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Quality of life and metabolic control in patients with diabetes mellitus type 1 treated by continuous subcutaneous insulin infusion or multiple daily insulin injections

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ABSTRACT

Objective: To assess the quality of life and metabolic control in patients with diabetes mellitus type 1 on continuous subcutaneous insulin infusion (CSII) in comparison with patients on multiple daily insulin injections (MDII).

Research design and methods: The study included 49 patients (13 males, 36 females), aged 41.4 ± 11.3 years (mean ± SD) on CSII for >1 year and 79 patients (43 males, 36 females), aged 43.1 ± 14.8 years on MDII for >1 year, from three Dutch diabetic clinics. There were no statistically significant differences in duration of diabetes, social class, level of education, marital status, smoking or recent admissions to hospital. The questionnaires used were a Diabetes Quality of Life scale adapted from the DCCT, the Diabetes Satisfaction Questionnaire (DTSQ), and the WHO Well-Being Questionnaire. HbA_{1c} was measured with an HPLC method (reference range 4.3 to 6.1 %).

Results: Using two-sided t-tests no statiscally significant differences were found between the patients on CSII and MDII with respect to quality of life (version A (<30 years) 4.32 ± 0.22 *vs* 4.20 ± 0.30; version B (≥30 years) 4.18 ± 0.25 *vs* 4.29 ± 0.28), well-being (48.59 ± 9.23 *vs* 50.99 ± 8.70), satisfaction with treatment (5.10 ± 0.69 *vs* 5.15 ± 0.71) and HbA_{1c} (8.14 ± 1.51 *vs* 8.47 ± 1.40). Frequency of daily blood glucose monitoring was slightly higher in CSII than in MDII patients (4.52 ± 1.19 *vs* 3.60 ± 1.47; p<0.0001).

Conclusion: The present data indicate that patients on CSII have similar QoL based on questionnaires when compared with patients on MDII. These data suggest that in patients with less optimal control on MDII, converting the treatment strategy to CSII is not associated with decreased quality of life.

OBJECTIVE

Over the last ten years, treatment with continuous subcutaneous insulin infusion (CSII) has become more popular, probably for a large part due to a more flexible lifestyle and a better quality of life. The great improvement in insulin pumps (for example, better technology, lighter and smaller devices) as well as the material (needles, catheters, gips, etc.) has made continuous subcutaneous insulin administration much easier. Although the multiple daily insulin injection (MDII) strategy has proven its benefits regarding diabetes control and complications, one of the remaining and important concerns is the frequency of hypoglycaemia events probably caused by the unpredictable absorption of subcutaneously injected insulin.[1,2] CSII therapy has probably solved this problem. CSII has been shown to improve glycaemic control as compared with MDII in reasonably well-controlled diabetes patients (0.35% HbA_{1c}).[3-5] In ad-

dition, in patients with poor metabolic control a 0.8% HbA_{1c} improvement in metabolic control was recently shown.[6] Moreover, several studies have shown an advantage in glycaemic control in CSII-treated patients with the use of a rapid-acting insulin analogue instead of unmodified human insulin.[7,8]

However, even with these improvements, many diabetologists still regard CSII therapy as the last resort in insulin treatment for patients with diabetes mellitus. One of the reasons for this could be the idea that CSII therapy is a psychological burden for the patient. This, however, is not supported by systematic studies. Some initial and small studies suggest a better quality of life with insulin pump treatment, especially when compared with conventional insulin treatment (for example, therapies consisting of twice-daily insulin mixtures) but show less or equal benefit when compared with MDII. These studies were performed with the older, currently outdated equipment and measured different aspects of quality of life, such as depression and anxiety separately.[3,9-14]

The aim of the present study was to compare the quality of life (QoL) in patients with diabetes mellitus type 1 on CSII to that in patients on MDII. To do so, we performed a cross-sectional study on items of QoL in two groups of patients with diabetes mellitus type 1 either treated with CSII or with MDII and who had been stable for a long time.

RESEARCH DESIGN AND METHODS

Patients with diabetes mellitus type 1 who had been stable for at least one year on insulin pump therapy were recruited from three different hospitals. In the three hospitals all patients with diabetes mellitus type 1 were treated with MDII (in total 945), and 95 patients were treated with CSII. At the time of the original cross-sectional study no patients with diabetes mellitus type 2 were treated with CSII and since at that time insulin analogues were only available for clinical trial purposes, no patients were treated with these new types of insulin. In total 55 patients using CSII were invited to an information evening on new developments in insulin pump treatment. Of these patients, 49 responded and they were asked to fill in a number of questionnaires. In each hospital twice as many patients with MDII were randomly selected and asked to fill in the questionnaires before the regular outpatient visit. In this group a total of 79 patients were recruited. Included patients had to have been treated with MDII or CSII for at least one year. Patients with a documented mental disorder were excluded from the study.

The patients received the questionnaires from their own physicians. All questionnaires were returned for analysis together with the most recent HbA_{1c} value of the patient. Patients spent about 30 minutes filling in the questionnaire. There was a general section, consisting of sociodemographic data, such as age, sex, marital status, education, smoking behaviour and more specific questions concerning the duration of diabetes, number of hypoglycaemic events, and number of blood sugar controls daily. In addition three quality of life measurements were carried out.

The quality of life for diabetic patients (DQOL)

This questionnaire measures the current situation, the influence of having diabetes on daily functioning and the worries arising from it. The questionnaire consists of four subscales: satisfaction, impact, worries associated with diabetes and worries in general. There are two versions of the last subscale: version A is for persons younger than 30 years and version B for 30 years and older.

The subscale 'satisfaction' contains 23 items, the subscale 'impact' 20 items, the subscale 'worries' associated with diabetes 16 items and the subscale 'worries in general' version A 10 and version B 9 items. In total, the questionnaire comprises 69 (version A) or 68 items (version B). A five-point scale is used in the DQOL, ranging from 1 (very unsatisfied) to 5 (very satisfied) or from 1 (never) to 5 (always). A high score on the DQOL means that the individual is very satisfied, the impact of diabetes on daily functioning is not experienced as strong and he/she has few general and diabetes-related worries. The internal consistency of the version A questionnaire was 0.9 and for version B 0.89, which is relatively high.[15]

Satisfaction with the therapy (DTSQ)

The DTSQ was developed for measuring satisfaction with the current therapy, and is suitable for people with diabetes type 1 and 2. The questionnaire was developed by Bradly in collaboration with the Diabetes Research Group in 1993.[16,17] The questionnaire consists of eight items and covers three subscales. The scale for this score ranges from 0 (very unsatisfied) to 6 (very satisfied). Two items give an indication of the frequency of hyperglycaemia and hypoglycaemia, the scale for this score ranges from 0 (never) to 6 (often). Hyperglycaemia was defined as a blood glucose value of more than 15.0 mmol/l. A severe hypoglycaemic event was defined as a blood glucose value for which third party assistance was necessary. The internal consistency of this questionnaire was 0.89, which is relatively high.[16,17]

Well-being questionnaire

The questionnaire concerning well-being was originally developed in 1982 to provide an instrument to measure depression, anxiety and the various aspects of well-being. This questionnaire is used by the WHO for measuring new treatment modalities in control of diabetes. The current questionnaire consists of 22 items and four subscales: depression, anxiety, energy and positive well-being. A total

score of general well-being will be obtained by counting the scores after inverting the subscales of depression and anxiety. A four-point scale is used, from 0 (never) to 3 (always). A higher score is consistent with the mental state described by the different subscales. The internal consistency of the subscales has been shown to be sufficient (0.46 to 0.89).[15]

To analyse the difference in quality of life in patients with diabetes mellitus who received a different type of intensive insulin treatment, patients on CSII treatment were compared with patients on MDII. Both groups were given the same questionnaires. Because of the cross-sectional design of the study, statistical analysis was performed by χ^2 for sociodemographic and medical results. All other results were tested by Student's t-test using the SPSS programme. A p value below 0.05 was considered to be statistically significant.

RESULTS

The patient population consisted of 55 patients on CSII who fulfilled the inclusion criteria. Of this group, 49 patients filled in the questionnaire, while six patients were not willing to participate in the trial. A randomly assigned group of 79 patients with MDII coming from the same outpatient clinics formed the control group. Social and demographic data are given in *table 1*. The frequency of self-measurement of blood glucose in the group treated with CSII was once daily in 81%, five to six times a week in 2%, three to four times a week in 2%, one to two times a week in 10% and never or seldom in 2%. In the MDII group these results were 63, 8, 6, 19 and 4%, respectively. The frequency of performing a full daily glucose profile in patients treated with CSII was 18%, consisting of the measurement of blood glucose four times or more in 63%, three times in 6%, twice in 12%, and once a day in 6%. In the MDII group, 8% of the patients performed a daily glucose profile: 43% four times or more, 11% three times, 25% twice and 8% once a day. In general, patients on CSII performed significantly more controls than the patients on MDII. The number of hypoglycaemic episodes that could be managed by the patient him/herself in the week and in two months before the questionnaire was filled in (*table 2*). No statistical differences were found between the two groups. The HbA_{1c} for the CSII group was 8.1 ± 1.5% and for the MDII group 8.5 ± 1.4%. Only the frequency of blood glucose control was statistically different between the two groups ($p<0.05$) (*table 2*). No difference was found regarding the outcome of the DQOL measurement between the two groups (*table 3*). Also the satisfaction of treatment measurement, in particular related to hyperglycaemias and hypoglycaemias, did not show any difference (*table 4*).

With regard to general well-being, the group treated with MDII only showed somewhat better results for the subscale 'energy' compared with the group treated with CSII. Regarding the other items there were no statistical differences between the two groups (*table 5*).

Table 1
Social and demographic data

	CSII	MDII
Number of patients	49	79
Sex (m/f) (n)	13/36	43/36
Age (years)	41.4 ± 11.3	43.1 ± 14.8
Marital status		
Married or living together (n)	40	55
Unmarried (n)	7	18
Divorced/widow (n)	2	6
Education (%)		
None	8	5
Low vocational	25	20
Low	8	16
Middle	37	11
Middle vocational	12	18
High	10	27
Unknown	0	3
Duration of diabetes (%)		
>10 years	65	73
5-10 years	29	14
2-5 years	6	10
<2 years	0	3
Retinopathy (%)	2	3
Nephropathy (%)	0.5	1
Smoking (%)	25	22

Table 2
Frequency of self-control, hyperglycaemias and hypoglycaemias

	CSII (%)	MDII
Daily blood glucose control*	81	63
5-6 times/week	2	8
3-4 times/week	4	6
1-2 times/week	10	19
Never or seldom	2	4
Non-serious hypoglycaemia last week (%)		
None	37	35
1	6	25
2-3	43	27
>4	14	9
Hypoglycaemia during the night (%)		
None	63	60
1	21	30
2	16	6
3	0	2
Not available	0	2
Severe hypoglycaemia last 2 months (%)	80	90
Never	16	6
Ones	2	3
Twice	2	0
3 times	0	0
4 times	0	1
HbA_{1c}	8.1 ± 1.5	8.5 ± 1.4

*$p<0.05$ *(regarding the number of daily controls)*.

Table 3
Results for to the subscales satisfaction, impact, diabetes and general related worries and the total DQOL score

QUALITY OF LIFE	CSII	MDII	P
Satisfaction	4.0 ± 0.6	4.0 ± 0.4	NS
Impact	4.0 ± 0.3	4.1 ± 0.3	NS
Diabetic worries	4.2 ± 0.3	4.2 ± 0.4	NS
Social worries A	4.7 ± 0.3	4.6 ± 0.4	NS
Social worries B	4.5 ± 0.5	4.6 ± 0.3	NS
DQOL A	4.3 ± 0.2	4.2 ± 0.3	NS
DQOL B	4.2 ± 0.2	4.3 ± 0.3	NS

Values are expressed as mean ± SD.

Table 4
Results satisfaction regarding mentioned hyperglycaemias (range 0-6) and hypoglycaemias (range 0-6) and DTSQ total (range 0-6)

DTSQ	CSII	MDII	P
Hyperglycaemia	2.8 ± 1.6	2.7 ± 1.6	NS
Hypoglycaemia	3.5 ± 1.7	3.1 ± 1.7	NS
Satisfaction total	5.1 ± 0.7	5.2 ± 0.7	NS

Values are expressed as mean ± SD.

Table 5
Results for subscales depression (range 0-3), anxiety (range 0-9), energy (range 0-12) and positive well-being (range 0-18) and total well-being (range 0-66)

WELL-BEING	CSII	MDII	P
Depression	3.7 ± 2.6	3.2 ± 2.2	NS
Anxiousness	4.5 ± 3.7	4.0 ± 3.2	NS
Energy	7.5 ± 2.4	8.7 ± 2.3	0.009
Positive well-being	13.2 ± 3.0	13.5 ± 2.8	NS
Well-being total	48.6 ± 9.2	51.0 ± 8.7	NS

Values are expressed as mean ± SD.

CONCLUSIONS

This study shows that patients treated with CSII have similar scores on quality of life scales and respond similarly to questionnaires regarding satisfaction with the treatment and general well-being in comparison with patients treated with MDII. Although we do not know why the patients chose CSII, the CSII group did not differ from the MDII group in duration of diabetes, frequency of complications, marital status and level of education. No statistical difference between the CSII and MDII groups regarding their HBA_{1c} values or the number of severe hypoglycaemias could be detected, although there was a tendency for a better HBA_{1c} for the group treated with the insulin pump, as has also been shown by the two recent meta-analyses.[3,14] The similar quality of life of patients receiving CSII to those on MDII is in line with previous studies, one of which even showed that the quality of life in patients on CSII had improved.[6] Even the fact that most of the patients who were on CSII therapy had a higher frequency of blood glucose control does not seem to interfere with their quality of life. Based on these results, it may be concluded that the idea some diabetologists seem to have about the impact of CSII therapy as an impairment in quality of life is actually a misconception. One of the main advantages of insulin pump treatment is the provision of a better basal insulin administration instead of the problematic pharmacokinetics and pharmacodynamics of intermittent insulin in case of MDII.[18,19] It may, in fact, be considered as remarkable that patients are capable of regulating their diabetes with these schedules. Also the possibility to temporarily change the basal insulin requirement during different activities in patients with CSII might be considered as at least a theoretical benefit of this treatment strategy and should cause less hypoglycaemias and hyperglycaemias.[18,19] Our study may have been too small to detect such differences. Nevertheless, the results of the group treated with CSII therapy (and those on MDII) might have been better if the patients had been treated with insulin analogues, such as lispro or aspart. In various studies insulin lispro and aspart were shown to result in a slightly better HbA_{1c} without causing an increased incidence of hypoglycaemias.[7,8,20-22]
This study, which is a cross-sectional study, has some limitations. The groups were not randomly assigned; the reasons for choosing CSII therapy were mainly caused by motivation of the patients, the Dawn phenomenon, badly controlled diabetes, and also problems related to the NPH insulin. Because of these reasons the groups are strictly speaking not comparable, although one can argue to what extent these differences could have an effect on the parameters evaluated in this study. Despite these limitations, our data suggest that patients who are in less than optimal control on MDII may be safely offered a trial of CSII therapy.

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