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Meta-analysis of ear acupoint therapy to treat sleep disorders in hemodialysis patients

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Author contributions

The design of the study was discussed and completed by all authors. The study was carried out by Wang Min, Li Jianlin and Shi Yu. Li Jianlin, Qin Yu, and Huang Jianfang performed auxiliary work for the study. Wang Min wrote the paper, and Shi Yu reviewed the paper.

Competing interests

The authors declare no conflicts of interest.

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Peer review information

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Abbreviations

HD, hemodialysis; ESKD, end-stage kidney disease; RCTs, randomized controlled trials; PSQI, Pittsburgh Sleep Quality Index; MD, mean difference; CI, confidence interval; SD, standard deviation.

Citation

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Abstract

Background: To evaluate the therapeutic effect of auricular therapy on sleep disorders in hemodialysis patients using meta-analysis methods, and to provide evidence-based support for clinical practice. **Methods:** PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database, China Journal Full-text Database, Chinese Science and Technology Journal Full-text Database, and Wanfang Resource Database were searched up to February 2023. Randomized controlled trials of auricular therapy for sleep disorders in hemodialysis patients were collected and included in the study. Meta-analysis was performed using RevMan 5.3 software. **Results:** 587 patients from 7 randomized controlled trial studies were included. The auricular therapy group had better sleep conditions than the conventional care group, as evaluated by the Pittsburgh Sleep Quality Index, in terms of total Pittsburgh Sleep Quality Index score (mean difference (MD) = –5.11, 95% confidence interval (CI) (–5.25, –4.96), $P < 0.00001$), subjective sleep quality (MD = –0.64, 95% CI (–0.72, –0.56), $P < 0.00001$), falling asleep time (MD = –0.37, 95% CI (–0.49, –0.26), $P < 0.00001$), sleep time (MD = –0.38, 95% CI (0.44, –0.32), $P < 0.00001$), sleep efficiency (MD = –0.15, 95% CI (–0.23, –0.07), $P < 0.0001$), sleep disturbances (MD = –0.18, 95% CI (–0.28, –0.09), $P = 0.0002$), daytime dysfunction (MD = –0.89, 95% CI (–1.18, –0.6), $P < 0.00001$), and hypnotic medication (MD = –0.22, 95% CI (–0.4, –0.03), $P = 0.02$). **Conclusion:** Auricular therapy is an effective method for improving sleep quality in hemodialysis patients, providing evidence-based support for clinical practice.

Keywords: hemodialysis; auricular therapy; insomnia; sleep; randomized controlled trial; meta-analysis

Introduction

Hemodialysis (HD) is the primary treatment method for patients with end-stage kidney disease (ESKD) [1]. The number of ESKD patients in China has exceeded 1.5 million, and it continues to grow rapidly at a rate of 100,000 to 150,000 per year. According to World Health Organization statistics, the global population of HD patients has reached 2.519 million [2, 3]. The survival rate of ESKD patients has improved due to advancements in HD technology. However, the intermittent nature of the treatment causes toxins and hemodynamics to remain in a relatively unstable state. This instability and high toxin levels directly impact the sleep quality of patients, which is why sleep disorders are more prevalent among dialysis patients compared to healthy individuals. Various factors contribute to sleep disorders in ESKD patients. Research suggests that ESKD-induced pharyngeal constriction can result in obstructive sleep apnea, and hypercapnia in some patients can disrupt ventilatory control due to increased ventilatory sensitivity. Restless leg syndrome, which may be caused by iron deficiency, electrolyte imbalances, and diabetes, can also contribute to sleep disorders [4–7].

The prevalence of sleep disorders in HD patients is reported to be as high as 84.5% [8]. Currently, psychotherapy, lifestyle adjustments, and medications are the main treatments for sleep disorders in HD patients [9]. In traditional Chinese medicine, China has a long history of applying meridian theory. It is believed that the ear is the gathering point of the meridians, where all twelve meridians of the human body converge. The *Jing-yue's Complete Works* (Ming dynasties) that insomnia originates from Yin (in Chinese philosophy, the female, latent, passive principle, characterized by dark, cold, wetness, passivity, disintegration, etc.) and that a calm mind leads to peaceful sleep, while restlessness leads to sleeplessness. Therefore, the Shenmen (TF_4), Pizhixia (AT_4), Xin (CO_{15}), Jiaogan (AH_{6a}), Shen (CO_{10}) acupoint is chosen to calm the mind. The stimulation of the skin can modulate the excitatory and inhibitory functions of the cerebral cortex, replenish Qi (Qi refers to the basic substance that constitutes the human body and maintains life activities, and is the unity of substance and function), and calm nerves. Both are main acupoints for treating insomnia. Ear point therapy, derived from auricular acupuncture, involves the use of needles, pills, magnetic beads, and electrical stimulation at specific points on the outer ear [10].

Ear point therapy is a purely physical therapy that is easy to implement, long-lasting, and inexpensive. It is not limited by time and place, making it an effective treatment for sleep disorders in HD patients [6]. In Chinese medicine, auricular point therapy is also known as the "pressing or burying seeds method". It involves using small seeds, pills, magnetic beads, or other hard objects (such as vicariate seeds) to apply pressure on specific ear acupoints. The procedure involves attaching the pressing pill to the acupoints and applying appropriate pressure. Generally, the acupoints are pressed 3–5 times a day, including once before sleeping, for 1–3 minutes each time. The treatment duration is typically 1–2 months [11]. However, there has been limited recent research on the effectiveness of ear point therapy, and the advantages and disadvantages of this method compared to conventional measures have not been thoroughly examined. In this study, we conducted a systematic review to compare ear point therapy with conventional measures. The findings revealed that the sleep quality of the ear acupoint therapy group was superior to that of the conventional care group, providing evidence for the use of this method in treating sleep disorders among HD patients.

Materials and methods

Inclusion and exclusion criteria

The following inclusion criteria were applied in this study: (1) study type: randomized controlled trials (RCTs) investigating the efficacy of ear acupoint therapy in improving sleep disorders among patients undergoing continuous HD, regardless of blinding; (2) study subjects: patients receiving maintenance HD who met the diagnostic criteria for insomnia; (3) intervention measures: the intervention group received ear acupoint therapy, while the control group received conventional treatment; (4) outcome measures: the Pittsburgh Sleep Quality Index (PSQI), a self-administered questionnaire assessing sleep quality and disturbances over a one-month period, was used to evaluate the outcome. The PSQI comprises seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The total score derived from these components indicates the presence of sleep disorders. For the assessment of sleep disorders, we selected patients with a PSQI total score of $n = 23$ or a higher score [12, 13].

The exclusion criteria for this study were as follows: (1) studies with unclear or unavailable data and essential materials; (2) duplicate studies.

Literature search strategy

A comprehensive search was conducted across multiple databases, including Web of Science, Embase, PubMed, Cochrane Library, Chinese Biomedical Database, Wanfang Data, Chinese Science and Technology Periodicals database, and China National Knowledge Infrastructure, from their inception to April 30, 2023. The search terms used included hemodialysis, haemodialysis, hemofiltration, haemofiltration, hemodiafiltration, haemodiafiltration, dialysis, sleep, insomnia, wakeful, sleepless, early awakening, auricular, acupressure, acupoint, auriculotherapy, randomized, randomly, controlled, placebo, and trial. Additionally, we manually searched the references of eligible studies to identify any additional relevant research.

Information extraction

The articles were categorized and organized, and duplicate records were removed. The titles and abstracts of the remaining articles were screened according to the predefined inclusion and exclusion criteria to exclude irrelevant studies. Subsequently, the full texts of the potentially relevant articles were obtained and assessed to determine if they met the inclusion criteria in terms of study theme, research design, outcome indicators, and other relevant factors. This process was conducted by two researchers, and any discrepancies were resolved through discussion or consultation with a third reviewer. The following information was extracted from the included studies: author information, total sample size, duration of the study, research location, details of the intervention measures, and outcome indicators.

Study quality evaluation

Two researchers independently assessed and graded the risk of bias in the included studies using the Cochrane RoB 2.0 [14] tool for randomized controlled trials. The evaluation criteria included randomization methods, allocation concealment, blinding, handling of incomplete data, and selective reporting. Based on these criteria, the studies were classified into three categories: class A, representing studies with the lowest risk of bias that fully met the criteria; class B, representing studies that partially met the criteria and had a moderate risk of bias; and class C, representing studies that did not meet the criteria and had a high risk of bias. The researchers evaluated the quality of each study based on the assessment criteria and reached a consensus through discussion. Any disagreements were resolved through further discussion.

Statistical analysis

The meta-analysis was performed using RevMan 5.3 software. Heterogeneity among the included studies was assessed using the I^2 statistic and the significance level (P-value). A low heterogeneity was considered if I^2 was less than 50% and the P-value was greater than 0.1, indicating that the studies had similar results and could be pooled using the random effects model. Sensitivity analyses were conducted to explore potential sources of heterogeneity, and if identified, those studies were removed from the analysis. The funnel plot method was employed to assess publication bias, where a symmetric funnel plot with scattered points distributed within the funnel indicated a low possibility of publication bias. Conversely, if the funnel plot was

asymmetric, publication bias might be present. If the *P*-value was less than or equal to 0.1 and the source of heterogeneity could not be identified, a meta-analysis was not conducted, and a descriptive analysis was used instead. For continuous data, such as PSQI scores, if the same measurement tool was used across the studies, the weighted mean difference (MD) was calculated along with the corresponding 95% confidence interval (CI). However, if different measurement tools were used, the standardized mean difference was utilized for the analysis.

Results

Search results

Initially, 550 articles were retrieved; 220 duplicate studies were excluded; after reading the titles and abstracts, 75 articles that were non-RCTs or that used other treatment measures were excluded. After reviewing the full texts of the remaining studies, 38 articles that did not use the desired outcome indicators were excluded, resulting in a final total of 7 included articles [15–21] Chinese literature. The study selection process is shown in Figure 1.

Basic characteristics of included studies

The meta-analysis included a total of 7 randomized controlled trials [15–21] involving 587 patients. These studies were published from the inception of the library until April 2023. Among the included studies, 6 studies comparing auricular acupoint therapy and conventional treatment, 1 studies comparing auricular acupoint therapy and drug therapy. Each study employed clear diagnostic criteria, which are summarized in Table 1.

Quality evaluation of included literature

The risk of bias in the included studies was assessed and graded by two researchers using the scoring standards of Cochrane RoB 2.0 [14]. For the randomization process, one article [15] did not provide sufficient information about how the randomization was conducted, resulting in an indeterminate judgment. Regarding the selection of the reported result, five articles [16, 17, 19–21] did not provide information on the selection process, also leading to an indeterminate

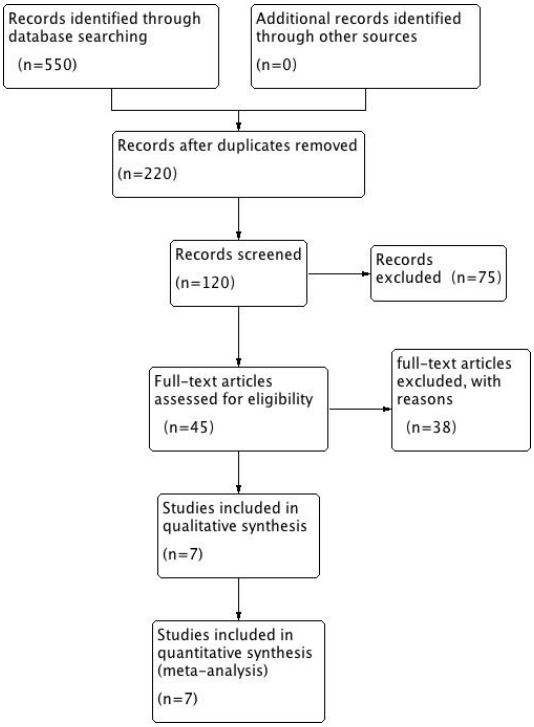

Figure 1 Flow chart of study selection process

Table 1 Characteristics of the included studies

Researcher	Country	Sample size		Intervention method		Period	Evaluation
		Experimental group	Control group	Experimental group	Control group		
Gao Yun (2017)	China	30	30	Earacupoint therapy	Conventional treatment	2 weeks	PSQI
Li Aiyun (2019)	China	40	40	Earacupoint therapy	Conventional treatment	4 weeks	PSQI
Li Xiaoping (2015)	China	45	45	Earacupoint therapy	Conventional treatment	20 day	PSQI
Wu Yuchi (2022)	China	63	69	Earacupoint therapy	On sham auricular acupressure	20 weeks	PSQI
Yang Guang (2016)	China	41	41	Earacupoint therapy	Conventional treatment	4 weeks	PSQI
Zheng Qinghai (2014)	China	40	40	Estazolam and earacupoint therapy	Estazolam	8 weeks	PSQI
Zou Cuan (2015)	China	32	31	Earacupoint therapy	On sham auricular acupressure	8 weeks	PSQI

PSQI, Pittsburgh Sleep Quality Index.

judgment. However, overall, the risk assessment results of the included studies suggest a low risk of bias, as depicted in Figure 2.

Meta-analysis results

The meta-analysis of the 7 included articles [15–21], which investigated the effect of ear acupoint therapy on the total PSQI score of 587 HD patients, revealed heterogeneity among the studies (I^2 = 96%, P < 0.00001). Therefore, a random effects model was utilized for analysis. HD patients in the ear acupoint therapy group had lower total PSQI scores than patients in the control group (MD = –5.11, 95% CI (–5.25, –4.96), Z = 68.91, P < 0.00001), as shown in Figure 3; lower PSQI scores indicate better sleep quality. Sensitivity analysis revealed one study was a source of heterogeneity [19]; after rerunning the analyses with the remaining 6 studies [15–18, 21], no significant heterogeneity was observed (I^2 = 14%, P = 0.32). Therefore, a fixed effects model was used and revealed that the total PSQI score of HD patients was still lower after ear acupoint therapy, and sleep disorders were significantly improved (MD = –2.26, 95% CI (–2.78, –1.75), Z = 8.66, P < 0.00001), consistent with the results of the analysis of all 8 studies

Effect of auricular point therapy on the subjective sleep quality of HD patients

A total of 5 papers [15–17, 19, 20] reported the effect of ear acupoint therapy on the subjective sleep quality of 392 HD patients. There was heterogeneity among the studies (I^2 = 85%, P < 0.0001). The random effects model was used for analysis. HD patients undergoing ear acupoint therapy had lower subjective sleep quality scores than patients in the control group, indicating better sleep quality (MD = –0.64, 95% CI (–0.72, –0.56), Z = 16.25, P < 0.00001) (Figure 4). Sensitivity analysis revealed that one study was a source of heterogeneity [16]; after rerunning the analyses on the remaining 4 studies [15, 17, 19, 20], no significant heterogeneity was observed (I^2 = 0%, P = 0.45). Therefore, a fixed effects model was used and revealed that HD patients in the ear acupoint therapy group still had lower subjective sleep quality scores than patients in the control group, indicating better sleep quality (MD = –0.7, 95% CI (–0.78, –0.62), Z = 16.98, P < 0.00001).

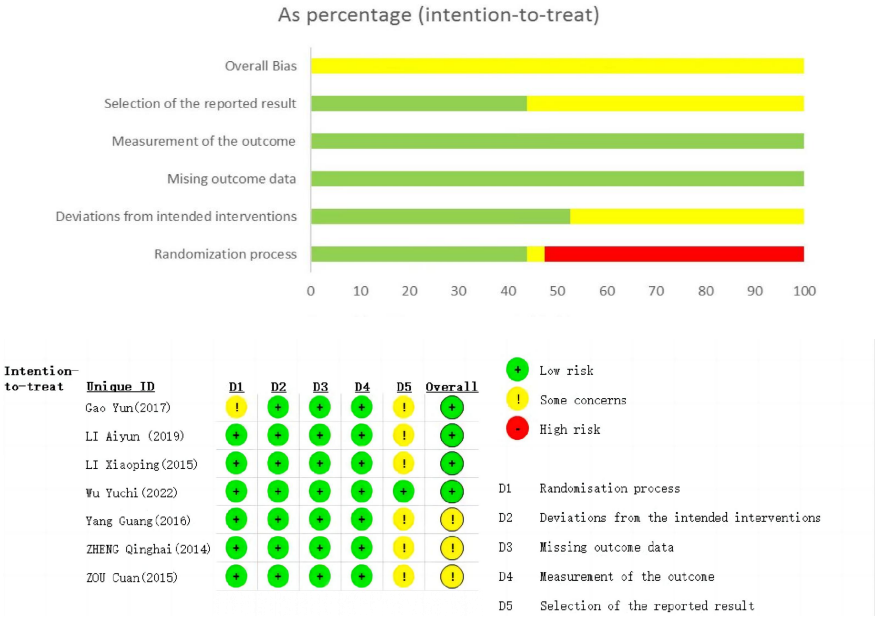

Figure 2 Risk of bias summary

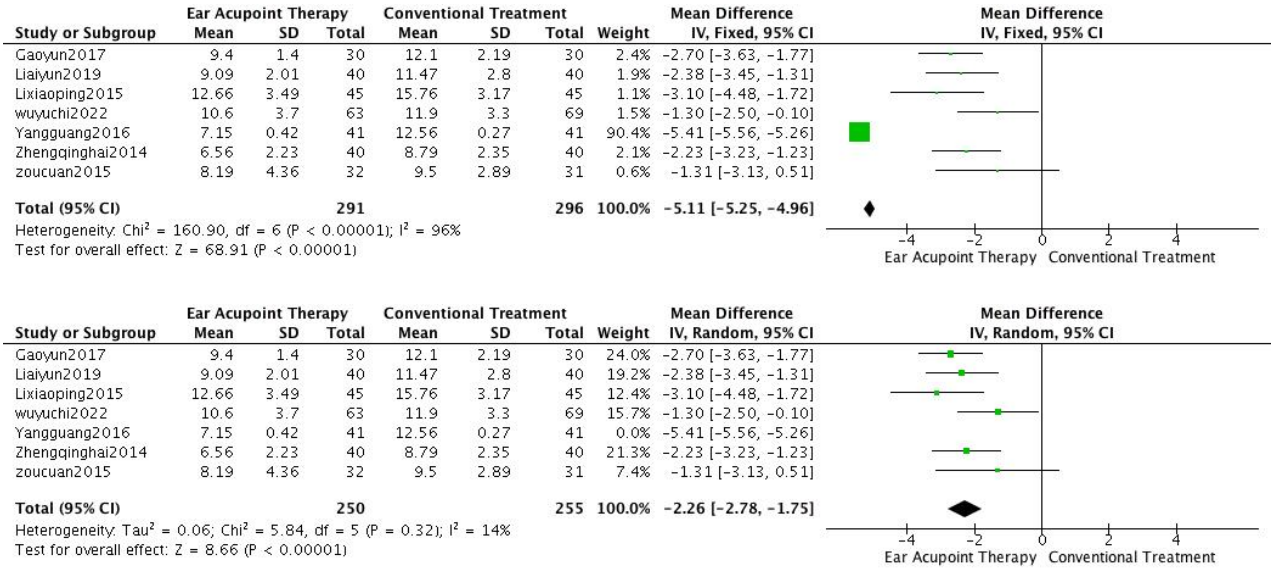

Figure 3 The meta-analysis of total PSQI scores. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

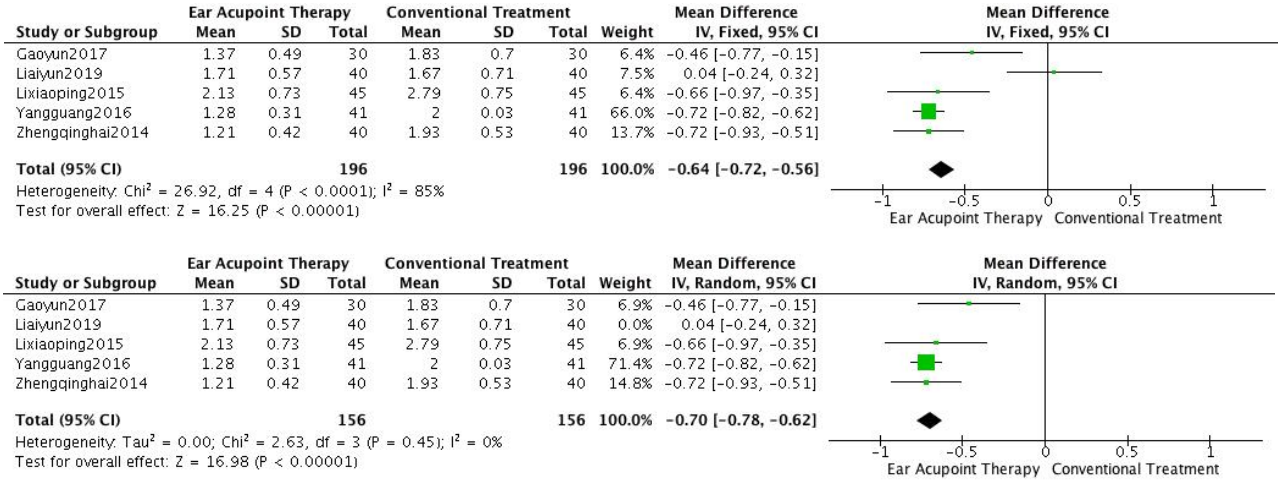

Figure 4 The meta-analysis of PSQI subjective sleep quality. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

Effect of auricular point therapy on the sleep time of HD patients

A total of 5 articles [15–17, 19, 20] investigated the effect of ear acupoint therapy on sleep time in 392 HD patients. Heterogeneity was present among the studies (I^2 = 89%, P < 0.00001). Using a random effects model, HD patients undergoing ear point therapy were found to have lower sleep time scores than patients in the control group, indicating longer sleep time (MD = –0.38, 95% CI (–0.44, –0.32), Z = 12.24, P < 0.00001) (Figure 5). Sensitivity analysis revealed two source of heterogeneity [17, 19]; after reanalyzing the remaining 3 studies [15, 16, 20], no significant heterogeneity was observed (I^2 = 0%, P = 0.44). Therefore, a fixed effects model was used and revealed that HD patients undergoing ear point therapy were still found to have lower sleep time scores than patients in the control group, indicating longer sleep time (MD = –0.64, 95% CI (–0.76, –0.52), Z = 10.78, P < 0.00001).

Effect of auricular point therapy on time to fall asleep in HD patients

A total of 5 papers [15–17, 19, 20] assessed the effect of ear acupuncture therapy on the time to fall asleep in 392 HD patients. The studies exhibited heterogeneity (I^2 = 68%, P = 0.01). Using a random effects model, HD patients undergoing ear point therapy were found to have lower falling asleep scores than patients in the control group, indicating faster falling asleep times (MD = –0.37, 95% CI (–0.49, –0.26), Z = 6.27, P < 0.00001) (Figure 6). Sensitivity analysis revealed 2 source of heterogeneity [15, 16]; after reanalyzing the remaining 3 studies [17, 19, 20], no significant heterogeneity was observed (I^2 = 0%, P = 0.65). Therefore, a fixed effects model was used and revealed that HD patients undergoing ear point therapy were found to have lower falling asleep scores than patients in the control group, indicating faster falling asleep times (MD = –0.88, 95% CI (–1.14, –0.62), Z = 6.66, P < 0.00001).

Effect of auricular point therapy on sleep efficiency in HD patients

A total of 5 articles [15–17, 19, 20] reported the effect of ear acupoint therapy on sleep efficiency in 392 HD patients. Heterogeneity was observed among the studies (I^2 = 93%, P < 0.00001). The random effects model was used, and it revealed that HD patients undergoing ear point therapy had lower sleep efficiency scores compared to patients in the control group, indicating higher sleep efficiency (MD = –0.15, 95% CI (–0.23, –0.07), Z = 3.6, P < 0.0001) (Figure 7). Sensitivity analysis identified 1 sources of heterogeneity [16]. After reanalyzing the remaining four studies [15, 17, 19, 20], no significant heterogeneity was observed (I^2 = 0%, P = 0.86). Using a fixed effects model, the results indicated that HD patients undergoing ear point therapy had lower sleep efficiency scores compared to patients in the control group, suggesting higher sleep efficiency (MD = –0.6, 95% CI (–0.75, –0.46), Z = 8.14, P < 0.00001).

Effect of auricular point therapy on sleep disorders of HD patients

A total of 5 articles [15–17, 19, 20] reported the effect of ear acupoint therapy on sleep disorders in 392 HD patients. Heterogeneity was observed among the studies (I^2 = 90%, P < 0.00001). The random effects model was used, indicating that HD patients undergoing ear point therapy had lower sleep disorder scores compared to patients in the control group, suggesting a reduction in sleep disorders (MD = –0.08, 95% CI (–0.14, –0.02), Z = 2.56, P = 0.01) (Figure 8). Sensitivity analysis revealed one sources of heterogeneity [19]. After reanalyzing the remaining four studies [15–17, 20], no significant heterogeneity was observed (I^2 = 0%, P = 0.71). Using a fixed effects model, the results showed that HD patients undergoing ear point therapy had lower sleep disorder scores compared to patients in the control group, indicating a reduction in sleep disorders (MD = –0.4, 95% CI (–0.51, –0.28), Z = 6.58, P < 0.00001).

Effect of auricular point therapy on daytime function of HD patients

A total of 5 articles [15–17, 19, 20] reported the effect of ear acupoint therapy on the daytime function of 392 HD patients, and there was no significant heterogeneity among the studies (I^2 = 47%, P = 0.11). Using a fixed effects model, the results showed that HD patients undergoing ear point therapy had lower daytime function scores than patients in the control group, indicating higher daytime function (MD = –0.89, 95% CI (–1.18, –0.6), Z = 6.09, P < 0.00001), as depicted in Figure 9.

Effect of auricular point therapy on hypnotics in HD patients

A total of 2 articles [16, 17] reported the effect of ear acupoint therapy on the use of hypnotic drugs in 170 HD patients. There was no significant heterogeneity among the studies (I^2 = 17%, P = 0.27), and thus, the fixed effects model was used. The results showed that HD patients undergoing ear point therapy had lower hypnotic drug scores than patients in the control group, indicating reduced dependence on hypnotic drugs. Ear acupoint therapy was found to reduce patients' reliance on hypnotic drugs (MD = –0.22, 95% CI (–0.4, 0.03), Z = 2.33, P = 0.02), as shown in Figure 10.

Discussion

Sleep disorders are a prevalent complication among maintenance HD patients, significantly impacting their quality of life and potentially leading to depression and suicidal tendencies [22]. In Chinese

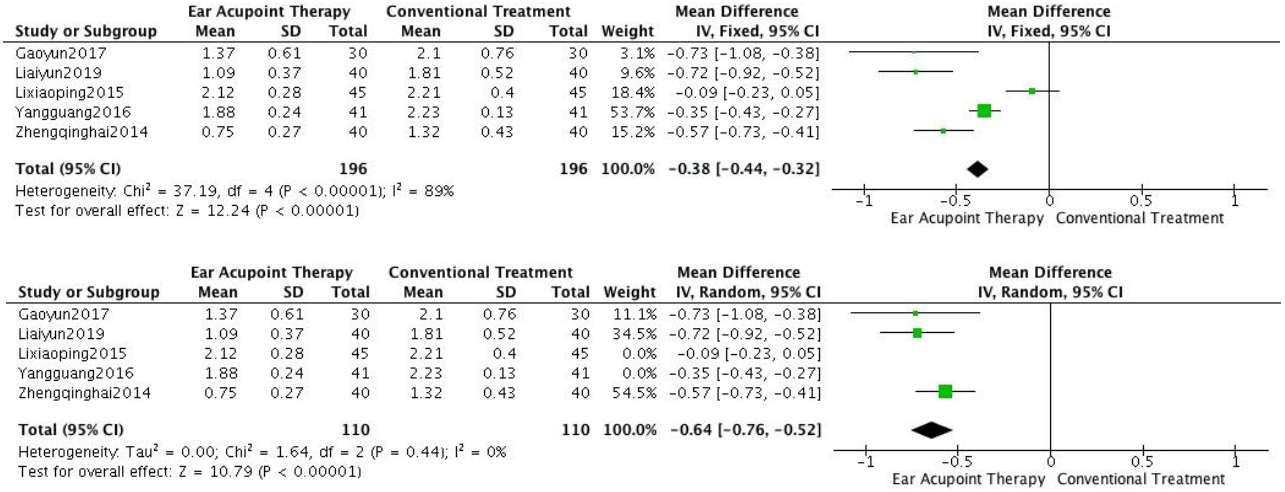

Figure 5 The meta-analysis of PSQI sleep time. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

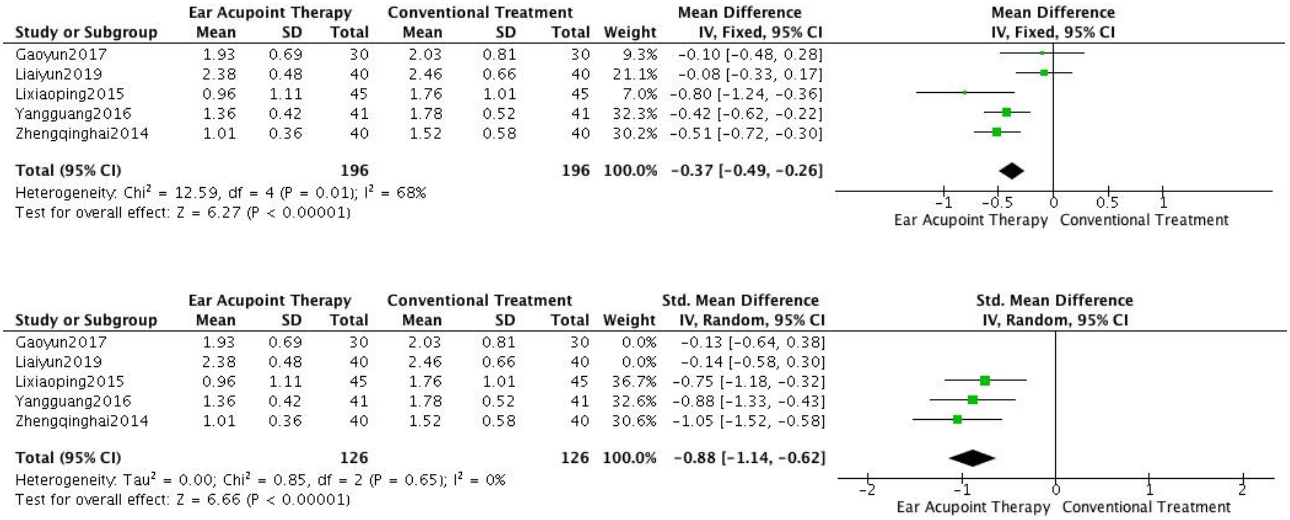

Figure 6 The meta-analysis of PSQI falling asleep time. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

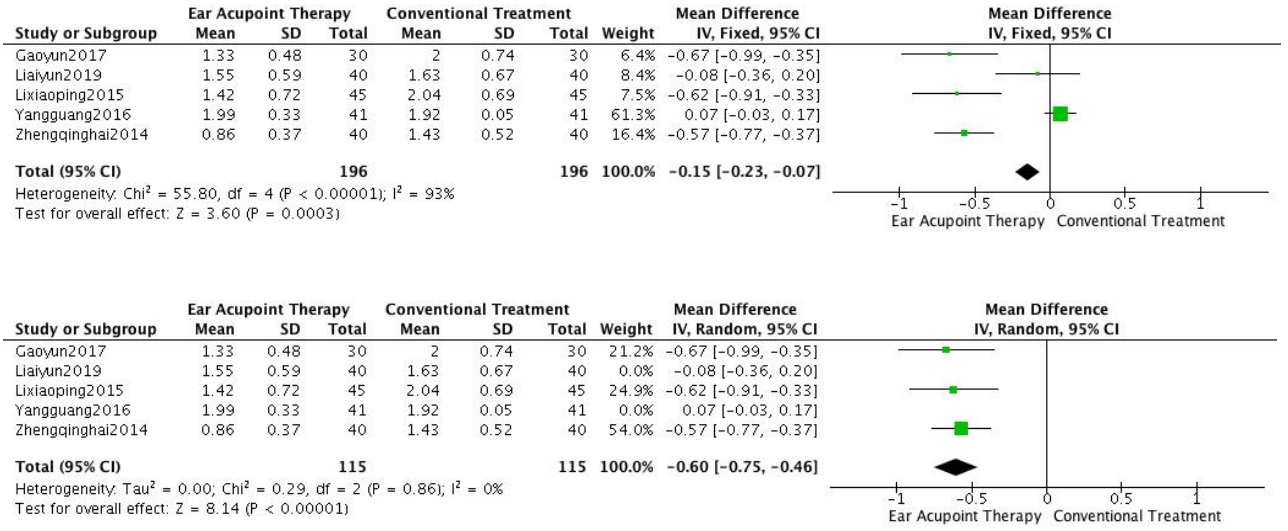

Figure 7 The meta-analysis of PSQI sleep efficiency. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

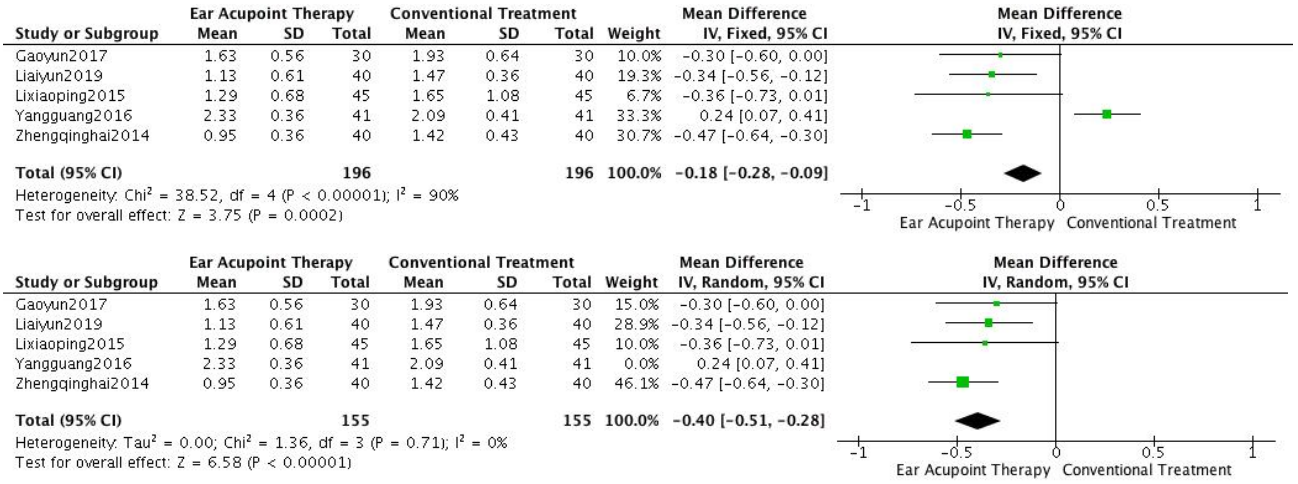

Figure 8 The meta-analysis of PSQI sleep disorders. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

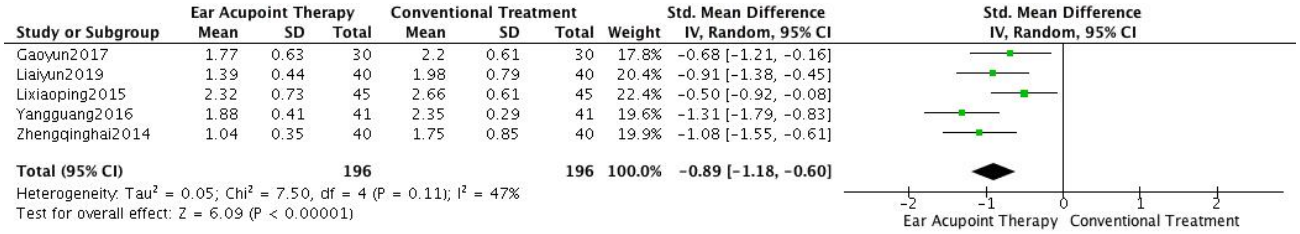

Figure 9 The meta-analysis of PSQI daytime function. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

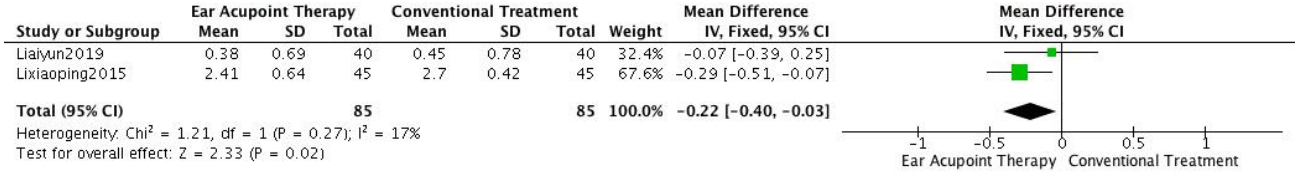

Figure 10 The meta-analysis of PSQI hypnotic drug. PSQI, Pittsburgh Sleep Quality Index; CI, confidence interval; SD, standard deviation.

medicine, sleep disorders are referred to as sleeplessness, insomnia, restless eyes, and vivid dreams. These disorders are believed to stem from an imbalance of body Yin and Yang (in Chinese philosophy, the masculine, active and positive principle, characterized by light, warmth, dryness, activity, etc.), where Yang fails to enter the Yin, resulting in sleeplessness. Furthermore, sleep disorders are associated with the heart, spleen, liver, kidney, and insufficient Yin and blood [23–26].

Ear acupuncture therapy is a technique that involves stimulating specific points on the ear to produce pressure and stimulate neurasthenia and deep sleep. This stimulation excites corresponding nerve receptors and sensory nerve endings, and upward impulses regulate the cerebral cortex. This process helps to restore the normal physiological sleep rhythm and improve sleep disorders in HD patients [10].

The Chinese version of the PSQI was utilized as an assessment tool for sleep disorders in all 7 studies analyzed. Lower scores on the PSQI indicated improved sleep disorders. Meta-integration of these studies revealed that HD patients who underwent auriculotherapy demonstrated better scores across various sub-dimensions of the PSQI compared to those receiving conventional treatment or drug control measures. These improvements were observed in subjective sleep quality, sleep onset time, sleep duration, sleep efficiency, sleep disorders, use of hypnotic drugs, and daytime dysfunction. The most commonly stimulated ear acupuncture points were the TF_4, AT_4, CO_{15}, AH_{6a}, CO_{10} acupoints. By applying pressure to these specific areas, auriculotherapy helps restore the normal physiological sleep rhythm and alleviate sleep disorders in HD patients.

Conclusion

The meta-analysis demonstrates that ear acupoint therapy is significantly more effective than conventional treatment in improving sleep disorders among HD patients, providing valuable evidence for clinical practice. However, there are several limitations in this study that should be acknowledged. Firstly, the inclusion of only 7 studies with a total of 587 cases results in a relatively small sample size. Secondly, the majority of the studies were single-center studies, with only one study being multicenter, which may limit the generalizability of the findings. Thirdly, the original studies primarily focused on short-term efficacy, while the long-term effectiveness of ear acupoint therapy requires further exploration. Lastly, the overall quality of the included articles was assessed as moderate, indicating the need for high-quality clinical randomized controlled trials to strengthen the evidence base. HD patients with sleep disorders often resort to oral hypnotic drugs. However, studies have indicated that frequent use of sleeping pills may contribute to higher mortality rates in dialysis patients. In contrast, multiple studies have confirmed that ear acupoint therapy, specifically applying pressure to specific ear points, is cost-effective and easy to administer. The results of this study also demonstrate that ear acupoint therapy can effectively improve sleep disorders in HD patients while reducing their dependence on sleeping drugs. These findings provide a solid evidence-based foundation for its application in clinical practice.

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