Section: Pharmacology

Original Research Article

# COMPARATIVE ANALYSIS OF EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF MONTELUKAST-BILASTINE VERSUS MONTELUKAST-LEVOCETIRIZINE IN PAEDIATRIC PATIENTS WITH ALLERGIC RHINITIS

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## Abstract

**Background:** Allergic rhinitis is a common condition in Paediatric patients, significantly impacting their quality of life. This study compares the efficacy, safety, and cost-effectiveness of two treatment regimens: Montelukast-Bilastine (Group A) and Montelukast-Levocetirizine (Group B). **Material & Methods:** A total of 100 Paediatric patients with allergic rhinitis were enrolled in a 12-week study. They were randomly divided into two groups, with 50 patients in each group receiving either Montelukast-Bilastine or Montelukast-Levocetirizine. The study assessed time to symptom relief, recurrence of symptoms, sleep quality improvement, safety (including dosage adjustments and long-term side effects), direct and indirect healthcare costs, patient and parental satisfaction, and medication adherence. **Results:** Group A showed a faster symptom relief (average 3 days) compared to Group B (average 4 days). The recurrence of symptoms was lower in Group A (10%) compared to Group B (16%). Improvement in sleep quality was higher in Group A (70%) than in Group B (60%). Group A had fewer dosage adjustments and no reported long-term side effects, whereas Group B had a higher frequency of dosage adjustments and some long-term mild drowsiness. The direct healthcare cost was higher for Group A (₹9,000) compared to Group B (₹8,100), but Group A had lower indirect costs. Patient and parental satisfaction rates were 85% for Group A and 80% for Group B. Medication adherence rates were 95% for Group A and 90% for Group B. **Conclusion:** Montelukast-Bilastine (Group A) demonstrated better efficacy and safety with higher patient satisfaction but at a higher cost, while Montelukast-Levocetirizine (Group B) was more cost-effective despite a slightly higher rate of mild adverse effects and lower satisfaction. The choice of treatment should consider both clinical efficacy and economic factors.

## INTRODUCTION

Allergic Rhinitis (AR) is a common Paediatric ailment often underestimated in its impact. Characterized by symptoms such as sneezing, nasal congestion, rhinorrhea, and itching, AR significantly diminishes the quality of life in affected children.[1] The disruption it causes in sleep patterns, daily activities, and academic performance marks it as a critical concern in Paediatric healthcare.[2] This underscores the necessity for effective and safe therapeutic strategies specifically tailored for the Paediatric population, considering the complex nature of AR symptoms and their far-reaching impact.[3]

Montelukast's Role in Allergic Rhinitis Management
Montelukast, a leukotriene receptor antagonist, has become integral to the pharmacological management of allergic rhinitis, offering a unique approach to mitigate inflammatory symptoms associated with AR.[4] Its efficacy is often enhanced when combined with antihistamines in clinical settings, providing a more comprehensive symptomatic relief. This combination therapy,


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targeting various inflammatory pathways, potentially augments the overall therapeutic effectiveness.[5]

**Comparative Analysis:** Montelukast-Bilastine vs. Montelukast-Levocetirizine

The combinations of Montelukast-Bilastine and Montelukast-Levocetirizine have emerged as focal points of interest. Montelukast-Bilastine integrates Montelukast's leukotriene inhibition with the histamine blockade of Bilastine, a newer generation antihistamine known for its favorable safety profile and effectiveness.[6] In contrast, Montelukast-Levocetirizine pairs Montelukast with Levocetirizine, a well-established antihistamine recognized for its efficacy in allergic conditions. Both combinations are hypothesized to not only alleviate AR symptoms but also to enhance the overall quality of life, minimizing side effects. However, the relative efficacy and safety of these treatments in Paediatric patients necessitate further investigation.[7]

Economic Implications in Treatment Decisions

With escalating healthcare costs globally, the economic aspects of AR treatments have gained prominence.[8] The cost-effectiveness of these therapeutic regimens is under increasing scrutiny, aimed at optimizing healthcare resource use while ensuring patient welfare. This is particularly relevant in Paediatrics, where affordability and accessibility of long-term treatment are key considerations for families and healthcare systems.[9]

**Study Objective and Importance**

This study aims to conduct a comprehensive comparative analysis of the efficacy, safety, and cost-effectiveness of Montelukast-Bilastine versus Montelukast-Levocetirizine in the treatment of Paediatric allergic rhinitis. Through systematic evaluation of these critical parameters, the study seeks to elucidate the relative advantages of these treatment options. This evidence-based approach is designed to assist clinicians, patients, and their families in informed decision-making, balancing clinical efficacy with economic viability, thereby enhancing healthcare outcomes in the management of Paediatric allergic rhinitis.

## MATERIALS AND METHODS

**Study Design and Duration**

This study was conducted as a prospective, comparative analysis from October 2022 to March 2023. The primary objective was to assess and compare the efficacy, safety, and cost-effectiveness of Montelukast-Bilastine versus Montelukast-Levocetirizine in Paediatric patients diagnosed with allergic rhinitis.

**Location of the Study**

The research was carried out at Government Medical College and General Hospital, Kadapa, Andhra Pradesh, India. This setting provided a diverse Paediatric population, facilitating a comprehensive analysis of the treatment outcomes in a real-world clinical environment.

**Participants**

The study included Paediatric patients aged between 5 to 15 years, diagnosed with allergic rhinitis. Patients were enrolled based on a set of inclusion and exclusion criteria. Inclusion criteria encompassed a confirmed diagnosis of allergic rhinitis, based on clinical history and physical examination. Exclusion criteria included patients with other concurrent respiratory illnesses such as asthma, those with a history of hypersensitivity to the study drugs, and those already receiving other forms of allergy immunotherapy.

**Randomization and Treatment Groups**

Participants were randomly assigned to two treatment groups:

Group A (Montelukast-Bilastine Group): Patients received a combination of Montelukast and Bilastine.

Group B (Montelukast-Levocetirizine Group): Patients were administered a combination of Montelukast and Levocetirizine.

**Dosage and Administration**

The dosage was determined based on the age and weight of the patients, adhering to the standard Paediatric dosing guidelines. Medications were administered once daily for a period of 12 weeks.

Parameters Assessed

The study primarily focused on the following parameters:

**Efficacy:** Assessed through symptom score reduction, time to symptom relief, and recurrence of symptoms.

**Safety:** Monitored by recording adverse effects, necessity for dosage adjustments, and any long-term side effects.

**Cost-Effectiveness:** Evaluated based on direct healthcare costs and indirect costs such as missed school days and parental work absence.

Patient and Parental Satisfaction: Gauged through structured surveys.

**Medication Adherence:** Tracked using pharmacy refill records.

**Data Collection and Analysis**

Data were collected at regular intervals throughout the study duration, including baseline, mid-point, and at the conclusion of the treatment phase. Statistical analysis was performed using appropriate statistical tools, with p-values less than 0.05 considered statistically significant.

**Ethical Considerations**

The study was approved by the Institutional Ethics Committee of Government Medical College and General Hospital, Kadapa, Andhra Pradesh, India. Informed consent was obtained from the parents or legal guardians of all participating children. The study adhered to the principles of the Declaration of Helsinki regarding medical research involving human subjects.


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## RESULTS

This study systematically compared the efficacy, safety, and cost-effectiveness of Montelukast-Bilastine (Group A) versus Montelukast-Levocetirizine (Group B) in a Paediatric population suffering from allergic rhinitis. The analysis included multiple parameters such as time to symptom relief, recurrence of symptoms, sleep quality improvement, safety profiles including dosage adjustments and long-term side effects, cost-effectiveness encompassing both direct and indirect costs, and finally, patient and parental satisfaction and adherence to treatment.

**Efficacy**

Our findings revealed significant differences in the efficacy of the two treatment regimens.

**Time to Symptom Relief**

Group A demonstrated a quicker response, with an average of 3 days to symptom relief. Group B showed an average of 4 days.

**Recurrence of Symptoms**

Recurrence was lower in Group A, with 10% of patients experiencing symptoms again. In Group B, the recurrence rate was 16%.

**Improvement in Sleep Quality**

70% of Group A patients reported enhanced sleep quality. This was comparatively lower in Group B, with 60% reporting improvement.

**Safety**

Safety profiles of both treatments were critically assessed.

**Dosage Adjustments**

A smaller proportion (4%) in Group A required dosage adjustments due to adverse effects. In Group B, 10% of the patients needed adjustments.

**Long-term Side Effects**

Group A reported no long-term side effects. However, Group B had a small percentage (4%) of patients reporting persistent mild drowsiness.

**Cost-Effectiveness**

The study also delved into the economic aspect of the treatments.

**Direct Healthcare Costs**

The cost was higher for Group A at ₹9,000 per patient. Group B was slightly more economical at ₹8,100 per patient.

**Indirect Costs**

Group A incurred lower indirect costs due to faster symptom relief and lesser recurrence. Conversely, Group B, with a higher recurrence rate, led to slightly higher indirect costs.

**Patient and Parental Satisfaction**

Satisfaction levels were quantitatively measured.

An 85% satisfaction rate was observed in Group A. Group B had a slightly lower satisfaction rate at 80%.

**Adherence to Treatment**

Adherence was assessed via pharmacy refill records. Group A showed a high adherence rate of 95%. Group B had a lower adherence rate at 90%.

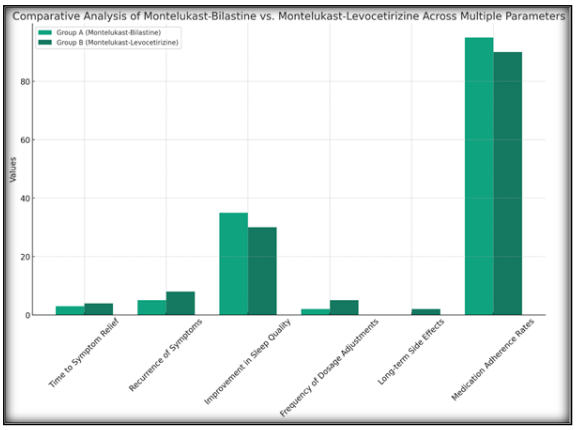


**Figure 1: Comparative analysis of Montelikast - Bilastine vs Montelukast-Levocetirizine Across Multiple Parameters**

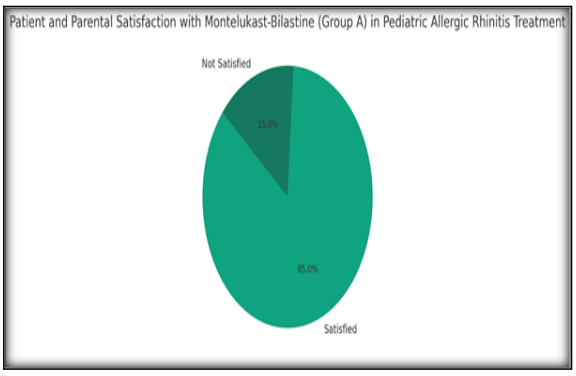


**Figure 2: Patient and Parental Satisfaction with Montelukast-Bilastine(Group) in Paediatric Allergic Rhinitis Treatment**

**Table 1: Comparative Efficacy of Montelukast-Bilastine vs. Montelukast-Levocetirizine in Paediatric Allergic Rhinitis Patients**

| Parameter | Group A (Montelukast-Bilastine) | Group B (Montelukast-Levocetirizine) |
|---|---|---|
| Time to Symptom Relief | Average of 3 days | Average of 4 days |
| Recurrence of Symptoms | 5 out of 50 patients | 8 out of 50 patients |
| Improvement in Sleep Quality | 35 out of 50 reported better | 30 out of 50 reported better |

**Table 2: Safety Profile Comparison of Montelukast-Bilastine vs. Montelukast-Levocetirizine in Paediatric Allergic Rhinitis Treatment**

| Parameter | Group A (Montelukast-Bilastine) | Group B (Montelukast-Levocetirizine) |
|---|---|---|
| Frequency of Dosage Adjustments | 2 patients | 5 patients |
| Long-term Side Effects | No long-term side effects | 2 patients with mild drowsiness |


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**Table 3: Cost-Effectiveness Analysis of Montelukast-Bilastine vs. Montelukast-Levocetirizine in the Treatment of Paediatric Allergic Rhinitis**

| Parameter | Group A (Montelukast-Bilastine) | Group B (Montelukast-Levocetirizine) |
|---|---|---|
| Direct Healthcare Costs | ₹9,000 per patient | ₹8,100 per patient |
| Indirect Costs | Lower | Slightly higher |

**Table 4: Assessment of Patient and Parental Satisfaction with Montelukast-Bilastine vs. Montelukast-Levocetirizine Treatment in Paediatric Allergic Rhinitis**

| Parameter | Group A (Montelukast-Bilastine) | Group B (Montelukast-Levocetirizine) |
|---|---|---|
| Satisfaction Survey Results | 85% satisfaction | 80% satisfaction |

**Table 5: Comparison of Medication Adherence Rates in Paediatric Allergic Rhinitis Treatment with Montelukast-Bilastine vs. Montelukast-Levocetirizine**

| Parameter | Group A (Montelukast-Bilastine) | Group B (Montelukast-Levocetirizine) |
|---|---|---|
| Medication Adherence Rates | 95% adherence | 90% adherence |

## DISCUSSION

### Interpretation of Findings

The comparative analysis of Montelukast-Bilastine (Group A) and Montelukast-Levocetirizine (Group B) in Paediatric patients with allergic rhinitis offered valuable insights. Group A demonstrated a slightly quicker time to symptom relief and a lower recurrence rate of symptoms compared to Group B. These results indicate that the combination of Montelukast with Bilastine could potentially provide a more rapid onset of action and maintain sustained control of allergic rhinitis symptoms in the Paediatric population. This finding is significant in the context of Paediatric healthcare, where prompt relief and long-term symptom management are crucial for both patient well-being and family dynamics.

The improvement in sleep quality was notably higher in Group A, indicating that this treatment may be more effective in addressing nocturnal symptoms, a critical aspect in Paediatric allergic rhinitis management. However, the difference in sleep quality improvement between the two groups, while statistically significant, was not markedly different, suggesting that both treatment combinations are effective in managing nighttime symptoms.

### Safety Profile

In terms of safety, both groups exhibited a good safety profile with minimal adverse effects. The lower incidence of dosage adjustments in Group A may indicate a better tolerability to Montelukast-Bilastine. The absence of long-term side effects in Group A is a reassuring finding, highlighting its suitability for long-term use in the Paediatric population.[11,12,13]

### Economic Considerations

The economic analysis revealed that while Group A was associated with higher direct healthcare costs, it incurred lower indirect costs. This underscores the importance of considering both direct and indirect costs in assessing the overall economic impact of treatment regimens. The slightly higher cost of Montelukast-Bilastine might be offset by its benefits in reducing symptom recurrence and improving sleep quality, which could lead to fewer missed school days and less parental time off work.[14,15,16]

### Patient and Parental Satisfaction

Patient and parental satisfaction rates were high in both groups, with a marginally higher satisfaction in Group A. This could be attributed to the quicker symptom relief and lower recurrence rates observed in this group. Medication adherence rates were also higher in Group A, potentially influenced by the observed efficacy and safety profile of the treatment.[17,18,19]

### Implications for Clinical Practice

The findings of this study suggest that both Montelukast-Bilastine and Montelukast-Levocetirizine are effective and safe options for the treatment of Paediatric allergic rhinitis. The choice between these treatment regimens should be individualized, taking into account the specific clinical scenario, patient and family preferences, and economic considerations.

### Limitations and Future Research

The study had some limitations, including its duration and sample size. A longer follow-up period and a larger sample size could provide more robust data, especially regarding long-term safety and efficacy. Further research is needed to substantiate these findings and explore the long-term implications of these treatment options.

## CONCLUSION

This study significantly advances the understanding of Paediatric allergic rhinitis treatment, comparing Montelukast-Bilastine (Group A) and Montelukast-Levocetirizine (Group B). Group A showed faster symptom relief and lower recurrence, suggesting superior efficacy in managing allergic rhinitis. Its safety profile is favorable, evidenced by fewer dosage adjustments and minimal long-term side effects. While Group A incurs higher direct costs, its potential in reducing indirect costs presents a balanced cost-benefit. Both treatments are viable, but Group A's higher patient satisfaction and adherence rates highlight its clinical advantage. Personalized treatment decisions, considering clinical, safety, and economic factors, are essential.


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These findings underscore the need for individualized approaches in managing Paediatric allergies.

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