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ORIGINAL RESEARCH PAIN MANAGEMENT

Effectiveness of localized vibration therapy on restless legs syndrome severity and sleep quality in hemodialysis patients: a randomized controlled trial

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ABSTRACT

Background & objective: Restless legs syndrome (RLS) is a common sensory and motor issue in patients on regular hemodialysis that contributes to sleep disturbances and impairs quality of life. This study aimed to find out whether vibration therapy improves RLS and related sleep quality in patients receiving hemodialysis.

Methodology: This clinical randomized controlled trial included 70 patients undergoing hemodialysis equally distributed into a study (interventional) group (receiving vibration therapy) and a control group (receiving routine care only) using a block randomization technique. Arabic version of the Restless Legs Syndrome Rating Scale was used to assess the RLS severity, and the Brief Pittsburgh Sleep Quality Index was used to assessed the sleep quality. These scales were used over three period of measurements (pretest, posttest one and posttest two).

Results: the study results demonstrate that the vibration therapy had a consistent and significant effect in reducing the RLS severity ($P < 0.001$) as well as enhancing sleep quality ($P < 0.001$) within the study group over time. While the control group did not present significant improvement across all three measures.

Conclusion: The study results demonstrates that vibration therapy was effective in significantly reducing the severity of RLS and improving sleep quality among the study group participants, while the control group showed no meaningful change over time.

Keywords: Hemodialysis, End Stage Renal Disease, Sleep quality, Restless legs syndrome

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1. INTRODUCTION

Restless Legs Syndrome (RLS), also referred to as Willis-Ekbom disease, is a persistent neurological issue described as an uncontrollable desire to move the legs, usually go along with unpleasant sensations such as tingling, burning, pain, numbness, or itching in the lower limbs.[1,2] The symptoms manifest during the rest periods, alleviated by physical activity, and exacerbate in the evening hours and while sleeping.[3,4] RLS is more common in adult patients with chronic kidney disease compared to the general population.[5] The rate of RLS prevalence in the general population is reported to be range from 4% to 14%, based on the diagnostic criteria and the demographic characteristics of the studied population.[6-8] However, in patients receiving regular

hemodialysis for end-stage renal disease (ESRD), the prevalence is markedly higher, with some studies reporting rates as high as 6.6% to 70%.[9,10] Several studies classified RLS into primary (idiopathic) including genetic predisposition or secondary in origin including iron dysregulation in the central nervous system, dopaminergic dysfunction, and a various chronic medical conditions, such as ESRD, iron deficiency anemia, and Parkinson's disease,[11-17] While another studies have indicated that classifying RLS into two types, primary and secondary, is no longer useful as a result of a more accurate and comprehensive understanding of the disease: RLS is now known as a multifactorial disorder characterized by the interaction of genetic, environmental, socio-economic factors, co-morbidities, as well as critical factors including uremia, iron deficiency, chronic inflammation, and imbalances in calcium and phosphorus metabolism that participate in the clinical presentation.[18-24] Dialysis-associated restless legs syndrome is attributed to a number of physical and psychological problems, including insomnia, daytime sleepiness, shorter sleep duration, exhaustion, concern, and depression, which have a negative influence on patients' quality of life and disease prognosis, and even increase the risk of cardiovascular disease and mortality.[5,17,25,26] These pathophysiological abnormalities result in pronounced nocturnal discomfort and limb movement that interrupts the continuity and quality of sleep [27]. Polysomnographic studies detect that individuals with RLS typically experience longer sleep latency, reduced REM sleep, reduced sleep efficiency, as well as increased sleep fragmentation[28]. Among hemodialysis patients, the impact of RLS is even more pronounced, often exacerbating existing sleep disturbances caused by pooling of uremic toxins and systemic inflammation, along with consequent changes in biochemical parameters, such as altered melatonin secretion[29]. Concerning to management of RLS, both non-pharmacological and pharmaceutical treatments are used as RLS management techniques [30]. Pharmacological management is typically the first option for treating RLS, especially in the general population. Dopaminergic agonists such as pramipexole and ropinirole, as well as gabapentin, opioids, and iron supplementation, have shown efficacy in mitigating symptoms.[31] However, the use of these agents to treat RLS in hemodialysis patients poses unique challenges. The risk of side effects may increase with increasing dosage, and rest RLS symptoms are common even when active therapies are used.[32,33] A growing body of research has suggested substantial negative effects related with dopaminergic treatments. Most crucially, a high number of RLS individuals treated with dopaminergic medications (direct agonists such as ropinirole) suffer augmentation syndrome (a paradoxical worsening of RLS symptoms with long-term dopaminergic therapy).[2,25,34] Non-pharmacological strategies are therefore considered alternatives to medications [30,35]. Modalities such as such as, massage, exercise, aromatherapy, reflexology, cryotherapy, and cold dialysis, they have been reported to reduce the RLS symptoms in patients receiving hemodialysis [2,36,37]. Some studies suggest that vibration therapy may alleviate RLS and have a positive effect in improving its symptoms [38]. However, the evidence base for these interventions in RLS individuals remains insufficient , and the lack of standardized protocols makes it challenging for clinicians to confidently recommend them [30,39,40]. In addition, these non-pharmacological approaches are offered in randomized studies that lack well-determined control groups, leading to a loss of clarity in the objective analysis of the study results [37,41]. Conducting a study fills this gap by providing empirical data to support or refute the potential benefits of this intervention. This contributes to the evidence base in nephrology and rehabilitation medicine. So the current study aims to find out whether vibration therapy relieves the intensity of RLS symptoms among patients undergoing hemodialysis. Exploring how vibration therapy affects symptoms like RLS can provide insights into the underlying mechanisms of these conditions in hemodialysis patients. As well as the positive findings from the study could potentially influence clinical practice guidelines for managing RLS and sleep disturbances in hemodialysis settings. Healthcare providers may consider integrating vibration therapy into multidisciplinary treatment plans to enhance symptom management and improve patient outcomes.

2. METHODOLOGY

This a clinical randomized controlled trial included 70 patients with RLS and related sleep disturbances, who are undergoing hemodialysis at the hemodialysis unit in the Specialized Center for Kidney Diseases and Transplant at Al-Sadr Medical City.

All patients during hemodialysis were assessed for eligibility which include; patients passing at least three months after first their hemodialysis, with age group above 20 years, presented with RLS according to International Restless Legs Syndrome Study Group (IRLSSG). Patients willing to participate, read and write, and who were alert and able to communicate verbally were recruited.

Emergency hemodialysis patients, using analgesics, using vibration therapy and massage techniques at home, and individuals with a history of peripheral vascular disease, deep vein thrombosis, peripheral neuropathy, dermatitis, skin ulcers, wounds, or lower extremity edema. Before implementing the intervention,

this study was approved by the International Review Board at the College of Nursing, University of Baghdad.

Table 1: Comparative severity of Restless Legs Syndrome over three measurement periods

Period of Measurement	Levels	Study Group	Control Group
Pretest	Moderate	20 (57.1)	18 (51.4)
	Severe	15 (42.9)	17 (48.6)
Posttest1	Mild	3 (8.6)	0 (0.0)
	Moderate	21 (60.0)	18 (51.4)
	Severe	11 (31.4)	17 (48.6)
Posttest2	Mild	20 (57.1)	0 (0.0)
	Moderate	15 (42.9)	19 (54.3)
	Severe	0 (0.0)	16 (45.7)

Data presented as n (%)

The study was registered in Clinical Trials Registry (ClinicalTrials.gov) under the ID NCT06889324. Each participant was asked for their informed consent after ensuring they understood the purpose, procedures, and their rights in the study. After that, the researcher used a block randomization to equally distribute participants into the study (receiving vibration therapy) and control groups (receiving only routine care). The randomization sequence and block arrangements were automatically generated in Microsoft Excel 2010 using the RAND function. This method ensured balanced group distribution and maintained allocation concealment throughout the participant recruitment process.

At baseline, self-reported sociodemographic characteristics, clinical characteristics, the severity of RLS and sleep quality were evaluated as pre-test for both groups. Severity of RLS was evaluated using the Arabic version of the RLS Rating Scale. It is 10-item scale; the maximum total score for the patient's answers is (40); higher scores point to more severe symptoms. The RLS severity is scored as no RLS (0), mild (1-10), moderate (11-20) severe (21-30), very severe (31-40). The sleep quality of the patients was evaluated using the Brief Pittsburgh Sleep Quality Index (B-PSQI), which consists of six items categorized and scored across five components: sleep quality, sleep efficiency, night awakenings, hours of sleep, and sleep latency. A total score less than 5, resulting from the sum of the five components, indicates good sleep quality, while values above 5 indicate poor sleep quality. Then on the first day, the vibration therapy was administered by localized vibration device (Thrive vibrator device model 717) with low voltage, one for each legs, applied on the calf muscle in the study group. The investigator used vibration therapy on the individuals for 10 minutes twice a week.

Two weeks after the intervention, the first post-test was assessed, and four weeks later, the second post-test was assessed. RLS and sleep quality also will be assessed as a post-test one at the end of second week, and post-test two after four weeks for the control group who receiving only routine care.

2.1. Statistical Analysis

IBM Statistical Package for Social Science (SPSS) Ver. 19, and the Microsoft Excel (2021) used to analyzing the study data. Frequencies, and Percentages used as a descriptive statistical data analysis. As well as, non-parametric tests were used because the normal distribution was not achieved. The Mann-Whitney (U) test used to determine whether there was a statistical significant difference between the study group and the control group regarding the severity of RLS and quality of sleep over three measurement periods.

3. RESULTS

Table 1 shows the severity of RLS among the participants of the study and control groups over three measurement periods: pre-test, first post-test, and second post-test. At pre-test, the study group's RLS severity

Table 2: Statistical differences in the severity of restless legs syndrome across three measurement periods

Period of Measurement	Mean Rank		Mann-Whitney Test	P-value
	Study Group	Control Group		
Pretest	36.14	34.86	590.00	0.791 NS
Posttest 1	27.64	43.36	337.50	0.001 HS
Posttest 2	21.91	49.09	137.00	0.000 HS

p. value= Probability value, NS= No Significant, Freq.= frequency, %= Percent, HS= High Significant

Table 3: Level of sleep quality in the study and control group individuals over three period of measurement

Period of Measurement	Levels	Study Group	Control Group
Pretest	Good	4 (11.4)	3 (8.6)
	Poor	31 (88.6)	32 (91)
Posttest 1	Good	5 (14)	3 (8.6)
	Poor	30 (85.7)	32 (91.4)
Posttest 2	Good	20 (57.1)	3 (8.6)
	Poor	15 (42.9)	32 (91.4)

Data presented as n (%)

Table 4: Statistical differences in the levels of Pittsburgh Sleep Quality Index between two groups through period of measurement

Period of Measurement	Mean Rank		Mann-Whitney test	P-value
	Study Group	Control Group		
Pretest	37.06	33.94	558.00	0.524 NS
Posttest 1	36.19	34.81	588.50	0.780 NS
Posttest 2	25.67	45.33	268.50	0.000 HS

P. value= Probability value, NS= No Significant, HS= High Significant

ranged from moderate (57.1%) to severe (42.9%). The control group showed a similar distribution, with (51.4%) of participants experiencing moderate RLS and (48.6%) experiencing severe RLS. At post-test 1, the study group showed a shift toward moderate RLS (60%), with an increase in mild RLS (8.6%) and a decrease in severe RLS (31.4%). Meanwhile, no significant change in the severity of RLS was observed in the control group participants compared to baseline. At the post-test 2, the study group showed a significant shift toward mild RLS (57.1%), a decrease in moderate RLS (42.9%), and an absence of severe RLS. In contrast, the control group showed a slight shift toward moderate RLS (54.3%) and a decrease in severe RLS (45.7%). At all periods, the study group showed a decrease in severe RLS, suggesting potential improvement.

Tables 3 and 4 showed there are no statistical significant changes in the pretest between the study and control groups (P = 0.791), indicating that both groups were comparable in severity of RLS before the intervention. However, in the first posttest (P = 0.001) and the second posttest (P = 0.000), statistical significant differences emerged between the two groups, with the study group showing lower mean ranks, reflecting a decrease in the severity of symptoms in comparison to the control group. These results indicate that the intervention (vibration therapy) was effective in decreasing severity of RLS symptom over time among patients in the vibrated group, while the control group did not present significant improvement.

At the beginning of the study (pre-test), the majority of individuals in both groups reported poor sleep quality, with no significant difference between the study (88.6%) and control groups (91.4%). After the first post-test, the distribution remained almost unchanged, indicating a slight improvement initially in the study group (14.3% good vs. 8.6% in the control group). However, in the post-test two, a significant improvement was observed inthe study group, with more than half of the participants (57.1%) reporting good sleep quality compared to only 11.4% at the beginning of the study. On the other hand, the control group did not get better; more than 90% reported that they still had sleep problems according to all three measures. This indicates that the vibration therapy given to the study group received gradually improved sleep quality over time, while the control group experienced persistently poor sleep quality.

Table 2 shows that the study and control groups are comparable in the baseline and early follow-up measurements, as there are no statistical significant differences between them in the pre-test (P = 0.524) and the first post-test (P = 0.780). Unlike the control group, the mean score of the study group on the second posttest was lower (P = 0.000), indicating a statistical significant difference between the two groups and an increase in sleep quality.

4. DISCUSSION

The study results showed that vibration had a consistent and significant effect in reducing the RLS severity in the study group over time, with a mean rank of (36.14 vs. 21.91), compared to the control group that got only routine care, which showed no statistical significant change in the RLS severity, with a mean rank of 34.86 at baseline and 49.09 in the post-measurement. This result highlights the effectiveness of vibration therapy applied in decreasing the RLS severity among patients on maintenance hemodialysis. Mitchell et al. (2016) showed that the WBV significantly reduced RLS-related

symptoms compared to baseline and in comparison to the control group.[42] Hosseini et al. (2016) proceed a study in Yazd hospitals to test the effect of vibration therapy on the severity of RLS among (80) dialysis patients.[43] The study showed a significant difference in the severity of RLS symptoms before and after applying vibration therapy. Therefore, it can be concluded that vibration therapy played an significant role in reducing and improving the symptoms of this syndrome among hemodialysis patients. Hornik et al. (2019) reported that localized mechanical vibration during dialysis is feasible and may improve comfort / muscle activity during sessions — relevant feasibility evidence for delivering vibration during dialysis.[44] Kessler et al, (2020) and Robinson et al. (2018), conducted a study to test the effect of WBV on diabetic peripheral neuropathy.[45,46] The both studies showed positive results in balance, vibration perception, and pain, supporting the hypothesis that vibration affects leg sensations. This study therefore supports the results of the current investigation, which states that vibration helped improve and reduce the severity of RLS symptoms by reducing the unpleasant sensations experienced by hemodialysis patients. In addition, most studies support the findings of the current study, which showed that vibration therapy works well to improve sleep quality in hemodialysis patients. These results are consistent with cross-over RCT study conducted by Azimpour et al. (2019) to assess the effect of vibration therapy and massage on the intensity of RLS symptoms and related sleep problems among 80 individuals receiving hemodialysis. The study results revealed that vibration therapy considerably reduced the intensity of RLS and improved quality of sleep in dialysis patients. Another randomized controlled study conducted by Su & Chang. (2024) on 58 patients in long-term care facilities, distributed onto two groups: a study group receiving vibration therapy and a control group receiving regular routine care.[47] The study results showed significant improvements in sleep efficiency, sleep quality, sleep latency, and sleep duration among individuals of the study group, in comparison to the individuals of the control group, in which no statistical differences were observed before and after the intervention. This study's conclusions therefore corroborate those of the present investigation. In two recent studies, ir was shown that vibration, as a non-pharmacological treatment, is a promising intervention in improving sleep quality and reducing the RLS severity among individuals receiving hemodialysis.[40,48] According to a meta-analysis research investigated by Burbank et al, (2013), presented that patients given vibratory stimulation pads observed a higher increase in their quality of sleep than those given sham pads.[49] Moreover, the enhancement in sleep observed in FDA-approved RLS medication trials was comparable to that reported with vibratory stimulation. In a clinical trial investigated by Azeredo et al. (2019), which included 31 individuals with metabolic syndrome, this trial pointed that vibration training may have a clinically significant effect in managing some factors related with poor sleep quality, demonstrating the effect of vibration in influencing quality of sleep. This result is consistent with the findings of the present study, which indicates the efficiency of vibration in alleviating sleep disturbances in hemodialysis patients. Vibration provides external sensory stimuli that compete with or mask abnormal sensations (tingling, discomfort) in the legs that trigger symptoms of restless legs syndrome. This mechanism is sometimes called the "counter-stimulus" mechanism. By stimulating mechanoreceptors (touch, pressure), vibration may inhibit the transmission of pathological sensory signals through the spinal cord or sensory pathways.[42] Thus, by reducing leg discomfort, sensory disturbances, and involuntary limb movements, vibration may reduce sleep interruptions, improve sleep continuity, increase time in deeper sleep stages.

5. LIMITATIONS

This study has several limitations. As a retrospective single-centre analysis, it was subject to missing or incomplete data and limited by its inability to establish causal relationships. The relatively small sample size (n = 75) may have reduced the statistical power, preventing some associations from reaching significance. Additionally, certain potentially influential variables, such as nutritional status, quality of life, and post-discharge outcomes, were not assessed.

6. CONCLUSION

This study confirms that vibration therapy is an effective, safe, and cost-effective intervention for reducing restless legs syndrome (RLS) symptom severity and improving sleep quality in patients undergoing regular hemodialysis. These findings emphasize the importance of addressing RLS with non-pharmacological approaches that are practical and well tolerated in this vulnerable population. The demonstrated benefits of vibration therapy suggest its potential as a complementary or alternative treatment to pharmacological options, which are often associated with adverse effects and increased costs.

7. Future direction

Moreover, the simplicity and affordability of this method support its broader application in clinical practice. Overall, this study provides a basis for further research to evaluate long-term outcomes, refine treatment protocols, and explore the wider applicability of

vibration therapy in managing RLS and related conditions.

8. Data availability

The numerical data generated during this research is available with the authors.

9. Conflict of Interest

The authors declare no conflict of interest.

10. Authors contribution

A.A.Sh: Conceptualization of the study, literature search, data collection, statistical analysis, manuscript writing and editing.

W.K.M: contributed to the conceptualization of the study, assisted in data collection and analysis, participated in drafting and revising the manuscript, provided critical feedback throughout the research process and helped shape the final version of the article.

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