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Assessing Subjective and Clinical Response to Flunisolide and Saline Nasal Irrigation In Patients With Allergic Rhinitis

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ABSTRACT

Objective: To assess subjective and clinical response to flunisolide and saline irrigation in patients with allergic rhinitis.
Study Design: Quasi-experimental study.
Place and Duration of Study: Combined Military Hospital (CMH), Rawalpindi, Pakistan, from Feb 2023 to Jan 2024.
Methodology: With consecutive sampling technique, 116 participants were included in the study. Those patients who were prescribed flunisolide nasal spray were labeled as the "exposed group" whereas patients receiving normal saline irrigation constituted the "unexposed/ control group". After 3 months, every patient had a thorough evaluation which included an endoscopic nasal examination, and a review of Sinonasal Outcome Test-22 (SNOT-22) questionnaire.
Results: Study included 81(69.80%) males and 35(30.20%) females. Mean age of the participants was 33.18±7.96 years. The change in median SNOT score after treatment was 37 in exposed group as compared to 14 in unexposed group which was statistically significant ($p < 0.001$). Individually, 16 out of 22 symptoms checked by SNOT questionnaire (all except dizziness, ear pain, facial pain, difficulty falling asleep, lack of good night sleep and fatigue) showed statistically significant improvement ($p < 0.001$) when flunisolide nasal spray was used instead of saline nasal irrigation.
Conclusion: Flunisolide is more effective in controlling symptoms of allergic rhinitis (AR) as compared to normal saline after a period of 3 months. These findings allow the therapy of allergic rhinitis to be tailored depending upon the specific symptoms of each patient.

Keywords: Allergic rhinitis, Flunisolide nasal spray, Saline nasal irrigation.

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INTRODUCTION

Allergic rhinitis is a commonly encountered disease in otorhinolaryngology that impacts a large percentage of world's population.[1] It is characterized by itching, rhinorrhea, sneezing, nasal obstruction and nasal congestion.[2] Allergic rhinitis severely lowers the quality of life and subjective well-being of affected people.[3] An extensive assessment requires medical history, anterior rhinoscopy and nasal endoscopy to diagnose allergic rhinitis (AR) while testing for allergen-specific IgE, such as serum-specific IgE testing or skin prick tests, may be performed under particular circumstances. Options for treatment include avoiding allergens, using medications such as intranasal corticosteroids (INCS) or H1-antihistamines, and allergen-specific immunotherapy (AIT).[4] Corticosteroid nasal spray flunisolide, known for its anti-inflammatory qualities, has been shown in several trials to be beneficial in mitigating the symptoms of AR.[5,6] On the other hand, saline nasal irrigation, an apparently harmless but increasingly popular treatment, is often used due to its ability to clear nasal passages and provide comfort.[7] At present, both flunisolide and saline nasal irrigation are prescribed by otolaryngologists in our setting. However, there is a paucity of data on which treatment offers more promise and for which symptoms. We sought to compare the effectiveness of both these therapies for allergic rhinitis and also provide insight into patient-reported outcomes and their response to each therapy. This will aid in broadening the range of treatments available for allergic rhinitis and offer the possibility of personalizing interventions depending on patient responses. Our research aims to help in creating personalized treatment strategies and improve AR management. Our study aims to analyse and estimate the efficacy of these two interventions, flunisolide nasal spray and saline nasal irrigation, in the management of AR, both in terms of subjective and clinical responses.

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METHODOLOGY

This Quasi-experimental study was conducted over the course of a year at Department of Ear, Nose and Throat (ENT), Combined Military Hospital, Rawalpindi, from February 2023 to January 2024, after the authorization of the hospital's ethics research committees (ERC) through letter ERC No. 522, dated 1 February 2023. A sample size of 116 was calculated using OpenEpi online calculator, keeping 95% confidence level, 80% precision, exposed: unexposed ratio of 1 and expected percentage of unexposed with outcome as 48% and exposed with outcome as 75% .[8,9] Non-probability consecutive sampling technique was used for enrolling every patient meeting the inclusion criteria who presented in ENT outpatient department (OPD) with AR between February 2023 and January 2024. Participants were given comprehensive information about the study, and their signed, informed consent was acquired.

Inclusion Criteria: Participants of either gender, aged between 18-65 years, based on predetermined criteria and diagnosed with AR as per Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines were included.

Exclusion Criteria: Patients who were pregnant or breastfeeding, history of recent nasal surgery, epistaxis, allergy to flunisolide or having chronic diseases, such as nasal polyps, were excluded.

Baseline assessment of participants was done using nasoendoscopy and SNOT-22 questionnaire before treatment. Sinus Rinse kits were used to teach patients how to use nasal irrigation techniques, supported by an instructive video. Patients prescribed 2 puffs of 0.025% of flunisolide nasal spray twice daily were labeled as the "Exposed Group" whereas those patients given normal saline nasal irrigation twice daily, constituted the "Unexposed/Control Group". Spray bottle was selected to provide optimal steroid contact with the sinus mucosa.[10] The use of a treatment diary improved drug adherence. After three months, every patient had a thorough evaluation with an endoscopic nasal examination, and a review of the SNOT-22 questionnaire where a total of 22 symptoms were assessed.[11,12] Each symptom had a score ranging from 0-5, (0 = no problem and 5 = severe symptoms) and total score was calculated out of 110. Patients were asked about adverse effects, such as dry nose, itching, discomfort, epistaxis, difficulty breathing, and blurring of vision, at each follow-up visit. IBM's Statistical Package for the Social Sciences (SPSS) version 29.00 was used for data input and analysis. Descriptive statistics were used to summarize socio-demographic variables. Categorical data were shown as frequencies and proportions (%) while numerical data were expressed as mean with standard deviation (SD) or median with interquartile range (IQR), depending on the data distribution. Kolmogorov-Smirnov and Shapiro-Wilk tests of normality were done to check normality of data. Mann-Whitney U test was used to compare the median SNOT score of each group before and after therapy, with a significance threshold of 0.05. The efficacy of flunisolide nasal spray in comparison to saline nasal irrigation was demonstrated by the improvement in SNOT score following treatment for each group. The Mann-Whitney U test was applied on the overall scores as well as separately to compare scores with respect to each of the 22 symptoms included in the SNOT-22 questionnaire.

RESULTS

A total of 120 patients were included in the study but with the exclusion of 4 patients, 2 from each group, who did not show up for the post-treatment examination, a total of 116 patients were included in the final data analysis. Outcome measures included median SNOT score, symptom-specific SNOT score and frequency of three most prevalent examination findings besides demographic variables. The mean age of the participants was 33.18±7.96 years. There were 81(69.80%) males and 35(30.20%) females. The age and gender distribution among exposed and unexposed was compared, as shown in Table I.

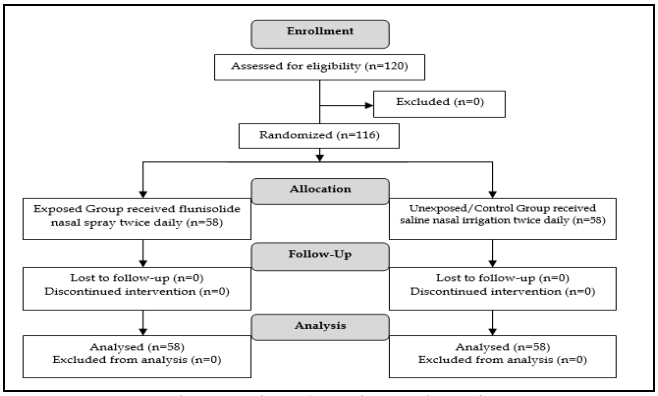

Figure: Patient Flow Diagram (n=116)

In exposed group, the change in median SNOT score after treatment was 37.00 as compared to 14.00 in unexposed group as shown in Table II. The improvement in SNOT score in exposed group as

compared to unexposed group was found to be statistically significant (p<0.001).

Table-I: Demographic Characteristics of Exposed and Unexposed Groups (n=116)

Characteristics	Study groups	
	Exposed n (%)	Unexposed n (%)
Gender		
Male	40(69.00%)	41(70.70%)
Female	18(31.00%)	17(29.30%)
Age (years)		
Median (IQR)	31(29-39)	32(27-37)

Table-II: Comparison of SNOT-22 Scores of Exposed and Unexposed Groups (n=116)

Scores	Groups	Median	IQR	*p* value
SNOT score (pre-treatment)	Exposed	75.00	72.00-77.00	<0.001 a
	Unexposed/control	72.00	69.00-74.00	
SNOT score (post-treatment)	Exposed	38.00	36.00-42.00	<0.001 a
	Unexposed/control	58.00	56.00-60.00	

a Mann-Whitney U test

Individuals receiving flunisolide nasal spray for AR showed statistically significant improvement in 16 out of 22 symptoms recorded on the SNOT-22 questionnaire. On the other hand, patients who received saline nasal irrigation showed statistically significant improvement in 1 out of 22 of the symptoms described (dizziness). No difference was observed in 4 symptoms (ear pain, facial pain, difficulty falling asleep, and fatigue) between those using flunisolide compared to normal saline. Lack of good night sleep showed improvement with flunisolide, but it was not statistically significant. The median scores and IQRs difference between the exposed and unexposed/control groups for each symptom are shown in Table-III.

The presence of various nasal findings was examined between the exposed and unexposed/control groups as shown in Table-IV. The endoscopic nasal examinations revealed a higher prevalence of inferior turbinate hypertrophy, edema, and nasal secretions in the flunisolide nasal spray group compared to the saline nasal irrigation group (p<0.001). These findings suggest that while the flunisolide nasal spray may have alleviated subjective symptoms, it did not necessarily reduce the underlying nasal mucosal inflammation or nasal congestion.

DISCUSSION

Table-III: Post-treatment Symptom-wise Analysis of SNOT-22 Scores Among Groups (n=116)

Symptoms (SNOT-22) Post-treatment	Study Group				p-value a
	Exposed (n= 58)		Unexposed/control (n=58)		
	Median	IQR	Median	IQR	
Need to Blow Nose	2.00	1.00-3.00	3.00	3.00-4.00	<0.001
Sneezing	2.00	1.00-2.00	3.50	3.00-4.00	<0.001
Runny Nose	1.50	1.00-2.00	3.00	3.00-4.00	<0.001
Cough	2.00	2.00-3.00	4.00	3.00-4.00	<0.001
Postnasal Discharge	2.00	1.00-2.00	3.00	3.00-4.00	<0.001
Thick Nasal Discharge	2.00	2.00-3.00	3.00	3.00-4.00	<0.001
Ear Fullness	2.00	2.00-3.00	4.00	3.00-4.00	<0.001
Dizziness	3.00	2.00-3.00	2.00	2.00-3.00	0.003
Ear Pain	2.00	1.00-2.00	2.00	1.00-2.00	0.907
Facial Pain	2.00	1.00-2.00	2.00	1.00-2.00	0.652
Difficulty Falling Asleep	2.00	1.00-2.00	2.00	1.00-2.00	0.803
Waking Up at Night	2.00	1.00-2.00	2.00	2.00-2.00	<0.001
Lack of Good Night Sleep	1.00	1.00-2.00	2.00	1.00-2.00	0.251
Waking Up Tired	1.00	1.00-2.00	2.00	1.00-2.00	<0.001
Fatigue	2.00	1.00-2.00	2.00	2.00-3.00	<0.001
Reduced Productivity	1.00	1.00-2.00	2.00	2.00-3.00	<0.001
Reduced Concentration	2.00	2.00-2.00	3.00	2.00-3.00	<0.001
Frustrated/Irritable	1.00	1.00-1.00	2.00	2.00-2.00	<0.001
Sad	2.00	1.00-2.00	3.00	2.00-3.00	<0.001
Embarrassed	2.00	1.00-2.00	3.00	2.00-3.00	<0.001
Decreased Sense of Smell/Taste	2.00	1.00-2.00	3.00	2.00-3.00	<0.001
Nasal Blockage	1.00	1.00-2.00	3.00	3.00-4.00	<0.001
a Mann-Whitney U test					

Table-IV: Comparison of Findings from Endoscopic Nasal Examination Between Exposed and Unexposed Groups (n=116)

Endoscopic Findings		Study groups		*p*-value
		Exposed n (%)	Unexposed n (%)	
Inferior Turbinate Hypertrophy	No	42 (72.40%)	55 (94.80%)	0.001
	Yes	16 (27.60%)	3 (5.20%)	
Edema	No	39 (67.20%)	52 (89.70%)	0.003
	Yes	19 (32.80%)	6 (10.30%)	
Nasal Secretions	No	31 (53.40%)	5 (86.20%)	<0.001
	Yes	27 (46.60%)	8 (13.80%)	
Pearson chi-square				

AR affects millions of people all over the world.[13] causing troublesome symptoms that has profound effects on daily activities, cognitive function, mood and sleep.[14] We observed notable reduction in SNOT 22 symptoms and the corresponding improvement in subjective well-being was noted in the flunisolide group. These findings provide compelling evidence for the efficacy of flunisolide in treating symptoms related to AR. One study concluded that despite the wide range of drugs presently available for therapy, a portion of people with AR still have uncontrollable symptoms.[15] Clinical practice guidelines in the United States (US) recommend that practitioners treat allergic rhinitis with intranasal corticosteroids on a regular basis as monotherapy.[16] A study, which compared the effectuality of budesonide irrigation with intranasal saline irrigation, found it to be a more convincing

treatment for AR.[17] During the endoscopic nasal examination, nasal secretions, nasal mucosal edema, and inferior turbinate hypertrophy were examined and when saline nasal irrigation was administered, nasal mucosal edema and nasal secretions significantly improved, most likely due to the the mechanical cleansing action which decreased nasal discharge, thus, this modality improves mucociliary clearance by reducing local concentrations of pro-inflammatory mediators.[18, 19] One study found that symptoms of nasal congestion and rhinorrhea improved to a great extent when patients were treated with intranasal isotonic and hypertonic saline for a period of 2 weeks.[20] Intranasal flunisolide is equally effective against non-allergic rhinitis[21, 22] and allergic rhinitis in pediatric group.[23] A trial, which compared the dexterity of intranasal budesonide and saline irrigation in managing symptoms of allergic rhinitis, found that patients receiving budesonide nasal irrigation had much better subjective and clinical outcomes than those receiving saline nasal irrigation treatment as assessed by SNOT-22 score, visual analogue scale score and modified Lund-Kennedy scores.[24] A randomized controlled trial showed an improvement in nasal symptom score in patients who received intranasal fluticasone furoate nasal spray compared to the patients who received a course of oral antihistamines, indicating a significant therapeutic role of intranasal corticosteroids in allergic rhinitis.[25] Our study shows that saline nasal irrigation may be recommended as an adjunct therapy for patients who are looking for non-pharmacological treatments or having adverse side effects to steroids.

LIMITATIONS OF STUDY

Long term safety and therapeutic potency of flunisolide and normal saline could not be determined due to relatively short study duration. The study could only evaluate improvement in patients' symptoms. Moreover, the two treatment modalities could not be compared in terms of their side effects and cost effectiveness.

CONCLUSION

Flunisolide was found to be more effective in alleviating symptoms of AR as compared to normal saline after a period of 3 months, making it an effective local treatment modality with minimum systemic side effects.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

AZ & FM: Data acquisition, data analysis, critical review, approval of the final version to be published.

NR & FS: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SS & RK: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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