6. Nervous System Diseases (including Alzheimer's Disease)

Reference

Ota T, Miura I, Kanno-Nozaki K, et al. Effects of shakuyaku-kanzo-to on extrapyramidal symptoms during antipsychotic treatment: a randomized, open-label study. *Journal of Clinical Psychopharmacology* 2015; 35: 304-7.

1. Objectives

To evaluate the effectiveness and safety of shakuyakukanzoto (芍薬甘草湯) on extrapyramidal symptoms during antipsychotic treatment.

2. Design

Randomized controlled trial (RCT).

3. Setting

Centers not described. (The authors belong to the Department of Neuropsychiatry and the Hospital), Japan.

4. Participants

Twenty-two psychiatric patients who had been taking antipsychotic drugs other than anti-Parkinson drugs for at least 4 weeks before the start of the study, who scored at least 2 for general severity on the Drug-Induced Extrapyramidal Sympton Scale (DIEPSS), and at least 2 for one subscale score or more. Patients with organic brain impairment and patients with drug or alcohol abuse problems were excluded.

5. Intervention

Arm 1: Shakuyakukanzoto (芍薬甘草湯) 7.5g/day (manufacturer name and administration frequency not mentioned) for 2 weeks (n=11).

Arm 2: Biperiden 3mg/day for 2 weeks (n=11).

6. Main outcome measures

Psychiatric symptoms were evaluated using the Positive and Negative Syndrome Scale (PANSS) and Clinical Global Impression (CGI). Extrapyramidal symptoms were evaluated using DIEPSS and the Barnes Akathisia Rating Scale (BARS). All evaluations were carried out at the start of the study and at its end, after 2 weeks of treatment. Blood samples were taken at those same times: plasma homovanillic acid (HVA) and serum prolactin (PRL) were measured.

7. Main results

One participant in arm 1 decided to stop taking the shakuyakukanzoto, one participant in arm 2 stopped taking biperiden due to dry mouth, so the results for 20 participants were analyzed. Overall DIEPSS scores improved significantly in arms 1 and 2 compared to the start of the study ($P<0.001$). No changes were observed in PANSS, CGI scale, BARS, plasma HVA, or serum PRL levels. Analysis of DIEPSS items found the time-drug interaction was significant for dystonia in arm 1 ($P=0.0059$). Although there was a significant difference between arms 1 and 2 for slowness of movement and dystonia at the start of the study ($P<0.05$), the dystonia score in the shakuyakukanzoto group had improved significantly at the study end compared to the start ($P=0.0038$).

8. Conclusion

Shakuyakukanzoto is effective for extrapyramidal symptoms during antipsychotic treatment and has an especially strong effect for dystonia.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No shakuyakukanzoto-induced adverse effects, including hypokalemia, were observed.

11. Abstractor's comments

This is an excellent clinical study verifying that shakuyakukanzoto is effective in generally improving extrapyramidal symptoms during antipsychotic treatment, especially dyskinesia. In regard to dyskinesia in particular being found to respond effectively to shakuyakukanzoto, considering that the scores in the shakuyakukanzoto group were significantly higher than the biperiden group at the start of the study, it is possible that it had an effect in comparing it with the effects of biperiden. On the other hand, the paper attempts consideration of the mechanism of action, not just effectiveness, so the authors have demonstrated an excellent approach to their research and their clinical study is praiseworthy.

12. Abstractor and date

Goto H, 8 January 2017.