

Comparison of EMLA cream with rattles on reducing immunization pain in four months infants

Mahdi Basiri-Moghadam,¹ Mojtaba Kianmehr,² Saeid Pasban-Noghabi,³ Kokab Basiri-Moghadam⁴

Abstract

Objective: To assess the effect of Eutectic Mixture of Local Anaesthetics cream and rattle on soothing the vaccination pain on four-month-infants.

Methods: The single blind randomised clinical trial was conducted from May 2012 to February 2013 at a clinic under the Gonabad University of Medical Sciences, Iran, and comprised four-month infants who were selected randomly and divided into three groups. In one group, 2g of eutectic mixture of local anaesthetics cream was rubbed on the injection spot before administration; for the other group, the rattle was shaken from 30s to 15s before injection. The last group consisted of controls. The infants were filmed after vaccination. Afterward, a pain questionnaire was filled out by a trained observer. SPSS 11.5 was used for statistical analysis.

Results: Of the 50 subjects in the study 16(32%) each were in the cream and rattle groups, while the rest (36%) were in the control group. The severity of the pain before intervention in the control, cream and rattle groups was 2.22 ± 0.88 , 2.12 ± 0.95 and 2.25 ± 1.06 respectively, which were not statistically significant ($p < 0.93$). Likewise, the mean severity of pain at the moment of intervention in the three above groups were 8.67 ± 0.77 , 7.12 ± 0.5 and 7.87 ± 0.96 respectively, which was significantly different ($p < 0.001$). The severity of pain 15seconds after the intervention in the groups was 5.06 ± 1.51 , 4.87 ± 1.31 and 4.19 ± 1.94 respectively, which were not statistically different ($p < 0.27$).

Conclusion: The eutectic mixture of local anaesthetics cream and shaking rattle were effective in attenuating pain of vaccination among the infants, but the latter was not as significant as the former.

Keywords: EMLA cream, Rattle, Vaccination. (JPMA 64: 874; 2014)

Introduction

Pain, by definition, is an unpleasant feeling caused by potential or actual injuries.¹ For many years, it was believed that infants and children do not feel pain or not as much as it is experienced by adults. However, such ideas are long proved wrong.² Several studies have demonstrated that infants feel pain and probably they are more susceptible to pain and feel it for longer period compared to older infants.^{3,4} The adults have ways to express and signal their feelings and to react by trying to stop the cause of pain or lessen its severity. However, children and particularly infants are different in this regard. Infants are not able to express their feelings regarding the spot of the pain, severity and type of pain or symptoms. Pain transferring neural path is developed in infants, while the reaction system is not developed enough. Therefore, there is a threat that they might memorise the painful experience.⁵

Pain triggers physiological, hormonal, and behavioural reactions in infants so that it may intensify behavioural and physiological responses regarding pain in later stages of life.⁵ Physiological symptoms of pain include shortness of breath and hyperventilation, tachycardia, body temperature increase, and mental issues such as nightmares. In addition, it appears that behavioural symptoms such as crying, screaming, moaning, frowning, facial expression, jaw shakes, spasticity and pertinent signals are seen when someone is experiencing pain. Adults, when they feel pain, try to find the cause of pain and soothe the symptoms. Increase in the level of stress hormones such as cortisone, and catecholamines which accelerate tissue damage, fluid retention, reduction of intestinal motions, immunity disorder, aggregation of unused energy in body, and cardiovascular responses such as tachycardia, abdominal symptoms and asthma.⁴ A study showed that painful experiences for long periods of time cause mental disorders.³

Function parameters such as short-term memory, intelligence quotient (IQ) and some of behaviour parameters are influenced by pain.⁶ By "non-pharmacological interventions" we refer clinical interventions that may attenuate the severity of pain. Such interventions are simple and safe and do not need

.....
^{1,4}Faculty Member of Nursing Department, Social Development & Health Promotion Research Center, ²Department of Medical Physics, Faculty of Medicine, ³Msc Student in Nursing Education, Student Research Committee, Center of Talent, Gonabad University of Medical Sciences, Gonabad, Iran.

Correspondence: Kokab Basiri-Moghadam. Email: pasban_saeid@yahoo.com

expensive equipment and great deal of time. In addition, there are no so-called drug side effects.⁷ Distraction, mental visualisation and skin irritation to control anxiety, pain, and fear are some of these types of interventions.⁸ In addition, non-pharmacological techniques such as mother and infant skin contact, breast-feeding, and taking edible sucrose solution are effective in lessening pain.⁹ One of these methods is cognitive behaviours skill.¹⁰ Whatever that prevents from thinking about pain might be used to soothe the pain. Playing with the child is one of the best ways to lessen pain and anxiety.⁷ However, distraction techniques do not suit everyone and the cases of high severity of pain are considerable.¹¹ Eutectic mixture of local anaesthetics (EMLA) cream contains 5% lidocaine-prilocaine cream (2.5% lidocaine and 2.5% prilocaine, EMLA, Astra, Canada).¹² ELMA cream is widely used as a pharmacological method to attenuate skin pain and discomfort and procedures such as vein-puncture, blood sampling, using lancet, and even Lumbar puncture.¹³

Pharmacological and non-pharmacological methods of pain relief are important and, the use of a cream for pain relief during and after the injection of Hepatitis B vaccine can be considered.¹⁴ The current study was planned to assess the effect of EMLA cream on soothing the vaccination pain among infants. Moreover, taking into account that the infants are more susceptible to rattles than kids of older ages, the study also compared the effect of EMLA cream and rattles for reducing the pain of vaccination among the subjects.

Patients and Methods

The single blind randomised clinical trial was conducted from May 2012 to February 2013 at a clinic under the Gonabad University of Medical Sciences, Iran, and comprised four-month infants who were selected randomly and divided into three groups. After approval from the institutional ethics committee, sample size was obtained using two independent samples formula and literature¹⁵ with Confidence Interval of 0.99, and test power of 0.90 equal with 11 participants ($S1=1.059$, $S2=1.831$, $\mu1=8.53$, $\mu2=6$, $ES=1.69$). To compensate probable leave of the cases, 16 participants were adopted for each group.

The inclusion criteria comprised voluntary participation, pain score below 3 before injection, being awake and calm, no symptom of diarrhoea or cold, infant term, no use of pain killers during the last 48 hours before the experiment, good physical health, and no congenital disorders. Subjects were excluded from the study upon request of their parents along

with those who were in sleep or crying. The mothers were asked not to talk to their child before, during, and after injection, and also not to shake or cuddle the child. Demographic information questionnaire (gender, type of delivery, delivery rank, gestational age of pregnancy, birth weight, four-month weight, Apgar 1m and Apgar 5m were filled out at beginning of the study). Regarding pain behavioural signals, infants' pain questionnaire, which is a modified scale of pain behavioural response for 4-6 months infants, was employed. Reliability and validity of the questionnaire has been confirmed for Iranian population.¹³ Pain special scale (1: smiling, 2: no facial gesture, 3: frightened look and face, 4: Frowning, heavy-lid eyes and stretched lips with or without pink face) body motions (1: natural motions, 2: calm and peaceful, 3: relative motions such as wrapping, avoiding pain by retreating the body limb, 4: restlessness and general motion of several body limbs, 5: spasticity), crying modes (1: laughing, 2: not crying; 3: moaning with low voice, sudden or strike of cry or sobbing; 4: burst into tear more severe than the early cry) were taken into consideration in the questionnaire. The questionnaire scores facial expression and body motions in the range of 0-3, and at the range of 0-4 for crying. All the scores were summed. Maximum and minimum obtained scores of pain behavioural response were 10 and 0 respectively.¹⁶ To determine the severity of pain experienced by the infants and to blind and control the intervention factor, the infants were filmed before, during and after injection (15s). The observer used the films to fill out the questionnaires. Only one individual was in charge of observation, who did not know about the classification of the participants. The infants were randomly grouped in one of the three groups using permutation blocks with blocks of three members. To ensure random selection, the researcher first chose a number out of a random number block and, depending on the right digit of the number, different combinations of words A (EMLA group), B for (rattle group), and C (control group) were adopted (1= ABC, 2 = BAC, 3 = CAB, 4 CBA, 5 = BCA, 6 = ACB; and re-selection of number for other digits).

One hour before injection, 2g of EMLA cream was rubbed on the spot of injection for the participants in group A and an anti-allergic tape was put on it. For the infants in group B, a rattle was shaken from 30s before administration to 15s afterward as a source of distraction. The infants in group C experienced a normal vaccination process. All the infants were vaccinated by one person, and injections were intramuscular at one-third lateral section of limb at Vastuslateralis muscle. The content of injection was 0.5cc

of triple vaccine administered using a needle with length of 2.5cm and gauge of 23.

The data gleaned in the study was analysed in SPSS 11.5 using one-way analysis of variance (ANOVA) and Kruskal Wallis. Level of significance was set less than 0.05. For comparing average of quantitative variable with normal distribution among the three groups, one-way ANOVA was used. For comparing of quantitative variable with non-normal distribution among the three groups, Kruskal Wallis test was used. In order to confirm normality, Kolmogorof-Smirnov test was used.

Results

Initially, 60 infants were recruited, but 14(23.3%) subsequently had to be excluded; 2(3.33%) did not meet the inclusion criteria, 4(6.66%) were vaccinated by another person, and the questionnaire for 4(6.66%) were not completely filled. The final study size comprised 50(83.33%) infants. The questionnaire was filled out for before, during and after intervention (15s) status. Demographic data for the 3 groups was initially noted (Table-1).

No significant difference was found among the groups ($p>0.05$).

One-way ANOVA showed that average of pain severity in the three groups was significantly different ($p<0.001$)

(Table-2). However, among the three groups, there was no significant difference regarding severity of pain before intervention ($p=0.93$). At the intervention stage, significant difference was found regarding severity of pain among the three groups. It was maximum in the control group and minimum in the EMLA group ($p<0.0001$). Concerning the average of pain 15s after intervention, it was minimum in the rattle group and maximum in the control group, though the difference was not significant. ($p=0.27$).

A statistical significant difference was also observed in the injection stage between the control and EMLA groups ($p<0.001$), control and rattle groups ($p=0.01$), and rattle and EMLA groups ($p=0.02$). In this regard, severity of pain at injection in the control group was higher than the EMLA and rattle groups; and comparing between the rattle and EMLA groups, it was more severe in the latter.

Discussion

As the results showed, significant statistical difference was obtained regarding behavioural reaction to pain of vaccination among the three groups. Average severity of pain in the control group was maximum and it was minimum in the EMLA group.

A clinical study showed that EMLA cream is effective in soothing the pain of vein-puncturing among children, as a significant relation was obtained between the EMLA and

Table-1: Demographic Characteristics in EMLA, Rattles and Control Groups.

Variable	EMLA group Mean±SD	Rattles group Mean±SD	Control group Mean±SD	P-value
Time between the last meal before vaccination (h)	7±3.5	9.31±4.73	9.17 ±3.53	0.18*
Birth rank Median (Interquartile rang)	1(1)	1(1)	1.5(1)	0.79**
Gestational age (week)	37.62±1.36	37.31±0.79	37.55±0.92	0.48**
Birth weight (g)	3250±248.02	3081.25±753.63	3294.44±333.82	0.43*
Weight on 4 mounth (g)	6862.5±858.19	6684.37±1454.73	6848.89±550.47	0.86*
Apgar 1	8.87±0.34	8.87±0.34	8.83±0.38	0.92**
Apgar 5	9.94±0.25	9.87±0.34	9.87±0.43	0.41**

EPLA: Eutectic Mixture of Local Anaesthetics.

*One-Way ANOVA was used.

**Kruskal Wallis test was used.

Table-2: Total point of pain behavioural response for the three groups.

Phase	EMLA group Mean±SD	Rattles group Mean±SD	Control group Mean±SD	P-value
Before	2.12±0.95	2.25±1.06	2.22±0.88	0.93
During	7.12±0.5	7.87±0.96	8.67±0.77	<0.001
After	4.87±1.31	4.19±1.94	5.06±1.51	0.27

EMLA: Eutectic Mixture of Local Anaesthetics.

control groups ($p < 0.001$).¹³ A controlled trial to compare two methods of distracting and taking edible sucrose on attenuating pain of vaccination among 4-month infants, the average of behavioural response to pain in the intervention group was less than the control group ($p = 0.0001$).¹⁷ However, the difference between the distraction and sucrose groups was not significant ($p = 0.58$).¹⁷

Another study titled "comparison of distraction and EMLA cream on severity of pain of vein-puncturing among thalassemia children" showed a significant difference regarding average of numerical and photographic pain between the distraction and EMLA cream groups on the one hand and the control group on the other hand ($p < 0.001$). However, no significant difference was obtained between the distraction and EMLA groups.¹⁸ One study showed that children who received painkiller and distraction experienced less severe pain than those who received only the medicine.¹⁹ As our results showed, total point of behavioural response to pain was minimum in the rattle group, though the relation was not significant ($p = 0.27$). A clinical study on 60 4-7 years old children surveyed the effect of blowing up a balloon on reducing the pain of intravenous injection. To this end they used Wang and Baker questionnaire. Their results showed a significant relation between blowing up a balloon and severity of the pain among children ($p < 0.001$).⁷

The results of a study on infants showed that the rattle group experienced considerably less pain and the difference was significant statistically ($p < 0.001$). The subjects were distracted by shaking a rattle from 30 seconds before intervention to 15 seconds after the intervention.¹⁴ In a study to compare the effect of distraction and local anaesthesia on soothing the pain caused by vaccination, a study observed that the severity of pain, as expressed by the subject, was at average level; statistically significant difference was observed while comparing with the control group.²⁰

To explain the effect of distraction, when enough sensory stimulation of different type reaches the neural network at the brain stem, the brain can stop transfer of feelings such as pain. In addition, distraction competes with painful stimulation and prevents concentration of awareness on the pain, which results in the attenuation of awareness of pain.²¹ No disorder except for mild arrhythmia at the spot the cream had been used was observed in the study. Similar studies also showed that dermatitis is one of side effects of EMLA cream.²² One limitation of the current study is that the results cannot be generalised for other ages, as children at this age are too sensitive to sound.

Personal differences regarding pain threshold among the infants is another limitation of the study.

Conclusion

EMLA cream and a shaking rattle are effective on attenuation of pain of vaccination among 4-month infants. However, distraction was not as effective as the cream. Therefore, taking into account that EMLA, as a pharmacological method has some side effects, must be used one hour before intervention and upon prescription of a physician, and that the shaking rattle is costless, easy, and with no side effects. Rattle can be used to lessen severity of pain experienced by infants. However, when reduction of severity of the pain experienced by the children is the target, EMLA cream is more effective.

Acknowledgements

We are grateful to the student research committee, Gonabad University of Medical Sciences, Iran, for commissioning the study and for assisting us to carry it out.

References

1. Miller RD, Pardo MC, editors. Basic of Anesthesia. 6th ed. Philadelphia (PA): Churchill Livingstone Elsevier; 2011.
2. Boxwell G. Neonatal intensive care nursing, 1sted, London and New York. Rout Ledge 2000; pp: 189-201.
3. Anand KJ, Hickey PR. Pain and its effects in the human neonate and fetus. *N Engl J Med* 1987; 317: 1321-9.
4. Fitzgerald M, Shaw A, MacIntosh N. Postnatal development of the cutaneous flexor reflex: comparative study of preterm infants and newborn rat pups. *Dev Med Child Neurol* 1988; 30: 520-6.
5. Fitzgerald M, Beggs S. The neurobiology of pain: developmental aspects. *Neuroscientist* 2001; 7: 246-57.
6. Kheirkah M, Moghadam H, Manesh MJ, Haghani H. Reducing Pain Due to Vaccination: Comparison of Distraction and Oral Sucrose. *Iran J Nurs* 2011; 24: 19-29.
7. Malekan Rad E, Momtazmanesh N, Barkatin R. The effects of glucose, breast milk and lidocaine cream on acute pain of arteriopuncture in term neonates. *J Kashan Univ Med Sci* 2004; 8: 15-9.
8. Sadeghi T, Neyshabouri M, Soleymani MA, Bahrami N. The effect of balloon inflating on venous opening pain in children. *J Qazvin Univ Medical Sci* 2010; 14: 67-72.
9. Movahedi AF, Rostami S, Salsali M, Keikhaee B, Moradi A. Effect of local refrigeration prior to venipuncture on pain related responses in school age children. *Aust J Adv Nurs* 2006-2007; 24: 51-5.
10. Chroinin MN, Murphy JF. Pain in newborns. *Iran Med J* 2002; 95: 229-30.
11. Jaanistea B, Brett H, Carl L, Von B. Effects of preparatory information and distraction on children's cold-pressor pain outcomes: A randomized controlled trial. *Behaviour Research and Therapy* 2007; 45: 2789-99.
12. Taghinejad H, Tahmasebi P. Pain and Its care. 1th ed. Eilam: Hamadan Danesh publications. 2007.
13. Mujeeb S, Akhtar J, Ahmed S. Comparison of eutectic mixture of local anesthetics cream with dorsal penile nerve block using lignocaine for circumcision in infants. *Pak J Med Sci* 2013; 29: 27-30.
14. Nikfarid L, GhamarYousefi R, Namaziyan M, Namdar F, Nezami MA. Comparison of EMLA cream versus local refrigeration for reducing venipuncture-related pain in pediatric patients of Children's Medical Center, 2008. *IJNR* 2010; 5: 32-37.

15. Schechter NL, Zempsky WT, Cohen LL, McGrath PJ, McMurtry CM, Bright NS. Pain reduction during pediatric immunizations: evidence-based review and recommendations. *Pediatrics* 2007; 119: 1184-98.
 16. HadadiMoghadam H, Kheirkhah M, JamshidiManesh M, Haghani H. The impact of Distraction Technique on Reducing the Infant's Pain due to Immunization. *J GonabadUniv Med Sci* 2011; 17: 20-6.
 17. Ali S, Taavoni S, Haghani H, NeisaniSamani L. Comparison of the Effect of Breast Sucking with Being in the Mother's Hug on Pain Relieving during Immunization Injection. *J Babol Unive Med Sci* 2009; 11: 32-7.
 18. Alavi A, Zargham A, Abed yazdan Z, Namnabat M. Comparative study of distraction and EMLA cream (EMLA) on pain intensity IV catheters in children with Thalassemia 12-5 years. *J Shahrekord Univ Med Sci* 2005; 7: 9-15.
 19. Tanabe P, Ferket K, Thomas R, Paice J, Marcantonio R. The effect of standard care, ibuprofen, and distraction on pain relief and patient satisfaction in children with musculoskeletal trauma. *J Emerg Nurs* 2002; 28: 118-25.
 20. Cohen LL, Blount RL, Cohen RJ, Schaen ER, Zaff JF. Comparative study of distraction versus topical anesthesia for pediatric pain management during immunizations. *Health Psychol* 1999; 18: 591-8.
 21. World Health Organization, Report. Paints mixed picture of immunization progress. *Lancet* 2002; 360: 1671-6.
 22. Lawrwnce J, Alcock D, McGrath P, Kay J, MacMurray SB, Dulderg C. The development of a tool to assess neonatal pain. *Neonatal netw* 1993; 12: 59-66.
-