COMPARATIVE EFFICACY OF NEBULIZED 7% HYPERTONIC SALINE VERSUS 3% HYPERTONIC SALINE IN CHILDREN WITH ACUTE BRONCHIOLITIS

ISLAM MS[1], MOLLAH AH[2], KHAN TH[3], SHAHA CK[4], UDDIN MZ[5], KHANAM S[6]

Abstract

Background: *Acute bronchiolitis is an acute viral lower respiratory tract infection in early childhood and is the leading cause of hospitalization in 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 3% hypertonic saline and 7% hypertonic saline has been used and found effective. However, which option is more effective to reduce clinical severity and length of hospital stay, still remain unsettled.*

Objective: *To determined the efficacy of 7% hypertonic saline in children with acute bronchiolitis.*

Methodology: *The study was a randomized controlled trial and carried out in the Department of Paediatrics, Dhaka Medical College Hospital (DMCH), Dhaka between January 2015 to December 2016. A total of 135 children from 1 month to 2 years of age irrespective of sex with clinical presentation of acute bronchiolitis admitted in the paediatrics ward of DMCH were included in the study and were randomly assigned to either 7% nebulized hypertonic saline (Group-I = 45) or to 3% nebulized hypertonic saline (Group-II = 90) in ratio (1:2). The main outcome variables were clinical severity score and length of hospital stay. The outcome was evaluated at 12 hourly and 24 hourly intervals till discharge (up to 120 hours)*

Result: *In this study both groups were almost similar with respect to their demographic characteristics like age and sex and baseline clinical characteristics. The study demonstrated that respiratory rate score, wheezing score, retraction score, general condition score and clinical severity score of both treatment modalities were reduced. Children of group-I(7% HS) 40(88.9%) recovered at the end of 72 hours where as 67(74.4%) of the children of group-II(3% HS) recovered from the disease during the same period. Length of hospital stay was shorter in 7% hypertonic saline group compared to 3% hypertonic saline group (56.36±16.33 hours vs63.07±21.48 hours, p=.067). The patients of 7% hypertonic saline group required a shorter duration of oxygen therapy compared to 3% hypertonic saline group (16.53±3.98) hours vs (20.25± 4.15) hours, (p=0.109) respectively.*

Conclusion: *Nebulized 7% hypertonic saline as well as 3% hypertonic saline both were effective in acute bronchiolitis and found no significant difference in efficacy between these options in terms of reducing clinical severity, length of hospital stay and duration of oxygen therapy. No side effect were observed in either group.*

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Introduction:

Acute bronchiolitis is the commonest viral lower respiratory tract infection of under 2 years children. More than 70% cases are due to respiratory syncytial virus which causing bronchiolitis, occurring in epidemics during winter months.[1,2] Others less common pathogens include parainfluenza, influenza, rhinovirus, adenovirus, human metapneumovirus, and mycoplasma pneumonae.

1. Dr. Md. Saiful Islam, Asstt. Registrar, Department of Paediatrics, Dhaka Medical College Hospital .
2. Prof. Md. Abid Hossain Mollah ,Professor and Head , Department of Paediatrics, BIRDEM General Hospital, Segun Bagicha, Dhaka.
3. Dr. Tafazzal Hossain Khan, Asso. Prof. of Neonatology, Dhaka Medical College Hospital, Dhaka.
4. Dr. Chandan Kumar Shaha, Asstt. Prof. of Neonatology Dhaka Medical College Hospital, Dhaka.
5. Dr. Md. Zahir Uddin, Asstt. Prof. of Neonatology, Dhaka Medical College Hospital, Dhaka.
6. Dr. Shahana Khanam, Associate Professor, Department of Microbiology, MH Samarita Medical College, Dhaka

Correspondence : Dr. Md. Saiful Islam, Email : dr.saif_53@yahoo.com

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Children become infected with RSV by age 2 years. Peak incidence of bronchiolitis is 2-6 months.[2] A substantial proportion of children will experience at least one episode with bronchiolitis during their life, and as much as 2-3% of all children will be hospitalized with bronchiolitis during their first year of life.[2] The infection starts in the upper respiratory tract, spreading to the lower airways within few days. The pathophysiology of bronchiolitis is quite distinct from that of asthma. Bronchiolitis is an infection of the bronchiolar epithelium, characterized by necrosis and sloughing of epithelial cells, oedema, increased secretion of mucus, and peribronchiolar mononuclear infiltration- changes that obstruct flow in the large and small airways, leading to hyperinflation and atelectasis.[1,2] and their treatment is virtually supportive, 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] Several studies reported on the use of nebulized hypertonic saline solution improve the cases through mucociliary clearance and reduce airway edema.[7,8,9] As there is limited data both home and abroad on the effectiveness of 7% hypertonic saline on the management of acute bronchiolitis. So We hypothesized that simply 7% hypertonic saline in the nebulization to these babies may improve the clinical severity scores and decrease the length of hospital stay.

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 2016. Informed written consent was obtained from a parent or legal guardian of each patient before 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 were 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 135 patients with acute bronchiolitis. The two groups were randomly assigned to 7% hypertonic saline nebulization Group-I(7%HS n=45) and 3% hypertonic saline nebulization Group-II (3%HS n=90) by lottery method in ratio(1:2). 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 a.l.[10]

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 3% hypertonic saline 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_{02}>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.

Result:

Table-I

Demographic characteristics of two groups

Demographic characteristics	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)	p-value
Age			
< 6	22(48.9)	66(73.3)	
6-12	15(33.3)	14(15.6)	
>12	8(17.8)	10(11.1)	
Mean ± SD#	7.81±5.32	5.81±4.62	0.06
Sex *			
Male	31(68.9)	62(68.9)	1.0
Female	14(31.1)	28(31.1)	

Table-II

Clinical presentation of cases and control on admission

	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)
Clinical presentation		
Breathing difficulty	45(100)	90(100)
Cough	45(100)	90(100)
Fever	25(55.6)	48(53.3)
Runny nose	45(100)	90(100)
Wheeze	45 (100)	90 (100)
Rhonchi	45 (100)	90 (100)
Chest indrawing	45(100)	90(100)
Tachypnoea	38(84.4)	82(91.1)
Tachycardia	35(77.7)	76(84.4)
Head nodding	2(4.4)	6(6.7)
Nasal flaring	2(4.4)	6(6.7)
Feeding difficulty	24(53.3)	44(48.9)
Radiological finding		
Increased translucency	41(91.11%)	86(95.5)
Hyperinflation	37(82.2%)	82(91.11%)
Low flat diaphragm	39(86.66)	86(95.5)

Table-III

Mean clinical severity score of both groups

Mean clinical severity score	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)	p-value
At baseline	7.9	8.4	.114
At 12 hours	6.8	7.4	.086
At 24 hours	3.8	4.4	.063
At 48 hours	1.5	1.8	.119
At 72 hours	1.3	2.1	.127

Table-IV

Comparison of duration of oxygen therapy between groups

Duration of oxygen therapy(hours)	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)	p-value
Mean ± SD	12.53±3.58	20.25±4.15	0.109

Table-V

Comparison of recovery and discharge from hospital between groups

Recovery and discharge	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)	p-value
Rapid (within 72 hours)	40(88.9%)	67(74.4%)	.084
Gradual (after 72 hours)	5(11.1%)	23(25.6%)	

Table-VII

Comparison of Length of hospital stays between groups

Length of hospital stay(hours)	Group Group-I 7%(HS) (n = 45)	Group-II (3%HS) (n = 90)	p-value
Length of hospital stay	56.36 ± 16.33	63.07 ± 21.48	.067

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 not statistically significant in children who received 7% nebulized hypertonic saline and who received 3% nebulized hypertonic saline (p-value >0.05) Length of hospital stay was shorter in 7% hypertonic saline group compared to 3% hypertonic saline group (56.36±16.33) hours vs (63.07±21.48) hours, p=.067).. Majority of the 7% hypertonic saline group children recovered within 72 hours, where as three fourth of the children of 3% hypertonic saline group recovered from the disease during the same period. The length of hospital stay was not statistically significant between these two groups(p-value =0.084). No side effect were observed in either group. Another study demonstrated no additional clinical benefit from inhaled 7% hypertonic saline with epinephrine when compared with 0.9% normal saline with epinephrine.[11] In this study mean time of oxygen requirements in 7% hypertonic saline group 12.0 hours and 20 hours in 3% hypertonic saline group (p=0.109). Many of them used acute bronchiolitis severity score to evaluate patients over time and they found that inhaled hypertonic saline administered by nebulization every 6-8 hours improved clinical severity score and reduced the length of hospital stay in hospitalized patients when compared with normal saline.[8,9] 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.[12] The use of both nebulized 7% hypertonic saline and 3% hypertonic saline in children admitted with acute bronchiolitis was safe and effective therapy depends on their availability, 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:

Both 7% hypertonic saline and 3% hypertonic saline were found effective in terms of reducing clinical severity, length of hospital stay and duration of oxygen therapy. No side effect were observed in either group.

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