Long-term Safety of Once-Daily Budesonide in Patients With Early-Onset Mild Persistent Asthma: Results of the Inhaled Steroid Treatment as Regular Therapy in Early Asthma (START) Study


PURPOSE OF THE STUDY. Inhaled corticosteroids are the recommended treatment for all patients with persistent asthma. The aim of this study was to evaluate the safety and tolerability of long-term treatment of patients with mild persistent asthma with once-daily budesonide.

STUDY POPULATION. Seven thousand two hundred twenty-two patients (aged 5–66 years) with mild persistent asthma diagnosed within 2 years of study entry, with wheeze, cough, dyspnea, or chest tightness weekly and demonstration of reversible airway obstruction, were enrolled into the study.

METHODS. This was a prospective, double-blind, placebo-controlled study. Patients were divided into 2 groups according to age. Those patients younger than 11 years received 200 µg of budesonide via a dry-powder inhaler or placebo, and patients 11 years and older received 400 µg of budesonide via dry-powder inhaler or placebo. All treatments were administered for 3 years and in addition to the patients’ usual asthma therapy.

RESULTS. Overall, 21,520 adverse events were reported (10,850 in the budesonide group and 10,670 in the placebo group). The most commonly reported events were respiratory infections such as rhinitis, pharyngitis, bronchitis, viral infections, and sinusitis. Oral candidiasis was more common in the budesonide group (1.2%) than in the placebo group (0.5%); the frequencies of other adverse effects previously reported to be associated with inhaled corticosteroids (skin disorders, psychiatric disorders, and allergic reactions) were similar between the 2 groups. The number of deaths and serious adverse events were similar for children and adults in both treatment groups.

CONCLUSIONS. Three-year treatment with budesonide (200 or 400 µg) is safe and well tolerated in both children and adults who have recent onset of mild persistent asthma.

REVIEWER COMMENTS. This study shows not only that budesonide dramatically reduces the overall risk of experiencing a severe asthma-related event but also that budesonide has very little risk of causing any significant adverse events. One of the most difficult, yet very important tasks as a physician is to educate the patient that inhaled corticosteroids are not the enemy, but rather that the patient’s health is at greater risk from asthma itself. Clearly, early intervention is safe and effective. This study provides valuable information and should help patients and their families to feel comfortable with long-term inhaled corticosteroids use in asthma.
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Helen Skolnick

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