13. Diseases of the Musculoskeletal System and Connective Tissue

Reference

Hayashi Y, Saito E, Takahashi O. Usefulness of hachimijiogan for lumbar spinal stenosis*. *Geriatric Medicine* 1994; 32: 585–91 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of hachimijiogan (八味地黄丸) for lumbar spinal stenosis.

2. Design

Quasi-Rrandomized controlled trial (quasi-RCT).

3. Setting

Not mentioned (the authors belong to the faculty of Tokyo Metropolitan Rehabilitation Hospital), Japan.

4. Participants

Twenty-seven patients with radiographically demonstrable spinal column stenosis and symptoms arising from compression of the sciatic nerve or its branches.

5. Intervention

Arm 1: oral administration of TSUMURA Hachimijiogan (八味地黄丸) Extract Granules 7.5 g/day for 8 weeks (n=19).
Arm 2: oral administration of propionic acid (details unknown) for 8 weeks (n=8).

6. Main outcome measures

Subjective symptoms including lumbar pain on motion, lower limb tightness, and coldness; objective parameters including lower back tension, time from the start of walking to the occurrence of intermittent claudication, and fingertips-to-floor distance in patients bending forward; Kampo medicine findings including physical strength, complexion and hot flashes; hematology/urinalysis; measurements of bilateral tibial nerve F-wave latency, blood substance P concentration, and blood β-endorphin concentration.

7. Main results

All subjective symptoms were significantly improved in arm 1 compared with arm 2. Among objective variables, duration of intermittent claudication was significantly improved in arm 1 (P=0.03), but bilateral tibial nerve F-wave latency, blood substance P concentration, and blood β endorphin concentration were not changed significantly in either arm.

8. Conclusions

Hachimijiogan improves subjective symptoms, but not objective measures of spinal column stenosis.

9. From Kampo medicine perspective

Within arm 1, significantly more patients without "*hie*" (冷え, a feeling of coldness in the body) than those with moderate or severe "*hie*" responded (P=0.001).

10. Safety assessment in the article

There were no adverse reactions.

11. Abstractor's comments

This is an epoch-making clinical study that investigated the efficacy of hachimijiogan for spinal column stenosis using not only subjective symptoms but also objective measures. However, the introduction states that patients were randomly allocated but the method section states that patients were allocated to arm 1 and arm 2 in the order of hospital arrival time. In addition, since the analysis population consisted of 19 patients in arm 1 and 8 patients in arm 2, the method of randomization should be specified. Similarly, the dosage and method of administration of propionic acid used as control were not mentioned and should be specified since the paper says that proprionic acid was not effective for subjective symptoms. Nevertheless, this is an excellent attempt because not only subjective symptoms but also objective measures are used to evaluate efficacy. Increasing its sample size would improve this excellent clinical study.

12. Abstractor and date

Goto H, 13 September 2008, 1 June 2010, 31 December 2013.