Abstracts

No-Slide Zone

Lisa J. Adams, Pharm D; Thuhai Phamle, Pharm D; Paulette Ginier, MD

VA Central California Health Care System, University California San Francisco
Fresno, California, United States
lisa.adams2@va.gov

Objective:

The objective was to implement diabetes best practice recommendations (i.e, basal–bolus insulin regimens without the use of sliding scale insulin, minimization of hypoglycemia, and individualized patient treatment goals) in the Extended Care Unit (ECU) at the VA Central California Heath Care System (VACCHCS) in Fresno, California.

Method:

Clinical pharmacists with experience in diabetes management, in collaboration with the endocrinologist, employed an evidence-based approach to formulate individualized and safe insulin regimens for a vulnerable population (frail elderly) within the setting of long-term care. The following factors were considered when starting an insulin regimen: (1) What is a realistic goal for glycemic control based on the patient's age and medical condition, weight, ethnicity, organ function, diabetes history, dietary intake (i.e., are they eating?), activity level (i.e., are they getting out of bed?), and system problems (late meals?); (2) How to emphasize safety and the use of pattern management rather than micromanaging individual blood glucose levels; and (3) How to write the orders for rapid-acting insulins to minimize hypoglycemia and still manage blood glucose levels.

Results:

To meet the unique challenges of this population in the long-term care setting, an equally unique solution came in the way the orders for rapid-acting insulin are written, which incorporates a margin of safety and maintains effectiveness without the use of a sliding scale insulin order. With specifically written orders, individualized treatment goals, weight-based dosing, and frequent monitoring by clinical pharmacists, the ECU has become a no-slide zone (sliding scale insulin orders have been abolished).

Conclusion:

With careful monitoring, frail elderly patients in the long-term care setting can be managed safely and effectively with basal–bolus insulin regimens without sliding scale insulin.

Synergistic Effect of Cichorium and Chromium Supplementation on Diabetic Rats

Soheir Ahmed Al-Masri

Department of Nutrition and Food Sciences, King Saud University
Riyadh, Saudi Arabia
Saalmasry@ksu.edu.sa

Objective:

The present study aims to investigate the synergistic effect of Cichorium and chromium supplementation on diabetic rats.

Methods:

Diabetic rats were classified into four groups: control positive, Cichorium group (15%), chromium group (80 microgram/kg body weight), and Cichorium with chromium. For each group, blood glucose, serum insulin, and liver enzymes were estimated.

Results:

The results revealed that Cichorium and chromium were of value for ameliorating diabetes mellitus and its side effects.

Conclusion:

The herbal medicine Cichorium with chromium as trace element supplementation has antioxidant effects due to plant phenolics indicating synergistic action in treatment of diabetes.

Use of the eGlycemic Management System by Glytec Provides Safe and Effective Meal Coverage for Cardiovascular Patients Managed on Intravenous Insulin Therapy

Joseph Aloi, MD; Paul Chidester, MD; Amy B. Henderson, RN, BSN;
Raymie S. McFarland, PT, BS; Robby Booth, BS;
Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP

Wake Forest Medical Center
Winston Salem, North Carolina, USA
jaloi@wakehealth.edu

Objective:

Nutrition is an important factor in the healing process, especially for patients undergoing surgery. Clinicians face challenges in maintaining optimal glycemic control while feeding patients carbohydrate-containing diets, particularly when using insulin infusions. This study evaluates the effectiveness of an intravenous (IV) meal bolus using Glucommander (GM) to keep patients in their target blood glucose (BG) range.

Method:

A total of 803 cardiovascular (CV) surgery patients consuming carbohydrates while on IV insulin therapy were evaluated. Qualifying patients were treated with IV insulin using GM. Efficacy and safety were evaluated by the following: (1) BG average (mg/dl) at three main measurement points (pre-meal, during meal, and at meal end); (2) percentage of hypoglycemic events <40 and <70 mg/dl; (3) percentage of BG readings in target 70–180 mg/dl; and (4) portion of meal consumed.

Results:

Patients placed on GM meal coverage had an average BG of 127.5 mg/dl pre-meal, 139 mg/dl during meal, 145.5 mg/dl at meal end, and 137.5 mg/dl total meal coverage average. Hypoglycemic events <40 mg/dl was 0.0% and hypoglycemic events <70 mg/dl was 0.01%. The percentage of BG readings in target was 93.1% during the treatment window. No change was noted in hypoglycemia <70 mg/dl post meal end. There were 1420 meals covered during the study period.

Conclusion:

Patients using the meal coverage option in GM achieved a significant number of BG values within the prescribed target range regardless of pre-, during, or post-meal timeframe, with a very low incidence of hypoglycemia (<70 mg/dl) and no incidence of critical hypoglycemia (<40 mg/dl). These results suggest that GM can safely maintain prescribed glucose targets with very minimal risk of hypoglycemia for CV surgery patients consuming carbohydrates and requiring IV insulin therapy.

Use of the eGlycemic Management System by Glytec Provides Safe and Effective Glucose Control for Cardiac Surgery Patients Managed on Intravenous Insulin Therapy

Joseph Aloi, MD; Paul Chidester, MD; Amy B. Henderson, RN, BSN;
Raymie S. McFarland, PT, BS; Robby Booth, BS;
Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP

Wake Forest Medical Center
Winston Salem, North Carolina, USA
jaloi@wakehealth.edu

Objective:

For patients undergoing cardiovascular (CV) surgery and receiving intravenous (IV) insulin infusions, clinicians are challenged with achieving CMS measures that have changed over time. This study was intended to evaluate the efficacy and safety using Glucommander (GM) to achieve different measurement timelines.

Method:

A total of 1804 patients undergoing CV surgery were evaluated. Glucose control was analyzed over time on Glucommander IV (GM IV) and Subcutaneous (GM SubQ) insulin therapy. Qualifying patients were started on GM IV insulin and transitioned to GM SubQ (179 patients) if ongoing therapy was deemed necessary. The efficacy and safety of IV and SubQ was evaluated by end anesthesia time intervals: (1) blood glucose (BG) average at 12–24 h and 12–72 h; (2) percentage of BG readings in target <180 mg/dl; (3) hypoglycemic events <40 mg/dl and <70 mg/dl; (4) average BG for subgroup who received meals during IV treatment.

Results:

Blood glucose average for patients was 114 mg/dl at 12–24 h and 120 mg/dl for 12–72 h. Percentage of readings in target <180 mg/dl was 98.6% for 12–24 h and 95.1% from 12–72 h. Hypoglycemia defined as <40 mg/dl or <70 mg/dl was 0.0% and 1.03%, respectively, for hours 12–24; whereas hypoglycemia was 0.01% and 0.6%, respectively, for the broader time range of 12–72 h. A total of 1010 meals containing carbohydrates were recorded on GM IV with an average meal BG of 122.7 mg/dl.

Conclusion:

Patients using GM IV and SubQ achieved BG values within the prescribed target range regardless of measurement time frame, with a very low incidence of hypoglycemia. These results suggest that GM IV and SubQ can safely maintain glucoses targets with very minimal risk of hypoglycemia for CV surgery patients, even for those who also need calorie intake.

Description of Practices Related to Insulin Injection Therapy and Sharps Disposal among Patients Attending the Diabetic Clinic, Colombo North Teaching Hospital, Sri Lanka

Kushani Rasangika Atukorala, MBBS; Deepama Sumanasekera, MBBS;
Kumudu Hasantha Wickramasinghe, MBBS; Sumudu Wickramasinghe, MBBS

Department of Physiology, Faculty of Medicine
University of SriJayawardenapura
Gangodawila, Nugegoda, Sri Lanka
kushaniatukorala@yahoo.com

Background:

Patients with diabetes on insulin therapy are compelled to use sharps, such as insulin needles and lancets, on a regular basis. As a result, they generate thousands of used sharps and bloodstained materials. While there is a huge concern over sharps disposal practices in health care settings, the sharps disposal practices of patients with diabetes living at home has been poorly documented.

Method:

A randomly selected sample of 158 diabetes patients were obtained from the diabetes clinic, Colombo North Teaching Hospital. Data were collected using an interviewer-administered questionnaire and clinic records.

Results:

Sample population was aged between 21–90 years and mean age was 60 years. The majority, 131/158 (83%), had used insulin for more than 1 year. Very few, 5/158 (3%), used the insulin pen while the majority used syringes to inject insulin. Only 10 (6%) regularly checked their blood glucose level using needles/lancets. The majority, 132/158 (84%), injected insulin more than twice per day and ≥50% used the same needle more than six times for more than 3 days. The majority, 150/153 (98%), of the syringe users recapped the needle. A significant number, 73/158 (46%), also involved others when injecting and disposing needles. Patients disposed of used needles/pens in a common household garbage bin, sharps container, toilet pit, garbage dump, and indiscriminately: 66 (42%), 9 (6%), 8 (5%), 4 (8%), 11 (7%), respectively. Some have collected sharps since the beginning without disposing: 15/158 (9.5%). Many respondents had received no information on how to dispose of their sharps. Those who recalled receiving information were more likely to dispose of their sharps safely.

Conclusion:

Diabetes patients who are insulin dependent are not educated on safe sharps disposal methods, leading to unsafe disposal of needles. Appropriate education on the correct disposal of sharps should be an integral part of their diabetes counseling.

Gold-Accu Blood Glucose Monitoring System: Novel 180-Degree Sampling Technology with Hospital-Grade Performance

Xiaohua Cai, PhD; Hongli Che, MD; Jiangfeng Fei, PhD

Sinocare Inc.
Changsha, Hunan, China
caixh@sinocare.com

Objective:

These studies aim to show that the performance of the next-generation Gold-Accu Glucose Monitoring System meets ISO 15197:2013 standards and hospital needs.

Method:

The Gold-Accu Glucose Monitoring System uses FAD-GDH (flavin adenine dinucleotide-glucose dehydrogenase) and a mediator for its test strips in conjunction with a handheld meter. Blood glucose (BG) concentration was measured from amperometric signal. Accuracy, stability, and interference studies were conducted with real human blood samples, and the YSI was used as the reference analyzer.

Results:

The newly innovated Gold-Accu BG testing strip combines the advantage of novel design, gold electrode material, and special formulation techniques to provide best-in-class results. The accuracy study showed compliance with ISO 15197:2013 standards: 99.8% of data points were within ±15 mg/dl when BG ≤100 mg/dl, 98.1% of data points were within ±15% when BG >100 mg/dl, and 100% were within the A zone of the consensus error grid. The stability study demonstrated that the strips are stable when exposed to high humidity (83% RH, 30 â„ƒ, open vials) for at least 6 days and high temperature (50 â„ƒ) for at least 4 weeks. The interference studies showed no effects from hematocrit (20–70% Hct), oxygen, and other major interferents that can be found in blood.

On top of the excellent performance, the unique design of the strip provides user-friendly multiple sampling angles. The users can take their blood sample from any point of the front, left corner, right corner, as well as the bottom of the strip. Such a feature is extremely important for sampling complication, which usually causes erratic test results.

Conclusion:

With the unique over-180-degree sampling feature, the Gold-Accu has demonstrated reliable hospital-grade accuracy, stability performance, and resistance to interferents.

Hyperglycemia Contributes to Surgical Site Infections in Colorectal Surgery

Joy Chen, MD; Yifei Ma, MS; Bruce Allen, MD; Kimberly Rhoads, MD

Department of Colorectal Surgery
Stanford University
Stanford, California, USA
joycc@stanford.edu

Objective:

The aim was to identify actionable predictors of surgical site infections (SSI) after colorectal surgery.

Method:

The Northern California Surgical Quality Collaborative (NCSQC) is a consortium of five hospitals participating in National Surgical Quality Improvement Project (NSQIP) targeted data collection on all colorectal operations performed from July 2011 to December 2013. Data were aggregated from the standard NSQIP data set and a 22-item supplemental questionnaire including patient characteristics (age, race, obesity, ASA class, diabetes, smoking, elective vs emergent operation, wound class; and history of cancer, immunosuppression or inflammatory bowel disease). The data set also includes practice-related variables (quality of bowel preparation, preoperative oral antibiotic use, stapled vs hand-sewn anastomosis, low rectal anastomosis, proximal diversion, wound closure technique, surgeon volume, and laparoscopic vs open approach).

Primary outcomes measured were number and type of SSI (superficial, deep, organ space, or any SSI) within 30 days. Poisson regression analysis estimated SSI prevalence rate ratios (PR) as a function of patient and practice level covariates. $P < 0.05$ and $PR \neq 1$ defined significance.

Results:

There were 1712 patients undergoing colorectal operations. Patient and practice characteristics varied across settings. Overall rate of SSI was 9.4%, including superficial (3.8%), deep (<1%) and organ space (5.3%). In Poisson regression models, the practice variables associated with any SSI included laparoscopy (PR 0.66, $p = 0.007$) and increasing perioperative glucose (PR 1.04, $p < 0.001$). A receiver operating characteristic curve was generated to understand the limits of the relationship between perioperative glucose and SSI. It showed a sharply increasing prevalence of SSI with glucose above 166 mg/dl.

Conclusion:

Hyperglycemia appears to have a strong association with SSI after colectomy. It may be more important than bowel preparation, oral antibiotics, and other commonly suggested contributors. Importantly, unlike many patient factors, it is actionable. Improved recognition and treatment of perioperative hyperglycemia may decrease the rate of SSI.

Continuous Glucose Monitoring Compared with Point-of-Care Testing in Hospitalized Type 2 Diabetes Patients on Basal–Bolus Insulin Therapy

Klaus Donsa, MSc; Lukas Schaupp, PhD; Katharina M. Neubauer, MSc;
Julia K. Mader, MD; Bernhard Höll, MSc; Stephan Spat, MSc; Peter Beck, PhD;
Johannes Plank, MD; Thomas R. Pieber, MD

Joanneum Research GmbH
HEALTH–Institute for Biomedicine and Health Sciences
Graz, Austria
klaus.donsa@joanneum.at

Objective:

Glycemic management in the hospital is based on glucose point-of-care testing (POCT) which lacks continuous information particularly in detecting low glycemia (hypoglycemic) events. The aim of this study was to analyze and compare the capability to detect hypo- (<70 mg/dl) and hyperglycemic (>250 mg/dl) episodes with either standard blood glucose (BG) POCT or continuous glucose monitoring (CGM) in hospitalized type 2 diabetes patients on basal–bolus insulin therapy.

Method:

Eighty-four patients (age 68 ± 10 years, hemoglobin A1c 72 ± 28 mmol/mol and body mass index 31 ± 7 kg/m^2) were treated with an algorithm driven basal–bolus insulin therapy based on four daily BG measurements (pre-meal and bedtime). Blinded CGM was performed with the iPro2 system (Medtronic MiniMed) and calibrated retrospectively. The incidence of hypo- and hyperglycemic episodes was analyzed for different times of the day. Hypo- and hyperglycemic episodes were defined as at least three consecutive CGM readings below or above a given threshold.

Results:

A total of 140,424 CGM and 2066 BG measurement values were analyzed. During the night (00:00-06:00), the number of hypo- and hyperglycemic episodes detected with CGM was 8.1 (<70 mg/dl) and 12.5 (>250 mg/dl) times higher than the number of episodes detected with BG measurements. During daytime, this difference was less pronounced. Most episodes <70 mg/dl occurred during the night, whereas most episodes >250 mg/dl were recorded during daytime. There were very low numbers of hypoglycemic episodes <50 mg/dl (CGM: $n = 8$; BG: $n = 3$).

Conclusion:

Standard BG POCT does not detect a substantial number of hypo- and hyperglycemic episodes, in particular during the night, if only bedtime glucose is measured. In such a setting, CGM could add important information for glycemic management.

Continuous, Noninvasive Glucose Monitoring with a Novel Technique

Rinat O. Esenaliev, PhD

Glucowave, Inc.
League City, Texas, USA
riesenal1@hotmail.com

Objective:

Continuous blood glucose (BG) monitoring is necessary for people with diabetes and hospital patients (both with and without diabetes). We proposed and patented a novel approach to continuous, noninvasive glucose monitoring. It is based on high-resolution ultrasound and utilizes detection of ultrasound signals from tissues, including skin.

Method:

We developed and built a novel, high resolution, lightweight, highly compact ultrasound system with specially designed probes and performed clinical tests of the system in subjects with and without diabetes. Oral glucose tolerance test and meal intake were used to increase BG concentration, which was measured with standard, invasive BG meters to provide reference values.

Results:

The ultrasound signals were recorded from the wrist area and used for system calibration at the beginning of the study and for BG concentration prediction during the study. After calibration, the system provided real-time, continuous, noninvasive BG concentrations for several hours. The noninvasive BG concentration closely followed the reference BG concentration during the increase and decrease of BG concentration in the 64–320 mg/dl range. Accuracy of BG concentration measurements with the ultrasound-based system is approaching that of the standard BG meters.

Conclusion:

The obtained results suggest that the proposed approach may provide continuous, noninvasive BG monitoring in people with diabetes and hospital patients.

First Nine Years Follow-Up of Autologous Stem Cell Implants in Patients with Type 2 Diabetes (Results of the Original Technique)

Roberto Fernandez Viña, MD; Jorge Saslavsky, MD; Francisco Vrsalovic, MD;
Liliana Camozzi, PhD; Janaina Ferreira Da Silva, MD;
Oberdan Andrin, MD; Federico Fernandez Viña, MD

Maimonides University & Fernandez Viña Foundation
Cells Therapy and Interventional Cardiology, San Nicolas, Argentina
robertofernandezvina@hotmail.com

Background and Aim:

Adult stem cells CD34(+)CD38(-) have demonstrated the capacity to differentiate in functional cells of an endocrine pancreas. In 2005, the first implant of stem cells in the pancreas of type 2 diabetes patients was performed using an original technique. Our aim is to evaluate the long-term performance of the stem cell implants after 9 years.

Method:

In 2005, our group reported the first implant in the world of AAS Cells by selective catheterization of spleen artery. After 9 years of follow-up on cell therapy for diabetes patients, the results are optimistic. In this study, we observed the progress of 42 patients with type 2 diabetes: 30 male/12 female, 31–71 years old. Twenty-six patients were under insulin therapy, and 26 patients used sulfonylureas + biguanides.

For the transplantation, bone marrow was harvested from the iliac crest by aspiration. The sample was processed using a density gradient separation method. 120 ml (±95) of CD34(+)CD38(-) solution was obtained.

The implants were performed by catheterization through spleen artery. No complications or further events were observed during the procedure.

Results:

The patients were subjected to clinical and blood samples control during the 9 years with intervals of 2 months after the implant:

- C Peptide (ng/ml): before implant 1.18; 6 months 1.17; 36 months 2.19; increment 48.42%
- C-Peptide after meal (ng/ml): before implant 2.22, 6 months 2.95, 36 months 4.40, increment 95.52% ($p = 0.0036$)
- HBC1: 9.14 basal, 8.25 at 6 months, 6.35 at 36 months, decrement 21.25% ($p = 0.003$)
- Insulin basal 12.33 (mU/ml), 6 months 15.27, 36 months 15.02, increment 25.26%
- Insulin after meal 19.11 (mU/ml), 6 months 15.27, 36 months 34.7, increment 58.75% ($p = 0.016$)

(continued)

- Pills per day: 2.25 before implant, after 36 months 0.33, decrement of use 44.36% ($p = 0.0007$)
- Insulin dose (IU/day): basal 50.59, after 36 months 9.55, decrement 89.03% ($p = 0.037$)

These general results were maintained for 9 years. No deaths, cancer, peripheral vascular disease complications, or leg or finger amputations have been reported.

Conclusion:

The implant of mononuclear CD34(+)CD38(-) stem cells from autologous bone marrow improved pancreatic function in patients with type 2 diabetes in a safe manner and has been maintained for at least 9 years without major complications.

A Study Comparing the Accuracy of a Continuous Glucose Monitoring Device to Finger Stick Blood Glucose Levels among Pediatric Intensive Care Patients in Diabetic Ketoacidosis

Shantaveer Gangu, MD; Cynthia Tinsley, MD; Shamel Abd-Allah, MD
Loma Linda University Children's Hospital
Loma Linda, California, USA
Sgangu@llu.edu

Objective:

Our aim was to compare the accuracy of a continuous glucose monitoring (CGM) device to glucose values obtained by the finger stick blood glucose (FSBG) method in patients with diabetes mellitus (DM) with diabetic ketoacidosis (DKA) admitted to the Pediatric Intensive Care Unit (PICU) at Loma Linda University Children's Hospital (LLUCH).

Method:

We enrolled 17 children, aged 7–17 years, with DM and DKA undergoing treatment in our PICU. After informed consent was obtained, a CGM sensor was inserted subcutaneously under aseptic conditions and device calibrated. Continuous interstitial glucose levels were recorded as long as the patient was on insulin drip for DKA treatment. The decision to treat was made by the FSBG values as part of the current PICU guidelines. The CGM was disconnected at the end of DKA treatment.

Results:

We compared the values of both FSBG and CGM for a total of 103 paired measurements. SPSS software was used for statistical analysis. FSBG and CGM values had a correlation of 0.682 ($p < 0.0001$) with overall mean absolute difference of 24.2 mg/dl and mean absolute relative difference of 20%. Clarke error grid analysis was used to compare the accuracy of both measurements with 96% of glucose recordings falling in zones A and B.

Conclusion:

Continuous glucose monitoring has the potential to provide better assessment of patient BG trending during DKA treatment. It can also reduce the number of painful finger sticks in these patients by more than 50%, which will improve patient sleep quality in ICU with less nursing workload.

Inpatient Hypoglycemia: Technology-Aided Education

E. Dessa Garnett, MSN, FNP-BC, CDE; Donna L. Jornsay, CPNP, CDE, CDTC; Lisa Rosen, ScM

Long Island Jewish Medical Center
New Hyde Park, New York, USA
dgarnett@nshs.edu

Objective:

Potential consequences of inpatient hypoglycemia include increased morbidity, mortality, length of stay, and readmissions and decreased reimbursement. Few guidelines exist that identify a target blood glucose threshold for ending hypoglycemia treatment. Nurses generally do not recognize or treat hypoglycemia uniformly. In this study, QR bar code technology was utilized to administer pre- and post-tests of staff's current practice regarding hypoglycemia recognition, assessment, treatment, and recurrence prevention.

Method:

A five-question online survey was developed and linked to a QR barcode, which allowed staff to complete the survey from virtually anywhere via cell phone, tablet, or computer. A total of 153 pre-tests and 127 post-tests were included. Duplications and incomplete responses were excluded. Once pre-test survey collection was completed, researchers used an interactive method of educating staff with Turning Point clicker technology.

Results:

The pre to post test comparison of correct answers for the first four questions reached statistical significance. Question five on frequency of insulin corrections had borderline significance. Staff responses during our recently acquired Joint Commission (JC) Advanced Inpatient Diabetes Certification survey demonstrated the effectiveness of this education.

Conclusion:

Inpatient nurses' receptivity to learning about hypoglycemia was enhanced by using technology. Multidisciplinary staff education is needed to recognize and treat hypoglycemia uniformly to an established target. These measures are instrumental in achieving JC Advanced Inpatient Diabetes Certification and necessary to decrease overall inpatient hypoglycemia occurrence and recurrence.

Currently underway is an analysis of RALS data to determine the relationship between knowledge of when to retest blood glucose and actual practice. Also, an online hypoglycemia education module for health care professionals is in development.

Usability of a Computerized Intravenous Insulin Application, Auto*Cal,* in the Management of Diabetic Ketoacidosis in a Medical–Surgical Unit

Harry Glauber, MD; Christine Olinghouse, MSN, FNP-BC, CDE, BC-ADM;
Karen Mularski, MD; Seema Kapadia-Steel, DO

Kaiser Permanente Sunnyside Hospital
Portland, Oregon, USA
harry.glauber@kp.org

Objective:

Admissions for diabetic ketoacidosis (DKA) in patients with known diabetes mellitus (DM) have dramatically increased in the past 10 years. The aim of this audit was to evaluate the outcome of patients admitted to a general ward using a computerized intravenous (IV) insulin application where the patient to nurse ratio is five to one. The familiar computerized program, Auto*Cal,* has already proven safe and efficacious for medical surgical patients with hyperglycemia.

Method:

A review was conducted of 40 cases treated in 2013 for DKA/hyperosmolar hyperglycemic state at Kaiser Permanente Sunnyside Medical Center using the automated IV insulin application Auto*Cal*. Auto*Cal* is a software application for a column-based protocol with adjustable rates of insulin based on blood glucose. Fluid resuscitation choices were not part of the computerized protocol, but were guided by suggestions in an electronic medical record order set.

Results:

There was no difference in the rate of resolution for patients in intensive care units (ICU) versus non-ICU. Auto*Cal* safely corrected hyperglycemia and resolved anion gap without occurrence of hypoglycemia. Average time to correction of hyperglycemia in patients with type 1 DM was 223 min (3.7 h) and 339 min (5.6 h) in type 2 DM. The average rate of fall of glucose per hour to <250 mg/dl in patients with type 1 DM was 94.3 mg/dl/h and 62 mg/dl/h in type 2 DM. The time to normalization of the anion gap in patients with type 1 DM was 10.5 h and 12.3 h in type 2 DM. Mild hypokalemia was common, but significant hypokalemia did not occur.

Conclusion:

Insulin titration in DKA can be safely managed in a non-ICU setting using a computerized column-based protocol without increased nursing workload.

Clinical Impact of Accurate Glucose Monitoring for Tight Glycemic Control in Severely Burned Children

Zachary R. Godwin, BS; Nam K. Tran, PhD, MS, FACB;
Amanda N. Steele, BS; Kelly M. Lima, BS; Charles Wade, PhD;
Steven Wolf, MD; Tina L. Palmieri, MD, FACS, FCCM

University of California Davis
Davis, California, USA
zgod89@gmail.com

Objective:

Intensive insulin therapy (IIT) for tight glycemic control (TGC) using an accurate blood glucose monitoring system (BGMS) in severely burned patients improves outcome by decreasing mortality and infection rates. BGMS inaccuracy is caused by endogenous and exogenous confounding factors including abnormal hematocrit and routine medications. Advances in biosensor technology has enabled the development of BGMSs that autocorrect for these confounding factors. The goal of this study is to evaluate the clinical impact of an autocorrecting BGMS in severely burned pediatric patients.

Method:

We conducted a retrospective study comparing a non-correcting BGMS (BGMS-1) (n = 63) against an autocorrecting BGMS (BGMS-2)(n = 33) in 96 children (age <18 years) with severe burns [≥20% total body surface area (TBSA)]. Patient demographics, glucose meter accuracy, mean insulin rates, frequency of hypoglycemic events, and glycemic variability were compared between the groups.

Results:

Patient demographics were similar between groups. BGMS-1 results differed significantly from central laboratory results with a mean (SD) bias of [6.2 (15.5), n = 535 measurements, $P < 0.001$] while BGMS-2 results did not [-2.1 (7.2), n = 381 measurements, $P = 0.252$]. Mean insulin infusion rates were significantly higher in the BGMS-1 group [5.1 (3.8) U/h, n = 535 vs 2.1 (1.5) U/h, n = 381, $P < 0.001$]. More patients in the BGMS-1 group (41.2%, $p < 0.001$) experienced at least one hypoglycemic event versus the BGMS-2 group (12.1%).

Glycemic variability was significantly higher in the BGMS-1 group and was predictive of mortality when controlled for age, TBSA, and inhalation injury (odds ratio 1.05, 95% confidence interval 1.0 – 1.12, $P = 0.021$).

Conclusion:

The use of an accurate autocorrecting BGMS optimizes IIT, improves TGC, and reduces risk for hypoglycemia and glycemic variability, potentially improving outcomes.

Challenges of Using a Pediatric Insulin Pump in a Low-Birth-Weight Neonate with Diabetes

Nuala Harkin, GCDEM, GDICHC; Kim Donaghue, MBBS, PhD, FRACP;
Anna Pham, BSc, GCDEM

Nuala Harkin, The Children's Hospital at Westmead
Westmead, Australia
nuala.harkin@health.nsw.gov.au

Objective:

To initiate continuous subcutaneous insulin infusion (CSII) in a 1.9kg (-2.97 z-score) term baby where intravenous insulin infusion and subcutaneous insulin produced dangerous and unacceptable glucose levels. This study aims to determine the starting dose of insulin and appropriate infusion set, suitable hypoglycemia management and achieve catch-up.

Method:

CSII commenced on day 14 of life. Starting insulin dose was 0.5 units/kg/day (1 unit/day). Insulin aspart was diluted with normal saline to 1:5. Cannula insertion sites were sparse due to limited subcutaneous fat. Bottle feeds were initiated at 1.3 concentration and given 2–3 hourly with no pre-feed boluses. Growth was monitored weekly aiming for ~150–200 g/week. Hypoglycemia was treated at <3.5 mmol/liter by 7 g of carbohydrates provided from 15 ml glucose polymer solution. The child was discharged at 5 weeks and parents were taught set changes and insulin dilution prior.

Results:

One mild hypoglycemic event of 3.2 mmol/liter was noted and treated with good effect. Cannula choice was limited with two breakages that resulted in silica remaining in buttocks. Pre-feed boluses (1 unit per 50 g carbohydrates) started on day 7. Feeds remained at 1.3 concentration up to 200 kcal/kg and 200 ml/kg/day. Weight gain was initially slow, averaging 135 g/week. Weight standard deviations improved from -3.65 at 1 month to -1.73 at 3 months, averaging 261 g/week. CSII insulin requirements gradually reduced and ceased at 3 months.

Conclusion:

The management of neonatal diabetes is complex due to the very small insulin dose requirements and paucity of subcutaneous fat. In our experience, CSII using diluted insulin is safe and achieved close-to-target blood glucose levels and fewer hypoglycemic events than Lantus insulin or insulin infusion. Added calories and within-target blood glucose levels are required for adequate growth. The low birth weight was consistent with the genotype 6q24 transient neonatal diabetes.

Use of the eGlycemic Management System by Glytec Achieves Glucose Targets Safely for Pediatric Diabetic Ketoacidotic Patients

Amy B. Henderson, RN, BSN; Harry Hebblewhite, MS; Raymie S. McFarland, PT, BS; Robby Booth, BS; Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP

Glytec
Greenville, South Carolina, USA
ahenderson@glytecsystems.com

Objective:

Diabetic ketoacidosis (DKA) occurs in up to 40% of children with new-onset diabetes mellitus and in children with existing diabetes who develop infection or who have missed insulin doses. DKA is a true medical emergency, carrying significant risk of mortality. The pediatric patient has many unique treatment requirements. Very little data is available on the treatment of pediatric DKA with the eGlycemic Management System™ (eGMS). This study evaluates the safety and efficacy of glucose control for pediatric DKA patients using the Glucommander (GM) for dosing.

Method:

The study evaluated 172 pediatric DKA (by ICD-9) patients treated with intravenous (IV) insulin therapy using GM. Qualifying pediatric DKA patients followed hospital protocol for fluid management and GM for IV insulin management. Glucose target range was set at 90–140 mg/dl. The safety and efficacy was evaluated by the following: (1) blood glucose (BG) average; (2) hypoglycemic events <40 mg/dl and <70 mg/dl; (3) time to target; (4) average glucose change velocity; and (5) percentage of glucose drop <100 mg/dl/h.

Results:

Initial BG average was 345 mg/dl (minimum 63 mg/dl and maximum 1186 mg/dl). Pediatric patients' average overall BG was 172 mg/dl. The average BG after target was reached was 123 mg/dl. Hypoglycemia <70 mg/dl was 1.6% and no BGs were <40 mg/dl. Average time to target was 11 h with an average glucose velocity drop of 20 mg/dl/h. 95% of glucose velocity drops were <89.8 mg/dl.

Conclusion:

Pediatric DKA patients using GM IV insulin therapy achieved a safe time-to-target glucose velocity drop with a very low incidence of hypoglycemia (<70 mg/dl) and no severe hypoglycemia <40 mg/dl. Glucose velocity brought levels down safely while target glucose was reached.

Maintaining Glycemic Control: Pharmacy Protocol for the Transition of Intravenous Insulin Infusion to Subcutaneous Insulin

Lynn Hendrick, PharmD; Dave Kanyer, RPh

Community Hospital of the Monterey Peninsula
Monterey, California, USA
Lynn.Hendrick@chomp.org

Objective:

The Community Hospital of the Monterey Peninsula's multidisciplinary inpatient diabetes team developed a pharmacy protocol (PP) for standardizing the conversion of patients receiving intravenous insulin infusion to subcutaneous insulin in 2011. The purpose of this study was to compare the ability to maintain glycemic control between the PP and physician-directed transitions (PDTs) from intravenous (IV) insulin to subcutaneous (SubQ) insulin regimens.

Method:

This was a retrospective chart review from June 2011 through December 2014 of patients transitioned from IV insulin infusion to SubQ insulin, comparing the PP with PDTs. Data in the first 24 h following transition was compared between the two groups with respect to the average blood glucose (BG) readings and the percentages of BG readings less than 70 mg/dl (hypoglycemia) and above 250 mg/dl (severe hyperglycemia).

Results:

Patients had better glycemic control in the PP group (n = 297) as compared with PDTs (n = 162) over the 3.5-year period. Patients in the PP group had lower average BG (174 mg/dl) versus the PDT group (200 mg/dl). In the PP group, there were 27 occurrences of hypoglycemia in the 297 patients (8%) whereas in the PDT group, there were 8 occurrences in the 162 patients (4.9%). Severe hyperglycemia, defined as BG >250 mg/dl, was higher in the PDT group versus the PP group (22% versus 13%).

Conclusion:

The pharmacy protocol for transition was more effective in achieving glycemic control than PDTs in the first 24 h, with few hypoglycemic events. This protocol has continued to show consistent results for 3.5 years.

Normalization of Blood Glucose Levels following Islet Cell Transplantation for Unstable Type 1 Diabetes Mellitus

Kathy Howe, CDE; Glenn Ward, DPhil; David Goodman, MD; Richard MacIsaac, PhD

St Vincent's Hospital
Fitzroy, Victoria, Australia
kathy.howe@svhm.org.au

Background:

Islet Transplantation (ITx) is a treatment option for people with type 1 diabetes mellitus (T1DM), recurrent hypoglycemia, and hypoglycemia unawareness.

Our patient is a 68-year-old female diagnosed with T1DM at the age of 18 months. She was referred to the Islet clinic in May 2005 complaining of recurrent severe hypoglycemic episodes, often relying on family members to recognize and treat hypoglycemia. This was despite adhering to the insulin pump regimen by her endocrinologist and performing blood glucose testing up to 10 times a day. Her total daily dose of insulin was 35 u/day and her hypoglycemia severity score was 2163 (Ryan). A score above >1000 indicates severe hypoglycemia. Her hemoglobin A1c was 7.5% and her C-peptide was undetectable.

Method and Results:

Over a 6-month period, we attempted to fine-tune her glycemic control. A 3-day continuous glucose monitoring system (CGMS) was performed to validate her glycemic lability. This showed mean glucose (MG) of 8.0 mmol/liter with glycemic variability as measured by standard deviation (SD) of 4.0 mmol/liter and glucose readings 16% within range of 3.9–7.8 mmol/liter. Unfortunately, her glycemic control did not change and she was listed for ITx.

In March 2009, she received her first ITx followed by a second ITx in September 2009. She became insulin independent on January 21, 2010. After 5 years, she remains free from hypoglycemia. Her hemoglobin A1c is 6.0%, C-peptide 0.84 mmol/liter, with a fasting glucose of 7.3 mmol/liter.

A repeat CGMS shows normalization of blood glucose without exogenous insulin (MG = 6.1 mmol/liter, SD = 0.6 mmol/liter) and glucose readings 100% within range of 3.9–7.8 mmol/liter. ITx is not without risks due to the procedure and the ongoing need for immunosuppressive therapy.

Conclusion:

Our case demonstrates that for selected patients who suffer severe and recurrent hypoglycemic episodes, blood glucose can be normalized. In our patient's own words, “This is a life-changing procedure.”

An Ex Vivo Automated Blood Glucose Monitoring System for Critical Care Settings

Kislaya Kunjan, MSME, MBA; Frank P. Lloyd, Jr., MD, FACS;
David T. Giddings, BA, MBA

Cascade Metrix, Inc.
Indianapolis, Indiana, USA
kkunjan@cascademetrix.com

Objective:

Automated/continuous blood glucose monitoring can effectively support truly tight glycemic control (TGC) in critical care settings. We describe the design and evaluation of an ex vivo intravenous (IV) patient-attached automated blood sampling system integrated with a laboratory quality reusable glucose sensor to enable TGC.

Method:

The automated glucose monitoring system (AGMS) comprises a pole-mountable miniature instrument console and a sterile disposable set. The disposable set is patient-dedicated and has a 72-hour life. It is made up of a customized micro-bore tube-set incorporating a novel zero dead volume luer adapter to attach to a 22-gauge IV catheter, an electrochemical flow-through glucose sensor, and a fluid pack. At each clinician-programmed measurement interval, the system performs the steps of: calibrating the sensor, drawing blood out from the patient, measuring/displaying the blood glucose concentration, and safely re-infusing the bulk of the blood back into the patient using normal saline, all in less than 1 minute. The system is fully automated and requires no infusion of heparin or any calibrant into the patient.

Results:

We evaluated the performance of the device using spiked samples across the dynamic glucose range of 30–500 mg/dl and found the mean absolute error to be 2.6%, with an $R = 0.998$. In the current embodiment, the blood loss per measurement is 0.2 ml, although this is expected to be brought down to 0.05 ml in the next design iteration.

Conclusion:

It is expected that the AGMS will seamlessly reduce hypoglycemia, glycemic variability, and nursing work burden, and become a cornerstone of safe and cost-effective glucose control. The product platform can also be readily adapted to measure lactate and other blood analytes of interest in critical care.

Analysis of Protocol-Based Post-Transplant Diabetes Mellitus Management in Hospitalized Patients Using Glucometrics

Om J. Lakhani, MD; Surender Kumar, MD, DM; Mitali Desai, MD;
Ashutosh Goyal, MD

Department of Endocrinology
Ganga Ram Institute of Postgraduate Medical Education & Research
New Delhi, India
omlakhani@yahoo.com

Objective:

Management of post-transplant diabetes mellitus involves two major challenges. On one hand, good glycemic control is required to maintain graft survival and, on the other hand, immunosuppressants such as tacrolimus and glucocorticoids have significant impact on the glycemic control. We use a strict protocol-based management of glycemia in post-transplant patients who are hospitalized. The objective of this study was to assess the quality of glycemic care in post-transplant patients using glucometrics.

Method:

This was a retrospective study where we collected the blood glucose (BG) records of 10 patients with post-transplant diabetes mellitus who were hospitalized and whose glycemia we managed using a protocol developed by the Endocrinology Department of our institute. Our protocol incorporates the possible effects of tacrolimus and glucocorticoids on BG levels. The 'patient stay' method of glucometrics was used to analyze the data. The results were compared with controls. Student's *t* test was used for statistical analysis. *P* value of < 0.05 was considered significant.

Results:

Five patients were post-renal-transplant patients, while five patients were post-liver transplant. Tacrolimus and prednisolone were used as immunosuppressants in all post-transplant patients. Mean pre-meal BG was 171 ± 32.9 mg/dl and mean bedtime BG was 196 ± 36.9 mg/dl. A total of 34.8% of pre-meal BG readings were in the target range of 100–140 mg/dl. Hypoglycemia (defined as BG <70 mg/dl) was noted in 0.19% readings while severe hyperglycemia (defined as BG >300 mg/dl) was noted in 3% of readings. Post-transplant patients had less severe hyperglycemia as compared to control patients ($p < 0.05$). No statistically significant difference was noted in other parameters in the post-transplant group when compared with controls.

Conclusion:

Good glycemic control can be achieved in post-transplant patients with protocol-based diabetes management.

Determinants of Basal Insulin Dose in Hospitalized Non-Critical Patients

Om J Lakhani, MD; Surender Kumar, MD, DM; Sudhir Tripathi, MD, DM;
Mitali Desai, MD; Ashutosh Goyal, MD; Sarifulla Sarafat, MD

Department of Endocrinology
Ganga Ram Institute of Postgraduate Medical Education & Research
New Delhi, India
omlakhani@yahoo.com

Objective:

Basal insulin is the cornerstone of diabetes management in hospitalized patients. The objective of the study was to analyze what determines the optimal basal insulin dose in hospitalized non-critical patients.

Method:

This was a retrospective study. The study included 180 diabetes patients on basal–bolus insulin therapy, with stable morning fasting blood glucose, and in the target range of 70–140 mg/dl for at least three consecutive days. Basal insulin glargine was used in all patients. The data collected for these patients included age, sex, current hemoglobin A1c (HbA1c), timing of basal insulin, basal insulin dose, basal insulin dose/weight, body mass index (BMI), and eGFR (estimated glomerular filtration rate). Basal insulin dose (BDose) and basal insulin dose/weight (BIDose/wt) were correlated with other parameters using regression analysis (Pearson's). Additionally, difference in BIDose/wt in various subgroups were analyzed using Student's *t* test. *P* value < 0.05 was considered as significant.

Results:

We found statistically significant correlation between BDose and Hba1c ($p = 0.021$) and BIDose/wt and HBa1c ($p = 0.044$). No significant correlation was found between BDose and BIDose/wt when compared with age, eGFR, and timing of basal insulin. When specific subgroup analysis were performed, BIDose/wt was significantly higher in patients with HbA1c ≥8.0% with mean value of 0.44 ± 0.08 U/kg compared with those with HbA1c <8.0% with mean value of 0.28 ± 0.11 U/kg ($p = 0.004$). BIDose/wt was higher in patients with chronic renal failure (CRF) (eGFR <60 ml/min/1.73 m^2) compared to those without CRF ($p = 0.013$). No statistically significant difference in BIDose/wt was found in the obese versus non-obese.

Conclusion:

Hemoglobin A1c is the most important parameter for basal insulin dose in hospitalized patients. Patients with CRF require a higher dose of basal insulin. Age, BMI, and timing of basal insulin have little impact on basal insulin dose.

Use of the eGlycemic Management System by Glytec Produces Less Hypoglycemia for Patients Managed on Subcutaneous Insulin Therapy

Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP; Joseph Aloi, MD;
Paul Chidester, MD; Amy B. Henderson, RN, BSN;
Raymie S. McFarland, PT, BS; Robby Booth, BS

Glytec
Greenville, South Carolina, USA
mmabrey@glytecsystems.com

Objective:

American Diabetes Association guidelines recommend a basal–bolus correction insulin regimen as the preferred method of treatment for non-critically ill hospitalized patients. The targets for pre-meal blood glucose (BG) of <140 mg/dl and random BG of <180 mg/dl are well defined. However, achieving these targets safely, without hypoglycemia, is challenging. In this study, we evaluated BG control before and after Glucommander Subcutaneous (GM SubQ) treatment for patients outside of the intensive care unit (ICU).

Method:

We evaluated 2240 non-ICU patients treated with subcutaneous insulin therapy, as directed by the provider, followed by insulin therapy directed by GM SubQ at 9 different hospitals. We compared therapy outcomes before Glucommander (BGM) and during GM (DGM) for all patients. After GM (AGM) was included if GM was stopped prior to discharge. GM BG target was set at 140–180 mg/dl for all groups. The safety of each was evaluated by the following: (1) BG average and (2) hypoglycemic events <70 mg/dl.

Results:

Patients BGM BG average was 237 mg/dl, DGM BG average was 172 mg/dl, and AGM was 187 mg/dl. Percentage of hypoglycemic events <70 mg/dl was 2.1% BGM, 1.1% DGM, and 3.3% AGM treatment. Patients averaged 5 glucose tests before Glucommander was initiated. Patients had an average of 18 glucose tests after treatment with GM. Duration of therapy BGM was 1.2 days, DGM 4.5 days, and AGM 4.2 days.

Conclusion:

Patients using GM SubQ achieved improved glycemic control with lower incidence of hypoglycemia (<70 mg/dl) compared with both before and after GM management. These results suggest that GM can safely maintain BG control with less hypoglycemia than standard basal–bolus treatment.

Use of the eGlycemic Management System by Glytec Achieved ADA Glycemic Targets with Low Incidence of Hypoglycemia for Patients Managed on Subcutaneous Insulin Therapy

Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP; Joseph Aloi, MD; Paul Chidester, MD; Jagdeesh Ullal, MD, MS; Amy B. Henderson, RN, BSN; Raymie S. McFarland, PT, BS; Robby Booth, BS

Glytec
Greenville, South Carolina, USA
mmabrey@glytecsystems.com

Objective:

American Diabetes Association (ADA) guidelines recommend a basal–bolus correction insulin regimen as the preferred method of treatment for non-critically ill hospitalized patients. The target for pre-meal blood glucose (BG) of <140 mg/dl and random BG of <180 mg/dl are well defined. However, achieving these targets safely, without hypoglycemia, is challenging. With this study, we evaluated BG control fasting at each meal for patients using Glucommander Subcutaneous (GM SubQ) treatment for insulin therapy.

Method:

We evaluated 769 patients treated with GM SubQ insulin therapy. Qualifying patients had two BGs >180 mg/dl in 24 h and required insulin. The target BG was set at 100–140 mg/dl fasting and pre-prandial. The safety and efficacy was evaluated at time points: before each meal (breakfast, lunch, dinner) and at bedtime via (1) BG averages, (2) BG reductions, and (3) hypoglycemic events <70 mg/dl and <40 mg/dl.

Results:

Patients treated on GM SubQ achieved an average pre-prandial BG of 120 mg/dl at breakfast, 121 mg/dl at lunch, 120 mg/dl at dinner, and 120 mg/dl at bedtime. Initial BG average was 227 mg/dl. Blood glucose average over length of stay was 132 mg/dl. Reduction of BG was 84 mg/dl at breakfast, 106 mg/dl at lunch, 100 mg/dl at dinner, and 105 mg/dl at bedtime. Average BG reduction was 98.75 mg/dl. Percentage of hypoglycemia <70 mg/dl was 2.3% at breakfast, 1.9% at lunch, 3.0% at dinner, and 2.0% at bedtime. Percentage of hypoglycemia <40 mg/dl was 0.0% at breakfast, 0.1% at lunch, 0.1% at dinner, and 0.1% at bedtime.

Conclusion:

Patients using GM SubQ achieved prescribed glycemic targets at each meal and bedtime with low incidence of hypoglycemia (<70 mg/dl and <40 mg/dl). These results suggest that GM SubQ can maintain glucose control within ADA recommended targets without increased risk of hypoglycemia.

Use of the eGlycemic Management Systems by Glytec to Identify, Treat and Improve Glycemic Care for Patients with Congestive Heart Failure

Melanie Mabrey, DNP, ACNP-BC, BC-ADM, FAANP; Joseph Aloi, MD; Paul Chidester, MD; Jagdeesh Ullal, MD, MS; Amy B. Henderson, RN, BSN; Raymie S. McFarland, PT, BS; Robby Booth, BS

Glytec
Greenville, South Carolina, USA
mmabrey@glytecsystems.com

Objective:

Patients with multiple chronic conditions have more hospital admissions. Patients with congestive heart failure (CHF) admitted to the hospital have very high rates of diabetes or hyperglycemia. Congestive heart failure has been included in multiple CMS measures from readmissions to mortality. This study sought to discover if the Glucommander (GM) surveillance system can find, treat, and improve glycemic conditions for CHF patients in the hospital.

Method:

The study reviewed 261 patients who were identified by GM surveillance as having two blood glucose (BG) values >180 mg/dl in a 24 h timeframe. Patients started on GM (intravenous) IV and transitioned from IV to subcutaneous (SubQ) using GM recommendations and then continued on GM SubQ, all with a target of 140–180 mg/dl. The safety and efficacy for glucose outcomes were evaluated including: (1) average BG, (2) reduction of initial BG to target, (3) hypoglycemia <40 mg/dl and <70 mg/dl, (4) percentage in prescribed target range.

Results:

Average BG from surveillance was 255 mg/dl. The average initial BG at the start of GM IV treatment was 289 mg/dl. The average reduction in BG on GM was 123 mg/dl, with an average BG of 166 mg/dl. The percentage of all hypoglycemia <70 mg/dl was 1.1% and there were no BGs <40 mg/dl. The percentage of BG in the prescribed target range of 140–180 mg/dl was 72.1%.

Conclusion:

Patients identified with GM surveillance and placed on GM achieved prescribed glycemic targets with low incidences of hypoglycemia. These results suggest that using GM surveillance can safely identify CHF patients in need of improved BG control. Patients with CHF on GM IV who transitioned to SubQ reached and maintained prescribed glucose targets with low incidence of hypoglycemia.

Insulin Therapy Initialization Using the Glucotab System

Julia K. Mader, MD; Klaus Donsa, MSc; Katharina M. Neubauer, MSc;
Felix Aberer, MD; Bernhard Höll, MSc; Stephan Spat, MSc; Lukas Schaupp, PhD;
Peter Beck, PhD; Johannes Plank, MD; Thomas R. Pieber, MD

Medical University of Graz
Graz, Styria, Austria
julia.mader@medunigraz.at

Objective:

Current guidelines suggest development and evaluation of evidence-based computerized decision support systems. This analysis evaluated the efficacy of GlucoTab to establish glycemic control within the first two inpatient treatment days.

Method:

GlucoTab is a computerized decision support system running a basal–bolus insulin titration algorithm for non-critically ill hospitalized patients with type 2 diabetes mellitus (T2DM). Glycemic management of 99 patients with T2DM at four general wards was performed by GlucoTab. The first total daily dose (TDD) recommendation could be either generated using the GlucoTab or prescribed by the treating physician. During consecutive treatment, TDD was suggested by GlucoTab, but could be overruled if deemed necessary. Blood glucose (BG) was measured four times a day (pre-meal and bedtime). Basal–bolus therapy was performed using insulin aspart and glargine.

Results:

A total of 86 patients (age 67 ± 11 years, hemoglobin A1c 63 ± 20 mmol/mol, body mass index 30.0 ± 6.6 kg/m^2, creatinine 1.9 ± 1.6 mg/dl, diabetes duration 13 ± 9 years) were initiated by the first TDD as suggested by GlucoTab (gTTD group). In 13 patients (age 65 ± 9 years, hemoglobin A1c 76 ± 28 mmol/mol, body mass index 32.4 ± 6.0 kg/m^2, creatinine 1.4 ± 0.5 mg/dl, diabetes duration 17 ± 9 years) the dose was determined by the physician (pTTD group). The initial administered TDD was 35 ± 15 IU (gTTD) vs 68 ± 40 IU (pTTD). Mean BG during the first 2 days was 165 ± 47 mg/dl (gTTD) vs 189 ± 53 mg/dl (pTTD). 66% (gTTD) vs 51% (pTTD) of BG values were between 70–180 mg/dl. Hypoglycemia rates during the first 2 days of treatment were the following for gTTD and pTTD: <70 mg/dl, 2.3% vs 1.3%; <60 mg/dl, 1.0% vs 1.3%; <50 mg/dl, 0.2% and 0.0%.

Conclusion:

GlucoTab-initiated treatment achieved better glycemic control with lower insulin doses during the first two treatment days. Special populations might need more refined therapy initiation and adjustment rules, which will be investigated further.

Standardized Glycemic Management with a Computerized Workflow and Decision Support System for Non-Critically Ill Inpatients with Type 2 Diabetes

Katharina M. Neubauer, MSc; Julia K. Mader, MD; Felix Aberer, MD;
Bernhard Höll, MSc; Klaus Donsa, MSc; Lukas Schaupp, PhD; Stephan Spat, MSc;
Peter Beck, PhD; Johannes Plank, MD; Thomas R. Pieber, MD

Division of Endocrinology and Metabolism
Medical University of Graz
Graz, Styria, Austria
katharina.neubauer@medunigraz.at

Objective:

The development and evaluation of evidence-based computerized decision support systems are recommended to guide nurses and physicians in improving glycemic management in the hospital. The objective of this trial was to investigate the efficacy, safety, and usability of standardized glycemic management by a computerized decision support system for non-critically ill inpatients with type 2 diabetes mellitus (T2DM).

Method:

The GlucoTab system guided glycemic management of 99 inpatients with T2DM (41 female, age 67 ± 11 years, hemoglobin A1c 65 ± 21 mmol/mol, body mass index 30.4 ± 6.5 kg/m^2) at general wards (Cardiology, Endocrinology, Nephrology, Plastic Surgery). This mobile system provides automated workflow support [including display for open tasks, facilitating documentation, providing visualization of blood glucose (BG) values, nutrition and insulin doses] and decision support suggestions for basal–bolus insulin therapy to nurses and physicians. At the end of the trial, nurses and physicians completed a usability questionnaire.

Results:

The overall mean BG was 154 ± 35 mg/dl and 72.5 % of all BG measurements were in the range of 70–180 mg/dl. BG measurements >180 mg/dl, 40–70 mg/dl, and <40 mg/dl occurred in 25.6%, 1.9%, and 0.0% of all measurements, respectively. Adherence to required BG measurements and to basal and bolus insulin injections was high (95.2%, 99.4%, and 94.2%). Adherence to insulin dosing suggestions was 96.5% for bolus insulin and 96.7% for basal insulin. 91% of the health care professionals felt confident in performing glycemic management with the GlucoTab system, 89% believed in its practicability, and 80% in its ability to prevent medication errors.

Conclusion:

An efficacious, safe, and user-accepted standardized glycemic management with the computerized workflow and decision support system was demonstrated.

Evolution of an Intravenous (IV) Insulin Calculator Application, Auto*Cal*, to a Fully Integrated Automated IV Insulin Calculator in the Electronic Medical Record, HealthConnect, within Kaiser Permanente

Christine Olinghouse, MSN, FNP-BC, CDE, BC-ADM;
Rosemary Grabowiecki, RN, CCRN; Karen Mularski, MD; Norbert Chien, MS;
Jerry Burns, BS; Archanaa-Sarguna Bharathi, BS; MaLi Dong

Kaiser Permanente Sunnyside Hospital
Portland, Oregon, USA
christine.olinghouse@kp.org

Objective:

Since 2009, Kaiser Permanente NW, has successfully used the application Auto*Cal* to calculate hourly intravenous (IV) insulin doses. The application link is embedded into the Kaiser Permanente version of EPIC, called HealthConnect. The link enables demographical data to be transferred to the application, but requires manual entry of the insulin dose back into the chart for documentation. Auto*Cal* reduced nursing time by an impressive 4 min per operation per hour, compared with using a paper protocol, but nursing asked for a fully integrated system without manual dose entry. The objective of this project was to integrate the calculator into HealthConnect.

Method:

This project took 2 years to complete and required collaboration among EPIC, IBM, the Kaiser Permanente Innovation group, HealthConnect, physicians, and nursing. The final prototype is seamlessly integrated into HealthConnect. Information is transferred out to the application and returned within half a second to the appropriate rows within HealthConnect available for the second nurse to co-sign by swiped badge.

Results:

The entire operation takes less than 1 min to complete, compared with 2 min using the application. With the entire cycle repeated every hour during a 12 h nursing shift, this is a time savings of 12 min per shift. The difference is most notable in the translation of staffing ratios. The new and improved integrated system allows one nurse to comfortably care for four to five patients, rather than the previous standard of one nurse to three patients, if one is on IV insulin therapy.

Conclusion:

Fully integrating the IV insulin calculator into the electronic medical record improved nursing satisfaction and allowed for an increase in patient load on the medical surgical ward.

Insulin Requirements and Management in Transcatheter versus Surgical Aortic Valve Replacement

Yunyan Qu, MD, PA-C; Roma Y. Gianchandani, MD, CDTC

University of Michigan
Ann Arbor, Michigan, USA
yunqu@umich.edu

Objective:

Transcatheter aortic valve replacement/transcatheter aortic valve implantation (TAVR/TAVI) are increasingly performed today. We compared insulin requirements between TAVR/TAVI and surgical aortic valve replacement (SAVR) patients with and without diabetes mellitus (DM) to determine optimal glucose management strategies during the perioperative period.

Methods:

Charts of consecutive patients undergoing aortic procedures were retrospectively reviewed for blood glucose (BG) ranges, insulin requirements, and routes of insulin administration (subcutaneous vs intravenous) for patients with and without DM to maintain BG <180 mg/dl, and compared between the surgical and transcatheter groups.

Results:

Patients with SAVRs without DM and hemoglobin A1c (A1C) <6.5%, needed low dose insulin infusions and could be transitioned to subcutaneous insulin by postoperative day 1.5. Patients with AVR and DM had higher insulin requirements and were transitioned by postoperative day 3.

Patients with TAVR/TAVI with no known DM did not need an insulin infusion in the perioperative period. Patients with TAVR/TAVI with DM and A1C <6.5% did not require insulin infusions during the procedure but only postoperatively, for short periods. Patients with DM and A1C ≥6.5%, required higher doses of insulin by infusion and transitioned to subcutaneous insulin by postoperative day 3.

Conclusions:

TAVR/TAVI surgery patients have different insulin requirements compared to SAVRs ($p < 0.05$). This information helps build a glucose management algorithm for a procedure that is increasingly performed.

Serum Calcium Levels and Lactose Intolerance: Any Relationship in Patients with Type 2 Diabetes?

Satya Vati Rana, PhD; Aastha Malik, MSc; Sanjay Bhadada, DM;
Rajesh K. Morya, MSc

Post Graduate Institute of Medical Education & Research
Chandigarh, India
svrana25@hotmail.com

Objective:

Patients with diabetes mellitus (DM) complain of flatulence and diarrhea. Lactose intolerance may be the reason for these symptoms. Although dairy products are a major source of calcium, people with lactose intolerance might avoid dairy products and may have low serum calcium levels. Therefore, this study was planned to investigate if there is a relationship between serum calcium levels and lactose intolerance in patients with type 2 DM.

Method:

Ninety patients with DM and age range 24–75 years, and 100 age- and sex- matched controls, were enrolled. A noninvasive lactose breath test was performed to diagnose lactose intolerance. 25g lactose dissolved in 250 ml water was given orally to subjects after measuring fasting breath. End expiratory breath was collected every 30 min up to 4 h and hydrogen and/or methane were measured. A rise ≥20 ppm over baseline value in H2 and/or CH4 concentrations in two consecutive readings was considered as lactose intolerance. Calcium levels were measured with a kit.

Results:

59 out of 90 (65.5%) DM patients were lactose intolerant, while 33 out of 100 (33%) controls were lactose intolerant. Moreover, 31 out of 59 (52.5%) lactose-intolerant DM patients had low serum calcium levels whereas all lactose-tolerant DM patients and all controls had normal serum calcium levels. Lactose-intolerant DM patients gave a history of not eating dairy products while lactose-tolerant patients were eating dairy products. All controls were also eating dairy products.

Conclusion:

This study suggests that patients with diabetes have more lactose intolerance and low serum calcium levels. The reason for this may be non-consumption of dairy products. It shows that lactose-intolerant DM patients should be advised to eat dairy products to avoid calcium deficiency.

Diabetes Patients' Perceptions of Preparedness for Self-Management Post Hospitalization

Virginia Regula, OMS IV; Jay H. Shubrook, DO; Elizabeth A. Beverly, PhD

Touro University California College of Osteopathic Medicine
Vallejo, California
jay.shubrook@tu.edu

Objective:

Despite the key role that diabetes education plays in self-management and adherence to diabetes treatment prescriptions, little is known about inpatient diabetes education, particularly patients' readiness to manage diabetes after hospital discharge. This study design explored patients' perceptions of preparedness for diabetes self-management via a 44-item survey.

Methods:

A descriptive cross-sectional study recruited patients from medical/surgical units of a community hospital from October 2013–December 2014. Eligible subjects included English-speaking adults admitted with a diagnosis of type 1 or type 2 diabetes mellitus. A total of 103 diabetes patients (mean age 59 ± 14 years, 51% women, 92% non-Hispanic white, 5% college education or higher, hemoglobin A1c of 9.7 ± 2.8%, 50% on insulin, 27% smokers) completed the survey.

Results:

Prior to hospital admission, 71% of the patients had received prior diabetes education. When asked about their preparedness to perform diabetes self-care behaviors, 57% felt extremely prepared to check blood glucose levels, 31% felt extremely prepared to manage medications, 32% felt extremely prepared to manage hyperglycemia, 32% felt extremely prepared to manage hypoglycemia, 12% felt extremely prepared to manage their diet, and 14% felt extremely prepared to manage physical activity. Only 50% of these patients had an appointment scheduled with their primary care physician post-hospitalization and 94% planned to keep that appointment.

Conclusions:

Most patients did not feel well-prepared to complete recommended diabetes self-care behaviors. Hospitalization is an opportunity to address self-management educational deficiencies, and in turn, improve patients' behavioral and clinical outcomes. Future trials are needed to explore the relationship between diabetes self-management preparedness and readmission rates.

Risk Factors Associated with Hypoglycemia in Hospitalized Patients

Archana Sadhu, MD; Harlan Sparrow, MA; Nelda Wray, MD

Houston Methodist
Houston, Texas, United States
arsadhu@houstonmethodist.org

Objective:

Our objective was to identify risk factors associated with hypoglycemia in patients admitted to a tertiary care hospital.

Methods:

We reviewed all admissions from January 2013 through July 2014. A total of 52,195 admissions aged ≥ 18 years who had at least one blood glucose (BG) measurement were evaluated. Hypoglycemia was defined as BG <70mg/dl. The admission was classified as hypoglycemic (HypoG) if one or more hypoglycemic episodes occurred or nonhypoglycemic (NG).

Results:

A total of 15.6% of admissions were HypoG and 11% of those were hypoglycemic on admission. Compared to NG, HypoG admissions were slightly older in age (61.2 vs 60.8 years, $P < 0.001$), more likely female (55% vs 52%, $P < 0.001$), had longer length of stay (11.6 vs 5.8 days $P < 0.001$), had higher mortality (6% vs 1.6%, $P < 0.001$), and a higher admission BG (151 vs 131 mg/dl, $P < 0.001$). Admissions with HypoG were much more likely to have their next admission be HypoG (46% vs 13%, $P < 0.001$). HypoG received insulin (68.4% vs 30.8%, $P < 0.001$), sulfonylurea (6.8% vs 2.5%, $P < 0.001$), and corticosteroids (38.1% vs 27.3%, $P < 0.001$) more frequently than NG. HypoG also had certain chronic conditions classified as present on admission more often than NG, including end-stage renal disease (19.3% vs 6.1%, $P < 0.001$), malnutrition (22.6% vs 8.6%, $P < 0.001$), chronic kidney disease (43.4% vs 18.6%, $P < 0.001$), anemia (50.1% vs 27.5%, $P < 0.001$), and congestive heart failure (31.6% vs 17.1%, $P < 0.001$). In a multivariate analysis controlling for insulin administration, these chronic conditions remained predictive of hypoglycemia.

Conclusion:

HypoG is associated with poor outcomes, including higher mortality and longer length of stay. We identified important predictors of HypoG. These predictors can be used in a risk assessment model to identify patients early and intervene to prevent hypoglycemia during the admission.

The Effects of a Neutral Protamine Hagedorn Insulin Protocol for Steroid-Induced Hyperglycemia in the Hospital Setting

Gerard A. Sebastian, MD; Nancy Mora-Becerra, MD; Amber Healy, DO;
Masato Nakasawa, PhD; Jay Shubrook, DO

Ohio University HCOM
Athens, Ohio, USA
jay.shubrook@tu.edu

Aims:

Our aims were to (1) compare a neutral protamine Hagedorn (NPH)-based hyperglycemic treatment regimen to routine insulin management for inpatients with glucocorticoid-induced hyperglycemia and (2) compare these regimens in those with known diabetes versus those with no history of diabetes.

Methods:

A randomized nonblinded pilot study was performed. Patients were randomized either to the experimental NPH insulin group or the routine care group (physician's choice of insulin regimen, basal–bolus or correction scale). The initial dose of NPH for steroid-induced hyperglycemia was 0.1 unit/kg/dose regardless of the patient's diabetes history. This dose was given concomitantly with each corticosteroid dose. Data were analyzed with linear mixed-effects regression (LMER) modeling. Data are presented in the text below as mean ± SD unless stated otherwise.

Results:

Twenty-four patients participated in the study (8 with known diabetes). The mean age of the participants was 57.2 years with mean weight 87.8 kg. The mean blood glucose (SE 95% CI) in routine care for those with known diabetes was 240.6 ± 21.7 mg/dl (198.0–283.2) and 145.9 ± 18.2 mg/dl (110.2–181.5) for those without DM. In the NPH group, the blood glucose means (SE 95% CI) after adjustment was 243.2 ± 23 mg/dl (198.2–288.2) for patients with DM and 154.3 ± 18.6 mg/dl (117.8–190.8) for patients without DM.

Conclusion:

The starting dose of NPH insulin at 0.1 unit/kg/dose was not effective in controlling the blood glucose levels of patients who received inpatient corticosteroids. The investigators believe that 0.1 unit/kg would be appropriate for those without diabetes but a dose of 0.3 units/kg is needed in those with diabetes.

Glycemic Control Mentors as Change Agents in Improving Glycemic Control and Care Coordination in Hospitals

Jane Seley, DNP, MPH, MSN, GNP, BC-ADM, CDE, CDTC

New York Presbyterian/Weill Cornell College
New York, New York, USA
diabetesdiva@gmail.com

Objective:

Although hospitals know that improving glycemic control is important, it is not an easy undertaking. The purpose of this project was to see if the availability of Society of Hospital Medicine (SHM) mentors would assist hospitals in planning and implementing innovative strategies to improve glycemic control. Society of Hospital Medicine conducted a survey to generate a list of best practices used in a variety of high-performing hospitals. The next step in this initiative was to test these best practices on a new cohort of hospitals.

Method:

Nine hospitals that varied in size, location, and type, were selected to participate in this initiative. Program participants scheduled conference calls with assigned mentors to discuss areas that needed improvement and steps to get there. Mentors worked in teams made up of a hospitalist or endocrinologist and a diabetes nurse practitioner or physician assistant. A key component of the mentoring experience was collecting, reviewing, and benchmarking glycemic data using the QuesGen Systems, Inc., data management program to identify areas in need of improvement to formulate appropriate changes.

Results:

Successful outcomes varied from hospital to hospital, such as a substantial reduction in non-ICU hypoglycemia rates form 8% to 5% without a subsequent increase in rates of hyperglycemia, the development and implementation of a focused insulin order-set to address the needs of a challenging population, and a protocol for managing patients on steroids.

Conclusion:

All teams (100%) created and implemented glycemic control and care coordination protocols with the assistance of mentors. Blood glucose analysis was key in driving change and evaluating outcomes. Opportunities to share ideas with mentors and other sites provided knowledge and support to improve glycemic control initiatives among participants.

Integration of a Mobile, Computerized Decision Support System for Insulin Dosing into a Hospital Information Technology Environment

Stephan Spat, MSc; Bernhard Höll, MSc; Peter Beck, PhD; Klaus Donsa, MSc; Katharina M. Neubauer, MSc; Lukas Schaupp, PhD; Thomas R. Pieber, MD

Joanneum Research GmbH
HEALTH–Institute for Biomedicine and Health Sciences
Graz, Austria
stephan.spat@joanneum.at

Objective:

We aimed to identify different technical integration scenarios for GlucoTab, a client–server medical software with a tablet-based user front end. GlucoTab provides decision and workflow support for insulin dosing of hospitalized patients with type 2 diabetes mellitus.

Method:

We sent an online questionnaire to 8 hospitals (6 Austria, 1 Denmark, 1 Germany) to analyze the available information technology (IT) infrastructure. The questionnaire surveyed: availability of Wi-Fi, devices and data transfer interfaces for blood glucose (BG) measurements, documentation of BG measurements (paper/software), availability of a communications server for clinical data transfer, and availability of mobile-device management systems. We compared the technical prerequisites for GlucoTab integration with feedback from the online questionnaire and additional telephone interviews to identify different integration scenarios.

Results:

Out of 8 hospitals, 6 provide Wi-Fi and transfer BG measurements for storage in a hospital information system (HIS). Three hospitals implement a user interface to manage BG measurements using a HIS. All hospitals use a communications server for Health Level-7 (HL7) message support. None of the hospitals provide mobile-device management. We identified four different integration scenarios: (1) Basic integration where the GlucoTab back end is installed on a hospital server, Wi-Fi is used for front-end communication to a server, and HL7 interface for automated patient management. (2) Extended integration additionally provides HL7 interface for automatic transfer of BG and creatinine measurements and an interface for the hospital user management. (3) Deep integration requires an electronic medical record (EMR) with a software-based vital signs chart and computerized physician order entry. GlucoTab and the EMR communicate via HL7. (4) If the EMR is certified as a medical device, GlucoTab functionality should be directly implemented in the EMR.

Conclusion:

Depending on the technical prerequisites of the hospital, GlucoTab can be integrated on different levels.

Qualitative Analysis of Subcutaneous Lispro and Regular Insulin Injections for Patients with Diabetes Receiving Continuous Nutrition

Mamie C. Stull, MD; Richard J. Strilka, MD; Scott B. Armen, MD

Department of Trauma and Critical Care Surgery
San Antonio Military Medical Center
Fort Sam Houston, Texas, USA
mamiestull@gmail.com

Objective:

Optimal glucose management is undefined for patients with type 1 or type 2 diabetes mellitus (T1DM or T2DM) receiving continuous feeds via an enteric tube. This study utilized computer simulations to compare the mean glucose concentration (MGC), hypoglycemic events, and glucose variability (GV) of subcutaenous (SQ) lispro and regular insulin in the context of a continuous source of nutrition.

Method:

A glucose–insulin feedback mathematical model was used to simulate two patients (one with T1DM and one with T2DM) receiving continuous nutrition. The mathematical model had five adjustable parameters that were fixed from detailed glucose concentration data derived from two actual patients with diabetes, validating the model. SQ lispro and regular insulin injections were simulated. The primary endpoints were MGC, GV, and hypoglycemic events.

Results:

In T1DM, both lispro and regular insulin decreased MGC. GV was increased by lispro and decreased by SQ regular insulin. In the T2DM patient, lispro and regular insulin decreased MGC. GV was decreased by lispro at low doses, but was increased at larger doses. SQ regular insulin decreased GV at all doses. Lispro was more prone to cause hypoglycemia than SQ regular insulin at high doses in both T1DM and T2DM.

Conclusion:

SQ regular insulin is the short-acting insulin of choice in glucose management of T1DM and T2DM patients receiving a continuous source of enteral nutrition. SQ lispro lowers mean glucose, but worsens GV.

Improving Treatment of Hypoglycemia in Hospitalized Cancer Patients on Insulin Therapy through Increased Utilization of a Hypoglycemia Order Set

Sonali Thosani, MD; Veronica Brady, MSN, RN, FNP-BC, BC-ADM, CDE; Katherine Cain, PharmD, RPH; Laura Cue, Pharm D, RPH; Doris Tran, RN; Johnny Rollins, MSN, ANP, RN; Chun Feng, MA; Victor Lavis, MD

University of Texas-MD Anderson Cancer Center
Department of Endocrine Neoplasia and Hormonal Disorders
Houston, Texas
Sthosani@mdanderson.org

Objective:

Our objective was to improve treatment of hypoglycemia in hospitalized cancer patients on insulin therapy through increased utilization of a hypoglycemia order set.

Method:

At the University of Texas-MD Anderson Cancer Center, a hypoglycemia order set guides management of hypoglycemia in hospitalized patients on insulin therapy. However, retrospective chart review showed that of 20% of patients who had blood glucose (BG) values <70 mg/dl, only 11% had a hypoglycemia order set utilized. Hypoglycemia treatment was documented in 40% of cases and 61% of patients had a BG value rechecked within 1 h after initial BG value <70 mg/dl. Our interventions included creating a new documentation record for recording bedside BG values, insulin administration and treatment documentation, and educating the subspecialty services staff including floor nurses, physicians, physician assistants, and nurse practitioners about utilizing the hypoglycemia order set and algorithm in patients on insulin therapy.

Results:

After implementing the new changes, we conducted a retrospective chart review of hospitalized patients who received insulin therapy, and identified 18% of patients with BG values <70 mg/dl. The hypoglycemia order set was utilized in 34% of patients, and hypoglycemia treatment was documented in 48% of cases, but only 44% of patients had a BG value rechecked within 1 h after initial BG <70 mg/dl. It was noted that more of these episodes occurred in the emergency room and intensive care settings where the hypoglycemia order set is rarely utilized.

Conclusion:

Utilization of a hypoglycemia order set improves treatment documentation for hospitalized patients on insulin therapy and requires education that involves nursing staff, physicians, physician assistants, and nurse practitioners in various inpatient settings.

Dapagliflozin Therapy in Patients with Type 2 Diabetes

Osokina Irina Vladimirovna, MD, PhD

Institute for Medical Studies of the North, Russian Academy of Science
Siberian Federal University Krasnoyarsk, Krasnoyarsk region, Russian Federation
osoka08@gmail.com

Objective:

Dapagliflozin is a selective sodium glucose co-transporter-2 (SGLT2) inhibitor that improves glycemic control and reduces body weight and systolic blood pressure in patients with type 2 diabetes mellitus (T2DM). In this study, the safety and efficacy of dapagliflozin administered were assessed over 12 weeks in Russian patients with T2DM.

Method:

In this study, 44 subjects with T2DM (mean age of 53 years, diabetes duration of 6.3 years) were examined. For 12 weeks, dapagliflozin was administered as a monotherapy (n = 20) or combination therapy (n = 24) with existing antihyperglycemic agents (sulfonylurea, glinides, metformin, alpha-glucosidase inhibitors or dipeptidyl peptidase-4 inhibitors) to Russian patients with T2DM and inadequate glycemic control. Treatment with dapagliflozin was initiated at 5 mg/day and titrated to 10 mg/day, as required. Changes in glycosylated hemoglobin (HbA1c), body weight, and blood pressure were assessed after 12 weeks of treatment.

Results:

Dapagliflozin therapy was well tolerated. The frequency of adverse events (AEs) over 12 weeks was 19.3%, and AEs were mostly mild or moderate. The incidence of hypoglycemia at 12 weeks was 2.6% in the monotherapy group and 4.1% in the combination therapy group. In both monotherapy and combination therapy groups, reductions from baseline to week 12 were observed in HbA1c (–0.5% in both groups), weight (–1.7 and –2.3 kg, respectively), and systolic blood pressure (–7.2 mmHg and –5.9 mmHg).

Conclusion:

Dapagliflozin is effective and well tolerated as a monotherapy or combination therapy over 12 weeks in Russian patients with T2DM. Dapagliflozin-induced SGLT2 inhibition is associated with reductions in blood pressure, HbA1c, and body weight.