Original Article (Pages: 16291-16301)

The Impact of Massage on the Pain and Fear Levels of Children during Venipuncture: A Clinical Trial

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Abstract

Background: Experiencing pain and fear caused by venipuncture in children and its management is challenging. Massage is a safe way to manage pain; however, no evidence was found about its effects on pain and fear of venipuncture in children. This study aimed to determine the effects of massage on pain and fear levels during venipuncture among children aged between 3 to 6 years old.

Methods: This pre-experimental factorial research was performed on 140 children admitted to the surgery ward. The participants were randomized into four groups; the children in group 1 received EMLA cream, the children in group 2 received massage, those in group 3 received both EMLA cream and massage, while those in group 4 (control group) received no method. The pain and fear levels were assessed independently from the perspective of children, mothers, and a nurse. The Wong-Baker Pain Scale and the Children's Fear Scale were applied for evaluating the levels of pain and fear in children, respectively. The data were analyzed by running the chi-square test and ANOVA at the significance level of P < 0.05. This study is presented in line with the CONSORT checklist.

Results: The groups were found to have a significant difference regarding the pain and fear scores in venipuncture (P<0.05). The lowest level of pain and fear perception was reported in the EMLA cream group. The group with massage and the EMLA cream and the massage group showed significantly higher scores compared to the EMLA cream group (P<0.05).

Conclusions: Massage does not beneficially affect children's pain and fear during venipuncture; consequently, employing this intervention requires more extensive studies.

Key Words: Children, EMLA Cream, Massage, Venipuncture.

* Please cite this article as: Neshat H, Jamshidi M, Aslani K, Abbasi M, Kianian T. The Impact of Massage on the Pain and Fear Levels of Children during Venipuncture: A Clinical Trial. Int J Pediatr 2022; 10 (7):16291-16301. DOI: 10.22038/ijp. 2022.59813.4653

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Received date: Aug.30,2021; Accepted date:May.09,2022

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1- NTRODUCTION

Acute pain and fear are the most common experiences of children following therapeutic measures (1). Venipuncture is one of these frequent procedures, which has been reported to be the major source of pain and fear among children aged 6 to 12 years (2).

Previous pain experienced by children is a factor in fear of the needle and caregivers which reduces their interaction with the healthcare team (3) Impaired interaction and avoidance behavior of the child may lead to traumatic consequences such as failure of subsequent venipunctures, loss of family satisfaction, reduced quality of care, and even weakened immune system (4). Studies acknowledged that the reason for these negative consequences could be attributed to the misdiagnosis of the child's pain intensity and poor management, the alleviation of which requires proper monitoring of the child's behavioral responses and the selection of appropriate methods (5).

Various pharmacological and nonpharmacological methods have been introduced to manage pediatric pain and fear (6-7). Some standard pharmacological methods include narcotic and non-narcotic analgesics and local anesthetics (8). Local anesthetics are the most straightforward, most effective, and most convenient strategy for patients undergoing simple procedures (9), which is the "gold standard" for relieving pain caused by needle-based procedures (3,10-11). The anesthetics' mechanism of action is to inhibit the initiation and conduction of nerve impulses in relation to sodium ions (3). One topical anesthetic is EMLA cream, which contains lidocaine and prilocaine and is prescribed to induce local anesthesia before venipuncture in children (12). However, some pediatricians have reported delayed effects skin complications (erythema, purpuric reactions, or vasoconstriction) caused by EMLA cream as disruptive factors in the venipuncture procedure (8, 13).

Other methods of pain management, which have received further support today, include non-invasive and nonprocedures pharmacological that are effective, simple, and low-risk interventions and do not require specific time and expensive equipment (14). The non-pharmacological methods in three categories of supportive, cognitive, and physical interventions allow the child to play an active role, overcome the feeling of victimhood, and experience peace and comfort (15). The supportive methods benefit from psychosocial care, such as reading books or playing games. The cognitive techniques use listening to music, daydreaming, and distraction. The physical measures include cryotherapy, transcutaneous electrical nerve stimulation (TENS), and massage (16).

Since massage provides relaxation and satisfaction for the child through tactile sensory stimulation, it has been used for many years as one of the most common ways to communicate emotionally with children and relieve their pain (17). Although the mechanism of massage is not yet fully understood (18), some researchers believe that tactile stimuli affect the central nervous system (CNS) and the release of analgesics (such as beta-endorphins and enkephalins), thus preventing the release of neurotransmitters and blocking the pain (17). Various studies have reported the positive effects of massage on controlling pain and fear in children (18). Bernstein et al. (2019) found massage an effective practical and uncomplicated pharmacological method for controlling pediatric procedural pain (15). Behdad et al. also reported that massage is a measure to relieve pediatric pain (19). The literature review revealed no evidence of the effect of massage on venipuncture pain in credible children and provided no information in this regard.

Since managing pain and fear associated with venipuncture in children is a significant and complex challenge, it is essential to be included in research priorities (8, 20). In addition, evaluating complementary therapies such as massage as an accessible and low-risk approach is of particular importance (18). The present study, then, aimed to investigate the effect of massage as a non-pharmacological and simple method, co-administered EMLA cream as a gold standard to suggest uncomplicated and inexpensive therapeutic strategy without heavy educational burden to pediatric nurses and healthcare professionals managing the venipuncture pain.

2- MATERIALS AND METHODS

This study aimed to identify the effects of massage on children's pain and fear during venipuncture.

2-1. Design

This pre-experimental clinical trial was performed using a factorial design. It consists of three intervention groups and one control group.

2-2. Participants

The participants included 140 children hospitalized in the surgery ward of Children's Hospital of Tabriz University, Iran, in 2017. For random allocation of the participants to the groups, the names of groups, including interventions 1- 3 and control, were written on papers and located in similar opaque envelopes. All children, who met the inclusion criteria, were assigned a number. After entering a child into the study, we opened one of the envelopes, and the subject was allotted to considered group. The children receiving EMLA cream were assigned to the first group, those receiving massage were included in the second group, those receiving both EMLA cream and massage were included in the third group, and those who went through a venipuncture with no

pain-reducing technique (control group) were assigned to the fourth group (**Fig. 1**)

2-2.1. Sample Size

The sample size was determined through the mean difference formula, considering a 95% confidence interval, the test power of 80%, and an accuracy of 0.05. This estimation was based on the study by Sahiner and Bal (21) in 2018, who compared the three non-pharmacological pain relief methods in children. Given the probable sample attrition, 15% was added to 30, which resulted in a final sample size of 35 children in each group.

Sampling was done using Convenience method. To recruit participants, at the end of the morning shift, the researcher attended the given surgical ward and obtained the participants' parental consent, and recorded their demographic characteristics. Afterward, from among children being candidates for the next day's operation and requiring venipuncture, the eligible ones were included in the study. Later, each child was randomly assigned to one of the four study groups.

$$n = \frac{\left(z_{1-(\alpha/2)} + z_{1-\beta}\right)^2 \times \left(s_1^2 + s_2^2\right)}{\left(\mu - \mu_2\right)^2} \approx 30$$

$$n = \frac{(1.96 + 0.84)^2 \times (0.77^2 + 1.40^2)}{(0.40 - 1.23)^2} \approx 30$$

2-2.2. Inclusion and Exclusion Criteria

The inclusion criteria encompassed participants aged 3 to 6 years, feeling no pain during venipuncture due to disease, complete alertness, no disabilities, no sedatives, painkiller or corticosteroid intakes, and no intellectual disability. Exclusion criteria included having an allergy to EMLA cream or reacting to it during its application, failed venipuncture in the first attempt, and the child or their parent's reluctance to continue cooperation.

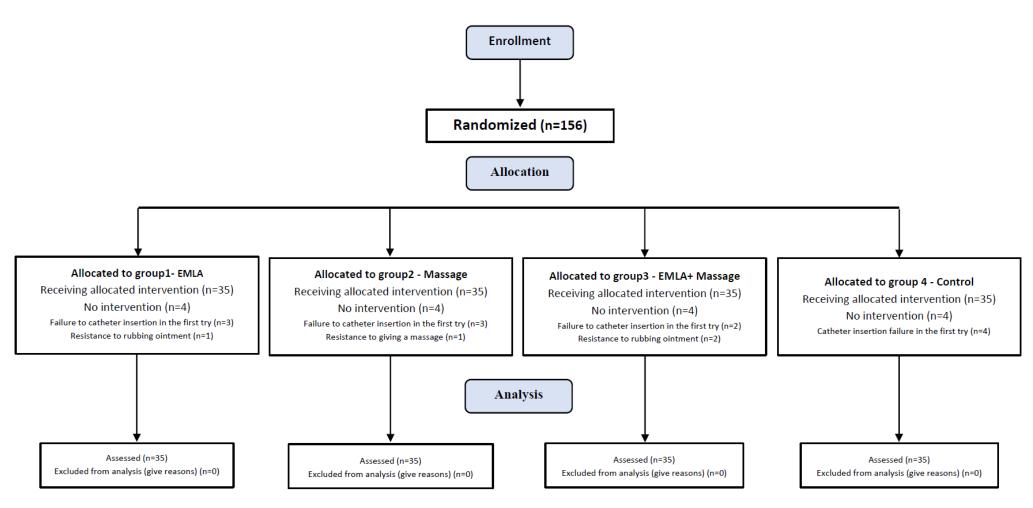


Fig. 1: Consort flow diagram of the trial

2-5. Instruments

2-5.1. Demographic Characteristics Form

The demographic form included the children's age, weight, and gender.

2-5.2. Wong-Baker FACES Pain Rating Scale

Wong and Baker designed this scale in 1988. It has six faces, each with a score ranging from 0-10, concerning the severity of the tolerated pain by the child (the value "0" refers to "no pain," and "10" refers to "severe pain"). The reliability of this instrument has been confirmed in a variety of studies (22-23).

2-5.3. Children's Fear Scale (CFS)

The visual instrument of CFS was developed by McMurtry et al. (24). It is a valid and reliable tool for measuring procedural fear in children. The tool has five faces, each of which gives a score of 0-4. The "0" point refers to "no fear," and "4" points refer to "severe fear" (24). In the present study, the fear and pain levels were assessed according to participants' report; the children's, mothers' and the nurse's statements on this scale were taken separately.

2-6. Venipuncture Procedure

Venipuncture was performed on the child's non-dominant hand on the dorsal vein by an expert nurse, using catheter 22 (Biçakcilar®, Istanbul, Turkey). venipuncture was performed by a nurse with ten years of experience in pediatric care and performing venipuncture. The main outcomes of this research were the levels of children's pain and fear. Before randomization. demographic characteristics were asked by conducting face-to-face interviews with mothers. Children, mothers, and the nurse were informed about the use of the scales. After randomization, the venipuncture performed in the presence of the child's

mother in a room considered for venipuncture. Before the procedure, all children were calm and comfortable and had no pain or fear.

- a) In intervention group1 (EMLA cream), based on the research by Kumar et al. suggesting that the use of EMLA cream 60 minutes prior to venipuncture is an efficient method that significantly reduces the children's pain (25), Sixty minutes before the venipuncture, 1.5 g (approximately 4 cm) of EMLA cream 5% (each gram contained Lidocaine (25 mg) and Prilocaine (25 mg)) was applied on the venipuncture site; later, it was covered using a preservative dressing. Sixty minutes later, after removing the dressing and cleaning the site, venipuncture was performed.
- b) In intervention group 2 (Massage), five minutes prior to and also during venipuncture, the participants received the effleurage massage technique (stroking) on the venipuncture site including the hand and the arm where the venous line was being inserted, performed by the researcher. The massage was done gently with patting-like movements, moderate palm pressure, and slow taps around the venipuncture area (26-27). The duration of the massage was the same for everyone.
- c) In intervention group 3 (EMLA cream and Massage), both EMLA cream and massage therapy were used before venipuncture.
- d) In intervention group 4 (control group), the routine procedure of the ward was performed according to. No intervention was performed for this group. Immediately after the venipuncture, the researcher asked the children to report the severity of the pain experienced using WB-FACES. Children's pain and fear responses were also evaluated by the nurse and mother independently using WB-FACES and CFS during the venipuncture procedure.

3-7. Data Analysis

SPSS 20.0 was used for data analysis (IBM Corp., USA). To analyze the data, ANOVA and Chi-square were used. P-value < 0.05 was regarded as significant.

3- RESULTS

Totally, 156 eligible children were included in the study, 16 of whom were

excluded. Moreover, 35 children were assigned to each intervention group and 35 children to the control group. Eighty-seven cases (62.1%) were male, and 53 cases (37.9%) were female. **Table 1** shows the main characteristics studied in four groups. No significant difference was found between the groups regarding the demographic information (P > .05).

Table-1: The comparison of the demographic information of the participants in the control and intervention groups

Participants	EMLA Cream	Massage	EMLA Cream + massage	Control	*P.Value
Age (mean ± SD)	4.58±1.15	4.54±1.08	4.48±0.94	4.40±1.04	P=0.89 F=0.20
Weight (mean ± SD)	17.65±4.24	17.18±3.77	16.88±3.08	16.64±3.17	P=0.67 F=0.51

^{*} ANOVA

3-1. Comparing Pain Levels

groups statistically The study had significant differences regarding The WB-FACES pain scores announced by the children. mothers. and the nurse (P<0.001). The EMLA Cream group reported better scores (less reported pain) according to children, mothers, and nurses' reports (P < .001) (Table 2). Moreover,

the Tukey post hoc test showed that there was a significant difference between the mean pain score reported by children, mothers, and the nurse in the control group and EMLA Cream group (P <0.05), and Massage group, and the EMLA Cream group (P<0.05), in_favor of the EMLA Cream group (Table 2).

Table-2: Comparing the venipuncture pain score of the subjects in all groups (n= 140)

Procedural pain Scores	EMLA Cream	Massage	EMLA Cream + massage	Control	*P.Value
Scores	$M \pm SD$	$M \pm SD$	$M \pm SD$	$M \pm SD$	
Child Reported	6.14±2.35	8.29±2.06	6.60±1.83	8.40±2.31	P<0.001 10.06 =F
Mother Reported	5.66±2.49	8.29±1.88	6.46±1.82	8.46±2.66	P<0.001 13.15 = F
Nurse Reported	5.20±2.62	7.94±2.44	6.23±2.43	8.77±2.52	P<0.001 F= 14.56

^{*} ANOVA

3-2. Comparing Fear Levels

According to mothers' and nurses' reports, no significant differences were observed between the fear mean scores of the children during the venipuncture (P >0.05). The fear scores of the EMLA cream and control groups were lower compared to cases in the EMLA Cream

and massage group and the massage groups in the reports of mothers and the nurse, respectively (P<0.001). Moreover, the Tukey post hoc test indicated significant differences between the mean scores of the fear reported by mothers and

the nurse in the massage group and EMLA Cream group (P < 0.05) and EMLA Cream group, and the EMLA Cream and massage group (P < 0.05), in favor of the EMLA Cream group (**Table 3**).

Table-3: Comparing the venipuncture fear score of the subjects in all groups (n= 140)

Procedural fear Scores	EMLA Cream	Massage	EMLA Cream + massage	Control	*P. Value
	$M \pm SD$	$M \pm SD$	$M \pm SD$	$M \pm SD$	
Mother-reported	3.31±1.18	4.09±1.12	4.06±0.83	3.54±1.50	P=0.01 F=3.65
Nurse-reported	2.89±1.15	3.69±1.10	3.66±0.96	3.40±1.45	P=0.01 F=3.41

^{*}ANOVA

4. DISCUSSION

In the present study, three different methods (massage, EMLA Cream, and EMLA Cream with massage) were assessed concerning their effect on the levels of children's pain and fear during venipuncture. The results of this study indicated that according to the statements of the children, mothers, and the nurse, children who received massage and those who received EMLA Cream with massage before venipuncture reported more pain and fear than the other intervention groups, respectively. There are few studies on this method. Chik et al. (2012) have reported that a 2-minute massage on the limb under the venipuncture can reduce neonatal pain: however, the difference between the intervention and control groups was not significant (28) In addition, Mirzarahimi et al. (2013) reported that message could not significantly reduce heel blood sampling pain in premature infants (29). Unlike the previous two studies, Zargham-Boroujeni et al. reported that massage at the venipuncture site could reduce infant pain (30).during this procedure discrepancy in the findings can be due to massage duration, pain control time, and checking tools.

On the other hand, different research communities may strongly influence the results of the study. In our review of the literature, no study was found to examine the massage effect on fear and pain due to venipuncture in children. Pain in children is affected by age, developmental level, as well as the cognitive and communication skills; therefore, children have unique challenges that require the consideration of physiological, psychological, behavioral, and developmental factors (31). In the present study, according to children's level of development and cognitive skills, a nurse's presence for massage has induced more fear and pain in the child. It should be noted that although the use of EMLA cream brought less pain and fear to children, it increased the child's pain and fear when combined with massage. This result suggests that keeping the child calm and reducing external stimuli can manage the severity of pain and fear because fear and worry are significant factors in perceiving pain (32). Based on the gate control theory, fear and worry may open the gate leading to increased pain perception (33). Thus, higher levels of fear can result in greater pain responses in children.

Another finding of the present study was that children receiving EMLA Cream before venipuncture experienced less pain and fear than the other intervention groups. This finding is confirmed by the findings of the following studies.

In a field study conducted on 6-8-year-old children in North Africa, Gwetu et al. (3) found that EMLA cream for local anesthesia effectively relieves children's venipuncture pain. In another study undertaken by Temsah et al. (34), after participants applied EMLA cream, the parents were requested to report their perception of their child's pain severity using the VAS tool. Results showed that the parents reported less pain and were more satisfied with the injection pain score after the intervention. A study by Nam et al. (35) likewise showed that using EMLA significantly cream could venipuncture pain; however, it had no impact on the severity of children's fear. Kumar et al. (25) suggested that using EMLA cream, 60 minutes prior to venipuncture, is an efficient method that significantly reduces the children's pain. However, in their study, the pain score was graded using a 4-point scale; and the pain was evaluated only by the researcher. In a systematic review comparing the control and the placebo groups, Ranjbar et al. (4) suggested that EMLA cream was the most effective way of reducing children's venipuncture pain. The results of the study by Stoltz et al. (11) showed that children on whom EMLA cream was applied prior to venipuncture reported less pain and fear after venipuncture. According to the literature, most studies have suggested topical anesthesia as the most effective way to relieve pain and sometimes fear of venipuncture. This effectiveness may be pertinent to the ingredients of EMLA cream, i.e., Lidocaine and Prilocaine, both of which prohibit the transmission of nerve stimulations and messages to the brain (36). On the other hand, EMLA cream,

having a low melting point, can easily pass through the skin surface and block the start and conduction of nerve impulses, altering the depolarization of the cell membrane (37). Therefore, EMLA cream is still recommended as one of the effective methods in reducing pain caused by venipuncture in children.

One of the strengths of this study is that it examines the pain and fear of the child separately and from different perspectives to differentiate the procedural fear of venipuncture pain in contrast to previous studies which have less addressed this issue.

4-1. Limitations of the study

This RCT should be interpreted in the context of some limitations. participants in this study were selected one ward, and various from only situational factors such as disease type. patients' past experiences, cultural and family influences, presence of strangers, and patient's preparation for the various phases of the study could influence the severity of the patient's fear and pain. Another limitation was the inability to blind children, mothers, and the nurse to the intervention.

5- CONCLUSIONS

According to this study finding, it might be recommended that the use of the massage should be limited during venipuncture procedures in the children group. It is necessary to update the knowledge of pediatric nurses about pain control methods by conducting further studies. The current research contributes to the literature on evidence-based pain and fear reduction during venipuncture. More research is needed to control the severity of fear and pain in children. Furthermore, considering that anxiety is a good criterion during venipuncture, it is recommended to consider it in future studies. Researchers suggest that in future studies, intervention groups be compared with a control group for which venipuncture is not performed; however, children are exposed to a nurse and venipuncture device (syringe, alcohol, and cotton).

6- ETHICAL CONSIDERATIONS

This research project was extracted from a project sponsored by Tabriz University of Medical Sciences. The institutional review board and the research ethics committee of Tabriz University of Medical Sciences (ethical code: IR.TBZMED.REC.1395: Clinical Trials.gov Identifier: IRCT20190201042579N1) approved the research protocol. The study objectives were explained to the subjects, and they signed written informed consent. The subjects were reassured that refusing to participate in the project would not affect continuing their treatment.

7- CONFLICT OF INTEREST STATEMENT

None.

8- AUTHORS CONTRIBUTIONS

Study conception and design: HN, MJ, TK.

Data collection: HN, KA, MA.

Data analysis and interpretation: HN, TK, MJ.

Drafting of the article: HN, TK.

Critical revision of the article: All authors.

9- ACKNOWLEDGMENT

The authors thank all children, parents, and nurses working in the surgical ward who contributed to this study. This research project was approved and sponsored by Tabriz University of Medical Sciences and received no funding from other institutions or organizations.

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