International Journal of Contemporary Pediatrics
*Khanom M et al. Int J Contemp Pediatr. 2025 Aug;12(8):1310-1315*
http://www.ijpediatrics.com
pISSN 2349-3283 | eISSN 2349-3291

DOI: https://dx.doi.org/10.18203/2349-3291.ijcp20252212

**Original Research Article**

# A comparative study of nebulized 3% hypertonic saline and normal saline in the management of respiratory syncytial virus-positive acute bronchiolitis in young infants

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**Received:** 02 June 2025
**Accepted:** 04 July 2025

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## ABSTRACT

**Background:** Acute bronchiolitis due to respiratory syncytial virus (RSV) is a major cause of hospitalization in infants, yet optimal therapeutic strategies are still under evaluation. Hypertonic saline has gained interest for its potential mucolytic and anti-edematous benefits. This study aimed to evaluate the clinical efficacy of nebulized 3% hypertonic saline compared to 0.9% normal saline in managing RSV-positive acute bronchiolitis in infants up to two months old.
**Methods:** A double-blind, randomized controlled trial was conducted at Dhaka Shishu (Children) hospital involving 90 infants aged≤60 days with confirmed RSV-positive bronchiolitis. Participants were randomly assigned to receive either nebulized 3% hypertonic saline or 0.9% normal saline, administered three times daily until discharge. Clinical efficacy was measured using the modified respiratory distress assessment instrument (MRDAI), duration of oxygen therapy, and length of hospital stay.
**Results:** The hypertonic saline group showed significantly greater clinical improvement starting at 12 hours post-intervention (MRDAI: 5.20±0.19 vs. 5.98±0.23; p=0.005). These infants also required shorter oxygen therapy (10.12±1.61 vs. 11.54±1.46 hours; p=0.025) and had significantly reduced hospital stays (62.98±2.29 vs. 79.64±3.69 hours; p=0.0001).
**Conclusions:** Nebulized 3% hypertonic saline is more effective than normal saline in improving clinical outcomes in RSV-positive bronchiolitis in infants under two months, significantly reducing disease severity, oxygen requirement, and hospitalization duration. Incorporation into treatment protocols is strongly recommended.

**Keywords:** Hypertonic saline, Normal saline, RSV, Bronchiolitis, Infants, MRDAI, Oxygen therapy, Hospital stay

## INTRODUCTION

Respiratory syncytial virus (RSV) bronchiolitis is a primary cause of lower respiratory tract illness and hospitalization in young infants globally.[1] Defined by the AAP guideline as an acute bronchiolar inflammation leading to edema, increased mucus, epithelial necrosis, and bronchospasm, it significantly contributes to

morbidity and mortality in children under five in Bangladesh, often occurring in epidemics during winter and early spring.[2,3]

Despite decades of effort, no definitive evidence-based treatment exists, and standard care remains supportive, focusing on oxygenation, hydration, and nutrition.[4] Pharmacological interventions like bronchodilators (salbutamol, adrenaline), anticholinergics, and saline nebulization have yielded inconsistent results. There is a lack of strong evidence for most interventions, including inhaled epinephrine, bronchodilators, steroids, anticholinergics, antibiotics, and chest physiotherapy. Glucocorticoids have largely shown no positive therapeutic effect, and while ß2-agonists, particularly epinephrine, sometimes offer short-term improvement, other studies report no significant benefit.[4-8] Antibiotics are frequently used in bronchiolitis (99% in one study by Teunissen et al) but are generally considered ineffective for the condition.[6]

Several studies propose nebulized 3% saline for infants with bronchiolitis, citing its potential to reduce secretion viscosity, decrease airway edema, and enhance mucociliary function. Evidence indicates hypertonic saline positively impacts mucociliary clearances.[9,10] Trials investigating nebulized 3% hypertonic saline have shown significant improvements in clinical severity scores and clinically significant reductions in hospital stay.[11-13] A Cochrane review concluded that nebulized 3% hypertonic saline might considerably shorter hospital stays and improve clinical severity scores in infants with acute viral bronchiolitis.[13] The mechanism is thought to involve osmotic water movement into airways, improving mucociliary clearance. Current AAP guidelines recommend supplemental oxygen if saturation is <90%, while NICE guidelines suggest <92%.[14] Notably, updated AAP guidelines now support using hypertonic saline nebulization for infants and children hospitalized for bronchiolitis.[15]

### *Objectives*

Objectives were to evaluate the efficacy of nebulized 3% hypertonic saline and nebulized normal saline in young infants with RSV-positive acute bronchiolitis.

## METHODS

### *Study design and setting*

This was a randomized clinical trial conducted in the department of pediatrics at Dhaka Shishu (Children) hospital, Dhaka, Bangladesh. The study duration was from June 2018 to July 2020. Ethical approval was obtained from the ethical review committee of Bangladesh institute of child health (BICH), Dhaka, and informed written consent was taken from the legal guardians of each child.

### *Study population*

Infants aged 0 to 2 months admitted with a diagnosis of RSV-positive acute bronchiolitis were eligible. Inclusion criteria were: first episode of respiratory distress with wheezing, preceding viral upper respiratory infection symptoms (cough, nasal blockage, tachypnoea, chest indrawing), MRDAI score >3, and no evidence of bacterial infection. Exclusion criteria included: age >2 months, RSV-negative bronchiolitis, history of two or more episodes of respiratory distress, chronic cardiopulmonary disease, history of mechanical ventilation in the neonatal period, or critical illness at presentation. Nasopharyngeal swabs were tested for RSV using RT-PCR.

A sample size of 45 in each group was targeted, calculated based on an expected mean length of hospital stay of 74.7 hours in the control group and 58.1 hours in the experimental group, with a standard deviation of 27.2, a 95% confidence level, and 90% power.

### *Randomization and interventions*

Patients were randomized by lottery method into two groups: an intervention group (HS group) receiving nebulized 3 ml of 3% hypertonic saline and a control group (NS group) receiving nebulized 3 ml of 0.9% normal saline. Nebulization was administered three times daily (8-hourly intervals) until discharge. Both groups received standard supportive care, including proper positioning, nasal and oropharyngeal suction as needed, IV fluids, appropriate feeding, oxygen therapy (if $SpO_2$<92%), and paracetamol for fever.

### *Outcome measures*

The primary outcome variables were: MRDAI score (clinical severity), assessed at admission, 12 hours after the first nebulization, and then daily until discharge. Clinical recovery, categorized as rapid (within 72 hours) or gradual (after 72 hours). Duration of oxygen therapy (hours from initiation to withdrawal, stopped when $SpO_2$≥95%).

Length of hospital stay (hours from admission to discharge). Secondary outcomes included respiratory rate, tachycardia, use of accessory muscles, cyanosis, auscultatory findings (wheezing/Ronchi), and $SpO_2$. Discharge criteria were: MRDAI score <3, infant feeding well, and $SpO_2$≥95% in room air.

### *Data collection and analysis*

Data were collected using a pre-tested, semi-structured questionnaire. Statistical analysis was performed using SPSS version 26.0. Categorical variables were compared using the chi-square ($X^2$) test, and continuous variables were compared using an unpaired t test. A $p<0.05$ was considered statistically significant.

***Ethical considerations***

The ethical review committee (ERC) of Bangladesh Shishu hospital and institute, Dhaka, approved the study protocol. The aims, objectives, risks, and benefits were explained to parents in clear, local language, and informed written consent was obtained. Confidentiality was ensured, and parents were told their participation would contribute to clinical knowledge and patient management. They could withdraw at any time without affecting their child's treatment.

## RESULTS

Table 1 shows the mean age of studied patients 36.91±1.76 days in HS group and 39.21±1.50 days in the NS group. The mean difference was not statistically significant between groups (p>0.05). Majority of patients were males in both groups, 33 (73.33%) in the HS group and 32 (71.11%) in NS group and females were 12 (26.67%) in HS group, 13 (28.89%) in NS group. The difference was not statistically significant (p>0.05).

**Table 1: Demographic characteristics of the studied patients, (n=90).**

| Variables | HS, n=45 (%) | NS, n=45 (%) | P value |
|---|---|---|---|
| **Age (in days)±SD** | 36.91±1.76 | 39.21±1.50 | [a]0.19[ns] |
| **Gender** | | | |
| Male | 33 (73.33%) | 32 (71.11%) | [b]1.0[ns] |
| Female | 12 (26.67%) | 13 (28.89%) | |

*Results are expressed as frequency, percentage and mean. ns=not significant, p<0.05=significant. [a]P value reached from unpaired t-test and [b]P value reached from Chi-square test.

***Intervention group:*** Nebulization with 3 ml of 3% hypertonic saline.

***Control group:*** Nebulization with 3 ml of normal saline.

Table 2 shows all the cases in both groups presented with breathing difficulty, cough, wheeze, tachypnea, chest indrawing, rhonchi, nasal blockage and feeding difficulty. Nasal flaring was present 15 (33.3%) cases in HS group and 10 (22.2%) cases in NS group. Tachycardia 44 (97.7%) in NS group and 42 (93.3%) in NS group. Cyanosis was present 13 928.8%) in HS group and 12 (26.6%) in NS group. Only 5 (11.1%) cases in HS group and 3 (6.6%) in NS group presented with apnea. According to clinical presentation both groups are same (p>0.05).

Bar diagram demonstrates that most of the young infant admitted in hospital with moderate respiratory distress according to a MRDAI score, among them 72% in HS group and 76% in NS group.

**Table 2: Clinical presentation of studied patients on admission.**

| Variables | HS, n=45 (%) | NS, n=45 (%) | P value |
|---|---|---|---|
| **Difficulty in breathing** | 45 (100) | 45 (100) | 1.0[ns] |
| **Cough** | 45 (100) | 45 (100) | 1.0[ns] |
| **Temperature** | 43 (95.5) | 42 (93.3) | 0.74[ns] |
| **Wheeze** | 45 (100) | 45 (100) | 1.0[ns] |
| **Ronchi** | 45 (100) | 45 (100) | 1.0[ns] |
| **Chest indrawing** | 45 (100) | 45 (100) | 1.0[ns] |
| **Nasal blockage** | 45 (100) | 45 (100) | 1.0[ns] |
| **Nasal flaring** | 15 (33.3) | 10 (22.2) | 0.24[ns] |
| **Tachycardia** | 44 (97.7) | 42 (93.3) | 0.56[ns] |
| **Tachypnoea** | 45 (100) | 45 (100) | 1.0[ns] |
| **Apnea** | 5 (11.1) | 3 (6.6) | 0.46[ns] |
| **Cyanosis** | 13 (28.8) | 12 (26.6) | 0.82[ns] |
| **Inability to feed** | 45 (100) | 45 (100) | 1.0[ns] |

*ns=not significant, result were expressed as frequency, percentage and p value reached from chi-square test.

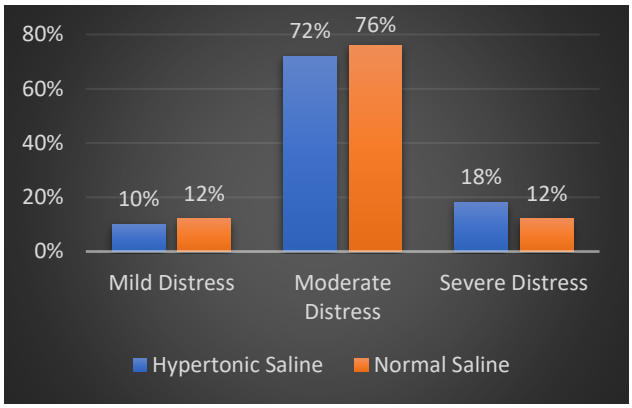


**Figure 1: Grading of respiratory distress of the study patient by MRDAI score.**

Table 3 shows hyper-translucency present 41 (91.1%) in HS group and 40 (88.8%) in NS group whereas hyperinflation 40 (88.8%) in HS group and 42 (93.3%) in NS group. Only 8 (17.7%) of atelectasis was present in HS group and 6 (13.3%) in NS group, according to radiological findings both groups are same (p>0.05).

**Table 3: Chest radiological findings of studied patients on admission.**

| Radiological finding | HS, n=45 (%) | NS, n=45 (%) | P value |
|---|---|---|---|
| **Hyperinflation** | 40 (88.8) | 42 (93.3) | 0.461[ns] |
| **Hyper translucency** | 41 (91.1) | 40 (88.8) | 0.710[ns] |
| **Atelectasis** | 8 (17.7) | 6 (13.3) | 0.603[ns] |

*ns=not significant, results were expressed as frequency, percentage and p value reached from chi-square test.

**Table 4: Mean MRDAI score comparison.**

| Time point | Hypertonic saline | Normal saline | P value |
|---|---|---|---|
| **Baseline** | 6.56±1.21 | 6.82±1.30 | 0.159 |
| **12 hours** | 5.20±0.19 | 5.98±0.23 | 0.005 |
| **Day 1** | 4.01±0.16 | 4.87±0.23 | 0.001 |
| **Day 2** | 2.80±0.13 | 3.60±0.21 | 0.001 |
| **Day 3** | 2.01±0.15 | 2.52±0.21 | 0.005 |
| **Day 4** | 1.29±0.18 | 2.31±0.13 | 0.003 |

Table 5 shows that the patients of HS group required 10.12±1.61 hours of oxygen therapy, while the patients of NS group required 11.54±1.46 hours of oxygen therapy. Duration of oxygen therapy significantly reduced in HS group compared to NS group ($p<0.05$).

**Table 5: Duration of oxygen therapy.**

| Group | Duration (hours) | P value |
|---|---|---|
| **Hypertonic saline** | 10.12±1.61 | 0.025 |
| **Normal saline** | 11.54±1.46 | |

Table 6 shows mean $SPO_2$ during admission 91.46±1.58 in HS group and 91.68±1.70 in NS group, which was not statistically significant whereas changes of $SPO_2$ was increased in HS group (93.13±0.16) than NS group (92.16±0.14) after 24 hours of nebulization ($p<0.05$).

**Table 6: Comparison of $SPO_2$ between groups.**

| Comparison of $SpO_2$ | HS, n=45 | NS, n=45 | P value |
|---|---|---|---|
| **At Admission** | 91.46±1.58 | 91.68±1.70 | $0.551^{ns}$ |
| **After 24 hours** | 93.13±0.16 | 92.16±0.14 | $0.012^{s}$ |

*n=not significant, s=significant, p value reached from the unpaired t-test

Table 7 shows mean hospital stay was 62.98±2.29 days in HS group and 79.64±3.69 hours in NS group, which means hospital stay was significantly less in HS group than NS group ($p<0.05$).

**Table 7: Length of hospital stay.**

| Group | Duration (hours) | P value |
|---|---|---|
| **Hypertonic saline** | 62.98±2.29 | 0.0001 |
| **Normal saline** | 79.64±3.69 | |

## DISCUSSION

This prospective, randomized clinical trial was conducted in the department of pediatrics at Dhaka Shishu (Children) hospital, involving 90 infants aged 0-2 months with confirmed RSV-positive acute bronchiolitis. The study found that nebulized 3% hypertonic saline significantly reduced clinical severity, duration of oxygen therapy, and length of hospital stay compared to 0.9% normal saline, supporting its potential as an effective treatment option in this age group.

In this study, the majority of participants (61%) were between 29-60 days of age, while 39% were neonates. The mean age in the hypertonic saline group was 36.91±1.76 days, and in the normal saline group, it was 39.21±1.50 days. This difference was not statistically significant ($p>0.05$), aligning with similar studies. Khanal et al reported a mean age of 15.88±9.1 days, Malik et al reported 6.03±3.71 months in the hypertonic saline group and 5.69±3.34 months in the normal saline group, while Islam et al found 5.2±3.2 months and 5.5±3.0 months in the respective groups.[16-18]

A male predominance was observed in both groups (HS: 73.33%, NS: 71.11%), though the difference was not statistically significant ($p>0.05$). This finding is consistent with other studies, including Malik et al, Kuzik et al and Restori et al which also noted a slightly higher incidence among males.[12,17,19] This may be explained by both the biological predisposition of males to bronchiolitis and by cultural tendencies in the Indian subcontinent to seek medical care more readily for male children.

Regarding clinical symptoms, all patients presented with breathing difficulty, cough, nasal blockage, wheezing, Ronchi, tachypnoea, chest indrawing, and feeding difficulty. Fever was present in 95.5% of the HS group and 93.3% of the NS group, and nasal flaring occurred in 33.3% and 22.2%, respectively. These differences were not statistically significant ($p>0.05$). These clinical findings align with those reported by Kabra et al and Alisamir et al where cough, fast breathing, and fever were the most common symptoms in bronchiolitis cases. Studies have consistently shown that wheezing is a hallmark feature of bronchiolitis, consistent with this study.[18-22]

Baseline $SpO_2$ levels were similar between groups (HS: 91.46±1.58%, NS: 91.68±1.70%), with no significant difference. However, 24 hours after treatment, the HS group showed significantly greater improvement (93.13±0.16% vs. 92.16±0.14%; $p<0.05$). These findings support previous research indicating better oxygenation with hypertonic saline. One study found a change in oxygen saturation of 0.44±0.43% in HS group compared to 0.36±0.50% in NS group ($p<0.05$), and Islam et al also reported significant improvement in $SpO_2$ ($p<0.001$).[18]

Radiological findings in this study included hyperinflation and increased translucency, which were the most common abnormalities. Similar findings have been documented by Amara and Amin et al who observed hyperinflation, increased interstitial markings, streaky densities, and “dirty lung” features in bronchiolitis cases.[23,24] These were also observed in studies by Caballero et al and Islam et al.[1,18]

At baseline, MRDAI scores were nearly identical between groups. A previous study reported baseline scores of 9.0±1.0 in the HS group and 9.3±1.8 in the NS group, showing no significant difference.[25] In our study, both groups showed improvement in MRDAI scores over time, but reduction was significantly greater in hypertonic saline group beginning at 12 hours post-intervention and continuing through day 4 ($p<0.05$). These findings correspond with studies by Khanal et al, Kabra et al and others, where hypertonic saline led to a more marked improvement in clinical severity scores.[16,20,24]

Furthermore, significant reductions in MRDAI scores between baseline and each follow-up point (12 hours, day 1, day 2, day 3, and day 4) were observed in the HS group compared to the NS group. In a separate study, a 16.7% reduction in clinical score was noted in the NS + adrenaline group, while a 13.2% reduction occurred in the 3% hypertonic saline group between day 1 and day 2, with statistical significance ($p<0.0001$).[24] Khanal et al also observed that clinical severity scores dropped more in the 3% HS group than in the NS or salbutamol groups by day 3 of treatment ($p<0.01$).[16]

In terms of oxygen therapy, the mean duration was shorter in the HS group (10.12±1.61 hours) than in the NS group (11.54±1.46 hours), with statistical significance ($p<0.05$). Amin et al also observed a significantly shorter oxygen therapy duration in their group I compared to group II (15.0±6.0 vs. 26.4±5.37 hours; $p<0.05$).[23] Islam et al reported similar results, with the HS group requiring 12.53±3.58 hours vs. 20.25±4.15 hours in the NS with salbutamol group ($p=0.009$).[18]

The mean hospital stay was significantly shorter in the HS group (62.98±2.29 hours) compared to the NS group (79.64±3.69 hours; $p<0.05$). Khanal et al found that the length of hospital stay was 3.4±1.7 days in the HS group versus 4.9±1.4 days in the NS group ($p=0.001$).[16] Kuzik et al reported similar findings (2.6±1.9 vs. 3.5±2.9 days; $p<0.05$).[12] A Cochrane meta-analysis by Zhang et al reported a 24% shorter stay with hypertonic saline, and Popp et al also supported this finding.[26,27] However, some studies, like those by Popp et al and Baron et al reported no significant differences in hospital stay duration.[10,27]

In summary, this study reinforces the clinical advantage of using nebulized 3% hypertonic saline in managing RSV-positive bronchiolitis in young infants. The intervention was associated with faster clinical improvement, enhanced oxygenation, and significantly reduced hospital resource use, supporting its incorporation into standard care protocols.

## CONCLUSION

This study demonstrates that nebulized 3% hypertonic saline provides significant clinical advantages over normal saline in the treatment of RSV-positive acute bronchiolitis in infants up to two months of age. Specifically, it leads to more rapid improvement in respiratory distress symptoms, as reflected by declining MRDAI scores, and results in shorter durations of both oxygen therapy and hospitalization. These findings support the incorporation of hypertonic saline into treatment protocols for this age group to enhance recovery and reduce healthcare burden.

## ACKNOWLEDGEMENTS

Authors would like to thank to medical and nursing staff of the neonatal unit of Bangladesh Shishu hospital and institute for their unwavering support and dedication during the study.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Khanom M, Sarkar PK, Sayeed KMI, Al Amin MM, Ferdous F, Tonny AS, et al. A comparative study of nebulized 3% hypertonic saline and normal saline in the management of respiratory syncytial virus-positive acute bronchiolitis in young infants. Int J Contemp Pediatr 2025;12:1310-5.