<u>Original research</u>

Refined Sound Therapy in Combination with Cognitive Behavioural Therapy to Treat Tinnitus: A Randomized Controlled Trial

Di Ji, MD; Xueqin Zhou, BM; Yao Fan, BM; Junjie Yang, BM; Baiyang Ren, MD; Shuanghong Chen, PhD; Anchun Deng, PhD

ABSTRACT

Background • Post-auricular injection of lidocaine and methylprednisolone sodium succinate is a commonly used treatment for outpatient patients with tinnitus, but it is invasive, painful and has uncertain efficacy. We need to try to replace it with more non-invasive and effective treatments. The 2014 guidelines of the American Academy of Otolaryngology-Head and Neck Surgery recommend the use of cognitive behavioral therapy (CBT) to treat tinnitus. Some clinical doctors have also attempted sound therapy for tinnitus. It is unclear whether sound therapy combined with CBT y is more effective than local injection of lidocaine and methylprednisolone sodium succinate in treating tinnitus.

Objective • To evaluate the efficacy and influencing factors of refined sound therapy combined with CBT in the treatment of tinnitus and compare it with post-auricular injection of lidocaine and methylprednisolone sodium succinate.

Methods • We recruited 100 patients with tinnitus; ultimately, 81 patients completed the experiment and underwent follow-up. Patients were randomly assigned to either the treatment group (refined sound therapy combined with CBT) or the control group (post-auricular injections of lidocaine and methylprednisolone sodium succinate). Data was collected from 49 patients in the treatment group and 32 patients in the control group. Pre- and post-treatment data were collected using the Self-Rating Depression Scale (SDS), Hamilton Anxiety Rating Scale (HAM-A), Visual Analogue Score (VAS), Tinnitus loudness and Tinnitus Handicap Inventory (THI) score. Comparisons between groups were

performed using the chi-square test, Fisher's exact test, or Wilcoxon rank-sum test. All tests were two-sided and considered statistically significant with P < .05.

Results • The THI, SDS and HAM-A scores in the treatment group decreased significantly. In the control group, there was a significant reduction in THI scores, but not in SDS and HAM-A scores. In addition, tinnitus loudness and VAS scores were significantly decreased in the 2 groups. There was a significant difference in the reduction of THI, SDS, HAM-A and VAS scores between the 2 groups; the treatment group showed a greater reduction. However, there was no significant difference in the reduction of tinnitus loudness. There was no statistical difference in the reduction of THI scores, SDS scores, VAS scores and tinnitus loudness in different frequency groups, but there was a statistical difference in the reduction of HAM-A scores. There was no statistical difference in the reduction of THI scores, SDS scores, HAM-A scores, VAS scores and tinnitus loudness between patients with and without hearing loss.

Conclusions • (1) This new combination is more effective than postauricular injection of lidocaine and methylprednisolone sodium succinate in treating tinnitus and improving psychological symptoms. The latter had no effect on improving psychological indicators. (2) With this combination, patients with different tinnitus frequencies experienced different improvements in anxiety. (3) Low-frequency tinnitus seems have been more likely to cause sound adaptation. (4) The improvement in tinnitus and anxiety was the same regardless of whether or not there was hearing loss. (Altern Ther Health Med. [E-pub ahead of print.])

Di Ji, MD; Xueqin Zhou, BM; Junjie Yang, BM; Baiyang Ren, MD; Anchun Deng, PhD, Department of Otolaryngology; The Second Affiliated Hospital of the Army Military Medical University; Chongqing; China. Yao Fan, BM, School of Public Health and Management; Chongqing Medical University; China. Shuanghong Chen, PhD, Department of Psychology; The Second Affiliated Hospital of the Army Military Medical University; Chongqing, China.

Corresponding author: Anchun Deng, PhD E-mail: denganchun2023@163.com

INTRODUCTION

Tinnitus is sound perceived when there is no external sound source, and it is a common disorder. Tinnitus can interfere with hearing, concentration and sleep, even leading to anxiety and depression.¹ Despite various attempts to cure

tinnitus, there is currently no treatment that can completely eliminate it. Although much progress has been made in clinical treatment in recent years, the overall effect is not satisfactory. Common treatment methods include drug therapy, hyperbaric oxygen therapy, cognitive behavior therapy (CBT), sound therapy, surgical treatment, etc. In view of the heterogeneity of tinnitus, its treatment needs to be completed by a multidisciplinary team including otology, neurology and psychiatry.

The mechanism of tinnitus is still unclear. The latest research suggests that the mechanism of tinnitus perception may be related to central gain.² So far, there is no available treatment that can completely resolve the symptoms of tinnitus; most available treatments help patients cope with tinnitus and increase their quality of life (QoL). Promoting the development of a positive psychological attitude in patients with tinnitus and improving their perception of social support may become the new approaches for the clinical management of tinnitus.³ According to the 2014

guideline from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNSF), clinicians should "educate" patients with persistent, bothersome tinnitus about management strategies. The guidelines point out that among many treatment methods, only cognitive behavioral therapy (CBT) has proven to be effective, while other treatment methods still lack evidence that proves their effectiveness. A meta-analysis has demonstrated the efficacy of sound therapy for tinnitus, while also confirming that sound therapy combined with other treatment methods is more effective than individual treatment alone.

Our study applies a novel and unique combination of refined matched tinnitus sound therapy and CBT in treating patients with tinnitus. The rationale of sound therapy is that it stimulates the auditory nerve and peripheral system, depolarizes the auditory nerve cells and reduces the generation or perception of tinnitus. the rationale for CBT is that it changes patients' negative cognition, reduces autonomous tinnitus arousal and reduces the negative impact of tinnitus. Therefore, this treatment intervenes from both the psychological and auditory standpoint. We hypothesised that this treatment can improve psychological and tinnitus symptoms and compared it with the commonly used postauricular injections of lidocaine and methylprednisolone sodium succinate in clinical practice to evaluate whether there is a difference in efficacy. At the same time, we also tried to find a difference in the curative effect in different types of tinnitus of this method, in order to make the suitable treatment population range more accurate.

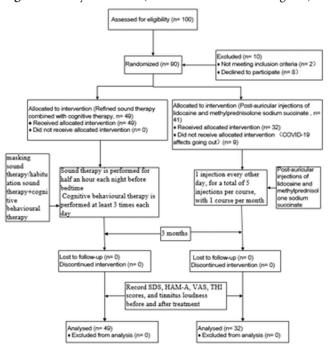
MATERIALS AND METHODS

General Information

Patients with subjective tinnitus who presented to the Department of Otolaryngology at The Second Affiliated Hospital of Army Medical University in China from July 2020 to February 2022 and met the inclusion criteria were selected and assessed for eligibility by an otolaryngologist. This study followed the CONSORT statement and all information was collected at the otolaryngology clinic. A total of 100 patients were recruited, but 10 were excluded from the study and 9 did not receive the intervention. Therefore, 81 people completed the trial, including 49 in the treatment group and 32 in the control group. The groups were comprised of 41 men and 40 women, 38 with bilateral tinnitus or cranial tinnitus, 22 with left-sided tinnitus and 21 with right-sided tinnitus. Overall, 75.3% of patients had hearing loss, mainly in the high frequencies (61.7%) and the frequency distribution of tinnitus was also dominated by high frequencies (60.5%). According to the Tinnitus Handicap Inventory (THI) grading, more than 85% of patients were mildly to moderately affected. There was no significant difference in age, disease course, severity of tinnitus or anxiety and depression between the 2 groups. The flowchart of the trial is shown in Figure 1.

This study was registered in the Chinese Clinical Trials Registry (https://www.chictr.org.cn/number, ChiCTR2200059466).

Figure 1. Study flowchart (CONSORT trial flow diagram).



Ethics Statement

This study was approved by the Institutional Ethics Committee (Medical Ethics Committee of Second Affiliated Hospital of Army Medical University) (2021-Research No. 033-01). The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from each patient for study participation and data publication.

Sample Size and Randomization

To calculate the sample size, the study was powered at 80% with a type I error of 5%. We assumed that a 5.9 difference in the THI score⁷ with an standard deviation (SD) of 8 between the treatment groups was significant, based on the study by Kaldo, et al.8 Assuming a loss of 30%, and in order to make a multiple of 10, each group required 50 patients. A random number sequence was generated using IBM SPSS software version 22.0. Informed consent was obtained from the patients entering the study before randomization. A researcher who was independent of the assessment of study outcomes and statistical analysis performed the random assignments. The grouping code results were placed in opaque envelopes to ensure group concealment. After inclusion was confirmed, the envelopes were distributed in the order of inclusion. The meaning of each group code was not available to check the grouping status until the start of the study.

Inclusion and exclusion criteria

Inclusion criteria. Patients (1) were of either gender and older than 18 years with a disease duration of more than 3 months; (2) had good compliance; (3) had tinnitus as one of

their main symptoms; (4) voluntarily signed informed consent; and (5) had residual hearing.

Exclusion criteria: Patients (1) had tinnitus caused by organic pathology such as acoustic neuroma and nasopharyngeal carcinoma, etc.; (2) had objective tinnitus; (3) had severe liver, kidney, lung or heart disease; (4) had poor cooperation, such as elderly patients with reduced mobility, had severe psychiatric disorders, etc.; (5) had missing clinical data; (6) had complete loss of hearing; (7) were allergic to methylprednisolone sodium succinate or lidocaine; and (8) had auditory hypersensitivity.

Due to the unknown impact of the 2 treatment methods on pregnant women, lactating women, and fetuses, these populations were excluded from the study.

Methodology

Treatment group intervention. The process of refined matched sound therapy (Tingnite TTS-1000A Model Tinnitus Comprehensive Diagnosis and Treatment Instrument. EMaker Tinnitus Mask Produced by Weidi Digital Technology Co., Ltd):

All patients underwent masking sound therapy (with a converging, overlapping or spacing pattern on the Friedman curve and a positive or partially positive residual inhibition test) or habituation sound therapy (with a separating or ineffective pattern on the Friedman curve and a negative or rebound residual inhibition test). The masking method was to mask tinnitus with matching tinnitus sounds, and the loudness requirement was sufficient to mask tinnitus without causing discomfort. The habituation method was used to mask tinnitus with background noise near the frequency of tinnitus, and the loudness requirement was the minimum masked loudness above the hearing threshold.

Cognitive behavioral therapy

All patients need to receive cognitive behavioral therapy (CBT) while receiving refined matched sound therapy. There are 3 CBT options available: A, B, and C; patients select option A or B according to their preference for treatment combined with Option C.

- A. Relaxation and distraction. Once thoughts of tinnitus arise, sit quietly or lie down with eyes closed; use the mind to control nerve and muscle and tension and gradually relax the muscles of the whole body. Meanwhile, immediately shift the attention to imagination such as listening to music, reading a book, or taking a tour. This distracts attention from the tinnitus, and enables the individual to develop pleasant emotions and cognition.
- **B. Recording method.** Once reflexive negative emotions (irritability, disgust, etc.) occur during tinnitus, immediately record the event in a special notebook and think about how to perceive it in a correct and more rational way (tinnitus is like the sound of wind and rain, so you can sleep or work with the beautiful sound of tinnitus); record this in the notebook as a comparison; constantly repeat this to strengthen the memory.

C. Continuous consultation and answering method. Help patients accurately perceive negative emotions, constantly answer questions and provide comforting and confidence-enhancing stimuli to help the patient resolve their doubts.

Course of treatment in the treatment group

Sound therapy was performed for half an hour each night before bedtime and CBT was performed at least 3 times every day for 3 months; all patients were assessed by the same audiologist.

Intervention in the control group

Post-auricular injection of lidocaine 5 ml:0.1g (Hubei Tiansheng Pharmaceutical Co., Ltd.) and methylprednisolone sodium succinate 1 ml:40mg (Chongqing Huabang Pharmaceutical Co., Ltd.): 0.5 ml of 2% lidocaine and 0.5 ml of methylprednisolone sodium succinate (20 mg) was drawn into an empty 1 ml syringe and the solution was injected in the subpapillary to the mastoid bone level to the superior border of the external auditory canal opening in the post-auricular sulcus, with the puncture facing in the direction of the external auditory canal.

Course of treatment in the control group: 1 injection every other day, for a total of 5 injections per course, with 1 course per month for 3 months; all injections were performed by the same clinician.

Outcome Measures

Primary outcome measure was the THI score, and the secondary outcome measures comprised Self-Rating Depression Scale (SDS) score,⁹ Hamilton Rating Scale for Anxiety (HAM-A) score,¹⁰ Visual Analog Scale (VAS) score¹¹ and tinnitus loudness were collected before and after 3 months of treatment, all by the same audiologist. Evaluation of the treatment effect was based on the change in the difference between each score prior to compared with after treatment.

Secondary outcome measures. The subjective effects of patients were recorded after treatment according to the predesigned checklist. The judgement criteria for subjective effects were:

- **1. Cured.** Tinnitus and accompanying symptoms disappeared completely; or complete adaptation at all times.
- 2. Significantly effective: with \geq 50% reduction in tinnitus and \geq 50% reduction in accompanying symptoms; or adaptation 80% of the time regardless of changes in tinnitus loudness.
- **3. Effective**: with $\geq 33.3\%$ reduction in tinnitus and $\geq 33.3\%$ reduction in accompanying symptoms; or partial adaptation 50% of the time, regardless of a change in tinnitus loudness.
- **4. Ineffective**: Tinnitus remains the same or worsens, accompanying symptoms remain the same or worsen or patient is unable to adapt most of the time regardless of changes in tinnitus loudness.

Table 1. Patient Demographics and Clinical Features

	Total Treatment Group		Control Group	
	(N=81)	(n=49)	(n=32)	P value
Gender				.295
Male	40 (49.4%)	22 (44.9%)	19 (59.4%)	
Female	41 (50.6%)	27 (55.1%)	13 (40.6%)	
Age (years)	45.0 (33-53)	46.0 (34-52)	38.5 (33.0-54.3)	.546
Affected Ear(s)				.348
Both ears	38 (46.9%)	26 (53.1%)	12 (37.5%)	
Right Ear	21 (25.9%)	12 (24.5%)	9 (28.1%)	
Left Ear	22 (27.2%)	11 (22.4%)	11 (34.4%)	
Disease duration (months)	12 (3-36)	12 (3-36)	12 (3-36)	.837
Tobacco and alcohol history				.107
No	62 (76.5%)	34 (69.4%)	28 (87.5%)	
Yes	19 (23.5%)	15 (30.6%)	4 (12.5%)	
Family history				.643ª
No	76 (93.8%)	45 (91.8%)	31 (96.9%)	
Yes	5 (6.2%)	4 (8.2%)	1 (3.1%)	
History of head trauma				1.000°
No	76 (93.8%)	46 (93.9%)	30 (93.8%)	
Yes	5 (6.2%)	3 (6.1%)	2 (6.3%)	
Noise exposure history				.029
No	65 (80.2%)	35 (71.4%)	30 (93.8%)	
Yes	16 (19.8%)	14 (28.6%)	2 (6.3%)	
Grade				.716a
1	17 (21.0%)	10 (20.4%)	7 (21.9%)	
2	41 (50.6%)	23 (46.9%)	18 (56.3%)	
3	11 (13.6%)	7 (14.3%)	4 (12.5%)	
4	7 (8.6%)	6 (12.2%)	1 (3.1%)	
5	5 (6.2%)	3 (6.1%)	2 (6.3%)	

^aFisher's exact test

Table 2. Comparison of Primary Outcomes in the Two Groups

	Treatment Group	Control Group	P value
THI	•	•	
Initial	28.0 (20.0 to 50.0)	28.0 (19.5 to 36.0)	.498
Final	18.0 (8.0 to 28.0)	24.0 (16.0 to 32.5)	.076
Difference	-10.0 (-24.0 to -2.0)	2.0 (-4.0 to 0.0)	<.001
SDS			
Initial	41.0 (35.0 to 50.0)	35.0 (30.0 to 40.0)	.039
Final	35.0 (29.0 to 40.0)	35.0 (28.8 to 41.0)	.942
Difference	-5.0 (-9.0 to -2.0)	0.0 (-4.0 to 0.8)	<.001
HAM-A			
Initial	7.0 (3.0 to 14.0)	9.0 (2.0 to 12.3)	.674
Final	5.0 (2.0 to 9.0)	6.0 (2.0 to 14.0)	.265
Difference	-2.0 (-5.0 to 0.0)	0.0 (-1.3 to 1.0)	.002
Tinnitus Loudness			
Initial	50.0 (31.0 to 62.0)	38.5 (30.0 to 55.5)	.218
Final	40.0 (30.0 to 55.0)	40.0 (26.5 to 50.3)	.504
Difference	-5.0 (-10.0 to -1.0)	-1.0 (-3.3 to 0.0)	.034
VAS			
Initial	5.0 (4.0 to 7.0)	5.0 (4.0 to 7.0)	.965
Final	4.0 (2.0 to 6.0)	5.0 (2.0 to 6.3)	.162
Difference	-1.0 (-3.0 to 0.0]	0.0 (-1.3 to 0.0]	.014

Abbreviations: HAM-A, Hamilton Anxiety Rating Scale; SDS, Self-rating Depression Scale; THI, Tinnitus Handicap Inventory; VAS, Visual Analog Scale

Statistical Analysis

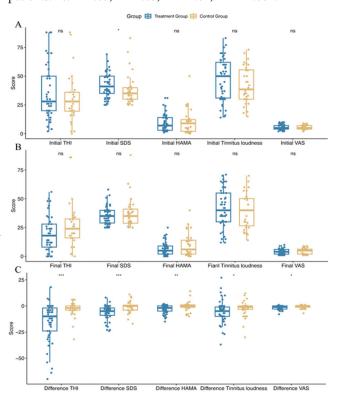
Normality tests for continuous variables were performed using the Shapiro-Wilk Normality test. Categorical variables were described by frequency (percentage) and continuous variables were described by median (1st quartile, 3rd quartile). Comparisons between groups were made using the chi-square test, Fisher's exact test, or Wilcoxon rank sum test. All tests were two-sided and considered statistically significant with P < .05. IBM SPSS version 22.0 software (IBM SPSS Statistics for Windows) was used for data analysis.

RESULTS

Patient Demographics and Clinical Features

Statistical tests revealed that all continuous variables in this study did not conform to normal distribution, so all continuous

Figure 2. Comparison of initial scores, final scores and changes in scores between the 2 groups. (2A) Comparison of baseline values between the 2 groups of patients. (2B) Comparison of endpoint values in the 2 groups of patients. (2C) Comparison of changes in THI score, SDS score, HAM-A score, tinnitus loudness value and VAS score in the 2 groups of patients. ns: P > .05; *P < .05; *P < .05; *P < .01; ***P < .001.



Abbreviations: HAM-A, Hamilton Anxiety Rating Scale; SDS, Self-rating Depression Scale; THI, Tinnitus Handicap Inventory; VAS, Visual Analog Scale.

variables were described using the median (first quartile, third quartile). As shown in Table 1, the 81 patients included in this study comprised 40 men (49.4%) and 41 women (50.6%) with an age distribution of 45 years (range 33 to 53) years. The differences in gender (P = .295), age (P = .546), affected ear(s) (P = .348), disease duration (P = .837), tobacco and alcohol history (P = .107), family history (P = .643), history of head trauma (P = 1.000) and grade (P = .716) between the treatment group and the control group were not statistically significant. The percentage of noise exposure was higher in the treatment group than in the control group (P = .029).

Comparison of Primary Outcomes in the Two Groups

The results of the Wilcoxon rank-sum test showed that all initial and final scores were not statistically different between the 2 groups, except the initial SDS score; compared with the control group, the treatment group had a higher initial SDS score (P = .039). After 3 months of treatment, all 5 primary outcome scores had decreased more (THI, P < .001; SDS, P < .001; HAM-A, P = .002; tinnitus loudness, P = .034; VAS, P = .014) in the treatment group relative to the control group (Table 2; Figure 2). These results suggest that

Table 3. Subjective Effects in the Treatment and Control Groups

	Treatment Group	Treatment Group	
	(n=49)	(n=32)	P value
Ineffective	8 (16.3%)	16 (50.0%)	
Effective	29 (59.2%)	14 (43.8%)	<.001
Significantly effective	12 (24.5%)	2 (6.2%)	

our new combination treatment (sound therapy + CBT) for tinnitus is more effective than conventional local injection of glucocorticoid and lidocaine therapy in all 5 areas of THI, SDS, HAM-A, tinnitus loudness and VAS.

Subjective Effects

After a 3-month treatment period, we asked patients about their subjective perception of the effects. None of the patients in the treatment group or the control group thought their tinnitus was cured. In the treatment group, 8 people (16.3%) thought the treatment was ineffective, 29 (59.2%) thought it was effective and 12 (24.5%) thought it was significantly effective. In the control group, 16 people (50.0%) thought the treatment was ineffective, 14 (43.8%) thought it was effective and 2 (6.2%) thought it was significantly effective. Since the subjective effect variable in this study is an ordered multi-category variable, we assigned ineffective, effective and significantly effective as 0, 1 and 2, respectively, and used the Wilcoxon rank-sum test to analyze whether there was a statistical difference between the 2 groups. Ultimately, we found that patients in the treatment group reported better subjective effects than patients in the control group (P < .001)(Table 3). This indicates that our new combination method for tinnitus (sound therapy + CBT) is more effective than the conventional local injection of glucocorticoid and lidocaine therapy in terms of subjective effects.

DISCUSSION

Tinnitus is defined as the perception of a sound in the ear or skull in the absence of an external sound source. 12 Most researchers believe that tinnitus is related to hearing loss 13 and that the tinnitus tuning curve correlates with the hearing loss curve, with the strongest correlation achieved when hearing loss reaches 50 dB. 14 In this study, 75.31% of patients had varying degrees of hearing loss, 90.16% of whom had high-frequency hearing loss. Some researchers have suggested that tinnitus is the result of stress-related neural remodelling, a theory supported by tests for hair cortisol and brain-derived neurotrophic factor, which is an indicator of neuroplasticity. 15 Overall, understanding of the neurological mechanisms of tinnitus is minimal.

This lack of understanding has led to current treatments being focused on improving the symptoms brought on by tinnitus rather than treatment of the root cause. The efficacy of CBT is generally considered to be positive, based on national diagnostic guidelines and large data samples. Sound therapy is recommended as an optional complementary treatment, and the therapeutic effects of sound therapy remain to be verified. Although there are many ways to treat

tinnitus, the internationally acknowledged intervention is counselling combined with sound therapy. To Our research replaced the psychological counselling in the combination with CBT, which also includes psychological counselling. This combination includes both psychotherapy and neurotherapy; we have confirmed the effectiveness of this innovative combination. But we acknowledge that support from more long-term follow-up and data from larger sample sizes are needed to support the use of this treatment method.

Based on the association of tinnitus with hearing loss, Cuesta, et al., treated 83 patients with sound therapy using narrowband noise matched to tinnitus. ¹⁵ In that study, 96% of patients achieved relief and the researchers found that the degree of reduction in THI depended on the baseline THI value. Sound therapy acts on the limbic system and auditory network by acoustically compensating for the loss of afferent, ¹⁸ altering auditory processing at a subconscious level in order to stimulate habituation of tinnitus perception. There is no uniform standard for the selection of sound for therapy and individualization is recommended.

Our study focuses on refining the matched tinnitus nature and frequency. During this course of treatment, the treatment sound changes according to the patient's tinnitus sound in order to promote synchronized discharge of the nerve collection near the tinnitus frequency. The choice of sound volume is also controversial. In this study, volume was set just above the hearing threshold without causing aversion and discomfort. Masking sound therapy plays a role by providing sound compensation to attenuate its own compensatory effect due to the loss of sound at that frequency. Habitual sound therapy, on the other hand, distracts the patient through sound and the environment, weakening the perception of tinnitus over time and achieving neural remodelling.¹⁹ The location of the masking device is crucial in masked sound therapy, and the latest research has shown that spatial masking (3D) is more effective than simply wearing headphones (2D).20 Allen, et al. reported a rise in speech perception thresholds when the direction of attention was different from the direction of the sound heard.¹⁴ It may be beneficial if positioned farther from the head to suppress attention paid to tinnitus and thus reduce perception. Experiments conducted by Yamato Kubota compared masking sound pressure to mask noise far from the ear and close to the ear and discovered that the former was lower than the latter 71% of the time.21

CBT is the only method in the guide⁴ that has a definite effect on improving the discomfort caused by tinnitus.²² CBT involves a combination of numerous psychological interventions developed from cognitive and behavioural therapies that achieves auditory desensitisation by establishing correct cognition in patients and closing the vicious cycle between the limbic system, the autonomic nervous system and the auditory conduction pathways. The main aim of CBT for tinnitus is to reduce the impact of tinnitus on quality of life, rather than directly altering the perceived loudness.²²

In this study, post-auricular injections of lidocaine and methylprednisolone sodium succinate improved the degree

of tinnitus disability and tinnitus loudness but had no significant effect on psychological symptoms and indicators. In addition to improving the degree of tinnitus disability, the combination of sound therapy and cognitive therapy also resulted in significant improvement in psychological indicators. This phenomenon tells us that in clinical situations in which tinnitus is accompanied by strong psychological disturbances, priority should be given to sound and cognitive therapy, or to combination with post-auricular injections, rather than solely post-auricular injections. We also found that with this treatment, the improvement in tinnitus symptoms in patients with different tinnitus frequencies was roughly the same, but the improvement in anxiety symptoms in patients with different tinnitus frequencies was different. Low-frequency tinnitus seems more likely to cause sound adaptation. At the same time, it was also found that there was no difference in the improvement in tinnitus and psychological indicators, regardless of whether there was hearing loss. Therefore, this combination is suitable for patients with tinnitus with anxiety or depression with or without hearing loss. A large number of studies have confirmed the effectiveness of sound therapy and CBT for tinnitus, but the total sample size was small, and the specific treatment methods, treatment time, and treatment population were different. 4,23-25 Some studies have also confirmed that sound therapy does not increase the effectiveness of CBT for tinnitus.26. The experiment has reduced bias by controlling the baseline between the 2 groups. This study covered patients with tinnitus of different age groups, genders, affected side(s), courses and underlying diseases. The results showed that different patients with tinnitus have good treatment effects, and we can reasonably infer that the program could benefit the general population.

Study Limitations

The limitations of this study are, for one, that it did not classify and analyze different sound therapy methods. Due to limitations in medical ethics, the study did not set up a blank control group, which to some extent will affect the research results. The treatment group was not compared with the individual refined sound therapy group or CBT group, resulting in uncertainty as to whether the treatment alone or in combination was more effective. This was a single-center experiment with a small sample size, and multi-center data from a large sample will be more convincing.

To make the treatment more precise, our next step is to focus on the differences in the effects of different degrees and types of tinnitus, as well as the respective influencing factors.

CONCLUSION

(1) The combination of refined sound therapy and CBT is more effective in treating tinnitus and improving psychological symptoms than post-auricular injection of lidocaine and methylprednisolone sodium succinate. (2) Post-auricular injection of lidocaine and methylprednisolone sodium succinate cannot improve psychological indicators.

(3) With this combination, the degree of anxiety improvement varied among patients with different tinnitus frequencies. (4) Low-frequency tinnitus seems to be more likely to cause sound adaptation. (5) Whether or not there is hearing loss, the improvement level of tinnitus and anxiety is the same. (6) When patients have tinnitus accompanied by anxiety and depression, it is recommended to use refined sound therapy combined with CBT, rather than post-auricular injection of drugs or individual sound therapy or CBT alone.

CONFLICT OF INTEREST

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