

mild persistent asthma, the ongoing need for and adherence to inhaled steroid controller therapy must be regularly assessed on an individual basis. These results might be useful when trying to balance the greater effectiveness and greater potential for adverse effects of daily inhaled steroid controller therapy in these patients.

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### **Effectiveness of Omalizumab in Reducing Corticosteroid Burden in Patients With Moderate to Severe Persistent Allergic Asthma**

Karpel J, Massanari M, Geba G, Fianifard F, Inhaber N, Zeldin R. *Ann Allergy Asthma Immunol.* 2010;105(6):465-470

**PURPOSE OF THE STUDY.** To assess whether the addition of omalizumab to inhaled corticosteroid (ICS) therapy reduces the steroid burden during long-term treatment and improves clinical outcomes.

**STUDY POPULATION.** Patients ( $N = 1071$ ) were aged 12 to 75 years with moderate-to-severe persistent allergic asthma that was inadequately controlled with ICSs. Eight percent of the patients were aged 12 to 18 years. All patients had confirmed allergic asthma, an immunoglobulin E (IgE) level between 30 and 700 IU/mL, and a baseline forced expiratory volume in 1 second (FEV<sub>1</sub>) between 40% and 80%. Data were pooled from 1 US and 1 international randomized, double-blind placebo-controlled multicenter trial.

**METHODS.** After a 4- to 6-week ICS stabilization run-in period, patients were randomly assigned to receive omalizumab or placebo. The ICS steroid dose was held constant for the first 16 weeks of treatment and then tapered by 25% every 2 weeks as tolerated for a total of 12 weeks. Patients were then maintained for 24 weeks on continued randomized treatment as well as the lowest possible dose of ICSs established during the steroid-reduction period, and clinically appropriate dose adjustments of ICSs were permitted during this period. Measured outcomes included steroid burden (change from baseline ICS dose and number of oral corticosteroid [OCS] bursts) as well as clinical outcomes.

**RESULTS.** Baseline characteristics were similar between the 2 groups: patients used an average of 670  $\mu\text{g}/\text{day}$  of inhaled beclomethasone and nearly 5 rescue puffs of albuterol daily, and their average IgE levels were in the 190s (IU/mL). At the end of the 3 study phases, there were statistically significant differences between the omalizumab and placebo groups in inhaled steroid dose (all  $P < .001$ ) and number of OCS bursts (all  $P < .001$ ). There were also significant reductions in frequency of

exacerbations, improvements in FEV<sub>1</sub> and quality of life, and reduction in peripheral blood eosinophilia in those on omalizumab compared with those on placebo ( $P < .001$ ).

**CONCLUSIONS.** Omalizumab use reduces corticosteroid burden and improves clinical outcomes in patients with moderate-to-severe persistent asthma.

**REVIEWER COMMENTS.** The results of this study add to a growing body of literature that substantiates the addition of omalizumab to the medical regimen of those with moderate-to-severe asthma. The high annual cost of this medication (\$10 000–\$30 000) and the need for supervised administration make it more suited to those who require frequent acute care for their asthma, frequent doses of oral steroids, or high-dose inhaled steroids. The study included a small but significant percentage of pediatric patients aged 12 to 17, for whom reduction in the amount of systemic steroid exposure is of arguably greater value. Ongoing studies are examining the safety of this medication in younger children.

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### **Randomized Trial of Omalizumab (Anti-IgE) for Asthma in Inner-City Children**

Busse WW, Morgan WJ, Gergen PJ, et al. *N Engl J Med.* 2011;364(11):1005-1015

**PURPOSE OF THE STUDY.** To evaluate the effectiveness of omalizumab in improving asthma control of inner-city children who are not adequately controlled on guideline-based therapy.

**STUDY POPULATION.** Inner-city children, adolescents, and young adults ( $N = 419$ ) with persistent allergic asthma were included in this study. Eligible patients were required to have a physician's diagnosis of asthma or documentation of asthma symptoms for longer than 1 year before entry into the study and evidence of uncontrolled asthma. All patients had at least 1 positive skin-test result to a perennial allergen, weighed between 20 and 150 kg, and had a total serum immunoglobulin E (IgE) level between 30 and 1300 IU/mL.

**METHODS.** Participants ( $n = 419$ ) were randomly assigned to receive subcutaneous injections of omalizumab or placebo every 2 or 4 weeks for a 60-week treatment period. Omalizumab doses were calculated on the basis of patient weight and total serum IgE level; the minimum monthly dose was 0.016 mg/kg body weight/IU IgE/mL. Routine clinic visits were scheduled every 3 months. Asthma-control assessment was based on Na-

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