

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

Kotani N, Oyama T, Sakai I, et al. Analgesic effect of an herbal medicine for treatment of primary dysmenorrhea - a double-blind study. *The American Journal of Chinese Medicine* 1997; 25: 205-12. CENTRAL ID: CN-00143317, Pubmed ID: 9288368

1. Objectives

To evaluate the efficacy of tokishakuyakusan (当帰芍薬散) on dysmenorrhea.

2. Design

Double-blind randomized controlled trial (DB-RCT).

3. Setting

Not indicated (the authors were affiliated with the Department of Anesthesiology, Hirosaki University School of Medicine), Japan.

4. Participants

Forty females suffering from dysmenorrhea for at least 1 year, with all *kikyo* (気虚, *qi deficiency*), *in* (陰, *yin*), and *oketsu* (瘀血, static blood) scores of 30 or more, without orthopedic disorders, and not receiving oral low-dose medications or prescribed anxiolytics.

5. Intervention

The study covered a total of 6 menstrual cycles (half a year): 2 cycles for baseline observation, followed by two cycles for treatment and then two cycles for follow-up observation.

Arm 1: oral administration of tokishakuyakusan (当帰芍薬散) (manufacturer unknown) 2.5 g t.i.d. (during the third to fourth menstrual cycles in the treatment period) (n=20).

Arm 2: oral administration of placebo (during the third to fourth menstrual cycles in the treatment period) (n=20).

6. Main outcome measures

Pain assessed on a visual analogue scale (VAS) and use of diclofenac sodium (Voltaren).

7. Main results

Dysmenorrhea was significantly improved in patients receiving tokishakuyakusan ($P < 0.001$).

8. Conclusions

Adding Kampo indices *kikyo*, *in*, and *oketsu* to the diagnostic criteria enables selection of patients indicated for tokishakuyakusan, who can benefit from its analgesic effect.

9. From Kampo medicine perspective

Although the usefulness of each score is mentioned, it is not discussed from a Kampo medicine perspective.

10. Safety assessment in the article

No adverse events occurred.

11. Abstractor's comments

This study can be recognized as an attempt to define the indications for tokishakuyakusan using the Kampo diagnostic system (i.e., rating *kikyo*, *in*, and *oketsu* in patients with dysmenorrhea. While it is important to reduce the use of analgesics through pain relief, continued studies are expected on, for example, whether tokishakuyakusan is also effective for patients not responding to analgesics and how patients indicated for tokishakuyakusan differ from those indicated for keishibukuryogan (桂枝茯苓丸) or shakuyakukanzoto (芍薬甘草湯).

12. Abstractor and date

Nakata H, 1 January 2008, 1 June 2010, 31 December 2013.