

Lothian service model for continuous subcutaneous insulin infusion

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Article points

1. Hypoglycaemia is a prevalent and potentially life-threatening side effect of insulin treatment for type 1 diabetes.
2. Continuous subcutaneous insulin infusion (pump therapy) is effective in reducing HbA_{1c}.
3. Education packages to accompany pump therapy make it more effective and improves the quality of life of people with type 1 diabetes.

Key words

- Continuous subcutaneous insulin infusion
- Diabetes education
- Hypoglycaemia

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Hypoglycaemia is a common side effect of insulin administration in the treatment of diabetes (Pramming et al, 1991). High levels of insulin decrease the levels of glucose in the blood stream, which starves the brain of its energy source and can lead to confusion or loss of consciousness (Pramming et al, 1991). Continuous subcutaneous insulin infusion (CSII or pump therapy) allows careful adjustment of insulin infusion rates to match the body's requirement. This study aimed to investigate the effectiveness of pump therapy in regulating blood glucose levels in people with type 1 diabetes. It also assessed the usefulness of the recent NICE education recommendations (NICE, 2003) to find out whether or not they allow people with diabetes to treat their condition effectively.

Hypoglycaemia is a common side effect of insulin treatment for type 1 diabetes, with an average frequency of approximately two episodes per week (Pramming et al, 1991; Pedersen-Bjergaard et al, 2004). Most of these episodes are recognised and treated appropriately by the individual and, as such, are classified as mild. However, sometimes the person with diabetes is unable to recognise hypoglycaemia sufficiently early to be able to prevent progression to a severe state. The human brain is dependent on glucose as its source of energy and glucose deprivation causes a rapid deterioration in

brain function (Deary, 1997). Consequently, severe hypoglycaemia is characterised by the development of confusion or even loss of consciousness that prevents self treatment and requires the intervention.

In studies in northern Europe involving unselected populations of people with type 1 diabetes using injectable therapies other than insulin pumps the estimated incidence of severe hypoglycaemia ranged from 1.0 to 1.7 episodes per patient per year (MacLeod et al, 1993; Pedersen-Bjergaard et al, 2004). The annual prevalence is between 30% and 40.5% (Diabetes Control and Complications Trial [DCCT] Research Group, 1993; MacLeod

et al, 1993; Stephenson and Fuller, 1994; ter Braak et al, 2000). However, there is a large degree of variability with some individuals never experiencing severe hypoglycaemia while others experience it frequently. Although recovery from severe hypoglycaemia is usually complete, it is very disruptive to daily life, may be a cause of great anxiety and may be dangerous if it occurs when the individual is driving or engaged in any other potentially dangerous activity.

The publication of results from the DCCT led to a drive towards intensified insulin therapy to minimise long-term complications (DCCT Research Group, 1993). While this approach delayed the onset and slowed the progression of long-term complications, it also increased the risk of hypoglycaemia. Results from the DCCT also suggest that the risk of hypoglycaemia can be increased by up to three times for people using intensive insulin treatment (DCCT Research Group, 1991). This probably represents an underestimation of the true incidence owing to the exclusion of individuals at high risk of severe hypoglycaemia in the DCCT.

Analysis of the data from the 1993 DCCT paper reveals that in order to achieve tight control of blood glucose levels, in the last year of the trial, 42% of participants were using continuous subcutaneous insulin infusion (CSII) as their method of insulin delivery. The National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance on the use of CSII therapy for people with diabetes recommends that it be reserved for those with type 1 diabetes for whom other therapies have been unable to maintain an HbA_{1c} of less than 7.5% without disabling hypoglycaemia (NICE, 2003). Further recommendations include the provision for review of people managing their diabetes with an insulin pump and a trained specialised team to provide ongoing support.

Lothian vision

Currently in Lothian, we have two cohorts of insulin pump users. The first group began pump therapy in 2000 before

opportunities for funding from the Lothian Health Board became available. The majority were on pump therapy due to hypoglycaemic episodes affecting quality of life. At this time, there was no formal arrangement for provision of reviews or ongoing support for these individuals. Given the fact that these people provided their own funding for their pump therapy, they were extremely motivated and committed towards this approach. The educational package for the pre-funding group involved a one-and-a-half-day training session delivered by an insulin pump manufacturer's representative. Education consisted of pump diabetes management rules relating to insulin pump therapy and carbohydrate counting. This included information on hypo- and hyperglycaemia, sick day rules and the emergency pack. Follow up was arranged as part of routine diabetes clinic appointments. However, a 24 hour telephone help line was available.

In 2004, limited funding became available to enable the initiation of pump therapy in a second group of patients. A process of assessment was introduced to ensure that those receiving funding for this therapy fulfilled the recently published NICE guidelines for pump treatment. A decision was made by the multidisciplinary working group for CSII in Lothian to provide funding for those individuals who were already on pump therapy who wished to continue with this management approach. A system was also developed to provide assessment, education and intensive support for those going on pumps, as displayed in *Figure 1*.

Those who initiate CSII therapy in Lothian are part of a multidisciplinary team. All have undergone insulin pump training. In addition to this, each Lothian hospital has a trained designated diabetes specialist pump link nurse. Training for the link pump DSNs, link dieticians and medical staff will be an ongoing process and part of continuing professional development in this highly specialised area.

Page points

1. There is a large degree of variability with some individuals never experiencing severe hypoglycaemia while others experience it frequently.
2. The National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance on the use of CSII therapy for people with diabetes recommends that it be reserved for those with type 1 diabetes for whom other therapies have been unable to maintain HbA_{1c} of less than 7.5% without disabling hypoglycaemia.

Figure 1. The Lothian insulin pump service model, which provides education and intensive support for people beginning pump therapy, leading to the commencement of pump therapy as recommended by NICE.



People with diabetes are referred from all Lothian hospital sites to the DSN Lothian lead nurse for CSII who is based at the Royal Infirmary of Edinburgh.

Those who are referred for consideration for CSII therapy are expected to commit to a structured learning programme leading to the commencement of pump therapy as recommended by NICE.

Individuals will be followed up until month 3, by which stage we would expect the user to be self managing. After this time, the person with diabetes will attend their routine diabetes clinic as before but, over and above this, will be invited to attend the pump user clinic with access to the CSII multidisciplinary team on an annual basis. If the individual requires further follow-up appointments to resolve insulin pump and diabetes management issues, they will be given an appointment at the insulin pump clinic the following week.

Study aims

The aim of this study was to assess the effectiveness of pump therapy in lowering HbA_{1c} and to review the education packages as per the previous and current CSII Lothian model. The study was designed to test the hypothesis that pump therapy results in decreased levels of HbA_{1c}. In addition, individuals with pre- and post-NICE education packages were compared to test whether or not the enhanced education package now offered is more effective than its predecessor.

CSII service models: Methods

When examining the group as a whole (n=34), HbA_{1c} values obtained prior to commencement of pump therapy were compared with the most recently obtained values. The group was subdivided into two cohorts; those who underwent conversion to pump therapy before NICE educational guidelines and those after this period. HbA_{1c} values obtained pre- and post-pump therapy were again compared. To assess the effect of education *per se* on glycaemic control,

the mean change in HbA_{1c} was compared between these two groups.

All analyses were performed using SPSS version 12.0 (SPSS UK, Woking). The Kolmogorov–Smirnov test was applied to check the normality of the variables. Depending on this, differences in HbA_{1c} pre- and post-pump therapy were analysed using either a paired sample *t* test or Wilcoxon sign rank test. The mean difference in HbA_{1c} between the groups was analysed using either the two-sample *t* test or Mann-Whitney-*U* test depending on normality of the variables.

Results

Ages ranged from 14 to 73 years and duration of diabetes varied from 5 to 25 years. A significant improvement in HbA_{1c} was observed when comparing values obtained pre- and post-pump therapy (9.7 ± 1.9% versus 8.3 ± 1.4%, respectively; *P*=0.003; *Figure 2*). The cohort was then subdivided into those who had commenced pump therapy prior to (n=17) and post (n=17) introduction of NICE educational guidelines and improvements in glycaemic control were examined. A statistically significant improvement in HbA_{1c} pre- and post-pump therapy was observed in both cohorts (*Figure 3*). The mean decrease in HbA_{1c} in each group was compared (0.51 ± 0.8% in the pre-NICE cohort versus 1.8 ± 1.2% in the post-NICE cohort).

Page points

1. The study aimed to measure HbA_{1c} in people with diabetes pre- and post-pump treatment.
2. It also assessed glucose control before and after NICE education recommendations were followed.
3. Results demonstrated that pump therapy decreased HbA_{1c} levels and this reduction was greater in the group who received education as recommended by NICE.

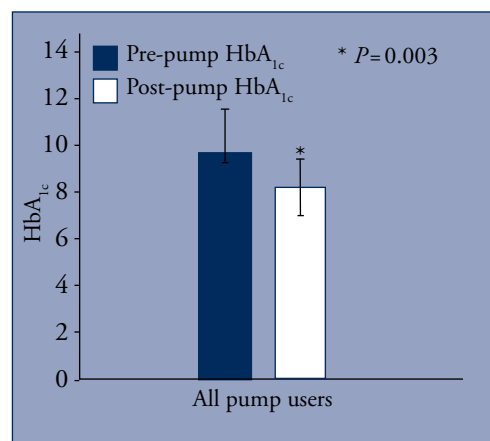
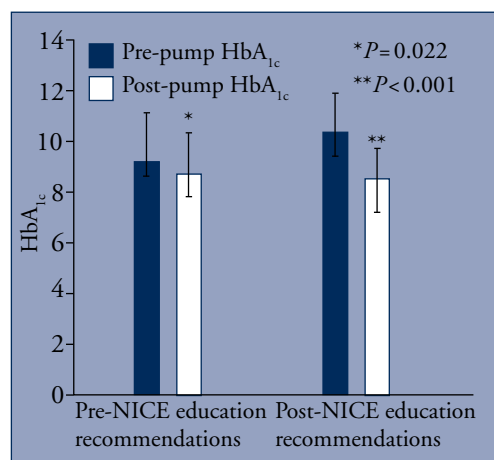


Figure 2. A comparison of pre- and post-pump HbA_{1c} levels.

Figure 3. A comparison of pre- and post-pump HbA_{1c} levels before and after the NICE education recommendations were introduced.



A significant difference in the reduction in HbA_{1c} was found when the two cohorts were compared ($P=0.004$), suggesting that education increases the ability of pump therapy to control blood glucose levels.

Discussion

The largest improvement was observed in those who had attended the structured education programme designed to meet NICE guidelines. Anecdotal evidence appears to suggest that it also seems to improve quality of life. However, in order to validate this service beyond the limited parameters we have examined already, further research is required.

Self-funding patients were determined to make pump therapy work, which they did once funding was available. This group were relieved of this financial burden but the study indicates that both groups require ongoing education.

With the drive towards tightening targets for glycaemic control, the demand for CSII will continue to increase. In Lothian, we will therefore strive to meet the needs of our pump users and continue providing and changing our insulin pump service.

Conclusion

Our limited analysis demonstrates that CSII significantly improves glycaemic control in people with type 1 diabetes and that the

benefits of treatment are increased if NICE guidelines on structured education are followed.

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Page points

1. Education increases the effect pump therapy has on reducing HbA_{1c}.
2. Further research would be useful to validate these education guidelines beyond the limited parameters examined here.