ORIGINAL ARTICLE

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The Importance of the Bolus Calculator Use for Improving Glycemic Control in Patients on the Insulin Pump Therapy

Bojana Carić[1,2], Katarina Lalić[3,4], Saša Marin[5], Ljubica Stošić[4], Snježana Popović Pejičić[1,2]

[1] University Clinical Center of the Republic of Srpska, Banja Luka; Clinic for Internal Diseases
[2] School of Medicine, University of Banja Luka, Republic of Srpska
[3] School of Medicine, University of Belgrade, Serbia
[4] Department of Endocrinology, Diabetes and Metabolic Diseases; Clinical Center of Serbia, Belgrade, Serbia
[5] Faculty of Medicine, University of Banja Luka, Study program Dentistry, Department of Oral Surgery, Republic of Srpska

Contact address:
Bojana Carić
University Clinical Center of the Republic of Srpska, Banja Luka; Clinic for Internal Diseases
Street address: 12 beba b.b.
78000 Banja Luka,
Republic of Srpska
Bosnia and Herzegovina
e-mail:bojanaradosevic@gmail.com
phone number: +387-65-841-294

ABSTRACT

Introduction: Bolus calculator is an advanced function of insulin pump (IP). The use of bolus calculator increases the accuracy of calculation of the proper meal or corrective dose of insulin in patients with type 1 diabetes (T1D).

Aim of the Study: Compare the difference in the parameters of glycemic control (HbA1c, postprandial increase of blood glucose and number of hypoglycemic episodes per week) between the group of patients who use bolus calculator for <50% of the total daily boluses, and the group of patients who use bolus calculator for ≥50% of total daily boluses.

Patients and Methods: This study included 36 patients aged over 18 years with T1D on IP therapy in the Republika of Srpska. All patients used IP for at least one year prior to participation in the study. Before the IP therapy was initiated, all the patients were trained for carbohydrate counting in course of flexible insulin therapy training (FIT). Professional software, CareLink Pro® Software (Medtronic Inc., Northridge, CA, USA) was used to download data from insulin pumps to a personal computer. The default frequency of bolus calculator use was ≥50% of total daily boluses.

Results: No statistically significant difference was found in HbA1c (6.61 ± 1.10 vs. 0.84 ± 6:56, p = 0.896) or the number of hypoglycemic episodes (2.00 (1.00, 4.00) (1.0 - 6.0) vs 3.00 (2.00, 4:00) (1.0 - 5.0), p = 0.298) between the group of patients who used bolus calculator for <50% of the total daily boluses, and the group of patients who used bolus calculator for ≥50% of total daily boluses. Patients who used bolus calculator had significantly lower postprandial increase in blood glucose after breakfast.

Conclusion: In order to maximize all the advantages of IP therapy, a regular re-education of both patients and diabetologists about advanced IP functions is needed for improving the glycoregulation in T1DM.

Keywords: Insulin pump, bolus calculator, T1D, glycoregulation

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Introduction

Insulin pump therapy (IP) represents one of two ways of applying intensive insulin therapy in type 1 diabetes (T1D), allowing precise dosing of basal and bolus insulin doses.[1]

Technological improvement of IP and use of rapid acting insulin analogues with faster onset of action has provided the development of a system that integrates IP and the system for continuous glucose monitoring (CGM), so-called sensor-augmented IP. This system has proved superiority in lowering HbA1c in comparation with conventional intensive insulin therapy.[2,3] By creating a control algorithm that automatically adjusts insulin delivery according to the measured blood glucose or assumed glucose values (i.e. insulin and glucagon in dual-hormone model of artificial pancreas), an artificial pancreas function is set.[4,5] In the last decade, the effectiveness of different models of artificial pancreas was demonstrated in order to achieve optimal glycemic control, with a lower incidence of hypoglycemia.[6-8] However, more studies with a larger number of participants will be needed to confirm the safety home use of artificial pancreas in unexpected situations.[9]

Automatic bolus calculators are integrated into commercial insulin pumps, and based on preprogrammed settings of specific algorithms, they suggest bolus dose, and thereby increase the accuracy of calculations in relation to mental calculation. These settings should be individually adjusted for each person, and should refer to the same parameters required for calculating bolus doses manually: insulin/carbohydrate ratio, corrective factor, active insulin time, target values of blood glucose and actual value of glycemia.[10,11]

"Smart" IPs have integrated bolus calculators which in the process of calculating the bolus dose also calculate the active insulin of the preceding dose. In that way, the bolus calculator use can accurately determine the bolus dose or the dose of insulin needed to correct high blood glucose. Furthermore, most commercial pumps with integrated bolus options provide three different types of bolus: 1) normal bolus- the pump delivers the entire bolus at once; 2) square bolus- the pump delivers equally required dosage of insulin during a period of time, and 3) combined bolus – the pump has options of two above mentioned pumps.[12] The previous studies who studied the impact of advanced IP functions on glycoregulation, have showed that the use of bolus calculator had no impact on the value of glycosylated hemoglobin HbA1c, but it could contribute to the glycemic excursion and postprandial glycemic decrease, and thus contribute to the improvement of glycemic control.[13]

Aim of the Study

To compare the parameters of glycemic control between the group of patients who use bolus calculator for <50% of the total daily boluses and the group of patients who use bolus calculator for ≥50% of total daily boluses based on the difference between the HbA1c, postprandial increase of glucose and the number of hypoglycemic episodes per week.

To compare the difference in the use of bolus option between the group of patients who use bolus calculator for <50% of the total daily boluses and the group of patients who use bolus calculator for ≥50% of total daily boluses.

Patients and Methods

This study included 36 patients aged over 18 years with T1D on IP therapy in the Republic of Srpska. The models used for the purpose of this study were IP MiniMed® Paradigm 722 (Medtronic Inc., Northridge, CA, USA) and MiniMed® Paradigm 754 (Medtronic Inc., Northridge, CA, USA) which had an integrated bolus calculator (Bolus Wizard) as an advanced insulin pump option. Most patients used MiniMed® Paradigm 754 (n = 20), while other patients preferred MiniMed® Paradigm 722 (n = 16). All patients used insulin pump for at least one year prior to participation in the study along with the therapy with short-acting insulin analogues. Implantation of insulin pumps was performed during the period from 2008 to the 2012 at the Department of Endocrinology, Diabetes and Metabolic Diseases at Clinical Center of Banja Luka. Before initiation of IP therapy the patients were trained for carbohydrate counting in course of flexible insulin therapy training (FIT).

Medtronic "CareLink® Pro" (Medtronic Inc., Northridge, CA, USA) is a software for professional management and monitoring of diabetes treatment for use on a personal computer. This software has been approved by the FDA for the market use in September 2010. In our study, the data from the insulin pumps were downloaded on a personal computer by Medtronic "CareLink® Pro 4.0c" (Medtronic Inc., Northridge, CA, USA) software. The amount of data within each pump varied depending on the degree of use of all insulin pump's technical possibilities and ranged from 63-266 days. For the purpose of our study, a period of nine weeks (63 days) was analyzed for each patient. The data were downloaded with a USB CareLink® (Medtronic Inc., Northridge, CA, USA) upon arrival of patients for a regular check-up, at the Department of Endocrinology of the Clinic for internal diseases of UCC Republika Srpska in Banja Luka. Body weight, demographic data and variables related to diabetes (the data of chronically complications presence, the data on the duration of diabetes, duration of pump therapy, the average number of hypoglycemia per week, the value of HbA1c and glucose profiles were gathered from patients. During the study, none of the patients used the CGM.

The default frequency of bolus calculator use was ≥50% of the total daily boluses.[15,16] Obtained value of HbA1c referred to the period of the observed 9 weeks within which the profile of preprandial and postprandial glycaemia was made. All patients on insulin pump therapy measure HbA1c at the Institute of Laboratory Diagnostic at the University Clinical Centre of Republic of Srpska using the Cobas c 501, Roche Diagnostics (Basel, Switzerland) apparatus, which is certified as having a documented trace ability to the Diabetes Control and Complications Trial reference method by the National Glycohemoglobin Standardization Program (NGSP). Glycemic profiles were measured using the Accu-Chek ® Performa glucometers, Roche Diagnostics (Basel, Switzerland), which has the possibility of wireless transmission of stored values to a computer via Accu-Chek Smart Pix devices (Basel, Switzerland). Informed written consent was obtained from all participants before enrollment in the study, providing patients' personal data protection in the case of the publication of results.

For statistical analysis, IBM SPSS Statistics 21.0 software was used. In order to compare the differences in the frequency of observed characteristics between the groups of respondents, the Pearson's $\chi 2$ contingency test was used. Distribution normalcy of the observed characteristics was tested with Kolmogorov-Smirnov normalcy test. In order to compare the average values of characteristics between the groups of respondents, the Student t test for independent samples was used (observed characteristics that have a normal distribution) and non-parametric Mann-Whitney U test for independent samples (observed characteristics that do not have a normal distribution). When using Student's t test for independent samples, F test was used in order to grasp the significance of differences in the variances of observed characteristics. As statistically significant, all the values in which $p < 0.05$ were taken/used.

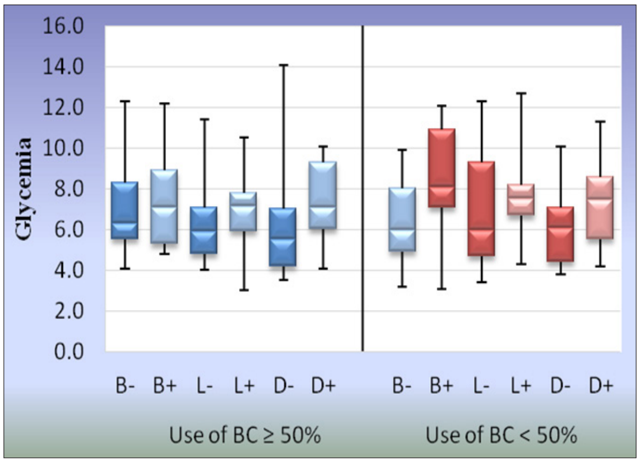
Results

A total of 36 adult patients with T1D on insulin pump therapy were included in the study and divided into two groups by bolus calculator use. The first group consisted of 17 patients (47.22%) used bolus calculator <50% of all daily boluses , and the other group consisted of 19 patients (52.78%) in which ≥50% of all given daily bolus were given by bolus calculator. Patients older than 30 years were majority in both groups (76.47% in the first group and 52.63% in the second group). The observed difference between the groups was not statistically significant. There was no statistically significant difference in duration of insulin pump therapy between the groups (4.35 vs. 3.74 ± 1:46 ± 2.13, p = 0.300).

Mean HbA1c was not significantly different between the two groups, although bolus calculator users had slightly lower HbA1c. (Table 1).

Patients who used bolus calculator for ≥50% of all given daily bolus, had a lower postprandial increase in blood glucose. Bolus calculator users had a significant lower postprandial increase after breakfast ($p < 0.034$). The difference between postprandial increase for lunch and dinner was not statistically significant. (Chart 1).

Figure 1. **Box-plot diagram for preprandial and postprandial for two groups of patients**



B- preprandial breakfast glycemia
B+ postprandial breakfast glycemia
L- preprandial lunch glycemia
L+ postprandial lunch glycemia
D- preprandial dinner glycemia
D+ postprandial dinner glycemia

The patients on IP therapy had an average of three hypoglycemic episodes per week. There was no statistically significant difference between the two groups, although bolus calculator users had slightly more frequent hypoglycemic episodes than bolus calculator non-users (Table 1).

Bolus calculator users had a lower average number of total boluses during the day and statistically significantly higher average number of boluses given with food as compared to bolus calculator non-users. A higher number of corrective boluses was observed in the group of bolus calculator users but with no statistically significant

Table 1. **The parameters of glycemic control and "bolus option" parameters for bolus calculator users (BC+) and bolus calculator non-users (BC-)**

	BC-	BC+	p
HbA1c (%)	6.61 ± 1.10	6.56 ± 0.84	p=0.896
The average number of hypoglycemic episodes/week	2.00 (1.00, 4.00) (1.0 - 6.0)	3.00 (2.00, 4.00) (1.0 - 5.0)	p=0.298
The average number of total boluses/day	7.35 (4.90, 7.79) (2.5 - 16.0)	5.30 (3.92, 6.59) (2.0 - 9.4)	p=0.136
The average number of manual boluses/day	5.46 (3.70, 6.63) (2.5 - 14.3)	0.11 (0.00, 1.00) (0.0 - 3.8)	**p<0.001**
The average number of boluses with food/day	0.11 (0.00, 1.67) (0.0 - 3.2)	3.03 (2.25, 4.13) (0.1 - 8.2)	**p<0.001**
The average number of corrective boluses/day	1.07 ± 1.06	1.90 ± 1.39	p=0.055
The average number of boluses given by BC	1.14 ± 1.12	4.63 ± 1.69	**p<0.001**
"Normal" boluses (%)	100.00 (97.60, 100.00) (64.8 - 100.0)	100.00 (93.12, 100.00) (55.6 - 100.0)	p=0.791
"Dual Wave" boluses (%)	0.00 (0.00, 1.08) (0.0 - 35.2)	0.00 (0.00, 6.88) (0.0 - 44.4)	p=0.873
"Square Wave boluses (%)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	p=0.530

differences between the groups. There was a statistically significant difference between the average number of bolus given by bolus calculator between two groups. The patients who used bolus calculator for <50% of total boluses were using bolus calculator to some extent.

According to the use of different types of bolus that bolus option offers, both groups of patients most commonly used "normal" boluses, but bolus calculator users had a slightly higher percentage of using "dual" and "square" boluses than bolus calculator non-users. This difference was not statistically significant (Table 1).

Discussion

Bolus calculator is used in 86% among all patients with T1D on IP therapy in Republic of Srpska. This result is significantly higher compared to results in other studies in which the use of bolus calculator varied from 16% to 58%.[16-18] The reason for high percentage of patients who use the bolus calculator in the Republic of Srpska could be the result of five days FIT education program, which is obligatory for all patients before IP therapy is initiated. In course of FIT program, all the patients were trained for carbohydrate. Observation of a large number of patients who used bolus calculator and who were at FIT program, was also available.[19]

The results from this study regarding the use of bolus calculator correspond to the results from other studies. Klup and colleagues have showed the effect of the use of bolus calculator on postprandial blood glucose level but not on HbA1c level.[20] In 12-months-long controlled randomized study, the use of bolus calculator did not show HbA1C decreasing but there was an effect on postprandial blood glucose level decreasing.[21] In contrast to the above mentioned, there are studies which confirm the effect of the use of bolus calculator on HbA1C decreasing.[22]

The effects of the use of bolus calculator on postprandial glucose decreasing level have been confirmed in numerous studies.[21,23,24] In our study, significant postprandial glucose decreasing level after breakfast was observed, which is a very important result since the highest glucose levels are usually after breakfast. One possibility for improving metabolic control among patients with DT1 could be prevention of postprandial glucose peaks after breakfast.[25]

When it comes to the total number of given bolus, patients who use bolus calculator give more bolus during meal, which should provide more food consumption. However, the patients who used bolus calculator used corrective boluses more frequently. This data is inconsistent with the statement about lesser postprandial increases with bolus calculator use.[15,24]

Walsh and colleagues have emphasized that imprecise insulin/carbohydrate ratio, corrective factor and active insulin time could diminish success of IP therapy, and also the use of "magical numbers" for preprogrammed settings by general practitioners. Due to the above mentioned patients who follow instructions of bolus calculator have to give more corrective bolus.[10] This point of view can explain a number of corrective bolus among bolus calculator users in our study.

Furthermore, a lack of education of patients who are not educated enough to change upgraded options of bolus calculator as well as the lack of interests and knowledge of professional team to constantly adjust upgraded settings of an insulin pump[26] may explain a low use of different bolus types in our study. In comparison to the normal boluses, the use of combined and square boluses showed a greater effect on the reduction of postprandial excursions for meals composed of fats and those that were composed of slowly absorbed ingredients.[27-30] Well educated patients used a combined bolus more often, and with its usage, the value of HbA1c may be decreased.[27] The results of our study, with patients who mostly used normal type of bolus and who did not use combined or squared boluses, do not confirm good education.

One of the reasons for not using the bolus calculator is avoiding self-control of blood glucose due to the lack of test stripes which patients treated with insulin pump receive from the Health Insurance Fund of the Republic of Srpska. The number of test stripes (100 units/month) is insufficient for the required number of glucose measurements for bolus calculator use. Furthermore, there is no bolus calculator on the market that account the impact of proteins and fats to glycoregulation[30, 31] which could be the point for improved effectiveness of bolus calculator and for the increase of number of patients who have enough confidence in the usage of bolus calculator.

The use of CareLink® Pro (Medtronic, Inc., Northridge, CA, USA) could practically facilitate therapeutic decision for diabetologists. This software can precisely determine how to use an insulin pump and to improve the compliance of patients. It is possible to define the main points in self-control and therapy and to modify certain parameters (basal rates, insulin/carbohydrate ratio, and corrective factor). Furthermore, it could provide precise instructions for nutrition adjustment and physical activity. Using professional software, less time would be spend on data interpretation and more time on conversation with patients about the everyday IP treatment challenges, which could contribute to improving glycemic control.

Conclusion

In order to maximize all the advantages of IP therapy, a regular re-education of both patients and diabetologists about advanced IP functions is needed for improving the glycoregulation in T1DM.

The professional team for IP management should be formed in the Endocrinology Department. The use of CareLink® Pro (Medtronic, Inc., Northridge, CA, USA) could practically facilitate therapeutic decision for diabetologists by giving precise instructions for insulin adjustment, nutrition and physical activity in order to improve the glycemic control.

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Značaj upotrebe bolus kalkulatora za poboljšanje glikoregulacije kod pacijenata na terapiji inzulinskom pumpom

SAŽETAK

Uvod: Bolus kalkulator predstavlja naprednu funkciju inzulinskih pumpi (IP) čijom se upotrebom povećava preciznost izračuna odgovarajuće doze inzulina za obrok, odnosno korektivne doze inzulina, kod pacijenata sa tipom 1 dijabetesa (T1D).

Cilj rada: Uporediti razliku u parametrima glikoregulacije (HbA1c, postprandijalnog porasta glikemije, broja hipoglikemijskih epizoda u nedelji dana) između grupe pacijenata koji bolus kalkulator koriste za <50% ukupno datih dnevnih bolusa i grupe pacijenata koji bolus kalkulator koriste za ≥50% ukupno datih dnevnih bolusa.

Ispitanici i metode: U studiji je učestvovalo 36 pacijenata starijih od 18 godina koji su liječeni IP najmanje godinu dana prije početka istraživanja. Prije inicijacije terapije IP, obavljena je strukturisana edukacija po principima fleksibilne inzulinske terapije u okviru koje su pacijenti obučeni za korištenje metode »brojanja ugljenih hidrata«. Profesionalni softver, CareLink Pro® Software (Medtronic Inc., Northridge, CA, USA) za praćenje liječenja T1D je korišten za preuzimanje podataka sa IP na personalni računar. Podrazumijevana frekvenca upotrebe bolus kalkulatora iznosila je ≥50% svih datih bolusa tokom dana.

Rezultati: Nije uočena statistički značajna razlika ni u HbA1c (6.61 ± 1.10 vs. 6.56 ± 0.84, p = 0.896) niti u broju hipoglikemijskih epizoda (2.00 (1.00, 4.00) (1.0 - 6.0) vs 3.00 (2.00, 4.00) (1.0 - 5.0), p = 0.298) između grupe pacijenata koji su koristili bolus kalkulator za <50% ukupno datih bolusa i grupe pacijenata koji bolus kalkulator koristili za ≥50% ukupno datih bolusa. Pacijenti koji su koristili bolus kalkulator imali su signifikantno manji postprandijalni porast glikemije nakon doručka.

Zaključak: Da bi se maksimalno iskoristile sve prednosti IP, potrebne su redovne reedukacije i pacijenata i dijabetologa o naprednim funkcijama IP, što bi doprinijelo njihovoj redovnoj upotrebi i poboljšanju glikoregulaije u T1D.

Ključne riječi: Inzulinska pumpa, bolus kalkulator, T1D, glikoregulacija