

'Stepping up' asthma treatment in children leads to improvement

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Children with asthma who continue to have symptoms while using low-dose inhaled corticosteroids could benefit from increasing the dosage or adding one of two asthma drugs, a new study by researchers at Washington University School of Medicine and other institutions finds.

Results of the study, called BADGER (Best ADd-on therapy Giving Effective Responses) may also allow physicians to better predict which of the three options will help a patient the most.

To treat children whose [asthma](#) is not well controlled while using low-dose inhaled corticosteroids, the National Heart, Lung, and Blood Institute (NHLBI) guides physicians to try one of three additional, or step-up, treatments: doubling the dosage of the inhaled corticosteroid or adding a long-acting beta antagonist (LABA) or a leukotriene receptor antagonist (LTRA) to the inhaled corticosteroid treatment.

However, physicians often find it difficult to predict which step-up treatment might work best for a particular child. So the researchers in the five-center, NHLBI-funded [Childhood Asthma](#) Research and Education (CARE) Network used a novel triple-crossover, double-blind approach to determine if the treatments improved asthma symptoms, and if so, which treatment might work best.

Robert C. Strunk, M.D., and Leonard B. Bacharier, M.D., both Washington University pediatric asthma specialists at St. Louis Children's Hospital, were coauthors on the study, published online

March 2, 2010, by the [New England Journal of Medicine](#) and presented the same day at the American Academy of Allergy, Asthma and Immunology's annual meeting in New Orleans.

For the yearlong study, Washington University researchers recruited 46 children ages 6-18 from the asthma clinics and the After Hours Call Center at St. Louis Children's Hospital. Each child received each one of the step-up options to use along with the inhaled corticosteroid in random order for 16 weeks. After 16 weeks, researchers measured lung function, the number of asthma exacerbations, or attacks, during the period, and how many days the child's asthma symptoms were under control. The patient was then given one of the other drugs for 16 weeks and continued the cycle until he or she had used all three treatments.

At the beginning of the study, the researchers' goal was for 25 percent of the 165 patients at all study sites to see a difference in their asthma symptoms while using at least one of the step-up treatments. However, researchers unexpectedly discovered that 161 patients, or 98 percent, showed substantial improvement in their asthma control by adding at least one of the options.

About 40 percent of patients showed the best response by adding the LABA, while nearly 30 percent of patients showed the best response by adding the LTRA and about 28 percent showed the best response by doubling the dose of inhaled corticosteroid. The LABA was more than 1.5 times as likely to produce the best response.

"All three therapies clearly have a place in the management of kids with persistent asthma not well controlled on low-dose inhaled corticosteroids alone," says Bacharier, associate professor of pediatrics and instructor in medicine at Washington University School of Medicine. "Statistically LABA therapy was most likely to help the most patients, but it's hard to look at an individual patient and know which one to choose."

Bacharier says three factors increase the chance that one drug will work better than the others: The Asthma Control Test score, eczema and ethnicity.

The Asthma Control Test is a standard evaluation scored from 0 to 25 and used to determine how often a patient had asthma symptoms over the past four weeks.

"We found that if a patient had a score over 19, the LABA treatment was clearly the best therapy," Bacharier says. "If it was 19 or under, there was no difference among the therapies in producing a differential response."

Second, patients who also had eczema, an allergic skin disorder that causes scaly and itchy rashes, did well on any of the three treatments. But patients who did not have eczema did better on the LABA.

Finally, ethnicity also played a role, the researchers say.

"African-Americans were equally likely to respond best to the LABA or increased inhaled corticosteroid treatment and least likely to respond to the LTRA treatment," Bacharier says. "In Caucasians, LABA was the therapy most likely to give the best response."

Surprisingly, researchers determined several factors that had no influence on a drug's effectiveness, including age, gender, allergies, bronchodilator response, recent exacerbations or several other tests.

"We used a few complicated and expensive tests we thought would help us determine which drug would be better, but they didn't help, so we can avoid these tests," says Strunk, the Donald Strominger Professor of Pediatrics at Washington University School of Medicine.

Although 98 percent of patients in the study showed improvement on at least one of the step-up options, there were still 120 asthma exacerbations, or attacks, among the 165 patients that required treatment with prednisone, a corticosteroid commonly used after an exacerbation that prevents the release of inflammatory substances in the body. Bacharier says that indicates none of these treatments provide perfect asthma control.

"There may not be an ideal therapy for every patient, but these step-up treatments allow for improved asthma control and outcomes over leaving them on low-dose steroids alone," Bacharier says.

More information: Lemanske R, Mauger D, Sorkness C, Jackson D, Boehmer S, Martinez F, Strunk R, Szefler S, Zeiger R, Bacharier L, Covar R, Guilbert T, Larsen G, Morgan W, Moss M, Spahn J, Taussig L. "Step-up Asthma Care in Children Uncontrolled on Inhaled Corticosteroids." *New England Journal of Medicine Online First*, March 2, 2010.

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