



The Comparison of Efficacy and Complication of Desloratadine with Fexofenadine in Patients with Allergic Rhinitis: A Randomized, Double-Blind Clinical Trial

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Abstract

Background: Allergic rhinitis is a very common disease which its clinical symptoms can reduce the patient's quality of life. This study aimed to compare the effects and side effects of desloratadine with fexofenadine on allergic rhinitis.

Methods: The present study is a clinical trial on 68 patients with allergic rhinitis who were randomly divided into two groups named A and B. In the A group, patients used 120 mg of fexofenadine for 4 weeks and in the B group, patients received 5 mg of desloratadine for 4 weeks. After two weeks of rest, patients in the A group received desloratadine, and patients in the B group received fexofenadine for 4 weeks. Then, the clinical conditions and efficiency of the drugs in both groups were compared.

Results: The severity of symptoms significantly decreased in the A and B groups before and after the treatment ($p < 0.001$ and $p = 0.007$, respectively). The severity of symptoms after taking the first and second drugs in the A group was lower than in the B group. In the A group, the changes in symptom severity after taking the first and second drugs were significantly greater than in the B group. Other symptoms were not significantly different between the two treatment groups ($p > 0.05$ in all cases).

Conclusion: In patients with allergic rhinitis, the use of fexofenadine compared to desloratadine can more effectively reduce the severity of the symptoms of the disease and can be prescribed as a suitable treatment option for these patients.

Keywords: Allergic rhinitis, Desloratadine, Fexofenadine

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Introduction

Allergic rhinitis is a common disease involving the upper and lower respiratory tract (1,2). The incidence of this disease is higher in developing countries (3) and various studies indicate the prevalence of rhino conjunctivitis in children aged 6-7 years and 13-14 years is 8.5 and 14.6% (4). The disease does not cause death on its own, but can be associated with significant cognitive and psychological disorders such as impaired concentration, decreased self-esteem, and ultimately reduced quality of life. In adults, allergic rhinitis is associated with anxiety, depression, and decreased activity (5,6).

Patients with allergic rhinitis are treated with second-generation antihistamines. Despite the similar efficacy of first- and second-generation antihistamines, the second-generation drugs have less effects on the central nervous system and are more preferred. These medications include loratadine, cetirizine, azelastine, and olopatadine. These lipophobic compounds have been developed to reduce the unpreventable effects of first-generation antihistamines on the central nervous system as well as reducing anticholinergic effects (7,8). The effectiveness of these drugs begins within an hour and peaks after 2 to 3 hr (9). Second-generation antihistamine metabolites such as fexofenadine (terfenadine metabolite), desloratadine (loratadine metabolite), and levocetirizine (cetirizine-enhanced isomer) are classified as third-generation antihistamines. These compounds have less effects on the central nervous system than second-generation drugs, although this has not yet been proven (10).

Oral antihistamines are used during the pollination seasons of many patients when the symptoms of allergic disease worsen. Due to the availability of a wide range of antihistamines, the most appropriate type of antihistamine for the patient is selected based on efficacy, side effects, cost, and diet. In addition, different structural systems of drugs can affect responses to some extent. There are few studies on the differences in the structural system of antihistamines and the differences in their efficacy. Therefore, more studies should be performed to compare different responses to antihistamines in patients. In the present study, the effectiveness of desloratadine with fexofenadine in patients with allergic rhinitis was compared and evaluated.

Materials and Methods

The present study was performed as a cross-over clinical trial (with the code IRCT20160516027929N11) in the period January 2020 until November 2021. Among 81 patients with allergic rhinitis referred to Masih Daneshvari Hospital in Tehran, Iran, 68 patients with allergic rhinitis older than 12 years were included in the study with written consent. The criteria for diagnosing allergic rhinitis in patients consisted of the detection of symptoms such as clear rhinorrhea and paleness of the nasal mucosa, red eyes, tears due to allergic causes, sneezing, nasal congestion, discharge from the nose, and itchy nose. Also the excluded ones were patients with allergies or adverse reactions to desloratadine and fexofenadine, patients previously treated with two or more drugs, and pregnant and lactating women. Then the patients were randomly divided into two groups.

In the A group, 33 patients used fexofenadine at a dose of 120 mg daily for 4 weeks. After two weeks of rest, 5 mg desloratadine was given to the patients for 4 weeks. Also, in group B, 35 people received desloratadine at a dose of 5 mg daily for 4 weeks. After two weeks of rest, these patients were given 120 mg fexofenadine daily. Demographic and clinical information of patients and medical history were collected by a pre-designed questionnaire. The safety of desloratadine and fexofenadine was evaluated based on possible and serious side effects. The initial efficacy of desloratadine and fexofenadine was evaluated based on the patient's initial symptoms at the first visit and the rate of symptom change at the second visit (end of treatment) and the overall symptom score based on a questionnaire that included changes in ocular and nasal symptoms. The severity of symptoms and rhinorrhea, sneezing or itchy nose, stuffy nose, itchy eyes and tears, itchy skin at the first and second visit in patients of each group based on four points (zero: asymptomatic, 1: mild, 2: moderate, 3: severe) was classified. To prevent the missing of samples, if patients did not want to go to the hospital, they were instructed by telephone and followed up.

Statistical analysis

The obtained data were reported in two descriptive and analytical sections. The descriptive part used frequency and percentage for quantitative variables.

The severity of the parameters between the first and second drugs was analyzed separately using the Wilcoxon rank test for each group. Also, the comparison of the severity of symptoms and other symptoms was performed with the Mann-Whitney U test between the two groups of A and B by period (after the first and second drugs). All the analyses were conducted using SPSS software version 22 at a significance level of 0.05 for all tests.

Results

Among 81 patients with allergic rhinitis referred to Masih Daneshvari Hospital in Tehran, Iran, 68 patients were included in this study. Of these, 37 were male and 31 were female. The mean age for the study group was 43.17 years. After random assignment, 33

patients were placed in the A group (fexofenadine +desloratadine) and 35 patients in the B group (desloratadine+fexofenadine). Figure 1 shows the consort flowcharts of the patients participating in the study and those who were excluded.

Examination of the history of the disease showed that 49 patients (72.1%) had no history of the disease, which was 71.4 and 72.7% in A and B groups, respectively (Table1).

Severity of disease symptoms and runny nose, sneezing or itchy nose, nasal congestion, itchy eyes and tears, itchy skin in the first and second visit in patients of two groups based on four points (0: no symptoms, 1: mild, 2: moderate, 3: severe) was classified.

Examining the severity of the symptoms of the

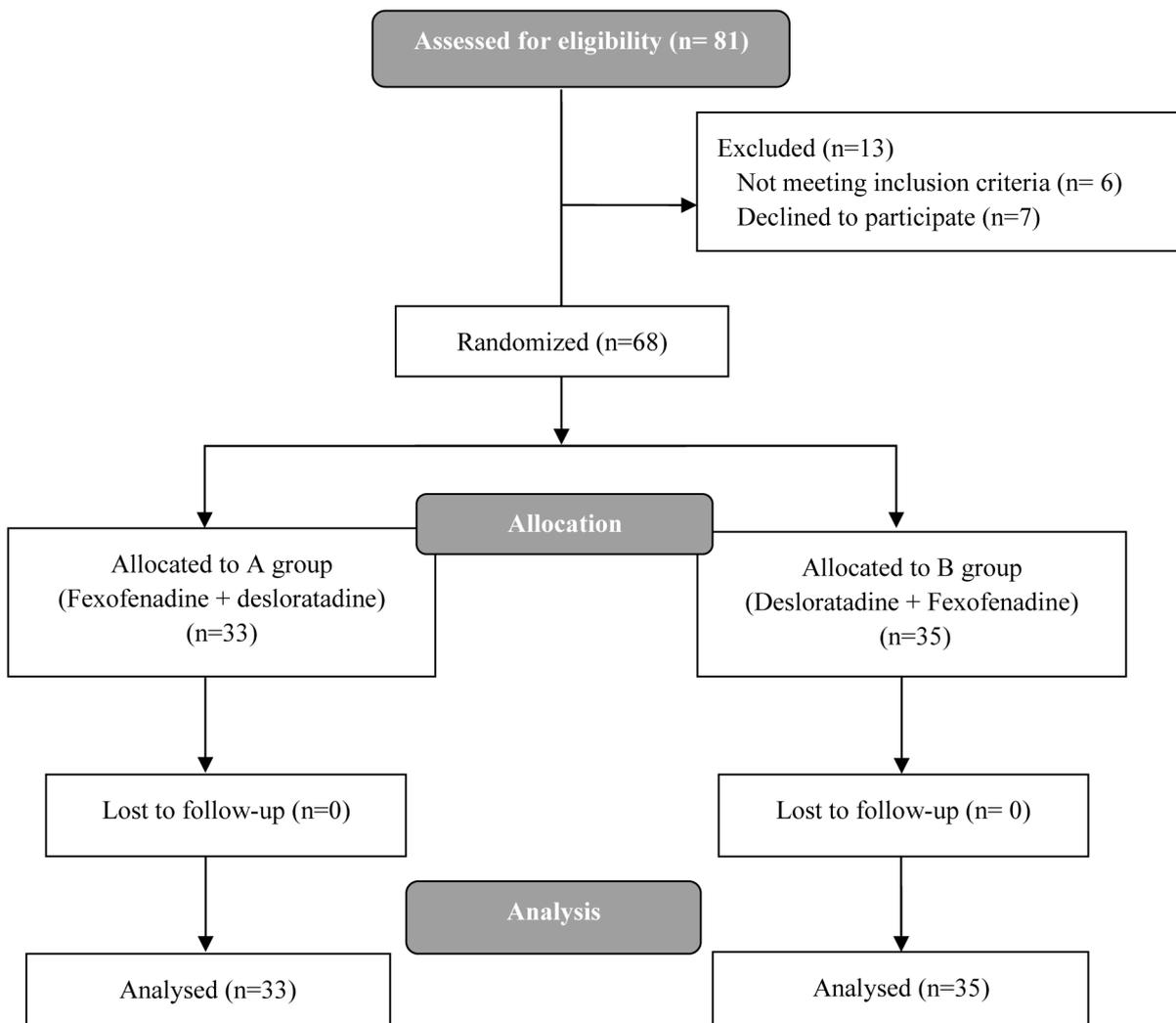


Figure 1. The consort flowcharts of the patients with allergic rhinitis participating in the study.

Table 1. Demographic information of the patients with allergic rhinitis participating in the study

Variables	Groups	B group N(%)	A group N(%)	Total N(%)
Gender	Male	18 (54.54)	19 (45.45)	37 (54.41)
	Female	15 (42.85)	16 (45.71)	31 (45.58)
Age		43.03	43.02	43.17
History of disease	Yes	9 (27.3)	10 (28.6)	19 (27.9)
	No	24 (72.7)	25 (71.4)	49 (72.1)

patients in the two groups under study demonstrated that in the A group, before the start of the treatment, 15 patients (22.1%) had the highest severity of allergic rhinitis symptoms. After taking desloratadine, this was reduced to one person, which indicates the successful effectiveness of desloratadine in the condition that it is prescribed from the beginning of the treatment process. After taking fexofenadine, the highest severity of the disease was not observed in any of the patients (Table 2).

In the B group, before starting the drug treatment, 17 patients (25%) had the highest severity of the disease, which decreased to 4 (8.2%) after receiving the first drug (desloratadine), and after receiving the second drug (fexofenadine), it increased to 5. In the other hands, the use of desloratadine in the first period of treatment protocol decreased allergic rhinitis symptoms and after taking fexofenadine, the number of people who had the highest severity of symptoms

increased.

The different symptoms of allergic rhinitis in patients of the two groups are presented in table 3. Our results have shown that in group A, there was no change in the number of patients with severe symptoms during the treatment period. While the number of patients who had the most Rhinorrhea symptoms in group B at the beginning of treatment (1.5%), increased after the end of the treatment period (2.9%). In addition, people who showed the least form of Rhinorrhea in group B decreased after the end of the treatment period [29 (42.6%) vs. 26 (38.2 %)]. In group A, the number of patients with the lowest Rhinorrhea increased after the treatment period [25 (36.8%) against 26 (38.2%)]. Also, none of the protocols have had an effect on sneezing or itchy nose and nasal congestion. Itchy eyes and tears decreased from 36.8 to 33.8% in group A and from 42.6 to 35.3% in group B. Also, the number of patients with the

Table 2. The severity of symptoms in the two groups of A and B at different times

Variable	Group A			Group B			
	Before treatment (%)	After receiving fexofenadine (%)	After receiving desloratadine (%)	Before treatment (%)	After receiving desloratadine (%)	After receiving fexofenadine (%)	
Severity of symptoms	1	0 (0%)	11 (22.4%)	12 (29.3%)	0 (0%)	5 (10.2%)	1 (2.4%)
	2	3 (4.4%)	6 (12.2%)	4 (9.8%)	1 (1.5%)	4 (8.2%)	1 (2.4%)
	3	15 (22.1%)	15 (30.6%)	16 (39%)	17 (25%)	3 (6.1%)	2 (4.9%)
	4	15 (22.1%)	1 (2%)	0 (0%)	17 (25%)	4 (8.2%)	5 (12.2%)
	Total	33 (48.5%)	30 (61.2%)	30 (73.2%)	35 (51.5%)	19 (38.8%)	11 (26.8%)

most symptoms (2.9%) decreased after the end of the treatment period (1.5%) in group A, but no change in skin itching was observed in group B after the end of the treatment period (Table 3).

Intra-group comparison of the severity of symptoms before and after the end of the treatment period by

Wilcoxon test demonstrated that the severity of symptoms was significant in the group A ($p < 0.001$) and group B ($p = 0.007$). Meanwhile, other symptoms include Rhinorrhea ($p = 0.792$ in group A and $P = 0.190$ in group B), sneezing or itchy nose ($p = 0.723$ in group A and $p = 0.999$ in group B), itchy eyes and tears

Table 3. Frequency and percentage of allergic rhinitis symptoms in the studied groups

Variable		Group A		Group B	
		Before treatment (%)	After treatment (%)	Before treatment (%)	After treatment (%)
Rhinorrhea	1	25 (36.8%)	26 (38.2%)	29 (42.6%)	26 (38.2%)
	2	6 (8.8%)	5 (55.6%)	3 (4.4%)	4 (44.4%)
	3	2 (2.9%)	2 (2.9%)	2 (2.9%)	3 (4.3%)
	4	0 (0%)	0 (0%)	1 (1.5%)	2 (2.9%)
	Total	33 (48.5%)	33 (48.5%)	35 (51.5%)	35 (100%)
Sneezing or itchy nose	1	23 (33.8%)	24 (35.5%)	27 (39.7%)	26 (38.2%)
	2	8 (11.8%)	7 (10.3%)	5 (7.4%)	7 (10.3%)
	3	2 (2.9%)	2 (2.9%)	2 (2.9%)	1 (1.5%)
	4	0 (0%)	0 (0%)	1 (1.5%)	1 (1.5%)
	Total	33 (48.5%)	33 (48.5%)	35 (51.5%)	35 (51.5%)
Nasal congestion	1	22 (32.4%)	21 (30.9%)	23 (33.8%)	19 (27.9%)
	2	6 (8.8%)	6 (8.8%)	7 (10.3%)	6 (8.8%)
	3	3 (4.4%)	4 (5.9%)	4 (5.9%)	8 (11.8%)
	4	2 (2.9%)	2 (2.9%)	1 (1.5%)	2 (2.9%)
	Total	33 (48.5%)	33 (48.5%)	35 (51.5%)	35 (51.5%)
Itchy eyes and tears	1	25 (36.8%)	23 (33.8%)	29 (42.6%)	24 (35.3%)
	2	5 (7.4%)	7 (10.3%)	2 (2.9%)	6 (8.8%)
	3	3 (4.4%)	2 (2.9%)	2 (2.9%)	3 (4.4%)
	4	0 (0%)	1 (1.5%)	2 (2.9%)	2 (2.9%)
	Total	33 (48.5%)	33 (48.5%)	35 (51.5%)	35 (51.5%)
Skin itching	1	23 (33.8%)	24 (35.3%)	27 (39.7%)	24 (35.3%)
	2	8 (11.8%)	6 (8.8%)	5 (7.4%)	7 (10.3%)
	3	0 (0%)	2 (2.9%)	2 (2.9%)	3 (4.4%)
	4	2 (2.9%)	1 (1.5%)	1 (1.5%)	1 (1.5%)
	Total	33 (48.5%)	33 (48.5%)	35 (51.5%)	35 (51.5%)

($p=0.414$ in group A and $p=0.145$ in group B), and skin itching (0.854 in group A and $p=0.380$ in group B) had no significant changes. Also, the course of nasal congestion changes in group B has decreased significantly ($p=0.039$) (Table 4).

Intergroup comparison of severity and symptoms of allergic rhinitis in groups A and B before and after treatment with the Mann-Whitney U test at a significance level of $p<0.05$ has shown significant changes in the severity of symptoms of the two groups before treatment and after receiving the first drug ($p<0.001$). Meanwhile, the severity of the disease symptoms after receiving the second drug had no significant change ($p=0.152$). Also, other symptoms

including rhinorrhea ($p=0.310$), sneezing or itchy nose ($p=0.592$), nasal congestion ($p=0.108$), itchy eyes and tears ($p=0.176$), and skin itching ($p=0.738$) did not change significantly (Table 5).

Discussion

Allergic rhinitis is a very common disease and causes many major problems for patients. Clinical signs of this disease can reduce the patient’s quality of life, which affects sleep, work, and daily activities (11). Today, anti-allergy therapies are based on avoiding the causative allergen, medication, specific immunotherapy, and education (12). Allergic rhinitis is mainly managed with oral intranasal H1 antihistamines, anticonvulsants, leukotriene receptor antagonists, and intranasal corticosteroids. Second-generation antihistamines have become increasingly popular due to their comparable efficacy and lower prevalence of side effects than first-generation antihistamines (13).

Given the different effects of available drugs, it is essential for the physician prescribing these drugs to evaluate these effects separately based on their therapeutic outcomes (11). Therefore, in the present study, the impact of desloratadine with fexofenadine on allergic rhinitis was compared in two groups. A total of 68 patients with allergic rhinitis in the two groups were evaluated for severity and type of symptoms. These two groups included: group A taking fexofenadine at a dose of 120 mg for 4 weeks

Table 4. Comparison of disease severity and symptoms within two groups

Variables	Groups		p-value
	A group	B group	
Severity of symptoms	<0.001	0.007	
Rhinorrhea	0.792	0.190	
Sneezing or itchy nose	0.783	0.999	
Nasal congestion	0.726	0.039	
Itchy eyes and tears	0.414	0.145	
Skin itching	0.854	0.380	

Table 5. Comparison of changes in the severity of symptoms and other symptoms between two groups

Variables changes	p-value
The severity of symptoms before the treatment and after taking the first drug	<0.001
The severity of symptoms between the before treatment and after taking the second drug	0.152
Rhinorrhea before and after treatment	0.310
Sneezing or itchy nose before and after treatment	0.592
Nasal congestion before and after treatment	0.108
Itchy eyes and tears before and after treatment	0.176
Skin itching before and after treatment	0.738

and after 2 weeks of rest, desloratadine at a dose of 5 mg daily for 4 weeks. In group B, patients consume desloratadine at a dose of 5 mg daily for 4 weeks and after 2 weeks of rest, the patients used fexofenadine at a dose of 120 mg daily for 4 weeks.

The results of our study showed that in the group A, the number of patients who had the highest severity of allergic rhinitis symptoms decreased significantly after taking the first drug (fexofenadine) and no increase was observed after taking desloratadine. In the patients of group B, the severity of symptoms after taking the first drug (desloratadine) significantly decreased compared to before treatment, but after taking the second drug (fexofenadine), the number of people who had the most severe symptoms increased slightly, and the number of people who had mild-to-moderate symptoms did not decrease significantly. Comparison of other symptoms such as rhinorrhea, sneezing or itching of the nose, itchy eyes and tears, and itchy skin after taking the first and second drugs were not significantly different. Among all the symptoms examined in the two groups, in the patients of group B, nasal congestion was significantly reduced due to the treatment protocol.

A comparison of the two methods of treatment shows that although both methods were effective in reducing the severity of symptoms of allergic rhinitis, in patients in the group A, the first and then the second drug was more effective in reducing the severity of symptoms than patients in group B. The changes in the severity of symptoms in patients in group A were more than in patients in group B compared to before the intervention.

There are few studies comparing the effectiveness of desloratadine and fexofenadine in allergic diseases. Similar to our study, Mahatme *et al* showed that fexofenadine is significantly more effective than levocetirizine in improving patients with allergic rhinitis (14). Also, a similar study is the Cauwenberge study, in which the effect of fexofenadine 120 mg and desloratadine 10 mg was compared with placebo on allergic rhinitis, was evaluated in 600 patients. In this study, fexofenadine was found to be significantly better than loratadine in improving pruritus, rhinorrhea, red eyes, nasal congestion, and quality of life (15). The clinical effects of fexofenadine and desloratadine on symptoms and nasal congestion in

49 patients with seasonal allergic rhinitis were also evaluated in the Wilson study. The results of this study suggested that taking 180 mg of fexofenadine and 5 mg of desloratadine once a day improved the peak of airflow and nasal symptoms in patients with allergic rhinitis. In this study, the potency of the H1 receptor antagonist with desloratadine was shown to be much higher compared with fexofenadine (16).

In contrast, some studies have confirmed the effective role of desloratadine in reducing allergic symptoms. The effect of desloratadine and fexofenadine compared to placebo or in combination with other antihistamines has been studied in several studies. In Horak *et al*'s study, the effects of desloratadine at a dose of 5 mg on interstitial airway and nasal obstruction in patients with seasonal allergic rhinitis were investigated. The researchers showed that treatment with desloratadine was associated with less nasal obstruction and nasal congestion was compared with placebo (17). In the study of Yonekura *et al*, the effect of desloratadine on controlling the symptoms of allergic rhinitis was reported to be more effective than placebo (18). Wandalsen *et al* confirmed the safety and efficacy of desloratadine combined with prednisolone in the treatment of acute symptoms in children with 2 to 12 years of age with allergic rhinitis (19). The results of our study suggested that reducing the severity of symptoms in patients in group A, which was first treated with fexofenadine and then desloratadine, was more effective than in patients in the B group. Symptoms decreased in both groups, but no significant differences were observed in the symptoms of rhinorrhea, sneezing or itching of the nose, nasal congestion, itchy eyes and tears, and itchy skin. This can be due to limitations such as the sample size, the dose of medication used, and the course of treatment.

Conclusion

According to the results of this study, the severity of symptoms of allergic rhinitis in patients who use first fexofenadine and then desloratadine is associated with a greater reduction than patients who first use desloratadine and then fexofenadine.

Acknowledgements

The present study was conducted in the form of a

thesis and was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences with code IR.SBMU.NRITLD.REC.1400.024. The authors thank all the colleagues of Masih Daneshvari Hospital in Tehran, Iran, who participated in the

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Conflict of Interest

There is no conflict of interest.

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