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Treatment Outcome of Intranasal Corticosteroid with Oral Antihistamines versus Oral Antihistamines Alone In Allergic Rhinitis.

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ABSTRACT

Background: Allergic rhinitis is one of the most common diseases affecting globally. The burden of this disease is huge, causing sickness absenteeism at school and workplace, dependence on medication, and suboptimal work performance by the affected population. The objective of this study is to compare the treatment outcome when intranasal corticosteroids administered along with oral antihistamines and leukotriene receptor antagonists versus oral antihistamines and leukotriene receptor antagonists alone. **Methods:** This is a single blinded prospective study from October 2015 to December 2016 performed at M.K.C.G Medical College, Berhampur. Diagnosis of allergic rhinitis was made from SFAR (score for allergic rhinitis) and skin prick test. The data was subjected to $\chi 2$ test and p values were obtained to see the difference between the control and study groups. **Results:** The combination of intranasal corticosteroids and oral antihistamines and LRA produced significantly greater relief than oral antihistamines and LRA alone. For nasal symptoms, mean score after 6 months was 6.8 with antihistamines+ LRA compared to a mean score of 4.1 when these medication given along with INS (p value =0.01). There was not much significant difference in eye symptoms. **Conclusion:** The results of this study support the use of intranasal corticosteroids in combination with oral antihistamines over oral antihistamines alone, in allergic rhinitis.

Keywords: Allergic rhinitis, antihistamines, leukotriene receptor antagonists, intra nasal corticosteroids.

INTRODUCTION

Allergic rhinitis is one of the most common chronic nasal diseases affecting about 10% to 25 % of the world population.[1,2] The prevalence appears to be increasing.[3] The burden of this disease is huge, causing sickness absenteeism at school and workplace,[4] dependence on medication, and suboptimal work performance by the affected population. It is an IgE mediated inflammation of the lining membranes of the nose, and is characterized by nasal congestion, rhinorrhea, sneezing, itching of the nose and/or post-nasal discharge.[5]

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It is regarded as a trivial disease not only in India but the worldwide prevalence is underestimated too. Allergic rhinitis patient have annoying symptoms, such as nasal symptoms (obstruction, rhinnorhea, itching, sneezing) and eye discomfort (itching and watering), and are bothered by concomitant symptoms such as headaches ,thirst, sleep disorders, fatigue and cognitive impairment.[6] Allergic rhinitis usually accompanies some syndromes or diseases, including acute or chronic rhinosinusitis, nasal polyps, otitis media with effusion and hearing impairment.[7] It is a potential risk factor for the orbital complications of acute rhinosinusitis, especially in children.[8] It is widely acknowledged that the condition can also cause irritability and impaired sleep which can affect quality of life by leading to poor performance at school or work,[9,10] absenteeism from school or work, and chronic tiredness.[11] Allergic rhinitis can also have detrimental effects on emotional and social wellbeing.[8,12]

Treatment of allergic rhinitis includes avoiding allergens (when possible), intranasal corticosteroids, short term decongestants, oral or topical H1 receptor antagonists (antihistamines), leukotriene receptor antagonists, intranasal cromoglycate, anticholinergic agents, and allergen immunotherapy.[13] Topical intranasal corticosteroids are said to be more effective than oral antihistamines in controlling nasal blockage and discharge.[12,14] Furthermore, oral

antihistamines are said to be better at treating nasal itch, sneezing, and eye symptoms.[12,14] The objective of this study is to compare the treatment outcome when intranasal corticosteroids administered along with oral antihistamines and leukotriene receptor antagonists versus oral antihistamines and leukotriene receptor antagonists alone.

MATERIALS AND METHOD

The present study was performed from October 2015 to December 2016 at the outpatient department of the M.K.C.G Medical College, Berhampur. It was approved by the ethical committee in M.K.C.G Medical College, Berhampur University. Diagnosis of allergic rhinitis was made by signs and symptoms according to the SFAR score (Score for Allergic Rhinitis) and Skin Prick Test was considered as the gold standard for diagnosis. The study was a single blinded study. Each outpatient filled in a questionnaire containing items on nasal problems and related features as in [Appendix-I] and was then examined by another clinician who was blinded to the answers of the questionnaire. The blind clinician then prescribed SPT to major allergens when he/she thought that it was necessary to ascertain atopic status of the outpatient. Standard aeroallergens were used to this end.

Each outpatient was also asked to report the severity of each symptom of allergic rhinitis in a range of 0-3 as in [Appendix–II] for the calculation of baseline symptom score of each individual symptom to assess the intensity of the symptoms which affect the patients' quality of life.[14]

Inclusion Criteria

1. Patients willing to participate in the study.

Exclusion Criteria

1. Patients having nasal polyp.
2. Patients with SFAR score <7.
3. Patients with SPT negative.

SFAR Score[15]

The epidemiological questionnaire on nasal problems [Appendix-I] included the following items as established by the panel of specialists in order to construct the quantitative score for AR, the SFAR:

1. Nasal symptoms in the past year, including sneezing, runny nose, and blocked nose when the subject did not have a cold or 'flu', in the past year;
2. Nasal symptoms accompanied by itchy-watery eyes (rhino-conjunctivitis);
3. Months of the year in which nasal symptoms occur. Seasonal(pollen season) vs. perennial rhinitis could then be assessed according to the pollen calendar of each region;
4. Triggers of nasal symptoms including pollens, house dust mites, house dust;
5. Perceived allergic status;
6. Previous medical diagnosis of allergy;
7. Previous positive tests of allergy;
8. Familial history of allergy.

For each outpatient, the SFAR based on the number of points made in the questionnaire was then set. The SFAR ranged between 0 and 16.[15]

Patients having SFAR score ≥7 were clinically diagnosed as AR positive following which they were subjected to skin prick test. Patients having both AR+ and SPT+ were divided into two equal groups .We treated one group with a combination of intranasal steroids and leukotriene receptor antagonists+ antihistamines and the other group was subjected to leukotriene receptor antagonists+ antihistamines. The outcome of each patient was followed up after 1 month and at the end of 6 months.

Statistical Analysis

For the purpose of statistical analysis the outcomes were analyzed as standardized mean differences by entering the data into SPSS software. The standardized mean difference is a statistic which expresses the difference in means between corticosteroid groups and control groups after treatment in units of the pooled SD. Symptom scores were calculated as per the self-reporting of patients. The data was subjected to $\chi 2$ test and p values were obtained to see the statistical difference between the control and study groups.

RESULTS

112 males and 38 females participated in the hospital study. The mean age 42, lowest being 18 yrs, the oldest being 56 yrs with a mean age of 42.0+/-9.43yrs. Main occupations were farmers (48.0%), teachers (30.6%), students (10.6%), clerks (10.6%) and technicians. The distribution of each item in these outpatients and baseline symptom score is shown in [Table 1 & 2].

Table 1: Age and Sex Distribution.

Age Group in Yrs.	Male		Female		Total	
	No.	%	No.	%	No.	%
15 - 30 Yrs.	24	21.4	06	15.8	30	20
31 - 45 Yrs.	48	42.8	20	52.6	68	45.3
46 - 60 Yrs.	40	35.7	12	31.6	52	34.7
Mean			42.0			
SD			9.43			
Median			45.0			
Min to Max			18 to 56			

Table 2: Baseline Symptom score.

Score	Sneezing	Running Nose	Nasal Itching	Nasal Obstruction	Watering Eyes	Itchy Eye
Mean	2.32	2.44	2.12	2.52	1.92	2.16
SD	0 .78	0.80	0.91	0.85	0.84	0.83
Median	2.0	3.0	2.0	3.0	2.0	2.0
Min to Max	0 to 3	0 to 3	0 to 3	0 to 3	0 to 3	0 to 3

Out of the initial 150 individuals, 134 (89.33%) of the subjects had both a clinical diagnosis of AR and positive SPT test; and 16 (10.67%) were diagnosed as suffering from AR but had negative SPT.

Out of 134 patients two groups of 67 patients each were divided and group 1 was subjected to intranasal steroid with antiH1+LRA and group 2 was given only antiH1+LRA and a baseline score was noted. The baseline scores of the outpatient on commencement of treatment was reviewed after 1 month and 6months of treatment by keeping the triggering factors in the questionnaire [Appendix-I] a constant in the next two visits to compare the treatment outcome of the two drug combinations.

Intranasal corticosteroids with antihistamines+ LRA produce significantly greater relief of nasal discharge than did oral antihistamines+ LRA alone (p=0.001). Intranasal corticosteroids with antihistamines+ LRA were also more effective in relieving sneezing. For nasal itch too, combination with intra-nasal corticosteroids produced significantly greater relief of itch than did oral antihistamines alone (p=0.005). Overall, the combination with intranasal corticosteroids produced significantly greater relief of total nasal symptoms score than did oral antihistamines (p=0.0011). The mean score after 6 months of treatment with intranasal steroids along with antiH1 and LRA for nasal symptoms came down to 10.38 to 4.1 in comparison to anti H1+LRA alone 10.38 to 6.8.(χ2=71.6,p=0.001) [Table 3].

Table 3: Comparison of Antihistamines with Leukotriene Antagonists against Corticosteroids in terms of Nasal Symptoms.

Nasal Symptoms	Baseline mean score on arrival	Mean score after 1 month	Mean score after 6 months	χ2test
Antihistamines+ LRA	10.38	7.6	6.8	χ2=71.6 p=0.001
Antihistamines+ LRA+ INS	10.38	5.4	4.1	

There was not much significant difference between eye symptoms of the two groups individually. Similar difference was noted in the nasal symptoms with eye score of outpatients as depicted in Table 4.

Table 4: Comparison of Antihistamines with Leukotriene Antagonists against Corticosteroids in terms of Nasal Symptoms and Eye Symptoms.

Nasal Symptoms +Eye Symptoms	Baseline mean score on arrival	Mean score after 1 month	Mean score after 6 months	χ2test
Antihistamines +LRA	12.40	8.4	7.4	χ2=42.65 p=0.005
Antihistamines +LRA+INS	12.40	7.0	5.8	

Appendix I: Self-completed questionnaire, attributed score and repartition of the item for the Score for Allergic Rhinitis (SFAR).

Items/discriminators	Score (points) attributed by experts	Cumulate score
Blocked nose, runny nose, sneezing in past year (nasal symptoms)	1 for each symptom	3
Months of the year	1 for perennial 1 for pollen season	5
Nasal symptoms plus itchy eyes (rhinoconjunctivius)	2	7
Triggers:'		
Pollens, house dust mites, dust	2	
Epithelia (cat dog)	1	9
Perceived allergic status	2	11
Previouspositive allergic tests	2	13
Previous Medical Diagnosis of allergy	1	14
Familial History of Allergy	2	16
Total points		16

Appendix II: TNSS [Table 1] Symptom score definitions.

Score	Grade	Guideline
0	None	No sign/symptom is evident
1	Mild	Sign/symptom clearly present,but minimal awareness;easily tolerated
2	Moderate	Definite awareness of sign/symptom that is bothersome,but tolerable
3	Severe	Sign/symptom that is hard to tolerate ; causes interference with activities during the challenge session

DISCUSSION

This is a single blinded prospective study done to find out the better treatment option in the management of allergic rhinitis as it is a disease which incapacitates the quality of life. The study showed significant difference in the symptom score at the end of 6 months when treated with a combination of intranasal corticosteroids and antihistamines as compared to the group which was treated with only oral antihistamines. Compared to all the other existing instruments, the SFAR used here has two advantages.[15] From the methodological point of view, the SFAR is a quantitative score, thus more informative than the other unidimensional instruments usually employed. This meant that better sensitivity, specificity and predictive values were obtained than with other instruments were obtained in ascertaining individuals suffering from AR.[15] The SFAR has a higher positive predictive value, higher sensitivity and specificity than the ISAAC questionnaire on rhinitis.[6,15]

Reporting in detail the months in which nasal symptoms occurred has not been shown to provide much better information because of recall bias. Actually, individuals are prone to report that nasal symptoms occurred in months of the year closer to

the period of the survey in Southern Odisha Coast. That is why we did not use the SFAR to discriminate between seasonal and perennial rhinitis. However, this could be done after further implementation and development of specific questions. More relevant information on the variety of AR can be obtained by considering the allergens to which the individual is sensitized which was difficult to obtain in our study.

According to systematic review studies done by John M Weiner, Michael J Abramson, Robert M Puy in Australia,[14] 16 randomised controlled trials that met that inclusion criteria were observed. The meta-analysis of these evaluable trials confirmed that intranasal corticosteroids were significantly more effective at relieving nasal blockage, discharge and itch and post nasal drip than were oral antihistamines. Intranasal steroids were also more effective in relieving sneezing and reducing total nasal symptoms. Intranasal corticosteroids are considered safe. Local adverse effects are usually mild (mucosal irritation, epistaxis), and nasal septal perforation is exceptionally rare.[14]

CONCLUSION

In this study, we have used SFAR score to assess the clinical status of allergic rhinitis and to arrive at a particular diagnosis. SFAR score is an easy tool to diagnose allergic rhinitis and determine its prevalence in a few minutes. The outcome of combination of intranasal corticosteroids with antihistamines and leukotriene receptor antagonists proved to be a better treatment option in terms of nasal symptoms and quality of life improvement in patients with allergic rhinitis.

Abbreviations

INS- Intranasal corticosteroid
LRA- Leukotriene Receptor Antagonists
SD- Standard Deviation
SFAR - Score For Allergic Rhinitis
AR- Allergic Rhinitis
Anti H1- H1 receptor antagonists(antihistamines)
SPT- Skin Prick Test
TNSS- Total Nasal Symptom Score

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