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A comparative study on pain perception in children, after application of pre-cooled and plain topical anesthetic gel during needle insertion for local anesthetic administration- In-vivo trial

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Abstract

Aim: Comparison of efficacy of Pre-cooled and plain 5% lidocaine topical gel on pain perception during needle insertion during LA administration in children.

Methods: Thirty children requiring bilateral infiltration anaesthesia of the age 6-10 years were selected for this split mouth study. Each injection site was randomly allotted to the control and intervention groups. Pulse rate, blood pressure was evaluated before; during and after LA infiltration and pain perception was evaluated using Won bakers scale. Data was statistically analysed using independent t-test and Man Whitney-U test (p-value <0.05).

Results: The results obtained with intervention group, during LA administration was statistically significant with respect to pulse rate, diastolic blood pressure and pain perception (p-value=0.001).

Conclusion: Pain experienced after application of pre-cooled topical anesthetic gel before LA infiltration is less compared to plain topical gel.

Keywords: Topical anesthesia, Pre-cooling, Cryoanesthesia, pain perception.

Introduction

Local anesthesia (LA) is required in any dental practice, including pedodontics, to alleviate the pain of dental procedures like extractions, pulpotomies, root canal treatments/ pulpectomies, drainage of abscesses, and minor oral surgical procedures. Delivery of effective dental local anesthesia to a child has always been a challenge due to the emotional trait-dental anxiety associated with pain during needle insertion However, the irony of the situation is that local anesthetics, which are the most effective drugs for the prevention and management of pain are themselves associated with pain, and this pain gets further aggravated due to the fear and anxiety caused by the sight of the needle and has been referred to as needle phobia or blenophobia.

Several methods have been used to reduce pain during injection of local anesthetics which can be pharmacologic or non-pharmacologic such as application of a topical anesthetic gel, which is the most common method, apart from this buffering the local anesthetics, adjusting the rate of infiltration, distraction technique, application of heat and cold, acupuncture, hypnosis, vibrating the surrounding tissue while administering the injection, and use of a mechanical delivery system, have been tried to minimize the pain experienced during the administration of local anesthetic agents.[6,7,8]

Cryoanesthesia (Ice) is a therapeutic agent used in medicine as an integral part of injury treatment and rehabilitation. Ice packs are widespread because of their effectiveness, convenience, low cost, and ease of transportation. It is believed to help control pain by inducing local anesthesia around the treatment area. Investigators have also shown that it decreases edema, nerve conduction velocities, cellular metabolism, and local blood flow.

In a medical study, Thompson et al. reported that cooling topical anesthetic gel to 4^0 C significantly reduced pain, compared to using 2% lignocaine topical gel at room temperature during catheter insertion in male patients. However, no studies are reporting the effect of the pre-cooled topical anesthetic gel on pain perception during needle insertion for oral anesthesia in children. Hence the present study aimed to evaluate the effect of Pre-cooled topical anesthetic gel on children's pain perception during local anesthetic administration.

Materials and Methods

The present *in-vivo* study was carried out in the department of Pedodontics& Preventive Dentistry, Bapuji Dental College & Hospital, Davangere.

The ethical approval was obtained from the Institutional Review Board on 24th September 2018 with ref no.: BDC/Exam/383/2018.

Patient selection

Based on the available information from the previous studies, the sample size was 30, with α that is, Type I error is set at 5%, and β, that is, Type II error, was set at 80%. Thirty children belonging to age group 6-10 years reporting to the Department of Pedodontics and Preventive Dentistry were recruited for the study based on the inclusion and exclusion criteria.[13,14,15]

Inclusion Criteria

- Children of 6 to 10 years of age with bilateral treatment requiring LA administration either in the maxillary or mandibular arch.
- Children who demonstrated positive or definitely positive behavior during pretreatment evaluation (ranking 3 or 4 on the Frankel scale).

Exclusion criteria

- Children with any systemic illness (ASA II & ASA III), with a history of allergy to any form of local anesthetic agent.
- Children requiring an emergency dental treatment.

Study

Group I (n= 30): Plain topical Anesthetic gel (5% Lidocaine)

Group II (n= 30): Pre-Cooled topical Anesthetic gel (5% Lidocaine)

Procedure

It was a split-mouth parallel randomized study; wherein patients requiring bilateral infiltration with a local anesthetic agent for any dental procedures were included. Written informed consent was obtained from the parents/ legal guardian of patients willing to participate in the study. The injection sites were then

identified and allocated to the study groups based on a simple randomization method.[4,14]

For Pre-cooled Anesthetic gel, the temperature was maintained using a standard drug refrigerator at 4°C. A single operator carried out the procedure for all the subjects throughout the study, and a single examiner measured the study's parameters to rule out any operator bias in recording the scores.[10,11]

Evaluation of the patient was done in four stages in a single visit:

Stage I: Baseline reading: After the patient was seated on the dental chair, but before any treatment, pulse rate was recorded, using the pulse oximeter following to which, using a digital sphygmomanometer, blood pressure was recorded. These readings obtained were considered baseline records for objective evaluation of the patient during that visit. [16, 17, 18, 19]

Stage II: The site of local anesthesia delivery was identified, cleaned with sterile gauge piece, and dried, and the respective topical agent was applied using a cotton tip applicator. After 1 min of application of the topical gel LA was administered. Pulse rate and blood pressure were continuously monitored. The highest pulse rate and, at the same time, blood pressure were recorded for the patient during needle insertion. [17,18]

Stage III: When the baseline reading was attained on the pulse oximeter, the local anesthetic solution was deposited. The highest pulse rate and the blood pressure post-injection were recorded. After the pulse rate had returned to baseline reading, the patient was made to complete the Visual analog scale (VAS) (Figure 1) for that injection for subjective pain perception evaluation.[14,19]

There were six levels of pain quality and intensity marked by word descriptors. Each patient was asked to point to the face or choose the number that most closely depicted their pain perception during the procedure. When interpreting the results, the six levels of pain intensity on the universal pain assessment tool were divided into three degrees of pain – Mild (level 1 -3), Moderate (level 4-6) and Severe (level 7-9) pain.

Stage IV: After completion of the treatment procedure, the pulse rate and blood pressure were re-recorded. The patient was sent after the baseline readings were attained. Necessary postoperative instructions were given to the parents and child verbally. The treatment procedure on the bilateral side was done one week after the first intervention.

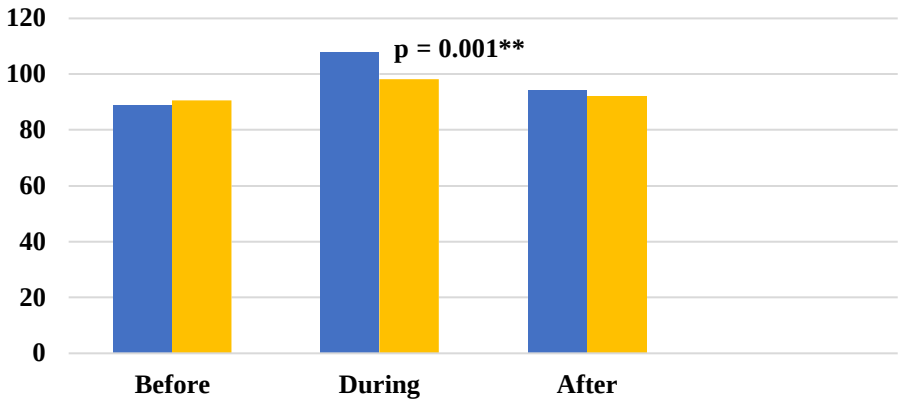
Statistical Analysis

The collected data were tabulated and subjected to statistical analysis using the SPSS version 22. The statistical test employed were Paired t-test for parametric data (pulse rate, systolic pressure, diastolic pressure) and Mann-Whitney U-test for nonparametric data (VAS score for pain perception) for comparison between the groups.

Results

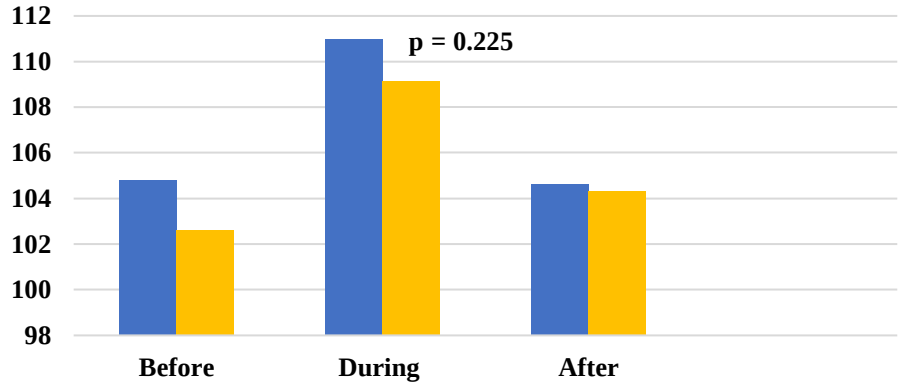
The research comprised 30 patients with a mean age of 8 years (range: 6-10 years). Comparison of the parameters between the study groups showed the following results. Concerning pulse rate, the Mean±SD pulse rate rise observed was 107.73 ±12.02 with Group I and 98.13 ± 10.04 with group II as observed in Figure 1. The difference in the pulse rate rise was less in the pre-cooled group and was highly statistically significant between the groups (p=0.001). As for systolic blood pressure, the Mean±SD systolic pressure rise observed was 110.96±6.00 with Group I and 109.13±5.55 with group II as noted in figure 2, which was not statistically significant. The systolic pressure rise difference was less in the pre-cooled group, but the result was not statistically significant between the groups (p=0.255). Concerning diastolic pressure, the Mean±SD diastolic pressure rise observed during needle insertion was 74.06±9.82 with Group I and 65.4±6.15 with group II as observed in Figure 3.

The difference in the diastolic pressure rise was less in the pre-cooled group and was highly statistically significant between the groups (p=0.001). The comparative evaluation between study groups and frequency distribution of pain perception among participants (Table 1). As observed in table 1 and chart 4 about pain perception when Group I was compared with Group II, it was found that 86.7% that is 26 subjects in Group II, experienced mild pain during needle insertion in comparison to Group I, whereas 60% that is 18 subjects experienced moderate pain, and 26.7% that is 8 subjects experienced severe pain. Also, none of the subjects experienced severe pain in Group II. It was observed that result was highly statistically significant (p=0.001).



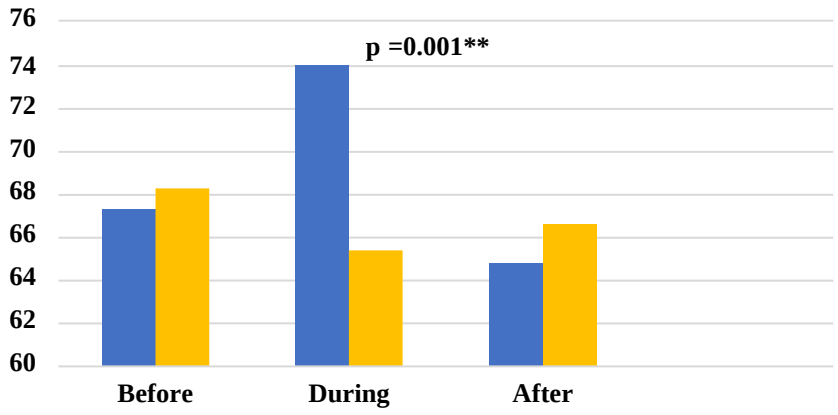
Group 1 - Plain Topical	89.03	107.73	94
Group 2 – Pre-cooled	90.7	98.13	92.3

Figure 1. Showing the comparison of pulse rates among the groups



Group 1 - Plain Topical	104.8	110.9667	104.6
Group 2 – Pre-cooled	102.6	109.1333	104.33

Figure 2. Showing the comparisons of systolic blood pressures among the groups

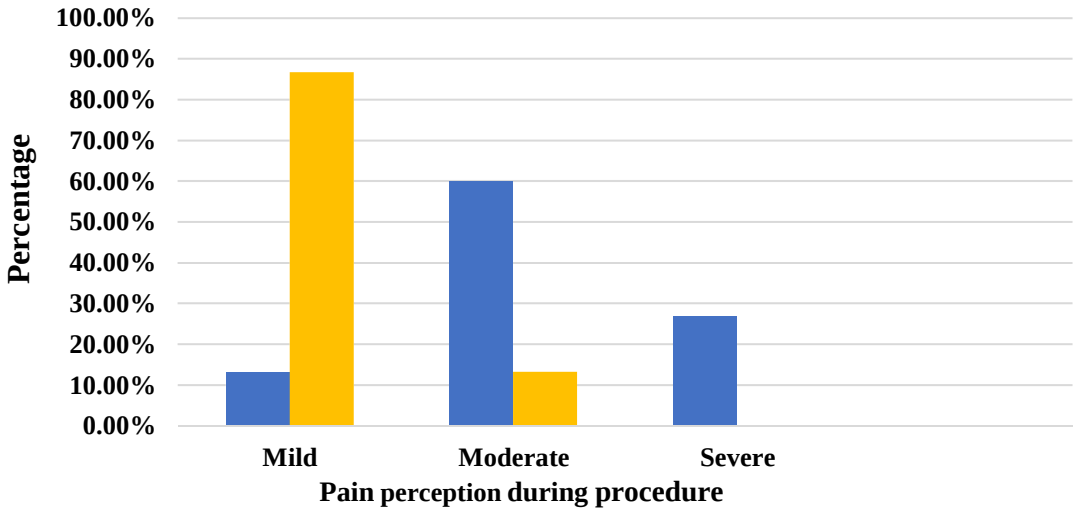


Group 1 - Plain Topical	67.3333	70.066	68.8
Group 2 – Pre-cooled	68.3	65.4	66.633

Figure 3. Showing the comparisons of diastolic blood pressures among the groups

Table 1: Comparative evaluation between study groups and Frequency distribution of pain perception among participants

Groups	Pain perception during procedure (%)			Mean Rank	p-value
	Mild	Moderate	Severe		
Plain topical	4 (13.3)	18 (60)	8 (26.7)	42.03	0.001**
Pre cooled topical	26 (86.7)	4 (13.3)	0 (0)	18.97	



Group 1 - Plain Topical	13.30%	60%	26.70 %
Group 2 - Pre-cooled Topical	86.70%	13.30%	0%

Chat 4: Shows statistical distribution of pain perception during La administration

Discussion

Pain control is a challenging task in clinical pediatric dentistry. Nontheless, conventional pain control techniques deal with only one aspect of pain control, i.e., pharmacological/ sensory, whereas the psychological component is often left unresolved. This is especially true for the pediatric population, where the fear of needles is a major deterrent to quality dental care. It is ironic that to eliminate pain, and we must momentarily create a painful stimulus. The anesthesia produced by cryoanesthesia is of concise duration (2 to 5 seconds), but it is sufficient to reduce the discomfort caused by the insertion of a needle. There are very few dental studies concerning cryoanesthesia.

Harbert used the Cooling technique for palatal injections to alleviate pain during needle insertion and was the first study in this regard. He reported that cooling of the palatal area before injection reduced pain perception. He reported that the application of a refrigerant as a pre-injection anesthetic was more effective than using a topical anesthetic gel for reducing the pain experienced by participants who received a posterior palatal injection.

Cryoanesthesia may be induced either by the use of refrigerant sprays or ice. The chief benefit of cryoanesthesia is that it acts on all the body cells and not just on the nerve cells as other topical anesthetics and analgesics do, thereby producing immediate anesthesia.Pre-cooling of injection sites have been achieved by either application of ice as recommended by authors such as Harbert 1989, Aminabadi 2009, Gadheri 2013, Mohiuddin et al. 2015 etc [7,8,19,26] or by application of a refrigerant recommended by authors such as Ducan et al. 1992, Kosaraju 2009, Lathhwal 2015, Hameed 2018 etc. No comparative study has been reported wherein the topical anesthetic has been pre-cooled and used in the dental field. However, as claimed by Thompson et al. in his study, it has been reported that pre-cooling a topical anesthetic produces a synergistic effect whereby cooling of the soft tissues as well as surface anesthesia is achieved hence creating an overall improved effect.[11] In the present study, a splitmouth comparison was made to avoid any bias while reporting pain. For objective evaluation of pain in children, the physiological parameters of pulse

rate and blood pressure were used as they are strongly associated with pain perception and anxiety.visual analog scale that is the Wong-Baker Faces Rating Scale (Figure 1) was used for subjective evaluation of pain as recommended by Kudo M, Langthasa, et al., San MartinLopez et al. The WB scale demonstrated adequate correlation with a measure of pain and was not mistaken for fear among school-aged children.

During needle insertion, for LA administration, a rise in pulse rate and diastolic blood pressure was significantly less in the pre-cooled anesthetic group (group-II) when compared to the plain topical anesthetic group (group-I) with a p-value being 0.001. When the subjective parameter of pain the perception was evaluated, it was observed that 86.7% of the subjects in the group II experienced mild pain during needle insertion compared to Group I, which was highly statistically significant (p=0.001). A direct comparison with previous studies cannot be made as a similar study has not yet been reported. However, the effectiveness of pre-cooled anesthetic can be attributed to its increased contact time with the tissues. Free nerve endings abound and terminate in all layers of mucosa and have different speeds of conduction. Hence, this increased contact time of pre-cooled anesthetic gel may have resulted in slowing the velocity of nerve impulse induction of almost all the types of nerve fibers, which is according to the gate control theory by Melzack and Wall.

This was followed by the action of lidocaine topical anesthetic on soft tissues, thereby producing surface anesthesia to the depth of 2-5 mm, which completely controlled pain that might occur during needle insertion. Hence, the use of pre-cooling as an adjunct (if not alternative) to topical anesthesia before local anesthesia administration can be an effective measure in reducing pain.

The author, therefore, recommends pre-cooling of the topical anesthetic gel before its application on the soft tissue before needle insertion. Moreover, complete drying of the soft tissue is advisable before applying the topical gel primarily to increase the contact time and better penetration of the gel within the soft tissues. Secondly, to prevent the rise in temperature of mucosa due to the presence of saliva. Lastly, it was observed that the injection rate should be maintained at 1ml/min to reduce pain on the administration of the local anesthetic solution.

Conclusion

Within the scope of this study, we can conclude that pre- a cooled topical gel is a simple and effective method of preventing pain and reducing anxiety caused during LA administration in children**.**

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