



Published in final edited form as:

Int Forum Allergy Rhinol. 2014 August ; 4(8): 663–669. doi:10.1002/alr.21333.

The impact of comorbid gastroesophageal reflux disease on endoscopic sinus surgery quality-of-life outcomes

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Abstract

Background—Chronic rhinosinusitis (CRS) and gastroesophageal reflux disease (GERD) are common entities that overlap in patient demographics. The pathophysiologic role of GERD has yet to be elucidated, but it is postulated the extra-esophageal reflux may contribute to worsening symptoms of CRS. This study seeks to investigate whether patients with CRS with and without a history of GERD experience comparable quality-of-life (QOL) improvement after endoscopic sinus surgery (ESS).

Methods—An adult cohort (n=229) with medically refractory CRS was prospectively assessed following ESS using three disease-specific QOL constructs. A patient subset with a history of comorbid GERD was retrospectively identified (n=72) and preoperative and postoperative QOL were compared to patients without GERD (n=157).

Results—Patients with comorbid GERD and CRS were comparable across all baseline patient characteristics (p>0.050) with the exception of patients with a history of GERD were less likely to have undergone allergy testing (p<0.002) and were older (53.8 years vs. 47.6; p<0.002). Similarly, baseline objective and subjective measures of disease were comparable between patients with CRS with and without GERD (p>0.050). Both groups experienced significant QOL improvement across all QOL constructs (p<0.021), and no difference was detected in the magnitude of that improvement between patients with and without a history of GERD (p>0.050). Similarly, patients on active medical therapy for GERD (n=49) had QOL gains comparable to patients not reporting GERD medical therapy (p>0.050).

Conclusions—Patients electing ESS for CRS with and without comorbid GERD have comparable baseline characteristics and QOL outcomes following surgery.

Keywords

Gastroesophageal reflux; outcome assessment; sinusitis; endoscopy; quality of life; confounding factors

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Potential Conflicts of Interest: None

Accepted for oral presentation to the American Rhinologic Society meeting at the 117th annual Combined Otolaryngologic Spring Meeting (COSM), Las Vegas, NV, May 14-18th, 2014. (**Abstract submission:** #586)

INTRODUCTION

Gastroesophageal reflux disease (GERD) occurs when retrograde flow of gastric contents outside of the stomach causes either symptoms or mucosal abnormalities.¹ Symptoms of GERD can be divided into esophageal symptoms (eg, pyrosis and regurgitation) and extra-esophageal symptoms (eg, asthma, laryngitis, otitis media)² with one-third of GERD patients suffering from extra-esophageal symptoms.³ The association of GERD with upper aerodigestive tract symptoms has led to a search for a correlation between reflux and chronic rhinosinusitis (CRS). Large epidemiologic evidence supports the association; patients that develop CRS are more likely to have a prior history of GERD.⁴

Data confirming the causative link is elusive, but increased reflux events may perpetuate sinonasal inflammation leading to either refractory disease or diminished therapeutic gains. Patients with medically and surgically refractory CRS have elevated levels of sinonasal pepsin suggesting that refluxate may perpetuate inflammation.^{5,6} Patients with a history of GERD also demonstrate a higher burden of sinonasal symptomatology.⁷ GERD has already been implicated as a negative prognostic factor for post-functional endoscopic sinus surgery symptomatic outcomes.⁸ The aim of the present study is to determine whether patients with CRS and GERD experience quality-of-life improvement after endoscopic sinus surgery (ESS) comparable to patients with no history of GERD.

MATERIALS and METHODS

Adult (> 18 years) study subjects were enrolled at Oregon Health & Science University (OHSU, Portland, Oregon, USA) between September, 2004 and November, 2012 as part of a continuing, multi-institutional, observational, prospective cohort study.^{9,10} All subjects had a confirmed diagnosis of CRS based on current Rhinosinusitis Task Force criteria,^{11,12} and were prospectively enrolled at the time each subject elected to pursue ESS after initial medical management was unsuccessful in symptom alleviation. Initial medical management consisted of either broad-spectrum or culture-directed antibiotics and at least one course of oral and topical steroid therapy. Informed consent and authorization was obtained by a trained coordinator and all protocols were approved by the Institutional Review Board at OHSU.

Baseline clinical characteristics of subjects were recorded upon initial enrollment. History of aspirin intolerance, history of allergies, history of positive allergy testing, asthma, tobacco use and depression were collected prospectively. Patient data collection efforts surrounding this cohort did not originally include information regarding symptomatic GERD or therapeutic interventions for GERD; therefore, the cohort was retrospectively evaluated for a history of GERD precluding use of diagnostic guidelines or objective testing. Review of the patient history at the time of presentation identified subjects reporting a history of GERD as well as active medications indicated for GERD. Either of these criteria was considered to indicate a positive history of GERD, and subjects were considered undergoing medical therapy for GERD if they reported medications indicated for GERD.

Inclusion Criteria

Study subjects with record of either of the following inclusion criteria were included for initial study evaluation:

1. A history of GERD (ICD-9 code #530.81 for gastroesophageal reflux) or,
2. Use of medications indicated for GERD including:
 - A. Proton-pump inhibitors (omeprazole, lansoprazole, dexlansoprazole, esomeprazole, pantoprazole, rabeprazole)
 - B. H₂-receptor antagonists (cimetidine, ranitidine, famotidine, nizatidine)

Exclusion Criteria

Study subjects reporting no diagnosis of GERD, but on anti-reflux medication for the purpose of gastrointestinal prophylaxis - specifically, chronic corticosteroid or chronic non-steroidal anti-inflammatory use.

QOL Evaluation and Objective Testing

Subjects were administered the Rhinosinusitis Disability Index (RSDI) survey instrument, the 22-item Sinonasal Outcome Test (SNOT-22), and the Chronic Sinusitis Survey (CSS) during the preoperative enrollment meeting and during 6-, 12-, and 18-month postoperative follow-up visits when possible. Prior study has found no significant differences in postoperative QOL responses beyond the 6-month time point for this population.¹³ Utilizing a Likert scale (range: 0-4), the RSDI measures sinusitis disease-specific morbidity using 30 questions divided into physical, functional, and emotional subscales. Total scores range from 0 (the lowest level of disease impact) to 120 (the greatest level of disease impact).¹⁴ Similarly, the SNOT-22 survey instrument evaluates the severity of sinonasal symptoms associated with chronic rhinosinusitis. Total scores range from 0 (no impact of disease) to 110 (most severe impact of disease).¹⁵ The duration-based CSS is a validated 6-item survey instrument developed to measure both symptom severity and medication use within the 8 weeks preceding survey completion. Total and subscale scores range from 0 (most severe impact of disease) to 100 (no impact of disease).¹⁶

Computed tomography images in the coronal plane were obtained preoperatively and evaluated by the enrolling surgeon (TLS) using the Lund-Mackay staging system (score range: 0-24) at the initial enrollment meeting.¹⁷ Fiberoptic, rigid sinonasal endoscopy was performed preoperatively and postoperatively at the 6-, 12-, and 18-month clinic appointments when possible to visualize pathologic states within the paranasal sinuses. The last available endoscopic exam was used for postoperative comparisons to baseline. Endoscopic exams were staged using the scoring system described by Lund and Kennedy (score range: 0-20).¹⁸

Statistical Analysis

Data were collected on standardized clinical research forms and transferred into a central database collection system (Microsoft Office Access 2007, Microsoft Inc., Redmond, WA). The final dataset was analyzed using SPSS version 22.0 statistical software (IBM

Corporation, Armonk, NY). Descriptive statistics were compiled for all patient cofactors to evaluate assumptions of normality. Two-sided independent t-tests or Mann-Whitney U tests were used to evaluate differences in all continuous variables and QOL responses and mean improvement between subgroups where appropriate. Chi-square tests were used to compare differences between the frequency of demographic factors and comorbid conditions between patients with and without a history of comorbid GERD. Matched paired t-tests and Wilcoxon signed-rank tests were used to determine significant improvement in QOL between preoperative and postoperative time points.

RESULTS

Preoperative Patient Characteristics and Disease Severity

A total of 229 patients enrolled in the study met inclusion criteria. Sixty-nine subjects (30.1%) presented with a diagnosis of GERD at initial evaluation. **Table 1** demonstrates preoperative characteristics of patients with and without a history of GERD and CRS. Patients reporting a history of GERD were more likely to be older (53.8 years versus 47.6; $p=0.002$) and less likely to have positive allergy testing (12.5% vs. 50%; $p=0.002$). All objective measurements of severity of CRS (mean endoscopy and computed tomography scores) were comparable between patients with and without comorbid GERD ($p>0.334$). Forty-nine (68.1%) of the subjects reporting a history of GERD also reported use of active medical therapy.

QOL Findings at Baseline

Subjects reporting a history of GERD reported similar impact of disease at baseline across all disease-specific QOL constructs. **Table 2** demonstrates comparisons of mean RSDI, SNOT-22, and CSS survey scores at initial evaluation.

QOL and Endoscopic Outcomes

Subjects were followed for an average duration of 15.3(6.3) months. Both groups with and without a history of GERD showed improvement in all QOL measures between preoperative and last postoperative assessments (**Table 3**). Both groups with and without comorbid GERD were found to have a significant ($p<0.001$) improvement in endoscopy scores ($-3.3(4.6)$ vs. $-4.4(4.2)$, respectively). Both groups experienced a similar degree of improvement over time across all QOL constructs (**Table 4**). Subgroup analysis of subjects reporting medical therapy for GERD and patients reporting no active medical therapy showed no difference across all QOL constructs (**Table 5**).

DISCUSSION

The role of GERD in the pathogenesis of CRS is not well understood. Classically, GERD is associated with caustic gastric contents causing the gastroesophageal symptoms of heartburn and reflux. When the refluxate or the impact of the refluxate reaches beyond the esophagus, extra-esophageal reflux can trigger symptoms typically associated with bronchitis, laryngitis, pharyngitis and sinusitis.¹⁹ Prior retrospective analysis of patients undergoing ESS found GERD as the only preoperative characteristic predictive of ESS failure.⁸

Although this study was limited by its lack of disease-specific QOL outcome measures, it raised the important question of the impact of comorbid GERD on ESS outcomes.

The present study sought to further explore the impact of GERD on CRS QOL outcomes after ESS. Patients with comorbid GERD tended to be older than patients without GERD in this cohort. Interestingly, epidemiological studies do support an increase in GERD symptoms with age, but patients with GERD experience more severe patterns of acid reflux and reflux esophagitis with aging potentially predisposing patients to increased extra-esophageal reflux.²⁰ Subjects with GERD were also less likely to have positive allergy testing. It may be that the lower rate of positive allergy testing reflects the fact that patients with GERD have CRS that is less likely to be fueled by allergic mechanisms. Regardless, patients with GERD and CRS still experience similar QOL and endoscopic gains after ESS as patients without GERD.

There is growing evidence implicating extra-esophageal reflux as an exacerbating factor for CRS. DeGaudio has demonstrated that patients with persistent CRS after ESS have more nasopharyngeal reflux by pH probe monitoring than patients that have undergone successful ESS.²¹ Caustic gastric contents that reach the level of the sinuses may contribute to the mucociliary paralysis and mucosal inflammation that defines CRS. Furthermore, patients with CRS that report symptomatic reflux have been found to have *Helicobacter pylori* DNA present in surgical specimens from ethmoid mucosa when examined with polymerase chain reaction linking direct contact of sinonasal mucosa to symptomatic CRS.²²

Swelling of the upper respiratory mucosa is thought to be mediated in part through direct contact, but may also be propagated by a vagal reflexive response to isolated esophageal stimulation.²³ Interestingly, animal models demonstrate that other mammals exhibit vagally mediated bronchoconstriction when the esophagus is stimulated with acid.²³ When patients suffering from CRS are compared to healthy volunteers with a two channel 24 hours ambulatory pH probe, patients with CRS exhibit six times as many esophageal events but no difference in hypopharyngeal events.²⁴

Regardless of the precise mechanism, there is evidence that the association of GERD and impaired sinonasal function may predispose patients to develop CRS. Patients with endoscopically diagnosed GERD with no evidence of sinonasal inflammation (i.e., patients with CRS were excluded) on endoscopy have slowed saccharin transit times.²⁵ This finding carries the implication that perhaps GERD serves to predispose normal sinuses to developing CRS. Population-level studies support this hypothesis with a higher incidence of GERD present in the two years prior to developing CRS than patients that do not go on to develop CRS.²⁶

There are important limitations to this study that may have contributed to our inability to detect a significant difference between subjects with and without comorbid GERD. It may be that symptoms of GERD were effectively managed and therefore had no impact on the disease process and treatment of CRS. Although we stratified patients with GERD by presence of medical therapy in an effort to discern the impact of GERD-treatment on CRS, we could not account for subjects achieving successful control of reflux through lifestyle

modification alone. Additionally, no formal diagnostic criteria were used to establish a diagnosis of GERD, which allows for potential underreporting of GERD. Underreporting of GERD introduces potential non-differential misclassification bias by including patients with GERD into the non-GERD subgroup. This error could lead to an underestimate of the difference between the subgroups. However, in clinical practice, formal diagnostic testing, such as pH monitoring or endoscopy, is only employed in patients with alarm symptoms or at high-risk for complications.²⁷ Although this biases the present study against finding a difference, the diagnosis of GERD on history alone mirrors the reality clinicians often confront. Furthermore, the prevalence of GERD is estimated between 18.1%-27.8% in North America, which is comparable to the present study's rate of 31.4%.²⁸

Future study of patients with comorbid GERD and CRS would ideally be prospective in nature. Coupling objective measures of reflux with CRS QOL outcomes would help clarify the causative role of extra-esophageal reflux in CRS pathophysiology. Clinical studies on the CRS impact of anti-reflux medical therapy in patients with comorbid GERD would help clarify the clinical significance of extra-esophageal reflux.

CONCLUSION

There is emerging evidence that GERD may play a role in instigating and propagating symptoms of CRS. However, we found patients who report a history of GERD have comparable treatment outcomes after ESS for CRS to patients without a history of GERD. Similarly, patients undergoing active medical therapy for GERD have no difference in outcomes after ESS compared to patients with GERD without medical therapy. Further prospective study of GERD and CRS will help elucidate the role and clinical significance of GERD in treatment outcomes for CRS.

Acknowledgments

Financial Disclosures: Timothy L. Smith, MD, MPH and Jess C. Mace, MPH, CCRP, are supported by a grant from the National Institute on Deafness and other Communication Disorders (NIDCD), one of the National Institutes of Health, Bethesda, Maryland. (RO1 DC005805; PI/PD: TL Smith). Public clinical trial registration (<http://www.clinicaltrials.gov>) ID# NCT01332136. Timothy L. Smith, MD, MPH is also a consultant for IntersectENT, Inc. (Menlo Park, CA) which is not affiliated with this investigation.

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Table 1

Comparison of baseline demographic and clinical characteristics for CRS patients with and without GERD

Baseline Characteristics:	History of GERD (n=72)			No GERD History (n=157)			p-value
	Mean (SD)	Range	N(%)	Mean (SD)	Range	N(%)	
Age (years)	53.8 (13.3)	[24 - 81]		47.6 (14.2)	[20 - 79]		0.002
Male			41 (56.9)			78 (49.7)	
Female			31 (43.1)			79 (50.3)	0.307
Medical therapy for GERD *			49 (68.1)	---	---	---	---
Previous sinus surgery			46 (63.9)			90 (57.3)	0.348
Nasal polyposis			33 (45.8)			81 (51.6)	0.418
Septal deviation			26 (36.1)			55 (35.0)	0.874
Asthma			24 (33.3)			61 (38.9)	0.422
Aspirin intolerance			5 (6.9)			18 (11.5)	0.291
Allergies (history)			7 (9.7)			17 (10.8)	0.800
Allergies (testing)			9 (12.5)			50 (31.8)	0.002
Depression			16 (22.2)			24 (15.3)	0.199
Current smoker			6 (8.3)			6 (3.8)	0.155
L-K Endoscopy score	7.8 (4.6)	[1 - 20]		7.7 (3.9)	[0 - 18]		0.957
L-M CT score	13.3 (6.6)	[2 - 24]		14.1 (5.9)	[2 - 24]		0.334

CRS, chronic rhinosinusitis; GERD, gastroesophageal reflux disease; SD, standard deviation; L-K, Lund-Kennedy; L-M, Lund-MacKay.

* Patient reporting use of H2-blocker or proton-pump inhibitor

Table 2

Comparison of baseline QOL scores for CRS patients with and without GERD

Baseline QOL measures:	History of GERD		No GERD History		p-value
	Mean (SD)	Range	Mean (SD)	Range	
	(n=72)		(n=157)		
RSDI physical subscale	19.4 (7.7)	[2 - 44]	19.5 (8.4)	[2 - 40]	0.925
RSDI functional subscale	15.5 (8.4)	[0 - 36]	15.2 (7.3)	[0 - 36]	0.756
RSDI emotional subscale	14.3 (8.9)	[0 - 37]	13.2 (7.8)	[0 - 40]	0.306
RSDI total	49.3 (22.4)	[3 - 111]	47.8 (20.9)	[5 - 116]	0.642
	(n=37)		(n=112)		
CSS symptom subscale	22.8 (22.1)	[0 - 92]	29.2 (27.2)	[0 - 92]	0.196
CSS medication subscale	47.3 (23.7)	[0 - 92]	47.4 (25.1)	[0 - 100]	0.983
CSS total	35.0 (17.4)	[0 - 80]	38.3 (19.1)	[0 - 84]	0.359
	(n=35)		(n=45)		
SNOT-22	54.2 (18.0)	[26 - 99]	59.1 (20.7)	[15 - 106]	0.274

QOL, quality of life; CRS, chronic rhinosinusitis; GERD, gastroesophageal reflux disease; SD, standard deviation; RSDI, Rhinosinusitis Disability Index; CSS, Chronic Sinusitis Survey; SNOT-22, 22-item Sinonasal Outcome Test

Table 3

Comparison in mean change of QOL scores post-ESS in CRS patients with and without GERD.

QOL Improvement:	History of GERD				p-value
	Preoperative		Postoperative		
	Mean (SD)	Range	Mean (SD)	Range	
	(n=72)				
RSDI physical subscale	19.4 (7.7)	[2 - 44]	10.0 (7.7)	[0 - 33]	<0.001
RSDI functional subscale	15.5 (8.4)	[0 - 36]	7.8 (7.4)	[0 - 32]	<0.001
RSDI emotional subscale	14.3 (8.9)	[0 - 37]	8.7 (8.2)	[0 - 39]	<0.001
RSDI total	49.3 (22.4)	[3 - 111]	26.5 (20.5)	[0 - 101]	<0.001
	(n=37)				
CSS symptom subscale	22.8 (22.1)	[0 - 92]	60.8 (25.7)	[0 - 100]	<0.001
CSS medication subscale	47.3 (23.7)	[0 - 92]	59.5 (23.6)	[0 - 100]	0.021
CSS total	35.0 (17.4)	[0 - 80]	60.1 (21.1)	[12 - 88]	<0.001
	(n=35)				
SNOT-22	54.2 (18.0)	[26 - 99]	33.2 (18.6)	[3 - 76]	<0.001

QOL Improvement:	No GERD History				p-value
	Preoperative		Postoperative		
	Mean (SD)	Range	Mean (SD)	Range	
	(n=157)				
RSDI physical subscale	19.5 (8.4)	[2 - 40]	10.3 (8.4)	[0 - 37]	<0.001
RSDI functional subscale	15.2 (7.3)	[0 - 36]	7.9 (7.8)	[0 - 35]	<0.001
RSDI emotional subscale	13.2 (7.8)	[0 - 40]	7.4 (7.6)	[0 - 40]	<0.001
RSDI total	47.8 (20.9)	[5 - 116]	25.6 (22.0)	[0 - 105]	<0.001
	(n=112)				
CSS symptom subscale	29.2 (27.2)	[0 - 92]	60.9 (30.1)	[0 - 100]	<0.001
CSS medication subscale	47.4 (25.1)	[0 - 100]	58.2 (25.6)	[0 - 100]	<0.001
CSS total	38.3 (19.1)	[0 - 84]	59.6 (21.0)	[12 - 100]	<0.001
	(n=45)				
SNOT-22	59.1 (20.7)	[15 - 106]	30.0 (23.0)	[2 - 104]	<0.001

QOL, quality of life; ESS, endoscopic sinus surgery; CRS, chronic rhinosinusitis; GERD, gastroesophageal reflux disease; SD, standard deviation; RSDI, Rhinosinusitis Disability Index; CSS, Chronic Sinusitis Survey; SNOT-22, 22-item Sinonasal Outcome Test

Table 4

Comparison of mean improvement in outcome measures between CRS patients with and without GERD.

QOL Improvement:	History of GERD		No GERD History		p-value
	Mean (SD)	Range	Mean (SD)	Range	
	(n=72)		(n=157)		
RSDI physical subscale	-9.3 (9.0)	[-44, 11]	-9.2 (9.2)	[-35, 27]	0.926
RSDI functional subscale	-7.8 (8.0)	[-24, 7]	-7.3 (7.6)	[-32, 13]	0.644
RSDI emotional subscale	-5.7 (8.3)	[-28, 16]	-5.8 (7.2)	[-31, 14]	0.884
RSDI total	-22.7 (22.1)	[-92, 25]	-22.2 (21.4)	[-92, 50]	0.878
	(n=37)		(n=112)		
CSS symptom subscale	38.0 (27.8)	[-17, 100]	31.8 (33.3)	[-67, 100]	0.303
CSS medication subscale	12.2 (30.6)	[-59, 100]	10.8 (26.2)	[-42, 84]	0.791
CSS total	25.1 (23.7)	[-30, 88]	21.3 (22.5)	[-46, 75]	0.378
	(n=35)		(n=45)		
SNOT-22	-21.0 (20.4)	[-71, 27]	-29.1 (26.0)	[-100, 65]	0.134

CRS, chronic rhinosinusitis; GERD, gastroesophageal reflux disease; QOL, quality of life; SD, standard deviation; RSDI, Rhinosinusitis Disability Index; CSS, Chronic Sinusitis Survey; SNOT-22, 22-item Sinonasal Outcome Test

Table 5

Comparison of QOL mean improvements in subjects with medically treated GERD and subjects with GERD reporting no medical treatment.

QOL Improvement:	Medically Treated GERD		Not Medically Treated GERD		p-value
	Mean (SD)	Range	Mean (SD)	Range	
	(n=49)		(n=23)		
RSDI physical subscale	-9.3 (9.3)	[-44, 101]	-9.3 (8.4)	[-27, 11]	0.847
RSDI functional subscale	-7.7 (8.2)	[-24, 7]	-7.8 (7.8)	[-21, 7]	0.904
RSDI emotional subscale	-5.6 (8.3)	[-28, 8]	-5.7 (8.3)	[-23, 16]	0.828
RSDI total	-22.7 (23.1)	[-92, 25]	-22.9 (20.1)	[-56, 19]	0.861
	(n=27)		(n=10)		
CSS symptom subscale	39.5 (27.0)	[0, 100]	34.2 (31.0)	[-17, 75]	0.880
CSS medication subscale	14.8 (26.1)	[-59, 50]	5.0 (41.2)	[-50, 100]	0.191
CSS total	27.2 (20.0)	[-17, 63]	19.6 (32.4)	[-30, 88]	0.229
	(n=22)		(n=13)		
SNOT-22	-19.7 (23.3)	[-71, 27]	-23.2 (14.8)	[-47, -2]	0.724

QOL, quality of life; GERD, gastroesophageal reflux disease; SD, standard deviation; RSDI, Rhinosinusitis Disability Index; CSS, Chronic Sinusitis Survey; SNOT-22, 22-item Sinonasal Outcome Test