

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

- Chronic spontaneous urticaria (CSU) is characterised by the occurrence of itchy wheals (hives), angioedema or both for >6 weeks, which occurs without specific external stimuli¹
- In the recently published real-world data from **A World-wide Antihistamine-Refractory chronic 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 study²
- However, CSU remains uncontrolled in many patients despite treatment and has a negative effect on health-related quality of life (HRQoL), including sleep³
- Real-world evidence describing the correlation of CSU symptom control and patients' quality of sleep is still limited⁴
- 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, multinational, global real-world AWARE study (Europe, Central and Latin America, Asia-Pacific, and the Middle East) that examined CSU patients with or without chronic inducible urticaria who were refractory with at least 1 course of H₁-antihistamines at approved dose^{5,6}

Study assessments

- Disease activity was measured by the UAS7,⁷ sleep quality by the sleep domain of the Chronic Urticaria Quality of Life questionnaire (CU-Q2oL),⁸ and HRQoL by the Dermatology Life Quality Index (DLQI)⁹
- The CU-Q2oL (recall period 2 weeks) covers 3 questions directly related to sleep and the domain scores range from 0–100
 - Do you have difficulties in falling asleep?
 - Do you wake up during the night?
 - Do you feel tired during the day because of your bad night's sleep?
- In the present analysis, CU-Q2oL 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 across UAS7 bands
 - DLQI status
- For all patient-reported outcomes described above higher scores indicates higher disease activity, worse HRQoL or sleep⁷⁻⁹

Statistical analysis

- The average CU-Q2oL sleep domain score for the different UAS7 disease activity bands and DLQI status were estimated using a repeated measurement model¹⁰ with age, sex, and angioedema as fixed effect and visits within subject up to Year 1 as 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-Q2oL sleep domain score for the different UAS7 disease activity bands by angioedema status (yes/no) at baseline
- Pearson correlation coefficients for CU-Q2oL 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, thereafter

RESULTS

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

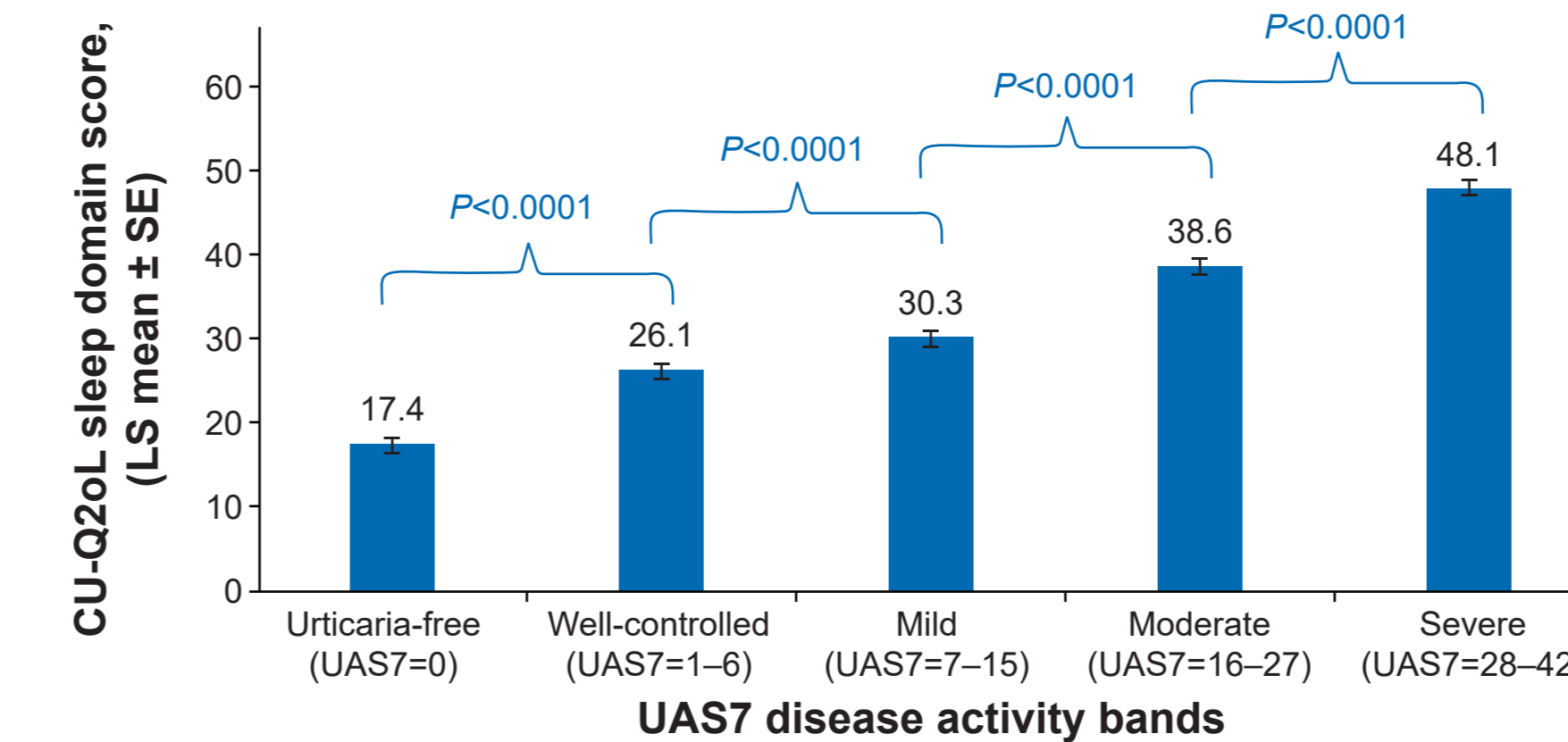
Variable	N=2931
Age, years	45.4 (15.0)
Women, n (%)	2144 (73.1)
Region, n (%)	
Europe	1947 (66.4)
LatAm	502 (17.1)
AMAC	482 (16.4)
Patients with CSU diagnosis only, n (%)	2152 (73.4)
Patients with CSU+CIIndU diagnosis, n (%)	779 (26.6)
Patients with angioedema, n (%)	1522 (51.9)
Time since diagnosis of CU, years	5.1 (7.4)
PRO scores	
UAS7	17.1 (12.4)
CU-Q2oL sleep domain	40.8 (28.2)
DLQI	8.6 (6.9)
CU-Q2oL	34.3 (21.1)

Data are presented as mean (SD), unless stated otherwise. AMAC, Asia-Pacific, Middle East and African Countries; CIIndU, chronic inducible urticaria; CSU, chronic spontaneous urticaria; CU, chronic urticaria; CU-Q2oL, Chronic Urticaria Quality of Life questionnaire; DLQI, Dermatology Life Quality Index; LatAm, Latin America; PROs, patient-reported outcomes; SD, standard deviation; UAS7, weekly Urticaria Activity Score

Correlation between CU-Q2oL sleep domain and UAS7 bands

- The CU-Q2oL sleep domain scores by UAS7 bands are presented in **Figure 1**
 - CU-Q2oL sleep domain score correlates with disease activity
 - Patients achieving UAS7=0 had significantly ($P<0.0001$) lower mean CU-Q2oL sleep domain scores versus patients with other UAS7 disease activity bands, indicating improved quality of sleep, in patients with complete symptom control
- The Pearson correlation coefficient between the CU-Q2oL sleep domain and UAS7 score was 0.45 ($P<0.0001$), indicating a significant positive correlation between symptoms and sleep

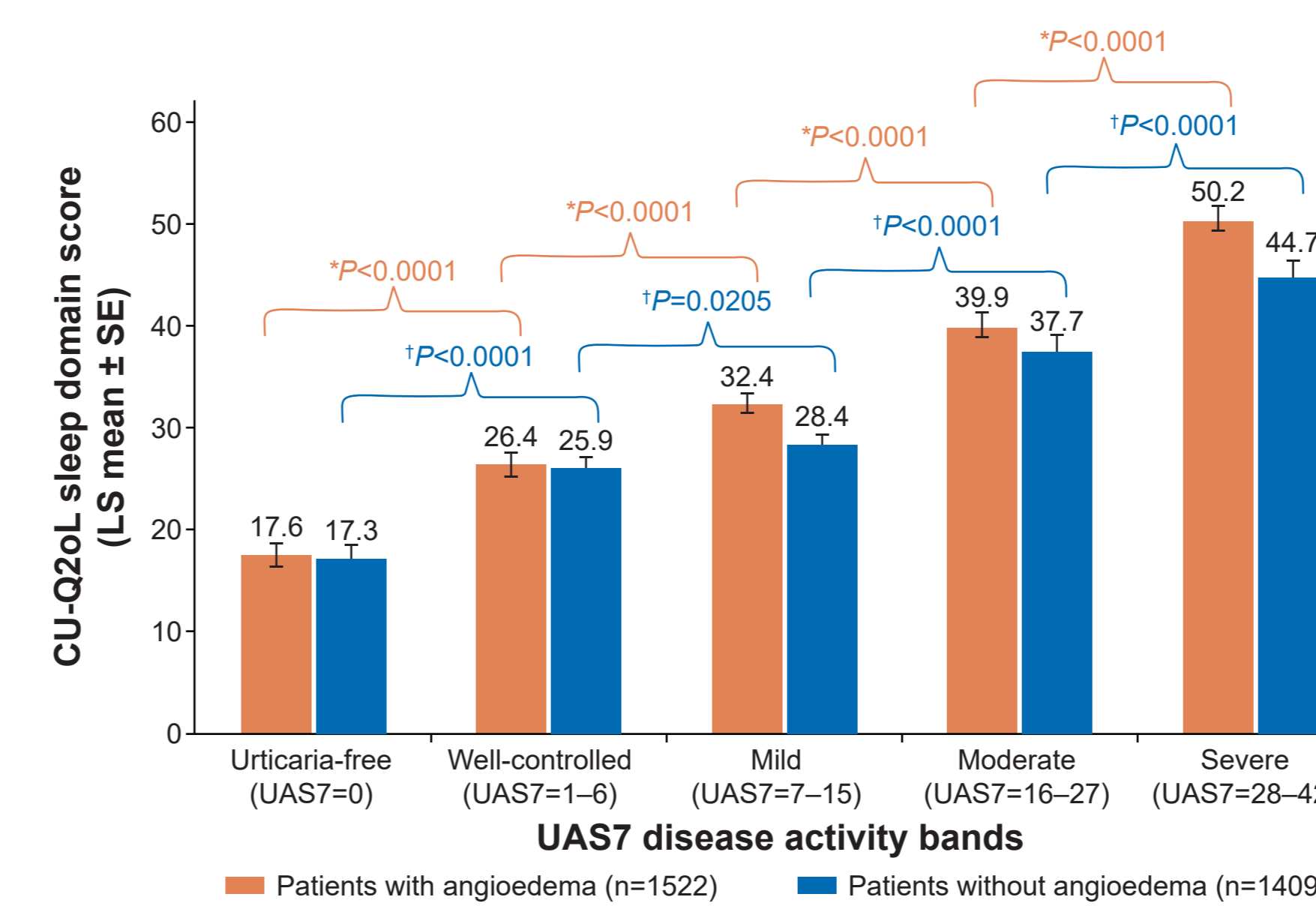
Figure 1. CU-Q2oL sleep domain scores by UAS7 bands from baseline up to Year 1 (N=2931)



For this analysis, data from patients across all timepoints up to Year 1 were considered. CU-Q2oL, Chronic Urticaria Quality-of-Life questionnaire; LS, least squares; SE, standard error; UAS7, weekly Urticaria Activity Score

- Regardless of patients' baseline angioedema status, similar results for the CU-Q2oL 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 2. CU-Q2oL sleep domain scores by UAS7 bands based on patients' angioedema status from baseline up to Year 1 (N=2931)

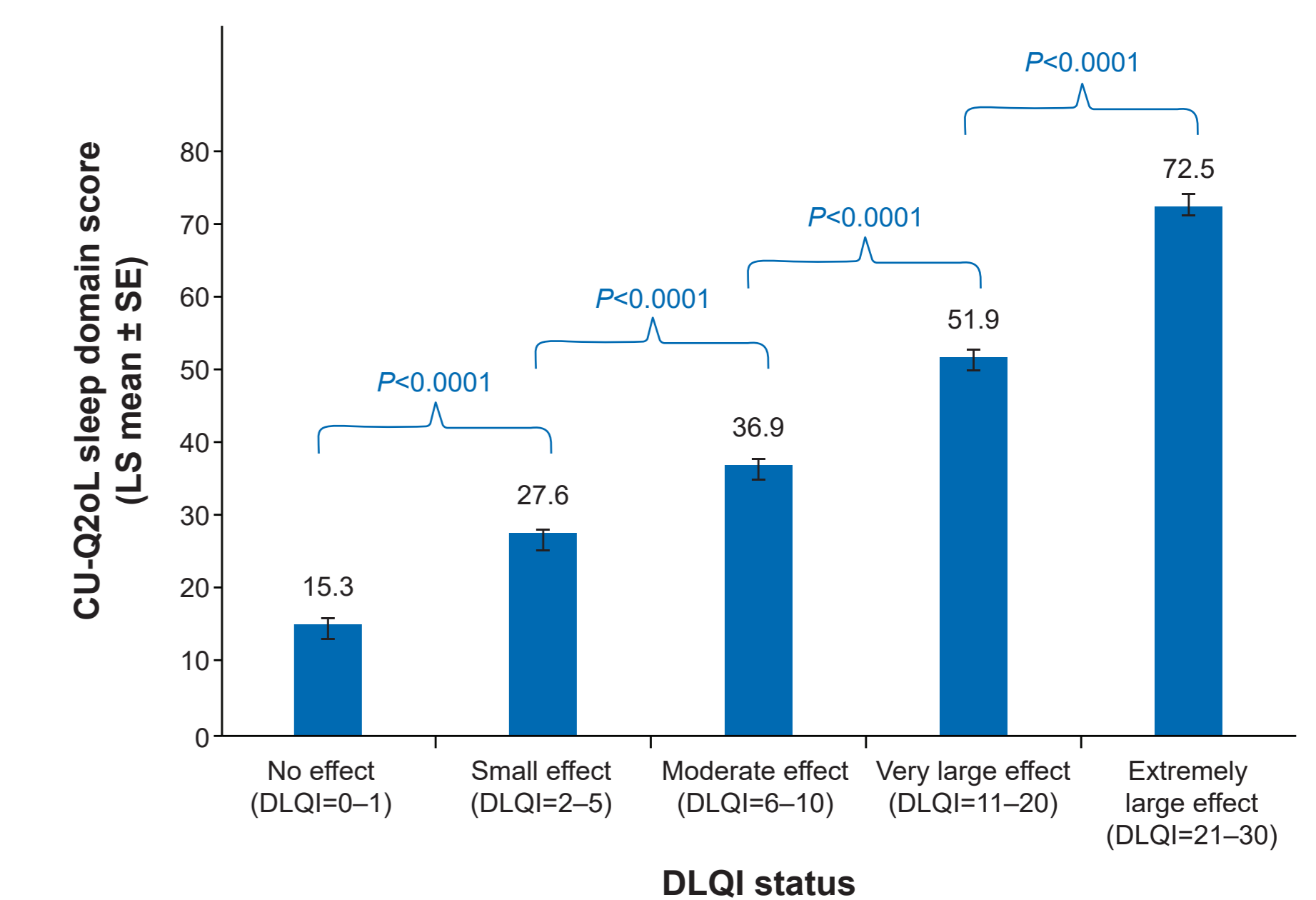


For this analysis, data from patients across all timepoints up to Year 1 were considered. *P values for patients with angioedema; †P values for patients without angioedema. CU-Q2oL, Chronic Urticaria Quality of Life questionnaire; LS, least squares; SE, standard error; UAS7, weekly Urticaria Activity Score

Correlation between CU-Q2oL sleep domain and DLQI status

- The CU-Q2oL sleep domain scores at Year 1 by DLQI status are presented in **Figure 3**
 - CU-Q2oL sleep domain score correlates with DLQI status
 - Patients achieving DLQI=0–1 had significantly ($P<0.0001$) lower mean CU-Q2oL sleep domain scores versus patients with subsequent DLQI status

Figure 3. CU-Q2oL sleep domain scores by DLQI status from baseline up to Year 1 (N=2837*)



For this analysis, data from patients across all timepoints up to Year 1 were considered. *DLQI scores were missing for 94 patients. CU-Q2oL, Chronic Urticaria Quality of Life questionnaire; DLQI, Dermatology Life Quality Index; LS, least squares; SE, standard error

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 management¹¹

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Conflict of interest

Laires PA, Janssens N, Kandra A, Barbier N, Ortmann CE, Smeets S, and Balp MM are employees of Novartis Pharma AG, Basel Switzerland. Weller K was a speaker and/or advisor for and/or has received research funding from CSL Behring, Dr. Pflieger, Moxie, Novartis, Shire/Takeda, and Uriach. **Poster presented at:** European Academy of Dermatology and Venereology Congress, 29 September – 02 October 2021, Vienna, Austria.