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EFFECTIVENESS OF ARTICAINE INFILTRATION IN ANESTHETIZING PULPOTOMIZED MANDIBULAR SECOND PRIMARY MOLARS(RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Articaine hydrochloride, with its high diffusion ability, could potentially be an alternative to Inferior alveolar nerve block in children due to its effectiveness in mandibular infiltration anesthesia.

AIM: Evaluating the effectiveness of Articaine infiltration versus conventional inferior alveolar nerve block in anesthetizing the second primary mandibular molars indicated for pulpotomy and stainless steel crown treatment, evaluating pain during injection and assessing any side effects occurred within 24 hours.

MATERIALS AND METHODS: Fifty-two healthy children aged 5-6 years, showing cooperative behavior, having at least one mandibular second primary molar indicated for pulpotomy were randomly and equally allocated into two groups according to the technique of anesthesia used. Group I (n =26) was assigned to Articaine infiltration anesthesia, while group II (n = 26) was assigned to the conventional IANB injection. Pain was assessed with physiological method (Heart rate), subjective method modified face pain scale (FPS).

RESULT: There was statistically significant difference in pain between group I and II during injection: the mean HR scores in group I was 109.0±8.45 compared to 117.0±10.26 in group II (p=0.006), and the modified FPS results showed that 50% of the children in group I were satisfied, compared to 0% in group II (p<0.001*). There was no statistically significant difference in pain during pulpotomy and SSC preparation between group I and II either by HR scores or modified FPS.

CONCLUSIONS: Articaine infiltration LA was as effective as IANB in pulpotomy procedures and SSC preparation of mandibular second primary molars and offered significantly less painful injections.

KEYWORDS: Infiltration local anesthesia, Articaine, Pulpotomy, Inferior alveolar nerve block

RUNNING TITLE: Effectiveness of Articaine in anesthetizing mandibular primary molars

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INTRODUCTION

Pain management is a crucial aspect of dentistry, especially with children, as appears discomfort and behavioral issues. Although local anaesthesia is highly efficient for pain management, injections during dental treatment elicit the most adverse reactions in children. Hence, minimal pain experience is essential for promoting future positive behaviour (1).

The inferior alveolar nerve (IAN) block is the predominant technique for administering local anaesthesia in the mandible. However, this approach has been found to have several drawbacks, including chronic paraesthesia with lip and cheek biting particularly in children (1, 2). Moreover, this technique has proved to be the most frustrating technique of all nerve blocks, and the one with the highest rate of clinical failures (approximately 15°to 20%) even when administered correctly. In an attempt to overcome limitations of IANB, infiltration LA, has been suggested as an alternative method, which has certain advantages over the IANB technique, such as a shorter duration, more confined area of soft tissue numbness and a simpler injection process (3).

Lidocaine LA is the benchmark in dentistry, but Articaine is widely used due to its superior properties. It is 1.5 times more powerful and 0.6 times more toxic than Lidocaine LA. Articaine's thiophene ring enhances lipid solubility and efficacy, allowing more dose penetration into neurons. Its better diffusion ensures more effective anesthesia, especially during infiltration of mandibular teeth (3).

For years, Lidocaine LA has long been regarded as the benchmark in dentistry, however presently. Articaine is extensively utilized in comparison to Lidocaine due to its superior properties (3). In comparison to

lidocaine, articaine is 1.5 times more powerful and only 0.6 times more highly toxic (3). Articaine distinct apart from other amide local anaesthetics (LAs) due to the presence of a thiophene ring instead of a benzene ring. The presence of the thiophene ring enhances the lipid solubility and efficacy of a drug, enabling a larger proportion of the supplied dose to penetrate neurons. Another important advantage of Articaine is its better diffusion so it pass through soft and hard tissue with greater reliably compared to the other anaesthetic drugs commonly used in dentistry, which can lead to a more effective anaesthesia (4,5) specially during infiltration of mandibular teeth.

Most of the pediatric dentists are still against the use of the infiltration technique in the mandible. The continued preference of IANB might be influenced by factors such as tradition, familiarity, or fear of ineffective LA.

Many studies have focused on comparing the effectiveness of Articaine infiltration to Lidocaine, rather than exploring Articaine as an anesthetic agent in the inferior alveolar nerve block (IANB) (6-8).

Therefore, the aim of this study was to evaluate the effectiveness of Articaine infiltration compared to the conventional inferior alveolar nerve block.

Additionally, the study aimed to compare the pain reactions of children during the injection, pulpotomy, and placement of stainless-steel crowns in second primary mandibular molars, while also assessing any adverse events occurring within 24 hours post-operatively.

The null hypothesis of the study proposed that there would be no significant difference in the effectiveness of mandibular infiltration local anesthesia versus the conventional inferior alveolar nerve block with 4% Articaine for pulpotomy of mandibular second primary molars and the placement of stainless-steel crowns. It also proposed that there would be no pain during the injection and no side effects observed within 24 hours post-operatively.

MATERIALS AND METHODS

Study design

The study was a two-arm randomized controlled clinical experiment. The study was organized and documented in compliance with the CONSORT criteria (9). The PICOT question was: Does the use of 4% articaine infiltration (Intervention; I) compared to inferior alveolar nerve block with 4% articaine (Control; C) result in different levels of anaesthesia effectiveness during pulpotomy in mandibular primary molars or any difference of pain reaction during injection in pediatric patients aged 5-6 years (Population; P) and if any side effects was encountered within a 24-hour timeframe (Time; T)? (Figure 1)

Study setting and location

The research was conducted in the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Alexandria University, Egypt.

Ethical consideration

The research protocol for this study was approved by the Research Ethics Committee at the Faculty of Dentistry, Alexandria University (IRB NO 0636_2/2023) and was subsequently filed in ClinicalTrials.gov with the identifier: NCT06201949. The procedures were carried out in compliance with the Helsinki Declaration and its subsequent adjustments. The study was reported according to the protocol outlined by the Consolidated Standards of Reporting Trials Statement (CONSORT) checklist (10).

Sample size calculation

Sample size was based on 95% confidence level to detect the difference in pain level during pulp excavation between Articaine infiltration and Articaine inferior alveolar nerve block. Ghadimi et al. (11) reported mean ± SD pain using modified behavioral pain scale during pulp excavation= 3.13±1.86 when Articaine was used in infiltration, and 4.52±2.55 in case of nerve block. The calculated mean ± SD difference= -1.39±2.21, 95% confidence interval= 0.06, 2.72. The required sample size was calculated to be 24 patients per group, increased to 26 to make up for cases lost to follow up.

The total required sample size= number of groups × number per group= 2 × 26= 52 patients (12).

Inclusion criteria

Fifty two healthy children aged 5-6 years, whom their parents provided consent to participate in the study were selected from the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, Egypt. Only cooperative children were selected with Frankl behavior rating scores 3 or 4. Each child selected had at least one mandibular second primary molar indicated for pulpotomy.

Exclusion criteria

Children with any systemic disease or special health care (13), history of allergy to local anaesthesia, radiographic evidence of periapical or inter-radicular radiolucency, patients with previous negative dental experience and presence of soft tissue lesions at the site of injection.

Examiner reliability

Single operator performed all the clinical procedure to ensure standardization in the clinical procedures, child behaviour and technique of injection. A dental assistant was trained to record the HR scores on ten cases not included in the study to insure reliability. Intra-examiner reliability was tested by Intraclass correlation (ICC) (14). The ICC yielded a score of 0.96, which ensured excellent agreement.

Randomization and Allocation Concealment

Participants complying with inclusion criteria were randomly assigned in a parallel group using a

computer – generated list of random numbers to one of the two arms (15).

*Group 1: assigned to articaine infiltration, Group II: assigned to articaine IANB injection

Allocation concealment

Each child included in the study was given a serial number that was used in the allocation. These numbers were written in identical sheets of paper with the group to which each child is allocated and placed inside opaque envelopes carrying the respective names of the children (16). A trial independent personnel was assigned to the role of keeping the envelopes and unfolding them only at the time of the local anaesthesia injection session so that the group the child was allocated to was concealed from the outcome evaluator.

Blinding

During the study, the researcher (operator) who performed all the injections, pulpotomies and SSC as well as the dental assistant who recorded HR measurements could not be blinded to the type of intervention. However, the statistician and the participants were blinded to the treatment groups. Therefore, this clinical trial is double-blinded.

Preliminary screening visit

Full medical and dental history was taken for each patient. Proper diagnosis with thorough clinical examination, and intraoral periapical radiograph of the tooth to be restored was done to ensure that the patient matched the inclusion criteria. During this visit the child was introduced to the dental unit and dental instruments using 'Tell Show Do' technique. No treatment was done to the child in order to build a strong patient-dentist relationship.

Intervention Visit

The anaesthesia administration process was explained to all the participants in simple terminology. The study involved anesthesia administration for dental procedures involving pulpotomy and SSC restorations. For both groups, Soft tissues were dried and 20% Benzocaine topical anaesthetic gel was applied. Local anaesthetic was injected by a single researcher for all patients. For both group infiltration was perfomed with 4% articaine and epinephrine 1/100000 (Artinibisa, Inbisa, Barcelona, Spain) for all patients in group 1 on their second primary molar. Approximately 25% to 33% of the cartridge had slowly discharged. A lingual infiltration was conducted to aid with the placement of rubber dam clamp, while conventional IANB was performed with 4% Articaine and epinipherine 1/100000 (Artinibisa, Inbisa, Barcelona, Spain) for all patients in group II using a 27-gauge dental disposable needle (C-KJet, CK Dental Ind, Co., LTD., Korea) was used.

After three to five minutes, treatment was started and numbness in the lower lip indicated that anesthesia has begun (17).

The assessment of numbness involved inserting a dental probe on gingiva at 30 seconds intervals and monitoring the occurrence of tingling in the lower lip. The procedure was performed according to AAPD guidelines (18-21). All carious teeth, other than those included in the study, were restored in subsequent visits for ethical considerations.

Outcome assessment

In this study, Pain experience during injection, pulpotomy and stainless steel crown was measured by two parameters :(1) Physiological parameter using heart rate (22): using the pulse oximeter and it was placed on the patient's index finger. Measurements were taken at four time points: Baseline measurements before LA, during injection, pulpotomy, and SSC procedure. (2) **Subjective parameter**: using a modified face pain scale (FPS) developed by Maunuksela et al. (23). This scale has three facial expressions that represent distinct states: (a) satisfaction, (b) indifference, (c) dissatisfaction. After each procedure, child selected the face that expressed their instant response towards each procedure

Assessment of occurrence of adverse event

All parents were followed up after 24 hours following the restorative procedures via phone calls to check if there are any post-operative adverse events such as lip biting or other unfavourable incidents.

Statistical analysis

Normality was checked for all quantitative variables using descriptive statistics, Q-Q plots, Histogram, and Shapiro-Wilk normality test. Data was found to be not normally distributed so median, inter-quartile range (IQR), minimum, and maximum values were calculated. Mean age and heart rate between both groups were compared using Mann- Whitney U test. While Wilcoxon signed – rank test was used for comparisons within each group. Qualitative data were expressed as frequencies and percentages and Pearson chi square test was used to compare gender and adverse effects between both groups. Fisher exact test was used to compare pain using the modified face scale between study groups using different dental procedures. Significance was inferred at p value < 0.05. Data were analysed using R statistical software (R version 4.2.0, March 1, 2023).

RESULTS

The study had a total of 52 children participated with 26 of each were assigned to the Group I and 26 assigned to Group II. The mean age of children assigned to group I was 5.44±0.51, whereas those assigned to group II were 5.36±0.49. In group I 53.8% were female and 46.2% were males, in group II 46.2% children were females and (53.8% were males. No statistically significant difference in age or gender was noted between the test and control groups ($p = 0.55$) and ($p = 0.58$) respectively. (Figure 2)

The results of the heart rate readings are displayed in Table 1 and Figure 3

There was no significant difference in the mean baseline HR between group I 79.19±3.44 and group II 80.58±9.45 (p=0.353). There was a significant difference in the mean HR during injection between group I and group II: 109.0±8.45 and 117.0±10.26 respectively. (p=0.006). The mean HR during pulpotomy in group I and II was 80.65±3.29 and 82.50±9.75, respectively, with no significant difference detected between the two groups (p=0.353). The mean HR during SSC preparation in group I and II was 82.15±3.12 and 83.65±7.36, respectively, with no significant difference determined between the two groups (p=0.402).

The Results of modified FPS Findings are displayed in Table 2 and Figure 4

During Anaesthesia: In group I 50% of children were satisfied, 42.3% were indifferent, and 7.7% were dissatisfied. In group II 0% were satisfied, 53.8% were indifference, and 46.2% were dissatisfied. There was a significant difference observed between the two groups (***p<0.001****). During Pulpotomy: In group I 53.8% of children were satisfied, 46.2% were indifferent, and 0.0% were dissatisfied. In group II 50.0% were satisfied, 46.2% were indifference, and 3.8% were dissatisfied. There was no statistically significant difference observed between the two groups (p=1.000). During SSC Preparation: In group I 76.9% of children were satisfied, 23.1% were indifferent, and 0.0% were dissatisfied. In group II 76.9% of children were satisfied, 23.1% were indifferent, and 0.0% were dissatisfied. There was no significant difference observed between the two groups (p=1.000)

Table 1: Comparison of heart rate between study groups before and after administering different procedures

		Group I (n = 26)	Group II (n = 26)	*P* value
Baseline (a)	Mean ± SD	79.19 ± 3.44	80.58 ± 9.45	**0.353**
	Min – Max	69.0 – 89.0	73.0 – 103.0	
	Median (IQR)	79.0 (78.0 – 80.0)	78.50 (74.0 – 82.0)	
During injection (b)	Mean ± SD	109.0 ± 8.45	117.0 ± 10.26	**0.006***
	Median (IQR)	109.0 (100.0 – 115.0)	119.0 (112.0 – 120.0)	
	Min – Max	99.0 – 125.0	100.0 – 135.0	
During Pulpotomy (c)	Mean ± SD	80.65 ± 3.29	82.50 ± 9.75	**0.353**
	Min – Max	71.0 – 90.0	74.0 – 107.0	
	Median (IQR)	81.0 (79.0 – 82.0)	79.0 (76.0 – 85.0)	
During SSC (d)	Mean ± SD	82.15 ± 3.12	83.65 ± 7.36	**0.402**
	Min – Max	73.0 – 92.0	74.0 – 102.0	
	Median (IQR)	82.0 (81.0 – 83.0)	81.50 (79.0 – 84.0)	

*Statistically significant difference at *P* value ≤ 0.05

Table 2: Comparison of pain using modified face scale between study groups using different dental procedures

		Group I (n=26)	Group II (n=26)	*P* value
		n (%)		
Anesthesia	Satisfaction (A)	13 (50.0%)	0 (0.0%)	***<0.001****
	Indifference (B)	11 (42.3%)	14 (53.8%)	
	Dissatisfaction(C)	2 (7.7%)	12 (46.2%)	
Pulpotomy	Satisfaction (A)	14 (53.8%)	13 (50.0%)	**MC p=1.000**
	Indifference (B)	12 (46.2%)	12 (46.2%)	
	Dissatisfaction(C)	0 (0.0%)	1 (3.8%)	
SSC	Satisfaction (A)	20 (76.9%)	20 (76.9%)	**1.000**
	Indifference (B)	6 (23.1%)	6 (23.1%)	
	Dissatisfaction(C)	0 (0.0%)	0 (0.0%)	

*Statistically significant difference at *P* value ≤ 0.05
MC: **Monte Carlo**

The results of lip biting in both groups are displayed in Figure 5

Twenty-two % of individuals assigned to the treatment in the study group reported adverse effects after injection compared to 64.0% in the IANB group with statistically significant difference P=0.005.

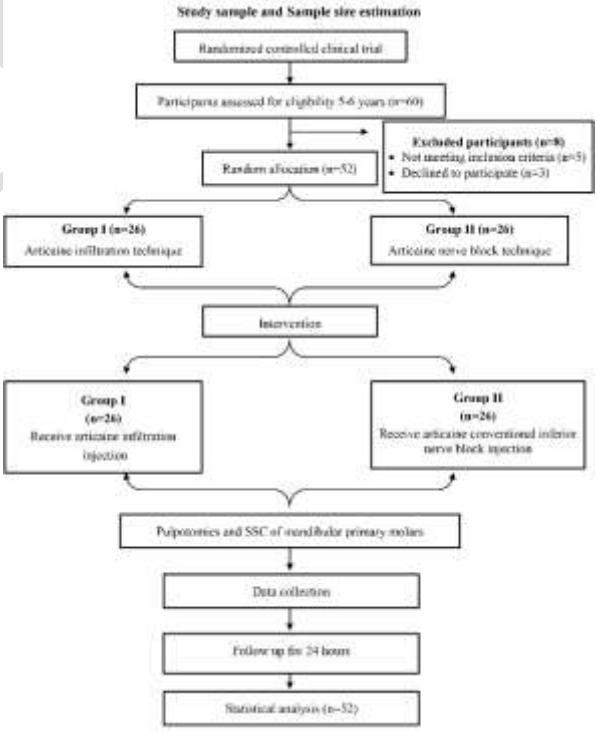

Figure 1: Study Plan Flow Chart.

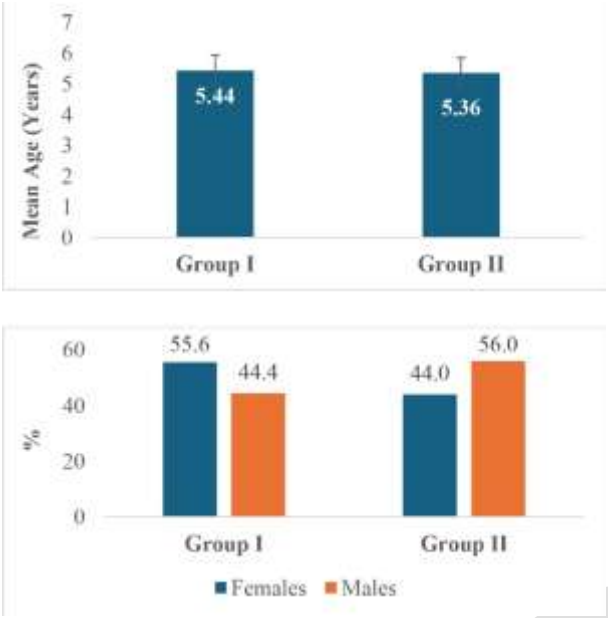

Figure 2: Demographic characteristics of study and control groups at baseline

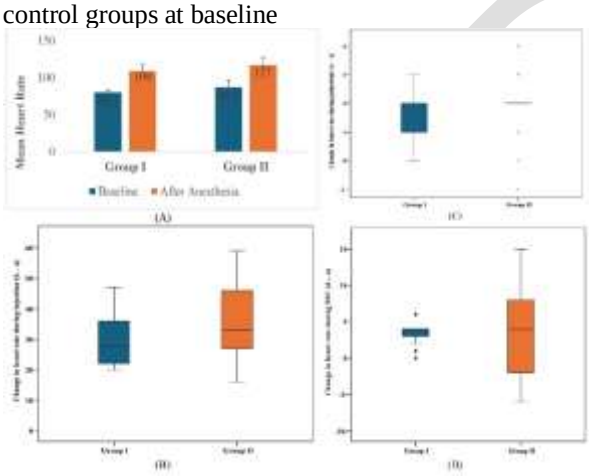

Figure 3: Comparison of heart rate between study groups before and after administering different procedures

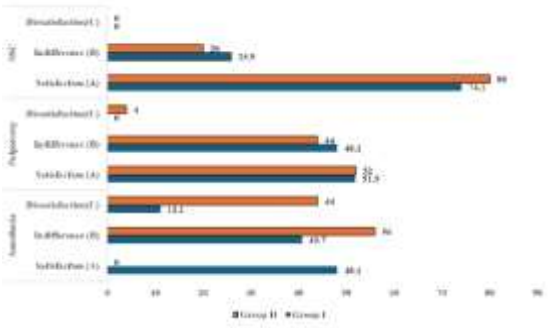

Figure 4: Comparison of pain using modified face scale between study groups using different dental procedures

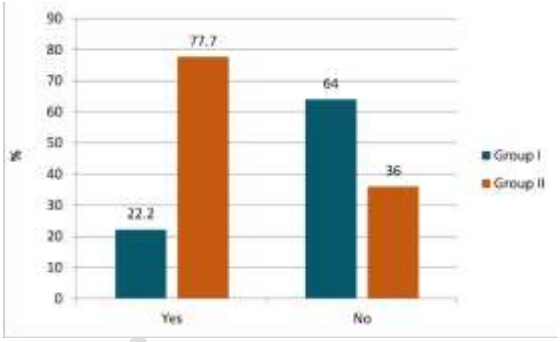

Figure 5: Comparison of adverse effects between the study group and control group at different dental procedures

DISCUSSION

The investigation of this study aimed to evaluate the effectiveness of Articaine infiltration versus conventional IANB in anesthetizing the second primary mandibular molars indicated for pulpotomy and SSC treatment, evaluating pain during injection and to assess any side effects occurred within 24 hours. Following statistical analysis, the study's finding revealed that there was a statistically significant difference in pain experienced by both groups during injections in heart rate and modified FPS. However, there was no significant difference in the effectiveness of mandibular infiltration anaesthesia and the conventional inferior alveolar nerve block when using 4% Articaine during pulpotomy of the mandibular second primary molars and SSC restoration, or any side effects was encountered within 24-hours post operatively, accordingly the null hypothesis of this study was partially rejected.

This study focused on children aged 5-6 years old to standardize bone density, which could impact bone density and LA absorption.

This study included children with positive and definitely positive behavior, as negative or definitely negative behavior might affect pain rating scales due to uncooperative behavior during dental procedures.

Since this study was carried out on pediatric patients it was a challenging aspect to assess the pain so its advisable to select a minimum of two pain measures to conduct behavioural research, because of their exaggerated responses. As a result, physiological, subjective pain assessment were applied using HR and FPS (23, 24), to enhance the simplicity and interpretability of the scale. This enhanced the child's response and reduced confusion.

The study's results revealed that the use of Articaine BI in children led to considerably reduced pain experiences during injection compared to IANB, as measured by HR, and FPS. This is due to the reduced needle penetration and less invasion, which leads to less tissue stress. The IANB method is a highly invasive technique, requiring a

thick, longer needle to penetrate deeper soft tissue layers, increasing pain due to anatomical structures in the mandibular foramen (25). This finding come in agreement with those found by Tirupathi and Rajasekhar (26), Jain, 2021 (27) and Ram and Peretz (28) who reported that the BI showed significantly lower pain level compared to the IANB.

Nevertheless, the results of this study contradicted the findings of Massignan 2020, who discovered that children aged 5-9 experienced a substantially higher level of pain following the injection of Articaine infiltration compared to IANB ($P = 0.02$). The distinction between our study and the previous research may be attributed to variations in the operator technique employed and the older age group between the 2 studies. In this trial, the infiltration injection was administrated very slowly in order to avoid pain that could arises either due to the pressure or the low PH of the anaesthetic solution (29).

The present study demonstrated that there was no significant difference in pain reaction between the study and control group during pulpotomy and SSC restorations, either when pain reaction was measured by heart rate, or FPS, scores. These findings align with prior studies indicating that the use of Articaine infiltration can be a viable alternative to IANB. This would eliminate the need for needle penetration into the oral mucosa and reducing potential complications. Rathi et al. 2019 (30), found that mandibular infiltration by Articaine local anesthesia in children showed significant less pain than IANB either subjectively by FPS ($P < 0.05$) or objectively by using the HR parameter ($p \leq 0.05$).

However, the findings of the current study were inconsistent with Arrow, 2012 who found that the mandibular nerve block was more effective than infiltration for pulpotomy of primary molars in children. This could explained that Arrow included a wider age range (5-13). It is well established that the bone mass density BMD gradually increases with age. Increase bone mineral density in older children might have influenced the dissociation and penetration of Articaine into that mandible and made the infiltration ineffective (31). The finding of this study were also inconsistent with Oulis et al and Al-jumaili et al. (32, 33) which demonstrated that infiltration was not effective in mandibular primary molars, due to their use of lidocaine which has limited penetration ability.

The current study demonstrated a significant decrease in lower lip biting in the infiltration group compared to the IANB group. The lip biting encountered in the study group was attributed to the administration of anesthesia to the mental nerve during injection (34). Compared to IANB, which affects a larger area beyond the specific teeth being targeted, children may have temporary or permanent loss of feeling in the lips and cheeks for an extended duration, lasting several hours (8, 35). No other detrimental incidents were reported.

However, limitations to the present study that the population included was only confined to children who showed positive behavior and age ranged from 5-6 years old. Therefore more studies should be done including children who shows negative behavior and older age group.

CONCLUSION

The results of the present study indicate that:

1. The use of Articaine mandibular local infiltration was equally effective as the IANB technique during pulpotomy procedure and SSC restoration in mandibular second primary molars.
2. Articaine BI has been found to be less painful compared to traditional injection techniques. This is particularly beneficial for children with dental phobias and anxiety.

Based on the majority of literature studies and the results of this study, pediatric dentist should reconsider the anesthetic injection technique they use on a daily basis in their routine practice. An alternative approach that could help children who have trouble receiving IANB injections could be the infiltration technique.

Conflict of interest

The authors declare that they have no conflict of interests.

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