

# TITLE: To evaluate the Anesthetic efficacy of 0.75%, 0.50% and 0.20% ropivacaine without vasoconstrictor in the minor and major Oral and Maxillofacial Surgical procedures.

Original  
Article

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## ABSTRACT

**Objective:** This study aims to evaluate the onset, duration, and quality of anesthesia, along with the duration of analgesia, in seventy-five randomly selected patients undergoing oral and maxillofacial surgery.

**Methods:** Patients were divided into three groups receiving local anesthesia with intraoral Ropivacaine. Onset of anesthesia was assessed verbally, and depth was measured using an electric pulp tester. Anesthesia quality was rated on a 7-point scale, and duration was determined by pain perception lapse.

**Results:** Onset durations for subjective symptoms were 0.75% (1.240.52± minutes), 0.50% (1.801± minute), and 0.20% (2.680.90± minutes). Objective symptom onsets were 0.75% (2.660.65± minutes), 0.50% (3.91.32± minutes), and 0.20% (6.841.26± minutes), with faster onset at 0.75%. Mean anesthesia duration was longest for 0.75% (8.021.11± hrs), and analgesia duration was also longest for 0.75% (4.493.29± hrs). Nine patients in 0.75% and eight in 0.50% reported no post-procedure pain, while all in 0.20% experienced pain. Anesthesia duration significantly differed ( $p=0.001$ ), but analgesia duration did not ( $p=0.09$ ).

**Conclusion:** This study demonstrates that anesthesia onset is faster and duration is longer with higher concentrations of Ropivacaine. While anesthesia duration significantly varied among concentrations, analgesia duration did not show significant differences.

**Key Words:** Onset of Anesthesia, Quality of Anesthesia, Ropivacaine , Different concentrations , Pain perception.

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## INTRODUCTION:

Within the domain of Oral and Maxillofacial Surgery, the judicious selection of an appropriate anesthetic agent stands as a pivotal determinant in both the success of surgical procedures and the overall comfort of patients. Ropivacaine, a commonly employed local anesthetic, offers a range of concentrations for clinical utilization. This acts by inhibiting nerve impulses reversibly, creating prolonged sensory or motor blockade for diverse surgeries. It undergoes extensive liver metabolism and urinary excretion. However, the optimal choice for addressing minor and major procedures in this specialized field remains the focal point of ongoing investigation. This study endeavours to perform a thorough assessment of the anesthetic effectiveness of three distinct concentrations of ropivacaine: 0.75%, 0.50%, and 0.20%, all administered without the inclusion of a vasoconstrictor. Across a diverse spectrum of oral and maxillofacial surgical procedures, our research seeks to illuminate the comparative performance of these anesthetic solutions,

aiming to offer valuable insights that can inform clinical decision-making and ultimately elevate the precision of patient care in this demanding surgical discipline.

## MATERIALS AND METHODS

The study was undertaken after obtaining ethical approval from the Pacific Dental College and Hospital's ethical committee. Written informed consent was obtained from all participants, assuring confidentiality and providing a comprehensive explanation of the associated risks and benefits. The research focused on patients classified under the American Society of Anesthesiologists class I (ASA I) who were in need of various minor and major oral and maxillofacial surgical procedures. A thorough case proforma was completed, gathering socio-demographic information about the patients.

**Sample Size: 75**

**Sample Selection:**

The study was conducted on seventy five randomly selected patients who reported to the department of

oral and maxillofacial surgery for various minor and major oral and maxillofacial surgical procedures.

**Inclusion Criteria :**

- Patients with ASA-1 systemic condition.
- Patients indicated for any surgical procedure which needs Local Anesthesia
- All patients with in ASA-1 classification
- No radiologic evidence of infection or inflammation around proposed surgical site.
- Patients with no analgesic before surgery

**Exclusion criteria:**

- Patients having systemic diseases ASA -2,ASA-3and ASA-4
- Allergic to amide group of local anesthetic agents
- Pregnant women

Armamentarium (Figure 1)

1. Syringes 27 gauge
2. Savlon and 5% betadine solution for the preoperative preparation.
3. Kidney tray
4. 0.2%, 0.5% and 0.75% ampules of ropivacaine
5. pulp tester
6. surgical instruments

**Study Design:** Randomized Double Blind Study

**Study Groups:**

Group I – Solution A (0.2% Ropivacaine)

Group II- Solution B (0.5% Ropivacaine)

Group III- Solution C (0.75% Ropivacaine)

**Procedure:**

Thorough medical histories were diligently documented for every patient, with each individual providing informed consent by signing a consent form. An anesthetist evaluated the patients' suitability for the surgical procedure.

In accordance with the criteria for patient selection, the patients were randomly divided into three groups, each composed of 25 participants. Notably, the researcher, statistician, and surgeon were all kept unaware of the solution's concentration throughout the study. Patients were then randomly allocated to Group I, Group II, and Group III. They received local anesthesia via Solution A, Solution B, and Solution C, respectively, administered through a standard inferior alveolar-lingual nerve block, complemented by buccal infiltration. Prior to the intraoral administration of ropivacaine, a skin test for local anesthesia sensitivity was performed for all cases. A single researcher, who was uninformed about both the group allocation and the specific solution used for local anesthesia, meticulously observed and recorded the onset, depth, quality, and duration of the anesthesia.

**Measuring Indexes :**

**Measuring the Onset of Anesthesia:**

To determine the onset of mandibular and maxillary anesthesia, patients were queried about the presence of any changes in sensation in their lower lip and upper lip.

**Measuring Depth of Anesthesia:**

An electric pulp tester was employed to evaluate pulpal anesthesia. Prior to the administration of the local anesthetic, the readings for the selected tooth were documented. Subsequently, readings were taken every 30 seconds after the local anesthesia was administered until the tooth ceased to respond.

**Measuring Quality of Anesthesia:**

The assessment of anesthesia quality during the extraction process was conducted using a 7-point scale (see Table 1). In cases where sufficient surgical anesthesia was not achieved, an additional dose of the test anesthetic solution was administered. A third dose of the test cartridge was given if anesthesia remained incomplete. Patients who did not achieve adequate anesthesia even after the third cartridge were rescheduled for the surgical procedure at a later time, utilizing a standard local anesthetic.

**Table 1.**

| Rating | Patient Response During Extraction   |
|--------|--|
| 1.     | No pain throughout procedure   |
| 2.     | Some discomfort during procedure, but reinjection not necessary                            |
| 3.     | Pain during procedure after first injection, but no pain after second injection            |
| 4.     | Some discomfort after second injection, but reinjection not necessary                      |
| 5.     | Pain during procedure after first and second injections, but no pain after third injection |
| 6.     | Some discomfort after third injection, but procedure completed                             |
| 7.     | Inadequate anesthesia after third injection, and procedure postponed                       |

**Measuring Duration of Anesthesia:**

The anesthesia duration was established based on the moment when sensation fully returned to the lower lip. The analgesia duration was defined by the onset of pain at the surgical site.

**Statistical Analysis :**

The data underwent statistical analysis using the Statistical Package for the Social Sciences (SPSS V.20). The study employed the ANNOVA test to identify the impact of each concentration, followed by post hoc testing to make group comparisons. Significance levels were defined as p-values less than 0.05 and highly significant differences as p-values less than 0.001.

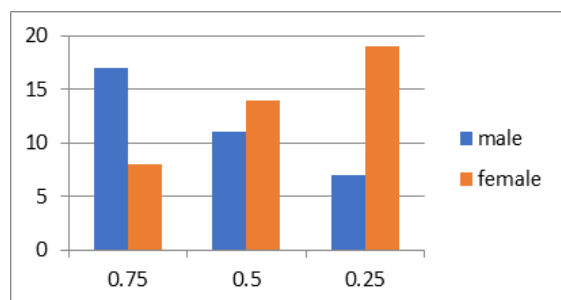
**RESULTS**

The study was conducted to evaluate the anesthetic efficacy of 0.75%, 0.5% and 0.20% ropivacaine without vasoconstrictor on the basis of onset, quality and duration of anesthesia in minor and major oral surgical procedures. For this purpose 75 patients were selected from the Out-patient Department of Oral and Maxillofacial surgery.

Seventy five men and women ranging in age from 18 to 40 years (average 28 years) participated in this study (Table- 2 and graph-1). All the patients were operated under local anesthesia 0.75%(Male-17,Female-8) 0.50%(Male-11,Female-14) and 0.20%(Male-7,Female-9) ropivacaine without epinephrine. All the patients were injected with standard volume of anesthetic solution in each nerve block. All the patients were followed-up by telephonic contact the same day.

**Table 2**

| concentration | Mean Age | Male / Female | std. Deviation |
|---------------|----------|---------------|----------------|
| 0.75%         | 27,96    | 17/8          | 6.25           |
| 0.50%         | 27,40    | 11/14         | 6.04           |
| 0.20%         | 28,80    | 7/19          | 6.86           |

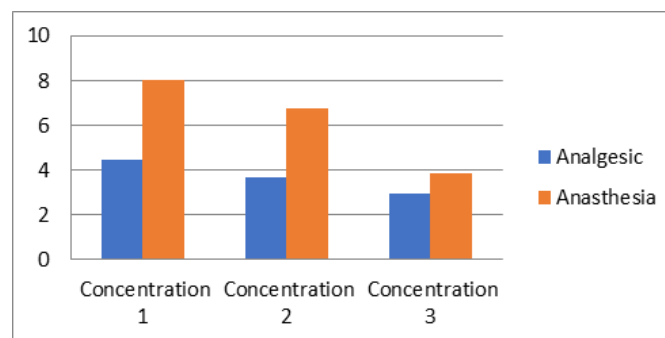


**Graph 1**

The Total mean duration of anesthesia was (in hours) 0.75%(8.02±1.11hrs) ,0.50%(6.76±0.94hrs) ,0.20%(3.88±0.56hrs) and analgesia mean duration 0.75%(4.49±3.29hrs) ,0.50%(3.66±2.65hrs) ,20%(2.96±0.47hrs). There was no pain in 9 patients of 0.75 % concentration and 8 patient of 0.50% concentration after procedure where as in 0.20% pain was observed in 25 patients. Mean duration of different concentration was significant with anesthesia (p=0.001) but non-significant with Analgesia (p=0.09) 7.33 ± 1.62hrs (Table- 3 and graph-2).

**Table 3**

| concentration | n  | Anesthesia   |                |         | Analgesia    |                |         |
|---------------|----|--------------|----------------|---------|--------------|----------------|---------|
|               |    | Mean (hours) | Std. Deviation | p-value | Mean (hours) | Std. Deviation | p-value |
| 0.75%         | 25 | 8.02         | 1.11           |         | 4.49         | 3.29           |         |
| 0.50%         | 25 | 6.76         | 0.94           | 0.001   | 3.66         | 2.65           | 0.09    |
| 0.20%         | 25 | 3.88         | 0.56           |         | 2.96         | 0.47           |         |
| Total         | 75 | 6.22         | 1.95           |         | 3.70         | 2.50           |         |

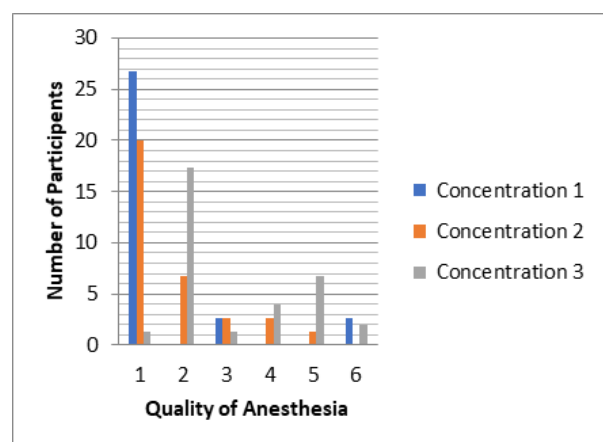


**Graph 2**

All the patients experienced clinically adequate anesthesia (Table- 4 and graph -3). Out of 75 patients, 0.75%(5), 0.50%(5), 0.20%(11) required reinjection of drug and 21 patients experienced mild discomfort during procedure.

**Table 4**

| concentration | Ratings    |           |          |          |          |          |   | Total       | p-value |
|---------------|------------|-----------|----------|----------|----------|----------|---|-------------|---------|
|               | 1          | 2         | 3        | 4        | 5        | 6        | 7 |             |         |
| 0.75%         | 20 (26.7%) | 0 (0%)    | 2 (2.7%) | 0 (0%)   | 1 (1.3%) | 2 (2.7%) | 0 | 25 (33.33%) | 0.001   |
| 0.50%         | 15 (20%)   | 5 (6.7%)  | 2 (2.7%) | 2 (2.7%) | 1 (1.3%) | 0 (0%)   | 0 | 25 (33.33%) | 0.001   |
| 0.20%         | 1 (1.3%)   | 13 (17.3) | 1 (1.3)  | 3 (4%)   | 5 (6.7%) | 2 (2.7%) | 0 | 25 (33.33%) | 0.001   |
| Total         | 36 (48%)   | 18 (24%)  | 5 (6.7%) | 5 (6.7%) | 7 (9.3)  | 4 (5.3%) | 0 | 75 (100%)   |         |

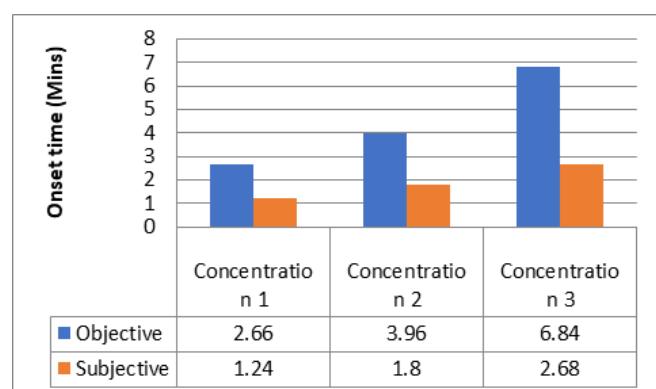


**Graph 3**

Total mean duration of onset, that is subjective symptoms is 0.75%(1.24±0.52min) ,0.50%(1.80±1min) ,0.20%(2.68±.90min) and objective symptom is 0.75%(2.66±0.65min), 0.50%(3.9±1.32min), 0.20%(6.84±1.26min) (Table- 5and graph- 4). Onset of these symptoms was rapid in 0.75% concentration compared with other two concentrations. Although the difference observed was statistically significant between different concentration in the objective category.

**Table 5**

| concentration | n  | subjective |                |         | objective  |                |         |
|---------------|----|------------|----------------|---------|------------|----------------|---------|
|               |    | Mean (Min) | Std. Deviation | p-value | Mean (Min) | Std. Deviation | p-value |
| 0.75%         | 25 | 1.24       | 0.52           |         | 2.66       | 0.65           |         |
| 0.50%         | 25 | 1.80       | 1.0            | 0.001   | 3.96       | 1.32           | 0.002   |
| 0.20%         | 25 | 2.68       | 0.90           |         | 6.84       | 1.62           |         |
| Total         | 75 | 1.91       | 1.01           |         | 4.48       | 2.07           |         |



**Graph 4**

**DISCUSSION:**

Local anesthetics exert their effects by transiently blocking voltage-gated sodium channels, making them a universally recognized method of pain control [1]. Ropivacaine, classified as a long-acting amide local anesthetic, was initially developed as a pure enantiomer. Its mechanism of action involves reversible inhibition of sodium ion influx in nerve fibers, akin to other local anesthetics. [2] The ideal local anesthetic should boast a rapid onset, minimal side effects, a substantial therapeutic index, and a predictable duration of action. Long-acting local anesthetics, such as ropivacaine, are particularly valuable for protracted dental procedures and surgeries, offering effective suppression of intraoperative and postoperative pain. However, their use is not without potential issues, including delayed onset of postoperative pain. [3]

Ropivacaine, with a chemical structure similar to other amino amides, is a potent blocker of Aδ and C fibers, which are associated with pain sensation [4]. Its introduction in 1996 marked a milestone in clinical use, attributed to its longer duration of action and reduced cardiac and neurologic toxicity compared to other options. [5] The efficacy of ropivacaine is concentration-dependent [6], with increasing concentrations leading to a faster onset of peripheral nerve block [7]. Notably, a 1% ropivacaine solution demonstrated over 4 hours of lip numbness, with complete sensation returning after more than 6 hours [8].

In a study involving three concentrations (0.75%, 0.50%, and 0.20%), the 0.75% concentration exhibited superior duration of analgesia and anesthesia compared to the other concentrations. The onset of anesthesia was similar between 0.75% and 0.50%, while 0.20% exhibited delayed onset. Quality of anesthesia was most effective with 0.75%, whereas 0.20% showed poor quality. El-Sharawy (2006) [9] found that the duration of anesthesia and analgesia for 0.75% concentration was 3.3 ± 0.3 and 6 ± 0.4 hours, respectively, outperforming 0.50% and 0.20% concentrations. Ernberg (2002) [10] reported 5.7 ± 2.9 hours of postoperative analgesia, similar to this study, but with lower anesthetic success and delayed onset.

Kennedy (2000) [11] reported 362.25 ± 80.60 minutes of anesthesia, resembling the current study but with lower aesthetic success and delayed onset. Jack W. van Kleef (1994) [12] found 100% anesthetic success and early onset of anesthesia with ropivacaine, aligning with the present findings. Meechan (2002) [13] observed onset times of 4.7 minutes and 3.6 minutes for 1% and 0.75% concentrations, respectively. In our study, onset times were 2.66 ± 0.65 minutes for 0.75%, 3.9 ± 1.32 minutes for 0.50%, and 6.84 ± 1.2 minutes for 0.20%, indicating a shorter onset time compared to Meechan's study.

All patients experienced a satisfactory duration of analgesia, leading to reduced demand for post-operative analgesics. Notably, 36% of those in the 0.75% concentration group and 32% in the 0.50% concentration group did not require any post-operative analgesics by the conclusion of the first post-operative day. The drug exhibited an early onset of action at both 0.75% and 0.50% concentrations, ensuring adequate anaesthesia for the performance of operative procedures. No adverse reactions or hypersensitivity were documented in any of the 75 patients who received ropivacaine. Based on the outcomes of the current study, we advocate for the utilization of 0.75% and 0.50% concentration ropivacaine as long-acting local anaesthetics in oral surgical procedures. This formulation may serve as a suitable local anaesthetic without vasoconstrictor for nerve block anaesthesia in dental practice.

#### **CONFLICT OF INTEREST**

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This clinical study was self-funded by the authors, with no conflict of interest.

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