ORIGINAL ARTICLE

Comparative efficacy of Nebulized Magnesium Sulphate plus Salbutamol versus Nebulized Salbutamol plus 0.9% NaCl in Acute Exacerbation of Asthmatic in Children

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ABSTRACT

Objective: To compare the effectiveness of magnesium sulphate ($MgSO_4$) plus salbutamol nebulization versus salbutamol plus normal saline nebulization in managing acute asthma exacerbations in children.

Study Design: Randomized multicenter clinical trial.

Place and Duration of Study: Govt. Allama Iqbal Memorial Teaching Hospital, Sialkot and Govt. Sardar Begum Teaching Hospital, Sialkot for 4 months between February 2023 and May 2023.

Material and Methods: 144 children with acute asthma exacerbations were randomly divided into two groups of equal size. Group Magnesium received $MgSO_4$ + salbutamol; Group Saline received salbutamol + normal saline via nebulizer. Participants received up to three treatment sessions every 20 minutes. Assessments were done by measuring the Pulmonary Index Score and peak expiratory flow rate before treatment and at 30, 60, and 90 minutes after treatment. Data was analyzed using SPSS v.25.

Results: The mean ages of children in magnesium and saline groups were 8.26 ± 1.85 and 8.39 ± 2.15 years, respectively, with no significant difference (p = 0.709). The mean PEFR increased and PIS decreased significantly over time in both groups. Magnesium group had significantly higher PEFR than saline group at 60 and 90 minutes. The groups did not differ significantly from pre-intervention to 30 minutes post-intervention. Regarding PIS, the groups differed significantly at all three post-intervention time points: magnesium group had significantly lower PIS scores than Saline group.

Conclusion: In pediatric asthma exacerbations, nebulized $MgSO_4$ with salbutamol significantly improves outcomes compared to nebulized salbutamol with normal saline.

Key Words: *Magnesium sulphate, Pulmonary index score, Peak expiratory flow rate, Global initiative for asthma, Short acting β-agonists, Inhaled corticosteroids, Forced expiratory volume in 1st second*.

INTRODUCTION

Asthma is a common chronic inflammatory respiratory disorder, affecting 1–18 % of the population in different countries.[1] Asthma exacerbations are flare-ups of symptoms such as dyspnea, cough, wheezing, or chest tightness, along with a decline in lung function.[2] Early

evaluation and close follow-up are required in severe exacerbations, which can otherwise be life-threatening.[3] Airflow obstruction is the hallmark of an asthma exacerbation.[4] The goal of management during an exacerbation is to rapidly relieve airway obstruction and hypoxemia, treat the underlying inflammation, and prevent relapse. First-line therapy in the emergency setting includes oxygen, short-acting β_2-agonists, and systemic corticosteroids.[5] In patients unresponsive to first-line treatment, ipratropium bromide, intravenous magnesium, theophylline or aminophylline, and high-dose inhaled corticosteroids may be used,[1,3,6]

Asthma attacks are a common cause of hospitalization and emergency room visits among children. Triggers include atypical bacterial or viral infections, certain drugs, air pollutants like smoke and dust, exercise, stress, and emotional factors.[7] Acute asthma attacks may occur in previously undiagnosed children or in diagnosed children who respond poorly to treatment or to whom compliance has been suboptimal.[1]

The National Institutes of Health recommends intensive use of β_2-agonists and systemic corticosteroids for patients experiencing moderate-to-severe acute asthma exacerbations. However, clinical trials have shown that 19 % to 50% of such patients treated with β_2-agonists and corticosteroids alone require hospitalization and often have incomplete response. In two studies, 31% of children treated with prednisone and intermittent frequent nebulization of salbutamol for moderate-to-severe exacerbations still required hospitalization. Given this, many patients with severe exacerbations may benefit from adjunctive therapies.[8]

The GINA guidelines recommend nebulized salbutamol with oxygen as first-line therapy for severe acute asthma exacerbations.[9] On the other hand, $MgSO_4$ has been reported as a potent adjunct for acute asthma.[10] Its use in asthma was first described in 1940. Magnesium has various biological effects relevant to the respiratory system, particularly smooth-muscle relaxation by antagonizing calcium entry.[11]

Patients with acute severe asthma may be extremely dyspneic at rest, unable to speak in sentences, agitated, and sitting upright.[12] Drowsiness or confusion are warning signs of impending respiratory failure. Danger signs include: respiratory rate >30 breaths/min, heart rate >120 beats/min, wheezing, accessory muscle use, suprasternal retractions, and pulsus paradoxus >12 mmHg.[12]

The ideal management plan treats exacerbations promptly. In the emergency context, a brief history including onset, triggers, severity, prior hospital or ICU admissions, and complicating conditions helps guide therapy. Oxygen, inhaled β_2-agonists, and systemic corticosteroids are the cornerstone of acute severe asthma care.[12] Since up to 30% of asthma patients do not fully respond to standard therapy, nebulized $MgSO_4$ is being explored as an adjunctive treatment to improve pulmonary function and reduce hospital stays in children with acute asthma attacks.[13]

MATERIAL AND METHODS

This was a randomized, multicenter clinical trial. Study design followed methodology of Turker et al.[3] Ethical approval was taken from Research Ethical Committee of Govt. Khawaja Muhammad Safdar Medical College, Sialkot vide letter no. 98/REC/KMSMC dated 15th January, 2023. Data was collected from the Pediatric Emergency Departments of Govt. Allama Iqbal Memorial Teaching Hospital, Sialkot and Govt. Sardar Begum Teaching Hospital, Sialkot between February 2023 and May 2023 after taking informed consent from patient's parents.

A total sample of 144 participants (72 in each group) was calculated based on expected post-treatment PIS means (171.0 ± 0.8 vs. 149.3 ± 1.5), producing an effect size of 0.492, $\alpha = 0.05$, and power = 90 %. Convenient sampling was used. Children aged 5–12 years suffering from moderate or severe asthma exacerbations were eligible. Exclusion criteria included: 1) use of steroids, theophylline, or ipratropium in the preceding three days; 2) fever or respiratory tract infection; 3) chronic diseases such as bronchopulmonary dysplasia or cystic fibrosis; 4) known allergy to salbutamol or $MgSO_4$; and 5) inability to perform peak flow measurement.

Sample Size Formula:

$$n = \frac{2(z_\alpha + z_\beta)^2}{(\delta/\sigma)^2}$$

n = sample size
$\delta = |\mu_0 - \mu_1|$ detectable difference in means
σ = population standard deviation
z_a = z-value for α level
z_β = z-value for β (Turker et al.)[3]

Data Analysis: Data was analyzed using SPSS version 25. Mean ± SD were reported for age, respiratory rate, heart rate, oxygen saturation, peak expiratory flow rate (PEFR), and PIS. Frequencies and percentages were used for categorical variables (e.g. gender). Independent-sample t-tests and repeated measures ANOVA were used to compare baseline characteristics and mean PEFR and PIS at different time points between groups. A p-value ≤0.05 was considered statistically significant.

RESULTS

A total of 144 participants, divided equally into two groups, completed the treatment. The mean ages in the magnesium and saline groups were 8.26 ± 1.85 and 8.39 ± 2.15 years, respectively, with no significant difference (p = 0.709) **(table 1)**. The Magnesium group included 43 males and 29 females; the Saline group included 41 males and 31 females **(table 2)**.

Baseline comparison using independent-sample t-tests showed no significant differences between groups in respiratory rate (p = 0.519), heart rate (p = 0.753), oxygen saturation (p = 0.524), PEFR (p = 0.720), or PIS (p = 0.203).

A repeated-measures ANOVA showed that mean PEFR changed significantly over time in both groups (p <0.001). Post-hoc LSD comparisons in the magnesium group revealed significant improvement from baseline to 30 min (p = 0.017) and from 30 to 60 min (p = 0.018), but the difference between 60 and 90 min was not significant (p = 0.144). In the saline group, although overall improvement was significant, individual time-interval differences (baseline to 30 min: p = 0.187; 30 to 60 min: p = 0.230; 60 to 90 min: p = 0.325) **(table 3)** were not statistically significant.

Similarly, repeated-measures ANOVA showed mean PIS scores changed significantly over time in both groups (p < 0.001). In the magnesium group, significant improvements occurred from baseline to 30 min (p < 0.001) and from 30 to 60 min (p < 0.001), but not from 60 to 90 min (p = 0.076). In the saline group, improvements were significant across all intervals: baseline to 30 min (p < 0.001), 30 to 60 min (p = 0.035), and 60 to 90 min (p = 0.016) **(table 4)**.

Between-group comparisons showed that at 60 and 90 min, the magnesium group had significantly higher PEFRs (156.9 ± 25.1 vs. 141.6 ± 35.6 L/min, p = 0.003 at 60 min; 166.4 ± 50.0 vs. 148.2 ± 44.7 L/min, p = 0.023 at 90 min). There was no significant difference at 30 min (142.4 ± 46.6 vs. 135.1 ± 35.8 L/min) **(table 5)**.

For PIS, the groups differed significantly at all three post-intervention times. At 30 min, magnesium vs. saline: 7.36 ± 1.38 vs. 8.35 ± 1.67 (p < 0.001); at 60 min: 6.28 ± 1.87 vs. 7.51 ± 2.62 (p = 0.001); at 90 min: 5.69 ± 2.24 vs. 6.68 ± 1.78 (p = 0.004) **(table 6)**. Here is consort flow diagram below:

Table 1: Age of the patients

Group	Mean	Range	p-value
MgSO4+ Salbutamol	8.26 ± 1.85	5 – 12	0.709
Salbutamol + normal saline group	8.39 ± 2.15	5 – 12	

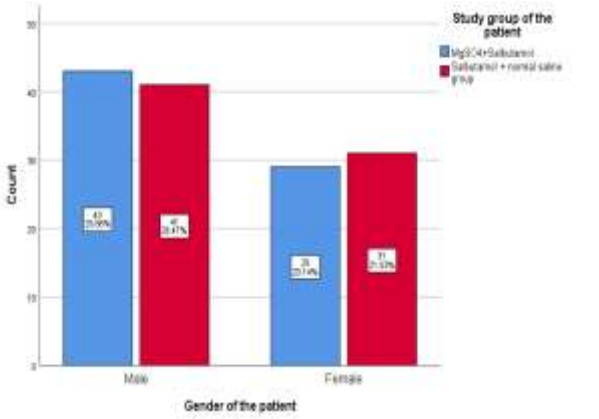

Figure 1: Gender of patients

TABLE 2: Comparison of baseline characteristics of the patients at the time of admission

Characteristics	MgSO4+Salbutamol (mean ± SD)	Salbutamol + normal saline group (mean ± SD)	p-value
Breathing rate	36.8 ± 3.3	36.4 ± 3.2	0.519
Heart Rate	143.2 ± 8.8	142.7 ± 9.2	0.753
Oxygen saturation	91.2 ± 1.1	91.1 ± 1.0	0.524
Peak expiratory flow rate (L/min)	127.9 ± 24.3	129.2 ± 18.9	0.720
Pulmonary Index Score	10.11 ± 1.62	10.47 ± 1.76	0.203

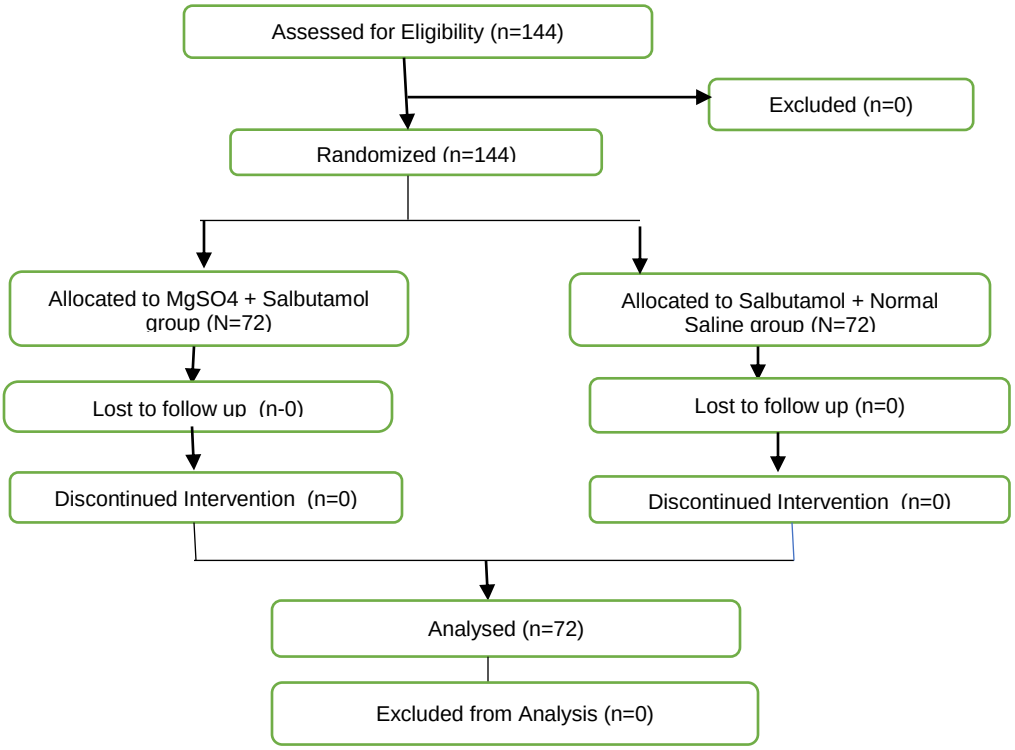

TABLE 3: Within the group change in PEFR (L/min) over the time

Characteristics	MgSO4+Salbutamol (mean ± SD)	Salbutamol + normal saline group (mean ± SD)
Pretreatment PEFR (L/min)	127.9 ± 24.3	129.2 ± 18.9
PEFR (L/min) after 30mintues of treatment	142.4 ± 46.6	135.1 ± 35.8
PEFR (L/min) after 60mintues of treatment	156.9 ± 25.1	141.6 ± 35.6
PEFR (L/min) after 90mintues of treatment	166.4 ± 50.0	148.2 ± 44.7
p-value	< 0.001	< 0.001

TABLE 4: Over the time within the group change in Pulmonary Index Score

Characteristics	MgSO4+Salbutamol (mean ± SD)	Salbutamol + normal saline group (mean ± SD)
Pretreatment Pulmonary Index Score	10.11 ± 1.623	10.47 ± 1.76
Pulmonary Index Score after 30minutes of treatment	7.36 ± 1.377	8.35 ± 1.671
Pulmonary Index Score after 60minutes of treatment	6.28 ± 1.871	7.51 ± 2.616
Pulmonary Index Score after 90minutes of treatment	5.69 ± 2.243	6.68 ± 1.775
p-value	< 0.001	< 0.001

TABLE 5: Over the time between the groups comparison of change in Pretreatment peak expiratory flow rate (L/min)

Characteristics	MgSO4+Salbutamol (mean ± SD)	Salbutamol + normal saline group (mean ± SD)	p-value
Pretreatment peak expiratory flow rate (L/min)	127.9 ± 24.3	129.2 ± 18.9	0.720
Peak expiratory flow rate (L/min) after 30mintues of treatment	142.4 ± 46.6	135.1 ± 35.8	0.291
Peak expiratory flow rate (L/min) after	156.9 ± 25.1	141.6 ± 35.6	0.003

60mintues of treatment Peak expiratory flow rate (L/min) after 90mintues of treatment	166.4 ± 50.0	148.2 ± 44.7	0.023

TABLE 6: Over the time between the groups comparison of change in Pretreatment Pulmonary Index Score

Characteristics	MgSO4+Salbutamol (mean ± SD)	Salbutamol + normal saline group (mean ± SD)	p-value
Pretreatment Pulmonary Index Score	10.11 ± 1.62	10.47 ± 1.76	0.203
Pulmonary Index Score after 30minutes of treatment	7.36 ± 1.38	8.35 ± 1.67	< 0.001
Pulmonary Index Score after 60minutes of treatment	6.28 ± 1.87	7.51 ± 2.62	0.001
Pulmonary Index Score after 90minutes of treatment	5.69 ± 2.24	6.68 ± 1.78	0.004

DISCUSSION

With inhalation of short-acting β_2-agonists (SABA) such as salbutamol - an asthma medication that relaxes airway smooth muscle and dilates the airways - many acute asthma exacerbations improve. However, in more severe cases, additional therapy (e.g. corticosteroids, magnesium sulfate, or mechanical ventilation) is often required. In patients with severe asthma exacerbations, adjunctive intravenous $MgSO_4$ has demonstrated efficacy in several systematic reviews and meta-analyses.[7,8,14-19.]

In the hospitals where this study was conducted, children with status asthmaticus commonly receive intravenous $MgSO_4$ to reduce severity and shorten hospital stay. However, this approach requires frequent venous punctures and monitoring of tendon reflexes for magnesium toxicity. Nebulized $MgSO_4$, in contrast, has the potential to be safer and more convenient, and previous work suggests it can be effective in children - with optimal results if started early, ideally within six hours of symptom onset.

The findings of our study showed that nebulized $MgSO_4$ added to salbutamol improves clinical parameters: increases PEFR, decreases heart rate (HR) and respiratory rate (RR), raises SpO_2, and lowers the Pulmonary Index Score (PIS). In comparison to salbutamol + normal saline, the combination of $MgSO_4$ + salbutamol achieved superior outcomes.

Some prior studies have reported less clear benefit. For example, Alansari et al. found that among 365 hospitalized pediatric patients, nebulized magnesium did not significantly shorten time to discharge readiness.[20] Powell et al. similarly reported limited clinical improvement despite statistical significance in inhaled magnesium use.[21] In a large multicenter UK trial of 508 children, inhaled magnesium was recommended for those with severe symptoms or SpO_2 <92% to be given alongside every bronchodilator dose during the first hour. This dosing guideline reflects a cautious but proactive approach. Our results demonstrating significant improvement in PIS and PEFR - are consistent with those supportive trials.

On the other hand, Bessmertny et al. studied adults with mild-to-moderate asthma and found that adding nebulized $MgSO_4$ to salbutamol offered no advantage over salbutamol + isotonic saline.[22] In their design, patients received three doses of nebulized salbutamol at 20-minute intervals, each followed by magnesium or saline. Our findings differ: we observed that from 60 minutes onward, PEFR was significantly higher in the magnesium group, although the difference was not significant in the first 30 minutes. Moreover, PIS improvements with $MgSO_4$ were significant at all post-intervention points (30, 60, 90 min). These results align with Abdelnabi et al., who showed that nebulized $MgSO_4$ improved clinical status, PEFR, and SpO_2 while reducing HR and RR in acute bronchial asthma.[23]

Our findings also echo those of Sarmin et al., a randomized double-blind study comparing nebulized salbutamol and $MgSO_4$ in acute asthma.[24] They found that both $MgSO_4$ and

salbutamol individually reduced respiratory rate and improved PEFR, though differences between the groups were not pronounced. In our protocol, we delivered magnesium with a carefully calibrated dose via standard nebulizer (ensuring adequate aerosol power) and used validated eligibility criteria (PIS & PEFR). This methodology helps overcome limitations of earlier studies and provides stronger support for using $MgSO_4$ as adjunct therapy in acute pediatric asthma.

Limitations:

1. **Diagnostic certainty** - we could not absolutely confirm the diagnosis of asthma for every enrolled child at the time of admission. In particular, younger children (age 5) who present with first-time wheezing may have alternative diagnoses; we excluded those with highly uncertain presentations.
2. **Severity distribution** - some children presented early to the ER with mild-to-moderate exacerbations, meaning few patients manifested severe respiratory distress, which may reduce the observable effect size.
3. **Inpatient admission decision bias** - although PIS is a well-validated clinical tool with good inter-rater reliability, the decision to hospitalize is influenced by system-level, clinician-level, and socioeconomic factors, which are not standardized. The randomized design mitigates, but does not eliminate, these biases.
4. **Sample size and follow-up duration** - our sample size was modest, and we only followed patients for 90 minutes post-intervention. A longer observation period would allow capturing longer-term outcomes (e.g. relapse, hospital admission).
5. **Generalisability** - the study was single-centered (though in two hospitals), so the findings may not generalize across different populations, resource settings, or nebulization delivery systems.

Because of these limitations, we cannot conclusively recommend nebulized $MgSO_4$ for all children with asthma exacerbations. Larger, multicenter trials with longer follow-up and standardized admission criteria would be valuable to confirm our results.

CONCLUSION

This study demonstrates that adding nebulized $MgSO_4$ to salbutamol significantly improves PEFR and reduces PIS scores compared to salbutamol plus normal saline in children experiencing acute asthma exacerbations. Based on our findings, we recommend considering the use of nebulized $MgSO_4$ as an adjunct to salbutamol in pediatric asthma exacerbations, especially where intravenous therapy is less convenient or carries greater risk.

Abbreviations: *$MgSO_4$ (Magnesium Sulphate), PIS (Pulmonary Index Score), PEFR (Peak Expiratory Flow Rate), GINA (Global Initiative for Asthma), ANOVA (Analysis of Variance), SABA (Short acting β-agonists), RR (Respiratory Rate), HR (Heart Rate), ICS (Inhaled corticosteroids), FEV1 (Forced Expiratory Volume in 1st second), SPSS (Statistical Package for Social Sciences), SD (Standard Deviation)*

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Authors' contribution

SB: Article writing, data analysis and editing
MH: Reviewed the final manuscript, principal investigator
SI: Data Collection
WY: Corresponding author, data collection, literature & referencing
AM: Data collection
AA: Data collection

All the authors have approved the final manuscript draft and accept the responsibility of research integrity.