Comparative Evaluation of Efficacy of Topical Lidocaine Spray, Tetrafluoroethane Spray and Orachill Before Intraoral Local Anesthesia – A Double Blind Randomized Clinical Trial

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ABSTRACT
Topical and local anesthesia is the cornerstone of the treatment in this modern-day dentistry. Background: Local anesthetics, one of the most used drugs to avert and manage pain, are associated with pain resulting from the situation's irony. Efforts are made to reduce this pain perception of injection. Along with lidocaine as topical anesthesia, cryoanesthesia has also reduced injection pain.
Aim: To evaluate the efficacy of lidocaine spray, tetrafluoroethane spray, and orachill mouthpiece concerning discomfort during needle insertion in pediatric patients for various dental procedures measured by Sound, Eye & Motor scale (SEM) (objective method), Visual Analog Scale (VAS) (subjective method), Wong-Baker Faces Pain Rating scale (WBFPRS) (subjective method) pain scales.
Study Design: In this double-blind, randomized clinical trial, 90 patients between the age group of 5 and 12 years were selected and randomly divided into three equal groups with 30 patients in each group. The three groups into which the study sample was divided were; Group 1 was lidocaine spray, Group 2 was tetrafluoroethane spray, and Group 3 was the orachill group.
Results: The mean of SEM for the sound score was 1.23+0.89; 0.93+0.64; 0.90+0.71 for lidocaine spray, tetrafluoroethane spray, and orachill group, respectively. The mean score for the eye was 1.23+ 1; 0.87+0.68; 0.73 +0.69 lidocaine spray, tetrafluoroethane spray, and orachill group, respectively. The mean score for the motor score was 1.20+0.76; 0.73+0.64; 0.97+0.67 for lidocaine spray, tetrafluoroethane spray, and orachill group, respectively. The mean WBFPS scores were found to be highest in Group 1 (3.80+ 1.42), followed by Group 2 (3.47 + 1.57), and the scores were lowest in Group 3 (2.53 + 1.66). The mean VAS scores were found to be highest in Group 1 (3.87+ 1.78), followed by Group 2 (3.23 + 1.22), and the scores were lowest in Group 3 (2.20+ 1.49).
Conclusion: The efficacy of the Orachill mouthpiece proved to be superior in comparison to lidocaine spray as a topical anesthetic agent. Orachill mouthpiece was comparable in efficacy to Tetrafluoroethane as a topical anesthetic agent..
Keywords: Topical anesthesia, lidocaine, cryoanesthesia, pain perception
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INTRODUCTION

In patients' minds, mainly those who underwent multiple extractions, surgery for periodontal disease, or having symptomatic teeth indicated for endodontic therapy for them, pain and dentistry go hand in hand. A dentist with no pain given during the treatment, the public perceives them as a good dentist, and the dentist identifies the anesthetic as a good topical anesthetic which allows them to focus on the procedure without distraction by the patient's movements due to pain. As stated by Rosenberg ES in 2002, anxiety related to dentistry is related to the pain of needle insertion during local anesthesia administration.[1] Due to the fear of needle insertion, the local anesthesia administration appears traumatic. It was found that patients were highly apprehensive of dental treatment because of the fear of needle insertion, thus showing high dental anxieties and missed or postponed their appointments, as mentioned in one of the surveys.[2] Topical anesthesia is becoming a routine in clinical practice by overcoming these problems.

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Lidocaine comes in various forms and concentrations in dentistry. It takes one to two minutes to start its action with fifteen minutes of the duration of action and maximum efficacy occurring at five minutes.[3,4] To alleviate the needle insertion pain, another method described in dentistry is using a refrigerant. Applying these cooling techniques is promising because of its potential for pre-operative. Cryoanesthesia produced is of two to five seconds, which is of minimum duration, is adequate to alleviate the pain caused by the needle insertion. 1,1,1,2 tetrafluoroethane (TFE) is a colorless and noncombustible gas. [5] Several studies show its biocompatibility with no carcinogenic or mutagenic effect on animals. [6]

A newer cryoanesthetic, a dental mouthpiece (Orachill), is being used nowadays for pain relief without side effects or complications of drugs. A medical-grade polymer infused with freezable harmless saline solution makes this mouthpiece. Once Frozen, Orachill then applied inside one's mouth as needed. The nerve sensations inside the mouth and jaw get blocked[7]. To reduce the unpleasant experience of the needle insertion during local anesthesia, this study evaluates and compares the effectiveness of lidocaine topical anesthetic spray and pre-cooling agents viz tetrafluoroethane spray and Orachill mouthpiece during the intraoral injection pain perception.

MATERIAL AND METHOD

An adequate sample size of 90 children, which was statistically determined, including males and females aged 5 to 12 years, was selected amongst the patients reporting to the Department of Pediatric and Preventive Dentistry. In those children requiring local anesthesia for various procedures such as pulpotomy/ pulpectomy/ extractions, medical and dental history was taken. After the clinical examination, children who fulfilled the inclusion criteria were selected, and from the child's parents, written consent was taken. The inclusion criteria were: 1. Patient in need of dental treatment requiring local anesthesia. 2. Patient should not be medically compromised (ASA classification 1) 3. no medication for pain taken before reporting to the dental office. 4. Children who are cooperative and ready to participate in the study. Exclusion criteria were children with 1. hypersensitive to local anesthetic drugs or contraindicated for local anesthesia delivery 2. special children which include handicapped and medically compromised belonging to this age group.

Using a lottery system, the participants were divided into three groups as one control group and two test groups as follow:

Group1: Patients in whom lidocaine spray was used and assessed for 3 minutes before injection of 2% lidocaine. (30 Patients) (Control group)

Group 2: Patients in whom tetrafluoroethane spray was applied for 5 seconds prior to injection of 2% lidocaine. (30 Patients) (Test group I)

Group 3: Patient in whom orachill was applied for 2 minutes prior to injection of 2% lidocaine. (30 Patients) (Test group II)

GROUP I (Lidocaine spray):

Before applying the topical anesthetic, the region where a block or local infiltration was to be administered was dried with sterile cotton gauze, and then lidocaine spray was sprayed from a 1 to 2 cm distance. A waiting period of 3 minutes increases the numbness in patients.

GROUP II (tetrafluoroethane):

Prepared the tissue site before injection for the refrigerant 1,1,1,2 tetrafluoroethane. The methods followed were as follows:

the refrigerant was dispersed in a small medicine cup about 5-milliliter; with a two-inch piece of gauze, the mucosa was dried; in the refrigerant, a cotton-tipped applicator was dipped then for five seconds placed on the tissue site. (Fig. 1)

GROUP III (Orachill):

The OraChill mouthpieces were placed in the freezer for at least 6 hours or overnight. It must be chilled before use. After opening the chilled OraChill mouthpiece, hold it by the clear pivot and give it a mouthpiece shape. Pushed OraChill back between cheeks and gums, holding only by the hinge- in front of the teeth, without touching with teeth. The top part is on the upper gums, and the bottom is on the lower gums. spread OraChill apart as far as possible, and for two minutes, left the OraChill mouthpiece in place. (Fig. 2)

For each of the study groups, after using a topical anesthetic, administration of local anesthesia, whether block or local infiltration, was carried out with a 24 gauge needle for checking the efficacy of topical anesthesia. The effectiveness of the topical anesthetic in this study was evaluated using three scales: SEM scale, VAS, and WBFPRS. A skilled observer (experienced pediatric dentist) who was unknown about the type of topical anesthetic used on that patient assessed the patient's reaction during the injection. The patients were also unaware of the topical anesthetics used.

The obtained data were subjected to statistical analysis to assess the effectiveness of topical anesthetics.

OBSERVATION AND RESULTS

In this study total of 90 patients (55 males and 35 females) with a mean age of 8.67 + 2.14 years (range: 5-12 years) were present.

Analysis of SEM

The means of Sound, eye and motor parameters individually differed in all the groups. The mean score for Sound was found to be highest in Group 1(lidocaine), which is 1.23+ 0.89, followed by Group 2(tetrafluoroethane), which is 0.93+0.64. The lowest score was shown by Group 3(Orachill) 0.90 +0.71, indicating superiority of orachill over the other two groups. The mean score for the eye was found to be highest in Group 1(lidocaine), which is 1.23+ 1.01, followed by Group 2(tetrafluoroethane), which is 0.87+0.68, and the lowest score was shown by Group 3(Orachill) 0.73 +0.69. The mean score for Sound was found to be highest in Group 1(lidocaine), which is 1.20+0.76, followed by Group 3(Orachill), which is 0.97+0.67. The lowest score was shown by Group 2(tetrafluoroethane) 0.73+0.64. among the groups, This difference was found to be statistically significant. ($p<0.05$) [Graph 1]

Analysis of VAS

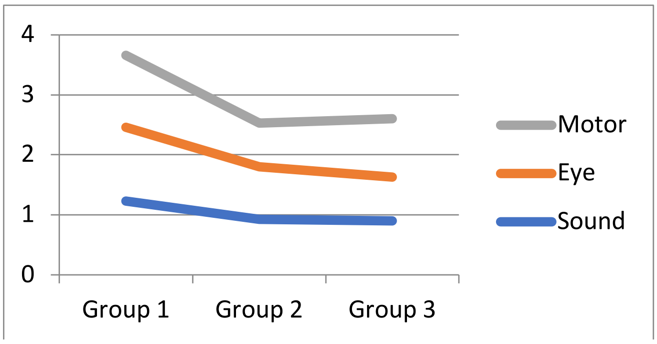
The highest mean for VAS scores was shown by Group 1 (3.87+1.78), followed by Group 2 (3.23 + 1.22). The lowest score in Group 3 (2.20+ 1.49) shows that orachill had the least pain score on the VAS scale, followed by tetrafluoroethane and lidocaine. Among the groups, this difference was statistically significant ($p<0.05$) [Table 1]

Analysis of WBFPRS

The mean WBFPS scores were highest in Group 1 (3.80+1.42), followed by Group 2 (3.47 +1.57). The scores were lowest in Group 3 (2.53 + 1.66), indicating superiority of orachill over the other two groups, followed by Tetrafluoroethane and lidocaine, respectively, and this difference was statistically significant among the three groups with a value of $p=0.006$. [Table 2]

Fig 1: APPLICATION OF TETRAFLUOROETHANE

Fig 2: APPLICATION OF ORACHILL



Graph 1: COMPARISON OF MEAN FOR OF SOUND, EYES AND MOTOR SCALE score using Kruskal- wallis test

Groups	Mean	S.D.	F-value	p-value
Group 1	3.87	1.78	9.253	0.0001*
Group 2	3.23	1.22		
Group 3	2.20	1.49		

Kruskal-wallis test applied, p-value significant at $p<0.05$

TABLE 1: COMPARISON OF VISUAL ANALOG SCALE AMONG THE THREE GROUPS Using Kruskal- Wallis Test

Groups	Mean	S.D.	F-value	p-value
Group 1	3.80	1.42	5.365	0.006*
Group 2	3.47	1.57		
Group 3	2.53	1.66		

Kruskalwallis test applied, p-value significant at $p<0.05$

TABLE 2: COMPARISON OF WONG BAKER FACES PAIN RATING SCALE SCORES AMONG THE THREE GROUPS using Kruskal- wallis test

DISCUSSION

The fear of dental injection has been shown to transfer into adulthood and can negatively affect the subsequent generation through the impression of the parent's fear onto their child. Therefore, making the dental injection as comfortable as possible is important, especially for the pediatric population.

Though many local anesthetic agents are used as a topical anesthetic, according to Malamed SF, lidocaine remains the touchstone due to its effectiveness, low hypersensitivity, and least lethal effect. Other authors such as Kumar SM and Saraf SP et al. have corroborated this in their research work.[8-10] In the present study, Lidocaine spray was taken as a control group for the reasons mentioned above. Frequently, patients describe the unpleasant taste of lidocaine as a primary factor contributing to the unpleasantness of the procedure, as confirmed by Bonaparte JP et al. in their research work.[11] So to overcome this drawback of the spray as being distasteful and its wash-out effect, a new alternative to this topical anesthetic is needed. This led to the advent of "Cryoanalgesia" in topical anesthesia. It is well documented that 1,1,1,2 tetrafluoroethane (TFE) is a topical anesthetic agent, but the off-label use of 1,1,1,2 tetrafluoroethane as topical anesthesia was suggested by Kosaraju A and Vanderwalle KS in dentistry.[12]

A newer cryoanesthetic, a dental mouthpiece (Orachill), is being used nowadays for pain relief without side effects or complications of drugs. It is a novel product by Vanskiver G et al. mainly used to provide cold to oral tissue for therapeutic effect. This mouthpiece is made of polymeric material. It is prepared by storing in a conventional freezer until it reaches a sub-zero temperature. It is a secure substitute for pregnant, drug-sensitive, cardiac, and other medically compromised patients.[7] No studies were found documenting the effectiveness of Orachill Mouthpiece as a topical anesthetic agent before local anesthetic injection, so we evaluated it alongside the gold standard in topical anesthetics viz. Lidocaine spray and 1,1,1,2 tetrafluoroethane (TFE) in our study.

The present study used the SEM scale to evaluate the patient's behavior. SEM scale is the scale that was originally developed as Glasgow Coma Scale. The scale is a non-self assessment scale where the reading of the patient's eye reflex, Sound, and motor reflex is taken. Habib-Agahi R et al., in 2017 had used the Sound, eyes, and motor scale in their study conducted on children from 4 years of age and found that the scale was very effective and reliable in this age group so was used in our study.[13] The pain was also evaluated based on children's self-report using VAS and WBFPRS, and according to McGrath P and Malviya S, these scales are the reliable and valid manner of describing the perception of the pain of a child as young as five years of age.[14,15] To eliminate any bias that may affect the needle insertion technique of local anesthesia or pain evaluation, double-blinding was used in this study. The double-blind RCT is mentioned as the minimal biased and almost non-discriminatory procedure ethically possible now, RCTs produce undistorted and objective information.[16]

The topical application of lidocaine spray was done as advocated by Sharma A et al. the region to which block or local infiltration was to be administered the lidocaine spray was applied, from 1 to 2 cm distance and the minimal time given to topical anesthetic to act was three minutes prior to needle insertion.[17] We followed the tetrafluoroethane application and site preparation methods as instructed by Kosaraju A and Vandewalle KS, i.e., a cotton-tipped applicator was dipped in the refrigerant and then for five seconds placed on the tissue site.[12] In the case of Orachill, the application was done by following the manufacturer's instructions.

Our finding with the SEM scale suggested that Orachill showed the lowest score for Sound. This result corroborates with a similar study done by Lathwal G et al. in 2015, where they concluded that to alleviate the pain perception associated with the needle insertion, all the three surface anesthetic agents were successful insignificantly. Benzocaine gel and Refrigerant spray (tetrafluoroethane)showed significantly lesser efficacy than ice cone.[18] For the eyes score, Orachill showed the lowest mean score. These test results are affirmed by similar work done in the year 2017 by Bhadauria US et al. in their study determined the consequences of using cryoanesthesia on the injection site for pain perception in patients and found that ice was more effective than lidocaine which supports our evidence that SEM scale values were superior for orachill as compared to lidocaine.[19] For motor score revealed that the lowest mean score was shown by tetrafluoroethane. The result was similar to a study done by Waterhouse MR et al. in 2013 reported that vapocoolant spray was found to show better efficacy than ice as an analgesic during pediatric intravenous catheter placement.[20]

Our result for VAS showed better efficacy of Orachill mouthpiece compared to tetrafluoroethane spray and lidocaine spray. The study done by Hindocha N et al. in 2019 showed similar results, which concluded that before a dental injection, the effective substitute to lidocaine 5% gel which also has a bitter taste, is the application of ice as topical anesthesia.[21]

The mean WBFPS score supports the result reported in 2018 by Hameed NN et al., who support the concept that topical cooling significantly decreases the pain threshold during the needle insertion and raises the painful sensation because of unpleasant sensation such as the needle insertion.[22] Tripathi SP and Rajasekhar S in the year 2020, in their systematic review, revealed that in alleviating pain during needle insertion in children pre-cooling with ice could be a successful addition to topical anesthesia when compared with refrigerant spray.[23] This was similar to results observed in our study, where the pain scores were less with the orachill and tetrafluorethane group in comparison to lidocaine spray group.

The present study supports the notion that anesthesia produced by cryoanesthesia is sufficient to alleviate needle insertion discomfort. The study's limitations include like placebo was not considered in the study; other factors such as the cooling group tissue temperature, rate of solution deposition, and needle penetrating depth. Although double-blinding was done to decrease the chances of bias in the present study, future research can be done to compare these materials to use in clinical application for pain-free administration of local anesthesia.

CONCLUSION.

The efficacy of the Orachill mouthpiece proved to be superior in comparison to lidocaine spray and comparable in efficacy to Tetrafluoroethane as a topical anesthetic agent.

CLINICAL IMPLICATION:

Orachill is a novel technology of topical anesthetic non-pharmacological and with superior efficacy to our gold standard lignocaine.

The risk of an allergic reaction and intoxication in young and medically compromised pediatric patients is eliminated.

It is easy to use with increased patient compliance, thereby an essential tool for managing invasive procedures in uncooperative patients.
It can be incorporated in first aid kits for managing traumatic dental injuries

REFERENCE

1. Rosenberg ES. A computer-controlled anesthetic delivery system in a periodontal practice: patient satisfaction and acceptance. J Esthet Restor Dent. 2002;14:39-46.

2. Robinson PD, Pitt Ford TR, McDonald F. Local anesthesia in dentistry. London: Reed Educational and Professional Publishing; 2000.

3. Ramos Campos EV, Silva de Melo NF, Guilherme VA, Paula ED, Rosa AH, DE Araujo RB et al: Preparation and characterization of

4. Lee H. Recent advances in topical anesthesia. Journal of Dental Anesthesia and Pain Medicine. 2016;16(4):237.

5. Arikan F, Gurkan A. Cryosurgical treatment of gingival melanin pigmentation with tetrafluoroethane. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2007;103:452-7.

6. Alexander DJ, Libretto SE, Chevalier HJ, Imamura T, Pappritz G, Wilson J. HFA-134a (1,1,1,2-tetrafluoroethane); lack of oncogenicity in rodents after inhalation. Hum Exp Toxicol.1995;14:706-14.

7. VanSkiver G, VanSkiver R. Hinged Therapeutic Mouthpiece. United States; 7527642, 2009

8. Malamed SF. Handbook of local anesthesia. 4th ed. St Louis: CV Mosby;1997.

9. Kumar SM. Efficacy of articaine over lidocaine – A review. J Pharm Sci Res. 2015 7:956–9.

10. Saraf SP, Saraf PA, Kamatagi L, Hugar S, Tamgond S, Patil J. A comparative evaluation of anesthetic efficacy of articaine 4% and lidocaine 2% with an anterior, middle superior alveolar nerve block and infraorbital nerve block: An in vivo study. J Conserv Dent. 2016;19(6):527-531.

11. Bonaparte JP, Corsten M, Rourke R. Reducing the Flavour of Oral Lidocaine: Randomized Controlled Trial Assessing the Efficacy of Mint-Flavoured Mouthwash. Journal of otolaryngology-head & neck. 2010;39:96-101

12. Kosaraju A, Vandewalle KS. A comparison of a refrigerant and a topical anesthetic gel as preinjection anesthetics. The Journal of the American Dental Association. 2009;140(1):68-72.

13. Habib-Agahi R, Gandjalikhan-Nassab SA, Hashemipour MA, Saidi AR, Eskandarizadeh A. Comparing pain and pain-related behavior in children with invented telescopic dental needles. J Oral Health Oral Epidemiol 2017;6(1): 33-9

14. McGrath P. An assessment of children's pain: a review of behavioral, physiological and direct scaling techniques. Pain. 1987;31(2):147-176.

15. Malviya S. Assessment of pain in children. Paper presented at: SPA 20th Annual meeting, University of Michigan;2006.

16. Kaptchuk T. The double-blind, randomized, placebo-controlled trial. Journal of Clinical Epidemiology. 2001;54(6):541-549.

17. Sharma A, Suprabha BS, Shenoy R, Rao A. Efficacy of Lignocaine in Gel and Spray form during Buccal Infiltration Anesthesia in Children: A Randomized Clinical Trial. J Contemp Dent Pract.2014;15(6):750-754

18. Lathwal G, Pandit IK, Gugnani N, Gupta M. Efficacy of Different Pre-cooling Agents and Topical Anesthetics on the Pain Perception during Intraoral Injection: A Comparative Clinical Study. Int J Clin Pediatr Dent. 2015;8(2):119-122.

19. Bhadauria US, Dasar PL, N S, Mishra P, Godha S. Effect of injection site pre-cooling on pain perception in patients attending a dental camp at LifeLine Express: A split-mouth interventional study. Medicine and Pharmacy Reports. 2017;90(2):220-225.

20. Waterhouse MR, Liu DR, Wang VJ. Cryotherapeutic topical analgesics for pediatric intravenous catheter placement: ice versus vapocoolant spray. Pediatr Emerg Care. 2013;29(1):8-12.

21. Hindocha N, Manheim F, Bäckryd E, Bågesund M. Ice versus lidocaine 5% gel for topical anaesthesia of oral mucosa – a randomized cross-over study. BMC Anesthesiol. 2019;19(1):227.

22. Hameed NN, Sargod SS, Bhat SS, Hegde SK, Bava MM. Effectiveness of pre-cooling the injection site using tetrafluorethane on pain perception in children.Journal of Indian Society of Pedodontics and Preventive Dentistry. 2018;36(3):296-300.

23. Tirupathi SP, Rajasekhar S. Effect of pre-cooling on pain during local anesthesia administration in children: a systematic review. J Dent Anesth Pain Med. 2020;20(3):119-127.

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