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Clinician's perspectives on the use of levocetirizine alone or in combination therapy in allergic rhinitis

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Abstract
Objective: To gather expert perspectives on the use of levocetirizine-montelukast combination in managing allergic rhinitis (AR) within the Indian context.
Methods: A cross-sectional study was conducted among clinical experts using a 24-item questionnaire to collect their opinion on the use of levocetirizine, both as monotherapy and in combination with montelukast, in the routine management of AR. The survey explored various aspects such as clinical observations, clinician preferences, and experiences with levocetirizine alone and in combination with montelukast. Data were analyzed using descriptive statistics.
Results: The survey included 551 experts. A substantial proportion (72%) indicated that patient visits for AR symptoms are most frequent during the winter season. Asthma emerged as the most commonly associated comorbidity, as reported by 86% of physicians. The majority (90%) identified levocetirizine as their preferred antihistamine in clinical practice. Around 78% of respondents consistently favored combining montelukast with antihistamines for treating AR, and 93% specifically preferred the levocetirizine-montelukast combination. Sedation was reported as the most frequent adverse effect associated with levocetirizine by 84% of respondents. Furthermore, 84% of practitioners indicated that their first-line approach for managing AR involves a combination of an antihistamine and montelukast. Additionally, 58% believed that incorporating montelukast with an antihistamine enhances treatment efficacy.
Conclusion: The survey highlights physicians' preference for levocetirizine, particularly when combined with montelukast, for managing AR due to its efficacy and tolerability. Asthma was the most commonly associated comorbidity, while sedation was the primary adverse effect reported. Combination therapy is widely favored as a first-line treatment strategy, especially during the winter season.

Keywords: Allergic rhinitis, levocetirizine, montelukast, combination, sedation, preferences

Introduction
Allergic rhinitis (AR) is a common chronic respiratory condition that significantly impacts quality of life, productivity, and healthcare systems worldwide. According to a 2007 estimate by the World Health Organization (WHO), approximately 400 million people globally were affected by AR. In the Asia-Pacific region, the prevalence among adults ranges from 10% to 32%, with rising rates attributed to rapid urbanization, increasing air pollution, lifestyle changes, and environmental exposures [1]. In India, AR is a growing public health concern, affecting an estimated 20% to 30% of the general population, with approximately 22% of adolescents currently suffering from the condition [2].
Effective management of AR often requires a combination therapy that targets multiple mediators involved in the allergic cascade [3]. Among the available options, the fixed-dose combination of levocetirizine, a second-generation antihistamine, and montelukast, a leukotriene receptor antagonist, has gained prominence in clinical practice [4]. This dual-acting regimen offers synergistic benefits by blocking both histamine and leukotriene-mediated pathways, providing comprehensive relief from nasal and non-nasal symptoms of AR [5].
Levocetirizine functions as a selective histamine H1 receptor antagonist, inhibiting histamine-induced effects such as smooth muscle contraction, increased vascular permeability, basophil activation, sensory nerve stimulation, and neurogenic inflammation [6]. On the other hand, montelukast is a highly selective cysteinyl leukotriene receptor antagonist

that binds with high affinity to leukotriene D4 and E4 receptors, thereby attenuating airway inflammation, bronchoconstriction, and mucus production [7].

Given the high burden of AR in India and the need for therapies that ensure both efficacy and patient adherence, this survey aims to explore the clinician's perspectives on clinical utility, efficacy, safety, and tolerability of the levocetirizine-montelukast combination in routine practice. The findings are intended to highlight its role in improving symptom control, treatment satisfaction, and long-term patient outcomes in the Indian setting.

Methodology

A cross-sectional study was conducted among clinicians specialized in managing AR in the major Indian cities from June 2024 to December 2024.

Questionnaire

The questionnaire booklet titled ACT-AR (Rational use of antihistamines and combination in treatment of allergic rhinitis) was sent to the doctors who were interested in participating in this study. The ACT-AR study comprised a 24-item multiple-response questionnaire designed to gather insights into current clinical practices and recommendations related to levocetirizine, both as monotherapy and in combination with montelukast, in routine clinical settings. The survey explored various dimensions, including physician preferences, clinical indications, perceived efficacy, adverse effects, and specific patient groups for whom these therapies are frequently recommended. The study was performed after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

Participants

An invitation was sent to clinical professionals across India based on their expertise and experience in treating AR in the month of March 2024 for participation in this Indian survey. About 551 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. They were instructed to complete the survey alone and not consult their colleagues. Written informed consent was obtained from all the participants prior to the study.

Statistical analysis

Descriptive statistics were used to analyze the data, with categorical variables presented as frequencies and corresponding percentages. Visual representations of these distributions, including graphs and pie charts, were created using Microsoft Excel 2013 (version 16.0.13901.20400).

Result

Of the 551 survey respondents, 39% of clinicians reported seeing 21-30 new cases of AR per month in patients under 18 years of age. According to 35% of physicians, the most commonly affected age group was 31-40 years. Regarding gender distribution, 34% of physicians indicated that 21-30% of their AR patients are women. A significant majority (72%) of respondents reported that patient visits for AR symptoms are most frequent during the winter season (Fig. 1).

Air pollution and dust were identified as the most common triggers for AR by 52% of respondents. Additionally, 86% of experts reported asthma as the most frequently associated comorbid condition (Fig. 2).

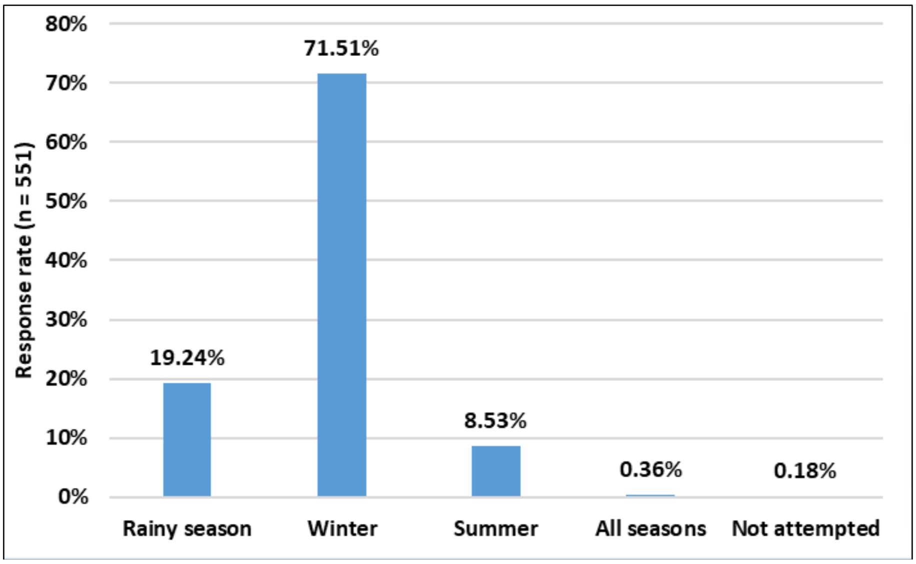

Fig 1: Distribution of responses on the season when patients visit frequently with AR

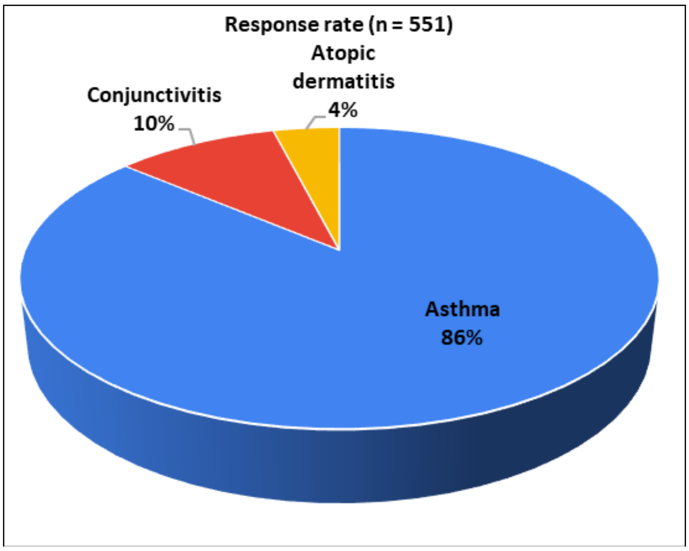

Fig 2: Distribution of responses on the most common comorbid condition associated with AR

About 43% of respondents reported that 10-20% of AR patients have a family history of atopy. Nearly 48% stated that food allergy is sometimes observed in patients with AR. Approximately 69% of participants reported that serum allergen-specific IgE testing is commonly used in the evaluation of AR.

Almost half (48.82%) of the respondents noted a variable correlation between serum IgE levels and disease severity. Around 71% indicated that they do not prefer first-generation antihistamines for the treatment of AR. A large majority (89.84%) reported that levocetirizine is the antihistamine most preferred based on their clinical experience (Table 1).

Table 1: Distribution of responses on preferred antihistamine in clinical experience

Preference	Response rate (n = 551)
Bilastine	4.54%
Desloratadine	1.09%
Fexofenadine	2.72%
Levocetirizine	89.84%
Less sedation and better compliance	0.91%

According to 45% of practitioners, 26-50% of their patients with AR experience nasal congestion and sleep disturbances. Nearly 78% of respondents consistently preferred the combination of montelukast with antihistamines for the treatment of AR (Fig. 3).

Approximately 93% of practitioners specifically favored the montelukast + levocetirizine combination (Table 2). A significant majority (83.85%) reported sedation as the most common side effect of levocetirizine that patients complain about (Fig. 4).

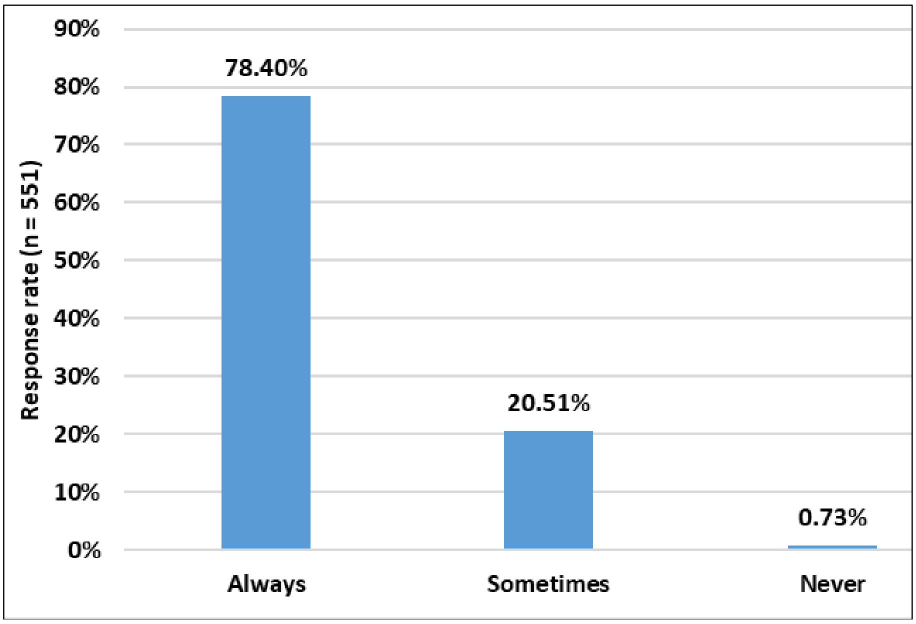

Fig 3: Distribution of responses on the frequency of preferring the combination of montelukast with antihistamines

Table 2: Distribution of responses on the most preferred combination for AR

Combination	Response rate (n = 551)
Montelukast + bilastine combination	3.81%
Montelukast + desloratidine	0.18%
Montelukast + fexofenadine combination	2.36%
Montelukast + levocetirizine combination	92.74%

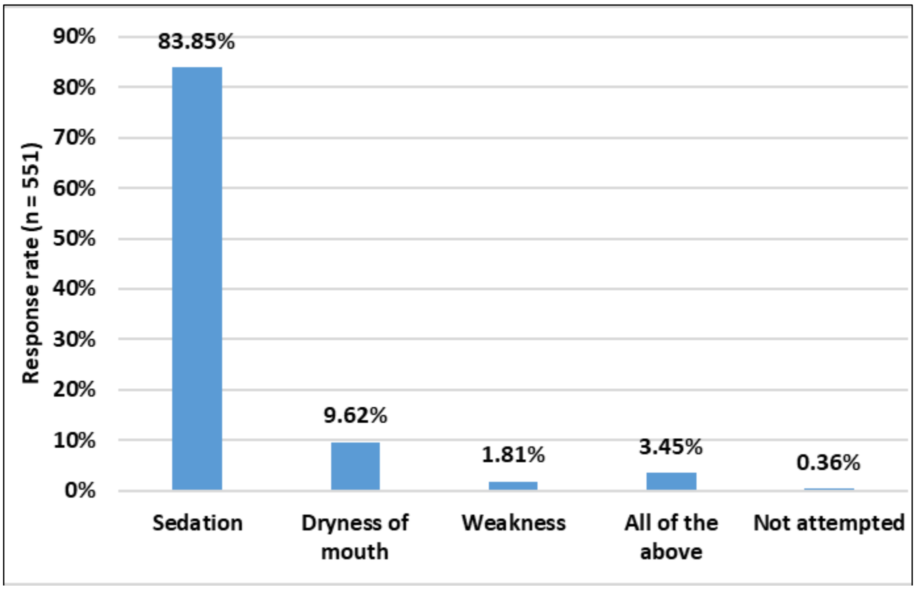

Fig 4: Distribution of responses on the common side effects reported by patients receiving levocetirizine

The majority (84.39%) of practitioners preferred a combination of an antihistamine and montelukast as their first-line treatment for managing AR (Table 3). Around 24% of participants reported 6 weeks as the most commonly prescribed duration for the levocetirizine-montelukast combination. More than half (58.08%) of practitioners believed that adding montelukast to an antihistamine improves treatment efficacy (Table 4).

Table 3: Distribution of responses on the preferred first choice for AR management

Preference	Response rate (n = 551)
Antihistamine	11.8%
Antihistamine + Montelukast	84.39%
Intranasal corticosteroids	2.9%

Table 4: Distribution of responses on opinion about the addition of montelukast to antihistamine

Opinion	Response rate (n = 551)
Improves efficacy	58.08%
Decreases the duration of treatment	21.78%
Provides long-term remission	19.06%
All of the above	0.54%

The majority of the practitioners (58.08%) reported occasionally using nasal decongestants alongside the levocetirizine-montelukast combination. A substantial proportion (78.22%) indicated that they do not recommend immunotherapy for patients with AR. Around 34% identified the advantages of the levocetirizine-montelukast combination as easy availability, effectiveness, better tolerability, and long-term control.

According to 48% of experts, 11-20% of their AR patients require multi-specialty collaboration, including paediatricians, consultant physicians, pulmonologists, or otolaryngologists, to manage complex cases. Around 42% stated that the most common reason for specialist referral was poor disease control despite appropriate pharmacotherapy.

Discussion

The survey findings revealed a distinct seasonal pattern, with the majority of respondents observing a higher frequency of AR cases during the winter months. Asthma was the most frequently reported comorbidity, consistent with the well-established association between upper and lower airway diseases. Levocetirizine emerged as the most preferred antihistamine in clinical practice, valued for its efficacy and tolerability. The majority consistently favored the use of a combination therapy, particularly montelukast plus levocetirizine, for routine management of AR.

The majority of visits occur during winter (72%), and the identification of air pollution and dust as the most common triggers (52%) underscores the significant seasonal and environmental influence on the burden of AR in Indian settings. These findings highlight the urgent need for preventive strategies such as allergen avoidance, improved air quality measures, and patient education on environmental control. Supporting this observation, Alharthi *et al*. reported that symptoms of AR, such as itchy and watery eyes, were more prevalent during the winter season (30.0%) than in other seasons. House dust was identified as the most common trigger, accounting for 73% of cases.[8] Additionally, Hyrkäs-Palmu *et al*. demonstrated that cold weather can exacerbate respiratory symptoms and lead to greater functional impairment in individuals with AR, further reinforcing the influence of winter conditions on symptom severity [9].

Asthma was identified as the most common comorbid condition by the majority of physicians in the survey, reaffirming the well-established relationship between AR and lower airway disease. Jaggi *et al*., in a survey conducted in India, found that 65% of asthma patients also had coexisting AR, with prevalence increasing in tandem with the severity of asthma [10]. Further supporting evidence from epidemiological studies by Leynaert *et al*. indicates that AR is present in 80% to 90% of asthmatic patients, underscoring the frequent comorbidity of these conditions as well as their shared pathophysiological mechanisms and treatment strategies [11].

The majority of survey participants reported levocetirizine as the most preferred antihistamine based on clinical experience. This preference is supported by several clinical studies highlighting its superior efficacy, duration of action, and tolerability profile. Kulkarni *et al*. demonstrated that levocetirizine provided significantly better symptom control and longer-lasting relief compared to fexofenadine and bilastine, with both patients and clinicians consistently rating its 24-hour effectiveness favourably [12]. Similarly, Jorissen *et al*. reported that levocetirizine was not only effective in reducing the frequency and severity of seasonal AR symptoms but was also preferred over other antihistamines due to its rapid onset of action and favorable safety profile [13].

The majority of respondents in the current survey consistently preferred the combination of montelukast with antihistamines for the treatment of allergic rhinitis and identified it as their first-line choice for AR management. This aligns with growing clinical evidence supporting the additive benefits of such combination therapy. Ciebiada *et al*. found that montelukast, whether used alone or in combination with antihistamines, led to a gradual improvement in nasal symptoms over a 6-week treatment period in patients with persistent AR [14]. Similarly, Krishnamoorthy *et al*. demonstrated that montelukast is more effective than placebo in alleviating overall symptoms of AR. Moreover, the combination of montelukast with an oral antihistamine proved to be more effective than either treatment alone [15].

The majority of survey respondents indicated a strong preference for the montelukast-levocetirizine combination in the management of AR, reflecting growing clinical evidence supporting its efficacy. Panchal *et al*., in a randomized, double-blind, multicenter Phase III trial, found that a fixed-dose combination of montelukast (10 mg) and levocetirizine (5 mg) was significantly more effective than either drug alone in reducing daytime nasal symptoms and enhancing quality of life in patients with seasonal AR. The combination was also well tolerated and demonstrated a favorable safety profile [16]. Similarly, Kim *et al*. evaluated this combination in pediatric patients with perennial AR and found it to be more effective than monotherapy in relieving both daytime and nighttime symptoms. Patients reported higher satisfaction levels and experienced fewer adverse events.[5] Further supporting this, Ciebiada *et al*., in a randomized, double-blind crossover study, confirmed that the combination therapy led to superior improvements in nasal symptom scores and significantly reduced eosinophil cationic protein levels, suggesting enhanced control of airway inflammation. The combination also resulted in reduced eosinophil cationic protein levels, indicating more effective inflammatory control [17].

A significant majority of respondents in the current survey reported sedation as the most common side effect of levocetirizine experienced by patients. This observation aligns with findings from Layton *et al*., who noted that sedation or drowsiness occurred in approximately 0.37% of patients taking levocetirizine, a rate statistically higher than that observed with desloratadine. Notably, the odds of experiencing sedation were more than six times higher in allergic rhinitis patients without coexisting asthma, indicating a possible differential tolerability profile based on comorbidity status [18]. Additionally, a study by Sarkar *et al*., comparing levocetirizine 10 mg with a combination of levocetirizine 5 mg and montelukast 10 mg in patients with chronic urticaria, found that sedation was significantly more common in the higher-dose levocetirizine group ($P = 0.013$), suggesting an increased risk of sedation with higher doses. These findings highlight the importance of dose optimization to minimize adverse effects while maintaining therapeutic efficacy [19].

This comprehensive survey of 551 respondents offers valuable insights into clinical practices and perceptions regarding the management of AR in Indian settings. A notable strength is the diversity of data captured, including age-specific prevalence, seasonal patterns, comorbidities, diagnostic preferences, and therapeutic strategies. The consistent reporting of asthma as a common comorbidity and air pollution as a major trigger reflects prevailing clinical realities. The study also highlights perspectives of the practitioners favoring the levocetirizine-montelukast combination. Data on diagnostic approaches, such as serum-specific IgE testing, along with detailed information on treatment duration and preferred combinations, further enhance the clinical relevance of the findings. Despite its strengths, the survey has certain limitations. Being a self-reported, cross-sectional study, the responses are subject to recall and reporting biases. The absence of geographic stratification may limit the generalizability of findings across India's diverse regions. Moreover, the survey did not capture patient-reported outcomes or long-term follow-up data, restricting deeper insights into treatment effectiveness, satisfaction, and adherence.

Conclusion

This study highlights key clinical preferences in AR management, with most physicians favoring montelukast-levocetirizine for its efficacy and tolerability. Asthma was the most common comorbidity, and patient visits peaked during winter. Sedation was the most reported side effect of levocetirizine. The survey findings also highlight the need for standardized guidelines to optimize AR care.

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