

## 8. Ear Diseases

**Reference**

Inoue H. Rapid effect of combination therapy with shoseiryuto and eppikajutsuto for acute otitis media with effusion in adults\*. *Jibi to Rinsho (Otologia Fukuoka)* 2001; 47: 361-6 (in Japanese). Ichushi Web ID: 2002064379

**1. Objectives**

To evaluate the efficacy of shoseiryuto (小青竜湯) combined with eppikajutsuto (越婢加朮湯) for otitis media with effusion (OME) in adults.

**2. Design**

A quasi-randomized controlled trial (quasi-RCT).

**3. Setting**

A clinic (otorhinolaryngology), Japan.

**4. Participants**

Thirty-four patients aged 16 years or older with acute OME.

Diagnostic criteria: eligible patients were those who complained chiefly of aural fullness, hearing loss, and autophony in the preceding three weeks at interview, and who had tympanic effusion evident under a binocular microscope.

**5. Intervention**

Arm 1: treatment with shoseiryuto (小青竜湯) extract 1 pack t.i.d. and eppikajutsuto (越婢加朮湯) 1 pack t.i.d. (after meals).

(a total of 28 ears of 20 patients; 11 males and 9 females; aged 38.1±16.9 years).

Arm 2: treatment with carbocisteine 500 mg t.i.d. and clarithromycin 200 mg b.i.d. (after meals).

(a total of 18 ears of 14 patients; 10 males and 4 females; aged 37.9±11.5 years).

Patients in both arms were treated for 7 days. If excellent or good response was obtained and subjective symptoms disappeared at 4 days, treatment was stopped at 4 days.

**6. Main outcome measures**

Main variables were symptoms (assessed on interview) and eardrum findings (under a microscope) at 4 and 7 days after the first visit. Symptoms were evaluated on a 4-point scale as follows: 'excellent response,' 'good response,' 'minimal response,' and 'no response.' Eardrums were checked primarily for tympanic effusion. Tympanogram was recorded at the first visit and 7 days later (or at 4 days in patients who showed improvement at that point).

**7. Main results**

'Excellent or good response' with normalization or improvement of the tympanogram and with disappearance of tympanic effusion was achieved in 38.9% of the control group (arm 2) vs 75.0% of the Kampo group (arm 1); the outcome was significantly better in the Kampo group ( $P=0.02$ , Wilcoxon rank sum test). In patients with abnormal tympanogram at the first visit, therapeutic response tended to be more pronounced in the Kampo group. Time to the onset of improvement of subjective ear symptoms was significantly shorter in arm 2 than arm 1 ( $P=0.05$ ).

**8. Conclusions**

In acute OME in adults, combination therapy with shoseiryuto extract and eppikajutsuto extract results in rapid disappearance of the effusion and improvement of ear symptoms.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Nausea was observed in one patient in arm 2, while no adverse drug reactions occurred in arm 1.

**11. Abstractor's comments**

This report is clinically relevant. Since patients were randomly assigned to each arm, based on odd- or even chart number, this study was strictly a randomized clinical controlled trial (CCT), not an RCT, and is classified as a quasi-randomized trial. Results from larger rigorously-designed trials are awaited.

**12. Abstractor and date**

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.