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.

Budesonide/Formoterol Combination Therapy as Both Maintenance and Reliever Medication in Asthma

PURPOSE OF THE STUDY. Previous studies have shown that the combination of inhaled corticosteroids (ICSs) with long-acting β₂ agonists improves asthma control and reduces exacerbations. The authors hypothesized that in patients already receiving daily budesonide/formoterol (B/F), replacing conventional short-acting β₂ agonist (SABA) rescue with the B/F combination drug would increase anti-inflammatory therapy while simultaneously giving rapid relief of symptoms. The investigators reasoned that using the B/F combination drug in this manner might reduce asthma exacerbations and improve asthma control compared with other possible regimens.

STUDY POPULATION. Subjects were 2760 patients with asthma (aged 4–80 years), all previously on ICSs.

METHODS. A double-blind parallel-group study was performed with subjects randomly assigned to 3 groups: B/F (80 mg/4.5 µg) twice daily for maintenance and also for rescue; B/F (80 mg/4.5 µg) twice daily with terbutaline 0.4 mg for rescue; or budesonide 320 µg twice daily with terbutaline 0.4 mg for rescue. Pediatric patients (11%–13% of each group) received half of the above-stated doses for maintenance. The primary outcome was time to first severe exacerbation, defined as asthma symptoms requiring an emergency department visit or hospitalization; an increase in ICS dose; use of oral steroids; or a morning peak expiratory flow rate ≤70% of baseline on 2 consecutive days.

RESULTS. Multiple positive outcomes were seen in the group using B/F for maintenance and rescue: a significant increase in the time to the first severe and mild exacerbations (P < .001); a 45% to 50% decrease in the number of severe exacerbations; significant decreases in the use of rescue medication, nighttime symptom score,
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