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The effects of cool dialysate on quality of sleep among patients undergoing hemodialysis: A randomized clinical trial

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Abstract:

INTRODUCTION: Low quality of sleep is a common problem among hemodialysis patients. This study was conducted to evaluate the effect of a cold dialysis solution on the quality of sleep in patients undergoing hemodialysis.

METHODOLOGY: This double-blind clinical trial was performed on 26 hemodialysis patients with chronic renal failure and sleep disorders in the dialysis center of Sabzevar, Iran, in 2016–2017. Of the 26 patients, 13 each were allocated to the intervention and control groups. The patients in both groups received 4 weeks of hemodialysis (3 sessions per week) using a standard solution with a temperature of 37°C. In the next stage, the control group continued to receive the standard-temperature dialysis, while the intervention group received dialysis using a solution with a temperature of 35.5°C for 4 weeks (3 sessions per week). The Pittsburgh Sleep Quality Index was used to assess and compare the quality of sleep before and after the intervention in the two groups. Data were analyzed using R 1.2.3 software, at 95% confidence level.

RESULTS: Although the mean scores of sleep quality were not significantly different between the intervention (9.53 ± 3.12) and control (11.23 ± 3.37) groups at baseline, postintervention, significant differences were observed (intervention group: 4.7 ± 4.55; control group: 10.61 ± 2.69; $P < 0.001$).

CONCLUSION: This study showed that dialysis with cold solution is a simple, cost-effective, and nonpharmacological method that can be used to improve sleep quality in patients undergoing hemodialysis.

Keywords:

Chronic renal failure, dialysis solution, hemodialysis, sleep quality

Introduction

Considering the growing prevalence of chronic renal disease over the past 2 decades, especially in developing countries, the number of patients undergoing hemodialysis has also increased dramatically.[1] Although hemodialysis is an effective and lifesaving treatment for patients with chronic renal failure, it is associated with adverse and unfavorable outcomes.[2]

Poor sleep quality is one of the most common problems experienced by hemodialysis patients. Over 85% of dialysis patients have been reported to suffer from sleep disorders.[3] Sleep is one of the physiological needs of the human body, which is necessary for the health and recovery of patients.[4]

The results of previous studies showed that while 7%–44% of the general population had poor sleep quality, the same was observed in 20%–83% of hemodialysis patients.[5-8]

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Sleep disturbances are among the most important factors in reducing the quality of life in patients. Recent studies have shown that insomnia, sleep deprivation, and general sleep disorders are associated with the exacerbation of cardiovascular diseases, decreased quality of life, and increased mortality in hemodialysis patients.[9]

The short-term effects of low sleep quality include weariness; drowsiness during the day; vertigo; blurred vision; and decreased memory capacity, cognitive ability, and immunity; while the long-term effects include hypertension, heart failure, diabetes, obesity, and premature aging. Poor sleep quality also affects work, social and leisure activities, mood and behavior, communication, sexual activities, pleasure in everyday life, and daily activities.[10]

The causes of sleep disorders in hemodialysis patients are unclear.[11] Identification and treatment of sleep disorders are significantly associated with the improvement of quality of life in dialysis patients.[12] To relieve sleep problems, sleeping medications, especially benzodiazepines, are normally prescribed.[13] Although these medications may induce or prolong the stages of sleep, sleep quality may remain poor. Further, resistance to the effects of medications and emergence of symptoms associated with abrupt withdrawal are among the other complications of benzodiazepines, which can sometimes exacerbate sleep disorders.[14]

On the other hand, alternative therapies such as acupuncture, acupressure, aromatherapy, reflexology, and therapeutic touch have been recommended for sleep disorders.[15] However, previous studies have shown that alternative treatments are not endorsed by patients due to time constraints and the potential physical, mental, and psychological complications.[16]

Given the high sensitivity and concerns of dialysis patients about the emergence of complications other than their underlying disease, nonpharmacological interventions (with few or no side effects) are welcomed by patients and medical staff for the prevention and treatment of hemodialysis complications and for increasing the adequacy of the procedure. One of these alternative methods is the use of a cold dialysis solution. Although the body temperature is lower in hemodialysis patients as compared with that in healthy people, it usually increases during dialysis. The increase in body temperature is due to the increased sympathetic nervous activity and the body's inability to discard the heat generated by the dialysis process.[16]

Increased body temperature and distension of the peripheral vascular bed result in increased itching, cardiovascular instability, and hypotension in patients and cause symptoms such as fatigue, nausea, dizziness, and muscle cramps. On the other hand, hypotension reduces fluid removal in the patient's body and exposes him/her to cerebral infarction, ischemic heart disease, and mesenteric arterial disease. In some cases, these complications can cause early weaning off hemodialysis, which in turn reduces the adequacy of procedure and disrupts the patient's sleep quality.[17]

When using a cold dialysis solution, heat exchange occurs between the blood and hemodialysis solution, thus preventing the increase in body temperature and aiding vascular contractions. A cold solution can prevent most complications of hemodialysis and can improve dialysis adequacy by increasing cardiac contractility, improving oxygen supply to tissues (especially to the skin), reducing the stimulation of the sympathetic nervous system, and reducing the reactivity of monocytes.[13,18]

Despite the potential risk of seizure associated with the use of a cold dialysis solution, most patients often show a good response to treatment.[19-21] Previous studies have revealed the effectiveness and safety of this approach.[21,22] According to these studies, the use of a cold dialysis solution can help patients feel energetic after dialysis, which has major positive effects on their general health.[13]

Today, there is a general agreement among nephrologists regarding the effectiveness of a low-temperature dialysis solution.[23] However, despite the tremendous advances in dialysis technologies, solution temperature has been neglected in patients undergoing long-term dialysis. On the other hand, the high adequacy of the procedure is found to be associated with reduced complications, disability, and mortality.[24]

In general, review of literature showed that few studies have been assessed the effect of cold dialysis on the quality of sleep in hemodialysis patients. According above mentioned studies, the cold dialysate can increase dialysis adequacy and reduce complications such as itching, fatigue, nausea, dizziness, and preventing hypotension. Therefore, it can probably improve the quality of sleep through reducing complication. Thus, this study aimed to determine the effects of a cold dialysis solution on the quality of sleep in patients undergoing hemodialysis.

Methodology

This double-blind, two-group, randomized clinical trial (IRCT: 2016060228219N1) was performed on 26 patients undergoing hemodialysis at Vasei Hospital of Sabzevar, Iran, from November 21, 2016, to February 20, 2017.

Participants

A total of 26 patients were recruited based on the following criteria: (1) registration in the weekly dialysis list; (2) undergoing dialysis 3 times a week, for 3–4 h; (3) willingness to participate in the study; (4) aged 18–75 years; (5) diagnosis of chronic renal failure according to the patient's medical record; (6) absence of physical or mental disabilities; (7) experience of dialysis for at least 6 months; (8) adequate awareness, hearing, and speaking abilities to answer the questions; (9) absence of mental or emotional disorders preventing effective communication; (10) scores >5 on the Pittsburgh Sleep Quality Index; (11) hemoglobin level >8 mg/dL; and (12) absence of nonendocrine disorders, such as hypothyroidism and hyperparathyroidism.

In addition, the following exclusion criteria were used: (1) severe complications during hemodialysis such as imbalance, embolism, dysrhythmia, cardiac and respiratory arrest, and coma; (2) transplant recipients; (3) changes in the frequency of dialysis sessions (more than 1 session); (4) intolerance of a cold dialysis solution; and (5) unwillingness to continue participation in the study.

Data collection and intervention

The data collection tools included the Pittsburgh Sleep Quality Index and a demographic questionnaire. The demographic questionnaire contained the demographic characteristics of the patients as well as information about the disease. To determine the validity of the researcher-made questionnaire, its content validity was determined. For this purpose, the questionnaire was presented to 10 instructors at the Faculty of Nursing and Midwifery and was applied in the study after making revisions.

The Pittsburgh Sleep Quality Index, developed by Buysse *et al.* in 1989, is a self-report instrument that examines the sleep quality over the past month. It contains 19 questions and 7 components, including subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the past month. The total score ranges between 0 and 21. Scores <5 indicate good sleep quality, while those >5 represent poor sleep quality.[22]

This standard questionnaire has high reliability and validity and has been applied in various studies to assess sleep quality and to identify sleep disturbances.[25,26] The validity of this questionnaire in the Iranian population has been determined in a study by Otaghi et al *et al*.[27] Moreover, Farrahi Moghaddam *et al*. revealed 100% sensitivity, 90% specificity, and 89% Cronbach's alpha for the Persian version of the questionnaire.[28] In the present study, the internal consistency of the tool was evaluated using the Cronbach's alpha (85%).

First, the researcher explained the study objectives, exclusion criteria, random group classification, possible advantages of the intervention, and importance of reporting any adverse events (especially unbearable shivering) to the participants. Participation in the study was voluntary, and the physicians, nursing staff, researcher, or assistant researcher did not insist on the participation of patients. Accordingly, signed informed consent form was obtained from eligible patients. It was emphasized that this form does not imply mandatory participation in the study, and the participants were allowed to withdraw from the study at any time.

The participants were assigned to the intervention and control groups, using block randomization. The blocks consisted of English letters, A, B, C, D, E, and F. The letters A, B, and C were attributed to the intervention group, while the letters D, E, and F were attributed to the control group. Each block included the English letters, A, B, C, D, E, and F, without any repetition.

The blocks were randomly selected; each block was removed after use and the next was randomly selected. Via block randomization, we could classify the participants into the intervention and control groups. For instance, a DACEFB block indicated that the first, fourth, and fifth participants from the right should be allocated to the intervention group, while the second, third, and sixth participants should be assigned to the control group. Finally, the patients were divided into two equal groups (13 patients each in the intervention and control groups).

The participants were requested to complete the information with accuracy and honesty. Considering the chronic condition of hemodialysis patients, they were completely familiar with the interventions and recognized the parameters on the hemodialysis machine. Therefore, to prevent bias, the temperature setting on the hemodialysis monitor was covered with a paper, after obtaining permission from the physician, head nurse, patient nurse, and the patient in both intervention and control groups.

It should be noted that the type of filter and ultrafiltration coefficient were similar in the groups, and the dialysis fluid flow was 500 ml/min. The patients in both groups underwent 4 weeks of hemodialysis (3 sessions per week), using a standard solution with a temperature of 37°C. Sleep quality was assessed by the Pittsburgh Sleep Quality Index in both groups. In the next step, the control group continued to receive hemodialysis with the standard temperature solution (37°C), while for the intervention

group, a dialysis solution with a temperature of 35.5°C was used during 4 weeks (3 sessions per week). Sleep quality of patients in both groups was evaluated after the intervention, using the Pittsburgh Sleep Quality Index.

Sample size and data analysis

According to the results reported by Parker *et al*., a sample size of 13 was determined to be sufficient for each group (90% power, 95% confidence interval [CI]). The normality of the distribution of the data was confirmed using the Shapiro–Wilk test. To evaluate quantitative variables with a normal distribution, the independent *t*-test was applied, while for quantitative variables without a normal distribution, the Mann–Whitney test, Fisher's exact test, Chi-square test, and analysis of covariance were performed. All analyses were performed using R 1.2.3 software (R is a environment for statistical computing. It was developed at Bell Laboratories by John Chambers and colleagues) at 95% CI. Finally, the results were compared between the groups.

Ethical considerations

All ethical considerations recommended for a clinical trial were observed in this study. The present study was approved by the Research Ethics Committee of Sabzevar University of Medical Sciences (ir. medsab. rec.1395.57; IRCT: 2016060228219N1). The patients' information remained confidential throughout the study. For this purpose, codes were used instead of names, and the researcher did not disclose the information under any circumstances.

Results

The analysis of the demographic characteristics showed that all participants were aged 18–75 years. The mean age of the participants in the intervention and control groups was 58.46 (9.64) and 56.30 (12.88) years, respectively. Overall, 53.8% of the participants were female and 46.2% were male. Most participants (34.6%) had elementary education. In addition, 50% of the participants were homemakers and 3.8% were disabled.

The cause of renal failure was hypertension (46.2%) in the majority of patients in the intervention group and diabetes plus hypertension (46.2%) in the control group. Further, 9.62% of the participants lived in urban areas. The results of Mann–Whitney test, Chi-square test, and Fisher's exact test revealed that the groups were not significantly different in terms of demographic variables such as age, gender, or education (95% CI; $P > 0.05$). Therefore, the two groups were considered homogenous.

According to the results presented in Table 1, among the studied variables, sleep quality at baseline (B = 0.68, $P < 0.001$) and group variable (cold dialysis group) (B = –5.34, $P = 0.001$) had major effects on the total score on sleep quality, indicating that the intervention was effective in significantly reducing the patients' scores on sleep quality. Specifically, as compared to the control group, the total score on sleep quality in the intervention group reduced by 5.34 points. Since reduction in the total score on sleep quality is indicative of improved sleep quality, the use of a cold dialysis solution is considered to be effective in improving the overall quality of sleep in the intervention group.

Table 1: Estimation of the effect of different variables on the overall score of sleep quality in hemodialysis patients based on covariance analysis

	Variable	Standardized coefficients	SE	Coefficient	*P*
Total score on sleep quality	Estimates		6.29	8.57	0.19
	Total score at baseline	0.50	0.18	0.68	0.001
	Group	−0.60	0.86	−5.34	0.001

SE=Standard error

At baseline, the mean total score on sleep quality was 9.53 ± 3.12 in the intervention group and 11.23 ± 3.37 in the control group. After the intervention, the same was 4.07 ± 3.45 in the intervention group and 10.61 ± 2.69 in the control group. Fisher's exact test results showed that 100% of the participants in the control group had low sleep quality after the intervention. On the other hand, 76.9% of the participants in the intervention group had good sleep quality, while only 23.1% reported poor sleep quality ($P < 0.001$).

According to the covariance analysis [Table 2], the intervention could reduce the score on subjective sleep quality in the intervention group (by 0.64 points). The score on sleep latency (1.21 points) and sleep onset reduced significantly in the intervention group in comparison with that in the control group. In addition, the scores on sleep duration, sleep efficiency, sleep disturbances, and daytime dysfunction reduced by 0.88, 1.18, 0.64, and 0.87 points in the intervention group, as compared to that in the control group, respectively. However, the use of sleep medications was not affected.

Discussion

In the present study, the effect of a cold dialysis solution on sleep quality was investigated in hemodialysis patients. The results showed that a cold dialysis solution could improve the total score on sleep quality and all its components after the intervention, except for that on the use of sleeping medications.

In the present study, 100% of the patients had low sleep quality at baseline. In this regard, Khosroshahi *et al*. reported that 86.6% of the patients had low sleep quality.[29] Similarly, in the studies by Otaghi *et al*. and

Table 2: Estimating the effect of different variables on the quality of sleep in patients undergoing hemodialysis based on covariance analysis

The total score on sleep quality	Variable	Standardized coefficients	SE	Coefficient	*P*
The score on subjective sleep quality	Subjective sleep quality at baseline	0.36	0.14	0.36	0.01
	Group	−0.52	0.15	−0.64	0.01
The score on sleep latency	Sleep latency at baseline	−0.56	0.18	0.70	0.01
	Group	−0.56	0.21	−1.21	<0.001
The scores on sleep duration	Sleep duration at baseline	0.55	0.20	0.66	<0.001
	Group	−0.44	0.27	−0.88	<0.001
The scores on sleep efficiency	Sleep efficiency at baseline	0.51	0.14	0.55	0.02
	Group	−0.55	0.25	−1.18	<0.001
The scores on sleep disturbances	Sleep disturbances at baseline	0.35	0.18	0.35	0.06
	Group	−0.46	0.20	−0.64	<0.001
The scores on daytime dysfunction	Daytime dysfunction at baseline	0.86	0.12	0.81	<0.001
	Group	−0.04	0.18	−0.07	0.68
The scores on sleep medications	Sleep medications at baseline	0.44	0.19	0.48	0.02
	Group	−0.51	0.22	−0.87	<0.001

SE=Standard error

Eryavuz *et al*., 83.7% and 88.5% of the patients reported poor sleep quality, respectively.[27,30] Thus, the findings of these studies are consistent with the present findings.

The present study showed that sleep quality improved by the use of a cold dialysis solution. One of the factors that can improve sleep quality is hemodynamic stability.[31] The results of a study by Suzuki *et al*. showed that a cold dialysis solution could improve hemodynamic stability, reduce the symptoms of hypotension, and eliminate the need for hypotension treatment measures.[31]

With increased hemodynamic stability, signs of hypotension, such as nausea, vomiting, fatigue, muscle cramp, and dizziness, decrease. It should be noted that these complications might cause early weaning off hemodialysis and reduce the adequacy of the procedure, thus affecting the patient's quality of sleep.[17] Consequently, improved hemodynamic stability prevents early weaning off dialysis, increases the efficacy of the procedure, and improves the sleep quality.

The cold dialysis solution fosters hemodynamic stability through various mechanisms, including the maintenance of body temperature, increased activity of the sympathetic nervous system, increased cardiac contractility and peripheral vascular resistance, induction of alpha-1 receptors in the visceral veins, decreased visceral vein capacity, and the consequent increase in the central blood volume and cardiac output. In addition, the cold dialysis solution inhibits the stimulation of monocytes.

One of the causes of sleep quality improvement in the present study might be the reduction of fatigue and improvement of comfort of patients after dialysis, as well as their increased vitality after using a cold dialysis solution.[13] The results of a study by Toth-Manikowski and Sozio showed that the use of a cold dialysis solution is effective in reducing fatigue among patients. After dialysis with a cold solution, patients feel energetic and lively, which can greatly affect their general health. It has also been reported that most patients with such experiences prefer dialysis with a cold solution for future procedures.[13]

In a study by Elder *et al*.,[5] the lower scores on sleep quality were associated with a variety of cardiovascular problems, mental disorders, depression, itching, and pain. Considering that a cold dialysis solution can be effective in improving cardiovascular problems, depression, pain, and itching,[9] sleep disturbances may be indirectly improved.

One of the other causes of sleep disorders in hemodialysis patients is the skin rash caused by the waste material in the body.[17] By relieving itching, sleep disturbances and sleep quality can be improved. In this regard, Rad *et al*. showed that the use of a cold dialysis solution could reduce the severity and duration of itching.[32] Moreover, in a study by Brekke *et al*., the most common causes of insomnia were anemia and depression.[33] The results of previous studies have shown that the use of a cold dialysis solution has many positive mental, psychological, and physical effects for hemodialysis patients.[17] Therefore, it can be said that reducing depression in patients can improve the quality of sleep.

In the present study, the effect of a cold dialysis solution on hemoglobin level was evaluated. According to the findings, the mean hemoglobin level increased from 10.94 ± 1.35 to 11.13 ± 1.22. Further, the hemoglobin level in the intervention group increased by 0.56 g/L after the intervention as compared to that in the control group. Overall, the treatment of anemia reduces frequent awakening during sleep, as well as other sleep disorders; moreover, it increases patients' physical activity and quality of life.[34]

Conclusion

According to the results of the present study, a cold dialysis solution has positive effects on the quality of sleep in hemodialysis patients. The use of a cold dialysis solution could improve all components of sleep (except for the use of sleeping medications), including sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, and daytime dysfunction in hemodialysis patients. Considering the results of previous studies and the confirmed effects of cold dialysis solution on the improvement of sleep disturbances, such interventions can be used to influence fatigue, itching, pain, muscle cramps, hypotension, depression, and anemia. This method can be used as a nonpharmocological, simple, and cost-effective method, without any side effects or adverse outcomes of drug interactions for hemodialysis patients. Further studies in this area are strongly suggested.

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Conflicts of interest

There are no conflicts of interest.

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