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Efficacy of Nebulized 3% Hypertonic Saline in the Treatment of RSV Positive Bronchiolitis Cases Up to Two Months of Age: A Randomized Control Trial

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ABSTRACT

Background: Respiratory Syncytial Virus (RSV) bronchiolitis is a leading cause of lower respiratory tract infection in infants, particularly in those under two months of age. While supportive care remains the mainstay of treatment, nebulized hypertonic saline (HS) has been explored for its potential to enhance airway clearance and improve clinical outcomes. **Objective:** To evaluate the efficacy of nebulized 3% hypertonic saline in reducing respiratory distress and improving recovery outcomes in infants under two months of age diagnosed with RSV-positive bronchiolitis. **Methods:** This randomized controlled trial included 45 infants aged ≤60 days diagnosed with RSV-positive bronchiolitis. All participants received nebulized 3% hypertonic saline every 8 hours for four consecutive days. Clinical outcomes were assessed using the Modified Respiratory Distress Assessment Instrument (MRDAI) scores, oxygen saturation (SpO_2), duration of oxygen therapy, and length of hospital stay. Descriptive statistics and repeated measures analysis were performed to evaluate treatment response over time. **Results:** The mean age of participants was 36.91 ± 1.76 days; 73.3% were male. Significant reductions in MRDAI scores were observed from baseline (6.56 ± 1.21) to Day 4 (1.29 ± 0.18), with a mean difference of 5.27 ± 0.97 ($p<0.001$). SpO_2 improved from 91.46 ± 1.58% at admission to 93.13 ± 0.16% after 24 hours. The average duration of oxygen therapy was 10.12 ± 1.61 hours. Rapid recovery within 72 hours occurred in 86.6% of cases. The mean hospital stay was 62.98 ± 2.29 hours. **Conclusion:** Nebulized 3% hypertonic saline is effective in improving respiratory distress, oxygenation, and recovery in RSV-positive bronchiolitis cases among infants ≤2 months.

Keywords: RSV, Bronchiolitis, Hypertonic Saline, Infants, Respiratory Distress, MRDAI, Oxygen Therapy.

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INTRODUCTION

Respiratory Syncytial Virus (RSV) bronchiolitis is the leading cause of lower respiratory tract infection and hospitalization in infants under two years of age globally, particularly affecting those younger than two months due to their immature immune and respiratory systems [1].

The clinical manifestations include cough, wheezing, nasal congestion, chest indrawing, and feeding difficulty, often requiring hospitalization and oxygen support [2]. In low- and middle-income countries (LMICs) like Bangladesh, RSV imposes a substantial burden on healthcare resources due to delayed care-seeking and limited access to advanced respiratory support [3]. Current management strategies for bronchiolitis are primarily supportive. Despite frequent use in clinical practice, bronchodilators, corticosteroids, and antibiotics have shown limited effectiveness and are not routinely recommended [4]. In this context, nebulized hypertonic saline (3% HS) has emerged as a promising therapeutic alternative. It is postulated to work by rehydrating the airway surface liquid, reducing mucosal edema, and improving mucociliary clearance [5, 6]. A number of randomized controlled trials and meta-analyses have shown that 3% HS significantly reduces the severity of illness and length of hospital stay in children with bronchiolitis [7, 8]. However, these studies predominantly involve infants older than two months, and there is a lack of high-quality data in neonates and young infants under two months, an age group that is particularly vulnerable to complications and prolonged hospitalization [9]. In Bangladesh, the use of 3% HS in infants with RSV bronchiolitis remains limited, and evidence supporting its routine use in this age group is scarce. Therefore, this study was undertaken to evaluate the clinical efficacy of nebulized 3% hypertonic saline in RSV-positive bronchiolitis cases up to two months of age. The findings aim to inform evidence-based clinical practice, especially in resource-constrained settings.

OBJECTIVE

To evaluate the clinical efficacy of nebulized 3% hypertonic saline in the treatment of RSV-positive bronchiolitis in infants up to two months of age, focusing on improvement in clinical severity scores, oxygen saturation, duration of oxygen therapy, and length of hospital stay.

METHODS

Study Design

This was a prospective, hospital-based, single-arm randomized controlled trial conducted at Dhaka Shishu Hospital (Children), Dhaka, from June 2018 to July 2020.

Study Population

A total of 45 infants, aged ≤ 60 days, admitted with a clinical diagnosis of bronchiolitis and confirmed RSV positivity, were included in the study.

Inclusion Criteria

Infants ≤ 2 months of age.

Positive RSV diagnosis via nasopharyngeal swab.

Clinical features of bronchiolitis (cough, wheeze, chest indrawing, tachypnea).

Exclusion Criteria

Prematurity (< 37 weeks gestational age).

Congenital heart disease.

Immunodeficiency.

History of reactive airway disease.

Prior treatment with nebulized HS or bronchodilators within 24 hours.

Intervention

All enrolled patients received nebulized 3% hypertonic saline (3 mL), administered every 8 hours via jet nebulizer with oxygen as the driving gas. Supportive care, including oxygen therapy, fluid management, and nutrition, was provided as per hospital protocol.

Data Collection

Baseline demographic and clinical characteristics were recorded. Clinical severity was assessed using the Modified Respiratory Distress Assessment Instrument (MRDAI) at baseline, 12 hours, and daily up to Day 4. SpO_2 was recorded at admission and after 24 hours. Chest radiographs were evaluated at admission. The need and duration of oxygen therapy and the total length of hospital stay were documented.

Outcome Measures

Primary Outcome:

Change in MRDAI score from baseline to Day 4.

Secondary Outcomes:

Improvement in SpO_2 after 24 hours

Duration of oxygen therapy

Time to clinical recovery and discharge

Statistical Analysis

Descriptive statistics were used for demographic data. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables as frequencies and percentages. Paired t-tests were used to compare baseline and follow-up MRDAI scores. A p-value < 0.05 was considered statistically significant.

RESULTS

Demographic Characteristics of Patients

The study enrolled 45 infants in the hypertonic saline (HS) group. The mean age of the patients was 36.91 ± 1.76 days, indicating that the population consisted of very young infants, mostly under 2 months of age. Among them, 73.33% (n = 33) were male and 26.67% (n = 12) were female, showing a male predominance in RSV bronchiolitis cases.

Table 1: Demographic Characteristics (HS Group, n = 45)

Characteristic	Value
Age (in days) ± SD	36.91 ± 1.76
Gender – Male (%)	33 (73.33%)
Gender – Female (%)	12 (26.67%)

Table 1 presents the demographic characteristics of the patients, including age and gender distribution. This information helps in understanding the baseline population under study. This table shows the age and sex distribution of the studied infants in the HS group, indicating the sample included mostly male infants with a mean age of about 37 days.

Radiological Findings on Admission

Chest radiographs were performed on all participants upon admission. The most common findings included hypertranslucency (91.1%) and hyperinflation (88.8%), while atelectasis was observed in a smaller subset (17.7%)

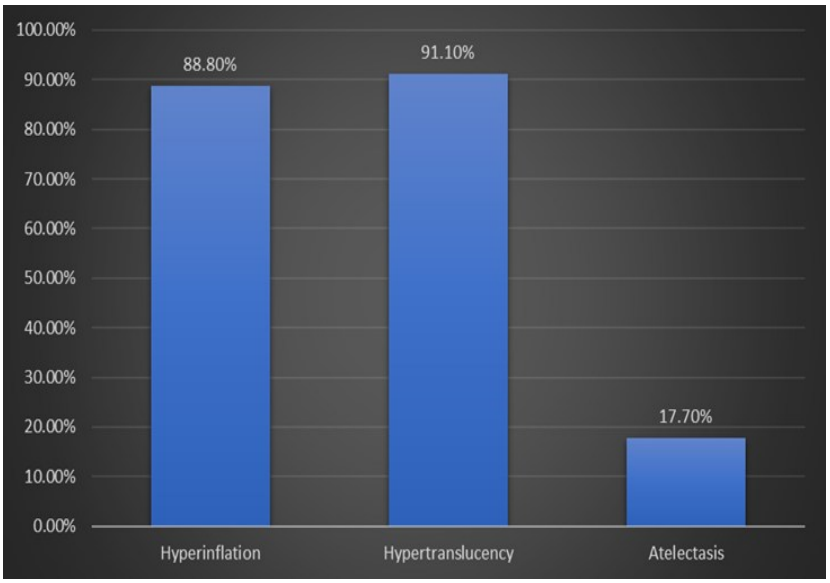

Figure 1: Radiological Findings (HS Group, n = 45)

Figure 1 lists the radiographic abnormalities found in patients, supporting the diagnosis of lower respiratory tract involvement and air trapping typical of bronchiolitis.

Clinical Presentation at Admission

All patients in the HS group presented with classic signs of bronchiolitis, including difficulty in breathing, cough, wheeze, ronchi, chest indrawing, nasal blockage, tachypnea, and inability to feed, with each of these present in 100% of the participants. Additional symptoms like fever (95.5%), tachycardia (97.7%), nasal flaring (33.3%), cyanosis (28.8%), and apnea (11.1%) were also observed, indicating varying severity.

Table 2: Clinical Presentations (HS Group, n = 45)

Symptom	Frequency (n)	Percentage (%)
Difficulty in breathing	45	100%
Cough	45	100%
Temperature	43	95.5%
Wheeze	45	100%
Ronchi	45	100%
Chest Indrawing	45	100%
Nasal Blockage	45	100%
Nasal Flaring	15	33.3%
Tachycardia	44	97.7%
Tachypnea	45	100%
Apnea	5	11.1%
Cyanosis	13	28.8%
Inability to Feed	45	100%

Table 2 summarizes the frequencies and percentages of clinical symptoms observed at the time of admission, highlighting the severity and consistency of presentation among the enrolled patients. This table provides a detailed account of the respiratory and systemic symptoms present at baseline, showing high clinical burden and the necessity for intensive supportive care.

Treatment Outcomes

The Modified Respiratory Distress Assessment Instrument (MRDAI) score was recorded at multiple time points. The mean MRDAI score significantly decreased from 6.56 ± 1.21 at baseline to 1.29 ± 0.18 on Day 4, reflecting substantial clinical improvement. The most rapid decline occurred within the first 48 hours.

Table 3: MRDAI Score Trend and Mean Differences (HS Group, n = 45)

Time Point	Mean MRDAI Score ± SD	Mean Difference from Baseline ± SD
Baseline	6.56 ± 1.21	—
12 Hours	5.20 ± 0.19	1.36 ± 0.26
Day 1	4.01 ± 0.16	2.56 ± 0.24
Day 2	2.80 ± 0.13	3.76 ± 0.23
Day 3	2.01 ± 0.15	4.55 ± 0.93
Day 4	1.29 ± 0.18	5.27 ± 0.97

Table 3 displays the progressive improvement in MRDAI scores along with the calculated mean differences from baseline, demonstrating the effectiveness of 3% HS nebulization in relieving respiratory distress. This table

illustrates the significant and steady reduction in respiratory distress symptoms over time as measured by MRDAI scores, confirming the therapeutic benefit of the intervention.

Advanced Treatment Outcomes

Further analysis of treatment outcomes revealed that the mean duration of oxygen therapy was 10.12 ± 1.61 hours, and there was a measurable improvement in SpO_2 from 91.46% to 93.13% after 24 hours. Rapid recovery (within 72 hours) occurred in 86.6% of cases. The average hospital stay was 62.98 ± 2.29 hours, indicating a relatively short duration of inpatient care.

Table 4: Key Clinical Recovery Indicators (HS Group, n = 45)

Outcome Parameter	Mean ± SD / n (%)
Duration of Oxygen Therapy (hrs)	10.12 ± 1.61
SpO_2 at Admission	91.46 ± 1.58
SpO_2 after 24 Hours	93.13 ± 0.16
Rapid Recovery (<72 hours)	39 (86.6%)
Gradual Recovery (>72 hours)	6 (13.4%)
Length of Hospital Stay (hrs)	62.98 ± 2.29

Table 4 outlines key clinical outcomes that reflect the speed of recovery and the overall clinical benefit of 3% HS therapy. This table summarizes critical recovery metrics such as oxygen use, oxygen saturation improvement, time to recovery, and duration of hospital stay, highlighting the rapid response to treatment.

Table 5: Summary of Clinical Effectiveness of 3% HS Nebulization

Outcome Measure	Interpretation
MRDAI Score ↓ 80.3% by Day 4	Significant and rapid symptom resolution
Oxygen Therapy <12 hrs	Quick relief from respiratory distress
SpO_2 ↑ from 91.46% to 93.13%	Improved oxygenation within 24 hours
86.6% Discharged within 72 hrs	Fast recovery and early hospital discharge
Mean Hospital Stay ~2.6 days	Shorter than typical bronchiolitis admissions

Table 5, demonstrating an 80.3% reduction in MRDAI score, fast improvement in oxygenation, and a high rate of discharge within 3 days. This table presents an overview of the efficacy indicators of 3% hypertonic saline, clearly showing the therapy's rapid action and success in reducing disease burden in infants with RSV bronchiolitis.

DISCUSSION

This randomized controlled trial investigated the therapeutic efficacy of nebulized 3% hypertonic saline (HS) in the management of RSV-positive bronchiolitis in infants up to two months of age. The findings demonstrate that HS is associated with rapid clinical improvement, reduced respiratory distress, shorter duration of oxygen therapy, and significantly decreased hospital stay. The present study showed a progressive and statistically significant reduction in MRDAI scores, with a mean decline from 6.56 at baseline to 1.29 by Day 4, accounting for an overall reduction of approximately 80.3%. This aligns with results from previous studies indicating that hypertonic saline enhances mucociliary clearance, reduces airway edema, and improves bronchial hydration, ultimately alleviating respiratory distress [5, 6]. Moreover, SpO_2 levels improved from 91.46% at admission to 93.13% after 24 hours, suggesting enhanced oxygenation, likely due to improved airway patency. This finding is consistent with a meta-analysis by Zhang *et al*., which found that 3% HS significantly improves oxygen saturation and clinical scores in infants with bronchiolitis compared to normal saline [5]. In our study, 86.6% of infants recovered and were discharged within 72 hours, and the mean hospital

stay was 62.98 hours. These findings are in agreement with studies by Mandelberg et al. and Sarrell *et al*., where the use of nebulized hypertonic saline led to shorter hospital stays and quicker symptom resolution compared to isotonic saline [10, 6]. Furthermore, the need for oxygen therapy was limited to a mean duration of 10.12 hours, indicating a reduction in respiratory support requirements. Similar outcomes were observed in a Cochrane review by Everard *et al*., which confirmed that 3% HS reduces the duration of oxygen therapy and hospital stay in hospitalized infants with bronchiolitis [11]. The chest radiographic findings in our study were typical of bronchiolitis, with hypertranslucency (91.1%) and hyperinflation (88.8%) being predominant. These are consistent with established literature indicating that such findings reflect small airway obstruction and air trapping, common in RSV infection [12]. It is also worth noting that our study targeted a narrow age group (infants ≤ 2 months), who are considered high-risk for severe RSV infections due to immature immune and respiratory systems. The rapid clinical response to 3% HS in this age group underlines its utility as a frontline therapy in younger populations. However, our findings contrast slightly with some studies that found minimal or no benefit of hypertonic saline compared to normal saline. For example, a multicenter RCT by Ralston *et al*. found no significant difference in hospital length of stay between the HS and control groups [4]. Such discrepancies may be attributed to differences in study design, inclusion criteria, frequency of administration, and clinical scoring systems used.

CONCLUSION

This randomized controlled trial highlights the significant therapeutic benefits of nebulized 3% hypertonic saline in managing RSV-positive bronchiolitis in infants up to two months of age. The intervention led to rapid clinical improvement, as evidenced by a marked reduction in MRDAI scores, improved oxygen saturation, decreased need for oxygen therapy, and shortened hospital stays. The majority of patients (86.6%) experienced recovery within 72 hours, underscoring the efficiency and safety of 3% HS in early infancy, a particularly vulnerable period for severe bronchiolitis. These findings support the routine use of nebulized hypertonic saline as an effective, non-invasive, and low-cost treatment option for bronchiolitis in young infants, especially in settings where rapid patient turnover and resource optimization are critical.

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