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Predictors of Early Response and Relapse in Chronic Spontaneous Urticaria Treated with Omalizumab: The Role of Age, Sex, Disease Duration, and UAS7

Mehmet Enes Güner[1], Perihan Öztürk[2], Ozan Can Yaray[2], Esra Merve Evran Kılıç[2], Mine Müjde Kuş[2]

1 Department of Dermatology, Besni State Hospital, Besni, Adiyaman, Turkey

2 Department of Dermatology, Kahramanmaras Sutcu Imam University, Kahramanmaras, Turkey

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Corresponding Author: Mehmet Enes Güner, MD. Department of Dermatology, Besni State Hospital, Besni, Adiyaman, Turkey. Email: mehmetenesguner171@hotmail.com Orcid ID: https://orcid.org/0000-0001-5424-4674

ABSTRACT

Introduction: Omalizumab is an established treatment for chronic spontaneous urticaria (CSU), yet variability in therapeutic response remains a clinical challenge. Identifying baseline predictors of early response may help optimize patient selection and management strategies.

Objectives: To evaluate the predictive value of age, sex, baseline disease severity, and disease duration for early response to omalizumab and to assess their relationship with relapse risk.

Methods: This retrospective study included 274 patients with CSU treated with omalizumab between 2011 and 2024. Early response was defined as achieving a UAS7 score <7 at one month. Baseline variables included age, sex, UAS7, and disease duration. Binary logistic regression and ROC curve analyses were conducted to identify independent predictors of early response.

Results: Among 274 patients (mean age 42.96±15.54 years; 66.4% female), early response was achieved in 37.6%. Early responders had significantly lower baseline UAS7 and shorter disease duration (both $P<0.001$). Logistic regression confirmed both variables as independent predictors. Age and sex were not independently associated with early response, although univariate analysis showed a higher early response rate in patients aged <45 years. ROC analysis demonstrated strong inverse

predictive value for UAS7 (AUC=0.917) and disease duration (AUC=0.940). Relapse risk was significantly lower in females and patients aged <45 years.

Conclusions: Lower baseline UAS7 and shorter disease duration independently predict early response to omalizumab. Younger age and female sex may be associated with lower relapse risk. These findings support earlier therapeutic intervention in patients with lower disease burden to improve outcomes.

Introduction

Urticaria is a condition characterized by the presence of wheals, angioedema, or both [1]. Its prevalence in females is 2– 4 times higher than in males [2]. Chronic urticaria is defined as urticaria persisting for more than six weeks. [1] Chronic spontaneous urticaria (CSU) is characterized by the spontaneous occurrence of symptoms lasting longer than six weeks. In CSU, lesions typically appear without a specific trigger. CSU is most commonly observed between the ages of 20 and 40 years, with the disease duration ranging between one and five years in most patients [3].

Second-generation antihistamines are the first-line treatment, but in patients who do not respond even after dose escalation up to four times the standard dose, omalizumab is added to the treatment regimen [1]. Omalizumab is a monoclonal anti-IgE antibody used in the treatment of asthma, allergic rhinitis, and chronic urticaria [4]. Omalizumab is now a well-established and highly effective therapeutic agent for patients with moderate-to-severe chronic spontaneous urticaria (CSU). Both pivotal randomized controlled trials and real-world observational studies have consistently demonstrated omalizumab's capacity to achieve disease control in a substantial proportion of patients. A meta-analysis encompassing 45 studies and 1,158 individuals with CSU reported that approximately 72% of patients achieved complete symptom resolution with omalizumab [5]. Nonetheless, response rates vary, and nearly one third of patients do not achieve adequate clinical benefit [6]. Furthermore, among responders, there is notable variability in the timing and extent of improvement. Some patients experience rapid relief of itching and hives within the first four weeks of therapy, whereas others require 2–3 months or longer to achieve well-controlled disease [7]. This heterogeneity in patient responses, both in terms of efficacy and speed of onset, underscores the need to better understand which patients are likely to benefit from omalizumab quickly, which may respond only later or partially, and which may fail to respond at all.

Given the variable outcomes with omalizumab, researchers have sought to identify baseline patient factors that predict treatment response. Demographic factors such as age and sex have been evaluated, but findings remain inconclusive. CSU occurs across all adult age groups, with a slight female predominance, yet sex has not emerged as a consistent predictor of omalizumab efficacy [5]. Similarly, the influence of age on treatment outcomes is unclear. Some real-world data suggest that older patients may achieve higher rates of disease control with omalizumab [8], whereas other studies report no significant age difference between responders and non-responders [5].

Disease severity at baseline has also been examined as a potential predictor of outcome. The urticaria activity score (UAS7), a 7-day composite itch and hive severity score, is often used to quantify baseline disease activity. There is evidence that patients with more severe baseline UAS7 scores tend to have poorer treatment responses to omalizumab. In a real-world cohort, non-responders had significantly higher median baseline UAS7 than did responders, and a baseline UAS7 above ~30 was found to predict non-response with moderate accuracy [5].

Another factor of interest is the duration of CSU prior to starting omalizumab. Long-standing disease might reflect a more entrenched or treatment-resistant urticaria endotype, potentially influencing outcomes. Some investigations have noted that longer disease duration is associated with an elevated risk of relapse after stopping omalizumab [9].

Determining predictors of early response and of relapse risk is of high clinical relevance in the management of CSU. Identifying patients likely to respond quickly to omalizumab could enable clinicians to optimize treatment plans, for instance, by continuing therapy in those showing early improvement or considering alternative strategies in those predicted to respond poorly. Early identification of likely non-responders may spare patients prolonged ineffective treatment and help guide the use of adjunctive therapies. In light of the above, the present study aimed to systematically evaluate the impact of four key patient factors (age, sex, baseline UAS7, and disease duration) on outcomes of omalizumab therapy in CSU. Specifically, we sought to determine whether any of these baseline characteristics predict an early treatment response to omalizumab, and whether they influence the risk of relapse after omalizumab discontinuation. By clarifying the role of age, sex, initial disease severity, and disease chronicity in early efficacy and post-treatment relapse, this study may help refine our ability to personalize CSU treatment and improve long-term management strategies.

Methods

Ethical approval for this study was obtained from the Clinical Research Ethics Committee (Date: 17.02.25, Session No: 2025/06, Decision No: 13).

This retrospective study included patients diagnosed with chronic spontaneous urticaria (CSU) who presented to the dermatology outpatient clinics of our hospital between June 2011 and January 2024 and who initiated omalizumab treatment. Patient records were reviewed to extract clinical data. The diagnosis of CSU and the assessment of disease activity were conducted in accordance with the EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for urticaria [1].

Patients were eligible for inclusion if they were over 18 years of age, had a confirmed diagnosis of CSU, were treated with omalizumab, and had completed at least 16 weeks of therapy without receiving additional systemic treatments. Patients with inducible urticaria were excluded. Disease activity was evaluated using the Urticaria Activity Score over 7 days (UAS7), which assesses the severity of wheals and pruritus.

Each patient received 300 mg of omalizumab every four weeks for 16 weeks. Disease activity and the therapeutic effect of omalizumab were evaluated using UAS7 measurements at baseline and at the 4th, 8th, 12th, and 16th week. Patients were then categorized based on their response to treatment over the 16-week period. Responders were defined as those with a UAS7 score <7, whereas non-responders were those with a UAS7 score of 7 or higher. "Early response" was defined as the resolution of CSU symptoms (UAS7 <7) within the first four weeks of omalizumab treatment [5].

After the initial treatment period, patients were followed for an additional eight weeks to monitor for relapse, defined as the need to reinitiate omalizumab due to recurrence of CSU symptoms after discontinuation.

The primary objective of the study was to evaluate early response and relapse rates according to age and sex. Secondary analyses explored the influence of baseline UAS7 and disease duration on treatment outcomes.

Statistical Analyses

Statistical analyses were conducted using IBM SPSS Statistics 26. Descriptive data are presented as N and % for categorical variables, and as mean ± standard deviation (Mean±SD) for continuous variables. The Kolmogorov–Smirnov and Shapiro–Wilk tests were used to assess the normality of continuous variables. Group comparisons were performed using the chi-square test for categorical variables and the Mann–Whitney U test for non-normally distributed continuous variables. A p-value of <0.05 was considered statistically significant.

Binary logistic regression analysis was performed to identify independent predictors of early treatment response, including baseline UAS7, disease duration, age group (<45 vs. ≥45 years), and sex. Results are reported as odds ratios (OR) with 95% confidence intervals (CI). Receiver operating characteristic (ROC) curve analyses were conducted to evaluate the discriminatory ability of baseline UAS7 and disease duration for predicting early response. The area under the curve (AUC) and optimal cutoff values were calculated based on sensitivity and specificity metrics.

Results

A total of 274 patients with chronic spontaneous urticaria (CSU) undergoing omalizumab treatment were included in the study, with a mean age of 42.96 ± 15.54 years (min=18, max=85). Among these, 92 (33.6%) were male, and 182 (66.4%) were female.

The mean duration of omalizumab treatment among the study participants was found to be 35.63 ± 27.78 months (min=3, max=120).

Among the patients, 143 (52.2%) were still continuing treatment, while 77 patients (28.1%) had discontinued treatment of their own will. The number of patients whose treatment was discontinued due to lack of efficacy was 15 (5.5%), while 36 patients (13.1%) initially responded to treatment but later discontinued due to loss of effectiveness. One patient discontinued treatment at the fourth month due to generalized numbness and fatigue. Another patient discontinued treatment at the fifth month due to a 7% reduction in body weight. Additionally, one patient developed a widespread maculopapular reaction within 24 hours after the fifth dose, leading to treatment discontinuation. Another patient experienced palpitations starting from the third dose, necessitating drug discontinuation. The total number of patients who discontinued treatment due to adverse effects was four (1.45%). Among these, two (0.74%) were male and two (0.74%) were female.

The mean age of male patients in the study was 43.15 ± 16.77 years, while that of female patients was 42.86 ± 14.93 years. No statistically significant difference was observed between the ages of male and female patients (P=0.885).

The mean follow-up duration for male patients was 35.52 ± 29.70 months, whereas for female patients, it was 35.68 ± 26.84 months. No significant difference was found between the sexes in terms of follow-up duration (P=0.964).

When evaluating early responders to omalizumab treatment based on sex, no statistically significant difference was observed between male and female patients in terms of initial response to the first dose (P=0.243) (Table 1).

Table 1. Treatment Response by Sex.

Sex	Number of Patients	Number of Early Responders	Number of Non-Responders	Relapse
Male	92	39	12	32
Female	184	64	25	42

Among patients who did not respond to omalizumab treatment, 12 were male, while 25 were female. No significant difference was found between the sexes regarding the lack of treatment response to omalizumab (P=0.874) (Table 1).

When evaluating relapse development in patients monitored after 16 weeks of omalizumab treatment, relapse was observed in 42 female patients (23.1%) and 32 male patients (34.8%). The relapse rate during omalizumab treatment was found to be significantly higher in male patients compared to female patients (p=0.02) (Table 1).

When patients who responded early to omalizumab treatment and those who did not were divided into two groups based on age—under 45 years and 45 years or older—a significant difference was observed in the response to the first dose in the younger age group compared to the older age group (P=0.01). Accordingly, the rate of benefiting from the first dose of omalizumab was significantly higher in patients under 45 years of age (Table 2).

When female patients who responded early to omalizumab treatment and those who did not were analyzed separately by age groups, no significant difference was found between the two age groups in terms of response to the first dose (P=0.446) (Table 2).

When relapse development after 16 weeks of omalizumab treatment was evaluated based on age groups, the recurrence rate was found to be significantly lower in the under 45 age group compared to the 45 years and older group (P=0.016) (Table 2).

Among the 274 patients, 103 (37.6%) achieved an early response to omalizumab as defined by a UAS7 <7 at the first month. Patients who achieved an early response had significantly lower baseline UAS7 scores compared to non-responders (P<0.001). Similarly, disease duration prior to omalizumab initiation was significantly shorter in early responders compared to non-responders (P<0.001).

Binary logistic regression was performed to determine whether baseline clinical characteristics were independently associated with early response to omalizumab (defined as UAS7 <7 at one month). The model was statistically significant (χ^2 = 277.765, P<0.001) and demonstrated good fit (Hosmer–Lemeshow test, P=0.788). Lower baseline UAS7 (odds ratio (OR): 0.657; 95% CI: 0.555–0.777; P<0.001) and shorter disease duration prior to omalizumab initiation (OR: 0.761; 95% CI: 0.697–0.831; P<0.001) were both independently associated with a higher likelihood of early treatment response. In contrast, sex (P=0.307) and age group (<45 vs. ≥45 years, P=0.872) were not independently associated with early response.

Notably, in univariate analysis, patients under 45 years of age showed a statistically significantly higher likelihood of achieving early response compared to those aged 45 years or older (P=0.01). However, this relationship did not persist after adjusting for disease duration and baseline UAS7 in multivariate analysis, suggesting the apparent age effect may be mediated through these clinical variables.

ROC curve analysis was performed to assess the ability of baseline UAS7 to predict early response to omalizumab. The area under the curve (AUC) was 0.083, indicating an inverse predictive relationship. Interpreted in clinical context, this corresponds to an AUC of 0.917 for lower baseline UAS7 predicting early response. Coordinate points suggested that patients with baseline UAS7 values below approximately 10–12 were most likely to achieve early response, whereas those with scores above 20 were highly unlikely to do so.

ROC curve analysis was conducted to assess the predictive value of disease duration for early response to omalizumab. The area under the curve (AUC) was 0.060, indicating an inverse association. Clinically, this corresponds to an AUC of 0.940 when interpreted for shorter disease duration predicting early response. Coordinate analysis suggested that a disease duration of less than six months was associated with the highest sensitivity for early treatment response, while durations exceeding 12–15 months were increasingly associated with non-response.

Discussion

In this study, we investigated the impact of age, sex, baseline UAS7, and disease duration on both early response and relapse risk in patients with chronic spontaneous urticaria treated with omalizumab. Our findings revealed that lower baseline UAS7 scores and shorter disease duration were both independently associated with a significantly higher likelihood of early response, while age and sex were not significant predictors in multivariate models. However, in univariate analysis, patients younger than 45 years were more likely to achieve early response. Additionally, relapse

Table 2. Treatment Response by Age Groups.

Age Groups	Number of Patients	Number of Early Responders	Non-Early Responders	Number of Female Early Responders	Number of Female Non-Early Responders	Relapse
UNDER 45 YEARS	151	67	84	39	65	32
46 YEARS AND ABOVE	123	36	87	25	53	42

rates were significantly higher in male patients and those aged 45 years or older, suggesting that these demographic factors may influence disease recurrence after treatment discontinuation. These findings support the clinical relevance of baseline disease burden and chronicity as predictors of early treatment benefit and also indicate that younger age and female sex may be associated with more sustained disease control following omalizumab therapy.

Chronic urticaria, defined as urticaria lasting more than six weeks, is reported to be 2–4 times more common in females than in males and is most frequently observed between the ages of 20 and 40 [1-3]. In our study, the mean age was 43 years, and the female-to-male ratio was found to be 1.97:1, consistent with previous epidemiologic data. This supports the representativeness of our study population in relation to the general CSU demographic.

Di Bona et al. reported a mean follow-up duration of 91 asthma patients treated with omalizumab as 45.6 months [10]. Similarly, in our study, the mean follow-up duration was found to be 35.5 months. In the same study by Di Bona et al. [10] six patients (6.6%) discontinued treatment due to adverse effects, whereas, in our study, the rate of treatment discontinuation due to adverse effects was lower, at 1.45%, suggesting a favorable tolerability profile of omalizumab across patient populations.

Sirufo et al. [11] conducted a study involving 26 female and 16 male patients and found that female patients had a better response to omalizumab. Additionally, at the end of the six-month initial treatment cycle, the recurrence rate was lower in female patients (15.4%) compared to male patients (50%). Conversely, a study by Bozat et al. [12] on pediatric patients with CSU suggested that sex did not influence treatment response. Similarly, Gouder et al. [13] investigated the effects, tolerability, and treatment responses of omalizumab in 17 male and 11 female asthma patients and found no significant differences between the sexes. In a study by Yu et al. [14], it was observed that the speed at which disease control was achieved with omalizumab was not associated with sex. In our study, no significant difference was found between the two sexes in terms of response to the first dose or lack of response to treatment, aligning with the general literature. However, when recurrence rates during omalizumab treatment were analyzed by sex, the recurrence rate was found to be significantly higher in male patients. In this regard, our study is consistent with the findings of Sirufo et al. [11], who suggested that this difference may be related to the effects of female hormones on histamine receptor profiles and mast cells [11].

In a study by Kitao et al. [15] involving 52 patients with chronic urticaria receiving omalizumab, patients were divided into two groups—those aged over 65 and those under 65—to examine the drug's effectiveness. They found that treatment response was significantly reduced in patients over 65 years of age. Similarly, Korn et al. [16] conducted a study on 174 asthma patients receiving omalizumab and found no significant difference in treatment response between patients aged over 50 and those under 50. Additionally, Ghazanfar et al. [17] analyzed 154 urticaria patients and found no association between older age and treatment response. In our study, when patients who benefited from the first dose of omalizumab were compared with those who did not, dividing them into two groups based on age (under 45 and 45 or older), the proportion of patients benefiting from the first dose was significantly higher in those under 45 years of age. In this aspect, our findings are consistent with the study by Kitao et al. [15]. Furthermore, in our study, when relapse development was analyzed based on age group, the recurrence rate was found to be significantly lower in the under 45 age group compared to the 45 years and older group. Overall, these results highlight that while age and sex may have some influence on relapse dynamics, they are unlikely to serve as stand-alone predictors of treatment response.

In addition to age and sex, we investigated baseline clinical factors that might predict early treatment response to omalizumab. Our findings revealed that lower baseline UAS7 scores and shorter disease duration were both significantly associated with achieving early response at four weeks. These observations suggest that patients with less severe disease activity and shorter-standing urticaria may experience faster clinical improvement following omalizumab initiation. Several previous studies support these observations. Chen et al. [5] demonstrated that CSU

patients with lower baseline UAS7 scores were significantly more likely to achieve early response to omalizumab (median UAS7 28 vs. 35, $P<0.01$), highlighting the relevance of initial disease severity in predicting treatment success. Similarly, Cubiro et al. [18] reported that patients with shorter disease duration exhibited better symptom control at 12 weeks, suggesting that early intervention may enhance therapeutic outcomes. In a Korean cohort, Kim et al. [19] further confirmed that shorter disease duration was independently associated with achieving disease control at three months. However, the literature also reflects some inconsistency. In contrast to our findings, Tonacci et al. [20] and Cubiro et al. [18] reported that baseline disease severity did not significantly influence response rates. Moreover, Marzano et al. [9] observed that while disease duration did not predict initial response to omalizumab, longer pre-treatment disease duration was associated with a higher risk of symptom relapse after therapy discontinuation.

Both baseline disease severity (UAS7) and chronicity (duration in months) showed strong discriminatory ability in predicting early response to omalizumab. ROC analysis revealed inverted AUC values of 0.917 and 0.940, respectively, for baseline UAS7 and disease duration. These findings suggest that initiating omalizumab in the earlier phases of CSU and in patients with lower symptom burden may substantially increase the probability of achieving early disease control.

Taken together, our findings suggest that early identification of patients with favorable baseline characteristics, such as lower disease activity and shorter duration of symptoms, may allow for a more tailored approach to omalizumab therapy in CSU. While sex and age did not independently predict initial response, their influence on relapse risk, particularly the higher recurrence observed in older and in male patients, highlights the importance of individualized follow-up and treatment continuation decisions. Integrating simple clinical parameters like baseline UAS7 and disease duration into treatment planning may help clinicians better predict treatment trajectory and optimize outcomes for CSU patients receiving omalizumab.

While our study provides clinically relevant insights, several limitations should be acknowledged. As a single-center retrospective study, generalizability may be limited, and certain laboratory biomarkers such as total IgE or autologous serum test results were not available for correlation. Relapse assessments were based on clinical follow-up without standardized timing, which may underestimate late recurrences. Despite these limitations, our findings reinforce the importance of baseline disease severity and duration as strong predictors of early omalizumab response. Additionally, the observed associations between younger age, female sex, and reduced relapse risk may guide treatment continuation and monitoring strategies. Integrating these accessible clinical parameters into treatment planning could support a more personalized approach in CSU management and improve patient outcomes.

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