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Clinical Observation of the Therapeutic Effect of Chrysanthemum Indicum Injection Combined with Budesonide Suspension Nebulization in the Treatment of Acute Suppurative Tonsillitis

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Abstract

Objective: To investigate the clinical efficacy of Chrysanthemum Indicum injection combined with Budesonide suspension nebulization in the treatment of acute suppurative tonsillitis. *Methods:* A total of 60 patients with acute suppurative tonsillitis admitted to our hospital from January 2021 to December 2022 were selected as the research subjects. Both groups received anti-inflammatory treatment with cefathiamidine. The control group (30 cases) also received dexamethasone nebulization therapy, while the treatment group (30 cases) received nebulization therapy with a combination of wild chrysanthemum injection and budesonide suspension. Before treatment, the age, gender, and clinical symptoms such as sore throat, tonsillar congestion, suppuration, fever, and cough of the patients were observed and recorded. The changes in clinical symptoms during the treatment period were continuously observed and recorded. On the day of treatment completion, the clinical symptoms of sore throat, tonsillar congestion, suppuration, fever, and cough were observed and recorded, and the number of patients who recovered was recorded. *Results:* Before treatment, there were no significant differences between the two groups of patients in terms of gender and age ($p > 0.05$). Additionally, there were no significant differences in the severity of symptoms such as sore throat, tonsillar congestion, purulence, fever, and cough ($p > 0.05$). After 3 days of treatment, symptoms like sore throat, tonsillar congestion, purulence, and cough were significantly alleviated, while fever showed no significant improvement. The total symptom scores between the groups were significantly different ($p < 0.05$). After 5 days of treatment, the clinical symptoms were further significantly improved, the total symptom scores remained significantly different ($p < 0.05$), and the number of patients who recovered increased significantly ($p < 0.05$). *Conclusion:* Nebulization therapy with a combination of wild chrysanthemum injection and budesonide suspension for acute suppurative tonsillitis is more effective than traditional dexamethasone nebulization therapy,

Keywords

Chrysanthemum indicum injection; Budesonide suspension; Dexamethasone; Acute suppurative tonsillitis

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1. Introduction

Acute suppurative tonsillitis (AST) is a common pharyngeal disease primarily caused by bacterial infections, with *Streptococcus pyogenes*, *Prevotella* spp., and *Streptococcus dysgalactiae* being frequently implicated [1,2]. Patients often present with symptoms such as sore throat, fever, cough, tonsillar congestion and swelling, and suppuration. Inadequate or delayed treatment may lead to complications including acute otitis media and acute sinusitis [3]. In recent years, increasing bacterial resistance has diminished the efficacy of antibiotic therapy. In comparison, glucocorticoids demonstrate superior therapeutic effects, although traditional dexamethasone treatment yields suboptimal outcomes [4]. Budesonide suspension is a novel glucocorticoid with high affinity for glucocorticoid receptors and potent anti-inflammatory action. Nebulization delivers high drug concentrations to the pharynx, effectively clearing inflammation, alleviating local pain, and promoting recovery [5]. Chrysanthemum indicum possesses heat-clearing, detoxifying, anti-inflammatory, and anti-edema properties, and has been shown to significantly inhibit pathogens such as Staphylococcus aureus and Salmonella typhi [6]. Therefore, this study analyzes the clinical efficacy of Chrysanthemum indicum injection combined with budesonide suspension nebulization for AST.

2. Materials and methods

2.1. Clinical data

Sixty AST patients admitted between January 2022 and January 2024 were enrolled and randomly assigned in a 1:1 ratio to either the treatment or control group using a random number table generated by SPSS 20.0. The treatment group comprised 17 males and 13 females with a mean age of 38.37 ± 14.68 years. The control group comprised 13 males and 17 females with a mean age of 40.20 ± 16.06 years. All patients provided informed consent, and the study was approved by the hospital's ethics committee.

2.2. Selection criteria

2.2.1. Diagnostic criteria

(1) TCM diagnostic criteria referred to the Chinese Society of Traditional Chinese Medicine Standards-Guidelines for Diagnosis and Treatment of Common Diseases in TCM Otolaryngology (China Press of Traditional Chinese Medicine, 2012).

(2) Western diagnostic criteria referred to the textbook Otolaryngology-Head and Neck Surgery (People's Medical Publishing House, 2nd Edition) edited by Kong Weijia.

2.2.2. Inclusion criteria

(1) Met the above diagnostic criteria;
(2) Aged 14–65 years;
(3) Acute onset with illness duration, within 1 week;
(4) No use of glucocorticoids, antibiotics, or other drugs affecting study outcomes within 1 week prior;
(5) Agreed not to use other interfering therapies during the study.

2.2.3. Exclusion criteria

(1) Complicated by severe laryngitis or lower respiratory tract infections;
(2) History of severe adverse reactions to the study drugs;
(3) Participation in other clinical trials;
(4) Conditions hindering participation (e.g., intellectual disability, communication barriers);
(5) Re-enrollment of the same patient.

2.2.4. Dropout and termination criteria

(1) Poor compliance;
(2) Occurrence of severe adverse events, complications, or physiological changes precluding continued participation;
(3) Voluntary withdrawal or loss to follow-up;
(4) Use of non-protocol treatments significantly affecting efficacy assessment

2.2.5. Elimination criteria

(1) Inadvertent enrollment despite not meeting inclusion or meeting exclusion criteria;
(2) No receipt of intervention or lack of usable data

2.3. Treatment and observation methods

All 60 patients received anti-infective treatment with cefathiamidine (Manufacturer: Guangzhou Baiyunshan Pharmaceutical Co., Ltd., National Medicine Permit No.: H44024253). The treatment group (n = 30) additionally received nebulization with Chrysanthemum indicum injection (Manufacturer: Jiangxi Zhongshan Pharmaceutical Co., Ltd., National Medicine Permit No.: Z20026529) combined with budesonide suspension (Manufacturer: AstraZeneca (Wuxi) Trading Co., Ltd., Import Drug Approval No.: H20140475). The control group (n = 30) received nebulization with traditional dexamethasone (Manufacturer: Tianjin Jinyao Group Hubei Tianyao Pharmaceutical Co., Ltd., National Medicine Permit No.: H42020019). Treatment was administered twice daily for 20 minutes per session, for 3–5 days. Patients were instructed to inhale the aerosol through the mouth and exhale through the nose to facilitate drug deposition in the pharynx. Eating and drinking were prohibited for 30 minutes post-nebulization to maintain efficacy. Any adverse events were recorded.

2.4. Efficacy observation indicators

(1) Primary outcomes
Sore throat, tonsillar congestion/swelling, tonsillar suppuration.

(2) Secondary outcomes
Fever, cough.

(3) Assessment timeline
Pre-treatment (admission day): Clinical signs and symptoms, including body temperature, sore throat, cough, as well as pharyngeal and tonsillar congestion, redness and swelling, and secretions, were observed and recorded. During treatment: The aforementioned clinical signs and symptoms were observed and recorded daily for patients in the treatment group. The time to resolution of fever, alleviation of sore throat, disappearance of exudates, reduction in tonsil size, and relief of tonsillar congestion were calculated. Post-treatment (final day) assessments of symptoms and signs were recorded. Time to fever resolution, sore throat relief, exudate disappearance, tonsil reduction, and congestion relief were calculated.

(4) Comprehensive efficacy criteria
Based on the reduction rate of total symptom score.

(5) Symptom quantification scores
Sore Throat: None (0 points); Mild，unaffected swallowing) (2 points); Moderate, significantly affected swallowing (4 points); Severe, persistent pain, severely affected swallowing (6 points). Tonsillar Congestion/Swelling: Normal (0 points); Mild congestion, swelling not exceeding the palatopharyngeal arch (I degree) (2 points); Moderate congestion, swelling exceeding the palatopharyngeal arch but not reaching the midline (II degree) (4 points); Severe congestion with exudate, swelling beyond the midline (III degree) (6 points). Tonsillar Suppuration: None (0 points); Unilateral suppuration (2 points); Bilateral suppuration, scattered pus points (4 points); Bilateral suppuration, confluent pus patches (6 points).Fever (Axillary Temperature):* ≤ 37.4 ℃ (0 points); 37.5–38.5 ℃ (1 point); > 38.6 ℃ (2 points). Cough: None (0 points); Occasional, single coughs (1 point); Paroxysmal, multiple coughs (2 points). Tonsillar congestion/swelling and suppuration were the primary outcomes for evaluation.

(6) Disease severity grading
Mild: total score 6–11; Moderate: 12–17; Severe: 18–22.

(7) Efficacy judgment standards (based on score reduction rate)
Cure: ≥ 90%; Marked effect: 70% to < 90%; Effective: 30% to < 70%; Ineffective: < 30%. Reduction rate = [(Pre-treatment score - Post-treatment score) / Pre-treatment score] × 100%. The disease efficacy criteria were established according to the guidelines outlined in “Diagnostic and Efficacy Criteria for Acute Suppurative Tonsillitis” (Hangzhou Conference, 1991) formulated by the Otolaryngology Committee of the Chinese Society of Traditional Chinese Medicine, and the “Guiding Principles for Clinical Research of New Chinese Medicines” (2002 Edition).

2.5. Statistical methods

SPSS 20.0 was used. Categorical data were analyzed by chi-square test. Measurement data are presented as mean ± standard deviation ($\overline{x} \pm s$). Inter-group comparisons used *t*-tests. $p < 0.05$ indicated statistical significance.

3. Results

3.1. Gender comparison

No significant difference was found between groups ($\chi^2 = 1.062$, $p = 0.302 > 0.05$), indicating comparability (**Table 1**).

3.2. Age comparison

No significant difference was found ($F = 0.713$, $t = -0.461$, $p = 0.402 > 0.05$), indicating comparability (**Table 2**).

3.3. Pre-treatment clinical symptoms

No significant differences in pre-treatment symptom scores were observed between groups ($p > 0.05$), indicating comparability (**Table 3**).

3.4. Pre-treatment disease severity

No significant difference in severity distribution was found ($\chi^2 = 1.130$, $p = 0.568 > 0.05$), indicating comparability (**Table 4**).

3.5. Clinical symptoms after 3 days of treatment

After 3 days, symptoms like sore throat, congestion, suppuration, and cough improved significantly in both groups, but fever improvement was insignificant. The total score difference between groups was significant ($p < 0.05$) (**Table 5**).

Table 1. Patient gender comparison

Group	n	Male	Female
Control	30	17	13
Treatment	30	13	17

Table 2. Patient age comparison ($\overline{x} \pm s$)

Group	n	Mean age (years)
Control	30	40.20 ± 16.06
Treatment	30	38.37 ± 14.68
t-value	/	-0.461
p-value	/	0.402

Table 3. Pre-treatment symptom scores ($\overline{x} \pm s$)

Group	Primary			Secondary		Total score
	Total score	Congestion	Suppuration	Fever	Cough	
Control	4.47 ± 1.39	4.00 ± 1.29	4.33 ± 1.40	1.23 ± 0.63	1.07 ± 0.79	15.10 ± 3.00
Treatment	4.20 ± 1.42	3.93 ± 1.53	4.67 ± 1.21	1.07 ± 0.79	1.10 ± 0.8	14.97 ± 3.32

Table 4. Pre-treatment disease severity (n)

Group	n	Mild	Moderate	Severe
Control	30	6	16	8
Treatment	30	4	20	6

3.6. Clinical symptoms after 5 days of treatment

After 5 days, all symptoms were significantly improved. The total score in the treatment group (3.31 ± 2.73) was significantly lower than in the control group (5.33 ± 4.16) ($p < 0.05$) (**Table 6**).

3.7. Recovery rates

After 5 days of treatment, the symptoms of the patients were significantly improved. In the control group, 4 cases were cured, 12 showed marked improvement, 11 had slight improvement, and 3 were essentially ineffective. Compared with traditional dexamethasone nebulization therapy, the combination of Chrysanthemum indicum injection and budesonide resulted in significantly greater symptom improvement ($\chi^2 = 4.80$, $p = 0.03 < 0.05$). Specifically, 7 patients were cured, 17 showed marked effect, 6 were effective, and 0 were ineffective (see **Table 7**). These results indicate that the combination therapy of Chrysanthemum indicum injection and budesonide is more effective for patients with acute suppurative tonsillitis.

4. Discussion

The tonsils are important immune organs. When inflamed, they can become a focus of infection, potentially leading to complications such as myocarditis, pneumonia, or cellulitis [7,8]. AST is common in spring and autumn, particularly among children, adolescents, and immunocompromised individuals, often accompanied by systemic symptoms like fever and chills [9]. Currently, antibiotic agents remain the primary therapeutic choice in clinical practice, such as azithromycin and penicillin. However, antibiotic therapy has certain limitations, including a tendency to promote bacterial resistance and the potential for adverse effects such as rashes and allergic reactions [8,10]. Furthermore, surgical intervention can achieve radical eradication of the disease. Nevertheless, considering the financial burden on patients and acceptability issues, it is not an optimal choice. Consequently, identifying therapeutic strategies that are economical, convenient, and highly efficacious represents the future direction for managing this condition.

In TCM, AST falls under “rǔ é” (tonsillitis) and “làn rǔ é” (suppurative tonsillitis)”. “Yì Zōng Jīn Jiàn” states its etiology involves internal heat and external wind-

Table 5. Symptom scores after 3 days of treatment ($\overline{x} \pm s$)

Group	Primary			Secondary		Total score
	Sore throat	Congestion	Suppuration	Fever	Cough	
Control	2.69 ± 1.26	3.27 ± 1.02	3.25 ± 1.57	0.18 ± 0.39	0.68 ± 0.61	8.98 ± 4.27
Treatment	2.56 ± 0.99	2.47 ± 0.92	1.8 ± 1.20	0.18 ± 0.39	0.61 ± 0.49	8.96 ± 2.98*

Note: $p < 0.05$ compared to control group total score.

Table 6. Symptom scores after 5 days of treatment ($\overline{x} \pm s$)

Group	Primary			Secondary		Total score
	Sore throat	Congestion	Suppuration	Fever	Cough	
Control	1.40 ± 1.19	2.20 ± 1.34	1.07 ± 1.72	0.03 ± 0.18	0.77 ± 0.68	5.33 ± 4.16
Treatment	0.87 ± 1.14	1.27 ± 0.98	0.47 ± 1.25	0.00 ± 0.00	0.50 ± 0.57	3.31 ± 2.73

Note: $p < 0.05$ compared to control group total score.

Table 7. Clinical efficacy after 5 days (n)

Group	Cure	Marked Effect	Effective	Ineffective
Control	4	12	11	3
Treatment	7	17	6	0

heat, making "heat" the key pathogen. Treatment should clear heat, detoxify, reduce swelling, and relieve pain [11]. Chrysanthemum indicum injection, with its primary component being Chrysanthemum indicum, fulfills this principle and is cost-effective [12]. It may also modulate immunity and has broad clinical applications [13].

Dexamethasone nebulization, previously common for AST, has drawbacks including higher systemic absorption and inferior anti-inflammatory potency compared to budesonide. Budesonide's advantages include as follows [14,15].

(1) High potency at low doses;
(2) Prolonged action due to esterification in the tissue
(3) Rapid onset and targeted delivery via nebulization, with minimal systemic exposure due to high first-pass metabolism [16,17]. One study reported 97.22% efficacy for budesonide in chronic nasopharyngitis versus 75% for dexamethasone [18]. Our study combined Chrysanthemum indicum injection with budesonide. Results showed significant improvement in most symptoms by day 3 and in all symptoms, including complete fever resolution, by day 5 in the treatment group, which also had significantly higher recovery rates. This demonstrates the superior efficacy of the combination therapy over dexamethasone for AST.

5. Conclusion

Nebulization with Chrysanthemum indicum injection combined with budesonide suspension can rapidly alleviate clinical symptoms in AST patients by delivering drugs directly to the site of infection, effectively reducing disease severity within a short period. This regimen demonstrates significant clinical efficacy and can be considered for clinical application.

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Disclosure statement

The authors declare no conflict of interest.

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