

8. Ear Diseases

Reference

Sato H, Nakamura H, Honjo I, et al. Clinical evaluation of Tsumura-Saireito in children with otitis media with effusion - A comparative randomized controlled study of cepharanthine -. *Jibiinkoka Rinsho (Practica otologica)* 1988; 81: 1383-7 (in Japanese with English abstract).

1. Objectives

To evaluate the efficacy of saireito (柴苓湯) compared with cepharanthine for otitis media with effusion.

2. Design

Randomized controlled trial (RCT)

3. Setting

Outpatient clinic at the Department of Otolaryngology, Kyoto University Hospital, Japan.

4. Participants

Sixty-four ears of 42 children diagnosed with otitis media with effusion as evidenced by type B tympanogram who had mean hearing level of 20 dB or more (at 3 frequency average levels: 500, 1000, and 2000 Hz).

5. Intervention

Arm 1: Thirty-two ears of 21 children aged 4-7 years (mean 5.2) were treated with TSUMURA Saireito (柴苓湯) Extract Granules 1.5 g b.i.d. for 4 weeks.

Arm 2: Thirty-two ears of 21 children aged 4-7 years (mean 5.0) were treated with cepharanthine 5.0-7.5 mg b.i.d. for 4 weeks.

6. Main outcome measures

Pure-tone audiogram and tympanogram were obtained before and after the treatment. In pure-tone audiometry, "improved" hearing after tympanoplasty was defined as an increase of 15 dB or more in mean hearing level, and "not changed" as an increase of less than a 15 dB. The otitis media with effusion was judged to be "improved" when the tympanogram changed to type A or C1, and "not changed" when it was type C2 or B. Patients were considered "responders" if either test indicated improvement and "non-responders" if neither test indicated improvement.

7. Main results

After treatment, mean hearing level increased 7.2 dB (the percentage of ears with improvement: 28.1%) in arm 1 and 3.8 dB (15.6%) in arm 2; the between-arm difference was not significant. The tympanogram was improved in 18.8% of ears in arm 1 and 3.1% of ears in arm 2; the between-arm difference was also not significant. In all, 43.8% of the saireito-treated and 18.8% of the cepharanthine-treated ears were classified as responders; the response rate was significantly higher in arm 1 (χ^2 test, $P < 0.05$).

8. Conclusions

Saireito is an effective conservative treatment for otitis media with effusion in children.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No notable adverse reactions were observed.

11. Abstractor's comments

This is an RCT of the efficacy of saireito for otitis media with effusion in children. Although it was published in 1988, which was before the term "EBM (evidence-based medicine)" became popular, this clinical study is well-designed. The inclusion and exclusion criteria and the outcome variables were clearly defined, and the results took into account participants who used other drugs as well. The authors also discussed the difficulty of blinding subjects to the intervention when the drugs could be identified by their respective odors. It may have been the best possible study design under the circumstances at that time.

12. Abstractor and date

Tsuruoka K, 28 September 2008, 1 June 2010, 31 December 2013.