



Type 1 Diabetes

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Introduction

01



Introduction

The findings of this study rekindled interest in the use of CSII therapy to improve glycemic outcomes. Since the publication of the Diabetes Control and Complications Trial, healthcare providers have worked with Type 1 patients to improve glycemic control using multiple daily injection (MDI) or continuous subcutaneous insulin infusion (CSII) treatment because it provides a more physiological way of doing things. However, the relative advantages of CSII and MDI in terms of lifestyle flexibility and quality of life (QoL) have rarely been studied, and some of the findings are contradictory.



Trials comparing CSII and MDI in adults with Type 1 diabetes (T1DM) have primarily focused on easily observable outcomes like glycated hemoglobin, showing that CSII improves glycemic control in a modest but worthwhile way. It is unknown if CSII has a different effect on women. In general, studies looking into the effects of CSII on T1DM QoL have been mixed

Some of these studies do indicate that CSII therapy benefits are:

- ✓ **Less severe hypoglycemia**
- ✓ **Improved quality of life**
- ✓ **Increased coping ability**
- ✓ **More freedom.**





- ◆ A recent randomized trial in **272 T1DM** patients compared CSII to NPH-based MDI and found that CSII treatment was associated with a significant reduction in hypoglycemic events and improved QoL
- ◆ Under routine clinical conditions, a large cohort of adults with T1DM were treated with either CSII or MDI (glargine-based or NPH-based) and patient satisfaction was measured. The aim of this extensive case–control study was to determine quality of life.

Research design and methods

02





Between January and December 2006, a case-control study was conducted. 10 cases and 10 controls were requested.

Cases:

Patients with T1DM who had been on CSII for at least 6 months and visiting diabetes clinics for a routine visit

Controls:

Patients had never been treated with CSII and had been receiving at least four insulin injections per day for ≥ 6 months.

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Patients following the same eligibility criteria, in centres without experience in the use of insulin pumps.



An additional control group was found in centers with no prior experience with insulin pumps, using the same eligibility criteria. The study protocol was reviewed by each institution's local research ethics committee.

If a patient was pregnant or had psychiatric issues that made it difficult for them to complete the questionnaires, they were excluded from the study. All of the patients signed a written informed consent form.

Measurements



We were able to normalize HbA1c as a result of this. Because HbA1c normal ranges differed by country, the percentage change from the top to the lower The normal value (the difference between the actual value and the upper normal limit) was calculated. and the result was multiplied by **6.0**. Participating Participating doctors gathered all demographic information as well as relevant diabetes history on ad hoc forms.

values with respect to a value of **6.0%**



On a dilated eye examination, eye complications were characterized as the presence of any grade of diabetic retinopathy or maculopathy. Micro- or macroalbuminuria, elevated serum creatinine levels (**> 132 mol/l**), and micro- or macroalbuminuria were among the renal complications.

Transplantation/dialysis Diabetic neuropathy is a condition that occurs as a result of diabetes. cataract, for example.

The SF-36 Health Survey is a questionnaire that asks about your health (SF-36).

All All patients completed a questionnaire at the start of the study, which included the Diabetes Specific Quality of Life Scale (DSQOLS), the Diabetes Treatment Satisfaction Questionnaire (DTSQ), and the Diabetes Quality of Life Scale (DSQOLS). and its relationship to the data gathered by participants A numerical code ensured the safety of doctors. The survey was completely anonymous.

03

Results



Results

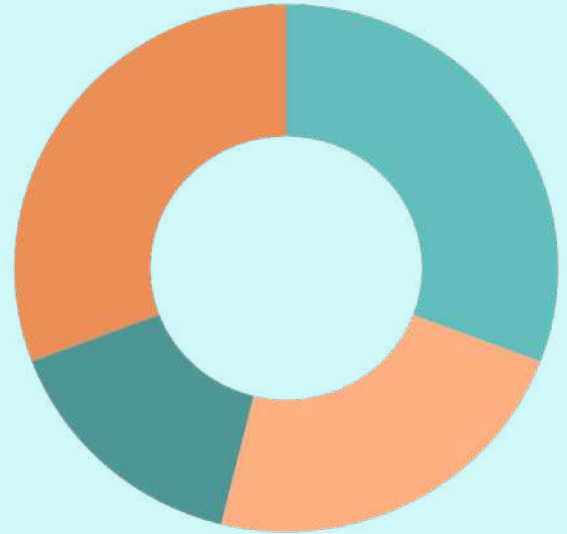


- Overall, 62 diabetes clinics enrolled 1341 patients, of whom 481 used CSII and 860 used MDI.

- The mean duration of CSII therapy was < 1 year in 16% of the patients, 1–3 years in 52.8% and > 3 years in 31.2% of the patients.

Of control subjects, 773 (90%) took glargine-based MDI regimens and 87 (10%) NPH-based MDI regimens.

- Median duration of glargine therapy was 24.6 months.



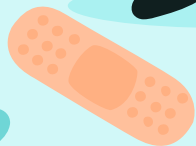
- Furthermore, CSII patients were more likely to self-manage insulin doses and use carbohydrate counting.
- All patients completed the QoL questionnaires. unadjusted QoL and satisfaction mean scores, and age, gender.
- Scores were similar in control patients enrolled in centres using CSII and those not using this regimen, apart from the DTSQ

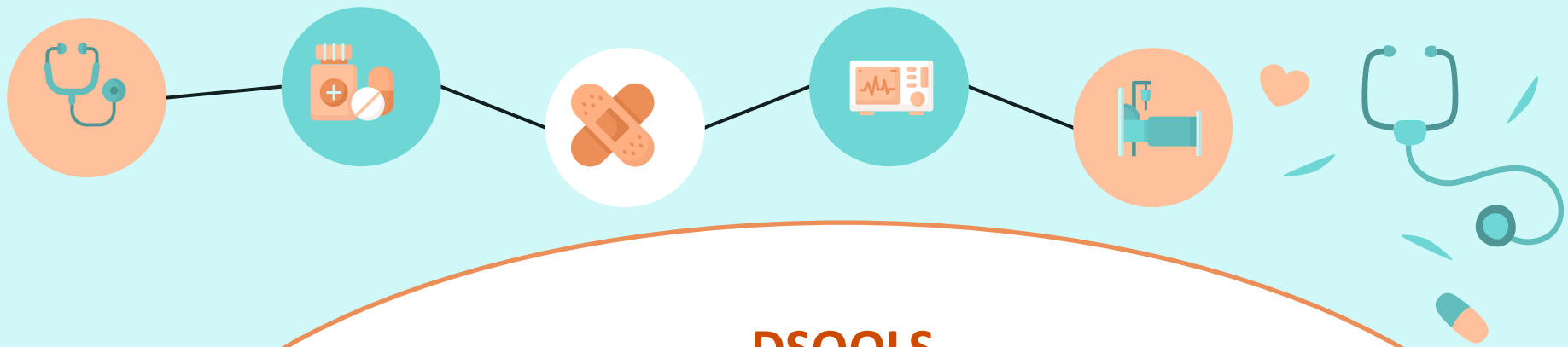


Patients' characteristics



	CSII (N = 481)	MDI (N = 860)
Gender		
Male	206 (42.8)	467 (54.3)
Female	275 (57.2)	393 (45.7)
Age (years)	35.1	34.9
School education (years)		
≤ 5	6 (1.3)	22 (2.6)
6–8	113 (23.5)	231 (26.7)
9–13	263 (54.7)	470 (54.4)
> 13	99 (20.6)	141 (16.3)
Occupation		
Employed	320 (69.4)	598 (69.7)
Retired	19 (4.1)	46 (5.4)
Unemployed/student	122 (26.5)	214 (24.9)
Marital status		
Single	202 (42.0)	460 (53.2)
Married	259 (54.0)	364 (42.1)
Divorced/widowed	20 (4.2)	40 (4.6)






DSQOLS

- Crude DSQOLS scores were significantly higher in CSII patients than in control subjects for ‘diet restrictions’,
- MDI patients had significantly higher scores than CSII patients for ‘leisure time flexibility’ and ‘physical complaints’ dimensions
- When the average DSQOLS scores were adjusted for age, gender and diabetes duration, patients treated with CSII had a significantly higher score than those treated with MDI.
- Women had lower scores than men for all the domains investigated.



SF-36

- Mean SF-36 scores were higher in MDI than in CSII patients; nevertheless, when the scores were adjusted for age, gender and diabetes duration, they did not significantly differ between cases and control subjects, with the single exception of a higher energy/vitality score for patients in the control group
 - After adjusting for additional potential confounders, no differences were detected for SF-36 subscales, either in multiple or logistic regression analyses. Similarly, no difference emerged when SF-36 scores in CSII patients were compared separately with patients treated with either glargine or NPH
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Discussion



Discussion



- **This is the largest study assessing QoL and treatment satisfaction in adults with T1DM treated with either CSII or MDI. It is also the first study comparing CSII with glargine-based MDI regimens.**
- **Both generic and disease-specific instruments were used to ascertain whether CSII could have an impact on broader aspects of health-related QoL**





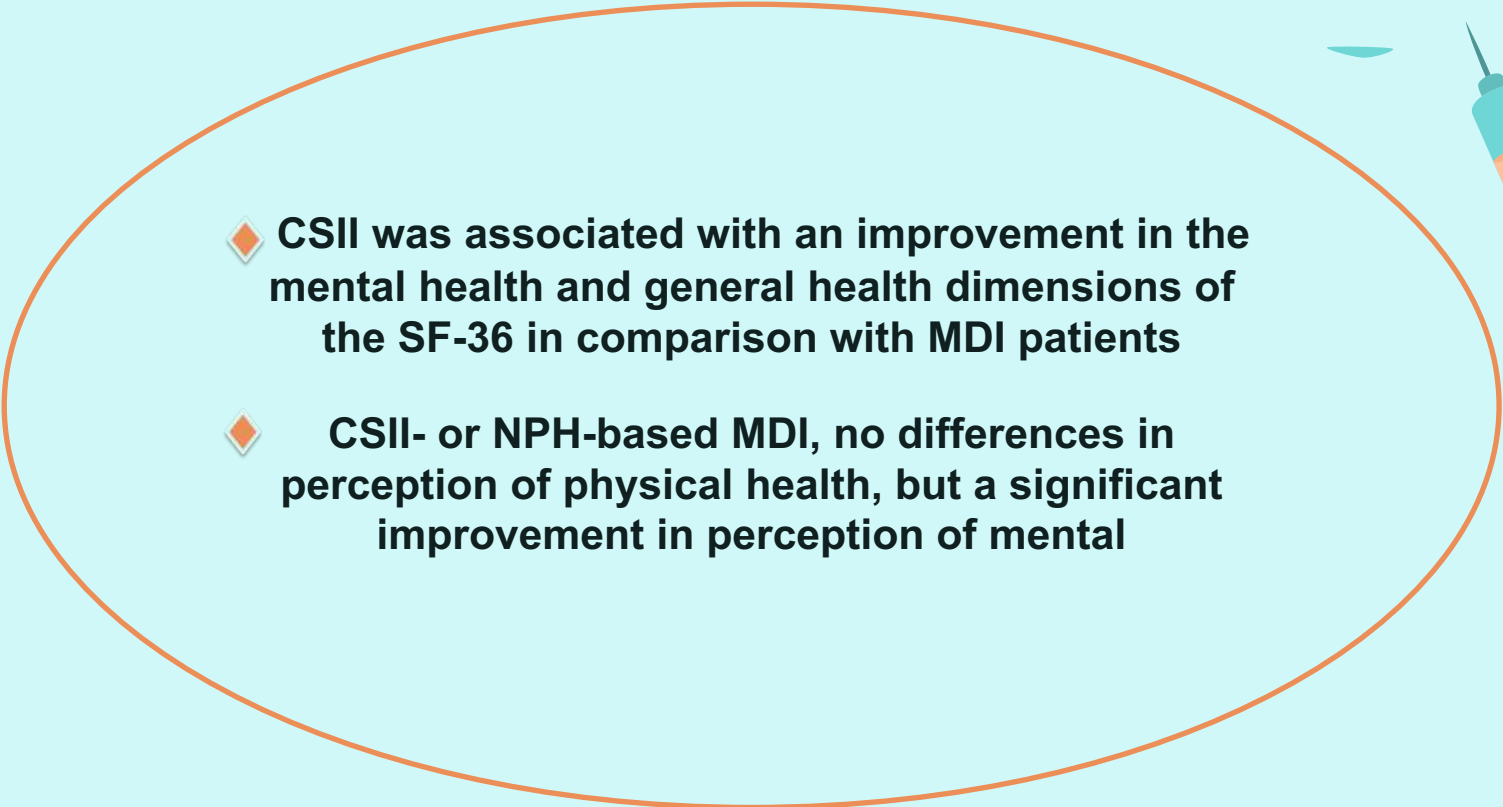
◆ **Our study shows that, despite having more severe disease (higher prevalence of complications, longer diabetes duration), patients treated with CSII have HbA1c levels almost identical to those of individuals treated with MDI, without any negative impact on QoL. On the contrary, CSII patients showed a lower perception of diabetes-specific burdens and restrictions.**

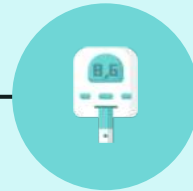
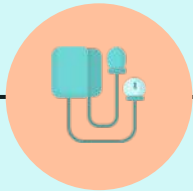
◆ **Therefore, effective treatment strategies must enable patients to achieve good glycemic control and, at the same time, they should interfere as little as possible with an independent and flexible lifestyle.**

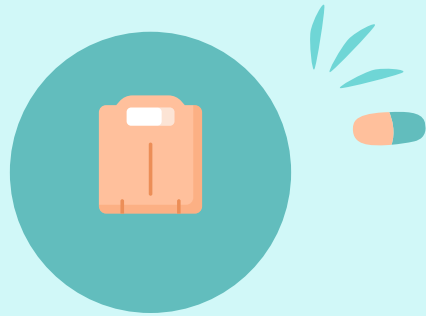




- ◆ **CSII was also associated with a markedly higher treatment satisfaction score in comparison with individuals treated with either glargine-based MDI**
- ◆ **The patients treated with CSII have less fear of hypoglycaemia, in comparison with NPH-MDI patients, but also with respect to patients treated with glargine-based MDI**

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- ◆ **CSII was associated with an improvement in the mental health and general health dimensions of the SF-36 in comparison with MDI patients**
 - ◆ **CSII- or NPH-based MDI, no differences in perception of physical health, but a significant improvement in perception of mental**



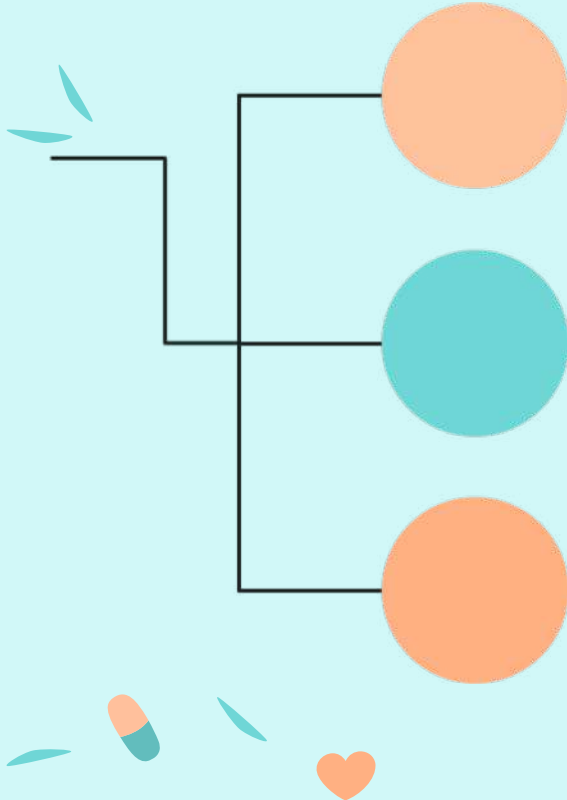


CSII is preferentially chosen by, or offered to, female patients, who generally tend to report poorer health-related QoL than men.

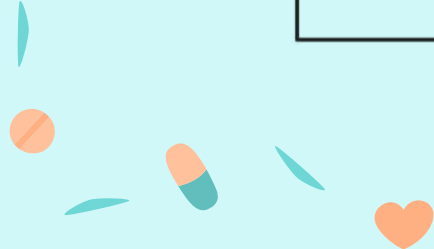


In our study we were unable to detect any psychological harm associated with CSII therapy.

Conclusion



- ◆ This is the first large study suggesting QoL gains deriving from greater lifestyle flexibility, less fear of hypoglycaemia, and higher treatment satisfaction, when CSII is compared with glargine-based MDI regimens
- ◆ CSII is not associated with deterioration in QoL. On the contrary, it is associated in both genders with a lower perceived burden of disease and higher treatment satisfaction compared with NPH-based MDI
- ◆ These findings are useful when weighing the benefits of different insulin therapy modalities against costs.



Reference

- ◆ (Nicolucci et al., 2008)



Thanks

