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Original Research Article

Safety and Short-Term Oxygenation Response to Nebulized Magnesium Sulphate in Children with Moderate Bronchiolitis

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Conflict of interest: Nil

Abstract

Background: Acute bronchiolitis is a common lower respiratory tract infection in infants and young children for which management remains predominantly supportive. Nebulized magnesium sulphate has potential bronchodilator effects, but its role in bronchiolitis remains uncertain.

Objective: To evaluate the safety and short-term oxygenation response to nebulized magnesium sulphate in children with moderate bronchiolitis.

Materials and Methods: This hospital-based prospective single-arm interventional study included 60 children aged 1–24 months with moderate bronchiolitis (Clinical Severity Score [CSS] 4–8). Each child received two doses of nebulized magnesium sulphate (150 mg) 30 minutes apart. Oxygen saturation (SpO_2) was assessed at baseline and 4 hours, while CSS and other clinical parameters were recorded at baseline, 1 hour, and 4 hours. Adverse effects were monitored throughout the observation period.

Results: The mean age was 7.5 ± 6.47 months, and 68.3% were male. Baseline hypoxia was present in 36.6% of children. Mean SpO_2 increased significantly from 90.15 ± 6.99% at baseline to 93.30 ± 4.48% at 4 hours ($p<0.001$); among hypoxic children, it increased from 82.41 ± 5.30% to 89.64 ± 5.25% ($p<0.001$). Mean CSS decreased from 6.00 ± 1.008 at baseline to 2.40 ± 1.564 at 4 hours ($p<0.001$), with significant improvements in respiratory rate, wheeze, retractions, and general condition. Overall, 88.3% of children showed clinical improvement.

Conclusion: Nebulized magnesium sulphate was associated with significant short-term improvement in oxygen saturation and clinical severity and was generally well tolerated in children with moderate bronchiolitis. However, controlled trials with larger samples and longer follow-up are required to establish its clinical efficacy.

Keywords: Acute Bronchiolitis; Magnesium Sulphate; Nebulization; Oxygen Saturation; Clinical Severity Score; Children.

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Introduction

Acute bronchiolitis is one of the most common lower respiratory tract infections in infants and young children and represents an important cause of emergency visits and hospitalization during the first two years of life. It is characterized by acute inflammation, edema, increased mucus production, and obstruction of the small airways, resulting clinically in tachypnea, wheezing, chest retractions, feeding difficulty, and, in more severe cases, hypoxemia. Despite its substantial clinical burden, treatment remains predominantly supportive, with maintenance of adequate hydration and oxygen supplementation when indicated. Pharmacological therapies have generally shown inconsistent benefits, creating continued interest in safe adjunctive treatments that may provide rapid clinical improvement [1]. Magnesium sulphate has bronchodilator properties attributed primarily to calcium antagonism and relaxation of bronchial smooth muscle. It may also influence airway responsiveness through effects on cellular calcium handling and other enzymatic pathways involved in bronchomotor tone. These properties have led to its evaluation in acute obstructive airway diseases,

particularly childhood asthma. Studies of nebulized magnesium sulphate in pediatric acute asthma have demonstrated acceptable tolerability, although the magnitude of clinical benefit has varied and has generally been modest [2, 3].

The potential role of magnesium sulphate in bronchiolitis, however, remains uncertain. An intravenous magnesium sulphate trial did not demonstrate meaningful benefit in infants with acute bronchiolitis, while studies using the nebulized route have produced variable results. An Indian randomized controlled trial by Debbarma et al. evaluated nebulized magnesium sulphate in children with moderate-to-severe bronchiolitis and found it to be well tolerated, but it was not superior to standard treatment in improving bronchiolitis severity scores or reducing hospital stay. Furthermore, the updated Cochrane review concluded that current evidence remains insufficient to establish the effectiveness of magnesium sulphate in children with acute bronchiolitis, emphasizing the need for further studies assessing clinically relevant outcomes and adverse effects [4,5].

Apart from overall efficacy, short-term physiological response and safety are clinically important when considering a nebulized intervention in young infants. Changes in oxygen saturation and clinical severity during the initial hours following therapy may provide useful information regarding immediate treatment response, while systematic monitoring of adverse events is essential to establish tolerability [6]. The present study therefore focused specifically on children with moderate bronchiolitis receiving two doses of nebulized magnesium sulphate, with oxygen saturation assessed before treatment and at 4 hours and clinical parameters evaluated serially during the observation period.

Therefore, the present study was undertaken to evaluate the safety and short-term oxygenation response to nebulized magnesium sulphate in children with moderate bronchiolitis, with additional assessment of early changes in clinical severity and physiological parameters.

Materials and methods

Study Design and Setting: This hospital-based prospective single-arm interventional study was conducted in the Department of Paediatrics, Karnataka Institute of Medical Sciences (KIMS), Hubballi, Karnataka, India, from 1 December 2018 to 30 June 2020 (19 months duration). Children aged 1–24 months admitted with moderate bronchiolitis were screened for eligibility.

Study Population: Children aged 1–24 months with clinically diagnosed bronchiolitis and a Clinical Severity Score (CSS) of 4–8 were included. Bronchiolitis was defined as the first episode of wheezing following a viral upper respiratory tract prodrome with increased respiratory effort. Children with previous wheezing, steroid use within 24 hours, immunodeficiency, and hypersensitivity to magnesium sulphate, chronic lung disease, or congenital heart disease were excluded.

Sample Size: Based on an expected reduction in mean CSS from 6.1 ± 1.11 to 4.7 ± 2.0 at 4 hours, with 99% power and 1% type I error, the minimum required sample size was 41. The final analysis included 60 children.

Baseline Clinical Assessment: Demographic and clinical details were recorded at enrolment. Baseline assessment included heart rate, room-air oxygen saturation (SpO_2), respiratory rate, wheezing, chest retractions, general condition, and CSS. SpO_2 was measured using a Nellcor pulse oximeter, with SpO_2 ≥92% considered normal. Complete hemogram and chest radiography were performed to exclude alternative respiratory illnesses, particularly pneumonia.

Intervention and Follow-up: Each child received 150 mg nebulized magnesium sulphate, prepared from 0.3 mL of 50% magnesium sulphate and diluted with 4 mL of 0.9% normal saline. Two nebulizations, each lasting approximately 10 minutes, were administered 30 minutes apart using an Equinox nebulizer. CSS was recorded at baseline, 1 hour, and 4 hours, while SpO_2 was measured at baseline and 4 hours.

Outcome Assessment: The primary outcomes were short-term change in SpO_2 and safety of nebulized magnesium sulphate. Secondary outcomes included changes in total CSS, respiratory-rate score, wheeze, retractions, general condition, and pulse rate during the 4-hour observation period. Oxygenation response was also assessed separately among children with and without baseline hypoxia.

Safety Monitoring: Children were monitored for adverse effects, including flushing, hypotension, arrhythmias, loss of deep tendon reflexes, somnolence, weakness, respiratory depression, and other manifestations of magnesium toxicity. Clinical deterioration to CSS >8 was considered treatment failure, and such children were shifted to standard bronchiolitis management.

Ethical Considerations: Institutional Ethics Committee approval was obtained before initiation of the study. Written informed consent was obtained from the parents or legal guardians of all participants.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using IBM SPSS

Statistics version 22.0. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Paired measurements before and after nebulization were compared using the repeated-measures ANOVA. A p value <0.05 was considered statistically significant.

Results

Sixty children with moderate bronchiolitis received two doses of nebulized magnesium sulphate. Oxygen saturation was assessed before treatment and at 4 hours, while clinical severity parameters were evaluated at baseline, 1 hour, and 4 hours. Safety was assessed by monitoring for adverse effects during the 4-hour observation period. The study included 60 children with a mean age of 7.5 ± 6.47 months. Males constituted 68.3% of participants, and baseline hypoxia was observed in 36.6%.

Table 1: Baseline characteristics of children receiving nebulized magnesium sulphate

Characteristic	Result
Total children	60
Mean age	7.5 ± 6.47 months
Male	41 (68.3%)
Female	19 (31.7%)
Normal baseline SpO_2	38 (63.3%)
Hypoxia at baseline	22 (36.6%)

Mean oxygen saturation increased from 90.15 ± 6.99% before nebulization to 93.30 ± 4.48% at 4 hours, representing a statistically significant short-term improvement (p<0.001).

Table 2: Overall short-term oxygen saturation response

Time point	n	Mean SpO_2 (%)	SD	P value
Before nebulization	60	90.15	6.99	—
4 hours after nebulization	60	93.30	4.48	<0.001

SpO_2 improved significantly in both groups, with a greater absolute increase among hypoxic children (82.41 ± 5.30% to 89.64 ± 5.25%) than non-hypoxic children (94.63 ± 2.42% to 95.45 ± 1.94%); both p<0.001.

Table 3: Oxygen saturation response according to baseline oxygenation status

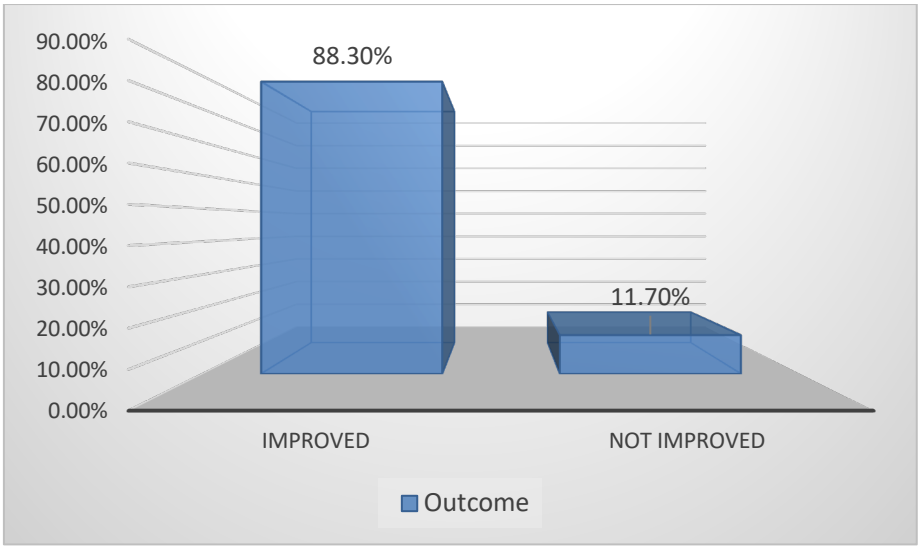
Baseline group	n	Pre-nebulization SpO_2, mean ± SD	Post-nebulization SpO_2, mean ± SD	P value
Hypoxic	22	82.41 ± 5.30	89.64 ± 5.25	<0.001
Non-hypoxic	38	94.63 ± 2.42	95.45 ± 1.94	<0.001

Clinical severity score decreased from 6.00 ± 1.008 at baseline to 2.40 ± 1.564 at 4 hours. Respiratory-rate, wheeze, retraction, general-condition scores, and pulse rate also showed significant improvement over the observation period (all p<0.001).

Table 4: Short-term clinical and physiological response after nebulized magnesium sulphate

Parameter	Baseline	1 hour	4 hours	P value*
Clinical severity score	6.00 ± 1.008	2.95 ± 1.395	2.40 ± 1.564	<0.001
Respiratory-rate score	2.58 ± 0.591	1.98 ± 0.624	1.70 ± 0.646	<0.001
Wheeze score	1.62 ± 0.691	0.52 ± 0.567	0.25 ± 0.508	<0.001
Retraction score	0.90 ± 0.303	0.20 ± 0.403	0.10 ± 0.354	<0.001
General-condition score	0.90 ± 1.386	0.30 ± 0.908	0.30 ± 0.908	<0.001
Pulse rate, beats/min	131.30 ± 23.30	129.00 ± 23.29	124.37 ± 22.52	<0.001

The majority of children 53 (88.3%) showed clinical improvement following nebulized magnesium sulphate, while 7 (11.7%) did not improve, indicating a high short-term clinical response rate.



Graph 1: Short-term clinical disposition following nebulized magnesium sulphate

Discussion

A significant improvement in oxygen saturation was observed, with mean SpO_2 increasing from 90.15 ± 6.99% at baseline to 93.30 ± 4.48% at 4 hours ($p<0.001$). The improvement was particularly marked among initially hypoxic children, in whom mean SpO_2 increased from 82.41 ± 5.30% to 89.64 ± 5.25%. These findings suggest a measurable short-term physiological improvement following nebulized magnesium sulphate.

Clinical severity also improved substantially during the observation period. Mean Clinical Severity Score decreased from 6.00 ± 1.008 at baseline to 2.95 ± 1.395 at 1 hour and 2.40 ± 1.564 at 4 hours ($p<0.001$). Significant reductions were also observed in respiratory-rate, wheeze, retraction, general-condition scores, and pulse rate. Overall, 88.3% of children demonstrated clinical improvement. The rapid improvement may be related to the smooth-muscle relaxant and bronchodilator properties of magnesium; however, because the present study lacked a concurrent control group, spontaneous improvement and other supportive measures cannot be excluded as contributors.

Evidence from controlled studies remains less conclusive. Alansari et al., in a randomized trial of 162 infants with bronchiolitis, found that intravenous magnesium sulphate did not significantly shorten time to medical readiness for discharge or improve bronchiolitis severity scores compared with placebo.[7] Similarly, available systematic-review evidence has found uncertain effects of magnesium sulphate on clinical severity in acute bronchiolitis, emphasizing the limited certainty of the current evidence.[8]

Evidence from pediatric acute asthma provides additional information regarding nebulized magnesium, although asthma and bronchiolitis have different pathophysiological mechanisms. Su et al., in a systematic review and meta-analysis, reported that nebulized magnesium sulphate did not significantly improve respiratory function or reduce hospital admission in children with acute asthma.[9] More recently, a 2024 systematic review involving 2,301 children likewise found no significant reduction in asthma severity, hospitalization, ICU admission, or duration of hospital stay, although minor improvements in pulmonary function were reported.[10] These observations indicate that improvements in short-term physiological parameters should not automatically be interpreted as evidence of improved major clinical outcomes.

Safety was reassuring in the present study. Most children experienced no adverse effect, while transient flushing was the principal minor event; clinical deterioration was uncommon. The study specifically monitored for hypotension, arrhythmia, somnolence, weakness, respiratory depression, and other manifestations of magnesium toxicity. This favorable tolerability is broadly consistent with paediatric evidence.

A systematic review of magnesium sulphate in children with severe acute asthma found nebulized administration to be generally well tolerated,[11] while the 2024 meta-analysis reported that adverse events were minor, infrequent, and comparable with control treatment.[10]

Limitations

The principal limitations were the single-arm design, small sample size, short four-hour observation period, and absence of a concurrent control group. Consequently, the observed improvements cannot be attributed exclusively to nebulized magnesium sulphate, as spontaneous

clinical improvement and supportive treatment may have contributed.

Conclusion:

Two doses of nebulized magnesium sulphate were associated with significant short-term improvements in oxygen saturation and clinical severity and were generally well tolerated in children with moderate bronchiolitis. However, these findings should be interpreted cautiously because of the uncontrolled study design. Larger randomized controlled trials evaluating clinically meaningful outcomes are required before routine use can be recommended.

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