Original Article

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# Clinical efficacy of 0.75% ropivacaine vs. 2% lignocaine hydrochloride with adrenaline (1:80,000) in patients undergoing removal of bilateral maxillary third molars: a randomized controlled trial

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**Background:** Lignocaine with adrenaline is routinely used as a local anesthetic for dental procedures. Adrenaline was added to increase the duration of anesthesia. However, epinephrine containing a local anesthetic solution is not recommended in conditions such as advanced cardiovascular diseases and hyperthyroidism. Recently, ropivacaine has gained popularity as a long-acting anesthetic with superior outcomes. The goal of this study was to assess and compare the effectiveness of 0.75% ropivacaine alone and 2% lignocaine with adrenaline (1:80,000) in the removal of bilateral maxillary wisdom teeth using the posterior superior alveolar nerve block technique.

**Methods:** This was a single-blind, randomized, split-mouth, prospective study assessing 15 systemically sound outpatients who needed bilateral removal of maxillary third molars. We randomly allocated the sides and sequences of ropivacaine and lignocaine with adrenaline administration. We evaluated the efficacy of both anesthetics with regard to the onset of anesthesia, intensity of pain, variation in heart rate, and blood pressure.

**Results:** The onset of anesthesia was faster with lignocaine (138 s) than with ropivacaine (168 s), with insignificant differences ($p = 0.001$). There was no need for additional local anesthetics in the ropivacaine group, while in the lignocaine with adrenaline group, 2 (13.3%) patients required additional anesthesia. Adequate intraoperative anesthesia was provided by ropivacaine and lignocaine solutions. No significant difference was observed in the perioperative variation in blood pressure and heart rate.

**Conclusion:** Ropivacaine (0.75%) is a safe and an adrenaline-free local anesthetic option for posterior superior alveolar nerve block, which provides adequate intraoperative anesthesia and a stable hemodynamic profile for the removal of the maxillary third molar.

**Keywords:** Analgesia; Anesthesia; Lignocaine; Ropivacaine.



## INTRODUCTION

The most frequently performed outpatient procedure in oral and maxillofacial surgery is tooth removal. Intraoperative pain management with local anesthesia is an essential aspect of this treatment. An ideal option for tooth extraction is a local anesthetic that acts for the optimal duration and provides good analgesia with insignificant toxicity [1].

In clinical dentistry, lignocaine is the recommended local anesthetic agent. Lignocaine solution has intrinsic

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vasodilative properties at commercially available concentrations. As a result, a vasoconstrictor is added (usually epinephrine) to ensure the optimal duration of anesthesia required to perform dental surgery. Lignocaine combined with epinephrine has a rapid onset and provides intermediate pulpal and soft tissue anesthesia [2]. However, in conditions such as hyperthyroidism and significant cardiovascular diseases (American Society of Anesthesiologists physical status grade 3–4), epinephrine containing a local anesthetic solution is not recommended [3]. Moreover, the addition of a vasoconstrictor decreases the pH of the solution, making the local anesthetic injections unpleasant for patients [3].

Ropivacaine has recently gained clinical attention. It has a more secure profile and is equipotent compared with bupivacaine [1]. Recently, ropivacaine has been regarded as superior to other long-acting local anesthetic agents [4]. When used at lower concentrations (such as 0.2%, 0.5%, 0.75%), ropivacaine can cause vasoconstriction, precluding the need for the addition of a vasoconstrictor [1,3]. In comparison to ropivacaine alone, the addition of adrenaline to the ropivacaine solution did not increase its efficacy [1]. Ropivacaine can be administered at various concentrations, including 0.5%, 0.75%, and 1% [4,5]. Compared to 0.5% ropivacaine, the 0.75% solution provides clinically sufficient pulpal anesthesia [2]. A recent study comparing 0.5% and 0.75% ropivacaine for inferior alveolar nerve block in lower third molar surgery showed that 0.75% ropivacaine was more efficacious and desirable [5]. A 2% lignocaine hydrochloride with adrenaline (1:80,000) is safe for hemodynamically healthy patients [6]. In addition, 2% lignocaine with 1:80000 adrenaline is a commonly used anesthetic solution in dentistry. Therefore, we aimed to study and compare 0.75% ropivacaine and 2% lignocaine hydrochloride with 1:80,000 adrenaline in patients undergoing removal of bilateral maxillary wisdom teeth.

## METHODS

### 1. Study design and participants:

This was a single-blind, randomized, split-mouth, prospective study with a crossover design that was approved by the Ethics Committee of our college (IRB No: TDC/IRB-EC/161/2017) and recorded on the Clinical Trials Registry of India (CTRI/2019/06/019653). The spirit checklist [7] was used to design, conduct, and report the study. The study participants were selected from among patients who visited the oral and maxillofacial surgery outpatient clinic of our college from June 2018 to June 2019. After thoroughly explaining the study, all participants read and signed the written informed consent.

### 2. Sample size determination:

Based on previous research findings [1] and using the G-Power software version 3.0.10 {power: 0.80, alpha error probability: 0.05, and pain score effect size of 1.0}, the sample size was computed. The size of each group was determined to be 14, which was rounded up to 15.

### 3. Sample selection:

After a detailed case history recording, followed by clinical and radiographic examinations of 85 patients, 15 patients met the inclusion criteria.

Inclusion criteria:

Patients who were ready to participate in the study. Healthy patients aged between 20–50 years, requiring the removal of bilateral maxillary third molars.

Exclusion criteria:

Patients who were allergic to amide-type local anesthetic agents, had any systemic disease (cardiovascular disease, hypertension, anxious patients, etc.), pregnant and lactating mothers, and those who were mentally challenged or unable to communicate were excluded.

### 4. Intervention

The extractions were planned on two different appointments with a minimum gap of seven days. An intradermal test dose of the respective local anesthetics was administered to all participants in the forearm on the day of the procedure. During the appointments,

Table 1. The sequence of the drug administration after the randomisation

| Patient No. | Drug administerd and Side on which drug administered during first session | Drug administerd and Side on which drug administered during second session |
|---|---|---|
| 1 | Ropivacaine (left Side) | Lignocaine with Adrenaline (right Side) |
| 2 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 3 | Lignocaine with Adrenaline (right Side) | Ropivacaine (left Side) |
| 4 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 5 | Ropivacaine (left Side) | Lignocaine with Adrenaline (right Side) |
| 6 | Ropivacaine (left Side) | Lignocaine with Adrenaline (right Side) |
| 7 | Lignocaine with Adrenaline (right Side) | Ropivacaine (left Side) |
| 8 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 9 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 10 | Ropivacaine (left Side) | Lignocaine with Adrenaline (right Side) |
| 11 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 12 | Lignocaine with Adrenaline (left Side) | Ropivacaine (right Side) |
| 13 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 14 | Ropivacaine (right Side) | Lignocaine with Adrenaline (left Side) |
| 15 | Lignocaine with Adrenaline (right Side) | Ropivacaine (left Side) |

participants were administered a posterior superior alveolar nerve block for the removal of the maxillary wisdom tooth with either 2 ml solution of 0.75% ropivacaine or 2 ml solution of 2% lignocaine hydrochloride with adrenaline (1:80000) on respective sides, as decided by randomization. A palatally greater palatine nerve block was administered. To administer the anesthetic solution, a sterile Luer lock disposable syringe with a 27-gauge needle was used, and tooth removal was performed. The same operator performed the extractions in all patients. The onset of anesthesia was recorded from the time of removal of the needle following administration of the local anesthetic until objective symptoms were noted. The onset of anesthesia was investigated by probing with a Moon probe per minute as long as the probing did not elicit pain stimulation. The need for additional local anesthesia was also recorded. The intensity of pain during extraction was assessed subjectively using the Verbal Rating Scale (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain) [8]. A multiparameter monitor was used to track the changes in heart rate and blood pressure 15 min before the anesthesia, 15 min after the anesthesia, and after the completion of the extraction. Following the extraction, the participants were prescribed antibiotics and analgesics. All data were recorded, including the onset of anesthesia, the intensity of pain during the extraction, the need for additional anesthesia, blood pressure on the right brachial artery, and heart rate in a semi-reclined position. The study was performed in accordance with the Declaration of Helsinki and its later amendments.

**Randomization and concealed random allocation:**

The first session's anesthetic solution was chosen by simple randomization using a random list with the order of 15. The list was created by the author (A: Lignocaine or B: Ropivacaine). The block randomization method was used with a block size of two to decide the tooth extraction side in the first appointment (AB or BA, A: right maxillary third molar, or B: left maxillary third molar). The orders of both lists were written individually on thick papers, and the papers were then stored in a secured paper pouch. Paper pouches were stored in two separate bins. From each bin, the patient selected a paper pouch. Table 1 shows the sequence of drug administration after randomization during each session.

## 5. Blinding

In our study, only patients were blinded to the type of local anesthetic administered during each appointment session.

Table 2. Demographic data

| n=15 (3 Male, 12 female) | Mean | Standard Deviation | Range |
|---|---|---|---|
| Age (Years) | 33.1333 | 8.3910 | 23-49 |
| Weight (kgs) | 64.4666 | 8.5177 | 53-82 |
| Height (cm) | 163.733 | 7.7687 | 149-180 |
| BMI | 24.0333 | 1.7674 | 20.7-26.6 |

BMI, body mass index.

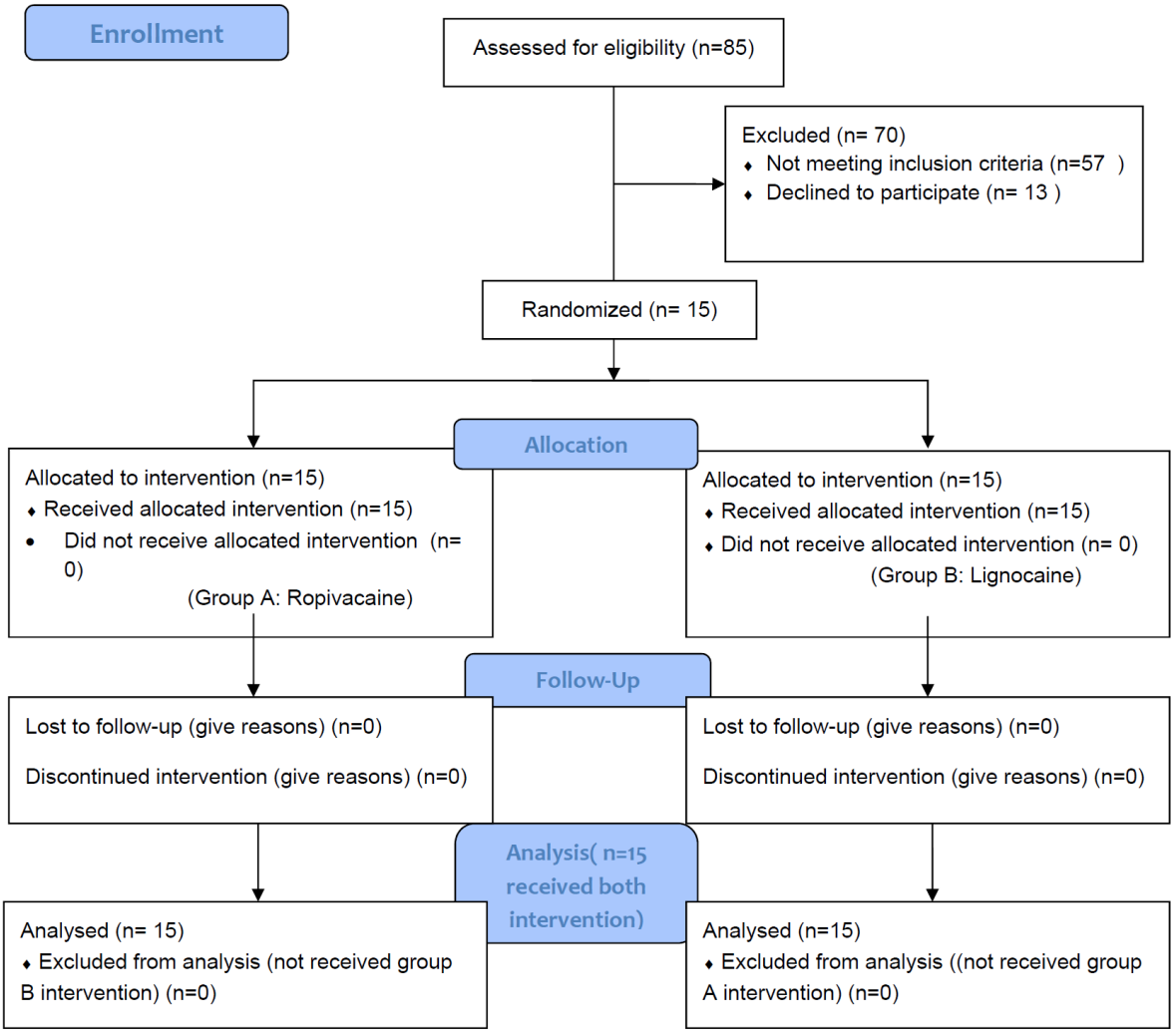


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram

## 6. Statistical analysis:

Windows-based 'MedCalc Statistical Software' version 19.0.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2019) was used for data analysis. Data normality was checked using the Shapiro-Wilk test. The data passed normality for most of the parameters. Hence, parametric tests were used in the analysis. The onset of anesthesia and vital parameters were compared for the difference between the two treatments (ropivacaine and lignocaine/adrenaline) using a paired t-test assuming equal variances. Fischer's exact test was used to compare the need for local anesthetics in the two groups. All tests were performed using two-sided tests at an alpha of 0.05. Thus, a "P" value of $< 0.05$ was used to reject the null hypothesis.

Table 3. Mean, median, SD of Ropivacaine group and Lignocaine with Adrenaline group

| | Ropivacaine (n=15) | | | | Lignocaine / Adrenaline (n=15) | | | |
|---|---|---|---|---|---|---|---|---|
| | Mean | Median | SD | Min - Max. | Mean | Median | SD | Min.- Max. |
| Onset (sec.) | 164.67 | 150 | 53.47 | 90 - 250 | 138.67 | 115 | 51.91 | 100 - 250 |
| SBP (pre) | 112.67 | 113 | 12.77 | 96 - 135 | 115.93 | 114 | 13.17 | 95 - 139 |
| DBP (pre) | 73.73 | 73 | 11.04 | 59 - 97 | 73.20 | 76 | 7.67 | 60 - 82 |
| SBP (post) | 117.13 | 120 | 12.18 | 100 - 140 | 120.87 | 119 | 14.16 | 105 - 146 |
| DBP (post) | 75.00 | 74 | 6.69 | 67 - 93 | 73.07 | 73 | 9.28 | 58 - 91 |
| SBP (end) | 116.20 | 116 | 13.66 | 96 - 143 | 119.20 | 117 | 14.26 | 100 - 148 |
| DBP (end) | 73.33 | 73 | 9.93 | 56 - 96 | 71.93 | 72 | 8.98 | 56 - 86 |
| HR (pre) | 78.93 | 78 | 4.98 | 72 - 89 | 79.73 | 80 | 6.77 | 70 - 98 |
| HR (post) | 83.40 | 82 | 5.74 | 76 - 95 | 87.53 | 84 | 8.88 | 77 - 106 |
| HR (end) | 79.40 | 79 | 6.58 | 70 - 88 | 83.67 | 83 | 6.56 | 70 - 96 |

Abbreviations: DBP, diastolic blood pressure; HR, heart rate; Max, maximum; Min, minimum; SBP, systolic blood pressure; SD, standard deviation. pre – 15 mins before administration of anesthesia, post – 15 mins after administration of anesthesia, end – after the completion of the procedure

## RESULTS

### 1. Demographic data

After examining 85 patients who visited the oral and maxillofacial surgery outpatient clinic of our college from June 2018 to June 2019, 15 participants (American Society of Anesthesiology [ASA] physical status 1) were enrolled in the study. Table 2 shows the demographic characteristics of the study population. All 15 participants completed the study, of which three were male and 12 were female. Flow diagram (Fig. 1) summarizes the progress of the subjects throughout the study.

### 2. Study parameters

Table 3 shows the mean onset of anesthesia in seconds, which was 164.67 seconds (SD ± 53.4) in the ropivacaine group and 138.67 seconds (SD ± 51.9) in the lignocaine with adrenaline group. In the ropivacaine group, mean systolic blood pressure (SBP) 15 min before the administration of local anesthetics was 112.67 mmHg (SD ± 12.7), 15 min after the administration of local anesthetics was 117.13 mmHg (SD ± 12.1), and at the end of the procedure was 116.20 mmHg (SD ± 13.6). In the lignocaine with adrenaline group, mean systolic blood pressure 15 min before the administration of local anesthetics was 115.93 mmHg (SD ± 13.1), 15 min after the administration of local anesthetics was 120.87 mmHg (SD ± 14.1), and at the end of the procedure was 119.20 mmHg (± 14.2). In the ropivacaine group, mean diastolic blood pressure (DBP) 15 min before the administration of local anesthetics was 73.73 mmHg (SD ± 11.0), 15 mins after the administration of local anesthetics was 75.00 mmHg (SD ± 6.69) and at the end of the procedure was 73.33 mmHg (SD ± 9.93). In the lignocaine with adrenaline group, mean diastolic blood pressure 15 mins before the administration of local anesthetics was 73.20 mmHg (SD ± 7.67), 15 min after the administration of local anesthetics was 73.07 mmHg (SD ± 9.28), and at the end of the procedure was 71.93 mmHg (SD ± 8.98). In the ropivacaine group, the mean heart rate 15 min before the administration of local anesthetics was 78.93 beats/mins [bpm] (SD ± 4.98), 15 min after the administration of local anesthetics was 83.40 bpm (SD ± 5.74), and at the end of the procedure was 79.40 bpm (SD ± 6.58). In the lignocaine with adrenaline group, the mean heart rate 15 min before the administration of local anesthetics was 79.73 bpm (SD ± 6.77), 15 min after the administration of local anesthetics was 87.53 bpm (SD ± 8.88), and at the end of the procedure was 83.67 bpm (SD ± 6.56).

Table 4 shows that ropivacaine and lignocaine with adrenaline showed no statistical difference in the onset of anesthesia. In addition, SBP, DBP, and heart rate at different periods were not significantly different between both groups.

Table 4. Comparison between the Ropivacaine group and Lignocaine with adrenaline group

| | Paired t-test | | | Difference | |
|---|---|---|---|---|---|
| | t | df | p | Mean | 95% C.I. |
| SBP (pre) | -0.690 | 28 | 0.496 | -3.27 | -12.97 to 6.44 |
| DBP (pre) | 0.154 | 28 | 0.879 | 0.53 | -6.58 to 7.64 |
| SBP (post) | -0.774 | 28 | 0.445 | -3.73 | -13.61 to 6.15 |
| DBP (post) | 0.655 | 28 | 0.518 | 1.93 | -4.12 to 7.98 |
| SBP (end) | -0.588 | 28 | 0.561 | -3.00 | -13.45 to 7.45 |
| DBP (end) | 0.405 | 28 | 0.688 | 1.40 | -5.68 to 8.48 |
| HR (pre) | -0.369 | 28 | 0.715 | -0.80 | -5.24 to 3.64 |
| HR (post) | -1.514 | 28 | 0.141 | -4.13 | -9.73 to 1.46 |
| HR (end) | -1.778 | 28 | 0.086 | -4.27 | -9.18 to 0.65 |
| | Wilcoxon test | | | | |
| | +ve differences | -ve differences | P | | |
| Onset (sec.) | 5 | 10 | 0.1205 | 26.00 | -13.41 to 65.41 |

Abbreviations: CI, confidence Interval; DBP, diastolic blood pressure; HR, heart rate; SBP, systolic blood pressure.
pre – 15 mins before administration of anesthesia, post – 15 mins after administration of anesthesia, end – after the completion of the procedure

Table 5. Comparison of the need for anaesthesia between Ropivacaine (n=15) and Lignocaine with adrenaline group (n=15)

| | Group | | |
|---|---|---|---|
| Need for LA | Ropivacaine | Lignocaine/Adrenaline | Total |
| Yes | 0 (0.0%) | 2 (13.3%) | 2 (6.7%) |
| No | 15 (100.0%) | 13 (86.7%) | 28 (93.3%) |
| | 15 | 15 | 30 |

Abbreviations: LA, local anesthetics.

Need for additional local anesthetics (Table 5): There was no need for additional local anesthetics in the ropivacaine group, while in the lignocaine with adrenaline group, 2 (13.3%) patients required additional anesthesia.

## DISCUSSION

For clinical use, mepivacaine and bupivacaine are currently being developed as racemic mixtures of equivalent proportions of the "S" & "R" configuration, whereas ropivacaine is being developed as the refined S-enantiomer (enantiomeric purity - 99.5%). Chemically, ropivacaine is the monohydrate of the hydrochloride salt 1-propyl-2',6'-pipecoloxylidide [9]. Ropivacaine has less lipophilic properties and hence has a lower likelihood of penetrating large myelinated motor fibers compared to bupivacaine. As a result, it preferentially acts on the pain-mediating Aδ and C nerves instead of the motor-functioning Aβ fibers [10].

After its commercial release, ropivacaine has been extensively used for perioperative pain relief in the medical field, with consistently better outcomes than other local anesthetic agents [4]. Its use in the dental discipline has expanded to studies on periodontic procedures to evaluate its anesthetic efficacy [11], topical anesthesia of the oral mucosa [12], simple extraction procedures [3,13,14], lower third molar surgeries [1,4,5,15-19], surgical removal of the upper third molars [20], surgical removal of chronic periapical lesions [21], oral aphthosis [22], mandibular osteotomy [23], and postoperative pain control after elective cleft palate repair in children [24].

### 1. Onset of anesthesia

In a study by Keramidas et al. [25], comparing digital block findings after administration of 0.75% ropivacaine versus 2% lignocaine, lignocaine was faster to induce

anesthesia. The mean onset time for ropivacaine & lignocaine was 4.5 min & 1.3 min, respectively. In bilateral symmetrically impacted mandibular wisdom teeth removal, Budharapu et al. [1] compared 0.5% ropivacaine and 2% lignocaine hydrochloride. The onset of anesthesia for lignocaine and ropivacaine varied from 1 to 2 min and 2 to 3 min, respectively, indicating that 2% lignocaine hydrochloride had the quickest onset of anesthesia. In a similar study by Reddy KV et al. [4] and Bansal V et al. [14], lignocaine was faster to act compared to ropivacaine. In our study, the mean onset of anesthesia was statistically insignificant for the ropivacaine group compared with the lignocaine with adrenaline group.

### 2. The intensity of pain

Pain intensity was assessed subjectively using the Verbal Rating Scale [8]. In our study, none of the participants from either group experienced any pain throughout the procedure, but they withstood the procedure well with comfort, indicating adequate pain control. These findings are similar to those of other studies, such as Budharapu et al. [1], Bansal et al. [14], Brković et al. [20], and Reddy et al. [4].

### 3. Need for additional anesthesia

There was no need for additional local anesthetics in the ropivacaine group, while in the lignocaine with adrenaline group, 13.3% of patients required additional anesthesia. The need for supplemental injections can be due to several factors such as the presence or absence of infection, the status of the tooth being removed, anesthetic technique, patient's anxiety, and pain perception during the procedure.

### 4. Blood Pressure and Heart Rate

In studies by Reddy et al. [4] and Mishra et al. [11], the perioperative changes in heart rate and blood pressure were insignificant. Bansal et al. [14] noted no statistically significant difference in the mean systolic and diastolic pressure values pre- and postoperatively 45 min after administration of 0.75% ropivacaine and 2% lignocaine with adrenaline, while the mean systolic blood pressure was increased in the ropivacaine and lignocaine groups. Keramidas et al. [25] observed no major difference between 0.75% ropivacaine and 2% lidocaine in the systolic blood pressure index for the digital-brachial artery. The short-term rise in heart rate and blood pressure was apparent in either group at different periods, but there were no significant differences in our study. The addition of a vasoconstrictor to the anesthetic solution slows down the absorption of the local anesthetic solution into the circulation, thus decreasing its systemic toxicity level. However, it transiently increases blood pressure and heart rate [26]. It has been observed that endogenous catecholamines are released in response to stress and pain immediately following administration of the local anesthetic injection, which leads to a short-term increase in heart rate and blood pressure; however, this is not due to the effect of the local anesthetic agent [4]. In our study, both solutions had slight effects on the cardiovascular system perioperatively.

Long-acting local anesthetics have the obvious advantage of delivering long-lasting analgesia, reducing the necessity for analgesic drugs post-surgery [4]. Although the duration of anesthesia was not evaluated in our study, the early postoperative duration of ropivacaine has been studied in the literature [10]. None of the procedures following the onset of anesthesia lasted for more than 30 min in our study.

Based on the findings of this study, we conclude that 0.75% ropivacaine acts as effectively as 2% lignocaine with 1:80000 adrenaline. It matches with the 'Gold standard" in terms of the onset of anesthesia, intensity of pain during extraction, need for additional anesthesia, heart rate, and blood pressure changes at different time periods. It may not be prudent to advocate for the superiority of one local anesthetic over the other. However, the use of any of the two anesthetics is satisfactory for its use in the removal of maxillary wisdom teeth. No adverse events were reported in any of the patients with either anesthetic solution. Hence,

0.75% ropivacaine is a safe, adrenaline-free, and hemodynamically stable local anesthetic option for dental practitioners. One of the drawbacks of our study was the small sample size, as our study included only 15 participants. This figure may not accurately reflect the general population. However, the justification for the small sample size was that it was important to conduct a randomized split-mouth case-control study. In addition, the duration of anesthesia was not assessed. Moreover, the authors included maxillary third molar extractions of similar difficulty to avoid bias, although this was not specified as an inclusion criterion. In the future, triple-blinded trials with a larger sample size and an assessment of the duration of anesthesia are recommended.


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**Sanjay S. Joshi:** Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Supervision, Writing – review & editing
**Charudatta Shridhar Naik:** Conceptualization, Data curation, Formal analysis, Methodology, Supervision, Validation, Writing – review & editing
**Bhupendra Vilas Mhatre:** Conceptualization, Data curation, Formal analysis, Methodology, Supervision, Writing – review & editing
**Arsalan Ansari:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation

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