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Comparison of Effectiveness of Precooling the Site of Injection Using Topical Ice and Topical Anesthetic Gel in Children Between 7- 12 Years- A Split Mouth Comparitive Study

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ABSTRACT

Background: Topical anesthetics help alleviate fear, anxiety, and pain in pediatric dental treatments. Cryotherapy may enhance pain management by cooling the oral mucosa. This split-mouth study evaluates the efficacy of cryo-anesthesia versus a topical anesthetic gel during inferior alveolar nerve blocks.

Aim: The aim of this study is to compare the effectiveness of topical ice and topical anesthetic gel in alleviating pain during local anesthesia administration in children aged 7 to 12 years.

Materials and Methods: Fifty children requiring bilateral mandibular local anesthesia participated. Topical anesthetic gel (precaine) was applied on one side during the first visit, while cryo-anesthesia was used on the opposite side in the second appointment. Pain intensities were evaluated using a 100-mm visual analog scale and the sound, eye, and motor scale. Data was analyzed using paired t-tests.

Results: VAS scores indicated significantly lower pain in the cryo-anesthesia group compared to the precaine group. Although SEM scores were lower for cryo-anesthesia, the difference was not statistically significant.

Conclusion: Cryo-anesthesia effectively reduces pain during local anesthesia administration in children compared to topical anesthetic. Its advantages include pain reduction, quicker application, and avoidance of unpleasant taste.

Keywords: *Cryotherapy, topical anesthetic, Pain Perception, Visual Analogue Scale and Dibucaine*

1. INTRODUCTION

Pain is thought to be the reason to seek dental care, but it is the same reason to neglect it.[1]. Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or is described in terms of such damage. Many treatments, particularly in pediatric dentistry, need the use of local anesthetics for pain management [2]. The fundamental principle of pediatric behavior management is excellent pain management during dental procedures [3]. Applying topical anesthetics, using distraction techniques, buffering the local anesthetics, counter irritating the area, slowing down the injection, modifying the rate of infiltration, and vibrating the surrounding tissue while the injection is being given are some

ways to lessen pain during local anesthetic injection.[4]. Another suggested method for alleviating patient's perceptions of pain that is successful, efficient, and economical is cryotherapy. The use of ice or refrigerant spray on the anesthetic site to prevent pain from being transmitted to the nerves is known as cryo-anesthesia [5]. Topical anesthetics are commonly applied before administration of local anesthesia to manage pain from the initial needle insertion. The limitation of applying topical anesthetics includes the duration of action of topical gels or sprays, which can range from 5 to 10 minutes, an unpleasant taste, and the diffusion of the anesthetic agent to areas beyond the injection site [6]. According to the majority of clinical study findings, cryotherapy aids individuals heal from a variety of ailments and reduce pain [7].

Why is the study needed: Studies on the physiological effects of cryotherapy revealed that it reduced edema, reduced pain perception, and caused vasoconstriction [8]. Hence, the objective of the research is to compare the effectiveness of pre-cooling the injection site with refrigerant such as ice and topical anesthetic gel (Precaine) before injection of local anesthesia.

2. MATERIALS AND METHODS:

1. **STUDY DESIGN AND DURATION:** The study is a, split mouth design which was conducted in the department of pediatric and preventive dentistry between June 2024 and December 2024 in outpatients.
2. **STUDY POPULATION:** Children between the age range of 7 and 12 who reported and received treatment in the Department of Pediatric and Preventive Dentistry participated in the study conducted at Adhiparasakthi dental college and hospital. The chosen participants had no conflicting medical histories and were in perfect physical and mental condition. The teeth that are being targeted were carious, mandibular primary first or second molars with pulpal involvement were used in this study.
3. **SAMPLE SIZE:** The sample size was calculated using G Power Software version 3.1.9.4 and was estimated as t- test: Means: Difference between two independent mean groups (matched pairs); Sample size: 100; Group 1- 50; Group 2- 50; Power of the study: 95%; Error: 5
4. **ETHICAL APROVAL:** The research proposal was presented and was approved in its entirety by the Institutional Review Board and Ethics Committee at Adhiparasakthi Dental College and Hospital (ECR/1742/APDCH PEDO-09/TN/NOV-2024). The participant's parents gave consent after informing them about the study.
5. **STUDY MATERIALS:**
   - **Cryo-anesthetic/ Ice pack**: To make the ice pack, sterile water was poured into the little finger of the small size latex gloves. The glove's water filled portion was tied and stored in the freezer. To reduce the chance of frostbite, the ice pack's temperature was adjusted between -4°C and 0°C [Figure 1]

Figure 1: Cryoanesthesia

Figure 2: Precaine

- **Topical anesthetic:** Precaine (Lidocaine 8% and Dibucaine 0.8%)

[Pascal Company, Inc, Bellevue, USA] [Figure 2]

- **Local anesthetic:** 2% Lignocaine with adrenaline 1: 80000 and 26-gauge 1.5" needle (unilock, Dispovan)
- **Pain measurement tool:** Intensity of pain perception was evaluated using the Sound, Eye and Motor (SEM) scale and Visual Analog Scale (VAS). The assessment of subjective pain perception was conducted by having the participant indicate their level on the scale, while the objective pain perception was evaluated utilizing the Sound Eyes Motor scale.

6. **INCLUSION CRITERIA:**
   i. Participants who come under Frankl behavior rating No: 3 and 4
   ii. Participants who need bilateral administration of mandibular nerve block (IANB) with local anesthesia for pulpectomies/pulpotomies and extractions
   iii. Participants should not have any systemic diseases
   iv. Participants who has no history of allergy to local anesthesia.
7. **EXCLUSION CRITERIA:**
   i. Participants who is allergic to local anesthetics
   ii. Participants who have been diagnosed with active pathology at the injection site
8. **STUDY PROCEDURE:** This study was conducted by single operator in 50 patients using a split-mouth design. During the initial appointment, dental work was performed after administering local anesthesia, utilizing a topical anesthetic gel (precaine) prior to the injection and patients were given second appointment, and in the subsequent appointment, cryo-anesthetic ice was applied on the opposite side before giving local anesthesia. During mandibular infiltration or IANB and lingual nerve block, 2% lidocaine was injected gradually using a 26-gauge 1.5" needle (unilock, Dispovan) after aspiration. Participant's behavior at the time of injection is evaluated using the SEM- sound, eye, and motor scale [Figure 3][9]. The SEM scores vary from 0 to 9, with each parameter scoring between 0 and 3 [Figure 4]. Participants were requested to indicate their pain intensities and discomfort with VAS-visual analog scale [Figure 5]. Participants were asked to indicate their pain level by pointing to the position. In this scale, scores vary from 0 to 10 by assessing the millimeter distance from the left end bar to the mark created by the child on the 10 cm line, which is represented by happy to sad faces, with a higher score signifying higher intensity of pain [Figure 6] [10]

Figure 3: Represents recording of objective score using sound eye motor scale.

Observation	1-Comfort	2-Enough uncomfortable	3-Enough painful	4 painful
Sound	No sound, of pain	No specific sound of pain	Complaint verbally by raising voice	Complaint verbally painful
Eyes	No pain	Eyes open, look concentrate	blink some times	Cry
			drop tears	tears drop to face
		no tears		
Motoric	calm	Hand holds chairs, show anxiety	Contact physically; hand and body movement	Aggressive movement to avoid treatment

Figure 4: Sound Eye Motor scale

Figure 5: Represents recording of objective score using Visual analogue scale

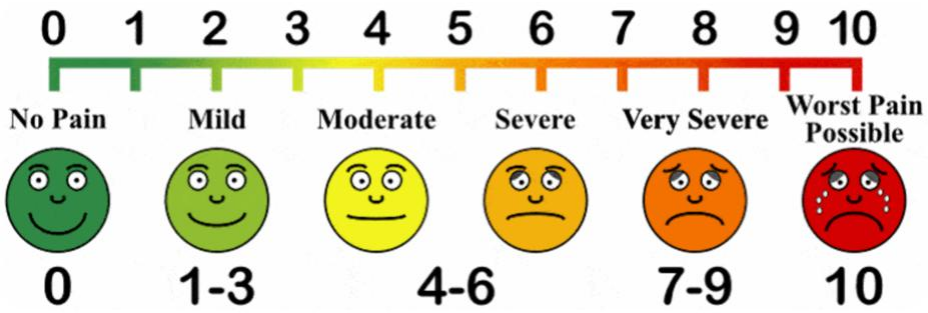

Figure 6: Visual analogue scale

9. STATISTICAL ANALYSIS:

The collected data were entered into Microsoft excel spread sheet and were subjected to statistical analysis by using SPSS software version 23o IBM USA. The descriptive statistics were performed for demographic study parameter. Since the data follows a normal distribution (Shapiro Wilks test) a paired t test is used for intergroup comparison with p value kept as less than or equal to 0.05 as statistically significant difference.

3. RESULTS:

TABLE 1 REPRESENTS THE DESCRIPTIVE DATA BASED ON AGE AND GENDER AMONG THE STUDY POPULATION

PARAMETER	OPTIONS	FREQUENCY	PERCENTAGE
AGE IN YEARS	7	18. 2	36.4
	8	15.9	31.8
	9	6.8	13.6
	10	4.5	9.1
	11	4.5	9.1
GENDER	9	20.45	40.9
	13	29.55	59.1

TABLE 1: Age Distribution: The study population consists of individuals aged between 7 and 11 years. Majority of participants are in the **younger** age groups (7 and 8 years **36.4%** and **31.8%** respectively), with these two groups collectively accounting for **68.2%** of the study population. **Gender Distribution:** The study population has a higher proportion of females-**59.1%** than males, with females constituting majority of the participants. The data shows a skewed distribution, with more participants in the younger age groups (7 and 8 years) and a greater number of females (59.1%) than males (40.9%). This could imply that younger children and females were more available or willing to participate in the study.

TABLE 2 REPRESENST THE INTERGROUP COMPARISON BETWEEN THE STUDY GROUPS IN VARIOUS PARAMETERS ASSESSED BY USING A PAIRED t- TEST.

PARAMETER	GROUPS	MEAN	S. D	95% CONFIDENCE INTERVAL		SIG
				LOWER	UPPER	
VAS SCALE	1	2.9091	1.60087	1.871	3.310	.000
	2	.3182	.89370			
SOUND	1	.9545	.21320	.860	1.049	.000
	2	.0000	.00000			
EYES	1	.9545	.21320	.525	.929	.000
	2	.2273	.42893			
MOTOR	1	1.1364	.35125	.447	1.007	.000
	2	.4091	.50324			

P value less than or equal to 0.05 which is considered as highly statistically significant difference

TABLE 2 represents that Group 1 exhibited a significantly higher score on the VAS scale compared to Group 2, indicating a greater intensity or response. Group 1 demonstrated a significantly higher sound parameter compared to Group 2. There was a significant difference between the groups, with Group 1 showing higher scores in eye-related parameters compared to Group 2. Group 1 had significantly higher motor parameter scores compared to Group 2 Overall, across all assessed parameters (VAS Scale, Sound, Eyes, and Motor), there was a statistically significant difference between Group 1 and Group 2 (p-value < 0.05). Group 1 consistently demonstrated higher mean values across all parameters, indicating a stronger or more pronounced effect or response compared to Group 2. The confidence intervals for Group 1 were consistent and narrow, reinforcing the reliability of the observed differences

TABLE 3 REPRESENTS THE GROUP 1 STUDY PARTICIPANTS DESCRIPTIVE STATISTICS IN DIFFERENT PARAMETERS

PARAMETER	OPTIONS	FREQUENCY	PERCENTAGE
VAS SCALE	**0**	**4.55**	9.1
	2	**22.75**	45.5
	4	**18.2**	36.4
	6	**4.55**	9.1
SOUND	**0**	**2.25**	4.5
	1	**47.75**	95.5
EYES	**0**	**2.25**	4.5
	1	**47.75**	95.5
MOTOR	**1**	**43.2**	86.4
	2	**6.8**	13.6

TABLE 3 represents the majority of participants (**45.5%**) in Group 1 had a VAS score of 2, indicating a moderate response in this parameter. Very few participants (**9.1%**) had either the lowest score (0) or the highest score (6); 2. Sound Parameter: Almost all participants (**95.5%)** in Group 1 demonstrated a sound response, indicating that this parameter is highly consistent among the group; 3. Eyes Parameter:1: 47.75 participants (95.5%) showed a positive response in the eye's parameter. Similar to the sound parameter, the majority of participants (95.5%) had a positive response in the eye's parameter, reflecting a consistent pattern across the group; 4. Motor Parameter: The motor parameter shows a slight variation, with most participants (86.4%) scoring 1, and a smaller proportion (13.6%) scoring 2. This indicates that motor responses were generally less intense among the group; VAS Scale: The data shows statistically significant differences in participant responses ($p \leq 0.05$), indicating clear trends and patterns across the parameters for Group 1.

TABLE 4 REPRESENTS THE GROUP 2 STUDY PARTICIPANTS DESCRIPTIVE STATISTICS IN DIFFERENT PARAMETERS

PARAMETER	OPTIONS	FREQUENCY	PERCENTAGE
VAS SCALE	**0**	**43.2**	86.4
	1	**2.25**	4.5
	3	**4.55**	9.1
	-	-	-
SOUND	**0**	**50**	100.0
	1	-	-
EYES	**0**	**38.65**	77.3
	1	**11.35**	22.7
MOTOR	**1**	**29.55**	59.1
	2	**20.45**	40.9

TABLE 4 represents the majority of participants in Group 2 (86.4%) scored 0 on the VAS scale, indicating minimal or no response, showing that Group 2 had significantly lower responses compared to Group 1. All participants in Group 2 (100%) showed no sound response, highlighting a stark contrast to Group 1, where most participants had a sound response. This

suggests a complete absence of this parameter in Group 2. Most participants (77.3%) in Group 2 did not show any response in the eyes parameter. However, a smaller subset (22.7%) did exhibit a positive response, indicating some variability in this parameter within the group. The motor parameter shows a more balanced distribution compared to the other parameters. While the majority of participants (59.1%) scored 1, a significant proportion (40.9%) scored 2. This suggests a wider range of motor responses within Group 2 compared to other parameters. Comparison to Group 1: Group 2 consistently shows lower responses across all parameters compared to Group 1. The lack of responses in the Sound and VAS Scale parameters, along with a limited response in the Eyes parameter, highlights a significant difference in outcomes between the groups. The Motor parameter demonstrates the most variation in Group 2 but is still significantly lower than Group 1. The statistically significant differences ($p \leq 0.05$) suggest that Group 2 consistently exhibits lower responses across the parameters, reflecting a clear distinction in outcomes when compared to Group 1.

4. DISCUSSION

Local anesthesia is considered as an essential tool in dentistry. The anxiety associated with pain and discomfort from local anesthetic injections can result in the avoidance of dental procedures and systemic issues like vasovagal syncope and tachycardia [11]. Given that pain management is the key factor in directing a child's behavior, dentists continually seek methods for the painless delivery of local anesthesia, with topical anesthetics proving to be highly beneficial in this effort [12].

Cryo-anesthesia is achieved through the application of refrigerants or by utilizing ice. The primary benefit of cryo-anesthesia is that, in contrast to other topical anesthetic agents and analgesics, it affects each and every cell type rather than solely nerve cells, leading to immediate anesthesia [13]. Even though the anesthesia produced by cryo-anesthesia lasts for about 25 seconds, it is efficient in alleviating pain linked to needle insertion [14] the use of cryo- anesthesia in dentistry has not become common practice [15].

This research aimed to assess the impact of precooling the site of injection with ice on oral mucosa and to assess the intensity of pain perception among pediatric dental patients, comparing it with Precaine- topical anesthetic gel. In this split-mouth design study, participants needing bilateral mandibular nerve block for dental procedures (pulpectomies or extractions) on either side of the lower jaw was enrolled to eliminate any bias due to the variation in pain perception among patients. Additionally, this study exclusively chose the standard inferior alveolar nerve block to be administered bilaterally, as it causes more pain compared to local infiltration, and the site of injection within the oral cavity is directly linked to pain and discomfort perception [16].

The results from this study provide valuable knowledge into the age and gender distribution of the study population, as well as the intergroup comparisons of various parameters. The demographic data indicates a predominance of younger participants, particularly those aged 7 and 8 years. This trend aligns with previous research that suggests younger children are often more available and willing to participate in studies [17]. Furthermore, the gender distribution reveals a higher proportion of females compared to males, which may reflect societal factors influencing participation rates in research [18].

The results were aligned with those of Harbert, 1989 who introduced a technique in which he utilizes topical ice on the palate prior local infiltration to relieve pain and found that it was widely accepted by patients and was physiologically effective [19]. Farahani and Aminabadi, 2009 showed that pre-cooling the site of injection for a nerve block at 0°C for 2 minutes before injection did significantly alleviate the pain perceived [3].

Duncan et al, 1992, he utilized dichlorodifluoromethane spray which was saturated in a cotton pellet and held against the injection site for 5 seconds to freeze a portion of the tissue surface to reduce discomfort in palatal injections [20]. Hameed et al, 2018, applied a refrigerant spray tetrafluorethane to cool the oral mucosa prior to giving an intraoral injection, achieved comparable outcomes [4]. These findings were consistent with the literature, which emphasizes the importance of subjective measures like the VAS (Brown et al., 2021) [21]. The sound and eyes parameters further illustrate the differences between the groups. In Group 1, 95.5% of participants showed a positive response in both parameters, indicating a strong and consistent reaction. Conversely, Group 2 showed a complete absence of sound response and a significant proportion (77.3%) with no eye response. This discrepancy may suggest that the interventions applied to Group 1 were not only effective but also engaging enough to elicit responses across multiple sensory modalities [22], visual stimuli [23], motor responses [24].

The results of the current research were supported by Kosaraju and Vanderwalle, 1986 [6], alongside Kuwahara and Skinner, 2001 who observed in different studies a decrease in pain from administering cryo-anesthesia to the area of injection [25].

5. LIMITATIONS

The current research has its specific limitations. The design of the current study was unable to facilitate a double-blind study. The current study did not assess additional variables like the depth of needle penetration, speed of injection delivery, and tissue temperature of the refrigerant. A research design incorporating negative controls, like a placebo spray, rather than using a topical lidocaine spray, would offer compelling evidence to substantiate the effectiveness of refrigerant.

6. CLINICAL SIGNIFICANCE

Topical ice application has been shown to be effective in managing extraoral pain and serves as a suitable alternative to intraoral topical anesthetic gel. Additionally, it can be used as a distraction for pediatric patients because of its cooling effect on the oral mucosa.

7. CONCLUSION

In conclusion, pre-cooling the injection site with ice significantly reduces pain perception in pediatric patients when compared to topical anesthetic gel such as precaine, proving to be a comfortable, effective, and cost-free technique. This method not only enhances patient acceptance but also minimizes discomfort during the procedure, making it valuable practice in pediatric dental care. Considering the unpleasant taste of topical anesthetic gel, it's duration of action and etc., cryo-anesthesia or topical ice is a good replacement.

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