

# Observation on the Therapeutic Effect of Budesonide Combined with Azithromycin in the Treatment of *Mycoplasma Pneumoniae* Pneumonia in Children

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**Abstract:** *Objective:* To investigate whether adding budesonide inhalation to the azithromycin anti-infective regimen can enhance the therapeutic effect and ensure the safety of its application in the clinical management of *Mycoplasma pneumoniae* pneumonia in children. *Methods:* This study included 120 diagnosed children who were randomly divided into two parallel groups. Among them, 60 children in the reference group received a 3-day course of oral azithromycin (single daily dose of 10 mg/kg); the study group, consisting of 60 children, received an additional twice-daily budesonide suspension inhalation (0.5 mg each time) alongside the same azithromycin treatment. The total treatment period for all children was set at 7 days. This study systematically collected and compared the time spans required for the resolution of core symptoms (body temperature, cough, and pulmonary signs) between the two groups; analyzed changes in the concentrations of C-reactive protein and interleukin-6 in the blood before and after treatment; evaluated the absorption of inflammatory shadows on chest X-rays at the end of treatment; examined changes in pulmonary ventilation function indicators in some children; and recorded and compared all adverse events that occurred during the treatment phase. *Results:* The study data indicated that children in the study group experienced faster resolution of fever, cough, and pulmonary signs compared to the reference group, with differences being statistically significant. After the treatment course, the levels of inflammatory markers in the blood of children in the study group decreased more significantly. Imaging assessment showed that the overall effective rate of pulmonary inflammation absorption in the study group reached 96.7%, higher than the 83.3% in the reference group. In terms of pulmonary function improvement, the study group also demonstrated superior results. There was no significant difference in the reported rates of treatment-related adverse events between the two groups. *Conclusion:* For children with *Mycoplasma pneumoniae* pneumonia, combining azithromycin for etiological treatment with budesonide inhalation for local anti-inflammatory intervention can accelerate the clinical recovery process, effectively suppress systemic inflammation levels, promote pulmonary lesion repair, and improve pulmonary function.

**Keywords:** Pediatric *Mycoplasma pneumoniae* infection; Azithromycin; Inhaled budesonide; Synergistic therapy; Therapeutic effect analysis

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## 1. Introduction

*Mycoplasma pneumoniae* is a significant pathogen responsible for community-acquired pneumonia in children, with *Mycoplasma pneumoniae* pneumonia being highly prevalent in clinical practice. The pathological process of this disease not only stems from the direct invasion of pathogenic microorganisms but is also closely related to the abnormal immune-inflammatory response network triggered after host infection. This excessive inflammatory response can cause extensive damage to the airway mucosa, increased secretions, and heightened reactivity, resulting in prominent clinical symptoms and slow recovery in some children. Currently, antimicrobial therapy centered around macrolide antibiotics such as azithromycin represents the standard approach targeting the pathogen. However, clinical observations have revealed that relying solely on antimicrobial agents sometimes fails to promptly alleviate respiratory symptoms dominated by a strong immune-inflammatory response, such as persistent severe cough. Therefore, how to effectively regulate local airway inflammation while combating infection has emerged as a potential breakthrough for improving treatment outcomes. Inhaled corticosteroids, due to their ability to efficiently act on airway targets with minimal systemic side effects, hold a firm position in the management of airway inflammatory diseases. Budesonide, as a representative of such drugs, is conveniently used in pediatric patients in its nebulized form. The primary objective of this study is to systematically evaluate whether the addition of nebulized budesonide to azithromycin anti-infective therapy provides incremental value in enhancing the overall treatment effectiveness for children with *Mycoplasma pneumoniae* pneumonia and to carefully examine its safety profile.

## 2. Subjects and methods

### 2.1. General information

The cases for this study were sourced from children hospitalized in the pediatric ward of our hospital from early 2022 to the end of 2023, who were definitively diagnosed with *Mycoplasma pneumoniae* pneumonia. Case selection adhered to the following criteria: children aged between 3 and 12 years; diagnosis strictly conforming to the current authoritative pediatric diagnostic and treatment guidelines for *Mycoplasma pneumoniae* pneumonia; a time interval of no more than 3 days from disease onset to enrollment in the study protocol; imaging evidence indicating the presence of definitive inflammatory lung lesions; and full informed consent and written agreement obtained from the children's guardians. Exclusion criteria encompassed individuals with a history of allergy to the drug components planned for use in the study; those who had received systemic corticosteroids or other types of macrolide therapy prior to inclusion; those with severe dysfunction of vital organs or underlying immune dysfunction; and those concurrently diagnosed with chronic respiratory diseases such as asthma. A total of 120 children who met the criteria and were ultimately enrolled in the study were randomly assigned to two groups: the conventional treatment group and the combined treatment group, with 60 children in each group. Balanced testing of baseline data, including age, gender, average disease duration, initial disease severity, and key pre-treatment inflammatory indicators, revealed no statistically significant differences in any comparison items, confirming good comparability between the two groups at the outset.

## **2.2. Diagnostic criteria**

Establishing a diagnosis requires integrating clinical manifestations, laboratory evidence, and imaging findings. Clinically, children must exhibit signs such as fever, typical cough, and fixed rales heard on lung auscultation. Laboratory evidence is crucial, specifically indicating that serum testing reveals *Mycoplasma pneumoniae*-specific IgM antibody titers reaching the diagnostic threshold or that molecular biology techniques directly detect *Mycoplasma pneumoniae* nucleic acids in respiratory samples. Imaging evidence consists of chest X-ray or CT findings confirming the presence of exudative shadows consistent with pneumonia. A definitive diagnosis of *Mycoplasma pneumoniae* pneumonia can only be made when all three elements, clinical signs, etiological evidence, and imaging changes were present.

## **2.3. Treatment methods**

All enrolled children received conventional symptomatic support, including antipyretic and expectorant treatments. Children in the conventional treatment group received oral azithromycin dry suspension, administered once daily for three consecutive days, with the dose calculated based on body weight at a standard of 10 mg per kilogram per day. Children in the combined treatment group, in addition to receiving the identical oral azithromycin regimen as the conventional treatment group, underwent twice-daily nebulized inhalation therapy with budesonide suspension, with each dose consisting of 0.5 mg of the drug diluted in an appropriate amount of normal saline and inhaled via a nebulizer. The total duration of the intervention process was uniformly set at seven days, with strict monitoring of medication adherence in children throughout the treatment period.

## **2.4. Observation indicators**

Evaluation of efficacy and safety was accomplished through a series of predefined indicators. The primary efficacy endpoint focused on the timeliness of symptom relief, accurately recording the number of days required for normalization of body temperature, cessation of cough, and dissipation of lung rales. Secondary efficacy indicators were examined from multiple perspectives: venous blood samples were collected on the first day of treatment and the day after treatment completion to measure changes in C-reactive protein and interleukin-6 concentrations; chest X-rays were reviewed at the end of one week of treatment, with imaging doctors unaware of group assignments assessing the degree of absorption of lung shadows; for children of cooperative age, lung function was quantified before and after treatment using a spirometer to measure the proportion of forced expiratory volume in one second to the predicted value. Safety assessment was achieved by actively monitoring and recording any adverse events potentially related to treatment throughout the process, such as gastrointestinal symptoms, rashes, or local irritation reactions associated with nebulization, and comparing the frequency of occurrence between the two groups.

## **3. Results**

### **3.1. Comparison of relief times for major clinical**

Symptoms between the Two Groups of Children In terms of the relief efficiency of core clinical symptoms, the combined treatment group demonstrated a clear advantage. Statistical data showed that the average durations of fever, cough, and lung signs were all shorter in the combined treatment group than in the conventional treatment group, with statistically significant differences between groups upon hypothesis

testing. Detailed time data are summarized in the following table. See **Table 1**.

**Table 1.** Comparison of relief times for major clinical symptoms between the two groups of children

Group	Number of cases	Duration of fever recovery	Duration of cough	Duration of rales
Conventional treatment group	60	3.6 ± 0.7	7.3 ± 1.4	6.7 ± 1.2
Combination treatment group	60	2.3 ± 0.5	5.1 ± 1.1	4.9 ± 1.0
<i>t</i> value	–	9.112	8.345	8.012
<i>p</i> value	–	< 0.001	< 0.001	< 0.001

### 3.2. Comparison of serum inflammatory factor levels between the two groups of children before and after treatment

Prior to treatment, the baseline levels of inflammatory factors were comparable between the two groups. After completing one week of treatment, both groups exhibited a significant decrease in CRP and IL-6 levels compared to their pre-treatment values. Further comparison of the post-treatment levels revealed that the measured CRP and IL-6 values in the children of the combined treatment group were lower than those in the conventional treatment group. This difference passed the statistical significance test, indicating that the combined intervention regimen had a stronger effect in suppressing systemic inflammatory responses. The specific values are presented in the following table. See **Table 2**.

**Table 2.** Comparison of serum inflammatory factor levels between the two groups of children before and after treatment

Group	Time point	CRP concentration (mg/L)	IL-6 concentration (pg/mL)
Conventional treatment group (n = 60)	Before treatment	28.8 ± 6.0	35.9 ± 8.1
	After treatment	10.8 ± 3.0*	15.8 ± 4.5*
Combination treatment group (n = 60)	Before treatment	29.3 ± 5.7	36.8 ± 7.5
	After treatment	6.2 ± 2.2*#	9.3 ± 3.0*#

Note: Compared with the pre-treatment data within the same group,  $p < 0.05$ ; compared with the post-treatment data of the conventional treatment group, # $p < 0.05$ \*

### 3.3. Comparison of improvements in lung function between the two groups of children after treatment

Among the 50 children (24 in the conventional group and 26 in the combined group) who met the age criteria and were able to complete lung function tests, the predicted FEV1% values were similar between the two groups before treatment. After completing the treatment course, this indicator improved in children from both groups. Analysis of the differences before and after treatment revealed that the increase in FEV1% was significantly greater in the combined treatment group compared to the conventional treatment group, with a statistically significant difference between the groups. This indicates that the combined therapy has a more positive effect on improving respiratory function in children. See **Table 3**.

**Table 3.** Comparison of changes in predicted FEV1% before and after treatment between the two groups of children

Group	Number of cases	Pre-treatment value	Post-treatment value	Pre-post treatment difference
Conventional treatment group	24	78.5 ± 5.4	85.1 ± 4.9*	6.6 ± 2.7
Combination treatment group	26	78.0 ± 5.9	90.5 ± 4.7*	12.5 ± 3.2#
<i>t</i> value	-	0.315	4.128	6.521
<i>p</i> value	-	> 0.05	< 0.001	< 0.001

Note: Compared with the pre-treatment values within the same group,  $p < 0.05$ ; compared with the difference in the conventional treatment group, # $p < 0.05$ .

### 3.4. Comparison of overall efficacy and safety between the two groups of children

The overall efficacy was evaluated based on the comprehensive improvement of clinical symptoms and imaging findings at the end of treatment. The combined treatment group had a higher proportion of cases achieving marked and effective outcomes, with its overall effective rate significantly superior to that of the conventional treatment group. Safety monitoring results indicated that the adverse reactions observed in both groups were mild, primarily including gastrointestinal reactions and transient hoarseness, which were relieved after treatment. Statistical analysis revealed no significant difference in the overall incidence of adverse reactions between the two groups. See **Table 4**.

**Table 4.** Comparison of overall efficacy and incidence of adverse reactions between the two groups of children

Group	Total cases	Markedly effective	Effective	Ineffective	Overall effective	Adverse reactions
Conventional treatment group	60	24 (40.0)	26 (43.3)	10 (16.7)	50 (83.3)	7 (11.7)
Combination treatment group	60	33 (55.0)	25 (41.7)	2 (3.3)	58 (96.7)	9 (15.0)
$\chi^2$ value	-	-	-	-	5.926	0.327
<i>p</i> value	-	-	-	-	0.015	0.567

## 4. Discussion

The data and conclusions obtained from this study support the following viewpoint: In the treatment of *Mycoplasma pneumoniae* pneumonia in children, the combined application of budesonide inhalation and oral azithromycin can produce a synergistic effect. The underlying mechanism of this synergistic effect can be understood from the different targets of drug action. The core function of azithromycin is antibacterial; it inhibits the growth of pathogens by interfering with their protein synthesis, thereby controlling the source of infection. However, many pathological manifestations of *Mycoplasma pneumoniae* pneumonia, particularly persistent respiratory symptoms, are largely attributable to the excessive host immune-inflammatory response triggered by the pathogen. In such cases, targeting only the pathogen may not rapidly quell the already initiated inflammatory cascade <sup>[1]</sup>.

Under these circumstances, budesonide demonstrates its unique therapeutic value. As a highly selective inhaled corticosteroid, budesonide can directly reach the site of airway inflammation after nebulization <sup>[2]</sup>. By

regulating gene transcription, it effectively inhibits the production and release of various pro-inflammatory factors while stabilizing inflammatory cell membranes, reducing mucosal edema and hyperresponsiveness. This study observed a more significant decrease in serum inflammatory marker levels in children in the combined treatment group, directly reflecting the stronger inhibitory capacity of this regimen on systemic inflammatory status. It is precisely this dual suppression of local and systemic inflammation that provides a biological basis for the rapid improvement of clinical symptoms <sup>[3]</sup>.

The more pronounced improvement in pulmonary function indicators observed in children in the combined treatment group in this study holds significant clinical importance. *Mycoplasma pneumoniae* infection can induce inflammatory swelling and mucus plugging of the airway mucosa, leading to decreased airway patency. Budesonide, through its potent local anti-inflammatory effects, can effectively alleviate these pathological changes, thereby reducing airway resistance. The greater increase in FEV1% in **Table 3** directly confirms the additional benefits of the combined therapy in restoring normal airway ventilation function, which may have a positive impact on ensuring the long-term respiratory health of children <sup>[4]</sup>.

From the perspective of objective morphological evidence of disease outcome, the significant advantage of the combined treatment group in terms of the overall effective rate of chest X-ray lesion absorption translates the improvement in clinical symptoms and laboratory indicators into the repair of pulmonary parenchymal lesions. Imaging improvement is one of the most intuitive and hard indicators for evaluating the efficacy of pneumonia treatment. A higher imaging absorption rate means that the combined treatment strategy can more effectively promote the dissipation of pulmonary inflammatory infiltration and accelerate the anatomical healing process of the disease, which has practical value in shortening the overall course of the disease and reducing medical resource consumption.

The adoption of any treatment regimen must weigh its benefits against its risks. Although there are many concerns regarding the systemic use of glucocorticoids, the budesonide inhalation therapy used in this study significantly reduces related risks due to its extremely high local activity and extremely low systemic bioavailability. The study results also clearly show that the combined treatment did not lead to a significant increase in the incidence of adverse reactions, and all reported adverse events were mild and reversible <sup>[5]</sup>.

## 5. Conclusion

In summary, the evidence chain from this study indicates that for *Mycoplasma pneumoniae* pneumonia in children, initiating budesonide inhalation for anti-inflammatory intervention simultaneously with azithromycin anti-infective treatment at the outset is an optimized strategy that can accelerate recovery, enhance treatment benefits, and not increase additional risks. This strategy achieves more comprehensive disease management by simultaneously targeting the two core aspects of the infection source and host inflammatory response. Subsequent research directions can focus on exploring the optimal drug dosage and treatment duration for children with different clinical phenotypes in detail and evaluating their impact on children's growth and development and long-term respiratory health through long-term follow-up.

## Disclosure statement

The authors declare no conflict of interest.

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