Abstract N°: 540

To compare the efficacy and safety of cyclosporine versus azathioprine in the treatment of refractory Chronic Spontaneous Urticaria

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Introduction & Objectives:

Background: Literature on efficacy of azathioprine in antihistamine refractory chronic spontaneous urticaria (CSU) is limited.

Objective: To compare the efficacy and safety of cyclosporine and azathioprine in the treatment of refractory CSU

Materials & Methods: ** In this prospective, randomized, active-controlled study, 80 patients of refractory CSU (>6 months of CSU not responding to treatment with 3 consecutive months of maximum licensed doses of antihistamines and requiring intermittent oral steroid intake) were administered either cyclosporine (group A, n=40) or azathioprine (group B, n=40) for 90 days and followed up for further 90 days. The treatment efficacy was assessed every 15th day using urticaria activity score (UAS7) and outcome scoring scale (OSS). Serum IgE levels, autologous serum skin test (ASST) and autologous plasma skin test (APST) were also measured at baseline and 90th day

Results:

Primary end point (≥75% reduction in UAS7 at 90th day) was achieved by 31/40 (79.5%) patients in group A and 32/40 (80%) patients in group B[**95% confidence interval (CI) -17.13 to 18.09**]. At 180th day**,** ≥75% reduction in UAS7 was maintained in 19/40 (47.95%) patients in group A and 24/40 (60%) patients in group B;[**95% CI -9.00 to 32.46**]. The number of patients who could maintain ≥75% reduction in UAS7, reduced significantly during follow-up in both group A**;[95% CI 30% (8.78 to 47.77)]**and B;[**95% CI 20% (-0.10 to 38.10)**]. The values of meanUAS7 significantly decreased from baseline values of 28.70 ± 4.42 and 28.88

± 4.25 to 5.56 ± 5.12 and 7.0 ± 4.48 at 90th day**; [**group A; **95% CI -23.27 (-25.33 to -21.22),**

group B, **95% CI -21.87 (-23.78 to -19.96)]**and increased to 9.98 ± 5.46 and 7.88 ± 5.53 at 180th

day, in group A**;[95% CI 4.55 (2.98 to 6.12)]**and group B**; [95% CI 0.88 (-0.82 to**

2.57)]respectively. The mean OSS significantly increased from 2.85 ± 1.04 and 2.70 ± 0.91 at

15th dayto 4.23 ± 0.70 and 4.05 ± 0.59at 90th day**;[**group A **95% CI 1.40(1.06 to 1.74), group B**

95% CI 1.35 (1.06 to 1.65)]and decreased to 3.59 ± 0.78 and 3.87 ± 0.79 at

180th** day, in group A; [**95% CI -0.68 (-0.89 to -0.45)**]and B; [**95% CI -0.18 (-0.41 to 0.06**)]**

respectively. The reduction in mean serum IgE levels at 90th day was significant in both

groups**;[95% CI 27.65 (-64.35 to -10.10,** Hodges – Lehman median difference)], although more

significant in group B**;[95% CI -88.57(-209.50 to -28.70,**Hodges – Lehman median

difference)]. The reduction in number of patients having positive ASST was not significant in

either of the groups.

Conclusion:

The present study concludes that azathioprine is not inferior to cyclosporine in the treatment of refractory CSU, and can be a valuable adjunct, especially in the resource poor settings.

Abstract N°: 733

chronic urticaria shared decision making tool

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Introduction & Objectives:

Chronic urticaria is a persistent skin condition with unpredictable hives, itching and discomfort that can significantly affect quality of life. Selecting appropriate treatment is challenging due to remitting and relapsing nature of the condition and varied patient responses. A mutual decision-making process ensures active involvement of patient in management of the disease, thus increasing patient satisfaction and giving healthcare professionals insight into the disease impact on patient life.

The Shared Decision-Making Tool provided by the Global Allergy & Airways Patient Platform in partnership with Pulse Marketing guides patients in evaluating their treatment experiences and preferences by assessing individual symptoms, treatment history and lifestyle goals, and generating a customized report to help healthcare providers make personalized treatment regimens for the patient.

Materials & Methods:

This tool is a stepwise questionnaire which aggregates patient responses to produce a customized report entailing key symptoms, impact on mental health and lifestyle, patient expectations,

treatment options, follow-up options and personalized goals. It can then be shared with the respective healthcare provider.

The application was piloted with 10 adults (6 females and 4 males) aged 18 to 50 years, who were assessed based on the mentioned parameters.

Results:

Follow-up interviews revealed that 9 of 10 patients felt the tool helped them better understand treatment options to manage their needs, thereby reducing the disease impact on daily life. 1 patient was lost to follow-up.

Conclusion:

The app relies on self-reported data which may be subject to bias, leading to inadequate treatment or over-management of symptoms.

Chronic urticaria is a long-term condition that may be overwhelming to manage due to constant change in symptomatology. Thus the use of an app provides a promising outlook to improve treatment outcomes for patient by means of enhanced communication and personalized care.

Abstract N°: 753

Efficacy of Vitamin D3 Supplementation as an Adjunct to Bilastine 40 mg in Chronic Spontaneous Urticaria Patients with Vitamin D3 Deficiency: A Randomized, Double-Blind, Placebo-Controlled Study

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is a debilitating condition characterized by recurrent wheals, angioedema, or both, lasting for six weeks or more. Emerging evidence suggests a potential role of vitamin D3 in modulating immune responses and inflammation, with deficiencies frequently observed in CSU patients, although its role in the pathogenesis and treatment of CSU remains unclear. This study aimed to evaluate the impact of vitamin D3 supplementation in conjunction with Bilastine 40 mg on disease activity and control in CSU patients with low serum vitamin D3 levels.

Aims and Objectives

- To compare the efficacy of vitamin D3 + Bilastine 40 mg vs. Bilastine alone in improving hives and pruritus in CSU patients with vitamin D3 deficiency, assessed by UAS7 change from baseline to week 8.
- Assess earlier efficacy at week 4 using UAS7 change.
- Evaluate urticaria control via UCT score changes at weeks 4 and 8.

Materials & Methods:

A double-blind, randomized, placebo-controlled trial was conducted on 60 patients (≥12 years) with chronic spontaneous urticaria (CSU) and low serum vitamin D3 levels (duration ≥6 weeks). Antihistamines were discontinued seven days prior to baseline. Exclusion criteria included recent use of systemic immunomodulators (past 1 month), omalizumab (past 12 months), pregnancy, lactation, terminal illness, or significant systemic disease.

Participants were randomized (computer-generated) into two groups:

- **Group 1** received Bilastine 40 mg daily + placebo (weekly for 8 weeks)
- **Group 2** received Bilastine 40 mg daily + vitamin D3 (60,000 IU weekly for 8 weeks)

All medications were masked and dispensed in coded containers. Patients were evaluated at baseline, 1 month, and 2 months using the Urticaria Activity Score (UAS) and Urticaria Control Test (UCT).

Results:

- Baseline Characteristics: The mean age of participants was 28.8 ± 10.59 years, with a female predominance (66.7%). The mean duration of CSU was 16.3 ± 17.25 months.
- Disease Activity (UAS): Both groups showed a significant decrease in UAS over time ($p < 0.0001$). However, intergroup comparison revealed a significantly greater reduction in UAS in the Bilastine 40mg+ Vitamin D3

group starting from the first follow-up ($p = 0.014$). By the second month, the mean UAS in Group 1 was 13.03 ± 6.71, whereas Group 2 had a lower UAS of 9.76 ± 6.69 ($p = 0.0001$).

- Disease Control (UCT): A significant improvement in UCT scores was noted in both groups ($p < 0.0001$), with a superior increase in Group 2 from the first follow-up onwards ($p = 0.008$). By the second month, the mean UCT in Group 1 was 12.56 ± 2.01 compared to 14.13 ± 1.45 in Group 2 ($p = 0.001$).
- Vitamin D3 Levels: The baseline serum vitamin D3 levels were similar between groups (15.83 ± 3.4 ng/mL).
- Safety and Tolerability: No significant adverse effects were reported in either group.

Conclusion:

Vitamin D3 supplementation in CSU patients with low serum vitamin D3 levels significantly enhances the therapeutic response to Bilastine. Patients receiving vitamin D3 demonstrated faster and more pronounced improvements in disease activity and control compared to those on Bilastine alone. These findings suggest that vitamin D3 supplementation could be a beneficial adjunct therapy in CSU management. However, the study's small sample size (n=60) limits generalizability, and the short follow-up period (8 weeks) prevents assessment of long-term effects on remission and relapse, warranting larger, extended studies.

Abstract N°: 955

Characterizing omalizumab dosing patterns and drug survival in adult patients with chronic spontaneous urticaria

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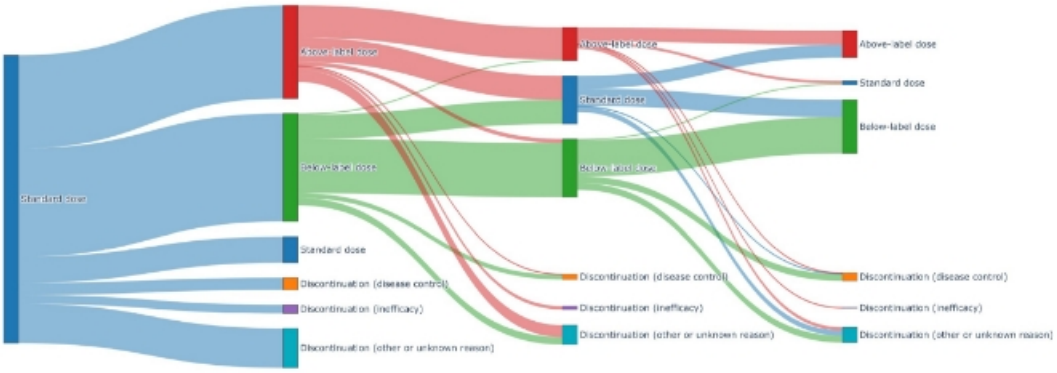
Characterizing omalizumab dosing patterns and drug survival in adult patients with chronic spontaneous urticaria

Introduction & Objectives: Omalizumab is an effective treatment for chronic spontaneous urticaria (CSU), but strategies and predictors for guiding long-term management and discontinuation remain limited. The objective of this study was to examine real-world treatment patterns, including dosing modifications and discontinuation, and identify potential predictive factors for these outcomes.

Materials & Methods: This was a retrospective, observational, real-life study of adult patients with CSU treated with omalizumab at a Urticaria Center of Reference and Excellence (UCARE) in Denmark, between May 20, 2015, and April 4, 2024. The Kaplan Meier estimator was used to visualize time to discontinuation and dose escalation/reduction (using standard label dosing as reference), and Cox regressions with hazard ratios (HR) were used to investigate potential predictive variables.

Results: Of 430 patients initiated on omalizumab, 139 (32.4%) escalated treatment, 161 (37.5%) reduced treatment, and 90 (21.0%) discontinued treatment directly from the standard dose. The median survival time for dose escalation was 2 years (95% CI: 1.17 – 3.55), and the strongest predictor was a positive basophil histamine release assay (BHRA) (HR: 2.79, 95% CI: 1.69 – 4.61). Fast treatment response (HR: 0.50, 95% CI: 0.33 – 0.75) and higher baseline UCT scores (HR: 0.89, 95% CI: 0.82 – 0.97) decreased risk of dose escalation. Median survival time to dose reduction dose was 1.2 years (95% CI: 0.98 – 1.49) and was more likely in males (HR: 1.68, 95% CI: 1.13 – 2.50) and patients with fast treatment response (HR: 1.66, 95% CI: 1.12 – 2.48). Median survival time to discontinuation (all reasons) of omalizumab was 3 years (95% CI: 2.35 – 3.64).

Conclusion: A considerable proportion of patients with CSU require modifications to the recommended omalizumab dosing regimen. A positive BHRA was the strongest predictor for dose escalation, while male sex and fast treatment response were the strongest predictors for dose reduction. Our study highlights the need of individualized strategies in managing CSU.


Standard dose
Above-label dose
Below-label dose
Standard dose
Discontinuation (disease control)
Discontinuation (inefficacy)
Discontinuation (other or unknown reason)
Above-label dose
Standard dose
Below-label dose
Discontinuation (disease control)
Discontinuation (inefficacy)
Discontinuation (other or unknown reason)
Above-label dose
Standard dose
Below-label dose
Discontinuation (disease control)
Discontinuation (inefficacy)
Discontinuation (other or unknown reason)

Abstract N°: 1015

Clinical Features of Urticaria: Disease Prognosis and Responding to Second Generation H1-antihistamine

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Introduction & Objectives:

Urticaria is a commonly found skin disease. This research aims to study and classify types of urticaria among patients undergoing treatments at a university hospital dermatologic clinic. We also explore the incidence of urticaria, comorbidities, laboratory results including disease prognosis, and the efficacy of second generation H1-antihistamines in the treatment of urticaria.

Materials & Methods:

The study was conducted based on a retrospective cohort study among patients diagnosed with urticaria undergoing treatments at Naresuan University Hospital in a five-year period between 1 October 2017 and 30 September 2022.

Results:

From the data collected at Naresuan University Hospital Dermatologist Clinic. Among 193 urticaria patients, 167 cases were chronic urticaria. 71.3% were female. The age group most affected was between 31-60 years old. For chronic urticaria patients, 89 patients (53.3%) came for the first follow-up appointment. 60 patients (67.4%) received cetirizine as medication. Cetirizine had the highest rate of well-controlled response or remission at 46.7% while loratadine with well-controlled response or remission was at 44.4%. Upon analyzing the response to treatment by using logistic regression model, the prediction variables were such as sex, age group, pre-diagnosis duration and antihistamine drug. Drug response categorized as remission and well controlled indicating improvement, and partly controlled and uncontrolled indicating no improvement. We had not found medications and factors which were statistically significant associated with the response of treatment.

Conclusion:

Chronic urticaria was more common than acute urticaria in dermatologist practice. Cetirizine and loratadine were common antihistamine prescriptions. The response rate was not differed between drugs. About half of patients were well controlled by antihistamine drugs.

Abstract N°: 1027

Mean Platelet Volume as a Potential Biomarker for Disease Severity in Chronic Spontaneous Urticaria: A Cross-Sectional Study

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is a heterogeneous skin disorder, often associated with autoimmune mechanisms. Identifying reliable biomarkers to predict disease severity and refractoriness remains a clinical challenge. Mean platelet volume (MPV), a marker of platelet activation and systemic inflammation, has been implicated in autoimmune diseases but remains understudied in CSU. The objective of this study was to evaluate the role of MPV in CSU patients and its correlation with disease severity (UAS7). Also, to compare MPV levels with existing inflammatory markers (D-dimer, serum IgE, CRP, anti-TPO antibodies) to assess its potential prognostic marker in CSU.

Materials & Methods: A single-center, cross-sectional study was conducted at a tertiary care hospital in India over 18 months. Thirty adult patients clinically diagnosed with CSU were consecutively enrolled . Disease severity was assessed using the Urticaria Activity Score over seven days (UAS7). Patients were classified into mild (UAS7: 7–15), moderate (UAS7: 16–25), and severe (UAS7: 28–42) categories. MPV levels were analyzed using cut-off values of 12 fL, alongside other inflammatory markers, including serum IgE, D-dimer, anti-thyroid peroxidase (anti-TPO) antibodies, and C-reactive protein (CRP).

Results: Among the 30 participants, 10% had mild disease, 56.7% had moderate disease, and 33.3% had severe disease. Using a reference cut-off of 12 fL, 23.3% (7/30) of patients had elevated MPV levels. Among them, 28.6% had moderate disease, while 71.4% had severe disease. This association was statistically significant ($p = 0.046$). The mean MPV was 9.77 ± 2.31 fL, with a range of 5.30–13.30 fL. ASST-positive patients exhibited a slightly higher MPV (10.65 ± 2.08 fL) compared to ASST-negative patients (9.80 ± 2.20 fL), but the difference was not statistically significant ($p = 0.39$). A weak positive correlation was noted between UAS7 and MPV ($r = 0.158$, $p = 0.40$).

Also, patients with elevated MPV tended to show numerically higher values in disease severity (UAS7) and inflammatory markers such as serum IgE, D-dimer, anti-thyroid peroxidase (anti-TPO) antibodies, and C-reactive protein (CRP), but these differences did not reach statistical significance in this study, likely due to the small study population.

Conclusion: This study suggests that elevated MPV is associated with increased CSU disease severity, particularly in moderate-to-severe cases. While MPV may serve as a useful biomarker, further large-scale studies are needed to validate its prognostic value in CSU management.

Abstract N°: 1029

Assessing Mean Platelet Volume as a Prognostic Biomarker in Chronic Spontaneous Urticaria: Does Threshold Selection Matter?

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Introduction & Objectives:

Background:

Chronic spontaneous urticaria (CSU) is a heterogeneous disorder, with an autoimmune subset characterized by autoreactivity, severe disease, and limited response to antihistamines. Mean platelet volume (MPV), a marker of platelet activation and systemic inflammation, has emerged as a potential biomarker but its utility remains controversial due to conflicting results and varying threshold definitions.

Objective:

To evaluate MPV as a prognostic biomarker for disease severity in CSU patients and assess whether threshold selection impacts its clinical significance.

Materials & Methods: We conducted an18-month observational, cross-sectional study at a tertiary care centre in India, enrolling 30 consecutive adult patients diagnosed with CSU. Disease severity was assessed using the Urticaria Activity Score (UAS7), and patients were stratified based on two MPV thresholds (>12fL and>9.1fL). Clinical, demographic, and biochemical parameters, including inflammatory markers (CRP, D-dimer,IgE), vitamin D3, anti-thyroid peroxidase (anti-TPO) antibodies, and autoreactivity (ASST), were analysed.

Results: The mean age of patients was 32.3 ± 9.3 years, with a female predominance (76.7%). Moderate CSU severity prevailed (mean UAS7: 22.40 ± 6.20). Using the higher MPV threshold (>12 fL), elevated MPV significantly correlated with severe CSU ($p = 0.046$): 71.43% of patients with elevated MPV had severe disease compared to 21.74% with normal MPV, with no cases of mild disease among elevated MPV patients. In contrast, at the lower MPV threshold (>9.1 fL), no significant association with severity was found ($p = 0.47$). Elevated MPV (>9.1 fL) showed nonsignificant trends toward higher inflammatory markers and longer disease duration, yet no statistically significant associations with CRP, IgE, D-dimer, anti-TPO antibodies, ASST positivity, or vitamin D3 levels were noted.

Conclusion: MPV may serve as a useful biomarker for severe CSU when using a higher threshold (>12 fL), whereas lower thresholds lack specificity. Further large-scale studies are necessary to confirm these findings and establish standardized MPV cut-offs.

Abstract N°: 1066

Sleep Disorders and Urticaria

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Introduction & Objectives:

Urticaria, a frequently encountered skin disorder in clinical practice, is often associated with a reduced quality of life, particularly concerning sleep. Sleep disturbances are commonly reported among patients with chronic urticaria, yet the overall impact of this association remains underexplored. This study aims to assess the prevalence of sleep disorders in patients with urticaria and analyze their impact on quality of life.

Materials & Methods:

We conducted a cross-sectional observational study involving 100 adult patients diagnosed with chronic urticaria. Sleep disturbances were assessed using the Pittsburgh Sleep Quality Index (PSQI), while quality of life was measured with the Urticaria Quality of Life (U-QOL) tool. Clinical, biological, and demographic data were also collected to explore associated factors.

Results:

Among the 100 patients included in the study, 112 completed all questionnaires and assessments (93.3% participation rate). The population consisted of 62 women (55.4%) and 50 men (44.6%), with a mean age of 43.5 ± 12.4 years. The median duration of urticaria was 24 months.

Sleep disorders were highly prevalent in this population, affecting 95 patients (85%). The most frequently reported disturbances included insomnia (68%), frequent nocturnal awakenings (62%), difficulty falling asleep (47%), and excessive daytime sleepiness (43%).

Analysis of PSQI scores revealed that 92 patients (82%) had a total score above 5, indicating poor sleep quality. The mean PSQI score was 8.3 ± 3.1, reflecting significant sleep impairment. A significant positive correlation was observed between poor sleep quality and urticaria symptom severity ($r = 0.68$; $p < 0.01$).

Sleep disturbances also had a marked impact on quality of life, particularly in the emotional and functional domains assessed by U-QOL scores. Patients with sleep disorders experienced an average reduction of 5.2 points in the emotional domain ($p < 0.01$) and 4.6 points in the functional domain ($p < 0.05$), highlighting significant impairment in these aspects.

Multivariate analysis identified several factors associated with the prevalence and severity of sleep disorders. A prolonged duration of urticaria (more than 12 months) was significantly associated with an increased risk of sleep disturbances (odds ratio = 2.3; $p < 0.01$). Additionally, patients with severe urticaria (Urticaria Activity Score > 25) were more likely to report sleep disorders (odds ratio = 1.9; $p < 0.05$). Furthermore, the presence of psychiatric comorbidities, such as anxiety or depressive disorders, was a major predictive factor for sleep disturbances, with an odds ratio of 3.2 ($p < 0.01$).

Conclusion:

Sleep disorders are frequently encountered in patients with chronic urticaria and significantly impact their quality of life. The management of urticaria should include systematic evaluation of sleep disturbances, and targeted therapeutic strategies could substantially improve patient well-being. These findings highlight the importance of a multidisciplinary approach in the treatment of chronic urticaria, particularly for patients suffering from sleep disorders.

Abstract N°: 1195

Epidemiology, clinical characteristics and treatment patterns of chronic spontaneous urticaria patients treated in Finnish secondary care: a register-based study

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is defined as recurring episodes of itchy wheals over a period of 6 weeks or more, with no clear external trigger for the symptoms, and is commonly associated with angioedema. CSU epidemiology and patient population in Finland has not been studied previously. The objective of this study was to describe epidemiology, demographics and treatment patterns of CSU in secondary care in Finland.

Materials & Methods:

This was a non-interventional, retrospective register study utilizing data from national registries in Finland. Finnish Care Register for Health Care, Register of Primary Health Care Visits and reimbursed drug purchases register were used. The study cohort consisted of all adult patients with at least two registered ICD-10 diagnoses codes L50.1, L50.8 or L50.9 in specialty care within an 18-month time during the inclusion period 1996-2022. Prevalence and incidence of CSU, as well as patient demographics and comorbidities, patient proportions on different medications, and use of combination treatments were determined.

Results:

The annual point prevalence of CSU was 0.21% in 2022, whereas incidence ranged from 6.9 to 12.58 cases per 100 000 persons (2001-2021). Total number of CSU patients in the cohort was 8784 with the mean age of 45.3 years at index diagnosis and 70.0% of the patients were female. The most common comorbidities diagnosed in specialty care were diseases of the respiratory system (35.6%), dermatitis and eczema (21.6%), benign neoplasms (15.9%), asthma (10.7%) and atopic dermatitis (9.3%). Depression was diagnosed in 8.6% and anxiety disorder in 5.2% of the cases. Antihistamines were used by 85.8% of patients, and 36.1% of all patients had used a combination of antihistamine and corticosteroids. For patients receiving omalizumab, in 86.4% this was preceded by antihistamine use, and the mean duration between first antihistamine treatment and omalizumab was 2.5 years. During omalizumab treatment, 74.9% of patients also used antihistamines, whereas only 7.6% used corticosteroids. Duration of omalizumab treatment was on average 16.7 months and ranged from 0.1 to 90.0 months (0-7.5 years).

Conclusion:

This is the first study to report CSU incidence and prevalence and to describe patient characteristics and treatment patterns within secondary care in Finland. Prevalence was in line with prevalence ranges reported from other European countries, and patient demographics correspond with previous reports. Atopic, autoimmune and psychiatric comorbidities were common among CSU cases. Antihistamine use was mostly in line with international treatment guidelines - interestingly almost half of patients using antihistamines also used corticosteroids, possibly

indicating need for treatment escalation. High concomitant use of antihistamines with omalizumab was in line with international treatment guidelines, whereas low corticosteroid use in these patients may indicate adequate symptom control in most patients. Limitations of the study include the lack of primary care CSU diagnosis data, data of drug doses and means to accurately identify patients with angioedema.

Abstract N°: 1998

Omalizumab Treated Urticaria Patients Display T Cell and Thrombocyte-Associated Gene Regulation

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Omalizumab Treated Urticaria Patients Display T Cell and Thrombocyte-Associated Gene Regulation

Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is a debilitating inflammatory skin disease with a prevalence of approximately 1% of the population. It is characterized by recurrent itchy wheals and/or angioedema for more than 6 weeks without known triggers leading to a high quality of life impairment. The pathogenesis of CSU remains not fully understood. This study aimed to explore the pathomechanism of CSU beyond mast cells and IgE-dependent histamine release and to identify possible biomarkers for the disease and its treatment.

Materials & Methods:

We investigated a patient cohort in the first month of omalizumab treatment regarding the IgE levels and changes in gene and miRNA expression in peripheral blood. The cohort was divided into responders and non-responders (depending on the score of the urticaria control test) and compared to a group of healthy controls.

Results:

Our messenger RNA and microRNA microarray analyses revealed the greatest changes in expression levels on Day 2 after the first omalizumab dose.

Conclusion:

We identified several genes and miRNAs of interest, most of which have not been described to be linked to CSU so far, underlining, for example, to T cell involvement or even suggesting platelet involvement.

Abstract N°: 2023

Association of Serum Biomarkers with Disease Severity in Chronic Spontaneous Urticaria: A Cross-Sectional Study

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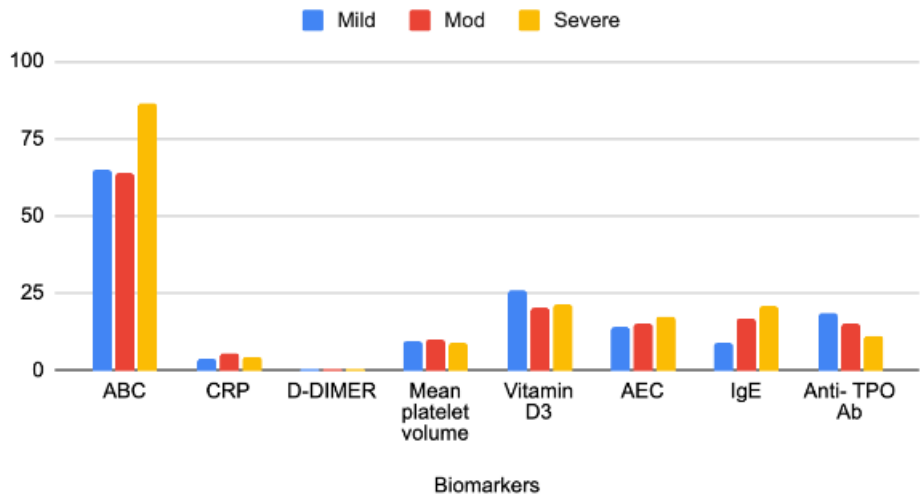
Introduction & Objectives: Chronic Spontaneous Urticaria (CSU) is a heterogeneous disorder with two distinct endotypes: type I and type IIb. The identification of these endotypes has improved our understanding of the pathogenesis of CSU and has implications in disease severity and management. Various inflammatory and immunological biomarkers have been studied for their correlation with disease activity, but consistent associations remain elusive. Our objective was **t**o evaluate the correlation between selected biomarkers and the severity of CSU as assessed by UAS7.

Materials & Methods: This was an observational cross-sectional study that included a total of 30 patients with CSU who were categorized into three groups based on UAS7 scores: mild (n=8), moderate (n=16), and severe (n=6). The following biomarkers were assessed: Absolute Basophil Count (ABC), C-reactive protein (CRP), D-dimer, Mean Platelet Volume (MPV), Vitamin D3, Absolute Eosinophil Count (AEC), Immunoglobulin E (IgE), and Anti-Thyroid Peroxidase Antibody (Anti-TPO Ab). Data were analyzed using ANOVA and Kruskal-Wallis tests, and Pearson correlation coefficients were calculated.

Results: In the present study, various biomarkers were analyzed across different severity levels of urticaria based on UAS7 scores. The mean absolute basophil count (ABC) was found to be 64.75 in the mild group, 63.88 in the moderate group, and 86.33 in the severe group, with no statistically significant difference ($p = 0.719$, ANOVA). The mean absolute eosinophil count (AEC) was 14.19 cells/µL in mild cases, 15.41 cells/µL in moderate cases, and 17.50 cells/µL in severe cases, again without a significant difference ($p = 0.7828$, Kruskal-Wallis test). The mean C-reactive protein (CRP) levels were 3.88 mg/L in mild cases, 5.50 mg/L in moderate cases, and 4.26 mg/L in severe cases, also showing no significant association with disease severity ($p = 0.690$, ANOVA). Mean D-dimer levels were fairly consistent across all groups—0.5212 µg/mL in mild, 0.5013 µg/mL in moderate, and 0.5033 µg/mL in severe cases—with a non-significant p-value of 0.992. The mean platelet volume (MPV) showed minimal variation, recorded as 9.34 fL in the mild group, 10.19 fL in moderate, and 9.22 fL in severe cases ($p = 0.581$, ANOVA). Mean Vitamin D3 levels were higher in the mild group (25.85 ng/mL) compared to moderate (20.39 ng/mL) and severe (21.52 ng/mL) groups, although this difference was not statistically significant ($p = 0.194$, ANOVA). Interestingly, serum mean IgE levels showed a rising trend with disease severity—8.88 IU/mL in the mild group, 16.87 IU/mL in moderate, and 20.67 IU/mL in severe cases—which was statistically significant ($p = 0.0304$, Kruskal-Wallis test), indicating a potential correlation between elevated IgE levels and increasing severity of urticaria. Lastly, anti-thyroid peroxidase antibody (anti-TPO Ab) levels were found to be 18.81 IU/mL in mild, 15.44 IU/mL in moderate, and 11.25 IU/mL in severe cases, but the difference did not reach statistical significance ($p = 0.2817$, Kruskal-Wallis test).

Conclusion: Our study revealed that among all biomarkers, only serum IgE has a statistically significant difference with disease severity. All other biomarkers, including ABC CRP, D-dimer, MPV, Vitamin D3, AEC and Anti-TPO Ab, showed no significant correlation. Further research with larger cohorts is warranted to explore the role of IgE and other markers in the pathogenesis and monitoring of CSU.


Mild
Mod
Severe
100
75
50
25
0
ABC
CRP
D-DIMER
Mean platelet volume
Vitamin D3
AEC
IgE
Anti- TPO Ab
Biomarkers

Abstract N°: 2291

Solar Urticaria: A Descriptive Study of a Series of 13 Cases

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Introduction & Objectives: Solar urticaria is a rare form of inducible urticaria with an unknown etiopathogenesis. It is an acquired photosensitivity disorder that typically begins in young adulthood. There is a female predominance, and it is associated with other photodermatoses and atopic dermatitis. This disease can severely affect patients' quality of life and limit their daily outdoor activities. The diagnosis should be suspected in patients with recurrent episodes of urticarial rash following sun exposure. Photobiological tests—primarily phototesting—support the diagnosis.

However, the treatment of solar urticaria remains a significant challenge. Avoidance of sun exposure and photoprotection using broad-spectrum sunscreens are essential. Second-generation antihistamine one receptor antagonist agents should be established as the first-line treatment. When these measures are ineffective, phototherapy and controlled sun exposure may be employed to induce tolerance (hardening) to sunlight. Reports in the literature describe the use of immunomodulators, plasmapheresis, immunoglobulins, and omalizumab, among other options, for managing recalcitrant cases, with varying degrees of success.

Materials & Methods: We conducted a descriptive analysis of a series of 13 patients diagnosed with solar urticaria, confirmed by phototesting, including ultraviolet (UV) A, UVB and visible light.

Results: The median age of the patients was 44 years (range: 14–66), with a clear male predominance (76.9%). Six patients (46%) had atopic dermatitis and/or other atopic comorbidities such as pollinosis or asthma. None of the patients had associated photodermatoses or spontaneous urticarial lesions.

Regarding phototesting, the majority of patients (84%) exhibited urticaria in response to visible light. The second most common trigger was UVA (61%), and 54% of patients reacted to a combination of both.

All patients were treated with antihistamines and advised on physical measures to avoid sun exposure. Five patients (58%) achieved good control with phototherapy and gradual sun exposure. However, six patients (46%) had recalcitrant urticaria that led to the initiation of omalizumab. Treatment had to be discontinued in two patients due to lack of response. In contrast, four patients responded well to omalizumab, allowing treatment spacing in two of them.

Conclusion: In conclusion, we present a descriptive study of 13 patients with solar urticaria and the various treatments administered, underscoring the therapeutic challenges posed by this condition.

Abstract N°: 2533

Leukemoid reaction with general symptoms in a patient with Chronic Spontaneous Urticaria treated with dapsone: a rare paradoxical effect.

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Introduction & Objectives: Dapsone (4,4'-diaminodiphenylsulfone) is an antimicrobial and anti-inflammatory agent commonly used in dermatology. While international guidelines recommend second-generation antihistamines as first- and second-line therapies for chronic spontaneous urticaria (CSU), 23–33% of patients remain uncontrolled, necessitating alternative therapies such as omalizumab or cyclosporine. Due to their cost and potential adverse effects, more affordable adjuvants like dapsone are sometimes used, despite limited evidence and the risk of serious side effects including haemolysis, agranulocytosis, and rarely DRESS syndrome or neuropathy.

Materials & Methods: We present the case of a 37-year-old woman with CSU unresponsive to up-dosed antihistamines and montelukast. After refusing omalizumab and cyclosporine, dapsone was initiated (50 mg/day) following a normal G6PD test. Partial symptom relief occurred, but she developed fatigue, low-grade fever, and neutrophilia without rash. Dapsone was discontinued due to suspected leukemoid reaction. Bone marrow aspirate revealed hypercellularity and immature myeloid forms without leukemia. Biopsy confirmed neutrophilic predominance without malignancy. Neutrophil counts peaked at 22,000/mm^3, then normalized within eight weeks after drug cessation (Table 1). Prednisolone (0.5 mg/kg/day for 10 days) was administered with good clinical outcome.

Results: Patient had favourable clinical response.

Conclusion: Dapsone's long half-life and enterohepatic recirculation contribute to its delayed adverse effects. Although agranulocytosis is a well-documented reaction, this case illustrates a rare neutrophilic (leukemoid) response to dapsone. The absence of DRESS syndrome and the self-resolving course post-discontinuation suggest a paradoxical drug-induced neutrophilic reaction. Only three similar cases are described in the literature. This report emphasizes the need for vigilant monitoring during dapsone therapy, especially in off-label contexts.

Table 1. Evolution of laboratory tests that changed during the use of dapsone and the patient's 7-day urticaria activity score (UAS7).

Laboratory and clinical parameters	Before dapsone	Dapsone 25 mg/day	Dapsone 50 mg/day	Dapsone withdrawal	After 4 weeks	After 8 weeks
Hemoglobin (g/dL)	13	13	13	13	13	13
Total White Blood cells (cells/mm3)	6700	9400	18300	21600	20140	8700
Rods (%)	2	3	4	7	2	1
Blasts (%)	0	0	0	2	0	0
Neutrophils (%)	66	69.5	72	88	71	56.5
Platlets/mm3	292000	318000	335000	324000	289000	288000
UAS7	42	34	28	21	40	38

Abstract N°: 2603

High level of Quality-of-Life impact among families of chronic spontaneous urticaria patients: Family Dermatology Quality of Life Index (FDLQI) multicenter project (FAMLI-CSU)

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Introduction & Objectives: Chronic Spontaneous Urticaria (CSU) can cause psychosocial and quality-of-life burden, for patients and their family members and caregivers. CSU is recognized as a debilitating disease, however, there is no data on how CSU can affect the lives of family members, hindering a complete understanding of the disease's broader impact. The aim was to apply the Family Dermatology Life Quality Index (FDLQI) questionnaire to evaluate how CSU affects the quality of life of family members who support patients in their daily

struggles, across different countries.

Materials & Methods: This is a cross-sectional, multicenter, and international study conducted between January and December 2024 in UCARE (Urticaria Centers of Reference and Excellence) centers located in countries including Brazil, China, Ecuador, Greece, India, Oman, Poland, Russia, Thailand, Turkey, and North Macedonia. Statistical analyses, including non-parametric tests and multiple regression models, were performed to explore associations between disease severity/control and family burden.

Results: Poorly controlled CSU significantly worsens family members' quality of life, especially in emotional, physical, and social domains. Higher disease severity and lower disease control scores were associated with more stress, greater caregiving burden, and increased household expenses. Stronger family ties, older age, and longer time since diagnosis helped mitigate negative impacts, while complex treatment regimens worsened them.

Conclusion: Inadequate control of CSU amplifies the burden on families, underscoring the need for effective, and supportive care strategies.

Abstract N°: 2750

Barzolvolimab Treatment Improves Urticaria Activity in Patients with Chronic Spontaneous Urticaria Regardless of Baseline IgE Levels

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[5]Medical University of Lublin, Lublin, Poland
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Introduction & Objectives:

Mast cells (MCs) are key effector cells in chronic spontaneous urticaria (CSU). Barzolvolimab, a humanized monoclonal antibody that inhibits KIT activation by SCF, demonstrates rapid and durable depletion of skin MCs. We previously reported that barzolvolimab demonstrated statistically significant and clinically meaningful improvement in weekly Urticaria Activity Score (UAS7) at 12 weeks, with deepening of response over 52 weeks in antihistamine-refractory CSU patients (NCT05368285), including patients who received prior omalizumab. Here we report the UAS7 and UAS7=0 results in relation to baseline total IgE level at Weeks 12 and 52.

Materials & Methods:

This double-blind, placebo-controlled trial randomized patients to receive barzolvolimab SC at 75mg Q4W, 150mg Q4W, 300mg Q8W or placebo during a 16-week placebo-controlled treatment phase followed by 36-weeks of active treatment and 24-weeks follow-up. Placebo and 75mg Q4W dose groups were re-randomized to 150mg Q4W or 300mg Q8W during active treatment period. Kinetics of clinical response were grouped by low circulating total IgE (≤40 IU/mL) and normal/high IgE (>40 IU/mL) at baseline in patients who received 150mg Q4W and 300mg Q8W doses.

Results:

208 patients were enrolled; of these, 52 and 51 were randomized into the 150mg Q4W and 300mg Q8W groups, respectively. Mean (SD) baseline UAS7 scores were 31 (7.7) and 31 (6.9) for the 150mg Q4W and 300mg Q8W groups respectively; median (IQR) IgE was 60 IU/mL (13-139) and 92 IU/mL (35-235) for the 150 Q4W and 300 Q8W groups, respectively. At Week 12, patients with low vs normal/high IgE had a mean 24- vs 26-point and 22- vs 23-point reduction from baseline in UAS7 in the 150 mg Q4W and 300 mg Q8W groups, respectively. Of the patients who achieved a complete response at week 12 in the 150 mg and 300 mg groups, 44% had baseline total IgE levels ≤40 kU/mL. The rate ratio (95%CI) of achieving a complete response in patients with low compared to

normal/high baseline total IgE was 1.37 (0.74-2.55) and 1.24 (0.71-2.16) in the 150mg Q4W and 300mg Q8W groups, respectively. At Week 52, similar results were observed.

Conclusion:

Barzolvolimab at 150mg Q4W and 300mg Q8W demonstrated similar clinically meaningful benefits in UAS7 and UAS7=0 in CSU patients regardless of baseline total IgE level, consistent with its mechanism of action.

Abstract N°: 2928

Refractory chronic spontaneous urticaria treated with Dupilumab: a case report.

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Introduction & Objectives: 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.

Materials & Methods: 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 4-year follow-up after treatment.

Results: A 50-year-old woman with occasional episodes of poorly controlled asthma, who for the last several years has presented recurrent outbreaks of CSU. Examination revealed generalized wheals without angioedema, with associated intense pruritus that negatively interfered with her quality of life. The diagnosis was confirmed by anatomopathological study on two separate visits.

The patient experienced secondary failure after 2 years of treatment despite receiving quadruple doses of antihistamines and Omalizumab 600mg every 4 weeks. She started treatment with Methotrexate 12.5mg injection, but had to stop after 3 weeks due to digestive side effects. Subsequently, she started treatment with Cyclosporine 300mg daily with good initial response, but there was an elevation of creatinine levels that forced to reduce the dose with new appearance of wheals. Finally, the patient started treatment with Dupilumab 300mg every 2 weeks with disappearance of skin lesions during the last 6 months and no new asthma flare-ups. As an adverse effect, mild eczema of the face and neck appeared after the first injections, which was satisfactorily controlled with topical corticosteroids.

Conclusion: Dupilumab appears to be a safe and effective therapeutic alternative to reduce skin lesions and pruritus in some patients with CSU who do not respond to currently approved treatments as demonstrated by the present and other recently published cases.

Abstract N°: 3114

National and regional drug survival of omalizumab in chronic spontaneous urticaria: A Danish cohort study

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National and regional drug survival of omalizumab in chronic spontaneous urticaria: A Danish cohort study
Introduction & Objectives: Omalizumab is an effective biological therapy for chronic spontaneous urticaria (CSU), but its high cost, the unpredictable nature of the disease, and limited long-term management guidance lead to varying treatment approaches. Drug survival (DS) studies may encompass various reasons for discontinuation, and remain a key metric for assessing drug effectiveness, utilization, and cost. However, the impact of varying treatment approaches and different data sources on DS estimates remains unclear.** The objective of this study was therefore to investigate DS of omalizumab in adult patients with CSU in Denmark and assess regional variations using national registry data.

Materials & Methods: Data from the Danish National Patient Registry (DNPR) were used to identify patients with CSU who initiated omalizumab treatment, excluding those with only chronic inducible urticaria or concurrent asthma. Analyses on DS were performed using Kaplan-Meier curves, based on the first treatment series, both nationally and stratified by five specialized regional departments.

Results: A total of 1,797 patients were analyzed. Median DS time was 2.20 years (95% CI: 2.03 – 2.36). For patients with multiple treatment series, median survival time for subsequent series was shorter at 1.00 year (95% CI: 0.93 – 1.19). Despite some regional variation in treatment approaches, survival curves were similar, with no statistical difference. However, we found considerable variation in DS when comparing administrative registry data with clinical database information.

Conclusion: Median survival time of omalizumab in adult patients with CSU was approximately 2 years. Despite regional variation in treatment approaches, DS remains consistent. However, a substantial discrepancy exists between DS estimates from different data sources, emphasizing the need to account for these variations when assessing and interpreting drug utilization.

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Abstract N°: 3173

Effectiveness and safety of omalizumab for chronic spontaneous urticaria during pregnancy: A systematic review

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is a relatively common disorder, with a global prevalence of approximately 1%, affecting most commonly females, especially during their reproductive age. Data have demonstrated that approximately 30% of pregnant urticaria patients experience disease worsening, necessitating evidence-based directions regarding the management of CSU during pregnancy. Omalizumab, a recombinant humanized IgG1K monoclonal antibody that selectively binds to human IgE, is an approved add-on therapy for patients with CSU refractory to H1-antihistamines. However, its safety and efficacy in pregnant women with CSU is not fully documented, necessitating a systematic evaluation of available evidence to inform clinical decision-making and optimize maternal and fetal outcomes. Thus, we have conducted this systematic review aiming to summarize the available evidence regarding the use of omalizumab during pregnancy.

Materials & Methods: This study was conducted in adherence with the PRISMA guidelines and was registered in PROSPERO. Systematic literature searches were conducted in MEDLINE/PubMed, Scopus and Web of Science, from their inception to March 2025 to identify studies reporting on pregnant women treated with omalizumab during pregnancy and/or conception. Two independent authors performed the screening and data extraction, resolving all disagreements with a third author.

Results: In total, 710 publications were originally identified and after the removal of duplicates using the Endnote reference manager, 550 were screened based on title and abstract. Full-text screening was performed for 45 articles, from which 12 met the eligibility criteria and were included in the systematic review. Altogether, 67 women that received omalizumab during a period of pregnancy or until delivery were reported. Among them, 27 had been treated with omalizumab before pregnancy and continued through pregnancy, 5 discontinued omalizumab when they were informed about the pregnancy but restarted due to flare-up of urticarial lesions, 7 had started during pregnancy due to poor disease control with H1 antihistamines while 28 patients decided to permanently discontinue omalizumab as soon as they found out they were pregnant. Only one miscarriage was reported along with a child being born with an aneurysm of the fetal ascending aorta/skin defect in the upper portion of umbilicus. No other pregnancy or fetal complications were reported. Five pre-term births were reported with no author raising specific concerns regarding omalizumab use. Among the studies with available clinical data, all patients on omalizumab achieved complete remission or good control of disease.

Conclusion: Albeit our study is limited by the small patients' sample reviewed along with the fact that most publications were case reports/series, our findings suggest that omalizumab is an effective and relatively safe option for the management of CSU during pregnancy. Further research is warranted, with well-designed, prospective studies evaluating the safety and effectiveness of omalizumab during pregnancy.

Abstract N°: 3349

Real-World Evaluation of the Effectiveness and Safety of Dupilumab in Chronic Urticaria: An Ambispective Multicenter Case Series

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Introduction: Chronic urticaria (CU) remains a challenging condition with significant unmet needs, particularly in cases refractory to antihistamines and omalizumab. Dupilumab, a monoclonal antibody targeting interleukin (IL)-4 and IL-13, currently approved for moderate-to-severe atopic dermatitis and prurigo nodularis, offers a promising alternative by modulating both IgE-dependent and -independent inflammatory pathways.

Objectives: Evaluate the effectiveness and safety of dupilumab in the treatment of CU in real world clinical practice.

Materials & Methods: A multicenter ambispective cohort study was conducted across 16 Spanish hospitals. Patients with CU—including chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU)—treated with dupilumab were included. All patients had a minimum follow-up of 4 weeks. Most received an initial 600 mg loading dose, followed by 300 mg every two weeks.

Outcomes and Measures: The primary outcome was the proportion of patients achieving well-controlled CU within 24 weeks, defined as Urticaria Control Test (UCT) ≥12 and/or a Urticaria Activity Score over 7 days (UAS7)

≤6. Secondary outcomes included the proportion of patients achieving well control and complete control (UCT = 16 and/or UAS7 = 0) at weeks 4, 12, 24, and 52; change from baseline in peak pruritus numerical rating scale (NRS) at given time points; adverse events; and reductions in the use of concomitant therapies.

Results: A total of 47 patients were included (median age 50.0 years, IQR 38.5–58.5; 66.0% female). CIndU was present in 59.6% of patients, with symptomatic dermographism being the most frequent subtype (31.9%). Median baseline UCT was 4.0 (IQR 2.0–7.0), and baseline UAS7 was 30.0 (IQR 23.5–36.0). The main indication for dupilumab was uncontrolled CU (90.0%), with five cases treated for concomitant conditions (3 atopic dermatitis, 1 asthma, 1 bullous pemphigoid). Most patients initiated dupilumab concomitantly with other medications, most frequently antihistamines (67.3%). Well-controlled CU was achieved in 57.4% (n=27/47) of patients by week 12, 82.1% (n=23/27) by week 24, and 100.0% (n=16/16) by week 52. Peak pruritus NRS decreased by 63.3% at week 12 and 75.4% at week 24. Concomitant treatment use decreased by 67.9% after 52 weeks. Six patients experienced mild adverse events (conjunctivitis n=2, xerophthalmia n=2, headache n=2, asthenia n=1). Dupilumab was discontinued in 8 patients, all due to lack of efficacy.

Conclusion: In this real-world cohort—the largest to date evaluating dupilumab in CU—patients with antihistamine- and/or omalizumab-refractory disease achieved high rates of disease control and significant symptom improvement. Dupilumab demonstrated a favourable safety profile and enabled a marked reduction in concomitant treatment use. These findings support dupilumab as an effective and well-tolerated treatment option for difficult-to-treat CU in routine clinical practice.

Abstract N°: 3367

CH50 as a Novel and Promising Biomarker for Chronic Urticaria Activity and Antihistamine Resistance: An Exploratory Analysis

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Introduction: Chronic urticaria (CU) is a chronic type 2 inflammatory skin disorder with heterogeneous and dynamic underlying mechanisms. Many patients do not respond adequately to the current stepwise treatment recommended in international guidelines, highlighting the need for better predictive biomarkers. Given the growing evidence that the coagulation cascade may contribute to its pathophysiology, the Total Hemolytic Complement (CH50) test—which assesses overall classical complement pathway activity—may serve as a novel biomarker in CU.

Objectives: To assess CH50 as a biomarker for disease activity and a predictor of treatment response in patients with CU.

Materials & Methods: This was an observational, ambispective study including 180 CU patients and 45 healthy controls. Serum CH50 levels were measured and correlated with clinical and immunological markers. Treatment response to second-generation antihistamines and omalizumab was evaluated at 3, 6, and 12 months.

Results: CH50 levels were significantly higher in CU patients than in healthy controls ($p < 0.001$) and were associated with more severe and prolonged disease. Clinically, CH50 correlated with UAS7 (rho = 0.300, $p < 0.0001$), UCT (rho = –0.250, $p < 0.001$), and a longer disease duration (rho = 0.280, $p = 0.0002$). Immunologically, CH50 correlated with D-dimer (rho = 0.310, $p < 0.001$), C4 (rho = 0.370, $p < 0.001$), and IgG anti-TPO (rho = 0.210, $p < 0.005$). Higher CH50 levels were associated with antihistamine resistance ($p < 0.001$), and CH50 showed a significantly higher AUC than D-dimer, C4, and UAS7 for predicting antihistamine resistance. No association was found between CH50 and omalizumab response.

Conclusion: CH50 is a promising biomarker for CU severity and antihistamine resistance. It outperforms previously established biomarkers in predicting treatment failure, and its integration into predictive models may improve treatment stratification and support endotype-driven approaches. Further validation in larger cohorts is needed.

Abstract N°: 3713

Efficacy, Safety, and Tolerability of Bilastine Versus Levocetirizine for Chronic Spontaneous Urticaria: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Introduction & Objectives: Chronic Spontaneous Urticaria (CSU) is defined as the spontaneous occurrence of wheals, angioedema, or both for 6 weeks or more, without an identifiable external trigger. The 2021 EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guideline recommends second-generation H1-antihistamines (SGAHs) as the first-line therapy for CSU, with dose escalation up to fourfold for insufficient responders. Among SGAHs, levocetirizine is a widely used agent known for its clinical effectiveness. Bilastine, a newer alternative, is noted for its high peripheral H1 receptor selectivity and minimal sedative effects. This systematic review and meta-analysis aim to compare the efficacy, safety, and tolerability of bilastine and levocetirizine.

Materials & Methods: A systematic literature search was conducted in accordance with the PRISMA guidelines to identify randomized controlled trials (RCTs) comparing bilastine and levocetirizine in the treatment of CSU. Two reviewers independently performed the comprehensive screening, selection process and data extraction. The primary outcome was the change in the Urticaria Activity Score over 7 days (UAS7). Secondary outcomes included changes in the Dermatology Life Quality Index (DLQI) and Visual Analog Scale (VAS) scores related to urticaria symptoms. Safety endpoints included the incidence of adverse events (AE) and somnolence. Continuous outcomes were analyzed using pooled mean differences (MD), and dichotomous safety outcomes were synthesized using risk ratios (RR), both under a DerSimonian–Laird random-effects model. Statistical heterogeneity was assessed using the I^2 statistic. The methodological quality of included RCTs was evaluated using the Cochrane RoB 2.0 tool.

Results: A total of 5 RCTs involving 1,127 patients were included, comparing bilastine 20 mg (n = 462) to levocetirizine 5 mg (n = 449), with 216 patients assigned to placebo or fexofenadine in third-arm studies. The eligible age range spanned from 12 to 70 years, 38.1% were men, and 61.9% were women. Risk of bias was low in 3 studies and raised some concerns in 2, primarily related to missing data. Regarding efficacy, there was no significant difference in UAS7 between bilastine and levocetirizine (MD: –0.09; 95% CI: –2.14 to 1.97; p = 0.94; I^2 = 86%; low certainty). Quality of life (QoL) outcomes assessed by DLQI showed a nonsignificant trend favoring levocetirizine (MD: –1.10; 95% CI: –3.52 to 1.33; p = 0.37; I^2 = 70%; low certainty), while VAS scores for discomfort were also comparable (MD: –2.40; 95% CI: –6.90 to 2.10; p = 0.30; I^2 = 62%; low certainty). AE rates were similar across groups (RR: 0.86; 95% CI: 0.63 to 1.18; p = 0.36; I^2 = 35%; moderate certainty), but bilastine demonstrated a significantly lower risk of somnolence (RR: 0.40; 95% CI: 0.26 to 0.63; p < 0.0001; I^2 = 0%; high certainty).

Conclusion: These findings confirm the expected lower sedative effect of bilastine while demonstrating comparable efficacy to levocetirizine in the management of CSU, as measured by UAS7, DLQI, and VAS scores. Although levocetirizine showed a slight numerical advantage in some QoL measures, differences were not

statistically significant. The consistently lower risk of somnolence with bilastine reinforces its role as a better-tolerated alternative. High heterogeneity across efficacy outcomes limits certainty, highlighting the need for further high-quality, head-to-head trials.

Abstract N°: 4001

Burden of Illness in Chronic Inducible Urticaria (CIndU): A Targeted Literature Review (TLR)

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Introduction & Objectives:

Chronic inducible urticaria (CIndU) is a subtype of chronic urticaria characterized by recurrent itchy wheals and/or angioedema lasting ≥6 weeks, triggered by specific physical or environmental stimuli (e.g., dermographism, cold, heat, cholinergic). The review aims to identify and summarize existing literature on the clinical and humanistic burden of CIndU and the associated unmet medical needs.

Materials & Methods:

A targeted literature review was conducted in December 2024 using Embase®, MEDLINE®, MEDLINE-In Process, and the Cochrane library, supplemented by hand searches of key conferences proceedings. English language studies reporting on the burden of illness in patients with CIndU were included. Study selection, data extraction, and reporting adhered to established best-practice guidelines.

Results:

Symptomatic dermographism (38%), cold (34%), and cholinergic (16%) urticaria are the most prevalent forms of CIndU globally. Few population-based studies have examined the epidemiology of CIndU. Recent real-world studies have reported prevalence, and incidence estimates of CIndU (Table 1), and its subtypes, symptomatic dermographism (0.0129%-0.0158%), cold and heat urticaria (0.0025%-0.0028%), and cholinergic urticaria (0.0016%-0.0022%) (Figure 1). Incidence and prevalence rates are generally higher in females, except for cholinergic urticaria, which predominates in males. Peak incidence occurs between 20 and 40 years of age. Diagnosis relies on patient history and provocation testing, with an average disease duration of approximately five years and frequent spontaneous remission. Although trigger avoidance is recommended, it is often impractical. CIndU commonly coexists with chronic spontaneous urticaria (CSU), particularly in patients with earlier onset and longer disease duration. Patients face significant clinical burden, with frequent comorbidities like allergies and depression, and over 57% have poorly controlled urticaria (UCT score < 12). Quality of life (QoL) is significantly impaired, with itch (69%), burning (15%), and pain (5%) being the most bothersome symptoms. CIndU patients have poor mental and physical health, with mental (MCS) and physical (PCS) component summary scores (<50) scores below 50. Additionally, 45%-70% report mild to severe anxiety (general anxiety disorder (GAD-7 ≥5)) and depression (patient health questionnaire-9 (PHQ-9 ≥5)).

Conclusion:

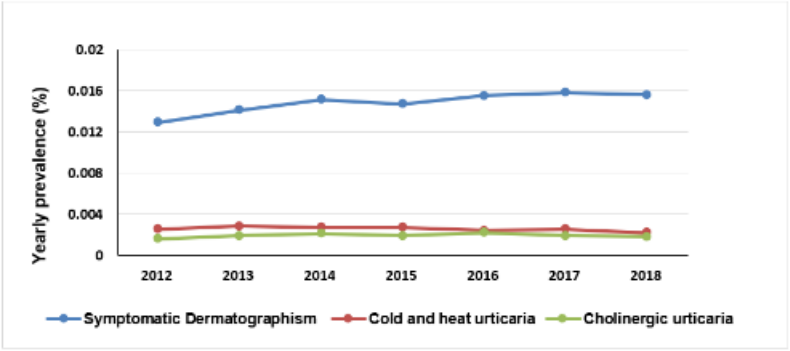
Robust epidemiological data on CIndU remain limited, and frequent overlap with CSU complicates interpretation. Well designed, population-based studies are needed to establish accurate incidence and prevalence estimates for each CIndU subtype. Moreover, the pathophysiology of CIndU is poorly characterized relative to CSU, and the full scope of clinical burden, QoL impact, and trigger avoidance strategies remain underexplored. Despite limited data, available information indicates that CIndU patients experience a significant burden. This includes a high prevalence of comorbidities such as allergies, anxiety, depression, asthma, and sleep difficulties, all of which significantly impact their QoL. Addressing these gaps is essential for developing targeted therapies.

Table 1 Prevalence and Incidence estimates from real-world studies

Reference	Country	Study Design	Time Period	Prevalence definition	Prevalence	Incidence definition	Incidence
Balp 2021	USA	Database Optum CDM	2012-2018	Diagnosed CIndU based on ≥ 2 ICD-9 and/or 10 codes	0.0164%-0.0227%	Diagnosed new CIndU cases based on ≥ 2 ICD-9 and/or 10 codes	0.0073%-0.0103%
		Database Market Scan	2012-2017		0.0118%-0.0206%		0.0058%-0.0093%
Weller 2022	Germany	Database (SHI claims)	2017	12-month prevalence of physician diagnosed CIndU	0.10%	12-month incidence of physician diagnosed CIndU	0.03%
Balp 2022	EU5	NHWS Survey	2020	Weighted 12-month prevalence for physician diagnosed CIndU	0.46%	-	-
Balp 2022	USA	NHWS Survey	2019	Weighted 12-month prevalence for physician diagnosed CIndU	0.36%	-	-
Balp 2022	Japan	NHWS Survey	2019	Weighted 12-month prevalence for physician diagnosed CIndU	0.39%	-	-

CDM: Clinformatics Data Mart; CIndU: Chronic Inducible Urticaria; EU: European Union; NHWS: National Health Wellness Survey; SHI: Statutory Health Insurance; USA: United States of America

Figure 1 Yearly prevalence of CIndU sub-types



CIndU: Chronic Inducible Urticaria

Abstract N°: 4189

Impact of Early vs Late Biologic Treatment Initiation on Health Care Resource Utilization in Patients With Chronic Spontaneous Urticaria: Results From a United States Claims Database Study

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is a skin condition characterized by the occurrence of itch, wheals, and/or angioedema lasting >6 weeks without a specific identifiable trigger, and is prevalent in 0.23% to 0.78% of the US population. Inadequately controlled CSU has been associated with increased clinical and economic burden. Here, we investigated health care resource utilization (HCRU) in patients with CSU in the United States (US), stratified by time to biologic treatment initiation.

Materials & Methods:

This real-world analysis utilized data of patients ≥18 years with a record of CSU diagnosis and linked electronic medical record (EMR) data from the US HealthVerity health insurance claims database (January 2016-October 2023). Patients were stratified according to time from CSU diagnosis to biologic initiation to manage CSU symptoms: ≤3 months (early) vs >3 to ≤12 months (late). HCRU was assessed following a CSU diagnosis (index date) during the first year post index: inpatient admissions, outpatient visits, emergency department (ED) visits, urgent care visits, and other visits. In the HCRU analysis, patients with a total number of days in an inpatient setting >3 standard deviations (SD) above the mean value were excluded. Results were summarized using descriptive statistics.

Results:

Of 73,937 patients with linked EMR data, 6785 (9.2%) were treated with biologics (93.0% omalizumab) within a year post index date. The mean (± SD) age at index was 44.9 ± 13.7 years and 78.4% were female. Early and late biologic initiation occurred in 46.8% (3177/6785) and 53.2% (3608/6785) of patients, respectively. A greater proportion of patients with late relative to early biologic initiation reported corticosteroid use (70.8% and 61.6%). A total of 6734 patients were included in the HCRU analysis (late biologic initiation, n = 3589; early biologic initiation, n = 3145) after excluding outliers. During follow-up, all-cause HCRU was generally higher in patients with late biologic initiation relative to early biologic initiation. Additionally, a greater proportion of patients with late biologic initiation reported CSU-related HCRU relative to patients with early biologic initiation, respectively: inpatient admissions (21.2% and 15.8%, fold change: 1.3 times); ED visits (13.7% and 8.2%, fold change: 1.7 times); urgent care visits (7.1% and 4.3%, fold change: 1.6 times). The mean (± SD) number of days with ED and urgent care visits was also greater for patients with late biologic initiation relative to early biologic initiation, respectively:

ED visits (0.3 ± 0.9 and 0.1 ± 0.6, fold change: 1.9 times) and urgent care visits (0.1 ± 0.4 and 0.06 ± 0.3, fold change: 1.7 times) (Table 1).

Conclusion:

Overall, few patients with CSU were escalated to advanced treatment with biologics. Among patients who were escalated, earlier biologic initiation, relative to later, was associated with reduced corticosteroid use and lower CSU-related HCRU, highlighting the value of timely treatment escalation.

Table 1. CSU-Related HCRU in Patients With Early and Late Biologic Initiation During the Follow-Up Period

	Early biologic initiation (≤3 months from CSU diagnosis) (n = 3177)	Late biologic initiation (>3 to ≤12 months from CSU diagnosis) (n = 3608)	Difference (%)	Fold change
Duration of follow-up period (years), mean (SD)	1.0 (0.0)	1.0 (0.0)	-	-
Corticosteroid use as a lack of disease control proxy event				
Patients with corticosteroid use, n (%)	1958 (61.6)	2554 (70.8)		
Days of corticosteroid use (PPPY), mean (SD)	9.0 (21.5)	10.4 (20.6)	-	-
CSU-related HCRU (PPPY)				
	n = 3145	**n = 3589**		
Patients with ≥1 inpatient admission, n (%)	498 (15.8)	760 (21.2)	33.7	1.3
Length of visit[a] days, mean (SD)	2.1 (3.2)	2.0 (3.7)	-	1.0
Patients with ≥1 outpatient visit, n (%)	3132 (99.6)	3572 (99.5)	−0.1	1.0
Number of days with visits, mean (SD)	13.2 (16.9)	11.5 (10.9)	-	0.9
Patients with ≥1 ED visit, n (%)	257 (8.2)	493 (13.7)	68.1	1.7
Number of days with visits, mean (SD)	0.1 (0.6)	0.3 (0.9)	-	1.9
Patients with ≥1 urgent care visit, n (%)	136 (4.3)	254 (7.1)	63.9	1.6
Number of days with visits, mean (SD)	0.06 (0.3)	0.1 (0.4)	-	1.7
Patients with ≥1 other visit[b] n (%)	49 (1.6)	52 (1.4)	−7.0	0.9
Number of days with visits, mean (SD)	0.03 (0.4)	0.03 (0.4)	-	0.9

[a]Calculated as the mean number of days per inpatient stay on a per-patient basis. [b]Visit classification leverages bill type, revenue codes, and HCPCS procedure codes. In cases where a visit cannot be identified as inpatient admission, outpatient visit, ED visit, or urgent care visit through these means, it is labeled "Other."

CSU, chronic spontaneous urticaria; ED, emergency department; HCPCS, Healthcare Common Procedure Coding System; HCRU, health care resource utilization; PPPY, per patient per year; SD, standard deviation.

Abstract N°: 4392

The Epidemiological Survey of Hereditary Angioedema shows large gaps and unmet needs in diagnosis and management: A brief report

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Introduction & Objectives:

The global prevalence of hereditary angioedema (HAE) has been reported to be varying from 1:10000 to 1:150000. However, there are no epidemiological data on HAE from developing countries including India. It has been estimated that there are at least 30,000 patients with HAE in India based on extrapolation from global prevalence. Therefore, in this study we carried out an epidemiological survey to understand the prevalence of HAE in India and extant practices for diagnosis and management of HAE amongst health care providers.

Materials & Methods:

A task force of physicians, who also are members of the HAE society of India (www.haesi.in), was formed in June 2024. A Google form-based questionnaire was created, was discussed amongst the members of the task force and edited as per the suggestions received from each. The questionnaire was circulated amongst Dermatologists, Pediatricians, Otolaryngorhinologists, Allergists, Immunologists, Rheumatologists and Gastroenterologists in India. The responses were collected between July 2024 to March 2025. Whenever in doubt, responses were reconfirmed from the physician who completed the questionnaire.

Results:

We received a total of 179 responses. Of these, 11 responses were omitted from the final analysis because of lack of complete information. Of the remaining 168 responses, 148 physicians (88%) reported having suspected a case of HAE at least once. Of these 148 physicians, 98 (66%) diagnosed at least one patient with HAE. The total number of diagnosed patients with HAE reported in the survey was 790 (HAEC1INH-Type 1: 551; HAEC1INH-Type 2: 82,

nlC1INH-HAE: 20 not sure: 137). Approximately 88% physicians confirmed the diagnosis of HAE using laboratory investigations while 12% diagnosed them clinically only. Responding to the question about how patients were screened, most physicians 65/98 (66%) used C4 and C1 inhibitor levels to screen HAE; 15/98 (15%) used C4, C1-INH levels and C1-INH function; 11/98 (11%) used C4 levels alone, 4/98 (4%) used C1-INH levels alone and 3/98 (3%) used genetic testing to screen patients. Large majority of physicians reported having diagnosed <5 patients. The most common speciality managing patients with HAE were Dermatology followed by Pediatrics, Pediatric Clinical Immunology & Rheumatology and Adult Clinical Immunology & Rheumatology.

For on demand therapy, fresh frozen plasma was reported to be used by 50/98 (51%) while plasma derived C1-inhibitor concentrate was used by 20/98 (20%). Use of icatibant was reported by 2 physicians. In the long-term prophylaxis, tranexamic acid was used by 59/98 (60%), danazol by 46/98 (47%) and stanazolol by 18/98 (18%). Use of lanadelumab was reported by 2 physicians.

Conclusion:

This epidemiological survey of HAE in India provides useful information about total number of diagnosed patients with HAE in India and the existent practices of diagnosis and management of HAE amongst physicians. The survey suggests a large number of patients with HAE in India still remain undiagnosed. This is largely because of lack of awareness amongst physicians in the country. Although the awareness is gradually improving and approximately 50-60 new patients with HAE are being identified in India.

Apart from a low diagnostic rate of HAE, the survey also reports several other challenges. Approximately 12% physicians diagnosed HAE clinically only and in 137/790 patients (17%), the type of HAE was not sure.

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Abstract N°: 5071

Variation in CSU management practices between dermatology and immunology/allergy – results from the REVEAL UK survey

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Introduction & Objectives:

The mast cell-driven disease chronic spontaneous urticaria (CSU) is characterized by recurrent wheals and/or angioedema (>6 weeks).1 The objective of the REVEAL survey was to gain a better understanding of the diagnosis, management, and treatment of patients in the UK *(figure 1)*.

Materials & Methods:

All consultant physicians directly involved in treatment and management of patients with CSU were invited to complete a 45-minute online survey, accompanied by Novartis Medical Science Liaisons. The survey explored 9 key areas of CSU treatment (*figure 1*). The sample comprised 33 dermatologists (76%, n=25 in secondary care, 21%, n=7 tertiary, 3%, n=1 in private care) and 17 immunologists/allergists (I/As) (24%, n=4 in secondary care, 76%, n=13 tertiary). Results were analysed descriptively.

Results:

Patients with CSU under the care of dermatologists currently wait median 5 months for appointments, whilst for I/As the wait is median 4 months. Notable differences by clinic with dermatologists in urticaria clinics having longer wait times than I/As, and I/A patients waiting longer for biologic clinics. Virtual appointments are also offered by fewer dermatologists, 58% (n=19/33) than I/As, 94% (n=16/17).

Dermatologists are more likely than I/As to refer patients on to another specialist (67%, n=22/33 vs 41%, n=7/17). I/As state they would not refer internally, but 41% (n=7/17) would refer to dermatology. When patients were referred by dermatologists, those with severe angioedema were sent to immunology/allergy, and patients with uncontrolled/non-responsive symptoms were sent to other dermatologists.

Antihistamines (AHs) at 4x licensed dose and leukotriene receptor antagonists (LTRAs) are the most commonly prescribed treatments for moderate CSU, irrespective of specialty. Dermatologists are also more likely to prescribe omalizumab in moderate CSU than I/As though >90% prescribe in severe CSU cases, and also more likely to prescribe ciclosporin than I/As *(figure 2).* Dermatologists are more likely to prescribe sedating AHs than I/As *(figure 3)*. More dermatologists would switch AHs before escalating treatment (39%, n=13/33) than I/As (12%, n=2/17).

LTRAs are more likely prescribed in tertiary vs secondary care (moderate 90%, n=18/20 vs 69%, n=20/29; severe 95%, n=19/20 vs 76%, n=22/28). Secondary care physicians are more likely than tertiary to prescribe topical

steroids (28%, n=8/29 vs 0%, n=0/20) – not listed in treatment guidelines2 - and phototherapy (34%, n=10/29 (dermatologists 36%, n=10/25, I/As 25%, n=1/4) vs 15%, n=3/20 (dermatologists 43%, n=3/7, I/As 0%, n=0/13)) in moderate or severe cases.

Conclusion:

Variation in management and treatment of patients with CSU is seen in this study between specialities, clinics and secondary vs tertiary care settings across the UK. Delays in treatment escalation in dermatology arise due to multi-step referrals and use of more varied and potentially less optimal treatment choices, highlighting opportunities to enhance patient pathways and improve access to effective care.

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Figure 1

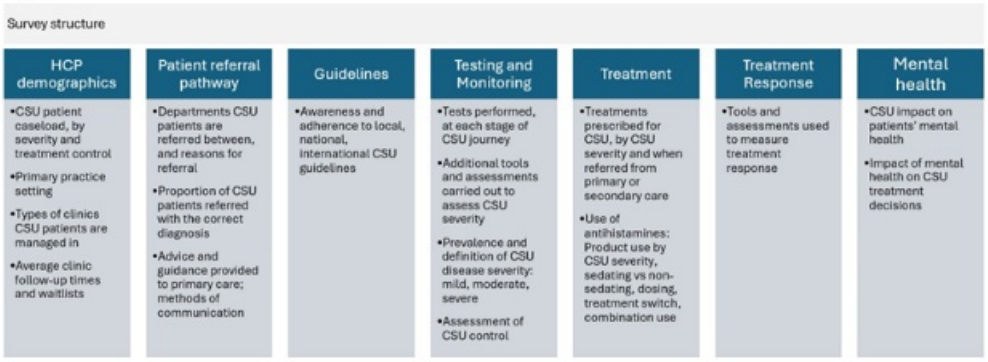


Figure 2

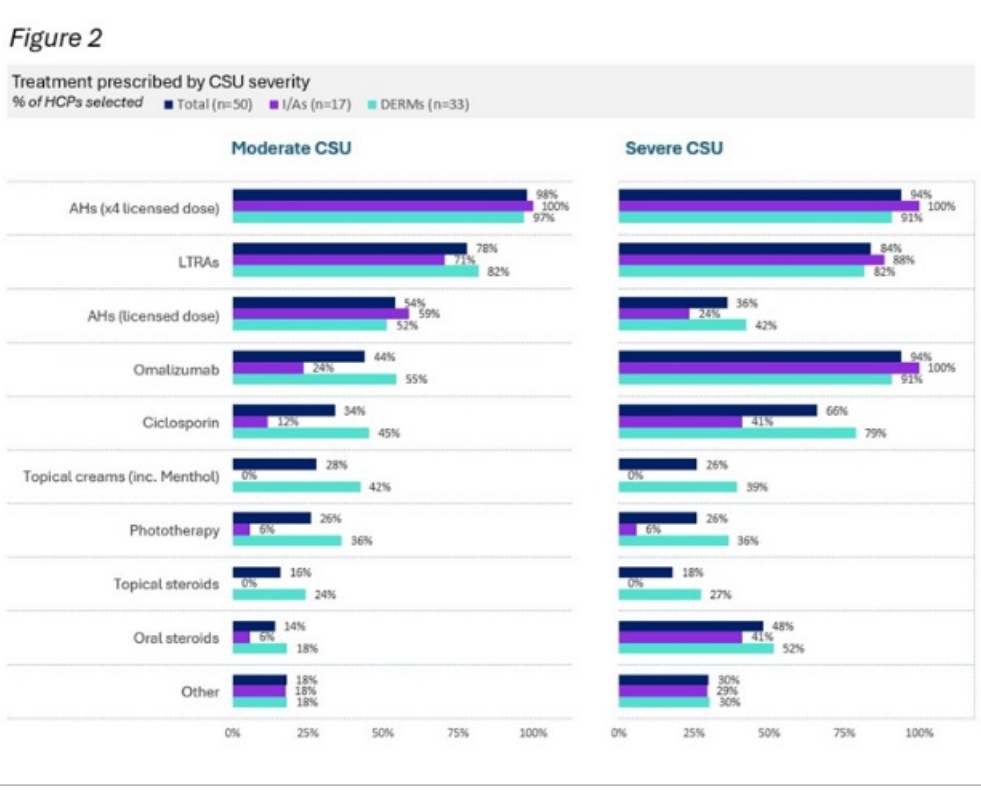
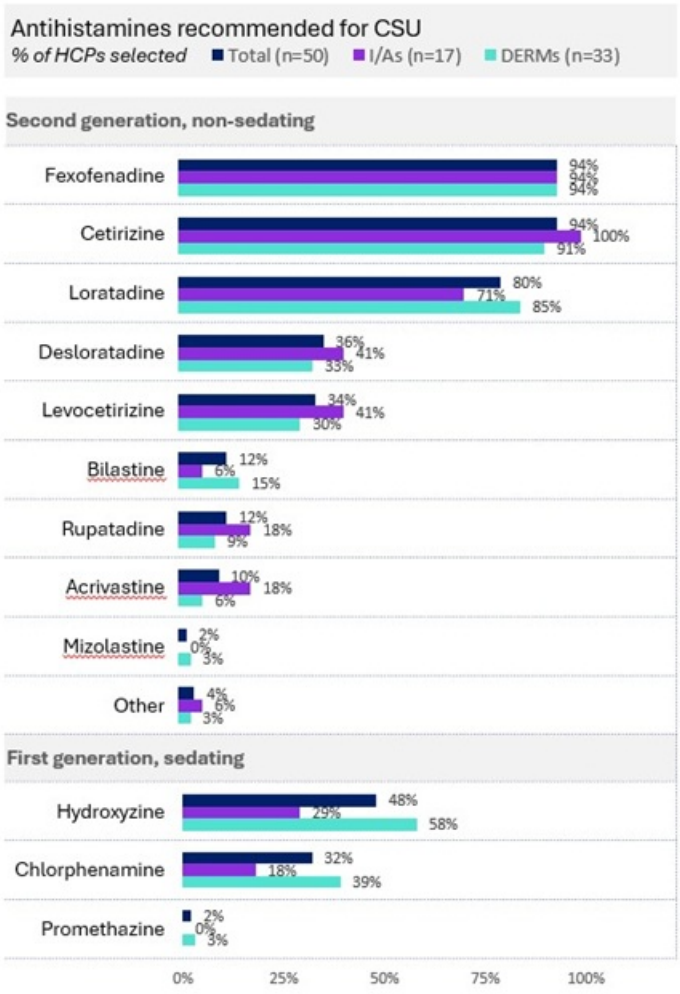


Figure 3


Antihistamines recommended for CSU
% of HCPs selected
Total (n=50)
I/As (n=17)
DERMs (n=33)
Second generation, non-sedating
Fexofenadine
94%
94%
94%
Cetirizine
94%
100%
91%
Loratadine
80%
71%
85%
Desloratadine
36%
41%
33%
Levocetirizine
34%
41%
30%
Bilastine
12%
6%
15%
Rupatadine
12%
18%
9%
Acrivastine
10%
18%
6%
Mizolastine
2%
0%
3%
Other
4%
6%
3%
First generation, sedating
Hydroxyzine
48%
29%
58%
Chlorphenamine
32%
18%
39%
Promethazine
2%
0%
3%
0%
25%
50%
75%
100%

Abstract N°: 5157

Status update of chronic spontaneous urticaria management and knowledge among Italian General Practitioners: BRIDGE Implementation Science study

Piergiacomo Calzavara-Pinton*[1], Riccardo Asero[2], Nadine Chapman-Rothe[3], Pallavi Saraswat[4], Vinodh Nallasamy[4], Abigail Herbst[5], Bridget Gaglio[5], Fabio Speranza[6], Ornella Bonavita[7], Tara Raftery[8], Enrico Iemoli[9]

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Introduction & Objectives:

Patients** with chronic spontaneous urticaria (CSU) experience prolonged delays in diagnosis and up to 50% remain symptomatic for prolonged periods on first-line treatments, highlighting a need for systematic evaluation of obstacles in CSU care. BRIDGE is a hybrid effectiveness-implementation science study with a pre-post design which aims to evaluate an implementation strategy to increase patient-reported outcome (PRO) usage in clinical practice and improve CSU care at the general practitioner (GP) level. Herein, we report the pre-implementation survey results on CSU management and knowledge among GPs in Italy.

Materials & Methods:

Prior to administering the implementation strategy, GPs completed a self-administered 30-minute online survey (May–July 2024) assessing CSU management and prevalence; PRO familiarity, use, and compatibility with workflow; and practice climate. Data were analysed descriptively.

Results:

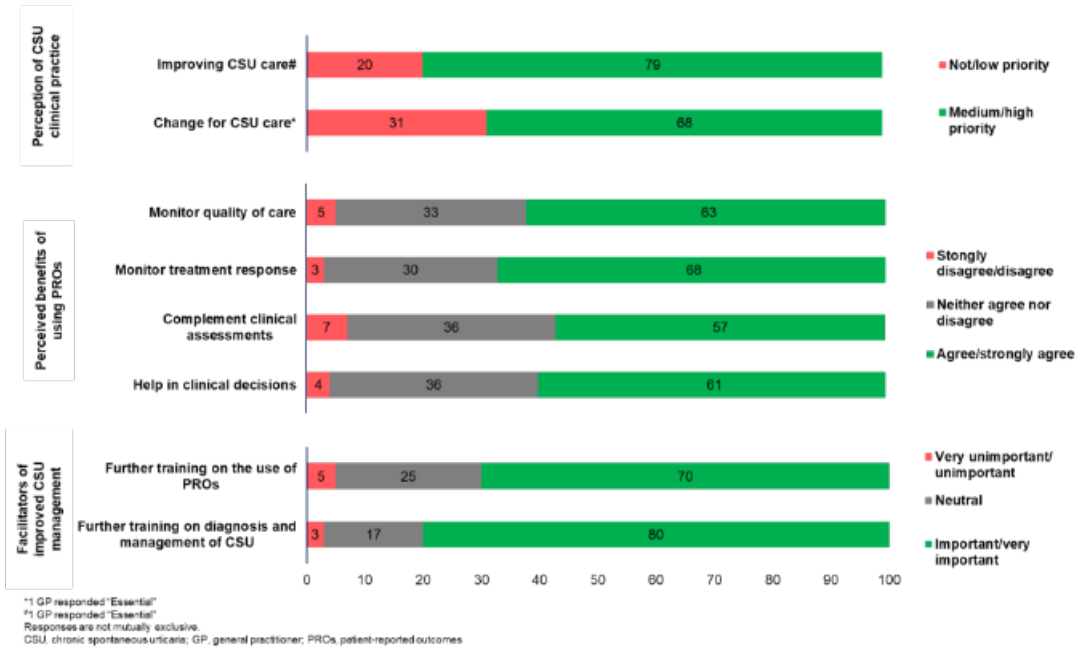
A total of 95 GPs completed the pre-implementation survey: mean±standard deviation age 37.7±7.9 years, 51% female and 10.1±7.3 years practicing medicine. On average, in the prior 6 months, GPs suspected 4 patients of having CSU, diagnosed 2 patients with CSU, and treated 2 patients for CSU. Nearly 60% of GPs had little to no knowledge of CSU and no awareness of CSU guidelines. Overall, 42.7% of GPs reported not feeling confident in diagnosing or treating CSU patients. Fifty percent of the GPs reported no experience with PROs during routine clinical care; fourteen GPs (14.7%) reported using PROs, although not for CSU in the prior 6 months. Nearly 70% of GPs reported improvements in CSU care as a medium to high priority in their clinical practice. Approximately 60% of GPs strongly agreed or agreed that PROs are beneficial in supporting clinical decisions and disease monitoring; however, insufficient time was reported as a barrier to PRO use by many (72%) GPs. More than half (52%) of the GPs reported none or a slight extent of workshops/seminars focused on evidence-based practices (EBP) in their clinical practices, and 57% reported none to slight extent for availability of EBP training materials/journals. Most of the GPs (80%) responded that it was important/very important to have educational support on the diagnosis and management of CSU and 70% reported training on use of PROs as important/very

important to improve CSU clinical care (**Figure**). Web/mobile application-based training was the preferred modality for ~70% of GPs.

Conclusion:

The survey findings highlighted a lack of knowledge of CSU guidelines and no use of CSU-specific PROs in the past 6 months among GPs in Italy. GPs recognize the need for improvements in CSU management to enhance care quality. GPs voiced a perceived benefit of using PROs in CSU care and a need to have educational and training support at their clinics. These findings informed key components of a tailored implementation strategy aiming at improving CSU patient care in Italy.

Figure. GP's perception on CSU management in Italy



*1 GP responded "Essential"
^1 GP responded "Essential"
Responses are not mutually exclusive.
CSU, chronic spontaneous urticaria; GP, general practitioner; PROs, patient-reported outcomes

Abstract N°: 5324

BLU-808, a potent and selective inhibitor of wild-type KIT, in patients with chronic inducible urticaria and chronic spontaneous urticaria: trial-in-progress

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Introduction & Objectives:

Overactivation of mast cells (MCs) is implicated in many allergic diseases, including urticaria, allergic rhinitis, allergic asthma, and MC activation syndrome (MCAS). Chronic urticaria (CU) is characterized by inappropriate activation of dermal MCs, resulting in wheals (hives) often accompanied by pruritus (itching) and/or angioedema. CU is classified as either chronic spontaneous urticaria (CSU) or chronic inducible urticaria (CIndU), with the latter triggered by specific stimuli. Current treatments, such as second-generation H1-antihistamines and the anti-IgE monoclonal antibody omalizumab, do not fully alleviate symptoms for many patients, underscoring the urgent need for therapies with novel mechanisms of action.

KIT is a receptor tyrosine kinase that plays a key role in the survival, proliferation, and activation of MCs. BLU-808, an oral, potent, and selective inhibitor of wild-type KIT, is under development to address an unmet need in managing allergic diseases by inhibiting MC activation and/or reducing MC numbers. Preclinical data have shown that BLU-808 shows high selectivity for KIT and effectively inhibits MC activation both *in vitro* and *in vivo*, highlighting its therapeutic potential in CSU, CIndU, and other MC disorders. Furthermore, recent first-in-human data involving healthy volunteers demonstrated that BLU-808 is safe and well-tolerated. The study also demonstrated that BLU-808 effectively reduces levels of the MC mediator, serum tryptase, and has pharmacokinetics that support once-daily dosing.

Materials & Methods:

BLU-808-1201 (NCT06931405) is a phase 2 study designed to evaluate the safety, tolerability, and clinical activity of BLU-808 in patients with CIndU and CSU.

The study comprises two parts: Part A will evaluate BLU-808 in patients with CIndU (cold-induced and symptomatic dermographism) while Part B will enroll patients with CSU. Patients with co-occurring CIndU and

CSU will also be included. The primary objectives are safety and tolerability of BLU-808 in these populations. Secondary objectives are pharmacokinetics (PK), changes in serum tryptase, and clinical activity of BLU-808 in CIndU and CSU.

Adults (≥18 years) with confirmed CIndU or inadequately controlled CSU despite second-generation H1-antihistamines will be enrolled. Several dosing regimens for BLU-808 will be investigated. In Part A, CIndU participants will receive open-label BLU-808 treatment. In Part B, CSU participants will be randomized to placebo or one of four BLU-808 regimens. Study endpoints will be assessed using predefined criteria, with a focus on evaluating dose-response relationships, safety profiles, patient-reported outcomes, and clinical efficacy measures across treatment groups.

Conclusion:

The BLU-808-1201 study will assess the safety, tolerability, and clinical activity of BLU-808 in patients with CIndU and CSU, potentially offering a new therapeutic option for patients with these conditions.

Abstract N°: 5391

Symptomatic Dermographism: Advances in Pathophysiology and Clinical Management

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Introduction & Objectives: **

Symptomatic dermographism (SD), the most prevalent subtype of physical urticaria, manifests as pruritic linear wheals triggered by mechanical skin stimulation. Chronic recurrence and associated discomfort impair patients' quality of life, yet SD remains underdiagnosed due to heterogeneous presentations. This review synthesizes recent advances in pathogenesis, diagnostic standardization, and therapeutic innovations to address gaps in systematic evidence and clinical management.

Materials & Methods:

A literature search (PubMed/Embase/Web of Science, 2010–2023) identified studies using keywords "dermographism," "symptomatic dermographism," "dermographic urticaria," and "physical urticaria." Inclusion criteria encompassed clinical trials, mechanistic studies, case reports and case series (≥10 patients). Data analysis focused on pathophysiology, diagnostic validation, therapeutic innovations, treatment efficacy, and quality-of-life metrics.

Results:

SD pathogenesis centers on mast cell dysregulation, with mechanical stimuli activating FcεRI-dependent histamine release. Emerging roles of IgE autoantibodies targeting dermal proteins and gut microbiota imbalances further modulate disease severity. Clinically, novel subtypes include red SD, follicular SD, cholinergic SD, cold-contact SD, food-exacerbated SD (postprandial aggravation) and food-dependent SD (requiring mechanical stimuli plus dietary cofactors). Physical exercise exacerbates symptoms via thermoregulatory and hemodynamic pathways.

Diagnostic standardization utilizes the FricTest® alongside patient-reported tools like the Urticaria Activity Score. While second-generation antihistamines remain first-line therapy, refractory cases benefit from omalizumab, which demonstrates clinically meaningful improvements in provocation thresholds and quality-of-life measures.

Conclusion:

SD is a multifactorial disorder with evolving pathophysiological insights and clinical subtypes. Advances in standardized diagnostics and targeted therapies like omalizumab redefine SD management, particularly for refractory cases. Future research should prioritize longitudinal efficacy studies and microbiota-based interventions to address unmet therapeutic needs.

Abstract N°: 5444

Addressing the Unmet Need in Chronic Spontaneous Urticaria: A Network Meta-Analysis of Novel and Established Therapies

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) remains a therapeutic challenge, particularly for patients with inadequate response to antihistamines. While multiple novel biologic and small-molecule therapies are under investigation, a systematic comparison of their efficacy and safety is lacking.

This study aimed to:

1. Compare the efficacy of emerging and established CSU treatments in improving symptom severity (UAS7, ISS7, HSS7) and quality of life (DLQI).
2. Evaluate the safety profiles of these therapies.
3. Provide an evidence-based hierarchy to guide clinical decision-making.

Materials & Methods:

Study Design:

- Frequentist network meta-analysis (NMA) using a random-effects model.
- Included phase II/III randomized placebo-controlled trials (RCTs).

Data Sources & Eligibility:

- Trials reporting primary outcomes:
  - Change from baseline (CFB) in UAS7, ISS7, HSS7, and DLQI.
  - Incidence of adverse events (AEs) and serious adverse events (SAEs).

Interventions:

- **Oral agents:** Cyclosporine, fenebrutinib, hydroxychloroquine, methotrexate, remibrutinib.
- **Subcutaneous agents:** Barzolvolimab, benralizumab, dupilumab, ligelizumab, omalizumab, quilizumab, tezepelumab.

Analysis:

- Relative treatment rankings assessed via SUCRA (surface under the cumulative ranking curve).

Results:

Study Population:

- 22 RCTs involving 5,636 CSU patients.

Key Findings:

1. Efficacy:
    i. All treatments except benralizumab, methotrexate, and quilizumab significantly improved UAS7, ISS7, HSS7, and DLQI vs. placebo.
    ii. Barzolvolimab (300 mg Q4W) ranked highest for reducing UAS7, HSS7, and ISS7 (SUCRA-based hierarchy).
2. Safety & Combined Outcomes:
    i. Omalizumab, dupilumab, ligelizumab, remibrutinib, and fenebrutinib demonstrated optimal balance between efficacy and safety.

Conclusion:

1. Barzolvolimab is the most effective therapy for symptom control (UAS7/HSS7/ISS7).
2. Remibrutinib is the top-ranked oral agent.
3. For combined efficacy and safety, omalizumab, dupilumab, ligelizumab, remibrutinib, and fenebrutinib are superior to other therapies, including barzolvolimab and conventional drugs.

This NMA supports personalized treatment selection for CSU, highlighting the potential of targeted biologics and small-molecule agents.

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Abstract N°: 5448

Serum metabolism analysis of CholU

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Introduction & Objectives:

Cholinergic urticaria (CholU) and chronic spontaneous urticaria (CSU) are distinct subtypes of chronic urticaria, yet the metabolic mechanisms underlying CholU remain poorly understood. Current therapeutic interventions for CholU often yield suboptimal responses, highlighting the critical need to identify novel biomarkers and dysregulated metabolic pathways to improve diagnosis and treatment. This study aims to address these gaps by investigating serum metabolic profiles in CholU patients using non-targeted metabolomics.

Materials & Methods:

Serum samples were collected from 26 CholU patients and 14 healthy controls. Non-targeted metabolomic profiling was performed using ultra-high performance liquid chromatography-mass spectrometry (UHPLC-MS). The obtained metabolic profiles were analysed. Dimensionality of multivariate data was reduced using partial least squares discriminant analysis (PLS-DA) and orthogonal PLS-DA (OPLS-DA). Differential metabolite screening was then carried out by combining variable importance in projection (VIP > 1), fold change (FC > 1.2 or < 0.8), and Mann-Whitney U test ($P < 0.05$) .The diagnostic relevance of these differential metabolites was evaluated via receiver operating characteristic (ROC) curve analysis to identify candidate biomarkers. Additionally, kyoto encyclopedia of genes and genomes (KEGG) analysis was performed to identify dysregulated metabolic pathways the candidate biomarkers involved. The clinical correlation of these biomarkers was also studied by analyzing their association with weekly cholinergic urticaria activity score (CholUAS7) and cholinergic urticaria severity index (CholUSI) using Mfuzz clustering analysis and Spearman's correlation tests.

Results:

From metabolomic profiling, significant differences were observed between CholU patients and controls, with 247 differentially expressed metabolites to be identified. ROC curve analysis revealed six metabolites with area under curve ROC > 0.8, including 15-HETE, 7-methyluric acid, aspartate semialdehyde, threonic acid, phosphate, and 5α-pregnan-3α,20β-diol disulfate, indicating their potential as diagnostic biomarkers for CholU. KEGG enrichment analysis highlighted metabolic pathways involving phenylalanine, tyrosine, and tryptophan biosynthesis, central carbon metabolism in cancer, cocaine addiction, protein digestion/absorption, and amphetamine addiction. Notably, 7-methyluric acid and 15-HETE showed significant or near-significant correlations with CholUSI and CholUAS7 scores, suggesting their potential to predict disease activity and treatment efficacy in CholU.

Conclusion:

This study demonstrates serum metabolomics as a powerful tool for distinguishing CholU from healthy controls. Serum 7-methyluric acid and 15-HETE identified from this study represent promising biomarkers for CholU, linking amino acid metabolism to disease severity and suggesting novel therapeutic targets for the disease.

Abstract N°: 5521

Activation of the coagulation/fibrinolysis cascade in acute urticaria: A retrospective study

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Introduction & Objectives:

Acute urticaria (AU) is a common dermatologic emergency characterized by sudden-onset wheals, sometimes accompanied by angioedema. Despite its clinical prevalence, the underlying pathophysiological mechanisms of AU remain poorly understood. Emerging evidence suggests potential involvement of the coagulation/fibrinolysis cascade, as elevated fibrin degradation products such as D-dimer have been observed during active urticaria episodes, with their levels returning to normal upon remission. However, researches on this relationship, particularly in pediatric populations, are limited, and the mechanistic role of coagulation dysregulation in AU pathogenesis remains unclear. In this study, we aim to investigate the role of coagulation and fibrinolysis in AU based on the key clinical and laboratory features in pediatric and adult AU patients.

Materials & Methods:

A retrospective analysis was conducted on 191 patients with moderate-to-severe acute urticaria (AU), including 64 pediatric patients (aged 7–12 years; predominantly male) and 127 adult patients (aged 28–53 years; predominantly female). Clinical features of the two cohorts, including precipitating factors, angioedema occurrence, and treatment duration were documented. Furthermore, laboratory parameters including D-dimer levels, platelet counts, prothrombin time (PT), eosinophil counts, and inflammatory markers (e.g., IL-6, basophils) were analyzed.

Results:

Clinical analysis identified infections as the most common precipitating factor for acute urticaria (AU) in both pediatric and adult cohorts. The incidence of angioedema was significantly higher in adults compared to children (11% vs. 1.6%, $P = 0.022$). Laboratory findings revealed elevated D-dimer levels in 58% of patients and eosinopenia in 44.5% of the study population. Notably, AU patients with eosinopenia exhibited shorter prothrombin time (PT) (15.49 ± 0.94 vs. 15.81 ± 1.38, $P = 0.004$) and higher platelet counts (301.57 ± 92.48 $\times 10^3/\mu L$ vs. 264.95 ± 66.37 $\times 10^3/\mu L$, $P = 0.043$) compared to those without eosinopenia. Collectively, these data indicate activation of the coagulation/fibrinolysis cascade in AU patients. While glucocorticoid dose escalation did not reduce treatment duration, we observed shorter time for symptom resolution in AU patients with higher IL-6 levels and increased basophil counts.

Conclusion:

This study demonstrates activation of the coagulation/fibrinolysis cascade in moderate-to-severe AU, with

elevated D-dimer levels and eosinopenia serving as key laboratory hallmarks. The correlation between eosinopenia and coagulation parameters (e.g., PT, platelet counts) suggests a potential mechanistic link, independent of angioedema or concomitant infections. Notably, treatment duration was influenced by IL-6 and basophil levels rather than glucocorticoid dosing. These findings highlight the need for prospective studies to validate the role of coagulation dysregulation in AU pathophysiology and optimize therapeutic strategies.

Abstract N°: 5542

Remibrutinib-treated patients with CSU who achieve well-controlled disease activity reach this by week 3 in the majority of patients: Results from REMIX-1/-2 studies

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is associated with the spontaneous occurrence of itch, wheals (hives) and/or angioedema lasting for >6 weeks, without an identifiable trigger. Remibrutinib, a novel, oral, highly selective Bruton's tyrosine kinase inhibitor, has demonstrated superiority vs placebo and a favourable safety profile in patients with CSU who remained symptomatic despite treatment with H1antihistamines (H1-AHs). In the phase 3 REMIX-1 and REMIX-2 studies, 52.1% and 50.4% of patients in the remibrutinib treatment arm vs 25.9% and 21.6% in the placebo arm, respectively, had wellcontrolled disease (weekly urticaria activity score [UAS7]≤6) by week 12 and 32.7% and 30.3% of patients in the remibrutinib arm vs 11.5% and 6.7% in the placebo arm, respectively, had complete control (UAS7=0) of CSU. The objective of this post hoc analysis of the pooled REMIX-1/-2 studies was to assess the time taken to achieve UAS7≤6 and UAS7=0 in the overall and responder populations, respectively.

Materials & Methods:

REMIX-1/-2 were multicentre, randomised, double-blind, placebo-controlled studies assessing the efficacy and safety of remibrutinib in patients with CSU who remained symptomatic despite treatment with second-generation H1-AHs. Patients were randomised 2:1 to remibrutinib 25 mg twice daily (bid) or placebo over a 24-week double-blind period, followed by 28-week open-label treatment with remibrutinib 25 mg bid (patients on placebo transitioned to remibrutinib at week 24). In this analysis, we assessed the achievement of UAS7≤6 (yes/no) and UAS7=0 (yes/no) response weekly up to week 24 based on pooled data from the REMIX-1/-2 studies. Time to first UAS7≤6 and UAS7=0 was assessed using Kaplan-Meier analysis in the overall population and descriptively in the responder population.

Results:

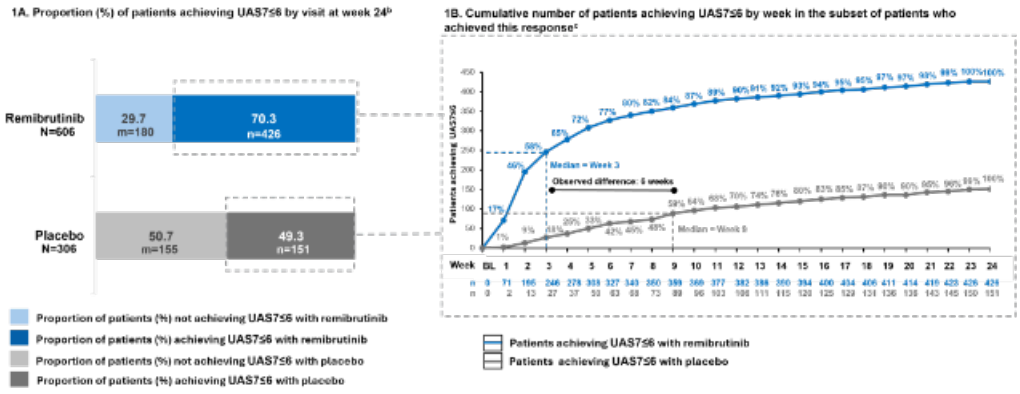
In the pooled REMIX-1/-2 analysis, 70.3% (426 of 606) of patients on remibrutinib and 49.3% (151 of 306) of patients on placebo achieved UAS7≤6 by week 24 (**Figure 1**). Proportions of patients achieving UAS7=0 by week

24 were 57.1% (346 of 606) in the remibrutinib arm and 27.5% (84 of 306) in the placebo arm (**Figure 2**). Among the patients who responded, median time to reach UAS7≤6 was 3 weeks (interquartile range, [IQR: 2-6]) in the remibrutinib arm compared to that of 9 weeks (IQR: 5-14) in the placebo arm (**Figure 1**), and median time to reach UAS=0 was 5 weeks (IQR: 2-10) in the remibrutinib arm vs 12 weeks (IQR: 7-17) in the placebo arm (**Figure 2**).

Conclusion:

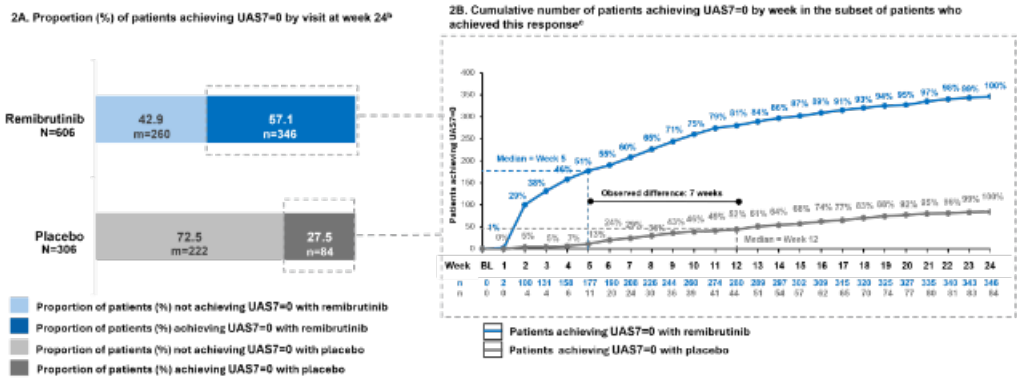
Remibrutinib showed a fast onset of action, in patients who achieved UAS7≤6 by week 24, as more than half of the patients in the remibrutinib arm achieved well-controlled disease by week 3, compared to week 9 in the placebo arm. Remibrutinib has the potential to be an effective, novel, oral treatment option to provide well-controlled symptoms early in patients with CSU, inadequately controlled with H1-AHs.

Figure 1: Time to achievement of UAS7≤6 by visit – Subpopulation of pooled full analysis set[a]



BL, baseline; m, number of patients not achieving UAS7≤6; N, total number of patients; n, number of patients achieving UAS7≤6; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on Kaplan-Meier analysis. [c]Based on the responder population that includes patients who achieved UAS7≤6 at any time up to week 24.

Figure 2: Time to achievement of UAS7=0 by visit – Subpopulation of pooled full analysis set[a]



BL, baseline; m, number of patients not achieving UAS7=0; N, total number of patients; n, number of patients achieving UAS7=0; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on Kaplan-Meier analysis. [c]Based on the responder population that includes patients who achieved UAS7=0 at any time up to week 24.

Abstract N°: 5566

Use of omalizumab in eosinophilic dermatoses: a case series including pediatric Wells syndrome and eosinophilic granuloma annulare

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Introduction & Objectives:

Eosinophilic dermatoses comprise a heterogeneous group of inflammatory diseases characterised by eosinophil-rich dermal infiltrate. Among them, Wells syndrome (eosinophilic cellulitis) and eosinophilic granuloma annulare are rare entities with recurrent course and variable response to conventional treatment. Evidence for the use of biologic therapies such as omalizumab in this setting is limited but growing.

The aim of this work is to describe the clinical course of a series of patients with eosinophilic dermatoses treated with omalizumab after insufficient response or adverse effects following antihistamines, systemic corticosteroids and/or other immunomodulatory therapies.

Materials & Methods:

Retrospective review of 6 patients diagnosed between 2021 and 2025 with histologically confirmed eosinophilic dermatoses. Among them we have 5 cases of Wells syndrome (3 adults and 2 paediatric patients aged 2 and 5 years at diagnosis) and 1 case of eosinophilic granuloma annulare in an 8-year-old girl. All had recurrences and insufficient response to other treatments such as corticosteroids and antihistamines. Omalizumab was started in all cases at a dose of 150-300 mg subcutaneously every 4 weeks, adjusted according to weight and clinical response. Clinical response, lesion recurrence, adverse effects and need for concomitant treatments were assessed.

Results:

All patients showed significant clinical improvement after initiation of omalizumab, with complete or near-complete resolution of skin lesions in the first 8-12 weeks. Systemic corticosteroids were successfully discontinued in all cases. No relevant adverse effects were observed. Treatment duration and follow-up time varied between cases. Of the 6 patients, 4 continue treatment with omalizumab, most of them in de-escalation. In 2 patients, discontinuation was achieved without clinical recurrence so far.

Conclusion:

Omalizumab may represent an effective and safe therapeutic alternative in patients with refractory eosinophilic dermatoses, including paediatric forms and rare entities such as Wells syndrome and eosinophilic granuloma annulare. This series supports its use as an emerging biologic option beyond approved indications.

Abstract N°: 5584

Genome-Wide Meta-Analysis Identifies Novel Genetic Drivers and Therapeutic Targets in Urticaria

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Introduction & Objectives:

Urticaria is a prevalent inflammatory skin disorder that manifests as pruritic hives and/or angioedema. While acute cases of urticaria resolve within six weeks, chronic urticaria (CU) persists longer and affects up to 5% of all urticaria patients. CU includes spontaneous (CSU) and the inducible (CIndU) forms, both of which lack precise etiology and often respond poorly to available treatments underscoring the need for improved mechanistic insights and targeted therapies. To define the genetic architecture of urticaria and identify therapeutic targets through integrative genomic and transcriptomic approaches.

Materials & Methods:

We performed a genome-wide meta-analysis of 34,908 CU cases and 1,157,220 controls of European ancestry. Loci were fine-mapped in silico using TWAS, and functionally annotated using spatial transcriptomics and scRNA-seq of CSU lesional skin and PBMCs. Compounds targeting some of the identified GWAS-candidate genes were cross-referenced with real-world clinical datasets (TriNetX) for drug repurposing in urticaria. Furthermore, genetic correlations with immune-mediated type two inflammatory diseases and urticaria were also assessed.

Results:

Twelve genome-wide significant non-HLA loci were identified, including four novel signals mapped to*IRF1* (Chr 5), *UBE2W/STAU2* (Chr 8), *EED* (Chr 11), and *PTGDR* (Chr 14). Previously reported loci—*FCER1A, CBLB, GCSAML, STAT6, NFKB1, TBL1XR1, TPSD1,* and *ZFPM1* were robustly replicated. Spatial transcriptomics and scRNA-seq revealed that *IRF1, UBE2W/STAU2,* and *EED* are predominantly expressed in the epidermis and papillary dermis in CSU-affected skin, while *PTGDR* is enriched in circulating NK cells in CSU patients. Genetic correlation analyses demonstrated significant overlap between urticaria and other type 2 inflammatory diseases, including asthma (r_g=0.45), atopic dermatitis (r_g=0.38), allergic rhinitis, and chronic rhinosinusitis with nasal polyps (CRSwNP), supporting a shared immunopathogenic axis.** Drug repurposing analyses identified several FDA-approved compounds targeting *PTGDR* and *NFKB1,* suggesting potential opportunities for repositioning these agents in the treatment of urticaria, pending further clinical investigation.

Conclusion:

Our study uncovers new genetic risk loci and cell-type-specific expression patterns in urticaria, links urticaria to broader type 2 inflammation, and highlights a precision medicine framework to guide future therapeutic development

Abstract N°: 5624

Medical interventions and aesthetic procedures in patients with chronic spontaneous urticaria: First results of the international, multicenter, case-control RIFA-CU study

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Introduction & Objectives:

Recent studies have reported that chronic spontaneous urticaria (CSU) can be triggered or aggravated by vaccination, e.g. COVID-19 vaccines, and other interventions. The RIFA-CU (Risk Factors and Life-Style in Chronic Urticaria) study compared various medical conditions and lifestyle factors including medical and aesthetic interventions between patients with CSU and controls, with the goal of identifying modifiable risk factors.

Materials & Methods:

The RIFA-CU study is an international, multicenter, cross-sectional UCARE (Urticaria Centers of Reference and Excellence) study. Data were collected from 1392 CSU patients and 1374 healthy controls across 19 countries. The study employed a standardized questionnaire capturing data about participants' experiences in the 3-6 months preceding the onset of urticaria. Statistical comparisons were performed to identify significant differences between the groups. Bonferroni-adjusted p-values for multiple comparisons (n=25) were calculated, and values less than 0.05 were considered statistically significant (Table 1).

Results:

CSU patients and control group did not differ in overall vaccination rate (17.7% vs. 16.3%). CSU patients more often received COVID-19 vaccinations prior to disease onset (11.3% vs. 6.5%, $p<0.001$) whereas control subjects had higher rates of hepatitis (3.2% vs. 1%), tetanus (4.4% vs. 2.2%) and influenza (6% vs. 4.3%) vaccinations. Rates of aesthetic interventions were lower in CSU patients compared with control group (8.8% vs. 20.2%, $p<0.001$) with laser being most frequently reported in CSU patients (3.6%) and botulinum toxin in the control group (5.3%). Prosthesis, implant and stent interventions were less common in CSU patients compared with control group (7.8% vs 12.7%, $p<0.001$). (The results of multivariate analysis will be presented during the presentation)

Conclusion:

Risk factors for CSU have been reported but they are generally not well studied. In this analysis we found that prior to disease onset CSU patients had a lower prevalence of aesthetic, prosthetic, dental implant and stent interventions compared to healthy controls, but significantly more COVID-19 vaccination and botulinum toxin

injections, which need further evaluation as possible risk factors for CSU onset.

Table 1

	Control	Patient	p	Adjusted p-value
Gender			0.126	
Female	922 (67.1%)	977 (70.2%)		
Male	452 (32.9%)	414 (29.8%)		
Vaccination (overall)			0.315	
Yes	218 (16.3%)	241 (17.7%)		
No	1121 (83.7%)	1118 (82.3%)		
Influenza vaccine			**0.046**	NS
Yes	87 (6%)	60 (4.3%)		
No	1372 (94%)	1332 (95.7)		
COVID19 vaccine			**<0.001**	**<0.05**
Yes	95(6.5%)	157(11.3%)		
No	1364(93.5%)	1235(88.7%)		
Hepatitis vaccine			**<0.001**	**<0.05**
Yes	47 (3.2%)	14 (1%)		
No	1412 (96.8%)	1478 (99%)		
Tetanus vaccine			**<0.001**	**<0.05**
Yes	64 (4.4.%)	30 (2.2.%)		
No	1395 (95.6%)	1362 (97.8%)		
Other vaccinations			0.227	
Yes	43 (2.9%)	31 (2.2%)		
No	1416 (97.1%)	1361 (97.8%)		
Blood transfusion			0.572	
Yes	11 (0.8%)	14 (1%)		
No	1328 (99.2)	1345 (99%)		
Dental implant			0.647	
Yes	153 (11.4%)	163 (12%)		
No	1186 (88.6%)	1196 (88%)		
Tattoo				
Yes	NA	49 (3.6%)		
No	NA	1310 (96.4%)		
Intrauterine device			0.874	
Yes	5 (1.9%)	9 (2.4%)		
No	260 (96.6%)	353 (96.4%)		
Not applicable	4 (1.5%)	5 (1.4%)		
Aesthetics (overall)			**<0.001**	**<0.05**
Yes	295 (20.2%)	123 (8.8%)		
No	1164 (79.8%)	1269 (91.2%)		
Botulinum toxin			**<0.001**	**<0.05**
Yes	77(5.3%)	23 (1.7%)		
No	1382(94.7%)	1369 (98.3%)		
Hyaluronic acid filler			**0.030**	NS
Yes	32 (2.2%)	16 (1.1%)		
No	1427 (97.8%)	1376 (98.9%)		

Other filler			0.073	
Yes	13 (0.9%)	5 (0.4%)		
No	1446 (99.1%)	1387 (99.6%)		
Mesotherapy			**<0.001**	**<0.05**
Yes	33 (2.3%)	6 (0.4%)		
No	1426 (97.7%)	1386 (94.6%)		
Chemical peel			0.709	
Yes	10 (0.7%)	8 (0.6%)		
No	1449 (99.3%)	1384 (99.4%)		
Laser			0.178	
Yes	67 (4.6%)	50 (3.6%)		
No	1392 (95.4%)	1342 (96.4%)		
Prosthesis / implant / stent (overall)			**<0.001**	**<0.05**
Yes	185 (12.7%)	108 (7.8%)		
No	1274 (97.3%)	1284 (92.2%)		
Dental prothesis			0.256	
Yes	50 (3.4%)	59 (4.2%)		
No	1409 (96.6%)	1333 (95.8%)		
Breast prothesis			0.521	
Yes	5 (0.3%)	3 (0.2%)		
No	1454 (99.7%)	1389 (99.8%)		
Stent			0.180	
Yes	3 (0.2%)	7 (0.5%)		
No	1456 (99.8%)	1385 (99.5%)		
Orthopedic prothesis			0.090	
Yes	1 (0.1%)	5 (0.4%)		
No	1458 (99.9%)	1387 (99.6%)		
Intraocular lenses			0.947	
Yes	4 (0.3%)	4 (0.3%)		
No	1455 (99.7%)	1388 (99.7%)		
General surgery			0.347	
Yes	77 (5.8%)	90 (6.6%)		
No	1262 (94.2%)	1269 (93.4%)		

*Adjusted using the Bonferroni method to account for multiple comparisons
NS: not significant
NA: not applicable

Abstract N°: 5779

The not-so-obvious face of urticaria after treatment with antithymocyte globulin.

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Introduction & Objectives:

Serum sickness as a type-three hypersensitivity reaction is not a casuistic diagnosis. The mechanism is based on the production of antigen-antibody complexes deposited in tissues (including the skin), activating the complement system and causing a local inflammatory reaction. A component of the above-mentioned complexes may be foreign proteins introduced into the oraganism for therapeutic purposes, as occurred in the following case report of a patient diagnosed with aplastic anemia, undergoing therapy with horse antithymocyte globulin variant.

Materials & Methods:

We present a patient with severe aplastic anemia, undergoing immunoablation, consulted for erythematous lesions in the area of the left upper limb and left breast. The first skin lesions in the area of the shoulder and left arm accompanied by upper limb pain appeared 2 days after the last dose of horse variant of antithymocyte globulin (ATG). After 4 days, there was an expansion of the skin lesions with involvement of the left breast and the appearance of lesions on the back on the left side. On examination at the time of consultation: erythematous and edematous lesions of the greatest intensity involving the entire left breast and diffuse oval-shaped, ring-shaped lesions in the area of the arm, shoulder and left subscapular region. The skin lesions had a marked edematous component. Pain was predominant - the patient denied burning, itching within the lesions. Doppler ultrasound excluded thrombosis. The clinical picture supports the diagnosis of urticaria as a symptom of serum sickness disease after treatment with antithymocyte globulin (ATG).

Results:

The clinical picture supported the diagnosis of serum sickness disease, of which case reports after antithymocyte globulin are rare.The patient received 160 mg SoluMedrol/d in the course of immunoablation. We administered: \1. antibiotic and steroid therapy- Clindamycin and continuation of Methylprednisolone \2. topical compresses of 2% tannin solution (on the breast)- 2x a day for 10-15 minutes each for 3-4 days Fluticasone ointment 1x a day for 7 days on erythematous lesions (in the area of: breast, left shoulder and back). \3. antihistaminic drug, e.g. bilastine After 4 days, the patient’s condition was observed to improve after the implemented treatment.

Conclusion:

A small number of cases of cutaneous complications of the use of horse antithymocyte globulin have been described. What is noteworthy, in the available literature, this globulin is characterized by a faster and stronger reduction in T-cell numbers in comparison with the rabbit version of antithymocyte globulin. Unfortunately, its action may be associated with a stronger allergic response in patients who have not been previously exposed to horse proteins. Symptoms such as fever, chills, arthralgia, skin reactions and anaphylactic reactions may occur more frequently than in cases where the rabbit version of antithymocyte globulin is used.

Abstract N°: 5809

Physical Exercise Improves Symptomatic Dermographism

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Introduction & Objectives: Short-term exercise may reduce disease activity in symptomatic dermographism (SD), but its prevalence and short- and long-term effects remain unclear and understudied. This study aims to assess the impact of both short-term and regular long-term exercise programs on disease activity in patients with SD.

Materials & Methods: We performed a short-term exercise test to assess the disease activity and the critical friction threshold, (CFT) using the FricTest® before (SDE1) and 10 minutes after (SDE2) this test on 34 SD patients. Afterwards, we asked the patients to carry on a one-month regular long-term exercise program according to the World Health Organization's physical activity recommendations. At the end of this one-month period, we performed the short-term exercise test using the FricTest® before (SDE3) and 10 minutes after (SDE4) the exercise test.

Results: Before a one-month regular exercise program, 32 of 34 patients (94.1%) showed a reduction in the critical friction threshold after the short-term exercise test (SDE1; 1.95 ± 0.88 vs SDE2; 0.81 ± 0.86). After a one-month regular exercise program, 29 of 34 patients (85%) showed a reduction in SD symptoms with short-term exercise test and the FricTest scores were significantly decreased (SDE3; 1.57 ± 0.80 vs SDE4; 1.01 ± 0.83). After the one-month regular exercise program, a statistically significant increase was seen in the patients' UCT scores and quality of life.

Conclusion: Our findings demonstrate that SD patients exhibit decreased whealing responses after short-term exercise and after a long-term regular exercise program. These findings highlight the importance of regular physical activity and exercise in patients with SD and physicians could recommend regular physical activity as part of the treatment to their SD patients. Identifying additional underlying mechanisms and facilitating factors might improve the understanding of the pathogenesis in CIndU patients.

Abstract N°: 5869

Effectiveness and Safety of Omalizumab in the Adjuvant Treatment of Refractory Acute Urticaria: A Real-world Case-Control Study

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Introduction & Objectives:

Severe acute urticaria with systemic involvement often remains uncontrolled despite systemic corticosteroid therapy, while prolonged high-dose regimens carry significant safety risks. This study aimed to evaluate the effectiveness and safety of omalizumab as an adjunctive therapy in refractory acute urticaria.

Materials & Methods:

We conducted a single-center, retrospective case-control study of 65 patients with refractory acute urticaria selected from 3,006 hospitalized acute urticaria cases (September 2021-August 2023). Patients aged 12-75 years received either intensified corticosteroids (control group, n=39) or single-dose omalizumab 300 mg as adjunct treatment to corticosteroids (omalizumab group, n= 26) after ≥3-day prednisone [1 mg·(kg·d)−1] failure.

Results:

Primary outcomes included post-intervention corticosteroid dosage and duration. After adjusting for the confounder (underlying diseases), the omalizumab group exhibited a 93.12 mg reduction in cumulative prednisone dose (*P=0.258*) and 0.92 fewer treatment days (*P=0.016*) compared to controls. Further exclusion of covariates with P□0.05 revealed statistically significant differences in both outcomes (P□0.05). Secondary outcomes demonstrated 2.41 days reduction in total prednisone exposure (*P=0.024*) and 8.70 mg·(kg·d)−1 lower peak corticosteroid dosage (*P=0.037*) in the omalizumab group versus controls. No significant intergroup differences in adverse events, hospitalization duration, direct medication costs or progression to chronic urticaria were observed.

Conclusion:

These findings suggest omalizumab as a safe and effective corticosteroid-sparing adjunct treatment for refractory acute urticaria.

Abstract N°: 6173

Gender differences in patients with chronic urticaria: A retrospective study and systematic review

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Introduction & Objectives:

Recently, there has been a notable interest in gender medicine, with a rowing focus on exploring gender and sex differences in skin diseases. In fact, women seem to be more prone to chronic spontaneous urticaria (CSU) than men. Thus, the aim of this study is to assess gender differences in CU through a hospital series and literature review.

Materials & Methods:

A retrospective study was conducted including all patients diagnosed with CSU and followed between 2018 and 2025. Diagnosis was established according to clinical presentation. Clinical manifestations and biological parameters were analysed, with statistical associations evaluated using SPSS 25Version.

Results:

Forty patients were included in our study (20 men and 20 women). Asthma, eczema, and atopy were the most common medical histories, with 14 patients (4 men and 10 women). Women appear to have more frequent history of allergies (asthma, eczema, atopy) than men. Men are more likely to have no medical history. Certain metabolic pathologies (diabetes, hypertension) are found predominantly in men. Atopy was significantly more common in women than in men in this study, and this difference was highly statistically significant ($p < 0.001$). There is a statistically significant association between sex and metabolic disease status in this dataset ($p = 0.027$), with metabolic disease present only in one sex group. There was a significant difference in total IgE levels. There is no significant difference in the distribution of thyroid peroxidase (TPO) antibodies** between the two sex groups ($p > 0.05$). Moreover, eosinophil levels differ significantly between sexes.

Conclusion:

All identified studies reported a higher prevalence and incidence of CSU in women. This difference is believed to be related to sex hormones and autoimmunity, both of which influence the disease's pathogenesis. Estrogen, whose levels rise during the fertile phase in women, is thought to enhance humoral immunity and antibody synthesis, while estradiol promotes mast cell activation. The mechanisms involved in the pathogenesis of CSU have been identified as type I autoallergic and type IIb autoimmune. In our study, a clear difference between men and women was observed regarding the history of metabolic diseases and atopy, as well as in eosinophil and IgE levels. Based on our study and systematic review of literature, we may conclude that there are only a few studies addressing gender differences in CSU and our study suggests, numerous gaps exist regarding why women and men differ in diseases. It is a fact and should not be further ignored in the era of personalized medicine that women and men exhibit different progressions in illnesses, and both genders deserve their own diagnostics and treatments.

Abstract N°: 6251

Psychometric properties of patient reported outcome instruments in patients with chronic inducible cold urticaria

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Introduction & Objectives: A phase 3 clinical trial (NCT04681729) evaluated the efficacy and safety of dupilumab in patients with Chronic Inducible Cold Urticaria (ColdU) using several single-item patient reported outcome measures (PROMs) after ice cube application to inform efficacy endpoints: Peak Pruritus-Numeric Rating Scale (PP-NRS), Peak Pain-NRS, and Peak Burning Sensation-NRS (PBS-NRS). Each item is rated on a scale from 0 (no symptom) to 10 (worst symptom severity). Psychometric properties of the three NRSs were assessed using data from the trial.

Materials & Methods: A total of 82 ColdU patients were randomized. The psychometric analyses included construct validity, reliability, and responsiveness; within-patient and between-group meaningful change thresholds (MCTs) were estimated using Patient Global Impression of Change/Severity (PGIC/S) as anchors.

Results: The baseline mean score for PP-NRS, Peak Pain-NRS and PBS-NRS were 6.47, 5.62 and 5.85, respectively. The three NRSs scales demonstrated a near to adequate test-retest reliability (interclass correlation coefficient ranges from 0.56 to 0.68) and an adequate convergent validity (moderate to strong correlation for both PP-NRS and PBS-NRS with several measures, including PGIS, and low to strong correlation for Peak Pain-NRS with the same measures). All scales demonstrated known-groups validity and were sensitive to detect change (all $p<0.05$). MCTs were estimated for within-patient (PP-NRS: 4, range: 3-6; Peak Pain-NRS: 3, range: 2-3 and PBS-NRS: 3, range: 2-5) and between-group (PP-NRS: 2.7, range: 2.5-3.3; Peak Pain-NRS: 2.2, range: 1.6-3.2 and PBS-NRS: 2.7, range: 1.6-3.4), respectively.

Conclusion: The findings demonstrate acceptable psychometric properties of the three NRSs under investigation and support their ability to capture meaningful change in symptoms experienced by the ColdU patients in a clinical trial context.

Funding: this study was sponsored by Sanofi and Regeneron.

Conflict of interest: SR, CI, IG, RO, and MK are employees of IQVIA who was contracted to conduct the psychometric analysis. JM, RM, EZ, LC, CC, and EB are employees of Sanofi and may hold stock or stock options in the company. JC is an employee of Regeneron and may hold stock or stock options in the company.

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Abstract N°: 6411

Comparative Efficacy of Omalizumab, Dupilumab, and Remibrutinib in Chronic Spontaneous Urticaria: A Network Meta-Analysis of Randomized Control Trials

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is a challenging dermatologic condition characterized by persistent hives and angioedema that significantly impairs quality of life. While omalizumab remains the standard treatment for patients with CSU who have failed antihistamines, emerging therapies have shown promise in randomized control trials (RCTs). However, a lack of direct comparative trials presents challenges in treatment selection. This study aims to compare the relative efficacy of omalizumab, dupilumab, and remibrutinib in CSU through a network meta-analysis (NMA).

Materials & Methods:

Four databases were searched through March 2025 for RCTs evaluating omalizumab (75/150/300 mg Q4W), dupilumab (300 mg Q2W), or remibrutinib (25 mg BID) in CSU. A frequentist random-effects NMA was conducted in R to assess the following outcomes at weeks 12/24: change in 7-day Urticaria Activity Score (UAS7), 7-day Itch Severity Score (ISS7), Dermatology Life Quality Index (DLQI), disease control (UAS7 ≤ 6), symptom remission (UAS7 = 0), and no quality-of-life impact (DLQI 0/1).

Results:

Fifteen trials with 4,913 (76.8% female) patients were included. Patients had severe disease activity (mean UAS7: 30.3) and significant itch (ISS7: 14.3) at baseline. CSU also had a very large impact on patient's quality of life at baseline, with a mean DLQI of 13.4.

NMA revealed that Omalizumab 300 mg Q4W consistently demonstrated the greatest effect sizes at efficacy endpoints. It yielded the largest reductions in UAS7 at both 12 weeks (MD -10.04; 95% CI -11.15 to -8.94) and 24 weeks (MD -10.38; 95% CI -14.24 to -6.52). Omalizumab 300 mg Q4W also had the highest odds of achieving symptom remission [ORs: 9.23; 95% CI 6.38-13.35 (week 12), 6.50; 95% CI 2.94-14.37 (week 24)], and disease control [ORs: 7.14; 95% CI 5.17–9.85 (week 12), 6.73; 95% CI 1.84–24.28 (week 24)] at both timepoints. Regarding patient-reported outcomes, omalizumab 300 mg Q4W showed the highest relative ISS7 reductions (week 12 MD -4.14; 95% CI -4.68 to -3.60, week 24 MD -4.53; 95% CI -5.66 to -3.41) and second highest DLQI improvement.

Remibrutinib 25 BID showed the highest DLQI improvement (MD -4.59) and second most favourable reduction in UAS7 (MD -7.48; 95% CI -9.01 to -5.84) and symptom remission (OR: 4.46; 95%CI 2.91-6.84) at 12 weeks. Dupilumab 300 mg Q2W demonstrated good itch control (MD -3.68; 95% CI -5.61 to -1.75) and the second most favourable reduction in UAS7 (MD -7.43; 95% CI -11.25 to -3.60) at 24 weeks, but mixed results in efficacy otherwise. Omalizumab 150mg and 75mg Q4W generally exhibited good efficacy at 12 weeks, but results were not sustained through 24 weeks.

Conclusion: Omalizumab 300 mg Q4W demonstrated the most consistent and durable improvements in disease activity, symptom remission, itch control. Remibrutinib showed promising effects on efficacy and quality of life at 12 weeks, and may be a useful option for patients refractory to omalizumab. These results emphasize the importance of individualized therapy based on patient response and CSU endotype, and highlight omalizumab's continued role as a first-line therapy. Newer options such as remibrutinib and dupilumab appear generally effective, offering promising tools which may help address unmet needs in CSU patients who fail standard treatments. Future studies are warranted to better characterize the role of emerging therapies in patients with CSU who exhibit an inadequate response to higher doses of omalizumab.

Abstract N°: 6446

Patient journey and disease burden in chronic inducible urticaria (CIndU): Analysis from the Urticaria Voices study

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Introduction & Objectives:

Chronic inducible urticaria (CIndU) is defined by itchy wheals (hives) and/or angioedema in response to a particular stimulus such as heat, cold or pressure, which results in severe symptoms, impacting patients' quality of life. Based on specific triggers, CIndU is further classified into different subtypes, for example, symptomatic dermographism, cold urticaria and others. This analysis from the Urticaria Voices study reports patients' journey and disease burden in patients with CIndU.

Materials & Methods:

Urticaria Voices is a global, cross-sectional, online survey conducted in patients with CIndU and physicians treating CIndU in the USA, Canada, UK, Germany, France, Italy and Japan. Adult patients who self-reported a physician-communicated CIndU diagnosis (isolated CIndU or one or more concomitant subtypes) completed survey questions on socio-demographics, treatment and burden of CIndU on patients' life. Data were analysed descriptively, and they are presented based on patients' self-reported triggers for their CIndU. The negative impact of CIndU was assessed using a 10-point scale and Top 3 box scores, that is, the percentage of respondents selecting the three highest ratings was reported.

Results:

This analysis included 480 patients with isolated CIndU, with mean±standard deviation (SD) age of 41.1±11.8 years; 64.6% were female. Patients reported a mean±SD duration of 9.9±10.7 years since symptom onset and 7.8±9.1 years since diagnosis, with a mean delay in diagnosis of 2.2 years. Angioedema (in the past 12 months)

was self-reported in 24.6% of patients with CIndU. Mean±SD number of physicians consulted before diagnosis was 6.7±15.3 and that after diagnosis was 5.6±10.8. Despite being on treatment for a mean duration of 6.0±8.2 years, 78.1% (375 of 480) of patients were still inadequately controlled. Seventy-eight percent of patients (374 of 480) were prescribed antihistamines, of which 79.4% (297 of 374) were inadequately controlled (Urticaria Control Test score of <12). CIndU had a high negative impact on daily life in 34% of patients, moderate negative impact in 52% and neutral impact in 14%. The negative impact was higher in patients with inadequately controlled disease than in those with adequate disease control (40% vs 11%). CIndU negatively impacted various aspects of patients' lives, including mental/emotional well-being (27%), social/intimate relationships (22%), daily activities (21%) and family life, professional life and finance (18%). Patients were also impacted when being asked whether they were contagious (30%), being stared in public (24%) and when being refused to touch or shake hands (16%).

Conclusion:

Patients with CIndU experience a prolonged disease journey from symptom onset to diagnosis, involving multiple physician consultations and negative impact on life. The high proportion of inadequately controlled patients treated with antihistamines further underscores the need for more effective treatments and early diagnostic approaches.

Abstract N°: 6483

Efficacy of remibrutinib in patients with CSU by demographics and baseline characteristics: Pooled analysis from REMIX-1/-2 studies

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Introduction & Objectives:

Remibrutinib, a novel, oral, highly selective Bruton's tyrosine kinase inhibitor, has previously shown superior efficacy vs placebo and favourable safety in pivotal phase 3 studies (REMIX-1/-2) in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite treatment with second-generation H1-antihistamines. In the REMIX studies, nearly half of the remibrutinib-treated patients with CSU achieved well-controlled disease (weekly Urticaria Activity Score [UAS7] ≤6) at week 12. This pooled analysis from the REMIX studies aimed to assess remibrutinib's ability to achieve well-controlled disease in patients with moderate to severe CSU, analysed by demographics and baseline characteristics.

Materials & Methods:

In the REMIX-1/-2 studies, patients with CSU were randomised 2:1 to remibrutinib 25 mg twice daily (bid) or placebo over a 24-week double-blind period, followed by 28-week open-label treatment with remibrutinib 25 mg bid. At week 24, patients on placebo were transitioned to remibrutinib. In this pooled analysis, the proportion of patients achieving UAS7≤6 was analysed across different baseline subgroups (age, gender, body mass index [BMI], CSU duration, disease severity and experience of angioedema) using a logistic regression model.

Results:

This analysis included 606 and 306 patients receiving remibrutinib and placebo, respectively. In general, baseline demographics and disease characteristics were balanced between the two arms.

Among the age groups of ≥18 to <65 years and ≥65 to <85 years at baseline, a higher proportion of remibrutinib-treated patients achieved UAS7≤6 at week 12 vs placebo patients. A higher proportion of male (44.8%) and female (50.4%) patients treated with remibrutinib achieved UAS7≤6 at week 12 vs placebo patients (17.6% and 24.5%, respectively). Similarly, a higher proportion of patients in the BMI categories of <25 kg/m2, ≥25 to <30 kg/m2 and ≥30 kg/m2 treated with remibrutinib achieved UAS7≤6 at week 12 (45.7%, 48.0% and 52.6%, respectively) vs placebo patients (20.0%, 21.5% and 25.3%, respectively).

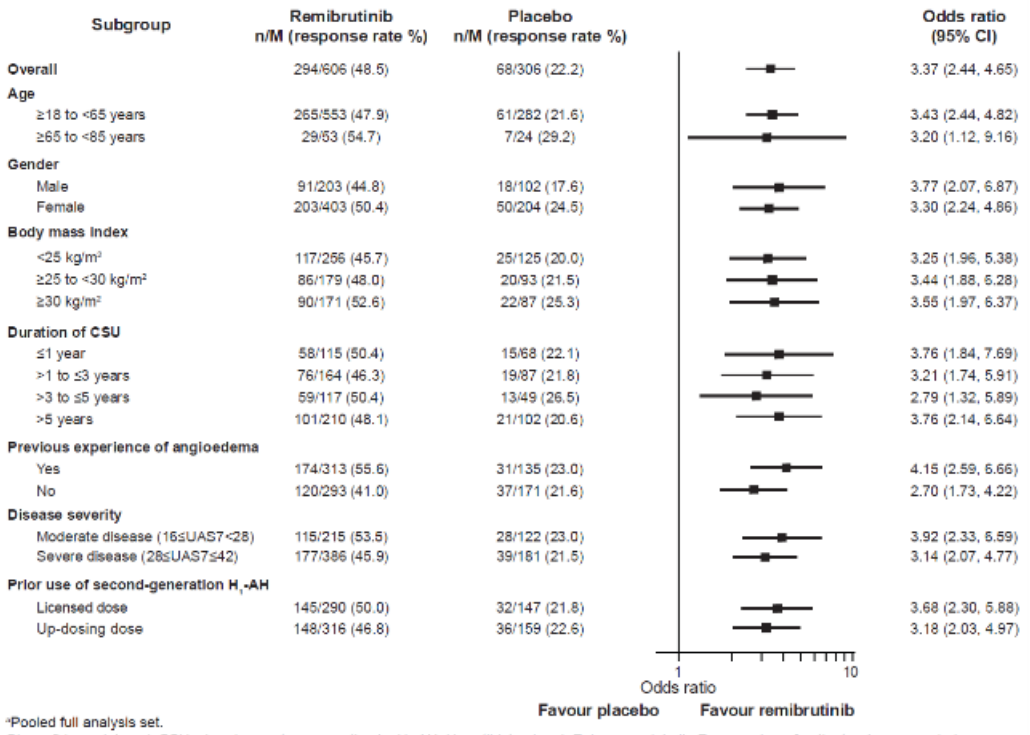
Among patients experiencing angioedema at baseline, 55.6% on remibrutinib treatment achieved UAS7≤6 vs 23.0% on placebo. In patients grouped by disease duration of ≤1 year, >1 to ≤3 years, >3 to ≤5 years and >5 years at baseline, a higher proportion of those treated with remibrutinib (50.4%, 46.3%, 50.4% and 48.1%, respectively) achieved UAS7≤6 at week 12 vs placebo patients (22.1%, 21.8%, 26.5% and 20.6%, respectively). Furthermore, a higher proportion of patients with moderate disease [16≤UAS7<28], severe disease

[28≤UAS7≤42], licensed dose of sgH1-AH or up-dosed H1-AH at baseline treated with remibrutinib (53.5%, 45.9%, 50.0% and 46.8%, respectively) achieved UAS7≤6 vs placebo patients (23.0%, 21.5%, 21.8% and 22.6%, respectively; **Figure**).

Conclusion:

This pooled analysis from REMIX-1/-2 studies showed that remibrutinib consistently improved CSU symptoms, regardless of demographics and baseline characteristics, indicating that remibrutinib could be an effective oral treatment option across a wide range of CSU patient profiles.

Figure. Proportion of patients achieving UAS7≤6 at week 12, stratified by baseline disease severity and clinical characteristics[a]



Subgroup	Remibrutinib n/M (response rate %)	Placebo n/M (response rate %)	Odds ratio (95% CI)
Overall	294/606 (48.5)	68/306 (22.2)	3.37 (2.44, 4.65)
Age			
≥18 to <65 years	265/553 (47.9)	61/282 (21.6)	3.43 (2.44, 4.82)
≥65 to <85 years	29/53 (54.7)	7/24 (29.2)	3.20 (1.12, 9.16)
Gender			
Male	91/203 (44.8)	18/102 (17.6)	3.77 (2.07, 6.87)
Female	203/403 (50.4)	50/204 (24.5)	3.30 (2.24, 4.86)
Body mass index			
<25 kg/m²	117/256 (45.7)	25/125 (20.0)	3.25 (1.96, 5.38)
≥25 to <30 kg/m²	86/179 (48.0)	20/93 (21.5)	3.44 (1.88, 6.28)
≥30 kg/m²	90/171 (52.6)	22/87 (25.3)	3.55 (1.97, 6.37)
Duration of CSU			
≤1 year	58/115 (50.4)	15/68 (22.1)	3.76 (1.84, 7.69)
>1 to ≤3 years	76/164 (46.3)	19/87 (21.8)	3.21 (1.74, 5.91)
>3 to ≤5 years	59/117 (50.4)	13/49 (26.5)	2.79 (1.32, 5.89)
>5 years	101/210 (48.1)	21/102 (20.6)	3.76 (2.14, 6.64)
Previous experience of angioedema			
Yes	174/313 (55.6)	31/135 (23.0)	4.15 (2.59, 6.66)
No	120/293 (41.0)	37/171 (21.6)	2.70 (1.73, 4.22)
Disease severity			
Moderate disease (16≤UAS7<28)	115/215 (53.5)	28/122 (23.0)	3.92 (2.33, 6.59)
Severe disease (28≤UAS7≤42)	177/386 (45.9)	39/181 (21.5)	3.14 (2.07, 4.77)
Prior use of second-generation H_1-AH			
Licensed dose	145/290 (50.0)	32/147 (21.8)	3.68 (2.30, 5.88)
Up-dosing dose	148/316 (46.8)	36/159 (22.6)	3.18 (2.03, 4.97)

[a]Pooled full analysis set.
CI, confidence interval; CSU, chronic spontaneous urticaria; H_1-AH, H_1-antihistamine; IgE, immunoglobulin E; n, number of patients who responded; M, total number of patients in the treatment group with the response variable defined; UAS7, weekly Urticaria Activity Score.
Covariates included in the logistic regression model are treatment group, geographical region, prior exposure to anti-IgE biologics, baseline score, study, subgroup variable and interaction subgroup by treatment.

Abstract N°: 6519

REMIX-1/-2: Long-term efficacy of remibrutinib in patients with CSU from the European region

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is characterised by the spontaneous occurrence of itchy wheals (hives) and/or angioedema lasting for >6 weeks. Remibrutinib, a novel, oral, highly selective Bruton's tyrosine kinase inhibitor, showed a favourable safety profile and sustained efficacy in patients with CSU in REMIX-1/-2 phase 3 studies. In this pooled analysis, we assessed the efficacy of remibrutinib in patients with CSU from the European region who participated in the phase 3 REMIX studies.

Materials & Methods:

REMIX-1/-2 were multicentre, randomised, double-blind, placebo-controlled studies assessing the efficacy and safety of remibrutinib in patients with CSU who remained symptomatic despite treatment with second-generation H1-antihistamines (H1-AHs). Patients were randomised 2:1 to remibrutinib 25 mg twice daily (bid) or placebo over a 24-week double-blind period, followed by 28-week open-label treatment with remibrutinib 25 mg bid (patients on placebo transitioned to remibrutinib at week 24 [placebo-remibrutinib]). Outcomes assessed in this pooled analysis of European subgroup patients were change from baseline in weekly Urticaria Activity Score (CFB-UAS7), proportion of patients achieving UAS7=0 (complete control) and UAS7≤6 (well-controlled disease) up to week 52.

Results:

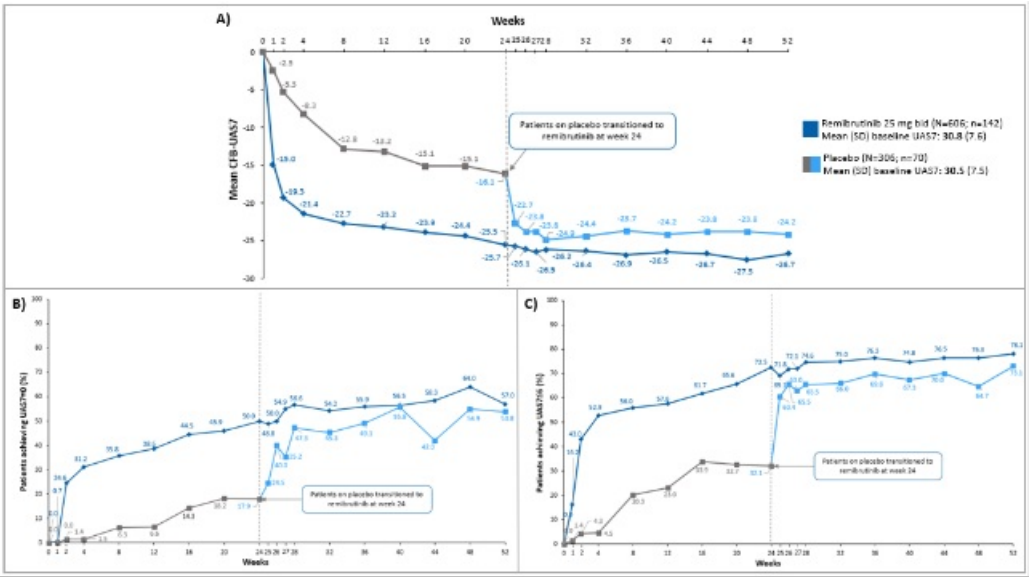
This pooled analysis included 23.4% (142 of 606) of patients from the remibrutinib arm and 22.9% (70 of 306) patients from the placebo arm of the REMIX-1/-2 studies from the European region. Remibrutinib showed greater improvements vs placebo in CFB-UAS7 at week 1 (mean: –15.0 vs –2.5) and week 12 (–23.2 vs –13.2). The improvements in CFB-UAS7 vs placebo were maintained up to week 24 (–25.5 vs –16.1), and efficacy was sustained up to week 52 (–26.7) in patients of the remibrutinib arm. At week 12, the proportion of patients achieving UAS7=0 was higher in the remibrutinib arm vs placebo arm (38.6% vs 6.6%). A higher proportion of patients in the remibrutinib arm achieved UAS7≤6 at week 2 (43.0% vs 4.3%) and week 12 (57.6% vs 23.0%) vs placebo. After transitioning from placebo to remibrutinib at week 24, the proportion of patients with UAS7=0 and UAS7≤6 increased as early as week 25 and the effect was sustained up to week 52 in both remibrutinib patients

and placebo-remibrutinib transitioned patients (**Figure**). In the overall REMIX population, remibrutinib was well tolerated with long-term treatment up to week 52, with no increase in exposure-adjusted incidence rates of adverse events (AEs)/serious AEs during the entire study period vs 24-week double-blind period.

Conclusion:

The European subgroup results reflect those of the overall population for fast efficacy of remibrutinib as early as week 1, with further improvements at week 12 that were sustained up to week 52. Remibrutinib has the potential to be an effective novel oral treatment option for patients with CSU remaining symptomatic despite treatment with H1-AH.

Figure: A) Mean CFB-UAS7, B) proportion of patients achieving UAS7=0 and C) proportion of patients achieving UAS7≤6 up to week 52 in European subgroup patients with CSU from the REMIX-1/-2 studies – pooled analysis (full analysis set, observed data)



CFB, change from baseline; CSU, chronic spontaneous urticaria; N, total number of patients in the pooled REMIX-1/-2 studies; n, number of patients from the European region in the pooled REMIX-1/-2 studies; SD, standard deviation; UAS7, weekly Urticaria Activity Score.

Abstract N°: 6535

Efficacy and safety of remibrutinib in chronic spontaneous urticaria : a systematic review and meta-analysis

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is an autoimmune debilitating condition characterized by red, recurrent wheals, angioedema, and pruritus lasting more than six weeks without identifiable factors. Remibrutinib, an oral, selective Bruton tyrosine kinase inhibitor, is becoming known as an effective choice for treating CSU. This research aims to demonstrate the efficacy and safety of remibrutinib in this condition.

Materials & Methods: From the inception to March 2025, randomized controlled studies comparing remibrutinib to placebo in CSU patients have been searched out using the PubMed, Scopus, Web of Science (WOS), Cochrane, and ClinicalTrials.gov databases. The outcomes to be studied were urticaria activity score during 7 days (UAS7), well-controlled disease (UAS7 ≤ 6), complete disease control (UAS7 = 0), dermatology life quality index (DLQI), and safety profile. The impact of different dosages was evaluated using subgroup analysis.

Results: A total of 3 studies were included in the meta-analysis, comprising 1236 patients with CSU. At 2 weeks, Remibrutinib 25mg twice daily showed significant improvement in UAS7 score (MD -11.50; 95% CI -14.23 to -8.77; P<0.00001). After 12 and 24 weeks, the therapeutic benefit was maintained, with continuous improvement (MD = -7.82; 95% CI -10.31 to -5.33; P < 0.00001) and (MD = -5.66; 95% CI -7.62 to -3.70; P < 0.00001), respectively. The safety outcomes of remibrutinib 25mg twice daily were comparable to placebo in terms of serious adverse events, patients who suffered from adverse events, and treatment discontinuation.

Conclusion: This meta-analysis shows that remibrutinib provides early and sustained efficacy with an acceptable safety profile in chronic spontaneous urticaria, with the 25mg twice daily regimen seems to be more beneficial.

Abstract N°: 6598

Temporal trends in the course and management of chronic urticaria at a tertiary care center in Denmark

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Introduction & Objectives:

In chronic urticaria (CU), treatment outcomes have significantly improved in the past decade. However, it is unclear whether these developments have affected the clinical presentation and disease course of CU in patients referred to tertiary specialist care. This study evaluated temporal trends in disease trajectories and clinical characteristics among patients with CU referred to a specialized CU center.

Materials & Methods: We retrospectively analyzed data on baseline demographics, disease characteristics, and biochemical parameters from all consecutive, newly referred patients with CU from a UCARE outpatient clinic at a university hospital from 2016 to 2025, with ongoing recruitment. Biochemical parameters, including basophil histamine release assay (BHRA), were collected from all patients. Patient-reported outcomes (PROs): weekly Urticaria Activity Score (UAS7), Urticaria Control Test (UCT), visual analogue scale (VAS) for overall disease burden, and Dermatology Life Quality Index (DLQI), were collected at baseline and at first follow-up (scheduled within the first year after omalizumab initiation; median: 8 months) and analyzed.

Descriptive statistics were reported as frequencies for categorical variables and as means with standard deviations (SD) or medians with interquartile ranges (IQR) for continuous variables. Chi-square tests and linear regression were used to assess differences in binary variables and trends over time.

Results:

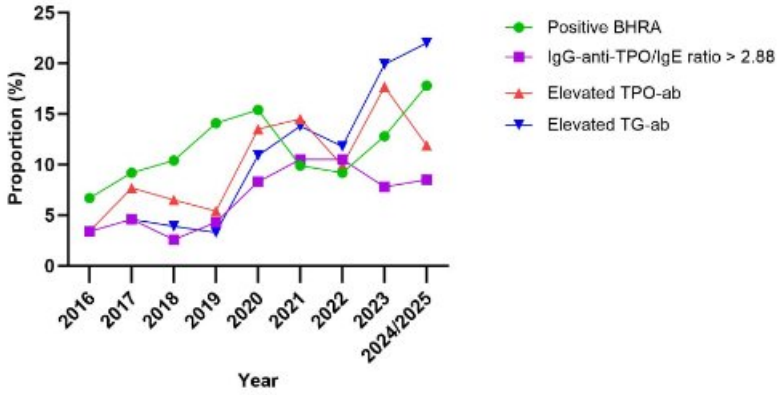
A total of 1,042 patients with CU were included, mainly adults (87.1%) with a mean (SD) age of 37.2 (16.4) years, and 68.7% were female. Overall, 60.6% of patients had isolated chronic spontaneous urticaria (CSU), 17.2% had only chronic inducible urticaria (CIndU), and 21.2% had both CSU and CIndU. Over the ten-year period, the proportion of patients who had consulted a dermatologist (57.3% in 2016 vs. 91.5% in 2024/2025, $p<0.001$) and used up-dosed antihistamines (61.8% vs. 89.0%, $p<0.001$) prior to hospital referral increased significantly. Mean (SD) duration from symptom onset to hospital referral declined from 79.0 (108.3) months to 44.5 (65.3) months, following a linear trend ($R2= 0.61$, $\beta= -3.5$ months per calendar year, 95% CI: -6.0 to -1.0, $p = 0.013$). Demographics, distribution of CU types (CSU vs. CIndU), and PRO scores at baseline remained stable over time, whereas recognized atopic comorbidities became more frequent. Increasing proportions of patients presented with a positive BHRA, elevated levels of thyroid peroxidase (TPO-ab) and thyroglobulin (TG-ab) autoantibodies,

and an elevated IgG-anti-TPO/IgE ratio (>2.88) (**Figure 1**). Among patients initiated on omalizumab, the proportion achieving disease control increased substantially from baseline to the first follow-up, with a UCT score ≥12 rising from 1.0% to 44.0%, and a UAS7 score <7 rising from 5.5% to 47.5%. This displayed a stable pattern over time.

Conclusion:

Over the past decade, referrals to specialized urticaria care occurred more promptly, with an increasing number of patients receiving appropriate treatment before their initial visit. There was a rise in biochemical markers associated with autoimmune (type IIb) CU, indicating a growing representation of this endotype among patients referred to tertiary care.

Figure 1. Temporal trends in the proportion of patients with a positive basophil histamine release assay (BHRA), elevated thyroid autoantibodies (TPO-ab and TG-ab), and an elevated IgG-anti-TPO/IgE ratio (>2.88).



Abstract N°: 6647

Isolated Solar Angioedema: A Rare Dermatologic Phenomenon Explored

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Introduction & Objectives: : Isolated solar angioedema (ISA) is a rare dermatologic condition characterized by localized, non-pitting swelling triggered by exposure to ultraviolet (UV) or visible light, without accompanying urticaria. While cases of solar angioedema combined with urticaria have been reported, ISA is underreported, with limited understanding in the literature.

We aim to report two patients diagnosed with ISA and review the existing literature to elucidate its clinical characteristics, diagnostic approaches, and management strategies

Materials & Methods:

Two patients with recurrent isolated solar angioedema were evaluated, with clinical histories, diagnostic workups, and therapeutic interventions documented. Clinical diagnosis was made by striking features of skin coloured soft tissue swelling in the eyelids and lip that hours after sun exposure and was clinically distinctive from solar urticaria in term of time frame, appearance and duration. A systematic review of published cases of ISA was conducted to compare findings and summarize treatment outcomes.

Results: Both patients exhibited clear associations between sun exposure and the onset of angioedema, with no systemic involvement or abnormalities in complement levels (C3 and C4) or other auto-immune markers. Preventative measures, including high-SPF sunscreen, protective clothing, and prophylactic antihistamines, were slightly effective in mitigating symtoms. A review of the literature identified few reported cases with ISA, highlighting the utility of photoprovocation testing and the efficacy of treatment options such as narrowband UVB phototherapy and short courses of corticosteroids.

Conclusion: ISA represents a distinct and rare photodermatosis requiring increased clinical awareness for timely diagnosis and appropriate management. Prophylactic antihistamines and sun avoidance strategies have demonstrated efficacy, but further research is necessary to clarify its pathogenesis and optimize therapeutic approaches.

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Abstract N°: 7113

Dupilumab Provides Early and Sustained Improvement in Itch in Patients With Chronic Spontaneous Urticaria: Pooled Results From LIBERTY-CSU CUPID Study A and Study C

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is a chronic inflammatory skin disease characterised by wheals with or without angioedema, with associated itch and burning that adversely impact patient quality of life. Dupilumab, an interleukin (IL)-4/IL-13 inhibitor, has demonstrated improvement in itch in antihistamine-resistant omalizumab-naïve patients with CSU in LIBERTY-CSU CUPID Study A. Here, we assessed the efficacy of dupilumab vs placebo on itch severity over time in a pooled analysis of the replicate studies CUPID Study A and CUPID Study C.

Materials & Methods: LIBERTY-CSU CUPID Study A and Study C (NCT04180488) were replicate, 24-week, randomised, double-blind, placebo-controlled, Phase 3 trials of dupilumab treatment in omalizumab-naïve patients aged ≥6 years with symptomatic CSU despite standard-of-care H1-antihistamine treatment (≤4-fold the licensed dose). Patients were randomised to receive add-on dupilumab (pooled: 144 patients) 300 mg (adults, adolescents: ≥60 kg) or 200 mg (adolescents: <60 kg, children: ≥30 kg) or matched placebo (pooled: 145 patients) subcutaneously every 2 weeks. Efficacy endpoints included change from baseline in Itch Severity Score over 7 days (ISS7; range 0–21) over time, from baseline to Week 24. All *P* values were nominal, with no adjustments for multiple testing.

Results: Dupilumab improved itch (ISS7) over time compared with placebo starting from Week 3 (least squares mean [standard error] change from baseline: dupilumab, −5.0 [0.5]; placebo, −3.6 [0.5]; nominal $P = 0.0153$) through Week 24 (dupilumab, −9.9 [0.7]; placebo, −6.7 [0.7]; nominal $P < 0.0001$). The occurrence of treatment-emergent adverse events (dupilumab vs placebo) was 53.5% vs 55.9%. Overall safety was generally consistent with the known dupilumab safety profile.

Conclusion: Dupilumab demonstrated early and sustained improvements in itch starting from Week 3, supporting dupilumab as a treatment for antihistamine-resistant CSU.

Acknowledgments

Data were originally presented at the Eastern Allergy Conference (EAC) 2025, Palm beach, Florida, USA; May 29–June 1, 2025.

Abstract N°: 7180

Dupilumab Efficacy Regardless of Baseline Total Serum IgE Levels: Results from the Pooled LIBERTY-CSU CUPID Study A and Study C

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is a chronic inflammatory skin disease characterised by pruritic wheals with or without angioedema. Many patients have an inadequate response to current therapies, which may be informed by total serum IgE (ImmunoglobulinE) levels.

Materials & Methods: LIBERTY-CSU CUPID Study A and Study C (NCT04180488) were replicate, 24-week, randomised, double-blind, placebo-controlled, Phase 3 trials of dupilumab treatment in omalizumab-naïve patients aged ≥6 years with symptomatic CSU despite standard-of-care H1-antihistamine treatment (≤4-fold the licensed dose). Patients were randomised to receive add-on dupilumab (pooled: 144 patients) 300 mg (adults, adolescents: ≥60 kg) or 200 mg (adolescents: <60 kg, children: ≥30 kg) or matched placebo (pooled: 145 patients) subcutaneously every 2 weeks. Efficacy endpoints included Itch Severity Score over 7 days (ISS7; range 0–21) and Urticaria Activity Score over 7 days (UAS7; range 0–42) at Week 24 in patients with baseline serum total IgE above and below 40, 60, or 103 IU/mL. Safety was also assessed.

Results: Dupilumab treatment improved itch and urticaria activity at Week 24, regardless of baseline serum IgE levels. Least squares mean change from baseline (dupilumab vs placebo) in ISS7 was IgE <40 IU/mL: −12.1 vs −7.7, ≥40 IU/mL: −9.6 vs −6.0, <60 IU/mL: −10.8 vs −7.0, ≥60 IU/mL: −9.8 vs −6.1, <103 IU/mL: −10.5 vs −6.2, and ≥103 IU/mL: −10.1 vs −7.3, and in UAS7 was IgE <40 IU/mL: −23.1 vs −14.7, ≥40 IU/mL: −18.6 vs −11.6, <60 IU/mL: −20.1 vs −13.0, ≥60 IU/mL: −19.3 vs −12.0, <103 IU/mL: −19.9 vs −12.0, and ≥103 IU/mL: −19.3 vs −13.7 (nominal *P* for interactions >0.05). The occurrence of treatment-emergent adverse events (dupilumab vs placebo) was 53.5% vs 55.9%. Overall safety was generally consistent with the known dupilumab safety profile.

Conclusion: Dupilumab demonstrated consistent improvement in CSU signs and symptoms, regardless of serum total IgE levels in omalizumab-naïve patients.

Acknowledgments

Data were originally presented at the Eastern Allergy Conference (EAC) 2025, Palm beach, Florida, USA; May 29–June 1, 2025.

Abstract N°: 7305

Comorbidities including infections and atopic conditions in CSU patients compared to healthy controls: results from the first, large, multinational case control study - RIFA-CU

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is associated with a significant disease burden, potentially exacerbated by various comorbidities. The aim of the RIFA-CU study is to assess various medical conditions and life style factors in CSU patients and compare them to controls, with the goal of identifying modifiable risk factors. This analysis compared the prevalence of systemic diseases, infections, psychiatric conditions, and allergic diseases in CSU patients and healthy controls to identify differences and potential risk factors.

Materials & Methods:

The RIFA-CU study is a prospective, international, multicenter, observational UCARE study. Data were collected from 1392 CSU patients and 1374 healthy controls across 19 countries. The study employed a standardized questionnaire capturing data about participants' experiences in the 3-6 months preceding the onset of urticaria. Statistical comparisons were performed to identify significant differences between the groups.

Results:

CSU patients exhibited a higher prevalence of systemic diseases, including diabetes mellitus (8.4% vs 5.1%), high lipids (14.8% vs 11.7%), stomach disease (23.8% vs 17.7%), thyroid disease (18.2% vs 9.6%), autoimmune disease (5.2% vs 3.3%), and osteoporosis (2.3% vs 1.2%) compared to controls (all $p<0.05$). Infections such as teeth infections (10.9% vs 8%), urinary tract infections (11.2% vs 7.1%), and parasitic infections (1.7% vs 0.8%) were more common in CSU patients ($p<0.05$). However, no significant difference was found for H. pylori infection (5.3% vs 4.8%, $p=0.07$) and recurrent herpes (6.5% vs 5.4%, $p=0.24$). Psychiatric conditions, including panic attacks (6.4% vs 3.9%) and anxiety (15% vs 10.7%), were also more prevalent in CSU patients ($p<0.05$). CSU patients showed a significantly higher prevalence of allergic diseases, such as proven food allergy (11.3% vs 4.5%), contact dermatitis

(5.8% vs 3.8%), allergic asthma (8.8% vs 5.8%), drug allergy (13.5% vs 6.6%), and NSAID hypersensitivity (13.6% vs 3.8%, all $p<0.05$). No significant differences were observed for atopic dermatitis or allergic rhinitis between the groups.

Conclusion:

CSU patients have a higher prevalence of autoimmune, infectious, psychiatric, and allergic comorbidities compared to healthy controls, highlighting the complex clinical profile of CSU. These findings emphasize the need for a multidisciplinary approach in managing CSU, addressing both dermatological and non-dermatological aspects to improve patient outcomes.

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Abstract N°: 7327

Safety and efficacy of bruton's tyrosine kinase inhibitors for the treatment of chronic spontaneous urticaria: a systematic review and meta-analysis of randomized controlled trials

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is characterized by the spontaneous recurrence of hives, angioedema, or both for six weeks or longer, without any identifiable cause. Although second-generation H1-antihistamines remain the first-line treatment, a significant proportion of patients experience inadequate symptom control, highlighting the ongoing need for more effective and targeted treatment strategies. Bruton's tyrosine kinase (BTK) inhibitors have emerged as a promising treatment option for CSU. The objective of this study was to evaluate the effectiveness and safety associated with BTK inhibitors for CSU.

Materials & Methods:

We performed a systematic review and meta-analysis of five randomized controlled trials (RCTs), following PRISMA guidelines, to compare BTK inhibitors, including remibrutinib, rilzabrutinib and fenebrutinib, to placebo at 4, 8, and 12 weeks in patients with CSU. We searched PubMed, Embase and Cochrane Central Register of Controlled Trials from inception to April 2025. The primary outcomes assessed included the weekly Urticaria Activity Score (UAS7), complete absence of itch and hives (UAS7=0), well-controlled CSU (UAS7 ≤6), and safety profiles.

Results:

A total of 1071 (71.93%) patients received BTK inhibitors and 418 (28.07%) received placebo. BTK inhibitors significantly led to the achievement of UAS7=0 at week 4 (21.11% vs 4.49%; RR 5.64; 95% CI 1.04 to 30.70; P = 0.05; I^2 = 60%; Figure 1), week 8 (28.14% vs 7.41%; RR 3.78; 95% CI 2.48 to 5.76; P < 0.00001; I^2 = 0%; Figure 2), and week 12 (28.40% vs 9.54%; RR 2.68; 95% CI 1.28 to 5.62; P = 0.02; I^2 = 37%; Figure 3). Consistent findings were also observed for UAS7 ≤6 at week 4 (41.57% vs 8.99%; RR 4.30; 95% CI 3.06 to 6.03; P < 0.00001; I^2 = 0%; Figure 4), week 8 (49.13% vs 18.86%; RR 2.60; 95% CI 2.02 to 3.33; P < 0.00001; I^2 = 0%; Figure 5), and week 12 (44.91% vs 21.91%; RR 2.05; 95% CI 1.68 to 2.50; P < 0.00001; I^2 = 0%; Figure 6). Neither the incidence of adverse events (AEs) (62.78% vs 61.46%; RR 1.06; 95% CI 0.84 to 1.33; P =0.47; I^2 = 43%; Figure 7), nor serious AEs (2.54% vs 1.95%; RR 1.17; 95% CI 0.34 to 4.02; P =0.71; I^2 = 3%; Figure 8) were significantly different in the BTK inhibitors group.

Conclusion:

BTK inhibitors offer a valuable, safe, and effective treatment option for CSU, particularly in cases that are refractory

to second-generation H1-antihistamines.

Figure 1. The proportion of patients achieving a UAS7 score of 0 at week 4

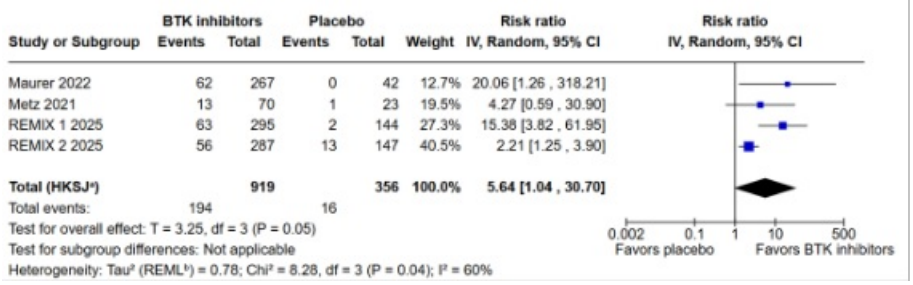


Figure 2. The proportion of patients achieving a UAS7 score of 0 at week 8

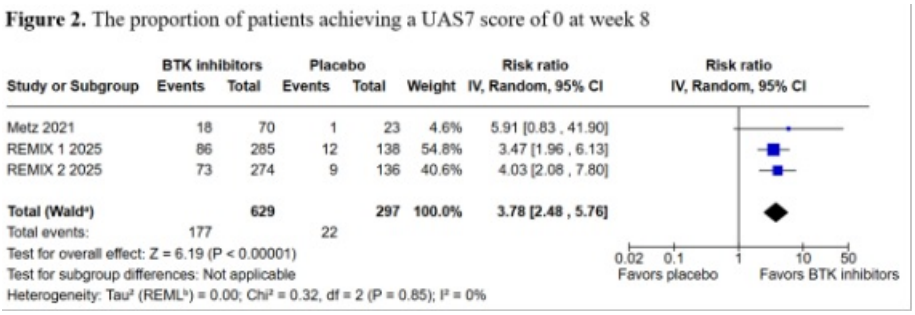


Figure 3. The proportion of patients achieving a UAS7 score of 0 at week 12

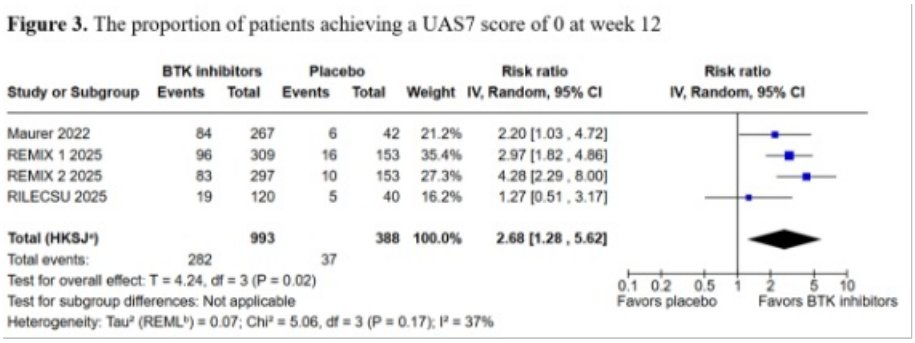


Figure 4. The proportion of patients achieving a UAS7 score ≤6 at week 4

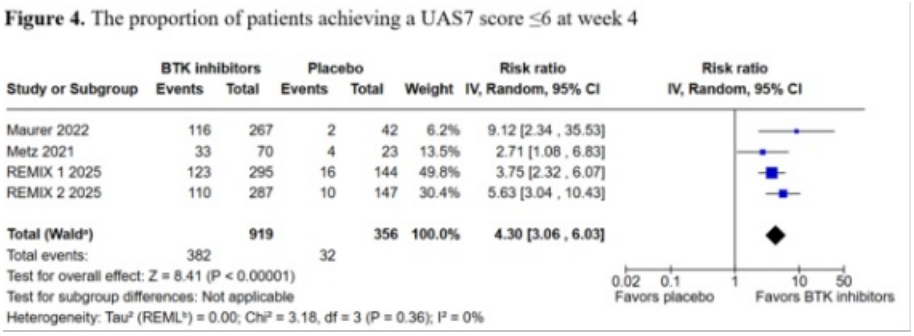


Figure 5. The proportion of patients achieving UAS7 score ≤6 at week 8

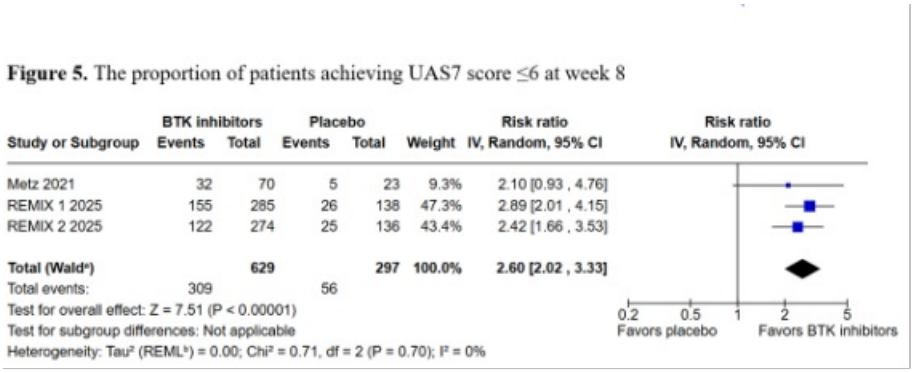


Figure 6. The proportion of patients achieving UAS7 score ≤6 at week 12

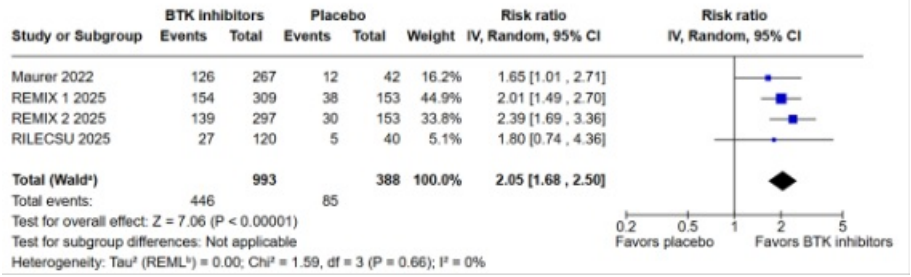


Figure 7. The incidence of at least one adverse event in the overall population

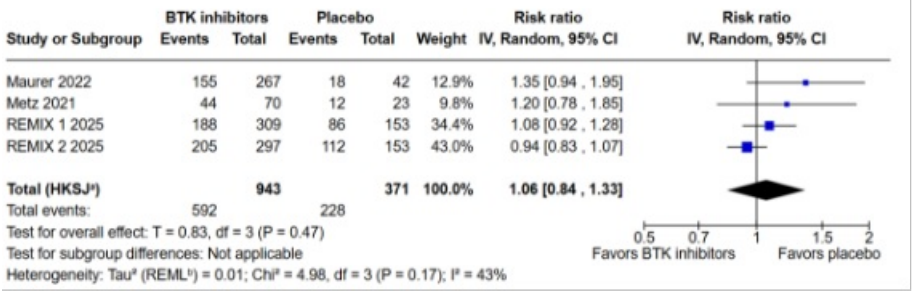
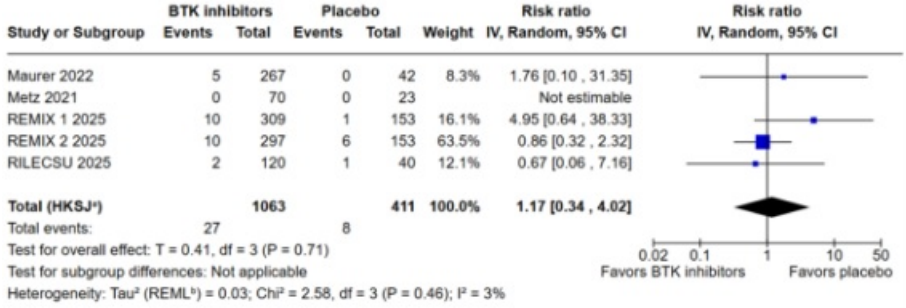


Figure 8. The incidence of serious adverse events in the overall population



Abstract N°: 7485

Dupilumab Provides Early and Sustained Improvement in Urticaria Activity in Patients With Chronic Spontaneous Urticaria: Pooled Results From LIBERTY-CSU CUPID Study A and Study C

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is a chronic inflammatory skin disease characterized by wheals with or without angioedema, with associated itch and burning that adversely impact patients' quality of life. Dupilumab, an interleukin (IL)-4/IL-13 inhibitor, has demonstrated improvement in urticaria activity in antihistamine-resistant, omalizumab-naïve patients with CSU in LIBERTY-CSU CUPID Study A. Here, we assessed the efficacy of dupilumab vs placebo on urticaria activity over time in a pooled analysis of the replicate studies CUPID Study A and CUPID Study C.

Materials & Methods:

LIBERTY-CSU CUPID Study A and Study C (NCT04180488) were replicate, 24-week, randomized, double-blind, placebo-controlled, phase 3 trials of dupilumab treatment in omalizumab-naïve patients aged ≥6 years with symptomatic CSU despite standard-of-care H1-antihistamine treatment (≤4-fold the approved dose). Patients were randomized to receive add-on dupilumab (pooled: 144 patients) 300 mg (adults, adolescents: ≥60 kg) or 200 mg (adolescents: <60 kg, children: ≥30 kg) or matched placebo (pooled: 145 patients) subcutaneously every 2 weeks. Efficacy endpoints included change from baseline in Urticaria Activity Score over 7 days (UAS7; range 0–42) over time, from baseline to Week 24. All *P* values were nominal, with no adjustments for multiple testing.

Results:

Dupilumab improved urticaria activity (UAS7) over time compared with placebo, starting from Week 3 (least squares mean [standard error] change from baseline: dupilumab, −9.9 [0.9]; placebo, −6.9 [0.9]; nominal $P = 0.0066$) through Week 24 (dupilumab, −19.3 [1.3]; placebo, −13.1 [1.3]; nominal $P < 0.0001$). The occurrence of treatment-emergent adverse events (dupilumab vs placebo) was 53.5% vs 55.9%. Overall safety was generally consistent with the known dupilumab safety profile.

Conclusion:

Dupilumab demonstrated early and sustained improvements in urticaria activity in omalizumab-naïve patients starting from Week 3, supporting dupilumab as a treatment for H1-antihistamine-resistant CSU.

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Abstract N°: 7577

Comparison of Clinical and Laboratory Differences Between Patients with Symptomatic Dermographism and Chronic Spontaneous Urticaria

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Introduction & Objectives: Chronic urticaria (CU) is a heterogeneous condition lasting more than six weeks, characterized by urticaria, angioedema (AE), or both, and significantly impacting quality of life. CU includes chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIU), with symptomatic dermographism (SD) being the most common CIU subtype. This study aimed to compare the demographic, clinical, and laboratory characteristics, exacerbating factors, and comorbidities of patients with SD, SD+CSU, and isolated CSU, with a particular focus on identifying the distinct features of SD and its impact on the clinical profile of CSU when the two conditions coexist.

Materials & Methods: This cross-sectional study was conducted at the Department of Dermatology and Venereology, Hacettepe University, between October 1, 2023, and March 31, 2025. Patients with SD, SD+CSU, and isolated CSU were included after providing informed consent. Data were collected through face-to-face interviews using structured questionnaires. Recorded variables included demographic characteristics, clinical findings, comorbidities, and exacerbating factors such as physical triggers, infections, medications, vaccines, menstruation, and psychological stress. Frictest was performed to confirm the diagnosis in the SD group, and UAS7 was calculated for patients with CSU. Laboratory parameters (CBC, CRP, ESR, TSH, anti-TPO, total IgE, ANA, C3, and C4) were retrospectively reviewed. Patient's current treatments were recorded. Statistical analyses were performed using SPSS version 23.0.

Results: A total of 138 patients (SD: 38, SD+CSU: 46, CSU: 54) were included. Female predominance was observed in all CU subtypes (84.1%). The SD group had a significantly lower mean age (35.0 ± 12.5 vs. 44.7 ± 12.91, $p = 0.002$) and earlier disease onset (29.37 ± 13.98 vs. 38.09 ± 13.93, $p = 0.009$) compared to the CSU group. AE was most frequent in the SD+CSU group (78.3%, $p < 0.001$), while 18.4% of SD patients had AE, the majority of whom (60%) were untreated. Atopy was most common in the SD group (57.9%) and more frequent in SD+CSU than in CSU. Allergic rhinitis was significantly associated with SD (44.7%, $p = 0.042$). Thyroid diseases were the most common comorbidity (18.8%), with similar prevalence across all groups. Psychological stress was the most frequently reported exacerbating factor, particularly in SD+CSU patients (91.3%, $p = 0.005$). Drug-induced exacerbations, especially with non-steroidal anti-inflammatory drugs (NSAIDs) and antibiotics, were frequently observed across all groups. The most common treatment in CSU was omalizumab plus antihistamines (AH), while most SD patients were untreated. Controlled disease (UAS7 < 6) was significantly associated with omalizumab combined with antihistamines (AH) in both CSU and SD+CSU patients ($p < 0.001$). Total IgE levels were comparably distributed among the groups. A significant association between disease activity and ESR ($p = 0.030$) and CRP ($p = 0.037$) levels was identified in SD+CSU group.

Conclusion: The SD+CSU group demonstrated a distinct combined endotype characterized by higher rates of angioedema, atopy, and disease activity compared to isolated CSU, despite similar comorbidity profiles and treatment responses. These findings emphasize the importance of evaluating angioedema history in SD patients and carefully reviewing medication use during urticaria flare-ups.

Abstract N°: 7862

The Golden Rash: Yellow Urticaria An Unexpected Outcome of Phototherapy

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Introduction & Objectives:

Urticaria is a common dermatological condition characterized by erythematous, edematous, pruritic and migratory wheals that typically resolve within 24 hours without residual marks. Yellow urticaria, however, is a rare manifestation, usually associated with hyperbilirubinemia in the setting of liver or biliary diseases, particularly cirrhosis. We report a rare case of yellow urticaria in a 7-day-old newborn.

Materials & Methods:

We present the case of a 7-day-old neonate admitted to the neonatal unit for phototherapy due to jaundice secondary to Rh incompatibility and hemolytic disease of the newborn. Laboratory findings showed hemolytic anemia with markedly elevated bilirubin levels (total: 282 mg/L, direct: 236 mg/L). Minutes after the fourth phototherapy session, a yellow rash developed in the irradiated areas. On clinical examination, multiple yellow papular lesions were noted across the entire body, associated with xerosis but no systemic signs. No additional investigations were performed. A diagnosis of phototherapy-induced yellow urticaria was made.

Results:

Yellow urticaria is an uncommon condition occurring in the context of hyperbilirubinemia, often involving hypersensitivity reactions and mast cell degranulation. It has been documented in liver and biliary diseases such as viral hepatitis, alcoholic or metabolic cirrhosis, and biliary obstruction, as well as in drug-induced hepatic injury. In our case, the yellow urticaria followed phototherapy, which was indicated for jaundice caused by Rh incompatibility. The maternal immune response against fetal Rh-positive red cells results in excessive bilirubin release, worsened by the immature hepatic metabolism in newborns. Differential diagnoses for yellow skin lesions include carotenemia, drug reactions, and metabolic or hereditary disorders such as Gilbert’s syndrome. Yellow urticaria is a clinical diagnosis. Though not routinely required, skin biopsy may reveal bilirubin crystals in the dermis, which could explain the persistent yellow discoloration of the skin beyond the resolution of the wheals. This residual pigmentation likely results from bilirubin’s affinity for elastic fibers in the dermis. In our patient, the lesions regressed spontaneously within hours, and no biopsy was deemed necessary. Careful clinical assessment is essential to recognize this rare presentation and to exclude other serious underlying conditions.

Conclusion:

We report a rare case of neonatal yellow urticaria following phototherapy. Though benign, it must be differentiated from other dermatologic or systemic disorders with similar appearance, such as xanthomas or storage diseases. Early recognition aids dermatologists in appropriate management and reassurance.

Abstract N°: 7914

Avapritinib improves symptoms and quality of life in indolent systemic mastocytosis: 6-month real-world outcomes from the AVATAR study

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Introduction: Indolent systemic mastocytosis (ISM) is a rare clonal disorder characterized by the accumulation of aberrant mast cells (MCs) in various organs, resulting in diverse and often debilitating symptoms. Avapritinib, a selective KIT D816V inhibitor, has demonstrated efficacy in clinical trials; however, data from real-world dermatology/allergology-led settings remain limited.

Methods: This monocentric retrospective analysis was conducted at the Institute of Allergology, Charité – Universitätsmedizin Berlin. Patients with ISM diagnosed according to the 2022 WHO/ICC criteria and treated with avapritinib 25 mg/day were included. As of February 2025, 7 patients had completed a 24-week follow-up and are included in this report.

Results: All patients presented with signs of uncontrolled disease despite symptomatic treatment at baseline, defined as at least one of the following: moderate to severe symptoms (Mastocytosis Activity Score [MAS] ≥28), impaired quality of life (Mastocytosis Quality of Life Questionnaire [MC-QoL] ≥52), clinically relevant skin involvement, limitations in daily life due to ISM symptoms, or poor disease control (Mastocytosis Control Test [MCT] <13). The mean age was 53 years (range 36–65), and 57% were female. All patients had cutaneous involvement; 43% reported prior anaphylaxis, 71% had osteopenia/osteoporosis, and 29% had organomegaly. Median serum tryptase levels decreased by 67.1% (from 83.7 ng/mL to 14.5 ng/mL, Table 1), and KIT D816V variant allele frequency (VAF) in peripheral blood dropped by 48.1% (from 2.80% to 1.26%) after 24 weeks of treatment. The mean total MC-QoL score improved by 76% (from 58 to 16), with improvement across all subdomains: symptoms (−55.0%), emotional well-being (−79.6%), social functioning (−87.0%), and skin-related burden (−76.5%). All mastocytosis-specific symptoms, including abdominal cramps, diarrhea, fatigue, flushing, pruritus, skin swelling, difficulty concentrating, and musculoskeletal pain, showed improvement. Importantly, no new episodes of anaphylaxis occurred during the treatment period. Finally, disease control improved significantly, with mean MCT scores increasing from 8 to 17 by week 24, indicating a transition from poorly to well-controlled disease.

Conclusion: In this real-world, single-center subcohort analysis, avapritinib 25mg/day was well-tolerated and led to clinically meaningful improvements in symptom burden, disease control, and quality of life in patients with ISM. Ongoing follow-up in larger cohorts is needed to further elucidate potential disease-modifying effects, including sustained protection against anaphylaxis, improvement in bone health, and prevention of disease progression.

Abstract N°: 8510

The Life of a CSU Patient in the Biologic Era in a Non-biologic Country

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Introduction & Objectives: Chronic spontaneous urticaria (CSU) is characterized by hives, angioedema, or both for more than 6 weeks. Unpredictable, often debilitating symptoms, lack of identifiable triggers, and unknown disease severity and duration impact significantly patients' quality of life and define the substantial individual and social burden. Current CSU guidelines recommend a stepwise treatment approach with updosing second-generation antihistamines (sgAH) and adding omalizumab in uncontrolled patients that is effective in most cases. However, the therapeutic options in our country are highly limited, with no available reimbursed treatment for CSU.

Materials & Methods: We conducted a retrospective evaluation of 303 patients admitted for CSU exacerbation between July 2022 and July 2024 in our University hospital, an UCARE center, and national reference center for CSU. We assessed the "iatrogenic" CSU burden due to lack of access to adequate treatment (number of hospitalizations, emergency visits, and inpatient days) and mistreatment (unnecessary dietary restrictions, use of first-generation antihistamines and systemic corticosteroids). Data were retrieved from patient records.

Results: Of 303 assessed patients (median age: 48 years; IQR: 36.5-60.1 years), 69.97% were female and all had severe CSU, defined by disease duration (median: 16 months; IQR: 4-72 months) and number of flares (median: 3; IQR: 2-5). 17.82% of patients had only hives, 7.59% reported AE only, and 73.92% suffered both. 23.10% had autoimmune thyroiditis, 66.66% had positive autologous serum skin test (autoimmune CSU), while elevated total immunoglobulin E level (autoallergic CSU) was present in 47.50% of patients (median: 120.4 IU/mL). The most frequently identified exacerbation trigger was infection (27.39%), followed by nonsteroidal anti-inflammatory drugs (26.07%), and stress (13.86%). 12.87% of patients had multiple readmissions within the evaluated period, with 2.64% being hospitalized more than 5 times. Ten patients reported more than 10 admissions, and 1 patient reported 16 hospitalizations for a 3-year period. One patient reported previous admission in Infectious disease clinic, 1 in Intensive care unit, and 3 had multiple admissions in Toxicology clinics. The median number of current inpatient days was 16.5 (IQR: 6-12). 47.52% of all patients visited the emergency room (ER). Of all ER visits, 88.19% were for angioedema. All subjects received sgAHs and 54.13% were updosed. 33.99% were additionally prescribed first-generation AHs. Systemic corticosteroids (CS) were administered in 68.05% of patients and 40.59% reported continuous (>5 days) use of oral CSs. Six people reported regular use of oral CSs, one received monthly depot CS. One patient received epinephrine twice and 4 were treated with cinnarizine. Unreasonable dietary restrictions were recommended to 31.02% of subjects. Of all severe CSU patients only 11.55% were treated with omalizumab in line with current guidelines and all were considered responders. Due to lack of access to omalizumab, 4 subjects were on methotrexate and 2 were on cyclosporine (as second-line treatment).

Conclusion: Our results emphasize the immense burden that lack of access to effective therapies poses on patients, society and healthcare system and highlight the unmet needs in terms of equal access to affordable treatment, especially in the light of rapidly evolving CSU landscape with new promising therapies on the horizon.

Abstract N°: 8765

Evaluating the efficacy of omalizumab in urticaria resistant to anti-histamines

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Introduction & Objectives:

Chronic spontaneous urticaria (CSU) is characterised by recurrent hives and/or angioedema lasting over six weeks without an identifiable cause. While second-generation H1-antihistamines are first-line therapy, many patients remain symptomatic at maximum doses. Omalizumab, an anti-IgE monoclonal antibody, has emerged over the past 15 years as a transformative treatment for antihistamine-refractory CSU. This review aims to provide a brief overview of the literature on omalizumab's efficacy in treating CSU.

Materials & Methods:

This narrative review draws on clinical trials, meta-analyses, and real-world studies published on PubMed over the past decade, focusing on omalizumab's efficacy, safety, and predictors of treatment response in CSU.

Results:

Real-world and clinical data strongly support omalizumab's effectiveness. Uysal and Erge (2018) reported complete symptom resolution with a single dose in various urticaria subtypes. He et al. (2022) found no significant difference in response between CSU and CIndU in a meta-analysis. Saini et al. (2015) demonstrated significantly reduced itch severity scores with 300 mg of omalizumab over 24 weeks versus placebo. In the POLARIS trial, Hide et al. (2017) reported greater improvements in ISS7 and UAS7 scores at Week 12 with omalizumab (−9.54 and −7.29 for 300 mg and 150 mg, respectively) versus placebo (−5.17), with symptom control achieved in as little as two weeks.

Salman et al. (2021) found that 70 of 102 patients achieved remission, with many discontinuing treatment; relapses, mainly in those under 40, were successfully managed by reintroducing omalizumab. Rubini et al. (2019) confirmed significant reductions in pruritus and wheals with 300 mg monthly doses and no increase in adverse events. The drug's mechanism—downregulating IgE and FcεRI expression—reduces mast cell and basophil activity.

Predictive factors have been identified: Nettis et al. (2018) associated higher baseline IgE and negative ASST with better outcomes. Chen et al. (2024) showed favourable responses in patients with lower UAS7, DLQI, and IL-17 levels. Ocak et al. (2020) demonstrated omalizumab's safety and efficacy in adolescents (12–18 years), with 96.5% responding and very few adverse events.

Giménez-Arnau (2017) reported rapid onset (<4 weeks), strong tolerability, and improved quality of life. Sánchez-Borges et al. (2020) recognised omalizumab as the current gold standard among CSU biologics.

Conclusion:

Omalizumab has consistently shown strong, rapid, and durable efficacy in antihistamine-refractory CSU, with an excellent safety profile. Individual response may vary, but most patients achieve relief within weeks. Future work on dosing and biomarkers will support more personalised care and improve outcomes.

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Chronic Spontaneous and Exercise-Induced Urticaria in an Adolescent: Case Report with Response to Omalizumab

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Introduction & Objectives:

Chronic urticaria (CU) is defined by the occurrence of wheals and/or angioedema for ≥6 weeks and subdivides into chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU). Exercise-induced urticaria, a rare form of CIndU, may be severe and even life-threatening. First-line treatment for CSU consists of second-generation H_1-antihistamines (up-dosed as needed), and omalizumab is approved for antihistamine-refractory CSU. We describe a mixed CSU/CIndU case in an adolescent, critically examining the observation that a drug licensed for spontaneous disease achieved excellent control of exercise-induced symptoms despite incomplete understanding of its mechanism in this setting.

Materials & Methods:

A 16-year-old male with a 1½-year history of exercise-induced urticaria developed frequent, severe spontaneous flares in early 2024, unresponsive to quadruple-dose cetirizine (10 mg QID), oral prednisone, and intramuscular Diprospan. Urticaria Activity Score over 7 days (UAS7) rose from 13 to 35. Laboratory evaluation showed total IgE 538 IU/mL, specific IgE to animal dander 14.9 IU/mL, mild eosinophilia (330 cells/mm^3), and otherwise unremarkable routine labs. Given refractory disease and impaired quality of life, omalizumab was initiated in March 2025. Clinical response and UAS7 were monitored monthly; exercise challenge tests were repeated after 4 weeks of therapy.

Results:

After one month of omalizumab, UAS7 fell from 35 to 2. The patient tolerated supervised exercise without recurrence of wheals or pruritus. No adverse effects were observed. Notably, omalizumab demonstrated robust efficacy against exercise-induced urticaria, although the precise pathophysiological drivers of CIndU and the drug's mechanism in this context remain unclear.

Conclusion:

This case underscores two key points: (1) omalizumab, while licensed for CSU, can provide rapid and sustained control of inducible forms such as exercise-triggered urticaria; (2) the disconnect between approved indications/mechanistic data and real-world efficacy in CIndU highlights important gaps in our understanding of urticaria pathophysiology and anti-IgE pharmacodynamics. Early recognition of mixed-pattern CU and timely introduction of biologic therapy can markedly improve patient outcomes even in less-studied urticaria subtypes.