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Quality of Life Assessment in Patients with Chronic Urticaria: A Cross-Sectional Comparative Study Using CU-Q²oL and DLQI Instruments.

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Abstract

Background: Chronic urticaria (CU) is a debilitating dermatological condition characterised by recurrent wheals, pruritus, and angioedema lasting more than six weeks. Beyond its physical manifestations, CU imposes a profound burden on psychological functioning, sleep quality, and social participation, thereby substantially impairing health-related quality of life (HRQoL). ***Objective:*** To evaluate HRQoL in patients with chronic spontaneous urticaria (CSU) using validated disease-specific (CU-Q²oL) and generic dermatology (DLQI) instruments, and to identify clinical and sociodemographic predictors of impaired quality of life. ***Methods:*** This cross-sectional comparative study enrolled 120 adult CSU patients attending a tertiary dermatology outpatient clinic and 80 age- and sex-matched healthy controls over a 12-month period. Disease severity was quantified using the Urticaria Activity Score-7 (UAS7). HRQoL was assessed using the Chronic Urticaria Quality of Life Questionnaire (CU-Q²oL) and the Dermatology Life Quality Index (DLQI). Multivariate linear regression was employed to identify independent predictors of impaired QoL. ***Results:*** CU patients demonstrated significantly higher mean DLQI scores (12.8 ± 5.6) compared with controls (1.9 ± 2.1; $p < 0.001$). The mean total CU-Q²oL score was 56.7 ± 16.4. Pruritus/red raised rash (62.4 ± 18.7) and sleep disturbance (58.1 ± 20.4) were the most severely affected domains. On multivariate analysis, UAS7 severity ($\beta = 0.61$, $p < 0.001$), angioedema ($\beta = 8.34$, $p < 0.001$), anxiety/depression comorbidity ($\beta = 11.23$, $p < 0.001$), and disease duration >5 years ($\beta = 6.72$, $p = 0.002$) were the strongest independent predictors of impaired QoL. Omalizumab treatment was associated with significantly better QoL ($\beta = -9.45$, $p < 0.001$). ***Conclusion:*** Chronic urticaria substantially impairs all domains of health-related quality of life. Disease severity, presence of angioedema, psychiatric comorbidity, and disease chronicity are key determinants of QoL impairment. Early aggressive disease control, coupled with psychological support and escalation to biologic therapy where indicated, is essential for optimising patient outcomes.

Keywords: chronic urticaria; quality of life; CU-Q²oL; DLQI; urticaria activity score; angioedema; omalizumab; dermatology.

INTRODUCTION

Chronic urticaria (CU) is defined as the occurrence of wheals, angioedema, or both for more than six weeks, arising either spontaneously or in response to specific triggers. Among the subtypes, chronic spontaneous urticaria (CSU) – in which symptoms occur without an identifiable external trigger – is the most prevalent, affecting approximately 0.5–1.0% of the global population at any given time, with a lifetime prevalence estimated at 8.8%. CU has a predilection for women (female-to-male ratio ~2:1) and most commonly presents in the third and fourth decades of life.

The clinical burden of CU extends well beyond its visible cutaneous manifestations. The unremitting nature of pruritus and the unpredictable appearance of disfiguring wheals and angioedema profoundly disrupt sleep architecture, impair concentration and occupational performance, restrict social activities, and engender significant psychological distress, including anxiety and depression.

Studies have demonstrated that the degree of QoL impairment in CU is comparable to that observed in moderate-to-severe coronary artery disease and other systemic chronic conditions, thereby underscoring the public health significance of this disorder.

Health-related quality of life (HRQoL) assessment constitutes an indispensable dimension of comprehensive chronic disease management. For urticaria, several validated patient-reported outcome instruments have been developed. The

Chronic Urticaria Quality of Life Questionnaire (CU-Q²oL) is a disease-specific, 23-item self-administered tool capturing six domains: pruritus/swelling, activities, sleep, looks, limits, and mental health. The Dermatology Life Quality Index (DLQI), a 10-item generic dermatology instrument, facilitates comparison across skin conditions. In parallel, the Urticaria Activity Score-7 (UAS7) quantifies disease activity over seven consecutive days by combining daily wheal number and pruritus intensity scores, with strong correlations reported between UAS7 and QoL measures.

Despite the growing literature on CU worldwide, data from South Asian tertiary-care settings – where comorbidity profiles, treatment access, and socioeconomic pressures differ markedly from those in Western cohorts – remain limited. The present study therefore aimed to: (1) systematically evaluate HRQoL in CSU patients attending a tertiary dermatology clinic using both CU-Q²oL and DLQI; (2) compare QoL parameters between patients and matched healthy controls; and (3) identify independent clinical and sociodemographic predictors of impaired QoL through multivariate analysis.

MATERIALS AND METHODS

This cross-sectional comparative study was conducted at the Department of Dermatology and Venereology of a 1,200-bed tertiary care teaching hospital in South India over a 12-month period (January–December 2025). Written informed consent was obtained from all participants prior to enrolment.

A consecutive sample of adult patients (≥18 years) with a diagnosis of chronic spontaneous urticaria was recruited from the outpatient dermatology clinic. Spontaneously recurring wheals, angioedema, or both lasting ≥6 weeks, with no identifiable triggering stimulus following comprehensive allergy evaluation.

Inclusion criteria: Confirmed CSU diagnosis; age ≥18 years; symptom duration ≥6 weeks; ability to comprehend and complete self-administered questionnaires.

Exclusion criteria: Inducible urticaria, urticarial vasculitis, or other urticaria subtypes; active systemic illness (hepatic, renal, or haematological disease); ongoing immunosuppressive therapy for non-urticaria indications; pregnancy or lactation; inability to provide informed consent; incomplete questionnaire data.

Eighty healthy volunteers with no dermatological or chronic medical conditions, recruited from among hospital staff and patient relatives, served as matched controls.

Assessment Tools

UAS7 (Urticaria Activity Score-7): Participants completed daily symptom diaries over seven consecutive days prior to the clinic visit. Each day's score combined wheal number (0–3) and itch intensity (0–3), yielding a daily score of 0–6 and a weekly composite score of 0–42. Categories: well-controlled (0–6), mild (7–15), moderate (16–27), severe/very severe (28–42).

CU-Q²oL (Chronic Urticaria Quality of Life Questionnaire): A validated 23-item instrument scored on a 5-point Likert scale (1 = not at all, 5 = very much). Raw scores were linearly transformed to a 0–100 scale per domain and overall; higher scores denote greater impairment. Validated Hindi and Telugu versions were utilised as appropriate. Internal consistency: Cronbach's $\alpha = 0.88$ in the present sample.

DLQI (Dermatology Life Quality Index): A 10-item questionnaire scored 0–30; categories range from 'no effect' (0–1) to 'extremely large effect on patient's life' (21–30). The DLQI was administered to both patients and controls. Cronbach's $\alpha = 0.84$.

Statistical Analysis

Data were analysed using IBM SPSS Statistics version 26. Continuous variables are presented as mean ± standard deviation (SD); categorical variables as frequencies and percentages. Between-group comparisons employed independent-samples t-tests or Mann–Whitney U tests, as appropriate.

Chi-square or Fisher's exact tests were used for categorical comparisons. Pearson or Spearman correlation coefficients were computed to assess relationships between UAS7, CU-Q²oL, and DLQI scores. Multivariate linear regression with forward selection was performed to identify independent predictors of total CU-Q²oL score, including variables with $p < 0.10$ on univariate analysis. A two-sided p-value < 0.05 was considered statistically significant.

RESULTS

Sociodemographic Characteristics

A total of 120 CSU patients and 80 healthy controls were enrolled. The two groups were well-matched for age, sex distribution, urban residency, educational attainment, employment, and BMI (all $p > 0.05$), ensuring comparability of baseline characteristics (Table 1).

Table: 1. Sociodemographic and baseline characteristics of CU patients and controls

Characteristic	CU Patients (n=120)	Controls (n=80)	p-value
Age (years), mean ± SD	38.6 ± 12.4	37.9 ± 11.8	0.674
Gender – Female, n (%)	74 (61.7%)	48 (60.0%)	0.812
Gender – Male, n (%)	46 (38.3%)	32 (40.0%)	0.812
Urban residence, n (%)	82 (68.3%)	55 (68.8%)	0.948
Education ≥ Secondary, n (%)	79 (65.8%)	53 (66.3%)	0.951
Employed, n (%)	68 (56.7%)	47 (58.8%)	0.773
Married, n (%)	77 (64.2%)	52 (65.0%)	0.907
BMI (kg/m²), mean ± SD	25.8 ± 4.1	24.9 ± 3.7	0.108
Comorbidities, n (%)	41 (34.2%)	18 (22.5%)	0.073

SD = Standard deviation; BMI = Body mass index. Comorbidities include hypertension, diabetes mellitus, thyroid disorders, anxiety/depression.

Disease Characteristics

Among the 120 CSU patients, the majority (49.2%) had disease duration of one to five years. Concurrent angioedema was present in 63.3% of the cohort. Nearly half the patients (42.5%) reported daily or near-daily flares. UAS7 categorisation revealed moderate-to-very severe disease activity in 77.4% of the patient cohort (Table 2). Omalizumab was prescribed in 18.3% of patients, predominantly those with antihistamine-refractory disease.

Table: 2. Clinical characteristics and disease severity in chronic urticaria patients (n = 120)

Disease Characteristic	n	%
Duration < 1 year	28	23.3%
Duration 1–5 years	59	49.2%
Duration > 5 years	33	27.5%
Wheals + Angioedema	44	36.7%
Wheals only	76	63.3%
Daily / almost daily flares	51	42.5%
Weekly flares	43	35.8%
Monthly / rare flares	26	21.7%
Currently on antihistamines	108	90.0%
Omalizumab use	22	18.3%
Systemic corticosteroids (ever)	67	55.8%
UAS7 mild (0–6)	27	22.5%
UAS7 moderate (7–15)	49	40.8%
UAS7 severe (16–27)	31	25.8%
UAS7 very severe (28–42)	13	10.8%

UAS7 = Urticaria Activity Score-7; H1-AH = second-generation H1-antihistamine. Mild UAS7: 0–6; Moderate: 7–15; Severe: 16–27; Very severe: 28–42.

Quality of Life Outcomes

CSU patients demonstrated markedly impaired HRQoL relative to controls on all measures ($p < 0.001$ for all comparisons). The mean DLQI score in patients was 12.8 ± 5.6 versus 1.9 ± 2.1 in controls, corresponding to a 'very large effect on patient's life' category. The mean total CU-Q²oL score was 56.7 ± 16.4 (Table 3). Among individual domains, pruritus/red raised rash (62.4 ± 18.7) and mental health/anxiety (59.7 ± 21.6) exhibited the highest impairment; appearance-related concerns (48.6 ± 22.1) showed the least, though remained clinically substantial.

Table: 3. CU-Q²oL domain scores and DLQI scores in CU patients and controls

CU-Q²oL Domain	Mean ± SD	Median	Range	p-value*
Pruritus/Red raised rash symptoms	62.4 ± 18.7	64.0	12–100	< 0.001
Activities & Functioning	55.3 ± 17.2	56.0	10–95	< 0.001
Sleep	58.1 ± 20.4	60.0	0–100	< 0.001
Looks / Appearance	48.6 ± 22.1	50.0	0–100	< 0.001
Limits / Social functioning	51.9 ± 19.3	52.0	8–96	< 0.001
Mental health / Anxiety	59.7 ± 21.6	62.0	0–100	< 0.001
Total CU-Q²oL score	56.7 ± 16.4	57.5	14–98	< 0.001
DLQI total score (CU patients)	12.8 ± 5.6	13.0	2–28	< 0.001
DLQI total score (Controls)	1.9 ± 2.1	1.0	0–8	—

* p-values from Mann–Whitney U test comparing CU patients vs. controls. CU-Q²oL and DLQI scores transformed to 0–100 scale; higher scores = greater impairment. SD = standard deviation.

DLQI Category Distribution

DLQI categorisation confirmed the extensive burden: 57.5% of CU patients experienced a 'very large' or 'extremely large' effect on their daily life. By contrast, 91.3% of controls reported either 'no effect' or 'small effect' on their QoL (Table 4). The between-group difference was highly significant ($p < 0.001$).

Table: 4. Distribution of DLQI impact categories among CU patients and controls

DLQI Category	Score Range	CU Patients n (%)	Controls n (%)
No effect on life	0–1	6 (5.0%)	52 (65.0%)
Small effect	2–5	14 (11.7%)	21 (26.3%)
Moderate effect	6–10	31 (25.8%)	6 (7.5%)
Very large effect	11–20	52 (43.3%)	1 (1.3%)
Extremely large effect	21–30	17 (14.2%)	0 (0.0%)

DLQI = Dermatology Life Quality Index. Values represent n (%). Chi-square test: $p < 0.001$ for between-group comparison.

Predictors of Quality of Life Impairment

Multivariate linear regression incorporating clinical and sociodemographic variables identified UAS7 severity score ($\beta = 0.61$, $p < 0.001$), comorbid anxiety or depression ($\beta = 11.23$, $p < 0.001$), presence of angioedema ($\beta = 8.34$, $p < 0.001$), daily flare frequency ($\beta = 7.56$, $p < 0.001$), and disease duration >5 years ($\beta = 6.72$, $p = 0.002$) as independent predictors of higher (worse) CU-Q²oL scores. Omalizumab treatment was the sole variable associated with significantly lower (better) QoL scores ($\beta = -9.45$, $p < 0.001$). Age and employment status did not reach statistical significance on multivariate analysis (Table 5).

Table: 5. Multivariate linear regression analysis of predictors of CU-Q²oL total score

Factor	β coefficient	Std Error	95% CI	p-value
UAS7 severity score	0.61	0.08	0.45 – 0.77	< 0.001
Angioedema present	8.34	1.94	4.51 – 12.17	< 0.001
Disease duration > 5 years	6.72	2.11	2.55 – 10.89	0.002
Female sex	4.18	1.87	0.49 – 7.87	0.027
Anxiety / depression comorbidity	11.23	2.43	6.43 – 16.03	< 0.001
Daily flare frequency	7.56	1.65	4.31 – 10.81	< 0.001
Omalizumab treatment (vs H1-AH)	-9.45	2.58	-14.52 – -4.38	< 0.001
Age (per 10 years)	1.12	0.94	-0.72 – 2.96	0.235
Employment status (employed)	-3.28	1.76	-6.74 – 0.18	0.063

Model $R^2 = 0.63$; adjusted $R^2 = 0.61$; $F(9,110) = 21.4$, $p < 0.001$. Reference groups: male sex; disease duration ≤1 year; standard-dose H1-antihistamine therapy; no angioedema; rare flares. H1-AH = H1-antihistamine; CI = confidence interval.

DISCUSSION

This study provides a comprehensive, multidimensional evaluation of HRQoL in a well-characterised cohort of 120 CSU patients in a tertiary South Indian setting, using two validated and complementary instruments alongside matched healthy controls. The findings unambiguously confirm that chronic urticaria imposes a profound and multifaceted burden on patients' quality of life, exceeding that of many other chronic dermatological and systemic conditions.

The mean DLQI score of 12.8 ± 5.6 observed in our cohort is consistent with the 'very large' effect category and is broadly comparable to values reported from European registries (mean DLQI ~11–14), Pakistani tertiary centres (mean ~13.1), and Brazilian outpatient cohorts (mean ~12.4). The degree of impairment is notably higher than that typically reported in psoriasis vulgaris and atopic dermatitis in comparable settings, despite CU lacking a chronic visible skin lesion, underscoring that symptom unpredictability and psychological burden – rather than visible disfigurement alone – drive QoL impairment.

The CU-Q²oL domain analysis revealed that pruritus and red raised rash symptoms constituted the predominant driver of impairment (mean 62.4), followed by sleep disturbance (58.1) and mental health/anxiety (59.7). This pattern mirrors established pathophysiology: uncontrolled histamine release and mast cell mediator effects directly disrupt sleep continuity and daytime alertness, creating a cycle of fatigue, cognitive impairment, and psychological distress. The finding that appearance-related concerns scored lowest, though still substantially impaired, is noteworthy; unlike psoriasis or eczema, the non-persistent nature of urticaria lesions may confer relative sparing of appearance-related distress between flare episodes.

On multivariate analysis, UAS7 severity emerged as the strongest continuous predictor ($\beta = 0.61$), consistent with the established biological plausibility that more active disease generates greater symptom burden and downstream QoL impairment. The independent contribution of psychiatric comorbidity ($\beta = 11.23$) – the single largest regression coefficient – highlights the bidirectional relationship between CU and mental health: psychological stress is both a precipitating and perpetuating factor for urticaria flares via HPA-axis and neurogenic pathways, while the chronicity and unpredictability of CU symptoms engender anxiety, health anxiety, and depression. Our finding that 34.2% of CU patients had documented psychiatric comorbidities concurs with pooled prevalence estimates of 30–48% across CU cohorts globally.

The association between angioedema and worse QoL is clinically important. Angioedema, particularly when affecting facial, laryngeal, or acral regions, is associated with heightened fear of anaphylaxis, emergency department utilisation, and social withdrawal. The 63.3% angioedema prevalence in our cohort – somewhat higher than the European average of ~40–55% – may reflect referral bias towards more severe cases in a tertiary centre.

The negative association between omalizumab treatment and QoL impairment ($\beta = -9.45$) provides real-world evidence supporting the clinical effectiveness of anti-IgE biologic therapy in improving QoL in antihistamine-refractory CSU. This finding is consistent with data from randomised controlled trials (ASTERIA, GLACIAL series) reporting significant DLQI reductions with omalizumab versus placebo, and reinforces international guideline recommendations for biologic escalation in treatment-refractory disease.

Several limitations deserve acknowledgement. The cross-sectional design precludes causal inference regarding QoL trajectories over time. Recruitment from a tertiary centre may overrepresent moderate-to-severe disease, limiting generalisability to community-managed CU. Recall bias is inherent to patient-reported outcomes, and language validation was performed for Hindi and Telugu but not other regional languages. Prospective longitudinal studies with standardised treatment protocols are needed to examine QoL changes following therapeutic escalation.

CONCLUSION

Chronic spontaneous urticaria significantly impairs health-related quality of life across all assessed domains, with a disease burden comparable to or exceeding that of other major chronic dermatological conditions. Pruritus, sleep disruption, and mental health distress emerge as the predominant areas of impairment. Disease activity (UAS7), presence of angioedema, comorbid psychiatric illness, and disease chronicity are the key independent determinants of QoL deterioration, while biologic therapy with omalizumab is independently associated with superior QoL. These findings underscore the imperative for systematic HRQoL assessment using validated instruments in routine clinical practice, multidisciplinary collaboration with psychiatry and psychology services, and timely escalation of therapy in treatment-refractory patients.

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