The purpose of this analysis was to examine changes in a symptom-based instrument, the UAS7, with increases in both UAS7 and DLQI can be seen in the follow-up period after week 24 (ASTERIA I and II). This indicates the extent to which change in a patient’s DLQI score is associated with change in their symptoms, as measured by the UAS7, a daily diary which asks patients to report the most recent urticaria activity level. The instrument has a one-week recall period.

HUMANISTIC BURDEN OF CSU/CIU

- CSU/CIU symptoms have a large effect on different domains of health-related quality of life (HRQoL) with a one-week recall period.
- Different categories of patient-reported outcomes (PRO) instruments (generic, dermatological or disease-specific) are used to assess the CIU/CSU disease burden.
- An important question to answer is whether our understanding of the humanistic burden of CSU/CIU is comparable regardless of the type of measure used. In particular, for instruments that are either dermatological-specific versus those that are CSU/CIU-specific, will assessments yield a similar understanding of patients’ disease severity, impact on HRQoL and their response to treatment.
- Given that these two PPOs are commonly used but potentially not with the same patients, and each uses a different recall period, it is important to understand what to what extent they provide a similar understanding of patients’ disease severity, impact on HRQoL and their response to treatment.
- If researchers and clinicians can have comparable understanding of patient’s condition and response to treatment, then the PROs can be used as a routine assessment tool in clinical practice.

METHODS

Data
- Data come from three pivotal, phase III clinical trials (ASTERIA I, ASTERIA II, GLACIAL) with the effects of omalizumab for patients with refractory CSU/CIU (Maurer et al., 2013).
- Treatment was administered once every 4 weeks for 24 weeks in the 40-week trials (ASTERIA I and GLACIAL), and until week 12 in the 28-week trial (ASTERIA II).
- All trials were a 16-week follow-up period with no active treatment.
- DLQI data were collected at baseline and weeks 4, 12, 24, and 40 in two trials (ASTERIA I and GLACIAL), and baseline and weeks 4, 12, and 28 (ASTERIA II).
- UAS7 scores were reported at baseline and every four weeks. UAS7 data from the same weeks as the DLQI were used for these analyses.

Analytic Methods
- Data from all studies were analysed using a growth curve analysis known as latent growth modeling to evaluate change across all assessment points for each patient, irrespective of treatment, and compare change in one variable with change in another.
- Unlike analyses that compare mean changes between groups of patients, latent growth models (LGMs) can be used to assess whether change in one variable is associated with change in another variable. The LGM approach is widely used in the statistical literature to assess HRQoL in patients with dermatological diseases and it was validated for use in patients with CSU/CIU (Lennox et al., 2004).
- The instrument has a one-week recall period.

RESULTS

- Across all three trials, the correlation between slopes of change in DLQI and UAS7 scores was very high (r = 0.98 - 0.99), indicating that the trajectory of change in a patient’s score on the DLQI very closely matches that of the UAS7 score.
- This is, if a patient’s score on the DLQI changed 1 standardized point, their score on the UAS7 changed nearly the same standardized amount.
- Increases in both UAS7 and DLQI can be seen in the follow-up period after week 24 (ASTERIA I and II), after treatment ended. Figure 1 presents these results for ASTERIA I; Figure 2 presents these results for ASTERIA II; Figure 3 presents these results for GLACIAL.

CONCLUSIONS

- The results of these latent growth models give clear and compelling evidence that the UAS7, a daily diary summed over seven days, and the DLQI, a brief, single assessment of HRQoL, referring to the previous week, showed nearly identical responses:
  - Improvements in symptoms, as measured by the UAS7, are reflected in improvements in HRQoL, as measured by the DLQI.
  - Changes in one PRO can inform a clinician about the extent of changes in the other PRO, so using either PRO can yield very good insights into changes in the patient’s condition or their response to treatment.
- These results suggest that collecting DLQI information in-clinic from patients with CSU/CIU:
  - Can provide an excellent indication about symptoms assessed with UAS7 score,
  - Less likely to suffer from potential data loss because of inconsistent completion of the daily diary, and
  - More efficient for routine clinical practice in assessing CSU/CIU patients.

- These analyses do not control for disease severity or duration of disease. Future analyses will explore
- The overall of this study support the use of the DLQI in routine clinical practice to assess and monitor CSU/CIU patients.

REFERENCES