

Comparative Evaluation of anaesthetic efficacy of ropivacaine and articaine with epinephrine for buccal infiltration anaesthesia in Maxilla Central Incisor and their effect on Cardiovascular parameters – a randomized control trial

ABSTRACT

Aim- To compare the effectiveness, latency time and onset of pulpal anaesthesia with 0.5% plain ropivacaine and 4% articaine with epinephrine 1:100 000 and to determine their probable effect on cardiovascular parameters.

Place and Duration of Study: Department of Conservative Dentistry and Endodontics, NPDCH, Visnagar, Gujarat between January 1st 2022 and January 31st 2022.

Methodology: 20 patients (10 male, 10 females) age range of 18-36 years were inserted 1.8 mL of the anaesthetic solution for buccal infiltration anaesthesia of maxillary central incisors deprived of caries, restorations or signs of pulpitis. The latency time, onset of pulpal anaesthesia and duration of pulp anaesthesia were assessed with an electric pulp tester. Heart rate and blood pressure were measured before, Immediate and after the onset of pulpal anaesthesia of the solutions. Data was sent for statistical analysis.

Results: The efficacy of anaesthesia of central incisors was 100% for both anaesthetics. The comparison of latency time and onset of pulpal anaesthesia were statistically significant for ropivacaine and articaine. Mean duration was less in Articaine group (206.50 ± 9.34) than Ropivacaine group (318.30 ± 43.21). Ropivacaine caused significant increases in blood pressure and heart rate.

Conclusion: Ropivacaine (0.5%) achieved effective and long duration of pulp anaesthesia. Ropivacaine could be beneficial for long lasting operative procedures without the need for a vasoconstrictor.

Keywords: dentistry, long lasting anesthetics, ropivacaine, articaine.

1. INTRODUCTION

“Dentists continue to search for long-acting anaesthetic solutions for actual pain regulator during treatment of irreversible pulpitis”¹. “Ropivacaine hydrochloride is a comparatively new local amide anaesthetic. It was used in 1992 for the first time in the Royal Hospital for Women in Sydney and adapted for clinical use in 1996”². “It is similar in structure to bupivacaine. It is a pure optical enantiomer of N-n-propyl-2',6'-pipecoloxylidine. Bupivacaine, gives an extensive safety margin with the same anaesthetic efficacy”³. “Its positive qualities such as low toxicity, long duration of action and exclusiveness for nerve fibres responsible for pain transmission than motor function. Ropivacaine has so far been successfully used in surgery, gynaecology and obstetrics, but is not at present available for dentists”⁴. “Ropivacaine has a biphasic vascular consequence, which could be beneficial in dentistry. In low concentration (0.062– 0.51%). Its demonstrations vasoconstriction per se and vasodilatation at high concentration (1.1%)”⁵.

“The maximum dose of 0.5% ropivacaine for negligible nerve blocks and infiltration is 200 mg. Despite many positive observations and widespread use in surgical anaesthesia and obstetrics. There is only a deficient article about the usage of ropivacaine in dentistry”⁶.

“The first study on the anaesthetic outcome of ropivacaine. They obtained only 69% efficacy of maxillary lateral incisor infiltration anaesthesia for a concentration of 0.5% ropivacaine without a vasoconstrictive drug and 79% efficacy for the same concentration with addition of epinephrine tested using an electrical pulp tester. The authors equated these results to bupivacaine with epinephrine and they had not found any important differences between the solutions”⁷.

“The low efficacy of ropivacaine probably stimulated to conduct a dose–effect study of ropivacaine in dental anaesthesia. The effect of 0.4%, 0.79% and 0.1% basic ropivacaine in a group of 32 patients (22 women, 10 men) was examined and also using an electrical pulp tester. They ascertained that these concentrations administered in a volume of 0.8 or 2 mL were not adequate for pulp anaesthesia. The effectiveness of infiltration anaesthesia was low for all

concentrations of ropivacaine. The effectiveness of inferior alveolar nerve block for the same solutions was twice as high possibly because a 1.8 mL volume was used⁸.

“Higher effectiveness of pulp anaesthesia was observed for 0.2% than 0.5% concentration in inferior alveolar nerve block and for 0.6 mL than 2 mL of 0.75% ropivacaine in infiltration anaesthesia⁹”.

The aim of this study was to evaluate the anaesthetic efficacy, onset of action, latency time and duration of pulp anaesthesia of a long-lasting anaesthetic solution (4% articaine with epinephrine 1: 1,00, 000) to 0.2% ropivacaine, for infiltration anaesthesia of maxillary central incisor. Also, to determine effect of these anaesthetic solutions on cardiovascular parameters.

2. Material and Method

Volunteers eligible for the study were well-versed of the potential risks and benefits of the medication. Before the start of the study, volunteers signed consent forms. They were recruited in Department of Conservative Dentistry and Endodontics at Narsinhbhai Patel Dental College and Hospital, Visnagar, Gujarat, India.

2.1 Inclusion and Exclusion Criteria

The inclusion criteria were the existence of maxillary incisor and they had healthy pulps that retorted to pulp testing. Pregnant women and participants with systemic diseases, which contraindicated the use of an anaesthetic with vasoconstrictors and volunteers with caries, fillings and periodontal disease of the tested teeth were excluded.

2.2 Study Design

Blood pressure, pulse and oxygen saturation were measured by Sphygmomanometer (Diamond BPLD123, KLM Healthcare and Equipment, Jaipur) and Pulse oximeter (EZ-LIFE, AHMEDABAD, GUJARAT, INDIA.) (fig. 1). The experimental tooth (maxillary central) was tested through an electrical pulp tester (Yusendent) (fig. 2) to verify the baseline response (Woz´niak et al.¹⁰) before the administration of the local anaesthetic. Afterward isolation with cotton rolls and drying with gauze, the pulp tester was positioned in the middle of the buccal surface of the crown of the tooth (Lin J et al¹¹).



Figure 1 Image showing Pulse oximeter and Sphygmomanometer.



Figure 2 Electric Pulp Tester (Digitest II) and EDTA

Because ropivacaine is not accessible in dental cartridges, 10-mL vials were used. Under sterile conditions, 1.8 mL of 0.2% ropivacaine was drawn from the original (NOVAPLUS; SAGENT PHARMACEUTICALS Schaumburg, IL 60195, USA) vial into a sterile syringe using a 0.4 · 19 mm needle. Each vial was used only once. 4% Articaine (Dentsply, Canada) was administered from dental cartridges using a 0.4 · 21 mm needle. 1.8 mL of the anaesthetic solution was administered in the region of right or left central incisor root apex (a standard maxillary infiltration injection). After aspiration, the solution deposited over a 30-s period. Blood pressure, pulse and Oxygen saturation measured after immediate administration of the local anaesthetic. The examination was terminated for each tooth when the patient responded to two consecutive stimulations (60 mA) of the central incisor. At last blood pressure, pulse and oxygen saturation at the end of examination. For scrutiny recorded data was sent to Statesian.

2.3 Statistical analysis

Data are described as the standard deviation (SD) and mean. Measuring the mean scores of subjects during three time point, Repeated Measure ANOVA. An unpaired Student's t-test, was used for evaluations.

3. Results and Discussion

3.1 Results

The effectiveness of the anaesthesia for the central incisor was 100% (10/10) for both anaesthetic solutions (Repeated In Articaine group, 50% were male and 50% were female study subjects. Mean age of females were 25.80 ± 3.76 years and male were 23.60 ± 3.50 years.

Mean age of male study subjects was 23.29 ± 3.90 years and female subject was 29.33 ± 3.05 years.

The results of the pulp anaesthesia with articaine and ropivacaine are shown in Fig 3.

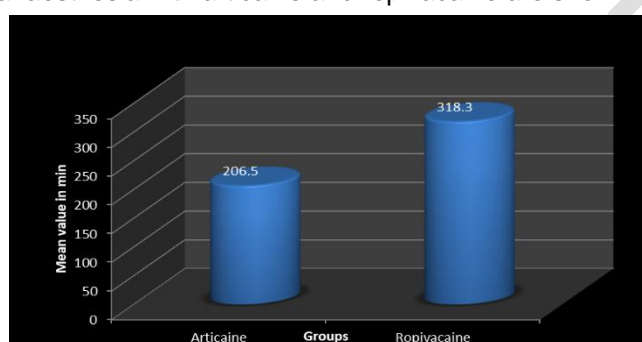


Figure 3 The extent of pulp anaesthesia: articaine with epinephrine (A) and ropivacaine (R). Data are shown as the means and standard deviations (SD). $P \leq 0.05$ *.

Mean duration was less in Articaine group (206.50 ± 9.34 min) than Ropivacaine group (318.30 ± 43.21 min). Statistically, significant difference was present in duration between Ropivacaine and Articaine group. The values of systolic and diastolic blood pressure, pulse rate and oxygen saturation before, immediate and postoperative the administration of the anaesthetics are shown in (Tables 1, 2, 3 and 4).

Table 1 Systolic BP wise distribution between Groups

Time period	Groups	Number (%)	Systolic BP		P Value
			Mean	SD	
Pre-operative	Articaine	10	130.60	5.25	> 0.05 **
	Ropivacaine	10	124.30	5.61	
Immediate	Articaine	10	130.80	5.07	> 0.05 **
	Ropivacaine	10	126.10	5.52	

Post-operative	Articaine	10	132.40	5.46	> 0.05 **
	Ropivacaine	10	128.90	5.74	

Level of Significance $P \leq 0.05$, * Significant, ** Non-Significant

Statistically, no significant difference was present in Systolic BP between Articaine and Ropivacaine group at pre-operative, immediate and post-operative time period.

Table 2 Diastolic BP wise distribution between Groups

Time period	Groups	Number (%)	Diastolic BP		P Value
			Mean	SD	
Pre-operative	Articaine	10	86.60	2.95	> 0.05 **
	Ropivacaine	10	89.30	2.71	
Immediate	Articaine	10	86.80	2.78	≤ 0.05 *
	Ropivacaine	10	80.70	1.94	
Post-operative	Articaine	10	88.50	3.10	≤ 0.05 *
	Ropivacaine	10	83.90	2.96	

Level of Significance $P \leq 0.05$, * Significant, ** Non- Significant

Table 3 Pulse rate wise distribution between Groups

Time period	Groups	Number (%)	Pulse rate		P Value
			Mean	SD	
Pre-operative	Articaine	10	76.10	2.60	> 0.05 **
	Ropivacaine	10	79.00	4.00	
Immediate	Articaine	10	77.90	2.72	≤ 0.05 *
	Ropivacaine	10	90.10	4.01	
Post-operative	Articaine	10	80.10	2.37	≤ 0.05 *
	Ropivacaine	10	91.50	4.03	

Level of Significance $P \leq 0.05$, * Significant, ** Non- Significant

Table 4 O2 wise distribution between Groups

Time period	Groups	Number (%)	O2		P Value
			Mean	SD	
Pre-operative	Articaine	10	98.50	0.70	> 0.05 **
	Ropivacaine	10	98.30	0.82	
Immediate	Articaine	10	98.70	0.67	> 0.05 **
	Ropivacaine	10	98.40	0.84	
Post-operative	Articaine	10	98.50	0.70	> 0.05 **
	Ropivacaine	10	98.40	0.84	

Level of Significance $P \leq 0.05$, * Significant, ** Non -Significant

Mean pulse rate was less in Articaine group (77.90 ± 2.72 BPM) than Ropivacaine group (90.10 ± 4.01 BPM) at immediate time period. Mean pulse rate was less in Articaine group (80.10 ± 2.37 BPM) than Ropivacaine group (91.50 ± 4.03 BPM) at post-operative time period. Statistically, significant difference was present in pulse rate between Articaine and Ropivacaine group in both immediate time period and post-operative time period.

Mean diastolic BP was more in Articaine group (86.80 ± 2.78 mm Hg) than Ropivacaine group (80.70 ± 1.94 mm Hg) at immediate time period. Mean diastolic BP was more in Articaine group (88.50 ± 3.10 mm Hg) than Ropivacaine group (83.90 ± 2.96 mm Hg) at post-operative time period. Statistically, significant difference was present in diastolic BP between Articaine and Ropivacaine group in both immediate time period and post-operative time period.

3.2 Discussion

“Extent of pulpal anaesthesia, Latency time and Cardiovascular parameters are the main parameters studied in other articles that use a same study design. It is hard to compare results as anaesthetics, dosages, methods differ and use of vasoconstrictors”¹³.

“Latency time was calculated as the interval between injection and the time when anaesthesia is achieved. It signifies a key factor when choosing the anesthetic solution. It can be determined using different calculations and will differ according to the areas under study or treatment. In the present study, the latency time was verbally evaluated by participants Immediately, 30 seconds before and

after 30 seconds. The onset of pulpal anaesthesia was evaluated verbally whether the effect of anaesthesia was triggered or not¹⁴.

The main difference between our study and earlier works¹³⁻¹⁶ is that we determined the efficacy of pulpal anaesthesia. We were able to find differences in both anesthetic solutions that could go unobserved otherwise. The administration of 1.8 mL of anesthetic solution helped to reduce the duration of anaesthesia.

The evaluation of pulpal anaesthesia, Dreven et al.¹⁶, and Certosimo and Archer¹⁷ “determined that pulpal anaesthesia was successful when readings of 82 were obtained from the electric pulp tester because those lower readings were related with pain during restoration. This criterion was not been included in our study for ethical reasons. All participants were healthy volunteers, anesthetic dosage was low (1.8 mL) and the foremost objective was to compare the efficacy of both solutions with no need for additional treatment. A 60-mA reading gained by the pulp tester was considered enough”.

“No statistically significant differences were found in the present study for both solutions used for anaesthesia of dental pulp. No statistical differences were found associated with other authors in terms of anesthetic efficacy reached at 5 minutes after infiltration. In our study, 0.5% ropivacaine and 4% articaine with epinephrine showed 100% onset of pulpal anaesthesia at 5 minutes”, whereas Gross et al.¹⁵ “the success of the infiltration of the 0.5% ropivacaine solution was 78%” and according to Kennedy et al.¹⁴ 81%.” A lesser result may be correlated with the use of a lower dose of anesthetic solution (0.9 mL). Articaine exhibited same result at 5 minutes, 70%”. Evans et al.¹² reported “a result of 88%. It is important to emphasize that such percentages may vary depending on the methodology used for analysis and the use of different anesthetic solutions”. For example, Gross et al.¹⁵ reported that “the proportion of successful anaesthesia in Lower Central incisors after maxillary infiltration with lidocaine solution was 97%”, while Evans et al.¹², using “a comparable methodology reported only a 62%”.

A duration of pulp anaesthesia observed in this study Mean duration was less in Articaine group (206.50 ± 9.34 min) than Ropivacaine group (318.30 ± 43.21 min). The time observed by Kennedy et al.¹⁴ “was only 12.45 min (SD \pm 11.12) for pure solution and 33.30 min (SD \pm 28.70) for ropivacaine with epinephrine. They obtained nearly identical results for bupivacaine with epinephrine

(33.40 min, SD \pm 24.00), which is astonishing, because bupivacaine is one of long-acting local anaesthetics". Ernberg et al.¹⁸ had "described longer duration of pulp anaesthesia, but the efficiency of maxillary infiltration anaesthesia and inferior alveolar nerve block was low". Axelsson et al.¹⁹ reported "a duration time of pulp anaesthesia that was similar to the present findings. A range of results for pulp anaesthesia observed in this study (40–145 min, SD \pm 23.63) and previously reported (Kennedy et al.¹⁴, Ernberg et al.¹⁸) is worth reflection". Data show that there are additional factors manipulating the absorption and distribution of ropivacaine, which need further study, E.g., because of dose-dependent pharmaco-kinetics of ropivacaine. Statistically, significant difference was present in duration between Ropivacaine and Articaine group.

The second aim of the present study was to control a probable influence of ropivacaine on cardiovascular parameters (O₂ saturation, Pulse rate and blood pressure) once used as a dental anaesthesia.

In the present study, Statistically, no significant difference was present in Systolic BP between Articaine and Ropivacaine group at pre-operative, immediate and post-operative time period. The study by Oliveira et al.²⁹ "based on the result of dental anaesthesia with ropivacaine on the cardiovascular system. Ropivacaine alone (plain) did not cause changes in the cardio-vascular parameters, but ropivacaine with epinephrine caused a transient increase in systolic blood pressure (6%) and heart rate (11%) 2 min after injection. Ropivacaine has a biphasic vascular result as do other long-acting local anaesthetics. Low concentrations of ropivacaine (0.063–0.6%) injected intradermally (0.11 mL) produced vasoconstriction, but higher concentration (1.1%) did not" (Kopacz et al.⁵, Cederholm et al.²¹). "Similar results were found after epidural administration of 0.5% ropivacaine" (Dahl et al.²²). "Studies on volunteers or animals have reported contradictory results of the cardiovascular effect of ropivacaine" (Reiz et al.²³, Scott et al.²⁴).

According to Raj Y²⁵ et al, "Statistically, no significant difference was present in diastolic BP between Articaine and Ropivacaine group at pre-operative time period. Mean diastolic BP was more in Articaine group (86.80 \pm 2.78 mm Hg) than Ropivacaine group (80.70 \pm 1.94 mm Hg). Statistically, significant difference was present in diastolic BP between Articaine and Ropivacaine group at immediate time period. Mean diastolic BP was more in Articaine group (88.50 \pm 3.10 mm Hg) than Ropivacaine group (83.90 \pm 2.96 mm Hg). Statistically, significant difference was present in diastolic

BP between Articaine and Ropivacaine group at post-operative time period. A favourable vasoconstrictive effect, which appears when 1.8 ml concentrations of ropivacaine were used, suppresses the need for epinephrine”.

. Krzemiński TF et al⁶ “ropivacaine has a biphasic vascular effect as do other long-acting local anaesthetics. The vasoconstriction effect at low concentrations is likely to underwrite to its duration of action in dental anaesthesia but then the question of its influence on cardiovascular parameters remains. Ropivacaine alone (plain) did not cause changes in the cardiovascular parameters, but ropivacaine with epinephrine caused a transient increase in systolic blood pressure and heart rate 2 min after injection. In the current study statistically, no significant difference was present in O₂ level between Ropivacaine and Articaine group at pre-operative, immediate and post-operative time period”.

Zanjir M. et al²⁷ stated that, “no significant difference was present in pulse rate between Articaine and Ropivacaine group at pre-operative time period. Mean pulse rate was less in Articaine group (77.90 ± 2.72 BPM) than Ropivacaine group (90.10 ± 4.01 BPM). Statistically, significant difference was present in pulse rate between Articaine and Ropivacaine group at immediate time period. Mean pulse rate was less in Articaine group (80.10 ± 2.37 BPM) than Ropivacaine group (91.50 ± 4.03 BPM). Statistically, significant difference was present in pulse rate between Articaine and Ropivacaine group at post-operative time period”.

“ In spite of the fact that these results were statistically noteworthy, such small fluctuations are not measured to be clinically important. Favourable vasoconstrictive effect, which seems when low concentrations of ropivacaine are used, the need for epinephrine. Previous studies on animals and humans had shown that addition of vasoconstrictive agents to ropivacaine did not result in any extra benefit. Ropivacaine is a long-acting and harmless local anaesthetic and could be applied when the use of epinephrine is contraindicated”²⁸.

4. CONCLUSION

Ropivacaine (0.5%) resulted in effective and long duration of pulp anaesthesia. Ropivacaine could be useful for long-lasting operative procedures without the need for a vasoconstrictor.

Ethical Approval

The study was directed with the approval of the Institutional Ethical Committee.

Consent

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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