important to improve glycemic control. In mothers SAP seems to increase both barriers and adherence to treatment. The impact of new technologies on QoL should be regularly evaluated because it is critical to better understand both the medical and psychological care of T1D.

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Insulin Pumps

ATTD8-0096

INSULIN PUMP THERAPY - INFLUENCE ON PARAMETERS OF METABOLIC SYNDROME IN T1D PATIENTS

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Background and Aims: Comparison of the changes of parameters of metabolic syndrome (MS) in T1D (diabetes mellitus typ 1) after switching from MDI regime (multiple dose insuline) to CSII (continuous subcutaneous insulin infusion).

Method: 31 patients, aged on average 33.3 ± 9.1 years, switched over from MDI to CSII. Parameters were evaluated before and 6 months after starting CSII. We evaluated anthropometric data, visceral fat area (VFA), lipid profiles, leptin and resistin.

Results: Before setting up CSII 13 % men and 25 % females met MS criteria, on CSII treatment 20 % men and 13 % females met MS criteria according to the IDF (International Diabetes Federation). The rise in waist circumference (WC) in men was responsible for the increase of the MS, while the reduction of the MS in females was predominantly caused by increase in HDL-C (high density lipoprotein cholesterol). In men the volume of VFA decreased ($p = 0.028$), in females VFA ($p = 0.098$) and TAG (triglycerides) levels decreased partially. Blood pressure in both sexes was without significant change. Leptin levels correlated with total body fat in females only. Resistin levels correlated positively with age ($p = 0.015$) and the duration of T1D (0.049), not with the MS parameters.

Conclusion: Treatment of CSII in T1D patients led to reduction of MS in premenopausal females but not in men according IDF criteria. In men, we observed an increase of WC but a decrease of VFA. WC may not correspond to changes in VFA in T1D men.

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Insulin Pumps

ATTD8-0378

ADAPTING AND IMPLEMENTING A SOCIAL SUPPORT TOOL INTERVENTION (GENIE) FOR INCORPORATING A NEW TECHNOLOGY: FOCUS GROUPS WITH INSULIN PUMP USERS AND CLINICIANS

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Background and Aims: Determining ways and means for people to address the challenges they come across in incorporating a new technology could have an impact on how people are able to self-manage. The social support tool (Genie) enables navigation to means of support and resources, but it is not known how Genie can be implemented with people using insulin pumps. We aimed to gather insights of pump users and clinicians to determine what strategies are likely to lead to normalisation of a new technology in their self-management of diabetes and establish how Genie needs to be adapted to be successfully implemented in clinics.

Method: A qualitative study using Focus Groups was undertaken with insulin pump users (N = 20) and clinicians (physicians, nurses, psychologists, dieticians) (N = 20). Focus Groups were analysed using the framework approach.

Results: HCPs were encouraging of additional ways to facilitate their patient's access to tailored support, especially outside of clinic hours. However, concerns were raised about the capacity to maintain and fund any additional provision of care. Pump users were enthusiastic about access to personalised, varied resources, and were keen to adapt Genie to allow registration of particular interests i.e. a local diabetes specific running group.

Conclusion: Genie was deemed as an attractive means to offer personalised support for people in the process of adaptation to a new health technology, by both clinicians and pump users. Key points for implementing a support tool into practice were; security of funding for ensured maintenance and the ability to actively engage with other people living with diabetes.

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Insulin Pumps

ATTD8-0174

SHORT TERM GLYCAEMIC VARIABILITY IN CSII VS MDI IN ADULTS WITH TYPE 1 DIABETES

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Background and Aims: A desire to improve glycaemic variability (GV) may be an indication to commence continuous

subcutaneous insulin infusion (CSII) therapy. However, the short term GV benefits of CSII therapy compared to multiple daily injection (MDI) treatment are unclear in the real-world setting. To determine if CSII therapy is associated with lower short term GV relative to MDI treatment in adults with Type 1 diabetes (T1D).

Method: Retrospective audit of six-day CGM (Medtronic iPro) records. Inclusion criteria were 48 hours of sensor, MDI or CSII for more than 1 year and HbA1c within three months of CGM. RT-CGM use and pregnancy was excluded. GV calculated using EasyGV *(8.8.3.R1 University of Oxford, UK)*. Socioeconomic data (postcode), complications and indication for CGM (hypoglycaemia or optimisation of glycaemic control) were obtained from the medical record.

Results: 98 records (59 MDI, 39 CSII) were analysed. Compared to MDI, CSII users were younger ($p = 0.013$) and less likely to be referred for CGM for investigation of hypoglycaemia ($p = 0.012$). Gender, socioeconomic status, chronic complication status and diabetes duration were similar. There was no difference in HbA1c (8.0(1.4)% (64(16) mmol/mol) MDI vs. 7.9 (1.2)% (62(14) mmol/mol) CSII). There was no difference in any parameter of short term glycaemic variability between MDI and CSII users when analysed as a whole, and by indication for CGM. Individuals referred for CGM to investigate hypoglycaemia had lower HbA1c (7.2(1.4)% (56(15)mmol/mol) vs. 8.3 (1.2)% (66(13) mmol/mol) ($p < 0.001$), longer disease duration ($p = 0.001$) and were more likely to have experienced severe hypoglycaemia ($p = 0.01$).

Conclusion: CSII therapy is associated with similar short-term GV compared to MDI in T1D.

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Insulin Pumps

ATTD8-0072

LIPOHYPERTROPHY IN CSII PATIENTS AND ITS RELATIONSHIP TO KEY CLINICAL PARAMETERS

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Background and Aims: Lipohypertrophy (LH) is found in up to half of insulin injecting patients and is associated with higher HbA1c, higher total daily doses (TDD) and more frequent hypoglycaemia and glycaemic variability. However little is known about the prevalence of LH in CSII patients or its clinical significance.

Method: We assess for LH in 70 CSII patients and analysed its impact on key clinical parameters.

Results: Patients were 59% female, all but 1 had type 1 DM and 87% used the abdomen as infusion site. 95.7% of patients claim to rotate their infusion sites with each new cannula and 82.9% of patients use a single cannula for 3-4 days. 41.4% were found to have visual LH and 58.6%, palpable LH. 96.6% of the visible LH could also be palpated but 31.7% of the palpable LH could not be seen visually. The mean size of abdominal LH was 29.9mm. 48.6% of patients infuse into lipohypertophy, 20% frequently (once per week). 14.5% of patients had frequent unexplained hypoglycaemia and 64.7%, glycaemic variability but neither was associated with the presence of LH or infusion into LH. We also did not find a relationship between LH and HbA1c, TDD or DKA.

Conclusion: LH is present in nearly 3 out of 5 CSII patients and palpation picks up more LH than visualization alone. In our CSII patients LH is not related to HbA1c, TDD, hypoglyaemia, glycaemic variability or DKA, suggesting that the mechanism and clinical implications in CSII patients may differ from those in insulin injectors.

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Insulin Pumps

ATTD8-0057

TEST FOR INSULIN PUMP USERS – THE TOOL TO TAILOR EDUCATION AND CHECK PATIENT'S KNOWLEDGE

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Background and Aims: In the Czech Republic insulin pump therapy is fully covered from health insurance (when a patient fulfils indication criteria) but not always expected diabetes compensation improvement occurs. To enhance patient's motivation and tailor the education a test based on our publication for insulin pump users was prepared.

Method: This tool (www.diabetickaasociace.cz/diatest) is based on Moodle, an interactive platform used for teaching and testing worldwide. Two frameworks were prepared, one for a dry run and one for a full run which is set to 60 minutes. The test consists of 42 single choice questions with four answer options. The test covers 8 domains crucial for insulin pump users. Study group: 27 females/23 males, mostly DM1 (only 3/50 other DM type), median of diabetes duration 13 yrs (2–52), 19/50 newly introduced to CSII therapy. Data were processed by SPSS sw.v.24.

Results: 38/50 patients had their first attempt successful (80% and more correct answers). Median of mistakes was 2/42 (range 0–21), the most problematic topics were Diet and Insulin regimes and its application. On contrary unproblematic were questions regarding basal adjustment. Patients already having chronic diabetic complications scored better ($p = 0.008$) but connection to other factors (age, sex, education, marital status, HbA1c, insulin dose, previous experience with CSII, BMI) was not observed.

Conclusion: This approach enables to adjust education and give us feedback on patient's knowledge improvement. We interpret better scoring of patients having complications as they are more cooperative because they have already recognised diabetes consequences (but further analysis is necessary).

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Insulin Pumps

ATTD8-0058

VALUE OF SIMPLE INSULIN INFUSION IN THE US – A PRAGMATIC HEALTH ECONOMIC MODEL ANALYSIS

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Background and Aims: Continuous subcutaneous insulin infusion (CSII) in patients with type 2 diabetes (T2DM) improves glycemic control (HbA1c) and reduces insulin dosage compared to multiple daily injections (MDI). However, CSII has not been widely adopted in T2DM due to costs, complexity and training requirements. New delivery devices, like PAQ®, a simple 3-day insulin delivery device (CeQur SA, Switzerland) provide simple insulin infusion (SII) and diminish traditional CSII obstacles. This analysis investigated cost-effectiveness in the United States of SII compared to MDI in patients with T2DM not in glycemic control, with the aim to assess the value of SII devices.

Method: Cost-effectiveness calculations were used that included: (1) costs of insulin and devices; (2) data from recent meta-analysis (Pickup et al 2017) on the relationship between baseline HbA1c levels and effect of treatment with CSII versus MDI on HbA1c; and (3) data from a recent systematic review (Hua et al 2017) on relationship between reduced HbA1c levels and increased life-expectancy along with increased quality-adjusted life-years (QALYs). Costs and outcomes were discounted at 3%. Incremental Cost-Effectiveness Ratios (ICERs) of costs per QALYs gained below 1xGDP per capita (2016: USD 57,467) were defined as 'highly cost-effective' and below 3xGDP as 'cost-effective'.

Results: Base-case results indicated that a SII device is cost-effective in a price range around $12 to $18 per patient per day, depending on baseline HbA1c value and the cost-effectiveness criteria used.

Conclusion: SII has potential to become a highly cost-effective treatment alternative in patients with T2DM on MDI not in glycemic control.

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ATTD8-0193

BASAL RATE DELIVERY ACCURACY OF DURABLE INSULIN PUMPS

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Background and Aims: Continuous infusion of a basal rate is one of the key elements of insulin pump therapy. Test settings to assess basal rate delivery are described in EN 60601-2-24. However, there are no normative requirements regarding acceptable minimum accuracy. In this study, the basal rate accuracy of different durable insulin pumps was tested.

Method: In an experimental setting following procedures of EN 60601-2-24, five insulin pumps with different insulin infusion sets (IIS) were evaluated, Accu-Chek® Insight with Accu-Chek® Insight Flex and Accu-Chek® Insight Rapid, Accu-Chek® Spirit Combo with Accu-Chek® FlexLink and Accu-Chek® Rapid-D Link, Animas® Vibe® with Inset™ II, MiniMed® 640G with MiniMed® Quick-set®, Paradigm® Veo™ with MiniMed® Mio™, MiniMed® Quick-set®, and MiniMed® Sure-T®. Insulin pumps were installed with the tip of the cannula in a water-filled beaker placed on an electronic balance. To avoid evaporation, an oil film was applied. Insulin pumps were set to a basal rate of 1.0 U/h and weight increase was recorded for 72 h. Each combination of insulin pump and IIS was tested 9 times.

Results: Over the whole 72 h, the systems showed a slightly higher mean weight increase (+0.2% to +1.6%) than expected with the programmed basal rate. Deviations were larger during the first 24 h. Regarding the mean delivery over 1-h windows, large variations between the individual windows were observed.

Conclusion: In this study, cumulative basal rate delivery deviations were within a range of ±5% for all tested insulin pump systems, as specified by the manufacturers.

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Insulin Pumps

ATTD8-0196

ACCURACY OF DURABLE INSULIN PUMPS WHEN DELIVERING LOW BASAL RATES

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Background and Aims: Continuous subcutaneous insulin infusion (CSII) is a common therapy for children with type 1 diabetes. Low basal rates are often used. In this study, the delivery accuracy of different durable insulin pumps at a low basal rate was tested.

Method: In an experimental setting following procedures of EN 60601-2-24, three insulin pumps with different insulin infusion sets (IIS) were evaluated, Accu-Chek® Insight with Accu-Chek® Insight Flex and Accu-Chek® Insight Rapid, Accu-Chek® Spirit Combo with Accu-Chek® FlexLink and Accu-Chek® Rapid-D Link, and Paradigm® Veo™ with MiniMed® Mio™, MiniMed® Quick-set®, and MiniMed® Sure-T®. Insulin pumps were installed with the tip of the cannula in a

water-filled beaker placed on an electronic balance. To avoid evaporation, an oil film was applied. Insulin pumps were set to a basal rate of 0.1 U/h and weight increase was recorded for 72 h. Each combination of insulin pump and IIS was tested 9 times.

Results: Over the whole 72 h, the systems showed a higher mean weight increase (+4.1% to +24.3%) (indicating insulin delivery) than expected with the programmed basal rate. Considering only the first 24 h, the deviations were even larger. Over 1-h windows, large variations between the individual windows were observed.

Conclusion: At the low basal rate of 0.1 U/h that was used in this test setting, insulin delivery of most pump systems was higher than expected in terms of weight increase, particularly during the first 24 h.

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Insulin Pumps

ATTD8-0022

INSULIN PUMP USE CHALLENGES IN PEDIATRIC TYPE1 DIABETES: A SURVEY OF DIABETES EDUCATORS

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Background and Aims: Managing pediatric type 1 diabetes can be challenging. insulin pump therapy has been demonstrated to improve glycemic control and patients' quality of life. The certified diabetes educators (CDE) are the first line of connection between patients, their families and technology advancement. Perception of CDEs on observed challenges is a very important factor to make the process a successful one.

Method: Four Certified Diabetes Educators (CDE) practicing in a pediatric diabetes outpatient clinic, were asked to independently complete a brief survey to arrange in order of frequency, several challenges identified as common problems in dealing with pediatric diabetes pump therapy.

The five major category were :

1- Financial/ Insurance factors
2- Recipient/Social factors
3- Provider's factor
4- Access/getting device to patient.
5- Incorrect use of device.

Results: All four certified diabetes educators placed the Financial/ Insurance factors as the most common challenge. This was followed by incorrect use of the device. Three of four certified diabetes educators placed Recipient/Social Factors in third place.

Conclusion: Our brief survey demonstrated that in our patient population the financial factor (copay, cost) appears to be the most important identified challenge. Many families may find the cost of owning and maintaining the insulin pump a prohibiting factor. Families may face a huge out of pocket expenses at the initiation of the insulin pump therapy and this by itself may delay the access to it. Understanding and analyzing the financial aspect of insulin pump therapy remains the most important first step to ensure success.

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Insulin Pumps

ATTD8-0025

CHALLENGES IN USING INSULIN PUMPS IN PEDIATRICS : A SELF REPORT BY FAMILIES

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Background and Aims: Type 1 Diabetes Mellitus (T1DM) is a chronic autoimmune condition that requires multiple daily insulin administration. Insulin pump therapy provides less injections and reduced episodes of hypoglycemia. This technology contributes to more flexibility in T1DM management, but requires frequent re-evaluations and adjustments for optimal management.

The discontinuation rate of insulin pump therapy is higher in adolescents compared to other groups. Previous studies have shown that a small number of pediatric patients discontinue pump therapy, but risk factors for discontinuation are unclear. The most common challenges reported in insulin pump discontinuation are disliking the pump, problems wearing it, and glycemic control problems that leads to burnout.

Method: One hundred families who have children with T1DM on insulin pumps were a part of a self-reported survey.

The survey was delivered during regular outpatient follow up visits.

The project was approved by the Institutional Review Board in our University.

Results: Sixty-three percent of the children using insulin pump therapy were between the age of 13 and 18 years. Fifty-six percent of the total patients had the insulin pump for more than 5 years. The reported problems in the first year while using pumps were:

Pump failure (60%), diabetes ketoacidosis (23%), and severe hypoglycemia (13%).

Conclusion: Technological problems remain the most common challenge for families. Insulin pump failure can easily lead to diabetes ketoacidosis (DKA). Other problems may include device misuse, site infections and adherence to skin, should be always explored. Further studies should examine concerns related body image, interference with daily activities, and other psycho-social factors.

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Insulin Pumps

ATTD8-0304

MANAGING PIZZA MARGHERITA WITH INSULIN PUMP. ANALYSIS OF GLUCOSE RESPONSE AFTER CONSUMPTION OF PIZZAS WITH DIFFERENT KINDS OF FERMENTATION, USING A SIMPLE WAVE BOLUS

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Background and Aims: Pizza is considered a ''junk food'', because of high content of fat and carbohydrates. The glycaemic response to pizza could change according to the fermentation of the dough. Dual-wave bolus is usually used to manage pizza meal.

Aim of our study was to evaluate glycemic response in a pediatric population with T1DM, after consumption of pizzas made with two different kinds of fermentation but the same Italian recipe, with a simple wave bolus.

Method: We enrolled 18 patients with T1DM on CSSI to evaluate their glycaemic response to the short and the long fermented pizza (less than 8 hours or more than 24 hours).

Results: We observed that glucose values were between 70 and 180 mg/dl for a good percentage of time in both types of pizza during all the periods of observation.

For male patients the mean percentage of time between 70–180 mg/dl, for 2 hours after bolus, was 71% for the first pizza and 95% for the second ($p = 0.044$).

Considering the same time window, there was a significant difference as far as percentage of time is concerned for patients with metabolic compensation ''not in target'' with SG <70 mg/dl ($p = 0.045$) and between 70 mg/dl and 180mg/dl ($p = 0.009$).

About the AUC of hypoglycemic events, we observed a statistically significant difference for the subset of prepuberal patients ($p = 0.05$) and for the patients with metabolic compensation ''not in target'' ($p = 0.024$).

Conclusion: Pizza can generate a good post-prandial glycemic response. Evaluating the fermentation time of the dough can help the diabetic patient in choosing the type of insulin bolus to self-administer.

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Insulin Pumps

ATTD8-0424

THE METABOLIC CONTROL IN CHILDREN WITH TYPE 1 DIABETES TREATED WITH CSII - IMPACT OF THE DISEASE DURATION

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Background and Aims: To evaluate the metabolic control in children with type 1 diabetes treated with CSII, according to gender, age at diagnosis and disease duration.

Method: Data of 326 T1D patients treated with CSII (172 boys) aged 1.5–18 years (avg. 12.6 ± 3.9) were analyzed. Average blood glucose for the past month (AVBG), HbA1c, number of glycemia measurements (SMBG), hypoglycemic episodes, total daily dose (TDD)/kg and basal insulin/kg were evaluated in terms of the age of T1D onset, duration of disease and duration of therapy with CSII.

Results: T1D was diagnosed at the age of 7.1 ± 3.7 years, T1D duration was 5.1 ± 3.5 years. CSII duration was 3.6 ± 2.8 years. Mean HbA1c was 8.3 ± 1.6%, mean AVBG was 176,3 ± 37.6 mg/dl. HbA1c correlated with age of diagnosis ($r = -0.13$, $p = 0.0382$). HbA1c and AVBG correlated with disease duration ($r = 0.24$, $p < 0.0001$ and $r = 0.22$, $p = 0.0009$, respectively). Likewise, metabolic control depended on the duration of CSII treatment (for AVBG $r = 0.18$, $p = 0.0067$, for HbA1c $r = 0.19$, $p = 0.0019$). Mean number of glycemia measurements was 7.0 ± 3.4 and it correlated with duration of diabetes ($r = -0.29$, $p = 0,00001$). Mean TTD/kg was 0.74 ± 0,24 U. Basal insulin/kg was 0.27 ± 0,12 U; base%TDD was 35.80 ± 12.03%; it did not correlated with gender, age of diagnosis and duration of disease.

Conclusion: The younger the child age at T1D presentation and therefore the longer duration of disease, the more difficult is to control diabetes properly, and the higher insulin dose is administrated. The duration of diabetes does not affect the number of hypoglycemia episodes.

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New Insulin Analogues

ATTD8-0056

FAST-ACTING INSULIN ASPART AT HIGH DOSES IN INDIVIDUALS WITH TYPE 2 DIABETES

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Background and Aims: The aim of this analysis was to explore if treatment with fast-acting insulin aspart (faster aspart) provided a benefit for postprandial plasma glucose (PPG) control in individuals with type 2 diabetes (T2D) receiving high doses of bolus insulin.

Method: *Post hoc* subgroup analysis of onset 2: a 26-week, randomised, double-blind phase 3a trial comparing mealtime faster aspart versus mealtime insulin aspart (IAsp), both in a basal–bolus regimen, in individuals with T2D uncontrolled on basal insulin therapy and metformin. The impact of faster aspart and IAsp on PPG control was assessed with a standard liquid meal test (80 g carbohydrate) after 26 weeks' treatment. Individuals were grouped into three post-randomisation subgroups: meal test bolus insulin dose ≤10 U (~25% of individuals), 10–20 U (~50% of individuals) or >20 U (~25% of individuals).

Results: In the >20 U subgroup, a statistically significant treatment difference in favour of faster aspart versus IAsp was observed for change in PPG increment at all post-meal time points from 1–4 h (Table). There were no significant treatment differences in favour of faster aspart in the ≤10 U and 10–20 U subgroups. There was no difference in change from baseline in HbA_{1c} between faster aspart and IAsp in any of the bolus insulin dose subgroups.

Conclusion: PPG control in high bolus insulin dose-requiring individuals with T2D remains an elusive target. Notwithstanding the risk of bias in this post-randomisation subgroup analysis, faster aspart may prove uniquely qualified as the bolus insulin of choice for these individuals.

Table. Change from baseline in PPG increment after 26 weeks of treatment with faster aspart in T2D stratified by bolus insulin dose subgroup.

Change from baseline after 26 weeks' treatment	ETD (95% CI) Bolus insulin dose subgroup		
	≤10 U	10–20 U	>20 U
1-h PPG increment (meal test), mmol/L	−0.63 (−1.58;0.32)	−0.28 (−1.02;0.45)	−1.31 (−2.35;−0.27)
2-h PPG increment (meal test), mmol/L	−0.06 (−0.89;0.76)	−0.07 (−0.71;0.56)	−1.23 (−2.14;−0.33)
3-h PPG increment (meal test), mmol/L	0.41 (−0.41;1.23)	−0.37 (−1.00;0.26)	−0.96 (−1.84;−0.07)
4-h PPG increment (meal test), mmol/L	0.80 (0.02;1.59)	−0.48 (−1.08;0.12)	−1.01 (−1.87;−0.15)

Change from baseline in PPG (meal test) increment is analysed using an analysis of variance model including treatment by dose group interaction, CGM strata and region as factors, and as covariates the actual bolus dose and total daily dose (nested within dose group), as well as baseline PPG (meal test) increment. ETD (faster aspart−IAsp).
CGM, continuous glucose monitoring; CI, confidence interval; ETD, estimated treatment difference; faster aspart, fast-acting insulin aspart; IAsp, insulin aspart; PPG, postprandial plasma glucose; T2D, type 2 diabetes; U, unit of insulin.

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New Insulin Analogues

ATTD8-0097

BIOCHAPERONE LISPRO, AN ULTRA-RAPID INSULIN LISPRO FORMULATION, IMPROVES POST-PRANDIAL BLOOD GLUCOSE CONTROL IN A 14-DAY MULTIPLE DAILY INSULIN INJECTIONS STUDY IN SUBJECTS WITH T2DM

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Background and Aims: BioChaperone Lispro (BCLIS) is an ultra-rapid insulin lispro formulation designed to better mimic the physiological timing of prandial insulin action.

Method: We investigated safety and post-prandial blood glucose (PPG) control with BCLIS and Humalog® in a double blind randomized crossover study in 51 T2DM participants treated with multiple daily injections [mean±SD age: 62 ± 9 yrs; BMI: 30.5 ± 4.1 kg/m^2; HbA1c: 7.1 ± 0.8%]. Participants used individualized doses of BCLIS or Humalog® as prandial insulin immediately before meals with unchanged basal regimens during two 14-day outpatient periods. PPG and pharmacokinetics were assessed during individualized solid mixed meal tests (MMTs) (50% carbs, 30% fat, 20% proteins) on days 1, 2, 13 and 14.

Results: BCLIS and Humalog® were well tolerated with no injection site reactions, similar overall hypoglycemic events and comparable outpatient glycemia based on SMPG. Daily prandial insulin doses were ~10% lower with BCLIS than with Humalog®. BCLIS showed a significantly faster absorption than Humalog® (Figure) with faster-in and faster-out characteristics underlined by significant reduction of early- and late-time-to-half-maximal insulin lispro blood concentrations by −21% ($p < 0.0001$) and −11% ($p < 0.013$) respectively. These characteristics were maintained after 14 days of use. BCLIS resulted in a significantly improved PPG control with >20% reductions in the first 2 hours when all MMTs were analyzed, mainly driven by differences on days 13-14.

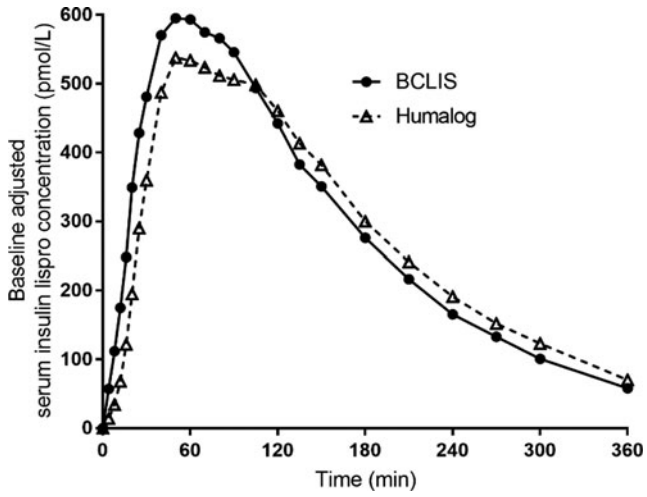

FIGURE: Mean pharmacokinetic profiles of BCLIS and Humalog in T2DM subjects (mean of Day 1-2).

Conclusion: BCLIS was well-tolerated over 14 days of MDI treatment and significantly improved PPG control vs. Humalog® in subjects with T2DM.

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New Insulin Analogues

ATTD8-0350

REDUCTION OF GLYCEMIC VARIABILITY AT 12 WEEKS OF TREATMENT WITH INSULIN DEGLUDEC IN PATIENTS WITH DIABETES WITH HIGH GLYCEMIC VARIABILITY AND HYPOGLYCEMIA

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Background and Aims: Insulin Degludec (IDeg) is an ultra-long-acting insulin, with a stable pharmacodynamic profile which leads to lower fluctuations in glucose levels. The effect of IDeg has not been specifically assessed in patients with increased basal glycemic variability (GV).

Method: A prospective before-after study type was conducted. The impact of the switch from a Glargine or Detemir insulin regimen to Ideg for 12 weeks on GV, measured by continuous glucose monitoring, on A1c levels and on the incidence of episodes of global and nocturnal hypoglycemia was assessed in a group of patients with increased baseline GV (coefficient of variation >34 %).

Results: 61 patients with basal bolus therapy and hystory of hypoglicemia were included. The difference between A1c levels was −1.04 % (95 % CI −0.42, −1.67), $p = 0.0013$. Total Daily Insulin Dose (TDID) was reduced from 0.45 u/kg to 0.37 u/kg ($p = 0.022$). 35 patients had high VG defined as CV% over 34%. In this group a reducction of 9.14 % (95 % CI, 6.72, 11.55, $p < 0.0001$) of CV% was found, also a reduction of the porcentage of patients with at least 1 episode of hypoglycemia <54 mg/dL which decreased from 44.1 % to 17.1 % (RR 0.32, 95 % CI, 0.11–0.49, $p < 0.01$) and from 37.14 % to 5.71 % (RR 0.154; IC 95 %, 0.017-0.678, $p < 0.01$) for global and nocturnal hypoglycemia, respectively.

Conclusion: these results suggest that treatment with IDeg significantly reduces GV and the incidence of global and nocturnal hypoglycaemia events in patients with increased basal GV.

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New Insulin Analogues

ATTD8-0206

LOCAL VASODILATION AND VASCULAR PERMEABILITY LEAD TO ACCELERATED ABSORPTION FOR LY900014, A NOVEL INSULIN LISPRO FORMULATION

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Background and Aims: Potential benefits of a prandial insulin with a faster onset compared to currently available insulin analogs include better prandial glycemic control, less hypoglycemia and weight gain, and better overall utility in closed-loop artificial pancreas systems. LY900014 is a novel formulation of insulin lispro in which the excipients citrate and treprostinil have been added to accelerate absorption for improvement of postprandial glucose.

MethodResults: In an in vivo Miles permeability assay, injection of citrate into the subcutaneous (sc) tissue of rats resulted in a localized increase in vascular permeability. The vasodilator treprostinil, a prostacyclin analog approved for clinical use, had little effect in this assay. On the other hand, sc injection of very low doses of treprostinil was shown to induce localized vasodilation in rats as assessed by laser Doppler imaging without causing systemic vasodilation. Citrate had minimal effects on vasodilation. To determine the impact of these excipients that influence local vascular permeability and blood flow on insulin lispro PK and glucodynamics, LY900014 was administered by sc injection to diabetic miniature swine. Compared to Humalog®, LY900014 resulted in significantly faster glucose lowering at time points up to 30 min post dose, and key PK parameters were significantly faster. NMR spectroscopy revealed that the proportion of insulin hexamers in formulations of insulin lispro with citrate and stabilizing excipients was comparable to that in Humalog, which demonstrates that monomeric insulin is not required to enable ultra-rapid absorption.

Conclusion: These results provide a mechanistic understanding for the ultra-rapid profile that LY900014 has demonstrated in clinical trials.

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New Insulin Analogues

ATTD8-0173

THE EFFECT OF HIGH CONCENTRATION INSULIN GLARGINE TO THE QUALITY OF LIFE OF THE PATIENTS WITH TYPE 2 DIABETES MELLITUS: A PRE-POST STUDY (HIGH-QOL STUDY)

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Background and Aims: This pre/post intervention study aimed to compare the pain accompanying subcutaneous injection of high concentration (300 units/ml) insulin glargine (U300G) to conventional (100 units/ml) insulin glargine (U100G).

Method: One hundred and eight patients with type 2 diabetes mellitus using U100G were recruited. U100G was switched to U300G basically at the same dosage. SoloStar pens (Sanofi K. K., Tokyo, Japan) and Nanopass 34G needles (Terumo Corporation, Tokyo, Japan) were used. A 150mm visual analog scale was used for the assessment of the quality of life.

Results: Subjects were aged 65 ± 12.6 years (diabetes duration 19.0 ± 10.5 years), male 52.8%, with body mass index 25.9 ± 4.6 and HbA1c 7.8 ± 1.1%. The number of patients who used insulin glargine at <10 units, ≥10 units and <20 units, ≥20 units and <30 units, and ≥30 units was 47, 34, 14 and 13, respectively. Significant improvement in pain score (−41.5 ± 28.0, $P = 0.01$*), ease of use score (−37.5 ± 32.2, $P = 0.01$*), force needed to inject score (−46.5 ± 28.6, $P = 0.01$*), and preference of U300G to U100G score (−45.8 ± 33.1, $P = 0.01$*) was observed after the switching from U100G to U300G. The pain score significantly improved in ≥10 units compared to <10 units (−48.1 ± 25.0 vs. −33.0 ± 29.7, $P = 0.01$*), as well as in ≥20 units compared to <20 units (−50.8 ± 22.7 vs. −38.4 ± 29.1, $P = 0.03$*), but did not reach statistical significance in ≥30 units compared to <30 units (−50.3 ± 24.0 vs. −40.4 ± 28.5, $P = 0.25$) (*$P < 0.05$).

Conclusion: Switching from U100G to U300G reduced pain accompanying injection. (UMIN-CTR: UMIN000023842).

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New Insulin Analogues

ATTD8-0236

INSULIN GLARGINE 300 U/ML (GLA-300) VS 100 U/ML (GLA-100) IN OLDER PEOPLE WITH T2DM: RESULTS FROM A RANDOMIZED TRIAL

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Background and Aims: The SENIOR trial compared the efficacy and safety of Gla-300 with Gla-100 in adults aged ≥65 years.

Method: SENIOR was a phase 3b, randomized, open-label, 2-arm, parallel-group, multicenter, 30-week trial. Insulin was titrated to the ADA-recommended glycemic target for healthy elderly individuals (fasting SMPG: 90–130 mg/dL [5.0–7.2 mmol/L]), a higher glycemic target than utilized previously in randomized controlled trials of Gla-300 versus Gla-100 in adults.

Results: In total, 1014 individuals ≥65 years of age with T2DM were included in the trial, of whom 241 were ≥75 years old. The primary endpoint of non-inferiority of mean change in HbA_{1c} for Gla-300 versus Gla-100 was achieved (least squares mean difference [95% CI]: 0.02, [–0.092 to 0.129] %). Overall, similar percentages of participants in both treatment groups reported confirmed (≤70 mg/dL) or severe hypoglycemia. The annualized rates of documented symptomatic (≤70 mg/dL) hypoglycemia were lower with Gla-300 versus Gla-100, both in the overall study population (1.85 vs 2.56 events/participant-year; rate ratio [RR] 0.74 [0.56 to 0.96]) and in the ≥75 years subpopulation (1.12 vs 2.71 events/participant-year; RR 0.45 [0.25 to 0.83]). Frequency of adverse events, including cardiovascular events, falls and fractures was similar between treatments in both the overall population and participants ≥75 years of age.

Conclusion: These results indicate that Gla-300 was effective in older people with T2DM, with a good safety profile, resulting in comparable reductions in HbA_{1c} and lower rates of documented symptomatic hypoglycemia versus Gla-100.

Sponsor: Sanofi (NCT02320721)

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New Insulin Analogues

ATTD8-0252

INSULIN GLARGINE 300 U/ML (GLA-300) VS 100 U/ML (GLA-100) IN PEOPLE ≥75 YEARS OLD WITH T2DM: SECONDARY ANALYSIS OF THE SENIOR STUDY

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Background and Aims: People aged ≥75 years with T2DM are at high risk of hypoglycemia and associated complications. This secondary analysis of data from the SENIOR trial compared the efficacy and safety of Gla-300 vs Gla-100 in this population with participants aged ≥65 to <75 years.

Method: SENIOR was a phase 3b, randomized, open-label, parallel-group, multicenter, 30-week trial in participants aged ≥65 years with T2DM. Insulin was titrated to the ADA-recommended fasting SMPG target of 90–130 mg/dL for healthy elderly individuals.

Results: 241/1014 participants were ≥75 years. Between-group difference in HbA_{1c} change confirmed non-inferiority for the <75 years (LS mean difference: 0.06 [–0.067, 0.179] %) and ≥75 years (–0.11 [–0.330, 0.106] %) subgroups. At endpoint, mean HbA_{1c} was comparable between subgroups (7.25–7.39 %), regardless of treatment. Pre-breakfast SMPG (125.5–130.6 mg/dL) was successfully titrated to target SMPG across all treatment and age groups.

Table. Percentage of participants with ≥1 hypoglycemic event and annualized event rates during the on-treatment period for populations <75 years of age and ≥75 years of age (safety population)

			<75 years of age subgroup			≥75 years of age subgroup		
			Gla-300 (N=373)	Gla-100 (N=399)	RR vs Gla-100 (95% CI)	Gla-300 (N=135)	Gla-100 (N=106)	RR vs Gla-100 (95% CI)
Number (%) of participants experiencing ≥1 event	Documented symptomatic hypoglycemia	≤70 mg/dL	134 (35.9)	139 (34.8)	1.02 (0.84, 1.23)	33 (24.4)	36 (34.0)	0.72 (0.48, 1.08)
		<54 mg/dL	30 (8.0)	33 (8.3)	0.98 (0.61, 1.56)	**2 (1.5)**	**11 (10.4)**	**0.33 (0.12, 0.90)**
	Confirmed or severe hypoglycemia	≤70 mg/dL	221 (59.2)	243 (60.9)	0.97 (0.86, 1.09)	74 (54.8)	63 (59.4)	0.91 (0.73, 1.13)
		<54 mg/dL	62 (16.6)	57 (14.3)	1.17 (0.84, 1.63)	10 (7.4)	16 (15.1)	0.52 (0.26, 1.02)
Number of events (events per participant-year)	Documented symptomatic hypoglycemia	≤70 mg/dL	387 (2.11)	492 (2.52)	0.83 (0.61, 1.12)	**74 (1.12)**	**138 (2.71)**	**0.45 (0.25, 0.83)**
		<54 mg/dL	41 (0.22)	53 (0.27)	0.78 (0.44, 1.38)	**2 (0.03)**	**18 (0.35)**	**0.08 (0.02, 0.42)**
	Confirmed or severe hypoglycemia	≤70 mg/dL	996 (5.43)	1245 (6.37)	0.83 (0.66, 1.04)	295 (4.46)	320 (6.28)	0.72 (0.48, 1.07)
		<54 mg/dL	87 (0.47)	98 (0.50)	0.91 (0.60, 1.36)	**12 (0.18)**	**26 (0.51)**	**0.36 (0.15, 0.89)**

CI, confidence interval; RR, relative risk for number of participants experiencing ≥1 event and rate ratio for annualized event rates. RR data adjusted by randomization strata of: HbA_{1c} levels at screening (<8.0 or ≥8.0 %); previous use of insulin (yes/no); and use of sulfonylureas or meglitinides at screening (yes/no)

Annualized rates of confirmed (<54 mg/dL) or severe hypoglycemia were lower for Gla-300 vs Gla-100 in the ≥75 years subgroup (ADA guidelines: <54 mg/dL indicative of serious, clinically significant hypoglycemia) (**Table**).

Fewer participants had ≥1 documented symptomatic (<54 mg/dL) hypoglycemic event with Gla-300 vs Gla-100 in the ≥75 years subgroup. Annualized rates of documented symptomatic (≤70 and <54 mg/dL) hypoglycemia were lower with Gla-300 vs Gla-100 in the ≥75 years, but not the <75 years subgroup.

Conclusion: These results indicate that Gla-300 was effectively and safely titrated in participants aged ≥75 years, resulting in comparable reductions in HbA_{1c} and lower rates of documented symptomatic hypoglycemia vs Gla-100.

Sponsor: Sanofi (NCT02320721)

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New Insulin Analogues

ATTD8-0164

THE IMPACT OF BASELINE BMI AND HBA1C ON GLYCAEMIC CONTROL AFTER TREATMENT WITH MEALTIME FAST-ACTING INSULIN ASPART IN PEOPLE WITH TYPE 1 DIABETES

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Background and Aims: This *post hoc* analysis of onset 1 investigated the impact of baseline body mass index (BMI; subgroups: <25, 25–30 and ≥30 kg/m^2) and HbA_{1c} (subgroups: ≤7.5%, 7.5–8.0% and ≥8.0%) on glycaemic control with mealtime fast-acting insulin aspart (faster aspart) and insulin aspart (IAsp).

Method: onset 1 was a 26-week, randomised trial evaluating the efficacy and safety of faster aspart in adults with type 1 diabetes (T1D). Patients were randomised to double-blind mealtime

Table. Change in HbA_{1c} with faster aspart in T1D stratified by baseline BMI and HbA_{1c}

	Baseline characteristics					
	BMI, kg/m²			HbA_{1c}, %		
	<25	25–30	≥30	≤7.5	7.5–8.0	≥8.0
onset 1 **N**						
Faster aspart/insulin aspart	144/129	168/174	69/77	188/201	83/84	110/95
Change in HbA_{1c} after 26 weeks ETD (95% CI)	−0.16 (−0.30;−0.03)	−0.15 (−0.27;−0.03)	−0.12 (−0.31;0.07)	−0.15 (−0.26;−0.04)	−0.23 (−0.40;−0.05)	−0.08 (−0.24;0.07)
Severe or BG-confirmed hypoglycaemia[a] event rate ratio at 26 weeks (95% CI)	0.95 (0.76;1.19)	0.96 (0.79;1.17)	1.27 (0.93;1.72)	0.97 (0.80;1.16)	1.12 (0.84;1.49)	1.00 (0.77;1.29)
Total daily insulin dose ratio at 26 weeks (95% CI)	1.04 (0.95;1.15)	1.01 (0.93;1.10)	0.82 (0.71;0.93)	0.95 (0.88;1.03)	0.96 (0.85;1.09)	1.02 (0.91;1.14)

Data from full analysis set. [a]An episode that is severe (requiring assistance of another person to actively administer carbohydrate or glucagon, or take other corrective actions) or BG-confirmed by a plasma glucose value <56 mg/dL with or without symptoms consistent with hypoglycaemia.
N-values correspond to faster aspart/insulin aspart. ETD [faster aspart – comparator]. Ratio [faster aspart versus comparator]. Change from baseline in HbA_{1c}, and log-transformed dose, respectively, are analysed using a mixed-effect model for repeated measures. Number of hypoglycaemic episodes are analysed using a negative binomial regression model with a log-link function. In addition to the pre-specified covariates, the models included interactions and main effects between treatment and baseline BMI and HbA_{1c}, respectively.
ETD, estimated treatment difference; CI, confidence interval; BMI, body mass index; T1D, type 1 diabetes.
ClinicalTrials.gov: NCT01831765

faster aspart (n = 381), IAsp (n = 380) or open-label post-meal faster aspart (n = 382); each with insulin detemir.

Results: In the overall population, change in HbA_{1c} after 26 weeks was non-inferior (0.4% limit) for mealtime faster aspart versus IAsp, with an estimated treatment difference (ETD [95% CI]) of –0.15% (–0.23;–0.07). ETD for change in HbA_{1c} was similar across analysed BMI and HbA_{1c} subgroups (Table). No major differences between treatments were observed for severe or blood glucose (BG)-confirmed hypoglycaemia across subgroups (Table). Total daily insulin dose was similar in patients across all baseline HbA_{1c} groups and the BMI <25 or 25–30 kg/m^2 groups, but was significantly lower with mealtime faster aspart compared with IAsp in subjects with baseline BMI >30 kg/m^2 (Table).

Conclusion: Treatment difference between faster aspart and IAsp for glycaemic control in people with T1D was not affected by baseline BMI or baseline HbA_{1c}.

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New Insulin Analogues

ATTD8-0008

COMPARISON OF INSULIN GLARGINE 300 U/ML, INSULIN DEGLUDEC AND INSULIN GLARGINE 100 U/ML, IN BASAL INSULIN THERAPY USING FREESTYLE LIBRE PRO: RANDOMISED TRIPLE CROSSOVER STUDY

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Background and Aims: We investigated which long-acting insulin is the most effective in reducing hypoglycaemia- insulin glargine 300 U/mL (Glargine 300), insulin degludec (Degludec) or insulin glargine 100 U/mL (Glargine100).

Method: We calculated a required sample size of 15 based on the results of clinical trials. Thirty patients with type 2 diabetes were randomly allocated to 3 groups. On admission, fasting plasma glucose (FPG) levels were stabilized at 80 mg/dL level with long-acting insulin, during the study period. Group1: FPG levels were stabilized with Glargine 300; next, patients wore a FreeStyle Libre Pro device and glycaemic variability was evaluated on days 3 and 4; Glargine 300 was then switched to Degludec, and glycaemic variability was evaluated on days 8 and 9; finally, Degludec was switched to Glargine 100 and glycaemic

	a: Glargine 300	b: Degludec	c: Glargine 100	p	p (a vs. b)	p (b vs. c)	p (a vs. c)
0:00 to 6:00 area over the glucose curve (AOC) (<70 mg/dL), mg · min/dL	0 (0-146.3)	1710.0 (495.0-5079.4)	3836.3 (2115.0-5810.6)	<0.0001	0.002	0.006	<0.0001
8:00 to 24:00 AOC (<70 mg/dL), mg · min/dL	0 (0-0)	146.3 (0-635.6)	1091.3 (140.6-2002.5)	<0.0001	0.04	0.0007	<0.0001
24 h AOC (<70 mg/dL), mg · min/dL	0 (0-180.0)	3453.8 (905.6-7621.9)	6120.0 (3538.1-10558.1)	<0.0001	0.0002	0.04	<0.0001
24 h M-value (target glucose level = 100 mg/dl)	5.6 (3.4-9.1)	9.7 (7.3-17.4)	13.5 (9.1-20.0)	<0.0001	0.0002	0.01	<0.0001
0:00 to 6:00 M-value (target glucose level = 90 mg/dl)	0.5 (0.3-0.9)	4.7 (2.0-10.5)	10.0 (4.7-23.4)	<0.0001	0.0002	0.004	<0.0001
Mean amplitude of glycemic excursion (MAGE), mg/dL (all evaluation days)	52.5 (41.8-65.0)	62.2 (51.6-72.6)	67.2 (54.8-77.3)	<0.0001	0.004	0.004	<0.0001
Mean of daily difference (MODD), mg/dL (all evaluation days)	19.5 (15.7-24.8)	23.2 (20.6-29.0)	29.2 (23.3-40.7)	<0.0001	0.0006	0.002	<0.0001
Average daily risk range (ADRR) (all evaluation days)	9.5 (6.3-17.3)	22.1 (15.3-34.3)	36.4 (26.3-36.4)	<0.0001	0.001	0.005	<0.0001
24 h mean glucose level, mg/dL	113.2 (108.5-127.3)	113.3 (102.2-131.7)	109.6 (100.3-123.3)	0.65	0.66	0.81	0.97
0:00 to 6:00 mean glucose level, mg/dL	81.8 (74.2-87.8)	74.0 (67.2-85.6)	72.7 (63.5-83.9)	0.08	0.2	0.97	0.12
24 h standard deviation (SD), mg/dL	38.0 (30.5-47.4)	45.5 (35.9-52.4)	49.7 (37.6-58.8)	<0.0001	0.004	0.004	<0.0001
0:00 to 6:00 SD, mg/dL	6.3 (4.6-9.3)	9.1 (7.7-12.0)	13.4 (10.6-16.8)	<0.0001	0.0009	0.0009	<0.0001
24 h AUC (≥0 mg/dL), mg · min/dL	162986.3 (156288.7-183318.7)	163087.5 (147202.5-189607.5)	157758.8 (144493.1-177601.9)	0.65	0.66	0.81	0.97
Basal insulin dose (evaluation duration), U/day	16.5 (11.8-28.0)	16.0 (13.3-28.3)	17.5 (13.3-32.3)	0.18	0.53	0.78	0.19
Mean absolute relative difference (MARD), %	8.7	8.9	9.0				

variability was evaluated on days 13 and 14. Group2: Long-acting insulin was administered in the order of Degludec, Glargine 100, Glargine 300, following the same regimen. Group3: Long-acting insulin was administered in the order of Glargine 100, Glargine 300, Degludec, following the same regimen. Long-acting insulin was administered at 08:00. Data collected on the second evaluation day were analysed. Testmeals were given.

Results: The area over the glucose curve (<70 mg/dL) was significantly lower in patients on Glargine 300, Degludec, Glargine 100, in that order (Friedman's test). The start time of hypoglycaemia occurrences was significantly earlier in patients on Glargine 100 than in those on Degludec (Glargine 100: median, 555.0 [minutes] (95% confidence interval, 502.5-607.5) vs. Degludec: 975.0 (843.8–1106.2); p = 0.02: log-rank test).

Conclusion: Glargine 300 may be the best long-acting insulin to reduce hypoglycaemia.

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New Insulin Analogues

ATTD8-0427

REAL-WORLD EVIDENCE DEMONSTRATES COMPARABLE CLINICAL OUTCOMES OF SWITCHING FROM INSULIN GLARGINE 100 U/ML TO INSULIN GLARGINE 300 U/ML VS INSULIN DEGLUDEC IN T2D PATIENTS

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Background and Aims: This study compared clinical outcomes of T2D patients switched from using insulin glargine 100U/mL (Gla-100) to insulin glargine 300U/mL (Gla-300) or insulin degludec (IDeg) in a real-world clinical setting.

Method: This retrospective, observational study used electronic medical records (EMRs) from Predictive Health Intelligence Environment database. Inclusion criteria: adults with T2D; switched to Gla-300 or IDeg from using Gla-100 during 6 months before the switch (index date: first switch between 03/01/2015–12/31/2016); active in EMR for ≥12 months prior to index date and followed for 6 months after; A1C measures during 6 months before switching (Gla-300, n = 2,893; IDeg, n = 853). Gla-300 and IDeg switchers were propensity score matched 1:1 on baseline characteristics. Endpoints were A1C change, hypoglycemia (ICD-9/ICD-10 and/or plasma-glucose level ≤70 mg/dL) incidence and event rate (all hypoglycemia and hypoglycemia associated with hospitalization/emergency-department service [hospitalization/ED-related]) during follow-up. A1C change was analyzed in a patient subgroup with A1C measures at both baseline and 3-6 months' follow-up in the matched cohorts.

Results: During follow-up, switching to Gla-300 (n = 810) and IDeg (n = 810) showed comparable hypoglycemia incidence (all: 11.9% vs 12.7%, respectively, $P = 0.45$; hospitalization/ED-related: 4.4% vs 3.8%, respectively, $P = 0.80$). Adjusted for baseline hypoglycemia, Gla-300 and IDeg showed similar hypoglycemia event rate during follow-up (all: $P = 0.88$; hospitalization/ED-related: $P = 0.82$). A1C decreased significantly from 8.95% to 8.46% for Gla-300 (n = 364) and from 8.98% to 8.49% for IDeg (n = 370) (both cohorts: $P < 0.01$) during follow-up (comparable reduction in both groups, $P = 0.97$).

Conclusion: In a real-world setting, T2D patients on Gla-100 switching to Gla-300 or IDeg showed comparable glycemic control, hypoglycemia incidence and hypoglycemia event rate.

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0333

NOVEL INSULIN INFUSION CATHETER PROVIDES FULL FUNCTIONALITY IN CLOGGED STATE – AN IMAGING STUDY

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Background and Aims: Insulin therapy via infusion pumps and catheters is a standard therapy for many diabetes patients. Therapy success strongly depends on the direct administration of the correct insulin dose to the tissue at a specified time. Many patients have reported kinked and subsequently clogged infusion catheters, e.g. when the tip of the catheter hits the abdominal muscle tissue, which often happens in younger patients and children. A clogged insulin infusion catheter can influence or even prevent the administration of the correct insulin dose, which can lead to life threatening situations.

Method: In this study, the functionality of a novel insulin infusion catheter was compared with a standard insulin infusion catheter (Inset II®, Unomediacal a/s). The performance of the novel insulin infusion catheter was tested in two different states (open and clogged). The injected insulin volume and the surface-to-volume ratio of each catheter were assessed by a μCT screening (Inveon Multimodality System, Siemens) after infusion of an insulin/contrast agent mixture into freshly explanted human subcutaneous adipose tissue.

Results: Results showed full functionality of the novel insulin catheter, independent of whether the catheter was open or clogged. Compared to an open standard catheter, no differences in terms of infused volume and surface-to-volume ration were observed. Therefore, this new insulin catheter would continue providing adequate insulin delivery even in a kink/tip occlusion situation, thereby significantly reducing patient discomfort and dissatisfaction.

Conclusion: We conclude that the novel infusion catheter can provide a valuable contribution to patient well-being and safety.

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0332

EASE OF USE AND FUNCTIONALITY OF THE NEWLY DEVELOPED ALLSTAR PRO® VERSUS THE CLIKSTAR® INSULIN PEN: EXPERIENCE OF PEOPLE WITH DIABETES AND DIABETES NURSE EDUCATORS

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Background and Aims: Reusable insulin pens provide an affordable, convenient insulin delivery mechanism that may lessen the burden of diabetes self-management and improve treatment adherence compared with syringes. Through interviews with people with diabetes and diabetes nurse educators (DNEs), we examined the ease of use and usability of the newly developed AllSTAR PRO® pen and the current ClikSTAR® pen.

Figure: Important features of an injectable device according to diabetes nurse educators (n=90) and people with diabetes (n=90)

Diabetes nurse educators	People with diabetes	Combined ranking
Easy to read dose display	Easy to dial right dose	Easy to dial right dose
Easy to dial right dose	Easy to read dose display	Easy to read dose display
Easy to change insulin cartridge	Easy to change insulin cartridge	Easy to press button*
Easy to press button	High quality	Easy to change insulin cartridge
Easy to learn/teach others to use	Right size to hold	Easy to learn/teach others to use
Right size to hold	Easy to learn/teach others to use	High quality
High quality	Robust	Right size to hold
Robust	Discreet	Robust
Appealing design overall	Right weight to hold	Comfortable to use in public†
Right weight to hold	Comfortable to use in public	Right weight to hold
Discreet	Appealing design overall	Discreet
		Appealing design overall

Most to least important feature of an injectable device‡

*Not asked to people with diabetes. †Not asked to diabetes nurse educators. ‡Features ranked according to the percentage of participants selecting them as 'very important'.

Method: Insulin pen users aged 18–65 years with type 1 or type 2 diabetes (n = 90; prior ClikSTAR® users [n = 45], non-ClikSTAR® users [n = 45]) and DNEs (n = 90) from Canada, Germany and the UK participated in a 30-minute face-to-face interview, including practical assessment of both reusable insulin pens.

Results: People with diabetes and DNEs who were shown various pen injector attributes generally found functional pen features to be of greatest importance (Figure). Very few people from either group experienced any issues when using AllSTAR PRO® or ClikSTAR®, and ≥90% correctly completed each step in the injection process for both insulin pens. Significantly more participants agreed that it was 'easy to dial the correct dose' with AllSTAR PRO® (88%) compared with ClikSTAR® (76%); this was considered the most important device feature overall. Significantly more participants agreed that AllSTAR PRO® was 'easy to learn/teach others to use' (93% vs 86%), 'comfortable to use in public' (72% vs 43%), 'discreet' (72% vs 32%) and 'easy to use overall' (92% vs 79%) compared with ClikSTAR®.

Conclusion: AllSTAR PRO® was significantly easier to use overall than ClikSTAR®, although very few problems were experienced by people using either insulin pen.

Market research sponsored by Sanofi

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0102

PHARMACOKINETIC AND PHARMACODYNAMIC PROPERTIES OF AN ULTRA-CONCENTRATED, RAPID-ACTING INSULIN ASPART FORMULATION

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Background and Aims: The development of ultra-high concentration insulin is important for the miniaturisation of next-generation wearable devices. However, increasing concentration of insulin leads to elongation of the time-action profile *in vivo* and also to a higher rate of aggregation and elevated viscosity. Novel absorption and stabilizing formulation technology has been developed to overcome these issues by utilizing excipients that promote faster diffusion from the injection site whilst improving stability and lowering viscosity, even at concentrations up to 1000 units.

Method: The effect of this new formulation was investigated in diabetic mini swine, a randomized full cross-over experiment was performed. Ten male hyperglycaemic animals received a dose of 0.2 U/Kg insulin aspart via subcutaneous injection. At standardized intervals over a 480 min period post-injection, blood glucose was measured and samples taken for assessment of insulin concentration.

Results: Pharmacokinetic (PK) assessment confirmed that the new U1000 aspart formulation significantly improves diffusion of insulin from the subcutaneous depot (T½ max of 7 mins, comparable to rapid-acting insulin analogues such as NovoRapid™ and Humalog™) and demonstrates a significantly faster PK profile than the control insulin aspart formulation at 1000 U/ml (T½max of 28.7 mins). The new U1000 aspart formulation also showed superior glucose lowering effects when compared to the control insulin formulation at 1000U/ml.

Conclusion: This novel aspart 1000U/ml formulation has the potential to offer a vastly superior mealtime insulin product for people requiring >200 U/day, and is also a critical step towards the advancement of next-generation artificial pancreas systems.

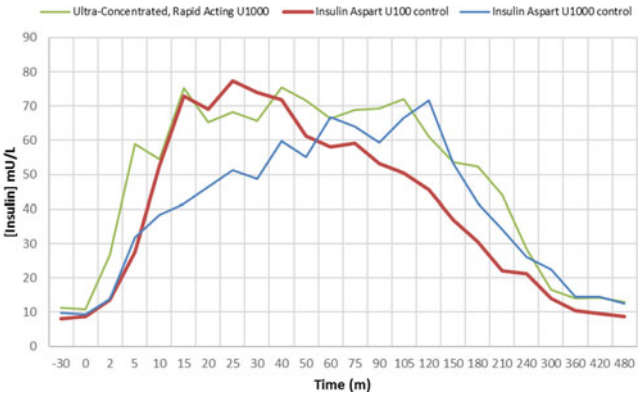

FIG. 1 PK profile of insulin aspart 1000U/ml in diabetic mini swine

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0418

EVALUATION OF A WEEKLY PHYSICIAN-DRIVEN INSULIN TITRATION ALGORITHM FOR A WEARABLE INSULIN DELIVERY DEVICE

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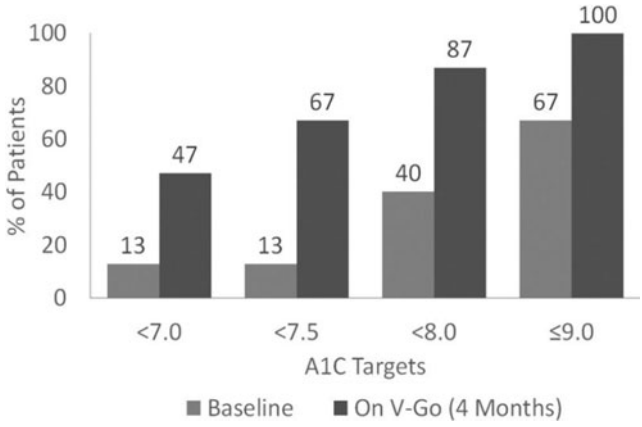
Background and Aims: Therapeutic inertia is prevalent with insulin intensification. To support development of dosing guidance, a weekly physician-driven insulin titration algorithm with V-Go was evaluated to formulate the design of a prospective patient-driven insulin titration study. Improvement in glycemic control with V-Go is well documented yet no data exists



evaluating efficacy and safety outcomes when a titration algorithm is applied. Primary endpoints of this evaluation were achievement of A1C targets (<7.5%) and incidence of hypoglycemia based on blood glucose logs.

Method: Data were obtained for this retrospective proof-of-concept study from electronic medical records. Bolus doses were up-titrated weekly/meal when two hour postprandial averages >170 mg/dl and down-titrated when <100 mg/dl. Basal rates adjusted if needed following bolus dose optimization. Four-point daily glucose profiles used for titration decisions.

Results: Fifteen patients with T2DM (mean age 60 y; A1C 8.7%; weight 116 kg) are evaluated after four months. Thirteen administered insulin (mean TDD 144 U/day) at baseline. After one week, bolus up-titration occurred in 73% of patients (18 to 33 bolus U/day) and active bolus titration continued for two additional weeks. Basal rates increased in five patients and decreased in one patient during the first month. A1C target achieved in 67% of patients. Hypoglycemia incidence decreased from 23% at baseline to 7% by four months despite significant A1C reduction (8.7 to 7.1%; $p < 0.001$). TDD of insulin decreased to 60 U/day; $p = 0.002$.

Conclusion: The adoption of this titration algorithm proved safe and resulted in clinically relevant glycemic improvement. Applying these findings to a patient-driven approach needs further investigation.

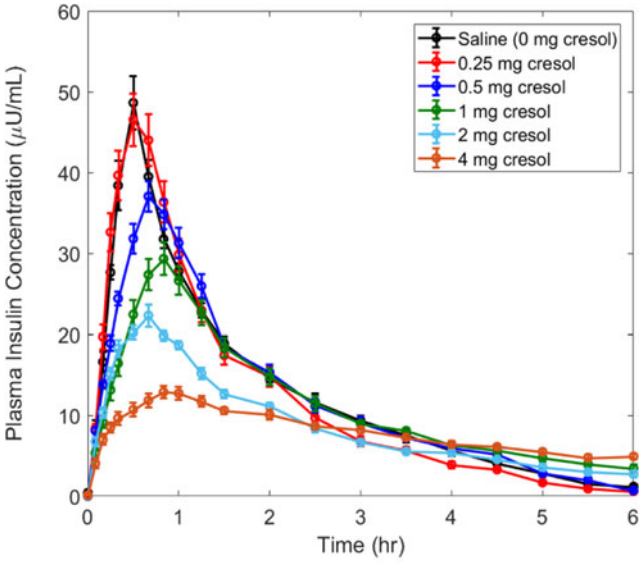


Figure 1: Insulin PK profile following SC insulin injection into sites pre-treated with different cresol doses (n≥5; mean±SEM).

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0107

SUBCUTANEOUS BOLUS ADMINISTRATION OF META-CRESOL DECREASES INSULIN ABSORPTION IN A SWINE MODEL

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Background and Aims: *In vitro* and *in vivo* studies have shown insulin phenolic excipients, meta-cresol and phenol, induce inflammation that could contribute to insulin infusion set wear times of less than three days. However, it is unknown if excipient-induced inflammation contributes to functional changes in insulin pharmacokinetics (PK) and absorption. This study shows that subcutaneous (SC) bolus *m*-cresol delivery decreases insulin absorption in a dose-dependent manner.

Method: Sinclair swine ($n \geq 5$) received SC *m*-cresol bolus injections at clinically relevant doses (0.25, 0.5, 1, 2 and 4 mg in 200 μL PBS; saline as negative control). Twenty-four hours later, a PK study was performed at the treated site via a 4 U injection of U100 insulin lispro (Humalog, Eli Lilly & Co.). Blood samples were taken over six hours, separated and analyzed for Humalog via radioimmunoassay. Treated sites were biopsied following the PK study and assayed for pro-inflammatory cytokines.

Results: Treatments of *m*-cresol ≥0.5 mg reduced insulin absorption, as C_{max}, AUC, and $AUC_{0\rightarrow60}$ were all significantly decreased relative to the saline control ($p < 0.05$). These PK shifts were associated with an increased local presence of pro-inflammatory IL-6 in SC tissue.

Conclusion: These data demonstrate cresol exposure significantly decreases SC insulin absorption in a dose-dependent fashion. A concomitant increase in tissue IL-6 concentration suggests excipient-induced inflammation is associated with altered insulin PK. As shifts in insulin PK and loss of glycemic control are cited as causes of limited infusion set wear time, these findings support continued study of excipient-induced tissue response as a factor affecting infusion set performance.

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0260

THE VIVI-CAP STABILIZES INSULIN IN EXTREME TEMPERATURE CONDITIONS

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Background and Aims: For long-term storage, Insulin is to be kept at 4-8° C (~39°F to 47°F) until use and once opened, is supposed to be stable for up to 30 days at room temperature. Extreme cold or heat lead to insulin degradation in a very short time with loss of its glucose-lowering efficacy. ViVi-Cap is a calorimetry-based portable storage devices, which fit all existing disposable pens It works without external power supply requirements based on space-derived vacuum insulation and additional heat consumption by phase-change material.

Method: Three disposable insulin pens (FlexPen, Insulin aspart) were kept for one week under extreme temperature conditions for 5 days (each day: 8 h at 50 °C and 16 h at 22 °C) either without protection, in a frio device (freshly prepared each da) and in the ViViCap. Samples were taken every day and insulin degradation was determined in accordance with EU pharmacopoia by appropriate HPLC methods for insulin aspart, and high

and low molecular weight degradation molecules. Each experiment was performed in triplicate.

Results: Insulin aspart without protection was shown to have more than 2 % impurities already after one day (Frio: 2 days, ViViCap: 5 days). High molecular weight products occured after two daystrage without protection (Frio: 3 days, ViViCap >5 days, $p < 0.01$ agains the other 2 storage conditions).

Conclusion: ViVi-Cap was superior to the other tested conditions with respect to stabilizing insulin aspart under extreme temperature changes. The device provides an easy to use solution for maintaining insulin efficacy under daily life conditions.

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0042

FASTER ABSORPTION OF FIASP INSULIN ASPART FOLLOWING INTRADERMAL ADMINISTRATION IN SPRAGUE-DAWLEY RATS

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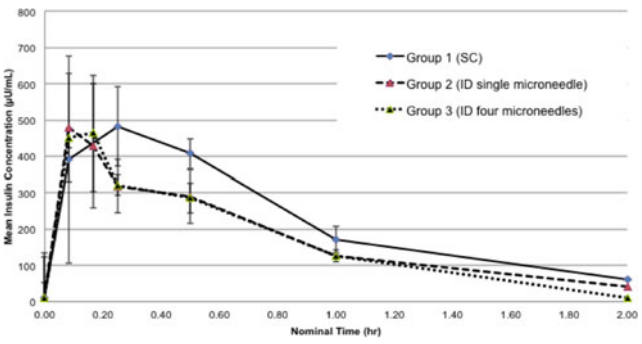
Background and Aims: Despite considerable advances in insulin therapy, there remains an unmet need for a mealtime insulin that can faithfully reproduce the post-prandial insulin profile that occurs in healthy persons. We evaluated the effect of intradermal (ID) vs subcutaneous (SC) administration in rats on the pharmacokinetics of Fiasp® (insulin aspart), a recently introduced faster-acting insulin.

Method: Male Sprague-Dawley rats, aged 6-8 weeks, were randomized to receive 1.0 U/kg of Fiasp by SC injection (Group 1, N = 8) with a 25-gauge 5/8'' needle or to one of two configurations of ID microneedles (700 μm height, 100 μm diameter). Group 2 (N = 8) was injected using a single ID microneedle and Group 3 (N = 8) was injected using a configuration of 4 equidistant microneedles. Plasma insulin and blood glucose (BG) were monitored using serial sampling (N = 4/timepoint) in a composite PK design.

Results: Plasma insulin Cmax values were comparable for all groups with mean values of 482, 480 and 464 μU/mL for Groups 1, 2 and 3, respectively. Tmax values of insulin were observed earlier with ID vs SC with Tmax at 15, 5 and 10 min for Groups 1, 2 and 3, respectively. Comparable decreases in BG were observed in all groups.



Conclusion: Intradermal administration of ultra-fast rapid-acting Fiasp® insulin in rats results in even faster absorption than SC dosing with comparable maximal plasma insulin concentrations for both routes. These data support further research to evaluate the potential of intradermal administration of mealtime insulins for improved post-prandial glucose control.

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New Insulin Delivery Systems: Inhaled, Transderma, Implanted Devices

ATTD8-0044

FLUOROSCOPIC ASSESSMENT OF PERCUTANEOUS CANNULA PENETRATION DEPTH

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Background and Aims: Self-administered injection is common practice for diabetes therapy and continues to increase in prevalence, with subcutaneous (SC) tissue the preferred administration site. Devices should enable consistent SC delivery regardless of variation in tissue morphology, injection location, and delivery technique. Therefore a preclinical fluoroscopic imaging method was developed to accurately visualize and measure cannula penetration depth (CPD) post injection.

Method: Currently no in vitro model exists to simulate the complexities of an intact in vivo integumentary system; animal models provide the best surrogate for evaluating injection dynamics/biomechanics. The skin and SC structures on the flank of 30–40 kg Yorkshire swine provide an effective facsimile of human abdominal tissue. 20μl injections (350 mg/ml Iohexol) using 5 different 6mm patient end length (PEL) syringes (n = 50/group) were made on swine flanks and imaged using fluoroscopy. The radiopaque injectate effectively indicates cannula tip location allowing CPD measurements.

Results: Mean CPD±SEM varied slightly across syringe types: A-7.32 ± 0.15mm, B–8.38 ± 0.13mm, C–7.24 ± 0.12mm, D–7.21 ± 0.12mm, E–7.45 ± 0.13mm. All syringes demonstrated CPD greater than nominal 6mm cannula PEL ($p < 0.0001$). Mean CPD of device B was statistically greater than any other device ($p < 0.001$); no other statistical differences were observed between devices.

Conclusion: CPD greater than cannula PEL may be due to differences in localized tissue compression created by device design or technique during the injection procedure. Devices with identical PEL produced different CPD, demonstrating that PEL alone may not be a reliable predictor of injection depth. Factors influencing CPD should be further examined to increase injection consistency. Fluoroscopic imaging provides a reliable method for evaluating these effects.

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New Medications for Treatment of Diabetes

ATTD8-0165

PRECLINICAL EFFICACY OF A STABLE AQUEOUS FORMULATION OF HUMAN GLUCAGON WITH BIOCHAPERONE TECHNOLOGY IN PIGS

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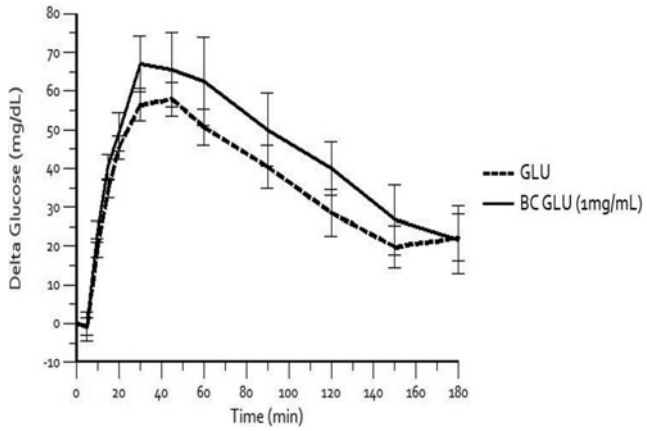

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[3]Adocia, Preclinics, Lyon, France
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Background and Aims: Human glucagon is an emergency drug used to rescue people with diabetes from severe hypoglycemia. Dual hormone artificial pancreas (DHAP) is designed to better mimic normal physiology by automatically infusing both insulin and glucagon as required. However, due to the poor solubility and stability of glucagon in solution, no commercial ready-to-use liquid formulation is available for rescue or for pump use in DHAP.

BioChaperone® Glucagon (BC GLU) is a stable, ready-to-use, neutral pH, aqueous formulation of glucagon based on BioChaperone® (BC) technology. Two formulations are developed for two uses: rescue and dual-hormone artificial pancreas, at 1 and 2 mg/mL.

Method: We investigated the pharmacokinetics and the pharmacodynamics of a single subcutaneous dose (1 μg/kg) of BC GLU (1 mg/mL) and BC GLU (2 mg/mL) against the freshly reconstituted commercial glucagon in 12 octreotide treated pigs.

Results: BC GLU (1 mg/mL) and glucagon displayed a similarly rapid absorption (time to early 50% t_{max}: 5 and 3 min respectively) resulting in similar incremental blood glucose levels, especially during the first 15 min after injection (mean ratio [95%CI] ΔBG15min: 1.16 [0.93; 1.45], ΔBG30min: 1.16 [0.85; 1.57], ΔAUCBG0-15min:1.25 [0.81; 1.92], ΔAUCBG0–30min: 1.14 [0.89; 1.47]). Similar results were obtained for BC GLU at 2 mg/mL.

Conclusion: In conclusion, the preclinical PKPD properties of BC GLU support its clinical development for both severe hypoglycemia rescue and DHAP applications.

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New Medications for Treatment of Diabetes

ATTD8-0012

ASSOCIATION OF SELENOPROTEIN S EXPRESSION AND ITS VARIANTS WITH METABOLIC SYNDROME IN SUBJECTS WITH CARDIOVASCULAR DISEASE

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Background and Aims: Selenoproteins S (SELS or VIMP) may regulate cytokine production, and thus play a key role in the control of the inflammatory response. The present study assesses the expression of two variants of VIMP in serum of cardiovascular subjects to achieve a probable metabolic syndrome (MetS) pathway.

Method: The study sample consisted of 136 Iranian patients with cardiovascular disease (65 MetS-affected and 71 MetS un-affected individuals) in the selengene study. Expression of two variants of VIMP including VIMP I and II were analyzed in all subjects using Real-Time PCR and ELISA.

Results: The level of VIMP was lower in $MetS^+$ compared to the $MetS^-$ subjects ($P < 0.05$). We found no significant differences in quantitative expression of VIMP I and VIMP II in both groups. Whereas VIMP I has reverse correlation with fasting blood sugar (FBS) ($r = -0.45$, $P = 0.009$), we did not find any significant correlation between these variants with waist circumference, systolic and diastolic blood pressure and HDL–cholesterol. However, SELS in protein level has negative correlation with WC ($r = -0.171$, $P = 0.049$) and positive correlation with HDL ($r = 0.176$, $P = 0.046$).

Conclusion: In the present assessment, it is evident that expression of VIMP varies highly among individuals with MetS as well as those without MetS. So regarding the functional role of this protein, it is possible to be deduced lower expression of it leads to higher secretion of unfolded protein to the cytosol and outside the cell which cannot play their exact role in different pathways.

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New Medications for Treatment of Diabetes

ATTD8-0300

PARAMETERS OF ANTIOXIDANT DEFENSE SYSTEM IN PATIENTS WITH DIABETES MELLITUS FROM VARIOUS ETHNICITY

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Background and Aims: Diabetes Mellitus (DM) are found worldwide and is regarded as one of the main risks to human health. Some studies are reported low DM morbidity rate among the aboriginal people in Arctic and Siberian peoples resulted from the presence of the protective alleles for this nosology. Oxidative stress induced by hyperglycemia and subsequent cellular damage is thought to be one of the major pathophysiological factors causing late complications in diabetes. The aim of this study was to compare antioxidant status in Mongoloids and Caucasians with DM.

Method: We examined 27 patients with type 1 diabetes mellitus (T1DM) (age range, 18 to 60 years) and 16 patients with type 2 diabetes mellitus (T2DM) (age range, 38 to 58 years) of Caucasians; 38 patients with T1DM and 17 patients with T2DM of analogous age of Mongoloids. There were no significant differences in diet habits and physical activity between the patients of both ethnic groups. Spectrophotometric and fluorometric methods were used.

Results: In patients with T1DM in Caucasians there has been marked significant decrease of superoxide dismutase activity for 15% and in patients of Mongoloids with T1DM – total antioxidant activity increased for 63% compare to controls. In patients

with T2DM of Mongoloids the concentration of reduced glutathione was elevated for 51% compare to control.

Conclusion: Thus, antioxidant activity system state in patients with diabetes mellitus of Caucasians and Mongoloids is differ.

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New Medications for Treatment of Diabetes

ATTD8-0301

LIPID PEROXIDATION PROCESSES IN PREPUBERTAL GIRLS WITH TYPE 1 DIABETES MELLITUS

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Background and Aims: Type 1 diabetes mellitus (T1DM) is characterized by varying levels of morbidity in different populations and its prevalence increase in the majority of developed countries during the last 30 years. This pathology may affect the tempo and course of pubertal growth and development, onset of menarche and the violation of menstrual function in girls**.** The aim of this research was to determine the state of lipid peroxidation (LPO) and antioxidant defense system in girls with T1DM of prepubertal age.

Method: This study enrolled 15 girls of 7–11 years old with T1DM and 15 healthy girls (control) matched by age. Spectrophotometric and fluorometric methods were applied. The state of LPO and antioxidant system was assessed also using the coefficient of oxidative stress that represented the ratio of LPO products to antioxidant defense system activity.

Results: The results of our study showed the increase of conjugated dienes (CDs) by 63% ($p < 0.05$) and thiobarbituric acid reactants (TBARs) by 42% ($p < 0.05$) concentrations in girls with T1DM in comparison to the control group. We demonstrated that GSH concentration in erythrocytes was significantly lower (by 21%) in the girls with T1DM compare to this parameter in control group ($p < 0.05$). The increased coefficient of oxidative stress (1.16) also was observed in this group in comparison to the control group (1.00).

Conclusion: In girls with T1DM of prepubertal period there is imbalance of state of lipid peroxidation process–antioxidant defense.

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New Medications for Treatment of Diabetes

ATTD8-0303

THE USE OF INTEGRAL INDICATOR OF OXIDATIVE STRESS IN WOMEN WITH DIABETES MELLITUS

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Background and Aims: Integral criteria are extensively used in clinical practice for detection of pathological states and diagnosis of a variety of disturbances caused by environmental factors. The aim of this study was to determine of oxidative stress index (OSI) in patients with type 1 diabetes mellitus (T1DM).

Method: The inclusion criteria for women with T1DM (main group, $N = 15$; mean age 35.0 ± 3.4 years, T1DM history 12.8 ± 2.0 years) were verified diagnosis of T1DM and insulin therapy. The control group consisted of 20 women (mean age 28.2 ± 1.5 years). Spectrophotometric and fluorometric methods were used.

Results: The content of lipid peroxidation (LPO) substrates in women with T1DM was elevated by 51% ($p < 0.05$) in comparison with the control group. The content of primary LPO products, conjugated dienes, was increased by 73% ($p < 0.05$). DM1 patients were also characterized by elevated content of the intermediate products of LPO: ketodienes and conjugated trienes (by 103%, $p < 0.05$) and TBA-reactive substances (by 48%, $p < 0.05$ in comparison with the control). Studying the AOD system revealed a decrease in superoxidismutase activity (by 16%, $p < 0.05$) and increase in oxidized glutathione content (by 15%, $p < 0.05$) in patients with T1DM in comparison with the control group. OSI in patients with T1DM was 8.5 in comparison with the control (1.00), respectively.

Conclusion: The integral criterion of OSI can be used for individual evaluation of the imbalance in the LPO–AOD system. Moreover, OSI holds much promise for personal evaluation of the effectiveness and correction of antioxidant therapy in this pathology.

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New Medications for Treatment of Diabetes

ATTD8-0078

FORXIGA (DAPAGLIFLOZIN) INDUCED DIABETIC KETOACIDOSIS (DKA) IS NOT UNCOMMON

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Background and Aims: SGLT2 inhibitors is a new class of oral anti-diabetic medications which work in insulin independent manner.It is licensed for use in type 2 diabetes patients but may be used in type 1 diabetes patients. We present a case report of patient on forxiga and presented with diabetic ketoacidosis for the first time

Method: Case report

A 46 years old lady known type 2 diabetes presented with intractable vomiting following 2 weeks travel to South America. She was known type 2 diabetes for more than 20 years and was on novorapid, levemir and metformin. Her past medical history included hypertension and dyslipidaemia. Two months prior to admission, she was started on forxiga 10mg once daily.

Results: She was found to be dehydrated (urea 15.6 mmol/L, creatinine 169 mmol/L, potassium 4.5 mmol/L) and acidotic (pH 6.96 on arterial blood gas, lactate 4.85mmol/L, bicarbonate 6.8 mmo/L, BE −25 mmol/L with positive urine dipstick for ketones and laboratory glucose of 45 mmol/l. Chest x-ray was normal.

She was treated with insulin infusion and intravenous fluids with significant improvement. Both metformin and forxiga were stopped and she was discharged home on insulin levemir 28 units twice a day.

Conclusion: SGLT2 inhibitors inhibit glucose reabsorption via SGLT2 at proximal renal tubule resulting in glycosuria. Recurrent genital infections and urinary tract infections are known common side effects.

SGLT2 inhibitors induced DKA is not uncommon. The risk is higher in patients with inter-current illness, therefore patients should be advised to check ketones levels when they are unwell even if their capillary glucose levels are within normal range.

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New Medications for Treatment of Diabetes

ATTD8-0335

SUMMATIVE HUMAN FACTORS STUDY OF A GLUCAGON AUTO-INJECTOR IN A SIMULATED SEVERE HYPOGLYCEMIA RESCUE SITUATION

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Background and Aims: Currently approved glucagon emergency kits (GEKs) for severe hypoglycemia (SH) rescue are based on lyophilized formulations that require manual reconstitution with a vial and syringe at time of use, thus are difficult to administer. This study was designed to validate whether an investigational ready-to-use glucagon autoinjector (GAI) and associated instructions for use (IFU) could be correctly, safely, and effectively used.

Method: This study was conducted with 75 volunteers: 15 first responders, 15 experienced adult caregivers of diabetic patients, and 30 naïve adult and 15 naïve adolescent caregivers. Neither the experienced adults (15) nor half of the naïve adult caregivers (15) received formal training. During the first session participants were either trained on the device and procedure, or given time to read the IFU and familiarize themselves with the device. Participants returned a week later to perform an unaided rescue attempt simulating a SH emergency.

Results: All but one participant (74/75, 98.7%), an untrained, naïve adult caregiver, successfully administered the rescue injection. All participants 1) successfully removed the device from the pouch, 2) removed the cap from the device, 3) exposed an appropriate injection site on the manikin, and 4) activated the injection by pressing the device against the skin. All participants (75/75, 100%) stated that had no difficulty with any aspect of the process and no concerns about their ability to safely and effectively use the GAI for SH rescue.

Conclusion: The current study validated that GAI and associated instructional materials can be correctly, safely, and effectively used by the intended user populations.

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New Medications for Treatment of Diabetes

ATTD8-0135

REAL WORLD EXPERIENCE WITH SGLT-2 INHIBITORS: AN AUDIT FROM A TERTIARY CARE HOSPITAL IN SINGAPORE

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Background and Aims: SGLT2 inhibitors (SGLT2i) are the newest class of oral glucose-lowering drugs available with effects on weight and blood pressure (BP) in addition to HbA1c. Urogenital infections (UI) and ketosis are concerns. An audit to assess the real-world therapeutic and adverse effects of SGLT2i use was done.

Method: Electronic health records of patients on SGLT2i (dapagliflozin, canagliflozin, empagliflozin) were retrieved. Demographic data, weight, BMI, systolic and diastolic BP, episodes of DKA and UI were collected for 6 months(m) prior to and 12m after prescription. Changes in HbA1c, weight, BMI, SBP and DBP were measured as the difference between the average/last pre-prescription measure and the average/last post-prescription measure. Episodes of ketosis (urine or blood), DKA and UI were compared.

Results: N = 1201 (Dapagliflozin-745(62%), Canagliflozin-371 (30.9%), Empagliflozin-85 (7.1%)) were included. 57.9% were men. Among those with a diabetes subtype diagnosis available (n = 814), 805 (98.9%) were type 2 diabetes, 2 (0.2%) were type 1 diabetes, 2 (0.2%) were LADA, 1 (0.1%) post-pancreatectomy diabetes and 4(0.5%) others. SGLT2i use was associated with a significant decrease in HbA1c (1.2 ± 1.3%), weight (2.3 ± 2.5 kg), SBP (5.0 ± 14.5 mmHg) and DBP (2.8 ± 7.2 mmHg), all $p < 0.001$. Those who developed ketosis (n = 12) while on SGLT2i had a significantly lower age (47 ± 10y vs 55 ± 9y, $p < 0.05$) and higher HbA1c (10 ± 1.6% vs 8.9 ± 1.3%, $p < 0.05$). 5/1201 (0.4%) developed DKA while on SGLT2i; all but one had additional precipitating factor(s). 13/1201 (1.1%) had UI while on SGLT2i.

Conclusion: The real-world therapeutic and adverse effect of SGLT2i use were similar to the data from clinical trials. Patients who developed DKA while on SGLT2i had additional precipitating factors.

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New Medications for Treatment of Diabetes

ATTD8-0093

EFFECT OF EXENATIDE-2MG WEEKLY IN EDERLY PATIENTS WITH TYPE 2 DIABETES

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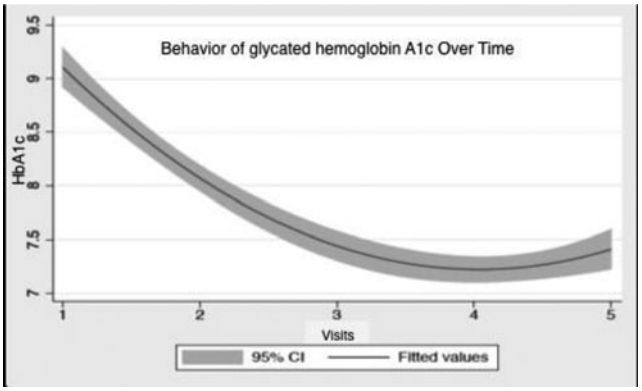
Background and Aims: Type-2 Diabetes (T2D) represents a therapeutic challenge in patients over 60 years old. Glucagon-like Peptide-1 receptor agonists (GLP-1) have a favorable effect by modifying cardiovascular risk factors, and exenatide improves adherence due to its weekly dose.

Method: Descriptive, retrospective cohort study, conducted between June-2013 and June-2016, one year follow-up, 4 visits, in a specialized center, in the city of Cali, Colombia. We included 39 outpatients with poorly controlled T2D, who were added to the standart treatment, exenatide at a subcutaneous dose of 2 mg every week. Repeated measurements were made over time of glycated hemoglobin (A1C), baseline glycemia, weight, body mass index (BMI) and blood pressure (BP). Paired T-Test were compared, and performed generalized estimation equations and quadratic predictions with confidence intervals.

Results: The mean age was 71 years old. The onset of T2D was 7.6 years old. Standard therapy in combination with exenatide showed an average decrease of: A1C of 1.7% (8.9% of admission value and 7.2% at 12 months; 95% CI, 1.45–1.94,



p < 0.0001); baseline glycemia of 106 milligrams per deciliter (95% CI, 87-125, p < 0.00001); Systolic-BP of 15.6 mmHg (95% CI 8.6–22.6, p < 0.0002) and Diastolic-BP of 5.8 mmHg (95% CI, 2.8–8.7, p < 0.0002). The largest decrease in A1C average occurred between first and second visit and no serious adverse events were observed.

Conclusion: Exenatide is a favorable therapeutic option in diabetic patients over 60 years old, with a beneficial effect on blood pressure and no serious adverse events. It Weekly dose ensures adequate adherence to the treatment.

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New Medications for Treatment of Diabetes

ATTD8-0221

USE OF LIRAGLUTIDE IN PATIENTS WITH TYPE 2 DIABETES; 12 MONTHS OF MONITORING. A REAL LIFE STUDY

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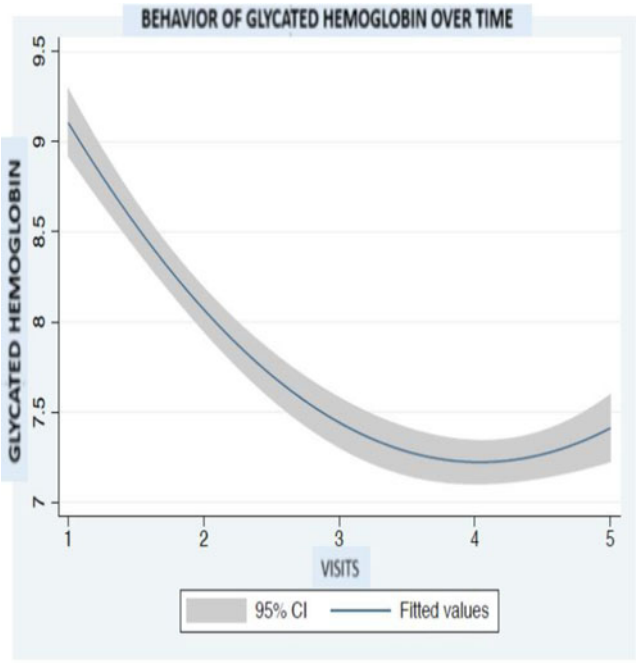
Background and Aims: Prevalence of Type-2 Diabetes (T2D) has increased over time. However, new molecules stablish several treatment options. Liraglutide, a Glucagon-like Peptide-1 receptor agonist (GLP-1) has shown to be effective in decrease glycated hemoglobin (A1c) levels and weight in diabetic patients.

Method: Descriptive, retrospective cohort study, conducted between January-2013 and June-2016, one-year follow-up, 5 visits in a specialized center, in the city of Cali-Colombia. We included 85 outpatients for Liraglutide at a subcutaneous dose of 1.8 miligrams (mg) daily, in adition to standard treatment. We made a comparison between the values variables (glycated hemoglobin (A1c), glycemia, weight, body mass index (BMI) and blood pressure (BP)) at admission and the fifth visit (12 months).Paired T-Test were compared, and performed generalized estimation equations and quadratic predictions with confidence intervals.

Results: The mean age was 59 years old. The onset time of T2D was 6.4 years old. Treatment with Liraglutide showed a decrease in: A1c of 1.8% (95%CI, 1.52–2.04; P < 0.0001); basal glycemia of 73 mg/dL (95% CI, 60.29–84.88; P < 0.0001); 5.1 kg of body weight (95% CI, 4.66–5.53; P < 0.0001);1.6 points BMI (95% CI, 1.44–1.71; P < 0.0001), and systolic blood pressure of 6.7 mmHg (95% CI, 0.90–12.45; P = 0.024). The main adverse events were nausea (27%), abdominal pain (18%) and hypoglycemia (14%). The largest decrease of A1c ocurred between the first and second visits (3 months), and stabilize over time.



Conclusion: Treatment with a dialy dose of Liraglutide-1.8 mg, in combination with standard therapy, showed a decrease in glycated hemoglobin levels and metabolic control in T2D patients.

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New Medications for Treatment of Diabetes

ATTD8-0115

SIMPLIFYING COMPLEX INSULIN REGIMENS WITH PRESERVING GOOD GLYCEMIC CONTROL IN TYPE 2 DIABETES

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Background and Aims: Type 2 diabetic patients presenting with severe hyperglycemia are often put on multiple daily insulin injections (MDI). If glucose toxicity resolves, the regimen may potentially be simplified, but there are no guidelines regarding this and a lot of patients are left on MDI. We aimed to examine the safety and efficacy of switching from MDI to once daily IDegLira, a fixed-ratio combination of insulin degludec and liraglutide, in relatively well controlled (HbA_{1c}<7.5%) subjects with type 2 diabetes using low total daily insulin dose (TDD).

Method: 30 adults with type 2 diabetes (mean±SD: age 62.9 ± 7.8 years, HbA_{1c} 6.34 ± 0.71%, BMI 32.90 ± 7.35 kg/m^2, bodyweight 92.57 + 18.9 kg, TDD 40 ± 10.7 units, duration of diabetes 10.8 ± 6.5 years) treated with MDI+metformin were enrolled in our study. Previous insulins were stopped and once daily IDegLira was started. IDegLira was titrated every 3 days with 2 dose steps (each dose step contains 1 unit of insulin degludec and 0.036mg of liraglutide) by the patients to achieve a self-measured pre-breakfast plasma glucose concentration of

<6 mmol/L. Metformin was continued and titrated up to the maximal tolerated dose.

Results: After 94.4 days of average follow-up good glycemic control was maintained, while BMI and bodyweight decreased significantly. Mean HbA_{1c} changed by −0.12% to 6.22 + 0.67% (p = 0.067), bodyweight changed by −4.38 kg to 88.19 + 18 kg (p = 0.0002) and BMI changed to 32.01 + 7.02 kg/m^2 (p = 0.0001). IDegLira+metformin combination therapy was safe and generally well tolerated.

Conclusion: In everyday clinical practice switching from low dose MDI to IDegLira in patients with well-controlled type 2 diabetes is safe, may induce weight loss and results in similar glycemic control.

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New Medications for Treatment of Diabetes

ATTD8-0242

ARACHIDONIC ACID RICH ARASCO OIL PREVENTS DIABETES MELLITUS

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Background and Aims: Previously, we showed that arachidonic acid (AA) prevents both alloxan and streptozotocin-induced type 1 and type 2 diabetes mellitus in Wistar rats. We investigated the effect of oral ARASCO oil that contains 40% AA in high-fat diet induced type 2 diabetes mellitus in Wistar rats.

Method: High fat diet induced type 2 diabetes mellitus model was sued for this study. ARASCO oil was given at the rate of 0.1 ml orally daily for the first 1 week and later once in a week till the end of the study. Plasma glucose, insulin, body weight and food intake were recorded. To Understand the mechanisms of action, plasma cytokines, expression of NF-kB, IkB and PDX in pancreas and adipose tissue lipocalin-1 expression were measured. PLasma lipoxin A4 levels were also measured.

Results: Oral ARASCO oil prevented development of type 2 diabetes mellitus. Plasma pro-inflammatory cytokines and expression of NF-kB and IkB in pancreas and adipose tissue were decreased. Adipose tissue lipocalin-2 expression was decreased and pancreatic tissue PDX expression was increased.

Conclusion: The results of the present study suggest that ARASCO, a rich source of AA, can effectively prevent HFD-induced type 2 diabetes mellitus in experimental animals by suppressing inflammatory process and by enhancing the expression of pancreatic homeobox protein expression that is needed for beta cell survival. Plasma lipoxin A4 levels were also enhanced in ARSCO fed animals. Lipoxin A4 is a potent anti-inflammatory metabolite of AA. ARASCO may be exploited as a potential diabetes preventing drug.

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New Technologies for Treating Obesity and Preventing Related Diabetes

ATTD8-0065

INTENSIFIED TELEMATIC TREATMENT FOR OBESITY - DROP OUT RATES AND PREDICTORS AT 6 MONTHS OF PREDIRCAM2 WEB INTERVENTION

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Table 1. Odds ratio for predictors of drop out at 6 months of the PREDIRCAM2 randomized trial

Variable	Whole sample analysis (n = 183)			Subgroup analysis					
				Non-technological internvention group (n= 92)			Technological intervention group (n= 91)		
	OR	95% CI	p value	OR	95% CI	p value	OR	95% CI	p value
Age (years)	0.9577	0.906 - 1.009	> 0.05	0.9190	0.835 - 0.997	= 0.05	0.9612	0.875 - 1.050	> 0.05
History of Obesity (years since diagnosis)	1.0100	0.979 - 1.042	> 0.05	1.0403	0.975 - 1.118	> 0.05	1.0053	0.966 - 1.047	> 0.05
HbA1c at baseline (%)	2.4441	0. 694 - 8.701	> 0.05	7.6712	0.426 - 231.6	> 0.05	1.8303	0.338 - 10.46	> 0.05
BMI baseline kg/m^2	0.3073	0.171 - 0.508	<0.001	0.4053	0.167 - 0.834	< 0.05	0.1855	0.064 - 0.428	< 0.001
BMI at 3 months kg/m^2	3.2093	1.728 - 6.849	<0.001	1.3165	0.351 - 5.081	> 0.05	5.6975	2.328 - 21.36	< 0.01
BMI at 6 months kg/m^2	1.0780	0.675 - 1.589	> 0.05	1.7905	0.686 - 5.332	> 0.05	1.0407	0.502 - 1.711	> 0.05
Dietary prescription at baseline (kcal)	1.0001	0.998 - 1.002	> 0.05	1.0010	0.998 - 1.005	> 0.05	0.9987	0.995 - 1.002	> 0.05
Physical activity prescription at baseline (kcal)	1.0006	0.999 - 1.001	> 0.05	1.0001	0.999 - 1.001	> 0.05	1.0007	0.999 - 1.002	> 0.05
Married (Yes)	0.6734	0.274 - 1.642	> 0.05	0.3749	0.068 - 1.811	> 0.05	0.9293	0.225 - 3.886	> 0.05
Fixed shift schedule (Yes)	0.9779	0.411 - 2.359	> 0.05	1.5370	0.333 - 7.950	> 0.05	0.5072	0.129 - 1.844	> 0.05
Personal history of depression (1)	1.7301	0.341 - 8.527	> 0.05	7.2825	0.226 - 171.1	> 0.05	1.023	0.118 - 9.409	> 0.05
Personal history of osteomuscular lesions (1)	3.3595	1.138 - 10.163	< 0.05	4.2157	0.617 - 30.31	> 0.05	5.0831	1.013 - 32.92	> 0.05
Previous treatments with technology/gadgets (1)	0.8508	0.307 - 2.269	> 0.05	1.003	0.169 - 5.438	> 0.05	0.4925	0.099 - 2.124	> 0.05
Reported anxiety towards food/eating (Yes)	1.2029	0.448 - 3.349	> 0.05	2.3893	0.424 - 18.34	> 0.05	1.1903	0.274 - 5.358	> 0.05

OR: Odds ratio calculated from coefficients of binomial logistic regression

Background and Aims: PREDIRCAM2 is a web-platform for obesity treatment and follow-up. A multicenter randomized-trial evaluates its effectiveness in obesity treatment and cardio-metabolic-risk prevention. Participants were randomized to an intensified-technological-intervention (TI) supported by PREDIRCAM2, or a traditional non-technological face-to-face-intensified-intervention (NTI). Both groups receive one year follow-up, 12 appointments, 4 exclusively telematic in TI group.

Method: Drop-outs were counted from the first week of intervention until 6 months to assess global, diferential rates, and reported reasons. Binomial logistic regression was used to detect potential predictors for the sample as a whole and by subgroups. Analysis was performed using RStudio v1.0.153.

Results: Overall drop-out rate is 24.6% (45/183), diferentials:31.9% (29/91)TI, 17.4%(16/92)NTI. Most frequent drop-out reasons were: finding interventions too time consuming (5/16NTI, 7/29TI), followed by lack of motivation (4/16NTI, 6/29TI), and family issues (2/16NTI, 6/29TI). Four of twenty-nine drop-outs from TI group (14%) reported the reason to be unfriendly technology. Baseline BMI was a negative predictor (OR0.31, p <0.001), while BMI at 3 months (OR3.2, p <0.001) and personal history of osteomuscular lesions (OR 3.36, p <0.05) were positive predictors of drop-out. Subgroup analysis showed BMI at 3 months was only a positive predictor of drop-out for the TI group (OR 5.7, p < 0.01). Previous treatments using technology and having fixed working schedules were negative predictors of drop-out for the TI group (OR0.49, p > 0.05), while neutral(OR1.03, p > 0.05) and positive (OR 1.5, p > 0.05) respectively for NTI group (Table 1).

Conclusion: TI group had more drop-outs. Most frequently reported reasons were not directly related to technology. Adequate selection of participants and friendlier technology could improve TI adherence.

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Glucose Sensors

ATTD8-0013

EVALUATION OF FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM ON GLYCEMIC CONTROL, HEALTH-RELATED QUALITY OF LIFE, AND FEAR OF HYPOGLYCEMIA IN PATIENTS WITH TYPE 1 DIABETES

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Background and Aims: In this study we evaluated the effect of FreeStyle Libre (FL) on glycemic control, hypoglycemia, health-related quality of life (QoL), and the fear of hypoglycemia (FOH) among children and young people with (T1D).

Method: A prospective study was performed on 47 T1DM patients between 13 and 19 years of age. The FL (FreeStyle Libre™; Abbott Diabetes Care) sensors were placed for each participant by a trained diabetes educator. At the end of study, the complete data from the sensors were downloaded to a computer to produce the ambulatory glucose profile in order to identify the number of scans during the study period. At baseline and 3 months, a trained interviewer administered the Questionnaire of Hypoglycemia Fear Survey (HFS-C) and Quality of Life questionnaire (PedsQL 3.0) to each patient.

Results: Compared to baseline, a significant positive improvement found on behavior of FOH ($p=0.012$), QoL ($p=0.005$), A1c ($p=0.002$) and hypoglycemia ($p=0.034$) at the end of the study. Compared to patients treated with insulin pump, there were significant positive improvement were found on HbA1c ($p=0.001$) and in hypoglycemia ($p=0.001$) among the MDI treated patients. Significant improvements were found on behavior (.682), worry (.831), QoL (.177), HbA1c (–.626) and hypoglycemia (–2.60). A positive correlation were found on behavior ($r=0.47$), QoL ($r=0.70$), HbA1c ($r=0.580$), hypoglycemia ($r=0.657$) and number of FL scans.

Conclusion: The frequent use of FL scanning reduced the frequency of hypoglycemia and HbA1c, fear of hypoglycemia and increased the QoL. Compared to self-testing by finger pricks, the FL increased the frequency of self-monitoring.

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Glucose Sensors

ATTD8-0136

GLUCOSE EXCURSION IN TYPE 1 DIABETES AUDIT COMBINING ABBOTT FLASH GLUCOSE MONITORING AND CELLNOVO INSULIN PUMP

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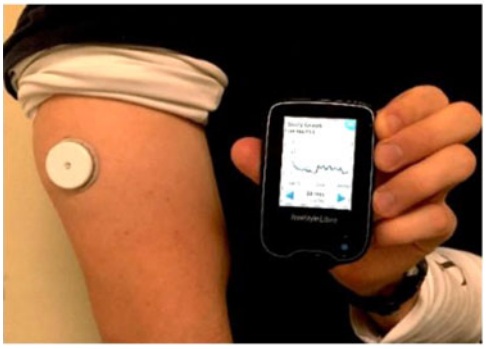
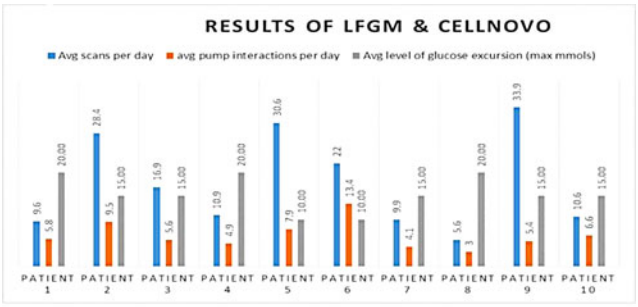
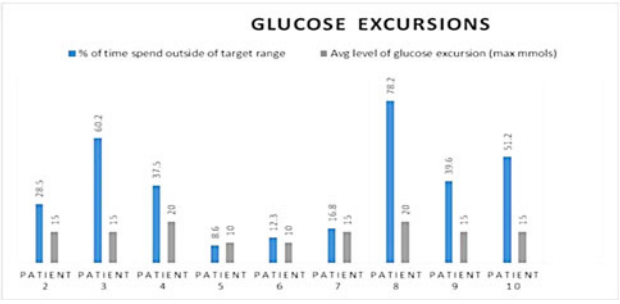
Background and Aims: The author aimed to explore Glucose Excursions (GE) in patients with Type 1 diabetes (T1D) who use an insulin pump. Patients were seen in a nurse led insulin pump clinic and volunteered to participate in this audit.

Method: 10 patients were audited who are using a Cellnovo insulin pump Each were given an Abbott Libre Flash Glucose Monitor (LFGM) which monitors the interstitial glucose levels every 15 mins for 14 days and is able to give a complete glucose profile over a 24 hours period. Once the LFGM data was collected, it was superimposed over the Cellnovo pump data to produce a complete picture of GE and the factors contributing to GE.







Results: Mean 247.5 hrs (total possible 336 hrs) data collected; participants scanned between 1-49 times per day (mean 15.8). All participants experienced GE to varying degrees, 80% had blood glucose levels >10mmols during a glucose excursion. The range of time spent outside target range (4–7mmols) varied between 8.6–78% of the 14 days (mean 40.8%).

Participants interaction with their insulin pump varied between 0–13 times per day (mean 6.6). The most common precipitating factor for GE was a meal bolus up to 1 hour before GE. Data showed that those who scanned and interacted with their LFGM and insulin pump had the lowest frequency and severity of GE

Conclusion: LFGM combined with insulin pump therapy appears to reduced GE in T1D for those who interacted the most with both devices.

While the study results are positive, its small scale has demonstrated a need for further studies.

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NEW MEDICATIONS FOR TREATMENT OF DIABETES

ATTD8-0322

RISK FACTORS THAT INCREASE INSULIN NEED IN PATIENTS WITH GESTATIONAL DIABETES MELLITUS

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Background and Aims: Our aim was to determine the risk factors associated with patients in need for insulin therapy and with gestational diabetes mellitus(GDM).

Method: We enrolled 212 pregnant women who were diagnosed with GDM by 75 gram oral glucose tolerance test (OGTT) at 24–28 week gestational weeks. The demographic features, insulin, and HbA1c levels were evaluated. 35.3% of the patients needed insulin therapy during pregnancy. We compared patients with GDM who needed insulin therapy during pregnancy (insulin group) and women treated with diet alone (diet group).

Results: The patient treated with insulin were older than the patients diet group (32.0 ± 0.4 vs. 37.8 ± 0.5; $p = 0.004$). Prenatal body mass index (BMI) was significantly higher in the insulin group compared to the diet group. (29 ± 0.8 vs. $33.1 \pm 0.6\ kg/m^2$, $p = 0.004$) while the mean fasting plasma glucose (FPG) levels was 101.6 ± 2.5 mg/dL in insulin group, it was 92.9 ± 1.0 mg/dL ($p < 0.001$). While there was no difference in OGTT 1 hour-plasma glucose levels between the two groups ($p = 0.065$), 2-hour plasma glucose levels were 160 ± 6.5mg/dL in the insulin group and 143.3 ± 4.1 mg/dL in the diet group ($p = 0.027$). HbA1c level was significantly higher in the insulin group compared to the diet group (5 ± 0.2 vs. 5.3 ± 0.2; $p = 0.001$). There was no difference in fasting insulin levels and HOMA-IR between the two groups ($p = 0.889$, $p = 0.074$).

Conclusion: Age family history of diabetes, prenatal BMI, FPG, and HbA1c were found to be risk factors associated with insulin need in patients with GDM.

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334 ADVANCED MEDICAL TECHNOLOGIES TO BE USED IN HOSPITALS
ATTD8-0313
NOVEL AND FUTURE THERAPIES FOR TYPE 1 DIABETES MELLITUS
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335 ADVANCED MEDICAL TECHNOLOGIES TO BE USED IN HOSPITALS
ATTD8-0375
ROLE OF PHOTOBIOMODULATION AND PULSED ELECTRO MAGNETIC FIELD EXPOSURE IN HEALING OF A CHRONIC DIABETIC HEEL ULCER
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336 ADVANCED MEDICAL TECHNOLOGIES TO BE USED IN HOSPITALS
ATTD8-0259
NANO-IMMUNO-ASSAY (NIA) - A CANTILEVER-BASED NANOSENSOR TECHNOLOGY FOR POINT-OF-CARE MEASUREMENT OF PROTEINS IN BIOLOGICAL SAMPLES
A. Pfützner[1], K. Kloppstech[2], A. Gal[3], E. Berry[3], A.H. Pfützner[4], A. Kaya[5]

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337 ARTIFICIAL PANCREAS
ATTD8-0349
THE ROLE OF THE HUMAN KIDNEYS IN GLUCOSE HOMEOSTASIS: A PHENOMENOLOGICAL BASED SEMIPHYSICAL MODEL
C. Builes-Montaño[1,2], L. Lema-Perez[3], A. Ramirez-Rincón[4,5], J. Garcia-Tirado[6], H. Alvarez[3]

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338 ARTIFICIAL PANCREAS
ATTD8-0061
PANCREATIC DIFFERENTIATION OF INDUCED PLURIPOTENT STEM CELLS IN ACTIVIN A-GRAFTED GELATIN-POLY(LACTIDE-CO-GLYCOLIDE) NANOPARTICLE SCAFFOLDS WITH INDUCTION OF LY294002 AND RETINOIC ACID
Y.C. Kuo[1], Y.C. Liu[2], R. Rajesh[2]

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339 BLOOD GLUCOSE MONITORING AND GLYCEMIC CONTROL IN THE HOSPITALS
ATTD8-0262
UTILIZING THE NEW GENERATION OF WEARABLE DEVICES IN A COMBINED DIABETES DIARY APPLICATION
O. Pektas[1,2], M. Muzny[1,3], E. Arsand[1,4], G. Hartvigsen[1,5], M. Koseoglu[2]

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340 BLOOD GLUCOSE MONITORING AND GLYCEMIC CONTROL IN THE HOSPITALS
ATTD8-0186
DIABETES DURATION BASED INITIATION OF INSULIN: IMPACT ON CLINICAL OUTCOMES, INSULIN DOSAGE AND QUALITY OF LIFE
J. Kesavadev[1], B. Saboo[2], A. Shankar[1], A. David[1], K. Jothydev[1], L. Ramachandran[1], G. Krishnan[1], S. Jothydev[1]

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341 BLOOD GLUCOSE MONITORING AND GLYCEMIC CONTROL IN THE HOSPITALS
ATTD8-0148
THE STUDY OF CONTROLLING HEALTHCARE PROGRAMS QUALITY OF TYPE 2 DIABETIC PATIENTS 2015-2016 , IRAN

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342 BLOOD GLUCOSE MONITORING AND GLYCEMIC CONTROL IN THE HOSPITALS
ATTD8-0059
SUCCESSFUL MANAGEMENT OF GLUCOSE CONTROL DURING KIDNEY TRANSPLANTATION WITH SENSOR AUGMENTED PUMP IN TYPE 1 DIABETES PATIENT: A CASE REPORT

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343 CLINICAL DECISION SUPPORT SYSTEMS/ADVISORS
ATTD8-0171
INNOVATION IN THE ONLINE LEARNING SPACE: A NEW WAY OF TEACHING DIABETES TO CLINICIANS

C. McNamara[1], V. Hagger[1], D.R. Brown[1], D.C. Adachi[2], D. Taylor[1]

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344 CLINICAL DECISION SUPPORT SYSTEMS/ADVISORS
ATTD8-0283
CLINICAL DECISION SUPPORT SYSTEM FOR PEOPLE WITH TYPE 1 DIABETES AND LOW SOCIAL STATUS IN COLOMBIA

P.S. Rivadeneira[1], M. Vallejo[1], F. Bolaños[1], G. Zapata-Madrigal[1], A. Ramirez-Rincón[2], C.E. Builes-Montaño[3]

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345 CLINICAL DECISION SUPPORT SYSTEMS/ADVISORS
ATTD8-0100
A COMBINED CASE OF SEVERE HYPOGLYCEMIA AND COELIAC DISEASE IN ELDERLY PATIENT

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[3]ENMEDIC clinic, Endocrinology, Tbilisi, Georgia

346 CLOSED-LOOP SYSTEM AND ALGORITHM
ATTD8-0310
INSULIN PUMP IN SAP-THERAPY WITH PREDICTIVE ALGORITHM IN TYPE 2 DIABETIC INSULIN-TREATED RECIPIENT OF DE NOVO KIDNEY TRANSPLANT

R. Villa[1], M. Carrano[1], R. Di Martino[1], P. De Rosa[2], G. Sarno[2]

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347 DEVICES FOCUSED ON DIABETIC PREVENTIONS
ATTD8-0156
A COGNITIVE BEHAVIORAL INTERVENTION TO REDUCE FEAR OF HYPOGLYCEMIA IN YOUNG ADULTS WITH TYPE 1 DIABETES

P. Martyn-Nemeth[1]

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348 DEVICES FOCUSED ON DIABETIC PREVENTIONS
ATTD8-0062
INTERACTION OF REDUCED FORM OF GLUTHATION WITH ZINC IN B-CELLS AS PROBABLE CAUSE FOR PREVENTION OF DIABETES CAUSED BY CHELAT CHEMICALS

G. Meyramov[1], O.N. Dupont[1], E. Kruschinski[2], A. Shaybek[1], Y. Laryushina[3], G. Kartbayeva[1], A. Alina[3], E. Aldungarov[4]

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349 DEVICES FOCUSED ON DIABETIC PREVENTIONS
ATTD8-0323
PERSONAL HEALTH RECORD SYSTEM BASED ON STANDARDIZED ITEM SETS GENERATES PERSONAL ADVICE IN ACCORDANCE WITH CLINICAL GUIDELINES

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350 GLUCOSE SENSORS
ATTD8-0123
TEST-RIG FOR AUTOMATED TESTING OF CONTINUOUS GLUCOSE SENSOR PROTOTYPES
P.C. Bösch[1,2], R. Ellingsen[2,3], A.L. Fougner[1,2], D.R. Hjelme[2,3], Ø. Stavdahl[1,2]

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351 GLUCOSE SENSORS
ATTD8-0311
IMPLANTABLE REAL-TIME CONTINUOUS GLUCOSE SENSOR IN DIABETIC KIDNEY TRANSPLANT RECIPIENT IN INSULIN PUMP THERAPY:
FIRST EXPERIENCE
G. Sarno[1], R. Villa[2], E. Russo[1], A. Ferrara[1], R. Di Martino[2], P. De Rosa[1], M. Carrano[2]

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352 INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES
ATTD8-0032
CONJOINT EFFECTS OF ACETYLCHOLINE, SEROTONIN AND NITRIC OXIDE ON GASTRIC MOTILITY
F. ALfayez[1]

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353 INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES
ATTD8-0179
DESIGN BETTER TOGETHER: CO-DESIGN WORKSHOP PROTOCOL TO DEVELOP AN MDIABETES DATA SHARING SYSTEM BETWEEN PATIENTS AND CLINICIANS
M. Bradway[1,2], A. Giordanengo[1,3], A. Grøttland[1], R. Morris[4], E. Årsand[1,2]

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[4]The University of Manchester's Institute of Population Health, Centre for Primary Care, Manchester, United Kingdom

354 INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES
ATTD8-0203
USING BIG DATA AND MACHINE LEARNING FOR INSULIN-DEPENDENT DIABETES ANALYTICS
T. Chomutare[1], M. Muzny[1], A. Giordanengo[1], A. Holubová[2], O. Pustovalova[3], G. Hartvigsen[4], E. Årsand[1]

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355 INFORMATICS IN THE SERVICE OF MEDICINE; TELEMEDICINE, SOFTWARE AND OTHER TECHNOLOGIES
ATTD8-0095
DEVELOPMENT AND FEASIBILITY STUDY OF A MOBILE-BASED SYSTEM (MHEALTH) FOR INSULIN DOSE ADJUSTMENT
F. Fatehi[1,2], H. Ding[2], D. Bird[1], A. Menon[1,3], M. Karunanithi[2], L. Gray[1], A. Russell[3,4]

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[4]Faculty of Medicine, The University of Queensland, Brisbane, Australia

356 INSULIN PUMPS
ATTD8-0125
IMPROVING GLYCAEMIC CONTROL IN MALAYSIAN PATIENTS WITH TYPE 2 DIABETES MELLITUS WITH INSULIN PUMP THERAPY - AN INTERIM ANALYSIS IN A SINGLE TERTIARY CENTRE
N.R.A. Abdullah[1], S. Khoo Sert Kim[1], A.B. Nasruddin[1], M. Mohammad[1], N. Mohd Noor[1], Z. Hussein[1]

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357 INSULIN PUMPS
ATTD8-0317
GLYCEMIC CONTROL IN MOTHERS ON CSII AFTER DISCONTINUED BREASTFEEDING
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358 INSULIN PUMPS
ATTD8-0128
MOBILE TECHNOLOGY SYSTEM FOR TYPE 1 DIABETES PATIENT USING MINIMED 640G: A CASE REPORT
G. Petrovski[1], F. Ali Khalaf[1], A. Elawwa[1]

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359 INSULIN PUMPS

ATTD8-0190

HANDLING STEP ANALYSIS OF INSULIN PUMP ROUTINE TASKS

D. Waldenmaier[1], S. Ulbrich[1], C. Haug[1], G. Freckmann[1]

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360 NEW INSULIN DELIVERY SYSTEMS: INHALED, TRANSDERMA, IMPLANTED DEVICES

ATTD8-0307

MOBILE APP - CONNECTED INSULIN INJECTOR FOR HOME HEALTH CARE, REPLACING NURSES HOME VISITS

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361 NEW INSULIN DELIVERY SYSTEMS: INHALED, TRANSDERMA, IMPLANTED DEVICES

ATTD8-0309

SYNTHETIC "SMART-GEL" BASED APPROACH TOWARD "ELECTRONICS-FREE" ARTIFICIAL PANCREAS

A. Matsumoto[1], M. Tanaka[2], H. Matsumoto[1], K. Ochi[2], Y. Moro-oka[1], H. Kuwata[3], H. Yamada[1], I. Shirakawa[4], T. Miyazawa[1], H. Ishii[3], K. Kataoka[5], Y. Ogawa[6], Y. Miyahara[1], T. Suganami[2]

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362 NEW TECHNOLOGIES FOR TREATING OBESITY AND PREVENTING RELATED DIABETES

ATTD8-0369

EFFECT OF ANTIMICROBIAL CALCIUM ALGINATE DRESSING ON DIABETIC FOOT ULCER

Z. Abdi[1], R. Alipour[2], M. Alipour[3]

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363 NEW TECHNOLOGIES FOR TREATING OBESITY AND PREVENTING RELATED DIABETES

ATTD8-0338

COMPUTATIONAL TECHNIQUES IN TREATMENT OF DIABETES

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CLINICAL DECISION SUPPORT SYSTEMS/ADVISORS

ATTD8-0220

THE CELLNOVO ONLINE PORTAL: ACCESS TO REAL-TIME DATA FACILITATES INCREASED SELF-MANAGEMENT

P. English[1], P. Kelly[1], R. Sally[1]

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GLUCOSE SENSORS

ATTD8-0200

DATA SECURITY TECHNIQUES AND PRIVACY CHALLENGES IN CLOUD COMPUTING FOR DATA MANAGEMENT SYSTEM

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