

Original article

10 COMPARATIVE EVALUATION OF EFFICACY OF EMLA CREAM AND A PLACEBO (MOISTURIZING CREAM) IN PRODUCING DERMAL ANALGESIA FOR VENOUS CANNULATION.

DR. NIPA DESAI (TUTOR), DR. GAURI M PANJABI (ASSOCIATE PROFESSOR), DR. PARTH PANDYA (1ST YR RESIDENT) Department of Anesthesiology, SMT SCL Hospital, Saraspur Ahmedabad.

Corresponding author. DR. GAURI M PANJABI (ASSOCIATE PROFESSOR), Department of Anesthesiology, SMT SCL Hospital, saraspur Ahmedabad.

ABSTRACT

BACKGROUND: Venous cannulation is the most commonly performed invasive procedure in hospital patients. It is painful and associated with a high incidence of vasovagal reactions and haemodynamic stress response in patients.

OBJECTIVES: This study aims at evaluating the efficacy of EMLA cream in producing dermal analgesia for venous cannulations & effect of it on hemodynamic stress response.

MATERIALS AND METHODS: 100 patients of age group 12 to 18 of ASA grade I /II were selected. Patients were randomly divided into two groups (N=50). In Group A EMLA cream and in Group B Moisturizing cream was applied 60 minutes before venous cannulations. Pain was assessed with the help of 4-point scale. Pain and hemodynamic stress response (blood pressure and heart rate) was noted before and after venous cannulations. Local and systemic side effects were also noted.

RESULTS : Group A patients (EMLA cream) had lower pain scores and decreased hemodynamic stress response to venous Cannulations when compared to group B (placebo-moisturing cream). Local side effects -redness was noted in only 1 patient in group A. (EMLA cream)

CONCLUSION: The application of EMLA cream for venous cannulation alleviated pain and also prevented hemodynamic stress response. The main advantage being in its single dosage and easy application. EMLA cream is effective in producing dermal analgesia with less hemodynamic stress response to venous cannulation.

KEY WORDS: EMLA cream, Venous Cannulation, 4-point scale.

INTRODUCTION:-

One of the most important pre-requisites of delivering anaesthesia to any patient is securing a safe and patent intravenous access for drug and fluid administration¹. Venous cannulation is the most commonly performed invasive procedure in hospital patients². It is painful and associated with a high incidence of vasovagal reactions and hemodynamic stress response in patients³. Further, the needle prick can also make a patient uncooperative.

From quick immunizations or glucose monitoring to venipuncture, laceration repair, dermatologic procedures, and even tattooing (and removal!), needle pain is a growing concern. The effects of untreated pain impact medical outcomes and are remembered by preverbal children.

Various strategies have been investigated to alleviate pain associated with venous cannulation including ethyl chloride spray, intradermal or subcutaneous injection of local anesthetic and distraction techniques⁴. With the advent of Eutectic Mixture of Local Anaesthetics (EMLA) cream, effective topical analgesia of intact skin is now claimed to be feasible without the need for subcutaneous injections or exposure to high concentrations of local anaesthetics⁵.

EMLA cream is 1:1% oil in water emulsion of 2.5% lignocaine and 2.5% prilocaine bases. This mixture is termed eutectic, as it has a melting point lower than its individual components. This mixture is liquid at room temperature, while individual components are crystalline substances⁶.

Therefore study was done to evaluate the effectiveness of topical Emla cream in obtunding the pain and hemodynamic stress response produced by intravenous cannulation.

AIMS AND OBJECTIVES:-

This study is done to evaluate the efficacy of EMLA cream in producing dermal analgesia for venous cannulation.

The objectives are

- 1) Pain
- 2) Hemodynamic stress response

MATERIALS AND METHODS:-

This clinical study was done in 100 patients of age group 12 to 18 of ASA grade I /II posted for elective surgeries. A routine pre-operative evaluation was done in all patients and investigations required for respective surgeries were reviewed. The purpose and procedure of the study was explained and informed consent was taken.

Exclusion criteria:

- 1)Hypersensitivity to EMLA cream \local anesthetics.
- 2)Patients with methemoglobinemia or on drugs that may cause methemoglobinemia.
- 3) Psychiatric illness.
- 4) Local infection.

The Patients were randomly divided into two Groups A & B (N=50). After explaining the procedure a suitable vein on the dorsum of the hand was selected and study drugs were applied before 60 minutes of intravenous cannulation. In group A, EMLA cream 1.5 to 2 gm/10 cm² area was applied in a thick layer as shown in figure 2. In group B patients, moisturizing cream was applied in similar method. This layer was then covered with an occlusive dressing.

After 60 minutes, the occlusive dressing was removed. The area was then wiped dry with gauze and observed for signs of any local reaction. After disinfecting with spirit, I.V cannulation was performed and pain noted by 4-point scale⁷ and graded as 0-No pain , 1- Mild facial grimace ,2- Verbal response ,3- Withdrawal of hand. Hemodynamic response-Heart rate and blood pressure were also recorded before and after cannulation.

STATISTICAL ANALYSIS:-

The results were presented as mean, standard deviation, numbers and percentages. Inferential analysis was performed using chi-square test. A two tailed p-value <0.05 was considered as statistically significant.



FIGURE 1 EMLA CREAM



FIGURE 2:- EMLA CREAM APPLIED

RESULTS AND OBSERVATIONS:-

The Study groups were compared with respect to Demographic parameters, pain scoring and hemodynamic variables. The Demographic parameters were comparable in both the groups as shown in Table-1.

Table 1 :- Demographic parameters

PARAMETERS	GROUP A	GROUP B
AGE(years)	15.38±2.32	14.66±1.93
ASAI/II	28/22	26/24
SEX(M/F)	30/20	29/21

Table 2:- Pain response to cannulation (4 point scale)

Groups	Pain score (no of patients)				Mean	Std. deviation	'p'
	0	1	2	3			
Group A	31	15	4	0	0.46	0.61	0.0001
Group B	0	12	8	30	2.36	0.85	

Pain response to intravenous cannulation was noted as shown in Table-2. Score comparison among the study groups showed a lower pain scores in the EMLA group which was statistically highly significant (p=0.0001). In group A(EMLA) 62% of patients had no pain, 30% patient had mild grimace, 8% of patient told verbally that they had pain and no patient had withdrawal of hand while in control group all patients had pain out of which 24% had mild grimace, 16% verbally responded and 60% had withdrawn their hand.

Table 3:- Comparison of heart rate variation

Annulations	Group	Min.	Max.	Mean	Std. deviation	'p'
Before	A	80	120	95.74	11..44	0.0644
	B	84	126	100.24	12.59	
After	A	84	122	85.49	11.24	<0.0001
	B	90	132	110.7	11.08	

Patients in the control group had a higher increase in heart rate when compared to group A which was statistically highly significant ($P < 0.005$).

Table 4:- comparison of systolic blood pressure variation

Annulations	Group	Min.	Max.	Mean	Std. deviation	'p'
Before	Group A	100	140	120.76	28.28	0.6483
	Group B	110	154	123.48	31.11	
After	Group A	107	126	116.96	13.43	0.0027
	Group B	128	160	128.4	22.62	

Patients in the control group had a significant rise in systolic blood pressure after cannulation which was statistically highly significant ($p < 0.005$)

Table 5: Comparison of diastolic blood pressure variation.

Annulations	Group	Min.	Max.	Mean	Std. deviation	'p'
Before	Group A	70	80	75.16	7.07	0.0220
	Group B	60	90	82.52	21.21	
After	Group A	70	78	75.08	5.65	0.0001
	Group B	70	94	86.54	16.97	

Patients in the control group had a significant rise in diastolic blood pressure after cannulation which was statistically highly significant ($p < 0.005$)

Table 6:-Side effects.

SIDE EFFECTS		GROUP A (NO OF PATIENTS)	GROUP B (NO OF PATIENTS)
LOCAL	REDNESS	1	0
	ITCHING	0	0
SYSTEMIC		0	0

Only 1 Patient in group A had redness at local site of application. No serious adverse reactions were seen in any of the patients.

DISCUSSION:

Pain is a complex matrix of biological, psychological and sociological phenomena; it is a vital function of the nervous system that provides information and helps avoid danger to the human body. The nociceptive apparatus associated with skin can often produce fear of medical procedures, causing discomfort, pain and anxiety, which sometimes lead to vasovagal attacks⁸. Venous cannulation is the most commonly performed invasive procedure in hospital patients². It is painful and associated with a high incidence of vasovagal reactions and pressor responses in patients³.

Many attempts have been made previously to provide analgesia to the skin. Monash S have suggested preparations containing lignocaine for topical anaesthesia of the unbroken skin⁹. Kligman and Brechner, Cohen and Pretsky suggested topical application of local anesthetic mixtures with dimethyl sulphoxide

(DMSO)^{10,11}. However, no formulation has gained wide acceptance mainly as a result of inadequate relief of pain, local irritation or toxic reactions.

Hopkins CS and Buckley CJ conducted a study in children treated with EMLA cream prior to venous cannulation and lower pain scores were recorded in them¹².

Heart rate, systolic blood pressure and diastolic blood pressure were recorded before and after cannulation in all our patients. In one another study done by Lindh et al the same finding was appreciated that EMLA cream application decreased the stress response to venepuncture in new-born infants¹³.

Our study was done in 100 patients of either sex belonging to the age group 12-18 years posted for elective surgeries. In group-A patients, EMLA cream and in group-B patients, a placebo (moisturizing cream) was applied 60 minutes before intravenous cannulation. Pain score was assessed in these patients for IV cannulation by the 4-point scale. The mean pain score obtained in group A was 0.46; compared to control group of 2.36. This showed that EMLA cream application is probably effective after applying for an hour for analgesic effect. In Group A (EMLA cream), 92% patients had lower pain scores of 0 and 1; whereas only 24% patients in the control group had low pain scores. The results were comparable to the study done by Wig J, Johl KS who has revealed reduced pain scores in 94% of their subjects with EMLA cream prior to cannulation compared to 24% of the placebo group¹⁴. Lower pain score was noted in EMLA group which was statistically highly significant.

EMLA group patients did not have a significant rise in hemodynamic variables after cannulation when compared to the control group which was statistically highly significant. Only one patient had redness at the site of EMLA cream application. There were no other side effects in any group.

CONCLUSION

The efficacy of a topical anesthetic formulation EMLA 5% cream (Eutectic mixture of local anaesthetics) in obtunding the pain and hemodynamic response produced by intravenous cannulaion was determined in our study. The main advantage of EMLA cream is in its single dosage and easy application without distorting anatomical landmarks. The only disadvantage is cost of EMLA cream.

Our study results revealed that application of EMLA cream for venous cannulation alleviated pain and also prevented a significant rise in heart rate and blood pressure.

To conclude with, application of EMLA cream prior to venous cannulation is advantageous in all patients. The cost factor could be overlooked considering the efficacy of EMLA cream in producing dermal analgesia especially in children, anxious adults and in patients exposed to repeated venous cannulation to reduce hemodynamic stress response

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