International Journal of Current Pharmaceutical Research

ISSN- 0975-7066 Vol 18, Issue 2, 2026

Original Article

NEBULIZED BUDESONIDE AS ADD-ON TO STANDARD THERAPY IN CHILDREN AGED 5-14 YEARS WITH ACUTE EXACERBATION OF ASTHMA

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Received: 11 Nov 2025, Revised and Accepted: 06 Jan 2026

ABSTRACT

Objective: Out of the top 20 chronic conditions for global ranking of disability adjusted life years in children, asthma is one of them and specifically in the mid-childhood ages i. e, 5–14 y it ranks amongst the top 10 diseases, so we planned this study to see the efficacy of nebulized budesonide as add-on to standard therapy in children aged 5-14 y with acute exacerbation of asthma.

Methods: This was a prospective, randomized, open labelled, interventional study conducted in 5-14 y old patients of moderate to severe asthma having acute exacerbation. Thirty children with acute exacerbation of asthma presenting in the Paediatric department at PGIMS, Rohtak were randomized and assessed for efficacy according to PRAM score.

Results: PRAM Score at various follow-up time intervals was recorded in both groups and it was observed that mean±SD of PRAM Score at baseline, at 30 min, at 60 min and at 180 min showed non-significant difference during inter-group comparison. At discharge PRAM score was 0.39±0.50 and 0.32±0.48 in group I and group II respectively.

Conclusion: This study showed that both nebulized budesonide as an add-on and standard therapy in children aged 5-14 y with acute exacerbation of asthma showed significant improvement in respiratory status in terms of relief of respiratory symptoms with good safety profile and greater satisfaction with nebulized.

Keywords: Asthma, Children, Budesonide, Salbutamol, Pram score

DOI: https://dx.doi.org/10.22159/ijcpr.2026v18i2.8083 Journal homepage: https://innovareacademics.in/journals/index.php/ijcpr

INTRODUCTION

National Institute of Health Guidelines (NIH Guidelines) define asthma as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role: in particular, macrophages, eosinophils, epithelial cells and T lymphocytes, neutrophils [1]. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, chest tightness, breathlessness and coughing, particularly at night or in the early morning. These episodes are associated with variable airflow obstruction that is reversible either spontaneously or with treatment. Asthma affects both adults and children, occurring in all populations and locations across the globe. Approximately 300 million people are suffering from asthma worldwide, out of which a 10% are living in India. Severe asthma is agitated sensorium, PEFR<60% with oxygen saturation<90%. Severe asthmatic attack is characterized by disturbance in level of consciousness, inability to speak and/or feed, severely diminished or absent breath sounds, central cyanosis, use of accessory muscles while breathing, increased respiratory and cardiac rate. Guidelines define severe asthma as-asthma which requires treatment with high dose of inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming “uncontrolled”, or which remains “uncontrolled” despite this therapy [2]. One factor strongly associated with severe asthma in children and adolescents is allergic sensitization. The 2018 update of Global Strategy for Asthma Management and Prevention recommends systemic or high-dose inhaled corticosteroid for asthma exacerbation [3]. In a study by Geelhoed, *et al.* [4], patients in budesonide group had a much shorter stay in hospital, a majority of them being fit for discharge soon after completion of three nebulisations. The faster improvement associated with inhaled budesonide was attributed to its rapid local effect on mucosal permeability in acute inflammation due to its high binding affinity and high blanching potency [5].

The factors that determine the risk of developing asthma, asthma severity and response to therapy can include host and environmental factors [6]. The host factors include genetics, sex and obesity. Important environmental factors include allergens, airborne pollutants and respiratory infections [7]. Family and twin studies have indicated that genetics also plays an important role in the development of asthma and allergy [8] and asthma is recognized as one of the three component of the atopic triad and has been classified as atopic or extrinsic asthma and non-atopic or intrinsic asthma. Atopic or extrinsic asthma is a term used to describe asthmatic patients with underlying atopic history. The observations suggested that some other environmental or genetic factors predispose to the development of asthma in atopic individuals [9]. Non-atopic or intrinsic asthma usually show later onset of disease (adult-onset asthma), and have more severe, persistent asthma without personal or family history of allergy. The classical immunological model presents it as a disease mediated by reaginic globulin (IgE). Exposure to allergens aggravates IgE production in genetically sensitive individuals [10]. Once produced, IgE antibodies bind to the mast cells in airway mucosa. On re-exposure to a specific antigen, antigen-antibody reaction on the surface of mast cell trigger both release of mediators stored in the cell’s granules and the synthesis and the release of other mediators (histamine, tryptases, leukotrienes and prostaglandins D2), IL-4, IL-5, IL-13, macrophage inflammatory protein-1 alpha and tumor necrosis factor alpha, which results in the bronchial muscle contraction and vascular leakage responsible for the acute bronchoconstriction of the asthmatic response. Presently, the established pharmacotherapy of asthma is broadly categorized as reliever and controller medications and are aimed to provide symptomatic relief during acute episode and to control future exacerbations, respectively. Controllers are used daily over a long period of time and generally have anti-inflammatory properties, while relievers act quickly to reverse bronchoconstriction and are used as needed [11]. These medications can be delivered by inhalation, orally or by injection. However, inhaled therapy is preferred due to lower risk of adverse reactions. Reliever medications include anticholinergic agents and beta2-

agonists. Anticholinergics: Anticholinergics such as tiotropium bromide act as antagonists of muscarinic receptors and block the effects of endogenous acetylcholine. Beta-2 adrenoceptor agonists are the most effective bronchodilators in asthma (short-acting and long-acting). Inhaled long-acting beta-2 agonists (salmeterol and formoterol) have largely replaced the older long-acting bronchodilators (orally administered, slow-release albuterol and theophylline slow-release preparation). Long-acting beta-2 agonists constitute the most effective anti-asthma therapy with inhaled corticosteroids. Inhaled corticosteroids, which act as controllers, are the potent anti-inflammatory agents and are the most effective drugs for treatment of asthma [11]. Inhaled corticosteroids (budesonide, beclomethasone dipropionate, mometasone, triamcinolone, fluticasone and ciclesonide) are the mainstay of asthma therapy which act to decrease asthma symptoms, control airway inflammation, decrease airway hyper-responsiveness and reduce frequency and severity of exacerbations and improve lung function. Inhaled corticosteroids like budesonide control asthma symptoms by reducing airway inflammation and mediators involved. This can lead to better lung function and more desirable lifestyle. Budesonide has been studied in children suffering from acute attack of asthma in different forms of inhaler and nebulized suspension [12]. Inhaled corticosteroid can be delivered via a pressurized metered dose inhaler [pMDI], with or without a spacer, a dry powder inhaler [DPI], or a nebulizer.

MATERIALS AND METHODS

This was a prospective, randomized, open labelled, interventional study conducted in the department of Pharmacology in collaboration with department of Paediatrics, Pt. B. D. Sharma Postgraduate Institute of Medical Sciences, Rohtak in 5-14 y old patients of moderate to severe asthma having acute exacerbation. The study was in accordance with the principles of Declaration of Helsinki and Good Clinical Practice. Written informed consent was obtained from all the patients enrolled for the study. Approval was taken from the Institutional Ethics Committee before commencement of the study. Thirty children with acute exacerbation of asthma presenting in the Paediatric department at Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, Rohtak were randomized according to following inclusion and exclusion criteria. Due to covid pandemic total number of patients could not be enrolled. The plan was to enrolled a total number of 60 patients but the study could enrolled only 30 patients. Permission was taken from the ethics committee for the same. Inclusion Criteria included Children aged 5-14 y diagnosed with acute exacerbation in moderate to severe cases of asthma, Patient/legal guardian willing to give written informed consent. Exclusion Criteria included Children with heart, liver, neurological or kidney diseases, Evidence of pneumonia, Respiratory rate more than 50, or fever more than 39 °C, congenital respiratory tract diseases, Metabolic and autoimmune diseases, Using Oral or inhaled glucocorticoid therapy in the past 24 h and who needs intensive care

Study procedure

The study subjects were selected as per the above inclusion and exclusion criteria. The enrolled patient and their guardian were given detailed information about the purpose of the study by patient information sheet explaining the procedure, risk and benefits and written informed consent was taken from the guardian of the patient and assent was taken from children aged more than 7 y. Demographic and clinical characteristics was recorded like age, gender, in patient number, type of asthma, history of asthma attack, current treatment etc as per the case record form.

Treatment protocol

Thirty patients were randomized to the following two treatment groups (n=15)

Group 1-Standard treatment-Oxygen therapy O2 (6-10 lpm), nebulized salbutamol (0.5% solution, 0.15 mg/kg diluted 1:2 with normal saline)

Group 2-Nebulized budesonide (800 microgram)+Standard treatment

Salbutamol and budesonide nebulization was given at admission and at 30 min, 60 min and 180 min intervals for four doses. The nebulisations were given with the help of a nebulizer chamber using a mask and oxygen at the rate of 8/lpm from a wall-mounted oxygen source.

Escape treatment-Patients having inadequate or no response to the above treatment was removed from the study and was treated by the physician accordingly.

Clinical assessment

It was carried out in all the patients in terms of efficacy of the treatment along with safety estimation with the provision to record any adverse drug reaction as and when reported by the patients.

Efficacy assessment

A) Primary efficacy endpoints

- Respiratory status evaluation
- Paediatric Respiratory Assessment Measure (PRAM)

B) Secondary efficacy endpoints

- Requirement of steroids (intravenous or oral)
- Period of hospitalization
- Satisfaction with nebulized budesonide

Respiratory status evaluation

All patients with acute exacerbation of asthma were enrolled in the study and medical history, physical examination (auscultation of wheeze, severity, time and location, respiratory accessory muscle use), respiratory rate (RR) and O2 saturation (SaO_2) was evaluated and recorded at baseline and also at 30 min, 1 and 3 h after intervention and at the time of discharge. The parameters used for evaluation of respiratory status were as follows:

•Respiratory rate (RR)-Respiratory rate was counted by observing abdominal and thoracic wall movements for 1 min when the child is at rest.

•Pulsus paradoxus-was measured with a sphygmomanometer and stethoscope.

•Colour-was assessed by observing colour of lips and oral mucosa and was categorized as pale, pink or cyanosed.

•Accessory muscle usage-were graded as

- Mild (mild intercostal indrawing),
- Moderate (moderate intercostal indrawing with tracheosternal retractions and use of sternocleidomastoids) and
- Severe (severe intercostal and tracheosternal retractions with nasal flaring).

•Chest retractions

•Wheezing-Auscultatory findings was graded as

- Mild (end-expiratory wheeze only),
- Moderate (wheeze during entire expiration and inspiration) and
- Severe (decreased air movement with or without wheeze).

•Oxygen saturation (SaO_2)-was monitored with the help of a hand-held pulse oximeter.

Respiratory distress assessment (RDA)

Respiratory distress was defined as an inappropriate degree of breathing effort based on an assessment of respiration rate, rhythm, and character. Inadequate responses were defined as increasing heart and respiratory rates, persistence of moderate respiratory distress and wheezing associated with pulsus paradoxus of>10-15 mmHg and SaO_2 between 91% and 95%. No response was defined as increasing heart and respiratory rates, persistence of severe respiratory distress with decreased air movement, pulsus paradoxus of>15 mmHg and SaO_2<90%.

Paediatric respiratory assessment measure (PRAM) [13]

This was a 12 points clinical scoring rubric that captures a patients asthma severity using a combination of scalene muscle contraction, suprasternal retractions, wheezing, air entry and oxygen saturation. It was a validated scoring tool to classify the severity of exacerbation and its response to treatment in children with asthma. It has a maximum score of 12. Score of 0-3, 4-7, and 8-12 indicates mild, moderate and severe severity respectively.

Satisfaction with treatment

Feeling of satisfaction was assessed with Inhaler (FSI-10) questionnaire [13] at the time of discharge. The FSI-10 was a self-completed 10-item questionnaire to assess patient opinions regarding ease or difficulty of use, portability, and usability of devices for delivery of inhaled medications. Each of the 10 items has 5 response options from poorer to greater ease of use, scored 1 to 5, respectively. The minimum score was 10 whereas the maximum was 50. Minimum the score better is quality of life.

Statistical analysis

The data thus obtained was entered in the current available version of Microsoft-Excel. The data was categorized as: (i) Ordinal: Respiratory distress score and pulmonary index. (ii) Continuous: SaO_2, RR and duration of stay in hospital in hours. (iii) Dichotomous: need intravenous or oral steroid therapy or not, need hospitalization or not, and improvement or not on respiratory distress grade. Between the groups, comparison of continuous data was carried out with the help of the two-tailed t-test. Dichotomous data was analysed using the Chi-squared test. A two-tailed p-value<0.05 was considered significant. Comparison of intergroup frequency was done using chi-square test and comparison of intergroup mean±SD using Anova test in baseline characteristic of study population. In PRAM Score all the data presented in mean+SD. Comparison of intergroup mean±SD using anova test.

RESULTS

Efficacy assessment of study population

The efficacy of the medications in the study population was assessed based on primary parameters which included respiratory status evaluation and PRAM score and secondary efficacy parameters.

Intragroup analysis

Comparison of values at the end of 30 min, 60 min, 180 min and at the end of discharge with baseline values is statistically significant ($p<0.05$)

Intergroup analysis

Comparison of values between Group 1 and Group 2 is not statistically significant ($p>0.05$)

Table 1: Baseline charactristics of study population

Parameters		Group-I (n=15)	Group-II (n=15)	P value
Age (Years)	<10	11 (73.3%)	11 (73.3%)	1.000
	≥10	4 (26.7%)	4 (26.7%)	
	Mean±SD	7.53±2.10	7.40±3.68	0.906#
Sex	Male	12 (80.0%)	5 (33.3%)	0.010
	Female	3 (20.0%)	10 (66.7%)	
Residence	Rural	8 (53.3%)	9 (60.0%)	0.713
	Urban	7 (46.7%)	6 (40.0%)	
Socioeconomic status	Lower	14 (93.3%)	13 (86.7%)	0.543
	Middle	1 (6.7%)	2 (13.3%)	

Table 2: Clinical characteristics of study population

Parameters		Group-I (n=15)	Group-II (n=15)	P value
Duration of illness (Days)		2.87±2.85	1.60±0.74	0.106
Frequency of day symptoms		1.60±0.99	1.53±1.06	0.853
Frequency of night symptoms		2.87±0.64	3.33±0.98	0.139
Hospitalized last year	No	11 (73.3%)	11 (73.3%)	1.000
	Yes	4 (26.7%)	4 (26.7%)	
No of Times child suffered from RTI in last one year	No	8 (53.3%)	9 (60.0%)	0.557
	Yes	7 (46.7%)	6 (40.0%)	
Co morbidity/Allergies	Absent	12 (80.0%)	7 (46.7%)	0.058
	Present	3 (20.0%)	8 (53.3%)	
Current Treatment	Absent	9 (60.0%)	5 (33.3%)	0.219
	Present	6 (40.0%)	10 (66.7%)	
Family history	Absent	13 (86.7%)	15 (100.0%)	0.143
	Present	2 (13.3%)	0 (0.0%)	

Table 3: Respiratory rate of study population

Respiratory rate at	Group-I (n=15)	Group-II (n=15)	P value*
Baseline	33.13+0.55	32.26+0.67	0.33
On 30 min	26.4+0.55	25+0.86	0.17
On 60 min	22.6+0.6	22.86+0.72	0.77
On 180 min	20.46+0.52	21.13+0.69	0.45
At discharge	19.33+0.37	19.2+0.32	0.39
P value	<0.00002	<0.00001	

Table 4: Respiratory status evaluation of the study population

		Group-I (n=15)	Group-II (n=15)	P value#
Accessory muscle usage	Base line	0 (0.0%)	5 (33.3%)	0.014
	30 Min	0 (0.0%)	0 (0.0%)	1.000
	60 Min	0 (0.0%)	0 (0.0%)	1.000
	180 Min	0 (0.0%)	0 (0.0%)	1.000
	Discharge	0 (0.0%)	0 (0.0%)	1.000
Chest retraction	Base line	9 (60.0%)	14 (93.3%)	0.014
	30 Min	5 (33.3%)	0 (0.0%)	0.014
	60 Min	0 (0.0%)	0 (0.0%)	1.000
	180 Min	0 (0.0%)	0 (0.0%)	1.000
	Discharge	0 (0.0%)	0 (0.0%)	1.000
Wheezing	Base line	15 (100.0%)	15 (100.0%)	1.000
	30 Min	13 (86.7%)	13 (86.7%)	1.000
	60 Min	3 (20.0%)	0 (0.0%)	0.068
	180 Min	0 (0.0%)	0 (0.0%)	1.000
	Discharge	0 (0.0%)	0 (0.0%)	1.000
Respiratory distress assessment	Base line	5 (33.3%)	4 (26.7%)	0.690
	30 Min	1 (6.7%)	0 (0.0%)	0.309
	60 Min	0 (0.0%)	0 (0.0%)	1.000
	180 Min	0 (0.0%)	0 (0.0%)	1.000
	Discharge	0 (0.0%)	0 (0.0%)	1.000
Colour (Pink)	Base line	15 (100.0%)	15 (100.0%)	1.000
	30 Min	15 (100.0%)	15 (100.0%)	1.000
	60 Min	15 (100.0%)	15 (100.0%)	1.000
	180 Min	15 (100.0%)	15 (100.0%)	1.000
	Discharge	15 (100.0%)	15 (100.0%)	1.000
Pulsus paradoxus	Base line	11.80±1.93	12.80±1.93	0.167
	30 Min	9.60±1.55	10.53±1.77	0.137
	60 Min	8.67±0.98	9.20±1.82	0.329
	180 Min	8.27±0.70	8.40±1.55	0.769
	Discharge	8.13±0.92	7.60±1.35	0.219
O_2 Saturation	Base line	91.20±3.69	90.27±2.84	0.446
	30 Min	94.93±3.06	94.27±3.24	0.571
	60 Min	96.8±2.81	97.53±1.68	0.395
	180 Min	99.13±0.99	99.20±0.86	0.838
	Discharge	99.60±0.74	99.87±0.35	0.212

Comparison of intergroup mean±SD using #Anova test and $p<0.05$ was considered as statistically significant.

Table 5: Pram score change overtime in study population

PRAM score at	Group-I (n=15)	Group-II (n=15)	P value*
Baseline	3.4±1.4	3.80±1.26	0.418
On 30 min	2.47±1.30	2.20±0.77	0.495
On 60 min	1.53±1.36	1.27±0.88	0.539
On 180 min	0.40±0.51	0.33±0.49	0.704
At Discharge	0.39±0.50	0.32±0.48	0.698
P value	<0.001	<0.001	

Intergroup analysis: Comparison of values between Group 1 and Group 2 is not statistically significant ($p>0.05$)

Table 6: Secondary efficacy assessment of study population

		Group-I (n=15)	Group-II (n=15)	P value*
Need of hospitalization	Yes	0 (0.0%)	2 (13.3%)	0.143
	No	15 (100.0%)	13 (86.7%)	
Need of steroid	Yes	0 (0.0%)	0 (0.0%)	1.000
	No	15 (100.0%)	15 (100.0%)	
Duration of stay	2.5 h	3 (20.0%)	2 (13.3%)	0.587
	3.0 h	4 (26.7%)	3 (20.0%)	
	3.5 h	4 (26.7%)	7 (46.7%)	
	4 h	4 (26.7%)	2 (13.3%)	
	4.5 h	0 (0.0%)	1 (6.7%)	

Comparison of intergroup frequency using *chi-square test and $p<0.05$ was considered as statistically significant

DISCUSSION

This study was planned to evaluate the effect of nebulised budesonide as add on therapy to standard treatment in acute exacerbation of bronchial asthma in children of 5-14 y. We divided the patients into two groups, a control group with standard treatment and one test group with nebulized budesonide as add on therapy to standard treatment. The groups were formed to assess

the effect of nebulized budesonide as an add-on to standard therapy in acute exacerbation of asthma. Drugs used in asthma, should be given by inhalational route whenever possible so that, beneficial effect can be achieved with a much smaller drug dose, thus causing lower systemic drug concentrations and fewer systemic adverse effects [14]. Control group was the standard treatment with oxygen therapy O2 (6-10 lpm) and nebulized salbutamol (0.5% solution, 0.15 mg/kg diluted 1:2 with normal saline). Test group was the nebulized budesonide (800 microgram)+Standard treatment Salbutamol and budesonide nebulization were given at admission and at 30 min, 60 min and 180 min intervals for four doses. The nebulization were given with the help of a nebulizer chamber using a mask and oxygen at the rate of 8/lpm from a wall-mounted oxygen source. In Escape treatment-Patients having inadequate or no response to the above treatment were removed from the study and were treated by the physician accordingly current literature suggests that inhaled corticosteroids may offer some benefit in patients with mild to moderate asthma in acute exacerbation and also offer the advantage of administration directly to the lungs [15]. In a study, conducted by Singhi *at al.* [16]. in 60 children between 3 and 12 y of age with an acute moderate exacerbation of asthma showed a significant improvement with aerosolized budesonide therapy in respiratory status at the end of 2 h these results are similar to our study results. In a study done by Geelhoed *at al*. [17]. They observed that Pulsed oxygen saturation (SpO_2) of 92% or less on presentation (before oxygen or bronchodilator treatment) is associated with higher morbidity and greater risk for hospitalization which is in contrast with the present study. In another study done by Littenberg *at al.* [18] observed that systemic corticosteroids given early in the course of treatment of acute asthma exacerbations in the ED showed effectiveness and are recommended by different asthma guidelines like GINA and EPR3 these results are similar to our study results. Devidayal *et al.* [19] compared the effectiveness of inhaled budesonide versus oral prednisolone in the emergency department and in children with acute asthma and reported that heart rate, respiratory rate, oxygen saturation (SpO_2) and respiratory distress were significantly improved in the budesonide group these results are similar to our study results. While MacLaughlin *et al.* [20] evaluated the risk of readmission in the emergency department in children younger than 8-year-old who had received nebulized budesonide. They demonstrated that budesonide decrease recurrence and readmission rates significantly up to 71% which is similar to the results observed in the present study.

CONCLUSION

This study showed that both nebulized budesonide as an add-on and standard therapy in children aged 5-14 y with acute exacerbation of asthma showed significant improvement in respiratory status in terms of relief of respiratory symptoms like difficulty of breathing, noisy breathing, chest tightness and persistent cough with good safety profile and greater satisfaction with nebulized.

ACKNOWLEDGEMENT

Dr Savita Verma

FUNDING

Nil

AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

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