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Comparative Evaluation of Tamarind Leaf Extract Gel and 2% Lignocaine Gel as an Intraoral Topical Anesthetic Agent in Children

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Abstract

Background: In pediatric dentistry, local anesthetics are widely used to ensure pain-free dental procedures. Topical anesthetics are especially important in minimizing the discomfort caused by needle pricks, making dental treatments more comfortable for children. Pain-free needle prick ensure the reduced fear and anxiety throughout the dental procedures. Tamarind has been widely utilized for its therapeutic benefits in the treatment of various ailments. Tamarind is commonly utilized for various health issues, including abdominal pain, gastrointestinal disturbances, bacterial and parasitic infections, wound healing, constipation and inflammation. However, its anaesthetic efficacy have yet to be fully understood. This study aimed to compare the efficacy of tamarind leaf extract gel and lignocaine gel in reducing pain perception following intraoral injections in children aged 6-10 years.

Method: This randomized, split mouth study compared the efficacy of tamarind leaf extract gel (Group A) with lignocaine gel (Group B) as pre-anesthetic agents in 38 children aged 6-10 years undergoing intraoral local anesthesia. Pain perception was assessed using the Sound, Eye and Motor (SEM) Scale and Memojis Pain Scale (MPS). Statistical analysis was performed using unpaired t-test and analysis of variance ($P<0.05$).

Results: The study showed a significant reduction in MPS and SEM scores, with the tamarind gel group demonstrating the greatest decrease. A highly significant difference ($P < 0.05$) was found between the tamarind and lignocaine gel groups, indicating tamarind gel's superior pain-relieving efficacy.

Conclusion: The topical application of 10% tamarind leaf extract gel was shown to be effective in alleviating pain, indicating its potential as pre-anesthetic agent.

Keywords: Anesthetics; Children; Lignocaine; Pain Perception; Tamarindus indica.

INTRODUCTION

Anticipatory anxiety is very commonly seen in children at dental operatory area. The roots of dental

anxiety in children often stem from an initial fear of diagnostic instruments, which can escalate into apprehension about therapeutic procedures, driven by concerns about pain, uncertainty and perceived danger [1]. Despite local anesthesia eliminating pain during dental procedures, the initial needle prick can still cause discomfort, triggering anxiety and fear in patients. There are several etiological factors that influence the discomfort associated with dental injections, including behaviour, cognitive function, prior exposure, child mood, parental behaviour, peer opinion and dental setup. In order to get over this, various techniques are adopted in the clinical scenario and it includes topical anesthesia, warming anesthetic solutions, controlled injection rates, buffering agents, counter-irritation, localized pre-cooling and distraction methods [2].

Pre-injection topical analgesia is now recognized as a best practice guideline for pediatric dental procedures [3]. Topical application of anesthetic gel or spray reversibly block sodium channels there by suppressing neural action potentials leading to surface anesthesia up to two or three millimetres(mm) [4]. The ligocaine is recognized as the gold standard for topical anesthesia in pediatric dentistry. These are available in the form of gel, patch, spray and solution. However it has certain drawbacks which include toxic responses, idiopathic soft tissue swelling, ulcerations, allergic reactions (0.1%-1%), overdosage and anaphylaxis (4.3%) [5,6].

Recent advances in botanical extracts have vast dental applications. Botanical extracts like cocoa, thymol, clove, betel leaf, papaya, peppermint, lavender and many more have shown anesthetic properties. Tamarindus indica (T. indica), commonly known as tamarind, remains an underexplored plant in dental research. From roots to leaves, T. indica's diverse components boast impressive nutritional profiles, medicinal properties and industrial applications, driving economic growth.

Despite its traditional medicinal uses, tamarind's topical anesthetic efficacy has not been scientifically studied. Hence, this pioneering study aimed to compare the efficacy of tamarind leaf extract gel and lignocaine gel in reducing pain during dental injections in children aged 6-10 years.

Pediatric pain evaluation utilizes dual methodologies: self-reporting and behavioral/observational assessment. This study assessed pain through self-reported (MPS) and behavioral (SEM scale) measures. The MPS was selected for its clarity, comprehensiveness and pediatric applicability [7]. The SEM scale evaluated pain levels through observational assessment of eye expressions, body language and vocal cues indicating discomfort [8].

METHODOLOGY

This study was a prospective, split mouth, cross over trial with equal allocation ration of 1:1. The Study was carried out on patients during the fun week the Department of Pediatric and Preventive Dentistry, AME's Dental College and Hospital – Raichur from 28/01/2025 to 10/02/2025.

This study was approved by the Institutional Ethics Committee (IEC) of AME's Dental College and Hospital (AME/DC/1133/24-25) and registered with the Clinical Trials Registry of India (REF/2025/01/097937). Informed consent was acquired from both the parents/legal guardians and the children who participated in the study. The study is registered in the Clinical Trials Registry of India: **REF/2025/01/097937** and conducted according to CONSORT guidelines (Flowchart 1).

Sample size estimation:

The sample size was estimated using GPower 3.1.9.7 software (Franz Faul, Universität Kiel, Kiel, Germany). Considering the effect size to be measured (f) at 48 percent–based on the difference in the mean pain perception scores as per the previous literature,7 power of the study at 80 percent and alpha

error at five percent–the total sample size is 15 [10].

This comparative study consisted of two groups:

GROUP A: 10% tamarind leaf extract gel.

GROUP B: 2% lignocaine hydrochloride gel (LOX*- 2% Jelly, Neon Laboratories Limited, Andheri, Mumbai, India).

Randomisation procedure

Randomization was performed by an independent postgraduate using a computer-generated sequence. A single experienced pediatric dentist executed procedures for Groups A and B. Participants, observers and the statistical analyst were blinded.

Inclusion And Exclusion Criteria

The study included children aged 6 to 10 years who required maxillary buccal infiltration anesthesia, demonstrated cooperative behavior with Frankl's scores of 3 or 4, were in good general health classified as ASA I (11) , and had no prior experience with local anesthesia. Exclusion criteria comprised children with special healthcare needs, systemic illnesses, anxiety disorders, or phobias; those with known lignocaine allergies; children presenting with dental abscesses, space infections, or active pathology at the injection site; and those taking medications that could alter pain perception.

Sample preparation Procedures

Fresh leaf material was properly gathered, washed, and allowed to dry for 15 days in the shade in order to retain the bioactive chemicals. After being ground into a fine powder with a grinder, the dried leaves were sieved. Two steps were involved in the formulation of the topical gel.

Stage 1: Soxhlet extraction: Tamarind leaf powder (40 g) was extracted using a Soxhlet apparatus with 400 ml of ethanol (1:10 w/v) as the solvent. The apparatus was heated in a water bath, and the extraction process was repeated for 6 hours (24 siphon cycles) to ensure comprehensive extraction of bioactive compounds. The resulting extract was then evaporated on a hot plate to remove excess solvent, yielding a soft and concentrated extract [10].

Stage 2: Gel preparation. A 1:1 w/w ratio of leaf extract to carbopol gel was used to prepare the final gel product. To prepare the gel, 100 mg of carbopol was added to 10 ml of distilled water in a clean beaker and stirred until fully dispersed. The carbopol mixture was sonicated for 5 cycles, each lasting 4 min to achieve optimal dissolution and homogeneous dispersion. The solution was neutralized by dropwise addition of triethanolamine, resulting in a transparent and clear gel at the desired pH. About 1 g of extract was gradually incorporated into the carbopol gel to achieve the desired consistency and was stored for a month.

In a split-mouth design, one quadrant of the patient's dental arch received 2% lignocaine topical anesthetic gel as a control (Group A), in the first appointment (Fig. 1 A) while the contralateral quadrant received tamarind leaf extract gel (Group B), in the second appointment (Fig. 1 B) and care was taken to avoid repetiton. Computer-generated random sequences were utilized to allocate participants to treatment groups. A 2-week washout period was implemented between the first and second appointments to eliminate residual symptoms and side effects. The application site for the topical anesthetic was selected based on the patient's specific treatment requirements. The anesthetic agent was then applied at the height of mucobuccal fold for 1 minute using a sterile cotton applicator. After application, 2% lignocaine (Lignox® 2% A, Warren, Navi Mumbai, India) was gradually injected (1 ml/min) after double aspiration using a short 27-gauge needle (1 inch, 25 mm) that was gently inserted into the mucosa until it reached

the bone. Following the application, procedures like pulp therapies and extractions were carried out. Trained dental clinic personnel evaluated patients' pain perception using the SEM scale, observing behavioral responses during needle puncture. Additionally, patients rated their pain experience using the MPS post-local anesthesia, with scores recorded accordingly (Fig. 2).

Pain perception during needle insertion was assessed using the Sound, Eye and Motor (SEM) scale by trained personnel in the dental operatory, observing patient behavior. The SEM scale assess pain objectively, using scores 1-4 for sounds, eye movements and motor responses, indicating comfort to severe discomfort, with total scores ranging from 3 to 12 [8].

Post-anesthesia, children were assessed for pain using the Memojis Pain Scale (MPS), where they selected the facial expression corresponding to their pain level and the score was recorded. The MPS is a subjective pain assessment tool, utilizing a 0-10 rating scale, where 0 represents no pain and 10 signifies the worst pain [9].

Statistical analysis

Data were tabulated in Microsoft Excel 2019 (Microsoft Corp., Redmond, Wash., USA). Statistical analysis was performed using SPSS 22.0 software (IBM Corp., Armonk, NY, USA). Unpaired t test was used to compare the SEM and MPS scores between the two groups. Statistical significance was set at $P < 0.05$.

RESULTS

1. Demographic Data

Of the 15 participants in the study, 9 were male and 6 were female, with a mean age of 9.2.

2. Subjective pain assessment

The mean values of the MPS score (Table 1) showed the greatest reduction in pain in the tamarind gel group with a mean value of 0.93, followed by the lignocaine gel with a mean value of 2.40. A highly significant difference ($P<0.05$) among the two groups was noted.

Groups	N	Minimum	Maximum	Mean	Standard deviation	P value
A	15	0.00	2.00	0.93	1.03	<0.001*
B	15	2.00	4.00	2.40	0.82	

*P < 0.05 is statistically significant

Table 1. Comparison of MPS score using Unpaired t test

3. Objective pain assessment

The mean values of the SEM score (Table 2) showed a greater reduction in pain in the tamarind gel group with a mean value of 1.20, followed by lignocaine gel with the mean value of 1.80. Statistically, there was a significant difference ($P < 0.05$) among the two groups.

Groups	N	Minimum	Maximum	Mean	Standard deviation	P value
A	15	0.00	2.00	1.20	0.77	<0.001*
B	15	1.00	3.00	1.80	0.77	

*P < 0.05 is statistically significant

Table 2. Comparison of SEM score using Unpaired t test

DISCUSSION

Local anesthesia injection is the predominant factor contributing to dental treatment discontinuation [12]. Trypanophobia, the fear of dental needles, profoundly affects patient's dental care experiences, leading to anxiety and avoidance [13]. Reducing dental fear in children improves their emotional and psychological well-being. Topical anesthetics produce localized and temporary analgesia.

Children aged six and above were selected for this study due to enhanced cognitive development [10]. The present study specifically selected children who required local anesthesia administration through buccal infiltration. Buccal infiltration may provide reduced risk of tissue damage and shallower needle penetration. This study ensured optimal isolation to enhance topical anesthetic retention on oral mucosa, minimizing dilution and removal by saliva. To minimize inter-examiner bias, the same individual administered all buccal infiltrations. To enhance pediatric patient tolerance and participation, reagent application was restricted to a maximum of one minute.

Botanicals have been used traditionally for their preventive and curative properties. Ayurveda, a traditional Indian practice, boasts a remarkable 5000-year history of promoting holistic well-being [14]. Herbal medicine constitutes the mainstay of healthcare for a significant proportion of the world's population, estimated at 75-80%. Herbal medicines are preferred due to their minimal side effects, ease of access and cost-effectiveness. According to WHO, the prevalence of herbal remedy use is substantially higher than that of conventional drug use, with a reported 2-3-fold difference [15].

Tamarind is a perennial herbaceous plant classified within the Leguminosae family. Originating from Africa, tamarind has spread to tropical and subtropical regions worldwide, tolerating average temperatures of 25°C [16]. Tamarind possesses a wide range of pharmacologically significant activities, including antidiabetic, antioxidant, anti-ulcerative, anti-venom, antibacterial, analgesic, anti-inflammatory and hepatoprotective effects [17].

The current study revealed that the 10% tamarind leaf extract gel (Group A) exhibited a significant reduction in pain levels than the lignocaine gel (Group B). The MPS scores for Group A and Group B were 0.93 and 2.40, respectively, indicating a significant difference in pain perception. Similarly, the SEM scale scores showed lower values for Group A (1.20) compared to Group B (1.80). These findings suggest that 10% tamarind leaf extract gel is a more potent anesthetic agent than lignocaine gel. The results of the current study align with the findings of Goyal et al. [18], who reported that an ethanolic extract of Tamarindus indica (400 mg) displayed enhanced analgesic efficacy relative to a standard analgesic in a mice model. A study conducted by Bandawane et al. [19] has substantiated the therapeutic potential of tamarind extract, exhibiting dose-dependent anti-inflammatory and central analgesic effects without inducing ulcers, thereby underscoring its prospects for pharmacological applications. Highab et al. proved that leaf extract of T. indica contains phytochemical constituents, including glycosides, flavonoids, saponins, alkaloids, reducing sugars, steroids and terpenoids [20]. Tamarind contains flavonoids such as catechin, apigenin and naringenin, which have been found to exhibit potent anti-inflammatory and analgesic properties. According to Fan et al. [21], catechin's anti-inflammatory and analgesic activities are attributed to its ability to modulate inflammation and oxidative stress related to cell signalling pathways, including NF-κB and mitogen-activated protein kinases. Shoubaky AG et al. [22] found that apigenin, a dietary flavonoid, exhibits analgesic and anti-inflammatory activities due to inhibition of Prostaglandin E2 and pro-inflammatory cytokines, including interleukin-1β and tumor necrosis factor-α. Additionally, Manchope FM et al. [23] discovered that naringenin possesses analgesic potential due to its ability to modulate transient receptor potential channels and inhibit superoxide anion-induced

inflammation-related pain. Hence, the cooling effect may be responsible for the anesthetic action of tamarind leaves. Further molecular studies need to be conducted proving tamarind's anesthetic properties. The present study has observed that when tamarind leaf extract gel was applied at injection sites, participants experienced a notable tastelessness and cooling effect. Applying ice or cold to injuries, fractures and swelling reduces pain by slowing inflammatory mediator release, activating inhibitory pain pathways and directly affecting peripheral nerves to increase the pain threshold. The application of cold therapy activates the gate control mechanism, resulting in the blockage of A-delta fibers and a subsequent reduction in pain signal transmission [24]. Research by Hindocha et al. [25] has shown that ice can provide effective topical anesthesia of the oral mucosa before dental injections, presenting a viable alternative to lidocaine 5% gel. Bhansa et a. [26] found that precooling is effective, affordable and easily accessible method to reduce injection pain, benefiting most patients.

The study's limitations include the lack of objective pain measures like blood pressure and heart rate, a narrow focus on buccal maxillary infiltrations, possible bias from first-visit injection experiences, and unaccounted individual hypersensitivity, all of which suggest the need for broader, more controlled research.

Future studies should verify these findings by investigating varying concentrations of tamarind leaf extract gel, utilizing larger sample sizes and comparing its topical anesthetic efficacy to other pain management modalities.

Conclusion

Our results demonstrate that 10% tamarind leaf extract gel is a viable alternative to lignocaine gel for pain management in pediatric patients prior to buccal infiltrations, offering a natural and potentially safer option.

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