Cost-effectiveness of Corticosteroid Nasal Spray vs Surgical Therapy in Patients With Severe to Extreme Anatomical Nasal Obstruction

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IMPORTANCE Health insurance companies commonly require a trial of corticosteroid nasal spray prior to authorizing nasal surgery, even in patients with severe to extreme anatomical nasal obstruction, despite lack of data supporting such medical therapy.

OBJECTIVES To provide a model for the comparative analysis of medical vs surgical treatment for nasal obstruction to help maximize health care benefit per dollar spent and to explore the cost-effectiveness of corticosteroid nasal spray in patients with severe to extreme nasal airway obstruction on Nasal Obstruction Symptom Evaluation (NOSE) scores.

DESIGN, SETTING, AND PARTICIPANTS A cost-efficiency frontier economic evaluation was performed. The economic perspective was that of the health care third-party payer. Effectiveness data were obtained from NOSE score questionnaires in 179 patients. An incremental cost-effectiveness ratio was determined from the cost and efficacy data. Comparative treatment groups were medical therapy with corticosteroid nasal spray vs surgical therapy for nasal airway obstruction. The study was conducted between January 1, 2011, and December 30, 2013. The time horizon included 1, 2, and 5 years. Data analysis was completed June 1, 2015.

MAIN OUTCOMES AND MEASURES The primary outcome was cost per quality-adjusted life-year (QALY). A modified Markov decision tree model was used. Costs were obtained from the Medicare 2015 physician fee schedule, and the mean was determined (owing to geographic disparity) along with wholesale and generic pharmaceutical pricing.

RESULTS Among 100 men and 79 women evaluated (mean [SD] age, 37.9 [12.9] years), surgical repair of severe nasal airway obstruction cost $6537 and produced a total of 1.15 QALYs at 1 year. Medical treatment involved a trial of corticosteroid nasal sprays, which cost $520 and produced a total of 1.03 QALYs. The surgical approach was markedly more effective but at greater short-term cost. In cases of extreme nasal obstruction, medical treatment cost $520.73 with 1.004 QALYs, demonstrating an incremental cost-effectiveness ratio (ICER) of $354 693 per QALY compared with no treatment. Conversely, surgical treatment cost $6536.64 and produced 1.136 QALYs, with an ICER of $45 633 compared with medical therapy. At 5 years, the ICER decreased from $45 634 to $8110 per QALY for surgical treatment of extreme nasal obstruction. The medical treatment ICER decreased from $354 693 per QALY at 1 year to $273 704 per QALY at 5 years. An ICER was performed and demonstrated a cost threshold of $50 554 per QALY for surgical treatment compared with $67 518 per QALY for medical treatment at 1 year for severe nasal obstruction. If the evaluation is extended to 5 years, surgical treatment cost $8984 per QALY compared with $52 571 per QALY for medical treatment. Owing to the improved effectiveness outcomes, greater cost savings per ICER was demonstrated in patients with extreme nasal obstruction.

CONCLUSIONS AND RELEVANCE Surgical treatment for patients with severe to extreme anatomical nasal obstruction demonstrates increased short-term expense but is cost-effective in the long term. These data suggest that treatment with corticosteroid nasal spray in patients with documented severe to extreme anatomical nasal obstruction is unnecessary and results in a delay in treatment.

LEVEL OF EVIDENCE NA.

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Nasal airway obstruction is one of the most common reasons for referral to an otolaryngology or facial plastic surgery clinic. Surgical improvement of nasal obstruction may involve septoplasty, repair of nasal valve stenosis (including functional rhinoplasty with osteotomies), and inferior turbinate reduction. Three basic methods for classifying nasal obstruction are (1) objective measures of the nasal airway; (2) patient-reported measures, such as questionnaires; and (3) physician examination and grading. A consensus, criterion-standard objective measure of nasal patency does not exist. Objective measurements of the nasal airway include acoustic rhinometry and rhinomanometry; however, these measures fail to strongly correlate to patient symptoms.\(^1,2,5\) Patient-reported, disease-specific quality-of-life (QOL) measures provide clinically meaningful data to quantify the severity of nasal obstruction and the effectiveness of treatment. Health-related QOL measures are patient-reported, validated questionnaires that reflect the severity of a disease and the effect on a patient’s life.\(^4\) The Nasal Obstruction Symptom Evaluation (NOSE) scale provides a brief, validated, and reliable tool to measure disturbances in QOL specific to nasal obstruction and has been used to develop a severity scale for nasal obstruction.\(^1,2,5\)

The causes of nasal obstruction may be classified by the physician as reversible or fixed. Reversible causes of nasal obstruction commonly involve edema of the nasal mucosa, often due to allergic or nonallergic rhinitis. Medical therapy in the form of corticosteroid nasal sprays may assist in reversing nasal obstruction secondary to mucosal edema. Nonreversible, fixed causes of nasal obstruction include soft-tissue masses, nasal valve stenosis, and nasal septal deviation. These osseous or cartilaginous obstructions usually fail to respond significantly to medical therapy. Ideally, a diagnostic tool would objectively measure the degree to which reversible and nonreversible causes contribute to the subjective sensation of nasal obstruction.\(^6\) Many insurance carriers require a mandatory trial of corticosteroid nasal sprays prior to authorization for surgical procedures to relieve nasal obstruction despite data from the physician, objective measures, and patient-derived questionnaires that may indicate otherwise.

Our study hypothesis was that patients with severe and extreme nasal airway obstruction based on NOSE questionnaires and documented anatomical obstruction would fail to improve with corticosteroid nasal sprays. Eliminating mandatory, nontherapeutic treatment would limit patients’ exposure to unnecessary medications while minimizing the delay to definitive surgical treatment. We further postulated that obligatory medical therapy may be less effective than proceeding directly to surgical therapy without obligatory medical treatment for patients with severe to extreme NOSE scores.

### Methods

This post hoc, retrospective study was conducted at Stanford University. The university’s human subjects committee approved the study, with waiver of informed consent. The data were deidentified.

### Patient Selection

A total of 657 adults (age, 18-65 years) presenting to the facial plastic and reconstructive surgery clinic with a diagnosis of nasal airway obstruction, deviated nasal septum, and nasal valve stenosis between January 1, 2011, and December 30, 2013, were evaluated. Patients met inclusion criteria if NOSE questionnaires were performed and a trial of a corticosteroid nasal spray had been prescribed and completed. Patients who demonstrated no symptomatic improvement after medical therapy were offered surgical intervention, and NOSE questionnaires were completed preoperatively and postoperatively. Exclusion criteria included incomplete NOSE survey responses, incomplete trial of corticosteroid nasal spray, or only cosmetic rhinoplasty (\(n = 431\)). In addition, patients with connective tissue disorders, cleft lip, septal perforation, prior nasal cutaneous malignant neoplasms, and nasal polyposis were excluded (\(n = 47\)). The final analysis included 179 patients.

### Statistical Analysis

NOSE responses were assessed to ascertain outcome data regarding the effectiveness of therapy following medical or surgical treatment. These responses were organized into severity classification categories as mild, moderate, severe, or extreme, as stratified in previous studies.\(^5\) In addition to the NOSE score, visual analog scale (VAS) scores were obtained with each NOSE survey. The VAS QOL index is often described in the literature\(^1\) and may be considered less disease specific than the NOSE questionnaire. Thus, VAS and NOSE scores were compared to assess for correlation. In addition, the mean NOSE and VAS scores were compared with the most recent systematic review of patient-reported nasal obstruction scores.\(^4\)

All patients underwent an initial office visit, 8 to 12 weeks of treatment with corticosteroid nasal spray, and a follow-up office visit. At that point, patients with adequate improvement could elect to continue with nasal corticosteroid spray with annual visits to their primary care physician or specialist for renewal of medication and evaluation. Conversely, if their symptoms demonstrated no improvement, they were offered surgical intervention and a postoperative office visit, as needed, depending on the efficacy of the surgical treatment and their clinical symptoms. If their symptoms had not improved, those patients were more likely to return to the office for revision surgery. These scenarios are illustrated with a decision tree diagram (eFigure 1 in the Supplement).

The quality-adjusted life-year (QALY) is a measure of the value of health outcomes expressed as the utility value induced by the treatment multiplied by the duration of the treatment effect. The QALYs are then incorporated with medical costs to arrive at a final denominator of cost per QALY; this factor may be used to compare cost-effectiveness of any treatment. The utility value is an interval scale in which 0 is an arbitrary value for death and 1 represents full health. Higher values correspond to more desirable states. Disability-adjusted life-year (DALY) is a measure of disease burden and is calculated on a scale in which 0 represents no disability and 1 represents burden equivalent to death; therefore, lower scores correspond to more desirable states.
The DALY calculations tend to be derived from a universal set of standard weights based on expert valuations. Our review of the literature did not find any standard disability weight or index for nasal obstruction. Therefore, we used the NOSE questionnaire, which asks 5 questions related to the severity of the patient’s nasal obstruction and provides a score between 0 and 100. Prior studies have categorized these scores as mild (0-25), moderate (26-50), severe (51-75), and extreme (76-100) based on NOSE scores. The NOSE score provides a relative disability index. The NOSE score was then divided by 100 to provide a value between 0 and 1, with values closer to 0 representing minimal burden of disease and values closer to 1 representing greater burden of disease.

It was assumed that the loss of QOL determined by the respective disease in QALY calculations is equivalent to the level of disability estimated in DALY calculations. Hence, \( q = 1 - d \), where \( q \) indicates the utility index and \( d \), the disability index.

The utility index was then incorporated into the QALY equation to calculate the QALY. The simplest method to measure QALY is multiplication of the utility \( q \) by the time factor. However, the utility value and time are different data types and cannot be combined by a simple product of their numerical values; life-years are expressed in a ratio scale with a true zero, and the utility value is an interval scale in which zero is an arbitrary value for death. Instead, a complex number model, rooted in the Pythagorean theorem, was chosen to calculate QALY. This model respects the interval separating the values on the utility and time scales rather than the exact values, thus respecting the numerical values assigned to the elements.

A health economic model was developed to capture the costs and QALYs. The perspective of this economic evaluation reflects the US health care third-party payer. All costs are expressed in US dollars as of April 2015. The primary outcome was QALY. The incremental cost-effectiveness ratio (ICER), a commonly used equation in health economics, describes the ratio of change in costs between 2 competing strategies divided by the effectiveness between the 2 strategies: (cost strategy A – cost strategy B) / (effectiveness strategy A – effectiveness strategy B).

Results from cost-effectiveness analysis are often presented on a cost-effectiveness plane demonstrating a graphical representation of all possible cost-effectiveness analysis results divided into 4 quadrants (eFigure 2 in the Supplement). The ICERs falling into the northwest and southeast quadrants require no decision; these are quadrants in which one of the treatments is more effective and less costly and therefore dominates the other treatments. In the northwest quadrant, the new treatment is less effective and costs more than the previous treatment and is therefore excluded from cost analysis. The other 2 quadrants (northeast and southwest) illustrate scenarios in which one intervention is more effective yet more costly (northeast quadrant) or less effective and less costly (southwest quadrant).

Cost data were obtained based on the direct costs of medication and Medicare reimbursement rates for physician office visits, surgeon professional services, and facility fee reimbursements. Because of the geographic disparity of Medicare reimbursement, the national payment amount was used as the carrier locality. Depending on provider Medicare assignment agreements, reimbursement rates may vary. Therefore, the means of the facility, nonfacility, and limited reimbursement costs were obtained to ascertain physician office reimbursement rates. Finally, the surgical procedure fee reflects the surgeon’s professional fee based on the Current Procedural Terminology (CPT) code along with the ambulatory surgery facility fees according to 2015 Medicare (CMS.org; https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html) physician fee schedules (eTable 1 in the Supplement).

Results

A total of 179 patients met our inclusion criteria; participants included 100 men (55.9%) and 79 women (44.1%) (mean [SD] age, 37.9 [12.9] years). The severity distribution of nasal airway obstruction on presentation based on initial NOSE responses is listed in Table 1. A total of 138 patients (77.1%) reported severe to extreme nasal obstruction compared with 41 patients (22.9%) reporting mild to moderate obstruction, with overall mean (SD) NOSE and VAS scores of 65.8 (19.5) and 6.7 (2.0), respectively (Table 2). All patients underwent a trial of corticosteroid nasal sprays and were assessed after 8 to 12 weeks. Most patients reported no improvement in their symptoms after use of the spray, with mean NOSE and VAS scores after treatment of 63.7 (20.3) and 6.6 (1.9), respectively (Table 2). These patients were offered surgical correction vs continued medical management with corticosteroid nasal sprays (Table 3).
spray. Surgical correction involved septoplasty, repair of nasal valve stenosis, and inferior turbinate reduction. The senior author (S.P.M.) performed all of the surgical procedures.

Eight patients (4.5%) reported symptomatic improvement following a course of medical therapy; 5 of these patients demonstrated decreases in NOSE scores resulting in decreased severity classification (eTable 2 in the Supplement). Among these 8 patients, the mean pretreatment NOSE and VAS scores were 56.3 (20.3) and 5.5 (2.4), respectively, followed by posttreatment NOSE and VAS scores of 40.6 (16.8) and 3.5 (1.7), respectively. Four of these patients (50.0%) demonstrated NOSE scores indicating mild to moderate obstruction on presentation; the number of patients increased to 6 (75.0%) after use of corticosteroid nasal spray. These patients are further evaluated in the Discussion section.

Of the 171 patients offered surgery after medical treatment failed, 111 (64.9%) underwent surgical correction, and postoperative NOSE scores were collected at the 1-, 3-, and 6-month evaluations (eFigure 1 in the Supplement). The mean postoperative NOSE and VAS scores 6 months postoperatively were 19.4 (17.7) and 2.0 (1.9), which reflect a 46.4-point difference between the mean NOSE scores before corticosteroid nasal spray treatment and postoperatively. Statistically significant differences exist between pretreatment corticosteroid nasal spray and postsurgical NOSE and VAS scores but not in the scores before and after corticosteroid nasal spray (P < .01) (Table 2).

The distribution of patients by severity classification is presented in Figure 1. The distribution of patients in each class (mild, moderate, severe, and extreme) did not change after corticosteroid nasal spray pretreatment. For example, the number of patients with mild nasal obstruction increased by 1 (from 10 to 11), and the number with extreme obstruction decreased by 1 (from 53 to 52) (Figure 1). However, after surgical treatment, the number of patients with extreme nasal obstruction decreased from 52 to 0, and the number with mild obstruction increased from 11 to 81 (Figure 1). Analysis using χ² testing revealed a significant change in distribution when comparing pretreatment to postsurgical severity scores (P < .01), while no change was noted when comparing pretreatment with posttreatment corticosteroid nasal spray scores (P = .40).

Cost data were obtained as demonstrated in eTable 1 and eTable 3 in the Supplement. The cost for medical therapy was approximately $296.59: net cost initial visit (level 4), 3-month trial of corticosteroid nasal spray (generic pricing), and follow-up established visit (level 4). The cost for surgical therapy was $6438.14: net cost initial visit (level 4); mean Medicare physician reimbursement rates based on CPT codes for septoplasty; repair of nasal valve stenosis; inferior turbinate reduction; and global follow-up established visit and facility reimbursement fee. In each case in this study, all 3 CPT codes (30465, 30520, and 30140) were billed.

The mean effectiveness of medical therapy in patients with mild and moderate nasal obstruction demonstrated decreased effectiveness with increased cost compared with no treatment; these treatment arms were eliminated from the analysis. However, the mean effectiveness of medical therapy in patients with severe and extreme nasal obstruction showed a slight improvement in NOSE score outcomes. In addition, all postsurgical patients demonstrated improved NOSE score outcomes but incurred a greater cost for third-party payers compared with medical treatment alone. The associated costs and effects of medical or surgical treatment for severe and extreme nasal obstruction were plotted on a cost-efficiency frontier model (Figure 2). Because both treatment modalities demonstrated improved effectiveness at increased costs compared with no treatment, the ICER associated with each treatment must be calculated to determine the most cost-effective option.

Table 3 reports the costs and effectiveness outcomes, expressed in QALYs, generated by medical and surgical treatment for patients with severe and extreme nasal obstruction. In a cost-utility analysis, costs and outcomes are compared by dividing the incremental cost by the incremental outcome of the observed QALYs. The incremental effectiveness and associated cost for medical therapy were calculated as $2271.55 and 0.07 QALYs, respectively. For surgical therapy, the incremental effectiveness and associated cost were $5798.51 and 0.10 QALYs, respectively. The ICER for medical therapy was $32,474.07/QALY, and the ICER for surgical therapy was $57,985.11/QALY. Because the incremental effectiveness was positive and the ICER was less than $50,000/QALY, medical therapy was considered the most cost-effective option.
If the severity of the nasal obstruction is extreme on presentation, medical treatment cost $520.73 with 1.004 QALYs, demonstrating an ICER of $354 693 per QALY compared with no treatment. Conversely, surgical treatment cost $6536.64 and produced 1.136 QALYs, with an ICER of $45 634 compared with medical therapy. At 5 years, the ICER decreased from $45 634 to $8110 per QALY for surgical treatment of extreme nasal obstruction. The medical treatment ICER decreased from $354 693 per QALY at 1 year to $273 703 per QALY at 5 years. Depending on the willingness-to-pay threshold per QALY, third-party payers may understand which methods of treatment are most efficient, providing the greatest improvement in effect at the lowest cost.

Discussion

Many insurance companies require documentation of treatment with corticosteroid nasal spray in all patients as a requisite to preauthorization for repair of nasal stenosis or even septoplasty, regardless of anatomical findings by the physician. Herein, we have provided evidence that, in patients with anatomical findings indicating severe to extreme nasal obstruction, mandatory use of corticosteroid nasal spray results in a delay in treatment. In many cases, nasal obstruction results from mixed inflammatory and fixed obstructions. Thus, treatment with corticosteroid nasal spray may be of some benefit. Our data suggest that the change in symptoms with corticosteroid nasal spray use in patients with severe to extreme nasal obstruction is minimal. From an insurers’ perspective, the initial cost savings of avoiding a surgical procedure are obvious. Preventing a surgical procedure, even if medical treatment with corticosteroid nasal spray represents just another hurdle for preauthorization, results in substantial savings for the insurer. However, from a patient’s or physician’s perspective, mandatory use of corticosteroid nasal spray results in a delay in surgery, which is the most efficacious therapy. Furthermore, use of corticosteroid nasal spray engenders a small risk of nasal septal perforation.

Herein, we have presented an economic evaluation suggesting that the surgical approach is the most cost-effective intervention compared with medical therapy for severe and extreme nasal airway obstruction. Using 1-, 2-, and 5-year time horizons to incorporate the cost and effect of treatment, both medical and surgical treatments demonstrated increased effectiveness at higher costs (compared with no treatment). Therefore, ICERs were determined to calculate the cost per QALY.

The utility ratio used in this study was based on a retrospective review of NOSE scores between 2011 and 2013 performed by one surgeon (S.P.M.) at Stanford University. Pre- and posttreatment NOSE scores for medical and surgical interventions were reviewed and categorized into severity of nasal obstruction. The effectiveness of surgical treatment in this study was compared with the most recent literature systematic review for surgical treatment of nasal obstruction, demonstrating similar outcomes. The mild- and moderate-severity nasal obstruction NOSE scores were similar for healthy and general populations when generated by a recent systematic review as well as data from our institution.4,5

### Table 3. Incremental Cost-Efficiency Ratios for Patients With Severe and Extreme Nasal Obstruction

<table>
<thead>
<tr>
<th>Time, y</th>
<th>Pretreatment</th>
<th>Net Cost, US $</th>
<th>QALY</th>
<th>ICER, US $</th>
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<td></td>
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<td>No treatment</td>
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<td>1.02888</td>
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<tr>
<td>Medical</td>
<td>520.73</td>
<td>1.03282</td>
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<td>55 087.67</td>
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<td>15 912.36</td>
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<tr>
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<td>5.16410</td>
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</table>

Abbreviations: ICER, incremental cost-effectiveness ratio; NA, not applicable; QALY, quality-adjusted life-year.

* For patients with severe pretreatment symptoms, the ICER was less costly for surgical treatment at all time points.

* The numbers were expanded as shown for calculation of the ICER; the values were rounded to 2 decimal places when the ICER was obtained.
As noted in the Methods section, patients with mild to moderately severe nasal obstruction were excluded from analysis since they demonstrated minimal to negative gains in NOSE scores. Herein, we only examined treatments located in the northeast corner of the diagram (eFigure 2 in the Supplement).

Surgical treatment demonstrated higher QALYs at all time points, and the associated cost per QALY was lower for surgical treatment of severe and extreme nasal obstruction at all time points. The surgical approach is markedly more effective but at a considerably greater cost in the short term, but it was more efficient in the long term. For example, after only 1 year, surgical repair in patients classified as having extreme pre-treatment nasal airway obstruction cost $6537 and produced a total of 1.136 QALYs compared with a treatment cost of $521 and 1.004 QALYs for medical therapy at the same time point. However, calculation of the ICER demonstrated a cost threshold of $45 634 per QALY for surgical treatment compared with $354 693 per QALY for medical treatment at 1 year. With the analysis extended to 5 years, surgical treatment produced $8110 per QALY compared with $273 704 per QALY for medical treatment. Thus, over time, surgical treatment for patients classified as having extreme nasal obstruction was more cost-effective owing to the larger change in QALYs.

Strengths of this economic evaluation include utilization of model data from the best available evidence (3-year cohort of patients by one surgeon [S.P.M.] coupled with a systematic review of the literature),4 use of a disease-specific QOL instrument, and use of a generalizable economic primary outcome (cost per QALY). Limitations of this study include the design of the economic model; the rates of complications with either treatment were not included (eg, adverse effects of pharmacotherapy, rates of septal perforation, cerebrospinal fluid leakage, or recurrence of nasal obstruction). These complication values would strengthen our economic decision model and more appropriately assign a QALY value. Our calculations were limited to the CPT codes 30465, 30520, and 30140. In some cases, other CPT codes may be used for repair of the nasal airway (eg, code 30420). Our economic model failed to report a willingness-to-pay threshold analysis, which could provide a degree of certainty that surgical vs medical treatment is the most cost-effective decision at various willingness-to-pay thresholds. Next, our cost reporting data involved only direct costs. Indirect costs, such as patient productivity loss, time loss required for multiple clinic visits compared with time off from work secondary to nasal obstruction, were not quantified. Finally, there may be a component of selection bias and questionnaire bias; our patients may be inclined to report higher NOSE scores after having invested time and money for a referral to a subspecialist and tertiary care center.

Conclusions

Nasal airway obstruction and treatment is a common presenting symptom in otolaryngology and facial plastic surgery clinics, resulting in substantial costs to health care systems. This economic efficiency frontier model evaluated the cost-effectiveness of medical vs surgical therapy for severe and extreme anatomical nasal obstruction using the best available evidence. Results from the study suggest that surgical treatment is likely to be the most cost-effective intervention compared with continuing medical treatment. This economic efficiency frontier model may allow third-party payers to assess the relative cost per effectiveness (QALY) of medical vs surgical therapy for nasal obstruction of various severity levels based on NOSE scores.

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Study concept and design: Akdagli, Most.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: All authors.
Critical revision of the manuscript for important intellectual content: Most.
Statistical analysis: Titi.
Administrative, technical, or material support: Akdagli, Most.
Study supervision: Most.

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REFERENCES