Comparative Efficacy and Safety of Low-Dose Fluticasone Propionate and Montelukast in Children With Persistent Asthma


PURPOSE OF THE STUDY. To evaluate efficacy, safety, health outcomes, and cost-effectiveness of fluticasone propionate (FP) versus montelukast in children with asthma

STUDY POPULATION. Children aged 6 to 12 years with persistent asthma.

METHODS. Multicenter, randomized, double-blind, double-dummy, parallel-group study of 342 children with persistent asthma. Children received either FP 50 µg twice daily via Diskus or montelukast 5 mg once daily for 12 weeks. The primary efficacy variable was percent change in morning predose forced expiratory volume in 1 second at the end point.

RESULTS. Compared with montelukast, children treated with FP experienced a significantly greater increase in mean percent forced expiratory volume in 1 second, mean morning peak expiratory flow rate, and mean evening peak expiratory flow rate. Children treated with FP also experienced significantly greater reductions in total supplemental albuterol use, mean nighttime albuterol use, and mean nighttime symptom scores compared with children treated with montelukast. There were no significant differences between the groups for daytime asthma symptom scores, daytime albuterol use, percent symptom-free days, or adverse events. Parent and physician satisfaction ratings were significantly higher for FP treatment. The daily total asthma-related cost per patient in the FP group was approximately one third of the cost in the montelukast group.

CONCLUSIONS. FP was significantly more effective than montelukast in improving pulmonary function, asthma symptoms, and rescue albuterol use. Both therapies had similar safety profiles.

REVIEWER COMMENTS. Comparative studies in adults and adolescents have previously shown greater efficacy with inhaled corticosteroids versus leukotriene receptor antagonists. This 12-week study reports similar findings for children 6 to 12 years of age with persistent asthma. Based on efficacy, cost, and safety profiles, low-dose inhaled corticosteroids should be considered first-line therapy in this age group.

Montelukast, Compared With Fluticasone, for Control of Asthma Among 6- to 14-Year-Old Patients With Mild Asthma: The Mosaic Study


PURPOSE OF THE STUDY. Per current asthma guidelines, montelukast is considered a suitable alternative to inhaled corticosteroids (ICSs) for the treatment of mild persistent asthma, and this study was conducted to evaluate the use of oral montelukast compared with inhaled fluticasone in children with mild asthma.

STUDY POPULATION. Children (aged 6–14 years) with mild persistent asthma participating in the Montelukast Study of Asthma in Children (MOSAIC) study.

METHODS. In this 12-month, multicenter, randomized, double-blind, noninferiority comparison study, patients were randomly assigned to receive oral montelukast 5 mg once a day (n = 495) or inhaled fluticasone 100 µg twice a day (n = 499) after an appropriate run-in period. After baseline evaluations, patients were evaluated at 4-month intervals with spirometry and review of an asthma diary card. The primary end point, the percentage of asthma rescue-free days (RFDs), included days with no rescue-medication use and no asthma-related primary care or urgent care visits or hospitalizations. Secondary end points included forced expiratory volume in 1 second (FEV₁), use of additional asthma medications, asthma attacks, β-agonist use, and peripheral blood eosinophil levels.

RESULTS. The mean percentage of RFDs was 84% in the montelukast group compared with 86.7% in the fluticasone group. The least-squares means difference was −2.8% (95% confidence interval: −4.7% to −0.9%), which represents a difference of <1 day/month. Both montelukast and fluticasone were associated with improvement in FEV₁ (percent predicted) from baseline as well as reduction in the percentage of days with β-agonist use, reduction in blood eosinophils, and improvement in patient-perceived asthma control and asthma quality-of-life scores; however, fluticasone was significantly favored in terms of FEV₁, β-agonist use, asthma control, and quality of life. Montelukast was associated with the increased use of systemic corticosteroids (17.8% vs 10.5%; P ≤ .001) and a higher percentage of patients with an asthma attack (32.2% vs 25.6%) compared with fluticasone.
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