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The Effect of Foot Massage on Pain of Preschoolers Undergoing Venipuncture: A Clinical Trial

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Abstract

Background: Foot massage is a distraction technique that can be used for directing children's attention away from the painful stimuli during invasive procedures.

Aim: This study aimed to assess the effect of foot massage on pain intensity among hospitalized preschoolers undergoing venipuncture.

Method: Seventy preschoolers were selected using convenience sampling in the present clinical trial, at the internal pediatric ward of Besat Hospital, Hamadan, Iran. They were randomly allocated into the experimental (n=35) and control groups (n=35). The experimental group was received a foot massage 5 minutes before venipuncture. The pain intensity was measured using the Face, Legs, Activity**,** Cry, Consolability scale immediately and two minutes after catheter insertion. Heart rate and arterial oxygen saturation were measured using a pulse oximeter five minutes before, immediately, and two minutes after catheter insertion as pain physiological indicators.

Results: The mean±SD of pain intensity in the experimental group and in the control group immediately and two minutes after intravenous catheter insertion were 2.71±1.36 and 1.11±0.86, and 7.54±1.33 and 4.20±1.52, respectively. The mean of pain intensity immediately and two minutes after venipuncture revealed a significant difference between the experimental and control groups (P<0.001). The mean of heart rate and arterial oxygen saturation between the two groups were significantly different only immediately after venipuncture (P<0.001).

Implications for Practice: This finding is clinically important in nursing care for reducing pain and anxiety as well as decreasing drug-related complications and adverse effects. Instructing and using this method are suggested to medical personnel, especially nurses.

Keywords: Massage, Pain, Preschoolers, Venipuncture

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Introduction

Venipuncture or intravenous catheter insertion is among the most invasive and common procedures performed in pediatrics clinical settings (1) which often cause pain and distress in children (2). Invasive and painful procedures have an emotional and psychological impact on the children (1). Moreover, these procedures cause needle anxiety, and Trypanophobia in severe cases which reducing children's cooperation with therapy (3).

Parents are often worried and unable to provide any support as their children are crying and refusing to collaborate (4). However, pain leads to physiological responses, like Tachycardia, Hypoxemia, sweating, pallor or flushing, dilated pupils, Hypertension, and Hypertonia (5). Previous studies have reported that over 50% of hospitalized children experience moderate to severe pain or anxiety due to venipuncture (1). Most children find any needle insertion procedures stressful, painful, annoying, and terrifying (6).

Anxiety and fear of pain are inversely related to children's age (4). Preschoolers are often more sensitive to pain than other age groups. Preschoolers cannot think abstractly. They also try to make connections between present situations in which there is no logical relation. Preschoolers fantasize about pain due to a lack of clear understanding of it according to the preoperational stage in Piaget's theory of cognitive development (5). They think of pain as a punishment or a consequence of their actions based on Erikson's theory of psychosocial development (7,8). However, the preschoolers are worried about the pain of needles seriously damages their body as they have limited imagination about it (5,9).

Pain relief is one of the human rights of hospitalized children and one of the main objectives of the nursing care plan (10,11). Relieving Pain and anxiety is one of the important issues in pediatric nursing (5). Relieving pain and anxiety inadequately may cause fear for future procedures in parents and children which is followed by serious problems such as reducing family satisfaction from health professionals' functioning (11).

Several pharmacological and non-pharmacological interventions can be used during painful procedures to deal with anxiety and distraction of children from the painful stimuli (11,12). Many medications are used to relieve pain with limitations and side effects, such as Lidocaine spray with allergic reactions, systemic absorption, and potentially cardiac dysrhythmia (13,14).

Complimentary or alternative medicine is one of the non-pharmacological interventions (11). Complementary interventions are well accepted by the children and their family which are feasible, simple, and cost-effective with no serious side effects or drug interactions contrary to the limitations of pharmacotherapy (14,15). Complementary medicine interventions include hypnosis, acupuncture, therapeutic touch, meditation, distraction, aromatherapy, music therapy, and massage therapy (16,17).

Foot massage therapy is a practical method among complementary interventions (11,12). Paying attention to massage therapy increases the possibility of providing comprehensive care to nurses (18). Massage therapy brings tissues metabolic balance, reduces muscle tension, promotes comfort, relieves pain, and decreases anxiety by manipulating soft tissues (19,20). Reflexologists believe that a life force or vital energy flows along the paths of the legs to all parts of the body. Any kind of barrier in this flowing will eventually lead to illness.

Stimulation of reflexology can break these barriers in the canal flow and release energy in each foot (19, 20), inactivates the pain paths by secreting morphine-like compounds (21), and changes the sympathetic-parasympathetic outcomes, such as decreased heart rates, decreased anxiety, decreased cortisol, relaxation, increased blood pressure, and elevated skin temperature.

Foot massage is usually a good option when there is no time or possibility to receive full body massage (22). The studies have also shown the positive effect of massage on pain intensity and anxiety of bone marrow aspiration in children with cancer (23), control of physiological parameters in children aged 3-6 years (24), and the reduction of pain due to vaccination in infants (25). Pain relief in children has received less consideration due to invasive diagnostic and therapeutic procedures (26). Most previous studies have been conducted on infants, neonates (25, 27, 28), or adults (20, 29).

Only a few studies, to the best of our knowledge, have been performed on preschool children (11). Some studies have used the other distraction techniques intervention during venipuncture in children, such as using Video Game Play Technique (7), acupressure (30, 31), and aromatherapy (32). Some studies indicated the effect of massage therapy on relieving pain in infants and children (11, 27), and another study rejected its effect (29).

A clinical trial states that there is a set of massage therapy which considerably affect pain and anxiety in hospitalized children. But these results need to be revised as they are based on single studies (33). Massage and complementary therapies are not yet formally a part of nursing care in many countries (34). It seems that more studies are needed in this field. This study aimed to assess the effect of foot massage on pain intensity among hospitalized preschool children undergoing venipuncture.

Methods

The present study was a clinical trial with two groups of pre- and post-test studies conducted at the internal pediatric ward of Besat Hospital, Hamadan, Iran October 2019-September 2020. The preschoolers who had required intravenous catheter insertion were selected using convenience-sampling. Then they were randomly assigned to the experimental and control groups based on sequentially numbered cards. Number one card was in the experimental group and number two was in the control group.

The inclusion criteria were: (a) no consumption of analgesics three hours before the venipuncture; (b) being conscious and oriented to person, place, and time; (c) absence of mental, verbal, or visual disability; (d) absence of respiratory problems; (e) absence of fever; (f) hospitalization for the first time; (g) experience venipuncture for the second time; (h) venipuncture was done with the first attempt; (i) no presence of chronic or acute pain caused (j) all venipuncture was performed by a nurse with at least two years of work experience in pediatric settings. The exclusion criteria were: (a) feet have sensitivity to touch; (b) failure to venipuncture in the first attempt; and (c) unwillingness to continue participating in the study.

The sample size was estimated based on the formula in Pouraboli et al.'s study (35) to compare the mean of a qualitative trait in two independent communities considering α=0.05, β=0.2, d=1, and 90% power. The estimated sample size was 74 preschoolers in total among which 37 of them were placed in the experimental group and 35 of them in the control group.

Drop outs occurred due to discharge patients in the control group during the study (n=1) and venipuncture was not done with the first attempt (n=1). The intervention was discontinued in some participants in the experimental group due to a change in physician order (n=1) and a lack of cooperation (n=1). In total, 70 participants (each group=35) were analyzed in both the experimental and control groups according to the trial profile.

The data collection tools included demographic survey questions and Face, Legs, Activity, Cry, Consolability (FLACC) pain scale, the physiological parameters form, and pulse oximeter. Demographic survey questions included age, gender, birth order, and the location of the participants. The validity of the demographic survey questions was confirmed based on 10 pediatric nurses' viewpoints.

The FLACC tool was developed at the University of Michigan, Ann Arbor, MI, USA. It is a standard observational pain assessment tool for young children between the ages of 2 months and 7 years who are unable to self-report their pain. It consists of five criteria: face, legs, activity, crying, and consolability which are each assigned a score of 0–2 point scale providing an overall pain score ranging from 0–10 (36). The inclusion of the categories makes the tool relatively simpler than the others. The overall score is divided into three categories: 0-3, mild: 4-7, moderate; and 8-10 severe pain. This study was double blinded by allocating the intervention and control groups with codes A and B and the study statistician was unaware of how the groups were assigned when analyzing the data.

Sadeghi et al. translated the FLACC into Persian. The reliability coefficient was 0.70 in their study (37). In the present study, the inter-rater reliability was evaluated by correlating scores assigned simultaneously by two observers and by measuring of exact agreement between raters, ten children during venipuncture were simultaneously observed in the supine posture by the data collector and trained nursing staff and each of them separately completed the tools. The assistant nurse had two years of work experience at pediatric wards. Cronbach's alpha α= 0.82 indicated proper internal consistency.

The physiological parameters form was used to observe the heart rate (HR) and arterial blood oxygen saturation (SpO_2). HR and SpO_2 were measured by a pulse oximeter. The SpO_2 and HR values were checked by the pulse oximeter and had similar values. The pulse oximeter device was Saadat. Model:

Alborz B9, 2011 and have been used since 2013 in pediatric settings. Therefore, we expected that the device had an acceptable validity (both sensitivity and specificity assumed to be 100%).
The pulse oximeter was calibrated by an engineer to determine the stability before the sampling and continuing with equal intervals (every 6 months). When the children in both groups were lying on the bed in the venipuncture room, HR and SpO_2 were measured five minutes before, immediately, and two minutes after intravenous catheter insertion via pulse oximeter. The method of distraction was used through playing jokes for encouraging the child to cooperate in using the pulse oximeter.
A trained nurse measured pain intensity immediately and two minutes after intravenous catheter insertion. Then the children were prepared for obtaining venipuncture. They were placed in a supine posture. The No. 24 gauge catheter was inserted into the dorsal veins of the hands and the whole venipuncture was performed by the same nurse who had two years of work experience in pediatric settings. The experimental group was received a five-minute foot massage by the researcher five minutes before catheter insertion.
The foot massage was as follows: the children's feet were gently massaged with baby oil after laying on the bed. Firstly, the entire soles, bridge, heels, and toes were gently massaged, then the children's feet were held with one hand, pressed, and the toes of each foot gently pulled with the other hand. The researcher made rotational movements from the heels by using the thumb of one hand. These movements were performed on both feet.

Statstical analysis

Data were analyzed using SPSS software 23. Kolmogorov–Smirnov test (KS-test) showed that the data distribution of pain intensity was not normal. Descriptive statistics, such as mean and percentage, were used to assess participants' characteristics. Chi-square and Fisher's exact tests were used for examining the homogeneity between the two groups. Independent T-test, a repeated-measures ANOVA, and Post Hoc tests were performed to compare the physiological parameters between the control and experimental groups. Mann-Whitney-Wilcoxon test was used to compare the pain intensity between the two groups. The confidence interval was 0.95.

Ethical considerations

Written informed consent was obtained and the purpose of the study was explained to the participant's parents. They were allowed to leave the study whenever they wanted. It is worth mentioning that the results of the study were anonymously reported to comply with the ethical criteria.

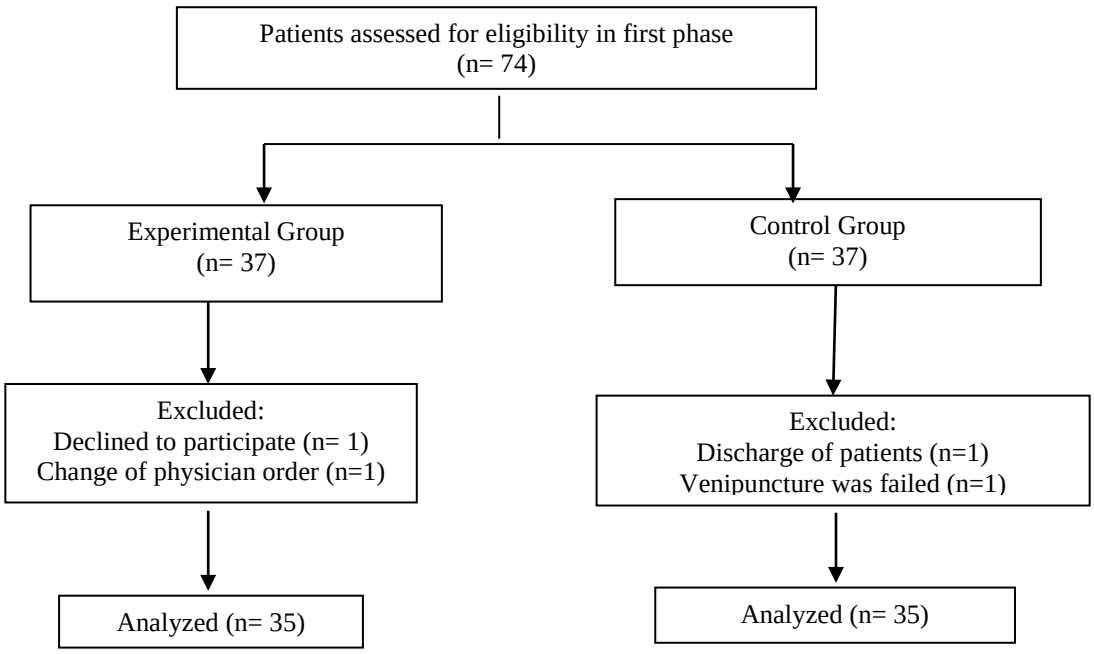

Figure 1. Trial profile

Results

Most of the children in both groups were girls (57.14%). The mean±SD age was 4.45±0.78 years in the experimental group and 4.50±0.86 years in the control group. (Table 1) Most of the children in the experimental group (42.85%) and the control group (57.14%) were the second child. The majority of children in both groups were living in rural areas (51.43%). Children in both groups had no significant differences in terms of demographic characteristics (P>0.05) The mean±SD pain intensity in the experimental group and the control group scores immediately and two minutes after intravenous catheter insertion which were 2.71±1.36 and 1.11±0.86, and 7.54±1.33 and 4.20±1.52, respectively. (table1).

The results showed that the pain intensity of most children in the experimental group was mild (68.4%) and in the control group was severe (77.1%) immediately after venipuncture. No child with severe pain was observed in the experimental group and no child with mild pain was observed in the control group. All children in the experimental group (100%) had mild pain intensity and most children in the control group (71.4%) had moderate pain intensity two minutes after venipuncture.

Moreover, there were significant differences between the mean pain intensity scores immediately and two minutes after intravenous catheter insertion in the experimental and in the control groups (P<0.001) according to the Mann-Whitney-Wilcoxon test (table 2). The mean pain intensity scores decreased in both groups. However, foot massage could reduce pain intensity in the experimental group more than in the control group based on the mean scores (table 2). In the present study, the effect size of this intervention in reducing pain in the subjests was 0.758.

The mean HR and SpO_2 were significantly different between the experimental and control groups only immediately after venipuncture (P<0.001). Furthermore, significant differences were observed between the mean HR and SpO_2 before, immediately, and two minutes after intravenous catheter insertion in both groups (P<0.001) (Table 2). Accordingly, HR decreased and SpO_2 increased between

Table 1. Demographic characteristics of the preschool children

Variables		Experimental Group(n= 35) n (%)	Control Group (n= 35) n (%)	Pvalue
Age (year)	3-4	11(31.42)	11(31.42)	0.999*
	4-5	12(34.28)	12(34.28)	
	5-6	12(34.28)	12(34.28)	
Gender	Girl	20(57.14)	20(57.14)	0.999*
	Boy	15(42.85)	15(42.85)	
Birth Rating	1	12(34.28)	10(28.57)	0.59*
	2	15(42.85)	20(57.14)	
	3	5(14.28)	4(11.42)	
	4	3(8.57)	1(2.28)	
Habitat	Urban	18(51.43)	17(48.57)	0.54*
	Rural	17(48.57)	18(51.43)	
Patient diagnosis	arthritis	7(20)	12(34.28)	0.993**
	Osteomyelitis	3(8.57)	1(2.85)	
	Gastroenteritis	5(14.28)	5(14.28)	
	Kawasaki	3(8.57)	4(11.43)	
	Meningitis	2(2.57)	1(2.85)	
	Urinary Tract Infection	5(14.28)	5(14.28)	
	Pneumonia	7(20)	6(17.14)	
Mother's education	Elementary	14(40)	13(37.14)	0.938*
	diploma	16(45.71)	16(45.71)	
	Academic	5(14.28)	6(17.14)	
Mother's job	housewife	6(17.14)	7(20)	0.532*
	practitioner	29(82.86)	28(80)	

*Chi-square test ** Fisher's exact tests

Table 2 .Comparison of pain intensity, heart rate, and arterial oxygen saturation in the experimental and control groups in units of time

Variable	Times	Experimental Group (n= 35)	Control Group (n= 35)	Between groups test
		Mean± SD	Mean± SD*	
Pain intensity	Immediately after	1.36±2.71	1.33±7.54	Z = 6.79 p<.001
	2 min. after	1.11±0.86	4.20±1.52	Z = 7.18 p<.001**
	Within group test	Z= -5.20 p <.001***	Z= -5.21 p <.001***	
Heart rate	Before	7.78±88.74	8.82±88.54	t= 0.11 P=0.92****
	Immediately after	8.29±91.31	109.62±10.32	t= -5.51 p<.001****
	2 min. after	8.26±92.51	8.76±94.48	t= -0.97 P=0.33****
	Statistics test	F = 94.81 df_1 = 2 df_2 = 68 P <.001******	F = 122.73 df_1 = 1.64 df_2 = 55.59 P <.001******	
oxygen saturation	Before	1.29±97.71	1.67±97.40	t=0.88 p=0.38****
	Immediately after	1.37±96.00	1.49±93.80	t= 6.42 p< .001****
	2 min. after	1.28±97.05	1.57±96.37	t= 1.99 p= .05****
	Statistics test	F = 39.58 df_1 = 1.52 df_2 = 51.79 P <.001*****	F = 129.25 df_1 = 1.42 df_2 = 48.27 P <.001*****	

*Standard Deviation, ** Mann-Whitney U, ***Wilcoxon signed-rank test, **** Independent T-test, ***** Repeated Measures Analysis of Variance

Note. HR = heart rate; b/m = beat per minute; min= minutes. SpO_2= arterial oxygen saturation; min= minutes.

the three evaluated time points in both groups. However, the mean HR values were lower, and the mean SpO_2 values were higher in the experimental group than the control one in the three evaluated time points (Table 2). Differences in the mean HR values and SpO_2 values were significant in the three evaluated time points in the experimental group and control group based on the pairwise comparison (P<0.001) (Table 3).

Table 3. The results of pairwise comparison of SpO_2 and HR in units of time in the experimental and control groups

Variable	Time	Experimental (n= 35)			Control (n= 35)		
		Mean Difference	Std. Error	p_{value}	Mean Difference	Std. Error	p_{value}
HR	Before&Immediately after	-8.77	0.63	<.001*	20.88	1.66	<.001*
	Before& 2 min after	-3.99	0.72	<.001*	-5.74	1.15	<.001*
	Immediately& 2 min after	4.88	0.56	<.001*	15.14	1.25	<.001*
SpO_2 (%)	Before&Immediately after	1.71	0.22	<.001*	3.6	0.27	<.001*
	Before& 2 min after	0.66	0.13	<.001*	1.03	0.14	<.001*
	Immediately& 2 min after	-1.66	0.22	<.001*	-2.57	0.26	<.001*

*ANOVA: multiple-comparison Post-Hoc LSD

Note. Std. Error = standard error; SpO_2= arterial oxygen saturation; HR = heart rate; b/m = beat per minute; min= minutes.

Discussion

In the present study, foot massage as a non-pharmacological intervention diminished the pain intensity and the variety of physiological parameters induced by venipuncture in preschool children in all the evaluated time points. The means of pain intensity in the two-time points were decreased in the experimental group compared with those in the control group. However, the means of pain intensity in the two-time points was diminished in the control group, as well. This may have occurred as intravenous catheter insertion has acute pain and its decline overtime is expected. According to the mean physiological parameters, the HR variability was lower and SpO_2 was improved in the experimental group immediately after venipuncture. However, the variability of HR and SpO_2 were normal in both groups.

The results of the present study were in line with some similar studies. Similar studies revealed that using foot massage two minutes before venous catheter insertion for the first time (27) or the heel lancing procedure (38) was effective in decreasing pain in infants. A randomized controlled trial with a sample of 1 to 12 month-old infants also showed that foot massage for 20–30 minutes before vaccine injection reduced the pain (25). Many studies have been conducted to investigate the use of complementary medicine interventions in reducing pain intensity in pediatric patients.

Another study concluded that aromatherapy with lavender essence could decrease the pain intensity of venipuncture in preschool children (32). Another study indicated that massaging acupressure at Hoku point (LI4) for 5 minutes before and during venous catheter insertion decreased the intensity of pain in children between 1 to 6-year-old using the FLACC pain scale (31). Moreover, Özkan and Balcı (2020) conducted a randomized controlled trial to determine the effects of acupressure on acute pain due to venous catheter insertion in children between 9 to 12-year-old. Their study showed that acupressure decreased the experienced pain in the intervention group (30).

In the present study, the comparison of SpO_2 and HR between the experimental and control groups after the intervention illustrated a significant difference between the two groups immediately after venipuncture ($p<0.001$). This finding was in line with similar studies (11, 25, 38). A study confirmed that foot massage could reduce the anxiety and vital signs including HR, blood pressure, and respiration rate in 6 to 12-year-old children with thalassemia during a blood transfusion (11). Özkan et al. (2019) conducted a study to support that massage was effective on lesser fluctuation of SpO_2 and HR during crying and heel lancing procedure in the newborns (38). Moreover, in another study, the 1 to 12 month-old infants in the foot massage group had lower HR, higher SpO_2, and shorter crying periods than the control group after vaccine injection (25). Samadi et al. (2014) evaluated the effect of a 15-minute foot massage on SpO_2 and HR of neonates admitted to NICU. The results showed that foot massage could maintain the variability of SpO_2 and HR in the normal range ($P<0.01$) (39).

However, Özkan and Balcı (2020) study, in contrast to the present study, suggested no significant changes in the SpO_2 and HR between the intervention and control groups after the acupressure intervention during venipuncture in children aged 9 -12 years (30). Aslani et al. assessed the effect of hand massage on controlling alterations in the SpO_2, HR, and respiratory rate from five minutes before until the end of venipuncture in children aged 3-6 years. The results showed that only HR was lower in the massage group than in the control group (24).

Study limitations

One of the limitations of the current study is the presence of the researcher at the time of venipuncture and the impact of social-cultural and psychological differences on reaction to the pain in children. The results of this study cannot be generalized to the community as available sampling was used. It is worth noting that confounding factors as crowdedness and excessive noise of the ward and the mood of the children were major limitations of the present research.

Implications for Practice

This finding is clinically important in nursing care as it presents a method for reducing pain and anxiety without medicines and drug-related complications or misused. Foot massage is an easy and inexpensive method without complications that could be used in routine care with other pharmacological or non-pharmacological interventions for reducing the pain of invasive procedures such as venipuncture in children. Therefore, nurses can use foot massage before invasive procedures to decrease the children's pain, create a better experience, establish a more effective relationship with

children and parents, and promote the quality of nursing care. However, few nurses have experience in massage therapy and need specialized training. Training and using this method have been suggested to medical personnel, especially nurses. Therefore, foot massage is a simple intervention in distraction with no side effects in the present study. The study of other groups is also recommended in this case.

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Conflicts of Interest
The authors declare that there is no conflict of interest.

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