

The Effect of Omalizumab on Allergic Rhinitis Symptoms: A Comparative Study

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ABSTRACT

Both Omalizumab and (Montelukast+Desloratadine) are effective treatments for allergic rhinitis. However, these treatments have not been compared clinically. Therefore, we aimed to compare their efficacy on allergic rhinitis symptoms. Between December 2018 and November 2019, 25 patients with both allergic rhinitis and chronic urticaria and 25 patients with allergic rhinitis alone were included in the study. Patients with both allergic rhinitis and chronic urticaria received Omalizumab (300 mg/month) (Omalizumab group), while patients with allergic rhinitis alone received (Montelukast+Desloratadine)/daily (Desloratadine group). In addition, both groups received fluticasone propionate nasal spray (100 mcg/day in each nostril). At baseline and after 8-10 weeks (follow-up), symptoms and quality of life were assessed. A visual analogue scale was used for the assessments.

Compared to baseline, both groups showed significant symptomatic improvements at follow-up. When the change from baseline to follow-up was compared, the groups were similar in terms of nasal congestion, rhinorrhoea, sneezing and quality of life. However, Omalizumab group was superior to Desloratadine group in terms of eye itching (68.55 ± 17.62 vs 55.46 ± 20.42 ; $p=0.010$).

In conclusion, Omalizumab is more effective than Montelukast plus Desloratadine for eye itching in allergic rhinitis.

Keywords: Omalizumab, Montelukast, Desloratadine, rhinitis, comparative study.

Introduction

Allergic rhinitis is a disease frequently encountered by physicians. The prevalence rate is 15-20% depending on the population (1,2). This high prevalence constitutes a significant economic burden (2). Pathologically, allergic rhinitis occurs when allergens pass through the impaired protective epithelium and adhere to the nasal mucosa, stimulating Th-mediated type 2 response and allergen-related IgE production (1). The main symptoms of allergic rhinitis include nasal congestion (~94.2%), rhinorrhea (~90.4%), sneezing, and itchy eyes (1). In addition, allergic rhinitis is associated with comorbidities including asthma, headache, sinusitis, eczema, conjunctivitis, and urticaria (1-3). In general, this disease negatively affects quality of life and leads to serious costs (2,4). Although the diagnosis of allergic rhinitis is mainly based on clinical symptomatology, history and physical examination (5), many diagnostic tools such as in vivo tests, in vitro tests, nasal tests and radiologic imaging have been proposed (2,4,6). Treatment of allergic

rhinitis aims to provide symptomatic relief and improve quality of life. In addition to non-pharmacologic measures (allergen avoidance, nasal irrigation), pharmacologic management is based on symptom severity and includes the use of antihistamines (e.g. Desloratadine), antileukotrienes (e.g. Montelukast), corticosteroids, decongestants, ipratropium, and immunotherapy (2,6). In addition to conventional treatments, biologic drugs (especially Omalizumab and Dupilumab) have been reported to be beneficial (7).

The combination of Montelukast and Desloratadine is a widely used conventional treatment option in allergic rhinitis. On the other hand, it has been suggested that Omalizumab is an effective biologic agent and can be used as an alternative or additional option for inadequately responding allergic rhinitis (8,9). Both Omalizumab and Montelukast plus desloratadine are effective treatments in allergic rhinitis, however, there are no studies comparing the effects of these treatments on allergic rhinitis symptoms. Omalizumab is an anti-IgE

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monoclonal antibody and targets IgE (10). Considering that allergic rhinitis is associated with various allergic comorbidities (1-3) and increased IgE production (1), it is reasonable to assume that Omalizumab may provide an overall improvement in allergic rhinitis symptoms and is worth comparing with conventional treatments such as Montelukast plus Desloratadine. However, Omalizumab is expensive and is not officially covered for allergic rhinitis in Turkey. Since Omalizumab is covered for chronic urticaria and the coexistence of rhinitis and urticaria is common (3), it was possible to evaluate the efficacy of Omalizumab on allergic rhinitis symptoms in patients with both allergic rhinitis and chronic urticaria. Therefore, the aim of this study was to compare the efficacy of Omalizumab and Montelukast plus Desloratadine on allergic rhinitis symptoms and quality of life in patients with both allergic rhinitis and chronic urticaria.

Materials and Methods

Ethical Approval: This study was approved by the institutional review board of Van Yüzüncü Yıl University Hospital. Written informed consent was obtained before starting the study. The study was conducted according to the principles of the Helsinki Medical Research Protocol. Between December 2018 and November 2019, 25 patients with both allergic rhinitis and chronic urticaria from the Department of Dermatology and 25 patients with allergic rhinitis only from the Department of Otorhinolaryngology were included in the study.

Medication: In this comparative effectiveness study, patients with both allergic rhinitis and chronic urticaria received Omalizumab (XOLAIR®, Novartis, Basel, Switzerland) subcutaneously (300 mg/month) (**Omalizumab group**). Patients with allergic rhinitis received Montelukast 10 mg and Desloratadine 5 mg (DESMONT®, Vitalis, Ankara, Turkey) orally (**Desloratadine group**). In addition, both groups received fluticasone propionate (DALMAN AQ®, Drogan, Ankara, Turkey) nasal spray (100 mcg/day per nostril).

Exclusion Criteria: All patients were checked for nasal and systemic diseases. Patients with the following conditions were excluded: <18 and >65 years of age, systemic comorbidities such as diabetes mellitus, hypertension, renal failure and hypothyroidism. In addition, patients with rhinosinusitis, nasal polyps, nasal septal deviation,

tumors, smoking and nasal surgery, and non-compliant patients were excluded from this study.

Outcome Measures: All participants were assessed for allergic rhinitis symptoms, including nasal congestion, rhinorrhea, sneezing and itchy eyes, and quality of life at baseline and 8-10 weeks after the start of treatments (follow-up). A self-report outcome, 10-cm linear visual analogue scale scores, was used to measure the severity of allergic rhinitis symptoms and quality of life. It has been reported that mild, moderate and severe allergic rhinitis can be measured using visual analogue scale (11).

Statistical Analysis: Data were statistically analyzed using IBM® SPSS® Statistics version 27.0. Statistical significance was set at $p < 0.05$. The Shapiro-Wilk test was used to evaluate whether continuous variables fit the normal distribution. Nonparametric tests (Mann-Whitney U and Wilcoxon) were applied to continuous variables with non-normal distribution. The statistical tests applied are indicated below the tables. Gender variables were evaluated using Fisher's exact test. Continuous and categorical variables are presented as Mean \pm SD (min-max) and frequency (percentage), respectively. The sample size was determined using the PASS 2021 program. The sample size was determined as 25 for each group for an α error value of 0.05, a $1-\beta$ value of 0.8, and an Area of Under the Curve value of 0.8.”

Results

Inter-Group Comparison of General Data: There were no statistically significant differences between the Omalizumab group and Desloratadine group in terms of age (34.71 \pm 9.83 vs 30.56 \pm 9.31; $p=0.085$), female/male ratio (11/14 vs 10/15; $p=0.999$), and total Ig E level (296.09 \pm 301.01 vs 307.24 \pm 349.98; $p=0.808$).

Inter- and Intra-Group Comparisons of Nasal Congestion Scores: Both baseline ($p=0.018$) and follow-up ($p=0.029$) scores of the Omalizumab group were significantly lower than the Desloratadine group. Follow-up scores were significantly lower than baseline scores in both Omalizumab ($p=0.001$) and Desloratadine ($p=0.001$) groups. The two groups were similar in terms of mean change (%) in nasal congestion from baseline to follow-up ($p=0.219$) (Table 1).

Inter- and Intra-Group Comparisons of Rhinorrhea Scores: The two groups were similar for both baseline ($p=0.095$) and follow-up

Table 1: Descriptive statistics and comparison results for nasal congestion

	Omalizumab group	Montelukast group	p
	Mean ± SD (min –max)	Mean ± SD (min –max)	
Baseline	6.76±1.98 (3.0-10.0)	8.16±1.72 (5.0-10.0)	0.018*
Follow-up	2.64±1.25 (1.0-6.0)	3.84±1.97 (1.0-8.0)	0.029*
p	<0.001**	<0.001**	
Change (%)	59.13±20.44 (0.0-88.9)	54.32±18.06 (20.0-85.7)	0.219*

SD: Standard deviation; Omalizumab group: Omalizumab (300 mg/month) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); Montelukast group: (Montelukast 10 mg with Desloratadine 5 mg) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); *The Mann-Whitney U test; **The Wilcoxon test

Table 2: Descriptive statistics and comparison results for rhinorrhea

	Omalizumab group	Montelukast group	p
	Mean ± SD (min –max)	Mean ± SD (min –max)	
Baseline	6.56±2.10 (3.0-10.0)	7.64±2.08 (4.0-10.0)	0.095*
Follow-up	2.52±1.29 (1.0-7.0)	2.84±2.21 (1.0-8.0)	0.639*
p	<0.001**	<0.001**	
Change (%)	60.86±15.80 (22.2-85.7)	65.50±20.23 (20.0-90.0)	0.179*

Omalizumab group: Omalizumab (300 mg/month) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); Montelukast group: (Montelukast 10 mg with Desloratadine 5 mg) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); *The Mann-Whitney U test; **The Wilcoxon test

Table 3: Descriptive statistics and comparison results for sneezing

	Omalizumab group	Montelukast group	p
	Mean ± SD (min –max)	Mean ± SD (min –max)	
Baseline	6.48±1.50 (4.0-10.0)	7.80±2.36 (3.0-10.0)	0.012*
Follow-up	2.92±1.53 (1.0-7.0)	3.16±1.46 (1.0-6.0)	0.463*
p	<0.001**	<0.001**	
Change (%)	54.33± 22.95 (0.0-87.7)	57.49±20.21 (00.0-88.9)	0.710*

Omalizumab group: Omalizumab (300 mg/month) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); Montelukast group: (Montelukast 10 mg with Desloratadine 5 mg) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); *The Mann-Whitney U test; **The Wilcoxon test

Table 4: Descriptive statistics and comparison results for eye itching

	Omalizumab group	Montelukast group	p
	Mean ± SD (min –max)	Mean ± SD (min –max)	
Baseline	6.60±1.76 (1.0-10.0)	7.20±2.22 (3.0-10.0)	0.360*
Follow-up	1.88±0.73 (1.0-4.0)	3.24±1.94 (1.0-8.0)	0.007*
p	<0.001**	<0.001**	
Change (%)	68.55±17.62 (0.0-87.5)	55.46±20.42 (20.0-88.9)	0.010*

Omalizumab group: Omalizumab (300 mg/month) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); Montelukast group: (Montelukast 10 mg with Desloratadine 5 mg) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); *The Mann-Whitney U test; **The Wilcoxon test

(p=0.639) scores. Follow-up scores were significantly lower than baseline scores in both the Omalizumab (p=0.001) and Desloratadine (p=0.001) groups. The two groups were similar in terms of mean change (%) in rhinorrhea from baseline to follow-up (p=0.179) (Table 2).

Inter- and Intra-Group Comparisons of Sneezing Scores: The two groups were

significantly different for baseline scores (p=0.012). However, they were similar for follow-up scores (p=0.463). Follow-up scores were significantly lower than baseline scores in both Omalizumab (p=0.001) and Desloratadine (p=0.001) groups. The two groups were similar in mean change (%) in sneezing from baseline to follow-up (p=0.710) (Table 3).

Table 5: Descriptive statistics and comparison results for quality of life

	Omalizumab group	Montelukast group	p
	Mean ± SD (min –max)	Mean ± SD (min –max)	
Baseline	7.00±1.35 (5.0-10.0)	8.60±1.66 (5.0-10.0)	<0.001*
Follow-up	2.72±0.94 (1.0-5.0)	3.72±1.43 (1.0-7.0)	0.008*
p	<0.001**	<0.001**	
Change (%)	59.99±14.18 (33.3-90.0)	56.45±15.16 (25.0-87.5)	0.397***

Omalizumab group: Omalizumab (300 mg/month) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); Montelukast group: (Montelukast 10 mg with Desloratadine 5 mg) plus fluticasone propionate nasal spray (100 mcg/day in each nostril); *The Mann-Whitney U test; **The Wilcoxon test; ***Independent samples test

Inter- and Intra-Group Comparisons of Itchy

Eye Scores: The two groups were similar in terms of baseline scores ($p=0.360$). However, the Omalizumab group had significantly lower follow-up scores than the Desloratadine group ($p=0.007$). Follow-up scores were significantly lower than baseline scores in both Omalizumab ($p=0.001$) and Desloratadine ($p=0.001$) groups. When the mean change (%) in ocular itch from baseline to follow-up was considered, the Omalizumab group had significantly higher scores than the Desloratadine group (Table 4).

Inter- and Intra-Group Comparisons of

Quality of Life Scores: Both baseline ($p=0.001$) and follow-up ($p=0.008$) scores of the Omalizumab group were significantly lower than the Desloratadine group. Follow-up scores were significantly lower than baseline scores in both Omalizumab ($p=0.001$) and Desloratadine ($p=0.001$) groups. The two groups were similar in terms of mean change (%) in quality of life from baseline to follow-up ($p=0.397$) (Table 5).

Discussion

This comparative effectiveness study compared the effects of Omalizumab and conventional treatment with Montelukast plus Desloratadine on allergic rhinitis. In comparisons between baseline and follow-up scores, both treatment groups were found to be effective for allergic rhinitis symptoms. When the degree of effect (change from baseline to follow-up) was considered, the two groups showed similar therapeutic efficacy in nasal congestion, rhinorrhea, sneezing, and quality of life. However, the Omalizumab group was superior to the Desloratadine group in eye itching. Accordingly, if eye itching is a prominent or persistent symptom in patients with allergic rhinitis, Omalizumab can be recommended.

The results of previous studies on the effect of combination therapy with Montelukast and

Desloratadine on allergic rhinitis were confirmed in this study. Previous studies reported that the combination of Montelukast and Desloratadine improved symptoms and quality of life in patients with allergic rhinitis (12,13). Consistent with the current findings, previous studies have also demonstrated the efficacy of Omalizumab on persistent allergic rhinitis (4,6,7). However, there are no studies comparing the effects of Montelukast plus Desloratadine combination with Omalizumab treatment on allergic rhinitis. Although both treatment options have been found to be beneficial in allergic rhinitis, comparative studies are needed to determine which is most effective. Based on this logical and scientific background and necessity, this study was conducted.

Current therapeutic management of allergic rhinitis includes non-pharmacologic measures and pharmacologic options (14). Furthermore, personalized treatment based on the main symptoms and laboratory characteristics has been proposed in patients with allergic rhinitis (15,16). According to this recommendation and considering that the current study showed that Omalizumab is more effective on itchy eyes, it may be recommended to use Omalizumab if itchy eyes is a prominent or persistent symptom in patients with allergic rhinitis. Consistent with this finding and suggestion, Tang et al. (17) reported that pre-seasonal administration of Omalizumab provided preventive efficacy in seasonal allergic rhinoconjunctivitis. Similarly, Kirikkaya and Değirmenci (18) demonstrated significant relief of allergic conjunctivitis in patients treated with Omalizumab for asthma. Furthermore, the potential and promising role of Omalizumab in vernal keratoconjunctivitis has been previously emphasized (19). All these data demonstrate the therapeutic power of Omalizumab for ocular symptoms associated with allergic rhinitis.

This study has several limitations. First of all, since Omalizumab is not covered by the official reimbursement for allergic rhinitis in our country and due to ethical issues, the Omalizumab group was composed of patients with both allergic rhinitis and chronic urticaria in which Omalizumab is effective and officially covered (20). Therefore, the results of this study may only apply to patients with allergic rhinitis. Second, the two groups were not similar in terms of some baseline parameters. These first and second limitations may have weakened the comparability of the groups. Nevertheless, comparisons including the degree of efficacy revealed the superior effect of omalizumab. Third, given the high cost of omalizumab treatment, the lack of a risk-benefit and cost analysis in the study should be considered other limitations. Finally, this study is a single-center study with a relatively small sample and therefore its results may not be strongly generalizable.

In conclusion, the treatment groups in this study showed similar therapeutic efficacy in nasal congestion, rhinorrhea, sneezing and quality of life. However, for itchy eyes, the efficacy of treatment with Omalizumab was superior to conventional treatment with Montelukast plus Desloratadine. Accordingly, if eye itching is one of the main symptoms in allergic rhinitis, Omalizumab can be recommended.

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