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Comparative efficacy of oral fexofenadine hydrochloride and intranasal fluticasone furoate in patients with moderate to severe allergic rhinitis: A prospective randomized comparative study.

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Abstract

Background

Allergic rhinitis (AR) is a prevalent chronic condition with a significant impact on quality of life. Pharmacotherapy with non-sedating antihistamines and intranasal corticosteroids remains the mainstay, though comparative evidence in Indian settings is limited. This study aimed to evaluate and compare the clinical efficacy of oral fexofenadine hydrochloride and intranasal fluticasone furoate in patients with moderate to severe AR.

Methods

A prospective comparative study was conducted on 100 patients aged 16–55 years presenting with moderate to severe AR at a tertiary care centre. Participants were randomized into two equal groups: oral fexofenadine 120 mg once daily (Group OF) and intranasal fluticasone furoate spray, one puff daily (Group NF). Baseline demographic characteristics, symptom scores, and visual analogue scale (VAS) ratings were recorded. Patients were followed up weekly for four weeks.

Results

Baseline demographic and clinical characteristics were comparable between groups (Table 1). Both groups demonstrated significant reduction in total symptom scores after 4 weeks ($p < 0.001$), with mean post-treatment scores of 1.16 ± 3.36 in Group OF and 1.90 ± 3.85 in Group NF (Table 2). Severity distribution showed that most patients shifted from severe to moderate categories without intergroup difference (Table 3). However, fluticasone produced greater improvement in nasal obstruction, sneezing, and nasal discharge compared with fexofenadine (Table 4). VAS scores confirmed the superior efficacy of intranasal fluticasone in reducing overall symptom burden (Table 5).

Conclusion

Both oral fexofenadine and intranasal fluticasone furoate are effective in alleviating symptoms of moderate to severe AR. Fluticasone demonstrated superior improvement in nasal symptoms and VAS reduction, suggesting it may be preferred as first-line therapy.

Recommendations

For patients with prominent nasal obstruction or persistent AR, intranasal corticosteroids should be prioritized. Antihistamines may be considered when systemic symptoms or patient preference for oral therapy exist.

Keywords: *Allergic rhinitis; Fexofenadine hydrochloride; Fluticasone furoate; Intranasal corticosteroids; Antihistamines*
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Introduction

Allergic rhinitis (AR) is a prevalent chronic inflammatory disorder of the nasal mucosa, clinically characterized by sneezing, nasal obstruction, rhinorrhoea, and nasal or ocular itching. It is primarily mediated by immunoglobulin E (IgE) in response to environmental allergens and contributes to significant morbidity through impaired sleep, reduced productivity, and compromised quality of life [1]. Globally,

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the prevalence of AR ranges from 10–25%, with an increasing trend documented in both developed and developing nations [1,2].

The disorder is often associated with comorbid conditions such as asthma, sinusitis, otitis media, and other atopic manifestations, thereby amplifying its burden on healthcare systems [2]. In India, where exposure to dust mites, pollens, and indoor allergens is widespread, AR has emerged as a significant public health concern, particularly among adolescents and young adults [3]. Despite being non–life threatening, its chronic course and impact on daily functioning warrant effective evidence-based treatment strategies.

Pharmacotherapy remains the cornerstone of management, encompassing antihistamines, intranasal corticosteroids, leukotriene receptor antagonists, and decongestants. Second-generation non-sedating antihistamines such as fexofenadine hydrochloride are widely recommended due to their efficacy in relieving sneezing, rhinorrhoea, and ocular symptoms while minimizing the sedative and cognitive adverse effects of earlier agents [4]. In contrast, intranasal corticosteroids such as fluticasone furoate have been consistently recognized as the most effective agents for reducing nasal inflammation and congestion, with favorable safety profiles at recommended doses [5].

Nevertheless, debate persists regarding whether antihistamines or intranasal corticosteroids should be prioritized as first-line therapy in patients with moderate-to-severe AR. While antihistamines provide systemic relief, corticosteroids act directly on local nasal mucosa and may offer superior symptom control [3–5]. The paucity of comparative data from Indian populations highlights the need for locally relevant clinical evidence to guide optimal treatment selection.

The present study was undertaken to compare the clinical efficacy of oral fexofenadine hydrochloride and intranasal fluticasone furoate in patients with moderate to severe AR. By evaluating symptom reduction, severity distribution, and patient-reported outcomes, this study seeks to generate practical insights for optimizing pharmacological management of AR.

Methodology

Study design and setting

This was a prospective, randomized, comparative study conducted in the Department of Otorhinolaryngology at Mamata Medical College and General Hospital, Khammam, Telangana, over a period of 24 months (August 2022 – July 2024).

Study population

A total of 100 patients aged between 16 and 55 years presenting with moderate to severe allergic rhinitis were enrolled. Eligible participants had at least three of the following symptoms: sneezing, nasal obstruction, nasal discharge, nasal itching, ocular symptoms (itching or watering of eyes), palatal itching, or ear itching. Only those with at least one symptom of moderate-to-severe intensity were included.

Inclusion criteria

Patients aged 16–55 years with clinically diagnosed moderate to severe allergic rhinitis.

Willingness to provide informed consent and comply with study procedures.

Exclusion criteria

Co-existing upper respiratory tract infection, sinusitis, or complications of AR.

Pregnant and lactating women.

Mild AR symptoms.

Patients with systemic comorbidities or a history of corticosteroid/antihistamine use within the past month.

Age <16 years or >60 years.

Randomization and intervention

Participants were randomly assigned in a 1:1 ratio to receive either oral fexofenadine hydrochloride (Group OF) or intranasal fluticasone furoate (Group NF).

Sequence generation

The random allocation sequence was generated using a computer-based random number generator (Random Allocation Software, version 2.0).

Type of randomization

A simple randomization procedure was employed without stratification. To ensure equal distribution, block randomization with a fixed block size of 10 was implemented.

Allocation concealment mechanism

Sequentially numbered, opaque, sealed envelopes (SNOSE) were used to conceal the allocation sequence. Each envelope contained the assigned treatment code and was opened only after participant enrollment, thereby maintaining concealment until the intervention was allocated.

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Original Article

Implementation
The random allocation sequence was generated by a statistician not involved in the trial's conduct. Patient enrollment was performed by one investigator, while intervention assignment was carried out by another clinician who was blinded to the sequence to prevent selection bias.

Blinding
As this was an open-label trial involving distinct routes of drug administration (oral vs. intranasal), participant and investigator blinding was not feasible. However, outcome assessment and statistical analysis were performed by independent evaluators blinded to treatment allocation to minimize assessment bias.

Sample size determination
A total sample size of 100 participants (50 per group) was calculated using the formula for comparing two means, considering a two-sided significance level of 0.05, a power of 80%, and an expected mean difference in symptom score reduction of 1.5 units between the two interventions, based on previous similar studies [1,6]. Accounting for a potential 10% dropout rate, the final sample size was rounded to 100.

Outcome measures
Baseline evaluation included demographic details, clinical history, and symptom scores. Symptom severity was graded using a four-point scale (0 = absent, + = mild, ++ = moderate, +++ = severe). Outcomes assessed were:
Total symptom score (TSS)
Individual symptom scores (sneezing, nasal obstruction, nasal discharge, nasal/ocular itching, watering of eyes, palatal and ear itching)
Severity distribution (moderate vs. severe)

Visual analogue scale (vas) scores
Follow-up evaluations were performed weekly for four weeks to document clinical response.

Statistical analysis
Data were analyzed using SPSS version 25. Descriptive statistics were expressed as mean ± standard deviation (SD) or percentages. Categorical variables were compared using the Chi-square or Fisher's exact test. Within-group comparisons of symptom scores were analyzed using the Wilcoxon signed-rank test, while between-group differences were assessed using the Mann–Whitney U test. A p-value <0.05 was considered statistically significant.

Ethical considerations
The study protocol was reviewed and approved by the Institutional Ethics Committee of Mamata Medical College, Khammam. Written informed consent was obtained from all participants before enrollment. Confidentiality of patient data was strictly maintained, and the study adhered to the ethical principles outlined in the Declaration of Helsinki.

Results
Participant flow
A total of 112 patients presenting with moderate to severe allergic rhinitis were screened for eligibility during the study period. Of these, 12 patients were excluded; 6 did not meet the inclusion criteria (3 had mild allergic rhinitis, 2 had concurrent sinusitis, and 1 had recent corticosteroid use), while 6 declined to participate.
The remaining 100 eligible participants were randomly allocated into two equal groups: Group OF (Oral Fexofenadine, n = 50), Group NF (Intranasal Fluticasone Furoate, n = 50). All randomized participants received the intended intervention. During the 4-week follow-up period, in Group OF, 2 participants were lost to follow-up (1 withdrew consent; 1 failed to attend subsequent visits).In Group NF, 3 participants discontinued (2 reported local nasal irritation; 1 was lost to follow-up). Hence, 48 patients in Group OF and 47 patients in Group NF were analyzed for the primary outcome; participant was excluded from analysis for protocol deviation. The overall study completion rate was 95%, with balanced retention across both groups. (Figure 1)

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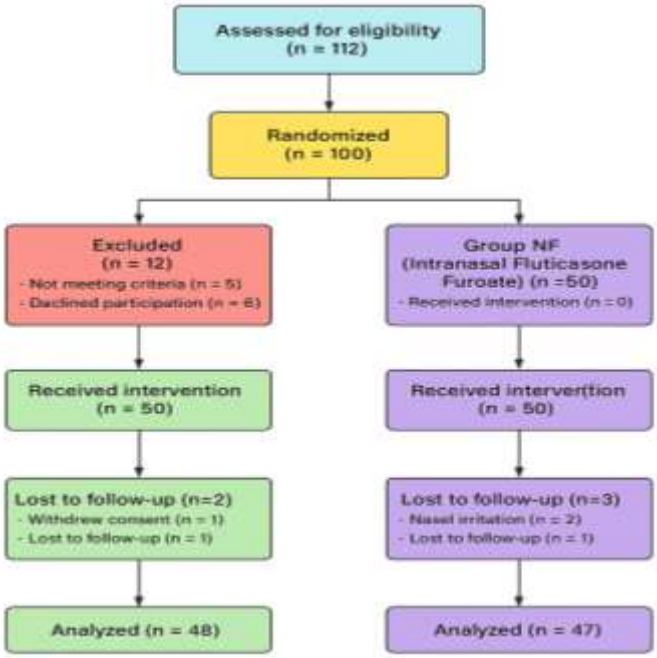

Figure 1: participant flow diagram

A total of 100 patients with moderate to severe allergic rhinitis were enrolled and randomly allocated into two groups: oral fexofenadine (n = 50) and intranasal fluticasone furoate (n = 50). Baseline demographic and clinical characteristics between the groups were comparable with no statistically significant differences. The mean age distribution showed a predominance of patients in the 26–50-year range. Females constituted a higher proportion in both groups, with a female preponderance in the oral fexofenadine arm (78% vs. 62%). The mean duration of illness was approximately 2–3 years in both groups, and the proportion of intermittent and persistent symptoms was nearly equal. A positive family history of allergic disorders was documented in 12% of patients in the oral fexofenadine group and 8% in the fluticasone group (Table 1).

Table 1. Demographic and clinical characteristics of study participants (n = 100)

Parameter	Oral Fexofenadine (n = 50)	Fluticasone Nasal Spray (n = 50)	*p*-value
Age Distribution	16–25 yr: 18% 26–40 yr: 26.7% 41–50 yr: 51.7% >50 yr: 4%	16–25 yr: 14% 26–40 yr: 46% 41–50 yr: 32% >50 yr: 8%	0.108
Gender	Male: 22% Female: 78%	Male: 38% Female: 62%	0.081
Duration of Illness	1 yr: 28% 2 yr: 24% 3 yr: 16% 4 yr: 24% 5 yr: 8%	1 yr: 36% 2 yr: 32% 3 yr: 20% 4 yr: 12% 5 yr: 0%	0.121
Symptom Type	Intermittent: 52% Persistent: 48%	Intermittent: 48% Persistent: 52%	0.689

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Original Article

Family History of Allergy	Present: 12% Absent: 88%	Present: 8% Absent: 92%	0.346

Symptom scores and severity

The baseline total symptom score was comparable between the groups (10.92 ± 2.30 vs. 11.28 ± 2.96, $p > 0.05$). Following 4 weeks of therapy, both groups demonstrated a highly significant reduction in symptom scores compared to baseline ($p < 0.001$ for both groups). Post-treatment, the mean score decreased to 1.16 ± 3.36 in the oral fexofenadine group and to 1.90 ± 3.85 in the fluticasone group, with no statistically significant intergroup difference (Table 2).

Table 2. Baseline and post-treatment symptom scores

Parameter	Oral Fexofenadine (Mean ± SD)	Fluticasone Nasal Spray (Mean ± SD)	*p*-value
Total Symptom Score (Baseline)	10.92 ± 2.30	11.28 ± 2.96	>0.05
Total Symptom Score (After 4 weeks)	1.16 ± 3.36	1.90 ± 3.85	>0.05
Within-group significance	p < 0.001	p < 0.001	–

When symptom severity was classified, most patients initially presented with moderate symptoms. After treatment, 68% in the fexofenadine group and 64% in the fluticasone group continued to have moderate symptoms, while severe symptoms persisted in 32% and 36% of patients, respectively. The difference between the two arms was not significant (Table 3).

Table 3. Symptom severity distribution

Severity	Oral Fexofenadine (n = 50)	Fluticasone Nasal Spray (n = 50)	*p*-value
Moderate	34 (68%)	32 (64%)	>0.05
Severe	16 (32%)	18 (36%)	>0.05

Effect on individual symptoms

Analysis of individual symptoms revealed marked improvement in both treatment arms, with a greater reduction observed in the fluticasone group. Sneezing, nasal obstruction, and nasal discharge improved significantly in both groups, though the magnitude of reduction was higher with fluticasone ($p < 0.001$). Symptoms such as eye itching, watering of eyes, palatal itching, and ear itching showed significant resolution in both groups, with near-complete resolution in the fluticasone group (Table 4).

Table 4. Effect of treatment on individual symptoms

Symptom	Oral Fexofenadine (Before → After)	Fluticasone Nasal Spray (Before → After)	*p*-value (within group)
Sneezing	100% → 88%	100% → 38%	OF: 0.012 NF: <0.001
Nasal Obstruction	100% → 84%	100% → 42%	OF: 0.003 NF: <0.001
Nasal Discharge	100% → 90%	100% → 56%	OF: 0.022 NF: <0.001
Nasal Itching	96% → 92%	76% → 58%	NS in both
Eye Itching	88% → 24%	88% → 20%	<0.001
Watering of Eyes	56% → 24%	40% → 4%	<0.001

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Original Article

Palatal Itching	64% → 12%	60% → 0%	<0.001
Ear Itching	44% → 10%	40% → 0%	<0.001

Visual analogue scale (vas)

The VAS scores, used to assess subjective symptom burden, showed a significant decline in both groups from baseline to week 4 ($p < 0.001$). However, the magnitude of improvement was more pronounced with fluticasone compared to oral fexofenadine, indicating superior efficacy of the intranasal corticosteroid in alleviating overall symptom severity (Table 5).

Table 5. Visual analogue scale (vas) score comparison

Group	Mean VAS (Baseline)	Mean VAS (After 4 Weeks)	*p*-value
Oral Fexofenadine	High baseline → significantly reduced	Reduction, but less pronounced	<0.001
Fluticasone Nasal Spray	High baseline → markedly reduced	Greater improvement than OF	<0.001

Discussion

The present prospective randomized comparative study evaluated the therapeutic efficacy of oral fexofenadine hydrochloride and intranasal fluticasone furoate in patients with moderate to severe allergic rhinitis. Both treatment groups demonstrated a highly significant reduction in total and individual symptom scores after four weeks of therapy, confirming their well-established role as first-line pharmacologic options in the management of allergic rhinitis, consistent with earlier randomized controlled trials [6,8]. Intranasal fluticasone furoate produced greater improvement in nasal obstruction, sneezing, and rhinorrhoea compared with oral fexofenadine, reflecting its potent local anti-inflammatory activity on the nasal mucosa. Comparable findings were observed in previous studies [1,2], which demonstrated superior efficacy of intranasal corticosteroids in controlling nasal congestion and sneezing compared with second-generation antihistamines. Collectively, these outcomes reaffirm that while both agents are clinically effective, fluticasone offers a distinct advantage in alleviating the core nasal manifestations that most affect patient comfort and daily function.

Second-generation antihistamines such as fexofenadine continue to be widely preferred owing to their non-sedating properties, minimal cognitive impairment, and systemic mode of action. In addition to nasal symptom relief, these agents are particularly beneficial in managing ocular and pharyngeal symptoms, which are often under-recognized in clinical practice [6,13]. In this study, fexofenadine provided marked improvement in itching and watering of the eyes, aligning with earlier clinical observations that antihistamines achieve superior control of ocular manifestations compared with intranasal therapy [6,13]. These observations emphasize that individual symptom profiles should guide therapeutic selection to maximize clinical benefit.

Intranasal corticosteroids remain the most effective agents for reducing nasal inflammation and congestion due to their strong topical anti-inflammatory effects. The superior efficacy of fluticasone furoate in relieving nasal blockage found in this study aligns with previous reports highlighting the predominance of corticosteroids over antihistamines for managing nasal obstruction [11]. Recent innovations, including fixed-dose combinations of fluticasone with oxymetazoline, have shown enhanced symptom relief and faster onset of action, providing further options for patients with moderate-to-severe disease [9].

Comprehensive evidence from regional and international studies consistently supports the use of intranasal corticosteroids as first-line therapy for moderate to severe allergic rhinitis [7]. Combined intranasal therapy with azelastine and fluticasone has demonstrated superior control of both nasal and ocular symptoms compared with monotherapy, suggesting an advantage for dual-mechanism approaches in refractory cases [7]. Current consensus recommendations and updated clinical algorithms, including the EUFOREA guidelines, also endorse corticosteroid-based therapies as the cornerstone of long-term disease management [10].

Although pharmacotherapy remains the mainstay of allergic rhinitis management, it primarily targets symptom relief rather than the underlying immune dysregulation. Allergen immunotherapy represents an alternative approach shown to reduce symptom severity and drug dependence, with meta-analyses confirming greater efficacy compared with pharmacotherapy alone [14]. Continued exploration of

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Original Article

novel therapeutic pathways that modulate immune and inflammatory responses is essential for achieving sustained remission and improving patient outcomes [12].

Generalizability

The findings of this study can be generalized to similar tertiary-care settings across India, where the clinical burden of allergic rhinitis is substantial. Because the study population included a broad age range and both genders with comparable baseline characteristics, the results are likely representative of typical patients with moderate to severe allergic rhinitis in the community. However, extrapolation to other populations should be made cautiously, as regional allergen exposure, environmental conditions, and adherence behaviors may influence treatment response. Larger multicentric studies involving diverse demographic and environmental backgrounds are warranted to confirm these findings and enhance external validity.

Conclusion

This prospective comparative study demonstrated that both oral fexofenadine hydrochloride and intranasal fluticasone furoate are effective in reducing symptoms of moderate to severe allergic rhinitis. While significant improvement was observed in both groups, fluticasone furoate provided superior relief of nasal congestion, sneezing, and nasal discharge, as well as greater reduction in visual analogue scale scores, underscoring its advantage as a first-line therapy. Fexofenadine proved particularly beneficial for ocular and extra-nasal symptoms, making it a valuable alternative in selected patients. Given the chronic and relapsing nature of allergic rhinitis, treatment should be tailored to the patient's symptom profile, preferences, and long-term tolerability.

Strengths and limitations

The strengths of this study include a prospective design, standardized symptom scoring, and head-to-head comparison of two widely used first-line agents. However, certain limitations must be acknowledged. The relatively short follow-up period (four weeks) may not fully capture long-term efficacy or safety. Additionally, being a single-centre study with a modest sample size, generalizability is limited. Future multicentric randomized controlled trials with longer follow-up and inclusion of quality-of-life measures are warranted.

Recommendations

Based on the findings of this study, intranasal fluticasone furoate should be considered as the preferred first-line therapy in patients with moderate to severe allergic rhinitis, particularly in those with predominant nasal obstruction and persistent symptoms. Oral fexofenadine hydrochloride remains an effective alternative, especially in individuals presenting with ocular and extra-nasal manifestations or where patient preference favors oral medication. A symptom-oriented approach is recommended to optimize therapeutic outcomes. Future multicentric studies with larger cohorts and longer follow-up are warranted to further validate these findings and to evaluate long-term safety and quality-of-life improvements associated with both treatment modalities.

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List of abbreviations

AR – Allergic Rhinitis
VAS – Visual Analogue Scale
OF – Oral Fexofenadine
NF – Nasal Fluticasone
ARIA – Allergic Rhinitis and its Impact on Asthma
IgE – Immunoglobulin E
HPA – Hypothalamo–Pituitary–Adrenal Axis
SD – Standard Deviation

Source of funding

The study had no funding.

Conflict of interest

The authors declare no conflict of interest.

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Author contributions

PKK-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript. **NCR**-Concept and design of the study, results interpretation, review of literature, preparing the first draft of the manuscript, and revision of the manuscript.**NS**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation. **MAN**-Review of literature and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.

Data availability

Data available on request

Author biography

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Original Article

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