

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Inoue M. Clinical study of effects of tsu-do-san on mastitis. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1993; 43: 517–21 (in Japanese).

1. Objectives

To evaluate the efficacy of tsudosan (通導散) in the treatment of mastitis.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Outpatient Department of Breast Medicine, Japanese Red Cross Medical Center, Japan.

4. Participants

Two-hundred and forty-eight patients diagnosed with mastopathy based on findings of breast imaging, ultrasonography, and mammography between July 1990 and June 1991, and classified into *chukansho* (中間証, intermediate pattern) or *jitsusho* (実証, excess pattern).

5. Intervention

Arm 1: TSUMURA Tsudosan (通導散) Extract Granules 2.5 g t.i.d. for 4 weeks (n=150).

Arm 2: TSUMURA Keishibukuryogan (桂枝茯苓丸群) Extract Granules 2.5 g t.i.d. for 4 weeks (n=33).

Patients were allocated to arm 1 and arm 2 at a ratio of 4:1.

6. Main outcome measures

The measures (disappearance of subjective breast pain and percent disappearance of mammary gland swelling) are not clear, since only exceptionally large reduction in mammary gland swelling was defined as a response.

7. Main results

Sixty-five patients dropped out. There was no difference in the efficacy of tsudosan between the *chukansho* (中間証, intermediate pattern) and *jitsusho* (実証, excess pattern) groups. The statistical significance of the difference in efficacy between tsudosan and keishibukuryogan was not mentioned.

8. Conclusions

No definite conclusions were reached.

9. From Kampo medicine perspective

The historical background of *oketsu* (才血, blood stasis) as an indication was discussed.

10. Safety assessment in the article

Twenty patients (14%) were withdrawn because of diarrhea/abdominal pain.

11. Abstractor's comments

The intention of this study was to investigate the efficacy of tsudosan for mastitis and thereby to provide another therapeutic option, while keishibukuryogan is used for treatment of patients with *jitsusho* (実証, excess pattern). Patients were classified into groups based on criteria (not mentioned) defining *chukansho* (中間証, intermediate pattern: medium build, well-developed breast, slightly weak or strong tone of the abdominal wall, good appetite, normal bowel movements or slight *hiketsu* [秘結, constipation], and normal menstruation), and *jitsusho* (実証, excess pattern: details not mentioned) by one physician. However, with a wide range of diagnostic criteria, the classification remains obscure. It is unclear whether the absence of difference between *chukansho* (中間証, intermediate pattern) and *jitsusho* (実証, excess pattern) groups reflects misclassification or the meaninglessness of the classification system itself. Although this paper demonstrated a response to tsudosan in some patients, it is desirable that the above problems be solved in a future report.

12. Abstractor and date

Nakata H, 10 January 2009, 1 June 2010.