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A Randomized controlled trial on the Efficacy of Nebulized Magnesium Sulphate versus Salbutamol with Normal Saline in the Treatment of Acute Bronchiolitis in Rajshahi Medical College Hospital

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ABSTRACT: ***Background:*** Acute bronchiolitis is one of the important causes of hospitalization among infants in Bangladesh. Although this condition is common, there is no widely accepted evidence-based treatment approach. ***Methods:*** The hospital based randomized controlled trial was carried out at the department of Pediatrics, Rajshahi Medical College Hospital, Rajshahi for 12 months period. Total 100 children (2-24 months) presenting with first episode of acute bronchiolitis were enrolled in this study and randomly divided into two groups: Group-A (n=50) was nebulized with 2 ml Magnesium sulphate diluted with 2 ml normal saline and Group-B (n=50) was nebulized with 2 ml normal saline along with 0.15 mg/kg/dose salbutamol solution. Data collection was carried out by the investigator herself by using separated case record form. Data analysis was done by SPSS 24. ***Results:*** The mean age was 9.90±4.49 and 9.94±4.56 months for the Group-A and Group-B with male predominance in both groups (56.0% of Group-A and 76.0% of Group-B). Both groups were similar in terms of age, sex, baseline clinical manifestations ($p>0.05$). The mean heart rate (HR) was significantly lower in Group-A than that in Group-B during follow up ($p<0.05$). The mean respiratory rate (RR) and clinical severity score (CSS) were significantly lower in Group-A compared to Group-B($p<0.05$). The mean SPO2 was notably higher in Group-A than in Group-B ($p<0.05$). The length of hospital stay was significantly higher for Group B in compared to group A ($p<0.05$). There was no significant difference between both groups in terms of secondary outcomes (hospital discharge, ICU admission, noninvasive ventilation and hospital stay). ***Conclusion:*** Significant improvement in clinical parameters was seen among the patients who received nebulization with MgSO4. Further multicenter studies may be carried out to recommend MgSO4 as a novel therapy for Bronchiolitis.

Keywords: Nebulized Salbutamol, Nebulized Mgso4, Acute Bronchiolitis.

Article at a glance:
Study Purpose*: To assess roxadustat's efficacy in modulating serum lipids and correcting anemia in cirrhotic patients, offering a dual-benefit therapeutic approach.*
Key findings: *The study found significant reductions in total cholesterol, LDL-C, and triglycerides with increased HDL-C, alongside marked hemoglobin improvement.*
Newer findings: *In addition to its established role in anemia management, roxadustat also beneficially modulates lipid metabolism, expanding its potential use in cirrhosis treatment.*
Abbreviations: *HIF: Hypoxia-Inducible Factor, LDL-C: Low-Density Lipoprotein Cholesterol, HDL-C: High-Density Lipoprotein Cholesterol, ALT: Alanine Transaminase.*

INTRODUCTION

Bronchiolitis is an infection of the bronchiolar epithelium, marked by epithelial cell necrosis and sloughing, submucosal oedema, increased secretion of mucus and peri-bronchiolar mononuclear infiltration and resulting in hyperinflation, atelectasis and wheezing.[1,2] A bulletin published by World Health Organization bulletin estimated that 150 million new cases of Bronchiolitis are diagnosed each year, with 11-20 million (7-13%) requiring hospital

treatment.[3] Bronchiolitis in children is mostly caused by respiratory syncytial virus (RSV). In India, rates of RSV identification in several hospital and community-based investigations including predominantly children range from 5% to 54 % and from 8% to 15%, respectively.[4] In recent research of Bangladesh, 3484 of the 5157 children under the age of five who were assessed had respiratory difficulties. Bronchiolitis is the most prevalent cause of respiratory distress (21%).[5] Acute bronchiolitis is treated supportively with oxygenation and maintaining adequate hydration and nutrition, short acting bronchodilators like salbutamol, adrenaline, anti-cholinergic drugs, ipratropium bromide and saline nebulization and outcome varies with different interventions.[6] Evidence based treatment approach is still lacking. All the interventions that are usually tried, including inhaled epinephrine, bronchodilators, steroids, anticholinergics, antibiotics and chest physiotherapy, none is specific. The use of β2 agonist occasionally resulted in a short-term improvement in patients with bronchiolitis while others failed to show a significant effect. Multiple studies have been published on management of bronchiolitis but with unproven efficacy and their role is controversial.[7]

Magnesium act as a bronchodialator by acting as a cofactor for enzymatic reactions and by playing role in muscular excitability by affecting calcium transport across cell membranes. Magnesium sulphate inhibits smooth muscle contraction & decrease inflammation. Studies revealed that it causes improvement in the asthmatic symptoms in children who failed to show improvement with β agonist treatment. As bronchiolitis and bronchial asthma has some forms of similarity in their pathophysiology, it is suggested that magnesium sulphate may be evaluated as a novel therapy for bronchiolitis.[8, 9] Some studies showed that magnesium sulphate was superior to 0.9% normal saline solution and other available option for nebulization with salbutamol and nebulized magnesium sulphate has been demonstrated to reduce hospital stay.[10] But in Bangladesh there is not much study about the magnesium sulphate nebulization is more effective in acute bronchiolitis. So, further studies are required to determine a cheap and effective therapy for children with acute bronchiolitis. This study was aimed to assess the efficacy of nebulized magnesium sulphate versus normal saline along with salbutamol as a bronchodilator in infants hospitalized with acute bronchiolitis.

MATERIALS AND METHODS

Study Design

A randomized controlled trial was conducted in department of paediatrics of Rajshahi Medical College Hospital over a period of 1st November 2021 to 30th November 2022. Total 100 children with first episode of acute bronchiolitis attending in Rajshahi Medical College Hospital were enrolled in the study. Clinical severity was assessed by Modified Tal Score.[11] Random sampling by Block method with 1:1 ratio with single blinding was used as sampling method. Study population was divided into two groups as group-A (n=50) and Group-B (n=50).

Inclusion Criteria

Childre aged 2 months to 24 months presented with first episode of acute bronchiolitis were included in this study.

Exclusion Criteria

Children presented with respiratory distress associated with other co morbidities like cardiac disease and covid 19 were excluded from this study.

Data Collection

Group A was nebulized with 2ml magnesium sulphate diluted with 2 ml normal saline. Nebulization was given over 10-15 minutes. Group-B was nebulized with 2ml normal saline along with 0.15mg/kg/dose salbutamol solution. Isotonic magnesium nebulization solution was prepared by adding 15.8 ml of 50% G-MAG Sulph solution to an amber colour sterile glass bottle. Then distilled water was added to reach the total volume of 100 ml.[8]

Each group received nebulization at 8 hours interval every day of hospital stay until the patients were ready for discharge. Each group received identical supportive measures like suction, fluid, feeding, oxygen therapy, paracetamol and counseling as required. All inhaled treatments were delivered to infant from standard air compressed nebulizer. Ten minutes after administration of each nebulization, clinical severity score and oxygen saturation were noted to assess the response to therapy and was recorded to follow up sheet. Detail history of patient, clinical examination findings, investigations were recorded in a semi structured case record form. The

patients were followed up daily until discharge from hospital.

Data Analysis

After collection of data, they were compiled, tabulated and analyzed by Software Statistical package for the social sciences version 24. Mean and standard deviation were used to express continuous data and frequency and percentage were used to express categorical data. Chi square test was used to determine association between categorical data. Independent t test was used to determine difference between continuous data. 5% acceptable error ($p<0.05$) at 95 confidence level was considered as significant.

Ethical Consideration

Ethical clearence was taken from Ehtical Review committee of Rajshahi Medical College prior to the study. After written informed consent of the parents, children were included in the study. Patients' confidentiality was strictly maintained and assured that refusal of the study would not hamper their care.

RESULT

This hospital based randomized controlled trial was conducted in the Department of Pediatrics, Rajshahi Medical College Hospital, Rajshahi. After thorough history taking, clinical examination and appropriate investigations based on inclusion and exclusion criteria, total 100 patients were enrolled in this study. Irrespective of their age, sex, race and ethnic group they were divided into two groups. Group A- Who received 2 ml magnessium sulphate nebulization diluted with 2 ml normal saline (Intervention), Group B- Who received 2 ml nebulization with normal saline along with 0.15 mg/kg/dose salbutamol solution (Control). This study was to assess the efficacy of nebulized magnesium sulphate compared to salbutamol along with normal saline, in the treatment of acute bronchiolitis in Rajshahi Medical College hospital- a randomized controlled trial. The results of the study are shown in table and figure. Details of the study result are described below.

Table 1: Age and gender distribution of the studied populations (n=100)

Variables	Group A n=50	Group B n=50	p-value
Age (in months) Mean±SD	9.90±4.49	9.94±4.56	0.965
Gender			0.057
Male	28 (56.0)	38 (76.0)	
Female	22 (44.0)	12 (24.0)	

Group A- Who received 2 ml magnesium sulphate nebulization diluted with 2 ml normal saline (Intervention), Group B- Who received 2 ml nebulization with normal saline along with 0.15 mg/kg/dose salbutamol solution (Control). The mean age was 9.90±4.49 and 9.94±4.56 in months for the Group A and Group B studied population respectively. The majority of participants in both groups were male. There was no significant difference in age or gender between two groups when compared.

Table 2: Clinical findings of the patients between groups (n=100)

Clinical findings	Group An=50	Group Bn=50	p-value**
RR (breaths/minute)	51.40±3.67	51.16±4.58	0.773
HR (Beats/minute)	148.92±9.06	150.28±8.92	0.451
SPO_2 (%)	91.52±3.98	91.24±4.38	0.738
Temperature (°C)	37.40±1.07	37.46±1.03	0.773

Table2 showed no significant difference regarding RR, HR, SPO_2 and temperature at baseline between two groups ($p>0.05$).

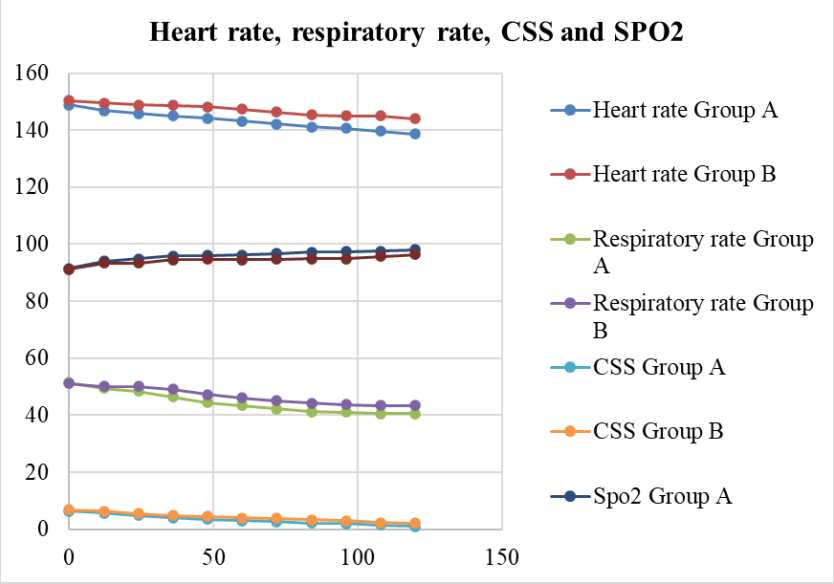

Figure 1: Comparison of Heart rate, Respiratory rate, CSS and SPO2 (%) between groups with time (n=100)

Figure 1showed that the mean of heart rate, respiratory rate and CSS was decreasing steadily from base line to 120 hours follow up for both of the groups. On the other hand, the mean SPO2 was increasing steadily from baseline to 120 hours follow up for both of the groups.

Table 3: Clinical outcome between two groups at the end of 120 hours treatment (n=100)

Variables	Group An=50	Group Bn=50	P-value**
Change in CSS score	4.7601.77	3.6001.54	0.001
Change in HR	10.3600.94	6.3601.17	<0.0001
Change in RR	10.8800.92	7.7000.76	<0.0001
Change in SPO_2	5.0400.88	3.4001.28	<0.0001

CSS: Clinical outcome between two groups at the end of 120 hours treatment (n=100) Table 3 showed change in CSS score, change in HR, change in RR, change in SPO2 were significantly more for the Group A patients compared to Group B (p-value 0.0001).

Table 4: Comparison of secondary outcomes between groups (n=100)

Variables	Group A n=50	Group B n=50	p-value*
Discharged	35 (70.0)	25 (50.0)	0.066
ICU admission	1 (2.0)	7 (14.0)	0.027
NIV	3 (6.0)	8 (16.0)	0.200

ICU: Intensive care unit. NIV: Noninvasive ventilation.

Table 4 showed that at the 120 hours follow up, requirement for ICU admission were significantly higher in Group B than in Group A. Fulfillment of discharge criteria were significantly higher in Group A than Group B. NIV required for 6.0% of Group A and 16.0% of Group B patients respectively. No significant difference was seen in terms of NIV.

DISCUSSION

Bronchiolitis is a frequent cause of lower respiratory tract infection and accounts for significant morbidity in children under 2 years of age.[12] But there is no specific evidence-based treatment approach and all are supportive. We conducted this study to compare the efficacy of nebulized magnesium

sulphate versus normal saline along with salbutamol for treatment of bronchiolitis. Epidemiologic data show that RSV accounts for about 65% of hospitalization due to Bronchiolitis. Total 100 patients were enrolled in this study fulfilling the inclusion criteria and they were divided into two groups. Group A- Who received 2 ml Magnesium sulphate nebulization diluted with 2 ml normal saline, Group B- Who received 2 ml nebulization with normal saline along with 0.15 mg/kg/dose salbutamol solution. In this present study, the mean age was 9.9004.49 and 9.9404.56 in months for the patients who received nebulization with MgSO4 and with normal saline along with salbutamol solution respectively. The majority were male in this study. There wasn't any significant difference regarding age and gender between groups when compared ($p>0.05$). A similar study was done among the infants with Bronchiolitis and it found the mean age for the patients was 9.8205.06 and 9.5104.28 (Sd) in months.[13]

In the current study, the mean duration of illness was 2.44±1.07 (SD) and 2.60±1.60 (SD) days for the patients who received nebulization with MgSO4 and normal saline along with salbutamol solution respectively. For both Groups initial clinical presentation was cyanosis, cough, fever, breathing difficulty, feeding difficulty, chest indrawing, nasal flaring, ronchi. In present study, there was no significant difference was seen regarding history of the present illness between groups when compared ($p>0.05$). Another study by Bush et al., showed the clinical features of bronchiolitis as coryzal symptoms, fever, cyanosis which is similar to the current study.[13] At baseline, no significant difference was identified between group A and group B for mean of RR, HR, SPO2, temperature, CSS score ($p>0.05$). Similar study was done by Mehmet Kose et al., and they also mentioned that there was no difference in CSS score and HR when compared between salbutamol and magnesium sulphate.[14] At baseline to 24 hours follow up, Heart rate and Respiratory rate wasn't significantly different between two groups. But from 36 hours onwards follow up the mean HR was better improved in the patients nebulized with MgSO4 than the patients who were nebulized with normal saline along with salbutamol. In respiratory rate (breaths/min) from 24 hours follow up significantly declined in group A ($p<0.05$) in compared to group B. In the study by Ghaiaty et al. concluded that, nebulization with magnesium sulphate gave better improvement in terms of HR and RR in comparison to salbutamol.[15] This was similar with the present study.

In terms of SPO2, at baseline the mean SPO2 wasn't significantly different between groups in the present study. But, at the 12, 24,36, 48, 60, 72, 84, 96, 108 and 120 hours follow up the mean SPO2 was significantly different between groups in this study as the p-value was <0.05. In the study by Ghaiaty et al. they found that patients who received MgSO4 nebulization had the significant improvement in O2 saturation and showed more effectiveness in acute Bronchiolitis management[15]. In the current study, at the 120 hours follow up, changes showed in terms of CSS score, HR, RR, SPO2 were significantly more for the patients nebulized with MgSO4 compared to the patients nebulized with normal saline along with salbutamol. Another similar randomized-controlled trial in India by Janakwade *et al.*, showed that, children with mild to severe bronchiolitis, magnesium sulphate nebulization improves respiratory distress and oxygen saturation.[16] Besides, at the 120 hours follow up, patients from group B required more ICU admission in compared to group A and it was significant ($p<0.05$). Though Debbarma et al. found no significant difference in ICU admission for magnesium sulphate and control group.[17]In this present study the length of hospital stay was significantly higher for Group B in compared to group A ($p<0.05$). But Chandelia *et al.* in their systemic review admit that magnesium sulphate had no effect on duration of hospital stay compared with salbutamol.[18-33] The duration of Oxygen requirements wasn't significantly different between two groups in the current study.

CONCLUSION

This study concludes that magnesium sulphate solution nebulization is more effective in acute bronchiolitis than normal saline along with salbutamol, as changes in clinical severity score, heart rate, respiratory rate and SPO2 were significantly more in magnesium sulphate solution. While ICU admission and hospital stay was significantly more in salbutamol with normal saline when compared between magnesium sulphate and salbutamol. However, no significant difference was seen in terms of hospital discharge, and non-intervention ventilation between groups.

Limitations of the Study

This study was carried out in a single center with small sample size. Multicenter randomized control trial may be planned in future for routine recommendation of nebulization with magnesium sulfate in Bronchiolitis.

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