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Analysis of the Effects of Different Medication Methods on the Acute Attack Rate, Pulmonary Function, and Safety of Prophylactic Treatment in Patients with Seasonal Asthma

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Abstract: *Objective:* To investigate the effects of different medication methods on the acute attack rate, pulmonary function, and safety of prophylactic treatment in patients with seasonal asthma. *Methods:* A total of 180 outpatient asthma patients with seasonal attack characteristics, admitted to our hospital from March 2022 to September 2025, were selected as the study subjects. They were randomly divided into two groups using the random number table method. Patients in the budesonide group inhaled budesonide-formoterol powder inhalation, while those in the montelukast group took oral montelukast sodium tablets. The acute attack rate, pulmonary function indicators, and medication safety were compared between the two groups. *Results:* The acute attack rate in the budesonide group (6.67%) was lower than that in the montelukast group (16.67%), with a statistically significant difference between the two groups ($P<0.05$). Before treatment, there were no significant differences in pulmonary function indicators such as FEV1% predicted, FEV1/FVC%, and PEF between the two groups ($P>0.05$). After treatment, both groups showed significant improvements in pulmonary function indicators, with the budesonide group significantly outperforming the montelukast group ($P<0.05$). During the treatment period, there was no statistically significant difference in the incidence of adverse reactions between the two groups ($P>0.05$). *Conclusion:* In the prophylactic treatment of seasonal asthma, the combined budesonide-formoterol inhalation regimen is superior to montelukast sodium in preventing acute attacks and improving pulmonary function, with comparable safety, and can be considered as the preferred prophylactic treatment option in clinical practice.

Keywords: Seasonal asthma; Budesonide; Formoterol; Montelukast sodium; Acute attack; Pulmonary function; Safety

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1. Inroduction

Seasonal asthma is a frequently occurring clinical respiratory disease characterized by wheezing, chest tightness, shortness of breath, and other symptoms. It exhibits seasonal characteristics and is prone to acute exacerbations during climate changes, particularly in relation to seasonal allergens such as climate change, pollen, and mold spores. Most patients experience spontaneous or treatment-induced remission with seasonal changes, but the condition has a high recurrence

rate, severely affecting patients' quality of life [1-3]. Therefore, initiating preventive treatment before the onset season is crucial to reduce the rate of acute exacerbations and protect lung function.

Currently, the commonly used preventive treatment drugs for asthma in clinical practice mainly include inhaled corticosteroids (ICS), long-acting β2-agonists (LABA), and leukotriene receptor antagonists (LTRA) [4-5]. Budesonide, a commonly used ICS, effectively suppresses airway inflammation [6]; formoterol, a LABA, rapidly dilates the bronchi. The combined inhalation of these two drugs exhibits synergistic anti-inflammatory and antiasthmatic effects[7-8]. Montelukast sodium, a LTRA, reduces airway inflammation and spasm by antagonizing leukotriene receptors and offers the convenience of oral administration [9]. However, comparative studies on the efficacy differences between these two medication regimens in the preventive treatment of seasonal asthma are still incomplete. This study aims to provide evidence-based medical evidence for selecting preventive treatment regimens for such patients by comparing the preventive treatment effects of budesonide-formoterol powder inhalation and oral montelukast sodium on seasonal asthma patients.

2. Materials and methods

2.1. General information

A total of 180 outpatient asthma patients with seasonal onset characteristics admitted to our hospital from March 2022 to September 2025 were selected and randomly divided into two groups, with 90 patients in each group. Among them, there were 81 males and 99 females, aged between 17 and 56 years, with a disease duration of 5 to 11 years and a body mass index (BMI) of 19 to 29 kg/m². No statistically significant differences were observed in the general information between the two groups ($P > 0.05$), as shown in **Table 1**.

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria for bronchial asthma as outlined in the "Guidelines for the Prevention and Treatment of Bronchial Asthma"[10]: The primary symptoms include recurrent episodes of wheezing, shortness of breath, chest tightness, or coughing. During episodes, scattered or diffuse wheezing sounds, predominantly in the expiratory phase, can be heard in both lungs, with prolonged expiration. (2) Asthma attacks exhibit distinct seasonality: Regular episodes occur annually from April to May and August to September. (3) At least one of the following three tests is positive: Positive bronchial provocation test or exercise test; Positive bronchodilator test; Diurnal PEF variability rate > 20%. (4) No acute exacerbation of bronchial asthma and no maintenance medication in the past three months. (5) The patient or their family member has signed an informed consent form.

2.1.2. Exclusion criteria

(1) Coexisting with confirmed respiratory diseases such as chronic obstructive pulmonary disease or tuberculosis. (2) Allergic to the medications used in this study. (3) Habitual smoking, alcohol consumption, or long-term intake of caffeinated beverages. (4) Female patients who are pregnant or breastfeeding. (5) Patients with mental disorders or cognitive impairments that prevent them from cooperating in completing the treatment.

Table 1. General information of patients in both groups [x±s, (n, %)]

Characteristic	Budesonide Group (n=90)	Montelukast Group (n=90)	Statistical Test (t/χ^2)	*P*-value
Gender (M/F, n)	41 / 49	40 / 50	0.022	0.881
Age (years, Mean ± SD)	34.88 ± 5.26	35.04 ± 5.41	0.201	0.841
Disease Duration (years, Mean ± SD)	4.13 ± 1.20	4.26 ± 1.51	0.639	0.523
BMI (kg/m², Mean ± SD)	24.01 ± 1.70	23.81 ± 1.64	0.803	0.423

2.2. Research methodology

Both groups of patients received asthma health education, covering topics such as avoiding allergens, correctly using inhalation devices, and identifying and pre-treating acute exacerbations.

2.2.1. Budesonide group

Inhalation of budesonide/formoterol fumarate inhalation powder (AstraZeneca AB, National Medical Products Administration Approval Number: H20140458, Specification: 60 inhalations per device, each inhalation containing 160 μg budesonide and 4.5 μg formoterol fumarate), 1 inhalation per dose, twice daily, followed by rinsing the mouth with water.

2.2.2. Montelukast group

Oral administration of montelukast sodium tablets (Hangzhou MSD Pharmaceutical Co., Ltd., National Medical Products Administration Approval Number: J20130047, Specification: 10 mg), 10 mg once nightly.

2.2.3. The preventive medication started on

March 1st to April 1st and August 1st to September 1st annually. Both groups of patients underwent outpatient follow-up every four weeks, totaling four visits, covering the preventive treatment cycles for the two exacerbation seasons. Follow-up methods included on-site visits, video consultations, and telephone calls, along with establishing a WeChat group for patients for daily management.

2.3. Observation indicators

(1) Acute Exacerbation Rate: Count the number of acute exacerbations and calculate the exacerbation rate in both groups during the follow-up period. Definition of acute asthma exacerbation: a significant worsening of symptoms such as wheezing, shortness of breath, chest tightness, or coughing, necessitating treatment with oral or intravenous systemic corticosteroids, or requiring emergency department visits/hospitalization.

(2) Compare the pulmonary function indicators of both groups before and after treatment, including observing the ratio of forced expiratory volume in one second to predicted value (FEV1% predicted), the ratio of FEV1 to forced vital capacity (FVC) (FEV1/FVC%), and changes in peak expiratory flow (PEF).

(3) Record the occurrence of adverse reactions during treatment in both groups, including oral infections, allergic reactions, gastrointestinal symptoms, as well as insomnia, headaches, emotional abnormalities, etc., and calculate the incidence of adverse reactions.

2.4. Statistical methods

The data obtained in this study were statistically analyzed using the SPSS 26.0 software package. Measurement data were expressed as ($x\pm s$) and analyzed using the t-test; count data were expressed as (n, %) and analyzed using the X^2 test. A P-value less than 0.05 was considered statistically significant.

3. Results

3.1. Comparison of acute exacerbation between the two groups

The acute exacerbation rate in the budesonide group (6.67%) was lower than that in the montelukast group (16.67%), with a statistically significant difference between the two groups ($P<0.05$), as shown in **Table 2**.

Table 2. Comparison of acute exacerbation between the two groups (n, %)

Outcome Measure	Budesonide Group (n=90)	Montelukast Group (n=90)
Number of Acute Exacerbations (n)	6	15
Exacerbation Rate (%)	6.67%	16.67%
χ^2 value	4.367	
P-value	0.037	

3.2. Comparison of pulmonary function indicators between the two groups

Before treatment, there were no significant differences in pulmonary function indicators such as FEV1% predicted, FEV1/FVC%, and PEF between the two groups (P>0.05). After treatment, pulmonary function indicators in both groups improved significantly, with the budesonide group showing significantly better results than the montelukast group (P<0.05), as shown in **Table 3**.

Table 3. Comparison of pulmonary function between the two groups (X±s)

Indicator	Time Point	Budesonide Group (n=90)	Montelukast Group (n=90)	t-value	P-value
FEV_1% Predicted (%)	Before Treatment	70.06 ± 5.91	69.89 ± 6.67	0.181	0.857
	After Treatment	78.62 ± 6.09*	75.21 ± 5.41*	3.971	<0.001
FEV_1/FVC (%)	Before Treatment	75.04 ± 5.50	75.20 ± 5.16	0.201	0.841
	After Treatment	82.28 ± 5.42*	80.62 ± 5.31*	2.075	0.039
PEF (L/s)	Before Treatment	5.13 ± 1.19	4.88 ± 1.92	1.050	0.295
	After Treatment	7.18 ± 1.95*	6.37 ± 1.23*	3.333	0.001

Note: Compared with the same group before treatment, *P<0.05.

3.3. Comparison of medication safety between the two groups

During the treatment period, a total of 11 adverse reactions occurred in the budesonide group, with an incidence rate of 12.22%; while 13 adverse reactions occurred in the montelukast group, with an incidence rate of 14.44%. There was no statistically significant difference in the incidence of adverse reactions between the two groups (P>0.05), as shown in **Table 4**.

Table 4. Comparison of medication safety between the two groups (n, %)

Adverse Reaction Category	Budesonide Group (n=90)	Montelukast Group (n=90)	χ^2 Value	P Value
Oral Infection	5	2	/	/
Allergic Reaction	3	1	/	/
Gastrointestinal Symptoms	1	6	/	/
Insomnia	0	1	/	/
Headache	1	2	/	/
Mood Disorder	1	1	/	/
Total Incidence	11 (12.22%)	13 (14.44%)	0.180	0.672

4. Discussion

Seasonal asthma is one of the common types of clinical asthma, which is related to allergens. The preventive treatment of this disease requires the suppression of airway hyperresponsiveness and the reduction of the release of inflammatory factors to alleviate tracheal spasm and thereby control the progression of the disease[11]. ICS, LABA, and LTRA are commonly used drugs in asthma prevention[12]. Therefore, in this study, patients with seasonal asthma were grouped and subjected to two intervention protocols: budesonide-formoterol and montelukast sodium, respectively. The acute attack rate, pulmonary function, and safety of the patients were compared to provide evidence-based medical evidence for selecting preventive treatment protocols for patients.

The results of this study showed that the acute attack rate in the budesonide group was significantly lower than that in the montelukast group (6.67% vs 16.67%) ($P<0.05$). The reason for this is that budesonide, as a glucocorticoid, can be dissolved through the bronchial mucosa and enter the cell membrane, directly acting on inflammatory cells and epithelial cells to achieve an anti-inflammatory effect[13]; formoterol, a long-acting β2 receptor agonist, can stimulate the adrenal β2 receptors for a long time, playing a role in dilating bronchial smooth muscle, and can also inhibit allergic reactions caused by the release of heparin, histamine, and 5-hydroxytryptamine from mast cells[14]. The combined application of the two can enhance the anti-inflammatory effect, rapidly suppress the symptoms of airway hyperresponsiveness in patients, alleviate clinical symptoms, and inhibit acute attacks. As a leukotriene modifier, montelukast sodium exerts anti-inflammatory effects solely through antagonizing leukotriene receptors and is unable to directly dilate the bronchi, resulting in poor preventive capacity against airway spasms[15]. Therefore, budesonide-formoterol offers more comprehensive preventive effects for patients with seasonal allergic asthma, reducing the rate of acute exacerbations.

In this study, analysis of pulmonary function indicators revealed that the predicted FEV1%, FEV1/FVC%, and PEF significantly improved in both groups after treatment compared to before treatment, with the budesonide group showing a significantly greater improvement than the montelukast group ($P < 0.05$). This reflects a more pronounced protective effect of the combination regimen on pulmonary ventilation function. The increases in predicted FEV1% and FEV1/FVC% indicate that the potent anti-inflammatory effect of budesonide can alleviate airway mucosal edema and inhibit airway remodeling. Meanwhile, the bronchodilatory effect of formoterol directly improves airflow limitation, resulting in a significant enhancement of airway patency under the dual action[16]. The advantage in PEF reflects the improvement effect of the combination regimen on respiratory muscle function and airway dynamic patency. Additionally, a comparison of the safety profiles of the two treatment regimens revealed no statistically significant difference in the incidence of adverse reactions between the groups (12.22% vs 14.44%, $P > 0.05$). However, there were notable differences in the spectrum of adverse reactions: the budesonide group primarily experienced oral infections, likely related to irritation of the oral mucosa by residual inhaled medication, which can be effectively prevented by rinsing the mouth after inhalation. The montelukast group predominantly experienced gastrointestinal symptoms, possibly due to irritation of the gastrointestinal mucosa by the oral medication. Nevertheless, the incidence of adverse reactions was low in both groups, indicating good safety profiles for both regimens in the preventive treatment of seasonal asthma[17].

In conclusion, in the preventive treatment of seasonal asthma, the budesonide-formoterol combination inhalation regimen outperforms montelukast sodium in preventing acute exacerbations and improving pulmonary function, with comparable safety profiles. Therefore, it can be considered a preferred preventive treatment option in clinical practice. However, the small sample size included in this study may affect the results obtained. Subsequent studies will further expand the sample size and include elderly and pediatric populations to provide more reliable intervention strategies for clinical seasonal asthma management.

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Disclosure statement

The author declares no conflict of interest.

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