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Authors

Buchanan, Jeanne
Zabinsky, Jennifer A
Ferrara-Cook, Christine
et al.

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Comparison of Insulin Pump Bolus Calculators Reveals Wide Variation in Dose Recommendations

Jeanne Buchanan, MSN, BC-ADM, CDCES[1], Jennifer A. Zabinsky, MD, MEng[1], Christine Ferrara-Cook, MD, PhD[1], Saleh Adi, MD[1], and Jenise C. Wong, MD, PhD[1]

Abstract

Background: The introduction of insulin pumps with bolus calculators (BCs) has improved glycemic outcomes and quality of life for those with type 1 diabetes. Despite the increased reliance on BCs, the formulas used to derive recommended boluses are not standardized. Our objective was to examine whether recommendations from different pump BCs vary significantly for identical clinical scenarios.

Methods: Three commercially available insulin pump BCs were programmed with identical settings and then presented with combinations of blood glucose (BG) and carbohydrates (CHOs) to generate a 4-unit bolus. At one- and two-hour time points, while there was insulin-on-board (IOB) present, we simulated various BG and CHO scenarios in order to compare BC-recommended doses.

Results: Differences in suggested doses were noted between BCs, as well as within the same brand. The greatest variation was apparent when BG was below target. Doses suggested by one BC varied depending on whether the IOB resulted from a previous dose given for BG or CHO, while the other two BCs adjusted for total IOB regardless of the source.

Conclusions: In this simulation study, there were large differences in recommended doses between BCs due to the unique way each manufacturer incorporates IOB into their formulas as well as the pharmacokinetics used to derive the IOB amount. Providers should be aware that identical pump settings will result in a different dose recommendation for each pump brand and advise patients accordingly.

Keywords

bolus calculator, insulin bolus, insulin pump, insulin pump comparison, type 1 diabetes

Introduction

Intensive insulin therapy for glucose management and prevention of short- and long-term complications of type 1 diabetes (T1D) has become the standard of care. The American Diabetes Association and other international academic societies support the use of continuous glucose monitoring (CGM) and insulin pumps that calculate and deliver precise doses of insulin, both continuously as basal rates and intermittently as boluses.[1] Manufacturers of Food and Drug Administration (FDA)-approved insulin pumps in the United States are at various stages of incorporating automated insulin delivery based on CGM data. Current automated insulin delivery systems as well as conventional pumps require manual entry of carbohydrate (CHO) intake, and, thus, bolus calculators (BCs) remain fundamental to appropriate dosing of insulin based on the amount of CHO consumed and current glucose.[2] To prevent "stacking" of insulin doses that can lead to hypoglycemia, BC formulas also incorporate the amount of remaining insulin from prior boluses that is still actively lowering blood glucose (BG), often referred to as "insulin-on-board" (IOB). Although current BCs do not account for additional variables such as accuracy of CHO counting, exercise, and meal composition, multiple studies have shown a positive effect of pump use in lowering both hemoglobin A1c and frequency of hypoglycemia when BCs are used consistently.[3-7]

[1]Division of Endocrinology, Department of Pediatrics, University of California San Francisco, CA, USA

Corresponding Author:
Jeanne Buchanan, MSN, BC-ADM, CDCES, UCSF Department of Pediatrics, Box 0434, 550 16th Street, 4th floor, San Francisco, CA, 94143, USA.
Email: jeanne.buchanan@ucsf.edu

The parameters entered by users and incorporated into BC formulas include an insulin-to-carbohydrate ratio (ICR), target BG, insulin sensitivity factor (ISF), and active insulin time (AIT). Using these same parameters, BCs from various manufacturers have different formulas for calculating dose recommendations. Although insulin pump manuals may provide examples of how insulin doses are calculated, such as if BG is above, below, or within target range,[8-10] the precise formulas being used for each BC are often not clearly presented to users.

It is critical to understand how these BC formulas vary because this may influence the guidance given by providers to their patients, such as how to give a bolus for food in the context of hypoglycemia or dose for multiple frequent snacks or meals. In addition, anecdotal experience indicates that patients may observe changes in glycemic trends when changing pump brands despite maintaining the same pump settings. We designed a simulation study of three FDA-approved insulin pumps widely used in the United States with the aim of determining the formulas used in the BCs and whether the dose recommendations would differ in given realistic scenarios.

Methods

Three FDA-approved insulin pump BCs were compared in a simulation study: the Insulet Omnipod UST 400 (Insulet Corporation, Billerica, MA, USA) hereafter referred to as BC1, Medtronic MiniMed 670G (Medtronic Diabetes, Northridge, CA, USA) hereafter referred to as BC2, and Tandem t:slim X2 (Tandem Diabetes Care, San Diego, CA, USA) hereafter referred to as BC3. Insulin pumps were not applied to any individuals; rather, pump use was simulated in manual mode by entering BG and CHO values to determine the dose recommendations. Each device was programmed with identical values for ICR, ISF, target BG, and AIT. Settings were selected as reasonable values that offer ease of comprehension for this simulation; they do not indicate a specific recommendation for patient care. The ICR was set at 15 (ie, 1 unit of insulin for every 15 g of CHO entered), the ISF was set at 50 (ie, 1 unit of insulin for every 50 mg/dL that BG was above target), and AIT was set at three hours (ie, bolus insulin will remain active in the user's body for three hours). Based on the AIT, BCs determine the IOB at a given time using different proprietary insulin decay models; BC1 uses a linear decay model, and both BC2 and BC3 use curvilinear decay models.[8,9,11]

A single identical target BG of 100 mg/dL was used to eliminate the variability between BCs that would occur if a target range was used. Therefore, the following were programmed: BC1 with "target [correct above]" at 100 [100], BC2 with "target BG" at 100-100, and BC3 with "target BG" at 100. To further align the pump settings, the "Reverse Correction" feature was turned on for BC1. When the BG is below target, BC2 suggests a reduced insulin bolus by default. BC3 subtracts insulin when BG is less than or equal to 70 mg/dL; however, when the BG is between 70 mg/dL and the preprogrammed target BG (100 mg/dL in our scenarios), the user is asked if they want to "Reduce Bolus Calc," which was accepted during simulations.

The following three scenarios were entered into each pump: (1) BG = 100 mg/dL plus 60 g of CHO, (2) BG = 200 mg/dL plus 30 g of CHO, and (3) BG = 300 mg/dL plus 0 g of CHO. Each scenario resulted in a dose recommendation of 4 units for all three pump BCs. A "baseline" bolus of 4 units was then delivered so that IOB would be incorporated into subsequent bolus calculations. At the one- and two-hour marks after each of the three baseline boluses, during which time there was still IOB, each pump was independently presented with BGs of 60, 75, 100, 150, 250, or 350 mg/dL along with each of the three CHO scenarios (0, 30, or 75 g), producing 108 "subsequent" bolus suggestions for each pump (Figure 1). Each simulation was done by a single investigator and was repeated three times with identical results.

Results

When there was no IOB from a prior bolus, all three BCs used the same formula, $\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}}$, and, therefore, recommended the same baseline bolus (ie, 4 units) for each of the BG and CHO combinations. By using common and realistic clinical scenarios that could occur after a baseline bolus, we compared subsequent doses recommended by each BC when there was IOB present. These included when BG was (1) above target, (2) at target, or (3) below target, combined with 0-75 g of CHO intake, at one and two hours after the delivery of the baseline bolus. The dose recommendations for the subsequent boluses varied between BCs, and these results were used to deduce the different formulas used by each pump brand. All simulation results are available in Supplemental Table S1.

Subsequent BG Above Target

When the subsequent BG was above the target BG, all three pump BCs first determined an amount of insulin needed for the CHO intake using the ICR. BC2 and BC3 calculated the dose indicated for the elevated BG using the ISF and target BG, subtracted any IOB to a minimum dose of zero, and then combined that amount with the dose calculated for CHO (Table 1). BC1 similarly used the ISF and target BG to calculate the dose for the high BG, but only the IOB resulting from the CHO portion of the prior baseline bolus (hereafter referred to as CHO IOB) was subtracted to a minimum dose of zero. The dose was further reduced by any IOB resulting from the BG portion of the prior baseline bolus (hereafter referred to as BG IOB). Because there is no zero-dose minimum in this part of the formula, this term could be negative and thereby subtracted from the CHO dose when combined for the final dose recommendation (Table 1).

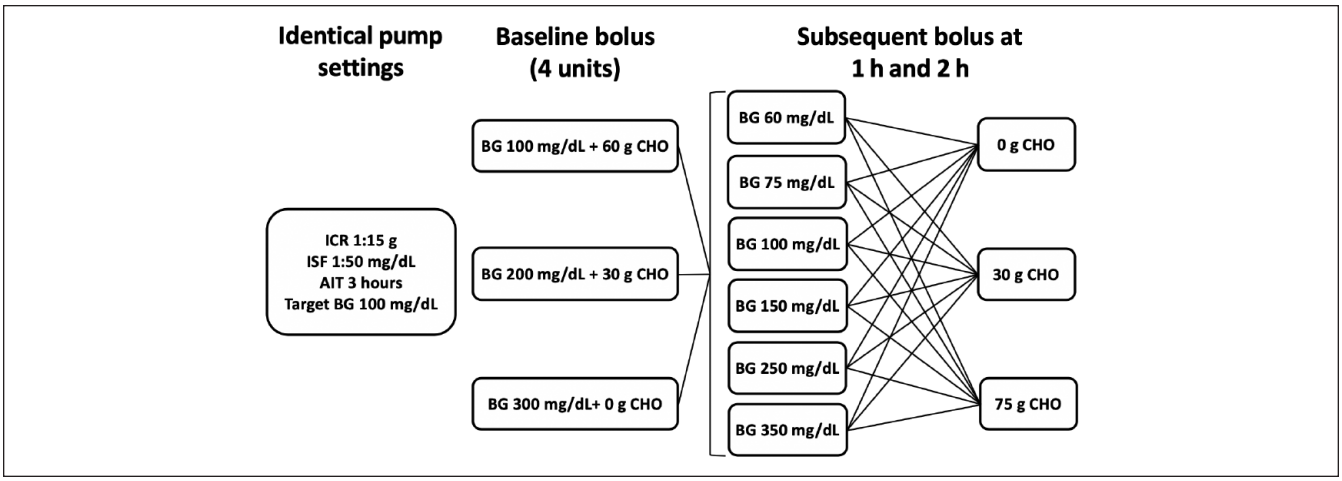

Figure 1. Overview of methodology for the simulated scenarios, resulting in a total of 108 suggested bolus doses from each bolus calculator at two timepoints (one and two hours).
AIT, active insulin time; BG, blood glucose; CHO, carbohydrate; ICR, insulin-to-carbohydrate ratio; ISF, insulin sensitivity factor.

Table 1. Formulas Used by Bolus Calculators When IOB Was Present.

BG is above target	
BC1	$\frac{\text{grams of CHO}}{\text{ICR}} + \left(\frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{CHO IOB, with\_min.\_dose\_of\_zero} \right) - \text{BG IOB}$
BC2	$\frac{\text{grams of CHO}}{\text{ICR}} + \left(\frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{IOB, with\_min.\_dose\_of\_zero} \right)$
BC3	$\frac{\text{grams of CHO}}{\text{ICR}} + \left(\frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{IOB, with\_min.\_dose\_of\_zero} \right)$
BG is at target	
BC1	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{BG IOB}$
BC2	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}}$
BC3	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}}$
BG is below target	
BC1	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{BG IOB}$
BC2	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}}$
BC3	$\frac{\text{grams of CHO}}{\text{ICR}} + \frac{\text{current BG} - \text{target BG}}{\text{ISF}} - \text{IOB}$

The term $\frac{\text{current BG} - \text{target BG}}{\text{ISF}}$ is positive when BG is above target, zero when BG is at target, and negative when BG is below target.

BC, bolus calculator; BG, blood glucose; CHO, carbohydrate; ICR, insulin-to-carbohydrate ratio; ISF, insulin sensitivity factor; IOB, insulin-on-board.

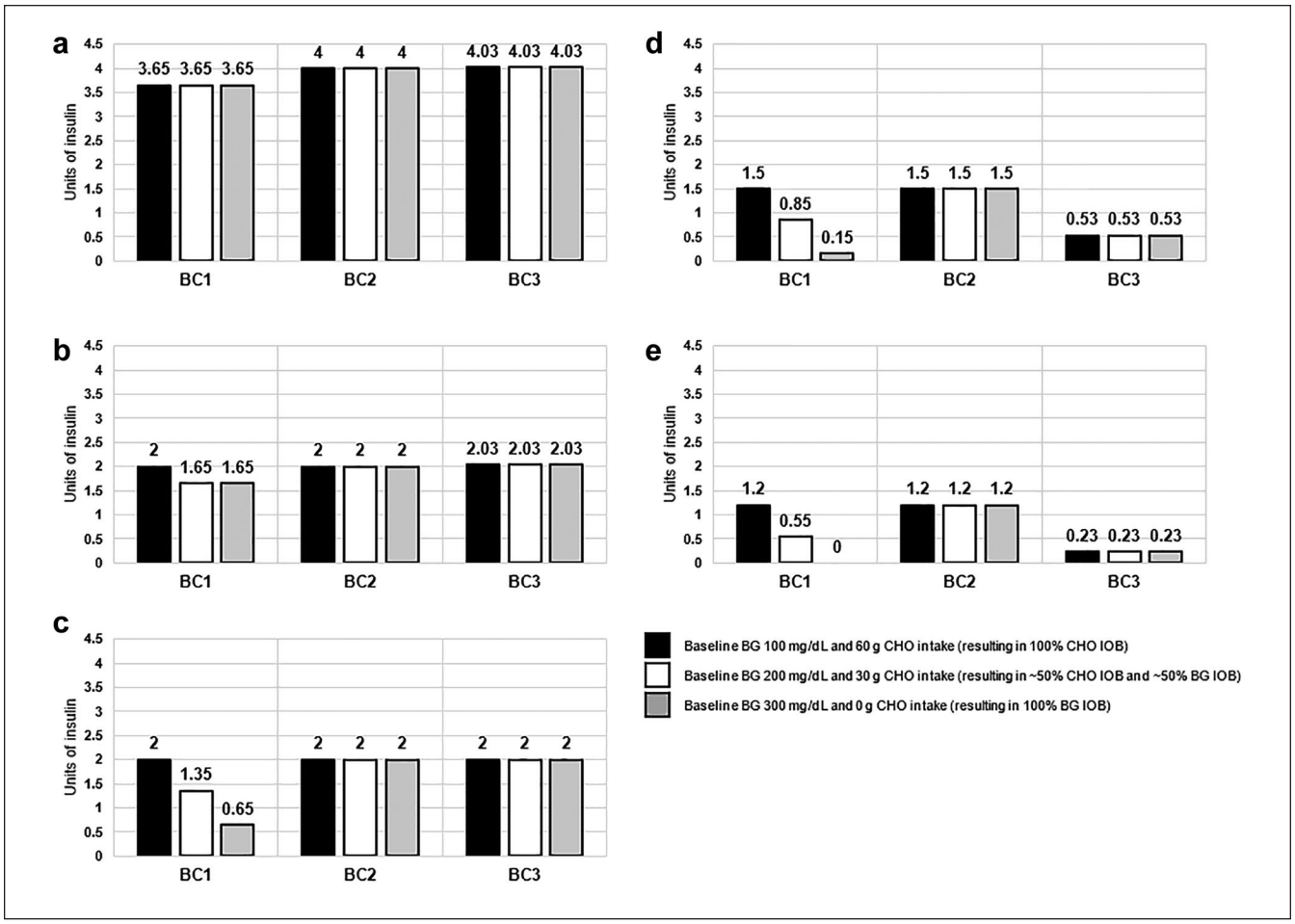

Figure 2. Bolus dose recommendations when insulin-on-board is present two hours after a 4-unit baseline bolus. Simulated scenarios shown are for 30 g of carbohydrate intake when subsequent blood glucose was (a) 250 mg/dL, (b) 150 mg/dL, (c) 100 mg/dL, (d) 75 mg/dL, and (e) 60 mg/dL.
BG, blood glucose; CHO, carbohydrate.

For scenarios when the subsequent BG was above target, BC2 and BC3 recommended doses that varied only slightly due to the difference in the calculated total IOB (Supplemental Table S1). BC1 recommended doses less than or equal to doses from BC2 and BC3 (Figure 2(a) and (b)). Within the BC1 brand, suggested doses differed depending on the source of IOB (Figure 2(b)). However, when the subsequent BG was high enough that the calculated high BG dose was greater than the CHO IOB, recommendations from BC1 showed no variation (Figure 2(a)).

Subsequent BG at Target

When the subsequent BG was equal to the target BG (100 mg/dL) and 30 g of CHO was to be eaten two hours after the baseline bolus, suggested doses ranged from 0.65 to 2 units, with variation in the doses only within those recommended by BC1, based on the amount of BG IOB (Figure 2(c)). BC1 reduced the CHO dose if any of the IOB was previously given for a high BG (Table 1). BC2 and BC3 calculated insulin doses to accommodate CHO to be consumed without consideration of any IOB. If the IOB was solely from CHO previously consumed, the doses suggested by all three BCs were identical (black bars in Figure 2(c)).

Subsequent BG Below Target

Insulin doses were the most variable between BCs when the subsequent BG was below target (Figure 2(d) and (e)). All BCs subtracted insulin to compensate for the BG being below target. BC3 further subtracted any IOB remaining from the baseline bolus that was given (Table 1). BC2 did not incorporate any IOB, resulting in a higher suggested dose of insulin than that suggested by BC3. BC1 only subtracted the BG IOB. Therefore, BC1 suggested varying insulin doses depending on the source of the IOB. For example, in the simulated scenario when BG was 75 mg/dL (below the 100 mg/dL target) and anticipated consumption

of CHO was 30 g, BC1 suggested insulin doses ranging from 0.15 to 1.5 units depending on the source of the baseline bolus (Figure 2(d)).

When there was BG IOB only (when the baseline bolus was given for a BG of 300 mg/dL and 0 g of CHO), BC2 suggested higher doses for the subsequent 30 g than both BC1 and BC3 at the two-hour point (gray bars in Figure 2(d) and (e)). In contrast, when there was only CHO IOB (when the baseline bolus was given for a BG of 100 mg/dL and 60 g of CHO), BC1 and BC2 did not incorporate any IOB and, therefore, suggested the same doses (black bars in Figure 2(d) and (e)). BC3, however, incorporated the total IOB and, therefore, recommended lower doses than both BC1 and BC2 in the same scenario.

Discussion

Insulin pumps have become essential tools in the management of T1D. They offer ease of insulin administration, and BCs add precision to insulin dose calculations. However, the specific formulas used in calculating insulin boluses are proprietary and not standardized. Our simulation study compared three insulin pump BCs, programmed with identical dosing parameters. We found considerable differences in recommended insulin doses by the BCs in the presence of IOB. Based on these findings, the unique formulas used by each manufacturer were derived (Table 1). Insulin dose recommendations from BC1 varied depending on the source of IOB, based on whether the previous bolus was for a high BG, CHO intake, or both, whereas BC2 and BC3 adjusted for total IOB regardless of the source.

The variations in recommended bolus amounts were most notable when the BG was below target, with as much as a 10-fold difference in some recommended doses. For example, one BC gave a recommendation of 1.2 units while another recommended zero for the same scenario (Figure 2(e)). Although it may be appropriate to be cautious with insulin doses when the BG is below target, insulin doses for CHO intake that are too conservative can result in rebound hyperglycemia. For example, this potential exists in our scenario when BG was 75 mg/dL, which is considered to be above hypoglycemic range for the majority of people with T1D.[12] For a BG of 75 mg/dL, BC3 recommended that 22 g of CHO be given "free" without any insulin coverage, by reducing the recommended insulin dose for 30 g of CHO by 1.47 units (final recommended dose 0.53 units). In contrast, BC2 allowed 7.5 of the 30 g to be consumed without coverage (final recommended dose 1.5 units). BC1 adjusted for the BG below target by allowing 7.5, 17, and almost 28 g of CHO to be unmatched with insulin depending on the source of the IOB from the baseline bolus (final recommended doses 1.5, 0.85, and 0.15 units, respectively).

Although different from each other, BC1 and BC2 use the same formulas within the brand when the BG is below target compared to when at target. BC3, however, uses a more conservative equation when the BG is below target and subtracts all of the IOB. The result is that a significantly different dose could be recommended for a BG only slightly below the target compared to a BG at target.

The fact that dose recommendations given by BC1 vary depending on the source of the IOB from the prior bolus is a nuance that is not widely known to diabetes providers or pump users. For scenarios when BG was at or below the target BG, insulin dose recommendations were significantly higher if the baseline dose was given for CHO vs for high BG. This may be due to the assumption that CHO IOB is matching "food on board" and may not result in a decrease in BG, while insulin previously given for a high BG will continue to lower BG until the end of the AIT. Interestingly, when the BG reached a tipping point (ie, when the high BG dose was greater than the CHO IOB), BC1 recommended the same doses regardless of whether the original bolus was for a high BG only, CHO only, or a combination (Figure 2(a)).

Another difference between the BCs is the insulin decay model considered in each algorithm. BC2 and BC3 calculated IOB based on curvilinear insulin decay while BC1 used linear insulin decay for its calculations. When compared to curvilinear decay, linear decay models will result in a lower IOB calculation initially and a higher IOB calculation subsequently.[11] For the given scenarios, the total IOB for all three BCs was very similar one hour after the baseline 4-unit bolus (2.7-2.8 units), and total IOB at two hours was 1.35 units for BC1, 1 unit for BC2, and 0.97 units for BC3. In this case, with approximately 37% more IOB used in the calculations at two hours for BC1, the way insulin decay is calculated does contribute to the variability in dose recommendations between the BCs. However, because the same amount of total IOB is used for all calculations for BC1, the use of linear decay has no effect on the differences in recommendations observed within the brand.

To our knowledge, this is the first published head-to-head comparison of specific dose recommendations from pump BCs in response to simulated clinical scenarios. Only two prior publications have described the differences in insulin pump BCs. A review of Medtronic, Animas, Deltec, and Insulet BCs attributed the variation in bolus dose recommendations to the way insulin decay was calculated (linear vs curvilinear decay).[13] At the time of that review, the Insulet BC did not incorporate any dose that was previously given for CHO intake as IOB. In a subsequent study, BC doses were evaluated in 24 participants with T1D.[14] The Accu-Chek and Animas BCs were shown to result in greater reductions in post-meal hyperglycemia than the Medtronic BC. The authors concluded that the differences were a result of both insulin decay calculations as well as pump-specific calculations used when a target BG range, rather than a single target BG value, was entered. Both publications noted the importance of providers and pump users understanding the functionality of BCs. Our study adds to the literature a detailed comparison of BCs in three FDA-approved pumps.

These comparisons provide important information to be considered by pump users when accepting BC-suggested insulin doses and by diabetes providers when adjusting pump settings or when switching patients from one pump brand to another.

Although there is debate regarding optimal calculations to use when setting the ICR, ISF, and AIT,[15] the purpose of this study was to identify key differences in BC recommendations that are not broadly apparent to providers and users when those parameters are controlled. Clearly, if any of the parameters were modified, including ICR, ISF, or AIT, or if a target range, instead of a single target BG, were used, the dose recommendations would differ.

Given that greater numbers of patients are using CGM[16] and are thus monitoring their BG within one to two hours after eating, when IOB from a previous insulin bolus should be considered, it can be argued that how BCs incorporate IOB to determine doses is increasingly relevant. A strength of our study is that it avoided the influence of confounding factors such as concomitant exercise, rate of CHO digestion, infusion site location, frequency of site changes, and CHO-counting accuracy by comparing dose recommendations rather than clinical effect.

While our study provided new information, it is not without limitations. Importantly, these data are generated from simulated scenarios and do not consider patient-specific variables including pubertal status, stress, and illness, among others. Furthermore, while we do detect differences in insulin boluses suggested by these BCs, the clinical effect on resultant BGs remains unknown. For this reason, further studies are required to provide clinical significance to this variability in pump algorithms. Finally, we did not consider the influence CGM data might have on a pump user's decision to override BC recommendations or the impact that closed-loop systems will eventually have on BCs.

Conclusion

In summary, there are large differences in the way pump BCs calculate insulin doses. By simulating specific scenarios, we were able to derive manufacturer-specific equations that could be compared. In the three BCs we examined, the variation was mostly due to how the formulas incorporate IOB from a previous bolus of insulin given in the preceding few hours. Our findings provide an explanation for why patients may experience a change in their glucose trends when they switch from one pump brand to another, and consequently, simply transferring the same settings from a prior pump to another brand may not produce the same results. Clinicians and patients should be aware of these differences and adjust pump settings accordingly.

We are not suggesting that pump manufacturers align their algorithms, as this could deter advances in technology. However, the details of algorithms currently available to providers are not presented in a way that allows for effective integration with the clinical data to inform management decisions. We recommend the requirement of manufacturers to provide all details of their dosing calculations, examples for standardized scenarios, and education regarding the specific algorithms. As pump algorithms become more complex with incorporation of automated insulin delivery technology, public disclosure becomes even more crucial to the understanding that providers must have in order to give appropriate and timely recommendations to their patients.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: JB, JZ, and CF declare that there is no conflict of interest. SA is a shareholder, consultant, and part of the speaker bureau for Dexcom, Inc, and he is a shareholder and consultant for Tandem Diabetes Care. JW has received grant support from Dexcom, Inc.

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ORCID iD


Jennifer A. Zabinsky https://orcid.org/0000-0002-6418-3366

Supplemental Material

Supplemental material for this article is available online.

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