9. Cardiovascular Diseases

References

Goto H, Satoh N, Hayashi Y, et al. A Chinese herbal medicine, tokishakuyakusan, reduces the worsening of impairments and independence after stroke: A 1-year randomized, controlled trial. *Evidence-based Complementary and Alternative Medicine* 2009: 1–6 (2011: 1-6. doi: 10.1093/ecam/nep026).
Evidence-based Complementary and Alternative Medicine 2009: 1-6. (2011: 1-6. doi: 10.1093/ecam/nep026) Pubmed ID: 19332457

1. Objectives

To evaluate the effectiveness of tokishakuyakusan (当帰芍薬散) in reducing impairment and increasing independence in post-stroke patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

Tonami General Hospital and Yoshimi Hospital, Japan.

4. Participants

Thirty-one post-stroke patients hospitalized between October 2005 and January 2006 with a history of cerebral bleeding, infarction, or subarachnoid hemorrhage as well as paralysis due to cerebral lesions. (cerebral infarction, 23 cases; cerebral bleeding, 7 cases; subarachnoid hemorrhage, 1 case). The patients were in the post-acute phase of recovery.

5. Intervention

Arm 1: Tokishakuyakusan (Tsumura Tokishakuyakusan [当帰芍薬散] Extract Granules [TJ-23] 7.5 g/day for 12 months).
Arm 2: no tokishakuyakusan treatment.

6. Main outcome measures

Impairments were assessed using the Stroke Impairment Assessment Set (SIAS). Independence status was assessed using the Functional Independence Measure (FIM).

7. Main results

SIAS scores for several items such as finger-function and knee-extension decreased significantly in arm 2 ($P<0.05$), whereas no significant change was observed in arm 1. Likewise, FIM scores indicated a worsening of functional status in arm 2 and prevention of that worsening in arm 1.

8. Conclusions

Tokishakuyakusan reduces the increase in impairment after stroke.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One patient in the tokishakuyaku arm withdrew because of numbness in his limbs, which was not attributable to tokishakusyakusan.

11. Abstractor's comments

This protocol of post-stroke tokishakusakusan administration was not expected (from the *Kampo* way of thinking) to prevent impairment. Suffice it to say that tokishakusakusan administration might reduce *kan-kekkyo*（肝血虚, liver blood deficiency）. The authors conducted this study on the basis of the reports suggesting the efficacy of tokishakuyakusan for the treatment of cognitive impairment due to Alzheimer's disease. As evidence-based medicine (EBM) becomes widely accepted, there will be more reports of applications that transcend classical *Kampo* theory. As societies age, the importance of preventing post-stroke impairment will increase, and therefore the result obtained in this study is meaningful.

12. Abstractor and date

Nakata H, 1 June 2010, 31 December 2013.