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Factors associated with disease duration in chronic spontaneous urticaria: A short- to midterm evaluation

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Abstract
This retrospective study was conducted to identify clinical, demographic, and biochemical factors associated with prolonged disease duration in chronic spontaneous urticaria (CSU) by including adults diagnosed with CSU between October 2023 and October 2024. Laboratory data examined included complete blood counts, C-reactive protein, hemoglobin, and serum iron, as well as specific measurements such as anti-thyroperoxidase antibodies and antinuclear antibody (ANA) positivity and total IgE. Age (at initial visit), sex, disease duration, presence of angioedema were retrieved from electronic records. Disease duration was calculated as the time from symptom onset to the most recent episode based on local hospital records and the Turkish Ministry of Health's National Health System (e-nabız) records. The population size was 203 (~70% females), with a mean age of 40.27 ± 15.03 years. Disease duration was unassociated with age ($p = 0.794$) and sex ($p = 0.366$). Angioedema and ANA positivity were respectively detected in 43.35% and 52.26% of patients, but were not associated with disease duration ($p = 0.301$ and $p = 0.824$). Notably, patients with a disease duration of >12 months had significantly lower total IgE ($p = 0.042$) and higher basophils ($p = 0.019$) compared to those with shorter disease duration. No significant relationships were found when disease duration was classified with thresholds of 24, 36, or 60 months. Basophil count was the only parameter with a very weak but significant correlation with disease duration ($r = 0.142$, $p = 0.044$). These results suggest that prolonged CSU duration may be associated with basophil counts and IgE levels; however, it appears that these relationships are weak and likely non-linear. Further research is needed to better understand whether quantifiable parameters might have use in predicting CSU-related characteristics.

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Introduction

Urticaria is a common skin disorder that can be diagnosed through clinical examinations, which reveal transient wheals and/or angioedema.[1] It is classified as acute (shorter than 6 weeks) or chronic (persisting for more than 6 weeks and often for years).[1] Chronic urticaria exerts a negative impact on the quality of life,[2,3] largely in parallel with the severity and duration of symptoms and the likelihood of recurrence.[4] The chronic form is further categorized as "inducible" or "spontaneous" depending on whether or not an external factor triggering the manifestations is demonstrable.[1] Interestingly, chronic spontaneous urticaria (CSU) is estimated to affect approximately 1% of the global population, with a female dominance (mostly 30–50 years of age).[5] The persistent or relapsing nature of CSU and the lack of an identifiable etiology complicates management strategies and disease management.

The clinical course of CSU is highly variable. While the disease may resolve within a few years in some cases, it can persist much longer in others.[6] Reported remission rates are 20–50% within 1 year and 45% within 5 years.[7-9] However, in approximately 20% of patients, symptoms may last longer than 5 years, which creates considerable challenges in disease management.[10] Additionally, in some patients, relapses are observed even after prolonged remission.[4] Considering the lack of clinical or laboratory variables that can aid in diagnostics and treatment, the unknown nature of the disease has prompted research to detect and investigate factors associated with remission, recurrence, and disease progression.

Current evidence suggests that certain factors may influence the prognosis of CSU. For instance, the presence of antithyroid antibodies (ATA), antihistamine resistance, high disease activity, elevated C-reactive protein (CRP) levels, and angioedema have been proposed as contributors to prolonged disease duration and increased recurrence risk.[11,12] However, these findings are poorly replicated in different studies, necessitating further research. Knowing which factors predict longer disease duration helps doctors counsel patients about what to expect and choose the best treatments for their individual situation.

In CSU, disease duration, spontaneous remission rates, and recurrence may be associated with various clinical and laboratory factors. Identifying these factors could aid in predicting the disease prognosis. Because previous studies show conflicting results and doctors need better ways to predict disease course, we aimed to identify clinical and laboratory factors associated with CSU duration that could help guide treatment decisions.

Materials and Methods

Study design, setting, and ethics

This retrospective study was conducted at the Immunology and Allergy Department of Samsun Training and Research Hospital, Samsun, Turkey, between October 2023 and October 2024. Ethics approval was obtained from the Non-Interventional Clinical Research Ethics Committee of Samsun University (Decision date: 23.10.2024, Decision no.: 2024/19/8), which confirmed that the study design complied with the Helsinki Declaration and its amendments.

Since the analysis was conducted retrospectively, informed consent was not required according to ethical guidelines, as no direct patient interventions or interactions were conducted for this specific analysis. We used a retrospective design to include as many patients as possible and study long-term disease patterns, despite that this approach may introduce recall bias since patients had to remember when their symptoms started.

Study population

The study included patients aged 18 and older who were diagnosed with CSU. Patients younger than 18, those with acute urticaria (symptoms lasting less than 6 weeks), urticaria with a known etiology or triggering factor, and patients with inadequate data (unclear chronicity, unclear diagnosis, loss to follow-up, or missing progress notes) were excluded from the study.

Diagnosis and treatment of chronic spontaneous urticaria

All CSU diagnoses were based on the criteria outlined in the 2018 guidelines of the European Academy of Allergy and Clinical Immunology, Global Allergy and Asthma European Network, European Dermatology Forum, and World Allergy Organization.[13] For a diagnosis to be considered valid, we required the presence of recurrent urticarial symptoms (itchy wheals and/or angioedema) for at least 6 weeks and the absence of identifiable triggers. Routine diagnostic evaluations included a complete blood count, CRP measurement, thyroid function tests, and ATA and ANA detections, along with physical examinations and detailed patient histories. Treatment protocols followed the same guidelines.[13]

Data collection

Data on age, sex, disease duration, presence of angioedema, and laboratory findings were retrieved from the hospital's electronic database. Age data were based on the time of the first clinic visit. Disease duration was determined from symptom onset to the most recent episode, which was identified by reviewing all available records, including patient reports, local hospital records, and the National Health System (e-nabız) records of the Turkish Ministry of Health. The presence of angioedema was evaluated retrospectively through documented diagnoses, clinical findings consistent with angioedema, and patient-reported histories. Symptoms were confirmed using electronic medical records, emergency visit notes, and clinical evaluation reports.

Laboratory findings included parameters measured at diagnosis, which were obtained retrospectively from digital records. All laboratory analyses had been conducted in the accredited blood chemistry laboratory of our hospital using calibrated and internationally standardized equipment.

Investigated parameters included antinuclear antibody (ANA) positivity; total IgE; thyroid peroxidase antibody (anti-TPO) levels; and platelets, white blood cells, neutrophils, lymphocytes, basophils, eosinophils, and monocyte counts; CRP; hemoglobin; and serum iron levels. An antinuclear antibody test was performed by the indirect immunofluorescence method, using the HEp-20-10 liver biochip (Euroimmun, Perkin Elmer Company, Lübeck, Germany) kit. Levels of complement were measured by nephelometry using an autoanalyzer (BN II system, Siemens, Germany). All measurements adhered to the manufacturer's guidelines and were compared with national and international reference values.

Study endpoints

The primary endpoint was to identify factors associated with the duration of CSU, with particular focus on 12-, 24-, 36-, and 60-month thresholds.

Statistical analysis

Relevant data were collected and stored in an SPSS database (.sav). The same software, with a significance threshold of $P < 0.05$, was used to perform analyses and obtain summary values (SPSS for Windows, Version 25.0; IBM, Armonk, NY, USA). Quantitative variables were plotted on histograms and Q-Q plots to check the normality of distribution. For these numerical values, normally distributed variables were summarized with mean ± standard deviation, while those with non-normal distributions were summarized with median (25th to 75th percentile). For categorical data, summaries were provided in frequency and relative percentage.

The Spearman correlation coefficient was used to assess relationships between variables and urticaria duration. The Student's t-test was used for comparisons that fulfilled parametric assumptions, while the Mann-Whitney U test was used in comparisons not fulfilling this requirement. Chi-square tests were used to compare the distributions of categorical variables.

Results

The study included 203 participants with CSU. The mean age of all participants was 40.27 ± 15.03 years, and 142 (69.95%) were females. Of the total cases, 100 had a disease duration of less than 12 months, while 103 had a duration of 12 months or more. Disease duration was not associated with age ($P = 0.794$) and sex distribution ($P = 0.366$). Angioedema was present in 88 (43.35%) patients; however, no significant relationship was observed between the presence of angioedema and urticaria duration ($P = 0.301$). ANA positivity was found in 104 (52.26%) patients, with no significant association with disease duration ($P = 0.824$). Patients with a disease duration of 12 months or more had significantly lower median total IgE levels ($P = 0.042$) and significantly higher median basophil levels ($P = 0.019$) compared to those with a CSU duration less than 12 months (Table 1).

Participants were further grouped based on disease durations of less than or greater than 24 (131 vs 72), 36 (151 vs 52), and 60 months (163 vs 40). However, there were again no significant relationships with any of the variables (Table 1) when comparisons were repeated within these subsets. Notably, the differences we found at 12 months were no longer present when we observed patients with disease lasting 24, 36, or 60 months, suggesting that these relationships may matter only in the early stages of the disease.

We found a statistically significant positive correlation between basophil count and disease duration ($r = 0.142$, $P = 0.044$); however, this relationship was quite weak and was not useful for predicting individual patient outcomes (Table 2).

Discussion

We investigated factors that might be associated with the duration of CSU and categorized patients according to their disease duration, based on four separate thresholds (12, 24, 36, and 60 months). Our results showed that patients with a disease duration of 12 months or longer had significantly lower serum total IgE levels and higher basophil counts compared to those with shorter disease. Age, sex, presence of angioedema, and other laboratory findings were not found to be associated with disease duration. Although disease duration showed a positive correlation with basophil count ($r = 0.142$, $P = 0.044$), this relationship was quite weak and may have limited practical value in clinical settings. This weak association suggests that basophil count alone would not be sufficient to predict disease course in individual patients, though it might contribute useful information when considered alongside other clinical factors. Our study design shows the relationships between factors and disease duration and cannot determine whether one causes the other. The connections we found should be seen as possible clues rather than proof of cause and effect.

Findings from a systematic review suggest that only disease severity might predict CSU duration.[14] In addition to CSU severity, this study also described relationships between disease duration and factors such as the Autologous Serum Skin Test (ASST), Autologous Plasma Skin Test (APST), angioedema, ANA positivity, thyroid autoimmunity, and serum IgE levels.[14] Kessel et al. reported a significantly higher frequency of elevated IgE levels in patients with longer disease duration,[15] which contrasts with our findings. The different findings about IgE levels across studies might be due to differences in patient groups, geographic locations, how CSU was diagnosed, or when in the disease course patients were studied. Further, a prior study noted that basophil count was a marker associated with the clinical course of CSU patients who received omalizumab treatment. Basophil counts rose to normal ranges after initiating omalizumab treatment, and intriguingly, the count decreased to undetectable levels after treatment termination. This study suggested that basophil count might indicate disease activity and could be used as a potential marker for monitoring treatment response.[16]

Altrichter et al. showed that high total IgE levels were associated with higher disease activity, longer disease

Table 1 Summary of variables with regard to duration of urticaria.

Variables	Overall	Duration of urticaria		P
		<12 months (n = 100)	≥12 months (n = 103)	
Age (years)	40.27 ± 15.03	39.99 ± 14.65	40.54 ± 15.46	0.794†
Sex				
Male	61 (30.05%)	33 (33.00%)	28 (27.18%)	0.366§
Female	142 (69.95%)	67 (67.00%)	75 (72.82%)	
Accompanying angioedema	88 (43.35%)	47 (47.00%)	41 (39.81%)	0.301§
ANA positivity	104 (52.26%)	52 (53.06%)	52 (51.49%)	0.824§
Total IgE (kU/L)	129.5 (62-238)	153 (74-235)	96 (41.73-259)	**0.042‡**
Anti-TPO (IU/mL)	9.73 (8.00-14.60)	9.21 (8-13.65)	10 (8-15.9)	0.368‡
Thrombocyte (x10^3)	270.50 ± 57.50	266.48 ± 53.48	274.40 ± 61.16	0.328†
WBC (x10^3)	7.52 ± 1.95	7.32 ± 1.54	7.71 ± 2.27	0.159†
Neutrophil (x10^3)	4.54 ± 1.60	4.43 ± 1.30	4.65 ± 1.84	0.327†
Lymphocyte (x10^3)	2.26 ± 0.67	2.19 ± 0.59	2.33 ± 0.74	0.120†
Basophil (x10^3)	0.02 (0.02-0.03)	0.02 (0.01-0.03)	0.03 (0.02-0.04)	**0.019‡**
Eosinophil (x10^3)	0.14 (0.08-0.21)	0.14 (0.08-0.20)	0.16 (0.08-0.24)	0.220‡
Monocyte (x10^3)	0.54 ± 0.18	0.53 ± 0.15	0.56 ± 0.19	0.123†
CRP (mg/L)	3.06 (1.38-6.23)	3.10 (1.28-6.35)	2.77 (1.40-5.84)	0.878‡
Hemoglobin (g/dL)	13.74 ± 1.63	13.80 ± 1.76	13.67 ± 1.50	0.563†
Serum iron (µg/dL)	78.44 (46.78-102.99)	74.94 (50.00-103.96)	80.78 (46.49-100.80)	0.996‡

Descriptive statistics are presented using mean ± standard deviation for normally distributed continuous variables, median (25th to 75th percentile) for non-normally distributed continuous variables and frequency (percentage) for categorical variables.
†Student's t test, ‡Mann-Whitney U test, §Chi-square test. Statistically significant P values are shown in bold.
ANA: Antinuclear antibody; Anti-TPO: Antithyroid peroxidase antibody; CRP: C-reactive protein; IgE: Immunoglobulin E; WBC: White blood cell count.

Table 2. Correlations between duration of urticaria and other variables.

	r	P
Age (years)	0.065	0.359
Sex, Female	0.085	0.227
Accompanying angioedema	−0.052	0.464
ANA positivity	−0.022	0.761
Total IgE (kU/L)	−0.103	0.143
Anti-TPO (IU/mL)	0.065	0.360
Thrombocyte (x10^3)	0.025	0.721
WBC (x10^3)	0.045	0.520
Neutrophil (x10^3)	−0.010	0.891
Lymphocyte (x10^3)	0.078	0.270
Basophil (x10^3)	0.142	**0.044**
Eosinophil (x10^3)	0.112	0.112
Monocyte (x10^3)	0.082	0.243
CRP (mg/L)	−0.042	0.556
Hemoglobin (g/dL)	−0.031	0.664
Serum iron (µg/dL)	0.040	0.576

r: Spearman correlation coefficient. Statistically significant P values are shown in bold.
ANA: Antinuclear antibody; Anti-TPO: Antithyroid peroxidase antibody; CRP: C-reactive protein; IgE: Immunoglobulin E; WBC: White blood cell count.

duration, better chances of responding to omalizumab treatment, quicker relapse after stopping omalizumab, and a lower chance of responding to cyclosporine.[17] One study found that greater urticaria severity, the presence of angioedema, positive ASST and APST results, and the presence of ATA were all significantly linked to longer disease duration.[7] Nebiolo et al. demonstrated that systemic hypertension prolonged the duration of CSU, while other factors examined (sex, atopic status, autoimmunity markers, ATA, positive ASST results, *Helicobacter pylori* infection) were not found to significantly affect urticaria duration.[18] Another systematic review showed that metabolic syndrome might be associated with the duration of CSU.[1]

A large-scale population-based study using data from the National Health Insurance Service eNational Sample Cohort identified 49,129 new-onset urticaria patients over 10 years.[19] Chronic urticaria remission was not associated with factors such as age, sex, residential area, or autoimmune thyroid disease. This exceptionally large data set appears to have provided some evidence regarding the impact of sex on the chronicity of urticaria. Females were more likely to develop new onset urticaria but had a lower risk of chronic urticaria compared to males. However, demographic factors and thyroid disease did not significantly influence remission rates.20 Although singular studies appear to miss underlying relationships between

thyroid autoimmunity and CSU, a systematic review highlighted a strong association between these characteristics.[12] Despite showing this relationship, no reliable link was found between ATA levels and CSU disease duration, severity, or activity.[12] Toubi et al. investigated the likelihood of recurrence following CSU remission. In patients with recurrence, 40% had bronchial asthma, 40% had elevated total IgE levels, and 44% had anti-TPO antibodies.[11]

An observational study on CSU in children linked higher baseline severity to a higher risk of non-remission at 3 and 5 years. Patients treated with a single dose of antihistamines had significantly higher remission rates (89% vs 54% and 67% at 5 years). However, this study found no relationship between age at onset and disease duration,[21] which might be a by-product of performing a pediatric study. In adults, age and sex have been associated with significant differences in remission. Patients aged 65 years and above were less likely to achieve remission compared to those aged 20–39, while female patients had a higher likelihood of remission than males.[22] These results were in agreement with the majority of the literature. However, entirely contrasting findings have also been reported, albeit with weak relationships or without significance. For instance, shorter disease duration was observed in older patients (aged 60 years and above, mean age: 67) compared to younger patients (below 60, mean age: 35.6), although the difference was not significant.[23]

This study has several limitations. The retrospective design prevented the collection of more comprehensive data, and the reliance on patient-reported information and hospital records reduced the reliability of available information. Disease activity scores (UAS7) or control measures (UCT) were not systematically collected at initial presentations because patients presented at varying stages of their disease course; some with active symptoms despite ongoing treatment, others well-controlled on medication, and some asymptomatic at the time of consultation despite having chronic disease. This heterogeneity in disease status at presentation, combined with the outpatient clinic setting where standardized assessment tools are not routinely implemented, precluded systematic disease activity evaluation. In our clinical practice, UCT is primarily used for monitoring patients receiving omalizumab therapy rather than for initial assessment. In relation to this, it is also possible that data concerning patient or disease characteristics were biased in relation to each patient's condition and disease severity. Moreover, psychosocial factors, including stressors, and sleep eating patterns, and overall quality of life, were not assessed in detail, potentially impacting the results. Most importantly, disease duration was determined based on the patient's reported duration of symptoms at diagnosis and the time to the most recent flare-up. This reliance introduces recall bias, which may have affected the accuracy of disease duration. These factors should be considered when interpreting the results.

Patients with CSU duration longer than 12 months had higher blood basophil counts and lower total IgE levels compared to those with a duration shorter than 12 months, although the clinical usefulness of these markers appears limited given the weak associations observed. However, this significant relationship disappeared when patients were dichotomized for disease durations of 24, 36, and 60 months, which suggests early variations but not long-term impacts for these variables. While our study presents promising results regarding the predictive value of basophil count and IgE levels for CSU duration, the identified relationships were very weak, and further research is needed to better understand the utility of these markers in determining CSU duration. Future studies are recommended to explore whether combining these parameters with other clinical variables improves their predictive value for disease progression.

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Consent for Publication

The author consents to the publication of this manuscript.

Competing Interests

The author declares no competing interests.

Author's Contributions

The author designed the study, collected and analyzed data, and wrote the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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