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Original Research Article

Effect of long-acting supplementary local anesthetic on intra and post operative pain in single visit root canal treatment: a randomized control trial

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ABSTRACT

Background: Patients often experience varying degrees of pain during or after root canal therapy. This study aimed to assess the effectiveness of long-acting local anesthetics, specifically Ropivacaine, in preventing intra and postoperative pain associated with endodontic treatment compared to lignocaine.
Methods: This double-blind, randomised clinical trial included 60 patients with single-rooted mandibular pre-molar teeth. Patients were divided into three groups: Group 1 received lignocaine as an inferior alveolar nerve block, Group 2 received lignocaine as an inferior alveolar nerve block with supplementary intraligamentary lignocaine, and Group 3 received lignocaine as an inferior alveolar nerve block with supplementary intraligamentary Ropivacaine. Pain levels were assessed using the visual analogue scale (VAS) before treatment, during treatment, and at 2, 6-, 12-, 24-, and 48-hours post-treatment. Statistical analysis included mean, standard deviation, Kruskal Wallis Test, Dunn's posthoc test, Chi-square, and Friedman's test followed by Wilcoxon signed rank post hoc test.
Results: Ropivacaine as a supplementary intraligamentary anesthetic significantly reduced intraoperative pain levels at working length ($p<0.001$) compared to lignocaine used alone or with supplementary intraligamentary lignocaine. Group 3 exhibited statistically significant differences in postoperative pain levels at 12-hour intervals ($p<0.001$), correlating with reduced intake of oral analgesics ($p=0.02$).
Conclusions: A single dose of 0.2 ml of 0.5% Ropivacaine as a supplementary intraligamentary anaesthetic may be more effective in reducing or preventing intraoperative and post-operative endodontic pain compared to lignocaine, irrespective of the technique used.

Keywords: Inferior alveolar nerve block, Lignocaine, Pain, Ropivacaine, Supplementary intraligamentary anesthetic technique

INTRODUCTION

The main rationale of endodontic treatment is the elimination of microorganisms from the infected root canal system by adequate chemo-mechanical debridement followed by a three-dimensional obturation to achieve a hermetic seal that will promote healing in the periradicular region.[1] There are various factors associated with the occurrence of pain during and post endodontic treatment such as the condition of pulp and periradicular tissues before treatment, immune system-mediated phenomena, psychological factors, level of pre-operative pain, periapical tissue pressure, etc. which in confluence with iatrogenic factors such as inadequate root canal instrumentation, extrusion of periapical debris, type of files used in endodontic treatment, etc.[2] The pain

accompanying endodontic treatment, despite being considered a poor indicator of pathology and an unreliable predictor for the long-term success of root canal treatment, needs to be addressed as it could have a sustained impact on the patient's mental perception of root canal treatment. Moderate to severe pain during endodontic treatment has ranged from 11% to 35% and even as high as 100% as reported by Abbot et al 2018.[3] The focus of pain management during the intraoperative period in endodontics revolves around attaining effective local anesthesia. Regrettably, individuals enduring intense pain from endodontic causes, notably symptomatic irreversible pulpitis, may encounter challenges in achieving sufficient pulpal anesthesia.

This may be attributed to altered pH, issues with techniques of anesthesia, or inflammation in surrounding tissues, leading to pharmacologic failure. Given that both patients and healthcare providers aim to avoid breakthrough pain during treatment, and negative past encounters can discourage patients from seeking dental care in the future, it is crucial for clinicians to deliver pain-free care.[4] The time, volume, and type of anesthetic including additives as well as the use of supplemental techniques have been employed in controlling perioperative pain. Meechan in 2002, reported that in 80% of patients with irreversible pulpitis, the inferior alveolar block is ineffective. Supplementary injections have proven to aid in achieving substantial anaesthetia. The use of supplementary intra-periodontal ligament injections resulted in 56-70% having successful anesthesia. The findings support the pursuit of an effective pain management solution during endodontic treatment.[5]

Managing postoperative pain can be one of the more challenging aspects of clinical practice in endodontics and one by which the skill of the clinician is often judged. Good anesthetic technique could eliminate pain during the procedure, but post-treatment endodontic pain remains a significant predicament to date.[6] The incidence of this post-endodontic pain (PEP), as reported by Sathorn et al, 2008, ranges from 3-58%. In 2011, Pak and White, among others, found that the incidence of PEP was 40% after 24 hours, decreasing to 11% after one week.[7,8] The highest intensity of PEP was observed within the initial six hours, followed by a gradual decline over the subsequent week. Several strategies have been adopted to manage the PEP such as premedication using corticosteroids, prophylactic analgesics, occlusal reduction, cryotherapy etc.

The effects of these strategies on short as well as long-term prevention of pain caused due to endodontic treatment have been studied extensively to determine the most suitable protocol to alleviate pain caused due to endodontic treatment. PEP is usually controlled by the use of mild oral analgesics or nonsteroidal anti-inflammatory drugs. However, nonsteroidal anti-inflammatory drugs may manifest side effects such as gastrointestinal irritation, systemic bleeding tendency, and allergic reactions. These observations justify efforts to find a method of postoperative pain control that does not provoke side effects. A considerable number of literatures on intraligamentary anesthetic technique (ILA) as an alternative technique for inferior alveolar nerve block (IANB) has been generated over the last few years. ILA solely necessitates an injection directly into the periodontal space of the tooth, employing relatively high pressure. The injected solution then disperses into the cancellous bone adjacent to the targeted tooth for effective anesthesia.

This results in a localized area of anesthetization, without the ill effects of nerve block with soft tissue anesthesia. Among the advantages of this technique are the rapid onset of action, a reasonable duration of 30-49 min, for generally employed lignocaine which is in line with standard dental treatment, Additionally, a minimal and secure quantity of anesthetic solution (approximately 0.2 ml per root) is used. This method is highly safe, making it suitable for pediatric patients, individuals with bleeding disorders, and those with medical conditions.[9] Ropivacaine, a long-acting anesthetic, having an onset of action of 2-4 mins, demonstrates a duration of anesthesia ranging between 7 and 11 hours for inferior alveolar nerve block and a mean of 9 hours for infiltration.[10] Hypothetically, this extended duration of anesthesia covers the time of greatest incidence and intensity of postoperative pain following endodontic therapy.

Most of the evidence-based PubMed search is on the effect of using long acting anesthetic on postoperative pain after tooth extraction or periodontal surgery, and this is why such a study is important where the model used is on postoperative pain after RCT.[11,12] Further, there is minimal clinical research into the comparison of the incidence of postoperative pain following single-visit endodontics between patients anesthetized with lignocaine and ropivacaine with the use of supplementary technique of ILA. Hence, an in vivo double-blind study was proposed to evaluate the effect of supplementary intraligamentary ropivacine on intra as well as post-operative pain in single-visit root canal treatment in teeth with symptomatic irreversible pulpitis and to compare the observations of both groups. The study hypothesis proposed was Null hypothesis (H0). There is no difference in the incidence of postoperative-pain in single-visit RCT under lignocaine alone as IANB, liognocaine as a supplementary ILA, and ropivacaine as a supplementary ILA when used as a local anesthetic agent.

METHODS

This randomised double blinded clinical trial consisted of patients chosen from the pool of patients referred to the Department of Conservative Dentistry and Endodontics, Vokkaligara Sangha Dental College and Hospital, Bangalore during the time period of December 2023 to January 2024. Sixty adult patients (36 women and 24 men) with an age range of 22-58 years participated in the same. The flowchart has been depicted in Figure 1.

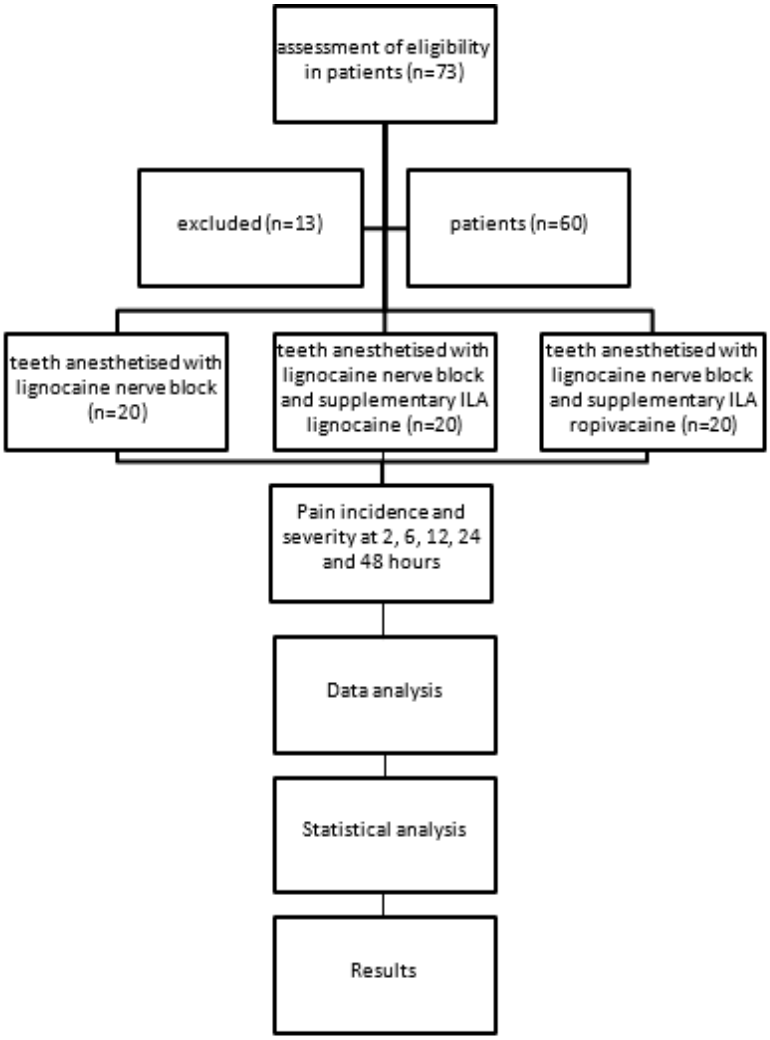

Figure 1: The selection and allocation of participants into the three study groups.

Inclusion criteria

Patients who require endodontic treatment in single-rooted premolar teeth with a clinical diagnosis of symptomatic irreversible pulpitis or symptomatic apical periodontitis, and who give a history of spontaneous, continuous, lingering, gnawing, or throbbing pain with a VAS score greater than 6, eliciting a response of lingering pain, delayed, or negative response on cold vitality testing, involving only one tooth in the quadrant without anatomic variations such as receded pulp chamber, calcified canals, or sharply curved canals, and who are not on analgesics or sedative medications 24-48 hours before root canal therapy, were included.

Exclusion criteria

Patients with known allergies to anesthetics, asymptomatic irreversible pulpitis, and other pulpal or periodontal disease diagnoses, as well as those who are diabetic, pregnant, or have any other systemic illness, and those requiring retreatment, were excluded.

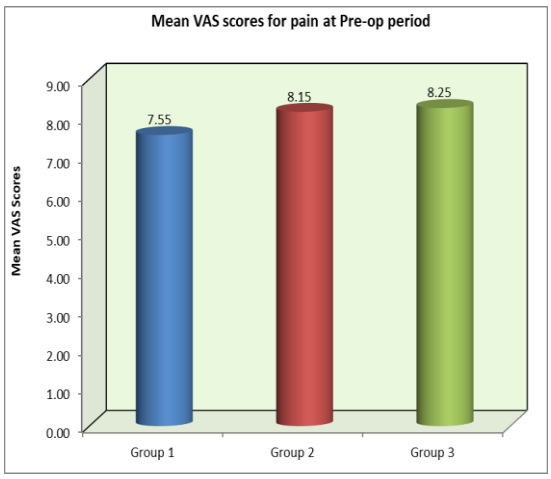

Figure 2: Mean values and standard deviation (SD) of preoperative pain scores on the visual analog scale (VAS) for patients in different groups.

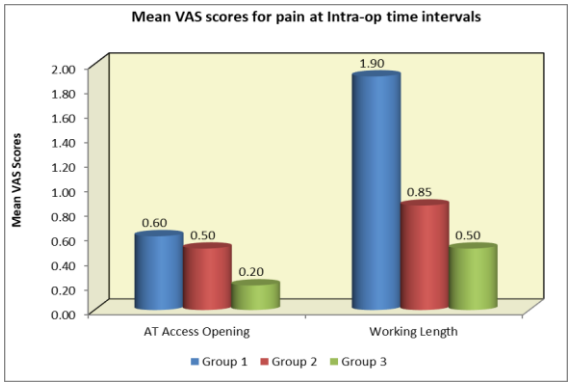

Figure 3: Comparison of intraoperative pain scores on the VAS scale at access opening and at working length determination among the three study groups.

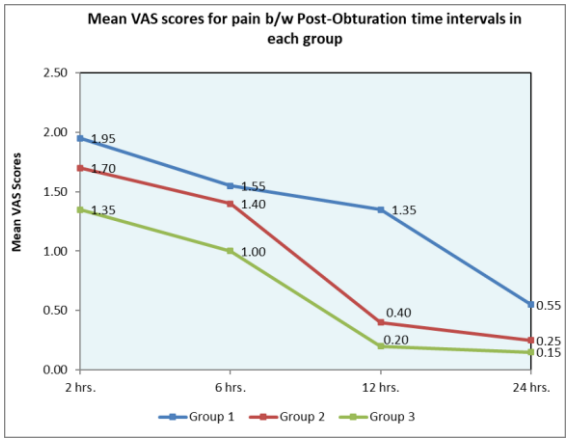

Figure 4: Comparison of analgesic intake among the three study groups, showing the percentage of patients who reported taking analgesics and those who did not.

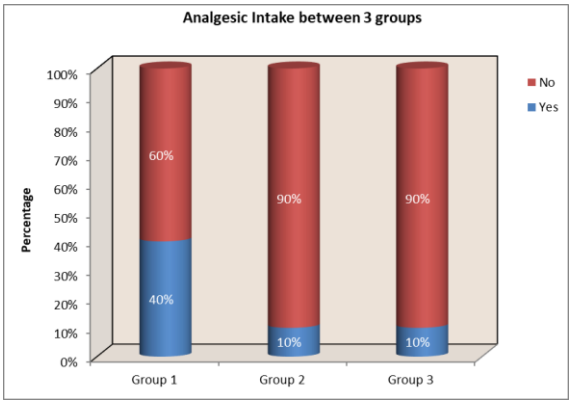

Figure 5: The mean levels of post-treatment pain intensity on the VAS scale at different time intervals (2, 6, 12, 24, and 48 hours) for all study groups.

Procedure

In total, 60 outpatients attending the Department of Conservative Dentistry and Endodontics from Vokkaligara Sangha Dental College, Bangalore, who had volunteered to participate were included in the study. Participating patients who are eligible under inclusion and exclusion criteria were selected. All patients were informed about the background of the study and all details about the trial. All participating patients signed the consent form in the presence of a witness. Before administration of the anesthetic, a test dose of 1:10 dilution of Lidocaine 2% with 1:80,000 epinephrine (Lignox A, Warren Indoco) or 0.5% ropivacaine was administered intradermally on the forearm to determine if the patient is allergic to the local anesthetic. After determining that the patient was not allergic to the anesthetic, the root canal procedure was carried out. The pain level associated with teeth was assessed using the Visual Analogue scale before the treatment procedure was initiated. A single operator was responsible for performing all of the procedures of anesthesia. After administration of local anesthesia, the tooth was isolated using a rubber dam, Hygenic rubber dam kit (Coltene Whaledent).

Group 1, 1.8 ml of Lidocaine 2% with 1:80,000 epinephrine (Lignox A, Warren Indoco) anesthetic solution is injected with a disposable 27-gauge injectable syringe (Hindustan unolok 2.5 ml syringes, India) administration of Inferior alveolar nerve block. Group 2, In addition to the procedure administered in group 1, a disposable 27-gauge injectable syringe (Hindustan unolok 2.5 ml syringes, India) with bevel facing towards the root was used, directed towards the long axis of the tooth with depth of gingival sulcus as the target area and 0.2 ml of 2% Lignocaine anesthetic solution will be deposited in about 20 seconds. Group 3, In addition to the procedure administered in group 1, the procedure same as that of the group 2 with 0.2 ml of 0.5% Ropivacaine (Ropin®, Neon Laboratories, Mumbai, India) anesthetic solution in supplementary Intraligamentary technique.

Endodontic procedure

Endodontic access opening of the teeth was done using Airtotor (NSK panair handpiece FB2) and #2 Endo access burs (Dentsply Maillefer, Ballaigues, Switzerland) and first intraoperative pain score was noted. 2.5% sodium hypochlorite (NaOCl) (Avinash chemicals, Bangalore) was used to disinfect the coronal access. The canals were cautiously probed with a #10 K type file (Mani, Japan) and pain scores were assessed. The WL was established with a #15 k file (Mani, Japan) and the Morita root ZX mini™ apex locator (J Morita Corp, Tokyo, Japan), and confirmed radiographically. The cervical and middle thirds of the canal were flared with an orifice shaper 25/0.12 file. The root canal was flushed with 2.5% NaOCl. Cleaning and shaping of root canals were done using X Smart endomotor (Dentsply Maillefer, Ballaigues, Switzerland) using Hyflex Rotary files (Coltene /Whaledent, Allstätten, Switzerland) selected according to suitable taper and size for different cases. For smear layer removal, the final irrigation was performed with 5 ml of 5.25% sodium hypochlorite for 1 min followed by 5 ml of distilled water and then 2 ml of 17% EDTA for 1 min. The canal was thoroughly rinsed with normal saline (Infutec Healthcare

Limited, Indore) and dried using paper points (Dentsply Maillefer, Ballaigues, Switzerland). Master Cone selection was done based on the taper of the preparation and snug apical fit is ensured using Periapical radiographs. Obturation was to be carried out with Gutta-percha (Dentsply Maillefer, Ballaigues, Switzerland) using Bioceramic root canal sealer (Bio-C Sealer; Angelus, PR, Brazil) using lateral condensation technique. All variables besides the local anesthetic used were standardized consistently. The access cavity was sealed with a cotton pellet and restored with Cavit (Interim Restorative Material). Patient pain levels were assessed using the visual analog scale 2, 6, 12, 24, and 48 hours after the treatment procedure. Patients were advised to reach out to the clinician in the event of severe pain and were reassured about the option to take pain medication, specifically ibuprofen 500 mg if needed.

Follow up

In case the patient has to take medications for severe pain, the time was noted. The findings from the VAS scale were tabulated. Anesthetic success and the degree of intra and postoperative pain among the three groups were analyzed.

Ethical approval

The protocol of this study was approved by the Ethics Committee of Kempegowda Institute of Medical Sciences (KIMS/IEC/A145/D/2023) obtained on 30-10-2023 and Clinical Trials Registry-India ID No. CTRI/2023/11/060116 obtained on 30/11/2023. Strict adherence to Consolidated Standards of Reporting Trials (CONSORT) was maintained.

Statistical analysis

Statistical Package for Social Sciences [SPSS] for Windows Version 22.0 Released 2013. Armonk, NY: IBM Corp., was used to perform statistical analyses. Descriptive analysis includes the expression of VAS scores for pain using mean and standard deviation. Kruskal Wallis Test followed by Dunn's post hoc Test was used to compare the mean age, and VAS scores at pre-op, intra-op and post-op obturation time intervals between 3 groups. The Chi-Square Test was used to compare the gender distribution and analgesic intake between the 3 groups. Friedman's Test followed by Wilcoxon Signed Rank Post hoc Test was used to compare the mean VAS scores between post-obturation time intervals in each group. The level of significance was set at $p<0.05$.

RESULTS

A total of Sixty adult patients (36 women and 24 men) were enrolled and participated in the study. They were randomly allocated into three groups IANB (9 Males and 11 Females), IANB+ILA Lignocaine (7 Males and 13 Females), and IANB+ILA Ropivacaine (7 Males and 13 Females). All groups showed similar distributions of patients' age and gender as represented in Table 1. Figure 2 shows the mean values and standard deviation (SD) of preoperative pain, for patients with the different categories of the variables. Overall, the mean value of pain

before root canal treatment was 7.98 on a VAS scale between 0 and 10. Figure 3 depicts the comparison of intraoperative pain scores on the VAS scale at access opening and at working length determination to assess the efficacy of anesthetic solution and technique indicates no statistically significant difference between groups at instance 1 i.e. at access opening. A statistically significant difference is observed at working length determination on comparison of Group 1 vs. Group 2 as well as Group 1 vs Group 3. The mean levels of post-treatment pain intensity on the VAS are graphically represented in Figure 4. In all the groups, the most intense pain on the VAS was reported 12 hours post-treatment.

Table 1: Mean age and gender distribution Among Different Study Groups.

Variable	Category	Group 1		Group 2		Group 3		P value
		Mean	SD	Mean	SD	Mean	SD	
Age	Mean	41.00	12.20	40.90	7.81	41.95	11.73	0.81[a]
	Range	21 - 58		29 - 54		19 - 58		
		N	%	N	%	N	%	
Gender	Males	9	45%	7	35%	7	35%	0.75[b]
	Females	11	55%	13	65%	13	65%	

[a]: Kruskal Wallis Test, [b]: Chi Square Test

The two-by-two comparison of the mean rank of pain between groups at different times shows No significant difference was detected at 2, 6 and 24, 48 hours ($p>0.05$), but the 12 hours pain intensity was significantly higher in the IANB alone and with ILA Lignocaine group ($p=0.016$). In all groups, the post-treatment pain followed a decreasing pattern after 24 hours post-treatment. The results of the Chi-Square Test indicate that there is a statistically significant difference in analgesic intake between the three groups. In Group 1, a higher proportion (40%) reported taking analgesics compared to Groups 2 and 3 where only 10% reported analgesic intake. Conversely, in Groups 2

and 3, a higher proportion (90%) reported not taking analgesics compared to Group 1 where 60% did not as represented by Figure 5.

DISCUSSION

Mitigating post-operative pain holds the utmost significance for both patients and dentists. This study sought to assess the effectiveness of prolonged-acting anesthesia in managing pain after RCT. Limited data is available to evaluate the effect of supplementary intraligamentary ropivacine on intra as well as post-operative pain in single-visit root canal treatment in teeth with symptomatic irreversible pulpitis and to compare the observations of both groups. The Null hypothesis (H0) assumed that there was no difference in the incidence of postoperative pain in single-sitting RCT under lignocaine alone as IANB, liognocaine as a supplementary ILA, and ropivacaine as a supplementary ILA when used as a local anesthetic agent. The findings of the current trial rejected the null hypothesis. For the sake of standardization, Inclusion criteria encompassed single-rooted pre-molar teeth exhibiting pulpitis along with clinical indications of moderate to severe preoperative pain and sensitivity to pressure, all without the presence of apical radiolucency. These criteria were deliberately selected as they have been identified as substantial predictors of postoperative pain in previous studies.[13-16] Numerous studies have emphasized the strong correlation between the severity of preoperative pain and the pain experienced during endodontic treatment.[17] Consequently, a comprehensive approach was taken in selecting participants who reported moderate or severe preoperative pain levels. To control other factors that could influence the participant's intraoperative pain, including operator factors, a single endodontist was responsible for IANB injection and supplementary local anesthetic technique, and a single experienced operator accredited to perform endodontic treatment and adopting identical preoperative restrictive inclusion standards were applied. To control patient- and teeth-related factors such as the preoperative pulp condition, the thermal test and patients without preoperative analgesic intake within the previous 24-48 hours were exclusively included. The current study employed the Visual Analog Scale (VAS) to assess pain intensity, a choice justified by its robust psychometric properties. The VAS, known for its excellent inter-observer and test-retest reliability, repeatability, acceptability, responsiveness, and validity was deemed suitable for this investigation. Moreover, the VAS demonstrated sensitivity to even slight alterations in pain intensity, enhancing its utility in gauging nuanced changes.[18] Discomfort represents the primary short-term complication associated with RCT. Research indicates that the likelihood of experiencing post-treatment discomfort is comparable between single-session and multiple-visit endodontic procedures, despite a notable difference in analgesic usage. Notably, patients undergoing multiple visit endodontics tend to require fewer pain-relieving medications. The prolonged working time during a single visit may contribute to a more pronounced inflammatory response, leading to increased pain immediately after the procedure.[19] A systematic review of single-visit RCTs suggests that patients may need more analgesics compared to when the treatment is distributed across multiple visits. Following the completion of RCT, pain typically emerges soon after the conclusion of local anesthesia, particularly around 6 hours post-administration in cases involving lignocaine anesthesia.[20]

The pain was assessed until 48 hours postoperatively because the incidence and severity of post-endodontic pain have been shown to be highest in the first 24 hours and decrease substantially to minimal levels.[8] Ropivacaine, although less recognized in dentistry, is a well-established and utilized anesthetic in various medical fields. Structurally linked to Bupivacaine, it serves as a prolonged-acting regional anesthetic. Ropivacaine was designed to address Bupivacaine's contraindications. They exhibit an extended duration of action, low toxicity, and selectivity for nerve fibers responsible for pain transmission rather than motor function.[21] The PDL injection technique is fundamentally an intraosseous injection. A small amount of anesthetic solution is deposited adjacent to the tooth to be anesthetized, and considerable diffusion of the anesthetic solution occurs within the alveolar bone, which provides pulpal anesthesia of one or more neighbouring teeth and associated periodontium. A study reported that successful anesthesia with supplemental PDL injection was obtained 56% of the time in patients presenting with irreversible pulpitis in mandibular posterior teeth when conventional IANB failed.[22]

Statistical analysis showed that both study groups were homogenous in terms of age, gender, and tooth type distribution; as well as preoperative pain intensity. The present study showed similar distributions of patients' age and gender. The pre, intra, and post-operative pain distribution in the current study showed no significant difference based on age or gender. Similar results were observed in several studies while contrasting reports have been observed in other studies.[23-25] It's important to take into account the varying eligibility criteria across these studies and the distinct psychological and physiological responses to pain between genders. The findings of the present study indicate that there was no variation in postoperative endodontic pain intensity among different age groups. This aligns with previous research suggesting that age does not exert an influence on postoperative endodontic pain.[26]

Individuals who have a preoperative pain score on the VAS scale>6 were included in the study. Our investigation showed equal distribution of preoperative pain values scores with a mean score of 7.98 since previous studies have shown that preoperative pain is strongly associated with postoperative pain. hence, patients with preoperative pain more commonly experienced a higher mean level of postoperative pain than patients who were asymptomatic before treatment. this could be explained by the

preoperative presence of an infected root canal system and/or periapical region, which, initially irritated, may become secondarily irritated during treatment, this explains the inclusion of such individuals to best understand the influence of control and experimental group on postoperative pain reduction.[25]

According to a systematic review and meta-analysis on assessing the anesthetic efficacy of supplemental intraligamentary injection in human mandibular teeth with irreversible pulpitis stated that Supplemental IL injections have a success rate of 50-96% for painless endodontic treatment, which is also agreeable to the results obtained in the current study our study showed greater anesthetic efficacy in administration of Ropivacaine than lignocaine intraligamentarily, at access opening which is in agreement of its rapid onset of action compared to lignocaine as well as during working length determination, contrary findings were obtained to a study previously conducted.[27-30] Following the completion of RCT, pain typically emerges soon after the conclusion of local anesthesia, particularly around 6 hours post-administration in cases involving lignocaine anesthesia. In the current study, the use of the intraligamentary technique as a supplementary to IANB has resulted in a statistically significant reduction in post-operative pain at 12 hours attributing to. Data from a study indicate that ropivacaine infiltration produces a longer anesthetic time when compared with lidocaine and articaine but not when compared to bupivacaine in dental procedures, which is also depicted in much lesser post-operative pain values at all time intervals.[12]

Notably, a systematic review on single-visit root canal treatment suggested that patients may require more analgesics compared to treatment spread across multiple visits.[20] The present study's results revealed a reduced overall consumption of analgesic medication in the ropivacaine group, with these patients reporting significantly less pain-requiring medication ($p<0.05$). Ibuprofen was prescribed as the post-treatment pain relief medication in this study. While one could argue that prescribing analgesics might impact the study's outcomes, several considerations were taken into account during the study's design. First, ethical guidelines recommend providing rescue medication for patients experiencing post-root canal treatment pain. Second, excluding patients who received medication after treatment would deviate from typical clinical practice. Additionally, gastric diseases were an exclusion criterion to ensure uniform ibuprofen usage for all patients, facilitating comparability. Lastly, prior investigations have allowed or prescribed medication use in response to pain, aiming to assess the influence of procedures or medications on patient's pain. No statistically significant difference was observed among patients across different age groups, indicating the need for a study with a larger sample size. It is strongly recommended that interventional research studies be conducted more frequently with significantly larger sample sizes and the inclusion of other relevant variables. This approach aims to improve the quality of research and enhance the likelihood of achieving higher accuracy in future results. Along with the use of Ropivacaine on endodontics to aid in the collection of substantial data on the possibility of its replacement as the new endodontic anesthetic.

One limitation of this study was the absence of a psychological evaluation during the recruitment process, which could be addressed in future research. Despite attempts to recruit a homogeneous participant cohort, individual variations in pain perception and treatment methods may influence responses to local anesthesia. Emotional reactions to pain could be linked to pessimistic views on pain-related fears, potentially impacting study outcomes. Future studies that include a larger sample size and inclusion of multirooted teeth need to be undertaken.

CONCLUSION

In conclusion, a single dose of 0.2 ml of 0.5% Ropivacaine when administered in a supplementary intraligamentary anesthetic technique could be more effective in the reduction or prevention of intraoperative and post-operative endodontic pain compared with lignocaine exclusive of the technique employed.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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