

## 12. Skin Diseases

**References**

**Ohkuma M. Treatment of acne by Chinese drugs and external application. *Wakan Iyaku Gakkaishi (Journal of Medical and Pharmaceutical Society for WAKAN-YAKU) 1993; 10: 131–4 (in Japanese with English abstract).***

Ohkuma M. Treatment of acne by Chinese drugs and external application - comparison with oral antibiotics -. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine) 1993;44:173–7 (in Japanese)*

**1. Objectives**

Efficacy of jumihaidokuto (十味敗毒湯) and orengedokuto (黄連解毒湯) for the treatment of acne vulgaris.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Not mentioned (author belongs to the Department of Dermatology, Kinki University School of Medicine), Japan.

**4. Participants**

Two hundred sixty-eight patients with acne vulgaris.

**5. Intervention**

Arm 1: oral administration of jumihaidokuto (十味敗毒湯) (manufacturer, not specified) 2.5 g t.i.d. and orengedokuto (黄連解毒湯) 2.5 g t.i.d. after meals + topical application of clindamycin lotion in the morning + 1% gentamicin sulfate-containing 0.12% betamethasone valerate lotion in the afternoon or evening + topical application of sulfur-camphor lotion before sleep for eruptions (n=90).

Arm 2: oral administration of jumihaidokuto (十味敗毒湯) (manufacturer, not specified) 2.5 g t.i.d. and orengedokuto (黄連解毒湯) 2.5 g t.i.d. after meals (n=91).

Arm 3: oral administration of jumihaidokuto (十味敗毒湯) (manufacturer, not specified) 2.5 g t.i.d. after meals (n=55).

Arm 4: oral administration of orengedokuto (黄連解毒湯) (manufacturer, not specified) 2.5 g t.i.d. after meals (n=20).

Arm 5: topical application of clindamycin lotion in the morning + 1% gentamicin sulfate-containing 0.12% betamethasone valerate lotion in the afternoon or evening + topical application of sulfur-camphor lotion before sleep for eruptions (n=12).

Observation period was 4 weeks or more.

**6. Main outcome measures**

Improvement in skin condition,

rated on the basis of disappearance of skin eruptions (comedones, small papules, pustules, etc.), was defined as marked (if 90% disappeared), moderate (if 50–90% disappeared), mild (if 10–50% disappeared), and absent (if less than 10% disappeared).

**7. Main results**

The percentage of patients who had marked response was 47, 52, 51, 20, and 8 in arms 1, 2, 3, 4, and 5, respectively. There was no significant difference in efficacy between arms 1 and 2, arms 1 and 3, and arms 2 and 3. The time to cure was significantly shorter in arm 1 than in arm 2 ( $P<0.001$ ).

**8. Conclusions**

Combined therapy with oral jumihaidokuto and orengedokuto plus clindamycin lotion, steroid lotion, and sulfur-camphor lotion is effective in reducing comedones, small papules, and pustules in acne vulgaris.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This clinical trial compared the effect of jumihaidokuto and orengedokuto on acne vulgaris with or without topical drugs. This interesting clinical study showed that although oral administration of jumihaidokuto or orengedokuto is itself effective for the treatment of acne, combination with topical agents can further shorten the duration of treatment. This paper notes that the patients were randomly assigned to each group, but the number of patients differs between groups. The reasons for dropping out should therefore be described. Although he also notes that “patients who improved only after 4 weeks or more and who had no response within the 4-week observation period were excluded from the analysis [sic],” it is questionable because the numbers of patients who participated in the study and whose outcomes are shown in the results are same. However, this study suggests the effect of combined therapy. Further clinical study that examines the placebo effect of combined topical agents is expected. The author has reported another study published in the *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine) 1993*, in which a non-randomized group treated with minocycline was compared to the groups included in this study.

**12. Abstractor and date**

Goto H, 12 September 2008, 1 June 2010, 31 December 2013.