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A comparative study to evaluate the effects and safety profile of intranasal corticosteroids used as treatment in rhinitis patients.

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ABSTRACT:

Background: Rhinitis, also known as coryza, is irritation and inflammation of the mucous membrane inside the nose. Allergic rhinitis is the most prevalent type of rhinitis and is usually triggered by airborne allergen such pollen and pet dander. Allergic rhinitis is an atopic disease characterized by symptoms of nasal congestion, rhinorrhea, sneezing, postnasal drip, and nasal pruritis. The allergens may also have an impact on the eyes, resulting in puffiness around the eyes and eyes that are watery, red, or itchy. It affects one in six individuals and is associated with significant morbidity, loss of productivity. Allergic rhinitis can be classified as either seasonal (intermittent) or perennial (chronic), with approximately 20% of cases being seasonal, 40% perennial, and 40% with features of both.

Aim: To evaluate Total Nasal Symptom Score (TNSS), Serum Immunoglobulin E (IgE), Serum Absolute Eosinophilic Count (AEC) in patients with rhinitis, pre and post-treatment with fluticasone furoate and mometasone furoate and to compare their safety profile

Methods: The randomized controlled study was conducted in the Department of Pharmacology and Otorhinolaryngology, at BRD Medical College, Gorakhpur over a period of 12 months. 156 patients diagnosed with rhinitis in the Department of Otorhinolaryngology of BRD Medical College were included in the study and divided into two groups of 78 patients .Each patient in the study were subjected to a detailed history and clinical examination. Subjective scoring for rhinitis symptoms, serum IgE level, and the eosinophilic count was done in all patients.

Results: 94 of the 156 patients were women.The age group 26 to 50 made up the majority (57.7%).Majority of patients (60.3%) had allergic rhinitis followed by non-allergic rhinitis (39.7%). Sneezing (97.4%) was the most common symptom among study subjects followed by rhinorrhea (69.2%), nasal congestion (57.7%), and nasal itching (49.4%). In comparison to fluticasone furoate nasal spray, mometasone nasal spray had higher mean TNSS, TOSS and TSS scores in patients with allergic and non-allergic rhinitis after treatment.

Conclusion: Fluticasone furoate was more effective and safer than Mometasone furoate

Keywords: Allergic rhinitis, Non-allergic rhinitis, Intranasal corticosteroids, total symptom score

I. INTRODUCTION

Rhinitis, also known as coryza, is irritation and inflammation of the mucous membrane inside the nose. Common symptoms are a stuffy nose, runny nose, sneezing, and post-nasal drip [1].

Allergic rhinitis is the most prevalent type of rhinitis and is usually triggered by airborne allergen such pollen and pet dander [2].Allergic rhinitis is an atopic disease characterized by symptoms of nasal congestion, rhinorrhea, sneezing, postnasal drip, and nasal pruritis. The allergens may also have an impact on the eyes, resulting in puffiness around the eyes and eyes that are watery, red, or itchy. It affects one in six individuals and is associated with significant morbidity, loss of productivity [3].

Allergic rhinitis can be classified as either seasonal (intermittent) or perennial (chronic), with approximately 20% of cases being seasonal, 40% perennial, and 40% with features of both [4].

Rhinitis is categorized into three types : (i) infectious rhinitis includes acute and chronic bacterial or viral infections

(ii) Non-allergic rhinitis- It is the term regrouping all the non-IgE mediated inflammation.

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(iii) Allergic rhinitis- It is induced after allergen exposure by an immunoglobulin E (IgE) mediated inflammation.

Rhinitis is a global health problem that causes major illness and disability worldwide. According to estimates, allergic rhinitis affects between 10-40 percent of the global population (>500 million). Reported incidence of allergic rhinitis in India also ranges between 20% and 30%. [5] Studies have revealed that during the past few years, allergic rhinitis has become increasingly prevalent in India.

Despite the large body of evidence that shows allergic rhinitis adversely impacts a patient's quality of life (including headache, fatigue, cognitive impairment, sleep disturbance and other systemic symptoms) and results in the development of comorbid conditions like acute sinusitis, otitis media, sleep apnea, respiratory infections, and an aggravation of or predisposition to asthma, if treated inadequately [6,7]. Still currently, allergic rhinitis is poorly managed and controlled [8].

The approach for treatment of AR is based on the patient's age and severity.Patients are advised to avoid known allergens and they should be educated about their condition. .For mild to moderate disease, intranasal corticosteroids should be the first line of treatment because they have been reported to be the most effective. Second-line medications, such as antihistamines, decongestants, leukotriene receptor antagonists, intranasal mast stabilisers, and other therapies including nasal irrigation, are used to treat moderate to severe disease that is not responsive to intranasal corticosteroids.Patients whose response to standard treatments is inadequate are evaluated for immunotherapy.[9]

The use of intranasal corticosteroids have been found to be highly effective in treating both allergic and non-allergic rhinitis. At least 75% of patients have their nasal symptoms under control, with comparable results for adults and children .All symptoms of allergic rhinitis, such as rhinorrhea, itching, sneezing, and obstruction, are reduced by intranasal corticosteroid treatment. In some cases, it also decreases ocular symptoms [10].

Currently available Intranasal corticosteroids (INCs) are beclomethasone dipropionate, budesonide, flunisolide and the newer INCs known as second generation intranasal steroids are triamcinolone acetonide nasal spray (NS), fluticasone propionate NS, mometasone furoate NS, and fluticasone furoate NS [11]

Although topical intransal steroids are the suggested first line of therapy for AR, however, response to different topical intranasal steroids for treatment of AR is varying [12,13,14]. The majority of commercially available topical intranasal steroids, according to systematic reviews and some clinical studies, are equally effective at treating allergic rhinitis (AR); the only factors that may influence a patient's acceptance of one over the other and encourage better adherence to therapy are differences in cost, documented safety during pregnancy, and sensory attributes [15].

Fluticasone furoate is a novel corticosteroid molecule that is distinct from mometasone furoate and fluticasone propionate. Seasonal allergic rhinitis can be effectively treated with fluticasone furoate, which offers several key benefits such as a very low systemic bioavailability (0.5%), 24-hour symptom relief with a once-daily dose, comprehensive coverage of both nasal and ocular symptoms, safety and tolerability with daily use, and availability in a novel, side-actuated delivery device that facilitates efficient and reliable medication administration.

Mometasone furoate, a synthetic glucocorticoid, is a potent and effective treatment for seasonal and perennial allergic rhinitis and nasal polyposis. Mometasone furoate does not produce side effects that are clinically significant or reach high systemic quantities. Mometasone furoate nasal spray's favorable benefit-risk ratio is supported by both its clinical efficacy and its favorable safety and tolerability profile..

The aim of this study was to compare the safety and efficacy of fluticasone furoate nasal spray and mometasone nasal spray.

Material and methods : The study was conducted in the Department of Otorhinolaryngology, at BRD Medical College. Gorakhpur over a period of 12 months starting from February 2022 after obtaining informed consent from the patients and ethical clearance from the institutional ethics committee.Clinically diagnosed subjects of rhinitis reporting to the Department of Otorhinolaryngology were recruited in the study.

Study design: Randomized controlled trial
Sample size:156 patients diagnosed with rhinitis in the Department of Otorhinolaryngology of BRD Medical College from February 2022 to 2023 were included in the study.

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Inclusion criteria:
1.All patients with symptoms and signs of allergic rhinitis and non-allergic rhinitis
2.All patients above 18 years irrespective of sex and providing consent for participation in the study.
Exclusion criteria:
1.Pregnant and lactating women
2.Paediatric allergic rhinitis
3.Systemic disease such as hypertension and diabetes mellitus.

Study protocol:

All patients with rhinitis who met the inclusion criteria and did not fall within the exclusion criteria were included in the study. Study participants were divided into two groups of 78 patients. Group 1 received Fluticasone furoate two spray actuation (27.5 micrograms per spray actuation) in each nostril once daily (total daily dose,110 micrograms) and Group 2 received Mometasone furoate two spray actuation (50 micrograms/actuation) in each nostril once daily (total dose 200 micrograms).

Each patient in the study were subjected to a detailed history and clinical examination. Subjective scoring for rhinitis symptoms, serum IgE level, and the eosinophilic count was done in all the patients.

Efficacy was assessed by mean change in total symptom score (TSS) which is the sum of total nasal symptom score (TNSS) and total ocular symptom score (TOSS) at the end of 3 months from the baseline.
History of medication taken for rhinitis was noted.

Examination :
Nasal examination usually included physical examination of external nose,
vestibule, anterior rhinoscopy, posterior rhinoscopy.

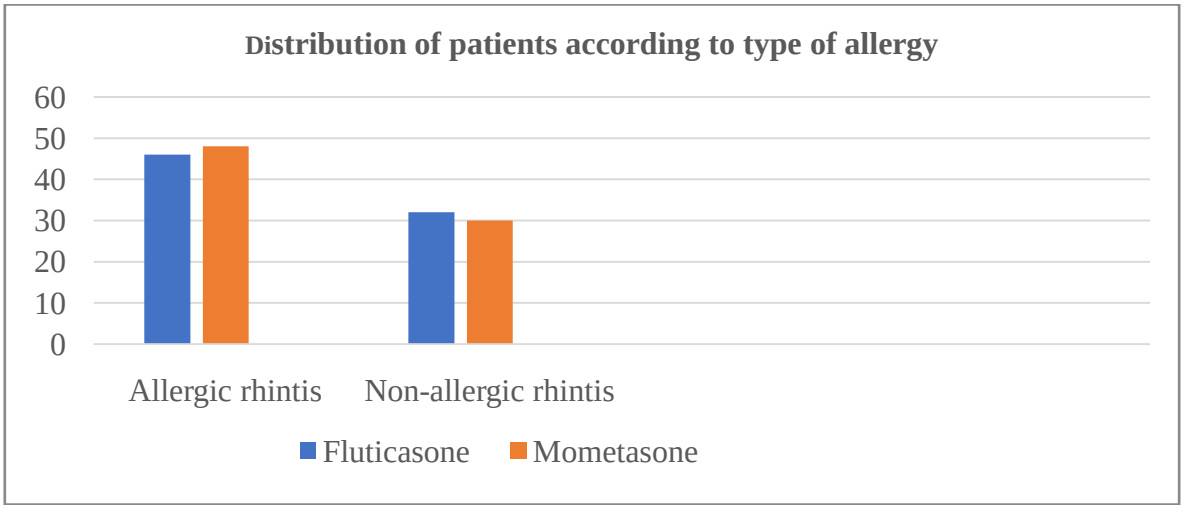
II. DATA MANAGEMENT & STATISTICAL ANALYSIS:

The data were collected and entered in MS excel 2010. Different statistical analyses were performed using SPSS software version 22. Normally distributed data were analyzed using parametric tests and non-Normally distributed data were analyzed using non-parametric tests. Descriptive statistics were calculated for quantitative categorical variables. Graphical representation of the variable has been shown to understand the results clearly and the categorical data were analyzed using the Chi-Square test.
If $p<0.05$, then the hypothesis is said to be statistically significant, and if $p>0.05$, then the hypothesis is said to be statistically insignificant.

III. RESULTS

Table 1:Distribution of patients according to type of allergy

Types of allergy	Fluticasone Group	Mometasone Group	Frequency	Percent
Allergic rhinitis	46	48	94	60.3
Non-allergic rhintis	32	30	62	39.7



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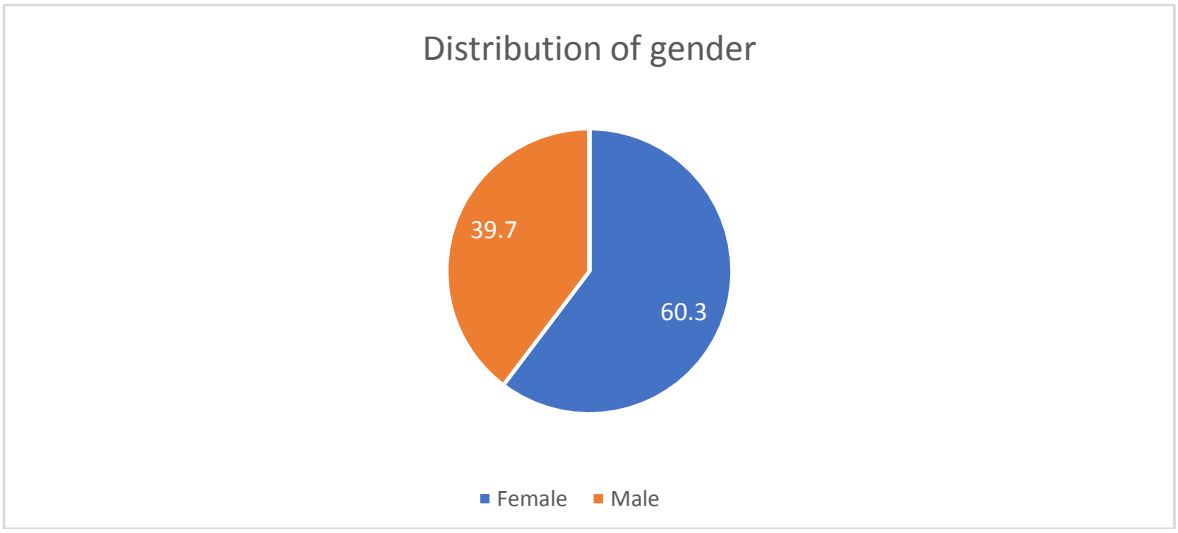

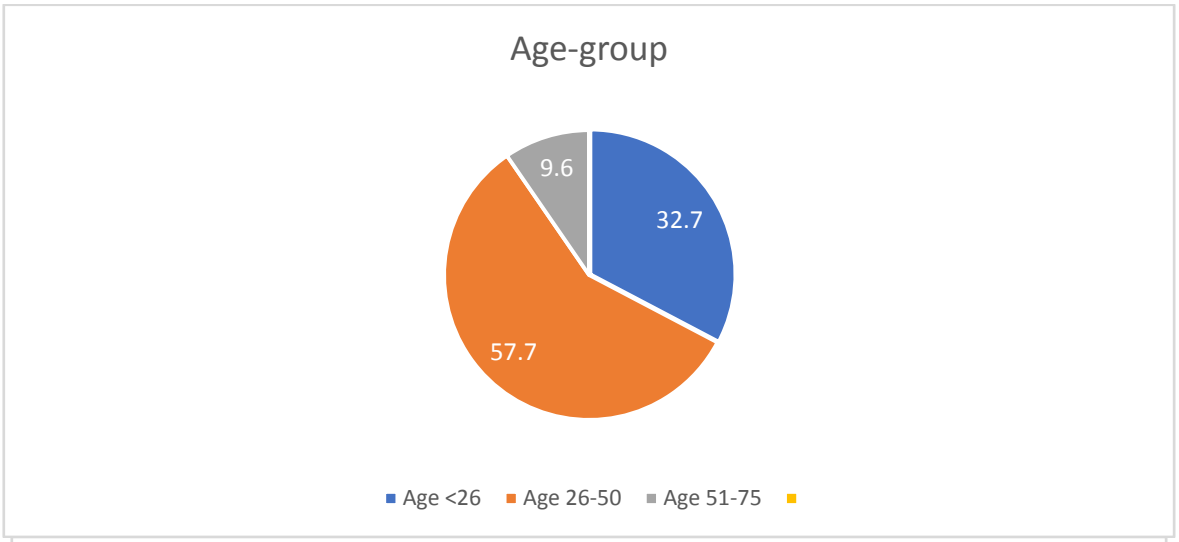

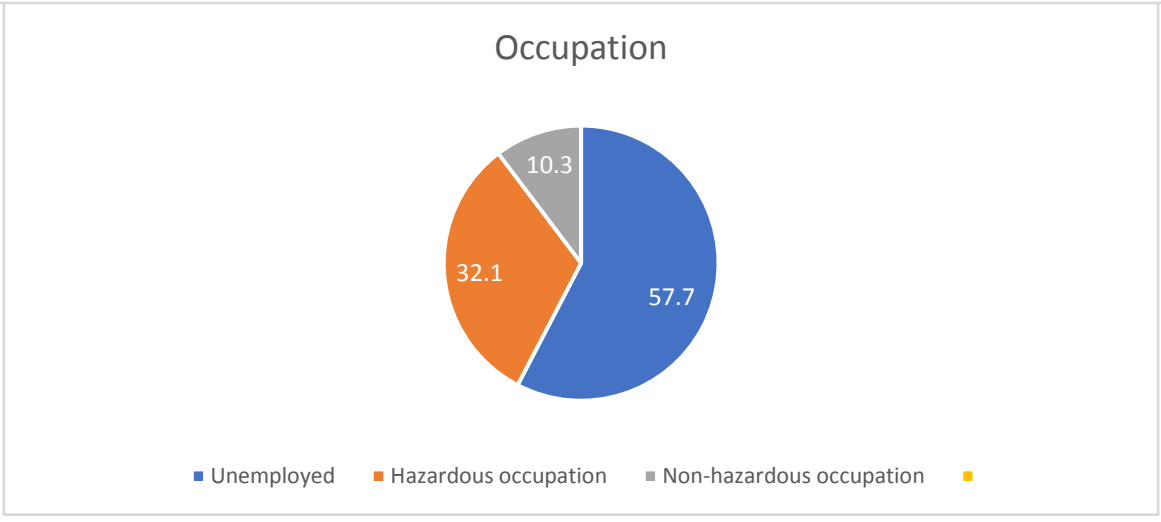

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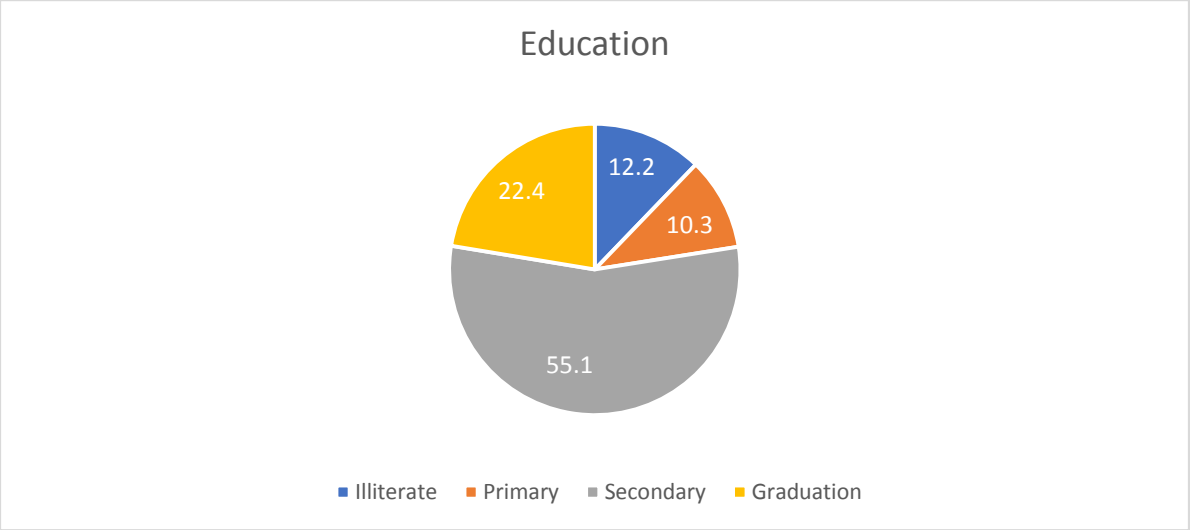

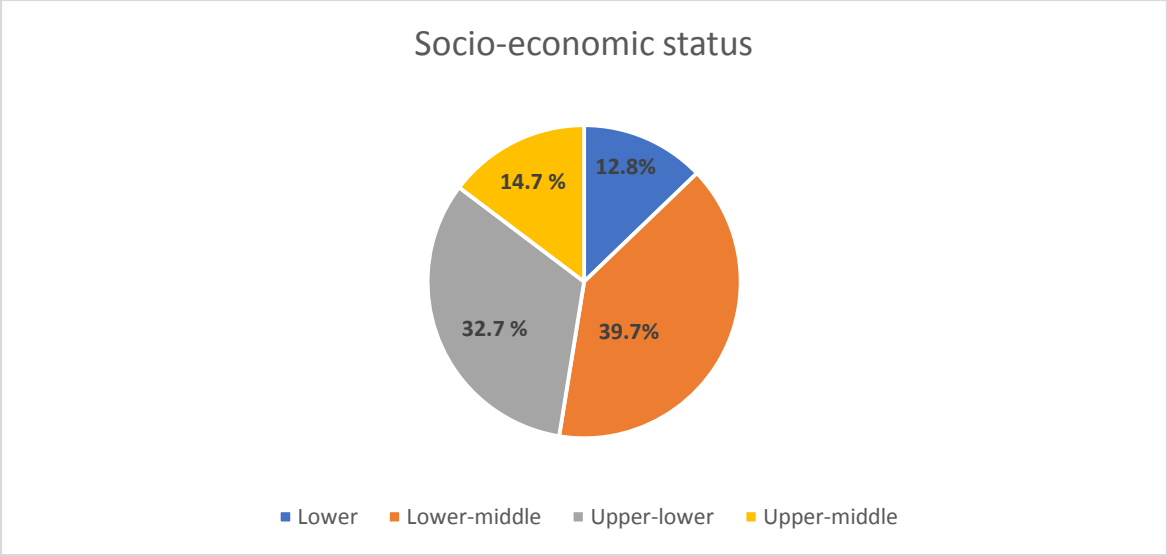

Table 2:Comparison of symptom score and clinical characteristics for treatment at baseline and after three months

Treatment		Fluticasone group	Mometasone group	p value*
TNSS	Baseline	8.22 ±2.8	8.56 ±26	<0.001
	After 3 months	2.83 ± 1.1	3.36± 0.1	<0.001
TOSS	Baseline	2.97±3.0	3.46±3.5	<0.001
	After 3 months	0.50± 0.8	1.01± 1.1	<0.001
TSS	Baseline	11.35±47.	12.12±4.9	<0.001
	After 3 months	3.33±1.7	4.37±1.6	<0.001
Absolute Eosinophilic count	Baseline	592.29±207.7	605.53±273.3	<0.001
	After 3 months	439.30± 147.3	451.52± 251.2	<0.001
IgE_level	Baseline	715.07±636.64	528.80±377.54	<0.001
	After 3 months	480.42± 298.43	425.59± 337.69	<0.001

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Paired t-test

Table 2 demonstrates significant baseline and post-treatment differences in the mean nasal symptom score, ocular symptom score, total symptom score, eosinophilic count, and IgE level between group 1and group 2. ($p<0.05$)

Table 3: Association of Adverse effects with treatment among patients with allergic rhinitis

Side Effects	Treatment	
	Fluticasone	**Mometasone**
Total	**78**	**78**
Dryness of nose	3(3.84%)	5(6.41)%
Nose Irritation	2(0.02%)	2(0.02) %
Sore throat	3(3.84%)	8(10.25%)
Headache	0	4(5.12%)
Nausea	4(5.12%)	4(5.12%)
Fatigue / tiredness	0	0
Epistaxis	0	0

Table 3 shows that mometasone-furoate had more adverse effects than fluticasone-furoate. No person shows any signs of fatigue, tiredness or bleeding nose.

IV. DISCUSSION

Two groups of 78 patients each were recruited for the current investigation, for a total of 156 study individuals. The age-wise distribution of the study participants showed that the bulk of cases were seen in the age group of 26 to 50 years, which accounted for 57.7% of all study subjects. However, the age group over 50 years old had the fewest research participants (9.6%). 60.3% of the study individuals overall were female. The majority of patients (57.7%) did not have a job, and those who did were mostly employed in hazardous jobs. The majority of the patients' families (39.7%) belonged to the lower middle class. Every research participant underwent a comprehensive clinical evaluation and history. Each patient's blood IgE level, rhinitis symptoms, and eosinophilic count were subjectively evaluated.

Sneezing (97.4%) was the most prevalent symptom among study participants, followed by rhinorrhea (69.2%), nasal congestion (57.7%), nasal itching (49.4%), headache/heaviness in the head (41.7%), recurrent cold (35.3%), smelling disorder (20.5%), post-nasal drip (17.9%), epistaxis (15.4%), nasal discharge and cough (12.8 %).

After three months, there was statistically significant difference in the nasal symptom score and the ocular symptom score between treatment group 1 (Fluticasone) and 2 (Mometasone). ($p=0.001,0.002$).Therefore, Fluticasone furoate was more effective in reducing the nasal and ocular symptoms of rhinitis as compared to Mometasone . After three months, the differences in Eosinophilic count and IgE level between treatment groups 1 (Fluticasone) and 2 (Mometasone) were found to be statistically insignificant.

As found in the current study, the most common adverse events were sore throat, dryness of nose, headache and nausea. Although the adverse effects were insignificantly associated with treatment received by both groups, fluticasone furoate appears to be safer than mometasone furoate .

V. CONCLUSION:

For this randomised controlled experiment, 156 research subjects were recruited, of which 62 were males and 94 were females. 78 of the 156 trial participants were assigned to Group 1(Fluticasone) and 78 to Group 2 (Mometasone). Follow up was done after three months.

The majority (61.5%) did not have a history of allergies in their families. About 60.3% had allergic rhinitis while the rest had non-allergic rhinitis. Smoke and fumes, wood dust, pollen dust, dusty winds, and house dust were the main causes of rhinitis in the majority of patients (43.6%). It is evident from the results of my current investigation that the Fluticasone is more effective than Mometasone. Additionally, compared to Mometasone , Fluticasone furoate was more safe.

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