

Diagnosis and Management of GERD

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Disclosure

Consultant: Braintree; Diversatek; Medpace;
Medtronic

Licensing Agreement: Medtronic

Speaker's Bureau: Medtronic; Phathom;
Sanofi/Regeneron



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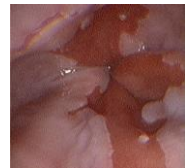
Outline

GERD

- GERD diagnosis
 - Empiric treatment trial vs GI evaluation (endoscopy +/- pH testing)
- GERD treatment – options and *personalizing*
 - *Acid suppressive therapy*
 - *Safety*
 - *Anti-reflux surgery*

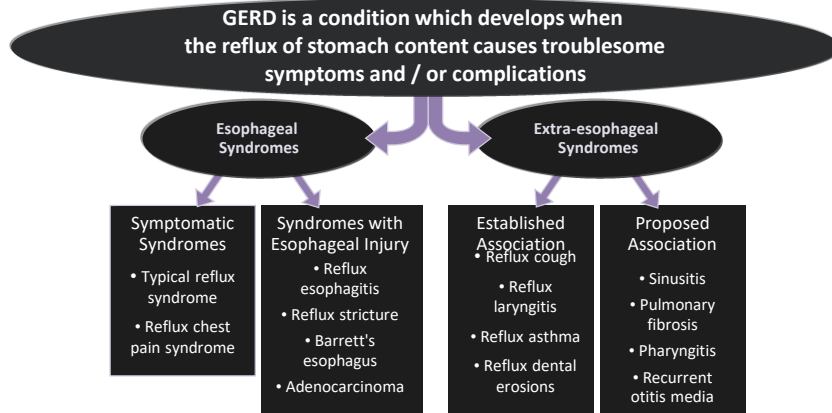
GERD

- ❖ *>4.5 million office visits/year*
- ❖ *>\$12 BILLION in health care expenditures (esophageal disease)*
- ❖ *Refractory symptoms*
 - **30-50 % of patients are unsatisfied with symptom control.**
- Patients are typically sent for endoscopy
- Most (~70%) patients with GERD will be EGD negative
 - “non-erosive GERD”



GERD – Definition

❖ Lyon consensus: “modern definition of actionable GERD requires conclusive evidence of reflux-related pathology on endoscopy and/or abnormal reflux in the presence of compatible troublesome symptoms



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Montreal Consensus: Vakil N et al. Am J Gastroenterol 2006;101:1900
Lyon consensus 2.0. Gyawali, CP, et al. Gut. 2024;73(2):361-71

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Cases

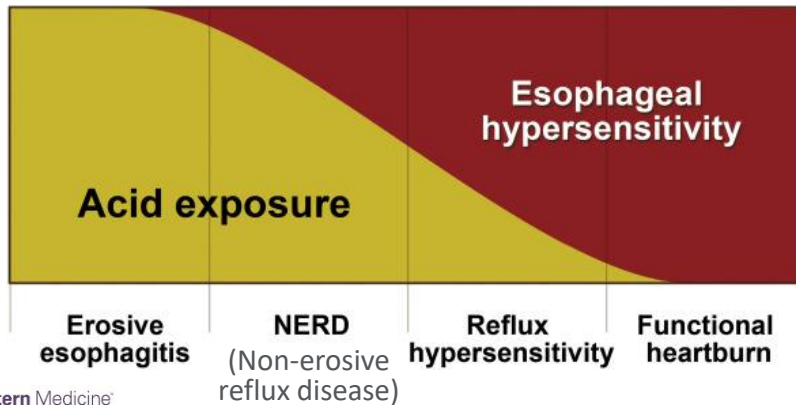
- 1) 48 yo F p/w heartburn
- 2) 32 yo F p/w heartburn
- 3) 54 yo M p/w heartburn

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GERD: Key Concepts Spectrum of 'Reflux' Disease States, i.e. GERD Phenotypes

❖ *Not all heartburn is GERD*



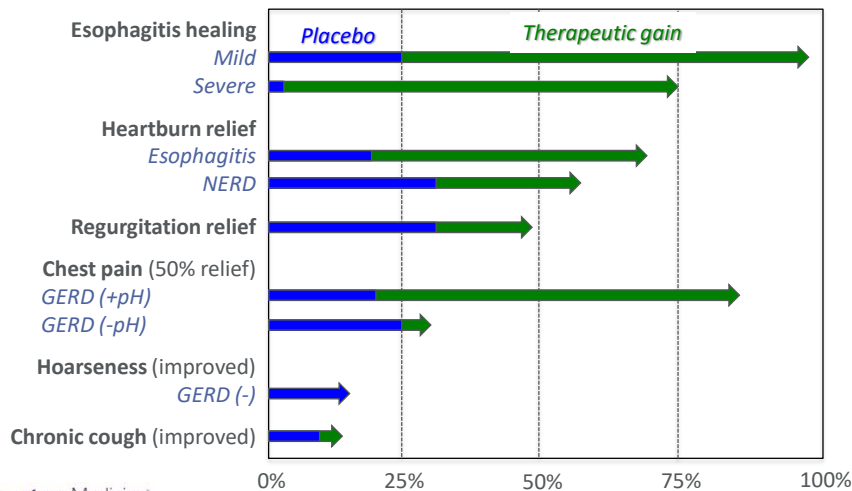
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ROME IV: Aziz Q, et al. *Gastroenterology*. 2016;150(6):1368-1379.

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GERD: Key Concepts Treatment Response Varies by GERD Manifestation PPI efficacy for potential manifestations of GERD

Estimates based on available RCT data



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Kahrilas, PJ, et al. *Am J Gastroenterol*. 2011 Aug;106(8):1419-25

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Case 1

1) 48 yo F p/w heartburn

- Heartburn ~3-5x/week for ~4 years
- +Nocturnal regurgitation
- Partial improvement on PPI:
 - OTC omeprazole 20mg daily x 3 months, then stopped PPI
- Solid food dysphagia, localized to chest for the past year
- +Weight gain; ~50 lbs; PCOS
 - BMI 41

CASE 1: 32 yo F with heartburn, regurgitation, and dysphagia

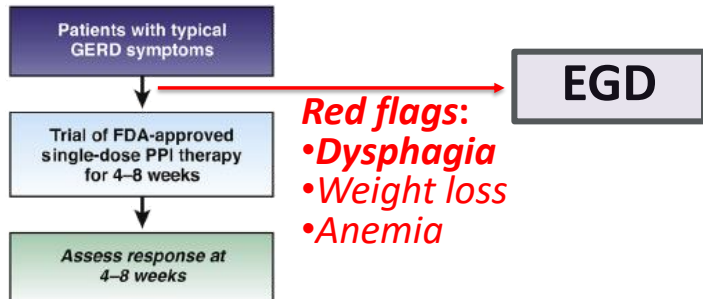
What Is the Next Step in Management?

- A. Empiric trial of proton pump inhibitor with omeprazole 40mg daily x 3 months
- B. Barium esophagram
- C. Upper endoscopy
- D. Reassure and schedule for clinical follow-up in 1 year

Upper Endoscopy for 'Alarm Symptoms' in GERD

ACG GERD Guideline

We recommend endoscopy as the first test for evaluation of patients presenting with dysphagia or other alarm symptoms (weight loss and GI bleeding) and for patients with multiple risk factors for Barrett's esophagus (strong recommendation, low level of evidence).



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Case 1 - Continues

- **1) 48 yo F p/w heartburn**
- Heartburn ~3-5x/week for ~4 years
- +Nocturnal regurgitation
- Partial improvement on PPI:
 - OTC omeprazole 20mg daily x 3 months, then stopped PPI
 - Solid food dysphagia, localized to chest for the past year
- +Weight gain; ~50 lbs; PCOS
 - BMI 41

- EGD (off PPI)
 - LA-D erosive esophagitis
 - Hiatal hernia (4cm)



- Started on omeprazole 40mg daily
 - Taken 30-60 min before dinner
- Significant improvement, but still occasional regurgitation > heartburn
- Repeat EGD on omeprazole – healed esophagitis; 4 cm HH

Diagnosis:
+GERD
(erosive esophagitis)

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Case 2

2) 32 yo F p/w heartburn

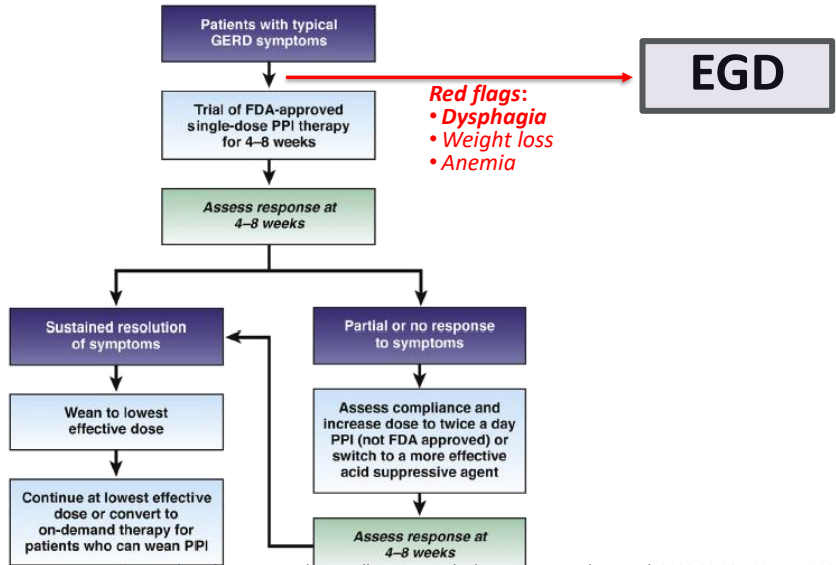
- Heartburn ~4-5x days per week for the past ~1 year
- Occasional regurgitation – after certain ‘trigger’ meals
- Transient relief with OTC antacids or famotidine
- Tried OTC PPI (omeprazole 20mg daily) x 2 months, then omeprazole 20mg 2x/day (qam and QHS) x 2 months
 - “50% improvement” on either PPI schedule
- No dysphagia or chest pain
- Intermittent bothersome cough
 - h/o asthma, on albuterol

CASE 2: 48 yo F with heartburn, regurgitation; partial PPI response

What Is the Next Step in Management?

- A. Continue empiric PPI treatment trial – increase omeprazole to 40mg BID
- B. Barium esophagram
- C. Upper endoscopy +/- esophageal pH testing
- D. Reassure and schedule for clinical follow-up in 1 year

2022 AGA Clinical Practice Update Utilization of Empiric PPI Therapy in GERD



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AGA Clinical Practice Update: Yadlapati R, et al. Clin Gastroenterol Hepatol. 2022;20:984-994.e1. 2022

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Empiric PPI Trial – Diagnostic Performance:

Sensitivity = 78% / 71 %

Specificity = 54% / 41%

❖ Response to PPI does not confirm GERD

Table 3. Diagnostic Evaluation of the Proton-Pump Inhibitor Test with 3 Reference Tests for Gastroesophageal Reflux Disease

Study (Reference)	Patients				Total	Proportion of Patients with Positive Response	Prevalence of GERD according to Reference Standard	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio
	True-Positive Results	False-Negative Results	False-Positive Results	True-Negative Results								
←----- n ----->												
Abnormal 24-hour pH monitoring												
Bate et al. (11)	22	10	11	15	58	0.57	0.55	0.69	0.58	0.67	0.60	1.64
Fass et al. (10)	28	7	3	4	42	0.74	0.83	0.80	0.57	0.90	0.36	1.86
Fass et al. (23)	21	0	8	6	35	0.83	0.60	1.00	0.43	0.72	1.00	1.75
Juul-Hansen et al. (9)	29	5	11	11	56	0.71	0.61	0.85	0.50	0.73	0.69	1.70
Schenk et al. (8)	15	7	7	12	41	0.54	0.54	0.69	0.62	0.68	0.63	1.84
Combined								0.78	0.54			
Esophagitis												
Carlsson et al. (20)	66	72	25	62	225	0.40	0.61	0.48	0.71	0.73	0.46	1.66
Galmiche et al. (24)	27	10	65	39	141	0.66	0.26	0.73	0.38	0.29	0.80	1.18
Hatlebakk et al. (25)	55	22	59	25	161	0.71	0.48	0.71	0.30	0.48	0.53	1.01
Schenk et al. (8)	9	6	13	13	41	0.54	0.37	0.60	0.50	0.41	0.68	1.20
Johnsson et al. (26)	50	17	8	5	80	0.73	0.84	0.74	0.38	0.86	0.23	1.19
Venables et al. (29)	80	21	120	109	330	0.61	0.31	0.70	0.30	0.40	0.84	1.52
Combined								0.71	0.41			

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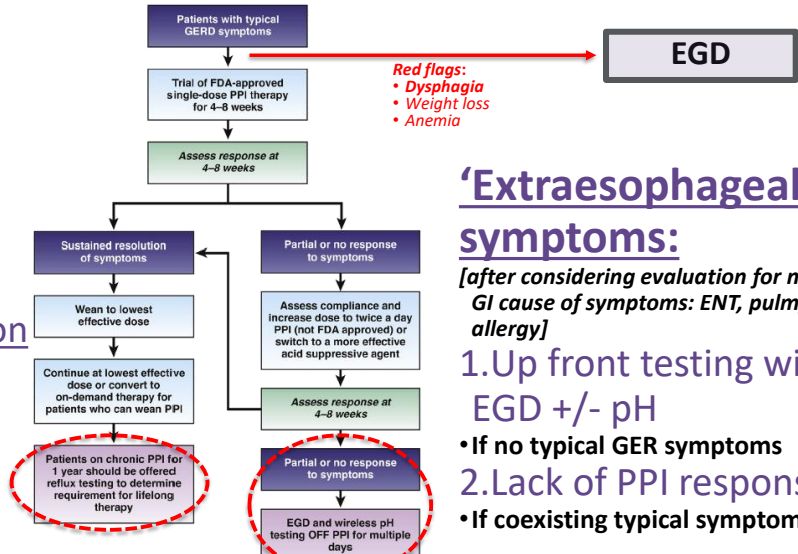
Numans, et al. Ann Intern Med 2004

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2022 AGA Clinical Practice Update Utilization of Empiric PPI Therapy in GERD

Typical GERD symptoms:

- (heartburn, regurg, chest pain)
1. Lack of response to PPI
 2. Offer to determine long-term GERD tx
 3. *Prior to consideration of antireflux surgery



'Extraesophageal' symptoms:

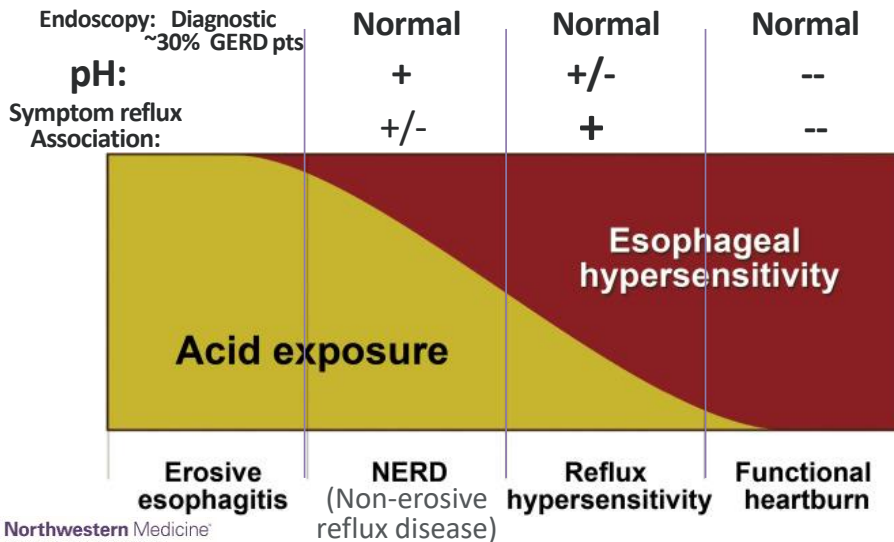
- [after considering evaluation for non-GI cause of symptoms: ENT, pulm, allergy]
1. Up front testing with EGD +/- pH
 - If no typical GER symptoms
 2. Lack of PPI response
 - If coexisting typical symptoms

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• AGA Clinical Practice Update: Yadlapati R, et al. Clin Gastroenterol Hepatol. 2022;20:984-994.e1. 2022
• AGA Clinical Practice Update: Chen J, et al. Clin Gastroenterol Hepatol. 2023; 21(6):1414-1421

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Use of Endoscopy and Ambulatory Reflux Monitoring Define 'Reflux' Disease States / Phenotype

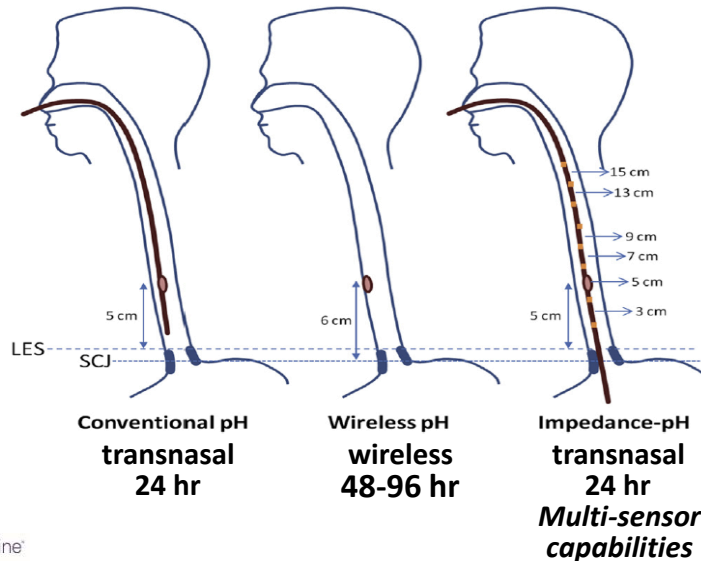


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ROME IV: Aziz Q, et al. Gastroenterology. 2016;150(6):1368-1379.

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Ambulatory Reflux Monitoring Options (Esophageal pH Test)



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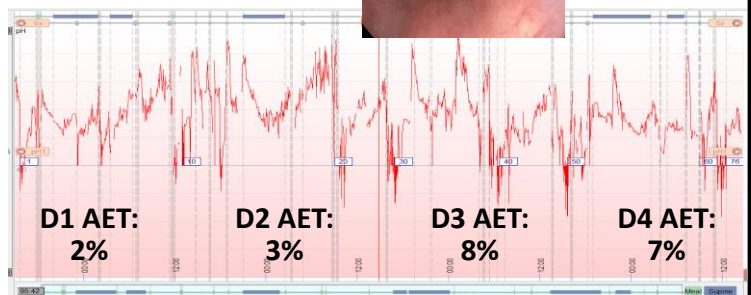
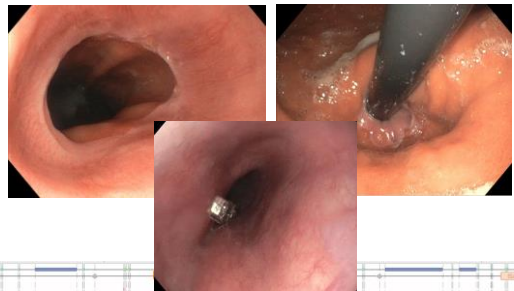
Carlson DA and Pandolfino JE. Gastroenterol Clin N Am 43 (2014) 89–104

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Case 2 - Continues

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- Heartburn ~4-5x days per week for the past ~1 year
- Occasional regurgitation – after certain meals
- Transient relief with OTC antacids or famotidine
- Tried OTC PPI (omeprazole 20mg daily) x 2 months, then omeprazole 20mg 2x/day (qam and QHS) x 2 months – “50% improvement”
- No dysphagia or chest pain
- Intermittent bothersome cough – h/o asthma, on albuterol

- EGD (off PPI)
 - Small hiatal hernia
 - Normal esophagus
 - Wireless pH capsule placed



Diagnosis:
+GERD
(non-erosive)

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[‘Normal’ esophageal acid exposure time = <4%]

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GERD Treatment Options

• Lifestyle

- Weight loss
- Head of bed elevation
- Sleep on left side
- CPAP (if OSA)
- *Avoid late meals (2-3 hrs from bedtime)*
- *Avoid/minimize 'trigger foods'*
- *Tobacco cessation*

• Medication

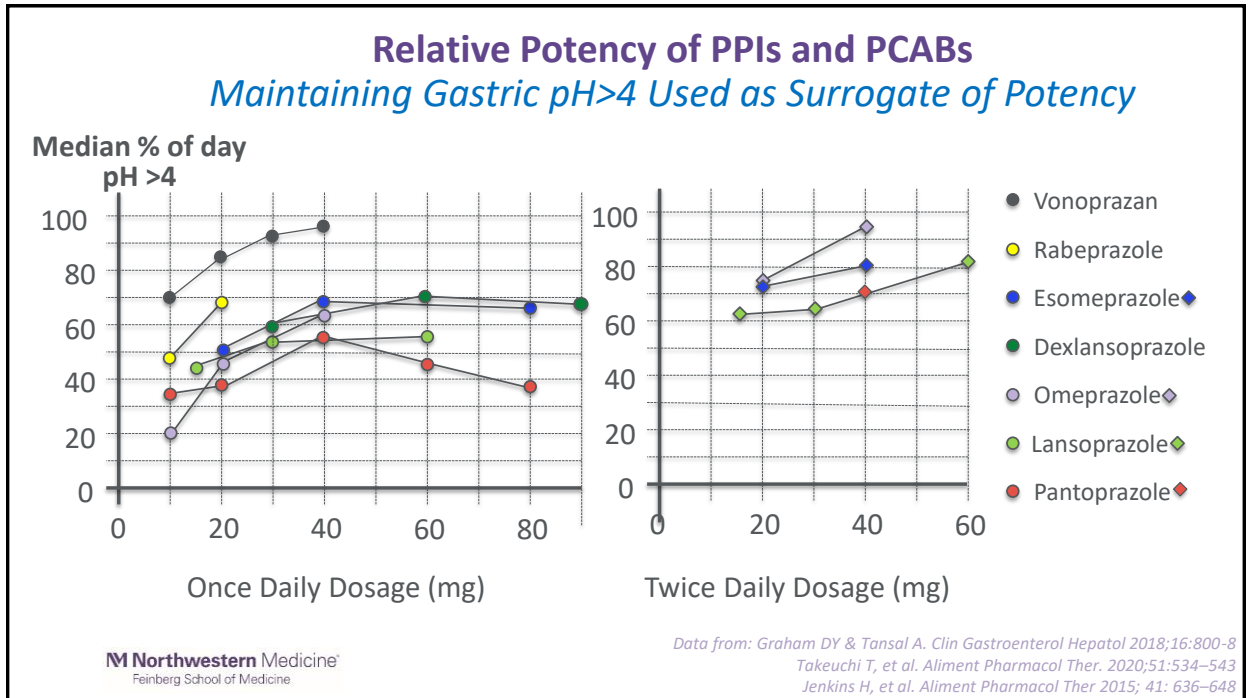
- Antacids
 - Alginate-containing
- H2RA's
 - Famotidine
 - Cimetidine
- **Proton pump inhibitors (PPIs)**
 - *Rabeprazole*
 - *Esomeprazole*
 - *Dexlansoprazole*
 - *Omeprazole*
 - *Lansoprazole*
 - *Pantoprazole*
- **Potassium competitive acid blockers (PCABs)**
 - *Vonoprazan*

• Anti-reflux surgery / procedures

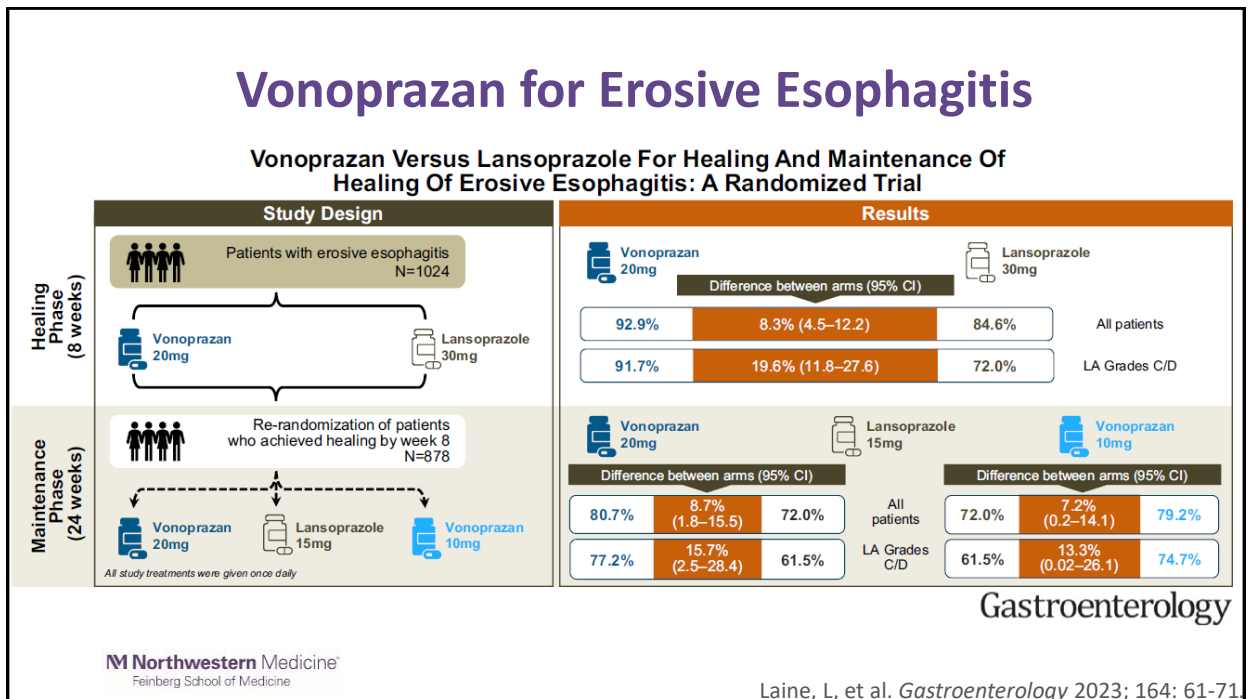
- *Hiatal hernia repair
- Laparoscopic fundoplication
 - 360° / Nissen
 - Partial (Toupet; Dor; etc)
- Magnetic sphincter augmentation
- Transoral incisionless fundoplication (TIF)
- cTIF (laparoscopic HH repair + TIF)
- Roux en y gastric bypass
- *others*

Medical Treatment of GERD

- Antacid – on demand use
 - Possible added benefit with alginate-containing antacid
- H2-receptor antagonists
 - On demand or nighttime use
 - Tachyphylaxis can limit consistent or long-term use
- PPIs are the current mainstay for medical treatment of erosive esophagitis and frequent GERD symptoms
 - ***Ideal use: take 30-60 minutes before a meal***
 - *Variable potency*
- PCABs (Potassium Competitive Acid Blockers) – *emerging role in erosive GERD and non-erosive heartburn control*



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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 17, 2019 VOL. 381 NO. 16

Randomized Trial of Medical versus Surgical Treatment for Refractory Heartburn

S.J. Spechler, J.G. Hunter, K.M. Jones, R. Lee, B.R. Smith, H. Mashimo, V.M. Sanchez, K.B. Dunbar, T.H. Pham, U.K. Murthy, T. Kim, C.S. Jackson, J.M. Wallen, E.C. von Rosenvinge, J.P. Pearl, L. Laine, A.W. Kim, A.M. Kaz, R.P. Tatum, Z.F. Gellad, S. Lagoo-Deenadayalan, J.H. Rubenstein, A.A. Ghaferi, W.-K. Lo, R.S. Fernando, B.S. Chan, S.C. Paski, D. Provenzale, D.O. Castell, D. Lieberman, R.F. Souza, W.D. Chey, S.R. Warren, A. Davis-Karim, S.D. Melton, R.M. Genta, T. Serpi,* K. Biswas, and G.D. Huang

- Patients with heartburn refractory to PPI:
 - 24 hour pH-impedance on omeprazole 20mg bid: AET >4.2% or SAP(heartburn)>95%
- RANDOMIZATION:
 - Laparoscopic Nissen fundoplication vs
 - PPI (omeprazole 20mg bid) + baclofen + desiprimine [“Active treatment”] vs
 - PPI (omeprazole 20mg bid) + placebo x 2 [“Control treatment”]

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Spechler, SJ, et al. NEJM 2019

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RCT: Surgical vs Medical Treatment for PPI-refractory Reflux-related Heartburn
Nissen fundoplication vs PPI+/- desipramine+baclofen

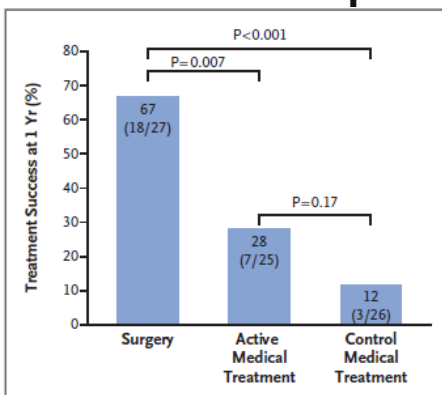


Figure 3. Treatment Success at 1 Year (Intention-to-Treat Analyses).

Treatment success was defined as an improvement (decrease) of 50% or more in the GERD-HRQL score from baseline.

Spechler, SJ, et al. NEJM 2019

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RCT: Surgical vs Medical Treatment for PPI-refractory Reflux-related Heartburn

Nissen fundoplication vs PPI+/- desipramine+baclofen

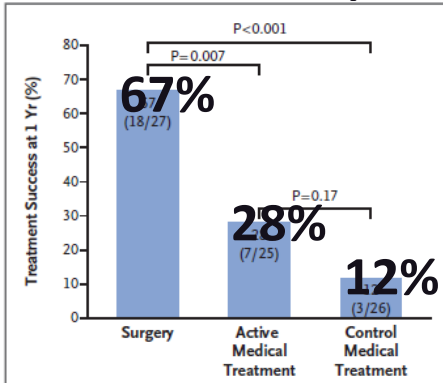
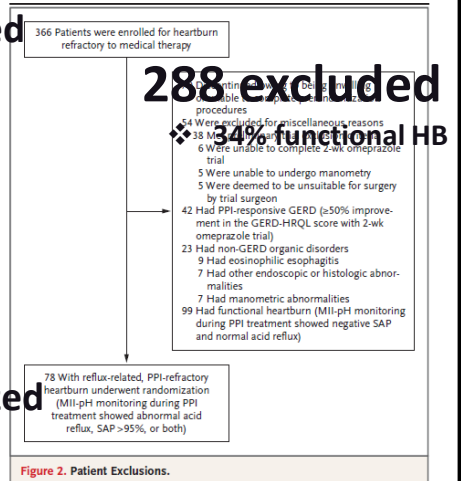


Figure 3. Treatment Success at 1 Year (Intention-to-Treat Analyses).

Treatment success was defined as an improvement (decrease) of 50% or more in the GERD-HRQL score from baseline.

366 enrolled



78 randomized

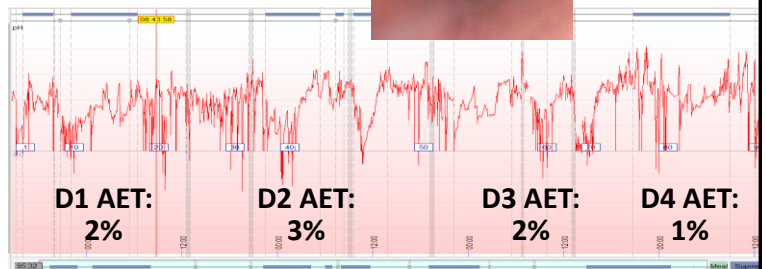
Figure 2. Patient Exclusions.

Spechler, SJ, et al. NEJM 2019

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Case 3

- 1) 54 yo M p/w heartburn
- Heartburn daily for the past 8 years
- Also with occasional regurgitation, chest pain, globus, and throat clearing
- On and off different PPIs for years
 - ~20-50% improvement when taking
- No dysphagia
- EGD 4 years ago – small hiatal hernia
 - told he ‘had GERD’
- EGD (off PPI)
 - Small hiatal hernia
 - Normal esophagus
 - Wireless pH capsule placed



Diagnosis:
Functional Heartburn

[‘Normal’ esophageal acid exposure time = <4%]

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Functional Esophageal Syndromes

Treatment options

- **‘Neuromodulators’ (Anti-depressants)**
 - **OFF LABEL USE**
 - Tri-cyclic [amitriptyline, nortriptyline, desipramine]
 - 10 to 25 mmg at bedtime with escalation of 10 to 25 mg increments to a target of 50-75 mg
 - Trazodone
 - 25mg QHs up to 100 mgHg
 - SSRIs [sertraline 50-200mg/day; citalopram 20mg/day]
 - SNRI [venlafaxine 75 mg/day]
- **Cognitive Behavioral therapy**
 - Diaphragmatic breathing

PPI Safety

❖ **“Do I need to be on PPI long-term?”**
“I heard I shouldn’t be on them for too long.”

- | | | |
|--|--|---|
| <ul style="list-style-type: none"> • 1) 48 yo F p/w heartburn • EGD = LA-D erosive esophagitis <ul style="list-style-type: none"> - Healed on omeprazole 40mg daily • Diagnosis: <ul style="list-style-type: none"> - +GERD - Erosive esophagitis | <ul style="list-style-type: none"> • 2) 32 yo F p/w heartburn • EGD – non-erosive; small HH • 96 hr wireless pH monitoring <ul style="list-style-type: none"> - 2/4 days with AET >6% • Diagnosis: <ul style="list-style-type: none"> - +GERD - Non-erosive | <ul style="list-style-type: none"> • 3) 54 yo M p/w heartburn • EGD – non-erosive; small HH • 96 hr wireless pH monitoring <ul style="list-style-type: none"> - 4/4 days with AET <4% • Diagnosis: <ul style="list-style-type: none"> - Functional heartburn - (negative GERD testing) |
|--|--|---|

Which of the Following Are Proven Complications Caused by Long-term Proton Pump Inhibitor (PPI) Use?

- A. Osteoporosis
- B. Dementia
- C. Kidney failure
- D. All of the above
- E. None of the above



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PPI Safety: Proposed Adverse Effects of Chronic PPI Therapy

Risk of Cancer	Risk of Infections	Absorption/ Metabolism Vitamins & Minerals	Effects on Other Drugs	Miscellaneous Adverse Effects
<ul style="list-style-type: none"> ▪ Gastric cancer after <i>H. pylori</i> treatment 	<ul style="list-style-type: none"> ▪ Enteric infections ▪ Pneumonia ▪ <i>C. difficile</i> ▪ SBP in cirrhotics ▪ COVID 	<ul style="list-style-type: none"> ▪ B12, iron, calcium ▪ Hypomagnesemia ▪ Osteoporosis ▪ Bone fracture 	<ul style="list-style-type: none"> ▪ Clopidogrel 	<ul style="list-style-type: none"> ▪ Interstitial nephritis ▪ Renal disease ▪ Colitis ▪ Celiac disease ▪ Myocardial infarction ▪ Stroke ▪ Dementia ▪ Early Death

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PPI Safety: Proposed Adverse Effects of Chronic PPI Therapy

Risk of Cancer	Risk of Infections	Absorption/ Metabolism Vitamins & Minerals	Effects on Other Drugs	Miscellaneous Adverse Effects
<ul style="list-style-type: none"> Gastric cancer after <i>H pylori</i> treatment 	<ul style="list-style-type: none"> Enteric infections Pneumonia <i>C difficile</i> SBP in cirrhotics COVID 	<ul style="list-style-type: none"> B12, iron, calcium Hypomagnesemia Osteoporosis Bone fracture 	<ul style="list-style-type: none"> Clopidogrel 	<ul style="list-style-type: none"> Interstitial nephritis Renal disease Colitis Celiac disease Myocardial infarction Stroke Dementia Early Death


• Vaezi M, et al. Gastroenterology 2017;153:35-48; Moayyedi P et al. Gastroenterology 2019;157:682-691.

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PPI Safety: Proposed Adverse Effects of Chronic PPI Therapy

Risk of Cancer	Risk of Infections	Absorption/ Metabolism Vitamins & Minerals	Effects on Other Drugs	Miscellaneous Adverse Effects
<ul style="list-style-type: none"> Gastric cancer after <i>H pylori</i> treatment 	<ul style="list-style-type: none"> Pneumonia COVID 	<ul style="list-style-type: none"> calcium 		<ul style="list-style-type: none"> nephritis Renal disease Celiac disease Myocardial infarction Stroke Dementia Early Death

Most identified by weak associations in observational studies that cannot establish cause and effect

High quality study established modest but significant association of PPI only with enteric infections

Any adverse effect related to decreased acid production and gastrin elevation likely will also pertain to PCABs


• Vaezi M, et al. Gastroenterology 2017;153:35-48; Moayyedi P et al. Gastroenterology 2019;157:682-691.

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PPI Safety

Gastroenterology 2019;157:682-691

Safety of Proton Pump Inhibitors Based on a Large, Multi-Year, Randomized Trial of Patients Receiving Rivaroxaban or Aspirin

Paul Moayyedi,¹ John W. Eikelboom,¹ Jackie Bosch,¹ Stuart J. Connolly,¹ Leanne Dyal,¹ Olga Shestakovska,¹ Darryl Leong,¹ Sonia S. Anand,¹ Stefan Störk,² Kelley R. H. Branch,³ Deepak L. Bhatt,⁴ Peter B. Verhamme,⁵ Martin O'Donnell,⁶ Aldo P. Maggioni,⁷ Eva M. Lonn,¹ Leopoldo S. Piegas,⁸ Georg Ertl,² Matyas Keltai,⁹ Nancy Cook Bruns,¹⁰ Eva Muehlhofer,¹⁰ Gilles R. Dagenais,¹¹ Jae-Hyung Kim,¹² Masatsugu Hori,¹³ P. Gabriel Steg,¹⁴ Robert G. Hart,¹ Rafael Diaz,¹⁵ Marco Alings,¹⁶ Petr Widimsky,¹⁷ Alvaro Avezum,¹⁸ Jeffrey Probstfield,¹⁹ Jun Zhu,²⁰ Yan Liang,²⁰ Patricio Lopez-Jaramillo,²¹ Ajay K. Kakkar,²² Alexander N. Parkhomenko,²³ Lars Ryden,²⁴ Nana Pogossova,²⁵ Antonio L. Dans,²⁶ Fernando Lanas,²⁷ Patrick J. Commerford,²⁸ Christian Torp-Pedersen,²⁹ Tomek J. Guzik,^{30,31} Dragos Vinereanu,³² Andrew M. Tonkin,³³ Basil S. Lewis,³⁴ Camilo Felix,³⁵ Khalid Yusoff,³⁶ Kaj P. Metsarinne,³⁷ Keith A. A. Fox,³⁸ and Salim Yusuf,¹ for the COMPASS Investigators



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Gastroenterology 2017;153:971-979

Association Between Proton Pump Inhibitor Use and Cognitive Function in Women

Paul Lochhead,^{1,2} Kaitlin Hagan,^{3,4} Amit D. Joshi,^{1,2} Hamed Khalili,^{1,2} Long H. Nguyen,^{1,2} Francine Grodstein,^{3,4} and Andrew T. Chan^{1,2,4}



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Gastroenterology 2019;157:682-691

Safety of Proton Pump Inhibitors Based on a Large, Multi-Year, Randomized Trial of Patients Receiving Rivaroxaban or Aspirin

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Association Between Proton Pump Inhibitor Use and Cognitive Function in Women

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The Relationship Between Proton Pump Inhibitor Use and Longitudinal Change in Bone Mineral Density: A Population-Based From the Canadian Multicentre Osteoporosis Study (CaMos)

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PPI Safety

❖ “Do I need to be on PPI long-term?”

- 1) 48 yo F p/w heartburn
- 2) 32 yo F p/w heartburn
- 3) 54 yo M p/w heartburn
- EGD = LA-D erosive esophagitis
- EGD – non-erosive; small HH
- EGD – non-erosive; small HH
- Healed on omeprazole 40mg daily
- 96 hr wireless pH monitoring
- 96 hr wireless pH monitoring
- 2/4 days with AET >6%
- 4/4 days with AET <4%
- **Diagnosis:**
- **Diagnosis:**
- +GERD
- +GERD
- Erosive esophagitis
- Non-erosive
- **Maintenance therapy indicated**
- **Could attempt to wean PPI, attempt on-demand tx**
- **PPI not needed**
- (PPI, PCAB, or surgery)
- **CBT or neuromodulator**

❖ Balance benefits of treatment vs (theoretic) risks

❖ Titrate to lowest, effective dosing

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Conclusions

Diagnosis and management of GERD

- Consider 'reflux symptom' and alarm symptoms to guide initial management strategy (e.g. empiric PPI vs endoscopy +/- pH)
- Objective GERD diagnosis (endoscopy + pH monitoring) to define GERD disease state ('phenotype') to guide treatment options
- PPIs are safe and effective; PCABs will offer a welcome new medical treatment option for GERD
- Anti-reflux surgery offers improved treatment response over medical management in carefully selected patients