

Correspondence

Has the cost-effectiveness of Xolair (omalizumab) been underestimated?

To the Editor:

In their recent article, Oba and Salzman¹ report on their cost-effectiveness analysis of Xolair (omalizumab) in adults and adolescents with moderate to severe allergic asthma. Additional discussion of some of the findings in this study would benefit your readers in interpreting these results.

Within the context of a cost-effectiveness study using randomized control trial (RCT) data, it was methodologically sound. In the absence of quality adjusted life year (QALY) data, they reported cost per successfully controlled day, which is an emerging standard (symptom-free days) in the literature. They used quality of life data and reported the cost to achieve a 0.5 point increase in quality of life. They performed a sensitivity analysis to deal with uncertainty in their model.

The use of RCT data in this manner is generally not representative of use and outcomes in the real world. We have a variety of issues with the manner in which Oba and Salzman¹ determined resource use from the RCTs.

First, the hospitalization rate is underestimated. Only 2 Xolair patients were hospitalized (<1% of patients), whereas 13 placebo patients were hospitalized (3% of patients). The employer-based study by Birnbaum et al² supports a hospitalization rate of 16%. Emergency department visits were likely also underestimated because patients likely receive urgent treatment from the study investigator, as opposed to having to make an emergency department visit. Furthermore, physician office visits were scheduled more often than one would expect in a nontrial setting.

A significant placebo effect is present whereby 67% of placebo arm patients had symptom improvement at the end of the extension phase. The dropout rate for unsatisfactory therapeutic effect in the placebo group versus Xolair group (eg, 14:1 in the 008 study) is not economically quantifiable.

Because the authors did not use QALYs as a unit of measure for cost-effectiveness analysis, it is difficult to compare Xolair with other treatments without a common outcome measure. There are no published data on the economic benefit of improvement in the Asthma Quality of Life Questionnaire.³ As the authors point out, it was inappropriate of them draw a comparison between their Asthma Quality of Life Questionnaire findings and QALYs.

Oba and Salzman¹ contend that Xolair is not cost-effective and should be reserved for a restricted group of patients with asthma. Given the methodological concerns and the potential errors associated with the inclusion of inappropriate hospital costs, the placebo and protocol effect, and emergency care, the cost-effectiveness of Xolair is likely greater than suggested.

Carl V. Asche, PhD, MSc, MBA

Diana I. Brixner, RPh, PhD

Gary M. Oderda, PharmD, MPH

Pharmacotherapy Outcomes Research Center

Department of Pharmacotherapy

College of Pharmacy

University of Utah

421 Wakara Way, Suite 208

Salt Lake City, UT 84108

Disclosure of potential conflict of interest: Carl V. Asche, none disclosed; Diana I. Brixner, none disclosed; Gary M. Oderda, none disclosed.

REFERENCES

1. Oba Y, Salzman GA. Cost-effectiveness analysis of omalizumab in adults and adolescents with moderate-to-severe allergic asthma. *J Allergy Clin Immunol* 2004;114:265-9.
2. Birnbaum HG, Berger WE, Greenberg PE, Holland M, Auerbach R, Atkins KM, et al. Direct and indirect costs of asthma to an employer. *J Allergy Clin Immunol* 2002;109:264-70.
3. Finn A, Gross G, van Bavel J, Lee T, Windom H, Everhard F, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol* 2003;111:278-84.

Available online March 23, 2005.

doi:10.1016/j.jaci.2004.12.1136

Reply

To the Editor:

We would like to reply to the comments of Asche et al.¹ The hospitalization rate in patients with asthma depends on the severity of the disease, compliance with the treatment, and the use of other asthma medications, especially inhaled corticosteroids. Comparing a hospitalization rate of an entirely different population with the one in our study is not appropriate. In the study by Birnbaum et al,² the hospitalization rate was not related to asthma only but was likely related to a number of other unidentified conditions. It is unlikely that omalizumab would be indicated in a significant number of patients in their population. There are no data in the study by Birnbaum et al² on the asthma controller medications provided to the patients. It is likely that regular use of inhaled steroids by employees with asthma in the study by Birnbaum et al² would have reduced the direct and indirect costs. A cost-effectiveness analysis of a new medication should be performed by using a population in which it would be used.

It may be true that the incidence of emergency department visits is actually greater in a real world setting. However, it is unlikely that we underestimated the cost-effectiveness of omalizumab, because the cost of emergency department visits was almost negligible in our study (\$0.01 per day in the omalizumab group and \$0.02 per day in the placebo group). The impact of emergency department visits on the cost effectiveness is still minimal even if we assume the incidence of emergency department visits is 10 times higher in a less controlled environment.