ABSTRACT:
Atopic dermatitis (AD) is a complex disease of obscure pathogenesis. A substantial portion of AD patients treated with conventional therapy become intractable after several cycles of recurrence. Over the last 25 years we have developed an alternative approach to treat many of these patients by diet and Kampo prescriptions. Although our approach is highly individualized and the Kampo formulae are sometimes complicated, we have tried to clarify the significance of each approach. As for hochuekkito which is often used with conventional therapy for correcting abnormal homeostasis of the body, we evaluated its efficacy and safety in the long-term management of Kikyo patients with AD using multicenter, double blind, randomized, placebo-controlled study. Ninety-one patients were enrolled. All patients continued their ordinary treatments before and after their protocol entry. Hochuekkito or placebo was orally administered twice daily for 24 weeks. The skin severity scores, total equivalent amount (TEA) of topical agents used for AD treatment, prominent efficacy rate and aggravated rate were monitored and evaluated. The TEA of topical agents (steroids and/or tacrolimus) was significantly ($P<0.05$) lower in the hochuekkito group than in the placebo group, although the overall skin severity scores were not statistically different. The aggravated rate was significantly ($P<0.05$) lower in the hochuekkito group (3%; 1 of 37) than in the placebo group (18%; 7 of 39). This study demonstrates that hochuekkito is a useful adjunct to conventional treatments for AD patients with Kikyo constitution.

KEYWORDS:
Kampo, atopic dermatitis, diet, hochuekkito, randomized placebo-controlled study

Kampo for atopic dermatitis
Atopic dermatitis (AD) is a common, chronic, relapsing eczematous skin disease with severe pruritus. The incidence of AD appears to be increasing worldwide, among which the percentage of adult-type AD cases have also been increasing. The precise pathogenesis of AD remains obscure and appears complex. Topical steroids, topical tacrolimus, emollients and oral antihistamines are used as the first-line treatments in standard therapeutic guidelines for AD. However, clinical experience has shown that some of AD patients are really refractory to these conventional treatments, and indeed current AD therapeutic guidelines recommend further intensive treatments such as ultraviolet phototherapy or oral cyclosporine for such patients.
In Japan, an alternative approach has been pursued to treat these grave and/or refractory AD patients with diet and oral Kampo prescriptions such as saikoseikanto, shofusan,
orengedokuto, byakkokaninjinto, hochuekkito and so on. As for diet, we recommend them to keep diet diaries for changing their dietary habits, leaving out fat-rich/high-caloric modern foods and returning to more vegetarian traditional Japanese foods in addition to the standard therapy. Kampo prescriptions are selected individually according to the pharmacological features and the constitution of each patient. Hochuekkito is composed of hot water extracts from 10 species of herbal plants and is used for patients with Kikyo constitution. After accumulating clinical and experimental study of hochuekkito for atopic dermatitis, we evaluated its efficacy and safety in the long-term management of Kikyo (delicate constitution) patients with AD using multicenter, double blind, randomized, placebo-controlled study. Ninety-one Kikyo patients with AD were enrolled. All patients continued their ordinary treatments (topical steroids, topical tacrolimus, emollients or oral antihistamines) before and after their protocol entry. Hochuekkito or placebo was orally administered twice daily for 24 weeks. The skin severity scores, total equivalent amount (TEA) of topical agents used for AD treatment, prominent efficacy (cases with skin severity score=0 at the end of the study) rate and aggravated rate (more than 50% increase of TEA of topical agents from the beginning of the study) were monitored and evaluated. The TEA of topical agents (steroids and/or tacrolimus) was significantly (P<0.05) lower in the hochuekkito group than in the placebo group, although the overall skin severity scores were not statistically different. The aggravated rate was significantly (P<0.05) lower in the hochuekkito group (3%; 1 of 37) than in the placebo group (18%; 7 of 39). Only mild adverse events such as nausea and diarrhea were noted in both groups without statistical difference.

CONCLUSION
Kampo therapy of adult atopic dermatitis is mainly composed of diet and administration of Kampo prescriptions. As for hochuekkito, one of those prescriptions, a placebo-controlled study demonstrates that hochuekkito is a useful adjunct to conventional treatments for AD patients with Kikyo constitution. Use of hochuekkito significantly reduces the dose of topical steroids and/or tacrolimus used for AD treatment without aggravating AD.

REFERENCES
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