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Feasibility of Tiotropium Bromide Treatment in Patients with Asthma-COPD Overlap Syndrome and its Effect on Lung Function

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Abstract: *Objective:* To explore the feasibility of tiotropium bromide therapy and its effect on the lung function of patients with asthma-COPD overlap syndrome (ACOS). *Method:* The 58 subjects selected in this study were all ACOS patients admitted to our hospital (Hohhot First Hospital) from October 2020 to October 2022. They were grouped according to the random number table method and divided into a control group (29 cases) and an observation group (29 cases). The control group received routine treatment plus salmeterol-fluticasone powder inhalation treatment, and the observation group received tiotropium bromide treatment. The relevant indicators of the two groups were compared. *Results:* The total clinical effective rate of the observation group was significantly higher than that of the control group. Besides, the forced vital capacity (FVC), forced expiratory volume in 1 second (FEV₁) levels, and ACT scores of the two groups increased after treatment, with the observation group having better results than the control group. The residual volume-total lung capacity ratio (RV/TLC), acute exacerbation frequency, and CAT scores all decreased, with the observation group showing smaller values than the control group. The difference between the results of both groups were significant (P < 0.05) *Conclusion:* Tiotropium bromide has a significant clinical effect in the treatment of ACOS patients and can effectively improve the lung function of patients.

Keywords: Asthma-COPD overlap syndrome; Tiotropium bromide; Lung function; Feasibility

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1. Introduction

Asthma-COPD Overlap Syndrome (ACOS) is a respiratory disease that is prevalent in China. The clinical feature is persistent airflow limitation, which has the characteristics of high fatality rate and severe damage to lung function, which poses a serious threat to the patients' lives ^[1]. Currently, salmeterol-fluticasone powder inhalation agent is widely used clinically. However, its onset of action is slow, and its effect on improving airflow is not ideal ^[2]. Tiotropium bromide is an anticholinergic drug that is long acting, efficient, and has a significant expansion effect on bronchial smooth muscle and is able to relieve clinical symptoms of patients ^[3]. Therefore, the purpose of this study is to explore the feasibility of tiotropium bromide treatment in ACOS patients and its effect on lung function, which is reported as follows.

2. Materials and method

2.1. General information

The qualifications of this study was reviewed and approved by the Medical Ethics Committee of the hospital. The patients and their families were informed about this study. The 58 subjects selected in this study were

all ACOS patients admitted to our hospital from October 2020 to October 2022. They were grouped according to the random number table method and divided into a control group (29 cases) and an observation group (29 cases). Among them, there were 16 males and 13 females in the control group; aged 40-79 years, with an average of 60.13 ± 7.45 years; their body mass index (BMI) were 21-28 kg/m², with an average of 24.06 ± 1.37 kg/m². The observation group consisted of 15 males and 14 females; aged 41-80 years, with an average of 60.24 ± 7.34 years; their BMI were 22-29 kg/m², with an average of (24.08 ± 1.35) kg/m². The baseline data of the two groups were compared and analyzed and P > 0.05 was obtained, indicating that there was no significant difference between the baseline data of both groups. Inclusion criteria: Those who meet the relevant diagnostic criteria of ACOS in "Experience in the Treatment of Asthma-COPD Overlap Syndrome" [4]; those who have not used hormone therapy recently; those with complete clinical data, etc. Exclusion criteria: Those who are allergic to the drugs used in this study; those with severe liver, kidney, or other important organ damage; those with blood system diseases, etc.

2.2. Methods

The control group was given routine treatment such as anti-infection and oxygen inhalation, and salmeterol-fluticasone inhalation powder (Approval number, H20150324; specification, 50 μ g/250 μ g/bubble) treatment, 1 inhalation/time, 2 times/d, with an interval of 12 hours between each time. The observation group was treated with tiotropium bromide inhalation powder (National drug approval number, H20090279; specification, 18 μ g) produced by Zhejiang Xianju Pharmaceutical Co., Ltd., 1 inhalation/time, 1 time/day. The treatment lasted for 3 months for both groups.

2.3. Observation indicators

- (i) Clinical curative effect
 - After treatment, the clinical efficacy of the two groups was evaluated according to "Experience in the Treatment of Asthma-COPD Overlap Syndrome." Disappearance of clinical symptoms and asthma attacks were considered to be markedly effective; significant improvement in clinical symptoms and the reduction of asthma attacks by >50% was considered effective; no improvement in clinical symptoms was considered as ineffective. Total efficacy = 1 efficacy.
- (ii) Lung function
 - The pulmonary function detector (model: MSA 100) provided by Jinan Jiawan Biotechnology Co., Ltd. was used to measure the forced vital capacity (FVC), forced expiratory volume in 1 second (FEV₁), and residual volume-total lung capacity ratio (RV/TLC) levels were tested before and after treatment.
- (iii) Asthma control test (ACT) score, chronic obstructive pulmonary disease assessment test (CAT) score, frequency of acute exacerbation
 - ACT and CAT scores ^[5,6] were used to evaluate the patient's condition before and after treatment, with a total score of 25 and 40 points, respectively. The more serious the patient's condition, the lower the ACT scores, whereas the lower the CAT score, the better the patient's condition. Besides, the frequency of acute exacerbation in the two groups was also recorded.

2.4. Statistical methods

The measurement data are represented by (mean \pm SD), and the t test is adopted. The count data are expressed in [case (%)], and the χ^2 test is used, and P < 0.05 indicates that the difference is statistically significant. Statistical analysis of the data was performed using SPSS 20.0 statistical software.

3. Results

3.1. Clinical efficacy

Table 1 shows that the total clinical effective rate of the observation group was 96.55% (28/29), which was significantly higher than that of the control group (65.52% [19/29]), P < 0.05, and the difference was significant.

Table 1. Comparison of clinical efficacy between the two groups [case (%)]

| Group | Number of cases | Markedly effective | Effective | Ineffective | Total effective rate |
|-------------------|-----------------|--------------------|------------|-------------|----------------------|
| Control group | 29 | 7 (24.14) | 12 (41.38) | 10 (34.48) | 19 (65.52) |
| Observation group | 29 | 19 (65.52) | 9 (31.03) | 1 (3.45) | 28 (96.55) |
| χ^2 | | | | | 7.180 |
| P | | | | | 0.007 |

3.2. Pulmonary function

Table 2 shows that the FVC and FEV₁ levels of the two groups increased after treatment, and the observation group showed bigger values than the control group; the RV/TLC of both groups decreased, in which the observation group showed smaller values than the control group; P < 0.05, the difference is significant.

Table 2. Comparison of lung function between the two groups (mean \pm SD)

| Group | N | FVC(L) | | FEV ₁ (L) | | RV/TLC (%) | |
|---------------|----------|-----------------|-------------------|----------------------|-------------------|------------------|--------------------|
| | Number | Before | After | Before | After | Before | After |
| | of cases | treatment | treatment | treatment | treatment | treatment | treatment |
| Control group | 29 | 1.13 ± 0.21 | $1.63 \pm 0.27^*$ | 1.52 ± 0.14 | $1.76 \pm 0.34^*$ | 43.12 ± 4.57 | $38.33 \pm 4.41^*$ |
| Observation | 29 | 1.16 ± 0.09 | $2.01 \pm 0.33^*$ | 1.50 ± 0.16 | $2.44 \pm 0.42^*$ | 43.09 ± 4.61 | $33.82 \pm 3.22^*$ |
| group | 29 | | | | | | |
| t | | 0.707 | 4.799 | 0.507 | 6.777 | 0.025 | 4.448 |
| P | | 0.482 | < 0.001 | 0.614 | < 0.001 | 0.980 | < 0.001 |

Note: ${}^*P < 0.05$, differences between before and after treatment of the same group

3.3. Frequency of acute exacerbations, ACT and CAT scores

Table 3 shows that the frequency of acute exacerbations and CAT scores of the two groups decreased after treatment, in which the observation group showed lower scores than the control group; the ACT score increased, and the observation group scored higher compared to the control group, with P < 0.05, which meant that the difference was significant.

Table 3. Comparison of acute exacerbation frequency, ACT and CAT scores between the two groups (mean \pm SD)

| Group | Number | Acute exacerbation frequency (times) | | ACT score (points) | | CAT score (points) | |
|-------------------|----------|--------------------------------------|-------------------|--------------------|--------------------|--------------------|--------------------|
| | of cases | Before | e After Before | | After | Before | After |
| | | treatment | treatment | treatment | treatment | treatment | treatment |
| Control group | 29 | 3.01 ± 0.06 | $2.11 \pm 0.44^*$ | 12.27 ± 1.38 | $18.45 \pm 1.67^*$ | 30.46 ± 3.03 | $22.17 \pm 2.24^*$ |
| Observation group | 29 | 3.03 ± 0.04 | $1.56 \pm 0.32^*$ | 12.24 ± 1.40 | $22.47 \pm 2.32^*$ | 30.55 ± 3.01 | $15.14 \pm 1.67^*$ |
| t | | 1.494 | 5.444 | 0.082 | 7.573 | 0.113 | 13.550 |
| P | | 0.141 | < 0.001 | 0.935 | < 0.001 | 0.910 | < 0.001 |

Note: ${}^*P < 0.05$, differences between before and after treatment of the same group

4. Discussion

ACOS is more common among the 40-year-old population, and it will lead to different degrees of chronic airway obstruction and inflammation in patients, which will lead to more serious damage to the lungs of the patients. If it is not treated in time, it will further develop into lung failure. The current clinical treatment to patients with ACOS usually involves bronchial dilation, inhalation of hormones, and control of airway inflammatory response. Among them salmeterol-fluticasone powder inhalation is commonly used in the form of combination therapy for the treatment of reversible obstructive airway disease. The drug is a type of $\beta 2$ receptor agonist, which has a certain effect on bronchial smooth muscle and can improve the lung function of patients, but the drug takes a long time to take effect, and the overall therapeutic effect is not ideal.

Tiotropium bromide is a M3 receptor selective blocker, which is a selective specific anticholinergic drug, which can significantly improve the symptoms of cough, sputum, respiratory limitation, dyspnea, and other symptoms. Besides, the drug can inhibit the expression of smooth muscle myosin, thereby significantly reducing the number of smooth muscle cells, which in turn inhibits the remodeling of airway smooth muscle, and the drug can have a long-term effect on M3 receptors, so as to achieve sustained role of bronchiectasis and the effect of reducing airway inflammatory response, thereby improving the lung function of patients, effectively relieving clinical symptoms, reducing the frequency of acute exacerbations, and improving clinical efficiency. The results of this study showed that the total clinical effective rate and ACT score of the observation group were higher than those of the control group, and the frequency of acute exacerbation and CAT score were lower than those of the control group. Yu *et al.* ^[7] found similar results.

FVC, FEV₁ and RV/TLC are indicators of lung function. When a patient's lung function is damaged, the levels of FVC and FEV₁ will decrease, while RV/TLC will increase. Tiotropium bromide is an anticholinergic drug that can act on M1 and M2 receptors and has a high affinity towards airway receptors. It inhibits M3 and M1 type muscarinic receptors, thus promoting long-term dilation of the bronchi. This results in an increase in inspiratory capacity, and the patient's end-expiratory volume can be significantly reduced, thereby improving the patient's dyspnea symptoms, further improving the patient's lung function. In addition, compared to $\beta 2$ agonists, tiotropium bromide has longer-lasting and milder drug effect. The results of this study show that the FVC and FEV₁ levels of the observation group were higher than those of the control group, and the RV/TLC was lower than that of the control group, which means that the effect of tiotropium bromide is better than that of salmeterol-ticasone. Tropium bromide treatment of ACOS patients can significantly improve the lung function of patients, which is consistent with the research results of Li *et al* [8].

5. Conclusion

In conclusion, tiotropium bromide has a significant clinical curative effect in the treatment of patients with ACOS and can effectively improve the lung function of patients, which makes it worthy of popularization.

Disclosure statement

The author declares no conflict of interest.

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