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USE OF TOPICAL ANAESTHESIA WITH EMLA CREAM FOR HARVESTING SPLIT SKIN GRAFT

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ABSTRACT: Harvesting a split skin graft is a painful procedure. A eutectic mixture of lidocaine and prilocaine (5% EMLA) which is capable of anaesthetizing intact skin is useful in this regard. **AIMS AND OBJECTIVES:** To evaluate the efficacy of anaesthetic effect and safety provided by topical application of EMLA cream for harvesting split skin graft and to compare the results of ELMA with or without sedative analgesic premedication. **MATERIAL AND METHODS:** All patients were randomly divided into two groups of 25 each. Group A (EMLA cream 10-15g/100cm² area) and Group B (EMLA cream 10-15g/100cm² area along with inj. Hydroxyzine hydrochloride 1mg/kg IM, inj. Midazolam hydrochloride 0.04mg/kg IV. and inj. Pentazocine 0.5mg/kg IV). Vital parameters, verbal pain score and satisfaction scores were recorded and compared in both groups. **RESULTS:** There were no statistically significant differences in pulse, Diastolic B.P (DBP) and respiratory rate between two groups. Systolic B. P (SBP) shows statistically significant difference (P value <0.05) at 45 min. and VPS shows statistically highly significant difference (P value <0.001) between 2 hours to 5 hours and significant difference (P value <0.05) at 1 hour and 6 hour. Only 20% of the patients in group A and 12% of the patients group B had pain of more than mild degree (VPS grade 1) and need intravenous ketamine supplement to complete the surgery. **CONCLUSION:** Topical use of EMLA cream is a safe, effective and convenient method of harvesting spilt skin graft and by using this method, we can avoid the hazards associated with general anaesthesia. We recommend this method as a routine especially in those patients who are not fit or high risk for anaesthesia. (Word 278).

KEYWORDS: Split Skin Graft, EMLA Cream.

INTRODUCTION: Pain is an "Unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".

In the recent practice of reconstructive plastic surgery split skin grafting is a very useful procedure where epidermis and a variable thickness of dermis is completely freed from its native blood supply are transplanted to a recipient site.

Harvesting a split skin graft is a painful procedure; various methods have been used to relieve pain during this procedure including infiltration anaesthesia, ⁽¹⁾ nerve block, regional, general, and topical anaesthesia.

In high risk patients in whom regional and general anaesthesia is contraindicated, topical anaesthesia can be used to avoid associated complications of general anaesthesia in these patients.

Topical anaesthesia remains a safe modality for pain relief prior to cutaneous procedure. With the emergence of new laser and surgical technique the need for more effective topical anaesthetic agent continues to grow. Now a day there are several new topical anaesthetic agents that are being used prior to various dermatological procedures. The main problem with topical anaesthetic agent delivery after application to skin is stratum corneum.

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A eutectic mixture of lidocaine and prilocaine (5% EMLA) which is capable of anaesthetizing intact skin is very useful in this regard. Only the superficial layer is anaesthetized and onset, duration and depth of anaesthesia depend on the site of application, its concentration, duration of application and thickness of layer. There have been several studies published about the use of 5% EMLA cream in split skin and full thickness graft harvesting.^(2,3,4,5,6,7,8,9,10,11)

The recommended dose of 5% EMLA cream is 15-30g per 100cm² when used on intact skin and the recommended time of application before surgical procedure is 2-5 hours.^(5,7,9-11) The only adverse reactions of EMLA cream as per literature are local reactions such as paleness, redness and oedema when used in appropriate doses.

Our study aims to evaluate the efficacy of anaesthetic effect and safety provided by application of topical anaesthetic cream 5% EMLA for harvesting split skin graft and to compare the results of EMLA with or without sedative analgesic premedication, in terms of final success rate and changes in the vital parameters.

MATERIAL& METHODS: This prospective study was conducted, on 50ASA (American society of anesthesiology) grade I to IV patients posted for split skin grafting, aged between 10 to 70 years with prior permission from ethical committee and a written informed consent from patients. Patients on long term steroid use, patients treated with class III anti-arrhythmic drugs, patients with congenital or idiopathic methemoglobinemia, or previous adverse reaction to EMLA, prilocaine or lidocaine were excluded from this study. In our study we have taken split skin graft ranging from 50cm² to 200 cm² sizes.

On arrival in operating room an intravenous line was secured on dorsum of hand and monitors attached including electrocardiogram, pulse oximetry, and non-invasive blood pressure monitoring. Patients were informed about verbal pain score at that point of time.

All patients were randomly divided into two groups of 25 patients each.

Group A patients received EMLA cream 10-15g/100cm² area and Group B received EMLA cream 10-15g/100cm² area along with inj. Hydroxyzine hydrochloride 1mg/kg IM, inj. Midazolam hydrochloride 0.04mg/kg IV., and inj. Pentazocine 0.5mg/kg IV.

After choosing the area for harvesting split skin graft (Medial aspect of thigh), the area was prepared by shaving the skin over donor site. Then the selected and prepared area was marked with indelible ink and EMLA cream applied (10-15g/100cm²) on the area to be anaesthetized. A thick even layer of the cream was spread all over the marked area using a spatula and after that a strip of transparent plastic film was applied to cover the layer of cream.

The cream was spread evenly and edges were taped with a surgical synthetic adhesive tape. The entire area was occlusively dressed using a bandage. After an hour bandage was removed and cream was massaged through film wrapping and again bandage was applied.

In group B thirty minutes before the procedure injection hydroxyzine hydrochloride 1mg/kg intramuscular (IM) was given. Injection Pentazocine 0.5mg/kg and injection Midazolam 0.04mg/kg intravenous were given just before the removal of occlusive dressing. After a minimum of two hours i.e. just prior to surgery, the occlusive bandage and plastic film were removed.

The cream was removed and the site was painted with povidone iodine and then split skin graft was taken from donor site. Surgeon was asked not to deviate from the anaesthetized site during harvesting the graft as it might cause pain and purpose would not be served.

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Vital parameters (Pulse, Blood pressure and Respiratory rate), verbal pain score and satisfaction score (Annexure 1) were recorded from 0 time (Harvesting the skin) at an interval of 15 minutes for 1 hour and then hourly till 6 hours postoperatively and then 12 hour after the surgery.

Any complaint/side effects were noted. Injection Ketamine 50 mg intravenous bolus was given as rescue analgesic to the patients who complained of pain during harvesting the skin graft.

After graft harvestation Injection Ketamine 1-2mg/kg, and injection propofol 1.5-2.5mg/kg intravenous were given for scrapping and graft placement at the recipient site.

RESULTS: In this study patients were selected randomly between 10-70 yrs. of age, belonging to ASA grade I to IV. Out of these 50 patients, 19 patients were either not fit for anaesthesia or were high risk for anaesthesia.

Pulse rate changes were significant ($p < 0.001$) at 0 min (96.08 ± 11.50) to 45 minutes (93.92 ± 8.57) and then at 6 hours (83.52 ± 7.52) and at 12 hours (81.84 ± 8.31) as compared to preoperative pulse rate (88.32 ± 12.32) in group A, while in Group B pulse rate changes were significant at 0 min. (96.32 ± 8.79) to 45 minutes (94.16 ± 5.71) and then from 3 hours (87.20 ± 6.56) to 12 hours (82.64 ± 6.68) as compared to preoperative pulse rate (90.72 ± 8.18). The decreases in the pulse rate between 2 hours to 12 hours were due to the effect of premedication, used in group B. (Table No. 2)

Increase in systolic blood pressure were significant at 0 min (133.20 ± 18.37) to 1 hours (128.16 ± 12.42) and at 3 hours (127.12 ± 15.36) in comparison to preoperative systolic B.P. (121.04 ± 20.59) in group A, while in group B increase in systolic B.P. were highly significantly between 30 min (132.40 ± 11.90) to 45 min (126.56 ± 10.48) in comparison to preoperative systolic B.P. (120.00 ± 16.83).

This rise in systolic B.P. at 0 min to 15 minute was less in group B as compared to group A, because of the sedative/anxiolytic and analgesic premedication in group B. Systolic B.P. changes were highly significant in both groups between 30-45 min. because of the effect of ketamine, which was given for scrapping and application of graft on the recipient site (Table No. 3).

Diastolic B.P. changes were significant at 0 min (82.56 ± 16.40) to 45 min. (83.20 ± 15.28) as compared to preoperative diastolic B.P. (80.80 ± 16.56) in group A, while in group B changes were highly significant from 30 min (79.76 ± 6.94) to 45 min (80.32 ± 6.05) and significant at 1 hour (79.84 ± 6.83), 4 hour (79.04 ± 6.64) and 5 hours (79.60 ± 6.22) as compared to preoperative diastolic B.P. (77.20 ± 7.37) (Table No. 4).

Respiratory rate changes were significant at 0 min. (19.48 ± 3.31) to 2 hours (17.88 ± 1.92) as compared to preoperative respiratory rate (16.48 ± 1.76) in group A while in group B, respiratory rate changes were significant from 0 min. (19.12 ± 2.71) to 45 minute (17.64 ± 1.32) as compared to preoperative respiratory rate (16.20 ± 1.78). Respiratory rate changes were more in group A (Up to 2 hours) as compared to group B (up to 45 min.) due to use of sedative/ anxiolytic, analgesic for premedication in group B (Table No. 5).

In our study verbal pain scores were more from 1 hours (1.32 ± 0.63) to 2 hours (1.04 ± 1.02) postoperatively in group A and from 3 hours (0.96 ± 0.79) to 4 hours (1.04 ± 0.89) postoperatively in group B. The delay in the appearance of postoperative pain in group B was due to the sedative/anxiolytic and Analgesic premedication used in group B patients (Table No. 6).

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Duration of postoperative analgesia was found more in group B (3.14 ± 1.75 hours) in comparison to group A (1.31 ± 0.82). Verbal pain scores (VPS) were found more between 1-2 hour postoperatively in group A and between 3-4 hour in group B (Table No. 8).

Satisfaction scores were rated excellent in both groups by patient, surgeon and Anaesthetist; although satisfaction scores were comparatively better in group B, as compared to group A (Table No. 9). These Fluctuations in vital parameters, delay in postoperative pain appearance, increased duration of analgesia and better satisfaction score in group B were due to additive pharmacological effect of sedative analgesic premedication used in this group.

There was no significant difference in terms of success rate of EMLA cream, in both groups. In group A 80% of the patients and in group B 88% of the patients had no complaint or only mild degree pain complaint during harvesting the graft, which was easily accepted by the patients. Only 20% of the patients in group A and 12% of the patients group B had pain of more than mild degree and need supplementation by general anaesthesia to complete the surgery.

In both groups no patient had local side effect of EMLA cream at the site of application.

DISCUSSION: This study was done to evaluate the efficacy of EMLA cream to relieve pain during harvesting the split skin graft and to evaluate the effect of the sedative, analgesic premedication on the final success rate and vital parameters.

There were 76% males as compared to 24% of females. Cause of this male preponderance and adult age group might be because this age group was more prone to injuries because of more mobility. (Table No. 1)

Out of the 50 patients selected in our study, 19 patients were either not fit for anaesthesia or were high risk for anaesthesia (General as well as Regional anaesthesia), had high/uncontrolled blood pressure, cardiac problems (Recent MI, CHF, previous history of Angina, LVF, Cardiomegaly in CXR, and significant ECG changes), Pulmonary pathology (Asthma, COPD, Koch's chest etc.), known case of uncontrolled diabetes, patient with raised fasting blood sugar and anaemic patients. Such patients were especially included in our study and had benefited by topical application of EMCA cream for harvesting split skin grafts.

Most of the patients in both groups had either no pain or only mild pain and only 20 % cases in group A and 12% cases in group B noticed discomforting, distressing or horrible pain. Group B patients had better results than group A, because of sedative/Anxiolytic and analgesic premedication, used in group B. No patients had excruciating pain in any group. In both groups injection Ketamine (50mg IV bolus) was given as rescue analgesic for pain of more than mild degree severity (Table No. 7).

Duration of postoperative analgesia was more in group B (3.14 ± 1.75 hours) as compared to group A (1.31 ± 0.82 hours). This increase in the duration may be because of additive pharmacological effect of premedication, used in group B. (Table No. 8)

Satisfaction scores were rated excellent in both groups by patient, surgeon and Anaesthetist, although satisfaction scores were comparatively better in group B. (Table No. 9).

There were no statistically significant differences in pulse, Diastolic B.P. and respiratory rate between two groups. Systolic B.P. shows statistically significant difference (P value<0.05) at 45min. and VPS shows statistically highly significant difference (P value<0.001) between 2 hours to 5 hours and significant difference (P value<0.05) at 1hour and 6hour (Table No. 10).

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Lahteenmaki T et al.⁽⁵⁾ (1988) used 30-60g of EMLA cream per 200cm² area, Janezic TF.⁽⁷⁾ (1998) used 15-30g of EMLA cream per 100cm² area and Wahlgren CF et al.⁽¹⁰⁾ (2001) used 15g of EMLA cream per 100 cm² area for harvesting skin graft. We used only 10-15g of EMLA cream per 100 cm² area for harvesting skin graft, in an attempt to reduce the cost of the procedure.

Ohslen et al.⁽⁹⁾ (1985), applied EMLA cream on donor site for 1 hour 30 minute before taking skin graft, Lahteenmaki T et al.⁽⁵⁾ (1988), Janezic TF et al.⁽⁷⁾ (1998) and Wahlgren CF et al.⁽¹⁰⁾ (2001) applied EMLA cream for 2-5hour before taking skin graft. We applied EMLA cream for a minimum of 2 hours duration before taking skin graft, which was more in comparison to Ohslen et al (1985) and comparable to the duration of application used by Lahteenmaki T et al (1988) and Janezic TF et al (1998).

Ohslen et al (1985) found that 84.3% of their patients experienced adequate analgesia, felt only the pressure of the dermatomes or only slight pain without objection to surgery, and 13.7% of patients described pain as being moderate, but the operation could be completed without further local or general anaesthesia. Only 2% of patients needed additional anaesthesia.

Lahteenmaki T et al (1988) found that 92% of their patients rated pain as either none or slight and only 8% rated it as either moderate or severe and Janezic TF et al (1998), found that surgical procedure were painless in both patients, on whom they applied EMLA cream.

We found that 80% of the patients in group A and 88% of patients in group B had either no pain or only mild pain during graft removal and felt only pressure on dermatomes. Only 20% of the patients in group A and 12% of the patients in group B had either discomfort, distressing or horrible pain, were supplemented with Injection Ketamine 50mg IV bolus.

Our results were comparable to Ohslen et al (1985) and slightly less as compared to Lahteenmaki T et al (1988), may be because of the less amount of drug we had used in our study.

Failure to achieve proper analgesia in some of the patients, observed in our study could be due to Insufficient dose of EMLA cream applied, Insufficient thickness of cream, Insufficient time for the cream to penetrate the dermis, Patchy spread or uneven thickness of the cream, Patients did not kept their limbs in proper horizontal position after application of cream causing uneven spread of the cream and collection of the cream on dependent site, which led to patchy, incomplete anaesthesia, Greasy or dirty skin, not cleaned properly before application of EMLA cream, and Failure of the surgeon to keep graft harvest within the marked, anaesthetised area and in some cases even on taking graft from the margins of the marked area.

CONCLUSION: With this study, we reached to the conclusion that topical use of 5% EMLA cream is a safe, effective and convenient method of harvesting spilt skin graft and by using this method, we can avoid the hazards associated with anaesthesia (Regional as well as general anaesthesia).

We recommend this method of spilt skin graft harvesting with topical application of EMLA cream as a routine especially in those patients who are either not fit or high risk for anaesthesia.

AGE (YEARS)	GROUP A		GROUP B	
	F	M	F	M
11-20	0	5	1	4
21-30	0	5	2	5
31-40	0	3	3	2
41-50	3	4	1	4
51-60	1	2	0	1

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61-70	1	0	0	2
70	0	1	-	-
TOTAL	5	20	7	18
Table 1: Patient characteristics				

This table shows that, most of the patients in both groups are males and between 20-50 years of age.

Group	Pre-op	Intraoperative and Postoperative										
		0 time	15 min	30 min	45 min	1 hrs.	2 hrs.	3 hrs.	4 hrs.	5 hrs.	6 hrs.	12 hrs.
A (mean)	88.32	96.08	94.28	100.32	93.92	89.68	88.08	87.92	86.40	84.96	83.52	81.84
A (S.D.)	12.32	11.50**	11.90**	9.71**	8.57**	9.07	7.91	9.67	9.22	8.89*	7.92**	8.31**
B (mean)	90.72	96.32	94.40	100.72	94.16	88.80	88.64	87.20	85.52	84.72	84.56	82.64
B (S.D.)	8.18	8.79**	8.76**	6.00**	5.71**	6.86	6.60*	6.56**	6.12**	7.39**	7.65**	6.68**
Table 2: Pulse Rate												

*p<0.05, **p<0.001

This table shows pulse rate at different interval and changes are highly significant (P<0.001) at 0min - 45 min and at 6 & 12 hours in group A and in group B changes are highly significant at 0min- 45 min and from 3 hours to 12 hours period.

Group	Pre-op	Intraoperative and Postoperative										
		0 time	15 min	30 min	45 min	1 hrs	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	12 hrs
A (mean)	121.04	133.20	132.72	137.52	134.48	128.16	125.60	127.12	124.16	121.84	120.96	121.36
A (S.D.)	20.59	18.37**	16.44**	15.18**	15.23**	12.42**	13.35*	15.36**	17.43	15.47	15.43	15.36
B (mean)	120.00	127.60	127.84	132.40	126.56	123.04	123.60	123.12	119.84	119.36	121.12	118.56
B (S.D.)	16.83	16.90*	16.19*	11.90**	10.48**	10.76	9.75	8.80	8.62	9.79	10.31	8.86
Table 3: Systolic Blood Pressure												

*p<0.05, **p<0.001

This table shows systolic B.P. changes at different time interval and shows that changes are highly significant between 0min-1 hours and at 3 hours in group A and between 30 min to 45 min. in group B.

Group	Pre-op	Intraoperative and Postoperative										
		0 time	15 min	30 min	45 min	1 hrs	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	12 hrs
A (mean)	80.80	82.56	82.56	83.36	83.20	82.48	82.64	81.68	80.16	80.40	80.40	80.40
A (S.D.)	16.56	16.40*	15.77*	15.49*	15.28*	15.42	15.09	15.78	16.13	15.94	15.84	15.94
B (mean)	77.20	78.48	78.64	79.76	80.32	79.84	79.04	78.72	79.04	79.60	78.24	78.00
B (S.D.)	7.37	7.24	6.80	6.94**	6.05**	6.83*	5.07	6.24	6.64*	6.22*	6.51	6.45
Table 4: Diastolic Blood Pressure												

*p<0.05, **p<0.001

Above table shows Diastolic B.P. at different interval and shows that changes are statistically significant from 0 min – 45 min in group A. Changes are highly significant from 30 min to 45 min & Significant at 4 & 5 hours in group B.

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Group	Preop	Intraoperative and Postoperative										
		0 time	15 min	30 min	45 min	1 hrs	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	12 hrs
A (mean)	16.48	19.48	18.88	18.40	18.08	17.96	17.88	17.60	16.48	16.48	16.08	15.28
A (S.D.)	1.76	3.31**	3.07**	1.44**	1.87**	2.88**	1.92**	1.41*	1.58	2.35	1.78	1.14
B (mean)	16.20	19.12	18.08	18.60	17.64	16.80	17.36	16.08	15.84	15.92	15.96	15.04
B (S.D.)	1.78	2.71**	2.33**	1.47**	1.32**	1.66	1.87*	1.71	1.43	2.25	1.40	1.02

Table 5: Respiratory Rate

*p<0.05, **p<0.001

This table shows respiratory rate at Different interval and shows that changes are highly significant from 0 min to 2 hours in group-A and 0 min to 45 min in group.

Group	Preop	Intraoperative & Postoperative										
		0 time	15 min	30 min	45 min	1 hrs	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	12 hrs
A (mean)	0.00	0.56	0.04	0.04	0.08	1.32	1.04	0.48	0.04	0.08	0.00	0.00
A (S.D.)	0.00	1.12	0.20	0.20	0.28	0.63	1.02	0.59	0.20	0.40	0.00	0.00
B (mean)	0.00	0.36	0.00	0.00	0.04	0.12	0.00	0.96	1.04	0.52	0.28	0.00
B (S.D.)	0.00	0.95	0.00	0.00	0.20	0.44	0.00	0.79	0.89	0.87	0.46	0.00

Table 6: verbal pain score

*p<0.05, **p<0.001

This table shows verbal pain scores at different interval & shows that verbal pain score are more from 1 to 2 hours postoperatively in group A & from 3 hours to 4 hours in group B.

	GROUP A	GROUP B
Nil	19	20
Mild	1	2
Discomfort	1	-
distress	3	2
Horrible	1	1
excruciating	-	-

Table 7: Intra operative pain complaint

This table shows that, most of the patients in both groups have either no complaint or only mild pain and only 20% cases in group A and 12% cases in group B noticed discomforting, distressing or horrible pain.

	GROUP A	GROUP B
Total surface area of application (cm²)	133±60.64	123.32±42.11
Amount of cream (g)	13.28±4.85	13.40±5.90
Duration between application and graft removal (hours)	2.99±0.73	2.70±0.68*
postoperative analgesia (hours)	1.31±0.82	3.14±1.75**

Table 8: Duration of application and postoperative analgesia

This table shows that, although duration between application and graft removal is more in group- A, duration of postoperative analgesia is more in group- B.

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Group	Patients Score				Surgeons Score				Anesthesiologist Score			
	Poor	Satisfactory	Good	Excellent	Poor	Satisfactory	Good	Excellent	Poor	Satisfactory	Good	Excellent
A (n=25)	5	1	0	19	4	2	0	19	3	3	0	19
B (n=25)	2	2	1	20	2	1	2	20	2	1	2	20

Table 9: Satisfaction Score

Above table shows that Satisfaction Scores are excellent in both groups as noticed by Surgeon, Anaesthetist and Patients by self. In group B Scores are comparatively better than group A.

Inter Group analysis	Preop	Intraoperative and Postoperative										
		0 time	15 min	30 min	45 min	1 hrs	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	12 hrs
Pulse rate	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Systolic BP	NS	NS	NS	NS	<0.05	NS	NS	NS	NS	NS	NS	NS
Diastolic BP	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Resp. rate	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
VPS	NS	NS	NS	NS	NS	<0.05	<0.001	<0.001	<0.001	<0.001	<0.05	NS

Table 10: Inter Group Analysis

This table shows that there are no significant differences in pulse, Diastolic B.P. and Respiratory rate between two groups. Systolic B.P. shows significant difference at 45 min and VPS shows highly significant difference between 2 to 5 hours and significant difference at 1 & 6 hours.

ANNEXURE: 1

Verbal pain score (VPS):

VPS will be estimated on a 0-5 scale as follows:-

0. No pain
1. Mild pain
2. Discomfort
3. Distress
4. Horrible pain
5. Excruciating pain

Satisfaction Score:

	Excellent (3)	Good (2)	Satisfactory (1)	Poor (0)
Patient				
Surgeon				
Anesthesiologist				

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