ORIGINAL RESEARCH

Intercomparison of Efficacy of Transcutaneous Electrical Nerve Stimulation and Precooling Vibration Device on Pain and Anxiety Management during Administration of Local Anesthesia Injection in 6–12-year-olds

Kopal Singh[1], Pulkit Jhingan[2], Shivani Mathur[3], Manvi Malik[4], Ketki Kashyap[5]

Abstract

Aim: To compare and evaluate the efficacy of transcutaneous electrical nerve stimulation (TENS) and a vibrational precooling system in reducing pain and anxiety during the administration of local anesthesia in children aged 6–12 years old.

Materials and methods: A total of 60 children aged 6–12 years old participated in this randomized controlled trial and were randomly allocated to three groups: the conventional method group, the vibrational precooling system group, and the TENS group. The Modified Dental Anxiety Scale (MDAS), pulse rate, and oxygen saturation were recorded to assess the preoperative anxiety of the participating children. Sound, motor, and eyes (SEM) and face, legs, activity, cry, and consolability (FLACC) scores were recorded during the procedure, along with pulse rate and oxygen saturation, to measure pain during the procedure. This was followed by a self-administered visual analog scale (VAS) to assess the discomfort felt by the child.

Results: A statistically significant reduction in pain was observed with the usage of the vibration system and TENS, as measured by the FLACC scale, compared to the conventional method group. Similarly, statistically significant differences in SEM scores were noted between the vibrational precooling system group and the conventional method group, as well as between the TENS group and the conventional method group, with the highest scores observed in the conventional method group. The children reported the highest comfort levels with the usage of the vibration system, as indicated by the self-administered VAS. However, no statistically significant difference was observed within any group.

Conclusion: The new vibrational precooling system as well as TENS can be effectively used to alleviate the pain experienced during the administration of local anesthesia.

Keywords: Behavior management, Pain management, Precooling vibration device, Transcutaneous electrical nerve stimulation.

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Introduction

Treating children can be one of the most rewarding experiences for a dentist. However, the most distressing aspect of pediatric dentistry is the fear and anxiety brought about by the dental office, especially during procedures like local anesthetic injections. Reducing pain and anxiety in children lays the foundation for successful behavior management and helps to provide an elevated overall dental experience for the patient.[1]

Various pharmacological and nonpharmacological behavior guidance techniques have been used to make dental procedures under local anesthesia more comfortable and a pleasant experience for children.[2] Some of the gold standard nonpharmacological techniques include distraction through games or audiovisual aids, the tell-show-do method, and modeling. On the other hand, oral sedation, nitrous oxide inhalation sedation, and general anesthesia are commonly employed pharmacological techniques. Other adjuvants used to reduce pain at the injection site include warming or buffering the anesthetic solution, modifying the rate at which local anesthetic is administered, cooling the site of injection before administration, and even the use of vibration. Continuous research is being carried out for newer techniques like VibraJect, DentalVibe, computerized systems for delivering local anesthesia (e.g., Wand), or the application of transcutaneous electrical nerve stimulation (TENS), which can make dental treatment under local anesthesia more agreeable.

Transcutaneous electrical nerve stimulation has been suggested as an effective adjunct in reducing pain and anxiety associated with administration of local anesthesia (LA) (Fig. 1A).[3]

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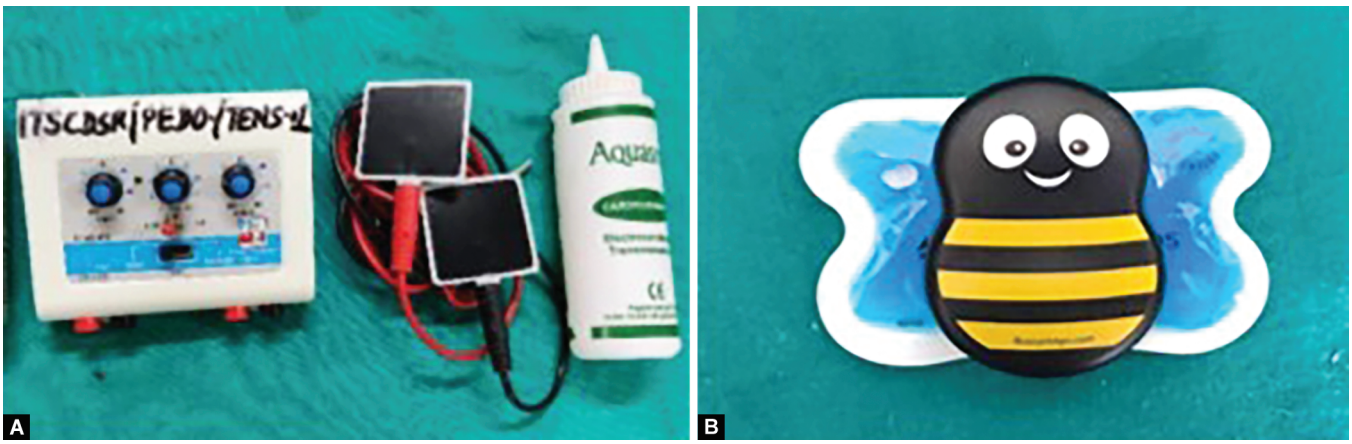

Figs 1A and B: (A) Transcutaneous electrical nerve stimulation unit; (B) Vibration precooling device

Using electrodes, low-intensity impulses are delivered across the intact skin surface, exciting superficial nerves for localized pain relief. Theories such as the gate control theory and endorphin release theory elucidate how TENS facilitates pain management. The gate control theory of pain, first proposed in 1965 by Melzack and Wall, suggests that the substantia gelatinosa in the spinal cord's dorsal horn functions as a gate control mechanism. This system regulates the signal patterns received from peripheral fibers before reaching the primary spinal cord's central transmitting cells. Unmyelinated "C" fibers, responsible for transmitting pain signals, keep these gates relatively open. Conversely, large myelinated A fibers inhibit signals from C fibers presynaptically, closing the gate and preventing impulses from reaching transmission cells. Pain management is achieved by intensifying input from large fibers and diminishing input from small fibers, ultimately closing the gate and reducing the perception of pain. The endogenous opioid theory proposes an alternative explanation for TENS's mechanism of action, suggesting it promotes the release of endogenous opioids in the spinal cord through activation of local spinal cord circuits or descending pain-inhibitory pathways. TENS was approved by the Food and Drug Administration (FDA) for pain relief and categorized as a class II device in 1972.[4]

A recent technology, which is a bee-shaped device uses a combination of vibration and precooling to distract patients as well as alleviate their pain and anxiety during administration of dental anesthesia administration (Fig. 1B).[5] The apparatus is positioned extraorally above the region to be administered local anesthesia. The main body of the bee delivers vibrations across the intact skin and the removable ice wings causes precooling of the injection site.[6] The vibration creates a distraction, causing the afferent nerves to relay the vibrations instead of the pain thereby giving room for the delivery of analgesia. The "masking effect of pain," as described by the gate control theory, is further enabled by the addition of the factor of cold, which further muddles the pain pathway's reception of signals.[7]

Due to the lack of evidence comparing the efficacy of TENS and external vibration precooling vibration devices, this study was undertaken. The purpose of this study was to compare and evaluate the effect of the external cooling and vibration system and TENS on pain and anxiety reduction during the injection of dental anesthesia in children aged 6–12 years old.

Materials and Methods

This randomized, interventional clinical study was conducted in the department of pediatric and preventive dentistry. Prior to the study, approval was obtained from the Internal Ethical Committee (ITSCDSR/IIEC/RP/2020/017). The study included 60 children aged 6–12 years who presented to the outpatient department and met the inclusion criteria.

Selection Criteria

Children with behavior falling in category three and four of the Frankl Rating Scale, those being treated on the dental chair, indicated for procedures requiring maxillary infiltration or inferior alveolar nerve block, those not allergic to topical anesthetic, and those whose parents gave consent for their children's participation were included in the study. Children requiring treatment under general anesthesia, or those with systemic diseases, intellectual disabilities, and psychiatric disorders, as well as children allergic to local anesthesia, were excluded from the study.

Patient Allocation

Random assignment of the patients was done into the following groups (Fig. 2).

Group I: Vibration System Group

- Subgroup A: Maxillary infiltration.
- Subgroup B: Inferior alveolar nerve block.

Group II: Transcutaneous Electrical Nerve Stimulation Group

- Subgroup A: maxillary infiltration.
- Subgroup B: Inferior alveolar nerve block.

Group III: Conventional Method Group

- Subgroup A: Maxillary infiltration.
- Subgroup B: Inferior alveolar nerve block.

Clinical Procedures

Before the study, a customized form was used to gather demographic data. The child was asked questions from the Modified Dental Anxiety Scale (MDAS), followed by recording preoperative pulse rate and oxygen saturation to assess the child's preoperative anxiety level. Children in groups I and II were familiarized with the device.

For group I, the wings were taken out from refrigeration as soon as the child was ready. The device was assembled and was placed at about 5 cm above the injection site extraorally and was switched on to initiate the vibration. After 30–60 seconds, administration of local anesthesia was done. The device needs to be in place the entire time (Fig. 3A).[8]

In the TENS group, using surgical spirit, the electrode pad site was carefully swabbed to eliminate any skin oils or contaminants that would obstruct the current passage. The electrode pads were then covered with electrode gel prior to placement, and surgical tape was used to hold them in place to reduce displacement. Once the equipment was turned on, the investigator increased the amplitude dial progressively until the subject experienced a noticeable amount of anesthesia. The amplitude level was first kept at that level for 20 seconds, and then, it was gradually increased until the lower lip fasciculation was observed, indicating that the "minimal therapeutic level" had been attained (Fig. 3B).

This was followed by administration of local anesthesia (Fig. 3C). Pulse rate and oxygen saturation levels were measured during and after the procedure as an objective measure; face, legs, activity, cry, and consolability (FLACC) score and sound, motor, and eyes (SEM) score was recorded during the administration of local anesthesia by the second investigator as a subjective measure. The child's discomfort was assessed using self-administered visual analog scale (VAS).

Statistical Analysis

The data gathered during the study were entered into Microsoft Excel XP software. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software program (SPSS 16 Inc., Chicago, Illinois, United States). Nonparametric tests were employed after the Shapiro–Wilk test was used to determine whether the data were normally distributed. Results indicated that the data were not normally distributed. Intergroup comparisons between the three groups were conducted using the Mann–Whitney *U* test and Kruskal–Wallis test, while intragroup comparisons were measured using the Wilcoxon signed-rank test and Friedman test. The level of significance was set at 0.05.

Results

In the present study, a total of 60 pediatric patients, presenting themselves to the department of pediatric and preventive dentistry were included based on the selection criteria. The selected patients were randomly divided into three groups, namely vibration and precooling system group (group I), TENS group (group II), and the conventional method group (group III). Prior to the treatment, the demographic data and Frankl behavior score were recorded. The mean age of patients in groups I, II, and III was 8.3 ± 1.98, 8.2 ± 2.48, and 8.05 ± 2.01, respectively. The intergroup comparison using Kruskal–Wallis H with no statistically significant difference among the three groups (Table 1). Upon statistical analysis, no statistically significant difference in MDAS scores, preoperative pulse rate, and oxygen saturation among all the groups as well as within the group indicating that children in all the groups had similar levels of anxiety prior to administration of local anesthesia (Tables 1 to 3).

During the procedure, the FLACC and SEM scores were used to evaluate the response of the patient during administration

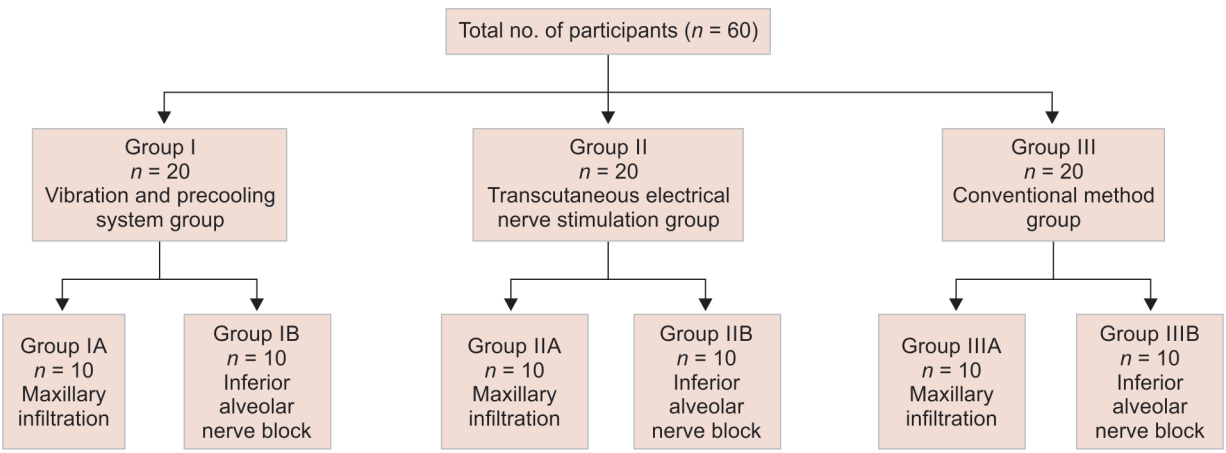

Fig. 2: The flowchart of children through the study

Figs 3A to C: (A)Vibration precooling device placed before administration of local anesthesia; (B) Electrode pads placed for delivery of TENS; (C) Administration of local anesthesia in conventional manner

Table 1: Age, pulse rates, oxygen saturation, MDAS, FLACC, SEM and VAS scores

		Group I	*Group II*	*Group III*	
Variables		*Mean ± standard deviation (SD)*	*Mean ± SD*	*Mean ± SD*	*p-value*
Age in years		8.3 ± 1.98	8.2 ± 2.48	8.05 ± 2.01	0.968^{NS}
Pulse rate	Pre	95.65 ± 15.7	94.05± 14.58	92.55 ± 16.19	0.825^{NS}
	Intra	90.9 ± 14.86	89.45 ± 14.56	99.4 ± 16.66	0.083^{NS}
	Post	91.05 ± 14.33	89.7 ± 14.65	96 ± 13.15	0.158^{NS}
Oxygen saturation	Pre	96.45 ± 3.09	96.15 ± 2.83	96.30 ± 3.03	0.843^{NS}
	Intra	97.35 ± 2.78	97.35 ± 2.78	96.75 ± 2.92	0.522^{NS}
	Post	98.05 ± 1.05	98.05 ± 1.05	97.85 ± 1.23	0.876^{NS}
MDAS		1.75 ± 0.72	1.50 ± 0.51	1.65 ± 0.59	0.533^{NS}
FLACC		1.7 ± 0.66	1.45 ± 0.6	2.45 ± 0.94	0**
SEM		3.7 ± 0.92	4 ± 0.79	4.3 ± 0.8	0.095^{NS}
VAS		2 ± 0.73	1.5 ± 0.51	1.3 ± 0.73	0.014*

Statistical analysis: Kruskal–Wallis H test; *, statistically significant if $p \leq 0.05$; **, highly statistically significant; NS: not significant

Table 2: Intergroup comparison of the age, pulse rates, oxygen saturation, MDAS, FLACC, SEM, and VAS scores

		Group I vs group II		*Group I vs group III*		*Group II vs group III*	
Variables		*Mean difference*	*p-value*	*Mean difference*	*p-value*	*Mean difference*	*p-value*
Age in years		0.10	0.862^{NS}	0.25	0.805^{NS}	0.15	0.956^{NS}
Pulse rate	Pre	1.60	0.892^{NS}	3.10	0.558^{NS}	1.50	0.664^{NS}
	Intra	1.45	0.903^{NS}	8.50	0.041*	9.95	0.042*
	Post	1.35	0.967^{NS}	4.95	0.081^{NS}	6.30	0.117^{NS}
Oxygen saturation	Pre	0.3	0.556^{NS}	0.15	0.809^{NS}	0.15	0.749^{NS}
	Intra	0	1.000^{NS}	0.6	0.330^{NS}	0.6	0.330^{NS}
	Post	0	1.000^{NS}	0.2	0.658^{NS}	0.2	0.658^{NS}
MDAS		0.25	0.277^{NS}	0.10	0.756^{NS}	0.15	0.439^{NS}
FLACC		0.25	0.184^{NS}	0.75	0.003**	1	0.000**
SEM		0.3	0.415^{NS}	0.6	0.036*	0.3	0.166^{NS}
VAS		0.5	0.025*	0.7	0.009**	0.2	0.45^{NS}

Statistical analysis: Kruskal–Wallis H test; S, *, statistically significant if $p \leq 0.05$; **, highly statistically significant; NS: not significant

Table 3: Intragroup comparison of age, pulse rates, oxygen saturation, MDAS, FLACC, SEM, and VAS scores

		Group I			*Group II*			*Group III*		
		Group IA	*Group IB*		*Group IIA*	*Group IIB*		*Group IIIA*	*Group IIIB*	
Variables		*Mean ± SD*	*Mean ± SD*	*p-value*	*Mean ± SD*	*Mean ± SD*	*p-value*	*Mean ± SD*	*Mean ± SD*	*p-value*
Age in years		9 ± 1.83	7.60 ± 1.96	0.112^{NS}	8.00 ± 2.36	8.40 ± 2.72	0.789^{NS}	7.70 ± 2.06	8.40 ± 2.01	0.32^{NS}
Pulse rate	Pre	100.70 ± 14.95	90.60 ± 15.49	0.148^{NS}	98.40 ± 14.92	89.70 ± 13.57	0.363^{NS}	90.90 ± 14.60	94.20 ± 18.27	0.446^{NS}
	Intra	97.80 ± 14.56	84.00 ± 12.18	0.064^{NS}	94.90 ± 14.80	84.00 ± 12.75	0.150^{NS}	105.30 ± 15.24	93.50 ± 16.61	0.118^{NS}
	Post	97.40 ± 14.11	84.70 ± 12.30	0.052^{NS}	95.40 ± 14.78	84.00 ± 12.74	0.109^{NS}	98.50 ± 11.07	93.50 ± 15.12	0.399^{NS}
Oxygen saturation	Pre	96.70 ± 3.0	96.20 ± 3.26	0.999^{NS}	96.30 ± 2.91	96.00 ± 2.91	0.93^{NS}	95.20 ± 3.08	97.40 ± 2.67	0.077^{NS}
	Intra	97.90 ± 2.13	96.80 ± 3.33	0.967^{NS}	97.90 ± 2.13	96.80 ± 3.33	0.967^{NS}	96.10 ± 2.96	97.40 ± 2.88	0.112^{NS}
	Post	98.30 ± 0.67	97.80 ± 1.32	0.446^{NS}	98.30 ± 0.67	97.80 ± 1.32	0.446^{NS}	97.40 ± 1.43	98.30 ± 0.82	0.132^{NS}
MDAS		1.60 ± 0.52	1.90 ± 0.88	0.483^{NS}	1.50 ± 0.53	1.50 ± 0.53	1.00 ^{NS}	1.50 ± 0.53	1.80 ± 0.63	0.282^{NS}
FLACC		1.5 ± 0.71	1.9 ± 0.57	0.21^{NS}	1.3 ± 0.67	1.6 ± 0.52	0.306^{NS}	2.7 ± 0.82	2.2 ± 1.03	0.28^{NS}
SEM		3.5 ± 1.08	3.9 ± 0.74	0.46^{NS}	3.7 ± 0.48	4.3 ± 0.95	0.112^{NS}	4.3 ± 0.82	4.3 ± 0.82	1.00^{NS}
VAS		1.4 ± 0.84	1.2 ± 0.63	0.41^{NS}	2.3 ± 0.67	1.7 ± 0.67	0.07^{NS}	1.5 ± 0.53	1.5 ± 0.53	1.00^{NS}

Statistical analysis: Friedman test; *, significant $p < 0.05$; NS: not significant

of LA. The mean FLACC scores were in the following decreasing order: 2.45 ± 0.94 (group III) > 1.7 ± 0.66 (group I) > 1.45 ± 0.6 (group II) (Table 1). Intergroup comparison of FLACC scores revealed a highly statistically significant difference between vibration and precooling system group and the conventional method group as well as between TENS group and the conventional method group ($p < 0.000$). However, no statistically significant difference was observed between the group using the vibration and precooling system and the TENS group ($p > 0.05$) (Table 2). The mean SEM scores were in the following decreasing order: 4.3 ± 0.8 (group III) > 4 ± 0.79 (group II) > 3.7 ± 0.92 (group I). On intergroup comparison, a statistically significant difference between vibration and precooling system group and the conventional method group was seen ($p < 0.05$) and no statistically significant difference between groups I and II as well as groups II and III ($p > 0.05$) (Table 2).

After the administration of local anesthesia, the participating children were asked to rate their discomfort on VAS. The mean VAS scores were in the following decreasing order: 2 ± 0.73 (group I) > 1.5 ± 0.51 (group III) > 1.3 ± 0.73 (group III) (Table 1). Intergroup comparison showed a statistically significant difference between groups I and II and groups I and III ($p < 0.05$) with no statistically significant difference between groups II and III ($p > 0.05$) (Table 2).

Pulse rate and oxygen saturation were also evaluated intraoperatively and postoperatively. The mean intraoperative pulse rate was in the following decreasing order: 99.4 ± 16.66 (group III) > 90.9 ± 14.86 (group I) > 89.45 ± 14.56 (group II) (Table 1). Statistical analysis revealed no statistically significant difference between groups I and II ($p > 0.05$) but statistically significant difference between groups II and III and groups I and III ($p < 0.05$) (Table 2). Also, the mean postoperative pulse rate had no statistically significant difference between the three groups (Tables 1 and 2). Mean oxygen saturation level showed no statistically significant difference intraoperatively and post operatively ($p > 0.05$) (Tables 1 and 2).

When comparisons were made within each group, no significant difference was observed in the pulse rates, oxygen saturation, MDAS, FLACC, SEM, and VAS scores between the maxillary infiltration and inferior alveolar nerve block subgroups (Table 3).

Discussion

The field of dentistry requires a continual search for a definitive method to alleviate the fear of needles, especially in children, and provide them with painless analgesia. Treating a pediatric patient involves not only addressing the disease but also considering the patient as a whole. Many dental treatments involve painful procedures, and the fear of pain during dental treatment can make patients anxious, often resulting in unsuccessful treatment outcomes. Therefore, effective behavior management begins with the effective management of pain and anxiety. This approach facilitates the development of a healthy rapport between the dentist and the child, fostering trust, alleviating worry and dread, and instilling good dental habits for the future.

Local anesthesia, the cornerstone of pain control, can be one of the most anxiety-provoking procedures, particularly among the pediatric population. The American Academy of Pediatric Dentistry (AAPD) has recommended various modalities to mitigate the discomfort of dental injections. These include warming the anesthetic, adjusting the rate of local anesthesia administration, cooling the injection site, or utilizing vibration techniques. These strategies aim to enhance the patient's comfort and reduce anxiety associated with receiving dental injections, thereby improving the overall dental experience for pediatric patients.[8]

In the present study, TENS and a vibration precooling device were utilized to evaluate their effectiveness in reducing pain and anxiety among 60 children undergoing maxillary infiltration or inferior alveolar nerve block, employing a randomized controlled clinical trial design. Prior to the administration of local anesthesia, children in all three groups exhibited similar levels of anxiety. There were no statistically significant differences in MDAS scores, preoperative pulse rates, and oxygen saturation levels among all groups as well as within each group (Tables 1 to 3).

Intraoperatively, FLACC and SEM scores were assessed to evaluate the response of the patient during administration of LA. The mean FLACC scores was highest in group III (2.45 ± 0.94) and least in group II (1.45 ± 0.6) (Table 1). Intergroup comparison revealed a highly statistically significant difference between groups I and III and groups II and III ($p < 0.000$) and no statically significant difference was seen between groups I and II ($p > 0.05$) (Table 2). The mean SEM scores were least in group I (3.7 ± 0.92) and highest in group III (4.3 ± 0.8). On intergroup comparison, a statistically significant difference between groups I and III ($p < 0.05$) and no statistically significant difference between groups I and II and groups II and III ($p > 0.05$) (Table 2). These results suggest maximum pain reduction was seen when TENS and vibration precooling system were used as an adjunct during administration of local anesthesia. The abovementioned results can be attributed to gate control theory that explains the mechanism of action of TENS and vibration precooling device. According to the gate control theory of pain, the substantia gelatinosa in the spinal cord's dorsal horn serves as a gate control mechanism, modulating the patterns of afferent activity from peripheral fibers before they reach the spinal cord's primary transmitting cells. Pain signals are carried by small, unmyelinated "C" fibers, which keep the gate open. Conversely, activity from large myelinated A fibers closes the gate, inhibiting input from C fibers. By reducing input from small fibers and increasing input from large fibers, the gate can be closed, thereby controlling pain.[4] Analgesia can be more effectively administered using the vibration precooling system because vibration serves as a distraction, diverting the attention of afferent nerves away from pain transmission. This "masking effect of pain" is enhanced by the inclusion of cold, which further confuses the pain pathway's reception of signals.[7] These results corroborate with the previous study conducted by Choudhari et al. and Siddiqui et al. who concluded TENS as a beneficial alternative in reducing pain and anxiety associated with conventional LA methods.[3,9] Also, the studies by Bilsin et al., Alanazi et al., and Suohu et al. revealed similar results when they compared the vibration and precooling system with conventional method of administration of local anesthesia.[7,10,11] However, studies by Dhindsa et al. and Varadharaja found that efficacy of TENS was comparable to 2% lignocaine while performing minor pediatric dental procedures.[12,13] Thus, it can be inferred that TENS as well as vibration and precooling system can be used to alleviate the pain caused by the local anesthesia by increasing the overall pain threshold explained by the gate control mechanism.

At the end of the procedure, the patient was asked to rate the discomfort on a VAS. The highest VAS scores were seen in group I (2 ± 0.73) and least in group III (1.3 ± 0.73). Intergroup comparison revealed a statistically significant difference between the vibration and precooling system group and the TENS group, as well as between the vibration and precooling system group and

the conventional method group ($p < 0.05$). However, there was no statistically significant difference between the TENS group and the conventional method group ($p > 0.05$) (Table 2). This suggests that the children were most comfortable using the vibration precooling device. This could be attributed to the design of the device that distracts the patient as well as the masking effect of pain caused by the vibration and precooling delivered across the skin surface. These outcomes were consistent with a study done by AlHareky et al. and Varadharaja et al. who concluded that the child experienced lesser pain and discomfort when the vibration precooling device and TENS were used compared to traditional method of local anesthesia administration.[6,13]

It was decided to use a pulse oximeter in this study to measure heart rate and oxygen saturation levels before, during, and after the administration of LA because studies by Beck and Weaver and Guinot Jimeno et al. have shown the value of this tool in measuring the degree of stress and anxiety in patients undergoing dental treatment.[14,15] The mean preoperative pulse rate and preoperative oxygen saturation showed no statistically significant difference among the three groups suggesting a similar level of anxiety among selected children. The mean intraoperative pulse rate was highest in group III, the conventional method group, and lowest in the TENS group (group II). There was no statistically significant difference between the vibration and precooling group and the TENS group ($p > 0.05$). However, there was a statistically significant difference between the TENS group and the conventional method group ($p < 0.05$), as well as between the vibration and precooling group and the conventional method group (Table 2). Also, the mean postoperative pulse rate had no statistically significant difference among the three groups (Tables 1 and 2). Mean oxygen saturation level showed statistically nonsignificant difference intra- and postoperatively ($p > 0.05$) (Tables 1 and 2). Thus, it can be inferred that TENS was able to alleviate maximum anxiety among the children participation in the study. Alanazi et al., Rayen et al., and Alshathri et al. showed similar results where a lower pulse rate was seen when external vibration was used as an adjunct.[7,16,17] Similarly, the results of a study by Varadharaja et al.[13] revealed a statistically significant lower pulse rate upon usage of TENS.[13] On the contrary, Suohu et al. concluded that there was no statistically significant difference in the mean pulse and oxygen saturation levels of children when a vibration precooling system was used to abate pain and anxiety of children receiving local anesthesia.[10]

Conclusion

After culminating the findings with previous evidence, it can be concluded that both the new vibration and precooling and TENS, are effective in alleviating the pain experienced during the administration of local anesthesia.

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