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.
- 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).

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 quality of life 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 H1-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: 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 activity 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).

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

<table>
<thead>
<tr>
<th>UAS7 Score</th>
<th>Urticaria Severity Level</th>
<th>Urticaria Activity Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>28-42</td>
<td>SEVERE urticaria</td>
<td>60-100</td>
</tr>
<tr>
<td>16-27</td>
<td>MODERATE urticaria</td>
<td>30-59</td>
</tr>
<tr>
<td>7-15</td>
<td>MILD urticaria</td>
<td>0-29</td>
</tr>
<tr>
<td>1-6</td>
<td>WELL-CONTROLLED urticaria</td>
<td>0-10</td>
</tr>
</tbody>
</table>

Data Analysis

- Data were summarized descriptively for each country. Mean values and standard deviations were reported for continuous variables and counts or 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; 0.72 (0.30) for Germany; 0.72 (0.31) for UK and 0.76 (0.27) for the Netherlands (Figure 1).

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/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.

REFERENCES


CONFLICT OF INTEREST

- 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 supports conferences and other research services for pharmaceutical, device, government, and non-government organizations. STA holds salaried position, they work with a variety of companies and organizations. They receive no payment or honoraria directly from these organizations and Hari Prasad V.S. (Novartis) for designing the poster layout.

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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% 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).