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Efficacy of topical anaesthetic EMLA (5% eutectic mixture of lidocaine and prilocaine) in alleviating pain during vaccination among children up to 2 years

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Abstract
Objectives: t*o evaluate the effectiveness of topical eutectic mixture of local anaesthetics (EMLA) cream in reducing the pain associated with vaccination injections.*
Methods: *This was a tertiary hospital based, Prospective and Interventional Randomized Comparative study including children from birth to 2 year age who presented for routine immunization. Eligible children were randomly assigned to receive either EMLA or placebo cream. The primary outcome measure neonatal pain was assessed using NIPS and FLACC Pain scale, reliable tools to assess neonatal painimmediately after the vaccine introduced, at 30 second, and at 3 minute after introduction of vaccine. Total duration of cry was noted.*
Results: *298 healthy term neonates were taken for our study. The study population was divided into two both the groups had 149 participants in each group. Our study observed that NIPS score and FLACC score immediately after vaccination, 30 seconds after vaccination, 3 minutes after vaccination and duration of cry were significantly different between EMLA and placebo children.*
Conclusion: *Application of EMLA cream can be effectively incorporated as a routine pain-relieving intervention within routine vaccination appointments.*
Key words: *Eutectic (EMLA), routine immunization, pain assessment.*

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I. Introduction

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[1] Acute pain is one of the most common adverse stimuli experienced by children, occurring as a result of injury, illness, and necessary medical procedures. Injections for vaccination are the most common source of iatrogenic pain in childhood and are administered repeatedly to almost all children throughout infancy, childhood and adolescence.[2]Pain due to immunization is unavoidable as all the children have to undergo repeated vaccine injections and is associated with such injections is a source of distress for children, their parents and those administering the injections.[3]Painful experiences may cause structural and physiological changes within the nervous system. Repeated painful procedures may result in decreased pain threshold and hypersensitivity to pain.[4]

NIPS and FLACC are valid, reliable and practical scales for assessing neonatal pain. FLACC is a behavioral scale for post-procedural pain in young children. It includes 5 indicators (face, legs, activity, cry and consolibility) with each item ranking on a three point scale (0-2) for severity by behavioral descriptions resulting in total score between 0-10. It is used in children from 2 months to 7 years.[5]Intense anxiety experienced by the parents and their children regarding vaccination may result in non-adherence to the recommended vaccination schedule.[6,7] Thus devising a less painful and less stressful route and method for vaccine administration may help in improving the compliance to vaccination.

The present study was planned to determine the acute pain response to injections from birth to 2 years of age. The aim of present study was to assess the effects of eutectic mixture of topical anesthetics (EMLA) on pain responses.

II. Subjects And Methods

This prospective and interventional randomized comparative study was conducted in immunization room of M.C.H. centre of Kamla Nehru State Hospital for Mother and child Shimla and IGMC Shimla. All healthy newborn babies up to 2-year age were included in the study between June 2018 to May 2019. Gestation less than 37 weeks, IUGR baby, newborn with any kind of illness (acute febrile illness), requiring any kind of supportive treatment after birth, with any major congenital malformations, born to those mothers who receive any drug which cause CNS depression in the baby, whose parent/ guardians refuse to give the consent for the study, with any skin allergy or local infection at site of injection, with a history of allergy to local anaesthetic or to any component of EMLA cream, received analgesic, anaesthetic or sedative less than 12 hours before the time of vaccination, with congenital or idiopathic methaemoglobenemia,G6PD deficiency, severe hepatic or renal disease, and use of class-1 anti-arrhythmic drugs were excluded.

All the study subjects were randomized to receive 0.5 gm of EMLA or placebo cream (an inert cream that could not be visually differentiated from EMLA).

The primary outcome measure neonatal pain was assessed using NIPS and FLACC Pain scale, a reliable tool to assess neonatal pain immediately after the vaccine introduced, at 30 second, and at 3 minutes after introduction of vaccine.

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables were compared using Student t-test between the two groups. Qualitative variables were compared using Chi-Square test /Fisher's exact test. P value <0.05 was considered significant. Statistical analysis was performed using SPSS v21.

III. Results

A total of 298 children were included in the study. Table 1 shows general characteristics of the study participants. 82.5% of children in EMLA group and 84.6% children in placebo group aged up to one year. 53% of all the children were males. Majority of the children belonged to lower middle class. Age distribution of children, sex, socioeconomic status, mother's age, gravida, and type of delivery were comparable between both the groups.

Anthropometric characteristics

Our study observed that weight (7.33±3.15 vs. 7.27±3.22; P=0.870), OFC (39.32±4.54 vs. 38.77±4.22; P=0.280), and length (59.97±10.67 vs. 58.62±10.07; P=0.262) were comparable between EMLA and placebo children (Table 2).

Effect of EMLA on NIPS score and duration of cry

Our study observed that NIPS score immediately after vaccination (3.79±1.13 vs. 5.59±0.61; P<0.0001), 30 seconds after vaccination (2.07±1.05 vs. 3.32±0.63; P<0.0001), 3 minutes after vaccination (0.45±0.60 vs. 1.15±0.49; P<0.0001), and duration of cry (25.08±4.39 vs. 145.44±7.29; P<0.0001) were significantly different between EMLA and placebo children(Table 3).

Effect of EMLA on FLACC score and duration of cry

Our study observed that FLACC score immediately after vaccination (4.27±0.83 vs. 5.52±1.24; P<0.0001), 30 seconds after vaccination (2.35±1.13 vs. 3.04±0.98; P=0.026), 3 minutes after vaccination (0.58±0.50 vs. 1.17±0.39; P<0.0001), and duration of cry (26.73±3.73 vs. 46.96±13.46; P<0.0001) were significantly different between EMLA and placebo children(Table 4).

IV. Discussion

Injections for vaccinations, the most common source of iatrogenic pain in childhood, are administered repeatedly to almost all Indian children throughout infancy, childhood and adolescence. The pain associated with such injections is a source of distress for children, their parents and those administering the injections. If not addressed, this pain can lead to pre procedural anxiety in the future, needle fears and health care avoidance behaviors, including non-adherence with vaccination schedules. It is estimated that up to 25% of adults have a fear of needles, with most fears developing in childhood. About 10% of the population avoids vaccination and other needle procedures because of needle fears.

One intervention that can be delivered by parents or health professionals prior to a needle insertion procedure is application of a topical anaesthetic. Several topical anaesthetics are available and can be used during invasive procedures for the prevention of pain in paediatric patients. Hence, this study aimed to determine the effectiveness of topical anaesthetic EMLA (5% eutectic mixture of lidocaine and prilocaine) in alleviating pain during vaccination given up to 2 years.

In our study pain was significantly higher in control group throughout the assessment and significantly decreased after use of EMLA patch at all time intervals that is immediately after vaccination, at 30 sec and at 3 minutes after vaccination. Results in present study revealed that EMLA cream significantly decreases NIPS and FLACC score up to 3 minutes of vaccination. Duration of cry was also significantly lower in EMLA group. This is in concordance with Abuelkheir et al[8] showed that use of EMLA cream for routine childhood vaccinations was effective in reducing the pain associated with either subcutaneous or intramuscular immunization.

These findings are also comparable with study done by Taddio et al[9] who reported a significant decrease in pain in the form of increase in the latency to first cry (MD, 0.90 sec ; 95%CL, .46 to 1.34 ; P<0.001) and decrease in duration of first cry (MD, -1.30sec; 95%Cl, -2.55 to – 0.05 ; P=0.04) for infant who received lidocain – prilocaine versus a placebo during DPT vaccination at 6, 10, 14 weeks, however they did not include newborns in their study.

Similarly, UhariM[10] also reported a lower mean VAS pain score (range, 0-10 cm) (2.5 vs 3.8; P<0.003) and VAS crying score (range, 0-10cm) (2.8 P<0.003) for infant who received lidocain-prilocain than for those who received placebo during DPT vaccination in infant. They also did not include newborns in their study and used VAS score for assessment of pain.

In a study of lidocaine – prilocaine and no intervention, Dilli et al[11], reported a significant reduction in the NIPS score (range, 3-7) (MD, -4.0095% CI, -4.83 to -3.17;P <0.001) in infants 6 to 12 months of age and in the CHEOPS score (range , 4-13) (P .001; data =NR) during different vaccines Hep B at 0- 2weeks, at 1 and 6 month and MMR at 9 months.

Some of the studies have reported effect of EMLA with circumcision, venepuncture, lumbar puncture and subcutaneous injection. But, none of the studies has compared effect of EMLA on intradermal injections.

The efficacy of EMLA in reducing overall injection pain is likely attributable to a decrease in pain as the needle penetrates the skin, as well as a reduction in the underlying muscle spasm that is associated with such pain. Abuelkheir et al[8] reported that application of EMLA cream can be effectively incorporated as a routine pain-relieving intervention within routine vaccination appointments.

V. Conclusion

Application of EMLA was associated with lower pain scores and less crying in infants during vaccination. The EMLA cream may thus be useful for premedication of infants before such procedures. The method of administration is crucial to the efficacy of EMLA; the fact that most parents were able to use it correctly suggests that it can be utilized in this setting.

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Table 1: General characteristics

	EMLA (n=149)	Placebo (n=149)	P value
Age (months) Up to 12 months >12 months	 123 26	 126 23	0.639
Sex (Male:Female)	81:68	78:71	0.728
Socioeconomic status Upper Middle Upper Lower Lower Middle	 21 24 104	 26 33 90	0.227
Mothers' age (years)	26.91±4.50	27.63±4.63	0.172
Gravida, Primi	61	64	0.725
Type of delivery NVD AVD LSCS	 93 17 39	 105 21 23	0.071

Table 2: Anthropometric characteristics

	EMLA (n=149)	Placebo (n=149)	P value
Weight (Kg)	7.33±3.15	7.27±3.22	0.870
OFC (cm)	39.32±4.54	38.77±4.22	0.280
Length (cm)	59.97±10.67	58.62±10.07	0.262

Table 3: Comparison of NIPS score and duration of cry between the groups

	EMLA (n=123)	**Placebo (n=126)**	**#P Value**
Immediately after vaccination	3.79±1.13	5.59±0.61	<0.0001
30 seconds after vaccination	2.07±1.05	3.32±0.63	<0.0001
3 minutes after vaccination	0.45±0.60	1.15±0.49	<0.0001
Duration of cry (Seconds)	25.08±4.39	45.44±7.29	<0.0001

Table 4: Comparison of FLACC score and duration of cry between the groups

	EMLA (n=23)	**Placebo (n=26)**	**#P Value**
Before vaccination	0	0	0
Immediately after vaccination	4.27±0.83	5.52±1.24	<0.0001
30 seconds after vaccination	2.35±1.13	3.04±0.98	0.026
3 minutes after vaccination	0.58±0.50	1.17±0.39	<0.0001
Duration of cry (Seconds)	26.73±3.73	46.96±13.46	<0.0001

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