

Metered Dose Inhaler with Spacer and Dry Powder Inhaler for Delivery of Salbutamol in Acute Exacerbation of Asthma: A Comparative Study

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Received: 10-01-2025 / Revised: 23-01-2025 / Accepted: 24-02-2025

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Conflict of interest: Nil

Abstract:

Background: Acute exacerbations of asthma in children are common emergencies requiring prompt and effective bronchodilator delivery. Among the most widely used options are the metered dose inhaler (MDI) with spacer and the dry powder inhaler (DPI), both used to administer salbutamol.

Objective: This study aimed to compare the clinical efficacy, onset of symptom relief, and patient compliance of salbutamol delivered via MDI with spacer versus DPI in children experiencing acute asthma exacerbations.

Methods: This prospective, comparative study was conducted in the Paediatric Department of Patna Medical College and Hospital between Nov 2022 and October 2023. A total of 130 children aged 5 to 12 years with mild to moderate acute asthma exacerbation were randomized into two equal groups to receive salbutamol via either MDI with spacer or DPI. Key outcomes including improvement in PEFR (Peak Expiratory Flow Rate), respiratory rate, and clinical asthma scores were assessed at baseline, 15, 30, and 60 minutes post-intervention.

Results: Both delivery methods resulted in significant improvement in PEFR and reduction in asthma scores. However, MDI with spacer showed a statistically faster onset of symptom relief within the first 15 minutes ($p < 0.05$). Compliance was higher in the MDI group, especially in younger children.

Conclusion: Both MDI with spacer and DPI are effective for bronchodilator delivery in pediatric asthma exacerbations. However, MDI with spacer offers earlier symptom relief and better compliance in younger children, making it a preferable choice in acute settings.

Keywords: Acute Asthma, Salbutamol, Metered Dose Inhaler, Spacer, Dry Powder Inhaler, Pediatric, Bronchodilator Therapy.

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Introduction

Asthma is one of the most prevalent chronic respiratory diseases affecting children worldwide. Characterized by episodic airway obstruction, bronchial hyperresponsiveness, and inflammation, it significantly contributes to pediatric morbidity, school absenteeism, and healthcare utilization. Acute exacerbations of asthma remain a common reason for emergency visits and hospital admissions, necessitating prompt and effective management to reduce the risk of complications and recurrence [1]. Inhaled β_2 -agonists, such as salbutamol, form the cornerstone of acute asthma management due to their rapid bronchodilatory action. The efficacy of salbutamol largely depends on the mode of delivery, which determines how efficiently the drug reaches the lower airways. Two commonly employed devices for administering salbutamol are the metered dose inhaler (MDI) with spacer and the dry powder inhaler (DPI). While both are recommended in various guidelines for the management of asthma in children, their relative effectiveness in acute exacerbations continues to be a subject of clinical interest and research [2].

MDI with spacer is often advocated in pediatric practice because it minimizes oropharyngeal deposition and enhances pulmonary drug delivery, especially in younger children who may lack the coordination needed for conventional inhalers [3]. Spacers also reduce the need for propellant-driven deep inspiration, making them suitable for use during respiratory distress. On the other hand, DPIs are breath-actuated devices that do not require coordination between actuation and inhalation, offering an alternative for children above a certain age with adequate inspiratory flow. However, the effectiveness of DPI may be compromised during acute exacerbations due to reduced inspiratory effort [4].

Several studies have suggested that MDI with spacer may be as effective as nebulization in mild to moderate asthma exacerbations, with additional benefits such as lower cost, portability, and fewer side effects [5]. However, direct comparisons between MDI with spacer and DPI in acute pediatric asthma settings, particularly in resource-limited

environments like India, remain limited. Moreover, device preference, ease of use, symptom relief time, and patient cooperation are critical determinants of clinical outcomes in emergency settings [6].

This study was therefore undertaken to comparatively evaluate the effectiveness of MDI with spacer and DPI for the delivery of salbutamol in children with acute asthma exacerbations. The aim was to assess and compare clinical outcomes, including improvement in peak expiratory flow rate (PEFR), reduction in respiratory distress, and user compliance, thereby contributing to optimized, evidence-based asthma care in pediatric populations.

Aim

To evaluate and compare the clinical efficacy, onset of action, and user compliance of salbutamol administered via Metered Dose Inhaler (MDI) with spacer and Dry Powder Inhaler (DPI) in children with acute exacerbation of asthma.

Objectives

1. To assess the improvement in clinical parameters, including Peak Expiratory Flow Rate (PEFR) and respiratory rate, following salbutamol administration via MDI with spacer and DPI.
2. To compare the onset of symptom relief and duration of clinical improvement between the two delivery devices.
3. To evaluate patient compliance, ease of use, and suitability of each device across different pediatric age groups.
4. To determine the safety and adverse event profile associated with each method of salbutamol delivery during acute asthma episodes.

Methods

Study Design and Setting: This was a prospective, comparative, interventional study conducted in the Department of Paediatrics at Patna Medical College and Hospital, Patna, Bihar. The study was carried out over a one-year period from Nov 2022 and October 2023.

Study Population: Children aged between 5 and 12 years presenting to the emergency department or outpatient unit with mild to moderate acute exacerbation of asthma were considered for inclusion. The diagnosis of asthma and classification of exacerbation severity were based on standard clinical criteria, including history of recurrent wheeze, response to bronchodilators, and examination findings consistent with bronchospasm.

Sample Size: A total of 130 children were enrolled in the study, with 65 children allocated to each group. The sample size was determined to provide adequate statistical power to detect a clinically

meaningful difference in PEFR improvement between the two groups, while maintaining feasibility within the study period.

Inclusion Criteria:

- Children aged 5 to 12 years
- Clinically diagnosed with mild to moderate acute asthma exacerbation
- Ability to use MDI with spacer or DPI after brief demonstration
- Parental/guardian consent obtained

Exclusion Criteria:

- Severe asthma exacerbation requiring immediate intensive intervention
- Children with associated respiratory conditions (e.g., pneumonia, bronchiolitis)
- Known cardiac illness or congenital anomalies
- Inability to perform PEFR reliably due to age or cooperation issues
- Hypersensitivity to salbutamol

Randomization and Intervention:

Eligible participants were randomly assigned into two equal groups using simple random sampling:

- **Group A:** Received salbutamol via MDI with spacer (2 puffs = 200 mcg)
- **Group B:** Received salbutamol via DPI (200 mcg equivalent dose)

All children were first trained and demonstrated the correct use of the assigned inhalation device. The drug was administered under supervision to ensure proper technique.

Assessment and Outcome Measures:

Clinical evaluation and PEFR measurements were conducted at the following time intervals:

- Baseline (before drug administration)
- 15 minutes post-intervention
- 30 minutes post-intervention
- 60 minutes post-intervention

The primary outcome measure was improvement in PEFR. Secondary outcomes included reduction in respiratory rate, wheezing severity (graded on a clinical asthma score), onset of symptomatic relief, and patient compliance.

Equipment and Measurements: PEFR was measured using a pediatric peak flow meter, and the best of three attempts was recorded. Compliance was assessed by observing technique and caregiver feedback. Adverse events, if any, were documented.

Statistical Analysis: Data were entered and analyzed using SPSS version 27. Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables as frequencies and percentages. Between-group

comparisons were made using the independent t-test for continuous variables and Chi-square test for categorical variables. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations: The study was approved by the Institutional Ethics Committee of Patna Medical College and Hospital. Written informed consent was obtained from the parent or legal guardian of each participant prior to enrollment.

Results

A total of 130 children with acute exacerbation of asthma were enrolled and equally divided into two groups: Metered Dose Inhaler (MDI) with spacer (n=65) and Dry Powder Inhaler (DPI) (n=65). Both groups were comparable in demographic and

baseline clinical characteristics, including age, gender distribution, baseline peak expiratory flow rate (PEFR), and respiratory rate. Salbutamol delivery via MDI with spacer resulted in significantly faster improvement in PEFR and clinical asthma scores compared to DPI, especially within the first 30 minutes of treatment. Respiratory rate decreased significantly in both groups without intergroup differences. Younger children demonstrated better compliance and correct device use with MDI plus spacer, reflected in higher patient and caregiver satisfaction scores. Both devices showed comparable safety profiles with minimal adverse effects. Although fewer children in the MDI group required repeat bronchodilator dosing within 2 hours, this difference was not statistically significant.

Table 1: Age-wise distribution of study participants

Age group (years)	Group A: MDI with Spacer (n = 65)	Group B: DPI (n = 65)	Total (n = 130)
5–7	24	23	47
8–10	21	22	43
11–12	20	20	40

Table 1 shows that the study population was well-matched in terms of age distribution. The majority of patients in both groups were between 5 and 10 years old. This ensured comparability when assessing device usability and efficacy. Equal

representation across younger and older children allowed for meaningful subgroup analysis, particularly in compliance and preference-related outcomes.

Table 2: Gender-wise distribution of participants

Gender	Group A: MDI with Spacer	Group B: DPI	Total
Male	38	36	74
Female	27	29	56

Table 2 indicates a nearly equal gender distribution between both groups. Males comprised 56.9% of the total study population. This balance reduced gender-based confounding in outcome interpretation, such

as preference or compliance. No significant gender bias was observed in clinical or subjective outcomes throughout the study.

Table 3: Baseline PEFR values between groups

Group	Mean PEFR ± SD (L/min)
MDI (Group A)	122.6 ± 21.3
DPI (Group B)	120.8 ± 22.1
p-value	0.58

Table 3 shows comparable baseline PEFR values between both groups (p = 0.58). This confirms that children in both arms had similar severity of airway

obstruction prior to salbutamol administration. This baseline parity validates further comparative analysis of treatment response.

Table 4: Reduction in respiratory rate over time

Time Point	Group A: MDI (breaths/min)	Group B: DPI (breaths/min)	p-value
Baseline	34.5 ± 3.9	34.8 ± 4.1	0.72
15 min	30.6 ± 3.6	31.2 ± 3.9	0.41
30 min	28.3 ± 3.2	28.9 ± 3.5	0.38
60 min	26.2 ± 3.4	27.1 ± 3.7	0.29

Table 4 demonstrates a steady decline in respiratory rate in both groups over 60 minutes. Within-group

reduction was statistically significant (p < 0.001 for both), but no statistically significant difference was

noted between groups at any time point ($p > 0.05$). This suggests that both devices were equally effective in improving respiratory distress.

Table 5: Asthma score trends over 60 minutes

Time Point	MDI Group (Mean \pm SD)	DPI Group (Mean \pm SD)	p-value
Baseline	6.1 \pm 1.4	6.3 \pm 1.2	0.32
15 min	4.5 \pm 1.2	5.1 \pm 1.3	0.02
30 min	3.2 \pm 1.0	3.8 \pm 1.1	0.01
60 min	2.1 \pm 0.8	2.3 \pm 0.9	0.18

Table 5 shows significant improvement in asthma scores in both groups. The MDI group showed faster clinical improvement within the first 30 minutes (p

< 0.05). However, by 60 minutes, the difference was no longer statistically significant, indicating convergence of outcomes.

Table 6: Time to peak PEFR improvement

Time to Peak PEFR	MDI Group (n, %)	DPI Group (n, %)	p-value
15 minutes	21 (32.3%)	14 (21.5%)	
30 minutes	29 (44.6%)	25 (38.5%)	
60 minutes	15 (23.1%)	26 (40.0%)	
p-value			0.001

Table 6 shows a significantly earlier peak PEFR response in the MDI group ($p = 0.001$). A larger proportion of children achieved their peak expiratory improvement within 30 minutes in the

MDI group. DPI showed a delayed but eventual improvement. This supports the faster onset of bronchodilation with MDI delivery.

Table 7: Device compliance by age group

Age Group	MDI Correct Use (%)	DPI Correct Use (%)	p-value
5–7	20/24 (83.3%)	11/23 (47.8%)	0.002
8–12	37/41 (90.2%)	39/42 (92.8%)	0.68

Table 7 shows that younger children (5–7 years) had significantly better compliance with MDI ($p = 0.002$). In older children (8–12 years), compliance

was high and comparable for both devices. This suggests that MDI with spacer is more age-adaptable, especially for younger users.

Table 8: Inhaler preference at discharge

Preferred Device	MDI Group (n, %)	DPI Group (n, %)	p-value
Yes	49 (75.4%)	35 (53.8%)	0.01
No	16 (24.6%)	30 (46.2%)	

Table 8 reveals that more children in the MDI group preferred their assigned inhaler by discharge ($p = 0.01$). Preference was likely driven by ease of use and comfort. DPI was less preferred, especially in

younger children. This highlights the long-term acceptability of MDI devices for ongoing asthma management.

Table 9: Caregiver satisfaction scores

Domain	MDI (Mean \pm SD)	DPI (Mean \pm SD)	p-value
Ease of teaching	4.6 \pm 0.5	3.8 \pm 0.7	0.003
Child cooperation	4.4 \pm 0.6	3.9 \pm 0.8	0.01
Overall satisfaction	4.5 \pm 0.5	3.9 \pm 0.6	0.005

Table 9 confirms significantly higher satisfaction among caregivers in the MDI group across all parameters ($p < 0.05$). These findings reinforce the

practicality of MDI in pediatric asthma care, especially when parental involvement is essential.

Table 10: Adverse events observed during treatment

Adverse Event	MDI Group (n, %)	DPI Group (n, %)	p-value
Tremors	5 (7.7%)	4 (6.2%)	
Palpitations	2 (3.1%)	2 (3.1%)	
None	58 (89.2%)	59 (90.7%)	0.77

Table 10 confirms that both MDI and DPI are safe with minimal adverse effects. No serious side effects

were recorded. The slight difference in minor effects was statistically insignificant ($p = 0.77$)

Table 11: PEFR improvement by gender

Gender	Mean PEFR Gain (MDI)	Mean PEFR Gain (DPI)	p-value
Male	61.2 ± 11.4	59.8 ± 12.1	0.39
Female	60.1 ± 10.9	58.3 ± 11.5	0.41

Table 11 shows that there were no significant gender-related differences in PEFR improvement in

either group ($p > 0.05$). The results confirm that device efficacy is consistent across genders.

Table 12: Repeat dosing within 2 hours

Group	Required Repeat Dose (n, %)	p-value
MDI	12 (18.5%)	
DPI	16 (24.6%)	0.39

Table 12 reveals that fewer children in the MDI group required repeat dosing, although the difference was not statistically significant ($p = 0.39$). This may reflect more rapid symptom resolution with MDI.

Discussion

This study aimed to compare the efficacy, ease of use, compliance, patient and caregiver satisfaction, and safety of salbutamol delivery via Metered Dose Inhaler (MDI) with spacer versus Dry Powder Inhaler (DPI) in children presenting with acute exacerbation of asthma. The results demonstrated that both devices are effective in delivering bronchodilator therapy and improving clinical outcomes, but several key differences favor the MDI with spacer [7].

The demographic comparability between the two groups, as evidenced by similar age and gender distributions, ensured unbiased comparison of treatment outcomes. Baseline clinical parameters, including peak expiratory flow rate (PEFR) and respiratory rate, were also similar, allowing for a valid assessment of response to therapy [8].

The study found that children receiving salbutamol via MDI with spacer experienced significantly faster improvement in PEFR within the first 15 to 30 minutes compared to those using DPI. This aligns with the pharmacokinetic rationale that MDI with spacer delivers aerosolized medication more efficiently and with less dependence on inspiratory effort, a critical factor in acute asthma where patients often have limited airflow and compromised inhalation capacity. The earlier onset of bronchodilation with MDI is clinically important, particularly in emergency settings where rapid relief

of airway obstruction is essential to prevent progression to respiratory failure [9,10].

Respiratory rate, an important marker of respiratory distress, decreased significantly in both groups without significant intergroup differences. This suggests that although the speed of bronchodilation differed, the overall clinical improvement in respiratory mechanics was comparable by 60 minutes post-treatment. Similarly, the clinical asthma score showed a more rapid decline in the MDI group during the early time points, with scores converging at 60 minutes, reinforcing the earlier therapeutic effect of MDI without long-term difference in efficacy [11].

Compliance and ease of device use are critical determinants of effective inhaler therapy, especially in pediatric populations. The study demonstrated that younger children (5–7 years) had significantly better compliance and correct technique with MDI plus spacer than with DPI. The MDI with spacer requires only tidal breathing and is less dependent on a strong inspiratory effort, which can be difficult for younger children to generate [12]. Older children showed high compliance with both devices, reflecting their better ability to coordinate inhalation maneuvers required by DPI. Patient preference and caregiver satisfaction were also higher with MDI, likely due to easier instruction, better cooperation, and faster perceived symptom relief [13].

Safety profiles were similar for both devices, with only minor and transient adverse effects such as tremors and palpitations observed. No serious adverse events were reported, supporting the safety of both delivery methods for short-term management of acute exacerbations [14].

Although the difference was not statistically significant, fewer children in the MDI group required repeat bronchodilator dosing within two hours, consistent with the earlier onset and potentially longer duration of action of MDI-delivered salbutamol. This trend suggests that MDI with spacer may reduce the need for frequent dosing, which can improve patient comfort and decrease treatment burden [15].

These findings are consistent with existing literature emphasizing the advantages of MDI with spacer in acute pediatric asthma management. The ability of MDI to deliver medication effectively regardless of inspiratory effort makes it particularly suitable for younger children and those in severe distress. DPI devices, while effective, require adequate inspiratory flow, which may limit their utility in acute episodes, especially in younger patients [16,17].

The study's strengths include a robust sample size, balanced group allocation, and detailed assessment of multiple clinical and user-centric parameters. Limitations include the single-center design and short duration of follow-up limited to acute treatment outcomes. Future studies could explore long-term outcomes, cost-effectiveness, and incorporation of objective lung function measures like spirometry and exhaled nitric oxide.

Salbutamol delivery via MDI with spacer offers faster bronchodilation, superior compliance in younger children, and higher patient and caregiver satisfaction compared to DPI, with similar safety profiles. These findings support the preferential use of MDI with spacer for managing acute exacerbations of asthma in pediatric patients, particularly in resource-limited settings where ease of use and rapid symptom control are paramount.

Conclusion

This comparative study demonstrates that Metered Dose Inhaler (MDI) with spacer is superior to Dry Powder Inhaler (DPI) for the delivery of salbutamol in children experiencing acute exacerbation of asthma. MDI with spacer provided faster and more significant improvement in peak expiratory flow rate and asthma symptom scores, particularly within the critical first 30 minutes of treatment. Younger children showed better compliance and correct inhaler technique with MDI, resulting in higher patient and caregiver satisfaction. Both devices exhibited comparable safety profiles with minimal adverse effects. Although the need for repeat bronchodilator dosing was lower in the MDI group, this difference was not statistically significant.

Considering these findings, MDI with spacer should be preferred for emergency and acute management of pediatric asthma, especially in younger children who may struggle with the inspiratory demands of

DPI. Its ease of use, rapid clinical effectiveness, and favorable acceptance make it an invaluable tool in pediatric asthma care. Further research may explore long-term outcomes and broader applicability in various clinical settings.

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