MINNESOTA REFLUX
& HEARTBURN CENTER

GERD Update

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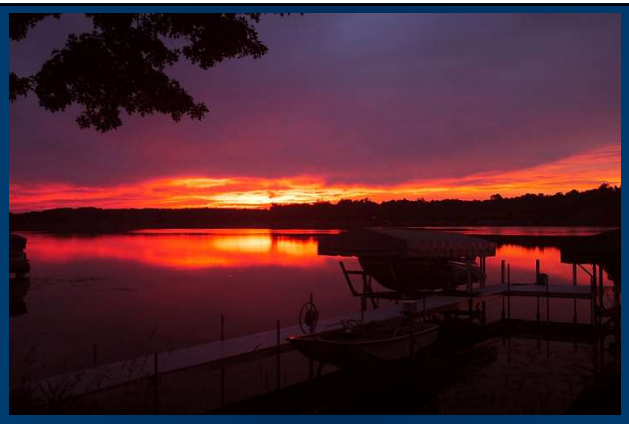
Disclosures

NONE



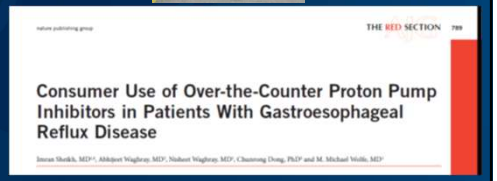
Minnesota Lake Country - Sunset over the Hospital

What's going on with GERD?

- Prevalent in at least 10% of the western population
  - > 100 million people
- It is the leading diagnosis in outpatient clinics
- Over $10 billion annual costs in the USA alone
- Significant contributor to absentee-ism and reduced productivity in the workplace
- GERD can lead to *esophageal adenocarcinoma* (EAC)
  - Not squamous cell ca (smoking and EtOH)

Who are the Doctors for GERD Patients??

- Google and your local pharmacy
- Not going to GI Docs
- PPI Providers
  - 37% Primary Care
  - 32% OTC
  - 31% GI
- **We've lost control of this disease!**


THE RED SECTION

Consumer Use of Over-the-Counter Proton Pump Inhibitors in Patients With Gastroesophageal Reflux Disease

The American Journal of GASTROENTEROLOGY 2014

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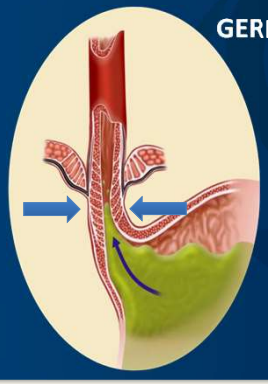
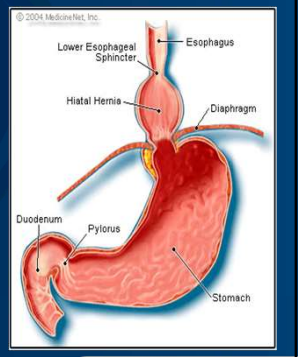
Your Body's Natural Barrier to Reflux



GERD is a chronic disease

1. Weak LES
(Lower Esophageal Sphincter)

2. Weak diaphragm
(Commonly complicated by Hiatal Hernia)



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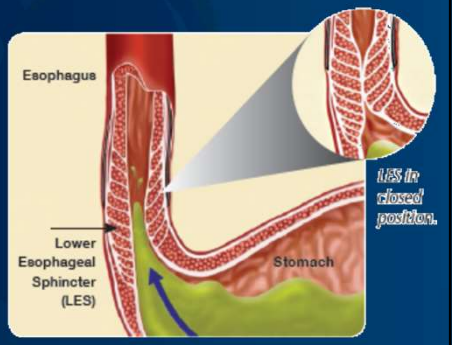
Why is the Sphincter (LES) weak?

- Family history
- LES shortens with full stomach, obesity, pregnancy
- Can weaken over time
- Drug effects
  - Alcohol, nicotine, caffeine
- Association with hiatal hernias
  - Genetic defect
  - Deficient collagen cross-linking



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Symptoms of GERD

- **Heartburn - NOT always present! ..... Silent GERD can lead to Barrett's**
- **Regurgitation**
- Hoarseness / Voice Changes
- Epigastric Pain
- Chest Pain
- Cough
- Sore Throat/Throat Clearing
- Difficulty Swallowing / Choking
- Sinus Symptoms
- Asthma
- Weight Loss
- Bitter / Bile taste
- Recurrent Pneumonia
- Bronchitis
- Dental Problems
- Bad Breath
- Excessive Belching
- "Lump" in the Throat
- Nausea / Vomiting

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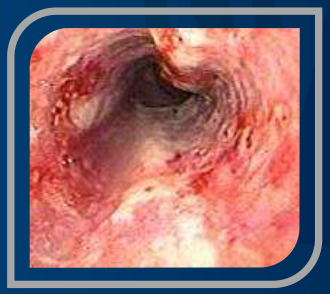
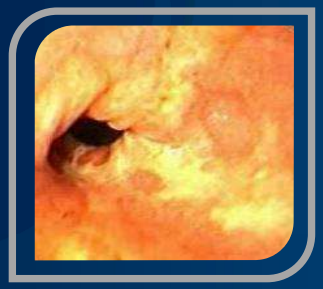
Complications of Reflux

Severe esophagitis with ulcers



Strictures



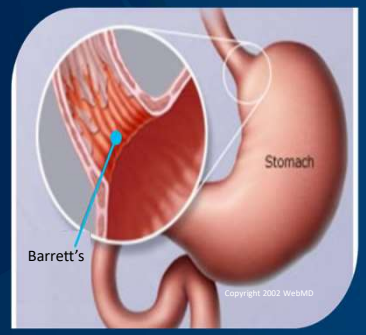
Complications of Reflux

Barrett's Esophagus

- Pre-cancerous lining
- Caused by chronic exposure to stomach contents
- Will occur in 15% of persons with GERD
- Increases the risk of esophageal cancer 40X
- Responsible for the massive increase in EAC

We must identify it, closely monitor it, and ablate it - BEFORE it becomes cancer!

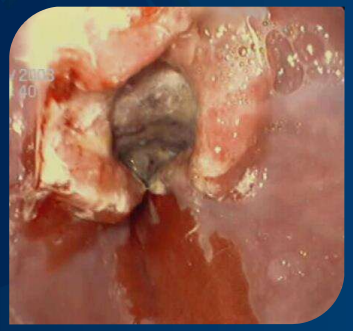
- This is actually a controversial position among many gastroenterologists



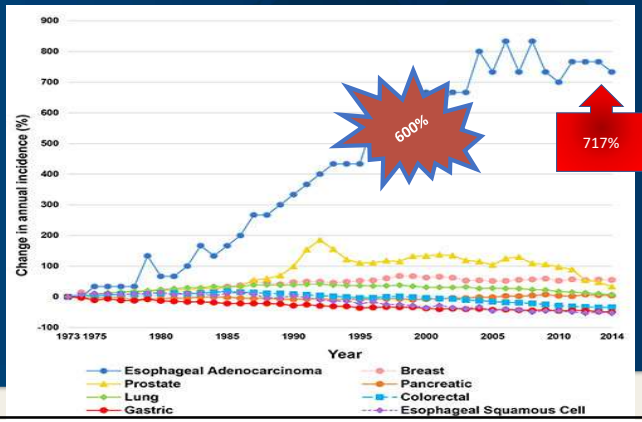
Complications of Reflux

Esophageal Cancer

- 6th most common cause of cancer death world-wide
- Estimated 20,000 new cases per year in the US alone
- Dramatic rise in incidence the last 40 years – 717%!!



The Epidemic of Esophageal Cancer



Why a Reflux Center?

- **GERD may be the most neglected disease in the USA, and it's the most common!**
  - Gastroenterologists and primary care can't help refractory GERD patients, rarely refer
  - Indifference to patients concerns about PPI's, cancer risk, and advanced solutions
- General surgeons (generally) have a poor understanding of the disease, minimal experience, marginal results with Nissen, and don't do revisions
  - GERD surgeons often don't do Roux-en-Y Gastric Bypass
  - Bariatric surgeons often don't do anti-reflux surgery
  - ***Centers that can merge Obesity and GERD can provide distinct advantages***
- Numerous new endoscopic and minimally invasive technologies offer attractive, game-changing alternatives to hopeful patients
- A highly personalized, ***"concierge service"*** is desired by patients
  - Nurse navigator service (ie. Cancer Centers)
  - Individualized education, public seminars (ie. Bariatric Centers)
  - Specialized centers are emerging

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The Comprehensive Center
Components for Success

1. The Team Approach
   - A dedicated Foregut, Esophageal or Swallowing Center
2. GI Lab
3. The Comprehensive Endoscopic Evaluation
4. The Consultation: Developing a "Lifeplan"
5. Comprehensive Therapeutic Alternatives
   - Medical
   - Endoscopic
   - Surgical
6. Lifelong surveillance

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1) THE TEAM APPROACH

Timothy LeMieur, MD
Andrew Loveitt, DO
Howard McCollister, MD
Shawn Roberts, MD
Paul Severson, MD
Evan Kelly, MD
Melissa Nelson, APRN-CNP
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Elisabeth Jenkins, PA
T.J. Hirsch, PA
Lea Carlson, RNC
Dawn Harcey, RN
Honi Strange, RN
Shelby Trebby , RN
Heather Erickson, LD, RD
Megan Perpich, LD, RD

Specialists in Reflux, Heartburn and Esophageal Disorders

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Reflux Center Nurse Coordinator

Patient advocate, sets up evaluation
Referring physician advocate
Expert in overall GERD care
Expert in understanding GERD diagnostics
Supplies continuity of care (nurse navigator)
Responsible for making everything happen
Provided by the center to manage THE TEAM

Presence of the Physician Champion and Effectiveness of the Nurse Coordinator are the best predictors of Reflux Center success

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How do you know it's GERD?

Eosinophilic Esophagitis

Gallbladder Disease

Atrophic Gastritis

Gastroparesis

AND MANY MORE…

ANSWER: ***You don't!***

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The Comprehensive Evaluation

Standard protocol – can be done ON THE SAME DAY!

1. Intake consultation
   - Complete Reflux Symptom Scale (HRQL)
   - Cardinal Gastroparesis Symptom Index
   - Additional tests may be ordered and arranged
2. Endoscopy (EGD)
3. pH monitoring
4. High Resolution Manometry with Impedance

- Comprehensive review consultation scheduled at 2 weeks
  - In-person or video-conference

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2) THE GI LAB

- **pH Outpatient Monitoring**
  - **Bravo** Wireless 48 hour pH monitoring*
    - Best tolerated
    - **DeMeester score**
      - Based on pH < 4
    - Upright, supine and post-prandial (with symptom association)
    - The vast majority of patients – ALMOST EVERYONE NEEDS THIS TEST!*
  - **Restech** oro-pharyngeal pH monitoring
    - Well tolerated
    - Extra-esophageal manifestations
    - **Ryan score**
  - **pH Impedance** monitoring - 24 hour Catheter-based
    - Not well tolerated – nasal catheter
    - The only test for non-acid, weakly acidic reflux
    - Dual channel (distal sensor in the stomach rules out achlorhydria, atrophic gastritis)
    - **DeMeester score**

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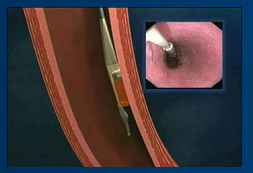
Bravo wireless pH monitoring



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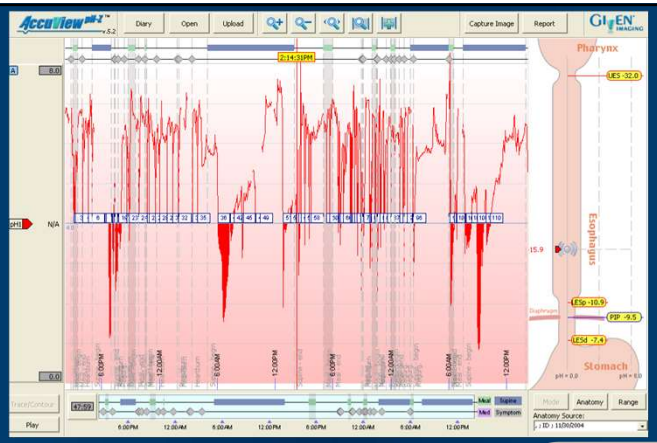

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Restech Oro-pharyngeal pH

- Detects aerosolized and liquid pH levels
  - Acid and alkali reflux
  - **Ryan score** calculated for acid, not alkali
    - pH < 5.5 upright, pH < 5.0 supine
- Probe placed trans-nasally posterior to the uvula
  - Well tolerated, above gag reflex
  - Does not impede swallowing or speaking
- Performed for ENT, atypical and inconclusive Bravo

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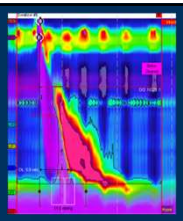
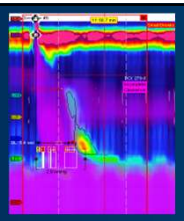
High Resolution Manometry with Impedance

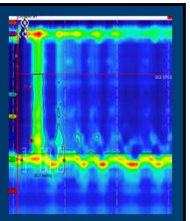
- Dysphagia
- Non-cardiac chest pain
- Pulmonary/aspiration
  - Chronic cough
  - Asthma
- Pseudo-achalasia
  - Opioids, THC, viagra



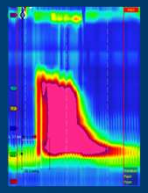
Normal swallow



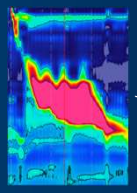
IEM



Achalasia I, II

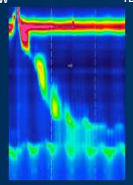


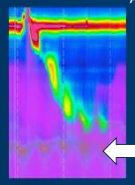
Achalasia III



Hypercontractile

Jackhammer Vs. Nutcracker





Impedance shows purple

Hiatal hernia with incomplete clearance

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3) THE COMPREHENSIVE ENDOSCOPIC EVALUATION

- **EGD: DO NOT "just look"!**
  - The comprehensive Reflux Center patients have usually had a previous EGD
  - A "normal" EGD does not exclude GERD
- **The quality parameters** of a comprehensive evaluation
  - White light and **NBI (Narrow Band Imaging)**
    - **Careful, prolonged, study of the distal esophagus**
      - **LA classification** for erosive esophagitis – with photos
    - **Hiatal hernia type with MEASUREMENTS**
      - **Define axial and radial dimensions of hiatal hernia**
    - **Hill Grade** (Gastro-Esophageal Flap Valve) – retroflexed view
    - **Barrett's length assessments: The Prague classification**
  - **Get biopsies**
    - Distal esophagus for Barrett's
    - Esophageal body for EoE
    - Stomach antrum for H.pylori, body/fundus for atrophic gastritis
    - Duodenum for celiac

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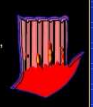
Los Angeles (LA) Grade Classification of Erosive Esophagitis

LA Grade A

One or more mucosal breaks no longer than 5mm, not bridging the tops of mucosal folds

LA Grade B

One or more mucosal breaks longer than 5mm, not bridging the tops of mucosal folds



LA Grade C

One or more mucosal breaks bridging the tops of mucosal folds involving <75% of the circumference

LA Grade D

One or more mucosal breaks bridging the tops of mucosal folds involving >75% of the circumference

Lundell et al. Gut. 1999;45:172-180.

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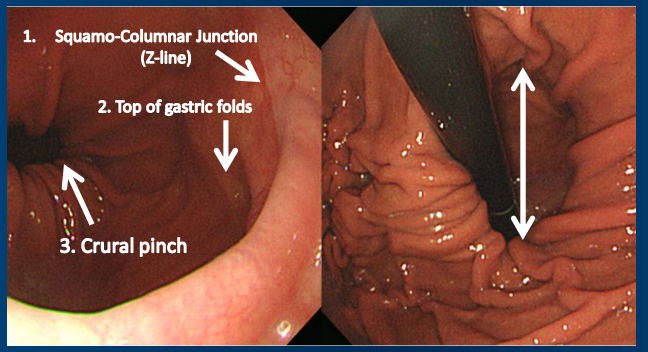
Hiatal Hernia: Calculate the dimensions!



Axial Length

Radial Diameter

Scope is about 1 cm

How many scopes?

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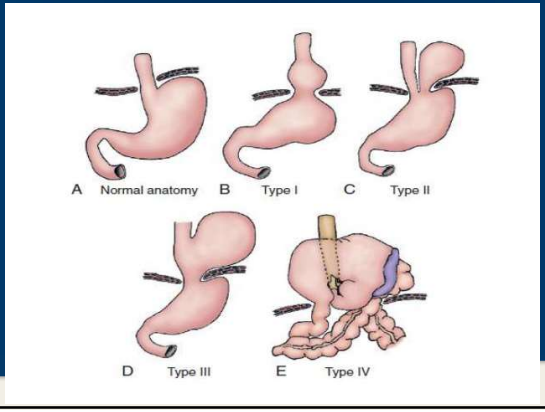
Hiatal Hernia Types



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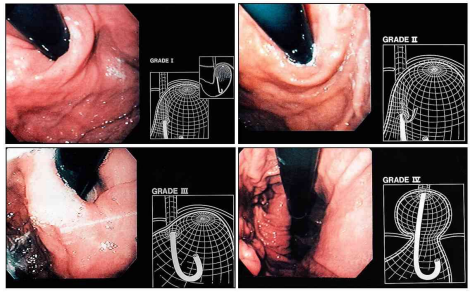
Gastroesophageal flap valve

- Endoscopic Hill grading system



Hill. Gastrointest Endosc 1996;44:541-547

Hill Grade

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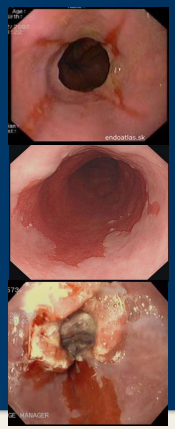
GERD: a pre-malignant disease



Squamous esophagus
Chronic inflammation
Barrett's metaplasia
Low-grade dysplasia
High-grade dysplasia
Invasive Adenocarcinoma

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Prague Classification for Barrett's Esophagus

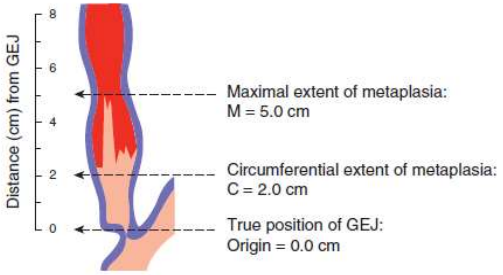

Figure 1. Illustration of Prague Classification for Barrett's esophagus (BE) where C indicates circumferential extent of metaplasia and M indicates maximal extent of metaplasia. Schema shows a C2M5 segment with identification of the gastroesophageal junction (GEJ) below the squamo-columnar junction. Reprinted with permission (24).

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Oncologic Evaluation for Barrett's

- Standard of care: **Seattle protocol tissue biopsies**
  - 4 quadrant biopsies at Squamo-Columnar Junction (SCJ)
  - Additional 4 quadrant biopsies every cm for entire distance
- How is Barrett's Esophagus defined?
  - US: Pathologic diagnosis
    - ***Goblet cell intestinal metaplasia (specialized mucosa) = Barrett's***
    - Dependent on tissue biopsies (the Seattle protocol)
- How good is the Seattle protocol?
  - ***Not very good*** compared to new technologies
    - **WATS3D**
    - Confocal Laser Endomicroscopy
  - …

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Seattle protocol sampling error

- Seattle protocol for Barrett's is sampling a clump of grass every 25 yards on a whole football field

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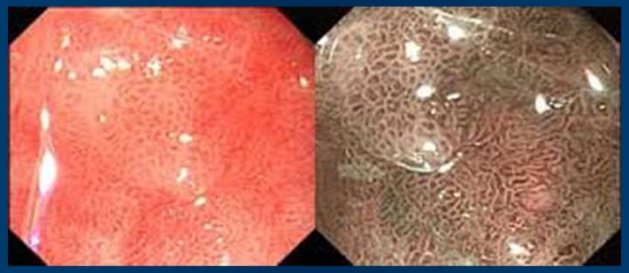
Narrow Band Imaging (NBI)
with Near Focus Image Enhancement



Is there visible columnar epithelium?
Then measure it!.... And biopsy it!!

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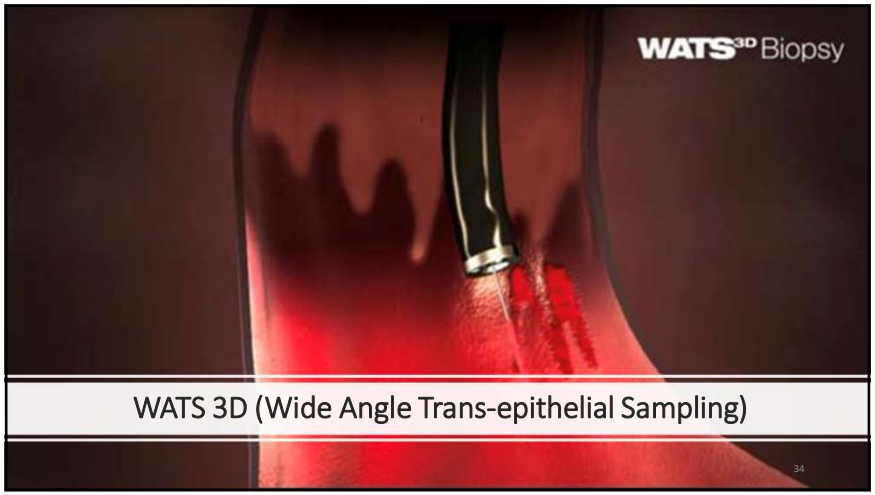

WATS 3D (Wide Angle Trans-epithelial Sampling)

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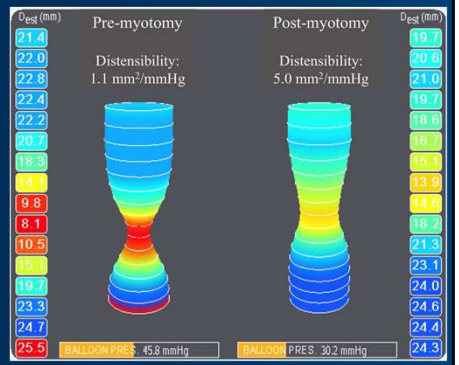
EndoFLIP™ Evaluation
FLIP = Functional Lumen Imaging Probe

- EndoFLIP balloon distension study
  1. 16 cm catheter for diagnostics in endoscopy suite
  2. 8 cm catheter for intraoperative calibration (recommended OR tool)
- Performed under sedation during EGD or under anesthesia in OR
- Provides confirmation of achalasia vs. pseudo-achalasia diagnosis
  - Treatment by changing to EsoFLIP catheter is excellent

Achalasia Treatment with EsoFLIP



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4) THE CONSULTATION

- Bringing it all together: the comprehensive review
  - GERD-HRQL and GCSI (Gastroparesis Cardinal Symptom Index)
    - **Off meds AND on meds**
  - EGD findings
  - Oncology assessment: biopsies, WATS 3D, etc.
  - pH study results
  - Manometry with Impedance
  - Personalized additional studies
    - Gastric emptying, Timed Barium Swallow, Marshmallow/Bagel
    - CT, Ultrasound and HIDA scan for possible gallbladder disease
    - Smart Pill – evaluates transit times through the entire gut
    - Pillcam SB – evaluates small intestine

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5) COMPREHENSIVE THERAPEUTIC ALTERNATIVES

- Recommendations:
  1. Optimized medical management
     - Timing, dosing of PPI Rx - ***based on pH study***
     - Defined follow-up – appointment for review of efficacy: 2-3 months!
       - GERD is a chronic pre-cancerous disease that needs surveillance
  2. Endoscopic solutions: Barrett's ablation, TIF, ESG
  3. Minimally Invasive Surgical options
     - Toupet fundoplication (Nissen becoming less utilized)
     - LINX magnetic sphincter augmentation
     - Collis gastroplasty for short esophagus
     - Revisional surgery
     - Gastric Bypass for GERD *AND* OBESITY

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Medical Treatment Options

Acid Suppression

PPI's - Proton Pump Inhibitors

- Blocks the acid pumps in the stomach's parietal cells
  - Prilosec (Omeprazole)
  - Prevacid (Lansoprazole)
  - Protonix (Pantoprazole)
  - Aciphex (Rabeprazole)
  - Nexium (Esomeprazole)
  - Dexilant (Dexlansoprazole)
- Annual expenditure: $75 million

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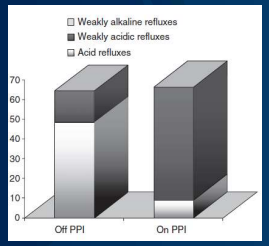
Myth: Medications Stop Reflux – BUSTED!

- Patients reflux the **same** amount **ON** or **OFF** medications
- Medications **mask the complications** of acidic GERD
- **Medications DO NOT** stop GERD
- **Medications are NOT** indicated for life-long, or even long-term use



Medium number of refluxes off and on PPI therapy

Frazzoni M, et al. Reflux patterns in patients with short-segment Barrett's oesophagus: a study using impedance-pH monitoring off and on proton pump inhibitor therapy. Alimentary Pharmacology & Therapeutics. 30(5):508-15, 2009 Sep 1.

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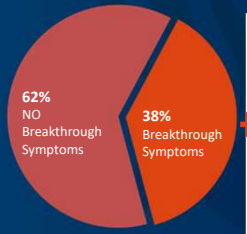
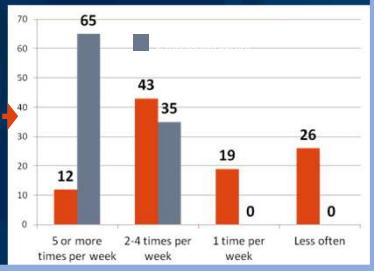
Acid Suppression Therapy

Percentage of patients experiencing breakthrough symptoms while on a PPI (among all patients)



How often breakthrough symptoms experienced (among patients with breakthrough symptoms)



AGA Institute Survey (n=1064)

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GERD Medical Treatment

So what's wrong with taking these pills – your whole life?

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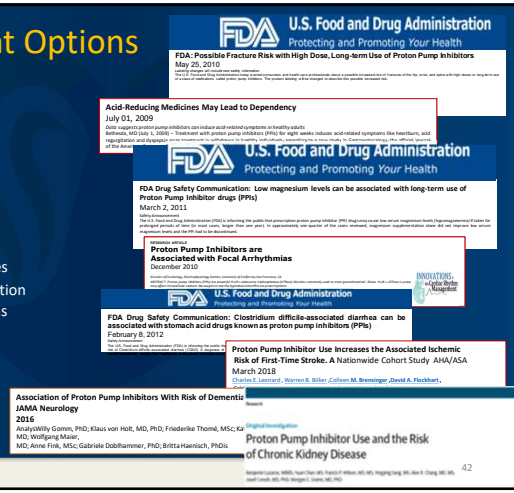
Medical Treatment Options

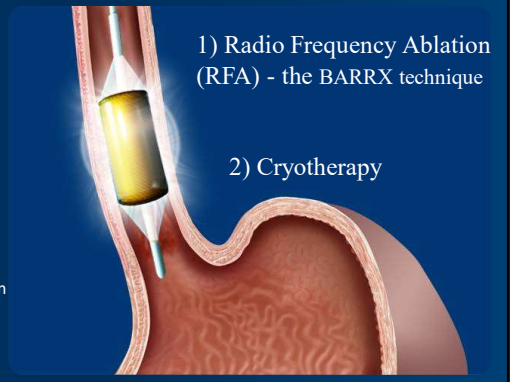
Problems:

- Disease progression continues
  - Rate of cancer on the rise
- LES remains weak
- Hiatal hernia still enlarges
- PPI's come with risks
  - Increased fracture risk, osteoporosis
  - Dependency
  - Magnesium, Iron and B12 deficiencies
  - Heart arrhythmias, myocardial infarction
  - Chronic diarrhea, C. difficile infections
  - Stroke
  - Dementia
  - Chronic kidney disease
  - Interaction with antiplatelet meds
  - Increased infection risk



Endoscopic Therapy

- Barrett's dysplasia
- Nodules/mass
  - EUS (Endoscopic US)
  - EMR/ESD
    - Endoscopic Mucosal Resection
    - Endoscopic Submucosal Dissection



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BARRX HALO Ablation Catheters

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Complete Response Post-ablation

Baseline Low Grade Dysplasia

4 month "cure"

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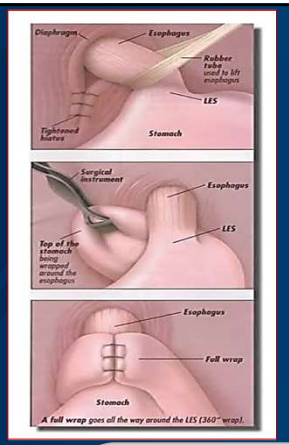
Fundoplication

The Gold Standard Repair

- Effective and reproducible
- Minimally invasive for the last 25 years
- Only 20,000 done annually
- Can be full (Nissen) or partial (Toupet)
  - Toupet now preferred due to minimal side effects
- ALWAYS includes hiatal hernia repair

Challenges

- Dysphagia (difficult swallowing) - *Nissen*
- Gas/Bloat – *Nissen*
- Recurrence of GERD (can loosen over time ~10%)
  - Usually due to recurrent hiatal hernia
- Obesity = High failure rate
  - 35% for obese individuals
  - Not advised for BMI >35



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Perception is Reality!

"Vomiting!"

"Bloating!"

"Gas!"

"Surgery is too radical, too painful"
"Oh come on - it's just heartburn"
"40% still on PPI's after surgery"

Internet Reputation

"Surgery will have to be re-done after 10 years"

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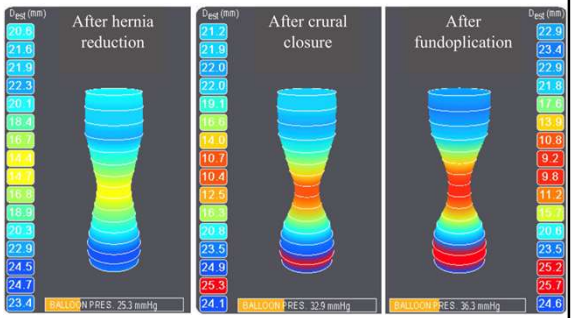
EndoFLIP

- Intra-operative calibration
- 8 cm balloon catheter
- 3 measurements:
  1. After hernia reduction
  2. After crural repair
  3. After fundoplication



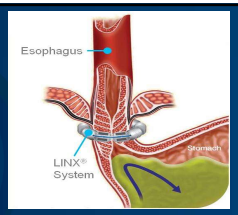
LINX Magnetic Sphincter Augmentation

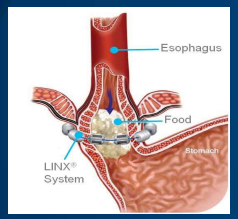
Advantages

- Magnetic support for LES
  - closes to prevent reflux, opens for food to pass
- Minimally invasive laparoscopic procedure
- Same day discharge to home
- No alteration of the stomach
- Retain ability to belch and vomit
- Reduced gas and bloating
- Removable

Challenges

- Dysphagia – usually transient
  - Intolerance due to excessive scarring
- MRI limit to 1.5 tesla
- Device erosion/migration (0.1%)
- Explants increasing (3.5 – 7%)





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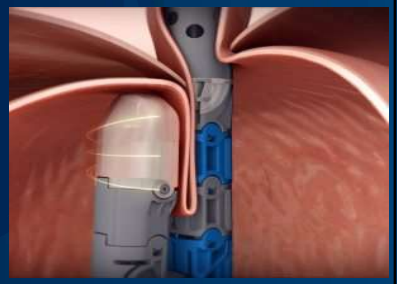
TIF – Transoral Incisionless Fundoplication

No Incisions –performed with endoscope

- Top of the stomach (fundus) is folded up and around the lower esophageal sphincter (LES) to support reflux barrier
- Anchored internally with surgical fasteners
- Simulates the Toupet partial fundoplication
- Same day surgery, general anesthesia
- No gas bloating
- No difficulties swallowing after
- Progressive liquid diet over the first 3 weeks

Challenges

- Cannot be used if hiatal hernia is larger than 2 cm
- Cannot be used for advanced GERD complications



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Robotic Assisted Anti-Reflux Procedures

3D high-definition view of surgical area with more precise dexterity

- Less surgical pain
- Faster recovery
- Less blood loss
- Less scarring

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6) LIFELONG SURVEILLANCE

- Start with this message at intake, or the public seminar
  - Every member of the team reinforces it
  - Tell every patient about your commitment to them!
- Always schedule a follow-up visit or procedure
  - GERD-HRQL and GCSI Questionnaire every visit
  - TIF/LINX/Toupet/Revisions: 1 year EGD with Bravo
    - Annual questionnaires with GERD-HRQL and GCSI
  - Barrett's: 1-3 year surveillance
- Develop a "lifeplan"
- Continuing education: Reading materials, websites, cards, magnets, displays, product demo's, videos, etc.

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Lifetime Strategy for GERD

- Based off orthopedic models for DJD, artificial joints may need to be replaced every 10-15 years
- Shouldn't we have a similar lifetime strategy for patients with GERD?

TIF/LINX → Toupet (10-15 yrs) → Revision (x1) → Roux-en-Y Bypass

- Set expectations for future surgery, explain strategy

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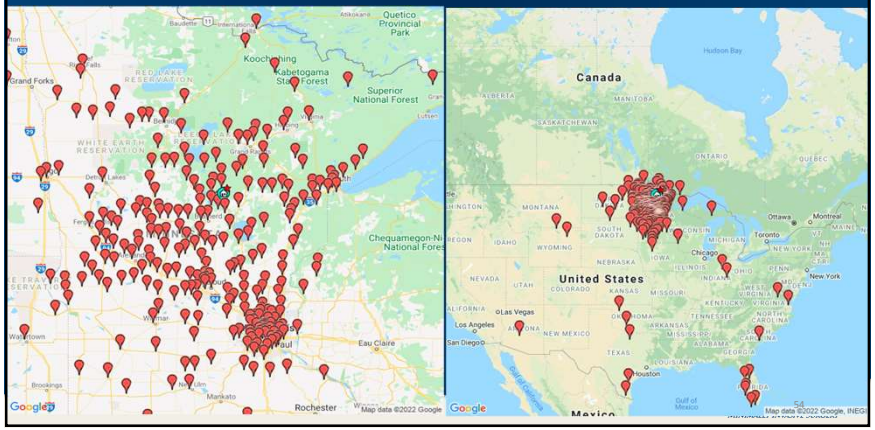

Coming next….

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The Obesity Epidemic

Paul Severson, MD, FACS, FASMBS