



Patient perspectives on international multidisciplinary consensus criteria for chronic rhinosinusitis disease control

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Abstract

Objectives: Recently, a set of consensus criteria and near-consensus criteria for the evaluation of chronic rhinosinusitis (CRS) disease control was identified by an international multidisciplinary panel of key stakeholders. The objective of this study is to evaluate patient perspectives on these disease control criteria.

Methods: This is a qualitative phenomenological study using constant comparative methodology. Twenty-one one-on-one interviews, ranging from 6 to 15 min and based on a standardized semi-structured script, with CRS patients from diverse backgrounds were performed. The authors analyzed transcripts of the interviews to identify recurrent themes in patient responses. Conclusions were drawn based on these themes.

Results: All participants agreed with the consensus criteria (overall symptom severity, nasal obstruction severity, patients' self-assessed CRS control, and need for CRS-related oral corticosteroids), and most participants agreed with near-consensus criteria (nasal endoscopy, smell loss and nasal drainage severities, impairment of day-to-day activities, and overall quality of life) identified by the international multidisciplinary panel. Some patients disagreed with inclusion of smell loss due to common etiologies—such as post-viral or iatrogenic causes—that would not necessarily be an indicator of active sinonasal inflammation. One theme that emerged was the need for a facial pain/pressure criterion to be added.

Conclusions: CRS patients overwhelmingly affirmed recently described consensus and near-consensus criteria for CRS disease control with the caveat that a question asking about facial pain/pressure should be included as well. Recently, identified consensus criteria for CRS disease control should be interpreted within the context of patient perspectives.

KEYWORDS

chronic rhinosinusitis, consensus, disease control, patient perspectives, qualitative study

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1 | INTRODUCTION

Chronic rhinosinusitis (CRS) disease control is a global metric of CRS that has previously been defined as the degree to which CRS manifestations are within acceptable limits.^{1,2} For CRS, as with other chronic conditions, achievement of disease control is a common overarching goal of treatment. As a result, the ability to understand what constitutes acceptability of a patient's disease—including what criteria are used to judge that acceptability—is essential for management.

Criteria by which CRS disease control could be assessed were first proposed in the 2012 European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS). These criteria were also preserved in EPOS 2020.^{3,4} However, in the ensuing years, at least 14 other, different sets of criteria have been used for judging CRS disease control.⁵ This inconsistency in CRS disease control criteria used in the scientific literature prompted an international multidisciplinary group of experts to determine consensus criteria using a modified Delphi methodology.⁶ This group identified consensus around overall symptom severity (OSS), the use of systemic corticosteroids for CRS in the past 6 months, severity of nasal obstruction, and patient-reported CRS control as essential criteria for the evaluation of CRS disease control.⁶ Several additional criteria that reached near-consensus included nasal endoscopy findings, overall quality of life, severity of smell loss, interference with performing day-to-day activities, and severity of nasal discharge.⁶ The broad agreement around these putative criteria for assessment of CRS disease control was an important first step in establishing consistency within the field.

However, one limitation of this multidisciplinary group was that only two CRS patients (out of 32 total participants) participated in the consensus development.⁶ In recent years, the inclusion of patient perspectives in the characterization and management of CRS has been emphasized by patients and clinicians.⁷⁻⁹ To that end, there remains a need to better understand what criteria patients, the primary stakeholders in the management of CRS, feel should be used to assess their CRS disease control. It has been shown that patients have a good understanding of the concept of CRS disease control, which broadly aligns with healthcare providers' views.¹⁰ However, previous work has also suggested that patients and healthcare providers may differ in the dominant criteria that they use to assess a patient's CRS disease control.¹¹ The objective of our study was to deeply explore CRS patients' perspectives about criteria—individually and as a whole—by which to assess CRS disease control. Using the recently identified consensus and near-consensus CRS disease control criteria that were determined in part with patient input as a framework, we performed interviews of CRS patients to qualitatively gauge their perspectives of these criteria as well as ascertain whether any additional criteria should be considered. We believe that the results of this study will serve to further advance the development of criteria for assessment of CRS disease control that will be broadly accepted by healthcare providers while aligning with patients' priorities as well.

2 | MATERIALS AND METHODS

2.1 | Study participants

This study was approved by the Institutional Review Board at the University of Cincinnati College of Medicine. Patients enrolled in the study were over 18 years of age and had a diagnosis of CRS made according to clinical practice guidelines.¹² All patients spoke English, and all interviews were conducted in-person after the patient's regularly scheduled clinic visit in the investigators' rhinology clinics. Informed consent was obtained prior to all interviews. Patients were selected by the treating physicians from their tertiary care rhinology clinics in urban and suburban locations to represent a diverse cohort of CRS patients. All interviews were conducted by researchers not involved in the patient's care. Patients were not compensated for the interviews. Demographic information, including gender and age, was recorded for each patient. Clinical characteristics, including a history of smoking, environmental allergies confirmed by skin prick testing, history of asthma, prior endoscopic sinus surgery, and history of nasal polyps or cystic fibrosis were obtained.

2.2 | Study design

This is a qualitative phenomenological study, which utilized constant comparative methodology and was designed as we have previously described.¹³ Each interviewer used a standardized and semi-structured script that was developed at the beginning of the study. Twenty-one one-on-one interviews were conducted by two of the authors (R.C. and F.H.), neither of whom was the treating physician of the patient. The interviews ranged from 6 to 15 min. Conversations were recorded and saved with the Rev App; no identifying patient information was saved in the app. Recordings were then transcribed using Microsoft Word and double-checked for accuracy. Transcriptions were then evaluated by two authors (R.C. and A.R.S.) who identified themes and representative quotations. Patients were interviewed until (i.e., the total number of patients was determined by when) data saturation was reached.¹³

2.3 | Data analysis

Descriptive statistics were used to evaluate patient demographics and clinical features. Iterative discussions between members of the research team were conducted throughout the interview process. Based on preliminary themes elicited from patient transcripts, it was determined that after 21 interviews, data saturation had been reached. A final round of transcript analysis was then conducted by members of the research team (R.C. and A.R.S.), and conclusions were subsequently made.

3 | RESULTS

3.1 | Demographics and clinical characteristics

A total of 21 patients participated in one-on-one interviews until content saturation was reached. There were 13 males and 8 females. Ages ranged from 23 to 81 years old with a mean age of 42.2 years old (SD = 17.6). Five participants (23.8%) had a history of smoking. Thirteen participants (61.9%) had environmental allergies confirmed by skin prick testing, while nine participants (42.9%) had a history of asthma. Thirteen participants (61.9%) had a history of endoscopic sinus surgery, nine (42.9%) had nasal polyps, and two (9.5%) had cystic fibrosis.

3.2 | Protocol/definitions

All interviews began by explaining to the study participant that the objective of our study was to determine what factors patients use to determine whether their CRS is under control. We defined CRS disease control to study participants as the degree to which manifestations of their CRS are within acceptable limits. We then explained that a multidisciplinary panel from around the world had identified criteria for assessing CRS disease control. Participants were asked to read over the list (Table 1) of consensus and near-consensus criteria identified by the multidisciplinary panel. We then asked patients a variety of questions about their perspectives on the criteria.

3.3 | Patient perspectives: agreement with disease control criteria

Participants were asked to read the nine consensus and near-consensus criteria. They were then asked if they disagreed with any of the criteria and, if so, to explain why. Nineteen of the 21 participants (90.5%) did not disagree with any of criteria to assess CRS disease control. The two participants who expressed disagreement with any of the criteria cited the sense of smell item.

"I'll never get my sense of smell or taste back to the way it was before... so that's never going to change for me."

TABLE 1 Consensus and near-consensus criteria assessed by patients.

Consensus criteria	Near-consensus criteria
Overall symptom severity	Nasal endoscopy findings
Use of systemic corticosteroids for CRS	Overall quality of life
Severity of nasal obstruction	Impairment of day-to-day activities
Patient-reported CRS control	Severity of smell loss
	Severity of nasal discharge

Abbreviation: CRS, chronic rhinosinusitis.

"I haven't been able to smell anything since 2019. So, for me, [smell loss] is repetitive all the time."

The common theme in disagreement with use of a smell loss criteria in assessment of CRS disease control was in relation to the possibility that permanent smell loss is not a reflection of active sinonasal inflammation, i.e. active, uncontrolled CRS.

3.4 | Patient perspectives: additions to disease control criteria

Patient responses were mixed when asked if there should be additional items added to the criteria. Nine of the 21 patients (42.9%) cited they would add criteria to the list. Three additions at least two participants mentioned included the following: ear discomfort (e.g. pressure), poor sleep, and facial pain/pressure:

"I always wonder if I'm the only one who has ear stuff... to me that's the thing that's bothering me right now is my ear pressure."

"I think quality of sleep could be added because I think that's why a lot of us come in."

"I don't know if other people get those pressure or sinus headaches because I don't see anything about that."

3.5 | Patient perspectives: redundancy of criteria

Patients were asked if any of the consensus or near-consensus criteria were redundant or unnecessary. Most participants did not find that any of the criteria were redundant or unnecessarily overlapped with one another. Of those who did, patients cited CRS-related impairment of day-to-day activities as possibly infrequent enough to be unnecessary or overlapping with quality of life:

"I just think like 'the extent to which chronic sinusitis prevents the patient from performing day-to-day activities' question is not really necessary because the pain isn't like severe enough for me to where I won't get up and do anything unless I had it mixed with something like a cold or the flu."

"I think overall quality of life and ability to perform day-to-day activities is pretty much the same thing because I'm a doer, I'm outside all the time, so that's the big thing for me and being able to do that."

3.6 | Patient perspectives: OSS

Patients were asked if the OSS criterion gave providers additional information that was not captured by asking about individual CRS

symptoms. All participants but one believed that the OSS criterion gave the provider additional information. For example:

"I think it would contextualize it. If there's blockage or drainage, but that's not causing as big of an issue as the decreased sense of smell or something, you might get a better glimpse of that from that first question [OSS]."

"I actually think that's probably the most important question in my mind because I think that just because one symptom is bad doesn't mean that overall it's bad or the other way around."

"I think that's a good starting point... that'd be a good overall to let the physician know how serious the patient thinks that it is."

3.7 | Patient perspectives: quality of life

Patients were asked if the quality of life criterion gave providers additional information that was not captured by asking about individual CRS symptoms. Overall, participants agreed that a question about quality of life provided additional information. Representative examples of patients' remarks are below:

"Yeah, that's why we're doing this. I have a physical job and sometimes I get busy, and I need to know that I'm not having to hang out with my mouth open the whole time in order to breathe correctly."

"I think it is important because you know for some people symptoms are so bad that they can't really do the things that they want to do, but some other people have bad sinuses and make do with it."

"You don't have any quality of life if you can't breathe, you can't go anywhere. You can't do nothing. All you're trying to do is gasp for air. You can't sleep at night."

3.8 | Patient perspectives: facial pain/pressure

Because facial pain/pressure is a cardinal, diagnostic criteria for CRS, we also asked the patients who did not volunteer its additional need for inclusion explicitly whether facial pain/pressure should be considered as a criterion for assessment of CRS disease control. The majority (78.9%) of patients responded in the affirmative:

"That will be a good one to put on there because I know I have a lot of facial pain when my sinuses start to act up and when they get really bad."

"I definitely think a question about pressure is important since that's one of the main symptoms I have."

"I don't experience facial pain often... but I think it's important to be able to know if you're in pain or not."

"It would definitely be helpful."

A few participants, however, did not believe facial pain/pressure should be a part of the list of criteria. One patient said:

"I don't think for chronic sinusitis that it should be on there. Because I don't really have facial pain anymore, and it still doesn't correlate with how blocked I get. No matter how blocked I get my face still doesn't hurt."

Participants who had a history of migraines were asked if they can differentiate between sinus headaches caused by facial pain/pressure and migraines. All 12 participants with a history of migraines said they would be able to differentiate the two headache types and they explained their reasoning, which included:

"Yeah, when you get a sinus headache everything just hurts behind your eyes and nose versus a migraine feels very different. It only hurts in one spot. I know the difference."

"Once you know where the sinuses are, you can identify a sinus headache."

3.9 | Patient perspectives: nasal drainage

Participants were asked to explain whether the nasal drainage criteria implied directionality (e.g. anterior or posterior drainage) in their experience. Patients' responses indicated that they attributed nasal drainage from CRS to be from anterior and/or posterior etiologies, with varied responses from patient to patient. Some patients described having anterior drainage, post-nasal drainage, or both that would contribute to their CRS disease control assessment:

"I think it's both the back of the throat or coming out through the front. And maybe that needs to be elaborated too to understand because maybe not all people have both."

"So that's when like the nasal cavity is having a lot of drainage in the back of the throat."

"Most of the time when I read [nasal drainage], I think in front and then post-nasal means something a little different to me."

Based on the varied responses, participants were asked if the nasal drainage criteria should specify that nasal drainage could potentially encompass discharge out the front of the nose and also down the back of the throat. All but one participant agreed that a nasal drainage criterion in the assessment of CRS disease control should specify directionality of nasal drainage.

4 | DISCUSSION

Determination of formal consensus around criteria for CRS disease control was an important step towards long-term consistency in the application of the disease control concept to CRS.⁶ However, the primary stakeholders in the determination of how CRS disease control should be evaluated are patients. Although patients have an understanding of CRS disease control that largely aligns with healthcare providers,¹⁰ differences in patient and physician perspectives on CRS disease control have been identified in the past.¹¹ Because patient advocates constituted a small fraction of participants in the recently reported consensus criteria for CRS disease control,⁶ confirmation of broad patient agreement with these criteria as well as clarifications of the criteria from the patient perspective were still needed. In this study, we addressed these knowledge gaps using qualitative methodology implemented through interviews with CRS patients that were specifically focused on the recently reported international multidisciplinary consensus CRS disease control criteria. Overall, we found that patients largely agreed with the essentiality of consensus and near-consensus CRS disease control criteria. Patients also provided novel insights about specific criteria and additionally advocated for inclusion of an item that assessed the severity of facial pain/pressure caused by CRS.

Previous studies have quantitatively investigated patients' perspectives of many of the individual consensus or near-consensus criteria for CRS disease control. For example, OSS score has been validated to reflect the mean of individual symptom severities experienced by patients.¹⁴ OSS accurately predicts when CRS symptoms are significantly affecting quality of life and also can be used to classify patients' CRS symptoms as mild, moderate, or severe.¹⁵ Patient-reported CRS control (i.e., how patients rate their own CRS disease control) is significantly associated with patients' quality of life,^{16,17} serves as a valid measure of CRS disease burden,¹⁸ and is the factor most greatly associated with how healthcare providers judge CRS disease control.¹⁹ Nasal symptoms of obstruction and discharge have been shown to be the symptoms most greatly associated with patient satisfaction²⁰ as well as both patients' and healthcare providers' assessments of CRS disease control.^{11,19} On the other hand, while smell loss has also been identified as an important symptom for CRS patients and advocated for as a criteria for CRS disease control, at least in CRS with nasal polyps,^{20,21} studies to date have found at most a minor association between the severity of smell loss and how healthcare providers and patients (both with and without nasal polyps) judge CRS disease control.^{19,22} The use of oral corticosteroids for CRS has not been found to be associated with how patients judge their

CRS control but prior studies have shown the number of CRS-related oral corticosteroids to be associated with patients' quality of life.^{23,24} While no study has directly sought patients' perspectives in relation to nasal endoscopy findings as a goal of treatment or component of CRS disease control, one previous study has shown that nasal endoscopy findings are a source of discordance between patients' rating of their own CRS disease control and CRS disease control judged according to EPOS criteria.²⁵ This may not be surprising since prior research has shown nasal endoscopy findings to be weakly correlated with patient-reported outcome measures reflecting CRS symptoms and quality of life.^{26,27} No prior studies have assessed patient perspectives on the impact of CRS on completing day-to-day activities, but prior studies have suggested associations between CRS-related activity impairment with mood and personality.²⁸⁻³⁰ Despite this extensive quantitative research on most of the recently identified consensus and near-consensus CRS disease control criteria individually, there is still need for not just explicit qualitative study of patients' perspectives of these CRS disease control criteria but also to assess patient perspectives on these consensus and near-consensus criteria together as a whole.

In our study, we found that the vast majority of patients agreed with all consensus and near-consensus criteria used to assess CRS disease control. The two patients who disagreed with any aspect of the expert criteria both cited that the severity of smell loss was unnecessary. These two patients' comments are consistent with prior research which has shown that smell loss is not a strong determinant of patient-reported or rhinologist-reported CRS control.^{19,22} Although patients largely affirmed the overall set of consensus and near-consensus criteria, results were mixed as to whether additional criteria were needed. The three additions that at least two participants proposed included criteria that assessed ear symptoms, sleep disturbance, and facial pain/pressure. In the determination of consensus CRS disease control criteria, inclusion of an item asking about ear discomfort never came close to reaching consensus—often ranking in the bottom third of possible criteria considered—and sleep disturbance reached near-consensus in the first round of the Delphi process but not in latter rounds.⁶ Facial pain/pressure, like sleep disturbance, is a component of EPOS CRS disease control criteria and was an addition that was ultimately affirmed by the majority of participating patients. In contrast to the perspectives expressed by the patients included in our study, stakeholders that identified the consensus CRS disease control criteria felt that facial pain/pressure could be too non-specific as it can be associated with other comorbidities such as migraines.^{6,31} Indeed, prior research has shown that greater severity of facial pain is associated with comorbid migraines in CRS patients.³¹ Although all participants in our study who had comorbid migraines believed they were able to differentiate between facial pain/pressure due to migraines vs. sinus disease; previous studies have shown that there is great potential for clinical overlap between these etiologies for facial pain/pressure.³²⁻³⁴ Nevertheless, because facial pain/pressure was cited as the most important symptom for some of our participants and with most of our participants endorsing it as important, its inclusion in disease control criteria

should be explored in the future to bridge the discordance of perspectives between experts and patients. Finally, patients considered all the consensus and near-consensus criteria reflective of global measures of disease status—OSS, patient-reported CRS disease control, and overall quality of life -- -to be important and complementary in expressing the totality of their disease burden. For example, patients expressed that it was possible to have severe symptoms that don't impact quality of life, while others may have severe symptoms that have a large impact on their quality of life.

Our study is important for the future development of CRS disease control criteria. The identification of consensus and near-consensus criteria for the assessment of CRS disease control by an international, multidisciplinary group of key stakeholders—including two patient advocates—was an important first step.⁶ However, the face validity of these criteria—together as a whole—must be well fleshed out within the CRS patient population. By including patient insights and perspectives, our study results now provide support for the validity of the recently identified consensus and near-consensus CRS disease control criteria as a whole and also identified areas for future investigation, such as the addition of a facial pain/pressure criterion.

Our results should be interpreted within the context of its limitations. The primary limitation of this study is that it only examines a patient population from one tertiary care center located in one geographic location in one country. It is possible that patients in other areas of the United States and other parts of the world may have different opinions on these consensus and near-consensus control criteria. We also did not account for factors such as disease severity or education level. Additionally, patients were recruited in a clinical setting by an associate of the care provider, which may have made patients feel they needed to participate or answer questions in a certain way. We do not believe this to be an important factor as patients were told participation had no impact on the care they received, and the interviewer was not a member of the healthcare team. Furthermore, there were several patients who decided not to participate in the study. Despite these limitations, we believe this study offers an important perspective on recently identified consensus and near-consensus CRS disease control criteria.

5 | CONCLUSION

The CRS patients participating in our study overwhelmingly affirmed and agreed with the consensus and near-consensus criteria for CRS disease control that were identified by an international, multidisciplinary group of key stakeholders. These patients also expressed the opinion that a criterion about facial pain/pressure should also be considered. Our CRS patients believe that OSS and overall quality of life provide additional information that are not captured by their individual symptomatology. While recently identified consensus and near-consensus criteria for CRS disease control reflect the opinions of an international, multidisciplinary group of key stakeholders, the

implementation of these criteria should ideally be in the context of the perspectives of CRS patients.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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