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ORIGINAL ARTICLE

Commentary on "Performance of a Glucose Meter with a Built-In Automated Bolus Calculator versus Manual Bolus Calculation in Insulin-Using Subjects"

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Abstract

Since the early 2000s, there has been an exponentially increasing development of new diabetes-applied technology, such as continuous glucose monitoring, bolus calculators, and "smart" pumps, with the expectation of partially overcoming clinical inertia and low patient compliance. However, its long-term efficacy in glucose control has not been unequivocally proven. In this issue of *Journal of Diabetes Science and Technology*, Sussman and colleagues evaluated a tool for the calculation of the prandial insulin dose. A total of 205 insulin-treated patients were asked to compute a bolus dose in two simulated conditions either manually or with the bolus calculator built into the FreeStyle InsuLinx meter, revealing the high frequency of wrong calculations when performed manually. Although the clinical impact of this study is limited, it highlights the potential implications of low diabetes-related numeracy in poor glycemic control. Educational programs aiming to increase patients' empowerment and caregivers' knowledge are needed in order to get full benefit of the technology.

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In developed countries, only 30% to 50% of diabetes patients meet criteria for good metabolic control. These disappointing results in terms of glycemic control may be explained, at least in part, by two phenomena sharing common mechanisms. The first is clinical inertia, i.e., inadequate health care provider adherence to current guidelines.[1] The second is low compliance, i.e., the lack of patient adherence to medical recommendations. Clinical inertia is a problem of the health care professional and the health care system. Clinical inertia is separate from patient-related issues of adherence and access to care and is due predominantly to three problems: overestimation of care provided; use of "soft" reasons to avoid intensification of therapy (e.g., "control was improving" or "dietary nonadherence"); and lack of education, training, and organizational procedures and practices focused on achieving therapeutic goals.[1] On the other hand, there is little doubt that patient self-management is a critical factor in achieving optimal care.[2] Complexity of treatment, barriers to access, a negative social environment, the degree to which the patient's everyday life is affected, poor health literacy, and

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Abbreviations: (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion

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diabetes-related numeracy are among the factors associated with low compliance and poor self-management skills.[3]

Since the early 2000s, there has been an exponentially increasing intrusion of technology into diabetes care, with the expectation that it would have overcome, at least partially, the problems of clinical inertia and poor compliance. While the final objective of diabetes-related technological research is the development of an artificial pancreas, efforts have been made to develop tools to ease the implementation of an effective insulin treatment, such as continuous glucose monitoring (CGM), sophisticated blood glucose meters, "smart" insulin pumps, pens, and bolus calculators/advisors. The expected outcome was that providing the patient and the physician with more data and helping the patient solving the problems related to a poor numeracy would have resulted in better glycemic control. However, the expectations have not been fully met, as shown by the weak results of the intervention trials, which failed to unequivocally demonstrate the long-term efficacy of CGM,[4] numeracy education programs,[5] and bolus calculators.[6]

In this issue of *Journal of Diabetes Science and Technology*, Sussman and colleagues[7] evaluated a tool for calculating prandial insulin dose. In particular, 205 insulin-treated patients (52.4% type 2 diabetes and 47.6% type 1 diabetes) were required to calculate the mealtime insulin dose manually (according to a formula that investigators gave to the participants) or using the bolus calculator built into the FreeStyle InsuLinx meter. Calculations were performed under simulated conditions of normoglycemia and hyperglycemia, where normal and high glucose control solutions were used instead of capillary blood. The bolus calculator considered two modes of operation: "easy mode" for patients who used fixed doses of rapid-acting insulin for meals and "advanced mode" for patients who performed carbohydrate counting to adjust their mealtime insulin doses. In the first case, patients had to calculate the correction insulin dose to be added to their fixed dose in order to adjust for preprandial glycemia. In the second case, patients had to calculate both the meal-size-related insulin dose and the correction insulin dose. After insulin dose determinations, the subjects completed opinion surveys. The number of errors, subject confidence and preference with manual calculation of insulin dose were assessed and compared with "automated" calculations.

Of the 409 insulin doses manually calculated by the subjects, 256 (63%) were incorrect as compared with only 23 (6%) of those obtained with the automated bolus calculator. The results were similar for the two modes of operation. The surveys showed that 83% of the subjects felt more confident using the automated bolus calculator in determining insulin doses and 87% of the subjects preferred using the FreeStyle InsuLinx meter to manual calculation. Sussman and colleagues[7] concluded that manual calculation of mealtime insulin dose is frequently erroneous, suggesting that the use of their bolus calculator may result in more accurate insulin dosing.

However, results of the presented work are of limited relevance to clinical practice for several reasons. The most important is that the bolus calculator was evaluated under simulated conditions, and thus no inference can be made about its impact on metabolic control. Nevertheless, results from this study highlight the potential implications of low diabetes-related numeracy. Low numeracy is highly prevalent, is associated with poor medication compliance,[8] and appears to adversely affect metabolic control.[9]

In theory, bolus calculators may help overcome the issue of low numeracy. In this regard, several studies have demonstrated superior postprandial performance of automated bolus calculation against manual bolus with a high degree of satisfaction by the patient,[6,10,11] probably reflecting better insulin dosing accuracy and ease of calculations. However, as already mentioned, a positive impact on long-term glucose control (hemoglobin A1c) has not been demonstrated.

Bolus calculators will be as efficient, as they are well tuned. Many parameters need to be taken into account and introduced into the device for the proper insulin dosing. Walsh and associates[12,13] pointed out incorrect tuning of carbohydrates factor, correction factor, and duration of insulin action as a limitation of the success of continuous subcutaneous insulin infusion (CSII), with preference to "magic" numbers or default settings by the physician. It is demonstrated that incorrect adjustment of, for instance, duration of insulin action for the computation of insulin on board can lead to over- or under-insulinization. This can profoundly affect the plasma glucose profile, requiring frequent corrections of the bolus recommendations given by the bolus calculators.[14] Even a correct tuning will still require manual adjustments due to high intrapatient variability of insulin sensitivity and even absorption depending on factors such as exercise, an intercurrent illness, and environmental temperature, among others.[14]

Thus a key aspect for the success of such technologies is education. On one hand, parallel to the development of diabetes-applied technology, we should promote implementation of programs directed at improving patient empowerment. Indeed, frequent use of dual wave boluses (which is very likely associated with a better diabetes education) has been linked to a decrease in hemoglobin A1c in a 2-year retrospective study of patients under CSII.[15] As demonstrated by several authors, square-wave and dual-wave profiles have been shown to be more effective than standard bolus in controlling postmeal glucose excursion in slow-absorption meals and meals with high fat content.[15–18] The more a patient can understand a technology and feel confident interpreting results from blood glucose monitoring, self-adjusting the prandial insulin dose, and (in the case of CSII) the bolus type, the more benefit he can get from it. On the other hand, continuing training of caregivers is necessary in order to reap the full benefit of the technology with optimal adjustments and to provide diabetes education in a more effective way.

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