

8. Ear Diseases

Reference

Machii K, Ikezono T, Utasato S, et al. Comparative study of the efficacy of saireito monotherapy versus antiallergic agent plus carbocysteine combination therapy for otitis media with effusion*. *Kampo Igaku (Kampo Medicine)* 1992; 16: 200-3 (in Japanese).

1. Objectives

To compare the efficacy of saireito (柴苓湯) monotherapy versus antiallergic agent plus S-carboxymethyl-L-cysteine (S-CMC; carbocysteine) combination therapy for otitis media with effusion.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital (outpatient clinic in the department of otorhinolaryngology), Japan.

4. Participants

Twenty patients with otitis media with effusion who had conductive hearing loss defined as air-bone gap (A-B GAP) of 15 dB or more (at 3 frequency average hearing levels). Otitis media with effusion was diagnosed based on eardrum findings, audiometry, and tympanogram.

5. Intervention

Arm 1: TSUMURA Saireito (柴苓湯) Extract Granules 9 g/day for patients weighing ≥ 40 kg, 6 g/day for patients weighing 20–40 kg, and 3 g/day for patients weighing < 20 kg for 4 weeks (n=10 [5 males and 5 females]; age, 7–64 years).

Arm 2: Ketotifen 1.2–2.0 mg/day or oxatamide 1 mg/kg/day for children and 60 mg/day for adults plus S-CMC 30 mg/kg/day for children and 1500 mg/day for adults for 4 weeks (n=10 [5 males and 5 females]; age, 4–60 years).

6. Main outcome measures

“Good response” was defined as hearing improvement of 10 dB or greater (at 3 frequencies) as measured by pure-tone audiometry, and improvements in tympanogram and eardrum findings; “minimal response” as 1–10 dB improvement (at 3 frequency average hearing levels) and improvements in tympanogram and eardrum findings; “no response” as no change by pure-tone audiometry; “worsening” as loss of hearing by pure-tone audiometry.

7. Main results

In arm 1 and arm 2, respectively, about 50% and 60% of patients achieved moderate or mild improvement, with the response to treatment characterized as “moderate improvement” in 2 and 3, “mild improvement” in 3 and 3, “no change” in 2 and 2, and “worsening” in 3 and 2 patients, respectively. There was no statistically significant between-group difference in the percent and number of responders and in pure-tone audiogram, tympanogram, and eardrum findings.

8. Conclusions

Saireito is effective for the treatment of otitis media with effusion as standard combination therapy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Notable adverse reactions were not observed.

11. Abstractor’s comments

This is a valuable RCT of the efficacy of saireito for otitis media with effusion. Comparing a monotherapy with combination therapy may make blinding of patients difficult because the number of drug(s) used is obviously different. In addition, since age range of patients was wide, the treatment regimen varied accordingly. Readers might have been confused by the change of terms for assessment from “response” as defined in the outcome measures section, to “improvement” as used in the results. Reassessment using a higher-quality study design is desirable.

12. Abstractor and date

Tsuruoka K, 27 September 2008, 1 June 2010, 31 December 2013.