Original article:

Study of effectiveness of treatment options in patients of Allergic Rhinitis

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ABSTRACT

Background: Allergic rhinitis is defined clinically by IgE mediated hypersensitivity disease of mucous membrane of nasal airways Allergic rhinitis is classified worldwide according to ARIA (allergic rhinitis and its impact on asthma) guidelines into. Mild ,Intermittent symptoms ,Moderate to severe one or more persistent symptoms.

Aims and objectives of the study were to determine the effectiveness of nasal decongestants, antihistamines and steroids in allergic rhinitis to know outcome of treatment of patients of allergic rhini**tis.**

Methodology: Source of Data was patients attending ENT OPD at a tertiary care centre . 50 patients were included in the study were diagnosed clinically with typical symptoms and signs of allergic rhinitis according to ARIA(Allergic rhinitis and its impact on asthma) guidelines. Patients were divided into five groups depending upon drugs given to them. Groups were made randomly. Three drugs taken in this study were Antihistamines, Nasal decongestants, Nasal corticosteroids.

Conclusion: The Intranasal corticosteroids were superior to other drugs as a monotherapy while intranasal steroids with an antihistamine were effective as combination therapy

Key words : Nasal steroids ,decongestants

INTRODUCTION

Allergic rhinitis is defined clinically by IgE mediated hypersensitivity disease of mucous membrane of nasal airways characterized by combination of two or more nasal symptoms: Running of nose; blocking of nose; itching of nose; and sneezing following exposure to allergy.[1] In India 20% of patients i.e. 1 in 5 patients in ENT OPD comes with symptoms similar to allergic rhinitis[2.] . Pollens, herbs, Molds etc. were held to be major culprits of allergic rhinitis in old days i.e. spectrum was restricted to vegetative forms of allergen.[3] Several studies support hygiene hypothesis. These include reduced seasonal allergic rhinitis and allergic sensitization in farmer's children compared to their peers in non-farming family.[4]

Allergic rhinitis is classified worldwide according to ARIA (allergic rhinitis and its impact on asthma) guidelines into.[5]

1. Mild
2. Intermittent symptoms
3. Moderate to severe one or more items
4. Persistent symptoms

In general total serum IgE and eosinophil count are high in allergic diseases.[6,7]

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Present study is an attempt to study treatment profile in the cases of allergic rhinitis.

AIMS AND OBJECTIVES

1. To determine the effectiveness of nasal decongestants, antihistamines and steroids in allergic rhinitis
2. To know outcome of treatment of patients of allergic rhinitis

MATERIALS AND METHODS

Source of Data – Patients attending ENT OPD at a tertiary care centre

Inclusion criteria:

- Sneezing
- Itching sensation in nose
- Watery discharge from nose
- Nasal obstruction .

Exclusion Criteria

- Grossly deviated nasal septum, nasal polyps, tumors.
- Patient requiring surgical management
- Use of any drug (That are used in study i.e. Antihistamines, oral corticosteroids, nasal corticosteroids, Nasal decongestants within last 30 days of entry visit),
- Any disease or surgery known to affect gastrointestinal absorption of drugs.

50 patients were included in the study were diagnosed clinically with typical symptoms and signs of allergic rhinitis according to ARIA(Allergic rhinitis and its impact on asthma) guidelines. Eligible subjects were identified by screening questionnaire designed to identify those with allergic rhinitis. Subjects were asked, Does any of the following symptoms cause you trouble when you do not have a cold or the flu: sneezing/running nose/blocked nose? If any response was “yes” subjects were asked, for how many years you have had these symptoms. Subjects were then asked to state whether symptoms were seasonal or perennial, and to rate the overall severity of their condition.

Patients were divided into five groups depending upon drugs given to them. Groups were made randomly. Three drugs taken in this study were Antihistamines, Nasal decongestants, Nasal corticosteroids. Groups made as follows, 10 patients per group included randomly.

Efficacy of each drug was assessed during weekly follow ups by relief of symptoms. Group ll drug i.e. oxymetazoline could not be given for more than two weeks due to risk of developing rhinitis medicamentosa, however duration after which rhinitis medicamentosa would appear is not fixed it can be given from three days to two weeks. Decongestants should be discontinued as soon as the symptom appear, hence in this study we have given topical decongestants for two weeks with close weekly follow up and after two weeks we shifted the patients on alkaline saline nasal drops. After giving saline nasal drops for two weeks we again shifted patients on nasal decongestants. Base line symptom scores were recorded in a diary forms which were provided to the subjects and they were asked to maintain it throughout the study period of 6 weeks. At each visit patients were asked to rate the severity of their nasal symptoms called Nasal symptom score (sneezing, itching, rhinorrhoea, obstruction) ocular symptom score (itchy eyes, watering of eyes) over previous seven days on four point scale for each of their symptom. Patients were asked to note down any side effects during treatment on back of the form.

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Symptom evaluation scale	Description	Definition
0	Absent	No symptom
1	Mild	Symptom presents but does not bother patient.
2	Moderate	Symptom moderate but patient can perform routine activity with Normal sleep.
3	Severe	Severe symptom cannot perform routine activities interferes with sleep

On the basis of above scale nasal and eye symptom score calculated, documented and studied. With the help of ANOVA (analysis of variance) test, efficacy of all the groups of treatment was studied for treating every symptom

OBSERVATION AND RESULTS

Study Design:

Prospective type of study, consisting of 50 patients is under taken to study and compare effectiveness of antihistamines, nasal decongestants, topical corticosteroids and combinations of these drugs in allergic rhinitis patients.

AGE DISTRIBUTION

AGE IN YRS	NUMBER	PERCENTAGE
10-20	9	18%
21-30	19	38%
31-40	11	22%
41-50	7	14%
51-60	1	2%
61-70	2	4%

SEX DISTRIBUTION

SEX	NUMBER	PERCENTAGE
FEMALE	12	24%
MALE	38	76%

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TOTAL SYMPTOM SCORE

	Group 1	**Group2**	**Group3**	**Group4**	**Group5**
Bt Mean Symptom Score	8.8	7.6	10	9.9	11
At Mean Symptom Score	5.4	5.8	5.8	5.9	4
Mean Difference In Sd	1.5	0.7	0.7	0.1	0.3
% Mean Change In Tss	38.8%	29.4%	43.7%	40%	63.5%
P Value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Anova Test Applied P Value <0.0001 , Ss , F Value 7.821					

TOTAL SYMPTOM SCORE

GROUP I

		Rhinor-rhoea	**Nasal obstruction**	**Sneezing**	**Lacrima-tion**	**Itching of eyes**
Before Treatment	Total	28	10	27	16	7
	Mean	2.8	1	2.7	1.6	0.7
	SD	0.42	1.41	0.674	1.26	1.059
	SE	0.132	0.446	0.213	0.398	0.335
	CI	3.064 - 2.5	1.89 - 0.108	3.12 – 2.27	2.39 -0.804	1.37 -0.03
After Treatment	Total	15	7	16	14	2
	Mean	1.5	0.7	1.6	1.4	0.2
	SD	1.08	0.82	1.17	1.07	0.42
	SE	0.341	0.259	0.370	0.338	0.132
	CI	2.18 -0.81	1.218 -0.182	2.34 -0.86	2.07 – 0.72	0.46 -0.06
	P Value	0.003 SS	0.27 NS	0.02 SS	0.16 NS	0.09 NS

Change in symptom scores compared with each other by applying ANOVA test

P VALUE 0.01, Statistically significant, F VALUE 0.74

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GROUP II

		Rhinorrhoea	**Nasal obstruction**	**Sneezing**	**Lacri-mation**	**Itching of eyes**
Before Treatment	Total	27	11	25	7	6
	Mean	2.7	1.1	2.5	0.7	0.6
	SD	0.67	1.28	0.7	1.59	1.26
	SE	0.212	0.40	0.22	0.50	0.398
	CI	1.12 – 0.276	1.9 – 0.3	2.94 – 2.06	1.7 – 0.3	2.05 – 0.46
After Treatment	Total	21	4	23	4	6
	Mean	2.1	0.4	2.3	0.4	0.6
	SD	0.99	0.69	1.49	0.84	1.26
	SE	0.313	0.218	0.47	0.265	0.398
	CI	2.7 – 1.47	0.83 – 0.03	3.24 – 1.36	0.93 – 0.13	1.39 – 0.19
	P VALUE	0.023 SS	0.02 SS	0.05 NS	0.34 NS	0 NS

P Value 0.002, Statistically Significant, F Value 0.67

GROUP III

		Rhinorr-hoea	**Nasal obstruction**	**Sneezing**	**Lacrima-tion**	**Itching of eyes**
Before Treatment	Total	26	11	25	24	18
	Mean	2.6	1.1	2.5	2.4	1.8
	SD	0.69	1.49	0.84	0.69	1.31
	SE	0.218	0.471	0.265	0.218	0.414
	CI	3.036 -2.16	1.51-0.63	3.03 – 1.97	2.83 – 1.96	2.62 – 0.97
After Treatment	Total	10	2	9	21	16
	Mean	1	0.2	0.9	2.1	1.6
	SD	0.66	0.44	0.73	0.56	1.26
	SE	0.208	0.139	0.231	0.177	0.398
	CI	1.41 – 0.58	0.478 – 0.078	1.36 – 0.43	2.45 – 1.74	2.39 – 0.80
	P Value	0.001 SS	0.54 NS	0.001 SS	0.08 NS	0.16 NS

P Value 0.19, Not Significant, F Value 0.33

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GROUP IV

		Rhinorr-hoea	**Nasal obstruction**	**Sneezing**	**Lacrima-tion**	**Itching of eyes**
Before Treatment	Total	27	14	26	15	17
	Mean	2.7	1.4	2.6	1.5	1.7
	SD	0.67	1.5	0.51	1.35	1.25
	SE	0.212	0.474	0.16	0.427	0.395
	CI	3.12 – 2.27	2.34 – 0.45	2.92 – 2.28	2.35 – 0.64	2.49-0.91
After Treatment	Total	16	7	13	12	11
	Mean	1.6	0.7	1.3	1.2	1.1
	SD	0.69	0.82	0.82	1.03	0.99
	SE	0.218	0.259	0.259	0.325	0.313
	CI	2.036 – 1.16	1.21 – 0.18	1.81 -0.78	1.85 – 0.55	1.7 – 0.48
	P Value	0.01 SS	0.02 SS	0.001 SS	0.08 NS	0.005 SS

P Value 0.28, Not Significant, F Value 0.193

GROUP V

		Rhinorr-hoea	**Nasal obstruction**	**Sneezing**	**Lacrima-tion**	**Itching of eyes**
Before Treatment	Total	27	20	27	19	17
	Mean	2.7	2	2.7	1.9	1.7
	SD	0.46	1.05	0.67	0.99	1.15
	SE	0.145	0.39	0.21	0.313	0.363
	CI	2.99 - 2.41	2.78 -1.22	3.12 – 2.28	2.526-1.274	2.426-0.97
After Treatment	Total	8	4	3	12	13
	Mean	0.8	0.4	0.3	1.2	1.3
	SD	0.42	0.69	0.48	0.63	0.94
	SE	0.132	0.218	0.157	0.199	0.297
	CI	1.064-0.536	0.836-(-0.036)	0.61-(0.01)	1.598-0.802	1.894-0.70
	P Value	<0.05 SS	<0.05 SS	<0.05 SS	<0.05 SS	<0.05 SS

P Value 0.81 Not Significant, F Value 0.031

- All the groups were effective significantly in treating rhinorrhoea.
- Nasal obstruction was significantly treated by Group l, ll & V.

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- Sneezing was significantly treated by Group l, lll, lV & V.
- Lacrimation was significantly treated by Group V only.
- Itching of eyes was significantly treated by Group lV.

Adverse effects noted with Group ll were rebound nasal congestion and early mucosal changes of rhinitis medicamentosa found in one patient at the end of two weeks who was shifted to nasal steroids

DISCUSSION

Levocetrizine was effective significantly in relieving rhinorrhoea with P value 0.003 which is statistically significant. This was in accordance with following studies. In a study conducted by Ciprandi G, Cirillo I, Vizzaccaro A, Sca MA (2004).[8] It was found that levocetrizine treatment induced significant symptoms relief (p 0.00009). In another study by Leynadier F, Mees K Arend T C, Pinelli M E (2001)[9] found that Levocetrizine was found to be significant and Superior to placebo in reducing the mean total symptom score over the 2 weeks (P=0.001). In another study by L. Klimek and Z Hundarf (2002)[10] on average 80-90% of all patients with allergic disease were observed to be symptoms free or have a marked improvement in symptoms at the final examination.

Mean total change in symptom score was 38.8% statistically significant in our study.It is well correlated with study conducted by R. Boev, D. Song, A Beddebaugh, J. M. Haeusler(2011).[11] Levocetrizine Evaluating active and placebo effect in pollen change vs. natural exposure studies Jan. 2011, where they found approx 40% total score improvement.

In another study conducted by P.C. Potter (2003)[12] et al, change in total symptom score was 40% at the end of 6 weeks, Levocetrizine is effective for symptom relief including nasal congestion in adolescent and adult (PAR) sensitized to house dust mites allergy. In this study fluticasone furoate nasal spray monotherapy was effective in relieving total nasal symptom score significantly (P value <0.001), results compared favorably with following studies.

In study by Holm AF et al (1999)[13] Fluticasone nasal spray group experienced significantly less sneezing and nasal itching compared to placebo group.Another study by Dykewiez MS et al (2003)[14] demonstrated that patients treated with fluticasone nasal spray had significantly greater reduction from baseline in total symptom score compared with placebo. (P<0.0001).

Fluticasone group also had a significantly greater (P < 0.001) mean reduction in individual symptom score of rhinorrhoea, sneezing nasal congestion compared with placebo. A study by Muhammad gill, Salahuddin Ayubi (2011)[15] demonstrated significant (P < 0.05) change in Nasal symptom score and Mucocilliary clearance in patients treated with topical steroids. A study by Han, Demin' Liu, Shixi, Zhang Yuan, Wang, Jiadong; Wang; Dehiv, Kong Weiilia; wang, shenging, cheng, Lei, Zhemy, Lyo Allergy asthma proceedings (2011)[16] demonstrated significant change in both total nasal and total ocular symptom score combination therapy with Antihistamines and nasal decongestants showed significant (P value < 0.001) changes in total symptom score however it was not effective in treating eye symptoms.

Nasal decongestants with alkaline saline nasal drops were significantly effective in treating nasal obstruction and rhinorrhoea (p value <0.001). however it is not effective in treating nasal itching, lacrimation. Combination of topical steroids i.e. fluticasone furoate and Antihistamines were effective significantly (P<0.001) in treating both, nasal and eye symptoms thus reducing total symptom score by 64% while treatment

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with only Antihistamines monotherapy i.e. Levocetrizine reduction in total symptom score was by 38.8%. Thus combination of topical steroids and Antihistamines is more effective in treating total symptom score.

In a study, second generation Antihistamine levocetrizine in combination with topical steroids is given to patients of allergic rhinitis by Barnes ML, ward J it, Farden T C Lipworth B J dini. (2006)[17]; found no significant difference in total symptom score when levocetrizine with placebo and levocetrizine with fluticasone in treating total symptoms score. Intranasal decongestants were significantly (p value < 0.001) effective in treating Nasal obstruction in our study however, it was not effective against eye symptoms. Because of its adverse effect profile, for short term therapy it is effective particularly when nasal obstruction is the presenting symptom. A study by Johnson and Hricik (1993) [18]; Johson et al (1997)[19]found that Nasal decongestants are effective in treating nasal obstruction in both allergic and non allergic rhinitis for short term. However they do not improve nasal itching, sneezing or rhinorrhea

CONCLUSION

Intranasal corticosteroids were superior to other drugs as a monotherapy while intranasal steroids with an antihistamine were effective as combination therapy

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