

Effect of acupuncture on the sleep quality of hemodialysis patients in a capital city in the Northeast of Brazil: randomized clinical trial

Efeito da acupuntura na qualidade do sono de pacientes hemodialíticos em uma capital do Nordeste do Brasil: ensaio clínico randomizado

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ABSTRACT

Objective: Analyze the effect of auricular acupuncture on the sleep quality of hemodialytic patients with chronic pain in a capital city in the Northeast of Brazil. **Methods:** This study includes double-blind, randomized in blocks and allocated at a rate of 1:1, controlled trial that was conducted in two hemodialysis clinics, with 94 chronic renal patients with chronic pain (auricular acupuncture [AA]: 47, sham acupuncture [SA]: 47). Both received 12 sessions for three months. We collected data using the Pittsburg Sleep Quality Index (PSQI). Data were analyzed using t-tests, Wilcoxon test and ANOVA. **Results:** Comparing the SA and AA groups, there was a statistically significant difference at baseline ($p < 0.001$), a significant intergroup difference, and the AA group had better sleep quality than the SA group during and at the end of the 12 sessions (< 0.001). A high magnitude of the effect of auricular acupuncture on sleep quality was found at the end of the sessions ($D = -1.94$). **Conclusion:** The auricular acupuncture intervention proved to be effective in improving the subjective sleep classification of renal patients.

Keywords: acupressure; kidney failure chronic; renal dialysis; sleep quality; complementary therapies.

RESUMO

Objetivo: analisar o efeito da acupuntura auricular na qualidade do sono de pacientes hemodialíticos com dor crônica em uma capital do Nordeste do Brasil. **Método:** este estudo inclui ensaio duplo-cego, randomizado em blocos e alocado na proporção de 1:1, controlado, realizado em duas clínicas de hemodiálise com 94 pacientes renais crônicos com dor crônica (acupuntura auricular [AA]: 47, acupuntura simulada [SA]: 47). Ambos receberam 12 sessões durante três meses. Coletamos dados utilizando o Índice de Qualidade do Sono de Pittsburg (PSQI). Os dados foram analisados por meio de testes t, teste de Wilcoxon e ANOVA. **Resultados:** comparando os grupos SA e AA, houve diferença estatisticamente significativa no início do estudo ($p < 0,001$) e diferença significativa intergrupos; o grupo AA apresentou melhor qualidade de sono que o grupo SA durante e ao final das 12 sessões ($< 0,001$). Foi encontrada elevada magnitude do efeito da acupuntura auricular na qualidade do sono ao final das sessões ($D = -1,94$). **Conclusão:** a intervenção de acupuntura auricular mostrou-se eficaz na melhoria da classificação subjetiva do sono de pacientes renais.

Palavras-chave: acupressão; insuficiência renal crônica; diálise renal; qualidade do sono; terapias complementares.

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INTRODUCTION

A persistent pain is one of the most frequent reasons for sleep disturbances in older adults.¹ The relationship between pain and sleep disturbance seems to be straightforward. Pain provokes disturbed sleep and sleep disturbances interferes with the ability to initiate and maintain sleep.²

The small study conducted in this geriatric unit with 77 patients, 38% of the individuals showed persistent pain. Sleep quality was assessed by the PSQI tool.³ Disturbed sleep was significantly more frequent in patients with persistent pain (45% vs. 13%, $p < 0,01$) in that study; however, the relationship between sleep and pain is more complex and it is not unidirectional.⁴

Interestingly, pain and sleep often interact and negatively affect each other and improvements of sleep are involved in the recovery from persistent pain.⁵ Therefore, sleep could be an important outcome marker in the effectiveness of treatment of persistent pain.

Chronic pain is quite common in renal hemodialysis patients. However, although the direct sleep-pain relationship remains uncertain, its chronicity may precede and precipitate poor sleep quality.⁶⁻⁷

When pain increased most patients perceived a worsening of sleep. Conversely, reduced pain improved sleep in half of the patients.⁸ Nearly one third of patients perceived pain to worsen with poorer sleep and better sleep was perceived to reduce pain. Pain was the symptom with the largest impact on sleep.⁹ The same observation was found in subjects with rheumatoid arthritis, supporting an impact of partial sleep deprivation on pain severity.¹⁰ The presence of bodily pain increased the risk for insomnia.¹¹

However, there are still consistent discussions about the cause-and-effect relationships in the deleterious mechanisms of pain on the quality of sleep and its effective restoration, or sleep quality in the perception of pain.¹²⁻¹⁴

So, finding new treatments for insomnia is an important task. Traditional Chinese medicine is clinically valued in recent years due to its low side effects and good efficacy, and has unique advantages in the treatment of insomnia.¹⁵ Study shows the existence of insomnia in hemodialysis patients and their respective improvement when using integrative practices, including aromatherapy.⁸

Acupuncture is a health intervention technique that can be used alone or integrated with other therapeutic resources. Originating from Traditional Chinese Medicine, it consists

of the precise stimulation of anatomical sites, utilizing the insertion of metallic wire needles for therapeutic purposes such as reduction of anxiety and depression, chronic pain relief, stress reduction, improvement of sleep, and decreased insomnia are some of the expected effects of acupressure intervention.¹⁶

A systematic review of new studies sought to analyze the effects of acupuncture application techniques on periodic kidney patients. Significant benefits were identified in quality of life, reduced fatigue and better sleep quality indices compared to baseline.¹⁷ The technique is simple, non-toxic, and low cost, making it a good therapeutic resource for intervention in insomnia.¹⁸ Therefore, the question is: what is the effect of auriculoacupuncture on the quality of sleep of chronic kidney disease patients on hemodialysis?

The objective of this study is to analyze the effect of auricular acupuncture on the quality of sleep of hemodialysis patients with chronic pain in a capital in the Northeast of Brazil.

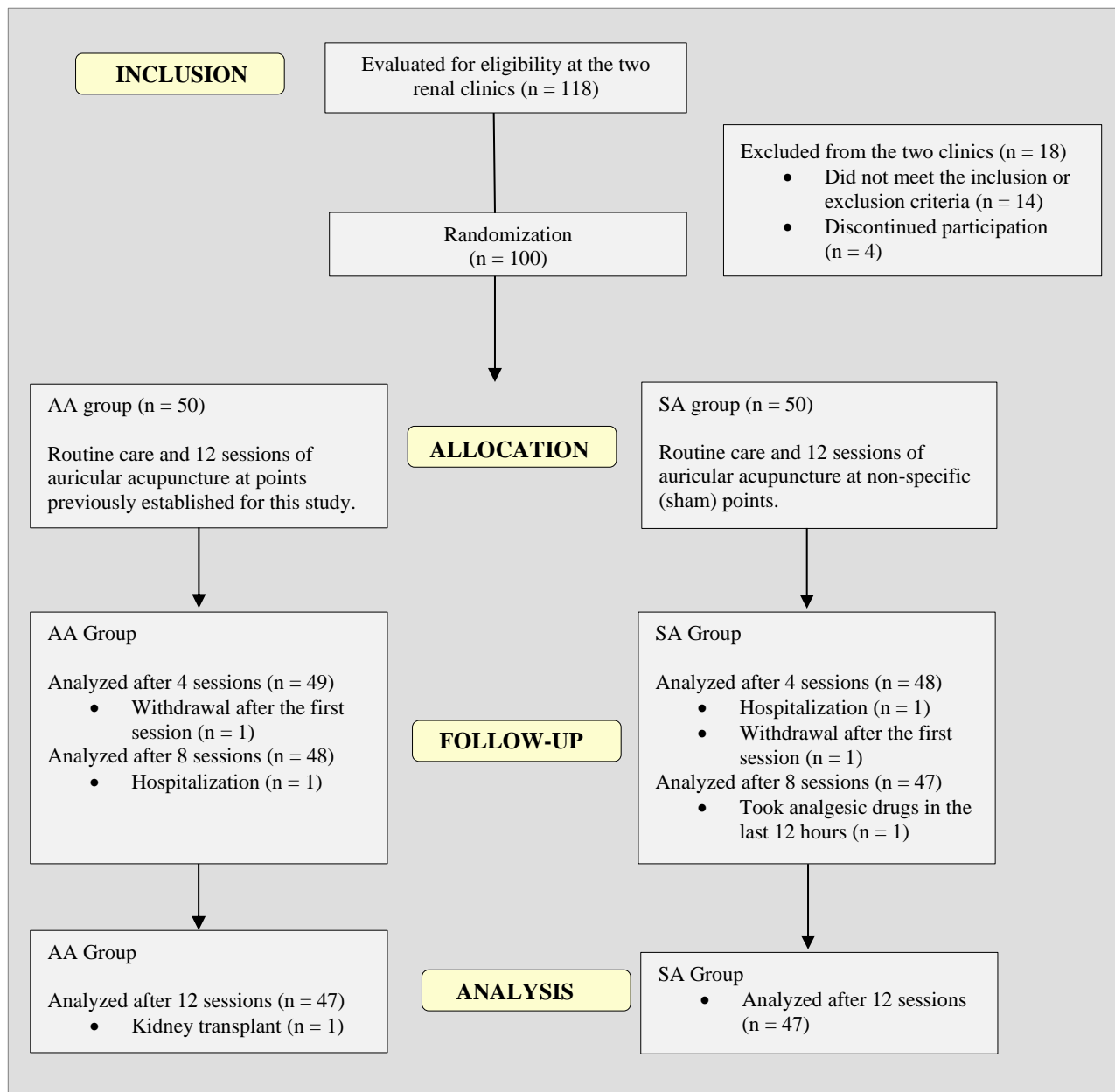
MATERIALS AND METHODS

A double-blind, randomized, controlled trial was conducted with renal patients on hemodialysis with chronic pain. This study followed the Consolidated Standards of Reporting Trial (CONSORT) and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines for designing and reporting controlled trials and was registered on the Brazilian Registry of Clinical Trials (REBEC), under number: RBR:3cpwwt, under opinion number: 2,583,162.

The population consisted of chronic renal patients undergoing hemodialysis, registered in two hemodialysis clinics, and recruited by convenience sampling. Inclusion criteria: age between 25 and 75 years, being on dialysis therapy for more than one year, having a self-perception of insomnia, and who could understand and speak Portuguese. The exclusion criteria were infection, inflammation, or injury to the pinna, other contraindications to auricular acupuncture, such as allergy to crystal or microporous tape, hearing impairment or psychiatric illness, having been treated with energy therapy until three months prior to admission to the trial, continuous use of opioids, and being pregnant. Next, it details the stages of participant recruitment (Figure 1).



Figure 1. Flowchart. Fortaleza, Ceará, 2019.



Patients were randomized in blocks.²¹ The distinct groups (AA and SA) were composed of weekdays; that is, one group was composed of patients who did dialysis on Mondays, Wednesdays, and Fridays in Clinic 2; and the other group was composed of patients who attended Clinic 1 on Tuesday, Thursday, and Saturday, defined through a draw by the Research Randomizer software (www.randomizer.org).

Thus, the study was composed of two groups, allocated at a rate of 1:1. One group was treated with AA at specific points, while the other was treated with AA at non-specific points (SA).

Treatment consisted of twelve sessions were performed using the pre-established protocol, once a week for three months in the AA group using a fixed-point prescription based on the

Auricular Protocol for Pain & Anxiety (APPA) in the points: Shenmen, Sympathetic Autonomic, Thalamus, Zero Point or Muscle Relaxation, and Suprarenal or Tranquilizer.²²

Immediately before the intervention, patients completed a visual analog scale (VAS) for pain, which consists of a ruler with a scale of 0 to 10 being the worst pain ever experienced by the subject and the self-report measure was administered at these time points: pre-clinical interview or baseline (BL), after four sessions (S4), after eight sessions (S8), and after 12 sessions (S12). The selected acupuncture points were based on the APPA protocol (Auricular Protocol for Pain & Anxiety), in the SA group, 12 acupuncture sessions were performed using non-specific points, also called placebo (or sham) points, once a week for three consecutive months.



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The assessment instruments were applied in the following time points: pre-clinical interview or baseline (BL), after four sessions (S4), after eight sessions (S8), and after 12 sessions (S12). Nine Helix points (HX 5-9) were used in this group.

The acupuncture session for both AA and SA were performed in the chair where the patient was undergoing a dialysis session. It should be clarified that the selected points were easily accessed with the patient in the sitting position.

As indicated in the pre-established protocol, first, the acupuncturist introduced himself to the patient and explained the procedure and all participants provided written informed consent. Ear exposure was requested to clean the pinna with 70% alcohol, and then crystal spheres (neutral spheres) were applied to the selected points. The 2.0 mm diameter spheres are sold with 1.0 cm × 1.0 cm micropore adhesives. The crystal sphere features a rounded shape, a smooth surface, and has a white to transparent color. Each sphere is fixated in the patient's ear with micropore adhesives. Patients were instructed to keep the spheres until the next session and to self-apply acupressure on each auricular point three times a day, throughout the week, with massage for three to five seconds at each point.

Sleep was measured using the Pittsburg Sleep Quality Index (PSQI).² The 19 questions of the questionnaire are categorized into seven components: (C1) subjective sleep quality, (C2) sleep latency, (C3) sleep duration, (C4) habitual sleep efficiency, (C5) sleep disorders, (C6) use of sleep medications, and (C7) daytime sleep dysfunction. Each rated on a scale of zero to three with the same weight, where the “three” reflects the negative extreme of the Likert-type scale. The sum of the values attributed to the seven components of the PSQI varies from zero to 21, indicating that the higher the score, the worse the sleep quality. Scores between 0 - 4,9 indicate good sleep quality, between 5 - 10,9 poor sleep quality, and greater than 10, sleep disorder.³

Two scholarship students collected data from August 2018 to August 2019. Data were double-checked and analyzed in four different time intervals (at baseline, after four, eight, and twelve sessions). The statistical analysis was performed using SPSS® (Statistical Package for the Social Sciences) version 23.

Descriptive statistical measures of 50% percentiles (median), maximum and minimum of the quantitative variables

were calculated. Before performing the statistical tests, scatter plots were drawn. The normality of the variables was verified by the Shapiro-Wilk test and the homogeneity by the Levene test.

Afterward, bivariate analytical statistics were used in the intersection of the different variables, using statistical tests according to the type of variable. The paired t-test was used to test for associations between variables that met the criteria of normality and homogeneity, and Wilcoxon tests were used for those that did not meet these characteristics among the numerical variables (the four intervention moments and the two control and intervention groups). An analysis of variance (ANOVA) for repeated measures was used to compare PSQI measures over time between the groups. The statistical significance level of 5% was considered in all tests.

RESULTS

There was a predominance of males (SA: 53.2% - 25; AA: 57.4% - 27), with an average age of 55 years (SA) and 57 years (AA), married (SA: 61.7% - 29; AA: 46.8% - 22), the majority declared being religious (SA: 87,2% - 41; AA: 89,3% - 42). The years of education ranged from zero to 24 years, with a mean of 12 years in the SA group and nine years in the AA group. Regarding income, Average monthly economic income is less than R\$ 2.000,00, equivalent to less than 400 dollars per month.

The duration of dialysis treatment ranged from one to 32 years, with an average of three years for SA and five years for AA. Most patients had an arteriovenous fistula as the access route (SA: 85.1% - 40; A: 80.9% - 38); were hypertensive at the beginning of the treatment, and had hypertension (associated or not with diabetes) as their major underlying disease (SA: 80.8% - 38; AA: 82.9% - 39).

In S12, presented statistical significance intergroup the data of the components: (C1, SA: 1.48; AA: 0.57, $p < 0.001$), sleep latency (C2, SA: 1.21; AA: 0.87, $p = 0.027$), sleep duration (C3, SA: 1.25; AA: 0.85, $p = 0.020$), sleep disorders (C5, SA: 1.21; AA: 0.87, $p = 0.027$), use of sleep medication (C6, SA: 0.82; AA: 0.51, $p = 0.036$), and daytime sleep dysfunction (C7, SA: 1.25; AA: 0.63, $p < 0.001$) the comparisons statistically relevant between the SA and AA groups denotes an improvement in the sleep quality index in the AA group at the end of the interventions (Table 1).



Table 1. Comparison between the Pittsburgh Sleep Quality Index classification in the SA and AA groups at baseline, S4, S8, and S12 (n = 94). Fortaleza, Brazil, 2019.

PSQI components	Baseline		S4		S8		S12	
	Mean (SD)*		Mean (SD)*		Mean (SD)*		Mean (SD)*	
	SA	AA	SA	AA	SA	AA	SA	AA
Subjective sleep quality (C1)	1.82 (0.89)	2.53 (0.71)	1.59 (0.99)	1.76 (0.75)	1.48 (0.43)	1.21 (0.83)	1.48 (0.97)	0.57 (0.58)
	p < 0.001		p = 0.353		p = 0.143		p < 0.001	
Sleep latency (C2)	1.23 (1.18)	1.80 (0.74)	1.42 (1.24)	1.40 (0.68)	1.21 (0.95)	1.04 (0.55)	1.21 (0.95)	0.87 (0.39)
	p = 0.006		p = 0.918		p = 0.293		p = 0.027	
Sleep duration (C3)	1.40 (1.01)	1.42 (1.03)	1.40 (0.97)	1.14 (0.85)	1.27 (0.90)	0.97 (0.79)	1.25 (0.92)	0.85 (0.72)
	p = 0.920		p = 0.180		p = 0.093		p = 0.020	
Sleep efficiency (C4)	0.10 (0.37)	0.06 (0.24)	0.10 (0.31)	0.02 (0.14)	0.06 (0.34)	0.02 (0.12)	0.06 (0.27)	0.02 (0.12)
	p = 0.518		p = 0.093		p = 0.312		p = 0.312	
Sleep disturbance (C5)	1.23 (1.18)	1.80 (0.74)	1.42 (1.24)	1.40 (0.68)	1.21 (0.95)	1.04 (0.55)	1.21 (0.95)	0.87 (0.39)
	p = 0.006		p = 0.918		p = 0.292		p = 0.026	
Use of hypnotic medications (C6)	1.00 (1.00)	2.21 (0.74)	1.00 (1.00)	1.53 (0.54)	0.82 (0.78)	0.89 (0.75)	0.82 (0.78)	0.51 (0.65)
	p < 0.001		p = 0.002		p = 0.690		p = 0.036	
Daytime dysfunction (C7)	1.19 (1.01)	1.87 (0.74)	1.36 (0.96)	1.38 (0.70)	1.25 (0.76)	0.87 (0.57)	1.25 (0.76)	0.63 (0.52)
	p < 0.001		p = 0.903		p = 0.007		p < 0.001	
Global PSQI score	8.23 (246)	11.80 (2.02)	8.40 (2.50)	8.70 (2.23)	7.87 (1.83)	6.10 (2.00)	7.89 (1.90)	4.46 (1.63)
	p < 0.001		p = 0.545		p < 0.001		p < 0.001	

Paired student's t-test.

The intervention had an 83% influence on the improvement of sleep quality in the intervention group (AA) compared to the control group (SA) at the end of 12 sessions,

measured by the PSQI. The linear regression analysis showed a statistically significant improvement ($F = 109.1$, $p < 0.00$), Table 2.

Table 2. Linear regression models of the Sleep Quality Index measured by PSQI between groups AA and SA at baseline, S4, S8, and S12 (n = 94). Fortaleza, Brazil, 2019.

Model	R ²	Adjusted R ²	Sum square	df*	Mean square	F [‡]	p [§]
PSQI score	Regression	0.83	0.82	19.522	4	4.881	109.1 < 0.001
	Residue			3.978	89	0.045	
	Total			23.500	93		

Note: *degrees of freedom, ‡strength; §significance test (p-value) referring to the calculation of the ANOVA test.

The intragroup analysis of the AA group showed an improvement in the mean sleep quality index at S12, which translates into a 62.20% improvement in the PSQI.

Thus, the intervention improves the subjective sleep rating. A high magnitude of the effect of AA on the sleep quality index was observed in patients at the end of 12 sessions ($D = -1.94$), Table 3.



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Table 3. Comparison of sleep quality means at the baseline, S4, S8, and S12 for AA and SA groups (n = 94). Fortaleza, Brazil, 2019.

Variables	AA group (n = 47)		SA group (n = 47)		Cohen's d*
	Mean	SD [‡]	Mean	SD [‡]	
Baseline	11.80	2.02	8.23	2.46	1.59
After 4 sessions of AA (S4 [¶])	8.70	2.23	8.40	2.50	0.12
After 8 sessions of AA (S8 ^{††})	6.10	2.00	7.87	1.83	- 0.92
After 12 sessions of AA (S12 ^{‡‡})	4.46	1.63	7.89	1.90	- 1.94

Note: *D Cohen test to measure the magnitude of the intervention effect; ‡standard deviation; §Analogic visual scale; ¶after four sessions of auricular acupuncture; ††after eight sessions of auricular acupuncture; ‡‡after 12 sessions of auricular acupuncture.

DISCUSSION

Thus, in this study, the APPA protocol was used in sleep management, an unusual way of applying this protocol. But, the findings of this study show that auricular acupuncture based on this protocol can improve the sleep quality of hemodialysis patients with chronic pain, as almost all PSQI components improved in the AA group (intervention).

Regarding the improvement in the pattern and quality of sleep, promising results were achieved in other similar studies, such as in a randomized controlled study that compared AA and SA for eight weeks, with stimulation of the Shenmen, Sympathetic Autonomic, Subcortex, Heart and Endocrine points in 63 patients on hemodialysis, in that study, observed that overall PSQI scores dropped by 3.75 ± 4.36 (95% CI - 5.32, - 2.18) in the AA group.²³

The response rate of the AA group was almost twice as high as that of the SA group (62.5% vs. 32.3%). The overall PSQI score decreased over time in both the AA group ($F = 8.47$, $p < 0.01$) and the SA group ($F = 4.09$, $p < 0.01$), with significant statistics in two of the seven evaluated domains ($p < 0.001$). Research evidence supported the use of acupuncture as an effective treatment to improve symptoms of insomnia. Compared with conventional Western medicine, acupuncture may be more effective in decreasing PSQI score.²⁴

A systematic review with meta-analysis involving 13 studies and 968 patients determined the effectiveness of acupuncture on sleep disorders. The study showed no statistical differences between acupressure modes (hands-on, auto-acupressure, or wristband), acupuncture points (ear, hands, feet, or other parts of the body), or age (adults and people older than 65 years). Furthermore, the review showed that traditional Chinese acupuncture resulted in an overall 13 - 19% improvement in PSQI scores compared to controls.²⁵

Regarding hemodialysis patients, the object of this research, a study with 48 Iranians undergoing renal hemodialysis therapy, has tested the use of an acupressure protocol at the Shenmen (C-7), He Gu (IG 4), and Sanyingjiao (BP 6) points, three times a week, for four consecutive weeks, administered one hour after starting hemodialysis.

The findings of the study mentioned above showed that the therapy improved overall sleep quality ($p < 0.001$) and specific sleep quality indices, such as subjective quality ($p < 0.001$), latency ($p < 0.001$), duration ($p < 0.001$), efficiency ($p = 0.006$), sleep disorders ($p < 0.001$), use of sleep medications ($p = 0.028$) and daytime dysfunction ($p < 0.001$).²⁶

Past research has provided evidence of the effectiveness of auricular acupuncture at specific ear acupoints on insomnia in a hemodialysis unit. For four weeks, 22 patients received AA and were evaluated using the PSQI.

The mean global PSQI score decreased significantly after the intervention ($p < 0.05$), and the participants reported an improved sleep quality ($p < 0.01$), lower sleep latency ($p < 0.05$), less sleep disturbance ($p < 0.01$), and less daytime dysfunction ($p = 0.01$). Furthermore, it was possible to evidence less dependency on sleep medications indicated by a reduction in the weekly estazolam consumption from 6.98 ± 4.44 pills to 4.23 ± 2.66 pills ($p < 0.01$).²⁷ Unfortunately, the reduction in the use of sleeping pill has not been evaluated.

It is observed that our study findings align with those of previous studies carried out in similar populations, confirming the positive effects of AA on sleep quality in hemodialysis patients. The therapeutic effects and mechanisms of different acupuncture techniques for CKD patients, acupuncture improves renal function, reduces proteinuria, controls hypertension, corrects anemia, relieves pain, and controls many hemodialysis-related to the regulation of sympathetic nerve and the activation of bioactive chemicals.²⁸ In conclusion, acupuncture is proved to be beneficial for CKD patients.

Some limitations of the present study include: the loss of patients during follow-up due to hospitalizations due to clinical complications or acute conditions, decreasing the sample during the study, the use of analgesics 24 hours before treatment, as treatment was discontinued because it was an exclusion criterion. New studies should be carried out to monitor the maintenance of sleep quality with polysomnography (PSG) and the use of standardized doses of medications used by patients using hypnotics.



CONCLUSION

Auricular acupuncture over a period of 12 weeks significantly improved the sleep quality of hemodialysis patients, considering the individual components of the PSQI, the usual efficiency on the last day of treatment and the overall PSQI score. Thus, AA is a good strategy, providing comfort to the patient and improving their quality of life.

INTEREST CONFLICTS

The authors declare that there is no conflict of interest in carrying out this work.

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