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Original Article

Montelukast Sodium combined with Erythromycin Cyclocarbonate shows promoting effects on Mycoplasma pneumoniae infection in children

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Abstract: Objective: This study aims to evaluate the efficacy of Montelukast Sodium in combination with Erythromycin Cyclocarbonate for the treatment of children with Mycoplasma Pneumoniae infection, as well as their effects on the improvements of lung function, serum stress indicators, and antioxidant capacity indicators. Methods: A retrospective analysis was conducted on 188 children with Mycoplasma Pneumoniae infection treated in Dujiangyan Shoujia Hospital from April 2023 to April 2024. The 188 children were divided into the research group (n=94) and the control group (n=94) according the treatment they received, with children in the research group receiving a combination of Erythromycin Cyclocarbonate and Montelukast Sodium tablets, while those in the control group receiving Erythromycin Cyclocarbonate only. The therapeutic efficacy, pulmonary function, symptom alleviation time, serum stress indicator levels, antioxidant capacity indicators, and serum IgA and IgM levels of participants were statistically analyzed and compared between the two groups. Results: In comparison to the control group, the research group demonstrated better clinical efficacy, shorter time for the clinical symptoms to disappear, significant improvement in pulmonary function indicators, markedly decreased serum stress indicators ($P < 0.05$), significantly increased serum IgA and IgM levels ($P < 0.05$), as well as notably improved antioxidant capacity indicators ($P < 0.05$). Conclusion: Montelukast Sodium in combination with Erythromycin Cyclocarbonate treatment regimen increases the efficacy in treating Mycoplasma Pneumoniae infection in children compared to the use of Erythromycin Cyclocarbonate alone. This combination therapy can alleviate clinical symptoms faster, improve pulmonary function, reduce serum stress indicators, reduce the occurrence of adverse events, and enhance immune function in children with Mycoplasma Pneumoniae infection post treatment.

Keywords: Montelukast Sodium, Erythromycin Cyclocarbonate, Mycoplasma pneumoniae, efficacy

Introduction

Mycoplasma pneumoniae (MP) is one of the primary pathogens leading to community-acquired pneumonia in children, accounting for 10% to 40% of all pediatric pneumonia cases [1]. The disease is highly contagious with a latent period of 1 to 3 weeks. It is often transmitted through respiratory droplets. Despite the fact that most of the infected cases are mild or moderate, severe cases could occur, resulting in extrapulmonary complications such as skin damage, central nerve system diseases, cardiovascular diseases, and so on [2]. Particularly, over recent years, MP infection treatment has become more complicated as a result of mutated pathogens and their increased resistance to drugs.

Erythromycin Cyclocarbonate, as a macrolide antibiotic, is one of the major medications for the treatment of MP infections. It plays its antibiotic role through inhibiting the synthesis of proteins in the pathogen, which has been applied widely in clinical settings. However, as the resistance of mycoplasma to drugs increases, the application of Erythromycin Cyclocarbonate alone cannot yield ideal therapeutic efficacy, manifesting as prolonged symptom alleviation time for infected children, accompanied by continuous existence of cough, fever etc. Additionally, long-term use of antibiotics might

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cause adverse events such as imbalanced intestinal microflora. However, these disadvantages, in turn, has urged researchers to explore more effective and safer treatment plans to improve therapeutic efficacies and reduce the occurrence of side events in addressing the illness.

Montelukast Sodium is a selective leukotriene receptor antagonist initially used to treat asthma and allergic rhinitis. It plays its role by disrupting the function of leukotriene within the respiratory tract, alleviating respiratory inflammation and contraction in the bronchial tube [3]. In recent years, studies have shown that Montelukast Sodium can not only mitigate respiratory inflammation but also regulates immune response and decrease the levels of inflammatory factors in the serum, thereby improving pulmonary function [4]. These capabilities of Montelukast Sodium have provided possibilities for its application in addressing MP infection. Especially when used in combination with antibiotics, Montelukast Sodium may exert a synergistic effect by reducing respiratory inflammation, shortening the course of the disease, and improving the overall health condition of children with MP infection [5-8].

Although Erythromycin Cyclocarbonate shows significant effects in the treatment of MP infections, the emergence of drug-resistant strains and poor response to a single drug in some children urgently demands a treatment regimen that can both improve efficacy and reduce adverse reactions. Therefore, Montelukast Sodium, as an inflammatory-resistant drug, shows potential for combination therapies, and it can complement the deficiencies of Erythromycin Cyclocarbonate in addressing MP infections. Through retrospective analysis, this study aims to systematically evaluate the efficacy and safety of Montelukast Sodium combined with Erythromycin Cyclocarbonate in the treatment of MP infections, with special attention paid to the impacts of the combined therapy on the improvement of patients' pulmonary function, serum stress indicators, antioxidant capacity, and immune response. The specific goal of this study is to provide a more effective combination drug regimen for the clinical treatment of MP infections, thereby facilitating symptom alleviation for affected children, enhancing therapeutic effects, and lowering the occurrence of adverse events.

Materials and methods

Case selection

A retrospective study was conducted on 188 children with MP infection treated in Dujiangyan Shoujia Hospital from April 2023 to April 2024. The 188 participants were divided into the research group (n=94) and the control group (n=94) according to the treatment they received. This study was approved by the medical ethics committee of Dujiangyan Shoujia Hospital.

Inclusion Criteria: children were included if they met the diagnostic criteria for MP infection [5]; had complete clinical data; had no serious cardiac, liver or renal dysfunctions; showed no other bacterial, viral or fungal infections.

Exclusion Criteria: children were excluded from the study if they had concurrent bacterial, viral, or other pathogenic infections; had malignant tumors; their clinical data were incomplete; allergic or intolerant to the study drugs; complicated with other severe systemic diseases (e.g., severe neurological or respiratory diseases); used antibiotics or antiviral drugs within one week prior to the treatment; and had participated in other clinical studies within the past month prior to the study.

Intervention methods

Children in the control group received oral treatment of Erythromycin Cyclocarbonate (National Drug Approval No.: H20090269, OmePharmaceutical (Hainan) Co., Ltd.), 30 mg/kg each time, twice daily. Children in the research group received a combination of Erythromycin Cyclocarbonate and Montelukast Sodium tablets (National Drug Approval No.: H20203346, Yangtze River Pharmaceutical Group Nanjing Hailing Pharmaceutical Co., Ltd.) at a dose of 5 mg per time for affected children aged between 6 years and 14 years, or 4 mg per time for those aged between 2 years and 5 years, once daily. The drugs were administered before bedtime. All children were observed for therapeutic effects after being treated for 14 consecutive days.

Data collection

Primary outcome measures: Clinical efficacy: It includes significant efficacy, which is defined as

Table 1. Comparison of general baseline data between the two groups (n, $\bar{x} \pm sd$)

Item	Gender (cases)		Age (years)	Disease course (years)
	Male	Female		
Research group (n=94)	52	42	6.14±1.60	4.15±0.82
Control group (n=94)	49	45	6.39±1.73	4.36±0.88
t/χ^2	0.086		-1.029	-1.693
P	0.770		0.305	0.092

significant alleviation in symptoms, no observed clinical symptoms and marked absorption of lesions by imaging examinations, as well as moderate efficacy, which is defined as partial alleviation in symptoms and partial absorption of lesions by imaging examinations. The significant and moderate efficacy rates were recorded and compared following 14-day treatment in accordance with the aforementioned definitions.

Symptom alleviation time: The time needed for the disappearance of clinical symptoms, such as cough, fever and chest pain, was recorded and compared between the control group and the research group.

Secondary outcome measures: Pulmonary function indicators: Pulmonary function indicators of participants, such as the Forced Expiratory Volume in 1 second (FEV1), Peak Expiratory Flow (PEF), Forced Vital Capacity (FVC), and the FEV1/FVC ratio, were measured and compared between the control group and research group.

Serum stress indicators: Fasting venous blood samples were drawn from participants in both groups in the morning on the admission day before treatment and 14 days after treatment. The samples were employed for measuring the levels of tumor necrosis factor-α (TNF-α), C-reactive protein (CRP), interleukin-6 (IL-6) and cortisol.

Immune function indicators: Serum IgM and IgA levels were measured using an automatic nephelometric immunoassay.

Antioxidant capacity indicators: The ELISA was carried out on the admission day before treatment and 14 days after treatment to measure the levels of total antioxidant capacity (TAC) and superoxide dismutase (SOD).

Adverse reactions: The occurrence of adverse reactions such as abdominal pain, itching, allergic purpura, liver function abnormalities, palpitations, abnormal blood counts, and loss of appetite during the treatment process in participants were recorded and compared between the two groups.

Statistical analysis

Statistical analysis was performed using SPSS 20.0 software. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm sd$), and t-test or paired t test was used for comparison between groups. Counting data were expressed as quantity and percentage (n, %), and differences between groups were compared by chi-square test (χ^2). A *P* value of < 0.05 indicated a statistically significant difference.

Results

Comparison of general baseline data between the two groups

There were no statistically significant differences in the baseline data of participants, including gender, age and disease courses, between the two groups (P > 0.05). See **Table 1**.

Comparison of clinical efficacy between the two groups

The research group demonstrated better clinical efficacy than the control group (P < 0.05). See **Table 2**.

Comparison of the time for clinical symptoms to disappear between the two groups

The time for clinical symptoms to disappear in the research group was shorter than that in the control group (P < 0.05). See **Table 3**.

Table 2. Comparison of clinical efficacy between the two groups (n, %)

Group	n	Recovery	Remarkable effect	Effective	Ineffective	Total remarkable effect	Total effective
Research group	94	18 (19.15)	30 (31.91)	30 (31.91)	16 (17.02)	48 (51.06)	78 (82.97)
Control group	94	32 (34.04)	38 (40.43)	20 (21.28)	4 (4.26)	70 (74.47)	90 (95.75)
χ^2						11.016	8.057
P						0.001	0.045

Table 3. Comparison of the time for clinical symptoms to disappear between the two groups (n, $\bar{x}$ ± sd)

Group	Fever resolution time (days)	Cough disappearance time (days)	Lung rales disappearance time (days)
Research group (n=94)	3.83±0.56	8.78±1.54	6.02±1.07
Control group (n=94)	3.25±0.66	6.83±1.49	4.48±1.18
t	-6.501	-8.823	-9.374
P	< 0.001	< 0.001	< 0.001

Table 4. Comparison of pulmonary function indicators between the two groups ($\bar{x}$ ± sd)

Indicators	Control group (n=94)	Research group (n=94)	t	P
FEV1/L				
Before treatment	1.33±0.30	1.29±0.22	-1.042	0.299
After treatment	1.83±0.41	1.99±0.32	2.983	0.003
PEF (L/s)				
Before treatment	2.13±0.23	2.16±0.26	0.838	0.403
After treatment	2.71±0.53	2.99±0.34	4.311	< 0.001
FEV/%				
Before treatment	57.78±5.12	56.34±5.23	-1.908	0.058
After treatment	76.31±6.12	84.01±6.45	8.396	< 0.001
FEV1/FVC ratio				
Before treatment	2.15±0.33	2.20±0.21	1.239	0.217
After treatment	2.71±0.53	2.99±0.34	4.311	< 0.001

Note: FEV1, forced expiratory volume in 1 second; PEF, peak expiratory flow; FVC, forced vital capacity.

Comparison of lung function indicators between the two groups

After treatment, pulmonary function indicators of children in both groups improved compared to those before treatment, with the indicators in the research group significantly higher than those in the control group (P < 0.05). See **Table 4**.

Comparison of serum stress indicators between the two groups

After treatment, the levels of stress indicators in both groups decreased compared to those before treatment, with the indicators in the research group significantly lower than those in the control group (P < 0.05). See **Table 5**.

Comparison of serum IgA and IgM levels between the two groups

After treatment, the serum IgA and IgM levels in both groups increased compared to those before treatment, with the levels in the research group markedly higher than those in the control group (P < 0.05). See **Figure 1**.

Comparison of antioxidant capacity indicators between the two groups

After treatment, the levels of TAC and SOD in the research group were significantly higher

Table 5. Comparison of serum stress indicators between the two groups ($\bar{x}$ ± sd)

Indicators	Control group (n=94)	Research group (n=94)	t	P
TNF-α/(ng/L)				
Before treatment	106.43±7.45	107.75±8.12	1.161	0.247
After treatment	50.67±4.35#	48.24±3.66#	-4.144	< 0.001
CRP/(mg/L)				
Before treatment	18.75±2.86	18.34±2.23	-1.096	0.274
After treatment	5.24±1.09#	4.12±1.02#	-7.274	< 0.001
IL-6 (pg/mL)				
Before treatment	15.67±3.54	16.12±3.47	0.880	0.380
After treatment	8.23±2.76#	6.14±2.05#	-5.894	< 0.001
Cortisol levels (ug/dL)				
Before treatment	18.45±3.22	18.72±3.10	0.586	0.559
After treatment	10.78±2.34#	8.45±1.97#	-7.385	< 0.001

Note: Compared to before treatment, #P < 0.05. TNF-α, tumor necrosis factor-α; CRP, C-reactive protein; IL-6, interleukin-6 (IL-6).

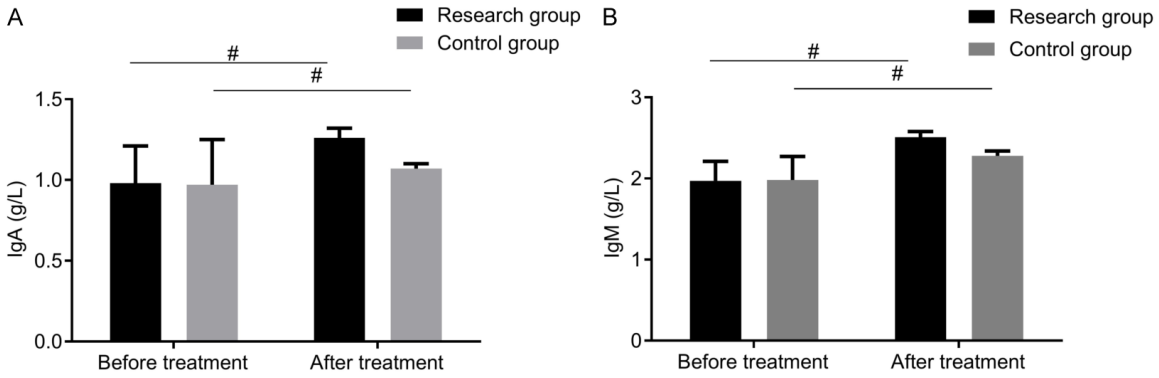

Figure 1. Comparison of the serum IgA and IgM levels between the two groups. A. Comparison of the serum IgA level; B. Comparison of the serum IgM level. Note: Compared to before treatment, #P < 0.05.

Table 6. Comparison of the TAC and SOD levels between the two groups ($\bar{x}$ ± sd)

Group	TAC (mmol/L)		SOD (U/mL)	
	Before treatment	After treatment	Before treatment	After treatment
Research group (n=94)	0.89±0.21	1.24±0.31#	85.67±12.34	104.56±14.23#
Control group (n=94)	0.91±0.22	1.56±0.35#	86.34±12.45	125.78±16.34#
t	0.638	6.636	0.371	9.495
P	0.525	< 0.001	0.711	< 0.001

Note: Compared to before treatment, #P < 0.05. TAC, capacity; SOD, superoxide dismutase.

than those in the control group (P < 0.05). See **Table 6**.

Comparison of adverse reaction incidence between the two groups

During the treatment process, the incidence rates of adverse reactions such as abdominal pain, itching, allergic purpura, liver function abnormalities, palpitations, abnormal blood counts, and loss of appetite were lower in the research group than those in the control group (P < 0.05). See **Table 7**.

Discussion

The results of this study showed that the combined treatment was significantly more effec-

Table 7. Comparison of the occurrence of adverse reactions between the two groups (n, %)

Group	n	Abdominal pain	Itching	Allergic purpura	Abnormal liver function	Palpitations	Abnormal blood routine	Loss of appetite	Total
Research group	94	4 (4.26)	4 (4.26)	4 (4.26)	0 (0.00)	2 (2.13)	4 (4.26)	0 (0.00)	18 (19.17)
Control group	94	0 (0.00)	2 (2.13)	2 (2.13)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	4 (4.26)
χ^2									10.089
P									0.002

tive than the application of a single therapy, with the demonstration of a markedly shorter symptom disappearance time, indicating that the combined treatment was rapid in alleviating clinical symptoms of patients with MP infections. This is consistent with the findings of previous studies [6, 7]. This effect is related to the anti-inflammatory and immunomodulatory properties of Montelukast Sodium, which reduces respiratory inflammation and enhances anti-infection capability within the body, thereby showing some advantages in disease alleviation [8, 9].

Montelukast Sodium, as a leukotriene receptor antagonist, can block the action of leukotrienes and alleviate inflammation in the respiratory mucosa, thereby alleviating symptoms such as cough and wheezing. Erythromycin Cyclocarbonate can effectively inhibit the growth and reproduction of MP. The combined use of both drugs can not only rapidly reduce the number of pathogens through direct antibacterial action but also alleviate inflammation through their anti-inflammatory effects. The dual mechanisms working together has resulted in a significantly shorter time for clinical symptoms to disappear, explaining the significant improvement in clinical symptoms.

Our findings also revealed that post treatment, children in the research group showed higher levels of FEV1, PEF, and FVC than the control group, indicating that the combined therapy was more effective in improving lung function in children. The findings of Zhao et al. also support this conclusion [10]. This might be explained by the fact that Montelukast Sodium can block leukotriene-mediated inflammatory responses, reduce bronchospasm and airway resistance, thereby improving pulmonary function [11, 12]. Additionally, Erythromycin Cyclocarbonate helps restore pulmonary function by inhibiting bacterial growth and reducing continuous irritation to the respiratory tract. Studies have shown that leukotrienes are important mediators in asthma and other allergic diseases, causing bronchial smooth muscle contraction and increased mucus secretion [13]. However, Montelukast Sodium can effectively alleviate these symptoms by antagonizing leukotriene receptors, significantly improving lung function. When combined with Erythromycin Cyclocarbonate, it not only inhibits pathogens but also further reduces inflammatory response. Obviously, the dual action would result in more significant improvement of lung function.

In terms of serum stress indicators, the research group showed marked improvements in the TNF-α, CRP, IL-6, and cortisol levels compared to the control group after treatment, indicating that the combined treatment was more effective in reducing inflammatory responses. This result has further validated the anti-inflammatory effects of Montelukast Sodium, which could reduce the systemic inflammatory response caused by MP infection [14, 15]. TNF-α and CRP are two common markers for assessing inflammatory response. The elevated IL-6 levels is closely associated with various inflammatory diseases as well. The increased cortisol levels are typically related to the stress response in the body. The antibacterial action of Erythromycin Cyclocarbonate can reduce the direct inflammation caused by pathogens, while the anti-inflammatory effects of Montelukast Sodium can mitigate inflammatory responses through various mechanisms, such as inhibiting the production and release of leukotrienes and reducing the aggregation and activation of inflammatory cells [16-19]. Therefore, the combined treatment will undoubtably reduce the levels of TNF-α, CRP, IL-6, and cortisol, thereby controlling inflammatory response within patients' bodies. Moreover, through reducing the cortisol levels, the combined treat-

ment can effectively alleviate the stress response in children, enhancing the overall effectiveness of the treatment. In conclusion, the synergistic effects of the combined treatment have manifested positive response to inflammations in children.

In terms of immune function indicators, the research group showed significantly higher levels of IgM and IgA compared to the control group post treatment, indicating that the combined therapy could enhance the immune function in children. Montelukast Sodium helps improve therapeutic efficacy by modulating the immune system [20-22]. IgM and IgA are important immunoglobulins that play key roles in the body's immune response. IgM is the primary antibody in the initial immune response, capable of quickly binding to and neutralizing pathogens. IgA is mainly present on mucosal surfaces and can prevent the invasion and spreading of pathogens [23, 24]. After the combined treatment, the significant increase in IgM and IgA levels in children indicated an effective enhancement in their immune system, which is crucial for improving resistance and preventing reinfection. Montelukast Sodium, by regulating the immune system, helps to enhance the production of immunoglobulins, thereby further improving the immune capacity in children with MP infections.

In terms of antioxidant capacity, TAC and SOD are two important indicators. TAC reflects the body's overall antioxidant capacity, capable of neutralizing free radicals and preventing oxidative damage to cells. SOD is a crucial antioxidant enzyme that catalyzes the dismutation of superoxide anion radicals into oxygen and hydrogen peroxide, thereby protecting cells from oxidative stress damage. The study results showed that the combined treatment significantly increased the levels of TAC and SOD in children, indicating that this treatment method not only effectively suppressed inflammatory responses but also enhanced the body's antioxidant capacity. Montelukast Sodium has been shown to have antioxidant effects, protecting cells by reducing free radical production and enhancing the activity of antioxidant enzymes. The antibacterial action of Erythromycin Cyclocarbonate has effectively controlled the source of infection, reducing the inflammatory burden on the body, which has also helped to decrease oxidative stress responses.

Additionally, the research group demonstrated a lower incidence of adverse reactions, indicating that the combined treatment was safer and more reliable. Montelukast Sodium, as a leukotriene receptor antagonist, produces few side effects. When used in combination with Erythromycin Cyclocarbonate, it can reduce the dosage and duration of antibiotics, thereby decreasing the incidence of adverse reactions. Traditional antibiotic treatments often cause a series of adverse reactions, such as gastrointestinal discomfort and liver function damage. In this study, the combined use of Montelukast Sodium can reduce dependency on traditional antibiotics through its anti-inflammatory and immune-regulating effects, thereby reducing the occurrence of adverse reactions. This finding is of significant importance for clinical practice, suggesting that a rational combination of drugs can improve treatment efficacy while minimizing side effects.

Despite the significant results obtained in this study, there are some limitations. First, as a retrospective study, the sample size is relatively small and lacks the rigorous design of a randomized controlled trial, which may result in selection and information biases. Second, the study period was short, and long-term efficacy and safety were not observed. Additionally, this study did not delve into the specific mechanisms of action of Montelukast Sodium. Future research could focus on animal experiments and molecular biology studies to further reveal its specific anti-inflammatory and immunomodulatory pathways. Furthermore, other drug combinations and treatment regimens could be explored to find more effective and safer treatment methods.

In summary, the clinical efficacy of Montelukast Sodium combined with Erythromycin Cyclocarbonate in treating MP infection in children is superior to using Erythromycin Cyclocarbonate alone. This combined treatment approach can more quickly alleviate clinical symptoms, improve lung function and improve serum stress indicators, providing new ideas and methods for addressing MP infection in clinical settings.

Disclosure of conflict of interest

None.

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