8. Ear Diseases

Reference

Suzuki T. *Clinical efficacy of chotosan for tinnitus. Pathology and treatment of tinnitus and dizziness*[*]. The 28th Chiba Symposium of Japanese Traditional Medicine Tokyo: Kudansha; 2001:8-20 (in Japanese). Ichushi Web ID: 2003129990

1. Objectives

To evaluate the efficacy of chotosan (釣藤散) for tinnitus.

2. Design

A crossover randomized controlled trial (RCT-crossover).

3. Setting

A community hospital (department of otorhinolaryngology), Japan.

4. Participants

Fifty-eight patients with tinnitus.

5. Intervention

Arm 1: oral administration of TSUMURA Chotosan (釣藤散) Extract Granules 2.5 g, t.i.d. for 4 weeks, followed by mecobalamin 0.5 mg, t.i.d. for 4 weeks (n=29).

Arm 2: oral administration of mecobalamin 0.5 mg, t.i.d. for 4 weeks, followed by TSUMURA Chotosan (釣藤散) Extract Granules 2.5 g, t.i.d. for 4 weeks (n=29).

6. Main outcome measures

The intensity (loudness level) and duration of tinnitus, and tinnitus-associated annoyance was evaluated on a 6-point scale (from 0 = disappearance to 5 = maximum) according to the diagnosis criteria established by a study group of the Japan Audiological Society. Scores of these three measures were summed before and after each treatment, and the degree of improvement was measured by reduction in the summed score from the pre-treatment value. 'Disappearance' was defined as reduction to zero, 'marked improvement' as reduction of 8 or more points, 'moderate improvement' as reduction of 4 to 7 points, 'mild improvement' as reduction of 1 to 3 points, 'no improvement' as no change in score, and 'worsening' as increase in score.

7. Main results

In the chotosan-first group (arm 1), scores were significantly reduced after 4 weeks of chotosan treatment, but significantly increased after the switch to mecobalamin treatment. In mecobalamin-first group (arm 2), scores did not change at 4 weeks, and significantly increased after the switch to chotosan treatment. The degree of improvement in tinnitus was significantly different between groups at 4 weeks, then similar at 8 weeks. Improvements were significant, as compared with the pre-treatment baseline values, in both groups. Tinnitus had disappeared in 5 ears, was markedly improved in 8 ears, and was moderately improved in 14 ears. Moderate-to-marked improvement was seen in 39.8% of ears and mild-to-marked improvement in 80.9%. There was no case of 'worsening' tinnitus. Regarding background factors, there were no between-group differences in sex, age, diagnosis, disease duration, side of diseased ear, and medical history. Chotosan showed significant efficacy for tinnitus with heaviness of head/ headache or shoulder stiffness, compared with other accompanying symptoms.

8. Conclusions

Chotosan is more effective than mecobalamin in improving tinnitus.

9. From Kampo medicine perspective

Although specific results were not provided, the author concluded that the treatment would be more effective when they took into account on the patient's condition.

10. Safety assessment in the article

Serious adverse drug reactions were not reported in either group.

11. Abstractor's comments

This study provided high-quality evidence that chotosan is efficacious for tinnitus, which is often difficult to treat. Chotosan tended to improve, though not significantly, Meniere's disease and tinnitus without hearing loss, but not C5dip-type sensorineural hearing loss. These points are helpful when the efficacy of chotosan is determined, and also provide useful insights in its mechanism. In addition, unlike previous reports showing that patients with shorter disease duration were more likely to respond, this study described striking improvement in some cases, such as 'marked improvement' in a patient with disease for 30–40 years and complete recovery in several patients with disease for 4–5 years. The problems of this study are as follows: 1) The presentation of the results is inconsistent. For example, results are presented on a patient basis at first, and then on an affected-ear basis. 2) The report is incomplete because results from a Kampo medicine perspective are not presented. And 3) there is no description of the randomization step or the method of assignment to arm 1 and arm 2. The randomization step may have been omitted because of the crossover design. Nevertheless, an accurate description is desired. However, the article presents future challenges, and further developments are expected.

12. Abstractor and date

Namiki T, 15 June 2007, 1 April 2008, 1 June 2010.