Title: One year following a real life experience of omalizumab for moderate to severe persistent allergic asthma in Malta

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Body: Background: The efficacy and safety of omalizumab as add on therapy in moderate-severe persistent allergic IgE-mediated asthma has been widely demonstrated in several randomised controlled trials (Schumann et al, 2012). Aim: The aim of this study was to evaluate the clinical effectiveness and tolerability of omalizumab following one year of treatment in such patients in Malta. Method: Adult patients who were started on omalizumab for moderate-severe persistent (IgE-mediated) asthma were included in this on-going prospective study. Patients' clinical response was evaluated using the Asthma Control Test (ACT) and physician’s assessment. Treatment effectiveness was evaluated at 16 and 52 weeks. Outcomes including unscheduled asthma-related hospitalizations and GP visits, exacerbations and oral corticosteroid (OCS) required one year pre- and post-treatment initiation were compared. Results: Our cohort included 17 patients (65% males, mean age 52±12) Omalizumab was stopped at 16 weeks in two patients in view of clinical ineffectiveness, in one patient prior to 16 weeks in another thereafter due to myalgias. Baseline FEV1 improved by 11% (p=0.25) and ACT score by 47% (p<0.001) (n=13). Hospitalizations were reduced by 25% (p=0.75), exacerbations not requiring hospitalization by 41% (p=0.03), unscheduled health care visits by 36% (p=0.27), and OCS courses by 63% (p=0.002) (n=13). The most common side effect reported was myalgias. There were no reports of anaphylaxis. Conclusion: Omalizumab therapy showed a response rate of 82% at 16 weeks and 76% at 12 months. Our local experience shows that omalizumab is a clinically effective and well tolerated add-on treatment option.