Individual symptom visual analogue scale severity scores for determining EPOS guideline-based chronic rhinosinusitis disease control*

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Abstract

Background: The goal of this study was to determine how to translate visual analogue scale (VAS) symptom scores to the binary, descriptive symptom scales used in the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) criteria for chronic rhinosinusitis (CRS) disease control.

Methods: 309 CRS patients were recruited. All patients rated their burden of 5 symptoms (nasal blockage, rhinorrhea/postnasal drip, facial pain/pressure, smell loss, sleep disturbance or fatigue) using the binary EPOS descriptive symptom scales and a VAS (on a scale of 0 to 10). In addition, participants completed a 22-item Sinonasal Outcome Test (SNOT-22) and rated their overall CRS disease control as "controlled", "partly controlled" or "uncontrolled".

Results: Symptom burdens measured by VAS, binary descriptive EPOS scale and SNOT-22 were associated with worsening CRS disease control reported by participants. Each symptom had a distinct VAS score cut-off that strongly predicted the uncontrolled option on the corresponding binary descriptive EPOS symptom scale. However, the predictive ability of VAS for rhinorrhea/postnasal drip was disparately worse than the other 4 symptoms. When considering all symptom data simultaneously, a VAS score >3.5 strongly predicted the uncontrolled option on the corresponding binary descriptive EPOS symptom scale for all 5 symptoms.

Conclusions: A VAS symptom score of >3.5 translates to the uncontrolled option in the binary, descriptive symptom scale of the EPOS control criteria. The rhinorrhea/postnasal drip descriptive symptom scale translates disparately worse to VAS scores and may be considered for revision in future criteria.

Key words: chronic rhinosinusitis, disease control, patient-reported outcome measure, EPOS, visual analogue scale

Introduction

The concept of disease control can be defined as the extent to which manifestations of a disease are within acceptable limits. For chronic diseases that cannot be cured, such as chronic rhinosinusitis (CRS), disease control serves as the overarching goal of treatment[1]. The 2012 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) first proposed criteria for the assessment of CRS disease control[2]. These EPOS 2012 control criteria included assessment of CRS symptom burden over the preceding month, a timeframe that reflects patient preferences for basing clinical and treatment decisions[3].

The EPOS 2020 guidelines reiterated the EPOS 2012 criteria for CRS disease control but with an important addition related to the assessment of CRS symptom burden[4]. The EPOS 2012 control criteria assessed the burden of individual CRS symptom using only descriptive criteria (for example, nasal blockage assessed as either "Not present or not bothersome" vs. "Present on most days"). While the EPOS 2020 control criteria use the same descriptive criteria for assessing individual symptoms, an alternative means of assessing individual symptoms was also proposed using visual analogue scale (VAS) scores to distinguish controlled vs. uncontrolled symptoms as VAS ≤ 5 vs. VAS > 5

(on a scale of 0 to 10), respectively. This alternative, quantitative means of assessing individual CRS symptom control was another important advancement in the development of CRS disease control criteria and was based on the work of Van der Veen et al.[5].

In the study by Van der Veen et al.[5], 389 CRS patients with a prior history of endoscopic sinus surgery were studied and their level of CRS disease control was deemed "controlled", "partly controlled" or "uncontrolled" based on EPOS 2012 guideline criteria. Individual symptom VAS scores from these 389 patients were then compared against the patients' corresponding level of overall CRS disease control (i.e., "controlled", "partly controlled" or "uncontrolled"). Van der Veen et al. found that when individual symptom VAS scores were >5, on a scale of 0 to 10, patients appeared much more likely to have EPOS-defined uncontrolled CRS.

Although the Van der Veen et al. study was not a direct study of translating symptom VAS scores to the EPOS descriptive symptom criteria, this VAS > 5 threshold was subsequently applied in the EPOS 2020 guidelines to the assessment of individual symptoms as an alternative to the EPOS descriptive symptom criteria (e.g., "Not present or not bothersome" vs. "Present on most days"). However, a definitive and direct study of this topic is still needed to directly translate individual symptom VAS scores to the descriptive symptom criteria in the EPOS disease control criteria. Given the importance of the EPOS disease control criteria both for research and clinical care, establishment of reliable and evidence-based means for assessing individual symptom criteria in these guidelines is needed. In this study, we directly investigate the relationship and translation of individual symptom VAS scores to the established, descriptive CRS symptom assessment in the EPOS disease control criteria. The results of this study may therefore directly impact clinical practice or research by determining VAS symptom score cut-offs for the symptom criteria in the implementation and utilization of the EPOS disease control criteria.

Materials and methods

Study participants

This study was approved by the University of Cincinnati Institutional Review Board. Adult patients (age 18 years or older) with CRS were recruited prospectively from the investigators' rhinology clinic and provided informed consent for inclusion into this study. All participants met consensus, guideline criteria for CRS established by the American Academy of Otolaryngology – Head and Neck Surgery[6]. Exclusion criteria included comorbid diagnoses of vasculitis, cystic fibrosis, sarcoidosis, and immunodeficiency. To remove the confounding effect of recent endoscopic sinus surgery, patients who had a history of endoscopic sinus surgery within the prior 6 months were also excluded. Inclusion and exclusion criteria were specifically chosen to recruit a cohort of participants that would be reflective of a real-world general population of primary CRS patients.

Study design

This was a cross-sectional study of the EPOS CRS control criteria. 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[7,8]. 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 aeroallergen hypersensitivity which was determined through formal allergy testing. Participants were interviewed to identify a history of previous sinus surgery or a history of aspirin sensitivity. The presence of nasal polyps and a history of prior sinus surgery were confirmed on nasal endoscopy. A Lund-Kennedy endoscopy score was also determined based on nasal endoscopy. All participants also completed a 22-item Sinonasal Outcome Test (SNOT-22) questionnaire as a general reflection of CRS-specific quality of life (QOL)[9].

EPOS disease control assessment

In accordance with EPOS disease control criteria, the control of 5 individual CRS symptoms over the prior month was assessed in all study participants: nasal blockage ("not present or not bothersome" vs. "present on most days of the week"), rhinorrhea/postnasal drip ("little and mucous" vs. "mucopurulent on most days of the week"), facial pain/pressure ("not present or not bothersome" vs. "present on most days of the week"), sense of smell ("normal or only slightly impaired" vs. "impaired"), and sleep disturbance or fatigue ("not present" vs. "present"). To help with participants' understanding of terminology, "rhinorrhea" was defined for participants as "nasal drainage" and "mucopurulent" was defined as "discolored (yellow/green)". The burden of each of these 5 symptoms over the prior month was also assessed using a VAS, ranging in score from 0 (no burden at all) to 10 (worst possible burden), measured in 0.1 increments. All participants were also asked to rate their level of CRS disease control as "controlled", "partly controlled" or "uncontrolled".

Statistical analysis

All analyses were performed using the statistical software package R (www.r-project.org)[10]. Standard descriptive statistics were performed. Ordinal regression modeling was used to check for association with patient-reported CRS disease control as a dependent variable. The ability of an individual symptom VAS score to predict the uncontrolled descriptive criteria in the corresponding EPOS symptom assessment (e.g. "present on most days of the week" was considered to be uncontrolled in comparison to "not present or not bothersome" for nasal blockage) was calculated using Receiver Operating Characteristic (ROC) curve

Table 1. Characteristics of study participants.

	All participants (N = 309)
Demographics	
Age, mean in years, (SD)	50.1 (15.5)
Gender, N (%)	
Male	140 (45.3%)
Female	169 (54.7%)
Smoking, N (%)	72 (23.3%)
Comorbidities, N (%)	
Aeroallergen hypersensitivity	201 (65.0%)
Asthma	91 (29.4%)
Aspirin sensitivity	13 (4.2%)
CRS characteristics at enrollment	
Nasal polyps, N (%)	89 (28.8%)
Previous endoscopic sinus surgery, N (%)	83 (26.9%)
SNOT-22 score, mean (SD)	40.7 (24.3)
Lund-Kennedy endoscopy score, mean (SD)	3.3 (3.3)

analysis. The area under the ROC curve (AUC) was calculated with the trapezoid rule and the 95% confidence interval of the AUC was calculated by performing 2000 bootstraps of the data. This study was powered to detect statistically significant predictive relationships between the VAS and the EPOS descriptive symptom assessments (coded as a binary outcome with 0 for the controlled option or 1 for the uncontrolled option) of small to medium effect size (AUC ≥ 0.600), assuming one to one allocation of uncontrolled vs. controlled symptoms[11]. ROC analysis was performed to identify VAS score cut-offs for each individual symptom. Subsequently, associations between individual VAS scores and having a descriptively defined uncontrolled symptom was performed with logistic regression. Associations with patient-reported disease control (considered an ordinal variable: "controlled", "partly controlled", or "uncontrolled") as the dependent variable were carried out with ordinal regression. For both forms of regression, a log odds ratio [OR] was calculated.

To determine a single VAS score cut-off value that could be proposed for application to all symptoms (rather than using individual symptom-specific VAS cut-off scores), ROC analysis was performed on all the symptom data (VAS scores and descriptive symptom scale data) simultaneously. This was implemented by concatenating the VAS scores of all symptoms and, in a paired manner, the descriptive symptom assessments (again coded as a 0 or 1). An ROC analysis was then performed on this data, which considered the performance of all the VAS scores in their ability to predict the uncontrolled option in the corresponding EPOS descriptive symptom scale - i.e., the performance of all VAS scores was weighted equally in determination of this single VAS score cut-off.

Table 2. Chronic rhinosinusitis symptom severities for EPOS disease control.

	All participants (N = 309)
Descriptive symptom scale, N (%)	
Nasal blockage	
Not present or not bothersome	96 (31.1%)
Present on most days of the week	213 (68.9%)
Rhinorrhea/postnasal drip	
Little and mucus	200 (64.7%)
Mucopurulent on most days of the week	109 (35.3%)
Facial pain/pressure	
Not present or not bothersome	167 (54.0%)
Present on most days of the week	142 (46.0%)
Sense of smell	
Normal or only slightly impaired	219 (70.9%)
Impaired	90 (29.1%)
Sleep disturbance or fatigue	
Not present	119 (38.5%)
Present	190 (61.5%)
Visual analogue scale scores	Mean (SD)
Nasal blockage	5.2 (3.3)
Rhinorrhea/postnasal drip	5.2 (3.2)
Facial pain/pressure	3.8 (3.4)
Sense of smell	3.0 (3.4)
Sleep disturbance or fatigue	4.6 (3.6)

Results

Characteristics of study participants

A total of 309 participants were recruited (89 with nasal polyps and 220 without nasal polyps). The characteristics of these participants are described in Table 1. Amongst the participants, the mean SNOT-22 score was 40.7 (SD: 24.3) and the mean endoscopy score was 3.3 (SD: 3.3). In terms of rating their own degree of CRS disease control, 17.8% rated it as controlled, 48.9% rated it as partly controlled and 33.3% rated it as uncontrolled. The distribution of how participants reported their individual EPOS control-related symptom burden with respect to the descriptive EPOS symptom control scale, as well as with the VAS, are shown in Table 2.

Patient-reported CRS disease control is associated with descriptive EPOS scale and visual analogue scale symptom scores

We first investigated whether patient-reported CRS disease control (rated as "controlled", "partly controlled" or "uncontrolled") was associated with the burden of individual symptoms using the descriptive EPOS scale. The degree to which patients

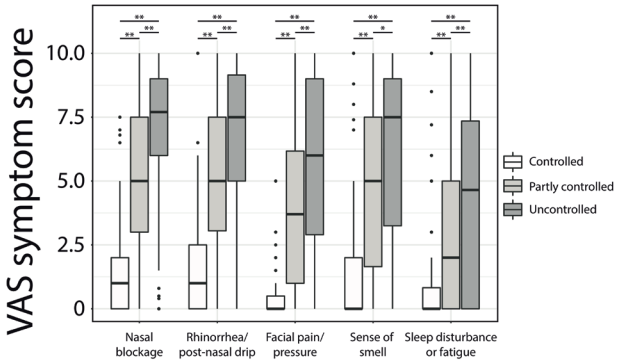

Figure 1. Box-and-whisker plots of participants' visual analogue scale symptoms scores in relation to how they rated their level of CRS disease control. Pairwise comparisons between VAS scores by Wilcoxon Rank Sum test are shown with * indicating p=0.038 and ** indicating p<0.001.

reported their CRS to be uncontrolled was associated with nasal obstruction that is "present on most days of the week" (odds ratio [OR] = 14.2, 95%CI: 7.8 – 25.9, p < 0.001), rhinorrhea/postnasal drip that is "mucopurulent on most days of the week" (OR = 3.7, 95%CI: 2.3 – 5.9, p < 0.001), facial pain/pressure that is "present on most days of the week" (OR = 6.5, 95%CI: 4.0 – 10.6, p < 0.001), sense of smell that is "impaired" (OR = 3.4, 95%CI: 2.1 – 5.6, p < 0.001) and sleep disturbance/fatigue that is "present" (OR = 3.1, 95%CI: 1.9 – 4.9, p < 0.001). We found association between patient-reported CRS disease control and patient-reported symptom burden measured using VAS scores (Figure 1). Patient-reported CRS disease control was also associated with VAS for nasal obstruction (OR = 1.52, 95%CI: 1.40 – 1.66, p < 0.001), rhinorrhea/postnasal drip (OR = 1.45, 95%CI: 1.34 – 1.58, p < 0.001), facial pain/pressure (OR = 1.39, 95%CI: 1.29 – 1.50, p < 0.001), loss of sense of smell (OR = 1.18, 95%CI: 1.10 – 1.26, p < 0.001) and sleep disturbance/fatigue (OR = 1.27, 95%CI: 1.19 – 1.36, p < 0.001).

In comparison to VAS symptom scores, we also found that the SNOT-22 score was associated with the level of patient-reported CRS disease control (OR = 1.06, 95%CI: 1.05 – 1.07, p < 0.001). The mean SNOT-22 score was 15.8 (SD: 16.7) in patients reporting "controlled" CRS, 39.6 (SD: 19.7) in patients reporting "partly controlled" CRS, and 55.6 (SD: 22.4) in patients reporting "uncontrolled" CRS. The SNOT-22 scores across these three categories of CRS disease control were significantly different (p < 0.001 by ANOVA and p < 0.001 for all intergroup comparisons by Tukey's post-hoc test).

Visual analogue scale symptom scores are highly predictive of descriptive EPOS symptom scales

We next checked to see if VAS symptom scores would be predictive of the descriptive EPOS symptom scales (Figures 2 and 3). We found that the nasal obstruction VAS score was predictive

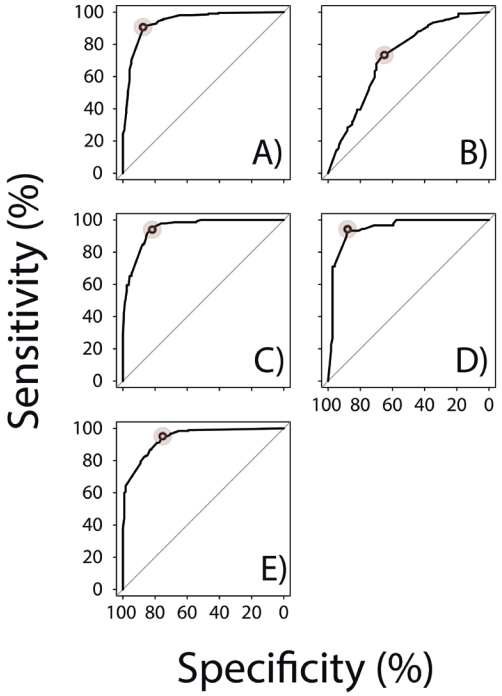

Figure 2. Receiver operating characteristic curves for the ability of visual analogue scale symptom scores to predict uncontrolled symptoms on the corresponding EPOS descriptive scale for (A) nasal blockage, (B) rhinorrhea/postnasal drip, (C) facial pain/pressure, (D) sense of smell and (E) sleep disturbance or fatigue.

of nasal obstruction that is "present on most days of the week" (AUC = 0.939, 95%CI: 0.910 – 0.969, p < 0.001) with an optimal VAS cut-off of >4.2 having 90.1% sensitivity and 87.5% specificity of identifying—and significantly associated (OR =64.0, 95%CI: 30.1 – 136.1, p<0.001) with—participants who reported nasal obstruction as "present on most days of the week" (Figures 2A and 3a). The rhinorrhea/postnasal drip VAS score was predictive of rhinorrhea/postnasal drip that is "mucopurulent on most days of the week" (AUC = 0.722, 95%CI: 0.666 – 0.779, p < 0.001) with an optimal VAS cut-off of >5.3 having 73.4% sensitivity and 66.0% specificity of identifying —and significantly associated (OR =5.4, 95%CI: 3.2 – 9.0, p<0.001) with—participants who reported rhinorrhea/postnasal drip as "mucopurulent on most days of the week" (Figures 2B and 3B). The facial pain/pressure VAS score was predictive of facial pain/pressure that is "present on most days of the week" (AUC = 0.948, 95%CI: 0.926 – 0.970, p < 0.001) with an optimal VAS cut-off of >2.8 having 94.3% sensitivity and 83.2% specificity of identifying—and significantly associated (OR =73.4, 95%CI: 33.4 – 161.3, p<0.001) with— participants who reported facial pain/pressure as "present on most days of the week" (Figures 2C and 3C). The smell loss VAS score was predictive of sense of smell that is "impaired" (AUC = 0.944, 95%CI: 0.919 – 0.970, p < 0.001) with an optimal VAS cut-off of >3.7 having 93.3% sensitivity and 87.6% specificity of identi-

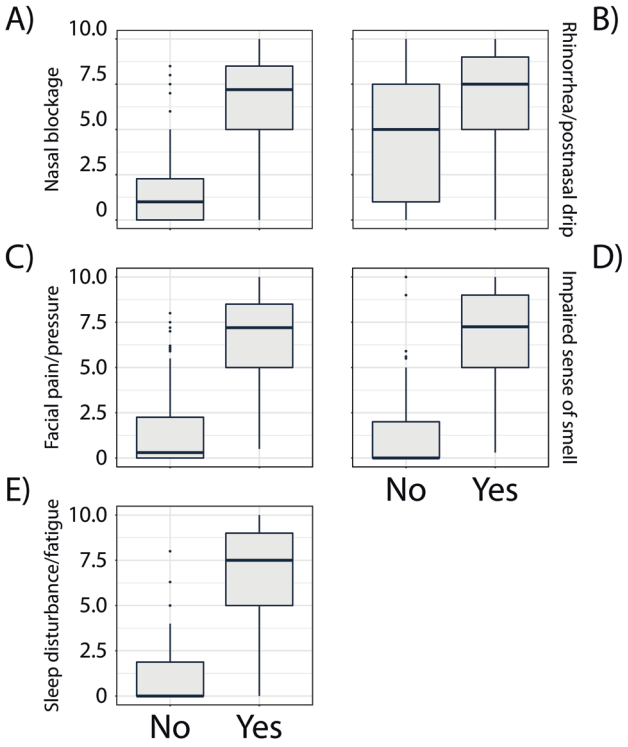

Figure 3. Box-and-whisker plots of visual analogue scale symptom scores in relation to the corresponding EPOS descriptive symptom scale score for (A) nasal blockage, (B) rhinorrhea/postnasal drip, (C) facial pain/pressure, (D) sense of smell and (E) sleep disturbance or fatigue.

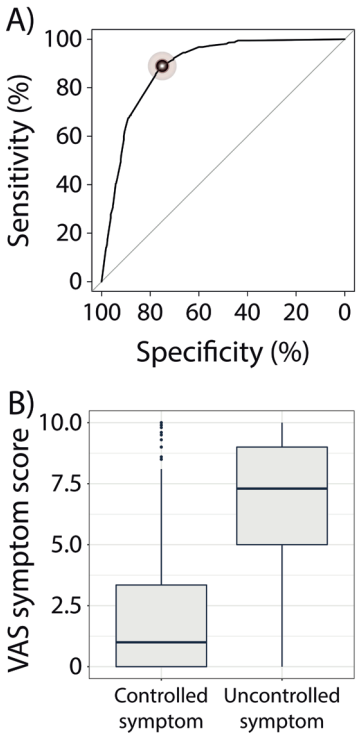

Figure 4. Considering all symptoms at once, (A) receiver operating characteristic curve for visual analogue scale symptom score as a predictor of the corresponding uncontrolled symptom on the EPOS descriptive scale and (B) box and whisker plot for visual analogue scale symptom scores in relation to how the corresponding symptom was scored (controlled vs. uncontrolled) on the binary EPOS descriptive scale.

fying—and significantly associated (OR =100.0, 95%CI: 39.6 – 250.1, p<0.001) with—participants who reported their sense of smell as "impaired" (Figures 2D and 3D). The sleep VAS score was predictive of sleep disturbance/fatigue that was "present" (AUC = 0.940, 95%CI: 0.915 – 0.964, p < 0.001) with an optimal VAS cut-off of >1.9 having 95.3% sensitivity and 75.4% specificity of identifying—and significantly associated (OR =62.4, 95%CI: 28.3 – 137.5, p<0.001) with— participants who reported that sleep disturbance or fatigue was "present" (Figures 2E and 3E).

Identifying a single visual analogue scale score threshold for translation to the descriptive EPOS symptom scale

To determine one VAS threshold score for predicting poorly controlled symptoms on the descriptive EPOS symptom scale that could be applied to all symptoms (rather than having a different cut-off for each symptom), we next concatenated all symptom VAS scores and simultaneously compared them to participants' corresponding descriptive EPOS symptom outcome which were also concatenated (so that the scoring of all symptom severities was used to calculate a single VAS threshold value). We found that, in general, a VAS score was predictive of the participant reporting that symptom to be uncontrolled on the descriptive EPOS scale (e.g., "present on most days of the week", "mucopurulent on most days of the week", "impaired", or "present" depending on the symptom) (AUC = 0.885, 95%CI: 0.868 – 0.902, p < 0.001) with an optimal VAS cut-off of >3.5 having 89.0% sensitivity and 75.6% specificity of identifying participants who reported the corresponding symptom to be uncontrolled on the descriptive EPOS scale (Figure 4). If the nasal drainage question, which had a disparately poorer predictive performance (Figures 2B and 3B), is not considered, an optimal VAS cut-off of >3.5 is still found (AUC=0.941, 95%CI: 0.928 – 0.954, p<0.001) but with 89.1% sensitivity and 86.1% specificity for identifying participants who reported the corresponding symptom to be uncontrolled on the descriptive EPOS scale. A VAS score cut-off of >3.5 had 91.5% sensitivity and 85.4% specificity for identifying participants who reported nasal obstruction as "present on most days of the week", 88.1% sensitivity and 44.0% specificity of identifying participants who reported rhinorrhea/postnasal drip as "mucopurulent on most days of the week", 90.8% sensitivity and 85.0% specificity of identifying participants who reported facial pain/pressure as "present on most days of the week", 93.3% sensitivity and 87.7% specificity of identifying participants who reported their sense of smell as "impaired", and 83.2% sensitivity and 85.7% specificity of identifying participants who reported that sleep disturbance or fatigue was "present".

Discussion

CRS is a disease that not only causes a significant QOL detriment but is also associated with tremendous costs to society[4,12-15]. As a result, treatment of CRS should be directed at minimizing the impact of CRS disease manifestations, which is reflected by the concept of CRS disease control[1]. The extent of control that is maintained over a patient's CRS is significantly associated with the downstream consequences of CRS, such as decreased QOL and lost productivity[16-18]. Developed from expert opinion, EPOS 2012 guidelines first introduced criteria for assessment of CRS disease control which included assessment of CRS symptoms using a binary descriptive scale to assess whether a symptom is controlled or not[2]. The EPOS 2020 CRS disease control criteria included the same descriptive scale but also proposed an alternative quantitative measurement of CRS symptoms using a VAS with a cut-off of >5 on a scale of 0 to 10 to reflect an uncontrolled symptom, which could be more amenable for use in research[4]. This VAS cut-off of >5 was derived from a study by Van der Veen et al., which found that when individual symptom VAS scores were > 5 on a scale of 0 to 10, patients appeared much more likely to have EPOS-defined uncontrolled CRS[5]. However, the study by Van der Veen et al. was not designed to specifically determine how an individual symptom's severity assessed using a VAS would translate to the binary descriptive symptom scale used in the CRS control criteria described in the EPOS 2012 guidelines. Given the great potential significance for the EPOS CRS disease control criteria to be used as an outcome measure of CRS disease burden, it is important that any quantitative symptom criteria be directly determined through scientific investigation. In this study, our objective was to perform a direct investigation of how CRS symptom VAS scores translate to the descriptive symptom scale in the EPOS CRS disease control criteria. The results of our study may therefore be used to implement VAS symptom scores in the determination of CRS disease control based on EPOS criteria.

While we found that each of the individual symptoms had a different VAS cut-off score that maximized prediction of uncontrolled symptoms on the corresponding EPOS descriptive symptom scale, we found that a VAS criterion of >3.5 could be applied to all symptoms with high predictive accuracy for uncontrolled symptoms on the EPOS descriptive scale. Interestingly, we found that the VAS symptom score for rhinorrhea/postnasal drip had a disparately poor predictive ability for predicting uncontrolled symptoms ("mucopurulent on most days of the week") on the corresponding EPOS descriptive scale compared to the other symptom VAS scores suggesting further study and validation of this question may be beneficial.

Previous studies have revealed interesting insights on the integration of CRS symptoms into the disease control concept. In an independent study, physician perspectives were largely found to mirror the expert opinion-derived EPOS 2012 CRS control criteria with the severity of nasal symptoms, poor sleep quality and craniofacial discomfort all associated with how physicians rated the CRS disease control of their patients[19]. By comparison, the CRS manifestations that contribute to patients' perceptions of their CRS are varied[20,21], so a general assessment by the patients of their CRS disease control may be an important metric of disease burden[22]. In general, however, the severity of nasal symptoms is most dominantly associated with how patients report their level of CRS disease control[19,23,24], with nasal obstruction and rhinorrhea as particularly important determinants of patient-reported CRS disease control[25].

While many previous studies have investigated which CRS symptoms are associated with perceptions of CRS disease control, fewer studies have provided guidance for how to translate the quantified burden of CRS symptoms to CRS control. Van der Veen et al. was the first study to investigate how the severity of CRS symptoms could be translated to CRS disease control based on EPOS 2012 criteria, finding that a CRS symptom severity >5 on a VAS, ranging in possible value from 0 to 10, was associated with uncontrolled CRS[5]. However, this study was not designed—nor intended—to determine how individual symptom severities would translate to the corresponding binary descriptive symptom scale in the EPOS CRS control criteria. Our study directly investigates and shows how symptom severity scored on a VAS can be used to determine CRS disease control using EPOS criteria, as intended by the EPOS 2020 guidelines.

Conclusion

Based on our study results, we propose consideration that a VAS symptom score cut-off of >3.5 (on a scale of 0 to 10) be used to translate to the corresponding "poorly controlled" symptom criteria on the EPOS descriptive scale. Our result is also consistent with a prior study finding that even moderate levels of CRS symptoms are associated with perception of poor CRS symptom control by patients[26]. Finally, we also propose consideration for future rewording of the EPOS descriptive control criteria for rhinorrhea/postnasal drip based on the relatively poorer correlation between VAS and descriptive scales. In between the range of "little and mucous" to "mucopurulent on most days of the week" we hypothesize that there may be CRS patients who have non-purulent but copious amounts of nasal drainage whose rhinorrhea symptoms would seemingly not be captured with the descriptive scale but instead may score quite high on the VAS. We postulate that even simple rewording of the uncontrolled rhinorrhea/postnasal drip response to "mucopurulent or most days of the week" may better reflect the intended uncontrolled rhinorrhea/postnasal drip disease state. However, our study was performed at a single center with patients recruited from one geographic region. Although patients from our center have largely reflected the same perspectives as patients in other regions[27], we nevertheless hope to see our study repeated in

other centers.

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None.

Authorship contribution

KMP: concept of study, collection of data, analysis of results, write up of manuscript, critical review of all contents; KWS: collection of data, write up of manuscript, critical review of all contents; ARS: concept of study, collection of data, analysis of results, write up of manuscript, critical review of all contents.

Conflict of interest

The authors declare that there are no conflicts of interests regarding the publication of this paper.

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