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Comparison of the Outcome of Treatment of Nebulized Salbutamol with and Without Nebulized Magnesium Sulphate in Children Presenting with Acute Asthma at Tertiary Care Hospital, Hyderabad

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Author`s Contribution

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A B S T R A C T

Objective: To compare the effectiveness of nebulized salbutamol with and without magnesium sulphate (*MgSO4*) in improving oxygen saturation among children presenting with acute asthma.

Methodology: A randomized controlled trial over six months at a tertiary care hospital, on 100 paediatric patients aged 2 to 16 years, with a clinical diagnosis of acute asthma (SpO2 <90% and Pediatric Asthma Severity Index (PASI) ≥12). Patients were randomly assigned them into two groups. Group A received nebulized salbutamol with 3 mL (150 mg) of magnesium sulphate, while Group B received nebulized salbutamol with 3 mL of normal saline. Subsequently each child was monitored for 90 minutes post-treatment and oxygen saturation (SpO_2) was measured as the primary outcome using pulse oximetry.

Results: Overall mean age and gender distribution were almost similar in both groups without significant difference. Post treatment at 90 minutes, Group A achieved significantly higher oxygen saturation (96.84±1.08%) compared to Group B (95.24±0.56%) (p=0.001), whereas both groups ultimately reached to normal levels of oxygen saturation. On post stratification analysis, older children (7–12 years) in Group B showed significantly better oxygen saturation compared to younger children (p=0.002), though no such age-related difference was found in Group A (p=0.224). There was no significant differences found in mean of oxygen saturation according to gender of children in both group (p>0.05).

Conclusion: Both treatment approaches ultimately restored the oxygen levels to the normal range, while the combination of nebulized magnesium sulphate and salbutamol achieving significantly better oxygen saturation at 90 minutes, with faster and more reliable clinical improvement.

Keywords: Asthma, Nebulization, Magnesium sulphate, Salbutamol, SpO_2

Introduction

Asthma and wheezing are highly prevalent conditions among children, and their occurrence in the pediatric population of Pakistan has surged from 5% to nearly 20% over the past two decades. Despite advancements in treatment, including more widespread use of inhalers and improved drug delivery methods through spacers and aerochambers, the rate of hospital admissions for asthma has increased eightfold during this period.[1-2] Magnesium, due to its bronchodilatory and anti-inflammatory effects, serves as an effective adjunct therapy for children experiencing acute severe asthma exacerbations who fail to respond adequately to standard treatment.[3] Inhaled magnesium sulfate ($MgSO_4$) is advised for use during asthma attacks in patients who do not show sufficient improvement with bronchodilators and corticosteroids. However, research indicates that intravenous administration of magnesium sulfate often yields more favorable outcomes (MgSO4).[4-5] Conversely, some studies have revealed that nebulized MgSO4 plays an insignificant role among children with acute severe asthma.[5] likewise a randomized trial, demonstrated that the nebulized MgSO4 group showed higher post-bronchodilator SpO2 values (92±4% versus. 88±5%) compared to the placebo group when given as an adjunct to standard treatment strategy.[6]

Acute asthma attacks are generally treated with a combination of β-adrenergic agonists and corticosteroids. Studies have demonstrated that adding repeated doses of nebulized ipratropium to this regimen can effectively decrease the likelihood of hospital admission and lessen the overall severity and complications associated with acute severe asthma.[7,8] Studies have shown that combining β- adrenergic agents with ipratropium can lead to a significant decrease in hospital admissions, ranging from 30% to

60%. However, in cases of mild to moderate acute asthma, the addition of a single dose of an anticholinergic drug does not appear to offer any noticeable advantage.[9] Although these medications are effective for many, a significant number of patients still exhibit an insufficient response and ultimately require hospitalization for further management.[10] The stepwise approach is endorsed for managing the acute asthma exacerbations, initiating with first-line standard therapy before moving on to additional options of the treatment. The response to the standard therapy varies considerably and is influenced by multiple factors; most likely genetic polymorphisms cannot be assessed quickly enough to guide urgent care judgments. For the cases, with poor response to the first-line therapy, progress can be observed using other additional therapeutic measures. Even though other second-line agents also produce bronchodilator effects, magnesium has advantages of easy availability, fewer side effects and cost effectiveness.

As per the nebulized salbutamol remains the standard first-line treatment for acute asthma in children, but certain children respond poorly to it alone, encouraging interest in adjuvant therapies like nebulize with MgSO4, given its known bronchodilator properties. On the other hand, existing evidence remains genuinely conflicting as some trials report faster symptom improvement and decreased hospital stays when MgSO4 is added to salbutamol,[11,12] while others find no significant added advantage.[13] Based on these controversies, combined with the practical need for a safe, feasible and non-invasive adjuvant therapy especially in resource-limited regions justifies the need of study, which purposes to directly compare treatment outcomes of nebulized salbutamol with and without nebulized MgSO4 among children with acute asthma.

Methodology

This randomized controlled trial and was conducted in the Department of Pediatrics, Civil Hospital, Hyderabad, after approval of the synopsis by the College of Physicians and Surgeons Pakistan (CPSP) and ethical approval from Ethical Review Committee (ERC) of LUMHS. Duration of study was done from November 2025 to February 2026. A calculated sample size of 100 patients (50 in each group) determined using OpenEpi software with an alpha level of 5%, a power of 80%, an assumed mean SpO2 of 92±4 in the nebulized salbutamol plus magnesium sulphate group, and 89±5.6 in the nebulized salbutamol alone group. The non-probability consecutive sampling technique was used. All the pediatric patients aged between 2 and 12 years of either gender presenting with acute asthma of duration ≤4 hours, with SpO2 less than 90%, with a Pediatric Asthma Severity Index (PASI) ≥12 were included. On the other hand all children with a history of pneumonia or tuberculosis, cleft lip and palate or congenital heart disease, thalassemia, history of drug allergy, other respiratory disorders such as sore throat, common cold, croup, or influenza, or prior pulmonary or thoracic surgery and those whose parents were not agree to take a part of study were excluded. Acute exacerbation of asthma was defined as an acute episode of progressively worsening shortness of breath, cough, wheezing, and chest tightness any one or more of these symptoms accompanied by a decrease in expiratory airflow with SpO2 less than 90% and a Pediatric Asthma Severity Index (PASI) ≥12. Informed consent was obtained from all the parents following the explaining of purpose of study along with risks and benefits. Parents were also informed that their participation was voluntary and that they were free to withdraw at any time without any consequences.

All the patients were then allocated to Group A or Group B using sealed envelopes. The baseline SpO2 was recorded of each patient in both groups at the initiation of treatment. The patients of Group A, were nebulized with salbutamol together with 3 mL (150 mg) of magnesium sulphate administered three times at 20-minute intervals, whereas the patients of Group B were nebulized with salbutamol together with 3 mL of normal saline as per similar schedule. Subsequently the patients were followed up and observed in the ward for 90 minutes and at the end, SpO2 was reassessed in all the cases of both groups using pulse oximetry. The outcome of treatment in both groups was assessed in terms of oxygen saturation (SpO2) achieved better or not at 90 minutes. All the relevant study variables were recorded by the structured proforma. Data were analyzed using SPSS version 22. For quantitative variables, the means and standard deviations were calculated, whereas categorical variables were expressed as frequencies and percentages. An independent t-test was used to compare the treatment outcomes ((SpO2) between the two groups. Stratification by age and gender was carried out to control for effect modifiers. A p-value ≤ 0.05 was considered statistically significant.

Results

Overall mean age was 4.60 ± 2.94 years, in Group A (salbutamol plus magnesium sulphate) and 4.89 ± 2.51 years in Group B (salbutamol plus normal saline) without significant difference (p=0.593). Likewise, the mean of PRAM scores at presentation was closely matched across the groups, around 6.90 ± 0.61 in Group A and 6.70 ± 0.64 in Group B, (p=0.116). The similarity in mean age and initial disease severity in

both groups, supporting the validity of subsequent outcome as presented in table I.

Table I: Mean age and mean PRAM score in both groups. (n=100)

Variables	Study group	N	Mean	SD	t-value	p-value
Age in Years	Group A	50	4.60	2.94	-0.537	0.593
	Group B	50	4.89	2.51		
PRAM Score	Group A	50	6.90	0.61	1.585	0.116
	Group B	50	6.70	0.64		

Group A= (Nebulized with salbutamol together with $MgSO_4$),
Group B =(Nebulized with salbutamol together Normal saline)

The gender distribution across the groups was also well balanced, with females around 46.0% of Group A and 48.0% of Group B, while males comprising 54.0% of Group A and 52.0% of Group B, out of a total of 47 females and 53 males overall, with insignificant difference between the groups (p=0.841). Figure 1.

The mean oxygen saturation at baseline was almost similar between the two groups, with 89.08 ± 1.68% in Group A and 88.34 ± 1.27% in group B, without significant difference (p=0.600). Subsequently, after 90 minutes of nebulization, it was reached to normal around 96.84 ± 1.08% in group A (salbutamol plus magnesium sulphate) compared to 95.24 ± 0.56% in Group B (p=0.001). Though, the mean oxygen saturation reached normal levels in both groups, indicating that both treatment approaches are ultimately effective in restoring adequate oxygenation, with addition significantly greater improvement by magnesium sulphate. Table II

Moreover, the In-Group B, older children (7–12 years) showed significantly higher oxygen saturation compared to younger children (2–6 years) (p=0.002), while in Group A, oxygen saturation was insignificant across both age groups without significant difference (p=0.224) indicating the advantage of magnesium sulphate is uniform across ages in children. On the other hand post-treatment oxygen saturation showed insignificant difference by gender in either group (p=0.860), as presented in table III & IV.

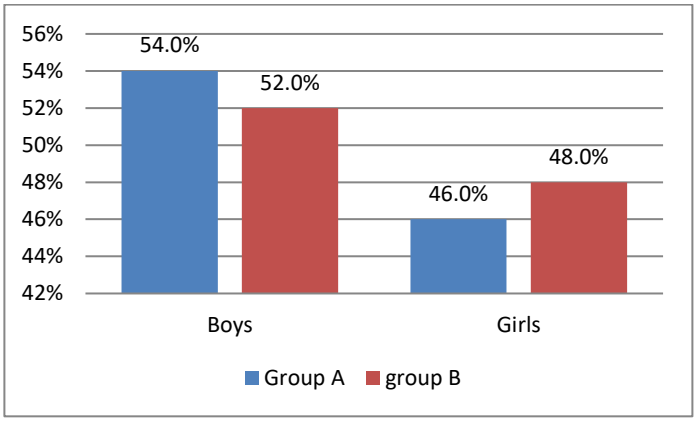

Figure 1. Gender distribution of groups. (n=100)

Discussion

The childhood asthma is one of the most common

Table II: Mean oxygen Saturation before and after nebulization in both groups. (n=100)

Oxygen Saturation	Study group	N	Mean	Std. Deviation	t-value	p-value
Oxygen Saturation (Baseline)	Group A	50	89.08	1.68	0.526	0.600
	Group B	50	88.34	1.27		
Oxygen Saturation after 90 minutes	Group A	50	96.84	1.076	9.344	0.001
	Group B	50	95.24	.555		

Group A= (Nebulized with salbutamol together with $MgSO_4$),
Group B =(Nebulized with salbutamol together Normal saline)

Table III: Mean oxygen Saturation after nebulization according to age groups n=100

Oxygen Saturation After 90 minutes	Age groups	Mean	Std. Deviation	t-value	p-value
Group B	2-6 years	95.11	.509	-3.357	0.002
	7-12 years	95.67	.492		
Group A	2-6 years	96.76	1.055	-1.181	0.224
	7-12 years	97.25	1.165		

Group A= (Nebulized with salbutamol together with $MgSO_4$),
Group B =(Nebulized with salbutamol together Normal saline)

Table IV: Mean oxygen Saturation after nebulization according to gender. (n=100)

Oxygen Saturation After 90 minutes	Age groups	Mean	Std. Deviation	t-value	p-value
Group B	Boys	95.29	0.550	0.777	0.441
	Girls	95.17	0.565		
Group A	Boys	96.81	1.111	-0.178	0.860
	Girls	96.87	1.058		

Group A= (Nebulized with salbutamol together with $MgSO_4$),
Group B = (Nebulized with salbutamol together Normal saline)

pediatric respiratory disorders, and if not managed rapidly and effectively, it can lead to severe exacerbations with decreased oxygen saturation, requiring emergency treatment with oxygen therapy, inhaled bronchodilators and corticosteroids. Numerous nebulized therapies with fluctuating efficacy have been investigated for the management of acute severe asthma; however, salbutamol remains the most widely used first-line bronchodilator. In this study the effectiveness of nebulized salbutamol with and without magnesium sulphate (*MgSO4*) was observed in terms of improving the oxygen saturation among children with acute asthma, where both groups were almost similar demographically and clinically, without significant difference in mean age (Group A: 4.60±2.94 years vs. Group B: 4.89±2.51 years, p=0.593), gender distribution (p=0.841), or the severity score (PRAM) (p=0.116).

These findings were supported by the Siddiqui H et al[11], where no significant difference was seen in mean age, gender distribution along with in baseline peak expiratory flow rate, HR, RR and SpO2 in two groups (with and without $MgSO_4$). In accordance with the findings of this study, the Asif R *et al[12] reported statistical insignificant different in* the baseline demographic characteristics, including mean age and gender distribution, across the four treatment groups: salbutamol alone compared with salbutamol combined with different doses of $MgSO_4$ (250 mg, 500 mg and 750 mg $MgSO_4$). The baseline similarity supports the validity of the findings by signifying that differences in oxygen saturation were likely due to the treatment effect of magnesium sulfate rather than demographic or disease-related confounding factors.

In this study, both treatment approaches ultimately restored oxygen levels to within the normal range with children receiving nebulized salbutamol plus magnesium sulphate achieved significantly higher oxygen saturation around (96.84±1.08%) compared to those receiving salbutamol with normal saline (95.24±0.56%) at 90 minutes, (p=0.001). A similar trend was noted by Iqbal S et al[14], where paediatric patients given $MgSO_4$ showed overall greater improvement overall, with mean PASS score fell by 5.3 ± 1.4 points to 4.1 ± 1.6 points in the salbutamol group (p=0.002), together with oxygen saturation more sharply raised in the $MgSO_4$ group, going from 89.3% ± 3.4 up to 96.8% ± 2.1, contrasted to an increase from 89.6% ± 3.6 to 95.2% ± 2.8 in the salbutamol group (p=0.03).[14] Comparable findings were also reported by Sarmin ZU et al[15], where nebulized $MgSO_4$ showed a notable bronchodilator effect, comparable to the salbutamol, in terms of significant rise in oxygen saturation, along with a drop in heart rate without side effects. On the other hand, our finding contrasts directly with the North Indian randomized controlled trial by Siddiqui H et al, where specifically measured SpO2, alongside PEFR, heart rate, and respiratory rate, among 85 children with resulting as, SpO2 improved in both the magnesium sulphate and salbutamol-alone groups, without statistically significant difference, and PEFR likewise increased gradually and significant decrease in heart rates in both groups without significant difference, while the respiratory rate differed significantly between groups only at 24 and 48 hours and SpO2 improved in both groups significantly without substantial difference across the groups.[11] Consistent with the present study, a previous research by Daengsuwan T et al, reported that, both of the nebulized and intravenous $MgSO_4$ technique were observed to be clinically beneficial and safe for Thai children having severe asthma exacerbations, while they did not include a control group for comparison.[16] In the comparison of this study, a Brazilin trail found that pediatric patients treated with magnesium had a significantly higher percentage-predicted peak expiratory flow rate compared to those on standard therapy alone, while a small improvement in the predicted PEFR and respiratory rate, contrasted to the standard medical therapy alone,[17] whereas national trial similarly found that combining salbutamol with higher doses of nebulized magnesium sulphate produced progressively improved clinical outcomes among asthmatic children.[12] Supporting the findings of this study, Aslan M et al[18] a comparison between the study groups revealed that the nebulized magnesium sulfate group showed significantly higher oxygen saturation at hour 1 ($p = 0.024$) and a significantly lower total PRAM score at hour 4 ($p = 0.008$), compared to the standard therapy group, whereas other variables did not showed significant difference across the groups at either the 1st or 4th-hour monitoring ($p > 0.05$). Moreover Ehsan S et al[19] also observed consisting findings, where patients initially received standard treatment according to established protocols; those who showed inadequate response to the initial therapy were subsequently given intravenous (I/V) magnesium sulfate infusion and found effective treatment outcomes by I/V route when added to conventional treatment, whereas they did compare control group.[19 11,20,21] However Masud S et al[22] concluded that there was a significant improvement in clinical outcomes in patients treated with nebulized magnesium sulfate compared to those nebulized with salbutamol and normal saline in the treatment of acute bronchiolitis.

Additionally, according to post stratification analysis older children (7–12 years) achieved significantly higher post-treatment SpO2 than younger children (2–6 years in salbutamol with normal saline group, whereas the effectiveness was insignificant in the

magnesium sulphate group (p=0.224). No previous study has specifically compared or evaluated this particular age pattern. Likewise our findings did not find any significant difference between the groups when stratified by gender; the both boys and girls showed almost similar oxygen saturation levels after treatment (p = 0.441 in the control group and p = 0.860 in the $MgSO_4$group). The findings were consistent with previous studies, which also reported that gender was not a significant predictor of treatment response or clinical outcomes among pediatric patients with acute asthma.[11,12,17]

Overall recent research evidences, support the findings of this study with growing evidence that nebulized magnesium sulfate, when added to salbutamol, may improve physiological parameters such as oxygen saturation and peak flow, while some studies did not observe this advantage and these variations are likely caused by variations in patient severity at presentation, higher difference in the sample size of the studies, sample selection criteria, magnesium dosing, and the specific outcome measures used. Additionally, its effect on other major clinical outcomes, including hospitalization rates and overall severity scores, was not analyzed in this study, which was also limited by a relatively small sample size, suggesting further locally relevant, well-designed comprehensive trials are very important to clarify the actual clinical value of magnesium sulphate among pediatric patients with acute asthma.

Conclusion

According to the study findings, both treatment approaches ultimately restored oxygen levels to within the normal range, with the combination of nebulized magnesium sulphate and salbutamol achieving significantly better oxygen saturation at 90 minutes, along with, the recovery in oxygen saturation remaining consistent across both age groups and genders. The findings support the use of nebulized magnesium sulphate as a valuable adjunct to standard salbutamol therapy in the management of acute asthma in children, potentially offering faster and more reliable clinical improvement.

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