

Insulin pump therapy: a fresh start for the UK

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ARTICLE POINTS

1 In the past, CSII use in the UK was limited because of concerns about hypoglycaemia and ketoacidosis.

2 Recent studies in the USA and Europe suggest that CSII is associated with improved glycaemic control, reduced severe hypoglycaemic episodes and improved quality of life.

3 The main advantage of CSII is its flexibility, and hence greater lifestyle choice for the patient.

4 Patient education, selection and support are of paramount importance.

KEY WORDS

- CSII
- Pump therapy
- Hypoglycaemia
- Ketoacidosis

Introduction

In recent years, more people with type I diabetes have switched from multiple daily injections (MDI) to continuous subcutaneous insulin infusion (CSII). Despite its popularity elsewhere, CSII is not widely accepted or trusted in the UK. The potential benefits of CSII are outlined below. It is argued that CSII can offer a significant advantage to selected patients, provided that they are aware of the pros and cons and an appropriate intensive education package is available. Poor 'image' in the past may have been due to poor patient selection, inadequate education and primitive technology.

The Diabetes Control and Complications Trial (DCCT) has shown convincingly that in type I diabetes, lower HbA_{1c} levels achieved through intensive insulin treatment are associated with reduced long-term risk for the development of microvascular complications (DCCT Research Group, 1993).

Unfortunately, normoglycaemia is rarely achieved in these patients. In many, the price of lowering HbA_{1c} levels is a substantially increased (nearly three-fold) risk of severe hypoglycaemia.

The insulin regimen for type I patients is usually based on a basal/bolus approach, i.e. short-acting insulin before each meal and long-acting insulin at night. This approach is not universally popular with patients, particularly teenagers and young adults (Shaw, 1997). This is not altogether surprising, given that it entails four injections every day (furthermore, most patients are also advised to leave a gap between injecting soluble insulin and eating).

Early use of CSII

Continuous subcutaneous insulin infusion (CSII) was introduced into clinical practice in the 1970s. Unfortunately, the pump looked and felt like a house brick. As well as providing a continuous background infusion of insulin, the early devices produced pre-meal boluses that were simply multiples of

the baseline rate and took up to 17 minutes to deliver (Pickup et al, 1978).

Despite sporadic enthusiasm, the pumps fell out of favour over the next decade, owing to reports that CSII was associated with increased rates of:

- Diabetic ketoacidosis
- Severe hypoglycaemia
- CSII-associated deaths.

Other negative factors included high cost and high drop-out rates (Mecklenburg et al, 1985).

Recent studies with CSII

Publication of the DCCT sparked renewed interest in intensive insulin regimens. This interest was augmented by the introduction of very rapid acting insulin analogues (Koivisto, 1998).

The technology associated with pumps has improved and, just as importantly, so has patient education about intensive insulin treatment. Within the DCCT, 42% of the intensively treated arm were using CSII to control their diabetes by the end of the study.

More recent studies suggest that CSII can improve diabetes control and reduce the risk of severe hypoglycaemia (Farkas-Hirsch and Hirsch, 1994; Bode et al, 1996). The reasons for this are not fully understood but may relate to:

- More predictable insulin absorption (Lauritzen et al, 1983)
- Reduction in total insulin requirements (Bode et al, 1996)

- The ability to pre-programme infusion rates to reduce hypoglycaemia risk, e.g. at night (Hoss et al, 1996).

For other patients, even if HbA_{1c} does not change significantly, pump use is associated with an improved quality of life compared with multiple daily injections (Chantelau et al, 1997).

Pump therapy defined

Briefly, pump therapy is the continuous delivery of short-acting insulin from a pump. The pump can be programmed to suit individual requirements.

The insulin is delivered at a pre-determined continuous basal rate supplemented by boluses. The patient decides the amount of insulin contained in each bolus. Considerations include carbohydrate consumed, current blood glucose value and anticipated exercise. The subcutaneous infusion set is replaced by the patient every 2–3 days.

CSII in use

The advantages and disadvantages of the pump, from the patient’s viewpoint, are listed in Tables 1 and 2 respectively.

The three case histories outlined below (see boxes on page 46) demonstrate some advantages of pump therapy. In the authors’ experience, patients using pump therapy generally feel that the advantages far outweigh the disadvantages.

Healthcare professionals may have many concerns regarding the use of pumps. Some of these are addressed below.

Hypoglycaemia

One of the major concerns about the pump is that it may continue to deliver insulin during hypoglycaemia or that the pump will malfunction and deliver too much insulin.

The most up-to-date insulin pumps are very reliable. Hypoglycaemia can also be more easily controlled.

In the authors’ experience, pump therapy reduces the frequency of hypoglycaemic episodes. Also, warning symptoms of impending hypoglycaemia return in all patients in whom they were reduced (Everett et al, 1999). This increases patients’ confidence in managing and treating hypoglycaemia. All the authors’ patients use

an insulin analogue in their pumps. As soon as they develop symptoms of impending hypoglycaemia, they switch off the pump for 30 minutes and take 10g of quick-acting carbohydrate such as glucose tablets or Lucozade.

Patients are taught to routinely reduce the basal rate of insulin during and after exercise, to reduce the possibility of hypos. Similarly, the basal rate can be decreased after alcohol consumption.

Table 1. Advantages of pump therapy

- The basal rate can be adjusted each hour. This is especially useful for meeting increased insulin requirements due to dawn phenomena, shift work, menstruation etc.
- The basal rate can be temporarily increased at times of stress, infection or illness.
- The basal rate can be temporarily reduced when exercising or drinking alcohol.
- Freedom from having to eat at regular times and to consume regular amounts.
- Meals may be safely omitted because of the background insulin; eating thus becomes a matter of choice, rather than of necessity.
- Blood glucose levels are more even and predictable, giving the patient an increased sense of well-being.
- A flexible lifestyle follows from the flexible insulin regimen. On an everyday level, the patient can be more spontaneous., e.g. he/she may make a snap decision to go on a trip, or may opt to have a ‘lie-in’.
- Low frequency of injections (once every 2–3 days).

Table 2. Disadvantages of pump therapy

- Neither the pump nor the consumables are available on the NHS. Pumps cost £2000 each and last for 4–10 years. The infusion sets, batteries and cartridges cost about £15 per week.
- The external pump serves as a visible reminder of diabetes.
- Patients have to be connected to the pump at least 23 hours each day (patients may disconnect for up to an hour during exercise).
- Some patients do not like being totally reliant on technology.
- Carbohydrate intake must be closely monitored.
- Cartridges must be filled manually.
- Air bubbles in tubing can be problematic. A large air bubble may mean no insulin delivery for a period of time.
- Insulin pens or syringe must always be carried.

Case study 1

A 33-YEAR-OLD MALE WITH RECURRING FASTING HYPERGLYCAEMIA DESPITE FREQUENT ADJUSTMENT OF INSULIN SPECIES, TYPE AND DOSAGE. HbA_{1c} was formerly 9–10% (normal range 4–6.5%). With CSII, his overnight insulin requirements could be more accurately matched by increasing the basal rate between 3 am and 8 am (at least twofold), compared with the rest of the day. Currently, he has fasting glucose levels of 6–7 mmol/l and an HbA_{1c} of 7.5%. He also has much more energy, his skin has cleared of acne and he feels 'more alive'.

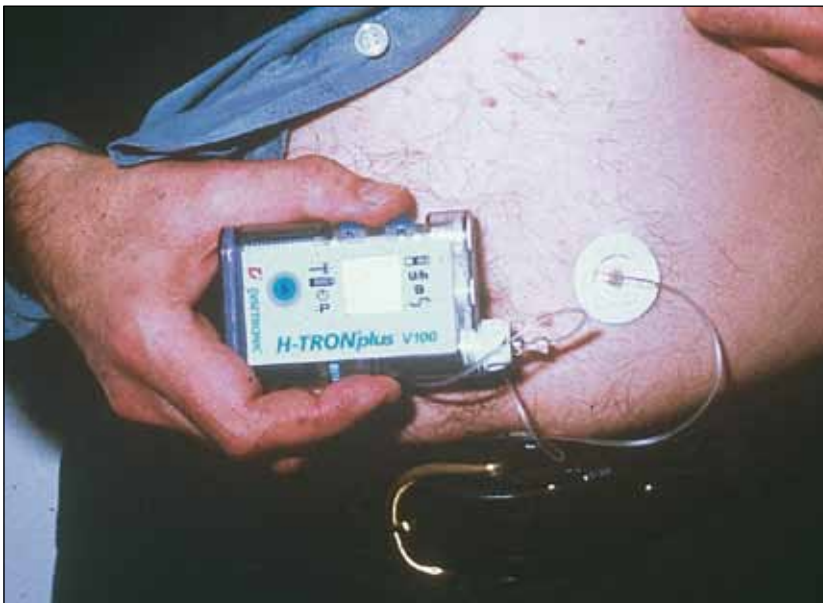
Case study 2

A 58-YEAR-OLD MALE, OF BMI 26, WITH GOOD GLYCAEMIC CONTROL (HbA_{1c} 7%). Despite this good control he complained of his blood glucose swinging between 'lows and highs'. This complaint was largely ignored because of his good HbA_{1c} . He said that his life was controlled by diabetes. He ate regularly to minimise hypos and stopped going out on his own. Despite these measures, he was having 10 hypos a week. There were very few warning symptoms of hypoglycaemia.

The patient started pump therapy 18 months ago and says it has made a tremendous difference to his life. His HbA_{1c} has not changed, but his blood glucose is more level and mostly within normal limits. He now has warning symptoms and recognises when his blood glucose falls below 4 mmol/l or rises above 11 mmol/l. He has reached his therapeutic target weight, reduced the amount of insulin he takes and eats when and what he likes. He has become active in local events, states that 'pump therapy is the best thing that has happened to him', and now feels that he controls his diabetes.

Case study 3

A 40-YEAR-OLD MALE WHO, SUBSEQUENT TO A PANCREATECTOMY, FOUND HIS DIABETES VERY DIFFICULT TO MANAGE ON A BASAL/BOLUS REGIMEN. His HbA_{1c} was 11% despite four injections a day and a total daily insulin dose of 76 units. Since commencing CSII, his HbA_{1c} has dropped to 7.1% and he has been able to gain some much-needed weight.



A person with diabetes receiving continuous subcutaneous insulin infusion (device manufactured by Disetronic Medical Systems Ltd).

Ketoacidosis

Because short-acting insulin is used, any interruption to supply will lead to hyperglycaemia and diabetic ketoacidosis within a short time. Under controlled conditions, ketones appear after 4.2 hours of interrupted supply of an insulin analogue and after 6.4 hours of regular insulin (Pein et al, 1996).

Hyperglycaemia can develop for the following reasons:

- The infusion set becomes dislodged, clogged-up or develops a leak, interrupting the insulin supply
- Insulin is not being absorbed properly
- Insulin requirement is increased due to illness or infection.

All of these situations can be detected and prevented by the patient using trouble-shooting strategies. This underlines the importance of patient education. It is essential that blood glucose readings are taken at least four times a day to detect any problems. Patients are given specific instructions and guidelines about the treatment of hyperglycaemia. They must test for ketones if blood glucose is above 15 mmol/l. If ketones are present, insulin should be given via a pen or syringe.

Site infections

Infusion sets should be changed every 2–3 days to avoid infection of the infusion site. In most cases, simple washing of the skin is all that is necessary before inserting infusion sets. The importance of hand washing and the 'no touch' rule (i.e. not touching the ends of the infusion sets unnecessarily) should always be explained to the patient. In the US, the skin is routinely cleaned with an antiseptic. This is not the case in some European countries.

The site needs to be inspected daily for inflammation, warmth, pain or leakage. If any of these are present, a different site must be used.

Implications for practice

At present, about 320 people use CSII in the UK, compared with 60 000 in the USA and 40 000 in Europe.

Demand for information about pump therapy is exploding as a result of patients' access to the internet. Diabetes healthcare

professionals in the UK must, at the very least, be knowledgeable about current literature on CSII because it is a tool that some patients have found useful in managing their diabetes more effectively. As with all tools, there are certain skills and knowledge to be learnt both by the patient and the professional.

Pump therapy is innovative and exciting. The benefits are clear: improved glycaemic control; reduced risk of hypoglycaemia; and improved quality of life. However, the full potential will only be realised with adequate education and careful patient selection. ■

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