Should Continuous Subcutaneous Insulin Infusion (CSII) Pumps Be Used During the Perioperative Period? Development of a Clinical Decision Algorithm

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According to the Centers for Disease Control and Prevention, there are 30.3 million Americans with diabetes mellitus (DM). It is estimated that more than 400,000 individuals with DM are using continuous subcutaneous insulin infusion (CSII) pumps as a method to maintain blood glucose control. An alternative to intermittent daily insulin injections, CSII more closely mimics normal physiologic insulin delivery. Maintaining glycemic control in the surgical patient using CSII requires a well-designed plan to minimize potential risks associated with this method of insulin delivery. A search strategy was formulated to examine the literature on CSII pumps use during the perioperative period as a method of maintaining glycemic control in surgical patients with DM. Seven potential sources were identified, which included a single case study and 3 retrospective cohort studies. Although methodologic concerns with the studies were found, the evidence suggests that CSII pumps can be safely utilized during the perioperative period when an established protocol is used. A multidisciplinary team at a large military medical center was formed to develop a decision-making algorithm to assist anesthesia providers in caring for patients with CSII pumps.

Keywords: Continuous subcutaneous insulin infusion, diabetes mellitus, hyperglycemia, hypoglycemia, insulin.

According to the Centers for Disease Control and Prevention, there are 30.3 million Americans with diabetes mellitus (DM).[1] Patients with DM are faced with numerous health implications because of their disease process. Patients with long-term, poorly controlled DM are at significant risk of cardiovascular, ophthalmic, kidney, and nervous system diseases, including an increased risk of distal extremity amputations.[1] Because of the multiple risk factors associated with DM, these individuals are more likely to require surgery, with nearly 50% of all patients with DM undergoing surgery during their lifetime.[2-5]

Surgical patients with DM are at risk of hyperglycemia during the perioperative period because of the glycemic response to surgical stress. Surgical stress causes a complex neuroendocrine response that leads to the activation of the sympathetic nervous system and results in the release of counterregulatory hormones, including catecholamines, cortisol, glucagon, and growth hormone.[6] These counterregulatory hormones act to raise the level of blood glucose by stimulating gluconeogenesis, glycogenolysis, ketosis, and other catabolic processes. In patients without DM, these counterregulatory hormones act as a natural defense mechanism against hypoglycemia. However, in the patient with DM, this compensatory response may be enough to convert a patient with normally well-controlled diabetes into a diabetic crisis during the perioperative period. Hyperglycemia in a patient with type 1 (insulin-dependent) diabetes may quickly cause ketoacidosis to develop if early recognition and treatment are not initiated.[7]

It is estimated that more than 400,000 individuals with DM are using continuous subcutaneous insulin infusion (CSII) pumps (commonly called insulin pumps) to maintain blood glucose control.[8] The number of patients using CSII is expected to increase as this technology advances. Continuous subcutaneous insulin infusion pumps were developed in the 1970s to provide basal, bolus, and correction insulin delivery that more closely mimics physiologic insulin release.[9] These CSII pumps use rapid-acting insulin analogs delivered through a portable pump worn by the patient to control blood glucose levels.

History and Review of the Literature

• ***History.*** Failure to manage glycemic control in a patient with DM throughout the perioperative period remains an independent risk factor for adverse outcomes. These adverse outcomes include delayed wound healing, an overall increase in mortality risk, and surgical site infection.[10,11] The primary perioperative treatment goal in the management of any patient with DM undergoing surgery is the maintenance of glycemic control. Preoperative glycemic control can be achieved with oral hypoglycemic drugs or the administration of exogenous insulin. Patients requiring insulin for glycemic control are typically receiving basal-bolus regimens. Basal insulin is used to maintain stable blood glucose levels when the person is fasting, whereas bolus insulin is given to maintain stable blood glucose levels after a meal or to correct hyperglycemia.

The American Association of Clinical Endocrinologists (AACE), American Diabetes Association (ADA), and Society for Ambulatory Anesthesia (SAMBA) all recommend that surgical patients with diabetes have intraoperative glycemic levels maintained at less than 180 mg/dL.[12,13] This recommendation is based on the treatment of hospitalized surgical patients with diabetes and applies only when the patient's DM is well controlled. The AACE and ADA also recommend using the subcutaneous route over intravenous (IV) bolus dosing of insulin, especially in noncritical patients.[13] Intravenous bolus dosing can cause large fluctuations in blood glucose levels because of the rapid onset and short duration of action that could potentially be harmful to patients.[12] Position statements outlining the goals of glycemic control have also been published by the American College of Endocrinology, in conjunction with the American Society of Anesthesiologists. Some of the goals outlined include maintenance of blood glucose levels below 180 mg/dL, providing basal insulin for patients who are insulin deficient, and the implementation of glycemic management protocols.[14]

Perioperative glycemic control of the patient with insulin-dependent DM can be accomplished with continuous IV insulin infusion, intermittent IV injections, or subcutaneous injections of insulin. In addition, insulin delivered via CSII has successfully been used during the perioperative period to provide glycemic control for surgical patients with insulin-dependent diabetes.[5,15-17] Maintaining glycemic control in the surgical patient using CSII requires a well-designed plan to minimize potential risks associated with this method of insulin delivery. The efficacy of CSII use during the perioperative period was examined through the development of a PICOT question.

• ***The PICOT Question.*** Evidence-based practice is a systematic critical appraisal of relevant evidence to answer a clinical question. It is an approach to clinical practice that seeks to use current evidence and guidelines to direct clinical decision making.[18] Evidence-based practice requires the clinician to develop a well-defined PICOT question. The PICOT (population, intervention, comparison, outcome, and time) format is one approach to formulate a focused clinical question. A PICOT question helps define the target population, formulate an intervention, compare alternatives, determine the desired outcome, and establish a timeframe. This format was used to answer the PICOT question, "In surgical patients with diabetes (P), how does the use of a continuous subcutaneous insulin infusion (I) affect glycemic control (O) during the perioperative period (T)?"

• ***Search Strategy.*** A literature review was conducted from January 2002 to December 2012 using PubMed, Cumulative Index to Nursing & Allied Health Literature (CINAHL), and The Cochrane Database of Systematic Reviews. Search terms used alone or in combination included the following: *diabetes mellitus, insulin, hypoglycemia, hyperglycemia, continuous subcutaneous insulin infusion, continuous insulin infusion, insulin pumps, preoperative, intraoperative, postoperative, surgery,* and *general anesthesia.* An extensive literature review was conducted with a focus on perioperative management of diabetes, to include the perioperative implications of CSII use during the surgical period. Inclusion criteria contained evidence pertaining to adults with both type 1 and type 2 DM from peer-reviewed journals. Sources examining CSII use in pediatrics were excluded. An evidence synthesis table was developed to evaluate the data collected for clinical relevance and applicability to the population being targeted (Table).

• ***Appraisal of the Literature.*** Seven evidence sources were selected that met the inclusion criteria. The evidence was appraised using a scoring system supported by Melynk and Fineout-Overholt.[19] The level of evidence ranged from level IV to level VII. One case study, 3 retrospective cohort studies, 1 consensus statement, and 3 expert opinion articles were reviewed.

Despite many published case reports regarding the general intraoperative glucose control for patients with diabetes, only one published case report was found that describes the use of CSII pump therapy during surgery. This patient had an ASA physical status 3 and type 1 diabetes and was undergoing general anesthesia for surgical repair of a herniated lumbar disk. Continuous subcutaneous insulin infusion was used to maintain the patient's fasting blood glucose level with a basal rate setting of 0.3 U/h with rapid-acting analog insulin lispro. During this 66-minute surgery, alterations to the CSII basal rate were not required. A blood glucose level of 118 mg/dL was obtained during the operative case, and a blood glucose level of 158 mg/dL was obtained during the recovery period. The authors concluded that CSII could simplify the overall glucose management during surgery by eliminating the need for extra infusions, including insulin and dextrose, and could be used safely by incorporating the patient in the plan of care. The authors also acknowledged potential problems that could be encountered with the use

Source, y	Level of evidence	Evidence type	Sample and other evidence information	Findings/ comments
Abdelmalak et al,[22] 2012	VII	Expert opinion	Review of current literature regarding CSII use during the perioperative period. No statistical analysis.	Institutional CSII algorithm developed and implement for the perioperative period
Boyle et al,[15] 2012	VII	Expert opinion	Used literature and multidisciplinary working group to address use of CSII in the surgical environment	Standardized guidelines and protocols were developed to guide the anesthesia provider at the particular facility
Corney et al,[16] 2012	IV	Retrospective study	N = 92, 53 with CSII continuation, 20 with conversion to IV insulin infusion, and 19 with CSII suspension with or without correctional boluses. Groups were compared on mean blood glucose levels intraoperatively.	CSII suspension group had highest percentage of blood glucose levels > 179 mg/dL
Joshi et al,[12] 2010	VII	Consensus statement	Systematic literature review using Cochrane Controlled Trials Register, The Cochrane Library, MEDLINE/PubMed, and Embase; included 1 systematic review and 9 trials including 5 RCTs	Provided consensus on treatment and management of diabetes and glycemic index during ambulatory anesthesia, including CSII use
Boyle et al,[20] 2012	IV	Retrospective study	N = 216, 108 in CSII group and 108 in non-CSII conventional insulin therapy group. Groups were matched by propensity and surgical category.	Patients in CSII group had lower fasting glucose levels on postoperative day 1, lower incidence of fevers, shorter time to suture removal, and shorter time to hospital discharge
Nassar et al,[17] 2012	IV	Retrospective record review	N = 35; 21 males and 14 females. Evaluated CSII use during surgical procedures with mean (SD) surgery times of 134 (95) minutes.	Glucose measurements were missing from 40% of surgical records. Recorded mean (SD) glucose values were 167 (64) mg/dL preoperatively, 173 (55) mg/dL intraoperatively, and 185 (54) mg/dL postoperatively.
White et al,[5] 2004	VII	Case study	Case review of CSII used during general anesthesia. No statistical analysis.	Demonstrates a case in which CSII was successfully used in the perioperative setting

Table. Evidence Sources Examined for Determining Perioperative Use of Continuous Subcutaneous Insulin Infusion (CSII) Pumps
Abbreviation: RCT, randomized controlled trial

of CSII during surgery, including catheter occlusion, unrecognized hypoglycemia, and catheter dislodgment. The authors of this case report recommended measuring the blood glucose hourly and examining the delivery system frequently to ensure correct insulin delivery.[5] Although this case demonstrated the safe use of CSII during surgery without complications, the use of CSII perioperatively cannot be generalized based on this single case report

In a retrospective record review of 50 surgical cases from 2006 through 2010, the use of CSII therapy during surgery was evaluated at the Mayo Clinic in Scottsdale, Arizona.[17] The analysis of these cases demonstrated a wide variation in the perioperative management of patients using CSII. The results revealed inconsistent documentation of insulin pump status during the perioperative period with glucose monitoring occurring in only 60% of cases. The average length of anesthesia, according to the record review, was 3 hours. The authors recommended the development and use of perioperative guidelines for patients using CSII pumps as a method of glucose management.[17] A multidisciplinary working group was also formed to address the management concerns of surgical patients using CSII during the perioperative period. The goal of the group was to develop a hospital policy for managing surgical patients with CSII. The group developed a policy based on a review of current information and published literature regarding the use of insulin pumps during the perioperative period. The group acknowledged CSII therapy could be continued throughout the perioperative period.

After implementation of the new policy at the Mayo Clinic in Scottsdale, Arizona, a second retrospective

record review was conducted to analyze the compliance and impact of the newly developed policy.[20] This record review revealed 23 records in which CSII therapy was used during the perioperative period. The implementation of this new policy resulted in more than 90% of providers documenting that a glucose level was checked both preoperatively and in the postanesthesia care unit. There was a 33% increase in documentation that a pump was present. However, there was a 22% decrease in documentation of the pump status as well as specific pump parameters compared with the previous study. The results of this study also provided evidence of no adverse events occurring with the continued use of CSII therapy. The authors concluded that CSII could be continued safely throughout the perioperative period but did not provide specific guidelines for management. They recommended that a standardized approach for the use of CSII during the perioperative period be developed to ensure patient safety. The authors also recommended that each institution establish its own guidelines to direct staff in the perioperative use of CSII and recognized the need for published consensus guidelines.[20]

The only study comparing CSII with other glycemic management strategies during the perioperative period was conducted by Corney et al.[16] In this 5-year retrospective single-institution investigation of CSII use during the perioperative period, 92 surgical patients with type 1 or type 2 diabetes were grouped based on an anesthesia provider's decision to (1) continue CSII at the current basal rate, (2) convert to IV insulin infusion, or (3) suspend CSII with or without correctional boluses. The study found that the CSII suspension group had a higher percentage of cases with 1 or more intraoperative blood glucose levels above 179 mg/dL. Suspension of CSII with or without correctional boluses was considered less successful at preventing hyperglycemia than either conversion to IV insulin infusion or continuing CSII therapy.[16]

The results of these studies suggest CSII therapy may be safely used in the perioperative setting when appropriate guidance is provided and when management algorithms are implemented.

Discussion of State of the Art

Continuation of CSII during surgery has been reported as a safe and more consistent method to maintain the blood glucose level over other means of insulin administration. Suggested guidelines for continued CSII use include maintaining the patient's basal infusion rate, eliminating preprandial boluses, measuring blood glucose levels at least hourly, and knowing the patient's typical correction or sensitivity factor (bolus required to decrease the blood glucose level by 50 mg/dL) Although CSII has been advocated for use during elective surgical procedures, caution is advised in the very young, unstable, and very ill patients requiring more intensive management.[21]

In the retrospective review conducted by Corney et al,[16] the authors found that blood glucose levels were generally the same in cases when CSII was continued as in those when CSII was replaced with continuous IV insulin infusions. They concluded that CSII continuation during the perioperative period was safe in stable noncritical patients. Their perioperative recommendations included continuation of the patient's basal rate dependent on the preoperative blood glucose level, checking blood glucose level hourly, and clinical parameters for providing correctional insulin boluses via the pump.[16] They also provided institutional guidelines on discontinuation of the pump and conversion to continuous IV insulin infusions. Recognizing a lack of standardized guidelines on CSII use, Boyle et al[20] developed institutional guidelines for the continued use of CSII during the preoperative, intraoperative, and postoperative periods. Their recommendations included confirmation of correct CSII operation throughout all phases of the perioperative period, hourly blood glucose level checks, and correctional insulin boluses administered via the pump at the discretion of the anesthesia provider.[20] Guidelines provided by SAMBA also recommended making no changes to the CSII pump based on normal blood glucose levels, and to use a patient's normal basal rate on the day of surgery.[12]

As the number of patients who use CSII increases and the technology associated with insulin pump changes, continued research is needed to determine CSII efficacy in maintaining intraoperative glycemic control compared with other methods of insulin delivery. It would also be important for future studies to determine the types and lengths of surgeries best suited for CSII use, as well as the most appropriate patient population. This literature review revealed a lack of consensus guidelines on the best management approach regarding glycemic control during the perioperative period. In addition, only a few published algorithms were located to guide the anesthesia provider in the perioperative management of diabetic patients presenting with a CSII pump.[7,10,11]

Algorithm Development

Recognizing a need for a standardized approach in the perioperative management of diabetic patients with CSII pumps, a multidisciplinary team was formed at a large military medical center to determine a best-practice approach for the use of CSII during the perioperative period. The team was composed of Certified Registered Nurse Anesthetists, anesthesiologists, and endocrinologists. The team was tasked to answer the following questions: (1) What is the current method used for perioperative blood glucose management in patients with DM?; (2) Should all patients with diabetes have a preoperative assessment completed to best manage their perioperative care, and if so, who should make the final recommendations?; (3) How would you manage a patient who pre-

sented for surgery with a CSII pump?; and (4) Is there a need for a CSII algorithm to help facilitate perioperative decision making? The team members evaluated current practices at the medical center to answer the proposed questions. The team concluded that the management of care for surgical patients with DM presenting with a CSII pump should be guided by individual provider experience and the use of a practice algorithm to assist providers in their decision making.

The multidisciplinary team met weekly for 1 month to discuss algorithm development, review, and revision. A review of the literature (see Table) and the clinical expertise of the multidisciplinary team guided the development of the institutional algorithm (Figure).[16,20,22] The algorithm was designed to address the perioperative care of patients presenting on the day of surgery with a CSII pump. Perioperative care was defined as preoperative, intraoperative, and immediate postoperative timeframe.

The algorithm encourages providers to consult with the inpatient glucose management team when CSII use is planned during surgery. Before surgery the presence of the CSII pump is documented, the insertion site is inspected, pump settings are confirmed, and a blood glucose level is obtained from the patient. Guidance is also provided for the treatment of hypoglycemia and hyperglycemia during the perioperative period. Blood glucose levels should be monitored every hour during surgery and on arrival to the recovery unit. Discontinuation of CSII therapy is recommended for the following conditions: large blood loss, pump failure, dislodged catheter, expected exposure to radiation (magnetic resonance imaging, computed tomography, or cardioversion), or admission to the intensive care unit. The algorithm developed by the team was formally presented to the anesthesia department as a method to assist with the perioperative planning and management of patients with a CSII pump. The algorithm was approved and distributed to the anesthesia department through the department's home page on the Intranet for future reference. The goal in the development of the algorithm was to provide a tool to assist anesthesia providers in the perioperative decision-making process when presented with a patient with a CSII pump.

Conclusion

Preparation for the intraoperative management of the patient with diabetes should begin before the day of surgery. The anesthesia plan for patients with diabetes should be tailored to the individual patient's needs based on type of diabetes, medication regimen, type of surgery, expected duration, and timing of the surgery. Preoperative testing such as hemoglobin A1C, electrocardiogram, and a basic metabolic panel can be used to assess glycemic control and help determine anesthetic and surgical risk.[12,23] Poor glycemic control during the perioperative period can have large ramifications on postoperative outcomes. Poor glycemic control can increase the risk of infections and affect wound healing after surgery. To emphasize the importance of intraoperative glycemic control and its impact on postoperative outcomes, The Joint Commission has made postoperative blood glucose values a core measure for cardiac surgical patients.[24]

Although CSII pump therapy may be advantageous in maintaining glycemic control for surgical patients, anesthesia providers must be cognizant of potential problems that can arise from the use of these pumps during the perioperative period. Given that short-acting insulin is used in CSII pumps, the provider must keep in mind that loss of glycemic control can occur on its discontinuation and can quickly lead to hyperglycemia. Other potential problems include intraoperative catheter occlusion or dislodgment, pump failure, and reduced insulin absorption at the site of administration.[5] The decision to discontinue a patient's CSII pump therapy is not without potential consequences. Continuous subcutaneous insulin infusion provides uninterrupted and constant delivery of insulin, and when insulin infusion is interrupted, there is a cessation of basal insulin delivery that can result in significant glucose elevations and/or ketoacidosis. A systematic review by Anstey et al[25] in 2015 revealed that clinical complications such as diabetic ketoacidosis were not found in hospitalized patients receiving CSII as their primary mode of glucose control.

This review identified a gap in the literature. Evidence from well-designed randomized controlled studies examining the use of CSII during the perioperative period is lacking. Consensus practice guidelines for CSII therapy from professional organizations directing the anesthesia provider on best practices are needed. Many questions remain unanswered regarding the use of CSII perioperatively. Some of these questions include the following: (1) What length and type of surgeries are appropriate for CSII use? and (2) What affects will surgical stress and comorbidities have on the pump's ability to maintain glycemic control during the perioperative period? Future studies are needed to determine best-practice recommendations regarding the appropriateness of CSII use throughout the perioperative period, especially as the number of CSII users continues to increase in the United States.

Despite a gap in the literature, there is some evidence to support the use of CSII during minor nonemergent procedures when institutional protocols are developed and a team approach is followed to establish a definitive management plan.[26] Patients having minor surgical procedures can maintain glycemic control while continuing to receive insulin via their CSII pump at their usual basal rate.[5] The decision to continue CSII use should be discussed with the patient to clarify his or her expectations of diabetic management before and after surgery. Successful CSII use during the perioperative period will depend on a collaborative approach between the

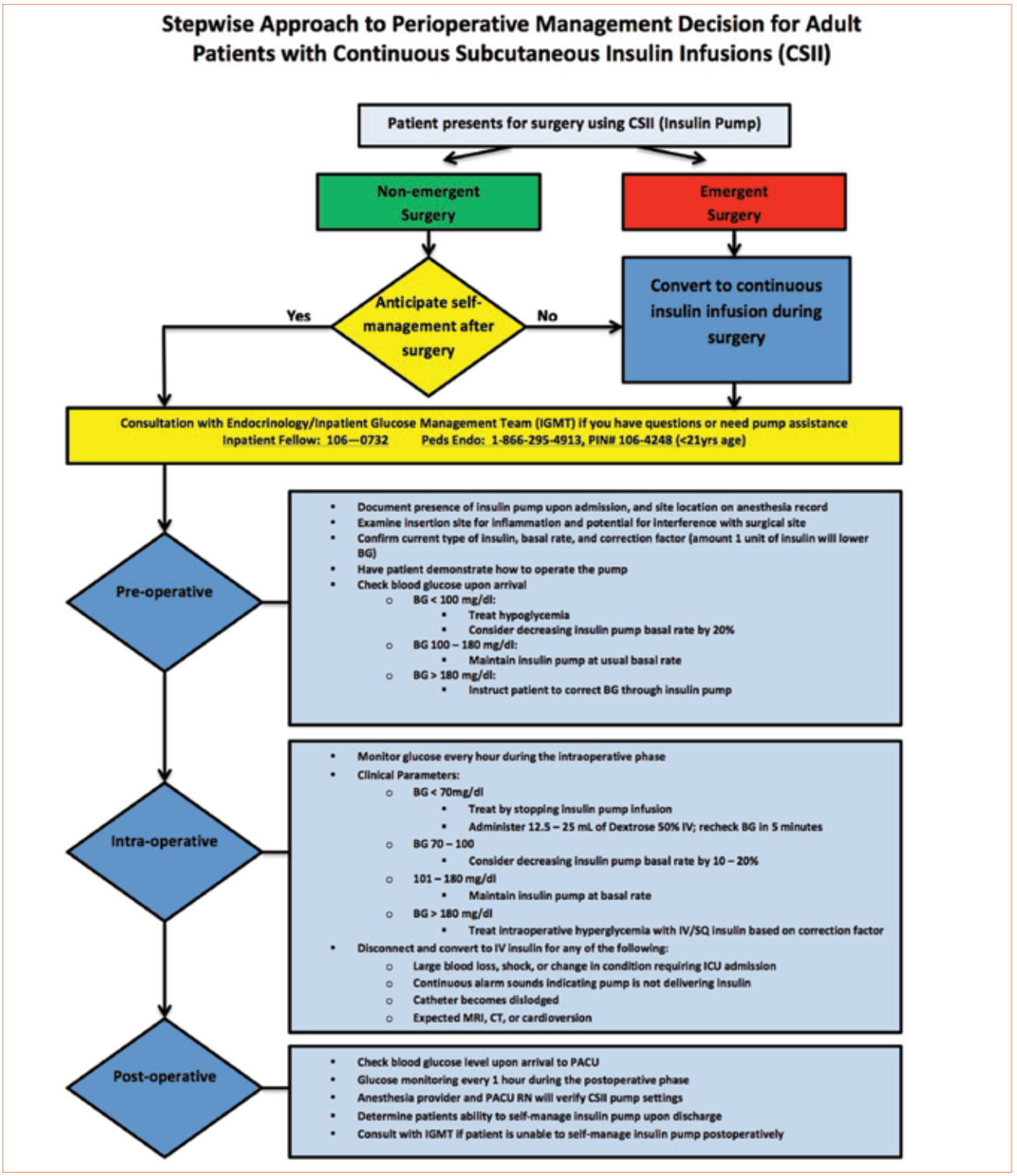

Figure. Continuous Subcutaneous Insulin Infusion (CSII) Algorithm

Abbreviations: BG, blood glucose level; CT, computed tomography; ICU, intensive care unit; IV, intravenous; MRI, magnetic resonance imaging; PACU, postanesthesia care unit; Peds Endo, pediatric endocrinology; RN, registered nurse; SQ, subcutaneous.

patient and family members and the anesthesia provider, surgeon, and endocrinology staff.

Clear institutional protocols, including comprehensive staff education, must be established regarding CSII pump use before surgical interventions. There remains limited evidence available in the literature regarding

CSII recommendations surrounding the perioperative period. Therefore, individual institutions are left with the decision to develop protocols based on current literature to drive their decision making regarding CSII use until national guidelines are established. The development of an institutional algorithm is recommended to guide the anesthesia provider in the management practice of CSII to avoid inadvertent intraoperative hyperglycemic or hypoglycemic events.

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