12. Skin Diseases

Reference

Ishioka T. Comparative evaluation of rokumigan and hachimi-jiogan on senile pruritus. *Therapeutic Research* 1995; 16: 1497–504 (in Japanese with English abstract). MOL, MOL-Lib

1. Objectives

To compare the efficacy of rokumigan (六味丸) and hachimijiogan (八味地黄丸) for the treatment of senile pruritus.

2. Design

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

3. Setting

One special nursing home for the elderly, Japan.

4. Participants

Nursing home residents with a diagnosis of senile pruritus and itching almost every night (9 males and 22 females; 62–95 years old; mean age, 77.5±9.4).

5. Intervention

Arm 1: TSUMURA Rokumigan (六味丸) Extract Granules 2.5 g t.i.d. before or after meals for two weeks followed by TSUMURA Hachimijiogan (八味地黄丸) Extract Granules 2.5 g t.i.d. before or after meals for two weeks (4 males and 11 females).

Arm 2: TSUMURA Hachimijiogan (八味地黄丸) Extract Granules 2.5 g t.i.d. before or after meals for two weeks followed by TSUMURA Rokumigan (六味丸) Extract Granules 2.5 g t.i.d. before or after meals for two weeks (5 males and 10 females).

6. Main outcome measures

Changes in the severity of itching were assessed after 2 and 4 weeks. The severity was evaluated on a 4-point scale: sleep disturbance due to itching (+++), intolerable itching but no sleep disturbance (++), barely tolerable itching (+), and just annoying itching (±).

Global ratings of symptom severity whether before or after treatment were as follows: (1) completely disappeared: “marked response,” (2) clearly improved: “moderate response,” (3) at least slightly improved: “mild response,” (4) no improvement: “no response,” (5) symptoms worsened: “worse.” In addition, global assessments according to patients’ physical strength were also performed.

7. Main results

Rokumigan resulted in marked response in 17 patients (56.7%), moderate response in 6 (20.0%), mild response in 1 (3.3%), and no response in 4 (13.3%), and symptoms worsened in 2 (6.7%); 23 had at least a moderate response (76.7%). Hachimijiogan resulted in marked response in 18 patients (60.0%), moderate response in 6 (20.0%), mild response in 2 (6.7%), and no response in 4 (13.3%); 24 had at least a moderate response (80%). There was no significant between-arm difference. In the 12 patients with more physical strength, the response to rokumigan was marked in 8 (66.7%), moderate in 3 (25.0%), and mild in 1 (8.3%), while the response to hachimijiogan was marked in 4 (33.3%), moderate in 5 (41.7%), and absent in 3 (25.3%); significantly more patients achieved marked responses to rokumigan ($P<0.05$). In the 18 patients with less physical strength, response to rokumigan was marked in 9 (50.0%), moderate in 3 (16.7%), and absent in 4 (22.2%), and symptoms worsened in 2 (11.1%), while the response to hachimijiogan was marked in 14 (77.8%), moderate in 1 (5.6%), mild in 2 (11.1%), and absent in 1 (5.6%). Significantly more patients had marked response to hachimijiogan ($P<0.05$).

8. Conclusions

Rokumigan and hachimijiogan have similar efficacy for the treatment of senile pruritus. More patients with greater physical strength achieved a marked response to rokumigan while more patients with less physical strength achieved a marked response to hachimijiogan.

9. From Kampo medicine perspective

The degree of general physical strength does not necessarily correlate with *jitsu-sho* (実証, excess pattern) or *kyo-sho* (虚証, deficiency pattern) in Kampo medicine. However, the authors noted that less physical strength, assessed on the basis of ability to play balloon volleyball, almost corresponds to the minimum criterion defining weak constitution in the guidelines used to select Kampo extract formulations.

10. Safety assessment in the article

One patient (in arm 1) dropped out because of nausea and was not included in the analyses.

11. Abstractor’s comments

This study expanded the previous RCT of hachimijiogan reported by same authors (Ishioka T, Aoi R. Comparative evaluation of hachimijiogan and ketotifen fumarate on senile pruritus*. *Shinyaku to Rinsho* [*Journal of New Remedies and Clinics*] 1992; 41: 2603–8). There was no wash out period as in the prior study. Moreover, the analyses were not performed on an intent-to-treat basis and the sample size was small, so these limitations might affect the results. Further developments are expected.

12. Abstractor and date

Tsuruoka K, 12 April 2008, 1 June 2010, 31 December 2013.