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Influence of Disease Activity and Angioedema on EQ-5D-5L Utility Scores in Chronic Spontaneous Urticaria

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Background and Objective

- Chronic spontaneous urticaria (CSU) is a dermatological condition characterised by spontaneous occurrence of itchy hives, angioedema, or both for 6 weeks or longer[1]
- Disease activity is measured using the Urticaria Activity Score (UAS), a validated daily diary encompassing hives and itch severity, allowing for assessments of treatment outcomes. The weekly score (UAS7) is derived by summing daily UAS scores over 7 days (score range from 0 to 42), with higher scores reflecting higher activity/worse urticaria
- Five health-states were validated based on UAS7 score ranges from urticaria free (UAS7 = 0) to severe urticaria activity (UAS7 = 28-42)[2]
- Limited published evidence exists on the relationship between CSU health states (based on UAS7 score ranges) and utility values[3] according to angioedema status
- The objective of this study was to generate EQ-5D utility scores by UAS7 health states, considering the presence of angioedema

Methods

Data

- Patient-level data from 2 randomised, double-blind, placebo-controlled phase 3 clinical trials (PEARL I and PEARL II) were analysed. The studies included patients aged ≥ 12 years, diagnosed with CSU and symptomatic despite H1-antihistamines, with or without angioedema.[4-6] Only results for adults, pooled across treatment arms are presented
- EQ-5D-5L data were collected at randomisation; routinely at Weeks 4, 8, 12, 24, and 52; at every visit in the follow-up period; and on completion on the first report of angioedema (event-driven data) within 3 visit windows (baseline to Week 4, Week 4 to Week 8, and Week 8 to Week 12)
- The United Kingdom value set in line with latest National Institute for Health and Care Excellence guidance [7,8] was used to calculate EQ-5D-5L utility values. Event driven, and routine visit data were included in the analysis

Analytic methods

- Descriptive statistics of utilities by health state and data collection (routine and event driven) were calculated
- A linear mixed model was fit to predict EQ-5D utility values for each of the health states and by angioedema status (at the time of the EQ-5D assessment). A parsimonious model was selected using backwards elimination, and marginal means for utilities are presented by health state and angioedema status
- No differences in utility values between studies were identified. Therefore, combined results are presented for PEARL I and PEARL II
- Analysis was conducted using Stata (Stata Corp; College Station, Texas)

Results

- Baseline information for the patients included in the statistical model (n=1902), mean age 42.7 years, 71.4% female, mean duration of CSU 4.7 years is shown in **Table 1**

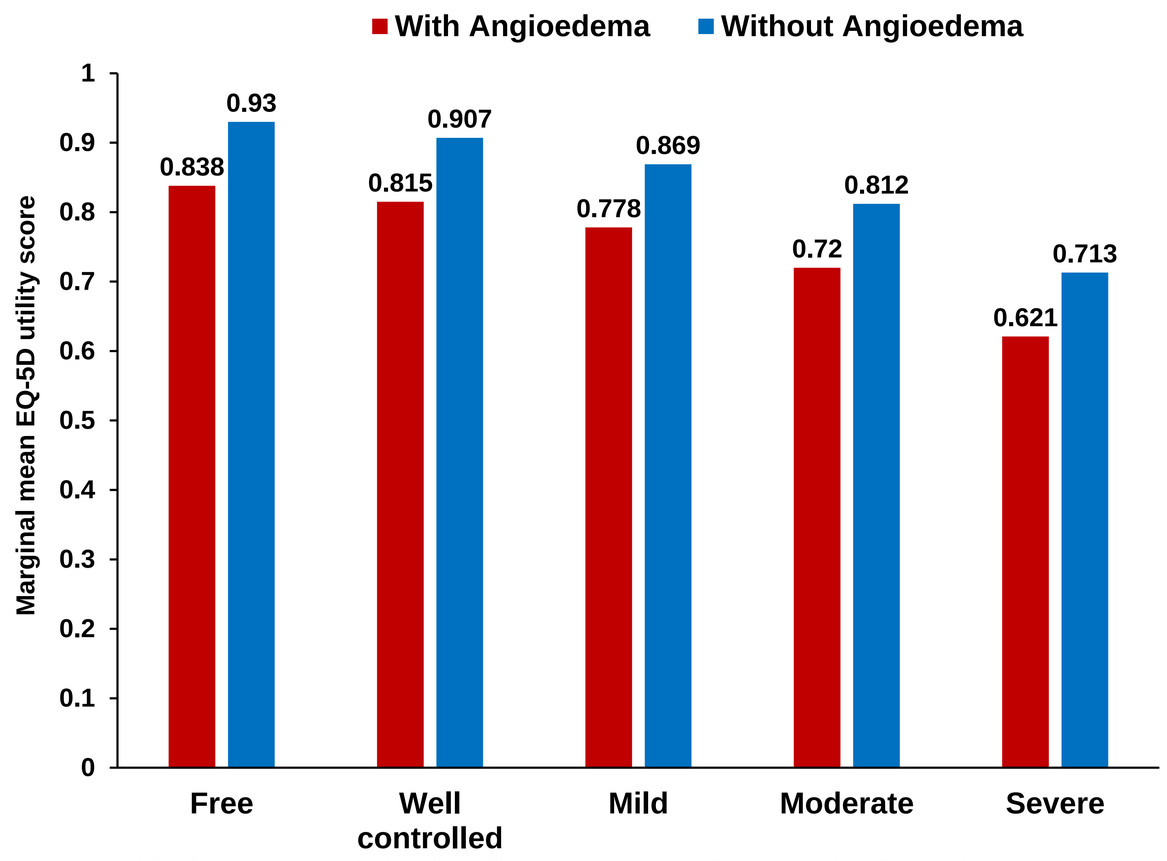
Table 1. Cluster demographics and clinical characteristics

	PEARL I and PEARL II combined n = 1,902
Age, mean (SD) years	42.7 (13.5)
Female, n (%)	1,358 (71.4%)
Duration of CSU	
Mean (SD) years [range]	4.7 (6.8) [0.8-59.4]
UAS7	
Mean (SD) [range]	30.2 (7.2) [16-42]
Weekly itch severity score	
Mean (SD) [range]	13.5 (4.3) [0.5-21]
EQ-5D utility at baseline, mean (SD)	0.704 (0.250)
Moderate urticaria (n = 692, 36.4%)	0.787 (0.189)
Severe urticaria (n = 1210, 63.6%)	0.656 (0.268)

Note: Baseline characteristics are shown for patients with EQ-5D data available at baseline, information available for the covariates included in the mixed model and EQ-5D data available at one or more follow-up timepoints.
ISS7: Weekly itch severity score

- Descriptive statistics showed higher (better) EQ-5D utility values with decreasing severity at all timepoints. This was observed for both those with and without angioedema
- Further, EQ-5D utilities values were statistically significantly lower (worse) for those with angioedema compared with those without angioedema across all health states by a mean of 0.092 (*p*-value < 0.0005)
- For those without angioedema, marginal mean (95% confidence interval [CI]) utilities ranged from 0.713 (0.703-0.723) for severe urticaria to 0.930 (0.922-0.937) for urticaria free, and for those with angioedema, from 0.621 (0.612-0.631) to 0.838 (0.827-0.849) **(Figure 1)**

Figure 1. Marginal mean utility values estimated from the mixed model stratified by angioedema



Note: The model includes covariates for baseline utility, sex, UAS7 at baseline, ISS7 at baseline, angioedema (event driven and on same day for routine visit). The model is based on observations for weeks ≤ 52 for per-protocol adult patients. The dependent variable for the mixed model is utility values at follow-up. Results are presented as marginal means, i.e., the estimated average utility values from the mixed model by health state and angioedema status, given at the mean of the baseline covariates (i.e., for a mean utility at baseline of 0.69 and mean ISS7 of 13.6).

Conclusion

- This analysis shows the negative impact that CSU has on patients' general status, aligned with previously published data,[3] and confirms that the higher the severity, the lower the utility values
- Further, the negative impact of angioedema on health status is captured through enhanced collection of EQ-5D-5L values linked to angioedema occurrence
- Higher disease activity and angioedema were both associated with lower (worse) utility scores, with angioedema having an additional negative impact on lowering utility scores across all health states
- EQ-5D utility scores allow the comparison of health-related quality of life and patient preferences across diseases by calculating quality-adjusted life-years, which are used in economic models. These are essential components of health technology assessments, which contribute to support decision-making for healthcare resource allocation

References

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