

Analgesic Efficacy of Tonsillar Bed Infiltration of Ropivacaine versus Bupivacaine in Tonsillectomy

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Abstract

Background: Postoperative pain has become a very crucial challenge for surgeons to manage following tonsillectomy, which leads to various post-operative morbidity such as dehydration and prolonged hospital stays. While bupivacaine is a routinely used local anaesthetic agent for pain management, its serious adverse effect causing cardiotoxicity has necessitated the need for safer alternatives like ropivacaine.

Objectives: The main aim of this study is to compare the analgesic efficacy and safety profile of tonsillar bed infiltration with ropivacaine versus bupivacaine in patients undergoing tonsillectomy.

Materials and Methods: This was a prospective, randomized, double-blind controlled trial involving 100 patients aged 7–40 years. Participants were divided into two groups: Group 1 received ropivacaine (0.2% or 0.5%) and Group 2 received bupivacaine (0.25% or 0.5%) infiltrated into the tonsillar bed post-haemostasis. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at 1, 2, 4, 8, 12, and 24 hours. Secondary outcomes included rescue analgesia requirements, time to resume oral intake, and incidence of complications following surgery.

Results: The ropivacaine group (Group 1) demonstrated statistically significant lower pain scores at all recorded intervals compared to the bupivacaine group (Group 2). Especially, at 1 hour, the mean VAS score for Group 1 was 5.65 ± 1.02 and 7.21 ± 1.45 for Group 2 ($p=0.004$), and at 24 hours, it was around 1.02 ± 0.12 and 3.09 ± 0.11 ($p=0.001$). There was no statistically significant difference between the two groups with respect to the time for first rescue analgesia, total amount of analgesic consumed, and functional recovery that is time taken to start oral feeds. Both the drugs were equally safe and no statistically significant difference was noted in postoperative nausea, vomiting, or bleeding, and no reported cases of local anaesthetic toxicity.

Conclusion: Both bupivacaine and ropivacaine are equally safe and efficient for managing pain in post-operative period. However, ropivacaine was found to provide better analgesic effect across all time intervals and a better choice considering its safety profile, thus making it an ideal choice for tonsillar bed infiltration, particularly in high-risk patients.

Keywords: Ropivacaine; Bupivacaine; Tonsillectomy.

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Introduction

Tonsillectomy remains one of the most frequently performed surgical procedures in ENT globally, primarily indicated for conditions such as recurrent tonsillitis, tonsillar abscesses, obstructive sleep apnoea (OSA) and as a gateway to other surgery. Despite advancements in surgical techniques, postoperative pain remains the most significant clinical challenge associated with the procedure, particularly in paediatric populations. Inadequately managed pain is not merely a matter of patient discomfort; it is a major cause of morbidity that can

lead to inadequate oral feeds, dehydration, weight loss, disturbed sleep, and prolonged hospital stay.[1] The pathophysiology of post-tonsillectomy pain is complex, initiated by local tissue damage that triggers the release of inflammatory mediators. These mediators activate the afferents of C-fibre located in the tonsillar space, which is well-innervated by branches of the trigeminal and glossopharyngeal nerves.[2] Furthermore, pharyngeal muscle spasms and nerve irritation contribute to a state of central nervous system

hyperexcitability, which can prolong the duration and intensity of the pain experienced by the patient.[3] Traditional systemic analgesic including opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and paracetamol—often prove inadequate. While effective, opioids carry significant risks of sedation, nausea, and respiratory depression, which are of particular concern in children with pre-existing OSA. NSAIDs provide effective analgesia but remain controversial due to their potential antiplatelet effects and the subsequent fear of postoperative haemorrhage. Consequently, there is substantial interest in tonsillar bed local anaesthetic infiltration as a component of multimodal analgesia to provide pain relief by blocking sensory pathways before surgical stimulus reaches the spinal cord. [1,4]

Bupivacaine is a long-lasting amide type local anaesthetic that has been widely utilized for this purpose, providing sensory blockade for up to 8 hours. However, bupivacaine carries a known risk of cardiotoxicity and neurotoxicity at increased serum levels, primarily due to its dextro-enantiomer. Ropivacaine, the S-enantiomer of bupivacaine, was developed as a safer alternative. It offers better safety profile with reduced central nervous system and cardiac toxicity while maintaining a longer duration of action up to 12 hours.[1]

Despite the widespread use of both agents, several clinical trials comparing ropivacaine and bupivacaine have given conflicting outcomes. Some studies suggest ropivacaine provides superior analgesia at specific time intervals, while others conclude that their clinical efficacy is equivalent. Furthermore, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) has endorsed against the regular use of local anaesthesia in tonsillectomy, due to lack of sufficient quantitative proof. Due to these pharmacological differences and the clinical use for optimized recovery, a proper evaluation of these two agents is needed. This study aims to compare the analgesic efficacy and safety profile of tonsillar bed ropivacaine versus bupivacaine infiltration in patients undergoing tonsillectomy to inform evidence-based clinical decision-making.[1]

Objective

- Compare the analgesic efficacy and
- Compare the safety profile of tonsillar bed infiltration with ropivacaine versus bupivacaine in patients undergoing tonsillectomy.

Materials and Methods

Study Design: prospective, randomized, double-blind controlled trial.

Sample size: 100

Inclusion Criteria

- Patients belonging to age group of 10- 40 years of either sex
- Patients with Hb >10g/dl

Exclusion Criteria [5]

- Patients with a known hypersensitivity to the study drugs
- Pre-existing coagulation disorders
- Systemic diseases (renal, hepatic, or cardiac)
- Chronic use of analgesic or sedative medications
- Active upper respiratory tract infection at the time of surgery.

Sampling Method: 100 participants were randomly allocated into study groups.

- Group 1 (Ropivacaine Group): Received tonsillar bed infiltration with ropivacaine (0.2% or 0.5%).
- Group 2 (Bupivacaine Group): Received tonsillar bed infiltration with bupivacaine (0.25% or 0.5%).

Methodology

Patients who presented to ENT OPD with complaints of throat pain, underwent a detailed history taking and clinical examination. And those who fulfilled the inclusion criteria were selected for the study. A written and informed consent was taken from all the patients. A standardized anaesthetic protocol was followed for all patients.

Premedication typically included intravenous glycopyrrolate or midazolam. General anaesthesia was induced with intravenous agents such as propofol (2 mg/kg) and fentanyl (1–2 µg/kg), followed by endotracheal intubation. Maintenance was achieved using sevoflurane in an oxygen/nitrous oxide mixture.

To ensure double-blinding, the study medications were prepared by an independent anaesthesiologist not involved in postoperative assessment. Syringes were standardized in volume and appearance, and neither the operating surgeon nor the clinician recording postoperative outcomes was aware of the group assignment. [6,12]

Tonsillectomy was then performed by a single senior surgeon by dissection and snare method. After achieving complete haemostasis, using a 23-gauge needle, the solution was injected into the tonsillar bed at the upper pole, lower pole, and the middle part on both sides, typically using a total volume of 3–5 mL per tonsil.

Outcome Measures [3,5]

Primary outcome was the severity of postoperative pain, assessed at fixed intervals (e.g., 1, 2, 4, 8, 12, and 24 hours). Validated tool was used, such as:

- VAS (Visual Analogue Scale) for older children capable of self-reporting >7years.

Secondary outcomes included:

- Time to first rescue analgesic request and total dose of supplemental analgesia (e.g., acetaminophen) consumed within 24 hours.
- Functional recovery, such as the time taken to first resume oral fluids or solids.
- Incidence of complications, including postoperative nausea and vomiting (PONV),

haemorrhage, airway obstruction, or signs of local anaesthetic toxicity.

Statistical Analysis: Data analysis was performed using SPSS or R software. Demographic data were analysed using Descriptive Statistics. Continuous variables (pain scores, time to first analgesic) were compared using unpaired student's t-tests or ANOVA, while non-parametric data were assessed using Mann-Whitney U or Kruskal-Wallis tests.

Categorical data (complication rates) were compared using the Chi-square or Fisher's exact test. A p-value of < 0.05 was defined as the threshold for statistical significance.

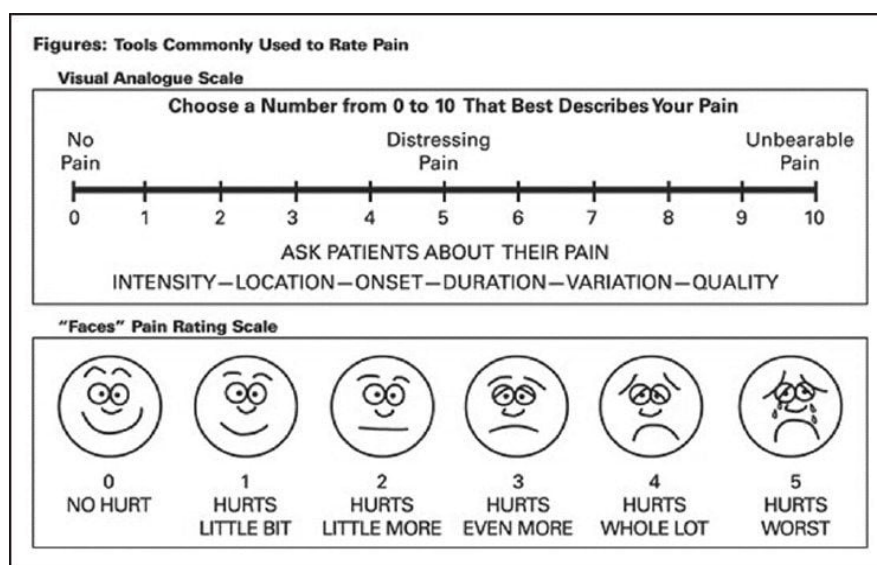


Figure 1:

Results

- The average age group in group 1 were 20.67±10.72 and group 2 were 21.59±9.52 years
- Group 1 had 20 (36.3%) males and 35 (63.6%) females and group 2 had 16 (35.5%) males and 29 (64.4%) females, showed no statistically

significant difference in gender distribution among the two groups.

Primary Outcome: Postoperative Pain Scores

- The clinical efficacy of ropivacaine and bupivacaine was evaluated at various intervals during the first 24 hours post-surgery.

Table 1:

Time(Hours)	Group 1 (Mean±Sd)	Group 2 (Mean±Sd)	P Value
1	5.65±1.02	7.21±1.45	0.004
2	5.45±1.11	6.92±1.32	0.003
4	4.76±0.98	6.32±1.76	0.002
8	3.55±1.68	5.02±0.56	0.001
12	2.87±0.23	4.45±0.23	0.001
24	1.02±0.12	3.09±0.11	0.001

Secondary Outcomes: Analgesic Requirements and Recovery

- Rescue Analgesia: There was no significant difference between the groups regarding the time to the first request for rescue analgesia
- Total Consumption: The total analgesic consumption (e.g., acetaminophen) was not statistically significant.
- Functional Recovery: Recovery indicators, such as the time taken to first resume oral fluid or solid intake, were largely similar in both the groups.

Table 2:

In First 24hr	Group 1	Group 2	P Value
No Of Children Receiving Pct	50	43	0.2
Total No Of Analgesic Consumption	82	79	0.1
Time To First Pct(Min)	80.1±10.6	78.98±16.65	0.1
Oral Intake After 4hours	52	41	0.75

Safety Profile and Complications: Both agents demonstrated a favourable and equivalent safety profile. There were no statistically significant differences in the incidence of:

- Postoperative Nausea and Vomiting (PONV): Rates were comparable between groups
- Haemorrhage: No significant difference in postoperative bleeding was observed.
- Local Anaesthetic Toxicity: No cases of systemic toxicity, cardiac arrhythmias, or airway obstruction were specifically attributed to the choice of ropivacaine versus bupivacaine at standard concentrations.
- Sedation: While one study (Unal, 2007) reported higher sedation scores in the bupivacaine group at the 5-minute mark, these scores equalized within the first two hours.[7]

Table 3:

Complications	Group 1	Group 2	P Value
Nausea/Vomiting	20	15	0.4
Bleeding	4	6	0.76
La Toxicity	0	0	1
Sedation	5	3	0.09

Discussion

Ropivacaine: It is a long-acting amide local anaesthetic developed as a pure enantiomer to enhance clinical safety. Compared to bupivacaine, this agent's lower lipophilicity reduces its ability to penetrate motor fibres, allowing for effective pain relief with minimal impact on physical movement. This chemical profile also ensures a higher safety margin by decreasing the risk of cardiotoxicity and central nervous system complications. It is processed by the liver and primarily eliminated through the kidneys. Ropivacaine is a versatile and well-tolerated option for regional anaesthesia due to its favourable sensory-motor block profile. In our study we have used (0.2% or 0.5%) ropivacaine at a dose of 1 mg/kg with maximum dose of 5 ml, injected in each tonsillar bed.[8]

Bupivacaine: It is a long-acting, amide-type local anaesthetic used extensively in medical and dental procedures to provide local or regional anaesthesia and analgesia. Bupivacaine functions by reversibly blocking the generation and conduction of nerve impulses. It is primarily metabolized in the liver.

Bupivacaine is notably the most toxic to the heart among local anaesthetics when administered in large doses, leading to potential arrhythmias or cardiac arrest. Accidental intravascular injection has been associated with cardiac arrest that is difficult to resuscitate, sometimes resulting in death. Ropivacaine was developed to mitigate this risk. In our study, we have used (0.25% or 0.5%) bupivacaine with the same dose of 1 mg/kg with a maximum of 5 ml in each tonsillar bed.[9] While the immediate postoperative period is critical for

preventing complications like dehydration and hospital readmission, our findings suggest that both long-acting local anaesthetics are effective components of a multimodal analgesic strategy.

Comparative Analgesic Efficacy: There was statistically significant difference in post-operative pain at all intervals between the 2 groups, with ropivacaine having a better efficacy. These findings are consistent with Rao et al. (2022) favoured ropivacaine across nearly all time intervals, whereas Unal et al. (2007) found bupivacaine superior at 2 and 6 hours post-surgery.[3,7] In contrast, studies by Akoglu (2006) and Gudi (2014), both of which concluded that the two agents offer similar degrees of relief.[10,11]

Safety Considerations: Despite these theoretical safety advantages, our meta-analysis found no significant differences in actual complication rates.

There were no reported cases of local anaesthetic systemic toxicity (LAST), and rates of postoperative haemorrhage, nausea, and airway obstruction were equivalent between the two groups. This suggests that at the concentrations and volumes typically used for tonsillar bed infiltration, both agents are safe.

Conclusion

Both ropivacaine and bupivacaine are effective and safe for reducing early post-tonsillectomy pain. While ropivacaine offers a superior theoretical safety profile and efficacy, hence it is recommended to choose ropivacaine over bupivacaine especially in high risk patients despite it being costlier than bupivacaine.

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