

Comparison of Outcome in Salbutamol Delivery through Metered Dose Inhaler versus Nebulizer in Children with Severe Acute Exacerbation of Asthma

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Abstract: Asthma is one of the most common chronic respiratory diseases among children worldwide, and severe acute exacerbations remain a leading cause of morbidity and healthcare utilization. Salbutamol, a short-acting β_2 -agonist, is the mainstay of therapy, commonly delivered either by nebulizer or metered-dose inhaler (MDI) with a spacer. The optimal delivery method for children, particularly in resource-limited settings like Pakistan, remains debated. **Objective:** To compare the efficacy of salbutamol delivered via nebulizer versus MDI with a spacer in children presenting with severe acute asthma exacerbations. **Methods:** This randomized controlled trial was conducted at the Department of Pediatric Medicine, Ibn-e-Siena Hospital, Multan, over a six-month period from May 2024 to October 2024. A total of 104 children aged 5–15 years with severe acute exacerbation of asthma (Pulmonary Score ≥ 7) were randomized into two groups: nebulizer ($n=52$) and MDI with spacer ($n=52$). Baseline demographic and clinical characteristics were recorded. All participants received adjunctive intravenous methylprednisolone and magnesium sulfate. The primary outcome was a reduction in respiratory rate at 20 minutes. Secondary outcomes included the change in pulmonary score at 4 hours and the requirement for hospitalization. Data were analyzed using SPSS version 23, with $p < 0.05$ considered significant. **Results:** The mean age of participants was 9.8 ± 2.7 years; 60.6% were male. At 20 minutes, the MDI group demonstrated a significantly greater reduction in respiratory rate compared to the nebulizer group (8.6 ± 2.4 vs. 6.9 ± 2.7 breaths/min, $p = 0.002$). At 4 hours, the MDI group had a lower mean pulmonary score (3.1 ± 1.2 vs. 3.8 ± 1.4 , $p = 0.01$). Hospitalization was required in 7.7% of children in the MDI group, compared to 17.3% in the nebulizer group, although this difference was not statistically significant ($p = 0.14$). Stratified analyses confirmed consistent superiority of MDI across most subgroups. **Conclusion:** MDI with a spacer proved more effective than a nebulizer in improving short-term respiratory outcomes in children with severe acute asthma exacerbations. Given its comparable efficacy, ease of use, and reduced need for specialized equipment, MDI with a spacer represents a practical and effective alternative to nebulization in resource-constrained pediatric emergency settings.

Keywords: Asthma, Children, Salbutamol, Nebulizer, Metered-dose inhaler, Randomized controlled trial, Pakistan

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Introduction

Asthma is a prevalent chronic respiratory condition characterized by airway inflammation and bronchoconstriction, which affects millions of children worldwide. According to the Global Initiative for Asthma (GINA), asthma exacerbations, particularly severe acute exacerbations, represent a significant cause of morbidity and health system utilization among pediatric populations. The management of acute asthma exacerbations often involves the administration of bronchodilators such as salbutamol, a short-acting β_2 -adrenergic agonist, which effectively alleviates bronchospasm. Standard delivery methods for salbutamol include nebulization and metered-dose inhalers (MDIs) with spacers. Each method presents unique advantages and disadvantages that can impact treatment outcomes in children (1,2).

Recent studies have increasingly focused on comparing the efficacy of nebulizers to MDIs, particularly in subsets like children experiencing acute exacerbations of asthma. A randomized clinical trial found that the combined use of nebulized salbutamol and ipratropium was frequently associated with more adverse effects than its administration via an MDI, where children showed better tolerance and comparable efficacy (1). Furthermore, another study has emphasized the central role of inhaled beta2-adrenergic agonists in asthma management (3). Additionally, it has been demonstrated that continuous nebulization may provide sustained bronchodilation in acute exacerbations, but intermittent dosing delivered

via MDIs showed similar effectiveness, suggesting potential advantages for the latter in reducing resource use and improving patient experience (4). The pediatric population, particularly in regions such as Pakistan, faces unique health service challenges related to asthma management, including access to advanced medical technologies for nebulization and concerns surrounding proper inhaler technique. One study noted the variability in nebulization practices in rural areas, suggesting that MDIs may be underutilized despite their advantages in emergency settings due to misconceptions regarding their efficacy compared to nebulization (5). Studies have also indicated that appropriate techniques in using spacers with MDIs can yield outcomes comparable to nebulizers while minimizing costs and the need for specialized equipment (5, 6).

The impact of socioeconomic factors further complicates asthma care in Pakistan, where healthcare facilities may not always be equipped to provide nebulization during acute attacks or where treatment protocols may vary substantially among practitioners. This inconsistency may lead to suboptimal management of severe acute exacerbations. Research supports the need for standardized protocols that leverage available technology and pharmacotherapy effectively, thereby decreasing hospital admission rates and enhancing clinical outcomes for children experiencing asthma exacerbations (7).

In summary, while both nebulization and MDI with spacer administration of salbutamol are effective for treating acute asthma exacerbations in children, ongoing research and clinical evaluations are essential to



determine the contextually appropriate delivery method in diverse settings. Comprehensive strategies that consider local healthcare capabilities and patient education regarding inhaler technology could significantly enhance asthma management, particularly in developing regions such as Pakistan.

The understanding of optimal salbutamol delivery mechanisms in children with severe acute exacerbations of asthma is crucial for improving clinical outcomes in Pakistan, where access to healthcare and treatment modalities may be inconsistent. Investigating the comparative efficacy of nebulization versus MDI can inform healthcare policy, optimize resource allocation, and improve pediatric asthma management strategies.

Methodology

The present randomized controlled trial was conducted in the Department of Pediatric Medicine at Ibn-e-Siena Hospital, Multan, over six months from May 2024 to October 2024, following approval of the study protocol by the institutional ethics review committee. Children aged 5 to 15 years who presented with a severe acute exacerbation of asthma were considered eligible for enrollment. The diagnosis of severe asthma was established using the Pulmonary Score, with a score of seven or above classified as severe. Patients of either gender with an acute exacerbation of asthma of less than or equal to twelve hours' duration were included. Exclusion criteria comprised children with known pulmonary or cardiac congenital malformations, those with bronchopulmonary dysplasia, cystic fibrosis, or post-infectious bronchiolitis obliterans, as well as children presenting with altered mental status suggestive of imminent respiratory failure.

The sample size was calculated using OpenEpi software based on the expected mean differences in respiratory rate reduction between treatment modalities, with a study power of 80% and a 95% confidence level. A total of 104 patients were required and subsequently recruited through non-probability consecutive sampling, with 52 children allocated to each group. Written informed consent was obtained from the parents or guardians of all participating children. Baseline demographic data, including age, gender, history of parental asthma, duration of asthma diagnosis, and use of asthma controller medications such as inhaled corticosteroids, long-acting beta-agonists, or montelukast, were documented. Baseline pulmonary scores and respiratory rates were also recorded at the time of presentation.

After initial stabilization, all enrolled children received adjunctive therapy consisting of intravenous methylprednisolone at a dose of 1 mg/kg and magnesium sulfate at 50 mg/kg within the first hour. Randomization into treatment arms was performed using the lottery method, with sealed opaque envelopes. Children assigned to the nebulizer group were administered salbutamol as a 0.5% aerosol solution (0.15 mg/kg body weight, up to a maximum of 5 mg) in 5 mL of normal saline, delivered via jet nebulizer with compressed air at 5 L/min and supplemental oxygen at 3 L/min through a Y-connection. The treatment was given every 20 minutes for the first 2 hours and subsequently every 30 minutes for the next 2 hours. Children in the metered dose inhaler group received two puffs of salbutamol (100 µg/puff) via MDI with a valved holding chamber and mask every 10 minutes for 2 hours, followed by every 30 minutes for another 2 hours. Oxygen supplementation was provided separately via

nasal cannula. After each puff, children were instructed to perform eight tidal inhalations to ensure optimal drug delivery.

Outcomes were assessed by a pediatrician who was blinded to the treatment allocation. The primary outcome was the reduction in respiratory rate at 20 minutes after initiation of therapy. Secondary outcomes included the change in pulmonary score at 4 hours of treatment and the requirement for hospitalization. Children fulfilling the hospitalization criteria, as defined by the operational definition, were admitted and managed in the pediatric intensive care unit. Those who improved were discharged with controller medications and advice regarding maintenance therapy.

All collected data were entered into a predesigned proforma and subsequently analyzed using SPSS version 23. Normality of numerical data was determined using the Shapiro–Wilk test. Continuous variables, such as age, duration of asthma diagnosis, baseline pulmonary score, and respiratory rate, were presented as means ± standard deviations. Categorical variables, including gender, parental history of asthma, controller use, and hospitalization status, were presented as frequencies and percentages. The independent sample t-test was used to compare the mean reduction in respiratory rate between groups, with a p-value of less than 0.05 considered statistically significant. Stratified analyses were performed by age, gender, parental asthma, use of controller medications, and duration of asthma diagnosis to identify potential effect modifiers. Post-stratification comparisons were made using independent sample t-tests.

Results

A total of 104 children aged 5–15 years with a severe acute exacerbation of asthma were enrolled and randomized into two equal groups: a nebulizer group (n = 52) and a metered-dose inhaler (MDI) with spacer group (n = 52). The overall mean age of participants was 9.8 ± 2.7 years. Males constituted 63 (60.6%), while females comprised 41 (39.4%), with a comparable gender distribution between the groups. A history of parental asthma was present in 29 (27.9%) children. The mean duration of asthma diagnosis was 3.2 ± 1.8 years, and the baseline pulmonary score averaged 8.4 ± 1.1, with no statistically significant difference between the two groups. (Table 1).

At 20 minutes after intervention, children in the MDI group had a greater mean reduction in respiratory rate (8.6 ± 2.4 breaths/min) compared with the nebulizer group (6.9 ± 2.7 breaths/min). This difference was statistically significant (p = 0.002). (Table 2).

At 4 hours of therapy, the mean pulmonary score improved significantly in both groups. The MDI group demonstrated a lower mean pulmonary score (3.1 ± 1.2) compared with the nebulizer group (3.8 ± 1.4, p = 0.01). Hospitalization was required in 9 (17.3%) patients in the nebulizer group compared to 4 (7.7%) in the MDI group, though the difference did not reach statistical significance (p = 0.14). No significant adverse effects were reported. (Table 3).

Stratification by age group, gender, parental asthma history, controller medication use, and duration of asthma diagnosis showed consistent benefit of MDI over nebulizer in terms of respiratory rate reduction. The superiority of MDI was statistically significant across most subgroups, except in children with parental asthma, where the difference was not significant (p = 0.09). (Table 4).

Table 1. Demographic and baseline characteristics of study participants (n=104)

Variable	Nebulizer group (n=52)	MDI group (n=52)	Total (n=104)	p-value
Age (years), mean ± SD	9.9 ± 2.6	9.7 ± 2.8	9.8 ± 2.7	0.71
Gender, n (%)	Male: 32 (61.5%) Female: 20 (38.5%)	Male: 31 (59.6%) Female: 21 (40.4%)	Male: 63 (60.6%) Female: 41 (39.4%)	0.84
Parental asthma, n (%)	15 (28.8%)	14 (26.9%)	29 (27.9%)	0.82
Duration of asthma diagnosis (years), mean ± SD	3.3 ± 1.7	3.1 ± 1.9	3.2 ± 1.8	0.64
Baseline pulmonary score, mean ± SD	8.5 ± 1.0	8.3 ± 1.2	8.4 ± 1.1	0.39

Table 2. Comparison of the mean reduction in respiratory rate at 20 minutes

Outcome	Nebulizer group (n=52)	MDI group (n=52)	p-value
Reduction in respiratory rate at 20 minutes (breaths/min), mean $\pm$ SD	6.9 $\pm$ 2.7	8.6 $\pm$ 2.4	0.002*

*Independent sample t-test applied, $p < 0.05$ considered significant.

Table 3. Secondary outcomes in both groups

Outcome	Nebulizer group (n=52)	MDI group (n=52)	p-value
Pulmonary score at 4 hours, mean $\pm$ SD	3.8 $\pm$ 1.4	3.1 $\pm$ 1.2	0.01*
Hospitalization required, n (%)	9 (17.3%)	4 (7.7%)	0.14

Table 4. Stratified analysis of respiratory rate reduction at 20 minutes

Variable	Subgroup	Nebulizer group, mean $\pm$ SD	MDI group, mean $\pm$ SD	p-value
Age group	5–10 years	6.7 $\pm$ 2.6	8.5 $\pm$ 2.5	0.004*
	11–15 years	7.1 $\pm$ 2.9	8.7 $\pm$ 2.3	0.01*
Gender	Male	6.8 $\pm$ 2.8	8.5 $\pm$ 2.5	0.003*
	Female	7.0 $\pm$ 2.6	8.8 $\pm$ 2.3	0.002*
Parental asthma	Yes	6.9 $\pm$ 2.4	8.0 $\pm$ 2.6	0.09
	No	6.8 $\pm$ 2.8	8.7 $\pm$ 2.3	0.002*
Controller use	Yes	6.7 $\pm$ 2.5	8.4 $\pm$ 2.4	0.01*
	No	7.1 $\pm$ 2.9	8.8 $\pm$ 2.3	0.002*
Duration of asthma diagnosis	≤ 3 years	6.8 $\pm$ 2.7	8.7 $\pm$ 2.4	0.003*
	> 3 years	7.0 $\pm$ 2.6	8.5 $\pm$ 2.5	0.01*

Discussion

In this study, we conducted a comparative analysis of the efficacy of salbutamol delivery through a nebulizer versus a metered-dose inhaler (MDI) with a spacer in treating severe acute exacerbations of asthma in children aged 5 to 15 years. The results we obtained highlighted significant findings, particularly concerning the reduction in respiratory rate and pulmonary scores at various time intervals following the intervention. The discussion will highlight these findings sequentially, drawing on current literature to ensure a comprehensive understanding of our results within the broader context of asthma management.

The demographic breakdown of our study participants revealed a mean age of 9.8 ± 2.7 years, with a slightly higher prevalence of males (60.6%). This gender distribution aligns with findings from Kirenga et al., who identified a higher prevalence of asthma exacerbations among boys compared to girls, emphasizing similar patterns in pediatric asthma populations (2018) (8). The presence of parental asthma in about 27.9% of our participants is consistent with previous studies indicating that a family history of asthma significantly increases the likelihood of severe exacerbations in children⁹. In terms of asthma duration, our mean duration of 3.2 ± 1.8 years echoes the findings of (9). Who noted that children with longer documented histories of asthma were at increased risk of exacerbations due to possible deterioration in control levels over time (9).

Both treatment groups exhibited comparable baseline characteristics, which reinforces the randomized nature of our study design and provides confidence in the comparability of outcomes across groups. Such a methodological structure is vital in delivering evidence-based recommendations in clinical practices, as noted by Papadopoulos et al., who emphasized the need for rigorous methodologies in studies evaluating pediatric asthma treatments amid variable response rates (10). At the 20-minute mark after intervention, our findings indicated that the MDI group exhibited a greater mean reduction in respiratory rate (8.6 ± 2.4 breaths/min) compared to the nebulizer group (6.9 ± 2.7 breaths/min), with this difference being statistically significant ($p = 0.002$). The superiority of MDI in achieving a more substantial initial response aligns with the work of Xu et al., who performed a meta-analysis indicating that MDIs can deliver quicker and more efficient bronchodilation (11). Their research also suggested that MDIs, when administered adequately with a spacer, provide a more effective aerosol delivery to the lungs, which could explain the superior outcomes observed in our study (11).

Moreover, our subgroup analysis by age confirmed the favorable efficacy of MDI across different age categories. Specifically, children aged 5–10 years and those aged 11–15 years achieved statistically significant reductions in respiratory rate compared to their nebulizer counterparts. This particular finding contributes to the discourse by aligning with the observations made by (12). Supporting that younger children tend to respond quicker to MDI treatments due to the efficient deposition of medication within their smaller airways (12).

Further supporting our primary outcomes, the pulmonary scores recorded at 4 hours demonstrated significant improvement in both groups. Still, the MDI group achieved a more favorable outcome with a lower mean pulmonary score (3.1 ± 1.2) compared to the nebulizer group (3.8 ± 1.4), which was statistically significant ($p = 0.01$). This finding is representative of previous investigations, such as that by (13). Which highlighted that MDI administration was linked to improved clinical scores in pediatric asthma and enhanced lung function assessments relative to nebulizer use (13). Their findings strongly advocated for the integration of MDIs in acute asthma management protocols in children, which aligns with our results indicating better overall clinical improvement.

Though hospitalization rates were lower in the MDI group (7.7% compared to 17.3%), the absence of statistical significance ($p = 0.14$) warrants perception within a larger context—suggesting both delivery methods were effective but requiring additional research for broader generalizations (14). In a similar vein, Sobieraj et al. noted that while there might be trends favoring one treatment modality over another in terms of hospitalization, variability in response among individuals remains significant (14).

Our stratified analysis provides an added layer of comprehensiveness, revealing a consistent advantage of MDI over nebulizer use across various subgroups, such as by gender and controller medication use. Notably, while comparisons based on parental asthma history did not yield significant differences, this highlights an area for further research, as noted by Papadopoulos et al., which stressed the variability in procedural efficacy among children whose familial history influences disease management (10).

The consistent findings across variables including age, gender, and duration of asthma Diagnosis emphasize a nuanced understanding of asthma exacerbation management, aligning with the observations made by Jorup et al. in advocating more personalized approaches to asthma therapy dependents on demographic and clinical histories (12). Thus, our

results contribute to ongoing discussions regarding interventions tailored to patient demographics to optimize efficacy.

The implications of our study have practical relevance, particularly within the Pakistani healthcare context, where access to nebulization equipment may be limited. Our findings suggest that MDIs, when effectively utilized, serve as a capable alternative for treating severe acute asthma exacerbations in pediatric populations. Hussain et al. have further argued that adopting MDI practices could enhance treatment accessibility while potentially lowering healthcare costs associated with nebulization setups (15).

Thus, our findings substantiate the emerging consensus that MDIs provide not only comparable but often superior respiratory management outcomes in pediatric asthma exacerbations when juxtaposed against nebulizers. Strong advocacy for optimizing such evidence-based practices is essential to foster more effective, accessible, and beneficial asthma care for children facing the challenges posed by acute exacerbations.

Conclusion

This study demonstrates that salbutamol delivered via MDI with a spacer is superior to nebulization in improving acute respiratory parameters among children with severe asthma exacerbations. MDI use can reduce reliance on nebulization equipment, lower costs, and enhance treatment accessibility, making it a viable and effective strategy for asthma management in resource-limited healthcare systems, such as those in Pakistan.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-24)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

NQ (PGR)

Manuscript drafting, Study Design,

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Review of Literature, Data entry, Data analysis, and drafting article.

AJ (Associate Professor)

Conception of Study, Development of Research Methodology Design,

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Study Design, manuscript review, critical input.

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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