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Original Article

Anaesthesia Section

Efficacy of Levobupivacaine versus Ropivacaine for Tonsillar Pillar Block in Patients undergoing Tonsillectomy: A Randomised Clinical Trial

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ABSTRACT

Introduction: Tonsillectomy, one of the most frequent otorhinolaryngologic procedures, causes considerable pain and dysphagia in the postoperative period. As previously stated, preoperative local anaesthetic infiltration contributes to the reduction of pain during and after the surgical operation, as well as the use of postoperative analgesics. The measurement of pain intensity commonly used is the Numerical Rating Scale (NRS).

Aim: To compare levobupivacaine and ropivacaine for post-tonsillectomy analgesia.

Materials and Methods: This hospital-based randomised double-blinded clinical trial was conducted at Mahatma Gandhi Medical College and Research Institute, Puducherry, India, between March 2023 and February 2024 on 60 American Society of Anaesthesiologists (ASA) physical status Class I and II patients aged between 7 and 25 years undergoing elective tonsillectomy under general anaesthesia. Patients were randomly allocated to either the Levobupivacaine group (Group L, n=30) or the Ropivacaine group (Group R, n=30). Pain intensity in the postoperative period was measured at 15 minutes, 1 hour, 4 hours, 12 hours, and 24 hours after surgery using the NRS. Rescue analgesia was administered if the patient's pain rating exceeded five. All continuous variables were reported as mean and Standard Deviation (SD), while categorical variables were compared using the Chi-square test or Fisher's-exact test with Yates correction, wherever necessary.

Results: The sample comprised 30 patients in each group. The mean ages of the participants were 16.86 and 17.55 years, respectively. The preoperative and intraoperative values of Heart Rate (HR), Systolic Blood Pressure (SBP), and Diastolic Blood Pressure (DBP) were comparatively lower in the ropivacaine group. The difference between the groups was statistically insignificant. Pain scores were significantly lower in the Ropivacaine group compared to the Levobupivacaine group at 15 minutes (p-value=0.004), one hour (p-value <0.001), four hours (p-value=0.027), and 12 hours (p-value <0.001) postoperatively. By 24 hours, pain scores were similar. The need for rescue analgesia was lower in the ropivacaine group, suggesting that the duration of analgesia was longer in this group. There were no significant side-effects in either of the groups.

Conclusion: The results of the study showed that patients who received ropivacaine had better postoperative pain control than those who received levobupivacaine in paediatric tonsillectomy patients. Compared to the levobupivacaine group, patients administered ropivacaine experienced reduced pain intensity at different time points and utilised fewer rescue analgesics, illustrating a prolonged and superior quality of analgesia.

Keywords: Analgesia, Local anaesthetic, Postoperative

INTRODUCTION

Tonsillectomy is a common otorhinolaryngological procedure that often results in significant post-surgical pain during swallowing. Inadequately controlled pain in children can lead to complications such as dehydration, malnutrition, and prolonged recovery times, affecting their return to normal activities [1]. Severe throat pain may hinder fluid and food intake, increasing the risk of dehydration and respiratory complications, while persistent pain can disrupt sleep patterns, leading to emotional distress. The rich vascular supply of the tonsils may complicate surgery due to primary and secondary hemorrhage, potentially requiring re-exploration and cauterisation of bleeding vessels. Literature suggests that preoperative infiltration of local anaesthetics can alleviate intraoperative pain and reduce postoperative analgesic needs by blocking peripheral nociceptive excitation and preventing Central Nervous System (CNS) sensitisation [2,3].

Scales such as the Visual Analogue Scale (VAS) and Numerical Rating Scale (NRS) effectively assess pain intensity, particularly in children aged seven and above. Traditional local anaesthetics like lignocaine and bupivacaine have been used for tonsillar pillar blocks; however, newer options such as levobupivacaine and ropivacaine offer safer, longer-acting alternatives with reduced cardiotoxicity [4-6]. There are limited studies on newer local anaesthetics, with less focus on haemodynamic variables. Hence, authors aimed to compare the effects of 0.15% levobupivacaine and 0.25% ropivacaine before tonsillectomy, evaluating intraoperative haemodynamics, postoperative pain, nausea, vomiting, surgical site bleeding, time to first oral intake, and the time to first analgesic request in the postoperative period.

MATERIALS AND METHODS

The present hospital-based randomised double-blinded clinical trial was conducted at Mahatma Gandhi Medical College and Research Institute, Puducherry, India on 60 American Society of Anaesthesiologists (ASA) physical status Class I and II patients aged between 7 and 25 years undergoing elective tonsillectomy under general anaesthesia, between March 2023 and February 2024. The study was approved by the Institutional Research and Ethics Committee (MGMCRI/Res/01/2021/11/IHEC/59). The study was registered with the Clinical Trials Registry India (CTRI) (CTRI/2024/07/069703).

Inclusion and Exclusion criteria: Patients aged between 7 and 25 years, belonging to ASA PS I-II and planned for tonsillectomy under general anaesthesia, were included in the study. Patients with signs of acute pharyngeal infection, fever, peritonsillar abscess, bleeding disorders, drug allergies, refusal to participate, or inability to understand and interpret the NRS scale were excluded from the study.

Sample size calculation: To detect a difference of 15 mm between the two groups and to achieve a power greater than 0.81 (SD of 15 mm), 30 patients in each group were required, assuming a two-tailed significance test at α=0.05 [7]. Assuming α=0.05 and β=20%, the sample size required was 30 per group.

$$n=\frac{2\sigma^2(Z_{1-\beta}+Z_{1-\alpha/2})^2}{(\mu_1-\mu_2)d^2}$$

- n: The sample size required for each group.
- σ^2: The variance of the population (the variability of the data) assumed to be equal for both groups.
- Z1-β: The critical value from the standard normal distribution corresponding to the probability of a Type II error (β); this represents the power of the test.
- $Z_{1-\alpha/2}$: The critical value from the standard normal distribution corresponding to the significance level (α). This is typically associated with the probability of making a Type I error, subdivided by 2 for two-tailed tests.
- μ_1: The mean of the first population.
- μ_2: The mean of the second population.

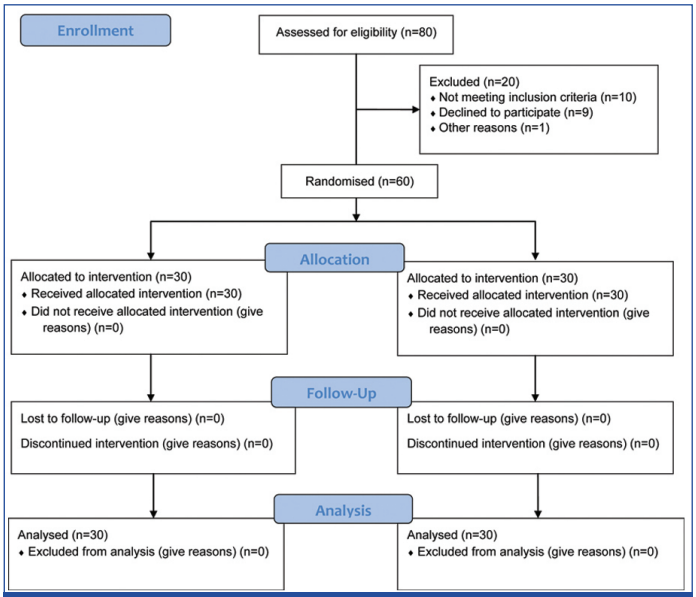
Study Procedure

Patients whose parents gave consent to enroll in the study were assigned to Group L (Levobupivacaine) or Group R (Ropivacaine) through computerised random sampling. All the parents of the participants were informed about the study, and informed written consent was obtained.

Group L (Levobupivacaine): 30

Group R (Ropivacaine): 30

Patients were randomised into two groups, namely Group L and Group R, using a computerised random number generator [Table/Fig-1]. This was a double-blinded study; therefore, the preparation of the drug solution and administration were carried out by a senior anesthesiologist not involved in the study. Monitoring of perioperative haemodynamic parameters and pain scores was performed by the principal investigator.



[Table/Fig-1]: Consodilated Standards of Reporting Trails (CONSORT) diagram (N=80).

During the pre-anaesthetic evaluation, a detailed clinical history was obtained, and a thorough general and systemic examination was conducted. Baseline haemodynamic parameters such as Heart Rate (HR), Blood Pressure (BP), Oxygen Saturation (SpO_2), and Electrocardiogram (ECG) were noted. Routine haematological and biochemical investigations were performed. All subjects were kept nil per os for six hours preoperatively for solids and two hours for clear fluids. The patients were brought into the operating theater, and intravenous (i.v.) access was obtained using an appropriately sized i.v. cannula. Intravenous Ringer's lactate was administered at a rate of 10 mL/kg body weight. Standard ASA monitors, including pulse oximeter, automated non invasive BP monitor, ECG, temperature, and baseline values, were recorded.

All patients were premedicated with Inj. Glycopyrrolate 5 mcg/kg i.v., Inj. Midazolam 0.02 mg/kg i.v., Inj. Fentanyl 2 mcg/kg i.v., and Inj. Dexamethasone 0.1 mg/kg i.v. five minutes prior to induction of anaesthesia. Preoxygenation was performed with 100% oxygen for three minutes. Induction was achieved with Inj. Thiopentone 5 mg/kg i.v., and intubation was facilitated with Inj. Atracurium 0.5 mg/kg i.v.. Intubation was performed, and anaesthesia was maintained with sevoflurane, nitrous oxide, and oxygen. Inj. Fentanyl 0.5 mcg/kg was administered in the event of tachycardia (defined as an increase of +20 beats per minute (bpm) from baseline) or hypertension (systolic blood pressure >20 mmHg or diastolic blood pressure >10 mmHg from baseline).

A standard surgical technique was used. Before the tonsillectomy, subjects were randomly assigned by a computer program to receive either 0.15% Levobupivacaine hydrochloride (Group L) or 0.25% Ropivacaine hydrochloride (Group R). The infiltration was performed into the anterior pillar at the lower pole and mid-pole of the tonsillar pillar (2.5 mL per site, totaling 5 mL per tonsil) using an aspiration injection technique.

To make both drugs equipotent, they were diluted as follows: Since, Levobupivacaine is available in a 0.5% concentration, 1.5 mL of Levobupivacaine was diluted with 3.5 mL of normal saline to create 5 mL of 0.15% Levobupivacaine. Similarly, Ropivacaine is also available in a 0.5% concentration; thus, 2.5 mL of Ropivacaine was diluted with 2.5 mL of normal saline to create 5 mL of 0.25% Ropivacaine.

After applying the Boyle Davis mouth gag, a straight 23-G needle was used for infiltration. The superficial injections caused the submucosal tissues of the tonsillar pillar to balloon out. The infiltrate was free of adrenaline, and neither the adenoid bed nor the body of the tonsil was injected. Tonsillectomies were performed by an otorhinolaryngologist using the blunt dissection snare technique, and haemostasis was achieved.

After the surgeon completed the surgery, oropharyngeal suction was performed under direct vision, and all patients were extubated in the tonsillectomy position. The patients' pain scores were assessed using the Numerical Rating Score (NRS) at fixed intervals after the surgery: 15 minutes, and 1, 4, 12, and 24 hours postoperatively. Patients were kept nil per os for the first four hours postoperatively. If the pain score was greater than 5, a rescue analgesic, Inj. Fentanyl at 1 mcg per kg, was administered and noted. Once patients tolerated fluids, oral acetaminophen at 10 mg per kg was given. The time to the first request for analgesia and any additional analgesic requirements were recorded. All adverse effects, including bleeding, nausea, vomiting, and otalgia, were also recorded.

STATISTICAL ANALYSIS

All the data were entered into Microsoft Excel. The analysis was conducted using Statistical Package for Social Sciences (SPSS) version 27.0. All continuous variables were reported as means and standard deviations, while categorical variables were compared using the Chi-square test or Fisher's-exact test with Yates correction, wherever necessary. Continuous variables were compared with binomial categorical data using the independent t-test. Serial measurements were compared using repeated measures Analysis of Variance (ANOVA). A p-value of less than 0.05 was considered statistically significant.

RESULTS

The study compared two groups, R and L, with mean ages of 16.86 and 17.55 years, and mean weights of 44.38 kg and 47.77 kg, respectively. Group R had a shorter mean surgery duration of 2.172 hours compared to 2.452 hours in Group L. Notably, Group R exhibited significantly lower HR, SBP, respiratory rates, and mean arterial pressure both post-block and intraoperatively, indicating better haemodynamic stability. Pain scores were significantly lower for Group R at multiple postoperative intervals, highlighting its superiority in pain control. The gender distribution and airway classification were similar across both groups. The baseline data for saturation and changes were insignificant. There were no significant side-effects in either group. The results has been summarised in [Table/Fig-2,3].

Variables	Group L	Group R	p-value
Mean age	17.55 years (SD=6.093)	16.86 years (SD=6.278)	0.33
Mean weight	47.77 kg (SD=12.287)	44.38 kg (SD=13.178)	0.35
Duration of surgery	2.452 hours (SD=0.6995)	2.17 hours (SD=0.3605)	0.45
Gender distribution	43.3:56.67 Male:female	50:50 Male:female	0.446
Mallampati classification II (n%)	73%	80%	0.112

[Table/Fig-2]: Demographic variables.

Variables	Group R (n=30)		Group L (n=30)		p-value#
First rescue analgesia n (%)					
Less than 6 hours	1	3.3	6	20	0.104
More than 6 hours	29	96.7	24	80	
SBP (mean±SD) (mmHg)					
Baseline	107.38±5.583		106.77±7.370		0.723
After block	106.28±5.700		107.87±6.712		0.327
Intrablock	103.03±5.362		109.55±6.767		<0.001
DBP (mean±SD) (mmHg)					
Baseline	67.45±6.208		67.16±6.729		0.865
After block	66.00±6.141		67.39±6.766		0.410
Intrablock	65.52±5.748		68.19±8.364		0.157
Respiratory rate changes (intraoperative) (breaths per minute)	19.1±0.939 (16)		19.3±1.08 (15.6)		0.043
VNRS pain					
15 minutes	3.48±0.785		4.10±0.790		0.004
1 hour	4.28±0.751		5.06±0.772		<0.001
4 hours	5.69±0.712		6.00±0.258		0.027
12 hours	7.59±0.780		8.65±0.661		<0.001
24 hours	9.07±1.252		8.94±1.153		0.669
Time to first analgesia (minutes)	286.2±45.25		468.55±78		0.01
Minimal bleeding	1		1		
First oral intake in minutes (Mean)	185.55		196.75		0.5

[Table/Fig-3]: Showing the variables and their values with probability showing NRS scores between the groups (N=60).

DISCUSSION

Tonsillectomy remains a commonly performed surgical procedure, particularly in paediatric populations, due to indications such as recurrent infections or Obstructive Sleep Apnoea (OSA)-disordered breathing. Ensuring effective perioperative and postoperative analgesia is a significant challenge to prevent complications such as reduced oral intake, malnutrition, and prolonged hospital stays. Numerous analgesic modalities have been explored over the years, with Local Anaesthetics (LAs) being a central component due to their ability to provide localised pain relief by blocking sensory pathways [8]. Levobupivacaine and ropivacaine are both amide-type local anaesthetics and S-enantiomers, with the former being the S(-) enantiomer of racemic bupivacaine. These agents are known for their lower cardiovascular and CNS toxicity compared to racemic bupivacaine, which has facilitated their increased use in various clinical settings for effective pain management. According to a study, levobupivacaine demonstrated a favorable safety profile with a reduced potential for cardiotoxicity and less depression of cardiac and CNS functions compared to bupivacaine [9]. Ropivacaine, similarly, exhibits minimal neurotoxic effects within the clinical dosage ranges. Postoperative pain following tonsillectomy is severe, and managing it effectively is critical for patient recovery. The NRS is validated for paediatric pain assessment and is commonly used due to its simplicity and reliability (Thalamati D et al., 2013) [10].

The present study employed the NRS for pain measurement, which revealed significantly lower NRS scores at 15 minutes and 1 hour post-surgery in the ropivacaine group compared to the levobupivacaine group. These findings highlight ropivacaine's superior efficacy in the immediate postoperative period. Rescue analgesia is often required post-tonsillectomy, and the demand for it can indicate the efficacy of the primary analgesic regimen. Our study found that fewer patients in the ropivacaine group required rescue analgesia within the first six hours compared to the levobupivacaine group (1 vs. 6 patients), although statistical significance was not established. This conclusion is consistent with findings from another author, who noted a delayed need for postoperative intramuscular analgesics and a decreased overall requirement in patients receiving ropivacaine compared to lidocaine [7].

Complications from peritonsillar blocks can range from mild issues like nausea and otalgia to severe ones such as airway obstruction and local anaesthetic toxicity. Notably, Ahmed SA and Omara AF, reported swallowing difficulties and loss of the gag reflex postoperatively due to glossopharyngeal nerve block [11]. However, our study did not encounter such complications, likely due to superficial injection techniques and the exclusion of adrenaline from the LA mixture. Additionally, complications like severe upper airway obstruction and deep cervical abscess have been documented in the literature [12], primarily associated with deeper and higher volume local anaesthetic infiltrations. Our controlled and superficial approach likely mitigated these risks, resulting in a safer profile for both ropivacaine and levobupivacaine.

In alignment with our findings, Unal Y et al., conducted a study comparing bupivacaine, ropivacaine, and saline, reporting no major complications and similar subjective symptom profiles across groups [13]. The present study further supports the safe and effective use of ropivacaine in paediatric populations. Another study [14], which compared levobupivacaine alone to a combination with adrenaline, found no significant differences in analgesic demand, emphasising the importance of the choice of LA and adjuncts for optimising postoperative pain management strategies [15].

Our randomised, double-blinded study concluded that ropivacaine provided superior early postoperative pain relief compared to levobupivacaine in paediatric tonsillectomy patients, with a lower need for rescue analgesia in the immediate postoperative period. There are many controversies regarding the concept of whether to focus on clinical usefulness or statistical differences. Our findings are consistent with existing literature, demonstrating the effectiveness and safety of ropivacaine as a local anaesthetic for peritonsillar block. Ropivacaine infiltration is an effective modality for post-tonsillectomy pain management in children, with minimal side-effects [16-19]. Local infiltration of lidocaine provides adequate postoperative analgesia, and the application of tranexamic acid during tonsillectomy surgery minimises postoperative bleeding and shortens surgery duration

[20]. The reduced cardiovascular and central nervous system toxicity profiles of both agents further support their use in clinical practice. The use of bupivacaine reduced the level of postoperative pain and the incidence of associated morbidities, along with a reduction in surgical time [21]. However, we used newer local anaesthetic drugs.

Limitation(s)

This randomised, double-blinded study comparing ropivacaine and levobupivacaine for postoperative pain in paediatric tonsillectomy patients has limitations. The short-term follow-up does not adequately assess long-term analgesic effectiveness. Pain evaluation is subjective; alternative scales might yield better insights. Additionally, the pharmacological differences between the drugs raise concerns about comparability. The lack of verification of blinding and unaddressed confounding variables further compromise the findings, emphasising the need for larger, more controlled studies.

CONCLUSION(S)

Ropivacaine offers postoperative pain relief that is more effective than levobupivacaine in children undergoing tonsillectomy based on the findings from the present study. Compared to the levobupivacaine group, patients administered ropivacaine experienced reduced pain intensity at different time points and utilised a lower number of rescue analgesics, illustrating prolonged and superior quality of analgesia. The clinical assessment found no significant clinical differences regarding haemodynamic stability and the overall incidence of side-effects between the two groups. Future studies should focus on enhancing the effective use of analgesics to improve manageability and patient satisfaction in this category. For future clinical applications, anaesthesia protocols may consider prioritising ropivacaine for tonsillectomy due to its superior early postoperative analgesia, which contributes to improved patient comfort and recovery outcomes. Further research could focus on optimising dosing strategies and exploring additional adjuncts to enhance the analgesic efficacy of these agents.

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