

18. Symptoms and Signs**Reference**

Toda Y, Effect of peony and licorice decoction on muscle hardness of gastrocnemius in patients with osteoarthritis of the knee* *Seikei Igaku (Orthopedic Surgery)* 2015; 66: 521-4.

1. Objectives

To evaluate the preventive effect and safety of shakuyakukanzoto (芍薬甘草湯) for gastrocnemius muscle hardness in knee osteoarthritis patients doing exercises at home.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One orthopedic clinic, Japan.

4. Participants

Eighty-three people aged 50-years of more, diagnosed with medial knee OA based on the American College of Rheumatology diagnostic criteria, with K-L classification grade 2 or more by simple knee X-ray.(70 females and 13 males)

5. Intervention

Arm 1: Shakuyakukanzoto (芍薬甘草湯) extract granules (manufacturer not mentioned) 5.0g/day (2.5g b.i.d.) taken orally before morning and evening meals (n=42).

Arm 2: No administration of shakuyakukanzoto (芍薬甘草湯) (n=41).

Participants were allocated in order of clinic visit. Observation period 4 weeks. Both groups received sodium hyaluronate joint injections (5 times/w), and were instructed to repeat 8 times (1 set) an exercise in which participants squeeze a roll of paper with 80% of maximum muscle effort in knee extension, and to repeat 3 sets, 1 to 2 minutes apart.

6. Main outcome measures

Medial gastrocnemius muscle hardness (measured by Neutone TDM-NAI), rate of muscle hardness change, presence/absence of calf muscle cramp, knee function (Lequesne severity index).

7. Main results

4 participants dropped out of arm 1, and 3 from arm 2, leaving 38 subjects for analysis in the two groups. No significant difference in distribution was observed between groups in age, gender, years duration of condition, BMI, and pre-treatment muscle hardness, Lequesne severity index or K-L classification. Rate of muscle hardness change after 1 week: Significantly decreased in arm 1 (96.1±9.9%) compared to arm 2 (102.8±14.9%) ($P=0.023$). The same trend was present in week 4, but there was no significant difference ($P=0.12$). Fewer patients complained of calf muscle cramp in arm 1 (2 cases, 5.3%) compared to arm 2 (8 cases, 21.1%), but the difference was not significant ($P=0.086$). There was no significant difference between the 2 groups in Lequesne severity index improvement ($P=0.093$).

8. Conclusion

Taking shakuyakukanzoto significantly decreases medial gastrocnemius muscle hardness in OA patients. It also tends to decrease the occurrence of calf muscle cramp.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

A number of participants in the shakuyakukanzoto group had to stop visiting the clinic (2 due to gastralgia, 1 due to eczema, and 1 due to busy schedule) and dropped out. The author did not mention the reasons for the dropouts from arm 2. There was no significant difference between groups in the dropout rate.

11. Abstractor's comments

A relatively large number of clinical trials have investigated the effect of shakuyakukanzoto on calf muscle cramp, yet few of them are randomized controlled trials, and the evidence level is still not high. Being a quasi-randomized controlled trial studying 83 subjects and presenting a high level of evidence, it is a paper with clinical significance. It also objectively sets out the effects of shakuyakukanzoto, given that it significantly decreased gastrocnemius muscle hardness 1 week after administration. However, as the authors mention, it is unfortunate that there was no significant difference in regard to complaints of calf muscle cramp. As it did tend to decrease calf muscle cramp, a repeat of this study with a larger number of participants is anticipated.

12. Abstractor and date

Kogure T, 28 December 2016.