Refractory GERD, Optimize Medical Therapy or Refer to Surgery

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Chair and Past-President, American Foregut Society

Foregut Consulting LLC

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Debate or Dialectic?

- Debate
  - A competition where the goal is to change someone's mind by force of argument. There must be a winner and loser.
- Dialectic
  - An rational exercise in which two people with different points of view discuss a topic to find the truth through reasoned argumentation. The goal of dialectic is to resolve disagreements through reason and reach a compromise or synergy that improves on both positions.
  - Dialectic excludes subjective elements like emotional appeal and rhetoric.
  - Gradual changes lead to turning points.

Refractory GERD, HOW TO Optimize Medical Therapy AND WHEN TO Refer to Surgery

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Two people with different points of view

- Yep.....

- Okay. And I won't say that Mike is
  - ~~Psychotic~~
  - ~~Blind to the Truth~~
  - ~~Weird~~
- ~~Even if he is~~

- So I’ve been fortunate enough to be involved in studies that have tried to understand WHEN TO.
- I’d like to share that journey with you because I admire the expertise of the GI and Surgeon Co-Authors that I’ve learned from.
- They’re pretty good at this.
- (And so is Mike)

Original Article

American Foregut Society Cooperative White Paper on Mechanisms of Pathologic Reflux and Antireflux Surgery

Foregut
1–11

DOI: 10.1177/26345161241276454
journals.sagepub.com/home/gut
Sage

Ninh T. Nguyen[1], Barham Abu Dayyeh[2], Kenneth Chang[1], John Lipham[3], Reginald Bell[4], Francis Paul Buckley[5], Christy M. Dunst[6], Ravinder K. Mittal[7], Nirav Thosani[8], Brant K. Oelschlager[9], Marcelo W. Hinojosa[1], Vitor Brunaldi[2], Rena Yadlapati[7], and Peter J. Kahrilas[10]

... “the dominance of a defective antireflux barrier as a primary pathophysiologic determinant differs widely, being greater for entities with mucosal damage and non- erosive reflux disease with quantitatively abnormal esophageal pH-metry.

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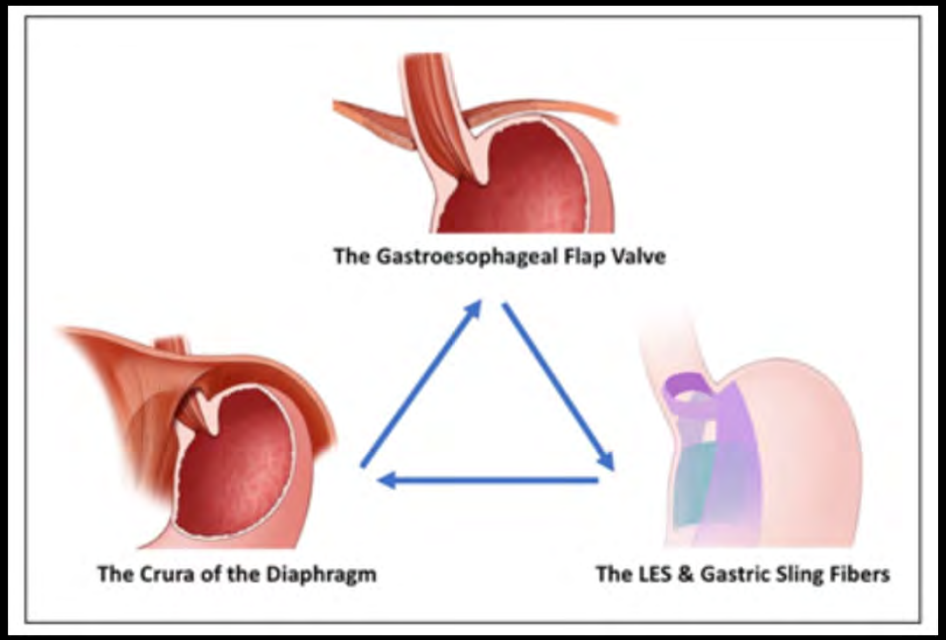

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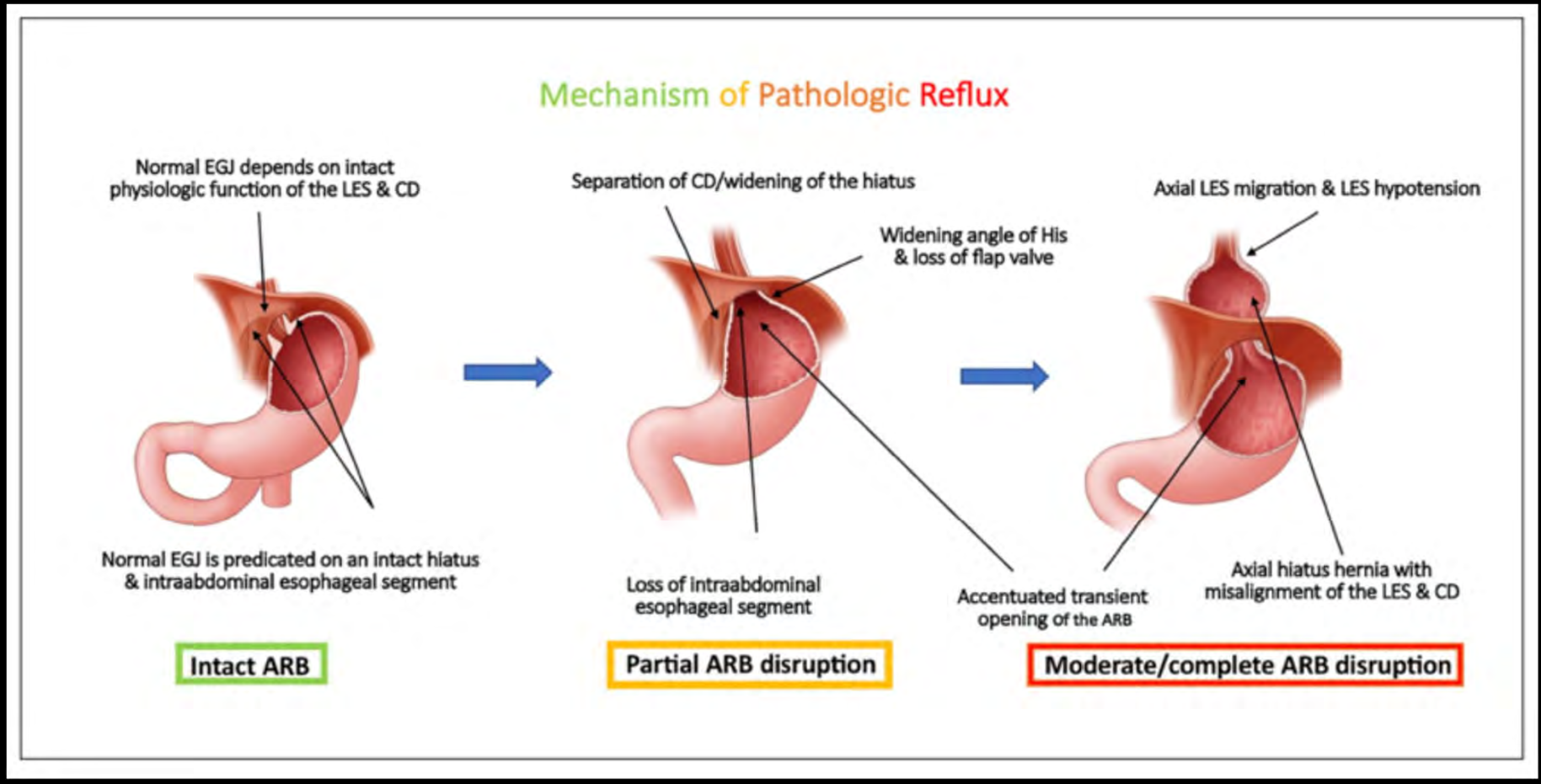

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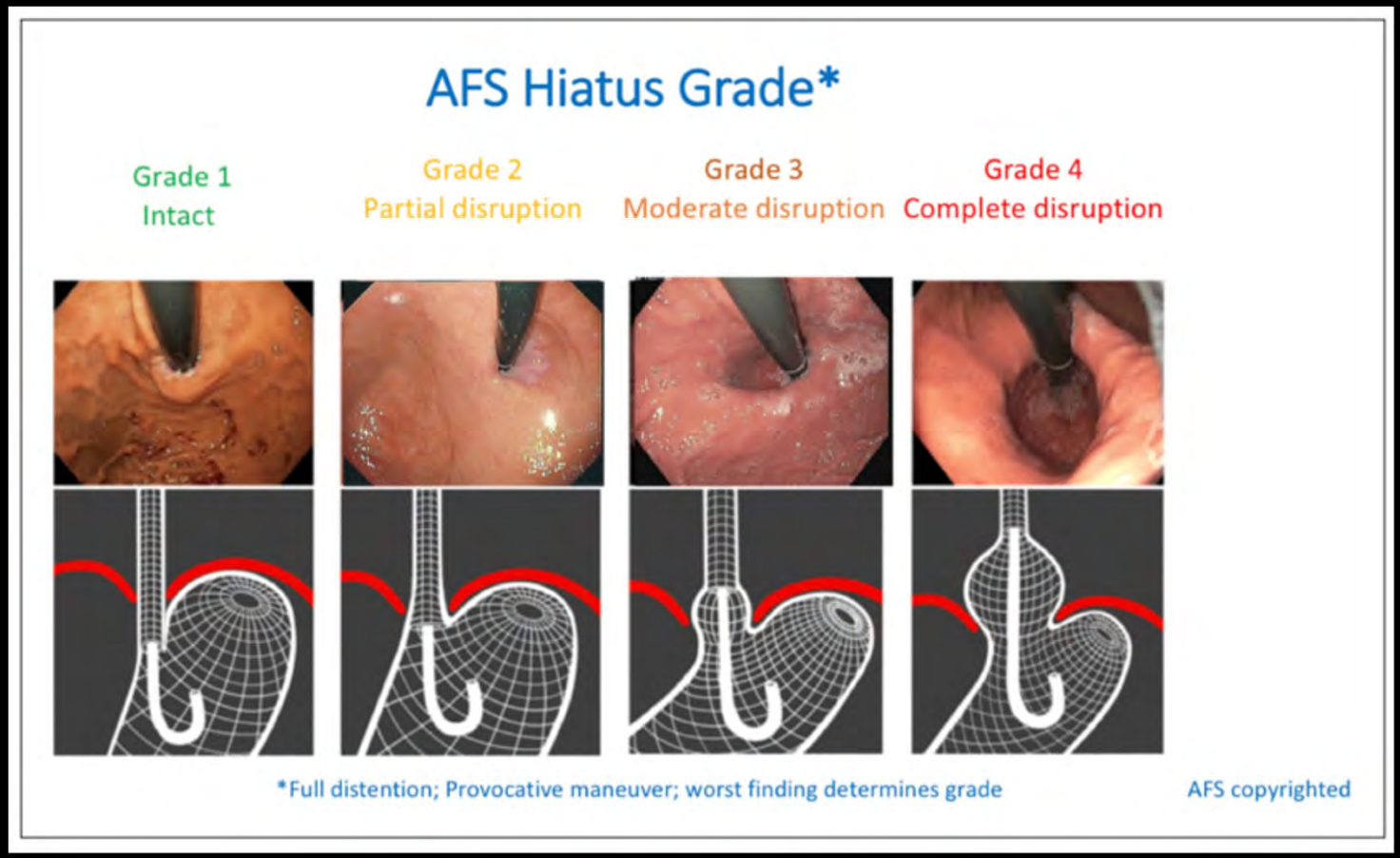
Length of axial herniation

Diameter of hiatus

Flap Valve



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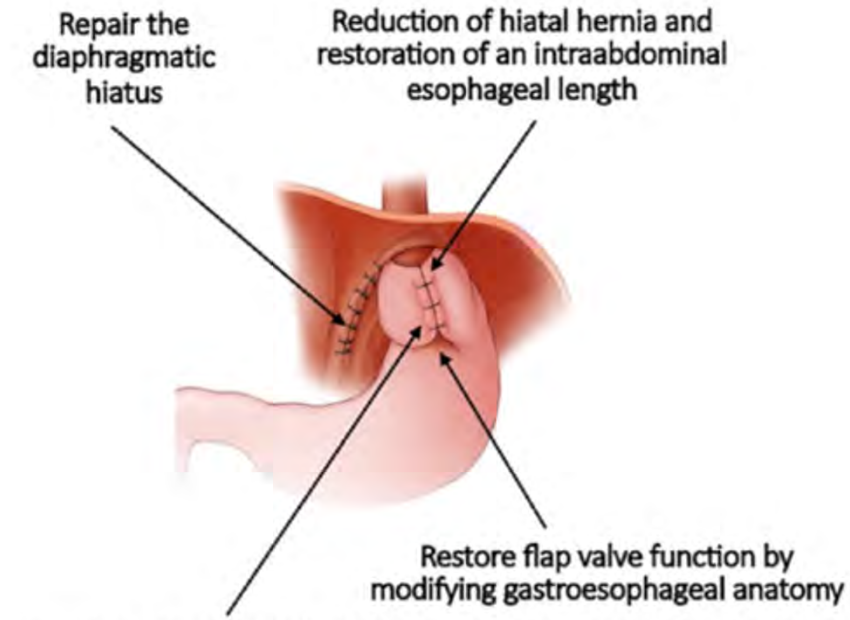
Factors by which ARS restore competence of the ARB



Antireflux surgery

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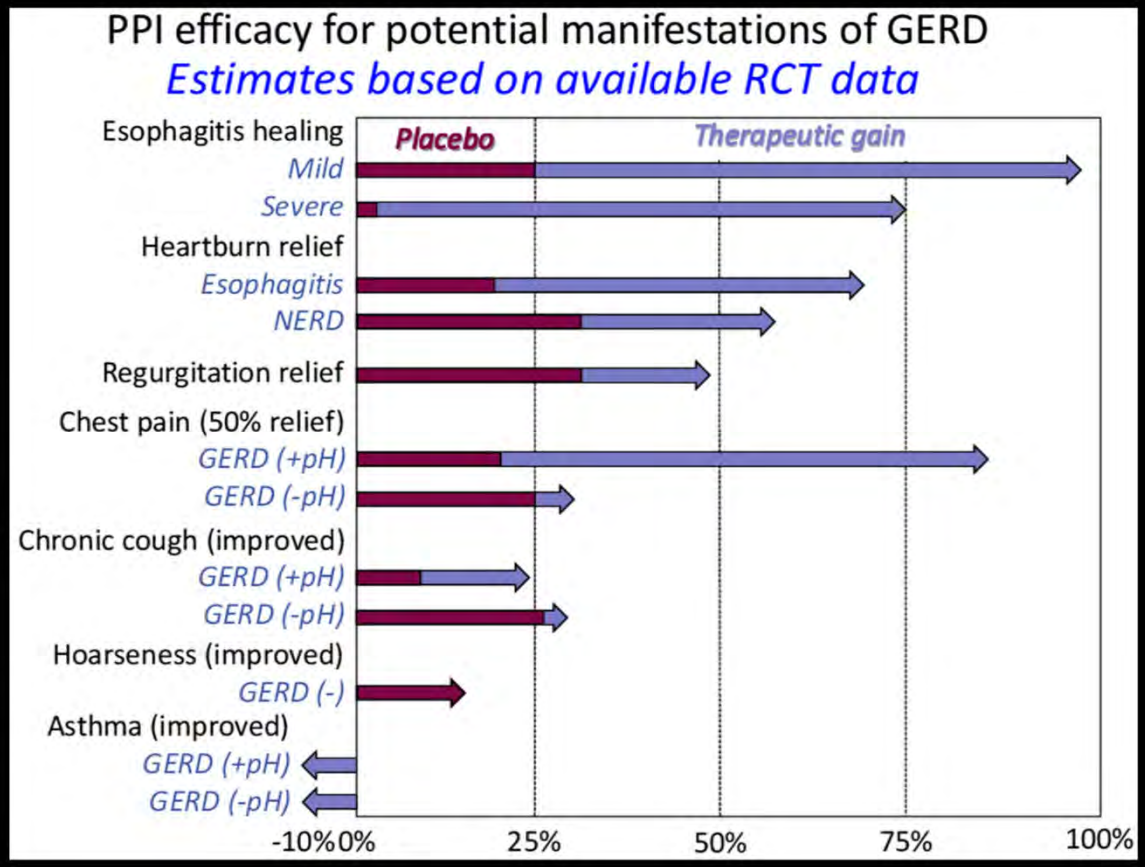
Factors by which PPIs restore competence of the ARB

Sorry Mike

Efficacy of PPI Therapy for GERD



Symptomatic reflux disease: the present, the past and the future
Guy Boeckxstaens, Hashem B El-Serag, André J P M Smout, Peter J Kahrilas
Gut.bmj.com
2015

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So….Why Not Operate on Everyone?

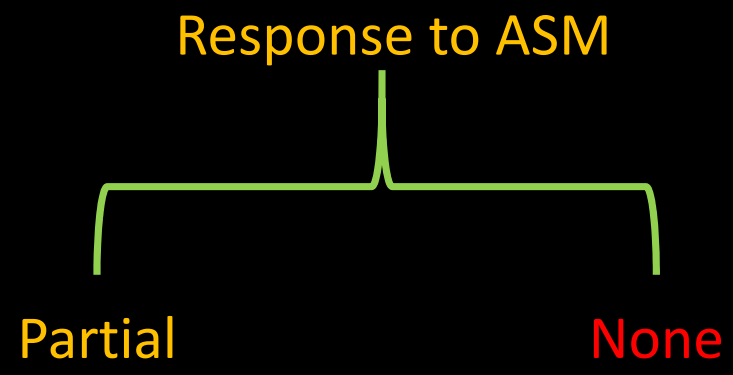
Or at least everyone with

- objective evidence of GERD
- a hiatal hernia?

So….Why Not Operate on Everyone with Objective evidence of GERD and a Hiatal Hernia?

- If operating for refractory symptoms – these symptoms may not be due to GERD.
- Surgery fails (miserably?)
- Surgery has side effects and can f--- up patient's lives
- It's a reconstructive procedure based on physiology and it's hard to find a good surgeon.

So the more common scenario is ongoing symptoms despite medical therapy.



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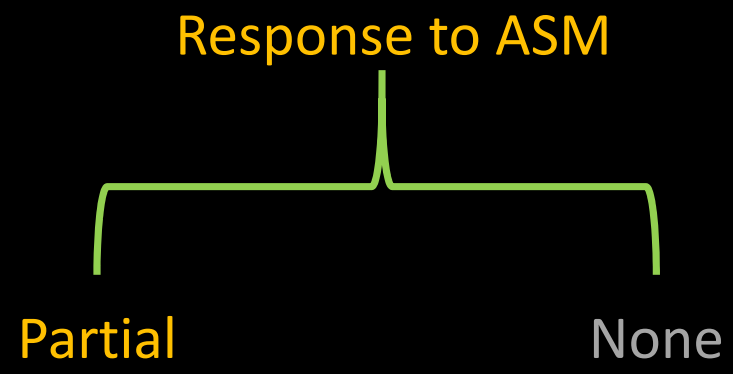
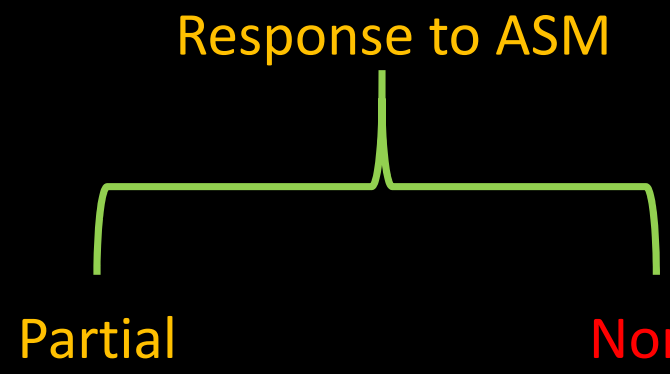


Easier to ascribe the symptoms to GERD

Taking a patient uncontrolled on medical therapy to controlled on medical therapy has not been an endpoint of clinical trials - but should probably be considered a therapeutic success.

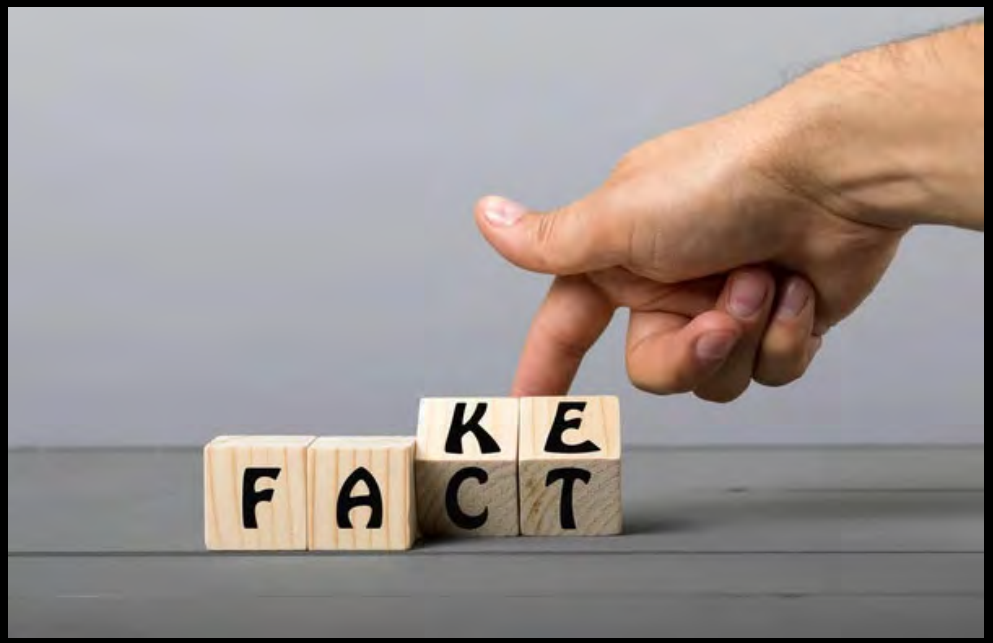
Procedures with lower success rates may be a reasonable option when less invasive.



There is an old adage that patients who do not have some response to PPIs are not candidates for antireflux procedures.

No Response to Meds: No Surgery!

How true is this?



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To begin with:

for regurgitative symptoms, complete absence of response to PPIs does not portend a bad outcome from surgery.

RCT of bid PPI v MSA in refractory regurgitation

- Patients with moderate-severe regurgitation despite qd 20mg omeprazole.
- 2:1 to bid 20mg omeprazole v MSA.
- Primary endpoint relief of moderate-severe regurgitation at 6 months

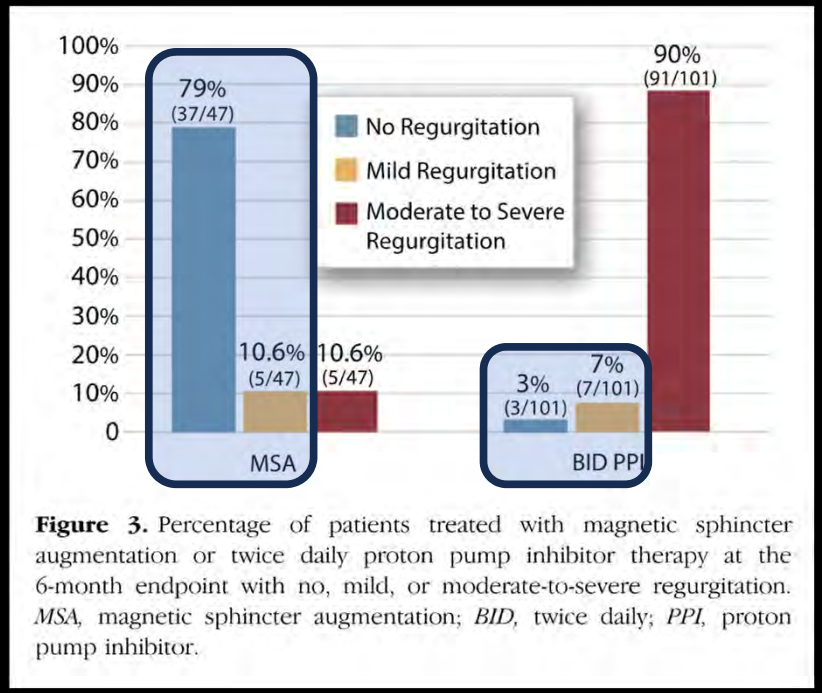

Figure 3. Percentage of patients treated with magnetic sphincter augmentation or twice daily proton pump inhibitor therapy at the 6-month endpoint with no, mild, or moderate-to-severe regurgitation. *MSA*, magnetic sphincter augmentation; *BID*, twice daily; *PPI*, proton pump inhibitor.

Bell et al, GIE 2019

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Sorry Mike

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And It Applies to Heartburn as Well in Regurgitation-Predominant GERD

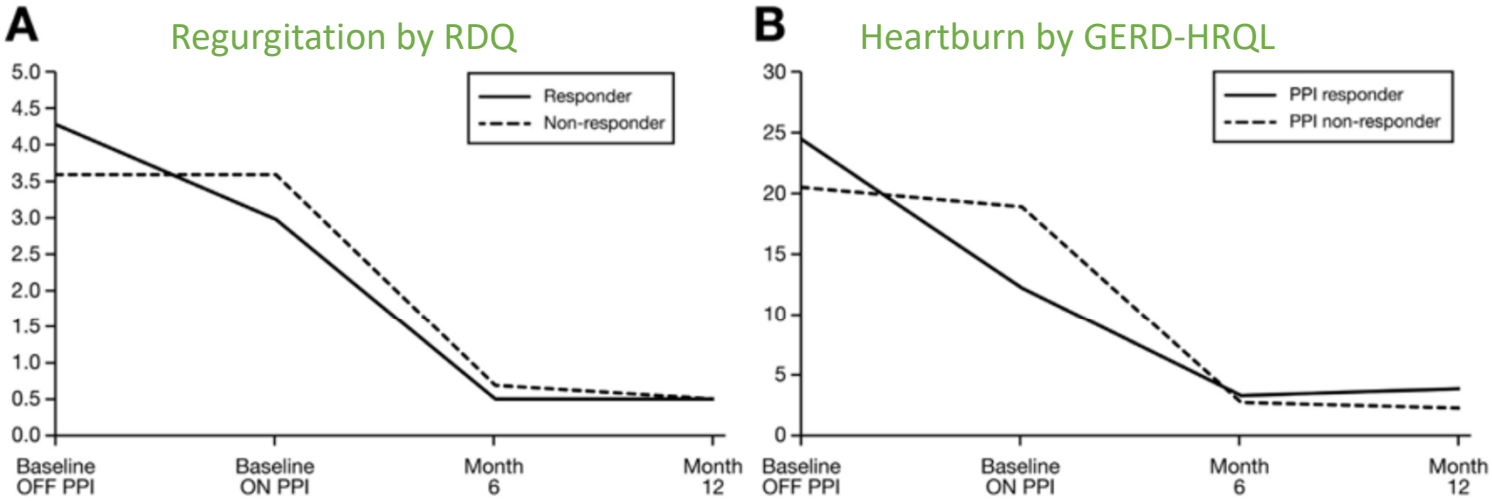

Figure 3. (*A*) Regurgitation and (*B*) heartburn scores for magnetic sphincter augmentation (MSA) patients by response to proton pump inhibitors (PPIs) at baseline. Responder is defined by having at least a half standard deviation change between on and off gastroesophageal reflux disease medication scores at baseline, compared with baseline, 6-month, and 12-month follow-up ($P < .001$) and nonresponders with responders at 6 and 12 months ($P > .28$) in all cases.

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Surgical and endoscopic management options for patients with GERD based on proton pump inhibitor symptom response: recommendations from an expert U.S. panel

Andrew J. Gawron, MD,[1] Reginald Bell, MD,[2] Barham K. Abu Dayyeh, MD,[3] F. P. Buckley, MD,[4] Kenneth Chang, MD,[5] Christy M. Dunst, MD,[6] Steven A. Edmundowicz, MD,[7] Blair Jobe, MD,[8] John C. Lipham, MD,[9] Dan Lister, MD,[10] Marcia Irene Canto, MD,[11] Michael S. Smith, MD, MBA,[12] Anthony A. Starpoli, MD,[13] George Triadafilopoulos, MD,[14] Thomas J. Watson, MD,[15] Erik Wilson, MD,[16] John E. Pandolfino, MD,[1] Alexander Kaizer, PhD,[7] Zoe Van De Voorde, BA,[7] Rena Yadlapati, MD, MSHSR[7,18]

(Interventional) GI and Foregut Surgeons

- OMT – Optimize Medical Therapy
- LF – Lap Fundoplication
- MSA – Magnetic Sphincter Augmentation
- TIF – Transoral Fundoplication
- TIFCR – TIF w Crural Repair

Percent Agreement

Median Score (0-9)

Range Score (0-9)

TABLE 3. Complete responder scenarios

Scenario	All experts				
	OMT	LF	MSA	TIF	TIFCR
Heartburn, + significant hernia	60, 7 (1-9)	100, 9 (7-9)	100, 9 (7-9)	0, 1 (1-2)	60, 7 (1-9)
Regurgitation, + significant hernia	40, 5 (1-9)	100, 9 (9-9)	100, 9 (7-9)	0, 1 (1-2)	60, 7 (1-9)
Heartburn, no significant hernia	100, 9 (7-9)	93, 9 (6-9)	100, 8 (7-9)	87, 8 (6-9)	40, 6 (1-9)
Regurgitations, no significant hernia	60, 9 (2-9)	87, 9 (6-9)	93, 9 (6-9)	80, 8 (6-9)	40, 6 (1-8)

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GASTROINTESTINAL ENDOSCOPY Volume 92, No. 1 : 2020

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Partial Responder Scenarios

- OMT – Optimize Medical Therapy
- LF – Lap Fundoplication
- MSA – Magnetic Sphincter Augmentation
- TIF – Transoral Fundoplication
- TIFCR – TIF w Crural Repair

Percent Agreement

Median Score (0-9)

Range Score (0-9)

TABLE 4. Partial responder scenarios

	All experts				
Scenario	**OMT**	**LF**	**MSA**	**TIF**	**TIFCR**
Heartburn, + significant hernia	33, 5 (2-7)	100, 9 (7-9)	100, 9 (7-9)	7, 1 (1-7)	53, 7 (1-9)
Regurgitation, + significant hernia	20, 3 (1-7)	100, 9 (7-9)	100, 9 (7-9)	7, 1 (1-7)	53, 7 (1-9)
Heartburn, no significant hernia	40, 6 (3-9)	87, 9 (6-9)	87, 9 (6-9)	93, 7 (6-9)	53, 7 (1-9)
Regurgitations, no significant hernia	27, 5 (1-7)	100, 9 (7-9)	100, 9 (7-9)	93, 7 (6-9)	60, 7 (1-9)

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Non-Responder Scenarios

- OMT – Optimize Medical Therapy
- LF – Lap Fundoplication
- MSA – Magnetic Sphincter Augmentation
- TIF – Transoral Fundoplication
- TIFCR – TIF w Crural Repair

Percent Agreement

Median Score (0-9)

Range Score (0-9)

TABLE 5. Nonresponder scenarios

	All experts				
Scenario	**OMT**	**LF**	**MSA**	**TIF**	**TIFCR**
Heartburn, + significant hernia	13, 2 (1-9)	80, 8 (2-9)	73, 8 (1-9)	0, 1 (1-6)	47, 6 (1-9)
Regurgitation, + significant hernia	13, 2 (1-9)	80, 9 (3-9)	80, 8 (3-9)	7, 1 (1-8)	60, 7 (1-9)
Heartburn, no significant hernia	27, 5 (2-9)	67, 7 (1-9)	73, 7 (2-9)	100, 7 (7-9)	20, 5 (1-7)
Regurgitations, no significant hernia	13, 4 (2-9)	73, 8 (1-9)	80, 8 (3-9)	100, 8 (7-9)	13, 5 (1-7)

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Non Responder Scenarios

Hernia size makes a difference in
(1)Probable success of medical therapy
(2)Probable success of ARS

Even in patients with heartburn unresponsive to medication, ARS may be appropriate

Scenario	OMT	LF
Heartburn, + significant hernia	2	8
Regurgitation, + significant hernia	2	9
Heartburn, no significant hernia	5	7
Regurgitations, no significant hernia	4	8

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PPI nonresponders with regurgitation-predominant GERD, normal acid exposure, negative symptom–reflux correlation, elevated reflux burden, and large hiatal hernia	20, 2 (1-8)	93, 9 (5-9)
PPI nonresponders with heartburn-predominant GERD, small or no hiatal hernia, and negative pH impedance study (normal acid exposure, negative symptom–reflux correlation, nonelevated reflux burden)	47, 6 (1-9)	53, 7 (1-9)

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Number of reflux episodes on pH-impedance monitoring associates with improved symptom outcome and treatment satisfaction in gastro-oesophageal reflux disease (GERD) patients with regurgitation

Benjamin D Rogers,[1] Luis R Valdovinos,[2] Michael D Crowell,[3] Reginald Bell ,[4] Marcelo F Vela,[3] C Prakash Gyawali [1]

1.What are the new findings?

- ► Magnetic sphincter augmentation (MSA) improves regurgitation in proven GERD better than maximal medical management.
- ► Reduction of reflux episodes to physiological levels, particularly to <35 is associated with improved treatment outcome in regurgitation predominant GERD.
- ► Reflux episodes >80 despite medical therapy predicts satisfaction with GERD management after MSA.

Rogers BD, *et al*. *Gut* 2020;**0**:1–6. doi:10.1136/gutjnl-2020-321395

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Lastly - Does Peristalsis Make a Difference?

Laparoscopic Fundoplication Is Effective Treatment for Patients with Gastroesophageal Reflux and Absent Esophageal Contractility

Steven Tran[1] · Ronan Gray[1] · Feruza Kholmurodova[2] · Sarah K. Thompson[1,2] · Jennifer C. Myers[2,3] · Tim Bright[1,2] · Tanya Irvine[1] · David I. Watson[1,2]

40 patients with absent contractility cf to propensity matched normal undergoing Lap Fundo

Multivariate analysis found that patients with absent contractility had worse preoperative dysphagia (adjusted mean difference 1.09, p = 0.048), but postoperatively there were **no significant differences in dysphagia** scores at 5- and 10-year follow-up.

Journal of Gastrointestinal Surgery
https://doi.org/10.1007/s11605-021-05006-0

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Putting it All Together

- It's the hernia
- There might be more to it than that.
- But if you take away one thing today:
  - Pay attention to the hernia
    - FIND IT!
    - MEASURE IT!
    - TREAT IT!

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Video of PEH and MSA

(I'll need to add this – about 3 minutes)

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