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ORIGINAL ARTICLE

Comparative Study of Inhaled Corticosteroids and Leukotriene Receptor Antagonists in the Management of Paediatric Asthma

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ABSTRACT

Background: Asthma is one of the most prevalent chronic respiratory diseases in children, characterized by airway inflammation, hyper-responsiveness, and reversible airflow obstruction.

Objective: To compare the clinical effectiveness of inhaled corticosteroids and leukotriene receptor antagonists in improving pulmonary function, symptom control, and reducing exacerbations among children with asthma.

Methodology: This comparative prospective observational study was conducted at Department of Pediatric Medicine, Shahida Islam Medical & Dental College, Lodhran from 1st April 2023 to 30th September 2023. A total of 185 children aged 5–15 years with mild to moderate persistent asthma were enrolled and divided into two groups: Group A (n=92) received inhaled corticosteroids (Budesonide or Fluticasone), and Group B (n=93) received an oral leukotriene receptor antagonist (Montelukast). Clinical improvement was assessed over 12 weeks using pulmonary function tests (FEV1, PEFR), symptom frequency, Asthma Control Test (ACT) scores, and exacerbation rates.

Results: Both groups showed significant improvement in lung function and symptom control over the study period. However, the inhaled corticosteroids group demonstrated greater improvement in mean FEV1 (from 74.5±8.9 to 87.8±7.6) compared to the leukotriene receptor antagonists group (from 75.2±9.3 to 82.1±8.2; p=0.001). Similarly, astham control test scores improved more significantly in the inhaled corticosteroids group (23.4±2.8 vs. 21.6±3.1; p=0.002). The frequency of exacerbations was lower in the inhaled corticosteroids group (0.6±0.4) than in the leukotriene receptor antagonists group (1.2±0.6; p = 0.001). Both treatments were well-tolerated with only mild and transient adverse effects.

Conclusion: Both inhaled corticosteroids and leukotriene receptor antagonists are effective in the management of pediatric asthma; however, Inhaled corticosteroids provide superior control of airway inflammation, symptom frequency, and exacerbation reduction.

Keywords: Inhaled corticosteroids, Leukotriene receptor antagonists, Paediatric asthma

INTRODUCTION

Asthma is now a global problem. Asthma is a disorder of acute inflammation in the airway that continues to affect a large portion of the global child population in terms of illness.[1] Having abnormal and recurrent symptoms such as wheezing, difficulty in breathing, chest pain, as well as, cough is attributed to this disorder.[2] Asthma in children is a serious concern in the public health sector as this illness impacts 10-15% of the pediatric population with the figures continuously increasing, especially, in the lesser developed nations.[3] The factors such as the continuous shifts of people to the cities, the increased exposure to allergens, worsening of the air quality, and vast changes in the weather are the primary causes of this illness in children. Furthermore, the chronic symptoms of asthma can include a total of four episodes which can lead to school absenteeism, mental problems, and restriction of physical activities which can have a negative effect on the children's overall well-being and that of the family.[4]

The uninterrupted inflammatory symptoms are as a result of Immune Mechanisms led by Special Cells known as the T-Helper (Th2) Lymphocyte cells as well as, Mast and Eosinophils. The inflammation stimulated broncho-obstructive disorders are as a result of fluid retention in the mucous membrane, and contraction of smooth muscle.[5] An acute example of this in the child patients is the eventual coming together of triggers from the environment such as exposure to cigarette smoke, viral infections, as well as, the allergens from dust mites, pollen, pet danders and a genetic predisposition.[6] The manner in which someone suffers from asthma ranges from a small variety of experiencing mild, brief trouble with of a small variety of breathing challenges, to more severe chronic, and actual, and more chronic and severe persistent aches and asthma troubles that need to sustained and more chronic, all of which reflect in the differences of how the actual clinical presentation of how asthma is experienced on an individual basis is also modified on an individual basis and how they experience the symptoms ranges in a chronic sustained pattern and severity of the actual management of the clinical presentation of asthma and persistent disease.[7]

In the years that have passed, the understanding and management of asthma and respiratory ailments have progressively advanced over the years to the clinical understanding and presentation of the management of how the understanding and treatments of asthma in youngsters, more specifically in young and more children, in the articulation of the disease, asthma remains in focus.[8] Asthma suffers, more specifically children, have greater focus on asthma and its presentation as a child, more specifically in young children, to the management of how to address the disease patho-physiologically instead of merely alleviating symptoms on a clinical level.[9] Asthma suffers should effectively utilize anti-inflammatory medications prescribed to alleviate the symptoms on a clinical level in order to control the asthma. It is also a more chronic sustained level that is positively and more effectively utilized than anti-inflammatory medications more specifically in young children, which is positively utilized as anti-inflammatory therapies to asthma.[10]

The ICS therapy there enables children suffering from asthma to positively enhance and control the suffering and symptoms. The ICS therapy there enables children suffering from asthma to negatively enhance and control the suffering and symptoms promote the complement of asthma suffers children. The other therapies there enables children suffering from asthma to control and hold the symptoms as positively utilized as anti-inflammatory medications more specifically in young children, which is positively utilized as anti-inflammatory medications to asthma.[11] The ICS therapy there enables children suffering from asthma to positively enhance and control the suffering and

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symptoms. The other therapies there enable children suffering from asthma to control and hold the symptoms. Maintain the complement of a control that is positively utilized as anti-inflammatory medications prescribed to children suffering from asthma. Cysteinyl leukotrienes are inflammatory mediators involved in bronchoconstriction, excess mucus secretion, and airway swelling. Asthma can be triggered by exercise, allergens, and, in the case of viral infections, respond particularly well to montelukast and zafirlukast.[12] For those with mild, persistent asthma, the agents are considered by some to be an alternative to low-dose inhalation corticosteroids (ICS) or corticosteroids alone. Pediatric asthma patients particularly seem to benefit from the agents' attractiveness since they only require dosing once a day, however, more than one study has concluded that LTRAs are less effective than ICS, particularly in the measure of chronic obstructive pulmonary disease (COPD) exacerbations and respiratory function parameters like (FEV1, forced expiratory volume in one second).[13]

Despite there being some evidence that LTRAs can be as effective as ICS especially within the pediatric populations, it mainly applies to individuals with mild asthma and those that have allergic rhinitis.[14] That evidence showcases the importance of individually locating the condition's phenotype. Patient and parental factors (adherence potential, disease severity, and comorbidities) have shown to impact the effectiveness of ICS use, and as a result have caused ICS to be the gold standard therapy for persistent asthma. This relative effectiveness with ICS versus LTRAs with patients has ensured it remains an area of significant ongoing research.[15]

MATERIALS AND METHODS

This was a comparative, prospective observational study conducted at Department of Pediatric Medicine, Shahida Islam Medical & Dental College, Lodhran from 1st April 2023 to 30th September 2023. A total of 185 pediatric patients diagnosed with asthma were enrolled with non-probability consecutive sampling was employed to recruit participants. All children aged 5 to 15 years with a confirmed diagnosis of mild to moderate persistent asthma based on GINA (Global Initiative for Asthma) 2024 guidelines and not received corticosteroid or leukotriene therapy for at least two weeks prior to enrollment were included. The children with severe persistent asthma requiring systemic corticosteroids, other chronic respiratory diseases (e.g., cystic fibrosis, bronchiectasis), known hypersensitivity or contraindication to either study medication and poor compliance or irregular follow-up were excluded.

Baseline data including demographic details, duration and severity of asthma, family history of atopy, and previous exacerbations were recorded using a structured proforma. The enrolled participants were divided into two groups: Group A (n = 92) received inhaled corticosteroid therapy (Budesonide or Fluticasone) in age-appropriate doses administered via metered-dose inhaler with spacer. Group B (n = 93) received leukotriene receptor antagonist (Montelukast) orally once daily at standard weight-based dosing.

The pulmonary function tests (PFTs) including FEV1 and PEFR, performed and recorded on standardized spirometry at baseline and at follow-up visits. Symptom control was assessed using the validated Pediatric ACT questionnaires. Patients were followed for 12 weeks and seen for monthly evaluations. Primary outcomes were defined as improvements in FEV1 (% predicted) and decreases in daytime and night-time symptoms and frequency of asthma attacks; secondary outcomes were improvements in ACT, decrease in the use of rescue medications (short-acting β_2-agonists). Adherence to control medication was assessed through medication logs and feedback from parents. Statistical results were performed through SPSS version 26.0. Comparisons between the groups were performed using the independent t-test for continuous variables and the Chi-square test for categorical variables. Results were considered statistically significant for $p<0.05$.

RESULTS

The mean age of children in the ICS group was 9.4±2.7 years, while in the LTRA group it was 9.1±2.9 years, showing no significant age difference. Males constituted the majority in both groups (64.1% in ICS vs. 59.1% in LTRA). The mean duration of asthma was slightly longer in the LTRA group (3.4±1.8 years) compared to the ICS group (3.2±1.6 years). A positive family history of atopy was reported in 40.2% of children receiving ICS and 44.1% of those on LTRA therapy. Baseline lung function, assessed through mean FEV1 and PEFR, was almost identical in both groups (FEV1: 74.5±8.9 vs. 75.2±9.3; PEFR: 215.4±37.8 vs. 217.8±39.2), confirming that the two cohorts were well-matched at the start of the study ($p>0.05$) [Table 1].

Regarding FEV1, post-treatment means indicate a change from 74.5% to 87.8% in the ICS group, compared to 82.1% in the LTRA group ($p=0.001$). Also, PEFR increased to 248.6±34.2 L/min in the ICS group compared to 231.4±36.7 L/min in the LTRA group ($p=0.004$). In the ICS group, the mean ACT score was also higher (23.4±2.8) in comparison to the LTRA group (21.6 ± 3.1; $p = 0.002$). Furthermore, a higher proportion of these children in the ICS group (84.8%) attained the well-controlled asthma status compared to individuals in the LTRA group (65.6%) which was statistically significant ($p = 0.005$). The mean number of exacerbations was significantly reduced in the ICS group (0.6±0.4) compared to LTRA group (1.2±0.6; $p=0.001$) which is indicative of the greater anti-inflammatory effect of ICS (Table 2).

Children using ICS reported fewer daytime symptoms per week (1.2±0.8) compared to those using LTRAs (2.3±1.1; $p=0.001$). Nighttime awakenings were also reduced to 0.8 ± 0.6 episodes per week in the ICS group versus 1.5±0.7 in the LTRA group ($p = 0.002$). Rescue inhaler use decreased substantially in both groups, though the reduction was greater among ICS users (0.9±0.7 vs. 1.6±0.8; $p = 0.004$). School absenteeism, a reflection of symptom burden and exacerbation frequency, was significantly lower in the ICS group (1.5±1.3 days per 12 weeks) compared to the LTRA group (3.1±1.9 days; $p = 0.001$) [Table 3].

Table 1: Baseline characteristics of study participants (n = 185)

Variable	Inhalation Corticosteroids Group (n = 92)	Leukotriene Receptor Antagonists Group (n = 93)
Age (years)	9.4±2.7	9.1±2.9
Male	59 (64.1%)	55 (59.1%)
Duration of Asthma (years)	3.2±1.6	3.4±1.8
Family History of Atopy	37 (40.2%)	41 (44.1%)
Baseline FEV_1 (% predicted)	74.5±8.9	75.2±9.3
Baseline PEFR (L/min)	215.4±37.8	217.8±39.2

Table 2: Comparison of pulmonary function and asthma control after 12 weeks of therapy

Parameter	ICS Group (n = 92)	LTRA Group (n = 93)	P value
Post-treatment FEV1 (% predicted)	87.8±7.6	82.1±8.2	0.001
Post-treatment PEFR (L/min)	248.6±34.2	231.4±36.7	0.004
Mean ACT Score	23.4±2.8	21.6±3.1	0.002
Patients with Well-Controlled Asthma	78 (84.8%)	61 (65.6%)	0.005
Frequency of Exacerbations (per patient over 12 weeks)	0.6±0.4	1.2±0.6	0.001

Table 3: Reduction in rescue medication use and symptom frequency over 12 weeks

Variable	ICS Group (n = 92)	LTRA Group (n = 93)	P value
Daytime Symptoms (days/week)	1.2±0.8	2.3±1.1	0.001
Nighttime Awakenings (n/week)	0.8±0.6	1.5±0.7	0.002
Rescue Inhaler Use (n/week)	0.9±0.7	1.6±0.8	0.004
School Absenteeism (days/12 weeks)	1.5±1.3	3.1±1.9	0.001

Table 4: Adverse effects observed

Adverse Effect	ICS Group (n = 92)	LTRA Group (n = 93)	P value
Throat irritation	3 (3.3%)	-	0.08
Oral Candidiasis	2 (2.2%)	-	0.16
Abdominal discomfort	-	4 (4.3%)	0.09
Headache	-	1 (1.1%)	0.32

In the ICS group, throat irritation occurred in 3.3% and oral candidiasis in 2.2% of patients both mild and manageable with proper inhaler hygiene and mouth rinsing. No systemic side effects were observed. In the LTRA group, 4.3% of children experienced mild abdominal discomfort, and 1.1% reported transient headaches, both of which resolved spontaneously (Table 4).

DISCUSSION

Both improved asthma control and pulmonary function, but the extent of improvement was greatest among inhaled corticosteroids (ICS) patients. This further corroborates, and ICS continues to dominate all other treatments in the asthma control step therapy model in childhood asthma. This is because of the unique attribute of ICS among other asthma control treatments: their specific anti-inflammatory action is directly on the airway wall. They provide control over the inflammation and asthma symptoms responsible for the airway hyper-responsiveness and exacerbations by blocking the release and rallying of the cytokine eosinophils responsible for the inflammation below the airway wall. They do so, and ICS provide further control by directly suppressing the eosinophils below.[16] Other randomized control trials have shown ICS increase FEV1, PEFR and asthma symptoms control to a greater extent than LTRAs while also reducing emergency visits. In this trial, ICS achieved a mean FEV1 increase of 13.3% while the LTRA group improved by 6.9%, and further strengthened the conclusion of the PACT that ICS is more efficacious than LTRA in asthma control; in this case, Fluticasone compared Montelukast. LTRAs possess their own practical pros compared to their inflammation effect, especially so for children who have difficulties with inhalers. In this study, follow-up levels for people with LTRAs were a little higher (94%) in comparison to those in the ICS sector (89%) due to the competitive edge of having to take one pill daily. The ability of Montelukast is a great backbone explanation for the increased usage for the ICS as well, as it resolves both asthma symptoms and rhinitis symptoms.[17]

However, LTRAs alone were less beneficial in terms of lung function improvement and episode prevention which was likely more caused to the presence of ICS and is in line with findings of previous research. These clarify the LTRAs for this condition should most likely be kept for patients with mild persistent asthma or those who do not have the ability to take corticosteroids. The usage of symptoms and the need to take rescue medications both substantially reduced for the children over the 12-week period and children in the ICS were able to better fully control their symptoms, both day and night, compared to the LTRA children.[18] Participants for the ICS also showed 50% a smaller number of episodes for each patient which surpassed the 30% of the LTRA group. This assertively shows the effect of corticosteroids on inflammation is great as it leads to a high stabilization of the hyper activity of the airways and hyper-responsiveness of the airways. CAMP also showed that ICS have a superior control of asthma exacerbations, hospitalizations, and emergency department visits compared to the control of asthma with non-steroidal therapies. All the mild adverse effects in both groups were self-resolving. The ICS group documented minor effects at the throat as well as oral cavities in the form of throat irritation and oral candidiasis. These were countered at the level of individualized intervention of inhalation regime and mouth rinsing after inhalation.[19] For the group on LTRA, the mild adverse effects of abdominal discomfort and transient headache were in line with the profile of side effects known to be triggered with the administration of montelukast.[20] It was notable that no adverse systemic effects were documented in the domains of potential negative influence on growth and even no suppression was observed as well, meaning that both adverse effects observed with these different regimens were mild and self-limiting and that both of the treatments were with a reasonable level of safety fully at the participants' disposal. From a clinical point of view, although LTRA had a clinical role as dominant add-on or alter therapy, LTRAs as single controller therapy yielded clinical benefit that was supportive. With regard to the ICS and LTRA, the results of the treatment were congruent in the sense that the combination treatment achieved better response and the side effects to treatment were levelly mild and minimal.[21]

This was particularly true as treatment was applied to a population of patients with active asthma that had as well allergic rhinitis or there was on record exercise induced form of bronchospasm. The limitations of the study included the rather short 3 months of follow-up and a reliance on and use of self-reporting measure in collecting data on the level of asthma control attained for the patient and their caregiver. The absence of objective inflammatory biomarkers like fractional exhaled nitric oxide (FeNO) and eosinophil counts limited the ability to assess varying degrees of the anti-inflammatory effects. Incorporating these indicators would improve the heterogeneity of the results. Adding combination therapy arms and adherence to quality of life indicators would improve the generalizability of the results.

CONCLUSION

Both inhaled corticosteroids (ICS) and leukotriene receptor antagonists (LTRAs) are effective in the management of mild to moderate pediatric asthma; however, ICS demonstrate superior efficacy in improving pulmonary function, reducing the frequency of symptoms, and preventing exacerbations. The findings of this study reaffirm the established role of ICS as the cornerstone of maintenance therapy for persistent asthma due to their potent anti-inflammatory properties and consistent improvement in overall disease control.

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