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Abstract N°: 2

Upadacitinib in Recalcitrant Chronic Spontaneous Urticaria – an Emerging therapeutic option

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Introduction

Chronic spontaneous urticaria (CSU) is defined as spontaneous wheals, angioedema, or both for ≥6 weeks without an identifiable trigger and remains refractory in up to 30–40% of patients despite guideline-directed escalation with high-dose second-generation antihistamines and omalizumab. Emerging insights into CSU pathobiology highlight persistent mast-cell activation, autoimmunity (Type I/IIb), and dysregulated cytokines including IL-4, IL-13, IL-31, IL-6 and IFN-γ, many of which converge through JAK1-mediated signalling. Upadacitinib, a selective JAK1 inhibitor, therefore represents a rational therapeutic option for difficult-to-treat disease.

Case Presentation

A 42-year-old woman presented with a 3-year history of daily urticarial wheals associated with intermittent angioedema involving the lips and eyelids. She had been treated with multiple antihistamines in maximally up-dosed regimens (cetirizine 20 mg twice daily and fexofenadine 180 mg daily), along with ranitidine and montelukast, and had also required repeated short courses of oral corticosteroids for severe flares. Despite this, she remained highly symptomatic with poor quality of life. She subsequently received omalizumab 300 mg every 4 weeks for 6 months, followed by dose-intensification to every 2 weeks for another 3 months, but continued to experience near-daily wheals with only marginal improvement (UAS7 ~30). Her baseline evaluation before initiating upadacitinib showed a UAS7 of 34 and UCT score of 6. Laboratory parameters including CBC, LFT, RFT, lipid profile, thyroid function, ANA, complement levels, chest radiograph and IGRA were all within normal limits. After counselling about the off-label nature of therapy, she was started on upadacitinib 15 mg once daily while continuing cetirizine. Steroids were tapered and stopped within 4 weeks.She reported noticeable improvement within the first month, with reduction of wheals to 2–3 episodes per week (UAS7 16) and complete resolution of angioedema. By week 12, her UAS7 had declined to 4, and at 24 weeks she achieved complete clinical remission (UAS7 = 0; UCT = 16).

Conclusion

Upadacitinib, a second-generation, highly selective Janus kinase-1 (JAK1) inhibitor, offers a rational therapeutic approach in this context. JAK1 is a key intracellular signaling node for multiple cytokines central to urticaria pathogenesis—including IL-4, IL-13, IL-31, TSLP, and interferons which collectively drive mast-cell activation, IgE-mediated signaling, eosinophil recruitment, and the neuroimmune pathways responsible for pruritus. By selectively blocking JAK1, upadacitinib interrupts these inflammatory circuits while minimizing the off-target toxicities associated with broader JAK inhibition.

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Assessment of Serum Levels of Janus Kinase 1 and 2 in Patients with Cholinergic Urticaria

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Introduction

Cholinergic urticaria (ChoiU) is a subtype of physical urticaria characterized by the rapid onset of small, itchy hives, often triggered by physical stimuli such as heat, exercise, or emotional stress. The condition, though not life-threatening, can significantly impact the quality of life for affected individuals due to its recurrent and unpredictable nature. Understanding the underlying mechanisms of CholU is crucial for improving therapeutic strategies, yet the pathophysiology remains incompletely understood.

Recent research has highlighted the role of various immune mediators and cellular pathways in the development and exacerbation of CholU. Among these, Janus Kinase (JAKs) have emerged as pivotal regulators of immune signaling pathways that mediate inflammation and cytokine release. JAK1 and JAK2, in particular, are involved in transmitting signals for various pro-inflammatory cytokines, making them potential markers for immune dysregulation in CholU patients. However, while JAK signaling has been extensively studied in other immune-related disorders, its role in CholU has not been thoroughly investigated.

Materials and Methods

This cross-sectional study was designed to assess the serum levels of JAK1 and JAK2 in patients with CholU. The study was approved by the Institutional Ethical and Research committees. Informed written consent was obtained from all participants before enrollment in the study. The study included 90 participants—45 patients with clinically diagnosed CholU and 45 age- and sex-matched healthy controls. The study involved comprehensive clinical evaluation, including medical history, physical examination, and provocation tests with physical exercise. Disease severity was assessed using CholUSI, and serum levels of JAK1 and JAK2 were measured using ELISA.

Results

Serum levels of JAK1 and JAK2 were significantly elevated in CholU patients compared to controls ($p < 0.001$). Univariate logistic regression identified both JAK1 and JAK2 as significant factors associated with CholU, though only JAK1 remained a significant independent predictor in multivariate analysis. Correlation analysis revealed that higher serum JAK1 and JAK2 levels were positively associated with CholU severity and activity scores. Diagnostic testing demonstrated that JAK1 and JAK2 have strong potential as biomarkers for CholU, with JAK1 showing 84.4% sensitivity and 82.2% specificity at a 4.3 ng/mL cutoff, and JAK2 showing 82.2% sensitivity and 88.9% specificity at a 3.3 ng/mL cutoff.

Conclusions

Elevated serum levels of JAK1 and JAK2 in patients with CholU, suggests a possible role for the JAK pathway in disease severity. JAK1, in particular, emerged as a potential biomarker for CholU, supporting its diagnostic value and the possibility of targeted treatments for managing this condition. Furthermore, the strong positive correlation of these markers with disease severity and activity emphasizes their potential as diagnostic and prognostic tools.

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Baseline assessment of chronic spontaneous urticaria management in German outpatient care: Pre-implementation results from the BRIDGE study

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Introduction

Chronic spontaneous urticaria (CSU) is associated with substantial disease burden and impaired quality of life. Despite evidence-based guideline recommendations, real-world CSU management remains heterogeneous, particularly with respect to disease assessment, use of patient-reported outcomes (PROs), and referral practices. BRIDGE is an implementation science study designed to evaluate strategies aimed at improving CSU management in German outpatient care. Herein, the pre-implementation survey results of the study are reported, characterizing current CSU management practices.

Materials and Methods

BRIDGE is a hybrid effectiveness–implementation study with a pre–post design (Figure 1) targeting office-based dermatologists and general practitioners. After study enrollment, all participants completed a self-administered, 30-minute quantitative baseline survey prior to implementation of the "Urticaria Care Package" (UCP), a structured educational intervention designed to support guideline-aligned CSU diagnosis, assessment, and management, including the use of PROs. Baseline surveys were administered via an online platform between 22 October 2024 and 11 January 2026 and assessed awareness, understanding and perceived benefit of CSU PROs, as well as CSU management practice, diagnostic and referral behavior and perceptions of training needs. Descriptive statistical analyses were performed, with subgroup analyses by medical specialty.

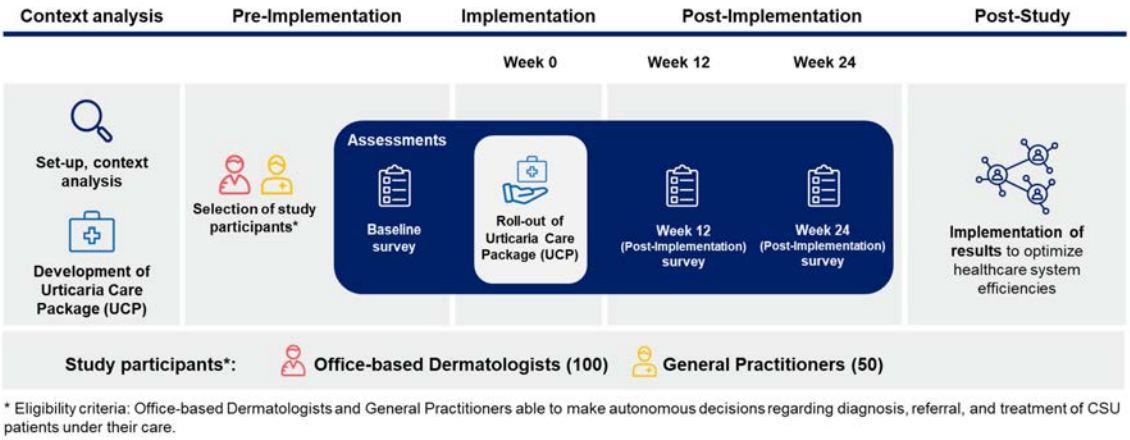

Figure 1. BRIDGE study design.

Results

A total of 155 physicians completed the baseline survey, including 101 office-based dermatologists and 54 general practitioners. Most participants reported experience in the diagnosis and treatment of CSU, reflecting routine involvement in CSU patient care. Dermatologists reported managing a substantially higher number of patients with suspected or confirmed CSU during the preceding 12 weeks compared with general practitioners (mean 30.3±36.0 vs 9.0±13.6 patients). Awareness of CSU-specific PROs differed markedly between specialties: While the majority of dermatologists were familiar with instruments such as the Dermatology Life Quality Index (93.1%), the Urticaria Control Test (63.4%) and the Urticaria Activity Score (61.4%), more than half of general practitioners (61.1%) reported no familiarity with any questionnaires/ scores from a given list of CSU PROs (Figure 2). Although the perceived benefit of PROs for disease monitoring, treatment decision-making, and quality of care was high, routine use of PROs in clinical practice remained limited, especially among general practitioners. Perceived lack of time and insufficient integration into existing workflows were identified as potential barriers. Treatment and referral behaviors varied across care settings, with 62.4% of dermatologists reporting not to refer their CSU patients (vs. 9.3% of general practitioners) and 85.2% of general practitioners reporting to mainly refer CSU patients to an office-based dermatologist, most frequently to have the CSU diagnosis confirmed. Across both specialties, there was clear interest in additional education and training on CSU management.

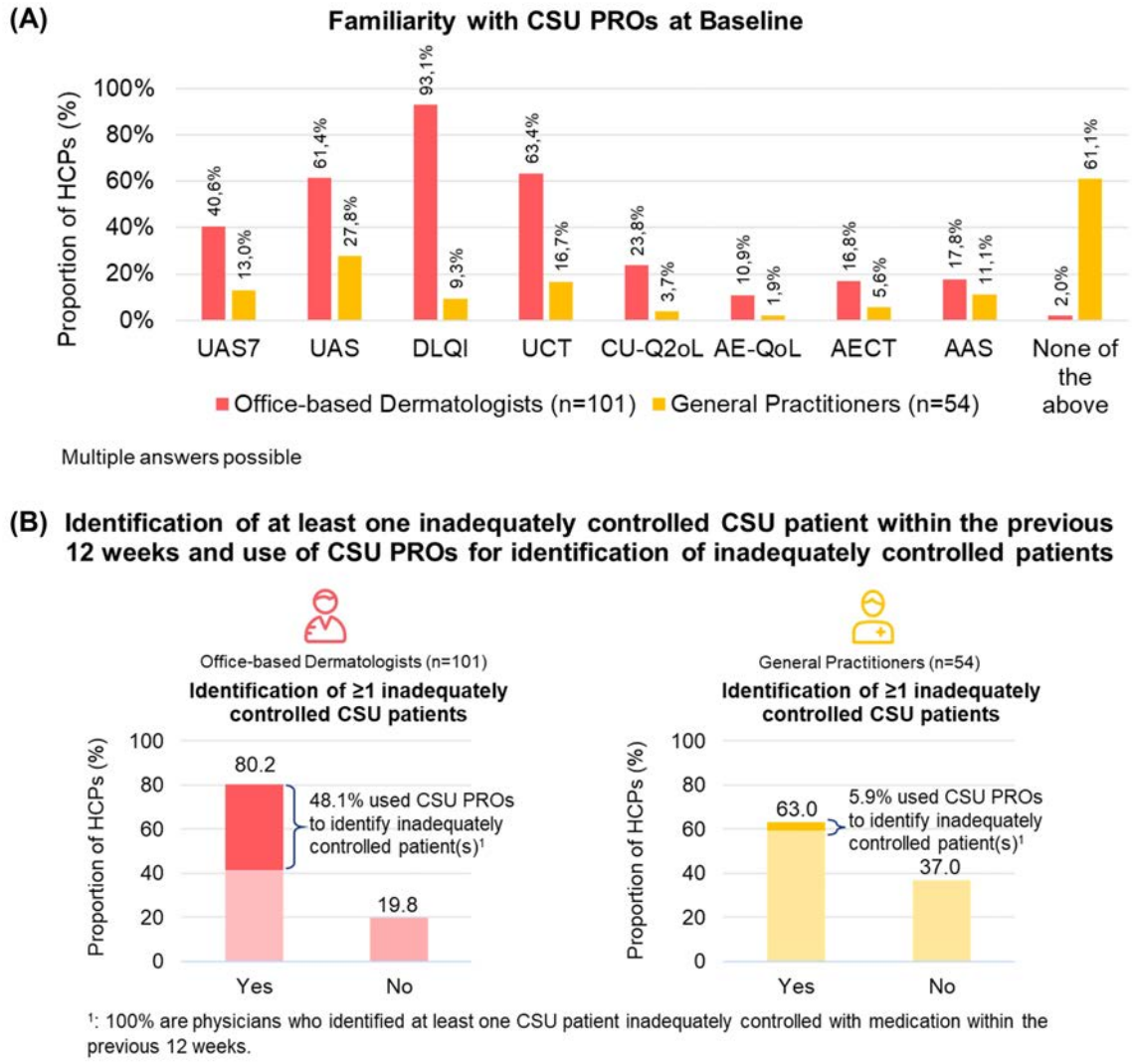

Figure 2. BRIDGE pre-implementation results. (A) Familiarity with CSU PROs at baseline. (B) Identification of at least one inadequately controlled CSU patient within the previous 12 weeks and use of CSU PROs for identification of inadequately controlled patients.

Conclusions

The pre-implementation results of the BRIDGE study show that most participating physicians have experience in

managing CSU, providing a strong foundation for the implementation of targeted improvement measures. However, awareness and routine use of CSU-specific PROs prior to implementation are limited, particularly among general practitioners, highlighting the need for structured educational interventions. Overall, the baseline data identify clear leverage points for the UCP to improve the understanding and use of CSU PROs for structured assessment of disease severity and control, to address knowledge gaps, and to support consistent treatment decisions, thereby promoting high-quality CSU care in German outpatient practice.

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Chronic Spontaneous Urticaria Patients with Angioedema: Clinical and Autoimmune Characteristics

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Introduction

Angioedema is a common and distressing symptom in patients with Chronic Spontaneous Urticaria (CSU). Understanding its prevalence and impact on disease severity can lead to improved patient management and quality of life. This study aims to enhance the understanding of angioedema in CSU, contributing to more effective approaches.

Materials and Methods

This study was conducted at the Dermatology Department of City General Hospital "8th September", Skopje North Macedonia. 230 CSU patients were included and angioedema was recorded. The Weekly Urticaria Activity Score (UAS7) was employed to evaluate disease activity by assessing CSU symptoms over seven consecutive days. Autoimmune status (categorized positive or negative) was determined based on a personal history of concomitant autoimmune disease or the presence of at least one type of autoantibodies. The Autologous Serum Skin Test (ASST) (categorized positive or negative) was performed by injecting the patient's own serum intradermally into the volar part of the forearm.

Results

Angioedema was present in 40% of CSU patients, occurring more frequently in: patients with a severe activity CSU compared to a moderate severe activity CSU (82.32% vs. 65.38%, p=0.026); patients with a severe activity CSU compared to a mild clinical activity CSU (82.32% vs. 65.96%, p=0.0360); and patients with a severe activity CSU compared to well-controlled disease (82.32% vs. 45.45%, p=0.0004). The association of autoimmune status and angioedema was statistically significant (p=0.025), patients with positive autoimmune status were significantly more likely to have angioedema compared to patients with negative autoimmune status (75.17% vs. 61.18%). Angioedema was noted more in patients with positive ASST compared to negative ASST patients (p=0.38); 72.14% of patients with a positive ASST test and 66.67% of patients with a negative ASST test had angioedema. The duration of CSU was significantly longer in patients with angioedema compared to those without angioedema (p=0.000012). Patients with angioedema had a mean CSU duration of 61.7 ± 46.2 months and a median disease duration of 54 months.

Conclusions

Our study brings more findings that underscore the complexity of CSU, particularly in patients with angioedema, and the need for comprehensive management strategies that consider disease activity, autoimmune status, and duration.

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Refining Quality of Life Assessment in CSU: Validation and Threshold Determination of the CU-Q2oL questionnaire

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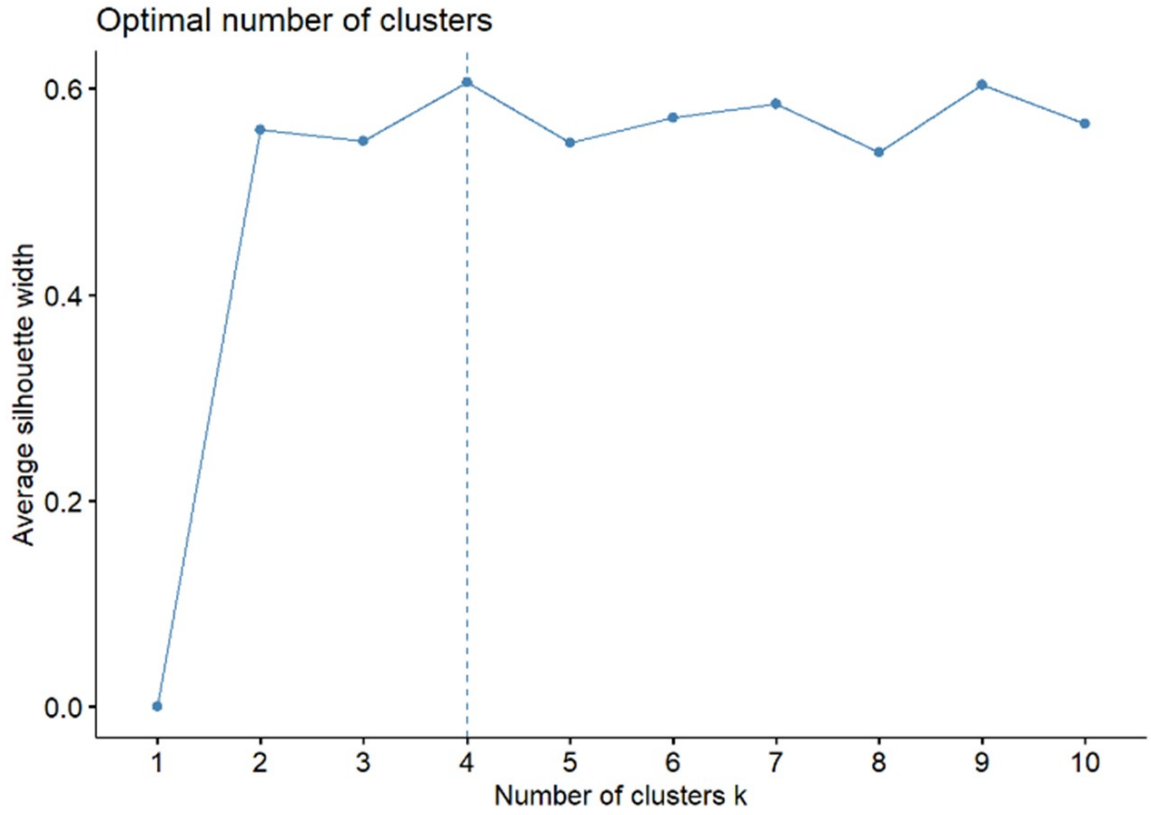
Introduction
Chronic spontaneous urticaria (CSU) significantly impairs patients' quality of life (QoL), yet no reliable biomarkers exist to monitor disease activity or treatment response. Patient-reported outcomes (PROs), such as the Urticaria Activity Score (UAS7), Urticaria Control Test (UCT), and quality of life tools including the Dermatology Life Quality Index (DLQI) and Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL), are essential for comprehensive assessment. However, variations in domain structures across translations hinder its standardized application.
We aim to evaluate the Brazilian-Portuguese version of the CU-Q2oL, assess its correlation with established PROs (UAS7, UCT, DLQI), and identify clinically meaningful cut-offs for disease burden stratification.

Materials and Methods
We conducted a multicenter cross-sectional study of 173 CSU patients in Portugal. Participants completed the UAS7, UCT, DLQI, and Brazilian-Portuguese CU-Q2oL. Correlation analyses were performed using Spearman's rank coefficients. Thresholds for CU-Q2oL total score were derived using predefined, DLQI-based, and data-driven clustering approaches. Classification performance was evaluated using multiclass ROC analyses.

Results
CU-Q2oL total scores correlated strongly with DLQI ($\rho = 0.80$, $p < 0.001$), moderately with UAS7 ($\rho = 0.62$), and inversely with UCT ($\rho = -0.68$). A four-tier CU-Q2oL severity model derived via silhouette-optimized clustering demonstrated excellent classification performance (AUC = 0.96). Women reported significantly worse scores across all PROs.



The plot displays average silhouette width across clustering solutions (k = 1 to 10). The maximum silhouette value was reached at k = 4, indicating that a four-cluster structure provides the best balance between internal cohesion and separation from neighboring groups. This informed the selection of the four-group CU-Q2oL model used in subsequent classification analyses.

Conclusions

The CU-Q2oL is a valid tool for assessing QoL in CSU. A four-tiered scoring model offers robust discrimination of disease burden and may enhance its clinical utility in patient stratification and treatment planning.

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Complement C5 defines two immunological endotypes in CSU, with distinct autoantibody profiles and omalizumab responses: The INCA study

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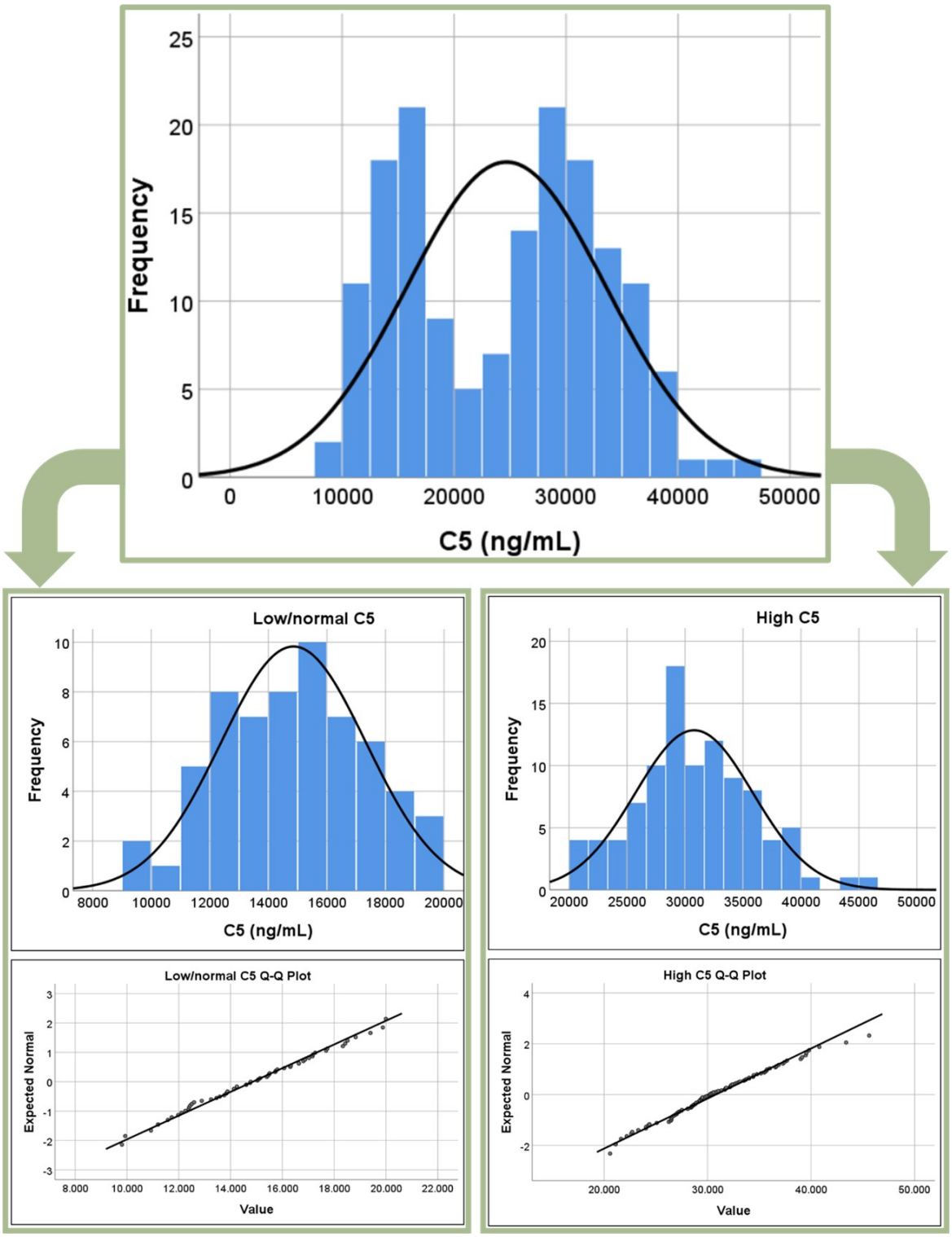
Introduction
Complement activation has long been implicated in chronic spontaneous urticaria (CSU), but the underlying mechanisms and its clinical relevance remain unclear.
We aimed to investigate the role of complement, particularly C3 and C5, among the immunological mechanisms of CSU and its response to therapy.

Materials and Methods
A multi-center cross-sectional study involving 159 CSU patients from Allergology and Immunology Centers in Portugal. Clinical data, patient-reported outcomes, complement fractions (C3, C5, C5a), total serum IgE and IgG/IgE autoantibodies were assessed. Patients were stratified according to C5 serum levels.

Results
C5 levels showed a bimodal distribution identifying 2 distinct subtypes, which include previously described autoallergic and autoimmune CSU endotypes:
- The low/normal C5 group (n=61) had lower C3 and C5a serum levels, higher total IgE, lower autoantibodies levels (IgG and IgE anti-TPO, and IgG anti-IgE), and an 89% response rate to standard-dose omalizumab.
- The high C5 group (n=96) exhibited elevated C3, C5, and C5a serum levels, higher rates of autoimmune thyroid disease, and higher prevalence of IgG and IgE autoantibodies. Omalizumab non-response and need for updosing were more common.



Histogram distribution of the C5 concentration and normality assessment. Histogram of the C5 concentrations in CSU patients revealed a bimodal distribution, indicating the presence of two distinct subpopulations. A cut-off at 20,000 ng/mL separated both subgroups (low/normal C5 and high C5), each of which with normally distributed C5 values. The normality was confirmed using Shapiro-Wilk tests, which showed both groups did not differ from a normal distribution (p=0.775 for the low/normal C5 group and p=0.506 for the high C5 group).

Conclusions

Complement C5 levels reveal two mechanistically and therapeutically relevant CSU endotypes: an IgE-driven, complement-independent subtype with a high response rate to omalizumab; and an autoimmune, complement-driven subtype, with increased autoantibodies and poorer response to omalizumab.

These findings identify C5 as a potential biomarker for stratification and a novel target in CSU.

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Predictors of response to updosed omalizumab in chronic urticaria

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Introduction
Chronic urticaria (CU) is a mast cell-driven inflammatory skin disorder characterized by recurrent wheals, angioedema, or both, and is associated with a substantial impairment in quality of life. Although second-generation H1-antihistamines are recommended as first-line therapy, a considerable proportion of patients remain symptomatic despite dose escalation. For these patients, omalizumab is the recommended add-on treatment at the licensed dose of 300 mg every 4 weeks; however, a relevant subset still fails to achieve adequate disease control. In clinical practice, dose escalation of omalizumab is increasingly used in refractory cases and has shown promising effectiveness. Nevertheless, real-world data on predictors of response to updosed omalizumab, particularly regarding clinical features, laboratory parameters, and delayed treatment responses, remain limited.

Materials and Methods
This retrospective real-world study included 57 patients with chronic urticaria treated with omalizumab 450 mg every 4 weeks after inadequate response to licensed-dose omalizumab. Demographic, clinical, and laboratory data were collected from medical records, including age, sex, body mass index, symptom duration, angioedema, urticaria subtype, family history of chronic urticaria, atopic and thyroid comorbidities, total IgE, anti-thyroid peroxidase antibody, antinuclear antibody, C-reactive protein, erythrocyte sedimentation rate, eosinophil count, and basophil count. Disease activity was assessed using the in-clinic Urticaria Activity Score, and disease control was assessed using the Urticaria Control Test (UCT). Responders were defined as patients achieving a UCT score ≥12 at month 3 and/or month 6, while late responders were defined as those achieving UCT ≥12 only after month 3. Clinical and laboratory characteristics were compared between responders and nonresponders, and between early and late responders.

Results
At month 3, 56.1% of patients achieved disease control with omalizumab 450 mg every 4 weeks. Overall, 71.9% achieved disease control or remission during 6 months of treatment. Among those who remained uncontrolled and were escalated to omalizumab 600 mg every 4 weeks, 80% achieved disease control at month 3, and all patients who continued treatment were controlled by month 6. Baseline UCT scores prior to omalizumab 450 mg initiation were significantly higher in responders than in nonresponders (9 vs. 7.5, p=0.015). In contrast, no significant differences were observed in baseline in-clinic Urticaria Activity Score, total IgE, anti-thyroid peroxidase antibody, antinuclear antibody positivity, eosinophil count, or basophil count between responders and nonresponders. Late responders constituted 34% of responders and had significantly higher rates of symptomatic dermographism (85.7% vs. 44.4%, p=0.011), family history of chronic urticaria (71.4% vs. 25.9%, p=0.005), and eosinopenia (57.1% vs. 25.9%, p=0.049) compared with early responders.

Conclusions
Updosed omalizumab is an effective therapeutic option in chronic urticaria patients who remain uncontrolled on

the licensed dose. Higher baseline UCT scores may predict a better response, whereas baseline endotype-related and immunologic markers do not appear to reliably identify responders. As late responses are not uncommon, treatment decisions should be individualized, and continuation beyond 12 weeks may be warranted in selected patients.

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Chronic Spontaneous Urticaria, Dupilumab, Efficacy, Safety, Urticaria Treatment

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Introduction
Chronic spontaneous urticaria (CSU) is a skin disorder driven by mast cells, characterized by recurring wheals,angioedema, or both, lasting for over six weeks. Managing CSU remains challenging due to limited responses to first- and second-linetreatments, such as second-generation H1-antihistamines and omalizumab. However, dupilumab, an emerging treatment that targets theIL-4 and IL-13 pathways, shows promise as a potential option for patients with refractory CSU. This systematic review evaluated theeffectiveness and safety of dupilumab in patients with CSU.

Materials and Methods
: The review adhered to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines andincluded searches of databases such as PubMed, EBSCO, Medline, Google Scholar, Wiley, and Web of Science. We used the keywords("Chronic Spontaneous Urticaria" OR "CSU") AND ("Dupilumab") AND ("treatment" OR "therapy" OR "efficacy") and applied filtersfor randomized controlled trials, cohort studies, human studies, and English-language publications. Eligible studies involved patientswith a confirmed CSU diagnosis receiving dupilumab, compared to placebo or standard care (e.g., antihistamines, omalizumab,corticosteroids). Outcomes included Urticaria Activity Score over 7 days (UAS7), complete response (UAS7 = 0), angioedema activity,itch severity, and adverse events. Studies on inducible urticaria or unrelated conditions were excluded. After reviewing 731 papers,seven articles were selected for the systematic review based on these criteria.

Results
This review demonstrated the efficacy and safety of dupilumab in treating CSU, particularly in patient's refractory toomalizumab and antihistamines. The age of the patients ranged from 2 to 73 years, and the duration of the disease varied from 3 monthsto 11 years. Dupilumab was administered as a subcutaneous injection of 300 mg biweekly for a period ranging from 4 to 34 months,including follow-up after treatment discontinuation. The treatment consistently showed significant improvements in disease activity anditch severity. There were substantial reductions in the UAS7, with complete remission achieved in 67% to 100% of patients acrossseveral studies. Additionally, significant improvements were noted in itch severity, reduction of wheals, and resolution of angioedema.Most adverse events reported were mild, with conjunctivitis and injection-site reactions being the most common. Serious adverse eventswere rare, and the rate of treatment discontinuation due to adverse events was low.

Conclusions
Dupilumab is a promising therapeutic option for patients with CSU, particularly those refractory to omalizumab andantihistamines. It demonstrates significant efficacy in reducing disease activity, improving quality of life, and achieving long-termremission in a substantial proportion of patients. The safety profile is favorable, with most adverse events being mild and manageable.These findings suggest that dupilumab could be a disease-modifying therapy for CSU, offering a durable and cost-effective treatmentoption for patients with difficult-to-treat disease. Further long-term studies are needed to confirm these results and explore the potentialfor disease modification.

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Abstract N°: 583

Severe acute urticaria is associated with elevated plasma levels of D-dimer

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Introduction

Evaluation of the disease severity of acute urticaria (AU) is essential for adequate treatment of patients. However, there are no reliable biomarkers for such an evaluation. D-dimer is a reliable laboratory biomarker for CU to determine disease activity and severity, as well as to predict sensitivity to antihistamines or biologics. Whereas a few articles have reported that patients with AU can exhibit elevated plasma D-dimer levels. We observed patients with severe AU having elevated plasma D-dimer levels. Thus, the objective of this study was to investigate the elevated D-dimer levels in patients with severe AU in more detail.

	D-dimer normal	D-dimer elevated	$t/Z/X^2$	*P*
Sex, *n* (%)				
Male	13 (59.1)	40 (34.2)		
Female	9 (40.9)	77 (65.8)		
Total	22 (100)	117 (100)	−2.20[d]	0.028[e]
Age, years Mean ± SD	43.23 ± 11.31	35.77 ± 15.61	2.315[b]	0.021[e]
Weight, kg Mean ± SD	65.08 ± 12.79	60.88 ± 13.45	3.28[c]	0.077
Prehospital time, days Mean ± SD	9.09 ± 4.89	6.01 ± 3.44	1.77[b]	0.001[e]
History, *n* (%)				
Yes	5 (22.7)	16 (13.7)		
No	17 (77.3)	101 (86.3)	−1.08[d]	0.278
Wheal, *n* (%)				
Yes	20 (90.9)	115 (98.3)		
No	2 (9.1)	2 (1.7)	−1.89[d]	0.058
Angioedema, *n* (%)				
Yes	2 (9.1)	18 (15.4)		
No	20 (90.9)	99 (84.6)	−0.77[d]	0.44
Gastrointestinal upset[a], *n* (%)				
Yes	6 (27.3)	36 (30.8)		
No	16 (72.7)	81 (69.2)	−0.35[d]	0.73
Fever, *n* (%)				
Yes	0	31 (26.5)		
No	22 (100)	86 (73.5)	−2.24[d]	0.025[e]
Breathlessness, *n* (%)				
Yes	0	17 (14.5)		
No	15 (100)	100 (85.5)	−1.90[d]	0.057
Pharyngalgia, *n* (%)				
Yes	2 (9.1)	22 (18.8)		
No	22 (90.9)	95 (81.2)	−1.10[d]	0.27
Joint pain, *n* (%)				
Yes	0	8 (6.8)		
No	22 (100)	109 (93.2)	−1.26[d]	0.21
Chest tightness, *n* (%)				
Yes	4 (18.2)	17 (14.5)		
No	18 (81.8)	100 (85.5)	−0.44[d]	0.66

Abbreviation: SD, standard deviation.

[a]Including nausea, vomiting, diarrhea, or abdominal pain.

[b]*t*-test or ANOVA.

[c]Nonparametric test.

[d]Chi-square test.

[e]The difference was statistically significant at the 0.05 test level.

TABLE 1 Clinical characteristics of the two patient groups

Materials and Methods

One hundred and thirty-nine hospital patients diagnosed with severe AU were enrolled. Baseline demographics, clinical presentations, and laboratory data were collected from medical records. Blood samples from all patients were collected in the inpatient ward within 24 h. Laboratory data during hospitalization, including complete blood counts (WBC, neutrophils, eosinophils, and basophils), serum biochemical tests (renal and liver function), lactate dehydrogenase (LDH), and C-reactive protein (CRP) levels, were acquired. Coagulation tests included D-dimer analyses.

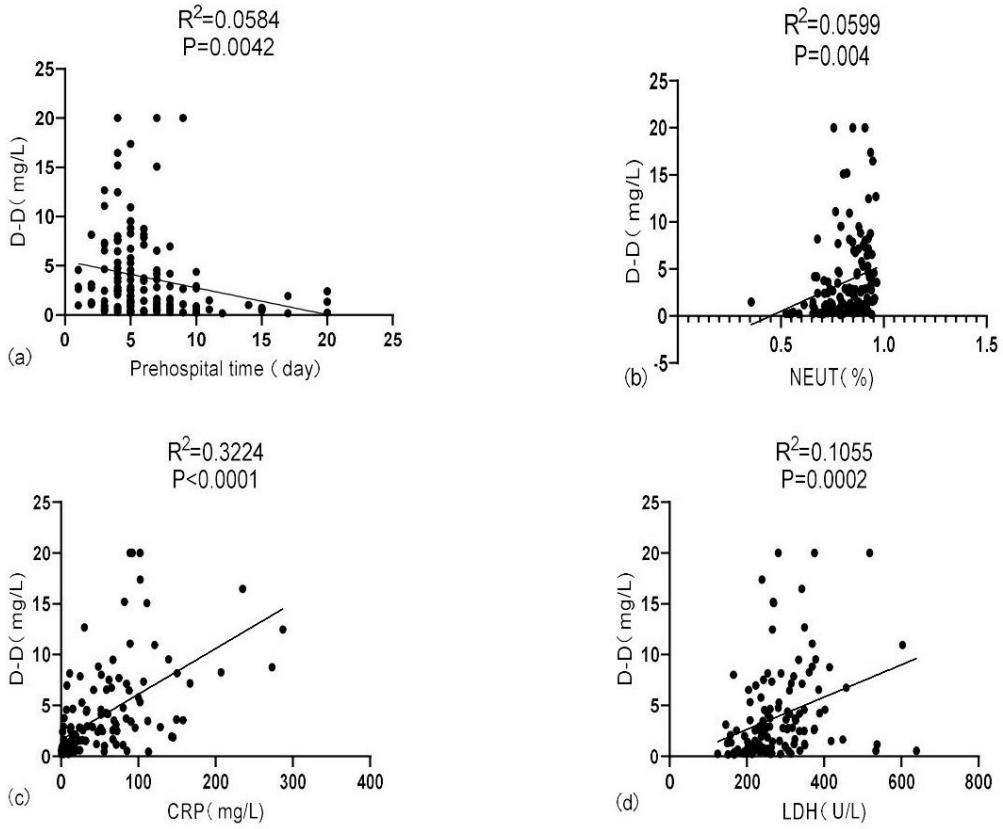

FIGURE 1 Scatterplots of D-dimer versus (a) prehospital time, (b) NEUT%, (c) CRP, and (d) LDH show the best-fit simple lines. The fit is significant (P = 0.004, 0.004, <0.001, and <0.001, respectively). NEUT%, percentage neutrophils; CRP, C-reactive protein; LDH, lactate dehydrogenase.

Results

One hundred and seventeen of the patients presented with elevated plasma D-dimer levels. Compared to the normal group, the elevated group had a significantly higher proportion of patients who were female, younger, febrile, and had a shorter prehospital time (P < 0.05). Univariate regression analysis showed that neutrophil percentage, CRP, and LDH levels increased as D-dimer levels increased, while prehospital time showed the opposite trend. Multiple regression analysis was used to estimate the simultaneous effects of CRP and LDH on D-dimer levels. Patients who responded to additional antibiotic treatment had higher levels of D-dimer. The group with highly elevated D-dimer levels required a higher maximum dose of daily glucocorticoids (GCs) to control the symptoms of AU.

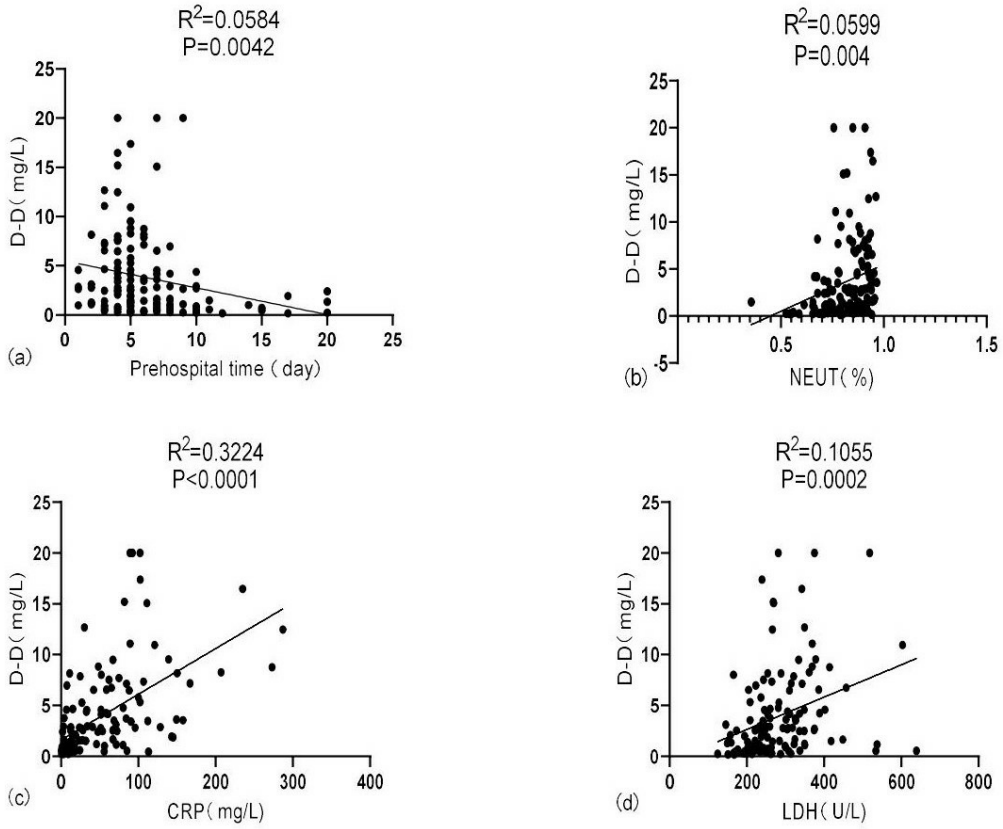

FIGURE 2 Three-dimensional plot of the best-fit multiple regression plane relating D-dimer to both CRP and LDH.

Conclusions

In conclusion, patients with severe AU might have elevated plasma D-dimer levels, which are positively correlated with CRP and LDH levels. Patients with severe AU with dramatically elevated D-dimer levels might need a higher dose of daily GCs and antibiotics to relieve symptoms. D-dimer may be a reasonable marker to evaluate the severity of AU and guide treatment.

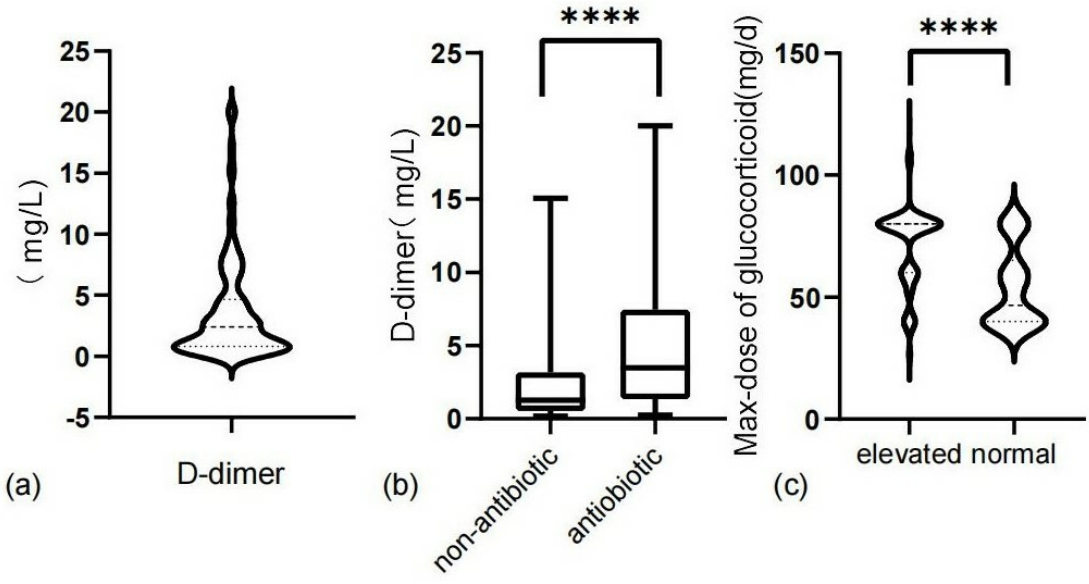

FIGURE 3 (a) Visualization of D-dimer levels. (b) D-dimer levels between the non-antibiotic and antibiotic groups. (c) Maximum dose of daily glucocorticoids (GCs) between the two groups.

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Abstract N°: 601

CD203c expression in skin mast cells before and after cold provocation in patients with cold urticaria

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Introduction

Cold urticaria (ColdU) is one of the most common types of chronic inducible urticaria. The pathomechanism of ColdU is not yet fully understood, but mast cells (MCs) and their activation play a significant role. CD203c is a surface marker on MCs. *In vitro* studies suggest that CD203c is upregulated after MC activation by translocation to the membrane rather than by transcriptional regulation. There is currently no data available on the expression of CD203c on MCs in ColdU patients. This study aims to identify and characterize the expression of MC surface marker CD203c in patients with ColdU before and after cold provocation. The primary aim was to analyze the number of CD203c-positive ($CD203c^+$) skin MCs in ColdU patients before and after cold provocation immunohistochemically. The secondary aim was to assess the dynamics of CD203c gene (ENPP3) expression in skin MCs after cold-induced activation and lesion induction, and to assess the dynamics of serum tryptase and carboxypeptidase A3 (CPA3) levels.

Materials and Methods

In n=10 ColdU patients, demographic and clinical patient data, along with laboratory routine parameters, were captured. A skin biopsy was performed on unprovoked skin, after a codeine prick-test and 1 hour, 24 hours and 48 hours after cold provocation. The tissue was immunohistochemically stained, and $CD203c^+$ and CD117-positive ($CD117^+$) skin cells were quantified in consecutive tissue sections. The expression of 477 genes related to skin homeostasis alongside ENPP3 was analyzed using highly multiplexed targeted spatial gene expression profiling to evaluate cells within their native tissue architecture across all time points. Tryptase and CPA3 levels were analyzed in patient serum before cold provocation, as well as 15 minutes and 48 hours after cold provocation.

Results

The median age of the analyzed ColdU patients (female n=8, male n=2) was 47 years, and the median disease duration was 29 months. The median TempTest® threshold was 16°C, and the median Urticaria-Control-Test (UCT) score was 12 points. Cell quantification following immunohistochemical staining indicated that the number of $CD203c^+$ cells in the skin biopsies was stable across all time points before (median 24 cells/mm^2, range 10-67) and after cold provocation (+1h median: 27 cells/mm^2, range 19-67; +24h median: 31, range 15-53; +48h median: 29, range 11-52). The median number of $CD203c^+$ and $CD117^+$ cells, assessed by single immunohistochemical staining on consecutive tissue sections, were comparable at all analyzed time points ($CD117^+$ median cells/mm^2: baseline: 36, +1h: 26, +24h: 29, +48h: 28). High-resolution spatial transcriptomic profiling revealed that CD203c mRNA is constitutively transcribed at high baseline levels in skin MCs natively. ENPP3 transcript levels did not

increase, despite a significant increase in activated MC-related transcripts such as FOSB, EGR1, EGR3 and CCL2 1 hour after provocation. Serum tryptase and CPA3 levels were stable across all time points before (median serum tryptase: 3.60 µg/l, median CPA3: 133.30 pg/ml) and after cold provocation (median serum tryptase: +15min: 3.43 µg/l, +48h: 3.56 µg/l; median CPA3: +15min: 122.08 pg/ml, +48h: 137.28 pg/ml).

Conclusions

This study provides novel insights in the expression of CD203c in skin MCs in ColdU. CD203c seems to be constitutively transcribed at stable levels in MCs of ColdU patients. CD203c is not substantially upregulated at the transcriptomic level following cold provocation. However, further investigation is required to fully characterize the CD203c expression in ColdU patients.

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Abstract N°: 621

Comparison of Tofacitinib and Baricitinib in the Treatment of Chronic Urticaria :A Prospective study

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Introduction

Chronic urticaria (CU) is a challenging condition with significant impact on patients' quality of life. Janus kinase (JAK) inhibitors, including tofacitinib and baricitinib, have emerged as potential therapeutic options in refractory cases.To compare the efficacy of tofacitinib and baricitinib in patients with chronic urticaria, focusing on disease activity and quality of life.To compare the efficacy of tofacitinib and baricitinib in patients with chronic urticaria, focusing on disease activity and quality of life.

Case Presentation

In this prospective study, 22 patients with chronic urticaria (7 males, 15 females) were enrolled and equally assigned to receive tofacitinib (n=11) or baricitinib (n=11). Three patients in the tofacitinib group discontinued treatment due to adverse effects. Disease activity was assessed using the Urticaria Activity Score over 7 days (UAS7), disease control using the Urticaria Control Test (UCT), and quality of life using the Dermatology Life Quality Index (DLQI) at baseline, 2 months, and 6 months.Results:Baseline UAS7 scores were 25 in the tofacitinib group and 28 in the baricitinib group. At 2 months, scores decreased to 20 and 17, respectively, and at 6 months to 10 and 8. Both treatments showed significant improvement over time ($p<0.05$), with no significant difference between groups.Baseline DLQI scores were 22 in the tofacitinib group and 20 in the baricitinib group. At 2 months, scores improved to 14 and 10, respectively, and at 6 months to 11 and 5. Improvement in quality of life was significantly greater in the baricitinib group ($p<0.05$).Baseline UCT scores were 14 and 15 in the tofacitinib and baricitinib groups, respectively. At the end of the study, UCT scores were below 12 in both groups, indicating improved disease control ($p<0.05$).

Conclusion

Tofacitinib and baricitinib demonstrated comparable efficacy in reducing urticaria activity. However, baricitinib was associated with greater improvement in quality of life, suggesting a potential advantage in overall patient-reported outcomes

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Abstract N°: 630

Validation and Reliability of Urticaria Activity Scores in the RILECSU Phase 2 Study: A Psychometric Analysis

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Introduction
Rilzabrutinib (SAR444671), is an oral BTK inhibitor with high-target specificity that rapidly restores immune balance through targeted mast cell and basophil modulation. This clinical study evaluated rilzabrutinib for the treatment of chronic spontaneous urticaria (CSU), with patient-reported outcomes (PROs) to assess disease burden and capture patient experiences.

Materials and Methods
The RILECSU study (NCT05107115) was a phase 2, randomized, double-blind, placebo-controlled trial evaluating rilzabrutinib in adults with moderate-to-severe CSU inadequately controlled with H1-antihistamine treatment. During the 12-week treatment period, participants (N=160) were randomized 1:1:1:1 to rilzabrutinib 1200 mg/day, 800 mg/day, 400 mg/day, or placebo. Psychometric properties of weekly scores derived from daily assessments, including the weekly Urticaria Activity Score (UAS7), weekly Itch Severity score (ISS7), and weekly Hives Severity Score (HSS7) were analyzed for reliability, consistency, and validity.

Results
Good to excellent test-retest reliability was demonstrated for UAS7, ISS7, and HSS7 (Intraclass Correlation Coefficient [ICC]: 0.75-0.93, 0.75-0.94, 0.74-0.91, respectively). Internal consistency reliability was also excellent across all measures (Spearman-Brown: 0.82-0.95). Evidence of convergent validity was demonstrated through moderate to strong correlations (*absolute* range: UAS7, 0.48-0.82; ISS7, 0.48-0.91; HSS7, 0.42-0.91) with measures of related constructs, and adequate known-groups validity was demonstrated.

Conclusions
The weekly UAS7, ISS7 and HSS7 evaluated in the RILECSU study demonstrated robust psychometric properties, including strong validity and reliability, supporting their ability to capture clinically meaningful changes in urticaria symptomatology over time.

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Abstract N°: 756

Real-World Omalizumab Dose Adjustment Patterns and Drug Survival in Chronic Spontaneous Urticaria

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Introduction
Chronic spontaneous urticaria (CSU) is an immune-mediated disease characterized by recurrent wheals lasting >6 weeks. Omalizumab is recommended as second-line therapy for patients inadequately controlled with second-generation H1 antihistamines. Given the self-limiting nature of CSU and increasing adoption of step-down strategies, real-world data on dosing patterns and drug survival are essential to optimize long-term management. However, such data remain limited, particularly in Asian populations. This study aimed to investigate real-world omalizumab dose adjustment patterns and drug survival in a large CSU cohort.

Materials and Methods
We conducted a retrospective cohort study of patients with CSU treated with omalizumab at a Urticaria Center of Reference and Excellence (UCARE) in Xi'an, China, between 2023 and 2026. Discontinuation was defined as a treatment interval exceeding 90 days. Treatment patterns were classified as fixed regimen, dose escalation, tapering (dose reduction and/or interval extension), or irregular patterns. Drug survival was defined as time from treatment initiation to discontinuation. Baseline clinical characteristics and longitudinal dosing changes were analyzed and visualized with Kaplan-Meier estimator.

Results
A total of 1,308 patients were included (56.3% female; median age, 40 years). Prior corticosteroid use was reported in 7.9% of patients. At initiation, 50.8% had inadequate disease control with a single antihistamine, while 49.2% had failed 2–6 antihistamines. Most patients (91.5%) initiated omalizumab at the standard dose.The majority (853, 65.2%) were maintained on a fixed regimen, with 300 mg every 4 weeks (Q4W) being the most common (546, 41.7%). Discontinuation after a single dose occurred in 244 patients (18.7%). Among patients undergoing dose adjustment, tapering strategies were more frequent than escalation: dose reduction in 277 patients (21.2%) and interval extension in 151 (11.5%). Dose escalation was rare (0.6%), and irregular patterns were uncommon (1.4%). The most common tapering approaches involved reducing the dose from 300 mg Q4W or extending the dosing interval.Transition analysis showed that approximately 60% of patients remained on the standard regimen at subsequent follow-up, 25% discontinued treatment, 15% underwent dose reduction, and <1% escalated dosing. Among those who tapered, more than half maintained the reduced regimen, while others discontinued.The median drug survival time was 277.5 days. Median time to discontinuation was 181 days for the standard regimen, compared with 338 days for escalation patterns and 360 days for tapering patterns, and 434 days for irregular patterns. Most discontinuations (97.0%) were due to effective disease control, with only 3.0% attributed to lack of efficacy and none to severe adverse events.

Conclusions
In this large real-world CSU cohort, most patients were treated with standard-dose omalizumab, while tapering strategies were more commonly implemented than escalation. Drug survival was longer among patients undergoing dose adjustment compared with those maintained on a fixed regimen. These findings support the feasibility of step-down approaches and highlight the importance of individualized treatment strategies in CSU management.

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Abstract N°: 757

Prediction of omalizumab response patterns in chronic spontaneous urticaria based on interpretable artificial intelligence

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Introduction
Chronic spontaneous urticaria (CSU) is an inflammatory skin disorder characterized by substantial interindividual variability in wheal morphology. The monoclonal anti–immunoglobulin E antibody Omalizumab has demonstrated efficacy in patients with CSU who are unresponsive to antihistamines. However, real-world evidence regarding the association between wheal characteristics and response to omalizumab remains limited. This study aimed to evaluate whether wheal characteristics can predict treatment response to omalizumab in CSU using both conventional logistic regression and interpretable machine learning approaches.

Materials and Methods
Baseline characteristics of CSU patients before omalizumab treatment were retrospectively collected. Patients were classified into early (≤ 1 month), late (≤ 3 months), and non-responders (> 3 months or no improvement). We employed logistic regression, Boruta, Maximum Relevance Minimum Redundancy (mRMR), Recursive Feature Elimination (RFE), and Least Absolute Shrinkage and Selection Operator (LASSO) to comprehensively select potential predictors, and respectively adopted four ML algorithms. Model performances were compared, and interpretability was evaluated by Shapley Additive exPlanations (SHAP).

Results
In this study of 119 patients, omalizumab response was not associated with wheal characteristics (color, morphology, density, predilection sites) in logistic regression. The best-performing RFE-XGBoost model (AUC = 0.870, 95% CI 0.719-0.972) showed dermatology life quality index (DLQI), urticaria activity score 7 (UAS7), and level of total IgE were the three most important features for predicting omalizumab response. Although color and density of wheal were incorporated, their predictive capacity remains weak.

Conclusions
Wheal characteristics cannot be used as a reliable clinical predictor of omalizumab response in CSU, while DLQI, UAS7, level of total IgE show potential predictive value.

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Abstract N°: 758

Tissue-dependent sex-biased immune programs in chronic spontaneous urticaria revealed by integrative clinical and transcriptomic profiling

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Introduction
Chronic spontaneous urticaria (CSU) exhibits a marked female predominance; however, whether sex differences are limited to disease prevalence or reflect underlying biological variation remains unclear. This study aimed to characterize the clinical and molecular basis of sex differences in CSU through integrated analyses of phenotypic features, lesional skin transcriptomes, and peripheral blood transcriptomes.

Materials and Methods
A total of 403 CSU patients (254 females, 149 males) were analyzed for demographic, clinical, and laboratory parameters. Publicly available lesional skin transcriptomic datasets with annotated sex information were analyzed using differential expression and module-based approaches to identify sex-biased functional programs. Module activity was subsequently evaluated in independent CSU peripheral blood transcriptomic datasets to assess tissue dependency.

Results
Females exhibited higher rates of anxiety, depression, and autoimmune comorbidities, together with significantly lower peripheral eosinophil and basophil counts. Module-based transcriptomic analysis identified five major functional programs, including chemokine inflammatory signaling, interferon-antigen presentation, cytoskeletal remodeling, DNA repair, and ribosome biogenesis. In lesional skin, females showed increased activity of immune-related modules, whereas males displayed enhanced activation of DNA repair and ribosome biogenesis pathways. Peripheral blood validation revealed tissue-dependent divergence, with attenuated sex differences across most modules compared with lesional skin, highlighting context-specific molecular regulation.

Conclusions
Sex differences in CSU extend beyond disease prevalence and involve distinct, tissue-dependent molecular programs. Female CSU is characterized by an immune-amplified lesional transcriptomic profile, whereas male patients exhibit relatively enhanced DNA maintenance, highlighting sex-biased molecular architecture in CSU pathogenesis.

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Abstract N°: 1066

Efficacy of Remibrutinib in Refractory Chronic Spontaneous Urticaria

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Introduction

Chronic spontaneous urticaria (CSU) is a debilitating skin condition characterized by the spontaneous appearance of wheals, angioedema, or both for more than six weeks. Its unpredictable course and significant impact on quality of life make it a clinical challenge.

Case Presentation

A case study of a patient with CSU who had not responded to treatment with antihistamines, biologic drugs and classical immunosuppressants. Clinical and sociodemographic characteristics were collected, with a 5-year follow-up after treatment. A 51-year-old woman with a history of intermittently poorly controlled asthma presented with recurrent flares of CSU over several years. Physical examination revealed generalized wheals without angioedema, accompanied by intense pruritus that significantly impaired her quality of life. The diagnosis was confirmed by histopathological examination on two separate occasions.

The patient developed secondary treatment failure after 2 years despite receiving quadruple-dose antihistamines and Omalizumab 600 mg every 4 weeks. Methotrexate (12.5 mg weekly, subcutaneous) was initiated but discontinued after 3 weeks due to gastrointestinal intolerance. Subsequently, Cyclosporine 300 mg daily was started, achieving an initial good response; however, treatment had to be dose-reduced due to elevated creatinine levels, leading to recurrence of wheals. Dupilumab 300 mg every 2 weeks was then initiated, resulting in complete resolution of skin lesions for 10 months and no further asthma exacerbations. As an adverse event, mild eczema of the face and neck developed after the first injections, which was successfully managed with topical corticosteroids. However, the patient experienced secondary loss of response, requiring discontinuation of Dupilumab and initiation of Remibrutinib 25 mg twice daily. A rapid and significant improvement in UAS7 and pruritus NRS scores was observed within a few days of treatment initiation. The patient has remained free of wheals for more than 3 months.

Conclusion

This case highlights Remibrutinib as an effective and fast-acting therapeutic option in patients with severe, refractory CSU who have failed multiple lines of treatment. The rapid improvement in disease activity and pruritus, together with sustained clinical remission, supports the potential role of BTK inhibition as a valuable strategy in difficult-to-treat CSU. Further studies are warranted to better define its positioning within the treatment algorithm and to confirm long-term efficacy and safety in real-world settings.

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Abstract N°: 1081

Evaluating dementia risk associated with second-generation H1-antihistamines in type 2 inflammatory diseases: findings from a real-world target-trial emulation

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Introduction

Type 2 chronic inflammatory conditions—including chronic urticaria (CU), chronic sinusitis (CS), and allergic rhinitis (AR)—are common and frequently managed with second-generation H1-antihistamines (sgAH). Although sgAH are generally regarded as safe, recent reports have suggested a potential link to dementia risk.

Materials and Methods

We performed a target-trial emulation using real-world data from the TriNetX electronic health record network, which includes more than 114 million patients. Individuals aged ≥50 years with CU, CS, or AR and no prior dementia diagnosis were eligible. Exposure groups consisted of users of sgAH, first-generation H1-antihistamines (fgAH), or non-antihistamine comparators (intranasal corticosteroids for AR and CS, oral steroids for CU). Propensity-score matching was conducted across 38 baseline variables. Dementia incidence over 5 years was evaluated using Kaplan–Meier curves and Cox proportional hazards models.

Results

After matching, analyses included 48,238 CU patients, 21,611 CS patients, and 36,802 AR patients, each with corresponding control cohorts. Across all disease groups, antihistamine use was not associated with an elevated risk of dementia compared with non-antihistamine alternatives. No significant differences emerged between sgAH and fgAH or corticosteroid comparators. A small but statistically significant increase in dementia risk was observed among AR patients treated with sgAH compared with intranasal steroids (HR 1.239, 95% CI 1.060–1.447, p=0.007), and this finding persisted in sensitivity analyses.

Conclusions

Overall, the data do not indicate that sgAH contribute to increased dementia risk. The modest elevation seen in AR likely reflects protective effects of corticosteroids, residual confounding, bias, or characteristics specific to this subgroup rather than a pharmacologic effect of sgAH, which lack anticholinergic activity and have limited central nervous system penetration. The absence of a similar signal in CU—where sgAH are used chronically and at higher doses—further supports this interpretation. Reports suggesting dementia risk with sgAH should therefore be viewed as artifacts of study design or data limitations rather than evidence of causality.

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Abstract N°: 1196

Histaglobulin as a Cost-Effective Adjunct in Chronic Spontaneous Urticaria: A Prospective Self-Controlled Interventional Study

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Introduction

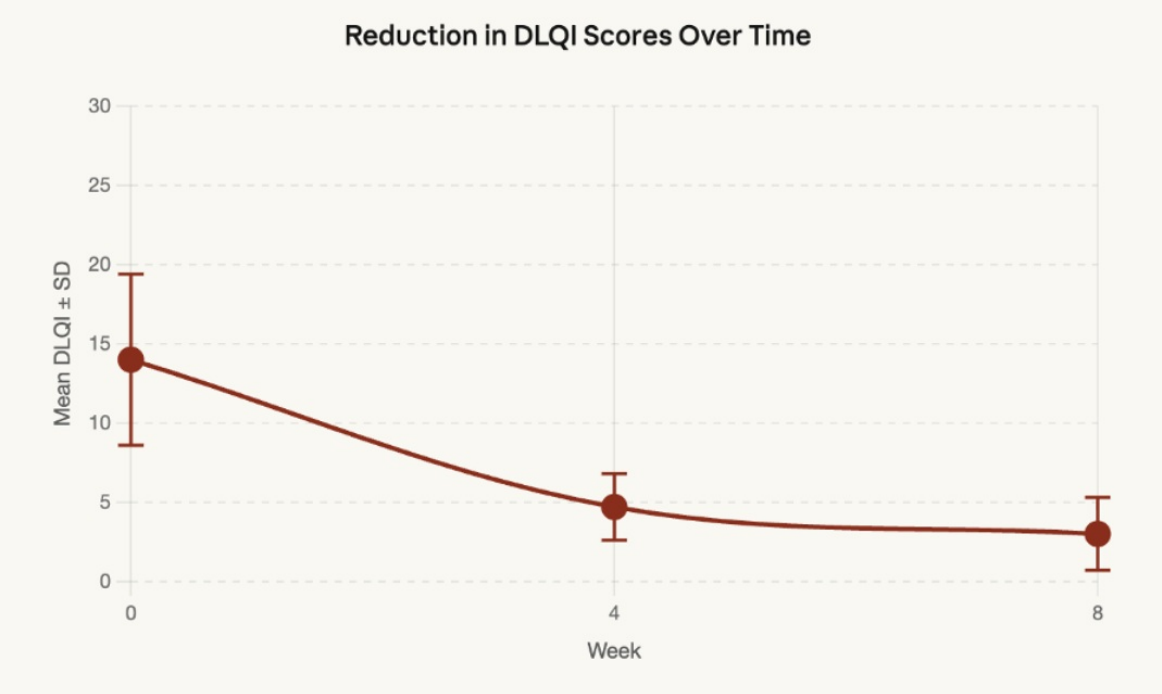
Chronic spontaneous urticaria (CSU) is characterized by recurrent wheals, angioedema, and/or pruritus persisting for more than 6 weeks, with a considerable proportion of patients remaining inadequately controlled despite second-generation H1-antihistamines. Although omalizumab has transformed the therapeutic landscape of CSU, its high cost and limited accessibility remain important barriers in resource-constrained settings in some countries. Histaglobulin, a lyophilized complex of human normal immunoglobulin and histamine dihydrochloride, has been proposed as an immunomodulatory therapy that may induce antihistamine antibodies, improve histamine-binding capacity, and reduce urticaria activity. This study evaluated the efficacy and safety of Histaglobulin as an adjunctive therapy in patients with antihistamine-refractory CSU.

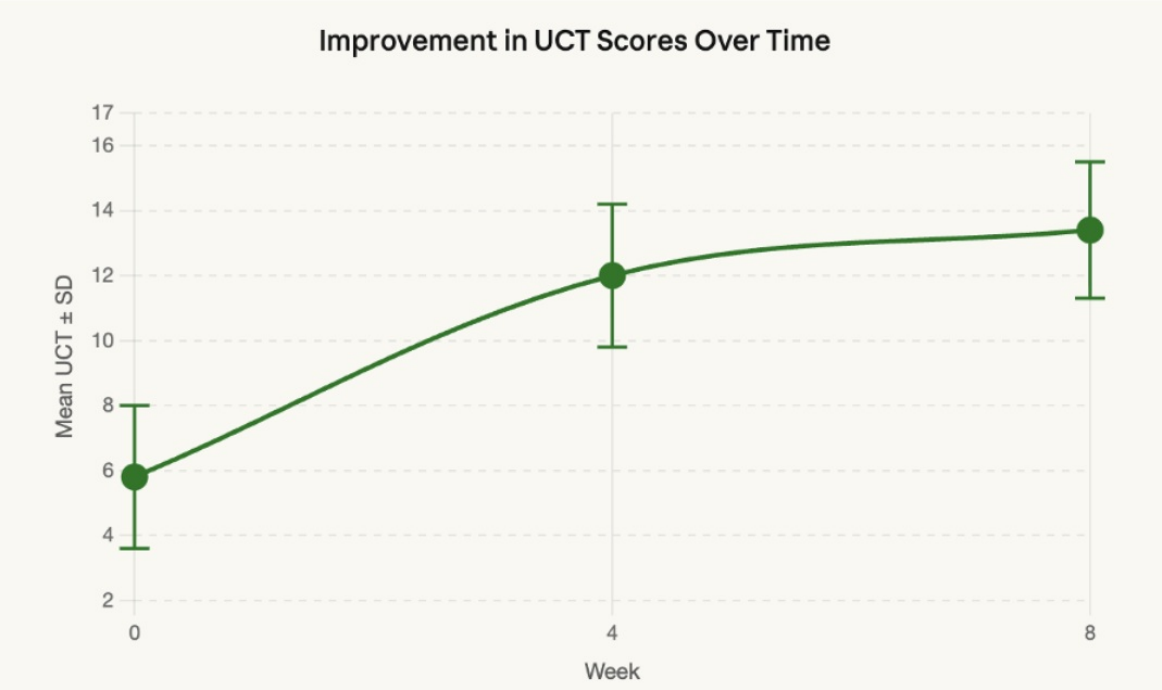
Materials and Methods

This prospective interventional analytical study from India included 17 patients aged 18–60 years with CSU inadequately controlled on levocetirizine, defined by UAS7 ≥7 and/or UCT <12. All participants received subcutaneous Histaglobulin 1 mL weekly for 8 weeks in addition to levocetirizine 5 mg daily. Patients were assessed using the Urticaria Activity Score over 7 days (UAS7) weekly and the Urticaria Control Test (UCT) and Dermatology Life Quality Index (DLQI) at baseline, week 4, and week 8. The primary endpoint was the change in mean UAS7 at week 8. Secondary endpoints included changes in UCT, DLQI, and treatment safety. Appropriate statistical tests were used for statistical analysis, with $p < 0.05$ considered significant.

Results

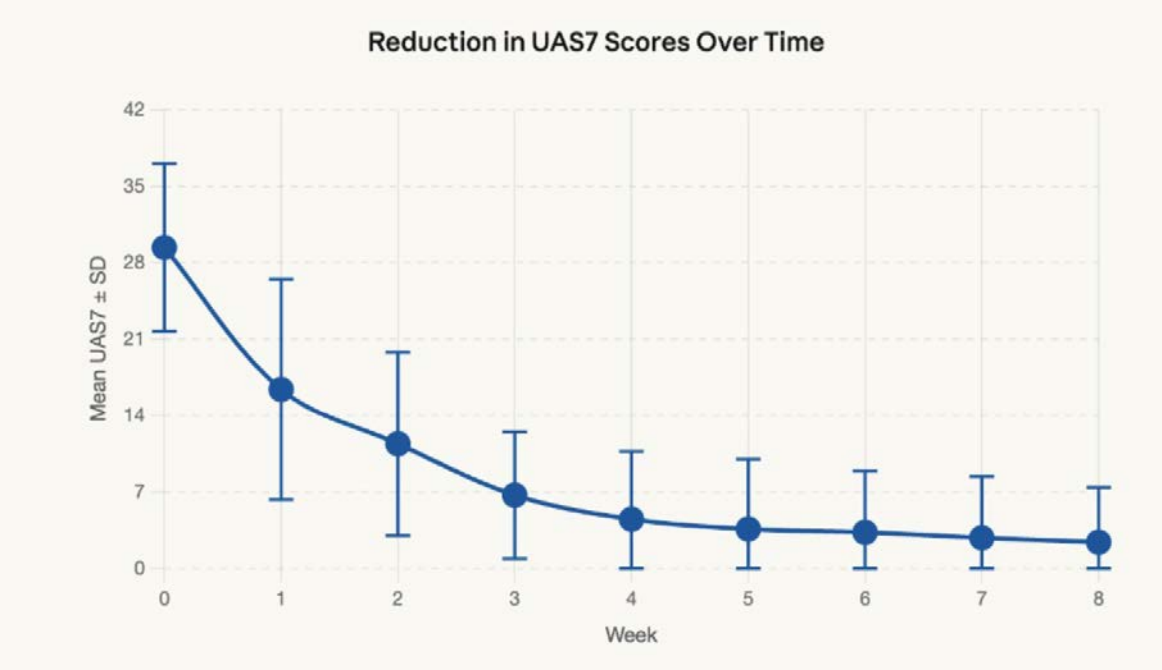
Seventeen patients were enrolled (13 females, 4 males; mean age 32.9 ± 8.8 years). Mean UAS7 decreased from 29.35 ± 7.69 at baseline to 16.35 ± 10.08 at Week 1 (44.3% reduction), 6.00 ± 6.59 at Week 4, and 2.41 ± 4.96 at Week 8, representing a 91.8% reduction from baseline ($p < 0.001$, Wilcoxon signed-rank test; $p < 0.001$, Friedman test). The mean delta UAS7 (Week 0 to Week 8) was 26.94± 9.48 points. By Week 8, 15/17 patients (88.2%) achieved well-controlled disease (UAS7 < 7), and 16/17 (94.1%) met the MCID threshold of ≥ 10 points improvement in UAS7. Mean UCT increased from 5.82 ± 2.19 at baseline to 12.00 ± 2.24 at Week 4 and 13.35 ± 2.09 at Week 8 ($p < 0.001$, Wilcoxon signed-rank test; $p < 0.001$, Friedman test). The mean delta UCT was +7.53±2.64 points with 16/17 patients (94.1%) achieving MCID ≥ 3 points. Mean DLQI decreased from 14.00 ± 5.37 at baseline to 4.71 ± 2.11 at Week 4 and 3.00 ± 2.35 at Week 8 ($p < 0.001$). Histaglobulin was well tolerated throughout the study period; no serious adverse events were reported, and only mild injection-site discomfort was observed.





Conclusions

Histaglobulin therapy produced rapid and sustained improvement in disease activity and CSU patients' quality of life. The treatment was well tolerated and potentially affordable, supporting its role as a pragmatic adjunctive option in settings where biologic therapy may be inaccessible. Randomized controlled studies are needed to confirm our findings.


Reduction in UAS7 Scores Over Time
Mean UAS7 ± SD
42
35
28
21
14
7
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7
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Week

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Abstract N°: 1212

JAK-family inhibitors in refractory chronic spontaneous urticaria: a systematic review

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Introduction
Chronic spontaneous urticaria (CSU) remains uncontrolled in some patients despite antihistamines, omalizumab and other systemic therapies. Janus kinase (JAK) inhibition offers a mechanistically distinct therapeutic strategy, but evidence has expanded rapidly across randomised trials, uncontrolled cohorts and case-based reports. We systematically evaluated the efficacy, response kinetics, durability, treatment context, biomarkers and safety of systemic JAK inhibitors in CSU.

Materials and Methods
PubMed, Embase, Scopus, ClinicalTrials.gov and WHO ICTRP were searched from inception to 21 August 2026. Original reports providing extractable CSU outcomes during systemic JAK inhibition were eligible. Multiple reports from the same study were linked to avoid double counting, and full-text and abstract-only evidence were synthesised separately. Methodological appraisal used design-specific tools. Quantitative pooling was not performed because agents, designs, treatment settings, outcome definitions and follow-up were substantially heterogeneous. The review was prospectively registered in PROSPERO (CRD420261353298).

Results
Twenty-seven reports representing 21 studies were included: 15 studies had full-text outcome reports and 6 were available only as conference abstracts. The only fully published randomised trial, TLL-018 (n=41), demonstrated placebo-adjusted week 4 UAS7 reductions of 11.5 and 16.0 points with 10 mg and 30 mg twice daily, respectively. The larger randomised phase 2 povorcitinib study (n=136) remained abstract-only; at week 12, UAS7 ≤6 was achieved by 62.9% with 75 mg versus 29.4% with placebo, with the clearest separation observed at the 75 mg dose.

Full-text uncontrolled studies extended the clinical signal into more treatment-refractory populations. In cohorts with inadequate omalizumab response, 11/14 patients responded in one study and 7/10 achieved UAS7 ≤6 at week 8 in another. Rapid improvement recurred across controlled, nonrandomised and case-based evidence, often within the first 1 to 4 weeks. Durability was less consistent: worsening after dose reduction and relapse after withdrawal were reported, with renewed control after dose escalation or rechallenge in some patients. Biomarker observations involving IgE, autoreactivity, eosinophils and type 2 signals were inconsistent and did not identify a reproducible responder phenotype. Long-term CSU-specific safety remained insufficiently characterised.

Conclusions
Systemic JAK inhibition shows credible short-term activity in CSU, while uncontrolled evidence supports a plausible rescue role after omalizumab or multidrug failure. Current evidence does not establish a class effect,

durable disease modification, biomarker-guided selection or long-term safety. Adequately powered trials should define efficacy after advanced-treatment failure, optimal agent and dose, durability after treatment withdrawal and long-term safety.

EA DV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 1426

Rapid Symptom Control in Advanced Therapies for Chronic Spontaneous Urticaria: A Network Meta-Analysis of Comparative Early-Onset Efficacy at Weeks 2 and 4

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Introduction

Chronic spontaneous urticaria (CSU) is an inflammatory skin condition characterized by wheals, angioedema and associated pruritus, with a substantial impact on patients' quality of life. Given this burden, rapid symptom relief is often a key therapeutic priority. In the absence of head-to-head trials, clinicians and patients may face uncertainty in selecting a treatment for early symptom control. Accordingly, this network meta-analysis aims to evaluate the relative early-onset efficacy of remibrutinib, omalizumab, and dupilumab in CSU.

Materials and Methods

Embase and MEDLINE were searched through April 2026 for clinical trials evaluating remibrutinib (25 mg BID), omalizumab (300/150 mg Q4W), or dupilumab (300 mg Q2W) in CSU. Articles were screened and extracted in duplicate, with week 2 and 4 data extracted from figures using automeris.io. Outcomes assessed included Urticaria Activity Score (UAS7), Itch Severity Score (ISS7), and Hives Severity Score (HSS7) over 7 days. Frequentist random-effects network meta-analyses were conducted in R (v4.4.2) to derive mean difference (MD) estimates compared to a common placebo.

Results

Ten articles encompassing 12 trials and 2536 participants (70% female; weighted average age 43.7 years) were included. Patients had an average baseline UAS7 score of 30.2, ISS7 of 14.4, HSS7 of 15.7, and DLQI of 13.3, indicating severe CSU activity, significant itch and wheal activity, and quality of life impairment.

Remibrutinib 25 mg BID had the largest reduction in UAS7 at both weeks 2 (MD -10.12, 95% CI -12.94; -7.29) and 4 (MD -11.5, 95% CI -14.02; -8.98), followed closely by omalizumab 300 mg Q4W with a mean reduction of approximately 9 points compared to placebo (Figure 1). Dupilumab 300 mg Q2W had the lowest reduction in UAS7 at week 2 (MD -0.90, 95% CI -2.88; 1.07), although improved by week 4 (MD -3.38, 95% CI -5.88; -0.87).

ISS7 and HSS7 data were available for omalizumab and dupilumab, but not for remibrutinib. Regarding itch control, omalizumab 300 mg Q4W had greater mean reduction in ISS7 at weeks 2 (MD -3.72, 95% CI -4.55; -2.88) and 4 (MD -3.99, 95% CI -4.82; -3.16) compared to dupilumab 300 mg Q2W (week 2 MD -0.49; week 4 MD -1.51) and omalizumab 150 mg Q4W (week 2 MD -1.60; week 4 MD -1.32). Similarly, omalizumab 300 mg Q4W had good early-onset wheal control, with the largest relative reductions in HSS7 at both timepoints (week 2 MD -5.51; week 4 MD -5.30) compared to dupilumab 300 Q2W (week 2 MD -0.45; week 4 -1.89) and omalizumab 150 mg Q4W (week 2 MD -2.13; week 4 MD -0.73).

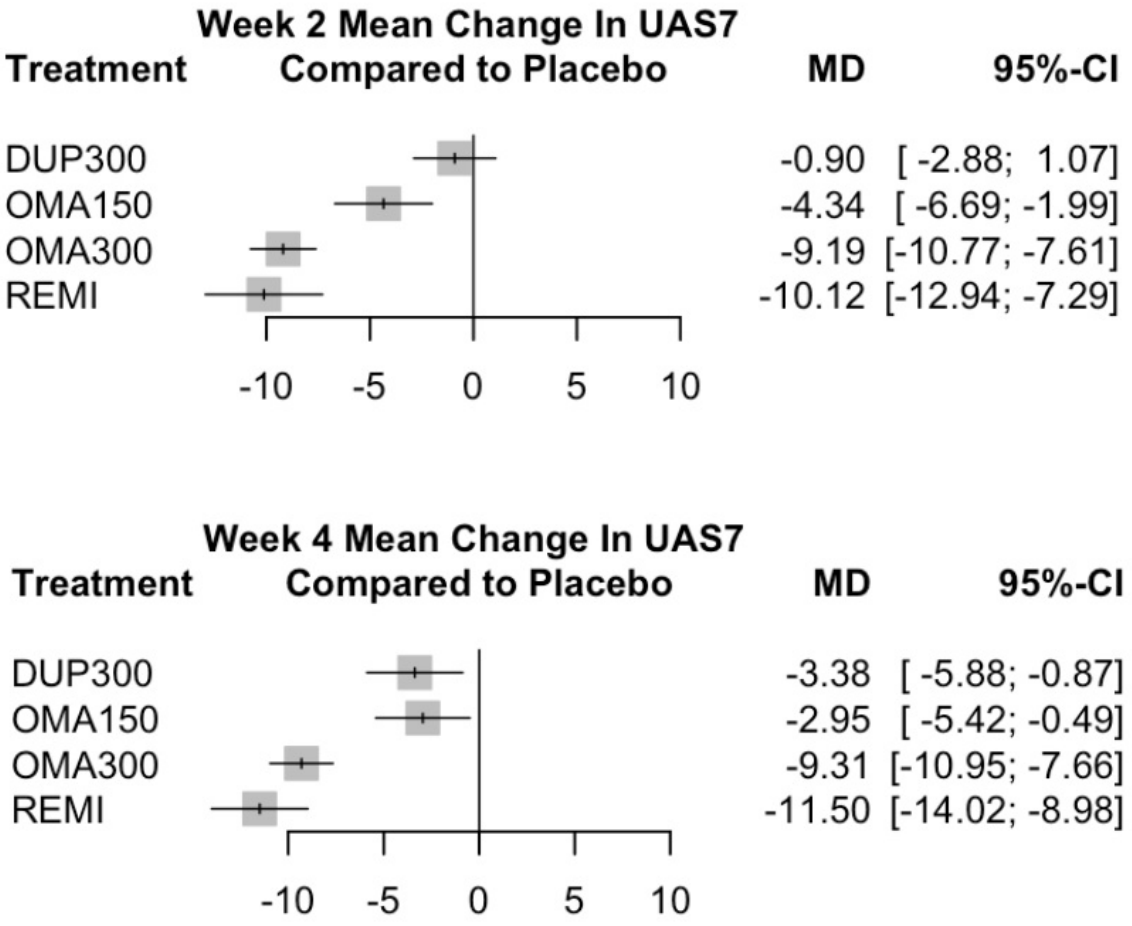

Figure 1. Forest plots depicting reduction in UAS7 compared to placebo at weeks 2 and 4 remibrutinib 25 mg twice daily. dupilumab 300 mg biweekly, omalizumab 300 mg and 150 mg every four weeks.

Conclusions

These results suggest that remibrutinib 25 mg BID may have the most rapid onset of action amongst common advanced therapies for CSU, with clinically meaningful reductions in UAS7 as early as week 2. This early symptom improvement may be associated with prior reports of remibrutinib's positive impact on quality-of-life outcomes. Omalizumab 300 mg Q4W similarly achieved near-clinically important mean reductions in UAS7 at weeks 2 and 4, supporting the agent's continued relevance as a mainstay of CSU therapy in this dosage. Although dupilumab 300 mg Q2W showed modest early-onset reductions in UAS7, effect sizes improved by week 4 and may be supportive of existing literature on dupilumab's delayed onset of action. The relative early-onset reductions in ISS7 and HSS7 observed in these agents followed a pattern similar to the reductions in UAS7, which is consistent with UAS7 being a composite measure of itch and wheal activity. Further research is needed to better characterize the impact of rapid symptom relief on patient-reported outcomes, patient experience, and treatment selection in CSU.

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Abstract N°: 1486

Long-Term Drug Survival of Omalizumab in Chronic Spontaneous Urticaria: A Systematic Review of Predictors of Discontinuation and Treatment Persistence

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Introduction

Chronic spontaneous urticaria (CSU) is a chronic, relapsing, immune-mediated condition that significantly impairs quality of life. Omalizumab, an anti-IgE monoclonal antibody, is the standard of care for patients refractory to antihistamines. However, variability in long-term treatment persistence and discontinuation patterns remains a key clinical challenge.

Materials and Methods

A systematic review was conducted using a structured search of MEDLINE (PubMed) and Web of science up to January 2025. Studies assessing omalizumab drug survival and discontinuation in CSU were included. Eligible designs comprised randomized controlled trials and observational cohort studies. Data extracted included treatment duration, discontinuation rates, reasons for discontinuation, and predictors of treatment persistence

Results

Twelve studies were included, encompassing randomized controlled trials and real-world cohorts. Omalizumab demonstrated variable drug survival, ranging from approximately 6 months to over 6 years. The most common reason for discontinuation was disease remission, followed by lack of efficacy and adverse events. Real-world studies showed greater variability in treatment persistence compared to clinical trials.

Several predictors of prolonged drug survival were identified. Early initiation of omalizumab and prior exposure to multiple therapies were associated with improved persistence, while delayed initiation was linked to shorter treatment duration. Autoimmune and atopic comorbidities were associated with reduced drug survival in some studies. Biomarkers, including baseline IgE levels, eosinophil counts, and anti-thyroid antibodies, were reported as potential predictors of response variability.

Discontinuation strategies influenced outcomes. Gradual tapering and interval extension were associated with longer remission and reduced relapse rates, whereas abrupt discontinuation was linked to earlier relapse. Retreatment after relapse was effective in most patients.

Conclusions

Omalizumab demonstrates sustained but variable drug survival in CSU, with remission, lack of efficacy, and adverse events as key drivers of discontinuation. Modifiable factors, particularly timing of initiation and discontinuation strategy, play an important role in long-term outcomes. These findings support a personalized approach to treatment, incorporating clinical characteristics and potential biomarkers to guide decision-making. Further prospective studies are needed to establish standardized discontinuation strategies and improve long-term disease control.

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Abstract N°: 1539

Predictors of Autoimmunity in Chronic Spontaneous Urticaria- A Single-centre Cross-sectional Analysis

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Introduction
Chronic spontaneous urticaria (CSU) is a common mast-cell mediated skin disorder. Autoimmune mechanisms play a key role in its pathogenesis.
Objective-To determine the frequency of autoimmune (AI) positivity in CSU and identify associated risk-factors.

Materials and Methods
We conducted an analytical cross-sectional study among CSU patients. Autoimmune positivity inferred a personal history of autoimmune disease and/or at least one positive autoantibody (anti-thyroid peroxidase [anti-TPO], antinuclear antibody [ANA], or rheumatoid factor [RF]). Patients were classified as type I (IgE normal/high, anti-TPO normal), type II (IgE low, anti-TPO high), or mixed/unclassified endotype. Clinical and laboratory parameters included UAS7, UCT, ASST, routine biochemistry, total IgE, and autoantibodies.

Results
Among 89 CSU patients (mean age 37.3 ± 12.3 years; 80% female), 24.7% exhibited autoimmune positivity—19.1% had at least one autoantibody (anti-TPO> RF) and 10.1% reported concomitant autoimmune disease, most commonly thyroiditis. Concomitant atopy was reported in 45% (allergic rhinitis> asthma). AI-positive patients were older (41.8±11.9 vs 35.8±12.2 years, p=0.04) and had higher disease activity (UAS7 24.6±12.9 vs 16.9±10.5, p=0.03). ASST positivity was more frequent in AI-positive cases (55.6% vs 50%, p=0.9). Type I endotype predominated overall (82%), whereas type II/mixed endotypes were commoner among AI-positive patients. Older age was an independent risk-factor for autoimmune positivity (OR 1.04, 95% CI 0.8–0.9).

Conclusions
Almost one in every four CSU patients exhibit autoimmune features. Older age, greater disease severity, and type II/mixed endotypes are strongly associated with autoimmune positivity, necessitating early screening for autoimmune comorbidities and tailored management.

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Abstract N°: 1548

Successful Treatment of Glucocorticoid-Dependent Refractory Chronic Spontaneous Urticaria with Remibrutinib: A Case Report

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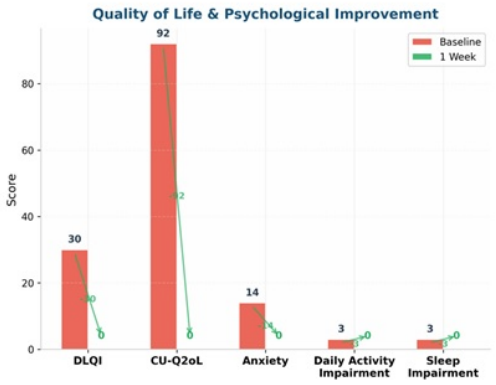
Introduction

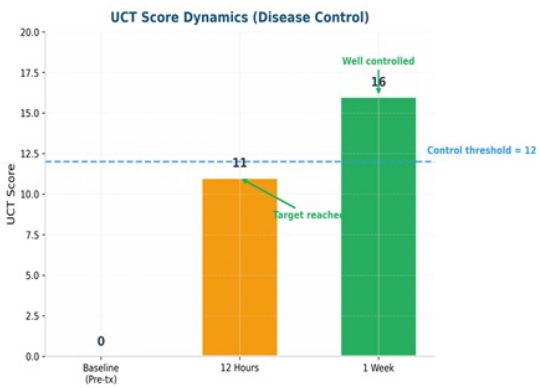
Chronic spontaneous urticaria is defined as the spontaneous occurrence of wheals, angioedema, or both for more than 6 weeks[1]. Although second-generation H1-antihistamines(sgH1AH) remain the first-line therapy, a subset of patients exhibits inadequate response even at up-dosed regimens[2], and a smaller proportion remains refractory to omalizumab[3], ultimately progressing to glucocorticoid dependence. Such glucocorticoid-dependent refractory CSU presents a considerable clinical challenge and represents a substantial unmet therapeutic need.

Case Presentation

A 21-year-old female presented with glucocorticoid-dependent refractory CSU following failure of fourfold sgH1AH (loratadine and ebastine) and omalizumab (300 mg every 4 weeks for 12 weeks). Six weeks prior to referral, due to frequent acute exacerbations, daily intramuscular dexamethasone (5 mg) was initiated for symptom control. Any delay in administration resulted in recurrence of diffuse wheals and pruritus within 24 hours, indicating profound glucocorticoid dependence. Daily intramuscular dexamethasone resulting in significant glucocorticoid-related adverse effects, including a 7.5 kg weight gain and anxiety. Laboratory investigations demonstrated an elevated total serum immunoglobulin E (IgE) level of 215 IU/mL(reference range: <165 IU/mL) and a positive autologous serum skin test (ASST) result.

Following initiation of remibrutinib (25 mg twice daily), rapid symptomatic improvement was observed within 12 hours, with near-complete resolution of wheals and pruritus by week 1. Complete glucocorticoid discontinuation was achieved by week 1. The Urticaria Control Test (UCT) score improved from 0 (uncontrolled) at baseline to 16 (completely controlled) at week 1; the Dermatology Life Quality Index (DLQI) and Hamilton Anxiety Scale (HAMA) scores declined from 30 and 14, respectively, to 0. No adverse events were reported. (**Figure**).





Conclusion

The ineffectiveness of omalizumab in this patient suggests that the underlying pathophysiological mechanisms

may not be predominantly mediated through the classic IgE-FcεRI axis. The mechanism of action of remibrutinib is thought to involve highly selective inhibition of BTK, a key signaling molecule positioned downstream of both FcεRI and BCR activation[4]. By inhibiting BTK, remibrutinib blocks mast cell degranulation and cytokine release, thereby suppressing the immediate effector response responsible for wheal formation and pruritus. In addition, BTK inhibition may modulate autoreactive B-cell function and autoantibody production through effects on BCR signaling, potentially addressing upstream autoimmune drivers of disease[5]. This dual mechanism—targeting both effector cell activation and autoreactive B-cell activity—may explain the therapeutic success observed in this patient, in whom both IgE-mediated and autoimmune mechanisms may be operative. Our findings are consistent with published data of remibrutinib[6] and extend them to an even more refractory population, specifically those with glucocorticoid-dependent disease and documented omalizumab failure.The rapid onset of action observed in this case—within 12 hours of the first dose—is particularly noteworthy. This is consistent with the pharmacodynamic characteristics of BTK inhibition, which acutely suppresses mediator release from activated mast cells and basophils[7].In conclusion, this case demonstrates that remibrutinib can achieve rapid and sustained disease control in glucocorticoid-dependent, omalizumab-refractory CSU, enabling successful glucocorticoid discontinuation and profound improvements in quality of life. These findings support the ongoing investigation of BTK inhibition as a therapeutic strategy for the most refractory forms of CSU.

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Abstract N°: 1658

Symptom Control in Chronic Urticaria with GLP-1 Agonist Therapy - Mechanism or Miracle?

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Introduction

Glucagon-like peptide 1 receptor (GLP-1) agonists are commonly utilised in the treatment of type 2 diabetes mellitus, and to support weight loss in obesity. Their beneficial effects in autoimmune and autoinflammatory conditions such as psoriasis and hidradenitis suppurativa are becoming increasingly more evident.

We present the cases of two patients with antihistamine-resistant cold urticaria who achieved complete symptom control following initiation of tirzapetide, suggesting a link between GLP-1 signalling and mast cell activation, and offering a potential novel therapeutic approach.

Case Presentation

A 30-year-old female presented to outpatient allergy clinic with a 12-month history of typical cold urticaria, which may have followed a viral infection several months earlier. Exposure to cold or cool winds, in addition to rain, and cold food and drinks triggered symptoms, with worsening during the winter. On occasions, exposure to cold winds as well as drinking cold drinks or eating ice cream induced tongue and throat swelling leading to breathing difficulty. There was no background atopy. Past medical history was significant for endometriosis and ADHD.

TempTest was positive with threshold 16-18 degrees Celsius. Bloods including cryoglobulins and fibrinogens were all negative. She was commenced on regular fexofenadine 360mg twice daily with cetirizine 10-20mg for breakthrough episodes, in addition to the provision of two adrenaline pens for severe episodes.

Despite maximum dose non-sedating antihistamines, she remained symptomatic and therefore was put forward as a candidate for a clinical trial evaluating the efficacy of an oral selective Bruton tyrosine kinase inhibitor, remibrutinib, in cold urticaria. At trial screening, ice cube test was positive. However, at baseline randomisation visit 3 weeks later, serial TempTests at three different sites were all negative, and ice cube test was only very weakly positive, but not itchy. This resulted in her no longer being eligible for the trial. Of note, she had commenced tirzepatide injections 6 weeks prior, with dose increase to 5mg weekly 2 weeks before the randomisation visit.

Interestingly, a couple of months later she reported relapse of her cold urticaria, which occurred within 4 days of a missed weekly dose of tirzepatide. When restarting tirzepatide, symptoms settled within 48 to 72 hours. On a subsequent planned trial of stopping tirzepatide for 18 days, there was reproducible return of symptoms within 2-3 days, with ice cube test positive and TempTest positive to a threshold of 16 degrees Celcius. Her most recent TempTest reading was weaker than the previous year, suggesting a possible modifying effect on cold urticaria, in addition to controlling symptoms.

To date her cold urticaria remains controlled on tirzepatide injections since restarting 10 months ago, with a significant effect on quality of life. She can now eat ice cream, drink cold drinks, hold cold objects and go into chilled ice spa rooms without symptoms.

Recently, another patient with cold urticaria +/- cholinergic urticaria for 8 years also reported a marked improvement in symptoms after starting tirzepatide, particularly when reaching 5mg weekly dosing.

Conclusion

In the literature, two cases of chronic spontaneous urticaria responding to semaglutide and tirzapetide respectively have been recently reported, similarly leading to exclusion from a clinical trial (1). Physicians should remain aware of the potential for GLP-1 agonists to have modifying effects on chronic urticaria.

Reference:

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Abstract N°: 1832

Defining Disease Burden and Unmet Needs among Patients with Chronic Spontaneous Urticaria in Belgium

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Introduction

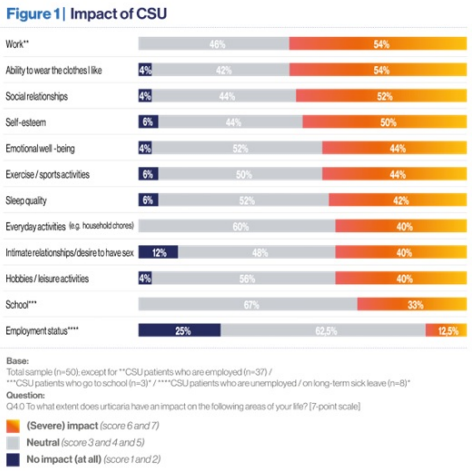
Chronic spontaneous urticaria (CSU) is a debilitating condition characterized by recurrent (> 6 weeks) wheals and/or angioedema without an identifiable external trigger.[1] Despite available therapies, previous studies indicate that many patients remain undertreated and that physicians show poor adherence to guideline recommendations, resulting in persistent symptoms and impaired quality of life.[2,3] This study aimed to characterize the perceived disease burden and unmet needs among patients with CSU in Belgium.

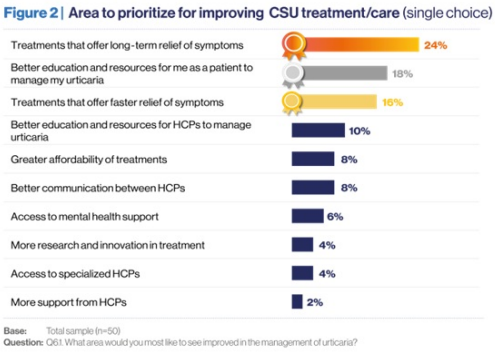
Materials and Methods

An online survey was conducted among patients with CSU treated with antihistamines (AHs). Patients with a confirmed diagnosis of CSU were recruited through a combination of physician referrals and screening within the general population. Data were collected using a standardized, quantitative questionnaire assessing symptomatology, impact on daily functioning, and treatment experiences. This research was conducted with the support of Ipsos.

Results

In total, 50 patients were surveyed (mean age 38.6 years; 48% male). Approximately half (46%) had a CSU diagnosis for 1–5 years and most (54%) were receiving a standard-dose AH regimen (1x/day). Two-thirds consulted more than one physician before diagnosis and in 40% the time from symptom onset to diagnosis exceeded one year. Healthcare resource use was high, particularly during flare-ups, with dermatologists most frequently consulted (average of 2.4 visits in 6 months). Eighty-two percent felt a constant threat of flare-ups and 74% reported that symptom unpredictability impaired daily life. Among employed patients, 54% reported a severe impact on their work, missing on average 4.8 workdays per month, while one-third experienced periods of long-term sick leave (Figure 1). Fifty-two percent indicated CSU severely impacted their social relationships and on average 4 days per month of social activities were cancelled due to CSU. Regarding mental well-being, patients experienced impaired ability to wear preferred clothing (54%), reduced self-esteem (50%), and reduced emotional well-being (44%) (Figure 1). Only half (50%) were satisfied with their current treatment strategy/management. When asked which area should be prioritized to improve, long-term relief, faster relief and better education and resources for the patients to manage their urticaria emerged as top priorities (Figure 2).





Conclusions

The study shows that Belgian patients with CSU experience a high disease burden and still have significant unmet needs despite current treatment options. Despite still experiencing a substantial disease burden most patients in this study were only treated with standard doses of AHs. This finding may suggest that patients are not treated according to international guidelines, which recommend dose and/or treatment escalation when inadequately controlled by standard doses of AHs.[1] Further research is needed to confirm this.

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Abstract N°: 1834

REASSERT: A global, prospective, non-interventional study evaluating the real-world effectiveness and safety of remibrutinib in adults with chronic spontaneous urticaria

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Introduction

Chronic spontaneous urticaria (CSU) is a mast-cell-driven condition characterized by recurrent itchy wheals (hives), angioedema, or both for more than six weeks. It disproportionately affects younger, working-age adults, indicating a potentially substantial and sustained health-economic burden. In addition to physical symptoms, CSU is associated with sleep interference, psychological comorbidities, and impaired health-related quality of life (HRQoL), which collectively contribute to reduced daily functioning, diminished work productivity, and increased healthcare resource utilization (HCRU). Despite guideline-recommended treatment with second-generation H1-antihistamines (sgH1-AHs), many patients remain inadequately controlled even after dose escalation, prolonging negative health-economic impacts. Remibrutinib, an oral Bruton's tyrosine kinase inhibitor, has demonstrated rapid and sustained symptom improvement in CSU. The REASSERT study aims to assess the short- (12-week) and long-term (24-month) real-world effectiveness and safety of remibrutinib and evaluate its impact on HRQoL, work productivity, and HCRU using patient-reported outcome measures in adults with CSU.

Materials and Methods

REASSERT (NCT07358364) is a recently initiated, 24-month, real-world, prospective, non-interventional study across eight countries: the United States, where enrolment is currently underway, followed by Germany, Italy, Spain, China, Japan, South Korea, and Canada (**Figure**). Globally, an estimated 3280 adults with inadequately-controlled CSU will be recruited from specialist/academic centres (30%) and office-based practices (70%) and allocated to one of three cohorts based on the treating physician's independent, pre-enrolment assessment: (1) participants escalating sgH1-AHs; (2) participants switching from sgH1-AHs to remibrutinib; or (3) participants switching from other CSU treatments to remibrutinib. The primary objective is to evaluate the real-world effectiveness of remibrutinib in adults who remain symptomatic despite prior treatments, including sgH1-AHs. Secondary objectives include characterizing real-world treatment patterns, concomitant CSU medications, and escalation patterns to remibrutinib from sgH1-AHs; assessing the real-world safety of remibrutinib and sgH1-AHs; describing HRQoL among treated participants; and evaluating work productivity (absenteeism, presenteeism, and overall work impairment) and activity impairment using the validated Work Productivity and Activity Impairment –

Chronic Urticaria instrument. HCRU measures, including the number of outpatient encounters, emergency and inpatient admissions, and duration of hospital stay, will be assessed at predefined intervals (**Figure**). Patient-reported outcomes will be gathered in real time via a secure, mobile application and supplemented with physician-reported clinical data. All assessments will be performed according to localised protocols.

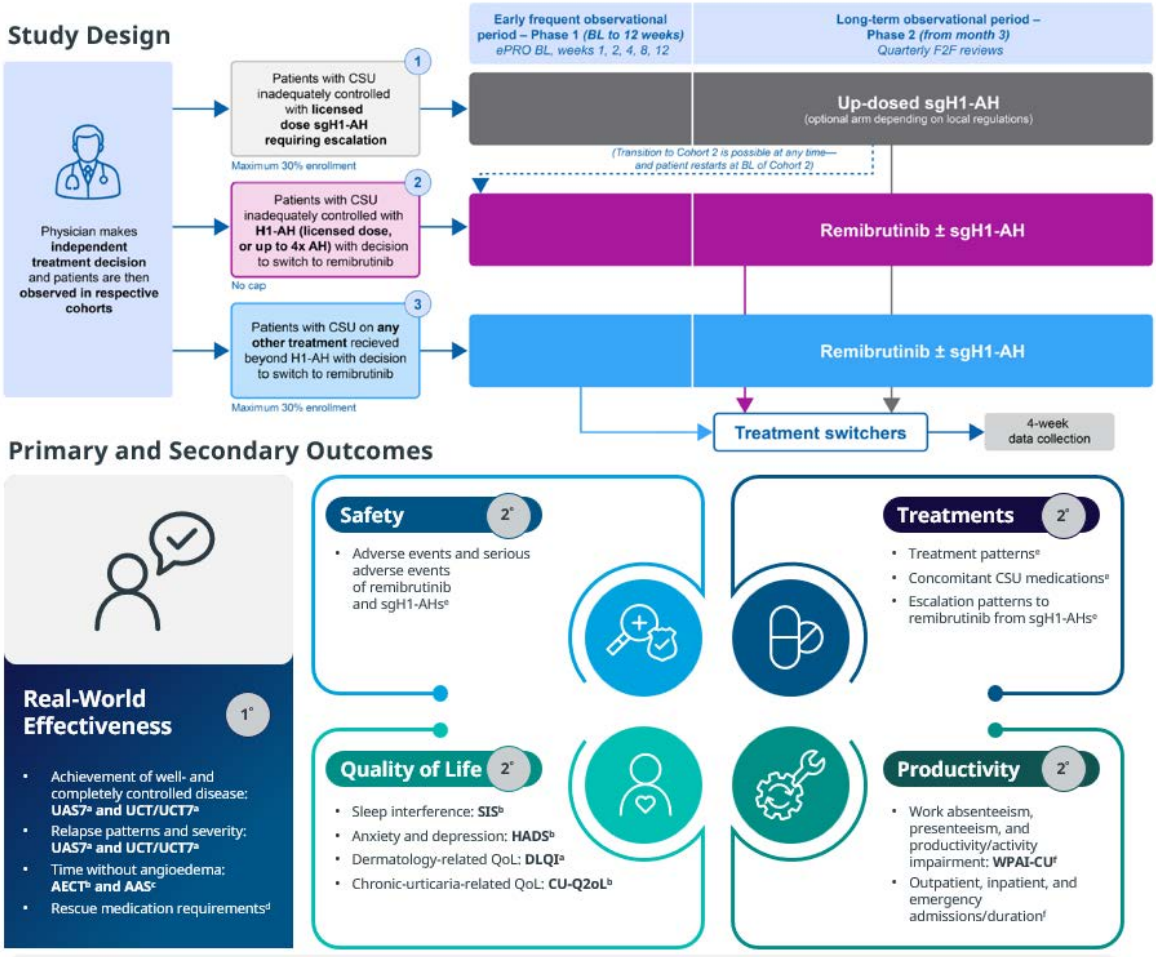
Results

This study will assess the real-world effectiveness, safety, and use of remibrutinib and provide insights regarding its impact on the HRQoL, work productivity, and HCRU of adults with CSU who remain uncontrolled on sgH1-AHs.

Conclusions

By capturing global longitudinal real-world data, REASSERT is expected to inform clinical decision making and support strategies aimed at controlling symptoms and improving HRQoL, ultimately reducing productivity impairment and HCRU of adults with CSU.

Figure: REASSERT study design with primary and secondary outcomes



[a]Baseline; Day 1; Weeks 1, 2, 4, 8, and 12; Months 6, 9, 12, 15, 18, and 21; Month 24. [b]Baseline; Weeks 1, 2, 4, 8, and 12; Months 6, 9, 12, 15, 18, and 21; Month 24. [c]Baseline; Weeks 1, 2, 4, 8, and 12; Months 6, 9, 12, 15, 18, and 21. [d]Weeks 1, 2, 4, 8, and 12. [e]Weeks 1, 2, 4, 8, and 12; Months 6, 9, 12, 15, 18, and 21; Month 24. [f]Week 12; Months 6, 9, 12, 15, 18, and 21; Month 24.

1°, primary outcome; **2°**, secondary outcome; **AAS**, Angioedema Activity Score; **AECT**, Angioedema Control Test; **BL**, baseline; **CSU**, chronic spontaneous urticaria; **CU-Q2oL**, Chronic Urticaria Quality of Life Questionnaire; **DLQI**, Dermatology Life Quality Index; **ePRO(s)**, electronic patient-reported outcome(s); **F2F**, face-to-face; **HADS**, Hospital Anxiety and Depression Scale; **H1-AH**, H1-antihistamine; **QoL**, quality of life; **sgH1-AH(s)**, second-generation H1 antihistamine(s); **SIS**, Sleep Interference Score; **UAS7**; Urticaria Activity Score over 7 days; **UCT(7)**, Urticaria Control Test (over 7 days)

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Abstract N°: 1865

Assessment of Quality of Life, Mental Wellbeing and Disease Activity in Patients with Chronic Urticaria: A Cross-Sectional, Observational Study

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Introduction
Chronic urticaria (CU) significantly affects patients quality of life (QoL) and mental well-being. This study aimed to assess QoL, and mental wellbeing in CU patients using the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) and the Hospital Anxiety and Depression Scale (HADS), and to evaluate disease activity using the Urticaria Activity Score (UAS-7). We correlated the QoL and mental well-being with disease activity.

Materials and Methods
This cross-sectional, observational study included 67 patients with CU attending the dermatology outpatient clinic of a tertiary care centre in South India, from September 2023 to May 2024. The CU-Q2oL, HADS, and UAS-7 were used to assess QoL, mental health, and disease activity, respectively. Statistical analyses included t-tests, Mann-Whitney U tests, Kruskal-Wallis tests, and Spearman's correlation.

Results
The mean CU-Q2oL score was 72.36 ± 20.64, with sleep disturbances and limitation of life activity being the most affected domains. Females had higher CU-Q2oL scores than males ($p = 0.014$). Age positively correlated with QoL scores ($p = 0.044$). Anxiety and depression were prevalent, with 29.9% and 22.4% of patients showing abnormal levels, respectively. Anxiety was significantly associated with disease activity ($p = 0.024$), though disease activity did not correlate with overall QoL.

Conclusions
CU significantly impacts QoL and mental well-being, particularly in females and older patients. Anxiety was more closely linked to disease activity, suggesting the need for psychological support alongside medical treatment. Further research on cultural and regional differences is needed for more targeted management strategies.

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Abstract N°: 1866

Chronic recurrent urticaria in patient with recurrent herpes labialis: complete remission after administration with Aciclovir and Antihistamines

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Introduction

The existing data in the world literature regarding herpes simplex virus infections and urticaria are limited. The presented information suggests both acute and chronic relapsing urticaria as possible related events within labial herpes simplex type 1 infection.
We present a 41-year-old female with primary complaints, dating for 2 months, of occasionally appearing and disappearing itching rashes over the whole body.

Laboratory tests were done prior to the hospitalization: test for H. Pylori Ag in feces - negative; test for intestinal protozoa and helminths - negative; testing for HbsAg/ Anti HCV antibodies came also negative; panoramic photo of teeth - no pathological changes; abdominal echography - liver slightly enlarged with a more hyperechoic structure, other organs - without complaints; chest x-ray - no complaints; IgM for toxoplasmosis - negative. The patient reported an occurrence of labial herpes in the last 3-4 years.

She was treated for generalized urticaria with beginning systemic involvement under the form of angioedema and bronchospasm with Prednisolone and Methylprednisolone (according to the scheme, with a temporary effect) and Montelucast 10 mg, Levocetirizine dihydrochloride 5 mg, Loratadine 10 mg, betamethasone/clotrimazole/gentamicin cream. The treatment resulted without significant effect. The last application of Methylprednisolone 100 mg was made in the emergency department due to angioedema and bronchospasm two days prior to the hospitalization.

Concomitant diseases: chronic herpes simplex type 1 infection; chronic chlamydial infection.

Case Presentation

The dermatological examination showed an urticarial rash, located in the area of the face (Fig.1a), right shoulder region (Fig.1b), right forearm (Fig.1c) and right abdomen (Fig.1d). A skin biopsy was taken from the right shoulder area (Fig.1d). The histological picture corresponded to urticaria.

During the hospitalization an elevation in IgG for herpes simplex type 1 IgG >58.40 (reference values up to 0.90-1.10) and IgG for Chlamydia trachomatis IgG > 2.25 (0.90-1.10) were observed. Additionally the patient reported slight but permanent vaginal discharge with an unpleasant odor and occurring discomfort during sexual intercourse.

Systemic therapy was started with Methylprednisolone 40 mg and Desloratadine 5 mg one, then two tablets, without improvement. Due to the positive herpes serology, it was decided to switch the systemic therapy to Aciclovir 400 mg three times a day in combination with an antihistamine - Desloratidine 5 mg. Already within the first two administrated tablets, we observed a complete reverse development of the urticaria and a significant reduction in the itching.


1a
1b



Fig.1a-d: Urticarial rash, located in the area of the face (Fig.1a), right shoulder region (Fig.1b), right forearm (Fig.1c) and right abdomen (Fig.1d). A skin biopsy was taken from the right shoulder area (Fig.1d).

Conclusion

The patient was discharged from the hospital with a change in a therapeutic regimen. Due to the chronic chlamydial infection, it was decided to discontinue systemic therapy with Aciclovir for 21 days and proceed with Doxycycline 100 mg twice a day. After finishing the regimen a prophylaxis for the chronic herpes simplex labialis, with Aciclovir 400 mg twice daily for a minimum of 6 months to 1 year, was recommended. Recurrence of the urticaria and massive pruritus were observed on the first day after discontinuing the Aciclovir therapy. The condition was successfully managed again with the administration of Aciclovir. A diagnosis of chronic recurrent urticaria in a patient with recurrent herpes labialis was made.

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Abstract N°: 2031

Relapse in chronic urticaria: identifying clinical and behavioral predictors in real-life practice

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Introduction
Chronic urticaria is a frequent inflammatory skin disease characterized by recurrent wheals with or without angioedema persisting for more than six weeks. Despite therapeutic advances, disease control remains suboptimal in a subset of patients, with frequent and unpredictable relapses. These recurrences contribute to a significant impairment in quality of life and increased healthcare utilization. Understanding the factors associated with relapse is essential to improve long-term disease management and to identify potentially modifiable risk factors in routine clinical practice.
This study aims to identify clinical, biological, and behavioral factors associated with relapse in patients with chronic urticaria and to evaluate their relative impact on disease recurrence.

Materials and Methods
We conducted a retrospective–prospective study including 60 patients diagnosed with chronic urticaria in a dermatology and allergology setting. Clinical data, disease duration, presence of angioedema, atopic history, exposure to suspected triggers, and treatment adherence were collected. Patients were classified into two groups according to the occurrence of at least one relapse during follow-up. Comparative analysis was performed, with a significance threshold set at $p < 0.05$.

Results
Among the 60 patients included, 38 (63%) experienced at least one relapse during follow-up, while 22 (37%) remained relapse-free. Disease duration showed a clear association with recurrence. Patients with a disease duration exceeding 12 months represented 71% of relapsing cases (27/38), suggesting that longer disease evolution is linked to a higher risk of instability and recurrence. Clinical severity markers were also associated with relapse. Angioedema was more frequent in the relapse group, observed in 31% of cases. Similarly, a personal history of atopy was reported in 50% of patients with recurrence, supporting a background of increased hypersensitivity in this subgroup.
Exposure to suspected triggering factors emerged as a major determinant of relapse. Among patients with persistent or repeated exposure to identified triggers (including food or drug-related factors), 80% (12/15) experienced recurrence. This highlights the strong impact of ongoing exposure on disease persistence.
Treatment adherence was the most strongly associated factor. Good adherence was associated with a lower relapse rate, observed in 32% (8/25) of patients. In contrast, relapse occurred in 86% (30/35) of patients with poor or irregular adherence. This difference was statistically significant ($p < 0.01$), indicating a strong relationship between adherence and disease control.
Overall, relapse was more frequent in patients with longer disease duration, atopic background, angioedema, persistent exposure to triggers, and especially poor treatment adherence, which appeared to be the most influential modifiable factor.

Conclusions

Relapse in chronic urticaria is a multifactorial phenomenon driven by both intrinsic disease characteristics and modifiable behavioral factors. Prolonged disease duration, angioedema, and atopic background are associated with increased relapse risk. However, persistent exposure to triggers and poor treatment adherence appear to be the strongest modifiable predictors of recurrence. These findings highlight the importance of patient education, strict adherence to therapy, and systematic identification of triggering factors to reduce relapse frequency and improve long-term outcomes.

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Abstract N°: 2043

The Value of Direct Immunofluorescence in Urticarial Vasculitis: Clinical and Pathological Correlations

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Introduction
Background: Direct immunofluorescence (DIF) is increasingly recognized for its role in subtyping urticarial vasculitis (UV). However, evidence regarding the association of DIF positivity with clinical, laboratory and histopathological features in real-world UV cohorts remains limited.
Objectives: To compare clinical features, laboratory parameters, histopathological findings and treatment response between DIF-positive and DIF-negative UV patients, and to evaluate the potential value of DIF for risk stratification.

Materials and Methods
A single-center retrospective study was conducted in 43 biopsy-proven UV patients. Based on skin DIF results, patients were divided into a DIF-positive group (n=22) and a DIF-negative group (n=21). Demographic data, cutaneous features, systemic symptoms, laboratory parameters, histopathological characteristics, treatment regimens, treatment response and recurrence were compared between the two groups.

Results
DIF-positive UV patients showed significantly higher frequencies of leukocytoclasis (54.5% vs. 19.0%, p=0.027) and endothelial swelling (50.0% vs. 14.3%, p=0.022) on histopathology. ANA positivity was significantly more common in the DIF-positive group (66.7% vs. 23.5%, p=0.031). Regarding urinary protein, 7 of 12 tested patients in the DIF-positive group were positive, whereas only 1 of 19 tested patients in the DIF-negative group was positive (p=0.042). No significant differences were observed between the two groups in hypocomplementemia, systemic symptoms, or the use of systemic glucocorticoids. The DIF-negative group showed a numerically wider range of recurrence episodes, but recurrence rates were similar between the two groups.

Conclusions
DIF-positive UV patients exhibit a stronger tendency for autoimmune abnormalities and more active acute-phase vascular injury on skin histopathology. However, DIF results do not predict treatment response or long-term recurrence risk.

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Remibrutinib for chronic spontaneous urticaria in "refractory" patients: a case from real-life clinical practice

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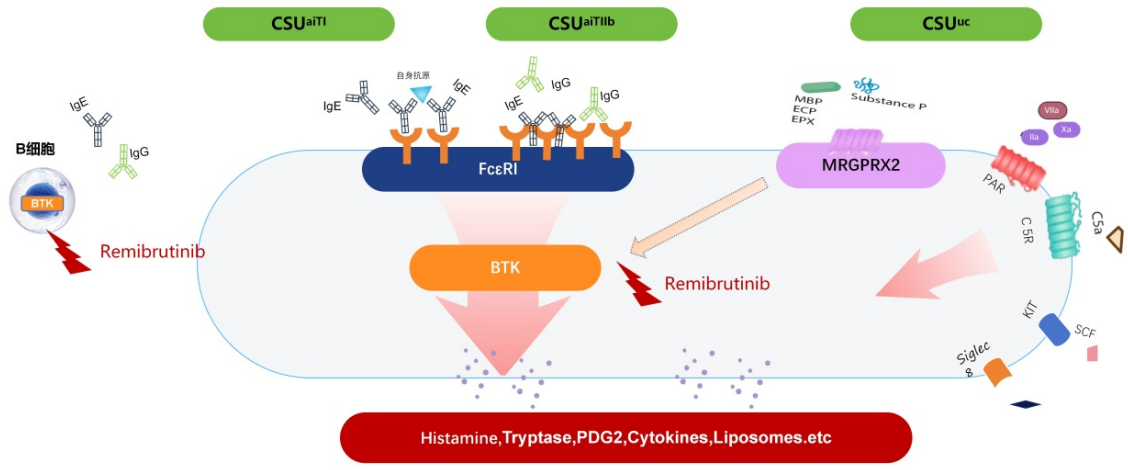
Introduction

Remibrutinib, as the world's first approved oral, small molecule, Bruton's tyrosine kinase inhibitor for adult patients with chronic spontaneous urticaria (CSU) inadequately controlled by H_1 antihistamines, entered clinical practice in March 2026.The safety and efficacy of remibrutinib in CSU patients has been established, but post-marketing data in real-life practice remains scarce. Here, we describe a patient with therapy-resistant CSU, who experienced symptom relief with the therapy of oral remibrutinib,providing practical references for its post-marketing clinical application.



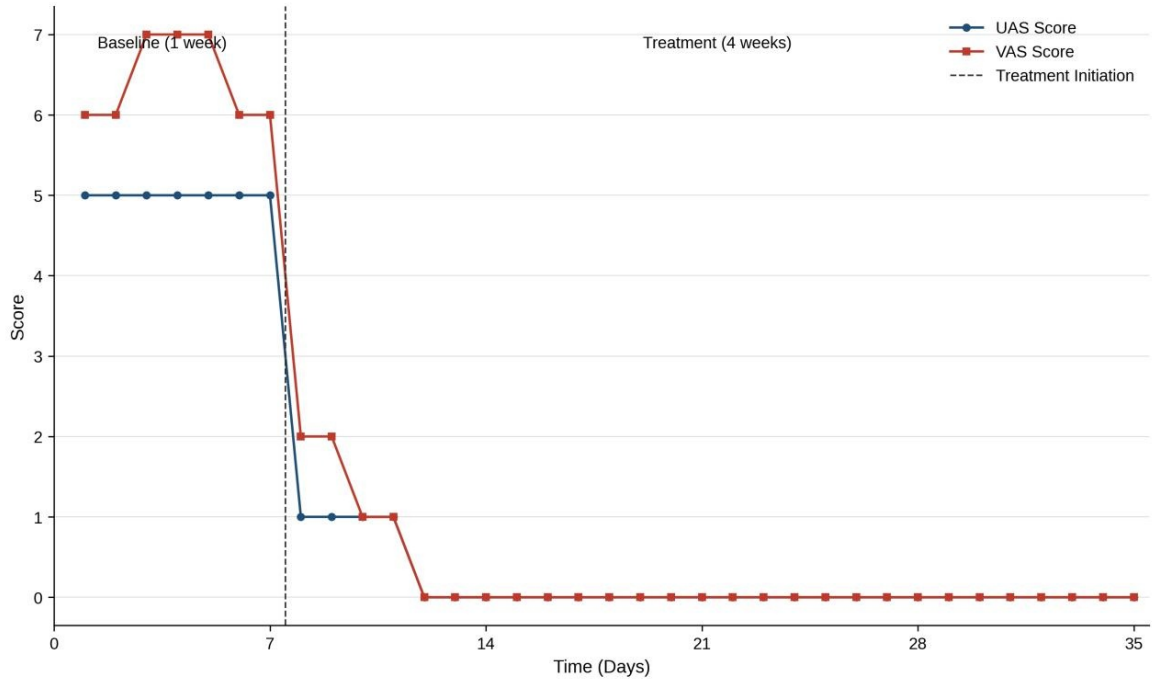
Mechanism of Action of Remibrutinib

Case Presentation

A 65-year-old male presented with recurrent generalized wheals , pruritus and episodes of angioedema for 4 months.He had previously received treatment with high-doses second-generation H1 -antihistamines and anti-infective agents , with poor therapeutic response.The patient had previously been hospitalized and treated with oral prednisone.Then the patient became symptom free for a few days,but relapsed after discharge. His medical history consisted of anxiety and hypertension. Physical examination revealed large areas of edematous erythema on the trunk, along with lip, scalp, and plantar angioedema.The 7-day Urticaria Activity Score (UAS7) was 35. Laboratory findings showed a total IgE level of 39.7 IU/mL. A definitive diagnosis of chronic spontaneous urticaria (moderate-to-severe, refractory) was made.

The patient was treated with remibrutinib 25 mg orally twice daily.At the next follow-up,swelling resolved within 2 hours after the first dose,and the patient reported no significant pruritus. The UAS score dropped to 0. The patient was symptom-free.4 weeks after the remibrutinib administration,no relapse occurred.Thus far, the patient has experienced a complete CSU regression.

No significant adverse events were observed during the 4-week treatment period. No other antihistamines or immunosuppressants were used concomitantly, and the patient's condition remained well controlled.



This line graph illustrates the daily fluctuations of Urticaria Activity Score (UAS) and Visual Analog Scale (VAS) scores across the entire 35-day study period, which consists of a 1-week pre-treatment baseline phase (Day 1 to Day 7) and a 4-week active treatment phase (Day 8 to Day 35).

Conclusion

Residual persistent pruritus is the most common treatment difficulty in CSU patients receiving optimized antihistamine therapy, which severely impairs patients' quality of life and cannot be resolved by H1-receptor blockade alone. Remibrutinib targets the upstream BTK-mediated mast cell activation pathway, fundamentally inhibiting inflammatory mediator release.This case verified that remibrutinib demonstrates rapid onset of action, definite efficacy, and a favorable safety profile in patients with refractory CSU who have an inadequate response to H_1 antihistamines. It provides a new and effective treatment option for refractory CSU in clinical practice. Further post-marketing cases are needed to accumulate more evidence and validate its long-term efficacy and safety.

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Predicting Response to Omalizumab in Chronic Spontaneous Urticaria: Initial Findings from the Global Multicenter UCARE SCOPUS Project

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Introduction
The therapeutic response to omalizumab in patients with chronic spontaneous urticaria (CSU) has been suggested to be predicted by a number of biomarkers, such as total IgE and IgG-anti-TPO. Nevertheless, a clear and therapeutically useful grading system incorporating these markers has not yet been developed. By first evaluating the diagnostic efficacy of well-established biomarkers and then creating a prediction model of treatment response, the SCOPUS project seeks to close this gap by converting this model into a useful and approachable

clinical scoring system.

Materials and Methods

SCOPUS is an ambispective study that includes CSU patients treated with omalizumab from multiple Urticaria Centers of Reference and Excellence (UCARE) worldwide. Demographic, clinical, laboratory and treatment-related parameters were recorded. Laboratory parameters assessed at baseline included eosinophil and basophil counts (eosinopenia and basopenia defined as absolute numbers equal 0), C-reactive protein (CRP), total IgE (low levels defined as <40 kU/L), total IgA, D-dimer, antinuclear antibody (ANA) and IgG-anti-TPO levels, basophil histamine release assay (BHRA), basophil activation test (BAT) and autologous serum skin test (ASST). All patients received the first dose of omalizumab at baseline and treatment response was evaluated repeatedly at 1, 3, 6 and 12 months using validated outcome measures including the Urticaria Control Test (UCT). CSU was defined as well controlled (UCT≥12) or poorly controlled (UCT<12). Variables were compared using chi-square or Fisher's exact tests. A two-sided p-value < 0.05 was considered statistically significant.

Results

In total, 1737 adult CSU patients across 39 UCARE centers in 24 countries have been included (female: 71.1%, mean age: 45.0 years, mean disease duration: 5.7 years, median UCT at baseline: 4.0). At baseline, eosinopenia, basopenia, elevated CRP, increased IgG-anti-TPO, positive ASST and positive basophil tests (BAT+BHRA) were seen in 14.4% (213/1467), 14.7% (210/1424), 34.2% (464/1355), 18.1% (216/1195), 45.5% (170/374) and 19.6% (29/148) of patients, respectively. At 3 months of treatment, patients with poorly controlled disease as compared to those with well controlled CSU, had significantly more frequently eosinopenia (16.6%, n=44/265 vs. 11.7%, n=87/742, p=0.043), low total IgE (37.6%, n=100/266 vs. 16.6%, n=122/737, p<0.001), elevated IgG-anti-TPO (23.9%, n=53/222 vs. 16.7%, n=106/635, p=0.018), positive BAT (48.0%, n=12/25 vs. 22.2%, n=6/27, p=0.051) and positive ASST (56.3%, n=54/96 vs. 42.3%, n=105/248, p=0.020) measured at baseline. At 3 months of treatment, patients with well controlled disease had higher rates of increased total IgE at baseline as compared to those with UCT<12 (57.9%, n=427/737 vs. 40.2%, n=107/266, p<0.001). Among all markers, only baseline total IgE levels and positive ASST results demonstrated consistent trends across the same comparisons at both 6- and 12-month follow-ups during omalizumab treatment (p<0.05).

Conclusions

CSU patients who achieve well-controlled versus poorly controlled disease during omalizumab treatment show distinct baseline biomarker profiles. Further analyses of the SCOPUS dataset will explore these differences in greater detail, with the goal of developing a clinically applicable grading system to predict treatment response.

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Dual-Phase Complement Dynamics in Chronic Spontaneous Urticaria: Correlation of Serum C3 and C4 Levels with Disease Severity

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Introduction
Chronic spontaneous urticaria (CSU) is a distressing mast cell-mediated disorder characterized by recurrent wheals and/or angioedema persisting for more than six weeks, with substantial impairment in quality of life. Increasing evidence suggests that CSU is not merely a cutaneous disease but a state of systemic inflammation involving innate immune pathways, including complement activation. While downstream complement mediators such as C3a and C5a have been implicated in CSU pathogenesis, the clinical significance of their precursor proteins C3 and C4 remains insufficiently explored. We aimed to evaluate serum complement levels in CSU and assess their relationship with disease activity.

Materials and Methods
A cross-sectional observational study was conducted over 18 months at a tertiary care centre in India. Sixty-two adults with clinically diagnosed CSU were enrolled after excluding conditions known to alter complement levels. Disease severity was assessed using the once-daily Urticaria Activity Score (UAS, range 0-6), and patients were categorized as mild, moderate, or severe. Serum C3 and C4 levels were quantified using enzyme-linked immunosorbent assay. Correlations between complement levels and disease severity were analysed statistically.

Results
The mean age of participants was 38.6 ± 13.8 years, with near-equal sex distribution. Most patients had moderate (48.4%) or severe (27.4%) disease. Median serum C3 levels were elevated (2.21 g/L), whereas median C4 levels were reduced (0.14 g/L) compared with standard reference ranges. No statistically significant differences in C3 or C4 were observed across categorical severity groups. However, continuous score analysis demonstrated weak but significant inverse correlations between UAS and both C3 ($r = -0.27$, $p = 0.037$) and C4 ($r = -0.28$, $p = 0.027$), indicating lower complement levels with increasing clinical activity. Longer disease duration and positive dermographism were also associated with greater severity.

Conclusions
These findings support a dynamic and stage-dependent role of complement dysregulation in CSU pathogenesis. Elevated C3 levels may reflect acute-phase hepatic upregulation driven by pro-inflammatory cytokines such as IL-6, consistent with the systemic inflammatory milieu increasingly recognized in CSU. Concurrently, reduced C4 levels suggest preferential activation of the classical complement pathway, potentially triggered by autoantibodies directed against IgE or FcεRI, mechanisms implicated in autoimmune endotypes of CSU. The inverse correlation between complement levels and symptom burden may represent progressive complement consumption during ongoing disease activity, with generation of anaphylatoxins such as C3a and C5a that further amplify mast cell

degranulation, vascular permeability, and wheal formation. Together, these findings suggest a biphasic model of early inflammatory complement upregulation followed by consumption in more active disease. Although C3 and C4 may not function as standalone severity markers, they hold promise as accessible adjunct biomarkers and merit further evaluation in longitudinal studies exploring prognosis, endotyping, and therapeutic response.

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Chronic Inducible Urticaria: A Five-Year Review of Real-world Practice

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Introduction

Chronic inducible urticaria (CIndU) encompasses disorders whereby urticarial wheals are induced by an environmental factor. Triggers include heat, cold, pressure, exercise, water, and ultraviolet light. CIndU results in significant morbidity and impaired quality of life for patients, both objectively and subjectively. Management can be challenging, and licenced treatment options are limited. Herein, we present a data set from patients with CIndU attending a tertiary dermatology clinic in the United Kingdom. We aimed to review patient demographics, CIndU subtype and management strategies.

Materials and Methods

This was a retrospective review of all adult patients with CIndU attending a dedicated Urticaria clinic in Scotland, UK over a 5-year period. Caldicott approval was sought and obtained. Data was collected using electronic records, recorded, and analysed using Microsoft excel.

Results

A total of 59 patients with CIndU were included, with a female predominance (45f:14m). Ages ranged from 17-77, with a median of 41 years. CIndU subtype was recorded, with pressure being the most common trigger (n=13), followed by cholinergic and cold CIndU (n=12 for each group), whilst 7 patients had multiple triggers for their CIndU. Chronic spontaneous urticaria co-existed in most patients in this cohort (n=36).

Management strategies were wide ranging, from standard avoidance of triggers and antihistamines through to systemic therapies (Table 1). High-dose antihistamines were used in all, with H2 blockade (Famotidine) and Montelukast utilised in the majority (n=34 and 46 respectively). Only 2 patients achieved good control with these measures. Good control was defined as the patient being documented to have well controlled disease, clear, or demonstrating good response to treatment. UAS7 scores pre- and during treatment were utilised when available. UAS7 was not recorded at baseline in 4 patients, whilst a further 2 patients had no UAS7 recorded on review whilst on treatment (n=6).

The most widely utilised, and effective, systemic therapy was Omalizumab. Used in 54 patients, it achieved good control of symptoms in the majority (n=45). UAS7 score average was 26 pre-treatment and 8 with treatment, DLQI also improved with a pre-treatment score average of 14, reducing to 6 with treatment. UVB phototherapy was trialled in 14 patients but only achieved good control of symptoms in 3 patients.

Treatment modalities (n=59, patients received multiple treatment modalities)	
Standard treatment	
Non-sedating antihistamines	59
Sodium cromoglycate	1
H2 receptor antagonists	34
Montelukast	46
Sedating antihistamines	2
Phototherapy	
Narrowband UVB	14
Systemic therapies	
Omalizumab	55
Prednisolone (short rescue courses)	8
Ciclosporin	6
Methotrexate	4
Hydroxychloroquine	2
Azathioprine	2
Dapsone	3
Mycophenolate mofetil	1
IV immunoglobulin	1
Dupilumab	1
Colchicine	1
Benralizumab (commenced for asthma)	1

Table 1: Treatment modalities used

Conclusions

Conclusions

Our cohort demonstrated pressure induced urticaria being the most common subtype of CIndU. Standard therapy with avoidance of triggers, antihistamines, Famotidine and Montelukast was generally not effective. The most efficacious systemic therapy was Omalizumab. This is in keeping with the literature, yet within the UK this remains an unlicenced treatment for CIndU. Further real-world, registry-based data is needed to inform the stepwise approach to management of CIndU.

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Abstract N°: 2282

Is it possible to use complete blood collection based systemic inflammatory indices as potential biomarkers for chronic spontaneous urticaria

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Introduction

Chronic spontaneous urticaria (CSU) is mediated not only by mast cells but also by eosinophils and basophils.

Materials and Methods

We evaluated whether complete blood collection based systemic inflammatory indices- including the systemic immune- inflammation index (SII), systemic inflammation response index (SIRI), aggregate Index of Systemic Inflammation (AISI), systemic inflammation modulation index (SIMI), neutrophil-to-lymphocyte ratio (NLR), eosinophil-to-lymphocyte ratio (ELR), platelet-to-lymphocyte ratio (PLR), basophil-to-lymphocyte ratio (BLR)- and platelet parameters (mean platelet volume [MPV], platelet distribution width [PDW], platelet large cell ratio [PLCR]) reflect CSU severity or treatment response.

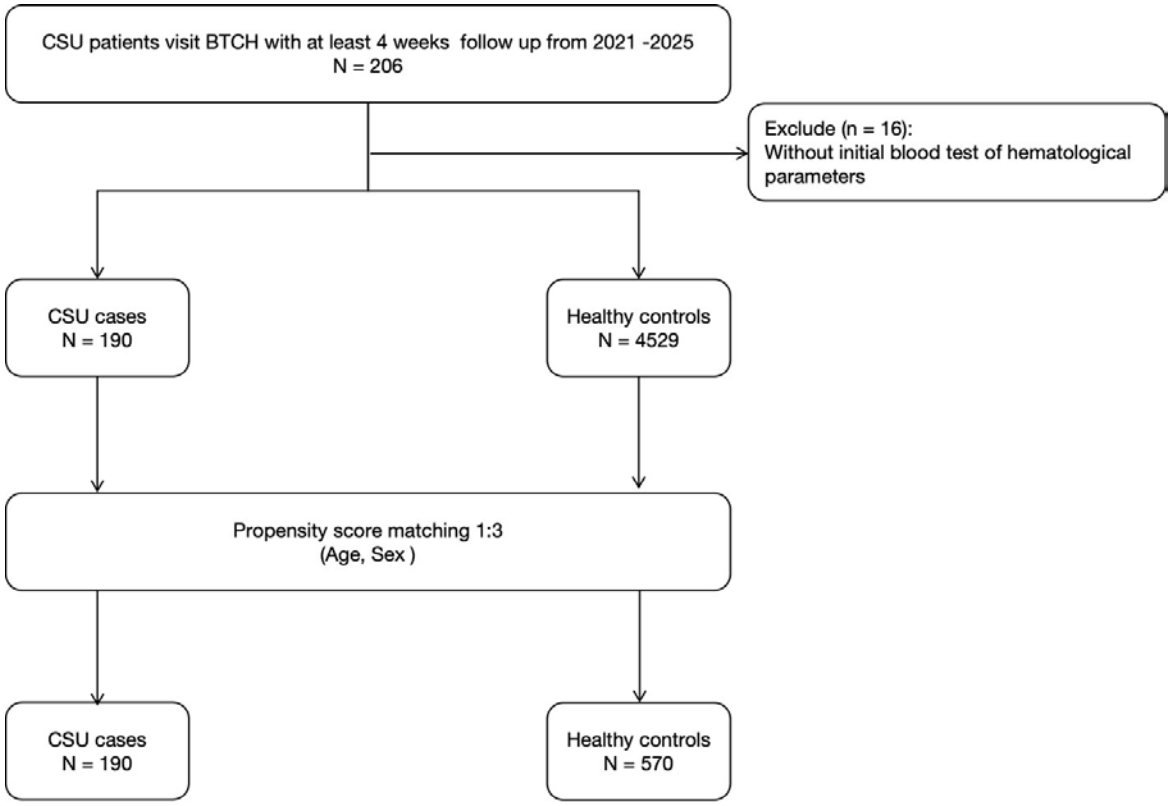

FIGURE 1 Flow diagram of patient inclusion, exclusion, and matching process.

Results

A retrospective study of 190 CSU patients and 570 matched controls was performed, with sensitivity analyses using propensity-score matching (PSM) and inverse-probability-of-treatment weighting (IPTW). Subgroup

analyses examined UAS7, antihistamine response and allergy history. As a result, CSU patients exhibited lower SII/SIRI, white blood cells (WBC), neutrophils, lymphocytes, and NLR, alongside higher MPV/PLCR and reduced PDW. NLR showed a weak correlation with UAS7, and systemic indices did not reliably differentiate standard-dosed and updosed antihistamine response. Patients with allergy history demonstrated lower eosinophils and ELR.

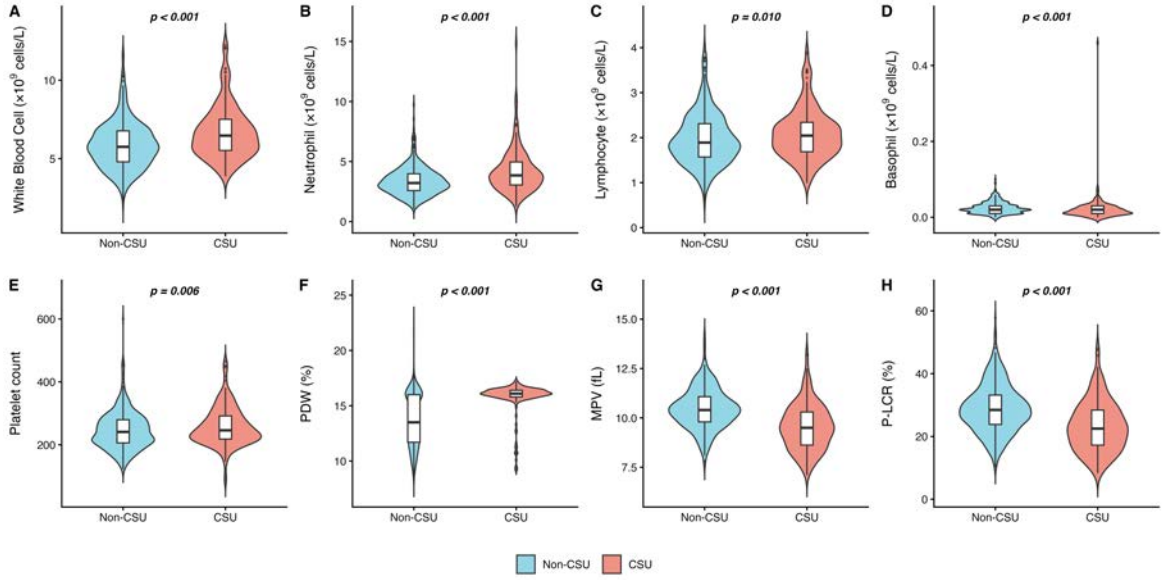

FIGURE 2 Eight violin plots comparing blood parameters between Non-CSU and CSU groups, showing statistically significant differences in white blood cell, neutrophil, lymphocyte, basophil counts, platelet count, PDW, MPV, and P-LCR, with Non-CSU in blue and CSU in red. Each is labeled A-H with corresponding p-values indicated above the plots. A color key below indicates group colors and labels. (A): Comparison of white blood cell count between Non-CSU and CSU groups. (B): Distribution of neutrophil count in Non-CSU versus CSU patients. (C): Differential analysis of lymphocyte count across study groups. (D): Significant elevation of basophil count in the CSU cohort. (E): Comparative assessment of platelet count between groups. (F): Distribution of platelet distribution width (PDW) in CSU and controls. (G): Reduction of mean platelet volume (MPV) in CSU patients. (H): Comparison of platelet-large cell ratio (P-LCR) between study populations.

Conclusions

CSU is characterized by reduced systemic inflammatory indices and enhanced platelet activation. Among these, NLR may serve as a cost-effective supplementary tool for assessing systemic inflammation trends of CSU.

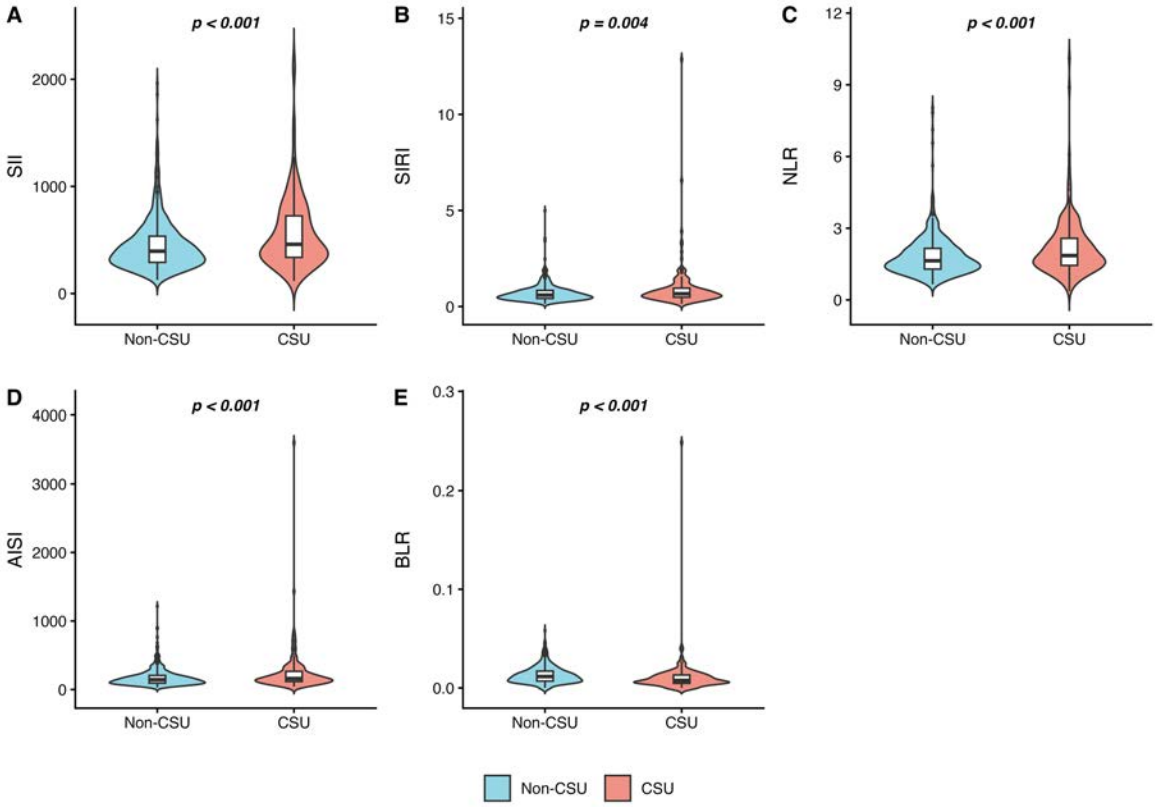

FIGURE 3 Violin plots compare five blood inflammation indices (SII, SIRI, NLR, BLR, AISI) between non-CSU (blue) and CSU (red) groups, with CSU values generally higher. P-values indicate statistically significant differences in all s. (A): Comparison of Systemic Immune-Inflammation Index (SII) between Non-CSU and CSU groups. (B): Distribution of Systemic Inflammation Response Index (SIRI) in Non-CSU versus CSU patients. (C): Analysis of Neutrophil-to-Lymphocyte Ratio (NLR) across study cohorts. (D): Comparison of Aggregate Index of Systemic Inflammation (AISI) between study groups. (E): Significant differences in Basophil-to-Lymphocyte Ratio (BLR) between Non-CSU and CSU populations.

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Abstract N°: 2321

Rethinking biomarkers in chronic spontaneous urticaria: D-dimer surpasses IgE and eosinophils

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Introduction

Chronic spontaneous urticaria (CSU) is a complex inflammatory disorder characterized by mast cell activation and mediator release, resulting in wheal formation and pruritus. Beyond classical IgE-mediated mechanisms, emerging evidence highlights a dynamic interplay between inflammation and coagulation in disease pathogenesis. Mast cell-derived mediators recruit and activate eosinophils, which express tissue factor and initiate the extrinsic coagulation cascade. This leads to thrombin generation, further enhancing vascular permeability and perpetuating mast cell activation, thereby sustaining the inflammatory cycle. Subsequent fibrinolysis results in the formation of D-dimer, a measurable end-product reflecting activation of the coagulation-fibrinolysis pathway. Despite these mechanistic insights, clinically applicable biomarkers that reliably reflect disease severity and guide therapeutic stratification remain limited.

Materials and Methods

Objective: To investigate the relationship of serum total IgE, absolute eosinophil count (AEC), and plasma D-dimer levels with disease severity, as measured by Urticaria Activity Score (UAS7), and antihistamine responsiveness in patients with CSU.
Methods: This cross-sectional study included 50 patients diagnosed with CSU. Disease activity was quantified using UAS7. Baseline measurements of serum IgE, AEC, and plasma D-dimer were obtained. To mitigate treatment-related confounding, individuals who had received systemic corticosteroids or immunomodulatory therapy within the preceding four weeks were excluded. Patients were stratified into antihistamine responders and non-responders based on symptom control despite administration of at least twice the standard dose of second-generation H1 antihistamines. Associations between biomarkers and disease severity were evaluated using Spearman’s correlation. Receiver operating characteristic (ROC) analysis was employed to determine discriminatory thresholds for severe CSU (UAS7 ≥16), and multivariable logistic regression was performed to identify independent predictors.

Results

Elevated serum IgE (>100 IU/mL) was observed in 90% of patients and showed a moderate positive correlation with UAS7 ($r = 0.368$, $p = 0.009$). AEC was elevated in 18% and did not demonstrate a significant association with disease severity. Plasma D-dimer demonstrated a strong positive correlation with UAS7 ($r = 0.723$, $p < 0.00001$). ROC analysis demonstrated good discriminatory ability of D-dimer in identifying severe CSU (UAS7 ≥16), with an area under the curve (AUC) of 0.81 and an optimal cut-off of approximately 177 ng/mL. Logistic regression analysis identified D-dimer as a significant independent predictor of severe CSU ($\beta = 0.0248$, OR = 1.025, $p = 0.012$), indicating that increasing D-dimer levels are associated with higher odds of severe disease. A substantial proportion of patients (64%) reported persistent symptoms despite antihistamine therapy. Given the strong association between D-dimer and disease severity, elevated D-dimer levels were more frequently observed in patients with higher disease activity, suggesting a potential link with treatment refractoriness.

Conclusions

Plasma D-dimer demonstrates a robust association with disease severity in CSU and provides clinically meaningful predictive value, outperforming conventional biomarkers such as IgE and AEC. These findings reinforce the role of coagulation pathway activation in CSU pathophysiology and highlight D-dimer as a practical, accessible biomarker for disease stratification. Its incorporation into routine evaluation may facilitate early identification of patients with severe or potentially antihistamine-refractory disease, supporting timely escalation to advanced therapies. Further prospective studies are warranted to validate these findings and define their role in guiding management.

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Abstract N°: 2380

Treatment choice and cardiovascular risk in chronic spontaneous urticaria

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Introduction

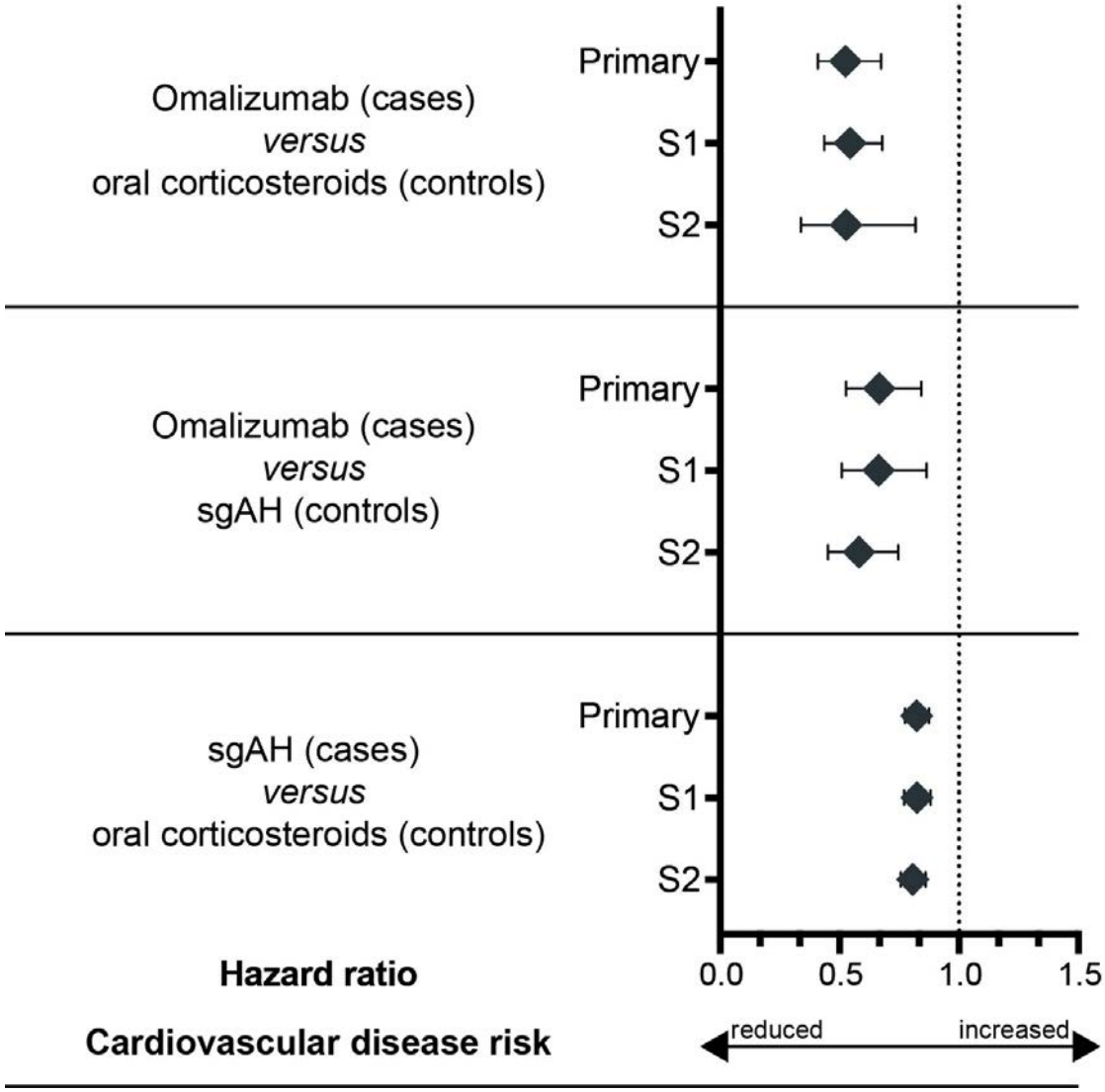
Chronic spontaneous urticaria (CSU) is increasingly recognized as a systemic inflammatory disease with elevated cardiovascular disease (CVD) risk. Whether the choice of CSU treatment influences subsequent CVD risk has not been previously addressed. Given the central role of inflammation in both CSU pathobiology and CVD, effective disease control could plausibly mitigate CVD risk.

Materials and Methods

Using the US Collaborative Network of TriNetX, we performed a retrospective matched cohort study comparing adult CSU patients treated with second-generation antihistamines (sgAH), omalizumab (OMA), or oral corticosteroids (oCS). Three pairwise propensity-score-matched analyses were conducted (OMA vs sgAH, OMA vs oCS, sgAH vs oCS). The primary outcome was any CVD; secondary outcomes included MACE, venous thromboembolism, and other CVD subtypes. Three predefined analyses were performed: a primary analysis (1 day–3 years), a sensitivity analysis excluding the first 3 months (S1), and one requiring mandatory follow-up between 1–3 years post-index (S2).

Results

After matching, baseline characteristics were well-balanced across cohorts (~3,300 for OMA comparisons; ~31,000 for sgAH vs oCS). OMA was consistently associated with lower any-CVD risk than oCS (e.g., primary: 3.55% vs 8.06%; adjusted hazard ratios 0.51–0.54; all $p<0.001$) and lower risk than sgAH across all predefined time windows. sgAH demonstrated modestly lower CVD risk than oCS. Secondary outcomes followed a similar hierarchy (OMA<sgAH<oCS), particularly for MACE and VTE, although several comparisons did not reach statistical significance.



Risk of any cardiovascular disease in patients with chronic spontaneous urticaria (CSU) treated with omalizumab, second-generation antihistamines, and oral corticosteroids: primary and sensitivity analyses. Adjusted hazard ratios (aHRs) and 95% confidence intervals for the primary analysis (1 day to 3 years after index), S1: 3 months to 3 years, and S2: mandatory follow-up between 1–3 years after index. $p<0.05$ for all depicted comparisons. Abbreviations: sgAH, second generation antihistamines

Conclusions

In a large real-world CSU cohort, CVD risk differed by treatment choice, with OMA consistently associated with the lowest risk. These findings support routine CVD risk assessment in CSU management and suggest that effective disease control may have systemic benefits beyond symptom relief. Whether the observed risk reduction reflects drug-specific effects or improved inflammatory control more broadly warrants further prospective investigation.

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Abstract N°: 2474

Angioedema and Urticaria Vasculitis as presentation of chronic lymphocytic leukemia: A Case Report and Red Flag

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Introduction

Chronic Lymphocytic Leukemia (CLL) is a chronic lymphoproliferative disorder characterized by monoclonal B cell proliferation. The primary disease sites include peripheral blood, spleen, lymph nodes, and bone marrow but different manifestations depending on where the abnormal cells are found. Skin is the most commonly affected non-lymphoid tissue, mainly involves the face and manifests as papules, macules, plaques, ulcers, blisters, or nodules. Nonspecific secondary cutaneous lesions may occur due to bleeding, vasculitis, and infection. We report a CLL case diagnosed after urticarial vasculitis manifestation.

Case Presentation

A 72-year-old man presented with recurrent urticarial lesions lasting longer than 24 hours, associated with purpura and episodes of angioedema on face. Symptoms started after a flu-like illness treated with penicillin and persisted despite initial management in Emergence department. He also reported a prior episode of angioedema one year earlier.

On examination, there were erythematous urticarial-like lesions with purpuric areas on the lower limbs, along with bilateral inguinal lymphadenopathy. Skin biopsy showed features suggestive of urticarial vasculitis, including perivascular inflammatory infiltrate with erythrodiapedesis and eosinophils. The patient presented normal serum complement levels, including C3, C4, CH50 and C1q.

Laboratory tests revealed leukocytosis (36,080 cells/mm^3) with marked lymphocytosis and the presence of Gumprecht shadows. Immunophenotyping study confirmed the diagnosis of CLL.

The patient was evaluated by Hematology Department, and given the stable disease, a watch-and-wait approach was adopted. From the dermatologic standpoint, he was treated with antihistamines, hydroxychloroquine, colchicine, and corticosteroids, with partial control. Azathioprine was later introduced, but the patient developed recurrent angioedema and persistent skin activity.

Conclusion

This case illustrates urticarial vasculitis as a possible presenting feature of CLL in elderly patients. Chronic spontaneous urticarial is not rare in elderly patients, however, urticarial vasculitis may to conduct clinical suspicion of malignant conditions. Persistent urticarial lesions, especially when associated with purpura, angioedema, or lymphadenopathy, should raise suspicion for an underlying systemic condition. Recognizing these patterns can help avoid delays in diagnosis and supports a more integrated approach between dermatology and hematology in complex cases.

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Abstract N°: 2488

Subcutaneous Injection of CGF at Tianshu (ST25) Point for Two Cases of Omalizumab-Refractory Urticaria

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Introduction

Chronic Spontaneous Urticaria (CSU) remains a therapeutic challenge, with approximately 30–40% of patients failing to achieve control with Omalizumab. These refractory cases often involve Type IIb autoimmunity or non-IgE-mediated pathways. Concentrated Growth Factors (CGF) represent a potent autologous source of TGF-β and other immunomodulatory proteins capable of stabilizing mast cells and inducing T-regulatory (Treg) cell differentiation. Furthermore, the "gut-skin axis" theory suggests that intestinal permeability and systemic inflammation contribute to the pathogenesis of CSU. By utilizing the Tianshu point (ST25)—the Front-Mu point of the Large Intestine—as an injection site, we proposed a synergistic intervention: bilateral subcutaneous injection of autologous CGF at the ST25 acupoint for CSU poorly controlled by Omalizumab to modulate the neuro-immune-endocrine network and restore immune homeostasis.

Materials and Methods

We retrospectively analyzed two CSU patients who remained symptomatic despite standard Omalizumab therapy. Patients received CGF injections at bilateral ST25 points once every two weeks for three months. Clinical outcomes were measured by changes in Body Surface Area (BSA) of lesions, recurrence severity, and relief of concomitant systemic symptoms.

Results

Both patients completed the 3-month regimen with significant clinical improvement and no adverse effects. In our first case, baseline daily BSA reduced from 10% to approximately 5%, with a marked decrease in the severity and frequency of flare-ups. In case two, significant reduction in skin lesions and the complete resolution of long-standing concomitant allergic conjunctivitis. Both patients reported a substantial increase in quality-of-life scores.

Conclusions

Subcutaneous CGF injection at the Tianshu point provides a safe and effective supplementary treatment for refractory CSU. This integrated approach likely works by combining the systemic immunomodulatory effects of CGF with the gut-skin axis regulation afforded by ST25 stimulation. This dual mechanism compensates for the limitations of Omalizumab's IgE-specific focus and offers a novel perspective on integrated Chinese and Western medicine for recalcitrant allergic diseases.

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Abstract N°: 2595

Remibrutinib Provides Fast Symptom Relief Within the First Week of Treatment in Chronic Spontaneous Urticaria, as Measured by Daily Urticaria Activity Score: Pooled REMIX-1/-2 Studies

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Introduction
Effective and fast symptom control is a key goal in managing chronic spontaneous urticaria (CSU). The Weekly Urticaria Activity Score (UAS7; range: 0-42) monitors disease activity over 7 days using daily hive counts and itch severity. To understand symptom control on a daily basis, we assessed the efficacy of remibrutinib, an oral, highly selective Bruton's tyrosine kinase inhibitor, using daily UAS (range: 0-6)

Materials and Methods
This pooled analysis of phase 3 REMIX-1/-2 studies (remibrutinib 25 mg bid: N=606; placebo: N=306) assessed daily UAS and proportion of patients shifting to lower UAS severity bands (0-1; no/mild CSU symptoms) from baseline to day 7. Daily UAS was calculated as the sum of daily hives and itch severity scores (HSS and ISS), with daily HSS and ISS derived by averaging morning and evening values, except for day 1, where only evening score (12 hours post-dose) was used

Results
At baseline (day −1), mean±SE UAS was 4.44±0.05 with remibrutinib and 4.30±0.07 with placebo. From days 1 to 7, remibrutinib showed greater reduction in disease activity versus placebo; mean±SE UAS within 12 hours was 3.96±0.07 versus 3.99±0.08, reducing to 3.09±0.07 versus 3.92±0.08 on day 2 and 2.25±0.08 versus 3.49±0.10 on day 7. At baseline, 1.3% of remibrutinib-treated patients versus 0.7% on placebo were in the lowest UAS band, increasing to 6.5% vs 2.4% within 12 hours and 37.0% vs 9.7% on day 7

Conclusions
Remibrutinib showed early CSU symptom control compared to placebo, with reduction in disease activity noted within the first 12 hours and sustained through day 7

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Abstract N°: 2640

Psychiatric risk in chronic spontaneous urticaria: A retrospective cohort study

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Introduction

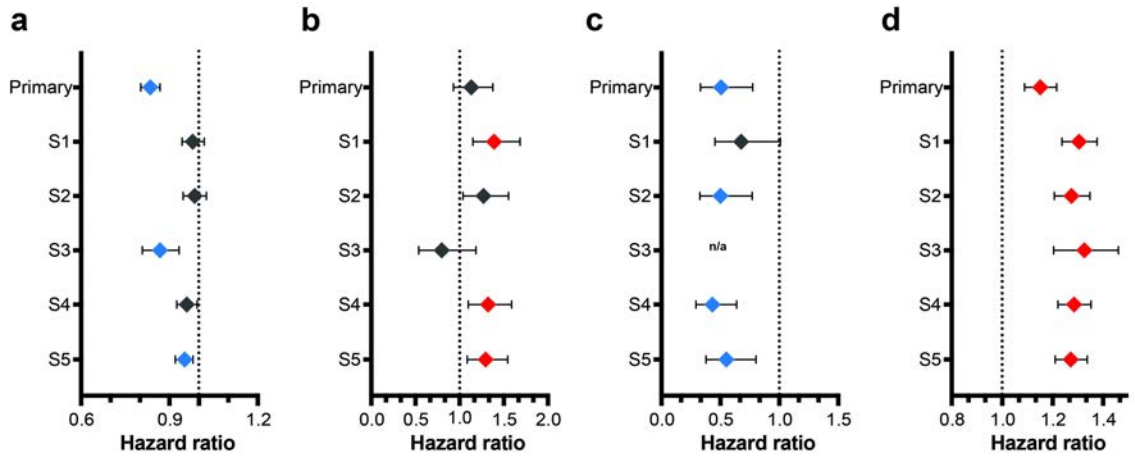
Prior real-world data and Mendelian randomization studies suggest that chronic spontaneous urticaria (CSU) is associated with psychiatric comorbidities, including depression and anxiety, prompting guideline recommendations for routine psychiatric screening. However, these studies have been limited by cross-sectional designs, reverse causation, and surveillance bias, leaving the true temporal risk of incident psychiatric disease in CSU unclear. To evaluate the risk of incident psychiatric disorders following a CSU diagnosis using a temporally anchored matched cohort design.

Materials and Methods

Retrospective matched cohort study using the TriNetX US Collaborative Network. Adults with newly diagnosed CSU and no prior psychiatric diagnoses were matched 1:1 by propensity score to non-CSU controls. Incident depression, stress-related and adjustment disorders, schizophrenia, and suicidal ideation or suicide attempts, assessed from cohort entry to three years of follow-up using Cox proportional hazards regression. Five pre-specified sensitivity analyses addressed surveillance bias, reverse causation, and temporal instability. Bonferroni correction was applied for multiple comparisons.

Results

After propensity-score matching, 98,785 individuals were included per group. CSU was associated with a modestly increased risk of stress-related and adjustment disorders (HR 1.15, 95%-CI, 1.09–1.22; $p<0.001$), consistent across all sensitivity analyses. No consistent increased risk was observed for depression, schizophrenia, or suicidal ideation and suicide attempts after accounting for temporality and confounding. A complementary association analysis, which did not exclude patients with pre-existing psychiatric disease, reproduced previously reported positive associations with depression and stress-related disorders.



Risk of psychiatric disorders in patients with chronic spontaneous urticaria (CSU) compared to non-CSU controls. The figure presents hazard ratios (HR) with 95% confidence intervals (CI) for the risk of (a) depression, (b) suicidal ideation or suicide attempts, (c) schizophrenia, and (d) reaction to severe stress and adjustment disorders in patients with CSU compared to propensity score-matched non-CSU controls. Data were derived from the TriNetX US Collaborative Network. The primary analysis and five sensitivity analyses (S1-S5) were conducted and time-to-event analysis with Kaplan–Meier estimates. While the overall risk for depression, suicide-related outcomes, and schizophrenia was comparable between groups, patients with CSU showed a consistently increased risk of stress-related disorders across all analyses. Diamonds represent HRs; horizontal bars represent 95% CIs. Red indicates statistically significant increased risk (Bonferroni-adjusted $p<0.0083$); blue indicates significantly reduced risk. Confidence intervals are unadjusted for multiple testing.

Conclusions

CSU was not associated with an increased risk of incident depression, schizophrenia, or suicide-related outcomes after accounting for temporality and surveillance bias. A small but consistent risk increment for stress-related disorders was confirmed. These findings support targeted screening for stress-related disorders at CSU diagnosis, while providing reassurance that the incident risk of most other psychiatric diseases is not meaningfully elevated.

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Abstract N°: 2667

Comparison of Adverse Effects of Omalizumab Therapy Between Geriatric and Non-Geriatric Patients with Chronic Spontaneous Urticaria: A Real Life Single Center Study

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Introduction

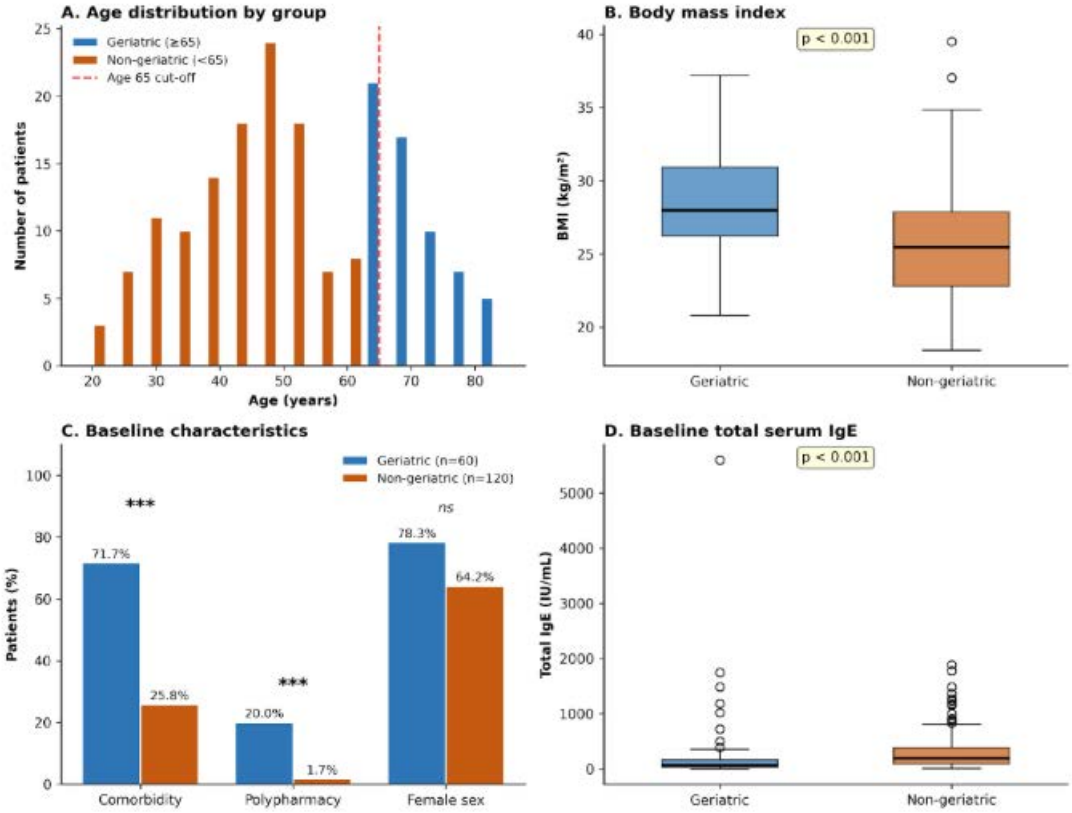
Chronic spontaneous urticaria (CSU) is a mast cell driven skin disease characterized by recurrent wheals and/or angioedema lasting >6 weeks without identifiable trigger. Adult point prevalence is 0.5–1%, with substantial impact on quality of life. Guidelines recommend H1-antihistamines as first line therapy and omalizumab as second line in refractory cases. Pivotal trials (ASTERIA I/II, GLACIAL) established its favorable safety profile. CSU prevalence in elderly is increasing, with up to a third of patients aged ≥65 years in some series. Elderly patients have lower IgE and higher comorbidity/polypharmacy burdens, but pivotal trials underrepresented this group, and comparative real life data remain scarce. This study compares adverse event incidence, treatment response, and the predictive role of baseline IgE between geriatric and non-geriatric CSU patients receiving omalizumab.

Materials and Methods

This single center, retrospective comparative study included adult CSU patients receiving omalizumab. Patients ≥65 years were classified as geriatric; <65 as non-geriatric. A priori power analysis (α=0.05, power=0.80, 1:2 allocation) yielded 60 geriatric and 120 non-geriatric patients. Eligible patients fulfilled EAACI guideline criteria and had received omalizumab for ≥3 months due to inadequate response to up-to-fourfold H1-antihistamines. Patients with chronic inducible urticaria, concomitant biologics, or incomplete data were excluded. Demographics, comorbidities, polypharmacy (≥5 medications), baseline IgE, omalizumab dose and duration were recorded. Response was assessed clinically by attack frequency (complete/partial/none). Fourteen adverse event categories were recorded and graded by CTCAE v5.0. Variables were compared with t test/Mann–Whitney U or chi-square/Fisher exact tests. IgE–outcome relationships were explored with Kruskal–Wallis and Spearman correlation, using cut-offs of 76, 100, and 164 IU/mL. Two-tailed $p<0.05$ was significant.

Results

180 patients were analyzed. Mean age was 71.0 ± 5.9 vs 42.4 ± 10.6 years ($p<0.001$). Geriatric patients had higher BMI (28.6 vs 25.8 kg/m^2, $p<0.001$), comorbidity (71.7% vs 25.8%, $p<0.001$) and polypharmacy (20.0% vs 1.7%, $p<0.001$), with lower baseline IgE (60 vs 192 IU/mL, $p<0.001$). Complete response was 96.7% vs 94.2% ($p=0.17$). Adverse events occurred in 11.7% vs 8.3% ($p=0.65$). Injection site reactions (3.3% vs 5.0%) and headache (1.7% vs 2.5%) were comparable. Fatigue was the only event significantly more frequent in geriatric patients (6.7% vs 0.8%, $p=0.043$). No anaphylaxis, cardiovascular, thromboembolic, infectious, or malignant events occurred. All adverse events were mild; none led to discontinuation. Baseline IgE did not predict adverse events ($p=0.26$) or response ($p=0.76$; Spearman $\rho=-0.086$).



Baseline characteristics of geriatric and non-geriatric CSU patients receiving omalizumab. (A) Age distribution of the two groups. (B) Body mass index (BMI), significantly higher in geriatric patients. (C) Comorbidity, polypharmacy, and female sex distribution. (D) Baseline total serum IgE levels, lower in geriatric patients. ***p<0.001; ns, not significant.

Conclusions

Omalizumab demonstrated equivalent efficacy and a comparable safety profile in geriatric and non-geriatric CSU patients despite the markedly higher comorbidity burden in the elderly. Complete response exceeded 94% in both groups. Fatigue was the only adverse event significantly more common in geriatric patients, but was mild and self limited. No serious adverse events occurred, and no patient discontinued therapy. Baseline IgE did not predict safety or efficacy outcomes, suggesting that lower IgE in elderly patients should not discourage treatment. These findings support confident use of omalizumab as second line therapy in elderly CSU patients, including those with multiple comorbidities and polypharmacy. Larger prospective multicenter studies are needed to validate these results and clarify the fatigue signal.

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Abstract N°: 2723

Effectiveness of Upadacitinib in Chronic Urticaria: A Multinational Real-World Case Series of 27 Patients

Clara Schwarz*[1], Yung-Tsu Cho[2, 3], Luis Felipe Ensina[4, 5], Daria Fomina[6, 7], Kiran Godse[8], Emek Kocatürk[9, 10, 11], Muthu Sendhil Kumaran[12], Alex Eustaquio Lacerda[4], Hermenio Lima[13], Indrashis Podder[14], Karla Robles[13, 15], Michael Rudenko[16], Andaç Salman[17], Jorge Sánchez[18], Simon Francis Thomsen[19]

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Introduction

Chronic urticaria (CU) is a common mast cell–driven inflammatory skin disorder characterized by recurrent pruritic wheals and/or angioedema persisting for ≥6 weeks. Although self-limiting, CU may persist for years, and its unpredictable symptoms substantially affect quality of life. Despite multiple available therapeutic options, a substantial proportion of patients remain inadequately controlled, highlighting an unmet need for additional off-label treatment strategies. Upadacitinib, a selective Janus kinase 1 (JAK1) inhibitor approved for atopic dermatitis and used in other chronic inflammatory conditions, has limited evidence supporting its use in CU. Therefore, this case series evaluated clinical outcomes in patients with CU treated with upadacitinib.

Materials and Methods

This study included patients with CU from tertiary centers worldwide (Brazil, Canada, Colombia, Denmark, India, Russia, Taiwan, Turkey, and the United Kingdom), where CU was the primary indication for initiating upadacitinib. A standardized template with predefined variables and an accompanying codebook was distributed to ensure consistent data collection across centers. Variables included demographics, disease duration (defined as time from symptom onset to initiation of upadacitinib), previous and concomitant treatments, comorbidities, and biochemical parameters (TPO ab, IgE, basophils, and eosinophils). Patient Reported Outcome Measures (PROMs), including UAS7 and UCT, were assessed before treatment initiation and at follow-up. Upadacitinib dosing and physician-assessed treatment response were also recorded.

Descriptive analyses were conducted using frequencies for categorical variables and means or medians for continuous variables. Normality was assessed using the Shapiro–Wilk test, and paired t-tests were used to assess differences in treatment outcomes following upadacitinib treatment. A p-value <0.05 was considered statistically significant. Analyses were performed using SPSS version 29.01.0 (171).

Results

A total of 27 patients with CU were included; mean (SD) age 44.9 (14.8) years, 66.7% females (Table 1). Most patients (81.5%) had chronic spontaneous urticaria (CSU), with concomitant chronic inducible urticaria (CIndU) in 14.8% and isolated CIndU in 3.7%. Atopic comorbidities were the most common, occurring in 29.6% of patients. Prior to treatment initiation, the mean (SD) baseline UCT was 4.1 (2.8) and the mean (SD) UAS7 was 33.8 (7.4). Most patients had previously received omalizumab, ciclosporin, and/or dupilumab, with partial or insufficient response.

Upadacitinib was administered at 15 mg daily in 77.8% of patients, and 15 (55.6%) patients remained on treatment (Table 2). Among those who discontinued treatment, the mean (SD) treatment duration was 6.1 (4.7) months, and discontinuation was mainly due to complete response (14.8%) or lack of response (14.8%). Overall, 14 (58.3%) patients achieved a complete response, 6 (25.0%) experienced a partial response, and 4 (16.7%) showed no response. A total of 5 patients experienced adverse events, most commonly nausea and acne. At follow-up, improvement in disease control was significant, with a mean (95% CI) increase in UCT score of 7.3 (5.5 to 9.1) ($p<0.001$) and a mean (95% CI) decrease in UAS7 of 25.1 (19.4 to 30.7) ($p<0.001$). In patients with angioedema (51.9%), the improvement in UCT and UAS7 scores was statistically significant ($p<0.001$) but slightly less pronounced.

Conclusions

This multinational case series suggests a potential clinical benefit of upadacitinib for patients with CU, with significantly improved disease control reflected by increased UCT and decreased UAS7 scores from baseline. As a JAK1 inhibitor targeting key inflammatory pathways in CU, upadacitinib represents a promising option, particularly for patients refractory to currently licensed therapies. Larger randomized controlled clinical trials are needed to confirm efficacy and safety in CU.

Table 1. Patient characteristics at baseline

	Patients with CU n=27
Age (years), mean (SD)	*44.9 (14.8)*
Female, % (n/n_{total})	*66.7 (18/27)*
BMI (kg/m²), mean (SD)	*26.3 (3.7)*
Disease duration (months), mean (SD)	*29.7 (45.2)*
CSU/CIndU, % (n/n_{total})	
CSU only	*81.5 (22/27)*
Concomitant CIndU	*14.8 (4/27)*
CIndU only	*3.7 (1/27)*
Angioedema, % (n/n_{total})	*51.9 (14/27)*
Atopic comorbidities, % (n/n_{total})	*29.6 (8/27)*
Baseline UCT, mean (SD)	*4.1 (2.8)*
Baseline UAS7, mean (SD)	*33.8 (7.4)*
Previous treatment, % (n/n_{total})	
AH (licensed dose)	*96.0 (24/25)*
AH (up dosed)	*88.9 (24/27)*
Omalizumab	*48.1 (13/27)*
Dupilumab	*19.2 (5/26)*
Ciclosporin	*33.2 (9/27)*
Current treatment, % (n/n_{total})	
AH (licensed dose)	*20.0 (5/25)*
AH (up dosed)	*68.0 (17/25)*
Prednisolone treatment, % (n/n_{total})	
On demand	*81.5 (22/27)*
Continuous	*11.1 (3/27)*
Low IgE (<40 IU/mL), % (n/n_{total})	*11.1 (3/27)*
Eosinopenia (<0.05 x 10^9/L) % (n/n_{total})	*16.7 (4/24)*
Basopenia (<0.01 x 10^9/L), % (n/n_{total})	*36.4 (8/22)*

Abbreviations: AH: Antihistamines, BMI: Body mass index, CIndU: Chronic inducible urticaria, CU: Chronic urticaria, IgE: Immunoglobulin E, SD: Standard deviation, UAS7: weekly Urticaria Activity Score, UCT: Urticaria Control Test

Table 2. Upadacitinib treatment characteristics and clinical outcomes

	Patients with CU n=27
Upadacitinib dose, % (n/n_{total})	
15 mg	*77.8 (21/27)*
30 mg	*22.2 (6/27)*
Upadacitinib treatment status, % (n/n_{total})	
Treatment ongoing	*55.6 (15/27)*
Treatment stopped	*44.4 (12/27)*
Treatment duration (months), mean (SD)	
All patients[a]	*8.8 (9.8)*
Discontinued patients	*6.1 (4.7)*
Upadacitinib treatment response, % (n/n_{total})	
Complete response[b]	*58.3 (14/24)*
Partial response[c]	*25.0 (6/24)*
No response[d]	*16.7 (4/24)*
Reasons for discontinuing upadacitinib, % (n/n_{total})	
Ongoing to date	*55.6 (15/27)*
Complete response[b]	*14.8 (4/27)*
Partial response[c]	*7.4 (2/27)*
No response[d]	*14.8 (4/27)*
High cost	*7.4 (2/27)*
Adverse events, % (n/n_{total})	*33.3 (5/15)*
UCT post treatment, mean (SD)	*11.5 (4.2)*
UAS7 post treatment, mean (SD)	*8.7 (10.9)*

Abbreviations: mg: milligroms, SD: Standard deviation, UAS7: weekly Urticaria Activity Score, UCT: Urticaria Control Test

Side 2

Footnotes table 2: a) Treatment duration for all patients was calculated up to the data lock date (28 April 2026), b) Complete response: > 90% symptom reduction, c) Partial response: 30-90% symptom reduction, d) No response: < 30% symptom reduction

EADV CONGRESS
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Abstract N°: 2746

When the Ephemeral Persists: Pediatric Urticarial Vasculitis – A Case Report

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Introduction

Urticarial vasculitis (UV) is an uncommon clinicopathological variant of leukocytoclastic vasculitis and is exceptional in children, accounting for fewer than 5% of cases. In the pediatric population, it is often preceded by an upper respiratory tract infection or drug exposure, particularly beta-lactam antibiotics, whereas adult cases are more frequently idiopathic. We report a pediatric case illustrating the diagnostic and prognostic features of normocomplementemic urticarial vasculitis.

Case Presentation

A 10-year-old girl was admitted for an acute pruritic dermatosis. Her history included a flu-like syndrome with abdominal pain and vomiting, treated with amoxicillin/clavulanic acid. A few days later, she developed a pruritic eruption associated with arthralgia and a decline in general condition. Physical examination showed bilateral asymmetric erythematous-violaceous purpuric plaques on the legs, with polycyclic borders and urticarial plaques on the thighs, forearms, and cheeks, without mucosal involvement.(Fig1) Laboratory tests revealed a marked inflammatory syndrome, minimal hematuria, negative proteinuria, and normal complement levels. Skin biopsy confirmed leukocytoclastic vasculitis, and direct immunofluorescence showed vascular deposits of IgG, IgM, and C3. Systemic corticosteroids and antihistamines led to complete regression within one week, with no sequelae at one-month follow-up.

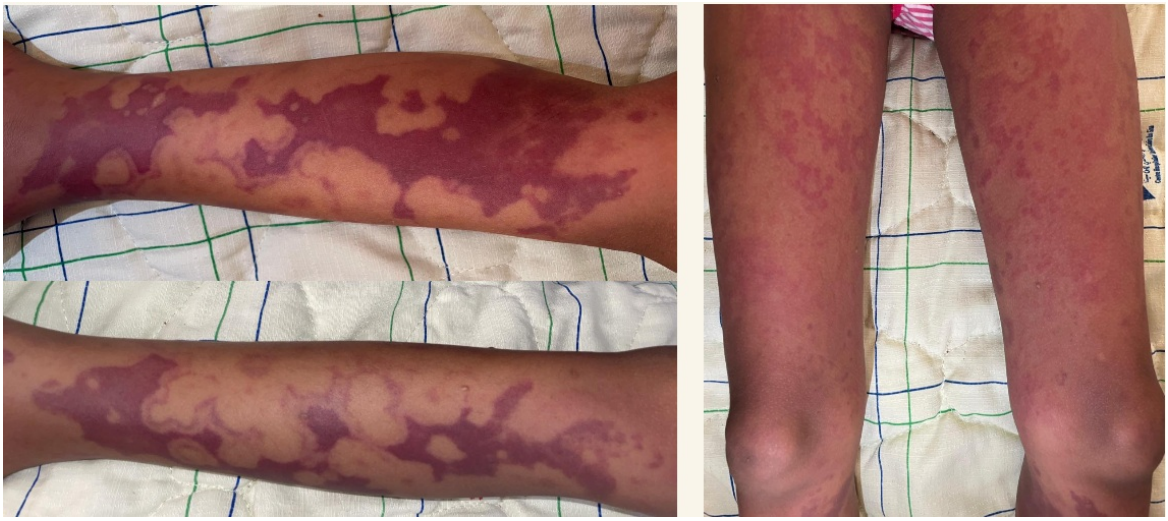

Figure 1. Clinical presentation of Urticarial vasculitis ; Bilateral asymmetric erythematous-violaceous purpuric plaques on the lower limbs with polycyclic borders and associated urticarial plaques.

Conclusion

Pediatric urticarial vasculitis is a rare entity that should be suspected in children with pruritic wheals persisting for more than 24 hours, especially when accompanied by purpura and systemic symptoms. Diagnosis relies on clinicopathological correlation, and complement testing is essential for prognostic stratification. Normocomplementemic disease usually has a favorable outcome, whereas hypocomplementemic forms are associated with a higher risk of chronic arthritis and renal involvement. This case underscores the generally excellent prognosis of uncomplicated pediatric UV when recognized early and managed appropriately.

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Abstract N°: 2823

"Dr Social Media Cured My Hives": Urticaria Misinformation on Social Media — A Cross-Sectional Analysis of Educational Quality and Engagement

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Introduction
Social media is an increasingly common source of health information, particularly in dermatology. Many patients use platforms such as Instagram, YouTube, and TikTok to seek dermatological information. Urticaria affects approximately one in five individuals, yet online information regarding the condition remains underexplored. This study evaluated the quality, accuracy, and engagement of urticaria-related content on social media across different creator groups.

Materials and Methods
A cross-sectional analysis was conducted across Instagram, YouTube, and TikTok. Posts and short-form videos containing the hashtags #urticaria, #chronicurticaria, #hives, or #wheals were included. Eligible content was English-language, human-related, and discussed urticaria symptoms, causes, or treatment. Data collected included views, likes, comments, and shares. Content creators were classified as dermatologists and medical doctors, other healthcare professionals, or non-medical creators. Content was independently assessed for educational quality and accuracy by two reviewers according to EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guidelines. Posts were graded as high, moderate, or poor educational quality. Misinformation was categorised into treatment-related misinformation, alternative therapies, diet-related misinformation, trigger myths, and others.

Results
A total of 150 posts were analysed, accounting for 29.7 million views and 436,895 likes. Overall, 56.7% of posts demonstrated high educational value, while 31.9% contained misinformation. Posts created by dermatologists or verified medical doctors were significantly more likely to have high educational value compared with posts from non-medical creators (88.6% vs 32.7%). Misinformation was substantially less frequent among doctor-created content (11.4% vs 67.3%). A significant association was observed between creator type and educational quality (χ^2 = 41.69, p = 1.07 × 10^{-10}). Non-medical creators had significantly greater odds of posting misinformation (OR 15.93, 95% CI 6.30–40.26).

Among misinformation posts, treatment-related misinformation was most common (91.1%), followed by alternative therapies (86.7%), diet-related misinformation (53.3%), and trigger avoidance myths (40.0%). Engagement differed significantly between educational and misinformation posts (Mann–Whitney U = 1800, p = 4.44 × 10^{-16}, r = 0.72). Although educational posts achieved higher mean views (284,728 vs 141,621), misinformation posts demonstrated higher median engagement (16,000 vs 5,128 views), suggesting more consistent audience reach.

Conclusions
Urticaria-related content made by dermatologists and medical doctors was significantly more accurate and

educational than other content creators, whose posts had much higher odds of misinformation. Misinformation posts had higher typical engagement (higher median views), whereas educational posts had greater variability and higher viral potential (higher mean and extreme outliers).

Treatment-related misinformation was particularly prevalent, highlighting the potential for social media content to negatively influence patient decision-making and healthcare-seeking behaviour. While educational content showed greater viral potential, misinformation achieved more consistent engagement.

Implications

We demonstrated the important role of dermatologists in the social media education space. Encouraging the creation of accurate, evidence-based, and educational content by dermatologists, alongside targeted interventions against misinformation, may improve the quality of online dermatology education and enhance patient safety.

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Abstract N°: 2902

Treatment patterns of patients with chronic urticaria before and after referral to specialized care: a nationwide Danish cohort study

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Introduction

Chronic urticaria (CU) is a debilitating condition that significantly affects patients' quality of life. Although treatment options and clinical guidelines are available for CU they are often not fully applied in clinical practice. We examined treatment patterns with urticaria-related medications in patients with CU before and after referral to specialized outpatient hospital dermatologist or allergologist care.

Materials and Methods

Patients identified between 1997 and 2022 in the Danish National Patient Registry with an outpatient hospital dermatologist or allergologist verified diagnosis of CU were included in this study. Their entire prescription history for urticaria-related medications were extracted from the Danish National Prescription Registry since its establishment in 1995. Sequences of continuous treatment with the same drug or drug group, changes between drugs, and dosing were examined. In general, treatments were considered continuous if a new prescription or in-hospital treatment was given within half a year, except for rituximab where it was one year and antihistamines (AH) where it was number of tablets filled in the prescription +60 days. With systemic glucocorticosteroids (GC) every filled prescription was regarded as a new treatment. Up-dosed second-generation H_1 AH (sg-H_1-AH) was calculated by dividing number of AH tablets in a prescription pick-up by number of days until next prescription pick-up.

Table 1 Overview of medication included in the study.

Subgroup	Drugs
2nd generation H_1 antihistamines	Cetirizin, Levocetirizin, Loratadin, Acrivastatin, Ebastin, Fexofenadin, Desloratadin, Rupatadin, Bilastin
Systemic glucocorticosteroids	Systemic glucocorticosteroids
Omalizumab	Omalizumab
Ciclosporine	Ciclosporin
1st generation H_1 antihistamines	Cinnarizin, Diphenhydramin, Clemastin, Promethazin, Cyclizin, Chlorcyclizin, Meclozin, Doxepin, Mirtazepine
H_2 antihistamines	Ranitidin, Cimetidin, Famotidin, Nizatidin, Niperotidin, Roxatidin, Ranitidinbismuthcitrat, Lafutidin
DMARDs	Methotrexate, Mycophenolate mofetil, Dapsone, Sulphasalazine, Hydroxychloroquine, Cyclophosphamide, Colchicine, Tacrolimus, Azathioprin
Leukotriene receptor antagonists	Leukotriene receptor antagonist, Montelukast
Anticoagulants	Warfarin, Heparin
UV light therapy	Narrow-band UVB, PUVA
Other biologics	Rituximab, Anakinra, Anti-TNF (etanercept, infliximab, adalimumab, certolizumab pegol, golimumab, afelimomab, opinercept), Interferon alpha.
Other treatments advocated in guideline	Danazol, Tranexamic acid, IVIG, Plasmapheresis, Camostat mesylate, Miltefosine
Topicals	Doxepin topical, Tacrolimus topical
Dupilumab	Dupilumab
Not possible to include: Pseudoallergen-free diet, autologous blood/serum, holistic medicine, vitamin D, remibrutinib.	

Results

The study included 11,215 patients with CU (mean (SD) age at diagnosis 41.7 (18.1) years ,69.1% women). Before diagnosis, patients had most frequently been treated with sg-H_1-AH (n=10,044; 89.6%), systemic GC (n=5,792; 51.6%), first generation H_1 AH (fg-H_1-AH) (n=1,600; 14.3%) and H_2 AH (n=1,470; 13.1%). The median time from first prescription pick-up until first hospital CU diagnosis was 1583.5 days (4.3 years) and 67% had tried two or more different types of sg-H_1-AH. Of the patients treated with sg-H_1-AH, 35.5% only received standard dose or less. In total, 34% of patients had received treatments with 3 or more different sub-groups of therapy and 40% had received 6 or more treatment series regardless of sub-groups. Following referral to specialized hospital care there was a decrease in the proportion of patients initiating sg-H_1-AH (89.6% to 69.7%), H_2-AH (13.1% to 5.6%) and systemic GC (51.6% to 42.6%). For almost all other treatment groups there was an increase.

Conclusions

Patients with CU are not treated according to guideline-recommendations prior to arrival at specialized care.

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Abstract N°: 3067

Limited Effectiveness of Current Therapies in Chronic Inducible Urticaria: Insights from the Chronic Urticaria Registry (CURE)

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Introduction

Approximately 43–80% of patients with chronic spontaneous urticaria (CSU) continue to experience symptoms despite treatment with currently available therapies, whereas much less is known about treatment response and disease control in chronic inducible urticaria (CIndU). Using data from the Chronic Urticaria Registry (CURE), this analysis sought to characterize real-world treatment patterns and highlight unmet clinical needs in the three most common CIndU subtypes: symptomatic dermographism (SD), cold urticaria (ColdU), and cholinergic urticaria (CholU).

Materials and Methods

CURE is a global, prospective registry that enrolls individuals with chronic urticaria and urticarial vasculitis. Adult

patients with predominant SD, ColdU, and CholU were included in this analysis. Treatment outcomes at baseline were assessed using Urticaria Control Test (UCT) scores (UCT=16 complete control, UCT 12-15 well controlled and UCT <12 poorly controlled disease). Treatment categories included no therapy, standard-dose or up-dosed second-generation H1-antihistamines (sgAHs), and omalizumab.

Results

Baseline UCT data were available for 774 adult CIndU patients (SD: 55.5%, n=430, ColdU: 24.4%, n=189, CholU: 20.0%, n=155) from 45 centers in 24 countries. Most were female (64.5%) with median age of 36 years (IQR: 26–47), and median disease duration of 2.39 years (IQR: 0.78–5.92). Across all treatments, 4.4% (34/774) had complete disease control, 26.4% were well controlled and 69.2% (536/774) of patients had poorly controlled disease. The highest rates of well-controlled/completely controlled disease (UCT≥12) were observed with omalizumab (45.7%, 16/35), whereas lower rates were found for no treatment (27.7%, 41/148), standard-dose sgAHs (27.0%, 91/337), and updosed sgAHs (19.6%, 40/204). This trend was comparable across all CIndU forms. Out of 148 patients with no treatment, 72.3% (n=107) had poorly controlled disease. ColdU was associated with higher rates of well controlled/completely controlled disease by comparison with SD and CholU (34.9% vs. 20.9% and 20.6%) especially on no treatment (44.0% vs. 15.9% and 19.2%).

Conclusions

Response rates to current therapies in CIndU are similar to - or lower than those observed in CSU. Approximately two-thirds of patients remain poorly controlled, and the underlying reasons warrant further investigation. Many patients receive no treatment despite inadequate disease control. ColdU patients show the highest proportion of well- or /completely-controlled disease, potentially reflecting the impact of trigger avoidance, including seasonal temperature changes. Upcoming analyses will evaluate follow-up data to determine the outcome of and predictors of treatment escalation.

This investigator-initiated study received funding from Novartis. The funder had no influence on the study design, data analysis or interpretation.

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Abstract N°: 3071

Avapritinib improves symptoms and quality of life in indolent systemic mastocytosis: 12-month outcome of the real-world AVATAR study

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Introduction
Avapritinib, a selective KIT D816V inhibitor, has demonstrated efficacy in indolent systemic mastocytosis (ISM) in clinical trials, yet real-world evidence remains limited. We report 12-month outcomes from a real-world study evaluating avapritinib in routine practice.

Materials and Methods
AVATAR is a real-world study conducted at Charité – Universitätsmedizin Berlin. Between December 2023 and December 2025, 20 patients fulfilling WHO/ICC 2022 criteria for ISM and treated with avapritinib 25mg once daily for ≥3 months and symptomatic treatment were included. The Mastocytosis Control Test (MCT) and Mastocytosis Quality of Life Questionnaire (MC-QoL), serum tryptase and safety parameters were assessed through week 48.

Results
Mean age was 54±11 years; 60% female; mean disease duration 17±12 years, all had skin involvement, 30% a history of anaphylaxis, and 40% osteoporosis. Median baseline MCT was 8 (5–11) and MC-QoL was 56 (42–68), indicating poor disease control and moderate-to-severe QoL impairment. By week 12, 73.7% achieved adequate disease control (MCT ≥13), with median MCT improving to 14 (12–17) and remaining stable at week 48. Severe QoL impairment declined from 42.1% at baseline to 0% at weeks 12 and 24, with 64.3% of the overall cohort demonstrated no/mild impairment at week 48 (Figure 1). Median serum tryptase decreased from 33.5 ng/ml to 11.7 ng/ml by week 24 (−67%) and to 11.1 ng/ml by week 48 (−67%). No new anaphylaxis or fractures occurred. Treatment was generally well tolerated.

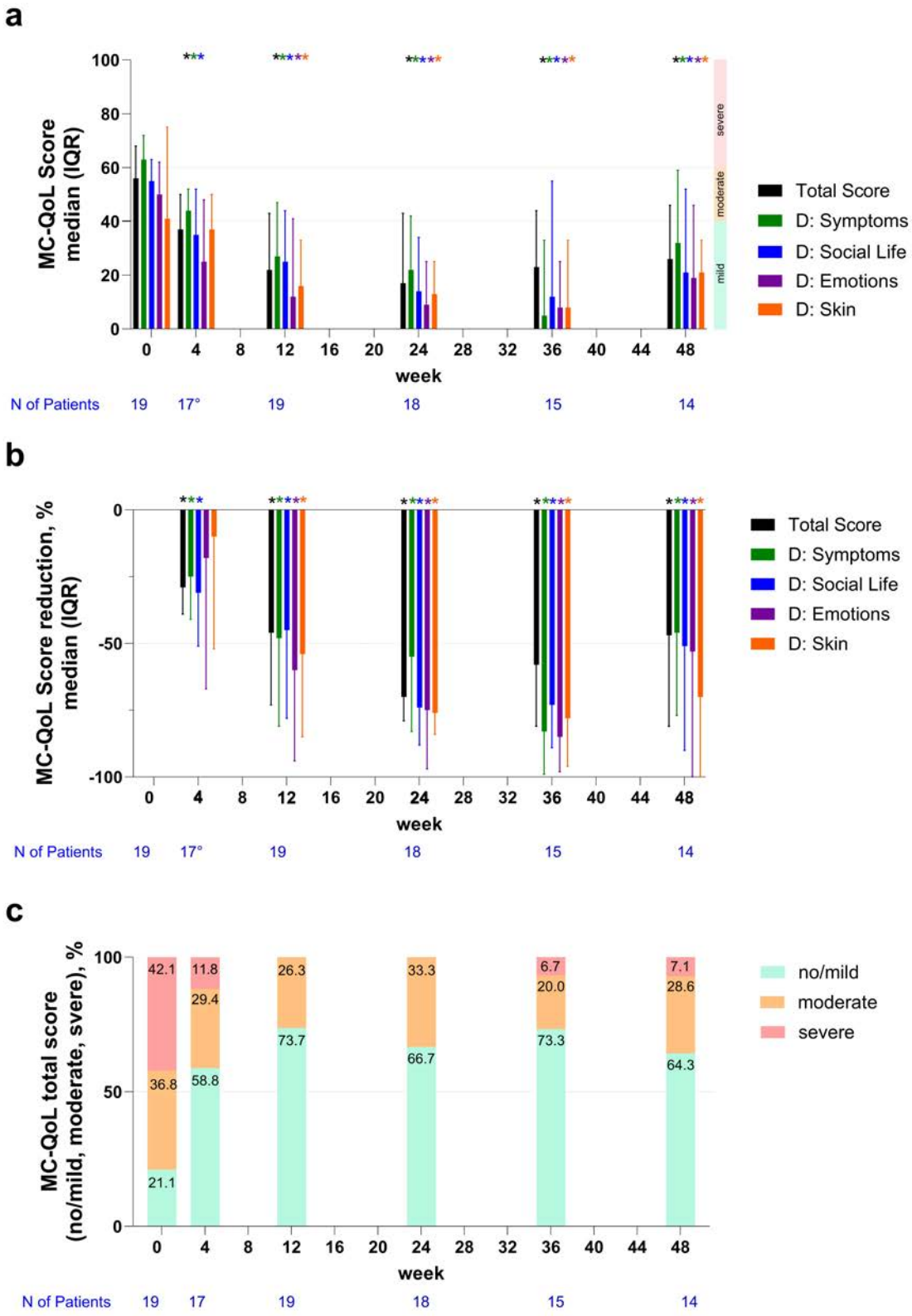

Figure 1. Improvement in mastocytosis-related quality of life during treatment

Conclusions

Avapritinib 25 mg daily was well-tolerated and led to rapid improvements in disease control, quality of life, and mast cell burden over 48 weeks.

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Abstract N°: 3073

Chronic spontaneous urticaria in older adults: distinct clinical subgroup with better disease control - insights from the CURE-AGE study

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Introduction

Older adults are underrepresented in chronic spontaneous urticaria (CSU) studies, and age-specific differences in

clinical presentation, comorbidities, and patient-reported outcomes remain poorly defined. Our objectives are to quantify age-related differences in clinical phenotype, comorbidities, disease activity, disease control and quality-of-life impairment in adults with CSU.

Materials and Methods

This cross-sectional analysis used baseline data from the ongoing, prospective, international, multicentre, observational Chronic Urticaria Registry (CURE) with a January 2026 data cut. Adults with predominant CSU were stratified into 3 predefined age groups: 18–39 years (young adults, YA), 40–64 years (middle-aged adults, MA) and ≥65 years (older adults, OA). Clinical features (i.e., itch, wheals, angioedema, angioedema locations and systemic symptoms), comorbidities, Urticaria Activity Score over 7 days (UAS7) scores, Urticaria Control Test (UCT) scores, Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) scores, Dermatology Life Quality Index (DLQI) scores and treatment outcomes were compared between age groups using Pearson's chi-square and Kruskal-Wallis tests.

Results

Among 3,674 adults with predominant CSU, 1,578 (43.0%) were YA, 1,700 (46.3%) were MA and 396 (10.8%) were OA. Compared with the younger age groups, OA more frequently had angioedema without wheals (YA vs MA vs OA: 1.9% vs 3.4% vs 7.4%; overall $p<0.001$) and tongue angioedema (10.1% vs 13.5% vs 16.0%; $p=0.001$), but less frequently had wheals with angioedema (57.1% vs 58.5% vs 51.1%; $p=0.029$), eyelid angioedema (36.8% vs 37.8% vs 28.1%; $p=0.002$), hand angioedema (21.4% vs 18.6% vs 11.0%; $p<0.001$) and foot angioedema (18.6% vs 17.2% vs 11.5%; $p=0.005$). They also reported lower frequencies of itch (94.1% vs 92.7% vs 90.3%; $p=0.030$), recurrent fever (7.2% vs 6.6% vs 2.2%; $p=0.009$), joint, bone or muscle pain (23.3% vs 25.4% vs 15.2%; $p=0.001$) and malaise (25.8% vs 23.6% vs 15.6%; $p=0.002$). In addition, OA had lower frequencies of concomitant inducible urticaria (26.6% vs 20.9% vs 14.2%; $p<0.001$), atopic disease (37.2% vs 32.5% vs 27.5%; $p<0.001$) and higher frequencies of autoimmune disease (8.9% vs 13.8% vs 20.1%; $p<0.001$) and thyroid disease (12.0% vs 20.1% vs 29.6%; $p<0.001$). They also showed a higher proportion of well-controlled disease (UCT≥12; 24.2% vs 27.2% vs 33.2%; $p=0.005$) and complete disease control (UCT=16; 6.8% vs 10.4% vs 13.4%; $p<0.001$). Across treatment groups, OA showed higher rates of UCT≥12 with licensed-dose second-generation H1-antihistamines alone (24.3% vs 27.1% vs 30.6%; $p=0.005$), updosed antihistamines alone (10.8% vs 16.1% vs 19.0%; $p=0.005$) and omalizumab (47.9% vs 47.2% vs 53.2%; $p=0.005$). Finally, OA had lower median CU-Q2oL (29.0 vs 31.0 vs 25.0; $p=0.015$) and DLQI (7.0 vs 7.0 vs 6.0; $p=0.002$) scores.

Conclusions

CSU patients aged ≥65 years appear to represent a distinct clinical subgroup with a different symptom and comorbidity profile, as well as better disease control and lower quality-of-life impairment than younger adults.

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Abstract N°: 3077

Mastocytosis Management Among Dermatologists in Germany: Results of the MAMAS-Derm Survey

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Introduction
Mastocytosis is a complex mast cell disorder with heterogeneous organ involvement requiring multidisciplinary management and access to specialized diagnostic procedures. The worldwide MAMAS study highlighted the central role of dermatologists as gatekeepers in the recognition and management of mastocytosis patients. Therefore, we conducted the MAMAS-Derm physician survey to assess current approaches to mastocytosis diagnosis and management among dermatologists in Germany.

Materials and Methods
The anonymous REDCap-based 14-item questionnaire was distributed nationally through the newsletter of the German Dermatological Society (DDG) between 15 and 31 May 2025. Of 97 initiated questionnaires, 63 completed responses were included in the final analysis.

Results
Most physicians worked in university clinics (43.9%, 29/63) or private practice (38.1%, 24/63), whereas 9.5% (6/63) worked at specialized mastocytosis centers (SMCs). Physicians reported caring for a median of 5 mastocytosis patients annually. The most frequently reported challenges included insufficient experience among specialists from other disciplines (46.8%, 29/62), limited multidisciplinary networks (45.2%, 28/62), lack of more effective treatment options (32.3%, 20/62), and restricted access to comprehensive diagnostic procedures (24.2%, 15/62). Serum basal tryptase assessment was included in the diagnostic workup by 96.8% (61/63) of physicians, whereas KIT D816V mutation analysis, abdominal ultrasound, bone marrow biopsy, and bone density assessment were performed by 65.1% (41/63), 54.0% (34/63), 52.4% (33/63), and 50.8% (32/63), respectively, with marked variability in the number of patients investigated. Bone marrow biopsy, the current gold standard for diagnosing systemic mastocytosis (SM), was performed by 52.4% (33/63) of physicians and was most commonly driven by abnormal blood counts (54.0%, 34/63), splenomegaly/hepatomegaly (44.4%, 28/63), KIT mutation detection (42.9%, 27/63), serum tryptase ≥20 ng/mL (38.1%, 24/63), extensive skin involvement (36.5%, 23/63), severe osteoporosis (34.9%, 22/63), uncontrolled gastrointestinal symptoms (33.3%, 21/63), and uncontrolled cutaneous symptoms (31.7%, 20/63). Most respondents (90.3%, 56/62) considered targeted therapies such as tyrosine kinase inhibitors beneficial for mastocytosis patients, with physicians estimating that approximately half of their patients may benefit from such approaches. Variability was also observed regarding symptom burden assessment and the use of mastocytosis-specific PROMs; 32.3% (20/62) were not aware of validated PROMs and 12.9% (8/62) reported uncertainty in assessing disease burden and quality of life. Most physicians (69.4%, 43/62) considered digital symptom-monitoring applications useful in clinical practice.

Conclusions

The diagnostic workup and management of mastocytosis among dermatologists in Germany remain heterogeneous. Strengthening multidisciplinary networks, improving access to specialized diagnostics, increasing awareness of validated PROMs, and expanding specialized mastocytosis centers may improve standardized patient care.

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Abstract N°: 3112

Dupilumab Improves Urticaria Activity Regardless of Baseline Clinical Characteristics: Results From Pooled LIBERTY-CSU CUPID Study A and Study C

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Introduction

Clinical characteristics at baseline may impact therapeutic response in patients with chronic spontaneous urticaria (CSU). Here, we evaluated the impact of baseline disease duration, Itch Severity Score over 7 days (ISS7), Hives Severity Score over 7 days (HSS7), and H1-antihistamine dose category (standard dose, 2-to-3–fold of standard dose, and 4-fold of standard dose) on the efficacy of dupilumab treatment vs placebo in patients with CSU.

Materials and Methods

This post hoc analysis used pooled data from LIBERTY-CSU CUPID (NCT04180488) Study A and Study C. All patients were omalizumab-naive and were randomized to receive dupilumab or placebo for a 24-week treatment period. Urticaria activity was evaluated using Urticaria Activity Score over 7 days (UAS7), reported as least squares (LS) mean change in UAS7 (95% confidence interval [CI]) from baseline at Week 24. Estimates were obtained using separate analysis of covariance models, each adjusted for baseline UAS7 and a single baseline covariate including disease duration, ISS7, HSS7, or baseline H1-antihistamine dose category (standard dose, 2-to-3–fold standard dose, or 4-fold standard dose). LS mean treatment effects were estimated as marginal means averaged over covariate levels. All *P*-values are nominal and no adjustment was made for multiple testing.

Results

289 omalizumab-naive patients with CSU were assessed (dupilumab/placebo, n = 144/145). Baseline demographic and disease characteristics were generally balanced between the dupilumab and placebo groups. The mean (standard deviation [SD]) of UAS7 score at baseline in the overall study population was 29.8 (7.7), indicating severe disease activity. At baseline, the disease duration (years), ISS7, and HSS7 mean (SD) in the overall study population was 6.1 (9.2), 15.5 (3.9), and 14.2 (4.7), respectively. At baseline, 51% (146/289), 36% (104/289), and 13% (39/289) of patients were included in the H1-antihistamine standard dose, 2-to-3–fold standard dose, and 4-fold standard dose category, respectively.

At Week 24, the adjusted LS mean reduction from baseline (95% CI) in UAS7 was significantly higher with dupilumab vs placebo when adjusted for baseline disease duration (−20.2 [−22.2, −18.2] vs −14.5 [−16.6, −12.4]); baseline ISS7 (−20.0 [−22.0, −18.0] vs −14.6 [−16.7, −12.5]); baseline HSS7 (−20.0 [−22.0, −18.0] vs −14.6 [−16.7, −12.5]) ($P < 0.001$ for each); and H1-antihistamine dose (−19.9 [−22.3, −17.4] vs −13.7 [−16.1, −11.4]; $P = 0.005$). The interaction effect for baseline disease duration, ISS7, HSS7, or baseline H1-antihistamine dose category on the LS mean change in UAS7 from baseline to Week 24 was non-significant (P for interaction 0.11, 0.56, 0.47, and 0.37, respectively). Safety was generally consistent with the known dupilumab safety profile.

Conclusions

Dupilumab significantly reduced urticaria activity from baseline to Week 24 compared with placebo regardless of baseline disease duration, ISS7, HSS7, and baseline H1 antihistamine dose.

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Abstract N°: 3116

Efficacy of Dupilumab on Urticaria Activity Is Consistent Across Pre-Treatment Levels of Laboratory Markers: Results From Pooled LIBERTY-CSU CUPID Study A and Study C

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Introduction

The peripheral eosinophil and basophil count and the total serum IgE level have been proposed as predictive markers for treatment response in chronic spontaneous urticaria (CSU). CSU with eosinopenia, basopenia, and/or low total serum IgE is associated with increased disease activity and poor response to H1-antihistamines and omalizumab. We assessed the impact of baseline levels of these markers on the improvement in urticaria activity with dupilumab vs placebo in LIBERTY-CSU CUPID (NCT04180488).

Materials and Methods

This was a post hoc analysis of pooled data from omalizumab-naive patients with CSU who received dupilumab for 24 weeks in LIBERTY-CSU CUPID Study A and Study C. Urticaria Activity Score over 7 days (UAS7) improvement was assessed as least squares (LS) mean change from baseline (95% confidence interval [CI]) at Week 24, adjusted with Analysis of Covariance (ANCOVA) for baseline eosinophil, basophil, and total IgE serum level covariates. Treatment effect and LS means were estimated at the mean value of the covariate. All *P* values are nominal and no adjustment was made for multiple testing.

Results

Data from 289 patients were assessed (dupilumab/placebo, n = 144/145). Baseline demographic and disease characteristics were generally balanced between the dupilumab and placebo groups. The mean (standard deviation [SD]) UAS7 score at baseline in the overall study population was 29.8 (7.7), indicating severe disease activity. At baseline, the eosinophil, basophil, and total serum IgE medians (interquartile ranges [IQR]) in the study population were 0.2 (0.1–0.2), 0.0 (0.0–0.1) and 97 (30–252) IU/mL, and the means (SD) were 0.2 (0.2), 0.0 (0.0) and 400 (1,706) IU/mL. Overall, 30% of patients had a baseline total serum IgE <40 IU/mL. The LS mean reduction from baseline (95% CI) in UAS7 at Week 24 was significantly higher with dupilumab vs placebo when adjusted for the baseline eosinophil count (−20.0 [−22.0, −18.0] vs −14.6 [−16.7, −12.5]), basophil count (−20.1 [−22.1,

−18.1] vs −14.6 [−16.7, −12.5]) and total serum IgE level (−20.0 [−22.0, −18.0] vs −14.6 [−16.7, −12.5]) (P < 0.001 for each). The interaction effect for baseline eosinophil count, basophil count, and total serum IgE level on the mean change from baseline in UAS7 at Week 24 was non-significant (P for interaction = 0.23, 0.40, and 0.56 respectively). Safety was generally consistent with the known dupilumab safety profile.

Conclusions

Baseline eosinophil and basophil counts and total serum IgE level did not significantly interact with the improvement in UAS7 with dupilumab vs placebo. Dupilumab treatment consistently reduced urticaria activity from baseline to Week 24 across baseline levels of eosinophils, basophils, and total serum IgE.

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Dupilumab Improves Disease-Specific Quality of Life in Omalizumab-Naïve Patients with Chronic Spontaneous Urticaria: A Post-hoc Pooled Analysis from the LIBERTY-CSU CUPID A and C Phase 3 Trials

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Introduction
Chronic spontaneous urticaria (CSU) significantly impairs health-related quality of life (HRQoL). The Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) is the only validated disease-specific HRQoL instrument for chronic urticaria, capturing the multifaceted impact on patients' lived experience. In the LIBERTY-CSU CUPID Phase 3 trials, dupilumab significantly improved itch and hives in omalizumab-naïve patients with CSU inadequately controlled with H1 antihistamines. Here, we present a comprehensive item- and domain-level analysis of dupilumab's effect on CSU patients' quality of life, as measured by the CU-Q2oL.

Materials and Methods
This post-hoc analysis used pooled data from the CUPID Study A and C Phase 3 trials (NCT04180488) in omalizumab-naïve CSU patients inadequately controlled with H1 antihistamines. The CU-Q2oL is a disease-specific, 23-item, self-administered questionnaire (recall period: past 2 weeks) used to assess the physical, psychosocial, and practical aspects of HRQoL in patients with chronic urticaria. Each item is scored on a 5-point Likert scale (1 = not at all to 5 = extremely bothered/limited/experienced). The individual items are summed to generate an overall score ranging from 0 to 100 (higher scores indicate greater HRQoL impairment) and six domain scores. The changes from baseline in overall and domain-level scores at Week 24 were analyzed using an analysis of covariance (ANCOVA) model adjusted for baseline value, study, intervention group, presence of angioedema at baseline, and region. The proportion of patients reporting the most favourable outcome (i.e., “not at all”) for the pruritus and swelling domains and for each item at Week 24 was compared between dupilumab and placebo arms using the Cochran–Mantel–Haenszel test, adjusted for baseline disease severity, item, presence of angioedema, study, and region. All p-values were nominal.

Results
The pooled intent-to-treat (ITT) population comprised 289 patients (dupilumab n = 144; placebo n = 145). At baseline, the mean overall CU-Q2oL score was 41.1 (standard deviation [SD] 20.2), with treatment arms well balanced. The most impacted items at baseline were itch (item 1) and hives (item 2), for which 74.7% and 67.0% of patients reported being "very much" or "extremely" bothered, respectively, in pooled treatment groups. At

Week 24, dupilumab significantly improved the CU-Q2oL overall score versus placebo (least square [LS] mean difference: −5.27 [95% confidence interval [CI]: −9.33, −1.20]; p = 0.0111). Dupilumab demonstrated significant improvement in three domains: pruritus (LS mean difference: −12.78 [95% CI: −19.61, −5.95]; p = 0.0002), limits (−5.18 [95% CI: −9.52, −0.83]; p = 0.0196), and looks (−5.29 [95% CI: −9.62, −0.96]; p = 0.0166), with numerically favourable trends in sleep problems (−5.07 [95% CI: −10.20, 0.06]; p = 0.0529), impact on life activities (−3.93 [95% CI: −8.68, 0.81]; p = 0.1042), and swelling (−3.09 [95% CI: −6.61, 0.43]; p = 0.0849) domains (**Figure 1**). At Week 24, significantly more dupilumab-treated patients reported the most favourable outcome for the pruritus domain (itch and hives; p = 0.0012) and the swelling domain (swelling of the eyes and swelling of the lips; p = 0.0061) (**Figure 2**), and for 22/23 CU-Q2oL items (p < 0.05 for all items except "Work" where p = 0.0555) (**Table 1**).

Table 1. Proportion of patients reporting the most favorable outcome ("not at all") for Cu-Q2oL items at Week 24 – pooled ITT Population

Cu-Q2oL items	Placebo (N=145)	Dupilumab (N=144)	OR (95% CI) vs. placebo	P-value
CU-Q2oL1 – Itching	17 (11.7)	36 (25.0)	2.90 (1.48, 5.68)	0.0014
CU-Q2oL2 - Hives	32 (22.1)	58 (40.3)	2.71 (1.55, 4.76)	0.0004
CU-Q2oL3 - Swelling of the Eyes	89 (61.4)	109 (75.7)	2.19 (1.21, 3.96)	0.0077
CU-Q2oL4 - Swelling of the Lips	101 (69.7)	119 (82.6)	2.13 (1.15, 3.95)	0.0122
CU-Q2oL5 - Work	82 (56.6)	101 (70.1)	1.65 (0.98, 2.79)	0.0555
CU-Q2oL6 - Physical Activity	75 (51.7)	96 (66.7)	2.14 (1.24, 3.71)	0.0060
CU-Q2oL7 - Sleep	59 (40.7)	79 (54.9)	2.02 (1.21, 3.37)	0.0083
CU-Q2oL8 - Free Time	75 (51.7)	100 (69.4)	2.33 (1.39, 3.92)	0.0009
CU-Q2oL9 - Relationships with Other People	87 (60.0)	101 (70.1)	1.80 (1.07, 3.04)	0.0265
CU-Q2oL10 - Eating	93 (64.1)	108 (75.0)	1.79 (1.03, 3.09)	0.0345
CU-Q2oL11 - Difficulty Falling Sleep	54 (37.2)	70 (48.6)	1.86 (1.11, 3.12)	0. 0177
CU-Q2oL12 - Wake Up During the Night	45 (31.0)	61 (42.4)	1.82 (1.08, 3.07)	0.0237
CU-Q2oL13 - Tired Day Due to Lack of Sleep	49 (33.8)	72 (50.0)	2.35 (1.38, 4.01)	0.0013
CU-Q2oL14 - Difficulty Concentrating	61 (42.1)	84 (58.3)	2.05 (1.21, 3.45)	0.0067
CU-Q2oL15 - Feel Nervous	58 (40.0)	80 (55.6)	2.13 (1.22, 3.71)	0.0067
CU-Q2oL16 - Feel Down	70 (48.3)	84 (58.3)	1.89 (1.10, 3.23)	0.0165
CU-Q2oL17 - Limit Choice of Food	71 (49.0)	92 (63.9)	2.06 (1.20, 3.54)	0.0089
CU-Q2oL18 - Embarrassed Marks on Body	52 (35.9)	82 (56.9)	3.10 (1.76, 5.45)	<.0001
CU-Q2oL19 - Embarrassed to Go Out in Public	73 (50.3)	97 (67.4)	2.20 (1.31, 3.71)	0.0024
CU-Q2oL20 - Difficulty Using Cosmetics	71 (49.0)	95 (66.0)	2.30 (1.32, 4.00)	0.0031
CU-Q2oL21 - Affected Choice of Clothing	66 (45.5)	86 (59.7)	1.93 (1.15, 3.25)	0.0122
CU-Q2oL22 - Limit Sports	75 (51.7)	96 (66.7)	1.82 (1.06, 3.15)	0.0278
CU-Q2oL23 - Bothered by Side Effects	81 (55.9)	102 (70.8)	2.09 (1.21, 3.63)	0.0074

Figure 1. LS Mean improvement from Baseline in CU-Q2oL Domain Scores at Week 24 – pooled ITT Population

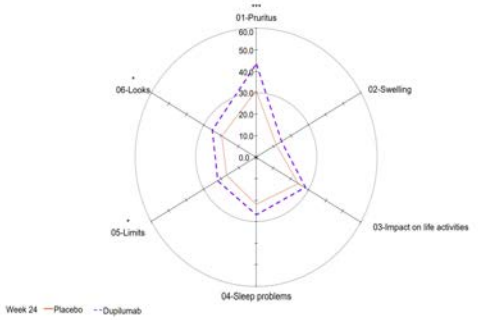
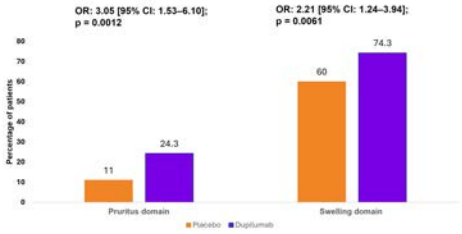


Figure 2. Proportion of patients reporting the most favorable outcome for the pruritus and swelling domains at Week 24 – pooled ITT population



Note: ***p < 0.001; *p < 0.05 vs. placebo. p-values are nominal. Abbreviations: CI, confidence interval; CU-Q2oL, Chronic Urticaria Quality of Life Questionnaire; ITT, intent-to-treat; OR, odds ratio

Conclusions

Dupilumab significantly improved overall disease-specific HRQoL in patients with CSU inadequately controlled with H1 antihistamines, with significant or numerical improvement seen across all six CU-Q2oL domains. Notably, dupilumab treatment resulted in significantly more patients reporting the most favourable outcome in the pruritus domain (consistent with Phase 3 primary data) and the swelling domain (suggesting efficacy on angioedema). These findings demonstrate dupilumab's comprehensive impact on CSU's multidimensional burden, addressing both physical symptoms and psychosocial well-being.

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Abstract N°: 3371

Chronic Spontaneous Urticaria: Retrospective Real-World Characterization of Patients Receiving Omalizumab for ≥5 Years

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Introduction
Chronic spontaneous urticaria (CSU) is a mast cell–driven inflammatory disease with a substantial impact on quality of life. Omalizumab is recommended as third-line therapy for antihistamine-refractory CSU, yet most evidence reflects short-to-mid-term follow-up. Real-world data describing patients who require very long omalizumab treatment courses (≥5 years) are limited. Characterising this subgroup may help inform individualized long-term management strategies.

Materials and Methods
Single-centre retrospective observational review of adults with CSU treated with omalizumab for ≥5 years. Data were extracted from routine medical records (no patient contact, interventions, blood sampling or study-specific testing). Collected variables included demographics, omalizumab exposure duration, recorded dose escalation, ongoing need for H1-antihistamines, file-documented comorbidities/autoimmunity, and available routine laboratory parameters (total IgE, CRP, eosinophils, basophils, D-dimer and others when present).

Results
Thirty-two patients were included (female 21/32, 65.6%); mean age was 52.62±15.55 years. Mean omalizumab exposure was 7.62±2.41 years (range 5–14), and 9/32 (28.1%) had received omalizumab for ≥10 years. Total IgE was heterogeneous (mean 656.84±552.88 IU/mL; range 4.76–2243.00); IgE was >300 IU/mL in 25/32 (78.1%) and >1000 IU/mL in 9/32 (28.1%). Notably, all patients in the ≥10-year subgroup had IgE >300 IU/mL (9/9, 100%). CRP was generally low (mean 2.61±2.40 mg/L; range 0.25–10.00), with CRP >5 mg/L in 5/31 (16.1%). Dose escalation (3×150–4×150 mg) was recorded in 3/32 (9.4%), and regular H1-antihistamine use persisted in 13/32 (40.6%). File documentation included associated findings such as thyroid disease (n=4), anti-TPO elevation (n=1), ANA/RF positivity (n=4) and Helicobacter pylori/antral gastritis (n=4).

Table 1. Demographic and laboratory characteristics

Parameter	N	Value / Mean ± SD (Min-Max)	Parameter	N	Value / Mean ± SD (Min-Max)
Sex (Female/Male)	32	21 Female (65.6%) / 11 Male (34.4%)	Basophils (×10³/µL)	30	0.04 ± 0.03 (0.00–0.13)
Age (years)	32	52.62 ± 15.55 (25–89)	CRP (mg/L)	31	2.61 ± 2.40 (0.25–10.00)
Omalizumab exposure (years)	32	7.62 ± 2.41 (5–14)	ESR (mm/h)	26	20.23 ± 12.16 (4.00–45.00)
Total IgE (IU/mL)	32	656.84 ± 552.88 (4.76–2243.00)	LDH (U/L)	20	188.60 ± 49.86 (134.00–344.00)
WBC (×10³/µL)	31	7.65 ± 2.20 (3.67–13.31)	TSH (mIU/L)	30	1.77 ± 0.94 (0.14–4.10)
Eosinophils (×10³/µL)	31	0.20 ± 0.21 (0.00–1.00)			

Values are derived from routine clinical records; N varies due to missing data.

Conclusions

A meaningful subset of CSU patients required prolonged omalizumab therapy. Elevated IgE was common while CRP remained generally low, supporting clinical–biological heterogeneity among long-term treated CSU patients. Larger studies with standardized documentation of discontinuation attempts and relapse outcomes are needed to clarify biomarkers associated with long-term treatment persistence.

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Abstract N°: 3439

Urticaria Burden in Caribbean Island Jurisdictions and North America: A Comparative Global Burden of Disease Analysis, 1990–2023

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Introduction

Urticaria (ICD-10: L50) is a recurrent inflammatory skin disease imposing substantial non-fatal morbidity, yet standardized comparative epidemiological data for Caribbean Island jurisdictions remain limited. No prior study has used Global Burden of Disease (GBD) estimates to compare the burden of urticaria across Caribbean Small Island Developing States (SIDS), large Caribbean Island jurisdictions, and North American comparators over three decades.

Materials and Methods

A retrospective ecological comparative analysis using GBD 2023 modelled estimates (IHME) was conducted. Seventeen locations were classified a priori as Caribbean SIDS/small island jurisdictions (n=10: Antigua and Barbuda, Bahamas, Barbados, Bermuda, Dominica, Grenada, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Trinidad and Tobago); large Caribbean island jurisdictions (n=5: Cuba, Dominican Republic, Haiti, Jamaica, Puerto Rico); and North American comparators (n=2: Canada, United States). Primary outcomes were 2023 age-standardized rates (ASRs) per 100,000 for prevalence, incidence, YLDs, and DALYs (combined for both sexes). Secondary analyses included sex-specific ASRs, age-specific rates (0–14, 15–49, 50+ years), the 1990–2023 percent change, and the estimated annual percentage change (EAPC) estimated via log-linear regression. No formal significance testing was applied as GBD estimates are modelled population data.

Results

In 2023, mean prevalence ASRs were 1,107.0 per 100,000 in Caribbean SIDS/small island jurisdictions, 1,108.0 in large Caribbean Island jurisdictions, and 1,227.0 in North American comparators (Canada 1,230.1, 95% UI 1,085.4–1,405.2; United States 1,223.9, 95% UI 1,079.6–1,399.2). Caribbean groups had prevalence ASRs approximately 0.90 times those of North American comparators and were nearly indistinguishable from each other (SIDS-to-large-island ratio 0.999). Mean YLD and DALY ASRs were identical within each group (Caribbean ~66.6; North America 73.5), confirming a non-fatal burden. Estimated total prevalent cases in 2023 were 4,450,107: North America 3,983,374; large Caribbean islands 440,415; Caribbean SIDS 26,318. Age-specific analysis showed nearly threefold higher prevalence in children aged 0–14 than in working-age adults (1,931–1,973 vs 734–968 per 100,000). The North American excess was concentrated in adults aged 15–49, where the female-to-male ratio reached 2.40, compared with 1.35 across Caribbean jurisdictions at all ages. Group-level F:M ratios were 1.51 (North America) and 1.35 (Caribbean) and remained stable over the 33-year period. All jurisdictions showed a decline in EAPC (range: −0.004% to −0.019%/year). Post-2010 trajectories diverged: North American EAPC accelerated (−0.018%/year), Caribbean SIDS remained stable (−0.008%/year), and large Caribbean islands stalled (≈0.000%/year). Bahamas (+0.001%/year) and Saint Kitts and Nevis (+0.007%/year) were the only jurisdictions with statistically supported increasing trends.

Conclusions

Urticaria burden was approximately 10% lower in Caribbean Island jurisdictions than in North American comparators, remained highly stable over three decades, and was almost entirely disability driven. Smaller Caribbean SIDS and larger Caribbean Island jurisdictions showed near-identical modelled ASRs. The geographic excess was concentrated among working-age adult females (North American F:M 2.40 vs. Caribbean 1.35 at ages 15–49), suggesting that healthcare access factors, rather than disease biology, drive the regional gradient. Post-2010 stalling of burden reduction in large Caribbean islands and increasing trends in two SIDS warrant targeted dermatological surveillance and healthcare investment. These findings provide a standardized benchmark for urticaria epidemiology in the Caribbean and a foundation for future research on allergic skin disease.

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Abstract N°: 3474

Unidirectional causal link between autoimmune thyroid disease and chronic spontaneous urticaria: evidence from a prospective cohort and Mendelian randomization study

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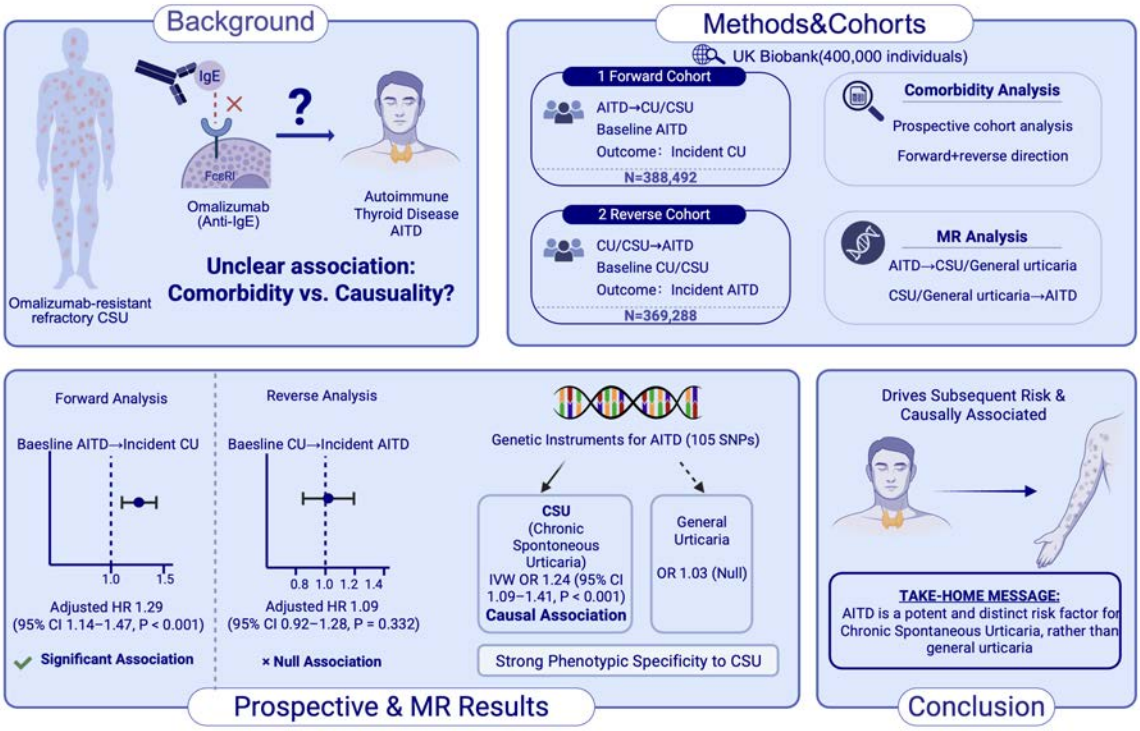
Introduction
Chronic spontaneous urticaria (CSU) is a heterogeneous inflammatory skin disorder in which autoimmune mechanisms are implicated in a clinically relevant subset of patients. Autoimmune thyroid disease (AITD) is one of the most consistently reported autoimmune comorbidities of CSU. However, it remains unclear whether this association reflects shared susceptibility, reverse causation, non-specific autoimmune comorbidity, or a directional relationship. Clarifying this issue may improve autoimmune endotype stratification in CSU and provide insight into comorbidities relevant to disease course and treatment response.

Materials and Methods
We used an integrated dual-track design combining prospective cohort analysis with bidirectional two-sample Mendelian randomisation. In the observational arm, approximately 400,000 participants from the UK Biobank were analysed to assess the temporal association between baseline AITD and incident chronic urticaria. To preserve statistical power in real-world coding data, chronic urticaria was used as the primary cohort outcome, while a more strictly defined CSU proxy was examined in sensitivity analyses. The reverse association, from baseline chronic urticaria to incident AITD, was also evaluated. In parallel, bidirectional Mendelian randomisation analyses were performed to test the potential causal direction between AITD and CSU. Additional analyses assessed whether the genetic association was specific to CSU or extended to general urticaria.

Results
In the prospective cohort, baseline AITD was significantly associated with an increased risk of incident chronic urticaria after covariate adjustment. In contrast, there was no clear evidence supporting the reverse temporal association, as baseline chronic urticaria was not significantly associated with subsequent AITD. Sensitivity analyses restricted to the more specific CSU proxy showed directionally consistent estimates, although with reduced precision. In the genetic analyses, genetically predicted AITD was associated with an increased risk of CSU, whereas genetically predicted CSU did not support a causal effect on AITD. Importantly, the association of genetically predicted AITD was specific to CSU rather than general urticaria, suggesting phenotypic specificity in the relationship between thyroid autoimmunity and CSU. Together, the observational and genetic findings provided complementary evidence supporting a unidirectional relationship from AITD to CSU.

Conclusions
By integrating large-scale prospective cohort data with bidirectional Mendelian randomisation, this study supports a unidirectional relationship from AITD to chronic urticaria/CSU. These findings suggest that thyroid autoimmunity may represent an upstream autoimmune determinant relevant to CSU pathogenesis, rather than merely a coincidental comorbidity or consequence of chronic urticaria. The observed phenotypic specificity for CSU further supports the relevance of AITD to the autoimmune endotype of CSU. Further studies are required to validate these findings in independent cohorts and to clarify the biological mechanisms linking thyroid autoimmunity to CSU.



Graphical abstract summarising the study design and main findings.

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Abstract N°: 3484

The Urticaria Care Package and its role in improving chronic spontaneous urticaria management: findings from the BRIDGE implementation study

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Introduction
Chronic spontaneous urticaria (CSU) is frequently diagnosed late, particularly in general practice. Current international guidelines recommend the systematic use of patient-reported outcomes (PROs) to assess disease activity, disease control, and health-related quality of life, thereby supporting treatment decisions and escalation. However, despite these recommendations and the availability of effective therapies, approximately half of patients remain uncontrolled, and PROs are underused in routine care. To address these gaps, the Urticaria Care Package (UCP), an educational package, was developed.

Materials and Methods
The UCP comprised specialist-led training sessions for general practitioners (GPs), supported by educational resources on CSU and PRO assessment, as well as practical guidance on referral pathways. The CSU training modules addressed key topics including disease definition and classification, pathophysiology and diagnosis, disease burden, patient journey, and the use of PRO instruments (Urticaria Activity Score, Urticaria Activity Score 7, Urticaria Control Test, and the Dermatology Life Quality Index). Live training sessions were offered over a two-month period, from August to October 2024, and all materials remained accessible to GPs until April 2025. The effectiveness of the UCP as an implementation strategy to increase routine PRO use and improve CSU care was assessed in the BRIDGE study involving GPs and specialists from the Lombardy region (Italy). The participants completed a self-administered online survey before (pre-UCP; 95 GPs, 2 specialists) and after (post-UCP; 92 GPs, 2 specialists) UCP adoption. Primary endpoints were the changes from pre- to post-UCP in PRO assessment, patient management, and referral practices. Secondary endpoints further examined attitudes toward PROs, the core component of the UCP, and additional UCP outcomes, including feasibility, acceptability, and appropriateness.

Results
Eighty-seven participants completed both surveys. From pre- to post-UCP, the routine use of PROs increased substantially (absolute increase: 41.4%), as did the use of CSU-specific PROs (absolute increase: 46.0%). The

number of patients diagnosed with suspected CSU remained stable, while the proportion referred to specialists decreased, suggesting greater GP confidence in diagnosing and managing CSU. Implementation outcomes (Table 1) indicated broad agreement on the value of using PROs in clinical practice, particularly in decision making, monitoring patient condition and assessing their response to treatment. At both survey timepoints, however, approximately half of participants reported insufficient time to use PROs in routine CSU care. Feasibility and appropriateness of the UCP were rated as moderate. Notably, more than 60% of GPs considered PRO use compatible with their workflow, at both assessments. Additional potential barriers to UCP implementation included limited leadership support, suboptimal implementation climate, low prioritization of changing CSU care among GPs, and patient willingness to complete PROs. Overall, knowledge and awareness of CSU improved substantially from pre- to post-UCP (Table 2). The proportion of GPs reporting low CSU knowledge decreased, while those indicating adequate knowledge and experience increased. Awareness of CSU guidelines among GPs rose markedly.

Table 1. Main implementation outcomes of the Urticaria Care Package (UCP) evaluated in the BRIDGE study[1]

	Pre-UCP	Post-UCP
Benefits of PROs for CSU care, n/N (%)[2]		
• Agreed/strongly agreed that using PROs would help make clinical decisions about their patients	55/90 (61.1%)	64/87 (73.5%)
• Agreed/strongly agreed that using PROs would help monitor patient condition	62/90 (68.9%)	68/87 (78.2%)
• Agreed/strongly agreed that using PROs would help monitor patient response to treatment	62/90 (68.9%)	70/87 (80.4%)
• Agreed/strongly agreed that using PROs would help monitor the quality of care	56/90 (62.2%)	57/87 (65.5%)
Barriers to or disadvantages of using PROs, n/N (%)[3]		
• Disagreed/strongly disagreed that PROs for CSU are not relevant to their clinical decisions	49/90 (54.4%)	63/87 (72.4%)
• Agreed/strongly agreed with not having enough time to use PROs for CSU	51/90 (56.7%)	46/87 (52.9%)
• Disagreed/strongly disagreed that PROs for CSU do not provide any additional information	60/90 (66.7%)	70/87 (80.5%)
• Disagreed/strongly disagreed that PROs for CSU may have a negative impact on their relationship with patients	65/90 (72.2%)	69/87 (79.3%)
Feasibility of implementing PROs for CSU, mean FIM score (SD)[4]	3.6 (0.57)	3.5 (0.61)
Appropriateness of implementing PROs for CSU, mean IAM score (SD)[5]	3.6 (0.63)	3.6 (0.65)

Table 2. Knowledge and awareness of chronic spontaneous urticaria (CSU) before and after the adoption of the Urticaria Care Package (UCP)[1]

	Pre-UCP	Post-UCP
GPs reporting little knowledge of CSU	55/95 (57.9%)	19/92 (20.7%)
GPs reporting knowledge and experience managing patients with CSU	18/95 (18.9%)	40/92 (43.5%)
GPs reporting awareness of CSU guidelines	37/95 (38.9%)	89/92 (96.7%)

Table 1. 1The table reports the attitudes of the general practitioners surveyed at both timepoints, pre-UCP (N=90) and post-UCP (N=87). 2Participants in the BRIDGE study were asked to indicate the extent to which they agreed or disagreed with several statements about the benefits of using PROs for CSU in clinical practice in the 6 months prior to the availability of the UCP and in the 6 months following UCP introduction. 3Participants in the BRIDGE study were asked to indicate the extent to which they agreed or disagreed with several statements about the barriers to or disadvantages of using PROs for CSU in clinical practice in the 6 months prior to the availability of the UCP and in the 6 months following UCP introduction. 4The FIM score consists of four statements, with response options ranging from “completely disagree” to “completely agree”. It is calculated by averaging the responses to the four statements. Scores closer to 0 indicate lower perceived feasibility of the intervention, while scores closer to 4 indicate higher perceived feasibility. 5The IAM score consists of four statements, with response rates ranging from “completely disagree” to “completely agree”. It is calculated by averaging the responses to the four statements. Scores closer to 0 indicate lower perceived appropriateness of the intervention, while scores closer to 4 indicate higher perceived appropriateness. Abbreviations: CSU, chronic spontaneous urticaria; FIM, Feasibility of Intervention Measure; IAM, Intervention Appropriateness Measure; PROs, patient-reported outcomes; SD, standard deviation; UCP, Urticaria Care Package. Table 2. 1The table summarizes additional results from the BRIDGE study obtained by asking GPs about their knowledge of CSU management before (N=95) and after (N=92) UCP implementation. Abbreviations: CSU, chronic spontaneous urticaria; GPs, general practitioners;

UCP, Urticaria Care Package.

Conclusions

This study shows an increase in PRO use among GPs and their patients post UCP implementation. The reduction in referrals to specialists suggests greater GP confidence in independently managing CSU. Implementation outcomes indicate that PRO use for CSU is moderately feasible and appropriate, although real-world barriers, particularly limited time, may hinder routine adoption. Strengthening leadership support, optimizing workflows, and providing targeted training may help sustain and expand these improvements.

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Abstract N°: 3506

Cytokine profiling reveals marked inter-individual immune heterogeneity in chronic spontaneous urticaria: Early findings of the MECSU project

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Introduction

Chronic spontaneous urticaria (CSU) is a heterogeneous inflammatory skin disease with incompletely understood immunological mechanisms. The Molecular Endotyping and Clustering of Chronic Spontaneous Urticaria by Serum Cytokine Profiling (MECSU) project aims to define molecular CSU endotypes through comprehensive cytokine profiling and integration with clinical, autoallergic, and autoimmune parameters. A major objective of the MECSU study is to determine whether specific autoimmune endotypes are characterized by distinct cytokine profiles.

Materials and Methods

Serum samples from sex and gender matched adult patients with CSU and healthy controls (HCs) were analyzed for cytokines, autoantibodies and other potential biomarkers. A 45-plex cytokine immunoassay was used to evaluate Th1/ Th2-, Th9/ Th17/ Th22/ Treg-associated cytokines, inflammatory cytokines, chemokines, and growth factors. IgE-anti-TPO, IgE-anti-IL-24, IgG-anti-FcεRI and IgG-anti-IgE were assessed by ELISA and total IgE and IgG-anti-TPO by ImmunoCAP. Mast cell activation tests (MAT), blood counts, inflammatory markers, and patient-reported outcome measures were also evaluated.

Results

In total, samples from 227 CSU patients and 180 HCs were analyzed (female rate 72.2% vs. 67.2%, median age 41.0 vs. 39.0). Fifty-four of 226 CSU patients (23.9%) were classified as MAT-positive using the 95th percentile of 180 healthy controls as cut-off. Compared with HCs, our unbiased CSU cohort exhibited heterogeneous circulating cytokine signatures. Several cytokines, including LIF, IP-10/CXCL10, BDNF, RANTES/CCL5, EGF, Eotaxin/CCL11, PDGF-BB, IL-8/CXCL8, SDF-1α, IL-7, IL-12p70, HGF, PlGF-1 and FGF-2, differed significantly between CSU and HCs (all $p<0.05$), with lower serum levels observed in CSU patients. Subsets of CSU patients showed cytokine levels above HC-derived 95th percentile cut-offs, most frequently for IL-1RA (27/227, 11.9%), IL-15 (24/227, 10.6%), IL-1α and IL-21 (each 17/227, 7.5%), IL-10, IL-27 and MCP-1/CCL2 (each 16/227, 7.0%), IFN-α and TNF (each 13/227, 5.7%), and IL-31 and IL-17A (each 12/227, 5.3%).

Conclusions

The MECSU project revealed heterogeneous circulating cytokine, chemokine, and growth-factor signatures in CSU.

While group-level differences were observed between CSU patients and healthy controls, distinct patient subsets showed elevations in selected inflammatory mediators above HC-derived cut-offs, suggesting biologically diverse inflammatory patterns within CSU. Principal component analysis will be performed to identify meaningful clusters linking clinical features, CSU endotypes, and cytokine profiles.

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Abstract N°: 3525

Sequential urticarial vasculitis and scar sarcoidosis revealing systemic sarcoidosis in a patient with omalizumab-refractory chronic urticaria

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Introduction

Chronic urticaria refractory to up-titrated anti-IgE therapy may warrant reconsideration of the diagnosis, with urticarial vasculitis (UV) representing an important mimicker. Scar sarcoidosis, in which non-caseating granulomas infiltrate pre-existing scars, frequently heralds systemic disease. The sequential occurrence of these two entities in a single patient has, to our knowledge, not been previously reported.

Case Presentation

A 45-year-old woman presented with a 4-month history of chronic urticaria and angioedema, refractory to four-fold up-titrated H1-antihistamines. Omalizumab was initiated and sequentially up-titrated to 600 mg every 4 weeks, but attacks continued. Lesional biopsy with direct immunofluorescence demonstrated leukocytoclastic vasculitis consistent with normocomplementaemic UV. Colchicine 0.5 mg three times daily was added to ongoing omalizumab, achieving complete remission within one month. Subsequently, the patient developed asymptomatic erythematous, infiltrated plaques restricted to a 30-year-old traumatic scar on the forehead and glabella. Serum angiotensin-converting enzyme was elevated and chest radiography revealed bilateral hilar lymphadenopathy. Repeat biopsy of the scar plaque demonstrated non-caseating epithelioid granulomas, consistent with scar sarcoidosis. The patient was diagnosed with systemic sarcoidosis and remains under multidisciplinary follow-up.

Conclusion

The sequential emergence of normocomplementaemic UV and subsequent scar sarcoidosis during ongoing anti-IgE therapy is, to our knowledge, unreported. We interpret the sequence as two manifestations of a shared Th1/Th17-biased inflammatory diathesis rather than a drug-induced phenomenon: immune-complex leukocytoclastic vasculitis can precede or accompany sarcoidosis in 30–40% of sarcoid-vasculitis cohorts. The 30-year-old traumatic scar likely provided a Koebner-type antigenic nidus for localised granulomatous expression. Although anti-IgE therapy has been listed among rarely-reported drugs in pharmacovigilance signals of sarcoidosis, the only mechanistic precedent was attributed to corticosteroid withdrawal, a mechanism that does not apply here, as our patient never received systemic steroids.
This case suggests UV and scar sarcoidosis can co-segregate in a sarcoid-susceptible host independently of biologic therapy, and exemplifies how new infiltrated lesions on long-standing scars can serve as a critical clue heralding systemic sarcoidosis. Re-biopsying refractory urticaria and investigating new lesions on long-standing scars remain essential diagnostic steps.

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Abstract N°: 3624

Continued improvement of quality of life with remibrutinib in patients with chronic spontaneous urticaria from the 24 week-long randomized withdrawal period of REMIXED extension study

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Introduction

Chronic spontaneous urticaria (CSU) is characterized by spontaneous occurrence of itch and wheals (hives) and/or angioedema lasting >6 weeks without any identifiable triggers.[1] Over 50% of patients with CSU remain symptomatic despite second-generation H1-antihistamines and continue to live with unpredictable and distressing symptoms, which negatively impact their quality of life. Remibrutinib, an oral highly-selective Bruton's tyrosine kinase inhibitor, has shown fast and sustained efficacy across 3 core phase 3 studies (REMIX-1, REMIX-2, and BISCUIT) in patients with CSU who remain symptomatic despite treatment with second-generation H1-antihistamines.[2-4] In the phase 3b REMIXED extension study, patients receiving remibrutinib had a 72% lower risk of relapse than those receiving placebo during the randomized withdrawal period. Here, we report the impact of

remibrutinib on Dermatology Life Quality Index (DLQI) total score during the randomized withdrawal period of REMIXED.

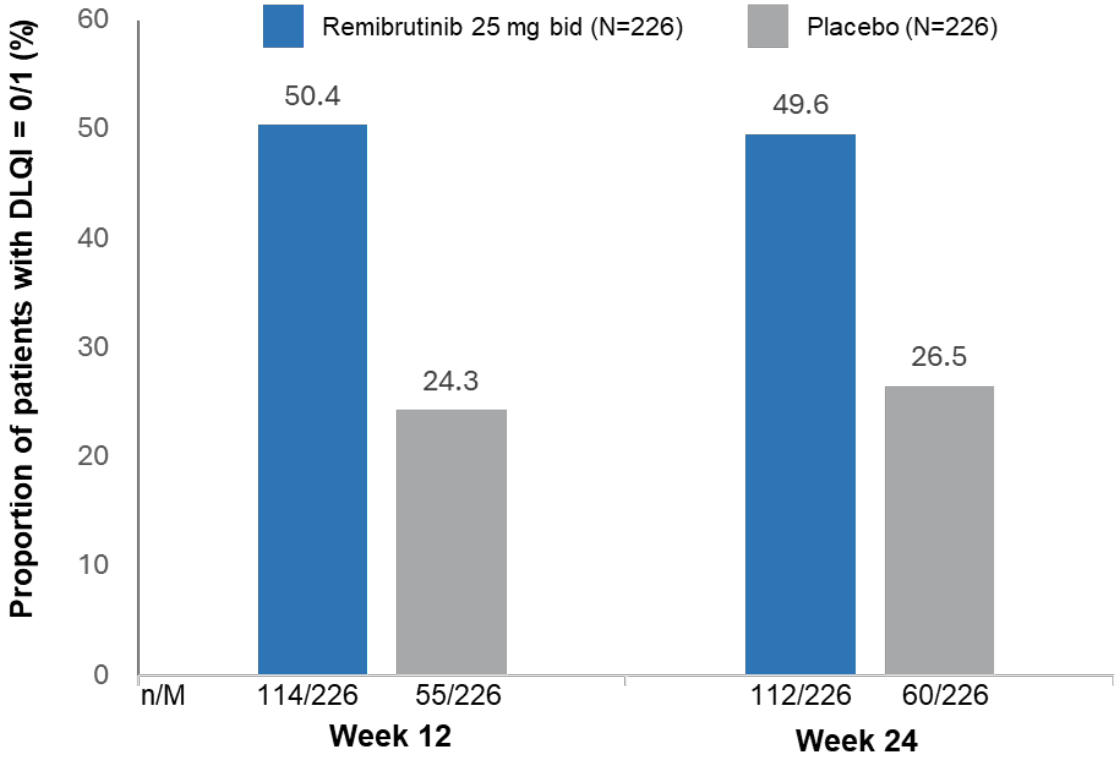
Materials and Methods

The REMIXED study is a phase 3b, multicentre, double-blind, placebo-controlled randomised withdrawal and open-label extension study (NCT05513001). Patients with CSU who had completed the remibrutinib core phase 3 studies with a mild disease or better (weekly Urticaria Activity Score [UAS7] <16) were randomised 1:1 to receive remibrutinib 25 mg twice daily or placebo for 24 weeks (randomised withdrawal period). Those who experienced a relapse (UAS7 ≥16, or study treatment discontinuation due to lack of efficacy or first intake of prohibited medication) during this period were switched to open label remibrutinib. DLQI, an exploratory endpoint, was assessed at baseline, week 12 and 24. Data were analysed descriptively (week 12 and 24; presented as mean ± standard deviation [SD] or percentage) and by logistic regression (week 24; presented as odds ratio [OR] and 95% CI). Analysis was performed based on non-responder imputation for binary endpoints (DLQI = 0/1; yes/no).

Results

The randomized withdrawal period included a total of 454 patients (227 remibrutinib; 227 placebo). The mean age was 47.3 years in the remibrutinib arm and 46.6 years in placebo arm. Females comprised approximately two-thirds of the study population. Mean (SD) DLQI at core study baseline was 14.1 (7.3) in the remibrutinib arm and 13.6 (6.8) in the placebo arm in pooled REMIX-1/-2, and 8.3 (5.2) in the remibrutinib arm in BISCUIT. At REMIXED study baseline, all patients were on remibrutinib 25 mg (core study treatment at rollover), with a mean (SD) DLQI score of 2.34 (3.91) in those randomised to remibrutinib and 2.61 (4.08) in those randomised to placebo, indicating a small impact of patient's quality of life. At Week 24, the percentage of participants achieving DLQI = 0/1 response was higher in the remibrutinib arm compared to the placebo arm [49.6% vs 26.5%; OR=2.87 (95% CI: 1.87, 4.41), one-sided p-value <0.001; non-responder imputation] indicating a treatment effect in favour of the continued remibrutinib treatment compared to the placebo arm; **Figure**). Adverse events reported in 42.5% vs 37.6% of patients on remibrutinib versus those on placebo, however, with longer median exposure to remibrutinib (24.0 weeks) than placebo (15.6 weeks).

Figure: Proportion of patients achieving DLQI = 0/1 up to Week 24 (non-responder imputation)



n, number of patients who respond; M, total number of patients with response variable available; N, total number of patients in the corresponding treatment arm; DLQI, Dermatology Life Quality Index; RT, re-treatment; RW, randomized withdrawal
This analysis was performed based on a non-responder imputation method; participants were imputed with non-response in RW period when they moved to the RT period after relapse or discontinued treatment in the RW period or with missing values.

Conclusions

In REMIXED study, patients receiving continued remibrutinib treatment maintained better quality of life as compared to those who switched to placebo, with a safety profile consistent with the REMIX-1/-2 studies.

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Abstract N°: 3795

Ciclosporin in Chronic Spontaneous Urticaria: An Ambispective Multicenter UCARE SCOPUS-C Study

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Introduction
Ciclosporin is recommended as a third-line treatment for chronic spontaneous urticaria (CSU) in patients unresponsive to high-dose antihistamines and omalizumab. Although its efficacy is well established, real-world data on safety, treatment patterns, and long-term outcomes—including remission and relapse after discontinuation—remain limited. The objective of the SCOPUS-C study is to evaluate the real-world effectiveness and safety of ciclosporin in patients with CSU treated across Urticaria Centers of Reference and Excellence (UCARE) centers, to assess remission and relapse patterns following treatment cessation, and to identify clinical and laboratory factors associated with (i) response to ciclosporin and (ii) remission and relapse after discontinuation.

Materials and Methods
This is an ambispective, global multicenter study ofadult patients with antihistamine- and/or omalizumab-refractory CSU. Anonymized datasets comprised demographic and clinical characteristics, prior treatments, and laboratory parameters prior to ciclosporin initiation. Disease activity and control were assessed using validated Patient-Reported Outcome Measures (PROMs), Urticaria Control Test (UCT), Dermatology Life Quality Index (DLQI), Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL), Angioedema Control Test (AECT), Angioedema Quality of Life Questionnaire (AE-QoL) and physicians` global assessment of treatment response. Laboratory data included total IgE, eosinophils, basophils, CRP, anti-TPO IgG, ANA, D-dimer, and basophil testing where available. Patients were followed during treatment (up to 6 months) and after ciclosporin discontinuation (≥1 follow-up at 3–12 months). Treatment response, adverse events, relapse after discontinuation, and sustained remission were evaluated. CSU was defined as poorly controlled (Urticaria Control Test, UCT<12) or well controlled (UCT≥12).

Results
In total, 480 CSU patients from 26 UCAREs and 18 countries were included at baseline and initiated treatment with ciclosporin (female: 77.5%, median age: 44 [34-54] years, median UCT: 6 [4-8]). The median starting dose was 3 (2.0-3.1) mg/kg/d, and the mean treatment duration was 8.2 months. Among them, 62.4% (186/298), 84.1% (206/245), and 83.9% (161/192) achieved well-controlled or completely controlled CSU (UCT≥12) at 1, 3, and 6 months, respectively. At 1 month of treatment, patients with well controlled disease vs. those with poorly controlled disease had shorter baseline disease duration (mean rank: 134.9 vs. 156.48, p=0.032; CSU duration less than 2 years: 53.8% (100/186) vs. 39.3% (44/112), p=0.017), less frequent nocturnal symptoms (53.8 (70/130) vs. 68.7% (57/83), p=0.033) and tended to receive higher starting dose of ciclosporin (mean rank: 152.23 vs. 134.0, p=0.069). Adverse events within the first month of treatment were reported in 12.3% (59/478) of patients, most commonly GI symptoms (n=22), creatinine increase (n=17), and hypertension (n=14), leading to treatment discontinuation in 40.7% (n=24/59) of patients. Three months after ciclosporin withdrawal, 43.4% (118/272) of patients had complete disease control, 33.5% (91/272) showed 90% improvement as compared to baseline disease control, 16.9% (46/272) had 30-90% improvement, and 6.3% (17/272) had poorly controlled disease. Patients with complete CSU control without treatment (remission) showed shorter baseline CSU duration as compared with patients with active disease (mean rank: 120.3 vs. 139.8, p=0.038).

Conclusions

In this large real-world UCARE cohort, ciclosporin showed substantial effectiveness in patients with difficult-to-treat CSU, with many achieving sustained remission after treatment discontinuation. These findings suggest that ciclosporin might contribute to disease modification in selected individuals, particularly when initiated early in the disease course—a hypothesis that warrants further investigation. Ongoing analyses of the SCOPUS-C follow-up data aim to clarify this potential and identify predictors of CSU remission.

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Abstract N°: 4006

Lifestyle Matters for Having CSU—But Does Not Influence Disease Control or Treatment Response: Findings from a large, controlled, multi-national cohort - RIFA-CU UCARE Study

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Introduction

Chronic spontaneous urticaria (CSU) is a mast cell–mediated inflammatory skin disease characterized by the spontaneous recurrence of wheals and/or angioedema lasting for more than six weeks. While several autoimmune, infectious, and metabolic mechanisms have been proposed, the exact underlying causes leading to disease manifestation remain insufficiently understood.

In the present study, we report the results of the Risk Factors and Lifestyle in Chronic Urticaria (RIFA-CU) study, conducted at participating Urticaria Centers of Reference and Excellence (UCARE) worldwide. We specifically investigate the role of lifestyle factors — including diet, physical activity, stress, smoking and alcohol consumption — on disease onset, symptom control, and treatment response in patients with CSU.

Materials and Methods

The RIFA-CU study is a prospective, controlled, international, multicenter observational project conducted globally across the UCARE network. The study enrolled adults (≥18 years) diagnosed with CSU, chronic inducible urticaria (CINDU), or both, alongside age- and sex-matched healthy controls. For this analysis only patients with CSU were included. Comprehensive data were gathered via standardized questionnaires, including the Simple Lifestyle Indicator Questionnaire (SLIQ) to assess lifestyle patterns. Disease control was evaluated using the Urticaria Control Test (UCT), with well-controlled disease defined as a score of ≥ 12 and uncontrolled disease as < 12.

Furthermore, blood samples were analyzed to determine various immunological and inflammatory biomarkers. Associations between SLIQ scores and disease-related characteristics, laboratory parameters, treatment responses, and disease endotypes were assessed. Multivariable analyses were performed to identify factors independently associated with SLIQ domain scores in patients with CSU. Categorical variables were compared using chi-square

tests, while continuous variables were compared using Kruskal–Wallis tests, as appropriate.

Results

A total of 1,364 CSU patients and 1,451 controls were analyzed. CSU patients were predominantly female (71%) and slightly older than controls (mean ± SD, 39.85 ± 14.18 vs 38.11 ± 13.49 years; $p<0.01$). Compared to controls, CSU patients exhibited a less favorable lifestyle profile, with a higher proportion in the unhealthiest diet category (48.1% vs 38.7%), lower engagement in vigorous physical activity (25.7% vs 35.8%), and higher stress levels (56.3% vs 45.5%) (all $p<0.001$). Smoking patterns differed slightly between groups with a higher proportion of current smokers among CSU patients compared to controls (29.4% vs 25.8%, $p=0.020$), while alcohol consumption did not differ (1.0% vs 0.5% reporting higher intake; $p=0.103$). Importantly, lifestyle factors were not associated with treatment response to antihistamines or omalizumab, and SLIQ scores were similar between controlled and uncontrolled patients. Correlation analyses demonstrated only weak associations between lifestyle factors and biomarkers, with limited links to inflammatory or immunologic parameters. More details about multivariable analysis will be provided during presentation.

Conclusions

These findings suggest that lifestyle factors are associated with disease presence but do not meaningfully influence disease control, treatment response, or underlying biological activity in CSU.

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Abstract N°: 4014

Urticaria Voices China study: Patient self-reported treatment patterns associated with Chronic Spontaneous Urticaria

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Introduction
Chronic spontaneous urticaria (CSU) causes recurrent episodes of itchy wheals (hives) and/or angioedema lasting beyond 6 weeks without identifiable triggers. CSU affects 1.3% of China's population and places significant physical and psychological burden on individuals, negatively impacting their quality of life. Although current research about CSU in China primarily focuses on epidemiological information, it lacks comprehensive insights from patients themselves. As a result, there is still a gap in understanding real-world patient experiences and outcomes. Here, we evaluated the patients' perspectives on different treatments offered to manage their CSU.

Materials and Methods
The Urticaria Voices (UV) China study is a non-interventional, cross-sectional, 40-minute online survey of patients with Chronic Urticaria (CU) and CU-treating physicians in China. This analysis focuses on Chinese patients aged ≥18 years with physician-confirmed CSU, recruited through multiple channels, including online panels and remunerated as per fair market value. Each patient provided an informed consent documented electronically before taking the survey. Observed data were analysed descriptively and reported as mean (standard deviation) or percentage.

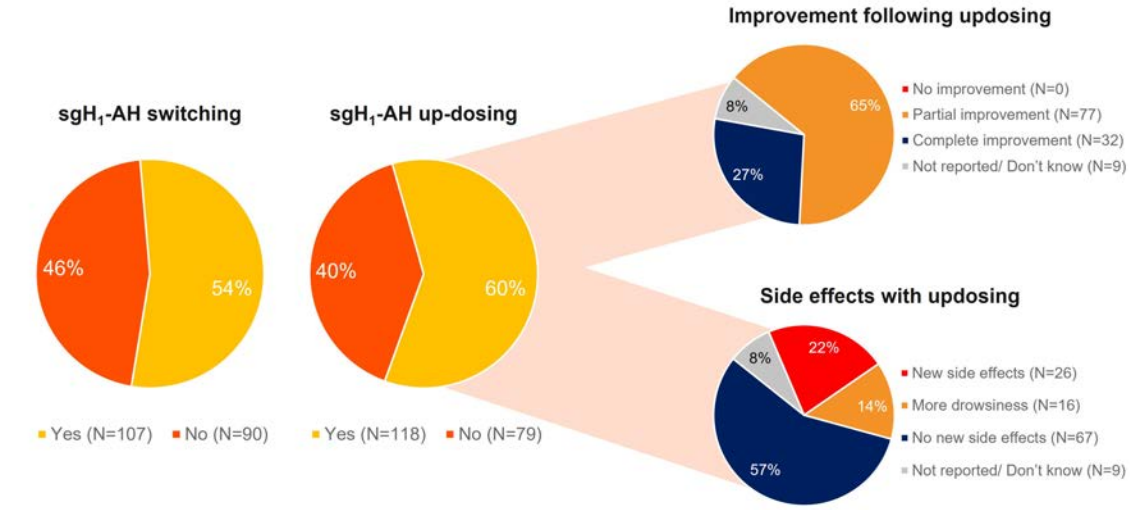
Results
Of the 552 CU patients enrolled in the study, 400 patients with CSU (mean age 35.1 (7.2) years; 55% male) and with a mean disease duration of 5.3 (4.9) years were included in this analysis. About 35% of patients reported inadequate disease control (UCT<12). Antihistamines (H_1-AH) were the first-line treatment, prescribed in 92% (366/400) of patients, either alone or in combination. Second-generation H_1-AH was prescribed in 89% (326/366) of patients; 60% (197/326) of these patients were exclusively treated with second-generation H_1-AH. Since the initiation of their first prescribed treatment for CSU (mean [SD]: 5.2 [4.9] years), 54% (107/197) of patients reported H_1-AH switching and 60% (118/197) reported up-dosing (average, 0.8 [0.9] and 0.7 [0.7] times, respectively). After up-dosing of second-generation H_1-AH therapy, 14% of patients reported more drowsiness and 22% reported additional side effects. No or partial symptom relief was reported among 65% of these patients

(figure). Of 197 patients, 19% reported complete control (UCT=16), 57% reported well-control, and 24% reported inadequate control (UCT <12) of their CSU symptoms. Patients (N=400) also reported having prescribed other treatment options (with or without H_1-AH) such as traditional Chinese medicine (TCM, including Lei-Gong-Teng): 12%; immunosuppressants: 10%; biologics: 7%; steroids and ciclosporin: 5% each; and antidepressants: 2%. TCM use was substantial (29% of patients had used previously and 9% using currently), in conjunction with conventional treatments. Patients avoided biologic use mainly due to concerns about side effects (58%), reduced immunity (44%), lack of information (32%), frequent hospital visits (25%) and injection issues (18%). Steroids were mainly administered as an emergency treatment—typically a single dose—for sudden symptom flare-ups in 28% of patients. In most instances, the total duration of steroid use was less than 10 days. Around 30% of patients took over-the-counter medication for 6.3 (6.7) years. About 90% used homeopathic & alternative medicine (herbal remedies) apart from prescription medicine.

Conclusions

Most patients rely primarily on second-generation antihistamine therapy, yet nearly one-third of patients continue to experience inadequate disease control. Up-dosing H_1-AH is often limited by the occurrence of side effects such as increased drowsiness, which may further hinder effective management. The substantial use of traditional Chinese medicine and alternative therapies reflects both cultural preferences and unmet clinical needs. These findings underscore the necessity for improved treatment options for patients with CSU in China.

Figure: Second-generation antihistamine treatment patterns



sgH1-AH, second generation H1-antihistamine. No patients with "no improvement". Percentages were rounded to the nearest percent value.

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Abstract N°: 4017

Alarmin-Centered Immunological Profiling in Chronic Urticaria

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Introduction
Chronic Urticaria is increasingly recognized as a heterogeneous immune-mediated disease with diverse pathogenic mechanisms and variable therapeutic responses. Current evidence supports the coexistence of autoallergic and autoimmune pathways; however, clinically useful biomarker models capable of reflecting this heterogeneity remain limited. Among emerging upstream mediators, IL-33 has gained attention as an epithelial-derived alarmin involved in mast cell activation, type 2 inflammation, and amplification of downstream inflammatory signaling. The present study investigated whether combining IL-33 with conventional laboratory biomarkers may help identify distinct immunological patterns in patients with chronic urticaria.

Materials and Methods
his pilot cross-sectional study included 46 patients with chronic urticaria who underwent immunological assessment including serum IL-33, total IgE, peripheral eosinophil counts, and thyroid autoantibodies (anti-TPO and anti-thyroglobulin antibodies). Exploratory multimarker analysis was performed to evaluate immune heterogeneity and identify potential biomarker-associated profiles.

Results
Substantial heterogeneity in IL-33 levels was observed across the cohort, with values ranging from 19.7 to 429.2 pg/mL (median 84.3 pg/mL). Elevated total IgE levels (>100 IU/mL) were identified in 15/46 patients (32.6%) and were frequently accompanied by higher peripheral eosinophil counts, supporting the presence of an autoallergic/type 2 inflammatory pattern in a subset of patients. Peripheral eosinophilia (>300 cells/μL) was detected in 3/46 patients (6.5%). Thyroid pathology, including thyroid autoantibody positivity and/or documented thyroid disease, was identified in 11/46 patients (23.9%), suggesting a considerable burden of autoimmune-associated comorbidity within the cohort. Patients with thyroid-associated abnormalities more commonly demonstrated comparatively lower IgE levels, supporting the presence of an autoimmune-associated immune pattern. Increased IL-33 levels were observed across both biomarker-associated profiles, indicating that alarmin-mediated signaling may represent a shared upstream inflammatory amplifier rather than a feature restricted to a single immunological subgroup. Exploratory clustering analyses suggested the presence of at least two partially overlapping immune profiles: an autoallergic/type 2-high inflammatory profile and an autoimmune-associated profile.

Conclusions
Integration of IL-33 with conventional biomarkers may improve characterization of immunological heterogeneity in chronic urticaria. These preliminary findings support the concept that alarmin-centered profiling could complement current biomarker approaches and contribute to future endotype-oriented patient stratification and personalized therapeutic strategies. Larger controlled studies are warranted to validate these preliminary observations.

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Abstract N°: 4075

IgE autoantibodies are associated with better control of chronic spontaneous urticaria: First insights from the prospective multicenter UCARE CU-TIGER study

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Introduction
Chronic spontaneous urticaria (CSU) is a common skin disease with heterogeneous mechanisms and variable treatment responses. While several biomarkers, including total IgE, IgG-anti-thyroid peroxidase (TPO), basophil-related assays, and IgE-anti-TPO/IL-24, have been proposed to reflect CSU endotypes, robust multicenter prospective data on their relationship with disease control and treatment response are lacking. The UCARE CU-TIGER study aims to identify markers associated with response to guideline-recommended treatment.

Materials and Methods
CU-TIGER is a prospective, non-interventional, multicenter UCARE study including adult CSU patients. Baseline sera and clinical data, with follow-up assessments at months 1, 3, 6, and optionally 8, were collected from participating centers. Biomarkers assessed centrally included total IgE, IgG-anti-TPO, tryptase, IgE-anti-TPO, IgE-anti-IL-24, IgG-anti-IgE, IgG-anti-FcεRI, mast cell activation test, and basophil histamine release assay; eosinopenia, basopenia, CRP, ASST, ANA, D-dimer, and IgA were also evaluated. CSU was defined as poorly controlled (Urticaria Control Test, UCT<12) or well controlled (UCT≥12).

Results
A total of 427 adult CSU patients from 19 UCARE centers in 17 countries were included. At baseline, 74.5% were female with the median age of 41.0 years (IQR 31.0–51.0), age at disease onset of 38.0 years (26.0–47.0), and CSU duration of 2.0 years (1.0–5.0). At baseline, 90.5% received second-generation H1-antihistamines, 0.7% omalizumab, and none cyclosporine. Median baseline UCT of 9 (5–12) improved to 14 (11–16) by month 6. At 1 and 3 months, compared with patients with UCT <12, those with UCT ≥12 had higher baseline IgE-anti-IL-24 levels (4.65 [2.13–5.77] vs 2.29 [1.84–4.69], p<0.001 and 3.10 [2.04–5.71] vs 2.29 [1.85–3.96], p=0.002) and baseline IgE-anti-TPO levels (3.24 [1.72–4.99] vs 1.92 [1.50–3.59], p<0.001 and 3.06 [1.60–4.74] vs 1.88 [1.51–3.55], p=0.006).

Conclusions
The initial findings of the CU-TIGER project indicate that IgE autoantibodies may be associated with better CSU control. Ongoing analysis of the CU-TIGER follow-up data is expected to deepen our understanding of these associations and clarify their potential clinical relevance.

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Abstract N°: 4088

Patient perspectives on disease burden, symptoms, and comorbidities: Findings from the Urticaria Voices China study in patients with chronic spontaneous urticaria

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Introduction
Chronic spontaneous urticaria (CSU) represents the most common subtype of chronic urticaria and is characterised by itchy wheals (hives) and/or angioedema lasting for more than 6 weeks. The associated symptoms significantly affect patients' overall quality of life (QoL), emphasising the ongoing need for fast symptom control. Although clinical evidence relating to CSU in China continues to expand, the extent of this burden is frequently underestimated, and patient perspectives remain insufficiently understood and acknowledged. The present analysis from the Urticaria Voices China study examines patient perspectives on CSU symptoms, comorbidities, and their impact on overall quality of life.

Materials and Methods
The Urticaria Voices (UV) China study is a non-interventional, cross-sectional, 40-minute online survey of patients with chronic urticaria (CU) and CU-treating physicians in China. This analysis focuses on Chinese patients aged ≥18 years with self-reported, physician-confirmed CSU, recruited through multiple channels, including online panels, and remunerated as per fair market value. Each patient provided an informed consent documented electronically before taking the survey. Observed data were analysed descriptively and are reported as mean (standard deviation) or percentage.

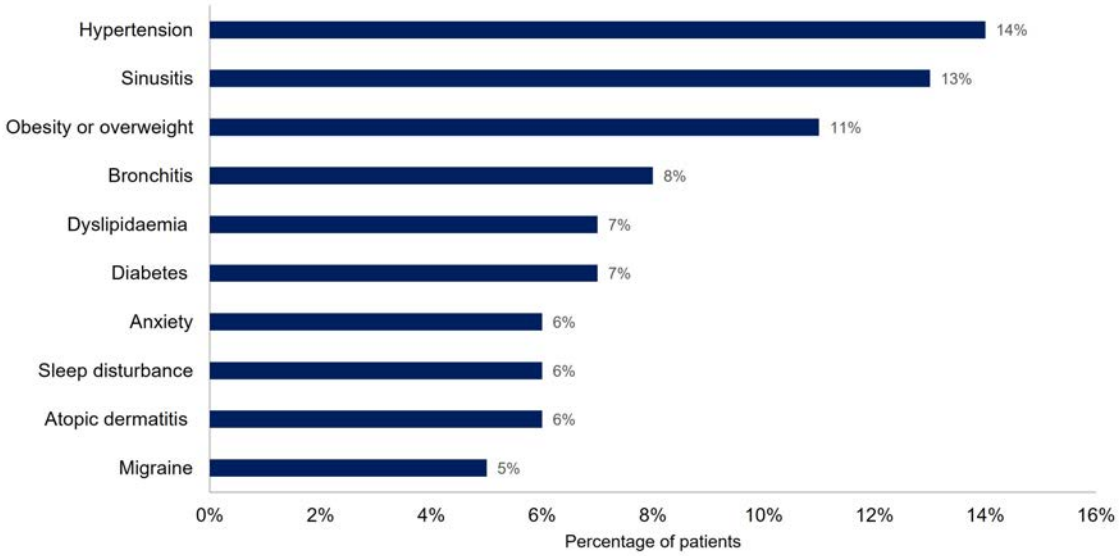
Results
The study included 400 patients with CSU (male: 55% and female: 45%) with mean (SD) age of 35.1 (7.2) years. The mean duration since patients first noticed their signs and symptoms was 5.3 (4.9) years and since diagnosis was 5.2 (4.9) years. The majority (96%) of patients with CSU were diagnosed by a dermatologist. Most common self-reported comorbidities (>10%) were hypertension (14%), sinusitis (13%), and obesity or overweight (11%) (**figure**). Overall, only 7% (26/400) of patients self-reported ever having angioedema, of those, 22 patients reported experiencing a mean of 4.7 (2.0) angioedema episodes in the last 12 months. These angioedema episodes were visible on the lips, hands, and face. In addition, sleeping problems (70%), fatigue (54%) and flushing (42%) were frequently reported physical symptoms during an exacerbation. Complete control was rated

as the most important goal (~8.5/10) by 80% of patients with CSU. However, only 58 (15%) patients achieved complete control (UCT=16). Based on the self-reported perception of symptom severity (Patient Global Impression of Severity) among patients with CSU who were inadequately controlled (n=140), 54% of patients experienced mild, 23% experienced moderate and 1% patients experienced severe symptoms in the past 7 days (before survey completion). About 56% of patients also reported a moderate impact, while 2% reported high impact on their mental & emotional well-being. Improving mental and emotional wellbeing was among the top treatment objectives reported by 47% of patients. About 46% of patients reported that CSU holds them back from reaching their full potential. Nearly half of patients with CSU reported experiencing difficulty in falling asleep (often or sometimes). Night-time awakening was experienced by 75% of patients, with 46% of patients waking up at least 2-3 times per week. Lack of sleep impacts daily life in 73% of patients. Most patients rely primarily on second generation antihistamines (82%), often requiring dose adjustments or switching treatments, yet complete control remains elusive for many (85%).

Conclusions

Long standing symptoms and comorbidities impose a significant burden on Chinese patients, affecting both physical health and mental and emotional wellbeing. Despite prompt diagnosis and treatment, at least half of patients self-report to experience continuous symptoms. These results suggest low patient awareness of disease symptoms and clinical manifestations, while underlining the need for more effective management strategies and therapies targeting early symptom control and aiming to improve overall quality of life and patient outcomes in China.

Figure: Percentage of common comorbidities (top 10) in Chinese patients with chronic spontaneous urticaria



Percentages were rounded to the nearest percent value.

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Abstract N°: 4174

Child chronic inducible urticaria: is it possible to control?

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Introduction

Despite the fact that in childhood chronic spontaneous urticaria (CSU) is the most common type of chronic urticaria and has been reported in 60–90% of cases, chronic inducible urticaria(CIndU) can occurs in children without CSU. Although in most types of CIndU the symptoms appear usually within 10 min after exposure to the trigger and resolve within 1–3 h after cessation of exposure, it significantly affects children's quality of life, limiting their daily activities. In clinical practice the most children with CIndU do not have an adequate response to non-sedating H1- antihistamines (H1-AN) even in 2 high doses. Recently, a growing body of research indicates the efficacy of omalizumab therapy in patients with CIndU. But even the biological therapy does not provide proper control over disease, which depends on the type of CIndU. The question of the optimal doses and duration of this therapy in CIndU children also remains open.

Materials and Methods

12 children that had only CIndU without CSU, aged 12 to 17 years, took part in our research. As for CIndU subtypes there were : cholinergic urticaria in 4 children (1 girl, 3 boys), cold urticaria in 4 children (3 girls, 1 boy), solar urticaria in 1 boy, dermographic urticaria in 1 girl and 1 boy and dermographic urticaria with delayed pressure urticaria in 1 girl. The diagnose of CIndU based on patients' history and challenge test results (ice cube test, walking on the treadmill until sweating began, moderate pressure, using a smooth flat object). Baseline total IgE in serum and IgG anti-TPO levels in serum were analysed by a chemiluminescence immunoassay with IMMULITE 2000 XPi System. All children were prescribed omalizumab at a dose of 300 mg every four weeks. Clinical control of the disease was defined by a UCT ≥ 12.

Results

2 patients with cold urticaria , 1 patient with solar urticaria and 1 patient with cholinergic urticaria had hay fever comorbidity**.** 1 patient with dermographic urticaria had autoimmune thyroiditis. Median baseline IgE serum level was 130 (85; 206). Autoimmunity markers (anti-TPO) was detected in 1 patient. According to patients' history all children did not respond to H_1-AN (licensed and increased doses). 8 patients also were unsuccessfully treated with montelucast and corticosteroids, 1 patient with solar urticaria was unsuccessfully treated with plasmapheresis, also photoprotection was without effect. All patients responded to omalizumab, all of them had fast clinical response. There were no non-responders or late responders to omalizumab. Achievement of UCT ≥ 12 at week 4 was in all patients. No patient needed updosing omalizumab to 450 mg every 4 weeks. It is important

to note that the initiation of omalizumab was accompanied by discontinuation of the use of H1-AN in all patients already on the first month of treatment. No adverse effects of omalizumab were evidenced in any patient even in long-term therapy schemes. In 4 patients (2 girls with cold urticaria, 1 boy with cholinergic and 1 boy with dermographic urticaria) presented complete remission. Thus, we observed more effective and shorter anti - IgE-treatment in children with cold urticaria, meanwhile for patients with cholinergic and dermographic urticaria therapy was a bit longer. As for other 8 patients they tended to present with flares or relapses if the omalizumab dose was lowered or the treatment stopped, which resulted in long-term therapy schemes. This patients had the normal baseline IgE level, that didn't change during treatment.

Conclusions

In order to be controlled over disease, children with all CIndU types need omalizumab treatment at a dose of 300 mg every four weeks. The duration of the biological therapy for each patient should be chosen individually. We suppose that children with CIndU have a need for long omalizumab treatment.

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Coagulation/Fibrinolysis Activation and Clinical Outcomes in Acute Urticaria: A Retrospective Study

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Introduction

Acute urticaria (AU) is a common dermatologic emergency in clinical practice, but its underlying pathophysiological mechanisms remain incompletely understood. This study aimed to evaluate key clinical and laboratory features in pediatric and adult patients with moderate-to-severe AU, with particular focus on coagulation/fibrinolysis activation and predictors of chronic progression.

Materials and Methods

This retrospective study included 72 pediatric and 166 adult patients with moderate-to-severe AU from an outpatient urticaria center. Clinical characteristics and laboratory parameters were compared between pediatric and adult groups, as well as between infectious and non-infectious subgroups. Propensity score matching was used to compare patients with and without eosinopenia. Logistic regression was performed to explore predictors of progression to chronic urticaria.

Results

Compared with adults, children had a higher proportion of males (66.7% vs. 30.7%, P < 0.001) and were more frequently diagnosed with infection-induced AU (69.4% vs. 38.6%, P = 0.001). Angioedema was more common in adults than in children, although the difference was not statistically significant (13.3% vs. 4.2%, P = 0.061). Children showed higher eosinophil counts, basophil counts, D-dimer levels, PT, and platelet counts than adults. After propensity score matching, patients with eosinopenia had higher basophil counts (1.03 ± 0.29 vs. 0.84 ± 0.37, P < 0.001), shorter TT (15.49 ± 0.94 vs. 15.81 ± 1.38, P = 0.004), and higher platelet counts (301.57 ± 92.48 vs. 264.95 ± 66.37, P = 0.043) than those without eosinopenia. In subgroup analyses, infection-related AU was associated with higher D-dimer levels in children, and with shorter TT and higher fibrinogen levels in adults. In the chronic progression model, respiratory symptoms at onset were associated with a lower risk of progression to chronic urticaria, whereas eosinophil percentage was positively associated with chronic progression.

Conclusions

Coagulation/fibrinolysis activation may be involved in AU and appears to vary according to age, infection status, and eosinophil-related inflammatory features. Respiratory symptoms and eosinophil percentage may help identify patients with different risks of chronic progression. These findings are preliminary and require validation in larger

prospective studies.

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Serum TG2 Activity in Chronic Spontaneous Urticaria: Expression Levels and Clinical Correlations in a Single-Center Study from China

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Introduction
Chronic spontaneous urticaria (CSU) is a chronic inflammatory pruritic skin disorder characterized by mast cell activation, which can significantly impair patients' quality of life. Previous studies have identified transglutaminase 2 (TG2) as autoallergens in CSU, with sIgE-TG2 significantly elevated in CSU serum. TG2 expression is increased in the tissues and serum of patients with autoimmune, inflammatory, and allergic diseases, such as inflammatory bowel disease, potentially contributing to pathogenesis via modulation of mast cell activation and immunoglobulin E (IgE)-mediated immune responses. Studies from other countries suggest that serum TG2 levels correlate with CSU severity; however, data from China are lacking, and research on TG2 activity expression in relation to clinical features, CSU subtypes, and laboratory parameters remains limited.

Materials and Methods
Eighty-five CSU patients and 42 healthy controls (HCs) were included in a Single-Center Study from China. Clinical characteristics, including disease duration, age, comorbidities, Urticaria Activity Score over 7 days (UAS7), Urticaria Control Test (UCT), and Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) scores, were collected. Venous blood samples were obtained, serum was separated and stored at −80°C, and TG2 activity was measured by enzyme-linked immunosorbent assay (ELISA). Serum TG2 activity in CSU patients was compared with HCs, and patients were stratified into TG2-elevated and normal groups using the 95th percentile of HCs as the cutoff. Continuous variables were analyzed using t-tests or Mann–Whitney U tests, and categorical variables using chi-square or Fisher's exact tests. Correlation analyses assessed relationships between TG2 activity and clinical/laboratory parameters.

Results
There were no significant differences in age or sex distribution between CSU patients and HCs ($p > 0.05$). Serum TG2 activity was significantly higher in the CSU group (84.19 [IQR 71.36–92.64], n=85) than in HCs (78.24 [IQR 71.57–83.36], n=42; p=0.040). No significant differences in demographics, disease activity, or laboratory parameters (including CRP and ESR) were observed between TG2-elevated and normal CSU groups. Serum TG2 levels in CSU patients were negatively correlated with platelet count (Spearman $r = -0.150$, $p = 0.044$) and showed a trend toward negative correlation with leukocyte count ($r = -0.116$, $p = 0.055$).

Conclusions
Serum TG2 activity is elevated in CSU patients, suggesting a potential role in disease pathogenesis, although its clinical relevance to disease activity and laboratory indices requires further investigation.

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Abstract N°: 4373

Expression Levels of Serum IL-24 in Patients with Chronic Spontaneous Urticaria and Their Clinical Correlations in a Single-Center Study from China

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Introduction
Chronic spontaneous urticaria (CSU) is a chronic inflammatory pruritic skin disorder characterized by mast cell activation, which can significantly impair patients' quality of life. Previous studies have identified interleukin-24 (IL-24) as autoallergens in CSU, with sIgE-IL-24 significantly elevated in CSU serum. However, data from China are lacking, and research on IL-24 expression in relation to clinical features, CSU subtypes, and laboratory parameters remains limited. IL-24, a cytokine of the IL-10 family, participates in inflammation and immune cell activation, yet its correlation with disease severity and clinical subtypes in CSU patients has not been extensively studied.

Materials and Methods
One hundred twenty-six CSU patients and 58 HCs were included for IL-24 analysis in a Single-Center Study from China. Demographic and clinical data (UAS7, UCT, CU-Q2oL) were collected. Serum IL-24 levels were measured by ELISA. Patients were divided into IL-24-elevated and normal groups using the 95th percentile of HCs as the cutoff. Group comparisons of clinical and laboratory parameters were conducted using t-tests, Mann–Whitney U tests, chi-square, or Fisher's exact tests as appropriate. Correlations between IL-24 levels and clinical/laboratory parameters were assessed. IL-24 was also analyzed as a continuous outcome using a Gamma regression model, with results expressed as rate ratios (RR) and 95% confidence intervals (CI). All analyses were performed using R software, with $p < 0.05$ considered statistically significant.

Results
Serum IL-24 levels were significantly elevated in CSU patients (727.22 [IQR 419.92–1268.37], n=126) compared to HCs (525.25 [IQR 184.03–994.27], n=58; p=0.001). IL-24-elevated patients had higher CU-Q2oL scores (62.00 [IQR 43.50–72.00]) than IL-24-normal patients (48.00 [IQR 29.00–64.50]; p=0.033), indicating worse self-reported quality of life (Mann–Whitney U test, Z = 2.05, p=0.04). Serum IL-24 levels were positively correlated with disease activity, quality of life impairment, and inflammatory markers (ESR, neutrophil count, leukocyte count, monocyte count; Spearman r = 0.248, 0.175, 0.170, 0.197; p = 0.001, 0.010, 0.020, 0.040), and negatively correlated with body weight and eosinophil percentage (r = −0.286, −0.221; p = 0.020, 0.037). Gamma regression identified ESR as an independent predictor of IL-24 levels (RR = 1.021, 95% CI 1.006–1.036, p = 0.007), with marginal effects observed for thyroid peroxidase antibody (TPOAb) and concurrent chronic inducible urticaria (CIndU) (RR = 0.999, 95% CI 0.999–1.000, p = 0.053; RR = 0.678, 95% CI 0.459–1.003, p = 0.054).

Conclusions
Serum IL-24 levels are increased in CSU patients and correlate positively with disease activity, quality of life impairment, and inflammatory markers, indicating its involvement in CSU-associated inflammation and

autoallergic mechanisms, and highlighting its potential as a biomarker for disease activity and patient-reported outcomes.

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Abstract N°: 4380

Serum sFcεRI, MRGPRX2, IL-9 and IL-31 in Chronic Spontaneous Urticaria: Associations with Disease Activity and Prediction of Omalizumab Response

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Introduction
Chronic spontaneous urticaria (CSU) is a heterogeneous disease involving both IgE-dependent and non-IgE-mediated mast cell activation, leading to variable disease activity and treatment response. Reliable biomarkers that reflect these pathways and predict response to omalizumab remain lacking.

To evaluate sFcεRI, MRGPRX2, IL-9, and IL-31 as biomarkers of disease activity and to determine their ability to predict early and sustained response to omalizumab.

Materials and Methods
A prospective case-control study was conducted at a tertiary referral dermatology centre. A total of 120 patients with CSU and 40 age- and sex-matched healthy controls were enrolled. Serum sFcεRI, MRGPRX2, IL-31, and IL-9 levels were measured by ELISA. Disease activity was assessed with the Urticaria Activity Score 7 (UAS7) and disease control with the Urticaria Control Test (UCT). Forty patients initiating omalizumab 300 mg/4 weeks were prospectively followed for three months. Patients achieving UAS7 ≤6 at month 1 were defined as super-responders; those achieving UAS7 ≤6 only at month 3 as good responders. Total IgE levels were recorded to assess IgE dependency. Statistical analyses included Mann-Whitney U test, Kruskal-Wallis test, Spearman correlation, and ROC curve analysis.

Results
All biomarkers were significantly elevated in CSU patients compared to controls, indicating activation of multiple inflammatory pathways.

sFcεRI, MRGPRX2, and IL-31 were associated with higher disease activity (UAS7) and poorer disease control (UCT), whereas IL-9 was associated with longer lesion duration, suggesting a role in sustained inflammation rather than disease activity. IL-9 showed good discrimination between CSU and controls (AUC=0.90).

Among omalizumab-treated patients, response rates increased over time, with 62.5% achieving response at month 1 and 82.5% at month 3. Early responders had markedly higher baseline sFcεRI and MRGPRX2 levels, whereas IL-9 levels were lower. sFcεRI demonstrated excellent predictive performance for early response (AUC=0.965), followed by MRGPRX2 (AUC=0.930).

In contrast, IL-31 was the strongest predictor of sustained response at month 3 (AUC=0.814). Biomarker levels were independent of total IgE levels.

Biomarker Performance Across Disease Activity and Omalizumab Response Prediction in CSU

Biomarker	Patient vs Control			Disease Activity		Omalizumab Response Prediction		
	CSU (mean ± SD)	Control (mean ± SD)	p value	UAS7 r	UCT r	Outcome	AUC (95% CI)	Sens / Spec
sFcεRI (ng/ml)	30.92 ± 27.83	18.64 ± 7.75	**0.025***	**0.293****	**−0.285****	Super-response, month 1	**0.965 (0.897–1.000)**	96% / 100%
MRGPRX2 (ng/ml)	63.35 ± 57.31	40.09 ± 28.75	**0.005****	**0.297****	**−0.293****	Super-response, month 1	**0.930 (0.845–1.000)**	84% / 88%
IL-31 (ng/L)	173.57 ± 153.43	101.94 ± 59.81	**0.015***	**0.480****	**−0.448****	Complete/good response, month 3	**0.814 (0.683–0.945)**	73% / 71%
IL-9 (pg/ml)†	2.97 ± 2.78	1.10 ± 0.42	**<0.001*****	NS	NS	Diagnosis (patient vs control)	**0.900 (0.804–0.996)**	83% / 82%

* p<0.05; ** p<0.01; *** p<0.001 (Spearman correlation for r values; Mann-Whitney U for patient vs control). † IL-9 measured in subset (n=30 patients, 11 controls); cut-off 1.51 pg/ml. NS = not significant. AUC = area under the ROC curve. Super-response: UAS7 ≤6 at month 1. Complete/good response: UAS7 ≤6 at month 3.

Conclusions

Serum sFcεRI, MRGPRX2, IL-9, and IL-31 are significantly elevated in CSU and reflect distinct aspects of disease pathophysiology. Pre-treatment sFcεRI is a highly accurate predictor of early super-response to omalizumab, while IL-31 predicts sustained response at three months. These biomarkers may enable a stratified, personalised approach to omalizumab therapy in CSU, warranting prospective validation in larger multicentre cohorts.

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Abstract N°: 4436

IgG-Dependent Mast Cell Activation in Chronic Spontaneous Urticaria Extends Beyond FcεRIα Autoimmunity

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Introduction
Chronic spontaneous urticaria (CSU) presents with wheals, angioedema, or both for more than six weeks without an identifiable external trigger. A substantial proportion of patients have functional mast cell and basophil-activating IgG autoantibodies directed against the alpha subunit of the high-affinity IgE receptor (FcεRIα) or, less commonly, against receptor-bound IgE (also called type IIb or autoimmune CSU). Clinically, autoimmune CSU is more severe and associated with poorer treatment responses. In this study, we investigated the prevalence and functionality of IgG-anti-FcεRIα in a large cohort of CSU patients to better understand their role in disease pathogenesis.

Materials and Methods
Sera of adult CSU patients were analysed using an IgG-anti-FcεRIα ELISA and the mast cell activation test (MAT). MAT-positive sera were pre-incubated with full-length recombinant FcεRIα protein to block autoantibody binding. Selected samples were further subjected to IgG purification using Protein G columns. IgG-depleted sera and purified IgG fractions were tested for their ability to activate mast cells in MAT. Additionally, ELISA and MAT were repeated using original, IgG-depleted, FcεRIα-blocked sera, and purified IgG fractions.

Results
In total, sera from 447 CSU patients (72% female, median age 41.5 years) were analysed. Across all sera, 3.8% (17/447) were positive for both IgG-anti-FcεRIα and MAT, 2.0% (9/447) only for IgG-anti-FcεRIα, 43.5% (194/447) only for MAT, and 50.7% (227/447) were double-negative. As compared to all remaining patients, those with double-positive sera showed significantly worse disease control (UCT 3.0 vs 7.0, p=0.006), higher rates of basopenia (76% vs 22%, p<0.001), elevated CRP (3.8 vs 1.5 mg/L, p=0.048), and higher rates of thyroid autoimmunity (47% vs 20%, p=0.013). Pre-incubation of MAT-positive sera with recombinant FcεRIα reduced mast cell activation by up to 70% in IgG-anti-FcεRIα-positive sera, while IgG-anti-FcεRIα-negative sera showed no inhibition. The incomplete inhibition observed in FcεRIα-blocked, ELISA-positive sera, together with complete abolition of mast cell activation upon IgG depletion, indicates the co-presence of additional functional IgG autoantibodies targeting antigens other than FcεRIα. IgG depletion reduced mast cell activation to baseline levels across all tested samples, including those lacking detectable IgG-anti-FcεRIα autoantibodies, and purified IgG fractions retained activating capacity, collectively confirming an IgG-dependent mechanism.

Conclusions
IgG-anti-FcεRIα accounted for only a minority of functional serum activity in CSU. IgG depletion consistently abolished mast cell activation in all tested MAT-positive sera, regardless of IgG-anti-FcεRIα status, indicating that

additional IgG autoantibodies targeting antigens beyond FcεRIα contribute to mast cell activation in both ELISA-positive and ELISA-negative patients. These findings highlight the complexity and heterogeneity of autoimmune mast cell activation in CSU and support further investigation into novel IgG autoantibody targets.

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Abstract N°: 4466

Paradoxical Flare Following Omalizumab in Chronic Spontaneous Urticaria: Clinical Patterns and Management Strategies

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Introduction

Omalizumab is a recommended add-on therapy for antihistamine-refractory chronic spontaneous urticaria (CSU) and is generally well tolerated. Nevertheless, paradoxical worsening of wheals and/or angioedema after omalizumab has been reported, but clinical patterns and practical management remain insufficiently described. We aimed to characterize timing, associated features, and management of post-omalizumab flare in CSU.

Materials and Methods

We conducted a single-center retrospective case series of chronic spontaneous urticaria patients who developed reproducible wheal/angioedema exacerbation after omalizumab. Demographic and clinical characteristics, laboratory parameters (CRP, ESR, total IgE, D-dimer, anti-TPO), flare onset time after injection, and treatments were extracted from medical records. Patients were descriptively summarized and stratified by flare timing (2–12 h vs >12 h).

Results

Eight CSU patients reporting exacerbation of wheals after omalizumab were evaluated. Median age was 31 years (21–52), 75% were female, and 50% had a family history of CSU. Median disease duration was 10 months (3–24), median wheal duration was 14 hours (6–24), and angioedema accompanied 50%. Stress was the most commonly reported trigger (62.5%). All patients had previously used high-dose antihistamines, and 75% had received systemic corticosteroids. Laboratory findings included elevated CRP in 37.5% and elevated ESR in 50%; median total IgE was 179 IU/mL (44.6–449). D-dimer and anti-TPO elevations were each observed in 25%.

Flare timing clustered into two groups: 2–12 hours (37.5%, n=3) versus >12 hours (62.5%, n=5) after injection. All patients began experiencing flares from the second omalizumab dose onward. The 2–12 hour group had higher median total IgE (378 vs 81.3 IU/mL) and more frequent family history (100% vs 20%) compared with the >12 hour group. For management, 6 patients improved with high-dose antihistamines, while 2 required short courses of systemic corticosteroids. After recurrent flares, omalizumab was split into 150 mg every 2 weeks; 2 patients had no further flares thereafter.

Conclusions

Current international CSU guidance recommends omalizumab 300 mg every 4 weeks and allows individualized adjustments in dosing/interval in selected settings [1]. While most literature focuses on nonresponse, paradoxical

flare following omalizumab has been described in case reports and small series [2–4]. Proposed mechanisms include non–IgE-mediated reactions and/or sensitivity to excipients (e.g., polysorbate), although evidence is limited and largely observational [2,4]. In our series, symptom worsening appeared after early treatment cycles and occurred within hours to >12 hours. The observation that dose-splitting reduced or prevented recurrence in some patients suggests that lowering per-injection exposure may be a practical option when flares recur, together with standard rescue therapy (updosed antihistamines ± short steroid course when necessary).

Omalizumab-triggered flare in CSU may emerge from early treatment cycles and present within hours to >12 hours after injection. Most flares were controlled with high-dose antihistamines, and dose-splitting to 150 mg every 2 weeks prevented recurrence in a subset. Recognition of this uncommon pattern and individualized dosing strategies may improve tolerability and continuation of therapy.