

## Comparative Evaluation of Efficacy and Safety of Intranasal Corticosteroids Versus Oral Levocetirizine in Patients with Allergic Rhinitis Attending a Tertiary Care Centre in North India

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### Abstract:

**Background:** Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa mediated by immunoglobulin E (IgE) after exposure to environmental allergens. It is characterized by sneezing, rhinorrhea, nasal obstruction, itching, and frequently associated ocular symptoms. Allergic rhinitis significantly impairs quality of life, sleep, school performance, and workplace productivity. Pharmacological management primarily includes intranasal corticosteroids and second-generation H1 antihistamines; however, their comparative effectiveness remains an area of clinical interest.

**Aim:** To compare the efficacy and safety of intranasal corticosteroids and oral levocetirizine in patients with allergic rhinitis.

**Materials and Methods:** A hospital-based observational comparative study was conducted in the Departments of Pharmacology and Otorhinolaryngology of Muzaffarnagar Medical College and Hospital, Uttar Pradesh. A total of 150 adult patients diagnosed with allergic rhinitis were enrolled. Patients were divided into two groups: Group A received intranasal corticosteroids and Group B received oral levocetirizine 5 mg. Clinical efficacy was assessed using Total Nasal Symptom Score (TNSS), Total Ocular Symptom Score (TOSS), and Total Symptom Score (TSS) at 1 week, 1 month, and 3 months. Adverse drug reactions were recorded during follow-up. Statistical analysis was performed using SPSS version 29, and  $p < 0.001$  was considered statistically significant.

**Results:** The mean age of participants was  $28.61 \pm 6.51$  years. Significant reductions in TNSS, TOSS, and TSS were observed in both treatment groups during follow-up. Group A demonstrated superior improvement in TNSS at 1 week ( $4.27 \pm 1.65$  vs  $6.03 \pm 2.05$ ), 1 month ( $1.49 \pm 0.95$  vs  $4.29 \pm 2.01$ ), and 3 months ( $0.95 \pm 0.84$  vs  $3.76 \pm 2.00$ ). Similarly, TSS was significantly lower in Group A at 1 month and 3 months. Adverse drug reactions occurred in 12% of patients receiving intranasal corticosteroids and 20% of patients receiving levocetirizine.

**Conclusion:** Intranasal corticosteroids demonstrated superior efficacy in controlling nasal symptoms and overall disease burden compared to oral levocetirizine. Both therapies were safe; however, intranasal corticosteroids showed better long-term symptom control with fewer systemic adverse effects.

**Keywords:** Allergic rhinitis, Intranasal corticosteroids, Levocetirizine, Antihistamines, TNSS, TOSS, TSS.

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## Introduction

Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa characterised by sneezing, rhinorrhea, nasal itching, and nasal obstruction following exposure to specific allergens in sensitised individuals. It is one of the most common allergic diseases worldwide and has emerged as a major public health concern because of its increasing prevalence, substantial socioeconomic burden, and significant impact on quality of life. Allergic rhinitis is no longer considered a trivial disease because persistent symptoms can adversely affect physical health, emotional well-being, sleep quality, academic performance, workplace productivity, and overall quality of life. [1–3].

The prevalence of allergic rhinitis has increased dramatically over the past few decades, particularly in developing countries undergoing rapid urbanization and industrialization. Epidemiological studies suggest that approximately 10–40% of the global population suffers from allergic rhinitis, making it one of the most prevalent chronic respiratory diseases. [4,5] In India, the prevalence has been reported to range between 20% and 30%, with higher rates observed among adolescents, young adults, and urban populations. [6]

The pathogenesis of allergic rhinitis is complex and involves genetic predisposition, environmental exposure, and immunological dysregulation. The disease is primarily mediated by immunoglobulin E (IgE)-dependent hypersensitivity reactions. During the sensitization phase, exposure to allergens such as pollen, house dust mites, molds, animal dander, and environmental pollutants stimulates antigen-presenting cells and T-helper type 2 (Th2) lymphocytes, resulting in production of allergen-specific IgE antibodies by B lymphocytes. [7, 8] These antibodies subsequently bind to high-affinity IgE receptors on mast cells and basophils & triggers mast cell degranulation and release of inflammatory mediators such as histamine, leukotrienes, prostaglandins, tryptase, and cytokines. [9]

Clinical manifestations of allergic rhinitis vary depending on the severity and duration of allergen exposure. Typical symptoms include recurrent sneezing, watery rhinorrhea, nasal congestion, nasal itching, postnasal drip, cough, and impaired olfaction. [10] Many patients also experience ocular symptoms such as itching, redness, tearing, and photophobia, collectively referred to as allergic rhinoconjunctivitis. [11]

Pharmacological treatment remains the cornerstone of symptom control and includes antihistamines, intranasal corticosteroids, leukotriene receptor antagonists, decongestants, mast-cell stabilizers, and combination therapies. [12]

Intranasal corticosteroids are regarded as the most effective medications for allergic rhinitis because they target multiple inflammatory pathways simultaneously. [13] These agents reduce eosinophilic infiltration, cytokine release, mucosal edema, vascular permeability, and glandular secretion.

H1-antihistamines constitute another major therapeutic class used in allergic rhinitis. Histamine is one of the principal mediators responsible for early allergic responses, and H1-antihistamines act by competitively blocking histamine receptors. [14] Levocetirizine, the active R-enantiomer of cetirizine, possesses high affinity for peripheral H1 receptors and rapid onset of action. [15] It effectively controls sneezing, rhinorrhea, itching, and ocular symptoms. However, antihistamines have limited efficacy in relieving nasal congestion because they primarily target histamine-mediated pathways and exert relatively weak anti-inflammatory effects. [16]

## Material & Methods

A hospital-based observational comparative study was conducted over 18 months in the Department of Pharmacology in collaboration with the Department of Otorhinolaryngology, Muzaffarnagar Medical College and Hospital, Uttar Pradesh, India. Adult patients ( $\geq 18$  years) clinically diagnosed with allergic rhinitis and presenting with symptoms such as sneezing, rhinorrhoea, nasal obstruction, and associated ocular symptoms were consecutively recruited from the ENT outpatient department via convenience sampling after obtaining written informed consent. Patients with other forms of rhinitis, structural nasal abnormalities, hypersensitivity to study medications, recent use of systemic corticosteroids, blood disorders including non-allergic eosinophilic syndrome or tropical eosinophilia, pregnant or lactating women, and those unwilling to participate were excluded. A total of 150 eligible patients were enrolled based on the average patient load over the preceding three years.

Participants were allocated to two treatment groups: Group A received an intranasal corticosteroid spray (one puff in each nostril twice daily for 7 days, followed by two puffs once daily for the next 7 days), while Group B received oral levocetirizine 5 mg twice daily for 14 days. Baseline demographic data were recorded using a structured case record form. Symptom severity was assessed using the Total Nasal Symptom Score (TNSS) and Total Ocular Symptom Score (TOSS), with each symptom graded on a 4-point scale (0–3). The Total Nasal Symptom Score (TNSS) was calculated by grading sneezing, rhinorrhoea, nasal itching, and nasal congestion, whereas the Total Ocular Symptom Score (TOSS) assessed ocular itching, redness, swelling and watering. The Total Symptom Score (TSS) was calculated as the sum of TNSS and TOSS. Patients were followed up

at 1 week, 1 month, and 3 months after initiation of therapy, and changes in TNSS, TOSS, and TSS were evaluated. Adverse drug reactions were documented using the ADR Reporting Form Version 1.4. Data were analysed using SPSS version 29, with continuous variables expressed as mean  $\pm$  standard deviation and categorical variables as frequencies and

percentages. Appropriate statistical tests were applied, and a p-value of  $<0.001$  was considered statistically significant. The Institutional Ethics Committee of Muzaffarnagar Medical College and Hospital approved the study protocol.

## Results

**Table 1: Demographic Characteristics of Study Participants**

Demographic Characteristics	Mean $\pm$ SD	
Age	28.61 $\pm$ 6.51	
Demographic Characteristics	Number(n)	Percentage
Gender		
Female	70	46.70%
Male	80	53.30%
Locality		
Rural	69	46.00%
Urban	81	54.00%
Occupation		
Businessman	45	30.00%
Bank Manager	03	2.00%
Student	45	30.00%
Daily Wager	03	2.00%
Farmer	06	4.00%
Government Service	01	1.00%
Housewives	20	13.00%
Rickshaw Puller	01	1.00%
Tailor	03	2.00%
Teacher	03	2.00%
Unemployed	01	1.00%

The average age of the participants was  $28.61 \pm 6.51$  years, suggesting that the study sample primarily consisted of young people. The gender distribution revealed that males comprised 53.30% (n = 80) of the sample population, while females represented 46.70% (n = 70), indicating a marginal male majority. Concerning 54.00% (n = 81) of participants hailed from urban regions, while 46.00% (n = 69) were from rural areas. With respect to occupation, the largest proportions of participants were businessmen 30.00% (n=45) and students 30.00%

(n=45) each constituting nearly one-third of the study population. Housewives accounted for 13.00% (n=20) of the participants. Farmers represented 4.00% (n=6) and smaller proportions included bank managers 2.00% (n=3), daily wagers 2.00% (n=3), tailors 2.00% (n=3), and teachers 2.00% (n=3). Minimal representation was observed among government service employees 1.00% (n=1), rickshaw pullers 1.00% (n=1) and unemployed individuals 1.00% (n=1).

**Table 2: Intergroup Comparison of Total Nasal Symptom Score at Different Follow-up Intervals**

TNSS	Drug group	Mean $\pm$ SD	p-value
1Week	A	4.27 $\pm$ 1.65	$<0.001^*$
	B	6.03 $\pm$ 2.05	
1Month	A	1.49 $\pm$ 0.95	$<0.001^*$
	B	4.29 $\pm$ 2.01	
3Month	A	0.95 $\pm$ 0.84	$<0.001^*$
	B	3.76 $\pm$ 2.00	

\*p-value $<0.001$  is significant

Table 2 depict the intergroup comparison of TNSS Score between Group A (intranasal corticosteroids) and Group B (tablet levocetirizine) at 1 week, 1 month, as well as three months of follow-up. At 1 week, the mean TNSS was significantly lower in Group A ( $4.27 \pm 1.65$ ) compared to Group B

( $6.03 \pm 2.05$ ). Similar and more pronounced differences were observed at 1month ( $1.49 \pm 0.95$  vs  $4.29 \pm 2.01$ ) and 3months ( $0.95 \pm 0.84$  vs  $3.76 \pm 2.00$ ). The intergroup differences in TNSS at all follow-up intervals were statistically significant.

**Table 3: Intergroup Comparison of TOSS Score at Different Follow-up Intervals**

TOSS	Drug group	Mean± SD	p-value
1Week	A	3.03±1.28	<0.001*
	B	1.92±0.97	
1Month	A	0.81±0.77	0.008*
	B	1.19±0.93	
3Month	A	0.56±0.70	<0.001*
	B	1.07±0.92	

\*p-value &lt;0.001 is significant

Group A (INS) and Group B (tablet levocetirizine) were compared at various follow-up intervals with respect to their TOSS Score, as shown in the table 3. Group A showed improved early control of ocular symptoms with antihistaminic medication, as indicated by a higher mean TOSS ( $3.03 \pm 1.28$ ) compared to Group B ( $1.92 \pm 0.97$ ) at 1 week. At the

one-month mark, Group A had a lower mean TOSS ( $0.81 \pm 0.77$ ) than Group B ( $1.19 \pm 0.93$ ). At 3 months, a comparable trend was noted, with Group A exhibiting an average TOSS of  $0.56 \pm 0.70$ , in contrast to Group B's  $1.07 \pm 0.92$ . At every follow-up interval, the differences between the groups in TOSS were statistically significant ( $p < 0.05$ ).

**Table 4: Comparison of TSS between Group A as well as B at Different Follow-up Intervals**

TSS	Drug group given	Mean± SD	p-value
1Week	A	7.29±2.20	0.087
	B	7.95±2.44	
1Month	A	2.31±1.29	<0.001*
	B	5.48±2.25	
3Month	A	1.51±1.20	<0.001*
	B	4.83±2.23	

\*p-value &lt;0.001 is significant

The TSS between Group A (INS) and Group B (tablet levocetirizine) was compared at 1 week, 1 month, and 3 months of follow-up, as shown in the table 4. There was no statistically significant difference between Group A and Group B at 1 week in terms of

mean TSS, which was  $7.29 \pm 2.20$  and  $7.95 \pm 2.44$ , respectively ( $p = 0.087$ ). Group B had a mean TSS of  $5.48 \pm 2.25$  at 1 month, while Group A had a much lower average of  $2.31 \pm 1.29$ . At 3 months, there was a greater and comparable difference ( $1.51 \pm 1.20$  versus  $4.83 \pm 2.23$ ).

**Table 5: Adverse Drug Reactions**

ADR	Group A (INS)	Group B (Tab Levocetirizine)	Percentage
Drowsiness	0	6	4%
Dry mouth	0	5	3%
Lethargy	0	4	3%
Nasal irritation/burning	6	0	4%
Sneezing after spray	3	0	2%
Total	9	15	16%

Table 5 depicts the frequency of adverse medication responses in Group A (INS) and Group B (tablet Levocetirizine). All ADRs were present in 16% of cases ( $n = 24$ ). Fatigue (3%,  $n = 4$ ), dry mouth (3%,  $n = 5$ ), and drowsiness (4%,  $n = 6$ ) were some of the

systemic side effects noted in Group B (tablet Levocetirizine). In contrast, most local adverse effects were reported by Group A, including sneezing after spray (2%,  $n = 3$ ), nose irritation/burning (4%,  $n = 6$ ).

**Table 6 Comparison of Adverse Drug Reactions between Group A and Group B**

No. of ADR	Drug group given		Total	p value
	A	B		
Number(n)	9	15	24	0.001*
Percentage	12.00%	20.00%	16.00%	

\*Indicates Significance (p-value&lt;0.001)

Table 6 depicts the comparison of the overall incidence of ADRs between Group A (INS) and Group

B (tablet levocetirizine). Adverse reactions were reported in 12.00% ( $n = 9$ ) of patients in Group A and

20.00% (n = 15) of patients in Group B, with an overall ADR incidence of 16.00% (n = 24) in the study population.

### Discussion

The present study was undertaken to compare the efficacy and safety of intranasal corticosteroids and oral levocetirizine in patients with allergic rhinitis. The findings demonstrated that both treatment modalities significantly improved symptoms; however, intranasal corticosteroids produced greater reductions in TNSS, TOSS, and TSS throughout the follow-up period. These observations support contemporary evidence indicating that intranasal corticosteroids remain the most effective pharmacological option for management of allergic rhinitis. [10, 16-22]

The mean age of study participants was approximately 28 years, indicating predominance among young adults. Similar age distributions have been reported in recent epidemiological studies from India and other developing countries. [5,6] Young adults frequently encounter occupational allergens, environmental pollution, indoor dust exposure, and lifestyle-related risk factors, which may contribute to increased disease prevalence. Urban residence was also common among study participants, supporting previous observations linking urbanisation and industrialization with allergic respiratory diseases.[23]

One of the most important findings of the present study was the marked reduction in TNSS among patients receiving intranasal corticosteroids. Nasal symptoms decreased significantly on each follow-up, demonstrating both rapid and sustained efficacy. Nasal obstruction showed particularly notable improvement. This finding is clinically important because nasal congestion is often the most troublesome symptom reported by patients and is associated with sleep disturbance, impaired concentration, and reduced quality of life. [11, 24]

The superior efficacy of intranasal corticosteroids can be explained by their broad anti-inflammatory actions. Unlike antihistamines, which primarily block histamine-mediated pathways, corticosteroids suppress multiple inflammatory mediators including cytokines, chemokines, eosinophils, mast cells, and adhesion molecules. [13, 25] Consequently, they effectively control both early-phase and late-phase allergic responses.[26]

Recent ARIA-EAACI guidelines updates published in 2025 reaffirm that intranasal corticosteroids are the preferred first-line treatment for moderate-to-severe allergic rhinitis because they provide superior symptoms control compared with oral antihistamines [21, 22] These recommendations are highly consistent with the finds of the present study.

The reduction in ocular symptoms observed among patients receiving intranasal corticosteroids is also

noteworthy. Although antihistamines traditionally provide rapid relief of ocular manifestations, prolonged anti-inflammatory therapy with corticosteroids resulted in sustained improvement. Similar observations have been reported in recent multicenter studies evaluating patient-reported outcomes in allergic rhino conjunctivitis. [13, 17]

Several systematic reviews and meta-analyses published during 2024–2026 have consistently demonstrated greater efficacy of intranasal corticosteroids than oral antihistamines. Sousa-Pinto et al. reported significantly greater reductions in symptom scores and improved quality-of-life measures among patients receiving corticosteroid-based therapy. [13, 22] Similarly, Soe et al. demonstrated superior effectiveness of intranasal corticosteroids across multiple symptom domains, including nasal congestion, rhinorrhea, and sneezing.[16]

Another important aspect of the present study is the improvement in total symptom score (TSS). The greater reduction observed in the corticosteroid group indicates comprehensive disease control. This finding supports the concept that allergic rhinitis is not merely a histamine-mediated disorder but a complex inflammatory disease involving multiple immune pathways. [9, 25]

The safety profile observed in the present study was favorable. Adverse effects associated with intranasal corticosteroids were generally mild and localized, including transient nasal irritation and sneezing. Conversely, levocetirizine was associated with drowsiness, fatigue, and dry mouth. Similar findings have been reported in contemporary pharmacovigilance studies. [15, 27]

The findings of the present study are consistent with most international and national treatment guidelines. The superiority of intranasal corticosteroids observed in our patient population reinforces recommendations supporting their use as first-line therapy for persistent allergic rhinitis. Antihistamines continue to have an important role, particularly in patients with mild intermittent symptoms, predominant ocular manifestations, or intolerance to corticosteroids. However, for comprehensive symptom control and long-term disease management, intranasal corticosteroids appear to provide the greatest therapeutic benefit.

### Conclusion

Intranasal corticosteroids demonstrated significantly superior efficacy compared to oral levocetirizine in reducing nasal symptoms, ocular symptoms, and overall symptom burden in patients with allergic rhinitis. Both therapies were safe and well tolerated; however, intranasal corticosteroids provided better long-term symptom control with fewer systemic adverse effects. Therefore, intranasal corticosteroids should be considered the preferred first-

line treatment for moderate-to-severe allergic rhinitis.

### Limitations

The limitation of our study was that it was done in one tertiary center & sample size was less.

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