ORIGINAL ARTICLE

Efficacy of Fexofenadine in the Indian Population suffering from Alergic Rhinitis & Chronic Urticaria

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Abstract

The present study was designed to evaluate the efficacy of fexofenadine in the Indian population suffering from allergic rhinitis and chronic urticaria. A total number of two hundred patients of either sex with similar demographic profile were included in the study according to inclusion and exclusion criteria. These patients were treated with fexofenadine 120mg once daily for allergic rhinitis and fexofenadine 180mg for chronic urticaria for 7 days. The efficacy was evaluated on the basis of symptoms evaluation scale score and medication effectiveness scale score at baseline, on the 3rd day and on the 7th day of completion of treatment. Results indicate that fexofenadine is highly effective in the Indian population ($p<0.001$) suffering from allergic rhinitis and chronic urticaria.

Key Words

Fexofenadine, Allergic Rhinitis, Chronic Urticaria.

Introduction

Fexofenadine hydrochloride, the active acid metabolite of H_1 antagonist terfenadine, has been developed for the treatment of the symptoms associated with allergic rhinitis and chronic urticaria (1).Terfenadine is an effective antihistaminic but it is associated with cardiac arrythmias with concomitant administration of macrolide antibiotics and certain antifungals. However, fexofenadine does not undergo hepatic biotransformation so it is unlikely to interact with the drug on hepatic metabolism (2).

Clinical trials have demonstrated fexofenadine hydrochloride to be safe and effective for treatment of seasonal allergic rhinitis at the dosages of 60, 120 and 240 mg twice daily compared to placebo treatment. In chronic urticaria patients, fexofenadine 180 or 240 mg once daily was significantly effective than with placebo. Trials showed a total reduction of symptoms score, reduced pruritis, improved sleep and daily activities after completion of treatment (4-5).

Recent studies suggest that fexofenadine possesses anti-inflammatory properties by modulating release of proinflammatory mediators (2), and it does not impair the driving and psychomotor performance even in patients with moderate alcohol consumption (6).

Comparative clinical trials have demonstrated that fexofenadine is equally effective as cetirizine and loratidine in patients with allergic rhinitis and chronic urticaria (7-8) So the present study was designed to evaluate efficacy of fexofenadine in the Indian population suffering from allergic rhinitis and chronic urticaria.

Material and Methods

A total of 200 patients of either sex with similar demographic profile with the diagnosis of allergic rhinitis or chronic urticaria receiving fexofenadine were included in this study.

Inclusion Criteria

1. Patients aged above 12 years of age
2. Patients with diagnosis of allergic rhinitis or chronic urticaria

Exclusion Criteria

Patients with upper respiratory tract infection, acute sinusitis, pregnancy, lactation, unstable medical conditions like diabetes mellitus, heart failure,

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hepatic and renal impairment or patients on any other medication.

In each patient, detailed history was taken with special reference to disease conditions. After baseline clinical examination and symptoms evaluation, 100 patients of allergic rhinitis (Group A) receiving fexofenadine 120 mg once daily for 7 days and 100 patients of chronic urticaria (Group B) receiving fexofenadine 180 mg once daily for 7 days were included in the study. Patients were advised to visit for total symptoms evaluation and medication efficacy evaluation on 3rd day and after completion of treatment on the 7th day (2).

A pre-designed performa was filled for each patient containing details about the total symptoms evaluation scale and medication effectiveness evaluation scale of fexofenadine along with clinical assessment (general and physical assessment) during the patients visit and on completion of treatment. Patients were evaluated for total symptoms evaluation scale score at baseline scale (Table 3A) and on 3rd day and 7th day of visit. Similarly on 3rd day and 7th day of visit, medication effectiveness evaluation scale score (Table 3B) was evaluated for both the groups (Group A and B) (2).

Statistical analysis : Data was entered in data base programme and data analysis was done to compare total symptoms score at baseline, 3rd day and 7th day of treatment and then medication effectiveness scale score on 3rd and 7th day of treatment by using ANOVA test.

Results

The present study involved 100 patients of allergic rhinitis who were treated with fexofenadine 120 mg once daily for 7 days and these patients were complained of very severe to intolerable symptoms initially at baseline which was reduced to moderate to mild or absent after 7th days of treatment. The efficacy on the basis of medication effectiveness scale score revealed moderate relieved on 3rd day marked relieved or complete remission on 7th day in majority of patients.($p<0.001$) (Table I, Fig I).

Similarly in Group B, 100 patients of chronic urticaria received fexofenadine 180 mg once daily for 7 days. Patients complained of initial very severe to intolerable symptoms at baseline, which was reduced to mild or absent on the 7th day and medication effectiveness scale score revealed moderate to marked or complete remission after 7th days of completion of treatment ($p<0.001$) (Table 2, Fig. 2).

Table 1 : Allergic Rhintis (Group A)

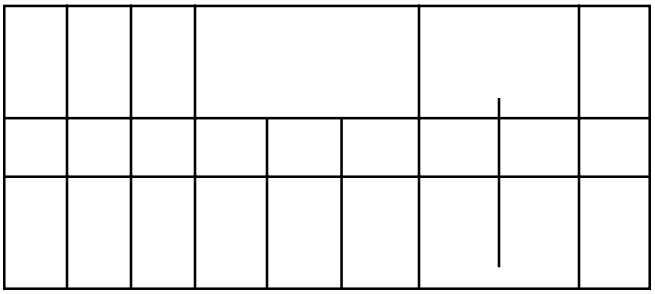

Table 2 : Urticaria (Group B)

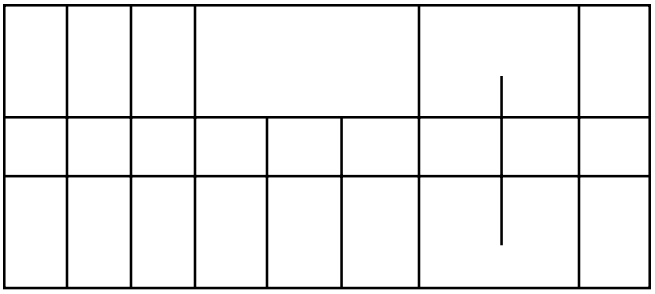

Table 3A : Sympton Evaluation Scale

Score	Description	Definition
0	Absent	Symptom is not present
1	Mild	Symptom is present but is not annoying or troublesome
2	Moderate	Symptom is frequently troublesome but would not interfere with normal daily activity or sleep
3	Severe	Symptom is sufficiently troublesome to interfere with normal daily activity or sleep
4	Very severe	Symptom is so severe or intolerable as to warrant immediate evaluation and/or treatment by the investigator

Table 3B : Medication Effectiveness Scale

Score	Description	Definition
0	Complete relief	Symptoms not present
1	Marked relief	Symptoms are vastly improved and, although still present, are scarcely troublesome
2	Moderate relief	Symptoms are noticeably improved but are still present and may be troublesome
3	Slight relief	Symptoms are present and only minimal improvement
4	No relief	Symptoms are unchanged or worse

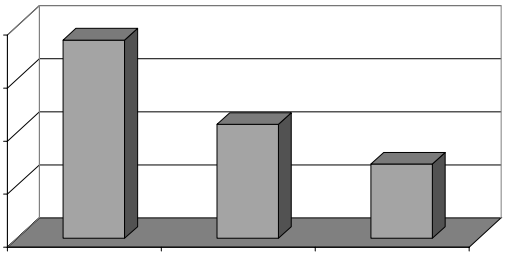

Fig. 1

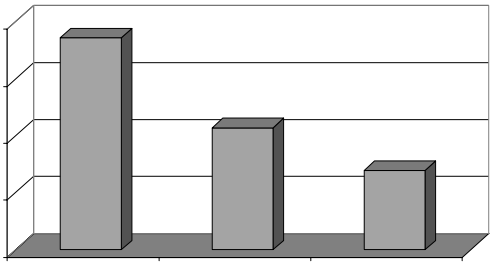

Fig. 2

Discussion

The present study indicates that patients with allergic rhinitis receiving fexofenadine 120 mg once daily showed high efficacy in terms of marked to complete relieved of symptoms. Similar finding was found in chronic urticaria patients receiving fexofenadine 180mg once daily for 7 days. These patients were reported with marked to complete relieved of symptoms after completion of treatment. Studies showed that fexofenadine is well tolerated and statistically superior to placebo in reducing sign and symptoms of allergic rhinitis and chronic urticaria, it also did not interfere with sleep and daily activitis (9). Doses of 60 mg twice daily or greater are most effective and significantly reduces pruritus severity, number of wheels (5). Other study indicate once daily fexofenadine 120 mg or 180 mg significantly improved quality of life and reduce performance impairment work and daily activities due to seasonal allergic rhinitis compared to placebo (10). Several other studies also showed better efficacy in allergic rhinitis patients in reliving eye symptoms and nasal congestion, quality of life, compared to loratidine, desloradine and cetirizine (11-14). Present study revealed that fexofenadine in different doses (120 & 180 mg) is well tolerated and efficacious in the Indian patients.

So the study concludes that fexofenadine is highly effective in the Indian population suffering from allergic rhinitis and chronic urticaria.

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