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A Survey of Indian Clinicians' Experiences with Montelukast-Levocetirizine for Concurrent Allergic Rhinitis and Asthma.

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Abstract

Background: Allergic rhinitis (AR) poses a substantial public health challenge in India. This study investigated Indian clinicians' perspectives on the use of montelukast and levocetirizine combination therapy for AR, particularly in patients with comorbid asthma.

Materials and Methods: A cross-sectional survey was conducted among 882 Indian clinicians using a 27-item questionnaire assessing their clinical experiences with montelukast and levocetirizine in AR management. Data were analyzed using descriptive statistics, and results were presented as percentages and visualized using charts.

Results: A significant proportion (64%) of clinicians recognized recurrent upper respiratory tract infections (URTIs) as a potential indicator of undiagnosed AR. The majority (81.63%) preferred antihistamine-leukotriene receptor antagonist (LTRA) combinations for long-term AR management, with levocetirizine being the preferred antihistamine (90.48%). Clinicians reported similar AR diagnosis rates across genders (80%) and observed morning symptom exacerbation in most patients (90.93%). The montelukast-levocetirizine combination was favored for its improved patient compliance (72%) and was frequently used in asthma patients before initiating inhalation therapy (77%).

Conclusion: This survey reveals a strong preference among Indian clinicians for montelukast and levocetirizine combination therapy in AR management due to its efficacy and enhanced patient compliance. Recurrent URTIs were identified as a potential marker for undiagnosed AR, and the frequent co-occurrence of asthma and allergic conjunctivitis was noted.

Keywords: Allergic rhinitis, Montelukast, Levocetirizine, Leukotriene receptor antagonists, Asthma, India.

Introduction

Allergic rhinitis (AR), a common inflammatory condition of the nasal mucosa, significantly impacts the quality of life, productivity, and overall well-being of individuals worldwide. In India, a country characterized by diverse environmental exposures, a large population, and varying socioeconomic strata, AR presents a substantial public health burden. Its prevalence, influenced by factors such as urbanization, pollution, and changing lifestyles, is steadily rising

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across all age groups, posing a significant challenge to the healthcare system. The clinical manifestations of AR, including nasal congestion, rhinorrhea, sneezing, and pruritus, can lead to sleep disturbances, impaired cognitive function, and increased healthcare utilization, underscoring the need for effective management strategies.

The pathogenesis of AR involves a complex interplay of genetic predisposition and environmental triggers, leading to an IgE-mediated inflammatory response. This cascade culminates in the release of various inflammatory mediators, including histamine and leukotrienes, which contribute to the characteristic symptoms of AR. Consequently, therapeutic interventions targeting these mediators are crucial in alleviating symptoms and improving patient outcomes.

Pharmacological management of AR typically involves the use of antihistamines, leukotriene receptor antagonists (LTRAs), intranasal corticosteroids, and decongestants. Antihistamines, particularly second-generation agents like levocetirizine, are widely used due to their efficacy in reducing nasal symptoms and their favorable safety profile. Levocetirizine, a potent and selective H1-receptor antagonist, offers rapid symptom relief and sustained efficacy, making it a cornerstone of AR therapy.

Leukotrienes, potent lipid mediators, play a significant role in the pathogenesis of AR and asthma, contributing to bronchoconstriction, mucus secretion, and airway inflammation. Montelukast, an LTRA, effectively blocks the action of leukotrienes, providing symptomatic relief in AR and asthma. Given the frequent co-occurrence of AR and asthma, particularly in India, where environmental triggers often exacerbate both conditions, the combined use of montelukast and levocetirizine has gained increasing attention.

The rationale behind combining montelukast and levocetirizine lies in their complementary mechanisms of action. While levocetirizine targets histamine-mediated symptoms, montelukast addresses leukotriene-mediated inflammation, potentially leading to synergistic effects and improved symptom control. This combination offers a convenient and potentially more effective approach to managing AR, particularly in patients with comorbid asthma, where both histamine and leukotrienes contribute to airway inflammation.

In the Indian context, the management of AR and comorbid asthma presents unique challenges. The diverse environmental exposures, including high levels of air pollution, pollen, and dust mites, contribute to the high prevalence and severity of these conditions. Additionally, socioeconomic factors, such as limited access to healthcare and affordability of medications, can influence treatment adherence and outcomes. Moreover, cultural practices and beliefs may influence patient perceptions and preferences regarding treatment options.

Despite the growing use of montelukast and levocetirizine combination therapy in India, there is a paucity of data on clinicians' perspectives and real-world experiences with this approach. Understanding clinicians' attitudes, practices, and perceived benefits and limitations of this combination is crucial for optimizing AR management in the Indian setting. This study aims to address this gap by surveying Indian clinicians to gather their insights on the use of montelukast and levocetirizine in managing AR and co-occurring asthma.

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Materials and Methods:

We carried out a cross-sectional study among specialists in managing AR in the major Indian cities from June 2018 to December 2018.

Questionnaire: The questionnaire booklet named CARA (Clinicinas 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.

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.

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).

Result:

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. 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. Approximately 90% reported levocetirizine as their preferred antihistamine for managing AR. 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. Approximately 31% of the participants reported that the 21-30 age group had the highest

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distribution of AR cases. Most clinicians (80%) indicated that the frequency of AR diagnoses was comparable across both genders. The majority (90.93%) of the participants observed improvements in morning AR symptoms with the montelukast + levocetirizine combination. 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. 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 urbaneducated 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. 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.

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

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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 cooccurrence 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.

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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 cooccurrence 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.

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