9. Cardiovascular Diseases

Reference

Shimada Y. Efficacy of tokishakuyakusan for hypofunction and decreased independence in patients with sequelae of cerebrovascular disorder*. *Kosei Rodo Kagaku Kenkyuhi Hojokin Choju Kagaku Kenkyu Jigyo Koreisha no Nokekkan Shogai no Shinten Yobo wo Mokuteki to Shita Kampoyaku niyoru Tailor-made Iryo no Kaihatsu - Heisei 18 Nendo Buntan Kenkyu Hokokusho* (*Ministry of Health, Labour and Welfare, Science Research Grant, Comprehensive Studies on Science of Aging, Development of Personalized Medicine using Kampo Medicines to Prevent Progression of Cerebrovascular Disorders in the Elderly: Working-group Research Report Fiscal Year 2006*) 2007: 22-30 (in Japanese)

1. Objectives

To evaluate the efficacy and safety of tokishakuyakusan (当帰芍薬散) for treatment of hypofunction and decreased independence in patients with sequelae of cerebrovascular disorder.

2. Design

Randomized controlled trial (RCT) (assigned by randomized allocation in 20 cases and chosen by the patient in 6 cases), Japan.

3. Setting

University hospital and community hospital.

4. Participants

Thirty-one patients with sequelae of cerebrovascular disorder.

5. Intervention

Arm 1: administration of 2.5 g t.i.d. of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules between meals (n=16) (for 12 months**)**.

Arm 2: no administration of Kampo medicines (n=15).

6. Main outcome measures

The Stroke Impairment Assessment Set (SIAS), Functional Independence Measure (FIM), body weight and *oketsu* (瘀血, static blood), *qikyo* (気虚, qi deficiency), *qiutsu* (気鬱, qi movement stagnation) and *jinky*o (腎虚, kidney deficiency), evaluated on a 5-point scale at baseline and every 3 months thereafter.

7. Main results

Both SIAS and FIM scores remained at baseline levels in arm 1 but decreased significantly in arm 2 at 12 months, resulting in a significant between-arm difference. In arm 2, stroke recurred at 9 or 12 months.

8. Conclusions

Tokishakuyakusan suppresses hypofunction and decreased independence in patients with sequelae of cerebrovascular disorder requiring an intermediate level of care.

9. From Kampo medicine perspective

At 12 months, *oketsu* and *jinkyo* significantly improved in arm 1, but *oketsu* remained unchanged and *jinkyo* worsened in arm 2, resulting in a significant between-arm difference. In contrast, there was no significant difference in *qikyo* and *qiutsu* between arms.

10. Safety assessment in the article

One patient in arm 1 felt numbness in hands and feet. Since the cause (tokishakuyakusan, amantadine hydrochloride, or captopril) was unclear, all these drugs were discontinued in this patient.

11. Abstractor's comments

In this valuable report about the 1-year follow-up of patients with sequelae of cerebrovascular disorder, tokishakuyakusan was shown to suppress the hypofunction and decreased independence observable in the control group at 12 months. Since the sample size is small (15 or 16 patients), a study with a larger sample size is expected in the future. Further exploration of Kampo medicines potentially able to improve this condition is also expected.

12. Abstractor and date

Namiki T, 12 March 2009, 1 June 2010.