



The effect of pre-cooling versus topical anesthesia on pain perception during palatal injections in children aged 7-9 years: a randomized split-mouth crossover clinical trial

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Background: To compare pain perception during palatal injection administration in children aged 7-9 years while using pre-cooling of the injection site versus application of topical anesthesia as a pre-injection anesthetic during the six months.

Method: A prospective randomized split-mouth crossover trial was conducted among 30 children aged 7-9 years, who received topical application of either a pencil of ice (test group) or 5% lignocaine gel (control group) for 2 min before injection. The primary and secondary outcome measures were pain perception and child satisfaction, measured by the composite pain score and the faces rating scale, respectively. Unpaired t-test was performed to determine significant differences between groups.

Results: The test group had significantly lower pain scores for self-report and behavioral measures ($P < 0.0001$). The changes in physiological parameters at the baseline ($P = 0.74$) during ($P = 0.37$) and after ($P = 0.88$) the injection prick were not statistically significant. Children felt better by the pre-cooling method ($P < 0.0001$).

Conclusion: Ice application using a pencil of ice for 2 min reduced pain perception significantly compared to the use of a topical anesthetic. Moreover, ice application was preferred by children.

Keywords: Children; Local Anesthesia; Palate; Pain Perception; Pre-cooling; Topical Anesthetic.



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INTRODUCTION

For the successful practice of pediatric dentistry, pain control is mandatory during any invasive procedure requiring the administration of local anesthesia (LA). Moreover, the administration of local anesthesia might be the only painful event throughout the procedure [1]. Anxiety and fear may arise due to poorly managed injection pain during childhood, and if appropriate steps are taken to reduce the pain associated with injections,

these reactions would not develop [2].

Despite numerous innovations in the field of dentistry, injection remains the standard method of choice for administering LA. Current trends and innovations for alleviating injection pain are expensive and anxiety-provoking for children [3]. This investigation explores a versatile, proficient, cost-effective, and child friendly approach by using a pencil of ice as a pre-injection anesthetic.

Cryotherapy or cold therapy is the local or systemic application of cold for therapeutic purposes and is said

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to have been used during the Hippocrates era. The potential benefits of using ice for pre-cooling rather than a topical anesthetic gel are pain reduction, ease of application, and avoidance of a displeasing taste. Topical cooling is a trusted first-aid remedy for numbing pain and reducing inflammation from trauma [4].

Literature reports mixed the results with the use of intraoral topical anesthetics for reducing discomfort during injections in children. Pre-cooling has been tested in adults during administration of a palatal injection [5] and in children during inferior alveolar nerve block [6,7] and maxillary buccal infiltration [7,8,9]. Since the palatal mucosa is one of the most painful sites to anesthetize locally, it can be used to assess the efficacy of topical anesthetics [10]. To date, data on pain perception is limited to self-report and behavioral methods [6,8,9,11], and a composite score of self-report and behavioral and physiological responses has not been measured.

To our knowledge, no study has been conducted to evaluate the effectiveness of pre-cooling the palatal soft tissues during the greater palatine block in children by measuring the composite pain score. Hence, this study was undertaken. The primary outcome of this study was to compare the effects of pre-cooling vs. topical anesthesia on pain perception during administration of palatal injections in children, and the secondary outcome was to assess the children's satisfaction regarding the intervention.

METHODS

This was a prospective, randomized, equivalence, crossover, split-mouth, quantitative, open-label study with a balanced allocation ratio of 1:1.

After obtaining Institutional Ethical Clearance (NDC/PG-2011-12/EC/2012), this study was carried out at the Department of Pedodontics and Preventive Dentistry, Narayana Dental College and Hospital, Nellore. Children were enrolled in the trial after obtaining signed informed consent from their parents/legal

guardians.

A total of 1680 children aged 7-9 years were examined (Fig. 1), and among them, 30 children were selected based on the following eligibility criteria: (1) children with definite indications necessitating the requirement of bilateral greater palatine nerve blocks; (2) no history of intraoral injections; (3) no history of post-traumatic stress disorders or specific phobia related to dental settings; (4) children without a history of systemic mental or physical disorders; and (5) children willing to cooperate. Children with (1) allergic reactions to lidocaine; (2) cold hypersensitivity; and (3) underlying vascular or immunological diseases were excluded from the study.

A sample of 25 children per group was required to determine an estimated 2-point decrease in pain intensity from the baseline on a self-report scale in both groups, with 80% power to detect the difference and a two-sided alpha error of 0.05. Additionally, 20% of the children were added to each group, given dropouts and missing data. Hence, a total of 30 children were allocated to each group. As this was a crossover study, each child served as his/her control and randomly received treatment with either topical anesthesia or the pre-cooling method. The order of treatment was randomized using a computer-generated chart (Graphpad Statmate version 1.01i).

This was an open trial. An experienced investigator not related to the study ascertained both the primary and secondary outcomes in the children. The statistical analyst was blinded to both the groups and the data were decoded only after the analysis of results.

Pain is a multidimensional construct; hence, a composite measure consisting of three categories—direct self-report, and behavioral and physiological measures—has been ascertained.

Armamentariums required for the preparation of a pencil of ice are (1) a 2 ml disposable syringe, (2) potable water, and (3) a refrigerator. The pencil of ice was prepared by cutting away the adaptor portion of the 2 ml syringe until the first millimeter marking on the barrel and filling it with potable water; this was then refrigerated at -40°C in an upright position.

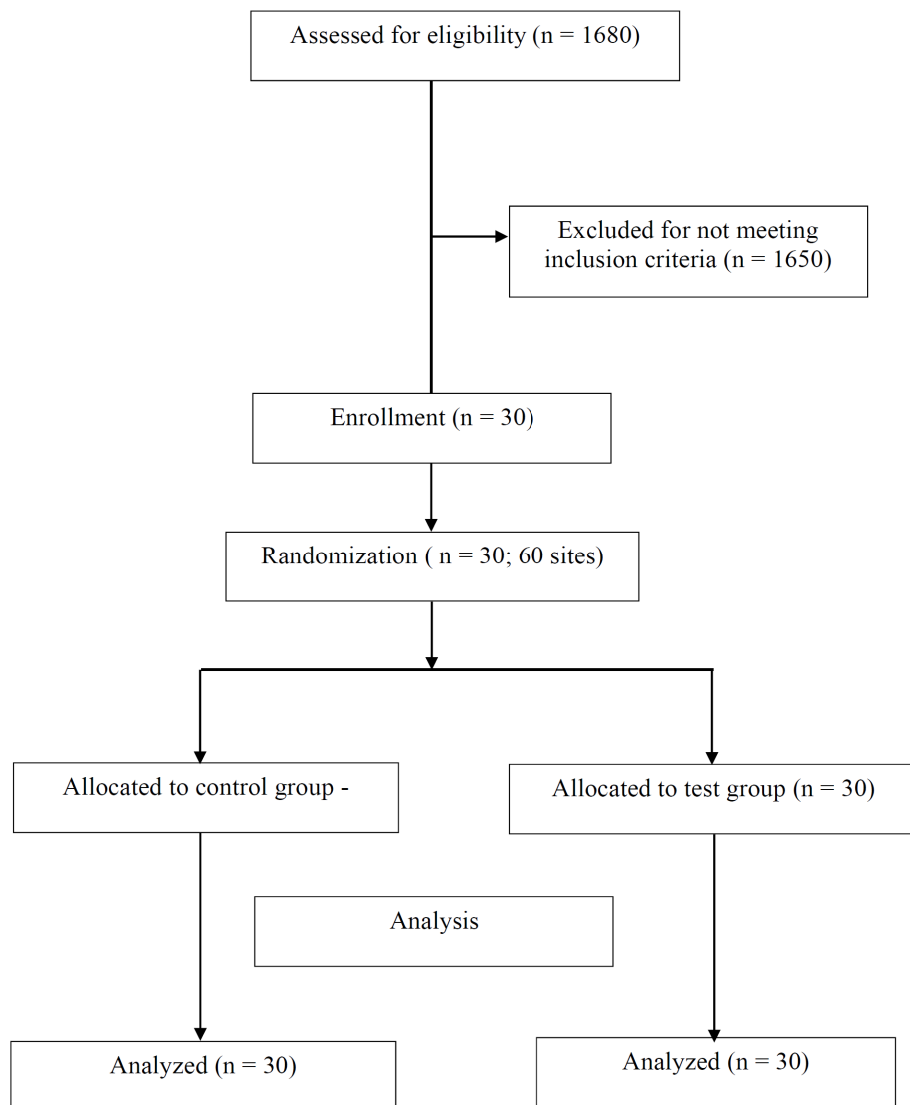


Fig. 1. CONSORT participant flow diagram

1. COLORED ANALOG SCALE (CAS)

This scale is a colored strip (Fig. 2) in which the color gradually changes from white (no pain = 0) through shades of pink to dark red (worst possible pain = 10). The child was asked to point to the area on the strip that shows their level of pain. A scale was placed parallel to the colored strip to obtain the number corresponding to the area where the child pointed at, for documentation. The score was recorded for pain immediately after the injection prick [12].

2. Face, Legs, Activity, Cry and Consolability (FLACC) behavior rating scale

The FLACC scale (Table 1) provides a simple structure for assessment while facilitating a reliable and objective means of quantifying pain behaviors in children. This tool includes five behavioral categories rated on a scale of 0 to 2 to provide an overall pain score ranging from 0 to 10. This score was recorded for pain during the injection prick. Before deciding upon a rating score, children were observed for at least 2-5 minutes, with their legs and body uncovered. If needed, consoling interventions were initiated [13,14].

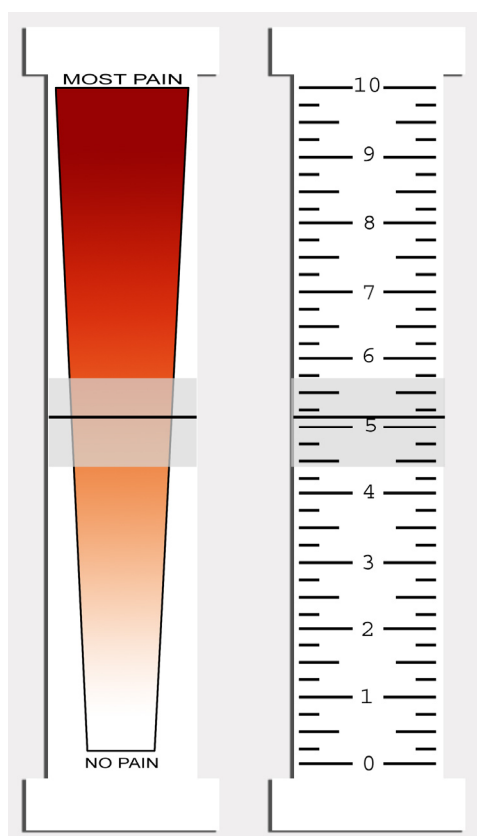


Fig. 2. Colored Analogue Scale

3. Pulse Oximeter For Physiological Score

The pulse rate of the child was measured using a fingertip pulse oximeter (Fingertip Pulse oximeter, MD300C29, Being Choice Electronic) with an integrated digital display of values pertaining to pulse rate and oxygen saturation.

The child was introduced to the dental operatory and desensitized to the device using the Tell-Show-Do (TSD) technique. The pulse oximeter was attached to the left index finger, and the pulse rate readings were recorded within 15 min before starting the procedure. All variations during this period were recorded, and the mean calculated from the findings was considered as the baseline data. The second and third readings were performed during the injection prick and 1 min post-injection, respectively. For both, the minimum and maximum parameter readings were recorded to indicate the range of the distribution.

Table 1. Scoring for Face, Legs, Activity, Cry and Consolability [FLACC] behavior rating scale

Categories	0	1	2
Face (F)	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, quivering chin, clenched jaw
Legs (L)	Normal position or relaxed	Uneasy, restless, tense	Kicking or drawing up legs
Activity (A)	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry (C)	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability (C)	Content, relaxed	Reassured by occasional touching, hugging, or being talked to; distractible	Difficult to console or comfort

4. Treatment Satisfaction

After individual appointments, each child was assessed and asked to indicate how he or she felt about the application of either topical anesthetic or pre-cooling during treatment (i.e., "How did you feel about the topical anesthetic/pre-cooling application during treatment) using a 5-point faces rating scale ranging from 1 (happy face) to 9 (sad face), with a score of 1 indicating extreme like and 9 indicating extreme dislike.

5. Intervention/Test Group

TSD and desensitization were performed for a pencil of ice before starting the procedure. Ice was applied at the injection site and moved to and fro as a counter stimulant for 2 min. In the meantime, the child was asked to imagine his favorite situation, which reduced attention to the current procedure [15]. Subsequently, pressure was applied at the injection site with the pencil of ice, and gentle insertion of a 27 gauge ultra-short needle was performed, followed by deposition of LA solution in its proximity, without removing the ice.

Carry-over effects are when the effects of one intervention are still present during the evaluation of another. This can be prevented by separating the study

Table 2. Comparison of the mean value of subjective, behavioral, and physiological responses and satisfaction outcome between the control and test groups

Pain	Control Group (n = 30)		Test Group (n = 30)		P value
	Mean	Standard Deviation	Mean	Standard Deviation	
Subjective Response					
CAS*	7.23	1.01	2.60	1.22	< 0.0001 [†]
Behavioral Response					
FLACC Scale [‡]	5.83	1.46	1.60	0.97	< 0.0001 [†]
Physiological Response (Pulse Rate)					
Baseline	87.73	5.18	87.27	5.88	0.74 (NS) [§]
During Injection Prick	98.17	9.23	96.00	9.38	0.37 (NS)
After Injection Prick	87.03	6.12	86.80	6.18	0.88 (NS)
Satisfaction					
FRS	6.17	1.56	2.23	0.94	< 0.0001 [†]

Control Group: Topical Anesthesia, Test Group: Pre-cooling

*Colored Analogue Scale, [‡]Face, Legs, Activity, Cry and Consolability scale, ^{||}FRS, Faces Rating Scale, [†]Statistically Significant, [§]NotSignificant

periods to enable the participants to be free of the influence of the previous intervention; this is known as the washout period. A period of at least one week was considered a washout period in the present study [16].

6. Control Group

Topical anesthetic gel (Lox-2% Jelly, Neon, Mumbai, India) was applied to the soft tissues at the greater palatine foramen region using a cotton tip applicator over dried mucosa, and the cotton tip applicator was moved gently to and fro as counter stimulation and was allowed to remain in contact with the palatal soft tissues for approximately 2 min. In the meantime, the child was asked to imagine a situation, which reduced attention to the injection procedure [15]. Then, pressure anesthesia was achieved by applying pressure to a cotton tip applicator at the injection site, and a 27 gauge ultra-short needle was gently inserted, and the solution was deposited slowly.

7. Statistical Analysis

The data were recorded into Microsoft Excel spreadsheet 2007. Statistical analysis was conducted using SPSS Version-17. Continuous data were presented as mean, median, range, and standard deviation. For normally distributed data, intergroup analysis was

performed by unpaired t-test. Non-normally distributed data were analyzed using a non-parametric Mann-Whitney U test. Categorical variables were analyzed using Fischer's exact test. Analyses between groups for physiological measures were carried out using multiple measures of ANOVA.

RESULTS

A total of 30 children (20 boys and 10 girls) who required the administration of bilateral greater palatine nerve blocks (60 sites) were analyzed and included in the study. The mean age of the children was 8.1 years. There was no significant difference between the two groups in terms of age (independent t-test, $P = 1$) or gender. No adverse events were observed during the study.

When the mean and standard deviation (SD) for CAS scores were compared between the control (mean = 7.23, SD = 1.01) and the test (mean: 2.6, SD = 1.22) groups, the reduction in pain score was statistically significant ($P < 0.0001$). A higher mean FLACC score was found in the control group (mean = 5.83, SD = 1.46) than in the test group (mean = 1.6, SD = 0.97), which indicates that the pain reduction in the test group was statistically

significant ($P < 0.0001$). Intergroup comparison between mean values of physiological parameters (heart rate) from baseline ($P = 0.74$) to during ($P = 0.37$) and after injection ($P = 0.88$) revealed that they were not statistically significant. When mean and SD values for faces rating scores were compared between the control (6.17) and test group (2.23), the satisfaction outcome was statistically significant ($P < 0.0001$). The results are summarized in Table 2.

DISCUSSION

Cryotherapy or cold therapy is the local or systemic application of cold for therapeutic purposes. The applications are versatile, inducing effects both locally (at the site of application) and at the level of the spinal cord via both neurologic and vascular mechanisms. Topical application of ice decreases the activation threshold of tissue nociceptors and the conduction velocity of pain nerve signals, which results in a local anesthetic effect called cold-induced neuropraxia. It decreases tissue blood flow by causing vasoconstriction, reduces tissue metabolism, oxygen utilization, and inflammation [17].

The potential benefits of topical ice application have been assessed widely in the medical literature for reducing needle-related pain. However, our literature search is limited to the field of dentistry, with only a few studies in adults during administration of a palatal injection [5] and in children during inferior alveolar nerve block [6,7] and maxillary buccal infiltration [7,8,9].

The quantification of pain involves the amalgamation of self-report and behavioral, psychological, and physiologic responses. Recognition of pain relies heavily on the expression of the child as well as the interpretation of the caregiver [18]. The three approaches to measure pain in children include self-report, observational or behavioral and physiological. Champion et al. suggested that a composite measure would be ideal, including self-report and one or more of these other approaches [19]. Hence, the CAS, FLACC scale, and pulse rate were

used for measuring self-report and the behavioral and physiological measures, respectively.

The self-report measure represents the gold standard for assessing children's pain, and it can be used for children aged over 6 years. CAS was developed to facilitate regular clinical documentation of a child's pain by providing vivid shades of color and area as well as in length so that children could concretely see how different scale positions reflect different values in their pain intensity. Concurrent validity was supported by the correlation between FLACC and CAS scores during needle-related procedures in children aged 5-16 years [14]. In the present study, intergroup comparison regarding CAS revealed that the difference was statistically significant.

Nonverbal expression of pain is an important source of information for observers through infancy as well as childhood. Interpretation of behavioral changes can augment or replace self-report in situations where the child is too distressed because of emotional or situational factors and cannot use a self-report scale accurately [20]. Crying, facial expression, and bodily activity can convey information that is of great importance to observers. Merkel et al. have stated that the FLACC scale is a reliable and valid tool for quantifying pain in children until 7 years of age [13]. Additionally, Von Baeyer and Spagrud have recommended its use for measuring pain during acute brief procedural events until 18 years of age [21]. In the present study, when the behavioral factors (FLACC) were considered, pre-cooling the soft tissues showed a significant reduction in pain scores.

In conjunction with the self-report of discomfort, heart rate is another important dimension in characterizing a specific response to a painful stimulus. A chain of physiological reactions triggered by anticipated stress may precipitate anxiety, resulting in variations in blood pressure and heart rate. Heart rate variability (HRV) during the injection of LA has shown mixed results in the literature. Pulse rate was elevated during LA administration in a few studies [22,23], whereas it was reduced in others [24]. Heart rate and blood pressure are

reliable indicators of stress and anxiety. Children with grossly observable physical activity during intraoral injection had significant acceleration in heart rate due to bodily movements [25]. Koenig and Jarczok conducted a systematic review in adults relating HRV and nociceptive stimuli and stated that HRV is a promising measure of autonomic reactivity to nociceptive stimulation [26]. In the present study, intergroup comparison of HRV due to nociceptive stimulus revealed that the changes in baseline ($P = 0.74$) to during ($P = 0.37$) and after ($P = 0.88$) injection were not statistically significant. Elevated heart rate was also correlated with large multiparameter monitor and improper behavior guidance regarding the equipment used for assessing heart rate [27]. In the present study, behavior guidance and desensitization were performed using a pulse oximeter before the procedure, and a relatively small fingertip pulse oximeter was used.

The results of the present study regarding pre-cooling the injection site were in concordance with other studies in the literature on intraoral injections [5,6,7,8,9,11].

The discomfort from ice contact is time-dependent, and the threshold is subjective. Recommendations for waiting time to allow for topical anesthetic penetration vary from 2 to 5 min. A 2-min contact with ice was used in the present study, as recommended by Aminabadi and Farahani [6] during inferior alveolar nerve block because 5 min of ice application would not be tolerated by children, although accepted by adults and teenagers [5].

The decreased pain perception due to topical cooling with ice in the present study can be explained through its direct and indirect effects. Application of cold is considered to decrease the ability of pain fibers to transmit pain impulses. According to the “gate control theory,” noxious inputs relayed by small myelinated A-delta fibers and unmyelinated C-fibers are inhibited by various non-noxious simultaneous inputs conducted by A-beta fibers to dorsal horn cells, resulting in a decrease in the number of ascending nociceptive stimuli [28]. Therefore, the cold applied in the present study would act as non-noxious stimuli and inhibit the noxious inputs

induced by LA injection. Another explanation is that skin cooling might suppress nociceptive receptor sensitivity. The suppression of afferent C-fiber responses to needle strokes by skin cooling was more pronounced and long-lasting than the effects of skin cooling on A-fiber responses. Thus, the sensitivity of nociceptive receptors might be suppressed by cooling, resulting in reduced autonomic responses and pain sensation [29].

Ghaderi and Rostami [9] evaluated pain perception among 50 children (8-10 years) using a cross over design with a 1-min application of ice on one side and only topical anesthetic gel (20% benzocaine) application on the other side. Pre-cooling the injection site significantly reduced the sound, eye, motor (SEM) and visual analog scale (VAS) scores.

Another study compared the efficacy of the refrigerant, benzocaine, and ice among 160 children aged 5-8 years who were randomly divided into two groups of 80 children each. The refrigerant was applied for 5 s, and the ice cone or benzocaine was applied for 1 min before either bilateral inferior alveolar nerve block or a bilateral greater palatine nerve block (split-mouth design). The efficacy of the ice cone was superior to that of benzocaine gel and the refrigerant [7].

A review of the literature on different non-pharmacological desensitization techniques comprising cooling techniques with ice popsicles or refrigerants (1,11,33-pentafluoropropane/1,11,2-tetrafluoroethane) at the injection site, warming or buffering LA before injection, using modern devices or techniques like vibration, computer-controlled local anesthetic delivery systems (CCLAD), and jet injectors, showed that ice popsicles and CCLAD seemed to be useful techniques before needle injection [30].

Aminah et al. [11] conducted a study among 40 children aged 7-13 years who were divided into four groups (10 per group) based on the technique used: the application of topical anesthetic gel (precaine gel), ice cubes made by filling water in latex glove fingers, the use of power-driven mini vibratory massagers along with distraction by looking at a blue, red, and green

sand-colored hourglass for 60 seconds, and administration of buffered LA with a purple sand-colored hourglass for distraction. The Wong-Baker faces pain rating scale was used, which showed the greatest pain reduction with pre-cooling, followed by vibration, buffered LA, and topical anesthesia.

A study conducted by Soni et al. [8] compared pre-cooling with ice for 4 min and lignocaine gel application for maxillary infiltrations among 50 children aged 7-12 years using VAS and SEM scales for subjective and objective analysis. They reported that the pre-cooling method is a safe and effective method that also provides distraction during the administration of LA.

Children were more satisfied when the pre-cooling method was employed, which might be due to a preference for ice, rather than experiencing the displeasing taste of the topical anesthetic. Children preferred an ice popsicle to a toy as a reward after undergoing treatment with LA because at 10 min and 30 min after treatment with LA, children reported that they felt better with the popsicle, which may be because the cold helped to overcome the feeling of discomfort due to the numbness caused by LA. Even with unsweetened ice, the feeling of discomfort and the biting of soft tissue and self-mutilation were reduced [31].

CONCLUSION

The main conclusion drawn from the present study is that pain perception in children was significantly reduced by pre-cooling the soft tissues for a period of 2 min with topical ice before needle prick. Furthermore, children were more satisfied with ice application than with the use of topical anesthetic. Ice is universally available and is easy to use, comfortable, economical, safe, physiologically effective, and child friendly. Hence, it can be used routinely to alleviate pain/discomfort during needle-related procedures in children receiving intraoral injections.

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AUTHOR CONTRIBUTIONS

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Nirmala SVSG: Conceptualization, Add, Supervision, Writing - original draft

Sivakumar Nuvvula: Visualization, Writing - review & editing, Supervision

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