GERD Clinical Overview

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GERD

- GERD is a chronic often progressive digestive disease caused by a weak Lower Esophageal Sphincter (LES)
- The LES is the body’s natural barrier to reflux
- GERD can have many symptoms:
  - Heartburn
  - Chest pain
  - Regurgitation
  - Asthma
  - Dental erosions
- GERD can lead to serious complications including esophageal cancer
How Do I Know If I Have GERD?

Diagnostic Tests

- Barium Esophagram (Upper GI)
- Upper Endoscopy (EGD)
- Esophageal Manometry
- pH (24-hour and Bravo)
Symptoms of GERD

► **Heartburn** *NOT* always present

► Regurgitation

► Hoarseness / Voice Changes

► Epigastric Pain

► Chest Pain

► Cough

► Sore Throat

► Difficulty Swallowing / Choking

► Weight Loss

► Bitter / Bile taste

► Asthma

► Recurrent Pneumonia

► Bronchitis

► Dental Problems

► Bad Breath

► Excessive Belching

► “Lump” in the Throat

► Nausea / Vomiting
GERD and Quality of Life

- GERD may also significantly impact quality of life
- Patients with reflux disease often suffer:
  - Poor quality of sleep
  - Reduced work productivity
  - Dietary compromises to avoid symptoms
- Reflux patients also may have concerns about the long-term effects of GERD or the consequences of lifelong dependence on GERD medications
Complications of GERD

**ESOPHAGITIS**
- Inflammation of the esophagus
- Erosion of the lining of the esophagus

**STRICTURE**
- Scarring of the esophagus
- Leads to dysphagia
  - Difficulty swallowing
  - Food “sticks” in the middle of the chest
Complications of GERD

PULMONARY PROBLEMS
► Asthma
► Cough
► Pneumonia
► Bronchitis
► Pulmonary Fibrosis (scarring of the lung)

ENT PROBLEMS
► Voice Changes
► Hoarseness
► Ear Infections
► Sore Throat
Barrett’s Esophagus

- **Pre-cancerous** lesion

- Caused by chronic exposure to stomach contents (GERD)

- **Change** in the lining of the esophagus

- Will occur in **10-15%** of people with GERD¹

- **40 x risk** of adenocarcinoma, a type of esophageal cancer²

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1. [www.ASGE.org](http://www.ASGE.org)
Esophageal Cancer

► **6th most common** cause of cancer death worldwide

► Estimated that there will be approximately **20,000 new cases** this year in the U.S. alone

► **Dramatic rise** in the incidence in the last 25 years

http://www.who.int/mediacentre/factsheets/fs297/en/

Growth in Esophageal Cancer

Pohl H and Welch HG. J Natl Cancer Inst 2005;95:142-146
Symptom Management of GERD

DIET MODIFICATION
► Spicy Foods
► Caffeine
► Fatty Foods
► Tomato-based Foods
► Fruits
► Chocolate
► Alcohol
► Carbonated Beverages

PILLOWS / BED ELEVATION
**Medications for GERD**

**Antacids**
- Mylanta
- Pepto-Bismol
- Rolaids
- Tums

**H2 Blockers**
- Pepcid
- Tagamet
- Zantac

**Proton Pump Inhibitors**
- Aciphex
- Nexium
- Prevacid
- Prilosec
GERD Medications

**BENEFITS**

► Reduces the amount of acid in the stomach

► May reduce inflammation of esophageal lining

► Provides symptom relief for many patients, but relief can be temporary

**LIMITATIONS**

► DOES NOT affect the cause of reflux (LES)

► DOES NOT prevent reflux

► May require life-long use and dose increases

► Side effects include:¹
  - Diarrhea
  - Nausea
  - Constipation
  - Headache

¹ Purplepill.com
Acid Suppression Therapy

AGA Institute Survey (n=1064)

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

- 62% NO Breakthrough Symptoms
- 38% Breakthrough Symptoms

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

- 5 or more times per week: 65
- 2-4 times per week: 43
- 1 time per week: 35
- Less often: 26

Frequency of symptoms prior to diagnosis & subsequent PPI use

AGA Institute Survey (n=1064)
Myth – Medications Stop Reflux

- Patients reflux the same amount **ON** or **OFF** medications
- Medications **mask the symptoms** of GERD
- **DO NOT** stop GERD

Medical Therapy for GERD – Potential Risks of Long-term PPI Use

**FDA: Possible Fracture Risk with High Dose, Long-term Use of Proton Pump Inhibitors**

May 25, 2010

*Labeling changes will include new safety information*

The U.S. Food and Drug Administration today warned consumers and health care professionals about a possible increased risk of fractures of the hip, wrist, and spine with high doses or long-term use of a class of medications called proton pump inhibitors. The product labeling will be changed to describe this possible increased risk.

**FDA Drug Safety Communication: Low magnesium levels can be associated with long-term use of Proton Pump Inhibitor drugs (PPIs)**

March 2, 2011

Safety Announcement

The U.S. Food and Drug Administration (FDA) is informing the public that prescription proton pump inhibitor (PPI) drugs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year). In approximately one-quarter of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and the PPI had to be discontinued.

**FDA Drug Safety Communication: Clostridium difficile-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)**

February 8, 2012

Safety Announcement

The U.S. Food and Drug Administration (FDA) is informing the public that the use of stomach acid drugs known as proton pump inhibitors (PPIs) may be associated with an increased risk of Clostridium difficile-associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve. Patients should immediately contact their healthcare professional and seek care if they take PPIs and develop diarrhea that does not improve.
Surgical Treatment Options

- Laparoscopic Nissen Fundoplication
- LINX
Why Consider Surgical Options?

• Continue to experience symptoms while taking medications
• GERD negatively impacting quality of life
• Concerns about potential risk and complications of GERD
  • Desire to be free of GERD medication
    – Concerns about side effects of long-term GERD medication use
    – Inconvenience
    – Cost

Treat the PROBLEM, not just the SYMPTOMS!
Nissen Fundoplication

- Laparoscopic
- 1-2 hour procedure
- Overnight stay often required
- Dietary restrictions after surgery
- Up to 1-2 weeks off work
- Side effects — difficulty belching and vomiting, gas bloat
LINX® Reflux Management System

• FDA approved in 2012
• Proven safe and effective
• Minimally invasive procedure
• Designed to be a permanent solution for GERD
Design allows augmentation without compression of esophagus

**Magnetic Cores** provide augmentation (~15 mm-Hg)

**Interlinked Titanium Beads** allow dynamic opening
How LINX® Works
LINX® Procedure: Dynamic Augmentation

Laparoscopic, minimally invasive LINX Procedure

- **Key steps:**
  - Minimal dissection (no alteration to gastric anatomy)
  - Sizing
  - Device placement and closure

- Outpatient procedure
- Normal diet as soon as tolerated
- Resume activities in a couple of days
- Removable
LINX® Procedure

► Laparoscopic, minimally invasive procedure

► Generally completed in less than one hour

► Patients typically go home the same day and resume a normal diet as soon as tolerated

► No alteration to the stomach

► Patients generally retain ability to belch and vomit; reduces gas bloat

► Removable
GERD Summary

• GERD is a chronic digestive disease caused by a weak lower esophageal sphincter (LES)
• Much more than heartburn
• GERD can lead to serious complications
  – Esophagitis
  – Strictures
  – Barrett’s Esophagus
  – Esophageal cancer
• Medications may provide symptom relief, but they:
  – Do NOT affect the cause of GERD
  – Do NOT prevent reflux
  – May require long-term (life-long) use
Final Proposal: Stop Reflux At Its Source

- GERD is a disorder of the sphincter
- A normal sphincter (valve) creates a barrier against reflux
- A weak sphincter allows reflux of acid and bile
- The problem is the valve! **Fix the valve**
Abridged Brief Statement

- The LINX® Reflux Management System is indicated for those patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.
- Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.
- Contraindications: Do not implant the LINX® System in patients with suspected or known allergies to titanium, stainless steel, nickel or ferrous materials.
- Warnings: The LINX® device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to 1.5-Tesla (1.5T). Laparoscopic placement of the LINX® device is major surgery.
- General Precautions: The LINX® device is a long-term implant for use in patients 21 years or older. Medical management of adverse reactions may include explanation and/or replacement.
- Potential Risks Associated with LINX® System: dysphagia, stomach bloating, nausea, odynophagia, increased belching, decreased appetite, inability to belch or vomit, flatulence, early satiety, device erosion, device migration, infection, pain, and worsening of preoperative symptoms.
- For more information on the LINX Reflux Management System, contact your physician or Torax Medical, Inc.
GERD Workup Pathway

Dissatisfied patient
Disease progressing

EGD*

Normal

pH testing

LINX® Workup

Esophagitis

Grade A/B with biopsy

LINX® Workup

Grade C/D

Surveillance + Anti-reflux Surgery (LINX® precaution)

Surveillance + Ablation + Anti-reflux Surgery (LINX® precaution)

Barrett’s

Surveillance + Anti-reflux Surgery (LINX® precaution)

*repeat EGD if > 3 years old, alarm symptoms, or due for surveillance
LINX® Workup

**Objective Reflux**
- pH testing
  - See pH pathways

**Anatomy**
- EGD

**Esophageal Function**
- Manometry
  - Distal amplitude pressures > 35 mmHg
    - >70% wave progression

**Hernia**
- >3 cm
  - LINX® Precaution

- <3 cm
  - Barium swallow to confirm < 3 cm
    - LINX® Candidate

- Unknown size
  - LINX® Candidate
Hiatal Hernia

• On EGD or prior Barium swallow, hernia size is often not mentioned or specified numerically by GI or radiologist
  – Can result in “surprise hernia” during surgery
  – Always review actual images or order new imaging
    • Radiologists may not comment on hiatal hernias if they think they are not “clinically significant”
    • “Small hernia” is a relative term – these can be 7-10 cm in actuality
    • Barium swallows are cheap and easy confirmatory tests – order a repeat if images unavailable
      • Can include soft/solid bolus as a “real world” assessment of dysphagia as well

• No hernia on images or EGD
  – Imaging and EGD not perfect for detecting hernia size
  – Only truly 100% accurate test is laparoscopy
    • Set patient expectations
Hiatal Hernia
Workup Pathway– pH testing

- Classic symptoms
  - Patient won’t tolerate nasal catheter
  - 48-hour Bravo
    - Negative: Impedance
      - Alternative Dx
    - Positive: LINX® Workup
  - Patient refuses to stop meds
    - 24-hour pH with impedance
      - Negative: 48-hour Bravo
        - Alternative Dx
48-hour Bravo

- Wireless monitoring (no nasal catheter)
- Placed during EGD
  - Must be calibrated by endo staff prior to placement
  - Placed 6 cm above the squamocolumnar junction
  - Placed by some surgeons at every initial EGD and for annual follow-up after surgery
    - Requires >10 probes in practice setting since receiver kept for 48 hours
- Well tolerated by patients but foreign body sensation or odynophagia possible
  - Probe typically detaches and passes by 2-7 days, occasionally >14 days
- Patients **must be off PPIs and H2 Blockers for at least 5 days prior**
  - A normal Demeester score on Bravo while on PPIs is expected. The test should be repeated off PPIs or impedance should be ordered instead.
  - Patients should engage in their normal daily behavior (don’t avoid trigger foods)
- Contraindicated in the presence of cardiac pacemaker (can lose data)
- Disposable probes about $225, receivers about 7K
24-hour Ambulatory pH Probe

- Typically placed without sedation and remains in place 24 hours
  - Nasal catheter not as well tolerated as Bravo but can be combined with impedance to capture non-acid reflux
- Proximal sensor positioned 5 cm above LES
  - Technician will need location of LES from previous manometry or endoscopy
  - If LES location not known, will have to perform manometry prior to placing pH catheter
- Stop PPIs or continue PPIs?
  - Some GI’s will leave refractory GERD patients on PPIs in attempt to determine whether non-acid reflux is causing their breakthrough symptoms
  - For a surgical workup, it is best to have them stop PPIs to establish a baseline
- Patients should engage in their normal daily behavior (don’t avoid trigger foods)
Impedance

• Measures changes in resistance of alternating electrical current passing between rings on the catheter

• When **combined with pH testing**, impedance can distinguish **acid and non-acid reflux events**
  – Reported with symptom index – score >50 considered positive

• When combined with High Resolution Manometry, impedance provides information on **bolus transit and contractions**

• **Key Take Away** – A normal Demeester score does not necessarily mean the test was normal – check the non-acid events and whether or not the patient was on or off their PPIs.
LINX® Workup

Objective Reflux
- pH testing
  - See pH pathways
- Hernia >3 cm
  - LINX® Precaution

Anatomy
- EGD
- Hernia <3 cm
  - Barium swallow to confirm < 3 cm
  - Hernia unknown size
- Hernia unknown size
  - >70% wave progression

Esophageal Function
- Manometry
  - Distal amplitude pressures > 35 mmHg.
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LINX® Candidate
Conventional Manometry

• Measures esophageal intraluminal pressure
• Typically placed transnasally and without sedation
• Positioning/Procedure
  – Distal ports passed into stomach and zeroed to gastric baseline, then withdrawn until positioned at high-pressure zone (LES)
  – Patient then asked to take 10 liquid and 10 viscous swallows 20-30 second apart.
  – Entire procedure takes 20-30 minutes.
• Software converts pressure readings into line tracings and topographic maps
  – Must be interpreted by a clinician
High Resolution Manometry

- Increased number of pressure sensors on catheter
  - Better detection of nutcracker esophageal, hyper/hypotensive LES, diffuse esophageal spasm, etc.
  - Allows for Chicago classification for achalasia
    - Identifies patients that may not benefit from a Heller Myotomy
- Better tolerated by patients
  - Can measure pressures from one fixed position (no repositioning = less gagging)
  - Faster than conventional manometry
- Produces automated analysis which can improve turn around time
  - Clinical interpretation still required
- When combined with High Resolution Manometry, impedance provides information on **bolus transit and contractions**
  - Abnormal esophageal manometry impedance: <70% incomplete bolus transit for liquid or <60% bolus transit for viscous
Manometry – Tips & Tricks

• Not well tolerated
  – Consider placing under sedation, time with EGD
• Slow turn around from GI due to reads
  – Consider getting trained with your equipment’s company
    • e.g. Sandhill/Castell course
  – Talk to hospital about upgraded high resolution equipment with easier analysis and Chicago classification
    • Improved quality and surgical turn around
• Consider alternative screening method
  – Modified barium swallow with soft/solid bolus
  – Protocol – prone, Trendelenburg
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LINX® Candidate

LINE® Precaution

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