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COMPARISON AND EVALUATION OF THE EFFECTIVENESS OF TENS, 2% LIGNOCAINE GEL AND VIBRATING DEVICE BEFORE LA INJECTION IN ALLEVIATING PAIN IN PEDIATRIC PATIENTS

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ABSTRACT

Background: Pediatric dentistry aims to provide holistic dental care to infants and children through adolescence which involves treating the patient's clinical symptoms and behaviour management.

Aim: To evaluate and compare the effectiveness of TENS, 2% lignocaine gel, and a vibration device in mitigating the pain experienced during local anesthetic injection in 6-12-year-old children.

Methodology: This randomized controlled clinical trial was performed on 90 children of 6 to 12 years of age visiting the outpatient department and those fulfilling the selection criteria were included in the study Approval from the Institutional Ethical Committee along with informed consent was obtained from each subject's parents before enrolling them in study. Three groups were randomly assigned to the participants, each comprising 30 children (n=30). In Group I (n=30), LA was administered in conjugation with TENS; for Group II (n=30), local anesthesia was administered after applying 2% Lignocaine gel and Group III (n=30) received LA with the vibrator device as an adjunct. Pain scale assessments were conducted using theWBPRS and FLACC following the use of LA. The gathered data were statistically examined.

Results: The highest pain score, evaluated using WBFPS, was seen in group II (4.36±0.99), and the least was seen in Group I (1.42±0.56) with a statistically significance difference. Also, a statistically significance difference in the FLACC score was the highest pain score in Group II (1.536 ± 0.50) lowest in Group-I(0.83 ±0.37)($p<0.05$).

Conclusion: The newly introduced TENS apparatus showed encouraging results, hence can be used as a safe and reliable technique to be used in pediatric dentistry.

Key words: 2% Lignocaine, TENS, Vibration device, Pain management

BACKGROUND

It is often known that anxiety and fear negatively affect the inclination of patients to receive dental care. Various dental therapies often evoke unavoidable feelings of threat.[1] It not only facilitates the development of a positive relationship between the dentist and the child but also helps in building trust, eliminating fear and anxiety, and fostering a positive dental attitude for the future.[2]

Dental pain is a distinctive and often debilitating discomfort arising within the oral cavity. It can manifest in various forms, from a persistent, dull ache to sharp, stabbing sensations, typically centered around a specific tooth or area. Common causes include tooth decay, gum disease, abscesses, or dental trauma. The primary goal of a pedodontist is to secure their patient's cooperation during various clinical procedures. Administering local anesthesia (LA) represents a significant and the most challenging aspect of this process.[3]

Local anesthesia serves as the foundation for effective pain control and is crucial for ensuring a pain-free dental practice. Nevertheless, receiving a local anesthetic injection can be quite anxiety-provoking, particularly in the field of pediatric dentistry.[4] Hence, it is crucial to implement an efficient approach to alleviate the fear of injections in children.

The American Academy of Pediatric Dentistry (2020) outline several non-pharmacological behavior guidance strategies. These include engaging children in games, utilizing the tell-show-do method, allowing for parental presence, encouraging motivated visualization, employing

distraction techniques, utilizing protective stabilization, using the hand-over-mouth method, and providing positive reinforcement.[5]

Ongoing research is focused on developing newer techniques like VibraJect, Dental Vibe,Transcutaneous Electrical Nerve Stimulation (TENS) to enhance the comfort of dental treatments conducted under local anesthesia.[1] Topical anesthetic agents are frequently applied before local anesthesia injections to the overall experience. They play a pivotal role in local anesthesia administration by influencing both the psychological and pharmacological aspects.[6]

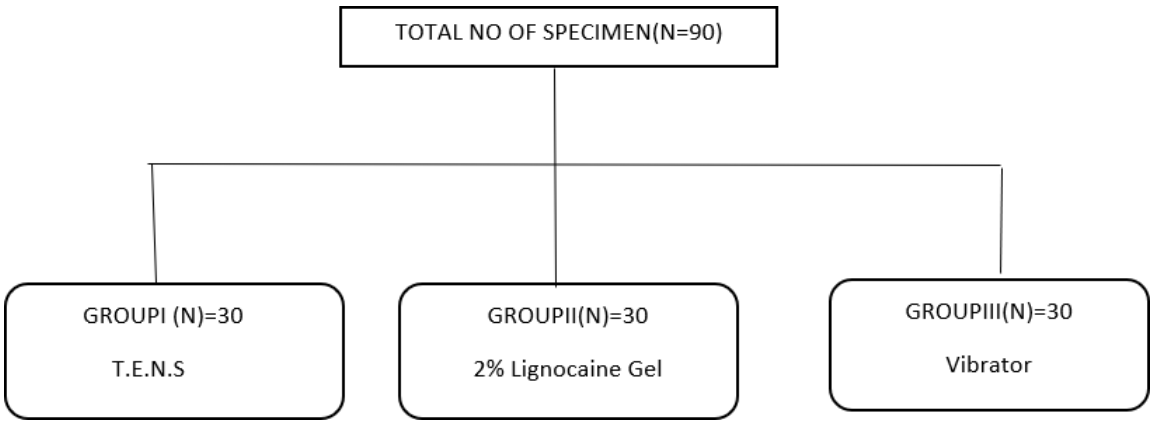
The vibration device techniques implements in reducing pain during LA administration, and it works on the principle of gate control theory of pain.[7] Inhibitory interneurons in the spinal cord get stimulated by touch and vibratory stimuli which restricts the information carried by A-δ and C fibers to second-order neurons of the spinal cord.[8] Therefore, this research sought to assess the effectiveness of different pain-relief techniques, including the use of TENS, a vibration device, and a topical anesthetic gel to mitigate pain in children receiving anesthesia for regular dental treatment.

AIM

Aim of the study was to assess and compare TENS, 2% lignocaine gel, and a vibration device's efficacy in reducing pediatric patients' pain after local anesthetic injection. Objectives of the study were (1) To assess and compare the children's pain scores at the time of dental anesthetic injectionusing three distinct pain management methods. (2) To compare and evaluate the efficacy of TENS,2% Lignocaine, and Vibrator on the reduction of pain stimulus through FLACC and WBFPS scales.

METHODOLOGY

1. **Source of data:** This study was conducted in the Department of Pediatric and Preventive Dentistry,Shree Bankey Bihari Dental College and Research Center, Ghaziabad, Uttar Pradesh.
2. **Type of study/study design**
   This was a randomized control trial. Prior to the study, approval was taken from theInstitutional Ethical committee (SBBDC/2022/384).
   Ninety children, lying in the age bracket of ages six to twelve years presenting themselves to outpatient department and fulfilling the selection criteria were included in the study.



A. Inclusion criteria

I. 6 to 12 years old pediatric patient.
II. Frankl rating 3,4.
III. Parental consent for participation of children in the study.
IV. Dental treatment requiring injectable local anesthesia.

B. Exclusion criteria

I. History of systemic disease. intellectual disability or psychiatric disorders.
II. Allergy to lignocaine.
III. Those requiring treatment under general anesthesia.
IV. Parents who did not give consent.

3. Data collection

Sample size

90 children were selected randomly based on selection criteria. Before each subject was included in the study, their parents gave their informed consent. Random assignment of the patients was done into the following groups: Group I: TENS ; GROUP II: 2% lignocaine gel ; GROUP III: Vibration device.

Before the study, a customized form was used to gather demographic data. The children's degree of pain postoperatively was evaluated using the WBFPS and FLACC Scale.

Group I (TENS Group): The TENS unit consists of electrode pads and a control unit. Extra-oral placement of the electrode pads was done followed by alteration of the unit's frequency and amplitude until the subject experienced a warm, twitching sensation. After that, the LA solution was delivered, and TENS stimulation was kept up until the solution was deposited into the tissues. Group II (2%Lignocaine Group): The injection site's soft tissue was coated with 2% lignocaine gel for two minutes, and then LA was administered. Group III

(Vibrator Group): An external vibrating device was placed at the injection site, with the intensity gradually raised from 0 to 2 modes until muscle twitching occurred. The vibration continued after administering the local anesthetic until the solution was fully deposited into the tissue. Pain scale assessments were conducted using the WBPRS and FLACC after the administration of LA.

Wong Bakers facial pain rating scale

It is a scale that uses facial expressions to assess the emotional state of an individual. This scale appears to range from a happy face at one end to a tearful one at the other, with scores ranging from 0 to 10. Following the technique, the participant is asked to select the expression on their face that best captures how they are feeling.

Face, Legs, Activity, Cry, Consolability scale (FLACC)

It is a scale to assess pain in individuals who may not be able to communicate their pain effectively, such as children or those with cognitive impairments. The FLACC scale typically assigns scores from 0 to 2 for each of the five categories (Face, Legs, Activity, Cry, Consolability), with a higher total score indicating a higher level of pain.

The sample size was determined based on the results of the pilot study using the followingformula:

$$\underline{n = (\sigma 12 + \sigma 22)\ (Z\ 1-\alpha/2 + Z\ 1-\beta)2}$$

$$\Delta 2$$

where n= sample size of Groups, σ1= standard deviation of Group, σ2= standard deviation of Group, □ = difference in group means, Z1-α/2 = two-sided Z value and Z1-β= power. GPower software (version 3.0) was used to estimate the sample size. The sample size for the F tests- ANOVA: Three groups' worth of fixed impact, omnibus, and one-way estimates were made. It was found that, given an alpha of 0.05, power of 80%, and effect size of 0.335 (measured for the variance in the WBFPS, from similar articles), a minimum total sample size of 90 (30 each group) would be sufficient.

4. Ethical approval and Informed consent

Ninety children were recruited from those visiting the clinics of Department of Pediatric and Preventive Dentistry, In Shree Bankey Bihari Dental College and Research Center, Ghaziabad, Uttar Pradesh. Before the study, approval was taken from the Institutional Ethical Committee. Informed consent was obtained from each subject's parents beforeenrolling

them in study.

5. Statistical analysis

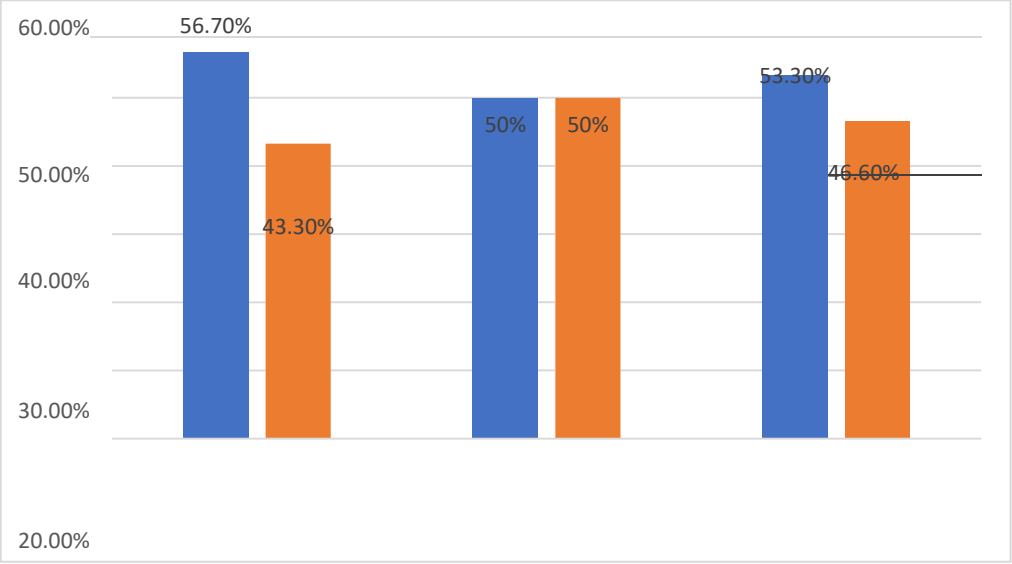
Data was recorded onto structured proforma and then into Microsoft Excel and SPSS statistics set at five percent. Standard deviation and mean were among the descriptive statistics. A significance level of 5% had been selected.

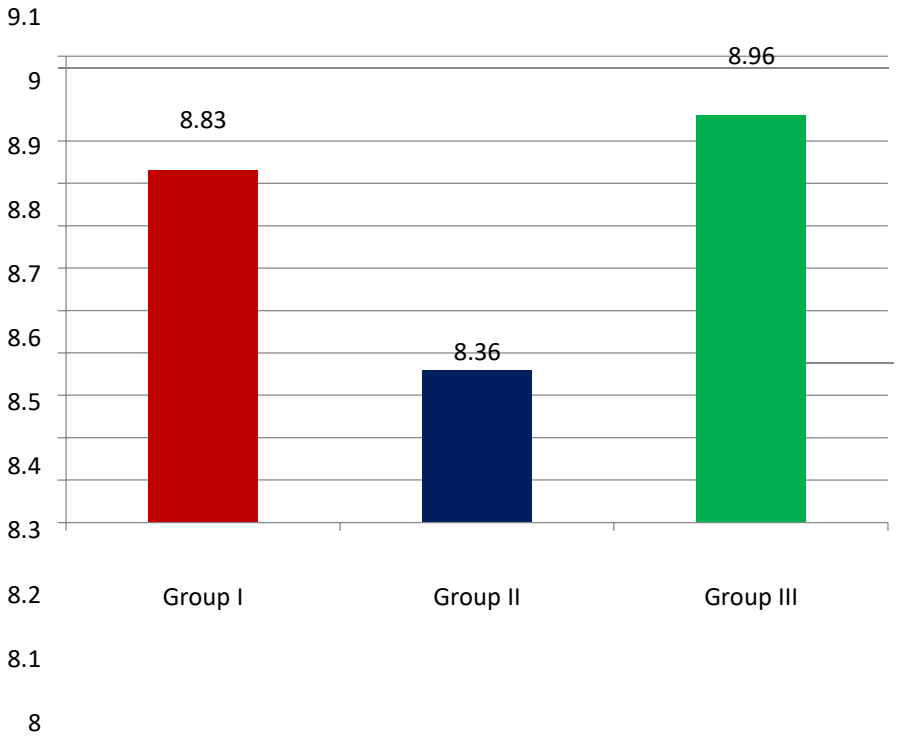
RESULT

Age wise distribution of Study Subjects among all the groups (Table 1, Graph 1)

	Mean	Standard Deviation	Standard Error	P value
Group I	8.83	1.59	0.214	0.981 (Non-Significant)
Group II	8.36	2.32	0.342	
Group III	8.96	1.75	0.267	

The mean age of participants varies slightly across the groups: 8.83 years for Tens, 8.36 years for Lignocaine, and 8.96 years for Vibratory Method. The standard deviation, which measures the spread of ages around the mean, varies from 1.59 years (Tens) to 2.32 years (Lignocaine), indicating a slightly broader age range in the Lignocaine group. upon statistical analysis, There was no discernible statistically significant variation in the age distribution of the research participants. ($p>0.05$)




9.1
9
8.9
8.8
8.7
8.6
8.5
8.4
8.3
8.2
8.1
8
8.83
8.36
8.96
Group I
Group II
Group III

Intergroup Comparison of Mean of WBFPS scores among Study Groups

(Table2, Graph 2)

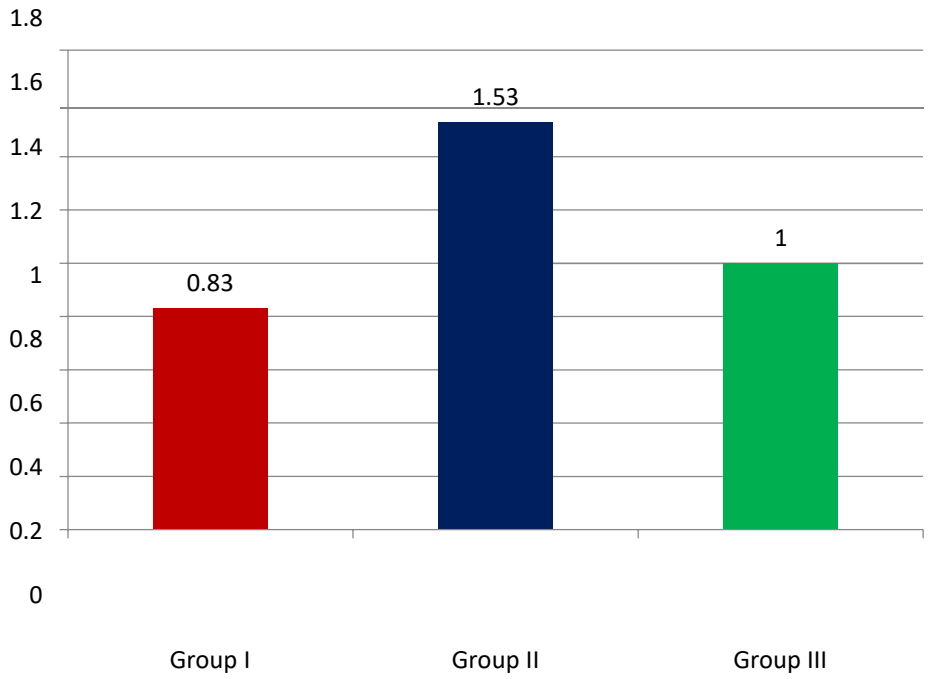
	Mean	Standard Deviation	Standard Error	F value	P value
Group I	1.42	0.56	0.12	133.664	0.001 (Sig)
Group II	4.36	0.99	0.24		
Group III	2.16	0.53	0.16		

These results indicate that the type of method used can significantly affect the level of dental pain (1.42±0.50) (4.36±0.99) in pediatric patients. The TENS group reported the least amount of pain, while the lignocaine group reported the most.

Intergroup Comparison of mean FLACC Scores Among Study Groups

(Table 3, Graph 3)

	Mean	SD	Std Error	F value	P value
Group I	0.83	0.37	0.11	30.976	0.001 (Sig)
Group II	1.53	0.50	0.19		
Group III	1.00	0.02	0.01		



DISCUSSION

In our present study, we have focused on techniques that could be supplemented

with a traditional local anesthetic injection to minimize the pain of pediatric patients experienced while administering LA. Three alternative techniques explored were TENS (Group 1), 2 % Lignocaine gel (Group 2), and Vibration device group (Group 3) to minimize the pain and discomfort caused by injections on 90 participants with the ultimate goal of achieving the best way of securing the child's cooperation during various procedures requiring the use of local anesthesia and hence providing successful treatment to the child.

Literature shows that 53–78% of participants preferred TENS over local anesthetic. TENS has been used extensively to drastically reduce discomfort in child patients during dental operations such as endodontics, small extractions, and cavity preparation.[9] In a study by Quarnstorm Fred, TENS was used to treat pediatric operations in which the patient experienced no discomfort throughout extraction.[10] Bishop TS used With a documented success rate of 92.8%, TENS is used to administer restorative therapy to pediatric patients.[11] According to Segura et al. (1995), patients between the ages of 7 and 12 who used TENS had the least level of pain during restorative procedures.[3]

Hochman concluded that TENS is less effective for "skeptical" and "extremely pain- sensitive" individuals. Another study by Siddiqui A, et al in 2021[12] reported that LA injectionalong with TENS produced much less discomfort ($p < 0.05$) when compared to topical application of a local anesthetic drug. Similar results were obtained by Choudhari SR et al (2017) in another trial, which demonstrated that TENS administration was more pleasant and considerably reduced pain. In pediatric dentistry, TENS is a practical, dependable, and safe substitute.[13]

Vibrating or pressure impulses can be applied manually or by positioning vibratory devices near to the location of injection in order to reduce the feeling of injection pain using the gate control principle.[14] Melzack and Wall put forth this notion in 1965. The core idea of the hypothesis Are such big myelinated fibres exist that transmit harmless The act of touching data is able to block the feeling of pain by shutting a spinal cord gate that is regulated by bothbenign (large-fibre activity) and noxious (small-fibre activity) inputs.[15] Studies have looked into the effectiveness of vibration therapy in mitigating discomfort during medical procedures such venipunctures, phlebotomies, vaccinations, and other needle-related procedures on children. Positive results were seen when the vibration device was used in addition to cold on the during the venipuncture vaccine. [16,17]

Similar to this, other studies that evaluated the effectiveness of vibration devices for children's dental injections had inconsistent findings. Application of DentalVibe, Hassanein et al. (2016) reported a decrease in pain experienced in pediatric mandibular nerve block injection.[18] Employing vibration during local anesthesia was proven to be effective in reducing injection pain by Hegde et al.[2] Tandon et al. concluded that vibratory stimulation had notable effects. Nevertheless, other research has not demonstrated that vibrating gadgets can lessen pediatric pain.[2]

Post-operative measures were explored by WBFPS and the FLACC scale. It is widely acknowledged that measuring pain in children can be a challenging issue

for medical experts. This is because children express pain differently than adults due to differences in their language, communication, and developmental stages.[19] Using scales of different facial expressions and matching a child's pain level to a face that resembles it, is one method of evaluating pain in children. The WBFPS measure is one faces pain measure that children and their parents frequently use to report the degree of theirsuffering. [20]

FLACC is a behavioral pain assessment scale used for self-reporting of level of pain. Pain is assessed through observation of face, legs, activity, cry, and consolability. [3] For individuals who are nonverbal or preverbal who are unable to self-report their level of pain, the behavioral pain assessment scale FLACC is utilized. Five categories—the face, legs, activity, cry, and consolability—are used to measure pain.[3]

In the present study, ninety healthy children between the ages of 6 and 12 who were indicatedfor procedures requiring LA injections for dental treatments were split into three groups, eachconsisting of 30 patients. The means of WBFPS and FLACC scores for each of the three groups were compared using one-way ANOVA and post Hoc Tukey Analysis.

The mean WPFBS score in TENS was 1.42 followed by the Vibrator group at 2.16 and lignocaine to be 4.36. The high F-value of 133.634 and a p-value of 0.001 suggest that the differences in pain levels among the groups are statistically significant. The mean FLACC score in the TENS group was 0.83 followed by the Vibration group at 0.50 and the lignocaine group was found to be 1.53. The F-value of 30.976 and a p-value of 0.001 suggest that the differences in pain levels among the groups are statistically significant. These results indicate that the type of method used can significantly affect the level of dental pain in paediatric patients.

CONCLUSION

After culminating the findings with previous evidences, it can be concluded that among all these three groups, TENS is more effective in terms of reducing pain in children during the administration of LA than 2% lignocaine and vibrating device group; and thus, can be used as an efficient adjunct to LA ultimately enhancing patient experience in pediatric dental settings.

CLINICAL SIGNIFICANCE

TENS, Vibrating devices are advantageous in every phase of treatment in pediatric dentistry. It can be implemented in a mini block type device attached with belt or clothing material to induce episodic or time fixed interval pain relief either during treatment or at home.

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