Original Research

DETERMINANTS OF DISEASE SEVERITY AND QUALITY OF LIFE IN CHRONIC URTICARIA: A COMPARATIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Chronic urticaria (CU) is a persistent inflammatory skin disorder characterized by recurrent wheals, angioedema, or both lasting longer than six weeks. Although disease activity is commonly assessed using validated scoring systems, the clinical determinants of severe disease and quality-of-life impairment remain incompletely defined.

Objective: To evaluate the clinical determinants of disease severity and quality-of-life impairment in patients with chronic urticaria.

Methods: This analytical cross-sectional study included 120 adult patients with chronic urticaria attending a tertiary care dermatology center between October 2024 and October 2025. Disease activity was assessed using the Urticaria Activity Score over seven days (UAS7), and quality of life was evaluated using the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL). Associations between clinical variables and severe disease (UAS7 ≥28) were analyzed using chi-square tests and multivariate logistic regression. Determinants of quality-of-life impairment were assessed using multivariate linear regression.

Results: The mean age of participants was 34.6 ± 11.2 years, and 56.7% were female. Severe disease was observed in 33.3% of patients. Angioedema ($\chi^2 = 8.72$, $p = 0.003$) and refractoriness to regular-dose antihistamines ($\chi^2 = 15.84$, $p < 0.001$) were significantly associated with severe disease. In multivariate analysis, refractoriness (aOR 3.12, 95% CI 1.41–6.89, $p = 0.004$) and angioedema (aOR 2.48, 95% CI 1.12–5.47, $p = 0.020$) independently predicted severe disease. Disease activity strongly correlated with quality-of-life impairment ($r = 0.69$, $p < 0.001$). UAS7 independently predicted CU-Q2oL scores ($\beta = 0.58$, $p < 0.001$), with the regression model explaining 52% of variance (adjusted $R^2 = 0.52$).

Conclusion: Refractoriness to antihistamines and the presence of angioedema are key determinants of severe chronic urticaria. Disease activity remains the principal driver of quality-of-life impairment. Early identification of high-risk patients and comprehensive severity assessment are essential for optimizing management strategies.

Keywords: Chronic Urticaria, UAS7, Quality of Life, Angioedema, Antihistamine Refractoriness.

INTRODUCTION

Chronic urticaria (CU) is a debilitating dermatologic condition characterized by the spontaneous occurrence of wheals, angioedema, or both, persisting for more than six weeks. It is broadly classified into chronic spontaneous urticaria (CSU), in which symptoms occur without an identifiable external trigger, and chronic inducible urticaria, where lesions are provoked by specific physical or environmental stimuli.

www.ajmrhs.com
eISSN: 2583-7761

Date of Received: 29-01-2026
Date Acceptance: 06-02-2026
Date of Publication: 07-03-2026

CSU accounts for the majority of chronic cases and poses significant clinical challenges due to its unpredictable course and fluctuating severity (1). Although often perceived as a benign skin disorder, CU substantially affects patients' physical comfort, emotional well-being, and social functioning.

The estimated point prevalence of chronic urticaria in the general population ranges between 0.5% and 1%, with a higher predilection among women and individuals in early to middle adulthood (2). Despite its relatively modest prevalence, the burden of disease is considerable. Recurrent pruritus, visible wheals, and episodic angioedema frequently interfere with sleep, work productivity, and interpersonal relationships. Patients often report embarrassment, frustration, and social withdrawal,

underscoring the multidimensional impact of the condition beyond cutaneous manifestations.

From a pathophysiological standpoint, chronic urticaria is increasingly recognized as a complex immune-mediated disorder. Central to its mechanism is mast cell activation and degranulation, leading to the release of histamine and other pro-inflammatory mediators. In a substantial subset of patients, autoimmune mechanisms particularly the presence of functional autoantibodies against IgE or the high-affinity IgE receptor have been implicated (3). Elevated total serum IgE levels and thyroid autoimmunity have also been observed in certain patient populations, suggesting heterogeneity in underlying mechanisms. This biological variability may contribute to differences in disease severity and therapeutic responsiveness.

Accurate assessment of disease activity is essential for both clinical management and research. The Urticaria Activity Score over seven days (UAS7) is widely accepted as a validated tool for quantifying symptom severity, incorporating daily wheal count and pruritus intensity (4). However, symptom severity alone does not fully capture the patient's lived experience. Quality of life (QoL) measures, particularly disease-specific instruments such as the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL), provide valuable insight into how the disease affects daily functioning, emotional stability, and social interactions (5). Several studies have demonstrated a correlation between higher UAS7 scores and greater QoL impairment, yet the extent to which clinical and laboratory factors independently determine QoL remains incompletely understood.

While previous investigations have explored associations between disease activity and quality of life, relatively few studies have comprehensively evaluated the independent determinants of severity and QoL impairment within a single analytical framework. In particular, the relative contributions of angioedema, disease duration, immunological markers, and psychological comorbidity warrant further clarification. Identifying these determinants is essential for risk stratification and for developing individualized management strategies that address both physical and psychosocial dimensions of the disease.

Aim

To evaluate the clinical determinants of disease severity and quality-of-life impairment in patients with chronic urticaria attending a tertiary care center.

Objectives

1. To assess disease severity in patients with chronic urticaria using UAS7.
2. To evaluate quality-of-life impairment using CU-Q2oL.
3. To identify clinical predictors of severe disease and impaired quality of life.

MATERIALS AND METHODS

Study Design and Setting

This one-year analytical cross-sectional study was carried out in the Department of Dermatology of a tertiary care teaching hospital from October 2024 to October 2025. The study aimed to identify clinical factors of illness severity and quality-of-life impairment in chronic urticaria patients. The methodology and reporting for this study followed the STROBE criteria (6).

Ethical Considerations

The Institutional Ethics Committee examined and approved the study protocol before it was initiated. All participants provided written informed permission after explaining the study's aim and procedures in their preferred language. The investigation followed the ethical guidelines specified in the Declaration of Helsinki and its modifications (7).

Study Population

The study population included adult patients who visited the dermatology outpatient department during the study period and met the diagnostic criteria for chronic urticaria. Chronic urticaria was defined as recurring wheals, angioedema, or both lasting more than six weeks (8). Eligible subjects were recruited sequentially.

Inclusion Criteria

1. Age 18 years or older.
2. Clinically diagnosed chronic urticaria (>6 weeks duration).
3. Willingness to provide written informed consent.
4. Ability to complete disease activity and quality-of-life assessments.

Exclusion Criteria

1. Acute urticaria (<6 weeks duration).
2. Urticarial vasculitis or hereditary angioedema.
3. Severe systemic illness that could confound evaluation.
4. Pregnant or lactating women.
5. Current use of systemic immunosuppressive therapy for unrelated conditions.
6. Inability to reliably complete questionnaires due to cognitive or communication limitations.

Sample Size

A total of 120 patients were included during the one-year study period. This sample size was considered feasible based on outpatient attendance and adequate to evaluate associations between the predefined clinical variables and primary outcomes. The selected number allowed inclusion of the principal predictors in multivariate regression analyses while minimizing overfitting (6).

Sampling Technique

Consecutive sampling was employed. All eligible patients presenting during the study period were

invited to participate until the target sample size of 120 was achieved.

Data Collection Procedure

Data were collected using a structured case record form. Demographic details, including age and sex, were recorded. A detailed clinical history was obtained, followed by dermatological examination performed by a consultant dermatologist.

Clinical Variables

The following predefined clinical variables were evaluated:

Presence of Angioedema:

Defined as transient, localized swelling involving the deeper dermis or subcutaneous tissue. Documentation was based on clinical examination and patient-reported episodes.

Inducible Urticaria:

Physical or inducible forms such as dermographism, cold urticaria, and pressure urticaria were identified based on history and, when appropriate, simple bedside provocation tests in accordance with current urticaria guidelines (8).

Duration of Disease:

Calculated from the onset of persistent urticarial symptoms and recorded in months. For analysis, duration was considered both as a continuous variable and categorized into clinically meaningful groups (<1 year, 1–3 years, and >3 years).

Refractory to Regular-Dose Antihistamines:

Refractory disease was defined as persistence of symptoms despite treatment with standard-dose second-generation H1-antihistamines for at least two weeks, in line with established management recommendations (9). Patients were categorized as responsive or refractory.

Assessment of Disease Severity

Disease activity was assessed using the Urticaria Activity Score over seven days (UAS7), a validated tool widely used in clinical research (10). Patients documented daily wheal count and pruritus intensity for seven consecutive days. The total score ranged from 0 to 42, with higher scores indicating greater disease activity. Severity categories were defined as mild (0–15), moderate (16–27), and severe (28–42).

Assessment of Quality of Life

Quality of life was measured using the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL), a disease-specific validated instrument (11). The questionnaire evaluates multiple domains, including pruritus, sleep disturbance, emotional distress, and social limitations. Scores were transformed to a 0–100 scale, with higher scores reflecting greater impairment.

Statistical Analysis

The data were imported into Microsoft Excel and analysed with SPSS version 25. Continuous variables were expressed as mean ± standard deviation or median with interquartile range depending on distribution. Categorical variables were presented as frequencies and percentages. The normality of the data was determined using the Shapiro-Wilk test.

Associations between clinical variables and disease severity were examined using the chi-square test or Fisher's exact test for categorical variables and independent t-test or Mann–Whitney U test for continuous variables. Correlation between UAS7 and CU-Q2oL scores was evaluated using Pearson or Spearman correlation coefficients as appropriate. Multivariate logistic regression analysis was performed to identify independent predictors of severe disease (UAS7 ≥28). Multivariate linear regression analysis was conducted to determine factors independently associated with quality-of-life impairment. Adjusted odds ratios or beta coefficients with 95% confidence intervals were reported. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

A total of 120 patients with chronic urticaria were included in the final analysis. The mean age of the participants was 34.6 ± 11.2 years. Females constituted 56.7% of the study population. The median duration of disease was 18 months. Angioedema was present in 36.7% of patients, while inducible urticaria was identified in 32.5%. Forty percent of patients were classified as refractory to regular-dose second-generation antihistamines.

Table 1. Baseline Demographic and Clinical Characteristics (n = 120)

Variable	n (%) / Mean ± SD
Age (years)	34.6 ± 11.2
Female	68 (56.7%)
Male	52 (43.3%)
Duration <1 year	46 (38.3%)
Duration 1–3 years	42 (35.0%)
Duration >3 years	32 (26.7%)
Presence of angioedema	44 (36.7%)
Inducible urticaria	39 (32.5%)
Refractory to regular-dose antihistamines	48 (40.0%)
Mean UAS7 score	24.1 ± 10.6
Mean CU-Q2oL score	44.8 ± 16.3

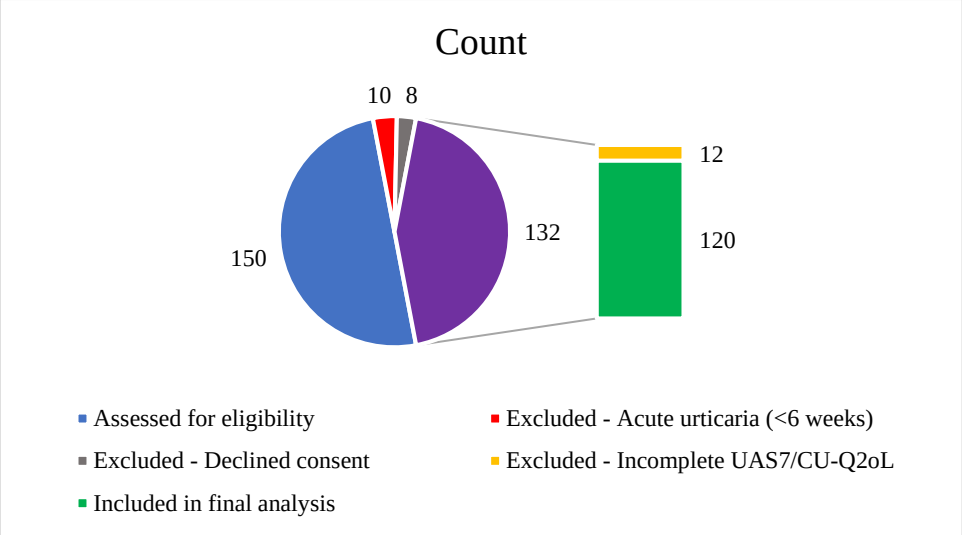


Figure 1. Flow Diagram

Distribution of Disease Severity

Based on UAS7 scoring, 31.7% of patients had mild disease, 35.0% had moderate disease, and 33.3% were categorized as having severe disease. The distribution of severity categories is presented in Table 2.

Table 2. Distribution of Disease Severity Based on UAS7

Severity Category	n (%)
Mild (0–15)	38 (31.7%)
Moderate (16–27)	42 (35.0%)
Severe (28–42)	40 (33.3%)

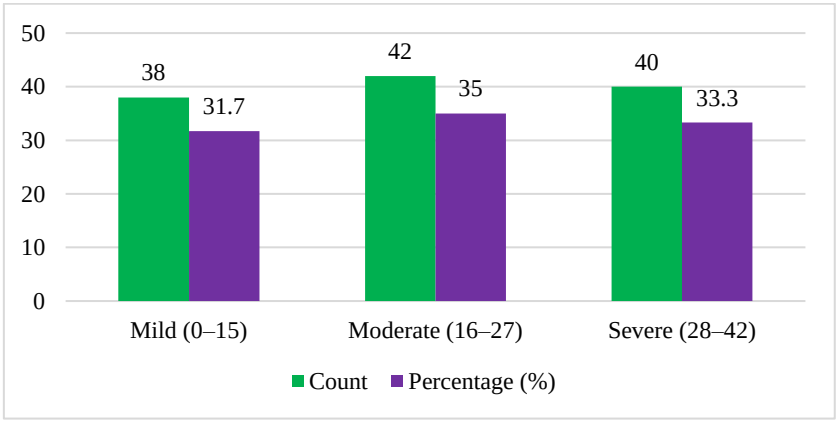


Figure 2. Distribution of Chronic Urticaria Severity Based on UAS7 Scores

Association between Clinical Variables and Disease Severity

The presence of angioedema demonstrated a statistically significant association with severe disease ($\chi^2 = 8.72$, df = 1, $p = 0.003$). Among patients with angioedema, 50.0% were categorized as having severe disease compared to 23.7% among those without angioedema.

Inducible urticaria was also significantly associated with increased disease severity ($\chi^2 = 6.51$, df = 1, $p = 0.011$). Similarly, longer disease duration (>3 years) showed a significant association with severe disease ($\chi^2 = 5.42$, df = 1, $p = 0.020$).

Refractoriness to regular-dose second-generation antihistamines demonstrated the strongest association with severe disease ($\chi^2 = 15.84$, df = 1, $p < 0.001$). More than half (54.2%) of refractory patients had severe disease compared to 19.4% among treatment-responsive individuals.

These associations are detailed in Table 3.

Table 3. Association between Clinical Variables and Severe Disease (UAS7 ≥28)

Variable	Severe n (%)	Non-Severe n (%)	p-value
Angioedema (Present)	22 (50.0%)	22 (50.0%)	0.003

Angioedema (Absent)	18 (23.7%)	58 (76.3%)	
Inducible urticaria (Present)	19 (48.7%)	20 (51.3%)	0.01
Inducible urticaria (Absent)	21 (25.9%)	60 (74.1%)	
Duration >3 years	15 (46.9%)	17 (53.1%)	0.02
Duration <1 year	10 (21.7%)	36 (78.3%)	
Refractory to antihistamines (Yes)	26 (54.2%)	22 (45.8%)	<0.001
Responsive (No)	14 (19.4%)	58 (80.6%)	

Quality of Life Assessment

The mean CU-Q2oL score for the entire cohort was 44.8 ± 16.3. Patients with severe disease demonstrated significantly higher quality-of-life impairment compared to those with mild and moderate disease.

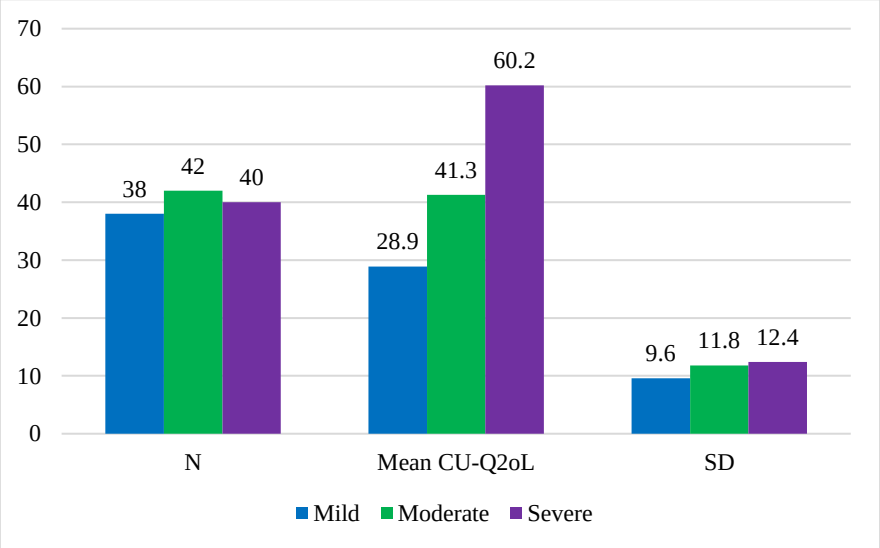
One-way ANOVA revealed a statistically significant difference in mean CU-Q2oL scores across severity categories ($F = 39.6$, $p < 0.001$). Post-hoc comparisons confirmed that patients with severe disease had significantly higher scores than both moderate and mild groups. The effect size was large ($\eta^2 = 0.38$), indicating substantial clinical relevance.

These findings are presented in Table 4.

Table 4. Comparison of Mean CU-Q2oL Scores across Severity Categories

Severity Category	Mean CU-Q2oL ± SD	p-value
Mild	28.9 ± 9.6	
Moderate	41.3 ± 11.8	
Severe	60.2 ± 12.4	<0.001

Figure 3. Comparison of Mean CU-Q2oL Scores Across Disease Severity Categories



Correlation between Disease Activity and Quality of Life

A strong positive correlation was observed between UAS7 and CU-Q2oL scores ($r = 0.69$, 95% CI 0.59–0.77, $p < 0.001$), indicating that increasing disease activity was associated with greater impairment in quality of life.

This relationship is summarized in Table 5.

Table 5. Correlation between UAS7 and CU-Q2oL

Variables	Correlation Coefficient (r)	p-value
UAS7 vs CU-Q2oL	0.69	<0.001

Multivariate Analysis

In multivariate logistic regression analysis, refractoriness to regular-dose antihistamines was independently associated with severe disease (adjusted odds ratio [aOR] 3.12, 95% CI 1.41–6.89, $p = 0.004$). Presence of angioedema also remained

an independent predictor (aOR 2.48, 95% CI 1.12–5.47, p = 0.020).

The logistic regression model demonstrated acceptable goodness-of-fit (Hosmer–Lemeshow test p = 0.62).

In multivariate linear regression analysis, UAS7 score was independently associated with CU-Q2oL impairment (β = 0.58, 95% CI 0.42–0.73, p < 0.001).

Refractoriness to antihistamines (β = 0.26, 95% CI 0.09–0.43, p = 0.010) and angioedema (β = 0.14, 95% CI 0.01–0.27, p = 0.040) also showed independent associations.

The overall linear regression model explained 52% of the variance in quality-of-life scores (adjusted R^2 = 0.52, F = 41.3, p < 0.001).

Tables 6 and 7 summarize the regression analyses.

Table 6. Multivariate Logistic Regression for Predictors of Severe Disease

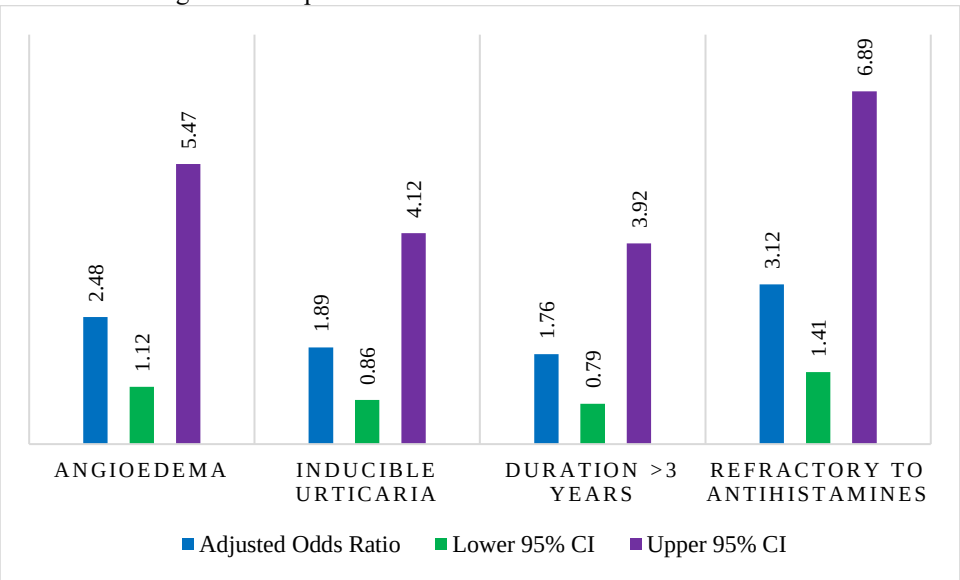
Variable	Adjusted Odds Ratio (aOR)	95% CI	p-value
Angioedema	2.48	1.12–5.47	0.02
Inducible urticaria	1.89	0.86–4.12	0.11
Duration >3 years	1.76	0.79–3.92	0.16
Refractory to antihistamines	3.12	1.41–6.89	0.004

Table 7. Multivariate Linear Regression for Determinants of CU-Q2oL

Variable	Beta (β)	95% CI	p-value
UAS7 Score	0.58	0.42–0.73	<0.001
Angioedema	0.14	0.01–0.27	0.04
Refractory to antihistamines	0.26	0.09–0.43	0.01

Adjusted R^2 = 0.52

Figure 4. Independent Predictors of Severe Chronic Urticaria



Overall, the findings indicate that angioedema and refractoriness to standard antihistamine therapy are significant determinants of severe disease. Increasing disease activity and treatment refractoriness independently contribute to greater impairment in quality of life among patients with chronic urticaria.

DISCUSSION

This study evaluated clinical determinants of disease severity and quality-of-life impairment among patients with chronic urticaria over a one-year period. Approximately one-third of the cohort exhibited severe disease activity, reflecting the substantial burden of uncontrolled symptoms in routine clinical practice. Importantly, multivariate modeling identified refractoriness to regular-dose antihistamines and the presence of angioedema as independent predictors of severe disease, while disease activity (UAS7) emerged as the strongest determinant of quality-of-life impairment.

The proportion of patients classified as having severe disease in the present cohort is comparable to findings reported in recent real-world and multicenter studies, which demonstrate that a considerable subset of patients continues to experience moderate-to-severe disease despite standard therapy (12). Chronic urticaria is

increasingly recognized as a heterogeneous disorder with fluctuating activity and variable treatment response, necessitating structured severity assessment in clinical practice.

In the present study, angioedema was significantly associated with severe disease in both unadjusted and multivariate analyses. Earlier investigations have similarly demonstrated that the coexistence of angioedema is associated with increased disease burden, greater healthcare utilization, and prolonged disease duration (13). The unpredictable and often disfiguring nature of angioedema episodes may amplify psychological distress, contributing to both perceived severity and measurable increases in disease activity scores.

Refractoriness to regular-dose second-generation antihistamines demonstrated the strongest independent association with severe disease. Current international guidelines recommend stepwise up-dosing of antihistamines and escalation to biologic therapy for patients with inadequate symptom control (14). Failure to respond to standard-dose therapy may reflect a more active inflammatory phenotype or distinct immunological endotype. Early identification of refractory patients is therefore critical to prevent sustained morbidity and deterioration in quality of life.

A key finding of this study is the strong positive correlation between disease activity and quality-of-life impairment ($r = 0.69$, $p < 0.001$). This magnitude of association is consistent with previous validation studies demonstrating that higher UAS7 scores correlate closely with impaired disease-specific quality-of-life measures (15). The regression model further indicated that disease activity independently explained a substantial proportion of the variance in CU-Q2oL scores, underscoring its central role in determining patient burden.

Although longer disease duration was associated with severity in univariate analysis, it did not retain independent significance in multivariate models. Prior studies have suggested that chronicity may contribute to cumulative psychosocial stress and functional impairment (16). However, our findings indicate that current inflammatory activity and treatment responsiveness may exert a more immediate impact on quality-of-life outcomes than duration alone.

The clinical implications of these findings are noteworthy. Assessment of angioedema and treatment response should form part of routine severity evaluation. Incorporation of validated patient-reported outcome measures alongside objective activity scores can provide a more comprehensive understanding of disease burden. Early recognition of high-risk or refractory patients may facilitate timely therapeutic escalation and improve long-term outcomes.

Several limitations warrant consideration. The cross-sectional design precludes causal inference and limits assessment of longitudinal changes in disease activity and quality of life. Additionally, the single-center setting may affect generalizability. Nevertheless, the use of validated instruments and multivariate statistical modeling strengthens the robustness of the findings.

In summary, refractoriness to standard-dose antihistamines and the presence of angioedema are key independent determinants of severe chronic urticaria. Disease activity remains the principal driver of quality-of-life impairment. These findings reinforce the importance of structured severity assessment and individualized, patient-centered management strategies.

CONCLUSION

This study demonstrates that refractoriness to regular-dose second-generation antihistamines and the presence of angioedema are independent clinical determinants of severe chronic urticaria. Patients exhibiting these features were significantly more likely to experience high disease activity and substantial impairment in quality of life.

Disease activity, as quantified by UAS7, showed a strong and consistent association with quality-of-life deterioration, explaining a substantial proportion of variability in CU-Q2oL scores. These findings reinforce the importance of systematic severity assessment using validated tools and highlight the central role of disease control in reducing patient burden.

Early identification of antihistamine-refractory disease and coexisting angioedema may facilitate timely therapeutic escalation and individualized management strategies. Incorporating patient-reported outcome measures alongside clinical activity scores can provide a more comprehensive evaluation of disease impact and guide optimized treatment decisions.

Overall, structured risk stratification and proactive management are essential to improve both clinical outcomes and quality-of-life measures in patients with chronic urticaria.

Conflict of Interest

The authors declare that there are no conflicts of interest associated with this study.

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How to cite this article: Dr. Revathi Tatavarthi, Dr. Shraddha Prabha, Dantuluri Priyadarshini, DETERMINANTS OF DISEASE SEVERITY AND QUALITY OF LIFE IN CHRONIC URTICARIA: A COMPARATIVE OBSERVATIONAL STUDY, Asian J. Med. Res. Health Sci., 2026; 4 (1):494-501.
Source of Support: Nil, Conflicts of Interest: None declared.