

Insulin pump therapy: a practical guide to optimising glycaemic control

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Abstract

Insulin pump services have been widely available in the UK for over 10 years. Despite this, the recent national Insulin Pump Audit identified that only 6% of patients with type 1 diabetes are managed with insulin pump therapy, far lower than anticipated. A key reason for the UK continuing to lag behind other European countries in the provision of insulin pump services is the lack of trained health care professionals.

This paper aims to provide diabetologists and diabetes specialist nurses with a basic understanding of the clinical approach to the patient with type 1 diabetes on insulin pump therapy. Copyright © 2014 John Wiley & Sons.

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Key words

insulin pump; CSII; type 1 diabetes

Introduction

Insulin pump therapy (CSII, continuous subcutaneous insulin infusion) offers a number of potential benefits for patients living with type 1 diabetes. CSII can lead to demonstrable improvements in glycaemic control, quality of life and a reduction in the frequency and severity of hypoglycaemia.¹ The utilisation of CSII therapy in the UK is only 6%, lower than the anticipated 15–20% and lagging behind other European countries such as Germany, Norway (>15%) and America (>40%).^{2,3} The recent United Kingdom Insulin Pump Audit confirmed a lack of trained health care professionals as a key factor limiting the expansion of CSII services within the UK and this has been further supported by a recent Young Diabetologists and Endocrinologists Forum survey.^{4,5}

The typical adult diabetes service in the UK cares for an average of 74 patients on CSII, with an additional 14 CSII starts per year.⁴ Despite increasing numbers of patients on CSII, the average adult UK diabetes centre has only one consultant and half of the diabetes specialist nurse team trained in CSII. In addition, only one-third of centres offer a CSII structured education programme designed to meet NICE guidance. The combination of these factors has limited the opportunities for patient education, reflected in a national over-reliance on the insulin pump manufacturers for both technical and clinical support.⁴

The main advantage of CSII is the ability to deliver a more physiological and accurate basal insulin. There is a significant reduction in the variability of basal insulin delivery from up to 55% with long-acting subcutaneous insulin compared to <3% for CSII therapy.⁶ As a result, the day-to-day variation in blood glucose is reduced. The more consistent, predictable blood glucose results obtained empower the patient and increase confidence in self-management. Furthermore, patients on CSII have the flexibility to adjust basal insulin from hour by hour or day by day to compensate for a variety of situations (e.g. dawn phenomenon, shift work, exercise, alcohol etc). They can also adjust their prandial bolus insulin with a variety of advanced bolus options for high fat or high carbohydrate meals.

The aim of this paper is to provide diabetologists and diabetes specialist nurses with a basic understanding of these features and to provide a step-by-step clinical approach to the patient on insulin pump therapy (see Figure 1).

Patient education

The algorithm presented in this paper for optimising glycaemic control is based on the assumption that patients have met the NICE criteria for CSII and have attended structured education in flexible intensive insulin therapy, such as DAFNE. Such programmes are based on the following.

Practice point

A guide to insulin pump therapy

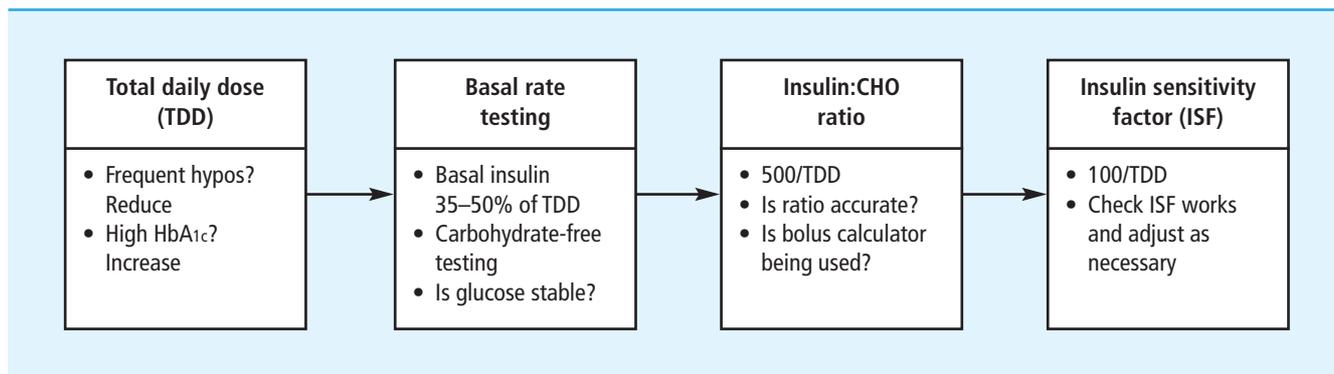


Figure 1. Step-by-step guide to optimising glycaemic control for patients on CSII

- Calculation of meal-time insulin based on carbohydrate counting and insulin to carbohydrate ratios.
- Correction doses of insulin to correct raised glucose levels.
- Regular evaluation of patterns to adjust ratios and background insulin.
- Adjustment of insulin in response to exercise, alcohol and illness.
- Regular blood glucose testing.

Without these skills, patients may not be able to fully utilise the advantages of insulin pump therapy, and indeed some patients who think they need a pump actually choose not to have one after completing a structured education course.⁷

Psychological issues

It is very important that patients understand what an insulin pump offers prior to starting therapy. Patient expectations of pump therapy should be identified and addressed. Many patients are falsely under the impression that insulin pumps calculate insulin doses and reduce the need for blood glucose testing. Others are anxious about being attached to a device 24/7 and concerned about the pump delivering insulin without their knowledge. Such issues should be addressed with the patient prior to a multidisciplinary decision to proceed with pump therapy. Many units create 'contracts' with patients clarifying the aims of treatment and expected improvements.

Mental health problems, such as anxiety and depression, are more prevalent in the insulin pump population compared with the general diabetes population.⁸ Those with psychological illness tend to do less well in terms of glycaemic control.⁸

CSII may not be the optimal route in all patients who fulfil NICE criteria and psychological assessment, therapy and intervention may be a more appropriate initial course of action in some patients. The wider implication is that all patients with diabetes should be regularly assessed for psychological problems and that there needs to be greater psychology/psychiatric support available to intensive diabetes clinics, especially as part of a pre-pump pathway.

Safety issues

The most important safety concern is that patients on CSII check their blood glucose at least four times a day. With multiple daily injection regimens, there is a subcutaneous depot of long-acting insulin present throughout the day which will prevent ketosis even if the rapid-acting insulin bolus is omitted. However, with CSII there is only a very small subcutaneous depot of rapid-acting insulin, so if insulin supply from the pump is interrupted, due to a pump malfunction or failure of the cannula, then the patient is at risk of ketosis. The first sign of an interruption in the supply of insulin is hyperglycaemia and if the patient fails to recognise and treat this appropriately then they will become unwell.

Unexpected hyperglycaemia does occur with CSII and is often related to the infusion cannula being left in for too long.⁹ It is very important to counsel patients that if they have an unexpected reading $>14\text{mmol/L}$ that is not because of missed bolus, overtreatment of hypo or illness, then they should take a correction dose of insulin and wait

60 minutes. If the glucose level has not started to fall then they should take a rescue dose of rapid-acting insulin via subcutaneous injection and change their infusion set as soon as possible. All patients on CSII should carry a supply of in-date insulin and syringes/pens with them as a safety precaution. Some patients on CSII will not have administered subcutaneous insulin for many years. Annual review of the use of insulin syringes/pens and the doses required in the event of pump failure is therefore advisable.

Total daily dose

The total daily dose (TDD) is the average number of insulin units per day as a total of both basal and bolus, usually calculated over the previous seven days. Usually the insulin to carbohydrate (CHO) ratio and insulin sensitivity factor (ISF) are calculated from the TDD, so it is important to get this right. When starting CSII, most centres use a calculation based on the TDD on multiple daily injections (MDI) minus 20%. In patients starting insulin pump therapy due to frequent hypoglycaemia, this can be reduced by a further 10%, and in those starting due to suboptimal glycaemic control, the 20% reduction can be ignored. Of course, many patients are starting CSII as they are poorly controlled on MDI and it stands to reason that their TDD on MDI will be incorrect, so an alternate strategy can be starting patients on a TDD of 0.6 units/kg. Once established on CSII if glucose levels remain high (without frequent hypoglycaemia), the TDD can be increased by 5–10%, distributed between basal and bolus components.¹⁰

Basal rates

The basal rate is the amount of insulin infused per hour via CSII. The basal rate can be set hour by hour, facilitating flexible basal insulin delivery in a manner which mimics the physiological needs of the patient. Most series report optimal control with basal insulin accounting for 35–50% of the TDD.^{11–13} However, basal requirements can vary greatly between individuals. For instance, if a patient consumes a low carbohydrate diet then there will be a higher basal component and, conversely, for those with high carbohydrate intake there will be a higher bolus proportion. Similarly, in pregnancy the bolus component of the TDD is increased while the basal insulin tends to account for only ~35% of the TDD.¹⁴

Overall, most adult patients tend to require an increase in the basal rate early in the morning, to counteract the 'dawn phenomenon', and lower rates between mid-morning and mid-afternoon. Some patients also require an increase in basal insulin in the evening, the 'dusk phenomenon', which may be related to a reduction in physical activity later in the day. If fixed periods of activity occur at the same time every day, such as walking or cycling to and from work, these can be accommodated for in the basal rate with reductions ~60–90 minutes prior to the activity. A variety of basal rates can be stored for different patterns (e.g. shift work, menstrual cycle etc). Blood insulin levels settle into a steady state approximately 2–3 hours after a basal rate change so it is desirable to change the basal rate in blocks of hours.¹⁵ Most patients will require multiple basal rates, usually 3–5 is optimal.¹³ The Type 1 Diabetes Exchange Registry from North America reported that those with excellent control (HbA_{1c} <6.5% [48mmol/mol]) performed more blood glucose tests (72 vs 36% did >5 tests/day) and had a greater number of basal rates (3.9±2.1 vs 3.4±2.0; p=0.001).¹³ Patients who use a flat basal profile are not harnessing the full potential that the insulin pump has to offer.¹⁶

Pump companies (Roche, Medtronic) have recently been

John has a target fasting glucose of 5mmol/L. His glucose before lunch is 11.8mmol/L. He is going to eat a sandwich which contains 46g of carbohydrate. How much insulin should he administer?

1. **Calculate the average insulin total daily dose (TDD)** from the last 7 'typical' days. This information is readily available on the insulin pump. John's average TDD is 36 units
2. **Use the '500 rule'** to calculate the dose of insulin required to cover the carbohydrate (CHO) in his sandwich.
 $\text{Insulin:CHO ratio} = 500/\text{TDD} = 500/36 = 13.9 = 1 \text{ unit}/14\text{g CHO}$
 $46\text{g} / 14 = 3.3 \text{ units}$
3. **Use the '100 rule'** to calculate the insulin sensitivity factor (ISF) and dose of insulin required to reach target glucose of 5mmol/L.
 $\text{ISF} = 100/\text{TDD} = 100/36 = 2.8 = 1 \text{ unit reduces glucose by } 2.8 \text{ mmol/L}$
 $11.8 - 5\text{mmol/L} = 6.8\text{mmol/L} / 2.8 = 2.4 \text{ units}$
4. Calculate total insulin dose required = 3.3 + 2.4 = 5.7 units

Such calculations are complex. It is important that patients are encouraged to use their bolus calculator to facilitate accurate insulin delivery. An accurate insulin bolus should bring the glucose close to target 4–5 hours after administration. If this is not the case, the ratios will need to be reassessed and altered as necessary

Box 1. Using the insulin:carbohydrate ratio and insulin sensitivity factor (ISF)

advocating 'circadian rhythm' basal rate profiles which involve initiating patients on a variable basal rate instead of a flat profile. Anecdotal reports suggest that this approach may minimise the number of changes and time taken to optimise control. However, the majority of the data underpinning circadian rhythm basal rates are from paediatric data and it is not yet clear whether starting with a 'circadian rhythm' is superior to starting with a flat basal rate. Regardless of the initial approach, the patient must test and retest their basal rates to optimise control.

Performing a basal rate test

The basal rates help to control and stabilise blood glucose levels throughout the day and unless basal rates are optimised it is impossible to ascertain accurate insulin:CHO ratios and ISFs. To test basal rates, the patient should ideally perform carbohydrate-free blood glucose monitoring. This involves checking the blood glucose every 2 hours during a period of fasting or, if this is not possible, during the consumption of carbohydrate-free meals. Ideally, basal rate testing should be performed on a 'normal' day with no stress, hypoglycaemia, exercise or alcohol within the preceding 24 hours. Basal rate testing is time

consuming and requires motivation and dedication but it is a crucial step in optimising glycaemic control for patients on insulin pump therapy, and should ideally be performed every three to six months.

Basal rate testing is broken down into blocks: overnight, morning, afternoon and evening. During the test, if the glucose levels rise then the basal rate should be increased by 0.05 to 0.1 units per hour, 2 hours before the rise is witnessed.¹⁰ Similarly, if glucose levels fall during a basal rate test then the rate should be reduced by 0.05 to 0.1 units per hour, 2 hours before the fall is witnessed. Basal rate testing should continue until the patient has satisfactory glucose values maintained throughout the 24-hour period. Once accurate basal rates have been established, it is then possible to assess and adjust mealtime insulin:CHO ratios.

Insulin to carbohydrate ratio

Accurate carbohydrate estimation is a limiting factor in achieving excellent diabetes control. Although CSII does not remove the potential for human error in this calculation, it does allow for accurate insulin to carbohydrate ratios, to the nearest 1g of carbohydrate. However, despite this, many patients on CSII

Practice point

A guide to insulin pump therapy

Topic	To discuss	Hints/tips
Glycaemic control	Accuracy of: <ul style="list-style-type: none"> • Total daily dose (TDD) • Basal rate • Insulin:carbohydrate (CHO) ratio • Insulin sensitivity factor (ISF) Recent basal rate testing results Use of and settings on bolus calculator	Accurate TDD = mean glucose/HbA _{1c} within target, with minimal hypoglycaemia Accurate basal rate = basal rate testing demonstrates stable glucose, within target Accurate insulin:CHO ratio = postprandial glucose within ~2mmol/L of starting glucose after 4–5 hours Accurate ISF = correction of high glucose values leads to within target glucose after 4–5 hours
Unexpectedly high glucose values	If unexpectedly high glucose values (>14mmol/L) fail to respond to a correction dose of insulin within 60 minutes, the whole infusion set and reservoir should be replaced	If any doubt about the function of the pump, subcutaneous insulin should be administered Ensure your patients know how to use their pens/syringes at their annual review (they may not have done this for some time)
Cannulas	Replacement of cannulas every 48–72 hours	Use beyond 48–72 hours is associated with cannula occlusion and raised glucose values
Holidays	Adequate supplies of insulin and pump consumables? Supply of insulin syringes/pens which can be used in the event of pump failure	Insulin syringes may be more useful as a back-up supply as insulin pens may go out of date without the patient realising
Illness	Sick day rules Ensure adequate supply of Ketostix	Local sick day rules for patients on CSII should be developed and regularly discussed with the patient

Table 1. Key aspects to cover in a consultation with a patient on continuous subcutaneous insulin infusion (CSII)

continue to use inaccurate and rounded ratios such as 1 unit:10g CHO or 1 unit:15g CHO.¹⁷ This practice reflects previous approaches utilised for manual calculations while on MDI therapy and, possibly, the preference of the health care provider. However, such an approach prevents the delivery of accurate insulin therapy which has implications for short- and long-term glycaemic control. For instance, changing the ratio from 1 unit:10g to 1 unit:9g can lower the post-prandial glucose by 1.8–2.9mmol/L at each meal for an average individual consuming 60–100g of carbohydrate.¹⁷

One of the methods used to recalculate insulin:CHO ratios is the '500 rule';¹⁸ 500 is divided by the total daily insulin dose to provide an indication of how many grams of carbohydrate 1 unit of insulin will cover (see Box 1). While it may not work perfectly for every patient, it is a good starting point and will

encourage both the health care provider and patient to think beyond simple rounded ratios, e.g. 1 unit:10g. Modern pumps have integrated bolus calculators, allowing the patient to programme their ratios, saving them from performing complex arithmetic at mealtimes. In consultation with patients on CSII it is worth ensuring that they are using the bolus calculator and that the settings are desirable and up to date. An adequate insulin:CHO ratio should control the post-prandial glucose and a rise of 2–4mmol/L at 2 hours would be considered reasonable outwith pregnancy. It is important to be aware that different meals will produce peak glucose at different times, with complex carbohydrate or the presence of fat in the meal delaying the peak glucose.¹⁹

Insulin sensitivity factor

The ISF, or correction factor, is a guide to how much 1 unit of insulin reduces the blood glucose by in

mmol/L. It is important to get this ratio correct as patients will rely on this to reduce unexpectedly high blood glucose values. Patients previously on MDI will have been used to crude corrections of 1 unit:2–3mmol/L which would often have prevented patients from correcting glucose values which were in single figures, e.g. 8mmol/L, due to a fear of hypoglycaemia. However, CSII allows for the delivery of correction doses to the nearest 0.1 unit of insulin which, combined with the reduced variation in the absorption of insulin, allows for accurate correction of near normal glucose values without the fear of hypoglycaemia.

To achieve the optimal ISF the 100 rule can be applied (see Box 1); 100 is divided by the TDD to provide an estimate of how much 1 unit of insulin will reduce the blood glucose by in mmol/L. Both the 500 and 100 rules are rough, easy to remember estimates to guide the insulin:CHO

Key points

- The use of CSII in the UK is expanding and those working with patients who have type 1 diabetes need to have a working knowledge of the basics of insulin pump therapy
- The first step in optimising control is to adjust the total daily dose (TDD), the main determinant of the mean glucose value
- The basal insulin infusion rate should mimic physiological insulin requirements, aiming to maintain a stable fasting glucose
- Once basal rates have been established and tested the insulin:carbohydrate (CHO) ratio and insulin sensitivity factor (ISF) need to be tested and altered as necessary
- Additional pump features, such as temporary basal rates and advanced bolus options, can be used to help maintain glycaemic control in challenging circumstances (e.g. exercise, high fat meals etc)

ratio and ISF. They encourage the health care provider and patient to think beyond simple ratios. It should be remembered that these are not absolute rules and should be used as rough starting points which should be adjusted based on subsequent glucose readings. Any adjustments to insulin:CHO ratios and ISFs need to be tested and revised accordingly. The ISF should bring the glucose into target after 4–5 hours. Ideally, the ISF should be tested when the patient's last bolus was more than 5 hours ago, carbohydrate was consumed more than 3 hours ago and the patient can wait 4–5 hours until they next eat. Ideally, the basal rate, insulin:CHO ratio and ISF should be in proportion throughout the day. For example, if the patient has a strong dawn phenomenon, then we would expect the insulin:CHO ratio and ISF to reflect this (i.e. higher insulin:CHO and lower ISF). It is important to remind patients that the ISF will not provide adequate insulin if the patient is unwell, in which case sick day rules should be used.

Advanced features

Temporary basal rates

A key advantage of insulin pump therapy is the ability to adjust basal insulin requirements. Temporary basal rates can be set to cover exercise, with reductions in absolute units (e.g. reduction from a usual rate of 0.6 units/hour down to 0.2 units/hour for 3 hours) or more commonly as a percentage of current basal rate (in the same example this will be a reduction to 33% of current basal rate for 3 hours). Similarly, in times of increased insulin requirements, illness for

example, patients can set temporary basal rates to 130 or 150% of usual rates (NB: this is equivalent to a 30 or 50% increase in basal insulin respectively).

Basal patterns/profiles

For patients whose daily activities vary significantly between days or weeks (for example, shift workers, women who require higher premenstrual rates) various basal rate profiles can be set which allow patients to switch between different basal rate patterns as required. This is useful in pregnancy where the pre-pregnancy insulin basal rate profile can be saved in the pump with a new profile used during the pregnancy. When the baby is delivered, insulin requirements fall quickly and the patient can easily return to pre-pregnancy insulin requirements which are saved in their pump.

Advanced bolus options

Modern insulin pumps offer advanced features such as extended/square wave boluses and multi-wave/dual wave boluses, with the aim of distributing meal-related insulin in order to minimise postprandial hyperglycaemia. These advanced features can help compensate for the delayed gastrointestinal emptying associated with high fat meals, although patient use of such advanced features is low (<50%).^{20,21} If the patient wishes to explore these features, a trial and error approach with a multi-wave bolus of 50–70% immediate bolus and the rest over ~4–6 hours for the consumption of high fat meals such as pizza, Chinese or Indian takeaway is a practical starting point.^{19,20}

Use of downloads

A rather undiscussed by-product of insulin pump therapy is the ability of the patient and health care professional to download data from the pump. If the patient uses the bolus calculator function, then comprehensive information about carbohydrate intake, glucose testing and pump use can be downloaded and used to make the consultation much more detailed and focused. Analysing the data generated can be challenging but, with practice, it can greatly enhance the patient's and the health care provider's understanding of insulin pump utilisation, and can also allow the electronic support of patients through peer networks or, where funded, through specialist nurses.

Key aspects of the consultation

There are some key aspects of a consultation with a patient on CSII therapy which must be covered to ensure the ongoing safety of the patient. A list of points which should ideally be covered at each consultation is provided in Table 1.

Conclusions

In conclusion, CSII has a lot to offer the patient in terms of improved quality of life, improved glycaemic control and reduced frequency and severity of hypoglycaemia. Maximising the potential benefits of CSII is labour intensive for both the patient and health care professional, especially during the initiation phase. However, a motivated and educated patient with adequate support to facilitate optimisation of therapy can achieve near normoglycaemia with minimal hypoglycaemia.

As health care professionals we have a duty of care to our patients to provide support and education to help them realise the potential that insulin pumps have to offer.

Declaration of interests

There are no conflicts of interest declared.

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