Surgery for Chronic Rhinosinusitis

Where is it Helpful?

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Disclosures

• None
Learning Objectives

1. Understand the broad spectrum of disease that falls under the heading of chronic rhinosinusitis
2. Appreciate the current challenges with accurately defining chronic rhinosinusitis
3. Review the current best available evidence for clinical outcomes after endoscopic sinus surgery
4. Understand important areas of progress and innovation
Surgery for Chronic Rhinosinusitis

- Impact of CRS
- Defining the Disease
- Clinical Outcomes
- Progress & Innovation
## The Economics of CRS

### Components of direct costs

<table>
<thead>
<tr>
<th>Component</th>
<th>Cost Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Physician Visits</td>
<td>$500 per patient per year</td>
</tr>
<tr>
<td>Prescription Medical Therapy</td>
<td>$400 per patient per year</td>
</tr>
<tr>
<td>ED Visits</td>
<td>$33 per patient per year</td>
</tr>
<tr>
<td>Endoscopic Sinus Surgery</td>
<td>$8,500 to $11,000 per case</td>
</tr>
</tbody>
</table>

- **3.5% to 5% CRS Prevalence:** 9 to 15 million CRS patients
- **$4.5 to $7.5 billion**
- **$1.5 to $6 billion**
- **$300 to $500 million**
- **$2 to $3 billion**

**Estimated Annual Incremental Direct Cost of CRS in US:** 
> $12.5 billion per year

### Mean per patient indirect costs/year

- **Diabetes:** $3,920.00 / yr
- **Chronic Migraine:** $5,755.52 / yr
- **Severe Asthma:** $7,260.86 / yr
- **Refractory CRS:** $10,077.07 / yr

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*Source: Blackwell DL, Lucas JW, Clarke TC. Vital and health statistics Series 10, Data from the National Health Survey 2014:1–161*

Treatment Pathways in CRS

9-14 million patients/year

Medical therapy

Symptoms resolve

Disease persists, "refractory CRS"

Endoscopic sinus surgery

Ongoing medical therapy

Typically severe disease, ~300,000/year

Factors That Impact Outcomes

- Pre-op Medical Rx (AMT)
- Patient Selection (Indications)
- Set Expectations (QoL)
- Surgical Technique & Experience Matters
- Timing of Surgery
- Post-op Care Critical

Optimizing Outcomes in Sinus Surgery
Surgery for Chronic Rhinosinusitis

Defining the Disease
## Definitions & Diagnostic Criteria for CRS

<table>
<thead>
<tr>
<th>Chronic rhinosinusitis (CRS)</th>
<th>Sinonasal inflammation persisting for more than 12 weeks. Symptoms must include at least 2 of the following:</th>
</tr>
</thead>
</table>
|                              | • nasal blockage/obstruction/congestion  
|                              | • nasal discharge (anterior/posterior)  
|                              | • facial pain/pressure  
|                              | • reduction/loss of smell  
|                              | Additionally, the diagnosis must be confirmed by:  
|                              | • Evidence of inflammation on paranasal sinus examination or computed tomography (CT)  
|                              | • Evidence of purulence coming from paranasal sinuses or ostiomeatal complex  
|                              | CRS is divided into CRSwNP or CRSSsNP based on the presence or absence of nasal polyps. |

*Orlandi RR, Kingdom TT, Hwang PH. International Consensus Statement on Allergy and Rhinology (ICAR), Int Forum Allergy Rhinol 2016*
Chronic Rhinosinusitis

*Spectrum of Disease*

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Not for Reproduction
Chronic Rhinosinusitis

*Spectrum of Disease*

Rhinitis

Rhinosinusitis

Hyperplastic Rhinosinusitis

Nasal Polyposis
Defining CRS

Are we getting any better?

Symptoms

“Phenotype”
CRSsNP vs CRSwNP

Eosinophilic vs non-eosinophilic

Inflammatory (molecular) profile

Zhang et al. JACI 2008

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Eosinophilic Phenotype

More severe asthma

Higher FeNO

Higher IgE levels

Higher Lund-MacKay scores

Higher blood eosinophilia

Worse pulmonary function

Non-eosinophilic phenotype:
Upper & lower airway poorly correlated

Wu et al. Ann Allergy Asthma Immunol 2017(118)
Not all CRSwNP patients fit eosinophilic profile

Gurrola & Borish, JACI 2017
Inflammatory Endotypes & Biomarkers

Tomassen et al. J Allergy Clin Immunol 2016;137;1449-1456
Personalized Medicine for CRS

Can we get there?

Precision Medicine is science – a new wave of evidence-based medicine

Personalized Medicine is a practice – managing a patient’s care more holistically

PRECISION
Targeted Therapies
Based on Molecular Diagnostics

PERSONALIZED
Prevention and Treatment based on Environment, Lifestyle, and Genes
Surgery for Chronic Rhinosinusitis

Outcomes – “Where does it help?”
Have we been asking the correct question?

"If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than 5 minutes."

- Albert Einstein
Measuring Disease
Nasal Polyp Score

Gavaert P, et al. JACI 2013
### Measuring Disease

**Lund-Mackay CT Score**

Lund-Mackey system.

<table>
<thead>
<tr>
<th>Sinus</th>
<th>Right sinus</th>
<th>Left sinus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frontal</td>
<td>0–2</td>
<td>0–2</td>
</tr>
<tr>
<td>Anterior ethmoids</td>
<td>0–2</td>
<td>0–2</td>
</tr>
<tr>
<td>Posterior ethmoids</td>
<td>0–2</td>
<td>0–2</td>
</tr>
<tr>
<td>Maxillary</td>
<td>0–2</td>
<td>0–2</td>
</tr>
<tr>
<td>Sphenoid</td>
<td>0–2</td>
<td>0–2</td>
</tr>
<tr>
<td>Ostiomeatal complex</td>
<td>0 or 2</td>
<td>0 or 2</td>
</tr>
</tbody>
</table>

For the sinuses: 0 = no inflammation; 1 = partial inflammation; 2 = 100% inflammation.

For the ostiomeatal complex: 0 = not occluded; 2 = occluded.

Maximum total score: 24.

*Hopkins et al., Otolaryngol Head Neck Surg 2007*
# Measuring Outcomes

## Sinonasal Outcome Test

### SNOT-22

Below you will find a list of symptoms and social/minor functional consequences of your rhinologic problems. We would like to have more about how severe the problem is when you experience it, and how often it happens, please rate each item below on how “Severe” it is by circling the number that corresponds with how you feel using this scale:

1. No Problem
   - 0
2. Minor Problem
   - 1
3. Moderate Problem
   - 2
4. Severe Problem
   - 3
5. Problem as usual
   - 4
6. Problem as usual, it can be a
   - 5

<table>
<thead>
<tr>
<th>Item</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Need to blow nose</td>
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<tr>
<td>2. Nasal Blockage</td>
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<tr>
<td>3. Sneezing</td>
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<tr>
<td>4. Runny nose</td>
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<tr>
<td>5. Cough</td>
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<tr>
<td>6. Post nasal discharge</td>
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<tr>
<td>7. Thick nasal discharge</td>
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<tr>
<td>8. Ear fullness</td>
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<tr>
<td>9. Dizziness</td>
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<tr>
<td>10. Bad smell</td>
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<tr>
<td>11. Failed pressure</td>
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<tr>
<td>12. Inconvenient sense of smell (time)</td>
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<tr>
<td>13. Difficulty falling asleep</td>
<td></td>
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<tr>
<td>14. Wake up at night</td>
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<tr>
<td>15. Lack of a good night's sleep</td>
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<tr>
<td>16. Wake up tired</td>
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<tr>
<td>17. Tiredness</td>
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<td>18. Reduced productivity</td>
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<td>19. Restricted communication</td>
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<tr>
<td>20. Frustrated at times</td>
<td></td>
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</tr>
<tr>
<td>21. Sad</td>
<td></td>
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<td></td>
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<tr>
<td>22. Embarrassed</td>
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</tr>
</tbody>
</table>

2. Please mark the most important items affecting your health (maximum of 5 items).

SNOT-22 Copyright © 1996 by Dr. F. K. Pitsillides, MD, Washington University School of Medicine, St. Louis, Missouri

SNOT-22 Developed from original SNOM-22 by National Cooperative Audit of Surgery for Nasal Polyposis and Rhinosinusitis Royal College of Surgeons of England

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Domains within the SNOT-22

<table>
<thead>
<tr>
<th>SNOT-22 Domains:</th>
<th>Survey Items:</th>
<th>Score Range:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhinologic Symptoms</td>
<td>#1, #2, #3, #6, #21, #22</td>
<td>0–30</td>
</tr>
<tr>
<td>Extra-Nasal Rhinologic Symptoms</td>
<td>#4, #5, #6</td>
<td>0–15</td>
</tr>
<tr>
<td>Ear/Facial Symptoms</td>
<td>#2, #7, #8, #9, #10</td>
<td>0–25</td>
</tr>
<tr>
<td>Psychological Dysfunction</td>
<td>#14, #15, #16, #17, #18, #19, #20</td>
<td>0–35</td>
</tr>
<tr>
<td>Sleep Dysfunction</td>
<td>#11, #12, #13, #14, #15</td>
<td>0–25</td>
</tr>
</tbody>
</table>

SNOT-22, 22-item Sinonasal Outcome Test

DeConde et al., Int Forum Allergy Rhinol 4(12):2014
Sinus surgery improves QOL

- Meta-analysis: SNOT-22 QOL scores improves mean 24 points
  - ~80% exceed MCID (8.9)
- All domains also improve beyond MCID
  - Nasal, ear/facial, extra-nasal, sleep dysfunction, psychological

Soler ZM, et al., Laryngoscope 2018;128(3)
CRS Treatment Outcomes

9-14 million patients/year

Initial presentation

Symptoms resolve

Disease persists, “refractory CRS”

Medical therapy

Endoscopic sinus surgery

Ongoing medical therapy

~300,000/year

- QOL improvement for some patients, exact percentage unclear
- Typically less severe baseline disease
- Stabilizes or slightly improves QOL
- Stabilizes productivity loss and health utility
- Meaningful improvement in QOL, productivity loss, health utility, olfaction
- Asthma, sleep, psychological impairment also often improve
- Many factors affect degree of improvement
- Endotypes, new treatments, biologic therapies

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Sinus Center
Health Utility Values

![Graph showing health utility values with and without treatment, including QALYs gained from treatment.]
Improvement in Health Utility after Specific Interventions

Soler et al. Laryngoscope 2011;121:2672-2678
Long-term Health Utility Outcomes


Mean SF-6D Utility Score

- Pre-op: 0.675
- Short term: 0.75
- Long term: 0.8

U.S. Norm = 0.81

Mean 5 years
Productivity Loss

- Total costs = direct costs + indirect costs
  - Indirect costs = productivity loss (PL)
- Per patient PL for refractory CRS is $10,077/yr
- Following sinus surgery (annual, per patient)
  - Absenteeism: 22 days → 3 days
  - Presenteeism: 41 days → 19 days
  - Household days: 12 days → 6 days
  - Monetized: $9190 → $3373

Rudmik, et al., Laryngoscope 2014 Sept;124(9)
Rudmik, et al., Laryngoscope 2016 Mar;126(3)
Smith, KA et al. Int Forum Allergy Rhinol 2014 4(10)
Olfaction

- Olfactory dysfunction (OD): up to 80% in CRS patients
  - OD associated with decreased QOL
  - Social, eating, mental health
- Objective olfactory testing
  - Threshold/discrimination/identification
  - Smell Identification Tests
- Improvement after sinus surgery (meta-analysis)
  - Greater improvement with polyposis, worse baseline olfactory function

Kohli et al., Otolaryngol Head Neck Surg 2016;155(6)
Sleep Quality

- CRS associated with poor sleep quality, worse oxygen saturation, REM sleep latency, snoring
- Sleep quality improves following sinus surgery
- ESS improves QOL for pts with CRS and obstructive sleep apnea (OSA)
  - Decrease in AHI in moderate/severe OSA

A systematic review and meta-analysis of asthma outcomes following endoscopic sinus surgery for chronic rhinosinusitis

Rishi Vashishta, MD¹, Zachary M. Soler, MD, MSc¹, Shaun A. Nguyen, MD, MA¹ and Rodney J. Schlosser, MD¹,²

- Systematic review & meta-analysis
- 22 studies, 891 patients
- Major limitations with available evidence
- Findings:
  - Improved reported asthma symptoms
  - Reduction in asthma related medication use, hospitalizations, emergency dept visits
  - No change in pulmonary function testing (PFTs)

Int Forum Allergy Rhinol 2013;3
Asthma quality of life and control after sinus surgery in patients with chronic rhinosinusitis

R. J. Schlosser¹, T. L. Smith², J. Mace² & Z. M. Soler¹

¹Department of Otolaryngology – Head and Neck Surgery, Medical University of South Carolina, Charleston, SC; ²Department of Otolaryngology – Head and Neck Surgery, Oregon Health Sciences University, Portland, OR, USA

• Prospective study of CRSsNP & CRSwNP patients

• Objectives:
  1. Examine validated, asthma-specific outcomes after ESS
  2. Determine factors predictive of asthma-specific outcomes after ESS

Allergy 2017;72:483-491
Asthma quality of life and control after sinus surgery in patients with chronic rhinosinusitis

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• Results (86 patients)
  • ESS improves asthma-specific QOL measures and control of disease
  • Factors predictive of better asthma-specific outcome
    • Steroid dependency & SNOT-22 change
    • More severe pre-op asthma
  • Unable to comment on PFTs, medication usage, or healthcare utilization

Allergy 2017;72:483-491
Factors Affecting Postoperative QOL Improvement

• Greater improvement after surgery
  • Greater preoperative QOL deficit, nasal polyps, allergic fungal rhinosinusitis, olfactory dysfunction

• Worse improvement after surgery
  • Obesity, anxiety, low socioeconomic status

• Unclear effect on postoperative outcomes
  • Sex, GERD, migraine, diabetes, trainee involvement in case, day of week of surgery, length of disease prior to surgery, revision vs. primary surgery
What Do Patients Think?

- Prospective assessment of patients who underwent surgery
- Preoperative symptom importance
  - Nasal obstruction > smell/taste dysfunction, discharge, sleep symptoms >> sadness, embarrassment
- Postoperative satisfaction depended on surgery improving most important symptoms
  - Not correlated with MCID on QOL instrument
  - But correlated with magnitude of QOL improvement

What Do Patients Think?

- Overall, 85% satisfied with decision for surgery and how surgery improved most important symptoms.
- Majority would pursue again or recommend


Smith, TL et al. *Long-term management of ESS in the management of adult CRS.* Int Forum Allergy Rhinol 2019
Surgery for Chronic Rhinosinusitis

Progress & Innovation
Office-Based Procedures

- Traditional Endoscopic Sinus Surgery
  - Nasal polypectomy
  - Maxillary antrostomy
  - Ethmoidectomy
  - Sphenoidotomy
  - Frontal sinusotomy

Key Advances Towards In-office Sinus Procedures

2005: FDA approves BSD
2009: In-office BSD
2011: CPT codes BSD
2014: Navigation for office
2018: Steroid eluding stents approved for polyps

BSD = Balloon Sinus Dilation
Office-Based Procedures

• Balloon Sinus Dilation (BSD)
  • Maxillary, frontal, and sphenoid sinus
  • Continued adoption
  • Safe & FDA approved
  • Impact on utilization & costs
  • Clinical efficacy still unsettled

Have Practice Patterns Changed?

*Use rates 2011 - 2014*

Large commercial insurance database, ages 7 to 65 years old

Chaaban et al. Int Forum Allergy Rhinol 2017
Evolving Trends in Sinus Surgery

Medicare Database 2011-2015

Svider et al., Laryngoscope 2018
The Present: Office Based Procedures

Survey of ARS Members, % Respondents Utilizing In Office

Lee, DelGaudio, Orlandi Am J Rhinol Allergy 2018
Drug-Eluting Implants (Stents)

- Improved post-op results
- Benefit in recurrent nasal polyposis
- Optimal clinical use still debated

Han JK & Kern RC, Int Forum Allergy Rhinol 2019;9:S22-S26
Drug-Eluting Stents in the Frontal Sinus
Biologics – Where Do they Fit?

Is Sinus Surgery Going Away?

Reports of my death have been greatly exaggerated. —Mark Twain, 1897 (popular version)
Dupilumab for CRSwNPs

- Approval June 2019
- Game changer?
- Earlier experience positive

The Role of Biologics in Chronic Rhinosinusitis

*We face important questions*

- How will providers & payers decide between different biologics?
- Where do they “fit” in the treatment algorithm?
- Are we studying the correct biomarkers?
- What is the cost–benefit ratio for this class of medications?
Management of Chronic Rhinosinusitis

*What Can You Do?*

- Partner with a trusted otolaryngology colleague
- Obtain imaging early
- Do not hesitate to refer
- This is a team sport
Thank You