

## REVIEW ARTICLES



# Clinical recommendations in the management of the patient with type 1 diabetes on insulin pump therapy in the perioperative period: a primer for the anaesthetist

H. Partridge<sup>1</sup>, B. Perkins<sup>2</sup>, S. Mathieu<sup>3</sup>, A. Nicholls<sup>1,\*</sup> and K. Adeniji<sup>3</sup>

<sup>1</sup>Department of Diabetes and Endocrinology, Royal Bournemouth Hospital, Bournemouth, UK, <sup>2</sup>Leadership Sinai Centre for Diabetes, Mount Sinai Hospital, Toronto, Canada, and <sup>3</sup>Department of Critical Care, Queen Alexandra Hospital, Portsmouth, UK

\*Corresponding author. E-mail: [adnicholls@doctors.org.uk](mailto:adnicholls@doctors.org.uk)

## Abstract

Insulin pump therapy is increasingly common in patients with type 1 diabetes. Many of these patients will require surgery at some point in their lifetime. Few doctors will have experience of managing these patients, and little evidence exists to assist in the development of guidelines for patients with insulin pump therapy, undergoing surgery.

It is clear that during emergency surgery insulin pump therapy is not appropriate and should be discontinued, but patients undergoing some elective surgery can and should continue insulin pump therapy, without any adverse effect on their blood sugar control, or on the outcome of their surgery. Individual hospitals need to formalize guidance on the management of patients receiving continuous subcutaneous insulin therapy, to allow patients the choice to continue their therapy during surgery. This expert opinion presents anaesthetists with a suggested clinical framework to help facilitate continued insulin pump therapy, during elective surgery and into the postoperative period.

**Key words:** diabetes mellitus, type 1; insulin infusion systems; surgery

Since its introduction in the 1970s insulin pump therapy is being used increasingly in the management of type 1 diabetes, with current estimates of between 20 to 30% of people in North America with type 1 diabetes being pump users,<sup>1,2</sup> and this number is increasing rapidly in the UK. Current NICE guidance in the UK recommends 15–20% of the population with type 1 diabetes should be eligible for insulin pump therapy. However, uptake remains very dependent on individual diabetes centres having sufficient expertise in this technology, and it remains a postcode lottery.<sup>3,4</sup> Original studies of continuous subcutaneous insulin infusion (CSII), compared patient groups randomized to either multiple daily injections (MDI) or insulin pump therapy. The initial studies using older non-analogue based insulin regimens, demonstrated improvements in glycaemic control, with reductions in HbA1c and hypoglycaemia with insulin pump therapy.<sup>5</sup> These results were later confirmed using newer basal insulin analogues<sup>6</sup> and

were demonstrated with an associated improved quality of life in both adults and children.<sup>7</sup> After publication of the results from the seminal Diabetes Control and Complications Trial (DCCT) in 1993, care for people with type 1 diabetes has focused on aiming to achieve intensive management of glucose control, hence reducing micro- and macrovascular risk.<sup>8</sup> Insulin pump therapy has been demonstrated to reduce HbA1c significantly over MDI in the first year of use in numerous studies<sup>9,10</sup> and we are now starting to see multicenter long-term outcome data, demonstrating similar results over 1–10 yr periods compared with prepump values<sup>11,12</sup> and in comparisons of matched cohorts continuing on MDI.<sup>13</sup>

The primary goal of insulin pump therapy is to mimic physiological insulin replacement, which is missing in people with type 1 diabetes, as a result of the autoimmune destruction of B-cells of the pancreas. It therefore follows that this therapy may also be

considered in people with total pancreatic failure from other causes, such as post total pancreatectomy<sup>14</sup> and pancreatitis although, currently in the UK this does not fall strictly within NICE guidelines.

There has long been interest in using insulin pump therapy in type 2 diabetes, which is characterized primarily by insulin resistance rather than insulin deficiency. However, pump therapy for type 2 diabetes is not recommended by the UK NICE guidelines, because of a lack of consistent and convincing evidence resulting from a few small scale randomized controlled trials, comparing multiple daily dose insulin to insulin pump therapy.<sup>15 16</sup> The recent large scale OpT2mise study, comparing insulin pump therapy against MDI use in people with type 2 diabetes, only demonstrated a cost-effective benefit from CSII use with a reduction in HbA1c of 1.1%, in those only in the highest tertile of HbA1C at baseline.<sup>17</sup>

Despite significant advances in technologies for diabetes management, insulin pump therapy is not for everyone. There are multiple reasons why pump therapy is not considered appropriate for all, such as visual and cognitive impairment, loss of manual dexterity and infusion site reactions. The use of the pumps during exercise, bathing and intimacy are perceived barriers, although are not usually insurmountable and indeed during sport the pump offers significant advantages, in allowing flexibility of diabetes management.<sup>18</sup> In addition, the psychological burden of being attached to a machine in many patients outweighs benefits and acts as a barrier to adopting CSII.<sup>19</sup> Personal choice also plays a crucial role in deciding on therapy for type 1 diabetes. The interaction between healthcare providers and individuals with diabetes is paramount, in weighing up the pros and cons in opting for insulin pump therapy.

Healthcare professionals from all specialties are increasingly likely to encounter situations where some knowledge of insulin pump therapy is essential. Up to 50% of people with type 1 diabetes are thought to require some form of surgery during their life and so anaesthetists may be required to manage people with type 1 diabetes on CSII through surgery. This article is based on expert opinion and a review of the literature and aims to discuss - for the primary care physician, the anaesthetist, and the surgeon - the general decision-making processes for the management of the patient with type 1 diabetes, on insulin pump therapy, undergoing surgical and investigational procedures. It intends to acquaint the reader with insulin pump mechanics, the language and concepts behind the insulin parameters, and

how the pump can fit within the scope of perioperative insulin management, for the patient with ketosis-prone type 1 diabetes.

Most pump users are highly motivated and educated around their diabetes management and are able to manage 'sick day rules' and unforeseen circumstances regarding their blood glucose control. Many will be reluctant to give up this form of therapy whilst being admitted to hospital or undergoing surgery. In these patients it should be possible to continue CSII with prior agreement and shared care between patient, family and healthcare professionals. Insulin pump therapy plays a major role in the self-management skills of diabetes, but under situations where the patient cannot self manage, or that ability is questioned (delirium, pain, medication, loss of consciousness), then management needs to be in the hands of the healthcare team reverting to protocols for the inpatient management of people with type 1 diabetes.<sup>20</sup>

Hospitals need to develop clear protocols for inpatient management of people on insulin pump therapy, with education for all healthcare professionals likely to encounter this technology and close liaison with the diabetes team. However, other than case reports, there is little evidence available to drive recommendations, specifically around pump therapy during surgery and protocols for the management of type 1 diabetes perioperatively, are often not standardized and based on local guidelines rather than national or international standards.<sup>21 22</sup> Other groups have specifically developed guidelines around insulin pump therapy perioperatively,<sup>23 24 25 26</sup> but there is limited evidence on the use of insulin pumps during surgery and a comprehensive set of current best practice recommendations have not been developed. The Joint British Diabetes Society guidelines offer protocols for the management of type 1 diabetes perioperatively and the recommendations here are in alignment with this guidance.<sup>27</sup>

## Principles of insulin infusion

The insulin pump is a small, battery-operated, programmable device (Fig. 1) which aims to mimic physiological insulin delivery over 24 h with basal and bolus insulin infusions of rapid acting insulin analogues (Novorapid®, Humalog®, Apidra®). Compared with MDI the pump offers quantitative administration of a basal infusion of insulin, with the capacity for instantaneous change and cessation, tailored bolusing with meals with on board calculators, to maximize dosing accuracy and a convenient method to calculate and administer additional doses of insulin, to correct high



Fig. 1 Examples of Insulin pump systems. (A) A traditional insulin pump with tubing attached directly to the infusion site cannula. (B) A 'patch pump' with a self-contained insulin cartridge in the adhesive pod worn attached to the skin with an integrated subcutaneous cannula and a hand held blue-tooth control device (<http://www.designbuzz.com/omnipod-insulin-management-system-living-easier-diabetes/>).

blood sugars independent of meals. It should be noted however that the physiological principles of insulin pump therapy are aligned with that of MDI subcutaneous injection therapy and whilst many people will be reluctant to suspend their pump, they need to be reassured that they will still be receiving an equivalent insulin therapy, either in the form of MDI or i.v. insulin.

## Basal and bolus insulin

Basal insulin infusion is the absolute requirement for a low insulin concentration, even in the fasted state to maintain euglycaemia and prevent ketosis, but at a sufficiently low concentration to allow hepatic gluconeogenesis to supply the brain and vital organs. The bolus dose of insulin is required to maintain euglycaemia, whilst absorbing a carbohydrate load and is administered at or just before meal times. The bolus dose may include a correction dose to account for hyperglycaemia, above a predetermined level in the blood test before the meal.

The basal rate is programmed to deliver small doses as a constant infusion over 24 h. Potentially by acting as a 'very long acting' insulin, the pump provides very stable insulin administration and excellent blood glucose control in the fasted state. The hourly infusion rate is tailored to the individual taking account of factors such as insulin sensitivity, the dawn phenomenon (the increase seen in blood sugars in the early morning h, caused by counter regulatory hormones such as cortisol and growth hormone<sup>28</sup>) and regular daily activities. The basal infusion usually accounts for approximately 50% of the total daily requirement for insulin, although this may vary, particularly in children.<sup>29</sup> Some people have different basal rates programmed for variations in activities of daily living. For example, if during the week insulin requirements are high as a result of a sedentary career, but are significantly lower at weekends because of being physically active, then the pump basal rate program can be switched from one during the week to one which delivers significantly less insulin during the weekend. This is termed an alternate basal rate. Temporary basal rates can be instituted for shorter periods of time to counteract changes in insulin requirement such as exercise. Women often use some of these facilities to counter the fluctuations in blood glucose around the menstrual cycle. Self-management skills allow for several different strategies to deal with variations in insulin and carbohydrate requirement encountered on a daily basis.

The meal time bolus dose is required when carbohydrate is taken in the diet. It is calculated based on the amount of carbohydrate ingested and the carbohydrate to insulin ratio. The carbohydrate to insulin ratio is defined as the amount of carbohydrate (in g) covered by 1 unit of insulin. This ratio (and the one for insulin sensitivity factor) are calculated from the total daily dose of insulin and are a reflection of the patient's sensitivity to insulin. They are individualized and preprogrammed into the pump. Therefore with an example ratio of 1:10, for every 10 g of carbohydrate ingested 1 unit of insulin will be required. This ratio can vary throughout the day and can be set at different levels for different time blocks. Many people find they require more insulin per carbohydrate in the mornings when some of the counter regulatory hormones are still high.

The insulin sensitivity factor is an individualized measure of by how much the blood glucose will decrease on infusion of 1 unit of insulin (for example for a ratio 1:3, 1 unit of insulin would be expected to decrease the blood sugar by 3 mmol litre<sup>-1</sup>). It is used with the bolus dose to correct a blood sugar above a pre-specified target, before the next meal is taken. Before food is ingested the user informs the pump of the current blood sugar (measured in the standard way with capillary blood glucose testing) and the

amount of carbohydrate to be ingested (in g). The on board calculator in the pump will then calculate the dose of insulin to be infused, which the user can either accept and deliver or override. This facility allows for expected variations in glucose sensitivity, for example, at times of exercise or stress, where a lesser or greater (respectively) dose of insulin may be required. The pump also contains a preset memory which calculates the time and size of the last insulin dose, therefore allowing an estimation of how much insulin is still active in the body. This system aims to prevent too many frequent or large corrections ('stacking'), thus protecting from hypoglycaemia.

All these parameters are calculated at the start of insulin pump therapy and rather than being fixed for the lifetime of the pump are subject to change according to physiological changes such as weight, exercise, menstruation. Usually people on insulin pump therapy will attend, in the maintenance phase of their therapy, a diabetes clinic every 3–6 months with a team specialized in pump therapy where changes to basal rates, insulin to carbohydrate ratios and insulin sensitivity factors or correction factors can be reviewed.

## How it all works

Most commonly, the user wears a disposable metal or plastic, subcutaneously-inserted cannula which is held in place on the skin surface and changed every 2–3 days. This is connected to the pump via a long flexible plastic tube. The insulin is held in a glass or plastic syringe within the pump. There are also 'patch pumps', which are tubeless insulin delivery devices, adherent to the skin, paired with a hand-held programming device (Fig. 1). Some pumps contain in built continuous glucose monitoring system devices (CGMS), with the ability to measure interstitial glucose, if an additional subcutaneous sensor is worn. Many different devices are now available from various manufacturers, each with their own unique selling point, but all working on the same principles.

## The down-sides of insulin pump therapy

Only short-acting insulin is infused in the insulin pump. Disconnection, occlusion or cessation of pump therapy will render the pump-user relatively insulin deficient within 1 h and absolutely insulin deficient within 4 h, with a severe risk of hyperglycaemia and ketosis subsequently. Initial clinical experience suggested that ketoacidosis was more common in people wearing insulin pumps, but this risk may have been over-estimated, as suggested by recent studies.<sup>30</sup> There are also cosmetic and psychological barriers to be considered for some people who prefer to remain on multi dose injections (MDI).

In the UK, availability of specialist pump centers may be one of the restrictive limiting factors. This method of insulin delivery has been approved by NICE, for people with type 1 diabetes who fulfil certain criteria with an HbA1c > 8.5%, despite using analogue insulins in an MDI regimen with appropriate diabetes team input, or individuals experiencing recurrent disabling hypoglycaemia or fear of hypoglycaemia.<sup>3</sup>

## Recommendations for management of people with type 1 diabetes on insulin pump therapy perioperatively

### The preoperative period

Elective surgery should be planned where possible in consultation with the patient and their diabetes team and should be

delayed until optimal glycaemic control has been achieved with HbA1c < 8.5% (~69 mmol mol<sup>-1</sup>),<sup>31</sup> using models such as the Bournemouth diabetes surgical pre-assessment service.<sup>32</sup> Current clinical guidelines recommend a long-term control goal of an HbA1c of 7% (6.5% in U.S) in the management of diabetes, to prevent long-term micro and macrovascular complications, but 8.5% is generally assumed to be consistent with safety in preparation for surgery.

Early communication with the specialist pump diabetes team, which may not be the local diabetes team, allows a definitive management plan to be drawn up in advance of surgery and advice on the competency of the patient in regard to the intricacies of their pump usage. Therefore, it should be assumed that

during a hospital admission, the patient (or parent/guardian if the patient is a child) will take responsibility for the insulin pump during the stay, except during the period of reduced consciousness during surgery when another allocated healthcare professional must take on that obligation. The inclusion of clear documentation of a concise management plan, detailing the planned continued use of the pump during surgery in the case notes, is imperative together with signed consent of the patient (or parent/guardian), to continue insulin pump therapy perioperatively.<sup>33</sup>

In preparation for surgery, it is necessary to establish a consistent stable blood glucose concentration in the fasted state, requiring a 'basal test' to be performed. This basal test allows the patient to assess the accuracy and appropriateness of the basal infusion rate. The early involvement of the diabetes team in people on an insulin pump preoperatively, is paramount to facilitate this optimization of glycaemic management. The overnight basal assessment can be performed (Fig. 2) at least a few days or weeks before surgery, to allow sufficient time for input from the diabetes specialists, if necessary, to adjust and confirm the new settings by repeating the basal assessment. The timing of the assessment can be extended to cover the proposed timings of the surgery. For example, if surgery is planned for 9 am then the basal assessment could cover the overnight period, up until late morning. In an ideal profile the blood glucose concentrations should increase or decrease by no more than 1.7 mmol litre<sup>-1</sup> and therefore would suggest that the blood glucose under normal fasting conditions would stay stable. The healthcare professionals in the local insulin pump service can oversee this assessment, if the patient is not confident to perform it independently. People with type 1 diabetes can experience huge blood glucose variability, even with the best self-management skills and 'perfect' settings on the insulin pump. Perfect overnight basal rates can be difficult to achieve, but the majority of pump patients display significantly more stability than those using analogue insulin injections. The ability to download this data from a continuous glucose monitor can demonstrate consistent, stable overnight glucose readings (Fig. 3).

With CSII, infusion cannulas are changed every two to three days, to prevent problems from erratic absorption at the insertion site. We recommend changing the infusion set the morning or afternoon of the day before surgery, with enough time to check two capillary blood glucose readings several h apart, to ensure the infusion set is functioning correctly. During surgery a plastic

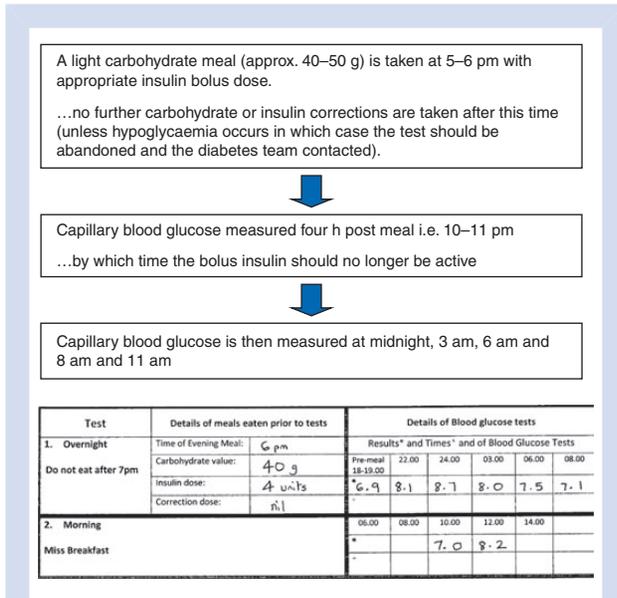


Fig. 2 How to perform a basal assessment. An example of a basal assessment trace. The 4 h post prandial blood glucose should vary by less than 1.7 mmol litre<sup>-1</sup> throughout the test, if the basal profile is correct. Any significant deviation from this or hypoglycaemia should prompt a consultation with the diabetes team BEFORE surgery is scheduled. Ideally the basal assessment should be conducted and repeated at least once after any adjustment to confirm accuracy.

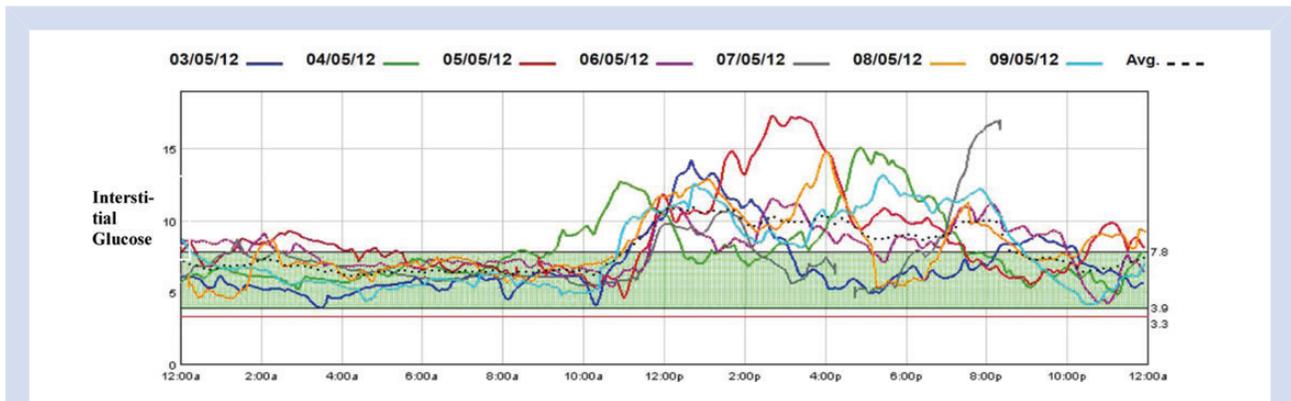


Fig. 3 Continuous glucose monitor (CGM) download. Each colour in the above diagram represents a different day of wearing the CGM system. The basal profile is very flat from about midnight through till 10 am when breakfast is introduced and the effect of carbohydrate on blood glucose control becomes evident. This patient was fasted from late evening and the effect of the carbohydrate from the evening meal no longer has an effect from about 11.30 pm. This is an example of what can be achieved with a personalized basal rate.

infusion set is preferred because of the risks of subcutaneous metals with diathermy, so the patient may have to switch infusion sets for the procedure. This needs to be considered well in advance, in order for the patient to obtain these from their provider. Consideration must also be given to the site of infusion, as this needs to be distant from the site of the surgery, away from the field of diathermy and should be readily accessible by the anaesthetist at all times during the surgery. Usually the infusion site is on the abdomen, thighs or buttocks. Depending on the surgery this site can be decided on and documented before theatre. It is possible using a patch pump to wear the pump on the arm, which may be more accessible. Problems may arise with the use of sterile drapes and though needing to obtain direct access to the pump is unlikely, this needs to be considered. Advice to the patient to bring an adequate supply of all necessary equipment and spares for safe use of the pump to cover the duration of the whole hospital admission is required.

### The perioperative period

Listing patients with diabetes for surgery requires attention to ensuring that fasting is kept to a minimum and therefore aiming to list them first. Insulin management plans for a patient listed for surgery must be made available in advance. For minor elective surgery or surgery requiring only one meal to be missed, the patient on a pump can continue their usual insulin regimen via the pump, whilst adhering to the recommendations with regard to fasting provided by the anaesthetic team. Once the fasting period begins the basal infusion can run and continue for the duration of surgery. Different protocols internationally recommend alternate basal infusion rates during surgery. Guidelines from Queensland, Australia recommend using 80% basal rates upon initiation of surgery, as a temporary basal rate, which can be restored to normal once the patient is conscious and able to manage their glucose control.<sup>24</sup> This is based on the assumption that the average patient on an insulin pump may have a supraphysiological basal rate (i.e. that many patients on insulin pump therapy run a higher basal rate than is physiologically required—usually in an attempt to drive the average blood glucose down). Good diabetes control requires that blood glucose is on

target for the fasting blood test first thing in the morning and hence the basal rate is sometimes erroneously used to bring the blood sugar down overnight. The recommendations in the UK for surgery call for continuation at 100% basal rate, on the assumption that basal rate assessments are performed pre surgery and the rates are corrected to allow stability using the basal profile.<sup>27</sup> Physiologically, surgery represents a time of metabolic stress and relative insulin deficiency<sup>34 35</sup> and hence a tendency to hyperglycaemia, therefore maintenance of the normal basal rate during short surgical procedures may be appropriate. It may be suitable to use the 80% basal rate, in patients who have been unable to perform the basal assessment before surgery as a countermeasure to hypoglycaemia. Those who can document a stable basal test could continue on 100% basal rate with blood glucose checks at three am and seven am on the morning of surgery. Capillary blood glucose must be measured hourly both preoperatively, perioperatively and postoperatively, until the patient is eating and drinking again and able to manage their own glucose control. The insulin sensitivity factor can be used in the perioperative period as a guide to correcting increases in blood sugar.

The appropriate perioperative glycaemic targets for minor or moderate surgeries are controversial. There are few intervention studies assessing the impact of tight glycaemic control on morbidity or mortality; however, a number of small studies in type 1 and type 2 diabetes, that compared different methods of achieving glycaemic control during minor and moderate surgeries, did not demonstrate any adverse effects of maintaining perioperative glycaemic concentrations between 5.0 and 11.0 mmol litre<sup>-1</sup>.<sup>36 37 38</sup> Most of the evidence for optimal blood glucose control is based around critically ill patients, who may not have diagnosed diabetes. NICE-SUGAR randomized 6104 intensive care patients to either conventional glucose (less than 10 mmol litre<sup>-1</sup>) or intensive glucose (4.5–6 mmol litre<sup>-1</sup>) control. Survival at 90 days was better in the conventional blood glucose control group. The incidence of severe hypoglycaemia was also reduced in the conventional group (0.5 vs. 6.8%).<sup>39</sup> Before NICE-SUGAR, our target glucose control was based mostly around two landmark papers by Van den Bergh. Both studies, the first in surgical patients and the second in a medical cohort, concluded that tight

**Table 1** Perioperative glycaemic management in patients with Type 1 Diabetes undergoing surgery GIK, Glucose-insulin-potassium; CSII, Continuous subcutaneous insulin infusions

Author, date	Patient Group	Study type	Key results
Bowen and colleagues <sup>42</sup>	20 patients undergoing elective surgery	Observational	Continuous GIK infusion (2 units insulin, 10 g glucose and 4 mmol potassium per h). Concluded that this was safe to use up to 4 h
Thomas and colleagues <sup>43</sup>	27 patients undergoing elective surgery	Observational	Before elective surgery, patients received either a proportion of their normal insulin dose with 25 g i.v. glucose (scheduled morning surgery) or full insulin dose with breakfast (scheduled afternoon surgery). Proportion then received GIK infusions perioperatively and continued for 4 h after surgery. Plasma glucose (& 3-hydroxybutyrate) values were lower in the GIK subjects at 4 h and at 72 h
Simmons and colleagues <sup>44</sup>	58 patients undergoing surgery	RCT	Continuous GIK infusion or a more complex, tailored two-pump protocol was used. Both methods provided similar overall glycaemic control but the GIK regimen required less changes and was considered safer by staff
Joint British Diabetes Society <sup>27</sup>	Perioperative care pathway for diabetic patients	Report	Providing only one meal is to be missed before elective surgery, patients can still be maintained on CSII Early preoperative assessment should be arranged to determine a perioperative diabetes management strategy

sugar control (4.4 mmol litre<sup>-1</sup>–6.1 mmol litre<sup>-1</sup>) improved mortality compared with a more conservative approach (<10 mmol litre<sup>-1</sup>).<sup>40 41</sup> However, these findings were not supported by the larger NICE-SUGAR study. A more conservative blood sugar target of 6–10 mmol litre<sup>-1</sup> has therefore been adopted. Studies looking specifically at insulin dependent type 1 diabetes are scarce (Table 1). The Joint British Diabetes Societies guidelines recommend perioperative capillary blood glucose concentrations between 6 and 10 mmol litre<sup>-1</sup>, but acceptable concentrations are between 4 and 12 mmol litre<sup>-1</sup>.<sup>27</sup>

It is important to remember that different anaesthetic regimes may have effects on glucose homeostasis during surgery. These effects are often mediated by stimulation or inhibition of the counter regulatory hormones cortisol and growth hormone, alteration in the sympathetic nervous system outflow and influences on the whole of the hypothalamic pituitary adrenal axis.<sup>45</sup>

Minor changes in blood glucose during surgery are to be expected and are not an indication to stop an insulin pump, but in the event of uncontrolled blood sugar perioperatively, removal of the pump and cannula and reversion to a variable rate insulin infusion for blood glucose control may be necessary. Although the pumps all differ in their software interface the main menu is readily accessible on all, with the ‘stop’ or ‘suspend’ basal function being easily located. However, for healthcare professionals not specialized in the use of insulin pump therapy, the first line measure would be to disconnect the pump from the insertion cannula, but leave the pump running. It is necessary then to start an i.v. insulin infusion immediately in these patients. Disconnection from an insulin pump renders the person with diabetes relatively insulin deficient within an h and rapid commencement of the i.v. insulin is imperative. The considerations for switching to and from i.v. insulin using individualized pump settings are provided in Fig. 4.

In the event of blood glucose concentrations decreasing below 4 mmol litre<sup>-1</sup>, hypoglycaemia is treated as per protocol with i.v. glucose if required. As a result of the relatively slow absorption of

insulin from the subcutaneous site, stopping the basal infusion at this point is unlikely to have an effect on glucose control for up to 2 h and therefore the pump can safely be left running. However, if the blood glucose becomes difficult to manage, or hypoglycaemia is recurrent, then the pump can be disconnected and an i.v. insulin infusion started immediately, with concurrent

Table 2 Changes to pump therapy with intra-operative radiology

Procedure	Recommendation
X-Ray	For dental X-Rays, pump should be covered by lead apron For body X-Rays pump should be removed
CT/MRI	Pump and metal infusion set should be removed
Ultrasound	No need to remove pump but transducer should not be pointed directly at the pump
Cardiac Catheterization	Pump should be removed
Pacemaker/Automatic Implantable Cardioverter-Defibrillator (AICD)	Pump should be removed
Colonoscopy/OGD	Pump can remain in place
Laser surgery	Pump can remain in place

Patient is nil by mouth or requires i.v. insulin?

- i.v. insulin should be ideally started at least 30 min before removing the pump and infused at the hourly basal rate initially but titrated to blood glucose.
- For example, a constant basal rate of 0.5 units per h subcutaneously via the pump could be substituted for 0.5 units per h intravenously or the total basal rate (TBR), available from the pump menu can be used to calculate an appropriate hourly rate
- On transitioning back to the pump, the pump should be connected and basal rate infused for at least two h before stopping the i.v. infusion.

Patient can be managed on a subcutaneous regimen and is eating and drinking?

- The 24 h basal dose of insulin (available from the pump menu) should be replaced with an equivalent subcutaneous injection of lantus (glargine) or levemir (detemir) in 2 divided doses 12 h apart. This allows for easy transition back to pump therapy. The pump should be discontinued two h after the first injection of basal insulin.
- For example, if the total daily basal dose of insulin is 22 units then transition would be to 11 units of lantus or levemir 12 hourly.
- Food bolus insulin and correction doses would be given according to the insulin to carbohydrate ratio and insulin sensitivity factor.

Fig. 4 What to do if the pump needs to be removed during a hospital admission?

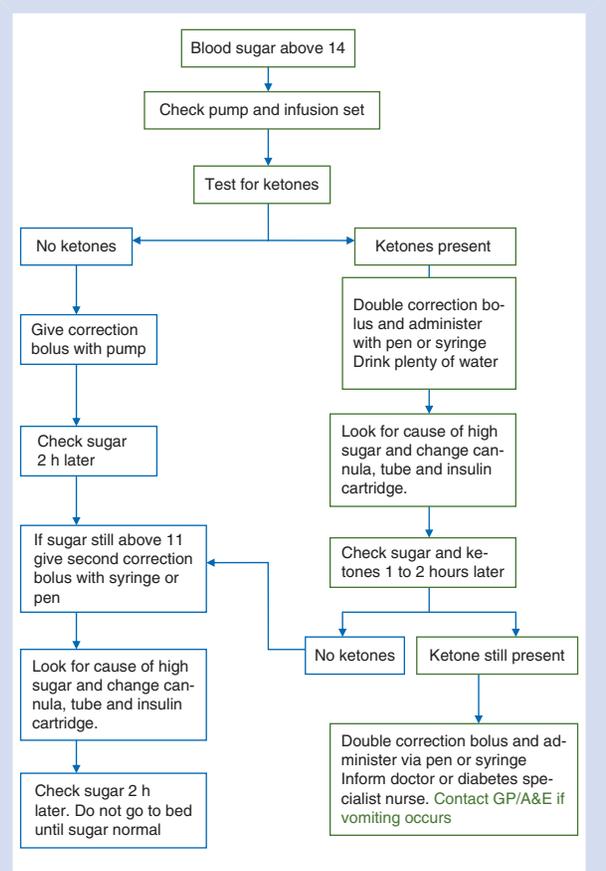


Fig. 5 ‘Sick Day Rules’ algorithm for managing high blood sugar on CSII.

adequate treatment of the hypoglycaemia. In an attempt to demonstrate the safety and efficacy of insulin pump therapy in the operative setting, Boyle and colleagues reviewed the case notes of 20 people who remained on insulin pump therapy during surgery, revealing no documented episodes of hypoglycaemia and infrequent need for correction doses of insulin or i.v. insulin.<sup>33</sup> Perhaps the largest study to date comes from a retrospective analysis from 4 centres in Italy, using CSII during delivery in 68 pregnant women with type 1 diabetes. In their analysis, between 56–85% of the women at the various centres underwent Caesarean section for delivery, whilst on insulin pump therapy (the remainder had normal vaginal delivery). The primary outcomes were necessity to convert to an i.v. insulin protocol because of metabolic decompensation and time spent in glucose target during delivery. In this study CSII was considered a safe alternative as a method of glucose control during operative delivery, with mean glucose remaining in range across the study and no patients requiring conversion to i.v. insulin.<sup>46</sup>

For major or emergency surgery insulin pump therapy is not appropriate and pump discontinuation is advocated, with resort to i.v. insulin as per local protocol. In addition we recommend that in people undergoing abdominal surgery, procedures likely to cause significant ileus, or in those who will be nil by mouth for *more than* one meal, then use of the insulin pump is not advocated during the perioperative period and a plan must be made to stop the pump preoperatively and transition to a variable rate insulin infusion. The basal rate of insulin infusion

programmed in a pump is a good guide to how much insulin is likely to be required i.v. The equivalent rates can be infused i.v. as subcutaneously and this rate monitored by hourly capillary blood glucose or venous/arterial blood according to the monitoring access lines available (Fig. 4). In view of the risk of rapid hyperglycaemia and ketosis on cessation of pump therapy, the i.v. insulin infusion should be started at least half an h before disconnection of the pump. Obviously under emergency situations this may not be possible, but there should be no delay in commencing i.v. insulin when this scenario arises. Upon pump restart, the i.v. insulin runs alongside the subcutaneous infusion for 2 h with hourly glucose monitoring to establish a subcutaneous depot before taking down the i.v. infusion.

There remains a concern of potential insulin pump failure after exposure to ionizing radiation or electromagnetic fields. According to the pump manufacturers' recommendations, all insulin pumps must not be exposed to screening radiological procedures. The management for glucose control should revert to that for emergency or major surgery if radiographic intervention (CT, MRI or screening) is required (Table 2). As we continue to gain experience in the utilization of these devices and with newer generations, I think it is fair to say that it is impossible to know, at this time, all of the possible ramifications concerning patient care and safety. Hence, our advice all relates to using manufacturers' instructions and current guidelines. If circumstances require it, then the pump must be removed and left outside the operating room in a safe location.

#### Pre-operative Preparation for CSII Patients

##### Topics for discussion with patient

- Choice of continuation with pump therapy during theatre
- Supply of adequate pump consumables required for entire in-patient stay
- Re-siting of infusion set on the day before surgery and monitor blood glucose
- Position of infusion site (eg. thigh -away from operative field, diathermy and accessibility for anaesthetist)
- Overnight basal assessment before to surgery
- Notification of the diabetes pump team (may not be the local diabetes team)
  - to confirm self-management competencies
  - to optimise basal rates, and glucose control before to surgery
  - to supply plastic infusion sets

##### Perioperative management for CSII

- Assess glucose hourly
- If blood glucose uncontrolled perioperatively-change to an i.v. insulin infusion
- If blood glucose falls to below 4mmol, treat as hypoglycaemia according to local policy
- If hypoglycaemia is recurrent – stop/disconnect the pump and commence an i.v. insulin infusion
- The pump should be disconnected in emergency surgery, if possible with a 30 min overlap with i.v. insulin
- The pump should not be used if screening radiology is required

##### Post-operative Management for CSII Patients

- Check capillary glucose hourly until the patient is conscious and able to manage the pump themselves
- Advise patients to increase frequency of testing for one to two days after surgery

Fig. 6 Managing CSII Patients throughout Surgery (All discussions and a proposed plan should be clearly documented).

Specific advice for the use of insulin pumps with regard to electrocautery in surgery is not available. It is prudent to site the pump as far distant to the site of likely use as possible. The concern with electrocautery is again related to electromagnetic induced pump malfunction, although this has not been documented and is not a contraindication for use of the pump in a surgical setting. Pump failure would be signalled by an alarm from the pump, or a marked deterioration in glucose control caused by failure of insulin infusion. Siting of the infusion cannula for this reason must be discussed with the patient and documented in the preoperative assessment.

With the insulin pump models which have an associated continuous glucose monitor (CGM), the CGM sensor device must not be used to track glucose values during surgery, because of the discrepancies between interstitial glucose measured by the CGM and capillary blood glucose as traditionally used to monitor blood glucose. These discrepancies may be exaggerated during surgery because of the changes in haemodynamics and subcutaneous perfusion induced by anaesthesia and fluid balance and positioning and stasis. This is also an important consideration for the optimum functioning of the insulin infusion pump which is dependent on adequate tissue perfusion and bp being maintained during surgery.

### The postoperative period

Post-surgery and in recovery, capillary blood glucose monitoring is continued hourly until the patient is fully conscious and capable of making decisions regarding the management of their pump.

In the event of blood glucose concentrations starting to increase in the h or two after surgery when the patient is alert and able to manage the pump, then the use of the pump's built in bolus calculator will allow the determination of the correction dose of insulin required to start to bring the blood glucose concentration down. Minor changes in blood glucose at this point may simply be monitored carefully and a subsequent correction given with the bolus dose for the carbohydrate ingested at the first meal postoperatively. More significant changes in blood glucose may reflect either a failure, or accidental disconnection of the pump, or as a result of the physiological stress response to surgery. Most people using insulin pump therapy are aware of 'sick day rules' and will be able to use these algorithms to correct for unexplained high blood glucose (Fig. 5). These same algorithms can be used in the postoperative period by healthcare professionals.

Patients are advised to continue increased frequency of blood glucose monitoring for 1–2 days after surgery, to re-establish their baseline status. Bolus dosing of insulin can start with the first postoperative carbohydrate ingestion.

Some evidence exists of a beneficial effect in terms of lower fasting glucose on the first postoperative day and more stable glucose in people remaining on insulin pump therapy during elective surgery, than those on non-pump regimens, but the trial design and data were somewhat ambiguous and not confirmed in other studies.<sup>47 48</sup> To date, there is no evidence demonstrating a detrimental effect of remaining on basal insulin infusion during surgery.

### Conclusion

With insulin pump therapy becoming an increasingly used modality for the management of type 1 diabetes and trials underway to consider its benefits in type 2 diabetes, it is increasingly important for healthcare professionals to be aware of the rudiments of

pump therapy and in the case of surgery and anaesthesia, for healthcare professionals in this field to be competent to manage such patients, in consultation with the endocrinologist and pump nurse specialists. A summary of the advice is shown in Fig. 6.

### Authors' contributions

Study conduct: A.N.

Writing paper: H.P., B.P., S.M.

Revising paper: all authors

### Declaration of interest

None declared.

### References

1. Grunberger G, Bailey T, Cohen AJ, et al. Statement by the American Association of Clinical Endocrinologists Consensus Panel on insulin pump management. *Endocr Pract* 2010; **16**: 746–62
2. Selam JL. Evolution of diabetes insulin delivery devices. *J Diabetes Sci Technol* 2010; **4**: 505–13
3. NICE. Diabetes Insulin Pump Therapy –Continuous subcutaneous insulin infusion for the treatment of diabetes. TA151 2008
4. Diabetes UK. Insulin Pump Therapy Position Status. 2011
5. Hoogma RP, Hammond PJ, Gomis R, et al. Comparison of the effects of continuous subcutaneous insulin infusion (CSII) and NPH-based multiple daily insulin injections (MDI) on glycaemic control and quality of life: results of the 5-Nations Trial. *Diabet Med* 2005; **23**: 141–7
6. Pickup JC, Sutton AJ. Severe hypoglycaemia and glycaemic control in type 1 diabetes: meta-analysis of multiple daily insulin injections compared with continuous subcutaneous insulin infusion. *Diabet Med* 2008; **25**: 765
7. Miss ML, Egberts KJ, Page M, et al. Continuous subcutaneous insulin infusion (CSII) versus multiple daily injections for type 1 diabetes mellitus. *Cochrane Database Syst Rev* 2010; **1**: CD005103
8. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993; **329**: 977–86
9. Jackish BI, Wagner VM, Heidtmann B, et al. Comparison of Continuous Subcutaneous Insulin Infusion (CSII) and Multiple Daily Injections (MDI) in Paediatric Type 1 Diabetes: a multicenter matched-pair cohort analysis over 3 years. *Diabet Med* 2008; **25**: 80–5
10. Partridge HL, Kerr D. Advantages of Insulin Pump Therapy. *Diabet Med* 2009; **26**: 1306
11. Nixon R, Folwel R, Pickup JC. Variations in the quality and sustainability of long term glycaemic control with continuous subcutaneous insulin infusion. *Diabet Med* 2014; **21**: 1174–7
12. Orr CJ, Hopman W, Yen JL, et al. Long Term Efficacy of Insulin Pump Therapy on Glycaemic Control in Adults with Type 1 Diabetes. *Diabetes Technol Ther* 2015; **17**: 49–54
13. Clements M, Matuleviciene V, Attvall S, et al. Predicting the Effectiveness of Insulin Pump Therapy on Glycaemic Control in Clinical Practice: A retrospective Study of Patients with Type 1 Diabetes from 10 Outpatients Diabetes Clinics in Sweden over 5 Years. *Diab Technol Ther* 2015; **17**: 21–8

14. Jamil LH, Chindris AM, Kanwar RS. Glycaemic Control after Total Pancreatectomy for Intraductal Papillary Mucinous Neoplasm: An Exploratory Study. *HPB Surg* 2012; **2012**: 381328
15. Raskin P, Bode BW, Marks JB, et al. Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes: a randomized parallel-group, 24 week study. *Diabetes Care* 2003; **26**: 2598–603
16. Berthe E, Lireux B, Coffin C, et al. Effectiveness of intensive insulin therapy by multiple daily injections and continuous subcutaneous insulin infusion: a comparison study in type 2 diabetes with conventional insulin regimen failure. *Horm Metab Res* 2007; **39**: 224–9
17. Reznik Y, Cohen O, Aronson R, et al. Insulin pump treatment compared with multiple daily insulin injections for the treatment of type 2 diabetes (OpT2mise): a randomized open-label controlled trial. *Lancet* 2014; **384**: 1265–72
18. Perkins BA, Riddell MC. Type 1 Diabetes and Exercise: Using the Insulin Pump to Maximum Advantage. *Can J Diab* 2006; **30**: 72–9
19. Klingensmith GJ, Giordano BP, McCabe ER, et al. The use of insulin pump therapy in adolescents. *Pediatrician* 1983; **12**: 220–8
20. Joint British Diabetes societies for Inpatient Care Group. Self-Management of Diabetes in hospital. Leicester: NHS Diabetes, 2012
21. Reis JP, Pignatelli D, Madeira D, Castedo JL, de Oliveira MC. Subcutaneous insulin pump therapy in a diabetic patient submitted to major surgery. *Postgrad Med J* 1988; **64**: 335
22. White WA Jr, Montalvo H, Monday JM. Continuous subcutaneous insulin infusion during general anesthesia: a case report. *AANA J* 2004; **72**: 353–7
23. University of Virginia Health System. Preparing for Surgery. 2010. Available from <http://www.healthsystem.virginia.edu/internet/vasi/prep.cfm>
24. Centre for Healthcare Improvement. Patient Safety and quality improvement service. Inpatient guidelines: Insulin infusion pump management: The state of Queensland. Available from [https://www.health.qld.gov.au/cpic/documents/inpatient\\_guidelines.pdf](https://www.health.qld.gov.au/cpic/documents/inpatient_guidelines.pdf)
25. Glistner BC, Vigersky RA. Perioperative management of type 1 diabetes mellitus. *Endocrinol Metab Clin North Am* 2003; **32**: 411–36
26. Dinardo M, Donihi AC, Forte P, et al. Standardized Glycaemic Management and Perioperative Glycaemic Outcomes in Patients with Diabetes Mellitus who Undergo Same Day Surgery. *Endocr Pract* 2011; **17**: 404–11
27. Joint British Diabetes societies for Inpatient Care Group. Management of adults with diabetes undergoing surgery and elective procedures: improving standards. Report of a joint working party NHS Diabetes 2011. Available from [www.diabetologistsabcd.org.uk/JBDS\\_IP\\_Surgery\\_Adults\\_Full.pdf](http://www.diabetologistsabcd.org.uk/JBDS_IP_Surgery_Adults_Full.pdf)
28. Beaufriere B, Beylot M, Metz C, et al. Dawn phenomenon in type 1 (insulin dependent) diabetic adolescents: influence of nocturnal growth hormone secretion. *Diabetologia* 1988; **31**: 607–11
29. Shashaj B, Sulli N. Difference in insulin usage patterns with pubertal development in children with type 1 diabetes during transition from multiple daily injections to continuous subcutaneous insulin infusion (CSII) and through the CSII treatment. *Diabetes Technol Ther* 2009; **11**: 767–74
30. Rodrigues IA, Reid HA, Ismail K, Amiel SA. Indications and efficacy of continuous subcutaneous insulin infusion (CSII) therapy in Type 1 diabetes mellitus: a clinical audit in a specialist service. *Diabet Med* 2005; **22**: 842–9
31. National Institute for Clinical Excellence CG15 Type 1 diabetes in adults. Available from [www.nice.org.uk/GC15](http://www.nice.org.uk/GC15)
32. Royal College of Anaesthetists. Perioperative Medicine. The Pathway to Better Surgical Care, 2015
33. Boyle M, Seifert K, Beer K, et al. Guidelines for Application of Continuous Subcutaneous Insulin Infusion (Insulin Pump) Therapy in the Perioperative Period. *J Diabetes Sci Technol* 2012; **6**: 184–90
34. Desborough JP. The stress response to trauma and surgery. *Br J Anaesth* 2000; **85**: 109–17
35. Watts LF, Miller J, Davidson MB, et al. Perioperative management in diabetes mellitus. *Anesthesiology* 1981; **55**: 104–9.
36. Christiansen CL, Schurizek BA, Malling B, et al. Insulin treatment of the insulin-dependent diabetic patient undergoing minor surgery. Continuous intravenous infusion compared with subcutaneous administration. *Anaesthesia* 1988; **43**: 533–7
37. Raucoules-Aimé M, Lugrin D, Boussofara M, et al. Intraoperative glycaemic control in non-insulin-dependent and insulin-dependent diabetes. *Br J Anaesth* 1994; **73**: 443–9
38. Hemmerling TM, Schmid MC, Schmidt J, et al. Comparison of a continuous glucose insulin-potassium infusion versus intermittent bolus application of insulin on perioperative glucose control and hormone status in insulin-treated type 2 diabetics. *J Clin Anesth* 2001; **13**: 293–300
39. NICE-SUGAR Study Investigators Finfer S, Chittock DR, Su SY, et al. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med* 2009; **360**: 1283–97
40. Van den Bergh G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001; **345**: 1359–67
41. Van den Berghe G, Wilmer A, Hermans G, et al. Intensive insulin therapy in the medical ICU. *N Engl J Med* 2006; **354**: 449–61
42. Bowen DJ, Nancekievill ML, Procter EA. Peri-operative management of insulin-dependent diabetic patients. Use of continuous intravenous infusion of insulin-glucose-potassium solution. *Anaesthesia* 1982; **37**: 852–5
43. Thomas DJB, Platt HS, Alberti KGMM. Insulin-dependent diabetes during the peri-operative period. An assessment of continuous glucose-insulin-potassium infusion, and traditional treatment. *Anaesthesia* 1984; **39**: 629–37
44. Simmons D, Morton K, Lauhton SJ, et al. A comparison of two intravenous insulin regimens among surgical patients with insulin-dependent diabetes mellitus. *Diabetes Educ* 1994; **20**: 422–7
45. Tao J, Youtan L. Impact of Anaesthesia on Systemic and Cerebral Glucose Metabolism in Diabetes Patients Undergoing Neurosurgery. *J Diabetes Metab* 2013; **4**: 297
46. Fresa R, Visalli N, Di Blasi V, Cavallaro V, Ansaldi E. Experiences of continuous subcutaneous insulin infusion in pregnant women with type 1 diabetes during delivery from four Italian centers: a retrospective observational study. *Diabetes Technol Ther* 2013; **15**: e328–34
47. Ma D, Chen C, Lu Y, et al. Short term effects of continuous subcutaneous insulin infusion therapy in perioperative patients with diabetes mellitus. *Diabetes Technol Ther* 2013; **15**: 1010–18
48. Corney S, Dukatz T, Rosenblatt S, et al. Comparison of insulin pump therapy (continuous subcutaneous insulin infusion) to alternative methods for peri operative glycaemic management in patients with planned postoperative admissions. *J Diab Sci Technol* 2012; **6**: 1003–10