

Comparative study assessing the efficacy of topical lignocaine prilocaine cream vs. lignocaine infiltration for dermatosurgical procedures

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ABSTRACT

Background: Dermatosurgery is one of the fastest expanding subspecialty of dermatology. Local anesthetic agents play an important role in these procedures. **Materials and Methods:** This was a prospective, interventional study that included eighty patients with forty patients in each group (groups A and B). Group A: Topical 2.5% lignocaine and 2.5% prilocaine cream. Group B: Infiltration of 2% lignocaine Injection. Patients satisfying the inclusion criteria were recruited for the study. The patients were asked to rate pain perception at the time of drug administration and, then, during and after the surgical procedure using a visual, analogue scale separately. **Results:** In our study, the most common age group at presentation was 21–40 years. Males constituted 57.8%, whereas females constituted 42.2%. The common procedures performed in our study were electrocautery 33.3%, intralesional steroid 18.9%, and intralesional PRP 15.7%. In the topical EMLA cream group, the VAS score during drug administration was 0. In the lignocaine infiltration group, 70% were found to have VAS a score of 4–6, and 30% had a VAS score of 1–3, preprocedurally. The mean VAS score during the procedure was 3.36 for the topical EMLA cream group and 1.33 for the lignocaine infiltration group. The post-procedural VAS score showed similar results as the procedural VAS score. **Conclusion:** The results of our study showed that topical EMLA cream is a better choice of anesthesia in superficial aesthetic and dermatosurgical procedures in providing adequate analgesia.

Key words: Topical anesthesia, EMLA, Lignocaine, Dermatosurgery

INTRODUCTION

Dermatosurgery is one of the swiftly expanding subspecialty of dermatology of the past decade with infinite and complex procedures being performed for various conditions [1]. Local anesthetics are defined as drugs applied topically or used as infiltration locally to produce a focal reversible loss of sensation such as pain and touch. A local anesthetic may be administered via scores of techniques. Traditionally, anesthetics were injected at the site, which by itself, may cause severe pain in some patients and may change the normal anatomy while performing some aesthetic and dermatosurgical procedures [2]. Local anesthetic agents, which were the basis of use of the modern local anesthetic agents in the field of dentistry

and medicine, have evolved [3]. The skin is one of the major avenues by which humans perceive the world and, in turn, are perceived by it. When these perceptions go awry, great distress may result. When the skin is markedly affected by a primary dermatologic condition, psychological sequelae in the form of comorbidity often follow, greatly impacting patient quality of life [4]. Some of the topical anesthetic creams such as lignocaine, prilocaine tetracaine, etc., are developed over a period to overcome the infiltration pain, following the administration of intralesional anesthetic agents. To escalate the potency of local anesthetic agents, to augment the depth of anesthesia and to extend the duration of topical anesthetic agents, varied combinations have been tried recently. When approaching these issues, it is important to explore

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psychiatric, and particularly psychotic, symptoms as well as compliance with medications [5]. A handful of studies were conducted to collate the efficacy of different amalgams of topical anesthetics in different dermatological and aesthetic procedures.

MATERIALS AND METHODS

The study was conducted at the department of dermatology, venereology, and leprosy at a tertiary-care center. This was a prospective, interventional study that included two groups with a total of eighty patients with forty patients each (groups A and B). The patients were allocated to groups in an alternating fashion (patient 1 to group A, patient 2 to group B, and so on).

Group A: The local anesthetic used was a eutectic combination of 2.5% lignocaine and 2.5% prilocaine cream (EMLA) [6]. Under aseptic precautions, the cream was applied as a thick film (1–2 mm thick) over the area to perform the procedure and covered with a thin occlusive and adhesive sheet, which was given inside the anesthetic package. After forty minutes of application, the EMLA cream was removed with the help of a wet saline gauze.

Group B: Infiltration with 2% lignocaine injection was used as local or regional infiltration anesthesia. The test dose was given on the left forearm 5 cm below the cubital fossa and waited for the allergic effect to take place. The procedure was done after a period of five minutes if no allergy was encountered to the infiltration agent [7].

The patients were thoroughly screened. A detailed history was taken, and clinical examination was done. Those patients satisfying the inclusion criteria were included in the study after obtaining informed and written consent. All patients were asked to rate pain perception at the time of drug administration and, then, during the surgical procedure using a visual analogue scale separately, along with the immediate post-procedure pain score also recorded using VAS.

Ethics Statement

This study was done after obtaining approval from Institutional Ethics Committee. The information of the subjects is kept confidential and all the ethical guidelines were followed during the process of this study. No humans or animals are harmed during the study.

RESULTS

A total of eighty patients attending the DVL op for dermatosurgical procedures department were examined and included in the study.

In our study, the most common age group at presentation was 21–40 years (50%), followed by < 20 years (25.6%) (Fig. 1). Males constituted 57.8%, whereas females constituted 42.2%. All three groups were found to be similar with respect to age and sex ($p = 0.143$; $p > 0.05$).

In our study, we included various dermatosurgical procedures where the local anesthetics were used. Among them, a majority of the patients had alopecia areata (27.5%), and the least had striae distensiae (1.25%), for which they underwent carbon laser therapy (Table 1).

We used local anesthetics in a variety of procedures, among them the biggest number constituted intralesional steroid injection (13.5%) (Table 2).

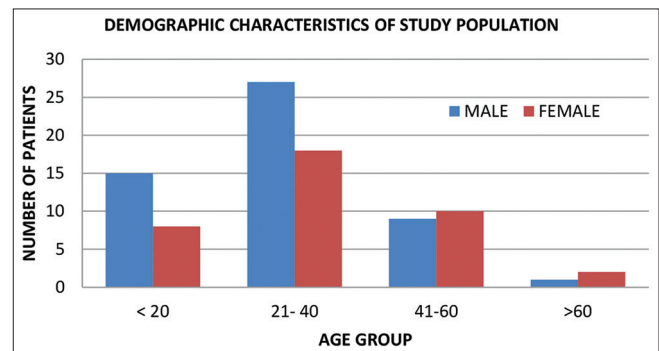


Figure 1: Age and sex distribution among the subjects.

Table 1: Dermatoses for which local anesthesia was administered.

Dermatoses	Topical EMLA cream		Lignocaine infiltration		TOTAL n=80	
	n	%	n	%	n	%
Acne scar	3	7.5	0	0	3	3.75
Alopecia (areata, androgenic)	12	30	10	2.5	22	27.5
Seborrheic keratosis & its variants	4	10	14	35	18	22.5
Colloid milium/milia	5	12.5	0	0	5	6.25
Chronic eczema (LSC)	3	7.5	2	5	5	10
Infections (MC, Verruca)	8	20	7	17.5	15	18.75
Naevus (compound/LEN)	2	5	1	2.5	3	3.75
Pyogenic granuloma	0	0	5	12.5	5	6.25
Striae distensae	1	2.5	0	0	1	1.25
Trachyonychia	2	5	1	2.5	3	3.75
TOTAL	40	100	40	100	80	100

$\chi^2 = 47.518$ p value = 0.138

Table 2: Distribution of planned procedures among the groups.

Planned procedure	Topical EMLA cream		Lignocaine infiltration		TOTAL n=80	
	n	%	n	%	n	%
Electrocautery	8	20.0	20	50	28	35
Extirpation	2	5	0	0	2	2.5
Intralesional bleomycin	2	5	2	5	4	5
Intralesional PRP	10	25	2	5	12	15
Microneedling & PRP	6	15	2	5	8	10
Intralesional steroid	8	20	3	7.5	11	13.5
Intralesional steroid with cryotherapy	1	2.5	1	2.5	2	2.5
Nail avulsion	0	0	6	15	6	7.5
Radiofrequency ablation	2	5	2	5	4	5
Shave excision	1	2.5	2	5	3	3.75
TOTAL	40	100	40	100	80	100

$\chi^2 = 32.625$ p value = 0.059

The mean procedure duration for the topical EMLA cream group and lignocaine infiltration group was 7.60 ± 3.20 minutes and 8.77 ± 4.04 minutes, respectively. The mean procedural time was found to be similar in both groups, with a p value of more than 0.05 (Table 3).

In the topical EMLA cream group, the VAS score during drug administration was 0. In the lignocaine infiltration group, 70% were found to have a VAS score of 4–6, and 30% had a VAS score of 1–3, pre-procedurally. The mean VAS score during the procedure was 3.36 for the topical EMLA cream group and 1.33 for the lignocaine infiltration group.

The mean VAS score during drug administration was zero in the topical EMLA and 3.83 in the lignocaine infiltration group. During the procedure, the VAS score for topical EMLA cream was 4.46 and 1.43 for lignocaine infiltration. The post-procedure VAS score was 2.8 for topical EMLA cream, 1.0 for lignocaine infiltration (Table 4). The mean VAS score during the procedure for the topical EMLA cream group was higher when compared to the other group. The above pattern was found to be statistically significant, with a p value of 0.001 (< 0.05) (Table 5).

The post-procedural VAS score was comparable to the procedural VAS score, with a VAS score higher in the topical EMLA cream group when compared with the other group (Table 6).

In our study, the mean VAS score according to site was lower in the face (1.32) and neck (1.78) when compared to other sites. In the topical EMLA cream group, the VAS score was lower in the neck (2) and face (2.14). In the lignocaine infiltration group, the VAS score was lower in the face (1) and lower limb (0.67) (Table 7).

Table 3: Comparison of mean procedure duration between the groups.

Group	n	Mean (minutes)	Std. Deviation	f Value	p Value
Topical EMLA cream	40	7.60	3.20	0.141	0.869
Lignocaine infiltration	40	8.77	4.04		

Table 4: Distribution of the Visual Analog Scale (VAS) score during drug administration among the groups.

VAS score	Topical EMLA cream		Lignocaine infiltration	
	n	%	n	%
0	40	100	0	0
1-3	0	0	12	30
4-6	0	0	28	70
> 6	0	0	0	0

Table 5: Comparison of the mean VAS score during the procedure between the groups.

Groups	n	Mean	Std. Deviation	f Value	p Value
Topical EMLA cream	40	4.46	2.31	43.74	0.001
Lignocaine infiltration	40	1.43	0.84		

Table 6: Post-procedural VAS score.

GROUP	n	Mean VAS Score
Topical EMLA cream	40	2.8
Lignocaine infiltration	40	1.0

Table 7: Comparison of VAS scores according to site between the groups.

Site	Topical EMLA Cream (mean VAS score)	Lignocaine Infiltration (mean VAS score)	Mean VAS Score
Face	2.14	1	1.32
Neck	2	1.33	1.78
Trunk	3.33	1.67	2.05
Upper Limb	4.17	1.25	2.01
Lower Limb	3	0.67	2.22
Scalp	3.42	2.25	2.33

The mean duration of pain relief for the topical EMLA cream group was 127.66 ± 8.14 minutes (minimum: 20 minutes; maximum: 300 minutes), and for the lignocaine infiltration group, it was 72.16 ± 6.15 minutes (minimum: 20 minutes; maximum: 240 minutes). The mean duration for pain relief was greater in the topical EMLA cream group than the lignocaine infiltration group. The above difference in the mean duration of pain relief was found to be statistically significant, with a p value of 0.001 (< 0.05).

In our study, around 84.5% did not show any adverse events. Among those who received topical EMLA cream, 6.7% had mild edema and 6.7% had mild itching at the site of application, which was short lived. In the lignocaine infiltration group, 6.7% had edema and

3.3% had very mild itching. All groups were found to be similar with respect to adverse events with a p value of 0.314 (> 0.05).

The VAS scores during drug administration or the pre-procedural, procedural, and post-procedural scores were also recorded in the patients. As these values were subjective, there was a chance of individual variations (Fig. 2).

DISCUSSION

In our study, a majority of the patients were in the age group of 20 to 40 years, accounting for 50% of the total study subjects. The mean age group of our study population was 30.9. This was similar to the age distribution of 35.4 years seen in a study by Fredman et al. [8]. This shows that the adolescent age group was more cosmetically concerned when compared with other age groups.

Our study showed a modest increase in the number of male subjects (57%) when compared to females (43%). This finding did not correlate with most of the other studies in which the female sex was more often involved.

In our study, waiting time for an infiltration anesthetic was five minutes when compared to forty minutes for topical creams. An infiltration anesthetic acts more quickly than topical creams, which take time to penetrate the skin layers. Various studies have a different cut-off for the waiting time. The study conducted by Carter et al. [9] suggested a waiting time of thirty minutes for superficial procedures.

The mean duration of procedure timing in our study for the various groups was around 7.27 \pm 1.99 minutes. This was similar to the study by Pratik et al. [2], in

which the duration of procedures was 5–7 minutes on average.

In the topical EMLA cream group, the pre-procedural VAS score for pain (during drug administration) was zero. In the lignocaine infiltration group, the mean VAS score for pain was 3.83, among which 70% were found to have a VAS score of 4–6, and 30% had a VAS score of 1–3 pre-procedurally.

The mean VAS score for pain during the procedure was 3.36 for the topical EMLA cream group and 1.33 for the lignocaine infiltration group. The mean VAS score for pain during the procedure for the topical EMLA cream group was higher when compared to the other group. This was similar to the study conducted by Alster et al. [10].

The significant higher VAS pain severity scores with EMLA cream in our study might have been due to the shorter application time. EMLA does not provide adequate anesthesia at peripheral skin margins. The depth of analgesia achieved after 60 minutes is 3 mm and 5 mm after 120 minutes of application. The time of application to achieve adequate anesthesia typically exceeds 60 minutes, limiting the practical use of the combination in a hectic clinical setting.

Regarding the need for additional requirement of anesthetic modality, we found that 93.3% in the topical EMLA group and 100% in the lignocaine infiltration group tolerated the procedure well and did not require any intervention. This was similar to the study conducted by Suzzane et al. [11], in which 95% of the patients tolerated the procedure without any additional anesthetic requirements.

The mean duration of pain relief for the topical EMLA cream group was 127.66 minutes (40–210 minutes) and for the lignocaine infiltration group, it was 72.16 minutes (12–130 minutes). The mean duration of pain relief was greater in the topical EMLA cream group than the lignocaine infiltration group. This was similar to study findings by Lischeng Kang et al. [12].

Regarding the need for additional requirement of anesthetic modality, we found that 93.3% in the topical EMLA group and 100% in the lignocaine infiltration group tolerated the procedure well and did not require any intervention. This was similar to the study conducted by Suzzane et al. [11], in which 95% of the patients tolerated the procedure without any additional anesthetic requirements. This shows that most of the

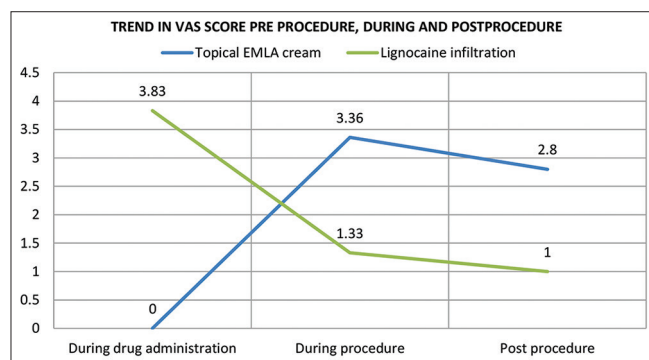


Figure 2: Preprocedural, procedural, and post-procedural VAS score.

common aesthetic procedures may be performed with topical anesthetics alone with less discomfort for the patient [13].

Lignocaine has a faster onset (1–5 minutes) and shorter duration of action (90–120 minutes). Lignocaine when combined with other anesthetics such as prilocaine (120–240 minutes) or tetracaine (180–600 minutes) has a longer duration of action. The onset of action and duration depend on the pKa and protein binding of the drug. Lignocaine and prilocaine with a low PKa (7.9) are faster-acting than tetracaine with higher PKa (8.5) [14]. Tetracaine being more lipophilic and more protein bound (76%) is slowly released from the epidermis and has a comparatively longer duration of action than prilocaine (protein binding 55%) [15].

In the side effect profile, most of the patients did not show any adverse effects, although a few had transient and self-limiting reactions. In the topical EMLA cream, $n = 2$ (6.7%) had edema and $n = 2$ (6.7%) had itching. In the lignocaine infiltration group, $n = 2$ (6.7%) had edema and $n = 1$ (3.3%) had itching. These side effects resolved without any intervention. This was similar to the study conducted by Pratik [2]. Early recognition of adverse effects as well as immediate treatment when needed may lead to good outcomes [16].

CONCLUSION

The results of our study showed that topical EMLA cream is a better choice of anesthesia in superficial dermatosurgical procedures by providing adequate analgesia, during and after the procedure, in comparison with the traditional lignocaine infiltration, which is invasive and painful to infiltrate. Tolerability of the infiltrative anesthesia varies between individuals. Adverse effects recorded were minimal, such as edema, itching, erythema, which were transient and self-limited without requiring treatment. There is a need to conduct varied research studies and include a bigger number of cases in a large-scale study to fill the gaps in the literature in this field of research.

Statement of Human and Animal Rights

All the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the 2008 revision of the Declaration of Helsinki of 1975.

Statement of Informed Consent

Informed consent for participation in this study was obtained from all patients.

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