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Continuous subcutaneous insulin infusion therapy: effects on quality of life

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Summary

Objective: To compare the diabetes-specific quality of life in subjects with type 1 diabetes treating their diabetes with multiple daily injections (MDI) to that of subjects on continuous subcutaneous insulin infusion (CSII).

Methods: Diabetes-specific quality of life was measured with the DSQOLS-Questionnaire in 81 adult subjects with type 1 diabetes on MDI and 78 subjects on CSII (*cross-sectional* study). In addition, 19 subjects were followed prospectively, measuring their quality of life before and after switching from MDI to CSII (*longitudinal* study).

Results: Preference-weighted treatment satisfaction score was significantly higher in subjects on CSII than in those on MDI in both the *longitudinal* (+63 points, 95%CI 37–89) and the *cross-sectional* study (+14 points, 95%CI 3 to 25). "Diet restrictions" were significantly less of a burden for CSII subjects in both the *longitudinal* (+6 points, 95%CI 1–10) and the *cross-sectional* study (+3 points, 95%CI 0 to 6). "Leisure time flexibility" (+3 points, 95%CI 0 to 7), "Physical complaints" (+4 points, 95%CI 1 to 8), "Daily hassles" (+4, 95%CI 0 to 7), and the overall quality of life (+29 points, 95%CI 3 to 54) were significantly better in CSII compared to MDI only in the *longitudinal* study. Despite a small overall rate of severe hypoglycaemia in both studies, subjects on CSII experienced fewer severe episodes than subjects on MDI.

Conclusions: Subjects with type 1 diabetes on CSII have a better quality of life than type 1 diabetic subjects on MDI. They are more satisfied with their treatment in respect to their metabolic goals as well as psychosocial factors, physical performance and protection from long-term complications and hypoglycaemia. Furthermore, the subjects on CSII experience greater flexibility in their daily routines, leisure time and diet than the subjects on MDI.

Key words: continuous subcutaneous insulin infusion; quality of life; treatment satisfaction; type 1 diabetes mellitus; diabetes-specific quality-of-life scale

Introduction

The Diabetes Control and Complications Trial (DCCT) study has conclusively shown that optimal metabolic control of type 1 diabetes mellitus substantially reduces the risk of long-term microvascular complications [1]. The preferred method for achieving optimal metabolic control is an intensive insulin treatment involving three or more daily insulin injections [1], accompanied by regular home blood glucose monitoring [1, 2]. Up to now, in its most widely used application, this has taken the form of intensified insulin treatment, consisting of up to 8 daily insulin injections, with the insulin dose being flexibly adapted according to blood glucose measurements and carbohydrate intake. In recent years, due to considerable technical progress, the insulin pump (continuous subcutaneous insulin infusion, CSII), now in existence for a good 20 years, has developed as a well-established alternative to the multiple injection model. The handling of the pump has become easier, the devices are smaller, patient safety has improved and because of the rapid

Abbreviations

BG	blood glucose
CSII	continuous subcutaneous insulin infusion
DCCT	Diabetes Control and Complications Trial
DQOL	Diabetes Quality-of-life
DSQOLS	Diabetes-specific Quality-of-life scale
MDI	multiple daily injections
PWTSS	preference-weighted treatment satisfaction score
CI	confidence interval
SD	standard deviation
IQR	interquartile range

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growth in the use of PCs and mobile phones, more patients are familiar with technical equipment in general [3].

Many studies have shown that metabolic control of patients with type 1 diabetes mellitus using CSII therapy has several advantages compared to MDI: blood glucose patterns are more regular and circadian variations can be reduced [3–5]. Good long-term blood glucose monitoring also accounts for better glycohaemoglobin levels [3–5] and the number of severe hypoglycaemias is significantly lower [3, 4, 6]. In several studies, one of many parameters to be compared has been the quality of life on multiple daily injections (MDI) and CSII, but chiefly by means of the Diabetes Quality-of-life (DQOL) questionnaire, which was devised for the purposes of the DCCT study [4, 7–10]. Several surveys showed no significant differences in quality of life between MDI and CSII subjects [4, 8, 10], whereas others documented an improvement in quality of life with CSII compared to MDI [11–13].

In this article, we also compare the quality of life of subjects using CSII with that of patients on MDI. Particular attention was paid to the questions about flexibility in daily life and leisure time, limitations imposed by diet restrictions and the harmful effects of hypoglycaemia. As our working tool we chose to use the Diabetes-specific Quality-of-live scale (DSQOLS) questionnaire by Bott. This questionnaire more specifically deals with the differences between the various forms of diabetes therapy than the DQOL questionnaire, while, on the other hand, the DQOL questionnaire is more sensitive in recording the negative effects arising from diabetic complications [14–19]. Unlike the DQOL, the DSQOLS investigates the level of satisfaction of the subjects with their current diabetes treatment in relation to their individual goals. Thus it is not based on generalized motivation [14]. It also subdivides the negative effects of diabetes into more finely defined categories than the DQOL, giving more accurate information about the nature of the problems caused [14]. The DSQOLS was validated by Bott in German [14], the native language of our subjects, and is also available in English [14].

Methods

Study design

The aim of our study was to compare the quality of life of subjects with type 1 diabetes on CSII with that of subjects with type 1 diabetes treating their diabetes using MDI. Therefore, we analyzed data obtained by means of a questionnaire completed by CSII users and by a control group with MDI therapy (*cross-sectional* study). We also *prospectively* observed 19 subjects who had their treatment changed during the course of the study from MDI to CSII (*longitudinal* study).

The study was based exclusively on data from the questionnaires and the patient records. No extra blood was drawn and no additional drugs were given. The study protocol was endorsed without detailed review by the local ethical committee.

Study subjects

All subjects were recruited from the specialist diabetes out-patient clinic of K. S. They had to be at least 18 years old, have type 1 diabetes mellitus and have been treated with intensive insulin therapy for over one year.

In the *cross-sectional* study all 92 subjects who had been switched from MDI to CSII therapy at least three months previously were contacted and asked to respond to the questionnaire. As control group, 111 subjects with type 1 diabetes mellitus treated by MDI were randomly selected from the same clinic within respective strata based on age (groups of five consecutive years) and gender. 22 consecutive subjects who were put on CSII between April 2000 and February 2001 were recruited for the *longitudinal* study. These subjects received their baseline questionnaire 2 weeks to 3 months prior to changing to CSII, and the follow-up questionnaire 4 to 6 months after having started on CSII. Their baseline questionnaire is also included within the 111 MDI subjects in the *cross-sectional* study.

All patients were treated in the out-patient clinic of one author (K.S.). In general, patients had medical visits every three months to discuss and possibly modify insulin therapy, including measuring the HbA_{1c} level. Assessment for long-term complications (micro-/albuminuria, creatinine, blood lipids, foot exams and eye fundus analysis by an ophthalmologist) was performed on an annual basis. In addition, all patients were welcome to contact their doctor at any time if they had any problems. All instruction in how to use the insulin pump was given by K. S. The aim of the training was to make the patients as independent and flexible as possible in dealing with their treatment. The insulin pump used was the "Disetronic H-Tron plus V-100" (Disetronic AG, Burgdorf, Switzerland), and all patients in the *longitudinal* study were treated with Insulin Lispro (Humalog®, Eli Lilly S.A., Vernier, Switzerland). Of the CSII users in the *cross-sectional* study, 23 (29%) used Humalog®, and the rest used regular insulin (Infusat®, Aventis, Zurich, Switzerland).

The main indications for CSII were: inadequate metabolic control on MDI, major fluctuations in blood glucose levels, very low insulin requirement, frequent severe hypoglycaemia, reduced awareness of hypoglycaemia or an irregular daily routine that called for the diabetes treatment to be as flexible as possible. These indications correspond to those applied worldwide [3, 6].

Questionnaire

In order to record the quality of life of our subjects, we used the "Questionnaire on the treatment goals, treatment satisfaction and burdens of subjects with insulin-treated diabetes" by Bott in its original (i.e. German) version [14]. This questionnaire consists of 10 questions on treatment goals, 10 questions on satisfaction with the way these goals are achieved and 57 questions on diabetes-related problems, divided into 7 categories: "Social relations", "Leisure-time flexibility", "Physical complaints", "Worries about the future", "Diet restrictions", "Daily hassles", and "Worries about hypoglycaemia".

Each question could be answered on a scale of 1 to 6.

To this questionnaire we added 8 questions to be completed by a close relative identified by the subject as well as a few questions to record personal information regarding education, occupation, marital status and current domestic circumstances. Finally, we also recorded the number of severe hypoglycaemias requiring help from other people in the previous 12 months. Filling in the questionnaire took less than 30 minutes.

Clinical data, laboratory measurements

We took clinical data and laboratory values from the patient files. Diabetic retinopathy was diagnosed by an ophthalmologist. Nephropathy was defined as micro-albuminuria of repeatedly >20 mg/l, and peripheral neuropathy as reduced sensitivity to vibration at the malleolus. Coronary heart disease was diagnosed on the basis of tests by a cardiologist and arterial hypertension was defined as blood pressure of ≥140/90 mm Hg. To compare the HbA_{1c} levels of the groups in the *cross-sectional* study, we calculated for each subject the average of all readings taken during the preceding year using the DCA 2000, Bayer (Tarrytown, NY) (in general this was 4 readings). In the same way we calculated the HbA_{1c} level before switching treatments in the *longitudinal* study. The level after the switch was measured once after 3 months on CSII. The number of severe hypoglycaemic episodes that had required the help of another person was also taken from the patient files, where it had been recorded on each 3-monthly visit. In all cases this number was equal to the number recorded in the questionnaire.

Statistics

We evaluated our data using the method presented by Bott [14]. In order to calculate a preference-weighted treatment satisfaction score, PWTSS, the information on the various treatment goals (1 = completely unimportant, 6 = very important) was multiplied by the corresponding degree of satisfaction with the extent to which these treatment goals were achieved (–2.5 = completely unsatisfied, 2.5 = fully satisfied). Summing these 10 results yielded the weighted overall treatment satisfaction score. The 57 questions on diabetes-specific burdens were grouped in the categories "Social relations", "Leisure-time flexibility", "Physical complaints", "Worries about the future", "Diet restrictions", "Daily hassles", and "Worries about hypoglycaemia". The answers to the various individual questions (1 = a serious burden to me, 6 = not at all a burden to me) were added up to work out the overall extent of the burden in each category. A higher value means the topic is less of a burden. To achieve a proxy for overall quality of life, the total scores for all categories of burdens were then added up. In this case, a higher value indicates a better quality of life. Finally, for ease of comparison, all subscale scores were converted to a 100 point scale.

Statistical comparisons were carried out using Stata version 8.2 (Stata Corporation, College Station, TX, USA). In the *cross-sectional* study we used a multiple linear regression model to assess differences in average scores between the MDI and the CSII group. Parameters were estimated using least square techniques. The analyses were adjusted for age, gender, duration of diabetes, HbA_{1c}, presence or absence of retinopathy, professional situation (working, disabled, retired) and accommodation (alone, with partner, with children, other). In the *longitudinal* study average values were compared using the 2-sided paired t-test. Proportions were compared using the Fisher exact test. A pvalue <0.05 was considered statistically significant.

Results

Response rate

Of the CSII group, 78 questionnaires were completed and returned (85%), from the MDI group 81 (73%), and from the subjects in the *longitudinal* study 19 (86%). The responders were similar to the non-responders in age and gender. Among the responders, the two groups in the *cross-sectional* study were similar in age, gender, duration of their diabetes, diabetes-related long-term complications, level of education or marital status (see table 1).

Treatment satisfaction

Compared to subjects on MDI, subjects on CSII were significantly more satisfied with their type of treatment (PWTSS; p = 0.01 in the *cross-sectional* study adjusted analysis, p <0.01 in the *longitudinal* study). The overall score of subjects in the *cross-sectional* study who were treated by CSII was on average 14 points higher (95% CI 3 to 25; p = 0.01) than in subjects treated by MDI. For the individual questions results are summarized in table 2.

In the *longitudinal* study, for all subjects, except for one, overall treatment satisfaction score increased after changing from MDI to CSII. The mean increase of scores was 63 points (95%CI 37–89; p <0.01) after changing to CSII. Analyses of the individual questions revealed a significant mean increase for all items (PWTSS1-10) in subjects changing from MDI to CSII (see table 2).

Burdens

In the *cross-sectional* study, "diet restrictions" were significantly less of a burden for the CSII than for the MDI subjects (mean +3 points, 95%CI 0–6; p <0.05). Scores for all other burdens were comparable in the two treatment groups (see table 3).

In the *longitudinal* study, after switching to CSII, the subjects also felt that "diet restrictions" were significantly less of a burden (mean +6 points, 95%CI 1–10; p = 0.01). They experienced greater freedom in their "leisure time flexibility" (mean +3, 95%CI 0-7; p <0.05), had fewer "physical complaints" (mean +4, 95%CI 1–8; p <0.05) and fewer "daily hassles" (mean +4, 95%CI 0–7; p <0.05) For all but four subjects the overall quality of life score was higher after changing to CSII, resulting in a significant difference for this question (mean +29, 95%CI 3–54; p = 0.03) (see table 3).

Metabolic parameters

In the *cross-sectional* study, HbA_{1c} levels were 7.1% (SD 1.0%) and 7.6% (SD 1.2) for subjects

Table 1

Clinical and demographical data.

	CSII group	MDI group	Longitudinal group (baseline)
Total patients (f/m)	78 (37/41)	81 (39/42)	19 (14/5)
Age, mean (SD), y	41.3 (13.3)	42.2 (11.8)	42.8 (11.2)
Duration of diabetes, mean (SD), y	19.4 (11.6)	17.4 (10.6)	18.2 (11.0)
Duration of CSII treatment, mean (SD), y	2.1 (2.6)		0.5 (0.1)
Number (%) of patients with:			
– Retinopathy	23 (29)	22 (27)	9 (47)
– Nephropathy	25 (32)	18 (22)	7 (37)
– Neuropathy	23 (29)	27 (33)	8 (42)
– arterial hypertension	30 (38)	22 (27)	7 (37)
– coronary heart disease	7 (9)	3 (4)	1 (5)
Number (%) of patients with:			
– primary education only	11 (14)	10 (12)	5 (26)
– professional education	57 (73)	58 (72)	13 (68)
– academic education	10 (13)	13 (16)	1 (5)
Number (%) of patients live:			
– alone	14 (18)	14 (17)	5 (26)
– with parents	5 (6)	4 (5)	0
– with partner	22 (28)	27 (33)	4 (20)
– with partner and children	34 (44)	34 (42)	10 (50)
Number (%) of patients are:			
– single	19 (24)	26 (32)	4 (21)
– married	52 (67)	47 (58)	12 (63)
– divorced	5 (6)	4 (5)	2 (11)
– widowed	2 (3)	3 (4)	1 (5)
Number (%) of patients are:			
– working	67 (86)	72 (89)	15 (79)
– unemployed	1 (1)	0	0
– disabled	5 (6)	3 (4)	2 (11)
– retired	5 (6)	6 (7)	2 (11)

Table 2

Preference-weighted treatment satisfaction score (PWTSS): mean (standard deviation). A higher value indicates a higher satisfaction with the individual topic.

	Cross-sectional study			Longitudinal study		
	MDI	CSII	Adjusted† mean difference (95% CI) between MDI and CSII	MDI	CSII	Mean difference (95% CI) between MDI and CSII
Blood glucose level	3.1 (5.8)	4.5 (5.3)	0.9 (-0.8 – 2.5)	–0.7 (6.4)	7.0 (6.6)	7.7 (3.9 – 11.5)*
Blood glucose stability	2.7 (5.9)	3.8 (5.9)	0.4 (-1.4 – 2.3)	–1.2 (7.1)	6.7 (6.8)	7.9 (3.5 – 12.4)*
Leisure time flexibility	7.8 (4.9)	9.2 (5.2)	1.1 (-0.5 – 2.6)	6.0 (5.9)	12.3 (3.8)	6.4 (3.0 – 9.7)*
Frequency of mild hypoglycaemia	4.3 (6.3)	7.0 (4.4)	2.8 (1.0 – 4.6)*	1.3 (7.9)	8.2 (6.9)	6.9 (3.5 – 10.2)*
Protection against late complications	5.0 (7.2)	7.4 (6.9)	2.2 (0.0 – 4.4)*	2.4 (7.9)	8.1 (7.2)	5.7 (2.2 – 9.2)*
Diet flexibility	7.6 (5.4)	10.3 (4.6)	2.4 (0.8 – 3.9)*	5.4 (4.9)	11.8 (3.7)	6.5 (4.1 – 8.8)*
Physical fitness	6.9 (7.1)	8.1 (6.1)	1.6 (-0.4 – 3.7)	2.4 (9.1)	10.6 (4.2)	8.2 (4.0 – 12.3)*
Protection against severe hypoglycaemia	7.4 (7.6)	9.8 (5.1)	2.3 (0.1 – 4.4)*	3.2 (10.3)	9.9 (7.0)	6.7 (2.1 – 11.3)*
Frequency of BG-self monitoring	3.5 (5.0)	4.3 (4.8)	0.4 (-1.2 – 2.0)	0.6 (5.6)	6.1 (5.2)	5.5 (1.6 – 9.5)*
Understanding of other people	2.4 (3.2)	2.6 (3.1)	0.3 (-0.7 – 1.3)	2.2 (3.8)	3.8 (4.2)	1.6 (0.0 – 3.2)*

† adjusted for age, gender, duration of diabetes, HbA_{1c}, presence or absence of retinopathy, professional situation (working, disabled, retired), accommodation (alone, with partner, with children, other), * $p < 0.05$

MDI, multiple daily injections; CSII, continuous subcutaneous insulin infusion

Table 3

Overall treatment satisfaction, daily restrictions and burdens, overall quality of life: mean (standard deviation). A higher value indicates a higher satisfaction, a better quality of life and that the individual topic is less of a burden, respectively.

	Cross-sectional study			Longitudinal study		
	MDI	**CSII**	**Adjusted* mean difference (95% CI) between MDI and CSII**	**MDI**	**CSII**	**Mean difference (95% CI) between MDI and CSII**
Overall treatment satisfaction	51 (38)	67 (30)	14 (3 – 25)**	22 (49)	85 (40)	63 (37 – 89)**
Social relations	58 (9)	57 (9)	–1 (–4 – 2)	57 (10)	60 (7)	3 (–1 – 8)
Leisure time flexibility	29 (6)	30 (6)	1 (–1 – 2)	28 (6)	31 (5)	3 (0 – 7)**
Physical complaints	44 (8)	45 (7)	0 (–2 – 2)	43 (9)	47 (5)	4 (1 – 8)**
Worries about future	20 (6)	21 (6)	1 (–1 – 3)	19 (5)	21 (6)	1 (–2 – 4)
Diet restrictions	37 (10)	40 (9)	3 (0 – 6)**	38 (8)	43 (8)	6 (1 – 10)**
Daily hassles	25 (6)	25 (7)	0 (–2 – 2)	23 (5)	27 (5)	4 (0 – 7)**
Worries about hypoglycaemia	46 (14)	47 (12)	0 (–4 – 5)	41 (17)	48 (13)	7 (–2 – 16)
Quality of life	258 (44)	264 (42)	4 (–9 – 18)	248 (45)	277 (34)	29 (3 – 54)**

MDI, multiple daily injections; CSII, continuous subcutaneous insulin infusion

* adjusted for age, gender, duration of diabetes, HbA_{1c}, presence or absence of retinopathy, professional situation (working, disabled, retired), accommodation (alone, with partner, with children, other). **p <0.05

on CSII and MDI, respectively. The adjusted analyses revealed that mean HbA_{1c} levels were on average 0.6% (95% CI 0.2–0.9%; p <0.01) lower when treated with CSII. In both groups only a minority of subjects suffered from severe hypoglycaemic episodes requiring help from other people during the preceding year (median [IQR] for the CSII group 0 [0–1.5] and 0 [0–1] for the MDI group). In the *longitudinal* study, the HbA_{1c} improved after switching to CSII from 7.9% (median, IQR 7.3–8.8%) to 7.0% (median, IQR 6.0–7.9%). Furthermore, the number of severe hypoglycaemias dropped substantially: In the year before switching to CSII, 8 of the 19 subjects experienced a total of 50 severe hypoglycaemias requiring help from other people (on average 2.6 [SD 5.3] episodes per year). During the total of 104 subject months between changing treatment and filling in the second questionnaire, there was only one case of severe hypoglycaemia.

Discussion

There have been many studies comparing different treatment methods in type 1 diabetes mellitus. However, relatively few are focusing on quality of life. To our knowledge, this is the first study to use the DSQOLS questionnaire to compare the quality of life of subjects with type 1 diabetes on MDI with subjects on CSII in Switzerland. The DSQOLS is very sensitive to differences in the form of treatment [14], assesses treatment satisfaction in terms of personal treatment goals and is therefore not only based on standard preferences [14]. An additional advantage of using the DSQOLS for our study was the fact that it had been devised and validated in German, the native language of our target population. However, it also is available in English [14]. In contrast to previous studies [4, 8–10] we combined a *cross-sectional* and a *longitudinal* study. A clear advantage of our study is the fact that all patients were followed in one centre by a single physician.

For ethical and practical reasons, our study subjects could not be randomly allocated to the MDI or CSII group. This is a clear weakness of our study. For obvious reasons the design of randomized and controlled trials testing the benefits of CSII is difficult. Subjects were switched to CSII for poor metabolic control, irregular lifestyle or frequency of hypoglycaemia. Therefore, the results might be biased by the fact that any change of treatment which would have resulted in better metabolic control might have resulted in a higher quality of life. This distortion might be relevant in the *longitudinal* study. In contrast, the analysis of the *cross-sectional* group should not be affected by this fact as most subjects had not been switched to CSII very recently (mean duration of CSII treatment 2.1 years). Furthermore, by adjusting statistical analysis for different parameters as mentioned above we accounted for potential influences, thereby limiting distortions.

In our study, the preference-weighted treatment satisfaction score was significantly higher for the subjects on CSII than those on MDI. This was the case in both the *longitudinal* and the *cross-sectional* study. The particular questions about treatment satisfaction did relate to metabolic goals (level and stability of blood glucose, number of hypoglycaemias), psycho-social factors (flexibility in daily routine, tolerance of the illness by other people), physical performance and protection from long-term complications and hypoglycaemia. The *longitudinal* study group was consid-

erably more satisfied in all respects after switching to the pump. Among the *cross-sectional* study population, the differences were greatest for the questions about hypoglycaemia and dietary flexibility.

In general, treatment effects seen in the *cross-sectional* study tended to the same direction but were clearly less distinct than in the *longitudinal* study. From our data we cannot give a clear explanation for this difference. One possible explanation is the fact that in the *longitudinal* study a greater reduction of HbA_{1c} was achieved. Although we tried to control for this fact statistically, this may have been relevant for various measures of treatment satisfaction. Alternatively, this discrepancy may also reflect differences between the two study groups that we were unable to detect.

As mentioned before, an important factor in switching patients to CSII is an increased frequency of hypoglycaemia, e.g. because of poor awareness of hypoglycaemia, irregular physical activity, or very low insulin requirement. Other authors have demonstrated that the number of severe hypoglycaemias is significantly reduced on CSII compared to MDI [3, 4, 6]. In our study as well, the CSII patients experienced significantly fewer severe hypoglycaemias requiring help from other people than the MDI subjects. In addition, we were able to show that the subjects using the insulin pump were significantly more satisfied with the number of hypoglycaemias than the MDI subjects. They also felt more protected against severe hypoglycaemia involving loss of consciousness. This is true for both the *longitudinal* and the *cross-sectional* study. Nevertheless, the problem of the ever-present fear of hypoglycaemia was scarcely reduced by CSII. Severe hypoglycaemia is also a major problem for the relatives of subjects with type 1 diabetes. They too are afraid that their relative could suddenly lose consciousness and that they would have to react correctly in an emergency situation. Not surprisingly, the fear of their family members suffering severe hypoglycaemia was significantly less among relatives of CSII patients than among relatives of MDI patients in both the *longitudinal* and the *cross-sectional* groups (data not shown). Thus, we were able to show that an insulin pump can make the major fear of severe hypoglycaemia more manageable for subjects with type 1 diabetes and their relatives. An increased risk of hypoglycaemia is a good reason to switch to CSII.

For many subjects with type 1 diabetes, the idea of an insulin pump is distressing, because they are anxious about always having to carry a "foreign object" with them [3]. However, this study shows that this inconvenience is offset by a considerable increase in freedom and flexibility. We demonstrated that flexibility in daily life, leisure time, and diet is greater with CSII than with MDI. The negative effects of dietary restrictions were in fact significantly less with CSII than with MDI for both the *cross-sectional* and the *longitudinal* studies. Correspondingly, satisfaction with the dietary flexibility was significantly higher. Satisfaction with leisure time flexibility was also greater, and the perceived restriction on this flexibility was less with CSII in the *longitudinal* group and virtually insignificant in the *cross-sectional* group. CSII therefore allows greater freedom in daily life with regard to eating, sleeping and sports. Of note, the difference in HbA_{1c} after changing to CSII in the *longitudinal* study better reflects glycaemic control of the subjects, thereby impacting on the protection against late complication and consequently on a better quality of life.

In summary, we demonstrated that diabetes treatment using CSII not only accounts for better metabolic control but also brings an improvement in quality of life and treatment satisfaction, in particular as a result of greater flexibility in diet, leisure time activities, and daily routines.

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