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Vibrating toothbrush, ice, or topical anesthetic agent to reduce pain of local anesthetic injection in 5- to 12-year-old children undergoing dental procedures — a randomized controlled trial

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Abstract

Background Application of topical anesthetic agent prior to injection is the most commonly used method to control initial needle penetration pain of local anesthetic injection. Ice and vibration stimulus application are other nonpharmacologic methods used to reduce painful sensations of injection. The present study aims to verify and compare topical anesthetic, ice pretreatment, and electric toothbrush as a vibratory device, to reduce the pain of local anesthetic injections.

The study was conducted on children aged 5–12 years, requiring extraction of a maxillary primary tooth. A randomized control trial design was used wherein each child was randomly assigned by permuted block randomization design method to receive either lignocaine 5% as topical anesthetic or ice pretreatment or motorized toothbrush as a vibratory device during local anesthetic injections. Sound, eye, and motor (SEM) scale was used for objective evaluation of pain during injection, and Faces Pain Scale (FPS) was used for subjective evaluation. For statistical analysis, nonparametric test — Kruskal Wallis/ANOVA test for three groups and between two groups Mann–Whitney *U*-test, was used to compare SEM and FPS values. Level of significance chosen was $p < 0.05$.

Results SEM (palatal) and FPS (palatal) scores were slightly higher in topical anesthetic group as compared to ice pretreatment or vibration group, but the differences were not statistically significant. There were no statistically significant differences among SEM (buccal) and FPS (buccal) scores in all the three groups.

Conclusions Ice cooling and electric toothbrush-induced vibration were as effective as topical anesthetic for reduction in pain due to injection.

Trial registration The CTRI number of the trial is CTRI/2021/03/032046.

Keywords Topical anesthetic, Ice pretreatment, Vibration, Electric toothbrush

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Background

Local anesthesia is essential for reducing pain during dental treatment and provision of quality and successful dental treatment. Though local anesthetic injection is a prerequisite for majority of dental procedures, it is one of the most anxiety-provoking stimulus for both children and adult patients in dentistry. The fear

of injection pain can be a big hurdle for proper dental care delivery in children. Successful behavior guidance depends on effective control of injection pain. Several methods have been described to reduce pain and anxiety caused by local anesthesia administration. These include application of topical anesthesia before injection, warming the local anesthetic solution, using thin gauge needles, reducing injection speed, and buffering the local anesthetic. Application of cold or vibration can be an effective nonpharmacological method which is fast acting, low cost, and easily applicable (Sapci et al. 2021).

Application of topical anesthetic agent prior to injection is the most commonly used method to control initial needle penetration pain. Various drawbacks of topical anesthetics are as follows: the variable duration of action from 5 to 10 min, unpleasant taste, and spread of the anesthetic agent to non-injection site areas (Hameed et al. 2018). It does not help in reducing the discomfort of deep regional block administration, such as inferior alveolar nerve block (IANB) injections (Ghorbanzadeh et al. 2019).

As per gate control theory, proposed by Melzack and Wall (1965), the nonpainful input closes the "gates" to painful input, which prevents pain sensation from travelling to the central nervous system. Cold application directly decreases pain by slowing down or completely stopping pain transmission. It increases pain threshold by causing vasoconstriction, which in turn activates gate control mechanism and closes the gates to pain (AmruthaVarshini et al. 2021). There is decreased transmission rate of small diameter nonmyelinated nerve fibers that transport painful stimuli from periphery to the center. Cold application resolves edema, swelling, and muscle spasms and thus indirectly alleviates pain (Sapci et al. 2021).

Vibration stimulus application is another nonpharmacologic method used to reduce painful sensations of local anesthesia injection. Regular and repeated vibratory movements activate gate control mechanism. These vibration stimuli are carried by large myelinated nerve fibers lying close to peripheral neurologic pain gates, leading to elevation of beta-endorphin levels. The beta-endorphins raise pain threshold and decrease pain sensation (Sapci et al. 2021).

In a recent edition of the journal *Pediatric Dermatology*, a paper highlights a novel use for an electric toothbrush — as a vibratory device to reduce the pain of injections (Duplisea et al. 2019). The present study aims to verify and compare topical anesthetic, ice pretreatment, and electric toothbrush as a vibratory device, to reduce the pain of local anesthetic injections.

Methods

Sample size calculation

As per literature survey, we found the expected mean ± SD of Group 1 and Group 2 as 9.6 ± 10.6 and 3.7 ± 3.7, respectively, and mean difference of two groups was 5.9. For $Z_{1-\alpha/2}$, Z 1.96 for 95% confidence interval, and $Z_{1-\beta}$, power 80%, the sample size was calculated using the below mentioned formula and software OpenEpi, Version 3. We found the sample size for each group to be 29, and we took it to be 30, and for three groups, it came to 90.

$$n = \frac{\left(\sigma 1^2 + \sigma 2^2\right)\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{\Delta^2} (\sigma 1 \text{ is standard deviation of Group 1, and } \sigma 2 \text{ is standard deviation of Group 2})$$

Children aged 5–12 years, undergoing treatment at the Department of Pediatric & Preventive Dentistry, ESIC Dental College, Delhi, India, participated in the study.

Inclusion criteria

1. Children with Frankl behavior rating of 3 or 4 (positive or definitely positive) and minimal anxiety
2. Children requiring extraction of maxillary primary tooth, due to pulp necrosis/irreversible pulpitis and extensive loss of crown structure
3. The tooth to be extracted is free of inflammation or infection in periodontium, so that the efficacy of local anesthesia is not affected.
4. Children belonging to ASA I group and having no history of allergy to local anesthetic solutions

Exclusion criteria

Children with any medical condition considered to affect child safety or the quality of the study were excluded.

Written informed consent from parents was obtained before starting treatment. The study was approved by institutional ethical committee, ESIC Dental College & Hospital, Delhi, vide letter no. 10/02/2020/IECDC. The CTRI number of the trial was CTRI/2021/03/032046.

A randomized control trial design was used wherein each child was randomly assigned by permuted block randomization design method to receive either lignocaine 5% as topical anesthetic or ice pretreatment or motorized toothbrush as a vibratory device during local anesthetic injections.

Children were divided into three groups — Group A received vibration with motorized toothbrush (Oral-B Pro 2 2000N Electric Rechargeable Toothbrush), Group B received ice stick pretreatment, and Group C received topical anesthesia with 5% lignocaine (Lignospan-O, Septodont, France) (Fig. 1).

Methodology

- Group A: Vibrations were given for 1 min before injection, and patient continued to receive vibrations during injection. For vibration application, the head of the motorized toothbrush was covered with any one of the finger parts of a disposable glove, brush switched on, and vibration applied with the bristles of the head facing onto the oral mucosa, as close as possible to the site of the injection. Once the procedure was over, the glove was discarded so that the toothbrush could be reused after chemical sterilization.
- Group B: Ice was prepared by filling a 2.0-ml plastic disposable syringe with tap water and freezing it in a freezer. The ice temperature was between −4 and 0 °C. Before administration, the tip of the plastic syringe was cut off with a scalpel, allowing the ice to be pressed out on the mucosa while it melted. Ice was applied for 1 min, followed by the local anesthetic injection.
- Group C: A total of 0.2-ml lignocaine 5% ointment (Lignospan-O, Septodont, France) was applied with a cotton roll on the dry oral mucosa for 1 min. After waiting for further 1 min, local anesthetic was injected.

All these applications were followed by injection of 2% lignocaine HCl with 1:80,000 adrenaline (Lignospan Special, Septodont, France) at the same site using standard cartridge (Septodont, France) and 30-gauge, 1/2-inch needle in all the groups.

All injections with topical applications/vibration were administered on both maxillary buccal and palatal mucosa. Tissues were dried with cotton gauze before application of any agent. Two researchers conducted the study, of which the primary researcher performed all the injections. Second researcher was an impartial observer who evaluated the pain during injection using SEM (sound, eye, motor) scale. At the end of both buccal and palatal injections, each patient was asked by the second researcher about the pain experienced during injection using Faces Pain Scale (FPS).

In SEM scale sound, eye and motor pain reactions of patient are observed. The reactions are classified on a scale from 1 to 4 categories: comfort, mild discomfort, moderately painful, and painful for each of the S, E, and M code (Table 1). The S, E, and M values of a child are added to get SEM score for that child. The second researcher standing at a distance of 1.5 m from the dental chair evaluated the patient's sounds, eye signs, and body movements during injection (Abdelmoniem & Mahmoud 2016) Tables 2, 3 and 4.

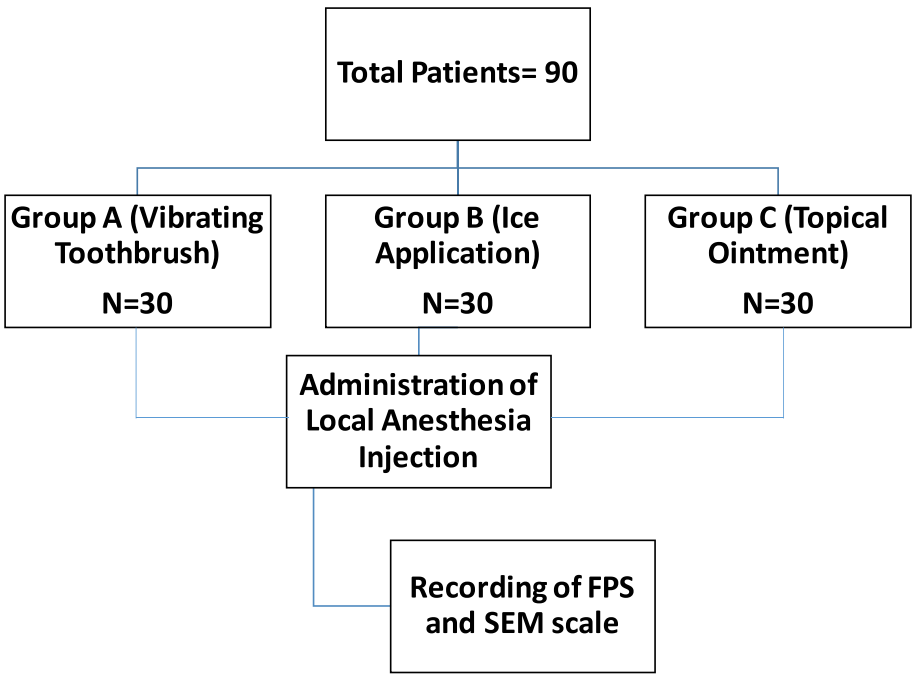

Fig. 1 Patient flow chart

Table 1 SEM score (Abdelmoniem & Mahmoud 2016)

	Designation	Sound	Eye	Motor
1	Comfort	No sound	No sign	Relaxed body hand status
2	Mild discomfort	Nonspecific sound (probable pain)	Dilated eye without fear (anxiety sign)	Muscular contraction, contraction of hands
3	Moderately painful	Verbal complaint, louder sound	Tears, sudden eye movements	Sudden body & hand movements
4	Painful	Verbal complaint, shouting, crying	Crying, tears all over the face	Hand movements for defense, turning the head to the opposite side

Table 2 Distribution of mean and SD of age in the three groups

Group	*N*	Mean age in years	Std. deviation	Std. error	95% confidence interval for mean	
					Lower bound	Upper bound
Vibration	30	8.80	2.355	0.430	7.92	9.68
Ice	30	9.47	2.345	0.428	8.59	10.34
Topical	30	9.10	2.734	0.499	8.08	10.12

Table 3 Frequency distribution *N* (%) of children in the three groups by their gender

Group	Female	Male	Total
Vibration	14 (46.7%)	16 (53.3%)	30 (100.0%)
Ice	14 (46.7%)	16 (53.3%)	30 (100.0%)
Topical	11 (36.7%)	19 (63.3%)	30 (100.0%)
Total	39 (43.3%)	51 (56.7%)	90 (100.0%)

The FPS is a self-report measure of pain intensity developed for children across the age range of 4–16 years which scores the sensation of pain on the widely accepted 0 to 10 metric (Garra et al. 2010; Abdelmoniem & Mahmoud 2016). (Fig. 2). Following the recording of both the scores, the required maxillary tooth was extracted.

Statistical analysis

Statistical analysis was performed using SPSS Statistics for Windows (version 22.0; SPSS, Inc., an IBM Company, Chicago, IL, USA). Nonparametric test — Kruskal–Wallis/ANOVA test for three groups and between two groups Mann Whitney *U*-test, was used to compare SEM and FPS values. Level of significance chosen was $p < 0.05$.

Results

Mean age ± SD of participating children was 8.8 ± 2.3, 9.47 ± 2.3, and 9.1 ± 2.7 in vibration (Group A), ice (Group B), and topical (Group C) group, respectively. Total number of children participating in each group was 30, of which 14 (46.7%) were females and 16 (53.3%) males in Group A; 14 (46.7%) females and 16 (53.3%)

Table 4 Distribution of mean and SD of parameters in the three groups and comparison by one-way ANOVA

Parameter	Group	*N*	Mean	Std. deviation	Std. error	95% confidence interval for mean		*F*-value	*p*-value
						Lower bound	Upper bound		
SEM buccal	Vibration	30	4.90	1.936	0.353	4.18	5.62	0.622	0.539
	ICE	30	4.43	1.888	0.345	3.73	5.14		
	Topical	30	4.93	1.999	0.365	4.19	5.68		
SEM palatal	Vibration	30	5.70	2.020	0.369	4.95	6.45	0.443	0.643
	ICE	30	5.60	2.111	0.385	4.81	6.39		
	Topical	30	6.07	1.929	0.352	5.35	6.79		
FPS buccal	Vibration	30	1.67	1.184	0.216	1.22	2.11	.026	0.975
	ICE	30	1.67	1.295	0.237	1.18	2.15		
	Topical	30	1.73	1.461	0.267	1.19	2.28		
FPS palatal	Vibration	30	3.13	1.795	0.328	2.46	3.80	1.288	0.281
	ICE	30	3.00	1.554	0.284	2.42	3.58		
	Topical	30	3.67	1.749	0.319	3.01	4.32		

Fig. 2 Faces Pain Scale

males in Group B; and 11 (36.7%) females and 19 (63.3%) males in Group C.

SEM (palatal) and FPS (palatal) scores were slightly higher in Group C as compared to Groups A and B, but the differences were not statistically significant. There were no statistically significant differences among SEM (buccal) and FPS (buccal) scores in all the three groups.

Discussion

Local anesthesia (LA) administration in children still remains challenging for a pediatric dentist especially in the current generation of kids with enhanced pain perception and overprotective parenting (Casamassimo et al. 2002). Many new techniques and instruments have been introduced to reduce the discomfort of an injection such as computer-controlled local anesthesia (CCLAD), DentalVibe, VibraJect, and needle-less anesthesia. These techniques do aid in making LA injection more acceptable to patients but have a common disadvantage of being expensive equipment. In order to reduce the cost of treatment in developing countries, alternate low-cost techniques need to be explored.

The present study investigated the effect of vibration (electric toothbrush induced), cooling, and topical anesthetic application on soft tissue on the pain perception of pediatric patients during the administration of local anesthesia for dental extractions. Both Wong Baker Facial Scale and SEM (sound, eye, motor) scale were used in order to do both subjective and objective assessment of pain perception (AAPD reference manual 2021).

The results of the study did not show any significant difference in the pain scales among all the three groups suggesting that both vibration and ice were as effective as topical anesthetic agent in reducing the pain of local anesthetic injection.

The effect of pre-cooling injection site with ice has been found to be as effective as topical anesthetic gel in lowering pain during LA injection in some of the previous studies (Amruthavarshini et al. 2021; Hindocha et al. 2019). Soni et al. (2020) have however found ice to be more effective than topical anesthetic. This could be attributed to the longer duration of ice application in their study which was 4 min as compared to 1 min in our study. Jayasuriya et al. (2017) reported zero pain score with ice, but they used pressure combined with ice in their study without any control group. A combination of ice and topical anesthetic gel has also been used by some of the authors where they have used ice to accentuate the effect of topical anesthesia, thus increasing its efficacy (Aminabadi and Farahani 2009; Ghaderi et al. 2013).

The difference in the site of injection can also affect the study outcomes. It is widely accepted that the site for inferior alveolar nerve block (IANB) administration is less accessible to topical anesthetic due to anatomical considerations and the presence of more saliva that tends to wash away the topical anesthetic faster as compared to that in the maxillary infiltration region. This could make ice more effective than topical anesthesia for IANB administration as reported by Aminabadi and Farahani (2009). A refrigerant spray containing tetrafluoroethane has also been investigated for creating an instant cooling effect at the injection site. It has the advantage of providing instant cooling and easy application (Hameed et al. 2018), but its efficacy remains variable because of a very short duration of action (2–5 s) and its effect being limited to the surface of the site of application (Lathwal et al. 2015). Mucosal ulcerations have also been reported in some cases with the use of refrigerant spray when it remains in contact for a longer duration (Wiswall et al. 2014). Thus, ice stick pretreatment offers a simple, economical, and safe method of providing topical anesthesia whether it is used with or without anesthetic gel.

DentalVibe, a vibratory device, has been extensively studied by many authors for providing comfortable injection procedure in both adults (Shaefer et al. 2017; Ghorbanzadeh et al. 2019) and children (Raslan & Masri 2018; Shilpapriya et al. 2015). Contrasting results have been reported when comparing DentalVibe to traditional injections. Some authors have reported no difference in pain perception with DentalVibe (Raslan

& Masri 2018). On the other hand, many studies have reported a definite improvement in pain control (Ghorbanzadeh et al. 2019; Shaefer et al. 2017; Shiplapriya et al. 2015); difference could be due to the reason that instead of topical anesthesia, DentalVibe in off mode was used as control (Ghorbanzadeh et al. 2019; Shaefer et al. 2017). Another reason could be that their study design was a crossover design (Ghorbanzadeh et al. 2019; Shaefer et al. 2017; Shiplapriya et al. 2015), which could have led to better comparative evaluation as compared to our study.

In the present study, an electric toothbrush was used to produce vibrations. Electric toothbrush is a nonthreatening, and familiar device, and easily accepted by children. Also, it is a cost-effective device and can prove to be a useful adjunct in low-resource settings such as community/school dental health programs to alleviate anxiety associated with dental injections.

It has also been suggested that pain reduction is greatest in the orofacial region if the source of vibration is applied not only within the area directly affected by pain but also when the firmness of vibration application stimulates the underlying bone on the same side as the pain (Melzack & Wall 1965). Thus, an external vibration device on the face with or without cooling has been used by some authors resulting in lower pain ratings during injections (Nanitsos et al. 2009; AlHareky et al. 2021; Alanazi et al. 2019; Tirupathi et al. 2022).

However, further research is required to compare the effects of internal and external vibratory stimulus on the pain reduction during intraoral injections.

There are certain drawbacks of using ice and electric toothbrush. It can be quite messy to use ice and is sometimes less readily tolerated by children (Hameed et al. 2018). With electric toothbrush, some redness/soreness developed on buccal mucosa due to the contact of bristles with the buccal mucosa despite covering them with glove sleeve. When the non-bristle head end was used in contact with buccal mucosa, the child could not clearly appreciate the vibrations. However, no redness or soreness was seen on palatal mucosa, so it could be easily used for palatal infiltration. Palatal infiltrations are more painful than buccal infiltrations, and the use of electric toothbrush can safely mitigate the pain of this procedure. However, careful usage of toothbrush is required, and it should not be kept at one place continuously to avoid injury to mucosa.

One of the limitations of using ice is that discomfort from ice contact is time dependent, and the threshold can be very subjective (Hameed et al. 2018; Aminabadi et al. 2009). The recommended waiting time to allow for its effect varies from 2 to 5 min (Aminabadi et al. 2009), and we waited for 1 min. Other factors that were not taken into account were speed of injection, whether it was patient's first experience of dental injection and initial anxiety levels. Not eliminating these sources of bias would reflect in children's responses to FPS. Sensitization to pain during first local anesthetic injection occurs, resulting in more anxiety, and such children may report more pain on subsequent local anesthetic injections (Versloot et al. 2008).

This aspect can be further explored in future trials involving a cohort of children receiving local anesthetic for the first time or multiple times to assess if vibration/ice/topical anesthetic reduces pain of local anesthetic injection to the same extent.

Conclusions

Ice cooling and electric toothbrush-induced vibration were as effective as topical anesthetic for reduction in pain due to injection. Thus, both can be used as useful adjuncts for local anesthetic administration in pediatric patients.

Abbreviations

SEM	Sound, eye, and motor
FPS	Faces Pain Scale
SD	Standard deviation

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Authors' contributions

Concepts, MM, AK, RC, GK, and SS. Definition of intellectual content, MM, AK, RC, GK, and SS. Design, MM and AK. Literature search, MM, RC, GK, and SS. Clinical work, MM and AK. Manuscript preparation, MM, RC, GK, and SS. Data collection and review, MM and AK. Manuscript editing, RC and GK. Manuscript review, AK, RC, GK, and SS. All authors have read and approved the manuscript. All authors whose names appear on the submission are as follows: (1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work; (2) drafted the work or revised it critically for important intellectual content; (3) approved the version to be published; and (4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Availability of data and materials

Data are not publicly available but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by institutional ethical committee, ESIC Dental College & Hospital, Delhi, vide letter no.10/02/2020/IECDC. Written informed consent from parents was obtained before starting treatment.

Consent for publication

Not applicable as manuscript does not contain data from any individual person.

Competing interests
The authors declare that they have no competing interests.

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