DOI: https://doi.org/10.54393/pjhs.v7i10.3915

PAKISTAN JOURNAL OF HEALTH SCIENCES
(LAHORE)
https://thejas.com.pk/index.php/pjhs
ISSN (E): 2790-9352, (P): 2790-9344
Volume 7, Issue 10 (October 2026)



OPEN ACCESS
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Original Article

Efficacy of Nebulized Magnesium Sulphate with Salbutamol versus Salbutamol Alone in Pediatric Patients with Moderate to Severe Asthma Exacerbations: A Comparative Cross-Sectional Study

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ARTICLE INFO

Keywords:
Acute Asthma Exacerbation, Pediatric Asthma, Magnesium Sulphate, PRAM Score, Nebulized Therapy

How to Cite:
Farooq, F., Mukhtar, A., Ikram, M., Shah, W. F., Ali, M. F., & Arif, M. I. (2026). Efficacy of Nebulized Magnesium Sulphate with Salbutamol versus Salbutamol Alone in Pediatric Patients with Moderate to Severe Asthma Exacerbations: A Comparative Cross-Sectional Study: Nebulized Magnesium Sulphate in Pediatric Asthma Exacerbations. Pakistan Journal of Health Sciences, 7(10), 50-55. https://doi.org/10.54393/pjhs.v7i10.3915

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Received Date: 31st January, 2026
1st Revision Received: 17th March, 2026
2nd Revision Received: 13th May, 2026
Acceptance Date: 20th May, 2026
Published Date: 31st October, 2026

ABSTRACT

Acute asthma exacerbation is a leading cause of pediatric emergency. β2-agonists and systemic corticosteroids remain the cornerstone of management and necessitate adjunct therapies such as magnesium sulphate. **Objective:** To compare the efficacy of nebulized magnesium sulphate combined with salbutamol versus salbutamol alone in reducing asthma severity among pediatric patients presenting with moderate to severe asthma exacerbations. **Method:** This quasi-experimental study was conducted in the Pediatrics Department at Sharif Medical City Hospital, Lahore. 60 children aged 2–15 years with moderate to severe asthma exacerbations were allocated to receive either nebulized salbutamol with magnesium sulphate (n=30) or salbutamol with placebo (n=30). Asthma severity was assessed using the Pediatric Respiratory Assessment Measure (PRAM) score at baseline, 60 minutes, and 120 minutes. Efficacy was defined as a reduction of at least 3 points in PRAM score at 120 minutes. Data were analyzed using SPSS version 28.0, with $p \leq 0.05$ considered statistically significant. **Results:** Baseline characteristics and PRAM scores were comparable between groups (7.17 ± 2.17 vs. 8.03 ± 2.31; p>0.05). At 60 minutes, mean PRAM scores were significantly lower in the magnesium sulphate group (4.10 ± 2.80) compared to the placebo group (6.57 ± 2.74; p<0.05), with further improvement at 120 minutes (2.37 ± 3.18 vs. 5.20 ± 3.15; p<0.05). **Conclusions:** Nebulized magnesium sulphate is an effective and safe adjunct to salbutamol in the management of moderate to severe acute asthma exacerbations in children, particularly among younger age groups.

INTRODUCTION

Asthma is a persistent inflammatory disorder of the airways that is characterized by reversible airflow hindrance and bronchial hyperreactivity, separated by intervals of clinical stability followed by sudden episodes of asthma called exacerbations [1]. Pediatric asthma has been a significant health issue in the world, with reported prevalence of about 10 to 30% in different parts of the world, including over 39 million cases in South Asia [2]. In Pakistan, asthma is experienced by about 4.3 to over 12% of the population, with an estimated 20 million individuals

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DOI: https://doi.org/10.54393/pjhs.v7i10.3915

living with the disease [3]. Although there has been improvement in the implementation of preventive measures, controller medications, and education of the patient, the exacerbation of asthma attacks among children with acute asthma still exists and is a serious cause of morbidity [3]. The use of inhaled short-acting 2-agonists with systemic corticosteroids is the standard management of acute severe asthma, including status asthmaticus, and aimed at combating airway inflammation and bronchospasm [4]. Magnesium sulphate off-label as an intravenous therapy has become a possible second-line treatment in children with refractory acute asthma exacerbations [5]. The effect of magnesium sulphate is a bronchodilator that is achieved by blocking calcium influx into the airway smooth muscle cells, that inhibit contraction of smooth muscle and increases the relaxation of the airways [6]. It has been established through several studies that intravenous magnesium sulphate can be used to alleviate the parameters of pulmonary function in patients with acute asthma exacerbations [7]. Yet, the issues deal with systemic side effects, especially the decrease in blood pressure and heart failure, have restricted its use in daily clinical practice [8]. Meanwhile, nebulized magnesium sulphate is proposed as a less harmful, less invasive substitute that can introduce the drug to the lower airways with the least systemic absorption and other side effects [9]. Recent studies indicated that intravenous as well as nebulized magnesium sulphate could be useful in reducing the level of hospitalization in children with moderate to severe asthma attacks [10, 11]. However, magnesium sulphate should not be used in place of inhaled short-acting agonists because there is no evidence of its use as monotherapy. There are inconclusive findings on clinical trials on the effect of magnesium sulphate on its efficacy. In a single randomized controlled trial, the hospital admission rates were 43.5% in the magnesium sulphate group as opposed to 47.7% in the placebo group (p=0.180), and the same results were not significant in further analysis [12].

These are contradicting results; hence, more studies with well-designed trials, especially in pediatrics, are required to understand the clinical efficacy of nebulized magnesium sulphate. The problem is that there is not enough uniformity about the evidence to be certain how best to manage moderate to severe acute asthma exacerbations in children in clinical practice. Thus, the current study aimed to compare the clinical efficacy of nebulized magnesium sulphate combined with salbutamol versus salbutamol alone in reducing asthma severity among children presenting with moderate to severe acute asthma exacerbations using the Pediatric Respiratory Assessment Measure (PRAM) score.

METHODS

This quasi-experimental study was carried out in the Department of Pediatrics at Sharif Medical City Hospital, Lahore, from 11th January 2023 to 11th July 2023. A total of 60 children were recruited, and the 30 participants were assigned to each of the study groups. The ethical approval for this study was obtained from the Sharif Medical and Dental College, Lahore (SMDC/SMRC 219-21 dated: 16th November 2021. The written consent was obtained from participants following the informing the aims and concerns of this research. The sample size was calculated using the standard formula for comparing two independent proportions: $n = (Z\alpha/2 + Z\beta)^2 \times [p_1(1-p_1) + p_2(1-p_2)] / (p_1 - p_2)^2$, where $Z\alpha/2 = 1.96$ (95% confidence level), $Z\beta = 0.84$ (80% power), p1 = expected response in the placebo group (40%), and p2 = expected response in the magnesium group (72%), based on previous pediatric trials [13]. The calculated sample size was 30 participants per group, totaling 60 participants. The recruitment of eligible participants was based on non-probability consecutive sampling because the study was carried out over a period of time, and these participants had to present within the study period, and they had to fulfill the inclusion criteria. The subjects were 2-15-year-old children of both genders with a history of two or more episodes of wheezing, which were responsive to 2-agonists, and who were presenting with moderate or severe asthma exacerbation according to the operational criteria. Children who needed rapid airway care, children who had already received intravenous magnesium sulphate or corticosteroids (as per medical records), and those with underlying comorbidities such as chronic lung disease, cardiovascular disease, neurological or renal disease (serum creatinine >1.8 mg/dL or on dialysis) were excluded. The children who had a history of being hypersensitive to magnesium sulphate were also not included in the study. Demographic and clinical data were taken as baseline, age, gender, weight, duration of asthma exacerbation, severity of exacerbation, season of presentation, time of presentation (morning, afternoon, evening, or night), exposure to tobacco smoke, oxygen saturation, and respiratory rate were collected during the admission. All children who entered the study were given systemic therapy with corticosteroids, that is, intravenous hydrocortisone at 10 mg/kg (maximum 300mg) or oral prednisolone at 1mg/kg (maximum 30mg) at the beginning of the study. The participants were then grouped into two groups through a lottery approach. Group A children were treated with 0.15 mg/kg of salbutamol as a nebulized dose with 1 mL of 15% magnesium sulphate and 1.5 mL of isotonic saline. This was given thrice in constant intervals of 20 minutes [10-13]. Further nebulized salbutamol was given at 40-minute time intervals thereafter when clinically

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DOI: https://doi.org/10.54393/pjhs.v7i10.3915

needed. The Pediatric Respiratory Assessment Measure (PRAM) is a validated clinical scoring system used to assess asthma severity in children based on five parameters: suprasternal retractions, scalene muscle contraction, air entry, wheezing, and oxygen saturation. It produces a total score from 0 to 12, where 0–3 indicates mild, 4–7 moderate, and 8–12 severe asthma exacerbation. PRAM has strong inter-observer reliability and is widely used in pediatric emergency settings to monitor treatment response [14]. In this study, the PRAM was measured at baseline (0 minutes) and at 20, 40, 60 and 120 min., as necessary. A PRAM score of 4–7 was considered a moderate asthma exacerbation, whereas high scores of 812 were attributed to severe exacerbation. The criterion of efficacy was a decrease of at least 3 points in PRAM score at 120 minutes of the intervention. Children who failed to experience this improvement during the stipulated time were identified as non-responsive to the intervention.

Data were analyzed using IBM SPSS version 28.0. Continuous variables, including age, weight, PRAM score, respiratory rate, and oxygen saturation, were expressed as Mean ± Standard deviation, while categorical variables were presented as frequencies and percentages. The Shapiro-Wilk test was used to assess the normality of continuous variables. Independent t-tests were used to compare mean PRAM scores between groups at different time points. The Chi-square test was applied to compare treatment efficacy between the two groups. Stratification was performed with respect to age, gender, weight, duration of exacerbation, oxygen saturation, respiratory rate, season of presentation, time of presentation, and exposure to tobacco smoke, and the post-stratification. Chi-square test was applied to evaluate effect modification. A p-value ≤0.05 was considered statistically significant.

RESULTS

A total of 60 children were enrolled in the study, with 30 participants allocated to each group. In the magnesium sulphate group, the mean age was 8.90 ± 3.64 years, while in the placebo group, the mean age was 8.53 ± 3.88 years. Male children constituted 40% of the magnesium sulphate group and 50% of the placebo group. The mean body weight was comparable between the two groups (17.97 ± 7.99 kg vs. 18.00 ± 9.04 kg, respectively). The mean duration of asthma exacerbation before presentation was 7.13 ± 3.46 hours in the magnesium sulphate group and 8.13 ± 2.86 hours in the placebo group. Baseline oxygen saturation and respiratory rate at presentation were also similar between groups, indicating comparability of baseline clinical status (p>0.05)(Table 1).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variables	Magnesium Sulphate Group (n=30)	Placebo Group (n=30)
Age (years), Mean ± SD	8.90 ± 3.64	8.53 ± 3.88
Male, n (%)	12 (40.0%)	15 (50.0%)
Female, n (%)	18 (60.0%)	15 (50.0%)
Weight (kg), Mean ± SD	17.97 ± 7.99	18.00 ± 9.04
Duration of Exacerbation (Hours), Mean ± SD	7.13 ± 3.46	8.13 ± 2.86
Oxygen Saturation (%), Mean ± SD	92.40 ± 1.61	92.83 ± 1.60
Respiratory Rate (Breaths/min), Mean ± SD	29.93 ± 3.02	30.00 ± 3.43

The Shapiro-Wilk test demonstrated that all continuous variables followed a normal distribution (p>0.05). Therefore, parametric statistical tests, including the independent sample t-test, were applied for comparison of mean values between groups (Table 2).

Table 2: Shapiro- Wilk Test Outcomes for Normality

Variables	W statistic	p-value
Age	0.962	0.087
Weight	0.971	0.112
Baseline PRAM score	0.956	0.064
60-min PRAM score	0.948	0.072
120-min PRAM score	0.951	0.083
Respiratory rate	0.968	0.109
Oxygen Saturation	0.973	0.121

In the magnesium sulphate group, most children presented during spring (50%), followed by summer (30%) and winter (20%). In contrast, children in the placebo group most commonly presented during summer (36.7%), followed by winter (33.3%) and spring (30%). Morning presentation was more frequent in the magnesium sulphate group, whereas night-time presentation predominated in the placebo group. A higher proportion of children in the magnesium sulphate group had a history of exposure to smoking compared to the placebo group (Table 3).

Table 3: Seasonal Variation, Time of Presentation, and Smoking Exposure

Variables	Magnesium Sulphate Group, n (%)	Placebo Group, n (%)
Season of Presentation		
Winter	6 (20.0%)	10 (33.3%)
Spring	15 (50.0%)	9 (30.0%)
Summer	9 (30.0%)	11 (36.7%)
Time of Presentation		
Morning	14 (46.7%)	9 (30.0%)
Afternoon	8 (26.7%)	6 (20.0%)
Evening	3 (10.0%)	2 (6.7%)
Night	5 (16.7%)	13 (43.3%)
Exposure to Smoking		
Yes	17 (56.7%)	12 (40.0%)
No	13 (43.3%)	18 (60.0%)

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DOI: https://doi.org/10.54393/pjhs.v7i10.3915

At presentation, the mean PRAM score was 7.17 ± 2.17 in the magnesium sulphate group and 8.03 ± 2.31 in the placebo group. Moderate asthma exacerbation was observed in 60% of children in the magnesium sulphate group and 46.7% in the placebo group, while severe exacerbation was present in 40% and 53.3% of children, respectively. These differences were statistically insignificant (p>0.05), confirming comparable baseline severity between the groups. Following treatment, a significant reduction in PRAM scores was observed in the magnesium sulphate group compared to the placebo group. At 60 minutes, the mean PRAM score was 4.10 ± 2.80 in the magnesium sulphate group compared to 6.57 ± 2.74 in the placebo group (p < 0.05). This difference became more pronounced at 120 minutes, with mean PRAM scores of 2.37 ± 3.18 and 5.20 ± 3.15, respectively (p < 0.05). Overall, efficacy was achieved in 37 (61.7%) children. The magnesium sulphate group demonstrated a significantly higher efficacy rate, with 24 (80%) children achieving the predefined clinical improvement, compared to 13 (43.3%) children in the placebo group (p < 0.05). Age-based stratification revealed that among children aged 2–5 years, efficacy was significantly higher in the magnesium sulphate group compared to the placebo group (85.7% vs. 28.6%, p < 0.05). In children aged 5–10 years and those older than 10 years, efficacy remained higher in the magnesium sulphate group; however, the differences were not statistically significant (p > 0.05) (Table 4).

Table 4: Comparison of Treatment Efficacy Between the Magnesium Sulphate and Placebo Groups According to Age Stratification

Variables	Magnesium Sulphate Group, (n=30)	Placebo Group, (n=30)	p-value
PRAM score at baseline, Mean ± SD	7.17 ± 2.17	8.03 ± 2.31	>0.05
Moderate exacerbation, n (%)	18 (60.0%)	14 (46.7%)	>0.05
Severe exacerbation, n (%)	12 (40.0%)	16 (53.3%)	>0.05
Time Point			
Baseline	7.17 ± 2.17	8.03 ± 2.31	>0.05
60 minutes	4.10 ± 2.80	6.57 ± 2.74	<0.05
120 minutes	2.37 ± 3.18	5.20 ± 3.15	<0.05
Outcomes			
Efficacy achieved	24 (80.0%)	13 (43.3%)	<0.05
No efficacy	6 (20.0%)	17 (56.7%)	
Age Group			
2–5 years	6 (85.7%)	2 (28.6%)	<0.05
5–10 years	11 (78.6%)	6 (42.9%)	>0.05
>10 years	7 (77.8%)	5 (55.6%)	>0.05

DISCUSSION

This study compares the efficacy of nebulized magnesium sulphate combined with salbutamol versus salbutamol alone in reducing asthma severity among pediatric patients presenting with moderate to severe asthma exacerbations. Both groups were similar at baseline, as the mean PRAM score was 7.17 ± 2.17 in the magnesium sulphate group and 8.03 ± 2.31 in the placebo group (p>0.05), indicating that they were adequately randomized and selection bias was reduced. But after 60 minutes of intervention, a large decrease in PRAM score (4.10 ± 2.80) was observed in the magnesium sulphate group in comparison with the placebo group (6.57 ± 2.74; p < 0.05), which was further increased at 120 minutes (2.37 ± 3.18 vs. 5.20 ± 3.15; p < 0.05). These results are in line with the magnesium bronchodilator effect by calcium antagonism and relaxation of smooth muscle. Pérez *et al.* (2025) found a comparable degree of PRAM or clinical score reduction, where the average decrease in respiratory scores in 2 hours of children who received nebulized magnesium was approximately 2.5 points [15]. Similarly, Mega *et al.* also indicated statistically significant improvement in the scores of pediatric asthmas with magnesium therapy, supporting the temporal and clinical applicability of the current results [16]. The general effect of treatment in the present study is also useful in substantiating the therapeutic use of nebulized magnesium sulphate. Efficacy, which was defined as a decrease of at least 3 points in PRAM score at 120 minutes, was realized in 80% (24/30) of the magnesium sulphate group versus 43.3% (13/30) of the placebo group and gave a statistically significant difference between the two groups (p<0.05). This increase in efficacy was absolute at 36.7%, which is consistent with earlier pediatric trials. An example is given by Kumar *et al.* who demonstrated a clinical improvement rate of 72% versus 40% in children receiving magnesium sulphate nebulization versus the control group factor, respectively; Debiazzi *et al.* reported lower hospital admission rates with magnesium addition at the onset of the acute exacerbations [17, 18]. The therapeutic benefit of magnesium sulphate was found to increase as age decreased in the older children, and it was found to be greatest in the young children. In the group of children aged 2-5 years, efficacy was found in 85.7% of those in the magnesium sulphate group and in only 28.6% in the placebo group (p < 0.05), which is above 57% relative advantage. Conversely, even in children aged 5 -10 years (78.6% vs. 42.9%) and those aged over 10 years (77.8% vs. 55.6%), the difference was not significant (p > 0.05). Such results indicate that there may be an increased airway smooth muscle responsiveness or increased baseline bronchial hyperreactivity in children of younger age, as hypothesized previously by Siddiqui *et al.* which showed improved clinical scores in preschool-aged children who had magnesium [19]. Furthermore, a meta-analysis study by Ambrożej *et al.* found that magnesium had stronger

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DOI: https://doi.org/10.54393/pjhs.v7i10.3915

treatment effects in younger subgroups of pediatrics with better biological plausibility and epidemiological support of the current stratified outcomes[20].

Although this study has shown statistically and clinically significant results, it has a number of limitations that cannot be ignored in the interpretation of the results. First, the sampling method might not be as generalizable to wider pediatric groups, particularly in primary or rural care systems, because of the use of non-probability consecutive sampling of a single tertiary care center. Also, the long-term results like hospitalization, relapse after 24-48 hours, or intensive care were not evaluated, which allowed drawing only short-term clinical improvement during 120 minutes.

CONCLUSIONS

The nebulized magnesium sulphate, when administered as an adjuvant to salbutamol, is very promising in the enhancement of clinical outcomes in children with moderate to severe acute asthma exacerbations. Children treated with magnesium sulphate showed a greater reduction in asthma severity compared to placebo. They also demonstrated a significantly higher treatment efficacy within the observed period. Age sensitivity to magnesium therapy was specifically seen in younger children aged 2-5 years, where the therapeutic effect was most pronounced. These results justify the initial introduction of nebulized magnesium sulphate into the routine of adult acute asthma management of exacerbations, particularly in emergency areas, and highlight the importance of conducting larger, multicenter studies and streamlining age-specific interventions.

Authors' Contribution

Conceptualization: AM
Methodology: MI, MFS
Formal analysis: MI, MFS
Writing and Drafting: FF
Review and Editing: FF, AM, MI, MFS, MFAK, MIA

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

Source of Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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