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Original Research Article

Efficacy of Nebulized 3% Hypertonic Saline in the Management of Bronchiolitis in Children Less Than 2 Years of Age

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Abstract: *Bronchiolitis is a major cause of hospitalization among infants and young children, particularly in developing countries like Pakistan. Despite advances in supportive care, optimal management strategies remain under evaluation. Nebulized 3% hypertonic saline (HS) has been proposed as a safe and effective therapy that improves mucociliary clearance, reduces airway edema, and accelerates recovery.* ***Objectives****: This randomized controlled trial aimed to evaluate the efficacy of nebulized 3% HS compared with 0.9% normal saline (NS) in children aged < 2 years with bronchiolitis.* ***Methods:*** *This single-center randomized controlled trial was conducted at the Department of Pediatric Medicine, Shaikh Zayed Hospital, Lahore, from August 2024 to January 2025. A total of 26 children under two years of age with a first episode of bronchiolitis were enrolled through non-probability consecutive sampling and randomly divided into two equal groups. Group A received nebulized 3% HS with salbutamol and budesonide, while Group B received nebulized 0.9% NS with the same adjuncts. The primary outcome was rapid clinical recovery and discharge within 72 hours; secondary outcomes included changes in the Wang Clinical Severity Score (WCSS) and the duration of hospital stay. Data were analyzed using SPSS v25, with a p-value ≤ 0.05 considered significant.* ***Results:*** *The mean age of participants was 11.2 ± 5.8 months, with equal gender distribution (61.5% male). Baseline WCSS was comparable between groups (7.31 ± 1.02 vs. 7.45 ± 0.97; p = 0.72). Significant improvement was observed in Group A at 60 minutes (p = 0.04), 90 minutes (p = 0.02), 24 hours (p < 0.001), and at discharge (2.71 ± 0.55 vs. 3.86 ± 0.67; p < 0.001). Rapid recovery within 72 hours occurred in 92.3% of Group A versus 53.8% of Group B (p = 0.03). The mean hospital stay was significantly shorter in the HS group (2.6 ± 0.8 days) compared to the NS group (4.1 ± 0.9 days; p < 0.001). Overall treatment efficacy was achieved in 92.3% of the HS group compared with 53.8% in the NS group (p = 0.02).* ***Conclusion:*** *Nebulized 3% hypertonic saline significantly improved clinical severity scores, accelerated recovery, and reduced hospital stay compared to normal saline in children under two years with bronchiolitis. Its use offers a cost-effective, evidence-based intervention that may substantially reduce pediatric morbidity and healthcare burden in resource-limited settings like Pakistan.*

Keywords: Bronchiolitis, Hypertonic saline, Nebulization, Pediatrics

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Introduction

Bronchiolitis is a common and significant respiratory illness affecting infants and children under two years of age, most frequently caused by viral infections, particularly Respiratory Syncytial Virus (RSV). The clinical manifestations of bronchiolitis typically include wheezing, cough, and difficulty breathing, often leading to hospitalization due to respiratory distress and dehydration. Bronchiolitis is a leading cause of pediatric emergency visits and accounts for numerous hospitalizations, highlighting the need for effective therapeutic strategies to mitigate its clinical impact (1, 2, 3).

Recent advancements in treatment protocols have included the use of nebulized hypertonic saline solutions. Hypertonic saline, particularly at 3%, has gained attention for its potential to reduce airway edema, enhance mucociliary clearance, and thereby improve clinical outcomes in infants diagnosed with bronchiolitis (4, 5, 6). The mechanism of action of hypertonic saline involves osmotic effects that enhance moisture in airway secretions, aiding mucus clearance and reducing airway obstruction (7, 8). Studies have reported that nebulized 3% hypertonic saline may lead to lower clinical severity scores and shorter hospital stays, providing a potential therapeutic advantage over standard treatments (9,10, 11).

However, the efficacy of nebulized hypertonic saline must be interpreted in light of contemporaneous evidence, which has yielded mixed results. For instance, some randomized controlled trials have found significant benefits of nebulized hypertonic saline, including symptom relief and shorter hospitalization (1, 2, 12). In contrast, others suggest that adding bronchodilators may not confer additional benefits and that outcomes may vary depending on patient demographics and clinical settings (11, 13, 14). Further comparison studies comparing 3% hypertonic saline with isotonic solutions, such as 0.9% saline, yield mixed evidence regarding clinical advantages, warranting ongoing investigation into the most effective management protocols for bronchiolitis (15, 16).

In evaluating the management of bronchiolitis in the Pakistani context, the condition's prevalence and implications warrant particular attention, given the varying healthcare infrastructure and resources. In Pakistan, where healthcare access may be limited, particularly in rural areas, adopting effective, evidence-based treatments such as nebulized hypertonic saline could provide a less resource-intensive way to manage a condition that significantly burdens pediatric health services. Studies have highlighted the need for local evidence to guide clinical practices, particularly as bronchiolitis is a leading cause of morbidity in the pediatric population, affecting many families across socioeconomic strata (17, 18,19). Thus, research on the efficacy of nebulized 3% hypertonic saline in a Pakistani population aims to enhance treatment protocols and improve healthcare outcomes for children with this common respiratory ailment.

Methodology

The present study was designed as a randomized controlled trial conducted in the Department of Pediatric Medicine at Shaikh Zayed Hospital, Lahore, over a period of six months, following ethical approval of the synopsis from August 2024 to January 2025. The study aimed to determine the efficacy of nebulized 3% hypertonic saline in the management of bronchiolitis among children less than two years of age. A total of 26 participants who met the inclusion criteria were enrolled in the study using a non-probability, consecutive sampling technique. The sample size was calculated at a 95% confidence level, with a 5% margin of error, assuming an expected efficacy of nebulized 3% hypertonic saline of 94% compared to 58% in the normal saline group, yielding 13 participants per arm.

Children aged less than 2 years, regardless of gender, presenting with the first episode of acute wheezing consistent with bronchiolitis, as defined by the American Academy of Pediatrics consensus guidelines, were included. Disease severity was determined using Wang's Clinical Severity Score, in which scores of 3–5 indicated mild bronchiolitis, 6–9 moderate, and 10–12 severe. Children with pre-existing pulmonary disorders (such as cystic fibrosis or bronchopulmonary dysplasia), congenital heart or renal disease, history of recurrent wheezing or asthma, those requiring mechanical ventilation, or those recently treated with bronchodilators or corticosteroids were excluded to minimize confounding factors.

After obtaining written informed consent from parents or guardians, the demographic data, clinical history, and physical examination findings were recorded on a predesigned proforma. Participants were randomly allocated by lottery to two equal groups. Children in Group A received nebulization with 3% hypertonic saline, combined with salbutamol and budesonide, whereas those in Group B received 0.9% normal saline with salbutamol and budesonide. Both groups received their respective nebulized solutions three times per day until their clinical condition improved sufficiently for discharge, defined as achieving a Wang score below 3. Each nebulization session involved a maximum of 4 doses administered over 2 hours, with a minimum 30-minute interval between sessions.

Nebulization was delivered using a standard hospital-grade ultrasonic nebulizer via a face mask. All children, regardless of group allocation, received standard supportive therapy per institutional pediatric guidelines, including head-end elevation, oxygen supplementation when saturation fell below 94%, acetaminophen for fever, and nasal lavage with sterile saline before and after each nebulization session. Nutritional support was prescribed at the treating physician's discretion, based on respiratory effort and feeding tolerance.

Each child was closely monitored by the research investigator for clinical response and any potential adverse effects. Vital signs, oxygen saturation, and respiratory parameters were assessed every 30 minutes for up to 120 minutes after the first dose, and subsequently at 4-hour intervals. Children whose condition deteriorated during the study were withdrawn and managed in accordance with standard hospital protocols. The primary outcome of the study was the proportion of children who achieved rapid recovery and were discharged within 72 hours of admission. Secondary outcomes included changes in the mean Wang's clinical severity score at 24 hours and the mean hospital stay duration (in days).

Data were analyzed using SPSS version 25.0. Quantitative variables, such as age, Wang clinical severity score, and hospital stay duration, were reported as mean ± standard deviation. In contrast, qualitative variables, such as gender, severity category, and treatment efficacy, were presented as frequencies and percentages. The independent-samples t-test was used to compare mean differences between the two groups, while the Chi-square test was used for categorical variables, such as efficacy outcomes. A p-value ≤ 0.05 was considered statistically significant. To control for potential effect modifiers, the data were stratified by age, gender, and disease severity, followed by post-stratification analysis using the Chi-square test.

Results

The demographic characteristics of the study participants are summarized in Table 1. A total of 26 children under 2 years of age were included, with 13 participants in each group: Group A (3% hypertonic saline) and Group B (0.9% normal saline). The overall mean age of the children was 11.2 ± 5.8 months, with a range of 2 to 24 months, and there was no statistically significant difference between the two groups ($p = 0.83$). There was a male predominance (61.5%) in both groups, with equal gender distribution ($p = 1.00$). In terms of disease severity, the majority of the children (65.4%) presented with moderate bronchiolitis, while 19.2% had mild and 15.4% had severe disease. The severity distribution was statistically comparable between the two groups ($p = 0.67$), confirming that randomization was effective and the baseline characteristics were homogenous. (Table 1).

In assessing the clinical progression of bronchiolitis, Table 2 presents the comparison of mean Wang clinical severity scores between the two groups over time. At baseline, the mean severity scores were comparable (7.31 ± 1.02 vs. 7.45 ± 0.97; $p = 0.72$). However, children in the hypertonic saline group demonstrated a faster reduction in clinical severity scores at subsequent time intervals. Significant improvements were observed as early as 60 minutes ($p = 0.04$), with further decreases at 90 minutes ($p = 0.02$), and highly significant improvements at 24 hours and discharge ($p < 0.001$). The final mean score at discharge was 2.71 ± 0.55 in Group A compared to 3.86 ± 0.67 in Group B, indicating a more rapid clinical recovery among those treated with 3% hypertonic saline. (Table 2).

As shown in Table 3, the primary outcome—rapid recovery and hospital discharge within 72 hours—was achieved by 92.3% of children in the hypertonic saline group compared to 53.8% in the normal saline group, and this difference was statistically significant ($p = 0.03$). This indicates that the use of hypertonic saline significantly shortened symptom duration and facilitated earlier discharge compared with conventional therapy.

The mean hospital stay duration, presented in Table 4, was also markedly shorter among those receiving hypertonic saline. The mean stay for Group A was 2.6 ± 0.8 days, compared to 4.1 ± 0.9 days in Group B ($p < 0.001$). The overall mean duration for the cohort was 3.4 ± 1.1 days, underscoring the therapeutic advantage of hypertonic saline in reducing hospitalization time and carrying significant implications for healthcare costs and resource utilization in pediatric care settings in Pakistan.

When overall treatment efficacy was evaluated—defined as rapid recovery, reduction in severity score, and hospital discharge within 72 hours—the hypertonic saline group again demonstrated superior outcomes. As shown in Table 5, 92.3% of patients in Group A achieved an effective treatment response, compared with 53.8% in Group B ($p = 0.02$). This reinforces the overall effectiveness of 3% hypertonic saline nebulization as an adjunct therapy for bronchiolitis in children less than two years of age.

Table 1. Demographic Characteristics of Study Participants (n = 26)

Variable	Category	Group A (3% HS) n = 13	Group B (0.9% NS) n = 13	Total n = 26 (%)	*p*-value
Age (months)	Mean ± SD	10.9 ± 6.1	11.4 ± 5.5	11.2 ± 5.8	0.83
Gender	Male	8 (61.5%)	8 (61.5%)	16 (61.5%)	1.00
	Female	5 (38.5%)	5 (38.5%)	10 (38.5%)	
Severity of bronchiolitis	Mild	3 (23.1%)	2 (15.4%)	5 (19.2%)	0.67
	Moderate	8 (61.5%)	9 (69.2%)	17 (65.4%)	
	Severe	2 (15.4%)	2 (15.4%)	4 (15.4%)	

Table 2. Comparison of Mean Wang Clinical Severity Scores Between Groups

Time Interval	Group A (3% HS) Mean ± SD	Group B (0.9% NS) Mean ± SD	*p*-value
Baseline	7.31 ± 1.02	7.45 ± 0.97	0.72
30 minutes	6.52 ± 0.88	7.12 ± 1.01	0.11
60 minutes	6.00 ± 0.84	6.69 ± 0.93	0.04 *
90 minutes	5.41 ± 0.91	6.30 ± 1.02	0.02 *
24 hours	4.82 ± 0.76	6.12 ± 0.83	<0.001 **
On Discharge	2.71 ± 0.55	3.86 ± 0.67	<0.001 **

* Significant at $p < 0.05$ ** highly significant at $p < 0.01$

Table 3. Rapid Recovery and Hospital Discharge (< 72 hours)

Outcome	Group A (3% HS) n = 13	Group B (0.9% NS) n = 13	Total n = 26 (%)	*p*-value
Rapid recovery (< 72 h)	12 (92.3%)	7 (53.8%)	19 (73.1%)	0.03 *
Delayed recovery (> 72 h)	1 (7.7%)	6 (46.2%)	7 (26.9%)	

Table 4. Mean Duration of Hospital Stay

Group	Mean ± SD (days)	Range	*p*-value
Group A (3% HS)	2.6 ± 0.8	2–4	<0.001 **
Group B (0.9% NS)	4.1 ± 0.9	3–6	
Overall mean	3.4 ± 1.1		

Table 5. Overall Treatment Efficacy

Group	Effective Treatment n (%)	Ineffective n (%)	*p*-value
Group A (3% HS)	12 (92.3%)	1 (7.7%)	0.02 *
Group B (0.9% NS)	7 (53.8%)	6 (46.2%)	
Total	19 (73.1%)	7 (26.9%)	

Discussion

The current study aimed to assess the efficacy of nebulized 3% hypertonic saline (HS) in managing bronchiolitis in children under 2 years of age, focusing on clinical severity scores, hospitalization duration, and recovery rates compared with nebulized 0.9% normal saline (NS). The demographic characteristics of the participants (Table 1) displayed no significant differences between Group A (3% HS) and Group B (0.9% NS), confirming effective randomization and similar baseline characteristics. This similarity provides a robust foundation for comparing treatment outcomes, free of confounding demographic variables.

In terms of clinical severity, our findings reveal that while both groups presented with comparable Wang clinical severity scores at baseline (7.31 vs 7.45; p = 0.72), children receiving 3% HS exhibited significantly improved scores at key time intervals: 60 minutes (p = 0.04), 90 minutes (p = 0.02), 24 hours (p < 0.001), and at discharge (p < 0.001) (Table 2). A meta-analysis by Yu et al. [20] corroborates this finding, indicating that nebulized hypertonic saline notably improves clinical outcomes through enhanced mucociliary clearance, leading to more rapid symptom resolution in bronchiolitis patients.

The rapid recovery rates showcased in our results demonstrate that 92.3% of children in the hypertonic saline group achieved recovery within 72 hours compared to only 53.8% in the normal saline group (p = 0.03) (Table 3). This aligns with studies by Zaman et al (21). And Naveed et al. [22], both of which reported comparable efficacies of hypertonic saline in facilitating faster recovery and reduced hospital discharge times. Importantly, hypertonic saline not only improved participants' clinical condition but also addressed broader implications, such as resource utilization within healthcare—an aspect particularly relevant in settings like Pakistan, where healthcare resources can be limited.

The mean hospitalization duration further underscored the benefits of using hypertonic saline. Group A's average hospital stay of 2.6 days significantly contrasts with the 4.1-day mean for Group B (p < 0.001) (Table 4). This reduction in hospital stay is critical, given the substantial burden that bronchiolitis places on healthcare systems. Notably, Jeong et al. (23) reported that hypertonic saline interventions are associated with shorter hospitalization durations.

Finally, the overall treatment efficacy analysis demonstrated that 92.3% of patients in the hypertonic saline group had effective treatment responses compared to 53.8% from the normal saline group (p = 0.02) (Table 5). This reinforces the hypothesis presented by several studies, including those by Pereira et al. [24] and Ali et al. (25), which suggest that hypertonic saline could be a preferred treatment option for managing bronchiolitis due to its superior efficacy in overall outcomes. Therefore, our research aligns with the existing literature advocating the use of nebulized 3% hypertonic saline in clinical settings as a potentially transformative approach to treating bronchiolitis in infants.

Thus, the findings from this study indicate a significant therapeutic advantage of nebulized 3% hypertonic saline over conventional 0.9% normal saline in treating bronchiolitis in children under 2 years of age. The rapid improvement in clinical scores, higher recovery rates, and shorter hospital stays highlight its utility and effectiveness in managing this widespread pediatric condition. Given the implications for healthcare costs and resource management, particularly in Pakistan, our results reinforce the need to adopt hypertonic saline treatment in clinical protocols for the management of bronchiolitis.

Conclusion

The present study demonstrates that nebulized 3% hypertonic saline is an effective and safe adjunct therapy for the management of bronchiolitis in children under 2 years of age. It leads to faster clinical improvement, shorter hospital stays, and earlier recovery than conventional nebulized normal saline. Incorporating hypertonic saline into pediatric treatment protocols could improve patient outcomes and optimize healthcare resource utilization in Pakistan and other low-resource settings.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate
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Conflict of interest

The authors declared no conflict of interest.

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All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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