

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

Inoue M. Clinical studies on effects of tokakujoki-to for fibro-cystic disease of the breast. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1992; 42: 415–8 (in Japanese).

1. Objectives

To evaluate the efficacy of tokakujokito (桃核承気湯) in the treatment of mastitis.

2. Design

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

3. Setting

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

4. Participants

One-hundred and ninety-six patients diagnosed with mastopathy based on findings of breast imaging, ultrasonography, and mammography between July 1989 and June 1990.

5. Intervention

Arm 1: tokakujokito (桃核承気湯) group, tokakujokito (桃核承気湯) (manufacturer unknown) 2.5 g t.i.d. (n=103).

Arm 2: keishibukuryogan (桂枝茯苓丸群) group, keishibukuryogan (桂枝茯苓丸群) (manufacturer unknown) 2.5 g t.i.d. (n=22)

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

Patients whose symptoms were resolved when efficacy was evaluated at 4 weeks were considered to be responders and treatment was ended. Patients showing a tendency for improvement were given the same prescription for an additional 4 weeks and final efficacy was evaluated at 8 weeks. Patients with no therapeutic effect at the time of the primary efficacy evaluation were considered to be non-responders and treatment was stopped.

6. Main outcome measures

The presence or absence of subjective breast pain and mammary gland swelling was used to evaluate efficacy, and therefore the criteria for efficacy are not clear.

7. Main results

There were 71 dropouts. The significance of the difference in efficacy between tokakujokito and keishibukuryogan was not indicated.

8. Conclusions

No definite conclusions were reached.

9. From Kampo medicine perspective

Aspects of the topic “crude drug” are discussed in the discussion section of the reference.

10. Safety assessment in the article

Treatment was stopped in 13 patients (11%) because of diarrhea and abdominal pain.

11. Abstractor’s comments

This paper reported the efficacy of tokakujokito for patients with mastopathy. Tokakujokito and keishibukuryogan had similar efficacy, but the former was associated with a higher incidence of diarrhea, which occurred in nearly half the patients treated. Without knowing the criteria used to select treatment with tokakujokito rather than keishibukuryogan, the intent of the article is obscure. A follow-up report with in-depth discussion on the indications for tokakujokito is awaited.

12. Abstractor and date

Nakata H, 10 January 2009, 1 June 2010.