Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

14. Genitourinary Tract Disorders (including Climacteric Disorders)

References

Takamatsu K, Musha C, Okano H, et al. Study of usefulness of Kampo therapy for climacteric disorders*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology*) 2002; 19: 111-6 (in Japanese) Ichushi Web ID: 2002193391

Takamatsu K. HRT and Kampo medicine*. *Nippon Konenki Igakukai Zasshi (The Journal of the Japan Menopause Society*) 2004; 12: 155-7 (in Japanese)

Takamatsu K, Makita K, Tanabe K, et al. HRT and Kampo medicine*. *Rinsho Kensa (The Journal of Medical Technology)* 2004; 48: 877-84 (in Japanese)

Takamatsu K, Tanabe K. Efficacy of Kampo medicine against climacteric disorders*. *Sanfujinka Chiryo (Obstetrical and Gynecological Therapy*) 2004; 89: 408-15 (in Japanese). MOL, MOL-Lib

Takamatsu K. Study of the usefulness of Kampo therapy for climacteric disorders – a randomized trial of three major Kampo medicines for treatment of gynecological disease—*. Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology) 2006; 23: 35-42 (in Japanese). Ichushi Web ID: 2006288782

1. Objectives

To compare the efficacy of Kampo therapy with that of hormone replacement therapy (HRT) for climacteric disorders and to compare the efficacy of three non-sho-based (非随証) Kampo medicines for gynecological disease.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Departments of Obstetrics and Gynecology, Tokyo Women's Medical University (1) and Keio University Hospital (2), Japan.

4. Participants

- (1) Seventy women receiving ambulatory treatment for climacteric disorders between November 2000 and January 2002.
- (2) One hundred women receiving ambulatory treatment for climacteric disorders between January 1993 and December 2000.

5. Intervention

Comparison of clinical efficacy of HRT and Kampo medicine

Arm 1: administration of 2.5 g t.i.d. of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules, TSUMURA Kamishoyosan (加味逍遙散) Extract Granules or TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules before meals for 4–8 weeks (n=70).

Arm 2: continuous coadministration of 0.625 mg t.i.d. of Premarin (conjugated equine estrogen) and 2.5 mg of Provera (medroxyprogesterone acetete) before meals for 4–8 weeks (n=110).

Evaluation of the efficacy of non-sho-based therapy with three major Kampo medicines for gynecological disease.

Arm 1: administration of 2.5 g t.i.d. of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules before meals for 4–8 weeks (n=23).

Arm 2: administration of 2.5 g t.i.d. of TSUMURA Kamishoyosan (加味逍遙散) Extract Granules before meals for 4–8 weeks (n=23).

Arm 3: administration of 2.5 g t.i.d. of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules before meals for 4–8 weeks (n=24).

6. Main outcome measures

Presence/absence and improvement of symptoms self-evaluated on a 4-point symptom severity scale using the Keio modified menopause index questionnaire.

7. Main results

Overall response rates for HRT and Kampo therapy were comparable (78.0% responders to HRT and 68.6% responders to Kampo therapy), although improvement was greater in patients receiving Kampo therapy (severity reduced by 2 or more points in 83.0% of patients receiving HRT and 21.4% of those receiving Kampo therapy). There was no difference in the percent who responded to the three non-*sho*-based therapies (65.2% were responders to tokishakuyakusan, 74.0% were responders to kamishoyosan, and 70.8% responders to keishibukuryogan). Kampo therapy was particularly effective for psychiatric manifestations including excitability, depression, irritation, anxiety, and brooding.

8. Conclusions

Using the same questionnaire, this study demonstrated that Kampo therapy has some effect on climacteric disorders, in particular, relieving subjective symptoms at almost the same rate as HRT and showing high efficacy against psychotic manifestations.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

In this paper, the rate of symptom improvement after Kampo therapy was approx. one-quarter that after HRT and the three Kampo medicines had comparable efficacy, showing that non-sho-based Kampo therapy for "climacteric disorders" is limited. Thus, this study is valuable in that it supports the importance of the zuisho (随証, based on pattern) approach to Kampo therapy in the treatment of climacteric disorders.

12. Abstractor and date

Ushiroyama T, 1 April 2008, 20 December 2008, 1 June 2010, 31 December 2013.