



# Investigating the Effect of Cold Water Bags on the Severity of Restless Leg Syndrome and Sleep Quality in Hemodialysis Patients

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## Abstract

**Background:** Restless legs syndrome is a neurological disorder in hemodialysis patients that causes disturbance and disability in rest, discomfort, sleep disturbance, fatigue, and stress.

**Objectives:** This study was done to evaluate the effect of cold water bags on the severity of restless leg syndrome and sleep quality in hemodialysis patients.

**Methods:** This is a quasi-experimental study (before and after) performed on patients referring to three hospitals in Yazd province. In this study, 40 patients with restless legs syndrome were selected from all patients who were referred to the hemodialysis ward by simple random sampling. The samples completed the Restless Legs Syndrome Symptoms Severity Questionnaire before and after using the cold water bag. Data were analyzed by SPSS 20 software and descriptive statistics and paired t-test at the significance level of  $< 0.05$ .

**Results:** This study showed a significant difference between the mean score of restless leg syndrome and sleep quality before and after the interventions ( $P = 0.000$ ). Furthermore, the mean scores of restless leg syndrome and sleep quality were different between the two intervention groups and statistically significant ( $P = 0.000$ ).

**Conclusions:** Based on the results, using a water bag reduces the symptoms of restless leg syndrome. Therefore, it is suggested that cold water bags should be used as an effective, safe, low-cost method.

**Keywords:** Hemodialysis, Restless Leg Syndrome, Sleep Quality, Cold Water Bag

## 1. Background

Chronic renal failure is defined as the progressive and irreversible loss of kidney function, often resulting in uremia and end-stage renal disease, and the effects of this problem on public health are very significant (1, 2). One of the alternative therapies for end-stage renal disease is hemodialysis (3). According to the latest statistics provided by the Iranian Society of Nephrology, currently, 16,600 hemodialysis patients in 355 chronic hemodialysis units in Iran are under chronic hemodialysis. The number of these patients is increasing by about 8% annually (4).

Hemodialysis, in addition to positive effects in the treatment of patients with chronic renal failure, is associated with adverse outcomes (5). Patients undergoing hemodialysis usually have multiple complications that some of them are related to end-stage renal failure, and some are related to the type of treatment. One of these complications is nervous and muscular complications of

restless legs syndrome (RLS), associated with sensory signs and motor disorders of the limbs, especially the legs (3, 6). Also, poor sleep quality is one of the most common problems reported by hemodialysis patients. More than 85% of dialysis patients suffer from sleep disorders (7).

RLS is a sensory-motor disorder with a strong tendency to move legs and sometimes other parts of the body, which is accompanied by discomfort, pain, anorexia, and numbness, and is exacerbated by rest and inactivity, especially at night and is decreased with activity (8).

Patients with this syndrome have an unpleasant sensation in the legs, usually in the depths of the inner surface of the leg between the knees and the ankle, especially when sitting or lying; however, it is sometimes in other parts of the body, such as the thighs, arms, and hands, which are mostly bilateral.

The treatment of these patients is based on pharmaceutical and non-pharmaceutical treatment and special

care. The drugs used include dopamine agonists and carbidopa, levodopa, gabapentin, and opioids, benzodiazepines. The proposed non-pharmacological treatments include regular daily exercise, such as walking, tensile movements, hot and cold water showers, acupuncture, and the use of electrical stimulation of the nerve via the skin (TENS), and refraining from caffeine, alcohol, and tobacco (3).

In cases where the severity of this syndrome increases and causes sleep disturbances, drug treatments begin, which initially may reduce the symptoms of the syndrome to some extent. However, after a while, the symptoms return, and a new drug is prescribed. Regarding the number of consumed drugs in these patients, it is necessary to provide non-pharmacological therapies for them. One of the non-pharmacological methods that affect restless leg syndrome is diathermy and cryotherapy (4, 8).

A common treatment for the relief of musculoskeletal pain is cryotherapy that reduces skin temperature. The physiological effects of cryotherapy include reducing blood flow by vasoconstriction, reducing tissue metabolism, reducing oxygen consumption, reducing inflammation, and increasing the threshold for pain stimulation (9). The initial response to cold is vasoconstriction. However, many studies have reported that the secondary response to vasoconstriction is vasodilatation (10).

The use of cold can prevent many complications of hemodialysis and improve dialysis adequacy due to increased heart contraction, improved oxygen delivery, reduced stimulation of the sympathetic nervous system, and reduced monocyte response (11).

## 2. Objectives

Therefore, due to the high prevalence of RLS, and reduced sleep quality in hemodialysis patients, and the high cost of drug treatments to control this syndrome and its numerous complications, this study aimed to investigate the effect of cold water bag on the severity of this syndrome and the quality of sleep in hemodialysis patients.

## 3. Methods

The present study was quasi-experimental. The statistical population of this study consisted of all hemodialysis patients in dialysis wards of Meybod, Ardakan, and Shahid Rahnemoun hospitals in Yazd. Based on a pilot study on ten patients and completing a questionnaire and calculating the obtained scores, and placing them in the sampling formula, the number of samples was determined to be 38 people.

Finally, among the dialysis patients admitted to the hemodialysis ward who met the inclusion and exclusion criteria (160 patients) and with a 10% chance of recurrence, 40 patients with RLS symptoms were randomized (simple) by purpose-based sampling. Four samples were excluded from the study due to lack of cooperation, and the intervention was performed on 36 patients. Inclusion criteria included chronic renal failure with at least three months of history of hemodialysis, the presence of restless leg symptoms, lack of consciousness, normal neurovascular and vascular status, lack of musculoskeletal disorders that impair physical activity, lack of wounds, and redness of limbs insensitive to cold. Exclusion criteria included patients with catabolic processes, such as cancer, diabetic neuropathy, people taking painkillers and narcotics 72 hours before the study, users of psychiatric drugs, neuromuscular disorders, and arthritis, and unwillingness to continue treatment. Patients who met the following four criteria were included in the group of patients with RLS: (1) frequent movement of the legs with discomfort in the legs; (2) temporary relief of unpleasant symptoms by moving the legs; (3) onset or exacerbation of symptoms with rest or immobility of the legs; and (4) onset or exacerbation of symptoms in the evening or at night. Then, in order to rule out differential diagnoses, the samples were examined by a neurologist to ensure that there were no specific neurological disorders or neuropathies and they were only suffering from RLS. After explaining the study objectives, the subjects entered the study with complete satisfaction. Data were collected by a two-part questionnaire assessing RLS by an interviewer. The first part of the questionnaire measured demographic information of patients, including sex, age, level of education, history of dialysis, pain relief methods, and analgesia, and the second part was related to the restless legs syndrome according to the criteria of the RLS International Study Group. The questionnaire consisted of ten questions with five options, and each question had zero to four points (very severe, severe, moderate, mild, and none). The severity of the symptoms of the disorder was classified into five categories based on the obtained points: no problem (0), mild (10 - 1), moderate (11 - 20), severe (21 - 30), and very severe (31 - 40). The scientific validity of the research tool and the reliability of the questionnaire (97%) were obtained using the content validity method by Meharaban et al. (12).

The third part was the Petersburg Sleep Quality Questionnaire (PSQI). PSQI examines the sleep quality during the last month in terms of subjects' reports. The questionnaire consisted of seven components (the person's general description from sleep quality, sleep latency, useful sleep duration, useful sleep (useful sleep duration ratio of total time spent in bed), sleep disorder and waking up

due to dyspnea, night cough, pain in the organs of the body, extreme cold and heat, use of hypnotic drugs, drowsiness and inability, and desire for daily activities due to bad sleeping, and ultimately, a total score was obtained. The scores for each questionnaire scale ranged from 0 to 3. The scores of 0, 1, 2, and 3 on each scale indicated normal status, mild, moderate, and severe sleep problems. The total score of five (resulting from the sum of the score of seven components) or more represents poor sleep quality, and a score below five indicates good sleep quality. PSQI has the validity and reliability of .86 and .89, respectively.

The intervention was performed for four weeks and a total of 12 sessions. At the end of the intervention, the questionnaire on the severity of restless legs symptoms was completed again. The cold water bag used was cold water at a temperature of 15°C, which was placed inside each bag of 5 cubes of ice and then covered with a towel on both bags. The cold water bags were placed by the researcher under both legs on the third day of dialysis. The duration of using bags was considered 20 minutes based on the book of principles and techniques of nursing (13).

#### 4. Results

The results of descriptive statistics showed that most of the subjects (64%) were in the age group of 60 years and older. Most of them (69.5%) were illiterate, and 61.5% had a history of dialysis treatment for one to five years (Table 1).

According to the results of Table 2, after using the cold bag, the RLS mean score decreased from  $19.53 \pm 3.68$  to  $14.22 \pm 1.58$ , and the sleep quality score decreased from  $9.73 \pm 0.91$  to  $86.6 \pm 3.31$ .

The findings of this study showed a significant difference between the mean score of RLS and sleep quality before and after the interventions ( $P = 0.000$ ). Furthermore, the mean scores of RLS and sleep quality were different between the two intervention groups and statistically significant ( $P = 0.000$ ) (Table 2).

#### 5. Discussion

The present study was a clinical trial, which aimed at determining the effect of cold water bag on the severity of RLS and sleep quality of 36 hemodialysis patients referring to the dialysis wards. In this study, the mean score of RLS severity and sleep quality before and after cold bag interventions were evaluated.

The findings of this study showed that 64% of the samples were in the age group of 60 years old and above, and 27.5% were in the age group of 40 - 60 years old (most of the studied subjects were over 50 years old). In the study

**Table 1.** Frequency of Demographic and Clinical Characteristics of the Studied Samples

Variables	No. (%)
<b>Age (y)</b>	
Less than 40	3 (8.5)
40 - 60	10 (27.5)
60 and older	23 (64)
Total	36 (100)
<b>Gender</b>	
Male	20 (55.5)
Female	16 (44.5)
Total	36 (100)
<b>Education</b>	
Illiterate	25 (69.5)
Primary	11 (30.5)
Total	36 (100)
<b>Dialysis history</b>	
Zero to one year	9 (25)
One to five years	22 (61.5)
More than five years	5 (13.5)
Total	36 (100)

by Jansz et al., the mean age of the study population was  $54 \pm 13$  years (14). The most common causes of end-stage renal disease are diabetes and hypertension, which their prevalence increases with age (15). Therefore, the prevalence of chronic renal failure increases with age, and most patients with chronic renal failure are old.

According to the findings of the present study, the mean score of RLS before the application of cold water bag was 19.53, which after using the cold water bag reduced to 22/14. Moreover, the t-test results showed a significant difference between the two groups regarding the mean score of RLS before and after using the cold water bag ( $P = 0.000$ ). Herrera et al. conducted a study and indicated that in all three interventions, neuromuscular, sensory, and motor function improved. It can be concluded that cryotherapy improves neurological, sensory, and motor function (16).

No study on the effect of diathermy and cryotherapy on RLS was found to be comparable with the current research. However, Dehghan and Farahid in 2014 showed that diathermy significantly reduced the pain compared to the other two groups. Furthermore, the pain score in the cryotherapy group decreased, which can be concluded that both cryotherapy and heat therapy was effective in reducing back pain in patients, which is in line with the findings of the present study (17). Abd El-Maksoud et al. per-

**Table 2.** Comparison of the Restless Legs Syndrome Mean Score Before and After Using Cold a Water Bag

Variables	Mean ± Standard Deviation	P-Value
<b>Restless Legs Syndrome Parameters</b>		
Restless legs syndrome before using a cold water bag	19.53 ± 3.68	0.000
Restless legs syndrome after using a cold water bag	14.22 ± 1.58	
<b>Sleep Quality Parameters</b>		
Sleep quality before using a cold water bag	9.72 ± 3.91	0.000
Sleep quality after using a cold water bag	8.86 ± 3.31	

formed a study and concluded that using the spasticity ice bag increased the range of motion and improved motor function (18).

Our results also showed that the sleep mean score decreased from 9.72 before the intervention to 8.86 after using the cold water bag. These findings indicate that sleep quality improved after using the cold water bag, and both groups showed a statistically significant difference regarding the sleep mean score before and after using the cold water bag (P = 0.000).

Ghanbarabadi et al. also showed that a cold dialysis solution could improve the total score of sleep quality and all its components after the intervention (19). The use of cold substances in dialysis, in addition to the necessary effects on increasing vascular contractions and maintaining body temperature, is effective in reducing fatigue and, consequently, depression, which ultimately leads to increased sleep quality in hemodialysis patients (15).

Sajadi et al. stated that cold dialysis could be performed as a routine intervention for all hemodialysis patients, especially dialysis patients who are very tired (20). Rad et al. (5) also showed that the use of cold dialysis is effective in the treatment of anemia in patients and consequently reduces sleep disorders. In addition, it increases the physical level.

**5.1. Conclusion**

According to the results of this study, cold water bags significantly decreased the severity of RLS and improved sleep quality in hemodialysis patients. Therefore, this method can be used in dialysis wards. Because the relief of pain and discomfort of patients is one of the main duties of nurses, this study can emphasize the importance of RLS and sleep disturbance and the necessity of holding re-training courses for nurses, especially in nephrology and hemodialysis wards. It is also suggested that in the curriculum of nurses at different levels, the RLS should be taught as an important complication and disease in chronic renal failure. Moreover, nursing students must be informed about the relief methods, including the use of cold wa-

ter bags, in order to be able to take care of these patients. Given that RLS is followed by physical and mental harm and exposes treatment financial burden on patients, nursing interventions, such as hot and cold water bags, can play a crucial role. We suggest developing a protocol for relieving RLS and improving sleep quality in hemodialysis wards, and training it to the personnel. It then should be monitored by the supervisors and head nurses.

The limitations of this study were the inability to blind the research and the specificity of the interventions beyond the researcher's control.

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**Footnotes**

**Authors' Contribution:** AE, was the main investigator; AE, collected the data and wrote the first draft; AE and KHN, analyzed the data; KHN, led the team, designed the study, and read and revised the final draft; AE and NB, collected the data and helped in writing the final draft.

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## References

- Allen RP, Picchietti D, Hening WA, Trenkwalder C, Walters AS, Montplaisi J, et al. Restless legs syndrome: diagnostic criteria, special considerations, and epidemiology. A report from the restless legs syndrome diagnosis and epidemiology workshop at the National Institutes of Health. *Sleep Med*. 2003;**4**(2):101-19. doi: [10.1016/s1389-9457\(03\)00010-8](https://doi.org/10.1016/s1389-9457(03)00010-8). [PubMed: [14592341](https://pubmed.ncbi.nlm.nih.gov/14592341/)].
- Alidosti M, Hemate Z, Reisi M. [Relationship between the quality of sleep and restless legs syndrome among]. *Feyz*. 2013;**17**(1):85-90. Persian.
- Khojandi S, Shahgholian N, Karimian J, Valiani M. [Comparison the effect of two methods of reflexology massage and stretching exercises on the severity of restless leg syndrome among patients undergoing hemodialysis]. *Iran J Nurs Res*. 2015;**10**(1):86-94. Persian.
- Tarsy D, Silber M, Hurtig H, Avidan A, Eichler A. *Treatment of restless legs syndrome in adults*. Alphen aan den Rijn, Netherlands: Wolters Kluwer Health; 2014.
- Rad M, Shomoosi N, Mirhosseini Z, Kashani E. Can cool dialysate alleviate restless leg syndrome in hemodialysis patients? *J Res Med Sci*. 2017;**22**:124. doi: [10.4103/jrms.JRMS\\_587\\_17](https://doi.org/10.4103/jrms.JRMS_587_17). [PubMed: [29259635](https://pubmed.ncbi.nlm.nih.gov/29259635/)]. [PubMed Central: [PMC5721490](https://pubmed.ncbi.nlm.nih.gov/PMC5721490/)].
- Karunaratne K, Taube D, Khalil N, Perry R, Malhotra PA. Neurological complications of renal dialysis and transplantation. *Pract Neurol*. 2018;**18**(2):115-25. doi: [10.1136/practneurol-2017-001657](https://doi.org/10.1136/practneurol-2017-001657). [PubMed: [29288211](https://pubmed.ncbi.nlm.nih.gov/29288211/)].
- Arab Z, Shariati AR, Bahrami HR, Asayesh H, Vakili MA. [The effect of acupressure on quality of sleep in hemodialysis patients]. *Nurs Midwifery J*. 2012;**10**(2). Persian.
- Klingelhofer L, Cova I, Gupta S, Chaudhuri KR. A review of current treatment strategies for restless legs syndrome (Willis-Ekbom disease). *Clin Med (Lond)*. 2014;**14**(5):520-4. doi: [10.7861/clinmedicine.14-5-520](https://doi.org/10.7861/clinmedicine.14-5-520). [PubMed: [25301914](https://pubmed.ncbi.nlm.nih.gov/25301914/)]. [PubMed Central: [PMC4951962](https://pubmed.ncbi.nlm.nih.gov/PMC4951962/)].
- Karunakara RG, Lephart SM, Pincivero DM. Changes in forearm blood flow during single and intermittent cold application. *J Orthop Sports Phys Ther*. 1999;**29**(3):177-80. doi: [10.2519/jospt.1999.29.3.177](https://doi.org/10.2519/jospt.1999.29.3.177). [PubMed: [10322591](https://pubmed.ncbi.nlm.nih.gov/10322591/)].
- Weston M, Taber C, Casagrande L, Cornwall M. Changes in local blood volume during cold gel pack application to traumatized ankles. *J Orthop Sports Phys Ther*. 1994;**19**(4):197-9. doi: [10.2519/jospt.1994.19.4.197](https://doi.org/10.2519/jospt.1994.19.4.197). [PubMed: [8173566](https://pubmed.ncbi.nlm.nih.gov/8173566/)].
- Ahmadinezhad M, Kargar M, Vizeshfah F, Hadianfard MJ. Comparison of the Effect of Acupressure and Pilates-Based Exercises on Sleep Quality of Postmenopausal Women: A Randomized Controlled Trial. *Iran J Nurs Midwifery Res*. 2017;**22**(2):140-6. doi: [10.4103/1735-9066.205954](https://doi.org/10.4103/1735-9066.205954). [PubMed: [28584553](https://pubmed.ncbi.nlm.nih.gov/28584553/)]. [PubMed Central: [PMC5442996](https://pubmed.ncbi.nlm.nih.gov/PMC5442996/)].
- Meharaban Z, Yahya S, Sadegniaat K. Restless Legs Syndrome During Pregnancy and Preterm Birth in Women Referred to Health Centers of Ardabil. *Iran Red Crescent Med J*. 2015;**17**(12). e24438. doi: [10.5812/ircmj.24438](https://doi.org/10.5812/ircmj.24438). [PubMed: [26756014](https://pubmed.ncbi.nlm.nih.gov/26756014/)]. [PubMed Central: [PMC4706982](https://pubmed.ncbi.nlm.nih.gov/PMC4706982/)].
- Perry AG, Potter PA, Ostendorf W. *Clinical nursing skills and techniques*. Amsterdam: Elsevier Health Sciences; 2013.
- Jansz TT, van Reekum FE, Özyilmaz A, de Jong PA, Boereboom FTJ, Hoekstra T, et al. Coronary artery calcification in hemodialysis and peritoneal dialysis. *Am J Nephrol*. 2018;**48**(5):369-77. doi: [10.1159/000494665](https://doi.org/10.1159/000494665). [PubMed: [30423550](https://pubmed.ncbi.nlm.nih.gov/30423550/)]. [PubMed Central: [PMC6390451](https://pubmed.ncbi.nlm.nih.gov/PMC6390451/)].
- Sekercioglu N, Curtis B, Murphy S, Barrett B. Sleep quality and its correlates in patients with chronic kidney disease: A cross-sectional design. *Ren Fail*. 2015;**37**(5):757-62. doi: [10.3109/0886022X.2015.1024555](https://doi.org/10.3109/0886022X.2015.1024555). [PubMed: [25782921](https://pubmed.ncbi.nlm.nih.gov/25782921/)].
- Herrera E, Sandoval MC, Camargo DM, Salvini TF. Effect of walking and resting after three cryotherapy modalities on the recovery of sensory and motor nerve conduction velocity in healthy subjects. *Rev Bras Fisioter*. 2011;**15**(3):233-40. doi: [10.1590/s1413-35552011000300010](https://doi.org/10.1590/s1413-35552011000300010). [PubMed: [21829988](https://pubmed.ncbi.nlm.nih.gov/21829988/)].
- Dehghan M, Farahid N. [Efficacy of duration of hot water bag usage on pain relief in the patients with acute low back pain]. *Health Sys Res*. 2014;**10**(2):345-53. Persian.
- Abd El-Maksoud GM, Sharaf MA, Rezk-Allah SS. Efficacy of cold therapy on spasticity and hand function in children with cerebral palsy. *J Adv Res*. 2011;**2**(4):319-25. doi: [10.1016/j.jare.2011.02.003](https://doi.org/10.1016/j.jare.2011.02.003).
- Ghanbarabadi R, Mirhosseini Z, Rakhshani MH, Estaji Z, Rad M. The effects of cool dialysate on quality of sleep among patients undergoing hemodialysis: A randomized clinical trial. *J Educ Health Promot*. 2019;**8**:56. doi: [10.4103/jehp.jehp\\_205\\_18](https://doi.org/10.4103/jehp.jehp_205_18). [PubMed: [31008123](https://pubmed.ncbi.nlm.nih.gov/31008123/)]. [PubMed Central: [PMC6442248](https://pubmed.ncbi.nlm.nih.gov/PMC6442248/)].
- Sajadi M, Gholami Z, Hekmatpou D, Soltani P, Haghverdi F. Cold Dialysis Solution for Hemodialysis Patients With Fatigue: A Cross-over Study. *Iran J Kidney Dis*. 2016;**10**(5):319-24. [PubMed: [27721231](https://pubmed.ncbi.nlm.nih.gov/27721231/)].