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Research Article

Comparing Treatment Outcome of Allergic Rhinitis Patients after Using Fluticasone Nasal Spray and Nasal Douching

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Abstract

Introduction: Allergic Rhinitis (AR) is a major public health issue with significant societal and financial costs, whose management requires time and resources. Although in recent years several new studies have been performed on treatment of the disease, scientific evidence remains poor because many of the studies had relevant methodologic problems.

Aims: To study and compare clinical profile of AR patients and their clinical symptomatic outcome after using: i)Fluticasone Propionate Nasal Spray regimen or ii)Saline Nasal Irrigation/Douching using subjective SNOT-22 questionnaire.

Material and Methods: A Prospective study was conducted on 74 AR patients (38 males and 36 females) with Moderate-Severe and Persistent symptoms, visiting Out-Patient Department of Otorhinolaryngology in a tertiary care institute. On a random basis, 37 patients were administered Fluticasone Propionate Nasal Spray treatment and 37 patients were given Saline Nasal Douching treatment regimen. The patients filled the SNOT-22 questionnaire prior to commencement of treatment as also post completion.The findings were statistically validated by using the Paired sample t-test.

Conclusion: The study establishes that for management of patients of AR with Moderate-Severe and Persistent symptoms, Fluticasone Propionate Nasal Spray regimen can be more effectively used for patients while Saline Nasal Irrigation/Douching though provided relief was lesser effective and produced lower reduction in SNOT-22 score.

Keywords: otorhinolaryngological symptoms; immunedeficiency; traditional chinese medicine; energy; homeopathy; hippocrates

Introduction

Allergic Rhinitis (AR) is a symptomatic rhinological disorder induced after allergen exposure due to an IgE-mediated inflammation of membranes lining the nose. Clinically, rhinitis is defined as a symptomatic condition having two or more symptoms of anterior or posterior rhinorrhoea, sneezing, nasal blockage and/or itching of nose during two or more consecutive days for more than one hour on most days.[1,2]

Allergic Rhinitis symptoms include sleep disturbance, exhaustion, low mood and impaired cognitive function and considerable absenteeism from work, all of which reduce productivity and quality of life. There may also be related dental malocclusion, facial abnormalities, postnasal drip, secretory otitis media, sinusitis, Eustachian tube dysfunction and allergic conjunctivitis. Domestic allergens such as mites, domestic animals, insects, plant derived allergens, pollens and moulds can cause AR. Also, occupational triggers like latex, cigarette smoke, vehicular exhaust as well as aspirin and other non-steroidal anti-inflammatory medicines may also cause AR. It can also be associated with co-morbid conditions like Asthma, Atopic Dermatitis and Nasal polyps.[3,4,5]

Allergic Rhinitis is affecting approximately between 0.8 to 39.7% of the world population according to International Study on Asthma and Allergy in Childhood (ISAAC 3). Prevalence of AR ranged from 25 to 30% in India, 3.6% to 22.8% for Africa, 3.5% to 54.5% for America, 1.0% to 47.9% for Asia and 1.0% to 43.9% for Europe according to a recent study on worldwide prevalence of Allergic Rhinitis.[6].Currently, developed urban lifestyle is showing more incidence of Allergic Rhinitis - may be due to reduced exposure to infective agents in urban areas which reduces Th1 response thus increasing Th2 immune response causing excessive production of IgE and atopy.[1]

Allergic Rhinitis can be managed by various pharmacological means like oral or topical antihistaminics, steroids, leukotriene receptor antagonists (LTRAs), sodium cromoglicate, nasal decongestants, topical ipratropium bromide spray, saline nasal douching and immunotherapy or desensitization. The symptoms can also be lessened by reducing the submucosal fibrotic tissue on the inferior turbinates. Complimentary treatments like homeopathy, acupuncture or herbal remedies can provide some symptomatic relief but no permanent cure has been proven by them. Reduction of allergen exposure has proven effective to decrease its prevalence.[7,8,9,10,11,12,13,14]

This study observes the clinical profile of patients with Allergic Rhinitis after using i) Fluticasone Propionate Nasal Spray regimen and ii) Saline Nasal Irrigation/Douching and also the outcome in terms of symptom improvement and patient satisfaction with the subjective SNOT-22 questionnaire [15,16,17] after using either modes of treatment.

Materials And Methods

Present study is a prospective study performed on the patients visiting the Out Patient Department (OPD) of Department of Otorhinolaryngology, of a tertiary care centre from August 2020 to December 2022 on a sample of 74 patients.

Study Participants

Inclusion Criteria

All cases of Allergic Rhinitis patients having moderate severe and persistent symptoms attending ENT clinic in a tertiary care centre, irrespective of both genders, aged between 18 to 57 years, who have completed the SNOT-22 questionnaire pre-treatment and within 3 months post treatment and giving informed consent.

Exclusion Criteria

Cases with growth in the nasal cavity, benign or malignant, with sinusitis and nasal polyps, Allergy, hypersensitivity, contraindication to steroids or with nasal septal perforation.

Cases who were not willing to participate in the study.

Sampling Technique

All the patients coming to ENT OPD during the study period and fulfilling the inclusion and exclusion criteria were included in the study.

Data Collection

Study Tools

Predesigned questionnaire was used which consisted of general and health related information.

Ethical Considerations

After getting institutional permission and the informed written consent from participants required information was collected.

Confidentiality was assured to all the study participants

Methodology

This study included patients with two or more symptoms of anterior or posterior rhinorrhoea, sneezing, nasal blockage and/or itching of nose during two or more consecutive days for more than 1 hour on four or more days of a week or greater than four consecutive weeks. All patients had moderate-severe symptoms (abnormal sleep, impairment of daily activities, sport, leisure); problems caused at school or work, troublesome symptoms.

The patients were examined by Anterior Rhinoscopy and Diagnostic Nasal Endoscopy (0-degree scopy) prior to commencement of treatment. Detailed clinical history of the participants was recorded in a pre-defined proforma. The participants were explained SNOT-22 questionnaire in English and native Marathi language and were asked to fill the same. Total 22 entities were asked and the score for each question ranged from 0 (no problem) to 5 (worse). It was ensured that participating patients were not taking any regular or occasional oral or parenteral antihistaminics during the study period.

On a random selection basis, 37 patients out of the total 74 were advised to take Fluticasone Propionate nasal spray - 2 puffs per nostril (50 mcg per spray) twice daily (once in the morning and one at night) for first three weeks and called to OPD for follow up, then 2 puffs once daily for next five weeks and called for follow up at the end of two months.

Other group of 37 patients were explained the nasal douching technique and asked to perform nasal douching twice daily for 1st three weeks then called for follow up, followed by once daily for next five weeks and called for follow up at the end of two months.

All patients were asked to fill the SNOT-22 Questionnaire again at the end.

Steps for using Fluticasone Propionate Nasal Spray

The spray was typically applied once or twice daily (once in the morning and once at night). The patients were instructed to use their finger to seal one nostril. Then bending the head forward and carefully inserting the nozzle into the other nostril, slowly inhaling through the nose, they squirted the spray into the nostril, while applying pressure with the fingers to the nozzle's widest part while exhaling through their mouth.[18]

Steps for Nasal Douching

Patients were advised to perform Nasal Douching using the nasal douching kit readily available in the medical stores - a 200 ml sterile squeeze bottle

and 10 sachets; each sachet consisting of 7.8g of pre- mixed dry powder of Sodium Chloride 4.0g, Sodium Bicarbonate and Xylitol.

The patients were told to empty the contents of entire one sachet into the bottle, pour previously boiled lukewarm water into the bottle upto 200ml and gently shake it until the powder dissolved. Bending over a basin, keeping the mouth open, they gently squeezed the bottle in pulsing action into the nostril. Allowing half of the solution to wash through the nasal passage and come out of the other nostril, the process was repeated for the other nostril.[19]

Statistical Analysis

A master sheet of meticulously collected data was prepared in Microsoft Excel sheet. The appropriate statistical analysis was done using Microsoft Excel and SNOT 22. Data was presented in the form of figures and tables.

Application of Paired sample T-test :

The findings were statistically validated by using the Paired sample t-test which compares the means of two variables for a single group - before and after treatment. The test compares the differences between values of two variables for each case and tests whether the average differs from 0.

Results

Sample Size : The study was conducted on a sample of total number of 74 patients, of which, 38 patients (51.35%) were males and 36 patients (48.64%) were females.

Incidence of Disease : While 46 patients (62.16%) had Perennial Allergic Rhinitis, 28 patients (37.84%) had Seasonal Allergic Rhinitis.

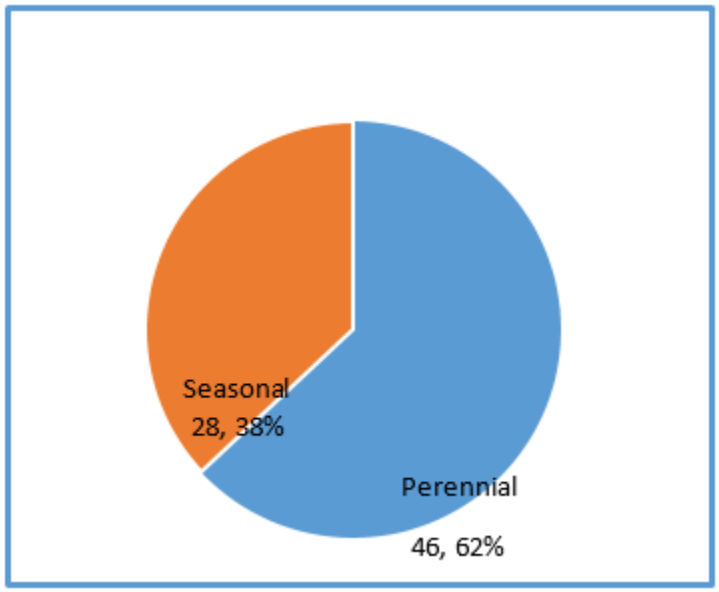

Figure 1: Distribution of patients as per incidence of disease - Perennial/Seasonal

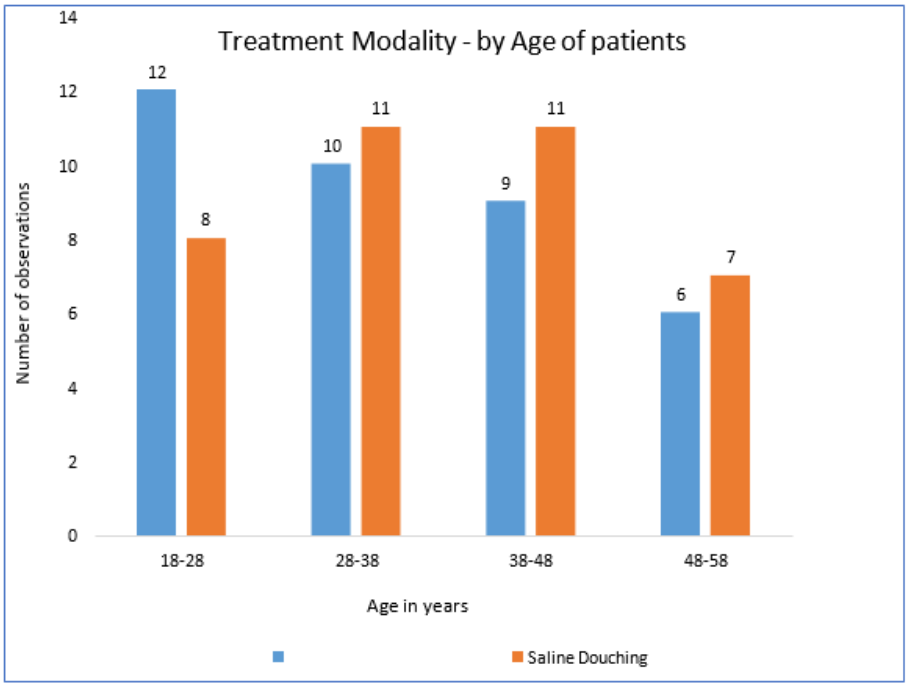

Figure 2 : Age wise distribution of patients with Treatment modality

Distribution of patients based on Anterior Rhinoscopy – Nasal Endoscopy

Anterior Rhinoscopy and Nasal Endoscopy	Frequency	Percentage
Bi-lateral Inferior Turbinate Hypertrophy	2	2.70%
Left Deviated Nasal Septum	11	14.86%
Left Inferior Turbinate Hypertrophy	8	10.81%
Normal examination	35	47.29%
Right Deviated Nasal Septum	8	10.81%
Right Inferior Turbinate Hypertrophy	7	9.45%
S-Shaped Deviated Nasal Septum	3	4.05%
Total	**74**	**100.00%**

Table 1 : Distribution Of Patients Based On Anterior Rhinoscopy And Nasal Endoscopic Findings

Total 22 entities were asked in the SNOT-22 questionnaire and the score for each question ranges from 0 (no problem) to 5 (worse). The total score could range from 0 to 110. Thus a higher mean/average SNOT-22 score indicated higher severity disease. The difference between Pre and Post Treatment SNOT scores in all the above groups was statistically highly significant as p-value was less than 0.001, and the mean SNOT score reduced from Pre to Post treatment.

Application of Paired sample T-test :

The findings of application of Paired sample t-test are given in tables here below :

Paired sample t-test results				
	Mean	**Number of observations**	**Standard Deviation**	**Standard Error Mean**
Male Patients				
Pre Treatment SNOT	82.68	38	13.89	2.25
Post Treatment SNOT	69.55	38	11.53	1.87
Female Patients				
Pre Treatment SNOT	80.03	36	14.57	2.46
Post Treatment SNOT	64.09	36	11.84	2.00
Perennial Disease patients				
Pre Treatment SNOT	85.20	46	13.66	2.01
Post Treatment SNOT	69.78	46	12.03	1.77
Seasonal Disease patients				
Pre Treatment SNOT	74.96	28	12.87	2.48
Post Treatment SNOT	62.07	28	10.21	1.96
Patients with Persistent Symptoms using Fluticasone Spray				
Pre Treatment SNOT	83.81	37	6.47	1.06
Post Treatment SNOT	63.89	37	9.30	1.53
Patients with Persistent Symptoms using Saline Douching				
Pre Treatment SNOT	82.67	37	6.41	1.07
Post Treatment SNOT	67.72	37	5.60	0.93
Patients with Right DNS				
Pre Treatment SNOT	80.37	8	17.96	6.35
Post Treatment SNOT	66.62	8	14.68	5.19
Patients with Left DNS				
Pre Treatment SNOT	88.09	11	13.49	4.07
Post Treatment SNOT	73.18	11	11.75	3.54
T-test statistics in Overall total patients				
Pre Treatment SNOT	83.24	74	14.18	1.66
Post Treatment SNOT	65.80	74	11.92	1.40

Table 2 : Paired Sample Statistics

Patient Group	Mean Pre SNOT Score	Mean Post SNOT Score	Mean Diff.	Std. Deviation	Std. Error Mean	95% Confidence Interval of the difference		T - Test Statistics (t)	Degree of Freedom (df)	Significance (2-tailed)
						Lower	Upper			
Gender Basis										
Males	82.68	69.55	13.13	4.40	0.71	11.68	14.58	18.39	37	3.30
Females	80.03	64.09	15.94	6.75	1.14	13.62	18.26	13.97	34	1.20
Seasonality Basis										
Perennial	85.20	69.78	15.42	4.80	0.71	13.98	16.84	21.77	45	1.57
Seasonal	74.96	62.07	12.89	6.98	1.34	10.13	15.65	9.60	26	4.89
Treatment Regimen Basis										
Fluticasone Nasal Spray	83.81	63.89	19.92	5.60	0.92	16.05	19.79	19.45	36	1.10
Saline Nasal Douching	82.67	67.72	14.95	3.35	0.58	9.81	12.08	19.62	35	1.81
Nasal Septum Deviation Basis										
Right deviated	80.38	66.63	13.75	4.20	1.49	10.24	17.26	9.26	7	0.35
Left deviated	88.09	73.18	14.91	3.11	0.94	12.82	17.00	15.88	10	2.01
Patient's Age Group Basis										
18 – 27 years	84.11	67.68	16.43	7.89	1.81	12.61	20.22	9.07	18	3.91
28 – 37 years	81.67	67.00	14.67	4.40	0.96	12.66	16.67	15.29	20	1.70
38 – 47 years	79.85	66.60	13.25	5.41	1.21	10.72	15.78	10.96	19	1.19
48 – 58 years	79.46	66.23	13.23	4.32	1.20	10.62	15.84	11.03	12	1.22

Table 3 : Paired Differences T-Test Results

The difference between Pre and Post treatment SNOT in all the above study groups is statistically highly significant as p-value is less than 0.001.

After using either treatment modalities significant reduction of Mean SNOT score indicates satisfactory symptomatic improvement in patients whether they used Fluticasone Nasal Spray regimen or Saline Nasal Douching. However, reduction in mean SNOT-22 score and symptomatic relief was better in Fluticasone spray group (Pre-treatment SNOT score - 83.81 and Post-treatment SNOT score - 63.89 and Mean reduction was 19.92) than the Saline Nasal Douching group (Pre-treatment SNOT score - 82.67 and Post-treatment SNOT score - 67.72 and Mean reduction was 14.95).

Discussion

Allergic Rhinitis is a highly prevalent condition in adults and children, with a large burden on patients and on the healthcare systems, both directly, from the cost of repeated healthcare visits and of chronic medical therapies, and indirectly, via absenteeism from work and loss of productivity.

The present study was conducted on a sample of 74 patients. Gender distribution in the present study had 38 males (51.35%) and 36 females (48.65%). While 37 patients (50%) were administered Fluticasone Nasal Spray treatment, 37 patients (50%) were given Saline Nasal Douching treatment regimen. Age-wise distribution of participants and treatment modality is indicated in Fig. 3.

In present study, while 46 patients (62.16%) had Perennial AR, 28 patients (37.84%) had Seasonal disease. Distribution of patients based on Anterior Rhinoscopy – Nasal Endoscopy is given in Table 1.

After using either treatment modalities there was significant reduction of Mean SNOT-22 score and satisfactory symptomatic improvement in patients whether they used Fluticasone Nasal Spray regimen or Saline Nasal Douching. Mean SNOT Scores in Pre-treatment and Post treatment under different scenarios is given in Table 3. On a comparative basis, the reduction in Mean SNOT-22 score was better in case of patients using Fluticasone Nasal Spray.

A prospective study by de Souza Fernandes et al. done in 2013-14 studied the usefulness of Peak Nasal Inspiratory Flow (PNIF) curves to assess treatment outcomes for children with AR. 40 children aged 8 to 15 with AR symptoms, diagnosed using AR and its Impact on Asthma (ARIA) guidelines, and confirmed by allergy testing, were monitored for 10 weeks for the two treatment modalities. The study concluded that Fluticasone Propionate nasal spray provided better symptomatic relief than saline irrigation. While above study covered only children, our study covered adult population with AR symptoms. Our study did not use PNIF curves but concluded upon Fluticasone treatment modality being better of the two by greater reduction in mean snot score pre and post treatment in this group.[20]

In 2014, Shaun A. Nguyen, MD, MA, Alkis J. Psaltis, MBBS, PhD, and Rodney J. Schlosser, MD, through their study on 40 patients concluded that large-volume, low–positive pressure nasal irrigation with isotonic saline is a very effective adjunctive modality to improve quality of life in patients with AR who are already on intranasal corticosteroid therapy as against intranasal corticosteroids treatment alone. Our study included patients who were not on any ongoing corticosteroids and we initiated their treatments on two treatment modalities and used SNOT-22 scores to compare the results.[21]

In 2021, P Kiruba Shankari, Swathi Suresh and Rukaiah Fatma Begum conducted a prospective comparative study on 62 patients of mild-to-moderate AR on the efficacy of intranasal Fluticasone Propionate and Budesonide in management of disease. While 30 patients received Intranasal Fluticasone Propionate aqueous spray, 32 patients received Intranasal

Budesonide aqueous spray. While both the groups showed statistically significant reduction in symptoms, Fluticasone Propionate was found to be significantly more effective (P<0.05) than Budesonide in reducing sneezing, nasal itching, ocular symptoms, eosinophil counts and individual symptom scores. Our study used Fluticasone Propionate spray alone and found to be effective treatment regimen and Budesonide spray was not used.[22]

Head K, Snidvongs K, Glew S, Scadding G, Schilder AGM, Philpott C, Hopkins C conducted a systematic review in 2018 regarding use of saline irrigation for AR (A Cochrane Database of Systematic Reviews 2018, Issue 6) - which highlighted that people who suffer from AR benefitted from using nasal saline irrigation, both in the short-term and long-term. Our study also used saline irrigation over a period of two months and proved its effectiveness.[23]

From the study findings, we can say that in patients with Moderate-Severe and Persistent symptoms of Allergic Rhinitis, both Fluticasone Nasal Spray regimen and Saline Nasal Douching provided symptomatic relief to the patients and can be used very effectively for patients with Seasonal disease or Perennial diseases, in any age group between 18 to 57 years, and in patients with deviated nasal septum or turbinate hypertrophy and causes similar symptomatic relief irrespective of gender.

However, Fluticasone Nasal Spray provided better symptomatic relief as observed from better reduction in Mean SNOT-22 score. None of the patients out of the total 74 patients reported experiencing any adverse/side-effects or worsening of their symptoms.

We can firmly comment that both modalities were proven to be effective and improved the quality of lives of the patients and provided symptomatic relief to them irrespective of gender. The reduction in mean SNOT-22 score and symptomatic relief was better in Fluticasone spray group (Pre-treatment SNOT score - 83.81 and Post-treatment SNOT score - 63.89 and Mean reduction was 19.92) than the Saline Nasal Douching group (Pre-treatment SNOT score - 82.67 and Post-treatment SNOT score - 67.72 and Mean reduction was 14.95).

Conclusion

Allergic Rhinitis is a global health problem with considerable economic & societal burdens. As the disease is a form of allergy, its management requires time and resources. Although in recent years several new studies have been performed on treatment of the disease, scientific evidence remains poor because many of the studies had relevant methodologic problems. This is further demonstrated by the very small number of studies that were specifically performed to evaluate the impact of Nasal Douching for the most common clinical conditions.

We can conclude that both the treatment modalities were proven to be effective and provided symptomatic relief and improved the lives of the patients as per subjective SNOT-22 questionnaire feedback provided by the sample patients covered in the Study. However, Fluticasone treatment modalities was proven to be better out of the two.

Thus, for patients with Moderate-Severe and persistent symptoms of Allergic Rhinitis initiation of Fluticasone Nasal Spray regimen is a better treatment option in comparison to Saline Nasal Douching which is more suitable in milder cases or as an adjuvant to steroid spray.

It is expected that this study will provide important guidance to other Otorhinolaryngologists in managing the patients of Allergic Rhinitis using Fluticasone Propionate Nasal Spray regimen and Saline Nasal Douching.

Abbreviations

Abb. used	Expanded Form
AR	Allergic Rhinitis
ARIA	Allergic rhinitis and its impact on Asthma
CI	Confidence Interval
DNS	Deviated nasal septum
IgE	Immuno globulin
INS	Intra Nasal Spray
ISAAC	International Study on Asthma and Allergy in Childhood
LTRAs	Leukotriene Receptor Antagonists
SNOT	Sino Nasal Outcome Test

Conflict of Interest

Conflict of Interest - Authors declare that they have no Economic Interest or Conflict of Interest.

No Economic or Conflict of Interest of the Authors is envisaged in this Study.

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