



A COMPARATIVE STUDY ON THE EFFICACY OF AMBROXOL HYDROCHLORIDE AND AMBROXOL HYDROCHLORIDE WITH N-ACETYL CYSTEINE IN THE TREATMENT OF BRONCHOPNEUMONIA IN CHILDREN AND THEIR INFLUENCE ON PROGNOSIS

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ABSTRACT

Background: About 2.5 million people died from bronchopneumonia in 2019. Almost a third of all victims were children younger than 5 years, it is the leading cause of death for children under 5 years, bronchopneumonia is an infection of the tiny air sacs of the lungs, called alveoli. We conducted a comparative study to evaluate the efficacy of ambroxol hcl and combination of N-acetylcysteine with ambroxol hcl for the treatment of bronchopneumonia in children. **Aim:** The main objective of the study is to compare the efficacy of Ambroxol Hcl and combination of N-acetyl cysteine with Ambroxol Hcl by comparing the symptoms disappearance time, adverse reactions and quality of life between the two groups. **Materials and Methods:** A comparative observational study was Conducted in pediatrics department in a tertiary-care hospital. The data was collected from the in-patient department after considering all the inclusion and exclusion criteria for a period of 6 months and a total of 116 children with bronchopneumonia were analyzed with data collection form and SF-36 scoring questionnaire and physical examination. statistical tools like chi-square test were applied to the data by using spas version -22, IBM software. **Results:** A total of 116 children with bronchopneumonia were enrolled in this study. Among them 60 children were treated with N-acetyl cysteine and Ambroxol HCl and comprised as group A, and 56 children were treated with Ambroxol HCL and comprised as group-B. children physical signs and adverse reactions to the treatment were recorded and observed, and symptoms disappearance time was recorded and the quality of life after the treatment was investigated. There was no significant difference in clinical data between two groups ($p > 0.05$). The effective rate in the group A (93.3%) was significantly higher than that in the group B (85.7%). The disappearance time of symptoms was significantly shorter in group A than in group B. ($p < 0.05$). The hospitalization time of children in group A was shorter than that in group B. The incidence of adverse reactions in group A was significantly lower than that in group B. **Conclusion:** By comparing the symptom disappearance time and adverse reaction between the two group, the total efficacy of combination of N-acetyl cysteine with Ambroxol HCL in the treatment of bronchopneumonia in children was higher than the children treated with only Ambroxol HCL. SF-36 scoring system concluded better quality of life in children receiving combination of Ambroxol HCL and N-acetyl cysteine compared to the children receiving Ambroxol HCL only.

KEYWORDS: Bronchopneumonia, ambroxol hydrochloride, N-acetyl cysteine, SF-36 scoring system.

1. INTRODUCTION

Bronchopneumonia refers to inflammation of the lung that is centered in the bronchioles and leads to the production of mucopurulent exudates that obstructs some of the small airways and causes patchy consolidation of the adjacent lobules^[1] (c.k. Dhanapal, 2009). Mycoplasma pneumoniae, together with bacteria and

viruses, is one of the most important cause of bronchopneumonia and there are also infections caused by both bacteria and viruses^[2] (Zhang XL, 2007). Symptoms of bronchopneumonia include fever, breathing difficulty, chest pain, coughing up mucus, sweating, chills or shivering, muscle aches, loss of appetite, nausea and vomiting^[3] (Aaron Kandola, 2018).

Oral antibiotics constitute the basic clinical treatment for bronchopneumonia. However, antibiotics cause great damage to the nervous system, blood system and liver function^[4] (Che XY, 2016). In the present study, aerosol inhalation was used for the treatment of bronchopneumonia in order to convert liquid medicine into water mist through ultrasonic electronic high frequency vibration. This method is convenient for children for active respiratory inhalation and as the drug directly targets lesions, and is also effective for expectoration, cough relief, anti-inflammation and spasmolysis^[5] (Chunyun, 2010).

Intravenous injection of ambroxol hydrochloride is a common treatment for bronchopneumonia in adults^[6] (Zhou WF, 2011). However, children often have fear of oral and injectable drugs, which affects treatment compliance and coordination, and requires long term hospitalization, increasing the risk of iatrogenic infections.^[7] (Pairet M, 2011). Therefore, in recent years, aerosol inhalation has been included in the treatment of pediatric bronchopneumonia, effectively reducing side effects and ensuring children safety^[8] (Behrendt G, 2013).

In clinical practice, commonly used drugs for bronchopneumonia are ambroxol hydrochloride and N-acetylcysteine, which are antitussive drugs, although N-acetylcysteine is an amino acid with strong mucus dissolution^[9] (Hongbo Liu, 2020). In the present study, the efficacy of ambroxol hydrochloride and N-acetylcysteine aerosol inhalation were compared in the treatment of children with bronchial pneumonia, as well as their effect on prognosis.

2. MATERIALS AND METHODS

From January 2018 to June 2019, 100 children with bronchopneumonia admitted to the Pediatric Department of Nanjing Pukou District Hospital of Traditional Chinese Medicine were enrolled as the study subjects. The children were assigned either to an observation group or a control group in a ratio of 1 : 1 using the random alphabet method. The study has been reviewed and approved by the medical ethics committee (no. 2018/14–524), and the family members of the children prior From January 2018 to June 2019, 100 children with bronchopneumonia admitted to the Pediatric Department of Nanjing Pukou District Hospital of Traditional Chinese Medicine were enrolled as the study

subjects. The children were assigned either to an observation group or a control group in a ratio of 1 : 1 using the random alphabet method. The study has been reviewed and approved by the medical ethics committee (no. 2018/14–524), and the family members of the children prior

2.1 General information: From January,2022 to June,2022, 110 children with bronchopneumonia admitted to the pediatric department of Kamineni hospital, hyderabad were enrolled as the study subjects. The study has been reviewed and approved by the medical ethics committee, and the family members of the children provided informed consent prior to its commencement

2.2 Inclusion and Exclusion criteria

2.2.1 Inclusion criteria: 1.children with <14 years of age, who met the diagnostic criteria for bronchial pneumonia (K.Asano, 2021); 2. Subjects who are receiving ambroxol hydrochloride and N-acetyl cysteine with ambroxol hcl; 3.Subjects family members or guardians willing to give consent; 4. Subjects with normal liver and kidney functioning

2.2.2 Exclusion criteria: 1.subjects aged >14 years of age; 2.subjects withdrawn from therapy; 3.subjects with other serious comorbidities; 4.subjects guardians or families not willing to give consent for study.

Statistical analysis

The data were statistically analysed by using MS-EXCEL and statistical package for social sciences (SPSS Version -22, IBM) software. Statistical tool chi-square test was executed to estimate the p value between the different collected data like age versus gender, symptoms disappearance time, adverse drug reactions, effective rate versus two groups P value is to estimate the statistical significance within statistical hypothesis significance for the efficacy for both groups.P value was set at 0.05 and confidence interval was 95%.

RESULTS

A total of 116(1-14 years) children with bronchopneumonia admitted in to the hospital were included in the study. Among them, 60 children were considered as group A, treated with ambroxol hcl and NAC of which 31 are boys and 29 are girls with a mean age of 3.4 ± 2.264 years and 50 children were considered as group B, treated with ambroxol hcl alone.

Age Distribution

Table 1: Represents age wise distribution of children treated with ambroxol hcl and N-acetylcysteine.

AGE	NO. OF CHILDREN	PERCENTAGE
>3YRS	38	63.33
4-14YRS	22	36.67

Table 2: Represents age wise distribution of children treated with ambroxol hcl.

AGE	NO. OF CHILDREN	PERCENTAGE
<3YRS	36	64.28
4-14 YRS	20	35.72

Gender Distribution**Table 3: Represents gender wise distribution of children treated with ambroxol hcl and N-acetylcysteine.**

GENDER	NO. OF CHILDREN	PERCENTAGE
BOYS	31	51.7
GIRLS	29	48.3

Table 4: Represents the gender wise distribution of children treated with ambroxol hcl.

GENDER	NO.OF CHILDREN	PERCENTAGE
BOYS	27	48.2
GIRLS	29	51.8

Table 5: Represents the pulmonary auscultation wise distribution in both groups.

Pulmonary auscultations	Group A	Group B
Pulmonary rales	35 (58.33%)	42 (75%)
Tubular sounds	25 (41.67%)	14 (25%)

Group A= children treated with combination of NAC
with Ambroxol hcl

Group B= children treated with ambroxol hcl only

Table 6: Represents hospitalization status of both groups.

Hospitalization time	Group A	Group B
<5 days	51	34
>5 days	9	22

Table 7: Represents the comparison of symptoms disappearance time between two groups.

GROUPS	NO OF CASES	FEVER	COUGH	COLD	RALES	SOB
Group A	60	1.33±0.86	5.03±2.09	5.03±1.48	1.92±1.9	1.42±1.81
Group B	56	1.25±1.03	7.36±1.47	4.61±2.76	1.82±1.26	1.20±1.11
T value		0.475	-6.879	1.043	0.305	0.780
P value		0.013	0.181	0.0	0.001	0.001

Table 8: Represents the comparison of adverse reactions in both group.

GROUP	NO OF CASES	VOMIT	ABDOMINALPAIN	DIARRHOEA	NAUSEA
Group A	60	1	0	1	0
Group B	56	3	2	2	1
X		1.185	2.18	0.417	1.081
P-Value		0.276	0.14	0.518	0.299

Table 9: Represents the comparison of efficacy of treatment in both groups.

Group	No of cases	Significantly effective cases	Effective cases	Ineffective cases	Total efficacy
Group A	60	32 (53.3)	24 (40)	4 (6.67)	56 (93.3)
Group B	56	28 (50)	20 (35.7)	8 (14.28)	48 (85.71)

Table 10: Comparison of quality of life between two groups.

Factors	Group A (n=60)	Group B (n=56)	t-value	p-value
Physiological Functioning	81.36±10.96	69.29±11.35	5.947	<0.001
Somatic Pain	88.05±10.49	69.23±12.54	8.885	<0.001
General Health Status	83.66±9.81	71.07±12.14	6.223	<0.001
Vitality	83.14±10.26	73.79±13.79	4.191	<0.001
Social Role Functioning	63.21±10.67	63.54±11.37	0.164	0.873
Emotional Role Functioning	72.63±12.09	69.98±12.04	0.232	1.202
Mental Health	83.62±10.48	81.18±10.46	1.276	0.2045

DISCUSSION

A comparative study on "The Efficacy Of Ambroxol Hcl And Combination Of N-Acetylcysteine With Ambroxol Hcl In The Treatment Of Bronchopneumonia In Children And Their Influence On Prognosis" was implemented in tertiary care hospital in inpatients of pediatrics department.

The main purpose of the present study was to compare the efficacy of treatment with Ambroxol HCl and combination of Ambroxol HCl and N-acetyl cysteine in children with bronchopneumonia. The results showed that the clinical symptoms relief time in children treated with Ambroxol HCl and N-acetyl cysteine aerosol inhalation was significantly shorter than that of children treated with single Ambroxol HCl and the total clinical effective rate was (93.3%), which was higher than that of children treated with Ambroxol HCl (85-71%) ($p < 0.05$).

In the present study the SF-36 scoring system. was also used to measure the quality of life of the two groups of patients after treatment, including the assessment of physiological functioning, somatic pain, general health status I, vitality, social functioning and mental health. The results revealed that the patients treated with Ambroxol HCl + N-acetyl cysteine had significantly higher scores than the patients treated with Ambroxol HCl. N-acetylcysteine combination with Ambroxol HCl dissolves sputum, reduces sputum adhesion force increase the cilia movement and inhibits the growth of pathogenic bacteria, reducing the local inflammation reaction, thus impairing des immunity system, so that the body's humoral immunity gradually returns to normal. In present study the number of patients selected were small and the results therefore limited. The reliability of the presented data needs to be further verified by future studies with greater sample size.

In summary the present study showed that total effective rate & quality of life in two group of children were significantly improved after different treatments. Combination of aerosol inhalation of N-acetyl cysteine and oral Ambroxol HCl can effectively improve the clinical symptoms and signs of children with bronchopneumonia and the curative effect is remarkable suggesting that N-acetyl cysteine with Ambroxol HCl treatment is worthy of use in clinic to decrease the hospitalization time.

CONCLUSION

By comparing the symptom disappearance time and adverse reaction between the two group, the total efficacy of combination therapy of Ambroxol HCl and N-acetyl cysteine in the treatment of bronchopneumonia in children was higher than the children treated only with Ambroxol HCl. SF-36 scoring system concluded better quality of life in children receiving combination of Ambroxol HCl and N-acetylcysteine compared to the children receiving Ambroxol HCl only.

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