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Corelation Between Symptomatic Relief and Regression of Mucosal Findings in Allergic Rhinitis after Treatment with Intranasal Fluticasone Propionate

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Abstract

Background: Allergic Rhinitis is an inflammatory, IgE-mediated disease nasal mucosa characterized by nasal congestion, rhinorrhea, paroxysmal sneezing, and/or nasal itching. It is a common and often debilitating disease, which can have a major detrimental impact on quality-of-life and social productivity based on which it can be classified as mild or moderately-severe. The management of allergic rhinitis includes avoidance of allergen, pharmacotherapy, and disease modifying immunotherapy. Our study is aimed to correlate the response of patient's symptomatic relief with the regression of mucosal findings on diagnostic nasal endoscopy with fluticasone propionate nasal spray. Objectives: 1. To classify allergic rhinitis patients as MILD and MODERATELY- SEVERE based on the total symptoms and sign score. 2. To give intranasal fluticasone propionate to all patients, and assess: the pre treatment and post treatment symptom scores. the pre-treatment and post treatment mucosal changes after treatment with Fluticasone Propionate nasal spray. 3. Correlation between the symptomatic relief and regression of mucosal changes. **Material and Methods:** A prospective study. Patients of clinically proven nasal allergy were accrued into the study. We have done diagnostic nasal endoscopy for all of them. We have assessed the patients TNSS(0-16) and signs(0-9)score. We have also assessed the effect of Allergic Rhinitis on quality of life through a questionnaire (0-12). We divided them into two groups (0-18) as MILD and (19-37) as MODERATELY-SEVERE. Both groups of patients received fluticasone propionate nasal spray 2 sprays once daily for 1month. Then follow up with post treatment nasal endoscopy was done after 2 weeks. Post treatment TNSS score, signs score and quality of life questionnaire score was done. **Results:** Fifty patients were included in this study, 25 each in mild and moderately-severe group according to ARIA guidelines. In both the groups there is a significant post treatment reduction in total signs scores after treatment with fluticasone propionate nasal spray($p < 0.05$).The reduction in mean TNSS and quality of life questionnaire is far more than that of endoscopic mean sign score post treatment suggesting that though the patient might have regression of symptoms clinically, the mucosal changes might not come back to normal. **Conclusion:** Diagnostic nasal endoscopy may reveal signs that are predictive of the severity of allergic rhinitis. It could be a better tool, to assess the disease regression on patient follow up.

Keywords: Allergic Rhinitis, Fluticasone Propionate nasal spray, Total Nasal Symptom Score TNSS, Diagnostic Nasal endoscopy.

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Introduction

Allergic Rhinitis is an inflammatory, IgE-mediated disease characterized by nasal congestion, rhinorrhea (nasal drainage), paroxysmal sneezing, and/or nasal itching. It is a common and often debilitating disease, it can have a major detrimental impact on quality-of-life and social productivity.[1] It is associated with development of squeal such as chronic rhinosinusitis, nasal polyps, serous otitis media, Bronchial Asthma, orthodontic problems and other ill effects of prolonged mouth breathing, especially in children.

Allergic Rhinitis symptom frequency has been divided into intermittent/ seasonal (<4 days/week or <4 weeks/year) and persistent/perineal (>4 days/week and >4 weeks/year).[2] Severity of Allergic Rhinitis can be classified as mild (when symptoms are present but are not interfering with quality of life) or more severe (when symptoms are bad enough to interfere with quality of life).[3]

Allergic Rhinitis arises following an initial sensitization phase, in which allergen comes in contact with nasal mucosa resulting in antibody (IgE) formation and development of atopy. Subsequently, depending upon the level of exposure and degree of sensitization, allergen can then trigger a humoral response, manifested by symptoms.

The nasal mucosa of patients with allergic rhinitis is typically inflamed and hypertrophied. There is polypoid degeneration of the epithelium as well as a marked edema of the mucosa.[4] Nasal obstruction is noted to be the most commonly presenting and debilitating symptom of allergic rhinitis, and it is caused by vasodilation of arterioles, venules, and capillaries as well as an increase in vessel permeability that leads to edema.[5]

The management of Allergic Rhinitis includes the prevention of exposure to allergen, effective symptomatic relief with pharmacotherapy and disease modifying immunotherapy. Most commonly followed is pharmacotherapy due to patient compliance.[6] Pharmacologic treatment of AR proposed by the guidelines is a stepwise approach based on classification of symptoms in terms of course and severity.[7] Intranasal corticosteroids (INCS) are first-line therapy for moderate to severe Allergic Rhinitis and are the most effective medication for controlling Allergic Rhinitis symptoms.[7] For several years, there has been discussion of whether first line pharmacological treatment of allergic rhinitis should be antihistamines or intranasal corticosteroids. Based on ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines 2010 strongly recommended Intranasal Glucocorticosteriods as first line treatment of choice for adults.[1] Intranasal corticosteroids exhibit potent anti-inflammatory action due to effects on several cell types, including topically on nasal mucosa.[8] They decrease release of inflammatory mediators and cytokines, thereby reducing nasal mucosal inflammation. They provide symptomatic and effective relief when used continuously or as needed.

Though the assessment of disease severity according to the ARIA guidelines, is based on the clinical presentation and follow-ups,[2] There are no objective measurements approved as a means for assessing disease severity. A Diagnostic nasal endoscopic examination is a quick test, which is part of the assessment of the otolaryngologist when examining a patient with nasal symptoms. It would be of great value if the nasal endoscope can have a role in the objective evaluation of patients with Allergic Rhinitis.

Literature search lacks studies that compare the response of patient's symptomatic relief to regression of mucosal findings after completion of medical management in a clinically diagnosed patient of Allergic Rhinitis. Hence this study was taken up to correlate the symptomatic relief with regression of mucosal changes after the course of treatment in a patient of Allergic rhinitis.

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Material and Methods

This is a Prospective observational study with sample size of 50 conducted in Department of Otorhinolaryngology and Head and Neck Surgery, Kamineni Institute of Medical Sciences, Narketpally from November 2021 – November 2022.

Inclusion Criteria

1. Clinically diagnosed cases of allergic rhinitis.
2. Sex: both males and females.
3. Age: 14 to 60 years.
4. Symptoms present for more than 6 months.
5. Willing for follow up regularly.

Exclusion Criteria

1. Non-Allergic Rhinitis.
2. Presence of acute or chronic rhinosinusitis.
3. Undergoing desensitizing therapy/alternate therapy.
4. Pregnant woman, breast feeding mothers.
5. Use of medications such as other steroids and anti-histamines within their washout period.
6. Patient with cardiac/hepatic/renal diseases or bronchial asthma.
7. Patients who have undergone nasal surgery.

All the patients were included into the study after taking proper informed consent and Institutional Ethics Committee Clearance. All details of the patient's symptoms, signs and follow up were entered into the Performa specially prepared for this study.

TNSS score and Questionnaire were utilized for symptomatic evaluation of the patient. Their severity was graded by Likert's scale.[9,10]

Objective evaluation for nasal obstruction was done by assessment of Cold Spatula Test and Diagnostic Nasal Endoscopy.

Table 1: Likert's Scale.[10]

Normal	Mild	Moderate	Severe	Very severe
0	1	2	3	4

Table 2: Total Symptom Score

Total Nasal Symptoms Score,[9]	Questionnaire
Sneezing – 0 1 2 3 4	Disruptions in school or work 0,1 2, 3 ,4
Nasal Obstruction – 0 1 2 3 4	Sleep Disturbances – 0 1 2 3 4
Rhinorrhea – 0 1 2 3 4	Problem in exercising/doing other Activities–0 1 2 3 4
Itching in the nose – 0 1 2 3 4	
(SCORE min = 0; max = 16)	(SCORE min = 0; max=12)

Cold Spatula Test

A cold metal stainless steel scale is kept about a cm below the nostril and the amount of fogging on the scale is observed after normal expiration.

Decreased mist formation indicates decreased patency of the airway on the corresponding side. Grading is as below:

0-NORMAL: Misting more than 1cm

1-DECREASED: Misting less than 1cm, but present.

2-ABSENT: Misting is absent.

(SCORE min=0; max=2)

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Diagnostic Nasal Endoscopy

Diagnostic nasal endoscopy was performed with the patient in supine position. Topical anesthesia was administered with 4% Xylocaine first as a nasal spray. Endoscopy was performed by three passes using 0^0 and 30^0 Stryker endoscopes:

a) First pass- Examination of nasopharynx and inferior meatus.
b) Second pass- Examination of spheno ethmoidal recess, superior meatus.
c) Third pass-Examination of middle meatus.

Diagnostic nasal endoscopy will be done to assess:

I. Turbinate hypertrophy

Table 3: Scoring of Turbinate Hypertrophy.

0	Normal
1	Mild: Obstructing 25% of the Nasal Cavity.
2	Moderate: Obstructing 50% of the Nasal Cavity.
3	Severe: Obstructing 75% of the Nasal Cavity.
4	Very Severe: Obstructing more than 75% of the Nasal Cavity.

(SCORE min=0; max= 4)

II. Mucosal Findings

Table 4: Scoring of Mucosal Findings

0	Normal
1	Congestion
2	EDEMA And Congestion
3	Polyp

(SCORE min=0; max=3)

Total Symptom Score= 28

[TNSS Score (16) +questionnaire (12)]

Total Objective Score= 9

[Cold Spatula Test (2) +Dne: Turbinate Hypertrophy (4) +Mucosal Findings (3)]

Total Score= 28+9 =37

Patients with a score of 0-18 will be graded as MILD and others will be graded as Moderately Severe.

All the patients were counselled to avoid exposure to allergens and were prescribed fluticasone propionate nasal SPRAY 2 puffs once daily for 1month. Follow up was done 2 weeks after the course of treatment. The post treatment results were evaluated and analyzed as earlier using TNSS, signs score and disruptions in quality-of-life score.

Statistical methods

- Paired T-test was used for analyzing total symptom scores, signs score and disruptions in quality-of-life score.
- For all the tests, P value of 0.05 or less was considered as statistically significant.

RESULTS

A total of 50 patients were accrued into our study. Age distribution revealed that maximum patients belong to the age group of 25 to 34 in both groups and most of the patients were females 20(40%) in group1, 15(30%) in group2.

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Table 5: Mean Pre and Post Treatment Symptoms Scores in Both the Groups (n = 50)

S NO.	Symptom	Group-1(n=25)		Group-2(n=25)		
		Mean Pre-Treatment Score	Mean Post-Treatment Score	Mean Pre-Treatment Score	Mean Post-Treatment Score	P value
1.	Nasal Discharge	2.4±0.5	1.08± 0.49	2.68±0.627	0.88± 0.525	p<0.0001
2.	Nasal Obstruction	1.84± 0.746	0.32± 0.476	2.24±1.422	0.76± 0.723	p<0.0001
3.	Bouts of Sneezing	2.52± 0.509	1.12± 0.331	3.48± 0.509	1	p<0.0001
4.	Itching of Nose	1.6± 0.816	0.8± 0.408	3.04± 1.206	0.76± 0.435	p<0.0001
5.	Disruptions in School or Work	1.36± 0.489	0.12± 0.332	1.92± 0.493	0.56± 0.506	p<0.0001
6.	Sleep Disturbances	0.92±0.408	0	2.04± 0.789	0.08± 0.276	p<0.0001
7.	Problem In Exercising or Doing Other Activities?	1	0.12± 0.332	1.84± 0.8	0.52± 0.509	p<0.0001

In both the groups the reduction in post treatment scores for all the symptoms was found to be clinically and statistically significant (p<0.0001).

Table 6: Mean Pre and Post Treatment Signs Score (n = 50)

S. No	Signs	Group-1 (N=25)		Group-2 (N=25)		
		Pre-Treatment Score	Post-Treatment Score	Pre-Treatment Score	Post-Treatment Score	P Value
1.	Cold Spatula Test	1	0.4± 0.5	1.52± 0.509	0.84± 0.374	p<0.0001
2.	Turbinate Hypertrophy	1.84±0.374	1	2.56± 0.506	1.08± 0.276	p<0.0001
3.	Mucosal Changes	1.44± 0.506	0.4± 0.5	1.92± 0.640	0.2± 0.408	p<0.0001

In both the groups the reduction in post treatment signs scores was found to be clinically and statistically significant (p<0.0001).

Side effects:

In our study side effects of intra nasal FLUTICASONE PROPIONATE were cough(n = 3), headache (n = 1).

Remien K et al in his study found minimal local side effects of intra nasal FLUTICASONE PROPIONATE (cough, dysphonia).[11]

DISCUSSION

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Allergic Rhinitis is the commonest immunologic disease and is the commonest chronic disease experienced by humans12.Even today despite the advances in the understanding of the numerous chemical mediators of allergy, only two major categories of drugs are in common use for the management, namely antihistamines and corticosteroids.

Though the assessment of disease severity according to the ARIA guidelines, is based on the clinical presentation and follow-ups 2, there are no objective measurements approved as a means for assessing disease severity.

Mean TNSS value in the present study is higher when compared to the Ratner PH et al,[13] Scott M. Kasuba et al,[14] but comparable with Kim CH et al.[15] In the present study, most of the patients come from a rural population where agriculture is the staple profession, which might be a reason for more exposure to allergens and understandably higher TNSS scores.

Table 7: Comparision of Mean TNSS Scores with Various Studies

Author	**Mean TNSS value**
Kim CH et al, 2015(n=258)	7.5
Ratner PH et al, 1998(n=569)	4.6
Scott M. Kasuba et al, 2001(n=88)	5.5
Present Study(n=150)	9.72

In both the groups there is a significant post treatment reduction in total signs scores after treatment with fluticasone propionate nasal spray. There are no studies in literature search comparing the mucosal and turbinate hypertrophy changes pre and post treatment.

The reduction in mean TNSS and quality of life questionnaire is far more than that of endoscopic mean sign score post treatment suggesting that though the patient might have regression of symptoms clinically, the mucosal changes might not come back to normal.

CONCLUSION

Fluticasone Propionate Nasal spray provides a good relief of symptoms and signs in Allergic Rhinitis irrespective of it's severity.

The reduction in TNSS is far more than that of endoscopic sign score post treatment suggesting that though the patient might have regression of symptoms clinically, the mucosal changes might not come back to normal.

Nasal endoscopy may reveal signs that are predictive of the severity of allergic rhinitis. It could be an adjuvant to clinical assessment, by tracking the regression of nasal mucosal signs along with symptom scores on patient follow up.

Well defined criteria for objective nasal endoscopic evaluation of Allergic Rhinitis is needed for better initial and further clinical assessments, patient response to the treament and thus better patient care.

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