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Comparative Efficacy of Buccal Infiltration Anesthesia with 4% Articaine versus Inferior Alveolar Nerve Block With 2% Lidocaine for Extraction of Primary Mandibular Molars: A Randomized Clinical Trial

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Abstract

Background and Aim: This study aimed to compare the efficacy of buccal infiltration anesthesia (BIA) with 4% articaine versus inferior alveolar nerve block (IANB) with 2% lidocaine for extraction of primary mandibular molars.

Materials and Methods: This single-blind randomized controlled clinical trial evaluated 100 children between 4-8 years requiring extraction of primary mandibular molars. The children were randomly assigned to two groups (n=50) of IANB with 2% lidocaine and 1:100,000 epinephrine (control), and BIA with 4% articaine and 1:200,000 epinephrine. The Wong-Baker Faces Pain Rating Scale (WBFPS) and the Face, Legs, Activity, Cry, and Consolability (FLACC) scale were used to assess the analgesic efficacy of each technique, and the resultant behavioral reaction of children. Data were analyzed by the Mann-Whitney, Chi-square, and independent t-tests (alpha=0.05).

Results: In total, 43 girls and 57 boys with a mean age of 6.59±1.20 years were evaluated. The mean FLACC score was 0.98 in the lidocaine and 1.44 in the articaine group with no significant difference (P=0.246). The mean WBFPS score was significantly higher in the articaine than in the lidocaine group (P=0.039), but the difference between the two groups separately for each tooth type was not significant (P>0.05).

Conclusion: Despite the significantly lower pain score of the IANB with lidocaine group, BIA with 4% articaine was comparable to IANB with 2% lidocaine in behavioral control of children, and may be considered as an acceptable alternative.

Keywords: Anesthesia, Local; Articaine; Lidocaine; Mandibular Nerve; Nerve Block

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Introduction

Tooth extraction is an invasive procedure. Thus, adequate depth of local anesthesia is highly important for anxiety reduction and behavioral control of children during the procedure. Local anesthetic agents are commonly used for this purpose. Although local anesthetic injection triggers pain, anxiety, and a negative response in children, it is imperative for the provision of a painless treatment. Thus, dental clinicians have always been in search of novel techniques to ease the procedure of anesthetic injection for pediatric dental patients [1, 2].

Several techniques have been proposed to minimize the pain and discomfort associated with local anesthetic injection, such as computer-assisted injection, precooling of the injection site, warming or buffering of the anesthetic agent, and vibration or compression of the injection site. Nonetheless, no consensus has been reached on the most effective technique for this purpose [3, 4].

Inferior alveolar nerve block (IANB) is commonly administered for local anesthesia of primary mandibular molars. Its main advantage is anesthesia induction in a large area. Nonetheless, it is associated with the highest level of discomfort compared with other local anesthesia techniques, which adversely affects the behavior of children. Also, the risk of damage to desensitized tissues as the result of accidental biting and ulceration exists, particularly in children. Furthermore, this technique has a higher failure rate than other techniques, ranging from 44% to 84% due to anatomical variations [5]. Thus, many dental clinicians prefer to use an alternative technique because the level of discomfort experienced by children during an IANB complicates their behavioral control [1].

Buccal infiltration anesthesia (BIA) was first suggested as an alternative technique for desensitization of primary mandibular molars by McCallum [6]. According to Kaufman et al. [7], this method has much lower pain than IANB. Also, this technique is associated with a lower risk of traumatization of the inferior alveolar nerve trunk and lingual nerve, and therefore, adverse complications such as trismus and non-surgical paresthesia are prevented [8, 9]. This technique is also preferred to IANB in hemophilic patients due to the lower risk of aspiration and hemorrhage [10]. However, its efficacy for procedures such as pulpotomy and tooth extraction is still a matter of question [11, 12].

Lidocaine is the most commonly used anesthetic agent [3]. It is an amidic anesthetic agent with a pH of around 3.5. It has acceptable efficacy and insignificant side effects and toxicity. Thus, it remains the gold standard anesthetic agent [1].

Articaine (Septocaine) is an amidic anesthetic agent that has gained recent popularity among dental clinicians. It is used in 4% concentration, which is double the regular concentration of 2% lidocaine (xylocaine). Several studies have reported the superior efficacy of articaine compared to lidocaine [13, 14]. However, the majority of such studies have been conducted on adult populations, and data obtained from clinical trials on pediatric dental patients are inconclusive [1].

Tong et al. [15] in their systematic review and meta-analysis on the anesthetic efficacy of articaine versus lidocaine in children pointed to significant differences in the reported results and a high risk of bias in the methodology of the reviewed studies. Also, Tirupathi and Rajasekhar [16] in their systematic review on the efficacy of BIA with 4% articaine for extraction of primary molar teeth called for further evidence to reach a final judgment in this regard.

Considering the gap of information regarding the efficacy of BIA with 4% articaine for extraction of primary mandibular molars in children as an alternative to IANB with 2% lidocaine, this study aimed to compare the efficacy of BIA with 4% articaine versus IANB with 2% lidocaine for extraction of primary mandibular molars. The null hypothesis of the study was that no significant difference would be found in the analgesic efficacy of BIA with 4%

articaine versus IANB with 2% lidocaine for extraction of primary mandibular molars.

Materials and Methods

This study was conducted at the Pediatric Dentistry Department of Shahid Beheshti Dental School between March 2021 and March 2022. The study protocol was approved by the ethics committee of the university (IR.SBMU.DRC.REC.1400.107) and registered in the Iranian Registry of Clinical Trials (IRCT20220129053868N1).

Trial design:

A single-blind randomized controlled clinical trial was designed in which the experimental group received BIA with 4% articaine while the control group received IANB with 2% lidocaine for extraction of primary mandibular molar teeth. The results were reported in accordance with the criteria of the Consolidated Standards of Reporting Trials.

Participants, eligibility criteria, and settings:

The inclusion criteria were 4-8-year-old children with a primary mandibular molar requiring extraction, systemic health (ASA I and II), speaking Farsi, no history of edema or pain, and no active abscess related to the respective tooth, Frankl behavior rating scale (FBRS) 3 and 4, the willingness of the child and parents for cooperation and participation in the study, no physical or mental retardation, and no infection at the injection site.

The sample consisted of 4-8-year-old children presenting to the pediatric dentistry private offices in Tehran, Iran, who were selected by convenience sampling.

Interventions:

Written informed consent was obtained from the parents prior to the procedure and study enrollment of their children. The maximum safe dosage of each anesthetic agent for each child was calculated based on the weight of the children according to the Malamed Handbook of Local Anesthesia [3], which was 5 mg/kg for articaine and 4 mg/kg for lidocaine.

In the experimental (articaine) group, one 1.8 mL cartridge of 4% articaine hydrochloride with 1:200,000 epinephrine (Dentacain, Exir, Iran) was injected at the vestibular depth adjacent to the apex of the respective mandibular molar tooth as BIA. The last few drops were then injected into the mesial and distal papillae of the respective tooth with pressure, causing a white color shift in the tissue [17].

In the control (lidocaine) group, one 1.8 mL cartridge of 2% lidocaine hydrochloride plus 1:100,000 epinephrine (Xylopen, Exir, Iran) was injected for IANB, and the last few drops were injected into the buccal mucosa and distal of last molar tooth parallel to the occlusal plane [3]. A self-aspirating metal dental syringe with a 27-gauge needle (AVA Dental Injection, Ava Pezeshk, Iran) was used for the injections, and the injections were performed at a standard speed of 1 mL/min.

The behavioral control methods such as verbal distraction, non-verbal distraction, and the tell-show-do technique were used during injections and also during the procedure. All interventions were performed by a pediatric dentist. Signs of soft tissue anesthesia were evaluated 10 minutes after BIA with articaine, and 15 minutes after IANB with lidocaine. Soft tissue anesthesia was ensured by asking the children and probing the buccal and lingual crevices [18]. After reaching the adequate depth of anesthesia, the extraction procedure was performed. The treatment was stopped if the child had any pain or discomfort, and a supplemental PDL injection or a conventional IANB was administered, the treatment was accomplished, and the child was excluded from the study [1].

The FBRS was used to analyze the behavior of children prior to the procedure, the Wong-Baker Faces Pain Rating Scale (WBFRS) was used for subjective post-extraction quantification of the level of pain experienced by children, and the Face, Legs, Activity, Cry, Consolability (FLACC) scale was used for objective assessment of pain [1].

Children with FBRS scores 3 and 4 were enrolled while those with FBRS scores 1 and 2 were excluded. Prior to using the WBFRS, the children verbally received the instructions on how to use it and were asked "How painful was the procedure?". They were then asked to report the level of pain they experienced during the procedure by selecting a face that best described their pain level [1]. For using the FLACC scale, the researcher stood at a 1.5 m distance from the child during the procedure and recorded the score for each parameter in the range of 0-2, yielding a total score of 0-10 [4].

Outcomes (primary and secondary):

The main objective of this study was to compare the anesthesia efficacy of BIA with 4% articaine versus IANB with 2% lidocaine for extraction of primary mandibular molars. There was no secondary outcome.

Sample size calculation:

The sample size was calculated to be 50 children in each group (a total of 100) according to a previous study [1] assuming alpha=0.05, beta=0.2, and study power of 80%.

Interim analyses and stopping guidelines:

No interim analyses were performed and no stopping guidelines were established.

Randomization:

The children were randomly assigned to the experimental and control groups by the permuted block randomization method. For this purpose, the blocks were arranged as follows: block 1: ABAB, block 2: AABB, block 3: ABBA, block 4: BBAA, block 5: BABA, and block 6: BAAB. The R software was then used to randomly select a number between 1-6. For instance, if blocks 6 and 2 were selected as the first and second blocks, respectively, AABB and BAAB blocks were assigned to the first 8 patients enrolled in the study, such that A indicated BIA with 4% articaine hydrochloride with 1:200,000 epinephrine along with inter-papillary injection, and B indicated IANB with 2% lidocaine hydrochloride with 1:100,000 epinephrine along with the long buccal injection. The number of patients receiving each type of intervention was the same (n=50).

Blinding:

Since the local anesthesia technique was different for the two groups, blinding of the operator was not possible. However, the children and the statistician who analyzed the data were blinded to the type of intervention and group allocation.

Statistical analysis:

The two groups were compared for quantitative variables with a normal distribution (i.e., age) by independent t-test and for nominal qualitative variables (i.e., gender, type of extracted tooth, and FBRS score) by the Chi-square test. The FLACC and WBFRS scores were compared between the two groups by the Mann-Whitney test due to the non-normal distribution of data or their ordinal type. All statistical analyses were performed using SPSS version 26 at a 0.05 level of significance.

Results

Participant flow:

The sample consisted of 100 children including 43 girls and 57 boys with a mean age of 6.59±1.20 years (range 4 to 8 years). There were 20 girls (40%) and 30 boys (60%) in the articaine group, and 23 girls (46%) and 27 boys (54%) in the lidocaine group. The Chi-square test showed no significant difference in gender distribution between the two groups (P=0.686). The mean age of children was 6.57±1.20 years in the articaine group and 6.61±1.23 years in the lidocaine group with no significant difference according to the independent t-test (P=0.870).

Table 1 presents the frequency distribution of the type of treated tooth in the two groups, which was not significantly different (P=0.902). Figure 1 shows the CONSORT flow diagram of patient selection and allocation. Due to inadequate depth of anesthesia, 5 children (10%) were excluded from the lidocaine group, and 4 children (8%) were excluded from the articaine group.

Harms:

No patients were harmed during the study.

Subgroup analysis:

Primary outcome:

Subjective pain assessment by WBFRS: Table 2 presents the level of pain experienced by children in the two groups according to the WBFRS. As shown, the level of experienced pain was significantly higher in the BIA with the articaine group than IANB with the lidocaine group (Mann-Whitney test, P=0.039). However, the difference in this regard between the two groups was not significant when the first and second primary molar teeth were separately compared (P>0.05).

Objective pain assessment by FLACC scale: As indicated in Table 3, the mean pain score in the articaine group was slightly, but not significantly, higher than that in the lidocaine group (Mann-Whitney test, P=0.246). The difference between the two groups based on tooth type was not significant (P>0.05).

Table 1. Frequency distribution of type of treated tooth in the two groups

Tooth type	Articaine group Number (%)	Lidocaine group Number (%)	Total Number (%)	P-value
Right D	14 (28%)	12(24%)	26(26%)	
Right E	6(12%)	8(16%)	14(14%)	
Left D	18(36%)	20(40%)	38(38%)	0.902
Left E	12(24%)	10(20%)	22(22%)	
Total	50(100%)	50(100%)	100(100%)	

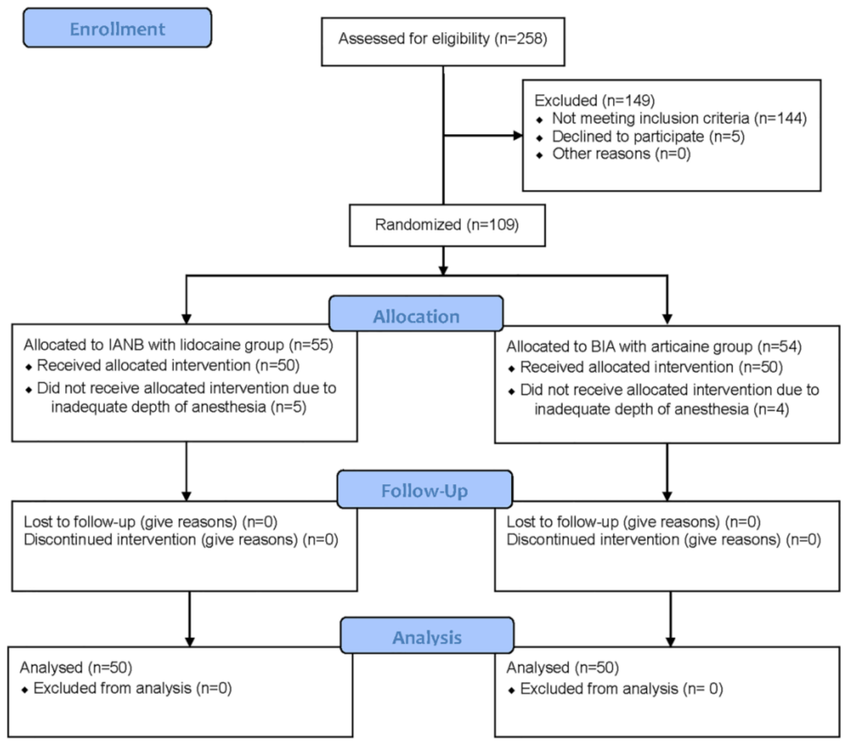

Figure 1. CONSORT flow diagram of patient selection and allocation

Table 2. Level of pain experienced by children in the two groups according to the WBFRS

Tooth type		Group		Total N(%)
		Articaine N(%)	Lidocaine N(%)	
D	No pain	11(34.4%)	16(50%)	27(42.2%)
	Mild pain	11(34.4%)	10(31.3%)	21(32.8%)
	Moderate pain	10(31.3%)	4(12.5%)	14(21.9%)
	Severe pain	0(0)	2(6.3%)	2(3.1%)
Ordinal mean		35.22	29.78	P= 0.213
E	No pain	8(44.4%)	12(66.7%)	20(55.6%)
	Mild pain	3(16.7%)	4(22.2%)	7(19.4%)
	Moderate pain	5(27.8%)	2(11.1%)	7(19.4%)
	Severe pain	2(11.1%)	0(0)	2(5.6%)
Ordinal mean		21.22	15.78	P=0.086
Total	No pain	19(38%)	28(56%)	47(47%)
	Mild pain	14(28%)	14(28%)	28(28%)
	Moderate pain	15(30%)	6(12%)	21(21%)
	Severe pain	2(4%)	2(4%)	4(4%)
Ordinal mean		56.08	44.92	P= 0.039

Table 3. Pain score of patients in the two groups according to the FLACC scale

Tooth type	FLACC	Group		Total N(%)
		Articaine N(%)	Lidocaine N(%)	
D	0	12(37.5%)	13(40.6%)	25(39.1%)
	1	10(31.3%)	8(25.0%)	18(28.1%)
	2	3(9.4%)	8(25.0%)	11(17.2%)
	3	5(15.6%)	3(9.4%)	8(12.5%)
	4	1(3.1%)	0(0.0%)	1(1.6%)
	5	1(3.1%)	0(0.0%)	1(1.6%)
Ordinal mean		33.36	31.64	P=0.699
E	0	6(33.3%)	8(44.4%)	14(38.9%)
	1	3(16.7%)	4(22.2%)	7(19.4%)
	2	4(22.2%)	6(33.3%)	10(27.8%)
	3	1(5.6%)	0(0.0%)	1(2.8%)
	4	2(11.1%)	0(0.0%)	2(5.6%)
	5	2(11.1%)	0(0.0%)	2(5.6%)
Ordinal mean		20.83	16.17	P=0.164
Total	0	18(36.0%)	21(42.0%)	39(39.0%)
	1	13(26.0%)	12(24.0%)	25(25.0%)
	2	7(14.0%)	14(28.0%)	21(21.0%)
	3	6(12.0%)	3(6.0%)	9(9.0%)
	4	3(6.0%)	0(0.0%)	3(3.0%)
	5	3(6.0%)	0(0.0%)	3(3.0%)
Ordinal mean		53.72	47.28	P=0.246

Discussion

Evidence shows that IANB is among the most painful dental injections, especially in children [19-21]. Articaine may be used for local infiltration anesthesia by using a small injection needle. Its injection volume is small and it is less painful than an IANB [22, 23]. Low toxicity, good local infiltration, and high biological safety are among the advantages of articaine. Also, it has a high success rate in dental infiltration anesthesia [24].

This study compared the efficacy of BIA with 4% articaine versus IANB with 2% lidocaine for extraction of primary mandibular molars. The null hypothesis of the study was that no significant difference would be found in the analgesic efficacy of BIA with 4% articaine versus IANB with 2% lidocaine for extraction of primary mandibular molars. The results showed that the mean WBFPS score was significantly higher in the articaine than in the lidocaine group but the difference in FLACC score was not significant between the two groups. Thus, the null hypothesis of the study was partially accepted and partially rejected.

Some previous studies reported higher efficacy of IANB with 2% lidocaine compared with BIA with articaine for procedures like pulpotomy and tooth extraction [11, 12]. Chen et al. [25] in their systematic review concluded that single buccal infiltration anesthesia with articaine was effective for the extraction of primary molars. Although articaine resulted in better anesthesia, its difference with lidocaine was not clinically important. In general, they concluded that evidence was poor in this regard and called for randomized clinical trials with a larger sample size in this respect. Also, Ghaffari et al. [17] stated that infiltration anesthesia with articaine was a better alternative to IANB for the extraction of primary mandibular molars.

The presence of a thiophene ring instead of a benzene ring (present in the chemical structure of lidocaine) increases the lipid solubility and anesthetizing efficacy of articaine compared with other anesthetic agents including lidocaine (1.5 times more potent than lidocaine) [6]. Unlike other amidic anesthetic agents, the bio-transformation of articaine occurs in both the liver and plasma, and therefore, it is metabolized fast within 30 to 60 minutes. Hydrolysis of articaine by blood esterases decreases its toxicity [18, 26].

Mittal et al. [27] reported that blinking, movements, and crying had a higher frequency during lidocaine infiltration compared with articaine infiltration. The pharmacokinetics of articaine is responsible for its optimal lipid solubility and potency [28]. Unlike lidocaine, articaine is commonly used in 4% concentration, since it has comparable analgesic efficacy with lower systemic toxicity in higher concentrations than other analgesic agents [29]. Considering the need for penetration into bone, being able to use a higher concentration of an anesthetic agent is an advantage. Also, due to this advantage, by using a lower volume of articaine, pain during injection and risks of concentration-dependent neurotoxicity can be minimized [18]. Other advantages of BIA with 4% articaine versus IANB with 2% lidocaine include easier administration, anesthetizing a smaller area of soft tissue, and shorter duration of anesthesia because articaine is metabolized both in the plasma and liver; accordingly, risk of incidental biting of the lips, tongue, and cheek by patients after termination of the dental procedure would be minimized [10, 29]. In the present study, 4% articaine with 1:200,000 epinephrine was used for its higher safety margin; although a previous study found no significant difference between 4% articaine with 1:100,000 and 1:200,000 epinephrine regarding hemodynamic parameters [30].

Despite a slightly higher FLACC score in the articaine group, the difference in this regard was not significant between the two groups in the present study, which was in agreement with the results of some previous studies [20, 31]. Similarly, Yassen [32] found no significant difference in the efficacy of BIA and IANB for mandibular canine teeth. However, unlike the present study, Jain et al. [20] used the Modified Behavioral Pain Scale and reported a higher frequency of crying in BIA with the articaine group than IANB with the lidocaine group. Also, Zafarmand et al. [33] reported that the majority of children in their study had eye, hand, foot, and body movements and mostly cried during BIA. This difference in the results may be attributed to the different densities of cortical bone in children of different ages, and the resultant variations in penetration of the injected anesthetic agent into the cortical bone, and subsequently variable levels of lingual soft tissue anesthesia. This is particularly important in interventions such as tooth extraction, which require sufficient soft tissue anesthesia in both the buccal and lingual cortical plates [20]. Ghaffari et al. [17] showed a reduction in all items of sound, eye, and motor scale following BIA with articaine for primary second molar extraction compared with IANB, showing a lower level of children's discomfort during BIA; although the analgesic efficacy of the two techniques was statistically the same.

Subjective pain assessment by the WBFRS in the present study showed significantly higher pain scores in the articaine group but the difference was not significant based on tooth type. Alzahrani et al. [1] reported a lower success rate of BIA with articaine (73.5%) for pulpotomy and extraction of primary molars compared with IANB with lidocaine (79.6%) but the difference did not reach statistical significance. Similarly, Jain et al. [20] found no significant difference between BIA with articaine and IANB with lidocaine according to the WBFRS. Unlike the present study, Arrow [2] reported a higher success rate and lower pain experience in IANB with lidocaine compared with BIA with articaine during restorative interventions in children. Differences in the results may be due to the different mean ages of patients in the study by Arrow [2] (12.4 years) and the present study (6.59 years). Also, the higher success rate in IANB could have been due to the higher experience of the clinician in the administration of IANB [2].

Using both a subjective and an objective scale for pain assessment was a strength of this study because self-reporting the pain level is the most appropriate method for quantification of the experienced pain [1]. However, when it comes to children, an objective scale should also be used to obtain more accurate results [1, 4]. Using the WBFRS was another advantage since it is among the most commonly used scales for pain assessment in children, and has the highest rate of sensitivity and specificity for low scores [34, 35]. Moreover, the two groups had no significant difference in age, gender, and tooth type, which was another strength, eliminating the possible effect of such confounders on the results.

This study had limitations as well. The study population comprised patients presenting to pediatric dentistry offices. Patients presenting to pediatric dentists often have a few negative previous dental experiences or have been referred to a pedodontist by a general dentist due to uncooperative behavior. Also, patients with FBRS 1 and 2 were excluded. Thus, the present study population may not be a true representative of the population of pediatric dental patients. Furthermore, blinding of the assessor was not possible in the present study since the interventions and assessment of behavior and pain of children were all performed by one operator.

Considering the subjectivity of pain perception, and its variations in different individuals, future studies are required to adopt a split-mouth design to eliminate the effect of inter-individual differences in pain perception on the results and increase the validity and reliability of the findings.

Conclusion

Despite the significantly lower pain score in the lidocaine group, BIA with 4% articaine was comparable to IANB with 2% lidocaine in behavioral control of children and may be considered an acceptable alternative.

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