Use of EMLA®: is it an injection free alternative?

A.K. Munshi* / Amitha M. Hegde** / R. Latha***

This study was conducted to evaluate the use of Eutectic Mixture of Local Anesthetics (EMLA®) for various clinical procedures such as extraction of the mobile primary teeth, root stumps as well as pulpal therapy procedures in the primary teeth. Thirty children in need of routine dental procedures were selected and procedures were done under a single anesthesia of EMLA®. Pain perception and the effectiveness of anesthesia were evaluated with the Eland's color scale and Lickert's scale respectively. Results showed that use of EMLA® could to some extent eliminate the use of the needle in the procedures performed especially in pediatric dentistry.
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INTRODUCTION

A number of different types of topical anesthetic agents for intraoral use are available. They appear to be equally effective in obtaining surface anesthesia of the oral mucosa.[1] However, effective administration of a local anesthetic without the need for injection would be a major advantage in dental pain control. Benefits to the patient and operators might include anxiety reduction and a decline in the number of needle stick injuries.[2]

Eutectic Mixture of Local Anesthetics (EMLA®) is a recently introduced topical anesthetic agent approved for medical applications.[3] The medical use is mainly to achieve anesthesia of the skin. The cream has been studied extensively since the first published study in 1980.[3] EMLA® has been shown to reduce the pain caused by venous cannulations and to provide sufficient anesthesia for the harvesting of skin grafts.[4-6] Eutectic mixture of Lignocaine and Prilocaine has been found to possess a local anesthetic effect on oral mucosa also.[7]

* Dr. A. K. Munshi, Senior Professor and Head, Department of Pedodontics and Preventive Children's Dentistry, A B Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangalore – 574160.

** Dr. Amitha M. Hegde, Associate Professor, Department of Pedodontics and Preventive Children's Dentistry, A B Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangalore – 574160.

*** Dr. R. Latha, Post Graduate student, Department of Pedodontics and Preventive Children's Dentistry, A B Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangalore – 574160.

Send all correspondence to Dr. A. K. Munshi, 3 C, Crescent Manor, New Balmatta Road, Mangalore — 575001, Kamataka, India.

Each gram of EMLA® contains[8] Lignocaine 25mg/ml, Prilocaine 25mg/ml, Arlatone 289® as emulsifier, Carbopol 234® 10 mg as thickener and sodium hydroxide added to bring the pH to 9.6. Lignocaine and Prilocaine have melting points of 69˚C and 37˚C respectively. However, when these agents are combined in eutectic form, the melting point of the mixture is lowered to 17˚C. This new physical property allows the anesthetic agents to form an oil at mouth temperature (37˚C) and thus facilitate increased absorption of the local anesthetic agents.[9] Additionally, if Lignocaine is emulsified, there is only about 20% active substance in each emulsion droplet, the rest being oil. Lignocaine and Prilocaine crystals when mixed, will form a eutectic mixture, which produces an emulsion droplet with approximately 80% of the active local anesthetic substance,[10] thus exposing the tissues to exceptionally high local anesthetic concentration.[8]

Vickers and Punnia-Moorthy[9] investigated the application of EMLA®, 10% lignocaine, and placebo on the response to electrical pulp testing of the maxillary central incisors respectively. Although their study was not subjected to statistical analysis, EMLA® was effective in reducing the pulpal response as 12 of the 13 volunteers in whom it was applied and who showed no response to electrical pulp testing between 15 and 30 minutes of application. However, some of the lignocaine and placebo treated cases also showed reductions in pulpal response including the failure to respond their maximum stimulation from the pulp tester.

Vickers *et al.*[11] performed an uncontrolled pilot study into the effectiveness of 1g topical EMLA® as an alternative to infiltration anesthesia as pain control for restorative procedures on teeth in 12 patients. They reported that 75% of the subjects obtained "adequate analgesia" for "drilling" and concluded that this method produced sufficient, but not complete, anesthesia to allow restorative dentistry to be performed.

Meechan and Donaldson[12] compared the effects of a 5 minutes application of 5% lignocaine and EMLA® in reducing the discomfort of the maxillary infiltration injections in children. No difference in injection discomfort was noted between the treatments.

After the application of EMLA® for about 4 minutes, the maximal analgesic effect was reached in 13 ± 8 minutes due to the rapid absorption of local anesthetics of EMLA®[8]. Because of relatively short application time, rapid absorption into the circulation, as well as good regenerative capacity of the oral mucosa, tissue toxicity does not impose a risk when EMLA® is topically applied on mucous membrane with techniques described.

Considering the above presented facts about EMIA®, this study was to evaluate the efficacy of the use of EMIA® for various clinical procedures in pediatric dentistry.

MATERIAL AND METHODS

Patient selection

Thirty children between 4 to 13 years in age, who were attending the pediatric dental clinic at A. B. Shetty Memorial Institute of Dental Sciences, Deralekatte, Mangalore were treated with the use of EMLA®, in order to evaluate the efficacy of EMIA® for various procedures in clinical pediatric dentistry. These children seeking dental treatment were otherwise healthy, co-operative and not color blind. They attended schools at the appropriate grade levels relative to their respective ages. They were receptive to dental treatment and did not require special intervention such as restraint or conscious sedation. They were not on any methemoglobulinemia-inducing drugs within the previous week. The parents of these children also consented to the procedure to be performed under anesthesia with EMLA®.

Based on the treatment required, these children were categorized as:

Category 1 Fifteen children requiring surgical treatment: including extraction of the mobile primary teeth, root stumps of primary teeth, incision and drainage of abscesses.

Category 2 Fifteen children requiring restorative and/or endodontic treatment: including rubber dam application, deep carious lesion restoration, pulpal therapy including indirect pulp capping, pulpotomy and pulpectomy and stainless steel crown restoration.

Procedure for application of EMLA®

The buccal sulcus in relation to the concerned tooth was wiped free of saliva and isolation was maintained with the cotton rolls and suction tip. About 0.5gm of EMLA® was taken on a 2"x 2" folded gauze piece. It was then placed on the buccal gingiva nearer the sulcus and kept in position for 10 minutes. Objective signs of anesthesia were then checked by a blunt probe. In the case of extraction, the lingual / palatal side was also anesthetized in a similar manner. After sufficient anesthesia was achieved, the required treatment procedure was done.

In case the topical anesthetic was found to be ineffective, conventional local anesthesia by means of injection was done.

Evaluation

The effectiveness of EMLA® was evaluated by the patient using the Eland's color scale.[13] Before the color scale was used, each child was interviewed about the events that had hurt in the past. Each child was presented eight colored squares in a row in the same order (yellow, orange, red, green, blue, purple, brown and black) across the top of a white felt board and then asked, which square he or she would choose when he or she had been hurt most, slightly less than the most hurting event, a mild hurt and no pain. The colors chosen by the child were arranged from the middle to the bottom of the felt board. They were assigned numerical values of 3, 2, 1, and 0 by the investigator.

The Eland's color scale was used before, during and after the respective procedure to assess the child's perception of pain. The child patient was asked to relate these painful experiences of the past of his or her to the present state of pain, at the time of dental procedure. The child's color selection was recorded corresponding to the following pain levels.

DEFINITION OF PAIN PERCEPTION SCORES

Score	Definition
3	An event identified by. the child as hurt the most.
2	An event identified by the child as hurt but less than the most painful event.
1	An event identified by the child as hurting a little.
0	No pain.

The effectiveness of anesthesia obtained was evaluated by the clinician by **5 point continuous (Licked) scale.**

Score	Definition
1	**Most ineffective**
2	**Ineffective**
3	**Slightly effective**
4	**Effective**
5	**Very effective**

Table 1. Pain perception scores by Eland's color scale by the patient

St. No.	Category	Eland Color Scale				Mean± SD
		0	1	2	3	
1	Category 1 (N=15)	2	7	4	2	1.4±0.91
2	Category 2 (N=15)	1	9	3	2	1.4±0.83

Table 2. Effectiveness of anesthesia by Lickert's scale by the clinician.

St. No.	Category	Lickert's Scale					Mean± SD
		1	2	3	4	5	
1	Category 1 (N=15)	0	2	0	7	6	3.88±1.41
2	Category 2 (N=15)	0	3	2	3	7	3.93±1.22

Table 3. Spearman's correlation coefficient between the scores by the patient and clinician.

St. No.	Category	Eland's Color Scale	Lickert's scale	Spearman's correlation	Signifi-cance
1	Category 1	1.4±0.91	3.88±1.41	r=0.716 at P<0.001	VHS*
2	Category 2	1.4±0.83	3.93±1.22	r=0.862 at P<0.0001	VHS*

* Very highly significant

Table 4. Success rates EMLA according to both the patient and the clinician

St.	Category	Acc. To the patient	Acc. To the clinician
1	Category 1	60.00%	86.60%
2	Category 2	66.76%	66.76%

The clinician's assessment of the effectiveness of anesthesia was based on the observation of the facial expression and the physical response (bodily movement) and on verbal complaints made by the patients at the time of the actual procedure.

STATISTICAL ANALYSIS

Data thus collected was later statistically analyzed by applying the Spearman's coefficient correlation between the clinician and the patient. Success rate was calculated by the percentage of the patients who felt no pain or mild pain according to the Bland's color scale and the percentage of the patients according to the clinician in whom the effectiveness of EMLA was effective or very effective according to the Lickert's scale.

RESULTS

Table 1 shows the pain perception scores by Eland's color scale by the patient. Table 2 shows the effectiveness: of anesthesia by Lickert's scale by the clinician. Table 3 shows Spearman's correlation coefficient between the scores by the patient and the clinician. Table 4 shows success rates of EMLA® according to both the patient and the clinician.

DISCUSSION

The ability of various topical anesthetics to penetrate the oral mucosa and produce anesthesia has been well documented.[15] Such applications in dentistry have led to the decrease in the level of pain experienced by the patients, thus resulting in greater acceptance of dental procedures.[16,17]

EMLA® is one such topical anesthetic, an eutectic mixture of Lignocaine and Prilocaine in equal proportions along with an emulsifier and a thickener.[3] Introduced for medical applications like, for intravenous cannulations and harvesting of skin grafts,[3] its use in the oral cavity was first documented by Holst and Evers in 1985. Since then, a number of studies have been conducted to investigate its efficacy for lowering the pain of injection[11,18] removal of arch bars,[19] and for increasing threshold to electrical pulp testing.[9] No study so far has attempted the various procedures of extractions, restorative / endodontic or periodontal treatment, under a single anesthesia of EMLA®. Hence this study was conducted to clinically evaluate the efficacy of EMLA® in the management of pain during various treatment procedures in children.

Both the patient and the clinician verbal descriptor scales were used to assess the pain perception and effectiveness of anesthesia before, during and after the procedure.

In category 1, 15 children, who underwent surgical treatment under the anesthesia of EMLA®, had mobile primary teeth or root stumps extracted along with a few teeth with more than 2/3rd roots intact. Using Eland's color scale, mean score for the category was 1.4 ± 0.91 indicating that majority of the patients felt only a mild hurt due to extraction, which was probably less than that would be experienced due to injection.

In category 2, 15 children underwent restorative / endodontic treatment, including deep carious lesion

restoration, pulpotomy, pulpectomy and stainless steel crown restoration under rubber dam application. While one child undergoing deep carious lesion experienced only mild pain, 4/5 patients undergoing pulpotomy were able to tolerate the procedure with just mild discomfort. Most of the patients undergoing pulpectomy were able to tolerate the coronal pulp extirpation, but when the root canal pulp extirpation was attempted, they tried to stop the treatment, indicating the failure of anesthesia. It must be noted that the teeth selected for pulpectomy were in the irreversible stage of pulpitis and had not undergone necrotic changes. Pulp extirpation attempted in one patient for a permanent tooth with the technique described by DeNunzio,[20] proved to be successful with the patient experiencing only mild discomfort.

Anesthesia is often a prerequisite for doing any treatment procedure likely to be associated with pain. However the act of inducing anesthesia through conventional injection itself acts as a deterrent and is cited to be one of ten fears children have about dental experience.[21] Hence EMLA®, though requiring a longer time of application under isolation, is still a valuable anesthetic technique in pediatric dentistry. Longer period of application could be appropriately used in verbal management, explaining about the procedure in simpler terms or even in counseling for oral hygiene.

Toxicity of Prilocaine has been said as one of the reasons for using EMLA® with caution. Two of the metabolites of Prilocaine, 4- hydroxy- 2 — methyl aniline and 0-toluidine, are capable of oxidizing hemoglobin to methemoglobin, EMLA® has the potential risk of inducing methemoglobinemia.[22] To date, only one clinically significant case of methemoglobinemia (methemoglobin concentration of 28%) has been reported following use of EMLA® cream.[17] This occurred with a prilocaine dose of 23.6mg/kg applied for 5 hrs in a 12 week old premature infant, who received concomitant trimethoprim-sulphamethoxozole, a therapy that is also capable of inducing methemoglobin formation. This case has been widely and erroneously publicized as proof of the danger of EMLA® cream to the newborn, even when applied in recommended doses.

Subsequently, three prospective studies[24-26] designed to investigate methemoglobin levels have been conducted in children and infants in which methemoglobin levels assessed up to 8 hours after the application were all within a normal range (maximum individual value was 2%). However, none of the children participating in our study showed any signs of cyanosis, symptomatic of methemoglobinemia considering the small amount of EMLA® required for anesthesia.

Svennson,[23] Meechan and Donaldson,[12] Meechan and Winter,[18] Vickers and Punnia-Moorthy,[9] advocated the use of orahesive bandages to keep EMLA® in position and isolation. In our study, placing EMLA® in contact with the mucosa with the help of a gauze piece and subsequent maintenance of isolation with cotton rolls and suction was adequate to obtain anesthesia. It is suggested that, if EMLA® impregnated intraoral patches impermeable to saliva, similar to the ones available for dermal use, are available it would be a major advance for its use intraorally.

In conclusion, it can be said that the use of EMLA® can be of help in eliminating the use of conventional injection in pediatric dentistry especially in performing the extraction of loose primary teeth or root stumps and cavity preparation under rubber dam and even pulpal therapy procedures like pulpotomy to some extent.

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