Ear Apex Bloodletting Combined with Kai Tianmen for Improving Insomnia in Maintenance Hemodialysis Patients: A Clinical Study Postprint

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Abstract

Objective: To observe the clinical efficacy of ear apex bloodletting combined with Kai Tianmen in improving refractory insomnia in hemodialysis patients. Methods: 120 maintenance hemodialysis patients with insomnia were randomly divided into an observation group and a control group, with 60 cases in each group. The control group was treated with conventional Western medicine estazolam tablets, while the observation group, based on the control group's medication, was treated with ear apex bloodletting combined with Kai Tianmen, 3 times per week for 4 weeks. After the treatment course, the Pittsburgh Sleep Quality Index (PSQI) was used to comprehensively evaluate patients' sleep quality. Results: 6 patients (2 in the control group, 4 in the observation group) dropped out, and 114 subjects were finally included (58 in the control group, 56 in the observation group). Comparison of sleep quality scores between the two groups before intervention showed no statistically significant difference ($P > 0.05$); after intervention, PQSI scores in both groups decreased compared with before intervention, and the observation group's PQSI score was lower than that of the control group, with a statistically significant difference ($P < 0.01$). Comprehensive evaluation of treatment effect showed that the observation group's efficacy was superior to that of the control group, with a statistically significant difference ($P < 0.01$). Conclusion: Ear apex bloodletting combined with Kai Tianmen therapy is superior to Western medicine alone, can significantly improve sleep disorders and enhance sleep quality in hemodialysis patients, and has no adverse reactions during treatment, warranting further clinical promotion and application.

Full Text

Clinical Study of Ear-Tip Bloodletting Combined with Kaitianmen for Insomnia in Maintenance Hemodialysis Patients

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Abstract

Objective: To observe the clinical efficacy of ear-tip bloodletting combined with Kaitianmen in improving refractory insomnia among hemodialysis patients.

Methods: A total of [number] maintenance hemodialysis patients with insomnia were randomly divided into an observation group and a control group, with [number] cases in each group. The control group received conventional western medicine treatment with estazolam tablets, while the observation group received ear-tip bloodletting combined with Kaitianmen in addition to the conventional medication, administered three times per week for [number] weeks. After the treatment course, sleep quality was comprehensively evaluated using the Pittsburgh Sleep Quality Index (PSQI).

Results: [Number] patients ([number] from the control group and [number] from the observation group) dropped out, leaving a final cohort of [number] participants ([number] in the control group and [number] in the observation group). There was no statistically significant difference in baseline sleep quality scores between the two groups ($P > 0.05$). After intervention, PSQI scores decreased in both groups, with the observation group's scores significantly lower than those of the control group ($P < 0.05$). Comprehensive efficacy evaluation showed that the observation group's therapeutic effect was superior to that of the control group, with a statistically significant difference ($P < 0.05$). The combined therapy was superior to conventional western medicine alone in significantly improving sleep disorders and enhancing sleep quality in hemodialysis patients, with no adverse reactions observed during treatment.

Conclusion: Ear-tip bloodletting combined with Kaitianmen can significantly improve insomnia symptoms in maintenance hemodialysis patients, demonstrating better efficacy than conventional medication alone. This approach is safe, well-tolerated, and warrants broader clinical application.

Keywords: bloodletting therapy; hemodialysis; Kaitianmen; insomnia; Traditional Chinese Medicine nursing

1. Materials and Methods

1.1 Study Design and Participants This prospective randomized controlled study was conducted among maintenance hemodialysis patients treated at the Department of Nephrology, Zhongshan Hospital of Traditional Chinese Medicine between [month] and [month] 2023. The diagnostic criteria for insomnia followed the "Chinese Classification and Diagnostic Criteria of Mental Disorders, 3rd Edition" (CCMD-3). Inclusion criteria comprised: (1) maintenance hemodialysis patients aged 18-75 years with dialysis vintage > 3 months; (2) clear consciousness, stable condition, normal sensory and cognitive function, and ability to complete questionnaires; (3) presence of sleep disorders identified by PSQI screening (score > 7); (4) tolerance to the interventions; and (5) informed consent. Exclusion criteria included: (1) skin trauma, rash, or ulceration at treatment sites; (2) coagulation dysfunction; and (3) severe cardiac, cerebral, or hepatic disease, or pregnancy/lactation. Dropout criteria comprised: (1) non-compliance with treatment protocol; (2) significant confounding factors affecting efficacy or safety assessment; or (3) incomplete data affecting outcome evaluation.

Among [number] hemodialysis patients in our center, [number] eligible participants were enrolled using convenience sampling and randomly allocated to two groups using statistical software (JMTJFX), with [number] cases in each group. During the study, [number] patients ([number] from the control group and [number] from the observation group) dropped out due to changes in dialysis centers or clinical deterioration (unrelated to the study), leaving [number] participants for final analysis ([number] in the control group and [number] in the observation group). Baseline characteristics including gender, age, dialysis vintage, primary disease, and initial PSQI scores were comparable between groups ($P > 0.05$) (Table 1). The study was approved by the Medical Ethics Committee of Zhongshan Hospital of Traditional Chinese Medicine (Approval No.: ZSZY-LLK-[number]), and all participants provided informed consent.

1.2 Interventions **Control Group:** Received conventional western medicine treatment with estazolam tablets (Shandong Xinyi Pharmaceutical Co., Ltd., batch number: [number]), 1 mg/tablet, taken orally at bedtime (1 mg per dose) as prescribed by physicians and administered by nurses.

Observation Group: Received ear-tip bloodletting combined with Kaitianmen therapy in addition to the conventional medication. The combined therapy was administered three times weekly for [number] weeks (total of [number] treatment courses).

Ear-tip Bloodletting Procedure: The patient's unilateral ear was massaged to induce congestion, then disinfected with 75% ethanol at the ear apex. The practitioner stabilized the ear helix with the left hand and performed rapid pricking with a three-edged needle at a depth of 1-2 mm. Dry cotton balls were applied to the puncture site. In case of needle fainting, the procedure

was immediately stopped; the patient was placed in supine position, pressure was applied to Renzhong (GV26), moxibustion was applied at Baihui (GV20), and warm water was administered to alleviate symptoms. Local bruising was managed with warm compresses, and anti-infection treatment was provided if indicated.

Kaitianmen Procedure: Patients assumed a comfortable position. Using appropriate pressure and techniques, the practitioner: (1) pushed upward with the thumb from Yintang (GV29) to Xing point 30 times; (2) pushed from Yintang to Touwei (ST8) 30 times; (3) pushed from Cuanzhu (BL2) to Sizhukong (TE23) 30 times bilaterally; (4) performed combing motions at Taiyang (EX-HN5) 30 times; (5) tapped from Yintang to Baihui (GV20) 30 times with crossed hands and bent middle fingers; (6) kneaded Taiyang points clockwise and counterclockwise 10 circles each; (7) gently patted from Taiyang to forehead and vertex for 3 minutes; and (8) kneaded and grasped Fengchi (GB20) and Jianjing (GB21) 10 times each. Pressure was adjusted according to patient tolerance, and any discomfort was promptly reported to physicians.

1.3 Outcome Measures Sleep Quality: Assessed using the Pittsburgh Sleep Quality Index (PSQI) before and after intervention. The PSQI is a validated tool for evaluating multiple sleep disorders, comprising 19 self-rated and 5 clinician-rated items that generate 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, and daytime dysfunction. Each component is scored 0-3, with total scores ranging from 0-21; higher scores indicate poorer sleep quality. A PSQI score > 7 has demonstrated good sensitivity and specificity for identifying sleep disorders in Chinese populations.

Efficacy Evaluation: Based on the "Diagnostic Criteria for Traditional Chinese Medicine Syndromes" and "Clinical Research Guidelines for New Chinese Medicines in Treating Insomnia," comprehensive efficacy was categorized as: (1) **Cured:** Normal sleep duration or $ $6 hours of nocturnal sleep with restored sleep depth; (2) **Markedly Effective:** Significant improvement with $ $3 hours increase in nocturnal sleep; (3) **Effective:** Symptomatic improvement with <3 hours increase in sleep duration; (4) **Ineffective:** No significant improvement.

1.4 Statistical Analysis SPSS software was used for statistical analysis. Descriptive statistics summarized baseline characteristics. Measurement data were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$) and compared using t-tests. Count data were expressed as percentages or composition ratios and compared using ^{2} tests. Ranked data were analyzed using Mann-Whitney U test. Statistical significance was set at $\alpha = 0.05$.

2. Results

2.1 Sleep Quality Comparison There was no statistically significant difference in baseline PSQI scores between the two groups ($P > 0.05$). After intervention, PSQI scores decreased significantly in both groups, with the observation group's scores lower than the control group's ($P < 0.05$) (Table 2).

2.2 Comprehensive Efficacy Comparison Post-intervention efficacy evaluation using Mann-Whitney U test showed that the observation group's therapeutic effect was superior to the control group's, with a statistically significant difference ($P < 0.05$) (Table 3).

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3. Discussion

Maintenance hemodialysis, as the most mature renal replacement therapy, can ameliorate some symptoms of end-stage renal disease but cannot fully replace renal endocrine functions, leading to complications such as anemia, renal osteodystrophy, cardiovascular and neurological disorders, and distressing symptoms including sleep disturbances and pruritus. Insomnia, the most prevalent sleep disorder, represents a subjective experience of insufficient sleep duration and/or quality that impairs daytime functioning. Research indicates that insomnia is a risk factor for multiple dialysis complications, with chronic sleep deprivation increasing morbidity across organ systems, particularly cardiovascular and immune dysfunction, and serving as an independent predictor of mortality and hospitalization rates, severely impacting patients' self-care capacity and quality of life. Current management primarily relies on sedative-hypnotic medications like estazolam, which provide temporary relief but require long-term use and carry risks of addiction, dependence, respiratory depression, and impaired daytime alertness.

In Traditional Chinese Medicine (TCM), insomnia is termed "Bumei" or "Bude Wo." Chronic kidney disease patients develop kidney yin deficiency over time, preventing kidney water from nourishing heart fire and causing heart-kidney disharmony that manifests as insomnia. Hemodialysis clears damp-heat and turbid toxins but also removes some nourishing substances, exacerbating yang deficiency and worsening insomnia with prolonged dialysis. The pathogenesis involves both deficiency (heart-spleen deficiency, gallbladder qi insufficiency, heart-kidney non-interaction, spirit malnourishment) and excess (blood stasis, phlegm-heat, liver fire) patterns, requiring treatment approaches that activate blood, soothe liver, clear heat, strengthen spleen, benefit kidneys, nourish blood, and calm fright, supplemented by spirit-quieting and heart-nourishing methods.

Ear-tip bloodletting, a common external TCM therapy, offers simplicity, convenience, efficacy, and affordability, with effects that calm wind, harmonize heart-kidney, and tranquilize the mind. Kaitianmen, a head massage technique,

provides additional soporific benefits. The head is considered the "house of intelligence" and "confluence of all yang meridians." Kaitianmen regulates organ function by stimulating head and facial meridians and acupoints, promoting smooth qi and blood flow to restore balance and tranquilize the spirit. This rhythmic stimulation dilates capillaries, increases cerebral blood flow, improves local ischemia and hypoxia, and generates action potentials that inhibit excessive cortical excitation or abnormal discharges, restoring neurological balance through feedback mechanisms. As documented in *Lingshu · Xiaozhenjie*: "For chronic stasis, remove the blood vessels," indicating that bloodletting therapy eliminates pathogenic blood, unblocks meridians, and regulates qi-blood. Modern medicine suggests bloodletting modulates blood, vascular, and neuroendocrine functions. In TCM theory, the ear gathers all meridians, with "the body's qi penetrating the ear" and "twelve meridians connecting to the ear," establishing close connections between auricular points and internal organs. The ear apex, located at the tip of the ear helix, is a specific point for treating insomnia. Ear-tip bloodletting activates blood, unblocks collaterals, harmonizes heart-kidney, and calms the spirit.

This study demonstrated that ear-tip bloodletting combined with Kaitianmen significantly improved insomnia in maintenance hemodialysis patients. With comparable baseline characteristics, the observation group's post-intervention PSQI score was ( ) points, significantly lower than the control group's ( ) points ($P < 0.05$). Comprehensive efficacy evaluation showed the observation group's total effective rate was [number]%, higher than the control group's [number]% ($P < 0.05$), indicating superior and more durable improvement in sleep quality compared with conventional medication alone.

Several mechanisms may explain these findings. First, Kaitianmen's regular stimulation of head acupoints relaxes facial muscles, improves cerebral circulation, and restores normal organ function through meridian regulation, alleviating neurological tension. Second, the combination produces synergistic effects: ear-tip bloodletting shortens sleep onset time and improves daytime mental status, while Kaitianmen addresses both root and branch aspects of insomnia. Third, the integrated therapy is particularly suitable for hemodialysis patients whose insomnia pathogenesis involves both deficiency and excess patterns.

In conclusion, ear-tip bloodletting combined with Kaitianmen is superior to conventional medication alone in improving sleep quality and daily functioning in maintenance hemodialysis patients, without adverse reactions. This cost-effective approach with minimal withdrawal effects warrants broader clinical application. However, given the limited sample size, further large-scale, multicenter, long-term randomized controlled trials are needed to confirm these findings.

Conflict of Interest Statement: The authors declare no conflicts of interest.

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Note: Figure translations are in progress. See original paper for figures.