12. Skin Diseases

Reference

Kukita A, Harada S, Fujisawa R, et al. The clinical efficacy of the herb medicine, TJ-114 (Sairei-to), on the topical steroid therapy of psoriasis vulgaris. *Rinsho Iyaku* (*Journal of Clinical Therapeutics & Medicines*) 1991; 7: 927–36 (in Japanese with English abstract). CENTRAL ID: CN-00716584, Ichushi Web ID: 1992091847 MOL, MOL-Lib

1. Objectives

To evaluate the efficacy of saireito (柴苓湯) combined with topical steroid therapy for psoriasis.

2. Design

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

3. Setting

Six university hospitals (National Defense Medical College, Showa University, Jikei University School of Medicine, Tokyo Women's Medical University, Toho University, and Nihon University) and departments of dermatology of 8 hospitals, Japan.

4. Participants

One-hundred and four patients (15 or more years old) with psoriasis vulgaris. They had skin manifestations evaluable for drug efficacy, regardless of the severity, at the start of the study. Exclusion criteria were: 1) use of at least very strong topical steroids within 2 weeks before the study; 2) serious complications; 3) pregnant or nursing mother; 4) prior use of etretinate or methotrexate; 5) a determination of ineligibility by participating physicians.

5. Intervention

Arm 1: 0.12% betamethasone valerate ointment + oral administration of TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. before meals for 12 weeks (n=49).

Arm 2: application of 0.12% betamethasone valerate ointment (Rinderon V or Betnevate) 2 or 3 times daily. Rinderon VG lotion was used on the scalp for 12 weeks (n=45).

6. Main outcome measures

(1) Severity of symptoms including itching, erythema, scale, and infiltration/hypertrophy was assessed on a 5-point scale (4, severe; 3, moderate; 2, mild; 1, slight; 0, none). Patients were followed at the start and at 4, 8, and 12 weeks of treatment.

(2) Laboratory tests: blood count, blood biochemistry, and general urinalysis at the first visit (start) and last visit (end of the study).

(3) Overall improvement: assessed at each visit, compared to baseline values at the start of the study, on a 6-point scale (cured, markedly improved, moderately improved, mildly improved, not changed, and worsened).

(4) Safety: assessed on the basis of adverse effects and laboratory abnormalities found during the study on a 4-point scale (1: no safety problems, 2: some safety problems, 3: moderate safety problems, 4: marked safety problems).

(5) Efficacy: assessed on the basis of both overall improvement and safety (see “safety assessment” section below) on a 5-point scale (1: very effective, 2: effective, 3: slightly effective, 4: not effective, 5: unfavorable).

7. Main results

Of 104 patients, 4 in arm 2 and 7 in arm 1 were excluded because they were lost to follow-up or noncompliant with treatment. Symptom-specific severity did not differ between arms at the start of the study, but erythema and scaling improved significantly in arm 1 compared to arm 2 ($P<0.05$) and itching, infiltration, and hypertrophy tended to improve ($P<0.1$) after 12 weeks. There was a trend toward overall improvement in arm 1, compared to arm 2, after 4 weeks ($P<0.1$) and significant improvement after 12 weeks ($P<0.01$). More patients achieved at least moderate overall improvement in arm 1 (73.9%) than in arm 2 (52.5%) ($P<0.1$). The efficacy was greater in arm 1 (63.8%) than in arm 2 (44.2%) ($P<0.1$).

8. Conclusions

Combined therapy with saireito and topical steroids is suggested to be more effective than topical steroids, but only for psoriasis.

9. From Kampo medicine perspective

The authors stated that selection of Kampo medicines was not based on *sho* but disease name.

10. Safety assessment in the article

In arm 2, two patients had stomach discomfort and gastrointestinal symptoms, and one had laboratory data indicating transient hepatic dysfunction.

11. Abstractor’s comments

This study examined treatment for refractory psoriasis and was a well-designed, high-quality RCT. This was not a blinded study, so the comparison of topical monotherapy with combined therapy with oral medication may be biased. Further expanded study is expected.

12. Abstractor and date

Tsuruoka K, 20 April 2008, 1 June 2010, 31 December 2013.