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Effect of Acupuncture-Like TENS on Restless Leg Syndrome in Haemodialysis Patients

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ABSTRACT

Background: Restless leg syndrome (RLS) is one of the annoying conditions that negatively impacts sleeping and quality of life in hemodialysis (HD) patients.

Objectives: This study aimed to detect the effectiveness of active versus sham acupuncture-like transcutaneous electrical nerve stimulation (Acu-TENS) on RLS in HD patients.

Patients and methods: Computerized block list was utilized to randomly allocate 60 hemodialysis (HD) patients into two groups: Study and control groups. Group A (n=30) received electrical stimulation over acupuncture points through the TENS unit on the left and right legs typically for 30 minutes during the dialysis session, 3 times a week for 3 months. Group B (n= 30) received sham Acu-TENS to non-true acupoint (2 cm away from true acupoints that were selected for the study group) bilaterally at the same time for 30 minutes three times weekly for 12 weeks.

Results: A significant improvements of International Restless Legs Syndrome Study Group Rating Scale (IRLSSG) and fatigue and quality of sleep were documented within group A but outcome of group B did not show the same improvements. After treatment, when the two groups were compared, group A's results significantly improved.

Conclusion: It was concluded that the application of Acu-TENS significantly improved symptoms of RLS, quality of sleep and fatigue, in HD patients with RLS.

Keywords: Acupuncture-like transcutaneous electrical nerve stimulation, RLS symptoms, Sleep quality, Fatigue, Hemodialysis.

INTRODUCTION

Hemodialysis (HD) primarily targets the elimination of urea and extra fluids from the blood, providing a vital treatment option for individuals with chronic kidney failure [(1)]. Restless leg syndrome (RLS) represents one of the various adverse reactions that hemodialysis patients typically experience, which can be caused by the treatment type or the end stage renal disease (ESRD) [(2)].

Itching in the calf's deep region between the knee and ankle joints, pins and needles, and insect crawling are among the unbearable discomforts associated with RLS, a sensory-motor disease linked to sleep. Physical activity relieves or eliminates RLS, which has a unique circadian pattern [(3)]. Signs of RLS are present day and night, develop worse at night, and cause sleep disorders and functional problems, particularly at night and in the evening. As a result, it lowers their quality of life (QoL) [(4)].

Patients receiving hemodialysis who suffer from RLS suffer less well sleep than those who do not. Humans need to sleep, and getting enough sleep is essential for both mental and physical health. Fatigue, inattention, worry, sadness, and a poor QoL are all consequences of poor sleep. Compared to individuals without RLS, patients with RLS who received HD are more probable to experience depression and have a worse QoL. In HD patients, the estimated incidence of RLS differed greatly, ranging from 6 to 60% [(5)]. This syndrome's pathophysiology is still unknown. However, research indicates that a number of factors, including iron deficiency, sex, gestation, body mass index (BMI), diabetes mellitus (DM), insufficient kidney function, and psychosocial variables may be linked to this condition [(6)].

Multiple approaches, including medication, non-pharmacotherapy, lifestyle modifications, cutaneous stimulation, and acupuncture or acupressure, can be used to treat RLS. Dopamine agonists (pramipexole), opiates (tramadol), tranquilizers, and hypnotics are among the drugs used to treat RLS. These drugs effectively reduce symptoms and lengthen sleep duration, but they also have negative adverse effects including headaches, sleepiness, emesis, and overall weakness that ultimately lead to the exacerbation of RLS symptoms [(7)].

Acupuncture triggers a therapeutic response by inducing mild physical stress, which in turn regulates the body's neuroendocrine and immune systems. Additionally, acupuncture has potent anti-inflammatory and immunomodulatory effects [(8-10)]. Research has shown that acupuncture can effectively treat neuromuscular discomfort. Transcutaneous electrical nerve stimulation (TENS), which is similar to acupuncture, was also demonstrated to reduce pain. Endorphin, which is released in response to afferent activity in the A delta fibers, is linked to the pain regulation of Acu-TENS. Electrical stimulation at levels tolerable to patient typically initiates the modifying effect [(11-13)].

Although, Acu-TENS is crucial for managing RLS symptoms, no randomized controlled trial has been done to evaluate how well it contributes to RLS in HD patients (active versus sham Acu-TENS). Therefore, this study was constructed to investigate this domain.

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PATIENTS AND METHODS

Sixty hemodialysis (HD) (men, n=26 and women, n=34) patients for both groups with restless leg syndrome (RLS) were recruited from the Hemodialysis Unit of Kom Hamada General Hospital, El-Behirah Government from September 2024 to November 2024. A randomized controlled trial was performed on RLS in HD patients during the dialysis session.

Subjects: Hemodialysis (HD) patients were randomly and equally allocated into 2 groups: Group A contained 11 men and 19 women patients and group B contained 15 men and 15 women patients (30 for each group).

Inclusion criteria: Sixty HD Patients (men = 26 and women = 34) who was on a regular HD therapy more than one year participated in this study. The HD patients complained RLS, which was diagnosed by the International Restless Leg syndrome Study Group (IRLSSG), patients' BMI was < 30 Kg/m^2, ages of patients ranged from 37-59 years old.

Exclusion criteria: Cancer patients, cardiac disease patients, chronic inflammatory autoimmune disease, Infectious illness (HIV/AIDS, hepatitis B or C, etc…), patients undergoing complementary managements/therapies (herbs, yoga, massage, vibration therapy, pneumatic compression, aerobic exercise, stretching exercises, aromatherapy, hot application, acupuncture, acupressure, etc..) for RLS within the last 6 months, patients with neurological disorders, patients with bad habits (smoking, alcohol and drug abuse), patients with diagnosed psychogenic diseases, patients with diabetes, hypertension, respiratory diseases, or other hepatic disorders (hepatic cancer, hepatitis, etc.) and patients with musculoskeletal disorders of lower limb (osteoarthritis) that may be present with RLS.

Methods: Patients were randomly and equally allocated into 2 groups: Group A contained 11 men and 19 women patients and group B contained 15 men and 15 women patients for each group. Group A received electrical stimulation over acupuncture points through the TENS unit.

The electrode pads of TENS unit were placed to the skin overlying four acupoints (ST36, GB41, BL60, and SP6) on the left and right legs. Group B, received sham Acu-TENS to non-true acupoint (2 cm away from true acupoints that were selected for group A). On-unit of the device was turned on to detect the time of session and the level of intensity buttons were not opened. Sessions of Acu-TENS were applied for 30 minutes during the dialysis session, three times weekly for 12 weeks in both groups was examined by the IRLSSG Rating Scale, Pittsburgh sleep quality index (PSQI) and fatigue severity scale (FFS).

Assessment instrumentation:

1 - **International Restless Legs Syndrome Study Group Rating Scale (questionnaire):** The IRLSSG questionnaire is a valid tool used to diagnose RLS. It comprises ten items with a rating from 0 (no effect) to 4 (extremely severe effect). It categorizes RLS severity into mild (0-10 points), moderate (11-20 points), severe (21-30 points), or very severe (31-40 points) [14].

2- Pittsburgh sleep quality index: It is a popular instrument for evaluating the quality and patterns of sleep subjectively in clinical settings and research. It is utilized for the self-evaluation of sleep quality throughout the previous month. Each PSQI question was scored on a scale of 0 to 3, with 3 being the negative end of the Likert scale. The PSQI score, which goes from 0 to 21, is the sum of the seven subscales. Poor sleep is indicated by an overall PSQI score greater than 5. Poorer general sleep patterns and quality are indicated by higher scores [14].

3-**Fatigue severity scale (FSS):** Each of the nine questions on the FSS has a value between 1 and 7, where 1 denotes no fatigue, 2 to 4 denotes moderate fatigue, and a score greater than 4 denotes severe exhaustion. Given that the questionnaire had a total score range of 9–63, weariness is indicated by a score of 36 or above. Therefore, larger scores correspond to greater levels of fatigue.

Ethical considerations: Before starting the study, approval was gained from The Institutional Ethical Committee, Faculty of Physical Therapy, Cairo University (P.T/REC/012/005450) and prior informed consent of all the subjects was obtained before conducting the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

All data were analyzed by the Statistical Program for Social Science (SPSS) version 23. Chi squared test was employed for comparing sex distribution. All data were normally distributed (Based on Smirnov's test). Quantitative data were displayed as mean ± SD. The paired T test was utilized for comparing within-group data, while the unpaired T test was conducted to compare two groups. A significant P-value was defined as ≤ 0.05.

RESULTS

No statistically significant changes (p-value = 0.518) were indicated across studied groups concerning the age (before). It was 50.23 ± 6.16 in group A and 51.30 ± 6.58 years in group B. Also, no statistically significant changes (p-value = 0.285) were indicated across studied groups regarding the BMI (before). It was 24.21 ± 3.12 in group A and 25.08 ± 3.13 kg/m^2 in group B (Table 1).

Table (1): Comparison of pre-treatment age and BMI between studied groups

		Group A (N = 30)	Group B (N = 30)	T	P-value
Age (years)	**Mean**	50.23	51.30	0.650	0.518NS
	±SD	6.16	6.58		
BMI (Kg/m^2)	**Mean**	24.21	25.08	1.078	0.285NS
	±SD	3.12	3.13		

T: independent sample T test; BMI: body mass index; NS: non-significant; p-value > 0.05 is significant

Regarding sex distribution, no statistically significant changes were revealed (p-value = 0.297) across studied groups. Group A contained 11 men and 19 women, while Group B contained 15 men and 15 women (Table 2).

Table (2): The frequency distribution and chi squared test for comparison of sex distribution across both groups

	Group A	Group B	χ2	p-value	Sig
Gender, n (%)					
Male	11 (36.66%)	15 (50%)	1.08	0.297	NS
Female	19 (63.33%)	15 (50%)			

X^2, Chi Square; Data are expressed as n (%), P-Value < 0.05 indicate statistical significance; NS: non-significant.

Comparison of outcomes between studied groups:

1) IRLSSG between studied groups: No statistically significant change (p-value = 0.684) was indicated across both groups regarding IRLSSG (before). It was 20.63 ± 5.42 in group A and 21.23 ± 5.95 in group B. Also, there was statistically significant (p-value = 0.0003) decreased IRLSSG (after) in group A (15.66 ± 4.67) when compared with group B (21.50 ± 6.76) (Table 3).

Table (3): Comparison of IRLSSG across studied groups

		Group A (N = 30)	Group B (N = 30)	T	P-value
IRLSSG before	**Mean ± SD**	20.63±5.42	21.23±5.95	0.40	0.684 NS
IRLSSG After	**Mean ± SD**	15.66±4.67	21.50±6.76	3.89	0.0003 S

T: independent sample T test; IRLSSG: International Restless Legs Syndrome Study Group; NS: non-significant (p-value > 0.05). S: significant (p-value < 0.05).

2) PSQI between studied groups: No statistically significant change (p-value = 0.636) was indicated across both groups regarding PSQI (before). It was 12.83 ± 3.78 in group A and 13.30 ± 3.88 in group B. Also, there was statistically significant (p-value = 0.003) decreased PSQI (after) in group A (10.70 ± 3.16) when compared with group B (13.46 ± 3.80) (Table 4).

Table (4): Comparison of PSQI across studied groups

		Group A (N = 30)	Group B (N = 30)	T	P-value
PSQI before	**Mean ± SD**	12.83±3.78	13.30±3.88	0.47	0.636 NS
PSQI After	**Mean ± SD**	10.70±3.16	13.46±3.80	3.05	0.003 S

T: independent sample T test; PSQI; Pittsburg sleeping quality index; NS: non-significant (p-value > 0.05). S: significant (p-value < 0.05).

3) FSS between studied groups: No statistically significant change (p-value = 0.543) was indicated across both groups regarding FSS (before). It was 48.86 ± 7.25 in group A and 50.03 ± 7.59 in group B. Also, there was statistically significant (p-value) decreased FSS (after) in group A (44.23 ± 7.29) when compared to group B (50.73 ± 8.75) (Table 5).

Table (5): Comparison of FSS across studied groups

		Group A (N = 30)	Group B (N = 30)	T	P-value
FSS before	**Mean ± SD**	48.86±7.25	50.03±7.59	0.61	0.543 NS
FSS After	**Mean ± SD**	44.23±7.29	50.73±8.75	3.12	0.002 S

T: independent sample T test; FSS: Fatigue severity scale; NS: non-significant (p-value > 0.05).
S: significant (p-value < 0.05).

DISCUSSION

This study was intended to detect the effectiveness of active versus sham Acu-TENS on RLS in hemodialysis (HD) patients. After 12-week intervention, a significant improvement of IRLSSG, PSQI and FFS was documented within group A but outcomes of group B did not show the same improvement. Our results are consistent with **Abedi *et al.*** [(15)] who reported that RLS who received 4-day TENS at a frequency of 100 Hz showed a significant improvement of RLS symptoms**.**

In our study, no statistically significant change (p-value = 0.684) was indicated across both groups regarding IRLSSG (before). It was 20.63 ± 5.42 in group A and 21.23 ± 5.95 in group B. Also, there was statistically significant (p-value = 0.0003) decreased IRLSSG (after) in group A (15.66 ± 4.67) when compared to group B (21.50 ± 6.76). In a single-blind research, 46 randomly selected participants with a diagnosis of RLS were split into two groups and given either pramipexole (0.25 mg daily) + 10 TENS sessions or pramipexole alone for four weeks. IRLSSG was measured before and after therapy, and at eight week follow-up. For every evaluating outcome, there was a significant time interaction across groups, indicating differences favoring the experimental group's IRLSSG. Both groups' IRLSSG showed a significant improvement at the completion of the intervention as well as during the 8-week follow-up. The study's findings demonstrated that TENS applied in combination with a low dosage of pramipexole is effective in the management of RLS throughout a follow-up period of 8-weeks when compared to pramipexole monotherapy [(16)]. Another study explored the efficacy of transcutaneous spinal cord stimulation on idiopathic RLS in a sample of 35 participants (15 RLS patients and 20 controls). The findings demonstrated a significant positive impact of transcutaneous spinal cord stimulation on RLS symptoms, with comprehensive evidence supporting the underlying neurophysiological mechanisms [(17)]. TENS was applied on HD patients with RLS at a frequency of 100 Hz in the experimental group (n= 30) and 20 Hz in the control one (n= 30). IRLSSG was utilized to determine the severity of RLS in both groups. Following the intervention, the independent t-test revealed a significant change (p=0.001) in the severity of RLS in both groups, which were 13.93 ± 2.56 and 17.63 ± 3.30 respectively, with the superiority of the intervention group [(18)].

Regarding the "Gate-Control Theory" of pain perception, TENS attenuates pain perception at the central nervous system by showing how afferent input, involving electrical stimulation, blocks painful stimulus at the level of the spinal cord [(19, 20)]**.** Hormonal secretion is another way by which TENS produces its sedative effects. Low-intensity and high-frequency TENS stimulation triggers the brain to release endogenous opioids, such as oxytocin and endorphins, which have analgesic effects and can relieve stress hormones like cortisol [(21)]**.**

The main finding of the presented trial can be summarized as improvements in RLS symptoms, sleep quality and fatigue after the application of 12-week Acu-TENS in HD patients with RLS.

LIMITATIONS

While, the study's findings were promising, there were several limitations that need to be addressed including the relatively small sample, and the limited study duration to 12 weeks. Future studies must aim to recruit larger samples and investigate the long-term effectiveness of active Acu-TENS on RLS symptoms in HD patients.

CONCLUSION

In conclusion, the current study provided evidence for the efficacy of active Acu-TENS in improving RLS symptoms, sleep quality and fatigue in HD patients. The treatment's neurophysiological effects, combined with its ease of administration and non-invasive nature, make it a valuable adjunctive therapy for RLS in HD patients.

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