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EVALUATION OF CLINICAL OUTCOMES OF FLUTICASONE FUROATE VS FLUTICASONE PROPIONATE NASAL SPRAYS IN ALLERGIC RHINITIS – A PROSPECTIVE STUDY

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ABSTRACT

Allergic rhinitis (AR) is an atopic disease characterized by symptoms of nasal congestion, clear rhinorrhoea, sneezing, postnasal drip, and nasal pruritis. The aim and objective of the study to compare the effects of these two nasal sprays on symptom relief and quality of life for patients suffering from allergic rhinitis. Fluticasone furoate and fluticasone propionate are both commonly used corticosteroids for the management of allergic rhinitis. The study was desigined a prospective study, the population of the study are 60 cases of allergic rhinitis and patients with mild-to-severe allergic rhinitis were selected for the study. They were randomly divided into two groups; group I consists of 30 patients who received intranasal Fluticasone Furoate nasal spray, total daily dose of 27.5g (110mcg) as 2 puffs in each nostril administered once daily, whereas the group II consists of 30 patients who received Fluticasone propionate nasal spray, total daily dose of 50 mcg as 2 puffs in each nostril administered twice daily. The conclusion

of the study was Analysis on patient-based symptoms revealed that both the groups showed statistically significant reduction in symptoms.

KEYWORDS: Allergic rhinitis, Fluticasone propionate, 2 puffs and Fluticasone furoate.

INTRODUCTION

Allergic rhinitis is a global health problem that affects ~500 million people worldwide.[1] The symptoms of allergic rhinitis include nasal congestion; cough; snoring; postnasal drip; reduced sense of smell; headache; and red, itching eyes, with symptoms being evident for >4 months of the year in approximately half of the patients. These symptoms can also affect patients' quality of life by reducing sleep quality, increasing irritability and depression, and impacting social activities[2] Corticosteroid nasal sprays are the therapeutic mainstay for patients with allergic rhinitis[3,4] However, these nasal sprays have sensory attributes, such as scent and/or odor, taste, and aftertaste. Patients' perceptions of these attributes may influence their preference for, and satisfaction with, treatment.[5] Furthermore, perceptions of nasal spray attributes have been shown to influence treatment compliance[6], with unpleasant sensory attributes leading to a reduction in adherence, which, in turn, can lead to poor symptom management.[7]

Classification of Allergic Rhinitis

- IgE-Mediated (Allergic) rhinitis
- Autonomic rhinitis
- Infectious rhinitis
- Idiopathic rhinitis.[8]

Epidemiology

The epidemiology of AR, factors such as prevalence, disease classification, allergen sensitization, co-morbidities, risk factors, genetic susceptibility, and costs, etc., are widely discussed.[9] The prevalence of AR is roughly 5% in children by 3 years of age, increases with age from 8.5% of 6–7 year-olds to 14.6% of 13–14 year-olds, and reaches more than 11.8% to 46% in people aged 20–44.[10] Notably, the incidence of AR is higher in males than in females before puberty, but this trend reverses after puberty.[11]

Etiology

Pollen, dust, mould or flakes of skin from certain animals.[12]

Treatment management

Antihistamines, intranasal steroids- Intranasal corticosteroid therapy can be as monotherapy or in combination with oral antihistamines in patients in patients with mild, moderate, or severe symptoms.

First-generation antihistamines-diphenhydramine, chlorpheniramine, and hydroxyzine, whereas fexofenadine, loratadine, desloratadine, and cetirizine are examples of second-generation antihistamines. Both first- and second-generation antihistamines are effective at controlling symptoms of AR.

Leukotriene receptor antagonists (LTRAs)- Leukotriene receptor antagonists (LTRAs) such as montelukast and zafirlukast can be beneficial in patients with AR, but they are not as efficacious as intranasal corticosteroids.

Immunotherapy[13]

Diagnosis

- Vasomotor rhinitis - noninflammatory rhinitis that can be triggered by a change in temperature, odors, or humidity
- Infectious rhinitis - viral or bacterial infections, most commonly seen in the pediatric population
- Cerebrospinal fluid leak - clear rhinitis refractory to treatment
- Non-allergic rhinitis with eosinophilia syndrome (NARES) - infiltration of eosinophils in nasal tissue without allergic sensitization
- Chemical rhinitis - exposure to chemicals through occupation, household chemicals, sport/leisure exposure.[14]

Prognosis

The belief is that the prevalence of allergic rhinitis peaks in adolescence and gradually decreases with advancing age. In a longitudinal study, at the time of the 23-year follow-up, 54.9% of patients showed improvement in symptoms, with 41.6% of those being symptom-free. Patients who had an onset of symptoms at a younger age were more likely to show improvement. The severity of AR can vary over time and depends on various factors such as location and season. Approximately 50% of patients receiving grass allergy immunotherapy noted improvement in symptoms that continued 3 years after discontinuation of therapy.[15,16]

Complications

nasal inflammation with symptoms of nasal congestion or discharge, nasal polyps and chronic inflammation of the paranasal sinus mucosa etc.[17]

Common symptoms on AR

- Sneezing
- Runny nose
- Nasal congestion
- Itching and irritation in the nose, throat, and eyes
- Postnasal drip.[18]

AIM AND OBJECTIVE

The aim and objective of the study to Evaluation Of Clinical Outcomes of Fluticasone Furoate Vs Fluticasone Propionate Nasal Sprays in Allergic Rhinitis - A Prospective Study.

METHODOLOGY

The study design is a Prospective, Comparative, Observational, Single Centre Study and the study site was conducted at Department of ENT at Medicover Hospitals, Madhapur, Hyderabad. The duration of the study was conducted for a period of 6 months. This study was approved by the Institutional Ethical Committee of Medicover Hospitals, Madhapur, Hyderabad. Depends upon the criterias are inclusion Criteria Patients suffering with Allergic Rhinitis and with symptoms like rhinorrhoea and exclusion criteria Pregnancy and lactating women, Patients with CAD, CHF, GERD and Patients treated with other drugs the popultion was included in this study. The size of the population was performed with 60 patients with 30 patients in each group. group I consists of 30 patients who received intranasal Fluticasone Furoate nasal spray, total daily dose of 27.5g (110mcg) as 2 puffs in each nostril administered once daily, whereas the group II consists of 30 patients who received Fluticasone propionate nasal spray, total daily dose of 50 mcg as 2 puffs in each nostril administered twice daily. The choice between the two drugs depends on choice convenience, patient preference, or specific clinical scenarios, as both drugs are effective and tolerated. Analysis on patient-based symptoms revealed that both the groupsshowed statistically significant reduction in symptoms. It supports the use of either intranasal fluticasone furoate or fluticasone propionate for the treatment.

RESULTS

A Prospective observational study was undertaken to assess the clinical outcomes of fluticasone furoate and fluticasone propionate nasal sprays in allergic rhinitis among patients seeking care in both out-patient and in-patient settings, alongside an investigation into the prevailing treatment patterns.

Over the course of study, a total of 60 patients representing a diverse spectrum of nasal and ocular symptoms and other symptoms were observed. This evaluation phase spanned from February 2024 to July 2024. Out of 60 participants group 1 consists of 30 patients received intranasal Fluticasone furoate nasal spray and group 2 consists of 30 patients received intranasal fluticasone propionate nasal spray.

The following results were observed from this study.

Baseline characteristics of all patients are as follows (Age, Gender, Associated Nasal and Ocular Symptoms, side effects)

Table 1: Distribution of patients according to age group.

S.No.	Age (years)	No. of patients (n)	Percentage (%)
1.	12-20	4	6.66%
2.	21-29	16	26.66%
3.	30-38	20	33.33%
4.	39-47	9	15%
5.	48-56	6	10%
6.	57-65	5	8.33%
	Total	**60**	**100%**

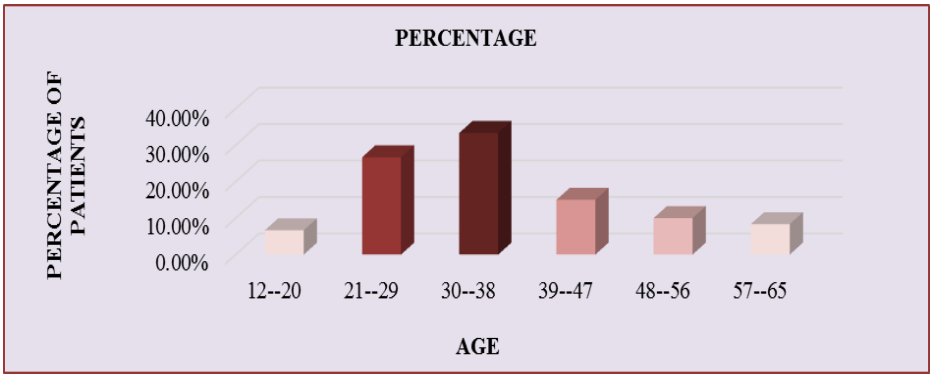

Fig 1: Distribution of patients according to age groups.

Among 60 patients observed, their ages were categorized into 6 groups. From the table and graph, the age group 30-38 exhibited the highest patient count, comprising 20 (33.33%) individuals of the total.

Table 2: Distribution of patients according to gender.

S.NO.	Gender	No. of patients (n)	Percentage (%)
1.	Female	24	40%
2.	Male	36	60%
	Total	**60**	**100%**

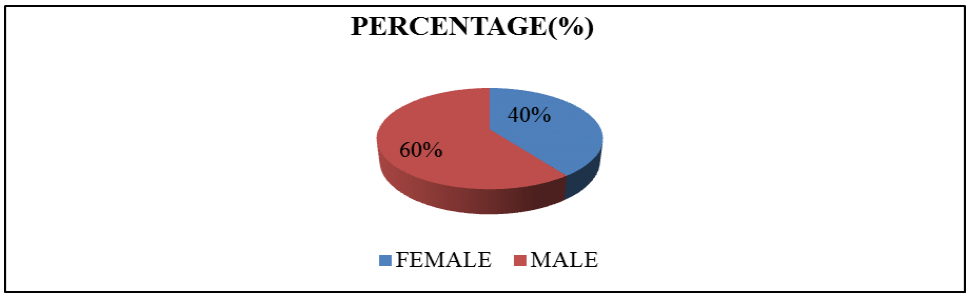

Fig 2: Distribution of patients according to gender.

The table and pie chart illustrates the patient distribution by gender.

Table 3: Distribution of patients based on blood pressure reading.

S.NO.	Blood pressure reading	No. of patients (n)	Percentage (%)
1.	Normal	19	31.66%
2.	Elevated	27	45%
3.	Dropped	14	23.33%
	Total	**60**	**100%**

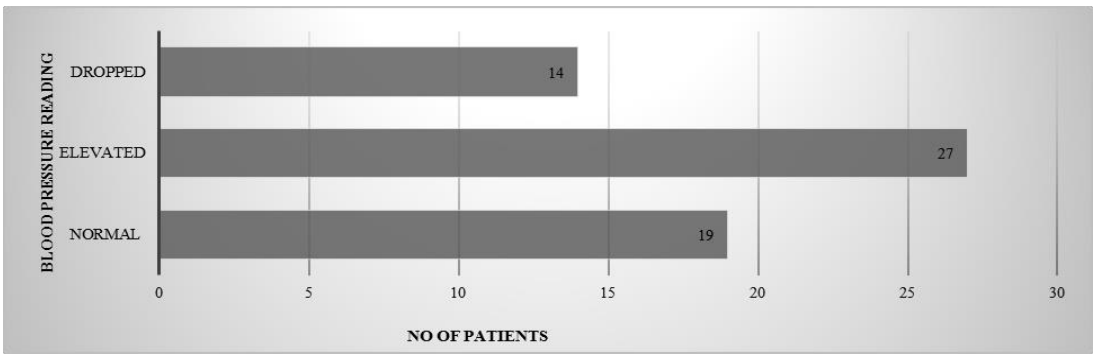

Fig 3: Distribution of patients based on blood pressure reading.

The provided table and graph illustrate the distribution of blood pressure readings within the studied population, predominantly the majority of observed patients exhibited elevated blood pressure readings consisting 45% (27 patients).

Table 4: Distribution of patients based on associated symptoms.

S.NO.	Associated symptoms	No. of patients (n)	Percentage (%)
1.	Runners	12	20%
2.	Blockers	18	30%
3.	Mixed	30	50%
	Total	**60**	**100%**

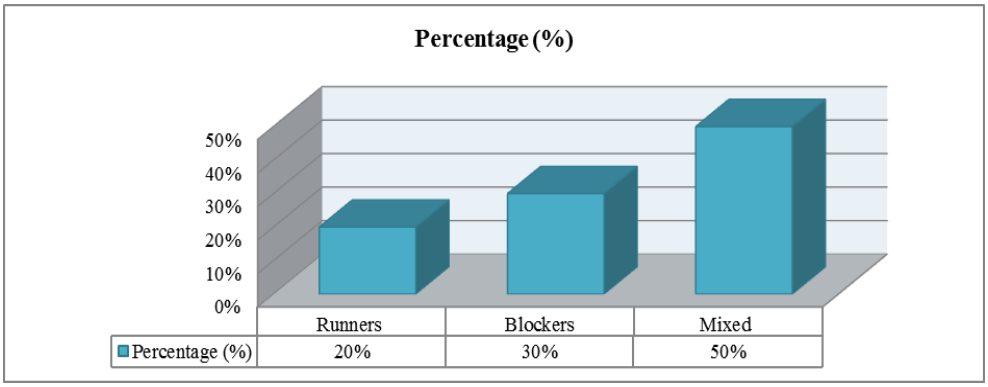

Fig 4: Distribution of patients based on associated symptoms.

The distribution of patients based on associated symptoms accompanying their chief complaints of nasal and ocular symptoms is presented in the provided table and graph.

Table 5: Distribution of patients based on diagnostic tests.

S.NO.	Diagnostic tests	No. of patients (n)
1.	Skin prick test	11
2.	Nasal endoscopy	60
P Value		<0.05

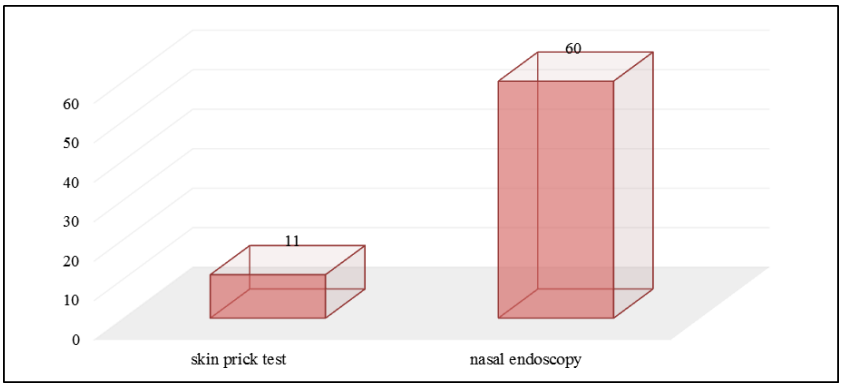

Fig 5: Distribution of patients based on diagnostic tests.

This table and graph illustrates the distribution based on Diagnostic tests. It shows that all 60 patients had Nasal Endoscopy to observe nasal polyps and nasal passages clearly.

Table 6: Distribution of patients based on treatment given.

S.NO.	Treatment	No. of patients (n)	Percentage (%)
1.	Fluticasone furoate	30	50%
2.	Fluticasone propionate	30	50%
	Total	**60**	**100%**

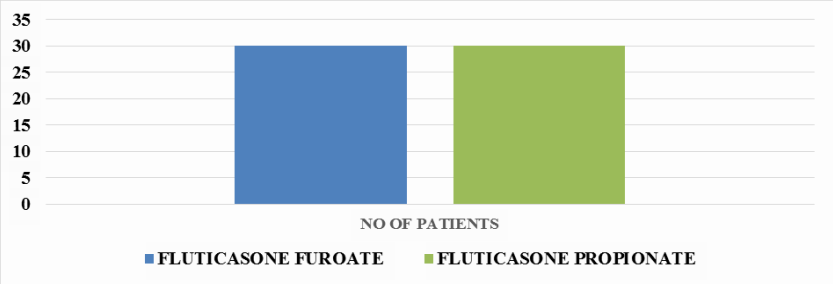

Fig 6: Distribution of patients based on treatment given.

The above table and graph depicts the distribution of patients based on the treatment given to the population.

Table 7: Distribution of patients according to fluticasone propionate side effects.

S.NO.	Associated side effects (FP)	No. of patients (n)	Percentage (%)
1.	Nasal irritation	10	33.33%
2.	Headache	5	16.66%
3.	Epistaxis	3	10%
4.	No side effects seen	12	40%
	Total	30	100%

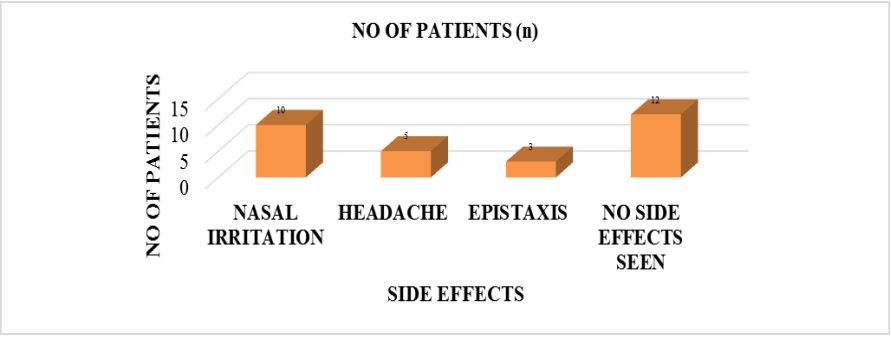

Fig 7: Distribution of patients according to fluticasone propionate side effects.

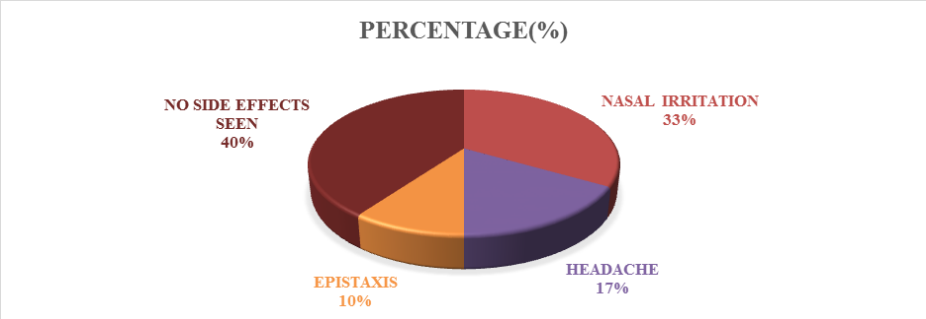

Fig 8: Distribution of patients according to fluticasone propionate side effects.

The distribution of patients based on side effects is presented in the provided table, graph and pie chart in 30 patients.

Table 8: Distribution of patients according to fluticasone furoate side effects.

S.NO.	Associated side effects of (FF)	No. of patients (n)	Percentage (%)
1.	Nasal inflammation	5	16.66%
2.	Pharyngitis	3	10%
3.	Epistaxis	3	10%
4.	SOB	1	3.33%
5.	No side effects seen	18	60%
	Total	30	100%

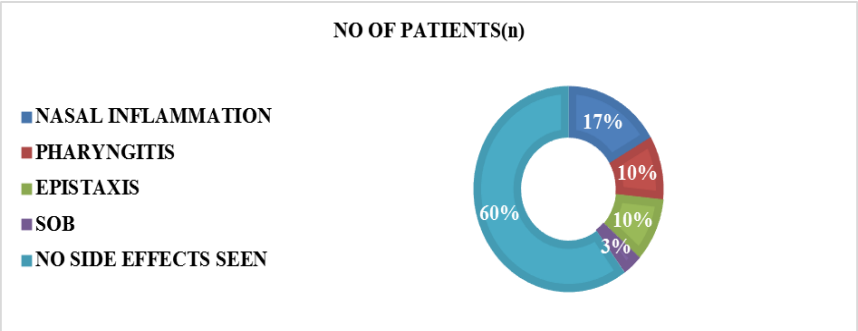

Fig 9: Distribution of patients according to fluticasone furoate side effects.

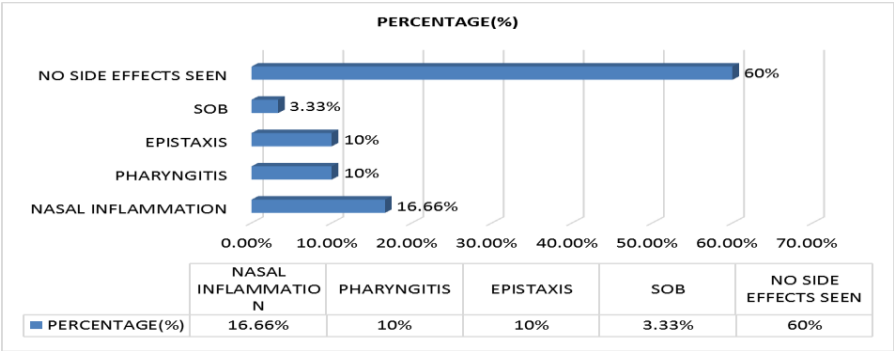

Fig 10: Distribution of patients according to fluticasone furoate side effects.

The distribution of patients based on side effects is presented in the provided table, graph and pie chart in 30 patients.

DISCUSSION

Fluticasone furoate and fluticasone propionate are both intranasal corticosteroid sprays commonly used in the treatment of allergic rhinitis, a condition characterized by inflammation of the nasal passages due to allergens such as pollen, dust mites, pet dander, and mould.

In a study involving two groups of 30 patients each, the efficacy and safety of fluticasone furoate and fluticasone propionate in alleviating symptoms of allergic rhinitis were evaluated. The results of the study highlighted some findings regarding the demographics of the patients with allergic rhinitis. Among 60 patients observed, their ages were categorized into 6 groups.

The age group 30-38 exhibited the highest patient count, comprising 20 (33.33%) individuals of the total. In contrast, the age groups 48–56, which included 6 (10%), and 57–65, which included 5 (8.33%), had the lowest overall presence of individuals. In addition, there were 16 patients (26.66%) aged 21-29 years, 9 patients (15%) aged 39-47 years, and 4 patients (6.66%) aged 12-20 years age group. It was observed that the 30-38 age groups exhibited the highest patient count affected by allergic rhinitis, indicating that this age range may be more susceptible to developing allergic reactions in the nasal passages.

Furthermore, the study also revealed a higher occurrence of allergic rhinitis among males, approximately accounting for 60% in 36 patients, compared to females who made up around 40% in 24 patients of the study population.

This gender disparity in the prevalence of allergic rhinitis is consistent with existing literature suggesting that males may be more predisposed to developing allergic conditions compared to females.

Additionally, the distribution of blood pressure readings within the studied population, predominantly the majority of observed patients exhibited elevated blood pressure readings consisting 45% (27 patients). In contrast, the smallest subset of patients displayed dropped blood pressure, accounting for 23.33% (14 patients), followed by 31.66% (19 patients) who presented with normal blood pressure. The study examined the relationship between allergic

rhinitis and blood pressure, noting that around 45% of the patients with allergic rhinitis exhibited elevated blood pressure levels.

This association between allergic rhinitis and elevated blood pressure underscores the importance of managing allergic conditions effectively to prevent potential cardiovascular complications linked to hypertension.

Moreover, patients based on associated symptoms accompanying their chief complaints of nasal and ocular symptoms. The most common symptoms were Mixed- nasal obstruction, sore throat, sinus pressure, laboured breathing, oedema, cough, fatigue and itching of palate affecting 30 patients (50%), while the least common symptoms was Runners- rhinorrhoea, headache, itchy eyes, lacrimation, Puffy or swollen eyelids, observed in 12 patients (20%).

Furthermore Blockers- facial pressure, nasal congestion shortness of breath, snoring, itchy nose and redness of eyes was the next most frequent symptoms present in 18 patients (30%). The study findings indicated that the patients with allergic rhinitis presented with a variety of mixed allergic symptoms, including sneezing, itching, nasal congestion, and runny nose and ocular symptoms which can significantly impact their daily functioning and quality of life.

To further assess the underlying causes of allergic rhinitis in the patients, diagnostic tests such as skin prick tests and nasal endoscopy were performed to identify specific allergens triggering the allergic reactions there was a significant decrease ($p<0.05$) in number of patients undergone with the skin prick test.

All 60 patients had Nasal Endoscopy to observe nasal polyps and nasal passages clearly. 11 patients underwent a skin prick test /atopy test to check for allergic reactions caused due to specific allergens. The distribution of patients based on the treatment given to the population. The first group of patients were recommended fluticasone furoate nasal spray with 30 patients (50%), total daily dose of 27.5g (110mcg) as two puffs in each nostril administered once daily. The second group of patients were recommended fluticasone propionate nasal spray with 30 patients (50%), total daily dose of 50mcg as two puffs in each nostril administered twice daily. The patient population was divided into two groups: one group received fluticasone furoate nasal spray with a once-daily dosing regimen, while the other group received fluticasone propionate nasal spray with a twice-daily dosing regimen.

Distribution of patients based on fluticasone propionate side effects in 30 patients. The most common side effect observed was nasal irritation in 10 patients (33.33%), the other side effects are headache observed in 5 patients (16.66%). while the least common side effect was epistaxis observed in 3 patients (10%). Further no side effects were observed in 12 patients (40%).

Distribution of patients based on side effects is presented in the provided table, graph and pie chart in 30 patients. The most common side effect was nasal inflammation in 5 patients (16.66%), the other side effects are pharyngitis and epistaxis in 3 patients (10%). while the least common symptom was SOB observed in 1 patient (20%). Further no side effects were observed in 18 patients (60%).

When comparing the efficacy and safety profiles of fluticasone furoate and fluticasone propionate in managing allergic rhinitis, a notable observation emerged. Patients treated with fluticasone furoate reported experiencing improved breathing patterns and minimal disruption to their daily activities and experiencing fewer adverse effects compared to fluticasone propionate suggesting a positive impact on their overall quality of life.

This suggests that fluticasone furoate may be a more well-tolerated treatment option for individuals with allergic rhinitis, potentially minimizing the occurrence of unwanted side effects commonly associated with corticosteroid therapy.

CONCLUSION

In this study, a reliable treatment for allergic rhinitis with maximum effectiveness and minimal side effects was assessed. This study compared the effectiveness of intranasal Fluticasone Furoate and Fluticasone Propionate in improving the nasal and ocular symptoms. This prospective study was conducted on 60 cases of allergic rhinitis and patients with mild-to-severe allergic rhinitis were selected for the study. They were randomly divided into two groups; group I consists of 30 patients who received intranasal Fluticasone Furoate nasal spray, total daily dose of 27.5g (110mcg) as 2 puffs in each nostril administered once daily, whereas the group II consists of 30 patients who received Fluticasone propionate nasal spray, total daily dose of 50 mcg as 2 puffs in each nostril administered twice daily. Analysis on patient-based symptoms revealed that both the groups showed statistically significant reduction in symptoms.

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CONFLICT OF INTEREST

The author were no the conflict of interest

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