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# Analysis of the Clinical Efficacy of Budesonide Combined With Ambroxol Inhalation Therapy for Neonatal Pneumonia

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**Abstract:** This study explores the clinical efficacy of budesonide combined with ambroxol inhalation therapy for neonatal pneumonia. A total of 68 neonatal pneumonia patients treated at Li County Hospital from January 2023 to December 2024 were randomly divided into a monotherapy group and a combination group, with 34 patients in each. The monotherapy group received ambroxol inhalation therapy, while the combination group received budesonide inhalation therapy in addition to ambroxol. The recovery progress, blood gas analysis indicators, inflammatory response improvement, and overall clinical efficacy were compared between the two groups. Results showed that the combination group experienced a significantly shorter time for body temperature normalization (3.36 ± 0.58 days vs. 4.59 ± 0.45 days), oxygen inhalation duration (4.89 ± 0.57min vs. 6.96 ± 0.79min), disappearance of shortness of breath and cough (4.56 ± 0.29 days vs. 6.63 ± 0.75 days), and resolution of lung wet rales (5.62 ± 1.46 days vs. 7.92 ± 1.28 days) compared to the monotherapy group ($P < 0.05$). Additionally, the total effective rate was significantly higher in the combination group (97.06%) than in the monotherapy group (73.52%) ($P < 0.05$). Post-treatment, the combination group exhibited significantly better blood gas analysis and inflammatory response indicators ($P < 0.05$). These findings suggest that budesonide combined with ambroxol inhalation therapy can effectively improve blood oxygen saturation, reduce inflammation, promote faster recovery, and enhance overall clinical efficacy, making it a reliable treatment option for neonatal pneumonia.

**Keywords:** Budesonide; Ambroxol; Inhalation therapy; Neonatal pneumonia; Clinical efficacy

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## 1. Introduction

Neonatal pneumonia is a common disease among newborns, primarily caused by amniotic fluid and meconium aspiration, pathogenic infection, etc. It can lead to symptoms such as fever, cough, poor reactivity, and shortness of breath. In severe cases, it can affect other organs or systems of the infant, causing complications such as respiratory failure and nervous system damage. Early intervention and treatment are necessary to reduce the risk

of adverse outcomes [1]. Scientific treatment of neonatal pneumonia is crucial to improve respiratory symptoms and control disease progression, thereby improving the prognosis of the infant. Neonatal pneumonia can lead to increased respiratory secretions, but infants cannot effectively expel phlegm. Therefore, ambroxol inhalation therapy measures are needed to dilute the phlegm, promote phlegm discharge, and improve respiratory tract patency [2].

Budesonide is a highly effective anti-inflammatory drug that can improve respiratory inflammatory responses, promote bronchodilation, and relieve symptoms of cough, asthma, and shortness of breath in infants. It can be used in combination with ambroxol to promote phlegm expulsion and improve symptoms such as shortness of breath. However, the specific effect of combining the two drugs via inhalation therapy for neonatal pneumonia is still unclear. Therefore, this study selected 68 infants with pneumonia treated in the neonatology department of Li County Hospital from January 2023 to December 2024 to compare and analyze the rehabilitation effect and medication safety of combined inhalation therapy.

## 2. Materials and methods

### 2.1 General information

Sixty-eight infants with pneumonia treated in the pediatrics department of Li County Hospital from January 2023 to December 2024 were selected as the research subjects. They were divided into a monotherapy group and a combination group using a random number table method, with 34 infants in each group. In the combination group, there were 18 males and 16 females, with a gestational age ranging from 4 to 22 days (average: 24.15 ± 3.12 days), a disease duration of 1 to 5 days (average: 3.75 ± 0.75 days), a body weight of 2418 to 3702 g (average: 3163.52 ± 152.52 g), and a gestational age of 37 to 42 weeks (average: 38.16 ± 1.61 weeks). In the monotherapy group, there were 19 males and 15 females, with a gestational age ranging from 4 to 23 days (average: 24.13 ± 3.15 days), a disease duration of 1 to 5 days (average: 3.82 ± 0.76 days), a body weight of 2419 to 3710 g (average: 3168.49 ± 152.57 g), and a gestational age of 37 to 42 weeks (average: 38.15 ± 1.53 weeks). The general information of the two groups was comparable ($p > 0.05$). This study was approved by the hospital ethics committee.

### 2.2 Inclusion and exclusion criteria

The inclusion criteria were:

(1) Diagnosed with neonatal pneumonia based on sputum culture and chest X-ray examination

(2) Presence of symptoms such as cough, expectoration, and fever

(3) Complete clinical and related maternity data of the infant

(4) No significant malformation of the respiratory system

(5) Family members of the infant have signed an informed consent form.

Meanwhile, the exclusion criteria includes:

(1) Abnormal liver, kidney, or heart function

(2) Comorbidities such as anemia

(3) Congenital malformations of the infant

(4) Received relevant treatment before admission

(5) Transferred to another hospital during treatment

(6) Presence of contraindications for inhalation therapy

## 2.3. Methods

The monotherapy group received ambroxol inhalation therapy: Ambroxol Hydrochloride Injection (Yinuoshu, Tianjin Institute of Pharmaceutical Research Pharmaceutical Co., Ltd., specification: 2ml:15mg*10 vials, National Medical Approval Number H20041473), mixed with 2–3mL of normal saline, was administered via nebulization, twice a day for a continuous treatment of 1 week. At the same time, nutritional support, anti-infection treatment, oxygen inhalation therapy, and correction of acid-base imbalance were provided according to the patient's condition.

The combination group received budesonide inhalation therapy on the basis of the monotherapy group: Budesonide Suspension for Inhalation (Chengdu Zhengda Tianqing Pharmaceutical Group Co., Ltd., specification: 2ml:1mg*5 vials, National Medical Approval Number H20203063), 1mL per time, was added to the nebulization solution (same as the monotherapy group), twice a day for a continuous treatment of 1 week.

## 2.4. Observation indicators

### 2.4.1. Observation of rehabilitation indicators

Observe and record the time for the child's body temperature to return to normal, oxygen inhalation time, disappearance time of shortness of breath and cough, and disappearance time of lung wet rales.

### 2.4.2. Therapeutic effect evaluation

Refer to "Practical Neonatology" to evaluate the treatment effect of patients:

(1) Cured: body temperature returns to normal, clinical symptoms completely resolve, and laboratory indicators basically return to normal

(2) Markedly effective: body temperature returns to normal, clinical symptoms and laboratory indicators significantly improve

(3) Effective: body temperature returns to normal, clinical symptoms and laboratory indicators improve

(4) Ineffective: fail to meet the above criteria, or the condition worsens.

The total effective rate is calculated by using the formula below [3]:

Total effective rate = (sample size - ineffective) / sample size × 100.00%

### 2.4.3. Blood gas index monitoring

Before and after treatment, use a BG-800A blood gas and electrolyte analyzer to measure arterial oxygen partial pressure, arterial carbon dioxide partial pressure, and oxygenation index, and measure the child's blood oxygen saturation. Compare the differences between the two groups.

### 2.4.4. Monitoring of inflammatory response indicators

Collect fasting venous blood before and after treatment, and detect serum C-reactive protein, white blood cell count, and procalcitonin levels by enzyme-linked immunosorbent assay.

### 2.4.5. Monitoring of adverse reactions

Observe whether children experience adverse reactions such as oral inflammation, nausea and vomiting, and skin rashes, and compare the incidence between the two groups.

## 2.5. Statistical methods

Analyze all data using SPSS 20.0 statistical software. Measurement data is expressed as mean ± standard deviation ($\bar{x} \pm s$) and tested using the t-test. Count data is expressed as (n,%) and tested using the $\chi 2$ test. $P < 0.05$ is considered statistically significant.

# 3. Results

## 3.1. Comparison of recovery indicators between the two groups

The time for body temperature to return to normal, oxygen inhalation time, disappearance time of shortness of breath and cough, and disappearance time of lung wet rales in the combination group were significantly shorter than those in the monotherapy group ($P < 0.05$). See **Table 1**.

**Table 1.** Comparison of recovery indicators between the two groups($\bar{x} \pm s$)

| Groups | *n* | Time for body temperature to return to normal (days) | Oxygen inhalation time (minutes) | Time for shortness of breath and cough to resolve (days) | Time for lung wet rales to disappear (days) |
|---|---|---|---|---|---|
| Combination group | 34 | 3.36 ± 0.58 | 4.89 ± 0.57 | 4.56 ± 0.29 | 5.62 ± 1.46 |
| Monotherapy group | 34 | 4.59 ± 0.45 | 6.96 ± 0.79 | 6.63 ± 0.75 | 7.92 ± 1.28 |
| *t* | | 5.502 | 6.098 | 4.918 | 5.609 |
| *P* | | 0.015 | 0.012 | 0.023 | 0.014 |

## 3.2. Comparison of total effective rates between the two groups

The total effective rate of the combination group (97.06%) was significantly higher than that of the monotherapy group (73.52%) ($P < 0.05$). See **Table 2**.

**Table 2.** Comparison of total effective rates between the two groups (n, %)

| Groups | *n* | Cured | Markedly effective | Effective | Ineffective | Total effective rate |
|---|---|---|---|---|---|---|
| Combination group | 34 | 12(35.23) | 13(38.24) | 8(23.53) | 1(2.3) | 33(97.06) |
| Monotherapy group | 34 | 8(23.53) | 11(32.35) | 6(17.65) | 9(26.47) | 25(73.52) |
| $\chi^2$ | | | | | | 5.326 |
| *P* | | | | | | 0.016 |

## 3.3. Comparison of blood gas indicators between the two groups

The blood gas indicators of both groups were significantly better after treatment compared to before treatment ($P < 0.05$). The arterial oxygen partial pressure, oxygenation index, and blood oxygen saturation were significantly higher in the combination group compared to the monotherapy group after treatment ($P < 0.05$), while the arterial carbon dioxide partial pressure was significantly lower in the combination group ($P < 0.05$). See **Table 3**.

**Table 3.** Comparison of blood gas analysis indicators($\bar{x} \pm s$)

| Groups | Arterial oxygen partial pressure(mmHg) | | Arterial carbon dioxide partial pressure(mmHg) | | Oxygenation index | | Blood oxygen saturation(%) | |
|---|---|---|---|---|---|---|---|---|
| | Before treatment | After treatment | Before treatment | After treatment | Before treatment | After treatment | Before treatment | After treatment |
| Combination group | 59.68 ± 4.11 | 78.69 ± 3.11* | 51.49 ± 3.16 | 42.69 ± 4.02* | 238.56 ± 5.19 | 301.25 ± 11.46* | 92.72 ± 1.76 | 98.22 ± 0.71* |
| Monotherapy group | 59.71 ± 4.13 | 74.69 ± 4.03* | 51.48 ± 3.19 | 47.31 ± 3.92* | 238.58 ± 5.21 | 279.68 ± 12.03* | 92.71 ± 1.74 | 96.25 ± 1.13* |
| *t* | 0.089 | 5.152 | 0.092 | 6.109 | 0.082 | 5.253 | 0.015 | 4.136 |
| *P* | 0.902 | 0.017 | 0.897 | 0.008 | 0.859 | 0.016 | 0.829 | 0.027 |

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

## 3.4. Comparison of inflammatory response indicators between the two groups

The inflammatory response indicators of both groups were significantly lower after treatment compared to before treatment ($P < 0.05$). The levels of C-reactive protein, white blood cell count, and procalcitonin were significantly lower in the combination group after treatment compared to the monotherapy group ($P < 0.05$). See **Table 4**.

**Table 4.** Comparison of inflammatory response indicators between the two groups($\bar{x} \pm s$)

| Groups | C-reactive protein (mg/L) | | White blood cell count ($\times 10^9$/L) | | Procalcitonin (ng/L) | |
|---|---|---|---|---|---|---|
| | Before treatment | After treatment | Before treatment | After treatment | Before treatment | After treatment |
| Combination group | 12.36 ± 1.57 | 4.23 ± 1.11* | 8.98 ± 1.02 | 4.56 ± 0.72* | 2.39 ± 0.25 | 0.86 ± 0.11* |
| Monotherapy group | 12.41 ± 1.54 | 7.98 ± 0.86* | 8.96 ± 1.03 | 6.59 ± 0.65* | 2.38 ± 0.26 | 0.43 ± 0.10* |
| *t* | 0.039 | 6.908 | 0.042 | 5.984 | 0.053 | 6.017 |
| *P* | 0.916 | 0.012 | 0.893 | 0.018 | 0.889 | 0.010 |

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

## 3.5. Monitoring of adverse reactions

In the combination group, there was 1 case of oral inflammation, 1 case of nausea and vomiting, and 1 case of rash. In the monotherapy group, there was 1 case of oral inflammation and 1 case of rash. There was no statistically significant difference in adverse reactions between the two groups (8.82%, 3/34; 5.88%, 2/34) ($P < 0.05$).

# 4. Discussion

Neonatal pneumonia is an important cause of neonatal death and belongs to infectious diseases with a relatively high incidence. Early diagnosis and timely standardized treatment of neonatal pneumonia can effectively improve the condition of the child, control disease progression, and reduce mortality [4]. The clinical treatment of neonatal pneumonia mainly focuses on antibiotic infection control and symptomatic supportive treatment, which can alleviate the patient's condition and requires early intervention. Children with neonatal pneumonia often have significant respiratory symptoms, such as cough, respiratory obstruction, and shortness of breath, which seriously affect normal breathing. Measures such as nebulized inhalation therapy should be taken in a timely manner to

improve respiratory obstruction and respiratory symptoms [5].

Ambroxol is a clinically commonly used drug for removing phlegm and promoting phlegm excretion. It can improve the movement of respiratory cilia, promote the excretion of respiratory secretions, and also increase the activity of surface factors on the airway mucosa, promote the dissolution and dilution of secretions, improve phlegm blockage, and facilitate phlegm excretion [6]. Children with neonatal pneumonia have a significant increase in respiratory secretions, but their ability to expectorate phlegm is limited. Reducing mucus adherence in the respiratory tract and using ambroxol nebulization inhalation therapy can promote the dissolution and excretion of respiratory mucus, which is beneficial for the recovery of respiratory function in children. However, some children may have a poor response to monotherapy, so combination therapy can be used to improve efficacy [7]. The pulmonary inflammatory response in children can damage tissue and organ functions. Budesonide is a highly effective glucocorticoid drug with strong anti-inflammatory effects. After administration through nebulized inhalation, it can bind to receptors in local cells, inhibit inflammatory reactions, reduce the release of related cytokines, reduce local mucosal tissue swelling, improve bronchial spasms, and promote the recovery of respiratory mucosal function. It has a reliable effect on improving airway symptoms in children with pneumonia [8]. The combination of budesonide and ambroxol for nebulized inhalation therapy can exert a synergistic effect. Relevant literature reports show that the combination of the two can exert dual effects of anti-inflammatory and promoting phlegm excretion, which helps to improve respiratory symptoms and blood gas analysis indicators in children with neonatal pneumonia [9]. This study also found that the combination of nebulized inhalation therapy can significantly improve children's blood gas analysis indicators and inflammatory response factors, thereby effectively improving the clinical efficacy and recovery speed of children, and has high application value. In addition, this study also found that there was no significant difference in the incidence of adverse reactions between the two groups, suggesting that the combination of nebulized inhalation therapy does not increase the risk of adverse reactions and has reliable safety.

## 5. Conclusion

In summary, the combination of nebulized inhalation therapy can effectively improve children's blood oxygen saturation and blood gas analysis indicators, and help reduce inflammatory reactions in children, promote their rapid recovery, and significantly improve the overall efficacy. The clinical application effect is reliable.

## Disclosure statement

The author declares no conflict of interest.

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