CONCLUSIONS. Montelukast was not inferior to fluticasone in terms of asthma RFDs; however, the use of montelukast was associated with more asthma attacks and more systemic steroid use. FEV₁, β-agonist use, and quality of life improved significantly better for those in the fluticasone group.

REVIEWER COMMENTS. This study represents the first direct comparison between montelukast and an ICS measuring differences in multiple parameters of asthma control in children with mild persistent asthma. This study establishes the noninferiority of montelukast compared with fluticasone in terms of RFDs; however, in terms of FEV₁, systemic corticosteroid use, number of asthma attacks and β-agonist use, fluticasone was significantly superior to montelukast. This study underscores the fact that asthma control cannot be determined with just one measure and confirms the role of montelukast as an alternative to ICSs as suggested by the current guidelines. The role of montelukast in future asthma guidelines is currently under investigation. Future studies are needed for evidence-based clinical application.

MONTELUKAST REDUCES ASTHMA EXACERBATIONS IN 2- TO 5-YEAR-OLD CHILDREN WITH INTERMITTENT ASTHMA


PURPOSE OF THE STUDY. To evaluate the role of montelukast in prevention of viral-induced asthma exacerbations among 2- to 5-year-old children with a history of intermittent asthma.

STUDY POPULATION. A total of 549 children aged 2 to 5 years (from 68 sites in 23 countries) with a history of intermittent wheezing associated with upper respiratory infections.

METHODS. This was a multicenter, double-blind, parallel-group randomized trial comparing once-daily oral montelukast (4- or 5-mg chewable tablets) with placebo for 12 months. Subjects were required to have been free of symptoms and β-agonist use in a typical week over the 3 months before enrollment. An asthma exacerbation was defined as any 3 consecutive days with daytime symptoms and at least 2 β-agonist treatments per day; rescue use of oral/inhaled corticosteroids during ≥1 days; or a hospitalization because of asthma. The primary efficacy end point was number of exacerbation episodes over 1 year. Numerous secondary outcomes were also measured.

RESULTS. In the montelukast group experienced a mean of 1.60 asthma-exacerbation episodes, compared with 2.34 in the placebo group, for a 31.9% rate reduction (P ≤ .001). Other end points with significant differences favoring the montelukast group included time to first exacerbation (median: 206 vs 147 days; P = .0024), rate of inhaled corticosteroid use (39.8% rate reduction; P = .027), and proportion of patients with asthma episodes (45% vs 56%; P = .008). There were no statistically significant differences in rates of oral corticosteroid use, average duration and severity of exacerbations, or proportion of patients who missed time from day care or school. Both groups experienced more exacerbations in the fall and fewer in the summer. Montelukast was well tolerated, and no patient discontinued therapy because of a drug-related adverse event.

CONCLUSIONS. The authors concluded that once-daily montelukast significantly reduces asthma exacerbations secondary to respiratory tract infections compared with placebo among 2- to 5-year-old children with intermittent asthma and also reduces time to first exacerbation and need for β-agonist or inhaled corticosteroid therapy. There was no difference in severity or duration of episodes, although the authors argue that the study was not specifically designed to detect differences in these end points.

REVIEWER COMMENTS. This study attempts to address the question of whether a controller medication may be useful in young children who wheeze with colds but are otherwise categorized as mild intermittent or even symptom-free. Asthma guidelines do not endorse use of preventive medications for such children, yet this study suggests that daily montelukast during the respiratory viral season may be useful to reduce exacerbations (although it did not reduce oral steroid use or severity of exacerbations). Montelukast during specified times might be a good option for many young children with intermittent asthma, but the cost/benefit ratio of chronic use is unclear, because the number of wheezing episodes per child was low even in the placebo group. Investigation of episodic use of montelukast with upper respiratory infections would be of interest.

A META-ANALYSIS ON INTRAVENOUS MAGNESIUM SULPHATE FOR TREATING ACUTE ASTHMA


PURPOSE OF THE STUDY. To evaluate the effectiveness of intravenous magnesium sulfate in the treatment of acute asthmatic attacks in children.
Montelukast Reduces Asthma Exacerbations in 2- to 5-Year-Old Children With Intermittent Asthma

Todd D. Green and Larry W. Williams

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