DOI: 10.53469/jcmp.2026.08(01).26

Clinical Efficacy of Modified Huangqin Xiebai Powder Plus Maxing Shigan Decoction for Phlegm-Heat Obstructing the Lung Syndrome with Pediatric Mycoplasma Pneumoniae

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Abstract: ***Objective**: To evaluate the clinical efficacy of modified Huangqin Xiebai powder combined with Maxing Shigan decoction in treating Phlegm-Heat Obstructing the Lung Syndrome with Mycoplasma pneumoniae pneumonia (MPP) in children. **Methods**: Sixty pediatric patients diagnosed with Phlegm-Heat Obstructing the Lung Syndrome with MPP, aged between 0 and 14 years and treated at our institution from October 2023 to January 2024, were recruited. These participants were randomly allocated into the experimental and control groups (n=30). The control group received standard medical therapy, whereas the experimental group received standard therapy supplemented with modified Huangqin Xiebai powder and Maxing Shigan decoction. Both groups underwent 7 consecutive days of treatment. Clinical efficacy, traditional Chinese medicine (TCM) syndrome scores, laboratory indices, and adverse event rates were evaluated and compared between groups. **Results**: The experimental group exhibited a significantly superior clinical response rate (96.66%) relative to the control group (χ^2=5.129, P=0.023). Following treatment, white blood cell (WBC) counts decreased in both groups, though without significant differences (P>0.05); however, the extent of reduction was more pronounced in the experimental group. C-reactive protein (CRP) levels declined substantially in both groups, with the experimental group demonstrating notably greater improvement (P<0.05). TCM syndrome scores in both groups showed significant improvement relative to baseline, with the experimental group showing more marked improvement (P<0.05). No severe adverse reactions were recorded in either group. **Conclusion**: In conclusion, the adjunctive use of Modified Huangqin Xiebai powder and Maxing Shigan decoction significantly improved clinical response, reduced inflammation (CRP), and alleviated TCM symptoms in Phlegm-Heat Obstructing the Lung Syndrome with Mycoplasma pneumoniae pneumonia (MPP) in childen, demonstrating a favorable benefit-risk profile.*

Keywords: Mycoplasma pneumoniae pneumonia, Children, Phlegm-Heat Obstructing the Lung Syndrome, Huangqin Xiebai powder, Maxing Shigan decoction, Efficacy.

1. Introduction

MPP represents an acute inflammatory respiratory disorder predominantly affecting pediatric populations, arising from Mycoplasma pneumoniae infections. Extensive epidemiological surveys have established Mycoplasma pneumoniae as one of the primary pathogens responsible for pediatric community-acquired pneumonia (CAP) in China, contributing to approximately 32.4% of CAP cases among children aged from 6 months to 14 years [1]. The primary clinical manifestations include fever, cough, and dyspnea. Without timely and effective interventions, the condition may rapidly progress to lobar pneumonia, severe pneumonia, or even extrapulmonary complications involving the cardiovascular or hematological systems [2]. Clinically, MPP is categorized into mild, severe, and critical types. Severe and critical cases often have high recurrence rates due to therapeutic difficulties and prolonged disease duration, adversely affecting prognosis and posing a threat to life [3].

Macrolide antibiotics constitute the first-line treatment for MPP in clinical practice. However, studies have demonstrated increasing macrolide resistance in MPP cases due to widespread and inappropriate antibiotic use. Resistance rates vary by region and year, with an average overall resistance rate reaching 24%. Such resistance may lead to suboptimal therapeutic responses, impaired lung function, and reduced quality of life [4].

Recently, integrated traditional Chinese and Western medicine has emerged as an important approach for enhancing therapeutic efficacy, which has shown promising therapeutic potential in the treatment of mycoplasma pneumoniae pneumonia (MPP), with emerging metabolomic and pharmacologic studies beginning to elucidate its complex mechanisms. Metabolomic analyses reveal that TCM interventions induce systemic shifts in lipid, amino acid, and energy metabolism, suggesting a holistic rebalancing of metabolic disturbances associated with MPP [5]. For instance, the Qingfei Mixture, combined with azithromycin, demonstrated enhanced symptom improvement and reduced pulmonary inflammation in both clinical and animal models, accompanied by significant reductions in IL-17 levels and improved lung ultrastructure [6]. Similarly, Shuang-Huang-Lian oral liquid exhibits multi-target, multi-pathway effects against Mycoplasma pneumoniae, as evidenced by network pharmacology analyses identifying 18 active ingredients influencing 53 protein targets involved in immunity, inflammation, and infection response [7]. From the perspective of TCM, MPP falls within the category of “Pneumonia-Asthma,” attributed to invasion by pathogenic heat. Based on this pathogenesis, this study aimed to evaluate the clinical efficacy of modified Huangqin Xiebai powder combined with Maxing Shigan decoction in treating children Phlegm-Heat Obstructing the Lung Syndrome with Pediatric Mycoplasma pneumoniae. Huangqin Xiebai powder, originating from “Symptomology-Etiology-Pulse-Treatment,” exerts therapeutic effects by clearing latent heat from the

lungs and resolving phlegm. Maxing Shigan decoction, derived from "Treatise on Cold Damage Disorders," functions through acrid-cool ventilation of the lungs and alleviation of dyspnea [8]. Through this study, a more scientific and systematic integrated TCM and Western medical approach can be explored to guide clinical drug administration, reduce antibiotic reliance and resistance, and improve clinical symptoms and quality of life, thereby providing a therapeutic basis for children with Phlegm-Heat Obstructing the Lung Syndrome with MPP.

2. Methods

2.1 General Information

Sixty pediatric patients diagnosed with Phlegm-Heat Obstructing the Lung Syndrome with MPP, aged between 0 and 14 years and treated at our institution from October 2023 to January 2024, were recruited. and subsequently randomized into experimental and control groups.

2.2 Study Design

This study employed an assessor-blinded, randomized controlled design. Randomization was performed using a computer-generated random number sequence, with allocation concealed until interventions were assigned. Allocation concealment was ensured by means of sequentially numbered, opaque, sealed envelopes (SNOSE), which were prepared by an independent research assistant not involved in the trial. Each envelope was opened only after the participant had been enrolled and baseline data had been collected, thereby preventing foreknowledge of treatment assignment. Given the relatively low incidence of Phlegm-Heat Obstructing the Lung Syndrome with MPP in the clinical setting, the sample size was determined primarily by the maximum number of eligible cases that could be consecutively recruited within the study period. A total of 60 participants (30 participants per group) were enrolled, which reflects the entirety of accessible patients meeting the inclusion criteria during the investigation timeframe. CONSORT flow diagram was shown as Figure 1.

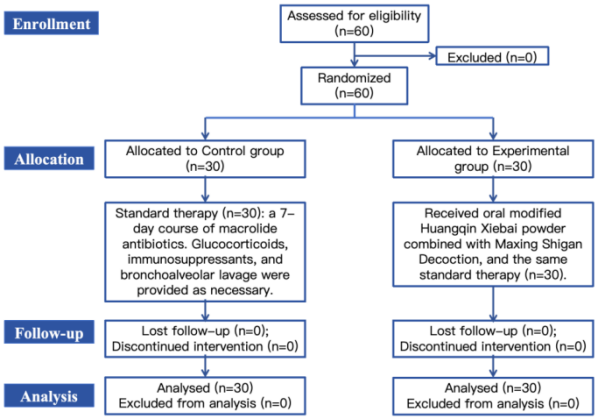

Figure 1: CONSORT flow diagram of the study

2.3 Inclusion and Exclusion Criteria

2.3.1 Inclusion criteria

(1) Children meeting diagnostic criteria for MPP [9]. (2) Children aged 0–14 years. (3) The TCM pattern conforms to Phlegm-Heat Obstructing the Lung Syndrome. (4) Parents provided informed consent for participation in the study.

2.3.2 Exclusion criteria

(1) Children allergic to medications used in this study. (2) Children with comorbid acute or chronic respiratory diseases, pulmonary tumors, or pulmonary tuberculosis. (3) Children with severe primary diseases, such as cardiovascular, hepatic, or renal disorders.

2.4 Formulation

The herbal treatment administered to the intervention group was a modified regimen derived from two classical formulas: Huangqin Xiebai San and Maxing Shigan Tang. The dosages, based on standard adult references from the classical texts, were as follows: Huangqin Xiebai San consisted of Scutellariae Radix (Huangqin) 10 g, Mori Cortex (Sangbaipi) 15 g, Lycii Cortex (Digupi) 15 g, and Glycyrrhizae Radix et Rhizoma (Gancao) 5 g; Maxing Shigan Tang included Ephedrae Herba (Mahuang) 9 g, Armeniacae Semen Amarum (Xingren) 9 g, Gypsum Fibrosum (Shigao) 18 g, and Glycyrrhizae Radix et Rhizoma (Gancao) 5 g. All herbs were sourced from the hospital pharmacy, which ensured the use of certified, high-quality crude materials that met the Chinese Pharmacopoeia standards.

The herb ratios strictly adhered to the original formulations from the classical texts, Shang Han Lun and Zheng Yin Mai Zhi. The decoction was prepared uniformly by the hospital's specialized pharmacy to maintain consistency. The preparation involved soaking the herbs in cold water in a ceramic pot for 30 minutes, ensuring the water level remained approximately 3 cm above the herbs. The mixture was then brought to a boil over high heat, followed by a simmer for 15-20 minutes. The first extraction liquid was decanted, and a second extraction was performed with reduced water volume, covering the herbs by 1-2 cm, and repeating the boiling and simmering process.

2.5 Treatment Methods

Both groups received symptomatic treatment, including antipyretics, cough suppression, sputum clearance, and maintenance of water-electrolyte balance (oral ibuprofen, inhaled budesonide combined with terbutaline, and intravenous glucose-saline solution). The control group was administered macrolide antibiotics for 7 days to inhibit Mycoplasma activity and relieve clinical symptoms. Glucocorticoids, immunosuppressants, and bronchoalveolar lavage were administered if necessary. In addition to this regimen, patients in the treatment group received oral administration of modified Huangqin Xiebai powder combined with Maxing Shigan Decoction. Dosages were administered as follows: 30 mL/time for neonates, 60–100 mL/time for infants, 150–200 mL/time for toddlers and preschool children, and 200–250 mL/time for school-age children, administered twice daily for 7 days. The dose for each pediatric patient was individually adjusted based on age and prominent clinical presentation, following the guidelines of the Expert consensus on clinical application of Chinese

herbal medicine decoction pieces [10]. In contrast, the control group received studard therapy, which was explicitly defined for this study.

2.6 Observation Indicators

Clinical efficacy was evaluated according to a comprehensive set of criteria adapted from the Guidelines for the Diagnosis and Treatment of Mycoplasma pneumoniae Pneumonia in Children (2023 Edition) and established clinical research standards [11, 12].

(1) Symptom changes: Body temperature, pulmonary signs, and imaging findings before and after treatment were recorded.

(2) TCM Syndrome Score Scale: The TCM syndrome score was assessed using a standardized quantitative method. Each main symptom was evaluated on a 4-point severity scale: 0 (normal), 1 (mild), 2 (moderate), and 3 (severe), based on predefined clinical criteria. Fever was graded by axillary temperature. Cough severity was classified by frequency and impact on daily life, ranging from occasional (score 1) to frequent bouts disrupting sleep and activities (score 3). Dyspnea with nasal flaring was assessed observationally, from mild tachypnea (1) to severe respiratory distress with pronounced flaring (3). The complete protocol for the TCM Syndrome Score Scale, including the specific scoring criteria, is documented in Table 1. The total score was calculated by summing individual symptom scores, providing a quantitative measure of syndrome severity for baseline assessment and evaluation of treatment response.

Table 1: Traditional Chinese Medicine Syndrome Questionnaire

Symptoms	Normal (0 points)	Mild (1 point)	Moderate (2 points)	Severe (3 points)
Primary Symptoms				
Fever	Axillary temperature, ≤37.2℃	Axillary temperature, 37.3-37.9℃	Axillary temperature, 38-38.9℃	Axillary temperature, ≥38.9℃
Cough	No symptoms reported	3-5 episodes per day	6-10 episodes per day, with no impact on daily activities or sleep.	≥10 episodes per day, impacting daily activities and sleep.
Tachypnea and Nasal Flaring	No symptoms reported	Tachypnea, mild dyspnea	Moderate to severe dyspnea	Respiratory distress with nasal flaring
Secondary Symptoms				
Rhinorrhea	No symptoms reported	Reported		
Poor Appetite	No symptoms reported	Reported		
Dry Mouth	No symptoms reported	Reported		
Dark Urine	No symptoms reported	Reported		
Constipation	No symptoms reported	Reported		

(3) Inflammatory biomarkers: WBC count, CRP levels before and after treatment were recorded.

(4) Clinical efficacy: Markedly effective: Stable normal body temperature maintained for two consecutive days, significant relief from cough and dyspnea, normal bilateral lung auscultation, complete absorption of lung lesions upon imaging, and significantly reduced WBC and CRP levels. Effective: Normal body temperature, notable relief from cough and dyspnea, minimal bilateral rales, decreased WBC and CRP levels, and partial absorption of lung lesions. Ineffective: No significant improvement or deterioration of symptoms and signs.

(5) Adverse drug reactions: Incidences of nausea, vomiting, diarrhea, and elevated blood pressure during treatment were recorded. Vital signs, including blood pressure, were measured and documented at each visit using standardized medical equipment. All events were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 to ensure consistent severity assessment. Any reported or observed ADRs were recorded in the patient's case report form with details regarding onset date, duration, severity, required interventions, and causality assessment relative to the study treatment.

3. Efficacy Criteria and Statistical Methods

3.1 Efficacy Criteria

Markedly effective [13]: Normal body temperature after treatment, disappearance of cough and dyspnea, normal bilateral lung auscultation, complete absorption of lung lesions, and significantly reduced WBC and CRP levels.

Effective: Normal body temperature, relief from cough and dyspnea, decreased bilateral rhonchi and rales, reduced WBC and CRP levels, and partial absorption of lung lesions.

Ineffective: No significant improvement or worsening of symptoms and signs.

The efficacy was also evaluated using changes in total TCM syndrome scores before and after treatment: a score difference < 3 indicated ineffective, 3–5 indicated effective, and > 5 indicated markedly effective. The total effective rate was calculated as (markedly effective + effective cases) / total cases × 100%.

3.2 Statistical Methods

Statistical analyses were conducted using SPSS version 23.0. For continuous data were presented as mean ± standard deviation (SD) or n (%) and analyzed via t-tests, or chi-square (χ^2) test. Statistical significance was determined at $P < 0.05$. Categorical data are expressed as frequencies and percentages. Comparisons of efficacy ratings were performed using Pearson's chi-square test. A two-sided p-value < 0.05 was considered statistically significant.

4. Results

4.1 Basic Information

No significant differences were noted in baseline characteristics between the experimental and control groups (Table 2), indicating that the groups were well-matched and comparable prior to intervention. These results confirm the success of randomization and provide a reliable foundation for subsequent comparative analysis of treatment effects.

Table 2: General information on two groups

Group	Male/female (n)	Age (year)	Temperature (℃, $\bar{x}$±s)	WBC ($\times 10^9$/L, $\bar{x}$±s)	CRP (mg/L, $\bar{x}$±s)	L% (%, $\bar{x}$±s)
Experimental group	16/14	7.253±2.073	37.96±0.951	8.563±3.934	15.11±18.354	45.477±11.22
Control group	19/11	6.308±2.893	37.743±1.122	8.669±3.415l	13.68±9.65	44.513±12.38
χ^2/t	0.617	-1.454	-0.806	0.111	-0.379	-0.316
P	0.432	0.151	0.432	0.912	0.706	0.753

4.2 Clinical Efficacy of Modified Huangqin Xiebai Powder Plus Maxing Shigan Decoction

Clinical efficacy analysis revealed that the total response rate in the experimental group (96.66%) was significantly superior (P = 0.023) (Table 3). A more detailed breakdown reveals that a substantially greater proportion of patients in the experimental group achieved a significantly effective outcome (53.33%) vs. those in the control group (36.67%). The distribution across the effective was similar between groups (43.33% vs. 40.00%). These results indicate that the adjunctive therapy administered to the experimental group was associated with a statistically significant improvement in clinical efficacy.

Table 3: The clinical efficacy comparison between the experimental group and the control group

Group	Ineffective (%)	Effective (%)	Markedly Effective (%)	Total Effective Rate (%)
Experimental group	1(3.33)	13(43.33)	16(53.33)	96.66
Control group	7(23.33)	12(40)	11(36.67)	76.67
χ^2				5.129
P				0.023

P<0.05

4.3 Comparative Efficacy on WBC Reduction

Comparison of WBC counts indicated no significant differences between groups at baseline (P > 0.05); however, following treatment, WBC reductions were notably more pronounced in the experimental group compared with controls (Table 4). These results demonstrate that while both interventions effectively reduced WBC counts, the experimental regimen did not yield a superior effect over the control.

Table 4: The experimental group and the control group were compared for changes in WBC counts before and after the treatment

Group	Pre-treatment WBC ($\times 10^9$/L, $\bar{x}$±s)	Post-tretment WBC ($\times 10^9$/L, $\bar{x}$±s)
Experimental group	8.563±3.934	6.521±2.292①
Control group	8.669±3.415	6.887±2.015①
t	0.111	0.656
P	0.912	0.613

① Comparison before and after treatment with the same group, P<0.05

4.4 Comparative Efficacy on CRP Level

Table 5: The experimental group and the control group were compared for CRP before and after the treatment

Group	Pre-treatment CRP (mg/L, $\bar{x}$±s)	Post-tretment CRP (mg/L, $\bar{x}$±s)
Experimental group	15.11±18.35	0.557±2.501①
Control group	13.68±9.61	3.09±3.478①
t	-0.379	3.239
P	0.706	0.002

① Comparison before and after treatment with the same group, P<0.05

Analysis of CRP revealed a significantly larger decrease in the experimental group than in the control group after intervention (P<0.05) (Table 5), indicating a more potent anti-inflammatory effect in the experimental group.

4.5 Comparative Efficacy of TCM Syndrome Scores

The comparison of TCM syndrome scores before and after treatment revealed significant improvements in both groups, exhibited considerable improvements in TCM syndrome scores following treatment relative to baseline, though the extent of score reduction was greater in the experimental group (P < 0.05) (Table 6). These results indicate that while standard therapy alone is effective, the integration of the modified Huangqin Xiebai powder and Maxing Shigan decoction contributed to a more substantial alleviation of TCM symptoms.

Table 6: The treatment comparison of traditional Chinese medicine syndrome scores between the experimental group and the control group before and after the treatment

Group	Pre-treatment	Post-tretment
Experimental group	9.33±1.709	2.56±0.569①
Control group	7.93±2.377	3.67±0.922①
t	-2.619	5.562
P	0.11	0.00

① Comparison before and after treatment with the same group, P<0.05

4.6 Clinical Safety of Modified Huangqin Xiebai Powder Plus Maxing Shigan Decoction

No adverse reactions occurred in either group during the study period, and all patients completed the treatment.

5. Discussion

Mycoplasma pneumoniae is the smallest prokaryotic microorganism found in nature. As one of the most common human pathogens, it spreads mainly through droplets and exhibits strong infectivity. It primarily infects the respiratory tract, causing pneumonia [14]. Recently, Mycoplasma pneumoniae infections have become increasingly frequent and diverse globally. After the COVID-19 pandemic, an epidemic peak of Mycoplasma pneumoniae infections in children occurred in 2023, characterized by a younger age of onset, macrolide resistance, and increased severity, posing new clinical challenges [15]. MPP progresses rapidly in children, often causing pulmonary consolidation and interstitial lung disease. Current Western medical treatments for MPP include anti-mycoplasma drugs, corticosteroids, intravenous immunoglobulin, and bronchoscopy-guided airway secretion clearance [16]. Although macrolide antibiotics, such as azithromycin, remain first-line treatments, increasing antibiotic resistance significantly compromises therapeutic outcomes [17].

In clinical practice, routine blood tests provide essential diagnostic and assessment information. WBC counts, CRP

levels, and lymphocyte ratios are common inflammatory biomarkers reflecting immune status, crucial for evaluating the severity of CAP [18, 19]. CRP demonstrates high sensitivity and specificity for diagnosing MPP in children, facilitating early infection identification and providing treatment guidance based on disease severity [20]. After respiratory infection with Mycoplasma pneumoniae, T lymphocytes play a dual role in immune response regulation, providing both protective immunity and potential immune-mediated damage. T cells release cytokines, aiding pathogen clearance; however, excessive T-cell responses may induce cytokine storms and subsequent tissue injury [21]. It was reported that MPP is characterized by an excessive immune-inflammatory response, and peripheral blood biomarkers such as WBC and L% serve as accessible indicators of systemic inflammation and immune activation [22]. Although WBC count may not always show a significant difference between severe and non-severe cases, it remains a routinely monitored parameter in infectious diseases to track overall trends in immune response. More importantly, L% often exhibits a more reliable correlation with disease severity in MPP. Elevated lymphocytes levels are frequently observed in severe cases, reflecting the role of lymphocytes in mediating lung inflammation and tissue damage during MP infection [23, 24]. According to the reference intervals established by the Chinese industry standard Reference intervals of blood cell analysis for children (WS/T 779-2021), both the WBC count measured in pediatric patients with Phlegm-Heat Obstructing the Lung Syndrome with MPP in this study remained within the age-specific normal ranges before and after treatment. In this study, inflammatory biomarkers significantly decreased after treatment in both groups, with more pronounced reductions in the experimental group. However, there were no statistically significant differences were observed in WBC count between the control and experimental groups after treatment, which can be attributed to multiple factors. Primarily, the standard therapeutic regimen for MPP effectively modulates the systemic inflammatory response in both groups. As a result, parameters like WBC and CRP may reduced in all patients, regardless of adjunctive therapy, diminishing inter-group variability. Additionally, the timing of laboratory assessment post-treatment is crucial; if measurements were taken after the peak inflammatory phase had subsided, the values in both groups might have stabilized at a lower level.

From the perspective of TCM, MPP belongs to the category of “Pneumonia-Asthma”, with its pathogenesis primarily linked to external pathogenic invasion such as wind-heat or wind-cold, causing dysregulation of lung Qi dispersion and descent. Subsequently, stagnation of phlegm and heat toxins causes symptoms including cough, shortness of breath, and fever. Symptoms can be categorized based on etiological factors, the depth of disease penetration, and pathological manifestations into syndromes such as wind-cold invading the lung, heat-toxin congestion, and external cold with internal fluid retention. Pneumonia with Cough and Dyspnea is a common pediatric condition in Traditional Chinese Medicine (TCM), equivalent to bronchopneumonia and other pulmonary inflammatory diseases in modern medicine. Its location is in the Lung, and the basic pathogenesis is the stagnation and obstruction of lung qi, which evolves dynamically with disease progression. In the acute phase, the main syndrome types are as follows: Wind-Cold Obstructing the Lung Syndrome: Caused by wind-cold fettering the exterior and lung qi failing to disperse. Manifestations include a clear or dull cough sound, thin white sputum, aversion to cold with fever, absence of sweating, and absence of thirst. The tongue is pale red with a thin white coating; the pulse is floating and tight. Treatment should aim to disperse the Lung with acrid-warm herbs, relieve cough, and calm wheezing. Wind-Heat Obstructing the Lung Syndrome: Caused by wind-heat invading the lung and impairing its depurative downbearing. Manifestations include cough with shortness of breath, yellow sticky sputum, high fever predominating over aversion to wind, presence of sweating, thirst, and a red throat. The tongue tip and edges are red with a thin yellow coating; the pulse is floating and rapid. Treatment should aim to disperse the Lung with acrid-cool herbs and clear heat to resolve phlegm. Phlegm-Heat Obstructing the Lung Syndrome: This is the most common severe pattern. Manifestations include persistent high fever, severe cough, dyspnea with flaring nostrils, gurgling phlegm in the throat, thick yellow or rust-colored/sputum mixed with pus and blood, chest pain, flushed face, and thirst. The tongue is red with a yellow greasy coating; the pulse is slippery and rapid. Treatment should aim to clear heat and purge phlegm, open the Lung, and settle panting. Toxic-Heat Obstructing the Lung Syndrome: The heat is even more intense, with toxic heat congesting internally. Manifestations include persistent high-grade fever, cough with severe dyspnea, irritability and thirst, cyanosis of the face and lips, dry stool, and scanty dark urine. The tongue is deep red or crimson with a yellow dry coating or prickles; the pulse is flooding and rapid. Treatment should aim to clear heat and resolve toxicity, drain the Lung, and open obstruction. Pediatric patients included in this study predominantly exhibited the syndrome of Phlegm-Heat Obstructing the Lung Syndrome, characterized pathologically by stagnation of lung Qi and obstruction, with phlegm-heat as the primary pathological product [25]. TCM treatment adheres to the principle of “treating the root cause of the disease”. Thus, therapeutic approaches for MPP focus on clearing lung obstruction and dissipating phlegm to relieve asthma while restoring the lung’s dispersing and descending functions.

This formula effectively treats pediatric patients with “phlegm-heat invading the lung” by clearing heat, resolving toxins, diffusing the lung, and transforming phlegm. In terms of herbal composition, the principal herb of Huangqin Xiebai powder, white mulberry bark, clears lung heat congestion, relieves cough, and alleviates asthma by directly acting on the lung. The addition of sweet-cold Cortex Lycii aids in clearing lung heat, restoring lung Qi descent, and nourishing lung Yin. Scutellaria baicalensis Georgi effectively clears latent lung heat and phlegm. The combination with baked licorice harmonizes the stomach, nourishes the middle jiao, fortifies earth to generate metal, coordinates drug actions, and supports healthy Qi to eliminate pathogenic factors [26]. This formula can remove pathogens without harming healthy Qi, simultaneously addressing both root and branch aspects, suitable for pediatric patients due to the physiological characteristics of “infantile Yin”, clearing lung heat, nourishing Yin, and moisturizing the lung, consistent with the delicate nature of pediatric lungs.

Additionally, the combination of acrid-warm and cold-cool herbs in Maxing Shigan decoction effectively diffuses lung Qi without fueling heat and clears lung heat without causing cold constraint. Ephedrae Herba, with acrid and warm properties, disperses lung Qi, relieves asthma, releases exterior pathogens, and expels pathogenic factors. Gypsum clears lung heat and enhances lung function. Together, these principal herbs synergistically disperse and clear lung heat, aligning with the combination principle "pungent fails to disperse and cold fails to consolidate". The pairing of ephedra and gypsum effectively resolves stagnant lung heat, disperses lung Qi, and relieves asthma. Apricot kernel, with bitter and warm properties, diffuses lung Qi and descends rebellious Qi, working together with ephedra to achieve balanced diffusion and descent. Baked licorice tonifies Qi, harmonizes the middle jiao, and moderates the cold nature of gypsum to maintain formula balance [27]. In summary, these four herbs collectively achieve the therapeutic effects of clearing heat, diffusing lung Qi, and alleviating cough and asthma. Consequently, combining and modifying these two formulas embodies the TCM principle of "addressing both symptoms and root causes", demonstrating unique advantages in treating Phlegm-Heat Obstructing the Lung Syndrome with MPP.

Pharmacological studies in TCM has identified several active constituents in Huangqin Xiebai powder, including baicalin, baicalein, chlorogenic acid, and mulberroside A [28]. Baicalin possesses anti-mycoplasmal properties and mitigates the release of pro-inflammatory mediators by modulating cytokines such as IL-1β, IL-6, IL-17A, and TNF-α, and modulating TLR4/NF-κB signaling pathways [29]. Chlorogenic acid and mulberroside A exert analgesic and anti-inflammatory effects through modulation of signaling pathways, particularly by preventing degradation of NF-κB inhibitors [30, 31]. Huangqin Xiebai powder inhibits IκBα phosphorylation, thereby obstructing NF-κB nuclear translocation and subsequent pro-inflammatory mediator release. Furthermore, through downregulation of COX-2 and iNOS expression, this formulation alleviates oxidative stress and tissue edema, thereby conferring airway-protective and anti-inflammatory effects. Thus, inflammation within the airway and adjacent tissues is effectively diminished, bronchial matrix damage and astructural airway injury are prevented, and respiratory function is improved [32, 33]. Maxing Shigan Decoction, containing ephedrine and glycyrrhizic acid, suppresses IL-6 overproduction and inhibits STAT3 phosphorylation, which collectively facilitate bronchial smooth muscle relaxation, enhanced pulmonary ventilation, reduced inflammatory responses, and decreased cough sensitivity [34]. Thus, when administered concurrently, Huangqin Xiebai powder acts upstream by attenuating NF-κB-mediated inflammation and reducing cytokines such as IL-6, while Maxing Shigan Decoction exerts downstream effects by blocking IL-6/STAT3 signaling, directly relieving bronchospasm. Thus, when administered concurrently, Huangqin Xiebai powder acts upstream by attenuating NF-κB-mediated inflammation and reducing pro-inflammatory cytokines such as IL-6, while Maxing Shigan Decoction exerts downstream effects by blocking the IL-6/STAT3 signaling pathway, directly relieving bronchospasm. However, this study focuses on the clinical evaluation of the therapeutic effects of Huangqin Xiebai powder combined with Maxing Shigan Decoction, and does not directly examine the molecular mechanisms underlying these effects. The proposed mechanisms, such as the modulation of NF-κB and IL-6/STAT3 pathways, are based on findings from existing literature and are not experimentally validated in this study. Future research involving animal models or in vitro cellular experiments is needed to verify these mechanisms and further elucidate the molecular targets of the formulations.

In the current clinical study, the experimental group treated with modified Huangqin Xiebai powder combined with Maxing Shigan decoction exhibited superior clinical efficacy compared to the control group. Improvements in lung auscultation and imaging were significantly greater in the experimental group. Scores of clinical symptoms such as fever, cough, dyspnea accompanied by nasal flaring, as well as TCM syndrome ratings, declined in both groups post-treatment, with the experimental group achieving notably superior improvements. Moreover, the experimental group demonstrated shorter fever duration and lower peak temperatures compared to controls. Consequently, these outcomes suggest that the combination of modified Huangqin Xiebai powder and Maxing Shigan decoction significantly mitigates inflammatory reactions and clinical manifestations in Phlegm-Heat Obstructing the Lung Syndrome with MPP. Importantly, no severe adverse events occurred in either cohort, highlighting the treatment's robust safety profile.

It is important to recognize the limitations of this study, including the small sample size, short observation period, and lack of long-term outcome data. With 60 participants, these findings may not be broadly applicable, and statistical power may be limited. The small sample size may not adequately reflect a broader patient population, potentially introducing bias into the results. Furthermore, the 7-day observation period limits the ability to assess the long-term effects of the intervention. Chronic conditions typically require longer follow-up periods to assess the durability of treatment effects and the likelihood of recurrence. While short-term outcomes appear positive, they should be interpreted cautiously due to the limited follow-up. To strengthen the evidence, future studies should incorporate larger sample sizes, extended follow-up periods, and more comprehensive assessments of long-term outcomes such as recurrence rates.

6. Conclusion

In conclusion, this study provides initial evidence that the adjunctive use of modified Huangqin Xiebai powder and Maxing Shigan decoction, combined with standard care, is associated with improved clinical response rates and greater reduction in inflammatory markers and TCM syndrome scores in pediatric patients with Phlegm-Heat Obstructing the Lung Syndrome with MPP, compared to standard therapy alone. The treatment regimen was well-tolerated with no severe adverse events reported. These findings suggest the potential of this integrated approach and call for further large-scale, multi-center studies to confirm these results.

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