Anesthetic Efficacy of Four Percent Articaine for Pulpal Anesthesia by Using Inferior Alveolar Nerve Block and Buccal Infiltration Techniques in Patients with Irreversible Pulpitis: A Prospective Randomized Double-blind Clinical Trial

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Abstract

Introduction: The study was designed as a randomized double-blind trial to evaluate the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine in inferior alveolar nerve block (IANB) and infiltration anesthetic techniques to anesthetize mandibular molars with irreversible pulpitis. Methods: The study was composed of 2 test arms and 1 control arm. Subjects in the test arms received either a standard IANB or a buccal infiltration (B Infil) of 4% articaine with 1:100,000 epinephrine, whereas the subjects in the control arm received a standard IANB of 2% lidocaine with 1:100,000 epinephrine. Subject’s self-reported pain response was recorded on Heft Parker Visual Analogue Scale after local anesthetic administration during access preparation and pulp extirpation. Results: For statistical analysis Pearson $\chi^2$, Student’s paired $t$ test, 1-way analysis of variance, and Friedman tests showed no significant difference in success rates among the 3 arms of the trial. Conclusions: Although B Infil and IANB of 4% articaine were equally effective, B Infil can be considered a viable alternative in IANB for pulp anesthesia in mandibular molars with irreversible pulpitis. (J Endod 2011;37:1603–1607)

Key Words
Articaine, buccal infiltration, irreversible pulpitis, pulpal anesthesia

Successful local anesthesia is the bedrock of pain control in endodontics. Effective pain control is essential to reduce fear and anxiety associated with endodontic procedures (1). There is substantial research interest in finding safe and more effective local anesthetics for pulpal anesthesia (2). Lidocaine (also known as lignocaine), the most frequently used local anesthetic, is the gold standard anesthetic agent used for comparison. It is an amide anesthetic with a short onset of action and an intermediate duration of anesthesia when associated with adrenaline (3). Articaine, also classified as an amide anesthetic, has increased liposolubility and potency because of presence of a thiophene ring. According to some authors, its ability to diffuse can produce pulpal anesthesia (4).

Mandibular molars are usually anesthetized by regional blockade of the inferior alveolar nerve. Furthermore, teeth with inflamed pulps and periradicular areas are particularly difficult to anesthetize, especially in the mandible. The literature reveals that failures occur more commonly with inferior alveolar nerve blocks (IANBs) than other nerve blocks. Hence, factors that modify mandibular anesthesia are commonly reviewed to obtain optimum pulpal anesthesia for endodontic procedures (7, 8). Time-honored supplemental techniques have been recommended, which are intraosseous injections, intraligamentary infiltration, and intrapulpal anesthetic techniques that might be used to supplement or replace the regional block (9).

Clinical studies comparing the success rate of 4% articaine with that of 2% lidocaine have shown that 4% articaine was superior to 2% lidocaine as a general-purpose anesthetic (10–15). Pulpal anesthesia was determined by using electric pulp tester in studies reported by Kanaa et al (12) and Jung et al (13). However, in painful vital pulp, the lack of response to vital pulp testing might not guarantee pulpal anesthesia. If the chamber is necrotic and the canals are vital, no objective test can predict the level of clinical anesthesia (16). Several others compared the anesthetic efficacy on access preparation, which is clinically more reliable (17, 18).

Although the literature reveals repeated clinical trials on the anesthetic efficacy of articaine, they have failed to demonstrate any clinical and statistical superiority of articaine infiltration over articaine nerve blocks in irreversible pulpitis. Evidence of buccal infiltrations of articaine alone producing pulpal anesthesia in up to 92% of uninflamed pulps has been cited earlier (11). The current trial was undertaken to test the same in irreversible pulpitis and compare it with that of IANB. Thus, the purpose of this preliminary, prospective, randomized, double-blind clinical trial was to evaluate the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine in IANB and infiltration anesthetic techniques to anesthetize mandibular molars with irreversible pulpitis.

Materials and Methods

This study was designed as a randomized double-blind clinical trial comparing the anesthetic effectiveness of 4% articaine with 1:100,000 epinephrine in IANB and infiltration anesthesia. The trial adhered to the CONSORT statement. The research protocol was approved by the Institutions Review Board at Ragas Dental College and Hospitals, Chennai. The study was conducted during March 2011–May 2011 at the Department of
Conservative Dentistry and Endodontics at Ragas Dental College and Hospitals. Written informed consent was obtained from all the subjects participating in this study.

Healthy adult volunteers aged between 18–30 years with active pain of \( \geq 54 \) mm in Heft-Parker Visual Analog Scale (HP VAS) in mandibular molar, prolonged response to cold testing with an ice stick (1,1,1,2 tetrafluoroethane; Hygenic Corp, Akron OH) and an electric pulp tester (Digitest; Parkell, Farmingdale, NY), and absence of any periapical radiolucency on radiographs except for a widened periodontal ligament and a vital coronal pulp on access opening were included for the study. Subjects placed under American Society of Anesthesiologists IV classification of systemic disorders or antecedents of complications associated with local anesthetics, pregnant and lactating women, and subjects under medication to alter pain perception were excluded from the study.

The study was designed with 2 test arms and 1 control arm. Subjects were randomly allocated to 1 of the 3 arms. A pilot study was conducted with 20 subjects. The results of the pilot study were used to calculate the sample size by using G Power Analysis (version 3.0.10). A power calculation indicated that 132 subjects would provide 90% chance of detecting an effect size 0.83 in a continuous outcome measure, assuming a significance level of 5%. The \( \beta \) error of the study was assumed as 0.10. Because an attrition rate of approximately 15% was expected, 52 subjects were to be enrolled in each group.

All subjects were asked to rate their pain on an HP VAS. Each subject was informed of the pain ratings on HP VAS and completed a baseline HP VAS to establish their preoperative pain level. HP VAS used was a 170-mm line with various descriptive terms. The subjects placed a mark on the scale where it best described their pain level. To interpret the data, the VAS was divided into the following 4 categories: no pain corresponded to 0 mm on the scale; mild pain was defined as \( >0 \) mm and \( <54 \) mm, which included descriptors of faint, weak, and mild pain; moderate pain was defined as \( >54 \) mm and \( <114 \) mm; severe pain was defined as \( \geq 114 \) and included the descriptors of strong, intense, and maximum possible.

The study subjects were allocated into the 3 study arms by using a simple randomization procedure. For allocation of the subjects, a computer-generated list of random numbers was used with a randomization ratio of 1:1:1 by using random allocation software (version 1.0, May 2004). Allocation sequence was concealed from the researchers who were a part of the study to reduce selection bias.

Test arm A consisted of subjects who received a standard IANB of 4% articaine with 1:100,000 epinephrine (Septanest; Septodont, Saint Maur des Fosses, France). Test arm B consisted of patients who received a buccal infiltration in the mucobuccal fold adjacent to mandibular first molar. Control arm consisted of subjects who received a standard IANB of 2% lidocaine with 1:100,000 epinephrine (Lignospan; Septodont). All local anesthetic injections were delivered by using a self-aspirating syringe (Sagima, Buenos Aires, Argentina) and 27-gauge long needles (Septoject; Septodont). After reaching the target area, aspiration was performed, and 1.8 mL of solution was deposited at a rate of 1 mL/min. All local anesthetic injections were given by a single operator.

Figure 1. Flow diagram showing information on excluded patients.
TABLE 1. Initial Values for the 3 Arms

<table>
<thead>
<tr>
<th>Value</th>
<th>IANB with 4% articaine (n = 52)</th>
<th>Buccal infiltration with 4% articaine (n = 52)</th>
<th>IANB with 4% lidocaine (n = 52)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age*</td>
<td>24.40 ± 4.19</td>
<td>23.46 ± 3.7</td>
<td>24.13 ± 4.21</td>
<td>.473</td>
</tr>
<tr>
<td>Male</td>
<td>28</td>
<td>30</td>
<td>32</td>
<td>.116</td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
<td>22</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Initial mean pain score(\text{\textsuperscript{1}})</td>
<td>2.35 ± 0.48</td>
<td>2.48 ± 0.51</td>
<td>2.33 ± 0.48</td>
<td>.217</td>
</tr>
</tbody>
</table>

*Mean ± standard deviation.
\(\text{\textsuperscript{1}}\) Mean ± standard deviation, HP VAS score.

who was not a part of the study process. This operator had no involvement with the study outcome. The trial adhered to established procedures to maintain separation among the operators.

After administration of the local anesthetic agent to the various test and control groups, subject’s self-reported assessment of pain was recorded on HP VAS. Assessments were done 20 minutes after the local anesthetic administration, following access preparation under rubber dam isolation by using Endo access bur (Maillefer, Dentsply, Ballaigues, Switzerland), and after pulp extirpation by using barbed broach (Medin, Jinsonice, Czech Republic). Success was defined as no pain or weak/mild pain during endodontic preparation and pulp extirpation. If the study subject’s self-reported pain on HP VAS was ≥54 mm during the access preparation or pulp extirpation, the procedure was stopped, the anesthesia was considered unsuccessful, and those subjects were excluded from further analysis in the study.

Analysis was undertaken in SPSS version 15 for Windows (SPSS Inc, Chicago, IL). The tests used were Pearson \(\chi^2\), Student’s paired \(t\) test, 1-way analysis of variance, and Friedman test.

**Results**

Volunteers recruited for the study included 90 men and 66 women. Figure 1 shows the total number of subjects who were enrolled for the trial and those who completed the trial. Table 1 shows the distribution of the study population on the basis of sex, mean age, and initial pain score at baseline. There were no significant differences in age, gender, and initial pain scores among the 3 arms. No adverse reactions were recorded after the 3 anesthetic techniques. All subjects included in the trial had profound anesthesia after 20 minutes. All patients showed a significant decrease in the pain scores after local anesthesia (\(P = .000\)).

Table 2 shows the distribution of the study population in the test and control arms among those who secured successful anesthesia during access preparation and pulp extirpation phase. Among the total 52 participants in each arm, 75% secured successful anesthesia in test arm A compared with 69.2% in test arm B and control arm. Similarly, during pulp extirpation 69.2% of the participants in test arm A secured successful anesthesia when compared with 65.4% participants in test arm B and control arm. However, the differences between the study groups were not statistically significant during access preparation and pulp extirpation phase.

**TABLE 2. Number and Percentage of Successful Anesthesia for 156 Volunteers**

<table>
<thead>
<tr>
<th>End point</th>
<th>Number of patients with successful anesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IANB with 4% articaine (n = 52)</td>
</tr>
<tr>
<td>Access preparation</td>
<td>N</td>
</tr>
<tr>
<td>39</td>
<td>75</td>
</tr>
<tr>
<td>Pulp extirpation</td>
<td>36</td>
</tr>
</tbody>
</table>

**Discussion**

The purpose of this trial was to determine the anesthetic efficacy of 4% articaine in buccal infiltration technique compared with 4% articaine and 2% lidocaine in IANB anesthetic technique.

Lidocaine hydrochloride has maintained its status as the most widely used local anesthetic in dentistry since its introduction. Proven efficacy, low allergenicity, and minimal toxicity through clinical use and research have confirmed the value and safety of this drug. Thus, it became labeled the gold standard to which all new local anesthetics are compared. Despite the gold standard status of lidocaine hydrochloride, numerous reports have advocated the use of articaine hydrochloride as a superior anesthetic agent, primarily on the basis of its enhanced anesthetic potency, which is 1.5 times greater than that of lidocaine, with faster onset and increased success rate (3).

Articaine, which is 4-methyl-3(2-[propylamino]propionamido)-2-thiophene carboxylic acid, methyl ester hydrochloride is the only amide local anesthetic that contains a thiophene ring and an additional ester ring (19). Lipid solubility is an intrinsic quality of local anesthetic potency. This quality permits the easier penetration of the anesthetic through the lipid nerve membrane and surrounding tissues (3). The degree of anesthetic molecules binding to the nerve membrane was suggested to dictate the duration of the anesthetic effect. The more secure a bond is, the slower the anesthetic is released from the receptor sites in the sodium channels, and the greater the duration of the anesthetic effect. As determined by Courtney et al (20), mere lipid solubility of a local anesthetic did not determine the action on the ionic channels. Instead, Uhlein et al (21) determined that binding properties of the local anesthetic agent to plasma proteins have a greater correlation to action on ionic channels than does lipid solubility. Available literature indicates that articaine is equally effective in nerve block and infiltration anesthetic techniques when compared with other local anesthetics including lidocaine with epinephrine, mepivacaine with epinephrine or with levonordefrin, mepivacaine with norepinephrine, and prilocaine with epinephrine (19, 22–33).

Although IANB is the local anesthesia technique of choice when treating mandibular molars, not all IANB injections result in successful pulpal anesthesia (7, 34, 35). The literature provides various explanations to the increased incidence of failure of IANB in patients with irreversible pulps. Initially, it was considered that there might be local acidosis because of tissue inflammation. The most plausible
explanation can be the activation of nociceptors by inflammation (17). Therefore, many studies have sought to improve the success rate of IANB or to identify alternative methods of anesthesia. Buccal infiltration is usually avoided in the mandibular molar regions because the presence of dense cortical bone impedes adequate diffusion of the anesthetic solution (36–38). Recently, Kanaa et al (12) reported that mandibular buccal infiltration is more effective with 4% articaine with 1:100,000 epinephrine than 2% lidocaine with 1:100,000 epinephrine. Hass et al (22) noted success for lower second molar pulpal anesthesia after mandibular buccal infiltration in 63% of subjects with 4% articaine and 53% with 4% prilocaine. Similarly, Yahatalo et al (23) did not find any differences between articaine and lidocaine, although the solutions had different concentrations of adrenaline.

A number of studies showed no significant differences between 4% articaine and 2% lidocaine in IANB, similar to the results of our trial (1, 7, 18). However, none have compared them with buccal infiltration of articaine in mandibular molars with irreversible pulps. The results of the present trial indicate that buccal infiltration of articaine produced success rates similar to that of IANB of articaine and that of lidocaine. Articaine contains a thiophene ring instead of a benzene ring found in lidocaine, which might allow the molecule to diffuse more readily. This speculation is corroborated by the claims that articaine is able to diffuse through soft and hard tissues more reliably than other local anesthetics (13). Our success rate of articaine in infiltration anesthetic technique was 65.4%, which is similar to that reported by Hass et al (24) and Kanaa et al (12).

Pain measurement is difficult to establish, because its perception and intensity are multifactorial, encompassing sensory and effective factors. Quantifying and standardizing pain objectively across a group of individuals can be challenging. Numeric and verbal self-rating scales or behavioral observation scales have traditionally been used in clinical studies. On the basis of their established criteria, the VAS was found to be methodologically sound, conceptually simple, easy to administer, and unobtrusive to the respondent. It has a continuous frequency distribution allowing for rigorous statistical tests on average pain levels. HP VAS is a combined metric scale for pain measurement that provides the subject with multiple cues that might improve communication and concordance between scales for individual pain determination. It integrates irregular spacing of 6 categorical scale descriptive words onto a 170-mm horizontal line. The inventors stressed that patients make categorical judgments on the basis of their understanding of the words, and that the categorical ratings are not an ordinal index (39). Although the HP VAS might show deficiencies regarding understanding and perception, it provides a validated and meaningful measure of anesthetic efficiency; it is used for this purpose by many authors (1).

Different methods have been used to determine pulpal anesthetic success. Bjorn (40) was the first to correlate a negative response to maximum output of electrical pulp stimulation to painless dental treatment. Dreven et al (41) evaluated the electric pulp tester as a measure of pulpal anesthesia before endodontic treatment in teeth with pulp diagnosis of normal, reversible pulps and irreversible pulps. However, in irreversible pulps, the lack of response to vital pulp testing might not guarantee pulpal anesthesia. Hence, recording pain response during access preparation and pulp extirpation is a viable alternative (16, 17).

All the volunteers in this study reported lip numbness after each injection. It should be noted that although all the patients had subjective symptoms of lip numbness, the anesthesia was not successful in all cases. Literature search revealed that this phenomenon is also seen in uninfamed pulps in which, despite successful lip numbness, the clinician failed to get no response to the maximum stimulus on electric pulp testing (42–45). To summarize, on the basis of the results of the present study, it can be concluded that there is no statistically significant difference among IANB and infiltration of articaine when compared with IANB of lidocaine in mandibular molars with irreversible pulpitis. Hence compared with inferior alveolar block, buccal infiltration can be considered a viable alternative to secure pulpal anesthesia for endodontic therapy.

References

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The authors deny any conflicts of interest related to this study.


