



ORIGINAL ARTICLE

Comparison of hypertonic-saline vs normal-saline nebulization in children with bronchiolitis.

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ABSTRACT... Objective: To compare the efficacy of 3% hypertonic saline (HS) with normal saline (NS) in children with bronchiolitis, in term of change in clinical severity score and duration of hospital stay. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Pediatrics, Central, Park Teaching Hospital, Lahore. **Period:** August 2018-January 2019. **Method & Material:** Sixty patients as per inclusion criteria, were randomly assigned into two groups. Group-A received nebulization with normal-saline (NS) and Group-B received nebulization with 3% hypertonic-Saline (HS). Data was collected regarding demographics, duration of illness, clinical severity score (CSS) as described by Wang et al., at time of presentation and after 24-hours of management as per assigned group, change in CSS after initial 24 hours of management, and total duration of hospitalization. Data was analyzed through SPSS-version-26. Paired sample t-test was applied to relate outcome of both the groups. **Result:** The principal outcome parameters studied were change in CSS and duration of hospital stay. Statistically nebulization with NS seems better than with HS with the p-value of 0.001 for both change in CSS after 24 hours and duration of hospital stay. **Conclusion:** Nebulization with normal saline has better impact on outcome of bronchiolitis, in terms of improving clinical severity score and hospital stay.

Key words: Hypertonic Saline, Inhalation, Viral Bronchiolitis, Respiratory Syncytial Virus.

INTRODUCTION

Bronchiolitis is one of immensely prevailing issue among 2-months to 2-years of age, majority of cases present during first year of life. Respiratory syncytial virus (RSV) is commonest causative organism, in about 80% of the cases but can also be caused by other respiratory viruses like influenzas, para-influenza, rhinovirus, mycoplasma, and adenovirus etc. The major pathophysiological changes include invasion of lower airway by virus that cause peribranchial infiltration of inflammatory cells, oedema of mucosa and submucosa, necrosis and shedding of respiratory epithelium and production of excess mucus which leads to impaired mucociliary clearance which altogether interfere with gas exchange, airway obstruction, atelectasis, and gas trapping.¹⁻⁵

Acute bronchiolitis usually has a benign course

but can be complicated to require hospitalization and mechanical ventilation. Bronchiolitis is one of the leading causes of hospitalization among infants and young children. In 2015, approximately 1.4 million hospital admission and 27,300 deaths occurred among admitted bronchiolitis patients, with peak age of 1-6 months.^{1,3,6}

Backbone of treatment is still supportive care with adequate hydration and oxygen inhalation to maintain normal saturation, with no defined role of antibiotics, steroids, and bronchodilator while few studies are favouring use of hypertonic saline in bronchiolitis by decline in duration of hospital stay and oxygen inhalation, whereas some other studies are reporting equivocal response with hypertonic saline and conventional therapy.⁷⁻¹¹

This study was conducted to assess the impact of nebulization with hypertonic saline (HS) i.e.

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3% saline, on outcome in term of duration of hospitalization and improvement in Clinical severity score (CSS) after initial 24-hours management in our setup, in comparison with control group being nebulized with normal saline (NS). So that guidelines can be delineated to improve the outcome that will reduce morbidity load over health care services.

MATERIAL & METHODS

The randomized clinical trial was conducted in the Pediatrics Department of Central Park Teaching Hospital, Lahore, Pakistan; after approval from institutional review board (Ref No. CPMRC/IRB/1719), from August 2018 till January 2019.

Sample size of 60 patients was calculated by keeping confidence interval 95%, power of study 80% and mean change of clinical severity score (CSS) as $2.26 + 1.15$ and $3.52 + 1.41$ with HS and NS nebulization respectively, by using WHO calculator.⁴ As per sample size, sixty pediatric patients accomplishing the inclusion and exclusion criteria were included in the study and were randomly divided into two groups by lottery method. Group-A (30 out of 60 patients) received nebulization with normal saline (NS) i.e. 0.9% saline & Group-B (30 out of 60 patients) received nebulization with hypertonic Saline (HS) i.e. 3% saline, rest of the supportive care was same for both the groups. Written informed consent was taken from the parents. children, from 2 month to 2 years of age, having first episode of moderate bronchiolitis with CSS of 4-9 and have not taken any treatment for it were included in the study, while exclusion criteria comprised of patents already on treatment, history of recurrent wheezing, patient having severe respiratory distress, oxygen saturation <90%, mild (CSS <4) or sever (CSS >9) bronchiolitis, all having underlying pulmonary or cardiac issues like bronchopulmonary dysplasia, congenital heart disease, cystic fibrosis, and immunodeficiency.

Required data for study was collected on pre-designed proforma from patients admitted through emergency and outpatient of pediatrics department with the diagnosis of bronchiolitis, included in the study as per inclusion and exclusion criteria. After randomization each patient was assessed for respiratory rate, wheezing, retraction, and general condition to calculate clinical severity score (CSS) as described by Wang et al., at time of presentation and after 24 hours of management according to their assigned group.¹² Second assessment for CSS was done to evaluate response in term of change in CSS, that was calculated by subtracting the CSS after 24 hours from CSS at the time of presentation, as per operational definition.

All the data was entered and analysed through SPSS-version-26. Descriptive analysis was done, qualitative parameter like gender was specified as frequencies and percentages while quantitative parameters like age, duration of disease, hospital stay, CSS and change in CSS were stated as median, mean + standard deviations (SD). Data from both groups was stratified regarding age, gender, duration of illness, CSS at baseline, change in CSS, and duration of disease to determine impact of effect modifier like age, duration, and severity of disease. Both groups were compared by post stratification t-test, taking p-value of <0.05 as significant.

Operational Definitions

Moderate Bronchiolitis

It is a Condition with clinical symptoms and signs including a viral upper respiratory prodrome with fever > 99 F, sneezing, rhinorrhea during last 2 weeks followed by increased respiratory effort and wheezing in children less than 2 years old with CSS= 4-9 as per Wang et al. criteria.¹³

Clinical Severity Score (CSS) by Wang et al.:¹²

Variables	Score			
	0	1	2	3
RR	<30	31-45	46-60	>60
Wheezing	None	Terminal expiration/ Only with stethoscope	Entire expiration or audible without stethoscope	Inspiration and expiration and audible without stethoscope
Retractions	None	Intercostal	Retrosternal	Severe with nasal flaring
General condition	Normal			Irritable, lethargic, poor feeding

Change in Clinical Severity Score

It was calculated by subtracting the CSS after 24 hours from CSS at the time of presentation.

RESULTS

During the study period 92 patients, with the clinical diagnosis of bronchiolitis, were admitted in the pediatrics department of central park teaching hospital. Sixty patients with the clinical diagnosis of bronchiolitis, fulfilling the inclusion criteria, participated in the study, and were randomized into two groups (30 patients in each group). Remaining 32 patients were excluded as per exclusion criteria. Patients in group-A nebulized with NS and group-B nebulized with HS, along with required supportive care.

Demographic data of both groups are comparable, minimum age at presentation reported 2 months

in both the groups keeping median age of presentation 6-months and 6.5 months in group A and B respectively. In group-A 73% were male and 27% were female while in group-B 63% were male and 37% were female. (Table-I)

Minimum score at the time of admission was 3, in both groups with mean of 5.3 ± 1.5 and 5.7 ± 1.5 in group-A and group-B, respectively. For both groups, minimum change noted in CSS is zero, while in group-A maximum change reported is 3 with mean 1.5 ± 0.78 and in group-B it is 4 with mean of 2.0 ± 0.9 . Minimum duration of hospital stay documented in both groups is same that is 1-day, whereas maximum hospital stay is 14 days with mean of 3.1 ± 3.3 and 5 days with mean of 2.3 ± 1.1 in group-A and group-B, correspondingly.

	Group-A (NS)	Group-B (HS)	Total
Gender:			
Male	19 (63.3%)	22 (73.3%)	41 (68.3%)
Female	11 (36.7%)	8 (26.7%)	19 (31.7%)
Age (In months):			
Minimum	2	2	2
Maximum	18	24	24
Mean \pm Sd deviation	8.1 ± 5.5	8.6 ± 6	8.3 ± 5.7

Table-I. Comparison of demographics

	Group-A (NS)	Group-B (HS)	Total
Clinical severity score (CSS):			
Minimum	3	3	3
Maximum	7	9	9
Mean \pm Sd Deviation	5.3 ± 1.5	5.7 ± 1.5	5.4 ± 1.5
Change in CSS:			
Minimum	0	0	0
Maximum	3	4	4
Mean \pm Sd Deviation	1.5 ± 0.78	2.0 ± 0.9	1.8 ± 0.87
p-value	0.001	0.69	
Hospital stay (in days):			
Minimum	1	1	1
Maximum	14	5	14
Mean \pm Sd Deviation	3.1 ± 3.3	2.3 ± 1.1	2.7 ± 2.5
p-value	0.001	0.163	

Table-II. Comparison of out come

Paired sample T-test was conducted to compare both groups. Group-A attained significant p-value of 0.001 for both change in CSS after 24 hours of management and hospital stay, in contrast Group-B achieved p-value of 0.690 and 0.163 for change in CSS after 24 hours of management and hospital stay, respectively, i.e. statistically insignificant.

DISCUSSION

Bronchiolitis is a commonest lower respiratory tract infection among infants, requiring admissions. It is an expensive and self-limited disease; symptomatic management is main stay of treatment. Acute bronchiolitis is the most common cause for hospitalization in early childhood, with 1–3 % of all infants admitted to hospital during their first winter. Although the infection occurs through out the year, the incidence increases during the winter season. In current study, maximum admissions were during November and December.²

As described in other studies, we also noted higher incidence of disease among males, as 41 out of 60 (68%) were male in this study.^{3,14} In current study, majority of bronchiolitis patients are younger than 1 year of age i.e. 45 out of 60 (75%) with mean age of 6-months. Likewise international study reporting large mass of the patients are less than 12 months of age, with peak age of 1 to 6 months.^{2,14,15}

Mean CSS (5.4 ± 1.5) of all participants at the time of randomization of this study is consistent to an international study of moderate bronchiolitis, that is reporting mean CSS of 5.7 ± 1.8 as per clinical scoring system by Wang et al.¹³

In this study, mean hospital stay reported is $3.1 + 3.3$ days among patients nebulized with normal-saline (group-A) whereas $2.3 + 1.1$ days among patients nebulized with hypertonic-saline (group-B) that corresponds with the results of study conducted by Wu S et al. that reported mean hospital stay of $3.92 + 5.24$ and $3.16 + 2.11$ days for patients nebulized with NS and HS, respectively.¹⁶

The study found that normal-saline nebulization is superior to hypertonic-saline nebulization with p-value of 0.001 regarding change in CSS after initial 24 hours of management, in comparison to another study showing better result with hypertonic-saline nebulization over control group with the p-value of 0.043.¹³ While Flores P et al. reported no difference in results of nebulization with normal-saline and hypertonic-saline in regard with change in clinical severity score (CSS).¹⁷

Regarding limitations and recommendations, the study was conducted on a small group of moderate bronchiolitis patients admitted in pediatric ward. Such study should be arranged with a large sample size, including all bronchiolitis patients being managed as out-patient, admitted in pediatric ward or requiring intensive care at any stage of disease and its management.

CONCLUSION

For the management of moderate bronchiolitis, nebulization with normal-saline is found superior to that of hypertonic-saline due to its contribution in changing the CSS and duration of hospital stay.





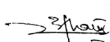
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