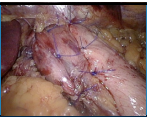



AAPA 2021



**Proton Pump Inhibitors
in 2021**


-SURGICAL, ENDOSCOPIC AND MEDICAL OPTIONS TO ADDRESS PROBLEMS W THE OVERUSE OF PPIs.

- Long term PPI addiction is a serious problem.
- Long term use PPI may cause serious complications
- There are many effective surgical, NOTES, medical, and nutritional solutions.
- \$11 billion/yr



1

Gerald T. Simons, PA-C



- PA
 - Medical & Surgical private practice
- Assistant Clinical Professor
 - Stony Brook PA Program
- Board of Directors
 - AASPA

– No disclosures.

2

QUESTION 1

- A 33-year-old graduate student is 8 months post op from a highly selective vagotomy for acid disease. He reports his pyrosis is well controlled but he has constant fatigue and weakness. The next appropriate action is

- Test for serum IgA H Pylori
- Order a upper endoscopy and Capsule endoscopy
- Order a Serum B12 level
- Educate the patient on proper diet and lifestyle modifications

3

QUESTION 2

- A 55 y/o M hedge fund manager with more than a 10 year history of GERD and Type I hiatal hernia returns for an annual evaluation. He reports that his reflux is well controlled with avoiding irritating foods and antacids as needed. He refuses to accept a refill of a proton pump inhibitor, sighting relief of symptoms. Physical exam is benign. Which of the following is appropriate?
 - A. H Pylori breath test
 - B. Continue to encourage lifestyle modifications
 - C. Upper endoscopy
 - D. Convert the patient to a H2RA and cryoprotection program

4

QUESTION 3

- Which of the following would NOT be eligible for long term PPI use?
 - A. Barrett's
 - B. High risk PUD with NSAIDs
 - C. Erosive esophagitis
 - D. Chronic heartburn

5

True/false

4. Patients on long term PPIs require DEXA scanning, especially men ____
5. Short term (2-6 weeks) therapy with PPI is generally safe and well tolerated ____
6. H2RAs when used appropriately have many of the benefits of PPIs w less the adverse effects ____
7. Cutting edge endoscopic techniques are effective alternatives to long term PPIs

6

True/False

8. Patients on PPIs are at a higher risk of gut infections, including c.diff and SIBO _____
9. When used, PPIs should be used at the lowest effective dose _____
10. In patients who are not responsive to PPIs, look for other problems _____

7

TODAYS HEADLINE #1

2 to 8 weeks to addiction

- Rebound acid is well documented with antacids...
 - Tx w PPIs for 8 wks induces acid-related symptoms once tx is withdrawn in healthy individuals.
 - >40% of healthy volunteers, who had never had acid symptoms, developed symptoms after stopping PPIs.
 - Rebound acid hypersecretion (an increase in gastric acid secretion above pre-treatment levels following antisecretory therapy) has been observed within 2 wks after stopping PPIs
- **A PPI can cause the very symptoms we are trying to treat!****

PPIs work well, maybe too well?

8

Today's headline #2

- “We found that PPI use, particularly twice-daily dosing, is associated with increased odds for reporting a positive COVID-19 test, even after accounting for a wide range of sociodemographic, lifestyle, and clinical variables” C.V. Almario, MD, MSHPM

© 2020 C.V. Almario, MD, MSHPM. All rights reserved. PPIs: A Double-Edged Sword.

9

HEADLINE #3

News about long term PPIs

More research coming

JAMA The Journal of the American Medical Association	2016: PPIs was independently associated with a 20% to 50% increase in incident CKD
ASN American Society of Nephrology	2016: Confirmed association PPIs with...CKD, Progression of ESRD, Doubling of Serum creatinine.
CMAJ Canadian Medical Association Journal	2015: PPI Therapy had increased risk of acute kidney injury and acute interstitial nephritis
PLOS ONE	2015 PLOS - General Population • PPI consumption increases chances of MI In general population also.
BMJ Open Gastroenterology 2014	2014 Japan - Hypomagnesemia • Long term PPI intake induces hypomagnesemia
Circulation American Heart Association	2013 & 2016 AHA - Circulation THE ADMA PATHWAY & PPI induced Endothelial aging.
thebmj	2011 PPI Interaction with Clopidogrel • PPI & Clopidogrel; similar CYP2 pathway, PPI reduces clopidogrel action by almost 45%

10

Then, in 2017...

- **“Evidence is inadequate to establish causal relationships between PPI therapy and many of the proposed associations”**
 - Except: Mg, Renal, Cdiff
 - ? Memory loss

– Vaezi MF, Yang YX, Howden CW. Complications of Proton Pump Inhibitor Therapy. *Gastroenterology*. 2017 Jul;153(1):35-48.

11

Headline #4

Know the LES

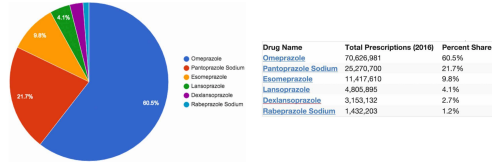
- In those with long term pyrosis, aggressively assess the LES!
- A poor functioning LES is often very amenable to fundoplication.

12

Headline #5

Total Prescriptions in (2016)

In 2016, 116,706,521 American's were prescribed PPI's. This does not include over the counter usage.



Prescription data source: Medical Expenditure Panel Survey (MEPS) 2006-2016, Agency for Healthcare Research and Quality (AHRQ).

ABIM: "More than half of the people who take PPIs probably do not need them."

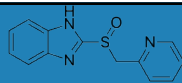
13

OBJECTIVES

- List the current indications for short term PPI use
- List the current indications for long term PPI use
- Discuss the side effects of PPI use including but not limited to renal disease, heart disease, metabolic abnormalities, and bone demineralization
- Recognize alternatives to PPI use including diet modification, anti-reflux surgery, and alternative medications
- Tell a patient about the pros and cons of PPI use

14

In the beginning...



- 1977 Forte and Lee
- Newly discovered proton pump (H^+/K^+ ATPase) in the secretory membrane of the parietal cell was the final step in acid secretion.
- 1989 Omeprazole approved in USA

Gastroenterology, 1977 Oct;73(4 Pt 2):921-6.

Gastric adenosine triphosphatases: a review of their possible role in HCl secretion.

Forte JG, Lee HC.

15

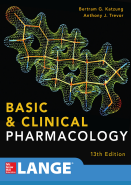
Also

- PPIs decrease dysplasia in Barrett's

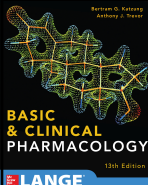
19

PPIs

“Since their introduction in the late 1980s, these efficacious acid inhibitory agents have assumed the major role for the treatment of acid-peptic disorders. PPIs are now among the most widely prescribed drugs worldwide due to their outstanding efficacy and safety.”



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“PPIs are the most effective agents for the Tx of nonerosive and erosive reflux disease, esophageal complications of reflux disease (peptic stricture or Barrett’s esophagus), and extraesophageal manifestations of reflux disease.

Once-daily dosing provides relief and tissue healing in 85% of patients; up to 15% of patients require twice-daily dosing. GERD symptoms recur in over 80% of patients within 6 months after discontinuation of a PPI.

Erosive esophagitis or esophageal complications, long-term daily maintenance therapy with a full-dose or half-dose PPI is usually needed. Many patients with nonerosive GERD may be treated successfully with intermittent courses of PPIs or H2 antagonists taken as needed (“on demand”) for recurrent symptoms.”

Long term effects of PPI?

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Omeprazole

.....INDICATIONS AND USAGE.....

PRILLOSEC is a proton pump inhibitor indicated for:

- Treatment in adults of duodenal ulcer (1.1) and gastric ulcer (1.2)
- Treatment in adults and children of gastroesophageal reflux disease (GERD) (1.3) and maintenance of healing of erosive esophagitis (1.4)

The safety and effectiveness of PRILLOSEC in pediatric patients <1 year of age have not been established. (8.4)

.....DOSAGE AND ADMINISTRATION.....

Indication	Omeprazole Dose	Frequency
Treatment of Active Duodenal Ulcer (2.1)	20 mg	Once daily for 4 weeks. Some patients may require an additional 4 weeks
H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence (2.2)		
<i>Triple Therapy:</i>		
PRILLOSEC	20 mg	Each drug twice daily for 10 days
Amoxicillin	1000 mg	
Clarithromycin	500 mg	
<i>Dual Therapy:</i>		
PRILLOSEC	40 mg	Once daily for 14 days
Clarithromycin	500 mg	Three times daily for 14 days
Gastric Ulcer (2.3)	40 mg	Once daily for 4 to 8 weeks
GERD (2.4)	20 mg	Once daily for 4 to 8 weeks
Maintenance of Healing of Erosive Esophagitis (2.5)	20 mg	Once daily
Pathological Hypersecretory Conditions (2.6)	60 mg (varies with individual patient)	Once daily
Pediatric Patients		
(1 to 16 years of age) (2.7)	Weight	Dose
GERD And Maintenance of Healing of Erosive Esophagitis	5 <10 kg	5 mg
	10<20 kg	10 mg
	≥20 kg	20 mg

package insert

2021

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Table 1. Recommended DEXILANT Capsules Dosage Regimen by Indication in Patients 12 Years of Age and Older

Indication	Dosage of DEXILANT Capsules	Duration
Healing of EE	One 60 mg capsule once daily.	Up to 8 weeks.
Maintenance of Healed EE and Relief of Heartburn	One 30 mg capsule once daily.	Controlled studies did not extend beyond 6 months in adults and 16 weeks in patients 12 to 17 years of age.
Symptomatic Non-Erosive GERD	One 30 mg capsule once daily.	4 weeks.

Table 2. Recommended DEXILANT SoluTab Dosage Regimen by Indication in Patients 12 Years of Age and Older

Indication	Dosage of DEXILANT SoluTab	Duration
Maintenance of Healed EE and Relief of Heartburn	One 30 mg tablet once daily.	Controlled studies did not extend beyond 6 months in adults and 16 weeks in patients 12 to 17 years of age.
Symptomatic Non-Erosive GERD	One 30 mg tablet once daily.	4 weeks.

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PPI best practices

- Use to diagnosis GERD
- Shortest course of therapy
- Lowest possible dose
- Take correctly
- Endoscopy for GERD >5 yrs
- Many PPI prescriptions are unnecessary
- Close monitoring in chronic use
- Consider H2RA

24

Why this addiction?

- Acid rebound= increasing doses
- Undiagnosed H pylori
- Undiagnosed dysbiosis/SIBO
- Hiatal Hernia !
 - i.e. there is not too much acid, its simply in the wrong place

Only 40% of patients are happy w the results of PPI therapy (*Fass J gastroenterology104*)

25

Do not write for refills!

REBOUND HYPERSECRETIONS

- Rebound hyperacid well documented w multiple meds!
- 33% continue to refill their Rx past the intended time period.
- Many refill their prescriptions because they have severe withdrawal symptoms each time they run out ... and are assuming they need MORE of the drug to help them?
 - WOW- rebound hypersecretion triggers us & the patient to take more PPIs!
- This is a vicious cycle, one that can easily lead to tolerance and dependency
- “If rebound acid hypersecretion induces acid-related symptoms, this might lead to PPI dependency. Our results justify the speculation that PPI dependency could be one of the explanations for the rapidly and continuously increasing use of PPIs.”

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Addressing PPI addiction hypersecretion & secretion...

- Patient education ..scare them!
 - Diet modification
- Poor compliance with diet
- Poor compliance w lifestyle changes
- H. Pylori
- Hiatal Hernia
- SIBO/Dysbiosis
- Diabetic gastroparesis
- **Get to know the LES**
 - Manometry. pH probe. endoscopy and esophogram!

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PPI Problems effects of long term use

The image shows a screenshot of a webpage from drugwatch.com. The main heading is 'Proton Pump Inhibitor (PPI) Lawsuits'. Below the heading, there is a short paragraph of text. At the bottom of the screenshot, there are several logos for medical journals: BMJ, Circulation, JAMA, BMJ Open Gastroenterology 2014, PLOS ONE, JASN, and CMAJ.

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Proton Pump Inhibitors Information

Proton pump inhibitors (PPIs) are used to treat certain gastrointestinal disorders and work by reducing the amount of acid in the stomach. They are available both as prescription and as over-the-counter (OTC) medications.

Current Safety Information

- FDA Drug Safety Communication: Clostridium difficile - associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs) 2/8/2012
- FDA Drug Safety Podcast for Healthcare Professionals: Clostridium difficile-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs) 2/8/2012
- Lansoprazole - Letter to Healthcare Professionals: Communication on lansoprazole delayed-release orally disintegrating tablets manufactured by Teva Pharmaceuticals [ARCHIVED] 4/15/2011
- FDA Drug Safety Communication: Low magnesium levels can be associated with long-term use of Proton Pump Inhibitor drugs (PPIs) [ARCHIVED] 3/2/2011
- FDA Drug Safety Podcast: Risk of Low Magnesium Levels Associated with Long-Term Use of Proton Pump Inhibitors [ARCHIVED] 3/11/2011
- FDA Drug Safety Podcast for Healthcare Professionals: Low magnesium levels can be associated with long-term use of Proton Pump Inhibitor drugs (PPIs) [ARCHIVED] 3/2/2011
- FDA Drug Safety Communication: Possible increased risk of fractures of the hip, wrist, and spine with the use of proton pump inhibitors [ARCHIVED] 5/25/2010; updated 3/23/2011
- Possible Increased Risk of Bone Fractures With Certain Antacid Drugs [ARCHIVED] FDA consumer update
- Podcast for Healthcare Professionals: Possible increased risk of fractures of the hip, wrist, and spine with the use of proton pump inhibitors [ARCHIVED] 5/28/2010

FDA

Accessed April 2020

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Accessed Mar 20 2021

CMS.gov

Proton Pump Inhibitors: Use in Adults


The Centers for Medicare & Medicaid Services (CMS) Medicaid Integrity Group (MIG) has identified issues with using medications in the proton pump inhibitor (PPI) drug therapy class. The U.S. Food and Drug Administration (FDA) approves product labeling for prescription drugs. The MIG has identified that some providers may have prescribed PPIs outside of FDA-approved product labeling for indication, age, dosage, or duration of therapy. Therefore, CMS wants to improve quality of care and enhance patient safety by educating providers on the proper use of PPIs in adult patients.

This fact sheet summarizes for providers the current FDA-approved product labeling for the use of PPI medications in adult patients. After reading this fact sheet, providers should be able to accurately:

- Recall the FDA-approved indications for PPI use in adults and the specific indications for each PPI;
- Recall the FDA-approved dosing options for PPI use in adults; and
- Describe the adverse reactions of, and risks related to, long-term use of PPIs.

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Principles and Practice of
HOSPITAL MEDICINE



-Increase the risk of C. diff acquisition and recurrence in hospitalized patients. Loss of the gastric acid barrier may make it easier for C. diff spores acquired in the hospital to reach the colon. -

-PPIs also have adverse effects on the gut microbiome. -

-Much PPI use in the hospital setting is not evidence-based, and PPIs can be discontinued or tapered in many hospitalized patients with ill effects

The longer the exposure the higher the risk.

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Medicine, April 2016
Higher risk of ESRD in patients w known renal disease

OBSERVATIONAL STUDY

Association Between the Use of Proton Pump Inhibitors and the Risk of ESRD in Renal Diseases: A Population-Based, Case-Control Study

Yen-Chen Peng, MD, Cheng-Li Lin, MD, Hung-Lin Tsai, MD, Chi-Nuo Cheng, MD, Yu-Lin Wu, PhD, and Chia-Hong Kuo, MD

Objective: Proton pump inhibitors (PPIs) are used to suppress acid secretion and ease food intake. The use of PPIs and development of end-stage renal disease (ESRD) were compared in patients with known renal disease and without renal disease.

Design: This was a population-based, case-control study using data from the Taiwan National Health Insurance Research Database (NHIRD). The exposure date and date of renal disease diagnosis were defined as the index date. The outcome was the date of ESRD diagnosis.

Setting: The study was conducted in Taiwan.


Participants: 5,456 patients with known renal disease and 5,456 patients without renal disease were included in the study.

Measurements and Main Results: The use of PPIs was associated with a significantly higher risk of ESRD (adjusted OR, 1.48, 95% CI, 1.11–2.03). The risk of ESRD was higher for all the types of PPI used in the patients (OR was 1.70 [95% CI, 1.12–2.51] for dexlansoprazole, 1.63 [95% CI, 1.12–2.36] for lansoprazole, 1.59 [95% CI, 1.11–2.28] for omeprazole, 1.48 [95% CI, 1.07–2.04] for pantoprazole, and 1.46 [95% CI, 1.07–2.00] for esomeprazole).

Conclusions: PPIs are associated with the risk of ESRD in patients with renal disease. It is necessary that appropriate prescription of PPIs consider renal function and the severity of gastric symptoms of patients hospitalized with renal disease.

DOI: 10.1093/medicine/mpv030

32




PPIP

Dementia

Bone fracture

- **PPI- Problems**
- **Lack of necessary levels of acid for digestion**
- **FDA: Increased fracture risk**
- **FDA: Hypomagnesemia**
- **Lack of intrinsic factor**

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PPIP 

- Increased risk of CAP and nosocomial pneumonia
- Prolonged hypergastrinemia
- Gastric atrophy/ depletion of gut microbiome
- Chronic hypochlorhydria
- Increased risk of fractures
 - 40 year old men with hip fractures?
- GI Malignancies
- Hypomagnesemia
- Iron and B12 malabsorption
- SIBO

Targownik, Am J Gastroent 2018: 113

34

PPI & Medication interactions

- “Chronic acid suppression can minimize the effectiveness of any medication requiring an acidic environment for absorption.”
 - Most common: ampicillin digoxin, atazanavir, ketoconazole, and iron.
- Risk of drug interactions between PPIs and medications metabolized via cytochrome P450 system.
 - clopidogrel and omeprazole

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PPIs and memory

- Prospective studies show that PPI uses had a 44% increased risk of Alzheimer’s
 - Mixed data

36

PPIs & Gut Mucosa

- Long-term PPI use causes histopathological changes
 - parietal cell protrusion into the gland lumen,
 - cystic dilation of gastric fundic glands
 - foveolar epithelial hyperplasia.
- Endoscopic examination as fundic gland polyps, hyperplastic polyps, multiple white and flat elevated lesions, cobblestone-like mucosa, or black spots.

Kim GH. Proton Pump Inhibitor-Related Gastric Mucosal Changes. Gut Liver. 2020 Apr 27.

37

PPIs & the Data

- Most on PPIs long term are older and have co-morbidities
- Studies are retrospective and observational
- Moayyedi et al Gastroenterology 2019
 - N= 17,598
 - RCT, DB
 - RESULTS= enteric infections higher, Cdiff double risk.

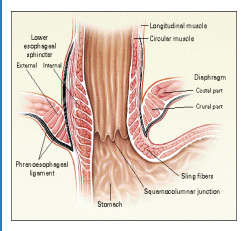
38

Data supports

- Monitoring long term patients
 - Document H Pylori neg
 - Magnesium
 - DEXA
 - Chemistry
 - Calcium, BUN/Creat
 - ?SIBO

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PPI Alternatives



- 80% of cases are due to malfunction of the LES!
- *What can we do as PAs to improve LES tone?*

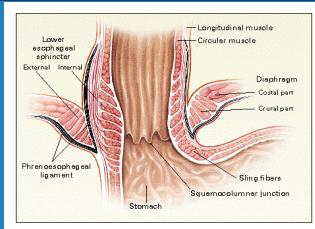
NEJM

40

Know the LES Phrenoesop. Ligament



- **Composed of:**
 - Pleura
 - Fascia
 - Peritoneum
- It's tough and secures the distal esophagus.



IMPORTANT SURGICAL STRUCTURE

**Muscle relaxation
allows food to pass**

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GERD



- Essentials of Diagnosis
- Heartburn.
- Regurgitation.
- HH on barium swallow.
- Esophagitis on endoscopy.
- Abnormal esophageal motility on manometry.
- Abnormal pH monitor.

GERD- think LES failure!

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GERD Danger signs



- N & V
- Weight Loss
- Anemia
- Blood in the stool
- Dysphagia
- Long Duration
- Especially in >50 y/o age group

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GERD - SYMPTOMS

ESOPHAGEAL

Heartburn
Acid regurgitation
Chest pain
Dysphagia

EXTRAESOPHAGEAL

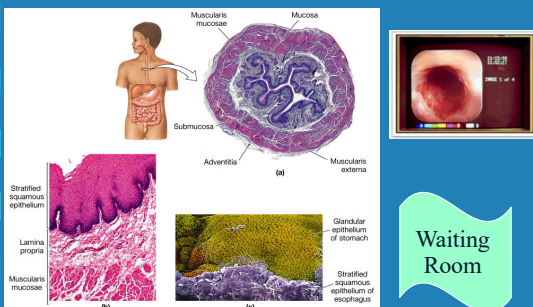
Chronic cough
Hoarseness
Laryngitis
Asthma
Dental erosions
Chest pain

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Where is the "Z-Line"

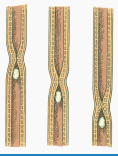
Don't be fooled:

"PA...after 5 years my GERD is cured!!"

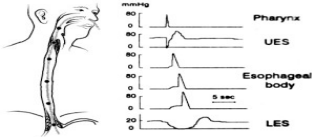


45

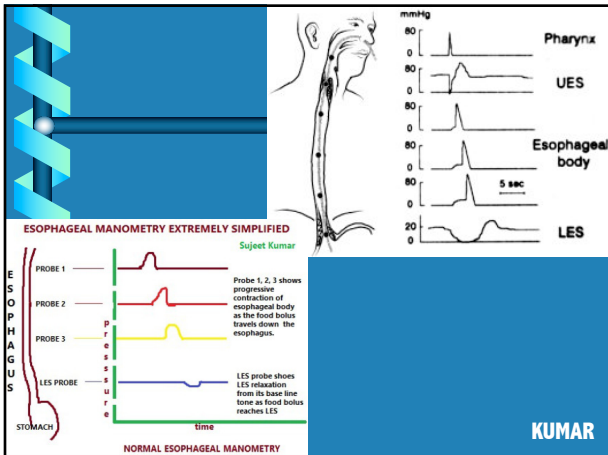
Esophagus-physiology USE MANOMETRY!



Esophageal peristalsis
Initiated by a swallow
Circular muscle contract above the bolus
Longitudinal muscle contract below
Bolus transported in 6 – 8 sec.



46

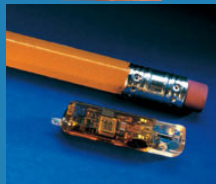
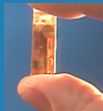


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pH probe

-The most sensitive test to diagnosis reflux!

- Wireless
- For resistant cases
- Documents need for surgical treatment




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Alternatives for patients on long term PPI



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PPI Reduction

- Start slow!
- BID to QD, then reduce am dose to lowest possible
- Skip a day on occasion
- H2RA or antacids for breakthrough
- May take months
- Make sure patient is taking correctly
- Regular coaching on diet!

50

Lifestyle Modification

- Most effective for infrequent heartburn
- Modify factors that may precipitate reflux:
 - Elevate head of bed
 - Decrease fat intake
 - Stop smoking
 - tobacco inhibits saliva, stimulates gastric acid, relaxes LES
 - Avoid recumbency 3 hours after eating
 - Lose weight
 - Manage constipation
 - Avoid tight clothing

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Lifestyle Modification

- Drink aloe juice before a meal
- Avoid foods that slow gastric emptying:
 - Cinnamon
 - ? Prokinetics
- Decrease LES pressure:
 - Chocolate, alcohol, peppermint, coffee, maybe onions and garlic
- Irritate damaged esophageal lining:
 - Citrus juice, tomato juice, pepper

52

DIETS!

- Food Combining: The stomach digests foods at different rates and by using different digestive enzymes throughout the breakdown process. Eating food combos together can help eliminate bloat, reduce weight, enhance nutritional value and gut health.

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GLUTAMINE

- Comprehensive support for the integrity and healthy function of the gastrointestinal lining.
- Helps heal the stomach lining and reduces symptoms of reflux
- Great if combined w Aloe!

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Saccharomyces

- Restores and maintains the normal balance of intestinal bacteria
- Helps defend against harmful bacteria, viruses and fungus
- Used in acute or chronic gastroenteritis, colitis, acute diarrhea, IBS and fragile digestive tract
- Counteracts toxins produced by certain bacteria
 - E. Coli and C. difficile

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Antacid Mechanisms

- Neutralize Stomach Acid
 - Sodium Bicarbonate (i.e. Alka-Seltzer)
 - Calcium Carbonate (Tums)
 - Magnesium Hydroxide (a.k.a. MOM)
 - Mg + Al Hydroxides (Maalox)
 - Mg + Al Hydroxides + Simethicone (Mylanta)
- Decrease Acid Secretion
- Improve Stomach Resistance to Acid

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Basic Antacids

- Calcium carbonate chews
 - 2400mg/d is maximum dose
 - Bismuth
 - Anti-microbial aspects
 - Limit those with aluminum
- (Anon, 2007)



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H2RA's

- Added to lifestyle changes and antacids
- OTC antacids relieve about 20% of patients
- Rx strength for 2-6 week trial more effective.
- Not as strong as PPI, but cheaper and less side effects!

58

Immunoglobulin G

- Trade names: ENTERAGAM, SBI Protect
- Reduces inflammation in the digestive tract, heals gut permeability
- Binds and neutralizes foreign microbes in the gut (Dysbiosis, SIBO)
- Supports lean muscle mass

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Other great ideas

- Baking soda and water
- Sleep positioning devices
 - Great for LPR
- Pancreatic enzymes w each meal
- Esophagitis
 - Steroid MDI, spray on that and swallow
- H. Pylori therapy
 - NEJM Mastic gum

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Surgical therapy

- FUNDOPLICATION
- MAGNET
- NOTES/ENDOSCOPIC

SURGICAL TX = FAST RESULTS




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Surgical Treatment of GERD

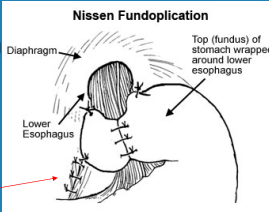
- Indications
 - Esophagitis
 - Barrett's metaplasia
 - Stricture
 - Failure of Medical Tx
 - Young patient –lifetime of PPI's?
 - Ulceration of Esophagus
 - Stricture
 - Bleeding Ulcer
 - Frequent Aspiration

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Antireflux Procedures

MOST COMMON:

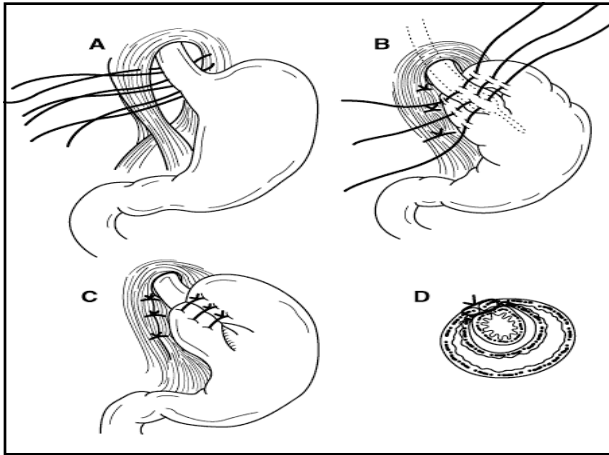
Nissen Fundoplication
360 Wrap
Laparoscopic



HH



63



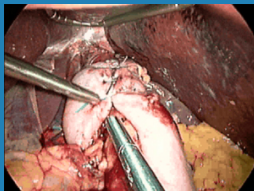
64

Partial fundoplication

HH repair

Gastroplasty

Endoscopic surgery





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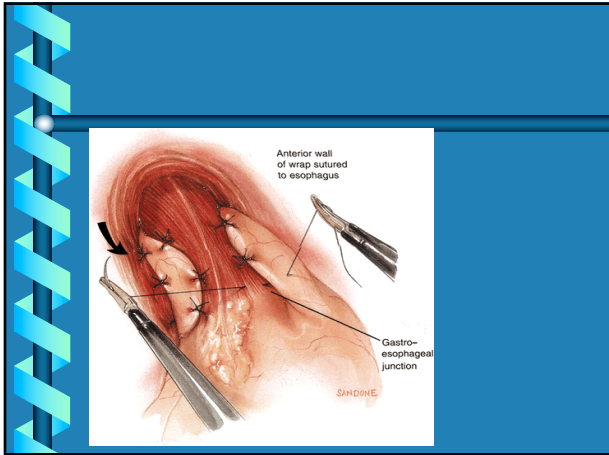
Toupet fundoplication

- 180 wrap
- Posterior
- For patients with abnormal muscle function/peristalsis

Partial Fundoplication

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Magnetic sphincter augmentation

Figure 1: A precision sizing tool is used to determine the appropriate size LINX System.

Figure 2: The LINX System is positioned around the LES using suture tails.

Figure 3: The ends of the LINX System are aligned and joined for secure closure.

TORAXMEDICAL LYNX

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Short-Term Outcomes Using Magnetic Sphincter Augmentation Versus Nissen Fundoplication for Medically Resistant Gastroesophageal Reflux Disease

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Background. In 2012 the United States Food and Drug Administration approved implantation of a magnetic sphincter to augment the native reflux barrier based on single-arm data. We sought to compare our initial experience with magnetic sphincter augmentation (MSA) with laparoscopic Nissen fundoplication (LNf).
Methods. A retrospective case-control study was performed of consecutive patients undergoing either procedure who had chronic gastrointestinal esophageal disease (GERD) and a hiatal hernia of less than 3 cm.
Results. Sixty-two patients underwent operations (34 MSA and 32 LNf). The groups were similar in reflux characteristics and hernia size. Operative time was longer for LNf (118 vs 75 min) and resulted in 1 return to the operating room and 1 readmission. Preoperative symptoms were abolished in both groups. At 6 months or longer postoperatively, scores on the Gastroesophageal Reflux Disease Health Related Quality of Life scale improved from 20.6 to 5.0 for MSA vs 22.8 to 5.5 for LNf. Postoperative DASH scores (14.2 vs 5.1, $p = 0.0001$) and the percentage of time pH was less than 4 (4.6 vs 1.1; $p = 0.0003$) were normalized in both groups but statistically different. MSA resulted in improved gassy and bloated feelings (1.32 vs 2.36; $p = 0.009$) and stabilized belching in 67% compared with none of the LNfs.
Conclusions. MSA results in similar objective control of GERD, symptom resolution, and improved quality of life compared with LNf. MSA seems to restore a more physiologic sphincter that allows physiologic reflux, facilitates belching, and creates less bloating and flatulence. This device has the potential to allow individualized treatment of patients with GERD and increase the surgical treatment of GERD.

(Ann Thorac Surg 2014;98:498-505)
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One Hundred Consecutive Patients Treated with Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease: 6 Years of Clinical Experience from a Single Center

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BACKGROUND: This study was undertaken to evaluate our clinical experience during a 6-year period with an implantable device that augments the lower esophageal sphincter for gastroesophageal reflux disease (GERD). The device uses magnetic sphincter augmentation (MSA) to strengthen the antireflux barrier.

STUDY DESIGN: In a single-center, prospective case series, 100 consecutive patients underwent laparoscopic MSA for GERD between March 2007 and February 2012. Clinical outcomes for each patient were tracked post implantation and compared with presurgical data for esophageal pH measurements, symptom scores, and proton pump inhibitor (PPI) use.

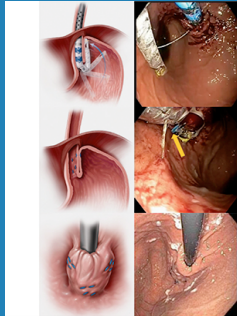
RESULTS: Median implant duration was 3 years (range 378 days to 6 years). Median total acid exposure time was reduced from 8.0% before implant to 3.2% post implant (p < 0.001). The median GERD Health Related Quality of Life score at baseline was 16 on PPIs and 24 off PPIs and improved to a score of 2 (p < 0.001). Freedom from daily dependence on PPIs was achieved in 85% of patients. There have been no long-term complications, such as device migrations or erosions. Three patients had the device laparoscopically removed for persistent GERD, odynophagia, or dysphagia, with subsequent resolution of symptoms.

CONCLUSIONS: Magnetic sphincter augmentation for GERD in clinical practice provides safe and long-term reduction of esophageal acid exposure, substantial symptom improvement, and elimination of daily PPI use. For candidates of antireflux surgery who have been carefully evaluated before surgery to confirm indication for MSA, MSA has become a standard treatment at our institution because control of reflux symptoms and pH normalization can be achieved with minimal side effects and preservation of gastric anatomy. *J Am Coll Surg* 2013;217:577-585. © 2013 by the American College of Surgeons

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Transoral incisionless fundoplication

HH < 2 cm
Normal manometry
Partial response to PPI



Trad K et al.
Surg Innov. 2015;22:26-40.

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Lastly, a word on who needs PPI GI prophylaxis

Major risk (need at least 1)

- Coagulopathy (INR > 1.5, Ptt < 50K, or PTT > 70)
- Mechanical ventilation > 48hrs
- GI ulceration or bleeding within the past year
- Traumatic brain or spinal cord injury
- Severe burn (>35% of the body surface area)

Minor risk (need > 2)

- Sepsis
- ICU stay > 1 week
- Occult GI bleeding > 6 d
- High dose glucocorticoid therapy (>250mg)
- Enteral feeding

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Inappropriate use of GI prophylaxis

- 27% - 71% patients on wards were placed on GI PPI
- 56% - 70% of patients received GI PPI with no indications
- 55% of patients receiving inappropriate GI ppx were discharged with acid suppressive medications
- Only 35% really needed it!

* Grube RR and May DB, "Stress ulcer prophylaxis in hospitalized patients not in intensive care units". Am J Health-Syst Pharm. Vol 64

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In summary, lessons for practice

- PPIs can cause rebound hyperacidity after 2 to 8 weeks of therapy. Use the lowest dose possible and the shortest period of time.
- Poor lifestyle choices, H. Pylori infection, and Hiatal hernias are common reasons why patients continue to have acid disease and symptoms after completing a course of PPIs
- Anti-reflux and anti-acid surgical procedures play a strong role on management of GERD cause by poor LES tone documented by pH probe
- Use PPIs: shortest dose, shortest period

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Lessons for practice

- Utilize more aggressive dietary modification with cytoprotection and remodeling of the gut microbiome
- Several published studies show that patients taking long term PPIs have an overall increase in mortality compared to those NOT on PPIs

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QUESTION 1

- A 33-year-old graduate student is 8 months post op from a highly selective vagotomy for acid disease. He reports his pyrosis is well controlled but he has constant fatigue and weakness. The next appropriate action is
 - A. Test for serum IgA H Pylori
 - B. Order a upper endoscopy and Capsule endoscopy
 - C. *Order a Serum B12 level
 - D. Educate the patient on proper diet and lifestyle modifications

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QUESTION 2

- A 55 y/o M hedge fund manager with more than a 10 year history of GERD and Type I hiatal hernia returns for an annual evaluation. He reports that his reflux is well controlled with avoiding irritating foods and antacids as needed. He refuses to accept a refill of a proton pump inhibitor, sighting relief of symptoms. Physical exam is benign. Which of the following is appropriate?
 - A. H Pylori breath test
 - B. Continue to encourage lifestyle modifications
 - *C. Upper endoscopy
 - D. Convert the patient to a H2RA and cryoprotection program

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QUESTION 3

- Which of the following would NOT be eligible for long term PPI use?
 - A. Barrett's
 - B. High risk PUD with NSAIDs
 - C. Erosive esophagitis
 - D. *Chronic heartburn

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True/false

4. Patients on long term PPIs require DEXA scanning, especially men ____
5. Short term (2-6 weeks) therapy with PPI is generally safe and well tolerated ____
6. H2RAs when used appropriately have many of the benefits of PPIs w less the adverse effects ____
7. Cutting edge endoscopic techniques are effective alternatives to long term PPIs

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True/False

8. Patients on PPIs are at a higher risk of gut infections, including c.diff and SIBO ____
9. When used, PPIs should be used at the lowest effective dose ____
10. In patients who are not responsive to PPIs, look for other problems ____

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Additional References

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AAPA 2022 & P-CABs?

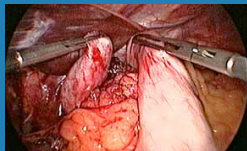
- **Potassium-competitive acid blockers**
 - bind reversibly to K^+ ions and block the H^+ , K^+ ATPase enzyme & prevents acid production.



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THANK YOU!

- It's a wrap!
- Limit PPIs
- Restore the gut microbiome
- Remember manometry & pH probe



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