Overall symptom severity as a patient-reported outcome measure for chronic rhinosinusitis: what it reflects and how to measure it

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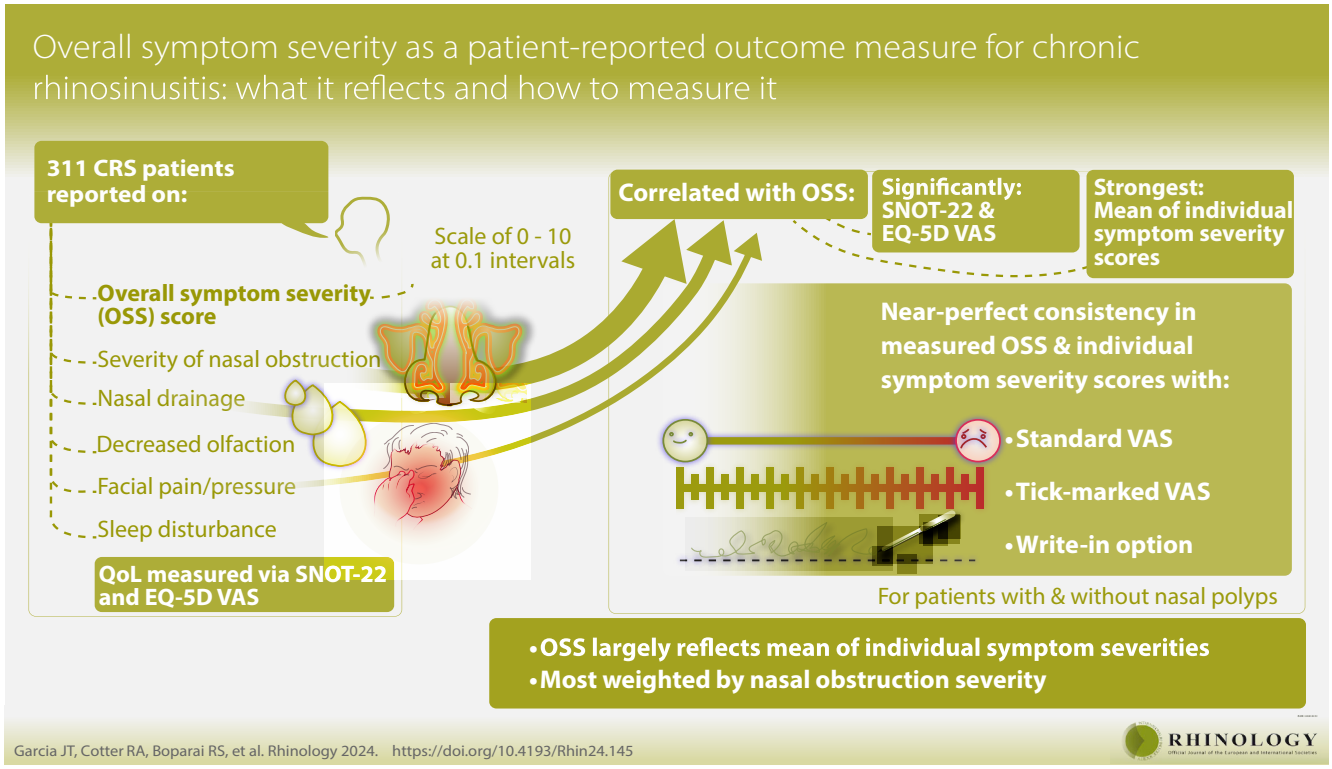

Abstract

Background: The objective of this study was to identify how - and to what extent - overall symptom severity (OSS) score reflects individual chronic rhinosinusitis (CRS) symptoms and whether it can be measured using alternatives to the standard visual analog scale (VAS). **Methods**: CRS patients from four sites across three continents rated their OSS scores, severities of nasal obstruction, nasal drainage, decreased sense of smell, facial pain/pressure and sleep disturbance using a standard VAS, VAS with labeled tick marks at every 1 centimeter, and by writing down their OSS on a scale of 0 - 100 (which was divided by 10), all of which lead to severity scores ranging from 0 - 10 in 0.1 intervals. Quality of life was measured using the SNOT-22 and EQ-5D VAS. **Results**: In 311 CRS patients, OSS score was significantly correlated with SNOT-22 and EQ-5D VAS. OSS score was most greatly associated with the mean of all individual symptom severity scores. From individual CRS symptoms, OSS was most greatly associated with nasal obstruction followed by nasal drainage and facial pain/pressure severities. These results held true for participants with and without nasal polyps. Measurement of OSS and individual symptom severity scores using a standard VAS, tick-marked VAS, and write-in option had near-perfect consistency. **Conclusions**: We demonstrate for the first time that OSS largely reflects the mean of individual CRS symptom severities, although OSS is=== most weighted by nasal obstruction severity. OSS and individual symptom severity scores can be measured using a standard VAS, tick-marked VAS or write-in prompt with near-perfect consistency.

Key words: chronic rhinosinusitis, overall symptom severity, total symptom score, patient-reported outcome, visual analog scale

Introduction

Patient-reported outcome measures (PROMs) are crucial for assessing the burden of chronic rhinosinusitis (CRS), a disease whose primary impact is on quality of life (QOL) [1,2]. PROMs for measuring the impact of CRS on affected patients include instruments that measure general and disease-specific QOL as well as instruments that measure symptom severity. PROMs have been developed to measure these constructs of CRS disease burden in different ways and with various response scales.

Overall symptom severity (OSS) is one of the first formally proposed means of staging CRS based on symptomatology and is traditionally measured using a visual analog scale (VAS) [3]. While individual symptom severity scores are intended to measure single dimensions of CRS symptomatology, the OSS score is intended to reflect the patient's global, big picture assessment of their CRS symptom severity [3]. OSS score has become a very important PROM for CRS. For example, the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) defines "severe" CRS based on OSS score [4]. The OSS score has also been adopted by international guidelines and societies for directing treatment decisions, including endoscopic sinus surgery and the use of biologics [4-6]. More recently, OSS has been identified as an important criterion in the assessment of CRS disease control [7]. Despite the utilization of the OSS score for such important functions, there is a paucity of studies that have investigated the functional properties of OSS.

There are two prominent knowledge gaps surrounding the OSS score. First, there has been little in-depth study of what OSS truly reflects. Specifically, it is unclear in what manner or to what extent the OSS score is a big picture assessment reflecting the different symptoms associated with CRS or if it is disproportionately affected by individual symptoms of CRS. Second, the VAS - the response scale with which the OSS score has traditionally been implemented - is a cumbersome tool. In its validated form, the standard VAS consists of a 10-centimeter line labeled on either end that must be marked by the patient on the point corresponding to their perceived OSS, with the OSS score calculated as the manually-measured distance between the patient's mark and the origin of the VAS. Given the possibly important roles for OSS, it is unclear if the OSS score can be reliably measured in a less cumbersome manner—a point that is of increasing importance with the development of electronic tools such as mobile applications for the measurement of OSS [8] as well as pragmatic considerations for clinical study design. The objective of our study was to address these knowledge gaps. Using an international multi-center design including CRS patients from three continents, we determine the manner in which OSS score is a reflection of individual CRS symptom severities as well as the CRS symptoms most dominantly affecting the OSS score, and whether the OSS score may be reliably measured using response scales other than the standard VAS.

Materials and methods

Study participants

This study was approved by the Institutional Review Boards of the University of Cincinnati College of Medicine (Cincinnati, OH, USA; protocol #2019-0397), King Saud University (Riyadh, Saudi Arabia; protocol #E-22-7125), University of Nevada, Reno School of Medicine (Reno, NV, USA; protocol #1988052-2), and Medical University of Vienna (Vienna, Austria; protocol #1348/2022). All participants were prospectively enrolled from the rhinology clinics of the investigators at these sites and provided informed consent for inclusion. Inclusion criteria included age 18 years or older and meeting consensus diagnostic criteria for CRS [4]. Patients with comorbid diagnoses of vasculitis, sarcoidosis, and immunodeficiency were excluded. Patients who had a history of endoscopic sinus surgery within the prior 3 months were also excluded.

Study design

This was a cross-sectional study designed to determine the relative contributions of different individual CRS symptom severities to a patient's scoring of OSS of their CRS and to investigate response scales for OSS score other than the standard VAS. All data was collected at enrollment. Demographic information, including age and gender, was obtained. A smoker was defined as any participant who currently smoked or reported a history of tobacco use [9,10]. At enrollment, participants were assessed by the evaluating physician for a history of asthma, diagnosed based on consensus guidelines, as well as a history of allergy which was determined through formal skin or serological testing. Participants were interviewed to identify a history of previous sinus surgery or a history of aspirin sensitivity. The presence of nasal polyps and the history of prior sinus surgery were confirmed on nasal endoscopy. A modified Lund-Kennedy endoscopy score was also determined based on nasal endoscopy [11]. All participants completed a 22-item Sinonasal Outcome Test (SNOT-22) questionnaire in the native language of the center as a reflection of disease-specific QOL [12-14]. All participants from the University of Cincinnati College of Medicine, University of Nevada, Reno School of Medicine, and Medical University of Vienna also completed the 5-dimension EuroQoL (EQ-5D) general health-related QOL questionnaire, from which the VAS (EQ-5D VAS) was used [15,16]. Finally, all participants rated their OSS and individual symptom severities using 3 different response scales (Figure 1).

Symptom severity measurements

Each participant was asked to rate their CRS OSS score and the severities of the following individual CRS symptoms: nasal obstruction, nasal drainage, decreased sense of smell, facial pain/pressure, and sleep disturbance, all of which have been identified in previous studies as dominant determinants of

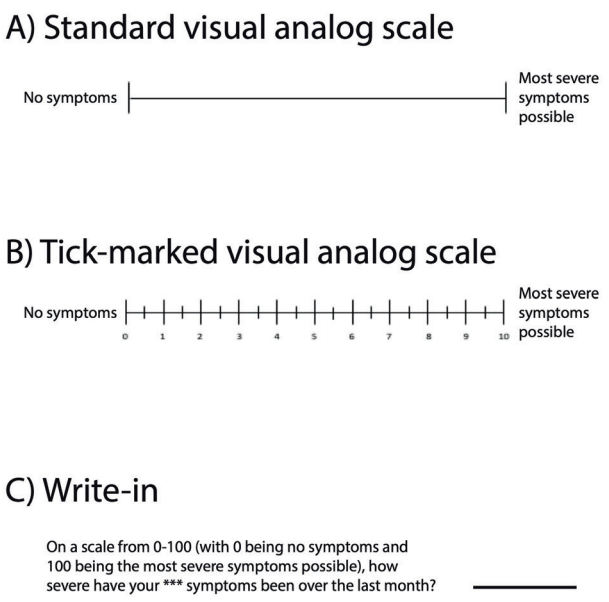

Figure 1. Response scales used for reporting chronic rhinosinusitis symptom severities: A) standard VAS, B) tick-marked VAS, C) write-in scale. Actual VAS given to participants measured 10 centimeters in length.

patients' perceptions of their CRS as well as its QOL impact [17-19]. Participants were asked to rate these symptom severities over the preceding month (as the preferred time scale for assessing CRS disease burden [20]) using 3 different response scales (Figure 1) having the same severity score output, ranging from 0 (no symptoms) to 10 (most severe symptoms possible) in increments of 0.1. These response scales included: 1) a standard VAS consisting of a 10-centimeter line with both ends labeled (0 [no symptoms] and 10 [most severe symptoms possible]) which the participant would mark, generating a score that was calculated as the length between the origin (0) and the mark in centimeters, 2) a standard VAS with tick marks (tick-marked VAS) every 0.5 centimeter that were labeled with their numeric values at every 1 centimeter, and 3) a simple prompt asking participants to write in their symptom severities on a scale of 0 – 100, which would then be divided by 10 to generate a final score ranging from 0 to 10 (the "write-in" scale). We chose these three response scales because each would produce a final OSS score on a scale of 0 to 10.0 in 0.1 increments, which is the OSS scoring convention that has been historically relied upon for guidelines on CRS staging and treatment decisions [4-6]. Moreover, the tick-marked VAS serves as a representative modified VAS while the write-in scale represents a maximally convenient implementation of the OSS score, either of which could serve as alternatives to the standard VAS in the real-world setting. All symptom severity questions were translated and cross-culturally adapted into the local language by the site investigators. All symptom severities were queried on paper, with each response scale being provided to participants on different sheets of paper, one at a time. Once a participant had rated their symptom severities using one response scale, that survey was taken away with no opportunity to review it or revise it. In order to reduce presentation bias related to response scale, participants were sequentially randomized (in the order that they were recruited at each site) to rate their symptom severities using these 3 different response scales in 1 of 6 different orders in which these 3 response scales could be used.

Statistical analysis

All statistics were performed using the statistical software R [21]. Standard descriptive statistics were performed. Association between OSS score (as dependent variable) and individual symptom severity scores (as independent variables) was calculated using univariate linear regression, and a linear regression coefficient (β) with 95% confidence interval (95%CI) was calculated. Recruitment was carried out to achieve power of at least 0.8 to detect univariate associations of small effect size at a significance level of 0.05. Correlation between symptom severity scores was calculated with Pearson's method. Intra-rater reliability of how participants rated their symptom severity scores using the 3 different response scales was measured using a two-way random effects intraclass correlation (ICC[2,1]) from which an intraclass correlation coefficient (ICC) was calculated [22]. Intra-rater reliability was deemed to be excellent when the ICC ≥ 0.90 [22].

Results

Study participants

A total of 311 participants with CRS were recruited from centers spanning 3 continents, and their characteristics are summarized in Table 1. Of all participants, 192 (61.7%) had CRS without nasal polyps (CRSsNP) and 119 (38.3%) had CRS with nasal polyps (CRSwNP). The mean SNOT-22 score of all participants was 36.3 (SD: 22.7), mean EQ-5D VAS was 72.1 (SD: 19.5) and mean endoscopy score was 3.3 (SD: 3.0).

Measurement technique for overall symptom severity

We first sought to determine whether the response scale used to measure OSS (standard VAS vs. tick-marked VAS vs. write-in) impacted the OSS score (Table 2). The mean OSS for all participants was 4.8 (SD: 3.0) using a standard VAS, 5.0 (SD: 3.1) using a tick-marked VAS and 4.9 (SD: 3.2) as a write-in value. The overall reliability of OSS scores across the three scales was excellent (ICC=0.93, 95%CI: 0.92–0.94, p<0.001). The same was true for individual symptom severity scores for nasal obstruction (ICC=0.94, 95%CI: 0.93–0.95, p<0.001), nasal drainage (ICC=0.94, 95%CI: 0.93–0.95, p<0.001), decreased senseof smell (ICC=0.98, 95%CI: 0.97–0.99, p<0.001), facial pain/pressure (ICC=0.95, 95%CI: 0.94–0.96, p<0.001) and sleep disturbance (ICC=0.96,

Table 1. Characteristics of study participants.

	All study participants (N=311)	Cincinnati participants (N = 174)	Reno participants (N = 51)	Riyadh participants (N = 50)	Vienna participants (N = 36)
Demographics					
Age, mean in years, (SD)	50.6 (15.8)	52.3 (15.4)	55.3 (16.8)	41.6 (12.0)	48.2 (15.9)
Gender, %					
Male	47.9%	43.1%	39.2%	66.0%	58.3%
Female	51.8%	56.3%	60.8%	34.0%	41.7%
Non-binary	0.3%	0.6%	0.0%	0.0%	0.0%
Smoking, %	29.9%	31.0%	39.2%	12.0%	36.1%
Comorbidities, %					
Aeroallergen hypersensitivity	65.6%	70.1%	80.4%	36.0%	63.9%
Asthma	38.3%	35.1%	41.2%	36.0%	52.8%
Aspirin sensitivity	6.1%	1.7%	5.6%	12.0%	19.4%
Cystic fibrosis	1.6%	2.9%	0.0%	0.0%	0.0%
CRS characteristics					
Polyps, %	38.3%	22.4%	31.4%	74.0%	75.0%
SNOT-22 score, mean (SD)	36.3 (22.7)	38.2 (21.9)	36.6 (24.6)	34.9 (24.1)	29.0 (21.2)
Modified Lund-Kennedy endoscopy score, mean (SD)	3.3 (3.0)	3.9 (3.1)	2.3 (2.7)	2.3 (2.2)	3.3 (2.8)

Table 2. Chronic rhinosinusitis symptom severity scores using different response scales.

	All study participants (N=311)	Cincinnati participants (N = 174)	Reno participants (N = 51)	Riyadh participants (N = 50)	Vienna participants (N = 36)
Standard VAS					
Overall symptom severity	4.8 (3.0)	4.7 (3.0)	5.4 (2.7)	5.0 (3.4)	4.3 (3.0)
Nasal obstruction	4.4 (3.2)	4.2 (3.1)	5.4 (3.3)	4.1 (3.6)	4.5 (3.2)
Nasal drainage	4.1 (3.0)	4.1 (3.0)	5.0 (3.1)	3.9 (3.1)	3.3 (3.0)
Decreased sense of smell	3.9 (3.8)	3.2 (3.6)	4.0 (3.7)	5.5 (3.9)	4.8 (3.7)
Facial pain/pressure	2.7 (2.9)	2.7 (2.9)	3.2 (2.8)	3.4 (3.3)	1.2 (1.8)
Sleep disturbance	3.6 (3.3)	3.5 (3.4)	4.1 (3.5)	4.0 (3.5)	2.6 (2.7)
Tick-marked VAS					
Overall symptom severity	5.0 (3.1)	5.0 (3.0)	5.6 (2.8)	4.5 (3.6)	4.5 (3.4)
Nasal obstruction	4.5 (3.3)	4.3 (3.2)	5.5 (3.5)	3.8 (3.6)	4.5 (3.3)
Nasal drainage	4.3 (3.1)	4.4 (3.1)	5.3 (3.2)	3.9 (3.3)	3.2 (2.9)
Decreased sense of smell	3.9 (3.8)	3.3 (3.7)	3.9 (3.7)	5.4 (4.0)	4.8 (3.6)
Facial pain/pressure	2.7 (3.0)	2.8 (2.9)	3.3 (2.9)	3.1 (3.3)	1.3 (2.1)
Sleep disturbance	3.7 (3.4)	3.7 (3.4)	4.1 (3.5)	4.0 (3.5)	2.7 (2.6)
Write-in					
Overall symptom severity	4.9 (3.2)	4.9 (3.2)	5.5 (2.9)	4.6 (3.7)	4.5 (3.2)
Nasal obstruction	4.4 (3.4)	4.2 (3.2)	5.5 (3.5)	3.7 (3.8)	4.6 (3.1)
Nasal drainage	4.1 (3.2)	4.3 (3.1)	5.0 (3.1)	3.4 (3.2)	3.3 (3.1)
Decreased sense of smell	3.8 (3.8)	3.3 (3.7)	3.8 (3.7)	5.3 (4.1)	4.8 (3.7)
Facial pain/pressure	2.7 (3.0)	2.7 (3.0)	3.3 (3.0)	2.9 (3.3)	1.3 (2.3)
Sleep disturbance	3.6 (3.4)	3.6 (3.5)	4.0 (3.5)	3.7 (3.4)	2.8 (2.7)

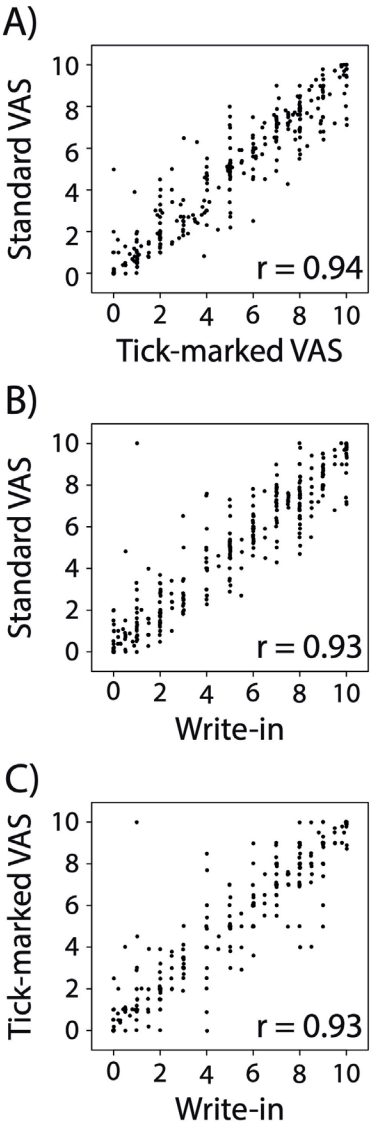

Figure 2. Dot plots of chronic rhinosinusitis overall symptom severity measured using A) standard VAS vs. tick-marked VAS, B) standard VAS vs. write-in scale, and C) tick-marked VAS vs. write-in scale. Pearson correlation coefficients included on each panel ($p < 0.001$ for all correlations).

95%CI: 0.96–0.97, p<0.001). The correlation of OSS scores obtained using different response scales (Figure 2) was uniformly excellent ($r \geq 0.93$, p<0.001 in all cases), which was also true for all individual symptom severity scores ($r \geq 0.93$, $p < 0.001$ in all cases). These relationships held true for all individual sites and whether participants had CRSwNP or CRSsNP.

Overall symptom severity as a reflection of chronic rhinosinusitis disease burden

OSS score was found to be correlated with QOL impact (Supplemental Figures 1A and 1B). EQ-5D VAS, reflecting general health-related QOL, was negatively but weakly correlated with OSS score measured using a standard VAS (r = -0.25, 95%CI: -0.37 to -0.14, p<0.001), tick-marked VAS (r = -0.29, 95%CI: -0.40 to -0.17, p<0.001), and write-in value (r = -0.31, 95%CI: -0.42 to -0.19, p<0.001). SNOT-22 score, reflecting CRS-specific QOL, was positively correlated with OSS score measured using a standard VAS (r = 0.62, 95%CI: 0.55 – 0.68, p<0.001), tick-marked VAS (r = 0.63, 95%CI: 0.55 – 0.69, p<0.001), and write-in value (r = 0.65, 95%CI: 0.58 – 0.71, p<0.001). The modified Lund-Kennedy endoscopy score, reflecting objective CRS disease burden, was positively but weakly correlated with OSS score (Supplemental Figure 1C) measured using a standard VAS (r=0.24, 95%CI: 0.14–0.35, p<0.001), tick-marked VAS (r=0.26, 95%CI: 0.15–0.36, p<0.001), and write-in value (r=0.25, 95%CI: 0.15–0.36, p<0.001). These relationships held true whether participants had CRSwNP or CRSsNP.

Determinants of overall symptom severity

We next sought to determine the degree to which OSS score was associated with the severity of individual CRS symptoms in the overall population of participants as well as in subgroups of participants with CRSsNP and CRSwNP. The results of these associations are shown in Table 3 and Figure 3 for the OSS score and individual symptom severity scores measured using a standard VAS. However, results of these associations using OSS score measured with a tick-marked VAS or write-in number were qualitatively the same (data not shown).

OSS score was most strongly associated with the severity of nasal obstruction for all participants (β=0.75, 95%CI: 0.69–0.81, p<0.001), participants with CRSsNP (β=0.71, 95%CI: 0.62–0.80, p<0.001) and participants with CRSwNP (β=0.80, 95%CI: 0.71–0.88, p<0.001). By comparison, OSS score was least associated with decreased sense of smell for all participants (β=0.33, 95%CI: 0.25–0.41, p<0.001), participants with CRSsNP (β=0.27, 95%CI: 0.17–0.38, p<0.001) and participants with CRSwNP (β =0.47, 95%CI: 0.33–0.60, p<0.001). However, the magnitude of the regression coefficient for association of OSS score with the severity of decreased sense of smell in participants with CRSwNP was significantly greater compared to those without CRSsNP (p=0.004). Inspection of the relationship between individual symptom severity scores and OSS score (Figures 3A-E) showed that for all measured symptoms, there were cases in which an individual symptom severity score was higher than the OSS score, illustrating that the OSS score (as an overall reflection of symptoms) was likely weighed down by other less severe symptoms. At the same time, there were cases where an individual symptom severity score was lower than the OSS score, showing that the OSS was likely elevated by other more burdensome symptoms. There were almost no cases where the OSS score was less than the severity of facial pain (only 5.4% of participants had an OSS score that was at least 1 point lower than facial pain severity), suggesting that the severity of facial pain may be a floor for OSS (Figure 3D).

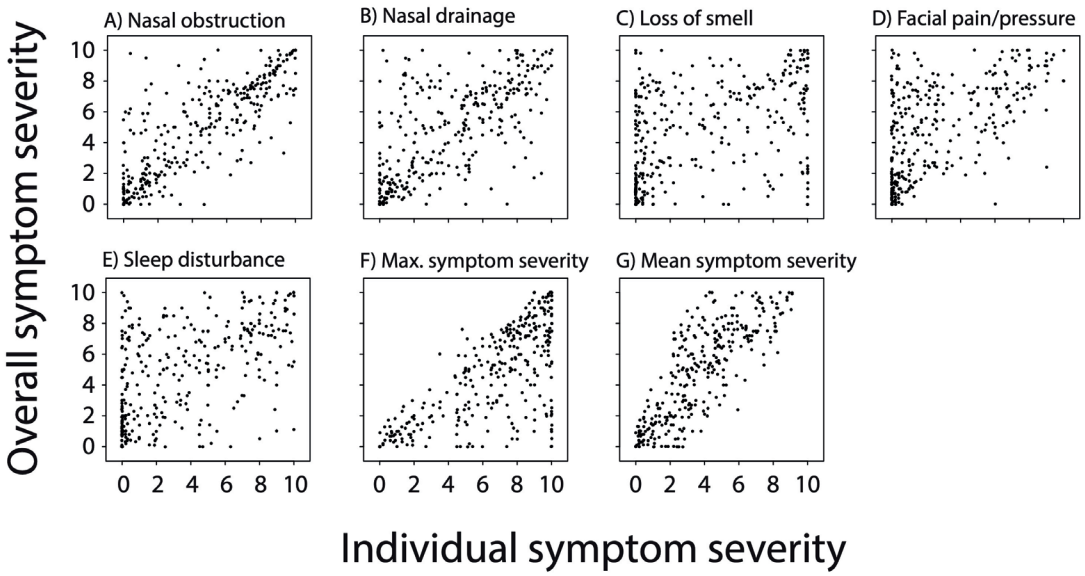

Figure 3. Dot plots of chronic rhinosinusitis overall symptom severity vs. severities of A) nasal obstruction, B) nasal drainage, C) decreased sense of smell, D) facial pain/pressure, E) sleep disturbance and F) the greatest individual symptom severity, G) the mean of all individual symptom severities, all measured using a standard VAS.

We next sought to determine the manner in which the OSS score reflects a patient's synthesis of all individual symptoms (Figures 3F and 3G). We first checked for association between OSS score and the individual symptom score with the greatest severity (Figure 3F) and found strong association for all participants (β=0.70, 95%CI: 0.61–0.78, p<0.001), participants with CRSsNP (β=0.68, 95%CI: 0.58–0.78, p<0.001) and participants with CRSwNP (β=0.72, 95%CI: 0.58–0.85, p<0.001). Interestingly, there were almost no cases where OSS score was greater than the most severe individual symptom (2.3% of participants had an OSS score at least 1 point greater than the maximum individual symptom severity experienced, while 49.1% of participants had an OSS score that was at least 1 point less than their maximum individual symptom severity), suggesting that the most severe individual symptom may serve as a ceiling for the OSS score (Figure 3F). Because the OSS was frequently lower than the most severe individual symptom suggesting its function as a global assessment of symptom burden, we next sought to determine a possible association between OSS score and the mean of all individual symptom severity scores (Figure 3G). We found strong association between OSS score and the mean of all individual symptom severities for all participants (β=1.04, 95%CI: 0.96–1.12, p<0.001), participants with CRSsNP (β=0.97, 95%CI: 0.85–1.08, p<0.001) and participants with CRSwNP (β=1.14, 95%CI: 1.02–1.27, p<0.001). The magnitude of the regression coefficient for association between OSS score and mean of all individual symptom severities was significantly greater than any other symptom determinant of OSS score that we evaluated.

Patient preferences for scale to measure overall symptom severity scale

Finally, we asked participants to rank (1 [most preferred], 2, or 3 [least preferred]) their preferences for OSS response scale from the standard VAS, tick-marked VAS, and write-in scale. The standard VAS had a mean rank of 2.3 and median rank of 3. The tick-marked VAS had a mean rank of 1.6 and median rank of 1. The write-in scale had a mean rank of 2.0 and median rank of 2. These preferences were similar across all sites.

Discussion

The OSS score is an important PROM for CRS that has continued to gain significance as an indicator of the clinically significant constructs of CRS severity and disease control [4,23], and a metric by which to make CRS treatment decisions [4-6]. Although OSS is clearly intended to serve as a global measure of CRS symptom burden, it has never been studied for how - or whether - it represents a synthesis of all CRS symptoms. In this international multi-center study including CRS patients from three different continents, we demonstrate for the first time that OSS is largely a reflection of the mean of individual symptom severities experienced by CRS patients, although it is most dominantly affected by the severity of nasal obstruction. Finally, we also show for the first time that the OSS can be reliably measured using modification to the VAS as well as with a simple write-in prompt, all with near-perfect consistency with a standard VAS.

A limited number of previous studies have examined properties of the OSS score. In a group of 116 CRS patients, Lim et al. showed that OSS score can be used to classify patients' overall

Table 3. Association between overall symptom severity and individual chronic rhinosinusitis symptom severities.*

	Overall symptom severity					
	All participants		CRS without NP		CRS with NP	
	β (95%CI)	P value	β (95%CI)	P value	β (95%CI)	P value
Nasal obstruction	0.75 (0.69 – 0.81)	< 0.001	0.71 (0.62 – 0.80)	< 0.001	0.80 (0.71 – 0.88)	< 0.001
Nasal drainage	0.64 (0.56 – 0.73)	< 0.001	0.61 (0.51 – 0.71)	< 0.001	0.71 (0.56 – 0.86)	< 0.001
Decreased sense of smell	0.3 (0.25 – 0.41)	< 0.001	0.27 (0.17 – 0.38)	< 0.001	0.47 (0.33 – 0.60)	< 0.001
Facial pain/pressure	0.60 (0.50 – 0.69)	< 0.001	0.54 (0.42 – 0.66)	< 0.001	0.68 (0.53 – 0.84)	< 0.001
Sleep disturbance	0.48 (0.39 – 0.57)	< 0.001	0.44 (0.33 – 0.54)	< 0.001	0.55 (0.40 – 0.70)	< 0.001
Most severe symptom	0.70 (0.61 – 0.78)	< 0.001	0.68 (0.58 – 0.78)	< 0.001	0.72 (0.58 – 0.85)	< 0.001
Mean symptom severity	1.04 (0.96 – 1.12)	< 0.001	0.97 (0.85 – 1.08)	< 0.001	1.14 (1.02 – 1.27)	< 0.001

*All symptom severities measured using a standard VAS.

symptoms as mild, moderate or severe , with an OSS score of ≥5 also able to identify patients whose CRS symptoms affected their QOL [24]. The OSS score has also been shown to be strongly correlated with SNOT-22 score [25]. However, there has remained a significant knowledge gap in understanding how the OSS score reflects as an agglomeration of individual CRS symptoms. Without this understanding, it is impossible to utilize the OSS score in a fully informed manner.

Addressing this knowledge gap, our study found that in both CRSsNP and CRSwNP patients, the OSS score largely represents an averaging of individual CRS symptom severities but is most dominantly influenced by nasal obstruction severity. After nasal obstruction, the OSS was next most heavily associated with the severities of nasal drainage and facial pain, followed by the severity of sleep disturbance. We also found that the severity of facial pain represented a possible floor for the value of the OSS score. These findings are consistent with prior studies establishing the importance of nasal obstruction and drainage as the symptoms most important to CRS patients [26,27], while sleep disturbance and facial pain have been identified as the primary determinants of QOL in CRS [17,28]. We also found that the OSS was least associated with the severity of decreased sense of smell. Although it is well recognized that decreased sense of smell is typically more severe in CRSwNP than CRSwNP [29], previous studies have been conflicting about the relative importance of hyposmia in both CRSwNP and CRSsNP. Decreased sense of smell has been described as an important symptom to CRS patients, especially in CRSwNP [26,30]. However, the general significance of smell loss has been questioned by other studies suggesting the importance of decreased sense of smell for patients is secondary to nasal obstruction and drainage for patients (including in CRSwNP) [27], may be most significant for the fraction of patients with the most severe disease [31,32], and may decrease with time [33].

Additionally, we found that OSS could be measured using a VAS modified with tick marks along its length as well as with a simple prompt to write down a number from 0 – 100 to rate their OSS, all with near identical results to what participants reported using a standard VAS. In fact, these alternatives to the standard VAS were more greatly preferred by patients compared to the standard VAS. These results held true across all sites and for participants with and without nasal polyps.

Our study's results have important implications for the use of the OSS both for clinical practice and in research. First, our results provide explicit demonstration for the first time of OSS score as an averaged, global reflection of CRS patients' symptomatology - although more biased towards nasal obstruction, nasal drainage and facial pain - in both CRSwNP and CRSsNP that can now be used in research and clinical practice with confidence for what OSS signifies.

Second, our findings show that the OSS score can be reliably collected using a modified VAS and a simple, conveniently implemented write-in method in addition to the standard VAS, any of which can be chosen for collection of the OSS score based on the specific needs of the circumstance. For example, the collection of the OSS using a non-standard VAS may be implemented for mobile applications [34]. Our results also open the possibility for easier, more convenient OSS score implementation through a write-in prompt, which may lead to increased real-world use of OSS score.

Our results should be interpreted within the constraints of our study limitations. While our choices of individual CRS symptoms to study were based on previous studies showing them to be important as determinants of patients' perceptions of their CRS or overall QOL, it is possible that other individual CRS symptoms that we did not study could have served as meaningful determinants of OSS score. Finally, although we chose alternative response scales to the standard VAS that could serve as a represen-

tative modification to the standard VAS (the tick-marked VAS) and a maximally convenient option for implementation (the "write-in" scale), measurement of the OSS score using a different response scale would be an extrapolation of our results and not directly supported.

Conclusion

The OSS score largely reflects an averaging of individual CRS symptom severities but is more heavily weighted by the severity of nasal obstruction, followed by the severities of nasal drainage and facial pain/pressure. These findings were found to hold true across all study sites as well as for both CRSwNP and CRSsNP patients. The OSS and individual symptom severity scores may be assessed on a scale of 0 - 10 using not only a standard VAS but also VAS modifications (e.g. with intermediate labeling/tick marks) as well as a simple write-in prompt - both of which were preferred by patients to the standard VAS and both of which may serve to make implementation of the OSS more convenient in the real-world setting.

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Authors' contributions

ARS: concept of study, study design, collection of data, analysis and interpretation of results, write up of manuscript, critical review of all contents. JTG, RAC, RSB, AA, SS, DTL, JED, NAP, FAH, MMC, JCM, SA, KMP: collection of data, interpretation of results, write up of manuscript, critical review of all contents.

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Conflicts of interest

The authors declare that they have no conflicts of interests regarding the publication of this paper.

Data availability

Data used in this study is available from the corresponding author (ARS) on reasonable request.

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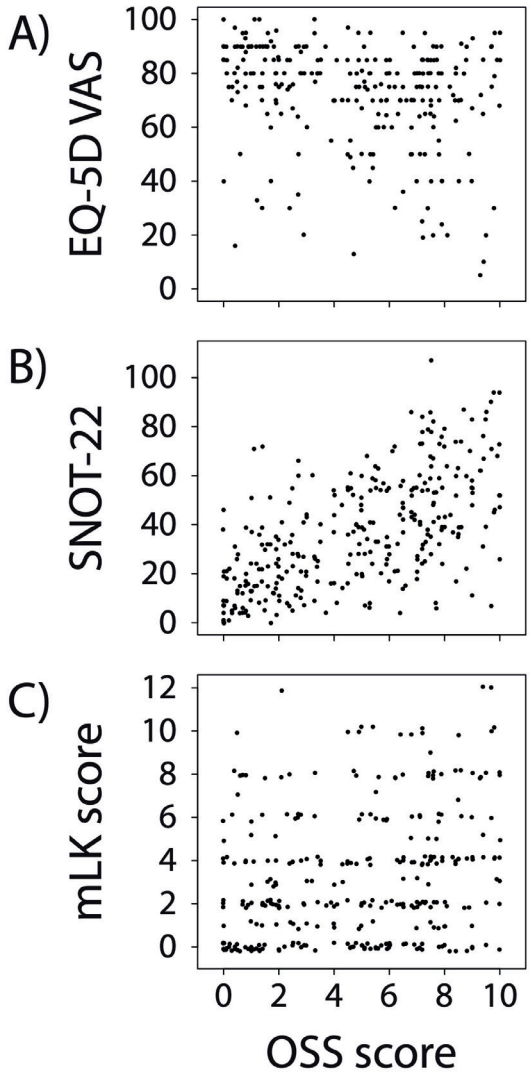

Figure S1. Dot plot of overall symptom severity score measured using a standard VAS vs. A) EQ-5D VAS, B) SNOT-22 score and C) modified Lund-Kennedy (mLK) endoscopy score.