

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Ishioka T. Comparison of the efficacy of junchoto and mashiningan for atonic constipation in the elderly stratified by physical strength*. *Kampo no Rinsho (Journal of Kampo Medicine)* 1996; 43: 1431-7 (in Japanese).

1. Objectives

To compare the efficacy of junchoto (潤腸湯) and mashiningan (麻子仁丸) for atonic constipation in the elderly.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

A special nursing home, Japan.

4. Participants

Thirty-two patients (8 males and 24 females) who usually had no bowel movements and were diagnosed with atonic constipation.

5. Intervention

Arm 1: treatment with TSUMURA Junchoto Extract Granules (潤腸湯) 2.5 g t.i.d., followed by TSUMURA Mashiningan Extract Granules (麻子仁丸) 2.5 g t.i.d. (n=14).

Arm 2: treatment with TSUMURA Mashiningan Extract Granules 2.5 g t.i.d., followed by TSUMURA Junchoto Extract Granules 2.5 g t.i.d. (n=17).

Thirty-one patients, after excluding one who withdrew, were included. After 2 weeks of the first treatment, patients were switched to the second drug without a wash-out period and followed up for 2 weeks.

6. Main outcome measures

Number of defecation supports (e.g., laxatives and enemas).

7. Main results

Disappearance of the need for defecation supports was rated as “marked response”, reduction of the number of defecation supports as “moderate response”, and no change in the number as “no response”. Response (marked + moderate) rate tended to be higher in the mashiningan-treated patients (74.2%) than in the junchoto-treated patients (61.3%) ($P<0.1$). Comparing arms 1 and 2, the efficacy was not influenced by the order of administration, and was superior in the mashiningan-treated patients in both arms ($P<0.05$). Response rate was not different between the two drugs in patients with moderate physical strength, whereas it was higher in mashiningan- than in junchoto-treated patients with low physical strength ($P<0.01$). While the rate of response to junchoto was independent of physical strength, the rate of response to mashiningan was higher in patients with low than in those with moderate physical strength ($P<0.05$).

8. Conclusions

For atonic constipation in the elderly, junchoto and mashiningan are effective drugs associated with very few adverse reactions. Mashiningan is especially effective for patients with low physical strength.

9. From Kampo medicine perspective

The response was evaluated separately in patients with moderate and low physical strength.

10. Safety assessment in the article

Compared with pretreatment levels, posttreatment levels of total cholesterol (T-Cho) ($P<0.01$) and Na ($P<0.05$) were increased and posttreatment level of uric acid (UA) was decreased ($P<0.01$). The one patient who withdrew complained of too many bowel movements during the junchoto treatment and was switched to other medications. Unusual subjective or objective symptoms were not observed.

11. Abstractor's comments

Junchoto and mashiningan are clinically difficult to use differentially. This valuable paper assesses these two drugs using a cross-over design and from a Kampo medicine perspective. However, cross-over design with no wash-out period might be unsuitable for evaluation of the efficacy of individual drugs. Also, to improve the quality of this study, its methodology should be clarified, such as the criteria used for classifying physical strength based on Kampo medicine and the standardization of empirically selected defecation supports to enable objective assessment of the response. It is hoped that higher quality studies on this clinically very interesting theme will be conducted.

12. Abstractor and date

Arai M, 9 November 2008, 1 June 2010, 31 December 2013.