

Original Research Article

The analgesic effect of plain bupivacaine infiltration in the management of postoperative pain following adenotonsillectomy: A comparative randomized study

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Abstract

Background: Adenotonsillectomy, a common surgery performed by otorhinolaryngologists worldwide, has postoperative pain as its commonest complication in children, which has remained an unresolved burden. Several modalities have been employed for postoperative analgesia with limitations. The study aimed to assess the analgesic effect of plain bupivacaine infiltration after adenotonsillectomy in children.

Materials and Methods: Ethical approval was obtained from the institution's Health Research and Ethics Committee. Eligible patients were randomized into group B (n=15) to receive plain bupivacaine infiltration and group P (n=15) to receive normal saline infiltration respectively. Pain scores and duration of analgesia were assessed and recorded. Data was collected and assessed using SPSS 21 for Windows. Numerical data was analyzed using unpaired Student t-test, while categorical data was analyzed using chi-squared test. A p-value < 0.05 was considered significant.

Result: The pain scores were significantly lower in group B compared with group P. While all the patients received rescue analgesia at the 6th hour of the infiltration in group P, only one patient received rescue analgesia at the same time. More than 90% of the patients in group B did not receive rescue analgesia during the study period. The duration of analgesia was significantly (p=0.000) longer in group B compared to group P.

Conclusion: Plain bupivacaine infiltration showed better analgesic profile with respect to lower pain scores, lower total analgesic consumption, and longer duration of analgesia when used for postoperative adenotonsillectomy pain relief in children.

Keywords: Postoperative analgesia, Plain bupivacaine infiltration, Adenotonsillectomy, Children.

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1. Introduction

Adenotonsillectomy is the surgical intervention that involves the complete or partial removal of the palatine tonsils and adenoids primarily to prevent recurring infections and inflammation.¹ It is one of the common surgeries performed by otorhinolaryngologists around the globe.² A study showed a high incidence of 73.6% surgical intervention among high and middle-income countries of the world population, while an incidence of 3.5% surgical intervention among low-income countries of the world population including Nigeria.³

In a study conducted by Atilade et al⁴ in Ekiti state of Nigeria, they reported an incidence of 51.7% for adenotonsillectomy in children, while Samdi et al⁵ reported an incidence of 49.5% of adenotonsillectomy in

their study conducted in Kaduna state. This shows the high burden of adenotonsillectomy with its complications.

Adenotonsillectomy is associated with significant tissue trauma with subsequent inflammatory response which causes high levels of pain and other post-operative morbidities (due to the accumulation of local tissue exudates around the surgical site).^{1,6} In addition, it causes collateral damage to the pharyngeal muscles and exposes nerve endings (tonsillar glossopharyngeal, maxillary trigeminal, and lesser palatine nerve branches), leading to post-operative complications such as severe pain, difficulty in swallowing, and otalgia.^{7,8} Postoperative pain is the commonest complication of adenotonsillectomy, which causes delay in oral intake and discharge from the hospital.¹

Despite the often-severe pain experienced by children after adenotonsillectomy, under treatment of pain has been consistently demonstrated. Some studies have reported that despite high prevalence of severe pain by parental report, over 40% of children received 2 or fewer doses of pain medication on postoperative day 1 after adenotonsillectomy, and over 60% received 2 or fewer doses on postoperative day 2.^{9,10} Several medications have been employed to manage post-adenotonsillectomy pain in children with their respective limitations. These include acetaminophen, nonsteroidal anti-inflammatory drugs such as ibuprofen and rectal diclofenac, opioids with an associated risk of respiratory depression, and dexamethasone. Despite all these, effective postoperative pain management after adenotonsillectomy in children remains an unresolved challenge,¹¹ as there is a need to find the best postoperative method of pain control with minimal side effects, as well as making sure the patient is well hydrated and resumes regular oral feeding as soon as possible.¹

Recently, local anesthetics have been employed in the management of postoperative pain following adenotonsillectomy. In a study conducted by Ankle et al¹ they reported that the use of plain bupivacaine infiltration following adenotonsillectomy was effective in reducing morbidity caused by pain and enhancing early oral feeding and hospital discharge. In another study by Kouser et al¹² which assessed the efficacy of bupivacaine infiltration in post tonsillectomy pain relief in mixed population aged 4-30 years under general anesthesia using 6ml of 0.25% plain bupivacaine, they reported that plain bupivacaine infiltration significantly reduced post tonsillectomy pain. In the above study, a high volume of plain bupivacaine was used in a mixed population of children and adults with varying thresholds for pain.

They were also exposed to increased risk to local anesthetic toxicity. Also, Mahmood et al¹³ in assessing post tonsillectomy pain control with pre-incisional infiltration with 3ml of 0.5% bupivacaine among patients aged 14-40 years, reported that plain bupivacaine infiltration significantly reduced post tonsillectomy pain in the first 6 hours. In this study, high concentration of local anesthetics was used exposing patients to risk of toxicity, and the study was conducted among mostly adults. The present study will be conducted among children with 1.5 mL of 0.25% plain bupivacaine on each side of the tonsillar fossa. However, literature search showed a paucity of studies evaluating the effect of bupivacaine in the management of post-adenotonsillectomy pain in children. Hence, this study is aimed at evaluating the analgesic effect of plain bupivacaine infiltration in the management of post-adenotonsillectomy pain in children.

2. Materials and Methods

Ethical clearance for this randomized double-blind study was obtained from the Health Research and Ethics Committee of the Federal Teaching Hospital Owerri, Imo State, with File No. FTH/OW/HREC/VOL.I/57 on 21st February 2024. A written informed consent from the patients was also obtained before they were enrolled in the study.

All children between 2-6yrs with ASA 11-111 scheduled for elective adenotonsillectomy under general anesthesia during the period of this study were recruited. Patients with hypersensitivity to bupivacaine and those who are unwilling to participate in the study were excluded. Pre-operative evaluation including thorough clinical history and physical examination of the patients was done.

The recruited and eligible patients were randomized into Group B (n=15) and Group P (n=15) in a balanced manner with a computer-generated number allotment that was concealed in an opaque envelope

All patients were fasted overnight. Clear liquids were allowed till 2 h before surgery. In the theatre, all the children were pre-medicated with 0.1 mg/kg midazolam intravenously for 10 min before induction of general anesthesia. After application of routine non-invasive monitoring devices (blood pressure, electrocardiogram, pulse oximeter), the patient was induced with 2-3 mg/kg propofol intravenously, or if venous access could not be performed, 8% sevoflurane in oxygen was administered by inhalation. Tracheal intubation was facilitated using 1.5 mg/kg succinylcholine. Anesthesia was maintained with 2% sevoflurane in oxygen. Analgesia was also

maintained with 15mg/kg of intravenous paracetamol. Heart rate, ECG were monitored continuously. The tonsils and adenoids were removed using the dissection and snare method.

At the end of surgery, patients were infiltrated with 1.5ml of 0.25% plain bupivacaine or 1.5ml of normal saline into each tonsillar fossa by the ENT surgeon who performed the surgery, who is also blinded to the study sample. All the patients received rectal diclofenac 1mg/kg. Subsequently, residual neuromuscular blockade was reversed with 0.04mg/kg neostigmine and 0.02 mg/kg atropine, and the patient's trachea was extubated when there was cough and gag reflex, grimace and purposeful movements. Signs and symptoms of airway irritability (laryngospasm, coughing) during emergence from anesthesia were assessed by the investigator who was blinded to the study drugs. Post-operative vomiting and agitation during emergence from anesthesia were assessed. The patient was transferred to the PACU.

Post operatively, pain was assessed by the investigator and ward nurses at 2hr, 4hr, 6hr, 12hr, 18hr, 24hr using the FLACC pain assessment scale, which assesses five variables (Face, Leg, Activity, Cry and Consolability with each variable scored 0 to 2 and an overall score of 10. A total score of 0 showed that the patient was relaxed and comfortable, 1-3 represents mild

discomfort, 4-6 reflects moderate pain, while 7-10 was regarded as severe discomfort/pain. Patient relative satisfaction of the postoperative pain management was assessed using Likert scale twenty-four hours after the infiltration with local anesthetics. The primary objective was to assess the mean pain score, while the secondary objectives included the duration of analgesia, which was the time of first request for analgesia or pain score greater than 4.

The sample was calculated with the WINPEPI program, Version 11.65 by using a previous study¹³ with total mean pain score of 1.01 ± 0.64 for test group and 2.24 ± 1.18 for control group while keeping the power at 80% and significance level of 95%, a sample size of 15 in each group was recruited for this study. Data was manually collected and entered into a data collection form and analyzed with the statistical package for social sciences (SPSS) 21 for Windows. Tables were used to present the results. Categorical variables were expressed as proportions and percentages and was analyzed using Chi-square test. Continuous data were expressed as mean and standard deviation for normally distributed data and median (interquartile range) for skewed data. The normally distributed continuous data were analyzed using unpaired Student's t-test. A p-value of <0.05 was considered significant.

3. Result

Table 1: Comparison of the demographics and duration of surgery between both groups

Variable	Group B	Group P	T	p-value
Age (years)	4.33 ± 2.3	4.23 ± 2.3	.124	0.902
Weight (kg)	17.14 ± 6.1	16.73 ± 4.2	.211	0.834
Duration of surgery (min)	54.2 ± 17.8	63.8 ± 16.8	-1.499	0.145

Table 2: Comparison of pain scores at specific times and number of patients that received rescue analgesia

Variables	N	Group B n (Mean $\pm$ SD)	N	Group P n (Mean $\pm$ SD)	t	p-value
Flacc@2hr	14	0(0.0 $\pm$ 0.0)	15	4 (3.0 $\pm$ 2.0)	-5.508	0.000
Flacc@4hr	14	1 (0.5 $\pm$ 1.6)	11	10(5.7 $\pm$ 1.6)	-8.192	0.000
Flacc@6hr	13	0(0.5 $\pm$ 0.9)	1	1 (8.0 $\pm$ 0.0)	-8.198	0.000
Flacc@12	13	0 (0.2 $\pm$ 0.6)	-	-		
Flacc@18hr	13	0(0.0 $\pm$ 0.0)	-	-		
Flacc@24hr	13	0(0.0 $\pm$ 0.0)	-	-		
Flacc@Rescue Analgesia		0.4 $\pm$ 1.6	-	6.0 $\pm$ 1.1	-11.081	0.000

n = number of patients that received rescue analgesia at specific times.

Table 3: Comparison of percentage of patients that received rescue analgesia at specific times

Variable	Group B	Group P
Flacc@2hr	0 (0%)	4(26.7%)
Flacc@4hr	1(7.1%)	10(66.7%)
Flacc@6hr	0 (0%)	1(6.7%)
Flacc@12hr	0 (0%)	
Flacc@18hr	0 (0%)	
Flacc@24hr	0 (0%)	

Table 4: Comparison of Duration of Analgesia between group B and group P

Variable	Group B	Group C	T	p-value
Duration of analgesia (min)	1354.29±320.7	216.00±67.3	13.499	0.000

4. Discussion

The result of this study revealed that group B has a significantly better analgesic profile in terms of duration of analgesia, lower pain scores, and reduced total analgesic consumption compared to those in group P for post-adenotonsillectomy pain relief in children.

The study showed that the Age, weight, and duration of surgery between the two groups were comparable (P=0.090) (P=0.834) (P=0.145).

However, it reported that the pain scores using FLACC were significantly (p=0.00) (p=0.00) (p=0.00) lower in group B (0.0±0.0) (0.5±1.6) (0.5±0.9) at 2hr, 4hr, 6hr when compared to group C (3.0±2.0) (5.7±1.6) (8.0±0.0) respectively (**Table 2**). Mahmood et al¹³ reported that there was a significant difference (p<0.005) in the total mean pain scores for the bupivacaine infiltration group (1.01±0.64) compared to the control group (2.24±1.18). Kousar et al¹² similarly reported that the pain scores were significantly (p=0.029) (p=0.022) (p=0.011) (p=0.001) lower in group bupivacaine infiltration (5.34±2.36) (4.34±2.03) (3.22±1.45) (2.19±1.33) at 30min, 2hr, 4hr, 6hr compared to control group (6.16±1.90) (5.28±2.20) (4.28±2.08) (3.56±2.23) respectively. Rakesh et al¹⁴ showed that mean pain scores were significantly (p<0.005) lower in the bupivacaine infiltration group (2.96) (1.76) (1.36) in the immediate postoperative period, 6hr and 24hr postoperatively, compared with the control group (5.52) (4.24) (2.64), respectively. Despite the similarity between the studies and the index study in the effect of bupivacaine infiltration, the difference in the mean pain scores of the bupivacaine infiltration groups between the index study and others may be attributed to the differences in their methodology. While the index study recruited children between 2yr to 6yr, Mahmood et al,¹³ Kousar et al,¹² and Rakesh et al¹⁴ recruited patients of age groups 14-40yr, 4

- 30yr and 9-27yr hence heterogenous sample groups. Yeziarski et al¹⁵ revealed that numerous age-related anatomical and functional changes have been documented to affect the somatosensory system, hence in pain physiology and pathophysiology. Immature and uncoordinated motor system change and restrict range of possible behavioral responses to pain stimuli, especially in children.¹⁶ Another difference in methodology is that the index study used FLACC in assessing pain, while Mahammod et al,¹³ Kousar et al¹² and Rakesh et al¹⁴ used VAS and Wong Baker Faces, respectively. While VAS and Wong Baker Faces are self-reporting pain scales and objective, FLACC is an observational pain scale and subjective in approach. Shindova et al¹⁷ reported that patients' self-reporting is the gold standard of pain assessment. Another difference in methodology between the index study and others is the amount of bupivacaine used. Although there is a similarity in the concentration of bupivacaine used in the index study and Kousar et al,¹² however, Kousar et al used 6ml of 0.25% bupivacaine while the index study used 1.5ml of 0.25% bupivacaine on each site (total of 3ml).¹² The difference in pain scores of the bupivacaine group of the index study with that of Kousar et al,¹² despite using larger volume of bupivacaine could be alluded to the fact that the index study utilized a multimodal analgesic approach postoperatively while Kousar et al¹² did not. Vasan et al¹⁸ and Kamal et al¹⁹ reported that a multimodal analgesic approach postoperatively is superior to unimodal analgesia as it provides better analgesia with lower pain scores.

The study also revealed that by the 6th hour of bupivacaine injection all the patients in the control group had received rescue analgesia, while only one patient (7.1%) received rescue analgesia in the bupivacaine group. However, by the 24th hour of the study 13 patients (92.9%) in the bupivacaine group had not received rescue analgesia (**Table 3**). This signifies that the control group

consumed higher number of total analgesics compared to those in the bupivacaine group. Rakesh et al¹⁴ similarly reported a significantly lower number of patients in the bupivacaine group having pain scores above 4 in the immediate postoperative period, 6hr, 24hr after the infiltration of bupivacaine compared to the control group; thereby signifying a lower total analgesic consumption in the bupivacaine infiltration group than in the control group. The similarity in both studies could be attributed to their use of multimodal postoperative analgesic approach; while the index study used rectal diclofenac 1mg/kg in addition to bupivacaine infiltration, Rakesh et al¹⁴ used oral ibuprofen 10mg/kg 8 hourly postoperatively. This is consistent with the report of Niraj et al²⁰ and Johnson et al²¹ that there is a relationship between good postoperative analgesia and reduced total analgesic consumption.

The duration of analgesia in the bupivacaine group (1354.29±320.7 min) of the index study was significantly (p=0.000) lower compared to the control group (216.00±67.3 min) (**Table 4**). Albazee et al²² reported that there is no significant difference in the time to first analgesic request, hence duration of analgesia between the control group and the intervention group. The index study used bupivacaine, while Albazee et al²² study reviewed studies done with ropivacaine. Although both drugs have similar durations of motor block, ropivacaine has a shorter duration of sensory block, hence duration of analgesia.²³

5. Conclusion

The study/ showed that infiltration with bupivacaine following adenotonsillectomy in children provides a better analgesic profile by prolonging the duration of analgesia, having lower pain scores, and reduced total analgesic consumption.

6. Clinical Significance

Bupivacaine infiltration following adenotonsillectomy demonstrated clinical significance by producing a meaningful reduction in postoperative pain and decreasing the need for rescue systemic analgesic thereby improving patient comfort and recovery. These findings support its use as an effective component of multimodal analgesia protocols where measurable improvements in patient-centered outcomes are desired.

7. Limitations

There is a paucity of published works on bupivacaine infiltration following adenotonsillectomy in children, as well as those assessing the duration of analgesia.

Most literature searches revealed studies with a heterogeneous population of children and adults.

Abbreviations

ASA: American society of Anesthesiologist
ECG: Electrocardiography
FLACC: Face, Leg, Activity, Cry and Consolability
PACU: Post-anesthesia Care Unit
SPSS: Statistical Package for Social Sciences

Authors' Contributions

I.I.A and CJO were involved in the conception and design of the study, definition of intellectual content, literature search, data collection and statistical analysis, manuscript preparation. RUO, JOI, IMA were involved in definition of intellectual content, literature search, statistical analysis. EME was involved in definition of intellectual content, data collection and analysis. All the authors edited and reviewed the manuscript.

Consent for Publication

Not applicable.

Ethics Approval and Consent to Participate

Ethical Approval for the study was received from the Health Research and Ethics Committee of Federal Teaching Hospital Owerri, Imo State with file no FTH/OW/HREC/VOL.I/57 on 21st February 2024, chaired by Dr. I.I.Ike (MBBS, FMCPAED).

Availability of Data

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

Source of Funding

There are no external financial support and funding

Conflict of Interest

The authors declare that they have no competing interest.

Use of Artificial Intelligence (AI)

The authors declare that no artificial intelligence (AI) tools were used in the generation, analysis, interpretation, or writing of this manuscript.

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