

The effect of foot reflexology massage on pain during vaccine injection in infants referred to Rasht Comprehensive Health Center: A randomized clinical trial

Parichehr Shahroudi¹, Minomitra Chehrzad², * Atefeh Ghanbari³, Parand Pourghane⁴,
Bahram Naderi-nabi⁵, Mohsen Mohammadi⁶, Zahra Atrkarroushan⁷

¹ Instructor, Department of Pediatric Nursing, Zeinab School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran.

² Assistant Professor, Department of Nursing, School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran.

³ Professor of Nursing, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Social Determinants of Health Research Center, Guilan University of Medical Sciences, Rasht, Iran.

⁴ Associate Professor, Department of Nursing, Zeinab School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran.

⁵ Professor of Pain Anesthesiology, Department of Anesthesiology, School of Medicine, Guilan University of Medical Sciences, Guilan, Iran.

⁶ Master, Department of Nursing, Ardabil School of Nursing and Midwifery, Ardabil University of Medical Sciences, Iran.

⁷ Associate Professor of Biostatistics, Department of Community Medicine, School of Medicine Otorhinolaryngology, Research Center Guilan University of Medical Sciences, Rasht, Iran.

Abstract

Background: Vaccination is one of the most common and painful methods of disease prevention that imposes stress on infants, and affects their parents, as well. Nurses are the main designers of nursing practices and one of their primary tasks is to play a supporting role in reducing pain during injections; so, they should be able to choose the most useful and safest methods of care. The present study, thus, aimed to determine the effect of foot reflexology massage on pain during vaccine injection in infants. **Methods:** This study was a double-blind clinical trial. The study population included 90 healthy infants aged 2-7 months who were brought by their parents to one of the comprehensive health centers of Rasht (Guilan province, Iran) for pentavalent vaccine injection. The infants were randomly divided into three groups: foot reflexology massage, neutral point massage (sham group) and control. Data collection instruments included a demographic information form and the Face, Legs, Activity, Cry, and Consolability scale (FLACC). Data were analyzed using Chi-square, ANOVA, independent t-test and repeated measures ANOVA in SPSS ver. 22.

Results: There was no significant difference between the three groups in terms of pre-vaccination pain level. Means \pm standard deviations of pain during vaccine injections in the intervention, sham, and control groups were 4.83 ± 1.08 , 7.96 ± 0.99 , and 8.40 ± 1.13 , respectively, which were significantly different ($p < 0.001$).

Conclusion: Foot reflexology massage can reduce the pain during pentavalent injection in infants and can be used as a simple and accessible non-pharmacological method to manage vaccination pain in infants.

Key Words: Clinical trial, Foot reflexology massage, Infant, Pain, Vaccination.

* Please cite this article as: Shahroudi P, Chehrzad M, Ghanbari A, Pourghane P, Naderi-nabi B, Mohammadi M, Atrkarroushan Z. The effect of foot reflexology massage on pain during vaccine injection in infants referred to Rasht Comprehensive Health Center: A randomized clinical trial. *Int J Pediatr* 2023; 11 (02):17366-17373. DOI: [10.22038/ijp.2023.65387.4932](https://doi.org/10.22038/ijp.2023.65387.4932)

*Corresponding Author:

Atefeh Ghanbari, Professor of Nursing, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Social Determinants of Health Research Center, Guilan University of Medical Sciences, Rasht, Iran. Email: at_ghanbari@yahoo.com

Received date: May.06,2022; Accepted date: Feb.05,2023

1- INTRODUCTION

Today, children are exposed to various preventive and therapeutic measures that cause different pain levels (1).

An important principle in pain management is that prevention is better than treatment. According to studies, infants are more sensitive to pain than other children and adults (2). Vaccination is the most common painful procedure in childhood, which is experienced by children very frequently according to the immunization program of each country (3). Numerous studies have shown that the pain and injection-related emotional stress may be one of the reasons for delayed child vaccination programs by their parents. For this reason, any procedure to reduce pain during vaccine injection is an important part of healthcare and should be considered in vaccination programs (1, 4).

Accordingly, pharmacological and non-pharmacological methods are used in medical procedures to reduce pain in children (5-7). Meanwhile, one of the major problems of modern medicine, such as pharmaceutical methods, is the use of chemicals that have side effects. For this reason, it is necessary to use complementary medicine in nursing (8). There have been numerous studies on the use of non-pharmacological methods of pain relief, including non-nutritive sucking, massage therapy, distraction, Hugo's point massage and music therapy by nurses (9-15). In this regard, reflexology massage is a simple, accessible and non-invasive technique. In other words, this technique is a non-pharmacological form of treatment in which specific points on the surface of the body, usually palms and soles are pressed regularly and according to certain principles to properly affect the internal organs of the body (16). Reflexology is a safe technique working on the reflex areas in hands, feet, and ears with gentle

pressure and massage to stimulate the nerves in the body and to relax the body in order to accelerate the body's self-healing process and enables endorphin and enkephalin release by stimulating the pituitary gland through the pressure and massage performed on reflex points in hands and feet (17). Reflexology is one of the most popular practices in pediatric settings and has been taught in institutes with qualifications for over 50 years in the UK, Australia, Thailand, Malaysia and many other countries (16).

Numerous studies have investigated the effect of foot reflexology massage, including its effects on infantile colic, pain due to bone marrow aspiration, and pain due to chemotherapy injection in children and adults. They have found that it is effective on pain relief; therefore, it can be used as a pain-relief technique (18-20). Since nurses are the main designers of nursing practices, they should be able to choose the most useful and safest methods of care. Moreover, one of their primary responsibilities during injections is to play a supporting role in reducing pain; and pediatric nurses can play a more effective role in pain management (8, 21, 22). Non-pharmacological pain management methods are not invasive and are considered an independent activity in nursing (21). In spite of the fact that some non-pharmacological pain management methods have been proposed by other researchers, it seems that there are limitations associated with the implementation of these methods during vaccination in the physical space allocated to comprehensive health centers. Therefore, foot reflexology massage, if effective, can provide benefits such as reducing the risk of aspiration and the absence of parents if they wish, as compared to methods such as breastfeeding, the use of oral sugar solution and kangaroo care. It can be also used as a complementary method along

with pharmacological methods to reduce the need for pharmacological analgesics. To the best knowledge of the authors, there are few studies on the effect of foot reflexology massage on vaccination pain in infants and it is also difficult to implement other complementary medicine techniques (such as hypnosis, acupuncture, biofeedback) to reduce pain in children. Therefore, the aim of the present study was to determine the effect of foot reflexology massage on physiological parameters, pain, and crying of infants during vaccine injection; and if this method yields effective results, the adverse effects arising from the uncontrolled pain in children can be reduced.

2- Materials and Methods

2-1. Design and population

This was a double-blind randomized clinical trial. The sampling process lasted for four months from September to December 2019. The study population included healthy 2-7-month-old infants who were referred to one of the comprehensive health service centers in Rasht by their parents to receive the pentavalent vaccine. The total sample size was estimated as 90 people ($n=30$ per group) using an almost similar study on the pain variable (23), and considering the probable drop out, type I error rate ($\alpha = 0.05$), type II error type ($\beta = 0.10$), experimental group $s_1 = 2.11$, control group $S_2 = 0.85$, effect size ($d = 1.5$), and 95% confidence interval.

2-2. Sampling

Convenience sampling was performed and individuals were then randomly assigned into the three groups using permutation block method (block size=six ABCABC). The letters "C", "B", and "A" were considered as the control, sham, and intervention groups, respectively. Blocks were recorded in all possible cases. Sampling was continued until reaching the

specified sample size in each group ($n=30$ people).

2-3. Inclusion and exclusion criteria

Inclusion criteria included infants aged 2 to 7 months with normal weight and height percentile, and fetal age between 38-42 weeks of gestation, infants that are calm with no crying before vaccination, body temperatures of $36-37.2^{\circ}\text{C}$, receiving no analgesic three hours before vaccination, no history of hospitalization, no disease such as thyroid disorders, epilepsy and cardiovascular diseases and acute diseases that reduce infant's consciousness level, and lack of sleep problems before vaccination. Exclusion criteria included any problems during vaccination, parents' unwillingness to continue with the research team, prematurity and developmental delay.

2-4. Data collection

Data collection instruments included a demographic questionnaire, and FLACC as a pain assessment checklist. FLACC scale had five components, including facial reactions, leg position, mobility, crying, and consolability. Each of these components has a score of 0 to 2, and scores are added together. Overall scores of 0 and 10 mean no pain and the most severe pain, respectively. The overall score is divided into three levels: Score 0-3, 4-7, and 7-10 indicate mild, moderate, and severe pain, respectively. The FLACC scale was developed by Merkel, Voepel-Lewis, Shayevitz, and Malviya in 1997 (1). This instrument has also been used in other studies in Iran; for example, Farhadi (24) Bagherian et al (25). To measure the reliability of this instrument in the present study, inter-rater reliability was used and the agreement coefficient was equal to 84%.

2-5. Procedure

Initially, the height and weight were measured. Underarm temperature was also

controlled using a mercury thermometer and a demographic questionnaire was completed. The eligible infants were assigned into intervention, sham or control groups according to the related blocks.

The intervention was performed by the first researcher who had a reflexology certificate. In the intervention group, the researcher washed his hands and soaked them in baby oil that had no therapeutic effect (Firooz brand) to reduce friction. The foot reflexology massage was performed according to the basic sequences including relaxation techniques, massage of all areas of the soles as well as specific areas related to the vaccine site. After warming up the hands, each foot was warmed up after a one-minute massage. Then, while the researcher holds the infant's foot with his left hand, he massages the relevant area on each sole for 15 minutes (a total of 30 minutes for each infant) with the thumb of his right hand. For Sham infants, the researcher washed his hands and soaked them in baby oil that had no therapeutic effect. He then performed the relaxation and massage technique on all areas of the soles, with the difference that sham infants received massage in a neutral point (area), i.e. below the outer ankle. The control group received no intervention, the vaccination was performed according to the routine procedure. All infants were placed in the supine position during vaccination, and the vaccine was injected intramuscularly in the anterior outer region of the thigh. Vaccinator, vaccination site, type and company of syringe and vaccine groups were the same in all samples. At baseline, the infants' pain levels were measured in all three and recorded by FLACC instrument, one minute before the massage. There was no significant difference between the intervention, sham and control groups in terms of the mean pain before foot reflexology massage. Then, the relevant

massage was performed in the intervention and sham groups. After this stage, the pain level was measured and recorded for one minute while administering the painful stimulus (from the moment of vaccine injection). The measurements were performed by a research colleague who was unaware of the random allocation.

2-6. Data analysis

Kolmogorov-Smirnov test was used to check the normality of the data distribution. Chi-square test was used to analyze the qualitative data. ANOVA test and independent t-test and repeated measures ANOVA were also used for quantitative variables. Data analysis was carried out in SPSS ver. 22 at $p < 0.05$.

3- RESULTS

The data of the foot reflexology group ($n=30$ individuals), the neutral point massage group ($n=30$ individuals) and the control group ($n=30$ individuals) were analyzed. The three study groups were homogeneous in terms of individual variables such as fetal age and temperature (**Table 1**).

The mean pain level during vaccine injection increased in all three groups, but this increase was different in the three groups, that is, it was significantly higher in sham and control groups ($p < 0.001$). The results of repeated measures ANOVA showed that the time effect ($p = 0.001$), group effect ($p = 0.001$) and also time-group interaction ($p = 0.001$) were statistically significant (**Table 2**).

4- DISCUSSION

The aim of the present study was to determine the effect of foot reflexology massage on the pain during vaccine injection in infants. The mean pain in the three groups of intervention, sham and control during vaccine injection and also the mean pain in the three groups before foot reflexology massage and during the

implementation of painful stimuli were compared. The results demonstrated that the mean pain score during vaccine injection in the intervention, sham, and control groups was 4.1 ± 83.08 , $7\% \pm 96.99$, and 8.1 ± 40.13 , respectively. Results of one-way ANOVA showed lower pain in the intervention group (foot reflexology massage) than in the sham and control groups. Therefore, there was a significant difference between the three groups in terms of pain score during vaccine injection ($p < 0.001$). The mean pain in the intervention, sham and control groups before foot reflexology massage

and during vaccine injection was also compared in the present study. Paired t-tests showed a significant difference between all three groups in terms of pain level before the foot reflexology massage and during vaccine injection. Thus, since there was no basal pain in all three groups, the pain level increased in all three groups following the painful stimulus (vaccine injection), but this increase was less significant in the intervention group. This means that the intervention group (foot reflexology massage) experienced less pain than did the sham and control groups ($p < 0.001$).

Table-1: Comparison of the characteristics of the participants in the three studied groups

Characteristics	Group			Test	P-value
	Reflex foot massage	Neutral point massage	Control		
Fetal age (weeks)	38.53±0.68	38.36±0.49	38.33±0/54	One-way ANOVA	0.36
Current age (months)	3.73±1.63	3.66±1.58	3.80±1.68	One-way ANOVA	0.95
Weight	6373.66±932.38	6431.00±852.93	6579.33±893.25	One-way ANOVA	0.65
Temperatures	36.47±0.29	36.40±0.30	36.50±0.19	One-way ANOVA	0.34
Sex	43/3	46.7	50.0	Chi_square	0.87
	56.7	53.3	50.0		
Type of nutrition	76.7	73.3	70.0	Chi_square	0.84
	23.3	26.7	30.0		

Table-2: Comparison of mean pain scores before reflexology massage and during the implementation of painful stimuli in the three groups

Group	Before foot reflexology massage	During implementation of painful stimulus	Repeated measures ANOVA		
			Time	Group	Time Group
Reflex foot massage	0.00±0.00	1.08±4.83	0.001	0.001	0.001
Neutral point massage	0.00±0.00	0.99±7.96			
Control	0.00±0.00	1.13±8.40			

In the same line with our research, Gazin et al. (2015) conducted a study to investigate the effect of foot reflexology massage on acute pain among 60 infants aged 1-12 months who were referred for

vaccination. The participants were divided into experimental and control groups (n=30 people per group). Their results were consistent with those of our study (23). Also, in a study on the effect of

reflexology massage on chronic and acute pain in children, Bertrand et al. (2019) showed that it had a significant effect on pain level in both groups of children suffering from chronic or acute pain; that is, the pain level decreased in both groups after the reflexology massage intervention (26). In this regard, in a study of the effect of Hugo's point massage with and without ice on the pain intensity of infant during vaccine injection, Khosrovan et al. (2018) concluded that the three groups experienced different pain intensities after vaccination and both interventions reduced the perception of pain in childhood vaccination (9). Although foot reflexology massage is different from acupressure and the technique takes less time, the two methods have a similar scientific basis and the results of that study confirms the results of the present study in terms of pain relief.

Similarly, in another study on the effects of upper limb massage on infant venipuncture pain, Quebec et al. revealed a significant difference between the intervention and control groups in terms of the mean pain intensity after the intervention; that is, infants in the intervention group had lower pain scores than those in the control group (27). On the other hand, Yilmaz (2021), in his study investigating the effect of foot reflexology on procedural pain before heel lancing in neonates, found no statistically significant difference between the intervention and control groups in the level of pain during heel lancing (28).

Mood and emotional differences and different pain tolerance thresholds are among uncontrollable limitations of the present study.

5- CONCLUSION

According to the results of the present study, foot reflexology massage can reduce the pain caused by pentavalent vaccine in infants and can be used as a

simple and accessible non-pharmacological method by nurses and other health professionals to manage vaccination pain.

6- ETHICAL CONSIDERATIONS

This study was approved by the Ethics Council of Guilan University of Medical Sciences and was registered in the Iranian Registry of Clinical Trials of the Ministry of Health of Iran. Informed written consent was obtained from all the parents.

7- ACKNOWLEDGEMENTS

The present study is the result of a master's thesis in pediatrics, which was funded by the Vice Chancellor for Research, Guilan University of Medical Sciences. Hereby, the authors would like to express their thanks to the university officials and all the families of the infants for their cooperation and participation in the present study.

8- REFERENCES

1. Hockenberry MJ, Wilson D. Wong's nursing care of infants and children- EBook: Elsevier Health Sciences; 2018.
2. Marcdante K, Kliegman RM. Nelson Essentials of Pediatrics EBook. Elsevier Health Sciences; 2014.
3. Izadpanah A, Farajzadeh Z, Khazae T. Impact of distraction technique on reducing the infants' vaccination pain. *Modern Care Journal*. 2014; 11(1):1-9.
4. Taddio A, McMurtry CM, Shah V, Riddell RP, Chambers CT, Noel M, et al. Reducing pain during vaccine injections: clinical practice guideline. *Cmaj*. 2015; 187(13):975-82.
5. Inal S, Canbulat N. Using distraction methods on procedural pain management of pediatric patients. *Güncel Pediatri*. 2015; 13(2):116-21.
6. Riddell RP, Racine NM, Craig KD, Campbell L. Psychological theories and

biopsychosocial models in pediatric pain. Oxford textbook of pediatric pain. 2014:85-94.

7. Eroğlu A, Arslan S. Yenidoğanda ağrının algılanması, değerlendirilmesi ve yönetimi. Düzce Üniversitesi Sağlık Bilimleri Enstitüsü Dergisi. 2018; 8(1):52-60.

8. Basiri-moghaddam M, Khosravan S, Mojtabavi SJ, Esmaili M. Effect of Foot Reflexology on Meconium Passage in Healthy Infants. Complementary Medicine Journal. 2016; 6 (2): 1521_1535.

9. Khosravan S, Atayee P, Mazloun Shahri SB, Mojtabavi SJ. Effect of Hugo's point massage with and without ice on vaccination-related pain in infants. Journal of hayat. 2018; 24(1):7-19.

10. Salawati Ghasemi S, Beyramijam M, Yarahmadi F, Nematifard T, Bahrani SS, Khalegh Verdi M. Comparison of the Effects of Hugo's Point Massage and Play on IV-Line Placement Pain in Children: A Randomized Clinical Trial. Pain Research and Management. 2021.

11. Probowati E, Soe Joenoes A, Wahyuni S, Mulyantoro DK, Widyawati MN, Fatmasari D. EFFECTIVENESS OF BREASTFEEDING AND NON-NUTRITIVE SUCKING ON PAIN RELIEF IN INFANT IMMUNIZATION. Belitung Nursing Journal. 2017; 3(2):102-9.

12. Özkan TK, Yüksel ED, Akar S. Effect of non-nutritive sucking on pain during the examination of retinopathy of prematurity. Journal of Neonatal Nursing. 2022; 28(3): 155-158.

13. Nurbayanti S. The effects of breast feeding and massage on neonatus pain during intravenous blood sampling procedures. Journal of Neonatal Nursing. 2021; 27(2):129-34.

14. Alemdar DK, Aktaş YY. The use of Buzzy, jet lidocaine, bubble-blowing and aromatherapy for reducing pediatric pain, stress and fear associated with phlebotomy. Journal of pediatric nursing. 2019; 45:e64-e72.

15. Ting B, Tsai C-L, Hsu W-T, Shen M-L, Tseng P-T, Chen DT-L, et al. Music intervention for pain control in the pediatric population: A systematic review and meta-analysis. Journal of clinical medicine. 2022; 11(4):991-1008.

16. Embong NH, Soh YC, Ming LC, Wong TW. Revisiting reflexology: Concept, evidence, current practice, and practitioner training. Journal of traditional and complementary medicine. 2015; 5(4):197-206.

17. Sağlık Wa, Refleksoloji, Baskı Şefik Matbaa, İstanbul: Dharma Yayınları. 2009:13-02.

18. Çelebioğlu A, Gürol A, Yildirim ZK, Büyükavci M. Effects of massage therapy on pain and anxiety arising from intrathecal therapy or bone marrow aspiration in children with cancer. International journal of nursing practice. 2015; 21(6):797-804.

19. Weaver MS, Riley B, Wolfe A, Bace S, Wichman C. Kneading Acceptance: Experiential Massage Therapy Education Fosters Nursing Acceptance of Massage Therapy for Pediatric Patients. The Journal of Alternative and Complementary Medicine. 2018; 24(11):1128-9.

20. Icke S, Genc R. Effect of Reflexology on Infantile Colic. The Journal of Alternative and Complementary Medicine. 2018; 24(6):584-8.

21. Organization WH. Reducing pain at the time of vaccination: WHO position paper—September 2015. Weekly Epidemiological Record= Relevé épidémiologique hebdomadaire. 2015; 90(39):505-10.

22. Aydin D, Sahiner NC, Ciftci EK. Non-pharmacological strategies used to reduce procedural pain in infants by nurses at family health centers. *JPMA*. 2017; 67(6): 889- 894.
23. Koç T, Gözen D. The effect of foot reflexology on acute pain in infants: A randomized controlled trial. *Worldviews on Evidence-Based Nursing*. 2015; 12(5):289-96.
24. Farhadi A, Farhadi S. Effect of Topical Tetracaine Gel %4 on Intensity of Pain Due to Intramuscular Injection of DPT Vaccine for 2 months of Age Infants. *Journal of research Development in Nursing & Midwifery*. 2012; 2(1): 9-15.
25. Bagherian S, Borhani F, Abbaszadeh A, Tehrani H, Pashandi S. The Severity of Pain in Children with Thalassemia during Venipuncture and Prior to Blood Transfusion. *Journal of Health and Development*. 2012; 1(2):138-46.
26. Bertrand A, Mauger-Vauglin C-E, Martin S, Goy F, Delafosse C, Marec-Berard P. Evaluation of efficacy and feasibility of foot reflexology in children experiencing chronic or persistent pain. *Bulletin du cancer*. 2019; 106(12):1073-9.
27. Bertrand A, Mauger-Vauglin C-E, Martin S, Goy F, Delafosse C, Marec-Berard P. Evaluation of efficacy and feasibility of foot reflexology in children experiencing chronic or persistent pain. *Bulletin du cancer*. 2019; 106(12):1073-9.
28. Yilmaz D, Kurt FY. The effect of foot reflexology on procedural pain before heel lancing in neonates. *Archives de Pédiatrie*. 2021; 28(4):278-84.