

Methods. START was a randomized, 3-year controlled trial of budesonide versus usual asthma therapy in early-onset asthma among 7165 subjects. Three age groups (5–10, 11–17, and ≥ 18 years) were studied separately and collectively. All patients were allowed to receive other asthma treatments including inhaled and oral corticosteroids, according to local practice. The cost-effectiveness evaluation of the START study was conducted primarily from the health care payer perspective (direct costs) and secondarily from the societal perspective (indirect costs). The primary outcome measure for effectiveness was the number of symptom-free days. This parameter was defined as a complete 24-hour period with no asthma symptoms and has been recognized as a clinical outcome with relevance to patients, providers, and other decision-makers. Unit costs in US dollars were based on reimbursed amounts for each of the health care–resource items such as hospital days, emergency department visits, physician and nurse visits, and telephone contacts. These costs were derived from a large medical- and pharmacy-claims database. The costs for school and work losses were estimated by using standard methods.

Results. Compared with usual therapy, patients receiving budesonide had 14.1 more symptom-free days per year, fewer hospital days and emergency department visits, and less school and work absence. Budesonide added \$0.41 per day to direct costs. After considering indirect cost offsets related to lower school and work absence, the net expense dropped to \$0.14 per day. Early intervention was most effective and cost saving in the youngest age group.

Conclusion. Long-term treatment with budesonide seems to be cost-effective in patients with mild persistent asthma of recent onset.

Reviewers' Comments. The health care system in the United States is only now beginning to experiment with methods that will raise awareness of direct health costs for patients/consumers. Although \$0.14 per day for better asthma control sounds like a great value, any comments that we currently make to patients or parents regarding cost-effectiveness of a given therapy usually fall on deaf ears. At the present time, we can better appeal to them by touting the improved quality of life associated with fewer days with symptoms, fewer asthma attacks, and lowered hospitalization risk and also by making it clear that the risks of disease far outweigh the risks of usual doses of ICS. This latter fact, so obvious to us, needs continued restating to parents of children with asthma.

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EFFECTS OF SHORT-TERM TREATMENT WITH INHALED CORTICOSTEROID ON AIRWAY WALL THICKENING IN ASTHMA

Niimi A, Matsumoto H, Amitami R, et al. *Am J Med.* 2004;116:725–731

Purpose of the Study. To examine the effect of inhaled corticosteroids (ICSs) on thickening of the asthmatic airway wall as measured by computed tomography (CT), pulmonary function, and serum levels of eosinophilic cationic protein (ECP).

Study Population. Fifty-one patients (mean age: 54.4 ± 13.8 years) with persistent asthma and 28 healthy controls (mean age: 48.1 ± 15.9 years).

Methods. Patients fulfilled American Thoracic Society criteria for asthma, and none had ever received systemic or inhaled steroids, cromones, or antileukotriene agents. Ex-

clusion criteria included asthma exacerbations or respiratory tract infections within 8 weeks before enrollment or a history of smoking. Cross-sectional, thin-section CT images of the right upper lobe apical bronchus were obtained before and after treatment. Using an enlarged image on a workstation, luminal and total airway areas (in millimeters squared) were calculated after manually tracing the internal and external perimeters of the airway. The airway wall area and airway wall area as a percentage of total wall area were used as indices of airway wall thickness. In asthmatic patients, CT, blood sampling for ECP, and pulmonary function tests were performed before and after treatment with beclomethasone dipropionate (400 μg) administered twice daily for 12 weeks.

Results. Before treatment, airway wall thickness was greater in asthma patients than controls ($P < .0001$). After treatment, airway wall thickness decreased by 11% ($P < .001$) but remained high ($P < .0001$ vs control). Serum ECP levels decreased significantly after treatment ($P < .001$). Forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), and FEV_1/FVC improved significantly after treatment, but the values remained lower than in controls. The decrease in wall thickness was associated with a decrease in the level of ECP ($r = 0.39$; $P = .009$) and an increase in the FEV_1 ($r = 0.45$; $P = .003$) and was inversely related to disease duration at entry ($r = -0.38$; $P = .009$). Posttreatment wall thickness was related to disease duration ($r = 0.45$; $P = .003$) and remaining airflow obstruction.

Conclusions. In patients with persistent asthma, treatment with inhaled beclomethasone for 12 weeks significantly reduced airway wall thickness as assessed by CT. Airway wall thickness remained significantly greater than in controls. ICSs had less of an effect on airway wall thickening in patients with long-standing asthma.

Reviewer's Comments. This study raises questions. Is the reduction in airway wall thickness indicative of reductions in airway inflammation? Additional studies (eg, with airway biopsy specimens) are needed to confirm this. Would earlier intervention with ICSs result in normalization of airway wall thickness? This is a particularly important question for those who treat children with asthma.

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EFFECTS OF INHALED FLUTICASONE PROPIONATE IN CHILDREN LESS THAN 2 YEARS OLD WITH RECURRENT WHEEZING

Teper AM, Colom AJ, Kofman CD, Maffey AF, Vidaureta SM, Bergada I. *Pediatr Pulmonol.* 2004;37:111–115

Purpose of the Study. To evaluate the efficacy and safety of inhaled fluticasone propionate in children < 2 years old with a history of recurrent wheezing and risk factors for asthma persisting into late childhood.

Study Population. Subjects were 30 children, aged 7 to 24 months, with ≥ 3 episodes of wheeze responsive to bronchodilators and a family history of asthma, allergic rhinitis, or eczema.

Methods. In this double-blind study, subjects were randomized to receive either inhaled 50 μg of fluticasone twice daily, 125 μg of fluticasone twice daily, or placebo for 6 months. Medication was administered with a metered-dose inhaler using an Aerochamber and mask. Efficacy end points included number of wheezing episodes and number of days on which albuterol was required. Parents were trained to record these clinical symptoms and medication use on a chart. Subjects were seen monthly to assess proper use of the medication device and evaluate daily symptom

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John E. Duplantier

Pediatrics 2005;116;565

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