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A Randomized Control Trial on the Comparative Efficacy of Hypertonic Saline Versus Adrenaline Nebulization in Acute Bronchiolitis

Farheena Shoaib[1], Syed Qamar Zaman[1]

[1]Department of Pediatrics, CMH Nowshera, Pakistan

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Correspondence to: Farheena Shoaib, Department of Pediatrics, CMH Nowshera, Pakistan.
Email: farheenashoaib073@gmail.com

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ABSTRACT

Background: Acute bronchiolitis is one of the main cause of lower respiratory illness in infants and children, producing airway blockage and hard breathing. Different nebulized medicines are used to reduce the symptoms, but the scientific proof is not uniform about how much hypertonic saline or adrenaline work better. Checking these treatments in local hospital condition is very important to find the most proper clinical method for managing the affected children. **Objective:** To compare the efficacy of nebulized hypertonic saline with adrenaline in improving clinical severity scores and reducing hospital stay in children with acute bronchiolitis. **Study Design:** Double-blind randomized controlled trial. **Duration and Place of Study:** The study was conducted from February 2025 to May 2025 in the Department of Pediatrics, CMH Nowshera. **Methodology:** A total of 62 children aged 1.5 months to 2 years with clinically diagnosed bronchiolitis were randomly assigned into two equal groups. Group A received nebulized adrenaline every six hours, while Group B received nebulized 3% hypertonic saline at the same interval. The Wood-Downes-Férres score was used to assess disease severity at baseline and 24 hours post-treatment. Oxygen requirement and total hospital stay were recorded. **Results:** The mean WDF score after 24 hours was significantly lower in the hypertonic saline group (3.77 ± 0.85) compared to the adrenaline group (4.65 ± 0.99; $p < 0.001$). The mean hospital stay was also shorter with hypertonic saline (2.65 ± 0.84 days) versus adrenaline (4.06 ± 1.41 days; $p < 0.001$). Oxygen requirement was reduced in the hypertonic saline group (6.5% vs 22.6%). **Conclusion:** Hypertonic saline nebulization is more effective than adrenaline in improving respiratory distress and reducing hospital stay among children with acute bronchiolitis.

INTRODUCTION

Acute bronchiolitis is a common lower respiratory tract infection seen mostly in infants and young children under two years of age.[1] It is usually caused by respiratory syncytial virus and it affects the small airways called bronchioles leading to swelling, mucus production and obstruction in airflow.[2] The disease presents with symptoms like cough, wheezing, rapid breathing and difficulty in feeding.[2] The infection causes inflammation of the airway walls and increased mucus which block the air passages making the child breathe harder.[3] Diagnosis is mainly clinical and it is based on signs like chest retraction, nasal flaring, and auscultation findings of crackles or wheezes.[3] Most cases are mild and self-limiting but some children develop severe distress needing hospitalization, oxygen therapy or nebulized medicines to improve breathing and oxygen saturation.[2,3]

Hypertonic saline nebulization has been used in acute bronchiolitis to help clear airway secretions and reduce airway swelling.[4] The solution usually contains 3% saline and it works by drawing water into the airway lumen, thinning mucus and helping in its removal through coughing or ciliary action.[5] It also reduces airway edema by osmotic action and improves mucociliary clearance which helps in easier breathing.[4,5] Several clinical studies have shown that hypertonic saline can reduce hospital stay duration and improve clinical severity scores in moderate cases of bronchiolitis.[6] It is generally well tolerated and can be given several times a day in nebulized form.[5] The therapy acts mainly on improving the airway environment rather than directly relieving bronchospasm, so it works best when combined with supportive care like hydration and oxygen.[6]

Adrenaline nebulization which is also called epinephrine is used in acute bronchiolitis because it has vasoconstrictive and bronchodilating action.[7] It works on alpha and beta adrenergic receptors and this causes reduction in airway mucosal edema through vasoconstriction and relaxation of bronchial smooth muscle.[8] The medicine helps in temporary airway opening and improves breathing by reducing wheeze and respiratory distress.[8] The improvement happens quickly but it lasts for short time

and then symptoms can come again after few hours.[9] Many clinical researches report that adrenaline gives early improvement in severity score compared to placebo but there is no strong evidence that it shortens hospital stay or decreases oxygen need for long period.[10] Adrenaline is commonly used in emergency or in severe stage of bronchiolitis where fast relief is needed to improve ventilation.[7] Comparison with hypertonic saline shows that hypertonic saline gives slower but more continuous improvement in clinical outcome while adrenaline works fast but for short time.[7]

Nazmul Hasan et al. reported that the mean Respiratory Distress Assessment Instrument (RDAI) score after 24 hours of treatment was 3.23 ± 1.51 in the 3% hypertonic saline group and 4.24 ± 1.28 in the adrenaline group, showing a statistically significant improvement ($p = 0.001$) in patients who received hypertonic saline nebulization.[11]

There is need to do this study in Nowshera, Pakistan because bronchiolitis is very common in children and many hospitals use different medicines without clear proof which one work better. Some doctors use adrenaline and some use hypertonic saline but there is no fixed rule in local hospitals. The climate, infection pattern and health facilities in Nowshera are different so result from other countries may not fit here. Doing this study will help to know which nebulization give better recovery and safety for babies in our area and help doctors make right treatment choice.

METHODOLOGY

The study was conducted in the Department of Pediatrics at CMH Nowshera as a double-blind randomized control trial. The trial took place from February 2025 to May 2025 after registration (Trial registration number NCT06267118) and followed a prospective design to compare the two nebulization therapies in children presenting with bronchiolitis. Approval for the study was taken from the institutional ethical committee of CMH Nowshera before starting the data collection. The committee reviewed the study protocol for safety and compliance. Written permission was granted to conduct the research inside the pediatric department. The number of participants was estimated using OpenEpi version 3.0 software. Reference values were taken from a previous study by Nazmul Hasan and colleagues,[11] where the mean Respiratory Distress Assessment Instrument (RDAI) score after 24 hours was 3.23 ± 1.51 in the 3% hypertonic saline group and 4.24 ± 1.28 in the adrenaline group. With a 95% confidence level, 80% power, and two-sided significance, the minimum sample required was calculated as 31 children in each arm, giving a total of 62 subjects. Participants were selected using simple random sampling by a computer-generated table, and allocation concealment was done with sealed envelopes.

Children aged between 1.5 months and 2 years who presented with respiratory distress and wheezing and had a Wood-Downes-Férres (WDF) score between 0 and 14 were included. Children with congenital heart disease, immunodeficiency, or other lung conditions were excluded. Any child needing ventilator support or showing allergic reaction to the test drugs was also not enrolled. The severity of bronchiolitis was described by WDF scoring system in which mild cases scored 1–3, moderate 4–7, and severe 8–14. Before data collection, parents or legal guardians of all participants were explained the purpose and process of the research, and their written consent was taken. Only those who agreed and remained available during the trial period were included. History and clinical examination were done at admission, focusing on symptoms like cough, fever, and wheeze. Chest findings, respiratory rate, retractions, and oxygen saturation were assessed daily and noted on a structured proforma.

Each child received one of two treatments: Group A was nebulized with 0.3 ml of adrenaline diluted in 2.5 ml normal saline every six hours, and Group B was nebulized with 3 ml of 3% hypertonic saline every six hours. The hypertonic saline was prepared by dissolving 5 ml sea salt in 200 ml of filtered water, heating, cooling, and storing for 24 hours. The study nurse, unaware of the drug identity, prepared and administered the treatment. Clinical improvement was measured by the change in WDF score after 24 hours, and patients were monitored for side effects, oxygen need, and total hospital stay duration. The main outcome was improvement in respiratory distress score, while the secondary outcome was reduction in hospital stay between the two groups. The severity score was defined by the WDF scale, based on respiratory rate, retraction level, and oxygen saturation percentage.

All data were entered and analyzed using SPSS version 23. Means and standard deviations were used for continuous variables, and frequencies and percentages for categorical data. The independent sample t-test compared the mean WDF score and hospital stay between both treatment arms, and p-values below 0.05 were taken as statistically significant.

RESULTS

The study enrolled 62 patients which was divided equally into two groups with 31 patients receiving adrenaline nebulization and 31 patients receiving hypertonic saline. In adrenaline nebulization group, the mean age of patients was 9.39 ± 6.57 months and mean weight was 7.66 ± 2.05 kg, while in hypertonic saline group, mean age were 8.18 ± 6.22 months and mean weight was 7.30 ± 2.27 kg. The C-reactive protein levels were comparable in both groups with mean values of 1.48 ± 0.51 in adrenaline group and 1.45 ± 0.51 in hypertonic saline group. The baseline WDF score on presentation was also similar between groups, being 6.48 ± 1.41 in adrenaline nebulization group and 6.55 ± 1.15 in hypertonic saline group. Regarding gender distribution, male patients was predominant in both groups where 20 patients (64.5%) was males in adrenaline group and 23 patients (74.2%) was males in hypertonic saline group, while female patients was 11 (35.5%) and 8 (25.8%) respectively. Most patients were admitted through OPD route where 20 patients (64.5%) in adrenaline group and 19 patients (61.3%) in hypertonic saline group was admitted from OPD, while 11 patients (35.5%) and 12 patients (38.7%) was admitted through emergency respectively. Majority of patients had history of prior upper respiratory tract infection with 25 patients (80.6%) in adrenaline group and 23 patients (74.2%) in hypertonic saline group reporting previous URTI, whereas 6 patients (19.4%) and 8 patients (25.8%) did not had

prior URTI history. The need of oxygen was less in hypertonic saline group where only 2 patients (6.5%) required oxygen compared to 7 patients (22.6%) in adrenaline group, while 29 patients (93.5%) and 24 patients (77.4%) did not required oxygen in respective groups (as shown in Table 1)

Table 1

Patient Demographics and Clinical Characteristics in Both Groups

Variables	Adrenaline Nebulization n=31 Mean ± SD	Hypertonic Saline n=31 Mean ± SD
Age (months)	9.39 ± 6.57	8.18 ± 6.22
Weight (kg)	7.66 ± 2.05	7.30 ± 2.27
CRP	1.48 ± 0.51	1.45 ± 0.51
WDF Score on Presentation	6.48 ± 1.41	6.55 ± 1.15
Gender	n (%)	n (%)
Male	20 (64.5%)	23 (74.2%)
Female	11 (35.5%)	8 (25.8%)
Mode of Admission		
Emergency	11 (35.5%)	12 (38.7%)
OPD	20 (64.5%)	19 (61.3%)
H/o Prior URTI		
Yes	25 (80.6%)	23 (74.2%)
No	6 (19.4%)	8 (25.8%)
Need of Oxygen		
Yes	7 (22.6%)	2 (6.5%)
No	24 (77.4%)	29 (93.5%)

CRP= C-reactive protein, **WDF**= Wood-Downes-Férres, **URTI**= Upper respiratory tract infection

When comparing clinical outcomes between two groups, the WDF score after 24 hours showed significant improvement in hypertonic saline group with mean score of 3.77 ± 0.85 compared to adrenaline nebulization group which had mean score of 4.65 ± 0.99, and this difference was statistically significant with p value <0.001. Similarly, the length of hospital stay was significantly shorter in hypertonic saline group with mean duration of 2.65 ± 0.84 days compared to adrenaline nebulization group where mean length of stay was 4.06 ± 1.41 days, and this difference was also highly significant with p value <0.001 (as shown in Table 2)

Table 2

Comparison of Clinical Outcomes in Both Groups

Outcomes	Adrenaline Nebulization n=31	Hypertonic Saline n=31	P Value
WDF Score after 24 hours	4.65 ± 0.99	3.77 ± 0.85	<0.001
Length of Hospital Stay (days)	4.06 ± 1.41	2.65 ± 0.84	<0.001

DISCUSSION

The most significant finding was reduction in WDF score after 24 hours where hypertonic saline group achieved mean score of 3.77 ± 0.85 compared to 4.65 ± 0.99 in adrenaline group with p value <0.001. This superior improvement in hypertonic saline group can be explained by mechanism of action where hypertonic saline draws water from submucosa into airway lumen through osmotic gradient which helps in rehydration of airway surface liquid and decreases mucus viscosity. The reduced viscosity of mucus allows better clearance through mucociliary action and cough mechanism which ultimately improves airway patency and reduces respiratory distress. In contrast, adrenaline works through alpha and beta adrenergic receptors stimulation which causes vasoconstriction and reduces airway edema temporarily but does not addresses the problem of mucus plugging which is main pathophysiology in bronchiolitis. The length of hospital stay was significantly shorter in hypertonic saline group with mean duration of 2.65 ± 0.84 days compared to 4.06 ± 1.41 days in adrenaline group with p value <0.001. This reduction in hospital stay was direct consequence of faster clinical improvement seen with hypertonic saline where patients achieved better WDF scores more quickly. The improved mucus clearance leads to better ventilation and oxygenation which allows earlier discharge from hospital. The need for oxygen was also less in hypertonic saline group where only 2 patients (6.5%) required oxygen compared to 7 patients (22.6%) in adrenaline group. This difference occurs because hypertonic saline improves ventilation perfusion matching by clearing airways more effectively whereas adrenaline provides only temporary relief without addressing underlying mucus obstruction which continues to cause hypoxemia.

The findings of present study demonstrate that hypertonic saline was superior to adrenaline nebulization in reducing WDF score and hospital stay duration, which is consistent with majority of published literature. Singh S, et al. [12] reported similar results where 3% hypertonic saline group showed significantly greater reduction in clinical scores compared to L-adrenaline group with scores of 1.4 ± 0.9 versus 2.3 ± 1.4 at discharge ($p < 0.05$), which supports our finding of better WDF score improvement in hypertonic saline group (3.77 ± 0.85) compared to adrenaline group (4.65 ± 0.99) with p value <0.001. Similarly, Hasan N, et al. [11] also demonstrated that 3% hypertonic saline significantly reduced clinical severity score and hospital stay relative to adrenaline where oxygen therapy duration was 15.0 ± 5.36 hours in hypertonic saline group versus 24.63 ± 11.64 hours in adrenaline group, which correlates with our observation that only 2 patients (6.5%) in hypertonic saline group required oxygen compared to 7 patients (22.6%) in adrenaline group. The mechanism behind superior efficacy of hypertonic saline is related to its osmotic properties which draws fluid into airway lumen and reduces mucus viscosity allowing better clearance, whereas adrenaline only provides temporary vasoconstriction without addressing mucus plugging which is central pathology in bronchiolitis.

Our finding of shorter hospital stay with hypertonic saline (2.65 ± 0.84 days) compared to adrenaline (4.06 ± 1.41 days) is supported by multiple studies including Islam KT, et al. [13] who reported hospital stay of 58.1 ± 22.0 hours with hypertonic saline versus 74.7 ± 27.2 hours with normal saline ($p = 0.002$), and Salman MK, et al. [14] who showed mean hospital stay of 3.47 ± 0.89 days with hypertonic saline versus 4.47 ± 1.03 days with normal saline ($p < 0.001$). Hossain RM, et al. [15] also reported hospital stay of 58.1 ± 22 hours with hypertonic saline versus 74.7 ± 27.2 hours with normal saline plus salbutamol, and discharge within 72 hours occurred in 94% of hypertonic saline group versus 58% in control

group. These consistent findings across different studies confirms that hypertonic saline is effective in reducing hospitalization duration through its ability to improve mucociliary clearance and airway patency more effectively than other nebulization therapies.

However, one study by Safdar S, et al. [16] showed contrasting results where nebulized epinephrine group had significantly shorter hospital stay (3.94 ± 0.14 days) compared to hypertonic saline group (4.80 ± 0.08 days) with p = 0.000, which is opposite to our findings. This difference can be explained by several factors including different study population where Safdar et al. included children aged 1 day to 24 months with mean age of 10.06 months in epinephrine group and 12.50 months in saline group, whereas our study had younger population with mean age of 9.39 months in adrenaline group and 8.18 months in hypertonic saline group. The difference in age distribution is important because younger infants may respond differently to treatments due to narrower airways and different immune response. Additionally, Safdar et al. used racemic epinephrine with different concentration (0.2 mL of 2.25% diluted with 1.8 mL water) and dosing frequency (every 6 hours) compared to our study protocol, and they also used 3% hypertonic saline with more frequent dosing (every 1-4 hours) which might have influenced the outcomes differently. The study also categorized patients as moderate bronchiolitis specifically, whereas our study included patients with variable severity as indicated by baseline WDF scores, which could affect treatment response.

The combination therapy of epinephrine with hypertonic saline was evaluated by Pereira RA, et al. [17] in meta-analysis which showed that epinephrine plus hypertonic saline combination resulted in significant reduction in length of stay (mean difference = −0.35 days; 95% CI −0.62 to −0.08; p = 0.01) and improved clinical severity scores compared to either treatment alone. This suggests that combination therapy might be more effective than monotherapy with either agent, and this finding is further supported by Sharmin S, et al. [18] who demonstrated that adrenaline with 3% hypertonic saline was superior to adrenaline with normal saline where reduction in severity score was significantly higher in combination group (4.6 versus 3; p < 0.05).

When comparing hypertonic saline with other treatments, Suleman M, et al. [19] showed that 3% saline was more effective than steroids plus salbutamol in reducing hospital stay (2.76 ± 0.51 days versus 3.58 ± 0.82 days, p = 0.00), which supports the superior efficacy of hypertonic saline over conventional therapies. However, Saleem M, et al. [20] reported no significant difference between hypertonic saline and normal saline with mean length of stay being 36.29 ± 18.4 hours versus 39.15 ± 16.1 hours (p = 0.2365), which suggests that in some populations the benefit of hypertonic saline may not be as pronounced.

The present study has several limitations that needs to be acknowledged. First, this was single center study conducted at one hospital which limits the generalizability of findings to other healthcare settings and populations with different demographic characteristics. The sample size was relatively small with only 31 patients in each group, which may not be adequate to detect smaller differences between treatments or to perform subgroup analyses based on age groups or disease severity. The study did not evaluate long-term outcomes or follow-up after discharge to assess recurrence rates or subsequent respiratory complications in these patients. Additionally, the study did not include comparison with combination therapy of hypertonic saline plus adrenaline which has shown promising results in other studies. The nebulization protocols including exact concentration, volume, and frequency of administration was standardized according to hospital protocol but may differ from other institutions which makes comparison difficult.

CONCLUSION

Our study has concluded that hypertonic saline nebulization is more effective than adrenaline nebulization in management of acute bronchiolitis in pediatric patients. The hypertonic saline group demonstrated significantly better improvement in clinical severity scores and achieved shorter duration of hospital stay compared to adrenaline nebulization group. The need for oxygen therapy was also reduced in patients receiving hypertonic saline treatment.

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