Omalizumab reduced inhaled corticosteroid use and exacerbations in childhood allergic asthma


QUESTION: In children with moderate to severe allergic asthma who require daily inhaled corticosteroid (ICS) treatment, is omalizumab (anti-immunoglobulin E [anti-IgE] antibody) more effective than placebo for reducing steroid use and asthma exacerbations?

Design
Randomised (allocation concealed†‡, blinded (clinicians, patients; outcome assessors, and statisticians) †‡), placebo controlled trial with 34 weeks of follow up.

Setting
Research centres in 12 US states and in Washington, DC.

Patients
334 asthmatic patients who were 6 to 12 years of age (mean age 9 y, 69% boys) and whose asthma was well controlled with ICSs (beclomethasone dipropionate [BDP]) and bronchodilator treatment for ≥ 3 months before randomisation. Other inclusion criteria were allergic asthma for ≥ 1 year; positive skin prick test result to ≥ 1 of house dust mite, cockroach, dog, or cat; total serum IgE level between 30 and 1500 IU/ml; body weight < 90 kg; forced expiratory volume at 1 second (FEV1) ≥ 60% of predicted normal; ≥ 12% increase in FEV1 from baseline within 30 minutes of taking albuterol; and stable asthma. Exclusion criteria were previous treatment with omalizumab; sinusitis, respiratory tract infection, or lung disease within 1 month or systemic disease within 3 months of randomisation; abnormal findings on an electrocardiogram or a chest radiograph or abnormal laboratory values; or elevated serum IgE concentrations for reasons other than atopy. All patients were analysed for the stable steroid phase and the steroid reduction phase.

Intervention
Patients were allocated to subcutaneous omalizumab 150 or 300 mg every 4 weeks; omalizumab 225, 300, or 375 mg every 2 weeks (minimum dose 0.016 IU/ml per 4 wk) (n=225); or placebo (n=109). For 16 weeks, the baseline BDP dose was maintained; during the next 8 weeks, BDP was reduced stepwise to establish an effective minimum dose.

Main outcome measures
Reduction of BDP dose and asthma exacerbations.

Main results
More patients who received omalizumab reduced the BDP dose than did patients who received placebo (p=0.002) (table). Asthma exacerbations occurred in fewer patients receiving omalizumab (p < 0.001) (table), and the mean number of exacerbations per patient was lower in omalizumab recipients (0.42 ± 0.72; p < 0.001).

Conclusion
In children with moderate to severe allergic asthma requiring daily inhaled corticosteroids, omalizumab reduced corticosteroid use and asthma exacerbations.

‡ Information provided by author.
† See glossary.
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