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Impact of errors in paper-based and computerized diabetes management with decision support for hospitalized patients with type 2 diabetes. A post-hoc analysis of a before and after study

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ABSTRACT

Objective: Most preventable adverse drug events and medication errors occur during medication ordering. Medication order entry and clinical decision support are available on paper or as computerized systems. In this post-hoc analysis we investigated frequency and clinical impact of blood glucose (BG) documentation- and user-related calculation errors as well as workflow deviations in diabetes management. We aimed to compare a paper-based protocol to a computerized medication management system combined with clinical workflow and decision support.

Methods: Seventy-nine hospitalized patients with type 2 diabetes mellitus were treated with an algorithm driven basal-bolus insulin regimen. BG measurements, which were the basis for insulin dose calculations, were manually entered either into the paper-based workflow protocol (PaperG: 37 patients) or into GlucoTab®—a mobile tablet PC based system (CompG: 42 patients). We used BG values from the laboratory information system as a reference. A workflow simulator was used to determine user calculation errors as well as workflow deviations and to estimate the effect of errors on insulin doses. The clinical impact of insulin dosing errors and workflow deviations on hypo- and hyperglycemia was investigated.

Results: The BG documentation error rate was similar for PaperG (4.9%) and CompG group (4.0%). In PaperG group, 11.1% of manual insulin dose calculations were erroneous and the odds ratio (OR) of a hypoglycemic event following an insulin dosing error was 3.1 (95% CI: 1.4–6.8). The number of BG values influenced by insulin dosing errors was eightfold higher than in the CompG group. In the CompG group, workflow deviations occurred in 5.0% of the tasks which led to an increased likelihood of hyperglycemia, OR 2.2 (95% CI: 1.1–4.6).

Discussion: Manual insulin dose calculations were the major source of error and had a particularly strong influence on hypoglycemia. By using GlucoTab®, user calculation errors were entirely excluded. The immediate availability and automated handling of BG values from medical devices directly at the point of care has a high potential to reduce errors. Computerized systems facilitate the safe use of more complex insulin dosing algorithms without compromising usability. In CompG group, missed or delayed tasks had a significant effect on hyperglycemia, while in PaperG group insufficient precision of documentation times limited analysis. The use of old BG measurements was clinically less relevant.

Conclusion: Insulin dosing errors and workflow deviations led to measurable changes in clinical outcome. Diabetes management systems including decision support should address nurses as well as physicians in a computerized way. Our analysis shows that such systems reduce the frequency of errors and therefore decrease the probability of hypo- and hyperglycemia.

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1. Introduction

Most preventable adverse drug events and medication errors are related to the medication process itself and mainly occur during ordering [1–3]. Computerized systems (medication order entry, patient data management) are cost effective [4], significantly reduce prescribing errors [5–8] and charting time [9]. Additionally, clinical decision support systems (CDSS) support calculation of drug doses and management of the increasing number of drugs, treatment regimens and side effects. The combination of medication order entry systems and CDSS reduces medication errors [5] and their use has also been recommended for diabetes therapy in hospitalized patients [10–13].

Around 20% of hospital inpatient days occur in diabetes patients who have an increased risk to experience adverse events during hospital stay [13–15]. An improvement in diabetes management results in lower rates of hospital complications in general medicine and surgery wards [16,17]. But a recent diabetes inpatient audit showed that 37% of diabetes patients experienced at least one diabetes medication error during hospitalization and that these patients were more than twice as likely to experience severe hypoglycemia [18]. International diabetes experts recommend a structured approach and an algorithm-driven basal-bolus insulin regimen for hospitalized type 2 diabetes mellitus (T2DM) patients [19]. This regimen involves long acting insulin to supplement basal insulin requirements during periods of fasting and separate injections of rapid acting insulin to prevent rises in blood glucose (BG) levels resulting from meals. Diabetes management requires complex and interdisciplinary cooperation of health care professionals (HCPs) involving ordering doses and correction schemes, BG measurement and timely administration of resulting insulin doses. Clear evidence that the combination of computerized medication order entry systems and CDSS reduces clinical adverse drug events is still missing [5].

We have integrated a customized version of a previously published algorithm for basal-bolus insulin therapy in T2DM patients [20–22] into the workflow of a general internal medicine ward. We first tested the basal-bolus insulin regimen in a paper-based version of a medication management protocol with insulin dosing decision support [23]. In a second step, the algorithm was refined and implemented in a computerized workflow and decision support system which was additionally tested in a clinical study on 4 different wards [24].

In the present post-hoc analysis we aimed to determine the frequency and clinical impact of blood glucose (BG) documentation-, user-related calculation errors and workflow deviations in diabetes management. We compared the paper-based protocol to the computerized medication management system including clinical workflow and decision support. The data collected in the clinical studies was analyzed to describe errors. To further analyze clinical impact of these errors a workflow simulator was used to estimate their effect on insulin doses.

2. Methods

2.1. Study design and patient characteristics

We used a subset of data (one ward) from two previously published clinical studies [23,24]. Both studies were conducted at the general ward of the Division of Endocrinology and Metabolism at the Department of Internal Medicine (Medical University of Graz, Austria). On this ward additional continuous glucose monitoring (CGM) was performed in both clinical studies. Both studies were approved by the local ethics committee and performed in accordance with the Declaration of Helsinki and the principles of Good Clinical Practice. Adult patients (≥18 years of age) with T2DM who were treated with diet alone and/or with any oral or injectable antihyperglycemic therapy and who were admitted to the general ward were included in the study. The study ended with hospital discharge, the transfer of the patient to a different ward, or after 21 treatment days.

For the post-hoc analysis we used a before and after study design: First, diabetes management was performed using a paper-based protocol for an algorithm driven basal-bolus insulin therapy from July 2011 to April 2012, (PaperG group). After 12 month of using routine care diabetes management to unlearn the procedures of the algorithm driven basal-bolus insulin therapy, diabetes management was conducted using a computerized system from May 2013 to December 2013, (CompG group). The paper-based protocol and the computerized system for medication management were specifically designed to support basal-bolus insulin therapy of T2DM patients. Both methods comprise the following functionalities which aid physicians and nurses: 1) medication order entry with insulin dosing decision support for physicians, 2) workflow management for physicians and nurses, 3) data entry at the bedside and 4) drug administration support including insulin dose calculation for nurses.

This study included data from 79 T2DM patients. BG measurements were entered manually, either into a paper-based workflow and medication management protocol (PaperG: 37 patients) or into GlucoTab®—a mobile Android tablet PC based system (CompG: 42 patients). The true measured BG values and measurement times were retrospectively extracted for both groups from the Laboratory Information System (LIS) and compared with the manually entered data. Insulin dose calculations were performed manually in the PaperG group and with GlucoTab® in the CompG group. In both groups, the users were trained in the correct use of the protocol/system and the insulin dosing algorithm. HCPs were unaware of the fact that medication errors were investigated.

2.2. Clinical workflow and insulin dosing algorithm

In both groups, dosing decisions were based on four daily capillary BG finger-stick measurements (three pre-meal and one bedtime measurement). Additional measurements were performed if deemed necessary by the HCPs. The algorithm was used to calculate the initial total daily dose (TDD) of insulin based on patient weight, age and renal function as well as to calculate a new TDD for the next 24 h based on the previous TDD and BG values of the preceding 24 h. The calculated TDD was either accepted or modified by the physicians and the ordered TDD was divided into 50% daily basal and 50% daily bolus insulin dose. The bolus dose was distributed among the three meals (breakfast, lunch, dinner). If pre-meal BG values were below the target range, the insulin bolus was reduced whereas BG values above the target range induced an increased bolus dose. The basal-bolus insulin algorithm aims for fasting and pre-meal BG levels of 100–140 mg/dL. In case of additional insulin suggested due to high BG, the algorithm further adjusted the dose using an insulin sensitivity parameter. Insulin sensitivity (sensitive, normal and resistant) was assessed by the attending physician during each morning round. Additional bolus injections were performed if deemed necessary by the HCPs. Authorized nurses were able to modify the suggestion of the decision support algorithm and after confirmation of the suggested insulin dose the insulin was injected subcutaneously. The underlying workflow and the sequence of operations of the used algorithm driven basal-bolus insulin regimen were identical in both groups (Fig. 1).

Paper-based workflow and decision support (PaperG group)

The use of the insulin dosing algorithm requires only basic arithmetic operations and HCPs were trained in the correct use. BG