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Original article

Effect of use of insulin pump with low glucose suspend feature on metabolic control in children with type 1diabetes

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Summary

Introduction. The automatic suspension of the insulin pump and discontinuation of insulin delivery in case of hypoglycemia is one of the features of Veo insulin pump when it is connected with the sensor used for continuous monitoring of glycemia (CGM). This type of therapy is currently considered to be the best one for achieving a good metabolic control in children with type 1 diabetes mellitus. The objective of the study was to check whether the use of an option for automatic suspension in case of hypoglycemia and combined bolus affects the metabolic control in children with type 1 diabetes mellitus using the insulin pump for a three-month period.

Methods. The study included 25 participants (13 girls and 12 boys), aged 7 to 15 years with average age 11.88 ± 3.15 years and average diabetes duration of 6.12 ± 2.5 years. On average, the participants have already been using the insulin pump Paradigm Veo TM MMT-754 for 3.08 ± 1.73 years. The measurements of HbA1c were done at the beginning of the study, then after three and six months.

Results. The percentage of glucose serum levels above 7.8 mmol/L insignificantly increased, while the percentage of glucose serum levels below 3.9 mmol/L decreased during the three-month period of CGM wearing. The initial HbA1c was 7.53 ± 0.87%. After three months of wearing, CGM HbA1c showed a slight decrease to 7.48 ± 0.73%, while at the follow-up after another three months without CGM HbA1c increased to 7.57 ± 0.98%.

Conclusion. This study shows that the use of an insulin pump with the option of automatic suspension in case of hypoglycemia and combined bolus is only associated with a certain improvement in the metabolic control after three months of continuous wearing without increasing the risk of hypoglycemia.

Key words: type 1 diabetes mellitus, children, Veo insulin pump, continuous glucose monitoring (CGM).

Introduction

Insulin pump therapy is considered to be an optimal type of insulin therapy in children with type 1 diabetes mellitus, since it resembles the physiological need for insulin during 24 hours. The insulin pump Veo in the combination with a continuous glucose monitoring (CGM) is a particularly effective way to apply insulin therapy because it automatically suspends supply of basal insulin in case of hypoglycemia. This option significantly reduces the severity and duration of hypoglycemic events simultaneously enabling the metabolic control of children with diabetes [1]. With regard to this, it was important to note that although HbA1c measurement is an objective method of assessing the long-term metabolic control over three last months, common hypoglycemia events could cause lower HbA1c levels, which would give a false picture of a good metabolic control. On the other side, it is well-known that both hypoglycemia and fear of it represent obstacles to achieving good metabolic control.

CGM refers to the interstitial glucose measurement every five minutes, which provides a detailed set of information including glucose variability and trends, as well as estimates of HbA1c. There are studies confirming that a longer use of CGM is advantageous compared to shorter periods of use, because its continuous use provides patients with insights on the glycemic dynamics which consequently improves long-lasting glycemic control with or without effects on hypoglycemia [2, 3]. For instance, the STAR3 study showed that using CGM together with the insulin pump led to a significant reduction in HbA1c by 0.6% ($p < 0.001$) compared with the group that used multiple insulin injections instead of pump during 12 to 18 months of following [3]. Moreover, in the SWITCH study the use of CGM control together with the insulin pump therapy resulted both in a decrease in HbA1c and a reduction in time spent in hypoglycemia [4, 5]. Ly and coworkers [6] compared standard insulin pump therapy with sensor augmented pump (SAP) therapy and low-glucose suspend (LGS) option on pumps, and found that this addition reduced severe and moderate hypoglycemia during 6 months of treatment. The first long-term study of efficacy and safety of insulin pump therapy with both SAP and LGS, which lasted for 47 months, showed a significant and sustained decrease in HbA1c and a reduction in hypoglycemic events [7]. Furthermore, in the ASPIRE study, using an option to automatically stop the delivery of insulin when close to hypoglycemia resulted in a decrease in the frequency and duration of nocturnal hypoglycemia without increasing HbA1c [8-10]. Also, several studies showed that safety and efficacy as well as satisfaction and tolerance of CGM were maintained at long-term follow up [11, 12].

The main aim of our study is to determine whether the capabilities of the VEO insulin pump, used together with the CGM device with automatic suspension in the event of hypoglycemia, affects the metabolic control in children with type 1 diabetes mellitus wearing insulin pumps. In addition, our objectives were to investigate whether patients would adhere to the recommended protocol in case of a hypoglycemic event and whether they would use the combined boluses when consuming highly caloric and fatty meals, which make a significant proportion of the traditional cuisine of the area.

Methods

The study was conducted at the Clinic for Children's Diseases, University Clinical Center in Banja Luka (The Republic of Srpska, Bosnia and Herzegovina) from January to June 2017. The study was approved by the Ethics Committee of Human Experimentation in Bosnia and Herzegovina. The participants were 25 children with type 1 diabetes mellitus, 12 boys and 13 girls, aged 7 to 16 years (with average age 11.88 ± 3.15 years and average diabetes duration 6.12 ± 2.5 years). All patients were using the insulin pump Paradigm Veo TM MMT-754 for 3.08 ± 1.73 years.

All participants and/or their parents or guardians had signed the consent for conducting research and they agreed to regularly come to check-ups to read the data from the insulin

pump and to discuss them with the researchers in order to improve the quality of the therapy. Each patient was equipped with CGM that included a glucose sensor (Enlite TM glucose sensor) with the Medtronic MiniLink transmitter, which sends data from the sensor to the screen at the pump. All participants used the Wizard option of the insulin pump Veo on the daily basis respecting the Dusseldorf model for carbohydrates calculation.

Prior to the beginning of the study the transmitter's mode of operation was explained to the participants and we explained the rules to be followed during wearing, which also included calibrating the sensor minimally four times daily. In addition, the meaning of the alarm and the procedures to be followed in the case of an alarm were explained to the patients. It is important to mention that all participants were able to see at any time the current value of glycemia, based on readings from the sensors. All participants had carried continuously CGM for three months during which we aimed to improve their glycemic profiles and reduce glycemic variability. At the regular monthly check-ups, we also tested whether the parameters of the pumps were correct.

In all patients on the insulin pump, hypoglycemia was defined as a blood glucose concentration of less than 3.9 mmol/L, while hyperglycemia was considered a blood glucose concentration higher than 7.8 mmol/L. The beginning of the study was marked by the measurement of HbA1c (done at the University Clinical Center Banja Luka on Cobas E601, the Roche apparatus) and installment of CGM for the period of three months. At the same day the demographical (age, sex, weight and height) and the clinical (basal and bolus insulin doses) data were collected.

After the first month, data were read from the insulin pump, the glycemic values were discussed, basal and bolus insulin doses and carbohydrate ratios were adjusted if needed. The same activity was repeated after the second and third month. During the whole time of the study, the patients were in constant contact with the doctor in case of necessary consultations. After three months, the measurement of HbA1c was repeated. Afterwards children worn an insulin pump without the sensors for the next three months. We again measured HbA1c after three months.

Statistical analysis. Data were analyzed using descriptive (frequencies and percentages for categorical variables, and central tendency and variability measures for numerical variables) and inferential statistics. Nonparametric inferential techniques were used when significant distribution asymmetry or existence of extreme scores were observed: for instance, in such cases the Friedman test was used instead of a repeated measures analysis of variance which was a preferred technique for detecting a statistical change. All analyses were performed using the statistical software IBM Statistical Package for the Social Sciences (Version 21; SPSS).

Results

The demographic characteristics of the participants are shown in Table 1. One can see that, based on age range, it consisted of two subgroups with a balanced gender ratio. All participants were examined for the time period of 2139 days out of which they were wearing CGMs for 1702 days, i.e. 79.6% of the time. In the first month this percentage was highest (around 85% of the time). These results indi-

Table 1. Demographic characteristics of the study participants.

Number of participants (n)	25
Girls (n)	12
Age, years	11.88±3.15
Number of participants age 7 - 11	13 (Girls: 5)
Number of participants age 12 - 16	12 (Girls: 7)
Years since the diagnosis of diabetes	6.12±2.5
Years on insulin pump therapy	3.08±1.73
BMI, kg/m^2	19.88±3.74
HbA1c% at baseline	7.53±0.87
HbA1c% after 3 months	7.48±0.73
HbA1c% after 6 months	7.57±0.98

Data are presented as number and as mean ± SD.
BMI = Body mass index, HbA1c = glycated hemoglobin

Table 2. Description of general glucometer and sensor data.

Variable	Month 1	Month 2	Month 3	p
Days in the study	27.56±7.34	28.94±7.03	29.04±7.96	0.687
Days on CGM	23.60±6.60	22.24±5.50	22.24±6.34	0.679
Number of measures on glucometer per day	7.4 [5.7, 9.3]	6.6 [5.6, 8.8]	7.2 [6.3, 10.4]	0.722
Number of measures on glucometer	214.2±100.2	209.3±69.3	227.6±95.1	0.591
% of glucometer measured values above 7.8 mmol/l	56.15±18.85	58.38±17.42	59.56±16.03	0.430
% of glucometer measured values below 3.9 mmol/l	2.54±3.42	2.08±2.83	1.85±3.22	0.349
Glucose value from glucometer, mmol/L	9.55±1.97	9.65±1.88	9.55±1.63	0.893
Glucose value from sensor, mmol/L	8.71±1.34	8.70±1.22	8.72±1.06	0.995
AUC above 7.8 mmol/l	1.94±1.00	1.86±0.78	1.93±0.75	0.839
AUC below 3.9 mmol/l	0.03±0.03	0.04±0.04	0.04±0.03	0.455

CGM = Continuous glucose monitoring. AUC = Area under the curve. Results are presented as mean ± SD with respective p-values obtained through repeated measures analysis of variance, except for the number of measures of glucometer per day for which median values with lower and upper quartiles were presented accompanied by p-values obtained through the Friedman's test.

cate that our patients were largely willing and motivated to cooperate during the examination period.

As can be seen from Table 1, wearing CGM for three months resulted in only a slight decrease in HbA1c. After that period, not wearing CGM resulted in an increase in HbA1c to a negligibly higher level than what was observed at baseline. Overall, these changes did not reach the level of statistical significance (Friedman test, p = 0.603).

Table 2 shows that the majority of participants made more than 6 measurements daily over the course of the study. The percentage of measures spent in glycemia above 7.8 mmol/L slightly increased over a three-month period during which the patients wore CGM, reaching a peak in the third month. This was not a statistically significant change (p = 0.430). On the other hand, out of the total number of measures, the percentage of glycemic levels below 3.9 mmol/L decreased constantly, while wearing CGM: from 2.50% during the first month to 1.85% during the third month. Again this was not statistically significant (p = 0.430). It is, however, important to stress that during the study neither a serious hypoglycemic episode nor a diabetic ketoacidosis case were reported. The area under the curve of serum glucose values (AUC) showed only a small variability throughout the study with the changes being far from either a statistical or clinical significance.

Table 3 shows that the use of the low glucose suspend option increased both during the day and during the night over three months, with total number of uses being almost double during the day compared to during the night. The number of discontinued options during the day was twice as high compared to the low glucose suspend use overnight, resulting in increased recurrent hypoglycemia during the day. The number of reactive hyperglycemia during the day was more frequent than reactive hyperglycemia over night. Also, the number of recurrent hypoglycemia and the number of hypoglycemia due to bolus was visibly higher during daytime than overnight. We also observed that some children corrected their hypoglycemia with carbohydrates, after which they gave themselves an insulin bolus which created a new hypoglycemia. Furthermore, a greater number of suspension options were recorded during the day than during overnight, which could be explained by the fact that children did not wear their insulin pumps during their physical activities or when taking bath.

Table 3 also shows that the number of low glucose suspend options increased over the course of the study, whereas the number of suspensions excluding the low suspend option and the number of interrupted low suspend options decreased.

Through CareLink Pro software we ob-

Table 3. Characteristics of recorded hypoglycemic events.

Variable	Month 1	Month 2	Month 3	p
Number of LGS during day	9.72±9.77	10.20±10.01	10.08±8.88	0.840
Number of LGS during night	4.64±4.80	5.44±5.08	5.52±4.11	0.368
Number of suspend without LGS during day	2.52±3.34	1.80±2.18	1.48±2.00	0.174
Number of suspend without LGS during night	0.48±0.77	0.32±0.90	0.52±1.05	0.223
Number of times when LGS event was interrupted by participant by day	9.44±9.66	9.64±9.95	8.72±7.77	0.660
Number of times when LGS event was interrupted by participant by night	3.52±4.11	4.20±4.72	3.88±2.95	0.729
Number of hyperglycemic events after hypoglycemic events by day	2.72±2.03	2.64±2.33	2.52±3.57	0.220
Number of hyperglycemic events after hypoglycemic events by night	0.80±1.04	0.76±1.03	0.92±1.73	0.455
Total number of hypoglycemic events	17.36±13.22	18.04±12.57	17.24±12.12	0.424
Repeated hypoglycemic events by day	1.28±1.81	0.92±1.26	1.24±1.64	0.768
Repeated hypoglycemic events by night	0.40±1.00	0.72±1.28	0.80±1.35	0.068
Hypoglycemic events caused by bolus by day	3.48±3.70	4.00±7.05	3.68±3.59	0.952
Hypoglycemic event caused by bolus by night	0.80±1.08	1.20±1.66	1.04±1.40	0.591
Number of hours when pump was suspended per participant	31.56±27.65	26.03±16.12	28.05±18.30	.852

Results are presented as mean ± SD. P-values were obtained through Friedman's test.
LGS = low glucose suspend

tained a record of glycemic variability of eight critical periods of the day. These periods were defined as follows: an hour before a regular meal and two hours after a meal, with breakfast being defined as time between 06:00 - 10:00, lunch 11:00 - 15:00, dinner 16:00 - 22:00, awakening time 05:00 - 09:00, and bedtime period 20:00 - 00:00. For these time periods the average values were calculated by the software.

Table 4 shows that there were no noticeable systemic trends in change of glucose values over the course of the study (all p-values > 0.10). Overall, this finding suggests that our patients did not change much their nutrition habits and that they probably retained their eating habits from the period before baseline. The lack of changes in carbohydrate intake further supports this assumption (Table 5).

Table 5 shows that the total insulin dosage did not change significantly over the course of the study. However, basal-bolus insulin ratio changed somewhat with the increase in basal insulin (39.6% to 42.5%, $p < 0.10$) and the decrease of bolus insulin (from 60.1% to 58.7%). All participants tended to use a bolus Wizard option, and only rarely gave themselves bolus insulin manually. It can be said that they adhered well to the recommendations from the

Table 4. Mean glucose levels (mmol/L) disaggregated by a critical period of the day

Measurement period	Month 1	Month 2	Month 3	p
Waking up	9.25±1.89	9.22±1.84	9.16±1.53	0.960
Before breakfast	8.17±2.01	8.53±2.24	8.29±1.58	0.524
After breakfast	9.88±2.78	10.15±2.83	10.18±2.09	0.780
Before lunch	8.04±1.89	8.40±1.94	8.00±1.24	0.276
After lunch	9.65±2.54	8.72±2.02	9.34±2.14	0.135
Before dinner	8.42±2.42	8.87±2.04	9.16±2.33	0.651
After dinner	9.40±2.23	9.02±1.76	9.06±1.95	0.605
Bedtime	9.56±2.21	9.93±2.35	9.87±2.29	0.633

Results are presented as mean ± SD. P-values were obtained through repeated measures analysis of variance.

Table 5. Insulin dosage, basal and bolus events during the study

Variable	Month 1	Month 2	Month 3	p
Total insulin, IU	40.13±15.91	40.46±16.71	39.87±15.37	0.818
Basal insulin, IU	15.78±7.55	16.39±7.65	16.62±7.54	0.010
Basal, %	39.60±9.19	41.43±8.67	42.54±12.52	0.091
Bolus insulin, IU	24.28±10.32	23.52±10.63	23.55±10.00	0.556
Bolus, %	60.12±9.12	59.13±9.33	58.67±9.00	0.215
Carbohydrate intake, g	221.52±99.92	210.68±81.12	218.34±80.50	0.535
Insulin to CH ratio, IU/g	10.02±4.48	9.73±4.36	10.04±3.70	0.780
Bolus Wizard event (per day)	7.04±2.84	6.90±2.85	6.71±2.63	0.444
Manual bolus event (per day)	0.42±1.25	0.42±1.29	0.38±1.24	0.216
Dual/Square bolus (total number)	12.36±17.57	14.88±26.71	15.40±23.57	0.422

CH = Carbohydrates. Results are presented as mean ± SD. P-values were obtained through repeated measures analysis of variance or Friedman's test where appropriate.

wizard program, because they accepted the insulin dosage in more than 95% of the cases. The use of dual-square bolus constantly increased over the course of the study (from 12.4% to 15.4%), which actually was aimed to happen. On the other side, the insulin-carbohydrates ratio did not change significantly, thus suggesting that initial settings were appropriate for the patients.

Discussion

This is the first study conducted on the territory of Bosnia and Herzegovina in patients with type 1 diabetes mellitus who had used the insulin pump Veo together with the CGM for the time period of three months. The study had multiple aims. First of all, we wanted to examine whether the use of the VEO insulin pump, used together with the CGM device with automatic suspension in the event of hypoglycemia, affects the metabolic control in children with type 1 diabetes. We measured this not only via HbA1c, but also considering hypoglycemic data. Although we found only a negligible and insignificant decrease in HbA1c, the results are still encouraging. Namely, during the period of the study the number of hypoglycemia did not increase. On the contrary, there was a small, albeit insignificant, decrease in hypoglycemic events over the course of the study, without any serious hypoglycemic episode or diabetic ketoacidosis events. When it comes to HbA1c levels, in a study conducted by Battelino et al. [5], the use of CGM for 6 months led to a reduction in HbA1c, and a period without CGM led to the increase in HbA1c. It might be the case that the period of wearing CGM was too short in our study to establish the needed habits to improve metabolic control. Another explanation for the lower reduction in HbA1c in our subjects compared to other studies is possibly due to an average lower Hba1c that our respondents had at the beginning of the study.

In addition, we wanted to examine to which degree the patients accepted wearing the pump and adhered to hypoglycemia algorithms. We also wanted to determine the use of dual/square bolus, particularly when consuming traditional meals of our region which are known to be highly caloric with simultaneously high levels of fat, protein and carbohydrates (i.e. pies, pizzas). With regard to this, we found that our participants used CGM for over 79.6% of time during three months which suggests that they accepted wearing it very well. Still,

when it comes to hypoglycemia algorithms, it is important to note that our participants sometimes interrupted the low glucose suspend option before the period without insulin ended. The patients then decided on their own to return to basal insulin, because they feared that they would enter hyperglycemia. This happened somewhat more often during the first two months of the study, and it is obvious that users did not allow the algorithm to work as intended, even though the researchers educated the patients to let the low suspend glucose option of the pump in function.

We must also add that, as clinicians, we observed several more advantages of using CGM: for example, bolus insulin was used more frequently and basal rates were more often modified in accordance to glucose levels. Also, we gained significantly more insight into patients' habits. For example, our patients often violated our advice and guidelines by correcting hypoglycemia both with carbohydrates ingestion and simultaneously with a certain dose of insulin. We can also confirm the findings of the SWITCH study that when the patients are provided with both a pump and a sensor, they are more involved in metabolic control by more frequently measuring their glycemia and by using more advanced options given in their pumps [5].

On the whole, the results of our study resembled to what was found in the ASPIRE in home study which examined the effectiveness of the added threshold-suspend feature compared to a standard sensor-augmented insulin-pump therapy [8]. The ASPIRE study was similar both in length and with regard to the results to our study since it showed reduction in nocturnal hypoglycemia without improving the HbA1c values compared to the control group. Nevertheless, we must state that the ASPIRE study had a better methodological design with a control group and better statistical power (in total 247 patients participated in it). Still, we believe that our study makes a contribution to regional research on the effectiveness of metabolic control via threshold-suspend feature in insulin pumps.

Conclusion

To summarize, the use of an insulin pump with CGM for three months only negligibly improved metabolic control after three months, but importantly, we have not observed increase in hypoglycemic events. At the same time, the use of CGM made it possible to use insulin pump more efficiently, with more boluses given throughout the day, more frequent use of temporary basal option, use of the low glucose suspend option, the use of combined bolus, but also more frequent self-control of glycemia compared to the usual numbers. We also observed that children with CGM were more involved around the insulin pump than in the absence of CGM. Interestingly, patients relied on the Wizard option, but we also noticed their frequent manual suspensions of the pump. This decision was motivated by the fear of later hyperglycemia stemming from the habitual reliance on provided measures. Finally, we should be reminded that the subsequent use of an insulin pump without CGM resulted in a negligible deterioration of metabolic control, but also in less frequent relevant self-adjustments to the insulin pump. In sum, we may conclude that although wearing CGM for three months might not dramatically improve usual measures of metabolic control, it seems that it contributes to better acceptance of the pumps, better adherence to algorithms for hypoglycemia and more frequent use of combined bolus.

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Autori izjavljuju da nemaju sukob interesa.

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Efekat upotrebe insulinske pumpe sa opcijom prekida rada u slučaju hipoglikemije na metaboličku kontrolu djece sa tipom 1 dijabetes melitusa

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Uvod. Automatsko isključenje insulinske pumpe i prekidanje isporuke insulina u slučaju hipoglikemije je karakteristika insulinske pumpe Veo kada je povezana sa sistemom za kontinuirano mjerenje glikemije. Takva vrsta terapije je najbolji vid za postizanje dobre metaboličke kontrole djece oboljele od tipa 1dijabetes melitusa. Cilj je provjeriti da li je moguće korišćenjem opcije automatskog isključenja insulinske pumpe, u slučaju hipoglikemije, i kombinovanih bolusa za obroke, uticati na metaboličku kontrolu djece oboljele od tipa1dijabetesa melitusa.

Metode. Studija je obuhvatila 25 učesnika (13 djevojčica i 12 dječaka) uzrasta od 7 do 15 godina, prosječne starosti 11,88 ± 3,15 godina i prosječnog trajanja dijabetesa 6,12 ± 2,5 godina. U prosjeku, učesnici studije su već koristili insulinsku pumpu Paradigm Veo TM MMT-754 tokom 3,08 ± 1,73 godine. HbA1c je mjeren na početku studije, nakon tri i šest mjeseci.

Rezultati. Procenat registrovanih vrednosti glikemije iznad 7,8 mmol/L je neznačajno porastao, dok je procenat glikemije ispod 3,9 mmol/L smanjen tokom tromjesečnog nošenja sistema za kontinuirano mjerenje glikemije. Početni HbA1c je iznosio 7,53 ± 0,87%. Nakon tri mjeseca nošenja glukoznog senzora HbA1c se neznatno smanjio na 7,48 ± 0,73 %, dok je nakon sljedeća tri mjeseca bez glukoznog senzora HbA1c porastao na 7,57 ± 0,98%.

Zaključak. Ova studija pokazuje da upotreba insulinske pumpe sa opcijom automatskog isključenja u slučaju hipoglikemije i kombinovanih bolusa je povezana sa blagim poboljšanjem metaboličke kontrole nakon tri mjeseca kontinuiranog nošenja bez porasta rizika od hipoglikemije.

Ključne riječi: dijabetes melitus tip 1, djeca, insilinska pumpa Veo, kontinuirani monitoring glikemije