Individual QI projects from single institutions

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Impact of Eliminating Local Anesthesia on Immediate Postoperative Analgesia in Pediatric Ambulatory Adenotonsillectomy

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Abstract

Introduction: Our goal was to standardize intraoperative analgesic regimens for pediatric ambulatory tonsillectomy by eliminating local anesthetic use and to determine its impact on postoperative pain measures, while controlling for other factors. **Methods:** We assembled a quality improvement team at an ambulatory surgery center. They introduced a standardized anesthetic protocol, involving American Society of Anesthesiologists Classification 1 and 2 patients undergoing adenotonsillectomy. Local anesthesia elimination was the project's single intervention. We collected pre-intervention data (79 cases) from July 5 to September 17, 2019 and post-intervention data (59 cases) from September 25 to December 17, 2019. The intervention requested that surgeons eliminate the use of local anesthetics. The following outcomes measures were evaluated using statistical process control charts and Shewhart's theory of variation: (1) maximum pain score in the post-anesthesia care unit, (2) total post-anesthesia care unit minutes, and (3) postoperative opioid rescue rate. **Results:** No special cause variation signal was detected in any of the measures following the intervention. **Conclusions:** Our data suggest that eliminating intraoperative local anesthetic use does not worsen postoperative pain control at our facility. The intervention eliminated the added expenses and possible risks associated with local anesthetic use. This series is unique in its standardization of anesthetic regimen in a high-volume ambulatory surgery center with the exception of local anesthesia practices. The study results may impact the standardized clinical protocol for pediatric ambulatory adenotonsillectomy at our institution and may hold relevance for other centers. *(Pediatr Qual Saf 2021;6:e405; doi: 10.1097/pq9.0000000000000405; Published online May 5, 2021.)*

INTRODUCTION

Adenotonsillectomy is among the most common surgical procedures performed in children in the United States.[1,2] Pain remains one of the most frequent causes of morbidity despite a wide range of surgical techniques and intraoperative adjuvant therapies to decrease rates of adverse events and improve postoperative outcomes. There is currently no standard protocol for post-tonsillectomy pain control, and controversy remains regarding the efficacy of adjuvant therapies such as intraoperative injection of local anesthetic agents.[3,4] Additionally, the American Academy of Otolaryngology – Head and Neck Surgery tonsillectomy guidelines do not have a stance on the use of intraoperative local anesthetic injection in pediatric tonsillectomy.[5] Providing adequate postoperative analgesia is crucial to optimize patient care, by allowing patients to resume oral intake quickly. A local anesthetic may be administered before or after the tonsils are removed, with potential benefits being pain reduction, reduced intraoperative bleeding, and improved dissection planes.[4] However, injection of a local anesthetic has been associated with many complications, including life-threatening upper airway obstruction, increased risk of dysphagia or postoperative aspiration due to reduced pharyngeal sensation, pulmonary edema, cardiac arrest, infection, and neurovascular events.[6–10] Additionally, existing studies evaluating the efficacy of local anesthetic injection show unclear benefit.[11–18]

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Hollis et al. conducted a systematic review examining six randomized controlled trials analyzing the effect of local anesthetic on postoperative pain relief in combined pediatric and adult patient populations.[18] All these studies examined the effect of local injection, except for one which evaluated topical spray.[13,18] Among the studies examining the effect of local injection, only 1 showed an improvement, with lower postoperative global pain scores in those who received bupivacaine infiltration.[17] Other studies failed to demonstrate any improvement in postoperative pain.[12,14–16] Additionally, there were no significant differences between treatment and control groups in the need for postoperative supplemental analgesia.[18] Arcioni et al. evaluated the effect of peritonsillar local anesthetic infiltration in children undergoing tonsillectomy, and found no significant difference in postoperative pain intensity between those who received local and those who did not.[16] Conversely, a systematic review, and meta-analysis by Grainger et al. suggested that local anesthetic may provide a modest reduction in post-tonsillectomy pain, but in most cases, there was no significant difference in the amount of postoperative supplemental analgesia required for pain control.[11] Unfortunately, existing studies are limited by a small sample size, lack of standardized anesthetic protocols, and absence of validated pain scales or analgesic consumption as postoperative pain indicators.[18] The lack of clear improvement in postoperative pain control and the potential for serious complications associated with local injection use forms the basis for this QI project.

Surgeons at our facility have not standardized local injection protocols; so we aimed to standardize our adenotonsillectomy analgesic protocol and implement best practices by eliminating local anesthetic use. Based on prior data collected at our site, we hypothesized that elimination of intraoperative local anesthetic would not result in a significant difference in postoperative pain control. Therefore, we developed an intervention eliminating the use of intraoperative local anesthetics in adenotonsillectomies performed with electrocautery. This opioid-sparing standardized anesthesia protocol is outlined in Table 1. We conducted this work in our ambulatory surgery center with a pre-existing standardized anesthetic protocol for pediatric adenotonsillectomy.[19] We aimed to eliminate the use of local anesthetic injection by surgeons and evaluate its effect on post-anesthesia care unit (PACU) pain scores, PACU length of stay, and postoperative opioid rescue rate (our primary outcome measures). Ultimately, we sought to optimize and standardize the surgical approach to pain control for pediatric patients undergoing adenotonsillectomy at our facility by January 2020.

MATERIALS AND METHODS

Context

Bellevue Clinic and Surgery Center (BCSC) is a satellite campus of Seattle Children's Hospital (SCH) located in Bellevue, Washington. It serves as an ambulatory surgery center, with a primary patient population consisting predominantly of American Society of Anesthesiologists class 1 and 2 patients. Exclusion criteria for surgery at BCSC include age <3 months, weight >120 kg, cyanotic heart disease, known difficult airway, home oxygen requirement, former premature infant, implanted devices, mitochondrial disease, and history of organ transplant. Specific exclusion criteria for adenotonsillectomy include age <3 years and an Apnea Hypopnea Index of ≥15. Previously BCSC has implemented a standardized, opioid-sparing anesthesia protocol for pediatric adenotonsillectomy, which was developed in a recent QI initiative and is the facility's current standard of care for intraoperative pain management for adenotonsillectomies.[19] The surgery center population at BCSC was chosen for this QI project because of the relative reduction of confounding variables. Further, BCSC has experience driving improved outcomes and implementing behavior changes by acting as a Learning Healthcare System.[20] Further, members of the care team (including surgeons, anesthesiologists, certified registered nurse anesthetists, and nurses) meet routinely to review current protocols, discuss best practices, and propose and develop standardized clinical protocols. Standardized clinical protocols are implemented for high-volume surgeries to optimize delivery and reliability of patient care and to maximize safety. Following the implementation of standardized clinical protocols, providers at BCSC track application and effect of interventions and perform QI work using Plan-Do-Study-Act (PDSA) cycles.[21] MDmetrix OR Advisor (MDmetrix, Seattle, Wash.) is a validated software program utilized at BCSC to visualize and analyze data and carry out QI projects.[22] We used the SQUIRE 2.0 Guidelines as a framework for reporting this QI project.[23]

Table 1. Standardized Opioid-sparing Anesthesia Protocol

Induction—Sevoflurane 8%/oxygen/nitrous oxide
Dexmedetomidine 1 mcg/kg IV bolus
Propofol 1–2 mg/kg IV
Ondansetron 0.15 mg/kg IV (max 4 mg)
Dexamethasone 0.15 mg/kg IV (max 4 mg)
Lactated Ringers 20 mL/kg IV
Maintenance—Sevoflurane 0.8–1.3 MAC/<30% oxygen/air
Ketorolac 0.5 mg/kg IV (max 30 mg) once surgery complete

IV, intravenous; kg, kilogram; MAC, minimum alveolar concentration; max, maximum; mcg, microgram; mg, milligram; mL, milliliter.

Intervention

Approximately 1200 tonsillectomies are performed at BCSC annually. At BCSC, 5 fellowship-trained pediatric otolaryngologists regularly perform adenotonsillectomies using electrocautery as their primary technique. Before this study, no standard existed regarding intraoperative local anesthetic use, and 2 of the 5 surgeons regularly utilized local anesthetic injections in their adenotonsillectomies. Before this intervention, patients either received local injection or no injection based on surgeon

preference. During the project's pre-intervention period, patients received a local injection of 3–6 mL of either a 50:50 mixture of 0.5% bupivacaine and 0.5% lidocaine with 1:200,000 epinephrine or 0.5% bupivacaine alone. After reviewing our historical data and discussions with otolaryngologists, intraoperative nurses, and anesthesiologists involved in adenotonsillectomy patients at BCSC, we decided that local anesthetic injections would be eliminated for all adenotonsillectomies performed using electrocautery. This was the first time that elimination of local injection for adenotonsillectomy had been proposed as an intervention at our institution. The intervention involved retrospective data review on past patients, education, and discussion with the surgical team, and a request for the surgeons to eliminate the use of local anesthetics. All data elements used for this QI project were obtained directly from our EMR data. We collected pre-intervention data (79 cases) from July 5 to September 17, 2019 and post-intervention data (59 cases) from September 25 to December 17, 2019.

This QI project included American Society of Anesthesiologists class 1–3 patients aged 2–19 years undergoing adenotonsillectomy via an electrocautery technique at BCSC. All patients met American Academy of Otolaryngology – Head & Neck Surgery Clinical Practice Guideline criteria for undergoing adenotonsillectomy.[2] Intracapsular tonsillectomies, tonsillectomies utilizing cold steel dissection, and those performed with a combination of suction electrocautery and cold steel dissection were excluded to avoid confounding the PDSA intervention with multiple adenotonsillectomy techniques. None of the 5 surgeons performing the procedure with electrocautery utilized intraoperative local anesthesia injection during the post-intervention PDSA cycle. Cohorts were separated by date of protocol change.

Measures

Maximum pain score in the PACU, PACU length of stay, and postoperative opioid (morphine and/or oxycodone) rescue rate in the PACU were selected as primary outcome measures.

Maximum PACU pain score was assessed and recorded by PACU nurses. Nurses assessed pain using 1 of 3 age-appropriate validated tools: the Faces, Legs, Activity, Cry, Consolability tool (recommended for ages 1–3 years),[24] the Faces Pain Scale–Revised (recommended for ages 3–6 years),[25] or a numerical 0–10 visual analog scale (recommended for ages 7+ years).[26,27] We converted all measurements to a new score on a uniform 11-point (0–10) scale for analysis.

We utilized postoperative opioid rescue rate in the PACU as an outcome measure to evaluate for postoperative pain. Morphine is the primary opioid used in the PACU, while oxycodone is rarely used. Recovery nurses administer opioids based on their assessment of patient pain level using the validated tools described above. Rescue opioid administration was at the discretion of the PACU nurses when pain scores were moderate (score 4–6) or severe (7–10).

The balancing measure, PACU length of stay, was evaluated as a proxy for patient recovery, impacted by pain management efficacy. Patient discharge criteria included all of the following: (1) surgical site was stable, (2) vital signs were at the patient's baseline and within normal limits for age or approved by an anesthesiologist, and (3) the recovery score according to the modified Aldrete scoring system was 10 or returned to pre-operative baseline.[28]

Analyses

Complete data for each cohort were extracted and imported into MDmetrix OR Advisor for initial analysis.[19,22] During both phases of the PDSA cycle, 138 patients met the criteria for inclusion into this project; complete data were obtained for all 138 patients. QI Macros Statistical Process Control (SPC) Software for Microsoft Excel was used for final analysis.

SPC charts combine time series analysis methods with a graphical presentation of data, and can distinguish random from non-random variation.[29,30] SPC charts were used according to the Shewhart method to visualize data and analyze for improvement in outcomes associated with the intervention.[29,31] We used X-bar charts to display average maximum PACU pain score and average PACU length of stay (minutes). A p-chart was used to display the frequency of rescue opioids in the PACU. The upper and lower control limits for the SPC charts were set at 3 standard deviations above and below the mean (three sigma).[30] We followed standard SPC guidelines to identify special cause variation (SCV), representing the presence of a change between and within cohorts.[30]

Ethical Considerations and Conflict of Interest

The SCH Institutional Review Board determined that this project met criteria for QI work and was exempt from IRB review. Dr. Low (co-author) is the Chief Medical Officer and founder of MDmetrix and Dr. Martin is an investor of MDmetrix.

RESULTS

A total of 138 pediatric patients were included in this study: 79 during the pre-intervention period and 59 during the post-intervention period. Among patients in the pre-intervention period, 43% received local injection as outlined previously. None of the patients in the post-intervention period received intraoperative local anesthetic injection. Demographic data for each cohort are shown in Table 2.

The X-bar chart for average maximum PACU pain score for the pre-intervention and post-intervention periods is shown in Figure 1A. There was no SCV, indicating there was no improvement or deterioration between the pre-intervention and post-intervention cohorts.

The X-bar chart for average PACU length of stay for the pre-intervention and intervention periods is shown in Figure 1B. A breach of the upper control limit was seen at the start of the pre-intervention period. However, this was attributed to a single significant outlier with a PACU time of 301 minutes. After this first point, all subsequent data points fell within the control limit range for both the pre-intervention and post-intervention periods, suggesting that the process is stable. No other SCV was present within or between cohorts.

The P-chart for average frequency of postoperative opioid rescue is shown in Figure 2. The absence of SCV indicates that there was no improvement or deterioration between cohorts concerning postoperative opioid rescue rate.

DISCUSSION

Summary

This QI project utilized a PDSA cycle to implement a protocol eliminating the intraoperative use of local anesthetic injection during adenotonsillectomy and evaluate the effect on postoperative pain and recovery time in an ambulatory surgery setting. Following the intervention, there were no changes in maximum pain score or recovery time in the PACU. There was also no difference in postoperative opioid rescue rates between cohorts.

The results of this project suggest that intraoperative local anesthetic does not improve immediate postoperative pain control in pediatric adenotonsillectomy at our facility, as measured by maximum PACU pain score, time spent in PACU, and frequency of postoperative opioid rescue. Due to a lack of clear benefit for postoperative pain control and concerns for significant risks associated with the use of local anesthetics, the results of our intervention led to a permanent change in our protocol that eliminated the use of local anesthetics. Given the cost of each local injection and the frequency of pediatric

Table 2. Patient Demographics

Characteristic	Mean (range) or n (%)	
	Pre-intervention (N = 79)	Post-intervention (N = 59)
Patient gender		
Men	42 (53.2%)	34 (57.6%)
Women	37 (46.8%)	25 (42.4%)
Patient ethnicity		
Non-Hispanic	63 (79.7%)	42 (71.2%)
Hispanic	13 (16.5%)	16 (27.1%)
Patient refused	3 (3.8%)	1 (1.7%)
Patient race		
White	49 (62.0%)	32 (54.2%)
Asian	6 (7.6%)	7 (11.9%)
Black or African American	3 (3.8%)	6 (10.2%)
2 or more races	4 (5.1%)	3 (5.1%)
Patient refused	3 (3.8%)	2 (3.4%)
Other	14 (17.7%)	9 (15.2%)
Patient language		
English	72 (91.1%)	52 (88.1%)
Spanish	4 (5.1%)	6 (10.2%)
Vietnamese	2 (2.5%)	
Somali	1 (1.3%)	
French		1 (1.7%)
Patient age (y)	6.6 (3–20)	6.7 (3–17)
Patient ASA		
1	17 (21.5%)	20 (33.9%)
2	58 (73.4%)	36 (61.0%)
3	4 (5.1%)	3 (5.1%)
Patient Weight (kg)	28.3 (11.8–76)	27.5 (13.9–71.4)
Patient BMI (kg/m^2)	17.6 (12.71–25.76)	17.2 (13.44–27.93)

ASA, American Society of Anesthesiologists Classification; BMI, body mass index; kg/m^2, kilograms per meter squared.

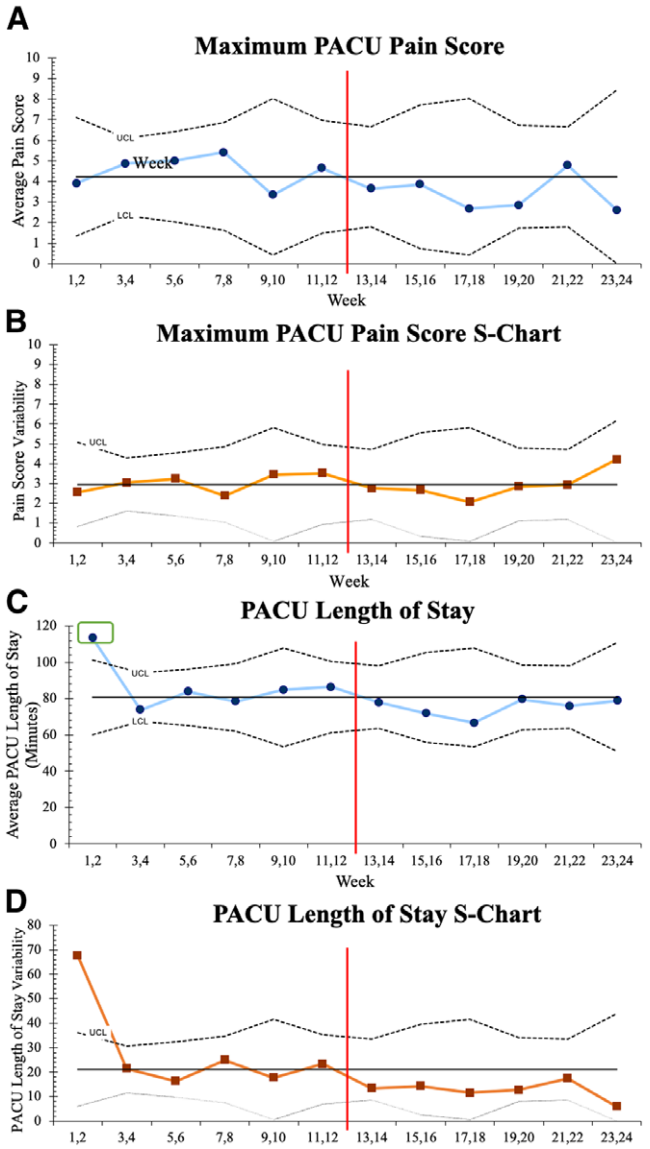

Fig. 1. PACU pain scores and length of stay. (A) Average maximum pain score in PACU X-bar chart. (B) Average maximum pain score in PACU S-chart. (C) Average PACU length of stay X-Bar chart. (D) Average PACU length of stay S-chart. Notes: Weeks 1–12 compose the pre-intervention period. Weeks 13–24 compose the intervention period. The mean for the pre-intervention and intervention periods are represented by the horizontal black line, and the average for each time-point is represented by the blue line. The transition from the pre-intervention to intervention period is represented by the red vertical line. The dashed lines indicate the upper and lower confidence limits, 3 standard deviations above and below the mean, respectively. SCV is highlighted with a green box.

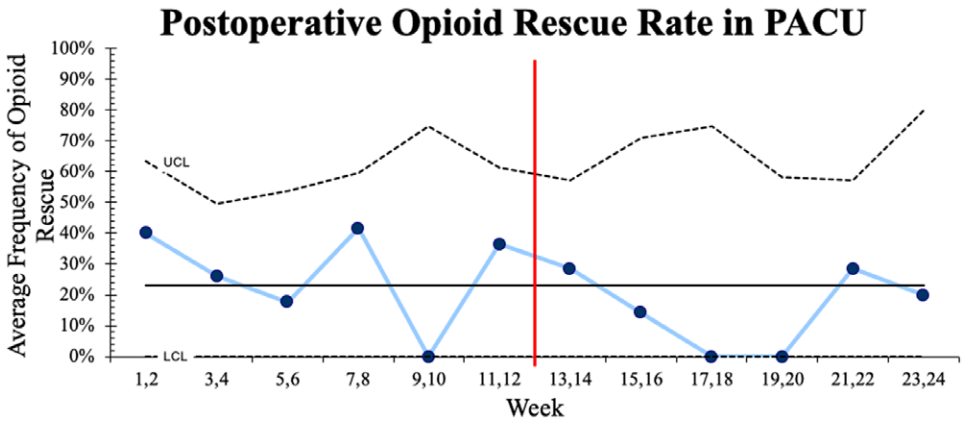

Fig. 2. Average Postoperative Opioid Rescue Rate in PACU P-Chart. Notes: Weeks 1–12 compose the pre-intervention period. Weeks 13–24 compose the intervention period. The mean for the pre-intervention and intervention periods are represented by the horizontal black line, and the average for each time-point is represented by the blue line. The transition from the pre-intervention to intervention period is represented by the red vertical line. The dashed lines indicate the upper and lower confidence limits, 3 standard deviations above and below the mean, respectively. No SCV is identified.

tonsillectomy, eliminating the use of intraoperative local anesthetics could also result in significant cost savings for the surgery center. We believe care team compliance with the protocol intervention was high, thanks to the culture focused on continuous improvement at BCSC.

Interpretation

Our results are consistent with prior studies evaluating the impact of local anesthetic injection during adenotonsillectomy on postoperative pain. Our PDSA cycle builds upon and agrees with prior research indicating no difference in postoperative pain control.[16,18] A particular strength of our study is that the intervention was conducted at a facility that had already implemented a highly optimized, standardized anesthetic protocol, thus eliminating this as a confounding factor and increasing the chance to detect a true positive signal.

The results of this QI project have impacted the standardized clinical protocol for adenotonsillectomy in pediatric patient populations at our ambulatory surgery center and may hold relevance for other centers. Our data suggest that eliminating intraoperative local anesthetic use would not result in more postoperative pain or increased PACU length of stay. Eliminating use of local anesthetics has the benefits of decreased expense and reduced risk for patients.

Limitations

Our study has several limitations that may impact internal validity. First, our study has a limited number of patients, which could affect the accuracy of the data and cause an increased margin of error. Second, objective pain measurement is challenging, especially in young children due to difficulty or reluctance to verbalize pain. In our study, pain intensity was measured by 1 of 3 age-appropriate validated tools, and measurements were converted to a new score on a uniform 11-point scale for analysis. While pain was evaluated using these validated pain assessment tools, administration of rescue pain medication was ultimately at the discretion of the nurse. Third, possible confounding factors include the use of a variety of cautery settings and cautery tips by different surgeons. Fourth, this was not a blinded study and all members of the healthcare team were included in discussions for planning the study, thus the Hawthorne effect may have influenced outcomes. Attempts to mitigate the Hawthorne effect included standardized anesthetic protocols and nursing protocols in the PACU for postoperative pain scoring and management.

There are also several factors in our study that may affect external validity. The results of this study are not likely generalizable to all adenotonsillectomy techniques, as our intervention was limited to surgeons utilizing electrocautery. This PDSA cycle was completed at BCSC, which is an ambulatory surgery center focused on continuous improvement with a relatively homogenous patient population. Therefore, the results may not be generalizable to patient populations at other surgery centers or inpatient operating room facilities. Our study examined pain control in the immediate postoperative period, although pain after adenotonsillectomy may be present for several days after surgery secondary to surgical site inflammation. Our outcome measures were only evaluated until the patient left the PACU because the purpose of our study was to evaluate the effect of eliminating intraoperative local anesthetic on immediate postoperative pain control.

Next Steps and Implications for Practice

Next steps for this QI project will be to expand the standardization of practice to the main operating room and inpatient cases. Further, this intervention could be conducted in other surgery centers with more disparate patient populations to better demonstrate generalizability.

DISCLOSURE

Drs. Lo, Martin, and Manning have invested in MDmetrix OR Advisor. The other authors have no other financial relationships, conflicts of interest, or funding to disclose.

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