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Effectiveness of topical bupivacaine versus topical lidocaine/adrenaline mixture for post-adenotonsillectomy pain management

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Abstract

Background This study aims to compare the topical administration of bupivacaine hydrochloride and lidocaine hydrochloride with epinephrine in alleviating post-tonsillectomy pain. Post-tonsillectomy pain has remained a challenge to both patient and doctors, and local anaesthetic agents applied to the tonsillar fossae post-operatively look promising.

Methods One hundred and twenty ASA I or II children aged 2–15 years of consenting parents undergoing adenoidectomy and/or tonsillectomy were enrolled in the study. This was a randomized double-blind study in which the children were allocated into either of two groups to receive 5 ml of 0.125% bupivacaine or equal volume of lidocaine plus 1:200,000 adrenaline-soaked swab applied directly on the tonsillar floor within the fossae and/or nasopharynx after haemostasis was secured for 5 min before discontinuation of anaesthesia.

Results Patients in the bupivacaine group had better extubating condition ($p=0.0001$). There was no difference in the time to eye opening in both groups (p -value 0.316). Patients in the lidocaine group had a time to first analgesic request between 1 and 6 h, whereas in the bupivacaine group, about 25 patients (44% of the group) had a time to first analgesic request that exceeded 6 h (6–10 h). The only complication recorded in both groups following oral feeds was vomiting, and there was no difference in both groups ($p=0.968$). Overall parental satisfaction was better with bupivacaine group ($p=0.00001$).

Conclusion Topical application of bupivacaine was associated with better extubation conditions and parental satisfaction when compared to topical lidocaine plus adrenaline while both demonstrated similar time to eye opening, analgesic request, haemodynamic parameters and incidence of complications.

Keywords Bupivacaine, Lidocaine, Post-tonsillectomy pain

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Background

Adenotonsillectomy is associated with significant post-operative pain especially in children, and its management remains a dilemma for the anaesthetist [1]. Failure of achieving good analgesia in children who undergo tonsillectomy and/or adenoidectomy will cause poor oral intake, which leads to oropharyngeal oedema due to non-mobility of the soft palate lassitude, delayed recovery of strength and well-being and occasionally requires overnight hospitalization in day-case surgical practice [2]. Thus, different methods have been studied and used to reduce pain, including improved intraoperative anaesthetic pain regimens, use of corticosteroids, adjustment of surgical technique and intraoperative local anaesthetic injection [3]. Tonsillectomy produces large areas of exposed muscle in the oropharynx, resulting in considerable pain from muscle spasm, irritation of nerve endings, and excessive dissection, and the use of cautery for haemostasis may produce even greater amount of inflammation and post-operative pain [4]. Many considerations are involved in the choice of analgesic for the management of pain in paediatric patients undergoing these procedures. Essential requirements include good analgesia, reduction in opioid-related respiratory depression, low risk of inducing nausea and vomiting precluding early alimentation and more importantly no risk of bleeding. Good quality, effective management of pain following adenotonsillectomy in children is therefore an essential component of paediatric ENT anaesthesia.

Various strategies have been proposed for the management of post-tonsillectomy pain like infiltration of the tonsillar fossae with local anaesthetic agents [5, 6], non-steroidal anti-inflammatory drugs (NSAID) [7], narcotic analgesics and oral analgesics [7]. The use of parenterally administered analgesics in the immediate post-operative period is the common practice in our hospital, which is usually associated with laryngeal spasm especially if the patient does not receive adequate analgesia, or patient is not fully awake and in a light plane of anaesthesia.

A potentially beneficial principle to adhere to for acute post-operative pain management is that local anaesthetics should be part of the initial pain management plan. Application of local anaesthetics to the surgical site either before or after the procedure by infiltration or topical administration has been used by many researchers for post-adenotonsillectomy pain management, with great discrepancy [8, 9]. Indeed, life-threatening upper airway obstruction after bupivacaine infiltration has been reported in children [10]. On the other hand, topical administration of bupivacaine hydrochloride has been found to provide an efficient pain control following tonsillectomy without any drug-related complication [4]. In order to avoid potential side effects of the infiltration

technique, this study is set to investigate the effectiveness of topical plain bupivacaine for post-adenotonsillectomy pain in our institution.

Methods

Following ethical approval, the patients recruited for this study were consented patients scheduled for adenotonsillectomy.

Sample determination

This was calculated using the formula for sample size determination when comparing two means:

$$n = \frac{(u + v)^2 \times (\sigma_1^2 + \sigma_0^2)}{(\mu_1 - \mu_0)^2}$$

n = minimum sample size for each group.

σ_1, σ_0 = Standard deviations.

$\mu_1 - \mu_0$ = Difference between the means.

u = One-sided percentage point of the normal distribution corresponding to 100% — the power. Power is set at 80%; therefore, $u = 0.84$.

v = Percentage point of the normal distribution corresponding to the (two-sided) significance level set at 5% therefore $v = 1.96$.

A similar study found 5-h post surgery pain scores of 0.51 ± 0.12 and 0.42 ± 0.22 in subjects who received topical bupivacaine and lidocaine/adrenaline, respectively⁴.

$$n = \frac{(0.84 + 1.96)^2 \times (0.12^2 + 0.22^2)}{(0.51 - 0.42)^2}$$

$$n = 61.54$$

A total of 120 patients were studied.

Study design

This was a prospective study in which 120 children, aged 2–15 years and ASA I or II of consenting parents undergoing adenoidectomy and/or tonsillectomy during the study period were enrolled into the study. All patients for the procedures were admitted a day prior to the surgery after showing normal results for routine investigations. The patients were divided into 2 study groups by randomly picking of group from an envelope. The first group (A) patients received 5 ml of 0.125% bupivacaine-soaked swab applied directly on the tonsillar fossae and/or nasopharynx after haemostasis was secured for 5 min before discontinuation of anaesthesia.

The second group (B) patients received gauze soaked in an equal volume of lidocaine/adrenaline mixture (1 in 4 dilutions of 2% lidocaine plus 1:200,000 adrenaline).

Inclusion criteria

All children scheduled for adenoidectomy and/or tonsillectomy within the age range 2–15 years.

Exclusion criteria

1. Underlying chronic diseases like, but not limited to sickle cell disease (SCD).
2. Synchronous surgical procedure in addition to adenotonsillectomy, e.g. myringotomy.
3. Patients on regular/routine analgesic medications.
4. Failure of parents to give consent.
5. Patients with history of allergy to study drugs.

Anaesthesia management

Standard general anaesthesia (GA) with endotracheal intubation and relaxant technique with intermittent positive pressure ventilation (IPPV) was administered, and intravenous paracetamol 10–15 mg/kg and intravenous fentanyl 2 µg/kg for intraoperative analgesia were given just before the commencement of surgery in the two groups.

The study drugs were applied by the Otorhinolaryngologist after ensuring adequate haemostasis by soaking appropriate size gauze packs with 5 ml of the study drugs adequate enough to fill each of the fossae of the adenoid and tonsillar beds for 5 min.

Adenoidectomy was carried out by curettage and tonsillectomy using the cold steel dissection method. Haemostasis was secured by swab packing for 5 min. The surgeries were performed by a Consultant Otorhinolaryngologist or Otorhinolaryngology resident who has had a similar level of experience under supervision.

All patients were extubated awake in the operating room after the removal of the pharyngeal pack and transferred to the recovery room.

In the recovery room, vital signs were monitored, and during this interval, any instance of crying, vomiting or agitation was recorded. The recovery room nurses and pain score observers were blinded to the identity of the study drugs. The time to eye opening to command (from the time of discontinuation of anaesthetic to opening of the eye) was noted while the pain scores were assessed using the modified Children's Hospital of Eastern Ontario Pain Scale (mCHEOPS) [11] (Appendix 1) for children less than 4 years and a verbal Rating Scale [12] for children above 4 years (Appendix 2).

The scoring was done at fixed intervals after the procedure every 15 min in the recovery room for the first 1 h, then every 30 min for the next 3 h, and in the ward every 2 h for the next 20 h, i.e. 0, 15, 30, 45 and 60 min and 0, 30, 60, 90, 120, 150 and 180 min then 0, 2, 4, 6 h, etc.

respectively post-operatively for each patient. All scoring was done by an attending resident blinded to the study groups. A pain score of 4 and above was assumed to be an indication for the administration of analgesics and the time was taken as time to first analgesic request.

The level of satisfaction of pain control was assessed for each patients' group using a 5-point Likert scale [13] (Appendix 3) response of patients or parents/guardians to the statement.

Post-operative complications like laryngeal spasm, nausea, vomiting and dysphagia to solid or liquid diets were observed and recorded.

Primary outcome measures.

- 1) Post-operative pain scores in both groups
- 2) Immediate airway complications following extubation in the groups

Secondary outcome measures.

- 1) Side effects of bupivacaine
- 2) Side effect of lidocaine/adrenaline mixture
- 3) Haemodynamic changes (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, peripheral arterial oxygen saturation and rate pressure product) in the immediate post-operative period in the groups
- 4) Patients' level of satisfaction in the study groups

Data analysis

Data obtained was analyzed using Statistical Package for Social Science (SPSS) version 22 applying univariate, bivariate and multivariate analysis. Nominal data were presented as percentages and analyzed using the chi-square test, while ordinal variables were presented in median and range and analyzed using the Mann–Whitney *U* test. Continuous variables were presented in means and standard deviation and analyzed using the paired Student's *T*-test. A *p*-value of <0.05 was considered statistically significant.

Results

A total of 120 patients were recruited for the study comprising 56 patients in the bupivacaine group and 64 in the lidocaine group. All the patients were ASA 1. The male-to-female ratio of the bupivacaine vs lidocaine group was 34:22 versus 37:27, respectively (*p*-value 0.764) (Table 1). There was no difference in the two groups in the other demographic data as shown in Table 1. Eleven (9.2%) patients were operated for tonsillar enlargement alone comprising 5 patients in the lidocaine group (L) and 6 in the bupivacaine group (B) while 109 (90.8%) for

Table 1 Demographic characteristics

	Bupivacaine	Lidocaine	p-value
Age (years)	Mean (SD)	Mean (SD)	
Weight (Kg)	5.1316 (3.164)	5.875 (4.402)	0.182
Height (m)	19.5 (9.56)	21.0156 (10.122)	0.338
Indication	1.0845 (0.10016)	1.1046 (0.19896)	0.311
Adenotonsillar enlargement*	51(46.8%)	5(45.5%)	0.932
Tonsillar enlargement*	58(53.2%)	6(55.5%)	
Gender			
Male*	34 (60.7%)	37 (57.8%)	0.746
Female*	22 (39.3%)	27 (42.2%)	

*numbers (percentage)

p-value is level of significance

SD= Standard Deviation

adenotonsillar enlargement as shown in Table 1. All were elective surgeries.

The mean baseline pulse rate (bpm) in the bupivacaine group versus the lidocaine group was 106.18 (9.475) and 107.42 (8.017), respectively (*p*-value 0.241), while the mean baseline systolic blood pressure (mmHg) in groups B vs L was 90.92 (3.649) vs 92.13 (6.275), respectively (*p*-value 0.141). Also, the mean baseline diastolic blood pressure in groups B vs L was 70.18 (0.865) vs 70.16 (1.250) respectively (*p*-value 0.451). Similarly, there was no difference in the mean baseline peripheral oxygen saturation as shown in Table 2. A total of 46 patients (82.1%) of the group size were extubated calmly in group B as against 29 (45.3%) in the L group (*p*-value 0.0001). The details of the remaining extubating conditions are shown in Table 3. The result showed that 37 (66.1%) and 45 (70.3%) of the patients in groups B and L opened their eyes within 5 min of discontinuation of anaesthesia, respectively. Overall, there was no difference in the time from discontinuation of anaesthesia to eye opening in both groups (*p*-value 0.316), as shown in Table 4. All the patients in the lidocaine group had a time to first analgesic request between 1 and 6 h, whereas in the bupivacaine group, about 25 patients (44% of the group) had a time to

Table 2 Showing Mean Baseline Haemodynamic variables

	Bupivacaine	Lid+ Adrenaline	p-Value
Pulse rate	106.18(9.475)	107.42 (8.017)	0.241
Systolic blood pressure	107.42 (8.017)	107.42 (8.017)	0.141
Diastolic blood pressure	70.18 (0.865)	70.16 (1.250)	0.451
Peripheral oxygen saturation.	98.08 (0.359)	98.03 (0.435)	0.978

Mean (SD)

Table 3 Showing extubating conditions of the patients

	Extubating conditions			Total
	Calm	Crying	Restless	
Bupivacaine	46 (82.1%)	7 (12.5%)	3 (5.4%)	56
Lid+ Adrenaline	29(45.3%)	20(31.3%)	15(23.4%)	64
Total	75	27	18	120

P value =0.0001

first analgesic request that exceeded 6 h (6–10 h). Overall, there was no statistical difference in the time to the first analgesic requirement in both groups as shown in Table 5. The only complication recorded in both groups following oral feeds was vomiting. In the bupivacaine group, the number of patients who had no complications versus the lidocaine group was 50 (89.55%) versus 57 (89.1%), respectively, while 6 (10.5%) and 7(10.9%) patients vomited in the bupivacaine and lidocaine groups following oral feeds respectively (*p*-value 0.968), as shown in Table 6. Thirty-four parents (60.7%) in the bupivacaine group and nine (14.0%) in the lidocaine group were very satisfied, respectively (*p*-value 0.00001). The details of the parental satisfaction scores are in Table 7.

Discussion

Overall, the study demonstrated similar time to eye opening, analgesic request, haemodynamic parameters and incidence of complications, whereas patients in the bupivacaine group had better extubation conditions and consequently better parental satisfaction.

Tonsillectomy is one of the commonest ENT surgeries performed in the paediatric age grade. It can also lead to significant post-operative pain. Post-tonsillectomy pain is common and under reported and may result in poor oral intake, dehydration, sleep disturbances, behavioural changes and emesis and late haemorrhage [4]; thus, post-operative pain control is an essential part of routine oral surgical procedures as it also encourages movement of the soft palate with a reduction in oedema and aspiration from lazy palatal movement. The institution of a multimodal analgesic regimen before the child awakes from GA will have a preemptive analgesic effect and ensure a smooth transition. Different methods have been used to reduce pain, including improved intraoperative anaesthetic pain regimens, intraoperative local anaesthesia infiltration or topical application in the peritonsillar space [14]. The intensity of post-tonsillectomy pain has been known to be reduced by local administration of lidocaine with adrenaline [15] although ENT surgeons tend to prefer the use of bupivacaine with or without adrenaline [4, 14, 16]. Both are amide local anaesthetic agents and very potent, and although bupivacaine is longer

Table 4 showing time(mins) from end of anaesthesia to eye opening

	Time from end of anesthesia to eye opening					Total
	</=3mins	4mins	5mins	6mins	>/=7mins	
Bupivacaine	7(12.5%)	13(23.2%)	17(30.4%)	6(10.7%)	13(23.2%)	56
Lid+ Adrenaline	12(18.8%)	11(17.2%)	22(34.4%)	7(10.9%)	12(18.8%)	64
Total	19	24	39	13	25	120

P value 0.316

Table 5 showing time(hours) to first analgesic requirement

Time (hours)	Bupivacaine	Lidoacaine+ Adr	Total
1	2	5	7
2	0	12	12
3	0	10	10
4	9	27	36
5	10	5	15
6	10	5	15
7	6	0	6
8	12	0	12
9	3	0	3
10	4	0	4
Total	56(46.7%)	64(53.3%)	120

Numbers, p value = 0.413

acting, the addition of adrenaline to lidocaine increases its duration of action and in some cases has been comparable to bupivacaine in terms of analgesic duration [17]. Although more patients in the bupivacaine group have

longer time to first analgesic request, the overall pain control was similar in both groups. This agrees with the findings of Ozmen et al. [4] but not with that of Ozkris et al. [14]. Ozkris et al. [14] found that the difference between the mean pain score of the bupivacaine versus lidocaine groups was statistically significant ($p < 0.001$). This could be because they employed bupivacaine with adrenaline in their study unlike plain bupivacaine that was used in this study. Adrenaline has been known to improve the duration of local anaesthetic by decreasing systemic absorption through local vasoconstriction. Although meta-analysis showed that the effect of adrenaline on prolonging the duration of bupivacaine could not be conclusively proven, some studies did report otherwise [18]. In our study, lidocaine with adrenaline did not confer analgesic properties beyond 6 h post-operatively. However, in the bupivacaine group, the time to first analgesic requirement was prolonged beyond 6 h in about 44.6% of the subgroup. This suggests that though the time to first analgesic request in both groups was comparable especially in the immediate post-operative period, in the long term, bupivacaine may offer extended analgesia more than lidocaine. This finding may be because of the prolonged duration of action of bupivacaine which is about 4–8 h [19]. There is a paucity of studies comparing time to first analgesic request following tonsillectomy in paediatric patients. This could be because of study design challenges. The paediatric age group is heterogenous varying from those who cannot verbalize and rely on emotions to communicate (infants) to those who can verbalize to communicate effectively, and this could

Table 7 shows Parental Satisfaction

Parental Satisfaction	Parental Satisfaction			Total
	Unsure	Satisfied	Very satisfied	
Bupivacaine	3(5.4%)	19(33.9%)	34(60.7%)	56 (46.7%)
Lidocaine+Adr	3(4.7%)	52(81.3%)	9(14.0%)	64 (53.3%)
Total	6 (0.05%)	71(59.2%)	43(35.8%)	120

p-value= 0.00001

Table 6 showing the incidence of complication with oral feed in both groups

	Presence of complication		Total
	Yes (vomiting)	No	
Bupivacaine	6 (10.5%)	50 (89.55%)	56 (46.7%)
Lidocaine+Adr	7(10.9%)	57 (89.1%)	64 (53.3%)
Total	13(10.8%)	107 (89.2%)	120

p-value 0.968

affect the ability to accurately know the exact time to first analgesic request. Assessment of post-operative pain in children can be challenging as the child may be unable to properly communicate and verbalize and may cry due to phobia of blood, fear of strangers, needle phobia, pain or a combination of these [20]. Thus, specific tools have been employed in pain assessment in children to adequately determine the time to first analgesic request. These include FLACC scale [21], Wong Baker's scale [22], verbal rating scale [12] and the modified CHEOPS pain score which has shown good reliability, validity and good inter observer variability [4, 11, 20]. The method employed in this study to determine the time to first analgesic is a reliable and validated method for that purpose [12, 20–22]. Hung et al. [23] also found that compared to placebo, topical bupivacaine reduced post-operative pain scores and prolonged the time to first analgesic request in paediatric day-case tonsillectomy in the first 6 h. Similarly, Ozmen et al. [4] showed that topical bupivacaine improved post-operative pain compared to lidocaine and placebo after the fifth hour. This is comparable to our study because all the patients in the lidocaine group had a time to first analgesic request less than or equal to 6 h, whereas 44% in the bupivacaine group had extended time to first analgesic request beyond 6 h up to 10 h. This finding by Ozmen et al. [4] continued until the sixth day and in some literatures up to 10 days [24, 25].

The concentration of bupivacaine and lidocaine employed in this study has been proven to be safe by meta-analysis and Cochrane studies [15], and indeed, higher concentrations of bupivacaine have resulted in serious life-threatening complications [10], although a lot of studies had previously employed infiltration of local anaesthetic agents at the tonsillar pillars with variable results. For example, while some found that it provided sufficient pain control [26, 27], others found otherwise [28]. However, the choice of infiltration of the tonsillar pillar which is very vascular carries a worrisome risk of accidental intravascular injection and its attendant complications including arrhythmias, cardiac arrest, convulsion, airway obstruction, facial nerve paralysis, vocal cord paralysis and brainstem stroke [4, 10, 17, 18]. Hence the choice of topical application with swab in this study as was also employed by Ozmen et al. [4] whose findings also agreed with us that topical application with swabs provided adequate pain relief while avoiding complications. This study found that topical application of local anaesthetic was associated with lower incidences of complications associated with tonsillectomy, and this agrees with the findings of Haksever et al. [29]. Haksever and colleagues [29] noticed a significant decrease in immediate post-operative pain, significant reduction in the incidence of post-operative morbidities such as trismus,

nausea, vomiting and otalgia, excessive crying and vomiting and all these equated to better patient recovery, improved service delivery and outcome and better parental satisfaction with the entire surgical and anaesthetic process. Likewise, Ozmen et al. [4] noted that topical application was associated with a decrease in the incidence of post-operative pyrexia, halitosis, nausea, vomiting and otalgia. In fact, meta-analyses of studies done using local application of local anaesthetic agents have demonstrated that the vasoconstrictive effects of these agents were associated with improved post-operative haematological parameters possibly through decreased blood loss, and all these will help to decrease the likelihood of post-tonsillectomy bleed and perioperative transfusions especially in the paediatric age group [25, 30].

Conclusion

Topical application of bupivacaine was associated with better extubation conditions and parental satisfaction when compared to topical lidocaine plus adrenaline while both demonstrated similar time to eye opening, analgesic request, haemodynamic parameters and incidence of complications.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s43163-024-00678-2>.

Supplementary Information.

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Authors' contributions

OO conceived the idea, designed and drafted the manuscript. OA analyzed the data and reviewed the manuscript. BO reviewed the manuscript. EI and A wrote the discussion and collected the data. SO, AO and AD performed the surgery and reviewed the manuscript. OO did the manuscript writing and final editing of this article. All the authors read and approved the final version of the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during this study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Obtained from the institution Ethical Review Committee of the University of Ilorin Teaching Hospital and each patient's completed an informed consent form before taking part in the study.

Consent for publication

An informed written consent for publication had been obtained from the patient's parent.

Competing interest

The authors declared that they have no competing interests.

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