Correlation between changes in urticaria symptoms and sleep experience in patients with chronic spontaneous/idiopathic urticaria (CSU/CIU): Results from two randomized, double-blind, placebo-controlled, Phase III trials of omalizumab

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ABSTRACT

Introduction and objectives: Patients with chronic spontaneous/idiopathic urticaria (CSU/CIU) report negative effects on sleep (e.g., interference with sleep and sleep disruption), which have consequences such as tiredness, daytime somnolence and lack of energy. There is no information on the association between improvement in urticaria signs and symptoms and improvements in sleep or reductions in daytime somnolence, the current study explores the correlations between the trajectories of change shown in the Weekly Urticaria Activity Score (UAS7) and Medical Outcomes Study (MOS) Sleep Scale (daytime somnolence and sleep disturbance subscales) across 40 weeks.

Material and methods: Data were obtained from two Phase III trials (ASTERIA I and GLACIAL), investigating the efficacy of omalizumab in patients with refractory CSU/CIU. Patient-reported outcome (PRO) data were collected at baseline and Weeks 4, 12, 24, and 40. Urticaria signs (wheals) and symptoms (itching) were measured using the UAS7. Effects on sleep were measured using two domains of the MOS Sleep Scale (a 12-item PRO comprising six dimensional measures that measure key aspects of daytime somnolence and sleep disturbance). Data were analyzed using latent growth modeling (LGM) wherein individual slopes of change and intercepts for UAS7 and MOS daytime somnolence and sleep disturbance were correlated for each patient.

Results: In both trials, mean baseline UAS7 score was 30 out of 42, mean MOS daytime somnolence score was 40 out of 100. These scores decreased to 10 for UAS7, 25 for MOS sleep disturbance at Week 24. Changes in UAS7 and MOS daytime somnolence were moderately to strongly correlated in ASTERIA I and GLACIAL (Figure 2).

METHODS

PRO data used for the analysis come from baseline and Weeks 4, 12, 24, and 40 in ASTERIA I and GLACIAL (Figure 1). UAS7 – daily diary measuring urticaria signs (wheals) and symptoms (itching). Both urticaria signs and symptoms are rated 0 to 42, with higher scores meaning more severe urticaria.

MOS Sleep Scale – a 12-item PRO comprising of six dimensions about key aspects of sleep. The current study focused on two domains of effects on sleep: daytime somnolence and sleep disturbance; scores range from 0 to 100, with higher scores meaning greater somnolence or sleep disturbance.

Data were analyzed using LGM wherein individual slopes of change and intercepts for UAS7 and MOS daytime somnolence and sleep disturbance were correlated for each patient (aged 12–75 years).

Conclusions: These results indicate strong empirical evidence that sleep is negatively affected by urticaria signs and symptoms and that improving these will reduce daytime somnolence and sleep disturbance. The results indicate strong empirical evidence that sleep is negatively affected by urticaria signs and symptoms and that improving these will reduce daytime somnolence and sleep disturbance. The results indicate strong empirical evidence that sleep is negatively affected by urticaria signs and symptoms and that improving these will reduce daytime somnolence and sleep disturbance. The results indicate strong empirical evidence that sleep is negatively affected by urticaria signs and symptoms and that improving these will reduce daytime somnolence and sleep disturbance. The results indicate strong empirical evidence that sleep is negatively affected by urticaria signs and symptoms and that improving these will reduce daytime somnolence and sleep disturbance.

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