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Traditional Chinese medicine ZHENG identification of bronchial asthma: Clinical investigation of 2500 adult cases

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ABSTRACT

Objectives: This study aims to employ more comprehensive approaches to analyze the primary and secondary symptoms of clinical common TCM ZHENG of bronchial asthma according to the clinical investigation of 2500 adult cases.

Methods: Patients met the inclusion criteria were surveyed by associate chief physician or chief physician through the TCM Clinical investigation questionnaire containing general demographic information, signs and symptoms, tongue and pulse conditions. Firstly, absolute frequency, cumulative frequency, Chi-squared test were adopted to reflect the clinical common ZHENG in three asthma stages, then the logistic regression analyses, the frequency methods were combined to distinguish the primary and secondary symptoms of the common ZHENG.

Results: Of the 2500 questionnaires, 2428 valid questionnaires were got, with the number in acute exacerbation stage was 1273, and that 586 in chronic persistent stage, and 569 in clinical remission stage, in which the number of excess syndromes, the deficiency-excess complex syndromes and deficiency syndromes corresponding to the above three stage respectively accounted on 55.7%, 69.97%, and 76.50%. According to the distribution of each ZHENG, ten clinical common ZHENG were distinguished by criteria of the frequency percent value at least 10.0% and cumulative percent value reach to 70% or above. Then based on the OR and frequency value of each symptom, the primary symptoms were tentative identified by OR value ≥ 3 with percent value $\geq 50\%$, and that of the secondary symptoms were OR value between 1 and 3 with percent value between 25% and 50%.

Conclusions: Ten common ZHENG of asthma with each primary and secondary symptoms in three stages are identified through the clinical investigation: Exterior cold with interior fluid retention, Phlegm-turbidity obstructing the lung, Phlegm-heat obstructing the lung, Wind-phlegm obstructing the lung, Blood stasis, Qi deficiency of the lung, Qi deficiency of the lung and spleen, Qi deficiency of the lung and kidney, Qi and Yin deficiency of the lung and kidney, Yang deficiency of the lung and kidney.

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1. Introduction

Bronchial asthma is a common, chronic respiratory disease characterized by variable and recurring symptoms, reversible airflow obstruction and bronchospasm,[1] affecting 1.2%–22.5% of the adult population in different countries and more than 300 million persons suffering from asthma.[2] In the United States, the number of asthmatics has increased from 7.3% in 2001 to 8.4% in 2010, and an estimated 18.7 million adults aged 18 and over had asthma.[3] According to the China Asthma and Risk factors Epidemiologic survey, the average prevalence is 1.24%.[4] Deaths from asthma have reached over 250,000 annually. Mortality among adults with asthma is 2.1 times than the control subjects by a 25-year large cohort study.[5]

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Under guidelines of The Global Initiative for Asthma (GINA) and US National Heart, Lung, and Blood Institute (NHLBI), patients are divided into three stages: acute exacerbation, chronic persistent, and clinical remission. Specific goals are the achievement of the most possible clinical control and reduction risk of adverse outcomes in the future.[5] Short-acting and long-acting bronchodilators, inhaled corticosteroids, and low-dose, slow-release theophylline are the interventions for asthma.[6] However, it is difficult to improve people's symptoms without suffering too many side effects or adverse events.[7]

Application of complementary and alternative medicine (CAM) have become increasingly popular as a symptom relief treatment and are quickly approaching conventional therapy in frequency of use, and the effects have been documented in numerous conditions.[8] Based on holistic principles, through inspection, listening and smelling, inquiry and pulse, from the comprehensive analyze of the symptoms, signs, disease cause and location of the illness, Traditional Chinese medicine (TCM) practitioners prescribe proper formulas to heal their disorders. TCM symptoms are very important for diagnostics in daily clinical practice.[9] A specific set of symptoms is referred to as a ZHENG or pattern.

TCM ZHENG classification has been used to identify specific subsets of patients within a few thousand years. ZHENG is a specific stratification of a disease according to a group of symptoms that can be regarded as a summary of the body's condition at a certain stage in the disease process.[10] ZHENG describes the differences in etiology and pathogenesis of a disease and emphasizes the variation in individuals' body constitution. Patients may present with different ZHENG because of individual differences in the complicated messages of the body.[11] Since ZHENG differentiation is a critical concept in TCM, it is especially important to identify the ZHENG of asthma.[12]

At present, the available asthma ZHENG was mainly established from the textbook, expert counseling and other literature analysis, however, there is limited evidence concerning clinical investigation and scientific assessment. In addition, the key shortcomings of the TCM diagnostic process lack standardization in disagreement on pattern differentiation among TCM practitioners. A potential way of establishing asthma ZHENG easily for research and clinical applicability can employ more comprehensive approaches. Therefore, this study aims to employ more comprehensive approaches to analyze the primary and secondary symptoms of clinical common ZHENG of bronchial asthma according to the clinical investigation of 2500 adult cases.

2. Materials and methods

2.1. Participants

Patients included should meet the following inclusion criteria: met the GINA and NHLBI diagnostic criteria of asthma[1,13]; met the TCM syndrom criteria of asthma[14,15]; aged between 18 and 80 years; syndrome differentiation by associate chief physician or above; received the observation voluntarily and signed informed consent. Asthma patients were excluded if they had confusion, dementia or any type of mental illness; chronic obstructive pulmonary disease (COPD); bronchiectasis, or active tuberculosis, pulmonary embolism, or diffuse panbronchiolitis; severe diseases such as tumor, heart failure, or haematopoietic system diseases.

2.2. Entry procedure

The study was approved by the Ethical Research Committees of The First Affiliated Hospital of Henan University of Traditional Chinese Medicine (batch number: YFYKYLL2011-001). Participants

were enrolled from out-patient departments in seventeen hospitals from April 2012 to November 2013 in Henan province, Shanxi province, Ningxia Hui Autonomous Region, Jilin province, Liaoning province, such as The First Affiliated Hospital of Henan University of TCM, Shanxi Provincial Hospital of TCM, Ningxia Medical University and the Second Affiliated Hospital of Liaoning University of TCM.

2.3. Clinical investigation questionnaire development

The team reviewed the relevant literature about asthma from ancient medical books to early modern era and contemporary era, referred the official document of asthma, such as the Guidelines for Diagnosis and Treatment of Common Internal Diseases in Chinese Medicine Symptoms of Modern Medicine and Criteria of diagnosis and therapeutic effect of internal diseases and syndromes in TCM, and then proposed the inclusion criteria and exclusion criteria and determined the project and the indexes of the questionnaires. Finally the TCM Clinical investigation questionnaire was establishment with good validity, reliability. The Cronbach's α, Split-half coefficient and Test-retest coefficient were 0.706, 0.714, 0.709, respectively; the correlation between domains to overall questionnaire correlation were 0.726–0.918.

The questionnaire contained twenty eight items for syndromes diagnosis, twenty one items for tongue coating, tongue body and tongue texture, seventeen items for pulse conditions, one hundred and two items for symptoms and signs. Due to the clinical syndromes were complicated, the type of the questionnaire was enclosed. When facing some items different from the questionnaire or no items in the questionnaire, the investigator can truthfully filled the clinical syndrome types or relevant diagnostic indexes in the blank.

2.4. Clinical investigation content

2.4.1. General demographic information

Generally conditions (living environment, age and gender), previous health status and related risk factors (inhaled factors, past history of respiratory system, digestive system, circulatory system and nervous system, glucocorticoids and antibiotic usage, allergy history and family history), current relevant information of asthma occurrence.

2.4.2. Signs and symptoms associated with asthma

The upper airway (pharyngeal itching, dry throat, sore throat, nasal obstruction, rhinocnesmus); cough (cough, dry cough without phlegm, little sputum, abundant sputum, uncomfortable phlegm out, wheezing due to retention of phlegm in throat); Shortness of breath (pant, palpitations wheeze, chest tightness, shortness of breath, worse when lie down and after activities); conditions of chills and fever, sweating, colour of face and skin, head and body, diet, urination or defecation and mental consciousness; signs (breathing palpitations with mouth open and shoulder shrink, skin flushing, wheezing sound, moist rales, lower extremity edema).

2.4.3. Tongue and pulse conditions

Tongue coating, tongue body, tongue texture, pulse conditions.

2.4.4. Drafted syndrome classification

The excess syndromes (Wind-cold invading the lung, Exterior cold with interior fluid retention, Phlegm-heat obstructing the lung, phlegm-turbidity obstructing the lung, liver fire invading lung, wind-phlegm obstructing the lung, reversed qi of lung and stomach, cold-heat complex pattern); The deficiency syndromes (Qi deficiency of the lung, Qi deficiency of the lung and spleen, Qi deficiency