Asthma affects 300 million people worldwide (1). Approximately 20 million people in the United States have asthma, of whom half have immunoglobulin E–mediated (allergic) asthma (2, 3). Allergic asthma sufferers produce IgE, a class of antibodies associated with allergic reactions, when they come into contact with allergens (4). The recommended treatment for patients with moderate-to-severe asthma is combination therapy with inhaled corticosteroids and a long-acting inhaled beta2-agonist (5, 6). One such combination therapy is salmeterol and fluticasone (7). Many patients with moderate-to-severe asthma remain poorly controlled despite receiving care that is consistent with the 2002 National Heart, Lung, and Blood Institute treatment guidelines (8, 9). Patient-reported outcomes among subjects with moderate-to-severe IgE-mediated (allergic) asthma (2, 3). 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METHODS

Study Design

A cross-sectional study design was utilized. Potential subjects completed an Internet-based screener to determine their eligibility, and then eligible subjects were immediately asked to complete an Internet-based questionnaire.

To be eligible to participate, subjects must have had patient-reported in vitro reactivity to a perennial allergen known to trigger allergic asthma and they must have either been on omalizumab for the past 4 to 12 months (omalizumab start group), hereafter referred to as (OSG) or on SFC (250/50 or 500/50 mcg/puff, one puff twice daily) for at least the past 12 months (SFC continuation group). In addition, subjects had to be between 18 and 55 years of age and a nonsmoker for at least 6 months. As a function of the study design, subjects also needed to have Internet access and be willing to provide online informed consent.

The screener and questionnaire were developed based on literature reviews and expert opinion from clinicians and outcomes researchers. The instruments were pretested in 10 subjects and modifications were made based on feedback received.

Four primary outcomes, each based on validated measures, were included in the final questionnaires to assess impact on sleep, work productivity, activity level, and asthma control. The Jenkins Sleep Evaluation Questionnaire (16) is a 4-item measure that evaluates the impact of therapies on sleep problems, with a 1-month recall period and scoring range of 0 to 20. Work Productivity Activity Impairment-Asthma (17) is a 9-item measure that assesses the percentage of work impairment and activity impairment because of the asthma during the past 7 days. The Valued Life Activities (VLA) Questionnaire (18) is a 32-item measure that assesses ability to perform activities that individuals enjoy or find meaningful with a 1-week recall period and scoring range of 0 to 3. The Asthma Control Test (ACT) (19) is a 5-item measure of asthma control with a 1-month recall period and scoring range of 5 to 25. An ACT score of 20 or higher is considered controlled asthma.

In addition, the final questionnaire included original single-item questions regarding the primary outcomes (i.e., asthma control, ability to sleep, ability to participate in leisure activities, and work productivity) in which subjects were asked to recall their status one year ago. These items served as baseline data in the analysis and were used as covariates in the models comparing the OSG and SFC groups. Additional covariates were included. Specifically, subjects who had a low propensity for receiving omalizumab (i.e., subjects in the bottom 3 quintiles) were excluded from the final analysis. This exclusion ensured that there was substantial overlap with respect to the level of control and severity between the SFC continuation group and the OSG, allowing for a robust statistical adjustment for the remaining group differences. Descriptive statistics were generated for demographics, medication use, and single-item patient-reported outcomes from one year ago.

In the analysis of primary outcomes, to assess asthma control, subjects were dichotomized into controlled (ACT ≥ 20) and uncontrolled (ACT < 20), and logistic regression models were generated to calculate the unadjusted and adjusted odds ratios (ORs) (OSG vs. SFC continuation group). For the remainder of the outcomes (mean sleep problems scale score, mean percent overall work impairment, mean percent activity impairment, mean VLA average difficulty rating), linear regression models were generated to calculate the unadjusted and adjusted least-squares means (LSM) differences between treatment groups. Analyses were adjusted for propensity score quintile, how the subject heard about the study, and the relevant single-item questions pertaining to the primary outcomes from one year ago.
example, in the analysis of the sleep problems scale score, the relevant single-item question that was included in the adjustment asked subjects how much their asthma affected their ability to sleep approximately one year ago, on a scale from 0 (no effect) to 10 (completely prevented me from sleeping). Sensitivity analyses were conducted using a 1:1 match on propensity score rather than adjusting for propensity quintile.

Missing data were rare. Three subjects had missing data for the single-item work impairment question in reference to 1 year ago, and 3 SFC continuation subjects had missing data with respect to change in medication dose. These subjects were excluded from relevant analyses. All other data were nonmissing.

RESULTS

A total of 92 OSG subjects and 1220 SFC continuation subjects were enrolled in the study between June and November 2006.

Propensity Modeling: Likelihood of Being in the OSG

Table 1 contains unadjusted and adjusted ORs that represent the likelihood of being in the OSG versus the SFC continuation group for various subject characteristics. The adjusted results control for variables such as demographics and level of functioning one year ago. Subjects were more likely to be in the OSG if they were male (adjusted OR, 1.94; \( p = 0.030 \)), if they were treated by an allergist or pulmonologist (adjusted OR, 17.38, \( p < 0.001 \), and 9.45, \( p < 0.001 \), respectively), and if they had commercial/preferred provider organization (PPO) or health maintenance organization (HMO) health insurance (adjusted OR, 3.54, \( p = 0.003 \), and 2.41, \( p = 0.047 \), respectively). Subjects with greater asthma control were less likely to be in the OSG (adjusted OR, 0.43; \( p < 0.001 \)) while subjects with greater leisure impairment were more likely to be in the OSG (adjusted OR, 1.15; \( p = 0.012 \)). Subjects with greater sleep and activity impairment appeared to have a greater propensity for being in the OSG in the unadjusted analysis; however, these variables were not significant in the adjusted analysis because of at least in part to their high correlations with leisure ability (ranging from \( r = 0.774 \) to 0.83) and asthma control (ranging from \( r = -0.63 \) to \(-0.68\)).

Based on these results, each subject was assigned a propensity score, indicating the likelihood of that subject being in the OSG based solely on his or her demographic or clinical characteristics from one year ago. As described in the methods section, subjects in quintiles 1 to 3, with the lowest likelihood of receiving omalizumab, were excluded. The excluded population had 790 subjects, 6 in the OSG and 784 in the SFC continuation group. The excluded population did not differ from the analysis population with respect to age, gender, race, or ethnicity. As expected, and in agreement with the OR analysis, fewer subjects in the excluded population were treated by a specialist for their asthma and more subjects in the excluded population had an insurance type other than commercial/PPO or HMO. In addition, subjects in the excluded population had better asthma control and less impairment caused by asthma on their ability to sleep, their productivity, and their ability to do regular daily activities.

Subjects who were excluded as a result of the propensity model results all had a predicted probability of being in the OSG of less than 2.92%. The following results were based on the remaining analysis population of 522 subjects, with 86 subjects in the OSG and 436 subjects in the SFC continuation group. As a sensitivity analysis, the adjusted models were regenerated without excluding patients on the basis of propensity score and similar results were obtained across all outcomes.

### Table 1.—Propensity score models for OSG vs. SFC continuation group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable OR†</th>
<th>95% CI</th>
<th>( p )</th>
<th>Multivariable Stepwise Logistic Regression OR‡</th>
<th>95% CI</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per 10 years)</td>
<td>0.98</td>
<td>(0.78, 1.23)</td>
<td>0.8609</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.17</td>
<td>(0.70, 1.94)</td>
<td>0.5468</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-White</td>
<td>1.26</td>
<td>(0.69, 2.28)</td>
<td>0.451</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.72</td>
<td>(0.41, 1.27)</td>
<td>0.2617</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College degree or higher</td>
<td>0.98</td>
<td>(0.64, 1.49)</td>
<td>0.9131</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pet(s)</td>
<td>0.63</td>
<td>(0.41, 0.99)</td>
<td>0.0427</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergist</td>
<td>19.6</td>
<td>(9.26, 41.47)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonologist</td>
<td>11.3</td>
<td>(4.98, 25.67)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insurance type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial/PPO</td>
<td>2.42</td>
<td>(1.18, 4.97)</td>
<td>0.0159</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HMO</td>
<td>2.08</td>
<td>(0.96, 4.50)</td>
<td>0.0634</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma control self-rated 1 year ago</td>
<td>0.34</td>
<td>(0.27, 0.43)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep ability affected 1 year ago</td>
<td>1.24</td>
<td>(1.16, 1.33)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work productivity affected 1 year ago</td>
<td>1.29</td>
<td>(1.19, 1.38)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity impairment affected 1 year</td>
<td>1.27</td>
<td>(1.17, 1.38)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leisure impairment affected 1 year</td>
<td>1.35</td>
<td>(1.25, 1.45)</td>
<td>&lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\( \text{CI} = \text{confidence interval;} \text{ HMO} = \text{health maintenance organization;} \text{ OSG} = \text{omalizumab start group;} \text{ PPO} = \text{preferred provider organization;} \text{ SFC} = \text{salmeterol/fluticasone combination.} \)

\( \text{‡} \text{OSG} (n = 92); \text{ SFC} \text{ continuation group} (n = 1220). \)

\( \text{§} \text{Denotes the odds of being in the OSG relative to the odds of being in the SFC continuation group.} \)

\( \text{Based on scale from 1–5, where 1 denotes not controlled and 5 denotes completely controlled.} \)

\( \text{Based on scale from 0–10, where 0 denotes no effect and 10 denotes complete prevention of activities.} \)

\( \text{Since this question was only asked of a subset of subjects (those currently employed) it was not considered in the construction of the propensity score model.} \)
Descriptive Statistics

Demographic characteristics were computed by treatment group (Table 2). The groups did not differ with respect to age, gender, or race/ethnicity. Significant differences were found between treatment groups in the type of physician that primarily treats their asthma. More subjects in the OSG (70.93%) were treated by an allergist or an immunologist. For both treatment groups, the most common health insurance type was commercial/PPO, followed by HMO.

The median number of months since initiating therapy was 8 for OSG subjects and 38 for SFC continuation subjects. How subjects heard about the study differed as expected because of the recruitment scheme. Most SFC continuation subjects (63.99%) were recruited online through HPOL. Other sources of recruitment among OSG subjects were other Internet sources (47.63%), health-care providers (1.38%), paper flyers (0.23%), and other sources (0.46%). The most common sources of recruitment among OSG subjects were other Internet sources (47.67%), paper flyers (20.93%), health-care providers (16.28%), and HPOL (16.28%).

In the OSG, 76.74% of subjects were on SFC from one year ago. In the SFC continuation group, by design, 100% of subjects were on SFC from one year ago. Over 60% of subjects in the SFC continuation group were on the 250/50 mg/puff (one puff twice daily) strength medication, and 69.95% had been on the same strength medication for at least a year.

Self-Reported Outcomes From One-Year Ago

The results of single-item questions related to the primary outcome measures from one year ago are presented in Table 3. Subjects in the OSG reported being significantly worse off one year ago to starting omalizumab than subjects in the SFC continuation group in terms of asthma control, sleep, work productivity, regular daily activities, and leisure activities.

Primary Outcomes

Figure 1 presents the current primary outcomes for the OSG versus the SFC continuation group as measured by multi-item validated scales, after adjustments for propensity score quintile, how the subject heard about the study, and the relevant single-item score from one year ago. The OSG was more than twice as likely to have controlled asthma than the SFC continuation group (OR, 2.62; \( p = 0.005 \)). In addition, the OSG had less activity impairment (17.47% vs 37.69%) (LSM difference, 13.36; \( p < 0.001 \)) and less work impairment (37% vs 50.90%) (LSM difference, 13.36; \( p < 0.001 \)) and less work impairment (17.47% vs 22.74%) compared with the SFC continuation group. There were no statistically significant differences on the work impairment scale (\( p = 0.163 \)). With scores of 3.14 versus 4.80 on the Jenkins Sleep scale, which ranges from 0 to 20, the OSG had fewer sleep problems than the SFC continuation group (LSM difference, −1.65; \( p = 0.004 \)) and, with VLA scores of 0.42 versus 0.66 on a scale of 0 to 3, the OSG also had less difficulty in valued life activities than
TABLE 3.—Single-item patient-reported outcomes from one year prior.

<table>
<thead>
<tr>
<th>Characteristic*</th>
<th>OSG (n = 86)</th>
<th>SFC continuation group (n = 436)</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>How would you rate your asthma control? (1–5)‡</td>
<td>2.16 (0.80)</td>
<td>2.80 (0.98)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>How much did asthma affect your ability to sleep? (0–10)§</td>
<td>5.21 (3.11)</td>
<td>4.01 (3.13)</td>
<td>0.0013</td>
</tr>
<tr>
<td>How much did asthma affect your productivity while you were working? (0–10)§</td>
<td>4.42 (3.22)</td>
<td>3.16 (2.90)</td>
<td>0.0025</td>
</tr>
<tr>
<td>How much did asthma affect your ability to do regular daily activities? (0–10)§</td>
<td>5.98 (2.86)</td>
<td>4.67 (3.09)</td>
<td>0.0003</td>
</tr>
<tr>
<td>How much did your asthma affect your ability to participate in leisure activities? (0–10)§</td>
<td>5.42 (3.01)</td>
<td>3.81 (2.96)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

OSG = omalizumab start group; SFC = salmeterol/fluticasone combination.

*Mean (SE), unless otherwise indicated.

†P values derived from Student’s t-test and chi-square test for continuous and categorical variables, respectively, unless otherwise indicated.

‡Based on scale from 1–5, where 1 denotes not controlled and 5 denotes completely controlled.

§Based on scale from 0–10, where 0 denotes no effect and 10 denotes complete prevention of activities.

the SFC continuation group (LSM difference, –0.24; p < 0.001).

Sensitivity analyses, using propensity score matching instead of a model-based adjustment for propensity score produced generally similar results. Based on this method the estimated effect of OSG on control was slightly lessened compared to the primary protocol-specified analysis, but remained statistically significant (OR = 2.1, p = 0.038). Effects on sleep, daily activities, and leisure activities were comparable between the two analyses. Additionally, the relationship between SFC continuation and work impairment was estimated to be somewhat greater (estimated difference of 11 percentage points, p = 0.015) using the matching approach.

**DISCUSSION**

Concurrent with the completion of this study, new guidelines were issued stating that “Omalizumab is used as..."
adjunctive therapy for patients 12 years of age who have sensitivity to relevant allergens (e.g., dust mite, cockroach, cat, or dog) and who require step 5 or 6 care (for severe persistent asthma) i.e., patients who are uncontrolled on Step 4” (22). Because OSG is specifically recommended for poorly controlled patients, identifying an appropriate comparison group in an observational study is a challenge. The objective of this study was to assess and compare patient-reported outcomes among subjects with IgE-mediated (allergic asthma) initiating omalizumab and a similarly poorly controlled cohort of subjects receiving moderate-to-high doses of SFC, who continued on SFC for at least a year without adding omalizumab. Results from an adjusted analysis of multi-item, validated instruments showed that subjects in the OSG reported greater asthma control, fewer sleep problems, less activity impairment, and less difficulty with valued life activities.

Future research may address some of the limitations of this study. The generalizability is limited by the use of an on-line questionnaire and a convenience sample. Because the questionnaire was administered online, the responses may not be representative of subjects who do not have Internet access or who are less familiar with the Internet. This limitation could be addressed by replicating the study with a paper questionnaire or personal interview. The extent to which the use of a convenience sample limits the generalizability is unknown and would best be addressed through a study with probability sampling. Selection bias may have been introduced into the study by the use of different recruitment sources for the OSG and SFC groups. Because of the difficulty in identifying OSG patients through traditional sources, OSG patients were primarily recruited through a specialty pharmacy. This limitation was addressed through the multivariable analysis. The study design is limited by the ascertainment of baseline data through patient recall of asthma status one year ago. Patients were asked a series of single-item questions regarding the primary outcomes, including asthma control, ability to sleep, ability to participate in leisure activities, and work productivity. This limitation could be addressed with a prospective study design.

Subjects who were identified as having a very low propensity for receiving omalizumab were excluded from the analysis, which resulted in the exclusion of 6 OSG subjects and 784 SFC continuation subjects. This raises the possibility that a more comprehensive approach to collecting baseline data could have identified additional subjects who were nearly certain to be treated with one strategy or the other. The success of the propensity score adjustment depends on having groups that are overlapping if not comparable. Furthermore, the success of a propensity score analysis depends on accounting for all important covariates. In this analysis, an effort was made to include all important covariates, but it is possible that one or more were omitted. In particularly, insufficient smoking data were collected to identify possible chronic obstructive pulmonary disease patients, and data on other comorbidities such as gastroesophageal reflux disease were not collected. Data were collected on emergency room visits and hospitalizations, but the timing relative to starting omalizumab was not collected, so the data could neither be used as a pre-treatment covariate or a post-treatment outcome. A prospective, randomized study would avoid selection bias while addressing these limitations of a propensity score analysis.

This study should not be misconstrued as a comparison of SFC versus omalizumab. Omalizumab is not a substitute for SFC. Many of the subjects in the OSG were also taking SFC, which reflects current practice patterns. Thus, the results of this study may help clinicians better understand the potential benefits of omalizumab as an add-on therapy.

Despite the limitations of this study, there is value in the use of a naturalistic design comparing 2 common treatment strategies. That is, continuation of SFC without omalizumab versus initiation of omalizumab. Research that mirrors how subjects are treated in the real world is helpful for health-care providers and decision makers.

In conclusion, subjects with allergic asthma who started taking omalizumab reported more improved outcomes than similar subjects who continued taking SFC therapy with regard to asthma control, sleep problems, activity impairment, and difficulty with valued life activities.

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