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Clinical and Quality-of-Life Outcomes of Omalizumab Treatment in Chronic Spontaneous Urticaria

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Abstract

Aims

To evaluate response to omalizumab in chronic spontaneous urticaria (CSU), assess concordance between symptom and quality-of-life scores, and identify predictors of response.

Methods

Single-centre retrospective review of adults with CSU treated with omalizumab in a dermatology department in the Midwest of Ireland. Data included demographics, disease duration, and baseline and latest Urticaria Severity Score (USS), Dermatology Life Quality Index (DLQI), and itch and rash scores. Responders were defined as ≥50% USS improvement. Associations were analysed using Spearman's correlation and Cohen's κ.

Results

Thirty-six patients were included; 22 (61%) responded, including 11 complete responders. Complete responders had lower baseline USS and DLQI. Correlations between USS and other measures were moderate, with slight–moderate agreement.

Discussion

Omalizumab improved CSU outcomes. Lower baseline severity predicted complete response, while symptom and quality-of-life improvements showed limited individual concordance.

Introduction

CSU is characterised by recurrent pruritic wheals, with or without angioedema, and is associated with significant impairment in quality of life (QoL).[1] International guidelines recommend second-generation H1 antihistamines as first-line therapy, with dose escalation up to fourfold in non-responders. Omalizumab, an anti-IgE monoclonal antibody, is recommended as add-on therapy for antihistamine-refractory disease.[2] While trials

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demonstrate concordance between symptom and quality-of-life improvement at a group level, individual-level concordance remains less studied.[3] We evaluated response to omalizumab using symptom and quality-of-life scores, assessed correlation, and explored predictors of response.

Methods

We conducted a single-centre retrospective chart review of adults treated with omalizumab for CSU in a dermatology department in the Midwest of Ireland. Ethical approval was obtained. Data collected included age, disease duration, prior treatments, and baseline and latest documented severity scores. Outcomes included the USS (department-modified UAS7, maximum 28), DLQI, and visual analogue scores (0–10) for itch and rash. Responders were defined as ≥50% improvement in USS. Associations between measures were analysed using Spearman's correlation and Cohen's κ.

Results

Thirty-six patients were included, 29 (81%) were female. Median age was 42 years (IQR 30–52). Median disease duration prior to omalizumab initiation was 104 weeks (IQR 31.4–273.4). At baseline, 21 patients (58%) were receiving fourfold-dose second-generation H1 antihistamines. Baseline and final severity scores are seen in Table 1.

All patients were commenced on standard dose of 300mg every 4 weeks. Four patients were titrated up to 450mg every 4 weeks and 4 patients to 600mg every 4 weeks. Twenty-two patients (61%) were responders and 14 (39%) were non-responders. Among responders, 11 (50%) achieved complete response (USS = 0). Of the 4 patients titrated to 450mg, 3 were responders and of the 4 titrated to 600mg one was a complete responder with a final USS of 0. Median treatment duration was 106 weeks (IQR 41–223), ranging from 1 to 327 weeks (maximum 81 doses). Seven patients (19%) discontinued treatment due to symptom resolution or improvement, while two (6%) discontinued for other reasons.

Complete responders had lower baseline severity scores (USS 6, DLQI 4) compared with responders (USS 21, DLQI 11) and non-responders (USS 18, DLQI 12). Spearman's correlations between USS and DLQI, itch, and rash scores were 0.396, 0.42, and 0.50, respectively. Cohen's κ values were 0.20 (DLQI), 0.44 (itch), and 0.31 (rash), indicating slight to moderate agreement between measures.

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Demographics n=36 (%) [IQR]	
Male	7 (19)
Female	29 (81)
Age (Median)	42 [30-52]
Median Disease Duration (months)	24 [7.75-45]
Median Treatment Duration (weeks)	106 [41-223]
Previous Treatment:	
Four fold dose antihistamine	21 (58)
1st Generation H1 antihistamine	1 (3)
2nd Generation H1 antihistamine	35 (97)
H2 antihistamine	7 (19)
Ciclosporin	3 (8)
Dapsone	1 (3)
Montelukast	30 (83)
Median Baseline Disease Severity Scores	
USS	17.8 [14.25-25.25]
DLQI	12 [6-17]
Itch Score	5.5 [2.52-8.12]
Rash Score	6.15 [1.1-8.12]
Median Final Disease Severity Scores	
USS	5 [0-12]
DLQI	1 [0-4.25]
Itch Score	1.3 [0-3.075]
Rash Score	1 [0-2.075]

Response Statistics

Response Category	Median Age [IQR]	Median Disease Duration (weeks) [IQR]	Median Treatment Duration (weeks) [IQR]	Median Baseline USS [IQR]	Median Baseline DLQI [IQR]	Median Baseline Itch Score [IQR]	Median Baseline Rash Score [IQR]
Complete Responders (Final USS of 0, n=11)	33 [30-38]	69 [21.7-208.3]	112 [73-194]	6 [1.5-20]	4 [2-10]	1.5 [0.5-3]	1.1 [0.5-3.9]
Responders (≥50% Improvement in USS, n=22)	43 [33-53]	104 [28.2-312.4]	152 [89-240]	21 [19-23.75]	11 [8-14.5]	4.9 [2.7-7.9]	6 [2.65-8.37]
Non-Responders (<50% Improvement in USS, n=14)	39 [28.5-48.25]	54.25 [35.8-104.1]	56 [26-110]	18 [3.75-26]	12 [16.5-20.5]	7.15 [1.2-8.37]	4.15 [0.425-7.95]

Table 1: *Demographics, Treatments received prior to omalizumab, median baseline and final disease severity scores, and response statistics.*

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Discussion

Prolonged disease duration before omalizumab initiation (median 104 weeks) and high baseline USS and DLQI indicate substantial disease burden. Omalizumab was associated with marked improvement in symptom severity and QoL, reflected by low final median USS (5) and DLQI (1) scores. These findings are consistent with previous clinical trials showing the efficacy of omalizumab in reducing symptom burden and improving QoL.[3]

Complete responders had substantially lower baseline scores compared with responders, particularly USS (median 6, IQR 1.5–20 vs 21, IQR 19–23.75) and DLQI (median 4, IQR 2–10 vs 11, IQR 8–14.5). This suggests that patients with lower baseline disease severity may be more likely to achieve complete symptom resolution. Conversely, patients with high baseline scores may experience improvement without reaching full remission, suggesting a possible ceiling effect. These findings support earlier initiation of omalizumab, before disease severity and quality-of-life impairment become pronounced, in keeping with previous studies identifying predictors of treatment response.[4, 5]

Percentage improvements showed moderate positive correlations between USS, DLQI, and itch and rash scores; however, Cohen's κ demonstrated only slight agreement (0.2) between USS and DLQI using a USS ≥50% response threshold. While pooled analyses of phase III trials report strong correlations between symptom severity and QoL, real-world studies may reflect group-level trends rather than individual-level concordance.[4, 6] Prior studies similarly report weak to moderate correlations between symptom and QoL measures in CSU.[7, 8] These findings suggest that quality-of-life outcomes may diverge from symptom severity at an individual level. DLQI captures broader psychosocial and functional domains that may improve differently from clinical symptoms, reflected in the moderate correlation ($\rho = 0.396$) and slight agreement ($\kappa = 0.2$) observed in this study.

This single-centre study with a small sample size may be limited by variable treatment duration and unmeasured confounders. In conclusion, omalizumab effectively improved CSU symptoms, particularly in patients with lower baseline severity. Symptom improvement did not always align with QoL gains, supporting assessment of both clinical and patient-reported outcomes.

Declarations of Conflicts of Interest:
None declared.

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