

Guidelines for Application of Continuous Subcutaneous Insulin Infusion (Insulin Pump) Therapy in the Perioperative Period

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Abstract

Case reports indicate that diabetes patients receiving outpatient insulin pump therapy have been allowed to continue treatment during surgical procedures. Although allowed during surgery, there is actually little information in the medical literature on how to manage patients receiving insulin pump therapy during a planned surgical procedure. A multidisciplinary work group reviewed current information regarding the use of insulin pumps in the perioperative period. Although the work group identified safety issues specific to surgical scenarios, it believed that with the use of standardized guidelines and a checklist, continuation of insulin pump therapy during the perioperative period is feasible. A sample set of protocols have been developed and are summarized. A policy outlining clear procedures should be established at the institutional level to guide physicians and other staff if the devices are to be employed during the perioperative period. Additional clinical experience with the technology in surgical scenarios is needed, and consensus should be developed for insulin pump use in the perioperative phases of care.

J Diabetes Sci Technol 2012;6(1):184-190

Introduction

An estimated 400,000 patients with diabetes mellitus in the United States are receiving continuous subcutaneous insulin infusion (CSII) therapy (also called insulin pump therapy) to achieve optimal glucose control.¹ With such a large number of insulin pump-treated patients, physicians

will be increasingly confronted with the challenge of managing therapy in different situations, including surgery. Limited case reports indicate that insulin pumps have been safely utilized during surgery.^{2,3} Some authors have suggested that, in principle, insulin pumps can be

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Abbreviations: (CSII) continuous subcutaneous insulin infusion, (PACU) postanesthesia care unit

Keywords: diabetes mellitus, insulin pump, perioperative care

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continued intraoperatively,^{4,7} although others believe that the patient should be disconnected from the device.⁸

Although CSII has been permitted during surgery, the experiences of patients, practitioners, and other staff with insulin pumps under surgical conditions are under-reported. Little data exist on current hospital practices and the use of insulin pumps during surgery, and there is no published information on how many patients using insulin pumps actually undergo surgery each year. Validated strategies for maintaining insulin pump systems during surgery are lacking, and best practices for managing insulin pumps in the perioperative period do not exist. While there are limited guidelines on the use of insulin pumps during surgery,^{6,7,9} a comprehensive set of recommendations have not been developed, and a broader discussion of the topic has not taken place.

Although intended primarily for use in the ambulatory setting, insulin pump technology is now appearing in clinical situations for which they were not originally intended. One example is the inpatient environment. Recognizing this, a strategy on how to use CSII therapy in the inpatient setting has been published.¹⁰ Follow-up analyses indicated that this approach successfully identifies patients who can continue to use insulin pumps in the hospital and that staff and patient compliance with required procedures is generally high.¹¹⁻¹³ The authors' experiences with inpatient CSII therapy¹¹⁻¹³ has served as a model for constructing processes related to perioperative management of insulin pump therapy. These protocols, along with a brief discussion of some of the safety issues related to perioperative pump use, are summarized here.

Why Are Guidelines Needed for CSII Therapy in the Perioperative Setting?

Lack of standardization of care

An analysis from our institution of 50 surgical cases involving patients on insulin pump therapy from 2006 through 2010 demonstrated wide variation in perioperative management.¹⁴ Documentation of the status of the insulin pump during the perioperative period was inconsistent, and it was unclear in most cases if the pump remained operational during the procedure itself. Moreover, intraoperative glucose monitoring occurred in only 60% of cases, despite the anesthesia duration lasting nearly 3 hours on average.¹⁴ This data confirmed the need to implement processes of care related to

the perioperative use of insulin pumps. Standardized procedures could eliminate intra-institutional variation in practice and possibly inter-institutional variations if standards are adopted. The safety of insulin pump use during perioperative care (if such therapy is going to be permitted) could be maximized.

Complexity and Heterogeneity of Patients and Surgical Procedures

The medical complexity of the patients themselves and the heterogeneity of surgical scenarios must be considered when addressing the use of an insulin pump during the perioperative period. These complexities create challenges in devising a standardized approach. Patients who use an insulin pump may have complications from diabetes or other comorbidities that increase surgical risk. Surgical procedures vary in type (e.g., elective vs. emergent), duration, and time needed for anesthesia. Other patients may need surgical procedures while they are already hospitalized. Thus, institutional guidelines for perioperative care of the patient receiving CSII therapy need to be applicable to all surgical scenarios, including elective, inpatient, and emergent settings.

Other Insulin Pump Safety Issues

Other considerations must be taken into account when standards are developed for use of insulin pumps during surgery. Patient movement could inadvertently disconnect the insulin pump catheter. Hence, it is important to inspect the pump insertion site and its connection to the device before, during, and after the procedure. For emergent procedures, it may be more prudent to remove the insulin pump. In those situations, the patients are probably seriously ill and may benefit more through use of intravenous insulin infusion to control blood glucose levels.

Another consideration is intraoperative radiography. Pump manufacturers recommend that the pump be placed out of range of radiation. Typically, the need for radiography is known beforehand, so the device can be disconnected and removed from the operating room according to the pump manufacturers' recommendation, if desired. Alternatively, the pump could simply be covered with a lead shield. Electrocautery may increase the risk of pump damage. For a specific brand of pump, electrocautery may or may not be an issue, so any guidelines or policy should include provisions to determine the manufacturer's recommendations for use of the specific pump during surgery.

Proposed Perioperative CSII Procedures

Recognizing a need to standardize care, the institution formed a multidisciplinary work group comprised by the authors to discuss guidelines for the use of CSII therapy during the perioperative period. The work group discussed institutional experiences with insulin pump use in the surgical patient and believed that the technology could be allowed. Safety data on insulin pumps in the perioperative period is lacking, and no information exists on whether CSII is effective in controlling intraoperative hyperglycemia. Therefore, it was not the intent of the work group to advocate for or against perioperative CSII use, but simply to acknowledge that such scenarios will arise and that a consistent approach to care was needed. The patient, hospital, and practitioners involved with the patient's care would need to collaborate on CSII therapy decision making during surgery, and that such interaction, along with a standardized approach to care, could provide a safer environment for patients if the decision was made to allow the technology into the operating room. However, if an institution decides that all CSII therapy should be discontinued for surgery, the facility must develop and implement protocols for alternative methods of insulin delivery to manage hyperglycemia in those patients.

The work group comprised representatives from endocrinology, general internal medicine, surgery, family medicine, anesthesiology, quality management, and nursing education. Perioperative care was considered to include four segments or phases: preadmission, preoperative, intraoperative, and postanesthesia. The work group met monthly to discuss policy development and the final policy and protocol were finalized after iterative cycles of review and revision. The suggested procedures that the work group developed and believed should occur during each of these segments are outlined.

Preadmission Procedures

The work group felt that a process should be put in place for pre-procedure contact with the patient so that CSII management in the perioperative period could be discussed. Suggested preadmission procedures are summarized in **Table 1**. This would allow documentation of the diabetes and insulin pump history (particularly if the patient's diabetes was not managed at the Mayo Clinic, Arizona).

Whenever possible, the patient's primary outpatient team managing the patient's diabetes and insulin pump

should be informed about the upcoming surgery so that the patient can be contacted and given suggestions for managing the pump or using alternative insulin treatment if the device will be disconnected. At Mayo Clinic Arizona, for instance, when a patient who uses an insulin pump is scheduled for elective surgery, the preadmission nurse must notify the endocrinology service through an electronic distribution list at least 24 hours before the procedure. One of the endocrinology providers contacts the patient to obtain an updated history (including current pump settings), to remind the patient to bring personal supplies in case the patient is hospitalized post-operatively, and to ask the patient to insert the infusion set outside the surgical field as appropriate. This contact with recommendations is documented in the electronic medical record. In more general terms, if an institution did not have access to endocrine specialty care, contact should be made with the patient's primary diabetes care provider (**Table 1**).

Preoperative, Intraoperative, and Postanesthesia Procedures

Suggested preoperative, intraoperative, and postanesthesia procedures are listed in **Table 2**. Throughout the entire process, proper operation of the pump should be confirmed. In the preoperative area, the nurse should check a point-of-care (bedside) blood glucose level and notify the anesthesiologist or surgeon if it is a critical

Table 1.
Suggested Preadmission Procedures Before Elective Surgery for Patients Receiving Insulin Pump Therapy

Preadmission nurse notifies the primary diabetes care provider when a patient using an insulin pump is scheduled for planned or elective surgery

Before the surgery date, the primary diabetes care provider contacts the patient to do the following:

- Verify basal rate settings and insulin to carbohydrate ratio, correction factor, and type of insulin used in pump
- Obtain recent blood glucose levels and information about episodes of hypoglycemia
- Remind patient to bring additional insulin and pump supplies to the hospital
- Remind patient to place a new pump infusion set away from the surgical site within 24 hours before surgery (for an abdominal procedure, the infusion set should be inserted in the arm or leg)
- Review institutional requirements for continued use of insulin pump in the event of admission
- Advise patient to identify self as an insulin pump user at admission for surgery

The primary diabetes care provider recommends insulin pump settings to the patient before surgery

value. The pump site is documented by the nurse and its function confirmed with the patient. In addition, the anesthesiologist should document the patient's history of diabetes, the insulin pump, and plan regarding its use intraoperatively. If the insulin pump is removed, the pump should be labeled with the patient's identifying information and placed with the patient's belongings until the appropriate time to return it to the patient. If the pump is disconnected, alternative insulin therapy must be provided.

In the operating room, the anesthesia team assumes responsibility for the insulin pump. The anesthesiologist should assess the insulin pump infusion site. If the patient arrives in the operating suite with the insulin infusion set in the surgical area, the pump is removed and insulin is administered at the direction of the anesthesiologist. A glucose level should be checked every hour during surgery and corrective doses of insulin given at the direction of the anesthesiologist (Table 2).

When the patient arrives in the postanesthesia care unit (PACU), the nurse confirms that the insulin pump is functioning, ensures that the infusion set is intact, and checks the point-of-care blood glucose level hourly. Critical values are reported to the surgical or anesthesia team. If pump therapy was discontinued during surgery, the surgical team is contacted for further insulin orders. At Mayo Clinic, Arizona, patients admitted post-operatively are transitioned to inpatient insulin pump therapy according to established policy.¹⁰ If the patient is discharged home from the PACU, and if the insulin pump was removed during surgery, the patient and the family or caregiver should be instructed to resume insulin pump therapy when the patient is alert and able to operate the device (Table 2). If insulin pump therapy was continued, the instructions should include contacting the primary diabetes care team for further direction.

Outcome Measures, Challenges, Limitations, Implementation, and Progress

Proposed Metrics

A set of metrics have been developed for future analysis to determine whether the perioperative insulin pump procedures are successful (Table 3). The metrics include demographic information, disease characteristics (diabetes type and duration), and pump characteristics (duration of therapy, manufacturer, and insulin type). The characteristics of the surgery will also be tracked (e.g., type of surgery, duration of surgery, and time under anesthesia).

Table 2.
Preoperative, Intraoperative, and Postanesthesia Procedures for Patients Continuing Insulin Pump Therapy During Elective Surgery

| |
|---|
| Preoperative phase |
| Nurse checks point-of-care blood glucose level and informs anesthesia or surgical team if it is a critical value |
| Nurse assesses and documents the insulin pump infusion site and location |
| Nurse confirms with patient that the insulin pump is working, and if assistance is needed, the nurse calls the primary diabetes provider or the customer service number on the back of the insulin pump |
| The anesthesiologist should document the patient's history of diabetes, the insulin pump, and the plan regarding its use intraoperatively |
| If the insulin pump is not functioning, the anesthesiologist is notified for further orders |
| If the insulin pump is removed, the pump is labeled with a patient label and is placed with the patient's belongings until the appropriate time to return it to the patient |
| Intraoperative phase |
| The anesthesiologist assesses the insulin pump infusion site |
| When the patient arrives in the operating room, the nurse or anesthesiologist confirms that the insulin pump is functioning and that the infusion set is intact |
| If the patient arrives in the operating room with the insulin infusion set in the surgical field, the pump is removed and insulin is administered at the direction of the anesthesiologist |
| Blood glucose level is checked every hour during surgery |
| Corrective doses of insulin are given at the direction of the anesthesiologist |
| Postanesthesia phase |
| When the patient arrives in the postanesthesia care unit (PACU), the nurse confirms that the insulin pump is functioning and that the infusion set is intact |
| Point-of-care blood glucose level is checked upon arrival and hourly if applicable |
| If a glucose value is critical, the nurse notifies the anesthesia or surgical team and insulin is administered as ordered |
| If the patient requires hospital admission, pump therapy is continued according to institutional policy |
| If the patient is discharged home from the PACU and the insulin pump was removed during surgery, the patient and the family or caregiver are instructed to resume insulin pump therapy when the patient is alert and able to operate the pump |
| If the patient is discharged home from the PACU and the insulin pump therapy was continued, further instruction on insulin administration is obtained from the patient's primary diabetes care provider |

Staff documentation related to the insulin pump will be recorded as well as the disposition of pump therapy

(i.e., continued or discontinued). Adherence to glucose measurements and the glucose values will be tracked. Discharge disposition (i.e., admitted or not admitted) after the procedure will also be recorded.

Challenges

Experiences with implementing the inpatient CSII policy¹⁰⁻¹³ have allowed the authors to anticipate potential challenges related to the introduction of an approach to perioperative insulin pump management. One of the foremost challenges will be the need for ongoing staff education to ensure adherence to protocols. During implementation of the inpatient insulin pump policy, education of the entire hospital nursing staff was required because patients with insulin pumps are admitted to any unit. However, staff education for the perioperative pump procedures will be somewhat easier because it will be limited to a smaller number of perioperative staff. The education process (accomplished through a series of briefings with the perioperative and nursing staff), was carried out by work group members belonging to the Departments of Clinical and Patient Education, Endocrinology, Surgery, and Anesthesiology. Nonetheless, with staff turnover (e.g., as new surgical resident physicians begin their training), ongoing education will be necessary.

Based on their experience with the use of inpatient insulin pumps, work group members anticipate that another challenge will be in identifying every patient with an insulin pump who has undergone surgery. The current method of tracking patients depends on the endocrinology team being notified before surgery so that information can be entered into the database. However, this is not likely to happen in every instance, and some cases may be missed for analysis. From a diagnostic coding perspective, patients with insulin pumps are comingled with the general population of diabetic inpatients (i.e., they currently do not receive a unique diagnostic code that distinguishes them from other diabetic patients). Applying existing diagnostic codes to CSII users would allow for easier identification in an electronic database for future retrospective analysis. Ongoing education of preadmission staff about this policy will ensure that the endocrinology service will be notified on all pump patients so that they can be contacted before the procedure and outcomes tracked.

Limitations

The perioperative insulin pump procedures proposed here do have certain limitations. First, the procedures were designed from the experiences and capabilities of the

Table 3.
Planned Metrics for Tracking Perioperative Insulin Pump Cases

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|---|
| Demographics (age, sex, race/ethnicity) |
| Disease characteristics |
| Diabetes type |
| Diabetes duration |
| Preoperative hemoglobin A _{1c} level |
| Insulin pump history |
| Duration of pump therapy |
| Insulin type |
| Pump manufacturer |
| Characteristics of surgery |
| Type of procedure |
| Duration of procedure |
| Duration of anesthesia |
| Contact with primary diabetes provider before surgery |
| History of insulin pump therapy documented in anesthesiology preoperative notes |
| Presence and location of insulin pump documented in preoperative, intraoperative, and postanesthesia recovery areas |
| Pump therapy status (continued or discontinued) |
| Glucose values |
| Discharge disposition (admitted or sent home) |

Mayo Clinic, Arizona. Because the facility is an adult acute care hospital, guidelines were not developed for the pediatric, adolescent, and obstetrical diabetes populations receiving CSII therapy. Second, the policy and processes outlined here are meant to apply to insulin pump users undergoing elective surgical procedures, rather than other types of procedures (e.g., colonoscopies, outpatient ophthalmologic or dermatologic operations). However, the general approach outlined should be adaptable to those patient types.

Implementation and progress

These procedures have been outlined in a formal written policy and have been reviewed and approved by the necessary institutional committees (e.g., Surgical Subcommittee, Legal Department).

Documentation and assurance of necessary procedures may be best accomplished through use of a checklist (Figure 1). This checklist is currently being incorporated into the electronic medical record. Besides improving patient safety, a dedicated perioperative checklist for

Sample Perioperative Insulin Pump Checklist

Preoperative

1. Insulin pump connected? Y N
 - a. Location of pump? _____ Outside of surgical scrub area? Y N
 - b. Current basal rate (per patient) _____
 - c. Anesthesiologist notified? Y N
 - 1) Leave pump on during surgery? Y N
 - 2) If pump will be off, what is the alternative insulin regimen? _____
2. POC blood glucose measurements
 - a. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
 - b. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____

Intraoperative

1. Insulin pump connected? Y N
 - a. If not connected, what is the alternative insulin regimen? _____
 - 1) Insulin drip? Y N Rate? _____ Time? _____
 - 2) Regular insulin boluses? Y N
 - b. If connected, location of pump? _____ Infusion rate? _____
2. POC blood glucose measurements
 - a. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
 - b. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
 - c. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
 - d. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
3. Pump complications during surgery? Y N Explain (if yes) _____
4. If insulin drip used, was rate changed during surgery? Y N
 - a. Rate _____ Time _____
 - b. Rate _____ Time _____

Postanesthesia

1. Insulin pump connected? Y N
 - a. Location of pump? _____
 - b. Infusion rate? _____
2. POC blood glucose measurements
 - a. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____
 - b. Glucose_{POC} = _____ Time _____ Insulin given? Type _____ Amount _____

Figure 1. Sample Perioperative Insulin Pump Checklist. N, no; POC, point-of-care; Y, yes.

patients receiving insulin pump therapy would permit easier data extraction to assess compliance with required procedures. A patient registry with the above metrics has been developed and baseline data has been collected that will allow future analysis of the impact of the new set of procedures on surgical insulin pump care.¹⁴ Formal education of the nursing, midlevel, and physician staff associated with the anesthesia and surgical departments is underway.

Conclusions

Insulin pumps have become a common and important adjunct of diabetes management. Although steps have been outlined to guide patients and staff, the decision to continue insulin pump therapy intraoperatively depends ultimately on the surgical and anesthesiology teams and on what they think is best for patient safety. The decision to allow insulin pump treatment during

surgery should be discussed with the patient at the outset and expectations identified. Similar to the approach taken to implementing an inpatient insulin pump policy, a successful approach to perioperative insulin pump use will depend on a collaborative relationship among the patient, the hospital staff, the patient's diabetes care provider, and the multiple other disciplines involved with the patient's care. Ongoing data collection will allow a future assessment of the effectiveness of the newly developed policy and procedures. Future studies should examine whether allowing perioperative use of insulin pumps offers better intraoperative glucose control compared with other methods (e.g., intravenous insulin infusions). With the lack of data and consensus in the literature, a broader dialogue on this topic is needed, especially as the number of CSII users in the United States continues to increase.

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