Section: Paediatrics

Original Research Article

EFFECTIVENESS AND SAFETY OF ADD ON-NEBULIZED MgSO4 WITH SALBUTAMOL AND SALBUTAMOL ALONE IN BRONCHIAL ASTHMA MANAGEMENT IN CHILDREN OF 6-12 YEARS. A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Acute aggravations of bronchial asthma signify an important causative factor for hospitalisations among school-aged children. Nebulised salbutamol is considered the primary treatment option, while a few patients do not respond sufficiently. Hence, alternative Nebulised magnesium sulfate ($MgSO_4$), having bronchodilatory and anti-inflammatory properties, has emerged as an adjunct therapy; yet evidence in children aged 6–12 years is still limited. **Objectives:** To evaluate the effectiveness and safety of nebulised magnesium sulphate combined with salbutamol associated with salbutamol alone in children aged 6–12 years suffering from acute bronchial asthma. **Materials and Methods:** This randomised controlled trial was conducted in the pediatric ward of a tertiary care hospital in Puducherry for a period of 18 months. A total of 126 progenies aged 6–12 years with acute bronchial asthma were included in the study and divided into two groups: Group A received nebulised magnesium sulfate along with salbutamol, while Group B received nebulised salbutamol alone. The Clinical Severity Score (CSS), duration of hospital stay (LOS), and adverse events were assessed. Statistical analysis was performed using independent t-tests and Chi-square tests. **Results:** The baseline characteristics exhibited comparability across the groups. Group A exhibited a markedly greater decrease in CSS starting from Day 1 ($p < 0.001$). The mean CSS at discharge was 0.3 ± 0.5 for Group A, in contrast to 0.9 ± 0.7 for Group B. The average duration of hospital stay was notably reduced in Group A (48.3 ± 18.2 hours) compared to Group B (62.1 ± 22.4 hours; $p < 0.001$). No significant adverse events were noted. **Conclusion:** The use of nebulised magnesium sulphate alongside salbutamol has been shown to enhance clinical recovery and decrease hospital duration in children aged 6–12 years suffering from acute bronchial asthma, without introducing additional safety issues.

INTRODUCTION

Bronchial asthma is among the most common chronic respiratory conditions in children and is a primary reason for emergency visits and hospitalisations. The prevalence among school-aged children in India varies from 2.7% to 13.1%, with acute exacerbations significantly impacting morbidity and the healthcare system.[1]

Nebulised salbutamol serves as the primary treatment for acute asthma exacerbations, owing to its swift bronchodilatory effects. Nonetheless, insufficient response in moderate to severe cases requires additional therapeutic interventions. Magnesium sulphate acts as a calcium antagonist, helping to relax airway smooth muscles and reduce inflammation. Intravenous magnesium sulphate is useful in severe asthma management, while nebulised magnesium delivers the drug directly to the airways and is considered safe.[2]

The evidence regarding the usage of nebulised magnesium sulphate in offspring is inconsistent,

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especially within the 6–12-year age group. This learning sought to measure the efficacy and security of nebulised magnesium sulphate as a supplementary treatment to salbutamol in managing acute bronchial asthma in school-aged children.[3]

MATERIALS AND METHODS

A randomised controlled trial was conducted in the paediatric ward of Aarupadai Veedu Medical College & Hospital, Puducherry. Participants in the study included children between the ages of 6 and 12 years who were experiencing acute bronchial asthma. Individuals under the age of six and those with cardiac conditions or other notable comorbidities were excluded. A total of 126 children were enrolled, with 63 participants in each group, determined through power analysis, assuming a clinically substantial change in peak expiratory flow rate. Participants were assigned to two equal groups through computer-generated randomisation sequences. Participants and outcome assessors were kept unaware of group allocation.

Group A: Nebulised salbutamol (2.5 mg) combined with magnesium sulfate (100 mg, 4% solution)

Group B: Nebulised salbutamol (2.5 mg) mixed with isotonic saline

Nebulisation was provided four times a day at 20-minute intervals.

The main outcome measured was the change in Clinical Severity Score (CSS). Secondary outcomes included the length of hospital stay and the occurrence of adverse events.

Data analysis was performed using SPSS version 25. Continuous variables were expressed as mean ± SD. Independent t-tests and Chi-square tests were used for statistical analysis, and a $p < 0.05$ was considered statistically significant.

RESULTS

A total of 126 participants were included in the study. At the beginning of the study, both groups had similar demographic and clinical characteristics. Compared to Group B Group A showed a significantly greater improvement in Clinical Severity Score (CSS) from admission to discharge ($p < 0.001$). The mean reduction in CSS at discharge was 92.7% in Group A, while Group B showed a reduction of only 78.6%.

Table 1: Comparison of CSS between the groups

Metric	Group A	Group B
CSS Reduction (%)	92.7	78.6

The average duration of hospital stay was significantly shorter in Group A (48.3 ± 18.2 hours) compared to Group B (62.1 ± 22.4 hours; $p < 0.001$). More patients in Group A (60.3%) were discharged within 48 hours, whereas only 34.9% of patients in Group B were discharged early. No significant adverse events were reported in either group.

Table 2: Duration of Hospital Stay

Duration (hours, mean ± SD)	Group A	Group B
Hospital Stay	48.3 ± 18.2	62.1 ± 22.4

DISCUSSION

This study shows that nebulised magnesium sulphate, when used along with salbutamol, helps improve recovery and shortens hospital stay in children aged 6–12 years with acute asthma. Both groups had similar baseline characteristics, which supports the reliability of the study results.[4]

Clinical Improvement

Group A showed greater improvement in Clinical Severity Score (92.7% reduction vs 78.6%, $p<0.001$) and shorter hospital stays (48.3 vs 62.1 hours, $p<0.001$) compared to Group B. This may be because magnesium helps relax bronchial smooth muscles by blocking calcium entry, leading to faster bronchodilation. It also reduces inflammation by stabilising mast cells and decreasing the release of inflammatory substances such as histamine and leukotrienes. Unlike previous meta-analyses that showed only minimal improvement in CSS, this study demonstrated clear symptom improvement, possibly due to differences in dosing or population characteristics.[5,6]

Comparison to other studies

Many randomised controlled trials (RCTs) have shown only small improvements in lung function with nebulised magnesium sulphate, such as a slight improvement in PEFR in children, but without reducing hospital admissions. An Indian study involving 85 children aged 6–14 years found no significant differences in PEFR after using 95 mg nebulised magnesium sulphate, although respiratory rates improved after 24–48 hours. Studies using higher doses of magnesium sulphate (250–750 mg) showed better improvement in PRAM scores, similar to the marked reduction in CSS and the 60.3% early discharge rate seen in this study. Meta-analyses of intravenous magnesium sulphate have also shown reduced hospital admissions, suggesting that nebulised magnesium may provide similar benefits by acting directly on the airways in selected cases.[7-10]

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Safety and Implications

No significant adverse events were observed in this study, similar to previous systematic reviews where minor side effects such as hypotension were rare (1–2%) and comparable to placebo. This supports the safety of nebulised magnesium sulphate. Evidence from 10 randomised controlled trials involving 2301 children also supports its use in moderate to severe asthma attacks that do not respond well to salbutamol alone. Future studies should use standardised doses and uniform Clinical Severity Scores (CSS) methods to reduce differences between global studies.[11]

CONCLUSION

Nebulised magnesium sulphate, when given along with salbutamol, is a safe and effective additional treatment for severe bronchial asthma in children aged 6-12 years. It helps children recover faster and reduces the length of hospital stay, making it a useful treatment option, especially in resource – limited settings.

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