

Long-term “real-life” safety of omalizumab in patients with severe uncontrolled asthma: A nine-year study

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Background: Randomized Controlled Trials showed that omalizumab exhibited a good safety and tolerability profile in patients with moderate-to-severe asthma. However, safety data of long-term treatment with omalizumab are scarce. Our aim was to assess the safety of omalizumab in patients under long-term treatment in a real-life setting.

Methods: Difficult-to-control asthmatic patients treated with omalizumab up to 9 years were retrospectively evaluated. Mild to severe adverse events and any reasons for discontinuation were recorded.

Results: Ninety-one patients (26.4% males, mean age 49.9 ± 14.9 years) were included: mean treatment length, 3.8 ± 2.6 years; mean individual monthly dose, 514.5 ± 345.7 mg (range, 150-1200 mg). A total of 10,472 single injections were given cumulatively to the 91 patients (115 single injections per patients, on average, over a treatment period up to 9 years). Fifty-nine patients (64.8%) were treated for a period of time from 3 to 9 years, 14 of whom from 6 to 9 years. A high proportion of patients who discontinued treatment dropped out within the first year (18, 39.1%), mainly for reasons unrelated to treatment. Six patients (6.6%) discontinued omalizumab for treatment-related adverse events: arthralgia/myalgia (3 patients); urticaria, angioedema (1 patients); metrorrhagia (1 patient); relapsing herpes labialis (1 patient). Four other patients complained of mild adverse events (rhinitis/conjunctivitis, injection site reaction, fatigue, thrombosis) but continued the treatment. Anaphylaxis was not reported.

Conclusions: Long-term treatment with omalizumab appears remarkably safe and well tolerated in real-life setting. Prolonged omalizumab treatment for many consecutive years did not increase the risk of side effects, particularly anaphylaxis.