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Comparative Evaluation Of 5% Eutectic Mixture of Local Anaesthesia (EMLA), 2% Lignocaine Gel and 5% Benzocaine Gel on the Pain Perception in Children Prior To Administration of Local Anaesthesia – An In Vivo Study

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ABSTRACT

Aim

To compare and evaluate the efficacy of 5% EMLA, 2% lignocaine gel and 20% benzocaine gel on pain perception during local anaesthesia administration in pediatric dental patients.

Material and Methods

A total of 69 participants in the age group of 8-10 years were divided into 3 groups randomly with 23 in each group. The cotton applicator with 5% EMLA was held in contact with the buccal mucosa for 60 seconds. Immediately after removal of cotton applicator, inferior alveolar nerve block administered. Similarly, 2% Lignocaine gel was used on participants. 0.1 mg of 20% Benzocaine gel was applied over the injection site contacting the buccal mucosa using sterile cotton applicator. The Faces, Legs, Activity, Cry and CONSOL ability Scale (FLACC) Evaluation was done by one trained personnel during the local anaesthesia administration.

Following local anaesthesia, participants were asked to rate their pain experience using Wong Bakers scale.

Results

The mean score of the 20% Benzocaine gel ,5 % EMLA and 2%Lignocaine gel were 2.91, 3.35 and 3.87 respectively using FLACC scale. The mean score of the 20% Benzocaine gel ,5 % EMLA and 2% Lignocaine gel were 4.61, 5.57 and 5.83 respectively using the Wong Bakers scale. Greater reduction in pain perception was observed in 20% Benzocaine group followed by 5% EMLA group and 2% Lignocaine group. It was not statistically significant ($p<0.005$).

Conclusion

5% EMLA, 2% lignocaine gel and 20% benzocaine gel were effective in reducing pain perception in children, thereby reducing their fear and anxiety. 20% Benzocaine group showed greater reduction in pain perception and higher efficacy than other groups, even though the results were not catechistically significant.

Keywords

5% EMLA; 2% lignocaine ;20% benzocaine; Pain perception; FLACC scale; Wong Bakers scale; topical anaesthetic gel, inferior alveolar nerve block.

INTRODUCTION

Effective management of dental pain is a crucial aspect of modern dentistry, as it significantly influences a patient's overall quality of life .To give patients a pain-free environment there are different ways such as desensitization of the oral location with topical anaesthesia .[1]

In recent years, development of topical anesthetic agents has been one of advancements in dental research. Most of these agents are safe and are widely used on the oral mucosa. [2] Due to the emotional attribute of dental anxiety, dental treatment for children has always been difficult topical anaesthetics have the ability to penetrate the oral mucosa and induce anaesthesia.[3]

Strengthening the bond between the child patient and the dentist, building trust and promoting positive behavioural attitude is necessary. [4]

Effective pain control is a fundamental component of modern dentistry, as it directly influences a patient's quality of life. In paediatric dentistry, dental anxiety presents a significant challenge, often leading children to resist treatment. This can be addressed by minimizing injection-related pain through measures such as adjusting the pH and temperature of the local anaesthetic solution and administering the injection slowly into the tissues.[5]

Topical anesthesia plays a crucial role in a wide range of dental procedures. Its primary purpose is to reduce or eliminate the pain caused by needle penetration, thereby providing effective control of both pain and patient anxiety.[6]

A randomized clinical trial by Courtney, et al stated that higher pain scores were observed in highly anxious participants however, topical anaesthetic agents reduced the effect of anxiety on needle insertion pain .[7]

Different forms of anaesthetic agents are available, including gels, lotions, solutions, patches, and lozenges. Topical anaesthesia works by penetrating the oral mucosal membrane to produce analgesia. When applied topically, an ideal local anaesthetic agent should be effective in achieving adequate pain relief.[8]

Signal conduction is inhibited at the terminal fibers of sensory nerves, producing surface anaesthesia to a

depth of approximately 2–3 mm. This effect occurs due to alterations in transmission through voltage-sensitive sodium channels, which increase the action potential threshold and thereby effectively reduce pain during needle insertion. In dentistry, earlier pioneering work on topical anaesthetics has demonstrated that simple drug combinations, such as benzocaine with amethocaine, can prolong the duration of anaesthesia due to their differing onset times of action. [9]

The eutectic mixture of local anaesthetics (EMLA) is a combination of 2.5% lidocaine and 2.5% prilocaine that has recently gained popularity in dental procedures. It is formulated as a 1:1 oil/water emulsion of the two crystalline powders. The eutectic blend has a melting point of 17°C, which is lower than the individual melting points of lidocaine and prilocaine. This allows the mixture to be liquid at body temperature, resulting in rapid absorption. As a result, EMLA can effectively penetrate intact skin or mucosa to 5mm depth .[10]

EMLA provides local anaesthesia in a variety of painful superficial procedures. In the oral cavity, satisfactory outcome has been proven in biopsy periodontal probes and prior to local anaesthesia. EMLA represented a very good profile with mild skin blanching.[11]

Therefore, aim of this study is to compare and evaluate the effectiveness of three topical anaesthetic gels on needle insertion pain during administration.[12]

MATERIALS AND METHODS

SOURCE OF DATA

The current study was conducted in Department of Pediatric and Preventive Dentistry at A J Institute of Dental Sciences, Mangalore after receiving the approval from the Ethical Committee. A total of 69 healthy children aged 8-10 years was be selected from the Out Patient Department (OPD) of Department of pedodontics.

INCLUSION CRITERIA

- Children aged 8-10 years requiring local anaesthesia for dental procedures.
- Healthy children without any systemic illness.
- Children who are willing to participate in study.
- Children who are co-operative

EXCLUSION CRITERIA

- Children with history of systemic disease, cognitive disorder, sensitive skin, dental abscess in procedure site.
- Children who had allergic history to local anaesthesia.
- Children who are unable to follow instructions or uncooperative.

MATERIALS USED FOR THE STUDY

1) Basic examination kit consisting of disposable mouth mask, gloves, kidney tray, explorer, probe, mouth mirror, tweezer and sterile 2×2-inch gauze.
2) Patient Drape
3) 5% Eutectic Mixture of Local Anaesthesia (EMLA)
4) 2% Lignocaine Gel
5) 20% Benzocaine Gel
6) Puritan Sterile Cotton Applicator (Tip diameter 15.8 mm/0.624 inch)
7) Local anaesthesia (LOX® 2% ADRENALINE 1:200000) 8) Syringe (Discardit II™ Syringe, 0.55 X 25 mm,24

SAMPLE SIZE ESTIMATION

On the basis of the study conducted by Maria el al and Manisha Nair et al sample size was estimated using

the standard deviation of pain in EMLA, Lignocaine and benzocaine groups . Assuming 95% confidence interval, 80% power with the pooled Standard deviation of 5 , the sample size estimated for the study is 23 in each group. Hence a total of 69 children, who meet the inclusion criteria will be considered for the study.

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 * 2 * \sigma^2}{(d)^2}$$

n-sample size

1. Level of significance=5%, Zα/2 for 3 groups=2.39
2. Power= 80%, Z_{β} = 0.84
3. Standard deviation of pain in 5% EMLA =0.66
   Standard deviation of pain in 2% lignocaine =0.62
   Standard deviation of pain in 20% Benzocaine =0.63
4. Expected mean difference=0.6
5. Estimated sample size 23 in each group

METHODOLOGY

69 participants in the age group of 8-10 years from the Department of Pediatric and Preventive Dentistry at A J Institute of Dental Sciences, Mangalore were selected based on the above-mentioned selection criteria and will be divided in 3 groups randomly.

Group A:

5% Eutectic Mixture of Local Anaesthesia (EMLA)

Group B:

2% Lignocaine Gel

Group C:

20% Benzocaine Gel

The children were allotted into respective groups based on Fish Bowl method (Single Random Sampling), according to the chits chosen by the participants.

1) 5% Eutectic Mixture of Local Anaesthesia (EMLA)

As per the manufacturer's guidelines,

- 5% Eutectic Mixture of Local Anaesthesia was applied over the injection site contacting the buccal mucosa using sterile cotton applicator.
- The cotton applicator with 5% Eutectic Mixture of Local Anaesthesia was held in contact with the buccal mucosa for 60 seconds.
- After the removal of the cotton applicator, immediately the inferior alveolar nerve block was administered.

2) 2% Lignocaine Gel

As per the manufacturer's guidelines,

- 0.1 mg of 2% Lignocaine Gel was applied over the injection site contacting the buccal mucosa using sterile cotton applicator.
- The cotton applicator with 2% Lignocaine Gel was held in contact with the buccal mucosa for 60 seconds.
- After the removal of the cotton applicator, immediately the inferior alveolar nerve block was administered.

3) 20% Benzocaine Gel

As per manufacturer's guidelines,

- 0.1 mg of 20% Benzocaine Gel was applied over the injection site contacting the buccal mucosa using sterile cotton applicator .
- The cotton applicator with benzocaine was held in contact with the buccal mucosa for 60 seconds.
- After the removal of the cotton applicator, immediately inferior alveolar nerve block was administered.

For each of group certain euphemistic phrase was used to relieve anxiety among pediatric patients. After

the application of topical anaesthetic agent, Local Anaesthesia (LOX 2% ADRENALINE 1:200000, Syringe: Discardit II^{TM,} 0.55 X 25 mm, 24G) was administered with standard protocols.

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 anaesthesia administration, the participants were asked to rate their pain experience using Wong Bakers Scale.

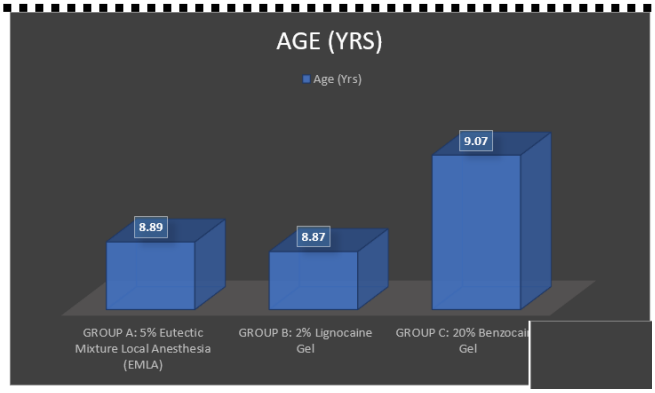
RESULTS

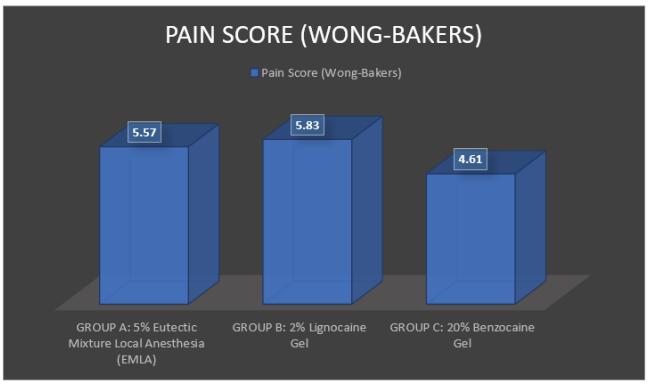
Data was tabulated and analysed using SPSS Software version 20.0 (SPSS Inc., Chicago, USA). Analysis Of Variance ANOVA / Kruskal-Wallis's test (depending on the normality assumption) was used to test the significant difference in the outcome between the groups in the pain perception during the procedure using the FLACC Scale and pain perception after the procedure using the Wong Bakers Scale. $p < 0.05$ determined as statistically significant.

The participants in the study, included 37 girls and 32 boys (N = 69), age s 8-10 years.

Table 1: Comparison of Age and Pain Scores Across Study Groups (One-Way ANOVA)

Variable	Group	N	Mean	SD	p-value
Age (Yrs)	GROUP A: 5% Eutectic Mixture Local Anesthesia (EMLA)	23	8.89	0.797	0.663
	GROUP B: 2% Lignocaine Gel	23	8.87	0.801	
	GROUP C: 20% Benzocaine Gel	23	9.07	0.788	
Pain Score (Wong-Bakers)	GROUP A: 5% Eutectic Mixture Local Anesthesia (EMLA)	23	5.57	1.343	0.051
	GROUP B: 2% Lignocaine Gel	23	5.83	1.696	
	GROUP C: 20% Benzocaine Gel	23	4.61	1.751	
Pain Score (FLACC Scale)	GROUP A: 5% Eutectic Mixture Local Anesthesia (EMLA)	23	3.35	1.112	0.172
	GROUP B: 2% Lignocaine Gel	23	3.87	1.687	
	GROUP C: 20% Benzocaine Gel	23	2.91	1.676	





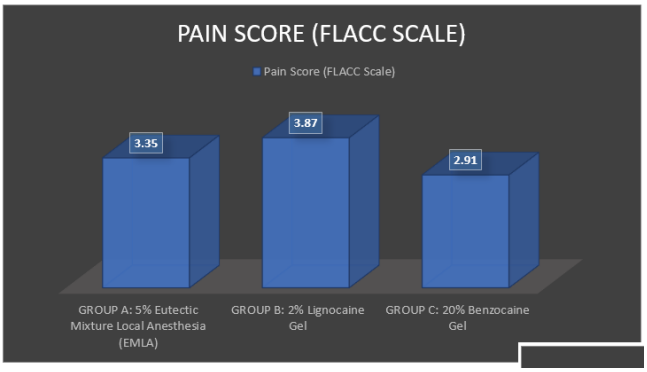


Table 2: Comparison of Gender Across Study Groups

GENDER	Group	FREQUENCY	PERCENTAGE
MALE	GROUP A: 5% Eutectic Mixture Local Anesthesia (EMLA)	11	15.9
	GROUP B: 2% Lignocaine Gel	11	15.9
	GROUP C: 20% Benzocaine Gel	10	14.5
FEMALE	GROUP A: 5% Eutectic Mixture Local Anesthesia (EMLA)	12	17.4
	GROUP B: 2% Lignocaine Gel	12	17.4
	GROUP C: 20% Benzocaine Gel	13	18.8

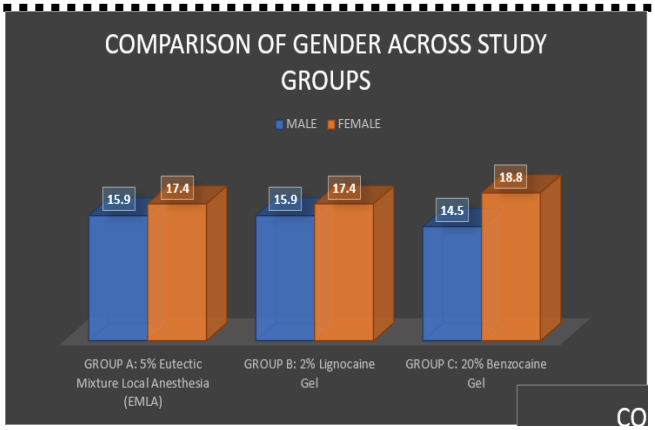


Table 3: Distribution of Gender Across Study Groups [n (%)]

Gender	GROUP A: 5% EMLA (n=23)	GROUP B: 2% Lignocaine Gel (n=23)	GROUP C: 20% Benzocaine Gel (n=23)	Total (N=69)	p-value
Male	11 (34.4%)	11 (34.4%)	10 (31.3%)	32 (100.0%)	0.943
Female	12 (32.4%)	12 (32.4%)	13 (35.1%)	37 (100.0%)	

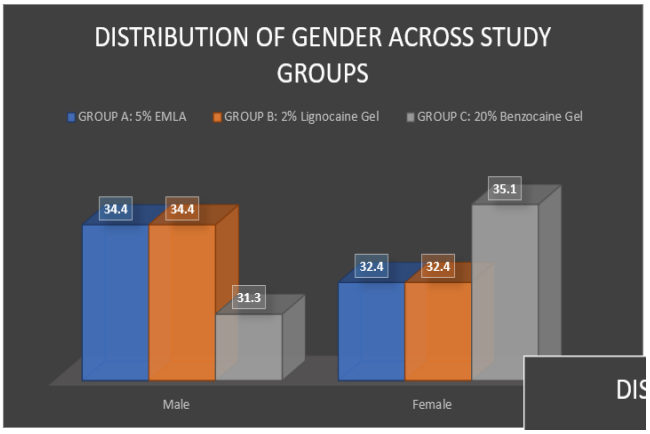


Table 4: Distribution of Wong-Bakers Pain Scores Across Study Groups [n (%)]

Table 4: Distribution of Wong-Bakers Pain Scores Across Study Groups [n (%)]

Pain Score (Wong-Bakers)	GROUP A: 5% EMLA (n=23)	GROUP B: 2% Lignocaine Gel (n=23)	GROUP C: 20% Benzocaine Gel (n=23)	Total (N=69)	p-value
2	0 (0.0%)	0 (0.0%)	4 (100.0%)	4 (100.0%)	0.034
4	8 (29.6%)	9 (33.3%)	10 (37.0%)	27 (100.0%)	
6	12 (46.2%)	7 (26.9%)	7 (26.9%)	26 (100.0%)	
8	3 (25.0%)	7 (58.3%)	2 (16.7%)	12 (100.0%)	

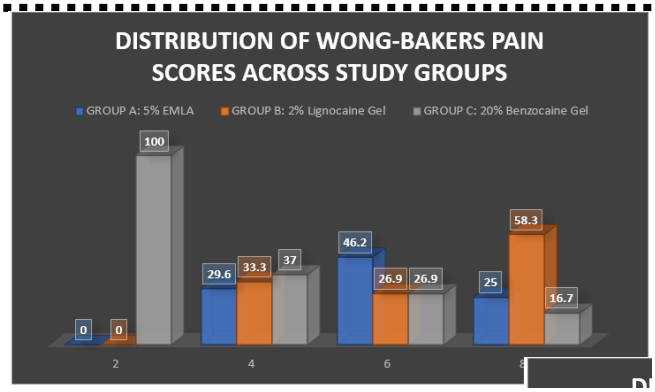
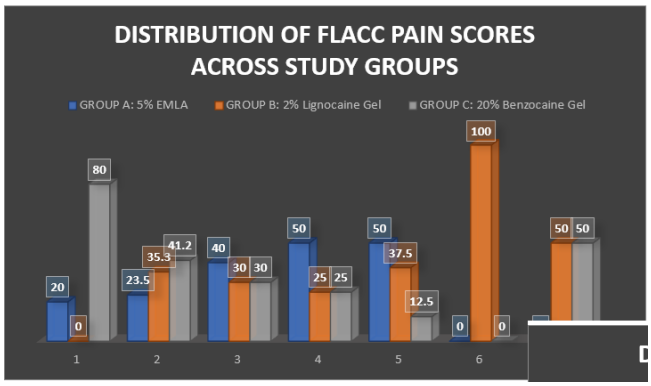


Table 5: Distribution of FLACC Scale Pain Scores Across Study Groups [n (%)]

Pain Score (FLACC Scale)	GROUP A: 5% EMLA (n=23)	GROUP B: 2% Lignocaine Gel (n=23)	GROUP C: 20% Benzocaine Gel (n=23)	Total (N=69)	p-value
1	1 (20.0%)	0 (0.0%)	4 (80.0%)	5 (100.0%)	0.126
2	4 (23.5%)	6 (35.3%)	7 (41.2%)	17 (100.0%)	
3	8 (40.0%)	6 (30.0%)	6 (30.0%)	20 (100.0%)	
4	6 (50.0%)	3 (25.0%)	3 (25.0%)	12 (100.0%)	
5	4 (50.0%)	3 (37.5%)	1 (12.5%)	8	
6	0 (0.0%				
7	0 (0.0%				

Pain Score (FLACC Scale)	GROUP A: 5% EMLA (n=23)	GROUP B: 2% Lignocaine Gel (n=23)	GROUP C: 20% Benzocaine Gel (n=23)
1	1 (20.0%)	0 (0.0%)	4 (80.0%)
2	4 (23.5%)	6 (35.3%)	7 (41.2%)



INTERPRETATION

Table 1: Comparison of Age and Pain Scores Across Study Groups (One-Way ANOVA)

- Age: The mean age of participants across all three groups is very similar (around 8.9 years), with a p-value of 0.663, indicating no statistically significant difference in age distribution among

the groups. This suggests that the groups were comparable in terms of age.

- Pain Score (Wong-Bakers): Group C (20% Benzocaine Gel) had the lowest mean pain score (4.61), while Group B (2% Lignocaine Gel) had the highest (5.83). The p-value is 0.051, which is just above the conventional threshold for significance ($p < 0.05$). This suggests a trend toward significance, meaning there may be a meaningful difference in pain scores among the groups, but it did not reach statistical significance.
- Pain Score (FLACC Scale): Group C again had the lowest mean pain score (2.91), and Group B the highest (3.87). The p-value is 0.172, indicating no statistically significant difference among the groups.

Table 2: Comparison of Gender Across Study Groups

- The distribution of males and females across the three groups is fairly even.
- Group A and B each have 11 males and 12 females; Group C has 10 males and 13 females.
- Percentages are based on the total sample (N=69), showing a slightly higher proportion of females overall.

Table 3: Distribution of Gender Across Study Groups [n (%)]

- This table confirms the even distribution of gender across groups.
- p-value = 0.943, indicating no statistically significant difference in gender distribution among the groups. This means the groups were well-balanced in terms of gender.

Table 4: Distribution of Wong-Bakers Pain Scores Across Study Groups [n (%)]

- A statistically significant difference was found (p = 0.034), indicating that the distribution of pain scores (Wong-Bakers) differs across the three groups.
- Notably, all participants with a pain score of 2 were in Group C (20% Benzocaine Gel), suggesting this group had more participants with very low pain.
- Group A had the highest proportion of scores at 6 (46.2%), while Group B had the highest at 8 (58.3%), indicating higher pain levels in these groups.

Table 5: Distribution of FLACC Scale Pain Scores Across Study Groups [n (%)]

- The p-value is 0.126, indicating no statistically significant difference in FLACC pain scores across the groups.
- However, some patterns are worth noting:
  - All participants with a pain score of 1 were in Groups A and C, with 80% in Group C.
  - All participants with a pain score of 6 were in Group B, suggesting higher pain in this group.
  - Group A had the highest proportion of scores at 4 and 5 (50% each), indicating moderate pain.

SUMMARY

- Groups were comparable in age and gender distribution, ensuring baseline homogeneity.
- Wong-Bakers pain scores showed a statistically significant difference among groups (p = 0.034), with Group C (20% Benzocaine Gel) appearing to have the most favorable pain outcomes.
- FLACC scale scores did not show statistically significant differences, but descriptive trends suggest Group C may still have an advantage in pain management.

- The trend toward significance in Wong-Bakers scores ($p = 0.051$) from ANOVA and the significant result in categorical distribution ($p = 0.034$) suggest that 20% Benzocaine Gel may be more effective in reducing pain compared to the other two agents.

DISCUSSION

Dental pain is a widespread concern affecting individuals across all age groups. It frequently results in avoidance of dental visits, compromising oral health. A major contributing factor to this pain is discomfort experienced during the procedures, especially during needle injections.[18,19]

Consequently, multiple pain-relief methods were implemented, like topical anesthesia application. [20,21] Therefore, dentists must find the best topical anaesthesia to alleviate pain during treatments[18,19] . this study aimed to evaluate the efficacy of 5% EMLA cream and 2% lidocaine gel in reducing pain during IANB compared with 20% Benzocaine in children aged 8–10 years.

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. In the current research, the patient's behavior was assessed for the pain perception using FLACC scale (objective) and Wong bakers scale 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 pain in young children. The FLACC scale provides a simple structure for evaluation and allows reliable and objective assessment of children's pain behaviour.

Children aged 8–10 years were selected for this study because they are cooperative and can express their pain using pain assessment scales [22,23]. Self-reported pain measured using the Wong-Baker Faces Pain Rating Scale is appropriate for pediatric patients[24,25]. The FLACC behavioral pain assessment scale used offered an objective method for evaluating pain. It is a tool for assessing pain across different age groups , including young children.[26,27] The inferior alveolar nerve block (IANB) is effective anaesthetic technique for treating primary teeth, yet it is often considered very painful and uncomfortable for patients.[28]

In the study, 2% lidocaine gel was used because it has rapid onset, less toxicity, and potency[29,30] Furthermore, 20% benzocaine gel was chosen owing to its common use and broad acceptance within dental practice.[31]Nonetheless, benzocaine administration may lead to adverse effects like soft tissue swelling, and allergic reactions[32]. "5% EMLA cream was selected for its demonstrated efficacy in reducing pain associated with minor dental procedures and palatal injections.[32,33] Each topical anaesthetic was applied for 2 min, which is similar to the Bhalla et al study.[34]

According to Dasarraju et al[35], topical gel was applied for 1 minute. Patil et al. [36] Demonstrated that EMLA cream is comparable to 2% lidocaine gel in mitigating pain during needle insertion, while Kotian et al. Reported that 5% lidocaine gel and 20% benzocaine gel exhibit similar efficacy in reducing pain . Findings of this study are consistent with Nair et al., who concluded that 20% benzocaine provides greater pain

relief than 2% lidocaine during IANB administration. However, the efficacy may be affected by the lidocaine concentration used.

However, the concentration of lidocaine administration used in the current study was higher than that employed in the study by Nair et al. Additionally, Milani et al. Reported that 5% EMLA cream is more effective than 20% benzocaine gel for maxillary infiltration injections in canine teeth. Furthermore, according to Abu Al-Melh et al[40] it is highly effective in alleviating pain during palatal injection compared to 20% benzocaine[40] . According to Maldonado-Ramírez et al a 5% EMLA patch was more effective than 20% benzocaine [41.] The differences between these findings may be explained by the influence of various psychological factors on pain. The pain experienced during local anaesthetic administration can be affected by the injection rate, pH of the anaesthetic solution, and the buffering capacity of tissues[35].

In current study, administration of local anaesthetic was performed slowly at 1 mL/min because according to de Souza Melo et al ,slow injections are associated with less pain and discomfort[42.] However, in this study, 2% lidocaine with epinephrine 1:80,000 solution was used that has approximately an acidic pH of 4 ,Sadananda et al ,causes greater pain sensation[43]. This finding may explain three topical anaesthetics evaluated in the present study. Injection-related pain appears to persist irrespective of the topical agent used. Consequently, null hypothesis was accepted, as 20% benzocaine did not demonstrate superior effectiveness over 5% EMLA cream and 2% lidocaine gel in reducing pain during IANB administration.

An important aspect of study is the allocation of participants into different groups, which helps decrease bias and increases the validity of the results.[44] Both different forms of anesthetic agents are available, including gels, lotions, solutions, patches, and lozenges. Topical anesthesia works by penetrating the oral mucosal membrane to produce analgesia. When applied topically, an ideal local anaesthetic agent should be effective in achieving adequate pain relief which provides a adequate assessment of children's responses to pain[45] .Nonetheless, this study has certain limitation. Primarily, narrow age range of the participants may restrict generalizability of the findings. [46] The current pain measurements tools fail to report pain accurately.

Wong-Baker FACES pain rating scale may be influenced by self-reporting bias, while the FLACC behavioral pain assessment scale can be affected by exaggerated pain behaviors.[47,48] Future studies must evaluate other topical anaesthetic formulations. Pain assessment in children could be further improved through the use of alternative measurement tools, including artificial intelligence–based methods. Additionally, clinical trials comparing combined approaches to pain management during dental injections may yield valuable insights. It is recommended to test other topical anaesthetic formulations. In addition, to assess pain using different pain measurement tools for children, such as artificial intelligence [49]. Furthermore, it could be beneficial to conduct future trials comparing conjunction approaches to pain management during dental injections.

CONCLUSION

Based on the results, topical anaesthetic application before IANB reduces pain in children, although 2% lidocaine gel was not more effective than 20% benzocaine or 5% EMLA in controlling pain during IANB administration.

Pain associated with needle insertion during local anaesthetic causes fear and anxiety in young children .Effective pre-injection pain control is therefore essential not only for patient comfort but also for improved cooperation, positive behavioral response, and successful treatment outcomes.

In this study, the effectiveness of 2% lignocaine gel and 20% benzocaine gel was evaluated using both subjective and objective pain assessment tools namely, the Wong– Baker FACES Pain Rating Scale and the FLACC (Face, Legs, Activity, Cry, Consolability) behavioral pain assessment scale. The use of dual assessment scales strengthened the reliability of pain evaluation by incorporating both the child's self-reported pain perception (Wong–Baker FACES) and the clinician's objective observation of behavioral responses (FLACC).

Based on the findings of this study, 5% EMLA, 2% lignocaine gel and 20% benzocaine gel demonstrated effectiveness in reducing needle insertion pain prior to local anaesthetic administration. Decrease in pain scores was observed in both groups on the Wong–Baker FACES scale, which indicates decreased subjective pain . Similarly, lower FLACC scores reflected reduced behavioral signs of discomfort, confirming the clinical efficacy of topical anaesthetic application.

The correlation between subjective (Wong–Baker) and objective (FLACC) scores further validates the effect of topical anaesthesia in young children. The application of topical anaesthetic gel significantly minimized needle penetration discomfort, thereby contributing to improved patient cooperation and smoother clinical procedures.

Within the limitations of the study, it can be concluded that topical agents have very effective when used as pre-injection topical anaesthetics in children. Incorporating topical anaesthetic application as a routine step prior to local anaesthetic administration is essential component of pediatric pain management protocols. Further studies with larger sample sizes and multicentric trials are recommended to establish stronger evidence and determine if one agent demonstrates consistent superiority under varied clinical conditions.

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