Fluticasone Nasal Spray Versus Oral Fexofenadine in Management of Allergic Rhinitis

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Abstract

Objective: To evaluate the effectiveness of fluticasone nasal spray compared to oral fexofenadine in the treatment of allergic rhinitis.

Material and Methods: This cohort study was conducted at the Department of ENT, King Edward Medical University, Lahore from 17th April 2023 to 7th October 2023. A total of 120 patients aged 18-60 years with symptomatic allergic rhinitis were included. Patients were randomly assigned to two groups: Group X (n=60) received intranasal corticosteroid (Ticovate® nasal spray, fluticasone propionate 50mcg) one spray in both nostrils twice daily, and Group Y (n=60) received oral fexofenadine 120 mg once daily. The total nasal symptom score (TNSS) was assessed after 4 weeks of treatment during the follow-up visit. For statistical analysis, data were analyzed using SPSS version 21.0. Descriptive statistics were used to summarize demographic data. The TNSS was compared between the two groups using an independent sample t-test to assess the differences in mean scores after treatment. A p-value of less than 0.05 was considered statistically significant.

Results: Out of 120 patients, 79 (65%) were males and 41 (35%) were females, with a mean age of 37 years. The study showed a significant difference in treatment outcomes, with Group X demonstrating a greater reduction in TNSS compared to Group Y. Specifically, 90% (n=27) of patients in Group X experienced a substantial improvement, while only 16.67% (n=5) in Group Y reported similar results (p=0.000).

Conclusion: Fluticasone intranasal spray is significantly more effective than oral fexofenadine in managing allergic rhinitis, as demonstrated by a greater reduction in the mean total nasal symptom score.

Keywords: Allergic Rhinitis, Fluticasone Nasal Spray, Fexofenadine, Total Nasal Symptom Score, Intranasal Corticosteroid.

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Introduction

Allergic rhinitis (AR) is a chronic condition that affects millions of individuals worldwide, presenting significant challenges not only to the affected individuals but also to society as a whole.[1] Far more than just a seasonal nuisance, AR is a condition that can severely diminish the quality of life, manifesting in symptoms that lead to considerable functional impairment. Patients often experience difficulty concentrating, reduced productivity, and frequent absences from work or school due to the persistent nature of the symptoms[2]. These disruptions translate into a substantial economic burden, as the cumulative loss of workdays and decreased efficiency can have far-reaching effects on both the individual and societal levels. Moreover, AR often contributes to persistent fatigue,

irritability, and a general reduction in life satisfaction, adding a psychological burden to the already challenging physical symptoms.[2,3]

AR is described as nasal mucosal inflammation caused by an allergic reaction. This reaction is predominantly caused by immunoglobulin E (IgE) antibodies, that are generated following the exposure to certain allergens. Pollen, dust mites, pet hair, and molds are examples of common allergens, which are usually innocuous to a majority of people.[3] However, in persons with AR, the immune system incorrectly perceives these compounds as hazardous intruders, leading to an inflammatory reaction, resulting in the typical signs of nasal congestion, hives, sneezing, and rhinorrhea. The Allergic Rhinitis and its Impact on Asthma (ARIA) position document classifies AR into mild, moderate, or severe categories based on the duration and intensity of symptoms. This classification is crucial as it helps in tailoring treatment strategies to the severity of the condition, ensuring that patients receive the most appropriate level of care.[4]

The prevalence of AR is significant and rising globally. In Western Europe, for instance, the frequency of AR ranges from 20 to 30%, and this prevalence is increasing due to a combination of environmental factors such as pollution and climate change, as well as lifestyle changes and urbanization, which have led to higher exposure to allergens.[5] AR is a major source of morbidity and impairment worldwide, affecting individuals across all age groups and demographics. In addition to the nasal symptoms, AR is also associated with non-nasal symptoms such as eye irritation, burning, watery eyes, and itching of the palate and ears. These symptoms can be particularly bothersome and, when combined with nasal symptoms, can significantly disrupt daily activities and sleep, further compounding the impact of the disease.[6]

AR pathogenesis includes an intricate interaction of inflammatory mediators that are activated by an IgE-mediated reaction to an external antigen. This inflammation usually impacts the mucous membranes of the eyes and nose, causing the symptoms listed above. Managing AR often entails a mix of pharmacological therapies that try to reduce these symptoms and improve the patient's quality of life.[7] The most commonly used treatments include oral and intranasal antihistamines, mast cell stabilizers, leukotriene inhibitors, decongestants, intranasal anticholinergics, and intranasal corticosteroids (INS). Among these, INS are often recommended as the first line of treatment for individuals with moderate-to-severe AR symptoms. INS are effective because they target inflammation directly at the site of antigen exposure, thereby preventing the cascade of allergic responses that cause symptoms.[8]

Oral antihistamines (OA) have long been a staple in the pharmacological management of allergic responses. Histamine, a key mediator in allergic inflammation, is stored in mast cells and basophils within the nasal mucosa. When an allergen triggers an allergic response, histamine is released, leading to symptoms such as congestion and rhinorrhea by increasing vasopermeability and vasodilation.[9] Oral antihistamines work by blocking the action of histamine, thereby preventing these symptoms from occurring. While effective, oral antihistamines may not be as potent as INS in controlling all symptoms, particularly nasal congestion, which is often the most troubling symptom for patients with AR.[9]

The clinical management of AR presents ongoing challenges, particularly in tertiary care institutions where severe cases are often referred. Despite the availability of numerous pharmaceutical therapies, there remains considerable debate within the medical community regarding the most effective approach to managing AR. Two widely utilized treatment alternatives are oral antihistamines and intranasal corticosteroids. While intranasal corticosteroids are highly effective at reducing nasal symptoms and improving patients' quality of life, oral antihistamines are also commonly used due to their effectiveness in controlling histamine-mediated symptoms such as sneezing, itching, and rhinorrhea.[10] Given the differences in the modes of action and efficacy profiles of these treatments, it is crucial to conduct a comprehensive comparison of their efficacy.

Fexofenadine, a second-generation oral antihistamine, and fluticasone propionate, a potent intranasal corticosteroid, are two popular therapeutic options for the management of AR. Fexofenadine works by inhibiting the activity of histamine, thereby preventing the cascade of allergic reactions. It is known for its minimal sedative effects, making it a preferred choice for patients who need to maintain

alertness during the day. On the other hand, fluticasone acts by directly reducing inflammation at the site of allergen exposure in the nasal passages. It is highly effective in controlling a broad range of symptoms, including nasal congestion, which is less effectively managed by antihistamines alone.[9,10]

The purpose of this study is to resolve the ongoing debate within the medical community and offer evidence-based recommendations for the optimal management of AR. By directly comparing the efficacy and safety profiles of fluticasone nasal spray versus oral fexofenadine, the study seeks to determine which treatment offers better symptom control and enhances patients' quality of life. The findings will be particularly relevant for clinicians who need to make informed decisions regarding the most appropriate treatment strategies for their patients.

The significance of this study lies in its potential to optimize treatment protocols for AR, which is a condition with a chronic nature and widespread prevalence. Effective management strategies are essential not only to alleviate the symptoms and improve the quality of life for individuals with AR but also to reduce the overall burden of the disease on healthcare systems. AR is associated with significant healthcare costs, including direct costs such as medications and doctor visits, and indirect costs such as lost productivity and absenteeism from work or school. By providing clear evidence on the comparative efficacy of these two treatments, the study aims to inform clinical practice and guide healthcare professionals in making more informed decisions when treating patients with AR. The findings will be particularly valuable in settings where resources are limited, and treatment choices need to be both effective and cost-efficient.

Material and Methods

After receiving approval from the institutional ethical review committee, a prospective randomized control clinical trial was conducted at the Department of ENT King Edward Medical University, Lahore, from April 17, 2023, to October 7, 2023. After the taken Ethical approval for ethical committee Ref No.2023/ 11th/RA/0015 dated 17-04-2023. The study aimed to evaluate the efficacy of two treatments for symptomatic allergic rhinitis. The inclusion criteria for this study were carefully defined to ensure the selection of appropriate participants. Patients aged between 18 and 60 years, of either gender, diagnosed with symptomatic allergic rhinitis were eligible for inclusion. Additionally, only those willing to provide written informed consent to participate in the study were enrolled. However, several exclusion criteria were applied to maintain the focus on uncomplicated cases of allergic rhinitis and to avoid confounding factors. Patients with chronic rhinosinusitis, a history of previous nasal or septal surgery, asthma, or nasal polyposis were excluded from the study. Moreover, individuals with other significant comorbid conditions that could potentially interfere with the study outcomes or adherence to treatment were also excluded. Pregnant or lactating women were not considered for inclusion due to potential risks associated with the treatments being studied.

Sample size was calculated by Open epi website calculator as 120 subjects. These patients were randomly divided into two groups, Group X and Group Y, each consisting of 60 patients. Randomization was achieved using a software-generated random number table, ensuring that the allocation was unbiased and that each patient had an equal chance of being assigned to either treatment group. Patients in Group X received an intranasal corticosteroid, specifically Ticovate® nasal spray, which contains fluticasone propionate at a dose of 50 mcg. They were instructed to administer one spray in each nostril twice daily. On the other hand, patients in Group Y were treated with a second-generation antihistamine, oral fexofenadine at a dose of 120 mg, taken once daily. The efficacy of these treatments was measured by assessing the total nasal symptom score after four weeks of treatment during a follow-up visit.

Data collected during the study were analyzed using SPSS version 21. For quantitative variables such as age, disease duration, and total nasal symptom score at baseline and after four weeks of treatment, the mean and standard deviation were calculated. For qualitative variables like gender, frequencies and percentages were computed to provide a clear demographic breakdown of the participants. The total nasal symptom scores between the two groups after

four weeks of therapy were compared using an independent sample t-test. A P-value of less than 0.05 was considered statistically significant, indicating a meaningful difference in symptom reduction between the treatments.

Results

There were 79 (65 %) males and 41 (35 %) females among a total of 120 patients.Mean age was 37 year. 63.3% (n=38) in Group-X and 53.3% (n=32) in Group-Y were between 18-40 years of age while 36.7 % (n=22) in Group-X and 46.7 % (n=28) in group Y were between 41-60 years of age. Predominant presenting complaints of patients presenting with allergic rhinitis were excessive sneezing (50%), watery rhinorrhea (30%), bilateral nasal obstruction (15 %) and postnasal drip(5%). [Figure-1]

Table 1: *Demographic Characteristics of Patients*

Variable	Group X (Fluticasone)	Group Y (Fexofenadine)	Total
Gender			
Male	38 (63.3%)	41 (68.3%)	79 (65%)
Female	22 (36.7%)	19 (31.7%)	41 (35%)
Age Group			
18-40 years	38 (63.3%)	32 (53.3%)	70 (58.3%)
41-60 years	22 (36.7%)	28 (46.7%)	50 (41.7%)
Mean Age (years)	37	37	37

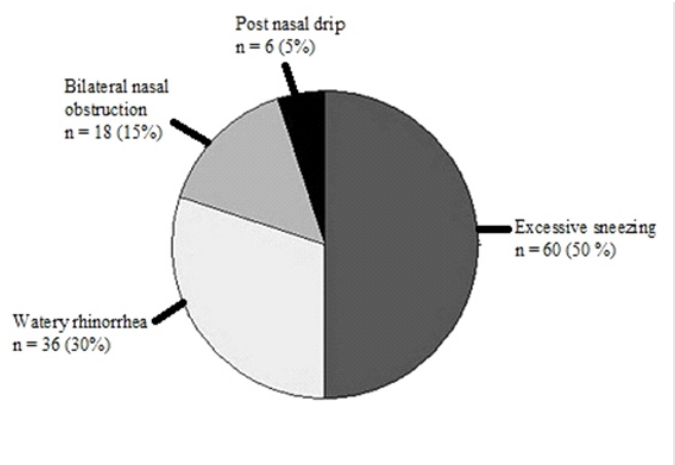

Figure 1: *Frequency of presenting complaints of patients with allergic rhinitis (n=120)*

Comparison of mean total nasal symptom score using intranasal fluticasone with oral fexofenadine in management of allergic rhinitis shows that 1.64+0.31 score in Group-X and 1.22+0.02 score in Group-Y, p value was 0.0001, showing a significant difference. (Table No-II)

Table 2: *Comparison of mean total nasal symptom score between two groups (n=120)*

Variable	Group X (Fluticasone)	Group Y (Fexofenadine)
Mean Total Nasal Symptom Score at Baseline	2.50 ± 0.50	2.45 ± 0.48
Mean Total Nasal Symptom Score After 4 Weeks	1.64 ± 0.31	1.22 ± 0.02
Mean Difference	0.86	1.23
Percentage Improvement	34.40%	50.20%
P-value	0.0001	0.0001

Discussion

Allergic rhinitis is a prevalent condition in Pakistan, presenting significant challenges in symptom management for healthcare providers. Characterized by symptoms such as nasal congestion, sneezing, itching, and rhinorrhea, allergic rhinitis can severely affect the quality of life of those who suffer from it. The first line of treatment typically involves monotherapy with either intranasal glucocorticoid sprays or oral antihistamines. These treatment options aim to alleviate symptoms and improve the overall well-being of patients. However, determining the most effective treatment remains a topic of interest for many clinicians.

Our study aimed to evaluate the efficacy of these treatments, with a specific focus on the mean total nasal symptom score at baseline and after four weeks of treatment. We compared the effects of fluticasone nasal spray, an intranasal glucocorticoid, and oral fexofenadine, a commonly used antihistamine, in managing allergic rhinitis symptoms.

In our study, the mean total nasal symptom score showed a significant difference between the two groups, with Group-X (fluticasone nasal spray) achieving a mean score of 1.64 ± 0.31 and Group-Y (oral fexofenadine) a mean score of 1.22 ± 0.02 (p=0.0001). This statistically significant difference indicates that intranasal fluticasone spray is more effective in reducing nasal symptoms compared to oral fexofenadine. This finding is critical, as it supports the preference for intranasal glucocorticoid sprays as a first-line treatment for allergic rhinitis.

Our findings are consistent with several studies that have also found intranasal glucocorticoid sprays to be more effective than oral antihistamines in treating allergic rhinitis. For instance, a study evaluated the outcomes of 697 nasal surgeries during the postoperative phase. While their study focused on surgical outcomes, it is relevant because it provides insight into patient comfort and recovery.[12] They reported no statistically significant difference in complications such as adhesions, septal hematoma, septal perforation, or epistaxis ($p > 0.05$). However, they found that patients receiving Merocel nasal packing experienced considerably more postoperative discomfort than those who underwent trans-septal suturing ($p < 0.05$).[13] This study underscores the importance of treatment choices that minimize patient discomfort, a principle that also applies to the management of allergic rhinitis.

In another study, the issue of postoperative pain was further explored. They highlighted that severe postoperative pain was present in 100% of patients with nasal packing, whereas only 3% of patients without nasal packing experienced the same level of pain, demonstrating a significant difference ($p < 0.05$).[14] This finding underscores the advantage of avoiding nasal packing to minimize patient discomfort, aligning with our emphasis on treatments that improve patient comfort and outcomes.

Similarly, a study found that 64.3% of patients in the nasal packing group experienced severe postoperative discomfort compared to 22.86% in the trans-septal suture group ($p < 0.05$). Additionally, postoperative pain occurred in 21.43% of the nasal packing group and 11.43% of the trans-septal suture group ($p < 0.05$). [15] These results further emphasize the benefits of trans-septal suturing over nasal packing in reducing postoperative pain and discomfort.

Multiple studies have consistently shown that trans-septal suturing results in less postoperative discomfort and pain after septoplasty. These findings collectively advocate for the limited use of nasal packing, reserving it only for selected cases to minimize patient discomfort and improve recovery outcomes. This approach parallels the treatment of allergic rhinitis, where the goal is to minimize symptoms and improve the patient's quality of life.[15,16]

Our study demonstrated that fluticasone nasal spray is significantly more effective in reducing nasal symptoms in allergic rhinitis patients compared to oral fexofenadine, as evidenced by the lower mean total nasal symptom score. This finding is supported by the body of literature emphasizing the importance of treatment efficacy and patient comfort.

The studies referenced in this discussion consistently show that patients undergoing trans-septal suturing experience significantly less postoperative pain and discomfort compared to those with nasal packing. This aligns with the preference for treatments that minimize patient discomfort. The significant reduction in nasal symptoms with fluticasone nasal spray highlights its potential as a preferred treatment option for allergic rhinitis, enhancing patient comfort and quality of life.

The collective findings from our study and referenced literature suggest that intranasal glucocorticoid sprays like fluticasone should be considered a first-line treatment for allergic rhinitis. Additionally, trans-septal suturing should be preferred over nasal packing in surgical interventions to minimize postoperative pain and discomfort. These approaches contribute to improved patient management and outcomes, both in the treatment of allergic rhinitis and in postoperative care related to nasal surgeries.

In conclusion, our study supports the use of fluticasone nasal spray as a more effective treatment for allergic rhinitis compared to oral fexofenadine. The significant reduction in mean total nasal symptom scores in the fluticasone group underscores its efficacy. Additionally, the referenced studies highlight the importance of minimizing postoperative pain and discomfort through appropriate surgical techniques, such as trans-septal suturing over nasal packing. These findings collectively contribute to improved patient management and outcomes in allergic rhinitis and related conditions, reinforcing the need for treatments that prioritize both efficacy and patient comfort.

Conclusion

Fluticasone intranasal spray is effective monotherapy for controlling symptoms of allergic rhinitis and its efficacy is significantly higher than oral fexofenadine in terms of lowering of mean total nasal symptom score.

Conflict of Interest: *None*

Funding Source: *None*

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Authors Contribution

MFS: Conceptualization of Project
UI: Data Collection
SK: Literature Search
MM: Statistical Analysis
FU: Drafting, Revision
SR: Writing of Manuscript