ejpmr, 2022,9(5), 411-416

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

EFFICACY OF 0.9% SALINE OVER 3% SALINE NEBULISATION IN HOSPITALISED CHILDREN WITH ACUTE BRONCHIOLITIS: A RANDOMISED CONTROLLED TRIAL

Dr. Yazhini*[1], Dr. Thumjaa Annamalai[2] and Dr. Jakanattane[3]

[1]MD Post Graduate, Department of Paediatrics, Aarupadai Veedu Medical College, Pondicherry, India.
[2]Professor, Department of Paediatrics, Aarupadai Veedu Medical College, Pondicherry, India.
[3]Assitant Professor, Department of Paedatrics, Aarupadai Veedu Medical College, Pondicherry, India.

***Corresponding Author: Dr. Yazhini**

MD Post Graduate, Department of Paediatrics, Aarupadai Veedu Medical College, Pondicherry, India.

Article Received on 21/03/2022 **Article Revised on 11/04/2022** **Article Accepted on 01/05/2022**

ABSTRACT

Introduction: Respiratory tract infections are one of the most common causes of illness among children and are responsible for nearly one-sixth of all deaths in children. The term LRTI is used to cover all those infections of respiratory tract that occur below the level of the larynx and include bronchiolitis, bronchitis, tracheitis, and bronchopneumonia. Acute bronchiolitis is one of the most common lower respiratory tract infections in infants and young children and generally has an underlying viral etiology. RSV is recognized as the most common viral pathogen. Objective of our study is to compare efficacy among 0.9% saline nebulization and 3% saline by monitoring the length of hospital stay and recording clinical severity score. **Methods:** Over the period of two years, Infants and young children aged (1-24 months) with diagnosis of acute bronchiolitis in Department of Paediatrics, after obtaining informed and written consent from the parents detailed history, clinical assessment and clinical severity scoring (Wang et al) was done. "All eligible infants and young children were randomized in consecutive manner and were divided into 2 subgroups and assigned to receive nebulization either with 4ml of 0.9% saline or 3% saline through conventional nebulizer with tight-fitting mask connected to a source pressurized oxygen set to a flow rate of 7L/min. Nebulization was continued till the nebulization chamber was empty". Hospitalized infants and young children were clinically assessed by clinical severity scoring (Wang et al)**Error! Bookmark not defined.** and length of hospital stay was noted. Discharge criteria included "orally feeding well, no need for oxygen supplementation and intravenous fluids, clinical severity score<3, absence of accessory muscle use or tachypnea and oxygen saturation >92% in room air". Data so collected was fed into computer using MS-Excel 2013 software. The data was compared between the two study groups using IBM Statistical Package for Social Sciences (IBM Inc., 2012). Chi square test was used for categorical data, Independent samples 't'-test was used for parametric data and Mann-Whitney U test was used for non-parametric data. **Results**: Out of the 110 children enrolled in the study, a total of 55 (50%) were allocated to Group 1 and were nebulized with 0.9% saline while remaining 55 (50%) were allocated to Group 2 and were nebulized with3% saline. Statistically, there was no significant difference between two groups in proportion of patients achieving clinical severity score $\leq$3 at different follow-up intervals ($p>0.05$). The median duration was 3 days in both the groups and there was no significant difference between two groups with respect to duration of hospital stay ($p>0.05$) **Conclusions:** On the basis of the findings of the present study it could be concluded that in patients presenting with mild to moderate severity of acute bronchiolitis both 0.9% as well as 3% saline nebulization were equally effective and use of 0.9% saline nebulization did not result in reduction of time taken for symptomatic recovery and duration of hospital stay.

KEYWORDS: Acute bronchiolitis, 0.9% Nacl Nebulization, 3%Nacl nebulisation.

INTRODUCTION

Respiratory tract infections are one of the most common diseases among children and are responsible for nearly one-sixth of all deaths in children.[1] The respiratory tract infections in children can be either acute or chronic/recurrent in nature. Of the two, recurrent infections more commonly affect the upper respiratory tract[1] while acute infections are predominated by lower respiratory tract infections (LRTI) that comprise nearly 80-85% of respiratory tract infections among children123. The term LRTI is used to cover all those infections of respiratory tract that occur below the level of the larynx and include bronchiolitis, bronchitis, tracheitis, and bronchopneumonia.[1] Respiratory tract infections account for one-third to half of the pediatric outpatient visits and 20%-30% of the pediatric hospital admissions.[1] The most common clinical presentation of these infections includes "cough, oropharyngeal

hyperemia, nasal discharge and signs like retraction, extended expiratory time, tachypnea, and wheezing or crackles on auscultation. Some of the common risk factors for LRTI in children include exposure to second-hand smoke, low socioeconomic status, sex, preterm birth, iron deficiency and day-care attendance"234. Acute bronchiolitis is one of the most common lower respiratory tract infections in infants and young children and generally has an underlying viral etiology. RSV is recognized as the most common viral pathogen. It is believed that nearly all the children experience an RSV infection upto two years of age3. Among the children affected by it, almost 40% develop LRTI. The objective of our study is to compare efficacy among 0.9% saline nebulization and 3% saline by monitoring the length of hospital stay and recording clinical severity score. Standardised treatment protocol of acute bronchiolitis is only supportive treatment (i.e) mucosal clearance by hypertonic saline. In our study by comparing the efficacy and reduction of burden of disease (length of hospital stay) of hypertonic saline with normal saline gives standardization of treatment with normal saline for mucosal clearance, as it is cost effective and with no/less side effects.

METHODS

Sample size was calculated based on the prevalence (total estimated sample size (n): 110 A Group(0.9% saline group): n=55 B Group(3% saline group): n=55). Study was registered under CTRI as soon as after the ethical clearance (IEC no: AVMC/IEC2019/71) and conducted in our hospital (department of paediatrics) Hospitalised infants and young children in AVMC&H with acute bronchiolitis meeting the inclusion criteria were taken under the study. This primary group was randomised in consecutive manner by lot method into two subgroups for intervention convenience and assigned to receive nebulization either with 4ml of 0.9% saline or 3% saline through conventional nebulizer with tight-fitting mask connected to a source pressurized oxygen set to a flow rate of 7L/min. Nebulization was continued till the nebulization chamber was empty". Hospitalized infants and young children were clinically assessed by clinical severity scoring (Wang et al) and length of hospital stay was noted. Discharge criteria included "orally feeding well, no need for oxygen supplementation and intravenous fluids, clinical severity score<3, absence of accessory muscle use or tachypnea and oxygen saturation >92% in room air".

Inclusion Criteria

1. Hospitalized infants and young children (1 to 24 months)
2. First episode of respiratory distress associated with wheezing
3. Clinical severity score >3

Exclusion Criteria

1. History of two or more episodes of respiratory distress in past
2. Family history of asthma
3. Associated cardiopulmonary disease *viz.*, congenital heart disease, cystic lung disease, etc
4. Preterm birth or history of mechanical ventilation in neonatal period
5. Patients with clinical signs of bacterial infection
6. Critically ill Infants and young children (1 to 24 months) suggesting severe acute bronchiolitis/incipient respiratory failure

Study Design

Randomized-controlled trial.

RESULTS

Data so collected was fed into computer using MS-Excel 2013 software. The data was compared between the two study groups using IBM Statistical Package for Social Sciences (IBM Inc., 2012). Chi square test was used for categorical data, Independent samples 't'-test was used for parametric data and Mann-Whitney U test was used for non-parametric data.

Comparison of Demographic Profile of Patients in two study groups.

SN	Characteristic	Group 1 (n=55)	Group 2 (n=55)	Statistical significance
1.	Mean age±SD (Range) in months	7.44±5.63 (1.0-24.0)	8.71±6.05 (1.0-24.0)	t=1.141; p=0.256
2.	Gender Male Female	 33 (60.0%) 22 (40.0%)	 33 (60.0%) 22 (40.0%)	χ^2=0; p=1
3.	Socioeconomic status			
	Upper middle	0 (0%)	3 (5.5%)	χ^2=4.157; p=0.245
	Lower middle	18 (32.7%)	14 (25.5%)	
	Upper lower	18 (32.7%)	22 (40.0%)	
	Lower	19 (34.5%)	16 (29.1%)	

Age of patients ranged from 1 to 24 months in both the groups. Mean age of patients was 7.44±5.63 months in Group 1 and 8.71±6.05 months in Group 2. Though the mean age of patients was higher in Group 1 as compared to that in Group 2 yet this difference was not significant statistically (p=0.256).

Distribution of cases in two groups according to mode of delivery.

SN	Characteristic	Group 1 (n=55)		Group 2 (n=55)	
		No.	%	No.	%
1.	LSCS	29	52.7	32	58.2
2.	NVD	26	47.3	23	41.8

χ^2=0.331; p=0.565

Majority of patients in both the groups were born through caesarean section. Though proportion of vaginally delivered children was higher in Group 1 (47.3%) as compared to that in Group 2 (41.8%) yet this difference was not significant statistically (p=0.565)

Distribution of cases in two groups according to presenting signs and symptoms.

SN	Signs and symptoms	Group 1 (n=55)		Group 2 (n=55)		Statistical significance	
		No.	%	No.	%	χ^2	'p'
1.	Fast breathing	55	100	55	100	-	-
2.	Noisy breathing	2	3.6	6	10.9	2.157	0.142
3.	Feeding/ breathing difficulty	18	32.7	23	41.8	0.972	0.324

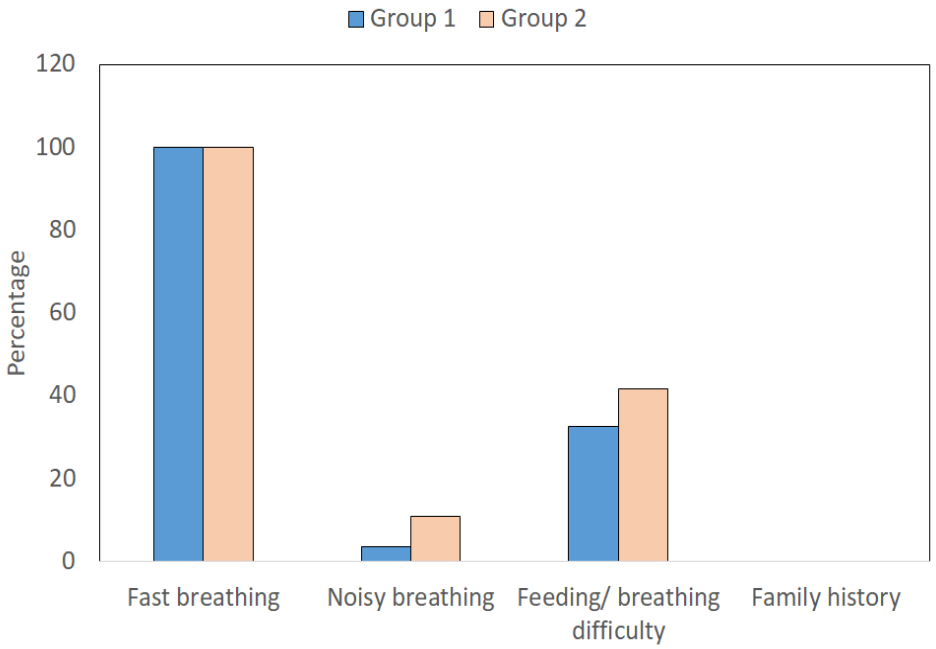

Fig. 01: Distribution of cases in two groups according to presenting signs and symptoms.

All the patients in both the groups presented with fast breathing. Presentation with noisy breathing was more common in Group 2 (10.9%) than in Group 1 (3.6%) but this difference was not significant statistically (p=0.142). Feeding/breathing difficulty was reported in 18 (32.7%) of Group 1 and 23 (41.8%) of Group 2 patients. Statistically, this difference was not significant (p=0.324)

Contact and social history

SN	History	Group 1 (n=55)		Group 2 (n=55)		Statistical significance	
		No.	%	No.	%	χ^2	'p'
1.	H/o TB contact	6	10.9	11	20.0	1.739	0.187
2.	Social history and secondary exposure to tobacco and pets	31	56.4	36	65.5	0.955	0.329

Tuberculosis contact history was seen in 6 (10.9%) of Group 1 and 11 (20%) of Group 2 patients (p=0.187). History of Secondary exposure to tobacco and pets was positive in 31 (56.4%) of Group 1 and 36 (65.5%) of Group 2 patients. Statistically, there was no significant difference between two groups with respect to contact and social history (p>0.05).

Comparison of Vital parameters between two study groups.

SN	Parameter	Group 1 (n=55)		Group 2 (n=55)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	Pulse rate (bpm)	127.69	16.34	124.64	18.43	1.221	0.225
2.	Respiratory rate (/min)	59.44	7.11	61.15	8.15	1.172	0.244
3.	Oxygen saturation (SpO_2) (%)	97.82	1.02	97.56	1.08	1.268	0.208

In Group 1 mean pulse rate, respiratory rate and oxygen saturation values were 127.69±16.34 bpm, 59.44±7.11/min and 97.82±1.02% respectively whereas in Group 2 the corresponding values were 124.64±18.43 bpm, 61.15±8.15/min and 97.56±1.08% respectively. Statistically, there was no significant difference between two groups with respect to any of these vital parameters (p>0.05)

Distribution of cases in two groups according to general status at presentation.

SN	Status	Group 1 (n=55)		Group 2 (n=55)		Statistical significance	
		No.	%	No.	%	χ^2	'p'
1.	Febrile	11	20.0	13	23.6	0.213	0.644
2.	Nasal flaring	3	5.5	8	14.5	2.525	0.112
3.	Decreased expiratory time	3	5.5	4	7.3	0.153	0.696
4.	Retractions	55	100	55	100	-	-
5.	Decreased breath sounds	3	5.5	4	7.3	0.153	0.696
6.	Wheezing	55	100	55	100	-	-
7.	Crackles	0	0	0	0	-	-
8.	Signs of bacterial infection	0	0	0	0	-	-

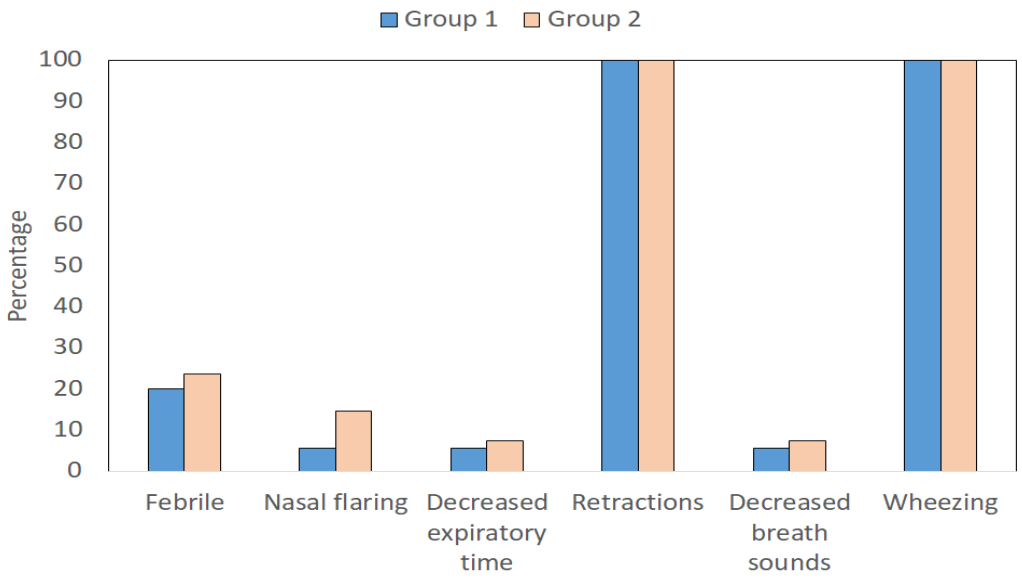

Fig. 02: Distribution of cases in two groups according to general status at presentation.

All the cases in both the groups presented with retractions and wheezing.

Among other features, in Group 1, there were 11 (22%) patients were febrile, 3 (5.5%) had nasal flaring, 3 (5.5%) each had decreased expiratory time and decreased breath sounds respectively. In Group 2, 13 (23.6%) patients were febrile, 8 (14.5%) had nasal flaring, 4 (7.3%) each had decreased expiratory time and decreased breath sounds respectively. None of the patients in either of two groups had crackles or signs of bacterial infection. No statistically significant difference was observed between two groups for any of these features (p>0.05)

At baseline (day 1 before nebulization) in both the groups all the patients had Clinical severity score ≥3.

Following nebulization clinical severity score ≥3 was seen in 92.7%, 58.2%, 26.2%, 0% and 0% patients respectively in Group 1 on days 1, 2, 3, 4 and 5 as compared to 96.4%, 65.5%, 34.8%, 7.4% and 0% patients respectively on the corresponding follow-up intervals in Group 2.

Statistically, there was no significant difference between two groups in proportion of patients achieving clinical severity score ≥3 at different follow-up intervals (p>0.05).

Comparison of Duration of hospital stay (days)

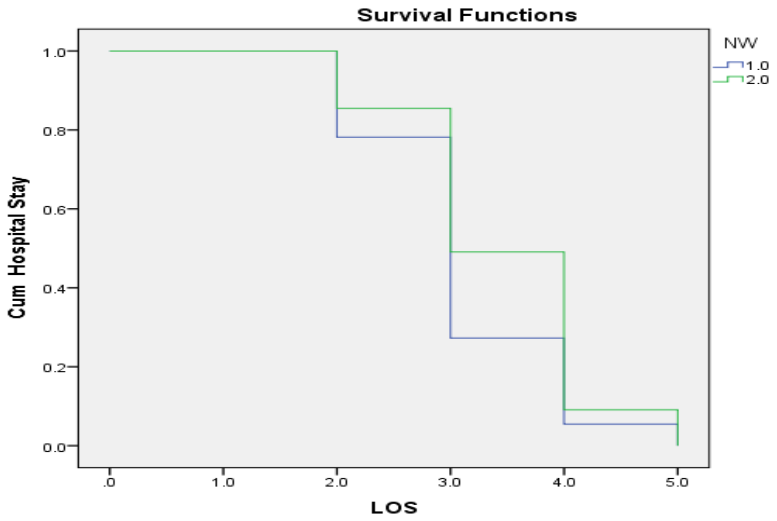

Fig. 03: Kaplan Meier Survival Curve for Hospital Stay and Discharge pattern.

Duration of hospital stay ranged from 2 to 5 days in both the groups. Mean duration was 3.11±0.81 days in Group 1 as compared to 3.44±0.86 days in Group 2. The median duration was 3 days in both the groups. Statistically, there was no significant difference between two groups with respect to duration of hospital stay ($p>0.05$)

DISCUSSION

Acute bronchiolitis is one of the most common cause of hospitalization among children, particularly in infanthood and early childhood. It may often be accompanied with prematurity, low birth weight, congenital lung abnormality, chronic lung disease, congenital heart disease and immunodeficiency Nearly 4 to 5% of babies born at term and from 10 to 100% of those born preterm need PICU admission for acute bronchiolitis with mechanical ventilation need ranging from 1 to 100%. Acute bronchiolitis is a cause of high concern and is responsible for a heavy burden of associated morbidity and mortality.

There are studies that report hypertonic saline to be comparable to normal saline as in the present study. However, majority of these studies find it to be more effective in terms of faster recovery in clinical severity and/or shorter duration of hospital stay. One of the reasons for discrepancies in the outcome of various study could be owing to difference in clinical severity of enrolled patients. In the present study, we have included children with mild to moderate severity of bronchiolitis only compared to some other studies that have reported a better performance of 3% hypertonic saline as compared to 0.9% saline had included moderate to severe or severe patients only. It might be possible that at lesser severity the efficacy of hypertonic saline could not be elucidated properly as in the present study.

In view of the divided evidence reporting a better efficacy, equal efficacy or poor efficacy of hypertonic saline nebulization and a possible risk of mild adverse effects, the use of hypertonic saline nebulization for management of acute bronchiolitis in children should be done in caution. There is requirement of more clinical evidence in multiple centres on a larger sample size to settle this issue. Further studies to corroborate the findings of the present study should be carried out.

CONCLUSIONS

On the basis of the findings of the present study it could be concluded that in patients presenting with mild to moderate severity of acute bronchiolitis both 0.9% as well as 3% saline nebulization were equally effective and use of 0.9% saline nebulization did not result in reduction of time taken for symptomatic recovery and duration of hospital stay. Further studies with change in concentration of normal saline to assess the safety and efficacy of normal saline nebulization are recommended.

LIMITATIONS

Following are some of the limitations of the present study, Small sample size, absence of patients with severe grade of bronchiolitis, absence of other outcomes of interest such as readmission rate and comparison of only 3% hypertonic saline with 0.9% saline.

REFERENCE

1. Garenne M, Ronsmans C and Campbell H.The magnitude of mortality from acute respiratory infections in children under 5 years in developing countries. World Health Statistics Qtl, 1992; 45: 180-191.
2. Couriel J. Assessment of the child with recurrent chest infections. British Medical Bulletin, 2002; 61(1): 115-132.
3. Tambe MP, Shivaram C, Chandrashekhar Y. Acute respiratory infection in children: a survey in the rural community. Indian J Med Sci., 1999 Jun; 53(6): 249-53.

4. Singh MP, Nayar S. Magnitude of acute respiratory infections in fewer than five children. J Commun Dis., 1996; 28: 273–8.
5. Jain N, Lodha R, Kabra SK. Upper respiratory tract infections. Indian J Pediatr, 2001; 68: 1135–8.
6. Boloursaz MR, Lotfian F, Aghahosseini F,Cheraghvandi A, Khalilzadeh, Khalilzadeh S, et al., Epidemiology of lower respiratory tract infections in children. Journal of Comprehensive Pediatrics, 2013; 4(2): 93–98.
7. United Nations Children‘s Fund. UNICEF; New York, The state of the world's children: a fair chance for every child, 2016, https://www.unicef.org/publications/files/UNICEF_SOWC_2016.pdf., 2016.
8. Nair H, Simões EAF, Rudan I, Gessner BD, Azziz-Baumgartner E, et al. Global and regional burden of hospital admissions for severe acute lower respiratory tract infections.
9. Rudan I, Boschi-Pinto C, Biloglav Z, Mulholland K, Campbell H. Epidemiology and etiology of childhood pneumonia. Bull World Health Organ, 2008; 86: 408–16.
10. Million Death Study Collaborators, Bassani DG, Kumar R, Awasthi S, Morris SK, Paul VK, et al. Causes of neonatal and child mortality in India: a nationally representative mortality survey. Lancet, 2010; 376: 1853–60.
11. da Silva ER, Pitrez MC, Arruda E, Mattiello R, Sarria EE, de Paula FE, et al. Severe lower respiratory tract infection in infants and toddlers from a non- affluent population: viral etiology and co-detection as risk factors. BMC Infect Dis., 2013 Jan 25; 13: 41.
12. Margolis PA, Greenberg RA, Keyes LL, LaVange LM, Chapman RS, Denny FW, et al. Lower respiratory illness in infants and low socioeconomic status. Am J Public Health, 1992; 82(8): 1119-1126.
13. Jackson S, Mathews KH, Pulanic D, et al. Risk factors for severe acute lower respiratory infections in children: a systematic review and meta- analysis. Croat Med J., 2013; 54(2): 110-121.
14. Hussain SQ, Ashraf M, Wani JG, Ahmed J. Low hemoglobin level a risk factor for acute lower respiratory tract infections (ALRTI) in children. J Clin Diagn Res., 2014 Apr; 8(4): PC01–PC03.
15. Wright AL, Taussig LM, Ray CG, Harrison HR, Holberg CJ. The Tucson Children's Respiratory Study. II. Lower respiratory tract illness in the first year of life. Am J Epidemiol, 1989 Jun; 129(6): 1232-46.