

# Evaluation of the Efficacy and Side Effects of Montelukast Sodium Combined with Salmeterol in Asthma-chronic Obstructive Pulmonary Disease Overlap Syndrome

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## Abstract

**Objective:** To evaluate the efficacy and adverse reactions of Montelukast sodium combined with salmeterol in asthma-chronic obstructive pulmonary disease overlap syndrome. **Methods:** A total of 290 patients with asthma-chronic obstructive pulmonary disease overlap syndrome admitted to our hospital from June 2022 to July 2023 were divided into a study group and control group by random number table method, with 145 cases in each group. The control group was given salmeterol treatment, while the study group was given Montelukast sodium combined with salmeterol treatment for 6 consecutive months. The therapeutic effect, lung function before and after treatment, and treatment safety were evaluated and compared between the two groups. **Results:** After treatment, the total effective rate of the study group was higher than that of the control group, the pulmonary function indexes such as FVC and PEF were higher than those of the control group, and the incidence of treatment-related adverse reactions was lower than that of the control group, with statistical significance ( $P < 0.05$ ). **Conclusion:** Montelukast sodium combined with salmeterol has higher efficacy and safety in the treatment of patients with asthma-chronic obstructive pulmonary disease overlap syndrome, and can effectively improve the lung function of patients.

## Keywords

Asthma-chronic obstructive pulmonary disease overlap syndrome, Montelukast sodium, Salmeterol, Therapeutic effect, Adverse reactions, Lung function

Bronchial asthma and chronic obstructive pulmonary disease are common respiratory diseases in modern people, both of which are chronic airway obstructive diseases, among which asthmatic patients are mainly characterized by wheezing and limited respiratory function, while chronic obstructive pulmonary disease is mainly characterized by persistent respiratory symptoms [1, 2]. In recent years, the incidence of these two diseases has shown an increasing trend, and the comorbidity of the two diseases is asthma-chronic obstructive pulmonary disease overlap syndrome. The term was coined in 2014 by the Global Initiative for Asthma and the Global Initiative for Chronic Obstructive Lung Disease and is becoming more common in clinical settings. In chronic obstructive airway diseases, the incidence of this lesion is about 15%-20% [3]. Patients with asthma-chronic obstructive pulmonary disease overlap

syndrome are characterized by airflow restriction, and the pathogenesis of this disease is complex. Common risk factors include smoking, old age, repeated respiratory infection, airway hyperresponsiveness, etc. [4, 5]. Compared with asthma or COPD alone, asthma-COPD overlap syndrome is more severe and difficult to treat. In recent years, our hospital has carried out combined medication for some patients with asthma-chronic obstructive pulmonary disease overlap syndrome, and the combined intervention of Montelukast sodium and salmeterol has obtained satisfactory results. Now we have analyzed the specific data of some cases.

## 1. Data and methods

### 1.1 General Information

A total of 290 patients with asthma-COPD overlap syndrome admitted to our hospital from June 2022 to July 2023, including 180 males and 110 females, aged 33-71 ( $54.28 \pm 6.23$ ) years old, were selected and divided into study group and control group by random number table method, with 145 cases each. There was no statistical significance in the comparison of general data between the two groups ( $P > 0.05$ ). Inclusion criteria: (1) Meeting the diagnostic criteria of asthma-chronic obstructive pulmonary disease overlap syndrome; (2) Conform to the relevant indications of the drugs used in this study; (3) All the data were complete and the medication history was clear; (4) Actively cooperate with treatment and follow-up; (5) no history of treatment related to asthma-chronic obstructive pulmonary disease overlap syndrome within 3 months before enrollment. Exclusion criteria: (1) speech and cognitive dysfunction; (2) with serious physical disease; (3) Malignant lesions; (4) Those with mental illness; (5) Have a history of chest surgery; (6) With infected persons.

### 1.2 Method

Both groups of asthma-chronic obstructive pulmonary disease overlap syndrome patients received basic treatment, combined with the disease to relieve cough and asthma, spasmodic expectorant treatment, improve anti-infection, oxygen, and other interventions, at the same time given inhaled glucocorticoid anti-inflammatory. The control group was given salmeterol treatment, combined with disease adjustment, mild to moderate 1 inhalation ( $50\mu\text{g}/250\mu\text{g}$ )/time, bid. Severe 1 inhalation ( $50\mu\text{g}/500\mu\text{g}$ )/time, bid, for 6 months. The study group was treated with Montelukast sodium combined with salmeterol. The latter was treated in the same way as the control group, Montelukast sodium was administered 10mg orally, qd, continuously for 6 months, and visit regularly during treatment.

### 1.3 Observation indicators

#### 1.3.1 Evaluation of efficacy

After treatment, the symptoms related to asthma-COPD overlap syndrome basically disappeared, reaching the standard of drug withdrawal was significant, symptoms improved after treatment, and audible wheezing and mild wheezing were effective, otherwise, they were ineffective.

#### 1.3.2 Pulmonary function assessment

Patients' pulmonary function was assessed by spirometer before and after treatment, and forced vital capacity (FVC) and maximum expiratory flow (PEF) were measured.

#### 1.3.3 Treatment safety evaluation

The incidence of drug-induced adverse reactions in the two groups during treatment was analyzed, including skin allergy, respiratory infection, dizziness, headache, musculoskeletal pain, palpitations, etc.

### 1.4 Statistical methods

SPSS23.0 statistical software was used for processing, measurement data were expressed as ( $\bar{x} \pm s$ ), comparison was performed by t-test,  $P < 0.05$  was considered statistically significant.

## 2. Result

### 2.1 The comparison of treatment effects between the two groups (Table 1)

Table 1. Comparison of treatment effect between two groups (case %)

Group	Remarkable	Effective	In vain	Total effective rate
Research team/145	88(60.69)	52(35.86)	5(3.48)	140(96.55)
Control group/145	49(33.79)	74(51.03)	22(15.17)	123(84.83)
$\chi^2$				11.803
P				0.001

### 2.2 The comparison of lung function before and after treatment between the two groups (Table 2)

Table 2. Comparison of pulmonary function indexes before and after treatment between the two groups ( $\bar{x} \pm s$ )

Group	FVC(L/s)		PEF(L/s)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Research team/145	2.28±0.71	3.39±0.44 <sup>△</sup>	8.12±1.18	10.95±1.15 <sup>△</sup>
Control group/145	2.33±0.70	2.81±0.57 <sup>△</sup>	8.20±1.12	9.23±1.09 <sup>△</sup>
t	0.604	9.699	0.592	13.071
P	0.546	< 0.001	0.554	< 0.001

Note: Compared with before treatment, <sup>△</sup>P < 0.05

### 2.3 The comparison of treatment safety between the two groups (Table 3)

Table 3. Comparison of treatment safety between two groups (e.g. %)

Group	Skin allergy	Espiratory infection	Dizziness, headache	Musculoskeletal pain	Palpitations	Total incidence
Research team/145	1(0.69)	1(0.69)	1(0.69)	0(0.00)	0(0.00)	3(2.07)
Control group/145	3(2.07)	3(2.07)	2(1.38)	2(1.38)	1(0.69)	11(7.59)
$\chi^2$						4.803
P						0.028

## 3. Discussion

As a heterogeneous disease, asthma is characterized by chronic airway inflammation, mainly manifested by respiratory symptoms, including wheezing, shortness of breath, chest tightness, and cough [6], which are related to airway stenosis caused by bronchoconstriction. Physical symptoms are related to the severity of the disease, and expiratory airflow is variable in patients with asthma [7]. Asthma has been proven to be an independent risk factor for patients with chronic obstructive pulmonary disease [8]. Chronic obstructive pulmonary disease (COPD) is mainly characterized by persistent respiratory symptoms and limited airflow, and is related to small airway diseases and lung parenchymal destruction caused by different factors. The occurrence of the disease is related to long-term exposure to toxic particles and gases, and the development of the lung is also related to the occurrence of the disease. Patients with asthma-chronic obstructive pulmonary disease overlap syndrome have the characteristics of both diseases, with persistent airflow limitation as the basic feature, and the diagnosis of this disease depends on the recognition of the common characteristics of asthma and chronic obstructive pulmonary disease [9]. In chronic obstructive pulmonary disease, the proportion of asthma-COPD overlap syndrome is about 10 to 40%, and in asthma patients, the proportion of asthma-COPD overlap syndrome is about 15 to 35%. Among people over 40 years old in China, the incidence

of asthma-chronic obstructive pulmonary disease overlap syndrome is over 37% [10], but over 60% of patients are diagnosed with asthma at the first diagnosis, and over 30% are diagnosed with chronic obstructive pulmonary disease. Compared with individuals with a single disease, asthma-COPD overlap syndrome has a poorer level of lung function [11] and is associated with a higher risk of acute episodes, resulting in higher rates of hospitalization, mortality, and associated disease burden.

This study mainly analyzed the value of Montelukast sodium combined with salmeterol in the treatment of asthma-chronic obstructive pulmonary disease overlap syndrome. The therapeutic effect evaluation showed that after 6 months of treatment, the total therapeutic effectiveness of patients in the study group was higher than that of the control group, indicating that the combination of drugs can promote the control of the disease and improve the curative effect. After treatment, FVC, PEF and other lung function indexes in the study group were higher than those in the control group, and the improvement of lung function level in the study group was better than that in the control group. The comparison of the incidence of treatment-related adverse reactions between the two groups showed that the incidence of the study group was lower than that of the control group, and the combination of drugs was safer. Salmeterol is a long-acting  $\beta_2$ -adrenergic receptor agonist, which has good efficacy in improving nocturnal asthma symptoms, treating chronic obstructive pulmonary disease, and preventing exercise-induced bronchospasm. It can play a good role in bronchiectasis and improve respiratory function in patients with asthma-chronic obstructive pulmonary disease overlap syndrome. The drug also has a good anti-inflammatory effect, can improve the local inflammation of the airway, suitable for the long-term treatment of asthma - chronic obstructive pulmonary disease overlap syndrome, and other airway obstruction diseases. Montelukast sodium is a commonly used drug in the clinical treatment of asthma. It is a cysteinylleukotriene receptor antagonist. It has a good effect on the long-term treatment and prevention of the disease, and can also be used in the treatment of allergic rhinitis, chronic urticaria and other diseases. Among the preasthma mediators, cysteinylleukotriene inflammatory mediators are extremely important and bind to cysteinylleukotriene receptors. Leukotriene, as a metabolite of arachidonic acid, is one of the main reasons for airway smooth muscle contraction, and its increased level will directly affect vascular permeability, promote mucus secretion and inflammatory cell aggregation, lead to airway stenosis, and affect respiratory function [12]. Leukotriene can also promote the proliferation of airway structural cells, which is closely related to airway remodeling. This drug has high affinity and selectivity for type I cysteinylleukotriene receptors, and can inhibit the binding process of the premediators, so as to effectively block the leukotriene-mediated effect, and play an ideal role in regulating airway response, anti-inflammatory and anti-asthma. It can effectively improve bronchoconstriction, regulate mucus secretion, and improve physical symptoms in patients with this disease. The safety of Montelukast sodium is relatively high, and the disease is generally well tolerated by patients. The treatment of patients with asthma-chronic obstructive pulmonary disease overlap syndrome should be combined with the characteristics and severity of the disease to choose the treatment plan. In this study, both groups of patients received basic treatment and combined with the specific conditions of patients, which can effectively control the physical disease. Both groups were treated with inhaled glucocorticoids, which is the core and basis for the treatment of asthma-COPD overlap syndrome. On the basis of conventional treatment, bronchodilator intervention can improve respiratory function. Combined intervention with cysteinylleukotriene receptor antagonists can further promote the control of symptoms and reduce the risk of recurrent disease. In this study, both groups of patients received 6 months of treatment, in which the amount of inhaled glucocorticoid should be gradually reduced about 3 to 6 months after the condition stabilized, and if the condition worsened, the amount should be increased as appropriate, that is, dynamic adjustment of this drug should be combined with the condition to ensure the safety of treatment. While Montelukast sodium and salmeterol can be administered for a long time, patients still need to be admitted to the hospital regularly for follow-up visits during treatment, for condition assessment, adjustment of treatment plan combined with patients' physical symptoms and lung function, and for ensure treatment effect and safety through individualized treatment.

#### 4. Conclusion

In summary, the application of Montelukast sodium combined with salmeterol in asthma-chronic obstructive pulmonary disease overlap syndrome has a definite effect, which can effectively promote the improvement of lung function in patients and reduce the risk of adverse reactions at the same time. It is an effective and safe treatment mode, which is worth carrying out.

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