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Cohorts in economic comparison might not have been comparable

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To the Editor:

Stempel et al¹ present interesting observational data from a large health care database comparing the clinical and economic consequences of alternative pharmacologic management decisions on patients with asthma uncontrolled by inhaled corticosteroids and short-acting bronchodilators. Current guidelines for asthma management specify various options for such patients, including add-on therapy with long-acting β_2 -agonists or leukotriene receptor antagonists, both of which have been shown to be effective in randomized controlled trials. However, guidelines do not specify which option is the most clinically effective or cost-effective for the individual patient or for groups of patients. The difficulties of generalizing results from the highly selected patients entering randomized controlled trials to the heterogeneous patients treated in general practice and the need for generalizable economic outcome data make such real-world observational studies valuable and relevant.

It is, however, imperative that such studies are performed to high standards and presented in published articles. Large electronic databases are powerful tools, and it is possible to trawl such data for statistically significant results that might be chance findings. Quality

markers for cohort and economic evaluations² and for observational studies³ have been published, and important elements that should be described include the following:

1. stated a priori hypotheses, with commitment to publish positive or negative results, regardless of the favorability of outcomes to the sponsor's product;
2. how the evaluation was made and the quality of the database used;
3. steering committee of investigators independent of pharmaceutical industry sponsors;
4. discussion addressing possible causes of bias in results; and
5. definition of baseline cohorts with respect to demographics, appropriateness and risk of therapies, and adjustments for inequalities in susceptibility to outcomes.

It is particularly important to be aware of the confounding factors resulting from nonrandom assignment of patients to different therapies, and in this study we have concerns that the cohorts of patients receiving the different therapies compared had important differences that might affect the outcomes. The baseline comparisons of the cohorts show that those receiving montelukast were younger and more likely to be male and had higher preindex management costs, indicating less well-controlled disease than seen in those in the salmeterol group. Although the authors state that these differences were "controlled for" in the multivariate analysis, it might point to significant differences in the cohorts that could undermine the very basis of the comparison. In addition, the nonasthma health costs were higher in the montelukast cohort than in the salmeterol cohort, indicating the possibility of greater comorbidity and again pointing to noncomparability of the groups.

We also have some concerns that the odds ratios for hospital and emergency department visits presented in the bar charts A and B did not contain CIs; in fact, the *P* values presented at the foot of the diagram show that difference on odds ratios between the inhaled corticosteroid plus montelukast and the inhaled corticosteroid plus salmeterol cohorts were not significant for any of the parameters examined.

Although we applaud the use of such real-world data to answer important questions regarding cost-effective management of asthma in the community, we have some concerns over the reported methodology of this study and would suggest that the conclusions be treated with some caution.

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1. Stempel DA, O'Donnell JC, Meyer JW. Inhaled corticosteroids plus salmeterol or montelukast: effects on resource utilization and costs. J Allergy Clin Immunol 2002;109:433-9.

MEDLINE

CROSSREF

ABSTRACT

FULL TEXT

2. Scottish Intercollegiate Guideline Network. Available at: <http://www.sign.ac.uk>. Accessed January 5, 2002.

3. Radford MJ, Foody JM. How do observational studies expand the evidence base for therapy? JAMA 2001;286:1228-30.

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