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 of2.5% 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. Thesescaling 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]

Thepresentstudywasconductedforassessingefficacyofeutecticmixtureoflocala nesthetic (EMLA)resulting in analgesia of skinforvenouscannulationinchildrenaged8-16 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 8-16yearsMATERIALS AND METHODS

SOURCE OF DATA

100 patients admitted at KempegowdaInstitute of MedicalSciences 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 experimentalgroup, group C controlgroup including children in the age group of 8-16 years posted for elective surgeries.

Sampling Method: Random sampling

INCLUSION CRITERIA:-

- Patients aged 8-16years.
- Consentfromparents/guardianwillbetakenandassentofthechild

- Undergoing electivesurgeries.

- Able to reportlevelofpainwithin specifiedpainscale

EXCLUSION CRITERIA:-

- Patients not willing to take part in thestudy.

- childrenhaving known allergytoEMLAcreamorlocalanesthetic drug

- Children whoarenonresponsiveorunabletounderstandorreportpainscale

Methodology

ThisstudywasperformedinKempegowdaInstituteofMedicalSciencesHospital,Bangalore.Afterinstitutionalethicalcommitteeclearance obtained, 100 admitted patients who are scheduled for surgeries belonging to ASA grade I and grade II wereselected.Thepatientsbelongedtoeithersexandwereoftheagegroupbetween 8 to 16years.

Aroutinepre-operativeevaluationwasdoneforallpatientsandthefollowingpatients wereexcluded:

- 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, experimentalgroup.

Group C, control group

Group E, included 50 patients in whom EMLA cream was applied 60 minutes prior to venous cannulation

GroupC, included50patientsinwhomvenouscannulationwasperformed without EMLAcream

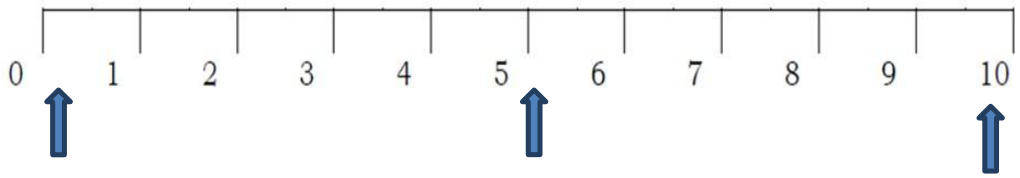
After being explained the procedure, non dominant hand (unless otherwise specified) was chosen and a suitable vein on the dorsum of the hand was selected.

In group C patients, intravenous cannulation was performed with 20/22gauge intravenous cannula and pain score was noted.

IngroupEpatients, EMLAcream1.5to2gm/10cm^2areawasappliedoverthesiteof 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.Theareawasthenwipeddrywithgauzeandobservedforsignsofanylocal reaction. After disinfecting with spirit venous cannulation was performed with20/22 gauge intravenous cannula and pain scorenoted.

Visual Analogue Scale



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

WhereZαisthenormaldeviateatlevelofsignificanceandZ1-βisthenormaldeviate at 1-β% power with β% of type IIerror.

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

Thedatacollectedinthestudyareanalysedstatisticallybypresentingdataintheform of frequency tables and expressing results in percentage. The difference in mean between the two groups was analysed by applying Student's t-test. The results is consideredstatisticallysignificantwheneverPvalueislessthanorequalto0.05.The proportions will be analysed using Z test and the results is considered statistically significant if P value is less than or equal to0.05.

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.

Graph I: Age distribution

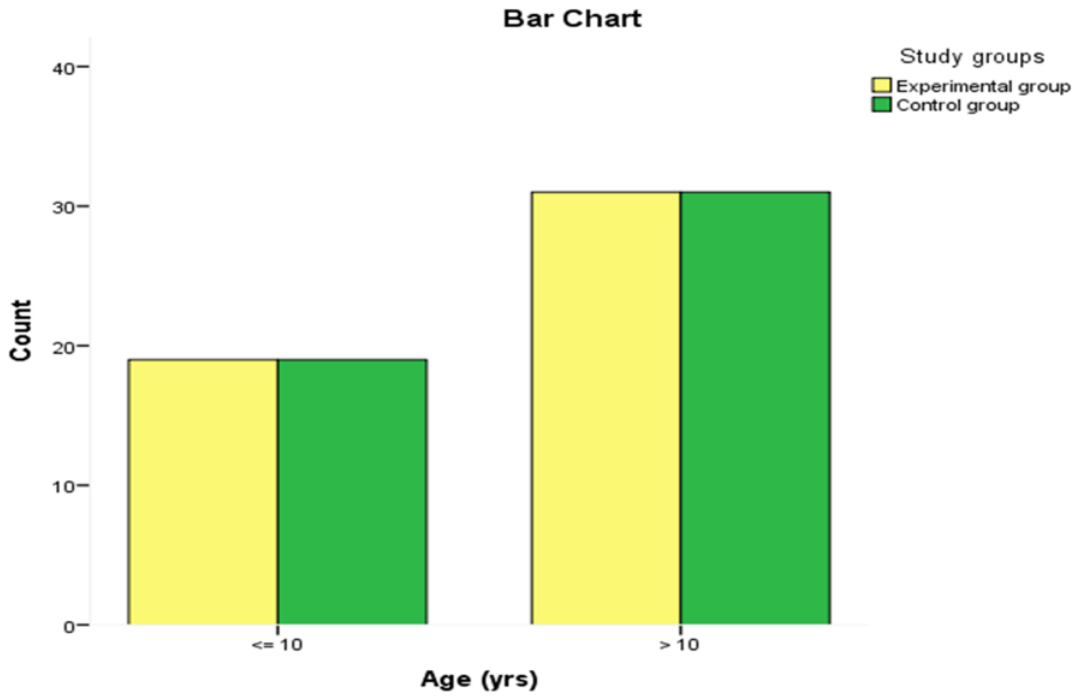


Table II: Sex distribution

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

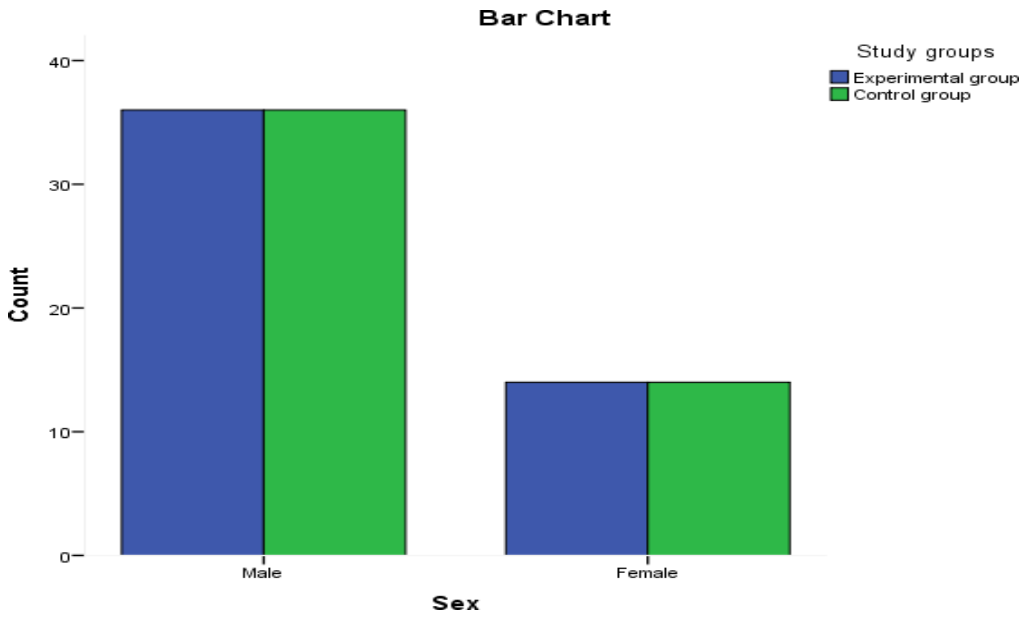


Table III: Comparison of VAS score during cannulation

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)			

VASscorescomparedbetweenthegroupsshowedhighestpainscoresforthecontrol group.Experimentalgrouphadlowerpainscores.Theresultsshowedhighstatistical 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**

2childreninthegroupEhaderythemafollowingEMLAapplication.ApplyingtheZ- 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 issafe.

DISCUSSION

Weconductedastudyon100childrenundergoingelectivesurgeriesintheagegroup 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)showedminimal 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 creamwas evident after 60 minutes of application forvenepuncture.[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.Thepainratingswereinfluencedbychild'sbehaviouraldistress.Our study included children aged more than 8 years, the pain scores wereinterpreted bythechildrenincludedinthestudy.Theselfinterpretationofpainscoresdecreasedthe 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 associatedwith 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)intheclinicalstudyoflignocaine-prilocainecreamtorelieve 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 experimentalgroupwas1.56comparedtothecontrolgroupwithmeanpainscoresas 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].

OneofthedrawbackofEMLAisitsdurationofapplication.Manystudieshavebeen 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 accustomedtotheenvironment.Hencethereisfurtherscopeforresearchtodecrease the duration of application of EMLA for effectiveanalgesia.

SUMMARY

Thepresentstudyentitled“ASSESSMENTOFTHEEFFICACYOFEUTECTIC MIXTURE OF LOCAL ANAESTHETIC (EMLA) CREAM FOR INTRAVENOUS CANNULATION IN PEDIATRICS” was conductedin 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-
GroupE-
experimentalgroup,receivingEMLAcream
Group C- controlgroup
AfterroutinepreoperativeassessmentEMLAcreamwasappliedonthedorsumofth e 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 painscores comparedto
thecontrolgroup.Themeanpainscoresthecontrolgroupwas6.82comparedto experimental group with mean scores of 1.56. The statistical analysis conducted usingStudent’s t-test had a P valueof 0.001 which was statistically significant.HenceuseofEMLAcream60minutesbeforevenouscannulationwasef fectivein providinganalgesia.

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 significantstatistically.Nootherseriousadversedrugreactionswereobservedduring the course of our study. Hence EMLA cream wassafe.

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