Conclusion: The number of asthma exacerbations among asthma patients decreased significantly post-omalizumab initiation compared to pre-omalizumab initiation in this real-world clinical setting.

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A REAL-WORLD ASSESSMENT OF OMALIZUMAB TREATMENT PATTERNS IN ASTHMA PATIENTS NEWLY TREATED WITH OMALIZUMAB

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Introduction: The study aimed to assess omalizumab treatment patterns in asthma patients in a real-world setting.

Methods: This retrospective observational cohort study utilized US claims data from the HealthCore Integrated Research Database between 01/01/2006 and 04/30/2016. The study population consisted of asthma patients newly treated with omalizumab (defined as ≥4 omalizumab claims within the first 6 months post-index period; index date=first omalizumab claim date), aged ≥6 years, and with ≥12-month pre- and post-index healthcare insurance enrollment. Descriptive statistics and the Kaplan-Meier method were used to examine omalizumab treatment patterns.

Results: The study identified 1,564 patients with a mean (SD) age of 44.9 (±15.67) years and 61.8% female. The mean (SD) post-index follow-up length was 1,181.4 (±748.56) days. Among all patients, 32.3% and 59.5% discontinued omalizumab within the 12-month post-index and the entire post-index period, respectively. The Kaplan-Meier analysis showed that the median (95% CI) omalizumab persistence was 690.0 (632.0, 757.0) days; the probability of persistence (95% CI) was 0.676 (0.653, 0.699) and 0.481 (0.454, 0.508) for the 12-, and 24-month post-index periods, respectively. Among the 930 patients who discontinued omalizumab, 38.0% restarted omalizumab. The mean (95% CI) time from discontinuation to first restart was 1,183.4 (1,124.9, 1,241.8) days. The probability of restart (95% CI) was 0.271 (0.243, 0.301), 0.356 (0.325, 0.389), and 0.402 (0.369, 0.438) within the 6, 12, and 24 months since first discontinuation, respectively.

Conclusion: Over one-half of asthma patients persisted on omalizumab beyond 12 months and more than one-third of those who discontinued omalizumab restarted omalizumab therapy.

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EFFICACY OF INHALED TIOTROPIUM FOR ASTHMATICS UNCONTROLLED USING INHALED CORTICOSTEROID PLUS A LONG-ACTING BETA2-AGONIST

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Introduction: For moderate persistent asthmatics that remain symptomatic on long-term anti-inflammatory inhaled corticosteroid (ICS) plus a long-acting beta2-agonist bronchodilator (LABA), the addition of inhaled tiotropium a long-acting anticholinergic agent, may provide additional efficacy in sub optimally controlled moderate persistent asthmatics.

Methods: In this open labeled 12-week trial, 40 patients with symptomatic asthma currently using ICS/LABA were randomized to receive the addition of 2 inhalations of tiotropium 1.25mcg (2.5mcg) once daily to their daily use of ICS/LABA or continue with only ICS/LABA therapy. The endpoints of the trial included: FEV1, PEF am, PEF pm, albuterol use, exacerbations rates, and a Quality of life (QOL) questionnaire. Written consent was obtained.

Results: Mean efficacy measurements at 12 weeks revealed significant improvement in all parameters examined in the treatment group as add-on Tiotropium to ICS/LABA compared to the group without the add-on therapy ICS/LABA alone. Analysis between both treatment groups revealed significant differences in all parameters monitored (FEV1, PEF am, PEF pm, albuterol use, exacerbations rates, nocturnal awakenings, limited activity, chest tightness, cough, wheezing, shortness of breath) in the group with the add-on Tiotropium to the maintenance therapy ICS/LABA.The addition of once-daily inhaled Tiotropium to the maintenance therapy is more effective than the maintenance therapy ICS plus LABA only. When tiotropium is added to ICS plus LABA all endpoints significantly improved.

Conclusion: The addition of inhaled Tiotropium to ICS/LABA has additive ,beneficial protective effects of bronchodilator, anti-inflammatory and anti-remodeling, and is a safer therapy given the long-term safety issues with high doses of inhaled corticosteroids.

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MEPOLIZUMAB INDUCTION THERAPY FOR EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

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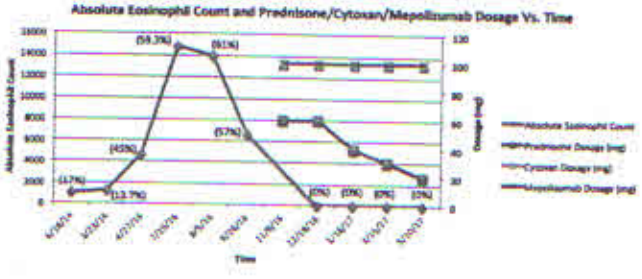
Rationale: Mepolizumab has been used as an adjuvant therapy for refractory EGPA. We report biopsy confirmed EGPA using conventional doses of Mepolizumab for induction treatment.

Background: Previous studies have reported high doses of Mepolizumab in EGPA refractory to immunosuppresants enabling lowering of glucocorticoid doses.

Case Presentation: A 61-year-old white male ex-smoker presented 2/14 with multi-year history of poorly-controlled asthma, recurrent rhinosinusistis S/P FESS, and polypectomy. Evaluation included FEV_1 1.7 L, positive skin test to mite, normal lung CT, IgE 229, C3d 5.7, TEC 96, ESR 15, normal creatinine, and negative ANCA. Omalizumab, dual controller therapy, budesonide nasal irrigations, and tiotropium bromide improved symptoms. In 7/16, TEC 14,766, decrease in PFT, creatinine 1.5, ESR 46, C3d 12.8, serum IL-5 21.0, and positive ANCA were noted. CT showed patchy consolidation and large mediastinal nodes. Bone marrow was normal. Lung biopsy revealed necrotizing eosinophilic vasculitis and scattered granuloma. In 11/16, Omalizumab was discontinued. 100 mg of Mepolizumab every four weeks; daily 100 mg Cyclophosphamide, 60 mg prednisone, and sulfamethoxazole and trimethoprim prophylaxis were started. After 6 months, TEC 0, normal CT, normal PFT, negative ANCA, serum IL-5 1.4, and creatinine 1.33 were noted. By 5/17, prednisone was decreased to 20 mg and Cyclophosphamide to 75 mg.

Discussion: This is the first case of conventional doses of Mepolizumab for induction treatment of EGPA. Improvement in symptoms, labs, lung imaging, and PFTs and tapering of steroids and Cyclophosphamide without flare were noted. Mepolizumab at conventional dosages should be considered as part of initial treatment for EGPA.



Once Mepolizumab was introduced, TEC went to 0. Mepolizumab also allowed tapering of prednisone (after 2 months) and Cytoxan (after 6 months) doses. Recorded in parentheses is percent of eosinophils.

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DESCRIPTION OF BASELINE CHARACTERISTICS OF PEDIATRIC ALLERGIC ASTHMA PATIENTS INCLUDING THOSE INITIATED ON OMALIZUMAB

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