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Efficacy of Tactile Method versus Visual Method to Define Needle Insertion Site of Inferior Alveolar Nerve Block for Pulpotomy in Children: A double-Blind, Randomized, Cross-over Study

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Abstract

Background

Effective pain control is a prerequisite for successful child dental treatment. This study was designed to evaluate the efficacy of tactile versus visual method to define needle insertion point of IANB for pulpotomy in children.

Materials and Methods: In this double-blind, cross-over, randomized clinical trial, 40 children (7-9 years old) requiring primary mandibular second molars pulpotomy were recruited. Study was performed in Zahedan Dental School in 2016. Children were randomly divided into two groups. Group I received IANB using tactile method in the right side in the first session, and using visual method in the left side in the second session. Group II received the visual method for the right and the tactile method for the left in two sessions respectively. Objective and subjective pains during injection were recorded using SEM and FIS, respectively. Reaction during cavity preparation; recorded by SEM, was evaluated as sign of anesthesia failure. Data were analyzed using the Mann-Whitney U, Wilcoxon Signed Rank and Fisher's Exact Tests at a significance level of 0.05.

Results: Regarding tactile method, comparing groups I and II showed no significant difference in any of the variables (P> 0.05). About visual method two groups showed a significant difference only in subjective pain (P= 0.013). In group I, visual method showed significant differences in objective and subjective pain versus tactile method (P<0.05). In group II, no significant differences were found between the two methods in variables. Totally, all variables were significantly different in favor of visual method versus tactile method (P<0.05).

Conclusion

The visual method reduced objective and subjective pain and yielded superior anesthesia success compared to tactile method.

Key Words: Mandibular nerve, Pain perception, Pediatric dentistry.

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1- INTRODUCTION

In pediatric dentistry, appropriate pain-controlling techniques not only allow the implementation of effective and high-quality treatments but also minimize dental fear and anxiety and ensure the child's future dental attendance (1-3). Given the nature of dental treatments, the administration of local anesthesia is among the most important modalities (4). On the other hand, children are afraid of intraoral injections, and this fear may itself cause anxiety and, consequently, misbehavior (5, 6). Different studies have considered various factors contributing to the anesthesia success rate and objective and subjective pain during injection. For example, studies have compared different local anesthesia solutions and techniques (7-12), topical anesthetics (13, 14), and anesthesia delivery instruments (15, 16).

In one study evaluating the efficacy of two anesthetic gels on reducing the pain of needle insertion in children, 20% benzocaine gel showed less pain than 2% lignocaine gel (17). In evaluating injection pain and success rate of inferior alveolar nerve block (IANB) in children using buffered lignocaine, 2% lignocaine, and 4% articaine, buffered lignocaine revealed the best results in both outcomes (11).

Moreover, Bonifacio reviewed different studies evaluating the efficacy of lidocaine IANB and articaine infiltration in child dental patients. No difference was found between self-reported pain and efficacy between two techniques (9). In addition, Ramadurai et al. in their study on children did not find any superiority of 2% articaine in decreasing subjective pain perception than 2% lignocaine (10).

However, we did not find any study that has investigated the relationship among the methods used to define the injection site, the pain reactions during injection, and the success of anesthesia. The IANB is the most commonly applied local anesthesia technique in children (3). IANB provides local anesthesia for mandibular tooth restoration and surgery (18). Given the invasive nature of this injection technique, considerable efforts have been made to develop easily performed and patient-friendly alternatives (4, 18). However, the use of traditional syringes to administer IANB is inevitable because of the high costs of the specific instruments required to employ the alternative techniques (18).

It is very important to define the exact site for the IANB (19). For this purpose, a tactile method that requires palpation of the coronoid notch and considers the occlusal plane is used. The current study examines a new definition of needle penetration site in IANB considering the landmark of pterygomandibular triangle, which comprises the pterygomandibular raphe, internal oblique ridge, and palatal arch, and inserting the needle at the tip of this triangle (i.e., visual method). In visual method, the injection is administered without touching the coronoid notch or considering the occlusal plane.

However, the ability of visual method to reduce children’s pain reactions upon injection and promote the success rate of local analgesia remains unknown. Studies have evaluated the pain reactions of children during injection (20-22), although none have investigated the effect of the method used to define the needle insertion site on these reactions or the success of analgesia. Painless injection is a necessary component in making the child cooperative and eliminating dental fear. In addition, extra time required to find the insertion site through sense of touch may cause the child to be apprehensive and lose the golden time to insert the needle. Therefore, the current study aimed to evaluate the efficacy of tactile versus visual method to define needle insertion point of IANB for pulpotomy in children.

2- MATERIALS AND METHODS

2-1. Study design and population

The study protocol was designated as double-blind, cross-over, randomized clinical trial. A total of 40 children ranging in age from 7 to 9 years old who were referred to the Department of Pediatric Dentistry of Zahedan Dental School, Iran, in September and October 2016 were enrolled into the study. The sample size was determined considering power of 90% and type I error of 0.05 based on an earlier study by Palm et al. (1). From 62 attending children, 55 had the inclusion criteria. Among them, 40 subjects were selected using a random number table (**Figure.1**).

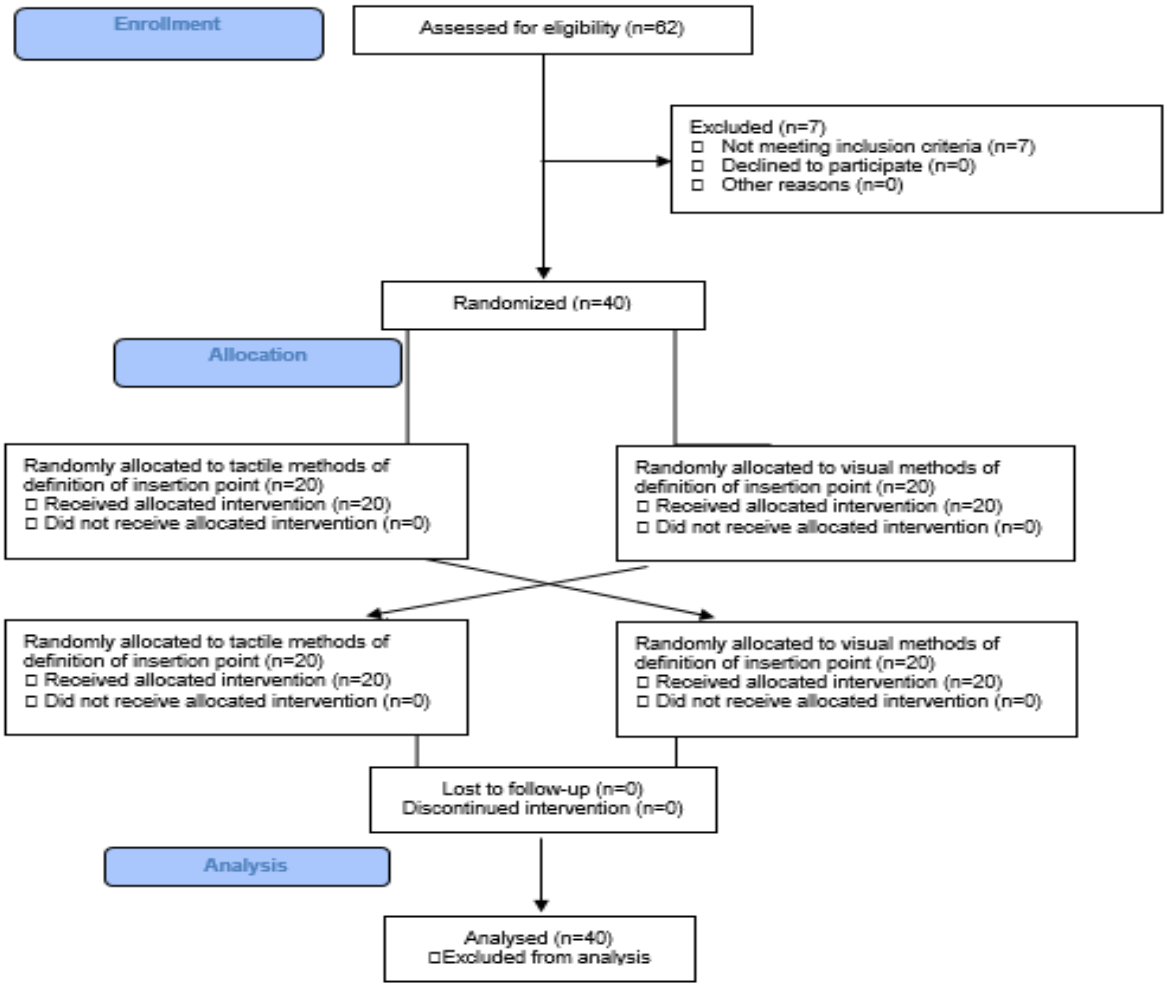

Fig1: Participants' flow diagram.

2-2. Methods

Parents were given full explanations of the protocol and they signed written informed consent forms after receiving an explanation of the study objectives and procedures. Children were randomly divided into two groups: I and II. All subjects attended twice, during two separate visits. In the first session, for pulpotomy of the second right molar under IANB, children in group I received tactile method and group II received visual method. In the second session, one week later for both groups of subjects, the other method of injection site definition not previously applied was used on the left side (group I: visual method; and group II: tactile method). In this study, each child was his or her self-control. Thus, both methods were performed for all subjects

through two separate sessions. Prior to the injection, a topical anesthesia gel (TOPEX, Sultan Healthcare, Hackensack, NJ, USA) was applied to the dried mucosa of the injection site with a cotton applicator for 60 seconds. To provide a mandibular nerve block based on the tactile method (i.e., standard method of injection site definition), the child was asked to open his/her mouth as much as possible. After placing the thumb in the coronoid notch on the anterior border of the mandible and placing the fingers on the posterior border of the mandible, the needle was inserted between the internal oblique ridge and pterygomandibular raphe while the bevel of the needle was oriented parallel to the bone at a level equal to the occlusal plane. The syringe barrel was placed in the corner of the lips on the side opposite the injection site. A small amount of solution was immediately injected after tissue penetration and injection was continued along the way to reach the mandibular foramen. The needle was pulled out by 1 or 2 mm once it touched the bone surface (1.5 to 2 cm in depth), and the injection was slowly deposited following negative aspiration (**Figure.2**). To administer IANB based on the visual method, the child opened his/her mouth as much as possible. Thereafter, the needle was placed in the tip of the pterygomandibular triangle (the intersection of the internal oblique ridge and pterygomandibular raphe) with the bevel oriented toward the bone, and the syringe was placed in the corner of the lips on the side opposite. The remaining procedure was similar to that described for the tactile method (**Figure.3**).

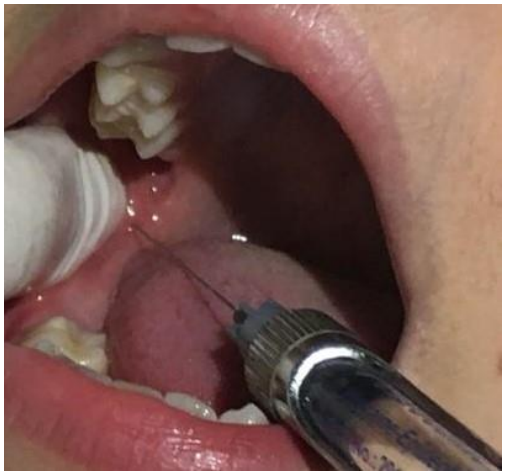

Fig.2: Tactile method to define insertion point for IANB.

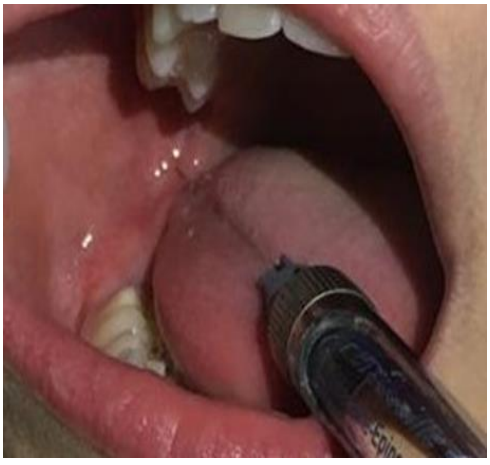

Fig.3: Visual method to define insertion point for IANB.

Single operator (an experienced pediatric dentist) administered injections to all subjects. Solution comprised 1 mL of 2% lidocaine plus 1/80000 epinephrine (Persocaine-E, Darou Pakhsh IND. CO, Iran) at 21 ℃. The injections were delivered over a 90-second period using syringe (Sterilife, Anthogyre Co., Sallanches, France) fitted with 27-gauge, 35-mm needles (C- KJECT, CK DENTAL IND. CO, Korea). During the injection, routine non-pharmacological techniques were used for behavior management. One blind observer who stood 1.5 m away from the dental chair recorded the children's objective pain reactions during the injections using the Sound Eye Motor scale (SEM). For this purpose, the sounds, eye signs, and physical movements produced by the child were observed and codified. The total SEM score was calculated by summing the three values of SEM parameters grades (23). For example, a child who was silent during the assessment by the observer received Grade 1 for the sound parameter. Similarly, if there was no eye sign, Grade 1 was assigned to his or her eye parameter. If the position of hands and body was in a relaxed and comfortable state, Grade 1 was considered for the movement parameter. Thus, the child received a total of 3, which indicated the absence of pain. As the numbers go up, the pain and its severity become apparent, which can be as high as 12. In order to get familiar and learn how to work with the SEM, the observer was trained using 10 live cases showing different reactions during intraoral injection based on SEM. Then, 10 videos were used to score children's reaction upon injection. After two weeks, reassessment re-assessing of the same video records was conducted to confirm the reliability of reactions scoring. All videos were diagnosed correctly, in both scoring and re-scoring. In this way, we were assured of intra-rater reliability. The SEM parameters and their grades are presented in **Table.1**.

Table-1: Objective Pain Assessment According to the SEM Scale (25).

Parameters	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort
Grade	1	2	3	4
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eye	No sign	Dilated eye without tear (anxiety sign)	Tears, sudden eye movements	Crying, tears all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defense, turning the head to the opposite side

SEM: Sound Eye Motor.

To assess subjective pain reactions during the injections, each child was asked to record his/her perceived level of injection pain immediately after the injection according to the facial image scale (FIS) using a five-point Likert-type scale (24). The children received training in the completion of the FIS before the subjective assessment just when the injection process was completed. The treatment was started following a 5-minute interval after injection. The same observer who determined the SEM scores recorded the anesthesia success rate under the same conditions, during the access cavity preparation. Any reaction by the child as the pulp was entered was considered as failure (received a score >3) according to the datasheets. In such circumstances, the treatment was stopped, the analgesic technique was reported as unsuccessful, and the treatment was continued after

repeating the IANB or administering adjunctive analgesia. Subjects' data, including demographic information (Confidential code, age and gender), group assignment, objective pain reaction, subjective pain reaction and success of anesthesia in each session (first and second) was recorded in a special form designed for the study. We note that all executive research steps were conducted in the Department of Pediatric Dentistry of Zahedan Dental School. One general practitioner recruited subjects, divided them randomly into two groups and supervised them throughout the study. He also trained the observer to record the child's reactions. An expert pediatric dentist administered dental injections and main treatment procedures.

2-3. Inclusion and exclusion criteria

The inclusion criteria were: the requirement for primary mandibular second molars pulpotomy (based on clinical and radiographic examination), no previous history of dental treatment, good physical and mental health, no allergy to the anesthesia solution, no dental emergency or toothache of pulpal origin, a preoperative behavioral assessment of positive or definitely positive according to the Frankel behavior rating scale (25), no need for premedication before the dental treatment, no history of using analgesic drug for any reason 24 hours before dental treatment, a clearly visible pterygomandibular triangle during an intraoral examination, and no dental developmental anomalies.

2-4. Ethical consideration

The study protocol was based on "Declaration of Helsinki", and was approved by the Institutional Review Board (IRB), and Ethics Committee of Zahedan University of Medical Sciences, Zahedan, Iran (code: IR.ZAUMS.REC.1394.32). The trial was registered in the Iranian Registry of Clinical Trials (IRCT201605116105N5).

2-5. Data Analyses

Finally, the data were analyzed using the Mann-Whitney U, Wilcoxon Signed Rank and Fisher's Exact Tests in the SPSS, version 22 (SPSS Inc., Chicago, IL, USA). A significance level of 0.05 was set.

3- RESULTS

A total of 40 children (25 females and 15 males) with a mean age of 96.8 ± 13.39 months were included and completed the trial. Data regarding objective and subjective pain reactions to and success rate of IANB using tactile method of defining the injection site in two groups are illustrated in **Table.2**. As shown in this table, in the tactile method, comparison of all studied variables in two groups showed no statistically significant difference (P> 0.05). In **Table.3**, which compares the variables studied in the visual method, group I versus group II showed a significant difference only in the variable of subjective pain reaction (P= 0.013).

Table-2: Objective pain, subjective pain and success rate of IANB using tactile method of defining the injection site in two groups.

Variables	Group I	Group II	P-value
Objective pain, Mean (SD)*	4.27 (1.132)	3.92 (1.185)	0.081
Subjective pain, Mean (SD)*	2.30 (1.363)	2.03 (0.971)	0.086
Success rate, Number (%) **	12 (60.0)	16 (80.0)	0.150

Group I: tactile method for the right side in the first session and visual method for the left side in the second session. Group II: visual method for the right side in the first session and tactile method for the left side in the second session. SD: standard deviation. IANB: inferior alveolar nerve block.

Table-3: Objective pain, subjective pain and success rate of IANB using visual method of defining the injection site in two groups.

Variables	Group I	Group II	P-value
Objective pain , Mean (SD)	3.50 (0.877)	3.48 (0.877)	0.997
Subjective pain , Mean (SD)	1.25 (0.439)	1.85 (0.802)	0.013
Success rate, Number (%)	18 (90.0)	16 (80.0)	0.340

Group I: tactile method for the right side in the first session and visual method for the left side in the second session. Group II: visual method for the right side in the first session and tactile method for the left side in the second session. SD: standard deviation. IANB: inferior alveolar nerve block.

Comparison of tactile method versus visual method in group I, in group II, as well as in whole study population is shown in **Table.4**. In group I, visual method showed significant differences in both objective and subjective pain reactions versus tactile method (P< 0.05). Although statistical analysis revealed no significant difference in two methods regarding success rate (P= 0.071). In group 2, no significant differences were found between the two methods in terms of the three studied variables. As presented in this table, in total, all three variables including objective and subjective pain reactions and success rate were significantly different in favor of visual method versus tactile method (P<0.05).

Table-4: Tactile method versus visual method of defining the injection site in each group, and in total.

Groups	Variable	Tactile	Visual	P-value
Group I	Objective pain, Mean (SD)	4.27 (1.132)	3.50 (0.877)	0.001
	Subjective pain, Mean (SD)	2.30 (1.363)	1.25 (0.439)	<0.001
	Success rate, Number (%)	12 (60.0)	18 (90.0)	0.071
Group II	Objective pain, Mean (SD)	3.92 (1.185)	3.48 (0.877)	0.056
	Subjective pain, Mean (SD)	2.03 (0.971)	1.85 (0.802)	0.093
	Success rate, Number (%)	16 (80.0)	16 (80.0)	1
Total	Objective pain, Mean (SD)	4.10 (1.165)	3.49 (0.871)	0.011
	Subjective pain, Mean (SD)	2.16 (1.191)	1.55 (0.710)	0.011
	Success rate, Number (%)	28 (70.0)	34 (85.0)	0.033

Group I: tactile method for the right side in the first session and visual method for the left side in the second session. Group II: visual method for the right side in the first session and tactile method for the left side in the second session. Total: Whole study sample regardless of grouping. SD: standard deviation.

4- DISCUSSION

The present study was conducted to assess the efficacy of tactile method versus visual method to define needle insertion point of IANB for pulpotomy in children. Our results indicated that the visual method provided superior pulpal anesthesia while causing significantly reduced objective and subjective pain reactions than the standard tactile method. In our study, the order of the method used to define the insertion point (the method that was used first) tactile versus visual (group I and group II) had no effect on the variables, except on subjective pain reaction in the visual method in favor of group I. Routinely, the IANB injection site is defined by tactile sense. Therefore, it remained unknown to what extent an injection into the tip of the pterygomandibular triangle could reduce pain reactions while providing adequate pulp anesthesia. In the only related study,

dental students preferred the visual method to the tactile method when defining the injection site (26). According to the results of that study, visual method was associated with higher preference score and improved self-esteem and comfort among the students. It is prudent to address the several mechanisms by which the method of needle insertion point definition may affect the behavior of child subjects (27).

The process of perceiving pain is influenced by many factors. In fact, pain is a subjective phenomenon in which physical and psychological factors play a role (28). The process of perceiving pain is related to numerous factors such as fear, stress, anxiety and discomfort. It is possible that in the tactile method, extra time required to put a finger to touch and find the insertion site will lead to stress and discomfort and consequently higher objective and subjective pain reactions.

We minimized other psychological possibilities as much as possible. Recruiting children with positive or definitely positive preoperative behavioral assessment and without history of past dental treatment, and using communication techniques throughout our research may have minimized the effect of fear, anxiety and stress on pain other than the stress of finger placement to touch insertion site. Besides these, the history of previous pain is critical in this regard (28), which is considered in our methodology.

Given the dissimilarities between the methodology of the current study and of others, we focused on the interpretation of our findings. Overall, the visual method yielded satisfactory results regarding superior anesthesia and reduced the participants' pain perceptions. However, such studies are inevitably limited by the child-dependent nature of subjective pain reactions. In the current study, we used the FIS to measure this parameter. The FIS is a simple, user-friendly scale that can be easily understood and performed by children (24). The scale contains five facial images demonstrating different facial expressions, and the children are asked to select the image that best reflects their sense of pain (13). However, the use of this self-reporting scale depends on the child's developmental level, and the image selection process carries a risk of bias. To compensate for the limitations of the FIS, the SEM scale was used for an objective comparison of pain reaction. In pain measuring, several markers including biological, behavioral or self-expressions are practical (3). Since body movements are among strong indicators of pain (3), we decided to use SEM index including one parameter of body movement. With reference to the SEM table, the presence and severity of pain is revealed. The SEM index used in our method is a valuable, easy-to-use, sensitive, and clinically applicable and reliable instrument that can measure the level of pain or degree of discomfort experienced by a child (23, 28).

SEM is strongly recommended for determining the presence or absence of pain or grading its severity (4). Notably, this scale evaluates details of the sounds (S), eye characteristics (E), and motor (M) components associated with the pain response (20). We minimized the risk of bias as much as possible in the current study by using specific methodologies, including SEM, to assess objective pain, as well as by blinding the observer and pediatric subjects. The perception of pain during injection occurs in three stages: insertion of the needle into the tissue, advance of the needle through the tissue to reach the target site, and deposition of analgesic solution. In addition to the need for appropriate anesthesia delivery techniques, psychological modalities can help to reduce pain during each of these stages (20). However, there was no opportunity to evaluate subjective pain during each of the mentioned stages in the current study, and children were asked to

self-report their pain levels after the anesthetic procedure. According to the results, the significant reduction in the pain reaction and superior anesthesia success rate with the visual method could be attributed to the different pathway of needle and additionally, proper deposition site. Although the definition of point for needle penetration is different by method, due to application of anesthetic gel, pain perception at the time of penetration is eliminated. Thus, what are different are the more accurate needle pathway and anesthetic deposition site found in visual method. The needle passes through the tissue differently at a visually defined injection site, compared with a tactile-defined site. The use of an anatomically more suitable penetration point and needle pathway reduced both the pain caused by the passage of the needle through the soft tissue, as well as the pain caused by the deposition of the anesthetic solution and simultaneously increased success rate. In brief, needle passage and deposition site associated with the visual method may reduce the objective and subjective pain reactions and improve success rate of anesthesia. Studies have reported IANB success rates exceeding 70% among teeth without pulpal inflammation (21, 29).

In our study, a blind observer using the SEM scale assessed the success rate; this individual stood at an exact distance, far from the child. The observer attempted to record the success or failure of the anesthesia based on any reaction of the child during access cavity preparation. Totally, in our study, the visual method yielded a success rate of 85%, compared to 70% with the tactile method. Both rates were within the acceptable range. The current study also implemented a 5-minute interval after injection when evaluating the success of IANB, which is the routine waiting time applied in dental practices (18). Another IANB or adjunctive anesthesia (e.g., intrapulpal injections) was administered to ensure a painless treatment after IANB failure. The higher success rate of the proposed visual method and, consequently, the reduced use of complementary analgesia suggests that our method may reduce the complications associated with IANB (e.g., long-term soft tissue numbness), which is an important topic in pediatric dentistry (8, 29-31). According to the results of different studies, approximately 13–16% of children develop soft tissue trauma after IANB.

Unfortunately, the frequency of lip biting was not evaluated in the current study. Therefore, we recommend an investigation of the side effects of soft tissue anesthesia following IANB administration using our proposed method. Our study had some strengths. Some dental developmental anomalies are associated with a risk of incomplete pulpal anesthesia (32). The authors therefore excluded children with dental development anomalies. In addition, the injections were administered to children within a narrow age range who required pulpotomy (without pulp canal inflammation). We selected children aged 7–9 years because the pain intensity self-report measures are not reliable in younger children (33).

To conduct a practical and accurate comparison between two methods of injection site definition, we aimed to eliminate other differences such as the type of anesthetic solution, applied dose, drug temperature, and needle type. Moreover, one single blind observer recorded data regarding SEM for all subjects. As pain reactions may be affected by the skill of the operator, all injections were administered by the same experienced pedodontist. The injection speed can also influence pain-related behaviors (4). Although the traditional syringes do not facilitate precise injection speed control, the operator attempted to apply a constant, slow injection speed and pressure during both methods. In addition, communicative

behavior management techniques were applied to enable an appropriate child-operator relationship. A lack of a previous history of intraoral injection was an inclusion criterion. According to Versloot et al.'s study (34), children with a history of dental treatment reported a higher level of pain during injection when compared to their counterparts. In fact, the variable of previous dental treatment experience significantly influences children's behavior during dental treatment. As each child in our study experienced both methods of insertion point definition in two successive sessions, a crossover design was used to neutralize the effect of the first session on the results of the second session. Accordingly, the children were divided into two groups, and each group received one method during the first session and the other method during the second session. It should be noted that the poor representation of the pterygomandibular triangle landmark could limit the application of our proposed method. As the current study evaluated children aged 7–9 years, the results cannot be generalized to children in other age groups; hence, we recommend a similar study of the effects of age on pain reactions and IANB success among children in a wider age range.

5- CONCLUSION

In conclusion, visual method led to significantly reduced pain reactions compared with those associated with the tactile method. Besides this, superior pulpal anesthesia was achieved by our proposed visual method. Hence, the visual method appears to be a valuable and appropriate alternative to the tactile method in terms of providing better pulpal analgesia while reducing pain reactions during injection and, consequently, the disruptive behaviors displayed by children during dental treatments.

6- CONFLICT OF INTEREST: None.

7- ACKNOWLEDGEMENTS

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