A positive correlation between changes in urticaria symptoms (UAS7) and dermatologic-related quality of life (DLQI) and urticaria-specific quality of life (CU-Q_2oL): Is it informative about the response to treatment in CSU/CIU patients?

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ABSTRACT

Introduction and objectives: To assess whether three patient-reported outcome (PRO) instruments are equally informative about response to treatment for chronic spontaneous/idiopathic urticaria (CSU/CIU). PRO instruments compared included: Weekly Urticaria Activity Score (UAS7; measuring daily pruritus scores and number of hives summed over 7 days for a weekly score); Dermatology Life Quality Index (DLQI; 10-item PRO with one-week recall assessing the impact of skin disease); and Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL; 23-item PRO with 2-week recall measuring urticaria-specific health-related quality of life [HRQoL] through rating of symptoms and their impact on aspects of life).

Materials and methods: Data were obtained from three Phase III clinical trials investigating the effects of omalizumab for patients with refractory CSU/CIU. PRO data were collected at baseline and Weeks 4, 12, 24 and 40 (ASTERIA I and GLACIAL), and baseline and Weeks 4, 12 and 28 (ASTERIA II). Data were analyzed using latent growth models (LGMs), irrespective of treatment. For each trial, correlations between changes in UAS7 and the other PROs were examined to investigate how closely dermatologic-related and urticaria-specific QoL changes mirrored symptom changes.

Results: In all three trials, mean baseline UAS7 score was 30 out of 42, corresponding to a large effect on patient's dermatologic-related HRQoL (DLQI mean score = 12 out of 30) and above-median disease-specific HRQoL (CU-Q_2oL median score = 43 out of 100). Over the course of each trial, changes in symptom and HRQoL scores were evident (4–15 scale points, depending on PRO). LGMs found changes in symptoms and HRQoL were highly correlated: 0.94, 0.88 and 0.92 (for ASTERIA I, ASTERIA II and GLACIAL, respectively) between DLQI and UAS7; 0.94, 0.93 and 0.90 (for each trial, respectively) between CU-Q_2oL and UAS7.

Conclusions: Collecting HRQoL information in-clinic (DLQI and CU-Q_2oL) can provide an excellent indication of UAS7 symptom score evolution. Results suggest that clinicians have a choice of instrument for assessing patient response to treatment.

BACKGROUND

- Chronic spontaneous/idiopathic urticaria (CSU/CIU) is defined by the latest European Academy of Allergy and Clinical Immunology (EAACI)/Global Allergy and Asthma European Network (GA^{2}LEN)/European Dermatology Forum (EDF)/World Allergy Organization (WAO) guidelines as the occurrence of wheals (hives), angioedema or both for 6 weeks or longer due to known or unknown causes.[1,2]
- Omalizumab, a humanized anti-IgE monoclonal antibody is the first and only therapy approved by the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) for the treatment of CSU/CIU in adult and adolescent (≥12 years) patients refractory to H_1-antihistamines.[3]
- CSU/CIU adversely impacts patients' HRQoL.[4] The progression of disease and its burden can be assessed with PRO measures for symptoms and HRQoL.

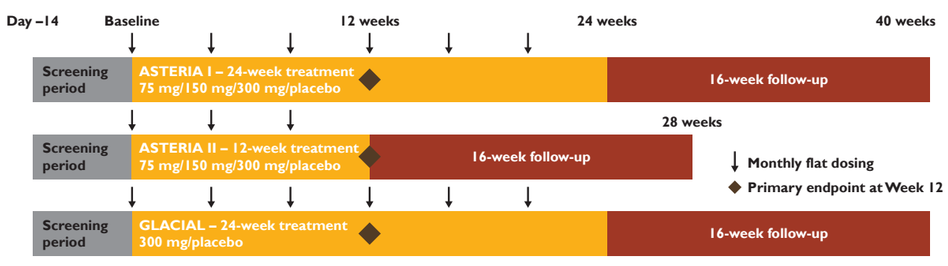
OBJECTIVE

- To assess whether three PRO measures (UAS7, DLQI and CU-Q_2oL) are equally informative about response to treatment of patients with CSU/CIU in ASTERIA I, ASTERIA II and GLACIAL Phase III trials (investigating the efficacy of omalizumab).

METHODS

- PRO data used for the analysis come from baseline and Weeks 4, 12, 24 and 40 in ASTERIA I and GLACIAL, and at baseline and Weeks 4, 12 and 28 in ASTERIA II (**Figure 1**).
- UAS7 – daily diary measuring urticaria signs (wheals) and symptoms (itching); weekly scores range from 0–42, with higher scores meaning more severe urticaria.
- DLQI – a 10-item PRO, measures impact of skin disease on patients; scores range from 0–30, with higher scores reflecting worse dermatologic QoL.
- CU-Q_2oL – a 23-item PRO, measures urticaria-specific QoL; scores range from 0–100, with higher scores indicating worse QoL.
- Data were analyzed using latent growth modeling[5] to evaluate changes across all assessment points for each patient (aged 12–75 years), irrespective of treatment, allowing direct comparison of change in one variable with change in another.

Figure 1. Design of Phase III studies with omalizumab

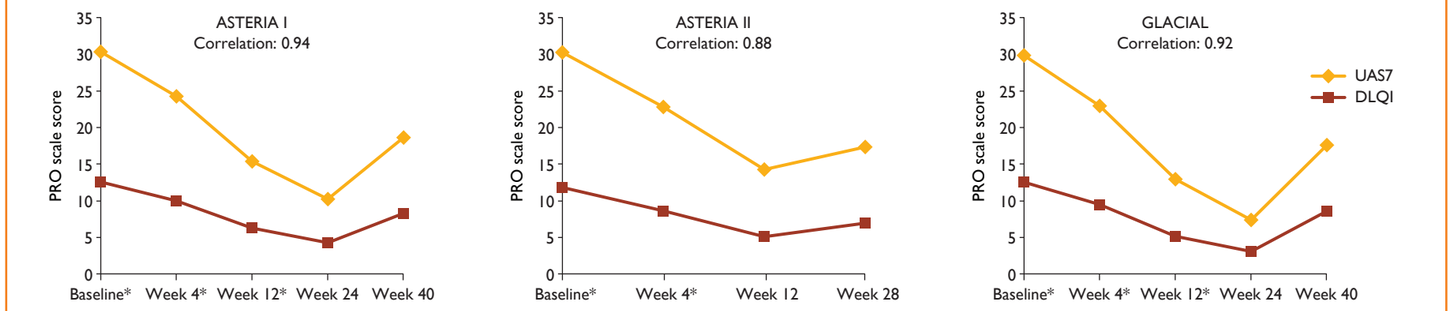


RESULTS

A near perfect association between UAS7 and DLQI

- In all three trials, the correlations between the UAS7 and DLQI ranged between 0.88 and 0.94 (**Figure 2**).

Figure 2. Trajectories of change in UAS7 and DLQI

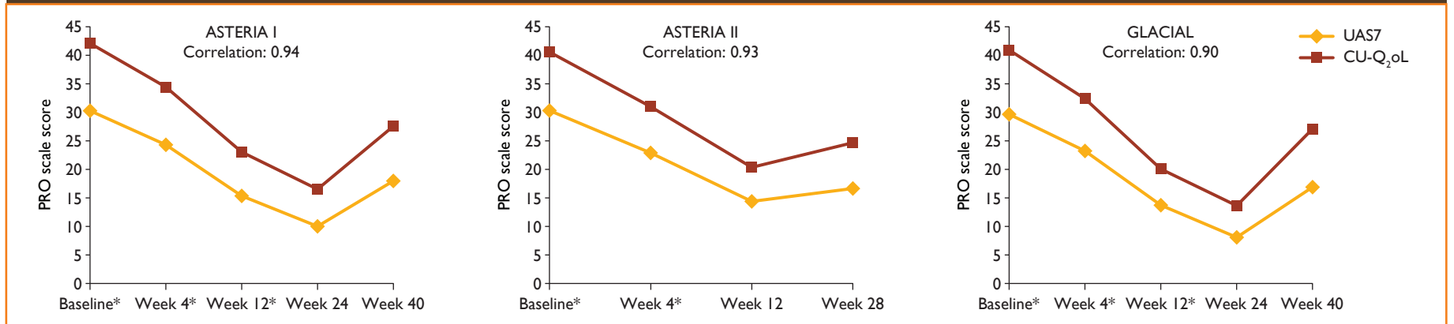


*Treatment administered; DLQI, Dermatology Life Quality Index; PRO, patient-reported outcome; UAS7, Weekly Urticaria Activity Score

A near perfect association between UAS7 and CU-Q_2oL

- In all three trials, the correlations between the UAS7 and CU-Q_2oL ranged between 0.90 and 0.94 (**Figure 3**).

Figure 3. Trajectories of change in UAS7 and CU-Q_2oL



*Treatment administered; CU-Q_2oL, Chronic Urticaria Quality of Life Questionnaire; PRO, patient-reported outcome; UAS7, Weekly Urticaria Activity Score

CONCLUSIONS

- The results provide evidence that any of the three PRO measures are suitable to evaluate a patient's severity of urticaria and response to treatment.
- Regardless of the measure used, clinicians will have comparable information about the evolution of a patient's symptoms and signs, and the changes in their HRQoL.
- Improvements in symptoms, as measured by the UAS7, are reflected in improvements in HRQoL, as measured by the DLQI and the CU-Q_2oL.
- Any of the three PRO measures could be implemented in a clinical setting to allow assessment of patient severity and response to treatment
  - DLQI and CU-Q_2oL may be easier to use in-clinic than a daily diary as they require only one administration.

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Acknowledgments

All authors participated in the development of the poster and approved the final poster for presentation. The authors thank Sucheta Ghosh (Novartis) for medical writing support and for collation and incorporation of comments from all authors. Editorial assistance was provided by Katy Cooke of Fishawack Communications, Oxford, UK and this service was funded by Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA.

This presentation was previously given orally at the 23rd European Academy of Dermatology and Venereology Congress, October 8–12, 2014, Amsterdam, The Netherlands and as a poster at the European Academy of Allergy and Clinical Immunology Congress, June 7–11, 2014, Copenhagen, Denmark; the Fall Clinical Dermatology Conference, October 16–19, 2014, Las Vegas, NV, USA; and the Winter Clinical Dermatology Conference, January 16–21, 2015, Kaanapali, HI, USA.

Funding

This study was funded by Novartis Pharma AG, Basel, Switzerland and Genentech, Inc., South San Francisco, CA, USA.

Presented at the 11th Annual Maui Derm for Dermatologists, January 26–30, 2015, Maui, HI, USA.