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Original Article

Clinical efficacy of azithromycin-budesonide combination therapy in pediatric Mycoplasma pneumoniae pneumonia

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Abstract: Objective: To evaluate the clinical outcomes of adjunctive budesonide (BUD) therapy combined with azithromycin (AZM) in pediatric patients diagnosed with *Mycoplasma pneumoniae* pneumonia (MPP). Methods: This retrospective cohort analysis examined 120 pediatric MPP cases. Participants were stratified into either a control group (n=55, standard AZM treatment) or an observation group (n=65, AZM in combination with BUD) based on their treatment regimen. Comprehensive assessments included treatment efficacy, safety profiles, resolution of clinical manifestations, serum immunoglobulins, serum inflammatory markers, quality of life, and parental satisfaction. Additionally, univariate and multivariate logistic regression analyses were employed to identify independent predictors for therapeutic response. Results: The observation group exhibited a significantly superior clinical response rate, improved quality of life, and higher parental satisfaction than the control group, with no significant difference in adverse event incidence. Accelerated symptom resolution was observed in the observation group. Furthermore, significant immunomodulatory and anti-inflammatory effects were noted in the observation group. Univariate and multivariate analyses identified four independent predictors for treatment outcomes: disease duration (Odds Ratio [OR]=3.555, 95% Confidence Interval [CI]: 1.123-11.254), pre-treatment IgG levels (OR=0.280, 95% CI: 0.098-0.794), pre-treatment IL-6 levels (OR=3.848, 95% CI: 1.280-11.572), and therapeutic approach (OR=3.517, 95% CI: 1.200-10.304). Conclusion: The combination of AZM with BUD demonstrated superior therapeutic outcomes in pediatric MPP management, including accelerated symptom resolution, enhanced immune function, reduced inflammation, and improved quality of life and parental satisfaction, without increasing adverse events.

Keywords: Azithromycin, budesonide, pediatric mycoplasma pneumoniae pneumonia, treatment response, efficacy analysis

Introduction

Mycoplasma pneumoniae pneumonia (MPP), representing 10.0-40.0% of community-acquired pneumonia cases, is primarily caused by respiratory tract infection with *Mycoplasma pneumoniae* (MP) [1]. Predominantly affecting children, MPP typically presents with mild, self-limiting symptoms and a favorable prognosis. Clinically, its manifestations often resemble other respiratory infections caused by common pathogens [2]. The main route of transmission is through respiratory droplets, particularly in household or community settings. Due to its relatively long incubation period, the disease usually lasts 2 to 4 weeks and is more prevalent during late autumn and winter [3, 4]. MPP is reported to account for 30.0-50.0% of pediatric pneumonia cases during peak seasons, although MP infections are observed year-round [5]. Delayed diagnosis and inappropriate treatment can drive disease progression to severe MPP, which is associated with serious pulmonary complications like lung abscesses, atelectasis, pleural effusion, necrotizing pneumonia, and obliterative bronchiolitis, profoundly compromising children's physical health; Hence, timely and effective therapeutic interventions are essential [6, 7].

Azithromycin (AZM), a macrolide antibiotic with broad-spectrum activity, remains the first-line treatment for MPP due to its favorable pharmacokinetic characteristics, including high oral

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bioavailability, acid stability, prolonged half-life, and extensive tissue penetration [8]. AZM not only inhibits mycoplasmal protein biosynthesis but also modulates host immune to effectively clear pathogens [9]. However, monotherapy with AZM often yields suboptimal clinical outcomes, contributing to delayed recovery and increased risk of antimicrobial resistance, particularly with prolonged use [10]. Budesonide (BUD), a non-halogenated steroid administered by nebulization, achieves high pulmonary deposition and provides targeted anti-inflammatory effects with minimal systemic absorption [11]. In addition to its safety and tolerability, BUD improves pulmonary function by modulating cytokine homeostasis [12]. A study by Chen et al. [13] reported BUD-assisted therapy for pediatric MPP significantly enhanced symptom resolution, including pyrexia, pulmonary rales, and chronic cough.

Nevertheless, comprehensive evaluations of AZM-BUD combination therapy in pediatric MPP remain insufficient, particularly regarding efficacy determinants. This study systematically evaluated the efficacy and safety of this combined regimen using multidimensional outcome indicators and identified prognostic factors influencing therapeutic outcomes, aiming to inform evidence-based optimization of management for pediatric MPP.

Clinical data

Study population and design

Conducted as a retrospective analysis, this study examined 120 pediatric MPP cases receiving treatment at Anhua County People's Hospital during the timeframe spanning June 2021 through June 2024. A comparative design was employed, with patients assigned to either a control group (n=55) receiving standard AZM monotherapy and an observation group (n=65) receiving an AZM-BUD combination therapy. The study was approved by the Ethics Committee of Anhua County People's Hospital.

Inclusion and exclusion criteria

Inclusion criteria: (1) Diagnosis of MPP confirmed by X-ray, sputum culture, and other examinations [14]; (2) Age between 1 and 14 years; (3) Presence of clinical manifestations including wheezing, fever, pulmonary rales, and cough; (4) Positive serum MP antibody test; (5) No prior use of glucocorticoids or antibiotics within two weeks before admission; (6) Availability of complete clinical records.

Exclusion criteria: (1) Comorbid respiratory diseases such as tuberculosis or bronchial asthma; (2) Known allergy to any study medications; (3) Primary immunodeficiency; (4) Concurrent pulmonary infections other than MPP; (5) Macrolide antibiotic resistance; (6) Congenital heart disease or severe dysfunction of the liver, kidneys, or other organs; (7) History of psychiatric disorders or cognitive impairment.

Treatment methods

All enrolled patients received standardized supportive care, including expectorants, antitussives, antipyretics, oxygen therapy, and electrolyte balance maintenance. In the control group, patients were administered intravenous AZM (Shanghai Yansheng Industrial Co., Ltd., YS-0044B) at a dosage of 10 mg/kg per dose once daily for 7 consecutive days. Upon normalization of body temperature, the treatment was transitioned to oral AZM dry suspension (Zhejiang Poly Pharm Co., Ltd., H20057604), maintaining the same dosage (10 mg/kg per dose once daily) for an additional 3 days, followed by a 4-day treatment-free interval. The observation group received the same AZM regimen as the control group, along with adjunctive inhaled BUD suspension (Chia Tai Tianqing Pharmaceutical Group Co., Ltd., H20203063) administered via nebulization at a dose of 2 mL per session, twice daily, for a total of 14 days. Additionally, airway secretions were cleared promptly to ensure airway patency. Clinical symptoms were continuously monitored and documented throughout the treatment period. Caregivers were instructed in detail regarding the medication schedule, proper administration techniques, potential side effects, and adherence strategies.

Analysis criteria

(1) Treatment Efficacy. Treatment efficacy was evaluated based on symptom improvement and radiologic findings. *Markedly effective:* significant alleviation of clinical symptoms (e.g., fever and cough), absence of dyspnea, and sig-

nificant radiographic improvement of pulmonary inflammation. *Effective:* partial symptom relief (e.g., reduced cough and dyspnea), declining fever, and partial radiographic resolution of inflammation. *Ineffective*: No improvement or worsening of clinical symptoms, with persistent radiologic evidence of inflammation. The total effective rate was calculated as the proportion of cases achieving either markedly effective or effective outcomes relative to the total number of cases.

(2) Safety. Adverse events, including injection site pain, rash, hoarseness, nausea/vomiting, and diarrhea were monitored and recorded throughout the treatment period. The incidence of each adverse event was subsequently calculated.

(3) Clinical symptom resolution. The duration until symptom resolution for chest tightness, pulmonary rales, cough, and fever, was recorded for both treatment groups.

(4) Serum immunoglobulins (Igs). Peripheral venous blood (2 mL, fasting) was collected at baseline and on post-treatment day 14. Following centrifugation, serum levels of IgG, IgA, and IgM were quantified using immunoturbidimetry on an automatic biochemical analyzer (Skillsmodel Biotech (Beijing) Co., Ltd., Catalyst One).

(5) Serum inflammatory markers. Levels of interleukin-6 (IL-6) and high-sensitivity C-reactive protein (hs-CRP) were measured at baseline and on day 14 using enzyme-linked immunosorbent assay (ELISA; Shanghai Yuanmu Biotech Co., Ltd., YM-SZ0049, YM-KJ0895).

(6) Quality of life. The Pediatric Quality of Life Inventory (PedsQL) 4.0 scale was employed to evaluate patients' quality of life, with parents serving as proxy respondents. The scale comprises 23 items across four domains: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and role functioning (5 items). Each item is rated on a 5-point Likert scale (0-4), where higher scores indicate better perceived quality of life.

(7) Parental satisfaction. Parental satisfaction was measured through a structured questionnaire. Responses were categorized as highly satisfied (85-100 points), moderately satisfied (60-84 points), or dissatisfied (below 60 points). The satisfaction rate = (highly satisfied cases + moderately satisfied cases)/total number of cases*100%.

Statistical methods

All statistical analyses were performed using SPSS software (version 20.0). Categorical variables were presented as frequencies and percentages (n/%), while continuous variables were expressed as mean ± standard error of the mean (SEM). Intergroup comparisons of categorical data used chi-square (χ^2) test. Between-group comparisons of continuous variables employed Student's t-test, and longitudinal comparisons within groups were analyzed using paired t-tests. Statistical significance was established at $P<0.05$.

Results

Baseline demographic characteristics

There were no significant differences between the control and observation groups in terms of gender distribution, age, disease duration, family medical history, or place of residence (all $P>0.05$), indicating good baseline comparability between groups (**Table 1**).

Treatment outcomes

The total effective rate was 86.15% in the observation group, significantly higher than 70.91% in the control group, indicating superior clinical efficacy of the combination therapy ($P<0.05$, **Table 2**).

Safety profiles

The incidence of adverse events, including injection site pain, rash, hoarseness, nausea/vomiting, and diarrhea, did not differ significantly between groups, suggesting a comparable safety profile ($P>0.05$, **Table 3**).

Symptom resolution time

The observation group demonstrated significantly shorter resolution time for all evaluated clinical symptoms, including chest tightness, pulmonary rales, cough, and fever, compared to the control group (all $P<0.05$) (**Table 4**).

Table 1. Comparison of baseline demographic characteristics between the two groups

Indicator	n	Control group (n=55)	Observation group (n=65)	χ^2/t	P
Gender				0.095	0.758
Male	68	32 (58.18)	36 (55.38)		
Female	52	23 (41.82)	29 (44.62)		
Age (years)	120	7.55±3.21	8.14±2.77	1.081	0.282
Disease duration (days)	120	8.25±2.85	8.57±2.88	0.609	0.544
Family medical history				0.806	0.369
No	102	45 (81.82)	57 (87.69)		
Yes	18	10 (18.18)	8 (12.31)		
Residence				0.186	0.666
Urban	68	30 (54.55)	38 (58.46)		
Rural	52	25 (45.45)	27 (41.54)		

Table 2. Comparison of treatment efficacy between the two groups

Indicator	Control group (n=55)	Observation group (n=65)	χ^2	P
Markedly effective	25 (45.45)	36 (55.38)		
Effective	14 (25.45)	20 (30.77)		
Ineffective	16 (29.09)	9 (13.85)		
Total effectiveness	39 (70.91)	56 (86.15)	4.198	0.041

Table 3. Comparison of safety profile between the two groups

Adverse events	Control group (n=55)	Observation group (n=65)	χ^2	P
Injection pain	1 (1.82)	1 (1.54)		
Rash	2 (3.64)	2 (3.08)		
Hoarseness	1 (1.82)	0 (0.00)		
Nausea/vomiting	3 (5.45)	2 (3.08)		
Diarrhea	2 (3.64)	2 (3.08)		
Total	9 (16.36)	7 (10.77)	0.807	0.369

Table 4. Comparison of symptom resolution time between the two groups

Indicator	Control group (n=55)	Observation group (n=65)	t	P
Chest tightness	4.80±1.61	4.23±1.48	2.019	0.046
Pulmonary rales	7.00±2.16	5.72±1.51	3.805	<0.001
Cough	8.71±2.64	7.12±2.36	3.482	<0.001
Pyrexia	10.44±2.62	8.32±2.03	4.990	<0.001

Serum immunoglobulin profiles

No significant differences were observed in baseline IgG, IgA, and IgM levels between the two groups (P>0.05). Post-intervention measurements revealed a significant elevation in all immunoglobulin levels compared to baseline in both groups (P< 0.05), with the observation group showing significantly higher post-treatment levels than the control group (P<0.05) (**Figure 1**).

Serum inflammatory markers

No significant intergroup differences were observed in baseline serum IL-6 or hs-CRP levels (P>0.05). Following intervention, both groups demonstrated significant reductions in IL-6 and hs-CRP levels compared to baseline (P<0.05), with greater reductions observed in the observation group (P<0.05) (**Figure 2**).

Quality of life assessment

Quality of life, assessed using the PedsQL 4.0 scale, showed no significant inter-group differences at baseline (P> 0.05). Following the intervention, the observation group demonstrated significant improvements across all the measured dimensions compared to both baseline and the control group (all P<0.05) (**Figure 3**).

Parental satisfaction evaluation

Parental satisfaction rate was markedly higher in the observation group than in the control group (92.31% versus 76.36%; P<0.05), indicating enhanced caregiver-perceived benefit of the combination therapy (**Table 5**).

Univariate analysis of factors influencing treatment efficacy in pediatric MPP patients

Univariate regression analysis identified no significant associations between treatment

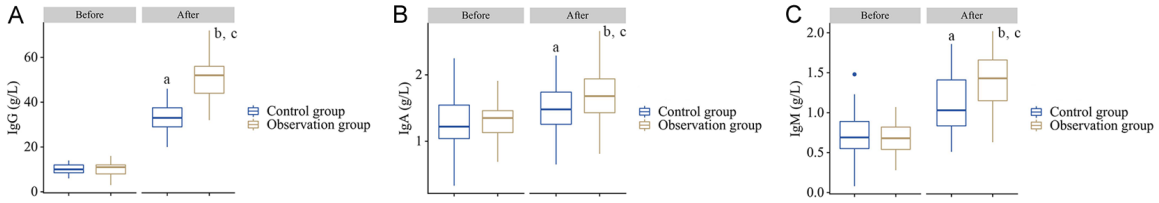

Figure 1. Comparison of serum immunoglobulin levels between the two groups before and after intervention. A: IgG level. B: IgA level. C: IgM level. Note: IgG/A/M, immunoglobulin G/A/M. [a]P<0.05, [b]P<0.01 versus baseline, [c]P<0.01 versus control group.

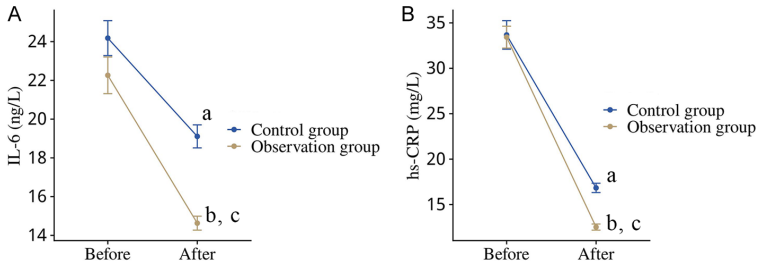

Figure 2. Comparison of inflammatory marker levels between the two groups before and after intervention. A: IL-6 level; B: hs-CRP level. Note: [a]P<0.05, [b]P<0.01 versus baseline measurements, [c]P<0.01 versus control group. IL-6, interleukin-6; hs-CRP, high-sensitivity C-reactive protein.

responses and gender, age, residence, or pre-treatment IgM, IgA levels (P>0.05). However, disease duration, family medical history, pre-treatment IgG, IL-6, hs-CRP levels, and treatment method demonstrated significant associations with therapeutic outcomes (P<0.05) (**Table 6**).

Multivariate analysis of factors influencing treatment efficacy in pediatric MPP patients

A multivariate logistic regression, incorporating all significant variable identified in univariate analysis as independent variables and therapeutic efficacy as the dependent variable, revealed four independent predictors of treatment efficacy: disease duration (Odds Ratio [OR]=3.555, 95% Confidence Interval [CI]: 1.123-11.254), pre-treatment IgG level (OR=0.280, 95% CI: 0.098-0.794), pre-treatment IL-6 level (OR=3.848, 95% CI: 1.280-11.572), and therapeutic approach (OR=3.517, 95% CI: 1.200-10.304; all P<0.05) (**Table 7**).

Discussion

Pediatric *Mycoplasma pneumoniae* pneumonia (MPP) is a clinically significant respiratory infection that may progress to severe pulmonary complications, including refractory pneumonia, chronic bronchitis, and asthma exacerbations, with potentially life-threatening consequences [15]. Contemporary clinical practice favors macrolide antibiotics as primary therapy for pediatric MPP, due to their favorable minimum inhibitory concentrations and established safety profiles. Nevertheless, the escalating prevalence of macrolide-resistant MPP strains has prompted the need for adjuvant corticosteroid therapy to optimize treatment outcomes [16]. This comparative study systematically evaluated the therapeutic benefits of AZM-BUD combination therapy versus AZM monotherapy in pediatric MPP, with the primary objective to determine whether the combination regimen offered superior therapeutic benefits and to provide an evidence-based rationale for its clinical application.

The present study yielded several clinically important findings. In terms of therapeutic efficacy, the combination regimen demonstrated statistically and clinically superior outcomes, with the total response rate increasing from 70.91% in the control group to 86.15% in the observation group. This improvement likely stems from the synergistic interaction between AZM's antimicrobial activity and BUD's potent anti-inflammatory effects. When administered by nebulization, BUD exhibits favorable pulmonary pharmacokinetics characterized by reduced systemic exposure, efficient local deposition, rapid onset of action, and high pulmonary bioavailability - all contributing to enhanced therapeutic effects [17]. These pharmacodynamic advantages corroborate Xu et al.'s findings [18], who reported significantly improved clinical out-

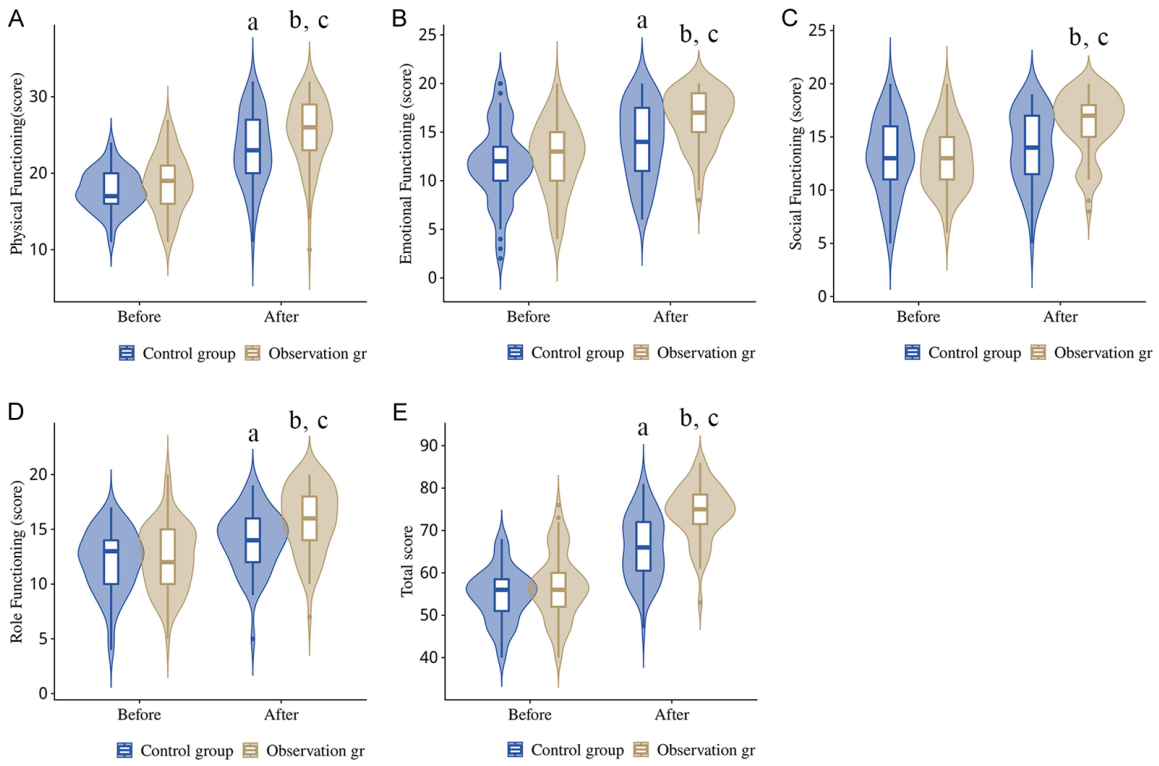

Figure 3. Comparison of quality-of-life scores between the two groups before and after intervention. A: Physical functioning scores. B: Emotional functioning scores. C: Social functioning scores. D: Role functioning scores. E: Total quality of life scores across all domains. Note: [a]P<0.05, [b]P<0.01 vs. pre-intervention, [c]P<0.01 vs. control group.

Table 5. Comparison of parental satisfaction between the two groups

Response	Control group (n=55)	Observation group (n=65)	χ^2	P
Highly satisfied	18 (32.73)	25 (38.46)		
Moderately satisfied	24 (43.64)	35 (53.85)		
Dissatisfied	13 (23.64)	5 (7.69)		
Satisfaction	42 (76.36)	60 (92.31)	5.940	0.015

comes when combining BUD with bronchoalveolar lavage in pediatric MPP cases.

Regarding the safety profile, the combination therapy demonstrated a comparable adverse event profile to AZM monotherapy. The short-term use of inhaled BUD in pediatric patients is supported by its pharmacological profile demonstrating minimal acute, subacute, and chronic toxicities across preclinical studies [19]. Research by Sheng et al. [20] similarly indicated that incorporating terbutaline inhalation into AZM sequential treatment posed no greater adverse reaction risks for MPP patients. These findings further support the safety and tolerability of BUD as an adjunct in pediatric respiratory infections.

Concerning symptomatic improvement, the AZM-BUD combination significantly accelerated clinical manifestation resolution such as chest tightness, pulmonary rales, cough, and pyrexia, indicating its efficacy in expediting symptom relief in pediatric MPP patients. This accelerated recovery likely results from BUD's ability to suppress enzymatic reactions, reduce bronchoconstrictive substances, and relax airway smooth muscle, thereby effectively alleviating respiratory symptoms (e.g., cough, wheezing) in pediatric MPP patients [21, 22]. These observations also corroborate Shen et al.'s findings [23], where BUD plus ambroxol hydrochloride for pediatric pneumonia demonstrated significant symptomatic relief (cough, respiratory distress, and lip cyanosis). Collectively, the data establish that the combination regimen

Table 6. Univariate analysis of predictors for treatment efficacy in pediatric MPP

Indicator	n	Ineffective group (n=25)	Effective group (n=95)	χ^2	P
Gender				0.692	0.406
Male	68	16 (64.00)	52 (54.74)		
Female	52	9 (36.00)	43 (45.26)		
Age (years)				1.062	0.303
<8	59	10 (40.00)	49 (51.58)		
≥8	61	15 (60.00)	46 (48.42)		
Disease duration (days)				4.055	0.044
<8	50	6 (24.100)	44 (46.32)		
≥8	70	19 (76.00)	51 (53.68)		
Family medical history				4.186	0.041
No	102	18 (72.00)	84 (88.42)		
Yes	18	7 (28.00)	11 (11.58)		
Residence				0.966	0.326
Urban	68	12 (48.00)	56 (58.95)		
Rural	52	13 (52.00)	39 (41.05)		
Pre-treatment IgG (g/L)				5.263	0.022
<10	48	15 (60.00)	33 (34.74)		
≥10	72	10 (40.00)	62 (65.26)		
Pre-treatment IgA (g/L)				0.564	0.453
<1.3	64	15 (60.00)	49 (51.58)		
≥1.3	56	10 (40.00)	46 (48.42)		
Pre-treatment IgM (g/L)				0.237	0.626
<0.7	62	14 (56.00)	48 (50.53)		
≥0.7	58	11 (44.00)	47 (49.47)		
Pre-treatment IL-6 (ng/L)				6.250	0.012
<24.0	65	8 (32.00)	57 (60.00)		
≥24.0	55	17 (68.00)	38 (40.00)		
Pre-treatment hs-CRP (mg/L)				5.322	0.021
<33.0	63	8 (32.00)	55 (57.89)		
≥33.0	57	17 (68.00)	40 (42.11)		
Therapeutic approach				4.198	0.041
Azithromycin	55	16 (64.00)	39 (41.05)		
Azithromycin + budesonide	65	9 (36.00)	56 (58.95)		

Note: MPP, *Mycoplasma pneumoniae* pneumonia; IgG/A/M, immunoglobulin G/A/M; IL-6, interleukin-6; hs-CRP, high-sensitivity C-reactive protein.

Table 7. Multivariate analysis of predictors of treatment efficacy

Indicator	B	SE	Wald	P	Exp (B)	95% CI
Disease duration (days)	1.268	0.588	4.653	0.031	3.555	1.123-11.254
Family medical history	1.115	0.684	2.661	0.103	3.050	0.799-11.644
Pre-treatment IgG (g/L)	-1.274	0.533	5.727	0.017	0.280	0.098-0.794
Pre-treatment IL-6 (ng/L)	1.348	0.562	5.757	0.016	3.848	1.280-11.572
Pre-treatment hs-CRP (mg/L)	0.817	0.561	2.126	0.145	2.264	0.755-6.792
Therapeutic approach	1.258	0.548	5.257	0.022	3.517	1.200-10.304

Note: MPP, Mycoplasma pneumoniae pneumonia; IgG, immunoglobulin G; IL-6, interleukin-6; hs-CRP, high-sensitivity C-reactive protein.

offers significant benefits in clinical symptom alleviation.

Furthermore, the AZM-BUD combination therapy exhibited enhanced immunomodulatory and anti-inflammatory effects in pediatric MPP patients, as evidenced by significantly greater increases in serum immunoglobulin levels (IgG, IgA, and IgM) and more pronounced reductions in IL-6 and hs-CRP levels compared to AZM monotherapy. This robust immunomodulatory activity suggests that this combination therapy may more effectively restore immune homeostasis in pediatric MPP patients. These findings align with previous reports by Zhao J et al. [24], who documented similar enhancements in efficacy, accelerated symptom resolution, and inflammation suppression without increased adverse actions. Our findings also corroborate Lin et al. [25], who demonstrated that co-administration of BUD and formoterol enhances cellular immunity while downregulating pro-inflammatory cytokines, particularly IL-6 and hs-CRP, thus mitigating systemic inflammatory cascades. These results confirm the pronounced immunoregulatory and anti-inflammatory efficacy of the AZM-BUD regimen. Subsequent studies also showed that the combined use of AZM and BUD significantly enhanced the quality of life in pediatric MPP patients and improved parental satisfaction.

Comprehensive univariate analysis identified several significant factors correlated with treatment response, including disease duration, family medical history, therapeutic approach, and pe-treatment IgG, IL-6, and hs-CRP levels. Multivariate analysis further confirmed four independent predictors of poor treatment outcomes: prolonged disease course (≥8 days), low baseline IgG levels (<10 g/L), elevated baseline IL-6 levels (≥24.0 ng/L), and AZM monotherapy. These results align with findings by Chen et al. [26], who reported that pediatric MPP patients with prolonged fever (≥7 days), high-grade fever, and markedly elevated serum IL-6 and CRP levels were at higher risk of unfavorable outcomes. These insights may facilitate early identification and targeted intervention for pediatric MPP patients at high risk of treatment failure.

Several limitations of this study should be acknowledged. First, there may have been selection bias given the single-center design, possibly limiting the broader applicability of the results. Future multicenter research with larger, more diverse populations would strengthen external validity. Second, the lack of a cost-effectiveness analysis precludes assessment of the economic feasibility of the AZM-BUD combination therapy. Third, the development of a predictive nomogram for treatment response may help ensure both statistical accuracy and clinical relevance.

Conclusion

The combined use of AZM and BUD demonstrates superior efficacy compared to AZM monotherapy in treating pediatric MPP. This regimen not only accelerates symptom resolution and enhances immune function but also effectively mitigates systemic inflammation, without significantly increasing adverse events. Additionally, the combined therapy contributes to measurable improvements in both the quality of life of pediatric patients and parental satisfaction. Pediatric MPP patients presenting with risk factors, such as disease duration ≥8 days, baseline IgG <10 g/L, IL-6 levels ≥24.0 ng/L, or initial treatment with AZM monotherapy, are at a higher risk of treatment failure. Close monitoring and timely therapeutic adjustments are recommended for these high-risk patients.

Disclosure of conflict of interest

None.

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