



# GERD Diagnosis Work-up & Patient Selection

Date/Place/Instructor

## **SAGES Guidelines for Surgical Treatment of Gastroesophageal Reflux Disease (GERD)**

Diagnosis of GERD is confirmed if at least one of the following exists:

- Mucosal break on endoscopy in a patient with typical symptoms
  - (Lundell, 1999)
- Barrett's esophagus on histology
- Peptic stricture in the absence of malignancy
- Positive pH-metry
- Multichannel Intraluminal Esophageal Impedance

## Anti-Reflux Surgery Indications

### Surgeon's View

Surgery should be **considered** if **at least one** of the following exists:

- Failure of medical management
- Fear of long term side effects of PPIs
- Patient's preference
- Complications of GERD (Barrett's, peptic stricture)
- Extra-esophageal manifestations

### Gastroenterologist's View

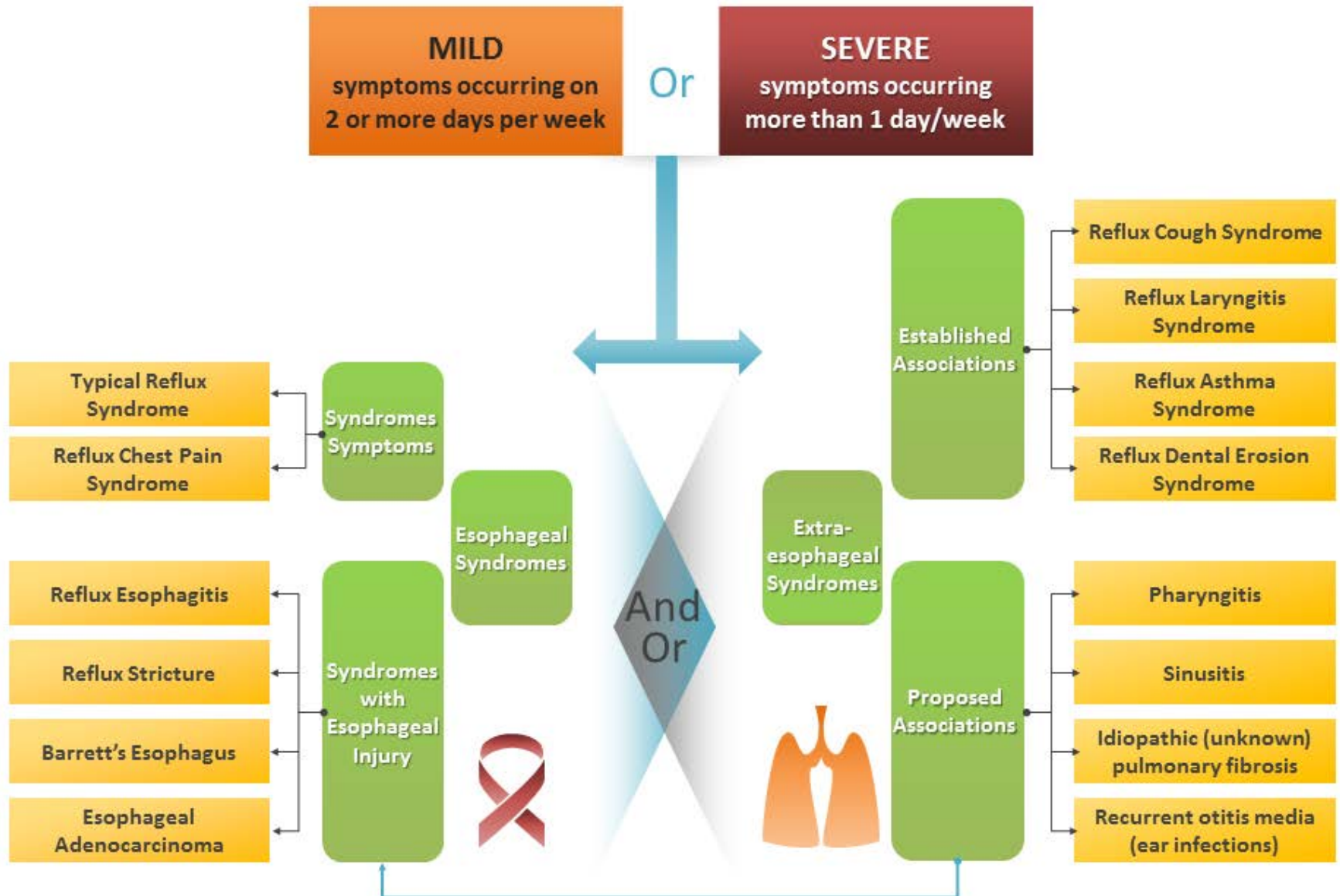
Surgery should be **considered** if **at least one** of the following exists:

- Intolerance to PPIs
- Persistent troublesome symptoms while on properly adjusted doses of PPI's – as defined by the Montreal Consensus

*SAGES Guidelines for Surgical Treatment of Gastroesophageal Reflux Disease (GERD)*

*AGA Medical Position Statement on the Management of Gastroesophageal Reflux Disease (GERD)*

## Montreal Definition: Troublesome Symptoms

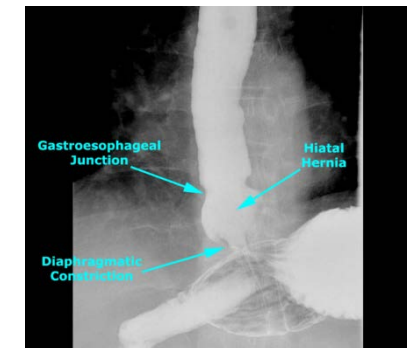
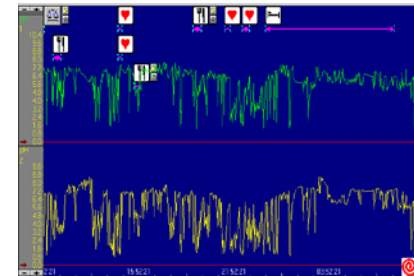
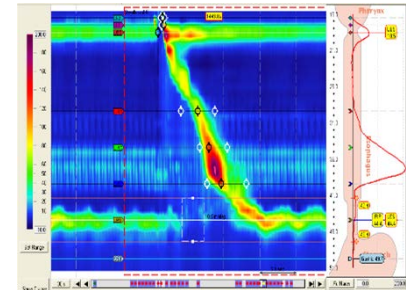


## Approach to Anti-Reflux Surgery Work-up

### Preoperative investigation goal:

Select the appropriate reflux patients to optimize outcomes.

1. **EGD:** All patients. Confirm the diagnosis of GERD, identify esophagogastric mucosal abnormalities, allows for biopsy.
2. **pH-metry:** Important when diagnosis of GERD not confirmed on EGD or when uncertainty exists.
3. **Manometry:** Identify conditions that might contraindicate fundoplication.
4. **Barium swallow (UGI):** Test for better delineation of the anatomy.



*Am. J. Gastroenterology, 2006, 101:1900-1920*

## Approach to Anti-Reflux Surgery Work-up

*Consider using other tools in assessing patients:*

### Questionnaires:

GERD-HRQL, RSI, GERSS, RDQ.

May be useful in showing quality of life changes after antireflux surgery.

### GERD Health-Related Quality of Life (GERD-HRQL) Questionnaire

**Scale:**  
 0=No Symptoms 1=Noticeable, but not bothersome 2=Noticeable, bothersome, but not every day  
 3=Bothersome daily 4=Bothersome and affects daily activities 5=Incapacitating to do daily activities

**Questions (circle one):**

How bad was the heartburn? 0 1 2 3 4 5

Heartburn when lying down? 0 1 2 3 4 5

Heartburn when standing up? 0 1 2 3 4 5

Heartburn after meals?

Does heartburn change your diet?

Does heartburn wake you from sleep?

Do you have difficulty swallowing?

Do you have pain while swallowing?

Do you have gassy or bloating feeling?

If you take reflux medication, does this affect your daily life?

**TOTAL SCORE (enter total here: 50 points)**

How bad is the regurgitation?

Regurgitation when lying down?

Regurgitation when standing up?

Regurgitation after meals?

Does regurgitation change your diet?

Does regurgitation wake you from sleep?

How satisfied are you with your current condition?

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Are you currently taking any medication for GERD?

Please circle any of the medications you are taking:

Nextium Prilosec Provacid Aciphex

Your first and last name: \_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

WORLDG-CIC, Milwaukee, WI (2007). The development of the GERD-HRQL questionnaire is a trademark of EndoGastric Solutions, Inc.

### Reflux Symptom Index (RSI) Questionnaire

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

Before TIF Surgery:  After TIF Surgery:  How long? \_\_\_\_\_ Months after TIF

On GERD Medication  How Often: Twice Daily  One Daily  Occasionally

Off GERD Medication

Questions below inquire about the presence and severity of your symptoms, their affect on your daily activities, and your satisfaction with your current health condition. Please answer **every** question using the scale below by putting an **x** in only **one** response that best describes how you have felt in the last 7 days. Questionnaires with even one missing response will not be considered valid.

Correct:  0  1  2  3  4  5

Incorrect:  0  1  2  3  4  5

**Definition:**  
 Heartburn - Representing discomfort or burning sensation behind the chestbone

**Scale:**  
 0=No Symptoms 1=Noticeable, but not bothersome 2=Noticeable, bothersome, but not every day  
 3=Bothersome daily 4=Bothersome and affects daily activities 5=Incapacitating to do daily activities

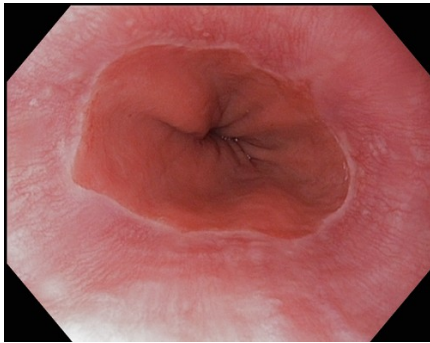
	None					Severe						
	0	1	2	3	4	5	0	1	2	3	4	5
Hoarseness or a problem with your voice?												
Clearing your throat?												
Excess throat mucus or postnasal drip?												
Difficulty swallowing foods, liquids, or pills?												
Coughing after you ate or after lying down?												
Breathing difficulties or choking episodes?												
Troublesome or annoying cough?												
Sensation or something sticking or a lump in your throat?												
Heartburn, chest pain, indigestion, or stomach acid coming up?												
Upper abdominal bloating, distention?												
Excess flatulence?												
*Subtotals (for physician use)												
**Total (for physician use) <input style="width: 50px;" type="text"/>												

\*Subtotals are calculated by adding up all the scores in respective columns.  
 \*\* Total is calculated by adding up all the subtotal scores.

## Pre-operative Work-up

### *Esophagitis – LA Classification*

Grade A



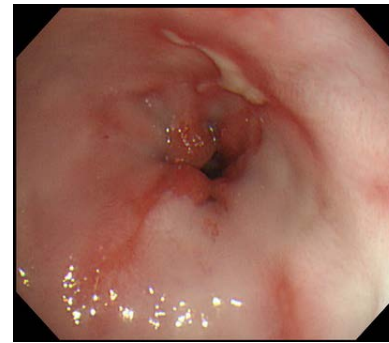
One or more mucosal breaks <5mm in maximal length

Grade B



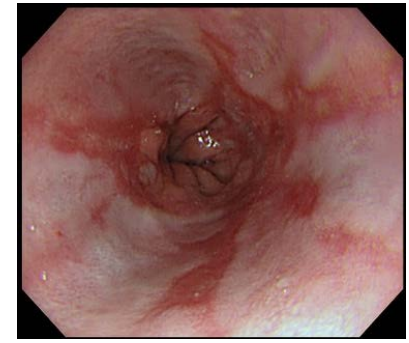
One or more mucosal breaks > 5mm, but without continuity across mucosal folds

Grade C



Mucosal breaks continuous between more than 2 mucosal folds, but involving less than 75% of the esophageal circumference

Grade D



Mucosal breaks involving more than 75% of esophageal circumference

*Lundell, et al. (1999) Endoscopic assessment of oesophagitis, Gut 45, 72-80*  
*Bell, et al. (1999) Patterns of success and failure with laparoscopic Toupet fundoplication, Surg Endosc 13: 1189-1194*

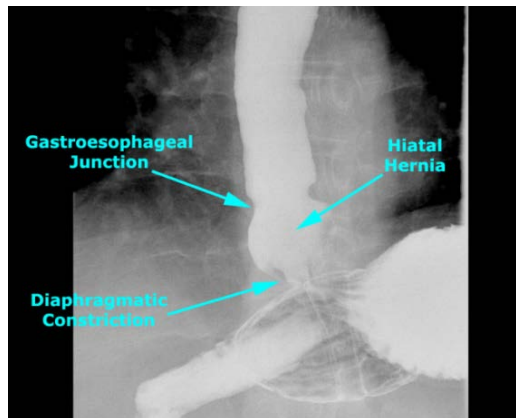
## Pre-operative Work-up

### *Assessing Hiatal Hernia*



#### **Straight Scope**

Axial height from Z-line to Diaphragmatic pinch



#### **Barium Swallow**

Axial height from diaphragm to Uppermost gastric folds



#### **Retroflex Scope**

Width measured using known scope diameter as a reference



## Pre-operative Work-up

### *Evaluating Hill Grade*

Grade I



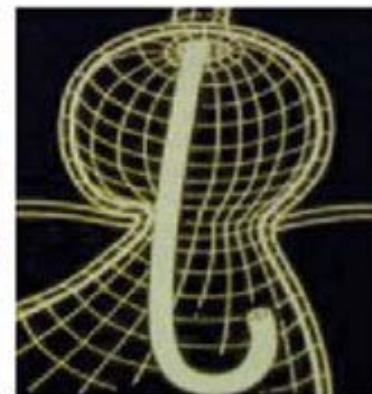
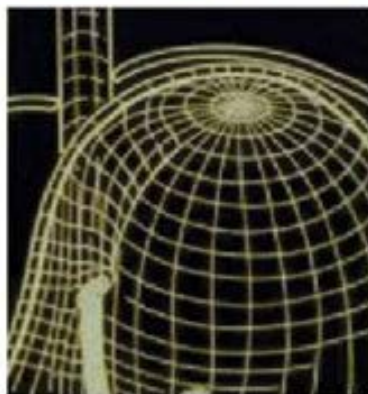
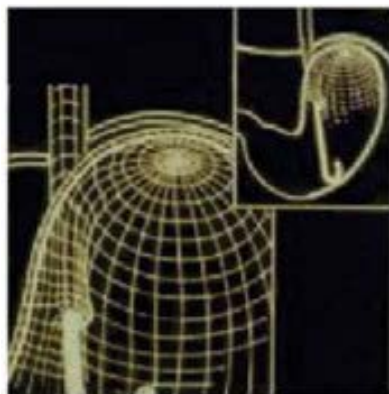
Grade II



Grade III



Grade IV



Normal edge of tissue closely approximated to the scope

Ridge is slightly less well defined and opens with respiration

Ridge is effaced and the hiatus is patulous

Hiatus is wide open at all times and displaced axially

## Hill Grade II – Endoscopic and Laparoscopic

### *Evaluating Hill Grade*



## Hill Grade III – Endoscopic and Laparoscopic

### *Evaluating Hill Grade*



## Special Considerations

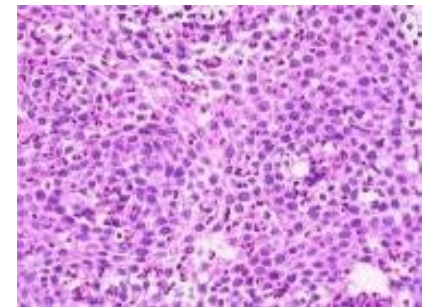
### *Recognize the following:*

1. Eosinophilic Esophagitis
2. Morbid Obesity
3. Motility disorders
4. PPI Non-Compliant vs. Non-responder

## Special Considerations

### *Eosinophilic Esophagitis*

- Should not perform TIF on this patient
- Mucosal rings on EGD
  - Corrugated « feline » esophagus
  - >20 eos/HPF (usually >40)
- GERD esophagitis
  - <10 eos/HPF
  - Distal involvement

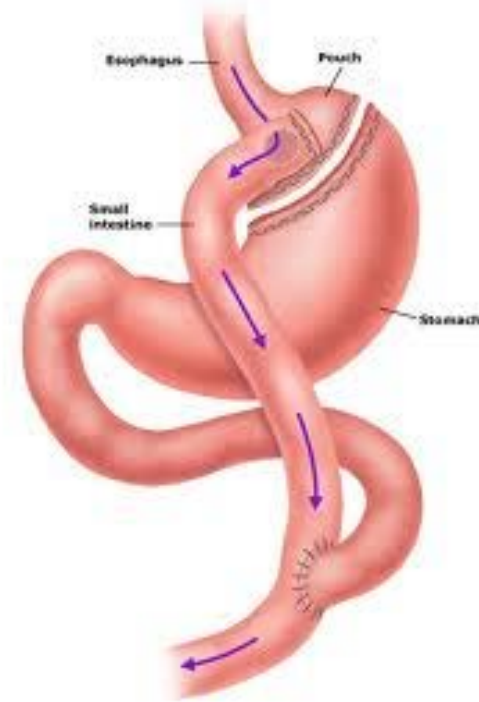


## Special Considerations

### *Morbid Obesity and GERD*

There is a clear association between GERD and morbid obesity with the disease being more prevalent as the body mass index (BMI) increases.

- Association between morbid obesity and GERD
  - El-Serag H (2008), Patti M (2009)
- Higher failure rates of LNF for BMI>30
  - Smith C (2007), Rattner D (2007)
- Obesity: a challenge to esophagogastric junction integrity
  - Pandolfino JE (2006)
- For BMI > 35:
  - Laparoscopic R-Y Gastric Bypass is THE procedure of choice
  - Shauer P (2002), Swanstrom (2003)
- Lap- Band may improve GERD symptoms;
  - Mixed results, not the procedure of choice



## Special Considerations

### GERD and Motility Disorders

- **Gastric Emptying Study:**
  - May provide another piece of information in assessing the foregut as a system.
- **Gastroparesis:**
  - Believed to adversely affect postoperative outcomes

### However...

Large prospective non-randomized trial  
(*Wayman, Br J Surg, 2007*)

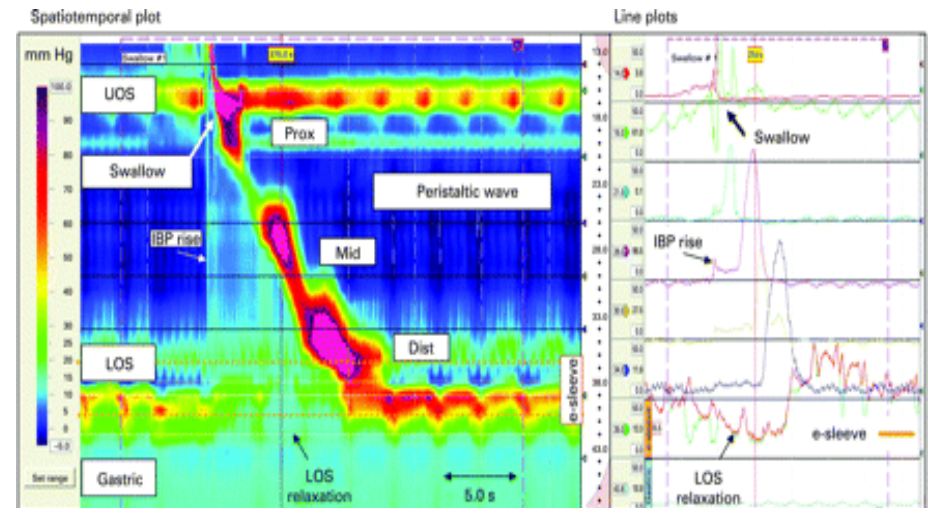
1. No correlation between delayed emptying and postfundoplication outcomes.
2. Recognize and treat pre-operatively with pro-motility agents.



## Special Considerations

### GERD and Motility Disorders

- **Esophageal hypomotility:**
  - Cut-off is distal amplitude of 30mmHg – required to overcome resistance of Nissen wrap
  - (*DeMeester, Castell*)
- No support in literature for the tailored approach
- Low LES not a requirement
  - (*Patti, 2003*)
- Absolute contraindications:
  - Scleroderma
  - Achalasia
  - Nutcracker esophagus





## Special Considerations

### *PPI Non-compliant vs Non-responder*

#### **PPIs as Predictors of Operative Success?**

- Pre-operative non-compliance with medical treatment:
  - Lesser post-operative improvement in Quality of Life Index
  - Higher rate of post-fundoplication dysphagia at 1 year  
*(Kamolz T, 2003)*
- Symptomatic response to pre-operative PPI's:
  - Excellent predictor of good response to fundoplication
  - HOWEVER:
    - Non-response is not a contra-indication *(Wilkerson, 2005)*
    - Role of combined pH/Impedance studies while on PPIs

## Patient Selection

### *GERD Treatment Goals*

- What are your goals or expectations in addressing GERD patients surgically?
- What expectations do you set for your patients?
- What is success for you?
- What is success for your patient?

## Patient Selection

### *Right patient for the TIF procedure?*

- Which patients respond best to treatment?
- I'm used to seeing severe GERD...which 'moderate' patients am I looking for in reference to the TIF procedure?
- I'm looking for the right patient for TIF procedure.

## Surgical Therapy Considerations

### *SAGES Guidelines for Surgical Treatment of Gastroesophageal Reflux Disease (GERD)*

**When diagnosis of reflux is objectively confirmed, surgical therapy should be considered in individuals who:**

1. Have failed medical management (inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side of effects.

**or**

2. Opt for surgery despite successful medical management (due to quality of life considerations, lifelong need for medication intake, expense of medications, etc.

**or**

3. Have complications of GERD (e.g., Barrett's esophagus, peptic stricture)

**or**

4. Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pain, aspiration)

## Who Are Candidates for the TIF procedure?

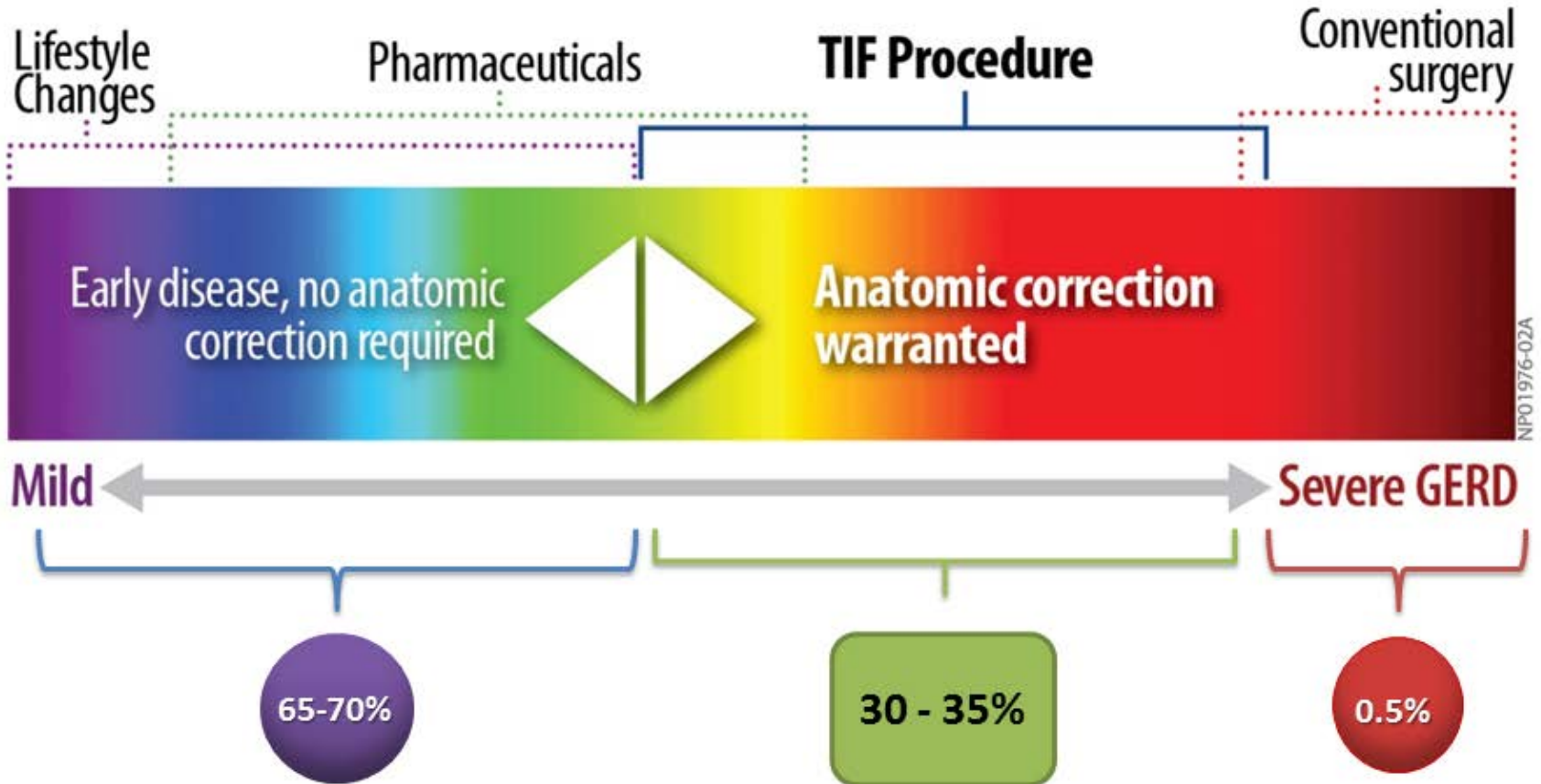
### *Success depends on...*

- Do all patients that are qualified for surgery respond the same?
- 10-20% of U.S. population with chronic GERD
- The simple answer:
  - SAGES indications for antireflux surgery
    - Objective documentation of GERD
    - Failed medical management
    - Patient opts for surgery
    - Complications from GERD
    - Extraesophageal symptoms
    - HH less than or equal to 2cm in size (Transverse and Axial)



## GERD Symptom and Treatment Continuum

Of the ~6.7M uncontrolled GERD sufferers, <30K elect surgery  
(due to invasiveness, high complication rates and side-effect profile)



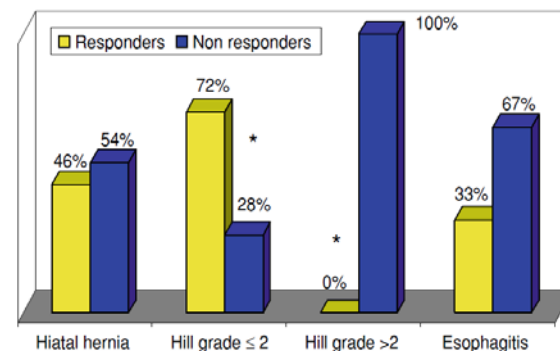
Reference: Reavis KM, Perry KA. Expert Rev Med Devices. 2014 Jul;11(4): 341-50.  
Subramanian, CR and Triadafilopoulos G. Refractory gastroesophageal reflux disease. Gastroenterol. Rep. (2015) 3(1): 4153.

## EsophyX Indications for Use

EsophyX<sup>®</sup><sub>2</sub> device with SerosaFuse<sup>®</sup> Fasteners and accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia  $\leq 2\text{cm}$  in size in patients with symptomatic chronic gastroesophageal reflux disease.

## Who Responds to TIF?

- Anatomic and disease related factors affecting outcomes
  - Pre-op occurrence and size of HH
  - Pre-op Hill Grade  $\leq$  II
  - Patients w/o complicated esophagitis
  - BMI
- Specific symptoms are not a limiting factor
  - Positive effect on typical symptoms
  - Positive effect on atypical symptoms
- Takeaway: Outcomes dependent on anatomical factors, not on type of symptom



Testoni *World J Surg* 2010



## TIF and Atypical Symptoms

## US TIF2.0 Results

	Bell	Barnes	lhde	Trad
	6 (3-14) mo n=33/37 <sup>1</sup>	7 (5-17) mo n=110/124 <sup>2</sup>	6 (1-11) mo n=42/48 <sup>3</sup>	14 (3-29) mo n=28/34 <sup>4</sup>
Heartburn GERD-HRQL scores $\geq$ 50% improved	80%	80%	79%	86%
Regurgitation Scores $\geq$ 50% improved	80%	75%	71%	75%
Atypical Symptoms RSI scores $\geq$ 50% improved	72%	79%	78%	79%
Off daily PPIs	81%	97%	76%	82%
pH Normalization Acid exposure/refluxates	61% / 89%	-	-	-
Satisfaction Health condition per GERD-HRQL	66%	83%	64%	68%

<sup>1</sup> Bell & Freeman (2011) *Surg Endosc* 25;1975-84<sup>3</sup> lhde et al (2011) *Am J Surg* doi :10.1016/j.amjsurg.2001.06.035<sup>2</sup> Barnes et al (2011) *Surg Innovation* 18(2) 119 –129<sup>4</sup> Trad & Turgeon (2011) *Surg Endosc* doi :10.1007/s00464-011-1932-6

## TIF procedure – Lessons Learned

### *Studies help to direct us to the right patients*

- In a 3yr study, 11 of 12 failures requiring revision showed baseline GEJ Hill Grade III or IV with a Hiatal Hernia present.
  - Muls et. al. (2012)
- Abnormal esophageal motility present in almost all non-responders.
  - Testoni (2011)
- Esophagitis at screening was a predictor for treatment failure.
  - Witteman et. al. (2012)
- Sudden increase in intra-abdominal pressure early post-op may predispose patient to anatomical failure of fundoplication. (level III)
  - Iqbal et. al. (2006)
- Hiatal Hernia's >3cm at original operation. (level II)
  - Iqbal et. al. (2006)

## TIF procedure – Lessons Learned

### *Contraindications*

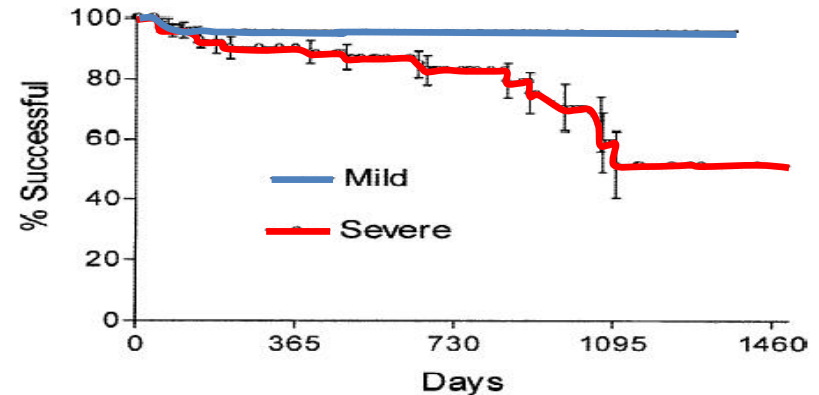
#### **Patients with:**

- Bleeding disorders
- Strictures
- Severe esophagitis
- Esophageal diverticulae
- Obstructions
- Paraesophageal hernia
- Limited neck mobility
- Any kind of normal or abnormal esophageal anatomy which would not permit insertion of a device
- Osteophytes of the spine
- Esophageal varices
- Esophageal infections or fungal disease
- Esophageal stenosis
- Chronic cough
- BMI > 35
- Hiatal hernia > 2cm

## Summary

### What have we learned?

- Milder patients
  - Non-complicated esophagitis
  - Hill Grade I-II
  - Normal esophageal motility
- Moderate patients
  - LA Grade C
  - Hill III
  - Multi-modality management vs. more invasive procedures
- PPI responders
  - EGS FDA clearance
  - Does not necessarily exclude non-responders
- Hiatal hernia  $\leq 2$  cm
  - EsophyX Indications for Use
  - SAGES Guidelines
- BMI  $\leq 35$



## Success?

### *Conclusion*

- Well selected patients = success with the TIF procedure

*TEMPO Abstract published in Gastroenterology (Trad et al, 2013)*

Questions?



**THANK YOU!**