URTICARIA, ANGIOEDEMA

ITALIAN REAL LIFE STUDY ON OMALIZUMAB IN CHRONIC SPONTANEOUS URTICARIA: CLINICAL EFFICACY, SAFETY, PREDICTORS OF TREATMENT OUTCOME AND TIME TO RESPONSE.

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Introduction: Chronic spontaneous urticaria (CSU) is characterized by recurrent episodes of spontaneous wheals and/or angioedema lasting for more than six weeks. CSU treatment is challenging as the underlying cause of the disease is difficult to identify. Second-generation non-sedating antihistamines remain mainstay of treatment in these patients. Omalizumab, an anti-IgE antibody, may be administered in CSU patients refractory to antihistamine therapy.

Objectives: This study assessed omalizumab efficacy, safety, predictors of treatment outcome and time lag to response by serum auto-reactivity test (ASST) in CSU patients refractory to second-generation antihistamines.

Methods: This observational study involved 23 Italian allergy- clinical immunology secondary care centers. The study comprised a 4-week pre-treatment period, a 24-week treatment period with omalizumab (300mg/month), and a 16-week follow-up period. Primary efficacy endpoints were mean and median change in 7-day urticaria activity score (UAS7), weekly itch severity score (ISS) and hive score from baseline to 4, 12 and 24 week values. Secondary endpoints included the proportion of patients ("responders") with well-controlled urticaria (UAS7 ≤6) and complete treatment response (UAS7=0). Safety was also assessed.

Results: Omalizumab significantly and consistently reduced the mean UAS7, ISS and hive score from baseline to weeks 4, 12, and 24, with a decreasing trend over time. At the end of treatment period (week 24), 84.2% of patients had a UAS7 score of ≤6 and 66.7% a UAS7 of 0. Higher pre-treatment IgE levels were less likely to be associated with poor treatment response (i.e. UAS7>6). Patients with a positive ASST were more likely to be "slow responders" to omalizumab treatment (i.e. response beyond 8 days since omalizumab administration) than ASST-negative patients (P< 0.001). No treatment-related adverse events were recorded.

Conclusions: Omalizumab is effective and well tolerated for CSU in real life. Monitoring baseline patient characteristics may help to predict treatment outcome and time lag to response.