ORIGINAL RESEARCH

Comparative Evaluation of Efficacy and Safety of Rupatadine and Olopatadine in Patients of Allergic Rhinitis: An Institutional Based Study

Chaudhari Umesh Dnyandeo[1], A Vasudeva Rao[2], Sachin B Khond[3], S. Boopathy[4]

[1]Assistant Professor, Department of Pharmacology, Prathima Institute of Medical Sciences, Nagunur, Karimnagar, Telangana, India.
[2]Assistant Professor, Department of Pharmacology, Shri B. M. Patil Medical College Hospital and Research Centre, Solapur Road, Vijayapura, Karnataka, India.
[3]Assistant Professor, Department of Pharmacology, Dr. B. R. Ambedkar Medical College and Hospital, Kadugondanahalli, Bangalore, Karnataka, India.
[4]Assistant Professor, Department of Pharmacology, Meenakshi Medical College Hospital and Research Institute, Kanchipuram, Tamil Nadu, India.

Corresponding Author:
Dr. S. Boopathy,
Assistant Professor, Department of Pharmacology, Meenakshi Medical College Hospital and Research Institute, Kanchipuram, Tamil Nadu, India.
Email: boopathyns@gmail.com

Received: 05 June, 2020 Accepted: 09 July, 2020

ABSTRACT

Background: This study was conducted to compare the efficacy and safety of rupatadine and olopatadine in patients of allergic rhinitis. **Material and Methods**: 100 AR (allergic rhinitis) patients. For two weeks, patients were split into two groups of 50, each of whom received 10 mg of olopatadine or 10 mg of rupatadine orally once daily. Total nasal symptom score (TNSS) was evaluated at different time intervals. Outcome was evaluated among all the patients. **Results**: 100 subjects were divided into two groups of 50 subjects each. Group 1 consisted of subjects receiving rupatadine while the subjects of group 2 received olopatadine. In this study, 60 subjects were males and 40 were females. In TNSS (Total Nasal Symptoms Score) at baseline, there was no statistically significant difference between the olopatadine and rupatadine groups. But after two weeks of therapy with olopatadine and rupatadine, TNSS in the olopatadine and rupatadine groups showed statistically significant differences.**Conclusion**: Because of its superior efficacy and safety profile, olopatadine is a preferable option for AR compared to rupatadine.

Keywords: Olopatadine, Rupatadine, Allergic Rhinitis, Efficacy, Safety, Drugs.

INTRODUCTION

Allergic rhinitis (AR) is one of the most prevalent atopic disorders that affect productivity and quality of life. AR is characterized by sneezing, itching, rhinorrhea, nasal congestion and nasal hypersensitivity, and signs of invasion of nasal mucosa by inflammatory cells.[1] 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.[2] It has a relevant impact on society because of its high prevalence, association with an impaired quality of life, and the presence of co-morbidities.[3] Because of the substantial medical care expenditure, the total burden of this disease goes beyond impairment of physical and social functioning. Rupatadine is a novel substance which, in addition to being an H1 antagonist, is also a potent platelet-activating factor (PAF) inhibitor. It belongs to the N-alkyl pyridine derivates. Animal and human models[4] have shown rupatadine to have dual antihistamine and PAF-antagonist properties. It is commercially available in Spain as 10-mg tablets and has already been approved in several other European countries.[5,6]

Olopatadine is a newly approved drug for the treatment of AR. It is a selective histamine H1-receptor antagonist, in addition possessing inhibitory effects on PAF and on the release of inflammatory lipid mediators such as LT and thromboxane (TX) from human polymorphonuclear leukocytes and eosinophils.[7] Olopatadine was shown to be highly useful for the treatment of AR, chronic urticaria, and conjunctivitis in double-blind clinical trials.[8,9] Hence, this study was conducted to compare the efficacy and safety of rupatadine and olopatadine in patients of allergic rhinitis.

MATERIAL AND METHODS

100 AR (allergic rhinitis) patients. For two weeks, patients were split into two groups of 50, each of whom received 10 mg of olopatadine or 10 mg of rupatadine orally once daily. Total nasal symptom score (TNSS) was evaluated at different time intervals. Outcome was evaluated among all the patients. The unpaired t-test was utilized to evaluate the regularly distributed variables, whereas non-parametric tests were employed to analyze the non-normally distributed variables. P less than 0.05 was deemed significant.

RESULTS

The 100 subjects were divided into two groups of 50 subjects each. Group 1 consisted of subjects receiving rupatadine while the subjects of group 2 received olopatadine. In this study, 60 subjects were males and 40 were females. In TNSS (Total Nasal Symptoms Score) at baseline, there was no statistically significant difference between the olopatadine and rupatadine groups. But after two weeks of therapy with olopatadine and rupatadine, TNSS in the olopatadine and rupatadine groups at baseline and the second week showed statistically significant differences. After two weeks of treatment, there was a greater difference in the TNSS score between the olopatadine and rupatadine groups. The baseline TNSS in group 1 and group 2 were 7.29 and 8.63, respectively. While comparing the TNSS among group 1 and group 2 after 2 weeks, significant results were obtained. 5 individuals receiving olopatadine and 13 patients receiving rupatadine reported adverse effects.

Table 1: Allocation of the subjects in the two groups.

Groups	Number of subjects	Percentage
Group 1 (Rupatadine)	50	50%
Group 2(Olopatadine)	50	50%
Total	100	100%

Table 2: Gender-wise distribution of subjects.

Gender	Group 1	Group 2	Total
Males	32	28	60
Females	18	22	40
Total	50	50	100

Table 3: Baseline demographic data and clinical characteristics of patients of allergic rhinitis.

Characteristics	Group 1	Group 2
Number of patients	50	50
Age (years)	34.3	35.9
Total leukocyte count (TLC)	8123	8001
Neutrophils (%)	63.12	65.63
Lymphocytes (%)	30.67	30.41
Eosinophils (%)	6.02	6.10
Monocytes (%)	0.83	0.91
Basophils (%)	0.49	0.51
SGOT (IU)	25.37	28.13
SGPT (IU)	20.14	19.31
Serum bilirubin (mg%)	0.56	0.59
Serum creatinine (mg%)	0.85	0.72
Blood urea (mg%)	18.29	19.63

SGOT= Serum Glutamic Oxaloacetic Transaminase, SGPT= Serum Glutamic Pyruvic Transaminase.

Table 4: Baseline total nasal symptoms score in olopatadine and rupatadine groups.

TNSS	Group 1	Group 2	p-value
Baseline	15.9	15.1	0.12
After 2 weeks	11.9	8.3	0.00 (Significant)

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 H1 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.[3,10] Olopatadine can reduce the amount of cell associated PAF by 52.8%, which is more than rupatadine.[10]

Allergic conditions are usually associated with the changes in the percentage of eosinophil and its absolute count and probably that's why the effects of the drugs have not been directly reflected on total leukocyte count and neutrophil count. The increase in eosinophil count is the hallmark of the late phase of AR. The scrupulous control of this parameter is an important therapeutic aim in the treatment of AR.[7] Hence, this study was conducted to compare the efficacy and safety of rupatadine and olopatadine in patients of allergic rhinitis.

The 100 subjects were divided into two groups of 50 subjects each. Group 1 consisted of subjects receiving rupatadine while the subjects of group 2 received olopatadine. In this study, 60 subjects were males and 40 were females. In TNSS (Total Nasal Symptoms Score) at baseline, there was no statistically significant difference between the olopatadine and rupatadine groups. But after two weeks of therapy with olopatadine and rupatadine, TNSS in the olopatadine and rupatadine groups at baseline and the second week showed statistically significant differences. After two weeks of treatment, there was a greater difference in the TNSS score between the olopatadine and rupatadine groups. Dakhale G et al[11] compared the efficacy, safety, and cost-effectiveness of rupatadine and olopatadine in patients of allergic rhinitis (AR). A 2-week, single-centered, randomized, double-blind, parallel group comparative clinical study was conducted on patients with AR. Following inclusion and exclusion criteria, 67 patients were recruited and randomized to two treatment groups and received the respective drugs for 2 weeks. At follow-up, parameters assessed were total nasal symptom score (TNSS), change in total and differential count of eosinophil. In olopatadine group, there was a significantly higher reduction in TNSS ($P < 0.05$) than that of rupatadine. Both the drugs significantly reduced the absolute eosinophil count, but olopatadine ($P < 0.001$) was found to be superior. The incidence of adverse effects was found to be less in olopatadine group when compared with rupatadine group. It was concluded that Olopatadine is a better choice in AR in comparison to rupatadine due to its better efficacy and safety profile.

The baseline TNSS in group 1 and group 2 were 7.29 and 8.63, respectively. While comparing the TNSS among group 1 and group 2 after 2 weeks, significant results were obtained. 5 individuals receiving olopatadine and 13 patients receiving rupatadine reported adverse effects. Ratner PH et al[12] evaluated the safety and efficacy of 2 concentrations of olopatadine nasal spray vs placebo nasal spray in patients with SAR to mountain cedar. This was a multicenter, randomized, double-blind, placebo-controlled study. After a 3- to 21-day placebo run-in, 677 patients aged 12 to 81 years were randomized to receive 0.4% or 0.6% olopatadine or placebo, 2 sprays per nostril twice daily for 2 weeks. Patients evaluated morning and evening reflective and instantaneous nasal symptoms (sneezing, stuffy nose, runny nose, and itchy nose, which compose the total nasal symptom score [TNSS]) and ocular symptoms. Olopatadine spray (0.4% and 0.6%) was statistically significantly superior to placebo for percentage change from baseline in overall reflective and instantaneous TNSSs. Also, 0.6% olopatadine was statistically significantly superior to placebo for reducing the reflective and instantaneous assessments of sneezing, runny nose, itchy nose, stuffy nose, itchy eyes, and watery eyes. Olopatadine spray exhibited a safety profile comparable with that of placebo. Olopatadine nasal spray (0.4% and 0.6%) provided statistically significant improvements in allergic rhinitis symptoms compared with placebo regarding TNSSs and individual symptoms, including congestion, itchy and runny nose, sneezing, and itchy and watery eyes, in patients with SAR to mountain cedar. Olopatadine nasal spray administered twice daily was safe and well tolerated in adolescents and adults.

CONCLUSION

Because of its superior efficacy and safety profile, olopatadine is a preferable option for AR compared to rupatadine.

REFERENCES

1. Al Suleimani YM, Walker MJ. Allergic rhinitis and its pharmacology. Pharmacol Ther. 2007;114:233–60.
2. Weber RW. Allergic rhinitis. Prim Care. 2008;35:1–10.
3. Picado C. Rupatadine: Pharmacological profile and its use in the treatment of allergic disorders. Expert OpinPharmacother. 2006;7:1989–2001.
4. Merlos M, Giral M, Balsa D, Ferrando R, Queralt M, Puigdemont A, et al. Rupatadine, a new potent, orally active dual antagonist of histamine and platelet-activating factor (PAF) J Pharmacol Exp Ther. 1997;280:114–121.
5. Vuurman E, Theunissen E, van Oers A, van Leeuwen C, Jolles J. Lack of effects between rupatadine 10 mg and placebo on actual driving performance of healthy volunteers. Hum Psychopharmacol. 2007;22:289–297.

6. Izquierdo I, Merlos M, García-Rafanell J. Rupatadine: a new selective histamine H1 receptor and platelet-activating factor (PAF) antagonist. A review of pharmacological profile and clinical management of allergic rhinitis. Drugs Today (Barc) 2003;39:451–468.
7. Maiti R, Jaida J, Rahman J, Gaddam R, Palani A. Olopatadine hydrochloride and rupatadine fumarate in seasonal allergic rhinitis: A comparative study of efficacy and safety. J PharmacolPharmacother. 2011;2:270–6.
8. Yamamoto H, Yamada T, Kubo S, Osawa Y, Kimura Y, Oh M, et al. Efficacy of oral olopatadine hydrochloride for the treatment of seasonal allergic rhinitis: A randomized, double-blind, placebo-controlled study. Allergy Asthma Proc. 2010;31:296–303.
9. Enomoto T, Lu HQ, Yin M, Sakoda T, Dake Y, Enomoto K, et al. Evaluation of the efficacy and safety of olopatadine and fexofenadine compared with placebo in Japanese cedar pollinosis using an environmental exposure unit. J InvestigAllergol Clin Immunol. 2009;19:299–305.
10. Barrón S, Ramis I, García-Rafanell J, Merlos M. Inhibitory activity of rupatadine on pro-inflammatory cytokine production, relationship with binding affinity. Methods Find Clin Pharmacol. 2005;27(Suppl 2):161–2.
11. Dakhale G, Tathod Y, Patel S, Pimpalkhute S, Raghute L, Khamkar A. Comparison of efficacy, safety, and cost-effectiveness of rupatadine and olopatadine in patients of allergic rhinitis: A prospective, randomized, double-blind, parallel group study. J PharmacolPharmacother. 2016 Oct-Dec;7(4):171-176.
12. Ratner PH, Hampel FC, Amar NJ, van Bavel JH, Mohar D, Marple BF, Roland PS, Wall GM, Brubaker MJ, Drake M, Turner D, Silver LH. Safety and efficacy of olopatadine hydrochloride nasal spray for the treatment of seasonal allergic rhinitis to mountain cedar. Ann Allergy Asthma Immunol. 2005 Nov;95(5):474-9.