

ORIGINAL ARTICLE

Comparison of inhaler corticosteroids and oral montelukast in children with reactive airways disease.

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ABSTRACT... **Objective:** To compare the efficacy of inhaler corticosteroids and oral montelukast in children with reactive airways disease. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Pediatrics, Lady Reading Hospital, Peshawar. **Period:** 20 July 2025 to 20 January 2026. **Methods:** A total of 60 children aged 1 to 5 year with reactive airway disease for more than 3 months were enrolled using a 95% confidence level and 80% power calculation. Participant were randomized into two equal groups of 30 each. Group A received inhaler corticosteroids at 200 microgram per day and Group B received oral montelukast at 4 mg once daily in children below 1 year and 5 mg once daily in children above 1 year. Efficacy was defined as complete absence of symptom after 3 months of treatment. Chi-square test and Fischer exact test were applied to compare efficacy between groups and across stratified variables. **Results:** Inhaler corticosteroids showed efficacy in 73.3% patients compared to 33.3% with oral montelukast ($p=0.002$). Age-stratified analysis showed significant efficacy in children aged 3 years or less (77.8% versus 40.0%, $p=0.041$). Female gender demonstrated superior response to inhaler corticosteroids (84.6% versus 35.3%, $p=0.012$). Urban residents showed better efficacy with inhaler corticosteroids (76.5% versus 31.3%, $p=0.007$). **Conclusion:** Inhaler corticosteroids are significantly more effective than oral montelukast in managing reactive airways disease in children.

Key words: Asthma, Child, Glucocorticoids, Leukotriene Antagonists, Montelukast, Reactive Airways Disease, Respiratory Tract Diseases.

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INTRODUCTION

Reactive airways disease is a widespread condition among children and is employed in describing frequent instances of wheezing, cough, chest tightness and shortness of breath particularly after the exposure to an irritant such as a viral infection, cold air, exercise or allergens.¹ Asthma is often diagnosed in young children where it is not easy to make a definite diagnosis but the airway inflammation and hyper-responsiveness are similar.² The airways are swollen and more mucus is produced; this causes the airway lumen to narrow and the problem in breathing.² The symptoms of reactive airways disease may be intermittent, and the severity may vary in children, and overall quality of life and daily activities may be impaired.³ Early detection and treatment is significant since the chronic inflammation with time may result in lasting airway alteration and improperly managed disease will result in greater hospitalization and absenteeism to school.⁴

Inhaler corticosteroids are regarded as the primary treatment of children with reactive airways disease due to their direct effect on airways inflammation.⁵ These medications act by inhibiting inflammatory cell activity, reducing mucus secretion and cutting short airway hyper-reactivity and consequently leads to improved symptom control.⁶ The inhaled corticosteroids are administered directly to the lungs hence their local action is high and the side effects are not so strong.⁷ They are not applied in case of acute relief but are generally applied in long-term control and prevention of symptoms. Repeated use was also proven to lower the frequency of wheezing attacks, lung performance, and rescue medication requirement.⁸ Their effectiveness can however be decreased by poor inhaler technique and low adherence and there are parental concerns about growth suppression, but in most cases the effect is low when used correctly.⁹

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Oral montelukast is an antagonist of leukotrienes that is an add-on or alternative therapy in children with reactive airways disease.¹⁰ It also acts by inhibiting leukotrienes that are inflammatory mediators that cause bronchoconstriction, airway edema, and mucus secretion.¹¹ The administration of montelukast is easy because it is taken by mouth in a single dose, unlike inhalers, which are not well administered by young children.¹² It is typically well accepted and needs no special technique hence compliance is usually improved. Its anti-inflammatory effect is however less potent in comparison to inhaled corticosteroids and it may also be inferior in managing moderate to severe symptoms.¹³ Neuropsychiatric side effects such as mood change or sleep disturbances have been reported in a few children and thus close attention is required in children under treatment.¹⁴ In a study by Jehan N, et al. has shown that efficacy of inhaler corticosteroids was 51.58% as compare to 16.75% with oral montelukast in children with reactive airways disease.¹⁵

Local data on the management of reactive airways disease among children in Peshawar is limited and most of the treatment directions are informed by research performed in other communities. Inhaler corticosteroids and oral montelukast are both extensively used in daily practice, although there is no evidence indicating which of the two is superior and will be acceptable in local children. Hence, it is required to do such a study in Peshawar in order to compare such treatments, hence more adequate and appropriate management approaches can be devised in regards to children in this region.

METHODS

This randomized controlled trial was carried out in the Department of Pediatrics Lady Reading Hospital Peshawar from 20 July 2025 to 20 January 2026 after approval of the synopsis. Approval for the study was taken from the ethical review committee of the institution before initiation of data collection (Ref. No. 76/LRH/MTI, dated 19/03/2024). All ethical principles were followed during the conduct of the study and confidentiality of patient information was maintained throughout the research process. The sample size was calculated using a 95% confidence level and 80% power of the study.

Expected response rates were taken as 51.58% for inhaler corticosteroids and 16.75% for oral montelukast.¹⁵ The total calculated sample size was 60 children which were equally divided into two groups with 30 participants in each arm. Children of both genders, aged from 1 year to 5 years presenting with reactive airways disease for more than 3 months were included in the study. Reactive airways disease was taken as recurrent episodes of cough, wheeze or shortness of breath with objective confirmation of reversible airflow limitation on pulmonary function testing. Children with known allergy to corticosteroids or montelukast, inability to use inhaler device, poor compliance with oral medication, congenital heart defects, pulmonary tuberculosis, pneumonia, gastroesophageal reflux or tracheoesophageal fistula were excluded from the study.

Written informed consent was obtained from parents or guardians before enrollment of the child in the study. Parent were clearly informed regarding the purpose of the study and assured that participation would not pose any risk to the child. Baseline demographic details were recorded including age, gender, duration of symptoms and body weight. A detailed clinical history was taken for each child focusing on respiratory symptoms and their duration. Physical examination was performed to assess general condition and respiratory status before starting treatment. After enrollment participants were randomized into two groups using blocked randomization method. Group A received inhaler corticosteroids at a dose of 200 microgram per day while Group B received oral montelukast given as 4 mg once daily in children below 1 year and 5 mg once daily in children above 1 year. All patient were followed monthly for a total period of 3 months, and treatment response was assessed during follow-up visits. Efficacy was recorded at the end of 3 months of treatment. Efficacy was taken as complete absence of symptoms related to reactive airways disease during follow-up period.

Data were entered and analyzed using SPSS version 26. Quantitative variables such as age, body weight and duration of symptoms were expressed as mean $\pm$ standard deviation. Qualitative variables including gender and efficacy were presented as frequencies

and percentages. Comparison of efficacy between the two groups was done using chi-square test, and a p-value less than 0.05 was considered statistically significant. Stratification was performed for age, gender, symptom duration and body weight and post-stratification chi-square test was applied to assess their effect on efficacy.

RESULTS

The patient demographics showed that in Group A receiving inhaler corticosteroids, there was 30 patients with mean age of 2.67 ± 1.04 years and mean weight of 13.57 ± 3.21 kg, while in Group B receiving oral montelukast, there was also 30 patients having mean age of 3.03 ± 1.27 years and mean weight of 13.89 ± 3.69 kg (as shown in Table I). The duration of disease was quite similar in both groups with 3.27 ± 1.14 months in Group A and 3.33 ± 1.03 months in Group B (as shown in Table I). Regarding gender distribution, Group A had 17 males (56.7%) and 13 females (43.3%), whereas Group B had 13 males (43.3%) and 17 females (56.7%) (as shown in Table I). For residence, rural patients was 13 (43.3%) in Group A and 14 (46.7%) in Group B, while urban patients was 17 (56.7%) in Group A and 16 (53.3%) in Group B (as shown in Table-I).

TABLE-I

Patient demographics in both groups

Variables	Inhaler Corticosteroids (Group A)	Oral Montelukast (Group B)
	n=30	n=30
	Mean $\pm$ SD	Mean $\pm$ SD
Age (years)	2.67 ± 1.04	3.03 ± 1.27
Weight (kg)	13.57 ± 3.21	13.89 ± 3.69
Duration (months)	3.27 ± 1.14	3.33 ± 1.03
Gender	n (%)	n (%)
Male	17 (56.7%)	13 (43.3%)
Female	13 (43.3%)	17 (56.7%)
Residence		
Rural	13 (43.3%)	14 (46.7%)
Urban	17 (56.7%)	16 (53.3%)

The comparison of efficacy between both treatment groups showed that inhaler corticosteroids was significantly more effective than oral montelukast.

In Group A, 22 patients (73.3%) showed efficacy while 8 patients (26.7%) did not show efficacy, but in Group B, only 10 patients (33.3%) showed efficacy and 20 patients (66.7%) did not show efficacy, with statistically significant difference ($p=0.002$) (as shown in Table-II).

TABLE-II

Comparison of efficacy between the two groups n=60

Efficacy	Inhaler Corticosteroids (Group A)	Oral Montelukast (Group B)	P-Value
	n=30	n=30	
	n (%)	n (%)	
Yes	22 (73.3%)	10 (33.3%)	0.002*
No	8 (26.7%)	20 (66.7%)	
Total	30 (100%)	30 (100%)	

*Chi-Square Test

When efficacy was analyzed according to demographic variables, several findings was observed. For age groups, in patients ≤ 3 years, Group A showed efficacy in 14 patients (77.8%) compared to only 6 patients (40.0%) in Group B ($p=0.041$), while in patients >3 years, Group A had efficacy in 8 patients (66.7%) and Group B in 4 patients (26.7%) ($p=0.094$) (as shown in Table-III). Gender analysis revealed that in males, Group A showed efficacy in 11 patients (64.7%) versus 4 patients (30.8%) in Group B ($p=0.065$), whereas in females, Group A demonstrated efficacy in 11 patients (84.6%) compared to 6 patients (35.3%) in Group B ($p=0.012$) (as shown in Table-III). For residence, among rural patients, efficacy was seen in 9 patients (69.2%) in Group A and 5 patients (35.7%) in Group B ($p=0.098$), while among urban patients, 13 patients (76.5%) in Group A and 5 patients (31.3%) in Group B showed efficacy ($p=0.007$) (as shown in Table-III). Weight-based stratification showed that in patients ≤ 15 kg, efficacy was observed in 15 patients (78.9%) in Group A versus 5 patients (31.3%) in Group B ($p=0.009$), and in patients >15 kg, 7 patients (63.6%) in Group A and 5 patients (35.7%) in Group B demonstrated efficacy ($p=0.189$) (as shown in Table-III). Duration analysis indicated that for disease duration ≤ 3 months, efficacy was present in 15 patients (75.0%) in Group A compared to 5 patients (31.3%) in Group B ($p=0.014$), while for duration >3 months, 7

patients (70.0%) in Group A and 5 patients (35.7%) in Group B showed efficacy ($p=0.094$) (as shown in Table-III).

TABLE-III

Association of efficacy with demographic variables

Demographics Variables	Group	Efficacy		P-Value
		Yes (n, %)	No (n, %)	
Age (years)	≤3	A 14 (77.8%)	4 (22.2%)	0.041*
		B 6 (40.0%)	9 (60.0%)	
	>3	A 8 (66.7%)	4 (33.3%)	0.094*
		B 4 (26.7%)	11 (73.3%)	
Gender	Male	A 11 (64.7%)	6 (35.3%)	0.065*
		B 4 (30.8%)	9 (69.2%)	
	Fe-male	A 11 (84.6%)	2 (15.4%)	0.012*
		B 6 (35.3%)	11 (64.7%)	
Residence	Rural	A 9 (69.2%)	4 (30.8%)	0.098*
		B 5 (35.7%)	9 (64.3%)	
	Urban	A 13 (76.5%)	4 (23.5%)	0.007*
		B 5 (31.3%)	11 (68.8%)	
Weight (kg)	≤15	A 15 (78.9%)	4 (21.1%)	0.009*
		B 5 (31.3%)	11 (68.8%)	
	>15	A 7 (63.6%)	4 (36.4%)	0.189*
		B 5 (35.7%)	9 (64.3%)	
Duration (months)	≤3	A 15 (75.0%)	5 (25.0%)	0.014*
		B 5 (31.3%)	11 (68.8%)	
	>3	A 7 (70.0%)	3 (30.0%)	0.094*
		B 5 (35.7%)	9 (64.3%)	

*Fischer Exact Test

DISCUSSION

Results of this study showed inhaled corticosteroids was much more effective than the oral montelukast with efficacy rate of 73.3% ($n=22$) and 33.3% ($n=10$) respectively ($p=0.002$). This is due to the fact that inhaled corticosteroids have a greater effect in this case due to direct action of the drug to the site repair being airways to produce higher local levels of drug and instant effect at disease center. Inhaled route of accessing corticosteroids also results in improved penetration in the bronchial mucosa where it may reduce the airways inflammation and hyperresponsiveness. As opposed to that, oral montelukast has a different mechanism of action because it is absorbed systemically and acts by blocking leukotrienes receptors, which is not the

only pathway of the inflammatory cascade in reactive airways disease causing corticosteroids to inhibit several inflammatory mediators such as cytokines, chemokines and adhesion molecules.

The age-stratified analysis showed that in children ≤3 years, inhaled corticosteroids had efficacy in 77.8% ($n=14$) compared to 40.0% ($n=6$) with montelukast ($p=0.041$). This finding suggests that younger children responds better to direct airway therapy because their airways is more reactive and responds quickly to topical anti-inflammatory agents. Female gender showed particularly significant benefit from inhaled corticosteroids with 84.6% ($n=11$) efficacy versus 35.3% ($n=6$) in montelukast group ($p=0.012$). This gender difference may be related to anatomical variations in airway size and hormonal influences on inflammatory responses. Urban residence also showed significant association with better response to inhaled corticosteroids, with 76.5% ($n=13$) efficacy compared to 31.3% ($n=5$) in montelukast group ($p=0.007$), possibly due to better technique of inhaler use and compliance in urban population. Children with weight ≤15 kg demonstrated superior response to inhaled corticosteroids with 78.9% ($n=15$) efficacy versus 31.3% ($n=5$) in montelukast group ($p=0.009$), which indicates that lighter children with smaller airways benefits more from direct topical therapy.

The present study findings was consistent with several previous studies regarding superior efficacy of inhaled corticosteroids over oral montelukast. The efficacy rate of 73.3% ($n=22$) for inhaled corticosteroids in current study was comparable to Keskin O et al.¹⁶ who demonstrated that high-dose inhaled corticosteroids was effective in treating children with asthma exacerbation with significant improvements in asthma scores and pulmonary function ($P<0.0001$), which supports the present study results. This similarity can be explained by similar mechanism of direct anti-inflammatory action of inhaled corticosteroids on airways mucosa in both studies. Wei B et al.¹⁷ also found that inhaled corticosteroid therapy group had fewer exacerbations and less severe exacerbations compared to non-ICS therapy group ($P=0.046$), which is consistent with present findings that inhaled corticosteroids provides better disease control. The

comparable findings across these studies suggests that inhaled corticosteroids consistently provides better control of airway inflammation through multiple anti-inflammatory pathways. However, some differences was also noted when comparing montelukast efficacy with other studies. The efficacy rate of 33.3% (n=10) for oral montelukast in present study was lower than findings reported by Hashmat N et al.¹⁸ who found that montelukast significantly reduced duration and severity of lung symptoms in children with bronchiolitis with symptom-free days being significantly higher in montelukast group ($P<0.0001$). This difference may be due to variation in disease condition as their study focused on bronchiolitis in younger age group (2 months to 2 years) while present study included reactive airways disease in slightly older children. Similarly, Zou Y et al.¹⁹ reported that montelukast sodium was clinically effective in treating virus-related wheezing with significant improvements in clinical symptom scores, which shows better efficacy than present study finding, possibly because their study specifically targeted virus-related wheezing where leukotriene pathway plays more prominent role. Li J et al.²⁰ found no significant difference in therapeutic effect between montelukast and ketotifen ($P>0.05$), however they demonstrated that montelukast effectively reduced inflammatory cytokines levels ($P<0.05$), which suggests montelukast has anti-inflammatory properties but may not translate to superior clinical efficacy in all populations.

The combination therapy approach was explored by several studies with different results. Sun W et al.²¹ evaluated combined treatment of montelukast and budesonide in children with cough variant asthma and found that combination significantly reduced symptoms and improved pulmonary function ($P<0.001$) with lower recurrence rate of 3.57% compared to budesonide alone group with 16.07% recurrence ($P=0.026$). This suggests that combination therapy might be more beneficial than monotherapy alone. Jin W et al.²² also demonstrated that montelukast combined with budesonide aerosol significantly improved airway function and regulated T lymphocyte levels ($P<0.05$), which indicates synergistic effect of both medications. These findings differs from present study where monotherapy with inhaled corticosteroids showed

superior efficacy of 73.3% (n=22) compared to montelukast monotherapy of 33.3% (n=10), suggesting that inhaled corticosteroids alone may be sufficient for disease control in reactive airways disease. The CARE Network study²³ found that both azithromycin and montelukast allowed for significant reduction in ICS doses in children with moderate to severe asthma ($P<0.05$), which indicates that montelukast has role as steroid-sparing agent rather than primary therapy, supporting present study findings that inhaled corticosteroids remains more effective primary treatment option. The age-related finding in present study where children ≤ 3 years showed 77.8% (n=14) efficacy with inhaled corticosteroids was indirectly supported by Zou Y et al.¹⁹ who demonstrated effectiveness of montelukast in infantile wheezing, though their focus was on younger age group. The gender difference observed in current study with females showing 84.6% (n=11) efficacy with inhaled corticosteroids was not specifically addressed in reviewed studies, as most studies did not stratify results by gender, which limits direct comparison. The weight-based stratification in present study showing 78.9% (n=15) efficacy in children ≤ 15 kg suggests that lighter children benefits more from topical airway therapy, however none of reviewed studies specifically analyzed treatment response based on weight categories. The urban versus rural difference in treatment response with urban patients showing 76.5% (n=13) efficacy in current study was not discussed in any of reviewed studies as they did not stratify results based on residence, which represents gap in existing literature regarding impact of socioeconomic and geographical factors on treatment outcomes.

The current research has a number of shortcomings that should be considered. First, it was a single center study carried out in a single hospital and hence it might not be generalizable to other populations and healthcare environments. Second, the sample used was relatively small consisting of 30 patients per group and this can be significant to the statistical power of study and the capability to notice smaller variations between groups. Third, the follow-up time was restricted to a disease duration of about 3 months and the follow-up time would require extended time before the long-term

effectiveness and safety of the two treatments could be determined. Fourth, compliance and adherence to the treatment regimens was not evaluated in the study and this may have affected the outcomes of the treatments particularly inhaler technique with inhaled corticosteroid regimen.

CONCLUSION

This research has made the conclusion that inhaled corticosteroids was much more effective than oral montelukast in the treatment of children with reactive airways disease. Compared to montelukast therapy, inhaled corticosteroids were found to be more effective in managing symptoms and better treatment results were achieved. The evidence indicates that inhalation route of delivering medication directly to airways has better therapeutic effect as compared to oral systemic route in children affected by reactive airways disease.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

1	Faiqa Shah: Writing draft.
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3	Fatima Riaz: Data analysis.
4	Maria Khalid: Draft reviewing, data collection.
5	Seema Nawaz: Data collection.