Tropical Journal of Pharmaceutical Research April 2024; 23 (4): 761-768
ISSN: 1596-5996 (print); 1596-9827 (electronic)

Available online at http://www.tjpr.org
http://dx.doi.org/10.4314/tjpr.v23i4.12

Original Research Article

Effect of mecobalamin combined with holographic copper acupuncture and scraping technique on tinnitus symptoms in patients with sudden sensorineural hearing loss

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Sent for review: 26 September 2023 *Revised accepted: 7 April 2024*

Abstract

Purpose: *To examine the effect of methylcobalamin combined with holistic copper acupuncture and scraping technique in ameliorating tinnitus symptoms in patients with sudden sensorineural hearing loss.*
Methods: *80 patients with sudden sensorineural hearing loss from Department of Otolaryngology, The Hefei First People's Hospital, Hefei, China were selected as subjects for this study. They were divided into control and study groups, respectively, with 40 patients in each group, based on the different treatment interventions received by the patients. Conventional interventions included the use of Ginkgo biloba extract, Tianmasu injection, dexamethasone pharmacological treatments. The control group received methylphenidate tablets in addition to the conventional treatment, while the study group received further intervention comprising the combination of holistic copper acupuncture and scraping technique on the ear, in addition to the treatment received by the control group. The evaluated outcomes included efficacy, auditory threshold levels, and Pittsburgh Sleep Quality Index (PSQI) score.*
Results: *The overall efficacy of the treatment in the control group was 77.5 %, whereas, it was significantly higher in the study group at 97.5 % ($p < 0.05$). Prior to treatment, there were no significant differences in pure tone audiometry thresholds between the two groups ($p > 0.05$). However, post-treatment, the study group exhibited significantly lower pure tone audiometry thresholds compared to the control group ($p < 0.05$). Before PSQI scores were similar for the two groups ($p > 0.05$). However, after treatment, the PSQI scores in the study group were significantly lower than those in the control group ($p < 0.05$).*
Conclusion: *The combined application of methylcobalamin, holistic copper acupuncture, and scraping technique is effective for the treatment of patients with sudden sensorineural hearing loss. This integrated treatment approach significantly alleviates tinnitus and improves sleep-related symptoms in patients with sudden sensorineural hearing loss. Furthermore, it promotes the recovery of pure tone audiometry thresholds and other related parameters.*

Keywords: *Methylcobalamin, Holistic copper acupuncture, Scraping, Gua sha, Ear, Sensorineural hearing loss, Tinnitus*

Tropical Journal of Pharmaceutical Research is indexed by Science Citation Index (SciSearch), Scopus, Web of Science, Chemical Abstracts, Embase, Index Copernicus, EBSCO, African Index Medicus, JournalSeek, Journal Citation Reports/Science Edition, Directory of Open Access Journals (DOAJ), African Journal Online, Bioline International, Open-J-Gate and Pharmacy Abstracts

INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is a sudden-onset auditory disorder with complex clinical manifestations, characterized by a rapid decrease in hearing of 30 dB or more within a short period, typically lasting within three days [1]. The occurrence of SSNHL not only significantly affects the patients' auditory function but is often accompanied by uncomfortable symptoms such as tinnitus and dizziness, severely disrupting their normal lives [2]. Tinnitus, as a common accompanying symptom of SSNHL, not only intensifies the patients' suffering but may also affect their emotional state, sleep quality, and social interactions, consequently reducing their overall quality of life [3]. Currently, various clinical treatment methods for SSNHL include medication, laser therapy, and auditory rehabilitation, among others [4]. However, the efficacy of these treatments varies, and there remains a lack of a well-established and effective treatment plan. Mecobalamin, a drug known for its protective effects on the auditory system, has been widely used in the treatment of hearing loss. However, its single application in improving tinnitus and other symptoms in patients with SSNHL has shown limited efficacy [5]. Holographic copper acupuncture and scraping technique for the ear is a traditional Chinese medicine therapy that combines scraping and needling in the ear area to adjust meridians, improve blood circulation, and regulate qi and blood, aiming to alleviate symptoms related to hearing loss, including tinnitus [6]. However, there is currently limited in-depth research on the application of holographic copper acupuncture and scraping technique for the treatment of patients with SSNHL. Therefore, this study attempts to apply holographic copper acupuncture and scraping technique to the treatment of patients with SSNHL, as well as in combination with mecobalamin to determine the efficacy of this combined approach in ameliorating tinnitus symptoms in patients with SSNHL. The aim is to provide a more effective treatment plan and approach for patients with SSNHL. It is hoped that the results of this research would also offer new insights and evidence for the management of patients with SSNHL.

METHODS

Patients

Eighty patients with sudden sensorineural hearing loss admitted to the First People's Hospital of Hefei City, China from April 2022 to April 2023 were selected for this study. Basic patient profile, such as gender, age, disease duration, comorbidities, and degree of hearing loss, was obtained. The patients were divided equally into control and an study groups (n = 40) based on the treatment/intervention mode. Control group received methylcobalamin treatment on top of the use of *Ginkgo biloba* extract, Tianmasu injection, dexamethasone pharmacological treatments, while the study group received additional intervention with holistic copper acupuncture and scraping technique on top of the treatments given to control group.

Ethical matters

This study obtained approval from the Ethics Committee of First People's Hospital of Hefei City (approval no. 20220203) and was conducted in accordance with the principles outlined in the Helsinki Declaration [7]. All patients signed the informed consent forms related to the research.

Inclusion criteria

The inclusion criteria for this study are as follows: individuals aged 18 and above, who meet the clinical diagnostic criteria for sudden sensorineural hearing loss, have tinnitus symptoms (including continuous, intermittent, or pulsatile tinnitus) perceived as bothersome, and are willing to participate in the study and able to comply with the treatment intervention and follow-up requirements outlined in the study protocol. Furthermore, participants must not have any other significant auditory system disorders, such as hearing loss related to genetic diseases or tumors, severe cardiovascular diseases, liver and kidney dysfunction, malignancies, or significant internal organ diseases. They should also not have any psychiatric or cognitive disorders that would hinder full cooperation during the treatment, and should not have had any previous exposure to relevant treatment interventions.

Exclusion criteria

They include the following: participants who do not meet the age requirements specified in the study's inclusion criteria; those who have had previous exposure to relevant treatment interventions or other interventions that may affect auditory function, individuals with hearing loss related to causes other than sudden sensorineural hearing loss, such as head trauma or acute sensorineural hearing loss; those with ear problems such as ear canal infections or foreign bodies in the ear canal; pregnant or lactating women. They also include individuals

with severe cardiovascular diseases, liver and kidney dysfunction, or other significant internal organ diseases; those with severe psychiatric disorders or cognitive impairment that would hinder cooperation during the treatment; and individuals who are currently participating in other clinical trials.

Treatments

Both groups of patients received routine treatment interventions upon enrollment. Routine interventions included the use of *Ginkgo biloba* extract, Tianmasu injection, dexamethasone treatments.

Control group

Patients in the control group received oral methylcobalamin tablets (Jiangxi Qingfeng Pharmaceutical Co. Ltd, National Drug approval no. H20051440) in addition to the conventional treatment. The dosage and frequency were as follows: 0.5 mg/dose, three times a day. The treatment course lasted for 2 weeks, with a total of 2 treatment courses.

Study group

The study group received additional intervention with holistic copper acupuncture and scraping technique on top of the treatment received by the control group. The choice of medications and dosages in the early stages of treatment for the study group were consistent with those of the control group. The holistic copper acupuncture and scraping technique intervention involved several specific measures and procedures. The patient's physical condition was assessed, and the skin condition of the scraping area was examined. Based on the patient's condition, a scraping plan was determined, and the patient was guided to adjust their breathing before the intervention began. To promote overall circulation, a medium was applied around the earlobe, followed by a 1-min circular massage. The main part of the intervention consisted of a 20-min session of basic scraping from the front to the back of the ear. Additionally, specific acupoints were scraped for 5 min based on the patient's syndrome differentiation. Thereafter, there was a focus on massaging the main acupoints for an additional 3 - 5 min, while providing instructions to the patient regarding precautions during the process. Each session of the holistic copper acupuncture and scraping technique on the ear lasted approximately 30 min. The intervention was repeated over a period of 2 weeks, with a total of two treatment courses conducted.

Evaluation of parameters/outcomes

Efficacy

Cure: Patients had their hearing restored to normal, reaching a healthy level or the level before the disease, and tinnitus symptoms completely disappeared. They were assessed using a tympanometer (Grason-Stadler, USAes).

Significant improvement: Patients experienced an improvement in hearing threshold of >30 dB after treatment, with tinnitus symptoms occasionally occurring at night or in quiet environments.

Effective: Patients showed improvement in hearing threshold between 15 and 30 dB after treatment, and tinnitus symptoms were alleviated, shifting from continuous to occasional occurrences in quiet environments or remaining consistent in noisy environments.

Ineffective: Patients had an improvement in hearing threshold of <15 dB after treatment, and tinnitus symptoms showed no significant improvement or worsened.

Hearing thresholds

Pure-tone audiometry thresholds of patients were measured before and after treatment using a pure-tone audiometer (Maico, Germany). Patients were seated in a quiet hearing testing room and wore headphones or earplugs. A series of pure tones with different frequencies, gradually increasing in volume from low to high frequencies, were generated by the audio equipment. Patients pressed a button or provided verbal responses when they heard the sound, and the intensity of the sound (measured in decibels, dB) was recorded.

Pittsburgh Sleep Quality Index (PSQI)

The sleep quality of patients was assessed before and after treatment using the Pittsburgh Sleep Quality Index questionnaire (PSQI) [7]. The PSQI questionnaire includes seven items related to sleep quality, sleep onset, and other aspects. Each item is scored from 0 to 3, with a total score of 21. A higher score indicates poorer sleep quality.

Statistical analysis

Data visualization was accomplished using GraphPad Prism 8 software, while data analysis was conducted using SPSS 22.0. Quantitative

data were summarized using descriptive statistics, including mean and standard deviation, and analyzed using t-tests or analysis of variance (ANOVA), as applicable. Categorical data were described by frequency and percentages, and analyzed using chi-square tests or Fisher's exact tests. The threshold for statistical significance was set at $p < 0.05$.

RESULTS

Patients' baseline data

As Table 1 shows, the baseline data of the two groups of patients are comparable, and there were no significant differences *(p* > 0.05).

Efficacy/effectiveness

Total efficacy in the control group was 77.5 %, while for the study group, it was 97.5 %. *(p* < 0.05), as shown in Table 2.

Pure tone audiometry threshold

As shown in Figure 1, the pure tone audiometric threshold in the control group before and after treatment was 83.27 ± 6.59 and 38.52 ± 5.45), respectively, while for the study group before and after treatment, it was 83.56 ± 7.21 and 23.83 ± 4.69, respectively. Thus, after treatment, the pure tone audiometric thresholds in the study group was significantly lower than those in the control group *(p* < 0.05).

Hemorheological properties

The PV values in the control group before and after treatment are shown in Figure 2. Prior to treatment, there were no statistically significant differences in the levels of PV, WBV, RCPP, and RCAI between the two groups (*p* > 0.05). Following treatment, the study group exhibited significantly lower PV, WBV, RCPP, and RCAI values compared to the control group (*p* < 0.05).

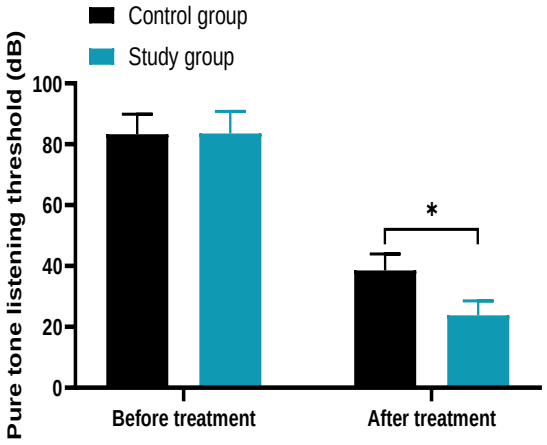

Figure 1: Comparison of pure tone audiometric threshold of the two groups. *$P < 0.05$

Table 1: Comparison of baseline data for the two groups of patients

Variable	Control (n = 40)	Study (n = 40)	t/x²	*P*-value
Gender			0.208	0.648
Male	23	25		
Female	17	15		
Mean age (years)	40.83±5.59	40.74±5.63	0.071	0.943
Mean disease duration (h)	42.85±4.69	43.11±4.58	0.250	0.802
Combined with chronic diseases			0.202	0.653
Yes	19	17		
No	21	23		
Degree of deafness			0.054	0.816
Mild	15	14		
Moderate	17	18		
Severe	8	8		

Table 2: Comparison of therapeutic effectiveness/efficacy (n = 4)

Group	Cure	Markedly effective	Efficient	Invalid	Overall efficacy
Control	7	11	13	9	77.5%
Study	14	15	10	1	97.5%
X^2	-	-	-	-	7.314
P-value	-	-	-	-	0.007

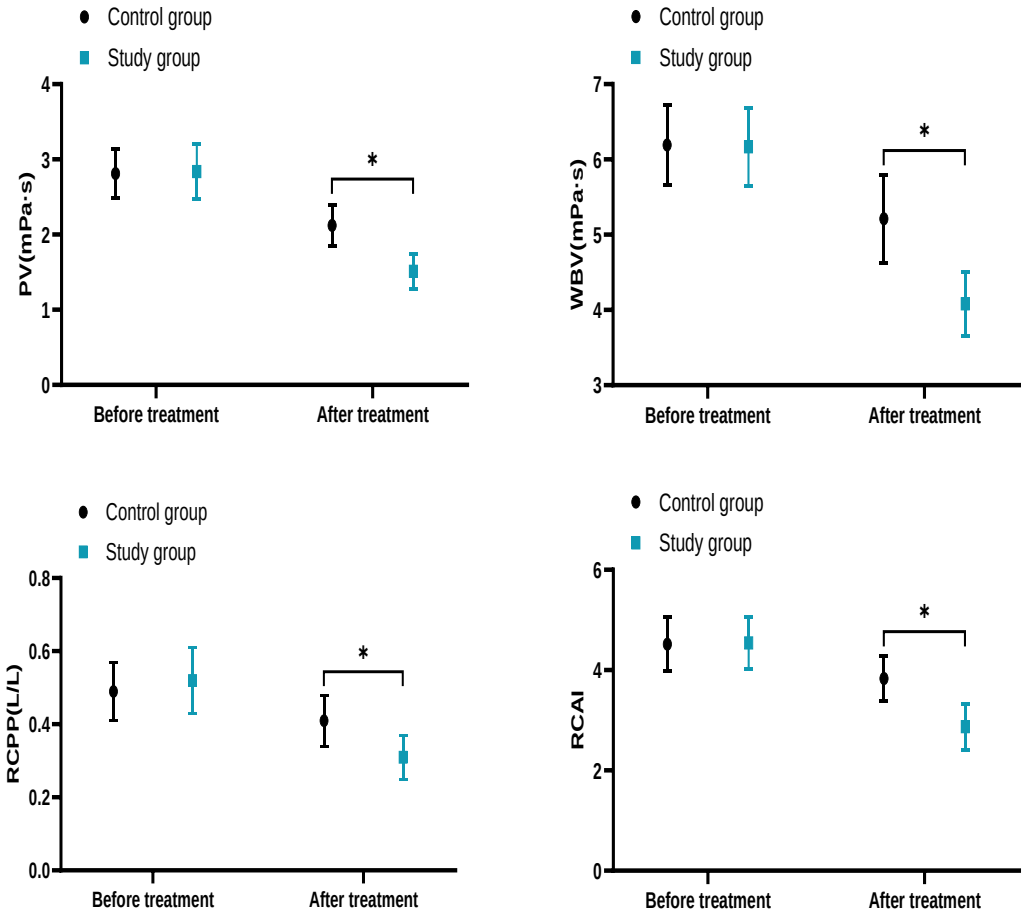

Figure 2: Comparison of hemorheological properties. of the two groups. *$P < 0.05$

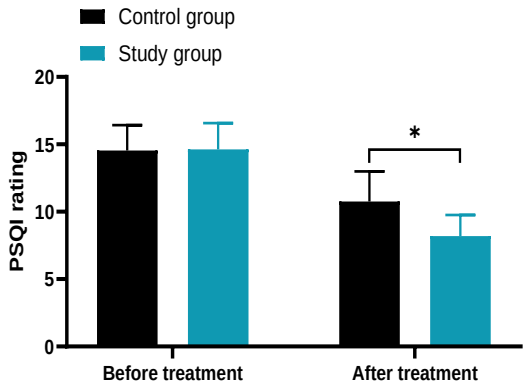

Figure 3: Comparison of Pittsburgh Sleep Quality Index (PSQI) scores for the two groups of patients. $P < 0.05$

Pittsburgh Sleep Quality Index (PSQI) scores

According to Figure 3, the PSQI scores in the control group before and after treatment were (14.54 ± 1.89) and (10.76 ± 2.23), respectively. In the study group, the PSQI scores before and after treatment were (14.63 ± 1.95) and (8.19 ± 1.56), respectively. Prior to treatment, there were no significant differences in the PSQI scores between the two groups ($p > 0.05$). However, following treatment, the PSQI score in the study group was significantly lower than that in the control group ($p < 0.05$).

DISCUSSION

Sudden sensorineural hearing loss (SSNHL) is a common emergency in otolaryngology, characterized by a rapid onset of hearing impairment without any apparent cause [4]. Previous studies [9] have shown that the pathogenesis of SSNHL is relatively complex and may be related to viral infections, vascular diseases, genetic factors, hypersensitivity reactions, and life stress. Additionally, SSNHL often manifests as unilateral hearing loss and exhibits a rapid progression. Other studies [10] have pointed out that SSNHL can lead to irreversible hearing loss, significantly impacting the patients' normal life and work, necessitating a high level of clinical attention.

Currently, the clinical treatment goals for sudden sensorineural hearing loss aim to restore patients' hearing as early as possible, alleviate symptoms such as tinnitus, and prevent further deterioration of the patient's condition. Treatment methods are often comprehensive, including medication, laser therapy, surgical intervention, and physical therapy [11]. Methylcobalamin is a commonly used medication for the treatment of sudden sensorineural hearing loss. It is an active form of vitamin B12 and has been found to repair inner ear nerve cells and damaged tissues. The mechanism of its treatment involves promoting blood circulation and metabolism in the cochlea, thus helping to protect auditory function and promote hearing recovery [13]. However, other studies suggest that the treatment duration for methylcobalamin when used alone is often long and could, therefore, lead to reduced patient compliance. Additionally, as a neurotrophic agent, its treatment effects may vary significantly among individuals [14]. Therefore, some studies recommend combining methylcobalamin with other treatment methods to further improve patient outcomes and facilitate recovery.

Holistic copper acupuncture and *scraping* therapy for the ear is based on the theory of holistic ear health and the principles of Li's copper acupuncture and scraping therapy [15]. Traditional Chinese medicine believes that the main principle of scraping therapy is to stimulate specific acupoints on the body's surface to promote the flow of *meridians* and channels, regulate the circulation of *qi* and blood, expel external pathogens, eliminate toxins, and address both the *root* and *branch* of the illness, as well as tonify deficiencies and disperse stagnation [16]. Additionally, research has confirmed that ear acupoints are closely related to various parts of the body, and the earlobe has a direct connection to internal organs via the nervous system [17]. Therefore, stimulating specific areas on the earlobe can influence corresponding internal organs through the nervous system.

Based on the findings of the present study, it is speculated that holistic copper acupuncture and scraping therapy may regulate meridians, balance organ functions, promote the circulation of qi and blood, and restore yin-yang equilibrium in the body. Hence, this study applied holistic copper acupuncture and *scraping* (*scraping*) technique in combination with methylcobalamin to treat patients with sudden sensorineural hearing loss in order to enhance therapeutic efficacy.

The results suggest that this combination is more effective in treating patients with sudden sensorineural hearing loss than methylcobalamin treatment alone. This could be due to the stimulation of catecholamine release, further generating endothelial relaxation factors, leading to vasodilation and improved blood circulation [18]. Simultaneously, the combined use of holistic copper acupuncture and scraping technique can promote the utilization of glucose and oxygen in ischemic tissues, accelerate local microcirculation, and improve inner ear microcirculation. They probably also alleviate local congestion, reduce vascular permeability, resolve edema, and accelerate the repair of damaged neural tissue. In addition, they could relieve local hypoxia and ischemia symptoms, improve clinical manifestations of ear stuffiness and tinnitus, and promote an increase in hearing levels, thereby enhancing efficacy [19]. Furthermore, body organs, limbs, and other functions are reflected in specific *reflex points* on the ear [20]. Therefore, stimulating corresponding *points* on the ear can help balance organ *yin* and *yang*, regulate organ function, and improve sleep quality.

Limitations of the study

The sample size in this study was relatively small (80 patients). This may affect the statistical power of the study and the reliability of the results. Furthermore, the study focused only on short-term treatment effects and did not address long-term outcomes or follow-up of the patients. During the study, it was observed that some nurses showed variations in the exertion of the intensity of *scraping* and the level of pressure and stimulation applied to ear acupoints. This could potentially affect the accuracy of the research.

CONCLUSION

The findings of this study indicate that the combination of methylcobalamin with holistic copper acupuncture and *scraping* technique seems to be an effective treatment approach for patients with sudden sensorineural hearing loss. This combined treatment approach addresses the limitations of using methylcobalamin alone and ameliorates symptoms such as tinnitus and poor sleep quality in patients with sudden sensorineural hearing loss. It also promotes the recovery of the patients' pure-tone audiometry thresholds. Therefore, in future research, efforts will be made to address these limitations to enhance the scientific rigor and credibility of the study.

DECLARATIONS

Acknowledgements

None provided.

Funding

None provided.

Ethical approval

This study was approved by the Ethics Committee of First People's Hospital of Hefei City (approval no. 20220203).

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them.

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