12. Skin Diseases

Reference

Ohkawara A, Furuya K, Kurisu Y, et al. Experience with Orengedokuto (TJ-15) and Goshajinkigan (TJ-107) for the treatment of senile pruritus*. *Nishinihon Hifuka* (*The Nishinihon Journal of Dermatology*) 1991; 53: 1234–41 (in Japanese). Ichushi Web ID: 1992177261

1. Objectives

To compare the efficacy and safety of orengedokuto (黄連解毒湯) and goshajinkigan (牛車腎気丸) with antihistamine for the treatment of senile pruritus.

2. Design

Randomized controlled trial (RCT).

3. Setting

Fourteen institutions: five universities (Hokkaido University, Kansai Medical University, University of Tokushima, Kyushu University, and Kagoshima University) and other related medical institutions, Japan.

4. Participants

Ninety-six patients (55 or more years old) who were diagnosed with pruritus. Exclusion criteria were: 1) infection or purulent skin disease; 2) serious impairment of the liver, kidney, cardiovascular system, or gastrointestinal system; 3) oral or injectable steroids within 2 weeks before the study; 4) topical steroids including very strong ones given within a week before the study; 5) others considered ineligible by participating physicians.

5. Intervention

Based on the score table for deficiency or excess pattern identification, patients were grouped as follows according to their body type, complexion, muscle strength, and abdominal muscles strength: A group: *chukan-sho* (中間証, intermediate pattern) to *jitsu-sho* (実証, excess pattern) type (10 points or more); B group: *chukan-sho* to *kyo-sho* (虚証, deficiency pattern) type (9 points or less).

Group A

Arm 1: administration of TSUMURA Orengedokuto (黄連解毒湯) Extract Granules 2.5 g t.i.d. before meals for 6 weeks (11 males and 5 females). The *sho* (証, pattern) score was 12.25±1.98.

Arm 2: administration of antihistamine (Tavegyl tablet) 1 mg b.i.d. after meals for 6 weeks, (10 males and 6 females). The *sho* score was 13.05±2.20.

Group B

Arm 3: administration of TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules 2.5 g t.i.d. before meals for 6 weeks (15 males and 10 females). The *sho* score was 6.12±1.50.

Arm 4: administration of antihistamine (Tavegyl tablet) 1 mg b.i.d. after meals for 6 weeks (19 males and 10 females). The *sho* score was 6.28±1.94.

6. Main outcome measures

One subjective symptom (itching assessed on a 3-point scale), objective symptoms (degree of scaling, dry skin, scratch marks, and ichthyosiform skin evaluated on a 4-point scale), and overall improvement (assessed on a 5-point scale: marked, moderate, and mild improvement, absent, and worse) at the start of the study and at 2, 4, and 6 weeks of treatment. Safety was evaluated on a 4-point scale based on side effects and laboratory findings.

7. Main results

At least moderate overall improvement was achieved in 68.8% (arm 1) *vs*. 50.0% (arm 2) in Group A, as well as 72.0% (arm 3) *vs.* 55.2% (arm 4) in Group B. When A and B groups are combined, 53.3% of patients given Tavegyl *vs*. 70.0% of patients given Kampo preparations achieved overall improvement, but the between-group difference was not significant. Likewise, the between-group difference in subjective or objective symptom-specific overall improvement and safety was not significant.

8. Conclusions

Orengedokuto and goshajinkigan are as effective as Tavegyl for senile pruritus.

9. From Kampo medicine perspective

Selection of the intervention was based on the *syo* score.

10. Safety assessment in the article

Two patients in arm 1 and one in arm 3 had gastrointestinal symptoms. One patient treated with Tavegyl had decreased urine volume.

11. Abstractor's comments

This was a well-designed RCT. Notably, the selection of the intervention with Kampo preparations was based on *sho* scores. The study could have been improved by introducing blinding methods.

12. Abstractor and date

Tsuruoka K, 10 April 2008, 1 June 2010.