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Original Research Article

Clinician's perspectives on montelukast and levocetirizine combination for managing allergic rhinitis and co-occurring asthma in the Indian context: A questionnaire based survey

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Abstract

Background: Allergic rhinitis (AR) is a significant public health concern in India, with a high prevalence across all age groups. This study aimed to gather clinicians' perspectives on the use of a combination of montelukast and levocetirizine for managing AR and co-occurring asthma in Indian settings.

Materials and Methods: A cross-sectional study was conducted among clinicians using the 27-item questionnaire focused on their clinical observations and experiences with montelukast and levocetirizine in managing AR. Data were analyzed using descriptive statistics, with results presented as percentages and visualized through pie and bar charts.

Results: Out of 882 clinicians, approximately 64% of them stated that recurrent upper respiratory tract infections (URTIs) might signal undiagnosed AR. Most of the respondents (81.63%) preferred a combination of antihistamines and leukotriene receptor antagonists (LTRAs) for long-term AR management. Most participants (90.48%) identified levocetirizine as their top choice among antihistamines. About 80% of the clinicians noted equal AR diagnosis rates across genders, with 90.93% observing symptom improvement in the morning. Around 72% of clinicians cited better patient compliance as a key benefit of the montelukast-levocetirizine combination. Additionally, 77% of clinicians favored this combination for asthma patients before initiating inhalation therapy.

Conclusion: The study highlights the widespread use of montelukast and levocetirizine for AR management, with strong clinician preference due to its efficacy and patient compliance benefits. Also, recurrent URTIs were identified as a potential indicator of undiagnosed AR, as well as the common presentation of concomitant conditions such as asthma and allergic conjunctivitis.

Keywords: Allergic rhinitis, Montelukast, Antihistamines, Levocetirizine, Leukotriene receptor antagonists.

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1. Introduction

Globally, allergic rhinitis (AR) affects over 400 million people, with prevalence rates ranging from 10% to 30% in adults and over 40% in children.^{1,2,3} In India, approximately 20% to 30% of the population suffers from AR, significantly impacting both children and adults. Among these, 75% of children and 80% of adults with asthma also experience AR symptoms. Despite being perceived as a minor condition, AR has a substantial personal impact, often impairing daily activities and overall well-being.⁴ AR and asthma are common comorbid conditions, frequently presenting complex diagnostic and treatment challenges. Both are chronic diseases that can severely affect quality of life, yet

they often remain undiagnosed, particularly in primary care settings.^{5,6}

The AR and its Impact on Asthma (ARIA) guidelines classify AR based on chronicity (intermittent or persistent) and severity (mild, moderate, or severe), using symptoms and their impact on quality of life as assessment criteria.⁷ Antihistamines are the mainstay of treatment; these medications block histamine receptors on nerve cells, effectively reducing the allergic response. However, antihistamines alone are often insufficient to treat all symptoms of AR, especially those related to inflammation. Therefore, combining antihistamines with leukotriene

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receptor antagonists (LTRA), such as montelukast, has become a more effective approach for managing the disease.⁸

Montelukast, a highly selective LTRA, binds to cysteinyl leukotriene receptors, particularly leukotrienes D4 and E4. By inhibiting the action of leukotrienes, montelukast reduces inflammation and prevents bronchoconstriction, making it especially beneficial for patients with both asthma and AR.⁹ Levocetirizine, on the other hand, is an antihistamine that selectively blocks the H1 histamine receptor. By preventing histamine from binding to this receptor, levocetirizine reduces common allergic symptoms, such as sneezing, itching, and nasal congestion. The dual action of montelukast and levocetirizine, targeting both histamine release and leukotriene-mediated inflammation, offers a comprehensive approach to managing AR.¹⁰

This combination has emerged as an effective strategy to address the limitations of monotherapy, offering better symptom control, particularly in patients with coexisting asthma. The treatment not only alleviates residual symptoms but also improves the overall quality of life for individuals suffering from the condition. In addition, the combination enhances treatment adherence, as it simplifies the management regimen, potentially leading to better long-term outcomes for patients with AR and asthma.^{8,11,12} Given the high prevalence of both asthma and AR in the country, combining these medications may improve patient management and help develop evidence-based guidelines tailored to the local population. This approach not only addresses the symptoms of AR but also considers the broader impact on the daily lives of patients, improving both clinical outcomes and patient satisfaction. Further research and clinical application of this combination therapy will help refine treatment strategies and optimize patient care. The objective of the present survey-based study is to understand clinicians' perspectives regarding the use of the montelukast and levocetirizine combination in the management of AR and co-occurring asthma in Indian settings.

2. Materials and Methods

We carried out a cross-sectional study among specialists in managing AR in the major Indian cities from June 2023 to December 2023.

2.1. Questionnaire

The questionnaire booklet named CARA (Clinicians feedback on allergic rhinitis and asthma in Indian Patients and usage of Montelukast and Levocetirizine) study was sent to the otorhinolaryngologists who were interested to participate. The CARA questionnaire booklet consisted of 27 questions regarding current feedback, clinical observations, and the clinical experience of specialists in managing AR with the combination of montelukast and levocetirizine. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee which was

recognized by the Indian Regulatory Authority, Drug Controller General of India.

2.2. Participants

An invitation was sent to leading otorhinolaryngologists in managing AR in the month of March 2023 for participation in this Indian survey. About 882 clinicians from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. Otorhinolaryngologists were requested to complete the questionnaire without discussing with peers. A written informed consent was obtained from each specialists prior initiation of the study.

2.3. Statistical analysis

The data were analysed using descriptive statistics. Categorical variables were presented as percentages to provide a clear insight into their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. To visualize the distribution of the categorical variables, pie, and bar charts were created using Microsoft Excel 2013 (version 16.0.13901.20400).

3. Results

Of the 882 survey participants, nearly 33% (33.09%) reported that 31-40 cases of co-occurrence of AR are observed monthly in routine practice. Half of the participants (50.45%) indicated that the most common concomitant diseases associated with AR are allergic conjunctivitis, sinusitis, middle ear infections, and asthma. About 64% of respondents agreed that recurrent URTIs could indicate undiagnosed AR (**Figure 1**).

Nearly 33% (32.54%) of the clinicians reported diagnosing 21-30 cases of AR monthly in their clinical practice. The majority (81.63%) of the participants preferred a combination of antihistamines and LTRA for the long-term management of AR (**Table 1**). Approximately 90% reported levocetirizine as their preferred antihistamine for managing AR (**Table 2**).

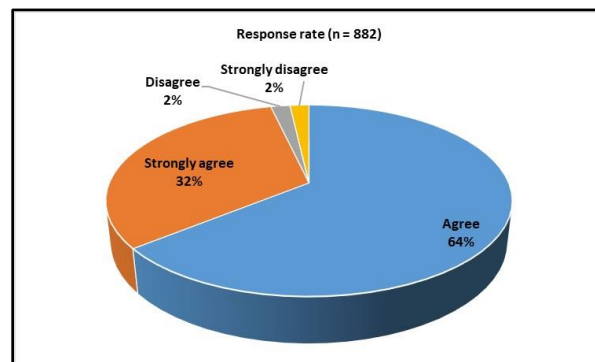


Figure 1: Distribution of responses regarding recurrent URTI as an indicator of undiagnosed AR

Table 1: Distribution of response to preferred choice for long-term management of AR in clinical practice

Long-term management	Response rate (n = 882)
Only antihistamines	6.92%
Only leukotriene receptor antagonists	10.88%
Combination of antihistamine and leukotriene receptor antagonists	81.63%
Intranasal corticosteroids	0.45%
Not Attempted	0.11%

Table 2: Distribution of response to preferred antihistamine for the management of AR in clinical practice

Preferred antihistamine	Response rate (n = 882)
Levocetirizine	90.48%
Fexofenadine	2.95%
Bilastine	5.56%
Loratadine	0.34%
Desloratadine	0.45%
Montelukast+ levocetirizine	0.11%
Not Attempted	0.11%

Around 35% of participants cited acute AR as the preferred indication for the montelukast + levocetirizine combination over plain antihistamine therapy. About 72% of respondents noted that improved patient compliance is the most compelling advantage of recommending the montelukast + levocetirizine combination for AR (

Figure 2). Approximately 31% of the participants reported that the 21-30 age group had the highest distribution of AR cases. Most clinicians (80%) indicated that the frequency of AR diagnoses was comparable across both genders (**Figure 3).**

The majority (90.93%) of the participants observed improvements in morning AR symptoms with the montelukast + levocetirizine combination (**Table 3).** Less than half (48.19%) stated that 26-50% of patients require a combination of montelukast and antihistamines for AR. About 68% of the clinicians reported that the benefits of montelukast + levocetirizine include improvements in daytime and nighttime nasal symptoms, as well as daytime eye symptoms (**Figure 4).**

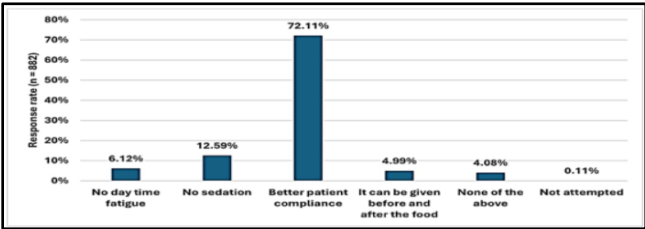


Figure 2: Distribution of response to the most compelling advantage for recommending montelukast + levocetirizine combination in clinical practice for AR.

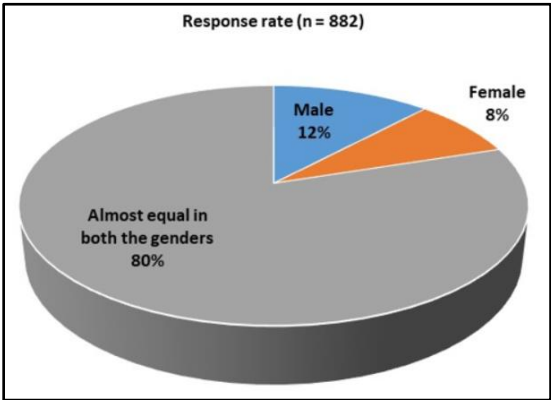


Figure 3: Distribution of response to frequency of AR diagnosis in clinical practice based on patient demographics

Table 3: Distribution of response to improvement in morning AR symptoms in clinical practice with treatment interventions.

Morning symptom improvement	Response rate n = 882
Montelukast + levocetirizine combination	90.93%
Montelukast + fexofenadine combination	4.08
Montelukast + bilastine combination	4.76%
All of the above	0.11%
Not attempted	0.11%

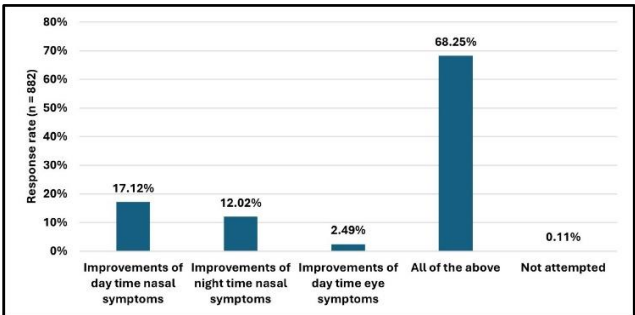


Figure 4: Distribution of response to clinical opinion regarding the benefits of montelukast + levocetirizine combination in the management of AR.

More than half (65.76%) of participants noted that morning symptoms are the most common complaints among AR patients. Approximately 46% recommended a 6-week duration for montelukast + levocetirizine therapy for AR with asthma. Nearly half (46.71%) of the participants rated the clinical efficacy of montelukast + levocetirizine as "very good" for the long-term management of AR. About 40% reported that adherence to medications is better among urban-educated AR patients. Around 60% of the participants indicated that more than 61% of the patients require

education on the dos and don'ts of AR management. About 54% of participants reported that pollen and dust mites are the most common causes of AR in their clinical practice. Approximately 55% stated that patients with AR and asthma are the preferred candidates for montelukast use. About 37% reported that the highest number of AR patient visits occurred in January and February. Half (49.66%) of them stated that the severity of allergies is a key factor in determining the choice of antihistamine for AR patients. Most participants (77%) preferred antihistamine + LTRA therapy for patients with bronchial asthma before initiating inhalation therapy (Table 4).

Table 4: Distribution of response to preferred therapy for patients with bronchial asthma before initiating inhalation therapy in clinical practice

Preferred therapy	Response rate (n = 882)
Antihistamine + corticosteroids	11.9%
Antihistamine	10.66%
Antihistamines+ leukotriene receptor antagonist	77.1%
Antihistamine plus bronchodilators, with steroids if wheeze is troublesome	0.11%
Not attempted	0.22%

About 61% of participants relied on clinical history for diagnosing AR. Approximately 46% of participants noted the efficacy advantages of the montelukast + levocetirizine combination for managing AR. About 54% of participants favoured mass education through social media as the preferred method for educating AR patients. Lastly, 63% identified lack of patient education as a factor associated with non-adherence to medication in AR management.

4. Discussion

One of the key findings of the current survey was that about 64% of the respondents believed recurrent URTI may indicate undiagnosed AR. This finding aligns with Kim et al., who noted that symptoms of viral URIs, such as nasal obstruction, rhinorrhea, and sneezing, often overlap with those of AR. This overlap can lead patients with AR to mistakenly believe they are experiencing recurrent viral infections, typically presenting as the common cold.¹³ Similarly, Nirouei et al. reported that AR, along with acute and chronic rhinosinusitis, are URI conditions.¹⁴

Majority of the participants preferred using a combination of antihistamines and LTRA for the long-term management of AR. Liu et al. noted that current evidence suggests the combination of LTRAs and H1 antihistamines improves therapeutic efficacy for daytime and composite nasal symptoms, such as rhinorrhea, sneezing, and itching. However, it does not affect nighttime nasal or eye symptoms. Patients with perennial AR may benefit more from this combination therapy.¹⁵ Similarly, Narasimhan et al. reported

that the combination of antihistamines and LTRA presents a promising approach to managing both AR and asthma, offering enhanced symptom relief and improved disease control.¹⁶

Most respondents indicated levocetirizine as their preferred antihistamine for managing AR. Pasquali et al. reported that levocetirizine is clinically effective and significantly improves rhinitis-asthma-related quality of life, helping patients manage both nasal and eye symptoms more effectively.¹⁷ Similarly, Bachert et al. found that levocetirizine not only improved symptoms and quality of life but also helped reduce the overall costs of managing the disease over a 6-month treatment period.¹⁸

Many respondents highlighted improved patient compliance as the key advantage of recommending the montelukast + levocetirizine combination for managing AR. Kim et al. suggested that a novel fixed-dose combination capsule containing 10/5 mg of montelukast and levocetirizine may enhance patient compliance compared to taking two separate tablets.¹⁹ Similarly, Chattopadhyay et al. reported that in India, many clinicians prefer the montelukast + levocetirizine combination because it improves patient compliance and reduces therapy costs.²⁰

Most participants in the current survey reported that the frequency of AR diagnoses is comparable between genders. However, Rosário et al. observed that AR prevalence is higher in boys than in girls during childhood (0–10 years). During adolescence (11–17 years), females exhibit a higher prevalence compared to males, and by adulthood (18–79 years), the prevalence becomes similar across genders. This gender-specific trend is particularly evident in the co-occurrence of AR and asthma.²⁰ Similarly, Frohlich et al. noted that while coexisting AR and asthma are more common in males during childhood, there is a shift to female predominance during adolescence.²¹

The majority of participants reported significant improvements in morning AR symptoms when using the montelukast + levocetirizine combination. Supporting this, Shao et al. demonstrated that combining montelukast with levocetirizine for treating nasal symptoms in AR with asthma was more effective than monotherapy, offering enhanced symptom relief and good safety profiles.²² Similarly, Gupta and Matreja reported that the combination of montelukast and levocetirizine was more effective in reducing daytime, nighttime, composite, and daytime eye symptom scores compared to levocetirizine alone.¹¹

The current survey noted that the combination of montelukast and levocetirizine provided benefits, including improvements in both daytime and nighttime nasal symptoms, as well as daytime eye symptoms. Gupta and Matreja reported that this combination was more effective than levocetirizine alone in reducing daytime, nighttime, composite, and daytime eye symptom scores.¹¹ Similarly,

Kim et al. concluded that the combination of montelukast and levocetirizine led to significantly greater improvements in both daytime and nighttime symptoms, as well as quality of life, demonstrating safety and efficacy for children with perennial AR.²³

Many participants preferred antihistamine + LTRA therapy for patients with bronchial asthma before initiating inhalation therapy. Liu et al. noted that the combination of LTRAs + H1 antihistamines enhances therapeutic efficacy for daytime and composite nasal symptoms, such as rhinorrhea, sneezing, and itching, but does not impact nighttime nasal symptoms or eye symptoms. Patients with perennial AR may benefit more from this combination therapy.¹⁵ Similarly, another study highlighted that combining LTRA with antihistamines can improve asthma control.²⁴

This study offers valuable insights into the clinical management of AR, particularly regarding treatment preferences and clinical experiences with the montelukast + levocetirizine combination. A major strength of the study is the inclusion of a large sample size of 882 clinicians. Additionally, it provides important gender- and age-based insights into the prevalence of AR and asthma, contributing to a deeper understanding of these conditions across demographics. However, studying has several limitations. The reliance on self-reported data from clinicians may introduce bias, as it may reflect personal opinions rather than objective outcomes. Regional biases also limit the generalizability of the findings, as healthcare practices and patient populations may differ in other areas. Furthermore, the study did not explore dosage, long-term outcomes, or the sustainability of the observed improvements. Future studies are needed to further explore these findings and improve clinical practice.

5. Conclusion

The study highlighted the benefits of montelukast and levocetirizine, with clinicians preferring this combination for improved patient compliance and symptom control, particularly for morning and nasal symptoms. The co-occurrence of asthma and AR is common, and patient education, especially via social media, is vital for improving adherence. Recurrent URTI may signal undiagnosed AR, underscoring the importance of thorough diagnosis and management.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Acknowledgement

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