Original Article

The Efficacy of the EMLA Analgesic Cream in Compare with Placebo in Pediatric Oncology Lumbar Puncture

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Abstract

Background

The present randomized clinical trial evaluated the efficacy of a topical lidocaine-prilocaine cream (EMLA) to relief pain during spinal puncture in pediatric oncology patients.

Materials and Methods

Sixty patients with malignancy candidate for spinal puncture were selected for this study. The patients were randomly allocated to two groups. Group A had topical EMLA cream and group B had placebo, which they received 60 to 90 minutes before spinal puncture. Pain score was rated using the Wong-Baker Faces rating score (0: no pain to 10: worst pain).

Results

Pain score does not reduce significantly in the topical EMLA cream in compared with placebo (p-value=0.126). No signs of infection were noted at the spinal puncture sites 24 or 48 hours after the procedure.

Conclusion

Results obtained from this study represents that the EMLA cream has not more analgesic effect than placebo in reducing the pain for spinal puncture.

Key words

Spinal Puncture, Pain, EMLA

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Introduction

Painful procedures in hematology-oncology are frequently seen in children as the most painful experiences during illness. Spinal puncture or lumbar puncture (LP) is one of the routine painful procedures in pediatrics and actually is not still used commonly though applying of anesthetic methods (1). Many attempts have been made to produce local analgesia and to allow painless procedures by the topical application of drugs. A major step in pharmaceutical research on topical drugs came with a serendipitous discovery that a specific mixture of crystalline bases of lidocaine and prilocaine had a lower melting point than the melting point of the individual drugs (2). EMLA, an eutectic mixture of two local anesthetics (lidocaine 2.5% and prilocaine 2.5%), provides several millimeters of skin analgesia by diffusion of local anesthetic through the epidermis and the dermis to the nociceptive receptors and nerve endings of the skin. The depth of analgesia depends on how long the cream is applied; 60 min are usually required to achieve a proper result (3, 4). EMLA has been shown to be useful to diminish pain during circumcision, venipuncture, arterial puncture, percutaneous venous catheter placement and even minor ontological surgery, minor gynecological, urological and anthological procedures. In general, eutectic lidocaine/prilocain cream is a novel formulation of local anesthetics that has proven to be effective and well-tolerated in the relief of pain associated with various minor interventions in adults and children (5). Also, some surveys have shown the usefulness of EMLA in alleviating the pain of lumbar puncture in children and newborns (6,7,8,9). However, some studies do not substantiate the efficacy of EMLA in alleviating the pain during LP, intravenous catheter insertion or BMB (10,11,12), thus the data is limited. Our study was designed to examine the efficacy of topical EMLA in diminishing pain during LP for diagnostic or therapeutic purposes in children suffering from cancer.

Materials and Methods

Following approval from the local ethics committee, a prospective, randomized, double-blind study was performed at the Shahid Sadoughi Hospital, Yazd, Iran. Following providing written informed consent, we included all children of 3-11years old affected by malignancy who were admitted in pediatric ward and undergone LP during six months in our study. Note that those with a previous positive history of methemoglubinemia or their family and their previous history of G6PD or allergy to lidocaine or prilocain were excluded. Randomly; we divided the children into two groups. For one group EMLA cream was applied and for another, placebo was used. EMLA cream and placebo were applied by a nurse blinded to the substance 60 to 90 min before LP. The amount used was 1gr of EMLA cream or placebo.

The surface of skin which the EMLA or placebo were robbed, was about 25cm^2. The nurse did not cover the site after applying creams. Then a trained observer blinded to patients' study groups recorded their action during lumbar puncture on the sheet and rated observed pain behavior on a 0-10 Faces rating score named Wong-Baker rating score (0: no pain to 10: worst pain).All children were relaxed and calm before the procedure. Some overall reviewing of results was done during the study by observers to assure accuracy of rating of pain behavior. Our nurses inspected the LP sites for any sign of infection at 24 or 48 h after LP. The exclusion criteria in this study were allergy to EMLA cream and happening of methemoglubinemia. We would stop the procedure if the children became uncomfortable severely.

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Statistical Analysis

Efficacy of EMLA cream versus placebo was performed using SPSS software (ver. 11.5), T test, Chi-square test and Mann-Whitney to process the data. P-value <0.050 was considered as significant.

Results

In this study 60 children were selected. These sixty patients consist of 42(70%) boys and 18(30%) girls. The mean +_SD age was 5.86+-2.43 years old, the smallest age was 3 and the oldest age was 11. Age, sex, and duration of time from diagnosis, numbers of LP since diagnosis and pain score were taken under investigation (table 1). Also, it is necessary to note that the LP was done successfully in both groups. None of the patients was excluded. By processing the pain scores in two groups; totally, it was shown that the EMLA group does not have a significant difference vs. placebo group. (P-value=0.126)(table2). Results revealed that the effect of sex, age, duration and numbers of LP did not significantly differ between two groups in evaluation of pain score. The intensity of pain did not differ between boys and girls (P-value= 0.164).Also, the age of patients (<5year or >5year) does not have a significant effect on the pain score (P-value=0.052).The duration of time since diagnosis (P-value=0.886) and numbers of LP (P-value= 0.775) were not important in the evaluation of intensity of pain, too. There was no sign of infection at the site of LP 24h or 48h after the procedure.

Table1. Demographic characteristic in placebo and EMLA groups

Variables		Placebo	EMLA	P-value
Sex	Boy (n, %)	11,73.3%	10,66.7%	0.690
	Girl (n, %)	4,26.7%	5,33.3%	
Age(year)	mean +_SD	5.2+_2.71	6.53+_1.99	0.137
Duration of disease(year)	mean +_SD	1.79+_1.16	1.7+_1.42	0.837
Numbers of LP since diagnosis	mean +_SD	8.26+_3.57	7.8+_4.19	0.745

Table2. Comparison of Intensity of pain during LP between two groups

	median	mean	SD	P-value
Placebo	5	5	1.60	
EMLA	3	3.93	2.86	o.126
Total	4	4.46	2.34	

Discussion

Lumbarpuncture is a painful procedure and reducing procedural pain is gaining recognition. Topical local anesthetic preparations, such as EMLA is a specific mixture of crystalline bases of lidocaine and prilocaine.

This study was shown that the pain of LP was not significantly less in the group receiving skin anesthesia by EMLA cream compared with that in the group receiving a placebo.

This is similar to study of Jimenez N. et al, on 116 Children 7–19 years of age who were randomized to receive 0.25 mL of 1% buffered lidocaine with J-Tip (n=57) or 2.5 g of EMLA (n =59) before IV cannulation that compared the effectiveness of J-Tip versus eutectic mixture of local anesthetics (EMLA) to facilitate IV cannulation and provide adequate analgesia before IV placement. J-Tip application of 1% buffered lidocaine before IV cannulation is not painful and has better anesthetic

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effectiveness compared with EMLA (11). In other study performed by Enad et al randomly assigned 49 neonates to 1g of EMLA or placebo in a blinded manner for 60 minutes before lumbar puncture. Heart rate, oxygen saturation level, and behavioral response (scored from 0 to 3) were assessed. Percent change from baseline values did not differ between groups, suggesting that EMLA is not efficacious agent for reducing the pain associated with LP (10).

In contrast Geetinder et al, on Sixty consecutive newborns (gestational age, _34 weeks) undergoing diagnostic lumbar puncture and stated that Eutectic mixture of local anesthetics is an efficacious agent for reducing the pain associated with needle insertion and withdrawal during lumbar puncture in newborns (8). Studies of Kapelushnik, et al (7) and Juárez Gimenez JC, et al (15) Halperin L et al, (16) confirmed that EMLA can reduce the pain of LP. But Holdsworth et al. showed that EMLA is effective in alleviating pain during LP but not for the BMA (12).

In a study conducted by Arts SE et al on 180 Children aged 4 to 16 years at surgery under general anesthesia via intravenous cannulation were randomly allocated to one of three interventions. They showed that Children who received lidocaine-prilocaine emulsion feeled less pain compared with placebo emulsion and with music distraction. They also reported that younger children, regardless of intervention, reported significantly more pain than the older children (17).

But Valenzuela RC et al, on 100 adult patients who had undergone thoracotomy or median sternotomy demonstrated postoperatively applying a topical anesthetic cream onto chest tube sites of chest surgery patients 3 h before chest tube removal is more effective than IV morphine in blunting pain response. They found that sex, duration of cancer tolerated by the child, age of patients and numbers of LP since diagnosis did not affect the intensity of pain (18). This is similar to our results.

This study has its own limitations. In contrast to many others studies, we did not covered the LP site with the dressing. This can show the probable effect of dressing in alleviating the pain. Conversely, not all of patches were well applied. In summary, this study shows that EMLA cream is an ineffective agent for comfort of children with cancer who is supposed to undergone LP.

Conclusion

According to the present study, EMLA cream was not effective so much to reduce the pain during spinal puncture in children with cancer. So, we do not recommend EMLA cream for local analgesia during lumbar puncture in pediatric oncology patients.

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Conflict of Interest

This study was supported by Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, Iran.

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