

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 18-36 years) were injected 1.8 mL of the anaesthetic solution for buccal infiltration anaesthesia of maxillary central incisors without 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. Blood pressure and heart rate were measured before, Immediate after administration 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 pulpitis¹. 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 familiarised for clinical use in 1996². 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 efficacy³. 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 dentists⁴. 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 an insufficient article about the use of ropivacaine in dentistry⁶.

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 compared these results to bupivacaine with epinephrine and found no important differences between the three solutions⁷.

The low efficacy of ropivacaine probably stimulated to conduct a dose–effect study of ropivacaine in dental anaesthesia. The effect of 0.1%, 0.4% and 0.79% basic ropivacaine in a group of 32 patients (10 men, 22 women) was examined 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 for all the concentrations of

ropivacaine was low. 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

The study was directed with the approval of the Institutional Ethical Committee. 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 presence of maxillary incisor and confirmation that they had healthy pulps that responded 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 with Pulse oximeter (EZ-LIFE) and Sphygmomanometer (Diamond BPLD123) (fig. 1) and also the experimental tooth (maxillary central) was tested with an electrical pulp tester (Yusendent) (fig. 2) to confirm the baseline response (Wozniak 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. In the region of right or left central incisor root apex in the buccal surface, 1.8 mL of the anaesthetic solution was administered (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. Recorded data was sent to Statesian for analysis.

2.3 Statistical analysis

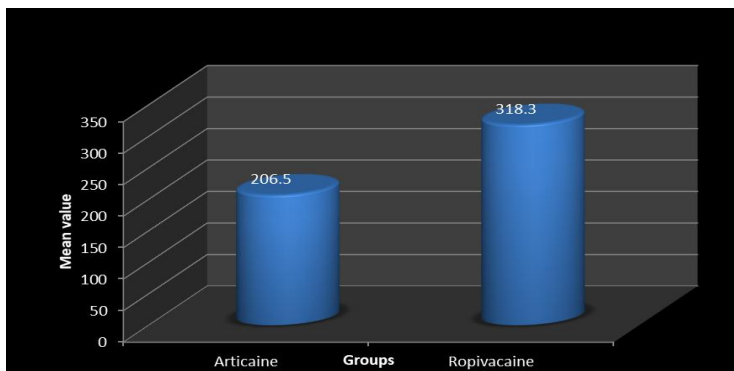
Data are described as the mean and standard deviation (SD). Measuring the mean scores of subjects during three time point, Repeated Measure ANOVA. An unpaired Student's t-test, was used for evaluations.

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 Articaïne group, 50% were male and 50% were female study subjects. Mean age of male study subjects was 23.60 ± 3.50 years and female subject was 25.80 ± 3.76 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 articaïne and ropivacaine are shown in Fig 3.

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

Mean duration was less in Articaïne group (206.50 ± 9.34) than Ropivacaine group (318.30 ± 43.21). Statistically, significant difference was present in duration between Articaïne Ropivacaine 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	Articaïne	10	130.60	5.25	> 0.05 **
	Ropivacaine	10	124.30	5.61	
Immediate	Articaïne	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) than Ropivacaine group (90.10 ± 4.01) at immediate time period. Mean pulse rate was less in Articaine group (80.10 ± 2.37) than Ropivacaine group (91.50 ± 4.03) 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) than Ropivacaine group (80.70 ± 1.94) at immediate time period. Mean diastolic BP was more in Articaine group (88.50 ± 3.10) than Ropivacaine group (83.90 ± 2.96) 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

Latency time, duration of pulpal anaesthesia and Cardiovascular parameters are the main parameters studied in other reports that use a similar study design. It is difficult to compare results as dosages, anaesthetics, use of vasoconstrictors and methods differ¹³.

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. Thus, we were able to find differences in both anesthetic solutions that could go unobserved otherwise. The administration of just 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 associated with pain during restoration. This criterion was not been comprised in our study for ethical reasons, all participants were healthy volunteers, anesthetic dosage was low (1.8 mL) and the main objective was to compare the efficacy of both solutions with no need for further treatment. Hence, 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 compared with other authors in terms of anesthetic efficacy achieved 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 lower result may be related with the use of a lower dose of anesthetic solution (0.9 mL). Articaine showed 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) than Ropivacaine group (318.30 ± 43.21). The time observed by Kennedy et al.¹⁴ was only 12.45 min (SD ± 11.12) for pure solution and 33.30 min (SD ± 28.70) for ropivacaine with epinephrine. They obtained nearly identical results for bupivacaine with epinephrine (33.40 min, SD ± 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 al¹⁹ 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 al¹⁴, Ernberg et al¹⁸) 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 pharmacokinetics of ropivacaine. Statistically, significant difference was present in duration between Articaine Ropivacaine group.

The second aim of the present study was to determine a possible influence of ropivacaine on cardiovascular parameters (Pulse rate, O₂ saturation and blood pressure) when 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 focused on the effect of dental anaesthesia with ropivacaine on the cardiovascular system. Ropivacaine alone (plain) did not cause changes in the cardiovascular 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.²⁰, 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) than Ropivacaine group (80.70 \pm 1.94). 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) than Ropivacaine group (83.90 \pm 2.96). 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 al²⁶ ropivacaine has a biphasic vascular effect as do other long-acting local anaesthetics. The vasoconstriction effect at low concentrations is likely to contribute to its duration of action in dental anaesthesia, but 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 present study, Statistically, no significant difference was present in O₂ level between Articaine and Ropivacaine 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) than Ropivacaine group (90.10 ± 4.01). 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) than Ropivacaine group (91.50 ± 4.03). 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 safe local anaesthetic and could be measured when the use of epinephrine is contraindicated²⁸.

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.

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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