Defining appropriateness criteria for endoscopic sinus surgery during management of uncomplicated adult chronic rhinosinusitis: a RAND/UCLA appropriateness study*

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Abstract

Introduction: Appropriate indications for endoscopic sinus surgery (ESS) for chronic rhinosinusitis (CRS) are currently poorly defined. The lack of clear surgical indications for ESS likely contributes to the large geographic variation in surgical rates and contributes to reduced quality of care. The objective of this study was to define appropriateness criteria for ESS during management of adult patients with uncomplicated CRS.

Methods: The RAND/UCLA appropriateness methodology was performed. An international, multi-disciplinary panel of 10 experts in CRS was formed and completed two rounds of a modified Delphi ranking process along with a face-to-face meeting.

Results: A total of 624 clinical scenarios were ranked, 312 scenarios each for CRS with and CRS without nasal polyps. For adult patients with uncomplicated CRS with nasal polyps, ESS can be appropriately offered when the CT Lund-Mackay score is ≥ 1 and there has been a minimum trial of a topical intranasal corticosteroid plus a short-course of systemic corticosteroid with a post-treatment total SNOT-22 score ≥ 20. For adult patients with uncomplicated CRS without nasal polyps, ESS can be appropriately offered when the CT Lund-Mackay score is ≥ 1 and there has been a minimum trial of a topical intranasal corticosteroid plus either a short-course of a broad spectrum/culture-directed systemic antibiotic or the use of a prolonged course of systemic low-dose anti-inflammatory antibiotic with a post-treatment total SNOT-22 score ≥ 20.

Conclusion: This study has developed and reported of list of appropriateness criteria to offer ESS as a treatment 'option' during management of uncomplicated adult CRS. The extent or technique of ESS was not addressed in this study and will depend on surgeon and patient factors. Furthermore, these criteria are the minimal threshold to make ESS a treatment 'option' and do not imply that all patients meeting these criteria require surgery. The decision to perform ESS should be made after an informed patient makes a preference-sensitive decision to proceed with surgery. Applying these appropriateness criteria for ESS may optimize patient selection, reduce the incidence of unwarranted surgery, and assist clinicians in providing high quality, patient-centered care to patients with CRS.

Key words: sinusitis, patient selection, criteria selection, sinus surgery, quality of health care

Introduction

Health systems are increasingly focused on quality improvement by promoting patient-centered care and reducing geographic variations in resource utilization [1]. For surgical interventions, this would translate into providing the correct surgery to the correct patient at the correct time. One important strategy to achieve this goal is to create appropriateness criteria to assist in clinical decision-making. "Appropriateness" refers to the relative balance of the benefits and harm of a health care intervention. An appropriate surgical procedure is defined as one where the expected health benefits exceeds the expected negative consequences by a sufficiently large margin that the procedure is worth doing regardless of monetary cost [2]. With the goal to reduce inappropriate health care utilization (i.e. overuse and underuse), defining appropriate indications for surgical interventions is an important step toward creating a high quality health care system.

Endoscopic sinus surgery (ESS) is a treatment option for select patients with chronic rhinosinusitis (CRS) who have persistent symptoms despite using appropriate medical therapies [3-6]. Although medical therapy is the cornerstone of successful long-term disease control [7], performing ESS in a timely manner [8-10] as a treatment adjunct has been shown to significantly improve clinical outcomes for refractory CRS [11-15]. However, despite an estimated 250,000 annual ESS procedures performed in the United States (US) alone [16], appropriateness criteria for ESS have not been defined. The lack of clear surgical indications for ESS may be a contributing factor to the large geographic variation of utilization [17-20] and creates the potential for inappropriate use of this common surgical procedure [21].

Given that patients and physicians must make clinical decisions in the face of imperfect evidence pertaining to the benefits and risks of ESS, the RAND/UCLA appropriateness methodology was developed to define appropriate care for patients in situations where strong evidence-based guidelines based on randomized trials are not possible [22,23]. This methodology combines the best available evidence with the collective judgment of international experts to develop criteria regarding the appropriateness of performing a procedure at the level of patient-specific symptoms, medical care history, and test results. Several surgical procedures have developed appropriateness criteria using the RAND/UCLA methodology such as bariatric surgery [24], coronary artery bypass grafting [25], hip replacement [26], carpal tunnel surgery [27], laminectomy [28], myringotomy with tympanostomy [29], and hysterectomy [30].

Using the RAND/UCLA appropriateness methodology, the objective of this study is to develop and report appropriateness criteria for ESS during the management of uncomplicated adult CRS. The overarching goal of this project is to begin improving the quality and value of care for patients with CRS by creating clear surgical indications for ESS.

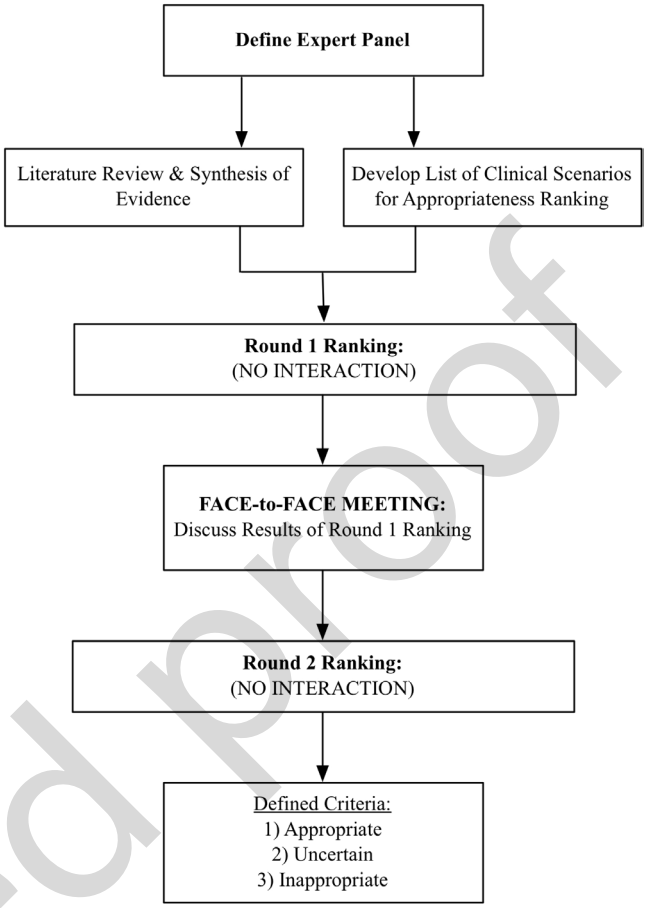

Figure 1. RAND/UCLA appropriateness methodology.

Methods

I. Overview

This study employed the RAND/UCLA appropriateness methodology using the multi-step process presented in Figure 1. The intended patient population is adults with uncomplicated CRS as defined in Table 1. ESS was defined as a surgical procedure that opens the paranasal sinuses using endoscopes for visualization and endoscopic instruments through the patient's nostrils. The procedure involves the relief of anatomical blockages, including removal and/or dilation of diseased/inflamed tissue in the paranasal sinuses, in order to open the sinus cavities and improve ventilation, mucus egress, and delivery of topical medications [31].

An international, multi-disciplinary expert panel of 10 members was assembled consisting of representatives from Canada, Europe, New Zealand, United Kingdom (UK), and the United States (US) (Table 2). Panel nomination was performed by the project leads (LR and TLS) and focused on the following criteria: 1) lea-

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Table 1. Defined uncomplicated adult CRS patient population for this study.

Adult	Age ≥18 years old
Guideline-based diagnosis of CRS[3,4,49]	Two of four symptoms for > 12 weeks: 1. Nasal congestion/obstruction 2. Nasal discharge 3. Facial pressure/fullness 4. Smell dysfunction Plus, one of three objective findings of sinonasal inflammation: 1. Presence of nasal polyps on exam 2. Inflammation or mucopurulence within the middle meatus 3. CT sinuses demonstrating opacification
Uncomplicated	**Absence** of the following comorbid conditions: 1. Cystic fibrosis 2. Organ transplant with immunosuppression 3. Chemotherapy with immunosuppression 4. Autoimmune disease affecting the paranasal sinuses 5. Systemic vasculitis (e.g. granulomatosis with polyangiitis) 6. Systemic granulomatous disease (e.g. sarcoidosis) 7. Ciliary dyskinesia 8. Isolated mucocele 9. Pregnancy 10. Suspected invasive fungal rhinosinusitis 11. Isolated fungal ball 12. Structural, non-inflammatory related CRS (e.g. mucus recirculation) 13. Pending intracranial or orbital complication

CRS, chronic rhinosinusitis; CT, computed tomography

Table 2. Expert panel members.

Name	Specialty	Country	Academic Affiliation	Potential COI
Luke Rudmik	Oto-HNS	Canada	University of Calgary	Consultant for BioInspire
Zachary M. Soler	Oto-HNS	USA	Medical University of South Carolina	Consultant for Olympus; Grants from Entellus, Optinose, and Intersect ENT
Claire Hopkins	Oto-HNS	UK	Guys's and St. Thomas' NHS Trust	None
Rodney J. Schlosser	Oto-HNS	USA	Ralph H. Johnson VA Medical Center	Consultant for Olympus and Meda; Grants from Entellus, Optinose, and Intersect ENT
Anju T. Peters	Allergy/ Immunology	USA	Northwestern University Feinberg School of Medicine	Consultant for Greer
Andrew A. White	Allergy/ Immunology	USA	Scripps Clinic, San Diego	None
Richard R. Orlandi	Oto-HNS	USA	University of Utah	Consultant for Intersect ENT, Medtronic, and BioInspire
Wytske J. Fokkens	Oto-HNS	Netherlands	Academic Medical Center	Grants from GSK and BioInspire
Richard Douglas	Oto-HNS	New Zealand	University of Auckland	None
Timothy L. Smith	Oto-HNS	USA	Oregon Health and Science University	Consultant for Intersect ENT

COI, conflicts of interest; USA, United States of America; UK, United Kingdom; Oto-HNS, otolaryngology – head and neck surgery

der in the management of CRS, 2) knowledgeable in evidence-based medicine, 3) geographic diversity, 4) diversity of research interests, and 5) lack conflicts of interest that would potentially influence the study outcomes.

It is recommended that the RAND/UCLA appropriateness methodology be performed for interventions that fulfill the criteria listed in Table 3. Based on the evidence [16-20,32-39], the expert panel decided that ESS fulfills all 5 criteria and it was justified to proceed with this study.

II. Variable selection and scenario development

The selection of clinical variables was based on which factors physicians take into account when deciding whether or not an adult patient with uncomplicated CRS is an appropriate candidate for ESS. Given the endotypic differences between CRS with and without nasal polyps, scenario rankings were performed separately for each subgroup. Based on the literature review, the important clinical variables for scenario development included: 1) appropriate medical therapy used prior to offering ESS as a treatment option, 2) degree of symptom or disease-specific quality of life (QoL) impairment after use of appropriate medical therapy, and 3) results of a computed tomography (CT) of the paranasal sinuses (Table 4).

The 22-item SinoNasal Outcome Test (SNOT-22) was selected as the patient-reported outcome measure (PROM) based on a systematic review and quality assessment demonstrating it was the highest quality and most commonly utilized instrument [40]. The threshold SNOT-22 score of 20 points was selected based on evidence demonstrating that more than 50% of patients with preoperative score < 20 failed to receive a consistent minimal clinically important difference (MCID) improvement and demonstrated a mean relative worsening compared to their preoperative scores [41,42]. Scenario rankings used Lund-Mackay

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Table 3. Criteria to perform a RAND/UCLA appropriateness study.

Criteria	ESS Fulfills	Supporting Evidence
Procedure is frequently used	Yes	ESS is in the top 10 most common ambulatory surgeries in the US [35] Estimated 250,000 ESS procedures per year in the US alone [16,35]
Procedure is associated with substantial potential morbidity or mortality	Yes	Overall complication rate is 1% with the potential for serious injury to the brain and eye [38] 5% risk of re-visit after ESS (67% ED visit; 19% surgery center; 14% inpatient admission) [33]
Procedure consumes significant resources	Yes	Estimated direct health care cost per case of ESS is between $8,200 to $10,000 in the US [39]; $3,500 to $5,000 in Canada [32] Estimated overall annual direct cost to the US health care system in excess of $10 billion [34,39]
Procedure with wide geographic variations in rates of use	Yes	There are large geographic variations of ESS utilization in the US[19,20], Canada[18], and UK [17]
Procedure is controversial	Yes	Indications for ESS are poorly defined and, at present, appropriate "indications" are considered controversial [36,37]

Table 4. List of variables used to develop the clinical scenarios.

Clinical Variable	Items Evaluated
Use of Appropriate Medical Therapies	1. High-volume sinonasal saline irrigations 2. Topical intranasal corticosteroid therapy 3. Short course of broad spectrum or culture-directed systemic antibiotic 4. Prolonged systemic low-dose anti-inflammatory antibiotic (i.e. macrolide, trimethoprim-sulfamethoxazole, or other) 5. Short course systemic corticosteroid 6. Leukotriene receptor antagonist
[a] SNOT-22 score after medical therapy (0 to 110)	1. Overall total score < 20 2. Overall total ≥ 20
[b] CT score using Lund-Mackay Staging (0 to 24)	1. Normal (score = 0) 2. Equivocal (score1 to 4) 3. Abnormal (score ≥ 5)

[a]Using a SNOT-22 cut-off score of 20 based on the outcomes from two independent studies (US/Canada and UK) demonstrating that patients with a SNOT-22 score < 20 fail to receive consistent improvement after ESS for CRS [41,42].

[b]A cut-off Lund-Mackay CT score of 5 was used based on the incidental scores from the non-CRS population [43].

SNOT, sinonasal outcome test; CRS, chronic rhinosinusitis; CT, computed tomography

CT score thresholds of 0, 1 and 5. A threshold CT Lund-MacKay score of 5 was used since this was reported as the 'incidental' score in the non-CRS population [43]. However, since CT findings correlate poorly with CRS-specific patient-centered outcomes [43-48], we also ranked scenarios using a threshold CT Lund-MacKay score of 1 to differentiate between a normal and abnormal CT scan for CRS. The panel applied evidence from recent systematic reviews [6,7] and practice guidelines [3,4,49] to make judgments on the appropriateness of medical therapy that must be trialed prior to consideration of ESS. Given the strength of evidence for the use of topical intranasal corticosteroid in patients with CRS [3,4,7,49], the panel assumed that all combination medical therapy scenarios must include the use of a topical intranasal corticosteroid agent thus effectively reducing the number of potential scenarios needing to be ranked by the panelists. The list of evidence-based medical therapy dosages and protocols assumed for this study are listed in Table 5.

III. Ranking and classifying appropriateness

The development of appropriateness criteria involved two rounds of ranking and a face-to-face meeting between the first and second rounds. During both rounds of ranking, each scenario was scored from 1 to 9, where 1 indicates that ESS is "highly inappropriate" and 9 indicates that ESS is "highly appropriate". Round one ranking was performed independently by panelists at their home location. The face-to-face meeting was performed on September 28th, 2015 in Dallas, Texas, USA. The purpose of the face-to-face meeting was to review the results from the round 1 ranking and focused on discussing any disagreements. In contrast to practice guideline development, the face-to-face meeting discussion is not intended to achieve consensus for each scenario but rather to improve the understanding of various panelist perspectives.

A 'disagreement' for a specific scenario was defined when at least one panelist ranked a score of 1 to 3 and another panelist ranked a score of 7 to 9, regardless of the mean score. Round two ranking was performed after the face-to-face meeting. During the ranking process, each panelist ranks each scenario for level of appropriateness using their best clinical judgment based on the evidence and considering the average adult patient with uncomplicated CRS as defined in Table 1. Panelists were specifically instructed to not consider the monetary cost implications of their judgments. Figure 2 provides an example of a scenario ranking form used in this RAND appropriateness project.

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Table 5. Defined evidence-based medical therapy protocols assumed for this study[6,7].

Term(s)	Definition	Evidence-based Dosing Options
High-volume (i.e. >100ml) sinonasal saline irrigations	≥ 8 weeks duration	Can involve either isotonic or hypertonic saline and used as a treatment adjunct to topical intranasal steroids
Topical intranasal corticosteroid therapy	≥ 8 weeks duration Can include either a low volume meter-dosed steroid spray (#1 to #8) or high volume steroid irrigation (#9) or drops (#10 and 11).	1. Mometasone furoate 50µg per spray QD to BID 2. Fluticasone propionate 50µg per spray QD to BID 3. Fluticasone furoate 50µg per spray QD to BID 4. Budesonide spray/turbuhaler QD to BID 5. Ciclesonide 50µg per spray QD to BID 6. Beclomethasone dipropionate monohydrate 42µg per spray QD to BID 7. Flunisolide QD to BID 8. Triamcinolone acetonide 55µg per spray QD to BID 9. Budesonide irrigations 0.5 to 2mg QD to BID 10. Prednisolone 1% nasal drops QD to BID 11. Dexamethasone 0.1% nasal drops QD to BID
Short course of broad spectrum/culture-directed systemic antibiotic	2 to 3 weeks in duration	1. Amoxicillin/Clavulanate 875mg BID 2. Cefuroxime 250mg BID 3. Trimethoprim-Sulfamethoxazole 160mg/800mg BID 4. Moxifloxacin 400mg QD
Prolonged systemic low-dose anti-inflammatory antibiotic	≥ 12 weeks in duration	1. Clarithromycin 250mg to 500mg QD 2. Roxithromycin 150mg QD 3. TMX 960mg BID x 2 weeks followed by 960mg QD
Short-course of systemic corticosteroid	1 to 3 weeks duration	1. Prednisone 30mg to 60mg QD 2. Methylprednisolone 8 to 50mg QD
Leukotriene receptor antagonist	≥2 weeks duration	Montelukast 10mg QD

QD, once per day; BID, twice per day; TMX, Trimethoprim-Sulfamethoxazole

The classification of appropriateness was based on both the mean panel ranking score for each clinical scenario after round two, and whether or not a 'disagreement' occurred. Appropriate indications achieved a mean score of 7 to 9 without any disagreements. Uncertain indications achieved a mean score of 4 to 6 OR any indication with a 'disagreement'. Inappropriate indications achieved a mean score from 1 and 3 without any disagreements.

Results

The expert panel ranked a total of 624 clinical scenarios, 312 scenarios for both CRS with and without nasal polyps. After round 1, there were 21 (6.7%) and 28 (8.9%) scenario's that resulted in a ranking disagreement for CRSsNP and CRSwNP, respectively. Each scenario with a disagreement was evaluated during the face-to-face meeting with the goal to discuss the best available evidence and clarify value judgments. After the round 2 ranking

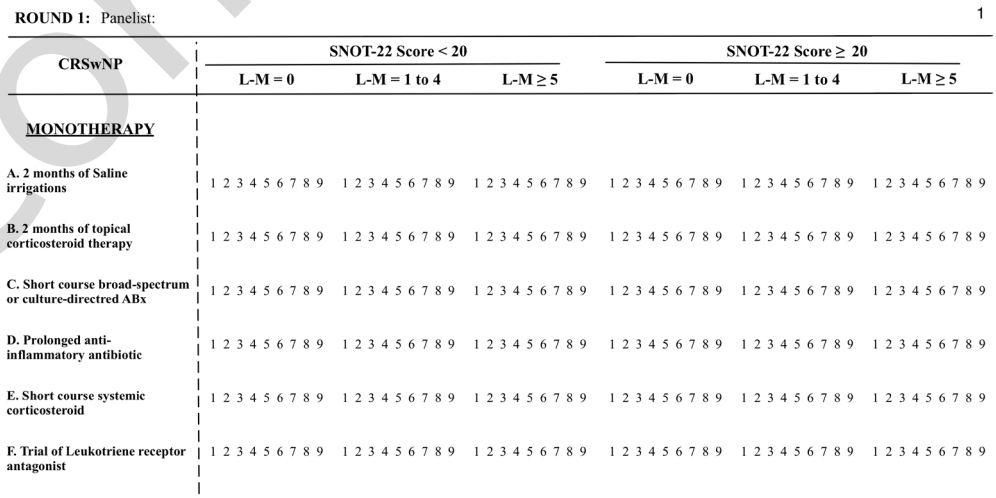

Figure 2. Example of a scenario ranking form for CRS with nasal polyps.

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Table 6. Appropriateness criteria for CRS with nasal polyps.

	Appropriateness Criteria		
	*Minimum Prior Medical Therapy	SNOT-22 Score after Appropriate medical therapy	CT Lund-Mackay score
Appropriate	Double therapy with: Topical intranasal corticosteroid (≥ 8 weeks duration) Plus, [a]Short-course of systemic corticosteroid (1 to 3 week duration)	≥ 20	≥ 1
Uncertain	Monotherapy with: Short course of systemic corticosteroid alone (1 to 3 week duration)	≥ 20	≥ 1
	Monotherapy with: Topical intranasal corticosteroid alone (≥ 8 weeks duration)	≥ 20	> 5
	Double therapy with: Topical intranasal corticosteroid (≥ 8 weeks duration) Plus, Short course of systemic corticosteroid (1 to 3 week duration)	< 20	≥ 1

*See Table 5 for the range of doses and duration for each medical therapy

[a]Caveat: if after a discussion about the potential benefits and risks of using a short-course of a systemic corticosteroid it is deemed that the risks outweigh the potential benefit, then a short-course of systemic corticosteroids can be avoided prior to being considered an appropriate candidate for ESS. SNOT, sinonasal outcome test; CRS, chronic rhinosinusitis; CT, computed tomography

process, there were no scenarios where the panelists held significant opposing views such as to create a ranking disagreement (i.e. presence of an inappropriate and appropriate ranking).

I. Appropriateness criteria for CRS with nasal polyps

For adult patients with uncomplicated CRS with nasal polyps, ESS can be appropriately offered as a treatment 'option' when the CT Lund-Mackay score is ≥ 1 and there has been a minimum trial of a topical intranasal corticosteroid plus a short-course of systemic corticosteroid with a post-treatment total SNOT-22 score ≥ 20 (Table 6).

II. Appropriateness criteria for CRS without nasal polyps

For adult patients with uncomplicated CRS without nasal polyps, ESS can be appropriately offered as a treatment 'option' when the CT Lund-Mackay score is ≥ 1 and there has been a minimum trial of a topical intranasal corticosteroid plus either a short-course of a broad spectrum/culture-directed systemic antibiotic or the use of a prolonged course of systemic low-dose anti-inflammatory antibiotic (i.e. macrolide, trimethoprim-sulfamethoxazole, or other) with a post-treatment total SNOT-22 score ≥ 20 (Table 7).

III. Inappropriate criteria for endoscopic sinus surgery

The majority of clinical scenario combinations evaluated in this study resulted in inappropriate ranking scores. Overall, the panelists agreed that there must be a minimum quality of life impairment to justify offering ESS as a potential treatment option. Except for an 'Uncertain' ranking for a single scenario in patients with CRSwNP (see Table 6), the panelists were in agreement that it was inappropriate to offer ESS to patients with a post-medical treatment SNOT-22 score of < 20 given the low probability of providing clinical benefit from surgery. The panelists were in full agreement that it was inappropriate to offer ESS for any clinical scenario where the sinus CT Lund-Mackay score was 0 (i.e. normal). It is important to emphasize that these inappropriate uses of ESS only apply to the clinical situation of uncomplicated adult CRS as delineated in Table 1. ESS may be appropriately offered as a treatment option in other clinical situations with complicated CRS or during cases outlined in the caveats section (Discussion; IV. Clinical Caveats).

Discussion

I. Summary

Careful selection of CRS patients for ESS is critical to achieving successful outcomes. Using the RAND/UCLA appropriateness methodology, this study has developed appropriateness criteria for ESS during the management of uncomplicated adult CRS with and without nasal polyps (Box 1). For CRS with nasal polyps, to optimize clinical effectiveness, the temporal relationship for medical therapy is intended that the topical corticosteroid therapy continue after completing the short-course of systemic corticosteroid [50]. Given the potential for adverse effects when using systemic corticosteroids or prolonged macrolide antibiotic [7], it is important that a discussion of the benefits and risks occur between the patient and physician before making a treatment decision. These appropriateness criteria will provide defined indications for ESS in adults with uncomplicated CRS and are

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Table 7. Appropriateness criteria for CRS without nasal polyps.

	Appropriateness Criteria		
	*Minimum Prior Medical Therapy	SNOT-22 Score after Appropriate medical therapy	CT Lund-Mackay score
Appropriate	Double therapy with: Topical intranasal corticosteroid (≥ 8 weeks duration) *Plus either:* Short course of broad-spectrum/culture-directed systemic antibiotic (2 to 3 weeks duration) OR, Prolonged course of systemic low-dose anti-inflammatory antibiotic (i.e. macrolide or TMX) (≥ 12 weeks duration)	≥ 20	≥ 1
Uncertain	Monotherapy with: Topical intranasal steroid alone (≥ 8 weeks duration)	≥ 20	≥ 1

*See Table 5 for the range of doses and duration for each medical therapy

SNOT, sinonasal outcome test; CRS, chronic rhinosinusitis; CT, computed tomography; TMX, Trimethoprim-Sulfamethoxazole

intended to improve the overall quality of care.

II. Endoscopic sinus surgery

Several systematic reviews of prospective observational cohort studies have concluded that ESS is an effective management option for patients with refractory CRS [51-54]. Outcomes have demonstrated that ESS followed by medical therapy can improve both short- and long-term QoL [12,55], nasal symptoms [51], asthma outcomes [56], sleep and fatigue [57], work productivity [58], and appears to be the more cost-effective option compared to ongoing medical therapy alone [59]. However, an estimated 20% to 25% of patients fail to receive a significant improvement in their baseline QoL after ESS [15] and 10% to 50% of patients will fail to achieve a MCID in their QoL [41,42]. Therefore, despite strong evidence supporting a benefit of ESS for the typical patient with refractory CRS, it is apparent that there is significant room for improving patient selection with the goal of avoiding surgery in patients who have a low probability for improvement.

Currently, there is a lack of clear surgical indications for ESS which likely contributes to the geographic variation in utilization [17-20] and may contribute to the poor surgical outcomes observed in some patients. Most experts would agree that patients must fail appropriate medical therapy (i.e. have persistent symptoms and reduced QoL); however, what constitutes appropriate medical therapy (often referred to a "maximal medical therapy) is vague and has never been defined using a robust methodology such as the RAND approach. In 2005, Lund concluded that based on the paucity of evidence a recommendation for a standardized medical therapy protocol prior to ESS could not be produced [37]. In 2015, a systematic review demonstrated that only 21% of studies evaluating ESS reported their indications for surgery and, when reported, included failure of a variety of medical therapy combinations along with endoscopic and radiologic changes after medical therapy [36]. Another important gap in current decision-making for ESS is the lack of a clear definition about what constitutes a 'failure' of medical therapy. Most experts agree that failure of medical therapy would involve persistent symptoms but the degree of symptom burden has not been quantified using a validated patient-centered metric.

III. Appropriateness criteria for endoscopic sinus surgery

The RAND/UCLA appropriateness methodology was developed in the mid 1980s as an instrument to measure the overuse of health care services [2]. After a set of appropriateness criteria is developed for a specific health care intervention, it can be applied either retrospectively or prospectively to assess the proportion of inappropriate interventions [60] (i.e. measure overuse or underuse) and assist in developing intervention decision aids. Several surgical procedures have defined appropriateness criteria [61] which has resulted in improved quality of care.

In 1994, Value Health Science (VHS) Inc. attempted to develop reimbursement guidelines by defining appropriateness criteria for sinus surgery. The results of 4 broad scenarios (2 pediatric and 2 adult) were published in the non-peer reviewed Bulletin for the American Academy of Otolaryngology [62]. This initiative applied the RAND methodology and used an expert panel from the US composed of 4 Rhinologists, 4 Allergists, and 1 infectious disease specialist. The appropriateness criteria for 'sinus surgery' in adult CRS included: 1) a 'strong' history combined with a positive CT scan and at least 28 days of antibiotics, 2) a 'suggestive' history requiring a longer period of antibiotic therapy, anatomic evidence of abnormality, and use of nasal steroids, and 3) surgery is not advisable if imaging has not been performed or antibiotics given for less than 15 days.

Although it was a noble attempt at improving the quality of care for CRS, the 1994 VHS appropriateness criteria for sinus surgery

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Box 1. Summary: Appropriateness criteria for ESS for uncomplicated adult CRS.

CRS with nasal polyps	**1. CT paranasal sinuses Lund-Mackay score ≥ 1** **2. Post-treatment SNOT-22 score ≥ 20** **3. Received appropriate medical therapy consisting of:** • Topical intranasal corticosteroid therapy for ≥ 8 weeks duration Plus, • Short-course of systemic corticosteroid for 1 to 3 weeks duration
CRS without nasal polyps	**1. CT paranasal sinuses Lund-Mackay score ≥ 1** **2. Post-treatment SNOT-22 score ≥ 20** **3. Received appropriate medical therapy consisting of:** • Topical intranasal corticosteroid therapy for ≥ 8 weeks duration Plus either • Short-course of broad-spectrum/culture-directed systemic antibiotic for 2 to 3 weeks duration OR • Prolonged course of systemic low-dose anti-inflammatory antibiotic for ≥ 12 weeks duration

SNOT, sinonasal outcome test; CT, computed tomography

have several major problems for use in current health care systems. First, the diagnostic criteria for CRS have changed significantly since 1994 and the understanding of the underlying pathophysiology has evolved to multifactorial etiologies which include both inflammatory and infectious drivers of inflammation [63,64]. Therefore, isolating medical therapy to antibiotic use does not reflect current standards of care. Second, they failed to incorporate a validated patient-centered outcome as one of the appropriateness criteria. Given the importance of quality of life and work productivity impairment in patients with CRS [65,66], the lack of a quantified patient-reported outcome to decide appropriateness of surgery fails to provide a patient-centered perspective during decision making. Third, endoscopic surgery techniques and experience were still developing in 1994 and the proportion of endoscopic vs. open sinus surgery along with the risk profile of ESS has changed which impacts the ability to generalize to the current management of CRS. Fourth, the scientific methodology reported in the 1994 report is vague and only included physicians from the US reducing generalizability to other countries. Lastly, it failed to incorporate validated metrics that predict outcomes after sinus surgery. The importance of the last limitation is highlighted in a study by Jones et al. (1998) which demonstrated that the VHS appropriateness criteria for sinus surgery failed to predict patient outcomes suggesting that patients who would have been classified as 'inappropriate' for sinus surgery often received improvement in disease-specific QoL [67].

Given the major limitations of the 1994 VHS report on sinus surgery appropriateness criteria, this panel felt it was important to develop an updated set of appropriateness criteria for ESS during management of uncomplicated adult CRS. The outcomes from this current RAND project have defined what constitutes 'appropriate medical therapy' and includes a quantified patient-centered definition of 'medical failure' (Box 1).

IV. Clinical caveats

The RAND methodology assigns appropriateness ranking based on the typical patient with the disease process under evaluation. Therefore, despite the majority of the pre-defined CRS population (Table 1) falling within the 'typical' clinical situation, there will be inherent outlier cases where ESS can be appropriately offered despite failing to meet the appropriateness criteria. This section will discuss the caveats that the panelists felt were important to report in order to minimize the risk of inappropriate underuse of ESS for CRS.

For CRS with nasal polyps, there were two scenarios involving a short-course of systemic corticosteroids that were ranked as 'uncertain' (Table 6). The panel felt it was important to provide a patient-centered caveat that if after a discussion between patient and physician about the potential benefits and risks of using a short-course of systemic corticosteroid it is deemed that the risks outweigh the potential benefit, then a short-course of a systemic corticosteroid can be avoided prior to being considered an appropriate candidate for ESS. Clinical scenarios when the risks of a short-course of systemic corticosteroid may outweigh benefits may include massive nasal polyposis where topical corticosteroids cannot be used effectively after the short-course of systemic corticosteroid is completed, the presence of comorbid diabetes mellitus, history of serious psychological illness that may be precipitated by systemic corticosteroids, and prior adverse event related to systemic corticosteroid use. If it is decided to forgo a short-course of systemic corticosteroids prior to ESS for CRS with nasal polyps, the panel feels it is important for the physician to document the reasons.

For CRS with nasal polyps, there was uncertainty regarding the scenario when the post-treatment total SNOT-22 score was < 20 yet CRS patients had received a short-course of systemic corticosteroid with topical intranasal corticosteroids (Table 6). The panel felt it was important to report that this uncertainty was reflected by the rare clinical situation when patients with polyps have isolated severe symptoms (score of 4 or 5) of nasal obstruction and reduced smell with minimal impacts on other quality of life domains, thus producing a total SNOT-22 score < 20. Although in the experts' experience, most patients with severe nasal obstruction and reduced smell typically have

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other symptoms to create a total SNOT-22 score ≥ 20, in this rare clinical scenario, the panel felt it was not inappropriate to discuss the role of ESS to improve nasal obstruction and smell outcomes.

There was less uncertainty surrounding scenarios for CRS without nasal polyps. There was a single scenario with uncertainty involving the appropriateness of ESS in a patient with a history of monotherapy using a topical intranasal corticosteroid and a post-treatment SNOT-22 ≥ 20 (Table 7). The panel felt it was important to report the discussion that occurred during the face-to-face meeting regarding this clinical scenario. The discussion focused on the need to balance the risks of inappropriate antibiotic use with the risk of inappropriate use of ESS. It was deemed that on 'average' the risks associated with inappropriate ESS were larger than the risks associated with incorporating a systemic antibiotic during management of CRS without nasal polyps. However, there may be outlier patients without nasal polyps that are contraindicated for systemic antibiotics or lack evidence of mucopurulence to justify systemic antibiotic use. Examples of cases where the risk of a systemic antibiotic may outweigh the benefit would include patients with multiple antibiotic allergies or those with a history of recurrent Clostridial difficile infections.

The appropriateness criteria developed from this study should be applied to the decision-making process for both primary and revision ESS. Although there are several potential reasons why an adult patient with uncomplicated CRS may require revision ESS, such as synechiae, incompletely dissected sinuses, or recurrent polyps, the decision to offer revision ESS should be driven by patient needs in the same manner as the decision is made for primary ESS. Applying these appropriateness criteria to the decision-making process for both primary and revision ESS will help ensure the decision is patient-centered and reduce unwarranted revision ESS.

Lastly, the panel felt it was important to emphasize that not all patients who fulfill the appropriateness criteria require ESS. These appropriateness criteria should be seen as the minimum requirements to make ESS an appropriate treatment 'option' and should not be confused as a medical 'necessity'. The decision for ESS is a preference-sensitive decision that should be made by a patient after they are adequately informed to their expected benefits and potential risks. Furthermore, the physician should be aware that non-CRS patients might produce a SNOT-22 score of ≥ 20 by reporting impairment in the non-sinonasal domains. Similarly, given that the mean Lund-Mackay sinus CT score in the non-CRS population is 4 to 543, physicians should be diligent to rule out non-CRS etiologies for patient symptoms when they present with a CT score of < 6. Examples of non-CRS etiologies that may mimic CRS include atypical facial pain, sinus migraines, and temporomandibular joint disease [68]. This emphasizes the importance for physicians to first make an accurate diagnosis of CRS and understand the limitations of using the SNOT-22 and Lund-Mackay scoring systems in isolation to determine whether or not a patient is an appropriate candidate for ESS.

V. Limitations

Although the RAND/UCLA appropriateness methodology has been validated to assess inappropriate resource utilization and improve the quality of care [60], there are several limitations that are pertinent when considering policy changes based on this study.

First, given the lack of high quality randomized trials, the appropriateness criteria developed in this study are based in part on the experts' interpretation of the best available evidence and may be influenced by their own experience, training, and geographic location. In general, panels with mixed clinical specialties and geographic locations have been shown to be more conservative and provide more balanced appropriateness outcomes [69]. The panel assembled for this RAND project involved eight surgeons and two allergists from five different countries (US – 6, Canada – 1, UK – 1, Netherlands – 1, New Zealand – 1) in order to provide input from various health care systems and clinical perspectives.

Second, the appropriateness rankings are based on judgments of the benefits and risks, including the magnitude and probability of post-surgical improvements. However, the estimation of effect size is often based on imperfect data and experts may differ in their judgments of risks and benefits [70]. To minimize the effects of this limitation, several systematic reviews [6,7,36,40] were performed prior to initiating this RAND project in order to optimize the reporting of clinical benefits and risks to each panel member.

Third, the criteria for ESS developed from this study included the total score from a CRS-specific PROM (i.e. SNOT-22). The primary advantage of incorporating the SNOT-22 score into appropriateness criteria includes providing a quantifiable and validated patient-centered factor into the decision-making process. However, despite the SNOT-22 being the most commonly used and highest quality CRS-specific PROM40, it is likely an imperfect instrument and there may be a small sub-group of patients with a total score of < 20 that may receive a MCID of 9 points yet fail to be considered appropriate candidates for surgery (i.e. risk of 'underuse' for ESS). Additionally, the MCID is derived from the population average and there may be patients in whom an improvement of less than the MCID is clinically meaningful and there may be patients who improve more than the MCID yet they report failure to obtain a clinically meaningful change. Although the caveats section outlined above (Discussion section IV) addresses certain clinical situations where patients with a total SNOT-22 score of < 20 may be appropriately offered ESS

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as a treatment option, the panelists agree that the SNOT-22 will need continued refinement to improve clinical decision making and outcome assessment with the goal to minimize the risk of underuse for ESS. Future modifications of the SNOT-22 will also likely require these RAND appropriateness criteria to be re-evaluated to reflect updated evidence. Lastly, incorporating the SNOT-22 score into clinical decision-making will have direct implications on a physician clinical practice since determining appropriateness for ESS will mandate the collection and reporting of this PROM.

Fourth, similar to using a PROM during the decision-making process, the use of an objective CT scoring system (i.e. the Lund-Mackay system) is imperfect and fails to predict clinically meaningful CRS when used in isolation. For example, the mean Lund-Mackay score in the non-CRS population is 4 to 5 which demonstrates that the presence of a Lund-Mackay score of > 1 does not equate to the patient having CRS [43]. Furthermore, it has been demonstrated that there is a poor correlation between CT scoring and severity of patient symptoms, quality of life impairment, and outcomes after treatment [44-48,71]. This emphasizes the concept that the Lund-Mackay and SNOT-22 scores measure different aspects of CRS disease burden and should be used together as opposed to being used in isolation during decision-making for ESS.

Fifth, the outcomes from this study have defined when it is appropriate to discuss ESS as a treatment option for adult patients with uncomplicated CRS and has not defined the appropriate "extent" of surgery or "technique" used during ESS. The panelists agree that addressing the extent or technique of ESS is an entirely different question and falls outside of the context of this RAND appropriateness study.
Lastly, the RAND approach focuses on defining appropriateness criteria for the 'average' patient and does not take into account patient preferences or expectations for outcomes. Therefore, the criteria for ESS developed from this project are intended to improve patient candidacy for ESS and cannot be the sole factor used to provide ESS. Once a patient with CRS is considered a candidate for ESS, based on the appropriateness criteria outlined in this study, then a discussion to elicit patient preferences for treatment should be performed in order to arrive at a patient-centered shared-decision for surgery. Furthermore, to reduce the heterogeneity of intended patient population, this project has explicitly defined the uncomplicated adult CRS patient cohort to which these criteria are applicable (Table 1).

VI. Future Directions

The development of appropriateness criteria for ESS performed during this RAND project will be an important step forward in improving the quality of care for adults with uncomplicated CRS. However, quality improvement is not a static process and future projects are required to continue advancing patient-centered care for CRS. First, the appropriateness criteria from this study need to be validated to determine if the improved patient selection will result in improved patient outcomes. This could be achieved by evaluating the outcomes after ESS for CRS patients who meet these appropriateness criteria compared to CRS patients that received ESS that failed to meet these criteria. Second, the degree of past inappropriate ESS should be quantified in order to identify factors associated with misuse. Once factors associated with inappropriate ESS are identified, strategies to modify these factors and improve appropriateness of ESS can be developed. Third, there is a need to develop clinical systems that enable physicians to measure PROMs at the point of care and translate these data into clinically meaningful information to drive patient-centered care. Fourth, the appropriateness criteria developed from this study need to be incorporated into a clinical decision aid capable of assisting patients and physicians to make an appropriate treatment decision. Lastly, given continued research on ESS for CRS, the appropriateness criteria developed from this initial RAND project should undergo regular audit and be appropriately updated to reflect best available evidence.

Conclusion

This study has developed and reported of list of appropriateness criteria to offer ESS as a treatment 'option' during management of uncomplicated adult CRS. The extent or technique of ESS was not addressed in this study and will depend on surgeon and patient factors. The criteria are based on best available research evidence and ranked based on a panel consisting of both surgeon and non-surgeon clinical experts in the field of CRS. The appropriateness criteria focus on defining three clinical factors: 1) the need for objective evidence of CRS using CT imaging, 2) the degree of patient-reported disease burden using a validated CRS-specific PROM, and 3) the medical therapy used prior to offering ESS. These criteria are the minimal threshold to make ESS a treatment 'option' and do not imply that all patients meeting these criteria require surgery. The decision to perform ESS should be made after an informed patient makes a preference-sensitive decision to proceed with surgery. Applying appropriate surgical indications for ESS will help standardize patient selection to offer ESS an a treatment 'option', reduce unwarranted practice variation, and assist clinicians in providing high quality, patient-centered care.

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Authorship contribution

LR: Project lead, Study design, Expert panel with rankings, Data

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analysis, Manuscript preparation; ZMS, CH, RJS, AP, AAW, RRO, WJF, RD: Study design, Expert panel with rankings, Manuscript review; TLS: Project lead, Study design, Expert panel with rankings, Data analysis, Manuscript review.

Conflict of interest

See Table 2.

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