Effect of Different Antiasthmatic Treatments on Exercise-Induced Bronchoconstriction in Children With Asthma


**PURPOSE OF THE STUDY.** To compare the effectiveness of different patterns of antiasthmatic treatments to protect children from exercise-induced bronchospasm (EIB).

**STUDY POPULATION.** This was a randomized, double-blind, placebo-controlled study of 100 children aged 6 to 18 years with atopic asthma sensitive only to house dust mites and EIB. Subjects must have had a resting forced expiratory volume in 1 second (FEV1) of ≥70% predicted and at least a 20% drop in FEV1 after exercise to qualify for the study.

**METHODS.** Participants were randomly assigned to a 4-week double-blind, placebo-controlled trial to receive 1 of the following treatments: (1) budesonide 100 μg + formoterol 4.5 μg twice daily; (2) budesonide 100 μg twice daily + montelukast 5 or 10 mg at bedtime; (3) montelukast 5 or 10 mg at bedtime; (4) budesonide 100 μg twice daily; or (5) placebo alone. All study arms had matching placebo medications from which active drugs were omitted (eg, group 1 had placebo tablets in place of montelukast, etc). At randomization and after 4 weeks on the study medication(s), a treadmill exercise test was performed to evaluate the effectiveness of treatment.

**RESULTS.** Ninety-one subjects with a median age of 11.3 to 12.2 years completed the study. Preexercise FEV1 and EIB, as represented by the area under the curve of time-response curve and by maximum percentage decrease in FEV1 after exercise, did not differ at baseline between the groups. EIB was diminished with all treatments when compared with placebo. The effect of treatment with budesonide plus montelukast and with montelukast alone were greater than budesonide alone or budesonide plus formoterol (*P* < .001). The budesonide-plus-formoterol group was also better than budesonide alone, but these results did not reach significance (*P* = .59).

**CONCLUSIONS.** Budesonide plus montelukast or montelukast alone were the most effective treatments for EIB in children.

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Adverse Effects of Inhaled Corticosteroids in Funded and Nonfunded Studies


**PURPOSE OF THE STUDY.** Evidence regarding the safety profile of drugs may vary depending on study sponsorship. The authors aimed to evaluate differences between studies funded by the pharmaceutical manufacturer of the drug (PF) and those with no pharmaceutical funding (NoPF) regarding the finding and interpretation of adverse effects of inhaled corticosteroids.

**METHODS.** The authors assessed the safety reporting of inhaled corticosteroids in 275 PF and 229 NoPF studies identified by a Medline search using prespecified criteria.

**RESULTS.** Overall, the finding of statistically significant differences for adverse effects was significantly less frequent in PF (34.5%) than in NoPF (65.1%) studies (prevalence ratio [PR]: 0.53 [95% confidence interval (CI): 0.44–0.64]). This association became nonsignificant (PR: 0.94 [95% CI: 0.77–1.15]) after controlling for design features (such as dose or use of parallel groups) that tended to be associated with less-frequent findings of adverse effects and were more common in PF studies. Among studies that found a statistically significant increase in adverse effects associated with the study drug, the authors of PF articles concluded that the drug was “safe” more frequently than the authors of NoPF studies (PR: 3.68 [95% CI: 2.14–6.33]).
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