

ORIGINAL ARTICLE

Comparison of Effects Beclomethasone Dipropionate with Flunisolide in Patients with Allergic RhinitisMaryyam Asghar^{1*}, Muhammad Tayyab Rasheed², Amir Akbar¹, Farhat Jabeen Malik³, Deepak Rai⁴, Liaquat Ali⁵**ABSTRACT**

Objective: To compare the effectiveness of beclomethasone dipropionate with flunisolide given twice daily in terms of improvement in symptom score after 14 days of treatment in allergic rhinitis patients.

Study Design: Quasi-Experimental Study.

Place and Duration of Study: The study was carried out at the Department of ENT, PAF Hospital E-9 Islamabad, Pakistan, from January 2021 to July 2021.

Materials and Methods: All patients of age 20-60 years of either gender having allergic rhinitis were included in the study. Allergic rhinitis was defined as any patient with a history of running nose with seasonal changes or exposure to allergens diagnosed by a consultant ENT surgeon. Patients with a history of smoking, asthma, having deviated nasal septum and inferior turbinate hypertrophy, patients already treated with Beclomethasone dipropionate or flunisolide, patients having an acute upper respiratory infection, and pregnant females were excluded from the study. A consecutive sampling technique was applied for the selection of participants. Patients were randomly divided into two groups: Group-A was given beclomethasone dipropionate, and Group-B Group-B was given flunisolide. The daily dose during treatment was 0.1 mg of beclomethasone dipropionate (50 ugs per puff) two-time each medicine daily. And dose of flunisolide nasal solution (flunisolide nasal spray 0.025%) flunisolide 50 micrograms in each nostril twice daily were 2 sprays (50 ugs) in each nostril 2 times a day: Treatment was continued for two weeks in each group. The symptoms score was estimated at baseline and after two weeks of intervention. Data were analyzed with the help of SPSS version 20.

Results: The mean age of the study participants was 41.17±8.58 years in beclomethasone dipropionate and 41.85±8.52 years in flunisolide. Efficacy of flunisolide was significantly higher in terms of improvement in symptom score after 14 days of treatment in patients of allergic rhinitis compared to beclomethasone dipropionate (85% vs 79.58, $p=0.035$).

Conclusion: Flunisolide inhaler is more effective when compared with beclomethasone dipropionate for treating allergic rhinitis.

Keywords: Allergic Rhinitis, Beclomethasone Dipropionate, Symptom Score.

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Introduction

Allergic rhinitis (AR) significantly correlates with asthmatic complications in patients with upper respiratory disorders.¹ Its prevalence varied greatly among locations, ranging from 4.5% to 80.3%.² Its rate is 21% among adults in Europe, 27% in South Korea, 25% in Canada, 32% in UAE, 75.5% in Saudi Arabia, and Pakistan has 24.62%.^{1,3,4} Rhinorrhea, sneezing, pruritus of the eyes and nose,

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and nasal congestion are the most common symptoms of AR. While less frequent symptoms are coughing, popping of ears, and throat clearing.⁵ It can stimulate recurrent or chronic nasal conditions, and if left undertreated or untreated, it can result in recurrent otitis media, recurrent sinusitis, dental malocclusions, and nasal polyps.^{6,7}

Systemic corticosteroids like Beclomethasone dipropionate, Flunisolide, and Dexamethasone are effective and first-line treatments for the treatment of AR.⁸ Nasal application of these corticosteroids has many benefits on the lungs as compared to other routes of administration.⁹ As the drug is given directly to the site of action, a less amount is needed for an appropriate therapeutic response.^{8,9} In one of the studies by Sipila et al. similar improvement in symptoms of AR was achieved in the flunisolide group (90%) and the beclomethasone dipropionate group (90.9%). They further revealed that there was no side effect in both groups.¹⁰

The rationale of this study was that AR has become a very common presentation in ENT OPDs in our local hospitals. Rhinorrhea disturbs the daily routine of life, and with the use of nasal steroids, it can be controlled. As limited local data is available regarding the effectiveness of beclomethasone versus flunisolide, we have designed this study to compare the effectiveness of beclomethasone dipropionate with flunisolide given twice daily in terms of improvement in symptom-score after 14 days of treatment in patients of AR in ENT OPD of our tertiary care hospital Islamabad. With the use of a nasal steroid spray having significant reduction in nasal mucous flow rate, symptoms including sneezing, nasal stuffiness, runny nose in allergic rhinitis patients can be controlled.

Materials and Methods

This was Quasi Experimental study was conducted at the department of ENT, PAF hospital E-9 Islamabad, Pakistan from January 2021 to July 2021. Sample size

was calculated using WHO sample size calculator, keeping 5% level of significance and 80% power of study and expected percentage as 85.7% patients on flunisolide and in 90.9% on beclomethasone dipropionate, the sample size was 480 patients in each group.^{8,9} All patients of age 20-60 years of either gender having allergic rhinitis were included in the study. Allergic rhinitis was defined as any patient with a history of running nose with seasonal changes or exposure to allergens diagnosed by a consultant ENT surgeon. Patients with history of smoking, asthma, having deviated nasal septum and inferior turbinate hypertrophy, patients already treated with Beclomethasone dipropionate or flunisolide, patients having acute upper respiratory infection and pregnant females were excluded from the study. Consecutive sampling technique was applied for selection of participants.

After the approval from the institutional Ethical Review Committee vide letter no ERC/28/8(20). Informed consent was obtained from all the eligible participants. The design of the study was single-blind, and patients were randomly allocated to one of the two treatment groups using lottery method. In Group-A; beclomethasone dipropionate and in Group-B; flunisolide were administered. The daily dose during treatment was 0.1 mg Beclomethasone dipropionate (50 ug per puff) two-time daily and dose of flunisolide nasal solution (flunisolide nasal spray 0.025%) in each nostril twice daily. Each group was kept on treatment for two weeks. During the trial period, patients were recorded nasal symptoms (stuffiness, stuffiness, and sneezing) with the use of symptoms scores as given in Table 1 on daily diary cards. A nasal speculum was used to examine the nose with the headlight, and postnasal drip was seen with the help of a tongue depressor. The same procedure was repeated on the same nostrils after two weeks of treatment in both medicine groups. The 50% reduction in the symptom score was considered as an improvement. (Table 1). The data were analyzed using SPSS version 20. Qualitative data like gender, symptoms, and improvements were analyzed in percentage and frequency. Quantitative variables like duration of rhinitis, age, symptom score, total score, and change in total score after 14 days were presented as mean

Table 1: Symptoms score

Symptoms	Presentation	Score
Sneezing	None	0
	1-5 times/day	1
	6-10 times/day	2
	>10 times/day	3
Runny nose	None	0
	1-5 times/day	1
	6-10 times/day	2
	>10 times/day	3
Stuffiness	None	0
	Mild, without mouth-breathing	1
	Moderate, with occasional mouth-breathing	2
	Severe, with frequent mouth-breathing	3

and standard deviation. For comparison of improvement between the two groups, the a chi-square test was applied. A p -value ≤ 0.05 was taken as statistically significant.

Results

The mean age of the study participants was 41.17 ± 8.58 years in beclomethasone dipropionate

and 41.85 ± 8.52 years in flunisolide. Gender distribution shows that 60.63% of beclomethasone dipropionate and 62.08% offlunisolide were males. The mean duration of rhinitis was 1.42 ± 0.58 months in beclomethasone dipropionate and 1.37 ± 0.43 months in flunisolide. (Table 2).

Table 2: Baseline information of study participants in both groups (n=960)

Heading	Group A (n=480)	Group B (n=480)
Age (years)		
20 to 40	237 (49.38)	223 (46.46)
41 to 60	243 (50.62)	257 (53.54)
Mean+SD	41.17 ± 8.58	41.85 ± 8.52
Gender		
Male	291 (60.63)	298 (62.08)
Female	189 (39.37)	182 (37.92)
Duration of disease (months)	1.42 ± 0.58	1.37 ± 0.43

Efficacy of flunisolide was significantly higher in terms of improvement in symptom score after 14 days of treatment in patients of allergic rhinitis as compared to beclomethasone dipropionate (85% vs. 79.58, $p=0.035$). (Figure 1).

Discussion

AR is characterized by rhinorrhea, sneezing, nasal and palate pruritus, and nasal obstruction.⁶ Other common symptoms are postnasal drip, irritability, cough, and tiredness. Some people suffer from allergic conjunctivitis and asthma.¹¹ When exposed

to certain allergens, symptoms might appear all year, seasonally, or episodically.^{6,11,12,13} Nasal application of corticosteroids regularly has a significant effect on the improvement of AR symptoms.^{9,14,15} In this study, we aimed to evaluate the difference in efficacy of flunisolide and beclomethasone dipropionate in AR. We found flunisolide more efficacious than beclomethasone dipropionate in terms of improvement in symptom score after 14 days of treatment in patients of AR. While in a previous study by Sipila et al., a similar improvement in symptoms of

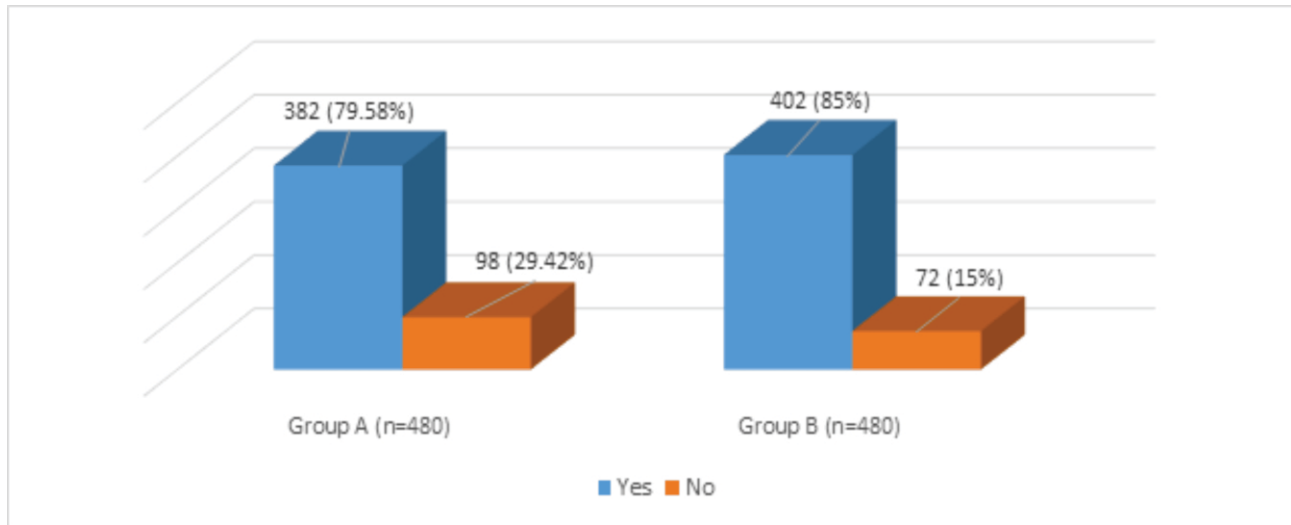


Fig 1: Comparison of efficacy between Group-A and B (n=960)

AR was achieved in the flunisolide group (90%) and beclomethasone dipropionate group (90.9%). They further revealed that there was no side effect in both groups.¹⁰ Ratner et al. found that fluticasone is safe and effective as beclomethasone dipropionate for seasonal AR.¹⁶ Fokkens et al. reported that patients who received fluticasone had significantly better outcomes than placebo.¹⁷ Jacobs et al. also revealed that fluticasone administered once daily had improved ocular and nasal symptoms compared to placebo in adult and adolescent patients with AR.¹⁸ Similarly, Bakshi et al. in their research found fluticasone more efficacious than mometasone furoate in the treatment of AR.¹⁹ Ramzan et al. conducted a study in Pakistan and found beclomethasone dipropionate treatment and mast cell stabilizer had a similar effect in patients with AR.²⁰ In another study by Corren et al. bronchial responsiveness was compared between nasal beclomethasone dipropionate and placebo in patients with asthma and AR. They concluded that patients treated with beclomethasone dipropionate had better response than placebo with $p=0.02$.²¹ Thus, evidence showed that daily use of these medications might benefit patients with AR.

The data of our study justify the hypothesis that “there is a difference in the effectiveness of beclomethasone dipropionate with flunisolide given twice daily in terms of improvement in symptom-score after 14 days of treatment in patients of AR minimal recent data is available comparing these

two modalities. Hence, more trials that are multicenter are required to validate our results.

Conclusion

We concluded that beclomethasone dipropionate is more effective when compared with flunisolide given twice daily in terms of improvement in symptom score after 14 days of treatment in patients of AR.

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