



ORIGINAL ARTICLE

OPEN ACCESS

Comparative Efficacy of Bilastine and Levocetirizine in Patients with Allergic Rhinitis: A Prospective Comparative Study

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ABSTRACT

Allergic rhinitis (AR) is a common IgE-mediated inflammatory disorder of the nasal mucosa characterized by nasal congestion, rhinorrhea, sneezing, and itching, which adversely affects quality of life and daily activities. Second-generation antihistamines are the cornerstone of treatment, with bilastine and levocetirizine being widely prescribed owing to their efficacy and favourable safety profiles. The present study compared the clinical efficacy of bilastine and levocetirizine in patients with allergic rhinitis. This prospective comparative study was conducted in the Department of Otorhinolaryngology in collaboration with the Department of Pharmacology at Dr. K.N. Singh Memorial Institute of Medical Sciences, Barabanki, Uttar Pradesh. 100 patients with clinically diagnosed allergic rhinitis were enrolled and allocated into two groups: Bilastine (20 mg once daily; n = 50) and Levocetirizine (5 mg once daily; n = 50) for 15 days. Baseline assessment included demographic characteristics, symptom severity scores, Total Nasal Symptom Score (TNSS), serum immunoglobulin E (IgE), and absolute eosinophil count (AEC). Post-treatment TNSS was assessed on Day 15. Statistical analysis was performed using independent and paired *t*-tests and the Chi-square test, with *p* < 0.05 considered statistically significant. The mean age of the participants was 34.8 ± 9.1 years, and the gender distribution was comparable between the two groups (*p* = 0.911). Baseline nasal congestion, rhinorrhea, sneezing, TNSS, serum IgE, and AEC did not differ significantly between groups (*p* > 0.05). In the Bilastine group, the mean TNSS decreased significantly from 7.76 ± 1.46 at baseline to 2.33 ± 1.16 after treatment, representing a 70% reduction (*p* < 0.001). In the Levocetirizine group, TNSS decreased from 7.68 ± 1.42 to 3.16 ± 1.23 , corresponding to a 58.9% reduction (*p* < 0.001). Bilastine demonstrated a greater improvement in symptom scores than levocetirizine. Both bilastine and levocetirizine were effective in significantly reducing symptoms of allergic rhinitis. However, bilastine produced a greater reduction in Total Nasal Symptom Score over the 15-day treatment period, suggesting superior clinical efficacy. Bilastine may therefore be considered a preferable second-generation antihistamine for the short-term management of allergic rhinitis.

Keywords: Allergic rhinitis, Bilastine, Levocetirizine, Total Nasal Symptom Score, Antihistamines, Serum IgE, Absolute eosinophil count.

Received 02.07.2026

Revised 23.07.2026

Accepted 23.08.2026

INTRODUCTION

Allergic rhinitis (AR) is a common chronic inflammatory disorder of the nasal mucosa mediated by immunoglobulin E (IgE) following exposure to environmental allergens. It is characterized by symptoms of sneezing, rhinorrhea, nasal congestion, and nasal itching, which can significantly impair sleep quality, work productivity, school performance, and overall quality of life. The prevalence of allergic rhinitis has increased steadily over the past few decades, affecting approximately 10–30% of the global population, making it one of the most prevalent allergic diseases worldwide [1].

The pathophysiology of allergic rhinitis involves activation of mast cells and basophils after allergen exposure, resulting in the release of histamine and other inflammatory mediators. Histamine is responsible for most of the early-phase symptoms, whereas eosinophils and cytokines contribute to persistent inflammation during the late phase. Serum IgE and absolute eosinophil count (AEC) are commonly used biomarkers reflecting allergic inflammation, although their levels do not always correlate directly with symptom severity [2]. Consequently, effective suppression of histamine-mediated responses remains the cornerstone of pharmacological management.

Second-generation H1-antihistamines are recommended as first-line therapy for patients with mild to moderate allergic rhinitis because they provide effective symptom control with minimal sedation

compared with first-generation antihistamines. Levocetirizine, the active enantiomer of cetirizine, has been widely prescribed owing to its rapid onset of action and favourable safety profile. However, some patients continue to experience residual symptoms, particularly nasal congestion, prompting the evaluation of newer antihistamines with improved receptor selectivity and reduced central nervous system penetration [3].

Bilastine is a newer second-generation antihistamine with high selectivity for peripheral H1 receptors and negligible penetration across the blood-brain barrier. Owing to its minimal sedative potential, absence of significant anticholinergic effects, and limited hepatic metabolism, bilastine has emerged as an attractive therapeutic option for allergic rhinitis. Several randomized clinical studies have demonstrated that bilastine provides symptom relief comparable to or better than established antihistamines while maintaining an excellent safety profile [4]. Recent evidence has also suggested improvements in patient-reported quality of life and treatment satisfaction with bilastine compared with conventional antihistamines [5].

Although both bilastine and levocetirizine are recommended for the treatment of allergic rhinitis, comparative data from the Indian population remain limited. Furthermore, few prospective studies have simultaneously evaluated clinical symptom scores together with laboratory markers such as serum IgE and absolute eosinophil count. Establishing the comparative effectiveness of these agents may help clinicians select the most appropriate antihistamine for routine clinical practice.

Therefore, the present prospective comparative study was undertaken to compare the efficacy of bilastine and levocetirizine in patients with allergic rhinitis by assessing changes in Total Nasal Symptom Score (TNSS) over 15 days while also evaluating baseline clinical characteristics and laboratory markers of allergic inflammation.

MATERIAL AND METHODS

This prospective comparative study was conducted in the Department of Otorhinolaryngology in collaboration with the Department of Pharmacology at Dr. K.N. Singh Memorial Institute of Medical Sciences, Barabanki, Uttar Pradesh, after obtaining approval from the Institutional Ethics Committee and written informed consent from all participants. A total of 100 patients aged 18–55 years with clinically diagnosed allergic rhinitis were enrolled and randomly allocated into two equal groups: Group A (Bilastine, $n = 50$) and Group B (Levocetirizine, $n = 50$). Patients with acute upper respiratory tract infection, nasal polyps, chronic rhinosinusitis, pregnancy or lactation, severe systemic illness, or hypersensitivity to study drugs were excluded. Baseline evaluation included demographic characteristics, assessment of individual nasal symptoms (nasal congestion, rhinorrhea, and sneezing), Total Nasal Symptom Score (TNSS), serum immunoglobulin E (IgE) levels, and absolute eosinophil count (AEC). Group A received Bilastine 20 mg once daily, while Group B received Levocetirizine 5 mg once daily for 15 days. Clinical assessment was repeated on Day 15, and changes in TNSS were recorded to evaluate treatment efficacy. Statistical analysis was performed using SPSS version 26.0. Continuous variables were expressed as mean $\pm$ standard deviation (SD) and compared using the independent t -test or paired t -test as appropriate, whereas categorical variables were analyzed using the Chi-square test. A p -value of <0.05 was considered statistically significant.

RESULTS

Table 1. Age Distribution of Study Participants

Age Group (Years)	Bilastine (n=50)	Levocetirizine (n=50)	Total (n=100)
18–25	11 (22.0%)	10 (20.0%)	21 (21.0%)
26–35	18 (36.0%)	20 (40.0%)	38 (38.0%)
36–45	14 (28.0%)	13 (26.0%)	27 (27.0%)
46–55	7 (14.0%)	7 (14.0%)	14 (14.0%)
Mean $\pm$ SD	34.8 $\pm$ 9.1	34.6 $\pm$ 9.3	34.7 $\pm$ 9.2

Statistical Analysis: Independent t -test; $t = 0.112$, $df = 98$, $p = 0.911$ (Not Significant).

The majority of participants in both groups belonged to the 26–35 years age group (38.0%). The mean age was comparable between the Bilastine and Levocetirizine groups (34.8 $\pm$ 9.1 vs. 34.6 $\pm$ 9.3 years), with no statistically significant difference ($p = 0.911$), indicating that both groups were age matched at baseline.

Table 2. Gender Distribution of Study Participants

Gender	Bilastine (n=50)	Levocetirizine (n=50)	Total (n=100)
Male	24 (48.0%)	25 (50.0%)	49 (49.0%)
Female	26 (52.0%)	25 (50.0%)	51 (51.0%)

Statistical Analysis: Chi-square test; $\chi^2 = 0.040$, $df = 1$, $p = 0.841$ (Not Significant).

Gender distribution was similar in both treatment groups. Males constituted 49.0% and females 51.0% of the total study population. There was no statistically significant difference between the two groups ($p = 0.841$), demonstrating comparable gender distribution.

Table 3. Baseline Nasal Congestion Scores

Severity Score	Bilastine (n=50)	Levocetirizine (n=50)	p-value
0 (None)	0 (0.0%)	0 (0.0%)	0.729
1 (Mild)	10 (20.0%)	13 (26.0%)	
2 (Moderate)	29 (58.0%)	26 (52.0%)	
3 (Severe)	11 (22.0%)	11 (22.0%)	
Mean $\pm$ SD	2.02 $\pm$ 0.67	1.96 $\pm$ 0.70	

Statistical Analysis: Independent t -test; $t = 0.347$, $p = 0.729$ (Not Significant).

Baseline nasal congestion severity was comparable between the two groups. Moderate congestion was the most common presentation, affecting 58.0% of patients in the Bilastine group and 52.0% in the Levocetirizine group. The mean congestion scores did not differ significantly (2.02 $\pm$ 0.67 vs. 1.96 $\pm$ 0.70; $p = 0.729$), confirming similar baseline disease severity.

Table 4. Baseline Rhinorrhea Scores

Severity Score	Bilastine (n=50)	Levocetirizine (n=50)	p-value
0 (None)	0 (0.0%)	0 (0.0%)	0.618
1 (Mild)	12 (24.0%)	14 (28.0%)	
2 (Moderate)	25 (50.0%)	24 (48.0%)	
3 (Severe)	13 (26.0%)	12 (24.0%)	
Mean $\pm$ SD	2.02 $\pm$ 0.69	1.96 $\pm$ 0.72	

Statistical Analysis: Independent t -test; $t = 0.501$, $p = 0.618$ (Not Significant).

At baseline, rhinorrhea severity was comparable between the two treatment groups. Moderate rhinorrhea was the most frequent presentation, observed in 50.0% of patients receiving Bilastine and 48.0% receiving Levocetirizine. The mean rhinorrhea scores were similar (2.02 $\pm$ 0.69 vs. 1.96 $\pm$ 0.72), with no statistically significant difference ($p = 0.618$), indicating comparable baseline symptom severity.

Table 5. Baseline Sneezing Scores

Severity Score	Bilastine (n=50)	Levocetirizine (n=50)	p-value
0 (None)	2 (4.0%)	3 (6.0%)	0.751
1 (Mild)	15 (30.0%)	16 (32.0%)	
2 (Moderate)	23 (46.0%)	21 (42.0%)	
3 (Severe)	10 (20.0%)	10 (20.0%)	
Mean $\pm$ SD	1.82 $\pm$ 0.74	1.76 $\pm$ 0.80	

Statistical Analysis: Independent t -test; $t = 0.318$, $p = 0.751$ (Not Significant).

Baseline sneezing scores were similar between the Bilastine and Levocetirizine groups. Nearly half of the participants in both groups experienced moderate sneezing, while one-fifth had severe symptoms. The mean sneezing scores showed no statistically significant difference (1.82 $\pm$ 0.74 vs. 1.76 $\pm$ 0.80; $p = 0.751$), confirming comparable baseline clinical status.

Table 6. Baseline Total Nasal Symptom Score (TNSS)

TNSS Range	Bilastine (n=50)	Levocetirizine (n=50)
5-6 (Mild)	13 (26.0%)	15 (30.0%)
7-8 (Moderate)	24 (48.0%)	23 (46.0%)
9-12 (Severe)	13 (26.0%)	12 (24.0%)
Mean $\pm$ SD	7.76 $\pm$ 1.46	7.68 $\pm$ 1.42
Range	5-11	5-11

Statistical Analysis: Independent t -test; $t = 0.79$, $p = 0.781$ (Not Significant).

The baseline Total Nasal Symptom Score (TNSS) was comparable between the two treatment groups. Approximately half of the patients in both groups had moderate disease severity, while about one-quarter had severe symptoms. The mean TNSS was 7.76 $\pm$ 1.46 in the Bilastine group and 7.68 $\pm$ 1.42 in the Levocetirizine group, with no statistically significant difference ($p = 0.781$). This indicates that both groups had similar overall symptom severity before treatment initiation.

Table 7. Baseline Serum IgE Levels

Parameter	Bilastine (n=50)	Levocetirizine (n=50)	p-value
Mean $\pm$ SD (IU/mL)	274.26 $\pm$ 88.41	278.13 $\pm$ 86.72	0.826
Median (IU/mL)	272.50	276.10	
Range (IU/mL)	126.4–501.8	138.1–515.2	
95% Confidence Interval (IU/mL)	249.14–299.38	253.49–302.77	

Statistical Analysis: Independent *t*-test; *t* = -0.221, *p* = 0.826 (Not Significant).

The baseline serum IgE levels were comparable between the Bilastine and Levocetirizine groups. The mean serum IgE level was 274.26 $\pm$ 88.41 IU/mL in the Bilastine group and 278.13 $\pm$ 86.72 IU/mL in the Levocetirizine group. The difference was not statistically significant (*p* = 0.826), indicating a similar allergic inflammatory status in both groups before treatment.

Table 8. Baseline Absolute Eosinophil Count (AEC)

Parameter	Bilastine (n=50)	Levocetirizine (n=50)	p-value
Mean $\pm$ SD (cells/ μ L)	469.12 $\pm$ 112.64	483.85 $\pm$ 126.37	0.597
Median (cells/ μ L)	466.00	480.00	
Range (cells/ μ L)	270–748	286–798	
95% Confidence Interval (cells/ μ L)	437.10–501.14	447.94–519.76	

Statistical Analysis: Independent *t*-test; *t* = -0.531, *p* = 0.597 (Not Significant).

Baseline absolute eosinophil counts were similar between the two treatment groups. The mean AEC was 469.12 $\pm$ 112.64 cells/ μ L in the Bilastine group and 483.85 $\pm$ 126.37 cells/ μ L in the Levocetirizine group, with no statistically significant difference (*p* = 0.597). This indicates comparable levels of eosinophilic inflammation at baseline.

Table 9. Post-Treatment TNSS in the Bilastine Group

Parameter	Baseline (Day 0)	Post-Treatment (Day 15)	Change
Mean $\pm$ SD	7.76 $\pm$ 1.46	2.33 $\pm$ 1.16	-5.43 $\pm$ 0.53
Median	8.00	2.00	-5.00
Range	5–11	0–5	—
% Reduction	—	—	70.0%
95% CI of Change	—	—	-5.58 to -5.28

Statistical Analysis: Paired *t*-test; *t* = 72.46, *df* = 49, *p* < 0.001 (Highly Significant).

Following 15 days of Bilastine therapy, the mean TNSS decreased significantly from 7.76 $\pm$ 1.46 to 2.33 $\pm$ 1.16, representing a 70.0% reduction in symptom severity. The improvement was highly statistically significant (paired *t*-test, *p* < 0.001), demonstrating excellent clinical efficacy of Bilastine in relieving symptoms of allergic rhinitis.

Table 10. Post-Treatment TNSS in the Levocetirizine Group

Parameter	Baseline (Day 0)	Post-Treatment (Day 15)	Change
Mean $\pm$ SD	7.68 $\pm$ 1.42	3.16 $\pm$ 1.23	-4.52 $\pm$ 0.50
Median	8.00	3.00	-5.00
Range	5–11	1–6	—
% Reduction	—	—	58.9%
95% CI of Change	—	—	-4.66 to -4.38

Statistical Analysis: Paired *t*-test; *t* = 63.92, *df* = 49, *p* < 0.001 (Highly Significant).

Levocetirizine treatment also produced a significant reduction in TNSS after 15 days, with the mean score decreasing from 7.68 $\pm$ 1.42 to 3.16 $\pm$ 1.23. This corresponded to a 58.9% reduction in symptom severity, which was highly significant (*p* < 0.001). Although Levocetirizine effectively improved allergic rhinitis symptoms, the magnitude of improvement was lower than that observed with Bilastine, suggesting comparatively better clinical efficacy of Bilastine.

DISCUSSION

The present prospective comparative study evaluated the efficacy of bilastine and levocetirizine in patients with allergic rhinitis. Both treatment groups were comparable at baseline with respect to age, gender distribution, severity of nasal symptoms, Total Nasal Symptom Score (TNSS), serum IgE levels, and absolute eosinophil count (AEC), indicating successful randomization and minimizing the possibility of selection

bias. The mean age of the participants was approximately 35 years, with an equal male-to-female ratio in both groups. Similar demographic characteristics have been reported in recent randomized studies evaluating antihistamines for allergic rhinitis, where most participants were young and middle-aged adults with no significant baseline differences between treatment groups (7, 8)

In the present study, baseline nasal congestion, rhinorrhea, sneezing, and overall TNSS were statistically comparable between the bilastine and levocetirizine groups ($p>0.05$). This ensured that any observed improvement after treatment could be attributed to the study drugs rather than differences in disease severity. Similar findings were observed by Singhal et al. (2024), who compared bilastine with fexofenadine and demonstrated comparable baseline symptom severity before initiation of therapy (8). Likewise, the recent randomized comparative study of montelukast–bilastine versus montelukast–levocetirizine also reported no significant baseline differences in TNSS between treatment groups (9).

Serum IgE and AEC are established biomarkers of allergic inflammation. In the present study, both parameters were comparable between groups before treatment, suggesting a similar allergic inflammatory burden. Although these laboratory parameters were not reassessed after treatment, their baseline similarity strengthens the internal validity of the comparison. Previous studies have similarly reported that serum IgE and eosinophil counts are useful for characterizing allergic rhinitis but do not always correlate directly with symptom severity or treatment response (10,11).

A major finding of the present study was the significant reduction in TNSS following treatment in both groups. Bilastine therapy reduced the mean TNSS from 7.76 ± 1.46 to 2.33 ± 1.16 , representing a 70% reduction, whereas levocetirizine reduced TNSS from 7.68 ± 1.42 to 3.16 ± 1.23 , corresponding to a 58.9% reduction. Both reductions were highly significant ($p<0.001$). However, the magnitude of symptom improvement was greater with bilastine, suggesting superior clinical efficacy over the 15-day treatment period.

These findings are consistent with the systematic review and meta-analysis by Radwan et al., which concluded that bilastine provides effective relief of nasal symptoms and has efficacy comparable or superior to established second-generation antihistamines while maintaining an excellent safety profile (9). Furthermore, the international Delphi consensus published in 2024 recommended bilastine as a preferred second-generation antihistamine because of its rapid onset of action, prolonged symptom control, minimal sedative effects, and excellent tolerability (11).

Our findings also agree with the recent randomized comparative study evaluating the fixed-dose combinations of montelukast–bilastine and montelukast–levocetirizine, in which both treatment groups showed marked improvement in TNSS over four weeks. Although the overall symptom reduction was similar, the bilastine-containing regimen demonstrated a better safety profile and greater cost-effectiveness. Similarly, the multicentre phase III randomized trial by Sinha et al. demonstrated significant improvement in allergic rhinitis symptoms with bilastine-containing therapy, confirming its effectiveness in routine clinical practice (12).

The superior improvement observed with bilastine in the present study may be explained by its high affinity and selectivity for peripheral H1 receptors, rapid onset of action, prolonged receptor occupancy, and negligible penetration of the blood-brain barrier. These pharmacological characteristics result in effective control of histamine-mediated symptoms while minimizing central nervous system adverse effects such as sedation (13, 14). In contrast, although levocetirizine is an effective second-generation antihistamine, mild sedative effects have been reported in some patients, which may influence overall patient satisfaction and adherence (10,11, 15).

The strengths of the present study include its prospective comparative design, comparable baseline characteristics between study groups, and the use of validated clinical outcome measures such as TNSS. Nevertheless, certain limitations should be acknowledged. The study was conducted at a single centre with a relatively small sample size and a short follow-up period of 15 days. Long-term symptom control, recurrence rates, quality-of-life assessment, adverse drug reactions, and post-treatment changes in inflammatory biomarkers were not evaluated. Larger multicentre randomized controlled trials with longer follow-up are therefore warranted to confirm these findings.

Overall, the findings of the present study indicate that both bilastine and levocetirizine are effective in improving symptoms of allergic rhinitis; however, bilastine produced a greater reduction in TNSS and may represent a more effective therapeutic option for short-term symptomatic management.

CONCLUSION

The present prospective comparative study demonstrated that both bilastine and levocetirizine were effective in improving the clinical symptoms of allergic rhinitis, with significant reductions in Total Nasal Symptom Score (TNSS) after 15 days of treatment. The two treatment groups were comparable at baseline

with respect to demographic characteristics, symptom severity, serum IgE levels, and absolute eosinophil count, ensuring a valid comparison of therapeutic outcomes. Although both antihistamines significantly improved nasal symptoms, bilastine achieved a greater reduction in TNSS (69.7%) compared with levocetirizine (58.6%), indicating superior clinical efficacy. These findings suggest that bilastine is an effective and well-tolerated therapeutic option and may offer better symptomatic relief than levocetirizine in patients with allergic rhinitis. Further multicentre studies with larger sample sizes, longer follow-up, and assessment of quality of life and adverse events are recommended to confirm these findings and establish long-term treatment outcomes.

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CITATION OF THIS ARTICLE

Chitra S, Irfan Ahmad K and Prince A. Comparative Efficacy of Bilastine and Levocetirizine in Patients with Allergic Rhinitis: A Prospective Comparative Study. *Bull. Env. Pharmacol. Life Sci.*, Vol 15 [9] August 2026. 115-120