

## EVALUATION OF THE EFFICACY OF NOVEL HERBAL TOPICAL ANESTHETIC GEL AND 2% LIGNOCAINE HYDROCHLORIDE GEL DURING THE ADMINISTRATION OF LOCAL ANESTHESIA IN CHILDREN: AN *IN VIVO* STUDY

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### ABSTRACT

**Objective:** This study evaluates the effectiveness of a novel herbal topical anesthetic gel compared to conventional 2% lignocaine hydrochloride gel during local anesthesia administration in children.

**Methods:** A randomized controlled trial with 42 children aged 5–14 years was conducted. Participants were divided into two groups (n=21 each): Group A received 2% lignocaine gel, and Group B received herbal gel. Pain response was measured using the Visual Analog Scale (VAS), sound eye motor (SEM) scale, and hedonic 9-point scale. An independent t-test was used for intergroup comparison.

**Results:** The mean VAS scores were  $5.67 \pm 1.32$  for lignocaine and  $5.19 \pm 0.87$  for herbal gel ( $p=0.175$ ). SEM scores were  $3.19 \pm 0.75$  for lignocaine and  $2.95 \pm 0.86$  for herbal gel ( $p=0.346$ ), indicating no statistically significant differences in pain perception. However, the hedonic 9-point scale showed significantly higher taste acceptability for the herbal gel ( $5.86 \pm 1.15$ ) compared to lignocaine ( $3.52 \pm 0.98$ ), with a  $p<0.001$ .

**Conclusion:** While both gels demonstrated similar efficacy in pain control, the herbal gel was significantly more palatable, suggesting it may be a more child-friendly alternative in pediatric dentistry.

**Keywords:** Topical anesthetics, Intraoral injection, Pain perception, Herbal topical gel.

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### INTRODUCTION

Fear is the biggest obstacles that prevent kids from getting proper dental care. Several dental treatments necessitate to administer the local anaesthesia (LA), which is perhaps the upsetting experience for a youngster [1]. Although this feeling of pain is a reason that children are not allowed to visit the dentist, topical anesthetics have been shown to be effective in managing the painful needle prick during dental procedures [2]. Local anesthetic can be used to control pain. Any patient can become fearful of needles; it can be challenging to persuade a child to receive injections. A topical anesthetic gel decreases pain during a needle prick [3]. Applying a topical anesthetic at the injection site before to the procedure is the method most commonly recommended for reducing the pain associated with LA. Gels containing lignocaine and benzocaine are the most commonly utilized agents [4].

Before dental procedures, including extractions, root canal treatments, pulpotomies, pulpectomies, abscess drainage, and small oral surgical procedures, LA is needed. Nonetheless, it is ironic that the effective medications for preventing and treating pain are local anesthetics [5]. Many pediatric dental procedures require topical or surface anaesthesia as a necessary precondition. Before a local anesthetic is applied, topical anesthetics not only provide anaesthesia but also relieve pain. The dentist must determine how much anesthesia is necessary based on how invasive the treatment is [6]. The type, duration, and dosage of topical anaesthesia that should be used to ensure maximal effectiveness without running the risk of toxicity should be well-understood by the pediatric dentist. They inhibit signaling in sensory nerve terminal fibers. The topical anesthetic is only effective to a depth of 2–3 mm [1]. Topical anesthetic gel has the property of mucosal membrane absorption,

which is effective on oral tissues. Compared to benzocaine, lignocaine is known to cause relatively lesser allergic reactions [7]. Topical anesthetics are sold commercially in different forms such as ointments, aerosols, pastes, gels, patches, and powders [2]. Herbal products are being extensively researched for a variety of therapeutic purposes, one of which is the local anesthetic effect. Using a local herbal anesthetic as the organic topical agent over the lignocaine gel will aid in achieving a synergistic effect in topical application, analgesic with improved anti-inflammatory and antimicrobial properties, and a combination of therapeutically acceptable additives [8]. Herbal drugs have been used in many diseases [1]. Plant pigments, which are found in herbal drugs as flavonoids, which are also found in fruits and vegetables, have many physiological activities [9].

This current study will compare 2% lignocaine hydrochloride gel I.P. (LOX 2% Jelly) with indigenously prepared herbal topical anesthetic gel. The aim of this study is to evaluate the efficacy of novel herbal topical anesthetic gel and 2% lignocaine hydrochloride gel while deposition of LA in children. To check pain perception, efficiency of pain control, and acceptability during the administration of local anesthesia after application of the herbal topical anesthetic gel using Visual Analog Scale (VAS), sound eye motor (SEM), and hedonic 9-point scale. To evaluate pain perception, efficiency of pain control, and acceptability during the administration of local anesthesia after application of the 2% lignocaine hydrochloride gel I.P. using VAS, SEM, and hedonic 9-point scale. To compare the effectiveness of pain perception, the efficiency of pain control, and acceptability of herbal topical anesthetic gel and lignocaine hydrochloride gel I.P. (LOX 2% Jelly) as a topical anesthetic during the administration of local anesthesia using VAS, SEM, and Hedonic 9-point scale (Table 1).

Table 1: Hedonic 9-point scale [6]

Dislike extremely	Dislike very much	Dislike moderately	Dislike slightly	Neither like or dislike	Like slightly	Like moderately	Like very much	Like extremely
1	2	3	4	5	6	7	8	9

## METHODS

The present study is conducted in the Department of Pediatric and Preventive Dentistry of Sharad Pawar Dental College, Sawangi (Meghe), Wardha. Ref. No. DMIHER(DU)/IEC/2023/1206 (Institutional Ethics Committee). A total of 42 patients requiring local anesthesia administration are concluded in the present study and randomly allocated in two groups of 21 each as follows:

- Group I: Topical lignocaine hydrochloride gel I.P. (LOX 2% Jelly) CONTROL
- Group II: Topical herbal local anesthetic gel.

## Inclusion criteria [10]

- Children of 5–14 years of the age group who are free of any systemic disease
- Children requiring local anesthesia for dental procedure
- Cooperative children (Frankl behavior scale: Definitely positive).

## Exclusion criteria [10]

- Children with medically compromised health status
- Children associated with syndrome
- Children on sedative medication
- Children having known allergy to local anesthesia.

## Patient preparation procedure

The children who fulfill the criteria mentioned above are taken into consideration. The procedure, its discomforts, and the benefits are explained to the patient and his parents in detail, and informed written consent was obtained. The patients were divided into two groups at random.

## Sample size calculation [4]

$$n1 = n2 = 2 \frac{(Z_{\alpha} + Z_{\beta})^2}{( )^2}$$

$Z_{\alpha} = 1.96$

$\alpha =$  Type I error at 5% at both sides two tailed

$Z_{\beta} = 0.84$  ( $1 - \beta$ ) = Power at 80%

$\sigma =$  Std. dev

Primary variable: VAS

VAS Mean in Lignocaine = 0.41

Standard deviation = 0.503

$N1 = 2 * [(1.96 + 0.84)^2 (0.503)^2] / (0.41)^2 = 21$

Total samples required = 21/group.

## Study procedure

### Group I

Each child was evaluated using the VAS and the SEM scale. All procedures were performed by a single operator. The test area was dried using sterile cotton gauze after isolation. A cotton applicator stick was used to apply topical anesthetic – lignocaine hydrochloride gel I.P. (LOX 2% Jelly) – for approximately 30 s. To standardize the amount of gel applied, the applicator tip was dipped into the gel and rotated three times in a clockwise direction. Excess topical anesthetic was then wiped off using gauze. Following this, a 24-gauge short sterile needle attached to a syringe was used to inject 1 mL of 2% lignocaine with 1:200,000 adrenaline. The child's pain response to the needle prick was assessed. In addition, a hedonic 9-point scale was used to evaluate the child's acceptance of the anesthetic's gel taste [10].

### Group II

For gel preparation, the gelling agent Carbopol 940 (0.8%) was dissolved in 100 mL of water, and triethanolamine was added

drop by drop with constant stirring until the pH was neutralized. Triethanolamine was added to the dispersion with continuous stirring to achieve a stiff gel consistency. Clove oil, eucalyptus oil, aloe vera gel, and extracts of cinnamon and peppermint were then incorporated to formulate the final product. The consistency was checked regularly to improve the viscosity of the preparation. The final volume was adjusted with glycerin and stirred continuously until a uniform gel was obtained. The VAS (Fig. 1), eye motor scale, and the hedonic 9-point scale were used to evaluate acceptance of the gel's taste (Fig. 2).

## Statistical analysis

A general methodology was used for statistical analysis, and tables of statistical descriptions were created to summarize variables such as the total number of participants along with their documented observations, standard deviation, mean, median, maximum, and minimum values. Statistical analysis was done by Statistical Package for the Social Sciences 23 version. Descriptive statistics were done with frequency and percentage distribution of the variables of both groups. Independent sample t-test was done between the two groups for determining the statistical significance at  $p < 0.05$ .

## RESULTS

Out of 42 children included in the study, 22 were boys and 20 were girls in the age group of 5–14 years with a mean age of 9.5 years.

Tables 2 and 3 show a comparison between both the test groups under VAS and SEM scales. The mean scores obtained for the lignocaine group were lower than the herbal group under both pain scales. However, the mean scores under both the pain scales were statistically not significant ( $p > 0.05$ ).

$p < 0.001$ , Table 4 shows a comparison between both the test groups under Hedonic 9-point scale. In Hedonic 9-point scale, the mean score for the herbal group is higher, so it has shown a highly significant result ( $p < 0.001$ ).

## Intergroup comparison of outcome measures

Table 5 presents a statistical comparison of outcome measures between Group A and Group B. The mean VAS score for Group A was  $5.67 \pm 1.32$ , while Group B had a slightly lower mean score of  $5.19 \pm 0.87$ . The difference between the groups was not statistically significant ( $p = 0.175$ ).

The SEM scale results indicate that Group A had a mean score of  $3.19 \pm 0.75$ , while Group B had a slightly lower mean of  $2.95 \pm 0.86$ . This difference was also not statistically significant ( $p = 0.346$ ).

However, a significant difference was observed in the Hedonic 9-point scale scores. Group A had a mean score of  $3.52 \pm 0.98$ , whereas Group B recorded a significantly higher mean score of  $5.86 \pm 1.15$ . This difference was statistically significant ( $p < 0.001$ ), indicating a meaningful distinction between the groups (Fig. 3).

## DISCUSSION

The effects of topical anesthetics are both psychological and pharmacological. The study's merits were explained to the kids and their parents before the administration of LA. Patients were found to be more amenable to a procedure involving the injection of local anesthetic when they were made aware of the advantages of topical anesthetics before their application. The amount of anesthetic penetration is influenced by the application's duration [12]. The topical anesthetics

gel application will be done for 30 s and then left on for a minute in the current study. There is a marked reduction of sensation of pain after applying the topical gel for 1 min. Many psychological and physiological

**Table 2: Comparison between both test product using VAS scale**

Groups	No. of children	Mean±SD	p-value
Lignocaine gel	21	5.67±1.32	0.1748
Herbal gel	21	5.19±0.87	0.1748

VAS: Visual Analog Scale, SD: Standard deviation.  $p < 0.05$

**Table 3: Comparison between both test product using SEM scale**

Groups	No. of children	Mean±SD	p-value
Lignocaine gel	21	3.19±0.75	0.3461
Herbal gel	21	2.95±0.86	0.3461

SEM: Sound eye motor, SD: Standard deviation.  $p < 0.05$

**Table 4: Comparison between both test product using Hedonic 9-point scale**

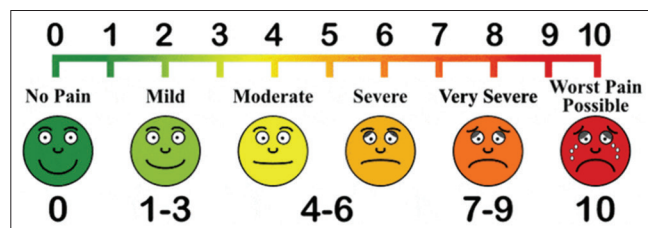
Groups	No. of children	Mean±SD	p-value
Lignocaine gel	21	3.52±0.98	0.0001
Herbal gel	21	5.86±1.15	0.0001

SD: Standard deviation

**Table 5: Intergroup comparison of outcome measures**

Group statistics						
Group	N	Mean	Standard deviation	Standard error mean	p-value	Mean difference
VAS						
1	21	5.6667	1.31656	0.28730	0.175	0.47619
2	21	5.1905	0.87287	0.19048		
Sound eye motor						
1	21	3.1905	0.74960	0.16358	0.176	0.47619
2	21	2.9524	0.86465	0.18868	0.346	0.23810
Hedonic						
1	21	3.5238	0.98077	0.21402	0.346	0.23810
2	21	5.8571	1.15264	0.25153	0.000	-2.33333
					0.000	-2.33333

VAS: Visual Analog Scale



**Fig. 1: Visual analog scale**

variables influence pain. Since pain is felt differently by each person, it is challenging to specify it [13].

Herbal anesthetic has properties of anesthetic, analgesic, and anti-inflammatory. Various different herbal gel preparations have anesthetic characteristics like thymol, clove, etc. Singh *et al.* stated herbal anesthetic gel has minimal side effects than the control group [2]. In the current study, VAS, SEM, and Hedonic 9-point scales were incorporated to check pain and taste perception. The VAS scale has mostly preferred for use because it is easy to use and requires no special training ability to measure distance with a ruler and calculate a score. The evaluation is very subjective, as it only takes a minute to complete. The similar study by Kotian *et al.* used commercially available lignocaine and benzocaine topical gel similar results were found on both pain scale several factors contribute to the elicitation of pain, including their verbal commands and the movement of the limbs and eyes, on the sounds, eyes, and motor scale [4].

In the present study, VAS and SEM scales were assessed for pain perception; in comparison, a statistically not significant result was obtained. However, the mean score was less for the herbal group. In Hedonic 9-point scale, the mean score for the herbal group is higher, so it has shown a highly significant result. Herbal gel was more preferable in taste than comparator. The contradictory study results were obtained with Kotian *et al.* performed a split-mouth study in children, where she checked the effectiveness of lignocaine and benzocaine as topical gel anesthetics before local anesthetic administration on the intraoral site [4]. A total of 44 patients, ages 4–10 recommended for pulpal therapy of their deciduous teeth under inferior dental block, were chosen. The subjects were categorized into two groups of 22 each at random. Before inferior alveolar nerve block, group one-lignocaine gel and group two-benzocaine gel were applied. The VAS and sound-eye motor scale are used to assess pain. She discovered that a topical anesthetic agent, lignocaine group had lower mean scores for these pain scale in comparison to benzocaine; results were almost statistically insignificant. However, when compared to benzocaine, lignocaine had a better taste [4].

Anantharaj *et al.* [10] evaluated clove-papaya gel, benzocaine, and ice for anesthetic effectiveness in children, finding no significant differences in pain perception across WBFPRS and SEM scales. Amruthavarshini *et al.* [3] found that ice application was most effective in reducing injection pain in children, followed by laser bio-stimulation and lignocaine gel, using SEM and Wong-baker scales. Singh *et al.* [2] compared 5% lignocaine and frozen cones with and without virtual reality distraction (VRD) in 60 children. Results showed frozen cones with VRD significantly reduced pain, suggesting VRD enhances effectiveness of ice as a pain distraction method. Ferrazzano *et al.* [14] studied 300 children aged 5–8, comparing pain responses with and without anesthetic gel. Significant differences were found in both face, legs, activity, cry, and consolability scale and Wong-Baker scales, showing the gel's effectiveness with minimal side effects and high parental satisfaction. There are differences in every child patient [15]. In the present study, both lignocaine and herbal gels were evaluated for their effectiveness in reducing pain and their taste acceptability in children. The VAS and SEM scale results revealed no statistically significant differences between the two groups, indicating

Possible indications of pain	Comfort or pain level			
	1—comfort	2—mild discomfort	3—moderately painful	4—painful
Sound	No sounds indicating pain	Nonspecific sounds; possible indication of pain	Specific verbal complaints (such as "ow"), raises voice	Verbal complaint indicates intense pain (such as screaming, sobbing)
Eye	No eye signs of discomfort	Eyes wide, show of concern, no tears	Watery eyes, eyes flinching	Crying tears running down face
Motor	Hands relaxed; no apparent body tension	Hands showing some distress or tension; grasping of chair owing to discomfort, muscular tension	Random movement of arms or body without aggressive intention of physical contact, grimacing, twitching	Movement of hands to make aggressive physical contact (such as pushing, pulling head away)

**Fig. 2: Sound-eye-motor scale [11]**

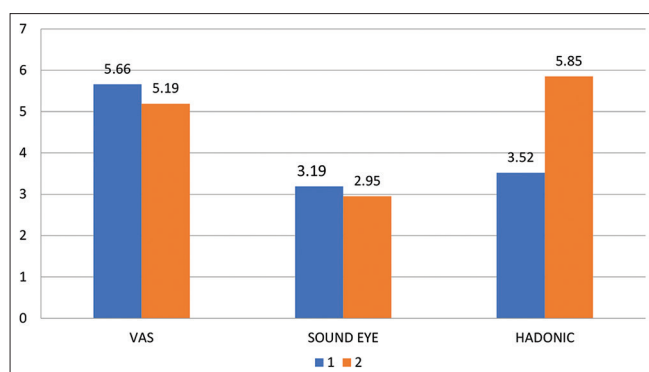


Fig. 3: Graphic representation of intergroup comparison

that both gels provided comparable levels of pain control during local anesthetic administration. However, the results of the Hedonic 9-point scale demonstrated a statistically significant difference, with the herbal gel showing higher mean scores, suggesting greater taste acceptability among children ( $p < 0.001$ ). This implies that while both gels were equally effective in pain management, the herbal formulation was more favorably accepted due to its taste, making it a potentially more child-friendly alternative in clinical settings.

## CONCLUSION

Novel herbal topical gel and lignocaine are equally effective in controlling pain during the administration of local anesthesia. Herbal topical gel was more preferred in taste when compared with lignocaine.

**CTRI Trial Registration Number:** CTRI/2023/11/060243. ([www.ctri.nic.in](http://www.ctri.nic.in))

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## AUTHOR'S CONTRIBUTIONS

Ishani Rahate (Writing - original draft) (Investigation); (Methodology); Punit Fulzele (Writing - original draft) (Validation) (Supervision); (Investigation); (Methodology); Nilima Thosar (Writing - original draft) (Methodology); (Validation) (Resources); Anita Wanjari (Writing - original draft) (Validation) (Supervision); (Investigation); (Methodology); Anjori Raut (Writing - original draft) (Conceptualization); (Formal analysis); (Resources); (Validation); (Writing - original draft) Rijuta Gujar (Writing - original draft) (Conceptualization); (Data curation); (Resources); Shepali Hule (Writing - review & editing); (Project administration). All authors reviewed the manuscript.

## CONFLICTS OF INTEREST

The authors declare no conflicts of interest, financial or otherwise.

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