

# Clinical Observation and Safety Evaluation of Zhuang Medicine Xiaoyan Zhiyang Formula for Dermatoses

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**Abstract** [Objectives] To observe the clinical efficacy and safety of Zhuang Medicine Xiaoyan Zhiyang Formula by retrospective analysis of clinical use. [Methods] A total of 225 cases were collected, including 117 males and 108 females, 115 cases of contact dermatitis and 110 cases of acute eczema. Zhuang Medicine Xiaoyan Zhiyang Formula was administered to 225 patients with contact dermatitis and acute eczema and the clinical efficacy was evaluated. [Results] After one week of treatment, among 225 patients with contact dermatitis and acute eczema, 76 cases were cured (33.78%), 133 cases showed marked response (59.11%), 16 cases (7.11%) were improved, 0 case was ineffective, and the overall response rate was 92.89%. After one week of Zhuang Medicine Xiaoyan Zhiyang Formula treatment, the symptoms of itching, pain and swelling were significantly improved in all patients, and the rash was partially crusted without new symptom, and there were no complications and adverse reactions. [Conclusions] Zhuang Medicine Xiaoyan Zhiyang Formula therapy has a remarkable effect in the treatment of contact dermatitis and acute eczema.

**Key words** Zhuang Medicine Xiaoyan Zhiyang Formula, Contact dermatitis, Acute eczema, Clinical drug use, Safety evaluation

## 1 Introduction

Zhuang Medicine Xiaoyan Zhiyang Formula is a Chinese medicine formula for the treatment of skin diseases formulated by Guangxi International Zhuang Medical Hospital for many years on the basis of the basic principles of TCM treatment of diseases "dialectical treatment", and with reference to some of the basic theories of Zhuang medicine. This formula has been successively used in Mingxiu Branch of Guangxi International Zhuang Medical Hospital (formerly Guangxi Zhuang Medical Hospital), Guangxi International Zhuang Medical Hospital processed the formula into decoction and provided it to patients for use, which has definite curative effect and can effectively improve the symptoms of patients.

Zhuang Medicine Xiaoyan Zhiyang Formula consists of six traditional Chinese medicines, namely, *Scutellariae Radix* (Huangqin), *Portulacae Herba* (Machixian), *Ilicis Rotundae Cortex* (Jiubiyang), *Herba Polygoni Chinensis* (Huotanmu), *Mahoniae Caulis* (Gonglaomu), and *Sanguisorbae Radix* (Diyu). It has been clinically applied for many years, and has the effect of clearing heat and removing dampness, cooling blood and detoxification, and generating muscle sores, and is used to treat acute dermatitis, eczema, contact dermatitis, burns and other skin diseases.

In the long-term clinical work, our team used Zhuang Medicine Xiaoyan Zhiyang Formula to treat acute dermatitis, eczema, contact dermatitis, burns and other skin diseases, and has achieved good results. The Zhuang Medicine Xiaoyan Zhiyang Formula has effect in clearing away heat, eliminate dampness, cooling blood, removing toxic materials, promote granulation, and healing sore; and can be used for treating acute dermatitis, eczema, contact dermatitis, *paederus dermatitis*, burn, scald, and other dermatoses. We summarized the clinical application of the cases systematically observed in the past three years (2021–2023) in this paper.

## 2 Basic information of the prescription

**2.1 Composition** The formula consists of *Scutellariae Radix* 15 g, *Portulacae Herba* 15 g, *Ilicis Rotundae Cortex* 15 g, *Herba Polygoni Chinensis* 15 g, *Mahoniae Caulis* 15 g, and *Sanguisorbae Radix* 15 g.

**2.2 Usage and dosage** It is decocted with water for external use, diluted with warm water (1:10–1:200), and apply (soak) to the affected part, 1 dose per day, 1–2 times.

**2.3 Functions and indications** It has effect in clearing away heat and toxic material, cooling blood, expelling pathogenic wind, eliminating dampness, and relieving itching. It can be used for treating dermatoses such as acute dermatitis, eczema, contact dermatitis, *paederus dermatitis*, and burn and scald.

**2.4 Prescription theory** In the formula, the *Ilicis Rotundae Cortex* has the effect of clearing away heat and toxic material, reducing swelling and relieving pain, promote diuresis and the like, is used as the sovereign medicinal in the formula, and is mainly used for treating eczema, impetigo, toothache, burn and scald, traumatic injury, traumatic hemorrhage, venomous snake bite and other diseases for external use. *Ilicis Rotundae Cortex* mainly contains saponins, aromatic compounds, steroids, aldehydes, flavonoids and others. Syringin and Pedunculoside are two typical

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triterpenoid saponins in *Ilicis Rotundae* Cortex, which have pharmacological activities such as antibacterial, anti-inflammatory, analgesic and antitumor. *Sanguisorbae Radix* has the effects of cooling blood, stopping bleeding, detoxifying and healing sores, and is mainly used for treating scald, eczema, sores and carbuncles. The chemical components of *Sanguisorbae Radix* are mainly tannins, phenolic acids, saponins, flavonoids, steroids and polysaccharides, which have antioxidant, anti-allergic, anti-inflammatory and antibacterial effects. *Mahoniae Caulis* has the effects of clearing heat, drying dampness and detoxifying, and is mainly used for treating sores, eczema, scalds and the like. The main chemical components of *Mahoniae Caulis* are alkaloids, flavonoids and volatile oils, which have antibacterial, anti-inflammatory, antiviral and antitumor activities. *Portulacae Herba* has the effect of clearing heat and detoxification, cooling blood and stopping bleeding, and is clinically used to treat inflammatory bowel disease, acute eczema, shingles, flat warts, uterine bleeding, diarrhea and breast abscess. *Portulacae Herba* has anti-inflammatory, analgesic, bacteriostatic, hypolipidemic, hypoglycemic, anti-tumor, antioxidant, anti-aging, enhance immunity and other effects, and is widely used in medicine, health food, skin care products and other fields. *Scutellariae Radix* has the effect of clearing heat and dampness, ephemeral fire and detoxification, and modern research has shown that it has antibacterial, anti-inflammatory, antiviral, antitumor and other pharmacological activities. *Herba Polygoni Chinensis* has the effect of clearing heat and moisture, cooling blood and detoxification, and has antioxidant, antibacterial, anti-inflammatory, antitumor and other effects. The combination of these medicines has the effect of clearing heat and removing dampness, cooling blood and detoxification, and generating muscle sores, and is used to treat acute dermatitis, eczema, contact dermatitis, cryptoptera dermatitis, burns and other skin diseases.

### 3 Observation of clinical medication

This clinical observation was formulated and implemented in accordance with the regulations and documents such as the *Detailed Rules for the Record Management of Traditional Chinese Medicine and Ethnic Medicine Preparations Prepared by Traditional Technology in Guangxi Medical Institutions*, the *Guiding Principles for Clinical Research of New Chinese Medicines*, and the *Technical Guidelines for Clinical Research of New Drugs in Syndrome Traditional Chinese Medicines*.

**3.1 General data** We observed 225 outpatients of dermatology at Guangxi International Zhuang Medical Hospital. Among them, 117 were males and 108 were females. In all these patients, 115 cases of contact dermatitis and 110 cases of acute eczema were diagnosed. The oldest was 60 years old, the youngest was 18 years old, the age range was 18–60 years old, and the average age was  $(33.11 \pm 9.34)$  years old; the course of disease was 1–14 d with an average  $(5.64 \pm 2.82)$  d. The age and gender distribution of patients are shown in Table 1, and the annual distribution of cases is shown in Table 2, and the distribution of diseases is 115 cases

(51.11%) of contact dermatitis and 110 cases (48.89%) of acute eczema.

**Table 1** Age and gender distribution of patients

Patient group years old	Number of cases	Gender	
		Male	Female
18–20	14	7	7
21–30	81	38	43
31–40	85	50	35
41–50	30	15	15
51–60	15	7	8

**Table 2** Annual distribution of cases

Year	Number of cases	Percentage//%
2021	67	29.78
2022	107	47.55
2023	51	22.67

**3.2 Diagnostic criteria** The diagnostic criteria were determined with reference to the relevant contents of *Chinese Zhuang Medicine* published by Guangxi Ethnic Publishing House, *Internal Medicine of Chinese Zhuang Medicine* published by Guangxi Science and Technology Publishing House, *Standards for Diagnosis and Treatment of Diseases and Syndromes in Chinese Zhuang Medicine* published by Guangxi Ethnic Publishing House, *Concise Zhuang Medicine* and *Traumatology of Zhuang Medicine* published by China Traditional Chinese Medicine Publishing House.

**3.2.1** Contact dermatitis. Clinical manifestations; This disease is mainly judged according to the characteristics of skin lesions. Most patients may have a rash with the same shape and scope as the contact site. In severe cases, erythema and swelling can be seen, often accompanied by blisters, bullae, papules, erosion, exudation and other conditions; some patients may also have subacute and chronic dermatitis eczema-like manifestations, such as mild erythema, papules, lichenoid changes, mild pruritus and so on.

**3.2.2** Diagnostic criteria for acute eczema. Clinical manifestations: Main symptoms: erythema, papules, exudation, erosion, scab, lichenoid and other polymorphous rash with severe pruritus. In acute cases, skin lesions are usually polymorphous, such as flushing, papules, blisters, erosion, exudation, crusts, desquamation, and many forms may exist at the same time. It is characterized by acute onset, self-conscious burning, and severe itching. Skin lesions are often symmetrically distributed, with more common in the head, face, distal extremities, scrotum, etc. It can spread throughout the body. It can develop into subacute or chronic wet sores, and it can be mild and severe, and recur.

Complications; irritability, sleeplessness, lack of breath and lazy speech, self-sweating, poor stools, heavy limbs, dry stools, yellow urine.

Visual signs; the white eye veins of the acute onset of "Le-da" are bright red, the edges of the white eye veins are infiltrated and turbid, the boundaries are unclear or the veins are scattered.

Tongue and pulse condition; The tongue is red with yellow greasy or white greasy coating, and the pulse is wiry and slippery or slippery and rapid.

Nail signs: The nail bed is light red or bright red, the nail body is smooth and moist, the nail fold is symmetrical and complete, and the blood color is restored evenly.

### 3.3 Observation content and method

**3.3.1** Safety indicators: truthfully fill in the adverse event (AE) report form.

(i) AE report form. Did the subject have an adverse event during the trial? ☐ No ☐ Yes. If "Yes", please fill in the following form.

Name of adverse event			
Occurrence time	Time: ____ hour, ____ min, Day ____ , Month ____ , Year ____	Time: ____ hour, ____ min, Day ____ , Month ____ , Year ____	Time: ____ hour, ____ min, Day ____ , Month ____ , Year ____
Severity of adverse event	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
Whether measures have been taken (If yes, please record the combined medication record form)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Effect on the dose of the study drug	<input type="checkbox"/> Not using <input type="checkbox"/> Discontinue using <input type="checkbox"/> End of using <input type="checkbox"/> Others	<input type="checkbox"/> Not using <input type="checkbox"/> Discontinue using <input type="checkbox"/> End of using <input type="checkbox"/> Others	<input type="checkbox"/> Not using <input type="checkbox"/> Discontinue using <input type="checkbox"/> End of using <input type="checkbox"/> Others
Relationship with the study drug	<input type="checkbox"/> Definitely related <input type="checkbox"/> Likely related <input type="checkbox"/> Possibly related <input type="checkbox"/> Possibly not related <input type="checkbox"/> Note related	<input type="checkbox"/> Definitely related <input type="checkbox"/> Likely related <input type="checkbox"/> Possibly related <input type="checkbox"/> Possibly not related <input type="checkbox"/> Note related	<input type="checkbox"/> Definitely related <input type="checkbox"/> Likely related <input type="checkbox"/> Possibly related <input type="checkbox"/> Possibly not related <input type="checkbox"/> Note related
Whether the serious adverse event is met (if so, please record the serious adverse event report form)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Complete the following sections at end of adverse events or at the end of the study			
The outcome of the adverse event that occurred	<input type="checkbox"/> Still exists <input type="checkbox"/> Alleviated <input type="checkbox"/> Cured <input type="checkbox"/> Not known Date and time of alleviation/cure:	<input type="checkbox"/> Still exists <input type="checkbox"/> Alleviated <input type="checkbox"/> Cured <input type="checkbox"/> Not known Date and time of alleviation/cure:	<input type="checkbox"/> Still exists <input type="checkbox"/> Alleviated <input type="checkbox"/> Cured <input type="checkbox"/> Not known Date and time of alleviation/cure:
Did the subject withdraw from the trial due to this adverse event?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Remarks			

(ii) Serious adverse event (SAE)

Type of report	<input type="checkbox"/> First report <input type="checkbox"/> Follow-up report <input type="checkbox"/> Summary report			Report date:	
Name of medical institution and department				Tel. :	
Name of applying unit				Tel. :	
Name of the drug for investigation	Chinese name:				
	English name:				
Classifications of drugs	<input type="checkbox"/> Traditional Chinese medicine <input type="checkbox"/> Chemical drugs <input type="checkbox"/> New biological products <input type="checkbox"/> Radioactive drugs <input type="checkbox"/> Imported <input type="checkbox"/> Others				Type ____
Stage of clinical study	<input type="checkbox"/> Stage I <input type="checkbox"/> Stage II <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IV <input type="checkbox"/> Bioequivalence test <input type="checkbox"/> Clinical trials				Dosage form: ____
Subject information	Name abbreviation: ____	Gender: ____	Date of birth: ____	Ethnic group: ____	
	Disease diagnosis:				
SAE condition	<input type="checkbox"/> Hospitalization <input type="checkbox"/> Extending the hospitalization time <input type="checkbox"/> Disability <input type="checkbox"/> Dysfunction <input type="checkbox"/> Congenital malformations <input type="checkbox"/> Endangering life or death <input type="checkbox"/> Others				
SAE occurrence time:				SAE severity: <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	
Action taken on the trial drug	<input type="checkbox"/> Not using <input type="checkbox"/> Discontinue using <input type="checkbox"/> End of using <input type="checkbox"/> Others				
SAE metastasis and progression	<input type="checkbox"/> Symptoms disappear (Sequelae <input type="checkbox"/> No <input type="checkbox"/> Yes) <input type="checkbox"/> Symptoms persist <input type="checkbox"/> Death (time: Month ____ Day ____ , Year ____)				
Relationship between SAE and investigational drug	<input type="checkbox"/> Definitely related <input type="checkbox"/> Likely related <input type="checkbox"/> Possibly related <input type="checkbox"/> Possibly not related <input type="checkbox"/> Note related				
Unblinding	<input type="checkbox"/> No <input type="checkbox"/> Yes (Unblinding time: Month ____ Day ____ , Year ____)				
Reported SAE	Domestic <input type="checkbox"/> Yes ____ <input type="checkbox"/> No ____ <input type="checkbox"/> No details Foreign <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No details				
Details of SAE occurrence and handling					

**3.3.2 Criteria for efficacy.** The criteria were formulated with reference to the *Guidelines for Clinical Research of New Chinese Medicines* published by the Administration of Traditional Chinese Medicine. The evaluation of clinical efficacy is divided into 4 levels: clinically cured, marked response, improved, and ineffective.

Symptom Score Reduce Index (SSRI) = (Total score before treatment – Total score after treatment) / Total score before treatment × 100% .

(i) Clinically cured: skin lesions disappeared completely and the symptoms disappeared, and the SSRI was ≥ 90% ;

(ii) Marked response: most of the skin lesions subsided and the symptoms were significantly relieved, SSRI was 60% – 89% ;

(iii) Improved: skin lesions were partially improved and symptoms were improved, SSRI was 30% – 59% ;

(iv) Ineffective: the improvement of skin lesions was not obvious, the symptoms were not improved or aggravated, and the SSRI was <30% .

Response rate = ( Basically cured + Marked response ) × 100% .

**3.4 Statistical analysis** SPSS software was used. The age, gender, course of disease and other general data of the patients were counted. Ridit analysis was used for rank data,  $X^2$  test was

carried out for technical data, and  $t(u)$  test was carried out for measurement data.

**4 Analysis of clinical efficacy**

**4.1 Overall clinical efficacy** The overall clinical overall response rate of 225 patients treated with Zhuang Medicine Xiaoyan Zhiyang Formula was 92.89% , of which 76 cases were cured, 133 cases were markedly effective, 16 cases were improved, and 0 case was ineffective. The specific analysis is shown in Table 3. The main diseases include contact dermatitis and acute eczema, and the overall response rate of each disease is within the range, as shown in Table 4.

**Table 3 Curative effect of Zhuang Medicine Xiaoyan Zhiyang Formula after one week of treatment**

Curative effect	Number of cases	Percentage//%
Clinically cured	76	33.78
Marked effective	133	59.11
Improved	16	7.11
Ineffective	0	0
Overall response rate	209	92.89

**Table 4 Curative effect of Zhuang Medicine Xiaoyan Zhiyang Formula for different diseases after one week of treatment**

Disease	Number of cases	Clinically cured//cases	Marked effective//cases	Improved//cases	Ineffective//cases	Overall response rate//%
Contact dermatitis	115	42	68	5	0	95.65
Acute eczema	110	34	65	11	0	90

**4.2 Safety** No serious adverse events, serious complications and adverse reactions occurred in 225 observed patients after medication.

found during the medication, and the prescription is safe and effective in clinical application.

**5 Conclusions**

The Zhuang Medicine Xiaoyan Zhiyang Formula has the effects of clearing away toxic heat, removing dampness, expelling pathogenic wind, dredging the channels of dragon fire, regulating the channels of grain and water, softening and resolving hard mass, killing parasites and relieving itching and pain. It can be used for treating dermatoses such as acute dermatitis, eczema, contact dermatitis, paederus dermatitis, and burn and scald. No adverse reaction is

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