ORIGINAL RESEARCH

Comparative Evaluation of Pain Perception with Conventional and Septoject XL Needle in 6–8-year-old Children: A Randomized Controlled Trial

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Abstract

Aims and background: To evaluate and compare pain perception with Septoject XL and conventional needles in 6–8 years old children.

Materials and methods: In this split-mouth randomized controlled trial, a single-blinded study, 24 children (6–8 years) were assigned at random to receive the local anesthetic (LA) injection for treatment needs either with Septoject XL or conventional needle for the first visit in one of the quadrants, while during the second visit in a different quadrant with the other one. Children's pain levels were assessed during each visit using an objective sound eye motor (SEM) scale and subjective Wong–Baker faces rating scale (FRS).

Results: The mean objective score rating using SEM for the conventional needle (3.8 ± 2.35) and Septoject XL needle (3.3 ± 2.01) was not found to be statistically significant among the two study groups Septoject XL or conventional needle (*Z* score—0.996, $p = 0.3$). Using the Wilcoxon test, the mean subjective rating score was not found to be statistically significant among the two study groups [*Z* score = 0.636 and *p*-value = 0.524, nonsignificant (NS)]. In the gender-wise comparison of male (n =15), (6.8667 ± 91548) and female (n = 9), (6.8889 ± 1.05409), NS mean ages of male and female study participants was observed ($p = 0.873$).

Conclusion: Statistically, NS difference was observed in the pain perception while administration of LA using Septoject XL or conventional needle in 6–8-year-old children.

Clinical significance: This research can be useful in the selection of the gauge of the needle to be used while planning the treatment for different behavior groups.

Keywords: Anxiety, Behavior, Local anesthesia, Pain, Septoject XL.

International Journal of Clinical Pediatric Dentistry (2024): 10.5005/jp-journals-10005-2897

Introduction

Pain is a multifaceted term that involves emotional, sensory and psychological feature processes. Pain management is an extremely important part of dentistry and is always associated with fear. Fear-related behavior is the most challenging part of managing a patient that could be a hindrance to excellent treatment and care.[1] Anticipated pain due to fear of injection can make the dental appointment all the more difficult. Patients behavior in relation to the pain experienced can either increase over time or they may become habitual to it.[2] In several countries, dental fear and anxiety in children have been identified as a public health concern. Persistent and intense anxiety in relation to a perceptible situation or object or dental instruments, in general, is a form of dental anxiety termed dental phobia.[3] The acquisition of dental fear and anxiety in childhood accounts for a major reason why, in adulthood, people dodge dental treatment. This acquired dental fear and anxiety needs to be taken care of from childhood so as to enhance the dental experience as well as improve the child's oral hygiene.[4] According to Welbury, the perceived pain rating by an individual is highly influenced by the fear and anxiety the person has developed toward the dental treatment because of painful experiences.[5]

Local anesthesia (LA) is regarded the foundation of pain management in dentistry.[6] All dental operations require correct and deep anesthesia, as well as easy injection with minimal pain and complications. Thus, pain management compromises not only developing a friendly rapport with the patient but also reducing the amount of pain experienced in the subsequent dental appointments.[7] Some clinicians, however, believe that using a smaller gauge needle is the most effective way to reduce injection discomfort.[8] Septoject XL is a single-use stainless steel dental needle with an enlarged bore. The "enlarged bore" (43% wider than a standard needle), according to Septodont, minimizes the level of pressure all through the injection, resulting in less pain for the patient.[9] As a result, this randomized controlled trial was designed to compare and evaluate the perception of pain with Septoject XL and conventional needles in children aged 6–8 years (Fig. 1).

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How to cite this article: Singh S, Goel D, Awasthi N, *et al.* Comparative Evaluation of Pain Perception with Conventional and Septoject XL Needle in 6–8-year-old Children: A Randomized Controlled Trial. Int J Clin Pediatr Dent 2024;17(7):802–806.

Source of support: Nil

Conflict of interest: None

Materials and Methods

The study is a split-mouth, single-blind, randomized controlled trial conducted in the Department of Pediatric and Preventive Dentistry, School of Dental Sciences, Sharda University, Greater Noida, Uttar Pradesh, India. The study was reviewed and approved by the Institutional Ethics Committee (ref. no. SU/SMS&R/76-A/2018/137). The inclusion criteria were met by the 24 children who were chosen for the study.

Inclusion Criteria

- Children aged 6–8 years old require treatment in at least two quadrants.
- Local anesthesia is required for extraction (retained, root stumps, and grossly decayed), pulp therapy (pulpectomy, pulpotomy), and placement of rubber dam and stainless-steel crown.
- A minimum of two clinical appointments on either of the jaws, each preceded by a LA administration.
- Children exhibiting positive or strongly positive behavior during the initial assessment (Frankl rating 4 or 3).
- Parents who gave consent for their children to take part in the study.

Exclusion Criteria

- Children in need of emergency treatment.
- Patients with abscess and space infection.
- Medically or physically compromised children.

Sample Size Determination

G*Power software was used to estimate the sample size (version 3.0). The sample size for the *t*-test was estimated, and the Wilcoxon signed-rank test (one-sample case) was chosen. Statistical Package for the Social Sciences (version 21) was used to analyze the data. The frequency of categorical variables was summarized. Means and standard deviations were used to summarize continuous variables. Microsoft Excel was used to create the graphs.

Categorical data were compared using the Chi-squared test. Wong–Baker faces rating scale (FRS) and sound eye motor (SEM) scores were compared using the Wilcoxon paired-rank test. The statistical significance level was set at 0.05.

Study Design

According to the inclusion criteria, 24 patients were selected for the study. Random allocation into two groups was done by flipping a coin (Fig. 2).

Control group—conventional needle (30-gauge).

Experimental group—Septoject XL.

In the first visit, the patient was administered with LA using either of the two needles. In the subsequent second visit, the patient was administered LA in the other quadrant using the other needle (Figs 3 and 4). The administration of LA was done by a single trained dentist according to the standard protocols. Patients were blinded, as they were not aware of the needle being used by the investigator. Prior to each treatment procedure, topical lignocaine hydrochloride gel (LOX—2% jelly) was applied, followed by infiltration with LA (2% lidocaine and 1:1,00,000 epinephrine). Children's pain level was assessed during each visit using an objective SEM scale in which the observation and rating were done. For the subjective aspect the Wong–Baker FRS was used. After the injection, the patient was explained as to what intensity of pain is being represented

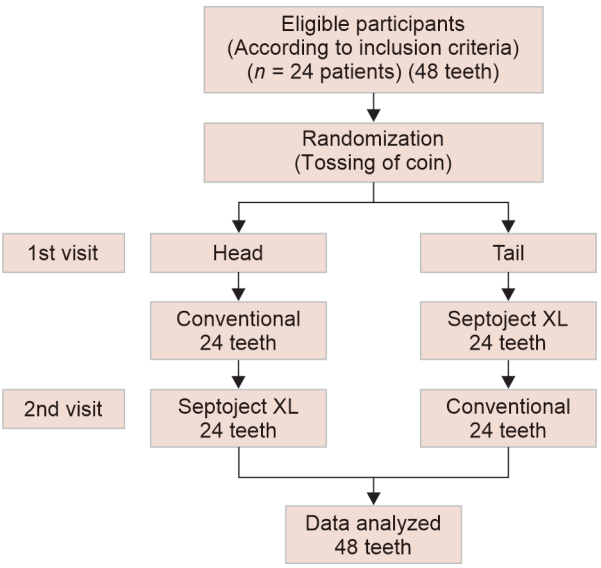

Fig. 2: Study flowchart

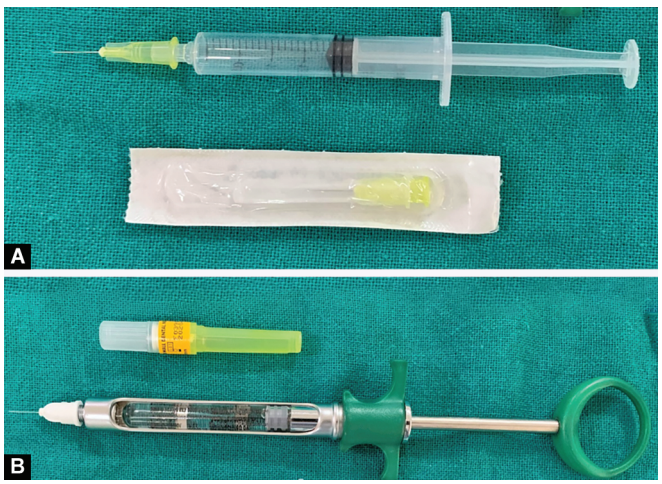

Fig. 1: Conventional needle and Septoject XL needle

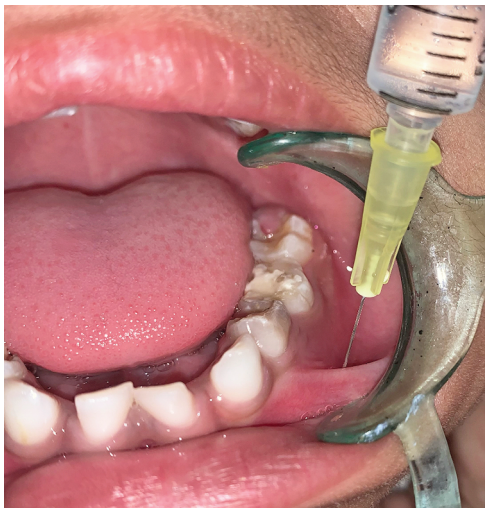

Fig. 3: Treatment with conventional needle

by each facial expression. After that, the patient was instructed to select the facial expression that was best depicting the pain they were undergoing. To obtain the results, the collected data was statistically analyzed.

Results

A total of 24 children, 15 boys and 9 girls, in the age-group of 6–8 years were recruited to be a part of the study.

Gender-wise Comparison of Mean

In the gender-based comparison of male ($n = 15$), (6.8667 ± 91548) and female ($n = 9$), (6.8889 ±1.05409), the mean age of male and female study participants was not statistically significant ($p = 0.873$) (Table 1 and Fig. 5).

Intergroup Comparison of Subjective Rating Score

The mean pain score using Wong–Bakers FRS for the conventional needle (30-gauge) was 4.2, while the mean pain score for the Septoject XL needle (30-gauge) was 4.0, using the Wilcoxon test, the mean subjective rating score was not found to be statistically significant among two study groups [Z score = 0.636 and p-value = 0.524, nonsignificant (NS)] (Table 2 and Fig. 6).

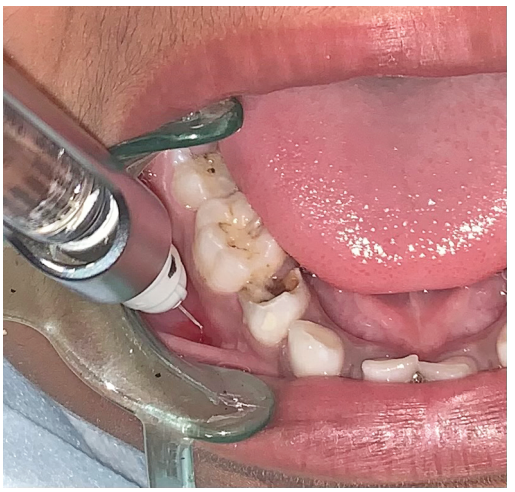

Fig. 4: Treatment with Septoject XL needle

Mean Objective Sound Eye Motor Score

The mean score for the conventional needle (3.8 ± 2.35) and Septoject XL needle (3.3 ± 2.01) was not found to be statistically significant among the two study groups (Z score = 0.996, $p = 0.3$) (Table 3 and Fig. 7).

Discussion

The American Academy of Pediatric Dentistry (AAPD) recognizes that pain can and does occur in children, infants, people with special health care needs (SHCN), and adolescents as a result of

Table 1: Gender-wise comparison of mean age

	Sex	*N*	*Mean*	*Standard deviation (SD)*	*p-value*
Age	Males	15	6.8667	0.91548	0.873, NS
	Females	9	6.8889	1.05409	

Table 2: Subjective rating score

	N	*Minimum*	*Maximum*	*Mean*	*SD*
Conventional technique	24	0.00	10.00	4.2500	2.38200
Septoject XL technique	24	2.00	10.00	4.0000	2.12644
Z score			–0.636		
p-value			0.524, NS		

Table 3: Sound eye motor score

	N	*Minimum*	*Maximum*	*Mean*	*SD*
Conventional technique	24	0.00	9.00	3.8333	2.35292
Septoject XL technique	24	1.00	7.00	3.3750	2.01759
Z score			–0.996		
p-value			0.319, NS		

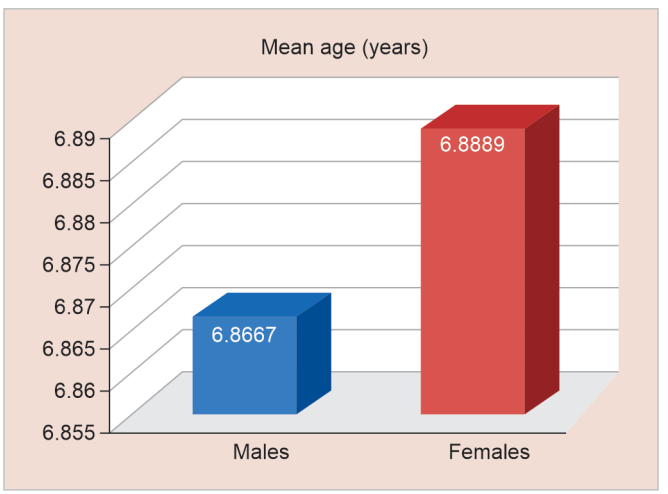

Fig. 5: Gender-wise comparison of mean age

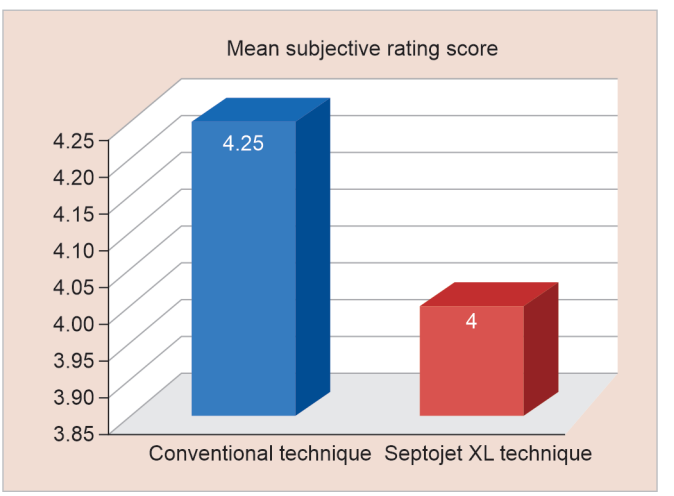

Fig. 6: Subjective rating score

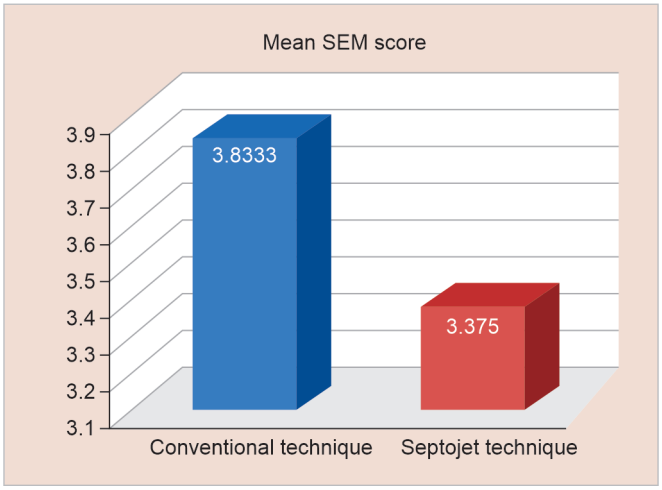

Fig. 7: Sound eye motor score

infection, orofacial/dental injury, and dental procedures. Inadequate management of pain can have serious psychological and physical repercussions on the patient. Knowledge about the pain process is critical for pain management. Childhood pain can influence future pain experiences in adulthood.[10] One of the foremost very important and troublesome facets of behavior management in youngsters throughout dental treatment is pain management. Many children take into account injection as the least desirable part of dental treatment.[11] While the use of LA eliminates any procedural discomfort or pain, the delivery of the LA solution is perceived as unpleasant and frequently causes anxiety, particularly in children.[12] In fact, injecting LA during dental procedures has generally been regarded as among the most agonizing aspects of dental treatment.[13,14] In a study based on an assessment of discomfort, pain, and anxiety experienced following extraction of deciduous canine in 44 children between the age-group of 10–13 years with palatally displaced canines, LA injection experience was ranked worse than that of extraction. A positive correlation between pain and dental anxiety scale was also observed in the abovementioned study.[15] Various advancements in anesthetic agents and techniques have been made to induce painless and comfortable anesthesia.[16] It is widely accepted that finer needles induce less pain in comparison to regular ones. A 25-gauge needle is commonly used by many practitioners. Finer needles are typically found in dental syringes (27- and 30-gauge). It is recommended that a 30- or 27-gauge needle should be used for infiltration. The initial penetration of the skin causes some of the pain associated with LA administration. A long needle allows a larger space below the surface to be infiltrated with a single skin puncture, reducing the number of skin punctures required.[17] Pain assessment strategies used in medical and dental research on children vary. SEM scale was used for objective evaluation which was designed by Wright et al. in 1991. The Wong–Baker FRS was used for subjective evaluation immediately following the injection (FRS). The findings of numerous studies show that the patient most aptly described his or her pain level. Thus, the gold standard of pain assessment is patients' self-report.[18]

In the present study, 6–8-year-old children were selected because children younger than 6 years of age lack the apt communication skills as well as vocabulary to describe their pain, and also, patients under the age of 4 consistently reported more pain than older patients. Hicks et al. discovered that children over the age of 5 could rate the intensity of their pain using age-appropriate scales.[19] There was no significant difference in pain seen among the participants in the current study when infiltration was performed with a 30-gauge conventional needle or a Septoject XL needle. Possible explanations for the lack of statistical significance are firstly, pain is a distressing sensation influenced by psychological, sociological, and biological factors. Numerous factors such as past pain experiences, cultural differences, and expectations all can have a considerable impact on the pain that is experienced that is beyond the activation of nociceptors. It also serves as an explanation as to why the same measurable pain parameters are perceived differently and also expressed as a different subjective pain response. Secondly, the manufacturer claims that their larger bore needles cause less pain during injection. According to Septodont, the expanded bore is 43% wider than a standard needle. However, the current study found that when compared to a standard-bore gauge needle, using a large-bore needle did not decrease the overall pain during injection. This study confirmed the findings of McPherson et al., who compared the efficacy of a 27-gauge larger-bore needle vs a 27-gauge standard-bore needle in reducing the pain during long buccal (LB) and inferior alveolar (IA) nerve block injections. It was observed that there was no reduction in pain perception when both were compared.[20] Given the lack of significance, the change in pain perception could be due to the needle gauge rather than the bore size. Many studies have been conducted in the past to explore the reason behind the difference in pain perception when using needle gauges of varying sizes. In 2014, Ghasemi et al. discovered a significant difference between 30- and 27-gauge needles, concluding that the 30-gauge needle is more advantageous in administering IA nerve block in children.[8] According to Brownbill, the difference in efficacy, pain, and aspiration between 25- and 30-gauge needles is statistically insignificant.[21] Ram et al. observed when comparing a 30-gauge needle with a 27-gauge needle while administering a mandibular nerve block, a 27-gauge needle was associated with more amount of subjective signs of pain than the 30-gauge needle.[22]

In contrast to the abovementioned studies in which the gauge of the needle did not show any significant difference in pain perception. Lehtinen clinically tested (for pain insertion and penetration resistance) two styles of needles. The force required by the 30-gauge needle (69 mN) was significantly less than that required by the 27-gauge needle (139 mN). Distinction in pain was not ascertained between the two.[23] Fuller et al. found no important variations in pain perception when injection was given with 27-, 25-, and 30-gauge needles.[24]

Findings of this randomized, split-mouth, single-blind clinical study indicate that using a large-bore needle with the same gauge did not reduce overall pain on injection.

Conclusion

It was concluded that there was no statistically significant difference between Septoject XL and the conventional needle in the aspect of subjective and objective measures of pain perception with the same gauge but different bore size needles. More studies with larger study populations need to be carried out in the future in order to obtain more confirmatory and conclusive results.

Clinical Significance

This research can be useful in selecting the gauge of the needle to be used while planning the treatment for different behavior groups.

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