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Eutectic mixture of Local Anaesthetic (EMLA) an alternative for painful palatal nerve blocks: Randomised controlled trial

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ABSTRACT

The purpose of this study is to compare the efficacy of EMLA to Palatal nerve blocks in providing anaesthesia to the palatal soft tissues during extraction. Seventy patients who reported for extraction of maxillary premolar and maxillary molar tooth were included in this study. These patients were divided into two groups randomly. One group consisted of patients receiving EMLA (Eutectic mixture of Lidocaine and Prilocaine) over the palatal soft tissues adjacent to the tooth with a cotton swab, and the other group consisted of patients receiving 0.4 – 0.6 ml of 2% lignocaine with 1;2,00,000 dilution adrenaline slightly anterior to the greater palatine foramen with a syringe. The mean score VAS while applying EMLA cream in group A was 0.00. In contrast, while giving palatal nerve block in group B, it was 4.09 that was statistically significant using the independent sample t-test. Likewise, the mean VAS score while extraction in the EMLA group was 0.11, whereas in palatal nerve block group was 0.00 that was not statistically significant using independent sample t-test. EMLA may be advantageous in providing palatal soft tissue anaesthesia during prophylactic extraction, thereby avoiding painful palatal nerve blocks.

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INTRODUCTION

Anaesthesia is a state of temporary controlled loss of sensation or awareness that is induced for medical purposes. Local Anaesthetic agents are available in different forms such as Gels, lotions, patches and solutions. Several combinations of analgesics and local anaesthetics are available in the market (Benzocaine, Butamben and Tetracaine available as Cetacaine®, Lidocaine and Prilocaine available as EMLA® and Oraquix®, Lidocaine and Tetracaine available as Synera®). These formulations are administered for various indications in the medical field. These formulations are approved by the US FDA (Food and Drug Administration society) as topical anaesthetic agents (Kumar *et al.*, 2015).

Topical anaesthetic agents in dentistry are a vital component in performing easy subgingival scaling, atraumatic administration of intraoral local anaesthesia, periodontal probing (Stuart, 2002; Strain, 2014). Pain is the most common symptom bringing patients to the dental office. So the main aim is to perform a painless procedure in the dental chair. (Schuller *et al.*, 2003).

Many topical anaesthetics are available over the counter for dental use (Gill and Orr, 1979). An Injectable anaesthetic is considered to be the Gold standard technique to anaesthetize the soft tissues before performing an extraction. Although they are effective in controlling pain, a few draw backs have

been reported by patients, such as, fear of needle, prolonged-lasting numbness of the adjacent tissues. Among various sites, the palatal injection is the most painful because of the thick keratinized palatal mucosa (Badr and Bacho, 2017). In pediatric patients, Injectable Anesthesia administration by palatal route causes pain and this affects the child co-operation in the dental procedure.

So injectable anaesthesia is commonly used in conjunction with a topical anaesthetic agent (Johnson and Primosch, 2003).

EMLA cream (Eutectic Mixture of Local Anaesthetics) is a 5% eutectic mixture of lidocaine and prilocaine in a ratio of 1:1 by weight. It was designed as a topical anaesthetic that can provide surface anaesthesia to intact skin surfaces (Ehrenström-Reiz and Reiz, 1982). EMLA provides sufficient local anaesthesia in a variety of painful superficial procedures including superficial surgery, laser surgery, debridement of leg ulcers, cannulation as reported by many authors. Its role in dentistry is to provide surface anaesthesia to the skin before insertion of an intravenous cannula for sedation or General anaesthesia (Ehrenström-Reiz and Reiz, 1982; Manner *et al.*, 1987).

EMLA was initially not indicated for oral mucosa, but several authors have reported it as the most effective topical agent in highly keratinized regions of the oral cavity. (Haasio *et al.*, 1990; Tanaka, 1248). Studies have shown it to be effective in various minor procedures like gingival surgeries, sinus puncture, biopsies, arch bar removal and restorative procedures (Pere, 1992).

The oral mucosa is thinner and more vascular when compared to the dermal tissues, which facilitates rapid absorption of the lipophilic drug. Even though the drug is rapidly absorbed, studies have shown that the plasma concentration of the drug following application in the oral mucosa is less than the known toxic level of prilocaine and lidocaine.

The purpose of this study was to compare the efficacy of EMLA to conventional Palatal nerve blocks with 2% lignocaine, in providing anaesthesia of the palatal soft tissues during tooth extraction. In our study , the null hypothesis was there is no difference in pain perception between EMLA and palatal nerve block in patients undergoing extraction of posterior maxillary teeth.

MATERIALS AND METHODS

The study participants were recruited from the pool of patients in the Department of Oral and Maxillofacial Surgery at Saveetha Dental College, Saveetha Institute of Medical and Technical Sciences, India. Sample size estimation was done, and the minimum sample size of both groups were calculated, following these input conditions: the power of 0.95 and $P \leq 0.05$ and sample size arrived was 35 per group. The study was carried for a period of three months.

Ethical Clearance

Approval was obtained from the Institutional Review Board of Saveetha Institute of Medical and Technical Science, India.

Inclusion criteria

1. Healthy subjects above 12 years without any systemic disease were included in this study.

2. Subjects not under any analgesics or other medications 24 hours before extraction.

3. Subjects not allergic to any medicament.

4. Subjects who reported for prophylactic removal of premolars.

Exclusion criteria

1. Subjects with systemic disease, pregnancy or lactation were excluded.

2. Subjects reported with palatal abscess due to infection from the tooth were excluded from the study.

3. Subjects who had taken any analgesics 24 hours before extraction were excluded.

4. Subjects allergic to any medicament were excluded from the study.

Randomization was done well in advance by a third person who was not related to the study. Computer-generated random numbers were used for simple randomization of subjects. Sequentially numbered, opaque sealed envelopes (SNOSE) method was used to conceal the randomization sequence effectively. The computer-generated method is random and had an equal chance of occupying the position. Therefore, based on the result, a group was assigned. The CONSORT flow chart is shown in Figure 2.

Study Groups

Group A

EMLA group (n=35)

Group B

Palatal nerve block group (n=35)

Before the treatment, a careful medical and dental history of the included patients were taken. The treatment and the study design were explained to the qualifying patients, and informed consent was obtained from the voluntary patients who were willing to participate in the study.

A single operator performed seventy extractions. The EMLA cream group (A) comprised of 35 individuals, who were given 0.5 mg Eutectic mixture of Lidocaine and Prilocaine cream over the palatal soft tissues adjacent to the tooth to be extracted 5 minutes before the procedure. The Greater palatine nerve block group (B) comprised of 35 individuals, who were given 2% lignocaine with 1: 2,00,000 dilution with adrenaline anterior to the greater palatine foramen using a 21 gauge syringe needle. Buccal infiltration with 2% lignocaine with 1:2, 00,000 dilution with adrenaline was given to both the study groups before performing the extraction procedure. The extraction was carried out atraumatically—postoperative prescriptions of Tab. Paracetamol 500mg three times daily for three days were given to all patients.

Assessment

One principal investigator evaluated all the patients. Each patient was assessed while applying the EMLA cream (A) and while giving the Palatal nerve block (B) for any pain or discomfort. If they had pain, their score was recorded in the Visual Analogue Scale. The extraction procedure was carried after giving a buccal subperiosteal infiltration concerning the tooth to be extracted. While extraction was carried if the patient felt any pain, it was recorded in the Visual analogue scale.

Pain measurement was done using the Visual Analogue Scale (VAS) on a scale of 0 to 10, shown in Figure 1.

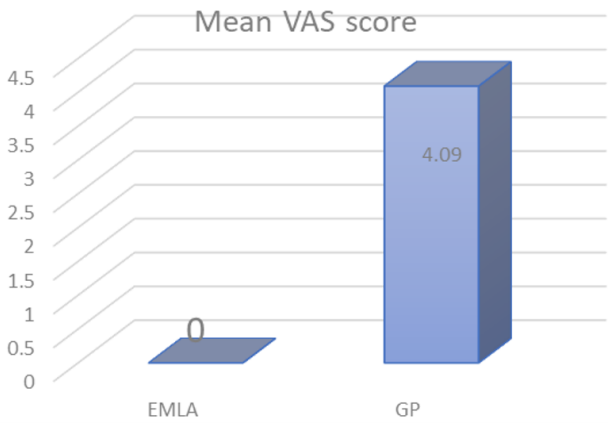
Statistics

The collected data from the patients were analyzed by using IBM SPSS statistics software 23.0 Version. The obtained data from the VAS was measured by Mean and SD and to find significant difference the Independent sample test was used. In the statistical analysis, the probability value of .05 is considered as significant.

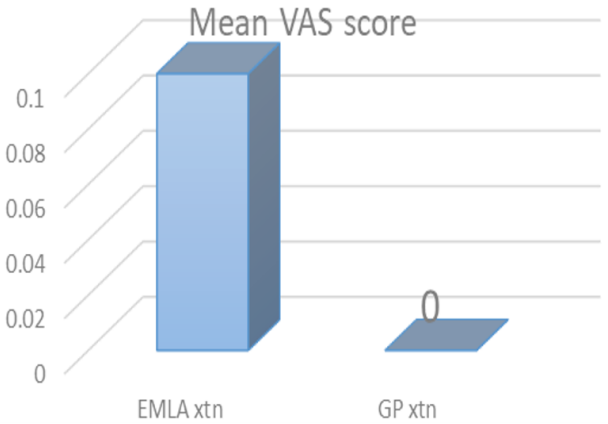
RESULTS AND DISCUSSION

VAS evaluated the experience of pain. The mean VAS score while applying EMLA cream in group A was 0.00, whereas while giving palatal nerve block in group B, it was 4.09 that was statistically significant. The results are described in Table 1 and shown graphically in Graphs 1 and 2. Likewise, the mean VAS score while extraction in the EMLA group was 0.11, whereas in palatal nerve block group was 0.00 that was not statistically significant.

Many authors describe the usage of EMLA intraorally in the literature (Svensson *et al.*, 1992; Svensson, 1992). Pere P and Lizuka T in their placebo-controlled trial showed 4g of EMLA when applied for a period of 4-min with a toothbrush was an effective regimen reducing the discomfort produced during arch bar removal used in managing mandibular fractures (Pere, 1992). Holst and Evers in their study compared EMLA to topical 10% lignocaine found both were effective in anaesthetizing the mesiobuccal fold after 2 min of application. EMLA was found to be more effective in anaesthetizing the palatal mucosa than lignocaine.



Graph 1: Mean VAS score while giving anaesthesia



Graph 2: Mean VAS score while extraction procedure

A placebo-controlled trial showed the application of EMLA on an oral adhesive bandage to palatal mucosa reduced the pain of palatal injections. In his investigation , he compared EMLA to 10% lignocaine in argon laser stimulation and reported EMLA was more effective in reducing the pain threshold of lower anterior labial gingiva (Svensson *et al.*, 1992). David Donaldson and John G. Meechan in their trial comparing topical use of EMLA and 5% lidocaine found EMLA cream was better in providing anaesthesia where gingival manipulation is required (Ehrenström-Reiz *et al.*, 1983).

In contrast, none of the above investigators com-

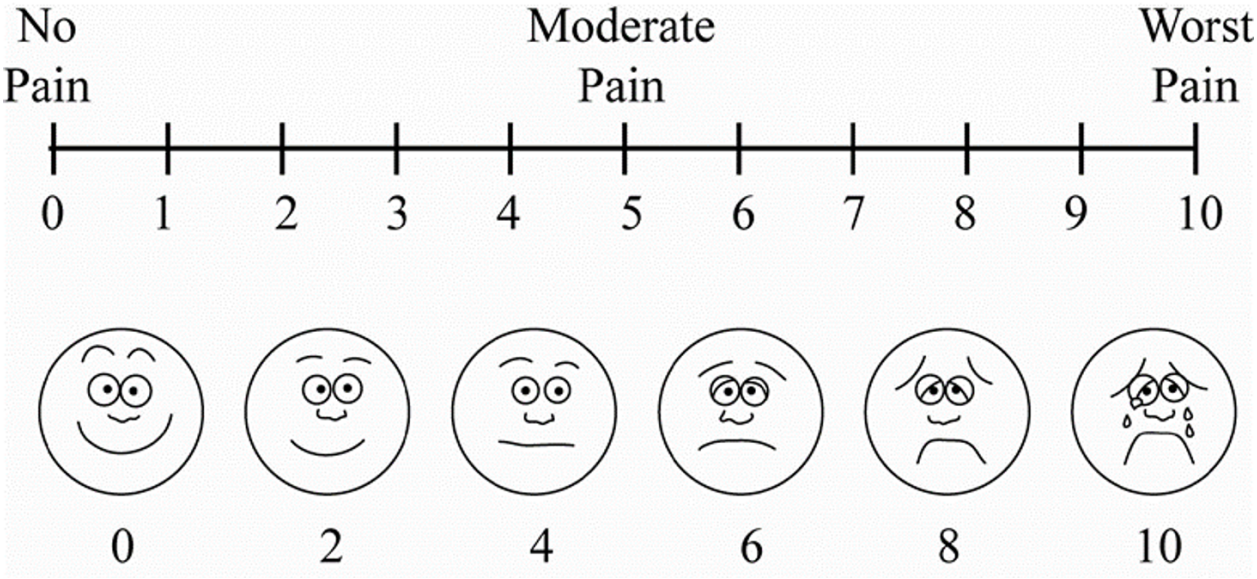


Figure 1: Visual Analogue Scale

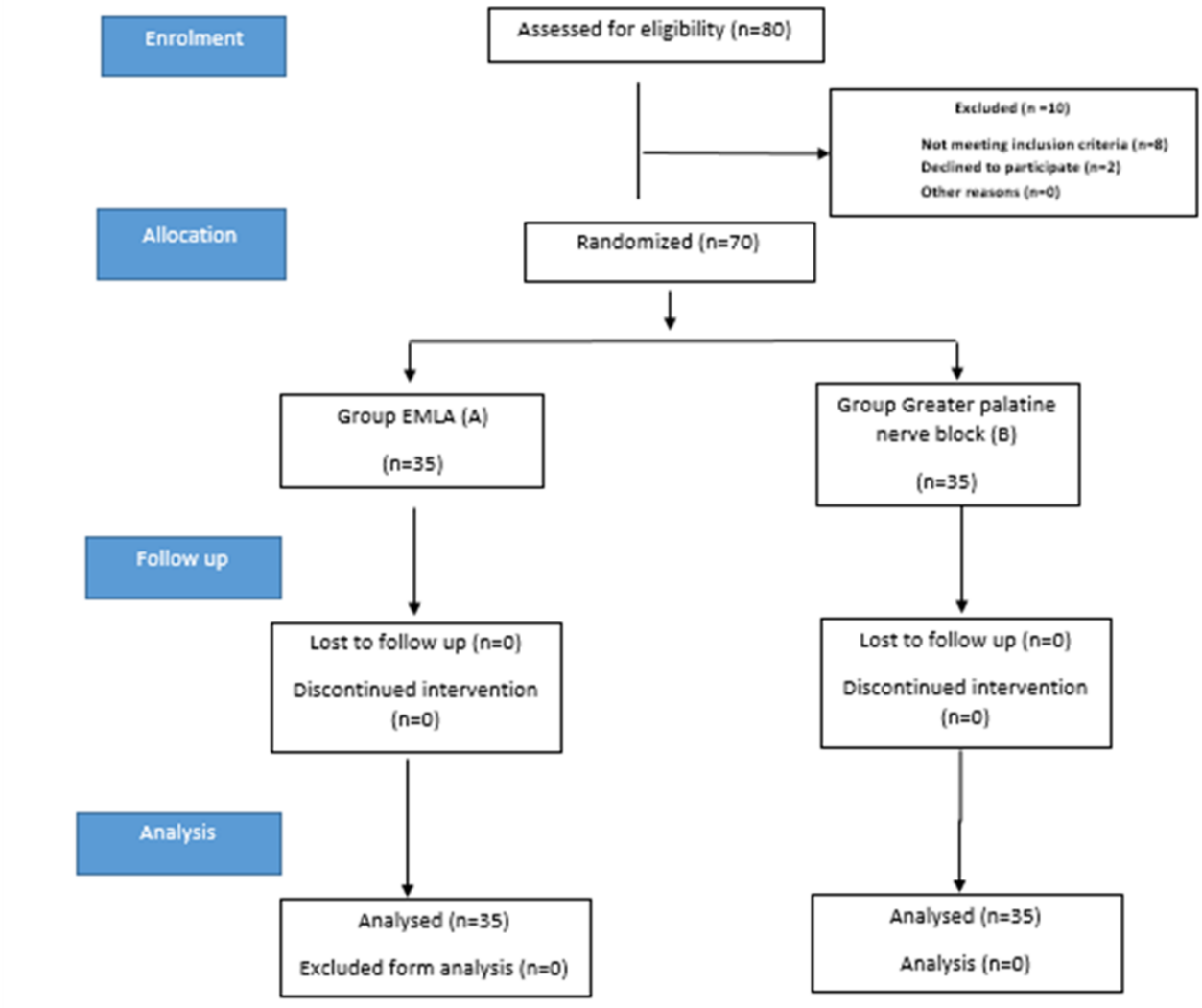


Figure 2: Consort flow chart of patient participation in the study

Table 1: Comparison of two groups with regards to pain experience by Independent sample Test

Time	Groups	N	Mean	Std. Deviation	Std. Error Mean	p-value
VAS while applying the cream (A) / giving nerve block (B)	A	35	.00	.800	.000	0.00
		35	4.09	.707	.781	
VAS while extraction	A	35	.11	.404	.068	.099
		35	.00	.00	.000	

pared EMLA with palatal nerve blocks or infiltration. In our study, we have compared EMLA with 2 % lignocaine palatal nerve blocks on providing anaesthesia to the palatal soft tissues. As far as we are aware, the use of EMLA as the sole means of palatal soft tissue anaesthesia for extraction has not been reported previously in the literature. In our present study, we have found that there was a significant difference in pain perception in favour of the EMLA group. So EMLA can be used as an alternative for palatal nerve blocks in the extraction procedure. While using topical anaesthetics in oral mucosa, it is absorbed systemically, and systemic effects are produced. Factors govern the systemic uptake of topical anaesthetic agents from the oral mucosa. 1. Total dose and 2. Time of application, so a short duration is advantageous (Nayak and Sudha, 2006). In the present study, the topical anaesthetic was kept in contact for 5 minutes, which is considered to be the limit of practical usefulness in the oral cavity. Haasio and Jokinen et al. (Haasio *et al.*, 1990) in their trial comparing 5% EMLA with 10 % lignocaine spray in producing topical anaesthesia of gingiva mucosa reported that the maximum plasma lidocaine concentration following application of 4g EMLA was 0.47 microgram /ml at 5 min. The value was found to be below the minimum toxic concentration of 5 microgram/ml. Hassio and Jokinen et al. noted that the systemic uptake of lidocaine from EMLA was similar to twice the amount of drug administered as 10% lignocaine spray (Haasio *et al.*, 1990).

The EMLA formulation used in this investigation was felt unpleasant by a few participants. It is possible to incorporate flavours into topical anaesthetics. Because of its low viscosity, it wasn't easy to maintain in one position following application [8]. Few authors have tried using custom made splints to increase the efficacy of the drug (Svensson and Petersen, 1992). No study is entirely flawless, In our study even though the assessor was blinded the operating surgeon is not blinded and owing to the small sample size within a short period further studies with large sample size and longer duration is required. (Lönnqvist, 2012)

CONCLUSIONS

In conclusion, this study suggests that EMLA may be advantageous in providing palatal soft tissue anaesthesia during prophylactic extraction, thereby avoiding painful palatal nerve blocks and preventing Local Anesthetic toxicity.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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