Original Article

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A Randomized Control Comparative Trial of Nebulized Magnesium Sulfate and Hypertonic Saline In Acute Bronchiolitis

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Abstract

Introduction: Acute bronchiolitis is the common lower respiratory tract illness requiring hospitalization in children < 2years. Vaious treatment modalities proposed to manage the acute bronchiolitis. But no study has been recommended for the treatment other than supportive management. Hence this study aims to study the efficacy of nebulized magnesium sulfate in acute bronchiolitis. **Subjects and Methods:** A hospital-based randomized prospective comparative clinical observational study conducted in 110 children with mild to moderate bronchiolitis, randomly divided into two groups; Group 1 received 4 ml of hypertonic saline nebulization with 100% oxygen at an interval of 20mins for the first three doses and then 4^{th} hourly. Group 2, received 0.1-0.2 ml/kg/dose of 25% magnesium sulfate made to 4ml with 0.9% normal saline. Heart rate, oxygen saturation, respiratory rate, and Respiratory Distress Assessment Instrument (RDAI) scores were monitored throughout the study. **Results:** The mean age was 7.5 + 3.2 months, 6.5 + 3 months in group 1, and group 2 without significant difference(p=0.6). 30(54.54%) cases, and 25(45.45) cases belongs to mild and moderate category of bronchiolitis in group1, and 28(52.7%) cases and 27 (47.27%) cases belongs to the mild and moderate category of bronchiolitis in group 2 (p>0.05). 8(14.54%) cases had leukocytosis and 2 (3.63%) cases had leucopenia in group 1, whereas, Leukocytosis and leucopenia were present in 12(21.81%) and 2(3.63%) cases respectively in group 2. The most common chest X-ray findings in acute bronchiolitis were hyperinflation followed by segmental atelectasis. The mean hospital stay in nebulized with hypertonic saline and magnesium sulfate was 3.5 + 1.0 days and 3.0 + 1.1 days, respectively. The length of hospital stay between hypertonic saline and magnesium sulfate group was slightly longer in moderate bronchiolitis. **Conclusion:** The mean hospital stay in nebulized with hypertonic saline is higher than and magnesium sulfate. RDAI score does not vary significantly between two groups after nebulization. Further trials with large sample size, the inclusion of children with severe bronchiolitis, and assessment of long-term outcomes are recommended.

Keywords: Bronchiolitis, hypertonic saline, magnesium sulfate, RDAI score.

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Introduction

Bronchiolitis is characterized by acute inflammation, necrosis, and edema of the epithelium covering the smaller airways with enhanced mucus production causing smaller airway obstruction with resultant atelectasis.[1] The American Academy of Paediatrics and European Respiratory Society defines bronchiolitis as a "Constellation of clinical signs and symptoms including a viral upper respiratory prodrome followed by increased respiratory effort and wheeze in children less than two years".[2]

Bronchiolitis is predominantly a viral disease. In 2015, the Global incidence of Respiratory Syncytial Virus (RSV) infection was 33.1 million, with 3.2 million requiring inpatient hospitalization and 59600 deaths occurring in children of age less than five years.[3] Other Viruses causing bronchiolitis are Influenza, Parainfluenza, Rhinovirus, Adenovirus, Human metapneumovirus, Coronavirus, and Human bocavirus.[4] Bronchiolitis most commonly presents with prodromal symptoms like mild coryza, low-grade fever, and nasal congestion lasting for 1-3 days. The symptoms then slowly progresses to severe cough, high-grade fever, tachypnea, tachycardia, increased work of breathing, expiratory wheeze, and crepitations on auscultation. Fever presents in about 50 percent of the cases.[5]

Bronchiolitis is an important cause of morbidity and mortality in young infants. In severe cases, prostration and respiratory failure occur, which leads to repeated episodes of apnea,

seizures and death. Investigations such as complete blood count, acute phase reactants such as C- Reactive Protein (CRP) and Erythrocyte sedimentation rate (ESR), blood culture, and chest radiograph are done only to support the diagnosis and exclude the other diagnosis (such as pneumonia).

Saturation is essential in monitoring the child and also deciding on the discharge. AAP recommends the use of intermittent pulse oximetry monitoring in acute bronchiolitis.[6]

Blood gas analysis is routinely not recommended in a child with bronchiolitis. However, higher carbon dioxide levels in blood gas analysis are associated with prolonged hospital stay and risk of intensive care unit admission.[7]

The chest radiograph findings of bronchiolitis include Bilateral hyperinflation, Flattening of the diaphragm, Increased antero-posterior diameter of the chest, Increased peribronchial markings, and Atelectasis.

Acute bronchiolitis is a self-limiting illness in most cases. Management of bronchiolitis in children is mostly supportive.

Indications for Hospitalization in Acute Bronchiolitisare Oxygen saturation of less than 90 % in room air, Respiratory distress, respiratory rate of more than 80/ min for a longer time, Altered sensorium, Child not able to take > 50 % of the feeds orally, Oliguria, Worsening of the general condition of the child.

Infants and children diagnosed with bronchiolitis may be administered nebulized hypertonic saline. Mechanisms of action of nebulized hypertonic saline are reducing the airway edema through its hygroscopic action, clearing the mucus secretion, thereby enhancing the airway clearance and reducing the airway edema. Hence reducing the airflow obstruction and thereby decreasing the duration of hospital stay. Magnesium sulfate has a bronchodilatory action through inhibition of calcium-mediated smooth muscle contraction mainly by inhibiting the calcium influx into the cell, Histamine release inhibition from mast cell by stabilizing the mast cells, Inhibition of nicotinic acetylcholine release, Nitric oxide, and prostacyclin release, thereby causing vasodilatory action on the pulmonary vasculature. Magnesium sulfate has been proposed as treatment option in asthma and has been included in the treatment adjuvant in Global Initiative for Asthma (GINA) guidelines.[7–10]Considering the pathophysiological similarities between asthma and bronchiolitis, the magnesium sulfate role is widely studied in acute bronchiolitis.

Hence, current study aims to identify the efficacy of nebulized magnesium sulfate and hypertonic saline in acute bronchiolitis by measuring hospital stay duration. A secondary outcome is to improve the Respiratory Distress Assessment Index (RDAI) score between children with acute bronchiolitis treated with nebulized magnesium sulfate and hypertonic saline.

Subjects and Methods

Sample size: a hospital-based randomized prospective comparative clinical observational study conducted at the department of pediatrics, Narayana Medical College and hospital, Nellore.

Total of 110 patients devided into two groups of age/sex-matched**.** Group 1 received 4ml of hypertonic saline nebulization with 100% oxygen at an interval of 20mins for the first three doses and then 4^{th} hourly. Group 2, received 0.1-0.2 ml/kg/dose of 25% magnesium sulfate made to 4ml with 0.9% normal saline.

Inclusion criteria are all children of age group less than 12 months with acute onset of respiratory symptoms associated with fever, cough, tachypnea, or a chest radiograph findings consistent with bronchiolitis (such as hyperinflation) and first episode of wheezing were included.

Exclusion criteria are History of chronic pulmonary, cardiac, neurologic, and immunological disorders, History of prematurity (<34 weeks), Radiographic evidence of pneumonia, Severe bronchiolitis.

Complete blood count, C reactive protein, and Chest X-ray were done for all the children.

Heart rate, respiratory rate, oxygen saturation, and Respiratory Distress Assessment Instrument (RDAI) score was recorded at 0 min, 20 mins, 40 mins, 1 hour, then every 12 hours till discharge. However, based on the child's clinical condition, the frequency of monitoring was increased if necessary. The child was monitored for any adverse events and deterioration of the clinical condition. The child was excluded from the study if there were any adverse effect and worsening of the general condition. And was treated as per unit protocol. Supportive treatment was provided if needed. The child was discharged if the child was stable clinically, able to take feeds orally, and had maintained oxygen saturation over 92% in room air for more than 4 hours, including a period of sleep.[11]

Statistics: The results were then tabulated in Microsoft excel separately for both groups , and then analyzed. Results on continuous measurements were presented on Mean ± SD (Min-Max), and results on categorical measurements were presented in number(%). Chi-square has been applied to find the significance of study parameters of categorical data between two groups.

Results

Demographics: Among group-1, of 55 children, there were 32 (58.18%) males, and 23 (41.81%) females. Among group-2, of 55 children, there were 31 (56.3 %) males and 24 (43.63%) females. In group 1 children, 29 (52.72%) children belong to age group <6 months, and 26 (47.27%) children between 6

months to 1 year. In group 2 children, 28 (50.9%) children belong to the age group of < 6 months, and 27(49.1%) children between 6 months to 1 year. The mean age in group 1 was 7.5 + 3.2 months, and in group2 was 6.5 + 3 months (p=0.6).

Severity: Among the Group 1 children, 30 (54.54%) cases and 25(45.45) cases constitute mild and moderate bronchiolitis, respectively. Among the Group 2 children, 28 (52.7%) cases belongs to the mild category, and 27 (47.27%) cases belongs to the moderate category of bronchiolitis. (p > 0.05).

Clinical characteristics: Among group 1, the most common presenting complaint was cough (98.18%) followed by breathlessness (90.90%), fever (43.63%) and coryza (36.36%). In group 2, most commonly with cough (100%) followed by breathlessness (98.18%), fever (50.90%) and coryza (32.72%).

Duration of Illness: The duration of illness among group 1 was 1- 3 days, 3- 5 days and more than 5 days in 10 (18.18%), 40(72.72%) and 5(9.09%) children respectively. In children of group 2, the duration of illness reported was 1- 3 days, 3- 5 days and more than 5 days in 14 (25.5 %), 34 (61.81%) and 7(12.72%) children respectively.

Complete Blood Count: Among group 1 children, 45 (81.81%) cases had normal Complete blood count (CBC), 8(14.54%) cases had leukocytosis and 2 (3.63%) cases had leucopenia. In group 2, CBC was normal in 41 (74.54%) cases, Leukocytosis and leucopenia was present in 12(21.81%) and 2(3.63%) cases respectively.

C-Reactive Protein: Among group 1, CRP was positive in 9 (16.36%) children and negative in 46 (83.63%) children. In group 2, CRP was positive in 11 (20%) children while negative in 44 (80%) children.

Chest X-ray: Among the group 1, the chest x-ray findings of Increased broncho vascular markings with or without hyperinflation, segmental atelectasis and consolidation and other pneumonia changes were present in 47 (85.45%), 6(10.90%), and 2(3.63%) children, respectively. In group 2 children, the X-ray findings of Increased broncho vascular markings with or without hyperinflation, segmental atelectasis and consolidation and other pneumonia changes were 48 (87.27%), 6 (10.90%), and 1 (1.81%) children, respectively.

RDAI score at admission: Among group 1, the mean RDAI score on admission was 7.6 + 1.6. Among group 2, the mean RDAI score was 8.1 + 1.7. The RDAI on admission was similar between the groups (p= 0.6).

Outcomes: The duration of hospital stay among the children of age group < 6 months, 6 months - 1 year and > 1 year was 3.5 + 1.5 days , 3.5 + 0.9 days and 2.0 + 1.5 days respectively. The length of the hospital stay was less in children of age group >1 years. The results were statistically significant with p-value of <0.05. The duration of stay was higher in male children in both the groups, but the results were not statistically significant(p>0.05). The RDAI score was significantly low at 40 mins and 1 hour after hospitalization in children of age group 6 months-1 year. (p<0.05).

The length of hospital stay in children treated with hypertonic saline and magnesium sulfate was slightly longer in moderate bronchiolitis. But the results were not statistically significant. (p>0.05). There was no significant difference in RDAI score between the mild and moderate bronchiolitis in group of children treated with hypertonic saline and magnesium sulfate nebulization. (p>0.05).

RDAI Score comparison: Among group 1, the mean RDAI score at admission, 20 mins, 40 mins, 1 hour, day 2, day 3, day 4 and day 5 of hospital stay were 7.9 + 1.7, 6.0 + 1.8, 4.6 + 1.8, 3.1 + 2.0, 3.7 + 1.8, 2.1 + 1.5, 0.8 + 1.1 and 0.1 + 0.6 respectively. Among group 2, the mean RDAI score at admission, 20 mins, 40 mins, 1 hour, day-2, day-3, day-4, and day-5 of hospital stay were 8.0 + 1.8, 6.1 + 1.9, 4.7 + 2.0, 3.2 + 2.2, 3.8 + 1.9, 2.1 + 1.5, 0.8 + 1.2, and 0.1 + 0.6 respectively. (p > 0.05).

Length of Hospital Stay: The mean hospital stay among group 1 and group 2 was 3.5 + 1.0 days, and 3.0 + 1.1 respectively (p=0.9).

Discussion

In our study, which included 110 children, 52.72% of the children belonged to the age group of < 6 months, 47.27% belongs to the age group of 6 months to 1 year.[11] The results were similar to the study conducted by Parrott et al,[12] who showed that the incidence of bronchiolitis was high among children of age less than 1 year.

In our study which included 110 children, bronchiolitis was more common in male children than female children. The results were similar to the previous studies conducted by Nagayama et al and Boezen HM et al.[13,14]

In our study, the most common presenting complaint was (98.18%) followed by breathlessness (90.90%), and fever (43.63%). The findings of our study were not similar to the results of the study conducted by shahib et al.[15]

Our study results showed that the most common chest X-ray findings in acute bronchiolitis were hyperinflation followed by segmental atelectasis.

The results were comparable to the studies conducted by Robert et al and Javed Akthar et al.[16,17] They also concluded that routine imaging of the children with bronchiolitis will help exclude the other diagnosis and initiate the antibiotics in case of co-infection.

In our study, CRP was positive in 9 (16.36%) children and negative in 46 (83.63%) children in group1, and CRP was positive in 11 (20%) children while negative in 44 (80%)

Table 1: Baseline clinical characteristics, laboratory and chestxray findings of childrens of both groups

	Hypertonic saline n (%)	Magnesium sulfate n (%)
CBC		
Normal	45 (81.81%)	41 (74.54%)
Leukocytosis	8 (14.54%)	12 (21.81%)
Leucopenia	2 (3.63%)	2 (3.63%)
CRP		
Positive	9 (16.36%)	11 (20%)
Negative	46 (83.63%)	44 (80%)
Chest x ray findings		
Increased bronchovascular markings with or without hyperinflation	47 (85.45%)	48 (87.27%),
Segmental atelectasis	6 (10.90%)	6 (10.90%)
Consolidation and other pneumonia changes	2 (3.63%)	1 (1.81%)
RDAI Score AT admission	7.6 + 1.6.	8.1 + 1.7

Table 2: Length of hospital stay between the children treated with hypertonic saline and magnesium sulfate

Hypertonic saline		Hospital stay		Total	P-value
		< 3 days	3 – 5 days		
Sex	Male	7	25	32	0.6
	Female	4	19	23	
Magnesium sulfate					
Sex	Male	7	24	31	0.5
	Female	4	20	24	
hypertonic saline					
Severity of	Mild	7	23	30	0.09
	Moderate	3	22	25	
magnesium sulfate					
Severity of	Mild	7	21	28	0.1
	Moderate	4	23	27	

Table 3: Comparison of RDAI Score

	Hypertonic saline		$MgSo_4$		P value
RDI Score	**Mean**	**SD**	**Mean**	**SD**	
At Admission	7.9	1.7	8.0	1.8	0.6
20 min	6.0	1.8	6.1	1.9	0.6
40 min	4.6	1.8	4.7	2.0	0.6
1 Hour	3.1	2.0	3.2	2.2	0.6
Day 2	3.7	1.8	3.8	1.9	0.9
Day 3	2.1	1.5	2.1	1.5	1.0
Day 4	0.8	1.1	0.8	1.2	0.7
Day 5	0.1	0.6	0.1	0.6	0.9

Table 4: Comparison of Length of Hospital Stay

	Hypertonic saline		MgSo4		P value
	Mean	SD	Mean	SD	0.9
Hospital stay duration	3.2	1.0 1.10.	3.2 9	1.1	

children in group 2. The results were similar to the study conducted by Kaur et al., Costa et al., and Mohamad Fares et al. They concluded that the C Reactive Protein was increased in bacterial co-infection cases. Hence the values will help in deciding the initiation of antibiotics and also predicting the disease severity.[18–20]

In our present study, the WBC count shows 8(14.54%) cases had leukocytosis, and 2 (3.63%) cases had leucopenia in group 1, and 12(21.81%) and 2(3.63%) cases had Leukocytosis and leucopenia in group 2 of the children with acute bronchiolitis. The results were similar to the study conducted by Saijoet al.[21] which showed that the mean WBC count in acute bronchiolitis was 9562 +2720/mm^3. The study also concluded that the WBC count was elevated in bronchiolitis cases with secondary bacterial infection and in cases of bacterial pneumonia.

The length of hospital stay in children treated with hypertonic saline and magnesium sulfate was slightly longer in moderate bronchiolitis. The mean hospital stay among group 1 and group 2 was 3.5 + 1.0 days, and 3.0 + 1.1 respectively (p=0.9). There was no adverse effects in the group treated with hypertonic saline. Our study results were not comparable with Bahadily et al.[22] who conducted a prospective study on 100 infants by comparing the 3 % hypertonic saline and 0.9 % saline in acute bronchiolitis. The mean duration of hospital stay in the group of children treated with 3 % hypertonic saline was 4.7 (±1.9) days, while the length of stay was 4.3 (± 1.6) days in children nebulized with 0.9% normal saline.

In our present study which included 110 children, there was no significant difference in length of hospital stay and reduction in the RDAI score between children treated with nebulized magnesium sulfate and hypertonic saline. To date, very few studies have compared the efficacy of magnesium sulfate nebulization with hypertonic saline.

Modaresi et al.[23] in his study on comparing the efficacy of magnesium sulfate nebulization with epinephrine found out that the most common age group of acute bronchiolitis was less than 6 months and there was increased susceptibility of bronchiolitis in male gender. The results were similar to our study. They also found out that nebulization with magnesium sulfate demonstrated no significant difference in the length of hospital stay and RDAI score on the first day of hospitalization compared with hypertonic saline nebulization. However, the study results showed that there was a significant improvement in RDAI score on day 2 and day 3 with magnesium sulfate nebulization.

The difference in the results could be due to the exclusion of severe bronchiolitis cases and the difference in the dose of a drug used in both studies.

A study conducted by Kose et al.[24] by comparing the efficacy of magnesium sulfate with salbutamol nebulization in moderate bronchiolitis cases. The baseline characteristics were similar to our study. The improvement in clinical severity score was compared between the groups. This study results demonstrates no significant difference in duration of hospital stay between the groups treated with salbutamol/magnesium sulfate and salbutamol and magnesium sulfate. However, the clinical severity score at 4 hours was low in children treated with magnesium sulfate plus salbutamol group when compared to the salbutamol and magnesium sulfate groups.

Conclusion

Bronchiolitis is the most common lower respiratory tract infection requiring hospitalization in children less than two years. Bronchiolitis carries an increased susceptibility in the male gender. The mean duration of hospital stay in acute bronchiolitis was 3 – 5 days. Investigations such as complete blood count, CRP, and chest X-ray are only supportive. It only helps in ruling out the co-infection and early initiation of antibiotics. The outcome in terms of hospital stay duration and RDAI score does not vary significantly between the children treated with nebulized magnesium sulfate and hypertonic saline. Further trials with a large sample size, including children with severe bronchiolitis, and assessing long-term outcomes are recommended.

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