Section: Paediatrics

Original Research Article

# EFFECTIVENESS OF N-ACETYL CYSTEINE VS 3% NACL NEBULISATION IN CHILDREN WITH ACUTE BRONCHIOLITIS AGED 6 MONTHS TO 2 YEARS: A RANDOMISED CONTROLLED TRIAL

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## ABSTRACT

**Background:** Acute bronchiolitis is a leading cause of lower respiratory tract infection and hospitalization in infants and young children under two years of age. Management is largely supportive, and the role of nebulized agents targeting airway secretions remains an area of active research. Hypertonic saline (3% NaCl) and N-acetyl cysteine (NAC) have been used to improve mucociliary clearance, but comparative evidence is limited. The aim is to determine the effectiveness of N-Acetyl Cysteine nebulisation in hospitalised children with acute bronchiolitis aged 6months to 2 years of mild to moderate severity. **Materials and Methods:** This randomized, single-blinded controlled trial was conducted in the Department of Paediatrics, Aarupadai Veedu Medical College and Hospital, Puducherry, over 18 months. Sixty children aged 6 months to 2 years with first-episode acute bronchiolitis were randomized into two groups: Group A received nebulized N-acetyl cysteine and Group B received nebulized 3% NaCl. Clinical severity was assessed using the Wang Clinical Severity Score before and after nebulization from Day 1 to Day 5. The duration of hospital stay was also recorded. Data were analyzed using descriptive statistics and chi-square test using SPSS version 26.0. Independent sample t test was used to analyze the before and after nebulisation and duration of hospital stay in days difference between both group A and group B. $P < 0.05$ is considered significant. **Result:** Baseline demographic and clinical characteristics were comparable between groups. Post-nebulization clinical severity scores were significantly lower in the NAC group from Day 1 onwards ($p < 0.05$), with faster and sustained clinical improvement. The mean hospital stay was significantly shorter in Group A ($3.50 \pm 0.51$ days) compared to Group B ($6.20 \pm 0.85$ days) ($p = 0.001$). **Conclusion:** Nebulized N-acetyl cysteine is more effective than 3% hypertonic saline in reducing clinical severity and hospital stay in children with acute bronchiolitis, making it a safe and beneficial therapeutic option.

## INTRODUCTION

Acute bronchiolitis is a common lower respiratory tract infection affecting infants and young children, typically under two years of age. It is characterized by inflammation, edema, and increased mucus production in the small airways, leading to clinical features such as cough, wheezing, tachypnea, and respiratory distress. Bronchiolitis is most frequently caused by viral infections, with respiratory syncytial virus (RSV) being the predominant pathogen.[1]

Acute viral bronchiolitis (AVB) is one of the leading causes of hospital admission in infancy and is almost entirely attributable to viral pathogens, with respiratory syncytial virus (RSV) being the most frequently implicated agent. The illness commonly begins with upper respiratory tract symptoms such as nasal congestion and rhinorrhea, followed by cough and progressive features of respiratory distress, including tachypnea, wheezing, and increased work of breathing.

Viral bronchiolitis is a leading cause of hospitalization in infants, accounting for nearly 20% of admissions in children under one year of age.[2] It primarily affects children under two years, with the highest incidence observed in infants between 2 and 5 months. Seasonal peaks generally occur from December to March.[3] Respiratory syncytial virus


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(RSV) is the predominant pathogen, responsible for 70–80% of lower respiratory tract infections during the high season.[4] Other viruses, including human metapneumovirus, adenovirus, parainfluenza virus type 3, influenza virus, and rhinovirus, can also cause bronchiolitis with clinical presentations similar to RSV infection. The condition contributes significantly to pediatric hospitalizations, particularly during the winter months, and poses a substantial burden on0 healthcare systems.[5]

Despite its high prevalence, there is no specific treatment for bronchiolitis, and management remains largely supportive. Although various therapies, including virus-specific antiviral agents like ribavirin and symptomatic treatments such as bronchodilators and corticosteroids, have been used, evidence supporting their routine use is limited.[6]

Management of acute bronchiolitis is primarily supportive, focusing on maintaining adequate oxygenation and hydration and monitoring for complications. Pharmacological interventions remain largely limited, and there is ongoing debate regarding the effectiveness of various therapeutic options. Nebulized agents that target airway secretions have been explored to alleviate symptoms and improve respiratory function. Hypertonic saline (3% NaCl) nebulization has been proposed to enhance mucociliary clearance and reduce airway obstruction.[7] N-acetylcysteine (NAC) is a mucolytic and antioxidant agent that works by breaking disulfide bonds in mucus, reducing viscosity and improving clearance.[8] It also increases intracellular glutathione levels, enhancing antioxidant defenses. NAC has been investigated in several respiratory conditions, including cystic fibrosis, chronic bronchitis, non-cystic fibrosis bronchiectasis, idiopathic pulmonary fibrosis, and bronchiolitis, and has shown potential to improve airway secretions and reduce oxidative stress in the lungs.[9]

Although both 3% NaCl and NAC have shown potential benefits in improving airway clearance in children with bronchiolitis, evidence directly comparing their efficacy is limited. Establishing the relative effectiveness of these agents is crucial for optimizing symptomatic management and potentially reducing hospital stay and morbidity in affected infants.[10] The present study aims to evaluate and compare the clinical outcomes of N-acetylcysteine versus 3% NaCl nebulization in children aged 6 months to 2 years with acute bronchiolitis, thereby providing evidence to guide effective and evidence-based therapeutic strategies in routine pediatric care.

## MATERIALS AND METHODS

A randomized controlled trial was conducted in the Department of Paediatrics, Outpatient Department, at Aarupadai Veedu Medical College and Hospital, Puducherry. The objective of this study was to compare the effectiveness of N-Acetyl Cysteine nebulisation vs 3% NaCl nebulisation in children with acute bronchiolitis in improvement of clinical severity (score by Wang Et Al) and duration of hospital stay aged from 6 months to 2 years. The duration of study was conducted for a period of 18 months from August 2023 to February 2025. Ethical approval was obtained from the Institutional Human Ethics Committee (IHEC No: AV/IHEC/01/2024/079), and the trial was registered with the Clinical Trials Registry of India (CTRI/2025/10/116255). The study included children aged 6 months to 2 years presenting with a first episode of respiratory distress associated with wheezing and a Clinical Severity Score (CSS) between 0 and 6. A total of 60 eligible children were enrolled and randomly allocated into two equal groups of 30 each: Group A received nebulization with N-acetyl cysteine and Group B received nebulization with 3% hypertonic saline. Children with congenital or acquired cardiac disease, features of impending respiratory failure, history of preterm birth or neonatal mechanical ventilation, or previous episodes of pneumonia were excluded. The sample size of 60 was calculated based on a similar study by Naz F et al. (2014), using comparison of means with a significance level of 5% and a power of 90%.[11] Randomization was performed using a computer-generated sequence, with allocation concealment ensured through sequentially numbered, opaque, sealed envelopes. The study followed a single-blinded design, wherein outcome assessment was performed by an observer blinded to group allocation. Written informed consent was obtained from parents or guardians prior to enrolment. Baseline demographic and clinical details were recorded using a structured proforma, and nebulization was administered by trained personnel following standard pediatric protocols. Respiratory rate and clinical severity were assessed using the Clinical Severity Score at baseline and at predefined intervals after nebulization, with all observations systematically recorded and analyzed. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) is used. The Normality tests, Kolmogorov-Smirnov and Shapiro-Wilks tests results revealed that the data follows normal distribution. Therefore, to analyse the data, parametric test was applied. Descriptive statistics determined the frequency, percentage, mean and standard deviation for the variables. Independent sample t test was used to analyze the before and after nebulisation and duration of hospital stay in days difference between both group A and group B from day 1 to day 5. Significance level is fixed as 5% ($\alpha = 0.05$). P-value $<0.05$ is considered to be statistically significance.

## RESULTS

A total of 60 children were enrolled and equally allocated into Group A (N-acetyl cysteine nebulisation) and Group B (3% hypertonic saline


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nebulisation). The mean age of participants was comparable between Group A (15.03 ± 5.85 months) and Group B (14.03 ± 5.39 months), with no statistically significant difference (p = 0.516). Gender distribution was also balanced, with males constituting 56.7% in Group A and 43.3% in Group B, while females accounted for 43.3% and 56.7% respectively.

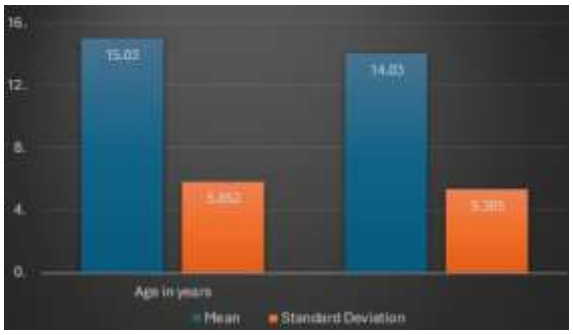


**Figure 1: Mean and Standard Deviation of age among the study participants**

Baseline scores on Day 1 before nebulisation did not differ significantly between the two groups (p = 0.09), indicating initial comparability. However, following nebulisation, Group A demonstrated significantly lower scores compared to Group B on Day 1 (p = 0.001). This trend of greater improvement in Group A persisted across subsequent days, with post-nebulisation scores showing statistically significant differences in favour of N-acetyl cysteine on Day 2 (p = 0.02), Day 3 (p = 0.006), Day 4 (p = 0.001), and Day 5 (p = 0.001). By Day 4, even pre-nebulisation scores were significantly lower in Group A (p = 0.003), reflecting faster clinical improvement. On Day 5, children in Group A achieved near-complete symptom resolution, while Group B continued to have higher scores. Additionally, the mean duration of hospital stay was significantly shorter in Group A (3.50 ± 0.51 days) compared to Group B (6.20 ± 0.85 days) (p = 0.001), highlighting the superior clinical efficacy of N-acetyl cysteine nebulisation over 3% hypertonic saline.

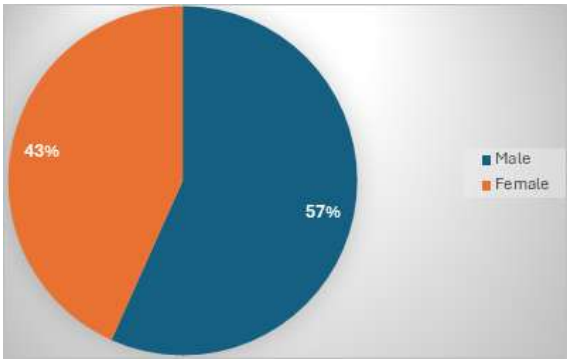


**Figure 2: Gender distribution of the study participants among Group A**

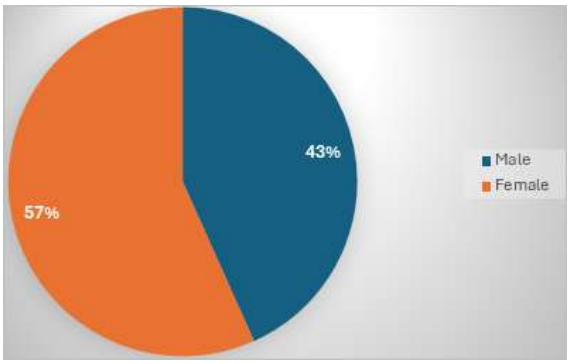


**Figure 3: Gender distribution of the study participants among Group B.**

**Table 1: Comparison of before and after Nebulisation between both the groups for Day 1**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Before Nebulisation | Group A | 30 | 5.40 | 0.498 | 0.091 | 0.09 |
| | Group B | 30 | 5.17 | 0.747 | 0.136 | |
| After Nebulisation | Group A | 30 | 4.17 | 0.379 | 0.069 | 0.001* |
| | Group B | 30 | 5.60 | 0.498 | 0.091 | |

**Table 2: Comparison of before and after Nebulisation between both the groups for Day 2**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Before Nebulisation | Group A | 30 | 4.43 | 0.679 | 0.124 | 0.88 |
| | Group B | 30 | 5.43 | 0.626 | 0.114 | |
| After Nebulisation | Group A | 30 | 2.97 | 1.066 | 0.195 | 0.02* |
| | Group B | 30 | 5.40 | 0.621 | 0.113 | |

**Table 3: Comparison of before and after Nebulisation between both the groups for Day 3**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Before Nebulisation | Group A | 30 | 3.10 | 0.995 | 0.182 | 0.74 |
| | Group B | 30 | 5.13 | 0.819 | 0.150 | |
| After Nebulisation | Group A | 30 | 2.00 | 1.083 | 0.198 | 0.006* |
| | Group B | 30 | 5.13 | 0.730 | 0.133 | |

**Table 4: Comparison of before and after Nebulisation between both the groups for Day 4**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Before Nebulisation | Group A | 30 | 1.70 | 1.368 | 0.250 | 0.003* |
| | Group B | 30 | 4.97 | 0.809 | 0.148 | |
| After Nebulisation | Group A | 30 | 1.10 | 0.305 | 0.056 | 0.002* |
| | Group B | 30 | 4.73 | 0.691 | 0.126 | |


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**Table 5: Comparison of before and after Nebulisation between both the groups for Day 5**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Before Nebulisation | Group A | 30 | 0.93 | 0.944 | 0.172 | 0.91 |
| | Group B | 30 | 4.67 | 0.959 | 0.175 | |
| After Nebulisation | Group A | 30 | 1.00 | 0.000 | 0.000 | 0.001* |
| | Group B | 30 | 4.00 | 0.695 | 0.127 | |

**Table 6: Mean and Standard Deviation for Hospital stay (days) among the study participants**

| Variable | Groups | N | Mean | Standard Deviation | Standard Error mean | P-value |
|---|---|---|---|---|---|---|
| Hospital stays | Group A | 30 | 3.50 | 0.509 | 0.093 | 0.001* |
| | Group B | 30 | 6.20 | 0.847 | 0.155 | |

## DISCUSSION

In the present study, the mean age of participants in Group A was 15.03 ± 5.85 months, while in Group B it was 14.03 ± 5.39 months, with no statistically significant difference. The study conducted by Meissner et al in 2016, Tian et al. in 2023 and Ouazoun Coulibaly et al in 2023 has similar study findings that acute bronchiolitis, which predominantly affects infants and toddlers under 2 years of age.[12-14] These studies similarly highlighted that children in this age group are at higher risk due to smaller airway diameter and immature immune responses, making age an important factor for both susceptibility and clinical severity. In contrast, Zorc and Hall (2010), reported that broader age range up to 5 years and a wider mean age distribution.[15]

In the present study, the gender distribution among the participants was relatively balanced, with Group A (N-acetyl cysteine) comprising 56.7% males and 43.3% females, while Group B (3% NaCl) had 43.3% males and 56.7% females. The similar studies conducted by Shangavi et al in 2024 and Nagayama et al in 2006 noted that males are generally more affected by bronchiolitis, potentially due to smaller airway diameters and higher susceptibility to severe viral infections.[16,17] In contrast, such as Zorc and Hall et al in 2010, reported a more equal gender distribution or even a slight female predominance in certain cohorts, particularly in studies including older infants and toddlers up to 5 years.[15]

In the present study on Day 1, baseline pre-nebulisation scores were comparable between Group A (N-acetylcysteine) and Group B (3% NaCl), with no statistically significant difference. However, post-nebulisation scores showed a significant reduction in Group A compared to Group B, indicating a better immediate response with N-acetylcysteine. On Day 2, baseline pre-nebulisation scores were comparable between Group A (N-acetylcysteine) and Group B (3% NaCl), with no statistically significant difference. However, post-nebulisation scores showed a significant reduction in Group A compared to Group B, indicating a better improvement with N-acetylcysteine. On Day 3, although pre-nebulisation scores remained comparable, post-nebulisation scores were significantly lower in Group A, demonstrating a greater clinical improvement with N-acetylcysteine. By Day 4, Group A showed significantly lower scores even before nebulisation, reflecting sustained improvement. This difference further widened after nebulisation, with Group A exhibiting markedly better scores than Group B. On Day 5, pre-nebulisation scores were similar between the groups, but post-nebulisation scores revealed complete or near-complete resolution of symptoms in Group A compared to persistent symptoms in Group B, with a statistically significant difference. Overall, these findings indicate that nebulised N-acetylcysteine led to a faster and more consistent reduction in clinical severity scores over successive days when compared with 3% hypertonic saline.

The present study demonstrated a statistically significant difference in the duration of hospital stay between the two groups. Children in Group A had a shorter mean hospital stay (3.50 ± 0.509 days) compared to Group B (6.20 ± 0.847 days), with the difference being highly significant. This finding suggests that the intervention used in Group A was more effective in accelerating clinical recovery and facilitating earlier discharge. The study conducted by Naz et al in 2014 reported significantly shorter hospitalization durations in N-acetyl cysteine (NAC) nebulisation group compared to 3% hypertonic saline (NaCl) nebulisation groups, findings that are consistent with the results of the present study.[18]

The present study demonstrated a significant improvement in clinical severity scores among children with acute bronchiolitis treated with nebulized N-acetylcysteine when compared to the comparator therapy. Children receiving N-acetylcysteine showed a more rapid and sustained reduction in bronchiolitis severity scores, indicating better clinical recovery. The decline in clinical severity was progressive and statistically significant on successive days of treatment, suggesting that N-acetylcysteine contributes to consistent symptomatic improvement. This therapeutic benefit may be attributed to its mucolytic and antioxidant properties, which facilitate clearance of airway secretions and reduce airway inflammation. In contrast, treatments primarily aimed at bronchodilation provide limited benefit in bronchiolitis, as airway obstruction in this condition is largely due to mucus plugging and inflammation rather than bronchospasm. The contrast study done by Zhang et al in 2008, Ansari et al in 2010 and Kellner et al in 2006 showed better result with mucolytic agents (hypertonic saline).[7,19,20]

In the present study, nebulized N-acetylcysteine was associated with a marked and clinically significant reduction in the duration of hospital stay among children with acute bronchiolitis. The mean length of


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hospitalization in Group A (N-acetylcysteine) was 3.50 ± 0.509 days, compared to 6.20 ± 0.847 days in Group B (3% hypertonic saline). This represents an absolute reduction of 2.7 days, corresponding to an approximate 43% decrease in hospital stay, which was statistically significant. The magnitude of reduction observed in the present study is greater than that reported in several earlier trials evaluating hypertonic saline nebulization, where reductions of approximately 25–26% in hospital stay were documented. This enhanced benefit may be attributed to the mucolytic, antioxidant, and anti-inflammatory properties of N-acetylcysteine, which facilitate airway clearance, reduce oxidative stress, and improve overall respiratory mechanics, thereby accelerating clinical recovery.

In contrast, Hsieh et al in 2020 study on hypertonic saline has been shown to shorten hospitalization in bronchiolitis, its use may be limited by adverse effects such as bronchoconstriction, particularly in children with underlying airway hyperreactivity, and it often requires concurrent bronchodilator therapy.[21] The findings of the present study suggest that nebulized N-acetylcysteine may offer a more effective and potentially safer alternative in reducing hospital stay. N-acetylcysteine was administered in the present study without any observed adverse effects, consistent with previous reports that have demonstrated its favorable safety and tolerability profile.[22,23]

## CONCLUSION

The present study concludes that nebulized N-acetylcysteine (NAC) is more effective than 3% hypertonic saline in the management of acute bronchiolitis among children aged 6 months to 2 years. NAC nebulisation resulted in faster and more sustained improvement in clinical severity scores, along with a significantly shorter duration of hospital stay. The two treatment groups were comparable at baseline with respect to age and gender distribution, thereby strengthening the validity of the observed treatment effects. Children treated with NAC demonstrated a consistent and progressive reduction in bronchiolitis severity over successive days, culminating in earlier clinical recovery and discharge when compared to those receiving 3% NaCl nebulisation. The substantial reduction in mean hospital stay observed with NAC highlights its potential to reduce healthcare burden and resource utilization. These clinical benefits are biologically plausible given the mucolytic, antioxidant, and anti-inflammatory properties of NAC, which directly address the key pathophysiological mechanisms of bronchiolitis, namely mucus plugging and airway inflammation. Importantly, nebulized NAC was well tolerated, with no adverse effects noted during the study period, supporting its favorable safety profile in the pediatric population. Overall, the findings suggest that nebulized N-acetylcysteine is a safe, cost-effective, and clinically beneficial therapeutic option for infants and young children with acute bronchiolitis.

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