

12. Skin Diseases

Reference

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 (in Japanese).

1. Objectives

To compare the efficacy of hachimijiogan (八味地黄丸) with that of antiallergic drugs 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

Thirty-two nursing home residents diagnosed with senile pruritus, who experienced itching almost every night (9 males and 23 females; mean age, 78.0±7.9).

5. Intervention

Arm 1: TSUMURA Hachimijiogan (八味地黄丸) Extract Granules 2.5 g t.i.d. before or after meals for two weeks followed by ketotifen fumarate (Zaditen) 1 mg b.i.d. for two weeks (5 males and 11 females).

Arm 2: ketotifen fumarate 1 mg b.i.d. 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 12 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: intolerable itching causing sleep disturbance (+++), intolerable itching but not causing 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.”

7. Main results

Hachimijiogan resulted in a marked response in 11 patients (34%), moderate response in 14 (44%), mild response in 2 (6%), and no response in 5 (16%); 25 had at least a moderate response (78%). Ketotifen fumarate resulted in a marked response in 15 patients (47%), moderate response in 10 (31%), mild response in 4 (13%), and no response in 2 (6%), and symptoms worsened in 1 (3%); 25 had at least a moderate response (78%). There was no significant between-arm difference. The efficacy of the drug administered later seemed to be more effective. When comparing drug efficacy in 13 patients with more physical strength with that in 19 patients with less physical strength, significantly more patients in the latter group achieved at least moderate response to hachimijiogan ($P<0.05$). The efficacy of ketotifen fumarate did not correlate with physical strength.

8. Conclusions

The responses to both hachimijiogan and antiallergic drugs for the treatment of senile pruritus are similar (response rate, 78%). They are similarly effective. Hachimijiogan is effective especially in patients with less physical strength.

9. From Kampo medicine perspective

Although there is no in-depth description regarding “*sho* (証, pattern),” analyses comparing “patients with more physical strength” and “patients with less physical strength” are informative.

10. Safety assessment in the article

No adverse reaction was observed.

11. Abstractor’s comments

This was an RCT with a cross-over design. Since the itching (depending on its severity) could interfere with sleep, sleepiness (an adverse reaction of ketotifen fumarate) was a concern. However, the authors stated that no drug-induced sleepiness was observed. Unfortunately, this study had no washout period, so a further more expanded study is expected.

12. Abstractor and date

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