Effectiveness of cryotherapy, sucrose solution and a combination therapy for pain control during local anesthesia in children: a split mouth study

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Background: *Pain management in dentistry is inevitable without the use of local anesthesia. However, the agonizing experience of dental injections incorporates a fear of dentist in children. Therefore, the painless administration of local anesthetic agents is crucial in providing optimum dental care.* ***Aim:*** *To compare the effectiveness of four different techniques in minimizing the pain during administration of local anesthesia in 7–11 years old children.* ***Study design:*** *In this split mouth study design, 132 healthy and cooperative children of age 7–11 years, who needed bilateral extraction of primary molars were children were randomly allocated to four different groups: Group I (cryotherapy), Group II (30% sucrose solution), Group III (combination of cryotherapy + sucrose) and Group IV (topical anesthetic agent). The pain perception during administration of local anesthesia (IANB) was recorded before, during and after anesthesia using VAS (visual analogue scale), oxygen saturation (SpO_2) and pulse rate (PR), SEM (sound, eye, body movement) and FLACC (face, legs, activity, cry, consolability) scale.* ***Results:*** *The mean difference of scores of VAS scale showed a statistically significant difference ($p < 0.05$) in all the groups. The FLACC and SEM scores, pulse rate (PR) and SpO_2 of Group I (popsicle) showed a statistically significant difference ($p < 0.05$) when compared to Group III (ice-cubes) and Group IV (topical anesthetic).* ***Conclusion:*** *Pain management using a combination of cryotherapy & sweet substance in pediatric patients can be a safe and effective alternative to the conventional topical anesthetic agents in minimizing pain as the sweet taste acts a reward and offers the advantage of providing a positive dental experience for the patient.*

Keywords: *Pain, Cryotherapy, Sucrose, Anesthesia*

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INTRODUCTION

Dental treatment and pain are often closely associated phenomenon in dentistry. Pain control is an important aspect of dentistry, particularly in management of pediatric patients and the practice of contemporary dentistry is inevitable without the use of local anesthesia. However, the agonizing experience of dental injections incorporates a fear of dentist in children [1,2]. And the dental fear and anxiety related to dental needles is one of the leading causes of missed dental appointments in children as well as adults [3]. These fear-related behaviors have been recognized to be the most difficult part of patient management and often becomes a barrier in providing optimum dental care to the patients.

Thus, the painless administration of local anesthetic agents forms a crucial step in avoiding fearful and uncooperative patients. The dental practitioners are in constant search for techniques which are non-invasive, more comfortable and pleasant in achieving local anesthesia before dental procedures. Previous studies have evaluated several methods to reduce pain during local anesthesia injection which include the application

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of topical anesthetics agents (*e.g.*, benzocaine), buffering the local anesthetics, pre-cooling the injection site, adjusting the injection rate and pre-treatment with lasers[4–6]. A number of studies have also reported the success of orally administrated sweet-tasting solutions for management of neonatal pain in the clinical setting. In the literature, a Cochrane review also confirmed efficacy and safety of sucrose for reducing procedural pain in neonates and infants. However, there is lack of evidence investigating the analgesic effect of sucrose prior to dental anesthesia in preschoolers and older children[5].

Hence, the present study aimed to compare the effectiveness of cryotherapy (ice-cubes), sweet-tasting solution (30% sucrose solution), a combination of cryotherapy and sweet solution (popsicle) in comparison to conventional topical anesthetics prior to the administration of dental anesthesia in minimizing the pain in 7–11 years old children.

MATERIALS AND METHOD

For the purpose of this randomized split mouth study, a total of 132 healthy and cooperative (Frankl behavior III and IV) children of age 7–11 years, who needed bilateral extraction of mandibular primary molars were selected. Uncooperative children (Frankl behavior I and II) and those with a history of abscess, redness, and fistula in the injection site or allergy to lidocaine were excluded from the study. A written informed consent was obtained from the parents of all the subjects included in the study. Before the commencement of the trial, an ethical approval was taken from the ethical committee review board (Ref No. : ITSCDSR/IIEC/2021/021).

In this split mouth study design, the treatment was completed in two visits and children were randomly allocated to four different groups: Group I (cryotherapy; ice cubes), Group II (30% sucrose solution), Group III (combination of cryotherapy + sucrose; popsicle) and Group IV (topical anesthetic agent).

Prior to administration of inferior alveolar nerve block, in Group I, ice cubes were placed at the injection site for a duration of 2 minutes. In Group II, the subjects were asked to hold 10 mL of 30% sucrose solution (prepared in phosphate buffer saline) in their mouth and spit it out after 2 minutes. In group III, the children were provided with an ice-cream (popsicle) and were asked to hold the popsicle at the injection site for 2 minutes. In Group IV, 2% lidocaine spray was delivered using a cotton swab and held in for a duration of 2 minutes.

The administration of local anesthesia in all patients were performed by a single operator who deposited 1.8 ml of 2% Lidocaine with 1/100,000 epinephrine using a 30-gauge short needle. The local anesthetic agent was deposited slowly, preceded by aspiration to prevent intravascular delivery and adverse reactions.

The pain perception during administration of local anesthesia was recorded in the same session by another dentist, unaware of the groups, using VAS (visual analogue scale) (Fig. 1), SEM (sound, eye, body movement) (Table 1) and FLACC (face, legs, activity, cry, consolability) scale (Table 2). Additionally, vital parameters such as oxygen saturation (SpO_2) and pulse rate (PR) were recorded before, during and after anesthesia.

RESULTS

Table 3 shows the inter-group comparison of SpO_2 values at pre-op, during and post-op. The SpO_2 values at pre-op ($p < 0.05$), during ($p < 0.05$) and post-op ($p < 0.05$) all showed a statistically significant difference while administration of local anesthesia.

Table illustrates the inter-group comparison of pulse rate values at pre-op, during and post-op. The pulse rate values showed a statistically significant difference at pre-op ($p < 0.05$), during ($p < 0.05$) and post-op ($p < 0.05$) in all the groups.

Table 5 depicts the inter-group comparisons of Wong Baker's Facial Pain Scale. The mean difference of scores of Wong Baker's Facial pain scale showed a statistically significant difference ($p < 0.05$) in all the groups.

Table 6 represents the inter-group comparison of FLACC scale. The mean difference of FLACC scores between Group I and III (5.81) and Group I and IV (5.60) showed a statistically significant difference ($p < 0.05$). Group I and II showed a mean difference of 0.45 and Group III and IV displayed a mean difference of 0.21, however this difference was not statistically significant ($p > 0.05$).

Table 7 shows the inter-group comparison of SEM scale. The mean difference of intergroup comparison of SEM scores in all the groups showed a statistically significant difference ($p < 0.05$), except between Group III and IV the mean difference of SEM scares was not statistically significant ($p > 0.05$).

DISCUSSION

Local anesthetics have been widely used to alleviate pain of dental procedures such as extractions, pulpotomies, root canal therapies/pulpectomies and drainage of abscess. However, it is ironical that the local anesthetic agents used to eliminate pain are themselves associated with pain, resulting in aggravation of fear and anxiety caused by the sight of needles, also referred to as *trypanophobia*[7,8].

The pain associated with dental anesthesia is a source of distress in children and often leads to preprocedural anxiety in future and has a negative impact on child's behavior in dental operatory. Lidocaine topical anesthetic gel/spray has been a gold standard in minimizing pain of oral injections[9,10]. Several researchers have also evaluated the success of cryoanaesthesia and administering oral sucrose solution prior to injections. But to best of authors knowledge, no study has been conducted to assess the numbing effect of cold and sweet together in children. Therefore, the aim of the present study was to compare the effectiveness of four different techniques in reducing pain prior to administering local anesthesia in 7–11-year-olds.

A split-mouth design was selected for the present study as the confounding factors of pain and discomfort varies from person to person, therefore, along with the subjective scale of Wong Baker's Facial pain scale, the objective scales of FLACC and SEM were also used to compare the experiences of different individuals. The results of the present study showed that the patients reported least amount of pain when a combination of cryotherapy + sucrose (popsicle) was applied prior to administration of local anesthesia and these results

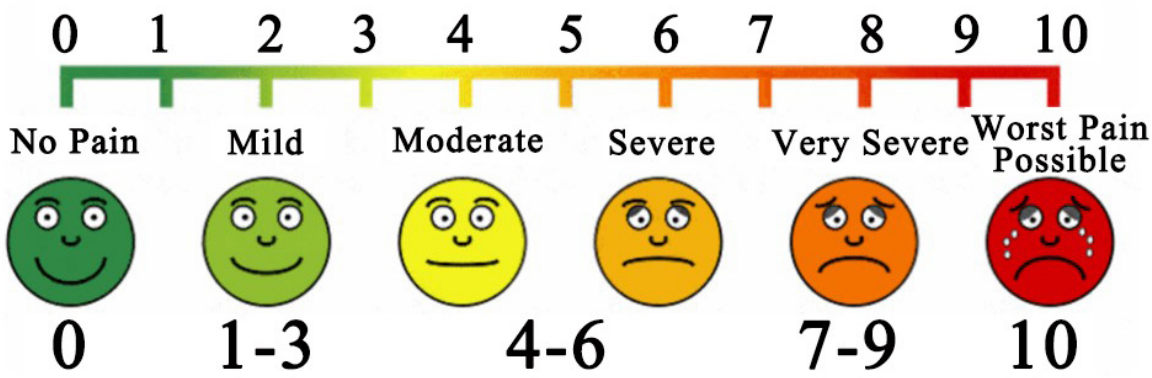

Figure 1: VAS pain scale (Visual Analogue Scale).

Table 1: SEM scale (Sound, Eye, Motor Scale).

Observations	1. Comfort	2. Mild Discomfort	3. Moderately Painful	4. Painful
Sounds	No sounds indicating pain	Non-specific sounds; possibly indicating pain	Specific verbal complaints, *e.g.*, "ow", raising voices	Verbal complaints indicating intense pain, *e.g.*, screaming, sobbing
Eyes	No eye signs of discomfort	Eyes wide, showing concern, but no tears	Watery eyes and/ or flinching eyes	Crying tears running down the face
Motor	Hands relaxed; no apparent body tenseness	Hands show some distress or tension, grasping chair due to discomfort, muscular tension	Random movements of arms or body without aggressive intention to make physical contact, grimace, twitch	Movement of hands trying to make aggressive physical contact *e.g.*, punching, pulling head away

Table 2: FLACC scale (Face, Leg, Activity, Cry & Consolability).

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

Table 3: Inter-group comparisons of SpO_2.

Groups	Group I (Popsicle) Mean ± SD	Group II (Sucrose) Mean ± SD	Group III (Ice Cube) Mean ± SD	Group IV (Topical) Mean ± SD	*p*-Value
Pre-op	95.79 ± 1.72	92.64 ± 2.44	93.42 ± 2.41	94.15 ± 2.69	0.000
During	95.21 ± 2.19	89.30 ± 4.31	89.61 ± 1.87	88.09 ± 1.84	0.000
Post-op	96.33 ± 1.33	94.48 ± 2.88	93.3 ± 1.51	95.06 ± 1.85	0.000

SD: standard deviation.

were statistically significant ($p < 0.05$). The objective parameters of SpO_2, pulse rate and SEM scale also showed a significant reduction ($p < 0.05$) in pain of needle stick in Group I (popsicle).

Typically, pain signals are rapidly transmitted via the myelinated A-delta fibres and the non-myelinated C-fibres are the slow-conducting fibres. As the tissue temperature decreases, the nerve conduction velocity also decreases in both A-delta and C-fibres. Thus, a fall in skin temperature tends to increase the pain threshold in an individual [11–14]. Additionally, sucrose also produces an analgesic effect by stimulating the gustatory receptors that subsequently, release endogenous opioid (β-endorphins) and resulted in a morphine like analgesia [15]. Hence, it was hypothesized that performing a combination of

Table 4: Inter-group comparisons of pulse rate.

Groups	Group I (Popsicle) Mean ± SD	Group II (Sucrose) Mean ± SD	Group III (Ice Cube) Mean ± SD	Group IV (Topical) Mean ± SD	*p*-Value
Pre-op	76.09 ± 5.64	78.30 ± 4.68	85.91 ± 4.36	85.61 ± 6.04	0.000
During	78.79 ± 5.92	85.79 ± 4.41	94.06 ± 6.16	95.12 ± 9.54	0.000
Post-op	72.55 ± 7.15	80.42 ± 5.19	86.18 ± 3.64	86.33 ± 5.96	0.000

SD: standard deviation.

Table 5: Inter-group comparisons of Wong Baker's Facial Pain Scale.

Groups		Mean Difference	*p*-Value
Group I (Popsicle)	Group II (Sucrose)	−1.424*	0.000
	Group III (Ice Cube)	−3.212*	0.000
	Group IV (Topical)	−6.000*	0.000
Group II (Sucrose)	Group III (Ice Cube)	−1.788*	0.000
	Group IV (Topical)	−4.576*	0.000
Group III (Ice Cube)	Group IV (Topical)	−2.788*	0.000

** : statistically significant difference.*

Table 6: Inter-group comparisons of FLACC scale.

Groups		Mean Difference	*p*-Value
Group I (Popsicle)	Group II (Sucrose)	−0.455	0.599
	Group III (Ice Cube)	−5.818*	0.000
	Group IV (Topical)	−5.606*	0.000
Group II (Sucrose)	Group III (Ice Cube)	−5.364*	0.000
	Group IV (Topical)	−5.152*	0.000
Group III (Ice Cube)	Group IV (Topical)	−0.212	0.000

** : statistically significant difference.*

Table 7: Inter-group comparisons of SEM scale.

Groups		Mean Difference	*p*-Value
Group I (Popsicle)	Group II (Sucrose)	−0.758*	0.000
	Group III (Ice Cube)	−1.727*	0.000
	Group IV (Topical)	−1.576*	0.000
Group II (Sucrose)	Group III (Ice Cube)	−0.970*	0.000
	Group IV (Topical)	−0.818*	0.000
Group III (Ice Cube)	Group IV (Topical)	−0.152	0.758

** : statistically significant difference.*

cryotherapy and sucrose (popsicle) resulted in reducing pain from local anesthetic injections.

Literature review revealed that no study has previously assessed the effect of popsicle on pain experienced while administering local anesthesia. However, studies conducted by Kankkunen *et al.*[16], and Ram *et al.*[17] concluded that children who received popsicle after dental treatment with local anesthesia experienced pain relief by eating ice-cream and also reported a lower score of pain on the Wong-Baker Faces Pain Rating Scale. This may be due to the fact that cold helped to overcome the feeling of discomfort after dental treatment with local anesthesia. In addition, the sweet taste of ice-cream acts as a reward leaving a pleasant experience for the patient which is not the case while using the conventional topical anesthetic agents.

In the present study, the inter-group comparison of FLACC and SEM scale between Group II (sucrose solution) and Group IV (topical anesthetic) showed statistically significant difference ($p < 0.05$). These results are in accordance with studies performed by Yilmaz G[18] and Kumar *et al.*[1] where they found that administration of oral sucrose solution before immunization showed significant reduction in pain as compared to application of topical local anesthetics. Stevens *et al.*[5] through a Cochrane library review also concluded that administration

of oral sucrose was safe and effective for reducing procedural pain from single events such as heel lance, venipuncture and intramuscular injection in both preterm and term infants. Another study presented by Ghaderi *et al.* [19] stating that holding 10 mL of 30% sucrose solution was effective in reducing pain of dental injections. Kakeda *et al.* [20] through the use of fMRI (function magnetic resonance imaging) demonstrated that holding a sweet-tasting solution in the mouth resulted in a positive elevated affective state; has the potential to reduce pain perception.

In the present study, the mean difference of FLACC & SEM scores between Group III (ice cubes) and Group IV (topical anesthetic) was not statistically significant ($p > 0.05$). Similar results were reported by Aminabadi [21], Mahshidfar [22], Hindocha N [23] and Havale [24] where both ice and topical anesthetic were equally effective in reducing pain after dental injections.

As our study was a preliminary one, that used cryotherapy and sucrose (popsicle) together, more studies should be conducted to evaluate the effect of such interventions on a larger sample size.

CONCLUSION

Considering the limitations of the present study, it can be concluded that administration of a combination of cryotherapy and sucrose (popsicle) prior to local anesthesia can reduce pain and discomfort in children. In today's era, where several methods are available for pain management, using sweet substance in pediatric patients can be a safe and effective alternative to the conventional topical anesthetic agents in minimizing pain as the sweet taste acts a reward and offers the advantage of providing a positive dental experience for the patient.

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CONFLICT OF INTEREST

No conflict of interest.

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