GERD Phenotypes and Response to AntiReflux Procedures

Reginald C.W. Bell M.D.

AFS Annual Meeting 2021



Disclosures

- Ethicon
- Intuitive
- B-D
- Medtronic
- Ambu



Surgeon response

• What the he... is a GERD Phenotype???



Phenotypes of Gastroesophageal Reflux Disease: Where Rome, Lyon, and Montreal Meet

David A. Katzka,* John E. Pandolfino,* and Peter J. Kahrilas*

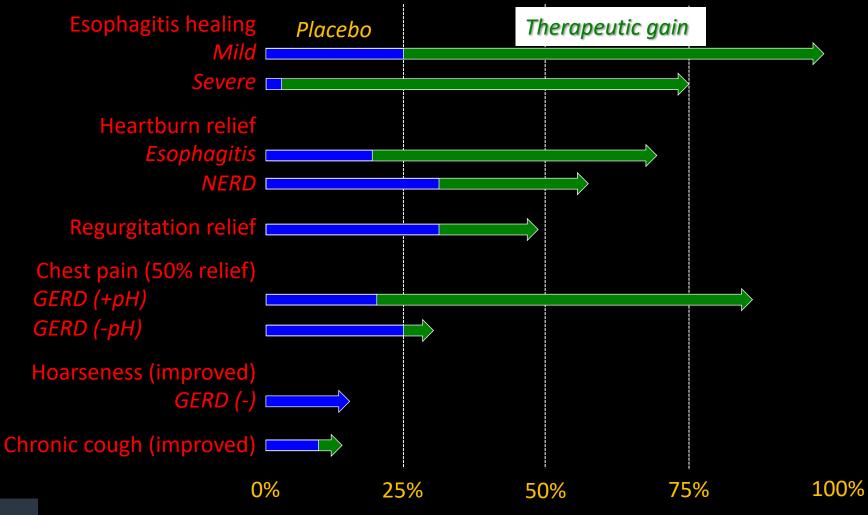
Table 1. Major GERD Phenotypes Along With Clinically Important Modulating Clinical Considerations

GERD syndrome	Modulating clinical considerations			
Nonerosive or endoscopy-negative reflux disease	When defined by physiological testing, very similar to low-grade esophagitis When defined by symptom assessment, overlaps with GERD hypersensitivity and functional heartburn			
GERD hypersensitivity	Conceptually differentiated by positive or negative symptom association on reflux testing			
Functional heartburn	In practice, these entities can be clinically indistinguishable			
Erosive esophagitis, low grade (LA grade A or B)	LA grade A esophagitis can be found in approximately 6% of asymptomatic controls, making it a nonspecific finding			
Erosive esophagitis, high grade (LA grade C or D)	Grossly abnormal EGJ function with supine reflux and abnormal esophageal acid clearance Usually associated with hiatus hemia			
Barrett's esophagus	Endoscopic spectrum from intestinal metaplasia at the EGJ to short segment to long segment (>3 cm)			
	Important biological spectrum from nondysplastic metaplasia to low-grade dysplasia to high-grade dysplasia			
Reflux chest pain syndrome	Noncardiac chest pain along with physiological evidence of GERD or accompanied by typical reflux symptoms is much more amenable to GERD therapy than chest pain without these features			
Regurgitation-dominant reflux disease	Indicative of grossly incompetent EGJ barrier with large-volume reflux			
	Need to differentiate from rumination and achalasia			
Laryngopharyngeal reflux	Although reflux may contribute, it is rarely the dominant pathophysiology, generally, there			
Chronic cough	are important cofactors			
	Strongly driven by neuronal hypersensitivity			
	More amenable to GERD therapy when accompanied by typical reflux symptoms			

EGJ, esophagogastric junction; GERD, gastroesophageal reflux disease; LA, Los Angeles.



PPI efficacy for potential manifestations of GERD





• Kahrilas PJ...Response of regurgitation to PPI therapy in clinical trials of GERD. AJG, 2011;106(8):1419-25;

Phenotypes of Gastroesophageal Reflux Disease: Where Rome, Lyon, and Montreal Meet

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Appropriate for Surgical Management

- Injury
 - Erosive esophagitis (B), C, D
 - Barrett's (>1cm), > 3cm
 - Peptic Stricture
- Symptoms w Objective GERD
 - Heartburn
 - Regurgitation-predominant
 - Reflux Chest Pain Syndrome
 - LPR
 - Chronic Cough

Not Appropriate for Surgical Management

- No objective evidence GERD
 - Functional Heartburn



Non-Erosive Reflux Disease GERD Hypersensitivity



Problems with design of most AntiReflux Procedure (ARP) studies

- Improvement in heartburn has been the primary measure of most studies.
- Medication resumption is considered a failure in ARP Studies.

• Sham effect very difficult to assess.

- Regurgitation is the symptom that is most responsive to antireflux surgery.
- Taking a patient uncontrolled on ASM to controlled on ASM is a therapeutic victory within the spectrum of personalized care. (Apart from issues with reasons for resumption of PPI therapy.)
- No solution.



Other Important Parts of the Puzzle

Symptom reporting is often unreliable.

Reflux testing is not dichotomous; symptom association is irrelevant

Response to PPI is probably irrelevant to ARP success.

The placebo effect of any intervention is significant.

Have more than one toy in your toybox



Symptoms

- Probably 80% of my patient consultation involves listening, questioning, repeating
 - Listening
 - Repeating back what I've heard
 - Refining their understanding of their symptoms
 - Setting expectations
- Regurgitation and Heartburn the most typical of symptoms – often confused
 - Throat burning, epigastric pain,
 - Patient is convinced they have regurgitation must have it – because of other symptoms. Especially in LPR patients.







Regurgitation

- An acid taste in your mouth
- Unpleasant movement of material breastbone upwards from the stomach



Heartburn

- A burning feeling behind your breastbone
- Pain behind your

Indigestion/Dyspepsia

- A burning feeling in the center of the upper stomach
- Pain in the center of the upper stomach





The Sham Effect



INTERNAL-MAMMARY-ARTERY LIGATION - COBB ET AL.

1115

AN EVALUATION OF INTERNAL-MAMMARY-ARTERY LIGATION BY A DOUBLE-BLIND TECHNIC*

LEONARD A. COBB, M.D.,† GEORGE I. THOMAS, M.D.,‡ DAVID H. DILLARD, M.D.,§ K. ALVIN MERENDINO, M.D.,¶ AND ROBERT A. BRUGE, M.D.,∥

SEATTLE, WASHINGTON

CONSIDERABLE relief of symptoms has been reported for patients with angina pectoris subjected to bilateral ligation of the internal mammary arteries. The physiologic basis for the relief of angina afforded by this rather simple operation is not clear. Allegedly, increased coronary flow is facilitated

A reasonably optimistic attitude on the physicians' part was maintained. The subjects were informed of the fact that this procedure had not been proved to be of value, and yet many were aware of the enthusiastic report published in the Reader's Digest.⁹

The patients were told only that they were participating in an evaluation of this operation; they were not informed of the double-blind nature of the study.

The estimated degree of subjective improvement during the first six months is shown in Table 1. The average improvement was 32 per cent for the ligated patients and 43 per cent for those whose internal mammary arteries were not ligated. Five patients Internal-mammary-artery ligation probably has no effect on the pathophysiology of coronary-artery disease. The subjective benefit from this operation is more likely to be on a psychological basis, although any spontaneous improvement in collateral circulation cannot be excluded. The value of the usual clinical evaluation of any form of surgical therapy designed to relieve the symptoms of angina pectoris is considered highly speculative.



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DR Google is not new!



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WOW!!!



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SHAM EFFECT 43%





Gastroenterology

Volume 125, Issue 3, September 2003, Pages 668-676



Clinical-alimentary tract

Improvement of gastroesophageal reflux symptoms after radiofrequency energy: a randomized, sham-controlled trial ★

Presented during the Digestive Disease Week meetings, May 22, 2002, at the plenary session of the American Society of Gastrointestinal Endoscopy.

Douglas A. Corley △ *‡‡ ☒, Philip Katz ⑤, John M. Wo ‖, Andreas Stefan ¶, Marco Patti ‡‡, Richard Rothstein #, Steven Edmundowicz **, Michael Kline ‡‡, Rodney Mason ‡‡, M.Michael Wolfe ‡‡

"More active vs. sham patients were without daily heartburn symptoms (n = 19[61%] vs. n = 7 [33%]; P =0.05), and more had a >50% improvement in their gastroesophageal reflux disease quality of life score (n = 19 [61%] vs. n = 6 [30%]; P = 0.03)."

SHAM EFFECT 33%



AP&T Alimentary Pharmacology and Therapeutics

Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD

B. Hakansson*, M. Montgomery*, G. B. Cadiere[†], A. Rajan[†], S. Bruley des Varannes[‡], M. Lerhun[‡], E. Coron[‡], J. Tack[§], R. Bischops[§], A. Thorell*, U. Arnelo[¶] & L. Lundell[¶]

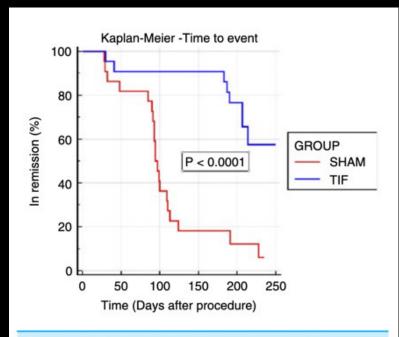


Figure 2 | Time in clinical remission after either transoral incisionless fundoplication (TIF) or sham intervention during the 6 months of follow-up.

- 44 patients randomized 1:1 TIF v Sham.
- Patients in both arms continued PPI for 42 days for healing
- 'Treatment failure' prevailed if at least one of the following criteria were fulfilled:
 - Moderate-severe HB or Regurgitation for 7 days prior to FU
 - requirement of continuous PPI for more than
 8 weeks to control reflux symptoms or
 - need for a reintervention.
- 82% of Sham resumed PPI by 6 mo
- 41% of TIF resumed PPI by 6 mo

SHAM EFFECT 18%



CLINICAL—ALIMENTARY TRACT

Efficacy of Transoral Fundoplication vs Omeprazole for Treatment of Regurgitation in a Randomized Controlled Trial



John G. Hunter, 1,* Peter J. Kahrilas, 2,* Reginald C. W. Bell, 3 Erik B. Wilson, 4 Karim S. Trad, 5,6 James P. Dolan, 1 Kyle A. Perry, 7 Brant K. Oelschlager, 8 Nathaniel J. Soper, 2 Brad E. Snyder, 4 Miguel A. Burch, 9 William Scott Melvin, 7 Kevin M. Reavis, 1,10 Daniel G. Turgeon, 5,6 Eric S. Hungness, 2 and Brian S. Diggs 1

 Patients with regurgitation despite daily PPI randomized to TIF + Placebo or Sham (EGD with manipulation) + PPI at baseline dosing At 3 months follow-up, 15 of 42 patients (36%) in the sham group met criteria for early failure, and 12 of 15 patients (80%) underwent crossover to TF. The 3 sham patients who had not crossed over completed the 6-month follow-up testing. In the TF/placebo group 10 of 87 patients (11%) met the criteria for early failure (P = .002) and all 10 returned to PPI treatment.

• The primary end point in this study, elimination of troublesome regurgitation, was achieved in a greater proportion of patients treated with TF than with omeprazole: 67% vs 45%



Reflux testing should not be interpreted in a dichotomous fashion

Especially with prolonged pH testing



Ambulatory Reflux Monitoring: Diagnostic Metrics

Acid Exposure Time # Reflux Events /24h

Pathologic GERD >6.0% >80

Grey Zone 4.0 to 6.0% 40 to 80

Positive Symptom Reflux Association (Symptom Index > 50%; Symptom Association Probability > 95%)

Highest likelihood of symptom response to anti-reflux management

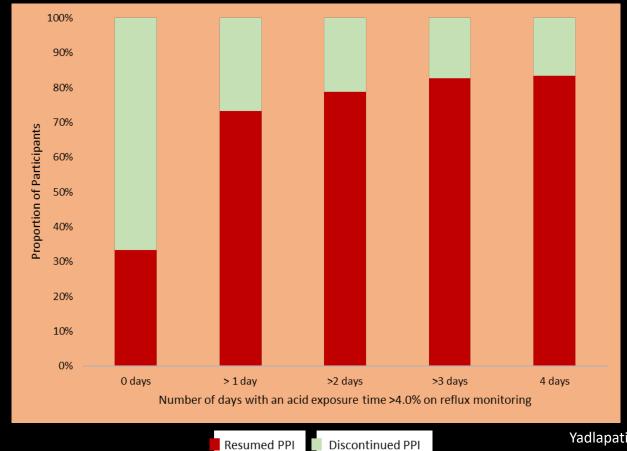
Increases confidence in GERD pathology, or may suggest hypersensitive mechanism

Suspect esophageal hypersensitivity

Gyawali CP, et al. Gut (2018) 67(7):1351-1362



2 Days Abnormal vs Worst Day





Yadlapati R, et al. Gastroenterology 2020 [Epub]

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

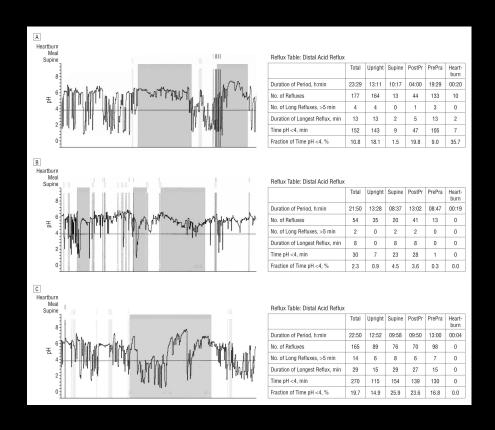
Benjamin D Rogers, Luis R Valdovinos, Michael D Crowell, Reginald Bell , Amarcelo F Vela, C Prakash Gyawali

Gut 2020;**0**:1–6. doi:10.1136/gutjnl-2020-321395

- Post hoc analysis of postintervention ph-impedance data from CALIBER Study.
- Conclusions:
 - 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.



Reflux Pattern Associations & Fundoplication

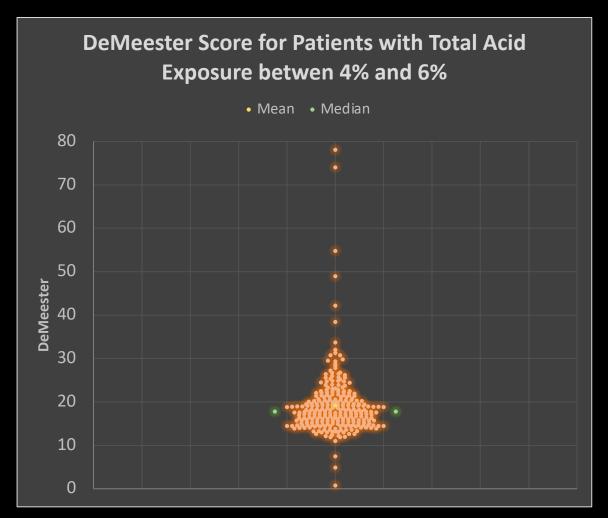


- Upright
 - TLESRs
 - More prone to Gas-Bloat
- Supine
 - Lower Risk of Gas-Bloat
- Bipositional
 - Associated with loss of intrinsic sphincter.
 - Associated with larger hiatal hernias



Is it Time to Revise Dichotomous Cutoff for the DeMeester Score?

Statistic	DeMeester
Nbr. of observations	267
Nbr. of missing values	0
Minimum	0.800
Maximum	78.100
Range	77.300
1st Quartile	15.200
Median	17.800
3rd Quartile	21.100
Mean	19.192
Standard deviation (n)	7.520
Lower bound on mean	
(95%)	18.284
Upper bound on mean	
(95%)	20.100





Response to PPIs Largely Irrelevant



The Classic Study

- Three factors significantly predictive of a successful outcome:
- Abnormal 24-hour pH score (OR= 5.4; 95% CI = 1.9–15.3),
- Typical primary symptom (OR= 5.1; 95% CI = 1.9–13.6),
- A clinical response to acid suppression therapy (OR= 3.3; 95% Cl = 1.3-8.7).

Multivariate analysis of factors predicting outcome after laparoscopic Nissen fundoplication ★

Guilherme M.R. Campos M.D., Jeffrey H. Peters M.D. A, Tom R. DeMeester M.D., Stefan Öberg M.D., Peter F. Crookes M.D., Silvia Tan M.S., Steven R. DeMeester M.D., Jeffrey A. Hagen M.D., Cedric G. Bremner M.D.

Table VI. Combined effect of predictors on outcome				
	24-hour pH score	Primary symptom	Response to acid suppression therapy	Odds ratio
Norm	Normal	Atypical	Poor/none	1.0
	Normal	Typical	Complete/partial	16.7
	Abnormal	Arypical	Complete/partial	17.7
	Ahnormal	Typical	Poor/none	27.2
Abnormal	Typical	Complete/partial	89.8	

<u>Journal of Gastrointestinal Surgery</u> <u>Volume 3, Issue 3</u>, May–June 1999, Pages 292-300



Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-Year Randomized Trial

Reginald Bell, MD,* John Lipham, MD,‡ Brian E. Louie, MD,§ Valerie Williams, MD,k James Luketich, MD,¶ Michael Hill, MD,# William Richards, MD,**Christy Dunst, MD,‡‡ Dan Lister, MD,§§ Lauren McDowell-Jacobs, MD,kkPatrick Reardon, MD,¶¶ Karen Woods, MD,jjjjjjjj Jon Gould, MD,##

F. Paul Buckley III, MD,*** Shanu Kothari, MD,‡‡‡ Leena Khaitan, MD,§§§ C. Daniel Smith, MD,jjjjjj Adrian Park, MD,¶¶¶ Christopher Smith, MD,### Garth Jacobsen, MD,****

Ghulam Abbas, MD,‡‡‡‡ and Philip Katz, MD§§§§

In patients with moderate-severe regurgitation on PPI, both regurgitation and heartburn resolved regardless of response to PPIs

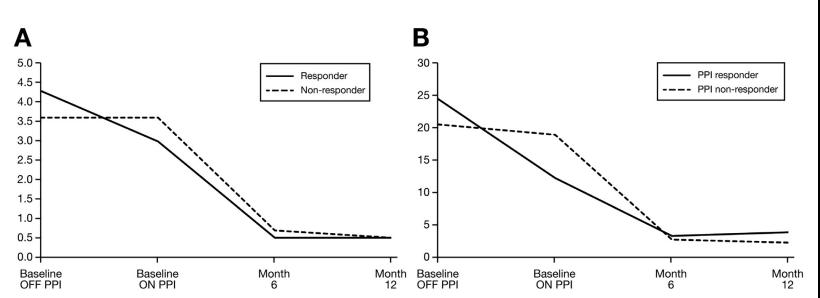


Figure 3. (A) Regurgitation and (B) heartburn scores for magnetic sphincter augmentation (MSA) patients by response to proton pump inhibitors (PPIs) at baseline. Responder is defined by having at least a half standard deviation change between on and off gastroesophageal reflux disease medication scores 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.

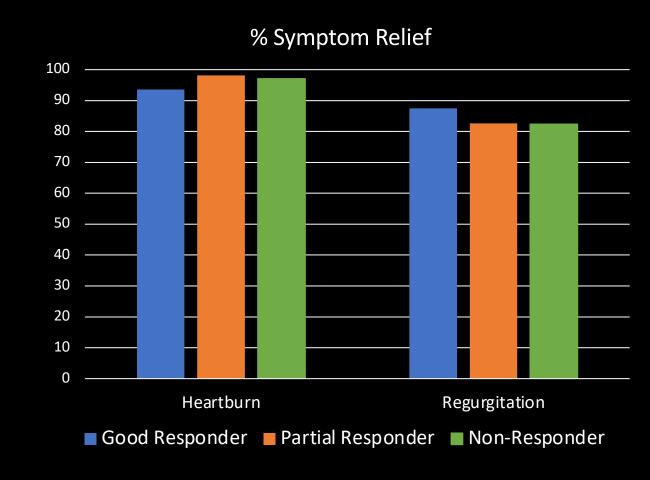


Clinical outcome after laparoscopic Nissen fundoplication in patients with GERD and PPI refractory heartburn

Diseases of the Esophagus (2020)**33**,1–6 DOI: 10.1093/dote/doz099

Katrin Schwameis, Daniel Oh, Kyle M. Green, Brenda Lin, Jörg Zehetner, John C. Lipham, Jeffrey A. Hagen, 5 Steven R. DeMeester, **

- Patients with heartburn primary symptom while on PPI
- ALL with ABNORMAL PH Tests
- Patient were categorized by preop % relief heartburn on PPI:
 - Good Responder: 76–100%
 - Partial Responder: 26–75%
 - Non-Responder 0–25%
- Median FU 48 mos in 75/129 patients.





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

GASTROINTESTINAL ENDOSCOPY Volume 92,

No. 1:2020

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,17 Alexander Kaizer, PhD,7 Zoe Van De Voorde, BA,7 Rena Yadlapati, MD, MSHSR7,1

RAND Consensus on Appropriateness (1-9) of procedural intervention assessed by panel of 8 Foregut Surgeons and 7 Interventional Gastroenterologists.

Higher number represents increased appropriateness of specific intervention

GERD + by pH, PPI Partial Responder

	Surgeon		Interventional GI		
	Lap ARS	TIF w/out HH Repair	Lap ARS	TIF w/out HH Repair	
Heartburn + HH	9	NA	8	NA	
Regurgitation + HH	9	NA	9	NA	
Heartburn – no HH	9	7	8	8	
Regurgitation – no HH	9	7	9	8	



GASTROINTESTINAL ENDOSCOPY Volume 92, No. 1 : 2020

RAND Consensus on Appropriateness (1-9) of procedural intervention assessed by panel of Foregut Surgeons and Interventional Gastroenterologists.

Higher number represents increase appropriateness of specific intervention

GERD + by pH, PPI Non-Responder

	Surgeon		Interventional GI		
	Lap ARS	TIF w/out HH Repair	Lap ARS	TIF w/out HH Repair	
Heartburn + HH	100%,8	NA	57% 7 (2-9)	NA	
Regurgitation + HH	100%, 9	NA	57%, 7 (3-9)	NA	
Heartburn – no HH	100%, 8	100%, 7	35%, 6 (2-9)	100%,8	
Regurgitation – no HH	100%, 8	100%, 7	50%, 7 (3-9)	100%,8	



GASTROINTESTINAL ENDOSCOPY Volume 92, No. 1 : 2020

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GASTROINTESTINAL ENDOSCOPY Volume 92, No. 1 : 2020

GERD + by pH, PPI Non-Responder

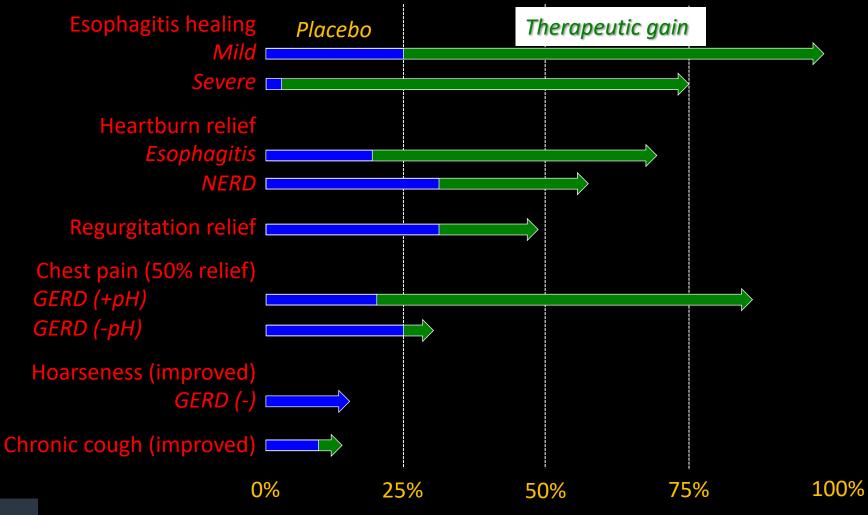
- Impedance-pH on Medication?
- May be of value
 - the patient with heartburn,(-) HH and evidence of reflux hypersensitivity
 - and the (-) HH patient with a completely normal impedance-pH study
- Otherwise of no value for LF and MSA



The Phenotypes



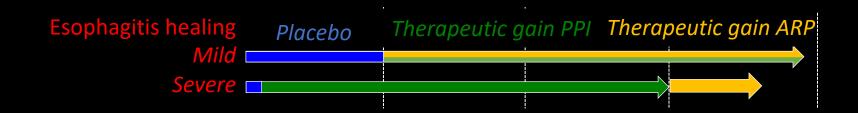
PPI efficacy for potential manifestations of GERD





• Kahrilas PJ...Response of regurgitation to PPI therapy in clinical trials of GERD. AJG, 2011;106(8):1419-25;

PPI and Surgical efficacy for potential manifestations of GERD



Not much specific data



0% 25% 50% 75% 100%

May 18, 2011

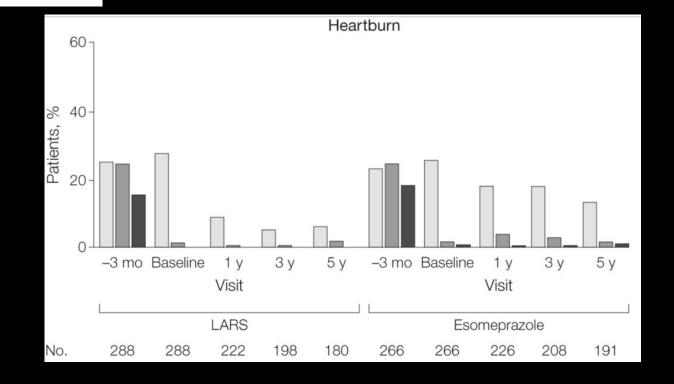
Laparoscopic Antireflux Surgery vs Esomeprazole Treatment for Chronic GERD The LOTUS Randomized Clinical Trial

Jean-Paul Galmiche, MD, FRCP; Jan Hatlebakk, MD, PhD; Stephen Attwood, MD, PhD; et al

≫ Author Affiliations | Article Information

JAMA. 2011;305(19):1969-1977. doi:10.1001/jama.2011.626

5 year results
Heartburn: LARS 8%,
PPI 16% (p=.14)
Regurgitation: LARS
2%, PPI 13% (p,0.001)





Long-term outcome of Nissen fundoplication in non-erosive and erosive gastro-oesophageal reflux disease[†]

J. A. Broeders, W. A. Draaisma, A. J. Bredenoord, A. J. Smout, I. A. Broeders, Professor H. G. Gooszen 🔀,

Outcome of laparoscopic antireflux surgery in patients with nonerosive reflux disease

Tanja Bammer 1, Mark Freeman, Ali Shahriari, Ronald A Hinder, Kenneth R DeVault, Sami R Achem

Laparoscopic Nissen fundoplication in patients with nonerosive reflux disease. Long-term quality-of-life assessment and surgical outcome

T Kamolz 1, F A Granderath, U M Schweiger, R Pointner

No Difference in outcomes between NERD and ERD with ARS



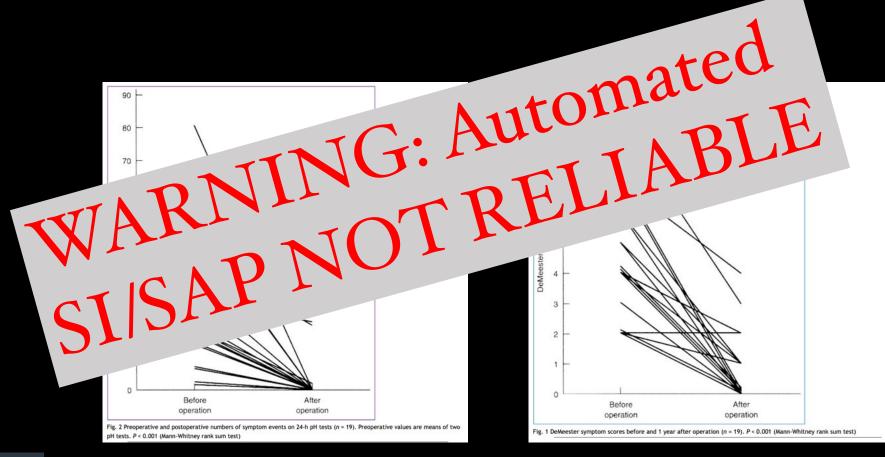
Laparoscopic antireflux surgery in the treatment of the acid-sensitive oesophagus

Author(s): Booth, M. I.; Stratford, J.; Thompson, E.; Dehn, T. C. B.

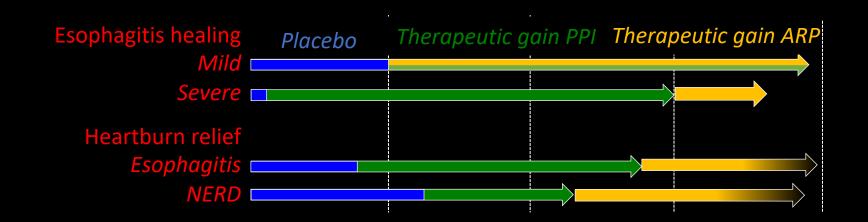
ISSN: 0007-1323

Issue: Volume 88(4), April 2001, pp 577-582

Accession: 00002413-200104000-00016









0% 25% 50% 75% 100%

"Better Together"

Magnetic Sphincter Augmentation Superior to Proton Pump Inhibitors for Regurgitation in a 1-Year Randomized Trial

Reginald Bell, MD,* John Lipham, MD,[‡] Brian E. Louie, MD,[§] Valerie Williams, MD, James Luketich, MD,[¶] Michael Hill, MD,[#] William Richards, MD,^{**} Christy Dunst, MD,^{‡‡} Dan Lister, MD,^{§§} Lauren McDowell-Jacobs, MD,[¶] Patrick Reardon, MD,[¶] Karen Woods, MD,[¶] Jon Gould, MD,^{##} F. Paul Buckley III, MD,*** Shanu Kothari, MD,^{‡‡‡} Leena Khaitan, MD,^{§§§} C. Daniel Smith, MD,[¶] Adrian Park, MD,[¶] Christopher Smith, MD,^{###} Garth Jacobsen, MD,^{****} Ghulam Abbas, MD,^{‡‡‡‡} and Philip Katz, MD^{§§§§}

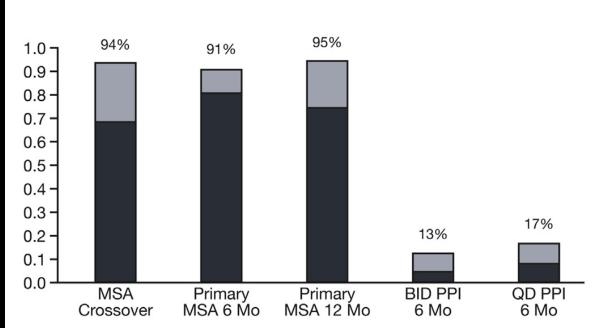
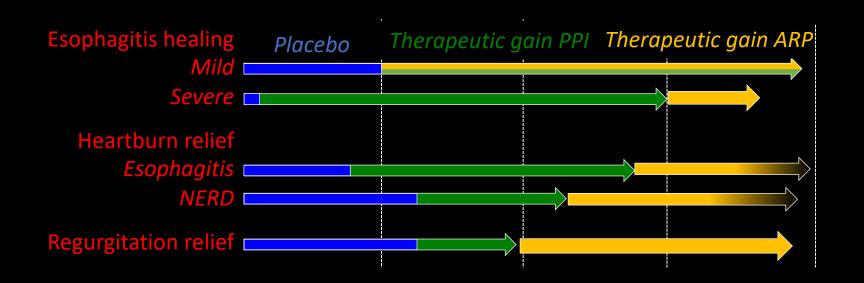


Figure 1. Percent of patients achieving relief of moderate-to-severe regurgitation by time after initiation of therapy. BID, twice daily; MSA, magnetic sphincter augmentation; PPI, proton pump inhibitor.







0% 25% 50% 75% 100%

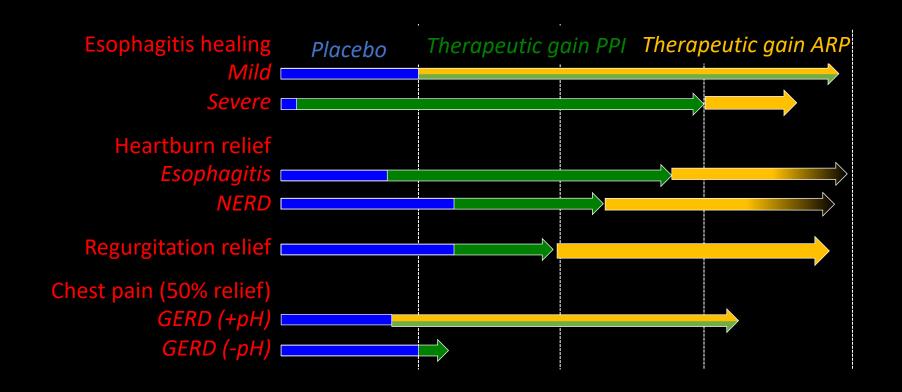
"Better Together"

Gastroesophageal reflux disease (GERD) and chest pain. Results of laparoscopic antireflux surgery

M G Patti 1, D Molena, P M Fisichella, S Perretta, L W Way

- Improvement in 165 patients with chest pain
- 65% of patients with negative SI
- 79% of with SI < 40%
- 96% of patients with SI >40%







Atypical







BJS (British Journal of Surgery) homepage

Original Article

Response of atypical symptoms of gastro-oesophageal reflux to antireflux surgery

Dr T. M. Farrell X, W. S. Richardson, T. L. Trus, C. D. Smith, J. G. Hunter,

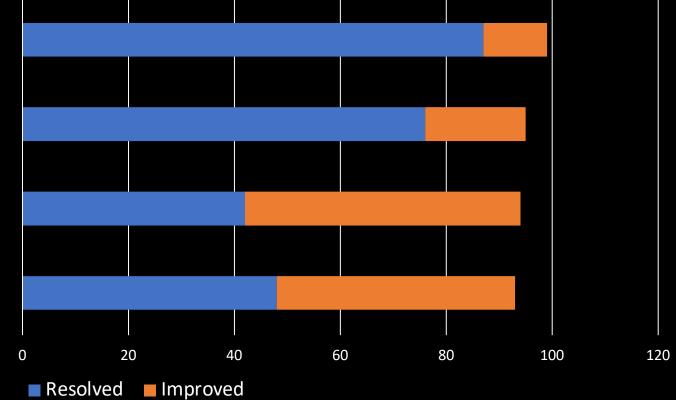
First published: 29 November 2002 | https://doi.org/10.1046/j.0007-1323.2001.01949.x | Citations: 60



Mod HB - HB Improvement

Mod HB - Atypical Improvment

No HB - Atypical Improvement





Surgical Treatment for Laryngopharyngeal Reflux Disease: A Systematic Review

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Jérôme R Lechien <sup>1 2 3 4 5</sup>, Giovanni Dapri <sup>3 6</sup>, Didier Dequanter <sup>3 5</sup>, Alexandra Rodriguez Ruiz <sup>3 5</sup>, Marie-Thérèse Marechal <sup>3 6</sup>, Lisa G De Marrez <sup>1 3</sup>, Sven Saussez <sup>1 3 4 5</sup>, Piero Marco Fisichella <sup>7 8</sup>
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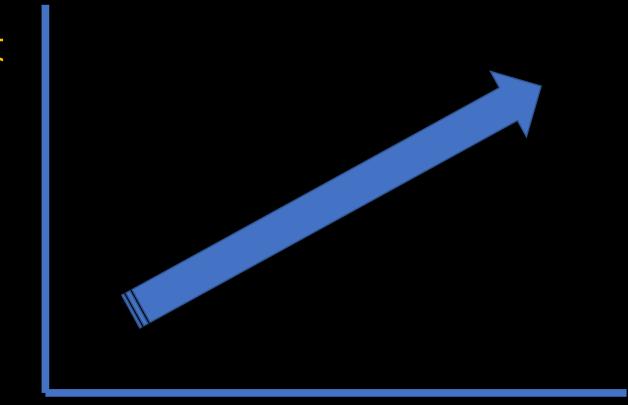
• A weighted mean of 83.0% of patients (95% CI, 79.7%-86.3%) experienced improvement and a weighted mean of 67.0% of patients (95% CI, 64.1%-69.9%) experienced a disappearance of symptoms

• High level of methodological heterogeneity among studies according to diagnostic method, exclusion criteria, and outcomes used to assess the efficacy of fundoplication.



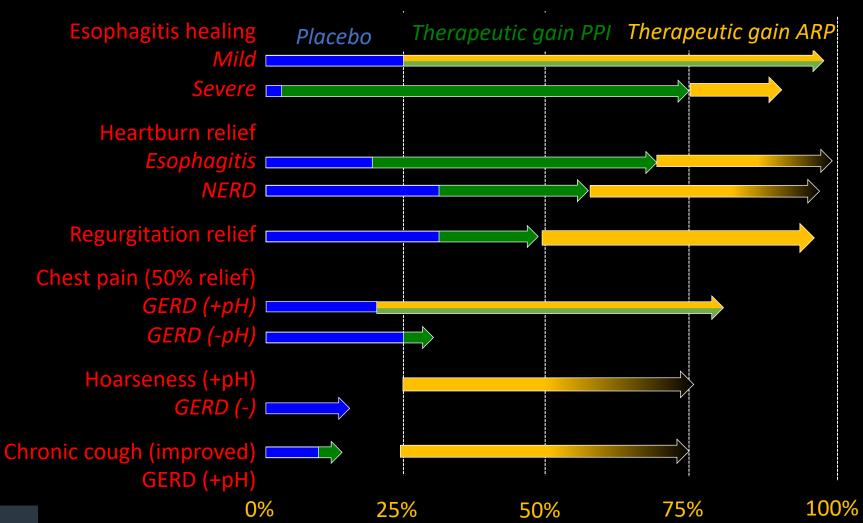
Supraesophageal GERD – Keep it simple

Amount of Distal Reflux by pH

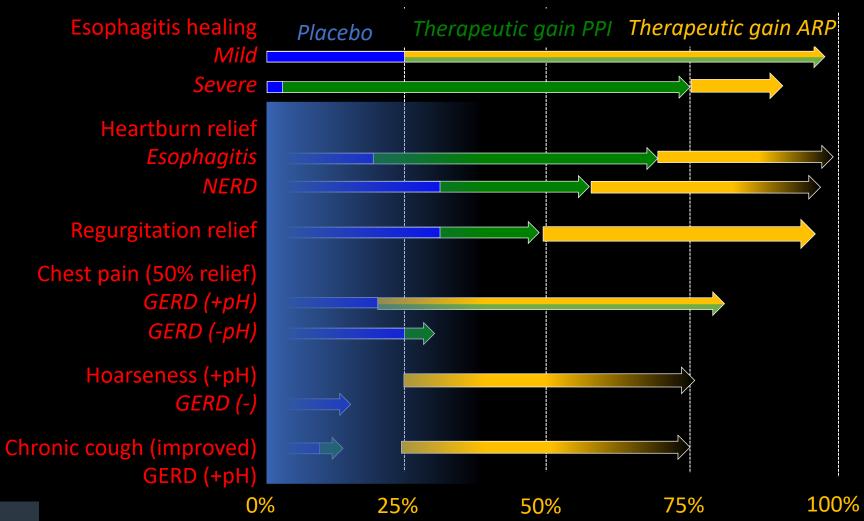


Probability of Success with ARP

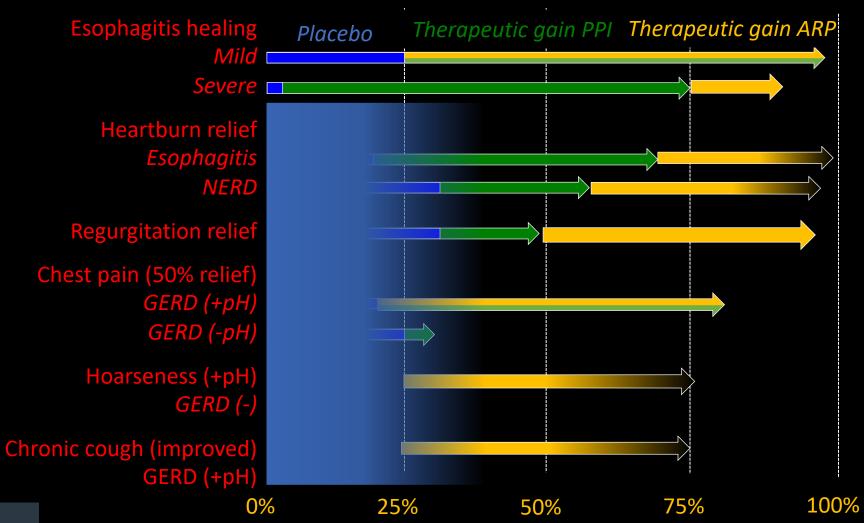




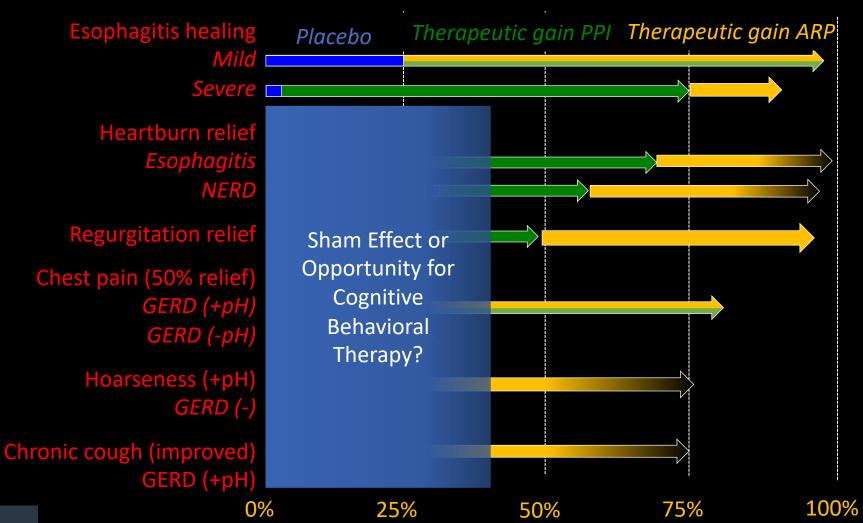














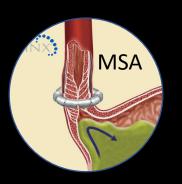
THE TOYBOX



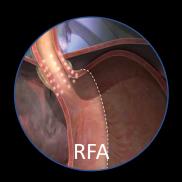
THE TOYBOX













Recapitulate

Symptom reporting is often unreliable.

Reflux testing is not dichotomous; symptom association is irrelevant

Response to PPI is probably irrelevant to ARP success.

The placebo effect of any intervention is significant.

Have more than one toy in your toybox



