

Original Research Article

A comparative study to evaluate the effects of intranasal steroid spray, isotonic saline nasal irrigation and combination therapy in patients with allergic rhinitis

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ABSTRACT

Background: Allergic rhinitis (AR) is characterized by inflammatory changes in the nasal mucosa caused by exposure to inhaled allergens. AR clinically having 2 or more symptoms of anterior or posterior rhinorrhea, sneezing, nasal blockage or itching of the nose during two or more consecutive days for more than 1 hour on most days which are caused by allergen exposure leading to an IgE mediated reaction. Nasal steroids and antihistamines are considered as gold standard treatment of choice in moderate to severe AR. This study was taken to evaluate the efficacy of intranasal steroid spray, isotonic saline nasal irrigation, combination therapy and to compare all 3 treatment modalities.

Methods: 75 patients of AR who met inclusion criteria were sequentially divided into 3 groups. Group A was intranasal steroid spray, group B was isotonic saline nasal irrigation, group C was combination of both intranasal steroid spray and saline nasal irrigation. Total nasal symptoms score was compared before and after 1 month of treatment.

Results: Mean total nasal symptoms score before treatment in groups A, B and C was found to be 13.72, 12.96 and 13.68 respectively and after 1 month of treatment total nasal symptoms score was seen 8.28, 8.76 and 3.72 respectively.

Conclusions: The combined use of saline nasal irrigation along with intranasal corticosteroids is found to be more effective in reducing the symptoms of patients with allergic rhinitis when compared to individual therapies.

Keywords: Allergic rhinitis, Isotonic saline nasal irrigation, Fluticasone furoate nasal spray, Total nasal symptoms score

INTRODUCTION

AR is characterized by inflammatory changes in the nasal mucosa caused by exposure to inhaled allergens.¹ It is a very common disease, affecting about 0.8 to 39.7% of the world population.¹ AR clinically having 2 or more symptoms of anterior or posterior rhinorrhea, sneezing, nasal blockage or itching of the nose during two or more consecutive days for more than 1 hour on most days which are caused by allergen exposure leading to an IgE

mediated reaction.² Patients with AR can also experience fatigue, sleep disturbance, social function impairment, depressed mood, anxiety, learning, attention impairment, increased work or school absenteeism, decreased work or school performance and productivity. The impact is made worse because of co-morbidities such as sinusitis, otitis media with effusion, allergic conjunctivitis, bronchial asthma and dental disorders.² AR can be classified as perennial or seasonal (hay fever), depending on timing and type of allergen exposure. Patients with AR present with exacerbation of symptoms more during pollen

season.³ According to ARIA, AR is divided into intermittent or persistent disease and severity into mild, moderate and severe.⁴ The management of AR includes patient education on avoidance of allergen as well as pharmacotherapy and allergen specific immunotherapy.⁵ Nasal steroids and antihistamines have been considered as gold standard treatment of choice in moderate to severe AR. In recent times, the safety and efficacy of saline nasal irrigation in managing sinonasal symptoms has shown promising results .

Aims and objectives

The aim and objective of this study were to evaluate the efficacy of intranasal steroid spray in moderate to severe allergic rhinitis, to evaluate the efficacy of isotonic saline nasal irrigation in moderate to severe allergic rhinitis, to evaluate efficacy of combination therapy of intranasal steroid spray and isotonic saline nasal irrigation, to compare all 3 treatment modalities.

METHODS

A comparative study was conducted in KIMS hospital Bengaluru from October 2019 to September 2020.

Inclusion criteria

Males and females aged 18 to 60 years, willing to participate were included in the study. Patients presenting with symptoms like sneezing, nasal obstruction, nasal discharge, watering of eyes and itching of nose, eyes and palate, patients with AEC >400 cells/mm³ and with positive skin prick test for atleast one allergen and patients diagnosed with moderate to severe AR were included in the study.

Exclusion criteria

Patients not giving consent for study, patients not willing for follow up, patients using oral/intranasal corticosteroids or antihistamines within 1 month of presentation to outpatient department, patients with co-existing upper respiratory tract infection, pregnant and lactating women, patients with mild symptoms of AR, patients with co-existing systemic diseases like cystic fibrosis, bronchial asthma, immunodeficiency disorders, ethmoidal or antrochoanal polyps and acute or chronic rhinitis and patients who have undergone previous nasal surgeries were excluded from the study.

Study design

This study performed was a cohort study.

Sampling method

The sampling method used in the study was a simple random sampling method.

Sampling size⁶

Sampling size= $4Pq/d^2$

Where P=prevalence, q=(1-P), d=absolute procession

P = 20%, q= (1- 80/ 100), d=10%,

Sample size (n) = 75

75 patients of AR who met the inclusion criteria were taken into our study and the severity was assessed by using the ARIA criteria for allergic rhinitis. The total nasal symptoms score was assessed for each of our study patients (Table 1).

Table 1: Total nasal symptom score (1) nasal congestion, (2) running nose, (3) nasal itching, (4) sneezing, (5) disturbed sleep.

Symptoms severity	Score
None	0
Mild (symptoms clearly present but easily tolerated)	1
Moderate (symptom bothersome but tolerable)	2
Severe (symptom difficult to tolerate-interferes with activities)	3

Score: 1-5=mild, 6-10=moderate, 11-15=severe.

Patients were sequentially randomised and divided into 3 groups. Group A (25 patients) intranasal steroid spray (fluticasone furoate), group B (25 patients) nasal irrigation (isotonic saline (0.9%) by low pressure bottle), group C (25 patients) combination of both intranasal steroid spray and saline nasal irrigation. Total nasal symptom score was compared at pre and post treatment for each group.

RESULTS

In our study most of the patients belonged to the age group of 20 to 40 years. There was no significant gender predilection observed in our study (Table 2).

Out of 75 patients, 80% patients had severe nasal congestion, 68% patients had severe nasal discharge, 76% had severe nasal itching and 56% had severe sneezing. None of the patients of the 3 groups had severe sleep disturbance (Table 3).

20% patients among our study patients had moderate nasal congestion, 32% patients had moderate nasal discharge, 24% patients had moderate nasal itching, 44% had moderate sneezing and 30.6% had moderate disturbance in sleep (Table 3).

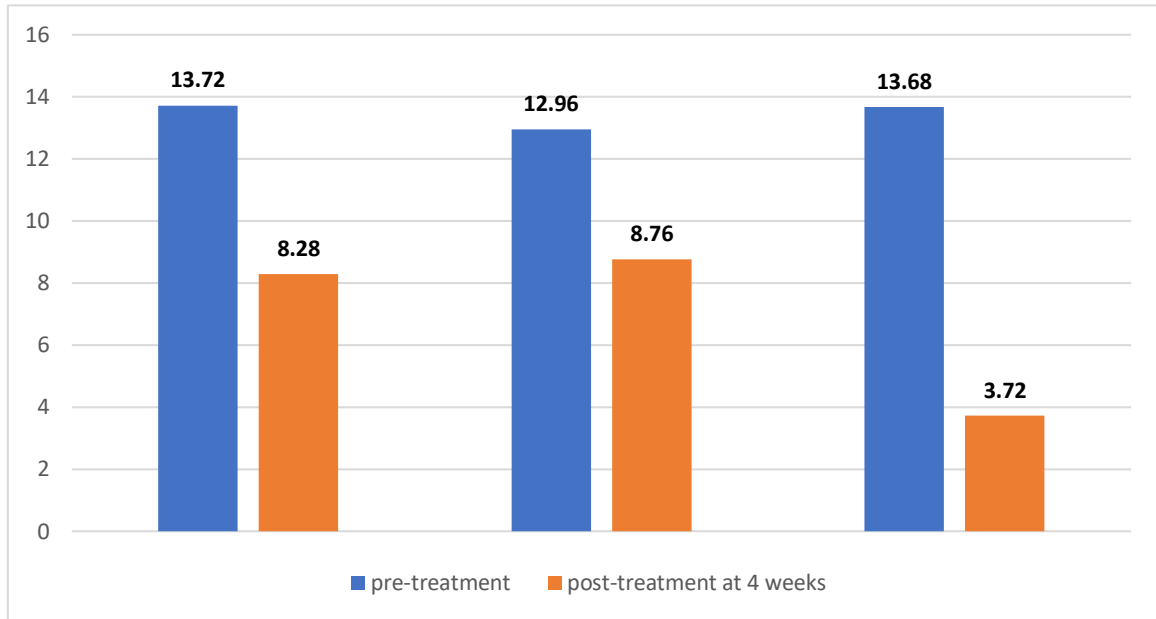


Figure 1: Comparison of mean total nasal symptom score at pre-treatment and post-treatment at 4 weeks.

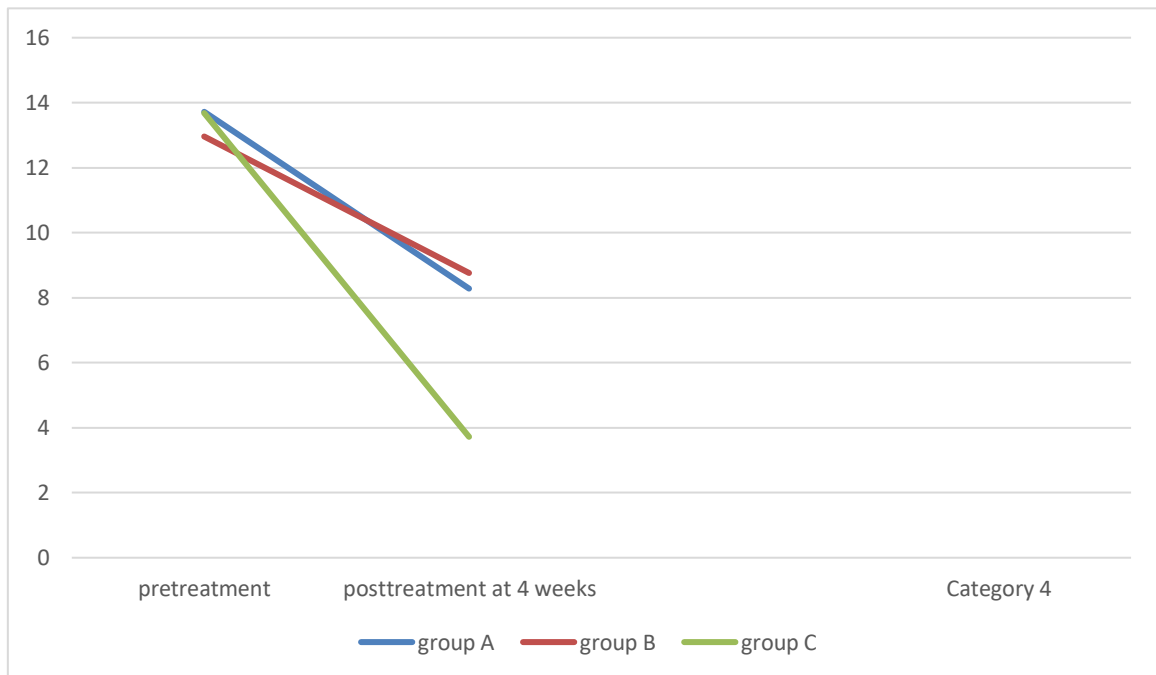


Figure 2: Mean total nasal symptom scores between pre-treatment and 4 weeks post-treatment period in each group.

Table 2: Age and gender distribution among different study groups.

Variables	Category	Group A		Group B		Group C		P value
		Mean	SD	Mean	SD	Mean	SD	
Age	Mean and SD	35.12	9.00	34.04	8.81	34.88	11.14	0.92
	Range (in years)	22-52		19-52		18-57		
		N	%	N	%	N	%	
Gender	Male	14	56	10	40	14	56	0.43
	Female	11	44	15	60	11	44	

Table 3: Each nasal symptom score before treatment in all groups.

Symptoms	Category	Group A		Group B		Group C		P value
		n	%	n	%	n	%	
Nasal congestion	Moderate	4	16	8	32	3	12	0.17
	Severe	21	84	17	68	22	88	
Nasal discharge	Moderate	7	28	11	44	6	24	0.28
	Severe	18	72	14	56	19	76	
Nasal itching	Moderate	4	16	8	32	6	24	0.42
	Severe	21	84	17	68	19	76	
Sneezing	Moderate	9	36	13	52	11	44	0.52
	Severe	16	64	12	48	14	56	
Disturbed sleep	Mild	17	68	14	56	18	72	0.47
	Moderate	8	32	11	44	7	28	

Table 4: Comparison of nasal symptoms between 3 groups at 4 weeks post-treatment period using Chi square test.

Symptoms	Category	Group A		Group B		Group C		P value
		n	%	n	%	n	%	
Nasal congestion	None	0	0	0	0	6	24	<0.001
	Mild	9	36	9	36	18	72	
	Moderate	16	64	16	64	1	4	
Nasal discharge	None	0	0	0	0	4	16	<0.001
	Mild	7	28	9	36	21	84	
	Moderate	18	72	16	64	0	0	
Nasal itching	None	0	0	0	0	18	72	<0.001
	Mild	7	28	6	24	7	28	
	Moderate	18	72	18	72	0	0	
	Severe	0	0	1	4	0	0	
Sneezing	None	0	0	0	0	16	64	<0.001
	Mild	15	60	9	36	9	36	
	Moderate	10	40	15	60	0	0	
	Severe	0	0	1	4	0	0	
Disturbed sleep	None	6	24	4	16	24	96	<0.001
	Mild	19	76	21	84	1	4	

Post treatment, all the groups showed significant reduction in individual symptoms. Patients with symptoms of severe intensity before treatment showed an improvement to an extent where most of the symptoms improved to be of moderate intensity and that of moderate reduced to mild intensity. Some of them even showed absent symptoms at the end of the treatment.

Post treatment, 44% out of 75 had moderate nasal congestion, 45.3% had moderate nasal discharge, 48% had moderate nasal itching, 33.3% had moderate sneezing.

48% had mild nasal congestion, 49.3% had mild nasal discharge, 26.7% had mild nasal itching, 44% had mild sneezing and 54.7% had mild disturbed sleep (Table 4).

0.8% patients reduced to having no nasal congestion, 0.13% had absent nasal discharge, 24% had no nasal

itching, 21.3% showed absent sneezing and 45.3% improved with sound sleep (Table 4).

DISCUSSION

AR is a global health problem.⁷ To relieve acute signs and symptoms, antihistamines and topical steroids are usually advised along with preventive measures. However, all these drugs reduce only symptoms but may not provide long term effects. Moreover, for some of them long term usage can result in relevant adverse effects. In our study there was no particular age and gender predilections, male and female were equally effected and treated accordingly.

Topical nasal steroids are recommended as 1st line of pharmacotherapy for moderate to severe AR.⁸ Fluticasone furoate is a synthetic topical intranasal trifluorinated glucocorticoid with potent anti-inflammatory effect through inhibition of production of many different

cytokines, chemokines, enzymes and cell adhesion molecules after interaction with intracellular glucocorticoid receptors. It has low systemic exposure. It comes as an aqueous suspension of micronized FF for topical administration to nasal mucosa by means of metering, atomizing spray pump. It has high receptor affinity with low equilibrium dissociation constant ($k_d=0.3\text{mmol/l}$) when compared to other steroid sprays.³ Use of intranasal steroids causes few side effects such as dryness, stinging, burning and epistaxis.⁹ In our study, 1 patient of group A showed epistaxis after 1 month of usage in which few patients showed dryness. To overcome these side effects saline nasal irrigation can be used to relieve AR symptoms.

Several studies have been done to evaluate the efficacy of nasal irrigation and proved to be effective in conditions like acute and chronic rhinosinusitis, allergic and nonallergic rhinitis, septal perforation, post op care of surgical patients and also helps to reduce post nasal discharge, improve MCC (mucociliary clearance).¹⁰ Apart from improvement in symptoms, it also helps in reducing usage of prescribed medications.¹¹ Exact mechanism of action is not known but most experts think it's primarily a mechanical intervention leading to direct cleaning of nasal mucosa, inflammatory mediators such as PGs, leukotrienes and antigens can be removed, favouring resolution of URTIs and AR.¹¹

Numerous clinical studies have been done using the different tonicities of sodium chloride solution for nasal irrigation. Isotonic saline has been shown to be more effective with least side effects compared to hypertonic and hypotonic saline. Yov et al showed that hypertonic saline (1 ml) 3 times/day for 1 month was associated with side effects due to local irritation of swollen, inflamed mucosa along with burning and itching sensation and also pain (Baraniuk et al).^{12,13} However, studies carried on adults have shown distribution of solution in nasal and sinus cavities to be more exhaustive with positive pressure than with negative pressure, nebulization or spray. To maximize efficacy, large volume with low pressure irrigation is preferred over low volume high pressure irrigation. Regarding devices, irrigation of nasal cavities and PNS is best achieved by compressible douching systems-good connection to nostril, a possible insertion into nasal cavity and irrigation stream directed upwards.¹⁴ In our study, we advised patients (group C) first nasal irrigation followed by intranasal steroid spray.

Fernandes et al compared the effect of corticosteroid nasal spray and isotonic saline nasal irrigation in 40 children with AR and the efficacy was measured through PNIF and clinical score.¹⁵ In contrast to our study, only nasal irrigation and intranasal steroid spray alone was marginally effective than compared to combination therapy.

In our study, 25 patients in group C showed significant improvement in quality of life with reduction of

symptoms using combination therapy, compared to group A and group B patients (Figure 1 and 2). The same result was shown in a study by Chen et al where comparison of nasal corticosteroids, nasal irrigation and a combination of nasal steroids and nasal irrigation was done. According to which, combination therapy was the most effective, but nasal irrigation alone was less effective than corticosteroids alone.

Limitations

The only limitation in our study would be a limited follow up period of 1 month. The emergence of COVID-19 pandemic and its consequences did affect our study in many ways, despite which we believe we could do justice.

CONCLUSION

The combined use of saline nasal irrigation along with intranasal corticosteroids is found to be more effective in reducing the symptoms of patients with allergic rhinitis when compared to individual therapies. The side effects of the individual therapies gets negated while there is an additive effect on the benefits with use of this combination therapy.

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