Participating in the Webinar

Listen using your computer audio. A headset is recommended but not required.

All attendees will be muted and will remain in Listen Only Mode.

Type your questions here so that the moderator can see them. Not all questions will be answered but we will get to as many as possible.

How to Receive CME and ABIM MOC Points

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ACG Virtual Grand Rounds

Join us for upcoming Virtual Grand Rounds!

Week 6: Celiac Disease: 10 Things Every Clinician Should Know
Amy S. Oxentenko, MD, FACG
April 30, 2020 at Noon EDT

Week 7: C. difficile and Fecal Microbiota Transplant: The Beginnings of Microbiome Therapy
Neil H. Stollman, MD, FACG
May 7, 2020 at Noon EDT

Visit gi.org/ACGVGR to Register
Disclosures:

Moderators:
Kenneth R. DeVault, MD, FACG  
Board of Directors: Mayo Clinic  
Consultant: Phathom Pharmaceuticals  
Research Grant: Ironwood; Ironwood Multicenter study where we are a site Phathom Central reading of endoscopy images

Speakers:
Philip O. Katz, MD, MACG  
Consultant: Medtronic, Phathom Pharmaceuticals

Off Label Use:
Dr. Katz will discuss off label uses for PPIs.

Refractory GERD: Approach and Options in 2020

Philip O. Katz, MD, MACG  
Professor of Medicine  
Director GI function Laboratories  
Weill Cornell Medicine
GERD is not a one size fits all disease

Symptom generation is multifactorial. Reasons for refractory symptoms vary from case to case. An algorithmic approach to refractory GERD can only be a guide.
Refractory GERD really means that the PPI is not controlling symptoms

- Scenario One: GERD has been objectively documented by the presence of erosive esophagitis and/or abnormal esophageal acid exposure on a prolonged pH monitoring study BUT unpleasant symptoms remain despite a PPI

- Scenario Two: A patient with symptoms suspected due to GERD has been treated empirically BUT symptoms have not been relieved to their satisfaction

Which scenario dominates is in part dependent on your practice

And will in part dictate the approach
The Question that must be answered in both scenarios is the same
Are the residual symptoms due to GER and if so why?

What Has Changed in Approach to Refractory GERD since 2013 Guidelines?

- PPI Adverse events mandate new options
- Level 1 evidence for Nissen fundoplication, magnetic sphincter augmentation and TIF success.
- Outcomes data on optimizing PPI
- Greater understanding of reasons for incomplete response to medical therapy

- Resulting in shift toward increased utilization of objective diagnostic testing
Transoral Fundoplication

Modern TIF procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Introduction</th>
<th># Cases to Date</th>
<th>% of Total Cases</th>
<th>Plication Type</th>
<th>Fastener Placement</th>
<th>Avg. # of Fasteners</th>
<th>Wrap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transoral Incisionless Fundoplication 2.0 (TIF 2.0)</td>
<td>2009</td>
<td>19,161</td>
<td>95.7%</td>
<td>Esophagogastric</td>
<td>1-3 cm above Z-line; more length along the greater curve of the stomach</td>
<td>12 to 23</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Procedures thru 2017

Gerson LB, 2018
**TIF: Regurgitation/Randomized Trial**

- Incomplete relief on PPI/troublesome regurgitation
- EGD
- HRM
- pH
- Included if HH<2cm, EE< gradeC, normal HRM, abnormal pH

Hunter JG, Gastro 2015

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**TIF v Sham/PPI**

- TIF v Sham
- All got PPI for 2 weeks then compared TIF/placebo v Sham/PPI once daily
- At 12 weeks increased PPI to BID for incomplete responders
- Final evaluation at 6 months

Hunter JG, 2015
TIF v Sham/PPI (Symptoms)

Hunter JG Gastro 2015

TIF v Sham/PPI (pH)

Hunter JG 2015
pH control TIF

pH Improved
Not normalized

TIF 5 yr follow up

Primary sx regurgitation

American College of Gastroenterology
10 yr follow up

N=51
Observational no controls

Testoni, 2018

Magnetic Sphincter Augmentation
MSA superior to PPI BID for regurgitation

Randomized trial
Refractory to PPI daily
Abnormal pH off
Normal HRM
MSA v PPI BID
2:1 randomized/cross over

Symptom Improvement

Bell, R et al GIE, 2019
MSA v PPI BID pH control

(A) Normal Reflux Episodes
(B) Normal DeMeester Score
(C) Normal pH

LINX Device | BID PPI

Nissen Fundoplication for Refractory Heartburn
Randomized VA trial
Heartburn Refractory to medical therapy: VA study

Spechler et al NEJM, 2019

Final eval 1 yr

American College of Gastroenterology
Success at 1 year

Improved HRQL

Success at 1 year

Why Proton Pump Inhibitors May Not Control Gastric Acidity

- Dose timing related to food not optimal
- Dose insufficient
- Genetic variability in PPI metabolism
- Hypersecretion (rare)
- PPI resistance (never documented)

PPIs are better for some things and not others

- **Esophagitis healing**
  - Mild
  - Severe
- **Heartburn relief**
  - Esophagitis
  - NERD
- **Regurgitation relief**
  - Chest pain (50% relief)
  - GERD (+pH)
  - GERD (-pH)
- **Hoarseness (improved)**
- **Chronic cough (improved)**

**Therapeutic gain**


Time of Day Taking PPI may make a difference

- **40 mg Before Breakfast**
  - 66.3%
- **40 mg Before Dinner**
  - 31.3*%
- **20 mg Before Breakfast and Dinner**
  - 20.5†%

**N = 18.**

*P = 0.01.
†P<0.02.

Non Acid Reflux Episodes Cause Symptoms

Optimal Omeprazole Dosing and Symptom Control: A Randomized Controlled Trial (OSCAR Trial)

- 64 patients with continued heartburn on BID omeprazole not taking optimally by history
- Randomized to optimal dosing or continued as they were doing
- 8 weeks significant decrease in frequency, severity of symptoms on optimal regimen

- Conclusion: Optimizing PPI dosing relative to meals improves outcomes

Digestive Diseases and Sciences
January 2019, pp 158–166
PPI optimization improves an important minority

Why is GERD refractory to medical therapy: What determines symptoms?

The refluxate (principally acid, weakly/non acidic, perhaps bile)
- Timing of reflux (post prandial, upright, nocturnal)
- Severity of mucosal disease
- Esophageal clearance
- Volume
- Anatomic/physiologic: Defective LES, hiatal hernia
- Gastric factors (accommodation, emptying)
What determines symptoms

- Esophageal sensitivity (to acid or volume)
- Coexistent functional syndrome unrelated to the esophagus

Many Just Simply Do Not Have GERD

Primary diagnosis

- GERD 65%
- Functional heartburn 32%
- Functional chest pain 24%
- Achalasia 9%
- Rumination 2%
- AET+/SAP+ 2%
- AET+/SAP− 2%
- AET−/SAP+ 1%

Herregods T et al
Neurogastro Motil. 2015
Therefore

- An abnormality or alteration in any of these features could be responsible in all or part for failure of therapy
- OR
- GERD is not the cause of the residual symptom: EoE, rumination, aerophagia, or primary gastroparesis
- OR
- The residual symptoms are functional

Objective Diagnosis of GERD: Evidence based consensus
Ultimately Medically Refractory GERD is Due To:

- Abnormal reflux control
- Mechanical or motility issues
- Symptoms not due to GERD

Refractory GERD

Previously empirically treated without objective work up

Optimize PPI

- Symptom relief
- Unsatisfactory symptom relief
  - Continue current treatment
  - Discuss long-term management options

Diagnostic EGD (off PPI)

- Normal EGD
- Abnormal EGD
  - Reflux monitoring (off PPIs)
  - Erosive Esophagitis
  - Barrett’s
  - Other cause for symptoms identified

GERD confirmed
Refractory GERD

Previously objectively defined GERD*

Optimize PPI
2-4 week therapy

Symptom relief

• Continue current treatment
• Discuss long term management options

Unsatisfactory symptom relief

Perform impedance pH monitoring on PPI

Normal

Abnormal

HRM/Continue PPI
Surgery/endo intervention
Increase PPI if not on BID

If primary symptom regurgitation consider surgery/endoscopic intervention

Treatment for co-existent functional disease or EMD

*Erosive esophagitis B/C/D or Abnormal pH monitoring

Thank you for listening

• A HERO IS AN ORDINARY INDIVIDUAL WHO FINDS THE STRENGTH TO PERSEVERE AND ENDURE IN SPITE OF OVERWHELMING OBSTACLES.

Christopher Reeves
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