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Safe and sufficient glycemic control by using a digital clinical decision support system for diabetes patients in a routine setting on general hospital wards

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List of Abbreviations:

Blood Glucose – BG

Body Mass Index – BMI

Clinical Decision Support – CDS

Abstract

The aim was to investigate the applicability of a clinical decision support system in a real-world inpatient setting for type 2 diabetes patients on general hospital wards.

A total of 150 type 2 diabetes patients requiring subcutaneous insulin therapy were treated with basal-bolus insulin therapy guided by a decision support system (GlucoTab) providing automated workflow tasks and suggestions for insulin dosing to healthcare professionals.

By using the system, a mean daily blood glucose (BG) of 159 ± 32 mg/dl was achieved. 68.8% of measurements were in the target range (70-<180 mg/dl). The percentage of BG values <40, <70 and ≥300 mg/dl was 0.02%, 2.2% and 2.3%, respectively. Healthcare professionals' adherence to suggested insulin doses and workflow tasks was high (>93% and 91%, respectively).

The decision support system facilitates safe and efficacious inpatient diabetes care by standardizing treatment workflow and providing decision support for basal-bolus insulin dosing.

Background

Optimized glycemic control on any clinical hospital ward can reduce the length of hospital stays, minimize infections, promote patients' safety, and increase healthcare professionals' satisfaction. Current guidelines suggest insulin therapy initiation for the treatment of persistent hyperglycemia. Complex therapies, such as basal-bolus insulin therapy, are difficult to implement due to limited availability of diabetes specialists on general wards. Clinical decision support (CDS) systems and algorithms have been designed to facilitate optimized glycemic control while reducing hypoglycemic events and was implemented in a digital tool, specifically developed to be used by non-diabetes specialists [1-8].

The aim of this study was to show the applicability of a CDS system in a real-world inpatient setting for type 2 diabetes patients on three general hospital wards by evaluating user adherence to workflow and dosing suggestions and the resulting safety and efficacy of blood glucose management.

Methods

Intervention

A computerized CDS system (GlucoTab®, decide Clinical Software GmbH, Graz, Austria) for subcutaneous insulin therapy that supports nurses and physicians in diabetes management at point-of-care was implemented in routine care for hospitalized patients with type 2 diabetes on three general wards (Divisions of Plastic Surgery, Cardiology, Endocrinology) at a tertiary center in Austria. Data interfaces were provided for submitting patient demographics and administrative information such as admissions and transfers as well as laboratory parameters such as blood glucose,

HbA1c and renal function from the electronic medical record (EMR). However, there was no EMR integration on the user interface level, the CDS system was used on mobile tablet devices and replaced the paper-based diabetes documentation including documentation of measured blood glucose (BG) measurements and insulin prescription and administration.

The CDS system assists nurses and physicians, with a focus on non-diabetes specialists, in organizing diabetes management by providing automated workflow support including display of open tasks (therapy adjustment, capillary BG measurements, insulin injections), facilitating documentation and providing visualization of capillary glucose values, food intake and insulin doses.

The CDS system assists physicians with the calculation and regular adjustment of total daily insulin dose and provides standardized recommendations based on a basal-bolus insulin dosing protocol [3-6] to achieve safe glycemic control, i.e. daily BG values <180 mg/dl without causing hypoglycemia (BG <70 mg/dl) [9]. In addition, the CDS system provides insulin dose suggestions for individual insulin administrations before each meal, at bedtime or whenever additional BG measurements are performed at healthcare professionals' discretion.

All healthcare professionals were trained according to a standardized one-hour training protocol and manual before using the system in accordance with local standard operating procedures. Most of the healthcare professionals were already familiar with the system because of a preceding interventional study where the CDS system was used on the same wards.

Study design and population

In this study, the patients received insulin aspart as bolus insulin and insulin glargine U100 as basal insulin. Oral antihyperglycemic agents were continued at the discretion of the treating physician; only sulfonylurea and glitazone-based therapies were discontinued during the study.

The study included non-critically ill patients aged ≥18 years with type 2 diabetes or new-onset hyperglycemia requiring subcutaneous insulin therapy during hospital stay. Exclusion criteria were type 1 diabetes, pregnancy, any mental condition rendering the patient incapable of giving consent, known or suspected allergy to the used insulins, continuous parenteral nutrition and intravenous insulin therapy.

A total of 150 hospitalized patients (56 female, age 68 ± 11 years, HbA1c 77 ± 24 mmol/mol [9.2 ± 4.3%], diabetes duration 15 ± 11 years, BMI 30 ± 6 kg/m^2) were recruited. All patients gave written informed consent prior to any study activity and the study was approved as an observational, open, non-controlled single-center study by the ethical board of the Medical University of Graz (EK-No. 26-072 ex 13/14, trial registration: NCT02053077). The study was conducted in full accordance with the principles of the Declaration of Helsinki and according to good clinical practice.

Analysis approach

Data from the digital CDS system covering all aspects of the diabetes management process including measured BG values and insulin therapy with dosing support were extracted from the database for subsequent statistical analysis. Data were analyzed by means of descriptive statistical methods. Means/standard deviations were used to describe the outcome variables. The statistical analysis was performed using the statistics software R 3.1.3 (2016, from http://www.r-project.org).

Results

User adherence of the CDS system in routine care

The adherence of healthcare professionals to the suggested performance of workflow tasks (n=9927) was very high: 96.4% of all suggested BG measurements, 93.1% of all suggested bolus insulin injections and 98.6% of all suggested basal insulin injections were performed by nurses as recommended by the CDS system. Also, 91.6% of all insulin dosing suggestions (n=7407) provided by the CDS system to the physicians (total daily insulin dose suggested usually during ward rounds) were accepted without modification. Insulin dosing suggestions provided by the CDS system to the nurses for individual insulin administrations were very well adhered to, i.e. 94.1% of bolus and 97.2% of basal insulin doses were accepted, respectively.

The mean number of additional suggestions of diabetes chart reviews by a physician was 2.1 ± 2.6 times per patient during his/her complete hospital stay. Main reasons for review were missed total daily dose adjustments (52%), later modification of entered data (27%) and missing BG values (21%).

Overall, the CDS system covered 71.4 ± 23.4% of the time of hospitalization (length of hospital stay 9 ± 7 days (median 7.0 days (min 2.0, max. 50.0)); 2.4 ± 4.3% of days are not covered by the CDS system at the beginning of hospital stay and 2.4 ± 5.3% of days are not covered by the CDS system at the end of hospital stay. In 26 patients (17.3%) the CDS system was used for the complete duration of the hospital stay.

Safety and efficacy of the CDS system in routine care

68.8% (n=4879) of all capillary BG measurements were in the acceptable range of 70 to <180 mg/dl. The percentage of BG values >180 mg/dl and ≥300 mg/dl was 29.0% and 2.3%, respectively. The percentage of BG values <70 mg/dl, <60 mg/dl and <54 mg/dl was 2.2%, 0.6% and 0.2%, respectively (Figure 1A, 1B). Hypoglycemic events

occurred throughout the day. Only one (0.02%) of the BG measurements was below 40 mg/dl (32 mg/dl) most likely due to manual doubling of the total daily insulin dose by the attending physician. Patients who experienced hypoglycemic events <70 mg/dl (n=56, age 70 ± 9 years) had on average lower HbA1c values (70 ± 22 vs. 81 ± 25 mmol/mol (8.6 ± 4.2 vs. 9.6 ± 4.4%), were hospitalized for a longer period (13 ± 9 vs. 7 ± 4 days) and had a longer diabetes duration (18 ± 11 vs. 13 ± 10 years) than patients without hypoglycemic events (n=94, age 68 ± 12 years).

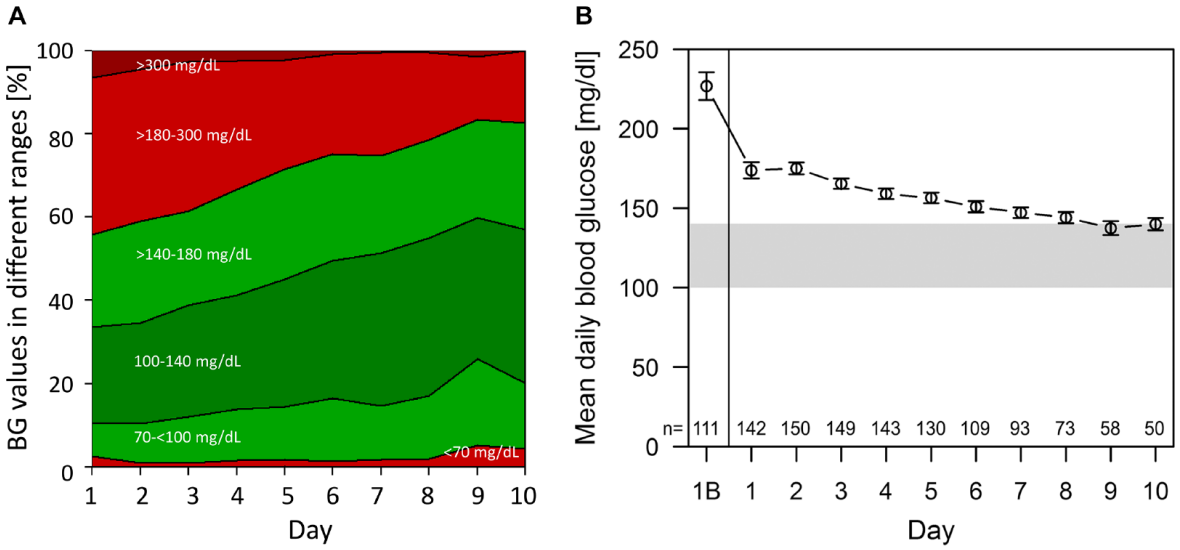

Figure 1. (a) Mean percentage of blood glucose (BG) values in different ranges (140-180 mg/dL, >180-300 mg/dL, >300 mg/dL) and (b) mean daily BG (1B refers to the baseline BG values on study day 1).

By using the CDS system in routine care, a mean daily BG of 159 ± 32 mg/dl was achieved. The overall pre-breakfast, pre-lunch, pre-dinner and bedtime BG values were 147 ± 38 mg/dl, 181 ± 47 mg/dl, 158 ± 35 mg/dl and 151 ± 37 mg/dl, respectively (Figure 1B).

Discussion

In summary, this study showed that the applied CDS system aided healthcare professionals to achieve safe, efficacious and user-friendly glycemic management when implementing a basal-bolus insulin therapy in hospital routine care. The occurrence of hypo- and hyperglycemia was low and comparable with other prospective studies investigating a basal-bolus insulin therapy in a hospital setting [4, 5].

The version of the CDS system available during the study covered around 70% of the time of hospitalization when managing diabetes patients on general wards. Additional features to provide a full digital diabetes management system, integrated in the EMR, allowing documentation of all aspects of blood glucose management as well as discharge management [1], are currently being developed. This will reduce entry barriers towards personalized diabetes management for each individual patient and facilitate individual selection of therapy regimens and algorithm support. To further reduce the required decision support reviews by physicians, CDS system development has also integrated daily dose adjustments by nurses rather than physicians when therapy and therapy adjustment are in safe ranges.

A limitation of the present study is the uncontrolled trial design. Therefore, we compare the study outcomes with results of previous trials on the wards also participating in the present study. In a retrospective analysis of glycemic control before introduction of the CDS system, two wards achieved rates of 57% (Endocrinology) and 51% (Cardiology) of glucose values in the range of 70–180 mg/dl under standard care [10]. Previously published data in a prospective ward-controlled trial performed at these two wards showed that patients in whom a paper-based basal bolus algorithm was used had a significantly higher percentage of BG measurements in the range of 70–180 mg/dl than

patients in routine care group (73% vs. 53%) [7]. Similar results on glycemic control with regard to BG measurements in the range of 70–180 mg/dl were confirmed once the algorithm was incorporated in a digital decision support system on both wards (Cardiology: 64.6%, Endocrinology: 70.6%) [6]. These results indicate that glycemic control can be improved by the use of the CDS system compared to standard care. In the present clinical trial these improvements could be maintained in a routine clinical setting, without close surveillance of the study team and limitations on the patient population by inclusion and exclusion criteria. The high rates of adherence with the suggested clinical workflow and insulin doses underline that the positive results are attributable to the CDS system.

Another limitation of the study is that the system was only tested in internal medicine and surgery. Of note, no relevant differences in the glycemic control were observed between patients hospitalized on internal medicine wards as compared to a surgery ward. Future research will look into applicability of the CDS system in other medical specialties such as neurology and gynecology/obstetrics.

Future research activities will include decision support for additional treatment regimens (e.g. basal-only insulin algorithm, basal-plus insulin algorithm, premixed insulin algorithm) for patients for whom simpler insulin therapy strategies are adequate or for patients requiring less stringent glycemic targets to further minimize hypoglycemic risk (e.g. geriatric patients).

Conclusion

CDS system implementation will facilitate automated 24-hour inpatient diabetes care on general wards by standardizing treatment workflow and providing decision support for dosing of basal-bolus insulin therapy to achieve safe glycemic control.

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Author contributions and statement of guarantor

KL, BH, LS, JP, PB, TP designed and performed the study, interpreted data and contributed to discussions. KL drafted the manuscript. FA, AT and FF performed the study. KD performed statistical analysis. JM interpreted data, contributed to discussions, supervised the project and is the guarantor of this work. All authors critically revised the article and approved the final version of the manuscript.

Author disclosure statement

Based on satisfactory study results and interests of other hospitals a spin-off was founded by Joanneum Research and the Medical University of Graz. KD, TP, PB and JM are co-founders of decide Clinical Software GmbH. TP is a member in the advisory board of Arecor, Novo Nordisk, Sanofi, Astra-Zeneca, Adocia and received speaker honoraria from Novo Nordisk. JM is a member in the advisory board of Becton-Dickinson, Boehringer Ingelheim, Eli Lilly, Medtronic, Prediktor A/S, Roche Diabetes Care, Sanofi-Aventis and received speaker honoraria from Abbott Diabetes Care, Astra Zeneca, Dexcom, Eli Lilly, MSD, NovoNordisk A/S, Roche Diabetes Care,

Sanofi, Servier and Takeda. FA received speaker honoraria from Astra Zeneca, Boehringer Ingelheim, Eli Lilly and MSD. The remaining authors have no conflict of interest to disclose.

Prior presentation of data

Presentations of the data include the American Diabetes Association's 76th Scientific Session, New Orleans, 10-13 June 2016 and the American Diabetes Association's 79th Scientific Session, San Francisco, 7-11 June 2019.

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