



Efficacy of adjuvant Chinese herbal formula treatment for chronic tinnitus: A retrospective observational study



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KEYWORDS

Chinese herbal medicine;
Chai-Hu-Jia-Long-Gu-Mu-Li-Tang;
Tinnitus;
Retrospective study

Summary

Background: The aim of this study was to evaluate the clinical efficacy of using western anti-tinnitus therapy with or without Chai-Hu-Jia-Long-Gu-Mu-Li-Tang (CHJLGMLT) to treat patients with chronic tinnitus.

Methods: A descriptive case series with chart review was established to compare patients with chronic tinnitus who had received CHJLGMLT with western anti-tinnitus therapy (the CHJLGMIT group) with those who received western anti-tinnitus therapy alone (the non-CHJLGMIT group). We included 21 patients, 10 patients in the CHJLGMIT group with CHJLGMLT and 11 patients in the non-CHJLGMIT group. Both groups were comparable in terms of patient demographics and clinical characteristics. The follow-up examinations included the assessment of Tinnitus Handicap Inventory (THI), Pittsburgh Sleep Quality Index (PSQI), Visual Analogue Scale (VAS) of 0–10 for tinnitus intensity, pure tone audiometry (PTA), and speech reception threshold (SRT). **Results:** After 2 months of treatment, THI and PSQI scores were reduced significantly more in the CHJLGMIT group ($p < 0.05$) than in the non-CHJLGMIT group. Scores on the emotional subscale

Abbreviations: CHJLGMLT, Chai-Hu-Jia-Long-Gu-Mu-Li-Tang; CHM, Chinese herbal medicine; FDA, Food and Drug Administration; GABA, γ -aminobutyric acid; GMP, good manufacturing procedures; PSQI, Pittsburgh Sleep Quality Index; PTA, pure tone audiometry; SRT, speech reception threshold; TCM, traditional Chinese medicine; THI, tinnitus handicap inventory; VAS, Visual Analogue Scale.

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of the THI were significantly reduced in the CHJLGMIT group ($p < 0.05$) after treatment, but the effects on the seven PSQI subscales did not differ significantly between the two groups ($p > 0.05$). Scores on the VAS for tinnitus loudness were significantly reduced in both groups ($p < 0.05$). No significant differences between the two groups were found on the binaural hearing tests (PTA and SRT).

Conclusions: Our study found that adjuvant CHJLGMIT therapy for chronic tinnitus may exert additional efficacy by improving psychological sensation of tinnitus and sleep quality. Future randomized controlled double-blind studies should be performed to elucidate its efficacy.

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Background

Chronic tinnitus is a bothersome health problem that can affect 10–15% of the general population.¹ Most cases of chronic tinnitus are subjective, meaning that only the patient can hear the sounds.² The disorder may be accompanied by otological, orthopaedic, metabolic, neurological, cardiovascular, dental, and pharmacological conditions, more than one of which may be present in the same individual.^{3,4} Chronic tinnitus can even be a devastating concern; a significant proportion of sufferers develop sleep disturbances, anxiety, depression, and other psychiatric comorbidities, and a small fraction commit suicide.^{5,6} Numerous drug regimens, retraining therapy, behavioural therapies, or noise-masking devices have been tried, with an overall disappointing lack of universal efficacy.^{1,7} Since there is currently no satisfactory treatment for tinnitus, the condition of these patients may be especially distressing.

In order to improve the therapeutic efficacy, many chronic tinnitus patients seek herbal medicine and other alternative and complementary therapies.^{8,9} This is particularly apparent in Asian patients, who have well-established preconceptions about Chinese herbal medicine (CHM).

The use of Chai-Hu-Jia-Long-Gu-Mu-Li-Tang (CHJLGMIT), which has a long history as part of the traditional Chinese pharmacopoeia, was first documented in the classical Chinese text *Shang Han Lun* (On Cold Damage) circa 210 A.D. by Zhong-Jing Zhang.¹⁰ In the classical literature, CHJLGMIT is prescribed to reconcile the qi of Shaoyang syndrome, relieve rigidity of the muscles and active collaterals, and tranquilize and allay excitement. TCM practitioners, who use CHJLGMIT to treat many difficult and complicated diseases, rely on traditional Chinese medicine (TCM) theory.¹¹

Several studies in China have shown that treatment with CHJLGMIT effectively improves debilitating conditions such as resistant hypertension, insomnia, neurosis, and tinnitus, and that patients treated with this herbal medicine typically exhibit fewer side effects than those treated with western medicines.^{12–15} Animal studies have also shown that CHJLGMIT has anti-depressive, stress relief, and sedative effects.^{16,17} Despite this documented research, questions regarding the beneficial effects of this TCM persist, and the exact mechanism by which CHJLGMIT improve chronic tinnitus remains unknown. The purpose of this study was to review and explore the effects of combining CHJLGMIT with western anti-tinnitus therapies on patients with chronic tinnitus.

Methods

Patients

We performed a retrospective observational study of adult outpatients with chronic tinnitus treated by an otolaryngologist at Liouying Chi-Mei Hospital, Tainan City, Taiwan, between June 2011 and January 2012. The eligibility criteria for inclusion were: (1) diagnosis of chronic tinnitus defined as a perceived noise of varying intensity, loudness, and pitch in the absence of an external sound lasting longer than 3 months;¹⁸ (2) no conductive hearing loss; (3) no major cognitive impairment or psychiatric disorders; and (4) no severe comorbidities (e.g., heart failure, unstable diabetes).

This study protocol was ethically approved in case No. 10206-L02 of the Chi-Mei Institutional Review Board (CMHIRB-10206-L02).

Treatment

The study, included patients with chronic tinnitus who had undergone current anti-tinnitus therapies. The patients were categorized into two groups. Each patient in CHJLGMIT group had been provided with adjuvant the CHJLGMIT formula for the 2-month period examined for the study. Patients in the non-CHJLGMIT group had received only anti-tinnitus therapies. The western medicine for chronic tinnitus are oral peripheral vasodilators (nicametate citrate 50mg and thiamine 100mg three times a day), which are

Table 1 Components of Chai-Hu-Jia-Long-Gu-Mu-Li-Tang (every 4g of dry extract was derived from 23.8g of the raw materials).

| Pharmaceutical name | Chinese Pinyin | Ratio (g) |
|--------------------------|----------------|-----------|
| Radix Bupleuri | Chaihut | 2.1 |
| Fossilia Osis Mastodi | Longku | 2.1 |
| Rhizoma Zingiberisrecens | Shengjiang | 2.1 |
| Radix Ginseng | Renshen | 2.1 |
| Poria | Fuling | 2.1 |
| Radix Scutellariae | Huangqin | 2.1 |
| Concha Ostreae | Muli | 2.1 |
| Ramulus Cinnamomi | Guizhi | 2.1 |
| Rhizoma Pinelliae | Banxia | 2.1 |
| Fructus Jujubae | Dazao | 2.1 |
| Rhizoma Rhei | Dahuang | 2.8 |

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