9. Cardiovascular Diseases

Reference

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 jinkyo (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.