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OUR EXPERIENCE WITH EMLA CREAM (FOR PAINLESS VENOUS CANNULATION IN CHILDREN)

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Abstract: The local analgesic efficacy of EMLA Cream (a eutectic mixture of lidocaine and prilocaine; Astra pharmaceuticals, Sweden) in reducing the pain at Venous cannulation was investigated in a randomized blind study in 75 children scheduled for elective surgery. In 25 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.

Key words: EMLA Cream local analgesic cream painless venous cannulation

INTRODUCTION

A topical anaesthetic can be of great help for a number of painful procedures, but it is difficult to obtain a suitable anaesthetic agent which penetrates deep into the superficial tissues. Although, many local anaesthetic agents have been tried, none has demonstrated a clinical satisfactory efficacy.

EMLA Cream, a recently introduced eutectic mixture of lidocaine base and prilocaine base in an emulsifier (Arlectone) contains high concentration of active local anaesthetics (80%). This composition (ASTRA pharmaceuticals, Sodertalje, Sweden) is an emulsion and thereby achieves adequate penetration and concentration in the superficial tissues. It has shown promise in relieving the pain associated with short surgical procedures i.e., split skin grafting without additional anaesthesia (1), removal of tattos, skin biopsy and epidermal surgery (2). It has also been used to provide painfree venous cannulation in some of the studies done abroad (3-7). Due to the paucity of any report on EMLA Cream in Indian literature and the recent availability of this cream to the investigators, we designed the present study to evaluate the efficacy of EMLA Cream in providing a painfree venepucture in children in our set up.

METHODS

In the present prospective, blind, randomised study, 75 children between the ages of 1½-10 yrs who were scheduled to undergo elective surgery were included. After obtaining the ethical committee clearance, an informed consent was taken from the parents. Children suspected to be allergic to local anaesthetic agents were not included in this study. Patients were premedicated with morphine sulphate (0.2 mg/kg i m) 90 min prior to surgery. At this stage patients were divided into 2 groups, i.e., Group A consisting of 25 children (6 males and 6 females in age group 1½-3 yrs; 9 males and 4 females in age group 3-10 yrs) in whom a placebo cream was applied to the skin over a vein selected for venous cannulation and Group B consisting of 50 children (15 males and 10 females) in age group 1½-3 yrs; 10 males and 15 females in age group 3-10 yrs) in whom EMLA Cream was applied at the similar site. The creambase used in EMLA Cream as well as the placebo cream was the same.

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An occlusive dressing (provided by the drug firm) was applied to cover the cream in both groups. The cream was applied one hour prior to the anticipated venous cannulation. In the operation room, patient's level of anxiety was assessed by one of the authors and was graded as; calm, somewhat frightened, frightened and extremely frightened (7).

Pain Assessment: Pain reaction to the insertion of venous cannula was evaluated by the authors and was graded as per Manners classification (7) as grade 1 : No pain, no grimacing or whimpering and no reflex movement; Grade II; Slight pain, slight grimacing and minor reflex movement and Grade III: Severe pain i.e., loud cry and intense reflex movement. The results of anxiety scoring were compared by 't' test while those of grading of pain by Kruskal-Wallis test and 'P' value of <0.05 was considered significant.

RESULTS

The children's anxiety scoring before the operation and venous cannulation is shown in table I and there was no significant difference between the groups. It can be seen (Table I) that 84% of children in group B had no pain (grade I) while the remaining 16% children had grade II-III pain. On the contrary, in group A, 72% patients experienced grade III pain while only 10% patients had no pain (grade I). This difference in the incidence of pain between the groups was highly significant (<0.005). Pallor was seen at the site of cream application but the incidence was comparable in both the groups (39% and 48.2%) in groups A and B respectively. No other side effects of EMLA Cream was seen in any of the patient.

TABLE I: Showing anxiety scoring before venous cannulation and grading of pain at cannulation as per Manner's classification (7) in children treated topically with a placebo cream (Group A) and with EMLA Cream (Group B).

	Group A (n = 25)	Group B (n = 50)
Anxiety Scores		
• Calm	7	13
• Somewhat frightened	8	15
• Frightened	4	12
• Extremely frightened	6	10
Grading of Pain		
• Grade I	4	42
• Grade II	3	4
• Grade III	18	4

Groups did not differ significantly (P>0.05; 't' test) in anxiety scores, while difference was significant (P<0.05; Kruskal wallis H test) in grading of pain.

DISCUSSION

The cutaneous receptors responding to mechanical stimuli are of the A-type with fast myelinated fibres and C-type the slow unmyelinated fibres (8). The C-type of fibres are also present in the subcutaneous tissues and in the vascular wall (9). A needle inserted through the skin is a strong mechanical stimulus and induces a discharge in both types of fibres (9). In the subcutaneous tissues, the C-fibre nerve endings have a more protected position; hence the effect of mechanical stimuli are more difficult to judge.

Many attempts have been made to obtain a suitable formulation of an effective topical analgesic e.g. lidocaine (10) benzocaine (11) and combination of local anaesthetic agents with dimethyl sulphonate (12). The main obstacle has been the poor penetration of local anaesthetic agent through an intact skin.

Due to the paucity of direct methods for assessing efficacy of local application, indirect methods were employed to measure pain and excitement by measuring catecholamines and cortisol levels in blood. Rise in peripheral venous plasma catecholamine levels following venous cannulation in patients has been an inconsistent finding (13, 7, 14). We, have adopted a simple and efficient clinical grading methods using Manner's classification (7) for assessing the efficacy of topical applications.

In the present study, the analgesic efficacy of

EMLA Cream was convincing in comparison with placebo. Patients were evenly distributed in the two groups as far as the degree of calmness before the venous cannulation was concerned (Table I) and this, apparently has no bearing on effects of local treatments. The analgesic properties of EMLA cream are attributed to a high concentration of two local analgesic bases. These two analgesics together with an emulsion Arlectone and thicker carbocole have the property to penetrate deep into the subcutaneous tissues. In contrast, only 20% active substance is present in an individually emulsified local anaesthetic formulation. Transient local pallor at the site of venous cannulation was the only clinically significant side effect. Since this pallor was also present in the placebo treated patients, it is likely to be related to the pharmaceutical formulation rather than the local anaesthetic itself. The only limitation of EMLA Cream is its long application time, which is around 60 mins and this may not permit its use for the emergency procedures. In conclusion, our study shows that the eutectic mixture of prilocaine and lidocaine available as EMLA Cream is quite effective in reducing the pain associated with venous cannulation in children scheduled for elective surgery. In our opinion EMLA deserves a place in the routine premedication of children.

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