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Clinical Trial

See the commentary by Mahmoudnia (J Parathyr Dis. 2021; 9:e11185)

The effects of effleurage massage and diluted vinegar on pruritus of hemodialysis patients; a randomized double-blind clinical trial study

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Abstract

Introduction: Massage therapy, due to its lower side effects and cost compared to drug treatment, can be a good alternative method for pruritus treatment of patients with hemodialysis.

Objectives: This study aimed to evaluate the effects of effleurage massage and diluted vinegar on the skin pruritus and dryness of hemodialysis patients.

Patients and Methods: In a clinical trial study, 52 hemodialysis patients were randomly divided into two groups' intervention and control. In the control group, routine and standard cares were considered. In the intervention group, in addition to routine and standard care, effleurage massage and diluted vinegar were conducted for patients. Pruritus and skin dryness scales were filled out by all patients at times before the intervention and end of sessions 3, 6, and 12. Data were collected and analyzed by SPSS version 22.

Results: Results showed that the severity of skin dryness between the two control and intervention groups at the end of hemodialysis sessions 3 and 6 was not significant, however, at the end of sessions 9 and 12, this difference became significant therefore, in the intervention group the severity of dryness significantly reduced, and skin pruritus scale between the two control and intervention groups at the end of hemodialysis session 3 was not significant; however, at the end of sessions 6, 9, and 12, this difference became significant, thereby in the intervention group the skin pruritus score significantly reduced.

Conclusion: Using effleurage massage in long-term use can reduce the skin pruritus and dryness of hemodialysis patients.

Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20160209026483N2; https:// fa.irct.ir/trial/28096, ethical code; IR.HUMS.REC.1396.021).

Keywords: Effleurage massage, Vinegar, Pruritus, Dryness, Hemodialysis, Secondary hyperparathyroidism, Parathormone

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Introduction

End-stage renal disease (ESRD) is a big global health problem, and hemodialysis is one of the most common renal replacement treatments for these patients (1,2). Hemodialysis patients usually struggle with skin and mucosal lesions such as pruritus, hyperpigmentation, calcification, skin dryness, and impaired homeostasis (3). Among these symptoms, pruritus, with a prevalence of 37% to 90% in ESRD and 80% in hemodialysis patients, is the most prevalent and bothersome symptom (1). The most common cause of pruritus in these patients is uremia, which is caused by various mechanisms, including secondary hyperparathyroidism (4), which is one of the most serious hemodialysis morbidities (5). Pruritus can directly affect people's quality of life by causing countless problems, including physical (6), mental, moral disorders, and even sexual problems, so it is necessary to control and treat such complications well (7, 8).

The most common pruritus treatment for hemodialysis patients is drug treatment, which is costly and has many side effects, and renal dysfunction can increase the risk of these side effects (9). Hence, complementary therapies with lower side effects have been alternative methods to reduce the patients' costs and side effects (10). Massage

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Implication for health policy/practice/research/ medical education

In a randomized, double-blind clinical trial study on 52 patients, we found that effleurage massage and diluted vinegar effectively reduce the skin pruritus and dryness of hemodialysis patients in long-term use.

therapy is a comprehensive type of complementary and alternative treatment in hemodialysis patients that is easy, safe, non-invasive, and relatively inexpensive to perform (11). Massage has various forms, including Swedish, reflexology, shiatsu (12), and effleurage massage (13). Effleurage massage is a type of Swedish massage performed in the form of manual massage of surface tissues with a brief pressure of two palms on the skin surface. Effleurage has a relaxing effect; however its main effect is lymphatic and vascular return, which reduces the pain, anxiety, and pruritus of patients (13).

Objectives

Pruritus is one of the most critical problems in hemodialysis patients, and massage therapy is a safe and non-invasive technique which can improve it. Considering the high incidence of skin pruritus and dryness in hemodialysis patients, this study aimed to evaluate the effects of effleurage massage and diluted vinegar on the skin pruritus and dryness of these patients.

Patients and Methods Study design

This study was a randomized, double-blind clinical trial study conducted on 52 patients with hemodialysis referred to the teaching hospital of Hormozgan University of Medical Sciences in Bandar Abbas during June and July 2017. At the beginning of the study, 60 hemodialysis patients were selected by convenience sampling method and randomly divided into control (30 patients) and intervention (30 patients) groups. Informed consent was obtained from all patients. Biochemical and hematology laboratory tests were checked, and demographic questionnaires, and skin pruritus and dryness scales were filled out by all patients. Routine and standard care of the hemodialysis department was conducted in the control group. In the intervention group, in addition to routine care, effleurage massage was performed, and diluted vinegar was rubbed on the pruritus areas. After the first intervention session and explanation of the study's purposes to the patients, five patients from the intervention group and three from the control group were excluded due to unwillingness to continue participating in the study. Finally, 25 people in the intervention group and 27 in the control group were subjected to the final analysis (Figure 1).

Inclusion and exclusion criteria

Inclusion criteria included having informed consent, being under hemodialysis for at least three months





and three times per week, age >18 years old, having a pruritus score >3, and having at least two times before the intervention. Exclusion criteria included using antipruritus drugs during the study, sensitivity to vinegar solution, unwillingness to continue the participation, serum phosphor >6 mg/dL, parathyroid hormone (PTH) > 600 pg/dL, and undergoing a kidney transplant.

Intervention protocol

In addition to the routine and standard care of the hemodialysis department, patients in the intervention group received effleurage massage and 3% diluted vinegar at the end of each hemodialysis session. In each session, at the end of hemodialysis, effleurage massage was performed on the back areas, including three areas (vertical back rub, horizontal back rub, and pulling thumbs on the spine), 15 times in each area and about 6 minutes. Additionally, massage was conducted in the front and back areas of the legs for 4 minutes (2 minutes for each leg) and for 20 times for each leg in each session after dialysis. The lubricating gel was used for a better effect of the massage and the smoothness of the massage area. The sponge was impregnated with diluted vinegar 3%, and the massage areas were applied to each area twice. Pruritus and skin dryness scales were refilled out by all patients at the end of sessions 3, 6, and 12. Data were collected and analyzed by SPSS version 22.

Data collection tools

Data collection method in this study was observation and interview. Data collection tools included blood tests to measure biochemical and hematology parameters, a demographic questionnaire, a skin pruritus scale, a visual

analog scale for skin pruritus severity, and a skin dryness scale. The skin pruritus scale was used to measure skin pruritus, which measures pruritus severity, frequency, and location. The pruritus severity score was between 0 to 4, frequency 0 to 3, and location 1 and 2, and in total, it was between 0 and 9, which a score of 9 being the most pruritus severity, 3 being the least, and less than 3 was no pruritus. The skin dryness scale was so that a score of 3 was the most severe dryness (whole body), a score of 2 was moderate (hands and legs), a score of 1 was mild (only legs), and 0 was no dryness.

Statistical analysis

Data were analyzed using the SPSS software (version 22). Ouantitative variables were conducted to describe the data center means, and standard deviations were conducted to describe the data distribution. Frequency and percentage were used to describe the data. A Kolmogorov-Smirnov test was used to evaluate the data normality. The chisquare test, independent t test, and Fisher's exact test were conducted to analyze the data. A P value less than 0.05 were considered significant.

Results

Results showed that most patients in both groups were male, had no previous history and treatment of pruritus, and married, with a mean age of 61.5 ± 11.9 years in the intervention group and 61.8 ± 13.4 years in the control. The most common location of pruritus was the leg and back. The mean hemodialysis time in the intervention group was 3.4 ± 0.5 hours and in the control group was 3.5 ± 4 hours. Results showed that the difference between the two groups was not significant in terms of age, gender,

Table 1. Demographic characteristics and characteristics related to dialysis of patients in both control and intervention groups

Variable	Intervention	Control	<i>P</i> value
Gender, No. (%)			
Male	13 (52)	14 (51.9)	0.001*
Female	12 (48)	13 (48.1)	0.991
Marital status, No. (%)			
Single	6 (24)	4 (14.8)	0.212*
Married	19 (76)	23 (85.2)	0.312
History of treatment, No. (%)			
Yes	9 (36)	13 (48.1)	0.271*
No	16 (64)	14 (51.9)	0.371
Pruritus location, No. (%)			
Legs	6 (24)	11 (4.7)	
Legs and back	12 (48)	10 (37)	0 (42***
Back, chest, abdomen	1 (4)	1 (3.7)	0.643
Whole body	6 (24)	5 (18.5)	
Age (y), Mean \pm SD	61.5 ± 11.9	61.8 ± 13.4	0.942**
Weight (kg), Mean ± SD			
Before	60 ± 11.4	62.2 ± 13.2	0.540**
After	58.8 ± 11.2	61 ± 13.2	0.508**
History of pruritus (months), Mean \pm SD	10.2 ± 8.6	9.8 ± 12.5	0.317**
Dialysis adequacy, Mean ± SD	1.4 ± 0.3	1.4 ± 0.3	0.621**
Dialysis time, Mean ± SD	3.4 ± 0.5	3.4 ± .05	0.832**
*Chi square: **Independent + test: *** Eisher's eva	t tost		

.hi-square; **Independent t test; Fisher's exact test

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marital status, previous history and treatment of pruritus, pruritus area, dialysis time and adequacy, and weight before and after hemodialysis (Table 1).

Results demonstrated that there was no significant difference between the two groups of control and intervention in terms of all biochemical and hematological parameters before the intervention (Table 2).

Results showed that the severity of skin dryness between the two control and intervention groups before the beginning of the intervention was not significant, and the two groups were similar (P > 0.05). At the end of hemodialysis sessions 3 and 6, the difference also was not significant (P > 0.05); however, at the end of sessions 9 and 12, this difference became significant (P < 0.05), therefore in the intervention group, the severity of skin dryness significantly reduced (Table 3).

Results showed that the skin pruritus score between the two control and intervention groups before the beginning of the intervention until the end of hemodialysis session 3 was insignificant, and the two groups were similar (P>0.05). However, at the end of sessions 6, 9, and 12, this difference became significant (P<0.05), hence in the intervention group, the skin pruritus score significantly reduced (Table 4).

Discussion

Pruritus is one of the most common skin symptoms in hemodialysis patients (14), treated mainly by drug treatment, which is costly and has many side effects (9). Massage therapy is one of the most common and safe complementary and alternative treatments worldwide (15). Effleurage massage is very relaxing, simple, and light, and as a result, it is easy to tolerate for all patients (16). This study aimed to evaluate the effects of effleurage massage and diluted vinegar on the skin pruritus and dryness of hemodialysis patients. Our study results showed that the severity of skin dryness between the two control and intervention groups at the end of hemodialysis sessions 3 and 6 was insignificant. However, at the end of sessions 9 and 12, this difference became significant so that in the intervention group, the severity of dryness significantly reduced. Also, results demonstrated that the skin pruritus score between the two control and intervention groups at the end of hemodialysis session 3 was insignificant, and the two groups were similar; However, at the end of sessions 6, 9, and 12, this difference became significant, so that in the intervention group, the skin pruritus score significantly reduced. All of these results demonstrate that massage therapy effectively reduced the skin pruritus and dryness in hemodialysis patients. In line with our

Table 2. Comparison of the biochemical and hematological parameters between two control and intervention groups before the intervention

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Parameter	Intervention Mean ± SD	Control Mean ± SD	<i>P</i> value*
Phosphor (P) (mg/dL)	5 ± 0.8	5.09 ± 0.6	0.530
Calcium (Ca) (mg/dL)	8.7 ± 0.1	8.8 ± 1	0.617
Parathormone (PTH) (pg/dL)	315 ± 172.6	288.9 ± 157.6	0.573
Alkaline phosphatase (IU/ml)	479.6 ± 412.6	382.6 ± 275.8	0.329
Ca in P (mg/dL)	43.1 ± 7.9	44.9 ± 7.8	0.419
Urea (mg/dL)	115.7 ± 37.7	121.5 ± 39.4	0.578
Blood urea nitrogen (mg/dL)	56.5 ± 21.5	65.3 ± 21.7	0.152
Creatinine (mg/dL)	6.8 ± 2.02	7.8 ± 2.4	0.114
Ferritin (ng/dL)	471.9 ± 586	449.8 ± 702.8	0.902
Hemoglobin (g/dL)	9.5 ±1.8	10.3 ± 2.1	0.150
Hematocrit (%)	30 ± 5.3	33.1 ± 6.6	0.771

* Independent t test.

Table 3. Comparison of skin dryness score between two control and intervention groups in times before and at the end of sessions 3, 6, and 12 after the beginning of the intervention

	Intervention			Control					
Time _	No. (%)				No. (%)				
	No	Mild	Moderate	Severe	No	Mild	Moderate	Severe	
Before	1 (4)	6 (24)	11 (44)	7 (28)	1 (3.7)	3 (11.1)	21 (77.8)	2 (7.4)	0.077
Session 3	2 (5)	4 (16)	13 (52)	6 (24)	1 (3.7)	3 (11.1)	20 (74.1)	3 (11.1)	0.409
Session 6	1 (4)	12 (48)	12 (48)	0 (0)	1 (3.7)	12 (44.4)	11 (40.7)	3 (11.1)	0.396
Session 9	4 (16)	18 (72)	3 (12)	0 (0)	1 (3.7)	10 (37)	14 (51.9)	2 (7.4)	0.004
Session 12	19 (76)	5 (5)	1 (4)	0 (0)	12 (45)	5 (18.5)	19 (70.4)	2 (7.4)	0.001

* Fisher's exact test.

Table 4. Comparison of skin pruritus score between two control andintervention groups in the times before and at the end of sessions 3, 6, and 12after the beginning of the study

Time	Intervention Mean ± SD	Control Mean ± SD	P value
Before	6.8 ± 0.5	5.7 ± 1.2	0.125
Session 3	5.8 ± 1.5	5.5 ± 1.1	0.390
Session 6	4.3 ± 1.5	5.2 ± 1.3	0.028
Session 9	3.08 ± 1.6	5.2 ± 1.2	0.001
Session 12	1.8 ± 1.2	5.2 ± 1.1	0.001

study, Tsay showed that massage therapy has a positive effect on relieving fatigue in end-stage renal patients (17), Khorsand et al reported that massage therapy is an effective complementary treatment method for relieving pruritus of hemodialysis patients with uremic pruritus (18). Narita et al said that massage therapy effectively affects in uremic pruritus in chronic kidney disease (CKD) patients (4). Shahriari et al stated that pruritus in patients with hemodialysis could be relieved by massage (14). According to our knowledge, no study has been found that approved the lack of effect of massage on skin pruritus and dryness in hemodialysis patients.

Today, massage is considered a therapeutic principle and is used by millions of people to relieve pain and stress and, generally to feel better. One of the most useful roles of massage is anti-itching, hives, burns, and inflammatory conditions (19).

Conclusion

The results showed that the effect of effleurage massage on the severity of skin pruritus and dryness of hemodialysis patients was low initially, but with the increase in massage duration, this effect increased. We concluded using effleurage massage in long-term use could reduce the skin pruritus and dryness of hemodialysis patients.

Limitations of the study

The non-cooperation of the patients to conduct the intervention was one of the limitations of the present study, which tried to solve this problem by giving incentives and planning according to their requested program. Individual, social, psychological, and family differences were uncontrollable variables of the present study that can affect the research results.

Authors' contribution

Conceptualization: FA and SA; Methodology: HY; Validation: HM and MA; Formal Analysis: HY; Investigation: MY and SD; Resources: EZ, MA, and FA; Data Curation: HY and MY; Writing— Original Draft Preparation: HM, SD and MA; Writing — Review and Editing: SA, EZ and MY; Visualization: SD; Supervision: EZ; Project Administration: FA.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical issues

The research was conducted in accordance with the tenets of the Declaration of Helsinki. This study was extracted from the MSc nursing thesis and approved by the ethics committee of Hormozgan University of Medical Sciences, Bandar Abbas, Iran (Ethical code: IR.HUMS.REC.1396.021). The study protocol was also registered as a clinical trial at the Iranian Registry of Clinical Trials (identifier: IRCT20160209026483N2; https://fa.irct.ir/trial/28096). Ethical issues (including plagiarism, data fabrication, and double publication) have been completely observed by the authors.

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