FIRST REAL-WORLD STUDY ASSESSING HEALTH UTILITY VALUES FOR CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA USING THE EQ-5D

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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 causes[1]
- Although chronic spontaneous (idiopathic) urticaria (CSU/CIU) is not life threatening, it can significantly impact a patient's life when not adequately controlled by medication. Patients experience disturbing itch, sometimes 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)[2-4]

OBJECTIVE

- The ASSURE-CSU study is 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 who are symptomatic despite treatment
- Here we present data on utility values among patients enrolled in Canada, Germany, UK, and the Netherlands

METHODS

Study Design

- This study included a 1-year retrospective medical record abstraction, a cross-sectional patient reported outcomes survey, and a 7-day prospective patient diary

Patient Population

- Adult patients with a clinician-confirmed, guideline-defined diagnosis of CSU/CIU
- Patients had received at least one treatment course with an H_1-antihistamine
- Patients had been symptomatic for more than 12 months at least 3 days per week and were currently symptomatic despite treatment

Outcomes

- EQ-5D-3L was completed by the patients at recruitment
  - EQ-5D-3L is a generic health status instrument which comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. A single utility score can be derived, with a maximum utility value of 1 (perfect health) and 0 (corresponding to death)
- Utility values were calculated and further stratified by disease severity defined by UAS7 scores
- Urticaria severity was assessed prospectively over the 7 days following enrolment using a patient diary called Urticaria Activity Score. Twice-daily pruritus and hives ratings are averaged to create a daily UAS score which is summed over 7 days (UAS7)
  - UAS7 score ranges from 0 to 42 (highest severity)
- UAS7 scores were used to define categorical disease states as described previously (**Table 1**)[5]

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

UAS7 Score	Urticaria Severity Level
28-42	SEVERE urticaria
16-27	MODERATE urticaria
7-15	MILD urticaria
1-6	WELL-CONTROLLED urticaria

UAS7: Weekly Urticaria Activity Score

Data Analysis

- Data were summarized descriptively for each country. Mean values and standard deviations were reported for continuous variables and counts and proportions for categorical variables

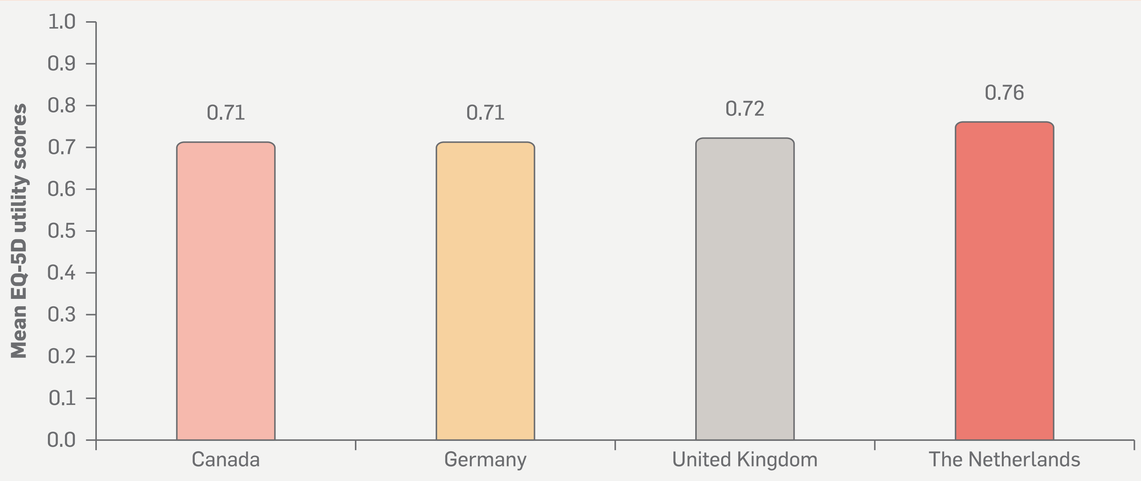
RESULTS

- A total of 88, 98, 79 and 99 patients completed the patient survey in Canada, Germany, UK and the Netherlands, respectively
- The mean age of patients at enrolment ranged from 45 to 50 years and the majority of patients were women (70% to 80%)

EQ-5D utility score

- The overall mean (SD) EQ-5D utility value was consistent across the 4 countries: 0.71 (0.30) for Canada; 0.71 (0.25) for Germany; 0.72 (0.31) for UK and 0.76 (0.27) for the Netherlands (**Figure 1**)

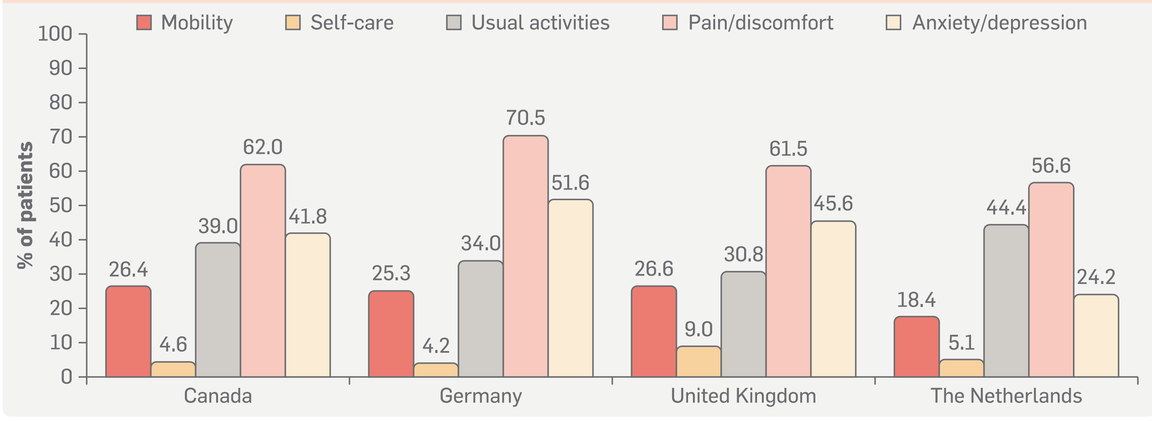
Figure 1. Mean EQ-5D utility values across the 4 countries



EQ-5D dimensions

- Among the different dimensions of EQ-5D, pain/discomfort was the most affected with 62.0%, 70.5%, 61.5% and 56.6% of patients reporting moderate to extreme problems, respectively (**Figure 2**)
- The second most affected dimension was anxiety/depression for Canada, Germany and UK with 41.8%, 51.6% and 45.6% of patients reporting moderate to extreme problems, respectively. For the Netherlands, usual activities (44.4%) was the second most affected dimension (**Figure 2**)

Figure 2. EQ-5D dimensions: percentage of patients with moderate-to-extreme problems



According to UAS7 disease health states

- With increasing severity of CSU/CIU, there was a consistent decrease in the mean utility scores (**Figure 3**)
- Similarly, impact across all dimensions also increased with disease severity (**Figure 4**)

Figure 3. Mean EQ-5D utility values as per the UAS7 health states

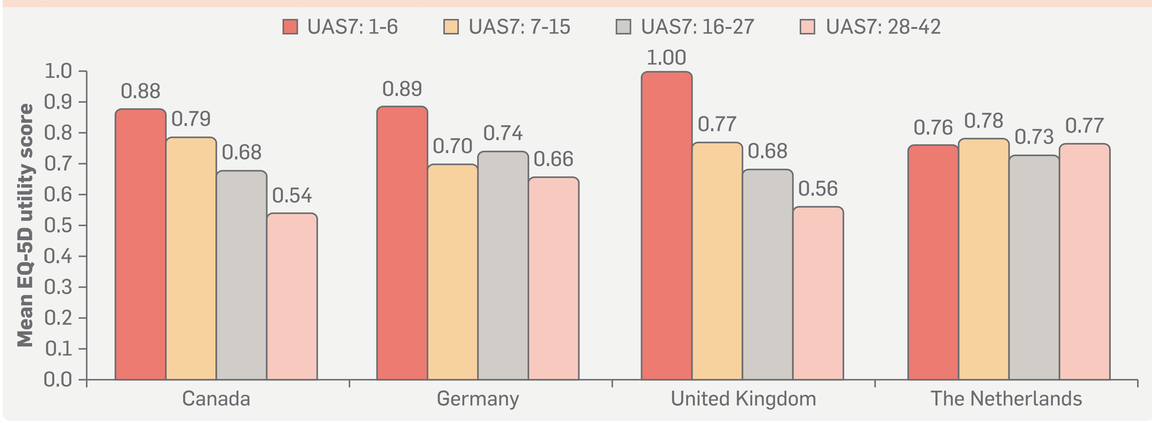
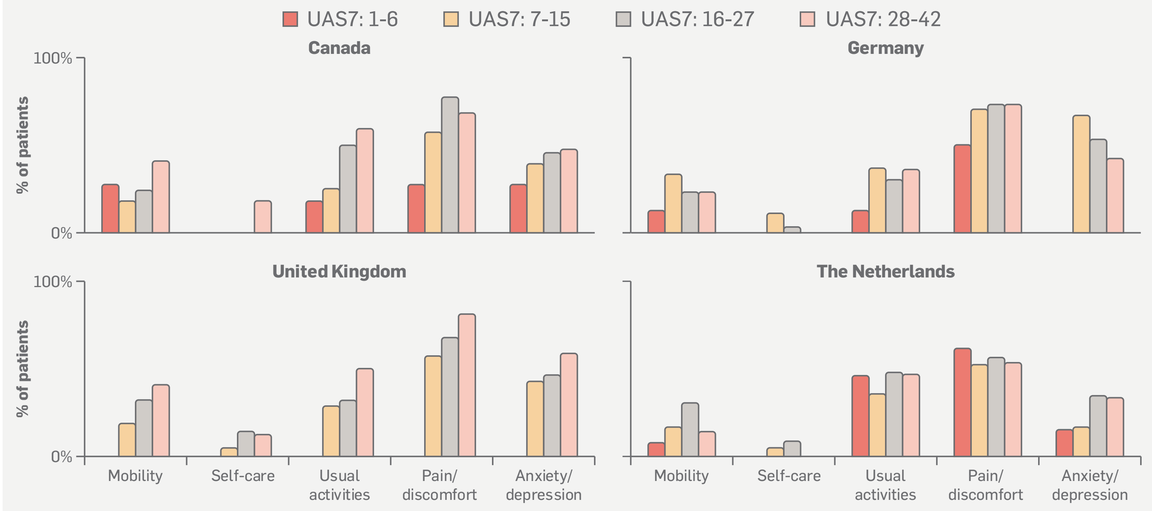


Figure 4. EQ-5D dimensions–percentage of patients with moderate-to-extreme problems according to UAS7 heath states



CONCLUSIONS

- ASSURE-CSU is the first real-world international study reporting utility values in CSU/CIU using EQ-5D
- Utility scores were similar among countries and ranged from 0.71 to 0.76, suggesting that CSU/CIU can have a significant impact on patients' quality of life across countries
- EQ-5D dimensions reflecting symptoms (pain/discomfort), common comorbidities (anxiety and depression) and daily activities were most affected by CSU/CIU
  - Small variations in the percentage of patients reporting impact on the 3 dimensions were seen in the 4 countries
- The results indicate that there is an association between HRQoL, as measured by EQ-5D, and disease severity, as measured by UAS7. Therefore, improvements in UAS7 symptom scores due to treatment may improve HRQoL for CSU/CIU patients

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CONFLICT OF INTEREST

CL has served as a consultant, principal investigator, and speaker for Amgen, AbbVie, Janssen, Novartis, Merck, Eli Lilly, LEO Pharma, and Celgene. 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. KW was recently a speaker, investigator and/or advisor for Novartis, RTI, Uriach, FAES, UCB, MSD, Shire, Viropharma, Biocryst and MOXIE. MM has received grant, research or clinical trial support from Novartis, Genentech, Uriach, Abbott Laboratories, FAES, UCB and Moxie. He has acted as a consultant/participated in advisory board meetings for Novartis, Genentech, Uriach, Abbott Laboratories, FAES, MSD, Almirall, UCB and Sanofi. ACK has received honoraria from Novartis for participation in advisory board Meetings, speaker fees and financial support for scientific studies. JNGOE has served as a speaker for Novartis. MA is a member of the Coeliac Disease Guidelines Development Group with N.I.C.E. CG has participated in an advisory board for Novartis, was a principal investigator for a Novartis supported study and has received honoraria for Novartis supported meetings. AN has received honoraria from Novartis for participation in advisory board Meetings in 2014. AH, HT, JK, MMB, NC-R, OC, SC-R and STA are employed by Novartis. CS, CR, DMcB, DW and KH 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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