

Effect of Foot Reflexology on Arteriovenous Fistula Access Pain: A Randomized Clinical Trial

Seyedeh Faezeh Razavi¹, Azizeh Farshbaf-Khalili², Sakineh Goljarian³,
Hamid Tayebi Khosroshahi⁴, Mohammad Gholipour⁵, Alehe Seyedrasooli^{6*}

Abstract

Background: Hemodialysis is the most commonly used method for dialysis; nonetheless, it causes some problems, such as the pain associated with fistula needle insertion. Pain relief is one of the main skills of nurses, and reflexology can be used as a golden key for this puzzle.

Aim: The present study aimed to assess the effect of foot reflexology on the pain of arteriovenous fistula (AVF) access.

Method: This parallel double-blind clinical trial study was conducted on 50 female patients referring to Imam Reza Medical Center in Tabriz, Iran, in 2020-2021. The participants were randomly allocated to two groups of intervention and control using block randomization in a 1: 1 ratio. The intervention group received foot reflexology before hemodialysis for 20 min (10 min for each foot), while the control group received routine ward care. The data were collected through demographic characteristics and visual analog scale (VAS) questionnaires. Data were analyzed in SPSS 23.

Results: In terms of place of residence, 96% and 88% of participants in the intervention and control groups lived in urban areas, respectively. Moreover, 72% and 64% of patients in the two groups of intervention and control had a history of hypertension, respectively. Furthermore, foot reflexology had a statistically significant effect on the mean score of pain intensity during three sessions of reflexology over time.

Implications for Practice: It is recommended that foot reflexology be used to reduce the pain of needle entry into the arteriovenous fistula in hemodialysis patients since reflexology is non-invasive nursing care with an easy procedure and effective in pain relief.

Keywords: Arteriovenous fistula, Hemodialysis, Pain, Patients, Reflexology

-
1. Assistant Professor, Department of Medical-Surgical Nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran
 2. Assistant Professor, Aging Research Institute, Physical Medicine and Rehabilitation Research Centre, Tabriz University of Medical Sciences, Tabriz, Iran
 3. Assistant Professor, Department of physiotherapy, Faculty of Rehabilitation, Tabriz University of Medical Sciences, Tabriz, Iran
 4. Kidney Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
 5. Bachelor of nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran
 6. Master of medical-surgical nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

* Corresponding author, Email: f.razavi1391@gmail.com

Introduction

Chronic kidney disease is a long-term progressive problem that affects kidney function (1). According to the CDC (Centers for Disease Control and Prevention), 15% of adults in the United States, about 37 million people, suffer from chronic kidney disease (2). Although kidney transplantation is the treatment of choice for patients at the End Stage Kidney Diseases (ESKD), dialysis is the predominant treatment in most countries (3). Hemodialysis is the most commonly used method among dialysis methods (4, 5). It has been predicted that by 2030, the use of alternative therapies for kidney function worldwide will be more than doubled to 5.4 million, and the highest growth rate will be in Asia (3).

Suitable vascular access is one of the main challenges in hemodialysis wards (6). Arteriovenous fistula (AVF) is considered the preferred vascular access option for most hemodialysis patients, offering the best results due to the need for less intervention to maintain function and lower risk of infection than other methods (3, 7, 8). One of the most common problems with AVF is pain during needle insertion into the fistula (9). In this regard, the pain of needle insertion into a fistula was very unbearable as reported by 50% of patients (10). The multiplicity of this problem during the life of these patients reduces their quality of life (11). The experience of repeated pain has a negative impact on various aspects of life in hemodialysis patients. Moreover, it decreases one's ability and performance in response to social problems and can also affect the level of hemodialysis acceptance in patients, thereby reducing their quality of life (12, 13).

The mitigation of patients' pain with nursing interventions is one of the remarkable skills of nurses. They are responsible for managing patients' pain with their measures and providing practical solutions for it (14). Multiple methods can be employed for reducing the pain of AVF needling, including the use of intradermal lidocaine, buttonhole technique, EMLA cream, ethyl chloride spray, and programmed distraction. Some of these strategies can negatively affect the function of AVF; therefore, they cannot be used for all patients. Topical medications may be less absorbed in hemodialysis patients due to some epidermal barriers, topical lidocaine makes venipuncture difficult, and EMLA ointment may cause skin allergies in some patients (15).

Reflexology is an independent nursing intervention and a branch of complementary medicine, which is a non-invasive, simple, low-cost, and uncomplicated method, and therefore, it can be considered one of the effective ways to manage pain in hemodialysis patients (16-18). Reflexology is based on the idea that each part of the body has a corresponding reflection area on the feet, hands, and ears as a mirror of the body. The stimulation of specific reflections in these areas affects related organs and systems (19).

Due to the contradictory results on the effect of reflexology as an effective nursing intervention in reducing pain (20, 21), the negative impact of other pain-relieving strategies, and the possibility of damage to the AVF, the present study aimed to determine the effect of foot reflexology on pain intensity associated with needle insertion into AVF in patients undergoing hemodialysis.

Methods

The present parallel-arm double-blind clinical trial study was conducted on 50 female patients undergoing hemodialysis through AVF in Imam Reza Medical Center in Tabriz as an educational center in northwestern Iran from January 2020 to June 2021. The researcher had held reflexology theory and practice training sessions in the School of Rehabilitation and received a certificate of intervention competence.

The inclusion criteria were as follows: the age range of ≥ 18 years, absence of neuropathological problems, no skin diseases in the patient's legs, and a history of hemodialysis through the AVF for at least three months. On the other hand, the exclusion criteria entailed being a candidate for kidney transplantation, receiving painkillers 8-12 hours before hemodialysis, drug addiction, as well as the presence of any wounds, fractures, amputation, and deep vein thrombosis in the legs.

The participants were randomly assigned to two groups of intervention and control. The sample size was calculated based on the pain variable, using G*POWER software (version 3.1.2) and based on a study by Arab et al. (22). In this regard, the sample size was estimated at 60 subjects ($n=30$ in each group) considering $mean_1=5.54$ and assuming 20% reduction in pain following Reflexology, $mean_2=4.39$, $sd_1=sd_2=1.22$ and considering 90% power, $\alpha=0.05$, using the two-tailed test, and 20% possible drop out. However, 10 cases did not meet the inclusion criteria and

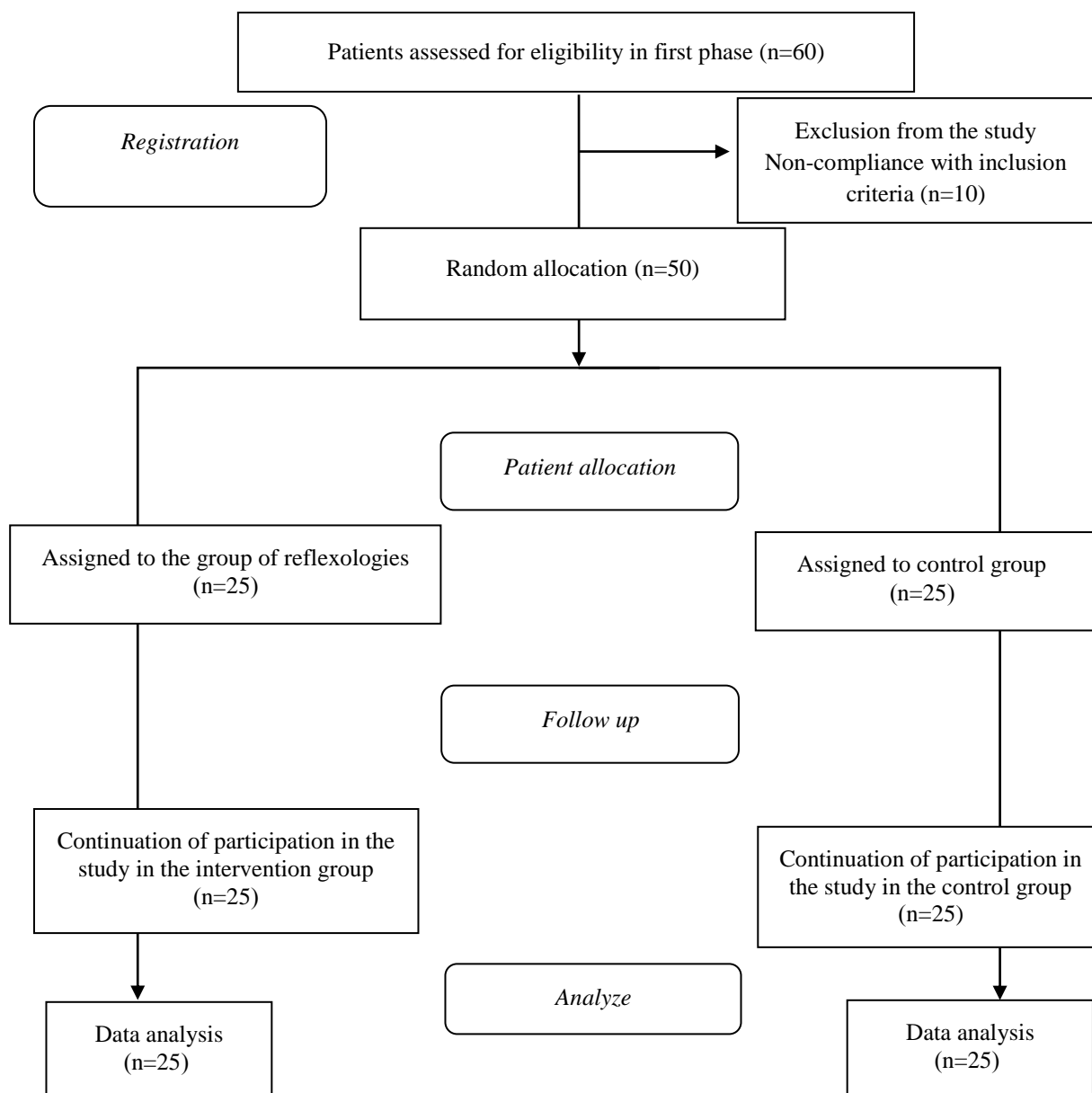


Figure 1. Clinical trial flowchart

were excluded (Figure 1).

Firstly, the participants were provided with the objectives of the study, the method of reflexology, and the routine care of the hemodialysis ward; thereafter, the eligibility criteria were investigated and eligible subjects signed a written consent form. Following that, the demographic characteristic form was filled out by the researcher and the needling pain was determined at baseline “during three hemodialysis sessions one week before the commencement of the intervention”.

Out of 60 patients who were initially assessed in this study, 50 cases were eligible for inclusion in the study and were randomly assigned to the reflexology and control (routine care) groups using RAS (Random Allocation Software) and random blocks with block sizes of 4 and 6 for in a 1: 1 ratio after baseline pain measurements. A random allocation sequence was generated by the person non-involved in the research. Allocation into the groups was concealed using sequence, uniform, opaque, and sealed envelopes which were numbered from one to the end. Envelope number one was given to the first patient included in the study, and this process continued until the end. Therefore, the researcher and the participants had no information about the type of intervention until the envelopes were opened. The assessment of study outcomes was performed by a clinician who was not involved in the

research. In this study, the statistical analyzer and outcome investigator were blind to the type of intervention.

Due to the condition of the Covid-19 pandemic, the researchers went to patients' beds after wearing personal protective equipment. Patients were evaluated over two periods. During the first period, three days a week, the intensity of pain was measured using the VAS when the needle was inserted into an arteriovenous fistula without any intervention for all patients. Thereafter, in the second period, the patients were randomly assigned to two groups: the first group received the intervention (reflexology), while the second group received the routine care of that ward.

In order to conduct reflexology, the patients lay on a hemodialysis special bed in a semi-sitting position with their head at a 30-degree angle to their body, and a small pillow was then put under their feet for their comfort. The room was well ventilated and quiet. Firstly, the participants learned how to use the study scale; subsequently, foot massage was started after the researcher washed his hands and cleaned the patient's feet according to their preference with water or a wet handkerchief. To prevent friction, Firoz baby oil which had been made in Iran and had no therapeutic properties was used.

The duration of reflexology in each session was 20 min (10 min for each foot), starting from the right foot and continuing with the left one. All parts of the right foot were massaged for 5 min; thereafter, the areas related to the kidney under the big toe and the solar plexus were massaged for 5 min. These steps were repeated for the left foot (10 min for the right foot and 10 min for the left one).

The patient's skin surface was cleaned with 70% alcohol-soaked cotton, and after 5 min, the alcohol was dried from the patient's skin, and a fistula needle was inserted by a nurse for each patient. In all cases, the needle entered the patient's fistula at an angle of 20-30 degrees and it was the same in terms of size (No. 16), shape, and company. The severity of patients' pain was recorded immediately after the insertion of the fistula needle based on patients' responses. In both intervention and control groups, data were measured and recorded with the help of an assistant who was not aware of the allocated intervention. After the massage, the researcher washed each patient's hands to dissipate negative energies in saltwater. In the control group, which received routine ward care, pain intensity was assessed similar to the reflexology group. To control study biases, the intervention was performed on even days and control on odd days.

The data collection tool consisted of two parts: the demographic characteristics from and the VAS questionnaire. This tool is a 10 cm ruler with the word painless written on the left end and the most severe pain on the right end, which should be marked with a dot only. The VAS was used for this purpose since the pain of needle insertion into AVF is considered acute pain which is one-dimensional. The VAS is a standard tool with good validity and reliability based on the study by Williamson and Hogarth (23). The validity and reliability of this tool have also been mentioned in nursing references (24, 25).

After data collection, their statistical analysis was performed in SPSS software (version 23). Firstly, the normality of data distribution was checked using the Kolmogorov-Smirnov test. Mann-Whitney test was used for the data which did not have a normal distribution. Independent t-test and chi-square test were used for analyzing data with normal distribution; moreover, repeated measures test was used to compare the effect of reflexology on pain intensity at different times adjusted for age and baseline pain scores. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 50 female patients aged 18 years and older participated in this study. The mean age scores of patients in the intervention and control groups were reported as 56.20 ± 10.13 and 61.56 ± 14.29 years, respectively. Moreover, 84% of patients in both groups were married and all were housewives. None of the patients had a history of smoking or drug abuse. Other personal social information is displayed in Table 1. The results indicated that there was no significant difference between the two groups in terms of demographic data (Table 1).

The mean score of pain intensity during fistula needle insertion in the first period in hemodialysis patients between the two groups is presented in Table 2. The results suggested that there were no statistically significant differences between the two groups, except for pain intensity in the first

Table 1. Distribution of Socio-demographic characteristics of hemodialysis patients in the two groups

Variables	Groups		P-value		
	Intervention (N=25) n (%)	Control (N=25) n (%)			
Duration of kidney failure	5.0 (10.5)	5.0 (7.0)	0.58*		
Duration of hemodialysis of the desired fistula	3.0 (3.0)	2.5 (2.20)	0.49*		
Level of Education	Illiterate	9 (36%)	15 (60%)	>0.418**	
	Literacy, reading and writing	8 (32%)	3 (12%)		
	High school	4 (16%)	3 (12%)		
	Diploma	2 (8%)	2 (8%)		
	Bachelor	2 (8%)	2 (8%)		
People with a history of disease	Diabetes	Yes	10 (40%)	15 (60%)	0.25***
		No	15 (60%)	10 (40%)	
	High blood fats	Yes	6 (24%)	9 (36%)	0.53***
		No	19 (76%)	16 (64%)	
	High blood pressure	Yes	18 (72%)	16 (64%)	0.76***
		No	7 (28%)	9 (36%)	
Kidney failure in first-degree relatives	Yes	1 (4%)	2 (8%)	>0.999***	
	No	24 (96%)	23 (92%)		
Place of residence	village	1 (4%)	3 (12%)	0.61 ***	
	City	24 (96%)	22 (88%)		

*Mann-Whitney

** Independent t-test

*** Fisher's exact test

Table 2. Mean score of pain intensity during fistula needle insertion before the intervention period in hemodialysis patients in the two groups

Variables	Groups		P-value
	Intervention (N=25) Standard deviation ± mean	Control (N=25) Standard deviation ± mean	
First session	5.75±2.70	4.00±2.12	0.015*
Second session	5.56±2.97	4.36±2.48	0.128*
Third session	5.40±3.07	4.28±2.76	0.181*

* Independent t-test

session (P=0.015). To determine the effect of reflexology intervention on pain intensity, the baseline scores in the first period and the age of the individuals during the statistical analysis were adjusted.

The mean score of pain intensity during fistula needle insertion in the second period among hemodialysis patients in the two study groups was examined in Table 3 and Figure 2. The results after data analysis indicated that reflexology had a statistically significant effect on the mean score of pain intensity during three sessions of reflexology over time (first session P=0.495, second session P=0.005, and third session P=0.015).

Table 3. Pairwise comparison of pain intensity during fistula needle insertion after intervention in hemodialysis patients in the two groups

Pain	Groups		Adjusted mean difference (confidence interval 95%)	P-value
	Intervention	Control		
First session	4.77± 2.00	4.39±2.10	-0.38 (-1.47 to 0.72)	0.495*
Second session	3.48±1.27	4.64±1.37	-1.59 (-0.51 to -2.67)	0.005*
Third session	3.84±1.26	4.64±1.44	-1.37 (-2.47 to -0.27)	0.015*

*Repeated measure ANOVA

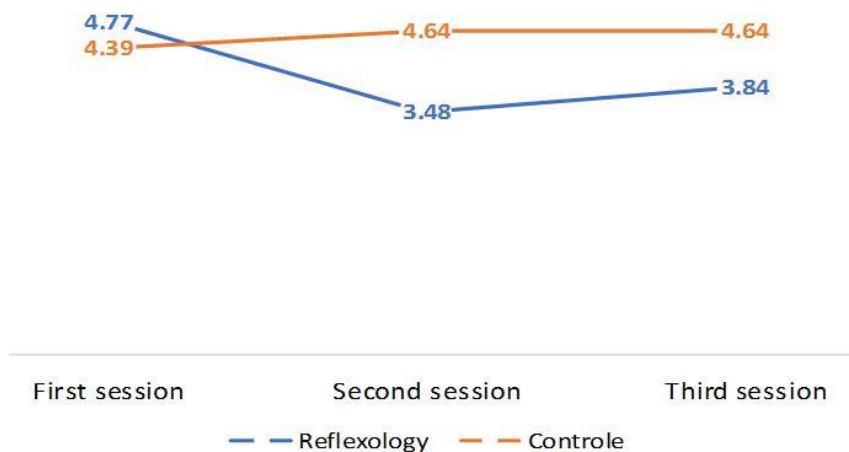


Figure 2. Mean score of pain intensity due to fistula needle insertion in the first to third sessions by study groups

Discussion

In recent years, non-pharmacological treatments, such as complementary medicine, have attracted the attention of all patients. Complementary medicine which has a comprehensive and accessible nature without any side effects can be used to increase the physical and mental comfort of patients. The present study aimed to evaluate the effect of foot reflexology on the intensity of pain associated with fistula needle insertion in hemodialysis patients. The results pointed to the significant effect of foot reflexology on pain intensity during fistula needle insertion during three reflexology sessions over time.

In agreement with the result of the present research, Sayari et al. (26) performed a study on 90 patients with acute myocardial infarction and concluded that the severity of myocardial infarction after 20 min of foot reflexology decreased significantly immediately after its completion. The literature review did not yield a study that examine the direct effect of reflexology on pain associated with fistula needle insertion in hemodialysis patients. Therefore, we compared and reviewed the present research with the most similar studies.

In the past, the results of most studies indicated the low or no effect of reflexology (27, 28); nonetheless, recent investigations have pointed to the marked effect of reflexology on the reduction of pain. For instance, in their study, Derrick et al. (29) introduced reflexology as a suitable solution to reduce neuromuscular pain in inpatients and outpatients. In a study carried out by Baluchi (30) entitled "Effect of acupressure of points SP6 and ST36 on pain caused by needle fistula in hemodialysis patients", the severity of needle pain in these patients was measured by VAS scale. The results showed a decrease in pain intensity in the acupressure group, as compared to that in the control group.

The results of the study by Korask et al. (31) demonstrated that foot massage reduced the severity of pain and anxiety in patients after laparoscopic cholecystectomy. Consistent with the results of the present study, in the stated research, foot massage over time had a more dramatic effect on the reduction of pain. Tian et al. (32) in their meta-analysis entitled "Effect of foot reflexology on pain and physiological indicators in postoperative patients" pointed to the effect of foot reflexology on the reduction of pain after surgery.

One of the strengths of this study was the great cooperation of patients and hemodialysis nurses. Numerous studies have been performed on the effect of reflexology on the reduction of pain, and it has been proved that reflexology can reduce acute pain. Therefore, the current study aimed to assess the effect of foot reflexology on pain of arteriovenous fistula (AVF) that had not been performed before. Among the notable limitations of this study, we can refer to participants' different perceptions of pain stimuli, and the impossibility of using a fixed nurse for all patients. Moreover, due to the gender restrictions of the sample and the mere inclusion of females, the results cannot be generalized to the whole community.

Implications for Practice

The results pointed to the effect of foot reflexology on the severity of pain at the site of fistula needle insertion in female patients undergoing hemodialysis. Based on the results of the present study, it is recommended to place foot reflexology for male hemodialysis patients before the needle is inserted into AVF since reflexology is non-invasive nursing care with an easy procedure, low cost, and effective in pain relief.

Acknowledgments

This study was extracted from an MSc thesis in Nursing. The study protocol was approved by the Ethics Committee of Tabriz University of Medical Sciences, Tabriz, Iran (IR.TBZMED.REC.1399.809), and it was then registered at the Iranian Registry of Clinical Trials (IRCT20200825048518N1). The study was sponsored by Tabriz University of Medical Sciences, Tabriz, Iran. The authors hereby sincerely appreciate all the contributions of the Research and Technology Deputy of Tabriz University of Medical Sciences, Tabriz, Iran. Their deepest appreciation goes to the staff of Imam Reza Medical Center Hemodialysis ward, Tabriz University of Medical Sciences, as well as the participants.

Conflicts of Interest

The authors declare that they have no conflict of interest regarding the publication of this study.

References

1. Dilek Efe Arslan PhD R, Nazan Kilic Akca PhD R. Pain following needle insertion into a hemodialysis fistula and influencing factors. *Int J Caring Sci.* 2018;11(3):1662-70.
2. Chronic Kidney Disease in the United States. US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019. Available from: <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>.
3. Thurlow JS, Joshi M, Yan G, Norris KC, Agodoa LY, Yuan CM, et al. Global epidemiology of end-stage kidney disease and disparities in kidney replacement therapy. *Am J Nephrol.* 2021;52(2):98-107.
4. Imani A, Karimi V, Moradi F, Pezeshki A. Effect of cooled hemodialysis fluid on the quality of life of hemodialysis patients. *JSSU.* 2018;26(9):750-758.
5. Himmelfarb J, Vanholder R, Mehrotra R, Tonelli M. The current and future landscape of dialysis. *Nat Rev Nephrol.* 2020;16(10):573-585.
6. Kumbar L. Complications of arteriovenous fistulae: beyond venous stenosis. *Adv Chronic Kidney Dis.* 2012;19(3):195-201.
7. Allon M, Robbin ML, Umphrey HR, Young CJ, Deierhoi MH, Goodman J, et al. Preoperative arterial microcalcification and clinical outcomes of arteriovenous fistulas for hemodialysis. *Am J Kidney Dis.* 2015;66(1):84-90.
8. Allon M. Vascular access for hemodialysis patients: New data should guide decision making. *Clin J Am Soc Nephrol.* 2019;14(6):954-961.
9. Figueiredo AE, Viegas A, Monteiro M, Poli-de-Figueiredo CE. Research into pain perception with arteriovenous fistula (avf) cannulation. *J Ren Care.* 2008;34(4):169-72.
10. Harris D, Davies S, Finkelstein F, Jha V, Donner J, Abraham G, et al. Working Groups of the International Society of Nephrology's 2nd Global Kidney Health Summit: Increasing access to integrated ESKD care as part of universal health coverage. *Kidney Int.* 2019;95(4S):S1-S33.
11. Shabandokht-Zarmi H, Bagheri-Nesami M, Shorofi SA, Mousavinasab SN. The effect of self-selected soothing music on fistula puncture-related pain in hemodialysis patients. *Complement Ther Clin Pract.* 2017;29:53-7.
12. Zyga S, Alikari V, Sachlas A, Stathoulis J, Aroni A, Theofilou P, et al. Management of pain and quality of life in patients with chronic kidney disease undergoing hemodialysis. *Pain Manag Nurs.* 2015;16(5):712-20.
13. Jafari-Koulaee A, Moosazadeh M, Bagheri Nesami M, Goudarzian AH. Effect of cryotherapy on arteriovenous fistula puncture-related pain in hemodialysis patients: A systematic review and meta-analysis. *Complement Ther Med.* 2020;49:102326.

14. American Nurses Association (ANA). ANA Position Statement: The ethical responsibility to manage pain and the suffering it causes; 2019.
15. Aghajano A, Ghafourifard M, Haririan H, Shiri Gheydari P. Comparison of the effects of cryotherapy and placebo on reducing the pain of arteriovenous fistula cannulation among hemodialysis patients: A randomized control trial. *S J Nursing*. 2016;3(1):59-65.
16. Gunnarsdottir TJ, Jonsdottir H. Does the experimental design capture the effects of complementary therapy? A study using reflexology for patients undergoing coronary artery bypass graft surgery. *J Clin Nurs*. 2007;16(4):777-85.
17. Bastani F, Rouhi Rahim Begloo E, Haghani H. Effectiveness of foot reflexology on maternal post C-section fatigue: a non-randomized clinical trial. *Evid Based Care J*. 2015;5(3):51-62.
18. Gholamzadeh H, Ilkhani M, Ameri A, Shakeri N. Effect of reflexology on the side effects of chemotherapy in cancer patients: an integrative review. *Evid Based Care J*. 2019;8(4):7-13
19. Rahmani Z, Rejeh N, Heravi-Karimooi M, Tadrissi SD, Vaismoradi M. Effect of hand reflexology on anxiety and physiological variables among patients hospitalized in the cardiac care unit: A randomized placebo controlled clinical trial. *J Nurs Educ Pract*. 2018;8(4):35-42.
20. Tiran D, Mackereth PA. *Clinical reflexology e-book: a guide for integrated practice*: Elsevier Health Sciences. 2010.
21. Radi ZA. Kidney pathophysiology, toxicology, and drug-induced Injury in drug development. *Int J Toxicol*. 2019;38(3):215-27.
22. Arab V, Bagheri-Nesami M, Mousavinasab SN, Espahbodi F, Pouresmail Z. Comparison of the effects of hegu point ice massage and 2% lidocaine gel on arteriovenous fistula puncture-related pain in hemodialysis patients: a randomized controlled trial. *J Caring Sci*. 2017;6(2):141-151.
23. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs*. 2005;14(7):798-804.
24. Taylor C. *Potter & Perry's fundamentals of nursing*: Elsevier Australia; 2008.
25. Hinkle JL, Cheever KH. *Brunner and Suddarth's textbook of medical-surgical nursing*: Wolters kluwer india Pvt Ltd; 2018.
26. Sayari S, Nobahar M, Ghorbani R. Effect of foot reflexology on chest pain and anxiety in patients with acute myocardial infarction: A double blind randomized clinical trial. *Complement Ther Clin Pract*. 2021;42:101296.
27. Ernst E, Posadzki P, Lee M. Reflexology: an update of a systematic review of randomised clinical trials. *Maturitas*. 2011;68(2):116-20.
28. Lee J, Han M, Chung Y, Kim J, Choi J. Effects of foot reflexology on fatigue, sleep and pain: a systematic review and meta-analysis. *J Korean Acad Nurs*. 2011;41(6):821-33.
29. Artioli DP, Tavares ALdF, Bertolini GRF. Foot reflexology in painful conditions: systematic review. *BrJP*. 2021;4(2).
30. Baloochi Beydokhti T, Ghadimifar A, Soleimani Moghaddam R. A comparative study on the effects of acupressure at sp6 and st36 acupoints on the pain caused by fistula needle placement in hemodialysis patients. *J Complement Med Res*. 2021;10(4):354-67.
31. Koraş K, Karabulut N. The effect of foot massage on postoperative pain and anxiety levels in laparoscopic cholecystectomy surgery: a randomized controlled experimental study. *J Perianesth Nurs*. 2019;34(3):551-558.
32. Tian L, Li M, Yan L. Effect of foot reflexology on pain and physiological indicators in postoperative patients: A systematic review and meta-analysis. *TMR Integ Nur*. 2021;5(1):8-20.