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Original Research Article.

To Compare the Efficacy and Safety of Rupatadine and Olopatadine in Patients of Allergic Rhinitis: An Institutional Based Study

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ABSTRACT

Background: Allergic rhinitis is one of the most common atopic disorders that affect productivity and quality of life. The present study was conducted to compare the efficacy and safety of rupatadine and olopatadine in patients of allergic rhinitis.

Materials and Methods: The present study was a prospective study conducted in 140 patients of Allergic rhinitis in Department of Pharmacology, Amaltas Institute of Medical Sciences, Dewas, Madhya Pradesh (India) over the period of 6 months. Patients were divided into two groups to receive either olopatadine 10 mg or rupatadine 10 mg once daily orally for 2 weeks. After clinical diagnosis of Allergic rhinitis, baseline investigations were carried out and patients were given drugs for 2 weeks. Clinical assessment of patients was done by the principal investigator. Patients were assessed for total nasal symptom score (TNSS). Vigilant follow-up of patients for adverse drug reaction. Statistical analysis was performed using the Statistical Package for the Social Sciences software version 21.0 (SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered significant.

Results: In the present study mean age of olopatadine group was 36.66 years and mean age of rupatadine group was 35.24. There was no statistically significant difference between olopatadine and rupatadine groups in TNSS at baseline. However, TNSS in olopatadine and rupatadine groups at baseline and 2nd week revealed statistically significant difference after 2 weeks of treatment with olopatadine and rupatadine. There was a significant decrease in neutrophil count, eosinophil count, and increase in lymphocyte count after 2 weeks of treatment in olopatadine group. There was no significant change in liver and kidney function after 2 weeks of treatment in both groups as compared to baseline. Adverse events were noted in 17 patients of olopatadine and 11 patients taking rupatadine. Sedation was the most common adverse event in both groups.

Conclusion: Our study concluded that Olopatadine is a better choice in AR in comparison to rupatadine due to its better efficacy. Adverse event rate was more in olopatadine group as compared to rupatadine group. As adverse events were tolerable olopatadine can be prescribed.

Keywords: Olopatadine, Rupatadine, Total Nasal Symptom Score.

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INTRODUCTION

Allergic rhinitis is one of the most prevalent atopic disorders and characterized by sneezing, itching, rhinorrhoea, nasal congestion and nasal hypersensitivity, and signs of invasion of nasal mucosa by inflammatory cells.[1] AR is associated with sleep disturbances that result in impaired work productivity and interference with cognitive and emotional functioning.[2] AR includes seasonal AR (SAR), perennial AR (PAR), and PAR with seasonal exacerbations. Prevalence of AR varies from population to population, but on an average, it can affect 25% to 35% of people.[3]

Symptoms are produced by inflammatory mediators that are released upon activation of mast cells by antigen-IgE interaction. Histamine is the primary mediator involved in the pathophysiology and this explains the prominent role of histamine H_1-receptor antagonists in the treatment of AR.[4-6] The current therapeutic modalities for the management of AR include: H1 receptor antagonists, decongestants, mast cell stabilizers, leukotriene receptor antagonists, corticosteroids, and anticholinergic agents in oral or topical nasal formulations.[4]

Two new second-generation H1-receptor antagonists, olopatadine and rupatadine, are known as dual blockers since both these drugs block the action of not only the histamine but also of other inflammatory mediators such as platelet-activating factor (PAF), LTs, and chemokines. Olopatadine is a newly approved drug for the treatment of AR.[2]

The unique effect of rupatadine on interleukins (IL-6, IL-8) and olopatadine on leukotrienes (LTs), thromboxane A2 (TXA2), tachykinin, CC chemokines, leucocyte function-associated antigen 1 (LFA-1) expression has prompted us to design the present study.[7-11] The present study was conducted to compare the efficacy and safety of rupatadine and olopatadine in patients of allergic rhinitis.

MATERIALS AND METHODS

The present study was a prospective study conducted in 140 patients of Allergic rhinitis in Department of Pharmacology, Amaltas Institute of Medical Sciences, Dewas, Madhya Pradesh (India) over the period of 6 months. Before commencement of study, permission was taken from the ethical committee of the institute and written informed consent was obtained from the patients.

Patients were divided into two groups with seventy patients in each group to receive either olopatadine 10 mg or rupatadine 10 mg once daily orally for 2 weeks.[2] Patients between 18 and 65 years of either gender with history of having intermittent or persistent mild, moderate, to severe allergic rhinitis, Patients with TNNS of ≥8 not treated with antihistamines in the last 3 days, Patients who could understand and were able to adhere to the dosing and visit schedules, Patients who agreed to record the adverse events accurately and consistently were included in the study. Patients with H/O asthma requiring chronic use of inhaled or systemic corticosteroids had been unresponsive to antihistamine treatment in the past, Patients with history of allergies to study medication or unable to tolerate antihistamines, use of study drug in the last 3 days before baseline, Subjects with significant systemic diseases, allergic conjunctivitis using steroid or antihistaminic eye drops, and pregnant women, nursing mothers were excluded from the study. After clinical diagnosis of Allergic rhinitis, baseline investigations were carried out and patients were given drugs for 2 weeks. After 2 weeks, again investigations were repeated, and data were analyzed. In total, 10 ml blood of each patient was withdrawn by taking all aseptic precautions at both 0 and 2 weeks. After initial screening, clinical examination, and laboratory investigations, patients were randomly allocated to receive either olopatadine (Group A) or rupatadine (Group B). All patients received one capsule filled with either olopatadine 10 mg or rupatadine 10 mg once a day at 10 p.m. Clinical findings and laboratory investigations were recorded. Clinical assessment of patients was done by the principal investigator. Patients were assessed for total nasal symptom score (TNSS) at each visit by the principal investigator. Symptom severity was determined by the TNSS which consisted of sneezing, rhinorrhoea, itching, and nasal congestion scored on a severity scale from 0 to 3 (0 = none, 1 = mild, 2 = moderate, and 3 = severe), such that the maximum possible TNSS was 12.[2,12] Total and differential leukocyte counts, renal, liver tests were performed at first visit (0 week) and last visit (2nd week). Vigilant follow-up of patients for adverse drug reaction, if any, was recorded in case report form and IEC was informed immediately. Necessary medical aid was provided to the volunteers and they were hospitalized in till complete recovery, at no extra cost to the patient. Statistical analysis was performed using the Statistical Package for the Social Sciences software version 21.0 (SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered significant.

Table 1: Comparison of effects of drugs after 2 weeks from baseline values

Variable	Olopatadine group(n=70)	Rupatadine group (n=70)	P= value
	Mean ± SD	Mean ± SD	
Age (yrs)	36.66±7.87	35.24±8.76	< 0.05
TLC	8123±987	8198±1105	
Neutrophils (%)	62.65±3.54	60.45±5.63	
Lymphocytes (%)	28.67±4.65	28.42±4.66	
Eosinophils (%)	6.71±1.43	6.53±1.47	
Basophils (%)	0.60±0.89	0.59±0.78	
Monocytes (%)	0.91±0.94	0.78±0.89	
Serum bilirubin (mg%)	0.67±0.19	0.61±0.21	
Serum creatinine (mg%)	0.74±0.21	0.89±0.23	
Blood urea(mg%)	21.67±3.22	18.64±4.21	
IgE(IU/ml)	322.12±75.66	319.45±73.56	
Total nasal symptom score	10.50±0.56	9.45±0.78	

Table 2: Comparison of adverse drug reaction of both drugs

Adverse events	Olopatadine group(n=70)	Rupatadine group (n=70)
Sedation	6	4
Headache	4	3
Dryness of mouth	3	1
Gastric irritation	4	3
Total	17	11

RESULTS

In the present study mean age of olopatadine group was 36.66 years and mean age of rupatadine group was 35.24. There was no statistically significant difference between olopatadine and rupatadine groups in TNSS at baseline. However, TNSS in olopatadine and rupatadine groups at baseline and 2nd week revealed statistically significant difference after 2 weeks of treatment with olopatadine and rupatadine. In olopatadine group, there was a significantly higher reduction in TNSS ($P < 0.05$) than that of rupatadine. There was a significant decrease in neutrophil count, eosinophil count, and increase in lymphocyte count after 2 weeks of treatment in olopatadine group. Both the drugs significantly reduced the absolute eosinophil count, but olopatadine ($P < 0.001$) was found to be superior. There was no significant change in liver and kidney function after 2 weeks of treatment in both groups as compared to baseline.

Adverse events were noted in 17 patients of olopatadine and 11 patients taking rupatadine. Sedation was the most common adverse event in both groups i.e with olopatadine in 6 patients and with rupatadine group in 4 patients. Headache was noted in 4 patients with olopatadine and in 3 patients with rupatadine. Dryness of mouth was noted in 3 patients with olopatadine and in 1 patient with rupatadine. Gastric irritation was noted in 4 patients with olopatadine and in 3 patients with rupatadine. Adverse event rate was more in olopatadine group as compared to rupatadine group.

DISCUSSION

Rupatadine and olopatadine both are known to be dual blockers i.e. other than their antihistaminic property; they can antagonize PAF also and that is the reason why both the drugs are highly effective in AR. The difference in their efficacy is due to their varied pharmacodynamic effects. Rupatadine has a high H_1 receptor binding affinity which allows the molecule to inhibit the histamine-induced interleukin (IL)-6 and IL-8 production using concentrations that are below the plasma levels reached at therapeutic dose.[7,13] Olopatadine can reduce the amount of cell-associated PAF by 52.8%, which is more than rupatadine.[13]

In the present study mean age of olopatadine group was 36.66 years and mean age of rupatadine group was 35.24. There was no statistically significant difference between olopatadine and rupatadine groups in TNSS at baseline. However, TNSS in olopatadine and rupatadine groups at baseline and 2nd week revealed statistically significant difference after 2 weeks of treatment with olopatadine and rupatadine. There was a significant decrease in neutrophil count, eosinophil count, and increase in lymphocyte count after 2 weeks of treatment in olopatadine group. There was no significant change in liver and kidney function after 2 weeks of treatment in both groups as compared to baseline. Adverse events were noted in 17 patients of olopatadine and 11 patients taking rupatadine. Sedation was the most common adverse event in both groups.

In a study conducted to test the efficacy of rupatadine in treating patients with AR, rupatadine was found to be effective in reducing nasal symptoms, improving signs secondary to mucosal inflammation with sustained and even improving results after 2 weeks of treatment.[15] Another comparative dose ranging trial of rupatadine showed improvement in nasal and ocular symptoms of AR.[16]

In a randomized, double-blind, placebo-controlled study, oral olopatadine significantly suppressed sneezing ($P < 0.001$), rhinorrhoea ($P < 0.001$), and nasal congestion ($P < 0.05$).[17]

In another comparative open-labelled study, olopatadine and rupatadine have decreased the TNSS, but olopatadine was found to be superior to rupatadine in reducing the TNSS.[2]

The comparative change in the differential count of eosinophil in olopatadine group was found to be significantly more as compared to the rupatadine group. This observation supports the previous study of analysis of rupatadine and olopatadine.[15]

CONCLUSION

Our study concluded that Olopatadine is a better choice in AR in comparison to rupatadine due to its better efficacy. Adverse event rate was more in olopatadine group as compared to rupatadine group. As adverse events were tolerable olopatadine can be prescribed.

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