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Clinical Effectiveness and Safety of TCM Oral Administration for the Treatment of Allergic Contact Dermatitis: A Meta Analysis

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ADMINISTRATIVE INFORMATION

Support - Gui Traditional Chinese Medicine TD He Zi [2022] No. 002.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 November 2023 and was last updated on 08 November 2023.

INTRODUCTION

Review question / Objective The purpose of this study is to investigate the differences in the efficacy and safety of traditional Chinese medicine in the treatment of ACD compared to Western medicine. The selected research method is the RCT experiment. The purpose of this study is to investigate the differences in the efficacy and safety of traditional Chinese medicine in the treatment of ACD compared to Western medicine.

Condition being studied Allergic contact dermatitis(ACD) is an inflammatory skin disease caused by skin contact with allergens, belonging to type IV hypersensitivity reaction [1-2]. The main clinical manifestations are erythema, edema, exudation, scabbing, blisters, and severe itching [3]. With the continuous development of social economy, its incidence rate is as high as 15%[4], which seriously affects the physical and mental health of patients as well as social economy. At present, Western medicine mainly uses antihistamines and glucocorticoids to treat this disease. However, Western medicine treatment may produce side effects such as diabetes, bone necrosis, weight gain, skin atrophy, etc.[5-6]. There are reports that in the efficacy indicators of treating ACD, traditional Chinese medicine oral treatment is superior to Western medicine treatment and has fewer side effects [7-8]. Therefore, clinical research on traditional Chinese medicine for ACD is of great significance. In traditional Chinese medicine, ACD belongs to the categories of "lacquer sores", "plaster wind", and "toilet ringworm". Name it according to the pathogenic substance, such as "lacquer sores" caused by contact with raw lacquer,"plaster wind" caused by contact with plaster, and "toilet ringworm" caused by the use of a toilet. There is an article in "Authentic Surgery" that states: "Lacquer ulcer: It comes from different sources. Lacquer is a toxic substance with spicy heat, and the skin, fur, and pancreas are not dense, so it is felt to be toxic." This means that the main cause of the disease is insufficient innate endowment and abnormal skin barrier, which makes the body unable to resist external toxins

and pathogens. Alternatively, the evil of dampness and heat may accumulate on the skin surface, consuming yin and blood for a long time. The skin loses nourishment, resulting in symptoms such as dryness, roughness, thickening, and scaling. The above traditional Chinese medicine theories indicate that the main causes of ACD are the invasion of external toxins, innate intolerance, and the accumulation of dampness and heat. Therefore, it is recommended to use drugs that expel wind and evil, dispel dampness and detoxify to treat ACD [10-11]. In addition, we searched databases such as CNKI, WF, VIP, and CBM using keywords such as "ACD", "Traditional Chinese Medicine", and "Integrated Traditional Chinese and Western Medicine", and found that traditional Chinese medicine oral administration is widely used in the treatment of ACD. Although it has been widely used in clinical practice, systematic evaluation has not yet been used to analyze the clinical efficacy and safety of ACD. Therefore, meta-analysis uses systematic evaluation to verify the clinical efficacy and safety of traditional Chinese medicine oral administration in the treatment of ACD, providing theoretical reference for its clinical treatment.

METHODS

Participant or population Patients with a clear diagnosis of ACD, regardless of age, gender, race, or ethnicity.

Intervention Treatment with oral administration of traditional Chinese medicine.

Comparator Western medicine treatment.

Study designs to be included RCT.

Eligibility criteria Studies were included if they fulfilled the following criteria 1.Inclusion criteria: ① Study subjects: Patients with a clear diagnosis of ACD, regardless of age, gender, race, or ethnicity. ② Research type: Randomized controlled trial (RCT), blind method unlimited; ③ Intervention measures: The experimental group was treated with traditional Chinese medicine orally, while the control group was treated with Western medicine; ④ Outcome indicators: total effective rate, recovery rate, visual analog scale (VAS), serum Th1/Th2 level analysis, EBV antibody level, and safety evaluation. 2Exclusion criteria：① Non RCT literature, regardless of language or age; ② The diagnostic criteria are not clear; ③ Review, case analysis, basic experiments, retrospective studies, and correspondence literature; ④ Inappropriate statistical methods, imprecise experimental design, and incomplete outcome indicator data; ⑤ Documents repeatedly included in the database.

Information sources Two trained investigators independently searched randomized controlled trials (RCTs) of treatment with oral administration of traditional Chinese medicine for ACD from the following databases: PubMed, EMBASE, Web of science, Chinese National Knowledge Infrastructure (CNKI), Wanfang Database, China BioMedical Literature (CBM), and VIP Journals Database from inception to July 28, 2023. On the other hand, additional relevant records were identified from published reviews and the reference lists of selected RCTs to avoid missing qualified studies.

Main outcome(s) Total effective rate, recovery rate, visual analog scale (VAS), serum Th1/Th2 level analysis, EBV antibody level, and safety evaluation.

Quality assessment / Risk of bias analysis Cochrane Tool.

Strategy of data synthesis Statistical analysis was conducted using RevMan5.4.1 software. Heterogeneity evaluation using I2 test: When (P50%), there is heterogeneity, and a random effects model is used to explain the source of heterogeneity; When ($P \geq 0.1$, $I2 \leq 50\%$), there is homogeneity and a fixed effect model is used. The counting data adopts the relative risk ratio (RR), and the measurement data adopts the mean difference (MD), represented by the effect value and its 95% confidence interval CI (Confidence interval). The difference was statistically significant with $P<0.05$. If the same outcome indicator is included in a study ($n \geq 10$), a funnel plot is used to evaluate the publication bias of the literature. If the funnel plot has poor symmetry, it indicates publication bias.

Subgroup analysis Conduct subgroup studies based on a course of treatment ≤ 14 days and a course of treatment>14 days.

Sensitivity analysis RevMan5.4.1 software conducts sensitivity analysis and translates the sensitivity of the article by examining the changes in the magnitude of the effect after deleting one of the articles.

Country(ies) involved China.

Keywords Allergic Contact Dermatitis; Traditional Chinese Medicine; Meta-analysis; Systematic evaluation.

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