18. Symptoms and Signs

Reference

Sekiguchi Y, Miyai K, Noguchi K, et al. Study of effects of anti-heat shock protein 60 antibody by ba wei di huang wan and qing xin lian zi yin (II). *Wakan Iyakugaku Zasshi* (*Journal of Traditional Medicines*) 1998; 15: 326-7 (in Japanese). CiNii

1. Objectives

To determine the effects of hachimijiogan (八味地黄丸) and seishinrenshiin (清心蓮子飲) on anti-heat shock protein (HSP) 60 antibody.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

Not mentioned (the authors are in the Department of Urology, Yokohama City Kowan Hospital), Japan.

4. Participants

Twelve patients with normal urinalysis who chiefly complained of urinary frequency, pain on urination, or incomplete emptying.

5. Intervention

Arm 1: treatment with TSUMURA Seishinrenshiin (清心蓮子飲) Extract Granules (dose, not specified) orally for 2 weeks → treatment with TSUMURA Hachimijiogan (八味地黄丸) Extract Granules (dose, not specified) orally for 2 weeks (n=7).

Arm 2: treatment with TSUMURA Hachimijiogan (八味地黄丸) Extract Granules (dose, not specified) orally for 2 weeks → treatment with TSUMURA Seishinrenshiin (清心蓮子飲) Extract Granules (dose, not specified) orally for 2 weeks (n=5).

6. Main outcome measures

General subjective symptoms and urinary symptoms were evaluated using the International Prostate Symptom Score (IPSS) questionnaire. The titer of anti-HSP60 antibody was measured in blood samples.

7. Main results

The titer of anti-HSP60 IgG1 antibody was significantly reduced compared with the pre-treatment level both in arms 1 and 2. No change was observed in the titer of anti-HSP60 IgG2 antibody in both arms. Overall, although there was no change in urinary subjective symptoms score after treatment in both arms, gender-specific analysis of these ratings showed significant improvements after treatment of the male patients of arm 1 and female patients of arm 2. The outcomes were compared between patients with subjective symptoms lasting one month or more and patients with subjective symptoms lasting less than one month. The titer of anti-HSP60 IgG1 antibody declined significantly from pre-treatment level both in arms 1 and 2 in patients with urinary frequency lasting one month or more, but not in patients with urinary frequency lasting less than one month. Then, the association between general subjective symptoms and anti-HSP60 antibody (IgG1) were examined. The anti-HSP60 antibody (IgG1) titer was significantly higher in patients who self-reported nervousness than in patients who didn't (P=0.028) and in patients who reported early waking than in patients who didn't (P=0.0074). Similarly, the anti-HSP60 antibody (IgG1) titer was significantly lower in patients who reported having a good night's sleep than in patients who didn't (P=0.0300), and in patients who reported stiff back (P=0.0390) or cold hands (P=0.0472) than in patients who didn't.

8. Conclusions

The reduction of the titer of anti-HSP60 antibody (IgG1) after the hachimijiogan and seishinrenshiin treatments varies depending on the gender and the duration of urinary tract symptoms.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinical study evaluated the effects of hachimijiogan and seishinrenshiin treatments on anti-HSP60 antibody. It is the only study to examine the association between anti-HSP60 antibody and urological symptoms. However, the paper was published in abstract form, and many details are omitted. One of the points that might significantly influence the results is wash-out period, which was not specified. The authors stated "the titer of anti-HSP60 IgG1 antibody was significantly reduced compared with the pre-treatment level both in arms 1 and 2". If the drugs were switched without wash-out, the anti-HSP60 IgG1 titer would remain low because the first drug is still present and active at the time of cross-over. So the length of the wash-out period needs to be stated. In addition, the authors found "significant improvements in male patients of arm 1 and female patients of arm 2 after the treatment", but this remarkable result might not be fully appreciated because details, including male/female ratio, are not available. Publication of the details of this study is needed to obtain further valuable insights into the association between Kampo medicine and anti-HSP60 antibody.

12. Abstractor and date

Goto H, 17 September 2008, 6 January 2010, 1 June 2010, 31 December 2013.