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Longitudinal improvement and stability of the SNOT-22 survey in the evaluation of surgical management of chronic rhinosinusitis

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Abstract

Background—Patients with chronic rhinosinusitis (CRS) have significant quality-of-life (QOL) improvements following endoscopic sinus surgery (ESS). These improvements remain stable and persist between 6-months and 20-months as measured by the Rhinosinusitis Disability Index and the Chronic Sinusitis Survey. There has yet to be an evaluation of the longitudinal stability of the Sinonasal Outcome Test-22 (SNOT-22) after ESS in patients with CRS.

Methods—Adults with medically recalcitrant CRS who were considered surgical candidates were enrolled in a prospective, multi-center, observational cohort study from February 2011 to February 2013. Baseline evaluation of subjects included assessment of clinical characteristics, measures of CRS-specific disease severity, and QOL evaluation using the SNOT-22. Subjects were then re-evaluated at approximately 6-month, 12-month, and 18-month intervals postoperatively. Data was analyzed using repeated measures ANOVA with Bonferroni corrections for matched pairwise comparisons.

Results—110 patients completed baseline evaluations and follow-up for all three postoperative time points. Significant improvement in SNOT-22 scores was seen between baseline and 6-months across both SNOT-22 total and subdomain scores ($p < 0.001$). There was no statistically significant difference between the 6-month, 12-month, and 18-month time points in the total SNOT-22 score or its domains ($p = 0.125$) for both the entire cohort or subgroups ($p = 0.077$).

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Conclusions—Postoperative improvement in CRS-specific QOL and symptom severity, as measured by the SNOT-22, suggest stability and durability between 6-months and 18-months. Further study on the longitudinal stability of the SNOT-22 past the 18-month timeframe will help further refine clinical study of CRS and provide further understanding of temporal improvements following ESS.

MeSH Key Words

sinusitis; therapeutics; quality of life; outcome assessment; endoscopy

INTRODUCTION

The interval change in patient quality of life (QOL) continues to be the most widely used metric of investigation to quantify outcomes after treatment for CRS.¹ Accurate determination of the minimum time interval required to capture significant and clinically meaningful change allows for efficient use of limited study resources. Multi-institutional prospective cohort data has shown that two CRS disease-specific QOL measures, the Rhinosinusitis Disability Index (RSDI) and the Chronic Sinusitis Survey (CSS), are stable between 6- and 20-months after endoscopic sinus surgery (ESS).² Additionally, a longitudinal investigation comparing patients with CRS electing surgical versus medical management demonstrated QOL stability using these same outcome measures.³

The Sinonasal Outcome Test-22 (SNOT-22) has emerged as a commonly used CRS-specific QOL metric and has been evaluated as the primary outcome in prospective studies.^{4–6} Longitudinal SNOT-22 data has similarly been reported across a variety of disease processes (e.g., CRS, anterior skull base neoplasms, cystic fibrosis associated sinusitis);^{7–11} however, the majority of these studies are retrospective in nature and derived from a single-institution experience. One notable exception is the English and Welsh cohort, which has investigated five year follow-up SNOT-22 scores undergoing ESS with and without nasal polyposis.⁴ Even though that investigation incorporated one of the largest real-life cohorts utilizing the SNOT-22 instrument, the study was limited and potentially biased by varied responses rates for each longitudinal time point. Additionally, surgical extent is notoriously more conservative in the National Health System as is acknowledged in prior reporting of this cohort as well as reflected in the operative times when compared to North American surgical standards.¹²

The present study seeks to characterize the longitudinal trends of post-intervention SNOT-22 scores however have yet to be prospectively evaluated to assess whether symptoms of CRS stabilize in a similar fashion in a North American patient population. Furthermore, the SNOT-22 instrument has been since found to contain five distinct sub-domains, which are differentially associated with treatment selection and are variably impacted by treatment interventions.¹³ The goal of the present study is to prospectively investigate whether patients report similar symptom improvement and stability after surgical management, as measured by SNOT-22 total and sub-domain scores, and to identify a minimal length of time required to achieve that improvement.

MATERIALS and METHODS

Patient Population and Inclusion Criteria

Adult patients with a confirmed diagnosis of CRS, as determined by the American Academy of Otolaryngology—Head and Neck Surgery Foundation consensus guidelines,¹⁴ were prospectively enrolled into an on-going observational cohort study across five academic rhinology practices (Oregon Health & Science University {Portland, OR.} the Medical University of South Carolina {Charleston, SC.}, Stanford University {Palo Alto, CA.}, University of Calgary {Calgary, Alberta, Canada},). Preliminary findings from this cohort have been previously reported.^{5,6,15–20} Inclusion criteria also required prior treatment with at least a 2-week course of broad-spectrum or culture directed antibiotics in addition to either nasal steroid spray for at least 3-weeks or at least a 7-day course of systemic steroids.

Participants that failed to improve with medical therapy were identified as candidates for ESS and were enrolled following counseling surrounding treatment options. Participants electing to proceed with ESS were included in the final analysis. Surgical management plans were tailored by the enrolling surgeon at each site based on reported disease burden and both radiologic and visual assessments of disease severity and location.

Study Data Collection and Management

Study participants were required to complete baseline surveys and provide informed consent in English. Demographic, medical comorbidity, and disease severity measures were collected during the initial screening and enrollment visit. All study data was de-identified and collected at each site using standardized clinical research forms, and manually transferred to a centralized database (Access 2007; Microsoft Inc., Redmond, WA.) for further analysis. Central review and study coordination was conducted at OHSU (eIRB #7198) while the Institutional Review Board at each enrollment site provided annual review and approval for all study protocols.

Baseline evaluations included completion of the Sinonasal Outcome Test (SNOT-22),²¹ Lund-Kennedy nasal endoscopy scoring²² and Lund-Mackay scoring of computed tomography (CT) of the sinuses.²³ Both endoscopy and CT scoring was performed by the enrolling surgeon at each site. Follow-up evaluations consisted of asking patients to complete the SNOT-22 instrument at 6-months, 12-months, and 18-months postoperatively either during routine follow-up appointments or via follow-up reminder mailings using the United States Postal Service with self-addressed return envelopes. Concurrent follow-up endoscopy examinations, with associated Lund-Kennedy scores, were collected at 6-month, 12-month, and 18-month intervals when feasible.

Exclusion Criteria

Subjects diagnosed with a current exacerbation of either recurrent acute sinusitis or CRS associated with either comorbid ciliary dyskinesia or cystic fibrosis were excluded from the final study cohort due to the heterogeneity of those underlying disease processes. Subjects were excluded from final analyses if they failed to complete baseline and all three follow-up

evaluations at the appropriate intervals or if they had not yet entered into the 18-month follow-up window.

Primary Outcome Measurements

The SNOT-22 is a validated, 22-item treatment outcome measure applicable to chronic sinonasal conditions (©2006, Washington University, St. Louis, MO, USA). Higher scores on the SNOT-22 survey items suggest worse patient functioning or symptom severity (total score range: 0–110). Scoring is conducted via Likert scale responses whereas 0=“No problem”, 1=“Very mild problem”, 2=“Mild or slight problem”, 3=“Moderate problem”, 4=“Severe problem”, and 5=“Problem as bad as it can be”. Individual sub-domain scores of the SNOT-22 were operationalized based upon prior analysis of the SNOT-22 that revealed 5 underlying sub-domains.¹⁹ The 22-items of the SNOT-22 survey were re-categorized and summarized into five distinct domains including: rhinologic symptoms, extra-nasal rhinologic symptoms, ear/facial symptoms, psychological dysfunction, and sleep dysfunction (Table 1).

Statistical Analysis

All statistical analyses were completed using a commercially available software application (SPSS v.22; IBM Corporation, Armonk, NY.). Descriptive analysis was used to evaluate means [standard deviations] and frequencies of all demographic, medical comorbidity, and disease severity measures. Two-sided matched pair *t* tests were used to determine significant changes in continuous SNOT-22 scores between two time points. Repeated measures analysis of variance (ANOVA) with a Greenhouse-Geisser correction was used to test within-subjects effects using either Level III or Level IV models. When F-tests identified overall significant associations, post hoc Bonferroni adjustments were used to evaluate matched pairwise comparisons between time points. All statistical analysis assumed a 0.050 error probability.

RESULTS

Final Study Population

Between February 2011, and February, 2013 a total of 119 participants met inclusion criteria and completed all follow-up evaluations (Figure 1). A total of 9 subjects were excluded due to either ciliary dyskinesia, cystic fibrosis related sinusitis, or recurrent acute rhinosinusitis leaving 110 subjects for final analysis. Baseline demographics, medical comorbidities and disease severity measures are described in Table 2. Mean follow-up times for all three required 6-, 12-, and 18-month interval visits were 6.3[1.3], 12.3[1.6], and 18.7[1.9] months, respectively.

Quality of life Outcome Trends

Longitudinal trends in average SNOT-22 aggregate scores for all subjects were found to significantly improve ($F_{(2,43)}=99.36$; $p<0.001$) within the first 6-months after surgical intervention (Figure 2). Aggregate scores remained statistically similar between 6-, 12-, and 18-month follow-up ($p=0.061$). Statistically significant improvements in SNOT-22 total scores were also found between baseline and 6-months post-intervention (Table 3) for all

study subgroups with the exception of current tobacco smokers potentially due to limited sample size (n=3).

Global comparisons of post-treatment follow-up SNOT-22 total scores revealed no significant differences between 6-month, 12-month, and 18-month mean scores for any of the study subgroups with the exception of those study participants with nasal polyposis (22.1[14.4], 23.1[17.0], 27.8[19.6], at 6-,12-,18-months, respectively; $F_{(1,92)}=3.63$; $p=0.033$). Post hoc pairwise comparisons revealed however that the average increase in SNOT-22 total scores in that subgroup between 6-month and 18-months was not significantly different at the conventional 0.050 alpha level ($p=0.077$; Table 4).

Similar to overall SNOT-22 results, repeated measures ANOVA determined that mean SNOT-22 scores significantly improved ($p<0.001$) between baseline and 6-month follow-up for all five sub-domains (Table 5), while post hoc Bonferroni corrections found no significant differences between any two follow-up time points for rhinologic symptom scores ($p=0.212$), extra-nasal rhinologic symptom scores ($p=0.597$), ear/facial symptom scores ($p=0.125$), psychological dysfunction scores ($p=0.374$), or sleep dysfunction scores ($p=0.286$).

Endoscopy Score Trends

Subjects with endoscopy examinations at all four study time points (n=24) were evaluated for longitudinal trends in mean Lund-Kennedy staging scores. Subjects were found with a mean baseline endoscopy score of 6.1[4.3], a 6-month mean score of 4.4[2.9], a 12-month mean score of 3.5[2.2], and 18-month mean score of 4.3[3.1]. While testing of within-subjects effects found a global improvement ($F_{(2,17)}=3.69$; $p=0.029$), pairwise comparisons were only able to identify significant improvement between baseline and 12-month scores.

DISCUSSION

This investigation was able to prospectively identify improvement durability and stability of SNOT-22 score between 6-month and 18-months following ESS. There were no significant differences in SNOT-22 total scores between 6-month and 18-month follow-up time points. Similarly, sub-domains of the SNOT-22 were not significantly different between 6-month and 18-month following surgical intervention. When SNOT-22 scores were stratified by medical comorbidities, which have been previously associated with diminished QOL improvement, average survey scores remained stable over time. Mean SNOT-22 aggregate scores did increase, on average, between 6-month, 12-month, and 18-months by approximately 4 score units, however that was not statistically significant nor does it reflect a minimal clinically important difference which has been found in prior study to approximate 9 points.²¹

Although there has been prior investigation using the RSDI and CSS to track longitudinal trends CRS-specific QOL measures in a North American prospective cohort study,² there has yet to be such an investigation into the SNOT-22. It was a common assumption that the SNOT-22 also has longitudinal stability beyond 6-months due to known correlations between the RSDI and SNOT-22.^{5,6,19,20,24} The present study serves as evidence that total

and subdomain scores of the SNOT-22, as well as the symptoms they measure, have inherent postoperative stability between 6-months and 18-months in patients with CRS undergoing ESS. This data suggests that 6 month SNOT-22 data could be considered a surrogate for 12–18 month SNOT-22 scores. Short-term follow-up (6–24 months) in many cases can be beneficial due to increased cost associated with longer-term study and standard patient attrition in academic, tertiary practices. However, we acknowledge that this does not abrogate the need for well-designed long-term QOL outcomes. Ideally, given the chronicity of CRS, studies including follow-up between 5 – 10 years would allow for a more accurate and complete understanding of the efficacy of a given intervention as well as its impact on revision surgery rates.

A prospective clinical trial of CRS utilizing follow-up procedures greater than 18-months can be a challenging endeavor, but clinicians routinely encounter patients that underwent prior ESS many years previously. One retrospective cohort study investigating the rate of revision surgery in subjects with CRS with nasal polyposis found that the mean time to revision surgery was on average approximately 5 years.²⁵ The present study identified that study participants with nasal polyposis had a rising burden of disease indicated by higher mean SNOT-22 scores, and although achieved statistical significance did not reach a clinically meaningful change over time, which has been reported to be approximately 9.0 points on the SNOT-22.²¹ However, in the context of the findings on long-term follow-up it's conceivable that our data is demonstrating manifestations of rising sinonasal inflammation and polyp recurrence. Taken together, this data highlights the importance of identifying treatment strategies that might reduce the rates of revision surgery or at least increase the interval between surgical interventions in the subtype of CRS. Due to the lifetime impact of CRS, we need to develop innovative strategies to accurately investigate the long-term outcomes (e.g. between 5 – 10 years) following CRS-related interventions.

Extrapolation of these findings needs to be carefully considered by the clinician. The data presented here represent sample means, which may not reflect an individual's particular course which may fall on either side of these sample means at a given time point. Furthermore, subjects with CRS can experience relapsing and remitting symptoms that may not have been captured at the studied time points.¹⁴ Some individuals may experience early (less-than 6-months) worsening of quality-of-life and need additional revision surgery, such as in the event of adverse healing that results in obstructed, symptomatic sinuses. In this event, nothing would be gained from waiting until 6 months.

These findings should also be carefully applied to future clinical study. For example, the longitudinal trends of the SNOT-22 have yet to be elucidated for continued medical therapy without surgical intervention as a treatment comparison cohort. There have been calls for long-term prospective studies for continued medical therapy,²⁶ but 'long-term' has yet to be defined in an academic, tertiary care setting. Although, a difference of ~4 points on the aggregate SNOT-22 scores between 6-months and 18-months is not clinically meaningful on a 110 point scale, larger cohort sample size might achieve greater differences through regression to the mean. With regards to the subdomains of the SNOT-22 there has never been any description of what constitutes a clinically meaningful difference. Future study direction should also focus on QOL changes within the 6-month follow-up period using

various shorter intervals (e.g., 1-week, 2-weeks, 1-month, 2-month, 3-month, etc). It is probable that even 6-months is gratuitously long and a higher resolution of early follow-up would also allow for investigation into interventions and comorbidities associated with expedited recovery after endoscopic sinus surgery.

CONCLUSION

Following ESS, SNOT-22 scores assessed at 6-month intervals significantly improve and remain stable up to 18 months after surgery. Further study on the longitudinal stability of the SNOT-22 past the 18-month timeframe will help further refine clinical study of CRS and provide further understanding of temporal improvements following ESS. Furthermore, study of an earlier time frame will help clarify the rate at which disease-specific QOL recovers after ESS.

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Figure 1.
Final cohort selection after inclusion and exclusion criteria

Figure 2.

Longitudinal trends in mean SNOT-22 aggregate scores for subjects with and without nasal polyposis.

Table 1

Categorized survey items for separate domains of the SNOT-22 instrument

SNOT-22 Domains:	Survey Items:	Score Range:
Rhinologic Symptoms	#1, #2, #3, #6, #21, #22	0–30
Extra-Nasal Rhinologic Symptoms	#4, #5, #6	0–15
Ear/Facial Symptoms	#2, #7, #8, #9, #10	0–25
Psychological Dysfunction	#14, #15, #16, #17, #18, #19, #20	0–35
Sleep Dysfunction	#11, #12, #13, #14, #15	0–25

SNOT-22, 22-item Sinonasal Outcome Test

Table 2

Baseline patient characteristics for subjects electing endoscopic sinus surgery (n=110)

Demographics:	Mean [SD]	N (%)
Age (years)	56.7 [12.2]	
Males		50 (45.5)
Females		60 (54.5)
White / caucasian		99 (90.0)
Hispanic / Latino		6 (5.5)
Medical comorbidity:		
Asthma		39 (35.5)
Nasal polyposis		41 (37.3)
Allergies (skin prick / RAST)		40 (36.4)
ASA intolerance		10 (9.1)
Depression		19 (17.3)
Current tobacco smoker		3 (2.7)
Previous sinus surgery		59 (53.6)
Baseline disease severity:		
Computed tomography score	12.8 [6.0]	
Endoscopy score	6.2 [3.9]	
SNOT-22 total score	52.8 [19.8]	
Rhinologic symptoms	16.4 [6.4]	
Extra-nasal rhinologic symptoms	9.0 [3.3]	
Ear / facial symptoms	9.3 [5.1]	
Psychological dysfunction	15.3 [8.7]	
Sleep dysfunction	13.3 [7.3]	

SD, standard deviation; RAST, radioallergosorbent testing; ASA, acetylsalicylic acid; SNOT-22, 22-item Sinonasal Outcome Test

Table 3

Mean SNOT-22 total scores between baseline and 6-month follow-up time points (n=110)

Characteristics:	Baseline Mean [SD]	6 Month Follow-up Mean [SD]	p-value
Males	44.9 [17.3]	23.3 [17.4]	<0.001
Females	59.4 [19.5]	24.9 [17.4]	<0.001
Asthma	54.2 [21.5]	24.2 [15.6]	<0.001
Nasal polyposis	52.3 [22.8]	22.1 [14.4]	<0.001
Allergies (skin prick / RAST)	55.8 [18.4]	24.6 [19.2]	<0.001
ASA intolerance	60.4 [23.7]	30.7 [18.9]	0.011
Depression	58.3 [14.7]	31.1 [20.4]	<0.001
Current tobacco smoker	50.0 [7.0]	9.0 [13.0]	0.109
Previous sinus surgery	54.6 [19.4]	29.0 [19.7]	<0.001

SD, standard deviation; RAST, radioallergosorbent testing; ASA, acetylsalicylic acid; SNOT-22, 22-item Sinonasal Outcome Test

Table 4

Mean post-treatment scores for SNOT-22 total scores (n=110)

Characteristics:	6 Month Follow-up Mean [SD]	12 Month Follow-up Mean [SD]	18 Month Follow-up Mean [SD]	F-test statistic	df	p-value
Males	23.3 [17.4]	24.8 [19.7]	27.3 [18.3]	1.82	1.97	0.168
Females	24.9 [17.4]	27.4 [21.7]	29.2 [21.5]	1.85	1.97	0.163
Asthma	24.2 [15.6]	26.8 [22.1]	29.5 [22.0]	2.26	1.89	0.115
Nasal polyposis	22.1 [14.4]	23.1 [17.0]	27.8 [19.6]	3.63	1.92	0.033
Allergies (skin prick / RAST)	24.6 [19.2]	26.4 [22.5]	25.3 [20.1]	0.32	1.95	0.724
ASA intolerance	30.7 [18.9]	37.0 [28.3]	35.4 [23.0]	0.70	1.41	0.467
Depression	31.1 [20.4]	29.1 [20.7]	32.4 [17.3]	0.31	1.53	0.676
Current tobacco smoker	9.0 [13.0]	14.0 [18.5]	18.0 [19.1]	0.28	1.13	0.672
Previous sinus surgery	29.0 [19.7]	31.0 [22.1]	32.7 [21.5]	1.25	1.99	0.289

SD, standard deviation; df, degrees of freedom; RAST, radioallergosorbent testing; ASA, acetylsalicylic acid; SNOT-22, 22-item Sinonasal Outcome Test

Longitudinal trends in mean SNOT-22 sub-domain scores following endoscopic sinus surgery (n=110)

Table 5

SNOT-22 Sub-domains:	Baseline Mean [SD]	6 Month Follow-up Mean [SD]	12 Month Follow-up Mean [SD]	18 Month Follow-up Mean [SD]	F-test statistic	df	p-value
Rhinologic symptoms	16.4 [6.4]	7.4 [6.0]	7.8 [6.3]	8.5 [6.1]	94.66	2,33	<0.001
Extra-Nasal Rhinologic Symptoms	9.0 [3.3]	4.1 [3.5]	4.3 [3.5]	4.6 [3.6]	101.99	2,54	<0.001
Ear/Facial Symptoms	9.3 [5.1]	4.1 [3.9]	4.6 [4.6]	5.0 [4.5]	60.11	2,60	<0.001
Psychological Dysfunction	15.3 [8.7]	7.0 [7.0]	7.6 [7.9]	8.1 [7.8]	55.84	2,29	<0.001
Sleep Dysfunction	13.3 [7.3]	6.8 [6.0]	7.4 [6.9]	7.9 [6.4]	48.74	2,41	<0.001

SD, standard deviation; df, degrees of freedom; SNOT-22, 22-item Sinonasal Outcome Test