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NEBULIZED 3% HYPERTONIC SALINE VERSUS NEBULIZED ADRENALINE FOR ACUTE BRONCHIOLITIS IN INFANTS: A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

Paediatrics

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ABSTRACT

Acute bronchiolitis is the most common lower respiratory tract illness and hospitalisation in infants under two. Clinical usage of nebulised 3% hypertonic saline and adrenaline is widespread, but their comparative efficacy is unclear. **Objective:** To compare the clinical efficacy of nebulized 3% hypertonic saline with nebulized adrenaline in infants with acute bronchiolitis. **Methods:** We conducted an 18-month randomised, single-blind, controlled study in a tertiary care hospital's Paediatric Intensive Care Unit. Seventy 1- to 2-year-olds with acute bronchiolitis were randomly assigned to two equal groups. Group A (35) received nebulised 4 mL of 3% hypertonic saline, while Group B received 1 mL adrenaline (1:1000) mixed with 3 mL normal saline. Until clinical recovery, nebulisation occurred every 6 hours. RDAI score improvement was the main effect. The secondary outcomes included heart rate, SpO_2, oxygen therapy duration, recovery time, and hospital stay. At $p < 0.05$, statistical significance was determined. **Results:** Baseline demographics and clinical parameters were similar between groups. The therapy groups improved heart rate and oxygen saturation after 24 hours, with no statistically significant changes. Group A demonstrated larger improvement in RDAI scores at 24 and 96 hours (3.24 ± 1.51 vs. 4.23 ± 1.28; $p = 0.0042$ and 1.65 ± 0.51 vs. 2.04 ± 0.75; $p = 0.0132$). Oxygen therapy time was substantially lower in Group A (15.00 ± 5.35 vs. 24.63 ± 11.63 hours; $p = 0.005$). Group A recovered faster than Group B (85.7% vs. 62.9% = 0.007) within 72 hours. Patients in Group A had a substantially larger hospital stay of ≤72 hours (85.7% vs. 62.9%; $p = 0.0298$).

KEYWORDS

Acute Bronchiolitis, Hypertonic Saline, Adrenaline, Nebulization, Respiratory Distress Assessment Instrument, Oxygen Therapy, Hospital Stay, Infants.

1. INTRODUCTION

Infants under two are hospitalised most often for acute bronchiolitis (AB), the most common lower respiratory tract illness [1]. More than 68% of newborns and neonates under one year old may have this disease [2,3]. Acute bronchiolitis is usually caused by respiratory syncytial virus (RSV) [1].

The main causes are RSV, rhinovirus, hMPV, par influenza virus, adenovirus, corona virus, influenza virus, and human bocavirus [4]. In about one-third of infants hospitalised with bronchiolitis, molecular diagnostics can detect co-infection with two or more viruses. RSV infection causes 2.9 respiratory fatalities per 100,000 newborns each year [5].

Male sex, prematurity, younger age, pre-existing conditions like bronchopul money dysplasia, chronic lung disease, neuromuscular disorders, and congenital heart disease (CHD) increases the risk of bronchiolitis and its severity [6]. Environmental tobacco smoke, higher birth order, younger mother age, shorter breastfeeding length, maternal asthma, and poor socioeconomic situations are also risk factors [6].

Diagnostics of bronchiolitis are mostly clinical. From rhino rhea and fever to tachypnea, wheezing, and chronic cough, the illness usually starts in the upper respiratory tract. Only apnoea may be present in preterm newborns. The condition often causes feeding problems. [7, 8].

IV hydration, humidified oxygen, and nutritional assistance have been traditional management strategies [9]. Therapy has not consistently improved the condition, which is usually self-limiting. Although clinical practice recommendations exist, practitioners disagree on specific management methods [9].Bronchodilators, corticosteroids, nebuliser epinephrine, and hypertonic saline have been explored, although their benefits are variable [10].

2. Literature Review

RSV causes 33 million lower respiratory tract infections (LRTIs) worldwide, 3.6 million hospital admissions, and over 100,000 fatalities in children under five [11]. LMICs are hardest hit. Infants under six months old, premature babies, and those with immune-deficient and cardiovascular disorders are more affected [12,13]. RSV infections typically require hospitalisation and rigorous treatment, which strains health care systems worldwide [14,15]. RSV-associated lower respiratory tract infections were projected at 33 million worldwide in 2019.[16].

Risk Factors

Age, sex, and medical conditions are unchangeable bronchiolitis risk factors. Infants with older siblings are more likely to get viral infections and need bronchiolitis hospitalisation [17]. Male newborns are more susceptible to bronchiolitis and have more severe disease necessitating hospitalisation, probably due to airway mechanics and smaller airways [18]. RSV bronchiolitis increases the incidence of wheeze, but there is no substantial relation to a topy history [19].

Viruses

Respiratory virus infections cause most acute coughs in children. Rhinovirus, enterovirus, influenza A and B viruses, par influenza virus, corona virus, human metapneumo virus, and RSV are highly prevalent [20]. At 70%, RSV is the most common cause. Due to seasonal outbreaks, it is found worldwide. In infected tissue cultures, the virus forms multinucleated large cells called syncytia, thus its name. Pleomorphic, single-stranded RNA virus RSV has two primary subgroups, A and B, which differ in virulence, genetics, and seasonal circulation (Fig. 1) [21].

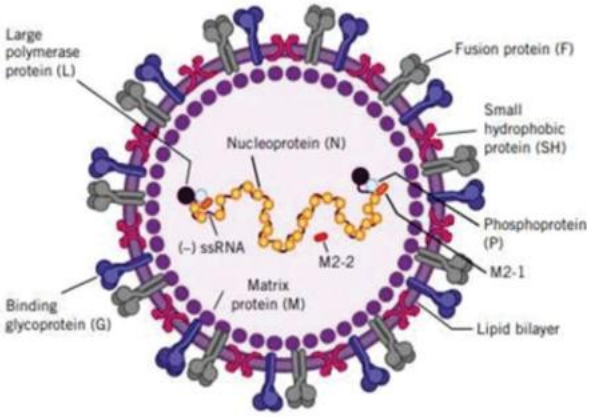

Figure1.Structure of Respiratory Syncytial Virus (RSV)[18].

Only 1–10% of acute bronchitis cases have identifiable bacteria. Bacterial causes may be more important in underdeveloped nations

[22].This is because viral cultures and serological tests are rarely done in children with acute bronchitis, even though viruses are the main cause [23]. SARS-CoV-2, which causes COVID-19, has increased the use of rapid diagnostic methods like home-based testing kits and PCR assays for confirmation [24].

Bacterial and Other Non-Viral Infectious Causes

Acute coughs in children are mostly caused by viruses, although bacterial and other diseases should also be examined. Early diagnosis of rare bacterial diseases such Bordetella pertussis, Mycoplasma pneumonia, and Chlamydophila pneumonia allows focused antibiotic therapy to reduce illness severity and spread. Posttussive vomiting has modest diagnostic accuracy, with a sensitivity of 60% and a specificity of 66% in children [25].

Foreign Body Aspiration

Especially in children under 3, foreign body aspiration should be considered in paediatric patients. Young children are at danger because they experiment with objects with their mouths, lack neuromuscular airway protecting mechanisms, and lack swallowing coordination [26].Other risks include early introduction of inappropriate solid foods, feeding high-risk items like peanuts, and unsupervised feeding. An extensive history may not reveal the aspiration event [27].

Changeable risk variables affect bronchiolitis occurrence and severity along with non-modifiable factors. Socioeconomic variables, ambient tobacco smoke exposure, and breastfeeding are some [28]. Hospitalisation for bronchiolitis is linked to parental smoking. Bronchiolitis hospitalisation is connected to postnatal and prenatal tobacco smoke from maternal smoking [29].Overcrowding and sharing sleeping arrangements may transfer respiratory virus infections and increase RSV hospitalisation risk [30].

3.MATERIALS AND METHODOLOGY

Study Design: This was a randomized controlled study.

Study Setting: The study was conducted in the Pediatric Intensive Care Unit (PICU).

(PICU) of Amaltas Institute of Medical Sciences, Dewas.

Duration of Study: The study was in itiated and completed with in duration of 18 months.

Study Participants: The study included all children admitted to the PICU at tertiary care centre who presented with clinical features suggestive of acute bronchiolitis.

Sample Size: The number of PICU hospitalisations and children diagnosed with acute bronchiolitis determined a minimum sample size of 70 patients over 18 months with a 95% confidence interval.

Subject Selection and Grouping: The enrolled subjects were randomly allocated into two groups:

Group A: Children who were nebulizer with 4ml of 3% hypertonicsaline.

Group B: Children who were nebulizer with 1 ml of adrenaline (1:1000) mixed with 3 ml of normal saline.

Inclusion Criteria

- Children aged between1month and 2 years.
- Presence of a clinical history suggestive of a viral prodrome.
- Patients who had not received prior treatment with nebulized 3% hypertonic saline or nebulized adrenaline during the current illness episode.RDAI Score> 4.

Exclusion Criteria

- Agelessthan1monthormorethan2years.
- History of two or more previous episodes of respiratory distress.
- Family history of asthma.
- Presence of congenital heart disease or chronic lung disease.
- Hemodynamically unstable patients requiring assisted ventilation.
- RDAIScore≤4.

Methodology

At least seventy individuals suffering from acute bronchiolitis were allowed to participate in the experiment after receiving clearance from the Institutional Ethics Committee. A randomised, single-blind, controlled experiment was conducted, and the caretakers were not informed about the mobilisation treatment that their children were receiving. Either 3% hypertonic saline or adrenaline (1:1000) was administered to the subjects in a random order. By employing a serial-number-based allocation method, participants were randomly assigned to two treatment groups, which resulted in a reduction in selection bias. Patients with odd serial numbers were assigned to Group A when the randomisation process was carried out, while patients with even serial numbers were assigned to Group B.Immediately after the patient was admitted, a comprehensive medical examination and a history from the parent or caretaker were taken. When the patient was admitted, the RDAI score as well as the oxygen saturation of the room air were assessed. A non-invasive method of measuring oxygen saturation was conducted via a pulse oximeter.The following clinical and laboratory investigations were performed for all infants included in the study:

- Hemoglobin (Hb) level.
- Total leukocyte count (TLC) and differential leukocyte count (DLC).
- Chest X-ray (poster anterior [PA] view) at the time of admission.

After parents or legal guardians gave written informed consent, the research drugs were given according to procedure. Participants in Group A were mobilised with 4 mL of 3% hypertonic saline, while Group B got 1 mL of adrenaline (1:1000) diluted with 3 mL of normal saline. 4 times a day at 6-hour intervals, nebulisation was continued until clinical improvement allowed hospital departure.

Figure 1. Respiratory Distress Assessment Instrument (RDAI)

Clinical Parameter	Score 0	Score 1	Score 2	Score 3	Score 4	Maximum Score
Wheezing – Expiration	None	End-expiration	Half of expiration	Three-fourths of expiration	Entire expiration	4
Wheezing – Inspiration	None	Partial inspiration	Entire inspiration	–	–	2
Wheezing – Lung fields	None	Segmental (≤2 of 4 lung fields)	Diffuse (≥3 of 4 lung fields)	–	–	2
Retractions – Supraclavicular	None	Mild	Moderate	Marked	–	3
Retractions – Intercostal	None	Mild	Moderate	Marked	–	3
Retractions – Subcostal	None	Mild	Moderate	Marked	–	3

Statistical Analysis

Microsoft Excel spreadsheets held data. Data was analysed using appropriate statistical software (20.0). Percentages and frequencies were calculated for continuous and categorical data. As needed, Chi-square or Fisher's exact tests compared categorical variables. Significant p-values were less than 0.05, and statistical analyses used a 95% confidence interval.

4. OBSERVATION AND RESULT

Table 2–Age-wise Distribution of Study Participants between GroupA and Group B

Age Group (Months)	Group A (n = 35)		Group B (n = 35)		p-value
	n	%	n	%	
1–6	22	62.86	20	57.14	0.724
7–12	8	22.86	11	31.43	
13–24	5	14.29	4	11.43	
Total	35	100.00	35	100.00	
Mean ± SD (months)	6.34 ± 3.89		6.06 ± 3.55		

Table 2.Participant Age Distribution in Groups A and BGroup A and B participants' ages were compared. In Group A, 62.86% of patients were 1–6 months old, and in Group B, 57.14%. At 6–12 months, Group A had 22.86% patients and Group B 31.43%. Group A had 14.29% 12–24-month patients and Group B 11.43%.Mean ages in Group A and B were 6.34 ± 3.89 and 6.06 ± 3.55 months, respectively. No difference was found (p=0.724), indicating a similar age distribution.

Table 3. Gender-wise Distribution of Study Participants between Group A and Group B

Gender	Group A (n = 35)		Group B (n = 35)		p-value
	n	%	n	%	
Male	27	77.10	25	71.40	0.468 (NS)
Female	8	22.90	10	28.60	
Total	35	100.00	35	100.00	

Table 3 compares the gender distribution of study participants in Groups A and B. Most patients in both groups were male children

(77.10% in Group A and 71.40% in Group B). Group A had 22.90 percent female children and Group B 28.60 percent.A non-significant gender distribution difference between groups (p = 0.468) (Table 2) showed that both groups were gender equivalent.

Table 3–Distribution of Clinical Features among Study Participants in Group A and Group B

Clinical Feature	Group A (n = 35)		Group B (n = 35)	
	n	%	n	%
Cough	35	100.00	35	100.00
Fever	31	88.57	28	80.00
Runny nose	33	94.29	33	94.29
Difficulty in breathing	35	100.00	35	100.00
Feeding difficulty	27	77.14	23	65.71
Irritability	8	22.86	10	28.57
Lethargy	9	25.71	11	31.43
Wheeze	30	85.71	28	80.00
Rhonchi	35	100.00	35	100.00
Chest indrawing	35	100.00	35	100.00
Nasal flaring	16	45.71	12	34.29
Tachypnea	3	8.57	5	14.29
Tachycardia	12	34.29	9	25.71

The clinical features of study participants were assessed and compared between Group A and Group B. It was observed that cough and difficulty in breathing were present in all patients (100%) in both groups. Similarly, ronchi and chest in drawing were also noted in all cases across both groups. Fever was observed in 88.57% in Group A and 80.00% in Group B, while Runny nose was present in 94.29% in both groups. Feeding difficulty occurredin77.14%and65.71%, respectively. Irritability and lethargy were noted in 22.86% and 25.71% in Group A, compared with 28.57% and 31.43% in Group B. Wheeze was seen in 85.71% and 80.00%, while nasal flaring was reported in 45.71% and 34.29%, (Table 3)

Table 4–Comparison of Physical Examination Parameters Between Group A and Group B

Parameter	Group A (n = 35) Mean ± SD	Group B (n = 35) Mean ± SD	p-value
Heart Rate (beats/min)			
Initial	132.06 ± 8.68	129.86 ± 9.18	0.3068
24 hours after nebulization	126.37 ± 6.98	127.00 ± 6.02	0.6872
Change in heart rate	5.68 ± 6.61	2.86 ± 5.87	0.0634
SpO_2 (%)			
Initial	90.22 ± 5.40	91.33 ± 5.83	0.4115
24 hours after nebulization	95.68 ± 2.92	96.62 ± 2.89	0.1803
Change in SpO_2	5.46 ± 3.62	5.28 ± 3.83	0.8194

In Table 4, the heart rates of Group A and Group B are compared. Group A had a mean heart rate of 132.06 ± 8.68 beats per minute at the beginning of the study, while Group B had a heart rate of 129.86 ± 9.18 beats per minute. There was no significant difference between the two groups (p = 0.3068). Group A experienced a decrease in their mean heart rate to 126.37 ± 6.98 beats per minute, whereas Group B experienced a reduction to 127.00 ± 6.02 beats per minute following a period of 24 hours of movement treatment. There was no statistically significant difference between the groups (p = 0.6872).

Table 5–Comparison of Mean RDAI Scores Between Group A and Group B at Different Time Intervals

Time Interval	Group A (n = 35) Mean ± SD	Group B (n = 35) Mean ± SD	p-value
At baseline	7.87 ± 1.58	7.65 ± 1.41	0.5409
At 12 hours	4.65 ± 1.36	5.25 ± 1.33	0.0663
At 24 hours	3.24 ± 1.51	4.23 ± 1.28	0.0042*
At 48 hours	3.01 ± 1.11	3.42 ± 1.30	0.1605
At 72 hours	2.68 ± 1.54	3.19 ± 1.20	0.1269
At 96 hours	1.65 ± 0.51	2.04 ± 0.75	0.0132*

The average RDAI scores for Group A and Group B are presented in Table 5. Group A and Group B both reported baseline RDAI scores that were equivalent (7.87 ± 1.58, 7.65 ± 1.41, p = 0.5409), which indicates that the harshness of the condition was the same when it was presented. Group A had a mean RDAI score of 4.65 ± 1.36 after 12 hours, while Group B had a score of 5.25 ± 1.33 according to the same criteria. Although the mean RDAI score of Group A was substantially lower (3.24 ± 1.51) at 24 hours compared to Group B (4.23 ± 1.28; p = 0.0042), the difference was not statistically significant (p = 0.0663).

Table 6 Comparison of Duration of Oxygen Therapy between Group A and Group B

Parameter	Group A (n = 16) Mean ± SD	Group B (n = 19) Mean ± SD	p-value
Duration of oxygen therapy (hours)	15.00 ± 5.35	24.63 ± 11.63	0.005 *

The duration of oxygen therapy was compared between Group A and Group B among patients who required oxygen supplementation. The mean duration of oxygen therapy was 15.00 ± 5.35 hours in Group A, compared with 24.63 ± 11.63 hours in Group B. Thus, patients in Group A required oxygen therapy for a shorter duration than those in Group B, indicating a more rapid clinical improvement. The groups differed significantly in statistical terms (p = 0.005), indicating shorter oxygen therapy in Group A (Table 6).

Table 7 Comparison of Recovery and Discharge between Group A and Group B

Recovery and Discharge	Group A (n = 35)	Group A (%)	Group B (n = 35)	Group B (%)	p-value
Rapid recovery (within 72 hours)	30	85.70	22	62.90	0.007 *
Gradual recovery (after 72 hours)	5	14.30	13	37.10	
Total	35	100.00	35	100.00	

Table 7 Comparison of Recovery and Discharge Between Group A and Group B,Recovery and discharge patterns were compared between Group A and Group B. It was observed that 85.70% of patients in Group A had rapid recovery within 72 hours, whereas 62.90% of patients in Group B showed rapid recovery. Gradual recovery after 72 hours was noted in 14.30% in Group A and 37.10% in Group B. The difference reach the statistical significance (p = 0.007), indicating that a higher proportion of patients in Group A recovered earlier compared to Group B (Table 7).

Table 8 Comparison of Duration of Hospital Stay between Group A and Group B

Duration of Hospital Stay	Group A (n = 35)	Group A (%)	Group B (n = 35)	Group B (%)	p-value
≤ 72 hours (Short stay)	30	85.71	22	62.86	0.0298 *
> 72 hours (Long stay)	5	14.29	13	37.14	
Total	35	100.00	35	100.00	

Hospital stays were compared between Groups A and B. Over 85.71% of Group A patients had a hospital stay of ≤72 hours, but only 62.86% of Group B patients were discharged within the same timeframe. Significantly, 14.29% of Group A patients needed a hospital stay beyond 72 hours compared to 37.14% in Group B. Group A individuals stayed in the hospital for substantially less than Group B participants (Table 8).

DISCUSSION

Acute bronchiolitis infants' clinical condition improved with both nebulisation regimens, but 3% hypertonic saline–based nebulisation (Group A) had better therapeutic outcomes than adrenaline with normal saline (Group B). A fair comparison was possible because the two groups had similar baseline demographics, clinical symptoms, heart rate, oxygen saturation, and respiratory distress severity. Although both treatments improved respiratory status, oxygenation, and clinical symptoms over time, Group A had a faster reduction in Respiratory Distress Assessment Instrument (RDAI) scores, shorter oxygen therapy, faster clinical recovery, earlier discharge, and shorter hospital stay. These data indicate that hypertonic saline improves mucociliary clearance, reduces airway oedema, and speeds symptom relief without affecting cardiovascular function. Infants with acute bronchiolitis may benefit from 3% hypertonic saline–based nebulisation, which improves short-term clinical outcomes and reduces healthcare resource use.Larger multicenter randomised controlled studies with extended follow-up are necessary to validate these findings and standardise clinical treatment guidelines.

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