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Health Utility Values for Patients with Recurrent Acute Rhinosinusitis Undergoing Endoscopic Sinus Surgery – A Nested Case Control Study

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Abstract

Background—Health utility scores quantify an individual’s valuation of particular health states and are vital components of health economic studies and cost-effectiveness research. We sought to characterize health utility values for patients with recurrent acute rhinosinusitis (RARS) both before and after endoscopic sinus surgery (ESS), as well as compare health utility to chronic rhinosinusitis without nasal polyposis (CRSsNP).

Methods—Patients with RARS (n=20) and CRSsNP (n=20) undergoing ESS were enrolled as part of a longitudinal, observational, prospective cohort. Case patients diagnosed with RARS were age and gender matched to controls with CRSsNP using a nested case-control design at a 1:1 ratio. Health utility was measured using the Medical Outcomes Study Short Form-6D (SF-6D) survey.

Results—Patients with RARS were followed for an average of 14.0[6.1] months compared to an average of 14.4[5.3] months for CRSsNP controls (p=0.779). Mean preoperative SF-6D health

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utility scores were statistically comparable between RARS (0.71[0.14]) and CRSsNP (0.66[0.12]; $p=0.341$). Both patients with RARS and CRSsNP reported significant postoperative improvement in SF-6D scores from 0.71[0.14] to 0.79[0.13] ($p=0.031$) and from 0.66[0.12] to 0.77[0.13] ($p=0.004$), respectively. No difference in last postoperative SF-6D scores were found between RARS and CRSsNP ($p=0.583$) or in the average magnitude of postoperative improvement (0.08[0.16] vs 0.11[0.13]; $p=0.620$).

Conclusions—Patients with RARS and CRSsNP report significant impairment in health utility as measured by the SF-6D. Endoscopic sinus surgery significantly improves health utility in patients with RARS and CRSsNP to near normative values. These data will help inform future economic analysis and cost-effectiveness research.

Keywords

Sinusitis; outcome assessment; patient outcome assessment; case-control studies; cost-benefit analysis

INTRODUCTION

Recurrent acute rhinosinusitis (RARS) is a relatively infrequent clinical entity characterized by four or more episodes of acute bacterial rhinosinusitis per year with resolution of disease specific symptoms in between episodes.¹ Recent literature suggests that patients with RARS report impairment in disease specific quality of life (QOL) and lost productivity to levels that parallel their CRS counterparts.^{2,3} Furthermore, direct costs (e.g. health care visits, prescription medications) associated with RARS surpass \$1,000 per year.⁴ Despite advances in RARS research, the true impact of disease process on overall healthcare costs has been challenging to demonstrate. In a climate of rising healthcare costs, providers are continually tested to provide beneficial, cost-effective medical and surgical therapies to optimize the value of care.⁵ Economic evaluations using generic QOL metrics, such as health-state utilities, can provide policy-makers with information to improve allocation of healthcare resources toward those patients who would benefit most.

A health state utility value represents an individual's valuation of his or her current health state.⁶ Measuring health utilities requires both defining health states of interest and valuing those health states. One of the methods through which healthy utility is measured is a preference based instrument such as the Medical Outcomes Study Short-Form-6D (SF-6D). These reported utility values are often used in cost-utility analyses to provide researchers, large pharmaceuticals, and policy-makers comparative information about which interventions are most effective for patients across different disease states.

The purpose of this study was to evaluate baseline and post-operative health utility values for patients with RARS undergoing endoscopic sinus surgery (ESS) using the SF-6D. Given the known significant impact of chronic rhinosinusitis (CRS) on health utility⁷, participants with RARS were matched by age and gender to patients with CRS to allow for comparison between sinusitis disease states. We hypothesized that patients with RARS would exhibit similar baseline impairment in health utility as those with CRS. Furthermore, we

hypothesized that patients with RARS would report significant post-operative improvement in SF-6D utility scores following surgery.

METHODS and MATERIALS

Study Population – Inclusion Criteria

Study patients were diagnosed with either medically refractory CRS without nasal polyposis (CRSsNP) or RARS as defined by both the American Academy of Otolaryngology-Head and Neck Surgery and the European Position Paper on Rhinosinusitis and Nasal Polyps 2012 (EPOS 2012).^{1,8} Adult study participants (age ≥ 18 years) were recruited as part of a prospective, multi-center, non-randomized, observational cohort study developed to evaluate treatment outcomes of ESS. Preliminary outcome studies of this cohort have been recently published.⁹⁻¹¹ Study enrollment sites consisted of sinus and skull base surgery centers located within academic hospital systems in North America including: Oregon Health & Science University (Portland, OR; eIRB#7198), Stanford University (Palo Alto, CA; IRB#4947), the Medical University of South Carolina (Charleston, SC; IRB#12409), and the University of Calgary (Calgary, Alberta, Canada; IRB#E-24208). Consenting study participants were assured by research personnel that participation involved minimal risk and was voluntary per good clinical practice guidelines established by the *International Conference on Harmonisation*.¹²

Study participants voluntarily selected ESS as the subsequent treatment option for mitigation of symptoms related to CRS following initial medical therapy including, but not limited to, at least one course of either topical corticosteroids (>21 days) or a 5 day course of oral corticosteroid therapy, and at least one course (>14 days) of culture-directed or broad spectrum antibiotic therapy. RARS patients were enrolled if they met criteria for RARS as outlined in the adult sinusitis guidelines.¹ Study enrollment occurred subsequent to study participants electing ESS, during which participants were screened for demographic data, as well as social and medical history. Participants were followed through the standard of care for up to 18 months following ESS and were asked to complete postoperative evaluation procedures at regular 6 month intervals, either during physician-directed clinical appointments or via follow-up mailings.

Sinus Surgery Procedures—Surgical intervention was non-standardized and dependent upon the intraoperative discretion of the enrolling physician at each enrollment location, reflecting individual patient requirements and disease progression. All study participants were either primary or revision ESS cases. Procedural types included unilateral or bilateral maxillary antrostomy, total or partial ethmoidectomy, sphenoidotomy, or frontal sinusotomy procedures (Draf 1, 2a, 2b, or 3), with either adjunctive inferior turbinate reduction or septoplasty as needed to maximize sinonasal openings. Image guidance visualization was used when necessary. Postoperative therapeutic regimens were prescribed as needed but included, at a minimum, high volume (>200ml.) daily nasal saline irrigations to promote postoperative healing.¹³

Exclusion Criteria—Participants were considered lost to follow-up if no postoperative evaluations were completed within 18 months after the date of ESS. Additionally, subjects

with either with immunodeficiency, ciliary dyskinesia, corticosteroid dependency, and autoimmune comorbidity were excluded due to potential heterogeneity of disease processes and variations in subsequent treatment.

Evaluations of Disease Severity—Measures of disease severity, collected as part of the standard of care, were used simultaneously for investigational purposes. Preoperative, high resolution computed tomography (CT) was evaluated without contrast to assess sinonasal disease severity using 1mm. contiguously sliced images of the axial plane. Bilateral image staging was completed by the enrolling physician at each site in accordance with the Lund-Mackay scoring system (range: 0 – 24) which estimates opacification severity in the maxillary, ethmoidal, sphenoidal, ostiomeatal complex, and frontal sinus regions.¹⁴ Postoperative CT images were not routinely collected, unless required by the standard of care, due to risk of elevated radiation exposure.

Anterior sinonasal regions were evaluated using rigid, fiberoptic endoscopes (Karl Storz, Tuttlingen, Germany) both before and after ESS. Bilateral endoscopic examinations were staged by each enrolling physician using the Lund-Kennedy scoring system (range: 0 – 20) which estimates pathologic characteristics within the paranasal sinuses including the severity of nasal polyposis, discharge, edema, scarring, and crusting.¹⁵ Higher total scores on either staging system reflect worse disease severity.

Primary Outcome Measure – SF-6D Scores—Study participants completed the SF-6D during each study evaluation time point. The SF-6D is a subset of 6 questions taken from the 36-item Medical Outcomes Study Short Form (SF-36) survey. Health states measured by SF-6D item scores are transformed into standardized health utility values, as described by Brazier et al., and used with permission from the Department of Health Economics and Decision Science at the University of Sheffield, Sheffield, United Kingdom.¹⁶ The SF-6D score describes a normalized value that an individual patient places on their particular health state. Health utility values range from 0.3 to 1.0 where lower values represent lower/worse valuations of health state and 1.0 representing perfect health. A change of 0.03 or greater over time has been defined as a minimal clinically important difference in SF-6D scores.¹⁷

Data Collection and Statistical Analyses—Sample size estimations were calculated using testing for two dependent means. A total of 20 subjects are required to detect a 0.08 within-subject mean difference on SF-6D scores, using a conventional between-group correlation coefficient ($R=0.50$), an equal variance assumption of 0.12, a two-tailed t-test, a 0.05 alpha level and an 80% ($1-\beta$) error probability. Case participants with RARS were age (within 2 years) and gender matched to control participants diagnosed with CRS without nasal polyposis (CRSsNP) using a 1:1 ratio in a nested case-control design. Case subjects were selected from CRSsNP subjects ($n=337$) enrolled within the same prospective cohort.

All data was coded using a unique study identification number and transferred to OHSU from each enrollment site after removal of all protected health information. All study data was manually entered into a relational database (Microsoft Access, Microsoft Corp., Redmond, WA) and statistical analyses were conducted using commercially available

software (SPSS v.22, IBM Corp., Armonk, NY). Preoperative cofactors, clinical measures of disease severity, measures of surgical extent, and primary outcome measures were evaluated descriptively while data normality was verified for all continuous measures using distributive analysis. Last available SF-6D score (6 months) was used to operationalize postoperative evaluations. The Mann Whitney U and chi-square testing (χ^2) was utilized to compare all independent, continuous and frequency measures, respectively, between cases and controls. Wilcoxon signed rank testing was used to evaluate matched pairings over time. Means and [standard deviations] were reported for all continuous variables. Two-tailed Spearman's rank correlation coefficients (Rs) were used to evaluate associations between continuous variables where appropriate. All statistical comparisons assumed a 0.050 type-I error probability.

RESULTS

Final Cohort Selection

A total of 20 participants, meeting all inclusion/exclusion criteria, undergoing ESS for symptoms of RARS were enrolled between July, 2011 and June, 2014 and available for analysis. Case participants with RARS were matched to 20 control participants undergoing ESS for CRSsNP between May, 2011 and March, 2014. Participants with RARS were followed for an average of 14.0[6.1] months compared to an average of 14.4[5.3] months for control subjects ($p=0.779$). Both cases and control groups were found to have a mean age of 35.3[9.1] years and were comprised of 14 females (70%) each. Participants with RARS reported higher rates of deviated septum 85% ($p=0.008$) and turbinate hypertrophy 60% ($p=0.008$), while comparisons of other participant characteristics and comorbid conditions found no differences between cases and controls. Comparisons of clinical measures of disease severity found significantly worse mean CT scores in CRSsNP controls (**Table 1**).

Case subjects with RARS reported significantly fewer previous sinus surgeries ($p=0.001$), less overall total ethmoidectomy ($p=0.001$), sphenoidotomy ($p=0.001$), frontal sinusotomy ($p=0.001$), and image guidance use ($p=0.008$) compared to controls. Conversely, RARS case subjects were found to undergo greater frequencies of maxillary antrostomy ($p=0.029$), partial ethmoidectomy ($p=0.001$), inferior turbinate reduction ($p=0.001$), and septoplasty procedures ($p=0.002$) as part of their surgical treatment.

Preoperative SF-6D Scores

Preoperative mean SF-6D utility scores were statistically comparable ($p=0.341$) between patients with RARS (0.71[0.14]; range: 0.46–0.92) and CRSsNP (0.66[0.12]; range: 0.51–0.92). No significant differences in preoperative SF-6D utility scores, between patients with RARS and CRSsNP, was found across any comorbid subgroup or demographic factor ($p=0.136$).

In cases with RARS, preoperative SF-6D utility scores were not found to significantly correlate with either preoperative CT scores ($R_s=-0.057$; $p=0.810$) or endoscopy scores ($R_s=-0.181$; $p=0.445$). For controls with CRSsNP, preoperative SF-6D utility scores did not

significantly correlate with either CT scores ($R_s=0.056$; $p=0.814$) or preoperative endoscopy scores ($R_s= -0.160$; $p=0.501$).

Postoperative Changes in SF-6D Health Utility

Cases with RARS ($n=20$) reported significant postoperative improvement ($p=0.031$) in SF-6D utility scores over time from 0.71[0.14] to 0.79[0.13]. Control participants with CRSsNP also reported significant postoperative improvement in SF-6D utility scores ($p=0.004$) from 0.66[0.12] to 0.77[0.13] (**Figure 1**). No significant difference was found between either the last postoperative SF-6D utility score for RARS and CRSsNP ($p=0.583$) or in the average magnitude of postoperative improvement over time (0.08[0.16] vs 0.11[0.13]; $p=0.620$). No significant differences in postoperative SF-6D utility score improvements, between patients with RARS and CRSsNP, was found across any comorbid subgroup or demographic factor ($p=0.132$).

DISCUSSION

With the growth of managed care organizations in the United States, many health care systems are forced to streamline resources to provide cost-effective and high value care.¹⁸ In health economics, the effectiveness of an intervention is often studied through cost-utility analysis, where the value of an intervention, or utility, is measured against cost.^{6,19} Health state utilities can be combined with survival estimates to generate quality-adjusted life-years (QALYS), which the US Public Health Service Panel on Cost Effectiveness in Health and Medicine has recommended be used as the standard measure of health benefit in cost-effectiveness research.²⁰ In the current healthcare climate, health state utilities are a critical component to outcomes-based research and evidence-based medicine.

In this study, patients with RARS reported significant improvement in SF-6D utility values following ESS, with similar preoperative and postoperative SF-6D utility values as age and gender matched CRSsNP controls. Both RARS and CRSsNP patients improved to a similar degree following ESS, suggesting a similar benefit from ESS for both disease processes. Subjects with RARS differed in that they had higher rates of septal deviation and turbinate hypertrophy, which corresponds with the higher rate of septoplasty and inferior turbinate reduction in that group. As expected, CRS patients had worse mean CT scores, but otherwise the groups were similar in mean endoscopic scores. Overall, RARS patients underwent less individual procedures, but had similar health utility improvement as their CRSsNP counterparts. Overall, both RARS cases and CRS controls reported significant improvement in SF-6D scores, indicating improvement across measured SF-6D general health domains of physical functioning, role participation, social functioning, bodily pain, mental health, and vitality.

Walters and Brazier defined a clinically significant gain as a score improvement of 0.03 on the SF-6D.¹⁷ Both RARS cases and CRSsNP controls in this study achieved this minimally clinically important difference threshold on average, which is consistent with data reported in prior studies examining health utility and CRS. In 2011, Soler et al. reported a gain in utility of 0.087 following ESS for CRS patients.⁷ A subsequent long-term utility study of the same cohort was performed by Rudmik et al., finding that average SF-6D scores in CRS

patients reach approximate U.S. population norms 5 years postoperatively.²¹ Luk et al. reported an improvement in health utility scores of approximately 0.08 points 12 months after ESS for patients with CRS, though patients with CRS in that cohort did not report significant improvement in health utility scores if they elected continued medical therapy instead of ESS.²²

Varying constructs have been employed to evaluate health utility in CRS patients. These have included EuroQOL 5-Dimension (EQ-5D), SF-6D, visual analogue scale (VAS), standard gamble, and time-trade off techniques. Both the EQ-5D and SF-6D are indirect measures of utility, meaning that utility scores are generated from responses to patient-based surveys evaluating unique healthcare dimensions such as vitality, physical functioning, and mental health. Normative values for SF-6D scores are 0.81²³, while ranges for patients with CRS have varied from 0.65-0.72.^{7,22,24} Recently, Ference et al. evaluated varying health utility measurements in CRS patients including standard gamble, time trade off, VAS, EQ-5D, and SF-6D in patients with CRS. Results from their study suggest that both EQ-5D and SF-6D are easy to administer and understand, leading to high reliability, whereas they may not respond as well to disease specific changes in utility.²⁴ Remenschneider evaluated patients with CRS undergoing ESS with the EQ-5D and found higher pre-operative utility scores (0.81) as compared to previously reported SF-6D values. Importantly, however; the improvement in utility following ESS was similar to the rates of improvement (0.08) reported by Soler et al., and Luk et al.^{7,22,25} In this study, RARS and CRSsNP patients reported improvement in mean SF-6D scores of 0.08 and 0.11 points, respectively. To put these data in perspective, the gains in health utility scores reported in this study are similar to improvements that patients with obstructive sleep apnea report one year after initiating continuous positive airway pressure therapy (0.10)²⁶ and to utility improvements in osteoarthritis patients (0.10) undergoing total hip arthroplasty²⁷ (**Figure 2**).²⁸⁻³³

While the prospective, multi-institutional nature of this study is an important strength of the study, there are several notable limitations. First, overall sample size is relatively low in RARS patients, and there is a possibility of type-2 error. Second, given that RARS is an episode process, there are potential limitations with reporting bias, as patients may have been asymptomatic during the time period in which follow up examinations took place. Lastly, it is recognized that both CRS and RARS patients exhibit improvement with medical therapies^{34,35} and future study will be needed to further quantify health utility improvement in medically managed RARS patients. Despite these limitations, this study provides data that will help to inform future cost-effectiveness analysis and is novel to the RARS literature.

CONCLUSION

Both patient groups with RARS and CRSsNP demonstrate significant and similar improvement in health utility values following ESS. As outcomes data for RARS patients continues to increase, data from this study will help facilitate future economic evaluations for the management of RARS.

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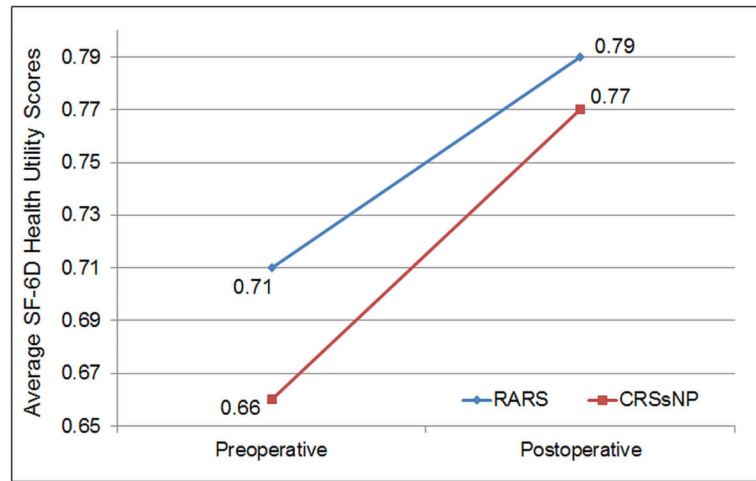


Figure 1. Postoperative improvement in health utility scores for both participants with RARS and CRSsNP. RARS, recurrent acute rhinosinusitis; CRSsNP, chronic rhinosinusitis without nasal polyposis;

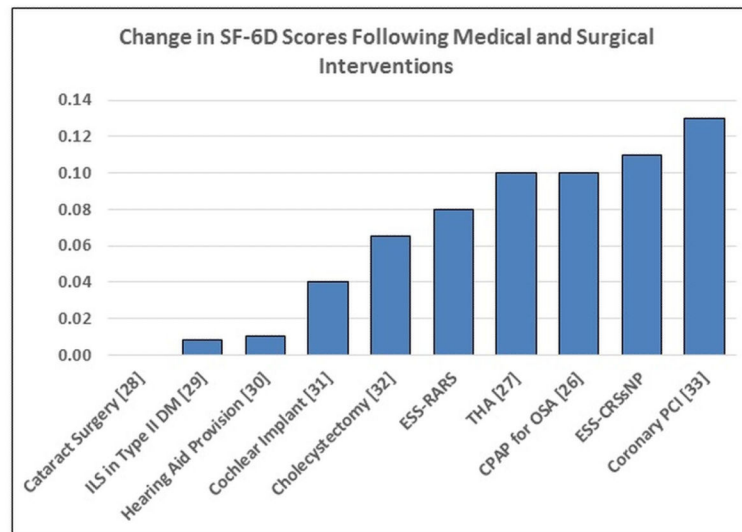


Figure 2.

ILS, Intensive Lifestyle Program; DM, Diabetes Mellitus; ESS, Endoscopic Sinus Surgery; RARS, Recurrent Acute Rhinosinusitis; THA, Total Hip Arthroplasty; CPAP, Continuous Positive Airway Pressure; OSA, Obstructive Sleep Apnea; CRSsNP, Chronic Rhinosinusitis Without Nasal Polyposis; PCI, Percutaneous Coronary Intervention.

Table 1

Clinical measures of disease severity of matched RARS case and CRSsNP control subjects (n=40)

Clinical measures of disease severity:	RARS (N=20) Mean [SD]	CRSsNP (n=20) Mean [SD]	p-value
CT total scores	4.8 [4.2]	8.5 [5.7]	0.030
Endoscopy total scores	2.5 [1.7]	4.3 [3.5]	0.108

RARS, recurrent acute rhinosinusitis; CRSsNP, chronic rhinosinusitis without nasal polyposis; CT, computed tomography. SD, standard deviation

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