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Perioperative interdisciplinary approach for reduction of opioid use in pediatric tonsillectomy: Protocol using dexmedetomidine and bupivicaine as adjunct agents

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A B S T R A C T

Importance: Pediatric tonsillectomy is a common procedure now being performed most often for patients with obstructive sleep apnea, which has been associated with increased sensitivity to the respiratory side effects of opioid medications. This study investigates a strategy to decrease the use of opiate medications in a particularly vulnerable population.
Objective: Describe an interdisciplinary approach between Otolaryngologists and Anesthesiologists to decrease opiate use in tonsillectomy patients. Demonstrate safety of this protocol. Evaluate the effect of the protocol on intraoperative need for opiate medications and inhaled anesthetic use. Perform cost analysis of the protocol.
Design: Retrospective case-control study with cost analysis.
Setting: Tertiary Care Hospital.
Participants: Pediatric patients undergoing tonsillectomy at a tertiary care hospital.
Interventions: Preoperative and intraoperative dexmedetomidine with local bupivacaine injection into the tonsillar fossa.
Measures: Intraoperative need for sevoflurane, opiate, and propofol. Post-operative pain scores, and utilization of post-operative opiate, acetaminophen, and ibuprofen pain medications. Post-operative adverse events. Cost analysis of protocol.
Results: This protocol led to a decrease in intraoperative opiate use by 49.6%, a decrease in intraoperative sevofluorane use by 18%, and a lower reported maximum post-operative pain score without any increase in adverse events. The protocol added a small increase in medication cost of $4.07 to each procedure.
Conclusion: The use of dexmedetomidine and local anesthetic in pediatric tonsillectomy is a safe and effective protocol that allows for the reduction of opiate use and improved post-operative pain control.
Key points: Question: Can the combination of dexmedetomidine and infiltration of local anesthetic reduce overall opioid use for peediatric patients undergoing tonsillectomy?
Findings: In this case-control study, use of dexmedetomidine and local anesthetic injected into the tonsillar fossa led to a decrease in intraoperative opiate use by 49.6%, a decrease in intraoperative sevofluorane use by 18%, and a lower reported maximum pain score without an increase in adverse events.
Meaning: Use of dexmedetomidine and local anesthetic as anesthetic adjuncts may help reduce need for intraoperative opiates and decrease the use of volatile anesthetic agents in pediatric tonsillectomy patients, which are undesirable medications in the pediatric population for their respective respiratory depression and potentially neurotoxic side effects.

1. Introduction

Tonsillectomy is the most common operation performed in the pediatric population and is being increasingly performed for patients with obstructive sleep apnea (OSA) compared to infectious indications [1,2]. This presents a challenging situation because patients with OSA are at increased risk for respiratory complications after general anesthesia while also being more sensitive to the respiratory depressant effects of opioids and benzodiazepines [3,4]. To reduce these risks, the use of adjunct anesthetic agents are being explored.

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Dexmedetomidine (Precedex) is an alpha-2 adrenoreceptor agonist used for sedation and analgesia with promising applications in pediatric anesthesia. It acts centrally, affecting receptors in the locus ceruleus nucleus of the brainstem to induce sleep and block nociceptive neurotransmission with minimal respiratory depression [5]. It is available in oral, nasal, and intravenous formulations. Intranasal premedication of pediatric patients with dexmedetomidine has been shown to be a safe and effective option to provide preoperative sedation [6]. When used IV in combination with general anesthesia, dexmedetomidine has been shown to decrease the use of narcotic and volatile anesthetics [7,8]. These characteristics make it an attractive option for patients with OSA and allow avoidance of respiratory depression in a high-risk population.

Another adjunct which can be used in tonsillectomy is the injection of local anesthetic, commonly bupivacaine or ropivacaine. Some studies have shown that the use of injected local anesthetic can decrease postoperative pain and result in lower need for postoperative pain medication without increasing complications [9–11]. To optimize care after tonsillectomy, an interdisciplinary protocol between Anesthesia and Otolaryngology providers utilizing both dexmedetomidine and local anesthetic infiltration was developed and studied.

2. Methods

2.1. Study design

Prior to data collection, internal review board approval was obtained (IRB HM20005468). Data was collected via retrospective chart review for cases and controls.

2.2. Subjects

Patients undergoing tonsillectomy at a tertiary care, academic center were included. Cases were gathered from those children who underwent tonsillectomy whose care utilized the described protocol from 2010 to 2015. The control group was selected from eligible patients between 2014 and 2015 who were treated with the alternative prevailing practice pattern at the institution. The attending surgeon differed between each arm of the study, but their operative techniques did not differ. Surgical residents performed the cases and fluctuated between each study arm.

Patients who underwent concurrent minor procedures (defined as adenoidectomy, myringotomy tubes, inferior turbinate cautery or direct laryngoscopy) were included in the data set. All patients with other more complex or invasive concurrent procedures were excluded. Patients with significant congenital head and neck malformations were also excluded. A total of 147 patients were identified, 64 cases and 83 controls, with ages ranging from 2 to 12 years. Chart review was performed to capture the clinical variables of age, sex, weight, body mass index (BMI), and presence of obstructive sleep apnea in each group. Statistical analysis was conducted to determine if significant differences existed between the cases and controls.

2.3. Control patients

The control group was treated with the common practice pattern of the institution, which consists of the option for premedication with midazolam, then induction and general anesthesia with a combination of sevofluorane, opiate, and propofol during the procedure. Both groups were given the same intraoperative single doses of dexamethasone, intravenous acetaminophen, and ondansetron.

2.4. Protocol

The protocol utilized begins with premedication in the preoperative holding area with dexmedetomidine 2 μg/kg intranasally via an atomizer 30–45 min prior to induction. If this was inadequate, the option for preoperative midazolam was allowed, but few patients (8 total) received this. Once in the operating room, anesthesia is induced using sevoflurane with oxygen and/or nitrous. After IV placement, the patient is intubated and intravenous dexmedetomidine (0.2–0.5 μg/kg) is run as an adjunct to anesthesia with propofol, opiate, and sevofluorane throughout the duration of the procedure. The intraoperative opiate is titrated to the lowest dose that maintains the appropriate plane of anesthesia for each patient. Intraoperatively, patients are also given single doses of intravenous dexamethasone (0.5 mg/kg, maximum dose of 10 mg), ondansetron (0.1 mg/kg), and intravenous acetaminophen (15 mg/kg). At the conclusion of the case, the surgeon infiltrates 1–2 mL of 0.25% bupivacaine into the bilateral tonsillar beds. Postoperatively, pain is managed with oral acetaminophen, ibuprofen, and opiate as needed based on pain scores reported to the nurse for both groups.

2.5. Outcome measures

The primary outcome measures in this study were the amount of intraoperative sevofluorane and opiate necessary, the post-operative medication administered (opiates, ibuprofen, acetaminophen, and antiemetics), maximum pain score recorded, total time in the post anesthesia care unit (PACU), and length of hospital stay. Other outcomes tested between groups were the amount of opiates administered during the operation and the average of volatile agents required to maintain anesthesia. Opiate drug doses were converted to oral morphine equivalents (OME) and divided by patient weight to standardize analysis. To account for variation in duration of hospitalization, the OME/kg value was also divided by the length of hospital stay in hours. Postoperative complications defined as bleeding, respiratory distress requiring reintubation, and poor oral intake requiring either readmission or an ED visit were also recorded.

2.6. Statistical methods

Data were analyzed using SAS (version 9.4; SAS Institute Inc., Cary, NC) software, and were presented as a frequency (n), percentage (%) for categorical variables; mean and standard deviation for continuous variables; and median and interquartile range for non-normally distributed continuous variables. For continuous variables, a *t*-test was performed to examine the mean difference between the cases and controls. The Chi-squared test (or Fisher's exact test when there were expected frequencies of < 5) was used for the categorical variables to examine whether the distribution of cases and controls was different for the respective variables. A p-value of < 0.05 was considered statistically significant. These tests were designed to assess differences between cases and controls on intraoperative medicine levels and various postoperative outcome measures. Support for the utility of the protocol (used with cases) will be determined by the extent to which measures for the cases are significantly better or similar (i.e., not significantly different) than the control group.

3. Results

Statistical analysis comparing baseline demographic variables between the case and control patients is shown in Table 1. The dexmedetomidine group (cases) and control group had no significant differences in prevalence of obstruction sleep apnea or in gender distribution. Compared to the control group, cases were more likely to be white (53% vs 32.5%, $p = 0.024$) and had a slightly lower body mass index (15.4 vs 15.8, $p = 0.018$).

Analysis of intraoperative medication use, shown in Table 2, revealed that cases received significantly lower doses of opiates intraoperatively by 49.6% when standardized by weight (4.11 OME/kg vs 8.28 OME/kg, $p < 0.0001$) and had lower average end tidal sevoflurane measurements by 18% when compared to controls (1.59 vs

Table 1
Baseline patient characteristics.

	Total sample[a] (n = 147)	Cases (n = 64)	Controls (n = 83)	p-Value
Patient characteristics				
Sex				
Male, n (%)	76 (51.7)	36 (56.3)	40 (48.2)	0.3324
Female, n (%)	71 (48.3)	28 (43.7)	43 (51.8)	
Race/Ethnicity				
White, n (%)	61 (41.5)	34 (53.1)	27 (32.5)	0.0238*,c
Black, n (%)	64 (43.5)	25 (39.1)	39 (47.0)	
Hispanic, n (%)	15 (10.2)	5 (7.8)	10 (12.0)	
Other, n (%)	6 (4.1)	0	6 (7.2)	
Unknown, n (%)	1 (0.7)	0	1 (1.2)	
BMI (kg/m^2)[b]	15.7 (14.5, 18.2)	15.4 (14.3, 17.3)	15.8 (14.6, 21.3)	0.0183*
Obstructive Sleep Apnea (OSA)				
Yes, n (%)	131 (89.1)	56 (87.5)	75 (90.4)	0.5807
No, n (%)	16 (10.9)	8 (12.5)	8 (9.6)	

[a] Values expressed as mean (standard deviation), unless noted.
[b] Values expressed as median (interquartile range).
[c] Fisher's Exact Test Statistic.
* Significant at 0.05 level.

Table 2
Intraoperative medication use.

	Total sample (n = 147)	Cases (n = 64)	Controls (n = 83)	p-Value
Intraoperative medication[a]				
Opiate (OME/kg)	6.46 (4.99)	4.11 (2.86)	8.28 (5.51)	< 0.0001*
Opiate (OME/kg/h)	0.85 (0.79)	0.54 (0.50)	1.08 (0.89)	< 0.0001*
Sevoflurane Avg End Tidal	1.78 (0.51)	1.59 (0.43)	1.94 (0.51)	< 0.0001*
Propofol (mg/kg)	2.80 (1.85)	3.16 (1.84)	2.52 (1.82)	0.0358*

[a] Values expressed as mean (standard deviation), unless noted.
* Significant at 0.05 level.

1.94, $p < 0.0001$) (see Fig. 1). Intraoperative opioid use was also divided by the length of surgery to adjust for variation in the duration of anesthetic per individual patient. This demonstrated the same relationship in intraoperative opioid use in cases compared to controls (0.54 OME/kg/h vs 1.08 OME/kg/h, $p < 0.0001$). Intraoperative propofol dosing per weight was increased by 25.4% in the cases compared to the controls (3.16 mg/kg vs 2.52 mg/kg, $p = 0.0358$).

Postoperative outcome measures are depicted in Table 3. The maximum post-operative pain score reported was significantly higher in the control group than in the case group (3.48 vs. 2.78, $p = 0.0458$) (see Fig. 2). On average, children in the dexmedetomidine group spent 11 more minutes in the PACU than those in the controls group ($p = 0.0185$). There was no difference in need for overnight stay, or overall total length of stay between the groups. There was no significant difference in the need for or amount of either opiate or acetaminophen used postoperatively between the groups (see Fig. 3, 4). The control group did receive significantly more ibuprofen than the case group (see Fig. 4).

A comparison of postoperative complications in cases compared to controls is shown in Table 4. There were no significant differences between cases and controls in any of the five measures. Two complications (reintubation and postoperative bleeding prior to discharge) were not experienced by children in either group.

3.1. Cost analysis

Costs shown in Table 5 are based on the lowest average wholesale price (AWP) obtained from this institution's pharmacy. This is quoted as a list-price and does not account for bulk discounts or the actual acquisition cost to a hospital, which varies between institutions and regions. AWP is used as a benchmark despite these limitations because it is a nationally set standard from which actual costs are usually derived. The cost per patient is calculated based on units of issue (UOI) for a model patient who weighs a representative 25 kg following both the typical protocol and control pathways.

Several medications are given at the same doses for both pathways, including dexamethasone, IV acetaminophen, and ondansetron. Preoperative midazolam is unique to the control pathway. Dexmedetomidine and bupivacaine are unique to the protocol pathway. Intraoperatively, the amount of sevoflurane, opioid, and propofol administered varied.

Sevoflurane consumption is a difficult measure to quantify [12]. It can be calculated using the weight difference in the vaporizer before and after anesthesia and the density of sevoflurane, but this is technically challenging. It requires an extremely precise scale and cannot be performed retrospectively. An alternative is to calculate the volume consumed from clinical parameters [13]. The inspired concentration of sevoflurane (Fi) can be calculated from the end tidal sevoflurane concentration (Fe) using the known ratio, Fe/Fi of 0.94 in pediatric patients [14]. The fluid volume of sevoflurane consumed can be determined using the fresh gas flow rate (FG flow, ml/min), the concentration of sevoflurane (%), and the duration it was utilized (min) [13]. The saturated gas volume for sevoflurane is known to be 184 mL of vapor per mL fluid [13]. For the purposes of standardizing variables in this cost analysis, a typical flow rate of 2 L/min and anesthetic time of 60 min were used.

$$\textit{Fluid Sevoflurane (mL)} = \frac{\textit{FG flow (mL/min)} \cdot \textit{Concentration (Vol\%)} \cdot \textit{Duration (min)}}{\textit{Saturated gas volume (mL/mL)} \cdot 100(\text{Vol\%})}$$

Sevoflurane has the highest UOI cost because it is supplied in multi-dose 250 mL bottles that interface with the anesthesia machine and must be stored carefully. There was a difference in the sevoflurane use of 2.65 mL which led to a calculated cost difference of $1.59.

The most commonly used opioid in this cohort was fentanyl, so for the purposes of cost comparison, the average OME/kg needed was converted to mcg of fentanyl. The difference in amount of opiate use

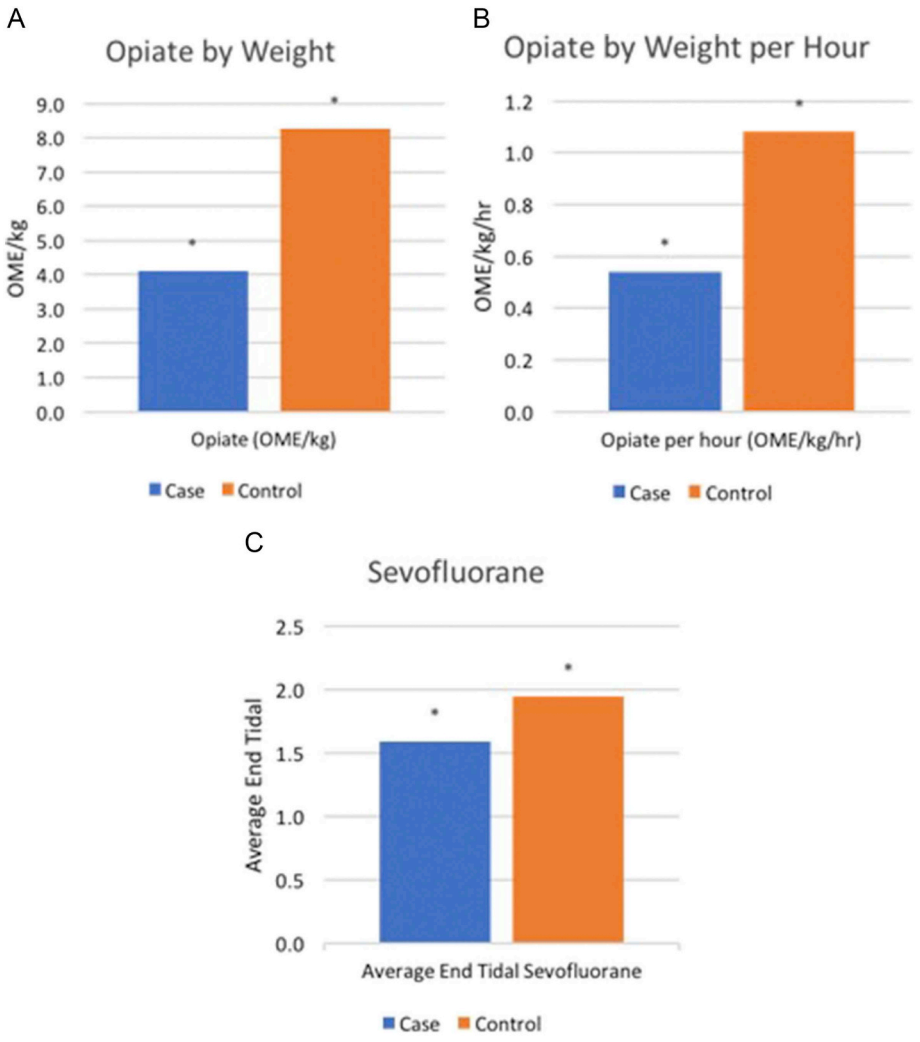

Fig. 1. a. Mean intraoperative weight-based opiate.
b. Mean intraoperative weight-based opiate by time.
c. Percent end tidal sevoflurane.

did not correspond with a change in the UOI per patient with this model.

Propofol is commonly available in 20, 50, and 100 mL vials. For this analysis, the use of one 20 mL bottle of 10 mg/mL propofol provides 200 mg of medication which is adequate for the model patient in both protocol and control requirements. Out of all the subjects in this study, there only three patients in the control group who required total doses of propofol above this 20 mL amount, which would have necessitated a larger, or use of a second, vial. All three were adolescents with high BMI. In a population with a higher percentage of overweight adolescents, this may require using the larger 50 mL vial, which has a slightly higher UOI cost of $14.10, adding $8.46 to the total.

Overall, for the model patient, the difference in total calculated cost was $4.07, largely attributable to the addition of the dexmedetomidine.

4. Discussion

In this protocol, the use of dexmedetomidine and bupivacaine was associated with a reduction in the total amount of intraoperative opiate needed by 49.6% and a decrease in the volatile anesthetic use by 18%. This is largely attributed to the dexmedetomidine because the bupivacaine is injected at the conclusion of the procedure. By reducing opiate use in half, it is suspected that side effects are also decreased, although this study was not explicitly designed to analyze this. Lower volatile anesthetic use is felt to be beneficial due to neurotoxicity concerns with these agents [15]. Intraoperative propofol use was higher in the protocol group. Propofol has been associated with reduced postoperative nausea and emergence delirium in children, so this is felt to be a beneficial exchange in anesthetic agent use [16]. Both reductions in opiate and sevoflurane are thought to be clinically impactful and further studies looking at emergence agitation, post-operative nausea, and respiratory depression are planned.

This protocol helped improved post-operative pain control by reducing the maximum postoperative pain score by 0.7 on a 10-point scale. This is a small numerical difference but any reduction in pain after tonsillectomy is felt to be beneficial for patients. This is attributed mainly to the bupivacaine injection and improved immediate post-operative pain scores early in the recovery process which is felt to set patients on a more favorable trajectory for the remainder of their course. There is data that suggests dexmedetomidine enhances the effects of local anesthetics [17], which reinforces the importance of interdisciplinary collaboration between surgeons and anesthesiologists

Table 3
Post-operative outcome measures.

Outcome measure[a]	Cases (n = 64)	Controls (n = 83)	p-Value
Max. Post Pain Score	2.78 (2.12)	3.48 (2.07)	0.0458*
Total Time in Post Anesthesia Care Unit (minutes)[b]	81 (58, 119.5)	70 (39, 108)	0.0185*
Overnight Stay			0.5291
Yes, n (%)	47 (73.4)	57 (68.7)	
No, n (%)	17 (26.6)	26 (31.3)	
Length of Hospital Stay (minutes)[b]	461 (359, 1436)	414 (321, 1527)	0.3531
Opiate (OME/kg/h)	0.007 (0.01)	0.005 (0.01)	0.1639
Total Opiate Used Post-Operatively (OME/kg)	0.13 (0.30)	0.08 (0.17)	0.2365
Any Opiate received?			
Yes, n (%)	28 (43.8)	27 (32.5)	0.1634
No, n (%)	36 (56.3)	56 (67.5)	
Ibuprofen (mg/kg/h)	0.65 (0.77)	1.26 (0.62)	< 0.0001*
Ibuprofen (mg/kg)	6.70 (9.76)	13.16 (10.19)	0.0002*
Any Ibuprofen received?			
Yes, n (%)	30 (46.9)	75 (90.4)	< 0.0001*
No, n (%)	34 (53.1)	8 (9.6)	
Acetaminophen (mg/kg/h)	0.38 (0.69)	0.35 (0.74)	0.8229
Acetaminophen (mg/kg)	7.34 (13.70)	8.64 (18.28)	0.6215
Any Acetaminophen received?			
Yes, n (%)	21 (32.8)	23 (27.7)	0.5031
No, n (%)	43 (67.2)	60 (72.3)	
Antiemetic (mg/kg/h)	0.0004 (0.002)	0.0002 (0.002)	0.4745
Antiemetic (mg/kg)	0.01 (0.05)	0.002 (0.02)	0.2055
Any Antiemetic received?			
Yes, n (%)	4 (6.2)	2 (2.4)	0.4040[c]
No, n (%)	60 (93.8)	81 (97.6)	
Received Any of the Four Postoperative Drugs?			0.0140*
Yes, n (%)	53 (82.8)	79 (95.2)	
No, n (%)	11 (17.2)	4 (4.8)	

[a] Values expressed as mean (standard deviation), unless noted.
[b] Values expressed as median (interquartile range).
[c] Fisher's Exact Test Statistic.
* Significant at 0.05 level.

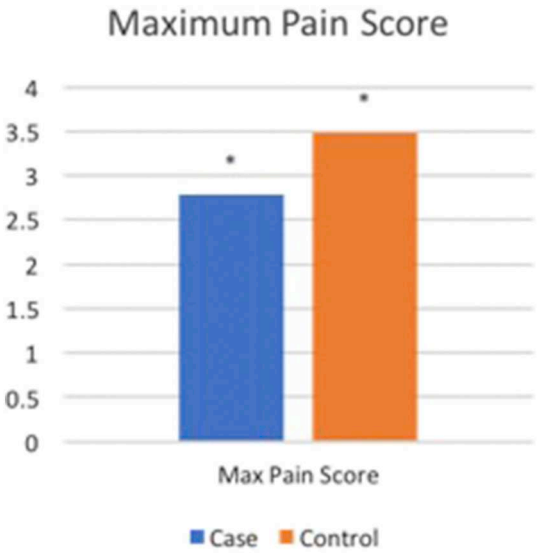

Fig. 2. Maximum post-operative reported pain score.

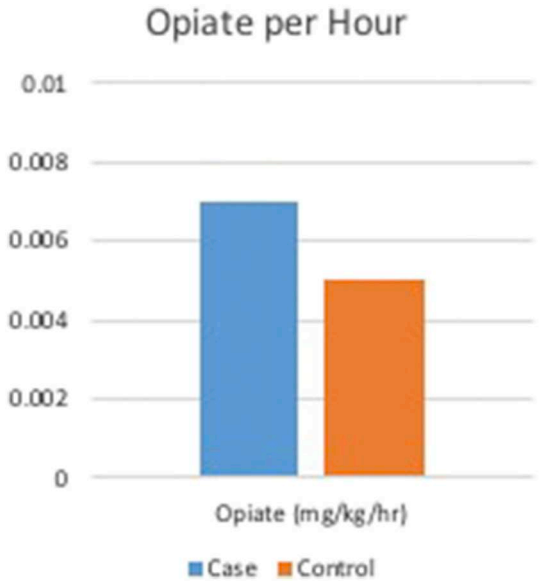

Fig. 3. Postoperative weight-based opiate per hour.

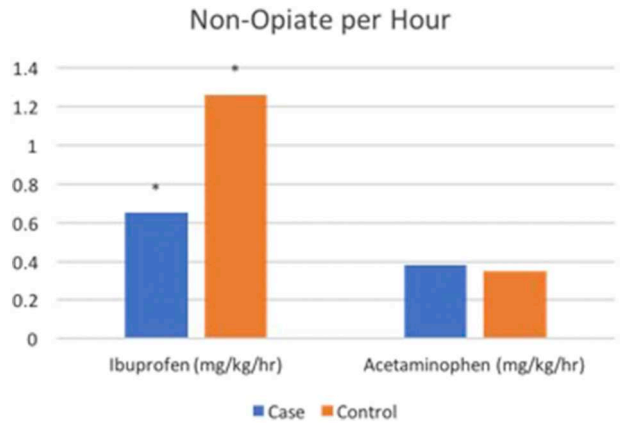

Fig. 4. Postoperative weight-based non-opiate per hour.

Table 4
Postoperative complications.

Indicator	Cases (n = 64)	Controls (n = 83)	p-Value
ED Visit[a]			
Yes, n (%)	2 (3.1)	2 (2.4)	0.3674[f]
No, n (%)	62 (96.9)	81 (97.6)	
Readmission[b]			
White, n (%)	2 (3.1)	1 (1.2)	0.3226[f]
Black, n (%)	62 (96.9)	82 (98.8)	
Reintubation[c]			
Yes, n (%)	0 (0)	0 (0)	NA[†]
No, n (%)	64 (100)	83 (100)	
Bleeding prior to discharge[d]			
Yes, n (%)	0 (0)	0 (0)	NA[†]
No, n (%)	64 (100)	83 (100)	
Bleeding after discharge[e]			
Yes, n (%)	1 (1.6)	1 (1.2)	0.4950[f]
No, n (%)	63 (98.4)	82 (98.8)	

[a] Did the Patient visit the Emergency Department after 30 days of initial discharge?
[b] Was the patient readmitted to the hospital within 30 days from discharge for an issue related to the initial operation?
[c] Did the patient have respiratory compromise after extubation that required reintubation?
[d] Did the patient have bleeding after their initial operation but prior to discharge from hospital?
[e] Did the patient have bleeding after discharge which required an ED visit?
[f] Fisher's Exact Test Statistic.
[†] Not applicable.

for maximum benefit. Further analysis looking at the timing of pain scores and medication dosing may help determine if this change coincides with the time period when the local anesthetic is in effect.

Clinically, the decrease in pain score was accompanied by a decreased need for postoperative ibuprofen by 48%. This reflects their need for less pain medication due to a lower reported pain score and also presents an opportunity for refinement of the pain management. If these patients receive ibuprofen in the same amounts as the control group, it may be possible to reduce their postoperative opiate need further.

There was a longer PACU stay associated with the use of this protocol, by 11 min. While it is statistically significant, the clinical ramifications of this amount of time are not thought to have much effect on practice patterns or patient flow at this institution. In a different clinical environment, this may impact patient flow, but this would be different center to center. No significant difference was identified in the need for overnight admission or length of hospital stay.

There was a statistically significant difference in the BMI and ethnicities between the protocol and control group, with the protocol group having a slightly lower BMI of 15.4 and a higher percentage of white patients (53%) compared to the control group with a slightly higher BMI of 15.8 and a higher percentage of black patients (47%). Black race has been associated with an increased risk of complications after tonsillectomy [18]. Despite the BMI difference being statistically significant, there was no difference in the presence of OSA between the groups, so this factor alone is not thought to be pertinent in this study's findings. No significant difference was detected in postoperative adverse events, but these are rare and more patients may need to be examined to achieve adequate study power.

Cost analysis is complex with many factors involved that can vary from institution to institution. For this protocol, sevoflurane consumption is especially difficult to measure and modeling this inherently introduces some amount of error. The $4.07 difference in cost not much for an individual patient but when multiplied across an entire health system may be consequential. Further dedicated studies looking directly at hospital charges and costs could be considered to get a more accurate analysis.

5. Conclusion

The described interdisciplinary approach for pediatric tonsillectomy between Anesthesia and Otolaryngology providers using dexmedetomidine and local anesthetic is beneficial in minimizing opiate use and avoiding volatile anesthetic exposure. This study showed improvement in postoperative pain scores and no increase in complications. Use of these adjuncts is a promising alternative to decrease the need for opiates in a patient population already vulnerable to their respiratory depressant effects.

Table 5
Cost analysis.

Medication	Unit formulation	UOI cost	Protocol patient				Control patient			
			Typical dose (/kg)	Total dose	UOI for dose	Typical cost	Typical dose (/kg)	Total dose	UOI for dose	Typical cost
Midazolam	118 ml bottle of 2 mg/mL	$4.08	–	–	–	–	0.39 mg/kg	9.75 mg	4.9 ml	$4.08
Dexmedetomidine (Nasal)	2 ml vial of 100 μg/mL	$8.23	2 μg/kg	50 μg	1 vial	$8.23	–	–	–	–
Dexmedetomidine (IV)	Same vial		0.53 μg/kg	13.25 μg	Same vial		–	–	–	–
Dexamethasone	1 ml of 10 mg/mL	$4.92	0.5 mg/kg	10 mg	1 vial	$4.92	0.5 mg/kg	10 mg	1 vial	$4.92
Acetaminophen (IV)	1 g vial	$13.00	15 mg/kg	375 mg	1 bottle	$13.00	15 mg/kg	375 mg	1 bottle	$13.00
Ondansetron	2 ml vial of 2 mg/mL	$4.57	0.1 mg/kg	2.5 mg	1 vial	$4.57	0.1 mg/kg	2.5 mg	1 vial	$4.57
Sevoflurane	1 bottle of 250 mL	$149.58		1.58%	10.95 mL	$6.55		1.96%	13.6 mL	$8.14
Fentanyl	2 ml vial of 50 μg/mL	$1.15	4.11 OME/kg	25.7 μg	1 vial	$1.15	8.28 OME/kg	51.75 μg	1 vial	$1.15
Propofol	20 ml vial of 10 mg/mL	$5.64	3.16 mg/kg	79 mg	1 vial	$5.64	2.52 mg/kg	63 mg	1 vial	$5.64
Bupivacaine	10 ml of 2.5 mg/mL	$1.51		2–4 mL	1 vial	$1.51	–	–	–	–
Total Cost						$45.57				$41.50

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