doi.org/10.36721/PJPS.2026.39.10.292.1

Comparison of therapeutic results with/without additional electroacupuncture therapy in sudden sensorineural hearing loss with anxiety or depression: A randomized controlled trial

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Abstract: **Background**: Sudden sensorineural hearing loss (SSNHL) is a medical emergency that can significantly impact patients' quality of life, often accompanied by anxiety and depression. Although pharmacotherapy is a common treatment, its effectiveness in improving both auditory and psychological outcomes remains limited. Acupuncture, especially electroacupuncture (EA), has shown potential in treating SSNHL and related affective disorders, but its adjunctive role with pharmacotherapy needs further investigation. **Objectives**: This randomized controlled trial aimed to evaluate the incremental benefits of adding EA to standard pharmacotherapy on audiological and psychological outcomes in patients with SSNHL accompanied by anxiety or depression. **Methods**: A randomized controlled trial was conducted involving 78 SSNHL patients, divided equally into two groups: P group (n=39) and EA+P group (n=39). The EA+P group received additional EA therapy for 7 days besides the pharmacological treatments. Baseline demographics, pure tone audiometric thresholds (0.25, 0.5, 1, 2, 4, 8 kHz) and psychological scores (HAMD, HAMA) were recorded. Pre-treatment and post-treatment assessments were performed to evaluate changes in hearing thresholds and mental health outcomes. **Results**: The EA+P group showed significant improvements at all frequencies ($p < 0.001$). Hearing gain was significantly greater in the EA+P group across all frequencies ($p \leq 0.044$). Besides, the EA+P group demonstrated significant reductions in HAMD and HAMA scores ($p < 0.001$), whereas the P group showed no significant changes ($p \geq 0.051$). **Conclusions**: Combined EA+P therapy significantly improves hearing recovery and reduces psychological symptom in SSNHL patients with anxiety and depression compared to drug treatment alone. This suggests a synergistic benefit of integrating acupuncture with conventional treatment.

Keywords: Electroacupuncture therapy; Pure tone audiogram; Randomized controlled trial; Sudden Sensorineural hearing loss

Submitted on 16-01-2026 – Revised on 21-03-2026 – Accepted on 27-03-2026

INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is typically defined as ≥ 30 decibels sensorineural hearing loss at 3 contiguous frequencies within a 72-hour window (Li *et al*., 2020). SSNHL has a devastating effect on a patient's daily life (Dallan *et al*., 2014). Each year, SSNHL impacts approximately 5 to 27 individuals per 100,000 population, with the United States reporting over 66,000 newly diagnosed cases annually (Alexander and Harris, 2013; Byl, 1977; Mattox and Simmons, 1977).

Despite its prevalence, the etiology of SSNHL remains elusive. For the majority of SSNHL cases, the underlying causes remain undetermined. Around 85% to 90% of such instances are classified as idiopathic. Potential etiological contributors encompass infections (particularly viral ones), autoimmune conditions, vascular blockages, disruptions in microcirculation, as well as aberrant stress reactions within the cochlea (Editorial and society of otorhinolaryngology head and neck surgery, 2015; Jeong *et al*., 2019; Atay *et al*., 2016).

Epidemiological evidence underscores a bidirectional relationship between SSNHL and affective disorders. A cohort study demonstrated that individuals with SSNHL exhibit a heightened risk of developing depression and anxiety, with incidence rates significantly exceeding those in the general population (Kim *et al*., 2018). Moreover, pre-existing depression or anxiety has been identified as a predisposing factor for SSNHL, suggesting a reciprocal pathophysiological interplay (Yeo *et al*., 2022). Quantitative analyses further reveal that SSNHL patients face a 2.2-fold increased likelihood of depression compared to non-affected individuals (Arslan *et al*., 2018). Thus, if clinicians pay more attention to the symptoms associated with anxiety and depression in SSNHL patients, this may have a positive impact on treatment (Sun *et al*., 2020).

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SSNHL is an urgent clinical condition requiring effective intervention to prevent permanent hearing impairment. Current treatment guidelines recommend glucocorticoids, such as prednisolone, as first-line treatment for SSNHL. However, the evidence for their efficacy is conflicting (Herrera *et al*., 2019). Moreover, for patients with anxiety or depression, the use of anxiolytics or antidepressants is usually accompanied by varying degrees of adverse effects, including headache, nausea, sexual dysfunction, mental acuity and memory loss and even cardiac, neurologic and hepatic side effects in severe cases (Anderson *et al*., 2012; Dodd *et al.*, 2018).

In contrast, a technique called electroacupuncture (EA), in which specific points on the body called acupoints are stimulated electrically (Wu *et al*., 2024), has emerged as a promising adjunct in SSNHL management, particularly in regions where acupuncture is culturally accepted. EA therapy has demonstrated efficacy in alleviating psychiatric symptoms like depression, anxiety and insomnia (Amorim *et al*., 2022; Xu *et al*., 2024; Zhou *et al*., 2022). Preliminary studies suggest EA therapy may enhance hearing recovery while reducing psychological distress, offering a potential dual benefit with a favorable side-effect profile compared to pharmacologic alternatives (Chang and Chan, 2017).

Although prior acupuncture and electroacupuncture studies have explored hearing recovery in SSNHL, few have systematically evaluated whether adding EA to standard pharmacological therapy yields incremental benefits on both audiological and psychological outcomes in patients with SSNHL accompanied by affective symptoms. This study specifically addresses the gap by (1) assessing the additive effect of EA on hearing thresholds across a full spectrum of frequencies during the acute 7-day period, (2) evaluating concurrent changes in anxiety and depression symptoms using validated scales.

MATERIALS AND METHODS

Participants

Based on the observed between-group difference in the primary outcome, namely the improvement in hearing threshold, from the pilot data, we conducted an a priori sample size calculation. The mean improvement was 15.56 dB in the treatment group and 5.45 dB in the control group, with a pooled standard deviation of 12.56 dB. With a two-sided significance level (α) of 0.05 and power (1 - β) of 0.90 and considering an anticipated 15% dropout rate, the required sample size was determined to be 39 participants per group.

All patients were diagnosed with SSNHL according to the American Academy of Otolaryngology-Head and Neck Surgery clinical practice guidelines. Inclusion and exclusion criteria are listed in table 1. The research protocol for this study received approval from the Ethics Committee and written consent, provided voluntarily and with full understanding, was secured from every participating patient. Recruitment period: April 15, 2024 to January 20, 2025.

Study design and interventions

This Randomized Controlled Trial was Registered with Chinese Clinical Trials Registry (Registration number: ChiCTR2400084145) on 11 May 2024. After written informed consent, a total of 78 patients were randomly allocated into two distinct groups using a computer-generated random sequence: 39 patients in the pharmacological treatment (P) group and another 39 patients in the EA therapy + pharmacological treatment (EA+P) group. For allocation concealment, sealed opaque envelopes were adopted.

P group: patients received methylprednisolone sodium succinate injection from Hanhui Pharmaceutical Co., Ltd. (80 mg/day for 3 days followed by 40 mg/day for 3 days), lidocaine hydrochloride injection from Hainan Kelun Co., Ltd.(10 mL/day for 7 days), betahistine injection from Topfond Pharmaceutical Co., Ltd. (20 mL/day for 7 days) and methylcobalamin injection from Shijiazhuang No. 4 Pharmaceutical Co., Ltd.(0.5 mg for 7 days).

EA+P group: patients received the same pharmacological treatment as the P group, with the addition of EA therapy. The electroacupuncture intervention was performed by licensed acupuncturists with more than 5 years of experience. EA: The acupuncturist performed acupuncture on specific points, including SJ17 (Yifeng, 0.5-1.0 cun depth), SJ21 (Ermen,0.5-1.0 cun depth), GB2 (Tinghui,0.5-0.8 cun depth), GB8 (Shuaigu,0.5-0.8 cun depth), LI4 (Hegu,0.5-1.0 cun depth), LR3 (Taichong,0.5-1.0 cun depth) and all needles were manipulated manually to achieve de qi. The 4 local points near the ear (SJ17, SJ21, GB2, GB8) were electrically stimulated at 2 Hz with an acupoint nerve stimulation instrument (Great Wall KWD-808). All needles were left in place for 30 minutes. The patients received 7 treatments over 7 days.

Blinding

Given that the study involved acupuncture treatment, the acupuncture operator had to be in direct contact with the patient and therefore it was not possible to blind the operator. Additionally, due to the inherent characteristics of electroacupuncture - which necessitates that patients perceive a mild electrical current - blinding the subjects themselves was not feasible. However, the study did implement blinding for other personnel involved, including those responsible for recording and inputting observational data, as well as those conducting data calculations.

Outcomes

The primary outcome was the absolute improvement in the average pure-tone audiogram after one week of treatment, as assessed by an audiologist blinded to treatment allocation.

Table 1: Inclusion and exclusion criteria

Inclusion and Exclusion Criteria
Sensorineural hearing loss of 30 dB or more covering at least three contiguous audiometric frequencies, during <3 days without specific causes
HAMD ≥ 8 points or HAMA ≥ 7 points
The hearing ability in the contralateral ear exhibits normal or nearly normal levels
Age between 18-70 years
Exclusion Criteria
Major depressive episodes or with other psychiatric disorders
Psychiatric medication such as anti-anxiety or anti-depressants within 2 weeks
Exclude retrocochlear pathology (e.g., vestibular schwannoma) will be excluded by magnetic resonance imaging.

Table 2: Demographics and baseline audiologic features of patients in the two groups.

	P group (n=39)	EA+P group (n=39)
Mean age (years)	48.49±13.08	45.36±14.63
Male/Female, n	14/25	17/22
Hearing level in each frequency (dB)		
0.25 kHz	67.31±26.33	66.41±23.40
0.5 kHz	70.00±26.71	71.03±28.57
1 kHz	70.26±26.53	68.46±28.20
2 kHz	72.69±28.26	64.10±28.14
4 kHz	69.62±27.56	62.31±30.09
8 kHz	69.10±27.48	61.15±30.03
HAMD score	22.92±8.27	23.95±7.31
HAMA score	18.08±7.50	18.59±5.19

When thresholds exceeded the measurable range of the audiometric equipment, they were documented as the maximum test level permitted by the device, which in this study was set at 120 dBHL in the present study. Hearing levels were recorded at 6 frequencies (0.25, 0.5, 1, 2, 4 and 8 kHz) before and after treatment in both groups and hearing gain was calculated.

The secondary outcome measures were the Hamilton Depression Scale (HAMD, 24-item version) and the Hamilton Anxiety Scale (HAMA), which were administered by trained raters at baseline and post-intervention to capture changes in symptom severity. Raters were blinded to participant allocation to minimise bias. The continuous scoring of the two scales accurately quantifies symptom severity over time and can be used to assess a patient's current state of anxiety and depression, with higher scores indicating greater severity.

Adverse events were actively monitored throughout the study by asking patients about any discomfort or side effects during each treatment session. Additionally, patients were instructed to report any adverse events to the study personnel immediately.

Statistical analysis

If the main outcome data of the participants are incomplete, they will be excluded from the analysis. The statistical analysis was conducted utilizing Statistic Package for Social Science (SPSS) software for the Windows operating system (Version 27.0; SPSS Inc., Chicago, IL, USA). Data are presented in the text as mean±standard deviation. To compare data between the EA and P groups, an independent samples t-test was employed. For within-group evaluations of dependent variables, parametric paired t-tests were utilized. A p-value below 0.05 was deemed to indicate statistical significance. All statistical tests performed were two-tailed.

RESULTS

A total of 78 patients with SSNHL were randomized into two groups: 39 patients in the P group and 39 patients in the EA+P group. All randomized participants were included in the final analysis. The flowcharts of each stage (i.e., enrollment, intervention allocation, follow-up, and data analysis) of the two groups of randomized trials are shown in Fig 1. A concise summary of the patients' demographics and baseline audiologic data was provided in table 2. No significant difference in age was observed between the patients in the two groups, with the EA+P group having an average age of 45.36±14.63 years and the P group having an average age of 48.49±13.08 years. Prior to treatment, across all tested frequencies in the affected ears, there were no notable differences in hearing thresholds between the two groups. Specifically, in the EA+P group, the mean hearing levels (± standard deviation) were as follows: 66.41±23.40 dB at 0.25 kHz, 71.03±28.57 dB at 0.5 kHz, 68.46±28.20 dB at 1 kHz, 64.10±28.14 dB at 2 kHz, 62.31±30.09 dB at 4 kHz and 61.15±30.03 dB at

8 kHz. Correspondingly, in the control group, the mean hearing levels (± standard deviation) were: 67.31±26.33 dB at 0.25 kHz, 70.00±26.71 dB at 0.5 kHz, 70.26±26.53 dB at 1 kHz, 72.69±28.26 dB at 2 kHz, 69.62±27.56 dB at 4 kHz and 69.10±27.48 dB at 8 kHz. In addition, the pre-treatment HAMD and HAMA scores in the p group were 22.92±8.27 and 18.08±7.50, respectively and those in the EA+P group were 23.95±7.31 and 18.59±5.19.

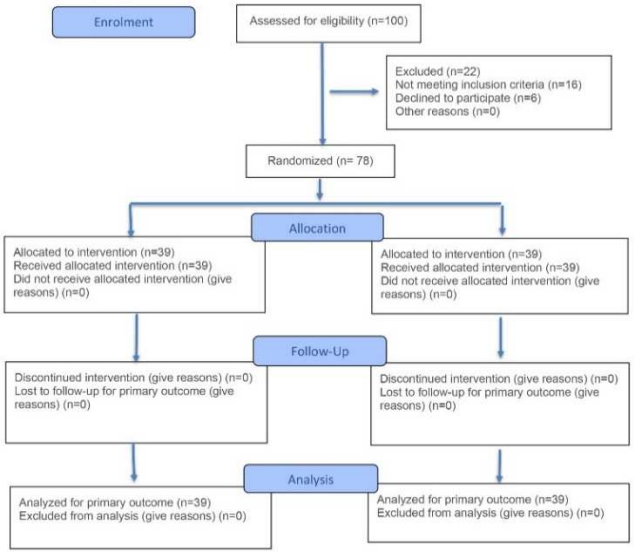

Fig. 1: CONSORT flow diagram.

All patients without any serious side effects. In the P group, significant improvements in hearing thresholds were observed at 0.25 kHz (mean difference = 5.00 dB, 95% CI [1.76,8.24], p=0.003), 1 kHz (mean difference = 4.10 dB, 95% CI [0.35,7.86], p=0.033), 2 kHz (mean difference = 7.18 dB, 95% CI [3.68,10.68], p<0.001), and 4 kHz (mean difference = 6.54 dB, 95% CI [3.34,9.74], p<0.001). However, no significant changes were found at 0.5 kHz (mean difference = 2.69 dB, 95% CI [−0.37,5.76], p=0.083) and 8 kHz (mean difference = 2.69 dB, 95% CI [−0.09,5.47], p=0.057)(As illustrated in Fig. 2). In the EA+P group, significant improvements were detected at all frequencies: 0.25 kHz (mean difference = 10.64 dB, 95% CI [5.66,15.62, p<0.001), 0.5 kHz (mean difference = 14.74 dB, 95% CI [9.54,19.95], p<0.001), 1 kHz (mean difference = 16.79 dB, 95% CI [10.89,22.70], p<0.001), 2 kHz (mean difference = 17.18 dB, 95% CI [11.88,22.47], p<0.001), 4 kHz (mean difference = 14.87 dB, 95% CI [10.12,19.63], p<0.001), and 8 kHz (mean difference = 9.10 dB, 95% CI [5.05,13.16], p<0.001)(As illustrated in Fig. 3). Furthermore, compared with the P group, the EA+P group demonstrated significantly greater hearing improvement at 0.5 kHz (mean difference = -12.05 dB, 95% CI [-18.02,-6.09], p<0.001), 1 kHz (mean difference = -12.69 dB, 95% CI [-19.60,-5.79], p<.0001), 2 kHz (mean difference = -10.00 dB, 95% CI [-16.26,-3.74], p=0.002), 4 kHz (mean difference = -8.33 dB, 95% CI [-13.99,-2.68], p=0.004), and 8 kHz (mean difference = -6.41 dB, 95% CI [-11.26,-1.56], p=0.010). The between-group difference at 0.25 kHz did not reach statistical significance (mean difference = -5.64 dB, 95% CI [-11.50, 0.22, p=0.059) (As illustrated in Fig 4).

After treatment, HAMD and HAMA scores for positive coping decreased significantly in the EA+P group (HAMD: mean difference =6.56, 95% CI [4.25, 8.88], p<0.001; HAMA: mean difference = 5.79, 95% CI [4.12, 7.47], p<0.001), whereas the decrease was not statistically significant in the P group (HAMD: mean difference =0.74, 95% CI [−0.05, 1.53], p=0.064; HAMA: mean difference = 0.74, 95% CI [−0.00, 1.49], p=0.051).As illustrated in Fig 5,6.

DISCUSSION

There are currently no clear-cut official guidelines from professional organizations regarding the treatment of SSNHL (Coelho *et al*., 2011). This lack of consensus reflects the limited strong evidence supporting the efficacy of any specific treatment modality or algorithm. Multidrug therapy remains the most common treatment choice for SSNHL (Plaza *et al*., 2011). In the present study, pharmacological therapy served as the control intervention, demonstrating partial auditory recovery at select frequencies (0.25 kHz, 1 kHz, 2 kHz and 4 kHz), whereas no statistically significant improvements were noted at 0.5 kHz and 8 kHz. Notably, the electroacupuncture-pharmacotherapy combination group (EA+P) exhibited consistent enhancement across all evaluated frequencies. Furthermore, the hearing gain in the EA+P group was significantly more pronounced than that in the P group across all frequencies, suggesting potential synergistic advantages of integrating EA with pharmacotherapy. These findings collectively support the beneficial role of EA therapy as an adjunctive treatment modality in the management of SSNHL.

Based on some studies, acupuncture's therapeutic mechanism for SSNHL involves three synergistic pathways: (1) Anti-inflammatory modulation, which helps attenuates excessive inflammatory responses triggered by infections or autoimmune disorders (Zaeifi and Azarnia, 2024), thereby mitigating cochlear damage (Ulloa, 2021); (2) Vascular regulation in the inner ear, which enhances capillary permeability to improve blood circulation in cochlear hair cells, alleviating local ischemia and promoting functional recovery of the inner ear; and (3) Central auditory plasticity enhancement, whereby acupuncture modulates the excitability of the auditory cortex to optimize neural processing of acoustic signals, maximizing the utilization of residual hearing capacity. These integrated effects contribute to auditory restoration through peripheral vascular improvement and central neural reorganization.

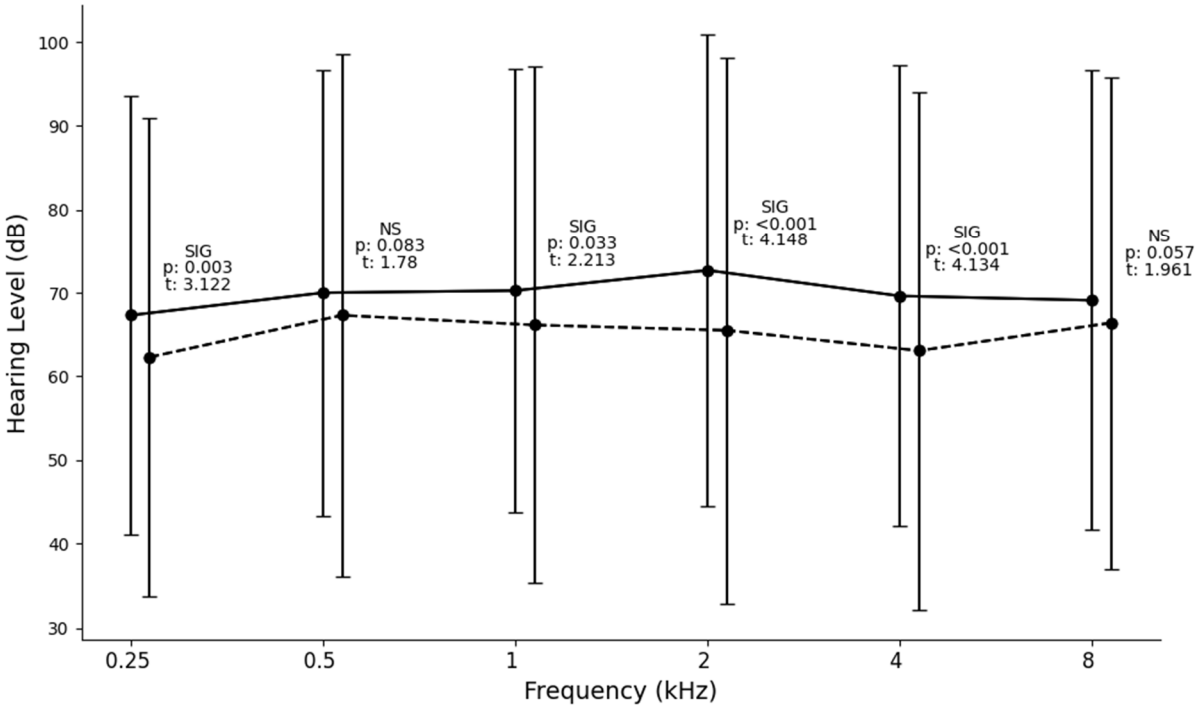

Fig. 2: Initial and final hearing thresholds at 6 frequencies (0.25, 0.5, 1, 2, 4 and 8 kHz) in the P group. The blue line represents the pre-treatment thresholds, while the orange line indicates the post-treatment thresholds following P intervention. Hz stands for Hertz, dB for decibel, t for Student's t-test, p for the p-value, SIG for significance, NS for non-significance. The error bars illustrate the standard deviation for each data point.

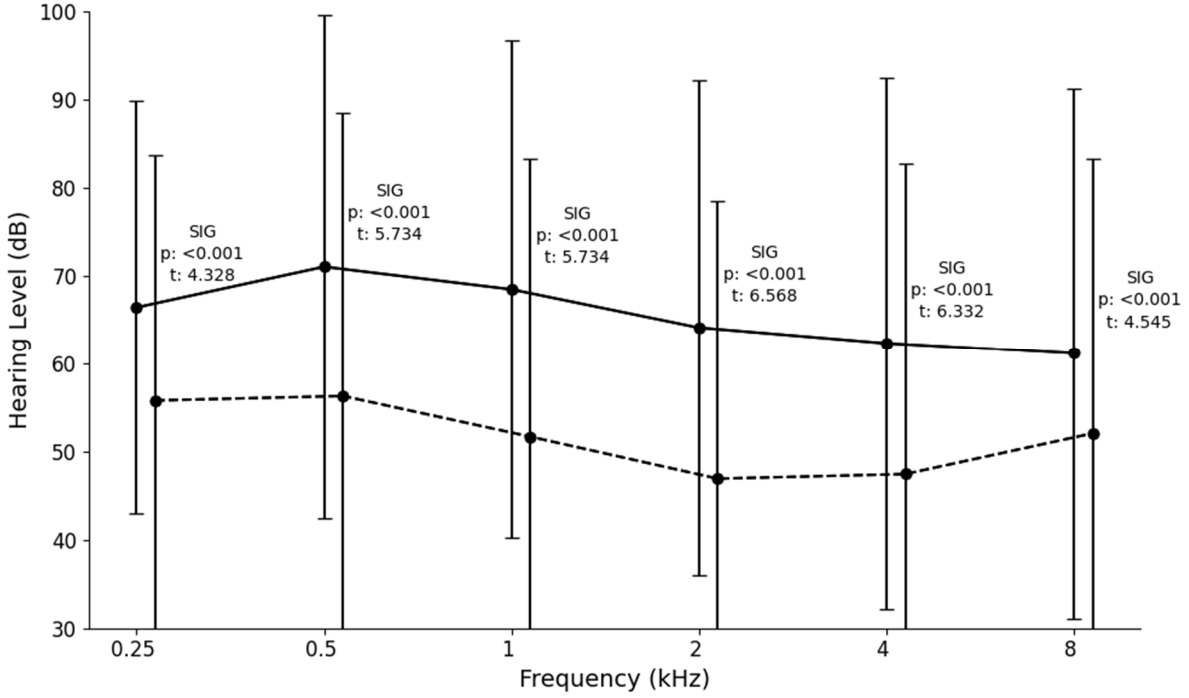

Fig. 3: Initial and final hearing thresholds at 6 frequencies (0.25, 0.5, 1,2, 4 and 8 kHz) in the EA+P group. The blue line represents the average hearing thresholds prior to EA+P treatment, whereas the orange line depicts the average hearing thresholds subsequent to the treatment. Hz stands for Hertz, dB for decibel, t for Student's t-test, p for the p-value, SIG for significance, NS for non-significance. The error bars illustrate the standard deviation for each data point.

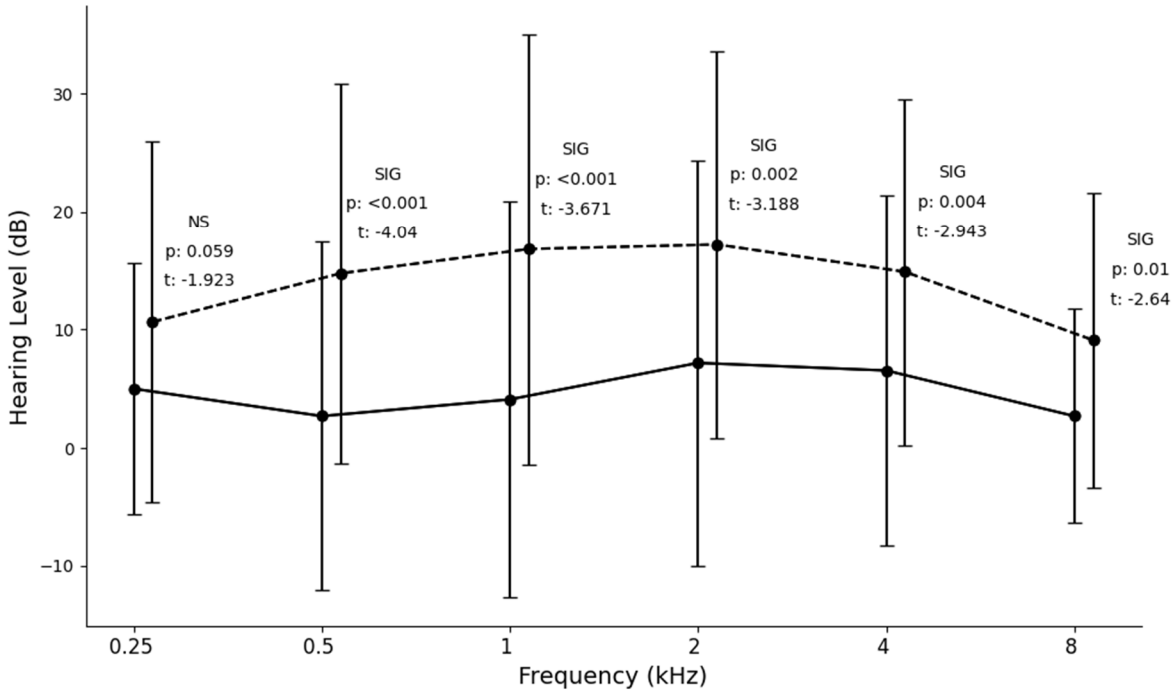

Fig. 4: Hearing gain at 6 frequencies in the P and EA+P groups. The blue line illustrates the average hearing improvement observed in the P group, while the orange line depicts the mean hearing gain achieved by the EA+P group. Hz stands for Hertz, dB for decibel, t for Student's t-test, p for the p-value, SIG for significance, NS for non-significance. The error bars illustrate the standard deviation for each data point.

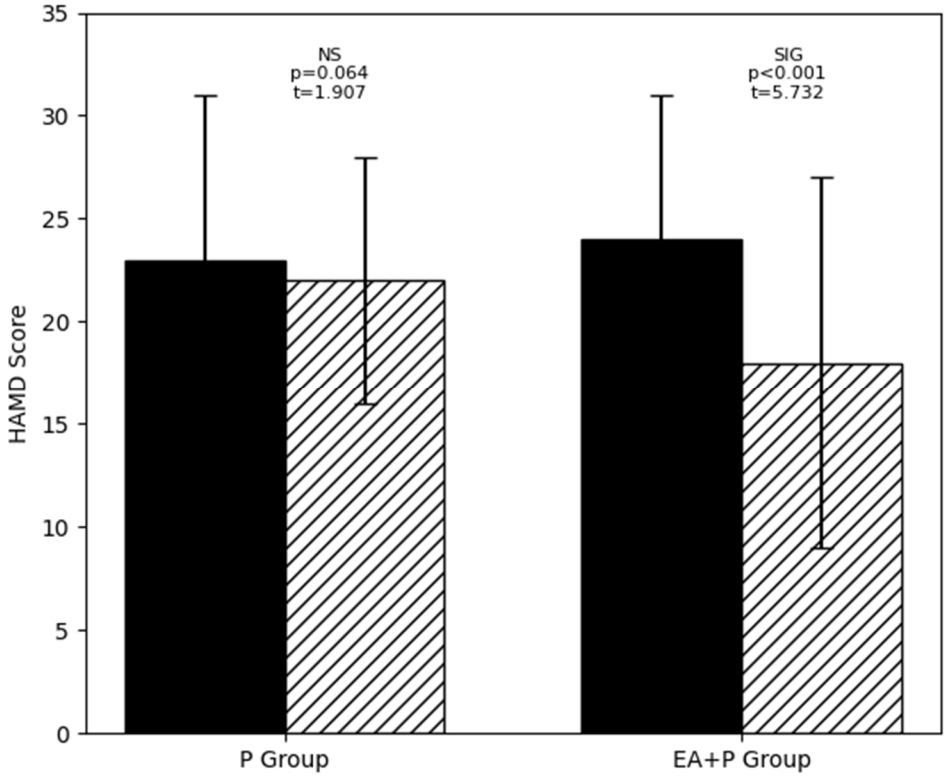

Fig. 5: Changes in the HAMD scores in the P and EA+P groups. t stands for Student's t test, p for the p value, SIG for significant, NS for non-significant. The error bars illustrate the standard deviation for each data point.

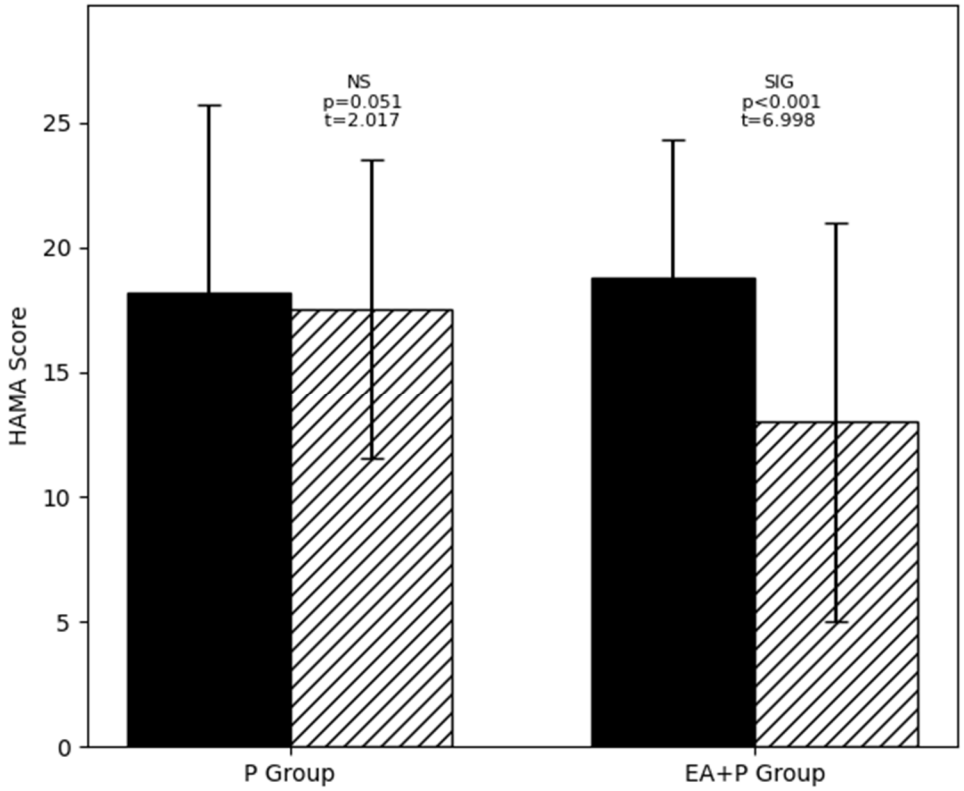

Fig. 6: Changes in the HAMA scores in the P and EA+P groups. t stands for Student's t test, p for the p value, SIG for significant, NS for non-significant. The error bars illustrate the standard deviation for each data point.

The above mechanism is based on the conclusions drawn from preclinical studies on animal models of hearing loss. Currently, there is a lack of direct evidence in cases of sudden sensorineural hearing loss in humans. We therefore present these mechanisms as hypotheses to be tested in future mechanistic studies, rather than definitive explanations. Additionally, the significant reductions in HAMD and HAMA scores observed in the EA+P group, but not in the P group, suggest that EA may alleviate comorbid anxiety and depression—factors known to negatively impact SSNHL prognosis. This dual improvement in auditory function and psychological status likely reflects a holistic therapeutic effect, where reduced emotional distress may further enhance physiological recovery. Studies have shown that EA may alleviate depression by preventing astrocyte atrophy, regulating neuropeptides and neurotransmitters, or modulating the expression of certain genes (Lin *et al*., 2023; Duan *et al*., 2014; Han *et al*., 2021). Frequently cited minor side effects encompass bruising, the formation of hematomas, or bleeding occurring at the acupuncture needle insertion sites. Additionally, vasovagal responses may manifest as fatigue, lightheadedness, syncope, or lingering discomfort at the points of needle entry (Baumler *et al*., 2021). Severe adverse events associated with acupuncture are uncommon, with an incidence rate estimated to be around 0.04 to 0.08 cases per 10,000 acupuncture sessions (Huang *et al*., 2024). Thus, acupuncture can be considered among the safer treatments in medicine. Throughout our EA treatment sessions, no noticeable side effects were observed, thereby highlighting the safety profile of EA therapy.

The lack of a sham-acupuncture control may introduce performance and placebo effects, particularly for psychological outcomes and is acknowledged as a limitation. Additionally, given the modest sample size and the absence of long-term follow-up data, cautious interpretation of the current findings is warranted. Outcomes were assessed at day 7 only, which may confound treatment effects with spontaneous recovery. While this provides an early signal of efficacy, longer-term follow-up is essential to determine the durability of audiological and psychological improvements. We recommend future studies incorporate follow-up assessments at 1, 3 and 6 months post-intervention. Future studies should aim to enroll a larger cohort and incorporate longitudinal assessments to validate these preliminary observations and elucidate the durability of the benefits associated with EA in SSNHL. However, the modest sample size and lack of long-term follow-up data warrant cautious interpretation of the findings. Future studies should focus on expanding enrollment and conducting longitudinal assessments to validate these preliminary observations and elucidate the durability of the benefits associated with EA in SSNHL.

This randomized trial provides evidence that integrating EA therapy with pharmacotherapy significantly enhances auditory outcomes in SSNHL patients with anxiety or depression across all tested frequencies, accompanied by marked improvements in psychological well-being. This suggests that EA has a synergistic benefit of the integration of acupuncture with conventional treatment. Given its therapeutic benefits and favorable safety profile, EA could be considered as a first-line adjunctive therapy in clinical settings for SSNHL patients with anxiety or depression.

Acknowledgements
None.

Authors' contributions
J.L. and L.Y: Conceived and design the experiments; J.L. and G.Z: Performed the experiments; J.L. and L.Y: Wrote the original draft manuscript; G.Z. and W.Z: Contributed to manuscript editing; all authors have read and approved the final manuscript.

Funding
This study was supported by the Medicine and Health Science and Technology Program, Hangzhou (project number: B20231938) and by Grants-in-Aid from Zhejiang Provincial Traditional Chinese Medicine Science and Technology Plan (project number: 2024ZL795).

Data availability statement
All data generated or analyzed during this study are included in this published article.

Ethical approval
This study was approved by the Ethical Committee of the First People's Hospital of Xiaoshan District, Xiaoshan Affiliated Hospital of Wenzhou Medical University (approval number: 2023-083) and all methods were performed in accordance with the relevant guidelines and regulations. Informed written consent was obtained from all patients. This study was performed in adherence with the CONSORT guidelines. See supplementary file for the CONSORT checklist.

Conflict of interest
The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Supplementary data
https://www.pjps.pk/uploads/2026/07/SUP1783856673.pdf

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