

ENDODONTOLOGY

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Efficacy of articaine and lidocaine in a primary intraligamentary injection administered with a computer-controlled local anesthetic delivery system

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Objective. The purpose of this prospective, randomized, double-blind study was to compare the anesthetic efficacy of the intraligamentary injection of 4% articaine with 1:100,000 epinephrine and of 2% lidocaine with 1:100,000 epinephrine, administered with computer-controlled local anesthetic delivery system, in mandibular posterior teeth.

Study design. Using a crossover design, intraligamentary injections of 1.4 mL of 4% articaine with 1:100,000 epinephrine and of 1.4 mL of 2% lidocaine with 1:100,000 epinephrine were randomly administered with a computer-controlled local anesthetic delivery system, in a double-blind manner on the mesial and distal aspects of a mandibular first molar, at 2 separate appointments to 51 subjects. A pulp tester was used to test for anesthesia, in 2-minute cycles for 60 minutes, of the mandibular first and second molars and second premolar. Anesthesia was considered successful when 2 consecutive 80 readings (highest output) were obtained within 20 minutes.

Results. Successful pulpal anesthesia was obtained 86% of the time for the first molar using the articaine solution and 74% of the time using the lidocaine solution. There were no significant differences ($P > .05$) between the articaine and lidocaine solutions. The mean onset times of pulpal anesthesia for the first molar were 1.3 minutes with articaine solution and 2.2 minutes with lidocaine solution. Duration of pulpal anesthesia for the first molar was 34 minutes for the articaine solution and 31 minutes for the lidocaine solution.

Conclusion. The efficacy of 4% articaine with 1:100,000 epinephrine was similar to the efficacy of 2% lidocaine with 1:100,000 epinephrine for intraligamentary injections.

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Articaine has a reputation of providing an improved local anesthetic effect.¹ Articaine was approved for use in the United States in April 2000.² The formulation is known as Septocaine (Septodont, New Castle, Del) and is available as a 4% solution with 1:100,000 epinephrine. Articaine is classified as an amide but contains a thiophene ring instead of the benzene ring of other amide local anesthetics.² A second molecular difference between articaine and other amide local anesthetics is the extra ester linkage incorporated into the articaine molecule,² which results in hydrolysis of articaine by plasma esterases. Isen³ states that 90% to 95% of articaine is metabolized in the blood and only 5% to 10% is broken down in the liver. The plasma half-life has been reported to be as low as 20 minutes.^{4,5}

A number of studies^{2,6-13} have evaluated articaine and concluded that it is safe when used in appropriate doses.

Both lidocaine and articaine have the same maximum milligram dose of 500 mg (recommended dose of 6.6 to 7 mg/kg) for the adult patient.¹⁴ Because articaine is marketed as a 4% solution, the maximum manufacturer's recommended dose for a healthy 70 kg adult would be 7 cartridges of an articaine solution, compared to 13 cartridges of a 2% lidocaine solution.¹⁴

The available literature indicates that articaine is equally effective when statistically compared to other local anesthetics.^{13,15-20} For example, Malamed et al¹⁵ studied the efficacy of articaine in 3 identical randomized, double-blind, multicenter clinical trials. Subjects ranged in age from 4 to 80 years and were given either 4% articaine with 1:100,000 epinephrine or 2% lidocaine with 1:100,000 epinephrine during both simple and complex dental procedures. A total of 1,325 subjects participated in the study. Articaine's onset time and duration were considered comparable to lidocaine. Malamed et al¹⁵ found no statistical difference between the 2 anesthetic solutions tested. Therefore, considering the results of many studies,^{13,15-20} articaine has not been found to be objectively superior to other local anesthetics.

The intraligamentary injection (periodontal ligament injection) allows placement of a local anesthetic solution into the cancellous bone adjacent to the tooth to be anesthetized.²¹ The success of the primary and supplemental intraligamentary injection in achieving pulpal anesthesia has been reported to be from 18% to 100%.²¹⁻³⁸ Traditionally, intraligamentary injections have been administered with a conventional syringe or high-pressure syringe.²¹⁻³⁸ The Wand Plus (CompuDent; Milestone Scientific, Deerfield, Ill) local anesthesia system was developed to deliver a controlled amount of anesthetic solution at a precise and continuous flow rate.³⁹ The Wand Plus has been advocated for infiltration injections, nerve block injections, and intraligamentary injections.³⁹ Additionally, the Wand Plus is potentially capable of delivering 1.4 mL of anesthetic solution intraosseously compared to only 0.4 mL with previous intraligamentary injections. Therefore, there is a possibility of delivering more anesthetic solution intraosseously.

The purpose of this prospective, randomized, double-blind study was to compare the anesthetic efficacy of the intraligamentary injection of 4% articaine with 1:100,000 epinephrine and of 2% lidocaine with 1:100,000 epinephrine, administered with computer-controlled local anesthetic delivery system, in mandibular posterior teeth.

MATERIAL AND METHODS

Fifty-one adult subjects participated in this study. All subjects were in good health and were not taking

any medication that would alter pain perception, as determined by a written health history and oral questioning. The Ohio State University Human Subjects Review Committee approved the study, and written informed consent was obtained from each subject.

Subjects randomly received intraligamentary injections of articaine and lidocaine solutions at 2 separate appointments spaced at least 1 week apart, in a double-blind crossover design. The 51 subjects received intraligamentary injections of 1.4 mL of 4% articaine (56 mg) with 1:100,000 epinephrine (14 µg) (Septocaine; Septodont) at one appointment and 1.4 mL of 2% lidocaine (28 mg) with 1:100,000 epinephrine (14 µg) (Xylocaine; Dentsply Pharmaceutical, York, Pa) at the other appointment using the Wand Plus local anesthesia system (CompuDent; Milestone Scientific). With the crossover design, there were 102 sets of intraligamentary injections administered and each subject served as his or her own control. Twenty-six sets of intraligamentary injections were administered on the right side and 25 sets of intraligamentary injections were administered on the left side. The same side randomly chosen for the first injection was used again for the second injection. The senior author gave all injections.

The test teeth were the mandibular first (anesthetized tooth) and second molars and second premolar. The contralateral mandibular canine was used as the unanesthetized control to ensure that the pulp tester was operating properly and that the subject was responding appropriately during the experiment. Clinical examinations indicated that all teeth were free of caries, large restorations, and periodontal disease, and that none had a history of trauma or sensitivity.

At the beginning of each appointment and before any injections were given, the experimental teeth and control canine were tested 3 times by means of a Kerr pulp tester (Analytic Technology Corp, Redmond, Wash) to record baseline vitality. After isolation with cotton rolls and drying with gauze, toothpaste was applied to the probe tip, which was placed midway between the gingival margin and the occlusal edge of the tooth to be tested. The current rate was set on the pulp tester at 25 seconds to increase from no output (0) to the maximum output (80). The number at initial sensation was recorded. Trained personnel who were blinded to the anesthetic solutions administered performed all preinjection and postinjection tests.

Before the experiment, the 2 anesthetic solutions were randomly assigned 6-digit numbers from a random number table. The random numbers were assigned to a subject to designate which anesthetic solution was to be administered at each appointment. The cartridges of anesthetic solutions administered were blinded by completely masking the aluminum caps with permanent

black marker and masking the appropriate cartridges with opaque labels which were labeled with the 6-digit numbers. The expiration dates on the cartridges were checked before they were masked. Two blinded cartridges of the same anesthetic solution (so the code would not have to be broken in the event of a broken or dropped cartridge) were placed in letter-sized envelopes labeled with the 6-digit code. Only the random numbers were recorded on the data collection sheets to further blind the experiment.

The computer-assisted local anesthesia system is a microprocessor-driven device that delivers a controlled infusion of anesthetic solution. The device accepts standard 1.8 mL dental anesthetic glass cartridges. The microprocessor monitors and varies the infusion pressure while maintaining a constant flow rate. An electronically driven plunger contacts the rubber plunger in the cartridge and expels the anesthetic solution at a precisely regulated rate. Sterile tubing connects the cartridge receptor to a pen-like hand-held plastic wand that is attached to a Luer-Lok needle, together forming a disposable syringe assembly. A small portion of solution from a standard cartridge is lost during the purge cycle and some of the solution remains in the cartridge and tubing, thus only 1.4 mL of anesthetic solution from a standard cartridge is delivered. Flow rate, initiation and cessation of flow, and aspiration are controlled with a foot pedal. To prevent cross-contamination, the handpiece, microtubing and anesthetic cartridge are designed for single use only.

One blinded cartridge was removed from the envelope, placed into the plastic barrel of the computer-assisted handpiece assembly, and placed into the cartridge holder socket with a quarter turn in a counterclockwise direction. The cap was removed from the needle and the foot pedal depressed once to activate the purge cycle to remove air from the plastic tubing and fill the line with anesthetic solution.

The intraligamentary injection, using the Wand Plus, was administered with a 27-gauge 1/2-inch Luer-Lok needle (Becton Dickinson, Franklin Lakes, NJ) attached to the disposable tubing and handpiece assembly (Milestone Scientific). The subject was informed that the injection would take almost 5 minutes and they would hear chimes during the injection. The subject was placed in a supine position. The injection was performed by inserting the needle in the gingival sulcus at the mesiobuccal line-angle of the tooth with the needle directed at an approximately 30-degree angle to the long axis of the mandibular first molar in the buccolingual plane. The needle was placed into the sulcus with the bevel facing away from the tooth and toward the alveolar bone. The needle was advanced with firm pressure until it could be advanced no farther. The Wand

Table 1. Percentages and number of patients who achieved anesthetic success with the intraligamentary technique

Tooth	Articaine	Lidocaine	P value*
First molar	86% (44/51)	74% (38/51)	.146
Second molar	84% (43/51)	74% (38/51)	.267
Second premolar	74% (38/51)	61% (31/51)	.144

n = 51.

*There were no significant differences ($P > .05$) when the articaine solution was compared to the lidocaine solution.

Plus unit was activated at a slow rate (by partially depressing the foot pedal) for 8 seconds, and then by removing the foot from the foot pedal the anesthesia delivery unit was activated on cruise control (continuous flow of anesthetic solution at the slow rate). Audible chimes from the machine and indicator lights on the front of the unit allowed monitoring of volume of anesthetic solution delivered.

Approximately 1 drop of anesthetic solution was delivered every other second on the slow setting. Once 0.7 mL of the anesthetic solution had been delivered, as shown by the indicator lights, the injection was stopped by lightly tapping the foot pedal once. The time to administer 0.7 mL of anesthetic solution was approximately 2 minutes and 22 seconds. The author waited 10 seconds before slowly removing the needle from the injection site. This step supposedly allows the anesthetic solution to dissipate within the tissue and reduces the amount of solution dripping from the site before needle withdrawal. However, in almost all cases, some anesthetic solution escaped upon removal of the needle from the sulcus. A pilot study determined the amount to be approximately 0.05 mL. The injection was then repeated on the distal aspect of the first molar using the same technique and sequence of steps listed above. The amount of anesthetic solution delivered was 0.7 mL.

For both injection sites, the author had direct vision of the injection site to monitor if anesthetic solution was being expressed from the sulcus. If notable solution escaped, depressing the foot pedal briefly stopped the flow of anesthetic solution and the needle was rotated with firm apical pressure into the sulcus. If the needle deformed, it was replaced with a new 27-gauge 1/2-inch needle.

The depth of anesthesia was monitored with the electric pulp tester. At 1 minute after completion of the intraligamentary injection, pulp test readings were obtained for the first molar and contralateral control canine. At 2 minutes, the second molar and second premolar were tested. The testing continued in 2-minute cycles for a period of 60 minutes.

No response from the subject to the maximum output (80 reading) of the pulp tester was used as the

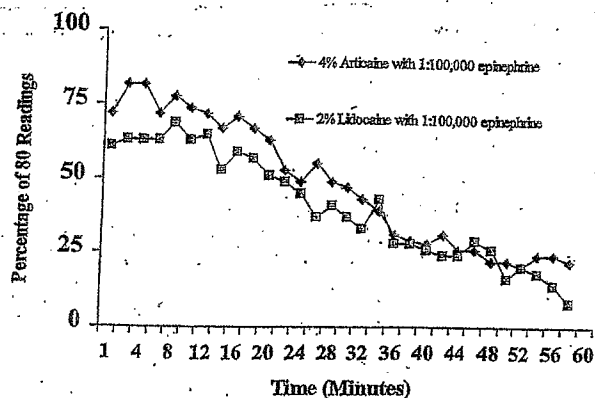


Fig 1. Incidence of anesthesia for mandibular first molar as determined by lack of response to electrical pulp testing at the maximum setting (percentage of 80 readings), at each postinjection time interval, for the 2 anesthetic solutions.

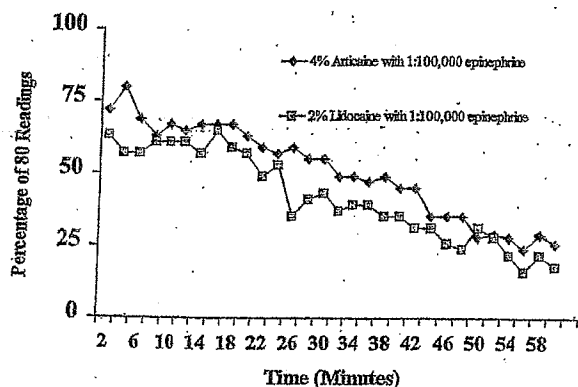


Fig 2. Incidence of anesthesia for mandibular second molar as determined by lack of response to electrical pulp testing at the maximum setting (percentage of 80 readings), at each postinjection time interval, for the 2 anesthetic solutions.

criterion for pulpal anesthesia. Anesthesia was considered successful when 2 consecutive no responses at the 80 reading were obtained within the first 20 minutes of testing. The onset of pulpal anesthesia was considered complete when the first of 2 consecutive no responses at the 80 reading was obtained. Duration of anesthesia was calculated using the time of the last of 2 consecutive no responses at the 80 reading.

The data were analyzed as follows. Between-solution differences in anesthetic success were analyzed using the McNemar test; differences in mean onset and mean duration times were assessed using the Wilcoxon, matched-pairs, signed-ranks test. With a nondirectional alpha risk of .05 and a power of 90%, a sample size of 51 subjects was required to demonstrate a difference of $\pm 30\%$ in anesthetic success. Comparisons were considered significant at $P < .05$.

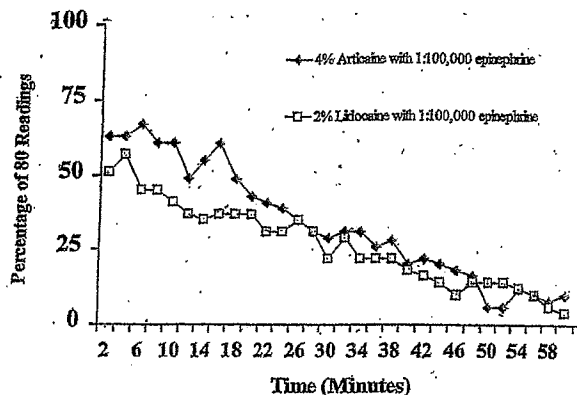


Fig 3. Incidence of anesthesia for mandibular second premolar as determined by lack of response to electrical pulp testing at the maximum setting (percentage of 80 readings), at each postinjection time interval, for the 2 anesthetic solutions.

Table II. Onset and duration of pulpal anesthesia for the articaine and lidocaine solutions

Tooth	Articaine	Lidocaine	P value
Onset (minutes) [†]			
First molar (n = 35)	1.3 \pm 1.4	2.2 \pm 2.7	.008*
Second molar (n = 34)	3.1 \pm 3.2	3.1 \pm 2.9	.891
Second premolar (n = 26)	3.0 \pm 2.1	3.5 \pm 3.8	.457
Duration (Minutes) [†]			
First molar (n = 35)	34.2 \pm 16.8	30.6 \pm 16.8	.333
Second molar (n = 34)	36.3 \pm 19.2	34.7 \pm 19.2	.625
Second premolar (n = 26)	28.1 \pm 18.4	25.3 \pm 18.6	.647

*There was a significant difference ($P < .05$) when the articaine solution was compared to the lidocaine solution.

[†]Numbers in parentheses indicate the number of matched pair teeth used for statistical analysis.

RESULTS

Fifty-one adult subjects, 25 men and 26 women from age 20 to 53 years with an average age of 26 years, participated.

Anesthetic success of the intraligamentary injection is presented in Table I. There were no significant differences between the articaine and lidocaine solutions. Incidence of pulpal anesthesia (80 readings) for the 2 anesthetic solutions are presented in Figs 1-3.

The onset of pulpal anesthesia is presented in Table II. There was a significant difference between the articaine and lidocaine solution for the first molar.

Duration of pulpal anesthesia is presented in Table II. There were no significant differences between the articaine and lidocaine solutions.

DISCUSSION

The use of no response to the 80 reading (maximum output of the pulp tester) as a criterion for pulpal

anesthesia was based on the clinical studies of Dreven et al⁴⁰ and Certosimo and Archer.⁴¹ These studies^{40,41} showed that no response at the 80 reading ensured pulpal anesthesia in vital asymptomatic teeth. Additionally, Certosimo and Archer⁴¹ demonstrated that electric pulp testing readings less than 80 resulted in pain during restorative procedures.

The 4% articaine with 1:100,000 epinephrine did not statistically improve anesthetic success of the intraligamentary injection when compared to 2% lidocaine with 1:100,000 epinephrine (Table I). No other study has objectively compared articaine to lidocaine in intraligamentary injections, so no comparison to other studies is possible. However, the literature contains numerous studies demonstrating an equal anesthetic effect for articaine and lidocaine.^{13,15-20} The results of the present study further confirm that articaine is not superior to lidocaine in anesthetic efficacy.

The first molar success rate was 86% for the articaine solution and 74% for the lidocaine solution and was similar to the results of an experimental intraligamentary study by White et al,³¹ who showed a 79% success rate in the mandibular first molar. The computer-assisted anesthetic delivery system should have been capable of delivering approximately 1.4 mL of anesthetic solution via the intraligamentary injection by consistently maintaining a precise flow rate. Previous studies²¹⁻³⁸ of intraligamentary anesthesia used approximately 0.4 mL of anesthetic solution delivered with a conventional or high-pressure syringe. Therefore, we would expect higher success rates using the computer-controlled anesthetic delivery system. Perhaps, a portion of the anesthetic solution may have leaked imperceptibly and slowly from the gingival sulcus while giving the injection over the 4 minutes and 45 seconds. Therefore, the intraligamentary injection was not 100% successful in delivering the anesthetic solution intraosseously. Other studies^{21,24} have shown reinjection increases the success rate of the intraligamentary technique. Whether reinjection with the computer-controlled anesthetic delivery system would increase success would have to be studied.

Anesthesia of adjacent teeth was observed in this study (Table II). Previous studies^{30-32,35} have also found that adjacent teeth become anesthetized with intraligamentary injections of a single tooth. The current study and the studies of Schleder et al,³² White et al,³¹ and Childers et al³⁵ have found that the tooth distal to the tooth injected had higher success rates than the mesial tooth. Because there are differences in success of anesthetizing adjacent teeth it would be prudent for the clinician to use intraligamentary injections on each tooth that requires pulpal anesthesia to maximize the anesthetic effect. Our results also reinforce that an intra-

ligamentary injection cannot be used to selectively anesthetize a single tooth.

The mean time of onset of pulpal anesthesia for the first molar was 1.3 minutes for the articaine solution and 2.2 minutes for the lidocaine solution (Table II). Other studies^{21,31,32} have also shown fairly quick onset times with the intraligamentary technique. The adjacent teeth had slower onset times and this would be related to pulp testing of these teeth at a later time than the first molar. The statistical finding of a faster onset time with the articaine solution would not be clinically significant because the difference between the articaine and lidocaine solution was less than 1 minute.

The mean time of duration of pulpal anesthesia for the first molar was 34 minutes for the articaine solution and 31 minutes for the lidocaine solution (Table II). Because there was no significant difference between the 2 anesthetic solutions, they acted in a similar manner. Adjacent teeth showed a similar pattern of duration of anesthesia as the first molar (Figs 1-3). White et al³¹ found that the primary intraligamentary injection of 2% lidocaine with 1:100,000 epinephrine in mandibular first molars resulted in a rapid decrease in pulpal anesthesia within the first 10 minutes. In the current study, pulpal anesthesia decreased more slowly with approximately 40% to 50% of the subjects still anesthetized at 30 minutes (Fig 1). White et al³¹ used a high-pressure syringe to deliver 0.4 mL of anesthetic solution. The longer duration recorded in the current study is likely related to the approximately 1.4 mL volume delivered with the computer-controlled anesthetic delivery system. Therefore, there is an advantage to using the Wand Plus to increase the duration of pulpal anesthesia. However, the clinician must be aware that anesthesia does decrease slowly over the hour.

We concluded that the efficacy of 4% articaine with 1:100,000 epinephrine was similar to the efficacy of 2% lidocaine with 1:100,000 epinephrine for intraligamentary injections. The success rate using the computer-assisted local anesthesia system for intraligamentary injections was similar to the success rate reported in previous experimental studies with a high-pressure syringe. However, the duration of pulpal anesthesia was longer than reported in previous experimental studies that used the high-pressure syringe.

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