Original Research

EFFICACY OF NEBULIZED 3% HYPERTONIC SALINE WITH OR WITHOUT SALBUTAMOL IN INFANTS HOSPITALIZED WITH ACUTE BRONCHIOLITIS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Acute bronchiolitis is one of the leading causes of hospitalization in infants and young children. Nebulized 3% hypertonic saline (HS) has been proposed to improve mucociliary clearance, while the routine use of bronchodilators such as salbutamol remains controversial[1–3].

Objective: To compare the efficacy and safety of nebulized 3% hypertonic saline with salbutamol versus 3% hypertonic saline alone in hospitalized children under two years with acute bronchiolitis.

Methods: In this randomized controlled trial, 80 children aged 2–24 months hospitalized with acute bronchiolitis over a 2-year period were randomized into two groups. Group A received nebulized 3% HS with salbutamol, and Group B received nebulized 3% HS alone. The primary outcome was length of hospital stay (LOS). Secondary outcomes included change in clinical severity score, duration of oxygen therapy, ICU transfer, and adverse events.

Results: Mean LOS was 3.1 ± 0.9 days in Group A and 3.3 ± 1.0 days in Group B (p = 0.28). Both groups demonstrated progressive clinical improvement over 72 hours, with no statistically significant intergroup difference. Minor adverse events were more frequent in the salbutamol group.

Conclusion: The addition of salbutamol to nebulized 3% hypertonic saline did not confer significant clinical benefit over hypertonic saline alone in hospitalized infants with acute bronchiolitis.

INTRODUCTION

Acute bronchiolitis is the most common lower respiratory tract infection in infants and young children and a major contributor to pediatric hospital admissions worldwide[1]. The disease is characterized by airway inflammation, edema, and mucus plugging of the small airways, most commonly caused by respiratory syncytial virus (RSV)[2].

Management of bronchiolitis is primarily supportive. Numerous pharmacologic interventions, including bronchodilators, corticosteroids, antibiotics, and nebulized hypertonic saline, have been evaluated with inconsistent results[3–5].

Nebulized 3% hypertonic saline is thought to enhance mucociliary clearance, reduce airway edema, and improve clinical outcomes[6]. Meta-analyses have reported a modest reduction in length of hospital stay; however, study heterogeneity remains significant[7].

Bronchodilators such as salbutamol continue to be used in clinical practice despite guideline recommendations discouraging their routine use due to lack of consistent benefit[4,8]. This study aims to compare nebulized 3% hypertonic saline with salbutamol versus hypertonic saline alone in hospitalized children under two years with acute bronchiolitis.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomized controlled trial, conducted over a 2-year period in a tertiary care pediatric hospital.

Participants

Inclusion criteria

- Age 2–24 months
- First episode of acute bronchiolitis

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- Moderate disease severity requiring hospitalization

Exclusion criteria

- Previous wheezing episodes or diagnosed asthma
- Congenital heart disease
- Chronic lung disease
- Severe malnutrition
- Requirement for mechanical ventilation at presentation

Sample Size

A total of 80 patients were included and randomized equally into two groups (n = 40 each).

Randomization and Allocation

Randomization was performed using a computer-generated random sequence with 1:1 allocation. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes. The study was conducted in an open-label manner due to differences in nebulization preparation.

Intervention

- **Group A (HS + Salbutamol):**Nebulized 3% hypertonic saline (4 mL) with salbutamol (0.15 mg/kg) (maximum 2.5 mg) every 8 hours
- **Group B (HS alone):**Nebulized 3% hypertonic saline (4 mL) every 8 hours

All patients received standard supportive care, including nasal suctioning, adequate hydration, antipyretics, and oxygen supplementation to maintain peripheral oxygen saturation (SpO_2) ≥ 92%.

Outcome Measures

Primary outcome

- Length of hospital stay (days)

Secondary outcomes

- Clinical severity score assessed using the Wang respiratory score (range 0–12) at baseline, 24, 48, and 72 hours
- Duration of oxygen therapy (hours)
- Requirement for ICU transfer
- Adverse events (tachycardia, tremor, bronchospasm, vomiting)

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation and compared using Student's *t*-test. Categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate. A p-value < 0.05 was considered statistically significant.

Ethical Statement-The study was approved by the Institutional Ethics Committee

RESULTS

Baseline Characteristics

Baseline demographic and clinical characteristics were comparable between the two groups.

Variable	Group A (n = 40)	Group B (n = 40)
Mean age (months)	8.6 ± 3.2	8.9 ± 3.5
Male sex (%)	62.5	60
Baseline Wang score	7.1 ± 1.2	7.0 ± 1.3
Admission SpO_2 (%)	91.8 ± 2.4	92.1 ± 2.6

Primary Outcome

The mean length of hospital stay was 3.1 ± 0.9 days in Group A and 3.3 ± 1.0 days in Group B. The difference was not statistically significant (p = 0.28).

Secondary Outcomes

Outcome	Group A	Group B	p value
Oxygen duration (hours)	36 ± 14	38 ± 16	0.44
Wang score at 72 hours	2.1 ± 0.9	2.3 ± 1.0	0.31
ICU transfer (%)	2.5	2.5	NS

Both ICU transfers were due to worsening respiratory distress requiring non-invasive ventilation.

Adverse Events

Minor adverse events were more frequent in Group A, including tachycardia (15%) and tremor (10%). No episodes of bronchospasm or serious adverse events were observed.

DISCUSSION

This randomized controlled trial demonstrates that the addition of salbutamol to nebulized 3% hypertonic saline does not significantly reduce hospital stay or improve clinical outcomes in infants hospitalized with acute bronchiolitis. These findings are consistent with international guideline recommendations that discourage routine bronchodilator use in bronchiolitis[4,8,9].

Both treatment groups exhibited gradual clinical improvement, reflecting the self-limiting nature of the disease. The higher incidence of minor adverse effects in the salbutamol group further limits its clinical utility in this population.

Limitations

This study is limited by its data design, single-center setting, and lack of viral subtype analysis.

CONCLUSION

In this study, nebulized 3% hypertonic saline with salbutamol did not demonstrate a significant clinical advantage over hypertonic saline alone in hospitalized children under two years with acute bronchiolitis and was associated with a higher incidence of minor adverse effects.

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