

Reasons for the discontinuation of therapy of personal insulin pump in children with type 1 diabetes

Przyczyny rezygnacji z terapii za pomocą osobistą pompą insulinową u dzieci z cukrzycą typu 1

¹Alicja Binek, ¹Agnieszka Rembierz-Knoll, ²Joanna Polańska, ³Przemysława Jarosz-Chobot

¹Department of Pediatrics, Endocrinology and Diabetes, Upper Silesia Centre for Child's Health

²System Engineering Group, The Silesian University of Technology, Gliwice, Poland

³Department of Pediatrics, Endocrinology and Diabetes, Medical University of Silesia

Abstract

Introduction. Pump discontinuation is rare. It is estimated that only about 4% of patients return to multiple daily injections (MDI). **Objective.** To study the factors that influence the decision to stop continuous subcutaneous insulin infusion therapy (CSII). **Material and methods.** Analysis of the anonymous questionnaires indicating factors that influenced pump discontinuation and return to the MDI. **Respondents.** 30 children (17 girls), mean age 14.3yr(± 3,57), at the start of CSII 11.06yr(± 4.01), at discontinuation of pump therapy 13,23yr(±3,82). **Results.** The mean duration of pump usage was significantly higher in boys: 3.28yr±2.31 vs 1, 27yr±1.04(p=0.01); mean HbA1c: boys-8.03%±1.03, girls-7.78±1.42. The most frequently reported disconnection reasons were: greater sense of disease (93%), difficulties in doing sports (70%), worse well-being during pump therapy (63%), having to attach the pump to the body (60%), embarrassment (56%), adhesions and pain in the place of needle insertion (50%), difficulties in controlling glycemia during physical exercise, fear (43%), high levels of HbA1c (36%), frequent blood glucose monitoring (26%). Problems with technical operation of the pump or frequent episodes of severe hypoglycemia or ketoacidosis were not reported. Among those who indicated difficulty in controlling glycaemia during physical exercise or infection, the average age at the time of quitting the pump was significantly lower than the rest: 12.3±3.33 vs. 14.69 ±2.82 (p=0.04). **Conclusions.** The individual psycho-emotional state of the child and appropriate education are important at the start and continuation of CSII.

Key words

diabetes type 1, children, continuous subcutaneous insulin infusion, multiple daily injections

Streszczenie

Wprowadzenie. Rezygnacja z terapii za pomocą osobistej pompy insulinowej należy do rzadkości. Szacuje się, że około 4% pacjentów powraca do metody wielokrotnych wstrzyknięć insuliny. **Cel pracy.** Określenie czynników, które miały wpływ na podjęcie decyzji o zaprzestaniu terapii za pomocą ciągłego podskórnego wlewu insuliny. **Materiał i metody.** Analiza anonimowego kwestionariusza wypełnionego przez pacjentów, gdzie spośród potencjalnych niedogodności związanych z tą metodą leczenia wskazywali te, które w ich przypadku występowały. **Materiał i metody.** 30 dzieci (17 dziewcząt), śr. wieku: 14.3 lat (± 3,57), wiek rozpoczęcia terapii CSII 11.06 lat (± 4.01), w chwili rezygnacji z pompy 13,23 lat (± 3,82). **Wyniki.** Czas stosowania pompy był dłuższy u chłopców: 3.28 lat±2.31 vs 1, 27lat±1.04(p=0.01); śr. HbA1c: chłopcy-8.03%±1.03, dziewczęta-7.78±1.42. Najczęściej wskazywaną przyczyną rezygnacji było większe poczucie choroby w przypadku podpiętej pompy (93%), trudności z uprawianiem sportu (70%), gorsze samopoczucie (63%), przywiązanie ciała do pompy (60%), zawstyżenie (56%), zrosty i ból w miejscu wkłucia (50%), trudności z kontrolowaniem glikemii podczas wysiłku fizycznego, lęk (43%), wyższy poziom HbA1c (36%), częste pomiary glikemii (26%). Nie zgłaszano problemów z obsługą techniczną pompy oraz epizodów hipoglikemii oraz kwasicy ketonowej. Pośród dzieci, które wskazały trudności z kontrolowaniem glikemii podczas wysiłku średni wiek w chwili przerwania terapii pompowej był zmiernie niższy niż pozostałych: 12.3±3.33 vs. 14.69 ±2.82 (p=0.04). **Wnioski.** Ocena stanu emocjonalnego pacjenta oraz odpowiednia edukacja są ważne w chwili rozpoczynania terapii CSII oraz w jej trakcie.

Słowa kluczowe

cukrzyca typu 1, dzieci, ciągły podskórny wlew insuliny, metoda wielokrotnych wstrzyknięć

Introduction

Personal insulin pump therapy is the best known method of imitating the physiological profile of insulin secretion by the pancreas [1]. In children, therapy using continuous subcutaneous insulin infusion (CSII) is a beneficial alternative for multiple daily injections of insulin (MDI) [2]. Effective functional insulin therapy using the personal insulin pump or pens depends on many factors, including age, lifestyle, self-control, and most of all, on individual preferences of the patients and their families. Patients and their families need to be thoroughly educated about intensive insulin therapy, proper eating regimens and quick reaction in case of emergencies if hypo- or hyperglycemia occurs. Patients using personal insulin pumps must also be properly trained with multiple insulin injections, so that they can revert to pens in case of equipment malfunction. Frequent monitoring of glycemia is required with both methods of insulin supply [3]. Despite the observed favorable tendency for reduction of hypoglycemia and lowering the concentration of glycosylated hemoglobin during therapy with insulin pumps [4]; a fraction of the patients reject this method and return to the previous model of therapy. Cessation of this therapy is extremely rare, according to research conducted in Germany and Austria only approximately 4% of patients return to the pens [5]. As a medical institution with extensive experience with insulin pumps, we have decided to turn to children who have terminated therapy with insulin pumps and their caregivers, and ask them about difficulties, inconveniences and emotional effects they experienced in association with CSII.

Aim of the study

The aim of the study was to analyze the subjective factors causing children with type 1 diabetes to terminate the use of personal insulin pumps and return to multiple insulin injections.

Material and methods

The study included the children under the care of the University regional diabetes center in Katowice. Participation in this study was voluntary. During the control visit to the Clinic, children and their caregivers were presented with an anonymous questionnaire which we had prepared. In the questionnaire there was a segment listing problems which could potentially result from using the pump. We asked the patients to select factors which contributed to their decision to stop the therapy. We also asked about the emotions which accompanied them during the therapy. The questionnaire was filled by 30 children and their caregivers – 17 girls and 13 boys. Three qualifying children refused to participate in the study. The duration of the study was 6 months. All statistical analyses were done in The Silesian University of Technology, Gliwice, Poland. The hypothesis about the consistency of the distributions of the analyzed variables with normal distribution was verified with the

use of the Lilliefors test. The hypothesis of homogeneous variation was verified using Fisher's F statistic. The analysis was carried out with Kruskal-Wallis ANOVA, U-Mann-Whitney test, and Spearman's rank correlation. $P < 0.05$ was considered statistically significant.

Results

The mean age of the subjects was 14.30 years (± 3.57), type 1 diabetes was diagnosed at the mean age 9.43 (± 3.78 years). The interval between going from MDI to CSII was on mean 1.60 (± 1.16 years). The mean age at the beginning of the use of the personal insulin pump was 11.06 \pm 4.01 years, while the mean age of quitting CSII was 13.23 \pm 3.82 years. The mean duration of pump usage was significantly higher in boys than in girls: 3.28 \pm 2.31 vs. 1.27 \pm 1.04 ($p=0.01$). The mean HbA1c during pump therapy did not statistically differ between boys and girls: 8.03 \pm 1.03 vs. 7.78 \pm 1.42 ($p=0.37$). After changing to the MDI therapy, the girls achieved improvement of metabolic control in comparison to the pump therapy (7.07% \pm 0.91), while among the boys there was a deterioration (8.48% \pm 1.49).

The most frequently indicated cause of quitting the regimen was the greater sense of disease associated with use of the pump; this factor was selected by 93% of the respondents – all girls and 11 boys [figure 1]. In the second place, in 70% of cases- difficulties in doing sports were indicated as a reason for quitting the pump (10 girls, 11 boys). Quite often, in 63% of cases, children reported worse well-being after receiving the pump (9 girls, 10 boys). Reluctance to attach the pump to the body was a reason to return to pens in 60% of cases (12 girls, 6 boys). In 50% of cases adhesions as well as pain occurred in the place of needle insertion (9 girls, 6 boys). Difficulties in controlling glycemia during physical exercise as well as during infections was observed in 43% (5 girls, 7 boys). 36% of patients selected high levels of glycosylated haemoglobin as a reason to return to pens (7 girls, 6 boys). Frequent blood glucose monitoring interfered with everyday functions of only 26% of patients. (3 girls, 5 boys). Problems with technical operation of the pump, or frequent episodes of severe hypoglycemia or ketoacidosis were selected by none of the patients as reasons for quitting CSII. When it comes to emotions and feelings which accompanied the children during treatment with CSII, children reported embarrassment (56%), fear (43%), nervousness and anger (33%), fatigue (20%). The girls felt significantly more anger than the boys (52.94% vs. 7.69%, $p=0.02$), while the boys reported nervousness significantly more often than the girls (61.54% vs. 17.65% $p=0.03$). 47% of children, who selected difficulties in doing sport also marked difficulties controlling glycemia during physical exercises (5 girls, 5 boys). Among those who indicated reluctance to attach the pump, the average time from the diagnosis of diabetes to the commencement of the pump therapy was significantly shorter than the rest: 1.03 \pm 0.72 vs. 1.86 \pm 1.04 ($p=0.02$), while this was a longer time in children who felt embarrassment during CSII:

1.93±0.98 vs. 0.86±0.58 ($p=0.002$). Among those who indicated difficulty in controlling glycemia during physical exercise or infection, the average age at the time of quitting the pump was significantly lower than the rest: 12.3±3.33 vs. 14.69 ±2.82 ($p=0.04$). Among those who felt embarrassment, the mean HbA1c during pump therapy was higher than the rest: 8.33 ±1.33 vs. 7.25 ±0.85 ($p=0.01$). Not surprisingly, among those who indicated high HbA1c levels, the average HbA1c concentration was indeed significantly higher than the rest: 9.19±1.39 vs. 7.19±0.77 ($p=0.0006$).

Discussion

Many studies have compared the two most common methods of intensive insulin therapy: the personal insulin pump, and insulin pens. Among other things, studies have evaluated the degree of diabetes control, daily insulin requirements, incidence of severe hypoglycaemia episodes and of ketoacidosis. The results were quite often ambiguous, but nonetheless, a recently published systematic review and meta-analysis of randomized studies [6] has shown that, in comparison with MDI, CSII therapy is associated with lower HbA1c levels, lower incidence of severe hypoglycemia, as well as improved quality of life. As mentioned above, cases of patients quitting the pump therapy are relatively rare and are estimated at a yearly rate of 5% in pediatric patients [5,7]. In our own regional center we have also had such cases occur at the same rate, having over 10 years of experience and having treated more than 700 patients. What we present here is an analysis of factors which led to the termination of the pump therapy in a representative group of patients in our center. This should be a subject for further studies and wider discussion. In all likelihood, the majority of children treated with CSII and their caregivers do not approach this method of treatment uncritically, certainly they have some reservations, however they do not decide to return to the MDI. In the patients surveyed in this study, the balance of pros and cons leaned towards the pens. For all respondents, the mean HbA1c levels during both methods of therapy were above the target values recommended by ISPAD and Polish Diabetes Association. With that said it shows a good selection by patients—ones that are motivated to change their therapy for a more effective one. After changing to the MDI therapy, the girls achieved the improvement of metabolic control in comparison to the pump therapy, while among the boys, it unfortunately deteriorated. This phenomenon may result from a greater motivation in girls to obtain a better control of the disease [8]. In this study group the average age of starting and quitting pump therapy is in the adolescent period. As we know this is a difficult time in a person's life, the time when one begins to develop independence; discontinuation of the pump is especially likely during puberty [9]. This is the time during which self-esteem is shaped mostly based on a comparison to certain binding patterns. Teenagers evaluate one another, they give great importance to their appearance [10]. It can be therefore assumed that it is during this age that the child per-

ceives him- or herself and his or her disease through its cognitive reflection in the psyche. The youth at this time usually lacks regularity in daily activities. Depending on the day, the pattern of sleep and physical activity is different. For many teenagers, especially boys, sport is an important element in this period of life. Diabetes should not limit the ability to practice sports [11]. Our subjects indicated difficulties in doing sports as the most common cause of their departure from CSII. However, only 47% of children who selected difficulties in doing sport have additionally marked difficulties controlling glycemia during physical exercises. Therefore, modification of insulin doses or monitoring glycemia (which is equally required in MDI) do not constitute the only disadvantage here. Rather, it appears that the continuous maneuvering, attaching and detaching the pump is perceived by the patients as uncomfortable and time-consuming. Additionally, the constant presence of the device on the child's body may be discouraging. Some concerns may also appear among educators and coaches, who, without sufficient knowledge, may exclude pump-bearing children. It is worth noting that difficulties with controlling glycemia during physical exercise and infections were reported by the significantly younger children in the study group. Similarly, the age of children at the time of discontinuing the pump therapy when the reason was a worsened well-being was lower than in those with good well-being, but without statistical significance. Also, the time from onset of the disease to the commencement of the pump therapy in children who had problems with glycemia, instability was significantly shorter than in children without this problem. We can suggest that, especially in younger children, in whom the method of insulin administration was changed to CSII shortly after the onset, glycemia fluctuations were most probably caused by ineffective education. Moreover, unsuited to the individual needs of the child and his or her caregivers, as well as inadequate experience in self-control. This would lead to discomfort of the child, discourage the parents, and eventually lead to the discontinuation of CSII. It should be stressed that the reason most frequently given by children for quitting the pump is the greater sense of illness that comes with using it. Presumably, just like during sport activity, the very presence of the device already has a negative significance. At school, being different among healthy children, creates in children and adolescents the feelings of frustration and difficulties with accepting the disease [12]. Additionally, concentrating on hiding the device from the surroundings reinforces the negative emotions. Such an attitude may contribute to the growing sense of alienation and negatively impact the child's self-image, and cause lack of confidence and fear. Treatment with multiple injections allows to "forget about diabetes after hiding the pen in the bag" [13]. Children whose HbA1c levels were higher while on the pump therapy felt embarrassment significantly more frequently. The time from the diagnosis to acquiring the pump was significantly longer in children who felt embarrassment during CSII. This may result from the negative attitude towards the pump being present prior to its inclusion in the therapy, causing the transition to be postponed. The girls felt more anger than the boys, while the boys felt anxiety more often than

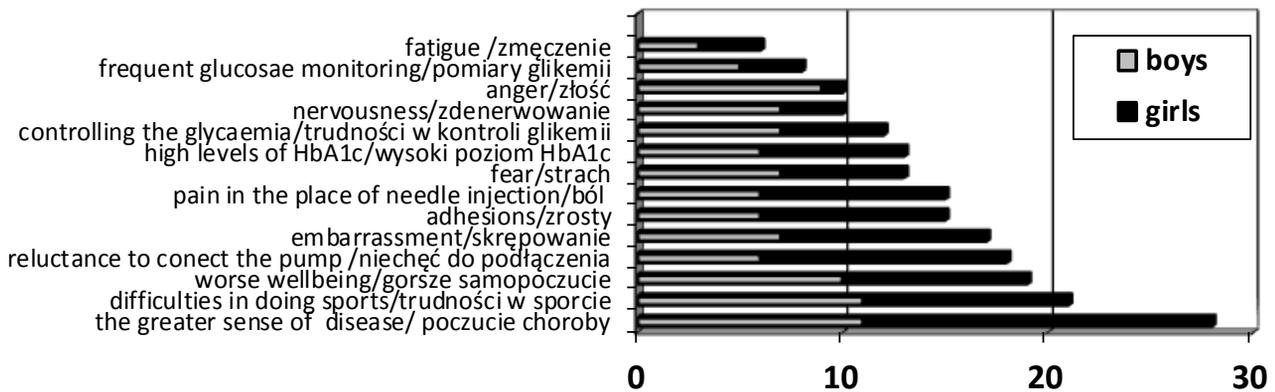


Fig. 1. Questionnaire listing problems which could potentially result from using the pump and the number of patients who selected listed factors which contributed to the decision to stop the pump therapy

Ryc. 1. Kwestionariusz zawierający wymienione niedogodnościami związane z terapią pompową oraz liczba pacjentów, która w ankiecie wskazała czynniki, które przyczyniły się do zakończenia terapii z użyciem pompy

the girls. These negative emotions may result from the psychological burden imposed on teenagers by the diminished sense of normalcy caused by the need to be constantly attached to the pump; and moreover, the worsened metabolic control with which we are dealing in these patients evokes discontent, and creates the feeling that “the pump will not fix anything”. The fear of being ostracized is another burden [14]. Patients also indicated inconveniences associated with the insertion of the needle, such as pain and adhesions. However, in our times, when technological gadgets are ubiquitous in daily life, the technical operation of the pump did not constitute any problems, and neither did equipment failures. Apparently, the necessity of regular measurements of glycemia was accepted by most patients as an integral part of life, and probably this is why only a small number of respondents regarded frequent glycemia measurements as an inconvenience. An interesting and important fact is that none of the respondents indicated that the reason for quitting CSII was increased incidence of hypoglycemia or ketoacidosis. This may indicate that the education

of children and their families on this topic is effective in giving them good skills of anticipating hypoglycemia or acidosis; as well as recognizing the symptoms and effectively coping with the lowered or elevated concentration of glucose.

Conclusions

1. The sense of disease and disadvantages associated with sport activities are the most often reported reasons for quitting the CSII therapy.
2. In children, especially girls, with higher HbA1c values, the return to intensive insulin therapy using multiple injections may help to improve the control of diabetes.
3. Consideration of the individual psycho-emotional state of the patient and his or her caregivers and appropriate education are important elements in the decision to start and continue this method of treatment.

References

1. Pickup J. *Insulin pumps*. Int J Clin Pract Suppl. 2011;170,16-19.
2. Jeitler K, Horvath K, Berghold A, i wsp. *Continuous subcutaneous insulin infusion versus multiple daily insulin injections in patients with diabetes mellitus, systematic review and meta-analysis*. Diabetologia. 2008;51,941-951.
3. Bangstad H, Danne T, Deeb L, Jarosz-Chobot P, Urakamie T, Hanas R. *Insulin treatment in children and adolescents with diabetes*. Pediatr Diabetes. 2009;10, 82-99.
4. Fendler W, Baranowska AI, Mianowska B, Szadkowska A, Mlynarski W. *Three-year comparison of subcutaneous insulin pump treatment with multi-daily injections on HbA1c, its variability and hospital burden of children with type 1 diabetes*. Acta Diabetol. 2012;49,363-370.
5. Hofer SE, Heidtmann B, Raile K, i wsp. *Discontinuation of insulin pump treatment in children, adolescents, and young adults. A mul-*

- ticenter analysis based on the DPV database in Germany and Austria.* Pediatr Diabetes. 2010;11,116-121.
6. Pańkowska E, Błazik M, Dziechciarz P, Szypowska A, Szajewska H. *Continuous subcutaneous insulin infusion vs. multiple daily injections in children with type 1 diabetes, a systematic review and meta-analysis of randomized control trials.* Pediatr Diabetes. 2009;10, 52-58.
 7. Wood JR, Moreland EC, Volkening LK, Svoren BM, Butler DA, Laf-fel LM . *Durability of insulin pump use in pediatric patients with type 1 diabetes.* Diabetes Care. 2006;29,2355-2360.
 8. Saraheimo M, Honkasalo M, Miettinen M. *Insulin therapy, for whom and why?* Duodecim. 2013;129,1571-1578.
 9. Babar GS, Ali O, Parton EA, Hoffmann RG, Alemzadeh R . *Factors associated with adherence to continuous subcutaneous insulin infusion in pediatric diabetes.* Diabetes Technol Ther. 2009;11,131-137.
 10. de Vries L, Grushka Y, Lebenthal Y, Shalitin S, Phillip M . *Factors associated with increased risk of insulin pump discontinuation in pediatric patients with type 1 diabetes.* Pediatr Diabetes. 2011;12, 506-512.
 11. Robertson K, Adolfsson P, Riddell M, Scheiner G, Hanas R. *Exercise in children and adolescents with diabetes.* Pediatr Diabetes. 2009;10,154-168.
 12. Peters JE, Mount E, Huggins CE, Rodda C, Silvers MA . *Insulin pump therapy in children and adolescents, changes in dietary habits, composition and quality of life.* J Paediatr Child Health. 2013;49,300-305.
 13. Raphael D, Brown I, Renwick R. *Psychometric properties of full and short versions of the Quality of Life Instrument Package.* Int Disabil Devel Educ. 1999;46,157-168.
 14. Rittholz MD, Smaldone A, Lee J, Castillo A, Wolpert H, Weinger K. *Perceptions of Psychosocial Factors and the Insulin Pump.* Diabetes Care. 2007;30,549-554.