

Clinicians' Insights on the use of Oral Second-Generation Antihistamine Bilastine in Allergic Rhinitis

Abstract

Objective: To assess expert opinion on the clinical use of bilastine in the management of allergic rhinitis (AR) in Indian settings.

Methods: The cross-sectional study was carried out by using a 24-item questionnaire which gathered insights from clinicians practicing in India on key aspects, including clinical observations, treatment preferences, and experiences with bilastine monotherapy. The collected data were analyzed using descriptive statistics.

Results: The survey included responses from 557 medical experts. Nearly half of the physicians (49%) reported that allergic rhinitis is most frequently diagnosed in adults. About 63% of respondents identified dust mites as the leading environmental trigger. According to 75% of participants, asthma was the most commonly associated comorbidity. For managing mild allergic rhinitis, 72% of physicians selected oral second-generation antihistamines as their first-line treatment. Over half (56.55%) acknowledged that immunotherapy can modulate immune responses and provide long-term relief when pharmacological treatment alone is inadequate. Additionally, 42% supported the continued use of immunotherapy for sustained benefit in allergic rhinitis cases. The majority (90%) favored bilastine as the antihistamine of choice for allergic rhinitis, with approximately 90% preferring it specifically for patients with renal impairment.

Conclusion: This study highlights current practices in the management of allergic rhinitis, with bilastine favored for its safety, efficacy, and suitability in special populations. Immunotherapy is recognized for its long-term benefits, although diagnostic practices vary.

Keywords: Allergic rhinitis; dust mites; asthma; immunotherapy; bilastine

Introduction

Allergic rhinitis (AR) is a prevalent chronic respiratory condition that significantly affects quality of life, work productivity, and healthcare systems worldwide. The prevalence varies across regions and age groups, ranging from 10% to 30% in adults and exceeding 40% in children.[1] In India, AR has emerged as a significant public health issue, affecting roughly 20% to 30% of the general population, including about 22% of adolescents currently experiencing symptoms. [2]

Second-generation oral antihistamines are widely recommended as the first-line treatment for mild-to-moderate allergic rhinitis, owing to their superior safety profile, minimal sedation, and longer duration of action compared to first-generation antihistamines. [3] Among these, bilastine stands out as a highly selective, non-sedating histamine H1 receptor antagonist with rapid onset and sustained efficacy. By selectively binding to peripheral H1 receptors and inhibiting their activation, bilastine effectively suppresses the cascade of allergic symptoms. Additionally, bilastine does not readily



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cross the blood-brain barrier, making it less likely to cause central nervous system side effects such as drowsiness, which is a significant advantage in maintaining daily functioning and quality of life [4].

Given the substantial burden of AR in India and the need for therapies that offer both clinical efficacy and promote patient adherence, this study aims to gather expert opinion on the clinical utility, effectiveness, safety, and tolerability of bilastine in routine practice within Indian settings.

Methodology

We carried out a cross-sectional study among clinicians actively engaged in AR management across India from June 2024 to December 2024. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

A convenient sampling technique was used, and an invitation was sent to leading clinicians in managing AR in the month of March 2024 for participation in this Indian survey. About 557 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. The questionnaire booklet titled BEAM (Bilastine and Montelukast- Expert Assessment in Management of Allergic Rhinitis) study was sent to clinicians who were interested in participating in this study. The BEAM study questionnaire consisted of 24 questions, which covered key areas such as current clinical practices related to bilastine in routine care, including physician preferences, clinical indications, perceived efficacy, adverse effects, and patient groups commonly prescribed bilastine. Reliability, as determined by a split-half test (coefficient alpha), was adequate but should be improved in future versions of the questionnaire. A study of criterion validity was undertaken to test the questionnaire and to develop methods of testing the validity of measures of Physicians' Perspectives. However, the extraneous variables in this include the clinician's experience, usage of the newer drugs, etc. The two criteria used were the doctors' perspectives from the clinical practice and the assessment of an external assessor and statistician. Clinicians had the option to skip any questions they preferred not to answer. They were instructed to complete the questionnaire independently, without consulting

their colleagues. Written informed consent was obtained from all participants before the study commenced.

Statistical analysis

Data were analyzed using descriptive statistics, with categorical variables summarized as frequencies and corresponding percentages. Visual representations, including graphs and pie charts, were generated using Microsoft Excel 2013 (version 16.0.13901.20400).

Results

The survey included 557 respondents, and 44% of experts reported that 21–30% of their patients suffer from AR in their clinical practice. According to 49% of physicians, AR is most commonly diagnosed in adults (Figure 1). Approximately 63% of respondents identified dust mites as the primary environmental trigger for AR (Figure 2).

About 48% of the participants reported that the impact of AR on patients' quality of life is moderate. Around 30% of physicians

identified sneezing as the most troubling symptom. Regarding seasonal patterns, 42% of physicians reported winter as the peak season for AR symptoms. Urban areas showed higher prevalence, with 44% of physicians reporting a greater occurrence of AR in these regions. Nearly 75% of respondents identified asthma as the most common comorbidity associated with AR (Table 1).

About 34% of respondents reported that the lack of effective treatment is a common challenge in diagnosing AR. Approximately 57% of clinicians stated that 11% to 20% of their patients with AR experience nasal congestion. Regarding diagnostic approaches, about 35% of physicians identified increased serum histamine levels as a key diagnostic criterion. Around 48% of respondents reported performing skin prick tests in less than 10% of their patients. Nearly 72% of physicians preferred oral second-generation antihistamines as the first-line pharmacological treatment for mild AR (Table 2).

About 43% of physicians reported that intranasal corticosteroids in combination with oral second-generation antihistamines is the treatment approach considered most effective for better symptom control in cases of moderate to severe AR. Approximately 33% of participants reported that regular exercise is a recommended non-pharmacological measure for reducing exposure to indoor allergens in AR patients. More than half (56.55%) of the experts reported that immunotherapy is a treatment option that can modify the immune response and provide long-term relief in AR, particularly in cases where usual treatment is insufficient (Figure 3).

Around 50% of respondents reported that the nasal mucosa should be regularly monitored for signs of atrophy in patients on long-term intranasal corticosteroid therapy. Nearly 42% of experts stated that immunotherapy should be continued as needed for optimal effectiveness in AR patients (Table 3). The majority of participants (90%) reported that bilastine is the preferred antihistamine for patients with AR (Figure 4).

Nearly 33% of participants responded that they preferred bilastine in routine practice for 31-40% of AR patients whose occupation involves driving. About 90% of participants reported that bilastine is the preferred antihistamine for renally compromised patients (Table 4).

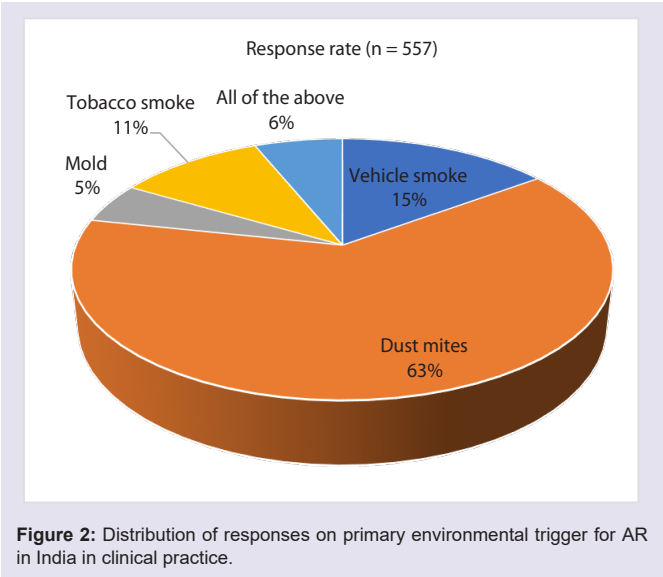
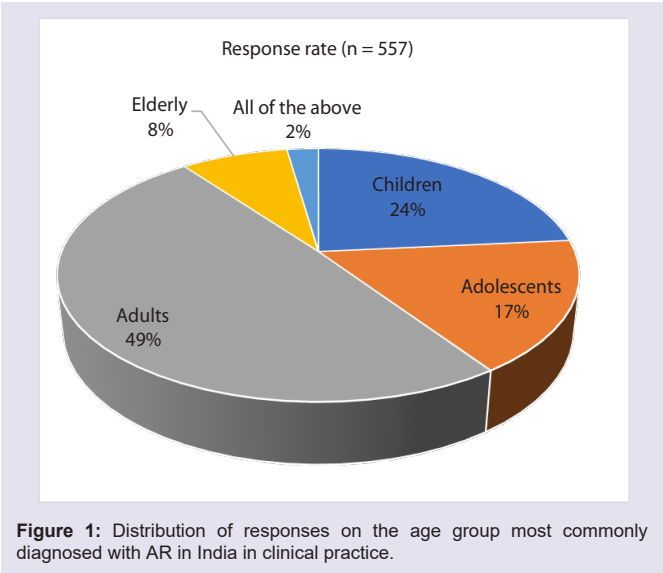


Table 1: Distribution of responses on the common comorbidity associated with AR.	
Common comorbidity	Response rate (n = 557)
Hypertension	3.77%
Atopic dermatitis	9.69%
Asthma	75.22%
Nasal polyp	11.13%
Not attempted	0.18%

Table 2: Distribution of responses on the first-line pharmacological treatment for mild AR in clinical practice.	
First-line treatment for mild AR	Response rate (n = 557)
Oral second-generation antihistamines	72.17%
Intranasal corticosteroids	10.95%
Leukotriene receptor antagonists	13.11%
Decongestants	3.41%
Not attempted	0.36%

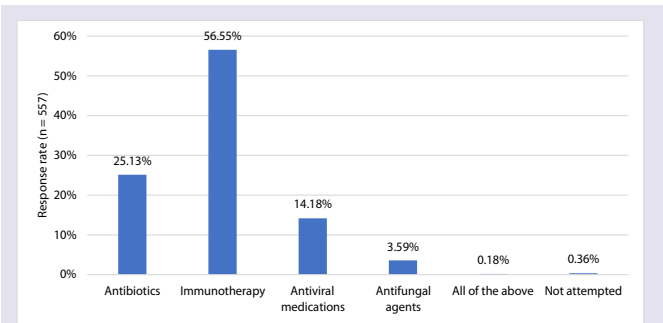


Figure 3: Distribution of responses to preferred antihistamine in patients with AR.

Table 3: Distribution of responses on the timing of immunotherapy to be continued for optimal effectiveness in AR patients in your clinical practice.

Duration	Response rate (n = 557)
1 month	25.67%
6 months	22.62%
12 months or longer	9.34%
As needed	42.01%
Not attempted	0.36%

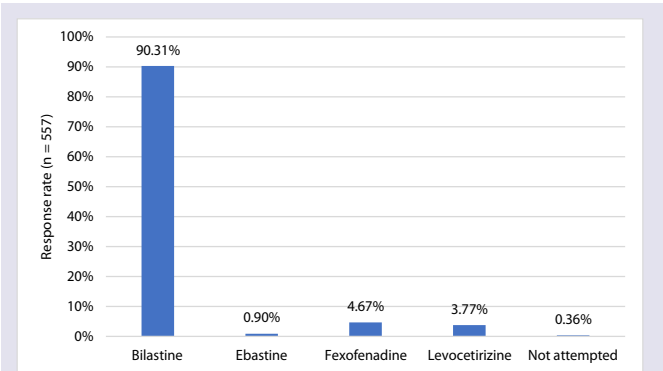


Figure 4: Distribution of responses to preferred antihistamine in patients with AR.

Table 4: Distribution of responses on the preferred antihistamine in renally compromised patients.

Antihistamine	Response rate (n = 557)
Bilastine	89.05%
Ebastine	2.15%
Fexofenadine	3.77%
Levocetirizine	4.67%
Not attempted	0.36%

About 40% of participants reported that the reduced sedative effect is the most frequently cited advantage of bilastine. Approximately 49% of the physicians reported that 21-30% of AR patients are prescribed bilastine, with or without the addition of montelukast. Around 40% stated that the combination of bilastine and montelukast is typically prescribed for 11-14 days in patients with AR.

Discussion

The present survey underscores the role of second-generation antihistamines, particularly bilastine, as a cornerstone in the management of AR due to their proven efficacy, tolerability, and safety, especially in sensitive populations such as drivers and individuals with renal impairment. A significant proportion of participants reported that AR is most commonly diagnosed in adults in clinical practice in India. This observation aligns with findings from Barne et al., who emphasized that AR poses a substantial health burden among Indian adults.[5] Similarly, Moitra et al. reported that approximately 22% of adolescents in India currently suffer from AR. However, the lack of comprehensive and robust epidemiological data, particularly from rural and suburban regions, suggests that the actual burden of AR may be underestimated.[2]

A significant number of participants in the present survey identified dust mites as the primary environmental trigger for AR in India. This finding is supported by a study conducted by Krishna et al. in Eastern India, which found that 96% of patients with naso-bronchial allergy were sensitized to house dust mites, with *Dermatophagoides pteronyssinus*, *Dermatophagoides farinae*, and *Blomia tropicalis* being the predominant species.[6] Similarly, a study by Ranjana and Maheshwari found that house dust mites were the most common allergen among patients with allergic rhinitis, ranking above other environmental triggers such as pollen, cockroach, and mold. [7]

The majority of survey respondents identified asthma as a common comorbidity associated with AR. This observation is consistent with findings from Narasimhan et al. and an expert panel consensus for India, both of which strongly recommend routine screening for asthma in AR patients and vice versa, due to the high rate of co-occurrence. The consensus reports that over 80% of asthma patients also suffer from comorbid AR, while 17-38% of individuals with AR concurrently experience asthma. Furthermore, severe AR has been shown to adversely affect asthma control, with some studies citing a co-prevalence rate of up to 65% in adult asthmatics.[8] These findings are further supported by Indian data from Pawankar et al., as well as international guidelines and multicenter studies from the Asia-Pacific region, which indicate that 60–80% of asthma patients exhibit rhinitis symptoms—underscoring the strong clinical interrelationship between these two conditions.[9]

Most survey respondents indicated that oral second-generation antihistamines are the first-line pharmacological treatment for mild AR. This preference aligns with findings by Abdullah et al., who reported that these agents are non-sedating, effective, and generally well-tolerated, making them the optimal choice for managing mild cases.[3] Supporting this, Recto et al. noted a rising prevalence of allergic diseases across the Asia–Pacific region, and reaffirmed that second-generation antihistamines continue to serve as the first-line treatment for both AR and urticaria.[10]

Many respondents recognized immunotherapy as a valuable treatment option capable of modifying the immune response and providing long-term relief in patients with AR. Studies by Sahiner et al. and Akdis and Akdis have demonstrated that allergen immunotherapy (AIT) can induce long-lasting immune tolerance, resulting in sustained clinical benefits even after discontinuation of therapy. The underlying mechanisms involve early desensitization of mast cells and basophils, modulation of T- and B-cell responses, and

the induction of regulatory T cells, which suppress allergen-specific Th2 responses. Additionally, AIT promotes a shift in antibody production from allergen-specific IgE to blocking antibodies such as IgG4 and IgA, which inhibit allergen-IgE binding and subsequent effector cell activation. These immunologic adaptations help reduce allergic inflammation and contribute to prolonged symptom improvement that may last for years following treatment cessation. [11,12]

Many participants in the survey reported that immunotherapy should be continued as needed to achieve optimal effectiveness in patients with AR. This aligns with findings by Penagos et al., who demonstrated that three years of subcutaneous or sublingual immunotherapy resulted in significant clinical improvement and immunological changes indicative of allergen-specific tolerance, with benefits persisting for at least 2-3 years after discontinuation. Based on such evidence, international guidelines recommend a minimum of three years of immunotherapy to ensure sustained, long-term efficacy.[13] Kouzegaran et al. demonstrated that subcutaneous immunotherapy reduces clinical symptoms and promotes immune tolerance in patients with AR, highlighting the role of continued treatment in sustaining symptom relief and modulating the immune response.[14]

The majority of participants reported that bilastine is the preferred antihistamine for use in patients with renal impairment. This preference is supported by pharmacokinetic studies, including one by Lasseter et al., which demonstrated that a 20 mg dose of bilastine is safe and well tolerated across all levels of renal dysfunction, including moderate to severe impairment. Despite elevated plasma concentrations in individuals with renal impairment, no dose adjustment was necessary, as bilastine exhibits a favorable safety profile, minimal central nervous system penetration, and a low potential for drug interactions. These characteristics make bilastine a particularly suitable option in patients with renal comorbidities, where safety and tolerability are paramount.[15] Moreover, the recent recommendations endorsed that newer antihistamines, including bilastine, are effective in improving AR symptoms as they block peripheral H₁ receptors without crossing the blood-brain barrier, which prevents central nervous system side effects. [16]

This large-scale survey, involving a significant number of clinicians across various Indian settings, provides valuable real-world insights into the management of AR in India. The comprehensive questionnaire addressed key areas such as epidemiology, diagnostic practices, and treatment trends, highlighting a strong preference for bilastine and growing recognition of immunotherapy's long-term benefits. However, the study's reliance on self-reported data introduces potential for recall and response bias. Furthermore, the lack of stratification by physician specialty or geographic location limits the scope for subgroup analysis. The absence of patient-level data and objective clinical outcomes also restricts the ability to directly correlate physician perceptions with actual clinical effectiveness.

Conclusion

This cross-sectional survey highlights the high burden of AR in adults, with dust mites identified as the primary trigger. Experts preferred bilastine, especially for patients requiring minimal sedation or those with renal impairment. Immunotherapy is valued for its long-term benefits, though diagnostic tools like skin prick tests remain underutilized. These findings emphasize the need for standardized, evidence-based approaches to optimize AR care in Indian settings.

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Author contributions

Both authors have contributed equally to the development of the manuscript.

Disclosure of compliance with ethical principles

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.

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