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.

Funding

This research was not funded by any agencies in the public, commercial and not-for-profit sectors.

Acknowledgements

Dr. Shade Steve Olorunju, Biostatistician, Biostatistics unit (University of Pretoria); South African Medical Research Council.

Dr. Cheryl Tosh, Scientific Editor, University of Pretoria.

References

[1] T. Ovesen, G. Kamarauskas, M. Dahl, J. Mainz, Pain and bleeding are the main determinants of unscheduled contacts after outpatient tonsillectomy, Dan. Med. J. 59 (2012) A4382.

[2] H.K. Tolska, A. Takala, K. Blomgren, K. Hamunen, V. Kontinen, Topical ropivacaine in prevention of post-tonsillectomy pain in adults, Anesth. Analg. 124 (2017) 1459–1466.

[3] H.A. Benzon, R.D. Shah, J. Hansen, et al., The effect of systemic magnesium on postsurgical pain in children undergoing tonsillectomies: a double-blinded, randomized, placebo-controlled trial, Anesth. Analg. 121 (2015) 1627.

[4] H.K. Cho, K.W. Kim, Y.M. Jeong, H.S. Lee, Y.J. Lee, S.H. Hwang, Efficacy of ketamine in improving pain after tonsillectomy in children: meta-analysis, PLoS One 9 (2014), e101259.

[5] R. Nikandish, B. Maghsoodi, S. Khademi, S. Motazedian, R. Kaboodkhani, Peritonsillar infiltration with bupivacaine and pethidine for relief of post-tonsillectomy pain: a randomised double-blind study, Anaesthesia 63 (2008) 20–25.

[6] E.I. Akural, S. Alahuhta, P. Ohtonen, H. Löppönen, Peritonsillar morphine infiltration to prevent early postoperative pain after tonsillectomy: a randomised controlled trial, Eur. J. Anaesthesiol. 33 (2016) 607–609.

[7] A. Williams, A. Hamilton, Topical lignocaine after tonsillectomy in children, Anaesthesia 41 (1986) 222.

[8] B.K. Dalwadi, J.B. Dalwadi, A comparison of pre-operative and post-operative use of 10% lignocaine aerosol for post-tonsillectomy pain relief in paediatric patients, Int. J. Res. Med. Sci. 3 (2015) 3074–3079.

[9] S.A. Hosseini Jahromi, S.M. Hosseini Valami, S. Hatamian, Comparison between effect of lidocaine, morphine and ketamine spray on post-tonsillectomy pain in children, Summer, Anesthesiol. Pain Med. 2 (1) (2012) 17–21, https://doi.org/10.5812/aapm.4092. Epub 2012 Jul 10.

[10] Medscape, lidocaine anesthetic. https://reference.medscape.com/drug/xylocaine-zingo-lidocaine-anesthetic-343363, 2018. (Accessed 19 April 2022).

[11] P.E. Kelley, Painless tonsillectomy, Curr. Opin. Otolaryngol. Head Neck Surg. 14 (2006) 369–374.

[12] S. Celebi, M. Topak, O.N. Develioglu, et al., Effect of thermal welding tonsillectomy on emergence agitation, J. Craniofac. Surg. 24 (2013) 1844–1848.

[13] M.Y. Al-Mahbashi, S.Q. Saeed, A.A. Al-Attab, Y.A. Raja'a, Comparison of three techniques for tonsillectomy during free medical camps in Yemen, Egypt. J. Otolaryngol. 30 (2014) 229–233.

[14] Y.L. Wilson, D.M. Merer, A.L. Moscatello, Comparison of three common tonsillectomy techniques: a prospective randomized, double-blinded clinical study, Laryngoscope 119 (2009) 162–170.

[15] T. Voepel-Lewis, J.R. Shayevitz, S. Malviya, The FLACC: a behavioral scale for scoring postoperative pain in young children, Pediatr. Nurs. 23 (1997) 293–297.

[16] L.L. Reduque, S.T. Verghese, Paediatric emergence delirium, Cont. Educ. Anaesth. Crit. Care Pain 13 (2012) 39–41,
https://doi.org/10.1093/bjaceaccp/mks051.10.1093/bjaceaccp/mks051.

[17] S. Khademi, F. Ghaffarpasand, H.R. Heiran, M.J. Yavari, S. Motazedian, M. Dehghankhalili, Intravenous and peritonsillar infiltration of ketamine for postoperative pain after adenotonsillectomy: a randomized placebo-controlled clinical trial, Med. Princ. Pract. 20 (2011) 433–437.

[18] J.-W. Chen, P.-W. Liao, C.-J. Hsieh, C.-C. Chen, S.-J. Chiou, Factors associated with changing indications for adenotonsillectomy: a population-based longitudinal study, PLoS One 13 (2018), e0193317, https://doi.org/10.1371/journal.pone.0193317.10.1371/journal.pone.0193317.

[19] U. Children's, Hospital of Pittsburgh, tonsillectomy and adenoidectomy. Otolaryngology (ENT), in: http://www.chp.edu/our-services/ent/patient-procedures/tonsillectomy-adenoidectomy, 2019.

[20] S. Nair, A. Wolf, Emergence delirium after paediatric anaesthesia: new strategies in avoidance and treatment, BJA Education 18 (2018) 30.

[21] K. Mason, Paediatric emergence delirium: a comprehensive review and interpretation of the literature, Br. J. Anaesth. 118 (2017) 335–343.

[22] K.C. Prasad, S.C. Prasad, Assessment of operative blood loss and the factors affecting it in tonsillectomy and adenotonsillectomy, Indian J. Otolaryngol. Head Neck Surg. 63 (2011) 343–348, https://doi.org/10.1007/s12070-011-0268-9.10.1007/s12070-011-0268-9.

[23] M. Hatami, M. Mirjalili, V. Ayatollahi, S. Vaziribozorg, V. Zand, Comparing the efficacy of peritonsillar injection of tramadol with honey in controlling post-tonsillectomy pain in adults, J. Craniofac. Surg. 29 (2018) e384–e387.

[24] M. Faramarzi, S. Safari, S. Roosta, Comparing cold/liquid diet vs regular diet on posttonsillectomy pain and bleeding, Otolaryngology-Head Neck Surg. (Tokyo) 159 (2018) 755–760. https://journals.sagepub.com/doi/abs/10.1177/0194599818788555.10.1177/0194599818788555.

[25] D. Stanko, R. Bergesio, K. Davies, M. Hegarty, B.S. von Ungern-Sternberg, Postoperative pain, nausea and vomiting following adeno-tonsillectomy – a long-term follow-up, Pediatr. Anesth. 23 (2013) 690–696, https://onlinelibrary.wiley.com/doi/abs/10.1111/pan.12170.

[26] G. De Luca Canto, C. Pachêco-Pereira, S. Aydinoz, et al., Adenotonsillectomy complications: a meta-analysis, Pediatrics 136 (2015) 702–718.

[27] J.P. Windfuhr, Y.-S. Chen, Incidence of post-tonsillectomy hemorrhage in children and adults: a study of 4,848 patients, ear, Nose Throat J. 81 (2002) 626–634. https://journals.sagepub.com/doi/abs/10.1177/014556130208100910.10.1177/014556130208100910.