0468 | Omalizumab retreatment of patients with chronic idiopathic urticaria / chronic spontaneous urticaria following return of symptoms: primary results of the optima study

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Introduction: Since approval of Omalizumab for CSU/CIU (chronic spontaneous urticaria/ chronic idiopathic urticaria) a number of data gaps regarding management of patients with anti-IgE treatment surfaced. The OPTIMA study (NCT02161562) was conducted to answer some key questions on how to optimize omalizumab treatment of patients with CIU/CSU. The primary objective and topic of this abstract is the efficacy of omalizumab retreatment.

Objectives: OPTIMA is a Phase 3b, international, multicenter, randomized, open-label, non-comparator study. Patients with CIU/CSU who were symptomatic despite H_1-antagonists were randomized 4:3 to omalizumab 150 or 300 mg for 24 weeks (1st dosing period). Based on UAS7 scores, patients entered one of the following phases: treatment withdrawal (if UAS7≤6), step-up to 300 mg (if 150 mg initially and UAS7>6 at week ≥8-24), or continued treatment for 12 more weeks (if 300 mg initially and UAS7>6 at week 24). Patients in the withdrawal group who relapsed (UAS7≥16) were retreated with their initial dose. The primary endpoint of the study was the proportion of patients clinically well controlled (UAS7≤6) upon retreatment in those who were initially well-controlled but relapsed after withdrawal.

Results: A total of 314 patients (73% female, 79% white, mean age 46 years, mean baseline UAS7 score 29.8) were randomized to either 150 mg (n=178) or 300 mg (n=136) omalizumab. The overall percentage of well-controlled patients after 24 weeks of treatment with omalizumab 150 mg or 300 mg was 15.2% and 64.7%, respectively. After treatment withdrawal, 44% of patients on 150 mg and 50% on 300 mg relapsed (USA7≥16) within 8 weeks. Mean time to relapse was 4.8 (150 mg) and 4.7 (300 mg) weeks. Upon retreatment, the majority of patients achieved UAS7≤6 (150 mg: 83.3% [95% CI, 62.2%−100%]; 300 mg: 89.2% [95% CI, 79.2%−99.2%]). Patients who responded to retreatment had a similar mean time to response between the 1st dosing period (3.5 weeks) and 2nd dosing period (3.1 weeks). Of all patients who were retreated (n=56), symptom control (UAS7 ≤ 6) after two doses was achieved in 80% (1st period) and 85% (2nd period) of patients; complete response (UAS7=0) occurred in 63% (1st period) and 56% (2nd period) of these patients. Omalizumab was well-tolerated during both dosing periods.

Conclusions: Omalizumab retreatment is safe and effective in patients with CIU/CSU who respond to initial treatment and relapse after withdrawal, with most patients regaining symptom control after a 2nd course of omalizumab.

0469 | Omalizumab administration in non-atopic chronic spontaneous urticaria patients prevents respiratory illnesses

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Introduction: Omalizumab administration in asthmatic individuals has been shown to reduce viral induced exacerbation. We sought to determine if omalizumab administration in refractory to H1 antihistamines chronic urticaria (CU) patients prevents respiratory illnesses, independently of their atopic status.

Objectives: In this longitudinal cohort study, all respiratory illnesses from all CU patients under regular omalizumab administration (300 mg Q4-weeks) from at least November 2015 until October 2016 were prospectively recorded. Patients with history of known respiratory conditions, like asthma, allergic rhinitis, chronic rhinitis/rhinosinusitis, or any type of immunodeficiency were excluded. All patients were followed up every 4 weeks at each omalizumab administration. The closest in age, healthy household member (spouse, partner, relative, roommate etc), when available, was used as a control individual.

Results: Thirty three patients (21 women) 45.1±16.6 years old and 30 age-matched control subjects (9 women, 46.6±9.6 years old) were enrolled. The CU-patients reported significantly less respiratory illnesses as compared with the control subjects (median: 0 vs 1, inter-quartile range 0-1 vs 1-1, min-max: 0-3 vs 0-4, respectively, *P*-value=.0095). The vaccination rate for influenza viruses was similar between patients and controls.

Conclusions: Omalizumab administration prevents common respiratory illnesses in CU patients even in the absence of any respiratory disorder or allergic sensitization. This finding suggests indirectly a role of IgE in the clinical expression of a respiratory infection independently of the patient's atopic status and implies the potential prophylactic role anti-IgE may have in this direction.