



A COMPARATIVE EVALUATION OF PAIN PERCEPTION FOLLOWING APPLICATION OF EUTECTIC MIXTURE OF LOCAL ANESTHETIC (EMLA) AND CLOVE GEL BEFORE INTRAORAL INJECTION IN CHILDREN

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ABSTRACT

Objectives: The aim of the present study was to evaluate the effect of topical application of 2% lignocaine local anesthetic agent, eutectic mixture of local anesthetics (EMLA) and clove based topical anesthetic agent before intraoral injection in children. **Subjects and methods:** A total of 96 children were selected on their need for infiltration anesthesia for operative procedures divided into three groups Group A (EMLA), Group B (Clove Oil) and Group C (Lignocaine 2%). Pain was evaluated using Wong-Baker FACES pain rating scale and Sound Eye Motor Scale (SEM) by observing the child behavior during anesthesia administration. **Results:** All three types of topical anesthetic agents decreased pain associated with a local anesthetic injection delivered via infiltration only. EMLA Group and Clove Oil Group had significantly lower pain scores than those in Lignocaine Group. **Conclusion:** Both EMLA Group and Clove Oil Group had better results in relief of pain than Lignocaine Group.

KEYWORDS: Local anesthetic, EMLA clove GEL, SEM, Wong-Baker.

INTRODUCTION

One of the most important components of contemporary dentistry that might impact a patient's quality of life is dental pain management. To give patients a pain-free environment, many strategies are offered. One of such techniques is desensitization of the oral location with topical anaesthetics ⁽¹⁾. One of the most significant advancements in dentistry research over the past few years has undoubtedly been the development of topical anaesthetic drugs. The majority of them are secure and are used on oral mucosa ⁽²⁾.

At present, these agents are various with different potent and indications, such as clove based an-

esthetic gel, EMLA "eutectic mixture of local anesthetics" and 2% lignocaine gel which can be used in pediatric patients⁽³⁾. According to the World Health Organization, 80% of the people in the developing countries most solely rely on herbal ayurvedic medicines for primary health care services ⁽⁴⁾.

Clove has historically been used as a seasoning in food, but it has also been applied topically to cure toothaches because it contains eugenol, an oily substance with analgesic and antibacterial characteristics that is frequently employed in dentistry ⁽⁵⁾. The commercially available clove was ground into a fine powder, and then it was combined in a 2:3 (clove: glycerin) by volume ratio with liquid glycerin to create the clove gel ⁽⁶⁾.

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Eutectic mixture of local anesthetics (EMLA) is a eutectic combination of 2.5% lidocaine and 2.5% prilocaine which has gained aficionados for dental procedures lately⁽⁷⁾. It consists of a mixture of two crystalline powders (2.5% lidocaine and 2.5% prilocaine), which has a melting point below room temperature which turn into a liquid oil. In this way, it would be able to penetrate intact skin or mucosa into a depth of 5 mm⁽⁸⁾. The aim of this study was to investigate the efficacy and compare the topical anesthetic effect of a clove based gel, 2% lignocaine gel and EMLA mixture in reducing pain from needle sticks.

SUBJECTS AND METHODS

Study design

A prospective blind randomized controlled clinical study.

Study setting and population

This study was conducted on (96) healthy children aged 6-10 years who requires local anesthetic injections for dental procedures. Children were selected from an Outpatient Clinic of the Department of Endodontics and Oral Health, Faculty of Dental Medicine, Al-Azhar University, Cairo, Boys. Consent from was taken from parents. Their selection was based on their need for infiltration anesthesia for operative procedures.

Children were equally divided according to used method into three groups as following: **Group A(EMLA):** In this group (n=32) children were received EMLA "Under trade name of EMLA 5% from AstraZeneca company, Sweden.

Group B (Clove oil): In this group (n=32) children were received clove gel as topical anesthetic agent.

Group C(2% Lignocaine): In this group (n=32) children were received 2% lignocaine "under trade name of lignocaine 2 % from The Nile Co. for pharmaceuticals & chemicals industries, Egypt.

Patient selection

Selection of patients were based on specific inclusion and exclusion criteria as the follow:

Inclusion criteria:

The inclusion criteria include an age ranged from (6-10) years, Patients requiring infiltration local anesthesia for dental procedures and Patients who are willing to participate in the study.

Exclusion criteria:

The exclusion criteria include Patients with a history of systemic disease, psychiatric disorders, sensitive skin or dental abscess in the site of the procedure, Patients who have allergic history to local anesthesia and Uncooperative patients.

Sample size calculation:

Sample size was estimated based on a previous study "Abdelmoniem & Mahmoud (2016)". Sample size calculation was done using G. Power program version 3.1.9.4. The minimum required sample size was calculated to be 96 (32 in each group) to be sufficient to detect effect size of $f = 0.432$, a power of 80%, and a significance level of 5%, all tests are 2 tailed⁽⁹⁾.

Ethical considerations:

The study was approved by the Pedodontics scientific Committee and department council, Faculty of Dental Medicine, Boys, Cairo, AlAzhar University. A signed informed consent was obtained from the parents of each subject prior to entry into the study with approval EC Ref. No. (537/2676).

Clove gel preparation:

The clove gel was prepared by grinding commercially available clove to fine powder and then mixing it with liquid glycerin from HUMCO company, India in a ratio of 2:3 (clove: glycerin) by volume⁽⁶⁾.

Procedures:

History taking:

History was taken from the child and his parents including personal, medical and dental history to assess inclusion criteria.

Clinical procedure:

All of the anesthetic injections were administered by the same operator in the three groups.

Technique for topical anesthesia application:⁽⁹⁾

Once the children are randomly allocated into the respective groups, the site for application of the topical anesthetic agent was to be determined, marked, and isolated. The site of the injection was dried then prepped with antiseptic solution (Betadine®) on a cotton tip applicator figure (1). The topical anesthetic agent was applied in the respective groups for 1 min using sterile cotton applicator on the mucosa at the site of treatment needs of the patient figure (2). Local anesthetic injection was performed.

Assessment:

Both subjective and objective assessment was done using Wong-Baker FACES and the Sound Eye Motor scale (SEM) where: For the subjective assessment, each child was given a printed form of the Wong-Baker Faces Pain Rating Scale and asked to choose one face that best describes the pain that he/she felt. The Wong-Baker scale includes 6 colored cartoon faces which values from 0 to 10. Where “0” = no hurt, “2” = hurts little bit, “4”= hurts little more, “6”= hurts even more, “8”= hurts whole lot and “10”= hurts worst. This scale was introduced and explained carefully to the children in advance.

For the objective assessment, the SEM scale was used. The Sound, Eye, Motor Scale (SEM scale)

evaluation was carried out by trained personnel present in the dental operator. The procedures were video recorded for future references. The scores were calculated and tabulated. This scale includes sound, eye (cry, tears) and motor(activity).



FIG (1) Applying antiseptic solution prior the injection.



FIG (2) Applying topical anesthesia prior the injection.

Sound, Eye, Motor Scale for the assessment of child’s behavior.

Score	Designation	Sounds	Eyes	Motor
0	Comfort	No sound indicating pain	No eye signs of discomfort	Hands, relaxed, no apparent body tenseness
1	Mild discomfort	Nonspecific possible pain indication	Eyes wide show of concern, no tears	Hands show some tension
2	Moderately painful	Specific verbal complaint e.g. ow! Voice raised	Watery eyes	Random movement of arms/body grimace, twitch
3	Painful	Verbal complaint indicates intense pain	Crying tears running down the face	Movement of hands to make aggressive physical contact, pulling head away punching

Score sum.

Statistical analysis of the data

With the aid of the IBM SPSS software package version 20.0, data were fed into the computer and evaluated. IBM Corp., Armonk, New York Number and percentage were used to describe qualitative data. The normality of the distribution was examined using the Shapiro-Wilk test. The range (minimum and maximum), mean, standard deviation, and median were used to characterize quantitative data. The significance of the results was assessed at the 5% level.

RESULTS

Relation between groups regarding to gender:

It has been shown that among the cases of EMLA group there were 15 (46.9%) females and 17 (53.1%) males, among the cases of Clove Oil group there were 14 (43.8%) females and 18 (56.2%) males and among the cases of Lignocaine group there were 19 (59.4%) females and 13 (40.6%) males.

The results of Chi-square test showed that there was no statistically significant difference between groups regarding to gender where $p = 0.417$ and were summarized in (Table 1).

TABLE (1) Distribution of the studied cases according to Gender

		Group (A) EMLA (n = 32)	Group(B) Clove oil (n = 32)	Group(C) Lignocaine (n = 32)	P
Gender	Female	No.	15	14	0.417
		%	46.9	43.8	
	Male	No.	17	18	
		%	53.1	56.2	

*SD: Standard deviation F: F for ANOVA test
p: p value for comparing between the studied groups*

SEM Scale

Table (2) summarizes Comparison between the three studied groups according to SEM Scale. There was a statistically a significant difference between groups ($p < 0.001^*$). **EMLA Group** showed a higher percentage of children showing a Comfort (81.3%) and only 18.8 % with Mild discomfort. **Clove Oil Group** showed a higher percentage of children showing a Comfort (81.3 %) with Mild discomfort and 18.8 % with Moderate while **Lignocaine Group** showed Mild discomfort to Moderate to Sever.

TABLE (2) Comparison between the three studied groups according to SEM Scale

SEM Scale	Group A (EMLA) (n = 32)		Group B (Clove Oil) (n = 32)		Group C (2% Lignocaine) (n = 32)		χ^2	MCp
	No.	%	No.	%	No.	%		
Comfort	26	81.3	0	0.0	0	0.0	90.140*	<0.001*
Mild discomfort	6	18.8	26	81.3	12	37.5		
Moderate	0	0.0	6	18.8	13	40.6		
Sever	0	0.0	0	0.0	7	21.9		

*c²: Chi square test MC: Monte Carlo
p: p value for comparing between the studied groups
: Statistically significant at $p \leq 0.05$

WBF Score

Table (3) summarizes Comparison between the three studied groups according to WBF Score. There was a statistically a significant difference between groups ($p < 0.001^*$). **Group A (EMLA)** showed a higher percentage of children showing No hurt (62.5 %) and only 18.8 % showed hurt little bit and

hurt little more. **Group B (Clove Oil) and Group C (2% Lignocaine)** showed a higher percentage of children showing No hurt (25.0%) with hurt Even more and (56.3 %), 6.3 % hurt Little bit and hurt Little more while **Group C (2% Lignocaine)** showed 40.6 % hurt Even more, 37.5 % hurt Whole lot and 21.9 % hurt Worst.

TABLE (3) Comparison between the three studied groups according to WBF Score

WBF Score	Group A (EMLA) (n = 32)		Group B (Clove Oil) (n = 32)		Group C (2% Lignocaine) (n = 32)		χ^2	MCp
	No.	%	No.	%	No.	%		
No hurt	20	62.5	8	25.0	0	0.0		
Hurt Little bit	6	18.8	2	6.3	0	0.0		
Hurt Little more	6	18.8	2	6.3	0	0.0		
Hurt Even more	0	0.0	18	56.3	13	40.6		<0.001*
Hurt Whole lot	0	0.0	2	6.3	12	37.5		
Hurt Worst	0	0.0	0	0.0	7	21.9		

χ^2 : Chi square test MC: Monte Carlo
 p: p value for comparing between the studied groups
 *: Statistically significant at $p \leq 0.05$

DISCUSSION

The results of the present study showed that, there was a statistically a significant difference between groups ($p < 0.001^*$). EMLA group showed a higher percentage of children showing a Comfort (81.3%) with no Comfort in the other two groups. 81.3% of Clove oil showed a Mild discomfort while Lignocaine group showed Mild discomfort to Moderate to Severe. In the present study, there was a statistically a significant difference between groups ($p < 0.001^*$). EMLA group showed a higher WBF Score percentage of children showing No

hurt (62.5%) while Clove oil and Lignocaine group showed a higher percentage of children showing No hurt (25.0, and 0.0% respectively. with hurt Even more and (56.3%, 40.6%) in Clove oil and Lidocaine groups. Regarding WBFPS in the present study, the results revealed that the use of EMLA cream prior to local anesthetic injection had a significant reduction in the perceived pain in the children ($p < 0.001^*$) compared to Clove oil and Lignocaine groups. These results were in agreement with Walimbe⁽¹⁰⁾ and Sruthi⁽¹¹⁾ who found that EMLA 5% cream proved to be superior in pain reduction.

In agreement to our results, a study by Nayak R⁽¹²⁾ concluded that 5% of EMLA cream provided superior pain reduction compared to 18% benzocaine gel and 5% lignocaine. However, it was a bilateral double-blinded interventional study done in two phases.

The superiority of EMLA cream in the present study could be attributed to the deeper depth of penetration i.e about 5mm whereas other topical anesthetics have a penetration depth of only 2-3 mm²³. EMLA has a high pH of 9.6 and Setnikar⁽¹³⁾ stated that increasing the pH increases the potency of the topical anaesthetic agent. Dasaraju⁽¹⁴⁾ contradict these results where they revealed that EMLA group had significantly higher pain scores for self-report ($P < 0.001$).

EMLA 5% cream was reported to be superior to four other topical agents and a placebo in its ability to increase pain threshold to intraoral pressure in adults⁽¹⁵⁾. This application to keratinized gingiva holds promise in reducing pain created by rubber dam clamp placement where isolation without local anesthesia is preferred for some clinical procedures such as sealants and preventive resin restorations. In a recent clinical trial, Tulga and Mutlu⁽¹⁶⁾ compared injection pain following the topical application of EMLA 5% cream to benzocaine 20% gel in 20 children, aged 10-15 years, receiving bilateral buccal infiltrations. They concluded, based on VAS measurements, that benzocaine and EMLA was statistically better in reducing injection pain during maxillary infiltration and that benzocaine had better taste acceptance in children.

Eutectic mixture of local anesthetics (EMLA) contains both lidocaine 2.5% and prilocaine 2.5%. It significantly reduced the injection pain among adults during the delivery of dental anesthetic. In addition, it was shown that EMLA 5% cream worked well to lessen the discomfort associated with basic restorative dental operations such gingival probing, periodontal scrubbing, and even the removal of

arch bars⁽¹⁷⁾ In a research by Holst and Evers that involved adult participants, EMLA was shown to be superior to “standard” intraoral topical treatments in the palate⁽¹⁸⁾.

The most well-known and often used spices in India are cloves, which have a variety of physiologically active chemicals that give them their therapeutic and anaesthetic effects. Because of these qualities, we chose both spices for our investigation. The synthesis of clove oil, which has active ingredients such eugenol, eugenyl acetate, and gallic acid and has antibacterial, anti-inflammatory, antifungal, antithrombotic, antidiabetic, analgesic, and anaesthetic effect, is how cloves are used commercially⁽¹⁹⁾. The stimulation of calcium and chloride channels in ganglion cells has been suggested as the mechanism underlying analgesic action. According to Raghavenra et al.⁽²⁰⁾, eugenol’s capacity to suppress prostaglandins and other inflammatory mediators is what gives it its analgesic properties. Daniel et al. demonstrated the peripheral analgesic efficacy of eugenol, demonstrating substantial action at dosages of 50, 75, and 100 mg/kg⁽²¹⁾.

In the present study, clove oil showed Clove oil showed a higher percentage of children showing a Comfort (81.3 %) with Mild discomfort and 18.8 % with Moderate. A study by Alqareer et al⁽²²⁾. found that clove gel and benzocaine gel significantly lowered the mean pain score, and no significant difference was observed between them. Similarly, when clove oil was compared with lignocaine in the present study, it was observed that clove oil was more potent.

CONCLUSION

Based on the results of the present study, the following conclusions can be delivered: Both EMLA Group and Clove Oil Group had better results in relief of pain than Lignocaine Group. There were significant differences between the three groups.

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