Update on a Quality Initiative to Standardize Perioperative Care for Continuous Subcutaneous Insulin Infusion Therapy

Journal of Diabetes Science and Technology
2015, Vol. 9(6) 1299–1306
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DOI: 10.1177/1932296815592027
dst.sagepub.com

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Abstract

Objective: The objective of the analysis was to review the effectiveness of a care process model (CPM) developed to guide management of patients on insulin pump therapy undergoing elective surgical procedures.

Methods: Electronic medical records were reviewed to assess the impact of the CPM on documentation of insulin pump status, glucose monitoring, and safety during the perioperative phase of care. Post-CPM care was compared with management provided before CPM implementation.

Results: We reviewed 45 cases on insulin pump therapy in the pre-CPM cohort and 106 in the post-CPM cohort. Demographic characteristics, categories of surgery, and perioperative times were not significantly different between the 2 groups. Recommended hemoglobin A1c monitoring occurred in 73% of cases in the pre-CPM cohort but improved to 94% in the post-CPM group ($P < .01$). There was a higher frequency of documentation of the insulin pump during the preoperative, intraoperative, and postanesthesia care unit segments of care in the post- vs pre-CPM periods (all $P < .01$). The number of cases with intraoperative glucose monitoring increased (57% pre-CPM vs 81% post-CPM; $P < .01$). Glycemic control was comparable between the 2 CPM periods. Hypoglycemia was rare, with only 3 episodes in the pre-CPM group and 4 in the post-CPM. No adverse events associated with perioperative insulin pump use were observed.

Conclusions: This analysis adds to previous data on use of insulin pump therapy during the perioperative period. Some processes require additional attention, but data continue to indicate that a standardized approach to care can lead to a successful and safe transition of insulin pump therapy throughout the perioperative period.

Keywords

CSII, insulin pump, perioperative, surgery, diabetes mellitus

Continuous subcutaneous insulin infusion (CSII) therapy (commonly termed *insulin pump therapy*) is used to treat outpatients with type 1 and type 2 diabetes mellitus. An estimated 400 000 US patients now use CSII for management of their diabetes.¹ Insulin pump technology is intended for use in ambulatory patients, but it is now being encountered by practitioners in scenarios beyond the outpatient setting. Consequently, health care personnel who most likely have little familiarity with the technology are increasingly being

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confronted with how to manage CSII-treated patients in these situations.

No data exist on how many patients on outpatient CSII treatment undergo surgical procedures annually. Although it is likely an uncommon scenario, it has the potential to create confusion among the perioperative staff. The surgical and anesthesiology teams have the option of either disconnecting patients from their devices and using alternate means for managing hyperglycemia, or allowing patients to wear the devices during the procedure. Emerging data indicate that insulin pumps can be safely allowed in the operating suites and may provide glucose control comparable to intravenous insulin infusions.²⁻⁴ Individual institutions are now developing care process models (CPMs) to provide guidance on use of CSII during the perioperative phase of surgical care,^{3,5} although some still recommend disconnecting the pump for procedures lasting longer than 3 hours.⁶

Despite rising interest in this topic, consensus strategies for maintaining insulin pump systems during surgery continue to lag, and subspecialty organizations and experts remain silent on the topic.⁷⁻¹¹ Previous work from the authors' institution with regard to use of perioperative CSII devices uncovered suboptimal documentation of whether the insulin pump was present and insufficient frequency of intraoperative glucose monitoring.¹² Lack of documentation suggests lack of staff awareness, and infrequent glucose monitoring risks that extremes in glucose levels will be missed—both potential safety issues. Other safety concerns include inadvertent dislodgement or disconnecting of the device, failure to move the insertion site out of the surgical field, and trauma to the insulin pump during transition of the position throughout the perioperative phase of care.

Because of the lack of consensus guidelines, a requirement to provide a structured approach to management to ensure patient safety, and the need to close gaps in our own institutional surgical care of the technology,¹² we developed a CPM that allowed CSII treatment to be transitioned through the different segments of perioperative care.⁵ Initial reports immediately after implementation of the CPM were positive in that necessary elements of management were being accomplished and that CSII therapy appeared to be safe during the perioperative period.² We now report on the longer-term performance of the CPM after being applied to a larger number of cases.

Methods

Overview of CPM

The CPM for management of CSII therapy in the surgical patient (Figure 1) was conceived as occurring in 2 phases: a preadmission phase and a perioperative phase. The perioperative phase was subdivided into 3 segments as previously defined: preoperative, intraoperative, and postanesthesia care unit (PACU). The perioperative period was defined as

the time from patient admission to the preoperative suite to the time of discharge from the PACU.^{12,13} Each of these perioperative segments include transition points in the care of the patient on CSII therapy, during which the status of the insulin pump and glycemic control should be assessed and documented.

Preadmission procedures included (1) ensuring that a hemoglobin A1c (HbA1c) value was available within 90 days before the procedure and (2) notifying the endocrinology service that a CSII patient was about to undergo surgery. This occurred via email from the preadmission nurse at least 24 hours before the procedure. The rationale for checking HbA1c relates to recent findings correlating elevated HbA1c value with adverse surgical outcomes.¹⁴⁻¹⁹ Per institutional policy, patients with values >8.0% are at risk for cancellation of their procedure, although there were no instances of this occurring in the post-CPM cohort.

During the pre-CPM period, patients with diabetes mellitus on CSII undergoing surgery were frequently identified only after hospital admission, with inconsistent notification of the endocrinology team. Consequently, cases that might have benefited from specialty input could have been missed. A nurse practitioner from the endocrinology team now contacts the patient after notification from the preadmission nurse. Patients are asked about their diabetes type and duration, their current glucose control, length of time that they have been using an insulin pump, the pump brand, current pump rates, settings, and brand of insulin used. The patient is asked to insert the infusion set outside the surgical field as appropriate. The institutional inpatient insulin pump procedures are reviewed with the patient and the patient is reminded to bring insulin pump supplies in the event that he/she requires admission following the procedure. The phone contact is documented in the electronic medical record.

Each segment of perioperative care should include documentation in the electronic medical record of the status of the insulin pump connection (ie, connected vs disconnected), whether the pump is infusing, and location of the insertion site (to document that it was placed outside the surgical area). Continued use of CSII treatment is approved by anesthesiology, and an order is documented in the preoperative area as to whether to continue use of the device. Intraoperative documentation of the insulin pump is required if the therapy is continued. If the pump has been disconnected, the device should be labeled and stored with the patient's belongings and alternative insulin orders must be provided.⁵ Finally, glucose monitoring is required in all 3 segments. Intraoperatively, glucose must be monitored hourly for procedures lasting 60 minutes or longer (Figure 1).⁵ For patients remaining on CSII, subcutaneous correction insulin was provided according to the institutional algorithm in the event that additional hyperglycemia therapy was necessary. There has been ongoing education of the anesthesiology and surgical staff of the required processes since implementation of the CPM. If a

Figure 1. Care process model for perioperative use of CSII. ^aPOC-BG to be measured at least hourly. CSII indicates continuous subcutaneous insulin infusion.

record review revealed a gap (eg, failure to document the status of the insulin pump), feedback has been given to the staff as a reminder regarding the necessary procedures. If the patient was admitted, inpatient procedures regarding continued CSII use were followed (Figure 1).²⁰⁻²⁴

Patient Selection

Analyses were restricted to ambulatory patients on CSII therapy undergoing elective surgery requiring general anesthesia. All patients were nonpregnant adults 18 years of age or older. Cases were reviewed from August 1, 2006, through February 28, 2011 (pre-CPM implementation) and from March 1, 2011, through December 31, 2014 (post-CPM implementation).

Data Analysis

Because a patient may have undergone more than 1 surgical procedure within the analytic period, each surgical encounter represented an opportunity to apply the correct processes and therefore was treated as an independent observation and unit of analysis, as previously described.² Each phase of care was reviewed in the electronic medical record to determine whether the protocols required in the CPM had been followed. For purposes of this analysis, the 2 outcomes of primary interest were documentation of the device and performance of glucose monitoring during the different segments of the perioperative period.

In abstraction of data from the electronic medical record, notation of the insulin pump by the staff was recorded as

Table 1. Characteristics of Patients With Diabetes on CSII Therapy Undergoing Elective Surgical Procedures.

Variable ^a	Pre-CPM cohort (n = 45)	Post-CPM cohort (n = 106)	P value
Age, mean (SD), years	57 (13)	54 (15)	.20
Male sex	23 (51)	55 (52)	.93
White race	45 (100)	100 (94)	.10
Type 1 diabetes	32 (71)	80 (75)	.70
Diabetes duration, mean (SD), years ^b	28 (13)	26 (14)	.50
Duration of CSII therapy, mean (SD), years ^c	6 (6)	8 (7)	.06
Body mass index, mean (SD), kg/m ²	30 (8.8)	30 (7.2)	.92
Established outpatient with endocrinology before surgery	29 (64)	51 (54)	.13
Hemoglobin A1c, mean (SD), % ^d	8.1 (1.2)	7.2 (0.8)	<.01
Type of surgery ^e			.13
Cardiothoracic	3 (7)	2 (2)	
Colorectal	0 (0)	3 (3)	
General surgery	9 (20)	15 (14)	
Gynecology	1 (2)	5 (5)	
Neurosurgery	1 (2)	8 (8)	
Orthopedic	17 (38)	29 (27)	
Otolaryngology	2 (4)	9 (8)	
Plastic	0 (0)	4 (4)	
Transplant	0 (0)	4 (4)	
Urology	7 (16)	18 (17)	
Vascular	5 (11)	9 (8)	
Total perioperative time, mean (SD), min	435 (134)	399 (148)	.13
Hospitalized after procedure	33 (74)	52 (49)	.01

Abbreviations: CPM, care process model; CSII, continuous subcutaneous insulin infusion.

^aValues are number (percentage), unless indicated otherwise.

^bAvailable in 44 of the pre-CPM cohort and in all of the post-CPM cohort.

^cAvailable in 41 of the pre-CPM cohort and in 67 of the post-CPM cohort.

^dPreoperative values available in 26 of the pre-CPM cohort and in 69 of the post-CPM cohort.

^eMay not sum to 100% because of rounding.

“documented” or “not documented.” Of particular interest was determining if the device was present in the operating suite, with the goal being direct documentation of the presence of the device by the providers. We noted any patient complications or adverse events that were specifically associated with the insulin pump.

Pre-CPM and post-CPM findings were compared. As this analysis was restricted to those patients undergoing elective procedures, the pre-CPM sample size was less the 50 previously reported, which included even cases undergoing urgent procedures.² Data are reported as mean (SD) or number (percentage), where applicable. Statistical differences in continuous variables were assessed via both parametric and nonparametric means with identical statistical conclusions. Therefore, differences between continuous variables are reported with *t* tests and differences in categorical variables were evaluated via χ^2 tests. Earlier analyses were deemed minimal risk by the Institutional Review Board and required periodic renewal,^{2,12} but recent reevaluation designated the project as quality improvement and no longer requiring review.

Results

Patient and Surgical Characteristics

After applying selection criteria (elective procedures involving general anesthesia), 45 surgical cases involving diabetes patients on CSII therapy were identified during the pre-CPM period and 106 cases in the post-CPM period (Table 1). Mean HbA1c was significantly lower in the post-CPM cohort than in the pre-CPM cohort; otherwise, demographic characteristics (eg, age, sex, race, duration of diabetes, duration of insulin pump therapy, body mass index) were comparable between the 2 groups. Many patients were already established with the institutional endocrinology outpatient department before surgery, and the proportion of such patients was similar in the pre-CPM and post-CPM periods.

The categories of surgical procedures were similar between the pre-CPM and post-CPM cohorts (Table 1) and spanned most surgical specialties. The top 3 categories of surgery in both cohorts were orthopedic, general surgical, and urologic. Total perioperative time was similar in the pre-CPM and post-CPM cohorts. A lower percentage of cases

Figure 2. Documented presence of CSII therapy by staff during the preoperative, intraoperative, and PACU segments of care. CPM indicates care process model.

required hospitalization in the post-CPM cohort. The post-CPM cohort included 4 patients undergoing elective living donor renal transplants.

Preadmission Procedures

The availability of HbA1c results improved significantly after implementation of the CPM, increasing from 73% of cases in the pre-CPM period to 94% of cases in the post-CPM period ($P < .01$). Preoperative contact with the patient by the endocrinology service was made in 87% of cases after CPM implementation. In the remaining cases, contact was attempted but was unsuccessful.

Perioperative Documentation of Insulin Pumps

We examined the documentation of the presence of the insulin pump during the preoperative, intraoperative, and PACU segments of care (Figure 2). There was a significant improvement in how well the presence of the pump was documented by staff when the patient was in the preoperative area. During the preoperative segment, 12 total patients in the post-CPM cohort were disconnected from the device and 1 placed in suspend. Patients who disconnected in the post-CPM did so at their preference, and all had preoperative phone contact with the endocrine team. In the PACU an additional 5 patients elected to disconnect and 2 were in suspend mode. There was 1 noted as having been disconnected in the pre-CPM cohort but documentation was poorer in this group. Excluding those cases that either were disconnected or placed their pump in suspend, there was a significant post-CPM improvement in documentation of the presence of the pump during all perioperative segments of care (Figure 2).

Figure 3. Frequency of preoperative, intraoperative, and PACU glucose measurements. For assessment of intraoperative glucose monitoring, only procedures lasting ≥ 60 minutes were considered. CPM indicates care process model.

Glucose Monitoring, Glucose Control, and Adverse events

After implementation of the CPM, the intraoperative segment of care showed a significant improvement in glucose monitoring (Figure 3) for patients with procedures lasting ≥ 60 minutes. No significant changes occurred during the preoperative and PACU segments, but both already had high compliance even during the pre-CPM period. Glucose monitoring overall was primarily via point-of-care blood glucose (POC-BG) testing, with 84% of values in the preoperative area, 98% intraoperatively, and 99% in the PACU being obtained via that method. In the pre-CPM and post-CPM cohorts, respective mean (SD) POC-BG values were 171 (66) and 167 (67) mg/dL during the preoperative segment of care and 179 (53) and 174 (51) mg/dL in the PACU ($P > .57$ for both). For patients who had surgical procedures lasting ≥ 60 minutes, mean intraoperative POC-BG was 172 (54) mg/dL and 176 (57) mg/dL in the pre-CPM and post-CPM groups, respectively ($P > .13$). Hypoglycemic events were rare, with only 3 episodes in the pre-CPM group and 4 in the post-CPM. No adverse events or safety issues were documented for any of the patients during any segment of perioperative care. There were no reports describing devices becoming inadvertently disconnected, devices damaged, catheters being kinked and infusions being interrupted, or insulin pumps being misplaced for those patients who were intentionally disconnected.

Discussion

Data on use of CSII in the perioperative period are limited, and no consensus guidelines on use of insulin pumps during surgery are available. Recent data suggest that CSII therapy

can be used safely throughout the perioperative period.²⁻⁴ The perioperative phase of surgery is characterized by a series of transitions, beginning with admission to the preoperative area, transfer to the operative suite, transfer to recovery, and then discharge either to home or to the inpatient setting. Each of these transitions has the potential to incur risk to the patient. In addition, the prolonged patient incapacitation due to anesthesia, and the absence of documentation and glucose monitoring, all contribute to a potentially high risk situation. If institutions are going to permit use of insulin pumps during surgery, there must be a set of procedures in place for patients and staff to follow to ensure patient safety.

Given the lack of consensus guidelines, a CPM was developed for patients on CSII therapy undergoing elective surgery. The CPM provided options for patients and staff regarding management of patients with insulin pumps and was intended to close previously identified gaps in care.^{5,12} To our knowledge, this report provides data on the largest number of surgical cases on CSII therapy. The data show improvements in care processes but also highlights some areas needing continued attention. The data also shows the complexity of the scenarios, with some patients voluntarily disconnecting from their devices while most remained on treatment. If steps had not been taken to standardize and improve documentation and monitoring, those situations in which the pump was disconnected could have gone unnoticed, resulting in potentially high glucose levels that might have gone untreated. Given the similarity in surgical services and perioperative length between the pre- and post-CPM cohorts, the data appears to be applicable to all elective surgical types and independent of length of procedure.

As part of the CPM, certain preadmission procedures were required. HbA1c measurement, an indicator of outpatient glycemic control, was recommended as part of the preoperative assessment, and the proportion of cases with this measure obtained increased significantly with implementation of the CPM. Lower HbA1c may be associated with better surgical outcomes, but data are limited.^{14,15} Measuring HbA1c is valuable because it identifies patients with chronic severe hyperglycemia, assists the surgical and anesthesia teams with decisions about proceeding with an elective procedure, and helps anticipate the degree of hyperglycemia perioperatively.

Preadmission contact was attempted in all patients before surgery and was successful in nearly all. Preadmission contact with the patient is of value to both the patient and endocrine specialty team, particularly if the patient requires admission and if the patient is not previously followed by the institution for diabetes care. Some prior history on the patient would facilitate a smoother transition to the hospital in the event that an admission is required. Preoperative contact is an opportune time to educate the patient on the inpatient insulin pump policy outside of the surgical day which is often accompanied by increased stress, unfamiliar transitions, and the

effects of anesthesia and pain medications. By reminding patients to insert the pump site outside of the surgical field and to bring additional pump supplies in case of inpatient admission, it is more likely the patient will be able to continue use of the pump throughout the perioperative and inpatient period; thus ensuring a smoother transition and discharge.

One of the areas in need of greatest improvement was documentation of the status of the CSII device. This documentation serves as the staff's acknowledgment of the insulin pump and how the patient's glucose levels are being managed. By requiring an assessment during each segment of perioperative care, we hoped to increase awareness and vigilance regarding the technology on the part of the staff so that potential problems could be avoided. A minority of patients disconnected from their insulin pump. The goal is to have 100% documentation indicating whether the patient was utilizing the insulin pump throughout the perioperative area. Although this goal was not yet achieved and requires additional reinforcement via staff education, the level of documentation definitely increased in both the intraoperative and PACU segments of perioperative care. In particular, a better understanding of the intraoperative status of the insulin pump was gained.

Another previously identified gap in perioperative management of CSII-treated patients was the low frequency of intraoperative glucose monitoring.⁵ As with documentation of the presence of the insulin pump, the goal is to have glucose measurements in all patients. The frequency of glucose monitoring was high in the preoperative and PACU areas, but further improvement is needed to reach the goal of 100% of cases. Progress was made with intraoperative glucose monitoring, with a significant increase in cases having their glucose levels measured. However, like the preoperative and PACU segments of care, ongoing staff education is needed to ensure that all CSII-treated patients have glucose monitoring performed, particularly those undergoing procedures lasting an hour or more.

The glucose measurements obtained in nearly all the perioperative segments were POC-BG values. Commercial glucose meters currently used in hospitals are known to be less accurate than laboratory-based analyses.²⁵⁻²⁷ Sampling source (eg, arterial, venous, or capillary blood) can also lead to variability in results.^{28,29} Nonetheless, any extreme or questionable values by POC-BG could always be confirmed via laboratory testing if needed. Our prior report identified a paucity of POC-BG devices in the operating suites, which was subsequently corrected.¹³ Despite its possible inaccuracies, increased availability of POC-BG testing capabilities seemed to facilitate more frequent glucose monitoring.

Although this report represents an analysis of the largest sample of perioperative CSII use to date, this clinical scenario is unlikely to be commonly encountered, and our experience with inpatient insulin pump management indicates that data accrual will have to occur over a prolonged period to fully assess safety and to determine the impact of the CPM on the

care of patients using insulin pumps.²⁰⁻²⁴ This reports a standardized approach from 1 institution, and experiences from other institutions with perioperative CSII management are needed and would contribute greatly to our understanding on how to approach care of these patients. Reviewing and aggregating these different institutional experiences would facilitate development of more generalizable recommendations.

This analysis should be viewed in the larger context of institutional efforts to improve perioperative care of all patients with diabetes, of which CSII users are a subset.^{13,30} The CPM was not intended to compare efficacy of glucose control from CSII with other methods of delivering insulin in the perioperative setting. Whether the processes outlined here can be generalized to institutions that do not have endocrinology specialty care available still needs to be determined. Finally, the CPM was intended for only elective surgical cases and not for emergent or urgent cases, situations for which patients likely would be required to disconnect from the device.

Conclusion

Although some aspects of care require continued improvement, these data suggest that the CPM provided a positive structure for management of patients on CSII during perioperative care. No adverse events related to permitting CSII in the operating room were documented, and the data continue to show that insulin pump therapy can be continued safely during the perioperative phase of surgical care. The unfamiliarity of health care providers with insulin pump technology, along with the complicated nature of CSII therapy, will require ongoing education and support of the perioperative staff to ensure that correct processes are followed in all cases. Additional work in this area requires better criteria of who should remain on CSII during surgery and the choice of alternative therapy in the event the patient is disconnected from the device. Greater staff knowledge, experience, and comfort levels with use of insulin pumps in the perioperative setting are needed, and a consensus should be achieved on steps needed to ensure their safe operation in the perioperative environment.

Abbreviations

CPM, care process model; CSII, continuous subcutaneous insulin infusion; HbA1c, hemoglobin A1c; PACU, postanesthesia care unit; POC-BG, point-of-care blood glucose.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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