

mild persistent asthma, the ongoing need for and adherence to inhaled steroid controller therapy must be regularly assessed on an individual basis. These results might be useful when trying to balance the greater effectiveness and greater potential for adverse effects of daily inhaled steroid controller therapy in these patients.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107NNN

Elinor Simons, MD, MSc
Toronto, Ontario, Canada

Effectiveness of Omalizumab in Reducing Corticosteroid Burden in Patients With Moderate to Severe Persistent Allergic Asthma

Karpel J, Massanari M, Geba G, Fianifard F, Inhaber N, Zeldin R. *Ann Allergy Asthma Immunol.* 2010;105(6):465-470

PURPOSE OF THE STUDY. To assess whether the addition of omalizumab to inhaled corticosteroid (ICS) therapy reduces the steroid burden during long-term treatment and improves clinical outcomes.

STUDY POPULATION. Patients ($N = 1071$) were aged 12 to 75 years with moderate-to-severe persistent allergic asthma that was inadequately controlled with ICSs. Eight percent of the patients were aged 12 to 18 years. All patients had confirmed allergic asthma, an immunoglobulin E (IgE) level between 30 and 700 IU/mL, and a baseline forced expiratory volume in 1 second (FEV₁) between 40% and 80%. Data were pooled from 1 US and 1 international randomized, double-blind placebo-controlled multicenter trial.

METHODS. After a 4- to 6-week ICS stabilization run-in period, patients were randomly assigned to receive omalizumab or placebo. The ICS steroid dose was held constant for the first 16 weeks of treatment and then tapered by 25% every 2 weeks as tolerated for a total of 12 weeks. Patients were then maintained for 24 weeks on continued randomized treatment as well as the lowest possible dose of ICSs established during the steroid-reduction period, and clinically appropriate dose adjustments of ICSs were permitted during this period. Measured outcomes included steroid burden (change from baseline ICS dose and number of oral corticosteroid [OCS] bursts) as well as clinical outcomes.

RESULTS. Baseline characteristics were similar between the 2 groups: patients used an average of 670 $\mu\text{g}/\text{day}$ of inhaled beclomethasone and nearly 5 rescue puffs of albuterol daily, and their average IgE levels were in the 190s (IU/mL). At the end of the 3 study phases, there were statistically significant differences between the omalizumab and placebo groups in inhaled steroid dose (all $P < .001$) and number of OCS bursts (all $P < .001$). There were also significant reductions in frequency of

exacerbations, improvements in FEV₁ and quality of life, and reduction in peripheral blood eosinophilia in those on omalizumab compared with those on placebo ($P < .001$).

CONCLUSIONS. Omalizumab use reduces corticosteroid burden and improves clinical outcomes in patients with moderate-to-severe persistent asthma.

REVIEWER COMMENTS. The results of this study add to a growing body of literature that substantiates the addition of omalizumab to the medical regimen of those with moderate-to-severe asthma. The high annual cost of this medication (\$10 000–\$30 000) and the need for supervised administration make it more suited to those who require frequent acute care for their asthma, frequent doses of oral steroids, or high-dose inhaled steroids. The study included a small but significant percentage of pediatric patients aged 12 to 17, for whom reduction in the amount of systemic steroid exposure is of arguably greater value. Ongoing studies are examining the safety of this medication in younger children.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107000

Sally A. Newbrough, MD, PhD
Paul V. Williams, MD
Seattle, WA

Randomized Trial of Omalizumab (Anti-IgE) for Asthma in Inner-City Children

Busse WW, Morgan WJ, Gergen PJ, et al. *N Engl J Med.* 2011;364(11):1005-1015

PURPOSE OF THE STUDY. To evaluate the effectiveness of omalizumab in improving asthma control of inner-city children who are not adequately controlled on guideline-based therapy.

STUDY POPULATION. Inner-city children, adolescents, and young adults ($N = 419$) with persistent allergic asthma were included in this study. Eligible patients were required to have a physician's diagnosis of asthma or documentation of asthma symptoms for longer than 1 year before entry into the study and evidence of uncontrolled asthma. All patients had at least 1 positive skin-test result to a perennial allergen, weighed between 20 and 150 kg, and had a total serum immunoglobulin E (IgE) level between 30 and 1300 IU/mL.

METHODS. Participants ($n = 419$) were randomly assigned to receive subcutaneous injections of omalizumab or placebo every 2 or 4 weeks for a 60-week treatment period. Omalizumab doses were calculated on the basis of patient weight and total serum IgE level; the minimum monthly dose was 0.016 mg/kg body weight/IU IgE/mL. Routine clinic visits were scheduled every 3 months. Asthma-control assessment was based on Na-

tional Asthma Education and Prevention Program (NAEPP) guidelines. The primary outcome evaluated at each injection visit was the number of symptomatic days in the previous 2 weeks. Numerous secondary outcomes were evaluated.

RESULTS. Compared with placebo, omalizumab treatment significantly reduced the mean number of symptomatic days per 2-week interval from 1.96 to 1.48, which is a 24.5% difference ($P < .001$). Significantly fewer exacerbations occurred during the treatment period in the omalizumab group; 30.3% of patients had an exacerbation compared with 48.8% of patients in the placebo group ($P < .001$). Similarly, the percentage of hospitalizations caused by asthma was 1.51% vs 6.3% in the placebo group ($P = .02$). Asthma control in the omalizumab group required significantly lower doses of inhaled glucocorticoids ($P < .001$) and long-acting β_2 agonists ($P = .003$). Finally, posthoc analysis revealed that omalizumab prevented the seasonal spikes in exacerbations seen in the placebo group. No differences in safety were seen.

CONCLUSIONS. Omalizumab improved asthma control in inner-city children, adolescents, and young adults when added to their previous guideline-based therapy.

REVIEWER COMMENTS. Omalizumab is an effective treatment option for patients with asthma and allergies whose conditions are not adequately controlled on guideline-based therapy. In this study, the effectiveness of omalizumab was shown at all levels of asthma severity. According to NAEPP guidelines, omalizumab is indicated for patients older than 11 years as a step 5 or 6 treatment option. Further data on the long-term safety of omalizumab in children is needed before we can fully advocate adjusting these current recommendations. Overall, this study provides us with further proof that the allergic component of asthma plays a key role in controlling this population's asthma. Further research to investigate the potential use of omalizumab for preventing seasonal peaks would also be beneficial at this time.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107PPP

Jennilee Mumm, PA-C
Todd A. Mahr, MD
La Crosse, WI

Cost-effectiveness of Metered-Dose Inhalers for Asthma Exacerbations in the Pediatric Emergency Department

Doan Q, Shefrin A, Johnson D. *Pediatrics*. 2011;127(5). Available at: www.pediatrics.org/cgi/content/full/127/5/e1105

PURPOSE OF THE STUDY. To compare the incremental cost and effects (eg, averted admission to hospital) of using a

metered-dose inhaler (MDI) against wet nebulization to deliver bronchodilators for the treatment of mildly to moderately severe asthma in pediatric emergency departments (EDs).

STUDY POPULATION. The population was obtained from a Cochrane systematic review in which the efficacy of using MDIs versus nebulizers for the delivery of albuterol to children who presented to the ED with asthma were compared.

METHODS. Cost data were obtained from hospitals and regional authorities involved in the Cochrane review studies. The incremental cost-effectiveness ratio was determined, and Monte Carlo simulations were used to perform probabilistic sensitivity analyses.

RESULTS. Using MDIs in the ED versus wet nebulization might result in a net savings of \$154.95 (Canadian dollars [CAN\$]) per patient. Models suggest that using MDIs is both more effective and less costly than wet nebulization. Sensitivity analyses revealed that MDIs would remain the better strategy even if the net cost of using an MDI was CAN\$70 more expensive than using nebulized bronchodilators.

CONCLUSIONS. Using MDIs with spacers instead of wet nebulizers to deliver albuterol to treat children with mild-to-moderate asthma exacerbations in the ED could lead to significant cost savings.

REVIEWER COMMENTS. Although not statistically significant ($P = .062$), the MDI protocol was more likely to prevent hospital admission than using nebulized bronchodilators. Each hospitalization averted would save CAN\$2499. At the same time, using albuterol MDI (CAN\$262.73) versus albuterol via nebulizer (CAN\$417.68) for acute asthma in the ED would also be less expensive (net cost savings: CAN\$154.95). The authors noted that these results are only generalizable to single-payer health care models similar to those assessed in Canada.

URL: www.pediatrics.org/cgi/doi/10.1542/peds.2011-2107QQQ

Frank S. Virant, MD
Seattle, WA

Cost-effectiveness Analysis of Fluticasone Versus Montelukast in Children With Mild-to-Moderate Persistent Asthma in the Pediatric Asthma Controller Trial

Wang L, Hollenbeak CS, Mauger DT, et al; Childhood Asthma Research and Education Network of the National Heart, Lung, and Blood Institute. *J Allergy Clin Immunol*. 2011;127(1):161-166

PURPOSE OF THE STUDY. To compare the cost-effectiveness of 2 commonly used asthma controllers, fluticasone and

Randomized Trial of Omalizumab (Anti-IgE) for Asthma in Inner-City Children

Jennilee Mumm and Todd A. Mahr

Pediatrics 2011;128;S132

DOI: 10.1542/peds.2011-2107PPP

Updated Information & Services	including high resolution figures, can be found at: http://pediatrics.aappublications.org/content/128/Supplement_3/S132.2
Subspecialty Collections	This article, along with others on similar topics, appears in the following collection(s): Allergy/Immunology http://www.aappublications.org/cgi/collection/allergy:immunology_sub Asthma http://www.aappublications.org/cgi/collection/asthma_sub
Permissions & Licensing	Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at: http://www.aappublications.org/site/misc/Permissions.xhtml
Reprints	Information about ordering reprints can be found online: http://www.aappublications.org/site/misc/reprints.xhtml

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Randomized Trial of Omalizumab (Anti-IgE) for Asthma in Inner-City Children

Jennilee Mumm and Todd A. Mahr

Pediatrics 2011;128;S132

DOI: 10.1542/peds.2011-2107PPP

The online version of this article, along with updated information and services, is located on the World Wide Web at:

http://pediatrics.aappublications.org/content/128/Supplement_3/S132.2

Pediatrics is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. Pediatrics is owned, published, and trademarked by the American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, Illinois, 60007. Copyright © 2011 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 1073-0397.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

