

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

Kawabata K, Nakano T, Tsutsumi J, et al. Evaluation of alleviation for lower-extremity peripheral neuropathy due to cancer chemotherapy. Effectiveness of the carbonate spring foot bath and goshajinkigan\*. *Journal of the Japanese Society of Footcare*. 2014; 12: 145-50 (in Japanese). Ichushi Web ID: 2015126257

**1. Objectives**

To evaluate the efficacy of the carbonate spring foot bath and goshajinkigan (牛車腎気丸) for lower-extremity peripheral neuropathy due to cancer chemotherapy.

**2. Design**

Randomized controlled trial using envelopes for allocation (RCT-envelope).

**3. Setting**

One university hospital, Japan.

**4. Participants**

Eighteen females with breast cancer aged <75 years who were to receive preoperative chemotherapy with paclitaxel (80 mg/m<sup>2</sup> once weekly, infused for 12 consecutive weeks).

**5. Intervention**

Arm 1: Spring foot bath with Kao carbonated tablets (炭酸足浴剤) diluted in 6 L of warm water maintained at 38°C to 40°C and administered for 15 minutes daily at a convenient time for 12 weeks (n=8).

Arm 2: TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules orally administered at 2.5 g t.i.d. for 12 weeks (n=4).

Arm 3: No treatment (n=6).

**6. Main outcome measures**

Eastern Cooperative Oncology Group (ECOG) Performance Status (PS), peripheral neuropathy (i.e., numbness measured on the CTC-AE version 4.0 grading scale), and foot skin temperature (measured by thermography) at Weeks 4, 8, and 12.

**7. Main results**

Peripheral neuropathy in the lower extremity (all grade 2 or less) occurred in 11 of the 18 subjects (61%). In the carbonate spring foot bath arm (n=8), the 4 subjects with no numbness compared to the remaining 4 subjects with numbness had higher median skin temperature (34.8°C vs. 31.1°C) and higher percent change in foot skin temperature over time. At Week 12 of paclitaxel chemotherapy, 4 subjects in the carbonate spring foot bath arm, 0 subjects in the goshajinkigan arm, and 3 subjects in the control arm had no numbness, and 2 subjects in the carbonate spring foot bath arm had no numbness for 12 consecutive weeks.

**8. Conclusions**

Lower-extremity numbness caused by preoperative once-weekly paclitaxel chemotherapy may be alleviated by bathing in carbonate spring foot bath; however, the number of subjects in this study was too small to draw clear conclusions.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This was a unique study evaluating the effects of carbonate spring foot bath on vasodilation, such as increased muscle blood flow, increased skin temperature, and alleviation of numbness. Presented only at the convention of the Japanese Society of Footcare, the study suggested that carbonate spring foot bath was effective for numbness in patients with non-small-cell lung cancer (NSCLC). Although there were 2 control arms (a goshajinkigan arm and no treatment arm), the number of subjects in each arm was small and no statistical analysis was mentioned in the article. Skin temperature should have been measured at baseline. Although the authors valued that the severity of peripheral neuropathy at the completion of the scheduled 12-week treatment was Grade 2 or lower in all subjects, it was not mentioned whether the treatment could be effective without dose reduction of paclitaxel. In addition, the description of the carbonate spring foot bath arm was mistakenly replaced by the description of the goshajinkigan arm in the third line of the Results section, and the number of subjects in the carbonate spring foot bath arm should be 8 instead of 6 in Table 4. It is anticipated that statistical evaluation of the efficacy of the carbonate spring foot bath will be possible once the number of subjects is increased.

**12. Abstractor and date**

Motoo Y, 31 March 2017.