ORIGINAL RESEARCH PAPER

Paediatrics

TO STUDY THE ROLE OF NEBULISATION OF 3% HYPERTONIC SALINE IN THE TREATMENT OF VIRAL BRONCHIOLITIS IN HOSPITALIZED CHILDREN UPTO AGE OF 18 MONTHS

KEY WORDS: Bronchiolitis , Nebulisation , Respiratory tract infection.

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ABSTRACT

Background and Objective: In this study we hypothesis that nebulisation with hypertonic saline is safe, potentially effective treatment reducing the duration of hospital stay in children with acute Bronchiolitis. The length of hospital stay observed in our study in children who received additional 3% hypertonic saline nebulisation is less when compared to children who received standard therapy alone.

Methods : A Prospective, Randomized controlstudy was conducted among children who were admitted in Meenakshi Medical College Hospital and Research Institute over a period of 4 months from March to June 2019. They were assessed with RDAI score and SPO2 readings by puloximeter. Patients were randomized to receive treatment either with nebulisation of study solution 3% hypertonic saline along with standard therapy or only standard therapy (i.e oxygen, salbutamol nebulisation, i.v fluids & paracetamol). The clinical response of both the groups were compared and data were analysed.

Results : The average reduction in the length of stay observed in our study in the children who received additional 3% hypertonic saline nebulisation is 39 hours when compared with the children who received standard therapy alone.

INTRODUCTION

Respirator syntial virus (RSV) is the most commonly isolated agent in 75% of children less than 2 years of age hospitalized for bronchiolitis.[2,5,6] Bronchiolitis is characterized by bronchiolar obstruction with edema, mucus plugs and cellular debris rather than bronchospasm.[8] Profuse coryza, congestion and a low grade fever clinically characterize the syndrome initially. Sixty percent of primary RSV infection are confined to upper airway.[3,4,9]

The primary treatment option therefore remains mainly supportive measures with fluids, supplemental oxygen administration, observation and mechanical ventilated support as needed.

According toWorld Health Organisation (WHO), 150 million new cases occur annually, out of which 11-20 million cases are serious enough to cause hospitalization. Worldwide majority of cases occur in developing countries.[7,11]

METHODOLOGY

Type of Study: Prospective,Randomized control study conducted in Meenakshi Medical College Hospital and Research Institute over a period of 4 months from March to June 2019.

Inclusion criteria:

Selection of patients was made according to diagnostic criteria for acute bronchiolitis:

a. History of a preceding viral upper respiratory infection,
b. The presence of wheezing and /or crackles on chest auscultation

Plus either oxygen saturation (SaO2) of < 94% in room air (Or) Significant respiratory distress as measured by a Respiratory Distress Assessment Instrument (RDAI)[88]

Exclusion criteria:

a. Mild or severe cases of bronchiolitis
b. Chronic cardiopulmonary disease
c. The use of nebulized hypertonic saline within the previous 12 hours

Study methods :

If inclusion / exclusion criteria were satisfied, then informed consent was obtained from parents and patients were randomized using custom random number generator to receive treatment either with: 3 ml of nebulised study solution containing 3% hypertonic saline along with standard therapy. i.e. HT+ ST (Study group) Or Only standard therapy. i.e. ST (Control group)Standard therapy was consisted of only nebulised salbutamol along with supportive therapy i.e. oxygen, i.v. fluids & paracetamol (in case of fever) Nebulised Salbutamol was given as per the clinical severity or at least 6th hourly. The study solution was administered every 8 th hourly daily until discharge. All inhaled therapies were delivered to an infant from a standard oxygen-derived hospital nebulizer through a tight fitting facemask or hood whichever was better tolerated by patient. Clinical response was determined by RDAI scores and SaO2 readings by the pulse-oximeter at study entry and then at least two times daily until discharge. At the daily assessment, parents were interviewed to determine if any adverse events were present.

Standard therapy :Nebulised salbutamol along with supportive therapy i.e. oxygen , i.v. fluids & paracetamol Nebulised Salbutamol to be given as per the clinical severity or at least 6th hourly. The study solution to be given every 8th hourly daily until discharge. All inhaled therapies to be delivered to an infant from a standard oxygen-derived hospital nebulizer through a tight fitting facemask or hood. Clinical response -- determined by RDAI scores and SaO2 readings by the pulse-oximeter at study entry and then at

least two times daily until discharge.

Table.1.Respiratory Distress Assessment Instrument (RDAI)

	0	1	2	3	4	Max
Wheezing						
Expiration	None	End	½	3/4	All	4
Inspiration	None	Part	All	--	--	2
Location	None	Segmental	Diffuse	--	--	2

	0	1	2	3	4	Max
Retractions						
Supraclavicular	None	Mild	Moderate	Marked	--	3
Intercostal	None	Mild	Moderate	Marked	--	3
Subcostal	None	Mild	Moderate	Marked	--	3
Total						17

Determination of length of stay (LOS) : LOS was defined as the time between study entry (within 12 hrs of admission to the hospital) and the time at which the patient reached the protocol defined discharge criterion. Protocol defined discharge criterion required both an RDAI score < 4 and Sao2 of atleast 95% in room air for 4 hrs.

Ethics

Ethical clearance was obtained from the Ethical committee meeting conducted at Meenakshi Medical College and Research Institute, Kanchipuram, Tamil Nadu. India Informed written consent was obtained from at least one parent of each patient before enrolment.

Statistical Analysis

Data were recorded on a predesigned proforma and managed on an excel spread sheet. Comparative analysis of baseline parameters of the two groups was done using chi square test to examine association between categorical variables and group, and independent sample t' tests and Levene's test for equality of variance to assess the association between numerical variables and group. All the statistical analysis was done by using SSPS. Outcome of the study was assessed by comparing mean length of stay in days between two groups.

RESULTS :

The average reduction in the length of stay observed in our study in the children who received additional 3% hypertonic saline nebulisation is 39 hours when compared with the children who received standard therapy alone.There was no side effects observed for hypertonic saline nebulisation during this study and al l the children tolerated the therapy well .There was no significant increase in the cost of treatment observed in our study.

Table.2.Comparision between groups in length of hospital stay.

t-TEST FOR EQUALITY OF MEANS

Group Statistics

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
LOSHRS	Equal variances assumed	.326	.569	-8.257	98	.000	-39.320	4.762	-48.770	-29.870
	Equal variances not assumed			-8.257	95.038	.000	-39.320	4.762	-48.774	-29.866

GROUP	STUDY	CONTROL
N	50	50
MEAN	71.80	111.12
SD	21.607	25.827
STD ERROR MEAN	3.056	3.653
T	- 8.257	
p VALUE	0.00	

The above table shows that, there is significant difference between study and control group (P < 0.05) in the total length of stay in hospital (in hours).

DISCUSSION

Earlier studies done, have demonstrated the efficacy of 3 % hypertonic saline in viral bronchiolitis. Kuzik et. al[8] showed a clinically relevant reduction (approximately 1 day) in the length of hospitalization in children with acute viral bronchiolitis treated with nebulized 3% hypertonic saline. Similarly, Mendelberg et. al[10] demonstrated that nebulized 3% saline could produce a reduction of 0.8 days in the mean length of hospital stay. Results of our study were comparable to data from these studies. We monitored for adverse effects to 3 % HS by interviewing parents at least two times daily. 3% hypertonic saline was well tolerated by infants in our study and there were no apparent adverse effects or worsening after treatment was noted.

Table .3. Data comparison between studies

DATA COMPARISON BETWEEN STUDIES

Study	Kuzik et. al 2007	Mendelberg et.al 2003	Our study
Number of cases in HS group (n)	47	30	50
Mean age of patients in months	4.7	2.9	6.96
Gender (male)	59 %	63%	64%
Mean Length of stay in hours (LOS)	62.4 ± 45.6	67.2 ± 31.2	71.8 ±21.38
Reduction in LOS in hours	21.6	19.2	39.32
Adverse effects	Nil	Nil	Nil

CONCLUSION :

The average reduction in the length of stay observed in our study in the children who received additional 3% hypertonic saline nebulisation is 39 hours when compared to children who received standard therapy alone.there was no side effects observed for hypertonic saline nebulisation during this study and all the children tolerated the therapy well.There was no significant increase in the cost of treatment observed in the study.

According to the World Health Organization bulletin worldwide, majority of all cases of bronchiolitis occur in developing countries. Acute viral bronchiolitis is associated with considerable acute morbidity with associated economic and social impacts on the community. Morbidity may be higher in less developed countries because of poor nutrition and lack of resources for supportive medical care. Treatment cost of 3 % hypertonic saline used for 3 days was on an average 10 rupees. Considering these facts use of 3% hypertonic saline can be safe, cost effective and has the potential of enormous economic benefit in developing countries like India with limited resources. Even half a day reduction in LOS as will substantially reduce hospital costs for bronchiolitis especially in public health care facilities.

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