174 Omalizumab for the Treatment of Chronic Rhinosinusitis: A Multi-Disciplinary Practice Review

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RATIONALE: Recently, anti-IgE monoclonal antibody has emerged as a potential therapy for CRS. However, to date evidence for its efficacy in this patient population is sparse. The purpose of this study is to evaluate the clinical treatment effect of omalizumab therapy for patients with recalcitrant CRS treated in a multi-disciplinary clinic.

METHODS: The charts of 194 patients on omalizumab were reviewed. 21 patients diagnosed with CRS and having failed surgical and/or medical therapy were identified. Data extraction was performed and targeted demographic details, asthma, environmental allergy and CRS specific disease related data including self-reported major symptom improvement. Nonparametric data was analysed with the Mann-Whitney test and binary data was analysed with Fisher's exact test.

RESULTS: The mean treatment duration was 17 months. The most common skin test positive environmental allergens were dust mites (100%) and cats (65%). 75% of the cohort had CRS with polyps. Six patients (30%) had AERD. The mean polyp score decreased from 1.8 to 1.0 (p=0.106). From the time of treatment initiation to the last omalizumab treatment dose, patients reported a mean 59% improvement in their olfaction, a mean 70.4% improvement in facial pain, a mean 78.2% improvement in nasal obstruction and a mean 68.1% improvement in the symptom of rhinorrhea. Patients reported a mean overall improvement in their sinus symptoms of 74.1%.

CONCLUSIONS: Omalizumab therapy provided a substantial improvement in the self-reported major symptom control for patients with recalcitrant CRS and asthma. A well-designed comparative study is needed to further assess its effectiveness in the CRS population.

175 Systematic Review of Omalizumab for the Treatment of Chronic Rhinosinusitis

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RATIONALE: Recently, literature has emerged describing omalizumab as a potential therapy for CRS. The purpose of this systematic review was to assess the effectiveness and safety of anti-IgE monoclonal antibody therapy for the treatment of adult patients with CRS and to identify evidence gaps to guide future research on anti-IgE monoclonal antibody therapy for the management of CRS.

METHODS: Methodology for the systematic review was registered with PROSPERO (No. CRD42014007600). A comprehensive literature search was performed of standard research databases, ClinicalTrials.gov and relevant grey literature sources. Only randomized controlled trials assessing anti-IgE therapy in adult patients for the treatment of CRS were included. Quality of evidence was evaluated using the GRADE approach. Two independent reviewers extracted data and discrepancies were settled by consensus and discussion amongst the reviewers.

RESULTS: Two studies met the inclusion criteria. The GRADE assessment of the quality of evidence was low. Comparison of omalizumab to placebo, there was significant differences in CT score and quality of life. There was a significant improvement in Lund-McKay score (n=1, 4.0 vs. -0.5, p=0.04) and AQLQ (n=1, 0.81 vs. 0.27, p=0.003). Mixed results

were found for total nasal endoscopic polyp score in the two studies. No serious complications were reported in either trial.

CONCLUSIONS: Currently insufficient evidence exists to determine whether omalizumab is more effective than placebo for the treatment of CRS. High quality studies are needed to supplement the evidence base in order to make a firm conclusion and to further assess anti-IgE monoclonal antibody therapy efficacy in this population.

176 Symptom Based Clustering in Chronic Rhinosinusitis Reveals Phenotypic Heterogeneity

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RATIONALE: Chronic rhinosinusitis (CRS) is a complex disorder in which the heterogeneity intrinsic to the disease has impeded efforts to outline optimal evaluation and management strategies. We sought to utilize data from a standardized, validated self-reported questionnaire to predict CRS subtypes.

METHODS: Adult patients with diagnosed CRS were identified by retrospective chart review. Sino-nasal Outcome Test-22 (SNOT-22) scores, clinical and demographic data were collected from randomly-selected patients meeting inclusion criteria over the 2-year study period (n=99). All of these patients underwent medical intervention. To determine symptom-based subtypes of CRS patients, unsupervised clustering/network visualization was performed on SNOT-22 scores.

RESULTS: Four distinct clusters were identified; patients with A) severe (n=9) or B) moderate symptoms (n=28) across all SNOT-22 questions, C) minimal symptoms (n=32) and D) with predominantly sinonasal-specific symptoms (n=30) (e.g. nasal congestion, anosmia). Patients in Cluster-A and D showed higher prevalence of polyps, history of aspirin sensitivity as compared to cluster-B or C. Compared to cluster-D however, cluster-A had a higher total SNOT-22 and lower CT scan score (Lund-Mackay). No significant differences were observed in the prevalence of allergic sensitization, blood eosinophil counts, and serum IgE levels, history of asthma, FEV1/FVC, and vitamin D levels amongst the four groups.

CONCLUSIONS: A proportion of CRS patients show more sinonasal-specific symptoms as compared to other SNOT-22 symptoms, and these patients may benefit from medical therapy targeting upper airway inflammation. Identifying subgroups of patients that may need adjunctive therapy to address pain, fatigue, and depression can help clinicians improve clinical outcomes for all CRS patients.