5. Psychiatric/Behavioral Disorders

Reference

Yamagiwa M, Sakakura Y, Harada T, et al. Therapeutic response to various drugs in patients with continuous or periodic discomfort in the throat. *Jibiinkoka Rinsho* (*Practica Otologica*) 1990; 83: 1687–92 (in Japanese with English abstract).

1. Objectives

To evaluate the efficacy of saibokuto (柴朴湯) for relieving discomfort in the throat.

2. Design

Randomized controlled trial (RCT).

3. Setting

The departments of otorhinolaryngology of Mie University Hospital and of related hospitals (not identified), Japan.

4. Participants

Four-hundred and ninety-four patients seen in the above hospitals with a chief complaint of discomfort in the throat, diagnosed with and treated for laryngopharyngeal discomfort without adverse drug reactions and with available efficacy data.

5. Intervention

Arm 1: placebo (sugar-coated tablet indistinguishable from Alprazolam tablets 0.4 mg), 3 tablets/day for 2 weeks (n=73).
Arm 2: lysozyme chloride granules, 270–300 mg/day for 2 weeks (n=91).
Arm 3: tiaprofenic acid, 6 tablets/day for 2 weeks (n=99).
Arm 4: Alprazolam 0.4 mg, 3 tablets/day for 2 weeks (n=72).
Arm 5: dosulepin hydrochloride, 1–2 capsules/day for 2 weeks (n=59).
Arm 6: saibokuto (柴苓湯) extract granules (manufacturer unknown), 7.5 g/day for 2 weeks (n=100).

6. Main outcome measures

The percentage of patients whose discomfort in the throat disappeared, evaluated at weeks 0, 1, 2, and 3 after the start of treatment in patients with "constant discomfort" and patients with "frequent discomfort" in arms 1–6.

7. Main results

In arms 1, 2, and 5, "frequent discomfort" disappeared in a higher percentage of patients than did "constant discomfort," showing that frequent discomfort is more tractable. In arms 3 and 6, there was no difference between the percentage of patients whose "frequent discomfort" disappeared and the percentage of patients whose "constant discomfort" disappeared. In arm 4, "frequent discomfort" disappeared in a higher percentage of patients than did "constant discomfort" during treatment, but "frequent discomfort" recurred in these patients at week 3.

8. Conclusions

"Constant discomfort" is not necessarily more intractable to treatment than "frequent discomfort."

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinical trial is unique because it investigated the rate of response to each treatment separately in patients with "constant discomfort" and patients with "frequent discomfort," but did not evaluate the efficacy of the investigational product over placebo. However, the number of participants varied among groups, and the method of allocation described in the paper as "randomly" allocated to treatment is not clear. Furthermore, the analysis population included only patients without adverse drug reactions and with available drug efficacy data. Indicating the method used to allocate the original medicines, reporting the number of dropouts, and evaluating the efficacy of the investigational product over placebo, would have improved this clinical trial.

12. Abstractor and date

Goto H, 17 August 2008, 1 June 2010.