

A Clinical Study on Efficacy of Nebulizations with Bronchodilators in Patients with Acute Bronchiolitis in a Tertiary Care Centre

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ABSTRACT

Objectives:

To compare the clinical efficacy and outcomes of nebulized levosalbutamol and adrenaline, administered sequentially with standard care, in children aged 1–24 months with acute bronchiolitis.

Methods:

This prospective comparative study was done at the Department of Paediatrics of a tertiary care hospital in Andhra Pradesh, India, over 18 months from October 2022 to March 2024. The study enrolled 120 children aged 1–24 months with clinically diagnosed acute bronchiolitis and Bronchiolitis Severity Score ≥ 4 . Alternative allocation of children was done into three groups (n=40 each) receiving nebulized levosalbutamol, adrenaline, or sequential adrenaline and levosalbutamol, respectively, along with standard care. Clinical severity, oxygen saturation, respiratory rate, hospital stay, discharge, ventilatory support, and mortality were assessed.

Results:

Compared with levosalbutamol and adrenaline, the sequential levosalbutamol–adrenaline group had significantly shorter mean hospital stay (2.46 ± 1.24 vs. 5.04 ± 2.02 vs. 4.42 ± 1.68 days; $p=0.0001$), higher discharge rates (97.5% vs. 80% vs. 85%; $P<0.005$), lesser NIV requirement (1 vs. 5 vs. 4 patients), lesser mechanical ventilation requirement (0 vs. 3 vs. 2 patients). At 24 hours, mean SpO_2 increased to $95.14 \pm 1.42\%$ in the combination group compared with $93.46 \pm 0.86\%$ and $93.89 \pm 1.02\%$ ($p=0.0001$), and at 48 hours reached $99.46 \pm 1.89\%$ versus $96.42 \pm 1.68\%$ and $96.86 \pm 1.74\%$ ($p=0.0001$). No mortality occurred in any group.

Conclusion:

Sequential nebulization with levosalbutamol and adrenaline, when administered with standard care, demonstrated favorable clinical outcomes in terms of improved respiratory status, shorter hospital stays, and higher discharge rates in children with acute bronchiolitis.

Keywords: adrenaline, bronchiolitis, oxygen saturation, respiratory rate

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Introduction:

Acute bronchiolitis is a common LRTI affecting children <2 years, which is characterized by inflammation of the bronchioles, mucosal edema, necrosis of epithelial cells lining small airways with increased mucus production and bronchospasm.¹ Respiratory Syncytial Virus (RSV) is accountable for infection in above half of the cases, with influenza, parainfluenza, adenovirus

and metapneumovirus being the other causative viruses.²

The peak incidence of the disease occurs in 3–6 months of age, with most of the severe cases affecting healthy term infants. The risk factors include being young, low socioeconomic class, feeding habits, congenital heart disease, prematurity, chronic lung disease, and immune deficiency.^{3,4}

Diagnosis is primarily established based on the characteristic clinical presentation, with rhinorrhea

being a common initial symptom that typically progresses over 2–4 days to a characteristic harsh, moist cough accompanied by low-grade fever, usually below 39°C.⁵ Physical examination may reveal tachypnea, chest retractions, increased use of accessory respiratory muscles, wheezing, crackles, and reduced oxygen saturation. In young infants, apnea may be an initial presenting feature and can occasionally occur without other typical clinical manifestations of bronchiolitis.⁶

Acute bronchiolitis typically resolves on its own, with most of these cases requiring only supportive measures. Hospitalized infants require minimal handling, nasal suction, humidified oxygen guided by pulse oximetry, and monitoring for apnea.⁷ The use of nebulization with bronchodilators like levosalbutamol and adrenaline in the treatment of bronchiolitis in infants is still under research.⁸

The aim of the study was to compare the safety, clinical progression, and adverse effects of nebulized levosalbutamol, adrenaline, and sequential adrenaline followed by levosalbutamol, each administered along with standard of care, in children aged 1–24 months admitted with acute bronchiolitis.

Methods

A comparative study was conducted in the Department of Paediatrics of a tertiary care hospital of Andhra Pradesh, India, for a period of 18 months, i.e. October 2022 to March 2024, after taking approval from Institutional ethical Committee. Children aged 1–24 months with fever, cough and signs of respiratory distress admitted in Paediatric ward during the study period were considered for the study.

Inclusion criteria included presence of clinically diagnosed acute bronchiolitis and whose parents provided written informed consent. Exclusion criteria included children with age > 2 years, presence of respiratory diseases like pneumonia, pleural effusion, foreign body ingestion; need for mechanical ventilation at admission, hemodynamically significant heart disease, cystic-fibrosis, bronchopulmonary dysplasia, severe acute malnutrition, immunodeficiency; and bacterial infection. Acute bronchiolitis was diagnosed clinically by the treating paediatrician based on the presenting history and physical examination. Children were evaluated for evidence of bacterial infection based on clinical examination and relevant laboratory and radiological investigations, including complete blood count, C-reactive protein, and chest radiography when indicated. Children with findings suggestive of bacterial infection were excluded.

Total 120 children aged 1–24 months presenting with cough, respiratory distress and clinical features consistent with acute bronchiolitis, with a Bronchiolitis Severity Score (BSS) ≥ 4 were included in the study after fulfilling the predefined

inclusion and exclusion criteria. **Error! Bookmark not defined.**

Detailed history was taken and through physical examination was done. Relevant radiological and hematological investigations were done if necessary.

Children in each treatment group received the assigned nebulization therapy in addition to standard supportive care. Nebulization was initially administered at short intervals according to the treating paediatrician's clinical assessment and was subsequently tapered to 4-hourly, 6-hourly, 8-hourly, and 12-hourly intervals according to clinical improvement.

Children were alternatively allocated to either group to receive the following treatments:

Group A, Levosalbutamol nebulization (n=40): Children in this group, in addition to the SOC treatment guidelines were given levosalbutamol nebulization in the dose of 0.63 mg for children > 1 year and 0.31 mg for infants < 1 year.

Group B, Adrenaline nebulization (n=40): Children received SOC treatment along with adrenaline nebulization in the dose of 0.1 ml - 0.3 ml/kg per dose of 1:1000 dilution. L-epinephrine nebulization was used due to non-availability of racemic epinephrine.

Group C, Combination of adrenaline and levosalbutamol administered sequentially (n=40): Adrenaline was administered at a dose of 0.1–0.3 mL/kg/dose of 1:1000 dilution, followed by levosalbutamol at a dose of 0.63 mg in children > 1 year and 0.31 mg in children < 1 year.

Baseline data included age, sex, weight, length, head circumference, duration and presenting clinical features, breastfeeding pattern, immunization status, socioeconomic status, respiratory rate, SpO₂, and baseline BSS. Socioeconomic status was assessed using the Modified Kuppuswamy socioeconomic scale.⁹

All children received standardized supportive care in addition to the assigned nebulization therapy. Supportive care included assessment and maintenance of hydration, appropriate enteral or intravenous fluid therapy, nasal saline drops and gentle suctioning, oxygen therapy when clinically indicated, respiratory support as required, antipyretic treatment for fever, and monitoring for disease progression. Oxygen saturation was monitored using a pulse oximeter, and children with persistently low SpO₂ (<95%) accompanied by signs of respiratory distress were administered humidified oxygen through nasal prongs.

Hydration status and ability to take fluids orally were assessed. Children having dehydration/difficulty in feeding were given IV fluids- IVF DNS, the dose of which was decided according to the hydration status. Children able to tolerate enteral feeds were given small frequent

feeds/orogastric/nasogastric feeds.

Parents were educated to clear the nostrils by administration of saline nasal drops and gentle suctioning before feeding to prevent nasal blocks. Nursing personnel checked the oxygen saturation (SPO₂) by Philips Pulse Oximeter. Children with SPO₂ which is persistently below 95% and signs of respiratory distress, i.e. nasal flaring, grunt, chest retractions (intercostal, subcostal), and cyanosis were given humidified oxygen by nasal prongs. Nursing staff and parents were educated about chest physiotherapy by vibration and percussion technique to clear the excessive respiratory secretions.

Disease severity was assessed using the Standard Bronchiolitis Severity Score (BSS) at admission (0 hours), 24 hours and 48 hours in all the 3 groups. The score comprised seven clinical parameters: respiratory rate, cyanosis, SpO₂, sensorium, nasal flaring/retractions, feeding, and air entry/wheezing. Each parameter was graded from 1 to 3, except nasal flaring/retractions, which was scored from 1 to 4 according to severity. Higher scores indicated greater disease severity. BSS was recorded at admission (0 hours), 24 hours, and 48 hours by the treating paediatrician using the same predefined scoring criteria.¹⁰

Clinically apparent adverse effects during nebulization were recorded and managed appropriately. Respiratory support was escalated to non-invasive or invasive mechanical ventilation when clinically indicated. All participants completed the 48-hour assessment with complete outcome data. Children were discharged when clinically stable and no longer requiring inpatient care. Hospital stay was recorded from admission until discharge.

Outcomes:

The primary outcome was improvement in BSS, assessed at baseline, 24 hours, and 48 hours. Secondary outcomes included improvement in SpO₂ and duration of hospital stay. Treatment-related adverse effects and need for mechanical ventilation were also recorded.

Statistical analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 22. Shapiro-Wilk test assessed normality. Continuous variables were compared among three groups by One-way ANOVA or Kruskal-Wallis test, and categorical variables by Chi-square or Fisher's exact test. Changes in BSS at 0, 24, and 48 hours were analyzed using repeated-measures analysis, with comparison among the three treatment groups. Post-hoc analysis was performed where appropriate. P-value <0.05 was taken to be statistically significant.

Results

Groups A, B and C were comparable in terms of mean age (10.64 ± 3.56 vs. 9.64 ± 2.98 vs. 10.12 ± 3.02 months, $p = 0.378$); gender (males: 70% vs. 60% vs. 62.5%, $p = 0.234$), socioeconomic status ($P=0.982$); and breastfeeding practices (exclusive breastfeeding: 15% vs. 20% vs. 10%; breastfeeding + formula feeding: 30% vs. 37.5% vs. 25%; exclusive formula feeding: 17.5% vs. 12.5% vs. 27.5% and breastfeeding with complementary feeds: 37.5% vs. 30% vs. 37.5%; $P=0.515$) (Table 1).

Groups A, B C were comparable in terms of symptoms like fever (45% vs. 57.5% 62.5%, $P = 0.269$), mean duration of fever (73.89 ± 48.37 vs. 84.62 ± 38.16 vs. 91.43 ± 51.25 , $P=0.234$), cough (95% vs. 100% 97.5%, $P = 0.358$), mean duration of cough (99.51 ± 48.16 vs. 88.32 ± 44.58 vs. 96.34 ± 43.62 hours, $P = 0.527$), SOB (80% vs. 87.5% vs. 85%, $P = 0.645$), mean duration of SOB (61.16 ± 43.53 vs. 58.54 ± 41.36 hours vs. 63.18 ± 44.62 hours, $P = 0.905$), wheezing (22.5% vs. 30% vs. 37.5%, $P = 0.677$), and mean duration of wheezing (56.26 ± 19.59 vs. 59.45 ± 20.46 vs. 61.48 ± 18.42 hours, $P = 0.485$) (Table 2).

At baseline, in Group A, 15 patients had mild BSS, while 19 and 6 had moderate and severe BSS, respectively. Similarly, Group B comprised 17 patients with mild, 18 with moderate, and 5 with severe BSS, whereas Group C included 16 patients with mild, 17 with moderate, and 7 with severe BSS. At 24 hours after treatment, 12 patients in Group A achieved a normal BSS, while 12, 11, and 5 had mild, moderate, and severe BSS, respectively. In Group B, 14 patients achieved a normal BSS, while 12, 10, and 4 had mild, moderate, and severe BSS, respectively. In Group C, 21 patients achieved a normal BSS, while 11, 5, and 3 had mild, moderate, and severe BSS, respectively. At 48 hours, normal BSS was observed in 27, 29, and 34 patients in Groups A, B, and C, respectively. Severe BSS persisted in 2 and 1 patients in Groups A and B, respectively, but none in Group C (Table 3).

BSS was significantly higher in Group C than in Groups A and B at 24 hours (32.5% vs. 35% vs. 52.5%, $P=0.007$) and at 48 hours (67.5%, 72.5%, and 85%, $P=0.013$). Baseline mean SpO₂ was comparable among the three groups ($P=0.354$). At 24 hours, SpO₂ increased significantly to $93.46 \pm 0.86\%$, $93.89 \pm 1.02\%$, and $95.14 \pm 1.42\%$ in Groups A, B, and C, respectively ($p = 0.0001$). At 48 hours, further improvement was observed, reaching $96.42 \pm 1.68\%$, $96.86 \pm 1.74\%$, and $99.46 \pm 1.89\%$, respectively ($p=0.0001$). Within-group changes in SpO₂ were also statistically significant in all three groups ($p=0.0001$).

Baseline respiratory rates were comparable among the three groups ($P=0.966$). At 24 hours, respiratory rate decreased to 56.64 ± 3.86 , 55.34 ± 3.46 , and 50.42 ± 2.42 breaths/min in Groups

A, B, and C, respectively ($p=0.0001$); and at 48 hours, it further decreased to 48.58 ± 1.42 , 47.82 ± 1.94 , and 40.82 ± 1.14 breaths/min, respectively ($P = 0.0001$). Moreover, the within-group reductions were statistically significant in all three groups ($p=0.0001$).

The mean duration of hospital stay was significantly shorter in Group C than Group A and Group B (2.46 ± 1.24 vs. 5.04 ± 2.02 vs. 4.42 ± 1.68 days, $p=0.0001$). Number of discharges were significantly more in Group C than Group A and Group B (97.5% vs. 80% vs. 85% , $P<0.005$). NIV was required in 5, 4, and 1 patients, respectively, while mechanical ventilation was required in 3, 2, and 0 patients. No deaths were reported in any group (Table 4).

Discussion

The study pertinently showed that the combination of nebulization with levosalbutamol and adrenaline, followed by standard of care provided better discharge rates, shorter hospital stays, and less need of mechanical ventilation or non-invasive ventilation, while mortality remained similar across all intervention groups.

These findings suggest that sequential nebulization with levosalbutamol and adrenaline may provide greater clinical benefit without compromising the dose of either intervention. Levosalbutamol selectively stimulates β_2 -adrenergic receptors and acts as a bronchodilator.¹¹ It relieves bronchospasm by relaxing bronchial smooth muscle, thereby improving airflow through narrowed airways in acute bronchiolitis.¹²

Adrenaline exerts both α - and β -adrenergic effects and acts as a potent vasoconstrictor, reducing mucosal edema and inflammation, while also producing bronchodilation and decreasing airway secretions. Thus, it may target multiple mechanisms contributing to airway obstruction in acute bronchiolitis.¹³

It has been suggested that salbutamol, which exerts minimal residual adrenergic activity, may cause more tachycardia than adrenaline, which, despite its potent adrenergic activity, may decrease heart rate.¹³

Both interventions reduced respiratory rate, with no mortality observed in any group. However, the combination produced greater improvement, potentially because of their complementary pharmacological actions. Levosalbutamol provides β_2 -mediated bronchodilation, whereas adrenaline additionally produces α -adrenergic vasoconstriction, which may reduce airway mucosal edema and congestion, thereby addressing multiple mechanisms contributing to airway obstruction.^{11,13}

To date, limited literature has directly compared salbutamol, levosalbutamol, and adrenaline in children with acute bronchiolitis. One study reported that nebulized levosalbutamol and

adrenaline were not associated with adverse effects and suggested better safety and efficacy with adrenaline than salbutamol.¹¹ Previous studies comparing nebulized salbutamol with adrenaline in children with acute bronchiolitis have also reported greater clinical improvement with adrenaline.¹²⁻

¹⁷ Compared with salbutamol, epinephrine was associated with more favorable changes in heart rate, respiratory rate, and Respiratory Distress Assessment Instrument (RDAI) scores, greater improvement in oxygen saturation, reduced duration of supplemental oxygen and intravenous fluid requirements, and shorter hospital stay.¹²⁻¹⁷

Our study compared the combination of adrenaline and levosalbutamol with the individual treatments. The combination demonstrated better clinical outcomes than either individual treatment.

To the best of our knowledge, the efficacy of sequential levosalbutamol followed by adrenaline in children with acute bronchiolitis has not been previously evaluated. The potential advantage of levosalbutamol over racemic salbutamol is related to its pharmacological composition. Salbutamol is a racemic mixture containing R- and S-isomers, whereas levosalbutamol contains only the pharmacologically active R-isomer. Bronchodilatory activity is primarily attributed to the R-isomer, while the S-isomer has been proposed to contribute to adverse effects.^{18,19} Furthermore, effective bronchodilation has been reported with lower doses of levosalbutamol compared with racemic salbutamol.²⁰

Overall, the mechanisms of action suggest that salbutamol or levosalbutamol combined with adrenaline may provide clinical benefit in bronchiolitis. Levosalbutamol may potentially cause fewer side effects than salbutamol.^{18,19} The present study adds to the limited literature on bronchodilator therapy in acute bronchiolitis by evaluating sequential levosalbutamol and adrenaline, a combination that has not been extensively investigated in this population.

Limitations

The study was limited by being single-center design which may limit generalization. Alternating allocation introduces potential selection bias. Moreover, placebo controls were not included. Viral confirmation was not performed. Follow-up was done for 48 hours only, thus long-term outcomes were not evaluated.

Future recommendations

Large sample-sized, multicentric randomized controlled trials should be conducted in future comprising placebo or control groups to validate these findings. Viral etiological confirmation should be done for evaluating treatment response across different pathogens. Future studies with longer follow-up is recommended to assess adverse effects and long-term outcomes of

combination therapy.

Conclusion

To conclude, sequential nebulization with levosalbutamol and adrenaline, in addition to standard care, demonstrated better clinical outcomes than either treatment alone in children below 2 years with acute bronchiolitis. The combination resulted in more improvement in respiratory status and oxygen saturation, shorter hospital stay, higher discharge rates, and decreased need of non-invasive and mechanical ventilation. No mortality was observed, and the interventions were generally well tolerated. These findings suggest that the complementary effects of levosalbutamol and adrenaline may provide more clinical benefit by addressing different mechanisms causing airway obstruction.

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Table 1: Demographic characteristics in children

Parameter	Group A	Group B	Group C	P-value
Age (months)[†]	10.64 ±3.56	9.64±2.98	10.12 ±3.02	0.378
Males, n(%)[*]	28(70%)	24(60%)	25(62.5%)	0.234
Socioeconomic status[*]				
Upper	2(5%)	1(2.5%)	3(7.5%)	0.982
Uppermiddle	4(10%)	3(7.5%)	3(7.5%)	
Lowermiddle	12(30%)	13(32.5%)	14(35%)	
Upperlower	15(37.5%)	14(35%)	12(30%)	
Lower	7(17.5%)	9(22.5%)	8(20%)	
Breast feeding[*]				
Exclusive breastfeed	6(15%)	8(20%)	4(10%)	0.515
Breastfeed +Formulafeed	12(30%)	15(37.5%)	10(25%)	
Exclusive Formulafe	7(17.5%)	5(12.5%)	11(27.5%)	

ed	(%)	(%)	(%)	
OnBreast Feed + Complimentaryfeeds	15(37.5%)	12(30%)	15(37.5%)	

[†] One-way Anova

^{*} Chi-square test

Table 2: Symptoms in children

Parameter	Group A	Group B	Group C	P-value
Fever				
Fever Yes/No [*]	18(45%)	23(57.5%)	25(62.5%)	0.269
Duration of fever (hours) [†]	73.89±48.37	84.62 ±38.16	91.42 ±51.25	0.234
Cough				
Cough Yes/No [*]	38(95%)	40(100%)	39(97.5%)	0.358
Duration of cough (hours) [†]	99.51±48.16	88.32 ±44.58	96.34 ±43.62	0.527
Shortness of breath (SOB)				
Shortness of breath Yes/No [*]	32(80%)	35(87.5%)	34(85%)	0.645
Duration of SOB (hours) [†]	61.16±43.53	58.54 ±41.36	63.18 ±44.62	0.905
Wheeze				
Wheeze	9(22.5%)	12(30%)	15(37.5%)	0.1

Yes/No*				677
Wheezeduration (hours) [†]	56.26±19.59	59.45±20.46	61.48±18.42	0.485

Table 3: Comparison of bronchiolitis severity score at baseline, 24 hours and 48 hours

Bronchiolitis severity score		Baseline	24 hours	48 hours
Group A (N=40)	Normal(<4)	0	12	27
	Mild(4-7)	15	12	6
	Moderate(8-14)	19	11	5
	Severe(15-21)	6	5	2
Group B (N=40)	Normal(<4)	0	14	29
	Mild(4-7)	17	12	6
	Moderate(8-14)	18	10	4
	Severe(15-21)	5	4	1
Group C (N=40)	Normal (<4)	0	21	34
	Mild(4-7)	16	11	4
	Moderate(8-14)	17	5	2
	Severe(15-21)	7	3	0

Table 4: Comparison of outcomes in children

Parameter	Group A	Group B	Group C	P-value
Improvement in Patients according to BSS				
24 hours	32.5%	35%	52.5%	0.007
48 hours	67.5%	72.5%	85%	0.013

SPO2 (mean±SD)				
Baseline	88.12±0.41	87.95±0.52	88.54±0.64	0.354
24 hours	93.46±0.86	93.89±1.02	95.14±1.42	0.0001
48 hours	96.42±1.68	96.86±1.74	99.46±1.89	0.0001
P-value	0.0001	0.0001	0.0001	
Respiratory rate (mean±SD)				
Baseline	63.22±5.43	64.53±6.14	64.89±5.72	0.966
24 hours	56.64±3.86	55.34±3.46	50.42±2.42	0.0001
48 hours	48.58±1.42	47.82±1.94	40.82±1.14	0.0001
P-value	0.0001	0.0001	0.0001	
Duration of Hospital stay	5.04±2.02	4.42±1.68	2.46±1.24	0.0001
Outcome				
Discharged	32	34	39	-
Non-invasive ventilation(NIV)	5	4	1	-
Mechanical ventilation(MV)	3	2	0	-
Death	0	0	0	-
Discharged	80%	85%	97.5%	<0.005