19. Post-anesthesia and Postoperative Pain

Reference

Watanabe Y, Asai S, Hida A, et al. Regarding the utility of saireito against keloid and hypertrophic scars following surgery and injury. *Igaku to Yakugaku* (*Japanese Journal of Medicine and Pharmaceutical Science*) 2012; 67: 245–9 (in Japanese). Ichushi Web ID: 2012256652, J-STAGE

1. Objectives

To evaluate the effectiveness and safety of saireito (柴苓湯) for keloid and hypertrophic scars following surgery, burn injury, and wound injury.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Department of Plastic and Reconstructive Surgery, Chukyo Hospital (1 center), Japan.

4. Participants

Fifty patients with confirmed subjective/objective symptoms including itchiness, tenderness, spontaneous pain, flushing, induration, or swelling of keloid and hypertrophic scars following surgery, burn injury, or wound injury.

5. Intervention

Allocation proceeded alternately in the order of consultation.

Arm 1: Kracie Saireito (柴苓湯) Extract Fine Granules 8.1 g/day in three divided doses orally before meals for at least 12 weeks (n=29).

Arm 2: no administration of saireito (柴苓湯) (n=21).

Compression, external preparations, and patches were applied depending on the symptom, but internal medicines such as tranilast were not given. Ointments containing steroids were used as appropriate in all patients. Compression gear was used for patients who had keloid and hypertrophic scars around limb joints.

6. Main outcome measures

Scar height and subjective/objective symptoms (itchiness, tenderness, spontaneous pain, flushing, induration, and swelling) were measured/evaluated on a 4-point scale (3: severe, 2: moderate, 1: mild, 0: none) at the start and in week 2, 4, 8 and 12 of the study.

7. Main results

The analysis included all 50 patients except those who took anti-allergy medicine during the study. In comparison to arm 2, arm 1 had significantly improved scores for itchiness and flushing starting on week 8 (week 8: $P<0.05$; week 12: $P<0.01$) and significantly improved scores for scar height, tenderness, spontaneous pain, induration, and swelling ($P<0.01$).

8. Conclusions

Saireito improves symptoms of keloid and hypertrophic scars following surgery, burn injury, or wound injury.

9. From Kampo medicine perspective

Not mentioned.

10. Safety assessment in the article

No adverse effects of saireito were observed.

11. Abstractor's comments

This clinical study investigated the effectiveness of saireito for keloid and hypertrophic scars following surgery and injury. It is an advanced study that attempted to investigate the effects of saireito on pathological conditions with no effective therapy and which occur in large numbers of plastic surgery patients. The authors mention the number of patients whose results were analyzed but not the initial number of participants. Given that patients who took anti-allergy drugs were excluded from the analysis, the authors should have given the initial number of participants and the reasons for exclusion. Furthermore, because compression, external preparations, and patches were also used (depending on the symptom), mentioning the number of such cases would have clarified the details of the study. Additionally, the patient background table shows that 11 participants in the saireito group and only one in the no treatment group had scars due to wound injury. Since hypertrophic scars improve more readily than keloid scars, the authors should have considered whether any bias was attributable to the primary disease. Moreover, scar height improved from 1.5 mm to 0.5–1.0 mm; unless centimeters were misreported as millimeters, this is an extremely small change. Thus, the authors should have described their measurement methods. Yet, this clinical study is praiseworthy for being based on past reports and for detecting an effect of saireito on a pathological condition with no established treatment. Hopefully the authors will further evaluate its effectiveness in a multicenter study.

12. Abstractor and date

Goto H, 31 December 2013.