Clinical profile of adult and paediatric patients with chronic spontaneous urticaria: a real-world study in the United States

Balp M-M.1, Geissbühler Y.1, Mcconnon A.2, Schäl J.2, Gomme J.3, Laires P. A.1, McKenna S.J.3, Soong W.3

1 Novartis Pharma AG, Basel, Switzerland; 2 Novartis Business Services Center, Dublin, Ireland; 3 Allervie Health-Alabama Allergy & Asthma Center, Clinical Research Center of Alabama, Birmingham, Al, United States

Background
- Chronic spontaneous urticaria (CSU), an inflammatory condition with itchy hives and/o angioedema, has manifestations that go beyond the skin and need to be further explored.

Objective
- The objective of this study was to evaluate the demographic and clinical characteristics of adult and paediatric patients diagnosed with CSU amongst the US population.

Methods
- The target population was identified in the Optum Electronic Health Record (EHR) based on ≥ 2 ICD-9 and/or ICD-10 codes of idiopathic or unspecified urticaria with/without angioedema ≥ 0 weeks apart during the study identification period (01-Jan-2012 and 31-Dec-2018) with data available for 12 months pre- and post-index date.
- Elixhauser comorbidity index (ECI) was calculated at baseline on 31 pre-specified comorbidities. ECI are stratified into groups (<0, 0–1, 1–4, n=5), with higher scores indicating higher burden.
- Duration of disease is the time between the index date and the final chronic urticaria (CU)-related diagnosis or prescription fill for a CU-related medication during the study period.
- Descriptive analysis was conducted for adults and paediatrics, separately.

Table 1. Characteristics of the study cohort

<table>
<thead>
<tr>
<th>Age (years), mean (SD)</th>
<th>Female, n (%)</th>
<th>Ethnicity, n (%)</th>
<th>Race, n (%)</th>
<th>Disease duration (years), mean (SD)</th>
<th>Insurance type, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=58,867</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47.3 (16.7)</td>
<td>44,523 (75.6)</td>
<td>3,581 (6.1)</td>
<td>3,447 (5.9)</td>
<td>2.5 (1.9)</td>
<td>37,085 (63.0)</td>
</tr>
<tr>
<td>Paediatrics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N=23,784</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.3 (5.3)</td>
<td>17,366 (73.0)</td>
<td>2,613 (11.0)</td>
<td>1,584 (6.7)</td>
<td>2.3 (1.8)</td>
<td>14,183 (59.6)</td>
</tr>
</tbody>
</table>

Results

Adults
- 58,867 patients were included in the analysis, of whom 75.6% were females and mean (SD) age was 47.3 (16.7) years (Figure 1a, Table 1).
- Baseline comorbidities: 12.3% and 14.0% of CSU adults had a comorbidity score (ECI) of 1 and ≥5, respectively.
- The most frequent comorbidities were uncontrolled hypertension, chronic pulmonary disease, anxiety, depression, and inflammatory gastro-intestinal (GI) diseases (Figure 2a).
- After CSU diagnosis: Most frequent newly diagnosed comorbidities were inflammatory GI, diseases, allergies, anxiety, chronic pulmonary disease, and obesity (Figure 2b).

Paediatrics
- 23,784 patients were included in the analysis, of whom 52.6% were females and mean (SD) age was 6.3 (5.3) years (Figure 1b, Table 1).
- Baseline comorbidities: 11.4% and 6.1% of CSU paediatrics had a comorbidity score (ECI) of 1 and ≥5, respectively.
- The most frequent comorbidities were chronic pulmonary disease, asthma, inflammatory GI diseases, allergies, and atopic dermatitis (Figure 3a).
- After CSU diagnosis: Most frequent newly diagnosed comorbidities were allergies, chronic pulmonary disease, asthma, inflammatory GI, and anxiety (Figure 3b).

Conclusions
- This real-world study reveals new insights about CSU patients’ clinical profile despite certain limitations typical for this methodology based on EHR analysis.
- There is a large increase in the percentage reporting comorbidities, such as inflammatory GI disease, allergies, after CSU diagnosis compared to baseline.
- Over a quarter of adult patients had diagnosed hypertension prior to CSU diagnosis and another 16% thereafter. Hypertension has been reported to be associated with longer disease duration.
- Adult and paediatric CSU patients tend to present with various comorbidities prior and post diagnosis, reflecting the potential systemic nature of disease and high burden on patients.

References

Acknowledgments
The authors acknowledge Ravneet Kohli (Novartis, Hyderabad) for editorial and medical writing support. The final responsibility for the content lies with the authors.