



"FLUTICASONE FUROATE VERSES FLUTICASONE FUROATE WITH AZELASTINE: A COMPARATIVE STUDY BY ASSESSMENT OF NASAL MUCOCILIARY CLEARANCE TIME ON PATIENTS WITH ALLERGIC RHINITIS"

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ABSTRACT

Background: Allergic Rhinitis is an inflammatory condition that has been on rise in recent years in India. This study compares efficacy of nasal spray Fluticasone furoate (FF) alone with combination of fluticasone furoate and azelastine using the nasal mucociliary clearance time (NMCT). **Methods:** This prospective study was conducted for 3 months on 80 patients, 40 patients each on FF and combination of FF and azelastine. Treatment was given for 2 months. Pretreatment and Post treatment NMCT was assessed by Saccharin Test. **Results:** There is no statistically significant change in NMCT between two groups before and after treatment. Average improvement of NMCT post treatment with both sprays is 2-3 minutes. **Conclusion:** Both drugs are equally efficacious in improving mucociliary clearance.

KEYWORDS : Allergic Rhinitis, Nasal Mucociliary Clearance Time, Fluticasone Furoate, Azelastine

INTRODUCTION

Allergic Rhinitis (AR) is a type of inflammatory response of the nasal mucosa that occurs when the immune system overreacts to allergens in the environment.[1] It is an IgE-mediated type I hypersensitivity reaction to exogenous substances like plant or animal allergens.[2]

Allergic rhinitis is one of the most common manifestations of allergic disorders affecting between 10%-25% of the population.[3] While it is difficult to explain this surge with conviction, a few of the probable contributing factors include higher levels of airborne pollution, growing dust mite populations, poor ventilation at homes and workplaces, dietary variables and a trend toward more sedentary lifestyles.[4] It is associated with a number of coexisting disorders including asthma, sinusitis, otitis media, atopic dermatitis, and nasal polyp. [5] It is a very morbid disease that imposes a significant social and economic burden due to indirect and direct costs associated with it.[6] Allergic rhinitis can be classified as seasonal or perennial.[7] Patients who suffer from intermittent or seasonal allergic rhinitis commonly experience symptoms such as rhinorrhea, sneezing and watery eyes, while the patients having perennial or chronic allergic rhinitis, often complain of chronic nasal congestion/blockage, postnasal drip and smell disorder.[8] During the physical examination, the doctors may see mouth breathing, recurrent sniffing and/or throat clearing, a transverse supra-tip nasal crease and black lines under the eyes (Allergic shiners). During an anterior rhinoscopy, it is common to see congestion of the nasal mucosa as well as clear, watery discharge. Cobble-stoning of the nasal mucosa and a bluish hue on the inferior turbinates are also possible symptoms of chronic allergic rhinitis.[9] The percutaneous skin test and IgE antibody test are the two most important diagnostic procedures for allergic rhinitis.[10] Oral or topical antihistamines and topical nasal steroids are the most efficient treatment modalities for allergic rhinitis.[11]

Fluticasone furoate (FF) is a synthetic trifluorinated glucocorticoid receptor agonist with high potency that has anti-inflammatory and vasoconstrictive actions via acting as a highly selective agonist at the glucocorticoid receptor.[12] The medication is available as a nasal spray in the metered atomizing spray pump.[13] The second-generation antihistamine azelastine hydrochloride has features of a mast cell stabiliser and inhibits the action of histamine at H₁-receptors.[12] It is a nasal spray that has one of the quickest (15 min) onset of action.[14] Azelastine effects continue for at least 12 hours, allowing for a once- or twice-daily dosing schedule.[15] The antihistamine property of azelastine

hydrochloride can be augmented by anti-inflammatory property of the intranasal steroid to attain better symptom control in moderate to severe cases of AR.[14]

This study aims to study the efficacy of intranasal steroids on nasal mucociliary clearance in patients with allergic rhinitis and also to compare the effectiveness of two commonly used intranasal steroids- Fluticasone furoate alone and combination of Fluticasone furoate with azelastine using the nasal mucociliary clearance time.

MATERIAL AND METHODS

This study took place at tertiary care hospital after getting approval of Ethical committee. Detailed history was taken along with clinical examination and relevant investigations. Patients aged between 12-50 years who were clinically diagnosed with allergic rhinitis were included in the study. Patients with deviated nasal septum (DNS), benign or malignant nasal polyp or mass, any form of sinusitis, adenoids and any previous history of nasal surgery were excluded from the study. Nasal Mucociliary Clearance test was carried out pre and post treatment at 3 months using Saccharine particles as described by Anderson et al in 1974.[16] 80 patients were grouped randomly into two groups (40 patients each).

Group I

1. In patients with allergic rhinitis, fluticasone furoate nasal spray was administered intranasally once daily.
2. Patients were given 2 puffs in each nostril for adults and for children > 12 years of age (each actuation delivered 27.5 g of FF in a volume of 50 L and recommended total dose for adults and for children > 12 years of age is 110 g/day).

Group II

1. In patients with allergic rhinitis, combination of Fluticasone furoate and Azelastine was administered intranasally twice daily.
2. Patients were given 1 puff in each nostril. 1 puff delivered Fluticasone furoate- 27.5 mcg and Azelastine Hydrochloride I.P. - 140 mcg. It was considered generally safer for children above 12 years of age.

In both groups, treatment was continued for at least 2 months. Patients' response to treatment was assessed on follow up.

RESULT

The nasal mucociliary clearance time was assessed before treatment and at 3 months with saccharin test. There was no statistically significant change in Nasal Mucociliary

Clearance Timing between Group I: Fluticasone Furoate and Group II: Fluticasone Furoate + Azelastine before and after treatment.(Figure-1)

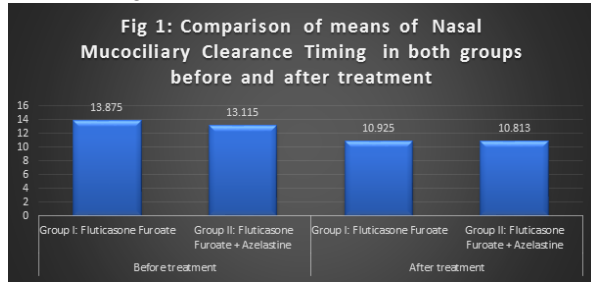


Table 1: Comparison Of Means Of Before And After Treatment Nasal Mucociliary Clearance Timing In Group I And Group II

Group I: Fluticasone Furoate

Nasal Mucociliary Clearance Timing (Min.)	N	Mean	Std. Deviation	t	p Value
Before treatment	40	13.875	2.70	15.39	<0.001
After treatment	40	10.925	2.12		

Group II: Fluticasone Furoate + Azelastine

Nasal Mucociliary Clearance Timing (Min.)	N	Mean	Std. Deviation	t	p Value
Before treatment	40	13.115	3.35	6.26	<0.001
After treatment	40	10.813	1.88		

Mean of Nasal Mucociliary Clearance Timing (Min.) was determined to be 13.875 min before treatment and 10.925 min after treatment in Group I: Fluticasone Furoate. In Group II: Fluticasone Furoate + Azelastine patients, mean of Nasal Mucociliary Clearance Timing (Min.) was 13.115 before treatment and 10.813 min after treatment. Nasal Mucociliary Clearance Timing decreased following treatment in both groups and the changes were statistically significant.(Table-1)

DISCUSSION

Allergic Rhinitis is a common immunological disease that affects all the age groups. It is a global health issue that has an influence on people's quality of life. Despite advancements in knowledge of the various chemical mediators of allergies, only two major groups of medicines are commonly used for therapy, notably antihistamines and corticosteroids.

A total of 80 allergic rhinitis diagnosed patients were enrolled in our study and were treated with topical therapy using fluticasone furoate alone or fluticasone furoate with azelastine, an antihistaminic pharmaceutical agent. We observed that mucociliary clearance(MCC) improved with intranasal fluticasone furoate and was found to be statistically significant at 3months. Improvement in mucociliary clearance can be attributed to anti-inflammatory action of steroids, as in allergic rhinitis ciliary structures are deteriorated due to chronic inflammation or mechanical obstruction due to nasal obstruction. Similarly Nambiar V[17] et al in their study found that mucociliary clearance improved from 17.92 minutes to 15.55 minutes. Also a study conducted by Ayubi et al[18] observed that MCC improved with steroid spray from 13.40 to 9.0 min (p-<0.05) after two months. Likewise Lee et al[19] in their study observed that mcc improved from 688 seconds pre-treatment to 579 sec post treatment though the results were insignificant. In present study mucociliary clearance improved with intranasal combination of fluticasone-azelastine and was found to be statistically significant at 3months. This is due to synergistic and complimentary anti-inflammatory action of combination of steroid fluticasone furoate and anti-histamine azelastine

on IgE mediated inflammation caused by allergic rhinitis. Ayubi et al[18] found that combination of steroid spray and oral antihistamine showed decreased mcc from 13.90 to 9.03 min after 2 months of study duration(p - < 0.05). However, In a similar study Lee et al[19] found that combination of oral antihistamine and steroid showed no improvement in mcc (pre-treatment vs post-treatment - 603 vs 617 sec). Our study showed statistical same results with intranasal combination of fluticasone-azelastine and intranasal fluticasone furoate. Similarly, Ayubi et al[18] found no significant difference in MCC in those using combination of oral antihistamine and steroid spray over steroid spray alone. In contrast Lee et al[19] in his study showed better improvement with steroid alone than combination of oral steroid and antihistamine though the results were statistically insignificant.

CONCLUSION

Our study was primarily aimed at comparing treatment of allergic rhinitis with fluticasone furoate nasal spray alone with an intranasal administration of combination of fluticasone furoate with azelastine. We safely conclude that fluticasone furoate nasal spray is as effective as combination of fluticasone-azelastine nasal spray therapy in improving mucociliary clearance.

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