Laparoscopic Management of GERD

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Disclosures

- **None**

Objectives

- **Discuss the current application of laparoscopic anti-reflux surgery**
- **Discuss the anatomy and technical aspects of hiatal hernia repair**

GERD: Epidemiology and Cost

- **In the U.S., more than 60 million adults experience GERD-like symptoms at least monthly**
  - **Most common outpatient diagnosis for patients with a GI complaint**
- **$12 billion spent on GERD treatment in 2004**
  - **2/3 attributed to PPIs**
  - **% of patients prescribed a PPI during outpatient visit doubled between 2002 and 2009**

Why do we treat GERD?

1. Symptom control - patient QoL
2. Acid control - management or prevention of complications
    - Esophagitis
    - Stricture
    - Barrett's esophagus

Medical Treatment

- Proton Pump Inhibitors
    - Most commonly used medications for GERD
    - Powerful acid blockers
    - Control symptoms and heal esophageal lining in most patients with GERD
        - High failure rate in pts w/ severe esophagitis
    - Requires continuous therapy, and may become less effective over time

Complications of PPI Therapy

- Increased risk of osteoporosis
    - Calcium non-absorption and bone fractures
- Increased enteric infections
    - C. difficile coilits
- Cost?
    - Name brand PPI → $$$
    - Six month cost can range from $204 to $4200
    - BID Nexium → $2,800 (235/mo)
- Drug-drug interaction issues
    - Plavix with PPI and increased risk of heart disease

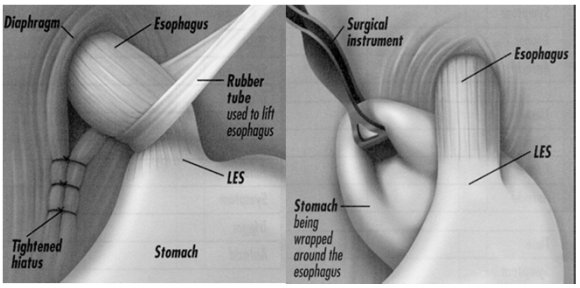
Indications for Procedural Treatment of GERD

- Complicated GERD (Stricture, Aspiration)
- GERD refractory to medical therapy
- GERD requiring daily PPI for control of symptoms

Predictors of Patient Satisfaction with Surgery

- Typical Symptoms of GERD
- Responsive to PPI's
- Abnormal 24 hour pH study
- Normal Esophageal Motility

Laparoscopic Nissen Fundoplication



Technique: The current surgical standard

- *for virtually all GERD except severe esophageal dysmotility*
- Short (1-2cm), floppy, 360 degree laparoscopic fundoplication performed over a large bougie (>56 french)
- Short gastric vessels divided
- Closure of right and left crus

Laparoscopic Nissen Fundoplication

- Overnight stay required
- Modified diet for 4-6 weeks
- Excellent Long Term Results (11 yrs):
  - 85% patients off PPI
  - Improved Quality of life
  - High rates of patient satisfaction

Objective Follow-up: Normalization of esophageal pH

Author	# pts pH Negative	Follow-up (months)
Hinder	21/24 (87%)	3-12
Hunter	49/54 (91%)	12
Watson	42/48 (87%)	3
Peters	26/28 (93%)	21

Subjective Follow-up: Long-Term

Series	FU (yrs)	HB relief (%)	Revisions (%)	Off meds (%)
Morganthal (USA)	11.0	89	10.8	70
Dallemange (BEL)	10.3	96	1.4	92
Bammer (USA)	6.4	94	1.0	86
Lafullarde (AUS)	6.0	87	14.2	88
Anvari (CAN)	5.0	--	3.6	89
Booth (GBR)	4.0	90	6.3	86

Morganthal et al, J Gastrointest Surg 2007;11:693-700

Head to Head: Surgery versus PPI's

- **554 pts randomized to 2 arms(multi center)**
  - **288 standardized LNF**
  - **266 20mg esomeprazole (could be increased)**
- **No significant difference in remission rate between PPI (92%) and LNF (85%) at 5 years of follow-up**

Surgery versus PPI's

Symptom	LNF (180)	PPI (192)	P-value
Heartburn	8%	16%	0.140
Regurgitation	2%	13%	<0.001
Dysphagia	11%	5%	<0.001
Bloating	40%	28%	<0.001
Flatulence	57%	40%	<0.001

Conclusion: Laparoscopic Nissen Fundoplication

- Excellent control of both symptoms and acid control
- Operator dependent
- Associated with side effects
- Fundoplication is best applied to the individual with severe symptomatic reflux disease, and/or mild to moderate esophageal damage.

Update on GERD Treatment, Techniques, and Technology

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Objectives

- Discuss the evolving trends in reflux management
- Review the currently available laparoscopic and endoscopic treatments and identify their niche in the management of GERD

Why Do We Treat GERD?

1. Symptom control - patient QoL
2. Acid control - management or prevention of complications
    - Esophagitis
    - Stricture
    - Barrett's esophagus

Indications for Procedural Treatment of GERD

- Complicated GERD (Stricture, Aspiration)
- GERD refractory to medical therapy
- GERD requiring daily PPI for control of symptoms
  - Intolerance to PPIs
  - Concern about long-term effects

Why do we need new treatment approaches for GERD?

- Proton Pump Inhibitors
  - Most commonly used medications for GERD
  - High failure rate in pts w/ severe esophagitis
  - Requires continuous therapy, and may become less effective over time (30% have breakthrough sx)
  - Concern about cost and risk of osteoporosis and enteric infections

Why do we need new treatment approaches for GERD?

- Laparoscopic Fundoplication
  - Highly efficacious – normalizes acid exposure
  - Invasive procedure with GI side effects
    - Dysphagia, flatulence and Bloating

Typical GERD Patient in Surgery Clinic

- 2009:
  - Severe GERD with very poor symptom control
  - Large hiatal hernia
- 2015
  - Patient with mild/moderate GERD symptoms +/- hiatal hernia with concerns about costs and side effects of long-term PPI use

Endolumenal GERD Treatments

- Radiofrequency energy application – Stretta
- Transoral Fundoplication – EsophyX

Indications for Endoscopic GERD Therapy

- Mild to moderate GERD symptoms
- Responsive to PPI therapy
- Objective evidence of GERD (pH study)
- Absent to minimal (<2cm) hiatal hernia
- <u>Forget it if</u>:
  - Complicated GERD
  - Long-segment Barrett's esophagus
  - Previous gastroesophageal surgery

Stretta: Procedure

- EGD with identification of GE junction
- Placement of catheter above GEJ
  - Rf Application, 45 degree rotation
  - 8 applications, 2 below, 6 above GE jxn
- Total time about 30 minutes
  - Outpatient
  - Under sedation in the GI suite

Summary of Stretta Outcomes

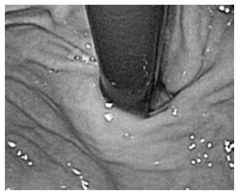
- Median drug requirement:
  PPI bid (baseline)→prn antacids (follow-up)
- Improvement in symptom scores and disease specific quality of life
- Acid exposure improved, but not normalized
- Low incidence of side effects
- Long-term data emerging with sustained efficacy in small cohort studies (8-10 years)

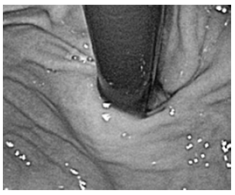
Stretta Conclusions

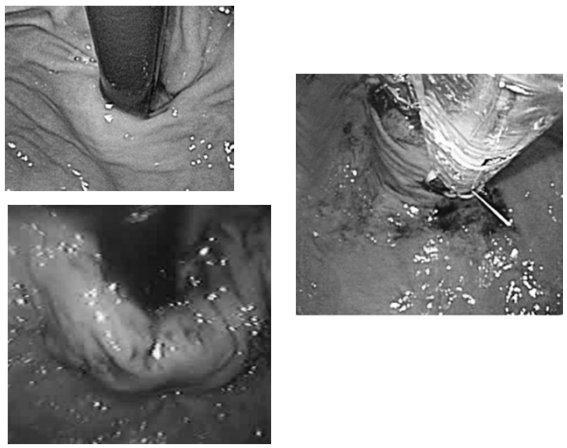
- Efficacy inferior to that achieved with fundoplication
- Relatively inexpensive outpatient procedure
- May represent a good option for patients with symptoms well controlled with medication but are:
  - Intolerant of PPIs
  - Concerned about long-term effects of PPI use
- Long-term data are needed to establish the cost-effectiveness of this approach

Transoral Fundoplication

- Over-the-scope device
- 45 - 60 minute procedure
- General anesthesia
- 14-20 transmural fasteners
- Overnight stay
- Post-op discomfort minimal
- Rapid recovery







Summary of TF Outcomes

- 2 RCT, several cohort studies
- Improved GERD symptoms and disease specific QoL at 6 mo (up to 3 yrs in cohort studies)
- Improved control of regurgitation symptoms compared to PPI therapy in sham controlled RCT
- Reduction in PPI use
- Esophageal perforations and GI bleeding have been reported
- Low incidence of GI related side effects

TF Conclusions

- Effectively reduces GERD symptoms in select patients
- Low incidence of side effects, but does not consistently normalize esophageal pH
- RCT data emerging to solidify efficacy of this procedure
- Expensive

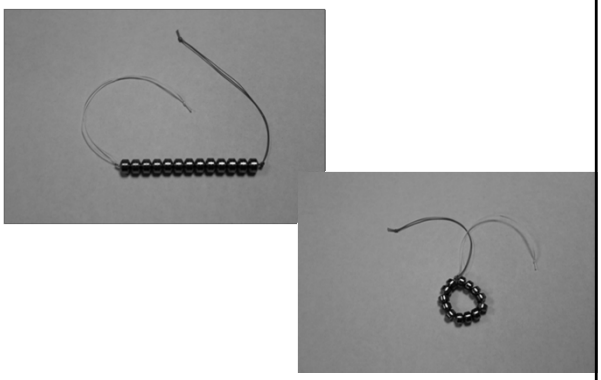
Endolumenal Therapy Conclusions

- Generally less efficacious, but with more favorable side effect profile compared to LNF
- May find a role for management of patients with symptoms well controlled with daily PPI and minimal or no hiatal hernia
- Need to achieve adequate efficacy at a relatively low cost to gain wider acceptance

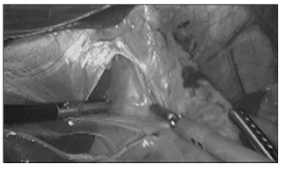
Linx: Technique

- **4 port laparoscopy – Similar to LNF**
- **Minimal dissection at the hiatus**
- **Device placed between the esophageal wall and posterior vagus nerve**

Linx: Device



Linx: Technique



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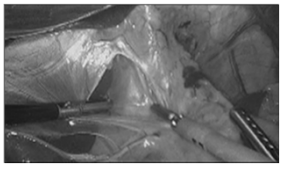

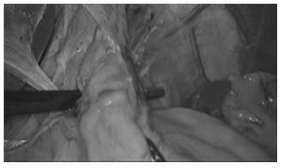

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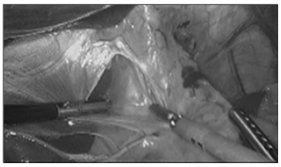

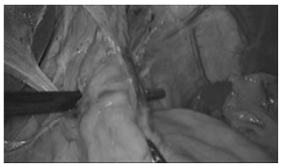

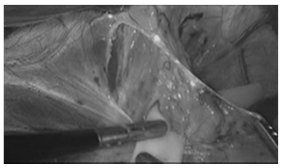

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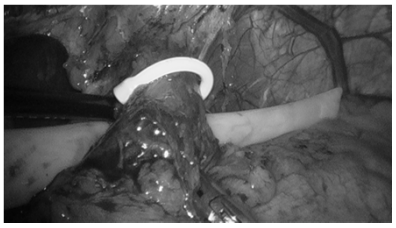

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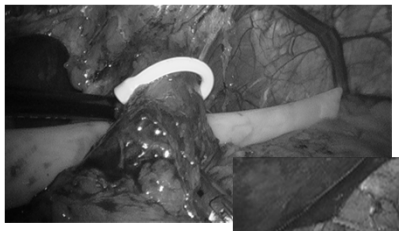
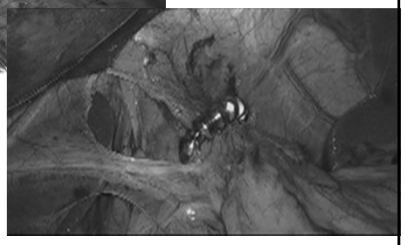
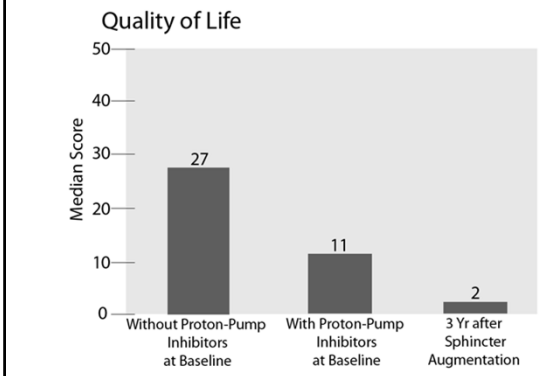




Linx: Results

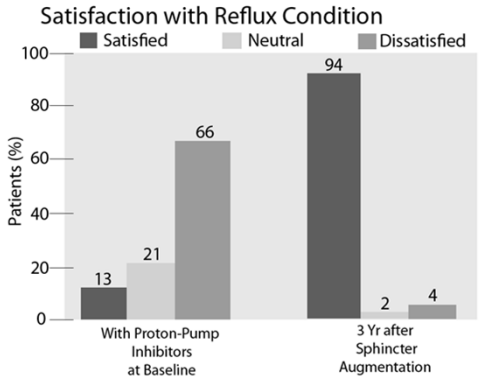
- 100 patients with 3 year follow up
- Primary endpoint - pH reduced by 50%
  - Achieved in 64%
  - pH normalized in 58%
- Secondary Endpoints
  - Symptom control
  - Quality of Life/Satisfaction
  - Complications

Linx: Results



Ganz et al. N Engl J Med 2013;368:719-727.

Linx: Results



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Linx: Complications/Side Effects

- **Dysphagia in 68%**
  - **Moderate to severe in 21%**
  - **3% required device removal**
- **Bloating – 14% (almost all mild)**
- **6 devices removed**
  - **3 for dysphagia**
  - **1 each for pain, emesis, and persistent symptoms**

Linx: Potential Advantages

- **Easy to standardize procedure**
- **Potential for durable GERD relief**

Linx: Questions

- **Durability**
  - **Erosion?**
- **Cost-benefit analysis**

GERD Treatment Strategy

- **Symptoms well controlled with PPI**
  - **Medical acid suppression**
  - **May consider Stretta in select patients**
- **Breakthrough symptoms without HH**
  - **Consider stretta, TF, Linx, LNF**
- **Breakthrough symptoms with small HH**
  - **Consider Linx, LNF**
- **Large HH or Complicated GERD → LNF**