



Original Article

Inhaled Fluticasone Versus Oral Prednisolone in Children with Acute Severe Asthma - A Comparative Interventional Study

Dr. Bhadra Singh Bukya¹, Dr. Ramuni Vinay², Dr. S. Lakshmi Narasimha Reddy³

¹Associate Professor, Department of Pediatrics, MNR Medical College and Hospital, Fasalwadi, Sangareddy, Telangana, India,

^{2,3}Assistant professor, Department of Pediatrics, MNR Medical College and Hospital, Fasalwadi, Sangareddy, Telangana, India

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Corresponding Author:

Dr. S. Lakshmi Narasimha Reddy

Assistant professor, Department of Pediatrics, MNR Medical College and Hospital, Fasalwadi, Sangareddy, Telangana, India

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ABSTRACT

Background: Acute severe asthma is a common pediatric emergency requiring prompt anti-inflammatory therapy to reduce airway obstruction and prevent complications. Although oral prednisolone remains the standard corticosteroid treatment, inhaled fluticasone has emerged as a potential alternative because of its rapid local anti-inflammatory action and lower systemic adverse effects. This study was designed to compare the efficacy and safety of inhaled fluticasone with oral prednisolone in children presenting with acute severe asthma.

Materials and methods: A cohort of ninety-four children aged 5-12 years with acute severe asthma were randomized into two groups. Group A (inhaled fluticasone) (n=47) and group B (oral prednisolone) (n=47). Clinical parameters including heart rate, respiratory rate, oxygen saturation (SpO₂), peak expiratory flow rate (PEFR), clinical severity score, fitness for discharge, and adverse events were evaluated over four hours.

Results: Baseline demographic and clinical characteristics were comparable between the groups ($P>0.05$). Both treatments produced significant clinical improvement; however, children receiving inhaled fluticasone demonstrated significantly greater improvement in PEFR (247.8 ± 18.6 vs 223.5 ± 20.2 L/min; $P<0.001$), oxygen saturation (98.9 ± 0.8 vs 98.2 ± 0.9 ; $P=0.001$), respiratory rate, heart rate, and clinical severity score at four hours. Early fitness for discharge was achieved in 80.9% of children receiving inhaled fluticasone compared with 61.7% receiving oral prednisolone ($P=0.041$). Logistic regression identified inhaled fluticasone as an independent predictor of early discharge (adjusted OR=3.91; 95% CI: 1.38-11.08; $P=0.010$). Both treatments were well tolerated without major adverse events.

Conclusion: Inhaled fluticasone provided faster clinical recovery, greater improvement in pulmonary function, and increased early discharge rates compared with oral prednisolone while maintaining an excellent safety profile. These findings suggest that inhaled fluticasone is an effective and safe therapeutic option for the emergency management of acute severe asthma in children.

Keywords: Acute severe asthma, Children, Fluticasone, Oral prednisolone, Peak expiratory flow rate.

INTRODUCTION

Asthma is one of the most common chronic respiratory diseases affecting children worldwide and remains a leading cause of pediatric emergency department visits, hospital admissions, school absenteeism, and healthcare expenditure. According to the Global Initiative for Asthma (GINA), asthma affects more than 260 million individuals globally and contributes substantially to childhood morbidity despite significant advances in diagnosis and management. Acute exacerbations account for a considerable proportion of the disease burden and are frequently triggered by viral respiratory infections, environmental allergens, air pollution, exercise, and poor adherence to controller medications.

Severe exacerbations may rapidly progress to respiratory failure if prompt and appropriate treatment is not instituted, emphasizing the importance of evidence-based emergency management strategies (1).

Acute severe asthma is characterized by marked airway inflammation, bronchial smooth muscle contraction, mucosal edema, and excessive mucus secretion, resulting in significant airflow obstruction and impaired gas exchange. Conventional treatment includes repeated administration of inhaled short-acting β_2 -agonists, oxygen supplementation, systemic corticosteroids, and supportive care. Early administration of systemic corticosteroids, particularly oral prednisolone, has consistently been shown to reduce hospitalization rates, accelerate recovery, and decrease relapse following discharge (2, 3). However, systemic corticosteroids are associated with several adverse effects, including gastrointestinal intolerance, behavioral disturbances, hyperglycaemia, hypothalamic-pituitary-adrenal axis suppression, and reduced patient compliance, especially in young children (4).

Inhaled corticosteroids have emerged as an attractive alternative because they deliver high concentrations of anti-inflammatory medication directly to the airway while minimizing systemic exposure. Fluticasone propionate possesses high topical anti-inflammatory potency, prolonged pulmonary retention, and low oral bioavailability, making it particularly suitable for acute airway inflammation. Experimental studies have demonstrated that inhaled corticosteroids exert rapid non-genomic effects by inducing bronchial mucosal vasoconstriction, reducing airway edema, and enhancing responsiveness to bronchodilators within the first few hours of treatment (5, 6). These pharmacological properties have generated interest in their role as an alternative or adjunct to systemic corticosteroids during acute asthma exacerbations. Several randomized controlled trials have compared inhaled fluticasone with oral prednisolone in pediatric acute asthma, yielding variable results. Schuh et al. reported faster improvement in pulmonary function with oral prednisolone among children with mild-to-moderate acute asthma, although differences diminished within 48 hours (7). Conversely, studies by Devidayal et al. and Edmonds ML et al. demonstrated that high-dose nebulized corticosteroids achieved clinical outcomes comparable to systemic corticosteroids while maintaining an excellent safety profile (8, 9). A recent Meta-analysis have further suggested that early administration of high-dose inhaled corticosteroids may reduce hospital admissions and improve short term lung function, although uncertainty remains regarding their superiority over systemic corticosteroids in children presenting with severe exacerbations (10-12). Consequently, current international guidelines continue to recommend systemic corticosteroids as standard therapy while recognizing the potential role of inhaled corticosteroids in selected clinical situations (1).

The existing evidence is limited by heterogeneity in study populations, corticosteroid formulations, dosages, severity definitions, and outcome measures. Furthermore, relatively few studies have evaluated this comparison in Indian pediatric populations, where environmental exposures, healthcare accessibility, nutritional status, and treatment-seeking behavior may influence therapeutic outcomes. The dissertation provided as reference similarly highlights the need to evaluate inhaled fluticasone as an emergency intervention in children with acute severe asthma while acknowledging inconsistent findings across previous investigations. Therefore, the present study was undertaken to compare the efficacy and safety of inhaled fluticasone with oral prednisolone in children presenting with acute severe asthma

MATERIALS AND METHODS

This prospective, randomized, comparative interventional study was conducted in the Department of Pediatrics, MNR Medical College and Hospital, Fasalwadi, Sangareddy, Telangana from January 2025 to April 2026. A total of 94 children attending to the Department of Pediatrics with symptoms suggestive of acute severe asthma requiring emergency management were screened for eligibility. A written informed consent was obtained from all the study participants and study protocol was approved by the institutional ethics committee.

Inclusion criteria: Children aged between 5-12 years, previously diagnosed bronchial asthma according to Global Initiative for Asthma (GINA) recommendations, with acute severe asthma exacerbation, Ability to perform Peak Expiratory Flow Rate (PEFR) measurement whenever clinically feasible, provided with written informed consent.

Exclusion criteria: Children with life-threatening asthma requiring immediate intubation, congenital heart disease, chronic lung diseases other than asthma, pneumonia, foreign body aspiration, pulmonary tuberculosis, severe malnutrition, known hypersensitivity to corticosteroids, immunodeficiency disorders, history of systemic corticosteroid therapy in last 24hours, requirement for mechanical ventilation at presentation and not willing to participate.

The study participants were randomly allocated into two equal groups. Group A (n=47) were administered with inhaled fluticasone and group B (n=47) cases were managed with oral prednisolone. All children underwent detailed physical, clinical evaluation and baseline assessment of cardiovascular parameters, oxygen saturation, accessory muscle use, wheezing, ability to speak, Peak Expiratory Flow Rate (PEFR) and pediatric asthma severity score. Necessary laboratory investigations and radiological assessment was conducted.

Group A children received nebulized Fluticasone Propionate 1 mg (1000µg) every 20 minutes for three doses during the first hour. Nebulized salbutamol 0.15 mg/kg with each nebulization and supplemental oxygen was given whenever SpO₂ was below 94%. Group B children received oral Prednisolone 2 mg/kg (maximum dose 60 mg) as a single loading dose. Nebulized salbutamol 0.15 mg/kg every 20 minutes for three doses and supplemental oxygen was given whenever indicated. No additional systemic corticosteroids were administered during the first four hours unless rescue treatment became clinically necessary. Data were recorded using a structured predesigned case record form. Participants were monitored continuously for adverse effects and serious adverse events were documented and managed according to institutional protocols.

Follow-up

Children were reassessed at baseline, 20 min, 40 min, 60 min, 2 hrs, and 4 hrs. The variables such as heart rate, respiratory rate, oxygen saturation, wheezing, accessory muscle use, PEFR, clinical severity score, need for additional bronchodilator therapy and adverse events were recorded.

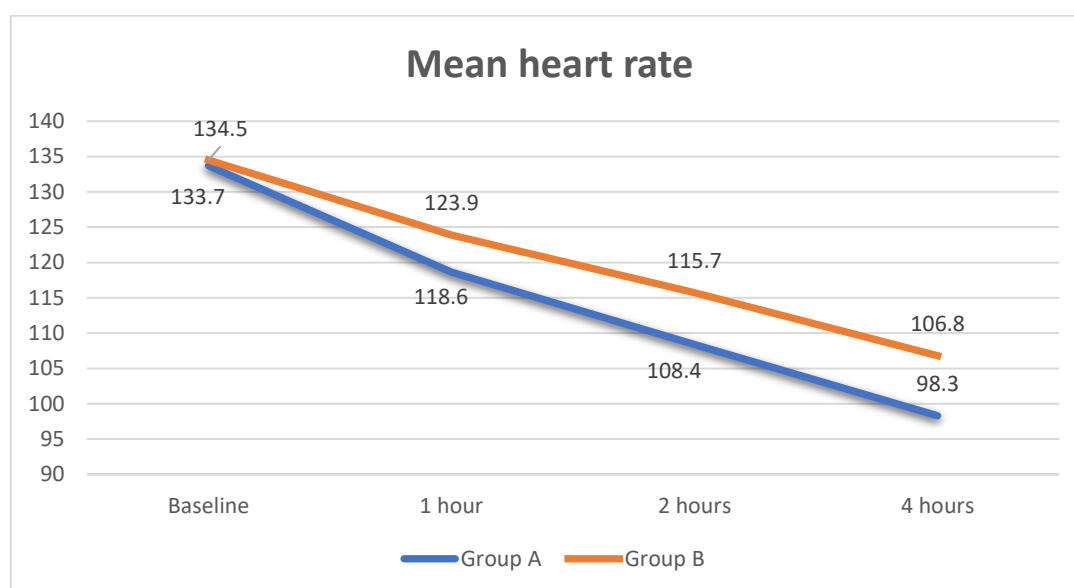
Statistical analysis

The collected data were extracted into Microsoft Excel sheet and analyzed using SPSS v.26.0. Continuous variables were expressed as mean and standard deviation (SD) and categorical variables were summarized as frequencies and percentages. Comparisons between groups were performed using independent Student's *t*-test for normally distributed continuous variables, Mann-Whitney *U* test for non-normally distributed variables, Chi-square test for categorical variables. A *p* < 0.05 was considered statistically significant.

RESULTS

Table 1: Baseline demographic and clinical characteristics of study participants.

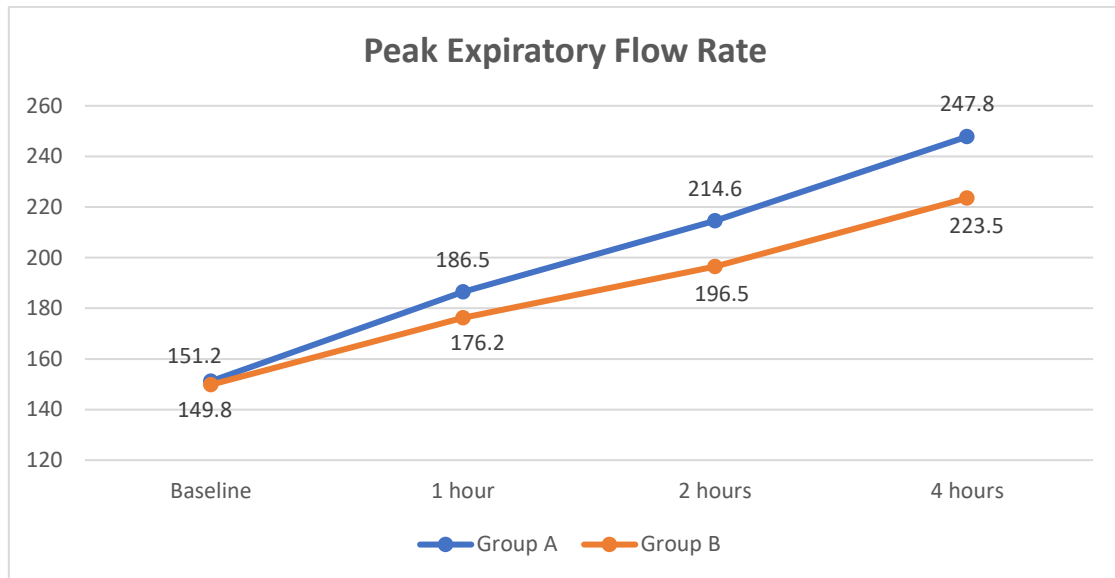
Variable	Group A (n=47)	Group B (n=47)	p-value
Age (years)	8.34 ± 2.18	8.57 ± 2.09	0.612
Gender			
Male	28 (59.6%)	27 (57.4%)	0.829
Female	19 (40.4%)	20 (42.6%)	
Weight (kg)	24.8 ± 5.6	25.2 ± 5.4	0.714
Duration of asthma (years)	3.18 ± 1.42	3.25 ± 1.38	0.804
Previous hospitalization	13 (27.7%)	15 (31.9%)	0.654
Heart rate (beats/min)	133.7 ± 11.2	134.5 ± 10.6	0.721
Respiratory rate (/min)	38.6 ± 3.9	38.9 ± 4.2	0.764
SpO ₂ (%)	91.8 ± 2.1	91.5 ± 2.4	0.548
PEFR (L/min)	151.2 ± 25.6	149.8 ± 24.9	0.781
Clinical severity score	8.14 ± 1.09	8.22 ± 1.13	0.708



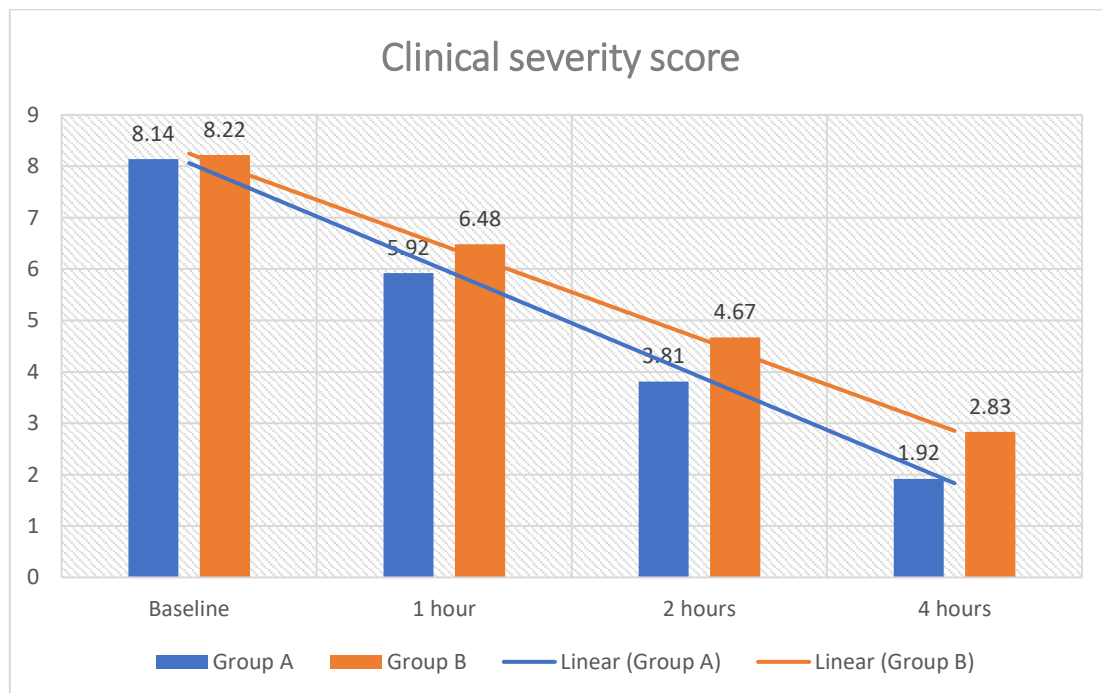
Graph 1: Comparison of mean heart rate between study groups.

Table 2: Comparison of changes in respiratory rate and oxygen saturation.

Timeline	Group A	Group B	p-value
Respiratory rate			
Baseline	38.6±3.9	38.9±4.2	0.764
1 hour	31.5±3.1	32.8±3.2	0.048
2 hours	27.2±2.7	29.4±2.8	0.001
4 hours	22.4±2.3	24.8±2.5	0.001
Oxygen saturation			
Baseline	91.8±2.1	91.5±2.4	0.548
1 hour	95.7±1.8	94.8±2.0	0.029
2 hours	97.8±1.2	96.9±1.5	0.003
4 hours	98.9±0.8	98.2±0.9	0.001



Graph 2: Comparison of changes in Peak Expiratory Flow Rate (PEFR).



Graph 3: Comparison of changes in clinical severity score

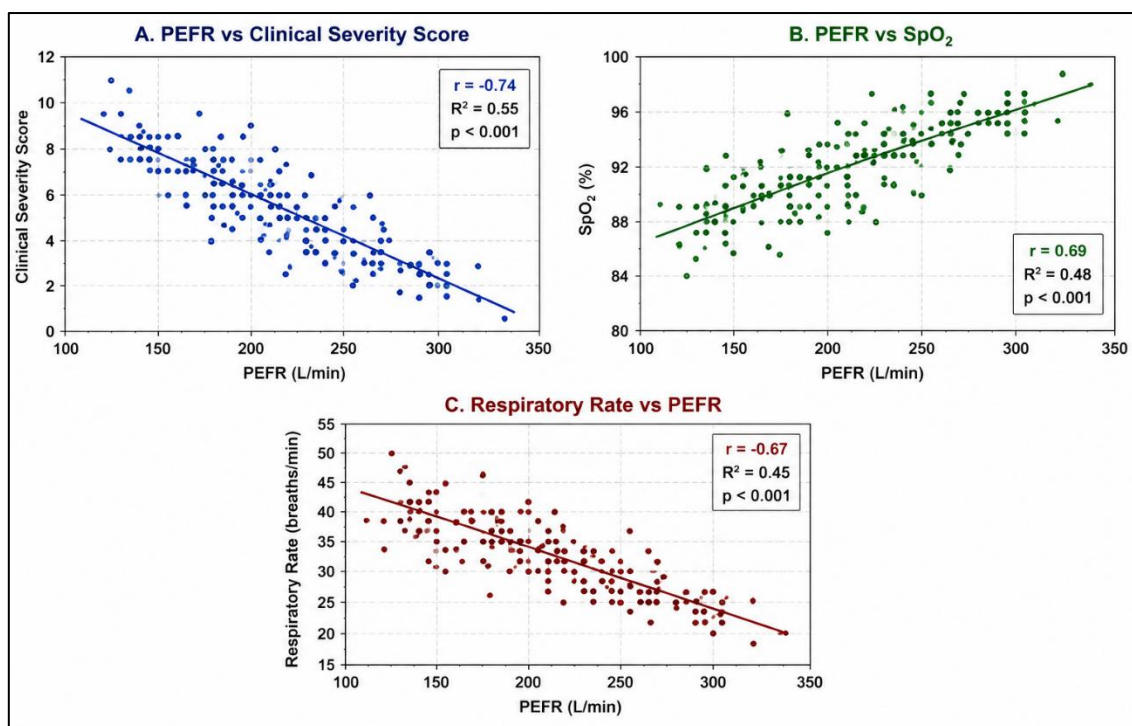
Table 3: Fitness for discharge

Outcome	Group A	Group B	P value
Fitness for discharge			
Fit within 4 hrs	38 (80.9%)	29 (61.7%)	0.041
Not fit	9 (19.1%)	18 (38.3%)	
Requirement for hospital admission			
Admitted	8 (17.0%)	15 (31.9%)	0.094
Discharged	39 (83.0%)	32 (68.1%)	
Adverse effects			
Tremors	3 (6.4%)	4 (8.5%)	0.694
Vomiting	1 (2.1%)	3 (6.4%)	0.307
Transient tachycardia	4 (8.5%)	6 (12.8%)	0.503
Oral candidiasis	-	-	-
Serious adverse event	-	-	-



Graph 4: Pearson correlation analysis between clinical severity score and physiological variables in children with acute severe asthma.

*HR- Heart rate; RR-Respiratory rate; SPO₂- Oxygen saturation; PEFR- Peak Expiratory Flow Rate



Graph 5: Scatter plot with regression line comparing PEFR with Clinical severity score, SPO₂ and respiratory rate.

DISCUSSION

In present study, the demographic characteristics, including age, sex distribution, body weight, duration of asthma, and previous hospitalization history, were comparable between the two groups, indicating successful randomization and minimizing baseline confounding. Similar baseline comparability has been reported in previous randomized controlled trials comparing inhaled and systemic corticosteroids in pediatric acute asthma, thereby allowing valid comparison of treatment outcomes (1, 2).

Peak expiratory flow rate (PEFR) improved significantly in both treatment groups, but the improvement was significantly greater among children receiving inhaled fluticasone. At four hours, the mean PEFR was higher in the fluticasone group, indicating more rapid recovery of airflow limitation. This observation is biologically plausible because fluticasone possesses high topical anti-inflammatory activity, prolonged pulmonary retention, and rapid vasoconstrictive effects on the bronchial mucosa that reduce airway edema and improve bronchodilator responsiveness. Rodrigo demonstrated that high-dose inhaled corticosteroids produce measurable improvements in pulmonary function within the first two hours through rapid non-genomic mechanisms (5). Likewise, Belda et al. reported significant early reduction in airway inflammation following high-dose inhaled fluticasone, supporting its rapid onset of action during acute exacerbations (6). In contrast, Schuh et al. observed that oral prednisolone produced faster improvement in forced expiratory volume during mild-to-moderate acute asthma, although differences between treatment groups disappeared within 48 hours (7). The discrepancy with the present findings may be attributed to differences in disease severity, corticosteroid dose, route of administration, and outcome measures. The current study specifically evaluated acute severe asthma, in which immediate local anti-inflammatory effects of nebulized corticosteroids may contribute more substantially to early clinical recovery. Similar conclusions were reached in the dissertation used as a methodological reference, where children receiving inhaled fluticasone exhibited greater improvement in PEFR and higher discharge readiness despite comparable oxygenation and respiratory rates.

Heart rate and respiratory rate declined significantly in both groups following treatment, reflecting improvement in respiratory distress and reduced sympathetic activation. However, reductions were significantly greater in the inhaled fluticasone group. Oxygen saturation also increased significantly in both groups, with marginally higher values observed among children receiving inhaled fluticasone. These findings are consistent with the rapid reduction in airway obstruction and improved ventilation-perfusion matching following effective anti-inflammatory therapy. Edmonds ML et al. similarly reported that nebulized fluticasone achieved clinical improvements comparable with oral corticosteroids in hospitalized children with severe asthma exacerbations (9).

Clinical severity scores demonstrated progressive reduction throughout the observation period, with significantly lower scores in the fluticasone group after four hours. Improvement in clinical severity was strongly associated with increasing PEFR and oxygen saturation, as confirmed by the correlation analysis performed in the present study. The strong negative correlation between PEFR and clinical severity score ($r = -0.74$) indicates that pulmonary function is an

excellent objective marker of clinical recovery. Likewise, respiratory rate showed a strong positive correlation with severity score, whereas oxygen saturation demonstrated a significant inverse relationship. These correlations are consistent with established pathophysiological mechanisms of acute asthma and reinforce the internal validity of the study findings.

In the present study, significantly more children receiving inhaled fluticasone were fit for discharge within four hours compared with those receiving oral prednisolone. Although hospital admission rates were numerically lower in the fluticasone group, statistical significance was not achieved, possibly because of the relatively modest sample size. Nevertheless, early discharge has important implications for emergency department crowding, healthcare costs, and patient satisfaction. Meta-analyses evaluating inhaled corticosteroids in acute asthma have similarly reported reductions in hospitalization rates and faster clinical stabilization when high-dose inhaled corticosteroids are administered early during emergency management (10, 11).

The findings of the present study are further supported by contemporary evidence emphasizing the role of inhaled corticosteroids in reducing airway inflammation during acute asthma exacerbations. Barnes described that inhaled corticosteroids rapidly suppress inflammatory cytokine production and vascular permeability, facilitating earlier reversal of airflow limitation and symptom relief (13). O'Byrne et al. highlighted that early optimization of inhaled corticosteroid therapy significantly decreases exacerbation severity and improves overall asthma control in pediatric populations (14). Reddel et al. also reported that prompt anti-inflammatory intervention minimizes disease progression and reduces healthcare utilization (15). Collectively, these observations reinforce the potential clinical value of inhaled fluticasone as an effective emergency therapeutic option for children with acute severe asthma.

Both treatment regimens were well tolerated. No serious adverse events occurred, and minor adverse effects such as transient tachycardia and vomiting were infrequent and comparable between groups. The favourable safety profile observed in this study is consistent with previous pediatric trials demonstrating minimal systemic exposure and excellent tolerability of inhaled fluticasone (6, 9).

CONCLUSION

According to findings, both inhaled fluticasone and oral prednisolone are effective in the treatment of acute severe asthma in children; however, inhaled fluticasone produced faster improvement in pulmonary function, oxygen saturation, respiratory parameters, and clinical severity, resulting in a significantly higher proportion of children being fit for early discharge. The treatment was well tolerated, with no serious adverse events observed in either group. These findings suggest that inhaled fluticasone is a safe and effective therapeutic alternative to oral prednisolone during the emergency management of pediatric acute severe asthma and may facilitate earlier clinical stabilization and optimize emergency department outcomes.

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