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# Characteristics of traditional Chinese medicine use for children with allergic rhinitis: A nationwide population-based study



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## ABSTRACT

*Objectives:* Allergic rhinitis (AR) is a common allergic disorder in children, some of whom seek complementary treatments, including acupuncture and Chinese herbs. Little, however, is known about the treatment of pediatric AR with traditional Chinese medicine (TCM). To characterize TCM use in pediatric AR, we conducted a nationwide population-based study.

*Methods*: We screened one million randomly sampled beneficiaries of the National Health Insurance Program in Taiwan from 2002 to 2010 to identify children <18 years of age with newly diagnosed allergic rhinitis (ICD-9 code 477.9). The subjects were categorized according to their use of TCM.

*Results:* We identified 97,401 children newly diagnosed with AR for inclusion in the study. Among these children, 63.11% (N = 61,472) had used TCM. There were significantly more TCM users than non-users among school-age children and adolescents (P < 0.001). Most (99.1%) pediatric TCM users received Chinese herbal remedies (99.1%); only 0.9% received acupuncture or manipulative therapies. Xin-Yi-Qing-Fei-Tang (Magnolia Flower Lung-Clearing Decoction) was the most frequently prescribed TCM formulation (23.44%), and the most commonly prescribed single herb was Chan-Tui (*Periostracum cicadae*; 13.78%). Regarding syndrome differentiation (ZHENG) according to TCM theory, prescriptions for the Cold Syndrome exceeded those for the Hot Syndrome throughout the year in Taiwan.

*Conclusions:* We found that approximately two-thirds of pediatric AR patients were prescribed TCM treatments in Taiwan. Further research is warranted to examine the efficacy and safety of TCM for pediatric AR patients.

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# 1. Introduction

Allergic rhinitis (AR) is a global problem affecting 400 million people worldwide that usually develops early in childhood [1]. In 2002, the prevalence of pediatric AR in central Taiwan, as established by the International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire, was 27.59% [2]. The cumulative 12-month prevalence in a 2005 ISAAC study of 10- to 12-yearold children in central Taiwan was even higher, at 43% [3]. Comorbidities such as asthma are common in children with AR,

Abbreviations: CAM, complementary and alternative medicine; AR, allergic rhinitis; NHIRD, National Health Insurance Research Database; TCM, traditional Chinese medicine; ICD-9-CM, the International Classification of Diseases, 9th Revision, Clinical Modification.

supporting the view that the upper and lower airways are united in their functions [4]. The increasing prevalence of AR and its impact on asthma create a significant burden, not only in Taiwan but also worldwide [5].

Many children with allergic disorders seek help from complementary and alternative medicine (CAM) [6]. The current mainstay treatments for pediatric AR include oral antihistamines and nasal corticosteroids [1,7]. Clinical evidence for efficacy of sublingual immunotherapy in children is also growing [8]. However, some patients experience poor control or are concerned about the side effects of these conventional treatments [9]. Several large-scale studies, including the ISAAC study [10] and the National Health Interview Survey (NHIS) [11], the Allergies, Immunotherapy, and Rhinoconjunctivitis (AIRS) survey [12] in the United States, have addressed pediatric AR issues, but comprehensive information regarding the use of traditional Chinese medicine (TCM) for pediatric AR has been lacking. Our previous questionnaire-based survey found that 34.4% of patients with rhinitis had used TCM [13]. In Taiwan, Japan, Korea and China, TCM is popular and is regarded as both an alternative and a mainstay therapy for some diseases [14]. We previously found in a population-based epidemiological study that a very high percentage (57.95%) of children with asthma used TCM [15]. Our recent nationwide study also found that AR was one of the four most common diseases for which children in Taiwan visited TCM clinics [16].

Descriptions of AR symptoms have been reported in the ancient Chinese literatures, and there are a number of classic formulae used in the TCM practice. From a TCM standpoint, AR is as a result of pernicious external pathogenic processes invading the lungs and affecting Qi of the lung, spleen and kidney. According to the Western medicine, these AR patients are considered to have the same disease, whereas in the view of TCM, they could be further categorized into two subtypes (TCM Syndromes; "ZHENG" in Chinese), the Cold Syndrome and the Hot Syndrome in the acute stage, based on an overall medical examination of symptoms [17]. Those with the Cold Syndrome present with a watery running nose, cold extremities, and a pale tongue, while those who with Hot Syndrome present with more or less sticky yellowish nasal discharge, thirst, and an erythematous tongue. TCM doctors prescribe different herbal formulas for the Hot and Cold Syndromes. AR patients in remission stages received consolidation treatment for the tonification of Qi. Therefore, the prescriptions for AR patients are difficult to standardize as a monotherapy. In light of the large pediatric population using TCM for AR [16], it is necessary to conduct a large-scale, population-based, pharmaco-epidemiologic analysis to investigate the characteristics and potential use of TCM for pediatric AR patients.

In Taiwan, the National Health Insurance program has reimbursed the costs of TCM since 1996. TCM is frequently used in Taiwan and is regarded as one of the mainstream therapies. In Taiwan, many of the public hospitals and university-affiliated teaching hospitals have TCM clinics. Taiwan installed TCM programs in higher education and has a pioneering TCM education program (8-year M.D. program) integrating Western and Chinese medicine together to nurture skilled TCM professionals since 1958. Graduates are proficient in their knowledge of Western and Chinese medicine, and the majority achieves dual licensures in Western and Chinese medicine after passing their board exams. There are also another post-baccalaureate TCM programs (5-year M.D. program) where graduates are qualified for only TCM board exam. 93.7% of Taiwanese hospitals/clinics are contracted with the National Health Insurance Program. By the end of 2010, approximately 23 million beneficiaries (nearly 99.89% of the Taiwanese population) were enrolled [18]. All claims data are stored in the National Health Insurance Research Database (NHIRD) and are available for academic research. This platform is suitable for evaluating the use of TCM treatments. To explore TCM use in children with AR, we analyzed a cohort of one million randomly sampled beneficiaries from the NHIRD.

## 2. Methods

# 2.1. Data source

This study analyzed datasets from the NHIRD of Taiwan. The National Health Insurance Program was launched in 1995 and has provided Western medical inpatient and outpatient services since that time; a TCM outpatient service followed in 1996 [18]. We retrieved data from the NHIRD (Longitudinal Health Insurance Database 2000; LHID 2000) from 1,000,000 randomly sampled persons who had enrolled in 2000. All of the data for enrollees from 2000 to 2010 were de-identified and further scrambled by the National Health Research Institutes in Taiwan before release, to avoid violating the privacy of the patients or healthcare providers. The Institutional Review Board of the China Medical University and Hospital approved this study (CMU-REC-101-012).

#### 2.2. Study subjects

The sampled cohort was screened to identify the 227,056 subjects who were <18 years of age (Fig. 1). The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes were used exclude children without AR (N = 95,452), leaving only the subjects with AR (ICD-9-CM code: 477.9). Children diagnosed with AR before the end of 2001 (N = 34,653) were also excluded, ensuring that all of the subjects had been newly diagnosed with AR after 2002. Overall, 97,401 children were included in the study cohort. Children who visited the TCM service between 2002 and 2010 were defined as TCM users (N = 61,472), while children with no TCM visit records were defined as non-TCM users (N = 35,929). Comorbidities of AR were identified by their ICD-9-CM codes (asthma ICD-9: 493; and atopic dermatitis ICD-9: 691). The prescribed Chinese herbal remedies were categorized according to their therapeutic actions and indications: the Cold Syndrome, the Hot Syndrome and the tonification of Qi. Monthly distributions of the Cold and Hot Syndromes were analyzed by comparing the monthly usage of their respective prescriptions.

# 2.3. Statistical analysis

The statistical analyses used SAS software, version 9.2 (SAS Institute, Inc., Cary, NC, USA). The data analysis consisted of descriptive statistics, including the frequency of prescriptions for TCM users stratified by the patients' demographic characteristics, the indications for prescribing TCM, and the most frequently prescribed herbal formulas and single herbs for treating pediatric AR. Primary indications were classified according to their ICD-9-CM codes. The diagnoses were coded according to the ICD-9 and were grouped into distinct broad disease categories. Comparisons of TCM users with non-TCM users employed univariate analysis. The relationships between the categorical variables and the differences between TCM users and non-TCM users were examined by Pearson's  $\chi^2$  tests: a *P*-value <0.05 was considered statistically significant.

#### 3. Results

#### 3.1. Demographic characteristics of study subjects

From 2002 to 2010, 97,401 pediatric patients were newly diagnosed with AR. Among these children, 61,472 had used TCM (63.11%) for AR, and 35,929 (36.89%) had not (Table 1). There were

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