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Journal

International Forum of Allergy & Rhinology, 6(3)

ISSN

2042-6976

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Publication Date

2016-03-01

DOI

10.1002/alr.21656

Peer reviewed

HHS Public Access

Author manuscript

Int Forum Allergy Rhinol. Author manuscript; available in PMC 2017 March 01.

Published in final edited form as:

Int Forum Allergy Rhinol. 2016 March ; 6(3): 315–321. doi:10.1002/alr.21656.

Patients electing medical versus surgical treatment: emotional domain of the rhinosinusitis disability index associates with treatment selection

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Abstract

Background—The Rhinosinusitis Disability Index (RSDI) consists of multiple subdomains shown to be useful in studying CRS. The objective of this study was to determine if RSDI subdomain scores are associated with selection of treatment modality (endoscopic sinus surgery (ESS) or continued medical management (CMM)) in subjects with CRS.

Methods—Patients with CRS were prospectively enrolled into a multi-institutional cohort study. Following an initial period of medical management, patients elected to undergo treatment with either ESS or CMM. Baseline RSDI total and subdomain scores were compared between patients electing different treatment modalities.

Results—A total of 684 subjects were enrolled with 122 (17.8%) electing CMM and 562 (82.2%) electing ESS. When compared to patients undergoing CMM, patients electing ESS exhibited significantly higher mean baseline RSDI total scores (mean ± [SD]: 48.1[24.9] vs. 40.1[24.1]; p=0.001) and subdomain scores (emotional: 13.2[9.1] vs. 10.4[8.3]; p=0.001; functional: 15.3[8.9] vs. 12.6[8.4]; p=0.002; and physical: 19.6[9.3] vs. 17.1[9.6]; p=0.007). Emotional subdomain scores were found to be the most associated with choice of treatment modality.

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Potential Conflicts of Interest: None to report

Financial disclosures: There are no financial disclosures for Quinn Orb, Toby Steele, or Steve Cox.

The abstract for this manuscript was accepted for oral presentation to the American Rhinologic Society during the American Academy of Otolaryngology-Head and Neck Surgery annual meeting in Dallas, Texas, September, 25-26th, 2015.

Conclusions—Patients with CRS electing ESS had worse baseline RSDI total and subdomain scores compared to those electing CMM. Although both rhinologic and non-rhinologic symptoms contributed to the selection of treatment modality, emotional symptoms appeared to exhibit the greatest influence on patient-centered treatment decisions.

MeSH Keywords

sinusitis; quality of life; patient selection; endoscopy; questionnaires

Introduction

Chronic rhinosinusitis (CRS) is a highly prevalent disease that negatively effects patient quality of life (QOL).[1] Rhinologic, or sinus-specific, symptoms have been associated with having the greatest influence on QOL among patients with CRS. However, current evidence suggests that alternate symptoms or comorbidities, such as sleep, cognition, fatigue, anxiety and depression, play a significant role in the QOL of patients with CRS.[2-7] In fact, a recent evaluation of the 22-item Sinonasal Outcomes Test (SNOT-22) survey demonstrated that general health-related QOL factors (psychological and sleep dysfunction) may have a greater influence on treatment selection than rhinologic symptoms.[8]

The rhinosinusitis disability index (RSDI) is a validated questionnaire consisting of physical, functional and emotional subdomains, which is effective in studying outcomes of CRS treatment. The RSDI questionnaire was engineered to measure subdomains corresponding to physical, emotional, and functional QOL in patients with CRS.[9] It was one of the first QOL surveys developed specifically for patients with CRS and has been used in numerous studies to evaluate QOL among patients undergoing treatment for the disease.[9] This study seeks to determine if baseline QOL scores on the RSDI are associated with patient selection of treatment modality. We hypothesized that the RSDI would provide additional utility as a measure for evaluating the influence of different CRS-specific QOL factors on electing surgical versus medical management of CRS.

The objectives of the current study were to: 1) investigate the predictive ability of the distinct RSDI subdomains toward electing endoscopic-sinus surgery (ESS) versus continued medical management (CMM), and 2) delineate any association between the discrete domains of both RSDI and SNOT-22 in a prospectively enrolled, multi-institutional population.

Materials and Methods

Inclusion criteria and treatment modalities

Adult subjects (≥18 years of age) with a diagnosis of medically refractory CRS were prospectively enrolled into an on-going, multi-center, observational cohort investigation. The Institutional Review Board (IRB) at each enrollment location governed the investigational protocol and specific informed consent procedure. The sites of enrollment consisted of Rhinology and Skull Base surgery clinics within academic, tertiary hospital systems including the University of Utah (Salt Lake City, UT, *IRB #61810*), Oregon Health

& Science University (OHSU; Portland, OR, *IRB #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*).

Patients were diagnosed with CRS using criteria and guidelines endorsed by the American Academy of Otolaryngology.[10] All patients had previously received medical therapies including at least one course (≥14-days) of broad spectrum or culture directed antibiotics and at least one trial of topical corticosteroids (≥21-days) or a 5-day course of oral corticosteroid therapy.

All enrolled study participants provided informed consent in English and agreed to complete all study-related evaluations. Participants were asked to provide personal demographic information, as well as social and medical history including, but not limited to: gender, age, ethnicity, race, known allergies (by radioallergosorbent testing or patient history or confirmed skin-prick), asthma, nasal polyposis, depression, ASA intolerance, current tobacco use, recurrent acute sinusitis, previous sinus surgery and ciliary dyskinesia /cystic fibrosis. Participants were assured study involvement was completely voluntary and standard of care was in no way altered during the study duration.

Following initial medical management, all enrolled patients were considered to be candidates for ESS. Patients then elected either CMM, as indicated, or ESS as the subsequent treatment course. Treatment assignments were not randomized and patients were observed throughout their standard of care for ∼18 months. For patients electing ESS, intraoperative surgical treatment was based on surgeon's discretion and disease severity. Surgical procedures consisted of either unilateral or bilateral maxillary antrostomy, partial or total ethmoidectomy, sphenoidotomy, frontal sinus procedures (*Draf* 1, 2a, 2b, or 3) including or excluding inferior turbinate reduction and septoplasty. Follow-up assessments occurred at 6-month intervals either during physician-directed clinical appointments or via follow-up mailings using self-addressed return envelopes.

Clinical disease severity measures

High resolution computed tomography (CT) with bone and tissue windows was also utilized to evaluate preoperative sinonasal disease severity using 1.0*mm* contiguous images in axial plane reconstituted to sagittal and coronal planes. Images were also staged by the enrolling physician at each enrollment site in accordance with the Lund-Mackay bilateral scoring system (score range: 0-24) which quantifies the severity of image opacification in the maxillary, ethmoidal, sphenoidal, ostiomeatal complex, and frontal sinus regions using a Likert scale.[11] Postoperative CT evaluations were not collected due to risks associated with elevated radiation exposure and divergence from the standard of care.

Standard clinical measures of disease severity, collected during preoperative evaluations, were used simultaneously for investigational purposes. The paranasal sinuses were evaluated bilaterally using rigid, 30° endoscopes (SCB Xenon 175, Karl Storz, Tuttlingen, Germany) by the enrolling physician. Endoscopic exams were staged by the enrolling physician at each site using the bilateral Lund-Kennedy scoring system (score range: 0-20) which, quantifies pathologic states within the paranasal sinuses including the severity of polyposis, discharge,

edema, scarring, and crusting on a Likert scale.[12] Higher scores on both staging systems reflect worse disease severity.

Exclusion criteria

Study participants determined to have comorbid recurrent acute rhinosinusitis (RARS) or evidence of ciliary dyskinesia were excluded from final analyses to minimize cohort heterogeneity. Additionally, patients initially electing medical management, only later to select ESS as an alternate treatment modality, were excluded from the study. Finally, patients failing to complete either baseline evaluations or attend follow-up appointments within the 18-month follow-up timeframe were excluded.

Disease-specific QOL measures

Study participants completed two patient-based, QOL surveys during preoperative evaluation as part of a larger total battery of evaluative instruments. The SNOT-22 is a validated survey developed to evaluate symptom severity in rhinosinusitis (©2006, Washington University, St. Louis, MO, USA).[13,14] Previous exploratory factor analysis of SNOT-22 scores, using this cohort, identified 5 distinct domains.[15] Domains include rhinologic symptoms (score range: 0-30), extra-nasal rhinologic symptoms (score range: 0-15), ear and/or facial symptoms (score range: 0-25), psychological dysfunction (score range: 0-35), and sleep dysfunction (score range: 0-25). Higher domain and SNOT-22 scores (score range: 0-110) represent worse QOL and symptom severity. The RSDI is a 30-item survey instrument comprised of 3 subdomains to assess the impacts of rhinosinusitis on a participants physical (score range: 0-44), functional (score range: 0-36), and emotional (score range: 0-40) status.[9] Higher subdomain and total RSDI scores (score range: 0-120) represent worse QOL and greater impact of rhinosinusitis symptoms on patients' daily function.

Data management and statistical analysis

Statistical analyses were completed using SPSS v.22 statistical software (IBM Corp., Armonk, NY). All study data was de-identified and manually entered into a relational database (Microsoft Access; Microsoft Corp., Redmond, WA). Data normality was verified for all continuous measures using graphical analysis. Baseline study population characteristics and disease-specific QOL scores were descriptively evaluated across treatment modalities.

Two-tailed post hoc sample size estimations were determined using mean improvement on SNOT-22 total scores from previously published literature using this multi-center cohort of patients with CRS.[8] Assuming equal variance between independent treatment groups, 80% power (1-β error probability), and a conventional 0.05 alpha level the final sample size (n=684) is adequate to detect a mean difference of ∼5.3 points (effect size (d)=0.28) between treatment modality groups using an approximate 1:5 ratio of participants electing CMM over ESS.

Two-tailed independent sample t-tests were used to evaluate unadjusted mean differences between treatment modality cohort groups for all continuous variables. Chi-square (χ^2)

testing was used to compare the prevalence of demographic and comorbidity variables between treatment groups using 2×2 contingency tables. All comparisons were reported with Type I error probability (p-value) determined at the 0.050 level for significant difference. Linear associations between RSDI and SNOT-22 scores were also evaluated using two-sided Pearson's correlation coefficients (Rp) without alpha-level adjustments for multiple comparison.

Results

Baseline characteristics

A total of 848 study participants were enrolled between March, 2011 and January, 2015 and 684 subjects were selected for final analysis following the exclusion criteria. The study population consisted of 122 (18%) subjects electing CMM and 562 (82%) electing ESS to alleviate symptoms associated with CRS (Figure 1). Baseline demographic factors, medical comorbidity, and disease severity measures were compared between treatment modality groups (Table 1).

Average Baseline Quality of Life Domains

Differences in mean unadjusted baseline RSDI and SNOT-22 subdomain scores were compared between treatment modality groups (Table 2). Baseline aggregate RSDI scores were significantly worse in the surgical cohort than the medical cohort (unadjusted mean difference: 8.1 [Standard Error (SE) =2.5]; p = 0.001) with the emotional subdomain exhibiting the greatest difference (2.9 [SE = 0.9]; p = 0.001) followed by the functional subdomain (2.7 [SE = 0.9]; p = 0.002). The difference between the physical subdomain scores of the two cohorts remained statistically significant, but exhibited the smallest difference of the three RSDI subdomains (2.5 [SE = 0.9]; p = 0.007). The SNOT-22 baseline subdomain scores revealed a similar pattern with the difference in scores between the two cohorts achieving statistical significance in all subdomains with the exception of ear/facial symptoms (p=0.054).

Correlation between RSDI and SNOT-22 domains

The RSDI and SNOT-22 aggregate and subdomain scores, overall, were highly correlated across all subdomains ($p \leq 0.001$). However, the magnitude of correlation between baseline scores revealed that the RSDI emotional subdomain was most strongly correlated with the psychological symptoms of the SNOT-22 subdomain ($R_p = 0.726$). Alternatively, the emotional subdomain had the weakest correlation with the sinus-related SNOT-22 subdomains of rhinologic symptoms ($R_p=0.276$) and extra-nasal rhinologic symptoms ($R_p=0.265$). Of the three RSDI subdomains, the physical subdomain scores were the most highly correlated overall with the SNOT-22 subdomains. The only exception to this pattern was the relatively weaker correlation of the physical RSDI subdomain with the SNOT-22 psychological symptoms subdomain ($R_p =0.694$), which was more strongly correlated with the emotional ($R_p =0.726$) and functional ($R_p =0.729$) RSDI subdomains (Table 3).

Discussion

Prior research has demonstrated that the clinical assessment of CRS with CT and nasal endoscopy does not correlate well with CRS-specific QOL measurements and is not predictive of treatment modality.[16-19] For example, in a study by Hwang et al., 35% of patients meeting criteria for CRS had normal CT scans,[20] and Hopkins et al. reported that 21% of patients undergoing ESS for medically refractory CRS had Lund-Mackay scores within normal ranges.[21] Additionally, CRS patients with low-stage CT scans, who selected ESS, exhibited statistically significant improvement in RSDI scores following surgery.[16] As a consequence of these discrepancies, it is important for clinicians treating CRS to have additional tools to aid in clinical decision-making and help set patient expectations with respect to treatment outcomes following surgical intervention. Unlike clinical and radiologic staging, validated questionnaires are capable of quantifying patient perception of disease severity. The RSDI is a questionnaire that measures CRS-specific QOL within the subdomains of physical, functional and emotional symptoms related to CRS.[9] Furthermore, the RSDI scores are highly correlated with general health QOL scores.[22]

Similar to the RSDI, the SNOT-22 questionnaire is also effective in evaluating QOL in patients with CRS,[13] and the current study demonstrated that there is a strong correlation between the two questionnaires. These results were consistent with previous work by Quintanilla-Dieck et al. showing that the SNOT-22 and the RSDI are highly correlated and provide valuable information regarding the emotional impact of CRS.[23] Furthermore, both the RSDI and the SNOT-22 can be separated into subdomains allowing for additional insight into the variable aspects of CRS-specific QOL. These subdomains offer additional clinical utility in guiding treatment as aggregate QOL scores can oversimplify results by ignoring specific emotional or functional aspects of CRS that may be significantly correlated with general health.[24,25] Additionally, DeConde et al. demonstrated that worse baseline scores in the SNOT-22 subdomains of ‘psychological dysfunction’ and ‘sleep dysfunction’ were associated with patients electing ESS over CMM for treatment of CRS.[8] However, the current study also revealed significantly elevated baseline SNOT-22 scores in the subdomains of sinus-specific symptoms and extra-rhinologic symptoms among patients electing ESS. The discrepancy between the two studies is likely due to a larger sample size in the current study resulting in an improved ability to detect significant differences in QOL measures between the two treatment cohorts. As a result, we were able to show that although psychological and sleep dysfunction continue to have the greatest influence on patient-directed treatment choices, it is likely that the severity of physical symptoms also plays a role in treatment selection.

Similar to our results regarding the SNOT-22 subdomains, we demonstrated that worse baseline scores in each of the RSDI subdomains were associated with patient selection of ESS. However, the greatest and most significant difference in scores between the two cohorts occurred in the emotional subdomain. Additionally, we found that the emotional subdomain had the highest correlation with the SNOT-22 psychological dysfunction subdomain. Our results were in line with the previous findings of DeConde et al. demonstrating that baseline SNOT-22 psychological dysfunction scores were better indicators of electing surgical treatment than those subdomains relating to sinus-specific

symptoms.[8] These findings suggest that the current metrics for evaluating patients with CRS (i.e. CT, endoscopy, and severity of physical symptoms) are not well aligned with the factors that have the greatest influence on patient selection of treatment modality. We believe that to properly counsel patients in treatment planning, there is a need for clinicians to become more aware of patient-centered treatment selection. Future research should focus on the specific factors within each subdomain of the RSDI with the intention of gaining a better understanding of the influences driving treatment choices. Additionally, further work comparing the RSDI subdomain scores of patients following treatment with either ESS or CMM is needed to provide better insight into appropriate, patient-centered management of subjects with CRS.

Given the similarities between the RSDI and the SNOT-22 questionnaires one may assume that the two questionnaires are redundant in nature, but a few defining characteristics outline their differences. First, the RSDI is unique in the directness of its survey questions. For example, the questionnaire contains simple, direct questions that assess the effect of CRS on aspects of daily life such as reading, travel, and sexual dysfunction. Second, the RSDI consists of more questions than the SNOT-22, but reportedly requires less time to complete, which is likely due to the specificity of the questions. [9,26] Furthermore, there are only three unique subdomains of the RSDI, which allows the practitioner to quickly determine the aspects of a patient's life that are most greatly affected. The questionnaire is well constructed and provides excellent test-retest reliability with good internal consistency over time. [27] Third, the RSDI was one of the first CRS specific QOL questionnaires developed and numerous studies have utilized RSDI data collected from patients who completed the survey. Although the SNOT-22 has gained popularity more recently, there are likely many otolaryngologists who are more comfortable with the RSDI and continue to use it in clinical practice. In this study we show that the two questionnaires are comparable in nature, and thus one QOL survey need not be abandoned for the other.

With the changing healthcare environment, there is an increasing emphasis on creating reliable tools to be used in medical decision-making and the measurement of patient outcomes. Validated QOL questionnaires are capable of quantifying the severity of disease and determining the efficacy of different treatment options.[9] Our results suggest that the RSDI aggregate and subdomain scores are useful in identifying patients who are more likely to elect ESS. Furthermore, the RSDI can play an important role in guiding management of CRS by improving the selection of ideal surgical candidates and assisting otolaryngologists with more effectively setting patient expectations prior to ESS.

The strengths of the current study include its prospective, multi-institutional design and utilization of multiple validated instruments to assess patient QOL before and after treatment. However, the study also has several limitations to consider. The majority of participants in the study elected to undergo surgical management of their disease. This may be a direct result of the referral pattern for each of the four study sites, as each site is a centralized tertiary care sinus center. Thus, the findings of this study may not be generalizable to patients seen in a community setting or patients who have not previously undergone maximal medical management of CRS.

Conclusion

In one of the largest prospective studies to date, we demonstrated that baseline RSDI scores were associated with of treatment modality selection in subjects with CRS. Subjects electing ESS had significantly worse baseline scores across all subdomains compared to subjects electing CMM. Although both rhinologic and non-rhinologic symptoms appeared to contribute to the selection of treatment modality, the greatest difference in scores between the two groups occurred in the emotional subdomain. Further investigation evaluating outcomes across the RSDI subdomains is needed to provide a better understanding of QOL changes following treatment and could further optimize patient-centered management of CRS.

Acknowledgments

Timothy L. Smith, Jess C. Mace, and Jeremiah A. Alt were supported for this investigation by a grant from the National Institute on Deafness and Other Communication Disorders (NIDCD), one of the National Institutes of Health, Bethesda, MD., USA (R01 DC005805; PI/PD: TL Smith). Timothy L. Smith and Adam S. DeConde are consultants for IntersectENT (Menlo Park, CA., USA) which is not affiliated with this investigation.

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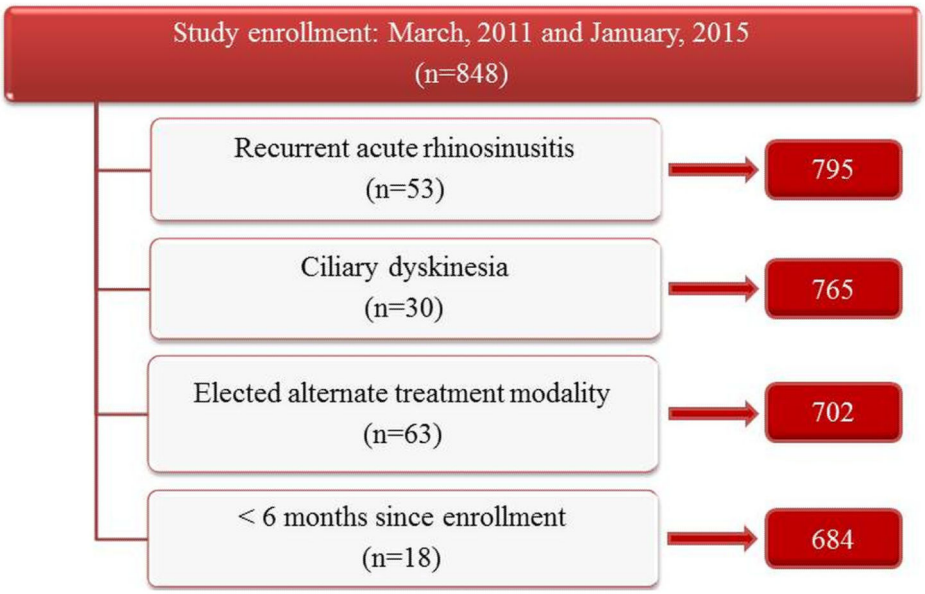

Figure 1.
Final cohort selection after all inclusion and exclusion criteria.

Table 1

Comparison of baseline demographics, medical comorbidity, and mean baseline disease severity measures between treatment modalities

	Continued Medical Management (n=122)		Functional Endoscopic Sinus Surgery (n=562)		
Demographics	**Mean [SD]**	**n (%)**	**Mean [SD]**	**n (%)**	**p-value**
Follow-up (months)	14.0 [5.0]		13.5 [5.4]		0.425
Age (years)	51.8 [13.7]		50.5 [15.2]		0.369
Males		56 (46%)		275 (49%)	----
Females		66 (54%)		287 (51%)	0.544
White / Caucasian		99 (81%)		487 (85%)	0.282
Hispanic / Latino		2 (2%)		34 (6%)	0.045
Medical comorbidity					
Asthma		49 (40%)		219 (39%)	0.806
Nasal polyposis		46 (38%)		221 (39%)	0.740
Allergies (mRAST or skin prick)		57 (47%)		262 (47%)	0.984
ASA intolerance		16 (13%)		50 (9%)	0.153
Depression		14 (12%)		83 (15%)	0.345
Current tobacco smoker		4 (3%)		34 (6%)	0.280
Previous sinus surgery		71 (59%)		309 (55%)	0.458
Disease severity measures					
Computed tomography (CT) scores	12.7 [5.9]		12.2 [6.1]		0.441
Endoscopy scores	6.0 [3.9]		6.1 [3.8]		0.904
SNOT-22 total scores	46.2 [19.9]		54.1 [20.3]		<0.001
RSDI total scores	40.1 [24.1]		48.1 [24.9]		0.001

SD, standard deviation; RAST, radioallergosorbent testing; ASA, acetylsalicylic acid; RSDI, Rhinosinusitis Disability Index; SNOT-22, 22-item SinoNasal Outcome Test.

Table 2

Comparison between unadjusted baseline mean RSDI and SNOT-22 subdomain scores between treatment modalities

	Continued Medical Management (n=122)	Functional Endoscopic Sinus Surgery (n=562)	Unadjusted mean difference		
SNOT-22 subdomain:	**Mean [SD]**	**Mean [SD]**	**B [SE]**	**t (682)**	**p-value**
Rhinologic symptoms	15.2 [6.1]	16.7 [6.3]	1.4 [0.6]	-2.31	0.021
Extra-nasal rhinologic symptoms	7.7 [3.4]	8.4 [3.6]	0.7 [0.4]	-1.98	0.048
Ear / facial symptoms	8.4 [5.6]	9.5 [5.2]	1.0 [0.5]	-1.93	0.054
Psychological dysfunction	12.9 [7.9]	16.4 [8.5]	3.4 [0.8]	-4.11	<0.001
Sleep dysfunction	11.6 [6.7]	14.1 [6.8]	2.5 [0.7]	-3.67	<0.001
RSDI subdomain:					
Physical	17.1 [9.6]	19.6 [9.3]	2.5 [0.9]	-2.69	0.007
Functional	12.6 [8.4]	15.3 [8.9]	2.7 [0.9]	-3.06	0.002
Emotional	10.4 [8.3]	13.2 [9.1]	2.9 [0.9]	-3.19	0.001

SNOT-22, 22-item SinoNasal Outcome Test. SD, standard deviation; SE, standard error of the mean difference; t, t-test statistic with degrees of freedom within parenthesis; RSDI, Rhinosinusitis Disability Index.

Table 3

Correlation coefficients (R_p) between baseline RSDI and SNOT-22 total and domain scores (n=684)

Baseline scores:	RSDI: Physical domain	RSDI: Functional domain	RSDI: Emotional domain	RSDI: Total
SNOT-22: Rhinologic symptoms	0.558*	0.376*	0.276*	0.443*
SNOT-22: Extra-nasal Rhinologic symptoms	0.435*	0.389*	0.265*	0.398*
SNOT-22: Ear / facial symptoms	0.642*	0.501*	0.455*	0.584*
SNOT-22: Psychological symptoms	0.694*	0.729*	0.726*	0.783*
SNOT-22: Sleep dysfunction	0.628*	0.553*	0.503*	0.615*
SNOT-22: Total	0.776*	0.682*	0.617*	0.758*

* indicates significant correlations with corresponding p-value <0.001. RSDI, Rhinosinusitis Disability Index; SNOT-22, 22-item SinoNasal Outcome Test.