12. Skin Diseases

References

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1. Objectives

To evaluate the efficacy and safety of hochuekkito (補中益気湯) in patients with *qikyo* (気虚, *qi* deficiency) associated with atopic dermatitis (AD).

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

Five university hospitals, 4 general hospitals, and 6 clinics, Japan.

4. Participants

Eighty-four patients with *qikyo* associated with atopic dermatitis.

5. Intervention

Arm 1: Kracie Hochuekkito Extract Granules 7.5 g/day in two divided doses for 24 weeks (n=40).
Arm 2: placebo granules for 24 weeks (n=44).
In both groups, treatment with topical preparations, etc., was continued according to the symptoms.

6. Main outcome measures

Skin lesion score (according to Japanese Dermatology Association criteria), dose of topical preparation (steroid/tacrolimus).

7. Main results

The analysis included 37 patients in the hochuekkito group and 40 patients in the placebo group. Seven patients (2 patients discontinued with worsening of skin symptoms and headache, and 5 patients with insufficient continuity of oral treatment) dropped out. There was a nonsignificant trend toward improvement in skin lesion score after 24 weeks, a significant decrease in the dose of topical preparation used after 24 weeks ($P<0.05$), a higher efficacy rate ($P=0.06$), and lower rate of worsening ($P<0.05$) in arm 1 than in arm 2. A reanalysis focusing on rash characteristics found that hochuekkito was successful for patients with rash that had low moisture/scabs and a high proportion of chronic stage papules, nodules, and lichenification.

8. Conclusions

Hochuekkito effectively improves skin symptoms and decreases the dose of topical preparation needed by patients with *qikyo* and atopic dermatitis.

9. From Kampo medicine perspective

The efficacy of hochuekkito for AD in patients with *qikyo* was evaluated. Changes in "*qikyo*" scores were not significantly different between the two arms.

10. Safety assessment in the article

Adverse events were reported in 32.5% and 27.3% of patients in the hochuekkito and placebo groups, respectively (no significant difference). Abnormal values were observed in glutamic-pyruvic transaminase (GPT), immunoglobulin (IgE), blood urea nitrogen (BUN), and potassium (K) in the hochuekkito group and in lactic dehydrogenase (LDH), glutamyl pyruvic transaminase (GOT), γ-glutamyl transpeptidase (GTP), and hemoglobin (Hb) in the placebo group. All symptoms including feeling queasy were mild in severity.

11. Abstractor's comments

This is an evidence-based appraisal of a 24-week multicenter, placebo-controlled RCT conducted using objective measures as endpoints. Since the efficacy of hochuekkito was more marked after 24 weeks than after 12 weeks, the authors state that it acts slowly. This finding may have clinical application. The results of the reanalysis of rash characteristics were suggestive of the features of rashes in the patients who ought to be given hochuekkito, which is clinically significant.

12. Abstractor and date

Kogure T, 1 June 2010, 31 December 2013, 6 June 2015.