

Comparative Efficacy of Nebulized 7% Hypertonic Saline versus 0.9% Normal Saline with Salbutamol in Children with Acute Bronchiolitis

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Abstracts

Background: Acute bronchiolitis is an acute viral lower respiratory tract infection of infants and is the leading cause of hospitalization of infants below 2 years of age. Being a viral disease, there is no effective treatment of this problem other than supportive care. To provide this care, both 0.9% normal saline with salbutamol and 3% hypertonic saline has been found effective. This study was undertaken to assess the efficacy of 7% hypertonic saline on recovery from acute bronchiolitis.

Methodology: This was a randomized controlled trial, carried out in the Department of Paediatrics, Dhaka Medical College Hospital (DMCH), Bangladesh between January 2015 to December 2015. A total of 90 children from 1 month to 2 years of age of either sex who were diagnosed and admitted as acute bronchiolitis were enrolled. After enrollment, they were randomly assigned to either 7% nebulized hypertonic saline (Group-I = 45) or to 0.9% nebulized normal saline with salbutamol (Group-II = 45). The efficacy was determined by assessing clinical severity score and length of hospital stay. Data were analyzed using computer software SPSS version 19.

Result: In this study the two groups were almost similar with respect to their demographic and baseline clinical severity score. After intervention the clinical severity score of both treatment modalities were reduced (Group-I(HS) were 7.9, 6.8, 3.8, 1.4, 1.33 while in Group-II(NS+ Salbutamol) score were 8.6, 7.6, 4.9, 3.11, 2.12) but the reduction was significant more in children who received 7% nebulized hypertonic saline than those who received 0.9% nebulized normal saline with salbutamol. Majority 42(93.3%) of group-I(HS) children recovered at the end of 72 hours whereas 17(37.8%) of the children of group-II (NS+ Salbutamol) recovered from the disease during the same period. Length of hospital stay was shorter in hypertonic saline group compared to normal saline with salbutamol group (56.36±12.33 hours vs 71.07±13.48 hours, $p<.001$). The patients of hypertonic saline group required a shorter duration of oxygen therapy compared to normal saline with salbutamol group (12.53±3.58) hours vs (20.25± 4.15) hours, ($p=0.009$).

Conclusion: 7% hypertonic saline was found more effective than 0.9% normal saline with salbutamol in terms of reducing clinical severity, length of hospital stays and duration of oxygen therapy.

Keywords: Acute Bronchiolitis, 7% Hypertonic saline

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Received: 21-04-2018

Accepted: 24-06-2019

Introduction

Acute bronchiolitis is the commonest viral lower respiratory tract infection of under 2 years children and their treatment is virtually supportive.^{1,2} like oxygen supplementation, ensuring adequate hydration and nutrition.³ Anti-cholinergic drugs e.g. ipratropium bromide and normal saline with salbutamol nebulization are variable.^{4,5} Antiviral agents available but expensive and role is controversial. Antibiotic has no role.⁶ However, there are evidence hypertonic saline solution are effective and improve the cases through mucociliary clearance and by reducing airway edema.⁷ Study shows, the

improvement in the clinical severity scores was significant, those was treated with hypertonic saline.^{8,9,10} To our knowledge, 7% hypertonic saline has not been previously investigated in our country. So, we hypothesized that simply 7% hypertonic saline in the nebulization without salbutamol to these babies may improve clinical severity scores and decrease the length of hospitalization.

Materials and methods

The study was a randomized controlled trial conducted in the department of Paediatrics, Dhaka Medical College Hospital (DMCH) from January 2015 to December 2015. Informed consent was obtained from a parent or legal guardian of each patient enrolled in the study. Children aged between one month to two years presenting with preceding or existing runny nose, cough, breathing difficulty, chest indrawing and whose chest x-ray showed

hyperinflation, hypertranslucency without any cardiac problem and admitted during the study period was enrolled consecutively as study population. Exclusion criteria were previous history of wheezing, any use of bronchodilators within 2 hours of presentation, chronic cardiac or respiratory disease or respiratory failure or requiring mechanical ventilation, inhaling the nebulized any hypertonic saline within 12 hours of intervention.

After inclusion and exclusion this study included 90 patients with acute bronchiolitis. The two groups were randomly assigned to 7% hypertonic saline nebulization (n=45) and 0.9% normal saline with salbutamol nebulization (n=45) by lottery method. Relevant history and physical findings were recorded in a pre-tested, semi-structured questionnaire. Variables like clinical severity score assessed by using respiratory distress assessment instrument described by Wang et al.¹¹

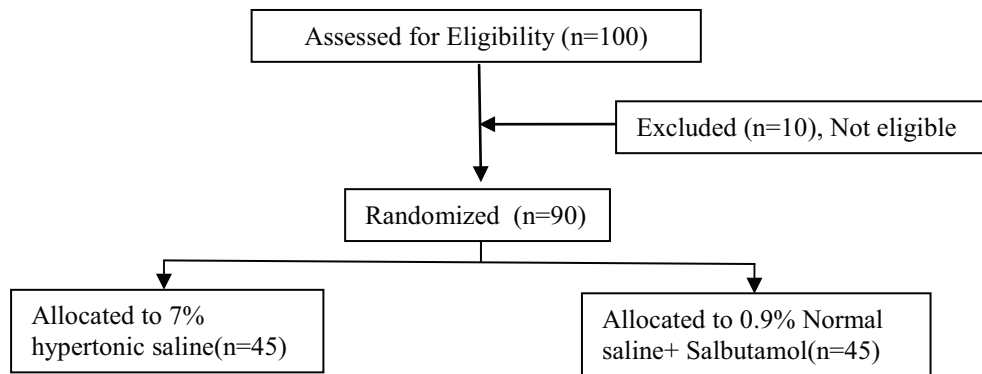


Fig: Flowchart

Table I
Respiratory distress Assessment Instrument

Variables	0	1	2	3	total
Respiratory rate	<30 breaths/min	31 to 45 Breaths/min	46 to 60 Breaths/min	>60 breaths/min	3
Wheezing	none	Terminal expiratory or only with stethoscope	Entire expiration or Audible on Expiration without stethoscope	Inspiration and expiration without stethoscope	3
Retraction	none	Intercostals only	Tracheosternal	Severe with nasal flaring.	3
General condition	normal			Irritable, lethargic, or poor feeding	3

Oxygen saturation was measured by using noninvasive pulse oxymeter and recorded on admission as baseline characteristics. A child with oxygen saturation value < 90% was designated as having significant hypoxia.⁶ After taking written informed consent drug was given according to dose schedule. Group-I received nebulization with 3 ml of 7% hypertonic saline and group-II received nebulization with 3 ml of 0.9% normal saline with 0.3ml salbutamol three times every day at intervals of 8 hours until they were improved enough for discharged. Each of the two groups received the same supportive measures like propped up positioning, o-p, nasal suction when needed, iv fluid, feeding, oxygen therapy (when oxygen saturation < 90%), paracetamol for fever, antibiotic and counseling. Cases were monitored by respiratory distress assessment instrument (RDAI) score at 12 hourly initially then 24 hourly till the patient was ready for discharge. The time required from the initiation to the withdrawal of oxygen therapy was recorded. Oxygen therapy was stopped when the patients maintaining $SP_{O_2} > 95\%$. Length of hospital stay from admission to time taken to discharged was measured. The decision to discharge the patients was made in the morning rounds by the attending physician, based on clinical grounds alone. The outcome variables were (1) clinical severity score (2) length of hospital stay (3) oxygen saturation in room air (4) duration of oxygen supplementation (5) Side effects of drugs. Collected data were processed and analyzed using computer software SPSS (Statistical Package for Social Sciences), version 19. The test statistics used to analyze the data presented on categorical scale were Chi-square and Unpaired t-Test (for comparison of data between groups). Level of significance was set 5% and p-value <0.05 was considered significant.

Table II
Demographic characteristics between groups

Demographic characteristics	Group		p-value
	Group-I (HS) (n = 45)	Group-II (NS+ Salbutamol) (n = 45)	
Age			
< 6	22(48.9)	33(73.3)	
6-12	15(33.3)	7(15.6)	
>12	8(17.8)	5(11.1)	
Mean \pm SD#	7.81 \pm 5.32	5.81 \pm 4.62	0.06
Sex *			
Male	31(68.9)	31(68.9)	1.0
Female	14(31.1)	14(31.1)	

Table III
Clinical presentation of the cases on admission

	Group	
	Group -I(HS) (n=45), No. (%)	Group-II (NS+ Salbutamol) (n=45), No. (%)
Clinical presentation		
Breathing difficulty	45(100)	45(100)
Cough	45(100)	45(100)
Fever	25(55.6)	24(53.3)
Runny nose	45(100)	45(100)
Wheeze	45 (100)	45 (100)
Rhonchi	45 (100)	45 (100)
Chest indrawing	45(100)	45(100)
Tachypnoea	38(84.4)	41(91.1)
Tachycardia	35(77.7)	38(84.4)
Head nodding	2(4.4)	3(6.7)
Nasal flaring	2(4.4)	3(6.7)
Feeding difficulty	24(53.3)	22(48.9)
Oxygen saturation (mean \pm SD) #	95.04 \pm 0.93	94.78 \pm 0.88
Radiological finding		
Increased translucency	41(91.11%)	43(95.5)
Hyperinflation	37(82.2%)	41(91.11%)
Low flat diaphragm	39(86.66)	43(95.5)

Table IV
Mean clinical severity score

Mean clinical severity score	Group-I (HS) (n = 45)	Group-II (NS+ Salbutamol) (n = 45)	p-value
	At baseline	7.9	
At 12 hours	6.8	7.6	.074
At 24 hours	3.8	4.9	.041*
At 48 hours	1.4	3.1	.012*
At 72 hours	1.3	2.1	.081

Table V

Comparison of duration of oxygen therapy between groups

Duration of oxygen therapy (hours)	Group		p-value
	Group- I (HS) (n = 5)	Group-II (NS+ Salbutamol) (n = 6)	
Mean ± SD	12.53±3.58	20.25±4.15	0.009*

Table VI

Comparison of recovery and discharge from hospital between groups

Recovery and discharge	Group		p-value
	Group-I (HS) (n = 45)	Group -II (NS+ Salbutamol) (n = 45)	
Rapid (within 72 hours)	42(93.3%)	17(37.8%)	< 0.001*
Gradual (after 72 hours)	3(6.7%)	28(62.2%)	

Table VII

Comparison of Length of hospital stays between groups

Length of hospital stay (hours)	Group		p-value
	Group- I (HS) (n = 45)	Group- II (NS+ Salbutamol) (n = 45)	
	56.36 ± 12.33	71.07 ± 13.48	< 0.001*

Discussion

Bronchiolitis is a major public health problem throughout the world exerting significant morbidity and mortality. This study demonstrated that clinical severity score of both the treatment groups were reduced but the reduction was much earlier in children who received 7% nebulized hypertonic saline than those who received 0.9% nebulized normal saline with salbutamol. Majority of the 7% hypertonic saline group children recovered within 72 hours, whereas one third of the children of 0.9% normal saline with salbutamol group recovered from the disease during the same period. No side effect

observed in either group. Similar observations were seen in another study, mean duration of hospital stay was shorter in hypertonic saline group.¹² Another study demonstrated no additional clinical benefit from inhaled 7% hypertonic saline with epinephrine when compared with 0.9% normal saline with epinephrine.¹³ In this study, mean time of O2 requirements in 7% hypertonic saline group was 12.0 hours and 20 hours in 0.9% normal saline with salbutamol group (p<0.009). Many of them used acute bronchiolitis severity score to evaluate patients over time and they found that inhaled 3% hypertonic saline with epinephrine administered by nebulization every 6-8 hours improved clinical severity score and reduced the length of hospital stay in hospitalized patients when compared with 0.9% saline with epinephrine.⁹ None of the studies reported any side-effects. These findings go in favour of the findings of this study. Hypertonic saline decreases airway oedema, enhances mucociliary clearance by improving mucus flow, and thus decreases airway obstruction.¹⁴ From the above discussion, it seems that the use of nebulized 7% hypertonic saline in children admitted with acute bronchiolitis is a safe and effective therapy, although the optimum dose is unknown. Early, pre-hospital intervention for bronchiolitis with this safe, effective, and inexpensive agent might save lives, reduce complications and hospitalizations, and be applicable for its wider use, including small communities where hospital care is not available.

Conclusion

7% hypertonic saline was found more effective than 0.9% normal saline with salbutamol in terms of reducing clinical severity, length of hospital stays and duration of oxygen therapy. No side effect was observed in either group.

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