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# Comparison of ropivacaine and articaine with epinephrine for infiltration anaesthesia in dentistry – a randomized study

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## Abstract

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**Aim** To compare the efficacy, onset time and duration of maxillary infiltration anaesthesia with 0.5% plain ropivacaine or 4% articaine with epinephrine  $1:100\ 000$  and to determine their possible influence on cardiovascular parameters.

**Methodology** Sixty volunteers received 1.8 mL of the anaesthetic for buccal infiltration anaesthesia of maxillary central and lateral incisors and canine teeth without caries, restorations or signs of pulpitis. The efficacy, onset time and duration of pulp anaesthesia were assessed with an electric pulp tester. The duration of numbness of the upper lip was also monitored. Blood pressure and heart rate were measured before and after administration of the solutions. **Results** The efficacy of anaesthesia of lateral and central incisors was 100% for both anaesthetics. There were insignificant differences in effectiveness of canine pulp anaesthesia. The mean onset time was significantly (P < 0.05) shorter for ropivacaine (2.22 min) when compared with articaine (4.08 min). The duration of action and soft tissue anaesthesia were also significantly (P < 0.05) longer for ropivacaine (79.2 and 264 min) when compared with articaine (63.7 and 195.2 min, respectively). Ropivacaine caused significant (P < 0.05) increases in blood pressure and heart rate.

**Conclusions** Ropivacaine (0.5%) achieved effective and long duration of uninflamed pulp and soft tissue anaesthesia. Ropivacaine could be useful for long-lasting operative procedures without the need for a vasoconstrictor.

**Keywords:** articaine, dentistry, local anaesthetics, ropivacaine.

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# Introduction

Dentists continue to search for long-acting anaesthetic solutions for effective pain control during treatment of irreversible pulpitis (Corbett *et al.* 2008, Abdulwahab *et al.* 2009, Kanaa *et al.* 2009, Segura-Egea *et al.* 2009, Srinivasan *et al.* 2009, Tortamano *et al.* 2009).

Ropivacaine hydrochloride is a relatively new local amide anaesthetic. It was used in 1992 for the first time in the Royal Hospital for Women in Sydney and introduced for clinical use in 1996 (Gatt *et al.* 1996, Markham & Faulds 1996). Ropivacaine is similar in structure to bupivacaine, but unlike the latter, it is a pure optical s(-) enantiomer of N-n-propyl-2',6'-pipecoloxylidine. The use of the s(-) enantiomer, ropivacaine instead of the racemic, bupivacaine, gives a wider safety margin with the same anaesthetic efficacy (Moller & Covino 1990, Alahuhta *et al.* 1995, Ekström & Gunnarsson 1996). Because of its favourable qualities such as low toxicity, long duration of action and selectiveness for nerve fibres responsible for pain transmission than motor function, ropivacaine has so far been successfully used in surgery, gynaecology and

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Krzemiński et al. Ropivacaine versus articaine

obstetrics, but is not currently available for dentists (Marsh & Hardy 1991, Alahuhta *et al.* 1995, Beilini *et al.* 1999, Bertini *et al.* 1999, Borgeat *et al.* 2000). Ropivacaine has a biphasic vascular effect, which could be useful in dentistry. In low concentration (0.063–0.5%), it shows vasoconstriction *per se* and vasodilatation at high concentration (1%) (Kopacz *et al.* 1989, Cederholm *et al.* 1992). The maximum dose of 0.5% ropivacaine for minor nerve blocks and infiltration is 200 mg.

Despite many positive observations and wide use in surgical anaesthesia and obstetrics, there are only a few articles about the use of ropivacaine in dentistry. Kennedy et al. (2001) published the first study on the anaesthetic effect of ropivacaine. They obtained only 68% efficacy of maxillary lateral incisor infiltration anaesthesia for a concentration of 0.5% ropivacaine without a vasoconstrictive drug and 75% efficacy for the same concentration with addition of epinephrine, when tested using an electrical pulp tester. The authors compared these results to bupivacaine with epinephrine and found no significant differences between the three solutions, but the anaesthetic effect was unacceptable. The low efficacy of ropivacaine probably encouraged Ernberg & Koop (2002) to conduct a dose-effect study of ropivacaine in dental anaesthesia. The effect of 0.2%, 0.5% and 0.75% plain ropivacaine in a group of 30 patients (8 women, 22 men) was investigated also using an electrical pulp tester. They ascertained that these concentrations administered in a volume of 0.5 or 1 mL were not sufficient for pulp anaesthesia. Surprisingly, the effectiveness of infiltration anaesthesia for all the concentrations of ropivacaine was low (5/30). However, the effectiveness of inferior alveolar nerve block for the same solutions was twice as high (10/30), probably because a 1.8 mL volume was used. It is surprising that Ernberg & Koop (2002) obtained higher efficacy of pulp anaesthesia for 0.2% than 0.5% concentration in inferior alveolar nerve block and for 0.5 mL than 1 mL of 0.75% ropivacaine in infiltration anaesthesia. The authors concluded that the administration of ropivacaine even in the highest concentration did not assure satisfactory anaesthesia. Nevertheless, it should be noted that the drug was administered as an infiltration anaesthesia at the maximal volume of 1 mL. As a consequence, subsequent studies were conducted with 0.75% concentration of ropivacaine, with a higher efficacy of pulp anaesthesia observed (Axelsson & Icsacsson 2004, Oliveira et al. 2006).

In addition, more recently, El-Sharrawy & Yagiela (2006) in a similar study with four concentrations of

ropivacaine (0.25%, 0.375%, 0.5%) and 0.75%) obtained successful inferior alveolar nerve anaesthesia with the two highest concentrations.

The first aim of this study was to compare the efficacy, onset of action, duration of pulp and soft tissue anaesthesia of a widely used local anaesthetic (4% articaine with epinephrine  $1 : 100\ 000$ ) to 0.5% ropivacaine, for infiltration anaesthesia of maxillary anterior teeth. The second aim was to determine their possible influence on cardiovascular parameters.

#### **Materials and methods**

This study was a randomized parallel-group trial. The study was conducted with the approval of the Local Ethical Committee. Volunteers eligible for the study were informed of the potential risks and benefits of the medication. Before the start of the study, volunteers signed consent forms previously approved by the review board. They were recruited in Zabrze at the Department of Conservative Dentistry with Endodontics, Medical University of Silesia, Poland.

## Sample-size calculation

Using duration of pulp anaesthesia as the primary outcome, with an expected mean difference of 30 min and an expected standard deviation of 40 min, the sample size was calculated to be 30 subjects per group. The single-tailed unpaired t-test was then used with a level of significance of 0.05 and a power of 80%.

#### Inclusion and exclusion criteria

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

#### Randomization

The drug containers were randomly assigned a number from 1 to 60 by one of the investigators. Sixty healthy adults aged 20–40 years were enrolled by another investigator who was not involved in assigning numbers to the drug containers. Each of the 60 participants was then randomly assigned a distinct number using a restricted randomization method, and the corresponding drug container was used. Thirty volunteers (women-16, men-14) received 1.8 mL of 4% articaine with epinephrine 1 : 100 000, and 30 volunteers (women-15, men-15) received 1.8 mL of 0.5% plain ropivacaine. All measurements (anaesthetic efficacy, onset and duration of pulp anaesthesia) were made by a separate investigator who was not involved in the previously mentioned procedures, including the administration of the drug. None of the volunteers were informed of the anaesthetic group they were assigned to. Although cartridges were distinguishable, volunteers were not able to recognize which drug was used in the study.

#### Study design

Blood pressure and pulse were measured by a trained nurse before the administration of the local anaesthetic. At the beginning of each appointment, before any injection was given, the experimental teeth (maxillary central, lateral incisor and canine) were tested with an electrical pulp tester (Unistom G90; Famed, Łódź, Poland) to confirm the baseline response (Woźniak *et al.* 2003). After isolation with cotton rolls and drying with gauze, the pulp tester was placed in the middle of the buccal surface of the crown of the tooth (Lin & Chandler 2008).

Because ropivacaine is not available in dental cartridges, 10-mL vials were used. Under sterile conditions, 1.8 mL of 0.5% ropivacaine was drawn from the original (Naropin; Astra Zeneca, London, UK) vial into a sterile syringe. Each vial was used only once. Articaine was administered from dental cartridges using a  $0.4 \times 21$  mm needle and ropivacaine from a sterile syringe using a  $0.4 \times 19$  mm needle.

In the region of right or left lateral 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 was deposited over a 30-s period. Five minutes after administration, the blood pressure and pulse were measured again. Cardiovascular parameters were measured prior to and after the administration of the solution, and for all measurements, the patient was seated and had rested for 5 min. Sensitivity of the tested tooth (lateral incisor) was measured with the pulp tester every 30 s after the end of the injection until total anaesthesia appeared. The anaesthetic effect (total anaesthesia) was recorded when the tooth gave a negative response to the maximal stimulus of the electrical pulp tester (current intensity of 60 mA). Measurements were then made every 5 min on the tested tooth and also on the adjacent central incisor and canine. The examination was terminated for each tooth when the patient responded to two consecutive stimulations (60 mA) of the lateral incisor. Soft tissue anaesthesia was measured as numbness of the gingiva and upper lip. Volunteers were instructed to palpate the upper lip every 10 min to determine at what time the numbness of the lip completely disappeared.

The onset time of anaesthesia was defined as the time from the end of injection to the time-point when the lateral incisor did not respond to the maximal stimulus of the pulp tester. The duration of anaesthesia was defined as the time from the onset to the time-point when the lateral incisor gave positive responses to two consecutive stimulations with maximal value of the pulp tester. Before the participant left the clinic, the orofacial area was inspected, adverse reactions were recorded, and the subject was asked about any complaints or health problems since the injection.

#### Statistical analysis

Data are reported as the mean and standard deviation (SD). Differences in anaesthetic effect were analysed by the Fisher's test. A paired or an unpaired Student's *t*-test, when appropriate, was used for comparisons. A *P* value of < 0.05 was considered significant.

# Results

There were no significant differences in demographics between the two experimental groups (Table 1). The effectiveness of the anaesthesia for the central and lateral incisor was 100% (30/30) for both anaesthetic solutions. The effectiveness of the anaesthesia for the canine for ropivacaine was 100% and articaine 96.67% (29/30), but the differences between the solutions were not significant (Fisher's test).

The results of the pulp and soft tissue anaesthesia with articaine and ropivacaine are shown in Figs 1 and 2. The

<b>Table 1</b> Characteristics of the study participants (mean $\pm$ SI	D)
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	0.5% Ropivacaine	4% Articaine (1 : 100 000 epinephrine)
Age (year)	25.1 (±3.3)	31.3 (±7.4)
Weight (kg)	67.9 (±14.8)	66.1 (±13.7)
Height (cm)	174.3 (±8.6)	171.6 (±8.9)

748



**Figure 1** The onset time of the two local anaesthetics: ropivacaine (R) and articaine with epinephrine (A). Data are shown as the means and standard deviations (SD). \*\*P < 0.01.



**Figure 2** The duration of pulp anaesthesia and numbress of upper lip of the local anaesthetics: ropivacaine (R) and articaine with epinephrine (A). Data are shown as the means and standard deviations (SD). \*\*P < 0.01.

onset of action for 0.5% ropivacaine  $(2.21 \pm 0.98 \text{ min})$ was more rapid than that for articaine  $(4.08 \pm 1.57 \text{ min})$ . Ropivacaine achieved a longer duration of both soft tissue and pulp anaesthesia (respectively,

Table 3	Comparison	of heart	rate befo	ore and	after ac	lminis-
tration o	of local anaes	sthetic (m	ean ± S	D)		

	Heart rate (b.p.m.)			
Anaesthetic	Before anaesthesia	After anaesthesia		
4% Articaine (1 : 100 000 epinephrine)	74.7 (±3.9)	75.3 (±6.2)		
0.5% Ropivacaine	86.0 (±10.0)	88.1 (±10.7)*		

\*Statistically significant differences (paired *t*-test, P < 0.01). b.p.m., beats per minute.

 $264.1 \pm 126.5$  and  $79.2 \pm 23.6$  min). The differences in the onset time, duration of pulp and soft tissue anaesthesia between ropivacaine and articaine were significant (unpaired Student's *t*-test, *P* < 0.05).

The values of systolic and diastolic blood pressure and heart rate before and after the administration of the anaesthetics are shown in Tables 2 and 3. Ropivacaine caused a significant increase in systolic (from 116.4 to 121.0 mmHg), diastolic pressure (from 73.5 to 78.8 mmHg) and heart rate (from 86.0 to 88.1 b.p.m.) (paired *t*-test, P < 0.05). There were no significant changes in blood pressure or heart rate after injection of articaine with epinephrine. No adverse events were reported by the participants.

#### Discussion

The present study was designed to compare pulp anaesthesia with 0.5% ropivacaine and a commonly used dental anaesthetic – 4% articaine with epinephrine. Overall, 0.5% ropivacaine resulted in 100% efficacy of anaesthesia for both incisors (lateral and central) and canine. In the present study, the onset time of anaesthesia with ropivacaine was similar to that reported by others (Kennedy *et al.* 2001, Ernberg & Koop 2002, Axelsson & Icsacsson 2004) and was more rapid when compared to articaine (Fig. 1). On the other hand, ropivacaine was used without epinephrine and that could have had an influence on the results.

Axelsson & Icsacsson (2004) investigated the efficacy of maxillary infiltration and inferior alveolar nerve block anaesthesia with 0.75% ropivacaine in volumes

Table 2 Comparison of arterial blood pressure before and after administration of local anaesthetic (mean  $\pm$  SD)

	Systolic blood pressure (mmHg)		Diastolic blood pressure (mmHg)	
Anaesthetic	Before anaesthesia	After anaesthesia	Before anaesthesia	After anaesthesia
4% Articaine (1 : 100 000 epinephrine)	124.2 (±16.0)	124.9 (±19.5)	83.2 (±8.2)	84.0 (±9.3)
0.5% Ropivacaine	116.4 (±17.8)	121.0 (±16.2)*	73.5 (±9.1)	78.8 (±9.5)*

\*Statistically significant differences between blood pressure before and after anaesthesia (paired t-test, P < 0.01).

of 1 or 2 mL. Their observed mean onset time of pulp anaesthesia was 2.1 min for the 1 mL volume of solution and 1.6 min for 2 mL. Oliveira *et al.* (2006) obtained much longer onset times with 1.8 mL 0.75% plain ropivacaine and 0.75% ropivacaine with epinephrine when used for the lingual and inferior alveolar nerve blocks anaesthesia.

In the present study, the duration of pulp anaesthesia was longer for ropivacaine (Fig. 2). The time observed by Kennedv et al. (2001) was only 12.45 min (SD  $\pm$  11.12) for plain solution and 33.30 min (SD  $\pm$  28.70) for ropivacaine with epinephrine. However, they obtained nearly identical results for bupivacaine with epinephrine  $(33.40 \text{ min}, \text{SD} \pm 24.00)$ , which is surprising, because bupivacaine is one of the longest acting local anaesthetics. Ernberg & Koop (2002) had reported longer duration of pulp anaesthesia, but the effectiveness of maxillary infiltration anaesthesia and inferior alveolar nerve block was low. Axelsson & Icsacsson (2004) 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.* 2001, Ernberg & Koop 2002) is worth consideration. Data show that there are additional factors influencing the absorption and distribution of ropivacaine, which require further study, e.g. due to dose-dependent pharmacokinetics of ropivacaine.

Besides the investigation on pulp anaesthesia using an electrical pulp tester, the duration of numbness of the upper lip reported by the participants was also registered. Ropivacaine was associated with much longer duration of numbness than articaine with epinephrine (Fig. 2). The present findings seem to confirm previous studies (Kennedy *et al.* 2001, Axelsson & Icsacsson 2004, Oliveira *et al.* 2006). Ropivacaine, which is one of the long-acting local anaesthetics, produces numbness of soft tissue even when used in a low concentration and without vasoconstrictive agents.

Meechan (2002) was the first to compare the efficacy of ropivacaine plain (in two concentrations -0.75%, 1%) and lidocaine with epinephrine when given as an intraligamentary anaesthetic. The data reported by Meechan (2002) are not comparable to the results of the present study, because of the different route of administration of the local anaesthetic. The effectiveness of intraligamentary anaesthesia is more related to the concentration of the vasoconstrictor than to the anaesthetic used (Kim 1986, Gray *et al.* 1987).

The second aim of the present study was to determine a possible influence of ropivacaine on

cardiovascular parameters when used as a dental anaesthesia. Ropivacaine has a biphasic vascular effect as do other long-acting local anaesthetics. Low concentrations of ropivacaine (0.063-0.5%) injected intradermally (0.1 mL) caused vasoconstriction, but higher concentration (1%) did not (Kopacz et al. 1989, Cederholm et al. 1992). Similar results were obtained after epidural administration of 0.5% ropivacaine (Dahl et al. 1990). 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. Studies on volunteers or animals have reported contradictory results of the cardiovascular effect of ropivacaine (Reiz et al. 1989, Scott et al. 1989). The study by Oliveira et al. (2006) 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.

In the present study, ropivacaine produced an increase in both systolic (4.6%) and diastolic (7.2%) pressure. The heart rate increased after injection of ropivacaine (2.4%) (Tables 2 and 3). Despite the fact that these results were statistically significant, such small fluctuations are not considered to be clinically important.

A favourable vasoconstrictive effect, which appears when low concentrations of ropivacaine are used, suppresses the need for epinephrine. Moreover, previous studies on animals and humans had shown that addition of vasoconstrictive agents to ropivacaine did not result in any additional benefit (Akerman *et al.* 1988, Weber *et al.* 2001). Ropivacaine is a long-acting and safe local anaesthetic and could be considered when the use of epinephrine is contraindicated.

#### Conclusion

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

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