Comparison of two bolus strategies for a high fat with high carbohydrate meal in T1D patients on CSII

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BACKGROUND AND AIMS

Food rich in fat and carbohydrates, such as pizza, is widely recognized to cause marked late postprandial hyperglycemia in T1D patients. Dietary fat and free fatty acids (FFAs) are known to impair insulin sensitivity and to enhance hepatic glucose production. The aim of this study was to evaluate postprandial glycemic response of a high carbohydrate/high fat meal in T1D patients on pump therapy, using two type of bolus we use in our practice: Split Super Bolus (SSB) and Augmented Dual Wave

METHODS

This was a interventional crossover clinical trial conducted in a single center. The study was approved by the institutional ethics committee and all participating subjects gave informed consent. The subjects were advised to have a specific meal (60 gr carb meal, <10 gr fat) six hour before the experiment was performed and instructions for achieving normal-range glycemia (70-180 mg/dL) before the intervention. They were cited twice on a Pizza chain restaurant, and were asked to eat 3 slices of pizza estimated to contain 75 g of carbohydrates and 34g of fat. The first time they received SSB: an insulin bolus calculated for 140% of the real carbohydrates before eating and a 40% booster at 120 minutes. On the second session the patients had the same 3 slices of the same pizza, and receive ADW: a dual wave bolus calculated for 180% of the carbohydrates, 50:50% over 2 h and the whole procedure was repeated. Capillary glycemia (CG) was measured every 30 minutes for 5 hours and registered. Hypoglycemia (<70 mg/dL) episodes were corrected using standarized fruit juice portions.
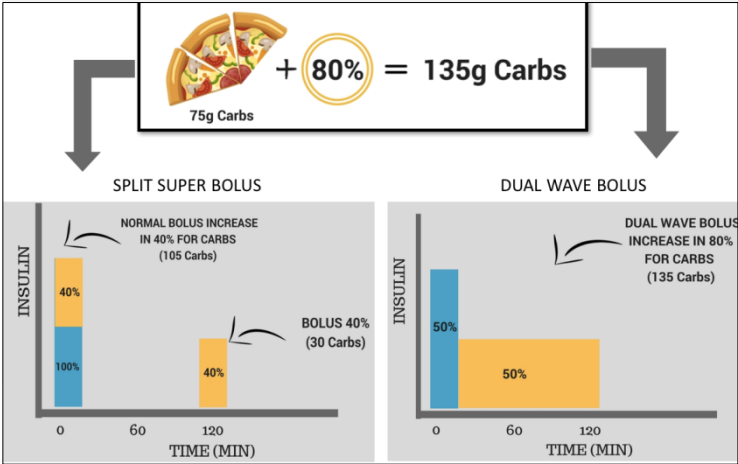

RESULTS

Sixteen patients with T1D on CSII (14 Medtronic Minimed 640g, 1 Paradigm veo and 1 Minimed 715) and CGM were enrolled in this study. The characteristics of the study group are presented in *Table 1.*

TABLE 1: Demographics Data of Patients

Demographic	Value
Gender (men/women)	9/7
Age (years)	33 ± 14,1
BMI (kg/m^2)	24,1 ± 2,5
Hba1c (%)	7,1 ± 0,8
Diabetes duration (years)	19,9 ± 14,2
Daily insuline dose (IU/kg/d)	40,2 ± 10,3
Basal insulin(%)	39,6 ± 8,6

Given non-normal distribution and paired samples, two tailed non parametrical tests for paired samples were used for testing statistical significance between samples. No significant differences were found on the insulin doses administered at the beginning of the experiment. Regarding our main objective, 76 % of CG resulted between 70-180 mg/dL in both groups over 5 hours, with a non significant trend for more hypoglycemia in SSB (10.5% vs. 7.5%, p = 0.44). CG on T-120' and T-310' were similar for SSB and ADW, with no significant differences. (graphic 1). More subjects required corrections of hypoglycemia in SSB (17 vs. 7), but it was not significant (p=0.44). Only one subject applied a bolus for correcting hyperglycemia, which was not statistically analyzed. No severe hypoglycemia occurred over the course of the experiment or the following 6 hours

CONCLUSION

The results from this experiment show that both bolus strategies get appropriate postprandial control after a meal rich in carbs and fat over the following 5 hours, with a non significant trend for lower risk of hypoglycemia for ADW. Future experiments are warranted for finding the most appropriate strategy with minimum risk.

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GRAPHIC 1: Average capillary mesuarments over time (every 30 min)

Time (minutes)	0'	30'	60'	90'	120'	150'	180'	210'	240'	280'	310'
SSB (mg/dL)	120,1	119,6	142,0	151,9	146,8	125,8	125,1	122,4	120,4	111,9	104,0
ADW (mg/dL)	122,3	112,9	132,7	148,2	152,6	143,1	138,7	132,1	129,5	133,9	138,4