Evaluation of an insulin pump service

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Article points

1. Twelve people with type 1 diabetes who had been on continuous subcutaneous insulin infusion (CSII) therapy for 1 year were evaluated for change in HbA_{1c} level and the severity and awareness of hypoglycaemia episodes.
2. The effects of maintaining strict glycaemic control can lead to an increased risk of severe hypoglycaemia and diminished response to hypoglycaemia.
3. Severe hypoglycaemia may have an adverse effect on an individual's quality of life.
4. The use of CSII has been shown to improve glycaemic control while minimising the severity of hypoglycaemia.
5. Service evaluation is a reliable method to assess the effectiveness of CSII therapy.

Key words

- Continuous subcutaneous insulin infusion
- Hypoglycaemia
- Service evaluation
- Type 1 diabetes

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Continuous subcutaneous insulin infusion (CSII) is recommended as a treatment option for adults or children with type 1 diabetes. Several studies have indicated that intensive diabetes management with CSII improves glycaemic control while reducing severe hypoglycaemia. In this service evaluation, the author analysed the resulting effects on HbA_{1c} level and the frequency and severity of hypoglycaemia 1 year after commencing insulin pump therapy. Twelve people with type 1 diabetes were initiated on insulin pump therapy by the specialist multidisciplinary team based in secondary care. It was anticipated that the evaluation would support the expansion of this new service development in the future.

The aim of modern insulin regimens, such as recombinant DNA technology producing insulin analogues, has been to replicate the natural phenomenon of glucose homeostasis, thus allowing people with type 1 diabetes to effectively mimic the body's natural insulin profile. Studies have demonstrated that improved glycaemic control slows the progression of diabetic nephropathy, peripheral and autonomic neuropathy and retinopathy (Boulton et al, 1982; Feldt-Rasmussen et al, 1986; Helve et al, 1987). However, hypoglycaemia may occur in people trying to maintain tight glycaemic control. The aim of insulin pump therapy is to provide excellent glycaemic control without the associated hypoglycaemia risks.

The Diabetes Control and Complications Trial (DCCT; DCCT Research Group, 1993) was a 10-year study involving 1441 people with type 1 diabetes in the US, comparing the effects of intensive versus standard glucose control. HbA_{1c} level targets were set at <6% (<42 mmol/mol). The lowest incidence of complications was found among those people receiving intensive treatment, including those on pumps, who achieved HbA_{1c} levels of approximately 7% (53 mmol/mol). Unfortunately, the effects of maintaining strict glycaemic control, as recommended by the DCCT Research Group (1993), can mean an increased risk of severe hypoglycaemia, which can, in turn, lead to a diminished neuroendocrine and symptomatic response to hypoglycaemia. This leads to altered glycaemic thresholds for activation of responses, which will result in impaired awareness of hypoglycaemia. Continuous subcutaneous insulin infusion (CSII) delivers a continuous and adjustable dose of insulin throughout a 24-hour profile with bolus doses given when carbohydrate is ingested. The use of CSII therapy has been shown to reduce the frequency of severe hypoglycaemic episodes, thereby increasing hypoglycaemic awareness while allowing for tight control of blood glucose levels (Pickup et al, 2005; Hoogma et al, 2006; Thomas et al, 2007).

The *Insulin Pump Services: Report of the Insulin Pumps Working Group* (Department of Health [DH], 2007) estimated that the usage of insulin pumps in people with type 1 diabetes represents as little as 1% of the population with diabetes in the UK. This

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1. If services are not evaluated in a rigorous and systematic way, then we cannot be sure that resources are being used to best effect.
2. This service evaluation took the form of a single group outcome (1-year post-continous subcutaneous insulin infusion [CSII] therapy) in which glycaemic control was assessed as HbA_{1c} level measurements and reduction of severe hypoglycaemia by a questionnaire.
3. All 12 individuals initiated onto CSII by the local specialist multidisciplinary team were included in this evaluation. All had type 1 diabetes.

is in contrast to other European countries of similar healthcare provision where the rates are approximately 10% in France, Sweden and The Netherlands and 15–20% in Germany (DH, 2007).

Original NICE guidance on the use of CSII therapy provided the basis for the local primary and secondary care trusts working together to develop a locally agreed care pathway, funding streams and supply chains for CSII therapy. However, applying these guidelines in practice became self-limiting for healthcare professionals and the individuals in whom it could be used. It was, therefore, with great anticipation that the revised NICE (2008) guidance was released, providing a wider cohort of patients with the opportunity to use CSII therapy, thereby extending its use to that of routine care within the UK, in line with our European neighbours. The indications for insulin pump therapy were extended from the original failure to achieve an HbA_{1c} level of <7.5% (<58 mmol/mol) without disabling hypoglycaemia to two new indicators: either disabling hypoglycaemia while trying to achieve target HbA_{1c} levels using multiple daily injections (MDI) or an HbA_{1c} level >8.5% (>69 mmol/mol) while on MDI, including the use of insulin analogues.

Clarke (1999) states that evaluation is presented as a form of applied social research, the primary purpose of which is not to discover new knowledge, but to study the effectiveness with which existing knowledge is used to inform and guide practical action. If services are not evaluated in a rigorous and systematic way, then we cannot be sure that resources are being used to best effect. Therefore, in this article, the author reports on the evaluation of an insulin pump service that was commissioned by the local primary care trust in 2006. The primary objectives of the evaluation were to determine if the use of CSII therapy in people with type 1 diabetes:

- Improves glycaemic control.
- Reduces the frequency of severe hypoglycaemic episodes.
- Improves hypoglycaemic awareness.

It was hoped that the outcomes would support the expansion of this service and provide evidence to commissioners regarding the benefits of insulin pump therapy for people with type 1 diabetes.

Table 1. Patient characteristics.

	Subjects (*n*=12)
Female	75%
Mean age at initiation of CSII (range)	32 years (18–68 years)
Mean diabetes duration (range)	19 years (7–45 years)

Methodology

This evaluation took the form of a single group outcome (1-year post-CSII therapy) in which glycaemic control was assessed as HbA_{1c} level measurements, based on the clinical effectiveness evidence published by NICE (2008), and reduction of severe hypoglycaemia by a questionnaire. With regard to the HbA_{1c} level data, existing patient records contain details of HbA_{1c} values prior to commencing CSII and are recorded annually thereafter on a database. A locally derived, self-reported hypoglycaemia questionnaire is completed prior to commencing CSII therapy as part of the routine assessment protocol for pump therapy and copies are held in each person's medical notes. Because this process is part of routine care, ethical approval was not required.

A quantitative approach was used to analyse the data. The individuals whose outcomes are measured include all patients receiving CSII therapy. No non-treatment or control group was used.

Sample of study participants

All 12 individuals initiated onto CSII by the local specialist multidisciplinary team (MDT) were included in this evaluation. All had type 1 diabetes. Further patient characteristics are given in *Table 1*.

One patient was pregnant when commencing CSII therapy; two patients were pregnant at the 1-year post-review stage. All patients were recognised as having unacceptable levels of hypoglycaemia, which was affecting their daily lives, together with poor glycaemic control.

Figure 1. Comparison of HbA_{1c} levels before and after CSII initiation.

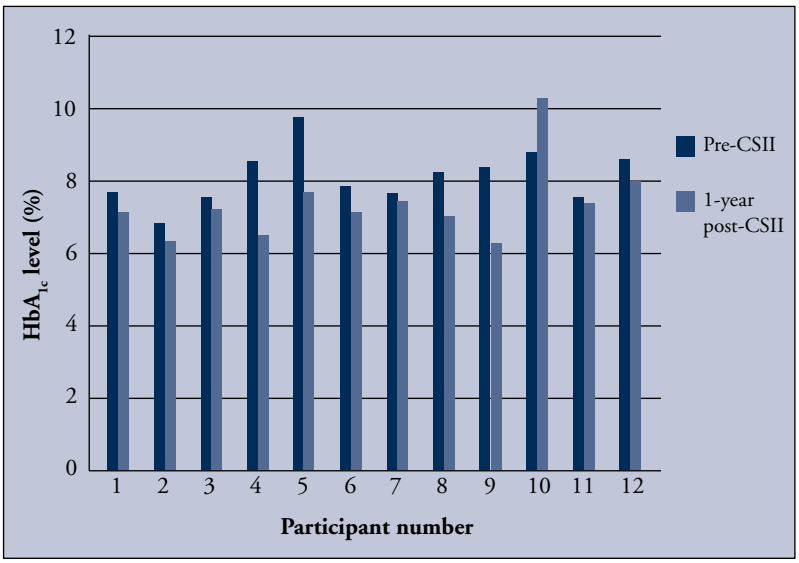


Figure 2. Average HbA_{1c} levels for the whole group before and after CSII initiation.

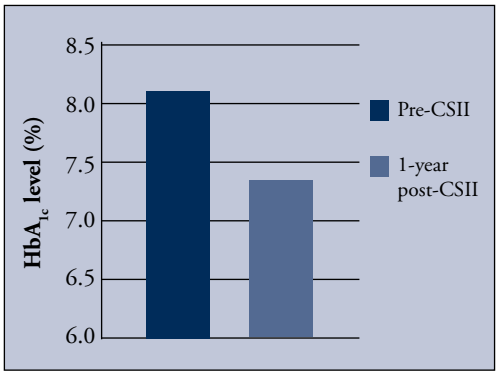
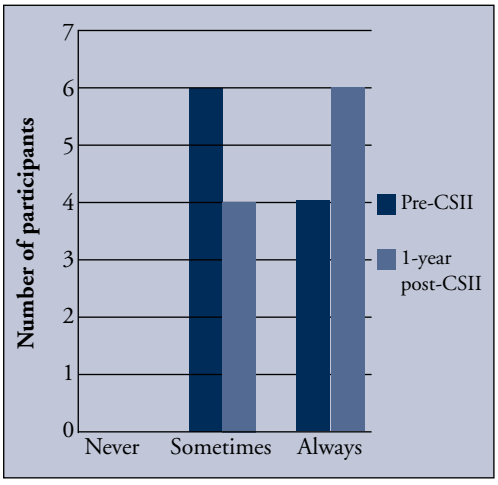


Figure 3. Responses to the question "When your blood glucose is low, do you have symptoms?"



All patients were previously on basal–bolus insulin regimens and had used long-acting insulin analogues. All patients were reviewed by the MDT to assess their suitability and commitment to CSII therapy. They all received education regarding carbohydrate counting and were reviewed by a dietitian prior to commencing CSII.

When reviewing the records of the group it became apparent that two patients had missing data, including responses to the pre-pump hypoglycaemia questionnaire. The author, therefore, did not include these patients in this hypoglycaemia assessment.

Results

Figure 1 demonstrates that after using CSII therapy for 1 year, 11 participants had reduced HbA_{1c} levels; this was irrespective of age and duration of diabetes.

The greatest reduction was achieved by participants 4, 5 and 9, whose HbA_{1c} level dropped by 2.1 percentage points, 2.2 percentage points and 2.1 percentage points, respectively. Participant 5 also had the highest starting HbA_{1c} level. This observation corresponds with findings in other studies. For example, Pickup and Sutton (2008) found that those with poorly controlled diabetes using MDI enjoyed the greatest reduction of HbA_{1c} level after commencing CSII.

The HbA_{1c} level of participant 10 increased by 1.4 percentage points. This may be an indicator that not all people are able to use CSII to good effect, which leads to questions relating to the support received by this individual or the person's ability to manage CSII effectively.

Figure 2 illustrates the average HbA_{1c} level reduction for the whole group at 1 year post-CSII. The mean starting HbA_{1c} level was 8.1% (65 mmol/mol; range 6.8–9.8% [51–84 mmol/mol]), while the mean HbA_{1c} level 1 year after CSII initiation was 7.3% (56 mmol/mol; range 6.3–10.3% [45–89 mmol/mol]). Thus, the average reduction in HbA_{1c} level was 0.8 percentage points (8.7 mmol/mol).

Hypoglycaemia was classed as a blood glucose level of <4 mmol/L. This symptom warns the individual that his or her blood glucose level is low, encouraging the ingestion of carbohydrates to restore blood glucose concentrations. *Figure 3* shows that 40% of the group always had hypoglycaemia

Figure 4. Responses to the question "Have you lost some of the symptoms that used to occur when your blood glucose levels were low?"

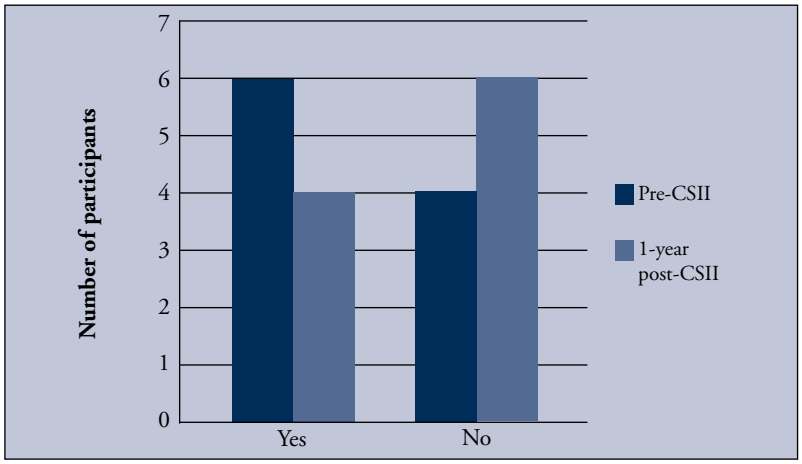


Figure 5. Responses to the question "In the past 12 months, have you had a severe hypoglycaemic attack that required medical assistance?"

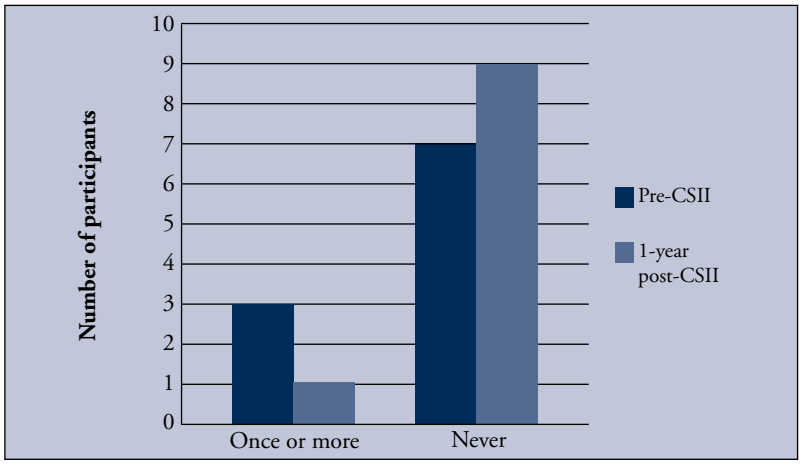
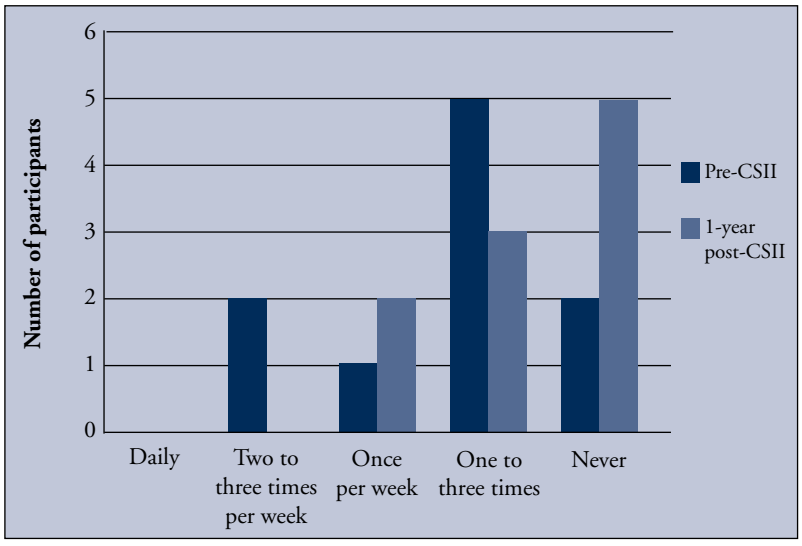


Figure 6. Responses to the question "How often in the last 6 months have you had blood glucose levels <3.5 mmol/L without symptoms?"



warning signs pre-CSII use. Post-CSII, this rate increased to 60%, indicating improved sensitivity to hypoglycaemia.

Figure 4 illustrates the changes in hypoglycaemia awareness within the group. In this group, 60% had lost some of the symptoms that they used to perceive to identify hypoglycaemia, the average duration of diabetes for the group being 19 years. In the post-CSII group, this had improved with 20% regaining symptoms.

Figure 5 demonstrates that pre-CSII, 30% of participants had one or more occasions when they required medical help (i.e. paramedic or hospital assistance) for a severe hypoglycaemic episode within the previous 12 months. At 1-year post-CSII, 90% of the group reported not having any severe hypoglycaemic episodes requiring medical assistance.

Figure 6 illustrates the frequency of hypoglycaemic episodes the group had without getting warning signs or symptoms. Hypoglycaemia without warning signs has implications in daily living activities – for example, driving or work situations. Pre-CSII, only 20% of the group stated that they never had hypoglycaemia without symptoms.

In contrast, the post-CSII responses demonstrated that 50% of the group never had hypoglycaemia without symptoms in the previous 6 months, with a further 30% having one to three episodes of hypoglycaemia without warning signs in the same period.

The point at which an individual experiences symptoms of low blood glucose levels is significant because the earlier that the hypoglycaemia is identified the easier it is to treat and for the individual to recover normal glycaemia. *Figure 7* shows that pre-CSII, 40% of the study group had blood glucose levels of <2.8 mmol/L before they felt hypoglycaemia. Post-CSII group, 60% of the cohort had regained a higher level of hypoglycaemia awareness (3.3–3.8 mmol/L). Significantly, post-CSII, no one reported having hypoglycaemia with blood glucose levels of <2.8 mmol/L without symptoms. It should be noted that study participants were using different blood glucose monitoring

meters, which may affect the accuracy of the readings.

Limitations

There are a number of limitations to this evaluation. As this CSII service is a new development, the sample size involved was very small, and so the results may not apply to a larger cohort. As such, any inferences drawn must be treated with caution.

A large proportion of the group were female, three of whom were pregnant during the evaluation period, and this may have biased the HbA_{1c} results as women are more motivated to gain better HbA_{1c} levels during pregnancy to prevent foetal abnormalities. The evaluation encompassed the first year of CSII therapy; a longer follow-up period is required to ensure that the improvements in glycaemic control continue rather than just occurring during the early stages of CSII therapy, when enthusiasm and commitment is high.

The use of a self-assessment hypoglycaemia questionnaire may lead to different interpretations and reporting of hypoglycaemic events. However, it does provide this evaluation with a detailed analysis of participants' personal hypoglycaemia experiences instead of merely reporting help by third parties or admissions to hospital. As there was no control group it could be said that the results are due to other reasons – for example, pregnancy or carbohydrate counting education.

Discussion

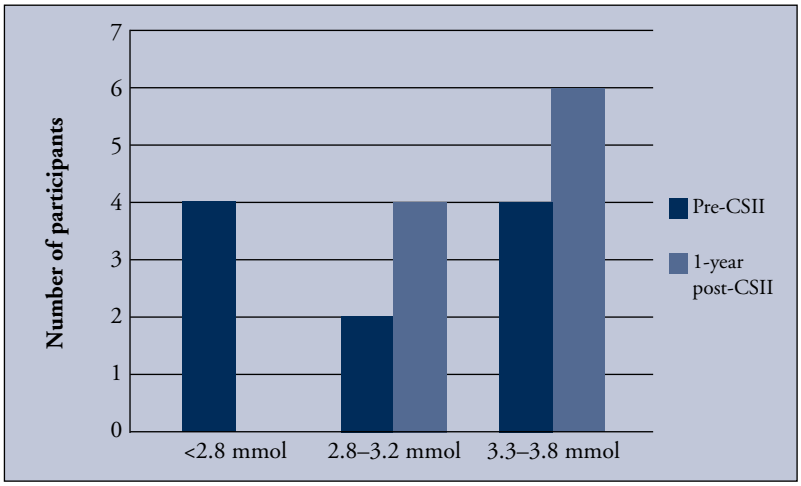
CSII therapy is a recommended treatment option for people with type 1 diabetes. It is an expensive resource and, as such, needs to be used responsibly for the benefit of those whose diabetes control is compromised when on MDI. The aim of this service evaluation was to assess improvements in glycaemic control and severe hypoglycaemic episodes in people with type 1 diabetes who were initiated onto CSII.

The results of this service evaluation demonstrated that HbA_{1c} levels were reduced at 1-year post-CSII by an average of 0.8 percentage points (8.7 mmol/mol); this is a significant reduction that is associated with a lower risk of developing diabetes complications, such as retinopathy, by as much as 50% (Diabetes UK, 2004). This reduction in HbA_{1c} level is comparable to that of other studies. Pickup and Sutton (2008) found an average reduction of 0.62 percentage points (6.8 mmol/mol) and De Vries et al (2002) found a 0.84 percentage point (9.2 mmol/mol) reduction. The participant with the poorest diabetes control prior to commencing CSII saw the greatest benefit in HbA_{1c} level reductions.

Insulin pump therapy is not a panacea for everyone with type 1 diabetes: only those with readiness to change can be expected to benefit. One participant in the group did not improve HbA_{1c} levels, instead demonstrating a 1.4 percentage point increase in the 1-year post-CSII value (*Figure 1*). This individual had received the same advice and support as others. This finding demonstrates the need to assess people with diabetes before commencing CSII therapy regarding their commitment to improving their diabetes control, and to make them aware that the pump itself does not improve glycaemic control without effort and skill on the individual's part in manipulating the pump functions, together with the use of carbohydrate counting to maximise its effectiveness.

The achievement of tight glycaemic control using MDI may mean that individuals suffer

Figure 7. Responses to the question "How low does your blood glucose level need to get before you feel symptoms?"



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1. The results of this service evaluation demonstrated that HbA_{1c} levels were reduced at 1-year post-continuous subcutaneous insulin infusion (CSII) by an average of 0.8 percentage points (8.7 mmol/mol).
2. The participant with the poorest diabetes control prior to commencing CSII saw the greatest benefit in HbA_{1c} level reductions.
3. Insulin pump therapy is not a panacea for everyone with type 1 diabetes, only those with readiness to change can be expected to benefit.

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from an increased number of episodes of hypoglycaemia. The use of CSII therapy allows for the lowering of blood glucose levels while minimising the risk of severe hypoglycaemia. In the author's experience, hypoglycaemia awareness diminishes in some people over time; this might be hazardous for the individual and could potentially have an adverse effect on their quality of life (QoL). Post-CSII, hypoglycaemia warning signs had improved for 60% of the participants and 50% stated that they never had blood glucose levels <3.5 mmol/L without warning signs in the previous 6 months.

Prior to using CSII there was a high incidence of hypoglycaemia that required help from a third party, including paramedic or medical assistance, whereas the post-CSII incidence was low (only 10%). These findings might potentially contribute to an enhanced QoL for CSII users, reducing anxieties and increasing their confidence in dealing with hypoglycaemia.

The initiation of CSII is growing in the author's locality. If this evaluation was repeated annually the study of larger numbers would make analysis of the data more reliable. All insulin pump centres within the local primary care trust area could be incorporated into the evaluation to provide a more extensive review of CSII therapy outcomes locally.

Conclusion

This service evaluation provides evidence that the use of CSII can improve diabetes control in people who were previously unable to achieve lower HbA_{1c} levels. In addition, CSII users typically experience fewer severe hypoglycaemic episodes and hypoglycaemic awareness is increased, potentially leading to enhanced QoL. These improvements may reduce the risk of long-term diabetes complications, the frequency of acute medical emergencies such as severe hypoglycaemia and, ultimately, the frequency of hospital admissions. ■

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