Original Article

Efficacy of Articaine Infiltration for Pulp Treatment in Mandibular Primary Molars: A Randomized Split-mouth Clinical Trial

Anchana Areethamsirkul[1], Siriruk Nakornchai[1], Benjamas Apipan[2]

[1]Department of Pediatric Dentistry, Faculty of Dentistry, Mahidol University, Bangkok

[2]Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Mahidol University, Bangkok

Abstract

This clinical trial aimed to compare pain scores and adverse events between buccal infiltration with 4 % articaine with epinephrine 1:200,000 and nerve block with 2 % lidocaine with epinephrine 1:100,000 in pulp treatment in mandibular primary molars. Twenty-six children received pulp treatments on both sides of the mandible with inferior alveolar nerve block with lidocaine and buccal infiltration with articaine in random sequences. Pain scores were assessed during injection and pulp removal by video observation and through participant's self-reporting after the procedure. Additional local anesthesia and adverse events were monitored. The Wilcoxon Signed-Rank test and the McNemar test were used for statistical analysis. Pain scores during injection in lidocaine nerve block (2.4±1.2) and articaine infiltration (1.7±0.9) were significantly different (p=0.002). There was no statistical difference in pain scores during pulp removal, overall pain from self-reporting and additional local anesthesia. One case in each method reported lip biting after treatment. No other adverse events were reported in this study. In conclusion, mandibular infiltration with articaine was not different from inferior alveolar nerve block with lidocaine in pain control and adverse events when performing pulp treatment in mandibular primary molars; however, it provided less pain during injection.

Keywords: Articaine, Infiltration anesthesia, Primary molar, Pulp treatment

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Correspondence to:

Siriruk Nakornchai, Department of Pediatric Dentistry, Faculty of Dentistry, Mahidol University, No. 6, Yothi Road, Ratchathewi District, Bangkok 10400, Thailand Tel: +662-200-7821 Fax: +662-200-7820 E-mail: siriruk.nak@mahidol.ac.th

Introduction

Local anesthesia plays an important role for pain control in dentistry, especially in the pediatric field since pain can directly affect the behavior of children.[1] Inadequate pain control can cause dental fear, anxiety and can lead to behavior disturbance and a negative attitude towards dental treatment in the future.[2] Inferior alveolar nerve block is a common local anesthetic technique used in mandibular teeth with the benefit of widely anesthetized tissue, which is useful for quadrant dentistry. There are several disadvantages of nerve block such as pain during the injection[3,4], prolonged numbness involving lip, tongue and buccal mucosa which lead to self-inflicted soft tissue trauma especially in young children[5], nerve injury, trismus, hematoma and facial nerve paresis.[6] Moreover, it has been found that failure rates of nerve block may range from 44-84 % due to variations of an anatomical landmark.[1,7] Mandibular infiltration showed the potential of tissue anesthetization indifferently to inferior alveolar nerve block with more advantages in several areas such as simplicity of usage, comfort when injected, less opportunity to damage the nerve, and less chance of post-operational soft tissue trauma.[8] Nonetheless, a limited anesthetized area by mandibular infiltration with lidocaine, which is considered as a gold standard of local anesthetic agent[9], showed less effectiveness than inferior alveolar nerve block when treating pulpotomy and extraction in children.[10]

Articaine hydrochloride has been used in dental practice since 1976.[11] It is the only amide anesthetic agent that consists of thiophene ring, which helps increasing lipid solubility and potency. In comparison to lidocaine, the potency of articaine is 1.5 times while its toxicity is only 0.6 times.[9] Studies of mandibular infiltration with 4 % articaine showed similar pulpal anesthesia compared to inferior alveolar nerve block with 2 % lidocaine in adults.[12,13] However, there were only few studies done in mandibular primary molars when treating pulpitis. In addition, none of them studied the adverse events.[7,14] Therefore, this study aimed to compare the efficacy, including pain scores and adverse events, of mandibular buccal infiltration with 4 % articaine with epinephrine 1:200,000 and inferior alveolar nerve and long buccal nerve block with 2 % lidocaine with epinephrine 1:100,000 in pulp treatment in mandibular primary molars.

Materials and Methods

This study was prospective, randomized clinical controlled trial and split mouth design, carried out from March 2017 to May 2018. Ethical approval was given by the institutional review board of the Faculties of Dentistry and Pharmacy, Mahidol University (MU-DT/PY-IRB 2017/012.2802). Trial registration number in clinicaltrials.in.th was TCTR20180221001. The sample size was calculated according to Arali[7], which compared pain scores during access opening in children who received pulp treatment between mandibular buccal infiltration with articaine and inferior alveolar nerve block with lidocaine. The difference in pain scores was 0.2. Therefore, the sample size in this study was 26 for each technique with 90 % power and 0.01 level of significance.

Healthy children aged 4-8 years old were screened from the Department of Pediatric Dentistry, the Faculty of Dentistry, Mahidol University, Bangkok and Pak Phayun hospital, Phatthalung, Thailand. Participants who presented with both sides of primary mandibular first or second molars with extensive dental caries that need pulp therapy and had co-operative behavior (Frankl behavior rating scale 3 or 4) were included in the study. Those who had a history of local anesthetic agent allergy, analgesic medication prior to dental treatment or signs of pulp necrosis such as periapical abscess, tooth mobility or facial swelling were excluded. Participants were randomized to particular treatment sequences either with 2 % lidocaine or 4 % articaine through selecting assigned numbers sealed in an envelope at the beginning of the process. All anesthetic and pulp treatment procedures were done by three postgraduate students, who had the same years of experience in pediatric dentistry. Each participant received treatment from the same operator and was blinded from anesthetic agents and techniques. All the procedures were video recorded. The procedure started from the right side of

the mandible at the first visit. Before injection, topical anesthesia with 20 % benzocaine (Pac Dent®, USA) was applied with cotton pellet at dried soft tissue at the site of injection for 1 minute. Then, the local anesthesia was given with 27-gauge, 21 millimeters needle (Terumo Dental needle®, Japan) with the injection rate of 1 milliliter/minute. After randomization, half of the participants received inferior alveolar and long buccal nerve block with 2 % lidocaine with epinephrine 1:100,000 (Medicaine™, Huons, Korea) 1.8 ml in their first dental visit, followed by buccal infiltration with 4 % articaine with epinephrine 1:200,000 (Septanest®N, Septodont, Canada) 0.8 ml at mucobuccal fold near the apex of the root and indirect injection of lingual soft tissue through interdental papilla distally to the treated tooth 0.3 ml during their second dental visit with at least 1-week interval. The other half of participants received treatment with alternate sequences. The local anesthesia was confirmed by participants' reporting of soft tissue numbness and probing at buccal and lingual sulcus of the treated tooth. Thereafter, rubber dam isolation was placed and pulpotomy or pulpectomy were performed. Pulpotomies were done in the teeth that were diagnosed with reversible pulpitis, while teeth with irreversible pulpitis were treated by pulpectomies. If inadequate pain control occurred, additional intrapulpal injection would be given. After all the procedures had been done, participants were asked to assess pain using the Faces Pain Scale-Revised (FPSR) [15] as shown in Figure 1. The pain scale was rated from 0 to 10; in which 0 indicated no pain and 10 indicated the most severe pain.

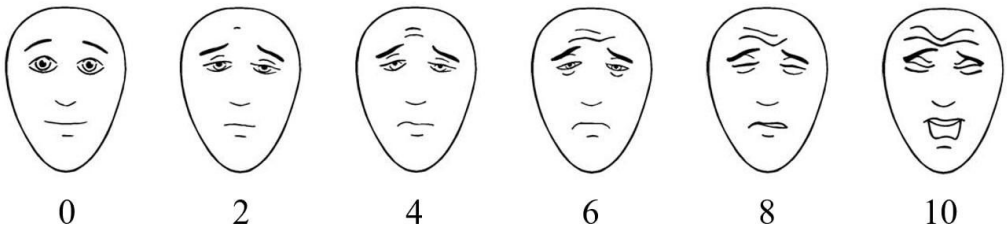

Figure 1 *Faces pain scale–revised.*

Complications were monitored during injection, after injection, after treatment and 24 hours after treatment via phone call. The video was cut into two parts: during injection of local anesthesia and during access opening and pulp removal, then labeled with code. The sound-eye-motor (SEM) score[16] as shown in Table 1 was evaluated by two blinded independent observers. Ten cases were used for the calibration of SEM score to ensure the reliability of examiners at a 2-week interval. When the scores were different, further discussion was done.

Table 1 *SEM pain scale.*

Observations	1 comfort	2 mild discomfort	3 moderately painful	4 painful
Sounds	No sounds indicating pain	Non-specific sounds; possible pain indications	Specific verbal complaints "OW" raises voice	Verbal complaint indicates intense pain e.g. scream, sobbing
Eyes	No eye signs of discomfort	Eye wide, show of concern, no tear	Watery eyes, eyes flinching	Crying, tears running down face
Motor	Hands relaxed no apparent body tenseness	Hands show some distress or tension	Random movement of arms or body without aggressive intention of physical contact, grimace, twitch	Movement of hands to make aggressive contact, e.g. punching, pulling head away

Statistical analysis

All data were processed by SPSS software (24.0, SPSS Inc., Chicago Ill, USA). Inter-examiner and intra-examiner reliability were tested by Cohen's Kappa statistics and results were 0.88 and 1 respectively. Wilcoxon Match-Pairs Signed-Rank test was used to analyze the difference of pain scores from video observation during injection and pulp removal as well as participants' self-reporting between the two local anesthetic techniques. The pain scores using the same local anesthetic technique with different time sequences was analyzed by Mann-Whitney U test. The McNemar test was used to compare the need of additional local anesthesia. A *p*-value less than 0.05 was accepted as a statistical significance.

Results

In this study, twenty-six participants, 13 boys and 13 girls, ages ranging from 4 to 7 years old (average 5.2±0.7 years) were included. One participant reported having the history of dental injection prior to the study. Sixteen mandibular first primary molars and 36 mandibular second primary molars were analyzed. Baseline variables are shown in Table 2.

Pain score during injection in lidocaine nerve block and articaine infiltration were statistically significant (p=0.002). On the contrary, pain scores during pulp removal and participant's self-reporting were not significantly different (p=0.115 and p=0.109). All pain scores are shown in Table 3.

Considering the effect of the tooth location, there were 18 participants who received treatment in the same tooth location in both sides of the mandible. The pain score during injection also showed the significant difference between articaine infiltration and lidocaine nerve block (p=0.004). Whereas, pain score during pulp removal and self-reported pain score were not different between articaine infiltration and lidocaine nerve block (p=0.396 and p=0.356) shown in Table 4.

Since the numbers of treatments in both groups were different, comparison of the same treatments was analyzed as shown in Table 5. Eight participants received pulpotomy and six participants received pulpectomy on both sides of the mandible. Pain scores during pulp removal and participant's self-reporting were not different between articaine infiltration and lidocaine nerve block.

The comparisons of pain scores using the same local anesthetic technique with different time sequence were shown in Table 6. There were no differences between the first and the second dental visits in both lidocaine nerve block and articaine infiltration.

There were 2/26 (7.7 %) cases in lidocaine nerve block and 3/26 (11.5 %) cases in articaine infiltration that required additional local anesthesia, which were not significantly different (p=1.000). There was one case in each method who reported self-inflicted soft tissue trauma at the lower lip after treatment. No other immediate and one day post-operative adverse events were found in this study.

Table 2 *Number of tooth types and pulp treatments in different local anesthetic techniques.*

Variables	Lidocaine nerve block	Articaine buccal infiltration	*p*-value
Tooth			
- First mandibular primary molar	7	9	0.727
- Second mandibular primary molar	19	17	
Treatment			
- Pulpotomy	10	18	0.039*
- Pulpectomy	16	8	

**statistically significant (p<0.05), McNemar's test*

Table 3 *Mean±SD of pain scores in different local anesthetic techniques.*

Procedures	Pain scores (mean±SD)		*p*-value
	Lidocaine nerve block	Articaine buccal infiltration	
Injection	2.4±1.2	1.7±0.9	0.002*
Pulp removal	1.8±1.0	1.5±0.8	0.115
Self-reported	1.3±1.7	0.7±1.3	0.109

**statistically significant (p<0.05), Wilcoxon match pairs Signed-Rank test*

Table 4 *Pain scores of the same tooth location in different local anesthetic techniques.*

Procedures	Pain scores (mean±SD)		*p*-value
	Lidocaine nerve block	Articaine buccal infiltration	
Injection	2.7±1.2	1.9±1.0	0.004*
Pulp removal	2.0±1.1	1.8±0.8	0.396
Self-reported	1.4±1.8	1.0±1.4	0.356

**statistically significant (p<0.05), Wilcoxon match pairs Signed-Rank test*

Table 5 *Comparison of pain scores in different local anesthetic techniques base on treatments.*

Treatments	Pain scores (mean±SD)		*p*-value
	Lidocaine nerve block	Articaine buccal infiltration	
Pulpotomy (8 cases)			
- Pulp removal	1.8±1.0	1.6±0.9	0.581
- Self-reported	0.8±1.0	1.0±1.5	0.739
Pulpectomy (6 cases)			
- Pulp removal	2.3±1.3	1.3±0.8	0.180
- Self-reported	1.0±1.7	0.0±0.0	0.066

**statistically significant (p<0.05), Wilcoxon match pairs Signed-Rank test*

Table 6 *Comparison of pain scores in different local anesthetic techniques base on visit sequence.*

Local anesthetic techniques	Pain scores (mean±SD)		*p*-value
	1st visit	2nd visit	
Lidocaine nerve block			
- Injection	2.4±1.2	2.4±1.3	0.815
- Pulp removal	2.0±0.9	1.7±1.1	0.185
- Self-reported	1.4±1.5	1.2±1.9	0.570
Articaine infiltration			
- Injection	1.7±0.8	1.8±1.1	1.000
- Pulp removal	1.5±0.7	1.5±0.8	1.000
- Self-reported	0.9±1.3	0.5±1.2	0.235

**statistically significant (p<0.05), Mann-Whitney U test*

Discussion

Pain was subjective and depended on an individual's experience.[14,17] This study was designed as the prospective randomized split mouth with at least 1-week wash out period, which minimized carryover effects. However, the carryover effect could not be completely eliminated. The same local anesthetic technique with different time sequences was statistically analyzed. We found no difference between the two different dental visits. Thus all data could be used in this study.

The local anesthetic technique used in this study was buccal infiltration with lingual indirect injection through interdental papilla, which has not been used in the previous studies.[7,14] The reason of indirect lingual injection is that buccal infiltration cannot provide adequate lingual soft tissue numbness, which is needed when performing pulp treatment with rubber dam isolation and restored with a full stainless steel crown.[18,19] The amount of articaine used in this study was 0.8 ml which is the lowest amount that could be effectively used in pulp treatment of mandibular primary molars.[14]

Pain assessment in this study focused on two aspects. First, the pain reported by participants, which is considered as the gold standard for pain evaluation.[15,20] FPSR was a scale that showed the highest validity and appropriateness for the participants' age in the study.[15] Another aspect for pain evaluation was also used, since children might have limitations when reporting their pain. Observational assessment with the SEM pain scale via video was done during injection and pulp removal. The SEM pain scale was suitable for monitoring participants when receiving dental treatment with great reliability.[16] Video was repeatable and observers should be blinded from the local anesthesia methods when evaluating the SEM pain scale during pulp removal. However, the injection technique could not be blinded when evaluating the SEM pain scale during injection because the different position of needle insertion.

Pain assessment by the SEM pain scale during injection in this study showed significant lower pain score of articaine buccal infiltration compared to lidocaine nerve block. The similar results were also found in previous studies.[7,14,21] More pain might be obtained with nerve block because of deeper tissue penetration and a higher amount of local anesthetic agent used compared to buccal infiltration.[22] On the contrary, one parallel randomized controlled trial found that the pain during injection was not different.[23] In addition, use of topical anesthesia before injection in a different site may affect pain. Mucosal dryness of the inferior alveolar nerve block area is more difficult than that of the buccal area. In our study, we were aware of the effect so we controlled dryness at both areas before applying topical anesthetic gel to maintain the efficacy of topical anesthesia.

Although, the number of pulpotomy and pulpectomy between the two groups were different but both treatments needed pulp removal. Pain scores during pulp removal and participant's self-reported overall pain were not different in this study, similar to the results of one previous study.[23] However, some studies showed a lower pain score of articaine infiltration compared to lidocaine nerve block during pulp removal[7,14] and participant's self-reporting.[7,14,21] This might result from the differences in the protocol of the studies, such as the different ages of the participants, the amount of local anesthesia used and the pain assessment methods.

The need of additional local anesthesia was found only in the second primary mandibular molars in all five cases, which later received profound anesthesia after additional intrapulpal injection. This might be due to the density of the bone, which can decrease the penetration of local anesthesia.[16] Moreover, this study used 0.8 milliliters for buccal infiltration which was the earlier reported minimum amount of local anesthesia.[14] Increasing the amount of local anesthetic agent could be considered when using articaine infiltration to provide better pain control compared to lidocaine nerve block.[7] Even though one paralleled study showed no difference when using a higher amount of local anesthesia.[23] The unsuccessful anesthesia of the inferior alveolar nerve block might be explained by the anatomical variation

of the mandibular foramen. Repeating the local anesthesia or a supplemental injection should be done to enhance the success rate of this technique.[24]

Immediate adverse events were not found in this study. The follow up protocol was designed to monitor via telephone for convenience and practical reasons. The only adverse event found in this study was lower lip biting in one case of each local anesthetic method. Both participants reported lip biting after receiving the first dental injection at the second primary mandibular molars. This result may demonstrate that not only infiltration, but also modified mental nerve block might be obtained after articaine infiltration which led to the numbness of the lower lip.[25] Similarly, the incidence of soft tissue injury was one out of forty-nine cases in both lidocaine and articaine injections in the previous parallel randomized controlled trial.[23] Therefore, postoperative advice of self-inflicted soft tissue trauma should be given even after buccal infiltration. No other adverse events were found in this study.

Conclusion

Buccal infiltration with articaine could be effectively used in pulp treatment of mandibular primary molars, with less pain during injection compared to nerve block with lidocaine. Postoperative advice of possible self-inflicted soft tissue trauma should be given after buccal infiltration.

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The author declares no conflict of interest.

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