


Defining the Health Utility Value of Medical Management of Chronic Rhinosinusitis: A Prospective Pilot Study

George A. Scangas, MD^{1,2,*}, Vinay K. Rathi, MD, MBA^{1,2,*},
Ralph B. Metson, MD^{1,2}, Benjamin S. Bleier, MD^{1,2},
Nicholas Y. Busaba, MD^{1,2}, Eric H. Holbrook, MD^{1,2},
and Stacey T. Gray, MD^{1,2}

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Abstract

The extent to which medical management of chronic rhinosinusitis (CRS) may improve health utility value (HUV) remains unknown. We conducted a prospective pilot study to longitudinally assess HUV via the EQ-5D-5L questionnaire in patients with CRS who were receiving medical therapy but did not undergo sinus surgery. The primary study outcome was HUV at 12-month follow-up; secondary end points included HUV at baseline and 3- and 24-month follow-up. Our study enrolled 115 patients who received the following medical treatments: saline irrigations ($n = 83$, 72.2%), steroid sprays ($n = 93$, 80.9%), antihistamines ($n = 64$, 55.7%), steroid irrigations ($n = 29$, 25.2%), and oral antibiotics ($n = 58$, 50.4%). There was a statistically significant improvement (mean, +0.073; $P = .003$) in HUV at 12 months (minimum clinically important difference, 0.055) as compared with baseline. However, there was no statistically significant trend in HUV over time between baseline and 24-month follow-up ($P = .3033$). These findings can inform cost-effectiveness research as new medical therapies for CRS emerge.

Keywords

chronic rhinosinusitis, CRS, health utility value, cost-utility analysis, EQ-5D-5L

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Chronic rhinosinusitis (CRS) can significantly reduce patient quality of life.¹ First-line treatment for CRS is typically medical management; patients whose medical management fails may subsequently be considered for endoscopic sinus surgery (ESS). Cost-utility analysis is a robust method of economic assessment that permits valuation and comparison of treatments intended to improve quality of life for patients with CRS.^{2,3} The most common unit of valuation is the quality-adjusted life year, which is calculated as the product of health utility value (HUV) and time.

The EQ-5D-5L questionnaire provides the highest-quality measure of generic HUV for patients with CRS.⁴ Prior research demonstrates that ESS is associated with improved HUV for patients with CRS.⁵ In contrast, the extent to which medical treatments for CRS (eg, nasal steroid sprays and saline irrigations) may improve HUV is currently unknown. We therefore performed a longitudinal assessment of HUV in cases of medically managed CRS among patients who did not undergo ESS.

Methods

We conducted a prospective pilot study of patients from 2 rhinologic practices at Massachusetts Eye and Ear. We consecutively enrolled patients in the study between April 8, 2015, and March 10, 2017. Study inclusion criteria were age >18 years, clinical diagnosis of CRS, and no planned ESS at enrollment. Study exclusion criteria were (1) history of prior sinus surgery; (2) diagnosis of sinonasal neoplasm, trauma, and cerebrospinal fluid leak; and (3) sinus surgery performed during the study period.

We extracted baseline demographic data and relevant medical comorbidities for all patients from the electronic medical record. The study was observational; individualized treatment plans were formulated by patients and their surgeons. We recorded whether patients received any of the following treatments during the study period: nasal saline irrigations, topical nasal steroid sprays, antihistamines (including oral agents and nasal azelastine spray), topical steroid nasal irrigations, oral antibiotic therapy, or oral steroids.

¹Department of Otolaryngology–Head and Neck Surgery, Massachusetts Eye and Ear, Boston, Massachusetts, USA

²Department of Otolaryngology–Head and Neck Surgery, Harvard Medical School, Boston, Massachusetts, USA

*These authors contributed equally to this article.

Corresponding Author:

Vinay K. Rathi, MD, MBA, Department of Otolaryngology–Head and Neck Surgery, Massachusetts Eye and Ear, 243 Charles St, Boston, MA 02114, USA.
Email: vinay_rathi@meei.harvard.edu



The primary study outcome measure was EQ-5D-5L score at 12 months following enrollment. We chose 12 months as the duration of primary outcome follow-up to permit adequate opportunity for medical management optimization. Secondary outcome measures included EQ-5D-5L scores at 0, 3, and 24 months. Patients completed the EQ-5D-5L instrument at scheduled follow-up appointments.

The EQ-5D-5L questionnaire evaluates 5 dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, the questionnaire asks respondents to categorize their problems using a 5-tiered system: no, slight, moderate, severe, and extreme problems. We estimated HUVs based on EQ-5D-5L responses using a US-based value set,⁶ which ranges from -0.573 (worse than death) to 1.000 (full health).

We used descriptive statistics to characterize patients at baseline and the medical treatments that patients received during the study period. We then used a linear mixed model with a patient-level random effect and Satterthwaite approximation⁷ to assess changes in EQ-5D-5L scores over time for statistical significance. We defined the minimum clinically importance difference in EQ-5D-5L scores as half of the standard deviation of the mean baseline score.

We performed all statistical analyses in R software (R Foundation). We obtained institutional review board approval from the Mass General Brigham Human Research Committee.

Results

Our study enrolled 115 participants (**Table 1**), of which 61 (53.0%) were female and 100 (87.0%) were Caucasian. At enrollment, the mean (SD) patient age was 48.2 (16.2) years. Among study participants, 32 (27.8%) had nasal polyps, 43 (37.4%) had asthma, and 70 (60.9%) had allergies. In addition to saline irrigations and nasal steroid sprays, treatments prescribed during the study period included antihistamines ($n = 64$ patients, 55.7%), nasal steroid irrigations ($n = 29$, 25.2%), and oral antibiotics ($n = 58$, 50.4%). Patient follow-up rates were 40.0% ($n = 46$) at 3 months, 27.8% ($n = 32$) at 12 months, and 23.5% ($n = 27$) at 24 months.

The mean (SD) baseline HUV of study participants was 0.844 (0.11; **Figure 1**). There was a statistically significant improvement (mean, $+0.073$; $P = .003$) in HUV at 12 months; this improvement exceeded the minimal clinically important difference (0.055). There was no statistically significant trend in HUV over time between baseline and 24-month follow-up ($P = .3033$).

Discussion

In this prospective pilot study, we found that medical management of CRS was associated with improved HUV at 12-month follow-up (mean, $+0.07$) but not at 3- or 24-month follow-up. Comparison between our findings and prior research⁵ suggests that baseline HUV (mean [SD]; ESS, 0.81 [0.13]; medical management, 0.84 [0.11]) is similar for patients undergoing ESS. However, patients undergoing ESS reported HUV increases (mean, $+0.08$) at 3 months

Table 1. Baseline Clinical Comorbidities and Study Treatments in Medically Managed Cases of Chronic Rhinosinusitis (115 Patients).

	Patients, No. (%)
Clinical comorbidity ^a	
Active smoker	2 (1.7)
Nasal polyps	32 (27.8)
Asthma	43 (37.4)
Allergies	70 (60.9)
Hypertension	5 (4.3)
Chronic obstructive pulmonary disease	5 (4.3)
Autoimmune disease	3 (2.6)
Diabetes	6 (5.2)
Gastroesophageal reflux disease	22 (19.1)
Headache	18 (15.7)
Study treatments ^b	
Saline irrigations	83 (72.2)
Nasal steroid sprays	93 (80.9)
Antihistamines	64 (55.7)
Nasal steroid irrigations	29 (25.2)
Oral antibiotics	58 (50.4)
Oral steroids	7 (6.1)

^aDiagnosis present at time of study enrollment.

^bWhether patient received treatment at any point during study.

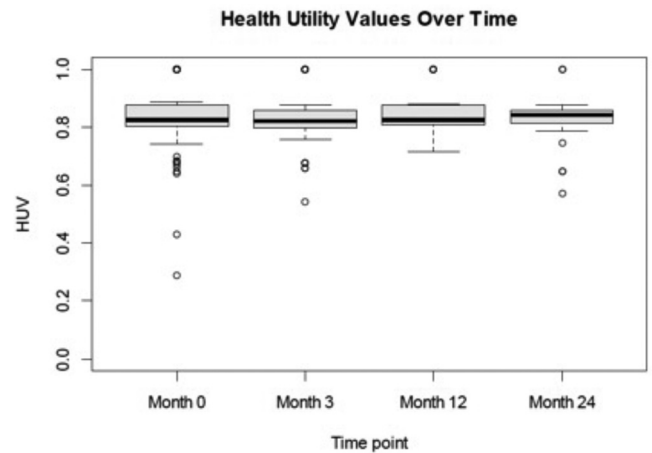


Figure 1. Box plots of health utility values in medically managed cases of chronic rhinosinusitis between enrollment and 24-month follow-up. Health utility value measured by EQ-5D-5L questionnaire. Line, median; box, interquartile range; error bars, 95% CI; circles, outliers.

postprocedure and sustained improvements at 12- and 24-month follow-up.⁵ Lack of HUV improvement in medically managed cases at 3-month follow-up may reflect ongoing treatment regimen optimization. Lack of HUV improvement at 24-month follow-up may be due to sequelae of long-term therapy, such as clinical tolerance or adverse effects.

Our study has several important limitations. First, patient follow-up rates were relatively low. We may therefore

underestimate the magnitude of HUV improvement associated with medical management if patients did not attend follow-up because they achieved symptom control. Second, we excluded patients who underwent ESS from our study cohort. This selection bias against patients failing medical management may result in overestimation of associated HUV improvements. Third, our study was not adequately powered to assess for differences between subgroups, such as patients with comorbid nasal polyposis. Further investigation is necessary to support cost-utility analyses as new medical therapies for CRS emerge.

Author Contributions

George A. Scangas, conception and design of this work, data acquisition, statistical analysis, and drafting the manuscript; analysis and interpretation of the data; critical revision of the manuscript for important intellectual content; **Ralph B. Metson**, conception and design of this work; data acquisition; analysis and interpretation of the data; critical revision of the manuscript for important intellectual content; **Benjamin S. Bleier**, analysis and interpretation of the data; data acquisition; critical revision the manuscript for important intellectual content; **Nicholas Y. Busaba**, analysis and interpretation of the data; data acquisition; critical revision the manuscript for important intellectual content; **Eric H. Holbrook**, analysis and interpretation of the data; data acquisition; critical revision the manuscript for important intellectual content; **Vinay K. Rathi**, drafting the manuscript; analysis and interpretation of the data; critical revision of the manuscript for important intellectual content; **Stacey T. Gray**, conception and design of this work, data acquisition, and drafting the manuscript; analysis and interpretation of the data; critical revision of the manuscript for important intellectual content.

Disclosures

Competing interests: None.

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Data Access and Responsibility

George A. Scangas had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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