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ASSESSMENT OF THE EFFICACY OF EUTECTIC MIXTURE OF LOCAL ANAESTHETIC (EMLA) CREAM FOR INTRAVENOUS CANNULATION IN PEDIATRICS

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INTRODUCTION

One of the readiness's prior to giving anaesthesia is securing an intravenous access for administering fluid and drugs safely. The procedure of Intravenous cannulation is done universally before induction of anaesthesia.[1]

Securing venous access is painful procedure causing significant anxiety, distress and discomfort.[2] this pain leads to lack of co-operation by children, unsuccessful procedural attempts, repeated attempts and increased total procedural time. Most often children only remember the painful venous cannulation.[3] Hence the quality of anaesthesia delivered is also marred.[4]

EMLA aka eutectic mixture of local anaesthetic cream is specific composition of oil in water emulsion of crystalline bases of 2.5% lidocaine and 2.5% prilocaine with lower melting point than that of individual drugs. This combination is liquid at room temperature. To obtain a suitable consistency a thickener, carbopol is added. Intact skin can be anesthetized effectively topically now feasible without causing pain with subcutaneous injection of local anaesthesia drugs.[5]

Behavioral observational scales are the primary tools currently available for the assessment of pain in the group of neonates, infants and children who are aged below 3 years. These scaling most often relies on subject's expression of face, motor response and physiological indices. Children between ages of 3 to 8 years are in general, able to self-report pain using 'faces scales' either photographs or drawings of faces. Children aged 8 years above can use more validated one-dimensional tools, namely verbal rating scale, visual analogue scale, and numeric rating scale as in adults.[5]

The present study was conducted for assessing efficacy of eutectic mixture of local anesthetic (EMLA) resulting in analgesia of skin for venous cannulation in children aged 8-16 years.

OBJECTIVESOFTHE STUDY

1. Assessing dermal analgesia for venous cannulation in children aged 8-16 years to eutectic composition of local anaesthetic (EMLA) cream.
2. To assess any side effects of the drug used to provide analgesia for venous cannulation in children aged 8-16years

MATERIALS AND METHODS

SOURCE OF DATA

100 patients admitted at Kempegowda Institute of Medical Sciences Hospital, Bangalore who

was posted for elective surgeries during the period of October 2017 to September 2019 are included in the study after obtaining institutional ethical clearance. The details of the procedure was explained for both children and their parents as well written informed consent was obtained from all parents enrolled in the study.

METHOD OF COLLECTION OF DATA

Study Design: Comparative randomized parallel open label controlled study
Sample Size: 50 subjects in each group – group E experimental group, group C control group including children in the age group of 8-16 years posted for elective surgeries.
Sampling Method: Random sampling

INCLUSION CRITERIA:-

- Patients aged 8-16years.
- Consent from parents/guardian will be taken
- Undergoing elective surgeries.
- Able to report level of pain within specified pain scale

EXCLUSION CRITERIA:-

- Patients not willing to take part in the study.
- Children having known allergy to EMLA cream or local anesthetic drug
- Children who are non responsive or unable to understand or report pain scale

Methodology

This study was performed in Kempegowda Institute of Medical Sciences Hospital, Bangalore. After institutional ethical committee clearance obtained, 100 admitted patients who are scheduled for surgeries belonging to ASA grade I and grade II were selected. The patients belonged to either sex and were of the age group between 8 to 16years.

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

- Children having known drug allergy to EMLA cream or any other local anaesthesia drug.
- Children having methemoglobinemia or currently who are on medications that may cause methemoglobinemia

Investigations included routine Hb, urine analysis, blood sugar and other specific tests as required for concerned surgeries. Details of the study had been explained as well the informed consent was obtained from the parents/ guardian of all patients.

PROCEDURE

Group of 100 subjects divided into two groups randomly Group E, experimental group.
Group C, control group
Group E, included 50 patients in whom EMLA cream was applied 60 minutes prior to venous cannulation
Group C, included 50 patients in whom venous cannulation was performed without EMLA cream
After being explained the procedure, non dominant hand (unless otherwise specified) was chosen and a suitable vein on the dorsum of the hand was selected.
In group C patients, intravenous cannulation was performed with 20/22gauge intravenous cannula and pain score was noted.
In group E patients, EMLA cream1.5to2gm/10cm^{2}area was applied over the site of cannulation

in a thick layer. This layer was then covered with an occlusive dressing. The surrounding area was cleaned with dry gauze. EMLA cream was applied for 60 minutes
After the prescribed time of application of EMLA cream, 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 venous cannulation was performed with20/22 gauge intravenous cannula and pain score noted.

NO PAIN MODERATE PAIN SEVEREPAIN

SAMPLE SIZE ESTIMATION

$$N = \frac{(r+1)\left(Z_{\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \sigma^2}{rd^2}$$

N= sample size
Where Zα is the normal deviate at level of significance and Z1-β is the normal deviate at 1-β% power with β% of type II error.
r=n1/n2 is the ratio of sample size required for two groups
σ and d are the pooled standard deviation and difference of means of 2 groups

STATISTICAL ANALYSIS

The data collected in the study are analyzed statistically by presenting data in the form of frequency tables and expressing results in percentage. The difference in mean between the two groups was analyzed by applying Student's t-test. The results is considered statistically significant whenever P value is less than or equal to 0.05.The proportions will be analyzed using Z test and the results is considered statistically significant if P value is less than or equal to 0.05.

RESULTS

Table-I: Age Distribution

Age (years)	**Experimental group**		**Control group**	
	No.	**Percentage**	**No.**	**Percentage**
≤ 10	19	38.00	19	38.00
> 10	31	62.00	31	62.00
Total	**50**	**100.00**	**50**	**100.00**

The two groups have similar age distribution. The percentage of children in 8-10 years in both the groups is 38 and in 11-16 years is 62 in both the groups.

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Graph I: Age distribution

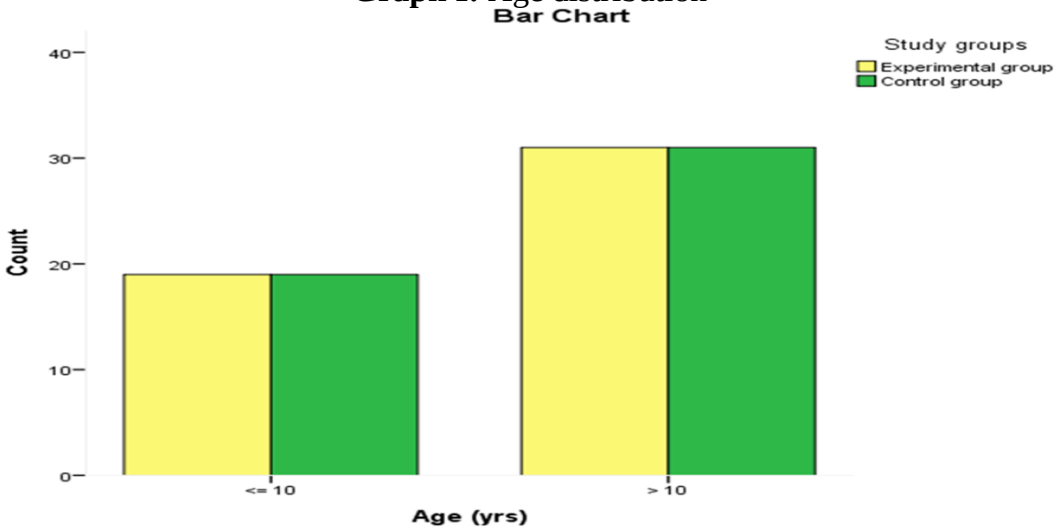

Table II: Sex distribution

Sex	Experimental group		Control group	
	No.	Percentage	No.	Percentage
Male	36	72.00	36	72.00
Female	14	28.00	14	28.00
Total	**50**	**100.00**	**50**	**100.00**

72 % of males were allotted to both the groups and 14% of females in both the groups, hence the distribution ratio in relation to sex was similar in both the groups.

Graph II: Sex distribution

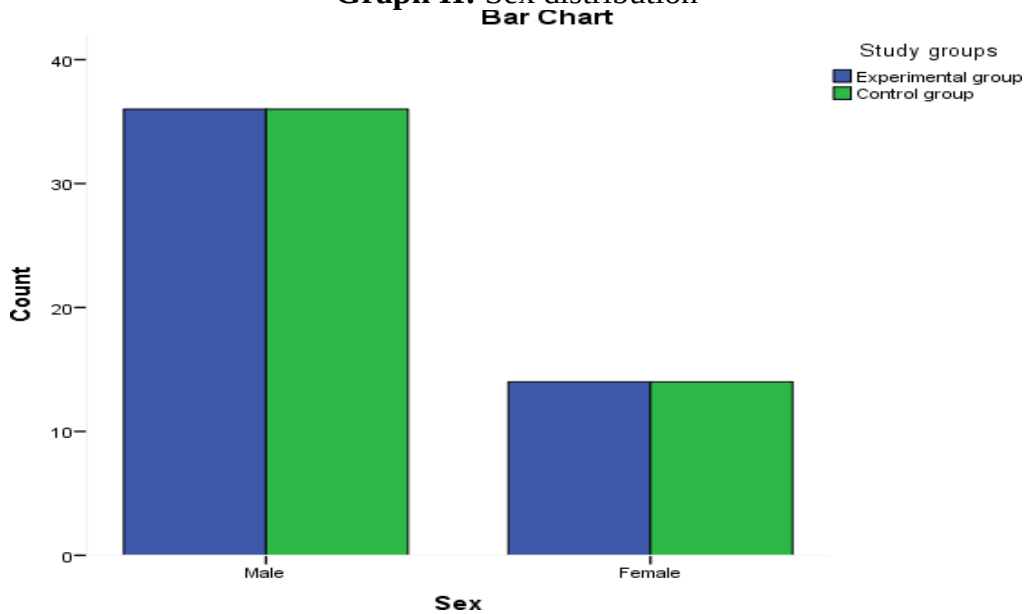

Table III: Comparison of VAS score during cannulation

Study group	Mean	SD	95% confidence interval for mean	t- value	P-value	Inference
Experimental group	1.56	1.31	(1.19, 1.93)	19.315	P= 0.001	Statistically highly Significant
Control group	6.82	1.41	(6.42, 7.22)			

VAS scores compared between the groups showed highest pain scores for the control group. Experimental group had lower pain scores. The results showed high statistical significance.

Table IV: Comparison of Erythema in the study groups

Erythema	**Experimental group**		**Control group**	
	No.	**Percentage**	**No.**	**Percentage**
yes	2	4	0	0
no	48	96	50	100
Total	**50**	**100.00**	**50**	**100.00**

2 children in the group E had erythema following EMLA application. Applying the Z- test for testing the difference between the 2 groups, Z=1.443 and P>0.0749, there is no statistical significance. Hence the EMLA cream is safe.

DISCUSSION

We conducted a study on 100 children undergoing elective surgeries in the age group between 8-16years of either sex to know EMLA's efficacy in causing analgesia to venous cannulation after an hour of application. Many attempts have been made in the past to study the effective duration of EMLA application.

Ehrenstrom, ReizG,ReizS[18]etal(1983)showed minimal time for effective analgesia after application of EMLA cream found to be 45 minutes prior to venous cannulation, while Hallen B, Olsson G C et al (1984) conducted a study to assess the effect of timing of application of EMLA cream and it revealed that the efficacy of cream was evident after 60 minutes of application for venepuncture.[19]In our study EMLA application was done 60 minutes before cannulation. Effective analgesia for venous cannulation was demonstrated in the EMLA group.

Taddio A et al[3] (2005) in a study on liposomal lidocaine to improve procedural successratesandreduceproceduralpainamongchildrenaged1month-17years,the pain scores in children less than 5 years was interpreted by parents and research assistant.The pain ratings were influenced by child's behavioural distress. Our study included children aged more than 8 years, the pain scores were interpreted by the children included in the study.The self interpretation of pain scores decreased the chances of undue high score reporting by the parents. These inferences were drawn from the study conducted by Fanurik D et al[41] and Taddio A et al[3].

Ehrenstrom Reiz et al[17](1982), used EMLA cream to reduce the pain associated with venous cannulation in 60 children aged 6 to 15years. EMLA cream yielded high plasma concentration of active substance and a significant difference in pain due to venous cannulation in favor of EMLA compared to placebo was found in the study (P<0.001).

HallenBetal[20](1985)in the clinical study of lignocaine-prilocaine cream to relieve the pain of venipuncture, 28 subjects had lower pain scores with EMLA and 3 subjects had similar pain scores between the EMLA and placebo group and transient skin reactions were observed in both thegroups.

Molodecka J and Stenhouse C (1994) conducted a study to assess the efficacy of topical amethocaine cream 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.[1]

In our study too the efficacy of EMLA for analgesia of venous cannulation was proved expect for one child who had pain scores of 9. The mean pain scores in the experimental group was 1.56 compared to the control group with mean pain scores as high as 6.82. The results of our study had a P value of 0.001 and had high statistical significance. The results of study is in par with

the study conducted by Ehrenstrom Reiz et al[17].
One of the drawback of EMLA Is its duration of application. Many studies have been conducted for alternative methods to decrease this waiting period.

CONCLUSION

In our study, the efficacy of 5% eutectic mixture of local anesthetic cream in providing analgesia for intravenous cannulation in children in the age group between8-16 years was proved and the results showed high statistical significance with a P value of < 0.05 when applied 60 minutes before cannulation.
The application of EMLA also increased the number of first time successful cannulation due to decreased movement of the child.
The analgesia provided by EMLA relieves the anxiety of the child

The main drawback is the long application time but it gives time for the child to get accustomed to the environment. Hence there is further scope for research to decrease the duration of application of EMLA for effective analgesia.

SUMMARY

The present study entitled "ASSESSMENTOFTHEEFFICACYOFEUTECTIC MIXTURE OF LOCAL ANAESTHETIC (EMLA) CREAM FOR INTRAVENOUS CANNULATION IN PEDIATRICS" was conducted in
Kempegowda institute of Medical Sciences and hospital from October 2017 to September 2019.

After obtaining institutional clearance and consent from the parents, a comparative randomized parallel open label controlled study was conducted on 100 children belonging to the age group between 8-16years of ASA I and ASA II physical status undergoing elective surgeries after satisfying the inclusion and exclusion criteria. They were randomly divided into 2 groups-
Group E-experimental group, receiving EMLA cream Group C- control group
After routine preoperative assessment EMLA cream was applied on the dorsum of the hand after selecting a suitable vein in the group E and cannulation was preformed after 60 minutes. In group C cannulation was performed without applying EMLA cream.
Pain was assessed using 10cm visual analogue scale.
Patients who treated with EMLA cream had decreased pain scores compared to the control group. The mean pain scores the control group was 6.82 compared to experimental group with mean scores of 1.56. The statistical analysis conducted using Student's t-test had a P value of 0.001 which was statistically significant. Hence use of EMLA cream 60 minutes before venous cannulation was effective in providing analgesia.
Two children in the experimental group, after application of EMLA had erythema which was observed during cannulation and the P value was 0.0749, which was not significant statistically. No other serious adverse drug reactions were observed during the course of our study. Hence EMLA cream was safe.

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