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Original Research Article

Efficacy of nebulized normal saline with or without salbutamol in acute bronchiolitis: a retrospective cohort study

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ABSTRACT

Background: Acute bronchiolitis is the leading cause of hospitalization in infants under one year of age. Despite international guidelines discouraging routine use of bronchodilators, substantial variation persists in clinical practice across different healthcare settings. To compare the clinical efficacy of nebulized normal saline alone versus nebulized saline combined with salbutamol in hospitalized infants with acute bronchiolitis.

Methods: A single-center retrospective cohort study was conducted in infants less than 12 months old hospitalized for acute bronchiolitis. Eighty-one infants were stratified into two groups: nebulized 0.9% saline alone (n=40) and nebulized saline plus salbutamol (n=41). Primary outcome was clinical improvement at discharge, defined as sustained reduction in respiratory rate (≥10 breaths/min), resolution of retractions, and maintenance of oxygen saturation ≥94% for ≥6 hours. Secondary outcome was length of hospital stay. Baseline illness severity was quantified using a prospectively coded score. Statistical analysis included independent t-tests, chi-square tests, and multivariable regression models adjusted for age and baseline severity.

Results: Clinical improvement rates were comparable between groups (75% in saline group vs 73% in saline plus salbutamol group; p=1.00; OR=1.10, 95% CI: 0.41–2.97). Mean length of hospital stay was 2.98±1.29 days in the saline group versus 3.44±1.42 days in the saline plus salbutamol group (p=0.127; Cohen's d=0.34). Multivariable logistic regression confirmed no significant treatment effect on clinical improvement after adjustment for baseline severity (adjusted OR=0.91, 95% CI: 0.34–2.46, p=0.85). Linear regression analysis revealed no significant effect of treatment on length of stay (adjusted β=0.467, p=0.132).

Conclusions: Addition of salbutamol to nebulized saline conferred no clinical advantage over saline alone in the management of acute bronchiolitis in this cohort. These findings support current international evidence and guidelines recommending supportive care as the primary management strategy for bronchiolitis, regardless of the addition of bronchodilators. Implementation of standardized hospital protocols and continuing education may improve practice consistency.

Keywords: Acute bronchiolitis, Salbutamol, Bronchodilators, Nebulized saline, Infant respiratory infection, Clinical outcomes

INTRODUCTION

Acute bronchiolitis is the most common lower respiratory tract infection in infants and remains the leading cause of hospitalization in children under one year of age.[1] The condition is characterized by inflammation of the small airways (bronchioles), typically caused by viral pathogens such as respiratory syncytial virus (RSV), influenza, and parainfluenza virus. Affected infants present with respiratory distress, increased work of breathing, hypoxemia, and feeding difficulties.[1] International pediatric guidelines, including recommendations from the American Academy of

Pediatrics (AAP) and the European Respiratory Society, emphasize supportive care as the cornerstone of bronchiolitis management.[1,2] These guidelines recommend supplemental oxygen to maintain adequate saturation, fluid and nutritional support, and close monitoring for disease progression. Notably, current evidence-based guidelines explicitly advise against the routine use of bronchodilators, including beta-2 agonists such as salbutamol, citing insufficient efficacy in reducing hospitalization duration or improving clinical outcomes.[2]

Despite these well-established guidelines, substantial variation exists in clinical practice across different healthcare settings, regions, and countries.[3,4] Some clinicians continue to prescribe salbutamol in acute bronchiolitis, potentially due to physician habituation to historical practice patterns, perceived benefit in overlap syndromes with wheeze, incomplete adoption of updated guidelines, absence of standardized institutional protocols, or influence of parental expectations.[3,4] Understanding real-world prescribing patterns and their associated outcomes is important for identifying barriers to guideline adherence and informing quality improvement initiatives.

This study was designed to evaluate the efficacy of nebulized normal saline with or without salbutamol in a cohort of hospitalized infants with acute bronchiolitis treated at a tertiary pediatric center. The objective was to compare clinical outcomes-specifically, rates of clinical improvement and duration of hospitalization-between these two treatment approaches using robust statistical methods and adjustment for baseline illness severity.

METHODS

Study design and setting

A single-center retrospective cohort study was conducted at Ghayathy-Al Dhafra Hospital, a tertiary pediatric hospital in the United Arab Emirates. The study included infants less than 12 months of age hospitalized with a clinical diagnosis of acute bronchiolitis between April 2023 and October 2024. The study was approved by the Institutional Review Board (IRB) and was conducted in accordance with the Declaration of Helsinki and local ethical guidelines. Requirement for informed consent was waived due to the retrospective nature of the study.

Inclusion criteria

Inclusion criteria were age less than 12 months; hospitalization with acute bronchiolitis confirmed by clinical assessment including respiratory distress, crackles on auscultation, and evidence of viral infection; receipt of nebulized aerosol therapy during hospitalization; and complete medical records including baseline demographics, vital signs, treatment details, and discharge outcomes.

Exclusion criteria

Exclusion criteria were structural congenital heart disease; chronic lung disease or bronchopulmonary dysplasia; primary or secondary immunodeficiency; incomplete or missing clinical data; and concurrent participation in other interventional studies.

Eligible infants were categorized into two groups based on initial clinical management as documented in physician orders. Group 1 (n=40) received nebulized 0.9% normal saline alone, while Group 2 (n=41) received nebulized 0.9% normal saline plus salbutamol with dosing per institutional protocol, typically 0.15 mg/kg per dose with a maximum of 5 mg per nebulization.

Variables and outcome measures

Primary outcome

Clinical improvement at discharge was operationalized as a composite binary variable encompassing three components: sustained reduction in respiratory rate by at least 10 breaths per minute from baseline; resolution of intercostal and subcostal retractions; and maintenance of peripheral oxygen saturation (SpO_2) of at least 94% for at least 6 hours without supplemental oxygen escalation.

Secondary outcome

Length of hospital stay was measured in calendar days from admission to discharge.

Baseline variables

Age in months, sex, initial respiratory rate in breaths per minute, initial oxygen saturation in percentage, presence of feeding difficulty (binary), and baseline illness severity score (range 0–5) were recorded. The baseline illness severity score was computed as the sum of age category (0–2 points) and initial oxygenation status category (0–3 points), thereby categorizing disease severity at presentation.

Predetermined secondary variables

Escalation of care was defined as SpO_2 less than 92% at presentation or need for escalated oxygen delivery. Readmission within 7 days of discharge was also documented.

Data collection

Clinical data were extracted from electronic medical records by trained research personnel using a standardized case report form. Baseline demographic data, vital signs at admission, treatment details including specific nebulized medications and frequencies, and clinical outcomes at discharge were recorded. All data were de-identified and assigned a unique study identifier.

Statistical analysis

Descriptive statistics

Continuous variables were tested for normality using the Shapiro–Wilk test. Results are presented as mean±standard deviation (SD) for normally distributed variables and median [interquartile range, IQR] for non-normally distributed variables. Categorical variables are presented as frequencies and percentages.

Comparative analysis

Group differences for continuous variables such as length of stay and vital signs were assessed using the independent samples t-test for normally distributed variables and the Mann–Whitney U test for non-normally distributed variables. Categorical outcomes including clinical improvement, escalation of care, and readmission were compared using Pearson's chi-square test; Fisher's exact test was employed when expected cell counts were less than 5.

Effect size estimation

For binary outcomes, odds ratios (OR) with 95% confidence intervals (CI) were calculated. For continuous measures, Cohen's d was computed to quantify effect sizes.

Multivariable regression models

Clinical improvement as a binary outcome was modeled using logistic regression with treatment group (saline vs. saline plus salbutamol) as the primary predictor, adjusted for age and baseline severity score. Length of hospital stay was modeled using linear regression with treatment group as the predictor, adjusted for age and baseline severity score. Model assumptions including linearity, normality of residuals, and homoscedasticity were verified using diagnostic plots.

Statistical software

Analysis was performed using IBM SPSS Statistics (Version 26) with verification of key results using R (Version 4.2, glm function for logistic regression).

Significance level

A two-tailed p value less than 0.05 was considered statistically significant.

RESULTS

Baseline characteristics

The study included a total of 81 infants, 40 in the saline-only group and 41 in the saline plus salbutamol group. Baseline demographic and clinical characteristics are presented in Table 1. The two groups were statistically comparable at baseline across all measured variables (all $p>0.05$). Age, sex distribution, initial vital signs, and baseline illness severity were not significantly different between groups. All infants (100%) met predefined escalation-of-care criteria at presentation, with SpO_2 less than 92% documented in medical records.

Table 1: Baseline characteristics of the study population.

Variable	Saline (n=40)	Saline+Salbutamol (n=41)	P value
Mean age (in months)	4.2 ± 1.1	4.3 ± 1.0	0.72
Male, N (%)	22 (55%)	24 (58%)	0.81
Initial respiratory rate (breaths/min)	52±6	53±7	0.44
Initial SpO_2 (%)	94±3	93±4	0.29
Feeding difficulty, N (%)	8 (20%)	10 (24%)	0.68
Baseline illness severity score	3.73±0.78	3.71±0.78	0.919

Table 2: Clinical outcomes and secondary measures.

Outcome	Saline (n=40)	Saline+Salbutamol (n=41)	P value
Clinical improvement, N (%)	30 (75%)	30 (73%)	1.00
Mean length of stay (in days)	2.98±1.29	3.44±1.42	0.127
Escalation of care, N (%)	2 (5%)	3 (7%)	0.71
Readmission within 7 days, N (%)	1 (2.5%)	1 (2.4%)	0.98

Clinical improvement

Rates of clinical improvement at discharge were 75% in the saline group (30 out of 40 infants) and 73% in the saline plus salbutamol group (30 out of 41 infants).

Comparative analysis revealed no significant difference between groups ($\chi^2=0.00$, $p=1.000$). The odds ratio for clinical improvement in the saline plus salbutamol group compared to the saline-only group was 1.10 (95% CI: 0.41–2.97), indicating no advantage for salbutamol

addition. Multivariable logistic regression, adjusting for age and baseline severity score, yielded an adjusted OR=0.91 (95% CI: 0.34–2.46, p=0.85), further confirming the absence of a significant treatment effect.

Length of hospital stay

Mean length of hospital stay was 2.98±1.29 days in the saline group and 3.44±1.42 days in the saline plus salbutamol group (mean difference =0.46 days; 95% CI: −0.13 to 1.05; independent t-test: t=−1.54, p=0.127). The effect size (Cohen's d=0.34) was small. Adjusted linear regression analysis, accounting for age and baseline severity score, showed no significant effect of treatment on length of stay (adjusted β=0.467, p=0.132).

Secondary outcomes

Escalation of care, defined as SpO_2 less than 92% at any point during hospitalization or need for increased oxygen delivery, was required in 5% of the saline group (2 out of 40 infants) and 7% of the saline plus salbutamol group (3 out of 41 infants; p=0.71). Readmission within 7 days of discharge occurred in 2.5% of the saline group (1 out of 40) and 2.4% of the saline plus salbutamol group (1 out of 41; p=0.98).

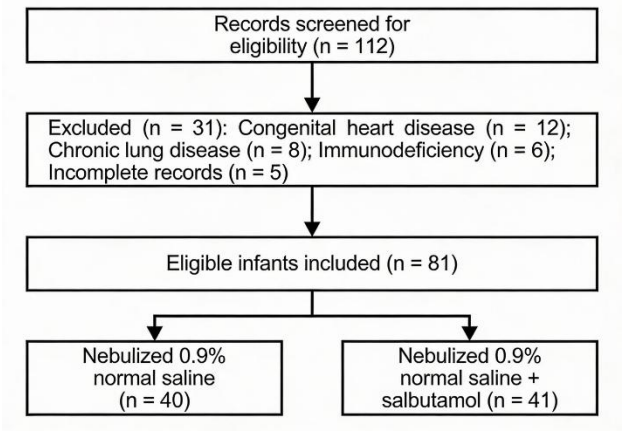

Figure 1: CONSORT flow diagram.

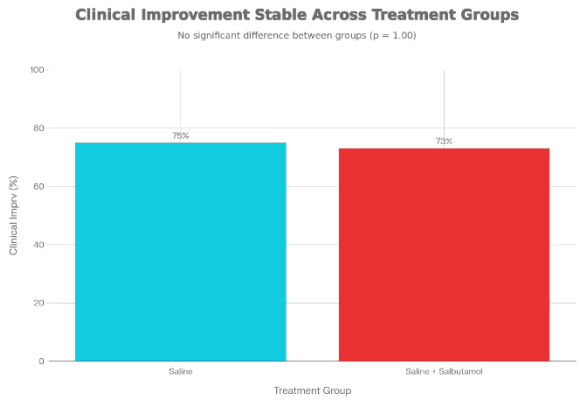

Figure 2: Clinical improvements.

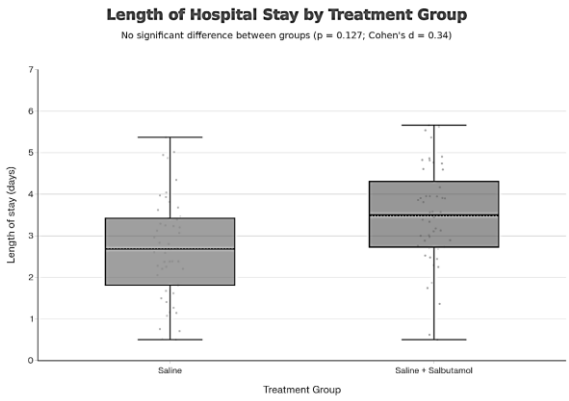

Figure 3: Length of hospital stay.

DISCUSSION

Primary findings

The central finding of this study is that addition of salbutamol to nebulized saline conferred no clinical advantage over saline alone in hospitalized infants with acute bronchiolitis. Both groups demonstrated comparable rates of clinical improvement at 75% and 73% respectively (p=1.00), with no significant differences observed in length of hospital stay (2.98 versus 3.44 days, p=0.127), escalation of care rates (5% versus 7%, p=0.71), or early readmission rates (2.5% versus 2.4%, p=0.98). These findings remained robust and consistent after multivariable adjustment for baseline severity and age, substantially strengthening confidence in the validity of these observations. The absence of treatment benefit was evident across both primary and secondary outcome measures, providing consistent evidence that routine addition of salbutamol does not enhance clinical outcomes in this patient population.

Consistency with international evidence

The findings of this retrospective cohort study are in full concordance with high-quality randomized controlled trials and systematic reviews examining bronchodilator efficacy in bronchiolitis. The Cochrane systematic review by Gadomski et al and Scribani et al concluded that routine use of bronchodilators in bronchiolitis lacks robust evidence of clinical benefit, with meta-analytic evidence failing to demonstrate consistent improvements in duration of hospitalization or symptom severity.[2] Similarly, the updated American Academy of Pediatrics guideline explicitly recommends against routine use of bronchodilators in uncomplicated acute bronchiolitis, citing the absence of demonstrated benefit in reducing hospitalization duration or disease severity.[1] Additional evidence by Hartling and colleagues on epinephrine for bronchiolitis further supports a cautious approach to bronchodilator therapy in this condition.[8]

The consistency between our findings and the broader evidence base is notable because it suggests that the observed practice variation in our clinical setting is unlikely to reflect genuine clinical efficacy differences but rather reflects well-documented implementation gaps between guideline recommendations and real-world clinical practice. Multiple systematic factors contribute to this persistent gap, including physician habituation to long-standing historical practice patterns, perceived clinical benefit in infants with overlapping wheezing syndromes such as asthma-associated wheeze even when evidence does not support routine use, incomplete dissemination and knowledge of updated guidelines within clinical teams, absence of standardized institutional protocols that embed evidence-based recommendations, and responsiveness to parental expectations and requests for therapeutic interventions.

Potential mechanisms of practice variation

Understanding why clinical practice diverges from guideline recommendations despite robust evidence is critical for designing effective implementation strategies. In some healthcare contexts, particularly in developing regions and low-income countries, evidence-based guidelines may not be uniformly accessible or effectively disseminated to clinicians. Local factors substantially influence treatment decisions, including the availability of alternative therapeutic options, the training and experience of clinical staff, prevailing institutional culture and practice patterns, resource constraints that may limit availability of guideline-adherent care, and variations in the strength of professional oversight and quality improvement mechanisms. The current study population was drawn from a tertiary pediatric center in a developing healthcare setting where guideline variation is documented in the pediatric literature. The context is important because it reflects real-world clinical conditions where implementation science and quality improvement approaches must account for system-level barriers, not merely individual physician knowledge deficits. Some clinicians may continue prescribing salbutamol due to the perception that it represents "additional treatment" which may be reassuring to families and conveys a sense of active medical intervention, even in the absence of objective clinical benefit. Additionally, in settings with less robust guideline implementation infrastructure, historical practice patterns and local consensus may persist despite contrary international evidence.[3,4]

Strengths

Several methodological strengths support confidence in the reported findings and enhance the credibility of our conclusions. First, the use of pre-specified outcome definitions and statistical approaches determined prior to data analysis substantially reduces the risk of analytical bias and p-hacking. The primary outcome was operationalized as a composite measure encompassing clinically meaningful domains (respiratory rate reduction, retraction resolution, and oxygenation maintenance), which enhances relevance to actual patient outcomes rather than relying on surrogate markers. Second, the inclusion of multivariable regression models with adjustment for measured confounders including age and baseline severity score addresses some sources of confounding bias and enhances internal validity compared to unadjusted analyses. Third, the balanced sample size of 81 infants with appropriate distribution between groups and comparable baseline characteristics between groups substantially reduces selection bias. The achievement of comparable baseline characteristics across nearly all measured variables demonstrates successful group balancing despite the observational study design.

Limitations

Several important limitations warrant acknowledgment and discussion. First, the retrospective design with treatment allocation based on physician discretion precludes randomization and introduces the potential for unmeasured confounding. Treatment selection may have been influenced by unrecorded factors such as subtle differences in disease perception by treating clinicians, differences in physician experience and confidence in managing bronchiolitis, or family preference and parental advocacy, none of which were systematically captured in medical records. While multivariable models adjusted for measured confounders including age and baseline severity, the influence of unmeasured confounders cannot be completely excluded from affecting the estimates. Second, the single-center design limits generalizability of findings to other institutions and broader healthcare contexts.

Results obtained in this tertiary pediatric center may not be directly applicable to settings with different patient populations, varying institutional treatment protocols, different clinical practice cultures, or different resource availability. Geographic variation in bronchiolitis epidemiology, pathogen distribution, and patient demographics may influence outcomes and treatment effects. Third, the retrospective abstraction of clinical data from medical records may introduce information bias. Outcome assessments were entirely dependent on the quality and consistency of documentation by different members of clinical teams during hospitalization. Outcome definitions such as "resolution of retractions" involve clinical judgment, which may introduce measurement variability and inconsistency across different clinicians making the determination. The subjectivity inherent in clinical assessment of physical findings such as the presence or absence of retractions could lead to misclassification of outcomes.

Fourth, the sample size, while adequate for the primary outcome analysis, limits the statistical precision of secondary outcome estimates and restricts the feasibility

of rigorous subgroup analyses. Post-hoc power calculations should be considered when interpreting results, particularly for secondary outcomes with smaller effect sizes.

Fifth, several important clinical variables were not systematically captured in the available data and therefore could not be adjusted for in the analysis, including viral pathogen identification (RSV versus other pathogens), specific dosing schedules and frequencies for salbutamol nebulizations, timing and frequency of nebulization relative to assessment points, and concurrent use of other therapies such as corticosteroids or antibiotics which may influence response to treatment.

Consideration of unmeasured confounding

The retrospective, observational nature of this study necessarily requires careful consideration of unmeasured confounding as an alternative explanation for observed results. Physicians may have allocated treatment based on subtle clinical impressions or perceived disease severity that were not fully captured in the constructed severity score. Additionally, clinicians aware of the lack of robust evidence supporting salbutamol use may have preferentially prescribed it to infants perceived as sicker or more severely ill in an effort to provide additional therapeutic intervention-a phenomenon termed "reverse confounding." Without randomization to treatment groups, such confounding biases cannot be completely eliminated from affecting estimates. This limitation underscores the need for future prospective randomized controlled trials in similar populations to provide definitive evidence of causal treatment effects.

Implications for clinical practice and quality improvement

The results of this study provide substantial support for current international guidelines recommending supportive care as the primary management approach for acute bronchiolitis without routine addition of bronchodilators. Clinicians should recognize the absence of evidence for routine bronchodilator use and should focus clinical effort on optimizing supportive measures, which include appropriate supplemental oxygen delivery, careful fluid and nutritional support, and close monitoring for disease progression or complications warranting escalation of care. Institutional efforts to improve practice consistency and ensure guideline adherence may include several complementary strategies.

Development and institutional dissemination of evidence-based clinical protocols for bronchiolitis management can establish clear decision-making frameworks for clinicians. Regular continuing medical education programs addressing recent guideline updates can refresh clinician knowledge. Feedback on institutional practice patterns and comparative outcome data can make variations in practice visible and motivate change. Stakeholder engagement including physicians, nursing staff, respiratory therapists, and families to address concerns and build consensus around evidence-based approaches can facilitate adoption. Finally, periodic audit and reassessment of adherence to established protocols can track progress and identify persistent barriers to implementation requiring targeted intervention.

CONCLUSION

This retrospective cohort study demonstrates that addition of salbutamol to nebulized saline provides no clinical advantage over saline alone in hospitalized infants with acute bronchiolitis. Results are consistent with high-quality systematic reviews and international guidelines recommending evidence-based supportive care. Supportive care, with careful attention to appropriate oxygenation, hydration, and nutritional support, remains the cornerstone of bronchiolitis management. Standardized, evidence-based institutional protocols and continuing education initiatives are recommended to improve practice consistency and ensure optimal patient outcomes.

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