Disparate Bolus Recommendations In Insulin Pump Therapy

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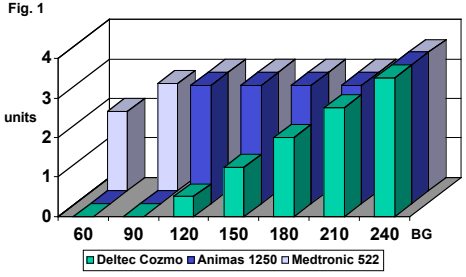
Introduction

Today's insulin pumps offer convenience and greater accuracy to users by calculating bolus doses needed to cover carb intake while accounting for the current blood sugar and residual bolus insulin on board (BOB) activity. However, when the BOB is greater than the current correction bolus need, insulin pumps begin to differ in the amount of bolus insulin they recommend. Though it seems obvious that excess bolus insulin activity would be applied to carb intake, some pumps do and some do not apply excess BOB to carb intake.

Fig. 1 shows one example of how bolus recommendations differ between pumps in the same clinical situation over a range of glucose values. In this graphic, an BOB of 3 units was entered into each pump. This equals the 3 units required to cover an anticipated carb intake of 30 grams.

Theoretically, no bolus for these carbs would be required. A range of blood glucose (BG) values was then entered into each pump to determine the exact carb and correction bolus each pump recommends.

Fig. 1



As can be seen, the boluses recommended by each insulin pump differ significantly at low BG levels, then gradually begin to agree as the BG rises and the insulin required to lower the rising blood glucose level overtakes that needed to cover the carb intake. (carb factor = 1u / 10 gr, corr. factor = 1 u / 40 mg/dl over 100 mg/dl, target BG = 100 mg/dl)

Objective: This study was designed to determine:

1. Usual time intervals between boluses of all types
2. How often boluses are given within 4.5 hours of a previous bolus
3. How often a blood glucose value is available when boluses are given
4. How often boluses are taken when BOB is present and carbs then eaten but no BG taken (blind boluses)
5. How often boluses have excess BOB when a BG is obtained
6. How often boluses have excess BOB when carb and BG are both recorded

This study observed how often significant residual bolus activity may be present that the user is unaware of and how often recommended bolus doses may differ between different insulin pumps.

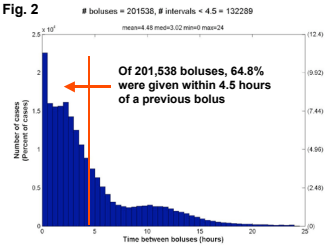
Methodology

Anonymous data from 541 Cozmo insulin pumps that had were largely used by Type 1 patients in the U.S. in the spring and summer of 2005 was collected courtesy of Deltec, Inc. and then analyzed using Matlab software at BioFormatix, Inc.

The Cozmo pump measures BOB in a linear fashion with a duration of insulin action (DIA) that can be set between 2 and 8 hours. To rule out variations caused by user-selected DIAs, a standard DIA of 4.5 hrs. was used for all bolus data analyses. In effect, any bolus given within 4.5 hours of a previous bolus will have BOB that is taken into account to determine the bolus required for carbs and/or BG corrections. This time is similar to a curvilinear DIA of 5 hrs used in some pumps. We believe this time is conservative in that it estimates a residual BOB activity that is slightly less than the true residual BOB values for most individuals.

In the Cozmo pump, the user may select to include a BG calculation but then leave this value at the default without actually measuring a blood glucose, with or without use of a CoZmonitor meter which directly enters all glucose values. To exclude this artificial BG data, all BG values equal to the user's target value were excluded from our calculations. This may slightly underestimate actual BOB, but prevents a larger artificial over-estimation of BOB.

Fig. 2



Results

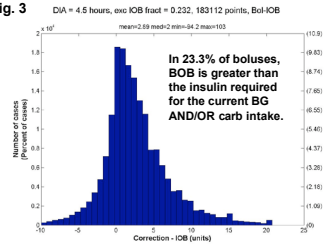
Overall, 201,538 of 204,005 total boluses were given within 24 hrs of another bolus. Distribution of bolus intervals is shown in Fig. 2.

Carb boluses averaged 3.4 per day (range: 0 to 17) and correction boluses averaged 2.0 per day (range: 0 to 8.1). More than a third of pump users averaged 5 or more carb boluses a day. The average for the maximum number of boluses per pump per day was 6.9 (range: 0 to 40).

64.8% or 132,289 of 204,005 boluses were given within 4.5 hours of a previous bolus, as shown in Fig 2. For carb boluses, 55.5% are given within 4.5 hrs.

23.2% of all boluses were given when residual BOB exceeded the amount needed to correct the current BG and/or the current carb intake (Fig 3).

Fig. 3



66,392 boluses or 32.5% of all boluses (in 444 total pumps) were given in conjunction with a BG test performed at the time. The remainder (67.5%) are given with no BG value, so the exact bolus required at the time is unknown (blind boluses).

Indirectly, it can be estimated that 15.6% (23.2% of 67.5%) of boluses are given without a glucose test, yet have excess BOB present (blind bolus with excess BOB).

Only 28,994 boluses or 14.2% of all boluses were given with both carb intake and a BG value recorded.

In 2.21% of boluses, the BOB is greater than the total bolus required for current BG and carb intake (Fig 4).

Fig. 4

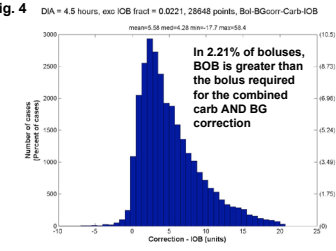
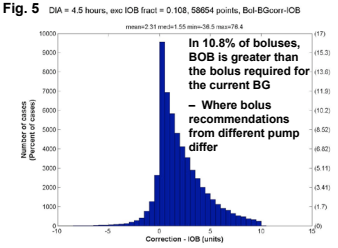


Fig. 5



In 14.0% of boluses (28,648 of 204,00), both a BG value and carb intake were entered at the time. In these boluses, the residual BOB was greater than the combined bolus requirement for the BG and carb intake on 2.21% of occasions.

Discussion

Calculation of bolus doses by software in insulin pumps is intended to provide pump users with accurate bolus recommendations. However, insulin pumps do not agree on the bolus amount to deliver when BOB is excessive and carb intake is planned because BOB may or may not be subtracted from the carb bolus. Differences in bolus recommendations arise whenever residual BOB is present with a low BG or is greater than the bolus dose required to lower a high glucose, and carbs will be eaten.

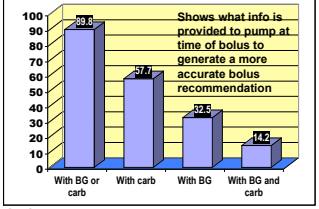
Given the frequency of bolus doses (64.8% are within 4.5 hrs of a previous bolus) and an increase in frequency of boluses on some days (avg. maximum of 6.9 per day), significant variations in recommended boluses are likely to be encountered by most pump users.

In 10.8% of boluses, BOB is greater than the bolus needed for the current BG and carb intake would be advised to offset the excess BOB. When this excess occurs in conjunction with carb intake, a common occurrence as indicated in Fig 6, differences arise in bolus recommendations.

In situations that appear to be common, excess bolus recommendations may occur.

67.5% of boluses given by smart pumps are little better than those given by older "dumb" pumps because no BG data is provided to guide the dose.

Fig. 6 **% of Boluses with BG or Carb Inputs**



Conclusions

1. Significant differences in bolus dose recommendations may occur between current insulin pumps despite identical clinical circumstances.
2. 65.6% of all boluses are given within 4.5 hrs of another bolus so that some BOB will be present.
3. In 67.5% of all boluses, no BG value is available to improve bolus accuracy.
4. Only 14.2% of boluses have both BG and carb intake provided to the pump.
5. 10.8% of boluses are given when BOB is greater than the correction bolus required at the time, so in about 1 of 9 boluses differences in bolus recommendations will arise. Some are small differences, some are not.
6. 2.21% of all boluses contain sufficient BOB that it is greater than the total bolus required to compensate for the BG and the planned carb intake.
7. These differences may result in significant differences in clinical outcomes and may induce compensatory basal insulin adjustments specific to each pump manufacturer.
8. Clinicians and patients must be aware of the unique approach to dosing provided by each pump and how to compensate for occasional excess bolus recommendations