PRIVATE PRACTICE EXPERIENCE WITH OMALIZUMAB FOR CHRONIC URTICARIA

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I. INTRODUCTION

Omalizumab is a humanized IgG1 kappa monoclonal antibody that binds specifically to the Fc epsilon RI receptor on mast cells and basophils. Omalizumab inhibits the inflammatory pathway mediated by IgE without enhancing degradation (1). In 2014, omalizumab was approved for therapy in children ages 12-17 years and adults with chronic urticaria defined as at least 6 weeks in duration not controlled with H1-antihistamines. The 300 mg dose monthly is associated with a primary outcome of 70% decrease in itch severity over 12 weeks versus 40% with placebo. Since 44-53% of patients with chronic spontaneous urticaria (CSU) experience spontaneous urticaria by extension, omalizumab therapy of such candidates is also efficacious in decreasing the episodes of angioedema (2).

A real-life study of omalizumab demonstrates efficacy and safety in 'complex' patients with comorbidities including cardiac, metabolic, oncologic, infectious, allergic, immunologic and psychiatric diseases (3). Obesity, elevated C3, arterial hypertension and CRP may be factors in increased resistance to omalizumab (4). We report in a single private practice real life experience with efficacy and safety in candidates with spontaneous urticaria and/or angioedema over 12 months. A retrospective chart review of 43 chronic urticarial patients with omalizumab between 2006 - 2015 reports that 90% (37/41) responded in 3 months (5-6). Cost effectiveness for CIU awaits manuscript. Pediatric guidelines for CIU management with omalizumab have been issued by Italian allergy specialists (9).

II. METHODS

We performed a de-identified, retrospective review of our two-providers private practice utilization and efficacy of omalizumab 300mg a month for chronic urticaria and/or angioedema. As approved by the FDA, omalizumab is designed for urticaria and/or angioedema intractable to high dose antihistamine and montelukast sodium x 6 weeks as indicated by urticarial control test, patient history and/or physical exam.

III. RESULTS

We reviewed 55 patients over a 5.5 year period between January 2014 and July 2019. Our candidates comprised 47 (85%) females and 8 (15%) males of which 5 were African American (10%), 9 were Hispanic (16%) and 41 were Caucasian (75%). Patients’ age range was 19 to 91 years with a mean of 72 years and median of 56 years. Thirty-four patients (62%) had a history of atopy and eleven patients (20%) had a history of asthma. Our patients also had a history of urticaria and/or angioedema with a range of 5 months to 30 years with a mean of 3 years and median of 6.3 years. They were on omalizumab for a range of 1 month to 6 years, mean 3 years and median 1.7 years. Thirty-eight patients (69%) had been on omalizumab exclusively for a range of zero to 5.6 years, with a mean of 1.3 years (16 months) and median of 1 year (12 months). Three patients (5%) failed taper and returned to control with omalizumab 300mg every 4 weeks whereas 4 candidates (8%) tapered off omalizumab for periods of 2 to 12 months. Of those patients, three (9%) are asymptomatic on no medication 2 - 12 months but one patient (2%) continues to experience periodic urticaria which either self-resolves or responds to minimal antihistamine, fexofenadine 180mg x 1 dose. Four candidates (8%) failed omalizumab therapy after at least 1.5 months to 2.5 years and have responded only to systemic steroids. Response to omalizumab usually occurred within 12 months. Two other candidates with highly elevated IgG (less than 8) did not respond to conventional dose 300mg a month for 6 months or 450mg q4 weeks x3 months.

IV. DISCUSSION

Response to omalizumab is noted in 70% of patients with CSU within the first week of treatment (9) and is related to IgE autoreactivities (10). Less optimal or a more delayed response is noted with positive diagnostic tests for Type II B Autimmune CSU including autologous serum skin test and basophil histamine (9, 11). In contrast, failure to respond is related to low baseline total IgG and total IgE within 4 weeks following the first injection (10, 12) and low baseline levels of Fc epsilon RI (13).

References