

**18. Symptoms and Signs****Reference**

Igarashi I. Clinical study of traditional Chinese medicine therapy for post-operative or post-traumatic swelling in lower extremities. *Seikeigeka (Orthopedic Surgery)* 1993; 44: 127–31 (in Japanese).

**1. Objectives**

To evaluate the efficacy and safety of saireito (柴苓湯) for posttraumatic or postoperative swelling in the lower extremities.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

The department of orthopedic surgery of one hospital, Japan.

**4. Participants**

Sixty-four inpatients receiving treatment for trauma or edema in the lower extremities.

**5. Intervention**

Arm 1: oral administration of TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. between or before meals (n=38).

Arm 2: no administration of Kampo medicine (n=26).

Analgesics were used as appropriate, but anti-swelling drugs were not used.

**6. Main outcome measures**

Swelling ratios calculated using circumferences of bilateral thighs, lower limbs and feet, and the number of days required for swelling disappearance.

**7. Main results**

Swelling resolution required 13–105 days after surgery or trauma (mean, 59.4 days) in arm 2, and 0–64 days (mean, 15.8 days) in arm 1. Swelling ratio was significantly smaller in arm 1 than in arm 2 at 1–6 weeks postoperatively (postoperative 1–6 weeks,  $P<0.05$ ; 2–5 weeks,  $P<0.01$ ). Nineteen patients in arm 1 who started saireito preoperatively required 0–56 days (mean, 9.5 days) for postoperative swelling resolution, and 10 of them did not develop swelling.

**8. Conclusions**

Saireito is effective for posttraumatic or postoperative swelling in the lower extremities.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Saireito administration was not associated with adverse reactions or electrolyte imbalance.

**11. Abstractor's comments**

This clinically useful, interesting study investigated the efficacy of saireito for swelling in the lower extremities after trauma or surgery. However, some patients in arm 1 had no swelling. Furthermore, 10 of 19 patients who started saireito preoperatively did not develop swelling, indicating that 10 of 38 patients in arm 1 had no swelling at the beginning of the study. In contrast, all patients in Arm 2 had swelling at the beginning of the study. This suggests a considerable between-arm difference in the baseline distribution of patients who had swelling. Preoperative patients without swelling or postoperative patients with swelling should have been allocated appropriately to meet the study objectives. Nevertheless, the focus of this study is excellent, and increasing sample size and dividing subjects into appropriate groups at the start will improve the study.

**12. Abstractor and date**

Goto H, 13 September 2008, 1 June 2010, 31 December 2013.