Emerging Technology: Latest Anti-reflux Endoscopic procedures & Surgeries

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Objectives
1) Describe types of reflux diseases
2) Identify the current diagnostic technology to distinguish GERD vs NERD
3) Describe briefly the current medical & surgical treatment for GERD
4) Identify the right patient for anti-reflux procedures

Reflux Diseases

1) GERD – Gastroesophageal Reflux
   - Backflow of stomach contents up the esophagus and into the throat
   - Gastric contents (food, saliva, pepsin, protein break down enzymes)
   - Also called gastric reflux
2) NERD – Non-Erosive Reflux
   - Typical reflux symptoms caused by the intraesophageal reflux of gastric contents
   - No visible esophageal mucosal injury
**GERD**

“A condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications” (Montreal Consensus)

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**GERD Overview**

- Gastroesophageal reflux disease (GERD) is a chronic disease which affects an estimated 38 million patients in the U.S.
- Weekly in approximately 20-25% of adults.
- Only 19 million are diagnosed annually.
- 35% of affected individuals do not seek medical care, preferring to self-medicate.
- The most common gastrointestinal diagnosis recorded on outpatient visits since 2006, surpassing abdominal pain.
- Increasing prevalence.
- Aging population.
- Obesity.
- Changes in diet & physical activity.
- Over-prescription of pharmaceutical therapies (PPIs).
- Americans spend in excess of $10 billion per year on Proton Pump Inhibitors (PPIs).
- The number of PPI prescriptions/year in the United States has doubled since 1999.


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**Pathophysiology of GERD**

Typical symptoms have been associated with Barrett’s Esophagus—a condition that increases risk for cancer.*

**GERD is Deceptively Complex**

**Typical**

- Heartburn
- Chest Pain
- Abdominal Pain
- Difficulty swallowing
- Regurgitation
- Nausea
- Hoarseness
- Excessive throat clearing
- Bad breath
- Dental erosions or gum disease

**Atypical**

- Persistent cough
- Chronic sore Throat
- Difficulty swallowing
- Frequent infections
- Hoarseness
- Excessive throat clearing
- Bad breath
- Sensitive to Some Foods & Liquids

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6 million suffer from GERD and asthma.
GERD Clinical Progression

Progression of GERD...

- Ulceration
- Hemorrhage
- Strictures
- Barrett's Esophagus
- Adenocarcinoma (Cancer)

Esophagitis is inflammation of the esophagus. It may be acute or chronic.

Physiological Reflux (Infrequent & Mild)
Symptomatic GERD (Frequent & Intense)

Esophagitis

Complex Esophagitis

Symptoms:
- Typical
  - Heartburn
  - Regurgitation
- Atypical
  - Chest pain
  - Difficulty swallowing
  - Cough
  - Asthma
  - Laryngitis

Evaluation:
- Endoscopy
- Extend of esophagitis
- H-pylori gastritis
- Ulcers
- Barrett's esophagus
- Strictures
- Varices
- Angiodysplasias
- Mallory-Weiss tear
- Tumors
- Gastric polyps

Bravo pH Monitoring System
- Catheter-free pH monitoring system
- pH capsule attached to the esophageal wall transmits data to pager-sized receiver
- Allows normal activities such as dietary habits, showering, and exercise and does not interfere with sleeping
- 48 to 72 hour pH reading of the esophagus
- Supine reflux
- Night time reflux
- Symptom correlation
- Monitor reflux on PPI as well as off PPI

Esophageal Manometry
- To accurately define esophageal motor function
- For preoperative assessment of patients being considered for antireflux surgery
- Note: Esophageal manometry is not indicated for ruling or confirming a suspected diagnosis of GERD

Indications:
- Achalasia
- Nutcracker esophagus
- Cricopharyngeal Achalasia
- Abnormal esophageal motility
Esophageal Impedance Testing

- 24-hour catheter-based test
- Patient carry the catheter and resume normal activities
- Allowing recognition of both acidic and weakly acidic reflux episodes
- The results of several studies suggest that impedance-pH monitoring is useful in the evaluation of patients with PPI-resistant typical reflux symptoms, and painful esophageal symptoms
  - Chronic unexplained cough
  - Excessive belching
  - Rumination
  - Motility disorders
  - Non-acid reflux

Barium x-ray

- X-ray examination of the esophagus, stomach, and first part of the small intestine
- Images obtained using fluoroscopy and oral barium
- Evaluate the anatomy and function
- Air-contrast or double-contrast upper GI
- Iodine contrast is used if recent GI surgery or barium allergy
- Indications:
  - Difficulty swallowing
  - An alternative to EGD or manometry if needed

GERD: Esophagitis, NERD, Functional Heartburn?

- GERD: Acid reflux disease
- NERD: Non-erosive reflux disease
- Functional heartburn

Lifestyle Modifications

- Rigorously timed meals
- Weight loss
- Eliminate smoking
- No pressure on stomach
- Sleeping in inclined sleeping position
- Unable to enjoy meals
- Sleep disturbances
- Fatigue
- Reduced overall productivity
- Altered social well-being
- Altered emotional well-being

Eliminate triggering foods & drinks
PPIs
Blocks the secretion of acid into the stomach

Escalated dosing of more complex medications...until pills stop working.

H2 Blockers
Blocks the body's signal to the stomach to produce acid

Antacids
Neutralize or buffer stomach acid

...and medications come with side effects and complications

Medical Management

GERD Suffering is Widespread

19 Million Daily
42 Million Weekly
20 Million Monthly
81 Million Total

¼ of Americans

Only 10.2 Million Visit a Doctor
6.3 Million Receive Tests to Diagnose
0.05 Million Receive Treatment with a Procedure

134 Million OTC & Rx

Vitamin B12 Deficiency
Increased Pneumonia Risk
Increased Risk of Osteoporosis Fractures
Reduced Gallbladder Motility
PPI Interaction with Plavix
Increased Risk of Fundic Gland Polyps
Increased Risk of Bacterial Gastroenteritis
Magnesium deficiency
Increased Risk of C. diff, Small Intestine Bacterial Overgrowth

Risks Associated With PPI Use

GERD Symptom and Treatment Continuum

Endoscopic Repair
Anti-Reflux Surgery—Decision

- Anti-reflux surgeries are an effective alternative to medical treatment.
- Symptom of transient lower esophageal relaxation.
- Indications (SAGE Guideline):
  - Symptoms refractory to pharmacological therapy.
  - Complications of GERD.
  - Barrett's esophagus.
  - Peptic stricture.
  - Large hiatal hernia.
  - Atypical symptoms.
  - Reflux documented on 24hr PH monitoring.

Pre-op work up

1. Upper Endoscopy
   - Visual and histopathological changes.
2. PH monitoring
   - Gold standard for pathologic acid reflux.
3. Esophageal Manometry
   - To identify dysmotility of esophagus.
4. Barium Swallow
   - To determine the anatomy.

Anti-reflux procedures

Normal Anatomy
- Normal anatomy.
- Functional valve.
- Physiological reflux.

Abnormal Anatomy
- Abnormal anatomy.
- Dysfunctional valve.
- Symptomatic GERD.

Solution:
- Restore anatomy to normal.
- Repair valve.
- Resolve symptoms.

Laparoscopic (LNF) vs Open technique for GERD (CNF)

Laparoscopic NISSEN Fundoplication vs Conventional NISSEN Fundoplication
- Less invasiveness and restore normal physiological function of LES, reconstruction of the hiatus, and repair of hernia.
- Less abdominal trauma and gold standard for surgical treatment.
- Shorter operative time.
- Shorter hospital stay.
- Less postoperative morbidity.
- Decreased pain.
- Less risk of abdominal hernia.
- Lower rate of infections.
Partial Vs Total Fundoplication

**Toupet**
- Partial-270 degree
- Fewer symptoms of bloating
- Able to vomit

**Nissen**
- Total-360 degree
- High rate of dysphagia
- Flatulence
- Bloating

_Toupet vs Nissen_
- Toupet done in 3.0 cm and 1.5 cm valve length
- 3.0 is superior in controlling reflux
- Dysphagia is higher in 3.0
- More studies required

_Anterior (DOR) vs Nissen_
- 120 degree anterior fundoplication
- Less post operative dysphagia
- Shown less effective in controlling reflux
- Most patients required re operation

Comparison

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<thead>
<tr>
<th></th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>Nissen</td>
<td>Effective in reflux control</td>
<td>Flatulence, bloating, dysphagia</td>
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<td></td>
<td>Less post-op dysphagia</td>
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<tr>
<td>DOR</td>
<td></td>
<td>Most patients required re operation</td>
</tr>
<tr>
<td>Toupet</td>
<td></td>
<td>Length of the wrap determines the quality of reflux control</td>
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Stomach Intestinal Pylorus Sparing Surgery (SIPS)

- Modified approach for morbidly obese pts
- Modified duodenal switch
- Involves sleeve gastrectomy and attaching pylorus to the midgut located 3 meters from the terminal ileum
- Novel technique for both obesity and GERD
- Early results are encouraging

(Zaveri et al. 2015)

Anti-reflux surgery-conclusion

- LNF is the gold standard procedure
- Failure rate: 3%-16%
- Dilatation, slipped fundoplication or herniation of the wrap
- Re-operation is safe
- High complication rates: gastric or esophageal perforation
- Longer operative times
- Higher conversion to open approach

(Anti-reflux Surgery-Conclusion)

Antireflux Endoscopic Procedures (History)

- Implanting Technique: Enteryx
- Radio Frequency: Stretta
- Suturing Devices: Endocinch, Plicator

Photography: Used with permission from (Endogastric Solutions)

Patient Selection Criteria

Inclusion Criteria:
- 18-80 years of age for adults or > 12 years and 25 kg for children
- Chronic symptomatic GERD for > 6 months
- Persistent GERD symptoms despite PPI therapy
- Demonstrated reflux (48-h pHmetry, UGI radiography or esophagitis B or C)
- Demonstrated gastroesophageal junction (HI grade II-III)
- Patient willing to comply with post-operative dietary recommendations

Exclusion Criteria:
- BMI > 35
- Irreducible hiatal hernia > 2 cm
- Esophagitis grade D
- Esophageal ulcer, fixed stricture or motility disorders
- Dysphagia

Patient selection criteria
TIF (Transoral Incisionless Fundoplication)

➢ No incisions
➢ No scarring
➢ No incisional herniation
➢ Less nosocomial infection
➢ No dysphagia

➢ 3rd generation in reflux surgery
➢ Surgical reconstruction transorally
➢ Sterile, single use device
➢ An evolution of current surgical procedure
➢ Based on long standing surgical principles
➢ Physiologically less invasive
➢ Future options open-adjustable
➢ Adaptive to patients anatomy

Endoscopic Retroflex View Before & After TIF Procedure
Evidence: Studied in over 70 peer-reviewed publications, for over 4000 individual patients.

Outcomes: High level of efficacy in improving subjective and objective measures of GERD.

Safety: Over 15,000 patients treated consecutively over 10 years.

Over 97% of patients eliminated daily regurgitation VS 50% for PPI group.

Over 90% of patients had esophagitis healed VS 38% for PPI group.

Over 62% of patients eliminated all symptoms VS 5% for PPI group.

Over 54% of patients had esophageal pH normalized VS 52% in the PPI group.

In the TEMPO randomized, controlled trial comparing the TIF 2.0 procedure to maximum dose PPI therapy, outcomes at 6 months:

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Endoscopic Fundoplication

All outcome measures of TIF were sustained and statistically unchanged between 6 and 12 months.

84% of TIF patients remained completely off PPI at 12 months vs. 90% at 6-month follow-up.

Esophagitis was healed or reduced in 100% of TIF patients at 12 months vs. 90% at 6 months.

77% of TIF patients experienced global elimination of regurgitation and atypical symptoms off PPIs at 12 months.

In the crossover group of patients, 71% were completely off PPIs 6 months post-TIF.

In crossover patients, TIF was superior to high dose PPIs in eliminating typical and atypical GERD symptoms.
Endoscopic Fundoplication

- TIF provides significant control of regurgitation, esophageal symptoms, and healing of esophagitis in patients with small hiatal hernias and as an inoperable reflux disease.
- TIF provides the undesirable post-fundoplication side-effects, dysphagia, gas-bloat, and belching. TIF is a safe, viable endoscopic alternative for existing anti-reflux procedures.
- TIF may also be viewed as an adjunct to PPI therapy in patients with incomplete control of regurgitation and esophageal symptoms.
- Outcomes of this study are consistent with other recently published data and demonstrate durability of results 12 months following TIF.

TIF vs Nissen or Toupet

- Safe and efficacious in symptom control
- TIF is a paradigm shift in the treatment of GERD
- TIF has shorter operating time and length of stay
- No complications or conversions
- High patient satisfaction

Conclusion

- Transoral fundoplication achieved elimination of daily dependence on PPIs in 75-80% of patients.
- Troublesome regurgitation was resolved in a greater proportion of patients treated with TIF than with omeprazole.
- TIF appears to be safe, without fundoplication side effects.
- Intra-esophageal and control improved following TIF.
- TIF should be considered in GERD patients with small or absent hiatal hernia who suffer from troublesome regurgitation, despite PPI therapy.

Linx

- Minimally invasive laparoscopic procedure
- Linx is implanted outside the LES.
- Preserves normal function can belch and vomit.
- Designed for lifetime, quarter in size, made of Titanium.
- One type is safe in MRI scanning.
**LINX® Reflux Management System**

- FDA approved in 2012
- Proven safe and effective
- Minimally invasive procedure
- Designed to be a permanent solution for GERD

**Journal Support**

2. Data on File, Torax Medical.

**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

**LINX® Benefits**

- 87% of patients completely eliminated medication use
- 98% patients reported no bothersome heartburn affecting their nightly sleep
- 98% of patients required no daily change to their diet from heartburn
- 94% of patients were satisfied with their overall condition after LINX

How LINX® Works

LINX helps keep the LES closed to prevent reflux
LINX expands to allow for normal swallowing

MUSE- Endostapler System

- FDA approved 2014
- The minimally invasive system is for the treatment of Gastroesophageal Reflux Disease (GERD).
- It performs an anterior fundoplication in lieu of current surgical procedures, without opening the abdominal cavity.
- SRS™ endoscope distal section including several sophisticated innovative technologies such as a surgical stapler, miniature camera and an ultrasound sensor
- The SRS system has the following principal advantages:
  - Provides the same results as in gold-standard laparoscopic surgery.
  - Faster than laparoscopic surgery.
  - A more attractive treatment than either surgery or lifelong medication.
  - A more efficient and cost-effective procedure.
  - Less time in the patient with no incisions.
  - The entire endoscope is disposable.

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**Endostim Therapy**

- Bipolar lead delivers low energy electrical impulses to LES
- Implanted through laparoscopic procedure
- Single-center (Chile) and International multicenter (open-label trials)
  - Prospective pilot studies evaluating safety and efficacy
  - 6-M and 12-M follow-up results published for single-center study
- Initial studies demonstrated safety and efficacy at 12 months follow-up in PPI-refractory sufferers
- Still upstream, but a potential treatment option for GERD

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**Ideal GERD Treatment**

- **Subjective Improvement:**
  - Symptom control
  - Medication use
  - Satisfaction
  - Durability
- **Objective Improvement:**
  - pH-metry
  - Esophagitis
  - Safe, few, and minor complications
  - Minimal side-effects

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**Thank you**

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**References**

8. MUSE endostapler system Photography: Retrieved from [http://www.medigus.com](http://www.medigus.com)
13. Photography: Used with permission from (GI Solutions/Arun Ohri, MD)
14. Photography: Used with permission from (Endogastric Solutions)