ORIGINAL RESEARCH

Comparison of Conventional Syringe with Camouflaged Syringe and Vibration-assisted Syringe for Pain and Fear Perception during Local Anesthetic Administration in Children: A Split-mouth Randomized Controlled Trial

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Abstract

Aim and background: Although local anesthesia (LA) eliminates pain and instills a positive dental attitude, the physical appearance of its syringe is highly fear provoking and often intolerable. Therefore, the purpose of this study was to evaluate the pain and fear perception in camouflaged syringe (CS) and vibration-assisted syringe (VA) when compared with conventional syringe and with each other (VACS) during local anesthetic administration in pediatric patients aged between 6 and 12 years.

Materials and methods: Eighty-five subjects were randomly assigned into three groups: CS group ($n = 7$), VA group ($n = 26$), and VACS group ($n = 27$). Physiological and psychometric scale readings were noted before and after injection. The primary outcome was to assess the change in patients' fear and pain levels using CS and VA vs conventional injection techniques, using the above scales. The secondary outcome was to learn the preference for a particular injection technique by the subjects.

Results: Based on the changes seen in the physiological and psychometric scales, pain and fear control was better in CS in the CS group ($p < 0.00$ for heart rate, VAS, and SEM score), vibration-assisted syringe in the VA group ($p < 0.00$ for VAS and SEM score), and vibration-assisted syringe in the VACS group ($p < 0.00$ for VAS score). The majority preference was CS in the CS group (64%), vibration-assisted syringe in the VA group (60%), and CS in the VACS group (52%).

Conclusion: VA followed by CS is better than the conventional syringe in terms of reducing pain and fear perceived during LA administration. Children preferred CS over VA or the conventional syringe.

Clinical significance: Children's disruptive behavior due to dental fear and pain often results in difficulty in providing effective dental treatment, which is frequently caused by the syringe used in LA delivery. Thus, techniques used to minimize this fear and pain are essential to provide safe, efficient, and quality dental care to children.

Trial registration: The trial was registered with the Clinical Trial Registry of India (CTRI/2023/11/059505).

Keywords: Camouflaged syringe, Fear, Local anesthesia, Pain, Vibration-assisted syringe.

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Introduction

With the modernization of dentistry and its intense research, an aspect that still lags in coverage is the management of fear and pain in patients, especially due to needle insertion in pediatric patients. There are various techniques described to manage pain, fear, and anxiety, but there are still relatively fewer studies to prove which method would be suitable for a pediatric dental patient. Trypanophobia, or in other words, the phobia of needle pricks, is the chief cause of dental fear, followed by the usage of dental drills. The sight and sensation of pain from the needle have consistently been proven to be the greatest fear-evoking stimuli for dentally apprehensive children.[1,2]

Dental anxiety is a type of fear expressed in anticipation of threatening dental stimuli.[3,4] Studies show that dental anxiety is mostly fueled by pain or the fear of pain, which is a major hindrance in seeking dental treatments.[5,6] Pain and fear go hand in hand. During the administration of a local anesthetic injection, a fearful patient may experience more intense and long-lasting pain than a patient who is less fearful.[7] Children who witness intense pain during dental procedures also typically display more behavioral issues at subsequent visits, necessitating more restraint and lengthier procedures. These children may also refuse to receive the necessary dental care, increasing their likelihood of avoiding future care as adults. While the primary goal of local anesthesia (LA) is to diminish pain, the actual administration process and

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its visual aspect could be fear provoking and painful due to the stimulation brought on by the insertion of the needle. Therefore, it becomes of utmost importance to not just reduce pain during needle insertion but also to control fear, which originates from visualizing the needle/injection.[8]

There are a variety of techniques that may be used to potentially deliver painless LA, which include pharmacological drugs such as topical anesthetics, physical techniques such as precooling the injection and acupuncture, and psychological interventions such as distraction techniques. All of these have been studied for pain management during needle-related procedures in young patients.[9]

One such method to lessen pain related to local anesthetic injection is vibratory stimulation. There have been relatively few attempts to use vibration to alleviate the discomfort of oral injections, although soft tissue vibration has been utilized to relieve pain in other parts of the body.[10,11] The concept of vibration is based on the gate control theory, wherein the vibration acts as a counter-stimulation at the injection site, which reduces pain.[12]

Some sensory modalities, such as visual stimuli, are often associated with pain.[13] Distraction is a behavior modification strategy that involves drawing the child's attention away from a painful stimulus while invasive dental procedures are being performed. The dental procedure, therefore, takes less time and fewer personnel to complete. It is also considered affordable and safe.[14,15]

Distraction could be useful, as even the mere sight of a needle makes patients less cooperative in the dental operatory. Pediatric patients perceive the needle to be a dangerous object both visually and psychologically. When fear levels rise, the perception of pain may change, appearing to be more severe and of longer duration.[16] It is therefore vital to find an approach that is practical and efficient for concealing the needle. One approach to achieve this is hiding the syringe in a sleeve, which can act as a distraction and help patients who are afraid of the needle feel less fearful.[17]

There are only a few studies on camouflaging the syringe, wherein the entire injection apparatus stays hidden from the sight of children. An autoclavable plastic, in the shape of a toy alligator (Angie Alligator sleeve, Angelus™, Brazil), fitted as a syringe sleeve can be used to conceal the threatening metal dental syringe.

Studies have shown that pain significantly alters physiological signs like tachycardia and hypoxemia. Fear and anxiety are also known to have psychological, behavioral, and physiological implications.[18] In a study, it was observed that there was a significant increase in heart rate and blood pressure due to fear from dental procedures when compared to the normal state as an autonomic response by the body.[19] Furthermore, pain and fear are internal sensations that are not readily accessible to others; hence, children's self-reports should be the primary source of information. Therefore, in the present study, the following scales are used to evaluate pain and fear perception: (A) Psychometric scales: self-reported face version of the visual analog scale (VAS) and sound, eye, and motor (SEM) pain scale; and (B) Physiological scales: heart rate (HR), SpO_2, respiratory rate (RR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) for assessment of both pain and fear.

Hence, the present research aims to evaluate the pain and fear perception in vibration-assisted syringe and camouflaged syringe (CS) when compared with conventional syringe technique and with each other for LA administration in pediatric patients aged between 6 and 12 years. The formulated null hypothesis of the present study is that "the CS and vibration-assisted syringe used in the study did not reduce the pain and fear perception during local anesthetic administration in pediatric patients."

Materials and Methods

Trial Design

The present clinical study was a randomized controlled trial with three parallel arms, with each arm consisting of a split-mouth study designed to evaluate pain and fear perception in vibration-assisted and CS vs conventional injection technique for LA administration in pediatric patients.

Ethical Approval and Registration

The study was approved by the Institutional Ethics Committee of the University (Ref. No. IECJNMC/698 dated 20/08/2022). The trial was registered with the Clinical Trial Registry of India (CTRI/2023/11/059505) prospectively.

The study followed the protocol recognized by the Consolidated Standards of Reporting Trials (CONSORT) statement, in accordance with the randomized controlled trial checklist.

Inclusion Criteria

- Children in the age-group of 6–12 years.
- Children who had their first dental visit.
- Children who required bilateral inferior alveolar nerve block for their treatment needs.
- Systemically healthy children with no congenital, developmental, neurosensory, or psychiatric disorders.
- Children exhibiting cooperation.

Exclusion Criteria

- Children who were suffering from medical illnesses or those who cannot comprehend the pain scales.
- Patients who were undergoing therapy with neurological, sedative, analgesic, and/or anti-inflammatory drugs.
- Patients who were having significant behavioral management problems.
- Patients with acute, symptomatic, or emergency dental conditions.
- Patients who had a history of allergy to any medication or food items.
- Patients who were not willing to participate in the study.

Sample Size Calculation

Sample size (n) = $(f(\alpha,\beta) \times \sigma^2)/(\mu1 - \mu2)^2$

Where,

σ = standard deviation of within subject mean difference = 5.41

$\mu1 - \mu2$ = mean difference = 3.50

$f(\alpha,\beta)$ = function of power and significance level of 5% ($\alpha = 0.05$, $\beta = 10.5$ for power 90%)

$$n = 10.5 \times 5.41 \times 5.41/(3.50)^2 = 25$$

With the help of pilot study values, it was found that the standard deviation of within-subject mean difference is 5.41 and the mean difference was 3.50 of two group parameters. The power analysis was done using Software G*Power version 3.1.9.764,65. The actual power and the effect size were 90 and 10.5%, respectively. Using the above formula, that is, by taking the split-mouth study design into consideration, it was found that the sample size for each group was 25, and the total sample size was 75. However, the sample size was increased to 85 to compensate for the expected dropouts.[20–22]

Sample Distribution

Based on inclusion and exclusion criteria and willingness to give consent, participants for this study were randomly divided into three groups, as shown in the CONSORT flowchart (Fig. 1). The three groups were:

CS group: Inferior alveolar nerve block (IANB) using CS (Angie Alligator sleeve, Angelus™, Brazil) vs conventional (control) syringe (Aspirating Syringe, Septodont®, France) (Figs 2A and B, respectively).

VA group: Inferior alveolar nerve block (IANB) using vibration-assisted syringe (Vibraject GoldenDent™ Miltex Inc, LLC, USA) vs conventional (control) syringe (Aspirating Syringe, Septodont®, France) (Figs 2C and D, respectively).

VACS group: Inferior alveolar nerve block (IANB) using vibration-assisted syringe (Vibraject GoldenDent™ Miltex Inc, LLC, USA) vs CS (Angie Alligator sleeve, Angelus™, Brazil) (Figs 2E and F, respectively).

Randomization

Patients were divided into these three groups using block randomization, where a block size of 6 was chosen, and 15 sequences were generated using online software. These sequences were written in 15 opaque, sealed envelopes, and one sequence was selected, which was followed for six consecutive patients.

After determining a particular group through block randomization, since this is a split-mouth study, each patient was subjected to both anesthetic injection techniques within a group on different lower quadrants in two subsequent visits. The side of the mouth to be injected, that is, either left or right, was determined based on the chief complaint of the patient, while the determination of which technique to follow first and which second was done through simple randomization using a coin. Randomization and allocation of participants were done by an independent, unbiased person who was not aware of the study.

Outcome Assessment

The primary outcome measure was to assess the change in patients' fear and pain levels using CS and VA vs conventional injection techniques, utilizing physiological scales (blood pressure, heart rate, SpO_2, respiratory rate) and psychometric scales (visual analog scale and sound, eye, motor scale). The secondary outcome was to learn the preference for a particular injection technique by the subjects.

Methodology

After allotment to a group through block randomization and determination of a particular injection technique by coin toss, the patient was administered an inferior alveolar nerve block using a self-aspirating syringe (Aspirating Syringe, Septodont®, France) with 2% lidocaine cartridges (with 1:80,000 adrenaline) (Lignospan special, Septodont®, France) and a 27-gauge needle (Septoject Septodont®, France). If the patient was in the CS group, a CS was used by encasing a camouflaging syringe sleeve on the conventional syringe, or the syringe remained conventional depending on the technique

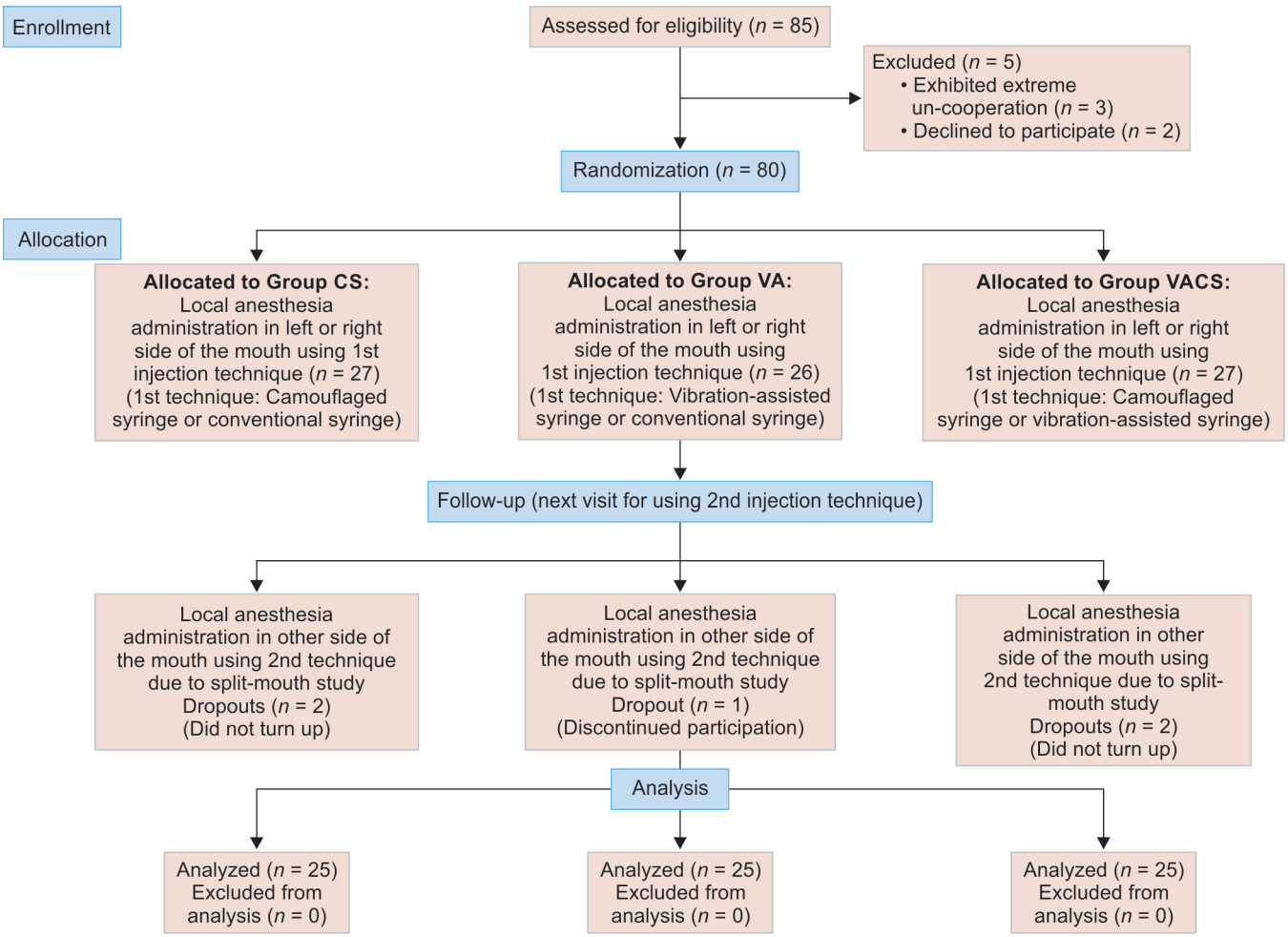
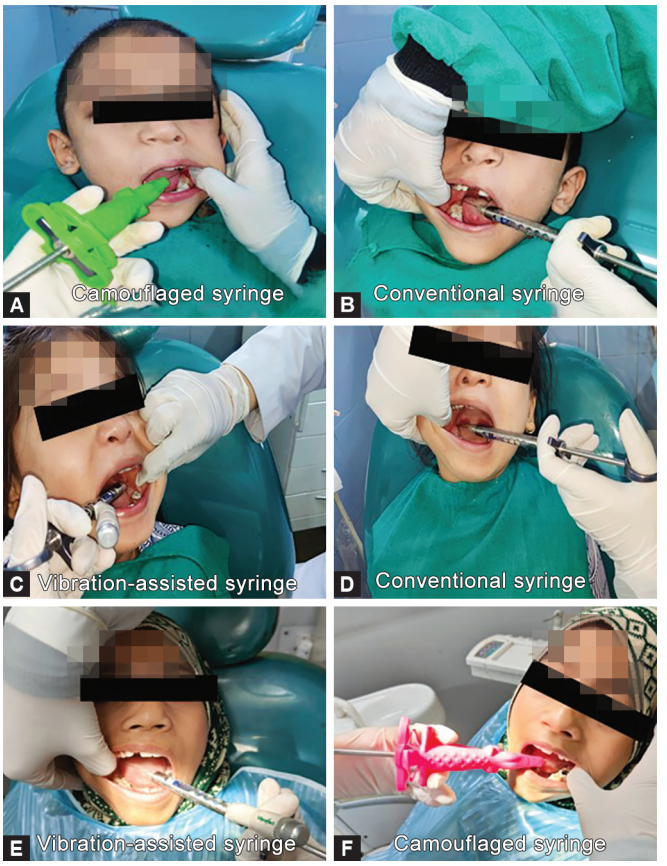


Fig. 1: CONSORT flowchart

allotted. If the patient belonged to the VA group, a vibrating device was clipped onto the conventional syringe and switched on for the vibration-assisted syringe, or the syringe remained conventional depending on the technique allotted. If the patient belonged to the VACS group, either the vibration-assisted syringe or the CS was used, based on the technique allotted. The patient was summoned again after an interval of one week. The procedures mentioned in the previous visit were repeated but were performed on the other side of the mouth and using the other technique for IANB administration



Figs 2A to F: CS group: (A) Camouflaged syringe; (B) Conventional syringe of the CS group; VA group: (C) Vibration-assisted syringe; (D) Conventional syringe of the VA group; VACS group: (E) Vibration-assisted syringe; (F) Camouflaged syringe of the VACS group

in that group. The patient was also asked which local anesthetic technique he or she preferred from the two techniques administered.

Immediately before and five minutes after injection, the injection-related assessment of pain and fear was done using physiological scales, which included blood pressure measured by a digital sphygmomanometer (Dr Trust, USA), heart rate measured by a pulse oximeter (Dr Morepen pulse oximeter), oxygen saturation measured by a pulse oximeter (Dr Morepen pulse oximeter), and respiratory rate measured with a digital watch (Samsung Watch 4). Psychometric scales included the face version of the visual analog scale (VAS) and the sound, eye, motor (SEM) scale. The anticipated preinjection fear was assessed using the VAS subjective scale, which was reused immediately postinjection to assess pain, fear, and overall experience by the patient. The SEM was assessed during IANB administration by an external evaluator who was unaware of the present study. Total scores for SEM range from 0 to 9 based on a score of 0–3 for each parameter, that is, sound, eye, and motor, with a higher score indicating a greater level of pain.[23]

Data Analysis

The statistical data analysis was done by employing the Statistical Package for the Social Sciences software package (SPSS 16 Inc, Chicago, IL, USA). The normality of data was tested using the Shapiro–Wilk test. The values obtained were statistically analyzed to compare the significance of means of the parameters between subgroups (that is, the two techniques in a group) and were tested using the independent *t*-test for normally distributed data. The significance of the qualitative data (i.e., patient preference) among the groups was tested using Pearson's Chi-squared test.

Results

A total of 85 children were assessed for eligibility, out of which five were excluded and five dropped out, leaving 25 children in each of the three groups. There were a total of 35 males and 40 females, with an overall mean age of 8.61 ± 1.85.

In the CS group, a statistically highly significant mean difference for postinjection VAS and SEM scores between the conventional and CS techniques was observed, which was 2.160 ($p = 0.000$) and 2.760 ($p = 0.000$), respectively. There was a statistically significant difference in the mean for postinjection heart rate between the conventional and CS techniques, which was 8.000 ($p = 0.047$) (Table 1). However, systolic and diastolic blood pressure, SpO_2, and respiratory rate showed no statistically significant difference

Table 1: Table showing mean postinjection values of physiological and psychometric scales and their respective *p*-values in all three groups

		Scale													
Group	*Technique*	*SBP*	*p-value*	*DBP*	*p-value*	*HR*	*p-value*	*RR*	*p-value*	*SpO_2*	*p-value*	*VAS*	*p-value*	*SEM*	*p-value*
CS	Camouflaged syringe	109.20	0.36	72.96	0.63	104.60	**0.001**	23.88	0.67	97.88	0.35	3.68	**0.00**	2.44	**0.00**
	Conventional syringe	111.68		73.84		112.60		24.04		97.56		5.84		5.20	
VA	Vibration-assisted syringe	109.72	0.93	70.36	**0.03**	102.62	**0.02**	23.68	0.32	98.20	0.15	3.22	**0.00**	2.20	**0.00**
	Conventional syringe	109.48		73.64		110.16		24.40		97.72		5.96		5.12	
VACS	Camouflaged syringe	108.04	0.70	70.04	0.38	104.20	0.07	24.44	0.61	97.88	0.41	4.48	**0.00**	3.28	**0.03**
	Vibration-assisted syringe	107.00		68.48		107.92		24.12		98.16		2.96		2.40	

Bold numbers represent statistically significant values ($p < 0.05$)

in postinjection values. Based on the significant values, it can be concluded that the CS produced a better response in reducing fear and pain in pediatric patients during LA administration.

In the VA group, a statistically highly significant mean difference was observed for postinjection VAS and SEM scores between the conventional and vibration-assisted syringe techniques, which were 2.740 ($p = 0.000$) and 2.920 ($p = 0.000$), respectively (Table 1). There was a significant difference in the mean for postinjection heart rate and diastolic blood pressure between the conventional and vibration-assisted syringe techniques, which were 7.535 ($p = 0.027$) and 3.280 ($p = 0.038$), respectively. Although systolic blood pressure, SpO_2, and respiratory rate showed no statistically significant difference in postinjection values, it can be concluded that the vibration-assisted syringe produced a better response in reducing fear and pain in pediatric patients during LA administration, taking into consideration the significant values.

In the VACS group, there was a statistically highly significant mean difference for postinjection VAS and SEM scores between the CS technique and the vibration-assisted syringe (Vibraject), which were 1.52 ($p = 0.002$) and 0.88 ($p = 0.037$), respectively (Table 1). Although systolic and diastolic blood pressure, heart rate, SpO_2, and respiratory rate showed no statistically significant difference in postinjection values, it can be concluded that the vibration-assisted syringe produced better results in reducing fear and pain in pediatric patients during LA administration based on the values of the psychometric scales.

The overall majority preference was for the CS in the CS group (64%), the vibration-assisted syringe in the VA group (60%), and the CS in the VACS group (52%).

Discussion

The administration of LA has always been a challenging problem in a pediatric dental operatory, owing to the highly fearful and anxious nature of pediatric patients. One reason for their specific fear of injections could be their exposure to multiple vaccinations from infancy through childhood.[24] It is also believed that a patient who is fearful or anxious might perceive relatively more severe and longer pain than a patient who is less fearful. Hence, procedures aimed at reducing fear and anxiety during the administration of injections may result in decreased pain perception.[25] Therefore, procedures in this study were used to reduce dental fear and pain during anesthetic administration in pediatric dental patients, incorporating a CS sleeve encased on a conventional self-aspirating syringe, which utilized the philosophy of distraction while administering local anesthetic solution. Another device used in this study was a vibration-assisted syringe, wherein a small, vibrating, battery-operated device was clipped onto the conventional self-aspirating syringe. This study evaluated and compared the fear and pain levels of the CS and vibration-assisted syringe with the conventional syringe and also compared them with each other (i.e., between the camouflaged and vibration-assisted syringes), using various physiological and psychometric scales.

In the CS group, postinjection HR, VAS, and SEM scores showed statistical differences in mean values for the CS compared to the conventional syringe (Fig. 3). Therefore, the CS turned out to be better than the conventional syringe in terms of reducing fear and pain in children receiving inferior alveolar nerve block (IANB). Similar results were reported by Bagher et al.[26] (2023), where the authors concluded that the CS was effective in improving children's anxiety and behavioral pain during LA administration compared to the traditional syringe. According to them, the visual stimulus affects the process of pain. Eliminating this stimulus during local anesthetic administration reduces anxiety and pain in children. Our results were also in accordance with Padminee and Hemalatha[27] (2019), where a split-mouth study was performed using the conventional and CSs, and their results suggested that the increase in mean heart rate was significantly more with the conventional syringe when compared to the CS.

In the VA group, postinjection HR, DBP, VAS, and SEM scores showed statistical differences in mean values for the vibration-assisted syringe and the conventional syringe (Fig. 3). Therefore, the vibration-assisted syringe turned out to be better than the conventional syringe in terms of reducing fear and pain in children receiving inferior alveolar nerve block (IANB). Similar results were shown by Bilsin et al.[28] (2019), who conducted a randomized controlled trial to learn the efficacy of a vibrating device on mandibular anesthesia, where they found that the mean pain score was lower in the vibratory group compared to the conventional group, and this was statistically significant. On the contrary, Razdan et al.[29] (2021), in their study, compared vibration anesthesia with precooling of the anesthesia site and suggested that there were no major variations within the groups using the SEM scale. One reason that can be thought of for this result is that they took only a sample size of 20 (10 per side due to split-mouth design) with a large age range of 4–12 years.

In the VACS group, postinjection VAS and SEM scores showed statistical differences in mean values between the vibration-assisted syringe and the CS (Fig. 3). Therefore, the vibration-assisted syringe turned out to be better than the CS in terms of reducing fear and pain in children receiving inferior alveolar nerve block (IANB). To the best of our knowledge, no study has directly compared the CS with the vibration-assisted syringe in terms of reducing fear and pain in children receiving LA. Thus, more studies with larger sample sizes are required to validate these results.

In the present study, the preference of the patient was also recorded at the end of the third visit. This was done to learn which of the two techniques applied to him/her (either the CS or the conventional syringe in the CS group, or the vibration-assisted syringe or the conventional syringe in the VA group, or the CS or the vibration-assisted syringe in the VACS group) was preferred. The overall majority preference was the CS in the CA group (64%),

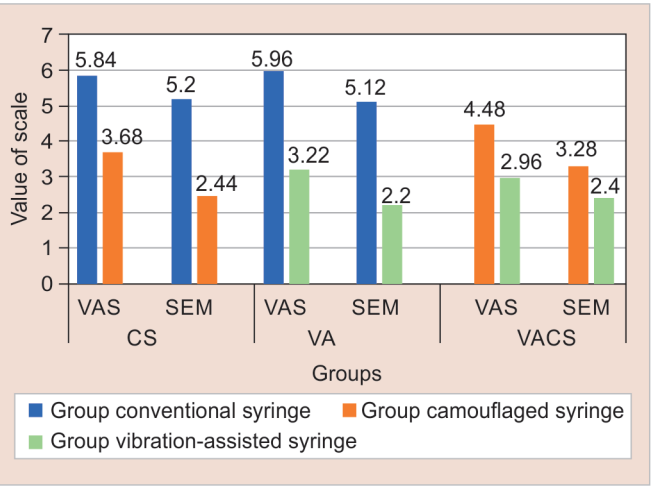


Fig. 3: Graph comparing psychometric scales in all three groups (VAS, visual analog scale; SEM, sound, eye, and motor)

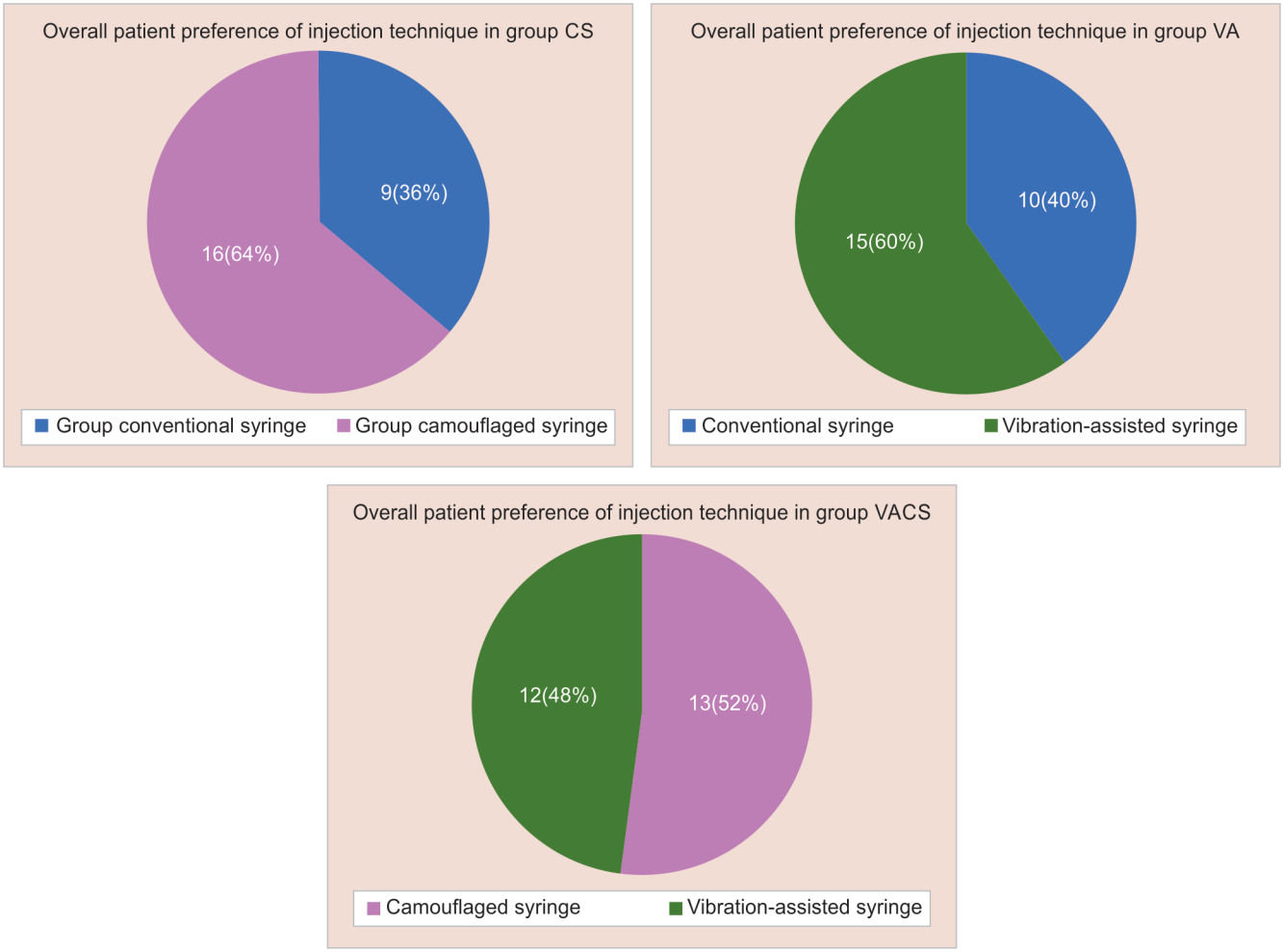


Fig. 4: Graph showing patient preference for injection techniques in all three groups

the vibration-assisted syringe in the VA group (60%), and the CS in the VACS group (52%) (Fig. 4). Similar to these results, Babaji et al.[30] (2017) evaluated child preference for the usage of the CS vs the conventional syringe and found that 78% of children (aged 6–10 years) preferred the CS over the conventional syringe. In accordance with these results, Saad et al.[31] (2019) performed a study comparing VibraJect™ with the conventional syringe and concluded that children showed higher acceptance, less pain, and lower anxiety with the VibraJect™ syringe.

Strengths of the Study

To the best of our knowledge, earlier studies have not taken into consideration multiple variables, including VAS score, SEM scale, BP, HR, SpO_2, and RR, all together in one study. Taking multiple variables helps to provide a clearer insight into the efficacy of the injection techniques used on pain and fear. Also, this study is of a split-mouth design, which in itself helps reduce intersubject variability, providing better accuracy with a smaller sample size. Earlier studies have also not directly compared the efficacy of reducing fear and pain using both the CS and the vibration-assisted syringe.

Limitations of the Study

Due to the nature of this study, neither the operator nor the subjects could be blinded. Also, the preference of the injection technique asked of the patient was at the end of the third visit, that is, with a week's gap between two injections, which can pose a risk of recall bias. Another limitation of the present study could be that only cooperative patients were incorporated in the study, which does not represent the actual presentation of the entire population.

Future Recommendations

Multicentric studies with larger sample sizes should be carried out to provide evidence in support of our study.

Conclusion

Therefore, it can be concluded that both the vibration-assisted syringe (VibraJect) and the CS have proven to be better than the conventional techniques in terms of reducing pain and fear during inferior alveolar nerve blocks in children aged 6–12 years. It can also be concluded that the vibration-assisted syringe has shown better control of fear and pain when compared to the other two techniques. The preference for the technique was also greater for the camouflaged and vibration-assisted syringes compared to the conventional syringe.

Clinical Significance

The disruptive behavior of children due to dental fear and pain can often result in troublesome management of dental problems

and effective dental treatment. This unruly behavior of the child is frequently caused by the fear of the needle used for local anesthetic delivery. It is also known that a fearful and anxious child will perceive more pain during treatments. Therefore, techniques used to minimize this fear and pain are essential to provide safe, efficient, and quality dental care to children, which is what this article aims to achieve.

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