

Acute Exacerbations Mediate Quality of Life Impairment in Chronic Rhinosinusitis



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What is already known about this topic? Antibiotic usage for chronic rhinosinusitis (CRS) is common, most often in the setting of acute exacerbations and superimposed acute rhinosinusitis. Greater antibiotic usage reflects poorer control of CRS.

What does this article add to our knowledge? This article establishes a link between CRS symptomatology and the need for sinusitis-related antibiotic usage. This article also shows that the need for antibiotics mediates the association between the nature of a patient's CRS, reflected by CRS symptomatology, and quality of life detriment in CRS. This mediation effect is shown to reflect the impact of acute exacerbations of CRS to decrease quality of life.

How does this study impact current management guidelines? This study demonstrates that acute exacerbations, for example from superimposed acute sinus infections, may be one aspect of CRS distinct from baseline symptomatology that can be targeted to improve patient quality of life.

BACKGROUND: Antibiotic usage in chronic rhinosinusitis (CRS) reflects poor disease control and may indicate the need for sinus surgery.

OBJECTIVES: The objective of this study was to (1) determine the association between CRS symptomatology, which reflects CRS pathophysiology, and sinusitis-related antibiotic usage, and (2) to determine the impact of antibiotic usage on quality of life (QOL).

METHODS: A prospective cross-sectional study enrolling 85 participants meeting consensus guideline criteria for CRS was conducted. Symptomatology was assessed using the 22-Item Sinonasal Outcomes Test (SNOT-22) and general health-related QOL was assessed using the EuroQol 5-dimensional visual analog scale (EQ5D-VAS). Association was sought between SNOT-22, the number of prescribed antibiotics for sinusitis in the past year, sinus infections in the past year, and EQ5D-VAS. Antibiotic usage and number of sinus infections were checked for mediation in the association between SNOT-22 and EQ5D-VAS.

RESULTS: The SNOT-22 score is associated with the number of antibiotics taken in the past year (relative risk = 1.02, 95% confidence interval [CI]: 1.01-1.03, $P = .002$) and EQ5D-VAS ($\beta = -0.37$, 95% CI: -0.52 to -0.22 , $P < .001$). Having taken more than 2 antibiotics for sinusitis in the past year mediated 31% of the effect of SNOT-22 on EQ5D-VAS, through a mediation effect ($P = .008$). Antibiotic usage highly correlated with the number of reported sinus infections ($\rho = 0.69$, 95% CI: 0.54-0.80, $P < .001$), which also showed a similar statistically significant mediation effect between SNOT-22 and EQ5D-VAS. **CONCLUSIONS:** Sinusitis-related antibiotic usage, likely reflecting the frequency of acute CRS exacerbations, mediates the association between CRS symptomatology and QOL. Reducing the frequency of acute exacerbations may significantly enhance QOL of CRS sufferers independent of baseline symptomatology. © 2016 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2017;5:422-6)

Key words: Acute exacerbations; Acute rhinosinusitis; Antibiotics; Chronic rhinosinusitis; EQ-5D; Quality of life; SNOT-22; Symptomatology

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Chronic rhinosinusitis (CRS) is an inflammatory disease of the sinonasal mucosa that is characterized by symptoms of nasal obstruction, mucopurulent drainage, facial pain/pressure, and hyposmia.^{1,2} CRS is a common disease, affecting 2% to 5% of the population, and it imparts a significant quality of life (QOL) detriment.³⁻⁵ The effects of CRS have been characterized from the standpoint of sinonasal symptoms as well as general health-related QOL impairments,^{6,7} both of which are associated with physician visits, medication usage, loss of productivity, and annual health care costs on the order of 10 billion dollars.⁸

The difficulty and expense in treating CRS in part arises from a lack of understanding the underlying pathophysiology of this

Abbreviations used

CRS- Chronic rhinosinusitis
EQ5D-VAS- EuroQol 5-dimensional survey visual analog scale
QOL- Quality of life
RR- Relative risk
SD- Standard deviation
SNOT-22- 22-Item Sinonasal Outcomes Test

disease. It is unlikely that there is one common pathway for the development of CRS. Instead, CRS is increasingly recognized as a heterogeneous disease, driven by factors such as atopy, immune dysfunction, microbes, and impaired mucociliary clearance,⁹⁻¹⁵ which all converge on the final clinical phenotype defined by consensus guideline criteria for the diagnosis of CRS. It is therefore likely that the varied pathophysiologic processes underlying CRS may differentially impact the disease course and the ultimate QOL deficit imparted to patients. One large issue related to the care of patients with CRS is with respect to the use of antibiotics. Because CRS is increasingly recognized as an inflammatory, rather than just microbial, disorder, the necessity of antibiotics in the long-term management and control of CRS is a point of debate.¹⁶ Moreover, disruption of the normal sinonasal microbiome, which may occur from antibiotic use,¹⁷ is associated with sub-optimal outcomes in patients with CRS as well.¹⁸ Nevertheless, millions of antibiotics are prescribed for CRS every year, often for acute CRS exacerbations.¹⁹ Antibiotic utilization is therefore used clinically as a measure for disease control, and the frequency of acute exacerbations is often used as an indicator of the need for more aggressive treatment, including endoscopic sinus surgery.^{20,21}

Despite the common use of antibiotics for patients with CRS, no studies have examined why patients with CRS need these antibiotics and how antibiotic usage impacts their disease course. As a first step toward studying this problem, we hypothesized that the nature of each patient's CRS, which is reflected in each patient's complex of symptoms,²² would be associated with the need for (and use of) antibiotics. A prospective study of this hypothesis was our primary objective, and our secondary objective was to understand how antibiotic usage may affect QOL in patients with CRS.

METHODS

Study participants

This study was approved by the Massachusetts Eye and Ear Infirmary Human Studies Committee. Adult patients (18 years or older) with CRS were recruited prospectively and provided informed consent for inclusion into this cross-sectional study. All participants met consensus guideline established criteria for CRS.^{1,2} Exclusion criteria included: (1) comorbid vasculitis, (2) comorbid cystic fibrosis, (3) comorbid sarcoidosis, and (4) the need for antibiotics for sinusitis at the time of recruitment.

Study design and data collection

This study was designed and powered as a prospective cross-sectional study to understand the relationship between a score on the 22-Item Sinonasal Outcomes Test (SNOT-22) that is representative of the baseline of a patient with CRS and his or her prescription antibiotic usage. A total of 85 participants were enrolled to power identification of an association of medium effect (defined as $r = 0.3$)²³ between the SNOT-22 score and the number of

prescribed antibiotics courses taken in the previous year for sinusitis at a significance level of 0.05 and a power of 0.80. Data collected directly from all participants included CRS-related symptomatology as measured by the validated SNOT-22 survey,²⁴ general health-related QOL as measured by the validated EuroQol 5-dimensional visual analog scale (EQ5D-VAS) given with the 5-level EQ5D questionnaire,²⁵ age, gender, whether the participant had previous sinus surgery, whether the participant was currently using an intranasal corticosteroid medication, the number of prescribed antibiotic courses for sinusitis that were taken in the previous 1-year period (participants were asked: "How many prescribed courses of antibiotics have you taken in the last year for your sinuses or sinus infections?"), and the number of sinus infections in the previous 1-year period (participants were asked: "How many sinus infections have you had in the last year?"). Data collected from the evaluating physician included whether the patient had a history of (1) aeroallergen hypersensitivity based on formal skin or serological allergy testing, (2) asthma based on a previous diagnosis that was confirmed by clinical history, and (3) nasal polyps.

Statistical analysis

All analysis was performed using the statistical software package R (www.r-project.org, R Core Team, Vienna, Austria). When correlations were performed, a Spearman correlation was used. Univariate and multivariable associations between the SNOT-22 score (as the independent variable) and the number of prescribed antibiotics courses taken for sinusitis in the previous year (as the dependent variable) were calculated using a negative binomial regression model. Associations between SNOT-22 and antibiotics usage (as the independent variables) and EQ5D-VAS (as the dependent variable) were sought using linear regression. The effects of antibiotic usage and the number of sinus infections in the last year as possible mediators in the association between the SNOT-22 score (independent variable) and the EQ5D-VAS score (dependent variable) were determined using Sobel's indirect test for mediation²⁶ implemented by the `proximal.med()` function of the `QuantPsyc` package²⁷ and bootstrapping over our dataset with 1000 iterations.

RESULTS

Study participants

A total of 85 patients, 52.9% males and 47.1% females, with CRS were recruited with a mean age of 52.3 years (standard deviation [SD] = 15.6 years). Of these study participants, 30.6% were present or former cigarette smokers, 29.4% had comorbid asthma, 51.8% had at least one aeroallergen hypersensitivity, 41.2% had nasal polyps, 37.6% had a history of at least one previous sinus surgery, and 64.7% reported the current use of an intranasal corticosteroid medication. The mean SNOT-22 score, reflecting CRS symptoms severity, was 36.8 (SD = 23.2). Over the previous year, study participants had taken a mean of 1.5 (SD = 1.9) and median of 1.0 (interquartile range = 2.0) courses of antibiotics for sinusitis. Although only patients with a suggestive clinical history were tested as a part of routine evaluation, only 1 patient in our cohort was found to have an immunodeficiency that was deemed to be a mild IgA and IgG subclass deficiency.

SNOT-22 score is associated with CRS-associated antibiotic usage

We first sought a relationship between the number of prescribed antibiotic courses that each participant completed in the

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