COMPARATIVE EVALUATION OF EFFICACY OF EMLA CREAM (EUTECTIC MIXTURE OF LOCAL ANESTHETIC) AND A PLACEBO (NORMAL SALINE) IN PRODUCING DERMAL ANALGESIA FOR VENOUS CANNULATION

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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 pressor responses in patients.*

Objectives: *The aim of the study is to evaluate the efficacy of eutectic mixture of local anesthetic cream in producing dermal analgesia for venous cannulation.*

Material and Method: *200 patients were selected randomly of either sex, and divided into two groups. In group-I EMLA cream was applied and in group-II normal saline (placebo) was applied. Pain for intravenous cannulation was assessed by VAS scale.*

Results: *The mean pain score for venous cannulation in patients with EMLA cream was very less when compared to the placebo group.*

Conclusion: *EMLA cream is effective in producing dermal analgesia in response to venous cannulation.*

Keywords: *Dermal analgesia, EMLA cream, Venous cannulation.*

INTRODUCTION

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 attacks[1]. Venous cannulation is the most commonly performed invasive procedure in hospital patients[2]. It is painful and associated with a high incidence of vasovagal reactions and pressor responses in patients[3].

Various methods have been employed to alleviate pain and anxiety resulting from venous cannulation, including ethyl chloride spray, intradermal or subcutaneous injection of lignocaine and distraction techniques[4].

The major step in pharmaceutical research on topical drugs came with a serendipitous discovery that a specific mixture of crystalline bases of lidocaine and prilocaine had a lower melting point than the melting point of the individual drugs. This combination is termed a eutectic mixture and such a combination of local anesthetics is a liquid at room temperature and the individual components are crystalline solids[5]. The EMLA (Eutectic Mixture of Local Anesthetic) cream consists of an oil in water emulsion of a eutectic mixture of lignocaine base 2.5% and prilocaine base 2.5% with a thickener (carbopol) added to obtain suitable consistency[6]. With the advent of eutectic mixture of local anesthetics (EMLA) cream, effective topical anesthesia of intact skin is now claimed to be feasible without the need for subcutaneous injections or exposure to high concentrations of local anesthetics[5].

AIMS AND OBJECTIVES

A study was conducted to evaluate the efficacy of eutectic mixture of local anesthetic (EMLA) cream in producing dermal analgesia in response to venous cannulation.

MATERIALS AND METHODS

After ethical committee approval and informed and written consent, ASA Physical status I and II a total of 200 patients undergoing elective operative procedure

were selected. The patients belonged to either sex and were of the age group between 18 and 60 years.

A routine pre-operative evaluation was done for all patients and the following patients were excluded:

- Patients with known hypersensitivity to EMLA cream or any other local anesthetics.
- Patients with methemoglobinemia or on drugs that may cause methemoglobinemia.
- Patients with mental illness.
- Patients with open wounds on dorsum of hand.

Investigations included routine haemogram, urine analysis, blood sugar and other specific tests like ECG, chest X-ray, blood urea, serum creatinine etc. as required for respective patients and surgeries. The purpose and procedure of the study was explained and informed consent was obtained from all patients. The patients were selected randomly and were divided into two groups.

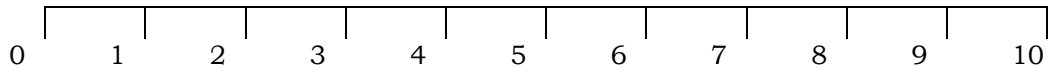
Group-I: Patients applied with EMLA cream before intravenous cannulation.

Group-II: Patients applied with placebo (normal saline) before intravenous cannulation.

After explaining the procedure, a suitable vein on the dorsum of the hand was selected. In group-I patients, EMLA cream 1.5 to 2 gm/ 10 cm^2 area was applied over the site of cannulation in a thick layer. This layer was then covered with an occlusive dressing. EMLA cream was applied for a minimum period of 1 hour. The occlusive dressing was removed just before the intravenous cannulation. The area was then wiped dry with gauze. After disinfecting with spirit, intravenous cannulation was performed with 18 gauge IV cannula. Pain during IV cannulation was scored using visual analogue scale. In group-II, Normal saline was applied over the site of cannulation for a minimum period of 1 hour. After disinfecting with spirit, intravenous cannulation was performed with 18 gauge IV cannula. Pain during IV cannulation was scored using visual analogue scale.

The perception of pain is highly subjective hence this variable was standardized by using data from visual analogue scale (VAS)[7]. First advocated by Revill and Robinson in 1976, VAS consists of a 10 cm line anchored at one end by a label such as 'no pain' and at the other end by a label such as 'worst pain imaginable'. The patient simply marks the line to indicate the pain intensity.

Visual Analogue Scale



RESULTS

In the present study, a total of 200 patients in Group-I and Group-II were compared with respect to age, sex and visual analogue pain scale. Data analysis was done by Z-test. Age difference among male and female was statistically insignificant in group-I ($z=1.22$, $p>0.05$)

Table 1: Age and Sex Wise Distribution of Cases in Group-I

Age	Sex		Total
	Male	Female	
18 – 27	15	19	34
28 – 37	13	14	27
38 – 47	13	06	19
48 – 57	10	08	18
58 – 67	01	01	02
Total	52	48	100.00
Mean	36.54	33.75	35.20
SD	10.43	12.25	11.84

Age difference among male and female patients is statistically insignificant in group-II ($z=1.93$, $p>0.05$.

Table 2: Age and Sex Wise Distribution of Cases in Group-II

Age	Sex		Total
	Male	Female	
18 – 27	13	13	26
28 – 37	17	17	34
38 – 47	17	09	26
48 – 57	07	03	10
58 – 67	04	00	04
Total	58	42	100
Mean	37.37	33.28	35.30
SD	11.23	9.84	10.68

The VAS pain score among group-I and group-II showed highly significant change ($z=40$, $p<0.01$). The mean pain score in group-I patients was very low when compared with the mean pain score in group-II patients (FIGURE 1)

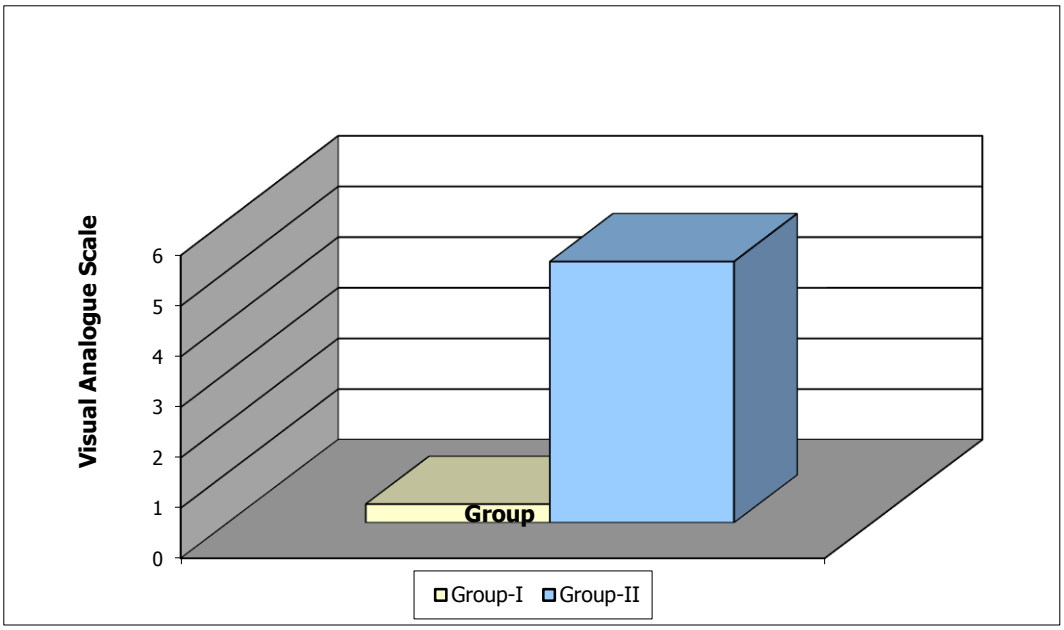


Figure1: Comparison of VAS Pain Score during Cannulation in Group-7I and Group-II

DISCUSSION

Our study was designed to evaluate the efficacy of eutectic mixture of local anesthetic cream in producing dermal analgesia to venous cannulation.

Over 200 patients of either sex belonging to the age group 18-60 years posted for elective surgeries were divided into two groups i.e., group-I and group-II with 100 patients in each group.
In group-I patients, EMLA cream was applied before intravenous cannulation. In group-II patients, a placebo (normal saline) was applied before intravenous cannulation. The groups were compared regarding age and sex and no statistical difference with respect to these variables was found. Pain score was assessed in these patients for intravenous cannulation by the visual analogue scale. In our study, we observed that the mean VAS pain score among the patients who were applied with EMLA cream was very less (0.37), when compared with the mean VAS pain score in the patients who were applied with the normal saline (5.17). The VAS pain score among group-I and group-II shows highly significant change ($z=40$, $p<0.01$).

Manner T et al[8] (1987) studied the local analgesic efficacy of EMLA cream in reducing pain at venous cannulation. Subjective pain scores, expressed with a visual analogue scale, were significantly lower in the EMLA group compared with both the groups treated with placebo cream and the open control group. In the study conducted by Cordoni A, Cordoni LE[9] (2001), intravenous insertion pain was scored by the patient using a 0 to 10 cm visual analogue scale. They also observed that the patients in the EMLA group experienced less pain than those in the placebo group. Moledocka J and Stenhouse C[10](1994) conducted a study wherein the efficacy of topical amethocaine cream was compared to 5% EMLA cream in alleviating pain of venous cannulation. Pain was assessed on a 4-point rank score. Good analgesia was obtained in all the groups. Hopkins CS, Buckley CJ, Bush GH[11] (1988) did a study in 111 children to assess the efficacy of EMLA 5% cream in the alleviation of venepuncture pain. Pain was assessed using both verbal rating scale and visual analogue scale methods. Significantly lower pain scores were recorded in children treated with EMLA cream. Another placebo-controlled study compared EMLA, placebo, and music distraction during intravenous cannulation in 180 children ages 4 to 16. In that study, Arts et al[12] (1994) also examined the influence of age using an age-stratified design. The principal investigator rated behavioral reactions, and the child rated the pain using a Face Pain Scale (FPS) and visual analog toy. In this study, mean FPS scores were significantly lower ($p \leq 0.001$) in the EMLA group ($M=1.42$) than the placebo ($M=2.58$) and music distraction groups ($M=2.62$). Younger children (4 to 6) reported significantly more pain than the older children (7 to 11 and 12 to 16), and EMLA exerted its maximal superiority in the youngest age group.

The observations in our study are in line with the observations made in the above studies. In our study, we applied the EMLA cream for a minimum period of 1 hour as per the recommendations made in various studies. Smith AJ and Stacey MR[13] (1996) conducted a study and revealed significantly lower pain scores for EMLA cream at 60 minutes. A study conducted by Vaghadia H, Al-Ahlan OA, Nevein K[14] (1997) revealed that EMLA patch when applied to the skin for 60-90 minutes before venous cannulation reduced the pain of venepuncture and also reduced vasovagal side effects. Hallen B, Olsson G et al[6] (1984) conducted a study to assess the effect of application of EMLA cream and their study also revealed that the effect of cream became evident at about 60 minutes for venepuncture. But a similar study conducted by Ehrenstrom, Reiz G, Reiz S et al[15] (1983) revealed a minimum effective application time of 45 minutes prior to IV cannulation. In our study, only two patients had blanching at the site of EMLA cream application. There were no other side effects. Wij J, Johl KS[16] (1990) studied the local analgesic efficacy of EMLA cream in reducing the pain at venous cannulation in a randomized blind study in 75 children scheduled for elective surgery. In 85 children placebo cream and in 50 children, EMLA cream was applied at the site of venous cannulation 1-hour prior. EMLA cream was found to be highly effective (84%

patients in contrast to 16% patients in placebo group) ($p<0.005$). Local side effects of EMLA cream were negligible.

A study was conducted by Moller C[17] (1985) to evaluate the efficacy of EMLA cream. The objectives were to test if EMLA diminishes pain from venepuncture, to evaluate possible adverse reactions and to determine if there is any influence upon the ease with which the insertion procedure is carried out. Pain was evaluated using a three-graded verbal rating scale. EMLA relieved pain significantly better than placebo ($p<0.001$) and the procedure was considered to be easier after EMLA treatment. No edema occurred, but few cases of local redness and paleness were observed after EMLA treatment. It was concluded that EMLA significantly reduces pain from venepuncture and side effects are mild and transient.

CONCLUSION

In our study, we have proved that the application of EMLA cream for venous cannulation alleviated pain. The effective time of application was found to be 60 minutes. EMLA cream has been found to be efficacious as a topical analgesic prior to venepuncture. The main advantage is being in its single dosage and easy application. The minor disadvantages include cost of EMLA cream and requirement of a rather long application time up to one hour. The cost factor could be overlooked considering the efficacy of EMLA cream in producing dermal analgesia especially in anxious adults. With this study we conclude that EMLA cream is a safe and alleviates effectively the pain associated with venepuncture and recommend the use of EMLA cream prior to venepuncture.

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