#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Special Committee for EBM, the Japan Society for Oriental Medicine

### 12. Skin Diseases

#### Reference

Kobayashi K, Ohkawara A. Therapeutic effect of jumihaidokuto on chronic eczema and atopic dermatitis<sup>\*</sup>. *Hifuka ni okeru Kampo Chiryo no Genkyo (Current Situation of Kampo Therapy in Dermatology)* 1994; 5:25–34 (in Japanese).

### 1. Objectives

Efficacy and safety of jumihaidokuto (十味敗毒湯) for the treatment of chronic eczema and atopic dermatitis.

## 2. Design

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

#### 3. Setting

Department of Dermatology, Hokkaido University Hospital and Asahikawa Medical College Hospital, and 8 hospital departments of dermatology.

## 4. Participants

Seventy-four patients (12 or more years old) with mild or moderate chronic eczema (except nummular eczema) and atopic dermatitis with little exudate and sporadic red rashes.

#### 5. Intervention

Arm 1: oral administration of TSUMURA Jumihaidokuto (十味敗毒湯) Extract Granules 2.5 g t.i.d. for 8 weeks (n=35).

Arm 2: oral administration of clemastine fumarate 1 mg b.i.d. for 8 weeks (n=39).

Mild/moderate-strength topical steroids were allowed.

### 6. Main outcome measures

Itching and skin manifestations (erythema, papules, nodules, lichenification, desquamation, and scratch marks) were evaluated separately on a 4-point scale at baseline and at weeks 1, 2, 4, 6, and 8, and then their improvements were evaluated on a 5-point scale as compared with baseline.

### 7. Main results

The improvements in patients with chronic eczema were evaluated separately from those in patients with atopic dermatitis. Seventeen participants in arm 1 and 19 in arm 2 had chronic eczema, while 18 in arm 1 and 20 in arm 2 had atopic dermatitis. Similar proportions of patients with chronic eczema in arms 1 and 2 had at least moderate overall improvement (64.7% vs. 63.2%) or at least mild overall improvement (82.4% vs. 84.2%). Likewise, overall improvement in atopic dermatitis was similar in both arms (50% vs. 60% with at least moderate improvement, and 88.9% vs. 90% with at least mild improvement).

### 8. Conclusions

Jumihaidokuto is as effective for chronic eczema and atopic dermatitis as clemastine fumarate.

## 9. From Kampo medicine perspective

Since jumihaidokuto is used for patients with moderate or more physical strength, the degree of obesity and type of physique were considered. Including only patients whose degree of obesity was 0 or more and muscular patients with negative obesity scores, analysis found 68.8% had at least moderate improvement and 93.8% had at least mild improvement in arm 1, which was insignificantly lower than in arm 2.

# 10. Safety assessment in the article

One patient (2.9%) in arm 1 developed hypertension and stopped taking medication. Three patients (7.7%) had sleepiness, 1 (2.6%) had leucopenia, and 1 (2.6%) had constipation in arm 2.

# 11. Abstractor's comments

This meaningful clinical study compares the effect of jumihaidokuto with that of clemastine fumarate on chronic eczema and atopic dermatitis and examines the effect of Kampo medicines on skin diseases often seen in daily clinical practice. However, the authors do not describe the way they evaluated overall improvement using outcome measures. The results for each measure are also interesting, so further detailed description is expected. Moreover, although they noted "one patient stopped medication due to hypertension" in arm 1, the data of all 35 participants in arm 1 were included in the analysis of overall improvement. In Kampo medicine, muscularity is not clearly defined; more detailed description is expected. Despite these limitations, this may be a valuable study demonstrating similar efficacy for jumihaidokuto and antihistamines. Given the adverse effects of antihistamines such as sleepiness, jumihaidokuto is important alternative treatment for skin diseases.

## 12. Abstractor and date

Goto H, 12 September 2008, 1 June 2010.