

The role of continuous subcutaneous insulin infusion in the management of diabetes

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Article points

1. Effective candidate selection is essential before commencing continuous subcutaneous insulin infusion (CSII) in order to assess individual suitability, deliver improved glycaemic control and avoid harm.
2. All pump users should have a blood glucose meter that can also test for ketones, due to the increased risk of ketoacidosis, especially when commencing CSII treatment. They should know their insulin sensitivity factor.
3. An effective partnership between the CSII multidisciplinary team and the pump user should be established. Insulin pump users should have support and education in order to improve their lifestyle and achieve their glycaemic targets.

Key words

- Diabetes management
- Glycaemic control
- Insulin pump therapy

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Continuous subcutaneous insulin infusion (CSII), also known as “insulin pump therapy”, is an insulin delivery system that is increasing in popularity for individuals with type 1 diabetes. There is evidence that demonstrates that CSII can improve quality of life, provide lifestyle flexibility and improve glycaemic control. However, despite these endorsements, hard evidence supporting the application of CSII in clinical practice is lacking. Indeed, NICE support the use of CSII for individuals with type 1 diabetes in specific circumstances, such as those with frequent episodes of hypoglycaemia despite optimised self-management. This article will discuss key issues surrounding the practical application of modern insulin pump therapy.

Within the UK, continuous subcutaneous insulin infusion (CSII), otherwise known as insulin pump therapy, is an insulin delivery system that is increasing in popularity for individuals with type 1 diabetes (T1D; NICE, 2002; Diabetes UK, 2013). The rationale is multifactorial and NICE now supports the use of insulin pump therapy in specific circumstances for people with T1D, such as frequent episodes of hypoglycaemia or if overall glycaemic control is ≥ 69 mmol/mol despite optimised self-management (NICE, 2008).

There is increasing evidence that demonstrates CSII can improve quality of life (Hoogma et al, 2006; Barnard et al, 2007), provide lifestyle flexibility and improve glycaemic control (Bode et al 2002a; Pickup et al, 2002), including a reduction of severe episodes of hypoglycaemia (Bode et al, 1996). This article will discuss key issues surrounding the practical application of modern insulin pump therapy.

The evidence

In general, robust evidence around the use of CSII is lacking. As highlighted in the Pickup et al (2002)

meta-analysis, there is a notable absence of solid large modern randomised multicentre trials to support the use of CSII, with most of the available studies underpowered, old and unrepresentative of current practice. While better glycaemic control is achieved on an insulin pump (Colquitt et al, 2003) or injections using rapid-acting analogue insulin, any study before the launch of insulin lispro, the first rapid-acting insulin, in 1996, must be viewed with particular caution. The modern practice of using optimised multi-dose injections (MDI), which requires the use of both long- and rapid-acting analogue insulin, was not possible until 2002, when insulin glargine was launched.

Candidate selection

Although controversial, effective candidate selection for CSII is crucial for ensuring success (Marcus and Fernandez, 1996; Pickup, 2005). The assessment process can be time consuming; for example, in our clinical practice, an initial review to consider if CSII is an appropriate treatment choice for an individual can take over two hours to perform. CSII can be a helpful management tool

Table 1. Disadvantages and advantages of using an insulin pump.

Disadvantages	Advantages
Risk of diabetic ketoacidosis (Bolderman, 2002; Walsh and Roberts, 2006; Bruttomesso et al, 2009; Hanas, 2010)	Lower HbA_{1c} (Pickup et al, 2002)
Need for regular home blood glucose monitoring (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)	Fewer glycaemic “swings” (Bruttomesso et al, 2009)
Attachment to pump 23 hours per day (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)	Helps manage the “dawn phenomenon” (Bolderman, 2002; American Diabetes Association, 2003; Walsh and Roberts, 2006; Hanas, 2010)
Pump can be seen by others (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)	Dietary freedom and meal time flexibility (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)
Altered body image (Bolderman, 2002)	Risk of hypoglycaemia is reduced and symptoms of hypoglycaemia are milder (Bode et al, 1996; Bode et al, 2002a; Morrison and Weston, 2008; Pickup and Sutton, 2008; Bruttomesso et al, 2009)
Cannula site infection/abscess (Bolderman, 2002; Walsh and Roberts, 2006; Bruttomesso et al, 2009; Hanas, 2010)	Flexible schedule (for example, with shift workers) (Walsh and Roberts, 2006)
Lipohypertrophy/lipoatrophy (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)	Easier to maintain glycaemic stability during exercise (Bolderman, 2002; Walsh and Roberts, 2006; Hanas, 2010)
	Easier to manage foreign travel/ different time zones (Morrison and Weston, 2012)
	Less insulin is required (Bode et al, 2000; Pickup et al, 2002)
	Increased flexibility with lifestyle issues (Hoogma et al, 2006; Walsh and Roberts, 2006; Barnard et al, 2007; Bruttomesso et al, 2009; Hanas, 2010)
	Improved quality of life and wellbeing (Hoogma et al, 2006; Walsh and Roberts, 2006; Barnard et al, 2007; Bruttomesso et al, 2009; Hanas, 2010)

if the prospective pump user is unable to maintain glycaemic stability despite an optimised insulin regimen and a high level of self-management (NICE, 2008). Such situations are highlighted in *Tables 1* and *2*.

As with any insulin regimen, CSII may not be the right management option for all individuals with insulin-requiring diabetes and should be considered as “one of a range of options”. If pump therapy is used inappropriately, there is risk of causing harm. Situations which should be viewed with caution are indicated in *Table 3*. Given that any criteria are not all encompassing, prospective candidates for insulin pump therapy should be assessed on their individual merits.

NICE opinion on CSII

Currently, CSII is not considered a “standard” treatment on the NHS and an individual must meet NICE (2008) criteria for NHS funding. Unfortunately, these criteria only allow access to pump therapy for individuals with type 1 diabetes, despite the fact that it has been found useful for individuals with other types of diabetes (Berthe et al, 2007). If a person is not covered by NICE (2008) guidance, an individual “case of need” funding request would need to be made and approved by the clinical commissioning group before a pump could be funded by the NHS. NICE (2008) also indicates when insulin pump therapy should be withdrawn, for example, from individuals who do not achieve a continued improvement in glycaemic control as demonstrated by a sustained fall in HbA_{1c} or a decrease in the rate of hypoglycaemia. In addition, NICE (2008) requires that individuals who started CSII under the age of 12 should have a trial of MDI between the ages of 12–18 years of age.

The principles of CSII therapy

Many authors, such as Pickup et al (2002), have highlighted that glycaemic control is superior in people using insulin pumps, as opposed to individuals on MDI. Insulin pump therapy is better placed to replicate the actual physiological insulin requirements of people without diabetes. The pump reproduces the individual’s basal rate requirements by automatically delivering small individualised doses of rapid-acting insulin on a virtually

continuous basis. Depending on the insulin pump model, the basal rate dose can be adjusted on either a half hour or hourly basis and be set as low as 0.025 units an hour.

The background insulin is supplemented by the pump user calculating and manually delivering bolus doses of insulin to accommodate the anticipated glycaemic rise following the consumption of carbohydrate (CHO) or to correct an elevated blood glucose level. Despite the physiological advantages pump therapy offers, the insulin is still infused into the subcutaneous tissue and not, as in normal physiology, into the portal system (Baggaley, 2001).

Insulin delivered via an insulin pump has been shown to have a higher level of day-to-day reproducibility than injected insulin (Haakens et al, 1990; Galloway and Chance, 1994). This suggests that pharmacokinetic factors assist pump users to have better glycaemic stability. CSII uses small individualised doses of rapid-acting insulin in the background, which helps to prevent hypoglycaemia that could occur from a large subcutaneous depot and the delayed absorption of any longer acting insulin (Marcus and Fernandez, 1996).

Adults on insulin pumps can use up to 26% less insulin than when they were on MDI. A greater percentage reduction was found in individuals who used insulin lispro and those with high daily doses (Bode et al, 2002b; Pickup et al, 2002). One advantage of this, according to Bode et al (1996), is that the lower amounts of insulin will be reflected in lower plasma levels, which will reduce the tendency towards hypoglycaemia. The reduced insulin doses may also help to facilitate weight loss, as observed by both Bode et al (2000) and Pickup (2005). Pump users tend to report that symptoms of hypoglycaemia are less severe and easier to treat than when using MDI (Morrison and Weston, 2008). Insulin delivery is individualised and more predictable on a pump, the blood glucose level drops more slowly, thus the pump user has more time to recognise and deal with their symptoms before the event becomes more severe (Walsh and Roberts, 2006). For individuals with hypoglycaemia unawareness, the evidence suggests that if hypoglycaemia events are avoided, then the warning signs and symptoms of low blood glucose will return (Fanelli et al, 1997; Morrison and

Table 2. Reasons to start an individual on insulin pump therapy.

Reason	Evidence base
Complex insulin needs, for example, wide glycaemic exertions and “dawn phenomenon”	Bolderman (2002); American Diabetes Association (2003); Walsh and Roberts (2006); NICE (2008); Bruttomesso et al (2009); Hanas (2010).
Complications associated with diabetes such as retinopathy, microalbuminuria, nephropathy, including those on dialysis, peripheral and autonomic neuropathy including gastroparesis	Viberti et al (1981); Dahl-Jorgensen et al (1986); Olsen et al (1987); Sharma et al (2011).
Recurrent severe hypoglycaemia	Bode et al (1996); NICE (2008); Pickup and Sutton (2008); Morrison and Weston (2008).
Impaired awareness of hypoglycaemia	NICE (2008); Pickup and Sutton (2008); Morrison and Weston (2008).
Sensitivity to insulin or insulin allergy	Bruttomesso et al (2009).
Type 2 diabetes	Berthe et al (2007).
Pre-conception/pregnancy/breastfeeding	Walsh and Roberts (2006); NICE (2008); Bruttomesso et al (2009).
High HbA _{1c} despite an optimised insulin regimen and best practice demonstrated by the individual	NICE (2008).
Children and young people	Walsh and Roberts (2006); NICE (2008); Bruttomesso et al (2009), Hanas (2010).

Weston, 2008). This reduction in hypoglycaemia occurrence will only happen if the pump has been correctly programmed and the pump user makes appropriate decisions when managing lifestyle issues and also interpreting and acting upon blood glucose values (Morrison and Weston, 2008).

Insulin choice

The insulin of choice for an insulin pump is a rapid-acting analogue, although soluble insulin is occasionally used. Colquitt et al (2003) found that the HbA_{1c} was 0.26% lower for individuals who used a rapid-acting analogue in their pumps rather than soluble insulin. Episodes of hypoglycaemia are also higher in individuals who use soluble insulin (Colquitt et al, 2003). Studies have indicated that aspart (Bode and Strange, 2001), lispro (Zinman et al, 1997) and glulisine (Hoogma and Schumicki, 2006) are all suitable insulins to use with CSII.

Bode et al (2002b) compared the outcomes of using

“The individual will require knowledge regarding the impact of fat, protein and fibre on glucose release in order to maximise the impact of bolus delivery.”

insulin lispro and insulin aspart in an insulin pump. They found that the HbA_{1c} results were virtually identical and there were no differences in the number of cannula occlusions.

Initiation of a basal rate

The basal rate is the key to glycaemic stability and the flexibility offered by the insulin pump. There appears to be no foolproof way of determining a perfect basal rate for the initiation of CSII, or what the individual’s total dose of insulin will be on a pump (Walsh and Roberts, 2006). Many methods

of initiating a basal rate are cited in the literature, with some based on the MDI total daily insulin dose (TDI), such as a reduction in the MDI TDI dose by 10–30%, or by the division of the long-acting analogue dose into 24-hour equal hourly doses, creating a flat basal rate (Bolderman, 2002). Other authors recommend converting on to CSII from MDI by varying basal rate to take account of the diurnal insulin needs. Such strategies include the use of the Renner slide rule or by the practice of 3–5 basal rate segment variations (American Diabetes Association [ADA], 2003; Hanas 2010). There are also calculations based on the prospective pump user’s weight, such as 0.3 units/kg (ADA, 2003) and a linear scale that gives a theoretical insulin dose based on weight and other variables (Walsh and Roberts, 2006). The evidence around all of the above methods is lacking and many clinicians have developed their own approaches to establishing a basal rate (Bolderman, 2002; Morrison et al, 2004; Walsh and Roberts, 2006; Hanas, 2010).

Bolus doses of CHO

For bolus doses to be effective following the ingestion of CHO, the pump user must be able to count CHO accurately and have a precise insulin to carbohydrate ratio (ICR; Bolderman, 2002; ADA, 2003; Walsh and Roberts, 2006; Hanas, 2010). The individual will require knowledge regarding the impact of fat, protein and fibre on glucose release in order to maximise the impact of bolus delivery (Walsh and Roberts, 2006; Hanas, 2010).

CHO bolus delivery

Chase et al (2002) found that the postprandial blood glucose levels are lower if a combination of extended bolus doses are used appropriately on the pump, when compared to individuals who use normal bolus doses alone. These results were echoed by Klupa et al (2011) who established that individuals using a combination bolus for CHO consumption improved their HbA_{1c} by 0.45% compared to pump users who used a normal bolus. In our practice, all individuals are educated to use the full range of bolus features from initiation of CSII. There are different ways a bolus dose can be delivered and there is evidence to suggest that glycaemic control is improved if used.

Table 3. Indications that insulin pump therapy may not be appropriate.

Reason	Evidence base
Current diabetes self-care is not optimised	NICE (2008)
No structured education programme for either conversion on to insulin pump therapy or to support ongoing needs	Bruttomesso et al (2009); NICE (2009)
A specialist team trained in insulin pump therapy is not available	NICE (2008); Bruttomesso et al (2009); NICE (2009)
Individuals not on optimised multiple daily injections	NICE (2008)
Poor motivation and apathy towards diabetes self-care	Bruttomesso et al (2009)
Individuals who do not work in partnership with healthcare professionals	Bruttomesso et al (2009)
Individuals with unrealistic expectations of insulin pump therapy	Bruttomesso et al (2009)
Lack of capacity, for example, physical, technical or cognitive	NICE (2008); Bruttomesso et al (2009)
No support from family or significant other	Bolderman (2002)
Infrequent home blood glucose monitoring	Walsh and Roberts (2006); NICE (2008); Bruttomesso et al (2009)
Significant mental health issues or psychological behaviours, for example people who manipulate their diabetes to gain attention	Bolderman (2002); NICE (2008); Bruttomesso et al (2009)

ICR and insulin sensitivity factor

Healthcare professionals and insulin pump users often do not appreciate how very small changes in the ICR can impact on glucose values. However, as Walsh et al (2010) highlight, there is little evidence available that can provide guidance on the initiation and optimisation of the ICR and the insulin sensitivity factor (ISF).

Various formulas have been suggested to calculate the ICR and ISF for insulin pumps users (Davidson et al, 2003; King and Armstrong et al, 2007). The precision of such calculations had been questioned, for example, the “100 rule” for ISF and the “500 rule” for ICR in clinical practice (Morrison et al, 2007; Weston et al, 2007; Walsh et al, 2010). Walsh et al (2010) indicate that there are particular inaccuracies if these methods are used in individuals with variations in body weight and insulin sensitivity away from the mean. Contrary to some UK practice, Walsh et al (2010) note that these calculations should be used with established insulin pump totals, not from those gained from the MDI. Both the ADA (2003) and Hanas (2010) recommend that when pump therapy is initiated, a suitable ICR for adults is 1 unit of insulin for every 10–15 g of carbohydrate, and for pre-pubertal children 1 unit of insulin for every 20–30 g of carbohydrate. However, as Walsh and Roberts (2006) highlight, the ICR can only be fully tested and refined once the basal rate has been correctly set.

As recommended by Walsh and Roberts (2006), the following steps should be taken if checking a pump user’s ICR:

1. No episodes of hypoglycaemia in the 8 hours leading up to an ICR check.
2. Pre-meal blood glucose levels should be in the range of 4–8.3 mmol/L.
3. The pump user should eat a set amount of “predictable” CHO, which is not high in fat or protein.
4. Following the bolus, the 1–2 hour blood glucose value should not rise or fall by more than 2.2–4.4 mmol/L post CHO.
5. At 4–5 hours post bolus, the blood glucose levels should be within 1.7 mmol/L of the starting value.

For correction doses, a pump user will need to know their ISF. As a rule of thumb, the ADA (2003) suggest an ISF of 1:2.8 mmol/L for most adults and 1:4.2–5.6 mmol/L for children and young people. The actual ISF decided upon should be considered in the context of the prospective pump user’s total MDI dose as this will provide an indication of their sensitivity. In our practice, we usually start with a ratio of 1:2.5 mmol/L for almost all adults (Morrison et al, 2007) and 1:3–6 mmol/L for children.

Walsh and Roberts (2006) also recommend that the pump user’s ISF can only be checked on an optimised basal rate by taking the following actions:

1. Test when the blood glucose is ≥ 11.1 mmol/L, at least 3 hours following CHO consumption and 5 hours since a bolus dose has been taken.

Page points

1. A cannula can be left in place for 2–3 days, however, a cannula is a foreign object causing a break in the natural barrier of the skin, therefore the user is at risk of developing an infection. In the worst-case scenario, an abscess may develop at an infusion site.
2. The evidence suggests that there is an increased risk of diabetic ketoacidosis in the period just after starting insulin pump therapy.
3. An effective partnership between the healthcare professional and the pump user is one of the key factors to facilitate the success of pump therapy and ongoing support for insulin pump users is an essential component of care.

2. No CHO for 5 hours.
3. If a hypoglycaemic event occurs, abandon the test.
4. After 5 hours the blood glucose value should be within 1.7 mmol/L of the target.

The pump user's education programme should include information on factors that will have a temporary impact on the individual's ISF or ICR, such as physiological problems (elevated blood glucose levels and ketones) and lifestyle events, such as exercise and the effects of alcohol consumption.

Infusion sites

A cannula can be left in place for 2–3 days depending on whether it is metal or Teflon® (Hanas, 2010). However, a cannula is a foreign object causing a break in the natural barrier of the skin. Therefore, the user is at risk of developing an infection at the site, which may require antibiotics. In the worst-case scenario, an abscess may develop at an infusion site, which may necessitate surgical drainage (Bolderman, 2002; Walsh and Roberts, 2006). Within the Liverpool cohort, the risk of abscess formation is <0.3% over 10 years (unpublished audit data).

Other site problems include the development of lipohypertrophy, particularly if cannulas are not replaced and rotated at the recommended time intervals, and even lipoatrophy (Hanas, 2010). Tegaderm™ or Duoderm™ can be used as effective skin barriers if the pump user has an allergy to the cannula plaster (Hanas, 2010). These products also have the added advantage of being available on an FP10 prescription. The pump user should be educated to appreciate the importance of filling the “dead space” within a new cannula with insulin and checking that the cannula is working effectively by checking their blood glucose levels 2 hours post insertion (Bolderman, 2002; Walsh and Roberts, 2006; Hanas 2010).

Diabetic ketoacidosis

The risk of diabetic ketoacidosis (DKA) in people who use insulin pumps increases in some studies (Dahl-Jørgensen et al, 1986; Hanas et al, 2009) and decreases in others (Bode et al, 1996; Tubiana-Rufi et al, 1996). The evidence suggests that there is an increased risk of DKA in the period just after starting insulin pump therapy (Mecklenburg et al, 1984; Hanas and Adolfsson, 2006). This

is probably a consequence of the new pump user not fully mastering their new form of treatment and has implications for the level of professional support individuals require when commencing CSII.

As the insulin depot is small in insulin pump therapy, the production of ketones will generally start to form approximately 4 hours following any interruption in the insulin supply (Torlone et al, 1996). It is difficult to be absolutely precise about the time it takes to develop ketones, as Hildebrandt and Vaag (1993) demonstrate. They found that thin people with a subcutaneous tissue level less than 10 mm had a reduced depot of insulin when compared to those with greater amounts (≥ 40 mm) of subcutaneous tissue. In simple terms, it is more likely that thin people will be more sensitive to an interrupted basal rate and will develop ketones much quicker than larger individuals.

Certain key situations place the individual at an increased risk of DKA due to an interruption in the insulin supply or inadequate amounts of insulin to meet physiological needs (Walsh and Roberts, 2006; Hanas, 2010). The interruption or lack of an adequate amount of insulin means that the pump user will soon develop symptoms of insulin deficiency and if the situation is not remedied quickly, DKA will occur. Given this risk, all pump users should have a blood glucose meter that can also test for ketones.

Insulin resistance changes in the presence of a significant amount of ketones, so a pump user should not calculate a correction dose using their usual ISF, as they will need to double their calculated dose, as well as drinking plenty of sugar-free fluids (Walsh and Roberts, 2006).

Support and education

An effective partnership between the CSII professional team and the pump user is one of the key factors to facilitate the success of pump therapy (Marcus and Fernandez, 1996). Ongoing support for insulin pump users is an essential component of care, which must be delivered from a multidisciplinary team who are experienced in CSII (NICE, 2008). All education should be structured and curriculum based with a programme that prepares the individual to deal with the worst-case scenario (Bolderman, 2002).

“Although solid evidence is lacking, insulin pump therapy can allow appropriately-selected individuals to achieve their target glycaemic control and stability, whilst allowing them to maximise lifestyle flexibility.”

Conclusion

Although solid evidence is lacking, insulin pump therapy can allow appropriately-selected individuals to achieve their target glycaemic control and stability, whilst allowing them to maximise lifestyle flexibility. However, these outcomes cannot be achieved without a specialist insulin pump team who can educate and adequately support people who may have very complex needs. ■

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Online CPD activity

Visit www.diabetesonthenet.com/cpd to record your answers and gain a certificate of participation

Participants should read the preceding article before answering the multiple choice questions below. There is ONE correct answer to each question. After submitting your answers online, you will be immediately notified of your score. A pass mark of 70% is required to obtain a certificate of successful participation; however, it is possible to take the test a maximum of three times. A short explanation of the correct answer is provided. Before accessing your certificate, you will be given the opportunity to evaluate the activity and reflect on the module, stating how you will use what you have learnt in practice. The CPD centre keeps a record of your CPD activities and provides the option to add items to an action plan, which will help you to collate evidence for your annual appraisal.

1. A key advantage of continuous subcutaneous insulin infusion (CSII) is:

Select ONE option only.

- A. Planning meals is less important
- B. Insulin adjustments are made automatically
- C. Rapid-acting insulin is delivered in a more physiological way
- D. Infrequent home blood glucose monitoring is required

2. Which of the following actions increases the safety of insulin pump use?

Select ONE option only.

- A. Checking blood glucose levels at least four times a day
- B. Carrying spare supplies such as a cannula, battery and dextrose tablets
- C. Have access to a meter that can test for blood ketones
- D. All of the above

3. Insulin pump therapy should be considered for which of the following?

Select ONE option only.

- A. Individuals who do not pay any attention to their diabetes management
- B. Those with severe psychological issues
- C. People with marked complications associated with their diabetes
- D. Those who dislike meal planning

4. Potential infusion site problems include which of the following?

Select ONE option only.

- A. Infection and abscess formation
- B. Lipohypertrophy and lipoatrophy
- C. Skin allergy to the cannula plaster
- D. All of the above

5. Under NICE (2008) criteria, which individuals are eligible for CSII

Select ONE option only.

- A. People with type 2 diabetes treated with multiple daily injections (MDI), associated with frequent episodes of hypoglycaemia
- B. People with secondary diabetes treated with MDI associated, with frequent episodes of diabetes
- C. People with type 2 diabetes where HbA_{1c} levels are ≥ 69 mmol/mol on MDI despite a high level of care
- D. People with type 1 diabetes where HbA_{1c} levels are ≥ 69 mmol/mol on MDI despite a high level of care

6. The first action a pump user with blood ketones of 1.6 mmol/L and blood glucose of 26 mmol/L should take is:

Select ONE option only.

- A. Give a calculated correction dose via a pen or syringe
- B. Go to hospital
- C. Change the cannula
- D. Change the cannula and then give a calculated correction dose via the pump

7. In an insulin pump, the use of a rapid-acting analogue insulin rather than soluble insulin is associated with:

Select ONE option only.

- A. Less hypoglycaemia and the same overall glycaemic control

- B. Less hypoglycaemia and better overall glycaemic control

- C. No difference in either hypoglycaemia or overall glycaemic control

- D. More hypoglycaemia but better overall glycaemic control

8. Which of the following must occur before insulin to carbohydrate ratio (ICR) can be tested?

Select ONE option only.

- A. The insulin sensitivity factor (ISF) must be established
- B. The pump user must eat a set amount of carbohydrate
- C. The blood glucose must be below 11 mmol/L
- D. The basal rate must be correct

9. Which of the following must occur before the ISF can be tested?

Select ONE option only.

- A. The ICR must be established
- B. The basal rate must be correct
- C. The blood glucose must be ≥ 13 mmol/L
- D. The person must not eat for 6 hours before the test starts

10. Individuals using combination bolus doses for carbohydrate consumption rather than normal bolus doses can on average:

Select ONE option only.

- A. Increase their HbA_{1c} by 0.45%
- B. Decrease their HbA_{1c} by 0.45%
- C. Increase their HbA_{1c} by 0.65%
- D. Decrease their HbA_{1c} by 0.65%