Objective: To determine the effectiveness of endoscopic sinus surgery (ESS) for individual symptoms, medication use, and related factors in patients with chronic rhinosinusitis (CRS).

Design: Nonrandomized, prospective, clinical trial.

Interventions: Adult patients with medically refractory CRS were examined before ESS with the Rhinosinusitis Symptom Inventory to catalog major and minor symptoms, medication use, physician visits, and missed workdays due to CRS. After a minimum 6-month follow-up after ESS, patients were examined to determine response to therapy. After computation of Rhinosinusitis Symptom Inventory domains, comparisons were conducted and effect sizes were computed for the change in symptoms after surgery.

Results: One hundred adults completed the examination, with a mean follow-up of 19.0 months. Before surgery, the mean major symptom scores ranged from 2.5 to 3.5 (Likert scale, from 0 [symptom absent] to 5 [maximum severity]) and the minor symptom scores ranged from 0.8 to 2.8. After surgery, statistically significant decreases in major and minor symptoms were noted (P<.001 for all). The largest effect sizes were noted for the decreases in facial pressure, congestion, nasal obstruction, rhinorrhea, and headache (absolute value of effect size >0.85 for all). Similarly, large effect sizes were noted for decreases in symptoms in the nasal (−1.30), facial (−1.13), and total (−1.25) symptom domains of the Rhinosinusitis Symptom Inventory. Medication use actually increased for topical nasal corticosteroids, but decreased for prescription antihistamines. A mean reduction of 1.1 antibiotic courses (mean decrease of 2.3 weeks taking antibiotics) was noted after ESS.

Conclusions: Endoscopic sinus surgery provides significant symptom relief for the nasal and facial symptoms associated with CRS. Patients will often still require topical nasal corticosteroids for the management of their CRS, but can expect decreases in antibiotic requirements after ESS.


CHRONIC RHINOSINUSITIS (CRS) is an extremely common clinical condition, affecting an estimated 20 million Americans.1 The quality-of-life health impact and cost of treatment of patients with CRS are notable and potentially staggering.2 In addition to quality-of-life impact, medical resource consumption for the treatment of CRS is significant. In a large cohort of patients undergoing examination and treatment for CRS, it was recently shown that, on average, yearly medical treatment of an individual patient with CRS consumes almost $1000 in medical costs and more than $1500 in overall economic costs.3 Similar findings have been reported by others.4 Therefore, cost-effective treatment regimens for CRS are strongly needed.

Recently, the effectiveness of endoscopic sinus surgery (ESS) has been questioned.5 Some researchers6,7 have cited recurrence rates and incomplete relief of symptoms as evidence against the effectiveness of ESS. Some of these evolving opinions contrast with previous evidence8-10 suggesting that ESS is effective for the treatment of CRS. Because the diagnosis of CRS is predicated on symptom criteria elaborated by the Task Force on Rhinosinusitis, determining the success or failure of a treatment regimen for CRS should naturally be based on an evaluation of symptom relief supplemented by quality-of-life assessments.11 Such information on symptom improvement would be useful in counseling patients who have specific bothersome symptoms from CRS with respect to the likelihood that such symptoms will respond to ESS.
In addition to expectations of subjective symptom improvement, physicians in the medical community are increasingly being asked to show that treatment modalities that they provide are cost-effective and efficient. In many instances, this includes demonstrating that a given treatment results in decreased medication use, reduced physician visits, and increased workplace productivity. This study was conducted to determine the effectiveness of ESS with respect to reduction in individual symptoms, medication use, and economic costs associated with CRS.

METHODS

A consecutive series of adult patients undergoing ESS for medically refractory CRS formed the population cohort for this nonrandomized, prospective, clinical trial. This study was approved by my hospital’s Committee on Clinical Investigations. Eligibility criteria for inclusion were as follows: (a) satisfaction of established clinical criteria for the diagnosis of CRS; (b) confirmatory radiographic evidence of CRS according to criteria proposed by Bhattacharyya and Fried; and (c) medical refractoriness of CRS demonstrated by persistent symptoms after a minimum of 12 weeks of therapy with topical nasal corticosteroids, broad-spectrum antibiotics, and, where clinically appropriate, nonsedating antihistamines.

Before surgical therapy, each patient completed the Rhinosinusitis Symptom Inventory (RSI), which catalogs major and minor symptoms of CRS on a 6-point Likert scale (0 indicates symptom absent; 5, symptom very severe). In addition, the RSI catalogs medication use (topical nasal corticosteroids, prescription antihistamines, and oral antibiotics), physician visits, and workdays missed due to CRS (Figure 1). The reliability and sensitivity to change for nasal interventions of this inventory have been previously described.

Each patient underwent ESS with a standard technique in the outpatient setting. The extent of surgery was determined according to the preoperative computed tomographic scan and nasal endoscopy. There were no major surgical complications. Postoperative management with medical therapy was determined by assessment of the postoperative endoscopic examination after healing and evaluation of tissue histopathological features obtained at surgery. In all instances, patients with gross polypoid rhinosinusitis were maintained on topical nasal corticosteroids for a minimum of 6 months after surgery according to protocol.

At a minimum of 6 months after surgery, patients completed the postoperative RSI. Data were tabulated and imported into a commercially available software program (SPSS for Windows, version 10.0; SPSS Inc, Chicago, Ill). Standard descriptive statistics were computed for demographic and staging variables. Symptom domain scores for the RSI were computed for the preoperative and postoperative inventories. The raw change and effect size were computed for each of the symptom variables as well. The effect size is calculated by dividing the measured change for a clinical variable by the pooled standard deviation for that clinical variable (ie, pooled over all patients). For reference, an intervention-related effect size of 0.2 is considered small, 0.5 is considered medium, and 0.8 is considered good or large. These ranges have been validated for patient-reported symptoms.

Symptom scores, domain scores, medication use, and medical resource use were compared before and after surgery with the paired Wilcoxon signed rank test or the McNemar test as appropriate, with significance set at .05. When necessary for patients with less than a full 12 months of follow-up after surgery, data for medication use and resource use were adjusted for the difference, with a weighted average to determine the medication use and resource use attributable to the postoperative period. To cross-check for this correction, the statistical analysis was repeated, excluding patients with less than 1 full year of follow-up.

RESULTS

SYMPTOM SCORES

A total of 150 patients were initially eligible for this trial. At follow-up, 100 patients (response rate, 66.7%) completed the postoperative RSI form. The mean patient age was 41.0 years, with a female-male ratio of 2:1. The mean preoperative Lund score was 9.0 (95% confidence interval, 7.8-10.2). The mean duration of follow-up for the study cohort was 19.0 months (range, 6.4-36.6 months).

The distribution of symptom scores for major and minor symptoms before and after surgery is depicted in Table 1. Scaled symptom scores according to nasal symptom, facial symptom, oropharyngeal symptom, systemic symptom, and total symptom domains before and after surgery are also depicted in Figure 2. Statistically
significant reductions in major and minor symptom scores were achieved for all symptoms. Large effect sizes were noted for reductions in facial pressure, nasal obstruction, congestion, and rhinorrhea. Similar large effect sizes were noted for reductions in headache and fatigue. Moderate effect sizes were noted for hyposmia, fever, halitosis, cough, and ear pain. The reduction in dental pain from surgery exhibited only a small effect size.

Statistically significant reductions in scaled symptom scores for each of the symptom domains were realized after ESS. Large effect sizes were noted for reductions in nasal and facial symptom domains, and lesser effect sizes were noted for reductions in systemic symptoms, followed by oropharyngeal symptoms. Overall, the decrease in the total symptoms was statistically significant and exhibited a large effect size (−1.25), indicating a pronounced improvement in symptoms after surgery.

**MEDICATION USE**

Table 2 displays before and after medication use for topical nasal corticosteroids, prescription antihistamines, and oral antibiotics for the study group. A statistically significant decrease in the fraction of patients using prescription antihistamines after surgery was noted, whereas the fractional decrease in the number of patients using topical nasal corticosteroids was not significant. In fact, weekly use of topical nasal corticosteroids was greater after surgery than before surgery. The mean number of courses of antibiotics and the mean number of weeks in use for antibiotics exhibited statistically significant decreases after surgery (Table 2). These decreases correlated strongly ($r=0.66$, $P<.001$) with the reported decrease in frequency of acute or chronic infection, indicating internal consistency of the data.

**RESOURCE CONSUMPTION**

Patients missed an average of 4.9 workdays and visited their physician 5.0 times because of CRS in the 12 months before surgery. After ESS, the mean number of missed workdays due to CRS decreased to 2.9 (net change, −2.0 days) and the mean number of physician visits for CRS declined to 2.7 (net change, −2.3 visits). Both of these reductions were statistically significant ($P=.03$ and $P<.001$, respectively). For resource consumption and medication use, a statistical cross-check excluding patients with less than 1 year of follow-up revealed no change in the statistical results.

The diagnosis, staging, pathophysiological features, medical management, and surgical treatment of CRS are still...
and colleagues evaluated symptom response to ESS with a Likert scale questionnaire. They documented significant percentage reductions in symptoms after ESS, with excellent results in terms of nasal obstruction, headache, and postnasal drip. However, minor symptoms, such as cough, dental pain, and otalgia, were not evaluated. Similarly, information regarding the net positive response for many symptoms after ESS can be extracted from analysis of the quality-of-life literature in patients with CRS. In general, the literature supports reductions in major symptoms of CRS after ESS.

These data clearly indicate that, from a symptom standpoint, ESS is effective at reducing most of the symptoms accompanying CRS. For comparison and discussion, the influence of surgery on symptom scores is related to effect size. The effect size is an excellent way to measure response for symptom scores, because it takes into account the overall pooled standard deviation, thereby standardizing the response variable into an interpretable coefficient. As noted, effect sizes greater than 0.8 may be considered quite good, thus indicating a substantial response to the intervention (ie, ESS). In general, the effect size is much more meaningful from a clinical standpoint than the raw change in symptom score. We found that for the major symptoms of CRS, ESS provided effective relief, with the exception of hyposmia. Interestingly, ESS was beneficial in terms of effect sizes in reducing the minor symptoms of CRS, but the noted response was less in magnitude. Although headache is considered a minor symptom of CRS, it did respond well to ESS, with a large effect size. I was somewhat surprised at the response of systemic symptoms (fever and fatigue) to ESS. This response to ESS argues that CRS does, indeed, symptomatically affect more than just the head and neck regions, perhaps relating to the global quality-of-life effects of CRS.

One drawback to the present study is the lack of a control group not undergoing ESS. There is a known placebo effect to surgical intervention, and this may in part account for some of the symptom responses. However, the effect sizes noted for major symptoms are substantially greater than would be expected by chance alone. Furthermore, extensive medical treatment has previously failed in these patients and, therefore, the patients are starting with a refractory state of health. Thus, there exists a selection bias for more difficult to treat cases that would tend to further emphasize the strength of the benefit realized from surgery. In addition, a previous investigation has shown that at least the radiographic com-

Table 2. Medication Use Before and After Endoscopic Sinus Surgery

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Before Surgery</th>
<th>After Surgery</th>
<th>Net Raw Change*</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical nasal corticosteroids</td>
<td></td>
<td></td>
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<tr>
<td>Patient use, %</td>
<td>53.0</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of courses, mean</td>
<td>3.0</td>
<td>2.1</td>
<td>−0.9</td>
<td>.001</td>
</tr>
<tr>
<td>Time in use, mean, wk</td>
<td>6.9</td>
<td>4.5</td>
<td>−2.4</td>
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*A negative value implies decrease in use. The value may not equal the pure difference between before and after surgery because of rounding.

subject to controversy. A significant advance in the diagnosis of CRS came with the American Academy of Otolaryngology’s Task Force on Chronic Rhinosinusitis, with the delineation of clinical criteria for the diagnosis of CRS. However, these diagnostic criteria have been questioned, especially when tested against radiographic criteria for the diagnosis of CRS. Recently, radiographic criteria based on the Lund system for the diagnosis of CRS were detailed. These criteria were used in the present study for the confirmatory diagnosis of CRS in this study cohort, and contribute to the uniformity of diagnosis in the patient population under study.

Traditionally, ESS has been reserved for medically refractory cases of CRS and is believed to be largely effective even in this refractory group of patients who would likely have a poor prognosis. Initially thought to be highly effective in the management of CRS, the relative effectiveness of ESS has recently been questioned, even in the popular press. Some of this controversy has stemmed from questions regarding the role of fungi in the pathophysiological features of CRS, recurrence rates after surgery, and the frequency of bacterial infection after ESS.

One of the problems in evaluating the success of ESS for CRS is that there are several ways to define a successful outcome. Historically, success with ESS has been categorized as marked improvement in symptoms or according to patient satisfaction with surgery, arguably nebulous measures. More objective measures, such as quality-of-life indicators, decreases in medical resource use, and the revision rate, have also been used as measures for success. Excellent previous reports have documented the effect of CRS on quality of life and the improvements in quality of life after ESS. However, given that the diagnosis of CRS is predicated on patients’ symptoms, measures of success in the treatment of CRS should be primarily based on these same diagnostic symptoms. Furthermore, an individual patient may have one or more symptoms that are clearly more bothersome than the other diagnostic symptom criteria for CRS. Such patients typically want to know before surgery the likelihood that their particular symptoms (severe rhinorrhea or severe dental pain) will respond to ESS. Therefore, the present study was undertaken not to determine quality-of-life improvements from ESS but rather to determine the responsiveness of individual symptoms of CRS to surgical therapy.

In a large series of patients undergoing ESS, Damm and colleagues evaluated symptom response to ESS with

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ponent of CRS is consistent and unlikely to respond in placebo fashion.

From a practical standpoint, these data indicate that patients expecting significant decreases in facial pressure, congestion, nasal obstruction, rhinorhea, and headache are likely to receive significant symptom benefit from ESS. Patients in whom other symptoms are their primary complaints accompanying a clinical diagnosis of CRS are less likely to achieve the desired benefit from ESS. Finally, fatigue seems to be an extremely common symptom of CRS, and patients commonly cite this symptom as a motivating force in seeking treatment for their CRS. With some confidence, these data again indicate that fatigue does tend to statistically and clinically significantly improve with ESS.

Although ESS seems effective in reducing symptom scores from CRS, it may be less effective in reducing certain medication requirements. I found that topical nasal corticosteroids were often still used by patients after CRS and in fact the weekly use rate was higher after surgery. Of the 47% of patients not actively using topical nasal corticosteroids just before surgical therapy, most had discontinued corticosteroid use because of ineffectiveness or local adverse effects, such as epistaxis. Similarly, although antihistamine use decreased after surgery, the decrease in weekly antihistamine use was not statistically significant. These data reinforce that CRS is indeed a chronic condition with a multifactorial cause, and that surgical therapy is only one element of the treatment regimen. Further medical management is often required and reinstituted after ESS. I attribute this degree of medication use after surgery to the relatively high Lund scores in this patient cohort and rigorous follow-up of these patients aimed at preventing disease recurrence.

More important, antibiotic use did significantly decrease after ESS. The medical community has voiced increasing concern about antibiotic overuse and potential developing resistance in the United States from the widespread use of antibiotics. Increasing bacterial resistance in patients with CRS and in patients with acute rhinosinusitis after ESS has recently been shown. Decreases in antibiotic use after ESS may translate into a decreased risk of developing antibiotic resistance. This potential benefit from ESS should be considered from a global perspective in treating the patient population with CRS and for individual patients who want to lessen their antibiotic use. It is possible that the reduction in antibiotic use (or the increase in nasal corticosteroid use) could result from investigator bias because these patients were all followed up by one investigator (N.B.). However, greater than 50% of these patients were also followed up by allergy specialists, and on review of the data, antibiotic prescriptions were equally likely to be given by the primary care physician or allergist vs the otolaryngologist. Nevertheless, investigator bias may affect the reported treatment results.

Finally, significant reductions in workdays missed and number of physician visits attributable to CRS were evident from the data. Both of these reductions translate into increased per-person productivity and decreased medical resource consumption after ESS for CRS. Similar economic benefits have been reported by others, and should also be considered in the decision-making process for ESS. For example, for patients in whom CRS is resulting in a significant number of workdays missed, the threshold for ESS might be lowered even in the setting of relatively low symptom scores. Thus, the decision for ESS should include consideration of symptom scores and their likely response to surgical therapy, medication use, and potential economic benefits.

Endoscopic sinus surgery is clinically effective for the treatment of medically refractory rhinosinusitis. Major CRS symptoms, headache and fatigue, can be expected to improve significantly after ESS. Similarly, ESS provides substantial improvement in the nasal, facial, and total symptoms due to CRS. Medication use after ESS may not decrease as much as expected, with the exception of antibiotic use, which does exhibit a substantial decrease. Endoscopic sinus surgery significantly decreases workdays missed and physician visits due to CRS.

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REFERENCES