To validate CSU/CIU health states defined by categorical UAS7 scores and compare them with the DLQI. Pooled patient-level data from baseline and Week 12 for UAS7 and DLQI from 3 randomized trials, and at baseline and Week 4, 12, and 28 for ASTERIA II trial. Small effect on patient’s life Extremely large effect on patient’s life

The UAS7 score is commonly used to assess the CSU/CIU disease activity (5) and has been well-validated as a measure of disease severity (5). It assesses urticaria activity over a 7-day period, giving UAS7 score (range: 0-42) with a higher score meaning higher disease severity (5). The DLQI data were collected at baseline and Week 4, 12, and 28 for ASTERIA II trial.

The results of the study suggested that five categorical CSU/CIU health states, based on UAS7 score-based health states were defined based on expert input as follows:

Table 1: Definition of health states based on UAS7 score

<table>
<thead>
<tr>
<th>UAS7 SCORES</th>
<th>HEALTH STATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>Urticaria-free</td>
</tr>
<tr>
<td>1-6</td>
<td>Well-controlled urticaria</td>
</tr>
<tr>
<td>7-15</td>
<td>Moderate urticaria</td>
</tr>
<tr>
<td>16-27</td>
<td>Severe urticaria</td>
</tr>
</tbody>
</table>

Well-controlled urticaria vs urticaria-free (2.25 vs 0.41), mild vs well-controlled urticaria (4.90 vs 2.25), moderate vs mild urticaria (8.07 vs 4.90), severe vs moderate urticaria (11.66 vs 8.07). Decrease in urticaria symptoms is associated with improvement in HRQoL.

At baseline pooled mean UAS7 score was 30.90 and pooled mean DLQI score was 13.22. UAS7 score-based health states were defined as expert input as follows (Table 1):

- Well-controlled urticaria vs urticaria-free (2.25 vs 0.41), mild vs well-controlled urticaria (4.90 vs 2.25), moderate vs mild urticaria (8.07 vs 4.90), severe vs moderate urticaria (11.66 vs 8.07).

At week 12, mean DLQI scores between adjacent UAS7 health states were statistically different (all p<0.0001) indicative of a greater impact on patients’ QoL with an increase in disease severity (Figure 2).

CONCLUSIONS

The results of the study suggested that five categorical CSU/CIU health states, based on symptoms and signs of the disease using UAS7 scores, can be further described with the impact on patients’ lives and HRQoL, using the DLQI.

This allows the understanding of the impact of each disease state on a patient’s life-improvements in symptoms, as measured by the UAS7, were reflected in improvements in HRQoL. Urticaria-free health state was correlated with no effect on patients’ lives. Each successively worse UAS7 health state was associated with a significantly greater effect on patients’ lives.

Therefore, it can be concluded that categorizing the UAS7 into five ranges efficiently describes CSU/CIU health states and these health states are distinct, correlate with HRQoL, and could be used in clinical practice.

Further research is warranted to explore the relationship between these five UAS7 categories and other patient-reported outcomes instruments.

REFERENCES

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FUNDING

The ASTERIA I, ASTERIA II, and GLACIAL trials were funded by Genentech, Inc., South San Francisco, CA, and Novartis Pharma AG, Basel, Switzerland.

ACKNOWLEDGMENTS

The authors thank Sanjiv Patel (Novartis) for assistance with poster content and Marcel Raman (Novartis) for designing the poster.