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Comparison of Pain Score in Differently Timed EMLA Cream Application in Pediatric Age Group

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Abstract
Background: *Securing a safe and patent intravenous access for drug and fluid administration is one of the most important pre requisites of delivering anesthesia to any patient. Intravenous cannulation is now performed almost universally before induction of anesthesia. This procedure has been reported to produce significant pain especially in pediatric population. Therefore it would be appropriate to use percutaneous anesthetic agents*
Methods and Material: *The efficacy of a topical anesthetic formulation, EMLA 5% cream (Eutectic Mixture of Local Anaesthetics), in obtunding the pain produced by intravenous cannulation was evaluated in our observational study. Pain scores were compared in total 50 patients with EMLA cream applied 30 minutes and 60 minutes prior to venous cannulation*
Results: *Patients in whom EMLA was applied 60 minutes prior to cannulation had the lowest pain score value with68% having pain score 0. Significant analgesia were produced in both 30minutes and 60 minutes group as shown by pain score 0&1, with 76% and 88% respectively*
Conclusions: *We recommend the use of EMLA cream prior to venepuncture in all pediatric patients. For maximum analgesic effect, EMLA should be applied for 60 minutes. Satisfactory analgesia can achieved after 30 minutes*
Keywords: *EMLA, cannulation, pain.*

Introduction

Securing a safe and patent intravenous access for drug and fluid administration is one of the most important prerequisites of delivering anaesthesia to any patient. Intravenous cannulation is now performed almost universally before induction of anesthesia [(1)]. However, this procedure is reported to produce significant pain especially in pediatric population. Therefore it would be appropriate to use percutaneous anaesthetic agents

Causing unnecessary pain during medical procedures can be considered as doing harm. The routine insertion of peripheral venous cannulae (PVC) is one example. As it goes by the basic principle of medicine - 'Do No Harm[1].[(2)]

Elimination or relief of pain and suffering, whenever possible, is an important responsibility of physicians caring for children. Increasing evidence has demonstrated that venous access procedures are an important source of pediatric

pain. Apart from the unpleasant feeling of pain associated with venous access procedures, it may also cause needle phobia. *Such* patients exhibit sometimes extreme adverse physiologic responses to needles, including vasovagal responses, changes in heart rate and stress hormone levels, and echocardiogram changes, they also may have increased morbidity and mortality throughout their lives as a result of chronic avoidance of medical care.[3] Intravenous induction of general anesthesia may produce severe distress and cause needle phobia, especially if the child requires subsequent repeat surgery. [4,5]

Although guidelines from many national and international associations for the study of pain call for multimodal strategies for prevention of needle stick pain, compliance with recommendations are often poor. Barriers to implementation of the guidelines include lack of knowledge among healthcare professionals regarding available pain assessment and treatment modalities, as well as perceived time constraints and inconvenience for administering local anesthetics[6]

There are many behavioural and pharmacological approaches to reduce pain during venous cannula-tion. Local anaesthetic creams are an important pharmacological approach. EMLA cream is a local anesthetic cream, which is a eutectic mixture of lidocaine and prilocaine in a ratio 1:1, which has a lower melting point than either component alone. Hence it exist as liquid oil in room temperature. This can penetrate more readily into the epidermal and dermal layers. The analgesic efficacy depends on the dosage and timing of application. Prolonged period of time necessary for onset of full action is a practical challenge in clinical setting.[7]

Many studies are avilable comparing EMLA with other topical agents in adullt and pediatric age groups. But, there is lack of enough studies comparing different timings of EMLA cream in pediatric age group, hence, a study to compare the analgesic effect of 30 minutes and 60 minutes application of cream using a pain score will help to optimize the use of EMLA cream.

Materials and Methods

This study was conducted in the department of anesthesiology and Critical Care**,** government medical college, Trivandrum during the year 2014 for period of 6 months

We conducted this study after obtaining the approval from the institutional research committee and ethics committee. Informed consent was taken from every patient willing to take part in the study. Patient confidentiality was strictly adhered to and data with no patient identifiers were recorded at any stage of the study or publication.

The study population consists of inpatients posted for surgeries belonging to ASA-PS (American Society of Anesthesiologist Physical Status) grade I and grade II, in whom venous cannulation was performed by an Anaesthesiologist. All patients aged between 7 to 12 years were eligible to take part in the study. We excluded patients with known hypersensitivity to EMLA cream or any other local anesthetics from the study. Patients with history of atopy, with open wound on the dorsum of the hand and those with methemoglobinemia were excluded from the study. Children with poor visible veins were also excluded. A formal sample size calculation prior to conducting the study was done. Sample size needed in each group was calculated as 25. All consecutive patients satisfying the inclusion and exclusion criteria were recruited into the study.

Routine blood tests, urine analysis, blood sugar and other relevant investigation specific for the surgery were done in all patients.

All patients recruited were premeditated with oral Midazolam 0.5mg/kg. Intravenous cannulation for administration of drugs was performed by the consultant anesthesiologist in all patients. Venous cannulation was performed following one of the three methods as per the preference of the anesthesiologist. These methods included cannulation without application of EMLA cream, 30 minutes after application of EMLA cream or 60 minutes after application of EMLA cream. Anesthesiologist followed a standardized procedure in our institution in applying the

cream. Non dominant hand was chosen and a suitable vein on the dorsum of the hand was selected. Consequently EMLA cream was applied in 3x3cm size with an occlusive dressing and the time noted. As per the consultant's practice, venous cannulation was done after the prescribed time. Venous cannulation was done using the 22G cannula. In Patients without EMLA cream, venous cannulation was done in the same standardized procedure. All patients in all groups were monitored with ECG, NIBP, pulse oximeter and blood pressure.

Data was collected using a pretested questionnaire by residents duly trained in data collection techniques. The data so collected was then entered into an excel database for analysis.

Primary outcome measured was pain score immediately after performing venous cannulation. This was assessed using the 4 point scale with 0 being no response, 1 mild facial grimace, 2 as verbal response and 3 as withdrawal of hands.

Statistical data analysis were done in r statistical software and graphpad prism software. Quantitative variables were described with mean and standard deviation. Categorical variables were summarized with percentages. Comparison between quantitative variables were done with t test and that between categorical variables were assessed with chi square test. A p value of less than 0.05 was considered as statistically significant.

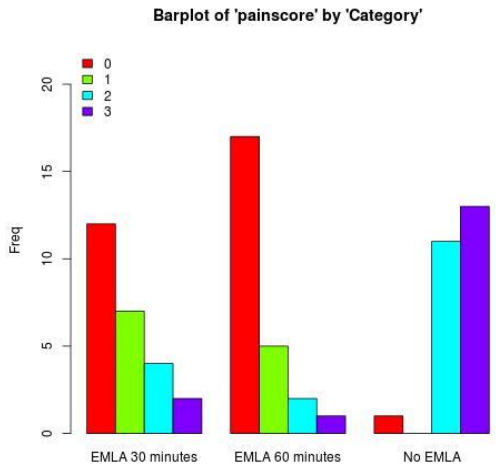
Results

We studied a total of 75 patients in this study with a median age of 8(7;10)years. These patients were divided into three groups called no EMLA group, EMLA 30minutes group and EMLA 60 minutes group. There were more males 44(59%) in our study. Of these patients 61(81.3%) belonged to the ASA grade 1. The median weight of the patients was 22(20;27)kg. There was no serious side effects for any of the patients. The three groups were comparable with respect to the baseline characteristics table 1.

Table I: Baseline characteristics

Var	(All) N= 75	EMLA 30 minutes N=25	EMLA 60 minutes N=25	no EMLA =25	P.Overall
Age	8.00 (7.00;10.0]	8.50 [7.00;10.0]	8.50 [7.00;10.0]	8.00 [7.00;10.0]	0.844
Sex					0.681
Female	31[41.3%]	12 [48.0%]	10 [40.0%]	9 [36.0%]	
Male	44 [58.7%]	13 [52.0?%]	15 60.0%]	16 [64.0%]	
ASA					0.657
1	61 [81.3%]	20 [80.0%]	22 [88.0%]	19 [76.0%]	
2	14 [18.7%]	5 [20.0%]	3 [12.0%]	6 [24.0%]	
Wt	22.0 [20.0;27.0]	23.0 [20.0;28.0]	22.0 [20.0;26.0]	21.0 [20.0;25.0]	0.875

There was statistically significant reduction in the pain score between the three groups as given in the **figure 1**.



As shown in the table II 68% of the EMLA 60 minutes group reported pain score of 0, followed by 48% in the EMLA 30 minutes group. However when pain score with 0 and 1 together taken as satisfactory analgesia, 30 minutes and 60 minutes EMLA groups showed comparable analgesia.

Table II Comparison of pain scores across groups

Variable pain score	(All) N= 75	EMLA 30 minutes N=25	EMLA 60 minutes N=25	no EMLAN =25	P. Overall 1
0 (No Response)	330[40.0%]	12 [48.0%]	17 [68.0%]	1 [4.00%]	<0.001
1 (Mild Facial Grimace)	12 [16.0%]	7 [28.0%0	5 [20.0%]	0 [0.00%]	
2 (Verbal Response)	17 [22.7%]	4 [16.0%]	2 [8.00%]	11 [44.0%]	
3 (Withdrawal of hands)	16 [21.3%]	2 [21.3%]	1 [4.00%]	13 [52.0%]	
Pain2					<0.001
Mild	42 [56.0%]	19 [76.0%]	22 [88.0%]	1 [4.00%]	
Severe	33 [44.0%]	6 [24.0%]	3 [12.0%]	24 [96.0%]	

Discussion

We conducted this study to compare the analgesic efficacy of EMLA cream in pediatric age group when applied 30 minutes and 60 minutes prior to cannulation. Our study included 50 patients of both sex belonging to age group 7-12 yrs posted for elective surgery. Different studies have been done to show the efficacy and timing of application of EMLA cream to provide analgesia. In our study 50 patients who received EMLA cream either 30 min or 60 min prior to cannulation had notably lower pain scores. Significantly lower pain scores was evident in 60 min EMLA cream when compared to 30 min EMLA cream. The percentage of patients with pain score 0 was 68 % in 60min group 48 % in 30 min and only 4% in no EMLA group. This showed that EMLA cream application was probably effective when applied 30 min prior to cannulation but for maximum analgesic effect it should be applied an hour before cannulation.

As per the study done by Molodecka J and Stenhouse C (1994),120 unpremedicated, ASA I and II women undergoing day case gynaecological procedures were divided into four groups: 5 % EMLA cream 2.5 g for 30 min (E- 30); 5% EMLA cream 2.5 g for 60 min (E-60); 5 % w/w amethocaine cream 1 g for 30 min (A-30); 5 % w/w amethocaine cream 1 g for 60 min (A-60) before venous cannulation. Pain was assessed using Visual Analogue Scale (VAS). Median VAS for groups E-30 and E-60 were 19 mm and 13.5 mm. Good analgesia was obtained in all groups and there was no statistically significant difference in pain scores between the groups. Likewise we also obtained reduced pain scores treated with EMLA cream. Out of 50 patients with EMLA cream 41 patients had lower pain *scores* of 0 and 1; whereas only 1 patient in the NO EMLA group had low pain scores.[8]

Cordoni et al (2001) conducted a study to explore the relation between the application of a mixture of lidocaine/prilocaine cream (eutectic mixture of local anesthetics [EMLA]) before intravenous cannula insertion and perceived pain in the pediatric patient. Out of 57 patients, 29 patients in the placebo group and 28 in the EMLA group, placebo or emla were applied 45 minutes before intravenous cannulation. The EMLA group experienced less pain(mean pain score, 1.25) than those in the placebo group (mean, 8.39). Thus they concluded that a topical preparation of lidocaine/prilocaine significantly reduces children's pain when applied 45 minutes prior to cannulation. In our study, we found that, when EMLA cream was applied 60 minutes prior to cannulation 68% patients had a pain score of zero, which shows significant reduction in pain.[9]

Sharma et al (1994) conducted a study that was designed to compare the efficacy of EMLA cream with that of infiltration with lidocaine in relieving the pain associated with administration of spinal anesthesia. They studied 41 ASA status I and II women scheduled for postpartum tubal ligation. Pain was assessed by a 10-cm visual analog scale. The EMLA group had significantly lower pain scores (mean, 1.5) than in the lidocaine group (mean, 3.52) ($P < .001$). Application of EMLA cream for at least 30 minutes prior to spinal needle insertion is adequate to provide good analgesia during needle insertion. In our study, 76% patients had satisfactory analgesia as evidenced by a pain score of either zero or one.[10]

The limitation of our study is that, this is not a randomised controlled trial. Also the sample size seems to be lower to make a strong recommendations based on our study. However, our observations points towards the scope of a double blinded randomised controlled trial in this regard.

Conclusion

Pain due to venous cannulation can be avoided by appropriate use of topical anesthetic. EMLA cream applied for 60 minutes can be used effectively to reduce this pain in children. In any situations where the patient cannot wait for 60 minutes, a 30 minutes application shall be considered to provide satisfactory analgesia.

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