

ASSURE-CSU PRELIMINARY CANADIAN RESULTS: REDEFINING OUR UNDERSTANDING OF THE CLINICAL CHARACTERISTICS OF PATIENTS WITH CSU/CIU REFRACTORY TO H₁-ANTIHISTAMINES

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BACKGROUND

- Chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) is the occurrence of wheals (hives), angioedema or both for 6 weeks or longer due to known or unknown causes¹
- Patients, of which 40% will have concomitant angioedema, experience disturbing itch, sometimes pain, lack of sleep which impact their daily function^{2,3}
- There is little information on the clinical characteristics of patients with CSU/CIU refractory to H₁-antihistamines

OBJECTIVES

- The ASSURE-CSU study is a non-interventional, multicenter study conducted in Canada, France, Germany, Italy, United Kingdom, Spain and the Netherlands to identify and quantify the humanistic and economic burden of illness in refractory CSU/CIU patients
- Here we present the clinical characteristics of Canadian patients enrolled in the study

METHODS

Study design

- This study included a retrospective patient medical record abstraction, a cross-sectional patient survey, and a 7-day patient diary

Patient population

- Adult patients (≥18 years) with a clinician-confirmed, guideline-defined diagnosis of CSU/CIU; who had received at least one treatment course with an H₁-antihistamine; and who had remained symptomatic for more than 12 months at least 3 days per week and were currently symptomatic despite treatment

Outcomes presented in this poster

- Collected from the medical charts (12 months prior to enrolment):
 - Demographics and history of disease
 - ICD (International Classification of Diseases) codes used by the physicians in the absence of specific code for CSU/CIU
 - Comorbidities at diagnosis
 - History of angioedema

Data Analysis

- Data were summarized descriptively using mean values and standard deviations for continuous variables and counts and proportions for categorical variables

RESULTS

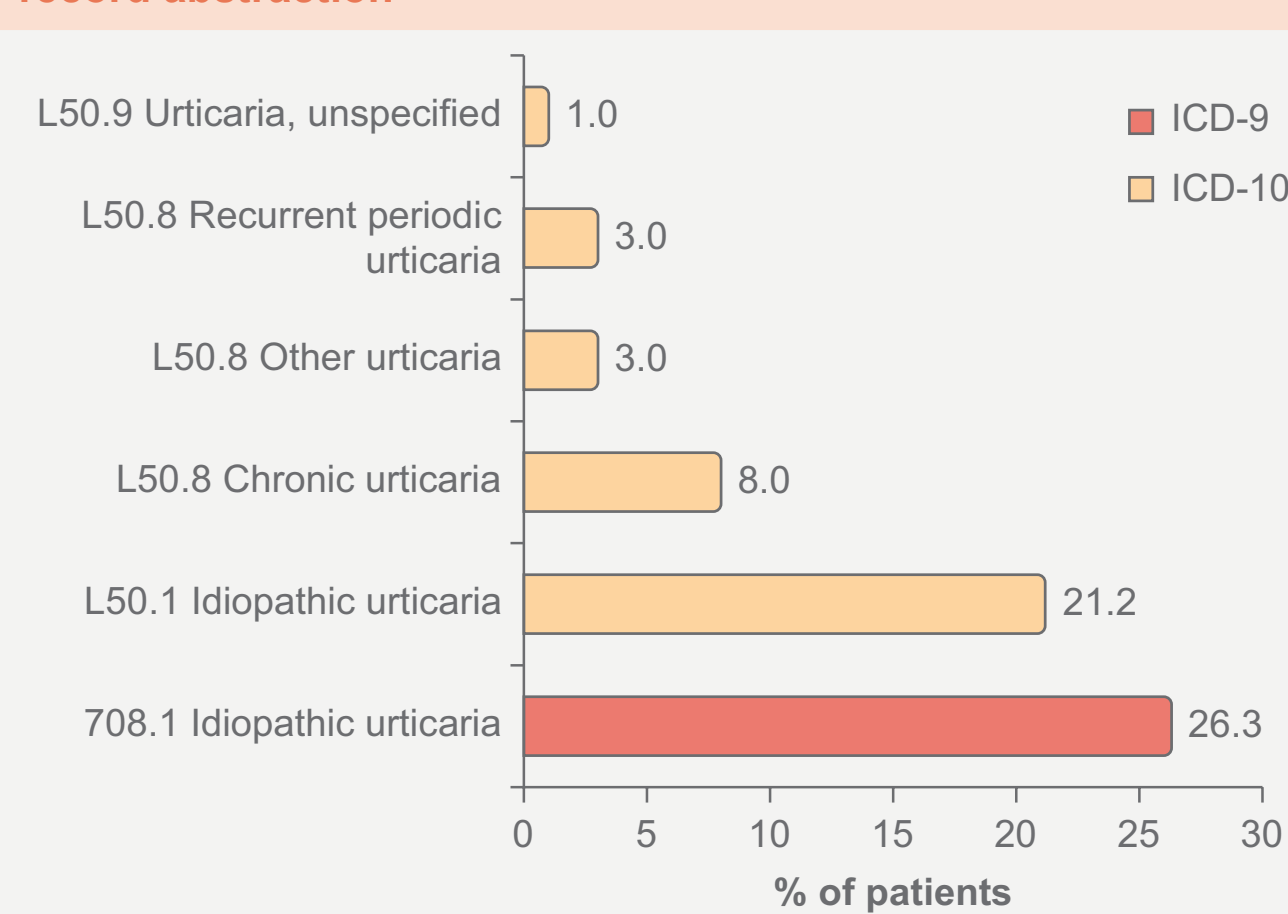
- A total of 9 sites participated in the study, of which, 7 were specialist centers, 1 was a specialist center and a hospital and 1 was 'other'
- Medical records were abstracted for 99 patients presenting with CSU/CIU as defined by the eligibility criteria
- Patients experienced onset of symptoms at a mean (SD) age of 42.9 (16.9) years and were diagnosed with CSU/CIU at a mean age of 45.8 (15.6) years
- The mean age of patients at enrolment was 50.8 (15.0) years, with a mean disease duration between diagnosis and enrolment of 5.2 (6.8) years

Table 1. Comorbidities at diagnosis

Comorbidity	n (%)
Asthma	16 (16.2%)
History of allergic disease	16 (16.2%)
Allergic rhinitis	12 (12.1%)
Family history of allergic disease	10 (10.1%)
Autoimmune diseases	
Lupus	0
Hashimoto's	5 (5.1%)
Vitiligo	0
Diabetes mellitus	2 (2.0%)
Rheumatoid arthritis	1 (1.0%)
Other autoimmune disease	6 (6.1%)
Connective tissue disease(s)	2 (2.0%)
Atopic eczema	2 (2.0%)
Myeloproliferative disease	0
Other	3 (3.0%)
Hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs)	12 (12.1%)

- The majority of enrolled patients were female (77.8%) and Caucasian (80.8%)
- The most commonly reported comorbidities at diagnosis included asthma (16.2%), patient history of allergic disease (16.2%), allergic rhinitis (12.1%), family history of allergic disease (10.1%), Hashimoto's disease (5.1%), connective tissue disease (2.0%), and atopic eczema (2.0%) (Table 1)
- Hypersensitivity to non-steroidal anti-inflammatory drugs was reported in 12.1% patients (Table 1)
- Diagnosis was coded using the ICD 9th and 10th version (ICD9 and ICD-10) in 62/99 patients (62.6%) with 26 patients having the ICD-9 code 708.1 of idiopathic urticaria. The rest had various ICD-10 codes with a majority being coded as L50.1 idiopathic urticaria (Figure 1)

Figure 1. ICD-9 and ICD-10 diagnosis codes from the medical record abstraction



- According to medical records, 49.5% of patients (n = 49) were reported to have angioedema associated with their CSU/CIU. Angioedema at the time of diagnosis was reported for 41.4% of patients (n = 41) and 28.3% (n = 28) experienced angioedema in the past 12 months
- The number of episodes was reported for 42.8% (12 out of 28) of patients having angioedema in the past 12 months with a mean of 12.4 (14.3) episodes during that 12 month period

CONCLUSIONS

- This Canadian-specific analysis from ASSURE-CSU suggests that patients with CSU/CIU refractory to H₁-antihistamines are in majority women, who have experienced symptoms for approximately three years before diagnosis, with average disease duration of more than five years from diagnosis to time of enrolment
- Approximately half of all patients presenting with CSU/CIU had angioedema at any time before enrolment
- There were also a number of other co-morbidities reported in the medical charts with the majority being related to allergic diseases
- Due to lack of specific ICD-9/10 codes for CSU/CIU, majority of the patients were coded as idiopathic urticaria. There is a need to develop a new code for CSU/CIU which will help in standardised diagnosis

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CONFLICT OF INTEREST

GS has acted as a consultant for Novartis and in the past three years, he has conducted studies for Novartis, CSL Behring, Merck, and DBV Technologies. He is also president of the Allergy, Asthma & Immunology Society of Ontario. CL has served as a consultant, principal investigator, and speaker for Amgen, AbbVie, Janssen, Novartis, Merck, Eli Lilly, LEO Pharma, and Celgene. AK reports personal fees from Novartis, advisory Boards from ViroPharma and speakers' honorarium and CME sponsorship from CSL Behring. JH reports personal fees from Novartis, Merck, Teva, CSL Behring, Baxter, Shire, GSK, Circassia, Pfizer, Roche, and Johnson and Johnson. KH, DMcB and RW are employed by RTI Health Solutions, which provides consulting and other research services to pharmaceutical, device, government, and non-government organizations. In this salaried position, they work with a variety of companies and organizations. They receive no payment or honoraria directly from these organizations for services rendered. SCR, OC, SK, MMB and HT are employed by Novartis