Original Research

Effects of glycerin oil and lavender oil massages on hemodialysis patients' restless legs syndrome

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ABSTRACT

Objectives: To determine the effects of glycerin oil and lavender oil massages on hemodialysis patients' restless legs syndrome (RLS).
Methods: Ninety hemodialysis patients with RLS were randomly allocated into two intervention groups and one control group, each consisting of 35 participants. The control group received routine care, and the intervention groups received effleurage massage with lavender and glycerin oil in addition to routine care for one month. RLS intensity was measured among the three groups using the Restless Legs Syndrome Rating Scale.
Results: At the beginning of the study, the results showed no significant difference among the three groups' scores. At the end of the study, the mean RLS scores were significantly lower in the intervention groups compared to the control group ($F = 63.4$, $p \leq 0.001$). This difference was not significant between the two intervention groups; nonetheless, the differences between the control and lavender oil groups, as well as the control and glycerin oil groups, were significant ($p < 0.05$).
Conclusion: The findings showed the effectiveness of the oils through the effleurage massage for reducing RLS in a sample of hemodialysis patients.

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1. Introduction

The global prevalence of chronic renal failure (CRF) is significantly elevated. Reports indicate a 10% worldwide rate for this disease (Chen et al., 2019). CRF patients often experience a variety of health challenges that require adherence to several therapeutic and medical interventions, including medication and hemodialysis (HD) (Rahimimoghadam et al., 2017). In CRF patients, HD is a frequent and effective intervention; however, this treatment may lead to multiple adverse complications, such as pain in the fistula, sleep disturbances, psychological disturbances, and restless legs syndrome (RLS) (Rahimimoghadam et al., 2019; Garcia-Borreguero, 2012; Einollahi and Izadianmehr, 2014; Novak et al., 2015).

RLS or Willis-Ekbom disease is a neurologic syndrome that manifests with sensorimotor symptoms, including atypical unpleasant sensations, such as paresthesia and uncontrolled movements in the lower extremities (Garcia-Borreguero, 2012). The symptoms mostly appear or deteriorate at the time of rest or inactivity, and inversely, may completely or partially subside through activity (Allen et al., 2003; Einollahi and Izadianmehr, 2014). Since dialysis sessions often take about four hours, RLS may be exacerbated during dialysis; therefore, this syndrome is one of frequent adverse effects of HD (Fonseca et al., 2016), and its prevalence is reported to reach 60% in HD patients (Giannaki et al., 2014; Tilma et al., 2014; Novak et al., 2015). Other undesirable effects of RLS include sleep disturbances, daytime fatigue, impaired ability to perform activities, social isolation, anxiety, depression, decreased quality of life, and poor general health (Garcia-Borreguero, 2012; Mortazavi et al., 2013; Novak et al., 2015).

The undesirable effects of chronic diseases and their treatments necessitate the development of innovative and unconventional medical interventions to help patients cope with their conditions

(Rahemi et al., 2017; Rahimimoghadam et al., 2017; Eshgh et al., 2011). In this regard, complementary and alternative medicine has been increasingly recommended for management of chronic diseases (Torabian et al., 2013; Abedi et al., 2018). The use of complementary and alternative medicine has also been encouraged to manage the adverse outcomes of HD, such as RLS (Mortazavi et al., 2013). To reduce the complications and discomfort, standard and pharmacological treatments have been frequently used. However, one study has reported that these treatments were effective in managing the syndrome in only 13% of patients (Innes and Selfe, 2012). Nonetheless, non-traditional and complementary/alternative therapies have been increasingly shown to be useful for management of the syndrome and to have fewer unpleasant side-effects (Gnatta et al., 2016). These therapies are recommended because of their convenience, safety, cost-effectiveness, and minimal adverse effects (Muzzarelli et al., 2006). Massage therapy and aromatherapy are among the most frequent non-traditional therapies for management of several complications associated with diseases or treatments (Gnatta et al., 2016).

Plant and/or aromatic oils, such as lavender, have been used via massage or inhalation in different studies (Vakilian et al., 2011). Researchers reported the effectiveness of lavender and lavender essence administered via several routes for recovery from a repertoire of symptoms. Lavender and lavender essence had analgesic effects on labor pain and pain in general as well as sedative and anti-depressant effects (Barzegar et al., 2016). They were also effective in healing wounds, such as burn wounds; healing from insect bites; and improving anti-bacterial, anti-fungal, and anti-flatulent mechanisms (Bagheri-Nesami et al., 2016). Additionally, lavender was shown to improve immune system functions and relieve muscle aches and skin problems, such as itching.

In HD patients, Ghods et al. (2015) showed that moderate pain associated with insertion of dialysis needles may be reduced by topical application of lavender. Another research team showed that lavender aromatherapy reduced the pain of needle insertion into a fistula (Nasiri et al., 2016). However, several research teams reported no significant effect on patients with different health conditions, such as insomnia, IUD insertion pain, anxiety, depression, and pain of breast biopsies (Kim et al., 2011a; Chen et al., 2016; Miccio and Cowen, 2018). Most of these researchers used lavender for their interventions; however, the use of glycerin was rare in these studies. Based on our literature review, only Chen and colleagues reported the use of glycerin in their study and found that massage with glycerin oil was not effective for reducing pain in cancer patients (Miccio and Cowen, 2018). There were no reported negative effects in terms of the application of lavender and glycerin oil in previous studies.

The review of relevant literature provided contradictory results regarding the effectiveness of lavender (Lewith et al., 2005; Kuriyama et al., 2005). The authors did not find any studies about the effects of glycerin oil. To our knowledge, no study compared the effects of glycerin and lavender oil massage on HD patients' restless legs syndrome (RLS). In Iran, using lavender and glycerin oil is a routine practice for moisturizing, smoothing, and healing the skin. We selected an innovative approach based on the values and needs of individual patients and their available resources to address RLS among HD patients (Rahemi et al., 2018). This study aimed to examine and compare the efficacy of glycerin and lavender oil massages on HD patients' RLS severity using three study groups: one control and two intervention groups.

2. Methods

2.1. Design, setting, and participants

A double-blind randomized clinical trial was performed on 90 patients with CRF undergoing HD in two centers: The Hemodialysis Center of Akhavan Hospital in Kashan and the Hemodialysis Center of Kamkar Hospital in Qom, Iran, from March 2014 to January 2016. The investigators contacted the centers' directors to request collaboration in recruiting the participants. Using Pocock's sample size formula (Pocock, 1983), the sample size in each group was estimated based on the following assumptions: $\beta = 0.20$, $\alpha = 0.05$, $S1 = 10$, $S_2 = 10$, $\mu1 - \mu2 = 7$. Taking these assumptions into account, the sample size was estimated to be 90. A total number of 15 participants, five participants in each group (about 15% of the total estimated sample size), was added to this number for handling possible attrition of participants over time, and the sample size of 105 was estimated.

All participants were receiving routine hemodialysis (HD) by Fresenius machines using semi-synthetic (cellulose diacetate) or synthetic (polysulfone) dialysis membranes and bicarbonate buffered dialysate, in morning or afternoon shifts, three or four times a week for at least six months. The blood flow rate was 250–400 mL/min, and the dialysate flow rate was 500 mL/min. Inclusion criteria for the study included ages between 18 and 65 years; the ability to write and read in Persian; having a medical diagnosis of CRF; being a habitual sportsperson; able to walk without support; no history of allergy, active wound below the knees, substance addiction, additional physiological or physical disorders, such as muscular dystrophies, or known psychiatric or cognitive disorders. Exclusion criteria included having a history of Deep Vein Thrombosis (DVT); receiving painkillers in the three hours prior to intervention; being a habitual consumer of caffeine, alcohol, tobacco; being uncooperative; hemoglobin less than 10 g/dL; and incidence or report of any allergic reactions. To rule out the patients with a massage contraindication, a physician assessed the patients who met the inclusion criteria. Patients with possible contraindications, such as DVT, were excluded. All the participants were assessed for DVT using a Doppler ultrasound.

Over the course of the study, a total of 323 patients with chronic renal failure undergoing HD were assessed. 146 patients did not meet the inclusion criteria; 35 patients declined to participate; and, 37 patients were excluded due to other reasons, such as exacerbation of the disease's complications, and a risk of DVT, such as pain or edema in the calves. Initially, a sample of 105 patients were randomly assigned into three groups, including two intervention groups—glycerin ($n = 35$) and lavender ($n = 35$) oil—and a control group ($n = 35$), using the block randomization method. During the intervention, out of 35 patients assigned to the glycerin oil group, 31 patients completed the study, and three patients were excluded due to onset of other illnesses, including myocardial infarction, hypertension crises, and appendectomy, and one patient was excluded because of traveling. In the lavender oil group, 29 patients completed the study, and 6 patients were excluded due to myocardial infarction, cerebrovascular accident, hypertensive crises, accident, and diagnosis of depression. In the control group, 5 patients were excluded due to death, cerebrovascular accident, and a decision to withdraw from the study. A total of 90 participants completed the study.

2.2. Procedures

Based on the inclusion and exclusion criteria, the third and fourth authors evaluated all the patients admitted in the HD wards and then randomly assigned the participants into three groups. Identical HD routine care was delivered for the three groups. Patients in the control group received no additional treatment. In the lavender and glycerin oil intervention groups, a simple effleurage massage using lavender and glycerin oil, respectively, was performed on both legs. The intervention protocol was performed based on Ray's protocol (Sadeghi Aval Shahr et al., 2015) one hour

after the beginning of dialysis sessions (Rahimimoghadam et al., 2017). A certified trained male nurse performed the interventions for male participants, and a certified trained female nurse completed the interventions for female participants. Massage sessions lasted 45 minutes. Each patient received the intervention for a month, three times a week.

The massage therapy included effleurage massage, which is a technique of massage using long, light, or firm strokes. Effleurage massage can be useful to promote circulatory and immune systems, skin and muscle tone, and relaxation (Zubareva et al., 2011; Sadeghi Aval Shahr et al., 2015). First, the effleurage massage was performed on each leg. Thumb movements from the plantar surface of the toes toward the heel were performed. Secondly, using the palm of the hands and thumbs, deep pressure was applied to the back of the calves from the ankle up to the knee and back down to the foot. The massage was performed using 10−15 mL of lavender oil 1.5% (1.5% concentration made from lavender blossoms, 2% linalool, 2% linalil Acetate, 35% authorized vegetable oils, and 59.5% water) or glycerin oil 2% (2% glycerin, 2% iodine, 2% potassium iodide, 40% authorized vegetable oil, and 54% water). This concentration was determined based on related studies (Ju et al., 2013; Bagheri-Nesami et al., 2016) and a consultation with an herbal medicine specialist. These products were prepared by the Barij Essence Pharmaceutical Company. Using the Restless Legs Syndrome Rating Scale, the RLS severity was measured in the three groups at the beginning of the study and one week after the end of the interventions.

2.3. Instruments

The measures included a demographic questionnaire and the Restless Legs Syndrome Rating Scale. The demographic questionnaire, including questions about age, gender, education, marital status, and occupational status, was completed by the participants. The Restless Legs Syndrome Rating Scale is a self-rating scale. The measure was originally developed in English to measure the severity of RLS. Psychometric properties of the scale were verified by Walters et al. (2003). The scale consists of 10 questions, and total scores range from 0 to 40. A higher score indicates a greater severity of RLS. Validity and reliability of the Persian version of the Scale were verified by Habibzade et al. (2011), and its Cronbach's alpha coefficient was reported to be 0.97.

2.4. Statistical analysis

Data analysis was performed using the SPSS software (version 14). Mean scores and standard deviations were calculated. The Chi-square, ANOVA, and LSD post hoc tests were used to compare the three groups. The paired *t*-test was used to compare the RLS scores in each group at the beginning and end of the study. The level of significance was set at .05.

2.5. Ethical considerations

Written informed consent forms were completed by the participants. Participation in the research was voluntary. Numbers were used regarding identification on surveys to maintain the confidentiality of data. The study was approved by the Ethics Committee of Kashan University of Medical Sciences.

3. Results

The results showed that 18 (39.1%) participants in the lavender oil group, 15 (32.6%) in the glycerin oil group, and 13 (28.3%) in the control group were females. The mean age was 57.5 ± 14.6 years in the lavender oil group, 56.4 ± 12.4 years in the glycerin oil group, and 56.10 ± 13.56 years in the control group. No significant difference was observed among the three groups in terms of sociodemographic variables (see Table 1).

The three groups' mean RLS scores were not significantly different at the beginning of the study ($F = 0.645$, $p = 0.52$). However, at the end of the study, the mean RLS scores were significantly lower in the intervention groups compared to the control group ($F = 63.4$, $p < 0.001$) (Table 2). Based on the LSD post hoc test, no significant difference was observed between the two intervention groups at the end of the study ($p = 0.21$). At the end of the study, the difference between the control and lavender oil groups ($p = 0.02$) as well as the control and glycerin oil groups ($p = 0.01$) were significant (see Table 2).

Based on the ANOVA test, the mean differences of the RLS scores (the differences between the mean scores of each group at the beginning and the end of the study) were significantly different among the three groups ($F = 67.5$, $p < 0.001$) (see Table 3). The LSD post hoc test showed that there was also no difference between the two intervention groups' mean difference scores. However, the difference between the control group and the two intervention groups was significant.

4. Discussion

Our results showed the effectiveness of massages with lavender

Table 2
Restless legs syndrome scores in intervention and control groups before and after the study.

RLS	Before Intervention	After Intervention	t	p
	Mean ± SD	Mean ± SD		
Lavender oil	24.09 ± 5.34	9.54 ± 4.64	13.22	0.0001
Glycerin oil	22.41 ± 7.67	12.41 ± 5.49	9.31	0.0001
Control	22.90 ± 4.38	23.91 ± 4.28	0.85	0.40
ANOVA	$F = 0.645$ $p = 0.52$	$F = 63.4$ $p = 0.0001$	−	−

Table 1
Comparisons of sociodemographic characteristics.

Variables		Glycerin oil	Lavender oil	Control	
Age (years)[*]		56.4 ± 12.4	57.5 ± 14.6	56.10 ± 13.56	$F = 0.519$ $p = 0.597$
Number of Hemodialysis/Week		3.56 ± 0.20	3.78 ± 0.25	3.82 ± 0.32	$F = 0.951$ $p = 0.391$
Gender	Female	15 (32.6%)	18 (39.1%)	13 (28.3%)	Chi-square = 2.21 $p = 0.33$
	Male	16 (36.4%)	11 (25)	17 (38.6%)	
Education	Elementary	22 (29.3%)	26 (36%)	26 (34.7%)	Chi-square = 5.64 $p = 0.059$
	Higher	9 (60%)	3 (13.3%)	4 (26.7%)	
Marital Status	Single	10 (32%)	9 (31%)	14(47%)	Chi-square = 1.947 $p = 0.378$
	Married	21 (68%)	20 (69%)	16 (53%)	
Occupational Status	Unemployed	19 (37.3%)	13 (25.5%)	19 (27.3%)	Chi-square = 2.46 $p = 0.29$
	Employed	12 (30.8%)	16 (41%)	11 (28.2%)	

Note. Differences between the groups were tested using ANOVA for continuous variables and chi-square for categorical variables.

Table 3
Comparison of the mean differences of restless legs syndrome scores among three groups at the beginning and end of the study.

Variable	Lavender oil Mean (SD)	Glycerin oil Mean (SD)	Control Mean (SD)	ANOVA
Restless Legs Syndrome Scores	14.55 ± 0.7	10 ± 2.18	1.01 ± 0.1	$F = 67.5$ $p = 0.0001$

and glycerin oil in reducing the severity of RLS in a sample of hemodialysis (HD) patients. The results showed no significant difference between the lavender and glycerin oil groups in terms of reducing severity of RLS; however, the differences between the control group and the lavender and glycerin oil intervention groups, were significant.

Russell et al. (2011) reported the effectiveness of lower extremity massage in a 35-year-old female with restless legs syndrome. Their results showed that RLS symptoms, including tingling sensations, involuntary leg movements, and sleeplessness, decreased over the course of intervention and three weeks after the intervention (Habibzade, 2011). Several studies have reported the effectiveness of massage on reducing RLS symptoms and severity (Novak et al., 2015; Bagheri-Nesami et al., 2016). Lewith et al. (2005) assessed the effects of inhaled lavender on mild insomnia and found no significant difference between the intervention and control groups. Kuriyama et al. (2005) also reported that aromatherapy and massage with lavender oil was not effective in reducing patients' anxiety. In addition, researchers did not find significant effects of lavender and glycerin aromatherapy on reducing pain in patients with breast biopsies and cancer surgery (Wilcock et al., 2004; Chen et al., 2016) and improving mood, quality of life, physical symptoms (Walters et al., 2003; Lewith et al., 2005; Zubareva et al., 2011; Ju et al., 2013; Kitson, 2018; Wilcock et al., 2004; Kim et al., 2011a,b; Russell, 2011) and quality of sleep among CCU and cancer patients (Kim et al., 2011a,b). However, our findings indicated that massages with lavender and glycerin oil was effective in reducing severity of RLS among a sample of HD patients.

Nonetheless, several research teams have addressed the effectiveness of lavender oil and essence in managing pain, wound healing, and infection as well as anxiety and depression in patients with different health conditions (Lee and Lee, 2006; Altaei, 2012; Ghods et al., 2015). In a study on patients with primary dysmenorrhea, Ou et al. (2012) reported the effectiveness of lower abdomen massage with lavender oil in reducing the intensity of pain compared to synthetic products. Another research team reported that topical application of lavender oil can be effective in reducing moderate pain associated with dialysis needle insertion (Ghods et al., 2015).

Lee and Lee (2006) indicated that lavender aromatherapy improved female college students' quality of sleep and reduced their depressive symptoms. In our study, it was shown that massage therapy in combination with applying lavender or glycerin can be effective in reducing the symptoms of RLS in HD patients. We found no significant difference between the effects of lavender and glycerin oil. Since we could not find research related to the effects of glycerin oil on RLS, further research is needed to investigate the effects of glycerin oil on RLS severity. It is worth noting that as a less aromatic product, glycerin oil may be desirable and tolerable in some chronic patients. Therefore, research on glycerin for massage therapy in chronic patients is important. However, the massage itself has its own advantages, and patients in general may benefit from the psychological, physical, and physiological effects of the massage, including relief of stress and pain (Zubareva et al., 2011; Sadeghi Aval Shahr et al., 2015). This issue is an important one to consider in future studies.

4.1. Limitations and recommendations

First, since we used a massage in addition to applying the lavender and glycerin oil, our findings may be influenced by the advantages of the massage in terms of reducing the participants' RLS severity. In future studies, assessing the effects of a massage with lavender or glycerin oil compared to a massage without oil could be beneficial for distinguishing the effectiveness of each intervention. Second, the effects of the lavender essential oil might be due to its fragrance inhaled by the participants, which we could not control. Lastly, we could not control some factors, such as major stress and medications, which may influence the severity of RLS. However, the randomized method of the study may reduce the effects of these factors. We also recommend studies on RLS in patients who have no other major pathologies to compare results and provide more accurate interpretation of findings.

5. Conclusions

With the increasing number of patients with chronic diseases, it is essential to introduce innovative strategies for disease management. In the current study, we found positive effects of massages with lavender and glycerin oil in reducing the participants' RLS severity. Based on our findings and considering the limitations of the current study, the authors recommend further research to confirm the results.

Clinical relevance

The undue outcomes of chronic diseases and their traditional treatments necessitate innovative medical interventions to help patients cope with their conditions. Healthcare professionals can use unconventional and alternative therapies, including massage with lavender and glycerin oil, for management of RLS syndrome.

Conflicts of interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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