Comparison of EMLA Cream versus Mucosal Vibration or Pre-cooling Systems as Topical Anesthetic Agents in Children

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Abstract:

Objective: Comparing EMLA cream versus mucosal vibration or pre-cooling systems as preanesthetic techniques to reduce pain associated with dental injection in children. **Materials and Methods:** Fifty children categorized as positive or definitely positive according to Frankl scale (behavior rating scale) and aged from 5-7 years were selected. They were indicated for bilateral inferior alveolar nerve block for dental treatment and selected from the pediatric dental clinic, Faculty of Dentistry, Mansoura University. Children were randomly divided into two equal groups, in which the injection site was prepared using mucosal vibration with electric tooth brush in group (A) and pre-cooling with iced cotton bud in group (B). In both groups, EMLA topical anesthetic cream was used in the injection site of opposite side as a control. Pain perception was assessed using Wong-Baker Faces Pain Scale (WBFPS) and Sound, Eye, and Motor scale (SEM). Data were collected, tabulated and statistically analyzed.**Results:** Pain perception during injection was significantly lower in the EMLA compared to the pre-cooling technique. However, there was no statistically significant difference between EMLA and vibration as indicated by WBFPS ($P < 0.05$). Regarding SEM scale, there was no statistically significant difference in the behavioral feedback of children during injection. However, better results were shown with EMLA followed by vibration then pre-cooling. **Conclusion:** EMLA topical cream and vibration techniques were more effective than pre-cooling technique in reducing the pain associated with local anesthesia injection.

Introduction:

Anesthesia injection, especially in children is considered the most difficult part of the dental appointment and may result in fear, anxiety, avoidance behavior and deteriorated oral health in children. That is why treating children with minimal discomfort & pain has always been of paramount importance in pediatric dentistry.

EMLA cream is a mixture of 2.5% lidocaine and 2.5% prilocaine which has proved good results in dentistry, lately[1]. It was first utilized orally by Holst and Evers[2] and their results proved good efficiency in the gingiva. Application of EMLA cream for reduction of pain from needle insertion has been documented by several studies[3,4].

Mucosal vibration as a non-pharmacological technique for reducing pain associated with local anesthetic injection has been used in many studies[5,6,7]. Melzack et al.[8] explained the analgesic effect of vibration by the gate control theory of pain.

Another non-pharmacological method to control pain of injection is pre-cooling the injection site. Evaluating the effect of pre-cooling the injection site in dentistry has been determined by several studies[9,10,11,12]. Researches have also proved that pre-cooling decreases edema, nerve conduction velocities, cellular metabolism, and local blood flow[13].

Reducing the pain associated with dental injections is one of the desires of pediatric dentist for gaining good experience of the child during dental treatment, reaching trust and, this cooperation. Therefore study was conducted to evaluate and compare the effect of EMLA topical cream, mucosal vibration and pre-cooling technique as preanesthetic techniques to address discomfort associated with dental injection.

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Materials and Methods:

1. Case selection:

A total number of 50 children aged 5-7 years were selected from patients visiting the pediatric dental clinic, Faculty of Dentistry, Mansoura University. They were positive or definitely positive on Frankel scale (behavior rating scale) and required bilateral inferior alveolar nerve block for dental treatment.

2. Ethical considerations:

The study protocol was approved by the ethical committee of Faculty of Dentistry, Mansoura University with code (M 01110619). The study and all procedures were explained in detail to the parents and written informed consents were obtained from them before participating in the study.

3. Grouping:

All children were divided into two main groups, Group A mucosal vibration and Group B pre-cooling. EMLA topical anesthetic cream was used in the two groups in the injection site of opposite side as a control. The calculated sample size of the study was 25 participants for each group. The sample size was calculated using the G-power sample size calculator[14]. The following assumptions were used to calculate sample size:

1. Expected proportion of reporting pain in the control group = 50%
2. Expected proportion of reporting pain in the experimental group = 20%
3. Alpha error = 5%
4. Study power = 80%

4. Procedures:

In this study, each child in both groups was subjected to two injections, first injection with the use of EMLA cream and the other injection with the vibrator in a group A and iced cotton bud in the other group B at two respective dental visits. One week interval was established between the two visits.

To determine the injection technique used in the second visit to the child, the child selected one of two cards (with either letter V for vibration technique or C for cooling technique) from an opaque bag. However, the chief complaint of the child was the main determinant for the side (right or left) to be first injected. All children had received local anesthesia and their treatment by the same operator.

For children receiving injection with EMLA cream, the injection site was dried and isolated using cotton roll and the topical EMLA cream was applied using sterile cotton dipped applicator to the injection site and left for 2-3 minutes after informing the child, then the anesthesia was administered[15].

For children receiving injection with vibration, the vibrator was covered by blue dental disposable wrap to avoid cross infection. The local anesthesia was administered by keeping the needle in close vicinity to the vibrator and the vibration continued for 15 seconds after removal of the needle[16].

For children receiving injection with iced cotton bud, the frozen cotton bud was held by its plastic tubing and the cold cotton end placed on the proposed anesthetic site with light pressure between 1and 2 minutes. The 27 gauge needle was used at a slow pace while maintaining pressure using the cotton bud[17].

5. Pain assessment:

The pain measuring scales used in this study:

A. Wong-Baker Face Pain Scale (WBFPS)

Immediately after the administration of local anesthesia, the participants were questioned about the level of pain they had experienced during the anesthesia by selecting one of the five faces that best represented their experience. Each face has an assigned numerical value that was recorded and tabulated.

B. Sound, eye and motor scale (SEM)

The children's reactions during the injection were evaluated based on the sound, eye, and movement of the children using SEM scale. Each category of SEM scale scored ranged from 1 (comfort) to 4 (painful). The procedure was videorecorded and pain assessment using SEM scale was evaluated objectively by two assessors. The total scores of the four categories were recorded and tabulated.

6. Statistical analysis and data interpretation:

Data were analyzed using SPSS program for Windows (Standard version 21). Kolmogorov-Smirnov test to assess data normality. Association between categorical variables was tested using monte carlo test. Continuous variables were presented as mean ± SD (standard deviation) for normally distributed data and median (min-max) for non-normal data. The two groups were compared by independent t test (parametric) and Mann Whitney test (non- parametric). Spearman correlation was used to correlate continuous variables.

Results:

Age and sex distribution among the experimental groups are shown in Table (1). There was no statistically significant difference in age and sex distribution among the 2 studied groups (p value >0.05).

Regarding WBFPS, the median scores of WBFPS for EMLA, vibration and pre-cooling were 0, 0 and 2 respectively. Lower pain scores were shown with EMLA cream and vibration compared to pre-cooling technique with a statistically significant difference ($P < 0.05$) as shown in Tables (2) and (3). However, there was no statistically significant difference among EMLA and vibration.

Table (1): Demographic data among studied groups

Demographic data	Vibration group (n=25)	Pre-cooling group (n=25)	Test of significance	p-value
Age (years) Mean ± SD Min-Max	 6.24±0.83 5-7	 5.96±0.78 5-7	t=1.22	0.228
Sex Male Female	 14 (56.0%) 11 (44.0%)	 15 (60.0%) 10 (40.0%)	χ^2 =0.082	0.774

Table (2): Comparison of WBFPS among EMLA and pre-cooling

Wong baker face scale	EMLA group (n=25)	Pre-cooling group (n=25)	p-value
Mean ± SD	**0.88±1.42**	**2.0±1.73**	**0.014***
Median (Min-Max)	**0 (0-4)**	**2(0-6)**	
0	17(68.0%)	8(32.0%)	
2	5 (20.0%)	10(40.0%)	
4	3 (12.05)	6(24.0)	0.06
6	0(0%)	1(4.0%)	

Table (3): Comparison of WBFPS among vibration and pre-cooling groups

Wong baker face scale	Vibration group (n=25)	Pre-cooling group (n=25)	p-value
Mean ± SD	**0.96±1.54**	**2.0±1.73**	
Median (Min-Max)	**0 (0-6)**	**2 (0-6)**	**0.018***
0	16 (64.0%)	8 (32.0%)	
2	7 (28.0%)	10 (40.0%)	
4	1 (4.0%)	6 (24.0%)	0.065
6	1 (4.0%)	1 (4.0%)	

Regarding SEM scale in the vibration group, the total mean score of SEM scale in the EMLA (control) and vibration (study) were 3.76±1.09 and 4.64±2.32 respectively. While in the pre-cooling group, the total mean score of SEM scale in the EMLA (control) and pre-cooling were 4.08±1.28 and 5.04±2.30 respectively. Mann Whitney test showed no significant difference between EMLA, vibration and pre-cooling techniques as regards SEM scale as shown in Tables (4),(5) and (6).

Table (4): Comparison of the mean ±SD of SEM scores among EMLA and vibration.

	Emla group (n=25)	Vibration group (n=25)	t –test	p-value
Sound Mean ± SD	1.08±0.27	1.24±0.83	0.914	0.365
Eye Mean ± SD	1.44±0.65	2.00±0.81	2.682	0.01*
Motor Mean ± SD	1.24±0.59	1.40±0.91	0.733	0.467
Total Mean ± SD	3.76±1.09	4.64±2.32	1.713	0.093

Table (5): Comparison of the mean ±SD of SEM scores among EMLA and pre-cooling.

	Emla group (n=25)	Pre-cooling group (n=25)	t –test	p-value
Sound Mean ± SD	1.24±0.66	1.36±0.81	0.573	0.569
Eye Mean ± SD	1.52±0.65	1.84±0.80	1.549	0.128
Motor Mean ± SD	1.32±0.47	1.83±1.14	2.10	0.041*
Total Mean ± SD	4.08±1.28	5.04±2.30	1.750	0.075

Table (6): Comparison of the mean ±SD of SEM scores among vibration and pre-cooling groups.

	Vibration group (n=25)	Pre-cooling group (n=25)	t –test	p-value
Sound Mean ± SD	1.24±0.83	1.36±0.81	0.517	0.608
Eye Mean ± SD	2.00±0.81	1.84±0.80	0.700	0.487
Motor Mean ± SD	1.40±0.91	1.83±1.14	1.50	0.139
Total Mean ± SD	4.64±2.32	5.04±2.30	0.612	0.544

Discussion:

This study was conducted as a comparative split-mouth clinical trial, so each child acted as his own control. Each child received two injections, in group (A), the child received injection with topical EMLA cream at one side(control) and a vibration-assisted at the other side where in group (B) the child received injection with EMLA and the other injection on the contralateral side with the iced cotton bud. The age range of selected children in the present study was 5-7 years old because dental problems are difficult to treat in this age group and they have more disruptive behavior so, they are the most difficult to manage.

Regarding WBFPS in the present study, the results revealed that the use of EMLA cream prior to local anesthetic injection had a significant reduction in the perceived pain in the children ($P < 0.05$) compared to pre-cooling. These results were in agreement with Walimbe et al.[18] and Sruthi et al.[19] who found that EMLA 5% cream proved to be superior in pain reduction. Dasarraju et al.[20] contradict these results where they revealed that EMLA group had significantly higher pain scores for self-report ($P < 0.001$) than Cetacaine group.

Results of vibration technique in the study revealed that there was a significant lower pain scores in the children compared to pre-cooling technique regarding WBFPS. These results were in acceptance with ching et al.[21], Tung et al.[22] and Hassanein et al.[6] who found a significant reduction in WBFPS for injections with the DentalVibe.

In the present study, The WBFPRS demonstrated an insignificant difference in pain scores during the inferior alveolar nerve block procedure with both vibration and EMLA topical cream, suggesting that both agents were equally efficient in pain reduction during the IANB procedure. The efficacy of vibration can be attributed to the distraction it causes with the counter-stimulation of vibration during the inferior alveolar nerve block procedure. Also, the continued application of the vibrator for 5 seconds after the removal of the needle provided a massaging effect and helped in the dissipation of the local anesthetic solution[16].

The superiority of EMLA cream in the present study could be attributed to the deeper depth of penetration i.e about 5mm whereas other topical anesthetics have a penetration depth of only 2-3 mm[23]. EMLA has a high pH of 9.6 and Setnikar et al.[24] stated that increasing the pH increases the potency of the topical anaesthetic agent. Also, a combination of two drugs (lidocaine and prilocaine) in a single agent could have contributed to the increased efficiency.

Regarding SEM scale in this study, there was no statistically significant difference in the total mean score of SEM scores among EMLA, vibration and pre-cooling techniques.

Limitations:

1. Inclusion of only cooperative children, so, the findings of the present research cannot be generalized to children displaying disruptive behavior in the dental office.
2. Including only nerve block anesthesia, so, the results of the present study cannot be generalized for more painful palatal injections.

Conclusion:

1. EMLA topical cream and vibration techniques were more effective than pre-cooling technique with a statistically significant difference ($P<0.05$) regarding WBFPS.
2. There was no statistically significant difference between EMLA, vibration and pre-cooling techniques regarding SEM scale ($P>0.05$). However, better results were shown by EMLA.

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