Continuous subcutaneous insulin infusion in young girls: a two-year follow-up study

A Lindholm Olinder, A Kernell, B Smide*

Abstract

Aims: To investigate why young girls decided to start continuous subcutaneous insulin infusion (CSII) therapy, and to examine their opinions and concerns with regard to using an insulin pump. In addition, the girls were evaluated for HbA_{1c} values, insulin requirements and body mass index standard deviation score (BMI SDS) over a period of two years after starting CSII compared with a group of girls using multiple daily injections (MDI).

Methods: Twelve girls (mean age 10.8 years) starting CSII were followed over a period of two years. Why the girls started CSII and whether they preferred CSII or MDI were investigated. Their statements about CSII were analysed and categorised by two paediatric diabetes nurses. On four occasions HbA_{1c} values, insulin requirement and BMI SDS were collected and compared with those of a control group of 12 girls using MDI for the same period of time.

Results: The girls started CSII due to a desire to test pump therapy, and their experiences of unstable blood glucose. They preferred CSII to MDI. The main positive statements were categorised as 'quality-of-life benefits'. The main negative category was 'the pump gets in the way'. In the CSII group, HbA_{1c} decreased from 8.5 (7.4–9.5) to 7.5 (6.9–8.1) ($p<0.05$) over two years, and the insulin requirement decreased by 30%. In the control group these values were unchanged. There were no changes in the BMI SDS mean values for either group.

Conclusion: CSII was well accepted by the young girls, facilitated a decrease in HbA_{1c} values, and did not result in weight gain.

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Key words

CSII; children; adolescents; females; type 1 diabetes

Introduction

Intensive therapy of type 1 diabetes, with multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII), is associated with improved metabolic control and predicts a decreased risk for long-term microvascular complications.[1]

Despite intensive therapy, it is hard to maintain good metabolic control in children and adolescents,[2] and metabolic control appears to be less satisfactory among girls than among boys. In Sweden, female teenagers with diabetes have a higher mean HbA_{1c} than males.[3]

CSII therapy has been used in paediatric diabetes care since 1979.[4] Recent years have seen increased interest in using this therapy for children.[5–8] In 2005, approximately 25% of Swedish children with diabetes used insulin pumps.[3] Previously, high HbA_{1c} values have been the primary reason for initiating pump therapy. Today other factors, such as life quality benefits and pain from needles, play an important role.[9]

In an interview study, it was found that girls in particular reported fashion-related inconveniences when wearing an insulin pump.[10] Before starting CSII, many children are interested in knowing whether they can disconnect their insulin pump for a variable amount of time, without having to re-insert a needle or catheter. There are methods to allow the infusion set and pump to be disconnected while the needle or catheter remains in place.[11]

Several studies have shown a decrease in HbA_{1c} values after initiating CSII.[1,5–8,12–17] A greater improvement has been shown in studies with patients who have been on pump therapy for a longer time.[7,8,14,15]

No previous studies focusing on young girls and CSII have been found. The questions raised are: do young girls accept pump therapy or do they prefer MDI, and are young girls able to decrease their HbA_{1c} values without gaining weight?

The aims of this study were to investigate why young girls decided to start CSII therapy, and to examine their opinions and concerns

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with regard to using an insulin pump. The study also aimed to evaluate the HbA_{1c} values, insulin requirement and body mass index standard deviation score (BMI SDS) over a period of two years after starting CSII compared with a group of girls using MDI.

Methods

Patients

The girls included in the current study were regularly attending the diabetes clinic at Sachs' Children's Hospital at Stockholm South General Hospital, Sweden. At the time the clinic was treating a total of 260 children with diabetes. All girls (n=12) who started CSII therapy during the course of one year were asked to participate in the study (mean age 10.8 years; range 7–15, and mean diabetes duration 5.1 years; range 2–12). They were given written and oral information about the study and all of them were positive about participating.

A control group was created of 12 girls with diabetes, treated with MDI at the same clinic and not interested in starting CSII at the time. They were matched with the closest diabetes onset and age to the CSII group (mean age 10.9 years; range 6–17, and mean diabetes duration 5.1 years; range 1–12). The girls in the control group and their parents were given written and oral information about the study and gave their written consent to allow the researcher to examine their medical records.

All the girls in the CSII group had used MDI with three to six injections daily before starting CSII. They used one of the infusion systems Disetronic or Minimed and received direct-acting insulin. The children in the control group used MDI with three to six injections daily. The control group used intermediate-acting insulin and direct- or short-acting insulin.

Measurements

Two questionnaires specially designed for this study, based on literature review and a special research protocol for the control group were made. One questionnaire was used on three data-collection occasions: the first before starting CSII, the second after three months, and the third after a year. It included demographic and diabetes-related questions: current weight and height; current HbA_{1c} value (high performance liquid chromatography [HPLC] method, ref: 3.4–5.0%; compared with the Diabetes Control and Complications Trial [DCCT] HbA_{1c} units – Swedish units give results that are approximately one percentage point lower); current insulin requirement (units/kg/day); a question in which the girls were to choose the appropriate alternatives for starting to use a pump, and a question formulated as a visual analogue scale,[18] in which the girls were asked to tick on a scaled line whether they preferred MDI or CSII.

Reasons	Number of statements
Unstable blood glucose	9
The child's desire to try a pump	9
High blood glucose at night or in the morning	6
High HbA_{1c}	3
Multiple injections too onerous	3
Pain from injections	2
Quality of life benefits	2
Hypoglycaemia	1
Total	35

Table 1. The girls' (n=12) reported reasons for pump initiation

The second questionnaire was used after two years and included the questions above, except those concerning reasons for initiating CSII. Two open-ended questions were added; the girls were asked for positive and negative statements concerning CSII and whether – and if applicable, when – they disconnected their insulin pump.

The research protocol for the control group included data about age, diabetes duration, current diabetes treatment, HbA_{1c} value, weight and height, and current insulin requirement.

Procedure

The questionnaires were presented to the girls using CSII and their parents in connection with regular visits to the diabetes nurse.

The research protocol for the control group was filled in by the researcher. Data were collected during the same period of time as for the CSII group; the girls' medical records were examined.

Analyses

A special ruler was made to measure the scores on the visual-analogue-like scale, a line on which the girls were asked to tick whether they preferred MDI (the left endpoint) or CSII (the right endpoint). The ruler was as long as the line, with a minimum of 0 (the girls preferred MDI) and a maximum of 10 (they preferred CSII). The ruler was accurate to one decimal point. Nonparametric statistics, median values and ranges were used for the analyses.

Statements about CSII and disconnecting the insulin pump were analysed by two paediatric nurses and different categories emerged. After discussion 100% agreement was reached.

BMI-index and BMI SDS were calculated from the weight and height values before start of the study, and after one and two years.[17]

Category	Examples of the 12 girls' written statements
Quality-of-life benefits (14 statements)	Easier life Possibility to sleep late occasionally You don't need to keep to a time Can eat at flexible times Can eat almost everything
Health benefits (4 statements)	Better to have insulin in the body all the time More stable blood sugar level Feeling better
Fewer shots (6 statements)	Good to be free from injections Free from the evening injection Free from all injections
The pump gets in the way (14 statements)	The pump is big It gets in the way Ugly on the stomach Problem wearing it with most dresses and skirts Afraid of getting the catheter stuck
Practical problems (6 statements)	Great deal of work when the pump fails Great deal of work with changing catheter and infusion set
Needle problems (5 statements)	Difficult to change the needle The needle hurts More blood glucose measurements

Table 2. Categories concerning positive and negative written statements about CSII, frequency of statements in the different categories, and examples

Data were analysed using the Statistical Package for Social Sciences (SPSS) software (version 12.0). Differences over time regarding HbA_{1c} values, insulin requirement and BMI SDS were analysed using paired *t*-test. Differences between the CSII and control groups were analysed using independent sample *t*-test. P-values of less than 0.05 were considered significant.

Ethics

The Karolinska Institute Ethics Committee, Dnr 504/02, approved the study.

Results

Reasons for initiating pump therapy

The 12 girls cited 35 reasons for initiating pump therapy, with 10 giving more than one reason. The most frequent reasons were 'unstable blood glucose' and 'the desire to try a pump' (Table 1). The quality-of-life benefits expected from CSII included a more flexible lifestyle and the ability to eat at flexible times (Table 2).

The girls' opinions and concerns with regard to using insulin pumps

The median values of the scorings on the visual-analogue-like scale showed that the girls preferred CSII to MDI on all four data collection occasions. Before starting CSII, only one of the girls preferred MDI, scoring less than five points. Scores ranged between 0.3 and 10 with a median of 7.2. After three months with CSII, the median score was 9.1 (range 4.5–10). The girl who preferred MDI from the start scored more than 7.4 on all the other occasions. After one and two years, all girls but one scored >7.4. The median value was 9.6 (range 3.2–10) after one year with CSII and 9.2 (range 3.3–9.8) after two years.

One eight-year-old girl scored 3.2 and 3.3 after one and two years, respectively. She had stopped using CSII after five months, but was positive about continuing to participate in the study. She thought that the infusion needle hurt, she had an allergic reaction to the tape on her stomach and too many peers asked about the pump.

The 12 girls' categorised statements about CSII and disconnecting the pump are presented in Tables 2 and 3.

All the girls disconnected their pumps for baths and showers. Some disconnected the pump for training and exercise but connected it hourly to receive insulin. Two girls disconnected the pump when they wore fine clothes; they then used insulin pens. One girl disconnected her pump and catheter before going to the beach, injecting insulin with an insulin pen every second hour, and replaced the catheter and connected the insulin pump on her return from the beach. Another girl disconnected her pump during the first summer and used insulin pens instead. As this did not work very well, she kept the pump connected the following summer.

Category	Number of comments (n=12)
Baths and showers	12
Exercising	5
Special clothes	2
Special occasions	2
Long-term disconnection	3

Table 3. Categorised comments from 12 girls about disconnecting the pump

HbA_{1c} values during the two-year period after starting CSII

The mean values for HbA_{1c} for the two groups were similar before starting CSII. HbA_{1c} decreased in the CSII group, but remained unchanged in the control group. After the two years with CSII the mean HbA_{1c} level was still significantly lower than HbA_{1c} at start (mean difference [95% confidence interval]: -1.0 [-1.7–(-0.2)] p<0.02). During the same time there was no change in HbA_{1c} level in the MDI group (mean difference [95% confidence interval]: -0.32 [-0.27–0.9] p=0.26) (Table 4).

Insulin requirement over a period of two years after starting CSII

The mean insulin requirement before introducing CSII was similar in both groups. After three months with CSII, the insulin requirement had decreased by more than 25% in the CSII group; in the MDI group the insulin requirement was unchanged. After two years the mean of the total daily doses was 30% lower than at the start in the CSII group, while in the MDI group the insulin requirement remained unchanged (Table 4).

BMI SDS during the two-year period after starting CSII

Before initiating CSII therapy the mean BMI SDS was slightly, but not significantly, higher in the MDI group than in the CSII group. There were no increases or decreases in either of the groups during the two years (Table 4).

Discussion

The young girls in the current study preferred CSII to MDI. CSII facilitated a decrease in HbA_{1c} values and did not result in weight gain.

All the girls, apart from one who stopped using CSII after five months, gave statements about CSII that could be placed in the category 'quality-of-life benefits'. The girls felt that the insulin pump gave them a more flexible life and the possibility to sleep late occasionally and eat at flexible times. At the same time, they felt that the pump got in the way, and was big and looked ugly on their stomach, but did not want to switch to MDI. Other studies have shown that most pump users want to continue insulin pump therapy;[5,10,12,13] even if HbA_{1c} remains high, they want to use their insulin pumps.[10,13]

Low *et al* found that pump users and their parents described quality-of-life issues as the most important benefit with pump therapy.[10] Other studies have measured 'quality of life' in children and adolescents treated with CSII compared with children and adolescents treated with MDI, using the Diabetes Quality of Life questionnaire for Youth (DQOLY).[7,12,17] Two studies did not find any differences between the treatment groups.[12,17] However, adolescents with CSII found coping with diabetes easier[12] and had greater treatment satisfaction[17] than adolescents with MDI. A more recent study found that children and adolescents felt a decreased impact of their diabetes and increased self-efficacy after pump initiation.[7] Furthermore, a better HbA_{1c} is associated with a better quality of life,[20] and those on CSII are often able to have a better HbA_{1c}.

Six of the positive statements dealt with fewer injections and five of the negative statements concerned needle problems. It is easy to believe that a patient with diabetes gets used to insulin injections; however, two of the girls

	At start	After 3 months	After 1 year#	After 2 years#
HbA_{1c} %				
CSII group	8.5 (7.4–9.5)	7.8 (7.0–8.7)*	7.6 (6.8–8.4)*	7.5 (6.9–8.1)*
MDI group	8.6 (7.6–9.6)	8.9 (7.5–10.3)	9.1 (7.7–10.5)	8.3 (7.3–9.2)
Insulin requirement (U/kg/24h)				
CSII group	1.05 (0.82–1.27)	0.78 (0.65–0.92)*	0.74 (0.62–0.85)*	0.71 (0.59–0.82)*
MDI group	1.07 (0.90–1.23)	1.07 (0.92–1.22)**	1.11 (0.92–1.29)**	1.15 (0.94–1.36)**
BMI SDS (kg/m^2)				
CSII group	1.09 (0.33–1.84)		1.22 (0.54–1.91)	1.27 (0.66–1.88)
MDI group	1.56 (1.04–2.00)		1.48 (1.00–1.94)	1.60 (1.05–2.14)

*p<0.05 *vs* start levels **p<0.05 between MDI and CSII group
One girl had stopped using insulin pump and was therefore excluded at one- and two-year follow-up

Table 4. HbA_{1c} value, insulin requirement and BMI SDS during the course of two years, for girls starting CSII (n=12) and a control group with MDI (n=12); data are means (95% confidence interval)

highlighted needle pain as a reason for starting pump therapy. However, they felt that the pump infusion needle or catheter hurt as well.

It is important to listen to these problems. Maniatis *et al* have shown that needle fear is associated with less satisfactory metabolic control, even with CSII.[6] Participants identified as being afraid of needles missed several bolus doses. The authors suggest that some behaviour-changing techniques should be taught to those identified as being afraid of needles before initiating CSII.[6] Perhaps the fear of pain causes the children to wait too long before changing the needle. These children can try another type of infusion set or insert the needle in another place. Local anaesthetics, e.g. Emla® cream, can make catheter insertion almost painless, and are often used by both children and adolescents who use a pump.[6,21]

In the current study, one of the most frequent reasons given for initiating insulin pump therapy was unstable blood sugar. Some of the positive statements about CSII stated that the girl's blood sugar had become more stable. Studies of adult patients with diabetes have shown that blood sugar variability decreases after starting CSII.[22]

In accordance with other studies, the HbA_{1c} values in the CSII group decreased with insulin pump therapy.[1,5–8,12–17] The major decrease was seen during the first three months; however, the girls maintained their HbA_{1c} during the two-year period. Other studies have also shown that patients with CSII are able to maintain a decreased HbA_{1c} for a long period of time.[7,8,14–16] A further decrease of the HbA_{1c} values to reach the Swedish national recommended value of HbA_{1c} (<6.5),[23] is desirable.

With the help of continuous blood glucose measurement, the basal rates could be optimised.[24] Some teenagers forget their mealtime bolus doses; this seems to be a major cause of increased HbA_{1c} values. If they could find a way to remember the bolus doses, they could have better metabolic control.[25]

The insulin requirement decreased by 30% in the CSII group and remained unchanged in the control group. This result differs from other studies: there was a greater decrease with CSII than other studies have shown.[5,9,14–16] There may be different explanations for this decrease and the difference between the groups, for example, a better physiological delivery system, better insulin absorption or a decrease in insulin resistance with CSII.[11,21] Perhaps the girls in the CSII group in fact needed more insulin to get a better HbA_{1c}. For some girls, one explanation for the difference may be missed injections with MDI therapy – perhaps they occasionally forgot the injections. With an insulin pump it is easy to check the pump's memory for the amount of insulin that has been used.

The effect of being included in a study must be discussed. When starting CSII treatment, the girls in the CSII group had the same training and rate of visits as other children receiving an insulin pump at the clinic. They were given 2.5 days of training when they started CSII. During the first month with CSII they had more contact with the diabetes nurse than normal. After the first month, they had the same visit frequency as the girls in the control group; four visits to the diabetes clinic per year (the normal frequency at the clinic). More training and visits to the clinic may be an explanation of the decrease in the HbA_{1c} levels in the CSII group. However, the effect of training on the HbA_{1c} level seldom lasts more than six months.[26]

Since the study period, 11 of the 12 girls in the CSII group still use insulin pumps and 9 of the 12 girls in the MDI group have started CSII.

Conclusion

CSII can be a good alternative for young girls struggling with high HbA_{1c} values. Even if they feel that the pump gets in the way, they find CSII better than using insulin pens. We recommend that CSII should be suggested to young females with unacceptable metabolic control.

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Conflict of interest statement:

None

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