Complete Control of Wheals and Itch in CSU Significantly Correlates with Better Sleep Quality: Analysis from a Worldwide Real-World Database (Aware Study)

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INTRODUCTION AND OBJECTIVES
Chronically spontaneous urticaria (CSU) is characterized by the occurrence of itchy wheals (hives) and/or angioedema for >6 weeks, which occurs without specific external stimuli.1

In the recently published real-world data from a World-wide Antihistamine Refractory chronically urticaria patient Evaluation (AWARE) study, the mean weekly Urticaria Activity Score (UAS7) consistently decreased throughout the 2-year study period from 17.6 at baseline to 5.2 by the end of the study.2

However, CSU remains uncontrolled in many patients despite treatment and has a negative effect on health-related quality of life (HRQoL), including sleep.3

Real-world evidence describing the correlation of CSU symptom control and patients’ quality of sleep is still limited.4

We aimed to investigate the correlation between CSU symptom control and sleep quality.

MATERIALS AND METHODS

Study design
We used data from the 2-year, prospective, non-interventional, global real-world AWARE study (Europe, Central and Latin America, Asia-Pacific, and the Middle East) that examined CSU patients with or without chronic intractable urticaria who were refractory with at least 1 course of H-antihistamine at approved dose.5

Study assessments
• Disease activity was measured by the UAS7, sleep quality by the sleep domain of the Chronic Urticaria Quality of Life questionnaire (CU-QoL),1,6 and HRQoL by the Dermatology Life Quality Index (DLQI).7

• The CU-QoL (recall period 2 weeks) covers 3 questions directly related to sleep and the domain scores range from 0–100.

1 Do you have difficulties in falling asleep?
2 Do you wake up during the night?
3 Do you feel tired during the day because of your bad night’s sleep?

• In the present analysis, CU-QoL sleep domain scores up to 1 year were assessed by comparing with:
  • UAS7 disease activity bands
  • In addition, data were analysed by patients’ baseline angioedema status from baseline up to Year 1 (N=2931)

Baseline demographics and disease characteristics
A total of 2931 patients were included in the analysis. Patients’ baseline demographics and disease characteristics are presented in Table 1.

Table 1. Patient demographics and baseline disease characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>45.4 (15.0)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>2931</td>
<td>2134 (75.1)</td>
</tr>
<tr>
<td>Region</td>
<td>1947 (66.4)</td>
<td></td>
</tr>
<tr>
<td>Europe</td>
<td>562 (17.1)</td>
<td></td>
</tr>
<tr>
<td>LatAm</td>
<td>482 (16.5)</td>
<td></td>
</tr>
<tr>
<td>Patients with CSU diagnosis, n (%)</td>
<td>2132 (72.3)</td>
<td></td>
</tr>
<tr>
<td>Patients with UAS7 in control (&gt;80%), n (%)</td>
<td>1702 (58.0)</td>
<td></td>
</tr>
<tr>
<td>Patients with angioedema, n (%)</td>
<td>1522 (51.9)</td>
<td></td>
</tr>
</tbody>
</table>

PRO scores
• UAS7: 17.1 (13.2)
• UAS7 sleep domain: 40.8 (28.2)
• CU-QoL: 34.3 (21.1)

RESULTS
Baseline demographics and disease characteristics
Regardless of patients’ baseline angioedema status, similar results for the UAS7 sleep domain score were observed (Figure 2) and were consistent with overall data.

A small difference between patients with and without angioedema was observed in patients who had mild, moderate and severe disease activity.

Figure 1. CU-QoL sleep domain scores by UAS7 bands from baseline up to Year 1 (N=2931)

For this analysis, data from patients across all timepoints up to Year 1 were considered.6

UAS7 disease activity bands
• UAS7 disease activity scores were calculated from baseline to Year 1, as previously described.1

Pearson correlation coefficients for CU-QoL sleep domain scores versus patients with other UAS7 disease activity bands were significant (P<0.0001).

For all patient-reported outcomes described above higher scores indicate worse disease activity, worse HRQoL or sleep.4

Statistical analysis
• The average CU-QoL sleep domain score for the different UAS7 disease activity bands and DLQI status were estimated using a repeated measurement model with age, sex, and angioedema as fixed effect and visits within subject up to Year 1 as a repeated factor.

• Within the repeated measurement model, a compound symmetry covariance matrix was chosen between visits. From this, model, least squares means for the different UAS7 bands and DLQI status were estimated.

• The same model was applied to analyse average CU-QoL sleep domain score for the different UAS7 disease activity bands by angioedema status (yes/no) at baseline.

• Pearson correlation coefficients for CU-QoL sleep domain scores with UAS7 disease activity scores were calculated.

• In the present analysis, data from patients across all timepoints up to Year 1 were considered. The cut-off date for the analysis was chosen at Year 1 due to limited data availability.9

The Pearson correlation coefficient between the CU-QoL sleep domain score and DLQI status was a very large effect size (R=0.8).10

CONCLUSIONS
Control of urticaria symptoms leads to improvements in HRQoL and sleep. Independent of patients’ angioedema status at baseline, a positive correlation was observed between symptom control and sleep.

In real life, CSU patients free from hives and itch had a significant improvement in HRQoL and sleep compared to those with higher disease activity (patients with symptoms), indicating that lower urticaria activity significantly correlates with better HRQoL and sleep.

These results highlight the importance of attaining complete symptom control in CSU management.11

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Conflict of Interest
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References