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Original Research

Comparison between anaesthetic efficacy of 0.5% ropivacaine and 0.75% ropivacaine in subjects undergoing surgical removal of bilateral impacted mandibular third molars – A prospective double-blind study

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ABSTRACT:
Background: The surgical removal of mandibular third molars is a routine but challenging procedure in oral and maxillofacial surgery, necessitating effective pain management. Traditional anaesthetic agents, like lidocaine, provide inadequate duration for prolonged procedures, often leading to tachyphylaxis and the need for repeated administration. Ropivacaine, a long-acting amide local anaesthetic with improved safety profiles, offers promise for addressing these limitations. This study compares the anaesthetic efficacy of 0.5% and 0.75% Ropivacaine for inferior alveolar nerve blocks in third molar surgery. **Methods:** This prospective, double-blind, randomized study involved 40 ASA Class I patients undergoing surgical removal of impacted mandibular third molars. Participants were divided into two groups: Group I (0.75% Ropivacaine) and Group II (0.5% Ropivacaine). Anaesthetic onset, depth, and duration were measured using the Numeric Rating Scale (NRS) and time-based monitoring. Cardiovascular stability was assessed via regular blood pressure and pulse measurements. Surgical protocols included mucoperiosteal flap reflection, bone removal, and tooth extraction, with postoperative parameters recorded. **Results:** The onset of anaesthesia was faster with 0.75% Ropivacaine (226.75 seconds) compared to 0.5% (275.25 seconds). The duration of anaesthesia was longer for the 0.75% group (442 minutes) versus the 0.5% group (376 minutes). Depth of anaesthesia was superior in the 0.75% group, as reflected by lower NRS scores. Cardiovascular parameters remained stable in both groups, with only a transient, clinically insignificant increase in pulse rate noted in the 0.75% group. **Conclusions:** Both 0.5% and 0.75% Ropivacaine are effective and safe for third molar surgeries. However, 0.75% provides a faster onset, prolonged duration, and superior depth of anaesthesia, making it preferable for longer and more complex procedures. Future studies should explore broader patient populations to further validate these findings.

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INTRODUCTION

"Of pain you could wish only one thing: that it should stop. Nothing in the world is as bad as physical pain. In the face of pain there are no heroes."

The effective control of pain is pivotal in oral and maxillofacial surgical procedures, particularly during the surgical removal of mandibular third molars. The introduction of advanced anaesthetics, such as Ropivacaine, has revolutionized pain management by offering enhanced efficacy and safety profiles tailored to these procedures. Local anaesthesia remains the cornerstone of pain management in such procedures.

Lidocaine hydrochloride is the most commonly used anaesthetic agent since its clinical availability in 1948. It is labelled as "gold standard" due to its efficacy, low allergenicity, and minimal toxicity.In addition to its anti-arrhythmic properties, the antinociceptive effects of parenteral use was subsequently confirmed in various acute and chronic pain states.[30]

However, duration of action with 2% lignocaine is not sufficient for long surgical procedures. One such procedure is removal of bony impacted mandibular third molar. The short-term action often leads to operator giving multiple blocks and then leading to

tachyphylaxis. To avoid tachyphylaxis and short duration of action of lignocaine long-acting local anaesthetics drugs are being tested.

Bupivacaine is a well-established long-acting regional anaesthetic, which like all amide anaesthetics has been associated with cardiotoxicity when used in high concentration or when accidentally administered intravascularly.

The development of new anaesthetic agents, such as Ropivacaine, has provided clinicians with options that combine efficacy with enhanced safety profiles.

Ropivacaine with 0.5% of concentration has rapid onset of action, short duration of pulp anaesthesia, longer duration of action compared to 2% lignocaine hydrochloride. It is indicated for prolonged minor surgical procedures and postoperative pain management in oral and maxillofacial surgery.

Concentration of 0.375% and 0.25% Ropivacaine has slower onset of action compared to 0.75% and 0.5% Ropivacaine. 0.375% and 0.25% Ropivacaine are not indicated for exodontia as it does not provide sufficient surgical anaesthesia.[10] As 0.75% and 0.5% Ropivacaine has rapid onset of action and is indicated in prolonged minor surgical procedure like removal of impacted mandibular third molar and post-operative pain management.

Ropivacaine 0.75 % has more arterial concentration when compared to 0.5%. In some studies, with the increase in the concentration from 0.5% to 0.75%, there are cardiovascular changes, as the concentration of the drug is more in the systematic circulation.[9]

The present study was conducted to compare the anaesthetic efficacy of 0.5% and 0.75 % Ropivacaine for inferior alveolar nerve block in surgical removal of impacted mandibular third molars.

AIMS AND OBJECTIVE

Aims

To compare the dose-dependent anaesthetic efficacy of 0.5% and 0.75% Ropivacaine in patients undergoing the surgical removal of mandibular third molars.

Objectives

1. To evaluate the efficacy (onset, depth, and duration of action) of 0.5% and 0.75% Ropivacaine.
2. To assess cardiovascular stability (blood pressure and pulse rate) associated with these concentrations.

MATERIALS AND METHODS

Study Design

This prospective, randomized, double-blind clinical study was conducted on 40 patients indicated for mandibular third molar extractions. Ethical approval was obtained from the Institutional Ethical Committee, and informed consent was secured from all participants. Patients were divided into two groups:

- **Group I:** 0.75% Ropivacaine
- **Group II:** 0.5% Ropivacaine

Inclusion and Exclusion Criteria

Inclusion Criteria

- ASA Class I patients aged 18 years and above.
- Patients providing informed consent and willing to follow postoperative protocols.

Exclusion Criteria

- Patients with ASA Class II-IV.
- History of systemic diseases, drug allergies, or substance abuse.
- Pregnant patients or those with reduced mouth opening.

Methodology

The study followed aseptic protocols. Local anaesthesia was administered as a mandibular block supplemented by long buccal nerve block. The onset of anaesthesia was measured from the time of injection until pain was absent during pinprick testing. The depth of anaesthesia was assessed using the Numeric Rating Scale (NRS), and its duration was recorded until the first report of pain. Cardiovascular parameters (blood pressure and pulse) were monitored at regular intervals of 2 minutes till 10 minutes post-administration and then at 15 minutes,30 minutes,45 minutes and 60 minutes post-injection.

Surgical Protocol

The surgical procedure included a full-thickness mucoperiosteal flap reflection, bone removal, tooth sectioning, and extraction. The surgical site was irrigated and sutured following adequate hemostasis. Postoperative instructions and medications were provided.

Pharmacology of Ropivacaine

Ropivacaine is a long-acting amide local anaesthetic with a unique pharmacokinetic and pharmacodynamic profile. Its stereoselective properties contribute to reduced central nervous system and cardiovascular toxicity. Ropivacaine primarily inhibits sodium ion influx in nerve fibres, effectively blocking pain transmission[29]. It has a high protein binding capacity, leading to prolonged duration and stable cardiovascular parameter.[25]

RESULTS AND OBSERVATIONS

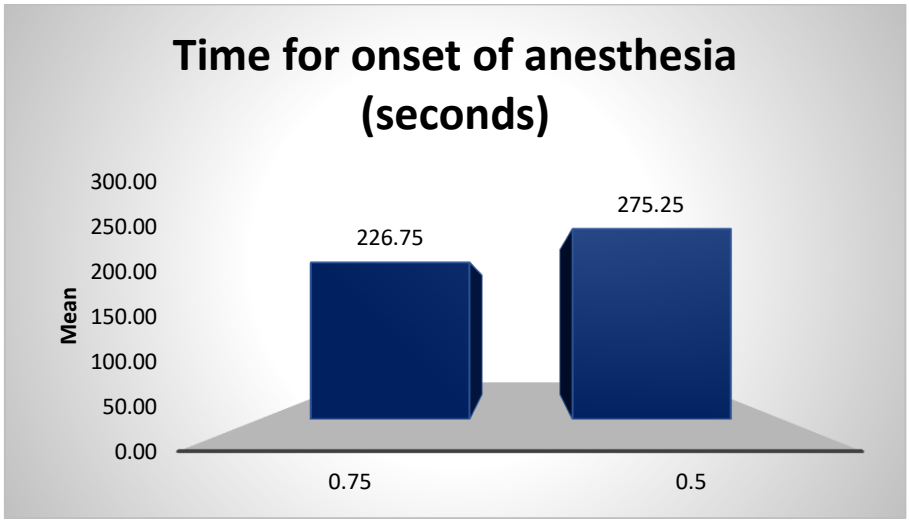
Anaesthetic Efficacy

- **Onset of Anaesthesia:** The onset was faster with 0.75% Ropivacaine (226.75 seconds) compared to 0.5% (275.25 seconds), resulting in quicker patient numbness and reduced waiting times for surgeons, which enhances procedural efficiency and overall patient experience.
- **Depth of Anaesthesia:** Patients in the 0.75% group reported significantly better pain control, with lower NRS scores.

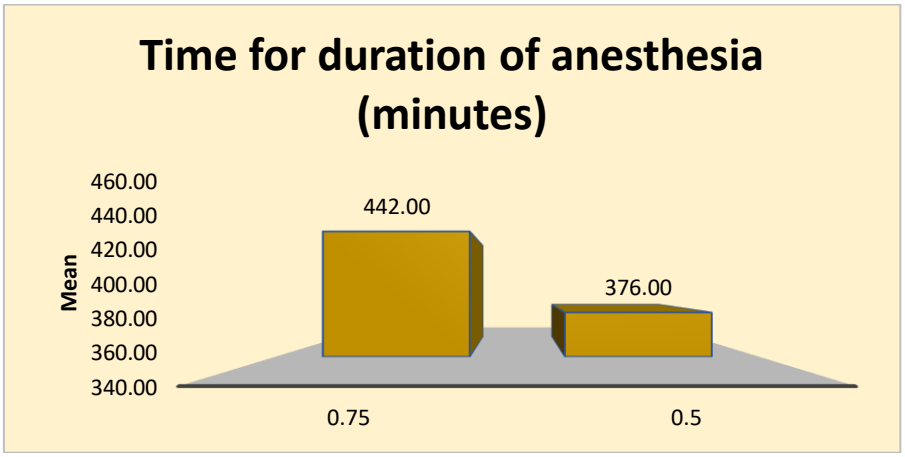
- **Duration of Anaesthesia:** The mean duration was 442 minutes for 0.75% Ropivacaine and 376 minutes for 0.5%, indicating a dose-dependent relationship.

Cardiovascular Stability

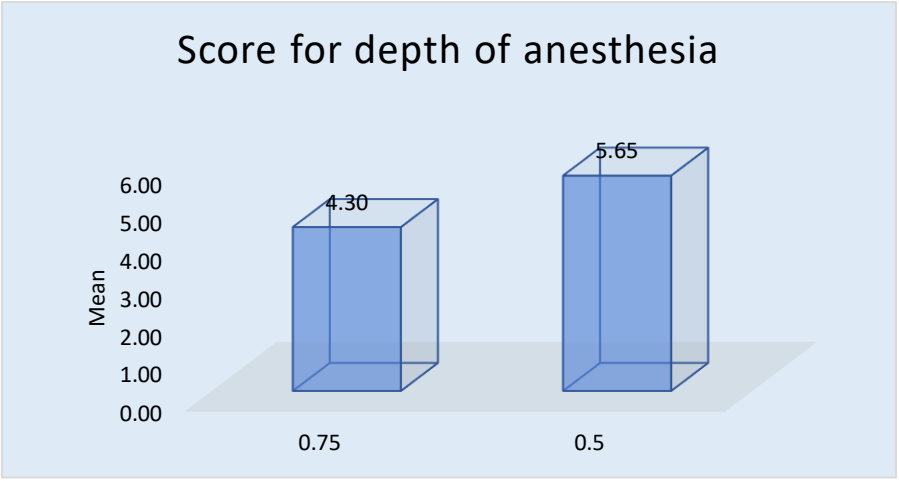
Both concentrations demonstrated stable cardiovascular profiles with no significant differences in systolic and diastolic blood pressure. A transient increase in pulse rate was observed at 60 minutes for the 0.75% group, though this was within clinically acceptable limits.



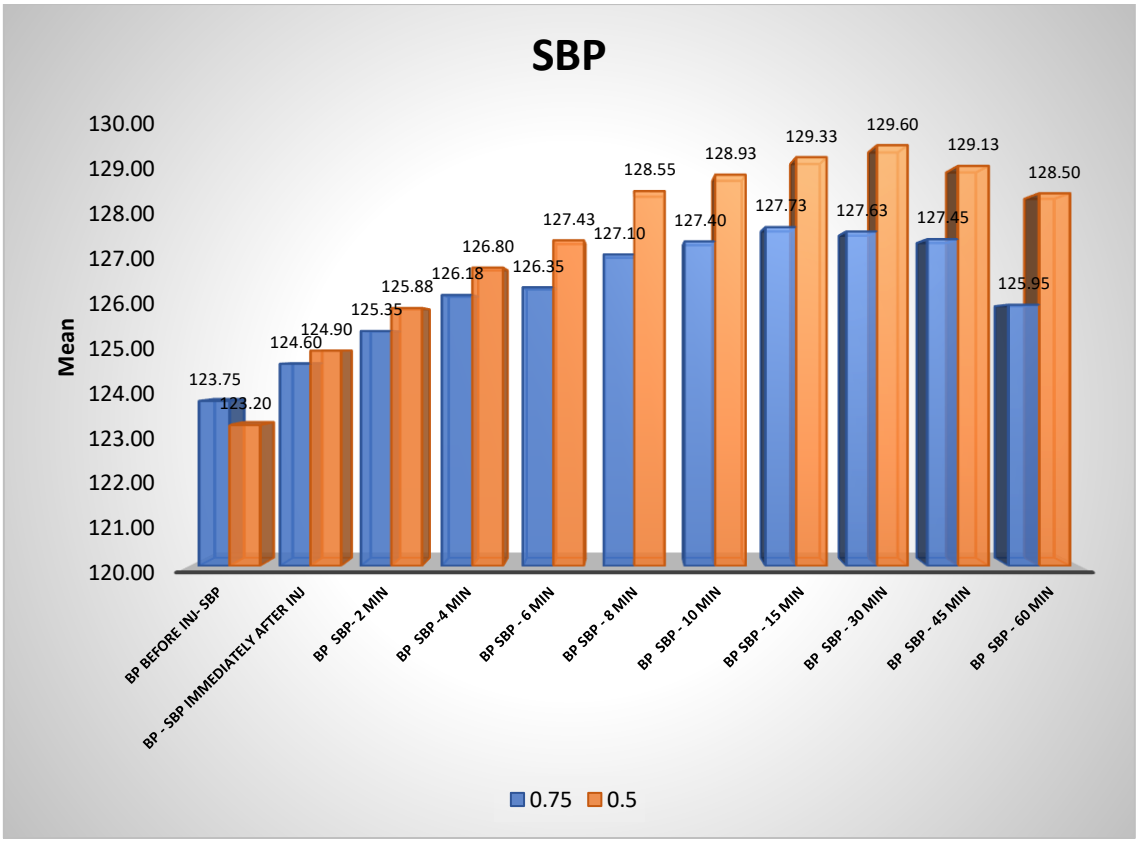
Graph 1: Time of Onset of Anaesthesia (Seconds)



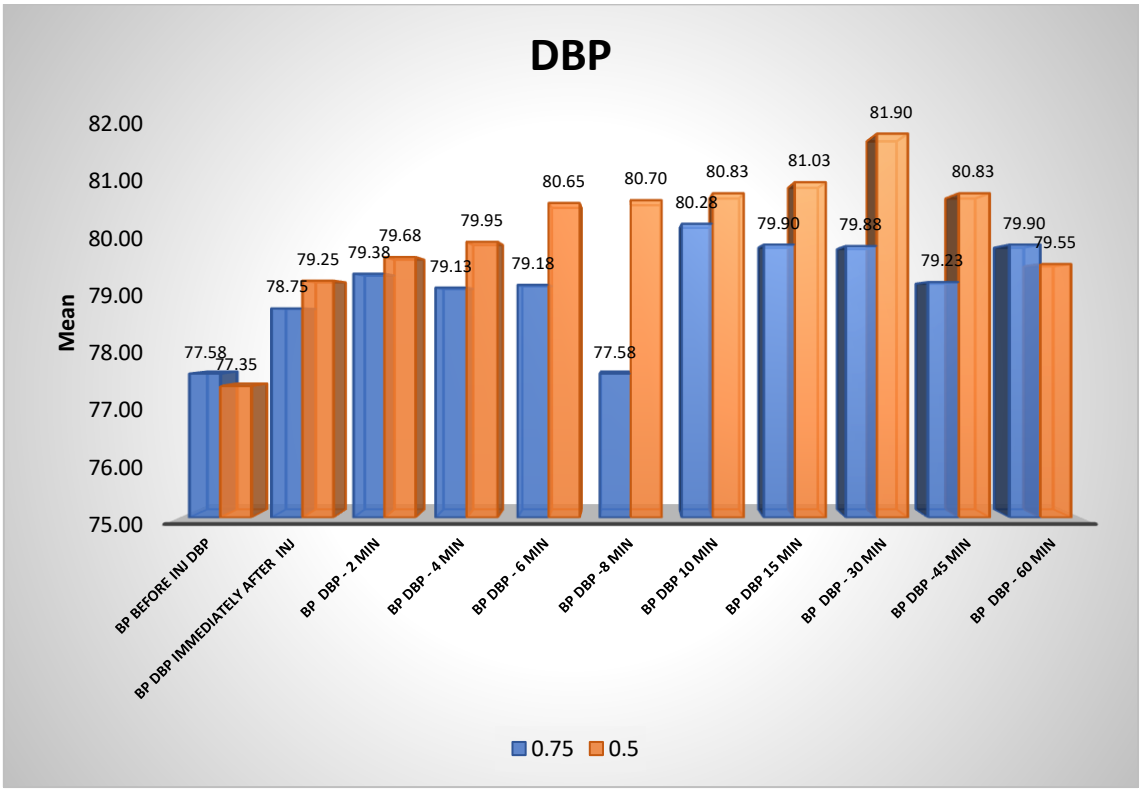
Graph 2: Duration of Anesthetic Effect (Minutes)



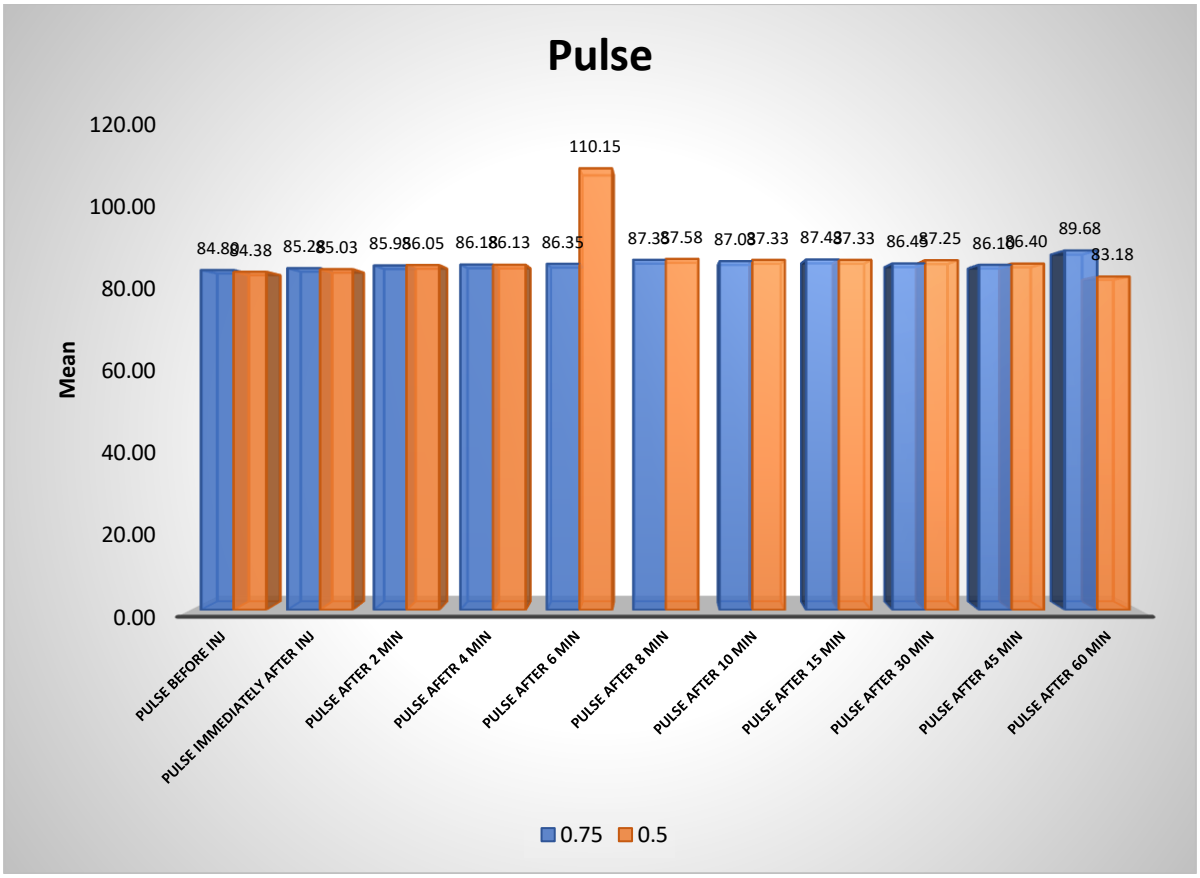
Graph 3: Depth of Anaesthesia (Numeric Rating Scale)



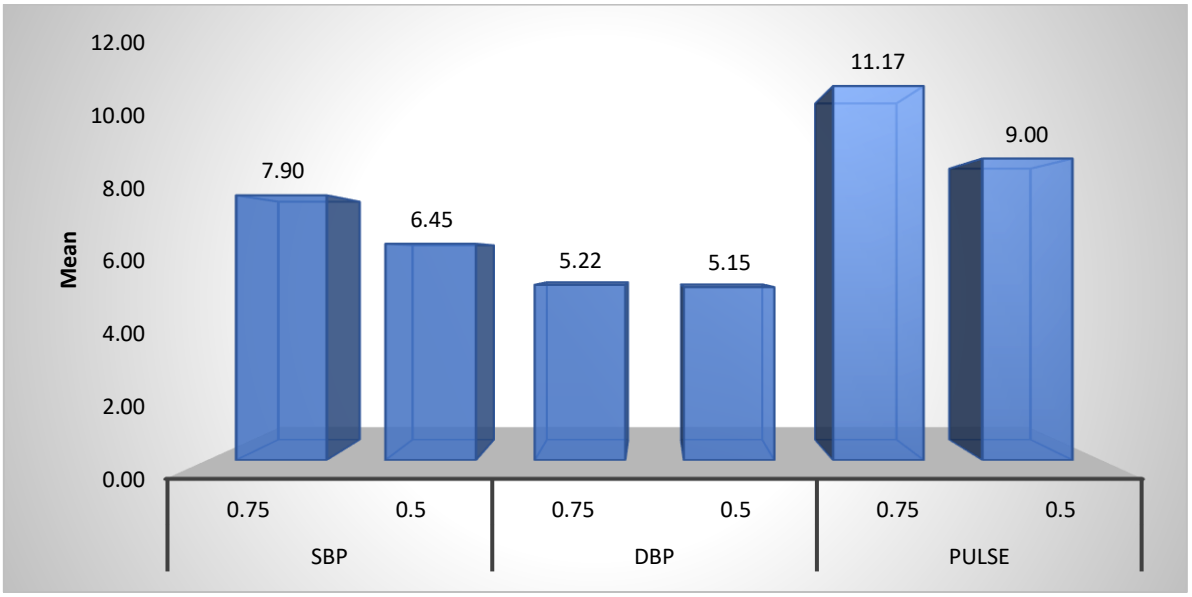
Graph 4: Changes in Systolic Blood Pressure (mm of Hg)



Graph 5: Changes in Diastolic Blood Pressure (mm of Hg)



Graph 6: Changes in Pulse Rate (Beats/minutes)



Graph 9: Comparison of Vitals between Group A and Group B

DISCUSSION

The surgical extraction of mandibular third molars is one of the most common procedures performed in oral and maxillofacial surgery, necessitating effective pain management strategies. Ropivacaine, as a long-acting local anaesthetic, has shown significant promise in improving intraoperative and postoperative pain control.

The study found that the onset of anaesthesia was faster with 0.75% Ropivacaine compared to 0.5%, which aligns with its higher concentration and pharmacological potency. The shorter onset time of 0.75% Ropivacaine can be attributed to its faster diffusion to nerve sites, a property enhanced by its vasoconstrictive characteristics. This finding is consistent with prior studies, such as those by Bhargava et al[13]. and Lahiri et al[22]., which reported

similar trends in onset times between different concentrations of Ropivacaine.

The duration of anaesthesia was significantly prolonged with 0.75% Ropivacaine, lasting 442 minutes compared to 376 minutes for 0.5% (Crincoli et al[14]; Goyal et al[19].). This prolonged action reduces the need for supplementary analgesics in the immediate postoperative phase, enhancing patient comfort. The high protein-binding capacity of Ropivacaine contributes to this effect by slowing systemic absorption and prolonging its action at the site of administration.

The depth of anaesthesia, assessed using the Numeric Rating Scale (NRS), was superior in the 0.75% group. Patients reported lower pain scores, indicating a more profound and effective block (El-Sharrawy & Yagiela[8]; Bansal et al.[16]). This is clinically significant as it minimizes patient discomfort and facilitates smoother surgical procedures. The dose-dependent relationship observed in this study underscores the importance of tailoring anaesthetic concentration to the surgical requirements.

Both concentrations of Ropivacaine demonstrated excellent cardiovascular stability. While a transient increase in pulse rate was noted in the 0.75% group at 60 minutes, this was not clinically significant. Blood pressure measurements remained stable across both groups, reflecting the safety profile of Ropivacaine . Previous studies, including those by Oliveira et al.[9] and Budharapu et al.[15], corroborate these findings, emphasizing the minimal cardiovascular effects of Ropivacaine even at higher concentrations.

Ropivacaine's selective action on Aδ and C pain-transmitting fibres, coupled with its reduced penetration of motor fibres, enhances its sensory specificity while minimizing motor blockade. This characteristic is particularly advantageous in oral and maxillofacial surgery, where motor function preservation is desirable. Additionally, Ropivacaine's inherent vasoconstrictive properties contribute to its prolonged duration and reduced systemic absorption, further enhancing its safety and efficacy.

Limitations and Future Directions

While the study provides valuable insights, it is not without limitations. The sample size was relatively small, and the study was conducted at a single centre, potentially limiting the generalizability of the findings. Pain perception, being inherently subjective, may introduce variability despite standardized assessment protocols. Future research should explore larger, multi-centre trials involving diverse patient populations, including those with systemic comorbidities, to validate and extend these findings. Specifically, additional studies should assess variables such as the impact of different concentrations of Ropivacaine on pain management in patients with cardiovascular or metabolic conditions, long-term safety outcomes, and patient-reported satisfaction with postoperative recovery[21,18].

CONCLUSION

Both 0.5% and 0.75% Ropivacaine are effective and safe for mandibular third molar surgeries. However, 0.75% Ropivacaine may be more suitable for procedures requiring longer duration of anaesthesia and better depth of pain control, while 0.5% could be preferred in cases where minimal cardiovascular impact is crucial, such as in patients with borderline cardiac conditions. However, 0.75% Ropivacaine offers superior anaesthetic efficacy with a faster onset and prolonged duration, making it the preferred choice for prolonged surgical procedures. Further studies involving larger sample sizes and diverse patient populations are recommended to validate these findings.

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