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Factors Influencing Relapse After Omalizumab in Chronic Urticaria. Does the Method of Discontinuation Influence Relapse?

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ABSTRACT

Introduction: Omalizumab is recommended for chronic urticaria (CU) until spontaneous remission occurs rather than for a specific period of time. The rate of relapse after treatment varies depending on the method of discontinuation.

Objectives: Our study aimed to investigate how the method of omalizumab discontinuation and other factors affect the rate of post-treatment relapses.

Methods: Patients with CU were divided into three groups based on their method of discontinuing omalizumab treatment: direct discontinuation, extending treatment intervals to eight weeks, and reducing the treatment dose to 150 mg/4 weeks. These groups were then compared for relapse rates.

Results: A total of 200 patients were included in this study. Among the 109 patients who discontinued omalizumab directly, 65.1% experienced a relapse. The relapse rate was 40.7% in those who extended the treatment intervals to eight weeks and 15.6% in those who reduced the dose to 150 mg/4 weeks. There was a statistically significant difference in post-treatment relapse rates according to the method of discontinuation ($P< 0.001$).

Conclusions: Gradual tapering of treatment rather than direct discontinuation has been shown to prolong remission. Achieving the lowest relapse rate with a reduction in the treatment dose to 150 mg/4 weeks is significant for the design of omalizumab discontinuation protocol and provides insights for future studies.

Introduction

Chronic urticaria (CU) is characterized by wheals and angioedema that persist for more than six weeks and significantly impair the quality of life of patients due to its pruritic nature. The prevalence of CU is estimated to be between 0.5% and 1% of the population [1]. Omalizumab is a monoclonal antibody that targets IgE and is the preferred third-line treatment for CU patients who have not responded to a fourfold dose of antihistamines (AHs). The efficacy and safety of omalizumab 300 mg in patients with CU refractory to AHs have been demonstrated in three pivotal Phase III randomized controlled trials in which 52.4% to 58.8% of patients achieved well-controlled urticaria [2].

In patients with a complete response to omalizumab, there is currently no consensus on the optimal method and timing for cessation of treatment. To determine whether the disease is in remission, periodic attempts to discontinue omalizumab in patients with completely controlled disease may be beneficial. This is frequently achieved by discontinuing omalizumab treatment within six months to one year in a significant proportion of patients [3]. To date, three distinct methods of discontinuation have been described in the literature: direct discontinuation, gradual extension of the dose intervals to eight weeks while maintaining a response for at least two doses within this period, and dose reduction to 150 mg every four weeks while maintaining a response for at least two doses at this level. Stepwise tapering has been linked to both improved disease control and a longer remission period. Patients who discontinued omalizumab directly were compared with those who gradually extended the dose intervals before discontinuation [4,5].

Objective

Given the limited literature available on this topic, the aim of our study was to investigate how the method of omalizumab discontinuation, as well as other factors, affects the rate of post-treatment relapses.

Methods

Ethics Approval

This study was approved by the local ethics committee and conducted in accordance with the tenets of the Declaration of Helsinki (05.2023.499.). Informed consent was obtained from all participants.

Study Population

This study included patients aged 12 years or older who were diagnosed with CU and treated with omalizumab at a dose of 300 mg every four weeks for at least three months between January 2009 and May 2022. Each patient was followed for at least 15 months after discontinuing omalizumab. Patients who were resistant to standard omalizumab treatment and required higher doses or intervals shorter than four weeks were excluded. Additionally, patients lost to follow-up after completing omalizumab treatment were also excluded.

Data Collection and Analysis

Patients with CU are followed at intervals of 4-8 weeks. At each visit, symptom severity and disease control are assessed using the 7-day Urticaria Activity Score (UAS7) and the Urticaria Control Test (UCT). Moreover, serum IgE and blood basophil levels are measured and documented at weeks 0 and 4 of treatment. The demographic and clinical characteristics of the patients, including age, sex, comorbidities, disease duration, presence of angioedema, concomitant treatments, method of omalizumab discontinuation, and time to relapse after treatment, were obtained from electronic medical records.

A UAS7 score of less than 6 is defined as a good response to omalizumab treatment [6]. In our study, we attempted to discontinue treatment in patients with a UAS7 score of less than 6 following omalizumab therapy. Patients were divided into three groups based on the method of discontinuing omalizumab treatment: direct discontinuation, extending the treatment intervals to eight weeks, and reducing the treatment dose to 150 mg every four weeks. Relapse in patients with CU was defined as the recurrence of symptoms after discontinuation of omalizumab treatment, determined by a UCT <12 or a UAS7 score >16 [7,8]. These groups were then compared for relapse rates.

Statistical Analysis

Statistical analysis of the data was performed using IBM SPSS 24.0. Descriptive statistics were calculated as mean (± standard deviation), median and range for continuous variables, and percentages for categorical variables. For categorical variables, the chi-squared test was used to compare independent groups. Continuous variables with a normal distribution were analyzed using an independent samples t-test for independent groups and a paired samples t-test for dependent groups. For non-normally distributed variables, the Mann-Whitney U test was used to analyze data between independent groups. A p-value of less than 0.05 was considered statistically significant.

Results

Demographic and Clinical Characteristics

The study included 200 patients with CU. The mean age of the patients was 45.86 years, and 66% (n = 132) of the

patients were female. The demographic, clinical, and laboratory characteristics of the patients are shown in Table 1.

The duration of CU prior to omalizumab treatment ranged from 1 to 39 months, with a median of 6.09 months. A history of angioedema was present in 49.5% (n=99) of the patients. At baseline and week 4 UAS7 scores of the patients were available for 154 and 151 patients, respectively. The mean baseline UAS7 score was 37.45, and the mean week 4 UAS7 score was 7.79. There was a statistically significant decrease in UAS7 scores at week 4 compared to baseline (P<0.001).

Laboratory Characteristics

Serum IgE levels at baseline and week 4 were available for 106 and 65 patients, respectively. The median IgE level was 101.50 IU/ml at baseline and 275 IU/ml at week 4. Forty-seven patients (90.4%) demonstrated an increase in IgE levels at week 4, while five (9.6%) showed a decrease. A statistically significant increase in serum IgE levels was observed from baseline to week 4 (P<0.001). Blood basophil levels were measured in 143 patients at baseline and in 52 patients at week 4. The mean basophil level remained at 0.03 (1000/µL) from baseline to week 4. Basopenia was present in 20 patients (13.9%) at baseline.

Omalizumab Treatment

All patients had used AHs prior to starting omalizumab. While 27 patients (13.5%) had not received any additional treatment, 173 patients (86.5%) continued to use AHs alongside omalizumab treatment. Of these, 125 (62.5%) adhered to the treatment regularly, with a mean duration of 4.90 months, while 48 patients (24%) used AHs only as needed (Table 2). The total duration of omalizumab use ranged from 3 to 39 months, with a mean duration of 19.47 months.

Post-Treatment Relapse Status

After at least three months of standard omalizumab treatment, 109 patients (54.5%) discontinued omalizumab treatment directly, 59 patients (29.5%) extended the dose intervals to eight weeks, and 32 patients (16%) reduced the dose to 150 mg/4 weeks before discontinuation. Among patients who completed treatment, relapse was observed in 100 patients (50%), with a median time to relapse of four months (range: 1–40). The most common relapse occurred in the third month, affecting 27% (n= 7) of the patients, and 49% (n=49) of patients experienced a relapse within the first three months of treatment (Table 2). Among those who discontinued omalizumab directly, relapse was observed in 65.1% (n=71) of cases, while among those who extended the dose intervals, relapse was observed in 40.7% (n=24) of cases. Among those who reduced the dose prior to discontinuation, relapse was observed in 15.6% (n=5) of cases. There was a statistically significant difference in post-treatment relapse rates according to the method of treatment discontinuation (P<0.001) (Table 3, Figure 1).

In patients who discontinued omalizumab directly, relapse occurred after an average of 6.77 months. For those who discontinued treatment by extending the dose intervals, the mean time to relapse was 6.71 months, while in patients who reduced the dose before discontinuation, it was 4.8 months. No statistically significant difference was observed between the groups in the time to relapse based on the method of discontinuation (P=0.841).

In addition to the method of discontinuation of omalizumab treatment, the impact of other demographic and clinical characteristics of patients with CU on relapse rates was evaluated (Table 4). The total disease duration before omalizumab treatment was 7.67 months in patients with relapses, while it was 4.51 months in patients without relapses. The pre-treatment disease duration was significantly longer in the relapse group (P<0.001). Patients who discontinued AHs within the first three months of omalizumab treatment had a significantly lower relapse rate than did those who continued AHs for a longer duration (P=0.005). The mean baseline UAS7 score was 39.21 for patients who experienced a relapse (n=78) compared to 35.64 for those who did not (n=76). A significantly higher relapse rate was observed in patients with higher baseline UAS7 scores (p=0.004). Subgroup analysis based on age, sex, coexisting angioedema, hypothyroidism, basopenia, previous treatments, treatment response time, baseline serum IgE level, reduction in UAS7 score, and increase in serum IgE level at week 4 of therapy did not reveal a statistically significant difference in terms of post-treatment relapse rates. After experiencing a post-treatment relapse, 10 patients (10%) achieved adequate symptom control with AH treatment, while 90 patients (90%) reinitiated omalizumab therapy.

Discussion

This study showed that the method of discontinuation of omalizumab significantly impacts the rate of post-treatment relapses. To our knowledge, this is the first study to compare three different methods of treatment discontinuation in terms of relapse rates. Our results suggest that reducing the dose or gradually increasing the intervals between doses, as opposed to direct discontinuation, leads to reduced relapse rates after omalizumab treatment.

The female-to-male ratio for CSU reported in the literature is consistent with our study findings [9]. A previous study reported that the prevalence of CSU was lowest in patients aged 18-24 years, while the disease was most commonly observed in the 45-54 age group [10]. The mean age

Table 1. The demographic, clinical, and laboratory characteristics of the patients.

Characteristics	N = 200
Sex, n (%)	
Female	132 (66)
Male	68 (34)
Age, years	
Mean ± SD (range)	45.86 ± 14.97 (12-79)
Duration of disease †, months	
Median (range)	6.09 (1-39)
Angioedema, n (%)	
Present	99 (49.5)
Absent	101 (50.5)
Comorbidities, n (%)	109 (54.5)
Hypertension	30 (15)
Allergic diseases	21 (10.5)
Diabetes mellitus	18 (9)
Hypothyroidism	14 (7)
Hyperlipidemia	8 (4)
Psychiatric diseases	6 (3)
Trigger factors, n (%)	150 (75)
Stress	90 (45)
Physical factors	37 (18.5)
Pressure	10 (5)
Heat	9 (4.5)
Cold	5 (2.5)
Dermographism	5 (2.5)
Drug	25 (12.5)
Food	24 (12)
İnfection	10 (5)
CU subtypes, n (%)	
CSU	163 (81.5)
CIU	14 (7)
CSU + CIU	23 (11.5)
Previous treatments, n (%)	
AH	200 (100)
Monotherapy	110 (55)
In combination‡	90 (45)
Systemic CS	78 (39)
Cyclosporine	5 (2.5)
Doxepin	3 (1.5)
UAS7 score, mean ± SD	
Baseline	37.45 ± 7.67
4th week of the treatment	7.79 ± 10.75
Serum IgE level, (IU/mL), median	
Baseline	101.5
4th weeks of the treatment	275
4th weeks of the treatment	2.7
Blood basophil level§, (1000/µl), mean ± SD (range)	
Baseline	0.03 ± 0.02
4th week	0.03 ± 0.03

Note: †The duration of disease encompasses the period before starting omalizumab treatment. ‡The group of patients utilizing antihistamines in combination, also received systemic corticosteroids, doxepin, and dapsone concurrently. §The laboratory's reference range for the measurements was 0.01–0.07 (1000/µl).

SD, standard deviation; CU, chronic urticaria; CSU, chronic spontaneous urticaria; CIU, chronic inducible urticaria; CS, corticosteroid; AH, antihistamine; UAS7, urticaria activity score over 7 days; IgE, Immunoglobulin E; IU, International unit.

Table 2. Characteristics of Omalizumab Treatment and Post-Treatment Relapse.

Characteristics	
Duration of treatment, months Mean ± SD (range)	19.47 ± 15.53 (3-39)
Concomitant AH use, n (%) Present Regular Occasional Absent	 173 (86.5) 125 (62.5) 48 (24) 27 (13.5)
Treatment response time, months, median (range) Fast (1st month), n (%) Slow (>1 month), n (%)	1 (1-12) 126 (70.3) 52 (29.7)
Duration of AH use, months Mean ± SD (range)	 4.90 ± 4.13 (1-24)
Treatment discontinuation method†, n (%) 300 mg/4 weeks 300 mg/8 weeks 150 mg/4 weeks	 109 (54.5) 59 (29.5) 32 (16)
Relapse rate, n (%) Present Absent	 100 (50) 100 (50)
Time to relapse, months Median (range)	 4 (1-40)
Relapse time, n (%) 1-3 months 4-6 months 7-12 months >12 months	 49 (49) 21 (21) 19 (19) 11 (11)
Post-relapse treatment, n (%) AH Omalizumab	 10 (10) 90 (90)

†Patients were categorized based on their approach to discontinuing omalizumab treatment: cessation directly (300 mg every 4 weeks), prolonging the dosing interval to 8 weeks (300 mg every 8 weeks), and reducing the dosage to 150 mg every 4 weeks.

SD, standard deviation; AH, antihistamines

Table 3. Relapse rates according to the method of discontinuing treatment.

	Relapsed, n (%)	Non-relapsed, n(%)	P value
300 mg/4 weeks	71 (65.1)	38 (34.9)	< 0.001*
300 mg/8 weeks	24 (40.7)	35 (59.3)	
150 mg/4 weeks	5 (15.6)	27 (84.4)	

*continuity correction test

in our study fell within the age range where the highest prevalence has been reported in the literature.

The relapse rate in this study is comparable to the 44.4% and 50% rates reported in the 6-month OPTIMA study and the 43.4% and 45.1% rates reported in the 24-to-48-week XTEND-CIU study [11]. Gradual tapering has been

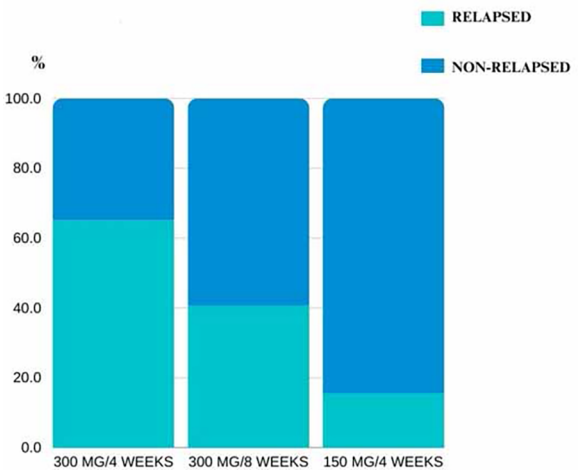

Figure 1. A statistically significant difference in the post-treatment relapse was observed according to the method of treatment discontinuation (P<0.001)

Table 4. The association between characteristics of patients and relapse rate.

		Relapse rate, n (%)		P value
		Relapsed	Non-relapsed	
Sex	Female Male Total	64 (48.5) 36 (52.9) 100 (50)	68 (51.5) 32 (47.1) 100 (50)	0.550*
Age	Mean ± SD (years) Total	46.43 ± 14.15 100 (50)	45.30 ± 15.74 100 (50)	0.594**
Angioedema	Present Absent Total	54 (54.5) 46 (45.5) 100 (50)	45 (45.5) 55 (54.5) 100 (50)	0.203*
Hypothyroidism	Present Absent Total	6 (42.9) 94 (50.5) 100 (50)	8 (57.1) 92 (49.5) 100 (50)	0.782***
Duration of disease	Mean ± SD (months) Total	7.67 ± 6.55 100 (50)	4.51 ± 4.40 100 (50)	**< 0.001****
Previous treatments	AH >1 agent Total	52 (47.3) 48 (53.3) 100 (50)	58 (52.7) 42 (46.7) 100 (50)	0.394*
Treatment response time	1st month >1 month Total	65 (51.6) 21 (40.4) 86 (48.3)	61 (48.4) 31 (59.6) 92 (51.7)	0.174*
Duration of AH use	≤3 months >3 months Total	22 (35.5) 38 (60.3) 60 (48)	40 (64.5) 25 (39.7) 65 (52)	**0.005***
Basopenia	Present Absent Total	7 (35) 63 (52.1) 70 (49.6)	13 (65) 58 (47.9) 71 (50.4)	0.241***
Baseline UAS7 score	Mean ± SD Total	39.21 ± 6.11 78 (50.65)	35.64 ± 8.66 76 (49.35)	**0.004****
The decrease in UAS7 score at the 1st month	Mean ± SD (Δ) Total	31.22 ± 12.32 76 (50.33)	27.84 ± 12.18 75 (49.66)	0.092**
Baseline serum IgE level (IU/mL)	Median Total	111 55 (51.88)	89 51 (48.12)	0.410**
Ratio of serum IgE level at week 4 to baseline	Mean ± SD Total	3.97 ± 1.73 25 (48.07)	4.31 ± 2.19 27 (51.93)	0.544**

*Pearson chi-squared test; **Independent sample t-test; ***continuity correction test SD, standard deviation; AH, antihistamines; UAS7, urticaria activity score over 7 days; IgE, Immunoglobulin E; IU, International unit.

associated with better disease control and longer remissions [4]. Our study results support these findings. When comparing discontinuation methods, the lowest relapse rates were observed in patients who discontinued omalizumab treatment by reducing the dose, followed by those who gradually extended the dose intervals. The highest relapse rates were observed in patients who discontinued treatment directly without altering the dose or dose interval. Previous studies have shown that patients who gradually tapered treatment by extending the dose intervals to eight weeks had a lower relapse rate compared to those who discontinued treatment directly. In the OPTIMA study, patients who discontinued omalizumab treatment by reducing the dose to 150 mg/4 weeks had a relapse rate of 44%, while patients who discontinued treatment at a dose of 300 mg/4 weeks had a relapse rate of 50% [4,5]. This may be because patients who tapered were able to stop treatment in a more controlled manner. Some patients who discontinued treatment directly did so independently of their physician, believing they had recovered, which likely contributed to higher relapse rates in this group.

Patients who tolerate step therapy not only require less medication but are also more likely to discontinue treatment. The duration that patients can tolerate varies as dose intervals are increased. In one study, patients were followed at 12-week intervals, while in another study, 6-week intervals were found to be adequate for symptom control; however,

patients could not tolerate further increases in dose intervals [3]. In our study, patients whose symptoms remained controlled or were well controlled (UAS7 <6) for at least two months were discontinued after tolerating 8-week dose intervals. To date, no study has compared relapse rates in patients who were tapered to 150 mg/4 weeks versus those who had their intervals extended to eight weeks. The observation of the lowest relapse rate after dose reduction in our study is an important finding for omalizumab discontinuation strategies. Further comprehensive studies are needed to support this hypothesis.

When analyzing the results of our study, no significant correlation was found between the relapse rates and the clinical and demographic characteristics of the patients. In a study conducted in China involving 235 patients, sex, age, disease duration, baseline IgE level, and, unlike in our study, baseline UAS7 score did not differ significantly between the relapse and non-relapse groups [12]. However, Chen et al. found that shorter disease duration and low baseline IgE levels (<100 IU/ml) were associated with a lower relapse rate [13]. Similarly, Ertaş et al. suggested that high baseline IgE levels (>100 IU/ml) correlated with faster relapse compared to normal serum IgE levels. They also found that IgE levels did not influence the response to omalizumab. It has been hypothesized that in patients with high baseline IgE levels, IgE is cleared from the blood within a few days after treatment discontinuation, leading to a faster onset of relapse due to rapid IgE synthesis [14]. In contrast to analyses suggesting that baseline serum IgE levels influence both relapse rate and frequency, our study found no significant association between baseline serum IgE levels and these outcomes. Further comprehensive studies are needed to fully elucidate the effect of IgE levels on relapse.

There is limited knowledge in the literature regarding the factors that influence relapse after omalizumab treatment. Predicting relapse duration is crucial to assessing disease prognosis and determining appropriate follow-up and treatment plans for patients [15]. Factors such as disease duration, baseline UAS7 score, and duration of concomitant AH use with omalizumab have been significantly associated with relapse. Higher relapse rates have been observed in patients with longer disease duration [15,16], which aligns with our findings that more severe clinical presentations are linked to a higher risk of relapse. Similarly, patients with high baseline UAS7 scores demonstrated significantly higher relapse rates. Additionally, those who used AHs with omalizumab for more than three months had a higher relapse rate than did those who used AHs for three months or less. This suggests that prolonged use of AHs may indicate a more severe course of CU and an increased risk of relapse. Notably, no study has been found in the literature that specifically compared the duration of concomitant AH use with relapse frequency. Marzano et al. found that high baseline UAS7 scores and longer disease duration were associated with higher relapse rates, while Salman et al. identified younger age (<40 years) as a factor contributing to more frequent relapses [4,16]. In a study of 152 patients, Su et al. found that longer disease duration was significantly associated with higher relapse rates, whereas duration of omalizumab treatment did not affect the occurrence of relapses [15]. Similarly, Sardana et al. concluded that omalizumab administration for longer than 6–12 months did not reduce relapse rates [17]. These findings underscore the lack of consensus among researchers regarding the factors influencing relapse rates.

Recent studies have reported that even when treatment was continued for at least one year, symptoms returned in approximately 61% of patients after omalizumab discontinuation. When symptoms worsened, AHs often proved to be inadequate, prompting the majority of patients to resume omalizumab treatment. Türk et al. reported that 91% of patients who achieved a complete response to omalizumab and experienced relapse after discontinuation needed to restart omalizumab [11,18]. Similarly, most patients in our study restarted omalizumab due to an inadequate response to AHs. When considering retreatment with omalizumab in relapsing patients, the clinician's assessment and the patient's expectations are important. According to an established algorithm, omalizumab should be reinitiated in relapsing patients if the UAS7 score is >6 or the UCT is <12. Furthermore, disease severity and history of angioedema are also important factors. From another perspective, if the patient's symptoms are milder, the patient should be followed and omalizumab treatment should be considered if the UAS7 score is >16 [19].

Limitations

There are several limitations to this study, including its retrospective nature, small sample size, lack of a control group, and short follow-up period. Extending the follow-up period might have provided more comprehensive results, particularly with regard to the occurrence of relapses beyond the initial 15 months.

Conclusion

The present study found a higher relapse rate in patients with longer disease duration, higher baseline UAS7 scores, and prolonged use of AHs with omalizumab for more than three months. These factors may serve as useful indicators for patient monitoring and treatment decisions. Gradual tapering of treatment rather than direct discontinuation has been shown to prolong remission. Achieving the lowest relapse rate by reducing the treatment dose to 150 mg/4 weeks is crucial to designing the omalizumab discontinuation protocol and provides valuable insights for future studies.

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