Journal of Health and Rehabilitation Research (2791-156X)
Volume 4, Issue 3
Double Blind Peer Reviewed.
https://jhrlmc.com/
DOI: https://doi.org/10.61919/jhrr.v4i3.1415
www.lmi.education/

A Double-Blind Split Mouth Study Comparing the Effects of 5% EMLA Cream and 20% Benzocaine on Pre-Injection Analgesia

Shaharyar Hamid Shaikh[1], Anwar Ali[2], Muhammad Ilyas[3], Safia Khatoon[4], Syeda Noureen Iqbal[5], Daud Sultan[6]

Correspondence
Shaharyar Hamid Shaikh
sheryshaikh37@gmail.com

Affiliations
1 Resident, FCPS, Oral and Maxillofacial Surgery Department, Dr. Ishrat-ul-Ebad Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi.
2 Professor, Oral and Maxillofacial Surgery Department, Dr. Ishrat-ul-Ebad Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi.
3 Associate Professor, Oral and Maxillofacial Surgery Department, Dr. Ishrat-ul-Ebad Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi.
4 Associate Professor, Oral and Maxillofacial Surgery Department, Sindh Institute of Oral Health Sciences, Jinnah Sindh Medical University, Karachi.
5 Assistant Professor, Oral and Maxillofacial Surgery Department, Dr. Ishrat-ul-Ebad Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi.
6 Oral and Maxillofacial Surgery Department, Dr. Ishrat-ul-Ebad Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi.

Keywords
EMLA Cream, Benzocaine Gel, Pre-Injection Analgesia, Dental Pain Management, Split-Mouth Study.

Disclaimers

Authors' Contributions	All authors significantly and equally.
Conflict of Interest	None declared
Data/supplements	Available on request.
Funding	None
Ethical Approval	Respective Ethical Review Board under Approval No. 2021/568
Study Registration	N/A
Acknowledgments	N/A

ABSTRACT

Background: Pain during local anesthetic injections is a common concern in dental procedures, often managed by topical anesthetics. However, no topical anesthetic has entirely eliminated this pain.

Objective: To compare the effectiveness of 5% EMLA cream and 20% benzocaine gel in reducing pre-injection pain.

Methods: A double-blind, split-mouth clinical trial was conducted with 70 participants, aged 18-35 years, undergoing bilateral dental extractions. 5% EMLA cream and 20% benzocaine gel were applied to separate sites before injection. Pain was assessed using a Visual Analog Scale (VAS) at 3, 6, and 9 minutes post-administration. Data were analyzed using an independent sample t-test with significance set at $p \leq 0.05$.

Results: The EMLA group showed significantly lower VAS scores compared to the benzocaine group at 3 minutes (3.00 ± 2.04 vs. 4.00 ± 1.00, $p = 0.035$), 6 minutes (3.00 ± 2.04 vs. 4.23 ± 1.38, $p = 0.005$), and 9 minutes (3.00 ± 2.04 vs. 4.00 ± 1.53, $p = 0.004$).

Conclusion: EMLA cream was more effective than benzocaine gel in reducing pre-injection pain. Clinicians should consider EMLA as a preferred option for enhanced patient comfort.

INTRODUCTION

Dental procedures often evoke significant anxiety and fear of pain in patients, particularly in relation to local anesthetic injections. The management of dental pain and anxiety has evolved considerably, with advancements in behavioral techniques and the use of oral and injectable sedatives (1). However, the cornerstone of modern dental practice remains local anesthesia, which, despite its essential role, is often associated with discomfort during injection. This discomfort can stem from various factors, such as the rapid expansion of tissues due to the anesthetic solution, the mechanical trauma caused by needle penetration, and the sudden pressure from the syringe's contents (2). Consequently, the application of topical anesthetics prior to needle insertion has become a common practice to minimize the discomfort associated with local anesthetic injections (3).

Among the topical anesthetics, benzocaine is widely used in dental procedures. Benzocaine is an FDA-approved anesthetic, available in different forms and concentrations, with a 20% gel being the most frequently used in dentistry due to its quick onset of action—typically within 30 seconds—and a duration of approximately 5 to 15 minutes (4, 5). EMLA, a eutectic mixture of lidocaine and prilocaine, is another topical anesthetic that has been extensively used in medical settings to reduce pain during procedures such as venous cannulation. The eutectic mixture allows for a lower melting point than its individual components, facilitating the application of higher concentrations of anesthetic (6). EMLA's effectiveness in alleviating discomfort in various medical contexts has prompted its consideration in dental procedures as well (7).

While there is a substantial body of literature documenting the pharmacological and psychological effects of both benzocaine and EMLA in pain management, there remains a gap in the evidence regarding their comparative effectiveness when used concurrently in oral mucosa, particularly in populations such as those in Karachi. This study aims to address this gap by evaluating the impact of 5% EMLA and 20% benzocaine on pain perception during local anesthetic injections in an adult population. By conducting this study in a split-mouth design, we sought to provide a direct comparison of these two topical anesthetics under controlled conditions, thereby contributing valuable insights into their relative efficacy in dental pain management (8, 9).

Manuscript Submitted under JHRR ID 1415: July 12/2024 | Accepted: August 09/2024

MATERIAL AND METHODS

The study was designed as a double-blind, split-mouth clinical trial and conducted in the Department of Oral and Maxillofacial Surgery at Dr. Ishrat-ul-Ebad Khan Institute of Oral Health Sciences, Dow University of Health Sciences, Karachi. Ethical approval was obtained from the institutional review board (Approval No. 2021/568), and the study adhered to the principles outlined in the Declaration of Helsinki, ensuring the ethical treatment of all participants.

A total of 70 patients, indicated for bilateral extraction with identical local anesthesia procedures, were recruited for the study. The sample size was calculated using the Epi calculator, ensuring adequate power to detect significant differences between the two treatment conditions. Patients aged 18 to 35 years, who were interested in participating, were included, while those with allergies to local anesthesia, a history of methemoglobinemia, current use of antidepressant or antipsychotic medications, or localized inflammation or discomfort at the injection site were excluded. Participants were informed about the study's purpose, procedures, and potential risks, and written informed consent was obtained before their inclusion in the trial.

Participants were asked to provide a detailed medical history, which was reviewed to confirm their eligibility. The study involved two conditions: Condition A, in which 5% EMLA cream was applied, and Condition B, where 20% benzocaine gel was used. The primary investigator was responsible for marking the injection sites on the oral mucosa before exiting the room. A consultant, blinded to the study conditions, applied the topical anesthetics—5% EMLA to the experimental area and 20% benzocaine to the control area. Following a pretreatment period with the topical anesthetic, the consultant administered local anesthesia to both sides using a standardized injection technique. The principal investigator, who was unaware of the treatment allocations, re-entered the room to assess the patients' pain levels using a Visual Analog Scale (VAS). The assessment was subsequently verified by a supervising consultant to ensure consistency and accuracy.

Data were collected and entered into a database for analysis. Demographic data, including age, gender, weight, and height, were recorded for each participant. The primary outcome measure was the VAS score, which was assessed at three time intervals: three, six, and nine minutes after the administration of local anesthesia. The VAS scores were compared between the two groups using an independent sample t-test, with stratification by age groups and topical anesthetic type to evaluate the effects on pain perception. A p-value of ≤0.05 was considered statistically significant. Data analysis was performed using SPSS version 25, with means and standard deviations calculated for quantitative variables.

Throughout the study, all procedures were conducted in accordance with the highest standards of clinical research, ensuring the validity and reliability of the findings. The double-blind design, along with the rigorous assessment and data analysis protocols, aimed to minimize bias and provide robust evidence on the comparative efficacy of 5% EMLA cream and 20% benzocaine gel in reducing pain during local anesthetic injections in the oral mucosa.

RESULTS

The study included a total of 70 participants, with an age range of 18 to 35 years and a median age of 29.4 years. The demographic characteristics of the participants are summarized in Table 1. The majority of participants were male (60%), with a mean weight of 65.43 kg (± 8.87) and a mean height of 155.9 cm (± 20.0).

Table 1: Demographics of Participants

Variable	Mean ± SD	Frequency (n)
Age (years)	29.66 ± 11.75	
Weight (kg)	65.43 ± 8.87	
Height (cm)	155.9 ± 20.0	
Gender (M/F)		42/28

The primary outcome measure was the Visual Analog Scale (VAS) score, recorded at three, six, and nine minutes post-administration of local anesthesia. The mean VAS scores for both the EMLA and benzocaine groups at each time point are presented in Table 2. The EMLA group consistently demonstrated lower mean VAS scores compared to the benzocaine group at all three time intervals.

Table 2: Comparison of VAS Scores Between EMLA and Benzocaine Groups

Time Point (Minutes)	EMLA Mean ± SD	Benzocaine Mean ± SD	p-value
3 Minutes	3.00 ± 2.04	4.00 ± 1.00	0.035
6 Minutes	3.00 ± 2.04	4.23 ± 1.38	0.005
9 Minutes	3.00 ± 2.04	4.00 ± 1.53	0.004

The results indicate a statistically significant difference in VAS scores between the EMLA and benzocaine groups at three, six, and nine minutes ($p < 0.05$). The EMLA group exhibited lower pain scores, suggesting that EMLA cream was more effective in reducing pain during local anesthetic injections than benzocaine gel.

Further analysis revealed no significant differences in VAS scores between the two groups when stratified by gender or age, indicating that both topical anesthetics were equally effective across these variables. The lack of significant interaction effects suggests that the effectiveness of EMLA

and benzocaine does not vary significantly with patient demographics.

Table 3: Analysis of Variance Between Groups

Variable	Mean Square	p-value
Benzocaine Group (3, 6, 9 min)	3.049	0.539
Within Groups	4.948	-
EMLA Group (3, 6, 9 min)	8.634	0.168
Within Groups	4.823	-

As shown in Table 3, the analysis of variance within the benzocaine and EMLA groups did not reveal statistically significant differences in mean VAS scores across the different time points. This further supports the finding that both anesthetics performed consistently over time.

In summary, the results of this study suggest that 5% EMLA cream is more effective than 20% benzocaine gel in reducing pain associated with local anesthetic injections, as evidenced by lower VAS scores at three, six, and nine minutes post-administration. Both topical anesthetics were equally effective across different genders and age groups, indicating their general applicability in clinical practice.

DISCUSSION

The findings of this study provide important insights into the comparative efficacy of 5% EMLA cream and 20% benzocaine gel in reducing pain associated with local anesthetic injections. The results demonstrated that EMLA cream was significantly more effective in lowering pain scores at all measured time points—three, six, and nine minutes post-administration—compared to benzocaine gel. These results align with previous research indicating the superior analgesic properties of EMLA, particularly in dental and minor surgical procedures (2, 9).

The effectiveness of EMLA can be attributed to its unique formulation, a eutectic mixture of lidocaine and prilocaine, which allows for deeper penetration into the mucosa and a more prolonged duration of action compared to benzocaine. Benzocaine, while effective in many clinical scenarios, has a shorter duration and may not penetrate the tissues as effectively as EMLA, which could explain the higher VAS scores observed in this study (Park et al., 2020; Rivera et al., 2020).

This study also highlighted the generalizability of the findings, as the effectiveness of both topical anesthetics was consistent across different age groups and genders. This suggests that the analgesic effects of EMLA and benzocaine are not significantly influenced by demographic factors, supporting their broad applicability in diverse patient populations. However, the lack of statistically significant differences within each group across the three time points may indicate that while EMLA was generally more effective, the temporal variation in pain reduction was minimal (18-20).

One of the strengths of this study was its double-blind, split-mouth design, which minimized potential biases and ensured that each participant served as their own control. This design is particularly valuable in pain research, where subjective measures such as VAS scores are used. Additionally, the use of a standardized injection technique and rigorous assessment protocols contributed to the reliability of the findings.

Despite these strengths, the study had certain limitations. The sample size, while calculated to be adequate, may not have been large enough to detect subtle differences in efficacy between the two anesthetics, particularly when stratified by demographic variables. Furthermore, the study was conducted in a single clinical setting, which may limit the generalizability of the findings to other populations or clinical environments. Another limitation was the reliance on VAS scores as the sole measure of pain, which, while widely used, is inherently subjective and may be influenced by factors such as patient anxiety or prior experiences with dental procedures (1, 4).

In light of these findings, it is recommended that clinicians consider the use of EMLA cream as a more effective alternative to benzocaine for pre-injection analgesia, particularly in procedures where deeper tissue penetration is required. Future research should explore the efficacy of these topical anesthetics in larger, more diverse populations and in different clinical settings to further validate these results. Additionally, studies incorporating objective measures of pain, such as physiological responses, could provide a more comprehensive understanding of the analgesic effects of these agents (19-22).

CONCLUSION

In conclusion, this study contributes to the growing body of evidence supporting the use of EMLA cream over benzocaine gel for reducing pain associated with local anesthetic injections. The findings have important implications for clinical practice, particularly in improving patient comfort and reducing anxiety during dental procedures. While further research is needed to confirm these results, the current study provides a strong rationale for the preference of EMLA in situations where effective and sustained analgesia is required.

REFERENCES

1. Solanki N, Mounsey A, Hadley A. EMLA Cream Versus Benzocaine for Topical Anesthesia in Minor Skin Procedures: A Systematic Review. J Am Board Fam Med. 2020;33(2):298-307.
2. Ekback G, Kalman S, Jakobsson JG. A Randomized, Double-Blind Study Comparing EMLA Cream with Benzocaine Gel for Pain Reduction During Minor

Dermatological Procedures. Acta Anaesthesiol Scand. 2019;63(6):759-764.
3. Patel T, Carlson D, Dove J. Efficacy of EMLA and Benzocaine for Pain Control During Pediatric Immunizations: A Comparative Study. Pediatr Pain Manag. 2019;7(3):124-129.
4. Lonsdale D, Medlicott NJ, Sud NZ. Comparing the Analgesic Effects of EMLA and Benzocaine in Pediatric Patients: A Randomized Clinical Trial. Anesth Pain Med. 2021;11(4).
5. Park S, Lee SJ, Cho S. Topical Anesthetics for Dental Procedures: A Comparison Between EMLA and Benzocaine. J Dent Anesth Pain Med. 2020;20(3):143-148.
6. Rivera B, Harshavardhan B, Thompson A. Effectiveness of EMLA Versus Benzocaine for Pain Relief During Peripheral Venous Cannulation in Adults: A Meta-Analysis. J Clin Anesth. 2020;64:109821.
7. Wong CY, Kaur A, Kouhestani F. EMLA Versus Benzocaine for Analgesia in Minor Surgical Procedures: A Comparative Study. Surg Med Open J. 2019;5(2):39-44.
8. Chen F, Han X, Tang Y. Efficacy of EMLA Cream and Benzocaine Gel for Pain Control in Children Undergoing Venipuncture: A Systematic Review and Meta-Analysis. J Clin Pediatr Dent. 2021;45(2):95-100.
9. Wang C, Zheng Z, Li J. Comparison of EMLA and Benzocaine for Reducing Pain During Urethral Catheterization in Children: A Randomized Controlled Trial. J Urol. 2021;205(5):1252-1258.
10. Zhang J, Wu T, Liu J. A Prospective Study on the Analgesic Effects of EMLA Cream and Benzocaine for Venipuncture in Pediatric Patients. Front Med. 2020;14(4):456-462.
11. McWilliams SR, Potts A, Flynn B. Comparing EMLA and Benzocaine in Reducing Pain During Intramuscular Injections: A Randomized Clinical Trial. Pain Pract. 2019;19(7):725-731.
12. Hutchins HS Jr, Young FA, Lackland DT, Fishburne CP. The Effectiveness of Topical Anesthesia and Vibration in Alleviating the Pain of Oral Injections. Anesth Prog. 1997;44(3):87-92.
13. Gupta S, Mehta R, Verma N. Efficacy of EMLA Versus Benzocaine for Pain Management During Arterial Blood Gas Sampling: A Double-Blind, Randomized Study. Pain Res Manag. 2020;2020:8739564.
14. Martin L, Burkard JF, Lerman J. EMLA Versus Benzocaine for Procedural Pain in Pediatric Oncology Patients: A Comparative Study. J Pediatr Oncol Nurs. 2021;38(5):267-274.
15. Johnson R, McDonald J, Peters M. A Randomized Controlled Trial Comparing EMLA and Benzocaine for Pain Relief During Venipuncture in Neonates. J Pain Symptom Manage. 2019;58(4):732-739.
16. Al-Melh MA, Andersson L. Comparison of Topical Anesthetics (EMLA/Oraqix vs. Benzocaine) on Pain Experienced During Palatal Needle Injection. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2007;103(5):16-20.
17. Singh S, Jayant BS, Gupta K. Diminution of Pain From Needle Insertion in Palatal Mucosa by Two Topical Anaesthetics: A Comparative Study Between Lidocaine/Prilocaine (EMLA) and Benzocaine. J Adv Med Dent Sci Res. 2015;3(3):9-15.
18. Primosch RE, Rolland-Asensi G. Comparison of Topical EMLA 5% Oral Adhesive to Benzocaine 20% on the Pain Experienced During Palatal Anesthetic Infiltration in Children. Pediatr Dent. 2001;23(1):11-14.
19. Bhalla J, Meechan JG, Lawrence HP, Grad HA, Haas DA. Effect of Time on Clinical Efficacy of Topical Anesthesia. Anesth Prog. 2009;56(2):36-41.
20. Hegedus F, Herb K. Benzocaine-Induced Methemoglobinemia. Anesth Prog. 2005;52(4):136-139.
21. Arendt-Nielsen L, Smith L, Petersen-Felix S. A Comparison of EMLA and Benzocaine for Reducing Pain During Minor Dermatological Procedures: A Double-Blind Study. Pain Med. 2019;20(12):2462-2469.
22. Tang Q, Wu H, Zheng C. Efficacy of EMLA Cream and Benzocaine Gel in Reducing Pain During IV Cannulation in Pediatric Patients: A Systematic Review. Pain Ther. 2021;10(1):41-52.