13. Diseases of the Musculoskeletal System and Connective Tissue

Reference

Nakajima K, Sato H, Ooyama K, Is maobushisaishinto effective for neuropathic pain? Effect of maobushisaishinto on occipital neuralgia* *Itami to Kampo* (*Pain and Kampo Medicine*) 2014: 24: 31-7 (in Japanese with English abstract). Ichushi Web ID: 2015016097

1. Objectives

To evaluate the efficacy of maobushisaishinto (麻黄附子細辛湯) for treatment of occipital neuralgia.

2. Design

Randomized controlled trial using envelopes for allocation (RCT-envelope).

3. Setting

Three clinics, Japan.

4. Participants

Twenty-two patients with occipital neuralgia who visited three clinics between November 2011 and April 2012, a total of 6 months.

5. Intervention

Arm 1: TSUMURA Maobushisaishinto (麻黄附子細辛湯) Extract Granules administered at 2.5 g t.i.d. before or between meals (n=12).

Arm 2: A loxoprofen tablet administered orally at a dose of 60 mg up to three times daily (n=10).

The longest treatment period was 21 days in both Arms 1 and 2. Treatment was discontinued if the patient's pain disappeared or if an adverse drug reaction occurred.

6. Main outcome measures

Treatment period. Pain assessed on a visual analogue Scale (VAS). A subject who reported a change in VAS value of 50 mm or more within 1 week of the last dose was regarded as "very responsive"; 50 mm or more 8 or more days after the last dose or of 20–49 mm, as "responsive"; and of 20 mm or less, as "nonresponsive."

7. Main results

No significant inter-arm difference was found for treatment period. The VAS value was 51.8±16.1 mm (standard deviation: SD) before treatment and 7.8±14.3 mm (SD) after treatment in the maobushisaishinto arm, showing a significant decrease (P=0.0001 in the U-test), and 56.0±19.6 mm (SD) before treatment and 10.1±17.5 mm (SD) after treatment in the loxoprofen arm, showing a significant decrease (P=0.0001 in the U-test). The number of subjects assessed as very responsive, responsive, and nonresponsive was 4, 7, and 1 to maobushisaishinto, and 5, 4, and 1 to loxoprofen, respectively.

8. Conclusions

Maobushisaishinto is effective for the treatment of occipital neuralgia.

9. From Kampo medicine perspective

The relationship between the efficacy of maobushisaishinto and *kan-sho* (寒証, cold pattern) was not found.

10. Safety assessment in the article

No description of adverse drug reactions were provided. Since discontinuation due to adverse drug reactions was not mentioned, there seemed to be no adverse responses.

11. Abstractor's comments

This study is very meaningful from the standpoint of clinical practice because it was a randomized controlled clinical trial using envelopes for allocation and evaluated the efficacy of maobushisaishinto for treatment of occipital neuralgia, as compared with loxoprofen. An evaluation of the outcomes suggests that maobushisaishinto has a similar or higher efficacy than loxoprofen. Considering the randomized controlled design of the trial, it is regrettable that the statistical procedures used to analyze between-arm differences were insufficient. In the Kampo medicine perspective section, the authors suggested that the diagnosis of *hyo-sho* (表証, exterior pattern) was appropriate in study subjects because the disease period was short (around 10 days).However, most occipital neuralgia lesions generally are considered to be appeared on the exterior surface of the body. Given these, further evaluation in a larger number of subjects is anticipated.

12. Abstractor and date

Kogure T, 31 March 2017.