Less severe hypoglycaemia, better metabolic control, and improved quality of life in type 1 diabetes mellitus with continuous subcutaneous insulin infusion (CSII) therapy; an observational study of 100 consecutive patients followed for a mean of 2 years

Background information

• Continuous subcutaneous insulin infusion (CSII) has been used since the late 1970s to improve glycemic control in patients with diabetes who have not achieved a sufficient level of control with multiple daily insulin injections.
• At the center where the present study was conducted, CSII was used mainly in patients with good metabolic control, but who would like greater treatment flexibility, those who frequently experience severe hypoglycemia, and those with hypoglycemia unawareness.

Aims

• To measure outcomes (glycemic control, incidence of hypoglycemia, and quality of life) in patients switching from intensive conventional insulin therapy (ICT) to CSII therapy.

Methods

• All patients with type 1 diabetes who started CSII therapy at the Heinrich-Heine University (Düsseldorf, Germany) between October 1995 and April 1999 were followed up for a mean of 1.8 years after beginning CSII therapy.
• Prior to CSII, patients had routinely received 2 injections of human NPH insulin and preprandial injections of regular human insulin.
• Of the 103 patients identified, 100 were still on CSII therapy at follow-up and were included in the study.
• The indications for CSII therapy were: (i) to improve metabolic control and the flexibility of treatment (n = 58; the ‘OF group’); and (ii) to prevent severe hypoglycemia (n = 42; the ‘HY group’).
• The outcomes measured included HbA1c levels and the frequency of hypoglycemic episodes and diabetic ketoacidosis. Quality of life was measured before and after CSII using the validated Diabetes-Specific Quality of Life Scale.

Results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Overall</th>
<th>OF group</th>
<th>HY group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICT</td>
<td>CSII</td>
<td>ICT</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>7.7 ± 1.1</td>
<td>7.2 ± 1.0***</td>
<td>7.8 ± 1.2</td>
</tr>
<tr>
<td>Hypoglycemic episodes (cases per patient-year)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>serious</td>
<td>1.23</td>
<td>0.29***</td>
<td>0.00</td>
</tr>
<tr>
<td>severe</td>
<td>0.70</td>
<td>0.06***</td>
<td>0.00</td>
</tr>
<tr>
<td>Diabetic ketoacidosis (cases per patient-year)</td>
<td>0.05</td>
<td>0.01</td>
<td>0.02</td>
</tr>
</tbody>
</table>

*p < 0.5, **p < 0.005, ***p < 0.001

HY group = patients starting CSII for prevention of hypoglycemic episodes; OF group = patients starting CSII for improvement of metabolic control and treatment flexibility

Table 1. HbA1c levels (mean ± SD) and frequency of complications in 100 patients switching from ICT to CSII-based therapy for type 1 diabetes

Key points

■ The reasons for starting continuous subcutaneous insulin infusion (CSII) therapy were optimization of metabolic control and improved flexibility (OF group) in 58 patients, and prevention of severe hypoglycemia (HY group) in 42 patients.

■ Significant reductions in HbA1c levels were seen in OF and HY groups. In the overall study population, HbA1c levels decreased from 7.7% to 7.2% (p < 0.001).

■ Overall, the frequencies of serious and severe hypoglycemic episodes were significantly reduced following the switch from injection-based to CSII therapy.

■ All of the quality of life parameters measured were significantly improved after switching to CSII therapy.
At the start of CSII therapy, the patients’ mean age was 33 ± 11 years (range 17–66), and the mean duration of diabetes was 18 ± 9 years (range 1–43). Fifty-six of the patients were women.

HbA1c levels decreased significantly after CSII therapy was started, regardless of the reason for therapy (Table 1).

Serious hypoglycemic episodes (i.e. those requiring external assistance) were also significantly reduced in frequency, from 1.23 to 0.29 cases per patient-year, after the switch from ICT to CSII. This reduction was due to a decrease in episodes among patients in the HY group (Table 1).

A similar pattern was seen for severe hypoglycemic episodes (loss of consciousness requiring administration of intravenous glucose or glucagon therapy).

Paired quality of life data were available for 50 patients. Quality of life scores improved significantly after switching to CSII for all of the quality of life parameters measured (Figure 1).

Conclusion

- Patients with type 1 diabetes experience a significant improvement in HbA1c levels after switching from injection- to CSII–based insulin therapy.
- CSII is effective in reducing the incidence of serious and severe hypoglycemic episodes in patients with a history of such episodes.
- Quality of life appears to be significantly improved by switching from injection- to CSII–based therapy.

From the authors

**CSII significantly decreased the incidence of serious and severe hypoglycaemia while achieving better metabolic control compared with ICT**