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Quality of Life Outcomes after Functional Endoscopic Sinus Surgery

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Abstract

Most patients with chronic rhinosinusitis seek medical treatment when the burden of symptoms negatively impacts their quality of life. The degree to which quality of life improves after sinus surgery is thus a critical indicator of surgical success. This article reviews quality of life outcomes after functional endoscopic sinus surgery, including relevant clinical factors, weaknesses in the current literature, and future research directions.

Keywords

Chronic Rhinosinusitis; Quality of life; Endoscopic sinus surgery; Sinusitis

Introduction

Clinicians have traditionally focused on objective findings in order to assess response after a given treatment; however, for many disease processes including chronic rhinosinusitis (CRS), objective measures fail to capture the full burden of disease experienced by the individual patient. The discordance between radiographic findings and patients' symptoms in CRS highlights this dilemma. Numerous studies have shown that the degree of sinonasal inflammation as measured by computed tomography (CT) scan or endoscopy fails to correlate with the extent of symptoms experienced by the individual patient¹. A patient may therefore have debilitating symptoms with only minimal mucosal thickening or vice versa. The lack of agreement between objective assessment and patient-centered assessment is not unique to CRS, but can also be seen in conditions such as obstructive sleep apnea, asthma, and low back pain²⁻⁵. At present, CRS remains a symptom-based diagnosis (corroborated by objective signs of inflammation) and the extent of symptoms remains the overriding factor motivating patients to seek medical treatment⁶. Given this situation, the study of patient-centered disease impact is critical to understanding outcomes after endoscopic sinus surgery (ESS). To date, a number of rhinologic-specific instruments have been developed to measure quality-of-life (QOL) in patients with rhinologic conditions, including the CSS, RSDI, RQLQ, and most recently the

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SNOT-22⁷⁻¹⁰. These instruments provide a validated means to objectively quantify a patient's perception of their disease burden both before and after intervention.

In General, QOL Improves After ESS

In general, patient-reported symptoms and QOL improve after ESS. One of the earliest studies was published by Kennedy in 1992, wherein 97% of 120 patients reported improvement in symptoms (85% marked improvement) after ESS with a mean follow-up of 18 months¹¹. A follow-up study on the same cohort showed these results to be durable up to 7.8 years after surgery¹². The development of validated, disease-specific QOL instruments in the mid 1990s added an additional layer of sophistication to ESS outcomes research. A recent literature review identified 45 articles published between 1966 and 2004 dedicated to the question of whether ESS leads to improvements in symptoms and/or QOL¹³. In that report, all 45 studies demonstrated improvements in CRS-related symptoms and QOL, including 11 prospective studies and 5 which utilized validated QOL instruments.

Since that time, additional large prospective studies have been published utilizing validated CRS-specific QOL instruments or symptom scales. Kountakis followed a cohort of 158 patients for 12 months after ESS, reporting statistically significant improvements in patient visual analog scale (VAS) scores for Rhinosinusitis Task Force (RSTF) symptoms¹⁴. Major RSTF symptom scores ranged from 4.5-5.7 (0-10 point scale) at baseline and improved to 0.3 to 0.9 after ESS, representing a greater than 80% change from baseline. SNOT-20 scores were also shown to improve by 77% after surgery.

Bhattacharyya performed a similar study following 100 patients for an average of 19 months after ESS¹⁵. RSI symptoms were examined at preoperative and postoperative time points utilizing Likert scales (0-5 range). After surgery, statistically significant decreases in major (facial pressure, nasal congestion, nasal obstruction, rhinorrhea, and hyposmia) and minor symptoms were noted ($p < 0.001$ for all). The net change in major symptom score ranged from 1.5 to 2.3 points (0-5 range) with effect sizes noted to be large.

Recent studies have also focused on nonspecific symptoms such as fatigue and bodily pain. Chester performed a systematic review and meta-analysis of available studies looking at the effect of ESS on fatigue, vitality, energy and malaise¹⁶. All 28 identified studies described substantial improvement in fatigue following ESS. A similar study by the same author showed improvements in bodily pain scores as recorded by the SF-36 instrument¹⁷.

One of the most comprehensive studies was published by Smith et al in 2009¹⁸. This multi-institutional study prospectively followed 302 patients at three medical centers for an average of 17.4 months after ESS. Mean scores improved on the RSDI by 18.9 points (15.8%; $p < 0.001$) and the CSS by 21.2 points (21.2%; $p < 0.001$). Put another way, among patients with poor baseline QOL, 71.7% experienced clinically significant improvement on the RSDI and 76.1% on the CSS.

The available literature provides a wealth of evidence demonstrating that CRS-specific symptoms and QOL improve after ESS to statistically significant levels; however, a "statistically significant" improvement may not necessarily translate into a clinically relevant change as perceived by the individual patient. One of the burdens of QOL research is to identify what has been called the "minimal clinically important difference" (MCID). The MCID is the minimal change in symptom or QOL after a given intervention which is perceptible and thus relevant to the individual patient. Establishing an MCID for a particular disease state and QOL instrument can be a difficult task. Until recently, little had been done to specifically define the MCID for CRS symptoms or CRS-specific QOL instruments. Instead, estimates of MCID were extrapolated from other disease states and used by proxy. For example, there has been much

interest using VAS scales for measuring pain in the operative and emergency department setting. Prior studies have shown the MCID for acute pain to be between 0.9 to 1.3 (10 point scale)¹⁹⁻²¹. Recent studies reporting scaled symptom scores by Kountakis, Bhattacharyya, and Smith all easily reach this threshold of clinical relevance^{14,15,22}. Similarly, estimates of MCID exist for general QOL instruments such as the SF-36, wherein 10 to 12.5 points (100 point scale) represents the minimum change felt to be clinically relevant for diseases such as asthma, chronic obstructive pulmonary disease and coronary artery disease²³. Studies by Smith and Kennedy evaluating long-term changes in SF-36 scores easily exceed these extrapolated thresholds^{11,18}.

The difficulty of defining an MCID is not unique to rhinologic QOL outcomes research. The most widely accepted solution in other disease states has been to use statistical constructs such as standard error and standard deviation to define the MCID. Generally speaking, QOL changes become clinically meaningful when they approximate 1/2 of the standard deviation of the baseline QOL value for the given population. This seemingly arbitrary definition of clinical relevance has been validated across many disease-specific and general QOL instruments²⁴. Considering the multi-institutional outcomes study by Smith et al, this threshold of clinical significance was exceeded for both the disease-specific (CSS, RSDI) and general QOL improvements after ESS¹⁸. Recently, attention has been given to defining the MCID for CRS-specific QOL instruments including the RQLQ and SNOT-22. Table 1 shows the available published MCID values for CRS-specific QOL instruments^{10,18,25}.

Even with the beneficial outcomes seen after ESS, one must not confuse “improvement” with complete symptomatic resolution or “cure.” ESS is most typically reserved for patients who are refractory to standard medical treatments. The preponderance of the QOL studies show that these patients will experience statistically and clinically significant improvement after ESS, but will likely still be left with some measurable burden of disease. For example, patients in the Bhattacharyya study showed average postoperative symptom scores ranging from 1.0 to 1.4 (0-5 scale)¹⁵. Table 2 shows symptom scores from a different cohort both before and after endoscopic sinus surgery²². Similarly, the multi-institutional Smith study reported average postoperative RSDI and CSS scores well above the norms for those without CRS¹⁸. These studies were done at tertiary referral centers and usually include a disproportionate number of patients with severe phenotype and revision surgical status. As such, reported results might not be fully generalizable to all patients undergoing ESS.

Various Clinical Factors Can Influence QOL

As detailed above, the majority of patients will perceive improvement in symptoms and QOL after ESS. However, there is variability as to the degree with which any individual patient will improve. Much attention has been given to identifying clinical factors which might enable treating physicians to predict a favorable or unfavorable outcome. Studies have looked at demographic factors (age, gender, ethnicity), medical comorbidities (asthma, allergies, ASA triad disease, depression, fibromyalgia, smoking, prior sinus surgery), and phenotypic qualities (polyposis, eosinophils) in order to identify characteristics which might allow outcome prediction^{18,26-34}. The results of these studies can at times seem conflicting given the subtle but important differences in study design/analysis as well as the interrelatedness of various factors which makes confounding difficult to fully eliminate.

Several factors have been shown to worsen baseline sinusitis-specific QOL, including ASA triad disease, depression, fibromyalgia, female gender, and non-Caucasian ethnicity^{18,27,29,33}. Patients with polyps and those of male gender have been shown to have slightly higher baseline QOL than the average CRS patient^{26,33}. Asthma, allergies, age, and revision surgical status seem to have little or no affect on baseline QOL^{18,28,31,32,33}. Regardless of their affect

on baseline disease-specific QOL, few of the above factors seem to influence the degree of improvement afforded by ESS. For example, patients with comorbid depression have worse disease-specific QOL scores at baseline and postoperatively compared to those without depression. However, they will experience the same absolute level of improvement with ESS as those without depression²⁷. Thus, at any one point in time a depressed patient will have worse QOL than a non-depressed patient, but the absolute change in QOL after ESS will be similar to those without depression. Similar results have been seen when closely examining patients with ASA triad disease, fibromyalgia, female gender, and non-Caucasian ethnicities^{18,29,30,33}. One recent study reported that a history of prior sinus surgery predicted less improvement in QOL after ESS¹⁸. In that study, patients undergoing primary ESS were 2.1 times more likely to improve as patients undergoing revision surgery (95%CI 1.2 to 3.4; $p<0.006$). No other factor was found to be similarly predictive by multivariate regression analysis.

Patients with nasal polyposis represent a unique clinical subgroup. The presence of nasal polyps naturally leads to worse objective disease severity as defined by imaging and endoscopic grading systems¹⁵. However, except for symptoms of nasal congestion, these patients appear to have a lighter burden of disease as measured by patient-centered symptom scores and QOL compared to patients without nasal polyps²⁶. Most clinicians have met the archetypal patient with polyps completely filling the nasal cavity yet relatively few complaints. Despite better preoperative QOL scores, patients with polyps tend to improve after ESS to a similar degree as those without polyps.

Recently, we reported the impact of mucosal eosinophilia on QOL outcomes in 102 patients with CRS³⁴. At the time of ESS, the degree of mucosal eosinophilia was quantified via microscopy. Although all patients demonstrated improvement after ESS, the subgroup of patients with mucosal eosinophilia (greater than 10 eosinophils/high powered field (HPF)) showed less improvement in disease-specific (CSS, RSDI) and general (SF-36) QOL than those without eosinophilia (less than 10 eosinophils/HPF) at an average follow-up of 16 months. Interestingly, patients without polyps but with mucosal eosinophilia performed the worst after ESS and patients without polyps or eosinophilia performed the best. The difference in outcomes between the groups clearly exceeded a threshold one would consider clinically relevant. Without pathologic review, these patients might otherwise be indistinguishable on clinical grounds alone. These findings are not unexpected and serve to support the commonly held clinical belief that patients with eosinophilic inflammation are especially difficult to treat.

Important Weaknesses Exist in Current QOL Outcomes Studies

Outcomes research for CRS has steadily improved over the last 25 years from short-term, single-institution studies of retrospective nature to prospective, multi-institution studies utilizing validated disease-specific QOL instruments. Despite these improvements, important weaknesses still exist in the current literature. The lack of a control arm is perhaps the biggest shortcoming of most studies. A control arm serves to minimize the chance that observed improvements simply represent the natural resolution of the disease process. Additionally, a control arm would minimize the placebo affect associated with any given treatment.

Randomized, double-blind, placebo-controlled trials (RDBPCT) remain the gold standard for many disease processes (level 1 evidence) and serve as the foundation for evidence-based reviews such as The Cochrane Database. However, the tenants of a RDBPCT are not easily applied to surgical outcomes as obvious problems with randomization, blinding, and sham surgeries arise. To our knowledge, only two randomized studies have compared medical regimens to ESS for adult patients with CRS^{35,36}. Both of these were done outside of the United States and showed no difference in outcomes when comparing ESS to medical treatments of

CRS. The Cochrane Review of these trials thus concluded that available evidence does not demonstrate ESS conferring additional benefit over medical treatment alone³⁷. However, the impact of the Cochrane Review has been mitigated by the fact that patients were randomized to ESS prior to receiving maximal medical treatments. The comparison was thus ESS versus a medical regimen as initial treatment of CRS. This up-front, direct comparison between surgery and medical therapy does not justly model current typical practice patterns. The typical current paradigm is to first treat CRS patients with maximal available medical treatments which often include antibiotic and anti-inflammatory regimens. Only those who fail these interventions are offered ESS, usually followed by ongoing medical treatments. Thus, to best mimic current treatment paradigms, one would begin with a cohort that has failed maximal medical management, and compare further treatment with ESS plus ongoing medical management to a control arm of continued medical management (level 2 evidence). Studies with the above construct would represent the strongest evidence likely to be achieved in the United States.

Future Outcomes Studies Should Incorporate Histologic, Molecular and Genetic Information

The initial objective of ESS outcomes research was to assess the effectiveness of ESS as a therapeutic option for CRS in general. Current thinking is that CRS represents a generic diagnosis of which there are many underlying etiologies and phenotypic subtypes. Various classifications schemes exist often based on clinical features such as presence of polyps and/or mucosal eosinophilia, although little consensus exists. As subtypes of chronic rhinosinusitis are identified and precisely classified, it will be important to understand variations in outcomes related to available therapies. Perhaps the greatest goal is to develop a comprehensive model of multiple pretreatment factors which predict disease-specific QOL outcomes after treatment. This model would include demographic, clinical, and radiographic measures as previously discussed. The discovery that mucosal eosinophilia predicts QOL outcomes after ESS suggests that further investigation is needed to define the underlying basis and characteristics of the inflammatory infiltrate comprising CRS. Evaluating cellular counts and other histologic parameters of mucosal inflammation represents a fairly crude method of assessment as compared with current molecular and genetic methodology. The study of molecular markers of inflammation and their genetic underpinnings remains a nascent research front just now beginning to flourish. Future studies will need to incorporate genetic markers and molecular markers of genetic expression into predictive models before a clear, comprehensive picture of outcomes is finally realized.

Conclusions

Implications for Clinical Practice

An abundance of evidence exists supporting the efficacy of ESS to improve long-term QOL outcomes in patients with CRS. Both CRS-specific and general QOL improve after ESS to levels considered statistically significant and clinically relevant. Variability in individual patient QOL can in part be explained by demographic factors, medical comorbidities, and histologic inflammatory phenotypes.

Implications for Research

Continued QOL outcomes research is necessary in both the medical and surgical treatment of CRS. Control arms should be incorporated where possible to minimize confounding and placebo effects. An overarching goal is to develop a comprehensive model of multiple pretreatment factors which predicts QOL outcomes and would guide clinical decision making.

This model will likely need to incorporate clinical, histologic, molecular, and genetic information to fully account for individual variability.

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Table 1

Minimal clinically important difference for chronic rhinosinusitis quality of life survey instruments

QoL Survey instrument Domains	[score range]	MCID
RSDI total	[0 - 120]	≥ 10.35
Physical	[0 - 44]	≥ 3.80
Functional	[0 - 36]	≥ 3.45
Emotional	[0 - 40]	≥ 4.20
CSS total	[0 - 100]	≥ 9.75
Symptoms	[0 - 100]	≥ 13.25
Medications	[0 - 100]	≥ 12.60
SNOT-22	[0 - 110]	≥ 8.90
RQLQ	[0 - 6]	≥ 0.62

QOL = quality of life, MCID = minimal clinically important difference, RSDI = Rhinosinusitis Disability Index, CSS = Chronic Sinusitis Survey, SNOT-22 = 22 Item Sinonasal Outcomes Test, RQLQ = Rhinitis Quality of Life Questionnaire.

Table 2

Individual symptom scores before and after endoscopic sinus surgery in a cohort of 152 patients with chronic rhinosinusitis

Symptoms: (n=152)	[range]	Preop mean $\pm$ SD	Postop mean $\pm$ SD	p-value
Nasal discharge	[0 - 10]	5.49 $\pm$ 3.06	3.38 $\pm$ 2.75	< 0.001
Nasal congestion	[0 - 10]	6.52 $\pm$ 2.84	3.36 $\pm$ 2.79	< 0.001
Facial pain	[0 - 10]	5.45 $\pm$ 2.91	2.34 $\pm$ 2.56	< 0.001
Decreased olfaction	[0 - 10]	5.54 $\pm$ 3.58	2.57 $\pm$ 3.06	< 0.001
Headache	[0 - 10]	4.13 $\pm$ 3.22	4.01 $\pm$ 3.27	0.699
Fatigue	[0 - 10]	6.03 $\pm$ 3.01	3.24 $\pm$ 2.80	< 0.001
Toothache	[0 - 10]	3.32 $\pm$ 3.25	1.17 $\pm$ 2.08	< 0.001
Sinus congestion	[0 - 10]	7.16 $\pm$ 2.46	3.37 $\pm$ 2.85	< 0.001

SD = standard deviation, $p < 0.05$ = significant. Soler ZM, Mace J, Smith TL. Symptom-based presentation of chronic rhinosinusitis and symptom-specific outcomes after endoscopic sinus surgery. *Am J Rhinol* 2008; 22:297-301