Canadian Sub-analysis of the ASSURE-CSU Study: Demographic Characteristics and Health Related Quality of Life in Patients with Chronic Idiopathic Urticaria

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Background

- Chronic idiopathic urticaria (CIU), also referred to as chronic spontaneous urticaria (CSU), is a debilitating disease marked by the spontaneous appearance of itchy hives, angioedema or both lasting more than six weeks, which have no demonstrable external trigger¹
- CIU/CSU is associated with a significant and underestimated disease burden that, in several dimensions, is comparable to the impairment suffered by patients with atopic dermatitis and psoriasis²
- Patients experience pain, lack of sleep, occupational disabilities and social isolation which results in a negative impact on their daily function, thus drastically lowering their health-related quality of life (HRQoL)³⁻⁵
- Little is published about the burden of disease on patients with refractory CIU/CSU

^{1.} Zuberbier T et al. Allergy 2014;69:868–87

^{2.} Grob JJ et al. Br J Dermatol 2005;152:289-95

^{3.} Yang HY et al. J Formos Med Assoc 2005;104:254-63

Objective

- The ASSURE-CSU study (ASsessment of the Economic and Humanistic Burden of Chronic Spontaneous/Idiopathic URticaria PatiEnts) is an observational, non-interventional, multinational, and multicenter study conducted in Canada, France, Germany, Italy, UK, Spain and Netherlands to identify and quantify the humanistic and economic burden of illness in refractory CIU/CSU patients
- Here we present the ASSURE-CSU Canadian sub-analysis on demographics, clinical characteristics including disease severity as evaluated by the Urticaria Activity Score over 7 days (UAS7), and HRQoL as evaluated by Dermatology Life Quality Index (DLQI) and Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)

Methods

Patients with a physician diagnosis of CIU/CSU and who have been symptomatic for more than 12 months despite treatment were included

Retrospective medical chart review

- Patient demographics
- Baseline medical history
- Severity of disease at diagnosis
- Angioedema

Cross-sectional patient survey

- DLQI (0-30, from best to worst)¹
- CU-Q2oL (0-100,from best to worst)²
- UAS7 (0-42, from best to worst)³
- Demographic data and clinical characteristics were analyzed for the full cohort. HRQoL was analyzed for the full cohort and by disease severity using prespecified cut-offs of the UAS7 (1-6: well-controlled; 7-15 mild, 16-27 moderate, and 28-42: severe urticaria)⁴

^{1.} Finlay AY, Khan GK. Clin and Experimental Dermatol 1994;19:210–16

^{3.} Maurer M et al. N Engl J Med 2013;368:924-35

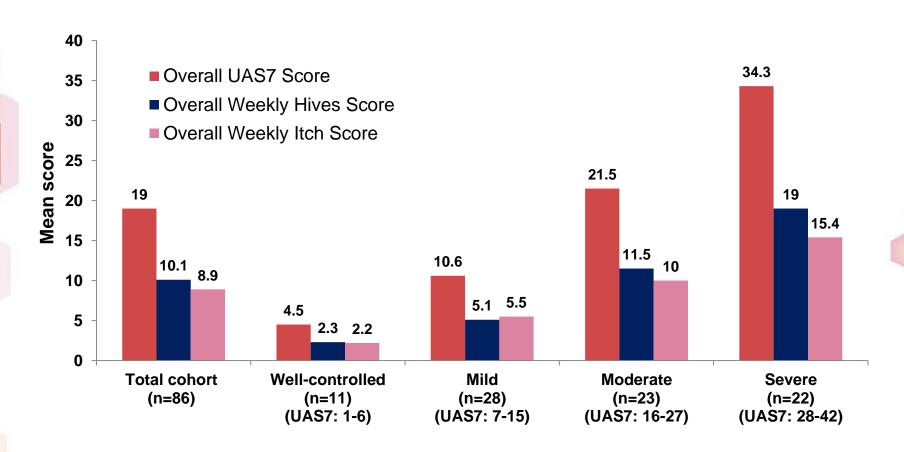
^{4.} Stull D, The European Academy of Allergy and Clinical Immunology, Copenhagen, Denmark, Jun 07-11, 2014

Results: Baseline Characteristics

Patient and Disease Characteristics (medical chart review)	Total (N=99)
Age at enrolment (years), mean (SD)	50.8 (15.01)
Age at symptom onset (years), mean (SD)	42.9 (16.87)
Age at diagnosis (years), mean (SD)	45.8 (15.55)
Females, n (%)	77 (77.8%)
Disease duration (months) since diagnosis to recruitment [mean (SD)]	62.0 (81.91)
CIU/CSU severity at the time of diagnosis, n (%)	
Mild	2 (2.0%)
Moderate	30 (30.3%)
Severe	42 (42.4%)
Data not available	24 (24.2%)
Angioedema associated with CIU/CSU, n (%)	49 (49.5%)

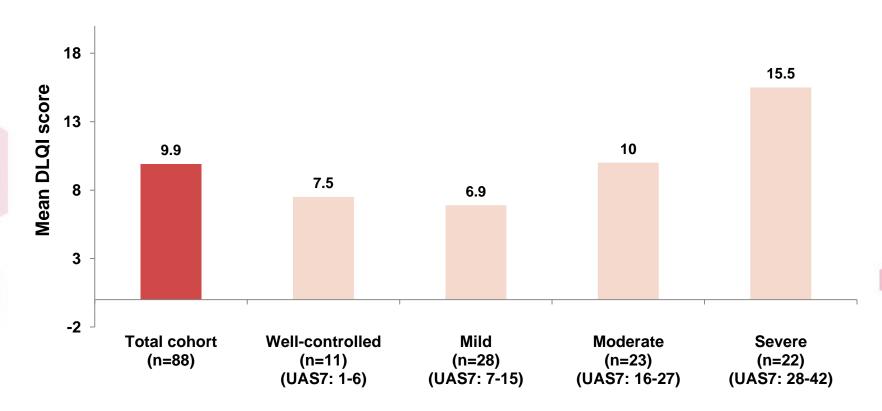
 CIU/CSU disease severity at diagnosis was most often determined by the number, duration and intensity of flares (54%), impact on HRQoL (49%) and medication requirements (32%); the UAS7 was only used in 9% of patient charts

Urticaria Symptoms based on the UAS7 collected in the Patient Diary at enrolment (Days 1-7)



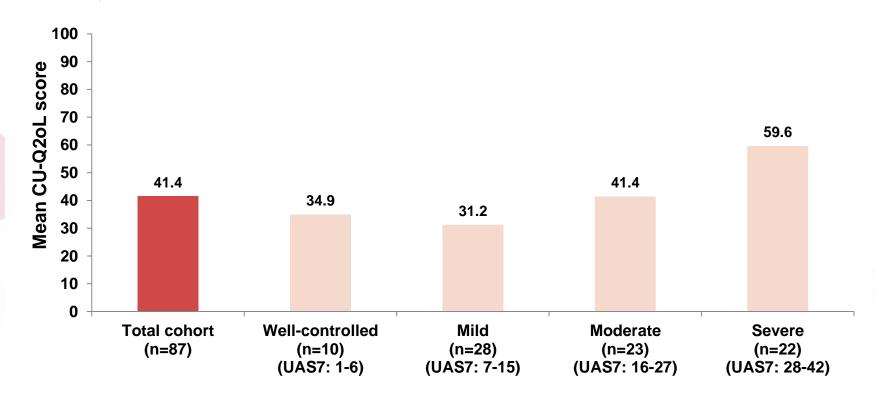
At enrolment, UAS7 was completed by 86 patients; data incomplete for 2 patients

Impact of CIU/CSU on HRQoL as assessed by the DLQI



- Overall mean DLQI score was 9.9 (n=88) with work and school, symptoms and feelings, and daily activities being the dimensions most affected
- DLQI score of 10 signifies that CIU/CSU has an impact on patients' QoL

Impact of CIU/CSU on HRQoL as assessed by the CU-Q2oL



 According to CU-Q2oL, pruritis, sleep problems and looks were the dimensions most affected

Conclusions

- This the first study to quantify the humanistic burden in refractory CIU/CSU patients. This analysis shows that these patients have long disease duration and long delays between symptom onset and diagnosis
- CIU/CSU has a significant impact on patients' lives; patients with more severe symptoms experience greater HRQoL impairment
- Consistent results were seen between the CU-Q2oL, a disease specific HRQoL tool, and the DLQI, a dermatological tool
- In addition to measuring disease symptoms (UAS7), the findings further support the need to measure HRQoL in patients suffering from CIU/CSU so that a holistic approach to patients' management is ensured
- Consistent use in daily practice of the tools available (UAS7, DLQI, and CU-Q2oL) could improve measurement of symptoms and HRQoL and ultimately patient care

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Conflict of Interest

- Ms. Sima Chiva-Razavi and Mr. Olivier Chambenoit are permanent employees of Novartis Pharmaceutical Canada Inc., Dorval, QC, Canada
- Dr. Maria-Magdalena Balp is a permanent employee of Novartis Pharma AG, Basel,
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