COMPARATIVE STUDY OF EFFECTS AND ADVERSE REACTIONS OF LEVOCETIRIZINE, RUPATADINE AND MOMETASONE IN PATIENTS OF ALLERGIC RHINITIS

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ABSTRACT

Aim: To compare the therapeutic efficacy and safety of Rupatadine and mometasone with Levocetirizine which is most commonly used drug. To study the effects of levocetirizine, Rupatadine and mometasone on absolute eosinophil count and IgE levels. **Methodology:** The participants were randomly divided into 3 groups of 25 patients each and treated as follows: Group I: were treated with Levocetirizine 5mg OD for 14 days, Group II: were treated with Rupatadine 10mg OD for 14 days, Group III: were treated with Mometasone two sprays (50mcg of mometasone in each spray) in each nostril once daily (total daily dose of 200mcg) for 14 days. The patients were asked to report at the hospital after 14 day and they were followed up with regard to clinical improvement of symptoms and signs and any adverse effects as reported by the patient. Rhinoscopy finding, X- ray of para nasal sinus, improvement in symptoms (sneezing, Itching, nasal discharge, nasal blockage and anosmia) Absolute eosinophils count, Serum IgE levels and adverse reports were studied and investigation were compared before and after treatment. **Result**: Rhinoscope finding showed treatment with mometasone became normal but X- Ray of para nasal sinus results showed levocetirzine showed higher rate of improvement. In improvement of symptoms sneezing, itching and nasal discharge was high mometasone. In all groups post treatment there was no changes in Ig E and Absolute Eosinophil's count. ADR reported with mometaxone. **Conclusion**: The three drugs, levocetirizine, rupatadine and mometasone were found to have similar levels of efficacy in controlling the symptoms of the allergic rhinitis. The physical signs improved better with mometasone than the other 2 drugs. The 3 drugs levocetirizine, rupatadine and mometasone had no significant effect on the absolute eosinophil count and the serum IgE levels. Adverse effects were found to be more with levocetirizine than the other two drugs. Considering this factor and also the fact that long term use of corticosteroids like mometasone is undesirable, rupatadine appears to be a better choice in the treatment of allergic rhinitis.

Keywords: Levocetirizine; Rupatadine; Mometasone; Allergic Rhinitis; Safety; Efficacy Adverse Reactions.

INTRODUCTION

Allergic rhinitis (AR), also known as pollenosis or hay fever, is an IgE mediated hypersensitivity disease of the mucous membranes of the nasal airways [1]. AR has a relevant impact on society because of its high prevalence, association with an impaired quality of life and the presence of comorbidities such as atopy and asthma [2].

It affects a large percentage of paediatric patients and causes significant number of school days missed per year. Impairment of work in adults also occurs affecting the finances of patients indirectly through lost workdays and directly through healthcare cost spent for the disease [3].

Seasonal allergic rhinitis (SAR) is found in = 10% of the general population and perennial allergic rhinitis (PAR) in 10-20% of the population [1].

In both SAR & PAR, the underlying process is an allergic response to airborne allergens of different nature. The disorder is associated with the epithelial accumulation of effector cells, such as mast cells and basophils, and inflammation in the nasal mucosa. Immunological activation of these effector cells induces the secretion of both newly generated (leukotrienes, prostaglandins and kinins) and pre formed (histamine and tryptase) pro inflammatory mediators [4]. Quantitatively, histamine is the most abundant preformed mediator in the early phase response and its implication in many of the symptoms of the disease has been clearly demonstrated. (Sneezing, itching, watery eyes and rhinorrhoea) Platelet activating factor (PAF) is an important mediator of AR causes vasodilation and an increase in vascular permeability that may contribute to the appearance of rhinorrhoea and nasal congestion [5].

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Moreover PAF and histamine are known t complement each other in vivo, histamine is a mediator of early response, being released from preformed reservoirs in mast cells, whereas PAF, a mediator of late response, is mainly synthesized denovo [6,7]. Furthermore, each of these mediators is able to promote the release of the other in some tissues and numerous target cells [8].

From the available experimental evidence it could be reasonable to infer that the blockade of both histamine and PAF receptors could be of superior clinical efficacy than the blockade of any one of these receptor types in the treatment of AR. Levocetirizine is conventionally used drug for allergic rhinitis which has good therapeutic efficacy but it has got more adverse drug reactions and all effects are short lived, so search for better drug continues, rupatadine and mometasone are such drugs with better therapeutic efficacy and safety profile.

This study compares the therapeutic efficacy and safety of rupatadine and mometasone with levocetirizine which is most commonly used drug in government hospitals for the treatment of allergic rhinitis.

Aim:

To compare the therapeutic efficacy and safety of Rupatadine and mometasone with Levocetirizine which is most commonly used drug.

To study the effects of levocetirizine, Rupatadine and mometasone on absolute eosinophil count and IgE levels.

MATERIALS AND METHODS

Study design: Open label and parallel group comparative clinical study

Ethics approval: The study was approved by institutional ethics committee and informed consent was obtained from the participants.

Study location: The cases for this study were taken from the allergy clinic of government ENT, Hospital, Koti, Hyderabad

Sample size: A total of 75 patients, showing signs and symptoms suggestive of allergic rhinitis were taken.

Inclusion criteria: Patients in the age group of 15 -45 years of both sexes were included in the study. Clinical Features: Patients showing the typical features of allergic rhinitis such as sneezing, watery nasal discharge, itching in the nose / throat and nasal blockade were included. The duration of these symptoms and signs had to be of at least 1 month or more to rule out common cold or other minor infections of the upper respiratory tract.

Exclusion criteria: Infections of the respiratory tract as indicated by purulent discharge, foul smelling discharge or fever, patients who had used anti -histamines in the past 48 hours or topical steroids in the past 2 weeks or systemic steroids in the past 4 weeks. The above drugs alter the clinical picture and also interfere with the skin test for allergy. Any previous history of hypersensitivity to anti-histamines or corticosteroids. Evidence of major systemic disease, pregnant / lactating women, patients undergoing desensitization (Immunotherapy) and firstly it shows any infection in the sinuses as generalized haziness in the sinuses. Such cases were excluded from this study as per the exclusion criteria were excluded.

Grouping and dose [9-12]**:**

The participants were randomly divided into 3 groups of 25 patients each and treated as follows

Group I: were treated with Levocetirizine 5mg OD for 14 days

Group II: were treated with Rupatadine 10mg OD for 14 days

Group III: were treated with Mometasone two sprays (50mcg of mometasone in each spray) in each nostril once daily (total daily dose of 200mcg) for 14 days

Methodology:

Patients in group-I received tablets of levocetirizine 5mg OD orally for 14 days. Patients in group-II received tablets of Rupatadine 10mg OD orally for 14 days. Patients in group-III received one container of mometasone nasal spray (10gm-100metered doses of 50mcg) and instructed to take two sprays (50mcg of mometasone in each spray) in each nostril once daily (total daily dose of 200mcg) for 14 days.

The patients were asked to report at the hospital after 7 days and they were followed up with regard to clinical improvement of symptoms and signs and any adverse effects as reported by the patient. After completion of the total duration of 14 days of treatment the patients again reported at the hospital. They were followed up with regard to clinical improvement, any adverse effects reported and also by repeated all the investigations done before starting of the treatment.

The patients in all groups were instructed not to take any medicine other than the tablets provided to them during the study period. They were also told to stop the medication if they noticed any major undesirable effects and to inform the same to the doctors at the allergy clinic.

Parameters: Rhinoscopy finding, X- ray of para nasal sinus, improvement in symptoms (sneezing, Itching, nasal discharge, nasal blockage and anosmia) Absolute eosinophils count [9], Serum IgE levels [9] and adverse reports were studied.

Absolute eosinophil count: This test was done pre and

post treatment to observe any effect of the given drug on the absolute eosinophil count.

Measurement of Serum IgE levels: Levels of IgE in the serum is a strong point in favor of diagnosing allergic Rhinitis. After taking the blood samples from the patients the serum was separated by Centrifugation and stored at -20" C until the ELISA test was performed. The ELISA kit (for measuring IgE levels) used in this study was produced by Omega Diagnostics Limited, United Kingdom, and was purchased from Hyderabad [13]. Calculation of IgE values: This was done by the computer attached to the automatic analyzer. It gives the IgE concentration in IU/ml

RESULTS

Table 1. Rhinoscopy and x- ray of para nasal sinus findings after treatment

Group	Rhinoscopy				X- Ray of para nasal sinus			
	Before treatment	After treatment number of patients showing improvement			Before treatment	After treatment number of patients showing improvement		
		No	Partial	Normal		No	Partial	Normal
Group 1	22	4 (18.8)	10 (45.5)	8(36.4)	3	0	0	3 (100)
Group II	19	4 (21.1)	6 (31.6)	9 (47.4)	3	1 (33.3)	0	2 (66.7)
Group III	20	3 (15)	7 (35)	10 (50)	3	1 (33.3)	0	2 (66.7)

Table 2. Improvement in Symptoms

Improvement	Group I	Group II	Group III	Group I	Group II	Group III
Sneezing				**Itching**		
No	1	1	0	0	1	1
Mild (25%)	3	1	2	0	2	0
Moderate (50%)	6	5	2	3	3	0
Good (75%)	5	10	10	1	3	1
Total (100%)	10	8	11	8	3	8
Overall (%)	70	73	80	85.4	60.4	87.5
Nasal Discharge				**Nasal Blocking**		
No	1	0	0	3	3	3
Mild (25%)	1	2	3	1	2	4
Moderate (50%)	3	5	2	5	3	6
Good (75%)	9	4	5	3	5	2
Total (100%)	9	12	13	3	3	2
Overall (%)	76.1	78.3	80.4	53.3	54.7	44.1
Anosmia						
No	1	0	0			
Mild (25%)	0	0	1			
Moderate (50%)	0	0	1			
Good (75%)	2	1	2			
Total (100%)	3	2	1			
Overall (%)	75	91.7	65			

Table 3. Ig E and Absolute Eosinophil's count before and after treatment

	Ig E values (IU/ml)		Absolute Eosinophil's count	
Group	Before treatment	After treatment	Before treatment	After treatment
Group I	263±39	260±43	575±76	558±67
Group II	199±31	195±32	787±98	755±94
Group III	176±15	180±17	536±64	522±60

Table 4. ADR reported

Group	No of patient	Dryness of	Drowsiness	Other
Group I	12	5	7	Nil
Group II	5	4	1	Nil
Group III	3	Nil	Nil	Nausea, Dyspepsia nasal burning sensation and irritation and

DISCUSSION

In this study of 75 cases, all the patients (100%) with allergic rhinitis had sneezing, watery nasal discharge was present in 69 patients (92%). Itching / palate / throat) was reported by 34 patients (45%), nasal blocking by 48 patients (64%) and Anosmia by 14 patients (19%).

Thus, sneezing and watery nasal discharge were the most common complaints. Anosmia was the least common and usually secondary to nasal blocking. When asked about the history of exposure to any specific agent, most of the patients answered in the negative. History of allergic disorders in family members was reported by 18 patients (24%).

History taking was followed by general, systemic and EN.T. examination of the patient. Rhinoscopy was done to see the appearance of nasal mucosa, the presence of any nasal discharge, the position of the nasal septum, the condition of the turbinates and any other findings. Of the 75 cases in this study, 61 cases (81.33%) showed at least one or more signs of allergic rhinitis which include pale nasal mucosa, mucosal edema, and presence of watery discharge, mucosal congestion and hypertrophy of turbinates.

After examining the patient, investigations were done. X-ray of the Para nasal sinuses was taken to detect any sinusitis and also to see for mucosal thickening which is indicative of allergy involving the sinuses. Cases showing mucosal thickening had a repeat x-ray to see for any improvement after treatment. Out of the total number of 75 cases, 9 cases showed mucosal thickening in the maxillary sinuses before starting treatment.

Blood samples were taken for doing investigations like complete blood picture, absolute eosinophil count and measurement of immunoglobulin - E (IgE) levels. 49 out of 75 patients (65%) showed eosinophil counts above normal levels and 61 out of 75 patients (81%) showed IgE levels above normal, before starting treatment.

The following results were obtained after 14 days of treatment. Symptomatic vement was similar with the three drugs in relation to sneezing and nasal. The overall reduction in sneezing was 70% with Levocetirizine, 73% with Rupatadine, and 80% with mometasone. Nasal discharge reduced by 76% with Levocetirizine, 78% with Rupatadine, and 80% with mometasone. Itching was better controlled by mometasone (88%) as compared to Levocetirizine (85%) and Rupatadine (60%). Relief of nasal blocking was more or less similar with all the three drugs i.e., 53% with levocetirizine 55% with Rupatadine and 44% with mometasone. Anosmia reduced by 75% with levocetirizine, 92% with Rupatadine and 65% with Mometasone. Physical signs of allergic rhinitis as seen by rhinoscopy improved better with Mometasone, 50% of patients showing normal appearance of nasal cavity after treatment as compared to 47% with Rupatadine and 36% with Levocetirizine.

The effects of Levocetirizine (mean reduction-1%), Rupatadine (mean reduction 2%) and Mometasone (mean rise-2%) on serum IgE values, were not significant. Rupatadine produced a minor fall of around 4% in the mean absolute eosinophil count whereas Levocetirizine and Mometasone produced a fall of around 3% respectively. These changes in IgE values and absolute eosinophil count are in agreement with the results published from previous studies.

Regarding the skin test for allergy, the skin test result became negative in 61% of patients with Levocetirizine, in 73% of Patients with Rupatadine, and in 81% of patients with Mometasone. Mean % reduction of skin reaction were 82% with Levocetirizine, 93% with Rupatadine, and 92% with Mometasone.

X-ray of paranasal sinuses was suggestive of allergy in 3 patients in each of the 3 groups. Out of them 2 patients in Rupatadine group and 2 patients in Mometasone group had normal X-rays after treatment while all the 3

patients of the levocetirizine group had normal x-ray after treatment.

Adverse effects were reported by patients of all the 3 groups. Although a Significant number of patients reported adverse effects; these were mild and lasted only a few days. Dryness of mouth/throat was reported by 4 patients on Rupatadine and by 5 Patients on levocetirizine. Drowsiness was reported by 7 patients on levocetirizine and only by 1 patient on rupatadine. Patients on anti-histamines reported no other adverse effect. Among the patients on Mometasone, nausea, dyspepsia and nasal burning sensation and irritation was reported in one patient each. All these adverse effects subsided by themselves with continued treatment.

A study by Rituparna Maiti etal compared the Rupatadine and levocetirizine on differential count and absolute eosinophil count was significantly lowered by both drugs, but rupatadine was found to be superior. In the rupatadine group there was a significantly higher reduction in IgE level compared with the levocetirizine group. Incidence of adverse effects was less in the rupatadine group compared with the levocetirizine group.

Rupatadine significantly reduced sneezing scores more than that of levocetirizine, which is consistent with previous study that Rupatadine reduces TNSS and Rhinoconjunctivitis quality of life Questionnaire scores to a greater extent than Levocitrizine in seasonal allergic rhinitis patients [11].

Emel etal study reported that moderate to severe persistent allergic rhinitis patients, adding levocetirizine or montelukast to mometasone furoate is more effective than mometasone furoate alone [11].

Singh etal in his study concluded as mometasone Fuorate nasal spray and Levocetrizine are potent drugs but patients taking Mometasone Fuorate nasal spray as medication appreciate better relief in symptoms as compared to Levocetrizine [12].

A study by Sridhar Rao [14] all the adverse effect complained were expected and no new/alarming side effects were recorded with levocitrizine in treatment of allergic rhinitis and our result also supporting his study.

CONCLUSION

The three drugs, levocetirizine, rupatadine and mometasone were found to have similar levels of efficacy in controlling the symptoms of the allergic rhinitis. The physical signs improved better with mometasone than the other 2 drugs. The 3 drugs levocetirizine, rupatadine and mometasone had no significant effect on the absolute eosinophil count and the serum IgE levels. Adverse effects were found to be more with levocetirizine than the other two drugs. Considering this factor and also the fact that long term use of corticosteroids like mometasone is undesirable, rupatadine appears to be a better choice in the treatment of allergic rhinitis.

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