The application of xylocaine 10% pump-spray to improve immediate post-adenotonsillectomy pain in children: A randomized controlled trial

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Abstract

Introduction: Post-adenotonsillectomy pain is often severe, requiring substantial analgesia in the first 48–72 h. This pain is not only distressing to the patient and his or her parents, but often reflects poorly on an otherwise well performed procedure. Safe, simple and effective post-adenotonsillectomy pain control is still clinically elusive, even though a multitude of surgical and analgesic interventions have been proposed.

Objectives: To investigate the analgesic properties of immediate post-operative application of xylocaine 10% pump spray to the tonsillar fossae in children having undergone adenotonsillectomy and how this impacts on anesthetic emergence and pain control in the first 24-h.

Methods: In this double-blinded, randomized, placebo-controlled trial, 80 children were stratified into two groups: Group I (3-8 years-old) and Group II (9–14 years-old). Within these groups, participants were randomized to receive either xylocaine 10% pump spray or normal saline 0.9% post-operatively. A standardized anesthetic/analgesic regime was used intra-operatively. The same surgeon performed all surgeries using bi-polar diathermy. Outcome variables included state of anesthetic emergence; pain scores at specific intervals; need for rescue analgesia; post-operative nausea and vomiting; time to first oral intake and comfort associated with initial oral intake**.**

Results: Xylocaine 10% pump spray consistently provided superior pain control at all time intervals compared to normal saline 0.9% ($p = 0.011$). This was most pronounced in children 3–8 years old (Group I). Xylocaine 10% pump spray and normal saline 0.9% provided similar pain relief in children 9–14 years old (Group (II) ($p = 0.640$). Children receiving xylocaine had a decreased incidence of emergence delirium and consistently required less rescue analgesia ($p = 0.005$). Children who received xylocaine did not eat sooner post-operatively, but they experienced less pain when ingesting liquids ($p = 0.003$) and solids ($p = 0.000$). Children who received xylocaine did not experience increased post-operative complications ($p = 1.000$) or nausea and vomiting ($p = 0.153$).

Conclusion: Xylocaine 10% spray may serve as a valuable adjunct to effective pain control post-adenotonsillectomy, especially if long acting opioids are contraindicated, as with patients with obstructive sleep apnea. The benefit of xylocaine appears to be negligible when a long acting opioid is administered. The benefits of xylocaine were most noteworthy in children aged 3–8 years old. This is the largest trial ($n = 80$) to date to assess the efficacy of xylocaine spray in isolation post-adenotonsillectomy. Xylocaine also offers improved comfort with oral intake and decreases emergence delirium and need for rescue analgesia without any increase in post-

operative complications. Local anesthesia may decrease costs and help to solve the conundrum of a painless adenotonsillectomy especially in resource-limited settings.

Keywords: Adenotonsillectomy; Tonsillectomy; Pain; Children; Local anesthetic; Xylocaine; Emergence delirium; Lidocaine; Lignocaine

1. Introduction

Adenotonsillectomy is one of the most painful otorhinolaryngological procedures, often requiring a variety of post-operative analgesic interventions. The search for *'The Painless Adenotonsillectomy'* is on-going and remains elusive. Emphasis should be given to the fact that post-adenotonsillectomy pain is multimodal in origin, and thus the management thereof would have to follow suit. Patients who are in pain may also recover poorly and have functional impairment for up to a week following surgery [1]. Post-adenotonsillectomy pain is the most common reason why patients contact their surgeon [1]. Most of the pain occurs in the tonsillar fossae rather than in the adenoid bed and is caused by surgical trauma to the mucosa and underlying muscle fibers. There is also local neurogenic irritation within the peri-tonsillar space. The resultant tissue inflammation and associated pharyngeal muscle spasms lead to ischemia and prolonged pain. The pain starts to subside once the mucosa covers the affected fossae [2,3].

The exact focus of the study was the 'immediate' post-operative period, (the first 2-h post-operatively and a subject-area with sparse data within literature). Pain management immediately after an adenotonsillectomy may afford an opportunity to improve recovery. Local anesthetic agents have previously been used in clinical practice to alleviate post-adenotonsillectomy pain but with mixed results [2,[4], [5], [6], [7], [8], [9]]. Local anesthetic agents are relatively safe and simple to administer either before or after an adenotonsillectomy. Pain management during the first 2 h post-operatively is crucial for setting the 'tone' for future pain control and preventing breakthrough pain. Reduced pain may prevent emergence delirium in children, reduce post-operative nausea, and calm both patients and parents [8].

Topical application of local anesthetics to reduce post-adenotonsillectomy pain is considered safer than local infiltration techniques. This could be of great advantage for children, where the systemic side-effects of intravenous agents are especially undesirable [2]. One such local anesthetic is xylocaine 10% pump-spray (lignocaine or lidocaine). The efficacy of xylocaine 10% pump spray for controlling immediate post-adenotonsillectomy pain has not been rigorously studied, barring a handful of studies - one of which included 49 children in 1986 by Williams, Hamilton [7] and another by Dalwadi, Dalwadi [8] in 2015. A third study conducted by Jahromi, Valami noted that lidocaine spray had the best pain controlling effect at 20 min, but after 40 min, ketamine and morphine sprays were more effective [9].

Each metered dose of xylocaine spray delivers 0.1 mL and contains 10 mg lignocaine (lidocaine), ethanol, polyethylene glycol, essence of banana, menthol, saccharin and purified water [10]. Lignocaine (lidocaine) inhibits the excitation of nerve endings through reversible binding to sodium channels [10]. The maximum infiltrative dose of lignocaine is 4.5 mg/kg, up to 300 mg without adrenaline; or 7 mg/kg, up to 500 mg with adrenaline [10]. Over-dosage may result in cardiovascular or neurological side effects [10].

During an adenotonsillectomy surgeons should limit coagulation, tissue necrosis, muscle spasms and duration of surgery. A well performed adenotonsillectomy will also help to ameliorate post-operative pain [11,12]. Adenotonsillectomy procedures vary according to setting. Al-Mahbashi, Saeed, Al-Attab, Raja'a [13] compared the procedures used to perform 12 280 tonsillectomies in Yemen and noted that cold steel was still the most common technique used. In the private healthcare setting and in developed countries, controlled ablation or coblation is preferred for performing adenotonsillectomies. Both coblation and microdebrider are associated with improved post-operative recovery and reduced pain [14]. The public healthcare sector in South Africa often only has access to diathermy for performing adenotonsillectomy, thus this technique was used in this study. When diathermy is to be utilized, it should be on minimal settings and coagulating should not occur for longer than 2 s at a time [2].

2. Objectives

2.1. Primary objective

- To investigate the effect of immediate post-operative application of Xylocaine 10% spray to the raw tonsillar fossae in children having undergone adenotonsillectomy; and how this impacts on their state of emergence and pain control in the first 24 h post-operatively.

2.2. Secondary objectives

- To determine the role of local anesthetics in the multimodal pain control needed in post-adenotonsillectomy patients.
- To review if local anesthetic application post-adenotonsillectomy can decrease emergence delirium and thus set the 'tone' for comprehensive pain control in the subsequent days and weeks to follow.
- To assess whether or not pain scores in specific subgroups, (e.g. male vs. female) are significantly different in the respective Normal Saline 0.9% or Xylocaine groups.

- To assess whether or not the application of a local anesthetic post-adenotonsillectomy will shorten time to first oral intake and improve comfort associated with this intake.

3. Methods

3.1. Study setting

Steve Biko Academic Hospital (SBAH) and Kalafong Provincial Tertiary Hospital (KPTH), Pretoria, South Africa.

3.2. Study design

This was a double-blind, randomized, placebo-controlled prospective clinical trial, which took place from the September 1, 2018 to the April 30, 2019. The researcher, nursing staff, anesthetists and patients were all blinded. Only the attending pharmacist, who prepared the two study-bottles (BOTTLE A and B), knew the contents. The pharmacist did not interact directly with the patients. The lead researcher (JO) was the only surgeon and used bipolar diathermy for all the surgeries.

3.3. Study population

We included patients who were admitted to SBAH or KPTH for adenotonsillectomy between the ages of 3 and 14 years old. These patients had a history of either recurrent bacterial tonsillitis or symptoms of obstructive sleep apnea due to adenotonsillar hypertrophy. Appropriate pre-operative investigations were performed.

3.3.1. Exclusion criteria

- Patients younger than three years and older than 14 years
- Children weighing less than 14 kg
- Patients with bleeding diathesis
- History of allergy to local anesthetics or constituents of Xylocaine 10% spray
- Patients with previous or current liver disease, epilepsy, cardiac or renal disease
- Patients with a history of malignant hyperthermia
- Acute tonsillitis currently or in the last seven days or acute peri-tonsillar abscess (Quinsy)
- Patients with pulmonary hypertension >30 mmHg, right heart dysfunction or requiring high care/ICU post-operatively or patients unfit for general anesthesia
- Any lesion on one or both tonsils not in keeping with recurrent bacterial infection, e.g. malignancy, tuberculosis, etc.
- Previous adenotonsillectomy/tonsillectomy.

3.4. Sampling method

The children and their parents who met the inclusion criteria were counselled and consent was signed. Children who were older than seven years also signed an assent form. Consenting parents received an information sheet outlining the study. Parents could withdraw their child at any time. Confidentiality was maintained at all times. Ethical clearance was obtained from the respective committees of the University of Pretoria (Reference no. 451/2018).

3.5. Sample size

Our study included 80 patients, who were randomly allocated to either a placebo (normal saline 0.9%) or xylocaine group, (40 participants in each). We calculated ideal sample size using Strata14 to detect an experimental-group proportion of 0.5 when the control-group proportion was 0.2; assuming a two-sided hypothesis test with a 5% significance level, desired power of 80% and that both groups had the same number of participants. The Pearson's chi-squared test was used to detect between group differences.

3.6. Randomization

Patients were placed into experimental groups using stratified randomization according to age. We prepared 80 letters addressed to the attending anesthetist. Forty letters requested Bottle ‘A’ (Letter A) to be handed to the surgeon after completing the adenotonsillectomy. Forty letters requested Bottle ‘B’ (Letter B).

We allocated 60 letters to children in the three to eight years old age group (Group I) and 20 letters to children in the nine to 14 years age group (Group II). This was done to ensure accurate representation of children usually presenting for adenotonsillectomy at SBAH and KPTH. For

Group I, 30 Letter As and 30 Letter Bs were placed into radio-opaque envelopes which concealed their allocation. The 60 concealed envelopes were randomly mixed, gathered and then sequentially numbered (001–060). Each envelope had an attached study booklet. On admission patients were asked to draw a letter from the Group I box.

The process was then repeated for Group II (aged 9–14 years old), with twenty radio-opaque envelopes (061–080). The two boxes and were kept safely in the ENT clinic in a locked cupboard. At the end of the trial, Group I had 62 participants and Group II had 18 participants, due to fewer children between nine and 14 years old presenting for adenotonsillectomy during the study period.

3.7. Bottle preparation and blinding

Before the study started, a senior pharmacist (Ms. T. Palane) filled an empty sterilized xylocaine pump-spray bottle with normal saline 0.9% and covered the exterior with occlusive tape. She then covered an unused bottle of xylocaine spray with the same occlusive tape, so that both bottles were identical. Lastly, she labelled the bottles on their bases as either 'A' or 'B'. The true content of each bottle was saved on her password controlled computer.

These two bottles were kept in a locked cupboard in the theatre complex. At the end of the study, following data analysis, the pharmacist reveal that Bottle A contained normal saline 0.9% and that Bottle B contained xylocaine.

3.8. Surgical methodology

The starved patient was accompanied by their parent to the theatre complex. None of the children received any pre-medication. A standard anesthetic protocol was used and administered to all the study participants:

1. Sufentantil (0.1–0.2mcg/kg IVI)
2. Paracetamol (10–15 mg/kg IVI)
3. Children aged 3–8 years old → Valoron drops (1drop/2.5 kg of weight)

Children aged 9–14 years old → Morphine (0,05–0,1 mg/kg IVI)

The anesthetists avoided any agents with associated analgesic properties, e.g. Ketamine. A standard approach to adenotonsillectomy was followed. 'Intra-operatively' was defined as the time from induction of anesthesia to just after rinsing the oro- and nasopharynx. 'Immediate post-operatively' was defined as just after rinsing, before collapsing and removing the gag until 2 h after applying the spray. Adenoids were removed via curette, followed by removing the palatine tonsils with bipolar diathermy. Bipolar diathermy settings were kept low (20) and used in short bursts. Tonsil swabs were soaked in dextrose and adrenaline.

After rinsing the nasopharynx and oropharynx and no residual hemorrhage was noted, the anesthetist handed the surgeon the specific spray bottle as indicated in the study envelope. The surgeon remained blinded to the label. The surgeon then applied two sprays of the given bottle to each tonsillar fossa, attempting to keep the spray within the tonsillar pillars. 'Spillage' was suctioned up by the surgeon immediately so that the hypopharynx and the laryngeal inlet were not anesthetized. The anesthetist was instructed not to suction the tonsillar fossa.

3.9. Data collection and measurements

The anesthetist recorded the pre-operative vitals, pain score and drugs administered during surgery. The surgeon recorded the surgical technique used, possible excessive bleeding and time of spray applied. In the recovery room, the surgical intern (blinded) took over data collection. Pain scores were measured using the Face, Legs, Activity, Cry and Consolability scale (FLACC) [15]. The intern recorded the patient's vital signs, need for rescue analgesia or any other analgesia given, and post-operative nausea and vomiting. Data were recorded after 5 min (recovery); 15 min; 30 min; 60 min; 120 min and 24 h. The WATCHA scale was used to assess for anesthetic emergence delirium [16].

4. Results

4.1. Basic demographics and pre-operative data

Participants in Group I and II had significantly different ages ($p = 0.00$, 95% CI 6–7); weights ($p = 0.00$, 95% CI 21.8–26.7), pre-operative pulse ($p = 0.0002$, 95% CI 105–113), pre-operative blood pressure ($p = 0.0003$, 95% CI 95–102, 95% CI 47–53) and pre-operative respiratory rate ($p = 0.0009$, 95% CI 21–23) (Table 1). These results were expected because the two groups were stratified according to age. All participants (Group I and II) had an initial pre-operative FLACC pain score of 0/10 ($p = 1.000$).

Participants who received normal saline 0.9% had similar demographic and pre-operative parameters to participants in xylocaine group (Table 2). In Group I, 33 children received xylocaine and 29 children received normal saline 0.9%. In Group II, seven children received xylocaine whereas 11 children received normal saline 0.9% ($p = 0.820$).

4.2. Duration of anesthesia

Participants in Group I [mean = 44min], and Group II [mean = 46min] had similar duration of anesthesia. Combined mean = 44.6min, 95% CI, 43–46min, $p = 0.2972$). Participants receiving normal saline 0.9% [mean = 45min] and xylocaine [mean = 44min] had similar duration of anesthesia as well. Combined mean = 44.5min, 95% CI, 43–46min, $p = 0.39$).

4.3. Pre-operative vitals vs. post-operative vitals

Children who received normal saline 0.9% showed significant changes in the following parameters post-operatively: pulse: $p = 0.0001$; systolic blood pressure: $p = 0.0000$; diastolic blood pressure: $p = 0.0066$ and pain score: $p = 0.0000$. Children who received xylocaine recorded similar pulse after adenotonsillectomy ($p = 0.1126$) suggesting improved pain control.

4.4. Post-operative pain scores

Participants in different age groups had similar pain scores at all time intervals except at 24 h, when children in group II had higher pain scores (Table 3). Children who received xylocaine had lower pain scores at all intervals (Table 3). Pain scores of all children decreased over time (Fig. 1). Children in Group I who received xylocaine had lower pain scores than children in Group I who received normal saline 0.9% ($p = 0.001$). Children in Group II had similar pain scores irrespective of receiving normal saline or xylocaine. The children in Group II received

Table 1. Demographics and pre-operative data of all participants, Group I (aged 3–8 years old) and Group II (9–14 years old). Standard deviation: SD.

	Total				**Group I**				**Group II**			
Gender	**Male 35 (44%)**		**Female 45 (56%)**		**Male 28 (45%)**		**Female 34 (55%)**		**Male 7 (39%)**		**Female 11 (61%)**	
Indication for Surgery	**Recurrent Tonsillitis 76 (95%)**		**Adenotonsillar hypertrophy 4 (5%)**		**Recurrent Tonsillitis 60 (97%)**		**Adenotonsillar hypertrophy 2 (3%)**		**Recurrent Tonsillitis 16 (89%)**		**Adenotonsillar hypertrophy 2 (11%)**	
	Mean (SD)	**Min**	**Max**	**Median**	**Mean (SD)**	**Min**	**Max**	**Median**	**Mean (SD)**	**Min**	**Max**	**Median**
Age (years)	6.5 (3)	3	14	6	5.1 (1.6)	3	8	5	11.3 (1.7)	9	14	11
Weight (kg)	24.2 (10.9)	14	62	20	20 (6.6)	14	53	19	38 (10.3)	27	62	38
Pulse	109 (17.7)	65	138	111	113 (15.3)	74	138	114	93 (17.2)	65	125	94
Blood Pressure	99/50 (15.6/12.3)	66/21	147/84	95/50	93/47 (12.4/11.3)	66/21	121/76	94/48	116/59 (13.4/11.5)	95/43	147/84	117/58
Respiratory rate	22 (3)	16	30	22	23 (3)	17	30	24	20 (3.1)	16	29	18

Table 2. Demographic characteristics and pre-operative data of participants in the placebo (normal saline, n = 40) and intervention group (xylocaine, n = 40).

Gender	**Normal saline (0.9%)**				**Xylocaine**			
	Male 19 (47%)		**Female 21 (53%)**		**Male 16 (40%)**		**Female 24 (60%)**	
Indication for Surgery	**Recurrent Tonsillitis 38 (95%)**		**Adenotonsillar hypertrophy 2 (5%)**		**Recurrent Tonsillitis 38 (95%)**		**Adenotonsillar hypertrophy 2 (5%)**	
	Mean (SD)	**Min**	**Max**	**Median**	**Mean (SD)**	**Min**	**Max**	**Median**
Age (years)	6.8 (3.4)	3	14	6	6.2 (2.7)	3	16	6
Weight (kg)	25.9 (12.8)	14	62	20.5	22.6 (8.4)	14	55	20
Pulse	106 (18.6)	65	136	108	112 (16.6)	74	138	111
Blood Pressure	101/52 (15.4/11)	73/29	147/78	98/51	96/48 (15.6/13.5)	66/21	131/84	93/48
Respiratory rate	22 (2.7)	18	28	22	22 (2.7)	18	28	22

morphine whereas those in Group I received Valoron drops as part of a standardized anesthetic protocol. Due to the half-life and potency of morphine, it may have masked any positive effects Xylocaine.

Table 3. Mean post-operative pain scores at different time intervals per age group and intervention. Significantly different pain scores are indicated in ***bold and italics*** ($p < 0.05$).

Mean pain score	All participants	Age group		Intervention	
		Group I	Group II	Normal saline 0.9%	Xylocaine
5-min	1.49	1.6	1.2	***2.17***	***0.8***
15-min	1.24	1.4	1.2	***1.88***	***0.6***
30-min	1.23	1.3	1.1	***1.8***	***0.65***
60-min	1.09	1.1	1.1	***1.63***	***0.55***
120-min	0.75	0.8	0.7	***1.07***	***0.42***
24-h	0.23	***0.2***	***0.5***	***0.4***	***0.05***

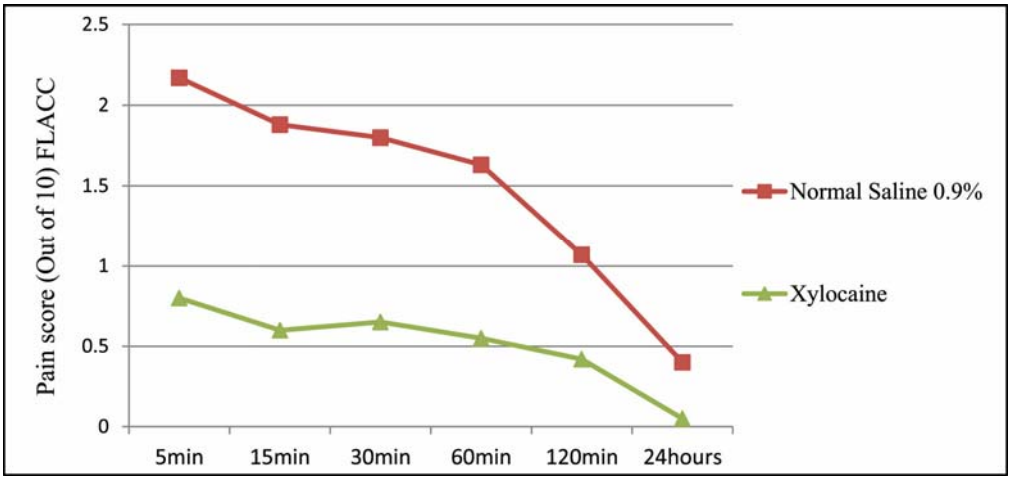

Fig. 1. Mean pain scores (Normal saline 0.9% vs. Xylocaine) at different time intervals.

Five children received rescue analgesia in the recovery room, of whom four received normal saline 0.9% and one child received xylocaine. Rescue analgesia comprised of either ketamine or sufentanil. The need for rescue analgesia was associated with emergence delirium ($p = 0.000$). Children in Group I, who received normal saline 0.9% seemed to have higher rates of emergence delirium and associated need for rescue analgesia, although the sample size was small. In Group II, emergence delirium and the need for rescue analgesia was not associated with receiving normal saline 0.9% ($p = 0.200$) or xylocaine ($p = 0.454$).

Pain scores were similar for boys and girls at all time intervals, irrespective of whether they received normal saline 0.9% ($p = 0.3654$), xylocaine ($p = 0.3517$) or were in Group I ($p = 0.6270$) or Group II ($p = 0.2482$). Regarding weight, no statistically significant difference between Group 1 and Group 2 ($p = 0.3570$); or between Normal Saline 0.9% or Xylocaine ($p = 0.9667$); or if assessed per group and per spray bottle combined ($p = 0.7988$).

4.5. Difficult cases

Out of 80 participants, we recorded 19 (23.75%) difficult cases, 11 from (Group II) and 8 from (Group I). These were assessed by the surgeon intra-operatively as either having had more

fibrotic bands impairing dissection; those with more hemorrhage or those requiring excessive diathermy use.

Although those 'difficult' cases receiving normal saline 0.9% had consistently elevated pain scores, this was only statistically significant at the 24-h mark (Table 4). Difficult cases would invariable have more coagulative injury and subsequently local anesthetic absorption would be limited.

Table 4. Mean pain scores of the 'difficult' cases (19) vs. all participants at various time intervals. Significant p-values in ***bold and italics*** ($p < 0.05$).

	Normal saline 0.9% (8 cases)	**Xylocaine (11 cases)**	**All participants**	**P-value**
5-min	2.38	1.91	2.11	0.57
15-min	1.25	1.09	1.16	0.73
30-min	1.38	0.73	1.00	0.17
60-min	1.25	0.55	0.84	0.06
120-min	0.75	0.27	0.47	0.11
24-h	0.75	0.00	0.32	***0.01***

4.6. Time to first oral intake and associated comfort

Participants had similar time to first oral intake, irrespective of age group ($p = 0.086$) and intervention ($p = 0.68$) (Table 5). When fluids were consumed, more children ($n = 24$) who received xylocaine recorded pain scores of 0, while more children ($n = 25$) in the normal saline group recorded pain scores of 1 ($p = 0.003$). When solids were consumed more children ($n = 34$) who received xylocaine recorded a pain score of 1, whereas ($n = 21$) who had received normal saline reported a score of 2 ($p = 0.000$)

Table 5. Time to first oral intake by age group and intervention.

	Total	**Age group**		**Intervention**	
		Group I	**Group II**	**Normal saline 0.9%**	**Xylocaine**
Number of participants	80	62	18	40	40
Mean time (min) (95% CI)	142 (131–153)	137 (125–147)	162 (134–188)	140 (131–153)	144 (125–163)

4.7. Post-operative aspiration; nausea and vomiting

None of the children had post-operative aspiration. Seven children experienced nausea and vomiting, three children in Group I and four children in Group II. Nausea and vomiting occurred at 60mins ($n = 2$), 120mins ($n = 2$) and 24 h ($n = 3$). Five bouts of nausea occurred in children who received xylocaine (60min = 2, 120min = 2, and 24 h = 1). Only two bouts of nausea occurred in children who received normal saline (24 h = 2). Bouts of nausea and vomiting were similar in the normal saline and xylocaine groups ($p = 0.153$).

4.8. Post-operative complications

Mild complications ranged from minimal uvula swelling to experiencing emergence delirium. Post-adenotonsillectomy sepsis with minimal bleeding was considered a moderate complication. Active post-adenotonsillectomy bleeding, hematemesis, hemodynamic

instability and any anesthetic complication were considered severe complications (Table 6). One child returned a week post-adenotonsillectomy with blood stained sputum and fever. He had a small clot in his left superior tonsillar pole and was taken for a re-look and admitted for 3 days of intravenous antibiotics.

Table 6. Post-operative complications per age group and intervention.

Complications		Age group		Intervention		Total
		Group I	Group II	Normal saline 0.9%	Xylocaine	
1 (none)		55 (88%)	17 (94%)	36 (90%)	36 (90%)	72
2 (mild)		6 (10%)	1 (6%)	3 (7.5%)	4 (10%)	7
3 (moderate)		1 (2%)	0	1 (2.5%)	0	1
4 (severe)		0	0	0	0	0
Total		62 (100%)	18 (100%)	40 (100%)	40 (100%)	80

5. Discussion

In this randomized controlled trial, we assessed the efficacy of xylocaine pump spray to improve immediate post-operative pain control after an adenotonsillectomy. Xylocaine was applied to the raw tonsillar fossae immediately after the procedure. Compared to normal saline, children who received xylocaine had lower pain scores at all time intervals. Although the time to first intake was similar, children who received xylocaine were more likely to record lower pain scores when drinking and eating. Direct application of xylocaine immediately after adenotonsillectomy seems to improve pain management, especially for younger children.

Our trial included mostly younger children between the ages of three and eight years old. We also included a smaller group of older children aged nine to 14 years old. Our sample compares well to sample sizes, demographic characteristics, including age, weight, gender and pre-operative vitals recorded in similar studies [3,4,8,17]. This trial is the largest to date to assess the efficacy of xylocaine spray in isolation versus a control and is the only study to stratify the sample according to age. We noted the strongest benefit to pain control in the younger children rather than in older children, who are known to struggle with pain after adenotonsillectomy. Most of the children in our trial were admitted for recurrent tonsillitis, which is the most common indication for adenotonsillectomy in children younger than 18 years old [18].

In our study, the time under anesthesia, from induction until the child was extubated, was on average 44 min irrespective of age or intervention. This was well within the time reported for adenotonsillectomies by the Children's Hospital of Pittsburgh [19]. All the adenotonsillectomies were performed by one surgeon using bi-polar diathermy. Bi-polar diathermy is also widely used in resource constrained settings, including the broader public health sector in South Africa. The standardized anesthetic protocol was also a unique aspect of the study.

In settings where bi-polar diathermy and cold steel [13] are used, xylocaine provides a useful modality for pain management. In our study, children who received xylocaine had similar pulse and respiratory rate before and after the procedure. These children also had better pain scores at all intervals, especially children between three and eight years old. The older children (Group II) received morphine, which may have masked any positive effects of xylocaine. Children in Group II also had similar rates of emergence delirium, irrespective of whether they received xylocaine or normal saline. The children in Group I who received normal saline had higher rates of emergence delirium requiring rescue analgesia. The incidence of emergence delirium

was however low for all children when compared to previous reports [20,21]. Children in Group II also comprised most of the difficult cases in this study (61%, 11/19). Children in Group II were older and may have had repeated episodes of recurrent tonsillitis; subsequent fibrosis and more adherent tonsils. Consequently, older children may have been exposed to over-coagulation leading to increased pain scores and less absorption of anesthetic drugs [2,22].

Children in both groups also received the same dosage of xylocaine, four sprays to their fossae. In terms of body weight, smaller children effectively received a relative higher dosage (3 mg/kg in a 14 kg child) compared to heavier children (0.8 mg/kg in a 50 kg child), which may also have influenced the efficacy of the xylocaine spray in the older children. Mixed results have been shown for the pain relieving properties of local anesthetics applied to the tonsillar fossae. Topical application of ropivacaine showed no improvement compared to placebo, which was attributed to poor absorption caused by possible over-coagulation [2]. Similarly, infiltrating bupivacaine in the peri-tonsillar space did not perform better than pethidine [5]. Dalwadi, Dalwadi [8] showed that xylocaine spray was effective for pain management after tonsillectomy. Jahromi, Valami [9] noted the short term efficacy of lidocaine spray over ketamine and morphine sprays.

In our study, older children also drank and ate on average 25 min later than children in Group I. Children in Group II may have been more sedated by the morphine they had received. Importantly, the nursing staff in the pediatric ward adhered to a strict 2-h post-operative nil per os rule, to mitigate for post-operative nausea and vomiting. All the children were thus offered liquids and food at the same time, explaining why the time to first ingestion was similar for the children who received normal saline and xylocaine. In our study, children who received xylocaine recorded consistently lower pain scores when ingesting liquids and solids, facilitating return to normal diet post-adenotonsillectomy leading to improved healing rates and reduced pain [23,24].

In our study, we noted few cases (7) of post-operative nausea and vomiting (9%), which is towards the lower end of previously reports of between 4 and 33% [25]. The rate of post-operative nausea and vomiting was similar for children in both age groups and was not associated the intervention. None of the study participants had post-operative aspiration. We also recorded low rates of post-operative complications (10%) compared to 22% reported in the literature [26]. Post-operative complications were not associated with intervention or with age. Post-adenotonsillectomy hemorrhage occurs in 2–5% of children [27]. Only one child in our study presented with post-adenotonsillectomy hemorrhage, which was treated accordingly. We only followed patients for 24 h, and may have recorded more complications if we had followed patients for longer, since many complications including dehydration, worsening pain and persistent nausea and vomiting are seen after 24-h [26].

Limitations to the study include the number of study participants (n = 80), that could be expanded on in future studies. As the focus of the study was improving *immediate* post-operative pain control, the children weren't followed up after 24-h and thus break-through pain in the subsequent days could not be commented on. The strict 2-h nil per os rule applied post-operatively in the pediatric ward by the nursing staff skewed results regarding time to first oral ingestion. A final limitation was the use of a standardize 4 sprays per child, instead of a mg/kg dose for administering xylocaine.

6. Conclusion

Xylocaine 10% spray may serve as a valuable adjunct to effective pain control post-adenotonsillectomy, especially if a long acting opioid is undesirable, such as when the patient suffers from obstructive sleep apnea. In our study, morphine given to the older children as part of their standard anesthetic protocol, negated the benefit of xylocaine. Xylocaine contributed to effective pain management in children aged 3–8 years old. Children in this group recorded lower pain scores at all intervals and were more comfortable when ingesting liquids and solids for the first time. This trial is the largest (80) to date to assess the efficacy of xylocaine spray in isolation for post-adenotonsillectomy pain control. Xylocaine seemed to reduce emergence delirium and need for rescue analgesia without any increase in post-operative complications. Local anesthesia can reduce costs and play an important role in solving the conundrum of a '*painless adenotonsillectomy*' especially in resource constrained environments.

7. Considerations for future investigations

- Conduct trials with larger sample sizes
- Investigate the use of coblation (controlled ablation) in combination with local anesthesia to obtain optimal pain control.
- Encourage early oral intake post-operatively which will not predispose the patient to post-operative nausea and vomiting.
- Consider adjusting the dosing of the local anesthetic to a mg/kg dose instead of a fixed dose of 4 sprays for all the children as this may improve efficacy especially for older children.

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