



## Original Article



## Comparative Efficacy of Hypertonic Versus Normal Saline Nebulization in Acute Bronchiolitis in Infants at a Tertiary Care Hospital

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### ABSTRACT

Acute bronchiolitis is a leading cause of hospitalization in infants and is managed mainly with supportive care. Nebulized 3% hypertonic saline (HS) has been used in some settings, but evidence from routine-care practice remains variable. **Objectives:** To compare short-term clinical outcomes of nebulized 3% hypertonic saline versus 0.9% normal saline administered as routine care in infants hospitalized with acute bronchiolitis at Mardan Medical Complex. **Methods:** This was a prospective quasi-experimental comparative cohort study to compare the outcomes between infants receiving 3% hypertonic saline and those receiving 0.9% normal saline. Participants were actively followed for up to 72 hours to assess clinical response, with treatment allocation based on routine clinical decisions made by the treating pediatrician. Efficacy was predefined as a  $\geq 2$ -point reduction in the Respiratory Distress Assessment Instrument (RDAI) score within 72 hours or discharge without supplemental oxygen. **Results:** Treatment response occurred in 27/30 (90%) in the 3% HS group versus 15/30 (50%) in the 0.9% NS group ( $p < 0.001$ ). Mean oxygen-therapy duration was shorter ( $17.3 \pm 4.2$  vs  $26.8 \pm 5.6$  hours;  $p < 0.001$ ), and hospital stay was shorter ( $2.6 \pm 0.8$  vs  $3.5 \pm 1.0$  days;  $p < 0.001$ ) in the 3% HS group. **Conclusions:** In this routine-care setting, nebulized 3% hypertonic saline was associated with a higher treatment-response rate and shorter oxygen-therapy duration and hospital stay than 0.9% normal saline.

### INTRODUCTION

Bronchiolitis is a common lower respiratory tract infection in infants and young children [1]. Most infants with bronchiolitis recover without complications, although neonates might develop respiratory failure [2]. Management of bronchiolitis is primarily supportive, focusing on hydration, oxygen supplementation when indicated, and feeding support [3]. Respiratory syncytial virus (RSV) is the most common etiologic agent of bronchiolitis. Although RSV can infect individuals across

the lifespan, bronchiolitis occurs primarily in infants and tends to be most severe in younger infants [4]. Symptomatic treatment is the key approach in managing bronchiolitis in infants [5]. It is important to thoroughly evaluate the hydration status, respiratory distress, and presence of hypoxia in all babies and children diagnosed with bronchiolitis [6, 7]. Supportive care, which involves maintaining sufficient oxygen exchange, hydration intake, and eating, is the established therapy for acute

bronchiolitis [8]. Evidence for adjunct pharmacologic therapies remains limited and inconsistent. Given that airway inflammation and mucus plugging contribute to bronchiolitis symptoms, therapies that may improve airway hydration and secretion clearance have been explored as adjuncts to supportive care. Due to its viral etiology, pharmacological treatments have not consistently demonstrated clear clinical benefit in the routine management of acute bronchiolitis. Nebulized 3% hypertonic saline may help reduce wheezing and respiratory distress in some infants with bronchiolitis [9]. Several studies have evaluated nebulized hypertonic saline as an adjunct to supportive care in bronchiolitis, with mixed findings across settings. Hypertonic saline has been studied as a potential adjunct therapy in bronchiolitis, with some studies reporting improvements in clinical severity scores and length of hospital stay; however, findings across studies and settings remain variable [10]. A study reported higher clinical improvement rates among infants receiving nebulized hypertonic saline than among those receiving normal saline in their study population [11].

It is common practice in many centers to administer inhalation therapy using salbutamol diluted in 0.9% normal saline for hospitalized children with acute bronchiolitis. However, evidence from routine-care tertiary settings in Pakistan, particularly regarding the use of hypertonic saline without bronchodilators, remains limited. In this prospective quasi-experimental comparative cohort study conducted under routine clinical care, we compared nebulized 3% hypertonic saline with 0.9% normal saline, without bronchodilators, in infants admitted with acute bronchiolitis. Treatment allocation was based on the pediatrician's clinical judgment, and participants were actively followed for 72 hours to assess clinical response. The study hypothesized that nebulized 3% hypertonic saline (without bronchodilators) would be associated with greater improvement in RDAI scores and a shorter hospital stay than 0.9% normal saline. Therefore, this study aimed to compare short-term clinical outcomes between infants receiving nebulized 3% hypertonic saline and those receiving 0.9% normal saline under routine care at Mardan Medical Complex.

## METHODS

This was a prospective quasi-experimental comparative cohort study conducted under routine clinical care at the Department of Pediatrics, Mardan Medical Complex, from April to September 2024. Ethical approval was obtained from the BKMC Ethical Review Board (Ref No. BKMC/473/2024-03; Dated 29th March, 2024), and written informed consent was obtained from parents or guardians before enrollment. Treatment allocation was based on routine clinical decisions made by the treating pediatrician,

and participants were actively followed for 72 hours to assess clinical response. The study assessed differences in outcomes between infants with acute bronchiolitis who received 3% hypertonic saline nebulization and those who received 0.9% normal saline nebulization as part of routine clinical management. Sample size was calculated using the WHO Sample Size Calculator (version 2.0) at a 95% confidence level ( $\alpha=0.05$ , power=80%), assuming a difference in clinical response rates reported in prior studies comparing hypertonic saline and normal saline nebulization in infants with bronchiolitis [11]. Based on this, 60 infants were included, with 30 in the hypertonic saline group (Group A) and 30 in the normal saline group (Group B), using a consecutive sampling design. Infants of both genders aged 1 month to 2 years with a diagnosis of bronchiolitis of  $\leq 48$  hours' duration were enrolled. Bronchiolitis was defined as presentation with a persistent dry cough and noisy breathing (wheezing) with a Respiratory Distress Assessment Instrument (RDAI) score between 4 and 15 on a scale with a total possible range of 0–17. The RDAI scores wheeze (expiration, inspiration, and location) and chest retractions (supraclavicular, intercostal, and subcostal) on an ordinal scale, with higher scores indicating more severe respiratory distress. RDAI scoring followed standard published criteria. Infants suffering from congenital or acquired cardiac disease, chronic respiratory conditions, or progressive respiratory distress necessitating respiratory assistance beyond supplemental oxygen, as well as those with preterm birth (gestational age  $< 37$  weeks) or a history of neonatal mechanical ventilation, were excluded. Treatment response (operationally defined for this study) was predefined as either (i) a  $\geq 2$ -point reduction in total RDAI score within 72 hours of nebulization initiation, or (ii) discharge within 72 hours without supplemental oxygen. This outcome definition was used to provide a clinically interpretable RDAI-based response measure, and the RDAI has published validity and reliability data in bronchiolitis [18]. Participants were followed for 72 hours after nebulization initiation or until discharge, whichever occurred first. During follow-up, RDAI was reassessed at routine clinical reviews using the same standardized scoring criteria. Infants treated with 4 mL of 3% hypertonic saline were classified as Group A, and those treated with 4 mL of 0.9% normal saline were classified as Group B. Nebulization was generally administered three times per day at approximately 8-hour intervals, according to the treating physician's judgment, until sufficient clinical improvement for discharge. All infants received standard supportive care, including propped-up positioning, suction as required, fluid administration, routine feeding, antipyretic therapy (paracetamol) for fever, and parental counseling. Supplemental oxygen was delivered via nasal cannula or face mask and initiated when oxygen saturation

persistently fell below 90%, then titrated to maintain oxygen saturation  $\geq 90\%$ . Inhalation treatments were delivered using a standard nebulizer machine. No bronchodilators (e.g., salbutamol) or inhaled corticosteroids were administered during the observation period. For each infant, treatment response status and continuous outcomes, including duration of oxygen therapy (hours) and length of hospital stay (days), were recorded on the study proforma.

Data were analyzed using SPSS version 25.0. Categorical variables, such as treatment response, were summarized as frequencies and percentages and compared between groups using the Chi-square test. Effect sizes were reported as appropriate with 95% confidence intervals. Continuous variables, such as oxygen-therapy hours and length of hospital stay, were expressed as mean  $\pm$  standard deviation and compared using independent-samples t-tests; normality was assessed (e.g., Shapiro-Wilk test and/or visual inspection). When normality was not satisfied, the Mann-Whitney U test was applied. A p-value of  $<0.05$  was considered statistically significant.

## RESULTS

A total of 60 infants were included in the study, with 30 in Group A (3% hypertonic saline) and 30 in Group B (0.9% normal saline). The infants were aged between 1 month and 2 years. In Group A, the mean age was  $5.43 \pm 3.58$  months, and the mean duration of complaints was  $23.23 \pm 7.37$  hours, whereas in Group B, the mean age was  $5.83 \pm 4.87$  months and the mean duration of complaints was  $17.50 \pm 4.99$  hours. Males were predominant in both groups. Baseline demographic characteristics were broadly similar between groups; however, baseline symptom duration was longer in Group A than in Group B, which may introduce residual confounding. This study was a prospective quasi-experimental comparative cohort study, where treatment allocation was based on the pediatrician's clinical judgment. Participants were actively followed for 72 hours to assess clinical response, with efficacy defined as a  $\geq 2$ -point reduction in RDAI or discharge without supplemental oxygen (Table 1).

**Table 1:** Basic Demographics of Patients and Clinical Characteristics of Infants

Demographic Characteristic	Group A (n=30), Mean $\pm$ SD	Group B (n=30), Mean $\pm$ SD
Age (Months)	5.433 $\pm$ 3.58	5.833 $\pm$ 4.87
Male	20 (66.67%)	18 (60%)
Female	10 (33.33%)	12 (40%)
Duration of Presenting Complaints (Hours)	23.233 $\pm$ 7.37	17.500 $\pm$ 4.99

Baseline symptom duration was longer in Group A than in Group B, reflecting usual-care treatment selection and potential residual confounding

In Group A, 27 of 30 infants (90%) met the predefined treatment-response criterion, compared with 15 of 30 (50%) in Group B. This difference is statistically significant ( $p < 0.001$ ), showing a higher proportion of infants meeting the predefined treatment-response criterion in Group A than in Group B. Treatment allocation was based on the pediatrician's clinical judgment, and patients were followed for 72 hours to assess clinical response. In both groups, infants were assessed over the first 72 hours; the proportion meeting the predefined treatment-response criterion was significantly higher in the hypertonic saline group. The risk ratio for treatment response was 1.80 (27/30 vs 15/30), and the absolute risk difference was 40.0 percentage points (Table 2).

**Table 2:** Comparison of Treatment Response Between the Two Groups

Treatment Response	Group A (3% HS), n (%)	Group B (0.9% NS), n (%)	p-value
Yes	27 (90.0%)	15 (50.0%)	<0.001
No	3 (10.0%)	15 (50.0%)	
Total	30 (100%)	30 (100%)	

As summarized, treatment response was more frequent in the hypertonic saline group than in the normal saline group across most strata. The difference was statistically significant in infants aged 1-12 months and in both complaint-duration categories ( $p = 0.016$  and  $p = 0.008$ ); no statistically significant difference was observed in the 13-24-month subgroup, which had a small sample size. Stratified analyses suggested that the higher response rate with 3% hypertonic saline was most evident in infants aged 1-12 months and in both complaint-duration strata; interpretation remains cautious due to non-assigned usual-care treatment selection (Table 3).

**Table 3:** Stratification of Treatment Response by Subgroups

Age	Group	Treatment Response		p-value
		Yes	No	
1-12 Months	A	24 (88.9%)	3 (11.1%)	0.002
	B	13 (50%)	13 (50%)	
13-24 Months	A	3 (100%)	0 (0%)	0.147
	B	2 (50%)	2 (50%)	
Male	A	17 (85%)	3 (15%)	0.005
	B	8 (44.4%)	10 (55.6%)	
Female	A	8 (80%)	2 (20%)	0.055
	B	6 (50%)	6 (50%)	
Duration 1-24 Hours	A (n=13)	12 (92.3%)	1 (7.7%)	0.016
	B (n=26)	14 (53.8%)	12 (46.2%)	
Duration 25-48 Hours	A (n=17)	15 (88.2%)	2 (11.8%)	0.008
	B (n=4)	1 (25%)	3 (75%)	

Infants treated with 3% hypertonic saline required significantly fewer hours of oxygen therapy ( $17.3 \pm 4.2$  vs.  $26.8 \pm 5.6$  hours,  $p < 0.001$ ) and had a shorter mean hospital stay ( $2.6 \pm 0.8$  vs.  $3.5 \pm 1.0$  days,  $p < 0.001$ ) than those treated

with normal saline, with shorter observed oxygen-therapy duration and hospital stay in the hypertonic saline group (Table 4).

**Table 4:** Oxygen Therapy Duration and Length of Hospital Stay

Outcomes	Group A (3% HS)	Group B (0.9% NS)	p-value
Oxygen Therapy, Hours (Mean ± SD)	17.3 ± 4.2	26.8 ± 5.6	<0.001
Length of Stay, Days (Mean ± SD)	2.6 ± 0.8	3.5 ± 1.0	

## DISCUSSION

Bronchiolitis is common among children under two years old and is a leading cause of hospitalization for respiratory illness in early childhood [12–14]. The objective of this study was to compare short-term clinical outcomes between infants receiving nebulized 3% hypertonic saline and those receiving 0.9% normal saline under routine clinical care. Both cohorts showed little demographic variation in age and sex, and clinical signs and symptoms were broadly similar at baseline. Baseline clinical features were comparable between groups; however, given the usual-care treatment selection, baseline differences in symptom duration were noted and cannot be fully excluded. Infants who received 3% hypertonic saline had a higher observed rate of clinical improvement than those who received normal saline (0.9%). The former group had an average of approximately 9 fewer hours of oxygen administration compared with the latter group. Approximately 90% of infants treated with 3% hypertonic saline met the predefined treatment-response criterion within 72 hours, compared with 50% of those treated with 0.9% normal saline [11]. No treatment-limiting adverse events were documented during hospitalization; however, adverse events were not collected using a dedicated active-surveillance tool. As the basic clinical parameters were broadly similar between the two groups, the observed variation in outcomes (with a higher treatment-response rate among those treated with nebulized 3% saline) may be associated with the type of saline used. However, causal inference is limited by the quasi-experimental study design (non-randomized treatment allocation). In this study, the utilization of 3% hypertonic saline was associated with a significantly shorter duration of hospitalization. These differences were accompanied by a significantly shorter length of hospital stay, with many patients in Group A being discharged within three days of treatment. Nonetheless, in infants with acute bronchiolitis, 3% hypertonic saline was associated with a higher RDAI-defined treatment response and shorter observed oxygen-therapy duration and hospital stay compared with 0.9% normal saline in this cohort. No treatment-limiting adverse events were documented during hospitalization. Our findings are broadly consistent with previous studies reporting reduced hospital stay in infants treated with 3% hypertonic

saline compared with normal saline [15]. The administration of oxygen should be guided by oxygen saturation. When oxygen saturation persistently falls below 90% in infants with bronchiolitis, supplemental oxygen is typically initiated and titrated according to oxygen saturation and clinical status [16]. In this study, the hypertonic saline group required fewer hours of oxygen therapy than the normal saline group (approximately 9 hours fewer on average), and a previous study reported a similar observation [17]. Prior studies have reported that nebulized 3% hypertonic saline may be associated with faster clinical improvement than 0.9% normal saline in infants with acute bronchiolitis. Several studies have also reported a shorter length of hospital stay with hypertonic saline compared with normal saline among admitted infants [18, 19]. Many investigations used bronchiolitis severity scores (including RDAI or similar validated scores) to assess changes over time. For example, studies evaluating nebulized 3% hypertonic saline administered with epinephrine every 6–8 hours reported improvements in bronchiolitis severity scores and shorter hospitalization duration compared with 0.9% saline with epinephrine. No serious adverse events were reported in those investigations [19, 20]. These findings are broadly consistent with the current study, as the oxygen-therapy duration in the hypertonic saline group was notably shorter (approximately 17 hours) compared to the normal saline group. Previous studies have reported mixed findings regarding the clinical benefit of nebulized hypertonic saline in infants with acute bronchiolitis [9]. However, another study investigating the utilization of 3% hypertonic saline in the accident and emergency room proposed that there may not be immediate therapeutic advantages seen with the administration of nebulized hypertonic saline [21]. Although hypertonic saline has been proposed to improve airway surface hydration and facilitate mucus clearance, these mechanisms were not directly assessed in the present study. Therefore, interpretation is based on observed clinical outcomes rather than physiological measures [22–24]. Nebulization with hypertonic saline (3%) was well tolerated in this cohort and was associated with a higher RDAI-defined treatment response and shorter observed oxygen-therapy duration and hospital stay than normal saline among infants hospitalized with acute bronchiolitis. No treatment-limiting adverse events were documented in routine records, although adverse events were not captured using a dedicated active-surveillance tool [18–20]. Hypertonic saline is inexpensive and widely available; however, formal cost-effectiveness was not evaluated in this study. Furthermore, our findings are consistent with the Cochrane review reporting shorter hospitalization in some settings with hypertonic saline [9].

Across both groups, respiratory rate, wheeze, retractions, overall clinical condition, and clinical severity scores improved over three days, with improved room-air oxygen saturation [25]. Our quantitative analysis shows substantially shorter oxygen use and hospital stay with hypertonic saline (both  $p < 0.001$ ).

However, because treatment was selected as part of routine care, residual confounding (including baseline symptom duration) cannot be excluded. Baseline symptom duration differed between groups, which may reflect confounding by indication. This was a single-center, quasi-experimental comparative cohort study with a modest sample size and no blinding, which may limit generalizability and introduce selection and measurement bias. Baseline imbalances suggest possible residual confounding, and adverse events were not captured using a dedicated surveillance tool. We did not separately analyze the proportion requiring supplemental oxygen; instead, we assessed oxygen-therapy duration as a more sensitive outcome. Larger multicenter studies with more rigorous designs and systematic adverse-event monitoring are warranted to confirm these observed associations.

## CONCLUSIONS

In this prospective quasi-experimental comparative cohort study, nebulized 3% hypertonic saline was associated with a higher RDAI-defined treatment response and shorter oxygen-therapy duration and hospital stay than 0.9% normal saline among infants admitted with acute bronchiolitis. These findings should be interpreted cautiously due to routine care treatment allocation, baseline differences, and potential residual confounding.

## Authors' Contribution

Conceptualization: KE

Methodology: KE, KA

Formal analysis: MRK, ZU

Writing and Drafting: KE, KA, WG, MRK, KP

Review and Editing: KE, KA, WG, MRK, KP, ZU

All authors approved the final manuscript and take responsibility for the integrity of the work

## Conflicts of Interest

All the authors declare no conflict of interest.

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