# Abstracts

# Prevention of Hypoglycemia

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## OBJECTIVE

The purpose of this study was to compare the performance of different blood glucose meters from different companies.

## METHOD

We evaluated the clinical performance of the GlucoTrack™ (Integrity Applications Ltd.), MediSmart® Diamond (Lobeck Medical Ltd.), GlucoSure Plus (Apex Biotechnology Corp.), EZ Smart (Tyson Bioresearch Inc.), and Element™ (Infopia Co Ltd.) glucose monitoring systems. Fingertip capillary blood glucose concentrations from 30 subjects with type 1 diabetes were measured using glucose monitoring systems and compared at the same time. Accuracy and precision of the GlucoTrack glucose monitoring system was assessed using several methods. A comparative study between the GlucoTrack and marketed monitoring systems was performed.

## RESULT

The 30 GlucoTrack readings covered a wide range from 3.0 to 31.0 mmol/liter. The comparative study showed that the GlucoTrack readings correlated well with the MediSmart Diamond values ($r$ = 0.92), EZ Smart values ($r$ = 0.90), GlucoSure Plus values ($r$ = 0.87), and Element values ($r$ = 0.75).

## CONCLUSIONS

GlucoTrack is a reliable glucose monitoring system that provides highly accurate and precise glucose readings over a wide range of glucose concentrations. One distinctive feature of this glucose meter is that, at low glycemia, it often shows very low values compared to other meters. This is a positive side to this meter, alerting the patient in advance of approaching hypoglycemia. The present study demonstrates that GlucoTrack is a reliable glucose monitoring system providing highly accurate and precise glucose readings that can be rated as a "good meter."

# Early Diagnosis of Diabetic Nephropathy in Children with Type 1 Diabetes

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## OBJECTIVE

The purpose of this study was to quickly and accurately diagnose diabetic neuropathy early in the outpatient treatment of children with type 1 diabetes.

## METHOD

The following tests were performed on all the children: fasting blood glucose, blood urea (using MultiSure™, Apex Biotechnology Corp.), urinary creatinine (Teco Diagnostics), urinalysis, blood pressure, microalbumin (Teco Diagnostics), and kidney ultrasound. Is it possible to use the MultiSure meter to determine the level of glucose and urea in capillary blood. Twenty children were diagnosed with diabetes for this purpose.

## RESULT

The average age of the patients was 14.6 ± 0.83 years with a diabetes duration of 7.1 ± 0.94 years. The average blood glucose was 345 ± 29.8 mg/dl, blood urea 345 ± 29.8 mg/dl, microalbumin 8.9 ± 7.9 mg/liter, and urinary creatinine 74 ± 102.5 mg/g.

## CONCLUSION

Only one patient was diagnosed with diabetic nephropathy. Simple routine methods can enable the diagnosis of diabetic nephropathy in children with type 1 diabetes.

# Sleeve Gastrectomy Diabetes Resolution Comparable to Gastric Bypass

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## OBJECTIVE

Pories and colleagues reported that 121 of 146 (83%) type 2 diabetes mellitus (T2DM) patients returned to normal plasma glucose levels following Roux-en-Y gastric bypass (RYGB). Abbatini and colleagues found an 81.2% resolution of diabetes with RYGB and 80.9% with vertical sleeve gastrectomy (VSG). We evaluated 369 T2DM patients who underwent either RYGB or VSG performed by two surgeons in the same private practice.

## METHOD

We performed a retrospective chart review of 835 laparoscopic RYGB and 766 laparoscopic VSG patients who underwent surgery between 2002–2010. We compared pre- and postoperative medication use for the 202 RYGB and 167 VSG diabetes patients as a measure of diabetes resolution. We also compared the incidence of overall complications in both surgeries.

## RESULT

In T2DM patients, 95 of 123 (77%) RYGB patients and 107 of 139 (77%) VSG patients who were on medications before surgery no longer required them postoperatively. The overall inpatient complication rate with the RYGB was 86.6% compared to 4.2% with the VSG. The VSG also resulted in fewer complications (9.0%) compared to the RYGB (36.6%) after discharge. The difference in diabetes resolution did not differ significantly between the two surgeries ($p$ = not significant). Vertical sleeve gastrectomy results in significantly fewer complications during in-patient stay and upon discharge ($p < .001$).

## CONCLUSION

The VSG and the RYGB both eliminate the need for diabetes medication in 77% of T2DM patients. However, VSG appears to be the safer surgery because of its lower incidence of overall complications.

# Self-Monitoring of Hemoglobin A1c

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## OBJECTIVE

The aim was to evaluate a self-monitoring software application that is able to guess hemoglobin A1c (HbA1c) levels without any blood sample (useful for people who have to check their glucose from three to six times daily).

## METHOD

The software application, Diabetes Management (version 1.2), is able to guess HbA1c levels. First, the diabetes patient checks their glucose level from 3 up to 6 times daily. Secondly, the diabetes patient adds up all the glucose results of the past 90 days. Then, he or she opens the diabetes management application and enters the total glucose result from the last 90 days (one number). The program divides this number by 90, which represents the last 90 days, and then divides the result by 4, which is the average time per day that the diabetes patient checked his/her glucose level. This number is then compared to an internal table with glucose values and possible HbA1c levels.

## RESULT

I have checked the Diabetes Management software application and asked diabetes patients in forums to use this software application and take the regular HbA1c test using their blood. Patients who checked both provided these results: program 6.1 % vs regular test 6.4 %; and program 6.0% vs regular test 6.3 %.

## CONCLUSION

The Diabetes Management application is able to guess HbA1c levels but is unable to replace the original HbA1c test with blood. It is, however, able to give diabetes patients an approximate level of their HbA1c. Thus, diabetes patients know whether or not they need to improve their medication. Diabetes patients found this program to be useful and downloaded it at *http://diabetes-management.software.informer.com* (downloaded 47 times in 1 month).

# Gastric Neurostimulation Relieves Symptoms of Diabetic Gastroparesis and Reduces the Frequency of Hospital Contacts

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## OBJECTIVE

Diabetic gastroparesis is most often asymptomatic but may present with continuous nausea and vomiting leading to hospitalization for fluid substitution and blood glucose control. The aim of this study was to describe the effect of gastric neurostimulation in patients suffering symptomatic diabetic gastroparesis.

## METHOD

Selected type 1 diabetes patients suffering severe symptoms of diabetic gastroparesis underwent extensive clinical examination to exclude other causes. Before and after implantation of a high-frequency, low-intensity gastric neurostimulator, patients were subjected to detailed clinical studies, including scintigraphic gastric emptying studies, cardiac autonomic function tests, gastroscopies, visceral-biomechanical studies, and qualitative symptomatic testing using validated questionnaires. Fifteen patients were included in the study: 7 male and 8 female, all with type 1 diabetes of long duration presenting with an array of late diabetic complications and attending the outpatient clinic. All had suffered symptoms of diabetic gastroparesis for several years resistant to standard treatment measures and all attempts of pharmacotherapy. All were frequently admitted to a hospital for this condition. A proportion of the patients had been considered to be candidates for irreversible gastrointestinal surgery.

## RESULT

Fifteen patients were relieved to varying degrees of their symptoms of diabetic gastroparesis. Two male patients and three female patients were completely relieved of nausea and vomiting. Several patients were admitted frequently to the hospital, predominantly for the treatment of competing diabetic late complications. Some did not require admittance to the hospital after implantation of the gastric neurostimulator. Some returned to full-time work.

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## CONCLUSION

We conclude that the patients selected and included in our study were significantly relieved of severe symptoms of diabetic gastroparesis and the overall frequency of hospital contacts were reduced.

# Paper Electrocardiogram Strips May Contain Overlooked Clinical Information

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## OBJECTIVE

A large number of nondigitized electrocardiogram (ECG) strips is routinely collected in larger cohort studies such as the ADDITION study (Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care). These ECG strips may contain overlooked information on the onset of cardiac autonomic dysfunction and the progression to autonomic neuropathy. The aim of this study was to investigate whether clinical information may be lost using manual RR-interval measurements.

## METHOD:

From the Danish part of the ADDITION study (a population-based stepwise screening program for type 2 diabetes mellitus in general practice), we randomly selected 120 patients. Resting 12-lead electrocardiographic recordings were collected from all patients. Analysis of the ECG strips was performed using two different methods: (1) by experienced technicians using rulers and (2) by experienced technicians using a high resolution computer-assisted method.

## RESULT:

A high degree of correlation was found between the two methods with Pearson's *r* of heart rate: 0.98; standard deviation of normal-to-normal intervals (SDNN): 0.76; and root mean square successive difference (RMSSD): 0.68. The high correlation between the two devices indicates that heart rate and heart rate variability (HRV) measurements by the computer-assisted and the manually based methods are highly correlated, but Bland-Altman plots and Pitman's test of difference in variance revealed poor agreements ($p < .01$) for both HRV measurements SDNN and RMSSD. Only heart rate showed substantiated agreement ($p = .54$) between the two methods.

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## CONCLUSION

Paper ECG strips may contain overlooked clinical information on the status of autonomic function. In our study, manual measurements of the RR interval were not sufficient to secure correct analysis of HRV. Based on this study, we recommend caution in the clinical use and interpretation of HRV based on manual measurements of RR intervals from ECG strips.

# Testing for Autonomic Neuropathy May Support the Diagnosis of Diabetic Gastroparesis

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## OBJECTIVE

Autonomic nerve damage is common in diabetes patients, and patients may suffer debilitating symptoms from various organs. Clinical features of autonomic nerve damage in longstanding diabetes may include gustatory sweating, diabetic gastroparesis, diabetic diarrhea, postural hypotension, and sexual dysfunction. The aim of this study was to describe the association between gastroparesis and cardiac autonomic neuropathy (CAN).

## METHOD

Nineteen consecutively recruited type 1 diabetes patients (6 males and 13 females) were studied. Age was 43 ± 14 years, diabetes duration 21 ± 8 years, and body mass index 26 ± 5. The degree of CAN was assessed by heart rate variability (HRV) parameters including expiration-to-inspiration (E:I) ratio, response to active standing (30:15), standard deviation of normal-to-normal intervals (SDNN) of 2 minutes, RR intervals, and QTI interval index. A $^{13}$C-octanoic breath test determined rate of gastric emptying and symptom scores were determined by a validated questionnaire. All patients underwent thorough physical, paraclinical, and clinical examinations including endoscopies.

## RESULT

Gastric emptying rates were all significantly increased (T50 = 152 ± 33 minutes). All patients but two were diagnosed with CAN. Of the 17 patients exhibiting CAN, 7 were at an early stage CAN with only one abnormal HRV-test whereas 10 were at an end stage of CAN. Standing blood pressure was significantly correlated with degree of CAN, signifying development of postural hypotension in late-stage CAN. On validated questionnaires, all patients demonstrated symptoms pathognomonic for gastroparesis and severe symptoms.

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## CONCLUSION

All consecutively recruited patients suffered symptomatic gastroparesis and all patients demonstrated cardiovascular autonomic dysfunction. The patients exhibited a close relationship between severe diabetic gastroparesis and cardiovascular autonomic neuropathy. Hence testing for autonomic neuropathy may support the diagnosis of diabetic gastroparesis.

# White-Coat Effect in Testing for Cardiovascular Autonomic Neuropathy

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## OBJECTIVE

Cardiovascular autonomic neuropathy (CAN) is associated with the development of a number of late complications. It is unknown if a "white-coat" phenomenon exists in autonomic neuropathy testing. The aim of this study was to evaluate any differences in the results of testing for CAN in a clinical setting versus a home setting.

## METHOD

Ten type 1 diabetes patients all showing signs of CAN and 10 healthy volunteers were recruited. All subjects underwent thorough clinical examinations. Participants underwent in-hospital testing for CAN before and after home monitoring using a novel hand-held device. For 6, consecutive home self-monitoring was performed every morning including expiration-to-inspiration (E:I) ratio, 30:15 ratio, Valsalva ratio, and resting heart rate variability (HRV) [standard deviation of normal-to-normal intervals (SDNN)] for 5 minutes). The intra- and interindividual reproducibility was determined by coefficient of variation (CV) and the reproducibility coefficient (RC).

## RESULT

A Bland-Altman analysis with Pitman's test of difference in variance showed no significant difference in variance between hospital and home measurements, indicating suitable agreement between the two measurements when using standard cardiovascular reflex tests (30:15; Valsalva, and E:I). However, systolic blood pressure was significant lower and HRV (SDNN) was significantly higher in self-monitoring at home compared with laboratory testing. Reproducibility was moderate to high in all measures, with RC ranging from 66–94% and CV ranging from 5–10%.

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## CONCLUSION

There was no significant difference between laboratory testing and self-monitoring when using autonomic reflex tests E:I, 30:15, and Valsalva maneuver. Resting HRV measurements (SDNN 5 minutes) was, however, significantly higher in both groups, indicating a possible presence of a white-coat effect in a laboratory testing for CAN. Thus, reflex testing may be more robust than passive testing.

# Thermal Threshold as an Early Indicator of Diabetic Polyneuropathy

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## OBJECTIVE

Distal polyneuropathy is a common complication in diabetes. Conduction velocity and electromyography are used to study it, but these only measure the function of the thick nervous fibers. It is believed that the damage of small fibers (studied with thermal sensation threshold) is more prevalent and occurs earlier. We compared nervous conduction velocity (NCV) versus thermal sensation threshold (TST), with the objective of demonstrating which of the two is an earlier indicator of neuropathic damage.

## METHOD

The sample consisted of 70 type 2 diabetes patients without symptoms of neuropathy, 31 women and 39 men, average age 54 years old, with an evolution of 16 ± 28 months. Thermal sensation threshold was assessed on hands, dorsum, and soles of feet. Motor NCV was assessed in the median and peroneal nerves; sensory latencies and NCV were assessed in the median, ulnar, and sural nerves.

## RESULTS

The NCV test showed two results: normal ($n$ = 57) and sensory or sensory-motor polyneuropathy ($n$ = 13). In the TST test, 30 cases showed abnormalities, while 40 were normal. So, 43% of patients showed abnormal TST, while only 19% showed alterations in NCV consistent with classic diabetic polyneuropathy. Alterations in TST tended to happen earlier and in younger patients, compared with abnormalities in NCV (52 versus 61 years old).

## CONCLUSIONS

In our study, TST showed more sensitivity than NCV in the early and subclinical diagnosis of diabetic neuropathy. In addition, we believe that abnormalities of TST occur in younger patients. Moreover, age (amongst others) is also an important factor in the severity of neuropathic damage. We support TST`s usefulness for early intervention in asymptomatic diabetes and even in impaired glucose tolerance.

# Professional Continuous Glucose Monitoring Improves Diabetes Outcomes in Children and Adolescents with Type 1 Diabetes

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## OBJECTIVE

Many children and adolescents with type 1 diabetes are unable to achieve optimal hemoglobin A1c (HbA1c) targets despite attempts at intensive management. Insulin analogs, insulin pumps, and various devices for self-monitoring of blood glucose have improved the ability to achieve intensive management. Professional (blinded) continuous glucose monitoring (CGM) is a maturing technology, but research on its effectiveness in children and adolescents is limited. In this study, we examine diabetes-specific outcomes in a group of pediatric patients undergoing blinded CGM with the iPro device.

## METHODS

Clinical outcomes [HbA1c, body mass index (BMI), insulin use, and the occurrence of diabetic ketoacidosis (DKA) and hypoglycemia] were examined in 38 children undergoing iPro insertion in a retrospective, cohort study design. The devices were downloaded in an office setting and tracings reviewed in the context of a detailed log of dietary intake, insulin use, and physical activity. Student's *t*-test and chi square analysis were employed to examine trends in diabetes outcomes prior to and after the insertion.

## RESULTS

HbA1c fell from 8.14 ± 0.14 before the iPro to 7.89 ± 0.13 within 6 months after ($p = .02$). The incidence of severe hypoglycemia fell from a baseline of 40.8/100 to just 3.3/100 patient-years ($p < .005$), while the occurrence of DKA showed no significant change. Body mass index standard deviation score was stable in participants in the 6 months after iPro insertion.

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## CONCLUSION

Blinded CGM improves HbA1c levels and decreases the numbers of severe hypoglycemic episodes in pediatric patients with suboptimal glycemic control. We are examining our insulin use data to determine the patterns of insulin delivery that contributed to our observations. The full impact of the use of this device on clinical outcomes will be assessed more accurately in a larger, prospective, randomized, case-control design.

# The Role of Vitamin $B_1$ in the Treatment of Diabetes Mellitus

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## OBJECTIVE

Vitamin $B_1$ (thiamine) acts as a coenzyme for transketolase (TK) and for the pyruvate dehydrogenase and α-ketoglutarate dehydrogenase complexes, which are enzymes that play fundamental roles in intracellular glucose metabolism. Therefore, it would be of interest to review the beneficial role of vitamin $B_1$ in treating diabetes mellitus (DM).

## METHOD

We reviewed the Medline database literature and discussed the relationship between vitamin $B_1$ and DM.

## RESULT

Thiamine levels and thiamine-dependent enzyme activities are reduced in DM. Genetic studies provide an opportunity to link the relationship between thiamine and DM (for example, using TK, SLC19A2 gene, transcription factor Sp1, α-1-antitrypsin, and p53). Thiamine and its derivatives have been demonstrated to prevent the activation of the biochemical pathways (increased flux through the polyol pathway, formation of advanced glycation end-products, activation of protein kinase C, and increased flux through the hexosamine biosynthesis pathway) induced by hyperglycemia in DM. Thiamine has a role in the diabetic endothelial vascular diseases (micro- and macroangiopathy), lipid profile, retinopathy, nephropathy, cardiopathy, and neuropathy.

## CONCLUSION

Vitamin $B_1$ definitively has a beneficial role in the treatment of diabetes.

# Use of the GlucoCare™ IGC System for Intensive Glycemic Control in >500 Cardiac Surgical Patients

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## BACKGROUND

The American Diabetes Association and American Association of Clinical Endocrinologists recommendations are to target patients to a relatively high blood glucose (BG) range of 140–180 mg/dl, largely as a direct result of the NICE-SUGAR trial, which highlighted the risk of hypoglycemia. Significant resistance to these high targets has emerged because of concerns about moving the pendulum too far away from the earlier recommended 80–110 mg/dl, resulting in unwarranted hyperglycemia.

## OBJECTIVE

To objective was to demonstrate that safe glucose control can be obtained by using a computerized insulin dosing calculator, GlucoCare™ (Intensive Glycemic Control) IGC System, based on the Yale 100–140 mg/dl protocol.

## METHOD

Postcardiac surgery patients admitted to the cardiothoracic intensive care unit at Westchester Medical Center (Valhalla, NY) were initiated on the GlucoCare IGC System. Initiation occurred either immediately after the procedure or once BG rose above 150 mg/dl. GlucoCare records all BG entries with a time stamp and alerts nurses as to when an additional BG level is required.

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## RESULT

In this study, 523 patients and the results of 15,493 BG samples were included. Median time to reaching the target was 3.9 hours. Mean BG once the target was reached was 122.3 mg/dl. No patient experienced a BG <40 mg/dl. The incidence of BG <70 mg/dl was 0.78%. Once reaching the target, 56.2% of all BG were within the target range and 95% were in the range of 70–180 mg/dl.

## CONCLUSION

These results indicate that lower BG targets can be achieved safely with the use of the GlucoCare IGC System, with an extremely low incidence of severe hypoglycemia and with 95% of posttarget glucose levels in a desired range. Moreover, the results reported compare favorably to the results of published protocols, either computerized or paper-driven.

# Position of Sitagliptin Therapy in Type 2 Diabetes Mellitus in Japan

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## OBJECTIVE

Use of incretin has the potential to expand clinical diabetologists choice in oral therapy. We examined the effectiveness and position of sitagliptin (dipeptidyl peptidase-4 inhibitor) in glycemic control in Japanese patients with type 2 diabetes mellitus (T2DM).

## METHOD

Twenty-two Japanese T2DM patients (13 males and 9 females, mean age 66 years) were administered 50 mg of sitagliptin per day for 6 months. In addition to a diabetologist's check, patients underwent tests for hemoglobin A1c (HbA1c) (%), body mass index (BMI), and blood glucose level (either fasting or postprandial) at least once a month. Data were compared before versus after 6 months. Combined oral drugs used throughout the 6 months were sulfonylurea (glimepiride) and biguanide (metformin).

## RESULT

The mean HbA1c level of 22 patients was decreased: 7.32 to 6.87 (-0.45%). Mean body weight was 69 kg. Mean sitagliptin dose per weight was 0.72 mg/kg. Mean BMI was 24 with no change. Fasting blood glucose was 173 mg/dl and changed to 160mg/dl. Postprandial glucose changed from 195 to 169. There were no side effects, including hypoglycemia.

## CONCLUSION

Sitagliptin (0.72 mg/kg) in combination with glimepiride and metformin may improve blood glucose levels in Japanese patients with mild T2DM.

# Diabetes Mellitus and Deep Vein Thrombosis after Craniotomy

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## OBJECTIVE

Longitudinal studies in medical patients showed that patients with diabetes mellitus (DM) have an increased incidence of deep venous thrombosis (DVT). A study found a decreased risk of symptomatic postoperative DVT in surgical patients with DM. Although DM is a hypercoagulable state, whether DM increases the risk for DVT in the perioperative period is controversial. Patients undergoing craniotomy frequently develop hyperglycemia second to the stress of surgery and treatment with steroids. After craniotomy, DVT develops as early as the second day, with the peak incidence between days 2 and 7. We investigated whether DM and/or perioperative hyperglycemia influence the incidence of DVT after craniotomy.

## METHOD

After institutional review board approval, electronic medical records in patients undergoing craniotomy for tumor or intracranial aneurysm from October 2009 to September 2010 were investigated. Patients were divided into three groups according to diabetes status: DM group (DMG)—patients with diagnosis of DM or on diabetes medications; hyperglycemia group (HG)—diagnosis of hyperglycemia on discharge; and non-DM group (NDMG)—no diagnosis of DM or diabetes medication. Deep venous thrombosis was diagnosed by ultrasound examinations of lower and upper extremities. Ultrasound screening was performed two times a week during hospitalization.

## RESULT

A total of 99 craniotomies were performed in the study period. The incidence of DVT was 19.2% (95% confidence interval 11.5, 26.9). There was no difference among groups regarding age, sex, and body mass index. The DMG had a higher incidence of DVT (28.0%) than both the HG (16.7%) and the NDMG (16.0%). The difference was not statistically significant ($p$ = .43), probably because the study was underpowered. Assuming that this trend in the incidence of DVT were to persist, a study with 184 patients per group would have been necessary to show the difference between the DMG and NMDG.

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## CONCLUSION

Our study showed that patients with hyperglycemia second to the stress of surgery or steroid use do not have an increased risk for DVT after craniotomy. Patients with a diagnosis of DM may have a higher incidence of DVT, but a prospective study with over 200 patients per group is needed to show the increased risk for DVT after craniotomy.

# Incidence of Sharps Injuries Using the Spring Universal Infusion Set

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## OBJECTIVE

The aim was to assess the rate of sharps injuries and significant problems, such as biohazard potential and infection, arising from the use of the hidden, autoretractable, needle safety feature built into the Spring™ Universal Infusion Set during simulated use. This study was based on background evidence that sharps injuries while inserting infusion sets used for subcutaneous delivery of medicines are not an uncommon occurrence.

## METHOD

Eight subjects treated with insulin pump therapy and two nurses experienced in educating patients in correct management of their insulin pump therapy were each required to test the Spring Universal Infusion Set 50 times by inserting the needle/cannula into an orange during various situations, e.g., gloved, wet hands, and normal insertion. An observer noted any problems during the procedure and assisted the subjects in filling out questionnaires describing their experiences.

## RESULT

No needlestick injuries or other significant problems occurred in 500 tests performed.

## CONCLUSION

Use of an automatic, hidden, autoretractable needle in an infusion set used for subcutaneous administration of medicine provides the user with enhanced safety and confidence.

# Use of a Controlled Fast for the Treatment of Severe Insulin Resistance in Patients with Type 2 Diabetes

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## OBJECTIVE

Patients with type 2 diabetes mellitus (T2DM) and severe insulin resistance often require large doses of insulin to achieve target glycemic control. As insulin dose increases over time, patients frequently have reduced treatment benefits and unfavorable metabolic side effects, including weight gain and increased hunger. The purpose of this institutional review board-approved study was to describe our experience on the effect of a controlled, prolonged fast on insulin requirements, hyperglycemic control, and weight loss in patients who have T2DM and severe insulin resistance.

## METHOD

A total of 18 patients completed 21 controlled, prolonged fasts, consisting of carbohydrate-free clear liquids. Pre- and postfast (up to 6 months) data were collected assessing the effects on hemoglobin A1c (HbA1c), total insulin requirements, weight, and body mass index (BMI).

## RESULT

The majority of the fasts were 72 hours long and occurred at home under medical supervision. Insulin was reduced by 50% in the first 36 hours and then adjusted individually. The mean HbA1c, insulin requirements, weight, and BMI were 10.1%, 267 units, 267 pounds, and 40.6 prefast; 8.7%, 128 units, 260 pounds, and 39.7 at 2 weeks postfast; 9.1%, 173 units, 251 pounds, and 37.3 at 1 month postfast; and 9.1%, 211 units, 244 pounds, 35.9 at 2–6 months postfast, respectively. There were three episodes of mild hypoglycemia reported, neither of which required medical intervention.

## CONCLUSION

Based on our findings, patients with T2DM and severe insulin resistance can be treated safely at home with a prolonged, controlled fast to achieve better glycemic control on smaller doses of insulin with continued weight loss and reduction in BMI.

# Use of Buccal Spray Insulin for Impaired Glucose Tolerance: The Prevoral 2 Trial

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## OBJECTIVE

In patients with impaired glucose tolerance (IGT), a third return to normal tolerance, a third continue with IGT, and the rest develop type 2 diabetes. Increased risk for cardiovascular disease occurs in the latter two groups even without progression to diabetes. A proof of concept study demonstrated that treatment with 12 puffs of buccal spray insulin was followed by a significant 29.6% decrease in mean plasma glucose at 2 hours and a 26.8% decrease at 3 hours.

## METHOD

We designed a randomized controlled trial in patients with IGT comparing buccal spray insulin (Generex Oral-lyn™) (12 puffs per meal) plus physical exercise and diet [group A, $n$ = 16, hemoglobin A1c (HbA1c) at entry 6.06 ± 0.5%] vs physical exercise and diet only (group B, $n$ = 16, HbA1c at entry 5.9 ± 0.3%). Hemoglobin A1c levels, metabolic parameters, and insulin antibodies were measured at baseline and every 3 months up to 6 months. The primary endpoint was the reduction of HbA1c by 0.3% at 6 months of therapy. Secondary endpoints included evaluation of insulin antibodies (IA), changes in body weight, and number of hypoglycemic events.

## RESULT

Subjects treated with buccal spray insulin achieved a significant reduction of HbA1c compared to the control group (ΔHbA1c 0–3 months, -0.3% vs +0.09%, $p$ = .002). There was no significant difference in body weight and no hypoglycemia or other adverse events were observed during the study period in both groups. No generation of IA was observed in subjects with IGT treated with buccal spray insulin.

## CONCLUSION

These preliminary results indicate that buccal spray insulin is an effective treatment in reducing HbA1c without adverse effects compared to diet and physical exercise in patients with IGT.

# Real-Life Utilization of Real-Time Continuous Glucose Monitoring: The Complete Picture

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## OBJECTIVE

Very few studies have analyzed the reasons why some people do not use real-time continuous glucose monitoring (RT-CGM) continuously, especially given its positive glycemic outcomes, or why some choose not to wear it at all even after learning about its benefits. The objective of this study was to assess real-life use of and issues surrounding RT-CGM.

## METHODS

A questionnaire was designed to assess real-life use of and issues surrounding RT-CGM. Hemoglobin A1c and duration of sensor use were also obtained from the patients' charts.

## RESULTS

The analysis included 58 pediatric and young adult subjects with type 1 diabetes (T1DM), average age 15.0 ± 4.8 years, T1DM duration 5.7 ± 3.8 years, HbA1c 8.8 ± 2.1%, 50% with RT-CGM. Hemoglobin A1c was lower with increased RT-CGM use. Real-time continuous glucose monitoring was ordered to improve control. Users liked the continuous data. The most disliked part was pain and discomfort. Occasional users described RT-CGM as annoying, a hassle, and interfering with their lives. Reasons for discontinuing RT-CGM included problematic equipment and inaccuracy (64%), intrusion in life (36%), and insurance issues (29%). Twenty-one percent of nonusers reported RT-CGM to be inconvenient, a hassle, or just did not want it. Fifty-two percent of subjects continued to use RT-CGM despite reported problems.

## CONCLUSION:

Real-time continuous glucose monitoring is a beneficial tool for improving glycemic control, and many use it despite reported problems and hassles with available devices. However, this technology has not been wholeheartedly embraced by many individuals with T1DM, especially in youngsters, because of the issues mentioned here. Based on the findings of this study, it is hoped that improvements will be made to RT-CGM technology so that more people with diabetes will embrace this beneficial tool.

# Glycated Albumin and End-Stage Renal Disease

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## OBJECTIVE

Circulating glycated albumin (GA) plays a major pathophysiological role in diabetic nephropathy and has been suggested as a short-term marker for managing diabetes patients on hemodialysis (HD). The potential clinical advantages of reconciling GA's pathophysiological role and its capacity as a marker are reviewed here.

## METHODS

A survey of the most current literature regarding GA and nephropathy, end-stage renal disease (ESRD), and hemodialysis was performed in order to assess the potential of GA as a monitoring tool in these patients.

## RESULTS

GA has been suggested as an alternative to glycated hemoglobin A1c because of its short turnover period and robustness through hemodialysis procedures. Despite its clear advantages, GA levels may be affected by age and other factors, and further studies are needed to fully evaluate the robustness of GA in diabetes patients on peritoneal dialysis.

The pathophysiological role of GA in diabetic nephropathy has been well established. Glycated albumin has been shown to affect macroscopic, microscopic, and genetic mechanisms in the pathogenesis of diabetic nephropathy. GA levels have also been shown to correlate with hallmarks of nephropathy and its complications. Several studies have started to explore GA as a therapeutic target in animal models, showing the amelioration of renal abnormalities after inhibiting the glycation of albumin. More work is required to show when glycation becomes irreversible—as a Schiff base or following Amadori rearrangement.

## CONCLUSION:

Point-of-care assessment of GA, as represented by existing enzymatic assays and emerging rapid immunochromatographic techniques, is promising and essential. GA may emerge as the ideal glycation marker for the evaluation of nephropathy while monitoring diabetes patients in ESRD.

# Investigation of a Continuous Glucose Monitoring System in Development during 7-Day Home Use

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## OBJECTIVE

Studies show greater benefit with more frequent use of a continuous glucose monitoring (CGM) system. Wearability is a key feature of CGM. This study evaluated the accuracy of a CGM system in development on day 7 of sensor wear and determined failures after a 7-day period.

## METHOD

Twenty subjects, type 1 or 2 diabetes ≥6 months, aged 18–65 years old, wore a CGM system for 7 days. The sensor was inserted by the subject on the abdomen under observation of a health care professional. Subjects were required to calibrate every 12 hours at home. Subjects returned on day 7. Yellow Springs Instrument (YSI), venous plasma glucose, and capillary glucose meter assays were performed. Subjects explanted the sensor following study staff instruction. Subjects were contacted 2–3 days after sensor removal to assess adverse events.

## RESULTS

All systems were calibrated after a 1-hour run time. On day 7, accuracy at 75–400 mg/dl for the 196 CGM data pairs compared to YSI had a mean and median APD of 15 and 13%, respectively. Ninety-nine percent of results were within zones A and B of Parkes consensus error grid. The 784 CGM data pairs compared to blood glucose monitoring had a mean and median APD of 16 and 13%, respectively. There was a 1.9% 7-day data loss due to algorithm or user error. No data loss was due to telemetry. Out of the 20 patients, 14 (70%) had wear success/glucose reporting for 7 days (168 hours). There were three adhesive failures and three software errors. One subject had two device-related adverse events of erythema and edema greater than "well defined" on the Draize scale.

## CONCLUSION

A new CGM device was easy for patients to insert and had a high degree of accuracy, reliability, and wearability over 7 days.

# Pump-Based Intensive Control of Sugar (PICS) in Hospitals

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## OBJECTIVE

The objective is to control in-patient diabetes intensively and to study its impact on overall hospitalization time, incidence of complications, morbidity indices, and cost.

## METHODS

We compared standards of care for inpatient diabetes management and found that most hospitals like to follow sliding scale-based insulin regimens for inpatient diabetes control. We compared the standard Stanford protocol for intensive insulin management in hospital floors in a control group of 25 patients in three different hospital floors (medical step-down unit, surgical step down unit, and cardiothoracic step-down unit) with another group of 25 patients in similar nursing floors on a basal bolus regimen of insulin via continuous infusion by pumps, with blood sugar monitoring by continuous glucose monitoring system (CGMS) devices. We proposed to collect data in these two groups and compare them by using standard statistical analysis tools for significance. Study group on insulin pump: regular insulin or analog, standard regimen of low = 0.5 units hourly basal, bolus at 2 units prebreakfast, 3 units prelunch, and 4 units predinner; medium = 1.0 unit hourly, 3 units prebreakfast, 4 units prelunch, and 5 units predinner; and high = 1.0 unit hourly, 3 units prebreakfast, 5 units prelunch, and 6 units predinner. Glucose checks by CGMS at 6 a.m., 10 a.m., 12 p.m., 3 p.m., 6 p.m., and 10 p.m. Control group on Stanford insulin protocol: "mild, moderate and aggressive," glucose checks before meals and at bedtime.

## RESULTS

The results were analyzed by standard statistical tools such as Student's *t* or chi square test (two by two tabular format). Primary end points: hypoglycemia, days of hospitalization postsurgery, wound infection (if any), need for transfer to intensive care unit for glycemic control, readmissions after discharge, CVA, and CAD. Secondary end points: pump malfunction/complications, timeliness of glucose checks and insulin delivery by sliding scale, CVA, and CAD immediately postdischarge.

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## CONCLUSIONS

The intensive management of diabetes mellitus on hospital floors is complicated by the availability of several different insulins. The clinical use of sliding scale of insulin in hospital floors is still wrought with confusion regarding types of insulin and results in adverse events of hypoglycemia. We predict that the control of glycemia can be made simpler and smoother by the use of pumps and continuous glucose monitoring without incurring more cost, and that there will be reduced incidence of complications such as hypoglycemia. This will lead to overall better metabolic control and improved indices of morbidity.