

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

Ota H. Positioning of Kampo therapy and hormone replacement therapy in treatment of climacteric disorders\*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2001; 18: 21-9 (in Japanese). Ichushi Web ID: 2002170744

**1. Objectives**

To compare hormone replacement therapy (HRT) and Kampo therapy as treatment of climacteric disorders.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

None. The author belonged to the Department of Obstetrics and Gynecology, Tokyo Women's Medical University, Japan.

**4. Participants**

Ninety-six postmenopausal or ovariectomized patients with climacteric disorders.

**5. Intervention**

Arm 1: Kampo therapy (keishibukuryogan (桂枝茯苓丸), n=19; kamishoyosan (加味逍遙散), n=11; goshajinkigan (牛車腎氣丸), n=8; tokishakuyakusan (当帰芍薬散), n=2; tokakujokito (桃核承氣湯), n=2; kihito (帰脾湯), n=2; nyoshinsan (女神散), n=2) (n=46).

Arm 2: HRT (0.625 mg of conjugated estrogen and 2.5 or 5 mg of medroxyprogesterone acetate) (n=50).

No details indicated in the original paper.

**6. Main outcome measures**

Score on Keio modified menopause index, measured at baseline, 1, 6, and 12 months after the start of administration. Severity was defined as mild for 0–10 points, moderate for 10–20 points, and severe for 20–30 points, and response was defined as a change from severe to moderate, moderate to mild, or a score reduction by two-thirds in mild cases.

**7. Main results**

HRT improved the following 6 symptoms in 1 month: vasomotor manifestations; nervousness; low back and back pain; depression; insomnia; and headache. In contrast, Kampo therapy did not improve any symptoms in 1 month but improved the following 4 symptoms in 6 months: vasomotor manifestations; malaise; low back and back pain; and nervousness. Among Kampo medicines, only goshajinkigan was effective for low back and back pain.

**8. Conclusions**

The therapeutic effect of HRT is superior for hot flashes, perspiration, depression, and insomnia, whereas that of Kampo therapy is superior for malaise and chill.

**9. From Kampo medicine perspective**

The number of patients receiving keishibukuryogan (n=19), kamishoyosan (n=11), or tokishakuyakusan (n=2) was explained by the small number of cases with *kyo-sho* (虚証, deficiency pattern).

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This paper outlines the characteristics of Kampo medicines and HRT. It recommends that Kampo medicine be administered in more responsive cases with specific symptoms. Subsequent publication of a study of individual Kampo medicines with more sensitive design is awaited.

**12. Abstractor and date**

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