2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)

Reference

Abe H, Kawai Y, Mori T, et al. The Kampo medicine goshajinkigan prevents neuropathy in breast cancer patients treated with docetaxel. *Asian Pacific Journal of Cancer Prevention* 2014; 14: 6351-6. Pubmed ID: 24377531

1. Objectives

To verify the effects of goshajinkigan (牛車腎気丸) for peripheral neuropathy during chemotherapy for breast cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

Single facility (hospital).

4. Participants

Sixty women aged 20-70 who were receiving chemotherapy with docetaxel for invasive breast cancer.

5. Intervention

Arm 1: GJG group: TSUMURA Goshajinkigan Extract Granules (7.5 g divided in two to three doses per day) taken either before or between meals (n=33).

Arm 2: B12 group: Mecobalamin (1500μg/day) taken after meals (n=27).

6. Main outcome measures

Assessment of the frequency of peripheral neuropathy (Neurotoxicity Criteria of Debiopharm [DEB-NTC], Common Terminology Criteria for Adverse Events [CTC-AE], and Visual analogue scale [VAS]).

7. Main results

The incidence of chemotherapy-induced peripheral neuropathy in the GJG group was 39.3% compared to 88.9% in the B12 group, which was significantly (P<0.01) lower. Twelve patients in the B12 group were assessed as DEB-NTC grade 3, a severe assessment, while 5 patients in the GJG group received that assessment, which was a significant difference (P<0.01). Similarly, 12 patients were assessed as CTC-AE grade 2 and 1 as grade 3 in the B12 group, while 6 patients in the GJG group were assessed as grade 2 and none as grade 3, which was a significant difference (P<0.01). The VAS scores for subjective symptom assessment were also significantly lower (P<0.01) in the GJG group (2.7±2.2) compared to the B12 group (4.9±2.4). Taking goshajinkigan during chemotherapy with docetaxel significantly reduced not only the occurrence of peripheral neuropathy but also the severity of subjective symptoms.

8. Conclusions

Preventive oral administration of goshajinkigan suppresses the occurrence of peripheral neuropathy and even when such neuropathy does occur, it reduces symptom severity, during chemotherapy with docetaxel for invasive breast cancer in female patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There was no clinically problematic adverse effect.

11. Abstractor's comments

This study confirmed the preventive effects of goshajinkigan for peripheral neuropathy, an inevitable adverse effect of chemotherapy for invasive breast cancer. It has great significance in clinical medicine and is a valuable study. Confirmation of this significant effect through a randomized trial, not based on the *zuisho* (随証, patterns) of Kampo medicine, means the results are worthy of being included in the guidelines for Western medical treatment. Hopefully the authors will conduct a robust study of its clinical effects under protocols including goshajinkigan's *zuisho* (随証, pattern), or at least whether *jinkyo* (腎虚, kidney deficiency) is present or not. Further research is anticipated.

12. Abstractor and date

Ushiroyama T, 31 March 2017.