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Assessment of Needleless Jet Injection in Pain and Anxiety Management during Vital Pulpotomy of Mandibular Primary Molars: A Split-Mouth Randomized-Controlled Clinical Study

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ABSTRACT

The purpose of the current study was to compare the effectiveness of needleless jet injection versus traditional inferior alveolar nerve block anesthesia (INAB) in management of pain and anxiety during vital pulpotomy of mandibular second primary molars in children. **Methods:** A randomized, split-mouth clinical trial was conducted on thirty children aged 4-8 years, who required vital pulpotomies for bilateral carious second mandibular primary molars. The children were divided equally into two main groups, the pre-school age group, before the eruption of lower first permanent molar, while the school age group, after the eruption of lower first permanent molar. Each group was subdivided according to the technique of local anesthesia, INAB subgroup (control side) and needleless jet injection subgroup (examined side), followed by pulpotomy and restored with stainless steel crown. The children's perceptions of pain were evaluated using Wong-Baker FACES Pain Rating Scale. Additionally, anxiety levels of children were evaluated using Venham's anxiety and behavioral rating scale. **Results: :** According to Wong-Baker FACES Pain Rating Scale, a significant difference between the control (2.67±2.69) and examined subgroups (1.33±0.98) observed in the preschool age group immediately after LA, while in school children age group, there was a highly significant difference between the control (1.47±1.19) and examined subgroups (0.53±0.92). During pulpotomy, results revealed non-significant difference between the control (1.33±0.63) and examined (1.73±0.92) subgroups for preschoolers, while in school children age group, results showed a considerable difference between the control (0.27±0.7) and examined (2.93±3.99) subgroups. On recording Venham's anxiety and behavioral rating scale for preschool children, results showed significant difference between the control (1.27±0.96, 0.73±0.63) and examined (0.73±0.46, 0.87±0.92) subgroups immediately after LA and during pulpotomy, respectively. While in school children, it showed differences with highly significance between the control (0.87±0.6) and examined (0.33±0.5) subgroups, immediately after LA, moreover during pulpotomy, results showed significant difference between the control (0.13±0.4) and examined (1.47±2.0) subgroups for both preschool and school children.

Conclusion: Jet injector was effective during pulpotomy of lower second primary molars in preschool children, while it was effective to some extent in school age children.

Keywords: Pain, anxiety, pulpotomy, local anesthesia, jet injection and behavioral rating scale and preschool children.

Introduction

The use of local anesthetic, which is considered the most painful phase of treatment, is one of the most efficient strategies to control discomfort during invasive dental operations. The administration of local anesthesia, a key method in mitigating discomfort during invasive dental procedures, ironically represents the most painful stage of treatment and often leads to its premature termination. This phase notably contributes to patient apprehension towards dental care. The amplification of pain perception due to stress caused by anxiety and fear is well-documented [1]. This heightened sensitivity to pain, in turn, exacerbates the patient's anxiety, creating a reinforcing loop [1,2]. The young patient's expectations for pain may significantly increase the complexity of the situation. As a result, receiving dental treatment may be viewed as an insurmountable problem. [3] Although dentists have little influence over such fears, some components of the procedure can be changed to make patients feel more comfortable[4].

Administering local anesthetics to children in a pain-free manner during dental treatments presents a considerable challenge. By mitigating the pain associated with injections, the child's anxiety and apprehension are reduced. This contributes to fostering a positive and trust-filled rapport between the child and the pediatric dentist, which is instrumental in cultivating a favorable dental attitude for the future [5].

The conventional method of anesthetic administration using a syringe often results in pain both during needle penetration and the injection process, primarily due to the reliance on a needle for delivery [6]. Furthermore, the pain experienced can be exacerbated by improper handling of the syringe [7], such as applying excessive pressure on the plunger or rapidly injecting large volumes of the anesthetic solution [8]. As one of the traditional methods of administering local anesthetic, the inferior alveolar nerve block (IANB) is frequently utilized to ensure pain control prior to a variety of dental treatments. These procedures include restorations, pulp therapy for mandibular primary and permanent molars, and surgical interventions [9].

The literature encompasses a range of explored methodologies to mitigate the pain associated with traditional syringe injections. These methods include the application of topical anesthetics prior to injection [10], exerting pressure at the injection site [11], employing computer-controlled anesthesia delivery systems [12], utilizing contemporary devices like Dental Vibe that incorporate vibration technology [13], implementing low-level laser therapy before the insertion of the needle [14], and adopting needleless jet injection techniques alongside computerized injection systems [15].

Needle-free injection systems offer a viable alternative to the conventional dental needle approach, primarily due to their lack of a needle, which crucially removes the associated pain and fear of needles and injections [16]. Such systems potentially provide greater ease of use, particularly in pediatric patients, enhancing the overall experience and compliance [17].

The needleless injection system, conceived by Robert Hingson in 1947, was initially developed for applications in dermatology, vaccination, and the administration of growth hormones, insulin, corticosteroids, and botox [18]. This system operates on the principle of propelling a small quantity of medication at high velocity through a tiny aperture. It typically utilizes a spring-connected mechanism capable of generating sufficient pressure [19] to actuate the plunger in the ampoule [20], enabling the anesthetic solution to be ejected through a micro-orifice at an appropriate speed. Munshi et al. [19] found in their study that a needleless system considerably lessened the sensation of pain in children receiving supraperiosteal anesthesia. Additionally, a significant portion of the child participants demonstrated a favor towards the needle-free injection system as opposed to traditional injection techniques.

The Comfort-inTM system (CIS; Mika Medical, Busan, Korea), developed approximately a decade ago, is designed for administering local anesthetic without using needles. This device consists of several components: the main injector body, a pressure box, a disposable needle-free nozzle (syringe), and a positioning cap **(Fig. 1)**. It employs the "liquid jet" technique, wherein the anesthetic fluid is rapidly propelled through a 0.15-millimeter aperture under high pressure.

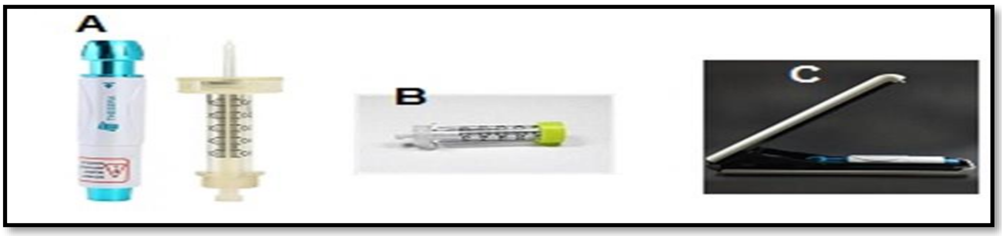

Fig. 1: Comfort-in™ injection system. A: main injector body, B: ampoule with positioning cap and C: a pressure box.

It is possible to use the needleless injection as an effective preparatory anesthetic before needle injections, which are usually uncomfortable. This is true even when topical analgesics are given. Infiltrations in the maxillary incisor area and palatal injections are specific examples of situations in which this is especially essential. Furthermore, it is advantageous for achieving analgesia during treatments such as the extraction of loose primary teeth, minor oral surgery, and the application of rubber dam clamps [21].

This research constitutes a pioneering investigation that aimed to compare the effectiveness of needleless jet injection in management of pain and anxiety during vital pulpotomy of mandibular second primary molars in children, versus traditional inferior alveolar nerve block anesthesia (INAB). This study tested a null hypothesis which stated that, there is no difference in management of pain and anxiety of the compared anesthetic techniques.

Patients and Methods

A randomized, split-mouth clinical trial was conducted with patients from the Outpatient Clinic at the Department of Pediatric Dentistry, Faculty of Dentistry, Suez Canal University, from January to June 2022 **(Fig.2)**.

Ethical Consideration:

An approval of the study was obtained from Suez Canal University Academic and Ethical Committee (No.# 416/2021). This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. The trial was registered on ClinicalTrials.gov under the identifier NCT06001710 on August 21, 2023. Data reporting was in line with the Consolidated

Standards of Reporting Trials Statement (CONSORT) checklist [22, 23]. The randomization sequence was created using computer-generated random numbers (CGRNs). Prior to the study, written informed consent was obtained from the parents and/or caregivers of the participating children, indicating their agreement to the treatment.

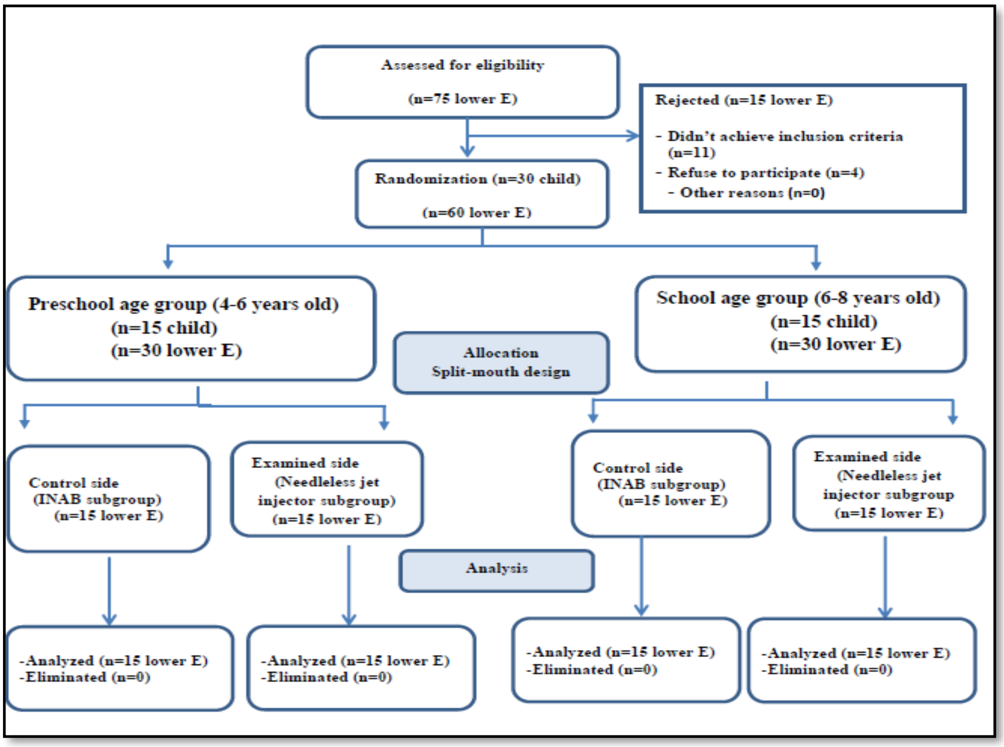

Fig. 2: Study's CONSORT flow diagram

Sample size calculations

The study determined that 30 patients is adequate to identify an effect size of 0.30, ensuring a statistical power (1-β) of 95% and a significance threshold (p) of less than 0.05. A total of 60 teeth, from both the right and left sides of these 30 patients, will be included, with random allocation to either the control or test groups. The sample size calculation was performed using the G*Power software, version 3.1.9.6. [24-26].

Participants' selection

- **Inclusion Criteria:** The research encompassed children between the ages of 4 and 8, of any gender, who required vital pulpotomy on both their right and left mandibular primary second molars. The need for treatment was established both clinically and radiographically [27]. Eligible participants were those with a "positive 2" or "negative 3" cooperation level as per the Frankl Behavior Scale (FBS), attending their first dental visit.
- **Exclusion Criteria:** Exclusion criteria for the study were determined based on clinical evaluations and medical history. Children with developmental or systemic conditions, allergies to materials used in the study, spontaneous pain, intra-oral facial swelling, or the presence of a fistula or sinus tract were not included. Absence of parental consent also resulted in exclusion. Furthermore, teeth exhibiting signs of irreversible pulpitis (indicated by extended bleeding over five minutes or dark to purple blood), pulp necrosis, external or internal root resorption, furcation radiolucency, or periapical pathosis were also disqualified from participation in the study.

Sample grouping and study design

The thirty participating children were categorized into two main age groups: preschool-aged and school-aged children. The preschool children group (n=15) was aged from 4 to 6 years old before the eruption of the lower first permanent molar, while the school children group (n=15) was aged from 6 to 8 years old after the eruption of the lower first permanent molar. Then, each main group was subdivided according to the technique of local anesthesia used into the INAB subgroup (control side) and needleless jet injection subgroup (examined side).

Clinical procedures:

To verify adherence to the eligibility criteria, each child participant was subjected to an extra-oral examination, intra-oral examination, and radiographic examination. The children's ability to follow the dentist's instructions during the clinical examination and to complete the radiographic examination with periapical films without crying determined their categorization as exhibiting "negative" or "positive" dental behavior, as defined by the Frankl Behavior Scale (FBS).

Both children and their parents or guardians were provided with a concise, age-appropriate explanation of the procedures. All dental instruments and procedures were introduced to the patients utilizing the "tell-show-do" approach. Furthermore, the injection procedure was explained to the young patients in an age-appropriate and understandable way, using child-friendly terms such as "putting the tooth to sleep" to describe the process.

Anesthesia protocols

This study follows the guidelines mentioned by AAPD (revised 2023) [28]. For both methods, subsequent to the drying of the area designated for injection, a modest amount of topical anesthetic gel (20% benzocaine, Septodont, France) was administered to the site. This gel was then maintained in position for 2 minutes [29].

In the INAB subgroup, a 4% Articaine solution with 1/100,000 epinephrine (Art Pharma, Egypt) was used, administered with a 27-gauge, 35-mm long needle (CK Dental, Korea). The needle's insertion point was located at three-fourths the anteroposterior distance from the coronoid notch to the deepest part of the pterygomandibular raphe, angling the bevel towards the bone. For preschool-aged children, the injection site was set approximately 2-3 mm below the occlusal plane, whereas for school-aged children, it was placed in line with the occlusal plane. This adjustment accounts for the upward shift of the mandibular foramen as children age [30]. Around 1.5 mL of the anesthetic was injected, and a waiting period of 5 minutes was observed before starting dental procedures.

The needle-free Comfort-In system [31] was utilized to administer 4% articaine with 1:100,000 epinephrine. This system features a pressurized spring mechanism and a silicone cap (recto cap) attached to an ampoule filled with the anesthetic. Its design is specifically aimed at safeguarding the periodontal tissues. To administer the anesthetic, the prepared injector was positioned securely on the gingiva adjacent to the tooth being treated, ensuring it was at a 90-degree angle to the mandible [21]. The anesthesia was delivered by pressing a button, which dispensed 0.5 mL of the anesthetic solution into the mucosal tissue at a pressure of 2000 psi in under two seconds (Fig. 3,a). To mitigate any potential anxiety, both children and their parents were pre-emptively informed about the popping sound that the device generates during the anesthetic solution's release [29]. Following the injection, the tip of the injector was maintained in contact with the injection site for a short period. Dental treatment began after a 5-minute waiting interval. A rubber dam was utilized for the vital pulpotomy procedure. If the child experienced pain during the coronal pulp amputation, additional anesthesia was provided. All dental procedures were conducted by the same practitioner.

Assessment methods:

The study utilized two distinct assessment methods: a subjective assessment embodied by the Wong-Baker FACES Pain Rating Scale and an objective assessment represented by Venham's Anxiety and Behavioral Rating Scale. Both of these scales were utilized at two key moments: right after the local anesthesia was administered and during the moment of pulp exposure in the pulpotomy procedure.

1- Wong Baker scale (subjective): The Wong-Baker FACES Pain Rating Scale was used to quantify the child's pain experience. This scale ranges from a neutral face, assigned a score of "0," indicating no pain, to a frowning face with a score of "10," representing the highest level of discomfort (Fig. 3,b). The scale was explained to the child, who was asked to choose the face that represented how much pain he or she felt during both anesthesia injection and pulpotomy from one of the graphic rating scales by pointing his finger at one of the six faces shown on the chart given to him [32].

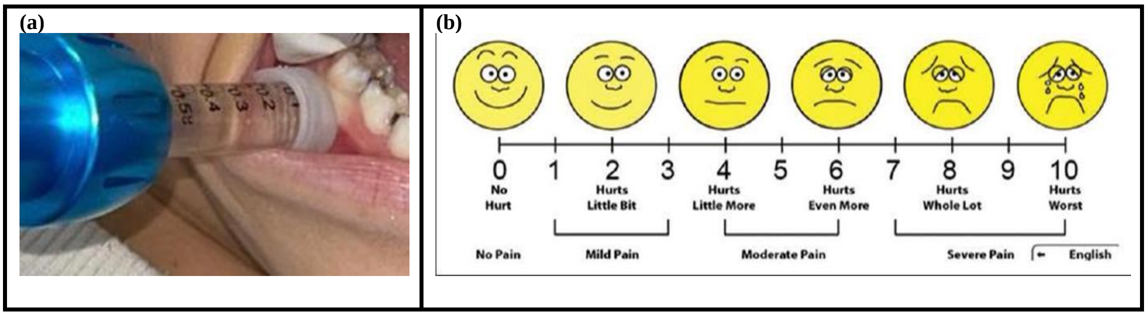

Figure (3): (a): Needleless jet injection anesthesia ; (b) Wong-Baker FACES Pain Rating scale

2- Venham's anxiety and behavioral rating scale (objective):

Assessment of dental anxiety by the operator and main supervisor, higher scores indicates more nervousness or a lack of collaboration, according to Venham's anxiety and behavioral rating scale, which has five behaviorally defined areas with scores ranging from 0 to 5[33] (Table 1).

Table [1]: Venham's anxiety and behavioral rating scale

Rating	Anxiety rating scale
0	Relaxed, smiling, willing, and able to converse
1	Uneasy, concerned. During stressful procedure may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression, may have tears in eyes
2	Child appears scared. Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, (quiet) crying, hands tense and raised, (not interfering much may touch dentist's hand or instrument, but not pull at it). Child interprets situation with reasonable accuracy and continues to work to cope with his/her anxiety
3	Shows reluctance to enter situation, difficulty in correctly assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance
4	Anxiety interferes with ability to assess situation. General crying not related to treatment. More prominent body movement. Child can be reached through verbal communication, and eventually with reluctance and great effort he or she begins the work of coping with the threat
5	Child out of contact with the reality of the threat. General loud crying, unable to listen to verbal communication, makes no effort to cope with threat.

Statistical analysis:

Data collected using Microsoft Excel 2016, statistical analysis was performed on the data to generate both graphical and numerical descriptive summaries. Parametric data was presented as mean and standard deviation, while nonparametric data was represented in terms of frequency (n, %). Inferential statistical analysis was conducted using repeated measures analysis of variance (ANOVA) or equivalent nonparametric methods. The purpose of these analyses was to assess and compare the efficacy of the two different treatments across the study, setting a significance threshold at 0.05. The comparison between the control and examined groups, as well as between the preschool and school children groups, was conducted using independent samples t-tests for parametric data and the Mann-Whitney test for nonparametric data, with a significance level set at 0.05. To assess the difference between after LA and during pulpotomy, Wilcoxon's signed rank was applied. Data analysis for this study was conducted using the Statistical Package for the Social Sciences (SPSS) software, specifically IBM-SPSS version 28.0. [34].

RESULTS

I) Demographic Results:

The present study showed the mean for the preschool age group (4-6 years) was 4.97± 0.69 while it was 7.07 ±0.68 for the school-age group (6-8 years), with a very highly significant difference between the two groups (Table 2). For the preschool age group, 46.7% of boys while girls 53.3%, while it was the reverse for the school-age group. The chi-square test showed a non-significant difference within each group (P >0.05) (Figure 4).

Table [2]: Age distribution in the study sample

Age	Mean	SD	**Chi-square**
Preschool age group (4-6 years)	**4.97**	±0.69	<0.001***
School age group (6-8 years)	**7.07**	±0.68	

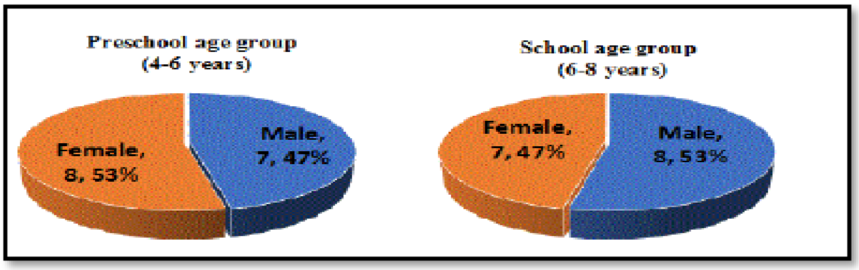

Fig. 5: Pie chart representing gender distribution in term of frequency (n, %).

II) Wong-Baker FACES Pain Rating Scale:

In Preschool age group (4-6 years) showed the majority of patients, 93.4% (14 children) in the INAB subgroup, immediately after LA, were distributed among no, mild, and moderate pain, while in the needleless jet injector subgroup, 100% (15 children) were distributed among no and mild pain only. The results used Wilcoxon's signed rank showed a significant variation between the control (INAB) and examined (needleless jet injector) subgroup immediately after LA, s (p=0.024*). During pulpotomy, most of the patients, 93.4% (14 children) in the INAB subgroup, were distributed among no and mild pain, while in the needleless jet injector subgroup, 66.7% (10 children) were distributed among no and mild pain. The results used Wilcoxon's signed rank showed a non-significant variation between the control (INAB subgroup) and examined (needleless jet injector subgroup) during pulpotomy, as (p>0.05) (Table 3).

In school age group (6-8 years) showed the majority of patients, 93.3% (14 children) in the INAB subgroup, immediately after LA, were distributed among no and mild pain, while for the needleless jet injector subgroup, all children (100%) were distributed among no and mild pain. The results used Wilcoxon's signed rank showed a highly significant variation between the control (INAB subgroup) and examined (needleless jet injector subgroup) immediately after LA, as (p=0.008**). During pulpotomy, it was noted that severe pain was recorded at 20% for the jet injector group only. The results used Wilcoxon's signed rank showed significant variation between the control (INAB subgroup) and examined (needleless jet injector subgroup) during pulpotomy, as (p=0.016*) (Table 4).

Table [3]: Descriptive statistics of Wong-Baker FACES Pain Rating Scale for preschool age group (4-6years), Immediate after LA and during pulpotomy

Wong-Baker FACES Pain Rating Scale of Preschool age group (4-6 years)				
Rating scale	Immediate after LA		During pulpotomy	
	Control (INAB)	**Examined (Jet injector)**	**Control (INAB)**	**Examined (Jet injector)**
No Pain (0)	4 (26.7%)	5 (33.3%)	7 (46.7%)	7 (46.7%)
Mild (1-3)	6 (40.0%)	10 (66.7%)	7 (46.7%)	3 (20.0%)
Moderate (4-6)	4 (26.7%)	0 (0.0%)	0 (0.0%)	5 (33.3%)
Sever (7-10)	1 (6.7%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
Mean	2.67	1.33	1.33	1.73
SD	±2.69	±0.98	±0.63	±0.92
p-value	0.024*		0.480 ns	

Table [4]: Descriptive statistics of Wong-Baker FACES Pain Rating Scale for school age group (6-8 y), Immediate after LA and during pulpotomy

Wong-Baker FACES Pain Rating Scale of school age group (6-8 y)				
Rating scale	**Immediate after LA**		**During pulpotomy**	
	Control (INAB)	**Examined (Jet injector)**	**Control (INAB)**	**Examined (Jet injector)**
No Pain (0)	5 (33.3%)	11 (73.3%)	13 (86.7%)	7 (46.7%)
Mild (1-3)	9 (60.0%)	4 (26.7%)	2 (13.3%)	4 (26.7%)
Moderate (4-6)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Sever (7-10)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (20.0%)
Mean	1.47	0.53	0.27	2.93
SD	±1.19	±0.92	±0.70	±3.99
p-value	**0.008****		**0.016***	

III) Venham's anxiety and behavioral rating scale:

In Preschool age group (4-6 years) showed the majority of patients, 86.7% (13 children) in the INAB subgroup, immediately after LA, were distributed among 0,1 and 2 scales, while in the needleless jet injector, subgroup100% (15 children) were distributed among scales 0 and 1 only. The results used Wilcoxon's signed rank showed a significant difference in Venham's anxiety and behavioral rating scale score between the control (INAB subgroup) and examined (needleless jet injector subgroup) immediately after LA, as (p=0.023*). During a pulpotomy, most of the patients, 93.4% (14 children) in the INAB subgroup, lay in (0) and (1) scales, whereas 98% (12 children) in the needleless jet injector subgroup lay in scales (0) and (2). The results used Wilcoxon's signed rank showed significant differences between the control (INAB subgroup) and examined (needleless jet injector subgroup) group during pulpotomy, as (*p*=0.046*) (Table 5).

In school age group (6-8 years) showed the majority of patients, 86.7% (13 children) in the INAB subgroup and 100% (15 children) in the needleless jet injector subgroup lied in scales (0) and (1) . The results used Wilcoxon's signed rank showed a significant difference in Venham's anxiety and behavioral rating scale scores between the control (INAB subgroup) and examined (needleless jet injector subgroup) immediately after LA, as (p=0.005*). During a pulpotomy, it was noted that scale (5) was recorded at 20% for the needleless jet injector group only. The results used Wilcoxon's signed rank showed significant differences between the control (INAB subgroup) and examined (needleless jet injector subgroup) during pulpotomy, as (p=0.016*) (Table 6).

[5]: Descriptive statistic of Venham's anxiety and behavioral rating scale for preschool group (4-6 years), immediate after LA and during pulpotomy

Venham's anxiety and behavioral rating scale of Preschool age group (4-6 years)				
Rating scale	**Immediate after LA**		**During pulpotomy**	
	Control (INAB)	**Examined (Jet injector)**	**Control (INAB)**	**Examined (Jet injector)**
0	3 (20.0%)	4 (26.7%)	7 (46.7%)	7 (46.7%)
1	7 (46.7%)	11 (73.3%)	7 (46.7%)	3 (20.0%)
2	3 (20.0%)	0 (0.0%)	1 (6.7%)	5 (33.3%)
3	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
5	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean	1.27	0.73	0.73	0.87
SD	±0.96	±0.46	±063	±0.92
p-value	0.023*		0.046*	

Table [6]: Descriptive statistic of Venham's anxiety and behavioral rating scale school group (6-8 years), immediate after LA and during pulpotomy

Venham's anxiety and behavioral rating scale of school age group (6-8 y)				
Rating scale	**Immediate after LA**		**During pulpotomy**	
	Control (INAB)	**Examined (Jet injector)**	**Control (INAB)**	**Examined (Jet injector)**
0	4 (26.7%)	10 (66.7%)	13 (86.7%)	7 (46.7%)
1	9 (60.0%)	5 (33.3%)	2 (13.3%)	4 (26.7%)
2	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
4	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
5	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (20.0%)

Mean	**0.87**	**0.33**	**0.13**	**1.47**
SD	**±0.6**	**±0.5**	**±0.4**	**±2.0**
p-value	**0.005****		**0.016***	

Discussion:

The concept of painless and effective local anesthesia administration holds significant importance in pediatric dentistry. It plays a vital role in influencing children's cooperation and managing their behavior during dental treatments. As a result, needle-free injection systems have gained recognition as an alternative approach for administering local anesthesia. These systems are especially beneficial for pediatric patients, as they remove the common fear associated with needles by eliminating the needle puncture and insertion phases, which are often the most anxiety-inducing parts of traditional injection methods. This approach greatly aids in fostering a positive disposition towards future dental treatments [13].

The inferior alveolar nerve block is frequently employed in the treatment of the pulp of mandibular primary molar teeth, offering relatively prolonged and profound anesthesia. However, this technique has the potential to cause trauma to soft tissues. Moreover, it is generally considered to be more painful than infiltration methods. This observation is consistent with the findings presented by Bataineh and Majid, Jorgenson and Burbridge, and Noble et al. [35-37].

Therefore, it makes sense to have a different anesthetic strategy with a shorter duration but with equivalent effectiveness. For this purpose, the needleless jet injector was utilized in the current investigation. Needleless jet injections are considered to have multiple advantages over traditional syringe methods, primarily due to the elimination of the puncture and needle insertion stages. This change could potentially make the administration of anesthesia less painful and result in reduced tissue damage. Additionally, these systems are considered easier to use and may facilitate faster absorption of the drug at the injection site [38]. To the best of our understanding, this study is the first to investigate the effectiveness of a needle-free anesthesia system in reducing pain during vital pulpotomy of mandibular second primary molars, in comparison to the traditional approach of inferior alveolar nerve block anesthesia.

The current study included two age groups of children, preschool (4 - 6 years) and school (6 - 8 years), as each of them has a different mentality to deal with. Also, they possess different cognitive and behavioral actions toward anesthesia [29]. In addition, each age group has a different bone density, which in turn affects the degree of diffusion of local anesthetic solution in accordance with Mass et al. [39]**.** The children of the age group from 4 to 6 years are the most difficult to treat as they exhibit more disruptive behavior, in agreement with Altan et al. [17].

This study employed a split-mouth design, whereby each participant served as their control. This approach enables within-patient comparisons rather than between-patient ones, effectively reducing inter-subject variability. Such a methodology enhances the accuracy and statistical power of the study, allowing for the detection of real differences with a smaller number of participants [40].

Frankl’s Behavior Rating Scale (FBRS) is recognized as one of the most reliable tools developed for assessing children's behavior in dental settings. It comprises four categories of behavior, ranging from "definitely positive" to "definitely negative." The treating clinician determines these categories and can be applied at various stages of the dental treatment process. Children were chosen following the Frankel scale and scored 2 or 3 [41]; those were expected to comply with dentist instructions cooperatively or those with some evidence of negative attitude but still can cooperate. Both could provide good measures for pain and anxiety related to dental anesthesia. Children who cried violently showed fear, refused medical attention, or displayed any other overt signs of extreme negativism were excluded from the current study because of the children's lack of collaboration, which has an impact on the evaluation of the effectiveness of results.

In assessing pain perception, the Wong-Baker FACES Pain Rating Scale was employed for subjective evaluation. This scale is favored for its simplicity and has been widely utilized by numerous researchers in various studies. This pain scale was initially created for children, but it can be used with any patient who is three years old or older because the child can readily select the face that best expresses how they feel [42]. Children might struggle to quantify their pain on a scale from 0 to 10, but they are capable of identifying with the emotions depicted by cartoon faces. They can select the face that "best matches their level of pain," providing a more intuitive measure of their discomfort. Patients who are unable to count should still use this pain scale [43]. Consequently, it has been utilized in the current investigation in line with Khatri and Namita [42]**.** This scale was recorded immediately after local anesthesia administration and during the pulpotomy procedure of primary molars (at exposure time), as they were the most painful times in the procedure of the current study.

Regarding the Wong-Baker FACES Pain Rating Scale immediately after LA results, the current study revealed a significant difference between the control side (INAB subgroup) and the examined side (needleless jet injector subgroup) among preschool age group and school age group, as the INAB resulted in more pain perception after administration of anesthesia than needle-free injections system (Comfort-In™). This result was in agreement with Makade et al. [44], who compared the efficacy of pressure anesthesia and classical needle infiltration anesthesia on twenty nonfearful patients with no previous experience with dental anesthesia. They claimed that the needle-free device considerably reduced the experience of discomfort. Altan et al. [17], observed that the use of the needle-free system (specifically, the Comfort-In™ system) during anesthesia administration resulted in lower pain perception scores compared to the traditional dental needle method. Conversely, a study conducted by Arapostathis et al. in 2010 [29] noted that when using the INJEX jet injection system, a significant portion of children reported experiencing higher levels of pain. This increase in pain perception might be attributed to the sensation of pressure and the popping sound produced during the administration of anesthesia.

In recording the Wong-Baker FACES Pain Rating Scale during the pulpotomy procedure, the results indicated a non-significant difference in pain levels between the inferior alveolar nerve block (INAB) subgroup and the needleless jet injector subgroup among the preschool-age group. While among the school-age group, results showed a significant difference between the INAB subgroup and needleless jet injector subgroup, as pain perception during pulpotomy was higher in needle-free injection system (Comfort-In™) than traditional nerve block which may be due to the age of children (8 years old) and density of bone which affect the degree of diffusion of local anesthesia.

Furthermore, Venham's anxiety and behavioral rating scale were used to assess dental pain and anxiety as a high degree of reliability even for untrained observers, in accordance with Narayan and Samuel [45]. Objective pain assessment scales have demonstrated their immense utility, particularly because children may not always possess the ability to express their pain verbally. Valuable information can be derived from their reactions, facial expressions, and crying. In this study, the assessment of this scale was conducted by the operator and further verified by the supervisor (via video recordings) to minimize any potential bias. The operator underwent training and calibration before assessing the child's dental anxiety. To ensure consistency in evaluations, the dental sessions of ten patients were recorded on video and later reviewed by the supervisor. The purpose was to assess the inter-examiner reliability of Venham's anxiety and behavioral rating scale using the Weighted Kappa test. The results indicated values ranging from 0.70 to 1.00, signifying a high level of reliability [46]. In the present study, this scale was utilized immediately following the administration of local anesthesia and during the pulpotomy procedure for primary molars, as these were identified as the most painful phases of the procedure.

With respect to Venham's anxiety and behavioral rating scale immediately after LA, the current study conducted that there was a significant difference between the INAB subgroup and needleless jet injector subgroup in both preschool and school-age groups, as less fear and anxiety during needle-free injection system (Comfort-In™) was reported compared with INAB. These results were in agreement with Makade et al. [44]**,** who reported that less pain and fear were observed during the procedure with needleless anesthesia, which may be due to the absence of a needle. In contradiction to Szmuk et al. [47], who reported that patients' anxiety during needle-free injection was higher than the traditional injection, which may be due to the popping sound of the jet injector or explosive release of anesthetic solution from the jet injector or bulky appearance of the device as reported by Gupta and Rajan [48].

Regarding Venham's anxiety and behavioral rating scale during pulpotomy, the current study conducted that there was a significant difference between the INAB subgroup and the needleless jet injector in both preschool and school-age groups, where more fear and anxiety levels were recorded during needle-free injection system (Comfort-In™) compared to INAB, the possible explanation could be due to the age of the children regarding the increased density of bone which in turn decreased the diffusion of LA.

The null hypothesis of the present study was accepted for the preschool children. While it was rejected for the school children where the traditional inferior alveolar nerve block was found to be more effective than needleless jet injector in reducing pain and anxiety during pulpotomy procedure.

One of the limitations of our study is the challenge of maintaining blinding for both the children and the operator regarding the anesthesia methods. Furthermore, the potential for carry over effect due to the split mouth design. Although articaine has been verified to be safe and effective local anesthetic to be utilized for both pediatric and adult patients, there is debate with its use for nerve blocks in children and evidence supporting its practice is limited.

Conclusion:

The positive clinical outcomes documented in this study highlight the effectiveness of the needle-less jet injector system in reducing anxiety and pain during the administration of local anesthesia in both preschool and school-age children. Its efficacy was notably pronounced in preschool children during the pulpotomy procedure of lower second primary molars.

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