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RESEARCH ARTICLE

A comparative study of efficacy and safety of rupatadine versus desloratadine in patients with chronic idiopathic urticaria

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ABSTRACT

Treatment of chronic idiopathic urticaria (CIU) is challenging because of its unpredictable course and negative influence on the quality of life. New treatments are being developed, but antihistaminics remain the cornerstone of the therapeutic approach. The purpose of this study was to compare the efficacy and safety of relatively new drug rupatadine with the established drug desloratadine in patients suffering from CIU. This prospective, randomized, open, outdoor-based clinical study was conducted at Department of Dermatology, Rajiv Gandhi Institute of medical sciences, Kadapa from February, 2013 to March, 2013. A total of 56 patients of CIU were randomized either to rupatadine group (n= 28) or desloratadine group (n=28). The efficacy variables were change in the total symptoms score(TSS), aerius quality of life questionnaire(AEQLQ) total score, differential count of eosinophil(DC-E), absolute eosinophil count(AEC) and serum IgE level from baseline visit to end of the study visit (after 4 weeks). Along with these the incidence of adverse effects were compared using different statistical tools. After four weeks, in rupatadine group, TSS decreased by 22.5 %(vs 10.8% in desloratadine group); AEQLQ total score decreased by 31 %(vs 17.7% in desloratadine group); AEC was decreased by 36.2% (vs 15% in desloratadine group); and serum IgE decreased by 13.3 %(vs 5.9% in desloratadine group). All the values were statistically significant ($p<0.05$) compared to desloratadine group. The overall incidence of adverse drug reactions was also found to be less in the rupatadine group. An analysis of the results of all the parameters of safety and efficacy proves the superiority of rupatadine over desloratadine for CIU.

Keywords: Total symptoms score, AEQLQ total score, chronic idiopathic urticaria, rupatadine, desloratadine.

1. INTRODUCTION:

Urticaria is a transient vascular reaction pattern characterized by circumscribed, edematous, itchy lesions, usually lasting for a few hours to one or two days. It affects 15-20% of the population once or more during a lifetime [1]. Chronic urticaria is defined by recurrent episodes occurring at least twice a week for 6 weeks [2]. In around 30% patients of urticaria, attacks often recur for months or years. Chronic urticaria that has no detectable cause is termed chronic idiopathic urticaria (CIU). Females are more commonly affected than males [3]. Also, CIU is associated with lower quality of life (QoL) levels [4,5].

Controlled trials have demonstrated the efficacy of antihistamines in the treatment of chronic idiopathic urticaria [6]. Second-generation antihistamines are the recommended first-line therapy for chronic idiopathic urticaria [7].

Rupatadine is a new, once-daily, nonsedating second generation H1 antihistamine. It has also been found to inhibit platelet-activating factor (PAF) through its

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interactions with specific receptors [8] and also probably has other additional mechanisms [9]. Rupatadine is well known as a dual blocker of histamine H1 and PAF-receptors, by means of a variety of experimental and clinical studies which provide scientific evidence that this can be an effective and well tolerated treatment for urticaria [10, 11].

Desloratadine, is an established second-generation antihistamine and is proven to be effective, safe, and provides rapid onset of action and long duration of symptom relief while improving QoL [12, 13].

A careful search of medline literature showed that there was no study done to compare these two agents in patients with CIU. So this study was done to compare the efficacy and safety of relatively new drug rupatadine with the established drug desloratadine in patients suffering from CIU.

2. METHODS

2.1. Study design:

The present study is a prospective, randomized, open, comparative clinical study between rupatadine and desloratadine in patients with CIU. Procedures followed in this study are in accordance with guidelines of the Declaration of Helsinki and Tokyo for humans and the study was approved by the Institutional Ethics Committee. A written informed consent was taken from all the patients included in the trial after explaining the patient's diagnosis, the nature and purpose of the proposed treatment, the risks and benefits of the proposed treatment (rupatadine/desloratadine), alternative treatment (corticosteroids), and the risks and benefits of the alternative treatment.

2.2. Subjects:

A total of 70 patients between the ages of 12 and 60 years, suffering from CIU were screened from the Dermatology Outpatient Department of Rajiv Gandhi Institute of Medical Sciences, Kadapa, Andhra Pradesh, India and finally 56 patients were recruited for the study who were eligible according to inclusion and exclusion criteria and their acceptance to participate in the study. Patients suffering from other forms of urticaria, with significant concomitant illness (e.g., malignancies or hepatic, psychiatric, endocrine or other major systemic diseases), pregnant women, lactating mothers, females on oral contraceptive pills, patients on antihistaminic therapy for 72 hours, or steroids for one month, were excluded from the study. Certain special tests, such as, test for dermographism, ice-cube test, and exercise test were carried out in selected patients, as suggested by the history of their illness, to rule out other forms of chronic urticaria. After systematic randomization, 56 patients who participated in the study were divided into two groups; 28 patients were assigned to receive rupatadine, 10 mg daily, and 28 patients received desloratadine 5 mg daily, for a period of four weeks. At the first visit, selected cases of CIU were thoroughly interviewed, individually, to record the circumstances that precipitated the attacks and a detailed history was taken on baseline symptomatology. The vital signs were measured as, routine clinical check up. Physical examinations, especially dermatological tests, the size of the wheals were measured, and baseline clinical investigations were carried out. At the four-week follow-up, a physical examination and baseline investigations were repeated and all post drug symptoms were recorded.

2.3. Efficacy measures:

The efficacy variables were change in the total symptoms score (TSS), Aerius Quality of Life Questionnaire (AEQLQ) total score, Differential Count of Eosinophil (DC-E), Absolute Eosinophil Count (AEC) and serum IgE level from baseline visit to end of the study visit (after 4 weeks).

The severity of the symptoms of CIU patients was assessed by calculating the total symptoms score (TSS) in which all patients were evaluated for the degree of pruritus, size of wheals, number of wheals, and number of separate urticarial episodes. Efficacy measures were scored according to the following scales: Pruritus: 0 (none), 1 (mild), 2 (moderate), and 3 (severe); Number of wheals: 0 (none), 1 (1 - 10 wheals), 2 (11 - 20 wheals), 3 (> 20 wheals); Size of wheals (mean diameter): 0 (no lesion), 1 (< 1.27 cm), 2 (1.27 - 2.54 cm), 3 (> 2.54 cm); Number of separate urticarial episodes: 0 (no episodes), 1 (1 episode), 2 (2 - 3 episodes), 3 (> 3 episodes). The maximum value of the total symptoms score (TSS) was 12 [14].

Quality of life was assessed using a chronic idiopathic urticaria-specific instrument, the Aerius Quality of Life Questionnaire (AEQLQ) , which consists of 10 equally weighted questions (severity of symptoms, interference with sleep, interference with outdoor activities, ability to participate in sports/physical activities, ability to participate in leisure/social activities, ability to work or study, feelings of self-consciousness, problems with partner/close friends/relatives, sexual dysfunction, and influence on dress). Each question is scored according to the answer given by the patient for that particular question such as 3 (very much), 2 (a lot), 1(a little) and 0 (not at all). So the range of total score can be from 0 to 30. A decrease in the score indicates improvement in the quality of life. This questionnaire is based on the Dermatology Life Quality Index (DLQI), a validated measure of QoL in subjects with skin diseases [15]; the AEQLQ substitutes a question on sleep for the DLQI's question on disease treatment. DC-E and AEC were done by hemocytometer and IgE level was estimated by chemiluminescent immunoassay.

2.4. Safety measures:

Safety and tolerability were assessed on the basis of the adverse events reported, or by comparing the baseline

symptoms with post-drug symptoms, or changes in vital signs and physical examination findings recorded before and at the end of treatment.

2.5. Statistical analysis:

Statistical analysis was carried out by Paired t-test / Wilcoxon Signed Rank test for within the group comparisions, unpaired t-test / Mann Whitney Rank Sum test for between the group comparisions and Fisher's exact test for knowing the statistical significance of adverse effects in between the groups. The statistical software used was Jandel SigmaStat version 2. Interval data have been expressed as Mean ± SD and categorical data in percentage. A P value of < 0.05 was considered as statistically significant.

3. RESULTS

Out of the total 70 patients screened, only 56 patients were selected based on the inclusion and exclusion criteria and based on their approval to participate in the study. These patients were randomized to the two treatment groups. At follow up, nine patients were lost and a total of 47 patients (24 in the rupatadine group and 23 in the desloratadine group) completed the study. Among the nine patients lost, four were from rupatidine group and the remaining five were from desloratadine group. **Figure 1** shows the flow of participants of this study though it's various phases.

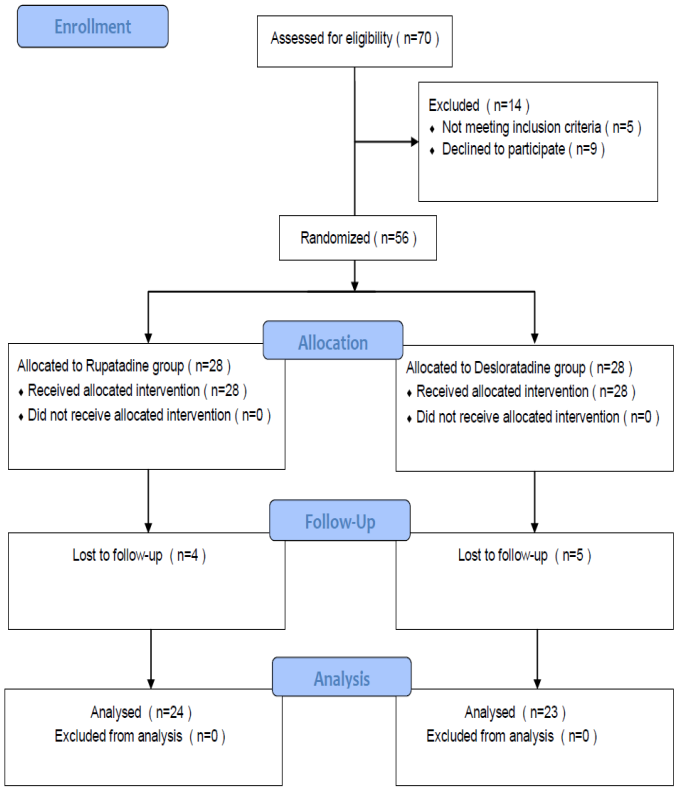

Figure 1: Consort flow diagram of patients

The two groups were homogenous with respect to baseline demographic data, including patients' age and sex, duration of disease, and severity **[Table 1]**. The percentages of the female patients were 58.3 and 56.5 in the rupatadine and desloratadine groups, respectively. The mean age of the patients was 35.2 and 34.8 years and the patients were symptomatic for a mean duration of 11.5 and 10.6 weeks in the rupatadine and desloratadine groups, respectively.

Parameter	Rupatadine	Desloratadine	P Value
Number of patients (at baseline)	28	28	
Number of patients (at the end of study)	24	23	
Female sex (%)	58.3	56.5	
Age	35.16 ± 12.43*	34.81 ± 12.19*	0.27†
Duration of illness weeks)	11.5 ± 2.7*	10.6 ± 2.3*	0.19†
DC-E	4.59 ± 1.73*	4.46 ± 1.39*	0.76†
AEC	376 ± 181*	361 ± 144*	0.73†
Serum Ig E (IU/ml)	329.6 ± 77.1*	331.1 ± 76.4*	0.94†
Total symptom score	7.43 ± 2.18*	7.68 ± 2.29*	0.68†
AEQLQ total score	11.74 ± 2.69*	12.11 ± 2.94*	0.63†

TSS: total symptoms score; AEQLQ: aerius quality of life questionnaire; DC-E: differential count of eosinophil; AEC: absolute eosinophil count; Ig: immunoglobulin; IU: international units;

* Values are given as mean ± standard deviation; † not statistically significant

Table 1: Baseline demographic data and clinical characteristics of the patients

3.1. Change in total symptoms score:

Total Symptoms Score (TSS) was calculated for the patients of both groups on their baseline and end of the study visits. There was a 1.67 (22.5%) decrease in TSS in the rupatadine group as compared to 0.83 (10.8%) in the desloratadine group **[Figure 2]**. The changes in both the rupatadine and desloratadine groups were statistically significant and when the changes in the two groups were compared, the change in the rupatadine group was found to be statistically significant compared to desloratadine group (P < 0.001) **[Table 2]**.

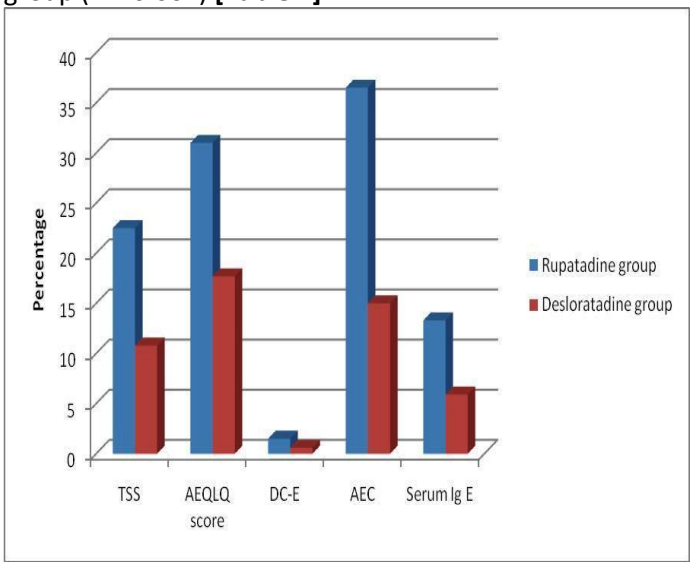

Figure 2: Percentage Change in efficacy parameters from baseline to end of study

3.2. Change in the AEQLQ total score:

The change in the AEQLQ total score was 3.64 (31.0%) in the rupatadine group whereas it was 2.14 (17.7%) in the desloratadine group **[Figure-2]**. The changes in both the

rupatadine and desloratadine groups were statistically significant and when the changes in the two groups were compared, the change in the rupatadine group was found to be statistically significant over desloratadine group (P = 0.007) **[Table 2]**.

Parameter	Rupatadine		Desloratadine		P value (Δ Rupatadine group Vs Δ Desloratadine group)
	Baseline (n=28)	End of study (n=24)	Baseline (n=28)	End of study (n=23)	
TSS	7.43 ± 2.18	5.76 ± 1.71	7.68 ± 2.29	6.85 ± 1.91	<0.001*
AEQLQ total score	11.74 ± 2.69	8.10 ± 2.07	12.11 ± 2.94	9.97 ± 2.38	0.007*
DC- E(%)	4.59 ± 1.73	3.11 ± 1.47	4.46 ± 1.39	3.91 ± 1.18	0.019*
AEC	376 ± 181	240 ± 129	361 ± 144	307 ± 135	<0.001*
Serum Ig E (IU/ml)	329.6 ± 77.1	285.9 ± 61.5	331.1 ± 76.4	312.3 ± 63.9	0.004*

TSS: total symptoms score; AEQLQ: aerius quality of life questionnaire; DC-E: differential count of eosinophil; AEC: absolute eosinophil count; Ig: immunoglobulin; IU: international units; Δ: difference; * P value is statistically significant (<0.05); All the values are given as mean ± standard deviation

Table 2: Comparative analysis of the changes in efficacy parameters in study groups

3.3. Change in differential count of eosinophil :

There was a 1.48% decrease in eosinophils in the rupatadine group in comparison to 0.55% in the desloratadine group **[Figure 2]**. The changes in both the groups were statistically significant and when the changes in the two groups were compared, the change in the rupatidine group was found to be statistically significant as compared to the desloratadine group (P = 0.019) **[Table 2]**.

3.4. Change in absolute eosinophil count :

The decrease in the Absolute Eosinophil Count (AEC) in the rupatadine group was 136 (36.2%) as compared to a decrease of 54(15.0%) in the desloratadine group **[Figure 2]**. The changes in both the groups were statistically significant and when the changes in the two groups were compared, the change in the rupatadine group was found to be statistically significant as compared to desloratadine (P <0.001) **[Table 2]**.

3.5. Change in serum IgE level:

In rupatadine group, there was a mean reduction of 43.7 (13.3%) in the serum IgE level in comparison to 18.8 (5.9%) in desloratadine group **[Figure 2]**. The individual changes in both the groups were statistically significant. The comparative analysis of the mean difference in rupatadine was statistically significant compared to desloratadine group (*P*=0.004).

3.6. Safety analysis:

No clinically significant changes in vital signs, laboratory parameters or physical examination were observed during the study in any group. In the desloratadine group, out of five patients who experienced adverse effects, two complained of drowsiness, one had headache, one had gastric irritation, and one patient had dryness of mouth. In the rupatadine group three patients complained of drowsiness. The overall incidence of adverse effects was 21.4 and 10.9% in the desloratadine and rupatidine groups, respectively. To compare the incidence of adverse effects of the two groups, the Fischer's Exact test was performed and it was found to be statistically non-significant (P = 0.85).

4. DISCUSSION

The most common approach to managing chronic urticaria is to prevent the release of histamine or to block its effects at receptor sites on nerves and endothelial cells. Therefore, H_1 antihistamines are the cornerstone of urticaria treatment. First-generation antihistamines (e.g., chlorpheniramine, diphenhydramine, and hydroxyzine) are effective, but they are also associated with adverse effects caused by their lack of selectivity for the H_1 receptor (e.g., antimuscarinic effects, appetite stimulation, weight gain, gastrointestinal effects), as well as their binding to cerebral H_1 receptors, which causes central nervous system effects, such as somnolence and cognitive impairment. Newer, second-generation agents are therefore generally preferred as first-line therapy for chronic urticaria due to their proven efficacy and favorable safety profiles [16].

While desloratadine is an established second generation antihistamine used in CIU, rupatadine is a relatively newer agent. This study was done to compare the efficacy and safety of rupatadine with the established drug desloratadine in CIU patients.

The baseline data shows that there is statistically no significant difference between the study groups with respect to the demographic and clinical parameters which indicates that the study subjects in the two groups are homogenous. The female predominance found in this study supports the previous studies where it has been found that CIU is more common in females [2,3].

With regard to severity of symptoms like degree of pruritus, size of wheals, number of wheals, and number of separate urticarial episodes, the total symptom scale was calculated on both the visits. The changes in both the rupatadine and desloratadine group were statistically significant and when the changes in the two groups were compared, the change in the desloratadine group was found to be statistically significant. The findings in the previous studies on rupatadine for CIU by Mullol et al., and Anuradha et al., support the findings of the present study [10,17]. The Total Symptom Score (TSS) is a widely accepted, standardized, and reliable tool to assess the efficacy of a drug in the treatment of urticaria and a decrease in the scoring suggests that there is an overall clinical improvement in the condition. The comparative

changes in TSS in the study groups clearly prove the superiority of rupatadine over desloratadine.

Although chronic urticaria occasionally resolves spontaneously, symptoms can potentially last for many years. The prolonged duration of the disease can have a profoundly negative impact on a patient's sense of well-being and most of the patients have lower quality of life (QoL) levels. In the present study, Quality of life was assessed by calculating the change in the Aerius Quality of Life Questionnaire total score in which it was found that changes in both treatment groups were statistically significant which is in line with the previous study done only with desloratadine by Kim et al., [18] and when the changes in the two groups were compared the change in the rupatadine group was more than that in desloratadine group. Long-lasting, safe, and effective second-generation antihistamines have been shown to substantially improve patient QoL and, therefore, remain the first choice for chronic urticaria therapy.

Coming to the laboratory parameters, differential count of eosinophils, absolute eosinophil count and serum Ig E were carried out at both visits and the results were compared between the groups. From the results obtained, the comparative changes in the differential count of eosinophils, absolute eosinophil count and serum Ig E were found to be significant, and the change in the rupatadine group was found to be statistically significant as compared to the desloratadine group. From these findings it can be concluded that there was a better control of these three investigational markers of CIU with rupatadine as compared to desloratadine.

On a quantitative measure, out of all the efficacy markers, the largest change was observed in the absolute eosinophil count (36.2% in rupatadine group vs 15% in desloratadine group) and the least change was observed in differential count of eosinophil (1.48% in rupatadine group vs 0.55% in desloratadine group)

Although the overall incidence of adverse effects in the desloratadine group has been found to be lower than in the rupatadine group, there was no significant difference between the two groups. There were no serious adverse effects in both the groups. This indicates that both the drugs were well tolerated by the patients with rupatadine having an edge over desloratadine.

The overall superiority of rupatadine over desloratadine can be explained by various additional mechanisms exhibited by it. One of its important additional mechanism of action is its inhibition of platelet activating facor(PAF), which is much greater than that of other second-generation antihistamines, which display little or no PAF antagonist activity. Rupatadine (0.3 – 10 mg/kg p.o.) inhibited the wheal induced by intradermal administration of histamine or PAF in dogs [19], whereas rupatadine and cetirizine only inhibited the histamine-induced wheal. The maximum effect of rupatadine occurred after 4 h and significant effects were still observed 24 h after the single-dose administration of the product, indicating a long-lasting effect.

Rupatadine inhibited mast cell degranulation induced by nonimmunological stimuli in rat peritoneal mast cells and also immunological stimuli in isolated skin mast cells from sensitised dogs [20]. Rupatadine also reduced tumour necrosis factor-α (TNF-α) release from canine skin mast cells and in the human mast cell line HMC-1 [21 ,22]. Eosinophils and lymphocytes are key effector cells in the late-phase response of allergy.

Rupatadine also inhibits the production of inflammatory cytokines. This effect was high for the TH2 cytokine IL-5 [23]. Rupatadine, in addition to all antihistamines, has anti-inflammatory effects that act directly on the H1 receptor. In this way, rupatadine has been shown to inhibit the activity of transcription factor AP-1 both dependently and independently from the H1 receptor [24] . Rupatadine also has a high H1 receptor binding affinity (Ki 1.6 nM), which allows the molecule to inhibit the histamine- induced IL-6 and IL-8 production using concentrations that are below the plasma levels reached at therapeutic dose [25]

5. CONCLUSION:

Analysis of the results of all the parameters of safety and efficacy proves that rupatadine is superior to desloratadine in CIU patients because of its multiple mechanisms of action. The findings of this exploratory study can be confirmed by multicentric, randomized, double-blind large population studies.

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