Original Article

Pain Control of Needle-less Jet Anesthesia VersusConventionalInfiltrationAnesthesiaforPulpotomyofMaxillaryPrimaryMolarsinChildren: A Randomized Controlled Trial

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Abstract

Aim: The objective of the current study was to assess the injection pain and intraoperative pain of the needleless jet injector in comparison to the conventional needle-attached syringe as infiltration local anesthesia during pulpotomy. **Subjects and methods**: Fifty-six vital deeply carious maxillary first primary molars indicated for pulpotomy were randomly assigned into two equal groups (N=28), where group I received maxillary infiltration anesthesia using the needle-less jet injector and group II received anesthesia using a conventional needle-attached syringe followed by pulpotomy and restored with stainless steel crown. Evaluation of pain was performed during injection, pulpotomy, and crown preparation using the Face Pain Scale-Revised (FPSR) and Sound, Eye, and Motor (SEM) Scale. **Results**: The Evaluation of pain scores using FPS-R and SEM Scale during injection, and pulpotomy showed no significant differences between both groups. Regarding crown preparation, pain scores using the SEM scale showed a significant difference between both groups, whereas FPS-R showed no significant differences. Besides, no correlation was detected between pain scores and age or gender. **Conclusions**: In primary teeth, the needle-less jet injector was successful in anesthetizing the maxillary first primary molars during the pulpotomy and crown preparation procedures.

Keywords: Needle-less Jet, Needle attached Syringe, Pain control, Primary Molars, Pulpotomy.

I. INTRODUCTION

A child reacts to dental care in a complicated manner that is influenced by a variety of factors, including the child's age, anxiety level, temperament, prior dental experiences, and parental anxiety (Barolet and Benohanian, 2018).

Pain associated with needle injections most commonly happens in dentistry during the administration of anesthesia causing an adverse emotional and cognitive response, particularly in children. The child may cooperate poorly during dental procedures, try to avoid dental treatment, and even become needle-phobic. Besides, more apprehension is often exhibited towards seeing a needle while receiving local anesthesia than from the actual therapy (Altan et al., 2021).

During dental treatment, delivery of local anesthetics painlessly to children has been always a very difficult task. Nevertheless, controlling pain and fear of the injection process helps in minimizing the child's worries and anxieties, contributes to building a positive and trustworthy relationship with the child, and assists in developing a future desirable positive dental attitude (Kaya and Yıldırım, 2022).

Needle-less jet injection has been suggested to be employed as an alternative to traditional needle injection. Jet injectors rely on the idea of driving a small volume of a drug with high velocity through a small aperture, commonly powered by a compressed spring or gas, creating a rapid liquid jet capable of tissue penetration. The absence of a needle has the main advantage of eliminating the issue of pain and fear of needles and injections (Schoppink and Rivas, 2022).

Previous studies comparing different types of jet injection systems and conventional needle injection didn't reach a consensus on the less painful anesthetic administration technique and to the best of our knowledge, there has been only a limited number of studies that evaluated the effectiveness of jet injectors during pulp therapy in children (Munshi, Hegde and Bashir, 2001; Altan et al., 2021). So, the objective of the current study was to assess the injection and intraoperative pain of the needle-less jet injector in comparison to the conventional needle-attached syringe as local infiltration anesthesia during pulpotomy.

II. SUBJECTS AND METHODS

Study Design

The present study is a parallel randomized superiority clinical study with an allocation ratio of 1:1.

Sample size calculation

The sample size was calculated based on the results of pain during injection reported by Sandeep et al., 2016 with a confidence level of 95% (alpha value of 0.05), a power of 80% (beta value of 0.2), 1.3 standard deviations, and an effect size of (1). The number of subjects was assessed to be 28 in each group, with 56 as the total sample size.

Ethical Approval

On March 31, 2020, the protocol was evaluated and approved by the Ethical Committee of the Faculty of Dentistry at Cairo University and was given approval number 19-7-43.

Study Registration

The study protocol was registered on ClinicalTrials.gov with the identifier NCT03917121.

Eligibility Criteria

Inclusion criteria:

- Children of both sexes between the ages of 6 and 8 years.
- 2. Children with vital deeply carious maxillary first primary molars indicated for pulpotomy.
- 3. Children attending their first dental visit.
- 4. Cooperative children with score 3 or 4 on the Frankl Category Rating Scale.

Exclusion criteria:

- 1. Children who reported a previous allergy to the local anesthetic or dental materials used.
- 2. Children whose parents or legal guardians refuse to sign the informed consent form.

Informed Consent

Participants and their parents were given clear explanations of the study's objectives, the dental procedure's detail, the direct benefits to children, and any potential negative outcomes, and signed informed consent was acquired.

Diagnostic procedure

An extra-oral examination, intra-oral examination, radiographic examination, and cold sensitivity test by spraying the Endo-ice on a cotton swab and applied to the buccal surface of the tooth were carried out to confirm adherence to eligibility criteria.

Randomization and Allocation concealment

The true random number service offered online at www.random.org was utilized to create the sequence of numbers. The envelopes, which were sequentially numbered from 1 to 56 and were opaque and sealed, were used to hide the allocation sequence.

Group I (Intervention group): 28 maxillary primary molars received maxillary infiltration anesthesia using the needle-less jet injector.

Group II (Control group): 28 maxillary primary molars received maxillary infiltration anesthesia using the conventional needleattached syringe.

Intraoperative procedure

The child's chair position was adjusted to a semi-supine position, and the child was asked to raise the chin upwards and tilt the head slightly towards the operator. The upper lip and cheek were retracted at the side of the injection with the left hand. For both groups, the injection site opposite the target tooth was dried with a sterile cotton swab, and 20% benzocaine topical anesthetic gel was applied to the site for 2 mins prior to the injection.

In group I, the jet injector was loaded with 4% Articaine with 1:100,000 epinephrine injectable local anesthetic solution as per the manufacturer's instructions, as shown in figure (1). The anesthetic solution was injected using the needle-less jet injector buccal to the target tooth according to the device's manufacturer's instructions. The silicon-capped end was placed in contact with the mucobuccal fold opposite to the target tooth and the activation button was pressed down to inject the first shot of anesthesia (0.1 ml). The injector was then reloaded to inject the second shot of anesthesia (0.5 ml) following the same procedure. After administering the anesthesia, the injector was left in place and lightly pressed against the site of injection for about five seconds while massaging in gentle and small circular motions to distribute the local anesthetic into the injection site and help prevent bleeding.

In group II, the conventional metal dental syringe was loaded with a carpule of the same anesthetic solution used in group I and attached to a 30-gauge short needle. Buccal infiltration was performed using the conventional needle-attached syringe. The needle was inserted into the height of the mucobuccal fold opposite to the target tooth close to the bone with the needle's bevel oriented to face it. The needle advanced a few millimeters until its bevel was at or above the apical region of the tooth and the injection was made slowly over 20 seconds.

Super absorbent pads and constant saliva ejection were used to maintain a dry isolated field during dental treatment. Formocresol pulpotomy procedure involved access cavity preparation, fixation using formocresol, and polymer-reinforced zinc oxide-eugenol for filling were performed and the tooth was finally restored with a stainless steel crown.



Figure (1): Photograph of loaded needle-free jet injector.

Assessment of the Outcomes

• <u>Pain assessment using Face Pain Scale-</u> <u>Revised:</u>

The FPS-R is a patient self-reported pain rating scale developed by Hicks et al., 2001 consisting of six gender-neutral line drawings of faces in different degrees of distress starting with a neutral face showing no pain which was categorized as a score zero and ending with a frowning face showing very much pain which was categorized as a score ten. The child was shown the FPS-R to select a face at the end of the anesthetic injection, pulpotomy procedure, and final restoration with stainless steel crown.

• <u>Pain assessment using Sound, Motor,</u> <u>Eye scale:</u>

The Sound, Motor, Eye (SEM) scale is a clinician-reported observational pain rating scale developed by Wright et al., 1991. It considers three types of physical observations, including sound, eye, and movement of the child, and categorizes them into four different levels of comfort or pain ranging from comfort which scored one, and painful which scored During the anesthetic injection, four. pulpotomy procedure, and final restoration with stainless steel crown, the primary investigator recorded three numerical scores for the three physical observations that were added to provide the child's SEM score ranging from three to twelve.

• The onset of pulpal anesthesia:

A cold sensitivity test was performed by applying the Endo-ice spray on a cotton swab on the buccal surface of the tooth to be treated at intervals of 20 seconds until a negative result was obtained and the onset of pulpal anesthesia was recorded in seconds.

• <u>The incidence of adverse effects:</u>

Any adverse effects observed by the principal investigator at the injection site following injection, including mucosal bleeding, hematoma, swelling, stinging, and bad taste were recorded in the patient assessment chart.

• <u>Criteria for the success of local</u> <u>anesthesia:</u>

The criteria for the success of local anesthesia were identified as the successful execution of the intended treatment without the need for additional anesthesia. If the child complained of pain while receiving treatment, the treatment was stopped, and the adequacy of local anesthesia and the need for additional anesthesia were assessed before continuing the Additional buccal infiltration procedure. administrated anesthesia was using а conventional needle-attached syringe if local anesthesia was considered inadequate.

Statistical analysis

The mean and standard deviation (SD) values were used to express quantitative data and the student t-test was employed to test the significant differences. Frequency and percentage distributions of qualitative data were shown, and Chi-square analysis was employed to test the significant differences. The p-value was deemed statistically significant if it was less than or equal to 0.05 and not significant if it was higher than 0.05.

III. RESULTS

• Demographic data:

In the current study, the age range of the participants was 6 to 8 years, with a mean age of 6.84 ± 0.69 years. The mean age was 6.70 ± 0.66 years in group I, and 6.98 ± 0.71 years in group II, with no statistically significant difference between both groups (Pvalue=0.125).

Regarding the gender distribution, males resembled 41.1% of the participants while females resembled 58.9%. Male participants constituted 35.7% of group I and female participants 64.3%, whereas male participants constituted 46.4% of group II and female participants 53.6% with no statistically significant difference between them (P-value=0.4151).

• <u>The onset of pulpal anesthesia:</u>

The onset of pulpal anesthesia among the study sample was 3.70 ± 2.57 minutes in group I, and 4.45 ± 3.10 minutes in group II, with no statistically significant difference between both groups (P-value=0.327).

• <u>The Evaluation of pain scores using Face</u> <u>Pain Scale-Revised:</u>

The evaluation of pain during injection, pulpotomy, and stainless steel crown preparation using the FPS-R showed no statistically significant difference between both groups with a P-value> 0.05, as presented in table (1).

• <u>The Evaluation of pain scores using</u> <u>Sound, Eye, Motor scale:</u>

The evaluation of pain during injection, pulpotomy, and stainless steel crown preparation utilizing the SEM scale showed only a statistically significant difference between both groups during the stainless steel crown preparation with a P-value=0.001, as presented in table (2).

• <u>The distribution of adverse effects after</u> <u>the anesthetic injection:</u>

Regarding the distribution of adverse effects, 7.1% of the participants had bleeding at the injection site in group I while 10.7% had bleeding at the injection site in group II. In terms of hematoma at the injection site, no participants had a hematoma in group I while 10.7% had a hematoma in group II with no statistically significant difference between both groups (P-value> 0.05), as presented in table (3).

• <u>The success of local anesthesia:</u>

The success of local anesthesia during the pulpotomy procedure was 89.3% in group I and 92.9% in group II, with no statistically significant difference between both groups (P-value=0.639). While the success of local anesthesia during the stainless steel crown preparation was 100% in group I and 92.9% in group II, with no statistically significant difference between both groups (P-value=0.150), as presented in figure (2).

• <u>The relation between scores of pain</u> <u>assessment scales and demographic</u> <u>characteristics:</u>

Pearson's correlation coefficient which evaluated the relation between scores of pain assessment scales and demographic data showed that both scores of FPS-R and SEM scale weren't correlated with age and gender with P-values >0.05, as shown in table (4).

IV. DISCUSSION

To improve the child's behavior during dental treatment, reduce or alleviate the fear of seeing the needle, and enhance patient cooperation, needle-free jet anesthesia for the administration of local anesthetic solution came into dental practice by applying the anesthetic solution with pressure to penetrate the tissues with spring-loaded devices in order to promote a positive attitude for dental procedure among the patients, especially for children (Altan et al., 2021).

The age range of the participants was 6 to 8 years, with a mean age of 6.84 ± 0.69 years in agreement with El Tawil and El Dokky, 2018; Altan et al., 2021. This can be attributed to the fact that most children develop the ability to cooperate and self-report pain above the age of five years (Le May et al., 2018; Hassan, Zahran and Saleh, 2019).

Regarding the gender distribution, 58.9% of participants were females and 41.1% were males which was consistent with Altan et al., 2021; Kaya and Yıldırım, 2022 and can be explained by the fact that females tend to seek dental treatment more than males (Hamasha et al., 2018).

FPS-R pain scores	Group I	Group II	P-value
After the injection	2.38±1.96	2.79±2.33	0.499
After the pulpotomy	1.29±1.36	1.43±1.71	0.730
After the stainless steel crown preparation	2.72±2.07	3.56±3.00	0.252

Table (1): Mean and standard deviation of the Face Pain Scale-Revised scores among the study sample

Table (2): Mean and standard deviation of the Sound, Eye, Motor scale scores among the study sample

SEM scale pain scores	Group I	Group II	P-value
During the injection	5.21±1.66	6.11±2.33	0.105
During the pulpotomy	4.18±1.85	4.46±1.90	0.570
During the stainless steel crown preparation	3.84±1.34	5.59±2.04	0.001*

*; significant (p-value ≤ 0.05) ns; non-significant (p-value>0.05)

Adverse Effects	Group I		Group II		P-value
	Number	Percentage	Number	Percentage	
leeding at the injection site	2	7.1%	3	10.7%	0.639

0%

0%

0%

0%

3

0

0

2

10.7%

0%

0%

7.1%

0.075

0

0

0.150

0

0

0

0

Bleeding at the injection site

Hematoma at the injection site

Swelling at the injection site

Stinging sensation

Bad taste

Table (3): The distribution of adverse effects among the study sample

*; significant (p-value ≤ 0.05) ns; non-significant (p-value>0.05)

Variable	Scale	Pearson's Correlation (r)	p-value
	FPS-R scores after injection	-0.15	0.133
	FPS-R scores after pulpotomy	-0.10	0.23
Age	FPS-R scores after stainless steel crown preparation	-0.15	0.130
	SEM scale scores after injection	-0.16	0.120
	SEM scale scores after pulpotomy	-0.16	0.11
	SEM scale scores after stainless steel crown preparation	-0.06	0.334
Gender	FPS-R scores after injection	-0.01	0.459
	FPS-R scores after pulpotomy	0.14	0.855
	FPS-R scores after stainless steel crown preparation	-0.06	0.343
	SEM scale scores after injection	0.11	0.799
	SEM scale scores after pulpotomy	0.16	0.873
	SEM scale scores after stainless steel crown preparation	0.08	0.722

 Table (4): Pearson's correlation coefficient (r) and p-value for the relation between scores of pain assessment scales and age and gender.

*; significant (p-value ≤ 0.05) ns; non-significant (p-value>0.05)

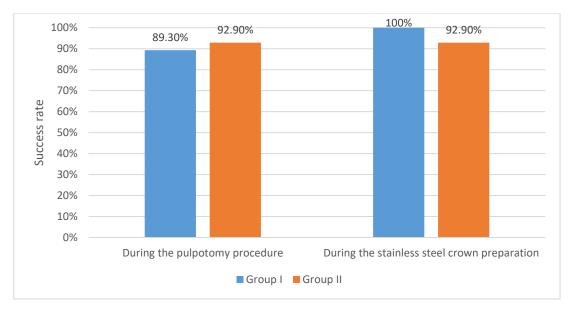


Figure (2): Bar chart showing the success of local anesthesia in both groups.

Both groups showed similar baseline characteristics including age and gender which was in agreement with Allegretti et al., 2016. This may be credited to randomization, which guaranteed similar distribution of known and unknown confounders. Therefore, the results obtained from both groups can be directly compared, and any potential impacts of these parameters can be reduced or even ignored (Gliklich, Dreyer and Leavy, 2020).

The onset of pulpal anesthesia among the study sample was 3.70 ± 2.57 minutes in group I, and 4.45 ± 3.10 minutes in group II, with no statistically significant difference between both groups which was in line with Dabarakis et al., 2007; Oliveira et al., 2019. This can be justified by the pediatric maxilla and mandible's cancellous structure, which permits the diffusion of the anesthetic agent (Brandt et al., 2011). Besides, the presence of a thiopene ring in the chemical structure of articaine gives it the benefit of having great penetration capabilities (Gazal et al., 2015; Bortoluzzi et al., 2018).

After the injection of the local anesthetic agent, the mean and standard deviation of pain scores using FPS-R was 2.38±1.96 for group I and 2.79±2.33 for group II, and using the SEM scale was 5.21±1.66 for group I and 6.11±2.33 for group II, with no statistically significant difference between both groups which was consistent with Oliveira et al., 2019; Ocak et al., 2020. This can be attributed to the sudden felt pressure and heard popping sound upon jet injection which might have accounted for fear of a sudden stimulus reflecting on pain perceived or misinterpretation of the pressure as pain (Kaya and Yıldırım, 2022).

On the contrary, Altan et al., 2021 reported a statistically significant difference between both groups which can be attributed to the lesser volume of anesthesia injected compared to the current study which might have contributed to less pain upon jet injection (Barolet and Benohanian, 2018). Besides, the use of a lower needle gauge might have contributed to higher pain perceived upon needle injection (Ram, Hermida and Amir, 2007).

After the pulpotomy procedure, the mean and standard deviation of pain scores using the FPS-R was 1.29 ± 1.36 for group I and 1.43 ± 1.71 for group II, and using the SEM scale was 4.18 ± 1.85 for group I and 4.46 ± 1.90 for group II, with no statistically significant difference between both groups which was in line with El Tawil and El Dokky, 2018; Altan et al., 2021. This can be explained by the ability of needle-free jet injectors to obtain optimum pulpal anesthesia in maxillary primary molars (Srinivasan et al., 2009; Alameeri et al., 2022).

After the stainless steel crown preparation, the mean and standard deviation of pain scores using the FPS-R was 2.72±2.07 for group I and 3.56±3.00 for group II, with no statistically significant difference between both groups. While using the SEM scale, the mean and standard deviation of pain scores during the stainless steel crown preparation was 3.84±1.34 for group I and 5.59±2.04 for group II, with a statistically significant difference between both groups. This can be attributed to the fact that anesthesia delivered by jet injection infiltrates the tissue in tiny droplet form better taken up by the myelin sheath of the supplying nerves (Munshi, Hegde and Bashir, 2001; Makade, Shenoi and Gunwal, 2014).

Besides. the greater initial concentration of local anesthetic deposited by the jet injector at one time creates a higher concentration gradient for diffusion and faster diffusion rate of anesthetic solution upon jet injection, accompanied by the unhindered flow of these liposoluble molecules in the direction of epineurium's fascicles. the nerve Accordingly, such infiltration pattern may be a reason for the better buccal and interproximal soft tissue anesthetization as well as better and faster anesthetic diffusion to the palatal soft tissues in case of jet injection resulting in better pain control during stainless steel crown restoration (Oliveira et al., 2019).

Neither hematoma, swelling at the injection site, stinging sensation, nor bad taste was reported in group I concerning the distribution of adverse effects, whereas only 7.1% of participants experienced bleeding at the injection site with no statistically significant difference between the two groups. These findings were in agreement with Makade, Shenoi and Gunwal, 2014; Ocak et al., 2020 and can be attributed to the technique of application of the Comfort-in jet syringe recommended by the manufacturer to be kept in place following injection while applying gentle pressure and massaging to prevent bleeding. Besides, the different designs of jet injectors might account for the difference in the properties of the jet stream ejected and hence resulting tissue response, such as driving pressure and its effect on penetration depth and risk of injury to vascular structures (Barolet and Benohanian, 2018).

The success of local anesthesia during the pulpotomy procedure was 89.3% in group I and 92.9% in group II, with no statistically significant difference between both groups which was in line with Munshi, Hegde and Bashir, 2001; Makade, Shenoi and Gunwal, 2014; El Tawil and El Dokky, 2018. Besides, the success of local anesthesia during the stainless steel crown preparation was 100% in group I and 92.9% in group II, with no statistically significant difference between both groups. This can be justified by the ability of the needle-free jet injector to obtain optimum pulpal anesthesia and the ability to diffuse and anesthetize palatal tissue in primary teeth (Brunton et al., 2022).

There was no correlation between pain as measured by the FPS-R and SEM scale and any demographic traits which were consistent with McEntarfer, DiPirro and Page, 2005; Khatri and Kalra, 2012. This finding can be justified by the fact that boys and girls experience pain similarly throughout all age ranges (McEntarfer, DiPirro and Page, 2005). On the contrary, Lautenbacher et al., 2005; Eltumi and Tashani, 2017 reported that pain thresholds elevated between the ages of 5 and 18 years, and females appear to be more sensitive to experimentally generated pain than males. The complexity of pain, the multi-dimensional phenomenon in which biological, psychological, emotional, cultural, and environmental factors can affect the pain experience of each individual may help to explain these conflicting findings (Pieretti et al., 2016; Gazerani, Aloisi and Ueda, 2021).

V. LIMITATIONS OF THE STUDY

The assessment of the multidimensional nature of pain with both scales, the FPS-R and the SEM scale, has shown some limitations and may not have accurately reflected the complexity of the pain experienced. During the administration of the anesthetic solution, it was impossible to keep the children and researchers blinded to the methods of administering local anesthesia.

VI. CONCLUSIONS

Within the limitations of this study, we can conclude that:

- The needle-less jet injection is a promising alternative to needle injection in anesthetizing the maxillary first primary molars during the pulpotomy and crown preparation.
- Although the onset of local anesthesia in needle-less jet injectors was shorter compared to needle-attached syringes, there was no statistically significant difference between them.
- During the injection of local anesthesia and the pulpotomy procedure, pain scores were comparable between the needle-less jet injectors and needle-attached syringes with no statistically significant difference.
- During the crown preparation, the needleless jet injector's pain scores were significantly lower in comparison to needle-attached syringes.

- Regarding the adverse events, bleeding at the injection site was the only adverse event recorded in the needle-less jet injector group. While bleeding and hematoma at the injection site were recorded in the needleattached syringes.
- No correlations were detected between pain scores and age or gender during different study procedures.

Conflict of Interest

No conflicts of interest are disclosed by the authors.

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