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Comparative Evaluation of Endo Ice® Refrigerant Spray, Endo Frost® Refrigerant Spray and Topical Anesthetic Agent Precaine B® on the Pain Perception in Children Prior to Administration of Local Anaesthesia – An Invivo Study

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Abstract:-

- ***Aim:***

To compare and evaluate the efficacy of Endo Ice® refrigerant spray, Endo Frost® refrigerant spray and topical anaesthetic agent Precaine B® on the pain perception during local anaesthesia administration in pediatric dental patients.

- ***Material and methods:***

A total of 87 participants in the age group of 6-12 years were divided into 3 groups randomly with 29 in each group. The cotton applicator sprayed with Endo Ice was held in contact with the buccal mucosa for 10 seconds. Immediately after the removal of the cotton applicator, inferior alveolar nerve block was administered. Similarly, Endo Frost was used on the participants. 0.1 mg of Precaine B was applied over the injection site contacting the buccal mucosa using sterile cotton applicator. FLACC evaluation was done by one trained personnel during the local anaesthesia administration. Following the local anesthesia, the participants were asked to rate their pain experience using VAS.

- ***Results:***

The mean score of the Endo ice, Endo frost, and Precaine B were 4.3793, 4.4828 and 5.5517 respectively using the FLACC scale. The mean score of the Endo ice, Endo frost, and Precaine B were 4.2069, 4.2069 and 4.931 respectively using the VAS scale. Greater reduction in pain perception were observed in Endo Ice group followed by Endo Frost group and Precaine group. It was not statistically significant ($p<0.005$).

- ***Conclusion:***

Endo ice, Endo frost and Precaine B were effective in reducing the pain perception in children, thereby reducing their fear and anxiety. Endo Ice group showed greater reduction in pain perception and higher efficacy than other groups, even though the results were not statististically significant.

Keywords:- *Cryotherapy ; Pain Perception ; Endoice ; Endofrost ; Precaine B ; FLACC Scale ; VAS Scale; Topical Anesthetic Gel, Precooling Agents.*

I. INTRODUCTION

Delivery of effective dental local anesthesia to a child has always been a challenge due to the dental anxiety associated with pain during needle insertion. But the irony of the situation is that local anesthetics, the most effective drugs to prevent and control pain is associated with pain itself because of the fear and anxiety of the sight of a needle called needle phobia.[1]

The major two aspects of local anesthetic injection that have the potential to cause pain are needle insertion and the deposition of the solution into the tissue. Topical anesthesia has been widely recommended as a method for minimizing the discomfort and tension associated with needle insertion and is an essential component of the atraumatic administration of intraoral local anesthesia. Each topical anesthetic formulation has two benefits. The first one is the pharmacological effect because of anesthetic agents. By blocking the transmission of signals from the terminal fibers of the sensory nerves, topical anesthetics regulate pain perception and hence modify the reaction to pain.[2] In addition to this, the topical anesthetic gel also has psychological advantages, which is mostly associated with the placebo effect.

Topical anesthetics are available in several forms as gels, sprays, ointments and adhesive patches. Benzocaine is the most commonly used topical anesthetic drug in dentistry because of its long-lasting effects and acceptable taste. Precaine B® is a topical anesthetic gel consisting of 20% benzocaine. Agents that are formulated to a 20% concentration typically show effects within thirty seconds, but it takes two to three minutes to reach an adequate depth and intensity. Benzocaine lessens pre-injection discomfort in the alveolar mucosa and is effective for anesthesia of the tongue. Single anesthetic gels typically anesthesize minimal thickness of mucosa (1-3mm). The palatal mucous membrane

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is thick and resilient, with densely organized nerves, so it is hardly effective for inducing anesthesia. The duration of action is approximately 5 to 15 minutes after anesthesia is obtained.[3] It is always beneficial to apply flavored anesthetic gels in children as they develop more acceptance.

The elements that impact the adequacy of topical anesthetics include the agent and its duration, concentration, and site of application. However, the disadvantage of the topical anesthetic gels is that additional time required to apply topical anesthesia may increase the child's apprehension concerning the approaching procedure and there is possibility of the topical anesthetic gel to anesthetize areas other than the site of injection owing to the gel's mixing with saliva and the patient's swallowing.[4]

Therefore, there is a need for an anesthetic agent which is simple, cost-effective, with ease of application and non-invasive aid for pain relief.

Cryoanesthesia is defined as the application of cold to a local part of an individual's body to block the local nerve conduction of pain impulses.[5] Cryoanalgesia is a simple, cost-effective, and non-invasive aid for pain relief. Cryoanesthesia works by stimulating myelinated A fibers and inhibiting the pain pathway that raises the pain threshold. The "gate control theory" explains the rationale for cryotherapy's pain-relieving effects. Because the brain can only recognize one sensation at a time, cryotherapy, used as a shield for an anesthetic injection, reaches the brain before the sensation of pain. Thus, counter stimulation (cryotherapy) reduces the perception of pain.[6] It slows nerve conduction, temporary vasoconstriction, decreased tissue metabolites, and upregulation of inflammatory mediators and neuropeptides, resulting in reduced pain. Cryoanesthesia can be given either by refrigerant spray or by ice. Ice touch discomfort is time-dependent, and the threshold is highly particular. Refrigerant sprays include Endo Frost spray and Endo-Ice sprays.Endo Frost® spray and Endo Ice® spray has composition of Butane (30-50%), Propane (30-50%) and Isobutane (10-20%) and 1,1,1,2 Tetrafluoroethane, respectively. The recommended duration to wait for topical anesthetic diffusion ranges from 2 to 5 minutes. The shorter application time of refrigerant sprays (five to 10 seconds) as compared with that of topical anesthetic gel (a minimum of two minutes) may increase provider compliance by improving clinical efficiency.

In pediatric dentistry, it is crucial to acknowledge that the pain sensation is not always dependent on tissue damage; it might be induced by condition stimuli, such as, the sound of the drill or the touch of the needle during local anesthetic injections. Anxiety is a primary issue impeding the quality of dental treatment in children, and the injection is one of the major anxiety-provoking procedure. Henceforth, it is necessary to discover more comfortable and pleasant methods for local anesthesia administration in children.

II. MATERIALS AND METHODS

This in vivo study was conducted in Department of pediatric and preventive dentistry, A .J Institute Of Dental Sciences. The ethical approval for the study was obtained from the Institutional Review Board. (Protocol no: IEC/PEDO22/122/V2). Before treatment, an informed consent was obtained from all parents and guardians.On the basis of the previous study conducted by Kosaraju A et al , assuming 95% confidence interval, 80% power with the pooled Standard deviation of 5 , the sample size estimated for the study was 28.6 ~ 29 in each group.

A total of 87 participants in the age group of 6-12 years were divided into 3 groups randomly with 29 in each group. They were subjected to initial clinical examination. Inclusion criteria were: (1) Children aged 6-12 years requiring local anesthesia (Inferior Alveolar nerve block) for dental procedures, (2) Healthy patients meeting the criteria of ASA Physical status 'I' and (3) Patients who were willing to participate in study. Exclusion criteria were children with (1) Patients with history of systemic disease, cognitive disorder, sensitive skin, dental abscess in procedure site, (2) Patient who are allergic history to local anesthesia and (3) Patient who are unable to follow instructions or uncooperative.

Buccal mucosa at the site of injection was dried with a 2×2-inch piece of gauze prior to application of Refrigerant sprays and Topical anesthetic agent. Endo Ice was sprayed on the sterile cotton applicator from a distance of 5mm for a period of 3 seconds (2-3 puffs)(Figure 1). The cotton applicator sprayed with Endo Ice was held in contact with the buccal mucosa for 10 seconds(Figure 2). Immediately after the removal of the cotton applicator, the inferior alveolar nerve block was administered. Similarly, Endo Frost was used on the participants. 0.1 mg of Precaine B was applied over the injection site contacting the buccal mucosa using sterile cotton applicator. The cotton applicator with Precaine B was held in contact with the buccal mucosa for 60 seconds(Figure 3). After the removal of the cotton applicator, immediately the inferior alveolar nerve block was be administered. The Faces, Legs, Activity, Cry and Consolability Scale (FLACC) Evaluation was done by one trained personnel present in the dental operatory during the local anaesthesia administration. Following the local anesthesia, the participants were asked to rate their pain experience using Visual Analog Scale (VAS)(Figure 4). That data was tabulated and subjected to statistical using SPSS 21.0. Analysis of Variance ANOVA/Kruskal-Wallis test was used to test the significant difference in the outcome between the groups.

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Fig 1: Refrigerant Sprayed Over the Cotton Applicator

Fig 2: Cotton Applicator with Refrigerant Spray at the Site of Injection

Fig 3: Cotton Applicator with Precaine B Topicalgel at the Site of Injection

Fig 4: Assessing Children's Pain Perception Using VAS Score

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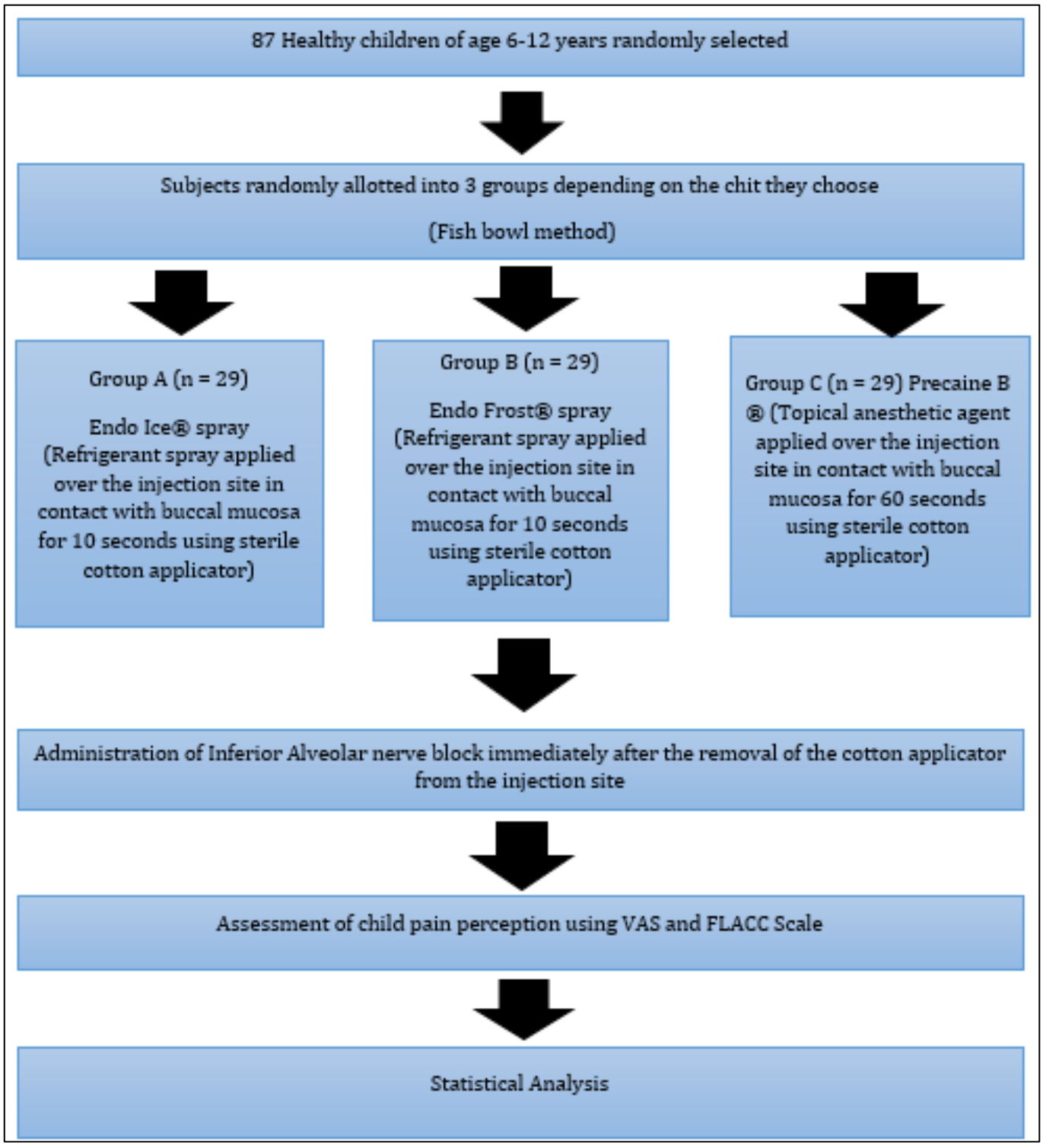

Fig 5: Study Design

III. RESULTS

The participants in the study, included 42 girls and 45 boys (N = 87), ages 6-12 years, with a mean age of 8.54 ± 1.73 years.

Graph 1 shows that the mean score of the Endo ice, Endo frost, and Precaine B were 4.3793 , 4.4828 and 5.5517 respectively using the objective scale i.e.,FLACC score. Lower the FLACC score it shows lower is the discomfort or pain felt by the children during local anaesthesia administration. Graph 1 indicates that a greater reduction in pain perception were observed in Endo Ice group followed by Endo Frost group and Precaine group.

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Graph 1: Mean Score of Three Groups Using FLACC Scale

ANOVA test (f value 2.072) showed no significant difference (p > 0.05) between the mean FLACC scores of Endo Ice , Endo Frost and Precaine group with p-value 0.132.(Table 1)

Table 1: Mean Score of three Groups Using FLACC Scale

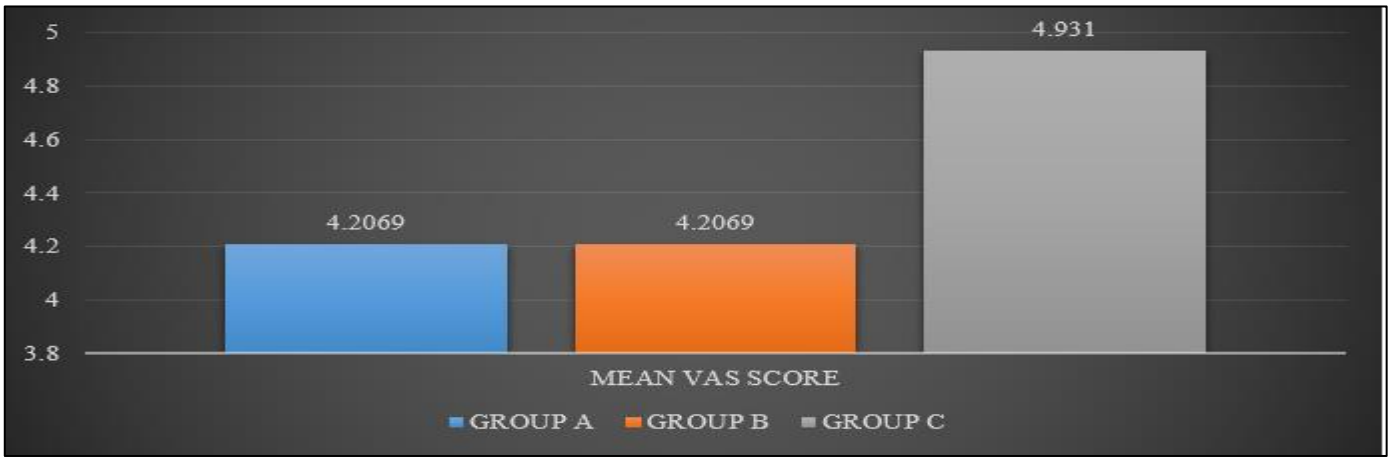
FLACC SCORE	MEAN	Standard deviation	F (ANOVA test)	Sig (p-value)
Group A	4.3793	2.58310	2.072	0.132 (NS)
Group B	4.4828	2.42930		
Group C	5.5517	2.26126		

When intragroup comparison was made between Endo Ice, Endo Frost and Precaine group on FLACC score using Kruskal-Wallis test. No significant difference (p > 0.05) was observed. p-value was 0.986 in comparison between endo ice and endo frost groups, 0.163 between endo ice and precaine group and 0.220 between endo frost and precaine groups.(Table 2).

Table 2: Multiple Group Comparison Between the Groups Using FLACC Scale

Group		Mean Difference	Standard Error	Sig. (p-value)	95% Confidence Interval	
					Lower Bound	Upper Bound
Group A	Group B	-.10345	.63765	.986(NS)	-1.6249	1.4180
	Group C	-1.17241	.63765	.163(NS)	-2.6938	.3490
Group B	Group C	-1.06897	.63765	.220(NS)	-2.5904	.4524

Graph 2 shows that the mean score of the Endo ice, Endo frost, and Precaine B were 4.2069 , 4.2069 and 4.931 respectively using the subjective scale i.e., VAS score. VAS score rates the discomfort of the injection on 10 cm scale, interprets lower the score lesser the discomfort. Graph 2 depicts that lower score were seen in both endo ice and endo frost group followed by precaine b group, thus refrigerant spays showed greater reduction in pain perception.



Graph 2: Mean Score of Three Groups Using VAS Scale

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ANOVA test (f value 0.839) showed no significant difference (p > 0.05) between the mean VAS scores of Endo Ice , Endo Frost and precaine B group with p-value 0.436.(Table 3)

Table 3: Mean Score of Three Groups Using VAS Scale

VAS score	Mean	Standard deviation	F (ANOVA test)	Sig. (p-value)
Group A	4.2069	2.49828	.839	.436(NS)
Group B	4.2069	2.73051		
Group C	4.9310	2.10325		

When intragroup comparison was made between Endo Ice, Endo Frost and Precaine B groups on VAS score using Kruskal-Wallis test. No significant difference (p > 0.05) was observed. p-value was 1.00 in comparison between endo ice and endo frost groups, 0.503 between endo ice and precaine b group and 0.503 between endo frost and precaine b groups.(Table 4)

Table 4: Multiple Group Comparison Between the Groups Using VAS Scale

Group		Mean Difference	Standard Error	Sig. (p-value)	95% Confidence Interval	
					Lower Bound	Upper Bound
Group A	Group B	.00000	.64542	1.000(NS)	-1.5399	1.5399
	Group C	-.72414	.64542	.503(NS)	-2.2641	.8158
Group B	Group C	-.72414	.64542	.503(NS)	-2.2641	.8158

IV. DISCUSSION

Local anesthesia is an indispensable part of dentistry. Fear of pain and discomfort associated with local anesthetic injection can cause avoidance towards dental treatment. Since control of pain is a key component of behaiour guidance, pediatric dentists are in a constant search of tools for painless administration of local anesthesia.[7] Providing enjoyable, comfortable, and happy memories for children throughout their dental visit is the most necessary aim of pediatric dentists.

Desensitizing the site of injection is also an accepted technique to reduce pain caused by local anaesthesia. Traditionally,anesthetic gels have been recommended as local preinjection medications.

Disadvantages of local anesthetic gels such as unpleasant taste, additional cost, and the lesser depth of penetration encouraged the use of other alternatives such as cryoanaesthesia.

Cryotherapy's mechanism of action is confined to the surface of application site, and it functions by rapidly cooling effect while evaporating faster from the mucous membrane. This mechanism has almost rapid onset of action. The anesthesia achieved by cryoanesthesia is of short duration (2 to 5 seconds) which is sufficient to lessen the discomfort associated with the insertion of a needle.

Richardso introduced an ether spray for topical anesthesia in 1866, followed by an ethyl chloride spray in 1891. So "to freeze" became synonymous with "to numb".[8]

Herbert[4] introduced the idea of the palatal injection pre-cooling technique and found palatal pre-cooling to be effective in relieving injection pain. Duncan et al [9]claimed that their findings showed less discomfort after using a cotton ball impregnated with dichlorodifluoromethane spray for 5 seconds before administering palatal injections. Vera et al in an invitro study observed that final irrigation of the root canals with cold saline significantly lessens the root surface temperature and subsequently post-operative endodontic pain.[10] In addition, Aminah et al. evaluated the effects of different desensitizing strategies to reduce injection pain in children, including local anesthetic gel, injection site precooling, vibration, and anesthetic solution buffering, and concluded that injection site precooling significantly reduced children's pain perception.[1]

Despite these advantages, direct contact with cryotherapy can also cause burning discomfort, stinging and frost bite. In order to prevent the direct contact with skin mucosa, Endo ice and Endo frost refrigerant sprays were sprayed on sterile cotton applicator first and then applied over the injection site for 10 seconds.

The aim of the current trial was to compare and evaluate the efficacy of Endo Ice® spray and Endo Frost® spray on the pain perception during local anaesthesia administration in pediatric dental patients. The study included pediatric patients requiring inferior alveolar nerve block for any of the dental procedures. Pain quantification involves combining pain reporting with behavioral, psychological, and physiological responses. The child's expression and the caregiver's interpretation are crucial in recognizing pain.11

In the current research, the patient's behavior was assessed for the pain perception using FLACC scale (objective) and VAS scale (subjective) by the operator.

Crying, body posture and mobility are valid indicators of whether a child is in pain. The FLACC is a behavioural scale with validation for the purpose of assessing the postoperative pain in young children. The FLACC scale provides a simple structure for evaluation and allows reliable and objective assessment of children's pain behavior.

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Visual Analog Scale is a form of cross-modality matching in which the length of a line is modified to match the intensity of the pain perception. On a 10-cm scale, with 0 denoting a happy child experiencing no pain, 5 representing a sad child experiencing moderate pain, and 10 representing a crying child experiencing severe pain, the children were asked to rate the discomfort experienced. [12]

Endo ice group showed lowest mean score (4.3793) using VAS scale. Endo ice and Endo frost both showed lowest mean score (4.2069) using FLACC scale. Similarly, intragroup and intergroup comparisons between endo ice, endo frost and precaine B groups revealed no statistically significant difference even though Endo ice group has showed better results.

The results of this research support the rationale that Endo Ice refrigerant spray application at the injection site significantly alleviates pain during needle insertion under local anesthesia compared to Endo frost refrigerant spray and precaine B gel. This was observed from VAS and FLACC scales that the scores were less in the Endo Ice group followed by Endo Frost group and precaine B group respectively.

The results were similar to the study done by Kosaraju et al [13] and Lathwal *et al*[14] compared a 5-second spray of refrigerant spray for 2 minutes with a local gel before injecting local anesthesia in the posterior palatal site.

It was observed that the topical gel administration prior to the anesthetic injection was less effective than the refrigerant sprays. But, the results obtained by Kosuraju et al., were not presented on an objective scale. It is challenging to gauge a sense like pain perception accurately just using the subjective scale (VAS) for assessment. To get more precise results objective scale (FLACC) was used in current research.

The shorter duration of action of Endo Ice and Endo frost refrigerant sprays (5–10 s) as compared with that of topical anesthetic precaine B gel (2–5 min) could increase provider compliance by improving clinical efficiency. Another benefit is the ease of application, as the refrigerant is applied locally and there is possibility of the topical anesthetic gel to anesthetize areas other than the site of injection owing to the gel's mixing with saliva and the patient's swallowing.[7]

Aminabadi et al [15] reported the effectiveness of a 2-minute application of cryotherapy before nerve block in reducing pain perception. Hameed, Sargod et al found that the use of the tetrafluoroethane spray was shown to be effective in relieving pain before the administration of local anesthesia in pediatric dental patients compared to the local anesthetic lidocaine spray. Ambreena khurshid et al revealed from the research that refrigerant (Endo Frost) had significant efficacy in reducing needle prick perception in contrast to ice, benzocaine, lignocaine and placebo groups. They concluded that cryoanaesthesia should be considered as a simple, reliable, and efficient technique to reduce discomfort and instill positive behavior in children toward dental treatment.[3]

The results of the current research support the notion that refrigerant sprays can be used as an adjunct to increase injection tolerance by precooling the injection site. The intervention of pre-cooling the injection site before local anesthesia can serve as an effective, inexpensive, and reliable method in alleviating pain and discomfort, especially in patients with fear (trypanophobia) and anxiety during dental procedures. Cryotherapy also helps to instill positive behavior among children and brings positive reinforcement towards dental treatment.

The limitation of this study includes the rate of injection and needle depth, which were consistent but not comparable because of the variable anatomy encountered. Unable to blind the participants, due to the temperature difference between refrigerant sprays and precaine B gel, and the different methods of application and taste, made it obvious which method was used. However, more research with a bigger sample size and comparing other topical agents, refrigerant sprays, and local anesthetics[10] may be warranted.

V. CONCLUSION

Though there are studies proving the advantages of use of preinjection medications in pediatric dentistry, it is not routinely used by dentists due to lack of knowledge about its benefits. Within the limitations of this study, preinjection medicaments such as Cryoanaesthetic agents can be used as a efficient and reliable method in alleviating pain and discomfort, and also instill a positive behavior and attitude towards dental treatment in children.

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