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An Analysis of the "Bolus Guide," A New Insulin Bolus Dosing Support Tool Based on Selection of Carbohydrate Ranges

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Shapira and colleagues present new concepts of carbohydrate load estimation in intensive insulin therapy. By using a mathematical model, they attempt to establish how accurately carbohydrate food content should be maintained in order to keep postprandial blood glucose levels in the recommended range. Their mathematical formula, the "bolus guide" (BG), is verified by simulating prandial insulin dosing and responding to proper blood glucose levels. Different variants such as insulin sensitivity factor, insulin-to-carbohydrate ratio, and target blood glucose were taken into this formula in establishing the calculated proper insulin dose. The new approach presented here estimates the carbohydrate content by rearranging the carbohydrate load instead of the simple point estimation that the current bolus calculators (BCs) use. Computerized estimations show that the BG directives, as compared to a BC, result in more glucose levels above 200 mg/dl and thus indicate less hypoglycemia readings.

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The current studies suggest that effective treatment of type 1 diabetes mellitus (T1DM) presents a challenge to health care providers. Evidence indicates that the basal/bolus, also referred to as intensive insulin therapy,[1] is currently the chosen method of treatment in patients with T1DM. Continuous subcutaneous insulin infusion (CSII) has become a convenient treatment method and is now offered frequently.[2] The CSII therapy is based on three main elements: (1) insulin administration, (2) blood glucose monitoring, and (3) food content calculation. Proper accounting for and proportioning of these three elements gives stable and satisfactory metabolic control to the diabetes patients. With CSII, many obvious, documented benefits are met by failures as well. The main documented reasons for CSII pump therapy failure, resulting in inappropriately high levels of hemoglobin A1c, are erroneous programming of the dose meter, setting a wrong type of bolus for a meal, or missing the existing prandial bolus.[3–5] All these set functions depend on the patient's compliance and level of knowledge. To facilitate this complex calculative process, and to make it more patient friendly and more efficient as well, health care providers and scientists are working on a technical device that could more adequately assist patients in making informed error-free decisions in their daily prandial insulin dose self-treatment routine. In addition to an already existing tool, the bolus calculator (BC), Shapira and colleagues[6] present the bolus guide (BG)—a new concept and new tool in prandial insulin dosing.

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Abbreviations: (BC) bolus calculator, (BG) bolus guide, (CSII) continuous subcutaneous insulin infusion, (CV) coefficient of variation, (ISF) insulin sensitivity factor, (ITC) insulin-to-carbohydrate ratio, (T1DM) type 1 diabetes mellitus, (TBG) target blood glucose

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A lively discussion on the way the food content is calculated in intensive insulin therapy is still open, with many, even some controversial, points of view given. The American Diabetes Association 2010 recommendation reads, "Monitoring carbohydrate, whether by carbohydrate counting, exchanges, or experience-based estimation, remains a key strategy in achieving glycemic control.[7]" Carbohydrate counting is a meal content planning approach, but it is not a specific proper diet individually adjusted for the diabetes patient. How precisely and accurately should this planning and calculating be done? The results of many studies that assessed the impact of precise carbohydrate quantification on postprandial glycemic control are not in concert. One of those studies presented by Smart and associates[8] calculated that the proper insulin dose for 60 g of carbohydrate maintained postprandial blood glucose levels for meals containing between 50 and 70 g of carbohydrate. However, contrary to this is the Mehta and coworkers[9] study in which young patients or their caregivers estimated carbohydrate contents precisely and accurately and achieved better metabolic control.

In this issue of *Journal of Diabetes Science and Technology*, in an article entitled *Bolus Guide: A Novel Insulin Bolus Dosing Decision Support Tool Based on Selection of Carbohydrate Ranges*, Shapira and colleagues[6] present a convincing hypothesis that prandial insulin dosage based on carbohydrate range selection is at least as effective as a carbohydrate point estimation, although it shows more results of glucose levels above 200 mg/dl and less hypoglycemia.

Shapira and colleagues[6] also analyzed the human error factor in food counting that was estimated in their pilot study: 60 participants, aged between 18 and 60 years, assessed 8 different packages of meals. The study shows that the mean percentage error tended to get larger with increasing carbohydrate load, and the coefficient of variation (CV) of the estimated carbohydrate was high for all meals, ranging from 28% to 46%. Following this, a computer simulation was performed, accounting for hundreds of carbohydrate estimation error values generated within the CV range (30–50%). In addition, in the study simulation, the reference values were selected to minimize hypoglycemia.[6] The BG took into account all contributing factors, such as insulin sensitivity factor (ISF), insulin-to-carbohydrate ratio (ITC), target blood glucose (TBG), current glucose, and insulin on board, necessary in advanced BCs. Finally, the data analysis was performed based on 1,612,800 generated observations, considering six carbohydrate estimation CVs of 0%, 10%, 20%, 30%, 40%, and 50% for 0% and 10% and 875,712 additional observations for the most common range of insulin and glucose parameters (ISF 40–110, TBG 80–120, ITC 8–31). The simulation clearly showed that the estimation of carbohydrate contents, when rounded by 15 mg/dl, does not lead into glucose deterioration (see Table 9 of Reference 6).

The strong argument of their study is the analysis of glucose outcomes related to the wide range of all variables that influence postprandial glycemia level. The BG was assessed by mathematical simulations; moreover, a comparison of the two algorithms—BG and BC—were conducted using a computer analysis. The presented technique is the first mathematical analysis integrating the most important factors in prandial insulin dosage, and as such, it could also be implemented in a custom-designed individual insulin therapy.

Shapira and colleagues also addressed the patient's convenience and satisfaction in using the BC and BG. The results of a questionnaire give new evidence of the ease in using and implementing even complex electronic medical devices in real life. In addition, patients' responses indicate equal preference of using the calculator as a built-in as well as separate unit of the insulin pump.

With all the tools currently available, a few questions still remain unanswered, such as how the age of patients can determine the physiological response to both ingesting the food and the process of glucose metabolism and the general expectation of young children requesting more precise carbohydrate estimation than adults. In addition, there is still an ongoing issue of rounding off effectiveness of the therapy when ingested carbohydrate products are high in glycemia load and glycemia index.

In conclusion, the BG is an important and new proposal for insulin dosage recommendation, stressing the role of meal content estimation and its impact on glycemia outcomes. Having a big impact on a bolus consumer's market and commercial representatives, the BG provides a much needed simplification of insulin dosing, learning, and using, making it a safer and more convenient therapy for all. In a continuous effort in further improvement of the product, an ongoing prospective clinical study should be performed in the future.

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