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Cost efficient workup and management of patients with chronic rhinosinusitis - challenges and unmet needs

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Abstract

Chronic rhinosinusitis (CRS) is a common disease, estimated to occur in 12-16% of the United States population. This prevalence creates a significant health burden with an estimated 15 million ambulatory visits for the condition annually. Consequently, practice guidelines have been designed to assist both the primary care provider and specialist in establishing a CRS diagnosis and prescribing effective treatment for CRS. The guidelines for CRS diagnosis have evolved since the United States Rhinosinusitis Task Force first published its symptom-based guidelines in 1997. Contemporary practice guidelines still require 12 weeks of appropriate symptoms, but now include corroboration of objective sinonasal inflammation demonstrated on physical exam, imaging, or endoscopy to arrive at a CRS diagnosis. While these diagnostic criteria are seemingly straightforward and are regarded as the gold standard for the diagnosis, the appropriate timing of imaging and endoscopy remain unspecified and continue to present challenges for both primary care and specialty providers. These considerations have to be measured by the direct and indirect costs of the diagnostic workup including office visits, CT scanning, endoscopy, as well as the potential for overuse of treatment modalities such as antibiotics and steroid medications. The goal of this review is to update the primary care provider and otolaryngologist on current evidence regarding the diagnosis and treatment of chronic rhinosinusitis, including the costs and timing of endoscopy and imaging.

Keywords

Chronic Rhinosinusitis; Cost Efficient; Diagnosis; Treatment; Endoscopy; Imaging

Introduction

Chronic rhinosinusitis (CRS) is a common entity, with prevalence in the United States estimated to be 12-16% [1-4]. Diagnostic criteria for the disease were first formalized in 1997 by the Rhinosinusitis Task Force, relying on a set of major and minor symptoms

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considered specific for the disease to create a diagnosis [5]. Over the next decade, however, it became clear that the symptom-only diagnostic criteria lacked the specificity and positive predictive for identifiable sinus inflammation or infection. These challenges resulted in the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) updating their clinical practice guidelines in 2007 [6, 7] followed closely by the European consensus guidelines [1]. These contemporary guidelines require the presence of two or more symptoms, which may consist of nasal blockage/obstruction/congestion, anterior or posterior discharge, facial pain/pressure, or loss of smell, along with either endoscopic findings (nasal polyps, mucopurulent discharge, edema) or changes on CT scan (mucosal changes within the osteomeatal complex or sinuses) for a diagnosis of CRS [8]. European guidelines stress that one of the two symptoms must be nasal obstruction or discharge although studies have not demonstrated that this improves diagnostic accuracy. Further position statements have sought to further clarify diagnosis and treatment as well as account for the concept that CRS with and without nasal polyposis appear to be separate disease entities [1].

Although the symptom-only diagnosis of CRS is considered inadequate by current practice guidelines, many primary care practitioners (PCPs) rely on these due to the lack of readily available nasal endoscopy or imaging. In fact, in patients diagnosed by their PCP with CRS with or without nasal polyposis, only 50% and 25% ever received CT or endoscopy respectively. Furthermore, utilization of these diagnostic modalities was skewed toward evaluation after the diagnosis and presumably treatment [9]. A CRS diagnosis established in the absence of endoscopic or CT scan findings is likely inaccurate as prior studies comparing symptoms against a gold standard of CT scan findings places the specificity of the guideline specified symptoms in the range of 2-12%, with positive predictive value in the 35-54% range in tertiary care patient populations [1, 4, 7, 10]. Another recent study found that 40% of patients diagnosed with CRS by symptoms alone lacked evidence of CRS on imaging [11]. Furthermore, a recent survey of tertiary care academic otolaryngologists demonstrated wide variability in adherence to actionable statements of the 2007 AAO-HNS guidelines for CRS diagnosis, with average rates of compliance to the 7 items regarding CRS ranging from 4 to 88% [12].

While the costs of inaccurate CRS diagnoses remain unknown, recent analysis of national ambulatory visits by Smith et al [13] found Rhinosinusitis (RS) to be the most common reason for ambulatory prescription of antibiotics. In the 5 years of national ambulatory visits examined, RS accounted for 47.9 million ambulatory visits with 69.3% of these visits resulting in antibiotic prescriptions [13]. Given the high rates of antibiotic prescription, low utilization of recommended diagnostic testing and low positive predictive value of symptoms for RS, there is reason to be concerned about widespread antibiotic overuse. Antibiotic overutilization creates the potential for unnecessary adverse events, allergic reactions, increased bacterial resistance, along with direct and indirect costs estimated as high as \$20 billion and \$35 billion respectively [14]. When one considers that commonly prescribed maximal medical regimens for CRS includes oral and nasal steroids and extended courses of antibiotics, the treatment related cost increases significantly [15-17]. In fact, costs related to direct treatment for CRS have been estimated to be approximately \$8.6 billion annually [2]. Until recently, however, there has been a paucity of literature examining indirect costs of CRS, namely absenteeism, presenteeism, and lost productivity time. These

factors have been analyzed by Rudmik et al [18] in a prospective, multi-institutional, observational cohort study that estimates annual productivity cost of refractory CRS to be approximately \$10,000 per patient per year when combining both work and household productivity lost. Together, these data demonstrate that the individual and societal costs of CRS are higher than commonly recognized; moreover increased investment is needed to fully examine optimal ways to diagnose the condition and evaluate the cost effectiveness of available diagnostic algorithms.

Section 1 Symptom Only

As defined by Lanza and Kennedy in 1997, the symptom-only diagnosis of CRS focused on major criteria (nasal obstruction, nasal discharge, post nasal drip, change in sense of smell, facial pain or pressure) and minor criteria (headache, fever, halitosis, fatigue, dental pain, cough, and ear symptoms) over a course of 12 weeks [5]. Further analysis of these criteria by Bhattacharyya [6], Stankiewicz and Chow [19], Benninger [20] and others have demonstrated the poor specificity of the symptom-only diagnosis compared to findings of inflammatory changes. Other studies have highlighted the relative importance of certain symptoms including anosmia, nasal obstruction, and discharge [4, 21]. Contemporary guidelines have steered away from the minor symptoms described by Lanza and Kennedy due to their overlap with many non-CRS conditions and refined the major symptoms to include nasal blockage, obstruction, congestion, discharge, facial pain, pressure, or loss of smell over 12 or more weeks [8]. Despite these refinements, analyses of symptom-only diagnosis using the contemporary criteria have not been shown to correlate well with objective findings of CRS, with Bhattacharyya et al describing that only 39.9% of patients with symptom positive criteria having gold standard CT scan findings [10]. A 2012 analysis by Amine et al described an ascending likelihood of positive objective disease with 2 or more symptoms yielding a 31% chance of objective findings increasing to 49% and 63% with 3 and 4 symptoms respectively [4]. An additional factor in many of these prior studies is that these studies have been retrospective studies conducted in tertiary care settings on patients in whom a CT was felt to be clinically indicated. The positive predictive value of symptoms for a CRS diagnosis in primary care remains unknown but is likely lower than that in tertiary care given the lower disease prevalence in that setting. However, using the expected true disease prevalence in symptomatic patients in the primary and tertiary care settings, empirically treating patients without confirming diagnosis via nasal endoscopy or CT imaging results in more costly care [22, 23].

Section 2 Endoscopy

Evaluation of the nasal airway has been reported to have significant diagnostic utility in the diagnosis of CRS [22, 24-26]. While anterior rhinoscopy is a commonly available means to evaluate the nasal airway and, at times, has been shown to be useful in visualizing polyps and accessing the middle meatus for cultures [27], it is typically an unreliable means of visualizing structures past the inferior turbinate. In contrast, nasal endoscopy, provides high resolution as well as sufficient illumination to visualize the entire sinonasal cavity, and is a fast, safe procedure available as a routine part of evaluation in the majority of otolaryngology practices. It provides the ability to obtain a focused exam of the sinus outflow tracts, obtain targeted cultures, differentiate between CRS with and without nasal

polypoid, and sometimes identify disease entities that can present similarly to CRS, including fungal disease, a posteriorly deviated septum, enlarged adenoids and intranasal tumors.

From a diagnostic standpoint, endoscopy has been shown to substantially increase the specificity and positive predictive value compared with symptom only diagnosis of CRS, with Bhattacharyya et al showing an improvement of specificity from 12% to 84% and PPV from 39% to 66% [10]. A recent comprehensive literature review by Wuister et al favors the use of endoscopy in the diagnosis of CRS, and notes that the inability of the CT gold standard to differentiate between opacification due to CRS or other disease conditions may in fact create an underestimation of the added value of endoscopy to diagnosis [25]. Endoscopy does, however, suffer from a 21%-35% false negative rate for patients with positive symptoms [4, 10, 21, 24] and limited inter rater reliability [28]. Given these issues, nasal endoscopy may be best suited as a first line diagnostic test to “rule in” CRS in patients with a high pre-test probability for CRS, especially CRS with nasal polypoid (CRSwNP) and may be less well suited for patients with a history or findings with low CRS risk.

Section 3 Imaging

Contemporary practice guidelines as well as current American College of Radiology (ACR) appropriateness criteria describe CT scanning without contrast as the imaging modality of choice for diagnosing CRS [29] but do not provide clear guidelines regarding the timing of the study [1, 8]. While MRI can be useful in complicated cases where there is concern for orbital or intracranial involvement, or when more information is required regarding a sinonasal mass, it is largely utilized as an adjunct imaging modality. Plain sinus radiographs are considered inaccurate by most experts and are not recommended in the diagnosis of CRS [29, 30].

Although CT scanning is considered the “gold standard” in many comparative studies of CRS, it is still typically not recommended as a first diagnostic step. European guidelines recommend imaging as a means to corroborate symptomatic and endoscopic findings when patients have failed medical therapy, with Canadian guidelines recommending CT scanning when a patient has failed maximal medical therapy and is being considered for surgical management [1, 31]. US guidelines provide more flexibility and allow for either endoscopy or CT scanning to confirm a diagnosis of CRS [8]. Significant concerns regarding imaging include radiation exposure and cost, although both have been reduced with advances in imaging technology and as CT imaging has become more mainstream [32]. Further reductions are possible through the use of cone beam CT, which provides significantly lower doses of radiation at the cost of poorer soft tissue resolution, albeit a concern if there is suspicion for sinonasal neoplasm [33, 34]. A recent survey of patient perception of CT imaging for sinus disease revealed a significant paucity of awareness about imaging associated radiation but also demonstrated that most patients would want a CT scan if it improved the accuracy of CRS associated diagnosis and treatments [35]. CT scanning for preoperative planning for CRS is similarly valuable for recognizing potential surgical hazards such as, a low hanging anterior ethmoid artery, exposed optic nerve or carotid artery, or dehiscence in the lamina papyracea or skull base, especially in the case of CRS

with polyposis or revision surgery. Further utility of CT imaging for surgical planning includes integration with image guidance systems (IGS) that may reduce intraoperative complication rates during endoscopic sinus surgery.[36]

Section 4 – Review of Timing and Cost Efficacy

When reviewing contemporary literature and guidelines it becomes clear that there are two separate questions that need to be addressed: “What is the most cost effective way for a PCP to diagnose and treat CRS?” and “What is the most cost effective way for an Otolaryngologist to diagnose and treat CRS?.” A cost effectiveness study of this problem has not been completed due to the evolving disease definitions and recommended treatment regimens along with understudied treatment outcomes and variable diagnostic and treatment costs. Furthermore, there remain few well-performed prospective evaluations of patient utility and outcomes following first line medical treatment regimens for CRS.

Medical therapy for CRS, generally consists of a course of antibiotics for 3 weeks or longer, nasal steroids, as well as saline rinses, although significant variation exists in the literature and clinical practice ([15-17, 37]. In an era when CT scanning was expensive and scarce [23], medical treatment for CRS was prescribed empirically for symptomatic patients regardless of endoscopy findings with CT scans reserved for only treatment failures. Sinus CT scans costs have since fallen with current Medicare reimbursement for sinus CT scanning (both technical and professional fees) totaling less than \$250, compared with the almost \$400 seen approximately 10 years earlier [19]. Other improvements include the advent of cone beam CT scanners that utilize 20%-50% of this dose to provide images of resolution sufficient to demonstrate sinus inflammation and can be available at the point of care [33, 34, 38].

Proponents of empiric medical therapy argue that overall costs of diagnosis and treatment are reduced primarily by reduced need for CT imaging. However, a 3 week prescription for antibiotics is no longer significantly less expensive than a CT scan, averaging approximately \$150, and when combined with the non-antibiotic medications incorporated in maximal medical therapy this can exceed on average \$250 [39]. Other studies demonstrate generally higher costs for empiric medical therapy, especially if nasal endoscopy was negative or if a CT could easily be obtained prior to initiating treatment [22, 23]. Other unquantified risks of antibiotic use includes risks of *C. Difficile* colitis that can be as frequent as 1 in 5000 antibiotic prescriptions [40]. The risk for avascular necrosis is real both in long term and intermittent high dose corticosteroid use and should be considered if prescribed empiric medical therapy includes use of systemic corticosteroids [40-43]. These data should urge a rethinking of empiric medical therapy in the patient with CRS symptoms that cannot be confirmed by nasal endoscopy or a CT scan. In fact, the most recent UK Commissioning guide on Rhinosinusitis recommends against use of antibiotics in settings where CRS cannot be confirmed by endoscopy or CT, citing concerns for poor treatment efficacy, increased antibiotic resistance, and poor diagnostic specificity without endoscopy or CT [44] (Figure 1). The differential diagnosis for patients presenting with symptoms consistent with possible sinusitis includes migraine, [45] uncontrolled allergic rhinitis and anatomic obstruction. The recommended treatment algorithms for these conditions differ significantly from those of

CRS - for example, studies have demonstrated triptan response among patients who have been assigned “sinus headache” diagnoses [46] and allergic rhinitis can be well controlled with topical nasal corticosteroids or antihistamines. While it is intuitive that more accurate diagnosis should lead to better outcomes, there remains no study demonstrating that treatment outcomes are improved better in patients with objective findings of CRS compared to those who have the symptoms but no inflammatory findings.

When considering more current studies of the costs and risks of diagnosis and treatment, cost related analyses appear to favor either upfront CT scanning prior to treatment of patients in primary care or specialty referral for the diagnosis of patients with CRS symptoms who are being considered for medical therapy [4, 23]. In specialty care where nasal endoscopy is available, appropriately symptomatic patients in whom the diagnosis cannot be made following nasal endoscopy should similarly be recommended to get a CT scan prior to initiating medical therapy consisting of an extended course of antibiotics (Figure 2). Revising previous cost estimates published by Stankiewicz et al [19] in 2003 to current diagnostic and therapeutic costs would also appear to favor upfront CT scanning by specialists. .

Summary

In order to accurately diagnose CRS, PCPs should not rely on a symptom only diagnosis to initiate medical therapy given the 50% or greater chance for misdiagnosis and inappropriate therapy. This creates the dilemma of whether to depend on upfront CT scanning or referral to an otolaryngologist for endoscopy. Using expected pre-test probability in primary care current cost analyses favor upfront CT scanning or referral to specialty care if PCPs are presented with patients who meet symptom criteria for CRS.

Otolaryngologists typically incorporate nasal endoscopy into their routine examination of patients who present for evaluation of CRS. The specificity and positive predictive value of nasal endoscopy support its use as a low risk, radiation-free means of diagnosing a patient at high risk for a CRS diagnosis. However, in patients who do have indeterminate endoscopic exams, or have a low pre-test risk for CRS, an upfront CT may lower overall costs by avoiding unnecessary treatment of a patient without CRS. More rigorous studies of treatment outcomes, diagnostic accuracy of physicians in their evaluation of patients with CRS symptoms are needed to develop evidence based, cost effective guidelines for diagnosing patients with CRS symptoms.

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Fig. 1.

A) Current scheme of evaluation in primary care. Bolder arrows indicate the preferred management strategy in the majority of cases as indicated by published studies. **B)** In the proposed strategy, patients being considered for systemic therapy would be referred to specialty care or for imaging

A- Current

B- Proposed

Fig. 2.

A) Current scheme of evaluation in otolaryngology care. Bolder arrows indicate the preferred management strategy in the majority of cases as indicated by published studies. **B)** In the proposed strategy, additional considerations include findings of endoscopy and the pretest likelihood of CRS