to 420 µg/day beclomethasone dipropionate and rescue albuterol as needed. Ninety percent of the patients were classified as having moderate/severe persistent asthma, and 10% were classified as having severe persistent asthma. The mean total serum immunoglobulin E level was 348 IU/mL (range: 20–1269 IU/mL).

**Methods.** This report included data from a previously published, 28-week study, which was a randomized, double-blind, placebo-controlled, parallel-group trial comparing the addition of omalizumab versus placebo for symptomatic patients receiving beclomethasone dipropionate. The patients who received omalizumab during the double-blind, 28-week study continued to receive open-label omalizumab without interruption for another 24 weeks and were studied with respect to the safety parameters described in this report.

**Results.** Approximately 93% of patients treated with omalizumab for 52 weeks reported experiencing an adverse event; 85% of those were rated as mild or moderate. This finding was similar to 89% of patients treated with omalizumab and 87% of patients treated with placebo reporting adverse events during the double-blind study. The only statistically significantly greater adverse event among omalizumab-treated patients, compared with placebo-treated patients, in the 28-week study was injury. The higher prevalence of injury among the actively treated patients was not considered to be attributable to treatment and was not associated with adverse events involving the nervous system. The finding was considered to be possibly attributable to increases in activity with improvements in asthma, leading to greater frequencies of injury and trauma among those patients. Among the patients who were treated for 52 weeks with omalizumab, adverse events were numerically greater (by percentage) in all categories, compared with those reported in the 28-week study for either active drug or placebo, but no statistical analysis was reported. The most frequently reported adverse events in the 52-week study were upper respiratory tract infections and headaches. No episodes of anaphylaxis were noted. Urticaria occurred for 11 patients (5%). Urticaria was considered to be possibly treatment-related for 5 patients but was reported to be severe for only 1 of those patients; for that patient, additional treatment with omalizumab was discontinued. Four serious adverse events were reported, but none was considered to be treatment-related. There was no evidence of omalizumab-related decreases in platelet counts among the patients treated for 52 weeks. Antibodies reactive with the antigen-binding fragment of omalizumab were tested for, and no antibodies were detected. Asthma control parameters were not the primary outcome measures in the 52-week extension study, but it was noted that inhaled corticosteroid dose reductions or discontinuation and reductions in asthma exacerbations were maintained at similar levels throughout the 28-week extension period.

**Conclusions.** Among children 5 to 12 years of age, 52-week treatment with omalizumab was well tolerated. The overall incidence of adverse events was high but was similar to the values reported in the 28-week study for both active drug and placebo. No anaphylactic reactions were reported. Treatment was discontinued for 1 patient because of severe urticaria, which was considered to be possibly treatment-related.

**Reviewer’s Comments.** Although the exact role of omalizumab in clinical practice is not entirely clear, these short-term safety data are reassuring.

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## Immunodeficiency

### IMMUNODEFICIENCY DISEASES

**PROSPECTIVE AUDIT OF ADVERSE REACTIONS OCCURRING IN 459 PRIMARY ANTIBODY-DEFICIENT PATIENTS RECEIVING INTRAVENOUS IMMUNOGLOBULIN**


**Purpose of the Study.** To determine the incidence of adverse reactions among a large group of patients receiving intravenous immunoglobulin (IVIG) replacement therapy in an institutional setting or at home, with or without supervision by a healthcare professional.

**Study Population.** The patients were 92 children (<18 years of age) and 367 adults (total: 459 patients). All had been diagnosed as having a primary antibody deficiency, and all had been receiving IVIG replacement therapy for ≥6 months before entry into the study. The majority of patients (290 total, 72 children) received IVIG therapy at home; 160 patients (19 children) received IVIG therapy as outpatients in a hospital, and 9 patients (1 child) received IVIG therapy in a primary care provider’s office.

**Methods.** IVIG therapy was administered according to the manufacturer’s guidelines. Prophylaxis (with nonsteroidal antiinflammatory drugs and/or antihistamines) to prevent adverse reactions varied among centers supervising IVIG therapy and was not uniform across the study population. Data were collected prospectively for 2 years (13,508 infusions). For infusions administered in institutional settings, data were recorded by healthcare professionals. Patients receiving IVIG therapy at home were self-infusing and recorded their own symptom data; these records were reviewed by investigators before assignment of a classification. All adverse reactions were classified as mild, moderate, or severe with uniform criteria for all centers.

**Results.** A total of 111 adverse reactions were documented (overall rate: 0.8%). Of these, 91 (82%) were mild and 20 (18%) were moderate. One patient accounted for 19 of the mild reactions. No severe adverse reactions were recorded. There was no significant variation in the rate of adverse reactions according to age or the setting in which IVIG therapy was administered. For 45 reactions (41%), there was an associated predisposing factor (infection, delay after previous infusion, or administration error [too rapid]); 47 reactions (42%) occurred despite prophylaxis, although the effect of prophylaxis on the overall reaction rate was not mentioned. Three of the 12 centers had relatively higher rates of adverse reactions; the reasons for this, if known, were not stated.

**Conclusions.** There was a low overall rate of adverse reactions to IVIG infusion and a very low rate (<0.007%) of severe adverse reactions to IVIG administration. The importance of recognizing and avoiding predisposing factors for adverse reactions was emphasized.

**Reviewer’s Comments.** Home IVIG infusion is clearly safe. More detailed analyses of the effects of prophylaxis on reaction rates and of the differences among centers would have been helpful.
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