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

12. Skin Diseases

Reference

Choi I, Kim S, Kim Y, et al. The effect of TJ-15 plus TJ-17 on atopic dermatitis: a pilot study based on the principle of pattern identification. *The Journal of Alternative and Complementary Medicine* 2012; 18: 576-82. Pubmed ID: 22784344

1. Objectives

To evaluate the efficacy and safety of orengedokuto (黄連解毒湯) and goreisan (五苓散) for dampness-heat pattern in atopic dermatitis (AD) patients.

2. Design

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

3. Setting

Kyung Hee University Hospital, South Korea.

4. Participants

Twenty-four dampness-heat pattern patients with AD diagnosed using Hanifin and Rajka Diagnostic Criteria. (Patients were excluded who took antihistamines and steroids within the previous four weeks; had serious disease including infection; had seizure disorder; were pregnant and lactating; and had abnormal alanine aminotransferase [ALT], aspartate aminotransferase [AST], blood urea nitrogen [BUN], or creatinine level.)

5. Intervention

Arm 1: orengedokuto + goreisan group: administration of a mixture of TSUMURA Orengedokuto (黄連解毒 湯) Extract Granules (1.25 g) and TSUMURA Goreisan (五苓散) Extract Granules (1.25 g) t.i.d. after meals for four weeks (n=12).

Arm 2: orengedokuto group: administration of TSUMURA Orengedokuto (黄連解毒湯) (2.5 g) t.i.d. after meals for four weeks (n=12).

6. Main outcome measures

Primary endpoints: SCORing Atopic Dermatitis (SCORAD) index, and Eczema Area and Severity Index (EASI). Secondary endpoints: symptom scores for nine dampness-heat pattern symptoms and six other symptoms.

7. Main results

The SCORAD index $(-27.2 \pm 8.9 \text{ in arm 1 and } -24.9 \pm 13.7 \text{ in arm 2})$ and EASI $(-16.9 \pm 12.1 \text{ in arm 1 and } -10.4 \pm 7.9 \text{ in arm 2})$ were significantly improved by combined treatment. There was no significant difference in primary endopoints between the two arms. Reductions in symptom scores were similar in both groups $(-2.4 \pm 1.3 \text{ in arm 1 and } -2.1 \pm 1.6 \text{ in arm 2})$. There was no significant difference in secondary endopoints between the two arms.

8. Conclusions

Orengedokuto and orengedokuto + goreisan may be similarly effective for dampness-heat pattern AD.

9. From Kampo medicine perspective

Although administration did not deliberately target specific patterns within the two groups, yang pattern (i.e., rapid advance of symptoms, strong itchiness, wet phase rash, and tachycardia) was identified in all patients and was the precondition for inclusion in the study.

10. Safety assessment in the article

Liver and kidney function was normal in both groups. However, even though liver and kidney function was described as normal in the beginning, patients who showed elevated AST, ALT, and BUN levels were excluded from the analysis, which makes evaluation more difficult.

11. Abstractor's comments

This is a clinically significant study indicating that orengedokuto and orengedokuto + goreisan are effective for AD with dampness-heat (湿熱) in a randomized and controlled manner. While the authors assess specific clinical symptoms as secondary endpoints, it might be possible to elucidate further the effectiveness of Kampo medicines by presenting a differential analysis of those symptoms. Further research is anticipated.

12. Abstractor and date

Kogure T, 31 December 2013.