A Study of Allergic Rhinitis with Special Reference to Use of Intranasal Corticosteroid in Its Treatment in a Tertiary Care Hospital

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ABSTRACT

BACKGROUND

Allergic rhinitis is a fairly common condition. A large number of patients of allergic rhinitis are usually found in daily ENT practice. Symptoms of allergic rhinitis are still a major problem, which can affect day to day activities of an individual. Intranasal corticosteroid has potent anti-inflammatory actions and is believed to exert its beneficial effects by inhibiting several types of cells and chemicals involved in immune and inflammatory responses. Present study determines the efficacy of intra nasal corticosteroid over placebo in patients of allergic rhinitis.

METHODS

A single blinded non-randomised trial was conducted among patients attending allergy clinic of ENT out-patient department of a Tertiary Medical College & Hospital of West Bengal, India from March 2008 to May 2008. Two groups of patients were selected from the total sample size of 100 patients by alternate sampling technique. One group (Gr-F) was treated by intranasal corticosteroid (fluticasone nasal spray) and the other group (Gr-P) by placebo (normal saline aqueous spray) for 6 consecutive weeks. Patients were asked about their subjective feeling of symptoms and relevant examinations & investigations were carried out. Improvements following treatment were judged by total nasal symptoms scoring. Collected data were analysed using SPSS version 20. McNemar's test was carried out on paired nominal data and p value of < 0.05 was considered to be statistically significant.

RESULTS

The present study revealed that 69 % male and 31 % female were suffering from allergic rhinitis. Most common symptom was nasal discharge followed by sneezing and nasal obstruction. 41 % had family history of allergic rhinitis. It was seen that inflamed nasal mucosa reverts back to normal in 35 % in fluticasone group after 6 weeks of treatment. Study also showed the decrease of blood eosinophil count in 60 % of patients in fluticasone group. 92 % of patients in the fluticasone group revealed that they improved after taking the drug, whereas 88 % of patients in placebo group did not improve after taking spray.

CONCLUSIONS

It can be concluded from the present study that intra nasal corticosteroid spray is more effective than placebo for treatment of allergic rhinitis.

KEYWORDS

Allergic Rhinitis, Intranasal, Fluticasone, Corticosteroid, Normal Saline, Efficacy

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BACKGROUND

Allergic rhinitis is a fairly common condition. Otorhinolaryngologists examine a relatively large number of patients of allergic rhinitis in daily ENT practice. Allergic rhinitis is characterised by more than one symptom like itching, nasal congestion, sneezing and rhinorrhoea.[1] The symptoms of allergic rhinitis is still a major problem not only in our country but also in Western countries having great advances in rhinology and associated immunology.[2] There are different triggering factors of allergic rhinitis like dust mites, domestic animals, outdoor allergens like pollens and moulds. Some of occupational allergens like latex, tobacco smoke, automobile exhaust also acts as additive factors in producing symptoms.[3] The result of customary treatment is very often disappointing and having various side effects. Fluticasone is a synthetic steroid of the glucocorticoid family of drugs that is used as intranasal spray for treating allergic rhinitis. Fluticasone has potent anti-inflammatory actions. It is believed that fluticasone exerts its beneficial effects by inhibiting several types of cells and chemicals involved in allergic, immune and inflammatory responses.[4] Successful studies of various research workers revealed varied proportion of efficacy of intranasal corticosteroid. Hence, the current study was performed to re-establish any beneficial effect of intranasal corticosteroid (fluticasone here) in the treatment of allergic rhinitis in our tropical atmosphere.

METHODS

A single blinded non-randomised trial was conducted among patients attending allergy clinic of ENT Out-Patient Department of a Tertiary Medical College & Hospital, Kolkata, West Bengal, India from March 2008 to May 2008. Prior institutional ethical clearance was taken. Patients who were willing to give informed verbal consent were included in the study. Patients suffering from vasomotor rhinitis, infectious rhinitis, hormonal rhinitis, drug induced rhinitis and rhinitis with polyp, were excluded from the study. Everyday first 10 patients belonging to the age group > 12 years, presenting with symptoms of allergic rhinitis in the allergy clinic, fulfilling the inclusion and exclusion criteria were selected as study sample. Thus the total sample size reached into 110 during the specified time period. Two groups of patients were selected from the total sample size by alternate sampling technique. One group (Gr-F) of the patient was treated by intranasal corticosteroid spray or INCS (fluticasone propionate nasal spray) for 6 consecutive weeks. Another Group (Gr-P) was treated for same duration by placebo (normal saline aqueous spray). Patients did not take any other medicine during the course of study. Among them 10 patients (5 from each group) were lost to follow up. Hence, the final sample size reached into 100 (50 in each group).

Patients were reviewed weekly for the presence of signs and symptoms, which was noted down in predesigned proforma. Routine blood examination and absolute blood eosinophil count was done in every patient. The nasal airway of each patient was measured by Clement Clarke's in check nasal inspiratory flow meter. Nasal endoscopy was performed in all cases. Nasal cytology was performed by taking nasal mucous secretion and eosinophil count in percentage was done initially before starting the treatment and after 6 weeks. Improvements following treatment were judged by total nasal symptoms scoring.

Grading of Symptoms

None: 0; Occasional: 1; Intermittent: 2; Constant: 3.

The patients were asked about their subjective feeling of symptoms and scores were plotted accordingly. Collected data were analysed using SPSS version 20. Descriptive statistics were performed to express proportions. McNemar's test was carried out on paired nominal data and chi square test was performed on categorical variables. At 95 % confidence interval, p value of < 0.05 was considered statistically significant.

RESULTS

The study was conducted to determine the beneficial effect of intra nasal corticosteroid on allergic rhinitis patients if present or absent. Inclusion of the eligible study subjects from the OPD (Out-Patient Department) and patients fulfilling the stated criteria was started on March 2008 and it has been continued till desired sample size has been reached. A total of 100 patients were selected for the study with symptoms of allergic rhinitis. The present study revealed that 69 % were male whereas 31 % patients were female. Male: Female ratio is 2.23:1. Maximum study participants were in the age group of 26 to 35 years (38 %), followed by 25 % in between 16 to 25 years. It has been revealed that most common symptom was nasal discharge (75 %) followed by sneezing (58 %). On nasal endoscopy most common finding was pale nasal mucosa (75 %) followed by turbinate hypertrophy (65 %). Positive family history of allergic rhinitis was noted in 41 % of study participants.

Table 1 revealed that, improvement of major symptoms like nasal discharge, nasal obstruction, nasal itching and sneezing were found to be statistically significant ($p < 0.05$) in fluticasone group compared to placebo group.

Table 2 revealed that, nasal mucosa changed into its normal colour in 35 patients in fluticasone group after 6 weeks of intake of nasal spray, whereas only 2 patients in placebo group showed similar improvement. Conjunctival congestion was dramatically normal in 14 patients out of 16 in fluticasone group, which was statistically significant ($p < 0.05$).

	Nasal Discharge (N = 75)		McNemar Value	Nasal Obstruction (N = 55)		McNemar Value	Nasal Itching (N = 34)		McNemar Value	Sneezing (N = 58)		McNemar Value
	F (N = 40)	P (N = 35)		F (N = 30)	P (N = 25)		F (N = 20)	P (N = 14)		F (N = 30)	P (N = 28)	
YES	38	10	χ^2 = 19.59 P = 0.000	28	10	χ^2 = 9.94 P = 0.001	20	5	χ^2 =9.09 P=0.002	30	3	χ^2 = 25.00 P = 0.000
NO	2	25		2	15		0	9		0	25	

Table 1. Comparison of Improvement of Major Symptoms in Both Groups

F: Patients taking Fluticasone Propionate Nasal Spray
P: Patients taking Normal Saline Nasal Spray

	Pale Nasal Mucosa (N = 75)		McNemar Value	Mucoid Nasal Discharge (N = 60)		McNemar Value	Polypoidal Change in Turbinates (N = 35)		McNemar Value	Conjunctival Congestion (N = 32)		McNemar Value
	(F) (N=40)	(P) (N=35)		(F) (N = 30)	(P) (N = 30)		(F) (N = 20)	(P) (N = 15)		(F) (N = 16)	(P) (N = 16)	
YES	35	2	χ^2=20.63 P = 0.000	28	3	χ^2 =21.55 P = 0.000	11	0	χ^2 =2.13 P = 0.144	14	1	χ^2 =9.94 P = 0.001
NO	5	33		2	27		8	15		2	15	

Table 2. Comparison of Improvement of Major Signs in Both Groups

F: Patients taking Fluticasone propionate nasal spray
P: Patients taking Normal saline nasal spray

Clement Clarke in-check nasal hand-held flow meter provides objective assessment of nasal airway patency. It was used in the present study to measure the Peak Nasal Inspiratory Flow rate (PNIFR). It was measured every week. Normal value is > 100 – 300 L / min. Initial data and at the end data were plotted in the following table [Table 3] and comparison made between two groups. Table 3 shows that patients of F-group having serial improvement in nasal airflow obstruction, whereas in P-group, nasal obstruction deteriorates from initial status and the difference was found to be statistically significant.

	< 50 L /min		McNemar Value	51-80 L /min		McNemar Value	81-100 L / min		McNemar value	> 100 L / min		McNemar Value
	F	P		F	P		F	P		F	P	
Initial	10	5	χ^2 =3.60, P = 0.057	14	25	χ2 = 16.95 P = 0.000	20	15	χ^2 =10.66 P = 0.001	6	5	χ^2 =11.83 P = 0.000
End	2	8		8	35		20	4		20	3	

Table 3. Comparison of Nasal Airflow Improvement between the Two Groups before and after Treatment

F: Patients taking Fluticasone Propionate Nasal Spray
P: Patients taking Normal Saline Nasal Spray

Study revealed that 65 % patients were having absolute blood eosinophil count level in between 441 - 540 cells / cu mm. After six weeks of treatment when it was repeated 46 % showed improvement in fluticasone group compared to placebo. Nasal cytology showed a decrease in eosinophil count & was seen in 60 percent of patients in F–group compared to placebo group where 50 percent showed no change which is statistically significant ($p < 0.05$).

Response	F-Group (N = 50)	P-Group (N = 50)	Chi Square Test
Unsatisfactory	4	44	χ^2=60.94, df= 1, p=0.000
Satisfactory	20	6	
Excellent	26	0	

Table 4. Distribution of Patients According to Subjective Improvement

F: Patients taking Fluticasone propionate nasal spray
P: Patients taking Normal saline nasal spray

That most common side effect in fluticasone group was dryness of nose only seen in 8 % of study population in this study followed by irritation in nose and sore throat (7 %). Bleeding from nose occurred in one patient from a small ulcer which was present in nasal septum. At the end of the study patients were asked of feeling of improvement of their disease symptoms.

Table 4 shows that 92 % of patients in the fluticasone group feels that they improved after taking the drug, whereas 88 % of patients in placebo group feels they did not improves at all after taking spray. Four patients in the fluticasone group were dissatisfied with the outcome, probably they presented with acute symptoms where alone fluticasone is not so much of active drug ($p < 0.05$).

DISCUSSION

Treatment of allergic rhinitis is one of the major challenges in daily ENT practice. Among the intranasal corticosteroids, fluticasone spray was selected for this study as it was claimed to be reasonably effective and having little side effect in the treatment of allergic rhinitis. In this current study intranasal administration of corticosteroid was carried out in a group of well selected cases of allergic rhinitis. The results were analysed to re-establish any beneficial effect of the drug.

In the present study 63 % patients were in between 16 - 35 years of age and 69 % were male in respect to 31 % female. Similar findings were reported by S.P.S. Yadav et al in Rohtak, Haryana, where allergic rhinitis prevalence found more in male (62 percent) than in females and maximum incidence found in 2nd and 3rd decade of life.[5] A study performed in Finland by Huovinen et al (1999)[6] the prevalence of allergic rhinitis was found to be more in females. This did not conform to the findings of the current study. The probable reason might be that, many female in West Bengal spend most of their time indoor and therefore are less exposed to allergen like pollen, air pollutants. Most common symptom was watery nasal discharge which was present in 75 % of the patients followed by sneezing in our study. This observation is persistent with the findings of the study done by Sibbald and Rink in 1991.[7] Nasal blockage and catarrh were more common presenting symptoms than in

seasonal rhinitis, and diurnal variation occurred less frequently. Likewise the study done by S.P.S. Yadav et al, in the Department of Otorhinolaryngology in Rohtak, Haryana revealed similar percentage of patients with nasal discharge and sneezing.[5] In present study it was found that 75 % patients presented with pale nasal mucosa and 65 percent of patients on examination showed hypertrophied turbinates, almost similar distribution of signs were reported by workers like Clarke et al and Mygind et al, 2001.[8] In this study allergic rhinitis was more common in young adolescence age group. Family history of allergic rhinitis or atopy was present in 41 % of cases in the present study. Varghese et al (2000) observed that 60 % of patient had a family history of allergic rhinitis in his study.[9]

The symptomatic improvement between the two groups was compared first. The present study showed that the major improvement occurred in the fluticasone group patients. 76 % of patients reported with diminished nasal discharge at the end of the study, similarly 93 % improved of their nasal obstruction, all those patient who were having nasal itching and sneezing completely improved with no residual symptoms ($p < 0.05$). In placebo (normal saline spray taking) group there were improvement of sneezing and nasal itching in 10 % and 35 % respectively. 34 % reported improvement of nasal discharge and 40 % with nasal obstruction. Ratner PH noted in their study this may be due to the washing effect of regular use of normal saline spray in nasal mucosa and also due to the "placebo effect".

The proposed mechanism of aqueous saline nasal spray involves its ability to wash away inflammatory mediators, cells, and secretions in the nasal mucosa.[10] Meltzer and Schatz noted that response rates may exceed 30 % with aqueous saline nasal spray.[11] Peak inspiratory nasal flow rate improvement was compared in both groups. It was seen that major improvement of flow rate occurred in the fluticasone taking group. After six-week treatment the mean improvement of PINF in fluticasone group was 123 L / min, whereas in placebo group it was about 100 L / min which tally with the study conducted by Martin BG et al in 1996 in Sweden.[12] In the current study 86 % of the patients in fluticasone group showed decreased eosinophil count after six weeks of treatment whereas only 2 patients in placebo group showed decreased count ($p < 0.05$). Eosinophilia was detected in 75 % of cases of allergic rhinitis in present study, which is more than the range of many international studies (Druce 2003[12], Naclerio 1994[13]). Examination of nasal smear was done prior and after the treatment. Pre-treatment smear showed plenty of eosinophils in all of the cases. This confirmed the presence of allergic reaction in the nasal mucosa. Post treatment nasal smear showed decreased eosinophil count in cases which was treated with fluticasone ($p < 0.05$) but majority in placebo group did not show any decrease.

At the end of the study about 92 % patient said they were happy with the outcome of the treatment, these patients were in INCS (fluticasone) group ($p < 0.05$) rather than those in placebo group, where 88 % were dissatisfied with the results.

There were few limitations of this study. In this study nasal culture, skin prick test, nasal provocation test and antigen specific IgE test could not be done. The superior clinical efficacy of INCS compared with placebo in relieving allergic rhinitis symptoms demonstrated in the present study has also been documented previously in other studies.

CONCLUSIONS

The present study found that intra nasal corticosteroid spray is more effective than placebo for treatment of allergic rhinitis. The role of intra nasal corticosteroid in the treatment of allergic rhinitis is well established. They are proven to be efficacious and are recommended as first-line therapy for individuals with persistent moderate / severe allergic rhinitis.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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