ASSURE-CSU CANADIAN RESULTS: ASSESSING THE IMPACT OF CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA ON WORK PRODUCTIVITY AND INDIRECT COSTS

PRS31

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INTRODUCTION

- The latest EAACI/GA2LEN/EDF/WAO* guidelines define chronic spontaneous (also known as idiopathic) urticaria (CSU/CIU) as the occurrence of wheals (hives) with or without angioedema for 6 weeks or longer due to known or unknown causes[1]
- Although CSU/CIU is not life threatening, when not adequately controlled with therapies it has an impact on patients' life. However, quantification of this burden in terms of different domains of health-related quality of life (HRQoL) is scarce[2–4]
- CSU/CIU has an impact on healthcare payers and also on society in terms of indirect costs (i.e., productivity losses arising from reduced performance at work or absence from work[5])
- There is limited real world research quantifying the humanistic and economic impact of CSU/CIU on patients symptomatic despite treatment

OBJECTIVE

- The ASSURE-CSU study (**AS**sessment of the Economic and Humanistic Burden of Chronic **S**pontaneous/Idiopathic **UR**ticaria Pati**E**nts) was an observational, non-interventional, multinational, and multicenter study conducted in Canada, France, Germany, Italy, United Kingdom (UK), Spain and the Netherlands to identify and quantify the humanistic and economic burden of illness in CSU/CIU patients
- Here we present the results of the Canadian cohort analysis on economic burden in terms of work productivity and indirect costs

METHODS

Study Design

- Study design was based on a combination of retrospective patient medical record abstraction, a cross-sectional patient survey, and a 7-day patient diary
- Data collected included: patient demographics, co-morbidities, medical resources, treatment patterns, disease severity, HRQoL and productivity

Patient Population

- Clinician-confirmed, guideline-defined and diagnosed adult (≥18 years) CSU/CIU patients with at least one treatment course of an H_1-antihistamine and with symptoms for more than 12 months were eligible to be part of the study

Outcomes

- CSU/CIU–related work days missed and productivity losses were measured using the Work Productivity and Activity Impairment—Specific Health Problem (WPAI-SHP)[6] which was completed by the patients on the 8th day following enrolment
- On the same day (8th day) patients were asked to recall and report previous 7 days of WPAI-SHP, which coincided with the 7 day UAS assessment
- WPAI-SHP measures four metrics pertaining to:
  - Absenteeism (the percentage of work time missed because of one's health problem in the past seven days)
  - Presenteeism (the percentage of impairment experienced while at work in the past seven days because of one's health problem)
  - Overall work productivity loss (an overall impairment estimate calculated by an algorithm of absenteeism and presenteeism)
  - Activity impairment (the percentage of impairment in daily activities because of one's health problem in the past seven days)
- Original WPAI-SHP scores were multiplied by 100 to be expressed as percentages. Higher scores reflect greater impairment and reduced productivity
- The associated indirect monthly costs were estimated based on 150 hours/month and average wage of 25.62 Canadian dollars (CAD) per hour. All cost data were adjusted to 2014 currency

Data Analysis

- Urticaria severity was assessed prospectively over the 7 days following enrolment using the Urticaria Activity Score (UAS), a patient daily diary covering level of itch and number of hives. A weekly score (UAS7) is calculated ranging from 0 (no symptoms and signs) to 42 (the highest severity)
- Based on UAS7 scores, five disease severity levels can be described (Table 1)

Table 1. Five CSU/CIU disease health states defined using UAS7 scores

UAS7 Score	Urticaria Severity Level
28-42	SEVERE urticaria (intense itch and >50 hives daily or almost daily over 7 days or confluent hives)
16-27	MODERATE urticaria (troublesome itch and <50 hives daily or almost daily over 7 days)
7-15	MILD urticaria (mild itch and around 20 hives over 7 days)
1-6	WELL-CONTROLLED urticaria (mild itch and no hives or fewer than 20 hives over 7 days)
0	URTICARIA-FREE: Itch free and Hive free

UAS7=Weekly Urticaria Activity Score

- Descriptive analyses were used for work days missed, productivity loss and indirect costs. Data were summarized descriptively using mean values, and standard deviations for continuous variables and counts and proportions for categorical variables
- The total number of patients included in the work impairment analysis varied as only employed patients were included (full-time [30 hours per week or more], part-time employed or self-employed); all patients were included for activity impairment

RESULTS

- In Canada, 9 sites (7 were specialist centers, 1 was specialist center and a hospital, and 1 was 'other') participated in the study and medical records were abstracted for 99 patients presenting with CSU/CIU as defined by the eligibility criteria
- Of the 99 patients included in the analysis, 88 (89%) completed the patient survey and 86 (87%) completed the patient diary. Two patients completed the patient diary but were not assigned a health state due to 3 or more missing daily urticaria activity scores. At baseline, one patient reported being itch free or hive free (UAS7=0), and was excluded from the analysis
- The mean age of patients at enrolment was 50.8 years, mean age of symptom onset was 42.9 years and age at the time of diagnosis was 45.8 years (Table 2)

Table 2. Demographic and baseline characteristics

Patient characteristics	Total cohort (N=99)
	Mean (SD)
Age at enrolment (years)	50.8 (15.0)
Age at symptom onset (years)	42.9 (16.9)
Age at diagnosis (years)	45.8 (15.6)
Disease duration since diagnosis to enrolment (years)	5.2 (6.8)
	n (%)
Female	77 (77.8)
Race and ethnicity	
Caucasian/white	80 (80.8)
Black	4 (4.0)
Asian	10 (10.1)
Other	3 (3.0)
Data not available	2 (2.0)
Full-time (30 hours per week or more), part-time employed or self-employed	47 (54.7)

SD=Standard Deviation

- WPAI-SHP measures for the four metrics pertaining to absenteeism, presenteeism, overall work productivity loss and activity impairment were 6.0%, 29.8%, 30.6% and 38.3%, respectively (Figure 1)
- Overall, presenteeism, work productivity loss, work impairment and activity impairment increased with disease severity of CSU/CIU (Figure 2)

Figure 1. Mean percentage of work productivity loss and activity impairment for total cohort

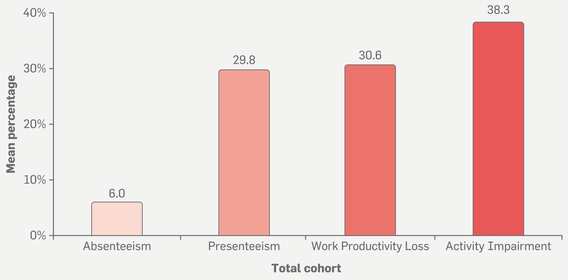
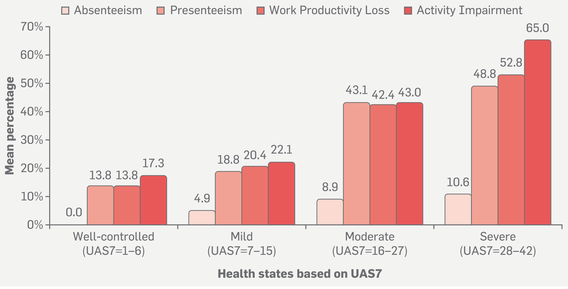
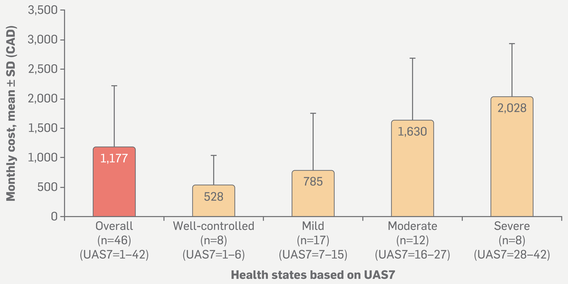


Figure 2. Mean percentage of work productivity loss and activity impairment per each UAS7 health state



- Total indirect monthly cost for work productivity loss (combination of absenteeism and presenteeism) was estimated to be a mean of CAD 1,177 per employed patient. The indirect costs increased with disease severity of CSU/CIU (Figure 3)

Figure 3. Indirect costs of work productivity loss



Note: One patient submitted an incomplete diary and therefore was not assigned a severity state
SD, standard deviation; only positive values are presented for SD;
Work productivity loss due to CSU/CIU (or overall work impairment) incorporates both absenteeism and presenteeism using the following validated Work Productivity and Activity Impairment algorithm: work productivity loss = absenteeism + (1-absenteeism)*presenteeism

DISCUSSION

- ASSURE-CSU is the first international study assessing the burden of CSU/CIU on symptomatic patients and the impact on healthcare and society
- The Canadian cohort included patients symptomatic despite different therapies with an average duration of disease between diagnosis and recruitment of 5.2 years
- As disease severity and impact on work and activity were assessed over the same period, the results suggest that symptoms have a negative impact on patient's capacity to perform overall activities and work
- Higher level of signs and symptoms shown by higher UAS7 scores have a greater impact on WPAI-SHP parameters: more absence from work, higher impairment at work and on daily activities
- The study further demonstrated that the indirect monthly costs increased with disease severity
- Therapies that would decrease CSU/CIU symptoms might have a positive impact on overall productivity and daily activities

CONCLUSIONS

- This analysis of Canadian data from ASSURE-CSU suggests that almost all employed patients are affected at work by their disease, either through absenteeism or reduced productivity at work resulting in substantial economic impact for employers and society
- Patients with inadequately controlled CSU/CIU who are symptomatic despite treatment reported that the disease had an impact on their overall activities. The disease impact increased with an increase in degree of disease severity

*Abbreviations
EAACI: European Academy of Allergy and Clinical Immunology
GA2LEN: Global Allergy and Asthma European Network
EDF: European Dermatology Forum
WAO: World Allergy Organization

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CONFLICT OF INTEREST

Sussman G 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

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Chiva-Razavi S, Tian H, Balp MM and Chambenoit O are employed by Novartis

Hollis K, McBride D and Westlund R 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

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