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The effects of vibration and massage on severity of symptoms of restless leg syndrome and sleep quality in hemodialysis patients; a randomized cross-over clinical trial

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ABSTRACT

Introduction: Restless leg syndrome (RLS) is a common sensory disturbance in hemodialysis patients causing mental disorders, sleep disturbances, and other problems.**Objectives:** This study compared the effects of massage and vibration on sleep quality and severity of symptoms of RLS in hemodialysis patients.**Patients and Methods:** This cross-over clinical trial was conducted on 80 hemodialysis patients with RLS who were assigned into two groups randomly. The first group received massage and the second group received vibration. Each group received the related intervention for one month three times per week each session lasting 10 minutes. One month after the first intervention, the interventions were changed in a cross-over design between the two groups. The severity of symptoms of RLS and sleep quality were assessed before and after interventions using the related questionnaire.**Results:** The means of severity of symptoms of RLS and sleep quality showed a significant improvement after both interventions of vibration and massage ($P < 0.001$). Additionally, a significant difference was observed in the means of severity of RLS and sleep quality after interventions between two groups hence vibration exerted a greater effect on improving the symptoms of RLS and sleep quality in patients compared to massage ($P = 0.001$).**Conclusion:** Our findings suggested that both vibration and massage reduce the mean of severity of RLS and improve sleep quality in hemodialysis patients, with vibration exerting a greater effect compared to massage.

Implication for health policy/practice/research/medical education:

In a study on 80 hemodialysis patients, we found vibration and massage therapy significantly reduced the mean intensity of restless leg syndrome symptoms and improved sleep quality in hemodialysis patients.

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Introduction

The end-stage of renal failure involves the irreversible and progressive reduction of kidney function which requires alternative treatment for kidney function (1). Currently, the most common treatment modality for pronounced renal failure around the world is hemodialysis (2). Although

hemodialysis has caused longer survival of hundreds of patients among thousands of end-stage renal disease (ESRD) patients, they are exposed to various problems and complications (3). Among them, nervous system complications, burning sensation in the body, restless leg syndrome (RLS), feet prolapse (podiatric ptosis), and even

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panplesia are examples for hemodialysis complications (4). RLS is one of the common complications among ESRD patients (5). It is a neurologic sensory-motor impairment (6) which is described as an unpleasant feeling in the feet occurring as a result of inclination for moving the lower extremities and relieves with movement (1). In the case of aggravation of symptoms, this condition can involve the arms and other parts of the body (7). These symptoms are usually manifested at night or at rest leading to sleep disturbances (1). On the basis of international standards of RLS, the diagnostic criteria of this syndrome are as follows: 1) Sensory symptoms in the feet leading to frequent uncontrollable movements in the feet, 2) Onset or deterioration of symptoms at rest, 3) Improvement or relief of symptoms at rest, and 4) Aggravation of symptoms in the evening or at night. Patients describe these unpleasant feelings as stinging, crawling of an organism on the skin, itching of the lower extremities, flow of water in the feet, feeling of presence of insects in the bone, or current flow in the feet (8). Almost 20%-80% of hemodialysis patients experience this syndrome while its prevalence in the public community is 2%-15%. In the study by Wong et al, 70% of the hemodialysis patients suffered from RLS (9). This syndrome can induce problems like insomnia, daily drowsiness, bad quality of life, and depression (7). It is one of the most important factors in creating sleep disorders in renal failure patients under hemodialysis which, according to present literature, affects 62% of these patients (10). The treatment of this syndrome includes both pharmaceutical and non-pharmaceutical therapies. Treatment depends on the severity and frequency of the symptoms. Mild forms of this syndrome may be managed by changing the life style and the severe forms may be treated by pharmaceutical therapy (11). Considering the numerous medicines used for treatment and the unexpected complications of these drugs in the patients, the provision of non-pharmaceutical treatment methods for these patients seems mandatory. The non-pharmaceutical factors recommended including changing the life style such as avoiding intake of caffeine or alcohol before going to bed, music therapy methods, palpation therapy (acupressure), cryotherapy, the application of heat, acupuncture, induction of relaxation in the patient (psychological suggestion), hypnosis, massage therapy, progressive muscular relaxation, and yoga are effective in controlling the severity of this syndrome (12). Some studies have demonstrated that vibration can increase flexibility along with increased maximal muscular power (13). Another potential effect of vibration is its ability to change histologic perfusion and modulation of vascular network (matrix) resulting in increased blood circulation in the body (14). Vibration increases vascular dilatation, enhances superficial and deep blood flow, and increases muscular temperature leading ultimately to decreased tissue viscosity and increased muscular elasticity. On the other hand, reduced pain after application of vibration

can predispose to increased ROM (range of motion) and facilitate flexibility through increasing pain threshold (15). Mitchell and Johnson showed in their study the effect of vibration on increasing the blood stream in RLS (16). Additionally, Doyle et al stated that whole body vibration before hemodialysis is acceptable and safe and is associated with improved physical function (17). Massage therapy is another non-pharmaceutical treatment for RLS. It increases plasma serotonin level which probably inhibits the transmission of harmful signals to the brain. Massage causes comfortable sleep leading to reduced pain sensation since somatostatin is normally released during deep sleep without which pain is felt. Hence, when individuals are deprived of deep sleep, somatostatin may be released to a lesser amount (18). Moreover, massage increases peripheral blood circulation, increased mechanical movement of fluids in the veins, lymphatic vessels, and blood vessels (19). Another study investigated the effect of massage of lower and upper back and feet on fatigue and sleep quality in hemodialysis patients. A biweekly one-month massage program resulted in diminished fatigue and improved sleep quality in the patients (20). Although pharmaceutical therapies are common for treating RLS, considering the concerns with the complications associated with drug therapy, the researchers are seeking complementary treatments which are cost-effective with little complications.

Objectives

Massage therapy and vibration are two complementary therapeutic methods many useful effects of which have been proved. However, no study has yet compared the effects of massage therapy and vibration on the severity of RLS and sleep quality. Therefore, this study aimed at comparing the efficacy of massage therapy and vibration in relieving the intensity of RLS symptoms and improving sleep quality in hemodialysis patients.

Patients and Methods

Study population

This was a randomized cross-over clinical trial conducted on 80 hemodialysis patients who were selected with purposive sampling method from among the hemodialysis patients presenting to three hospitals in Meibod, Ardakan, and Yazd in Iran and assigned randomly into two groups. Four samples were excluded from the study due to lack of their cooperation, so, the study was carried out on 76 patients. The inclusion criteria were; passage of at least three months after hemodialysis, presence of RLS (a score of 11+), absence of consciousness impairment, enjoying proper neurological, skeletal, and vascular status, and absence of any malignancy, ulcer, and dermal erythematosis. In addition, the exclusion criteria were; intake of analgesics, drug abuse, taking of psychiatric and neurologic medicines, lack of inclination for participation, and the use of vibration and massage at

home. The research goals, procedures, and stages were explained completely to the participants while informed written consent was obtained from each patient. The data were collected by one of the researchers by interviews using RLS International Questionnaire and Pittsburgh Sleep Quality Index. First, the patients were selected with RLS International Questionnaire. This inventory included ten 5-point items ranging between 0 and 4 points with the total score of the tool ranging between 0 and 40. The severity of the disorder was divided into five classes on the basis of the obtained scores including without problem=0, mild problem=1-10, severe problem=21-30, and very severe problem=31-40. The individuals who scored 11+ entered the study. The content validity of the questionnaire was verified scientifically and its reliability was established by Molahosseini et al as 95% (21). The patients were randomly assigned into two groups of 40 (vibration group and massage group). First, the researcher completed the demographic information questionnaire including age, gender, occupation, education level, history of dialysis, pain relief methods, and analgesics intake and also completed the Pittsburgh Sleep Quality Index that measured sleep quality during one month regardless of the patient's opinion. This questionnaire includes seven categories including the patient's general description of sleep quality, latency in going to sleep, duration of useful sleep, the proportion of useful sleep time to the total time spent in the bed, sleep disorder, awakening due to dyspnea or apnea, nocturnal cough, limbs pain, extreme cold, extreme heat, the use of narcotic drugs for going to sleep, drowsiness, and lack of interest for doing ADL (activity of daily living) due to impaired sleep. Each scale of the tool receives a score between 0 and 3. A total score of 5 or more indicates low sleep quality and a score less than 5 demonstrates high quality of sleep. Farrahi et al obtained sensitivity of 100%, specificity of 93%, and Cronbach's α of 89% for the Persian version of this questionnaire (22). In group A, the patients underwent massage therapy for one month at the time of dialysis. Massaging was performed by a trained person three times per week each session lasting 10 minutes using hacking massage in both feet. This method uses sequential rapid hacking massage without pauses with the side of the hands using two modalities.

The first modality

Longitudinal; both hands move together along the length of the muscle.

The second modality

Convergent-divergent method; both hands are placed on the superior and inferior surfaces of the muscle converging to each other with hacking massage and then diverge. In group B, the patients underwent vibration therapy for one month on both feet three sessions per week each session lasting 10 minutes at the time of hemodialysis, and vibration was conducted at low voltage (Thrive Model

717A). The severity of RLS symptoms and sleep quality were measured in both groups after a 4-week intervention. After a 4-week wash out interval (with no intervention), the message group underwent vibration therapy for one month three sessions per week in a cross-over design. In addition, the vibration group underwent massage therapy for one month three sessions per week in a cross-over design. Again, the severity of RLS symptoms and sleep quality were measured in both groups before and after interventions.

Ethical issues

This research was performed based on the Declaration of Helsinki principles. Informed written consent was obtained from each patient. All information about individuals was coded and kept confidential. This study was approved by the Committee of Ethics in Human Research at Rafsanjan University of Medical Sciences with code Ir.rums.rec.1394.193 dated 20/2/2015 and registered in Iranian Registry of Clinical Trials (IRCT) (identifier: IRCT2016022826814N1; <http://www.irct.ir/trial/22121>).

Statistical analysis

All data were analyzed using SPSS 18. Results are expressed as mean \pm SD or percentage. Data were analyzed using statistical tests including the *t* test, to compare massage and vibration variables. Also findings before and after intervention in each group were analyzed using paired samples *t* test. Additionally, *P* values of less than 0.05 were considered statistically significant.

Results

Our findings indicated that the mean age of the samples was 61.41 years, 57.5% of the patients were male, most of the participants (48.8%) were illiterate, and most of them (43.8%) were unemployed. The results demonstrated that most patients were at the moderate (68.8%) and severe (31.3%) levels of severity of RLS symptoms before intervention, while, they were at the mild (16.3%) and moderate (78.8%) levels of severity of RLS symptoms after vibration therapy. Furthermore, they were at the moderate (93.8%) and severe (1.3%) levels of severity of RLS symptoms after massage therapy (Table 1).

Our findings also suggested that both intervention modalities exerted an effect on RLS with the mean of RLS score decreasing after both vibration and massage therapy

Table 1. Frequency distribution of severity of RLS before and after interventions.

RLS	Before intervention	After vibration	After massage
	No. (%)	No. (%)	No. (%)
Mild	0 (0)	13 (16.3)	0 (0)
Moderate	55 (68.8)	63 (78.8)	75 (93.8)
Severe	25 (31.3)	0 (0)	1 (1.3)
Total	80 (100)	76 (100)	76 (100)

($P=0.001$). Moreover, a comparison of the two methods revealed that vibration therapy was more effective on RLS symptoms than massage therapy indicating a statistically significant difference ($P=0.001$; Table 2).

Additionally, the study on the effects of massage therapy and vibration on sleep quality indicated that the mean score of sleep quality decreased after vibration and massage therapy indicating improved quality of sleep since the results of paired t test indicated a significant difference in sleep quality before and after interventions ($P=0.001$). Furthermore, in comparing two methods of massage therapy and vibration, the results of t -test suggested a significant difference in sleep quality between the two groups after interventions ($P=0.001$) (Table 3).

Discussion

Our findings indicated that the mean score of RLS symptoms decreased after vibration therapy in the study population (12.82 versus 18.99). Yoosefinejad et al showed that vibration affects the muscular power and balance in type II diabetic patients with neuropathy (23). Moreover, Junggi reported reduced pain and improved balance and gait coordination in type 2 diabetic patients with peripheral neuropathy after an 8-week vibration therapy program (24). Additionally, a review study by del Pozo-Cruz et al reported the positive effect of WBV (whole-body vibration) on gait, balance, proprioception, strength, and health-related life quality of patients with neurological conditions (25). Moreover, the study by Boucher et al investigated the short-term effects of five 1-minute sessions of vibration on the neuromuscular body response in patients with chronic back pain and in healthy individuals. The results suggested increased lumbar EMG (electromyography) activity after WBV (26). The findings of the study above showed a reduced RLS mean score after massage. Russell postulated that massage therapy is effective in decreasing the severity of symptoms of RLS with the reduction being greater in the warmer foot. The study recommended exercises and massaging with heat to treat RLS (27). Hashemi et al declared that a three-week massage program with lavender oil is effective in diminishing the symptoms of RLS in hemodialysis

patients (6). Kumar et al also announced the efficacy of massage therapy in reducing back pain (28). Furlan et al showed that massage therapy significantly diminishes pain intensity and disability compared to acupuncture (29). A study by Hayes and Cox on the effect of five minutes of podiatric massaging in ICU patients, concluded that podiatric massaging potentially increases relaxation during a short-term intervention in ICU patients and recommended it as a proper intervention for decreasing stress (30). Nonetheless, some review studies like that of Lewis et al on the impact of massage therapy on musculo-skeletal pain or (31), the review study by Ernst on the impact of massage therapy on pain reduction (32), and the study by Haraldsson et al on performance pain in patients with neck ache (33) did not approve the efficacy of massage in reducing musculo-skeletal pain, though they do not completely reject its efficacy by stating that on sufficient reasons for the use of massage therapy in decreasing musculo-skeletal pain was existed. The study by Metin and Ozdemir, aiming to investigate the comparative effect of massage aromatherapy and reflexology on pain and fatigue in patients with rheumatoid arthritis in three groups (the massage group=17 patients, knee massage for 30 minutes; plantar reflexology group=17 patients, podiatric massage for 40 minutes; and control group=17 individuals with no intervention) for 6 weeks. They concluded that both interventions can positively affect pain and fatigue in patients with rheumatoid arthritis. Of course, the reflexology intervention reduced pain and fatigue more significantly compared to aromatherapy (34). Lundeberg et al demonstrated that vibration with moderate speed is effective in decreasing acute or chronic musculo-skeletal pain (35).

Most studies on the effect of vibration and massage therapy approve the findings of the present study in effect that vibration and massage improve the symptoms of RLS. Our results revealed that vibration improved sleep quality in patients. The study by Burbank on the effect of vibration on the value of sleep in RLS patients found that RLS-related sleep disturbance significantly decreased after one month of vibration therapy (36). These findings are consistent with our results, while vibration therapy exerts a positive

Table 2. Comparison of severity of RLS symptoms before and after massage therapy and vibration therapy

	Before intervention	After intervention	Differences in means	P value (Paired t test)
	Mean±SD	Mean±SD		
Massage	18.99±3.292	15.50±2.436	3.49	0.0001
Vibration	18.99±3.292	12.82±2.726	6.17	0.001

Table 3. Comparison of sleep quality before and after massage therapy and vibration therapy

	Sleep quality before intervention	Sleep quality after intervention	Differences in means	P value (Paired t test)
	Mean±SD	Mean±SD		
Massage	10.16±3.96	9.22±3.48	0.94	0.001
Vibration	10.16±3.966	8.43±3.19	1.73	0.001

effect on improving the RLS symptoms. The results of another study revealed that massage therapy improved sleep quality. Furthermore, the study by Malekshahi et al demonstrated the efficacy of massaging on improving sleep and life quality of ESRD patients recommending this method as a non-invasive treatment for patients with sleep disorders (37). Moreover, the study by Unal and Akpin, exploring the effect of back massage and plantar reflexology on fatigue and sleep quality in hemodialysis patients indicated that these methods improved sleep quality and fatigue in hemodialysis patients, with plantar reflexology being more effective than lower back and upper back massage (20). Since the acquisition of these methods is rather simple and their performance is possible and cheap for almost all patients, they can be recommended as non-pharmaceutical methods to be used in reducing this syndrome which is common among hemodialysis patients. Therefore, the patients can readily master these procedures and perform them at home to enjoy the positive effects of vibration and massage therapy through increasing blood supply to muscles and reducing tension and anxiety to diminish the severity of RLS symptoms and improve their sleep quality to gain better efficiency. Patients may also be educated in performing these methods under supervision to reduce the annoying symptoms of this syndrome during hemodialysis. This will be a major step in decreasing the complications by the treatment team.

Conclusion

Our results suggested that vibration and massage therapy significantly reduced the mean intensity of RLS symptoms and improved sleep quality in hemodialysis patients.

Limitations of the study

One of the limitations of this study was the researcher's inability to blind the study as it was out of control. It is recommended that future studies be focused on comparing the effects of other methods of complementary medicine on sleep quality and severity of RLS symptoms in hemodialysis patients.

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Authors' contribution

SA participated in research design, the writing of the paper, and the performance of the research. HH and MK contributed to the study design, preparation of the manuscript and final revision. AF acted as the consultant of study. All authors read and approved the paper.

Conflicts of interest

The authors declare no conflict of interest.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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