Better treatment of outpatients with type 1 diabetes after introduction of continuous subcutaneous insulin infusion

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ABSTRACT

INTRODUCTION: Continuous subcutaneous insulin infusion (CSII) was introduced in the outpatient diabetes clinic in Fredericia, Denmark, in 2005. The aim of this study was to evaluate the quality of metabolic control and patient satisfaction in type 1 diabetic patients treated with CSII.

MATERIAL AND METHODS: In 2009-2010, a database with registration of metabolic variables and patient satisfaction was established. The collected material is a combination of retrospective and prospective data. Patient satisfaction was measured by use of the Diabetes Treatment Satisfaction Questionnaire Status (DTSQs) and change (DTSQc) versions.

RESULTS: By 31 December 2010, the database contained data from 68 active patients. Compared with before the initiation of CSII, glycohaemoglobin (HbA_{1c}) had decreased significantly from 8.0% (5.8-13.7%) to 7.6% (6.1-9.5%). The improved glycaemic control was maintained each year until ≤ 4 years after initiation of CSII ($p < 0.01$).The fraction of patients with an $HbA_{1c} \leq 7\%$ had increased from 13% to 24%, the fraction of patients with an $HbA_{1c} > 9\%$ had decreased from 18% to 3%, and the number of serious attacks of hypoglycaemia had decreased ($p < 0.05$). Only three episodes of ketoacidosis were observed. The DTSQs and DTSQc showed a higher patient satisfaction during CSII treatment ($p < 0.01$) than before its introduction. Compared with before the introduction of CSII, the patient satisfaction score had increased from 19 (12-33) to 34.5 (27-36) ($p < 0.01$).

CONCLUSION: Type 1 diabetes patients who were changed from treatment with multi-injection therapy to CSII showed improved glycaemic control, a reduced number of hypoglycaemic attacks and improved and very high levels of patient satisfaction.

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Treatment with continuous subcutaneous insulin infusion (CSII) of patients with Type 1 diabetes was introduced in diabetes care some decades ago [1, 2]. CSII treatment subsequently became less popular in Denmark due to episodes of ketoacidosis and high treatment costs. In 2003, a questionnaire answered by the diabetes clinics in Denmark showed that only few patients were being treated with CSII, while foreign experience showed better glycaemic control with less hypoglycaemia in patients treated with CSII in comparison with other treatment regimens [1, 2]. Since 2003, CSII has achieved a renaissance in Denmark, and today a large number of patients receive this treatment. The National Board of Health has called for quality data on patients who are being treated with CSII [3].

In the outpatient diabetes clinic in Fredericia, Denmark, treatment with CSII was resumed in 2005. In 2009, a database on the quality of diabetes treatment with CSII in daily clinical practice was established. Data from the quality report are presented here. The data include treatment outcome and patient satisfaction.

MATERIAL AND METHODS

The insulin pump database was established in 2009-2010. Data on the patients before this time were obtained retrospectively from the patients' journals or by patient interviews, while later data were obtained prospectively. Patients were seen at the outpatient clinic at least twice a year. A control was performed once a year with emphasis on diabetes education, risk factors and complications, and these data were registered in the database. Data from patients having started CSII in other diabetes clinics were only registered at the first visit in Fredericia. If patients moved away from the diabetes clinic or if CSII treatment was stopped, this was registered in the database and the reason was stated. Serious hypoglycaemia was defined as a low level of plasma glucose combined with the need for help from another person.

Patient satisfaction was measured by the validated Diabetes Treatment Satisfaction Questionnaire status (DTSQs) and change (DTSQc) version [4, 5]. Both questionnaires contain eight items scored on seven-point scales.

Six items (questions one and four to eight) measure treatment satisfaction (satisfaction with current treatment; convenience of the treatment; flexibility; satisfaction with own understanding of their diabetes; how

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TABLE 1

Yearly HbA_{1c} before and after continuous subcutaneous insulin infusion (median and range).

	HbA_{1c}, %		
Number of years on CSII	median	range	p value
0 (n = 62)	8.0	5.8-13.7	
1 (n = 52)	7.5	6.1-9.7	< 0.01
2 (n = 41)	7.6	6.5-10.8	< 0.01
3 (n = 27)	7.5	6.4-9.5	< 0.01
≥ 4 (n = 18) (last measurement)	7.4	6.3-8.8	< 0.01

CSII = continuous subcutaneous insulin infusion; HbA_{1c} = glycohaemoglobin.

TABLE 2

Number of patients with HbA_{1c} at different levels before continuous subcutaneous insulin infusion and at the most recent follow-up.

	HbA_{1c}, %			
	≤ 7	7.1-8	8.1-9	> 9
Before CSII (n = 62)	13	42	27	18
Most recent registration (n = 58)	24	47	26	3

CSII = Continuous subcutaneous insulin infusion; HbA_{1c} = glycohaemoglobin.

likely respondents are to recommend their present treatment; and how satisfied they are to continue with their present treatment). The individual item scores are summed to produce a total treatment satisfaction score. Questions two and three, concerning perceived frequency of hyperglycaemia (perceived hyperglycaemia) and perceived frequency of hypoglycaemia (perceived hypoglycaemia) respectively, are treated separately from the satisfaction items and from each other. On these two items, low scores represent a good perceived blood glucose control. DTSQs scores range from, e.g, 6 = very satisfied to 0 = very dissatisfied; and DTSQc scores range from +3 = much more satisfied now to –3 = much less satisfied now, with 0 (midpoint) representing no change. The total satisfaction score when using the DTSQs ranges from 0 to 36 and when using the DTSQc from -18 to 18; and the total score is obtained from summed scores from questions one and four to eight.

Both questionnaires were used since the DTSQs gives an evaluation of the level of satisfaction, while the DTSQc gives better information of patient preference, especially if the level of satisfaction with treatment is high before shifting to CSII. The DTSQs was filled in before initiation of the CSII and after one year, and the DTSQc was filled in after one year.

No standards were set to define good quality, but an evaluation of quality was performed by comparing our data with data from the literature.

Data were expressed as medians and ranges.

Comparison of paired data was performed with the Student t-test for paired data or Wilcoxon's test for non-parametric paired data.

Trial registration: not relevant.

RESULTS

A total of 77 patients were included in the database at the follow-up by 31 December 2010. Three patients had moved from the area and six had stopped CSII, three on their own initiative and three were terminated on the initiative of the diabetes clinic, one due to two occasions of ketoacidosis and two due to poor compliance. The remaining 68 patients were registered as active patients in the database; 33 men and 35 women. Seven of the patients started on CSII in another diabetes clinic. Their average age was 41 years (22-66), diabetes duration 21 years (1-52), weight 78 kg (53-125), total cholesterol level 4.2 mmol/liter (2.1-6.1) and duration of treatment with CSII 2.2 years (0-25). A total of 55 patients had normoalbuminuria, ten had microalbuminuria and two had macroalbuminuria and/or reduced renal function. In all, 44 patients had normal eye background, ten had simplex retinopathy and 11 had proliferative retinopathy. In one and three patients, respectively, information about diabetic renal or eye involvement was lacking.

The indication for CSII was hyperglycaemia in 57% of the active patients, hypoglycaemia in 49%, irregular daily living in 57% and other reasons in 7%. Many of the patients had more than one indication.

The level of glycohaemoglobin (HbA_{1c}) was reduced significantly from 8.0% (5.8-13.7%) before initiation of CSII to 7.6% (6.1-9.5%) ($p < 0.01$) after a median follow-up period of three years (1-25 years). The significant reduction in HbA_{1c} after one year was maintained during the following years on CSII ($p < 0.01$) (**Table 1**). The HbA_{1c} value measured in patients with a pump duration ≥ 4 years was taken from the last measurement in 2010. Patient weight and cholesterol level were unchanged during CSII.

The number of patients at different levels of HbA_{1c} before CSII and at the last annual follow-up is shown in **Table 2**. Before CSII, 13% had an $HbA_{1c} \leq 7\%$, and 18% had an $HbA_{1c} > 9\%$. During CSII, 24% had an $HbA_{1c} \leq 7\%$ and only 3% had an $HbA_{1c} > 9\%$.

Among all the patients in the database, three episodes of diabetic ketoacidosis were registered, two episodes occurred in the same patient. After the second episode of ketoacidosis, the CSII was removed.

During the year before CSII was initiated, 11 patients experienced episodes of serious hypoglycaemia, while nine patients experienced episodes of serious hypoglycaemia during the latest year of CSII. The number of serious hypoglycaemic attacks was signifi-

cantly reduced from 37 during the year before CSII treatment initiation to 14 during the latest year of the treatment ($p < 0.05$).

Patient satisfaction questionnaires were introduced to the patients in 2009. Therefore, only a limited number of patients have filled in the questionnaires (**Table 3** and **Table 4**). Patient satisfaction with diabetes treatment measured by the DTSQs was significantly higher during CSII with a very high satisfaction score of 34.5 (27-36) in contrast to a satisfaction score of 19 (12-33) before CSII ($p < 0.01$) (Table 3). For each of the eight different aspects of patient satisfaction, a very high degree of satisfaction was registered on CSII, and satisfaction was significantly higher than that seen before the introduction of CSII ($p < 0.01$). Only patients' understanding of diabetes was not significantly better while patients were receiving CSII.

The DTSQc questionnaire also showed greater patient satisfaction with diabetes therapy on CSII with a satisfaction score of 16 (9-18) ($p < 0.01$). In fact, CSII was associated with greater satisfaction with every aspect of diabetes therapy, including patients' understanding of diabetes ($p < 0.01$) (Table 4).

DISCUSSION

After shifting from multi-injection therapy to CSII with a median follow-up period of three years (range 1-25 years), HbA_{1c} was reduced from 8.0% to 7.6%. The improved glycaemic control was sustained until ≥ 4 years of CSII. No standards were set to define good quality, but we believe that our results in patients from an outpatient clinic show good quality of treatment of hyperglycaemia. The results were obtained without a change in body weight. Our result from daily clinical practice with a median HbA_{1c} value of 7.6% is comparable to the 7.5% reported in a meta-analysis of clinical studies of CSII [6]. Improvement of glycaemic control reduces the risk of development of late diabetes complications and the costs of diabetes treatment [7]

Further improvement of glycaemic control during treatment with CSII can be obtained in some patients if they are simultaneously using continuous glucose monitoring [8] (**Figure 1**). In our study, 18 (26%) of the patients used continuous glucose monitoring. Only few patients in Denmark are treated with continuous glucose monitoring, but the diabetes clinic in Fredericia and the clinic in Hvidovre have incorporated this diabetes treatment improvement into daily use [8, 9].

In our patients, the rate of severe hypoglycaemic attacks was reduced during treatment with CSII. The level on CSII was as low as 14 episodes in 62 patients, which yields a rate of 0.2 episodes per patient per year. In an unselected Danish material on type 1 diabetic patients, the overall rate of severe hypoglycaemia was 1.3 episodes per patient per year [10]. Patients also reported a lower perceived frequency of hypoglycaemia in the satisfaction questionnaires during CSII. A reduced number of hypoglycaemic attacks are also assumed to be among the advantages of CSII [11]. CSII therapy should therefore be considered in patients with hypoglycaemic attacks on multiple injection therapy [3].

Episodes of ketoacidosis were rather rare with only three episodes in two patients. Our data show that this complication is rare if patient selection is performed carefully.

Patient satisfaction with CSII was evaluated by use of the validated questionnaires DTSQs and DTSQc. The use of the DTSQs questionnaire was initiated in patients enrolled in the study from 2009 and only in patients initiating treatment with CSII in our clinic. The questionnaires were therefore filled in by only a fraction of the

TABLE 3

Treatment satisfaction by use of Diabetes Satisfaction Questionnaire. Status version before (n = 19) and after (n = 24) one year of treatment with continuous subcutaneous insulin infusion.

	Score, median (range)[a]		
Item	at baseline	after one year	p value
1. Satisfaction with current treatment	3 (0-6)	6 (3-6)	< 0.01
2. Perceived hyperglycaemia	4 (1-6)	1 (0-5)	< 0.01
3. Perceived hypoglycaemia	3 (1-5)	1 (0-5)	< 0.01
4. Convenience of current treatment	3 (1-6)	5 (1-6)	< 0.01
5. Flexibility of current treatment	3 (1-5)	6 (4-6)	< 0.01
6. Satisfaction with own understanding of diabetes	5 (4-6)	6 (4-6)	ns
7. Recommend present treatment	3 (1-6)	6 (5-6)	< 0.01
8. Satisfied to continue present treatment	3 (0-5)	6 (4-6)	< 0.01
Overall satisfaction score[b]	19 (12-33)	34.5 (27-36)	< 0.01

ns = non-significant.
a) Scores range from 6 = very satisfied, to 0 = very dissatisfied.
b) Overall satisfaction score is calculated by adding scores from items 1, 4, 5, 6, 7 and 8.

TABLE 4

Treatment satisfaction by use of Diabetes Treatment Satisfaction Questionnaire. Change (DTSQc) version one year after initiation of continuous subcutaneous insulin infusion (n = 25).

Item	Score after one year, median (range)[a]	p value
1. More/less satisfied with current treatment	3 (1-3)	< 0.01
2. More/less perceived hyperglycaemia	–2 (–3-2)	< 0.01
3. More/less perceived hypoglycaemia	–2 (–3-0)	< 0.01
4. More/less convenience of current treatment	3 (–2-3)	< 0.01
5. More/less flexibility of current treatment	3 (2-3)	< 0.01
6. More/less satisfied with own understanding of diabetes	2 (0-3)	< 0.01
7. Recommend present treatment in comparison to previous	3 (2-3)	< 0.01
8. Satisfied to continue present treatment in comparison to previous	3 (2-3)	< 0.01
Overall satisfaction score in comparison to previous[b]	16 (9-18)	< 0.01

a) Scores range from 3 = much more satisfied now, to –3 = much less satisfied now, with 0 = no change;
b) Overall satisfaction difference score is calculated by adding scores from items 1, 4, 5, 6, 7 and 8.

FIGURE 1

Picture of device for continuous subcutaneous insulin infusion (right) and continuous glucose monitoring (left).
Source: Medtronic.

patients. Despite this, the questionnaires showed a very high degree of satisfaction with all aspects of the treatment. All active patients would recommend CSII to other type 1 diabetes subjects, and all active patients wanted to continue the treatment. A higher patient satisfaction on CSII has been reported elsewhere [12-15]. The use of continuous glucose monitoring in many of our patients may have contributed to the high level of satisfaction. Not all patients preferred CSII, however. Three patients stopped treatment on their own initiative. When stopping CSII, the patients were no longer classified as active patients in the database.

The Danish National Board of Health has outlined criteria for CSII [3]. The Board describes that the treatment should not be initiated in adults with an HbA_{1c} value below 7.5% on multiple injection therapy. In our study, 11 of the patients had an HbA_{1c} level below 7.5% prior to initiation of CSII. Nine of these patients had considerable trouble with hypoglycaemia on multiple injections. All of them experienced fewer hypoglycaemic attacks during treatment with CSII.

Owing to our finding of improved patient satisfaction while on CSII and the improvement in hypoglycaemia, we believe that the narrow indication established for this treatment by excluding adult patients with an HbA_{1c} below 7.5% should be broadened by removing the 7.5% from the criteria defined by The National Board of Health.

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