

Effect of traditional Chinese medicine on skin lesions and quality of life in patients with moderate to severe eczema



Atopic dermatitis (AD) is a common allergic inflammatory skin disorder that is estimated to cost as much as \$3.8 billion in health care expenses annually for treatment.¹ A total of 50.4% of patients with AD report using complementary and alternative therapies, such as traditional Chinese medicine (TCM), but reports on TCM efficacy and safety remain inconclusive.^{2,3} We were interested to learn whether combined TCM therapy could suppress T_H2 inflammation and benefit patients with AD. We report a case series of 14 patients with AD treated with this approach and analyses of the TCM herbs in murine and in vitro models.

Medical record review was conducted for 16 consecutive patients with AD referred to Ming Qi Natural Healthcare/Integrative Health and Acupuncture Center for TCM. Fourteen patients met the inclusion criteria of moderate to severe AD, 3 months of topical steroid therapy adherence before TCM, and completion of a minimum 3 months of the following combined TCM approach: *Phellodendron chinensis* formula herbal bath additive and herbal cream, as described previously,⁴ with additional herbs for cream (*Fructus tribuli*, *Radix angelicae sinensis*, *Flos lonicerae*, *Potentillae chinensis* Herba, and *Indigo naturalis*) and internal tea (*Sclerotium Poriae Cocos*, *Cortex moutan*, *Fructus kochiae*, *Massa fermentata praeparata*, *Flos lonicerae*, *Radix arnebiae*, *Fructus forsythiae*, *Indigo naturalis*, *Radix glycyrrhizae*).

Medical records were reviewed for: medication use, SCORing Atopic Dermatitis (SCORAD) scores,⁵ Dermatology Life Quality Index (DLQI) scores,⁶ safety monitoring lab results, and IgE levels. Toxicity studies were performed in a mouse model, and effect of the herbal tea on T_H2 cytokine interleukin 4 (IL-4) production was tested in a murine T_H2 clone (D10G4.1), as previously described.⁷ Studies were approved by the Mount Sinai Institutional Review Board.

All 13 children and 1 adult following the TCM regimen reported infantile onset of AD and family history of allergy. The median age was 5.4 years (interquartile range [IQR], 0.5–52 years), with a median disease duration of 40 months (IQR, 4 months to 14 years). Study participants were primarily white (57%) and highly allergic, with elevated total IgE levels (median, 4,545 kU/L; IQR, 95–37,390), asthma (4 of 14 participants), and/or food allergy (13 of 14 participants). Prevalence of sensitization (prick skin tests or serum IgE) was common for food (70%–90%) and inhalant (30%–50%) allergens. In addition to daily topical steroid use, half of the patients reported using oral corticosteroids for AD. Severe disease (SCORAD score >50) was present in 13 of the 14 patients, with an overall baseline SCORAD score of 89 (range, 42–103). The median DLQI score was 17 (range, 10–30) before starting TCM treatment.

Dichotomous variables were analyzed at the 3-month follow-up visit, and continuous variables were analyzed at the last

documented clinic visit, which occurred at a median of 8 months (range, 3–24 months) of treatment, compared with baseline. Disease severity scores decreased in all patients but at variable rates and degrees, with a median posttreatment SCORAD score of 11 (range, 0–62; $P < .001$) compared with baseline. The DLQI score decreased to 1 (range, 0–14; $P < .0001$) compared with baseline. A total of 69% of patients reported stopping use of topical steroids, 80% stopped use of oral steroids, and 80% stopped use of antihistamines. The one patient who was using cyclosporine also discontinued its use after 3 months. The total serum IgE level decreased in 7 of 10 patients and increased in 2 of 10 patients. Peanut specific IgE levels were available for 9 patients and decreased by a median of 16.8 kU/L (IQR, –30.2 to 1.5).

Treatment was well tolerated in all patients. The only inconvenience reported was transient blue discoloration of the skin caused by the herb *Indigo naturalis* in the cream. This discoloration is because the color stains damaged surface epithelial cells (Fig 1, A–C). As the skin recovered, the discoloration resolved (Fig 1, D and E). No abnormal liver or kidney functions or blood cell counts occurred. The 9 patients using antibiotics for *Staphylococcus aureus* superinfection at the onset of TCM treatment all discontinued use of antibiotics, and no superinfections occurred during treatment in any patient. Murine testing of herbal tea at 5 and 10 times the prescribed dose in humans showed no acute or subacute toxic effects. In addition, all mouse organs appeared normal by gross examination as did hematologic and biochemical testing. D10 cells cultured with herbal tea up to 500 μ g/mL, maintained normal viability, and exhibited dose-dependent decreases in IL-4 production with a half maximal inhibitory concentration of 30 μ g/mL and undetectable IL-4 at 500 μ g/mL.

This case series describes the favorable response of patients with moderate to severe AD to treatment with combined topical and ingested TCM herbal therapy. Our report supports previous studies that have found that AD improves after TCM treatment.⁸ However, making definitive conclusions about past TCM studies is difficult because of varied herbal formulations, administration routes, and outcome measurements.^{3,8} Major barriers to acceptance of TCM are a concern for toxic effects, lack of standardized treatment, and limited quality trials and mechanistic data.^{3,6,9} The combined TCM treatment regimen in the 14 patients appeared to be safe based on clinical observations and laboratory data, and the herbal tea showed a high safety profile as no toxicity was observed in mice following oral administration of up to 10 times the effective daily dose.

Previous studies have found that other classic TCM formulas may be useful to help prevent food anaphylaxis, reduce allergen-stimulated basophil activity, and decrease IL-5 production in human peripheral blood mononuclear cells.⁷ This is the first proof-of-concept data to suggest that the ingested TCM formulation used by patients in this series may also modify the T_H2 axis, evidenced by decreased IL-4 production in vitro. However, the exact mechanisms of TCM, including possible effects on skin barrier function and other immune parameters, require further investigation. Combined TCM uses mixtures of similar herbs administered simultaneously through ingested and topical routes, an approach that perhaps conveys certain benefits over single-route administration.

Given that current treatments, including novel biologics, are costly and provide no cure for AD, alternative treatment strategies are desperately needed.¹⁰ Despite the noted limitations in this case series, including the unblinded, uncontrolled study design and small sample

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Figure 1. Photographs of patient 6. A and B, Start of traditional Chinese medicine (TCM) treatment; C, 6 months after TCM treatment; D, 8 months after TCM treatment; and E, 14 months after TCM treatment. The blue color on the skin is from herbal cream.

size, our results suggest that TCM may be a complementary therapy to consider among patients with moderate to severe AD, possibly to wean off corticosteroids. Our findings also support the need for more mechanistic studies that compare individual constituents of the TCM formula prescribed in this case series to determine whether internal herbal tea alone or external TCM remedies will be as effective as the combined TCM approach used in this case series. Larger and longer-term clinical outcomes on TCM using a more rigorous prospective study design are warranted.

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