FUNCTIONAL MEDICINE
Continuing Education

Chronic PPI Use and the Pitfalls of PPI Withdrawal: The Gut-Healing Protocol to Successfully Reduce PPI Usage

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Disclosures

- Neutraceutical Consultant:
  - Orthomolecular Products - Clinical Expert
  - United Naturals - Clinical Advisor
- Health Tech Consultant:
  - Fullscript - Clinical Advisor
  - MBODY360 - Chief Medical Officer

Objectives

- Understand the mechanism of action of PPI's
- Review a case study as an example of successful, but complicated PPI withdrawal
- Develop a strategy for withdrawing PPI's
- Discuss treatment strategies for "acid reflux"
- Review gut-healing supplements
- Address the challenges and pitfalls of PPI withdrawal

Case Study

- 30 y/o male presented to my office with 6 months of worsening GI symptoms: gas, flatulence and poorly-formed stools. Symptoms initially started after a BBQ July 4th weekend.
- PMHx: Stress fracture in Left foot 5 months prior, for which he took an NSAID for 10 days. GI symptoms worsened after this.
- 4 months ago: GI placed him on a PPI (concern for ulcer)
- Rx: Dexlansoprazole 30mg once daily for 2 months
- EGD: normal. Bx negative for H. pylori & Celiac dz.
- Stool study: neg for H. pylori

Case Study

Other Symptoms:

- While on the Dexlansoprazole he developed:
  - Diarrhea
  - Gas / lots of burping

Diet: he kept a food diary to try to tease out food triggers

- Tried cutting out gluten – no difference
- Egg-free – felt better

Additional Tests: SIBO Breath Test (after Dexlansoprazole course) 2 months prior:

  – Positive for mixed H2S-predominant/CH4 SIBO

Case Study

SIBO Tx (with his prior internist):

- Rx: Rifaxamin 550mg TID for 14 days
  - Temporary improvement
  - Symptoms return 3—4 weeks later

Diet: concerned about food allergies with his symptoms

- Food allergy testing
  - Neg for any food reactions
  - Pos for cats, roaches, and birch tree pollen (cross-react w/ stone fruit)

Case Study: 1st Visit Plan

Diet: SIBO-specific food plan (low-FODMAP)

- He basically follows a modified Paleo Diet

Repeat SIBO Breath Test:

- Positive for H2-predominant SIBO

Repeat Rx:

- Repeat Rifaxamin 550mg TID for 14 days
- Add Slippery elm bark powder to complement Atbx treatment
- Add Herbal anti-microbial

Further Testing: **Comprehensive Digestive Stool Analysis (CDSA)**

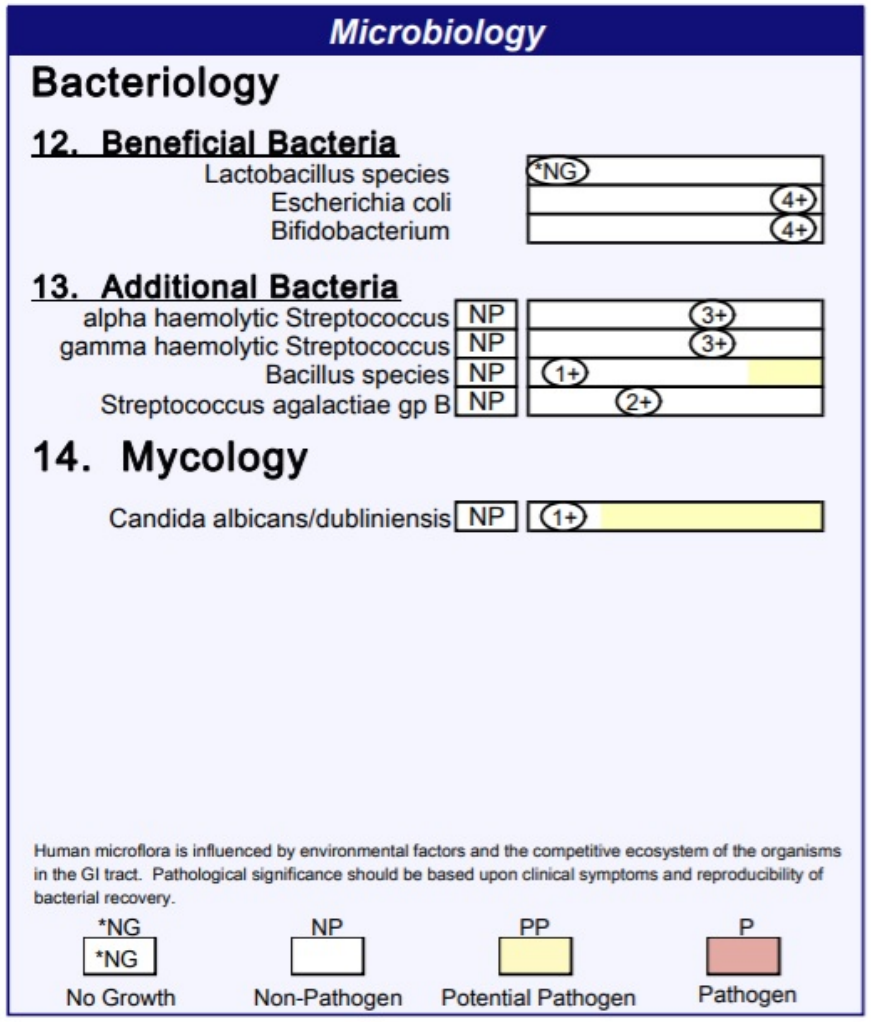
- Rule out dysbiosis
- Rule out yeast overgrowth

Case Study: 2nd Visit Results

CDSA:

- Yeast overgrowth
- Dysbiotic flora:

  No growth *Lactobacillus*



Microbiology

Bacteriology

12. Beneficial Bacteria

Lactobacillus species		*NG
Escherichia coli		4+
Bifidobacterium		4+

13. Additional Bacteria

alpha haemolytic Streptococcus	NP	3+
gamma haemolytic Streptococcus	NP	3+
Bacillus species	NP	1+
Streptococcus agalactiae gp B	NP	2+

14. Mycology

Candida albicans/dubliniensis	NP	1+

Human microflora is influenced by environmental factors and the competitive ecosystem of the organisms in the GI tract. Pathological significance should be based upon clinical symptoms and reproducibility of bacterial recovery.

*NG	NP	PP	P
*NG			
No Growth	Non-Pathogen	Potential Pathogen	Pathogen

Case Study Questions

- Did the PPI (Dexlansoprazole) make matters worse?
- Did the PPI cause yeast overgrowth?
- Did the PPI contribute to his development of SIBO?
- Could he still be experiencing side-effects from the PPI even after having stopped it?

PPIs (Proton Pump Inhibitors)

What are they?

Why do the Pharma companies love them?

Why are they so hard to stop once started?

PPIs (Proton Pump Inhibitors)

- Most potent inhibitor of stomach acid secretion available[1]
- One of the most highly prescribed medications worldwide, accounting for $1B annually
- No clear evidence that one PPI works better than another[2]

1. Sachs, G.; Shin, J. M.; Howden, C. W. (2006). "Review article: The clinical pharmacology of proton pump inhibitors". *Alimentary Pharmacology and Therapeutics*. **23**: 2–8. doi:10.1111/j.1365-2036.2006.02943.x. PMID 16700898
2. "Comparative effectiveness of proton pump inhibitors | Therapeutics Initiative". 28 June 2016. Retrieved 24 June 2018.

PPIs (Proton Pump Inhibitors)

- Omeprazole*: first drug in class (introduced in 1989)
- Lansoprazole (1995)
- Rabeprazole (1999)
- Pantoprazole (2000)
- Esomeprazole† (2001)
- Omeprazole/sodium bicarbonate (2004)
- Dexlansoprazole (2009)

*In 2003, Omeprazole became available OTC
†In 2014, Esomeprazole became available OTC.

PPI Indications

- Duodenal or gastric ulcer
- Gastroesophageal reflux disease (GERD)
- Erosive esophagitis (treatment)
- Erosive esophagitis (maintenance)
- NSAID-induced ulcer
- Hospital admission (stress gastritis)*
- Zollinger-Ellison Syndrome

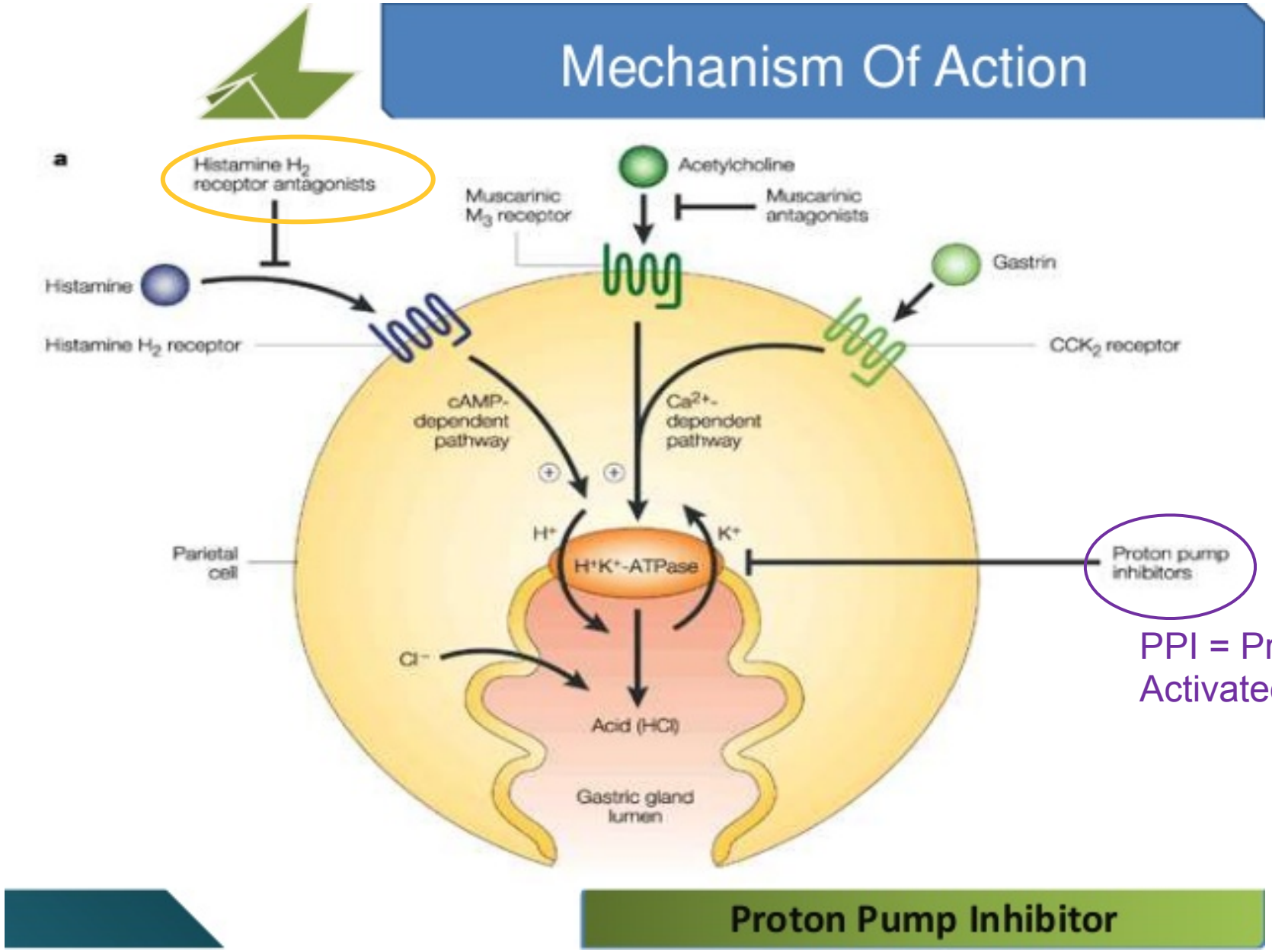
* Mostly for prophylaxis: PPI prescriptions rates often doubled on discharge.

PPIs (Proton Pump Inhibitors)

Mechanism of Action:

- Blocks last enzyme in system that actively transports H^+ ions into the gastric lumen from the parietal cells
- Enzyme blocked = hydrogen-potassium adenoside triphosphatase (proton pump)
- Acid secretion activates PPIs
- Consumption of food is necessary to activate prodrug

PPI



PPI = Prodrug
Activated in acidic environment

Slide 9: https://www.slideshare.net/asiful1990/proton-pump-inhibitor. Accessed on June 24, 2018.

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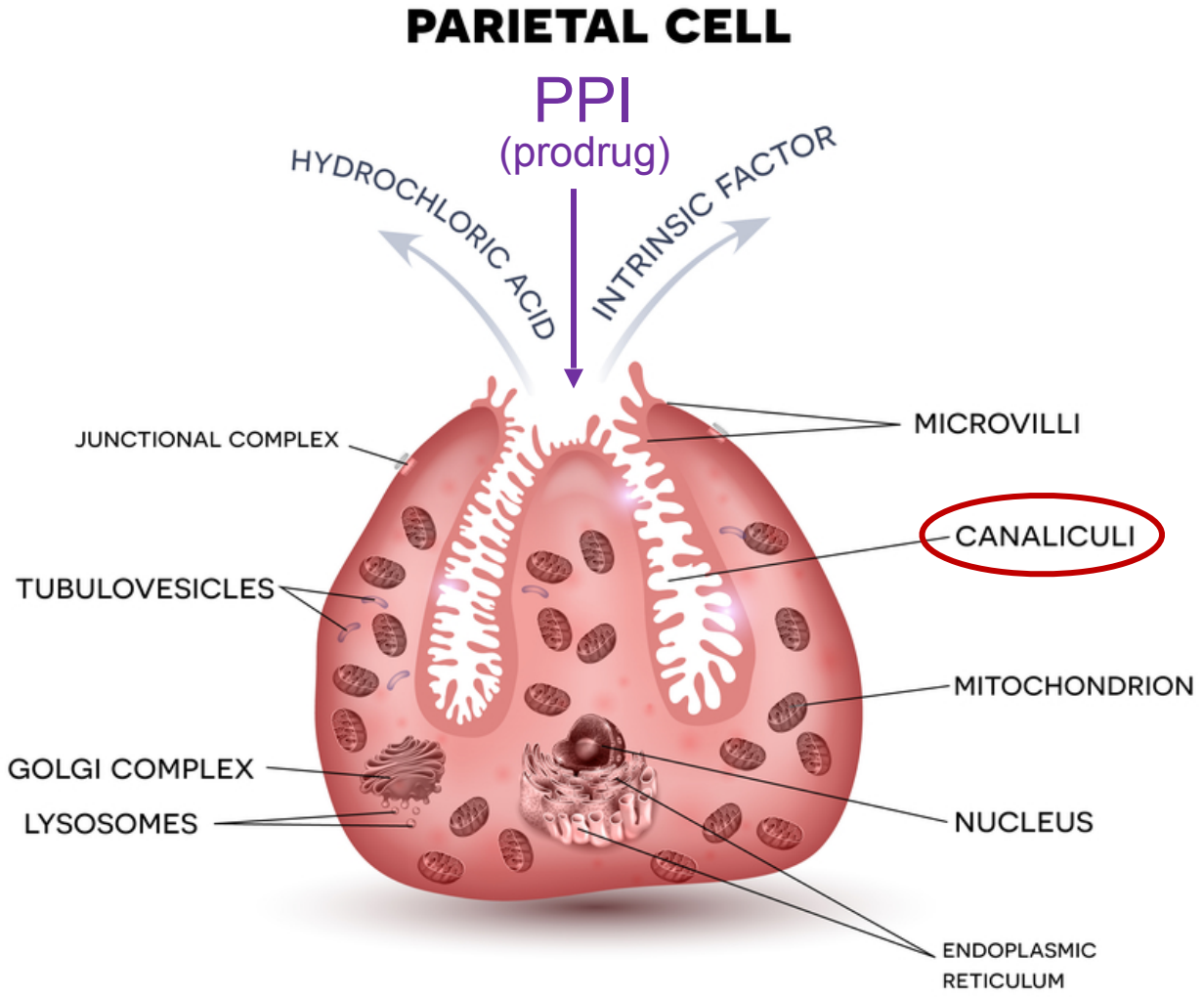
Understanding PPIs



PPIs (Proton Pump Inhibitors)

Mechanism of Action:

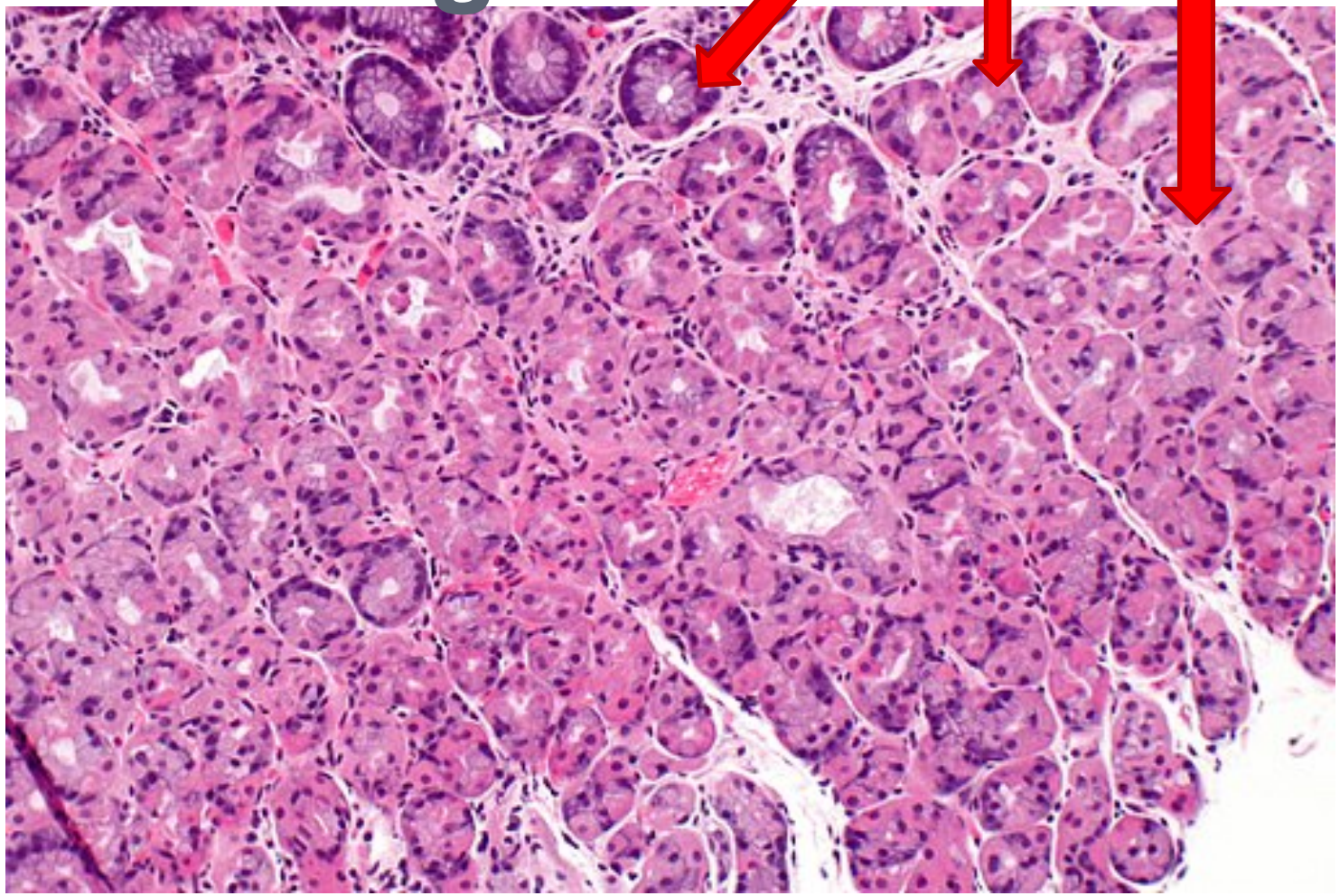
- Prodrug converted into sulfenamide in the acidic secretory canaliculi of the parietal cell
- Sulfenamide irreversibly binds covalently with sulfhydryl groups in the proton pump, thus inhibiting its activity

PPIs (Proton Pump Inhibitors)

Pharmacokinetics:

- Elimination half-life of PPIs = 0.5 – 2.0 hrs
- However, effect of a single dose can last for up to 3 days
- Hepatic disease (fatty liver): reduces clearance of esomeprazole and lansoprazole

Understanding PPIs



Your Stomach on a PPI

Understanding PPIs: Parietal Cell Hyperplasia

Problems with PPIs

- Irritable bowel syndrome (usually with diarrhea)
- Impaired nutrient absorption (decreased B12, calcium, magnesium, and iron absorption)
- Increased risk of osteoporosis and bone fracture
- Yeast overgrowth (like Candida)
- Increased risk for small intestine bacterial overgrowth (SIBO)

Osteoporos Int. 2015 Oct;26(10):2501-7. doi: 10.1007/s00198-015-3168-0. Epub 2015 May 19.

Use of proton pump inhibitors is associated with fractures in young adults: a population-based study.

Freedberg DE[1], Haynes K[2], Denburg MR[3], Zemel BS[4], Leonard MB[5], Abrams JA[6], Yang YX[2,7].

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In this population-based, case-control study, PPI use was associated with fracture in young adults.

association between PPIs and fracture in young adults, with evidence of a dose-response effect. Young adults who use PPIs should be cautioned regarding risk for fracture.

INTRODUCTION: Proton pump inhibitors (PPIs) are associated with fracture in adults with osteoporosis. Because PPI therapy may interfere with bone accrual and attainment of peak bone mineral density, we studied the association between use of PPIs and fracture in children and young adults.

METHODS: We conducted a population-based, case-control study nested within records from general medical practices from 1994 to 2013. Participants were 4-29 years old with ≥ 1 year of follow-up who lacked chronic conditions associated with use of long-term acid suppression. Cases of fracture were defined as the first incident fracture at any site. Using incidence density sampling, cases were matched with up to five controls by age, sex, medical practice, and start of follow-up. PPI exposure was defined as 180 or more cumulative doses of PPIs. Conditional logistic regression was used to estimate the odds ratio and confidence interval for use of PPIs and fracture.

RESULTS: We identified 124,799 cases and 605,643 controls. The adjusted odds ratio for the risk of fracture associated with PPI exposure was 1.13 (95% CI 0.92 to 1.39) among children aged < 18 years old and 1.39 (95% CI 1.26 to 1.53) among young adults aged 18-29 years old. In young adults but not children, we observed a dose-response effect with increased total exposure to PPIs (p for trend <0.001).

CONCLUSIONS: PPI use was associated with fracture in young adults, but overall evidence did not support a PPI-fracture relationship in children. Young adults who use PPIs should be cautioned regarding potentially increased risk for fracture, even if they lack traditional fracture risk factors.

Problems with PPIs

- Increased risk of *Clostridium difficile* infection
- Suppressed immunity – increasing risk for a community-acquired or hospital-acquired pneumonia
- Parietal cell hypertrophy and hyperplasia
- Difficulty weaning off once on chronic therapy

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EDITORIAL

After adjusting for other risk factors for **pneumonia**, use of acid-suppression drugs may be associated with up to a 30% increased risk for developing hospital-acquired **pneumonia**. The association was statistically significant for **proton pump inhibitors**, but not for H2 blockers.

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Abstract

Over the past two decades, proton pump inhibitors (PPIs) have emerged as highly effective and relatively safe agents for the treatment of a variety of gastrointestinal disorders. Unfortunately, this desirable pharmacological profile has also contributed to superfluous and widespread use in both the inpatient and outpatient settings. While generally well-tolerated, research published over the last decade has associated these agents with increased risks of *Clostridium difficile* disease, fractures likely due to calcium malabsorption and both community-acquired (CAP) and hospital-acquired pneumonias (HAP). The mechanism behind PPI-associated pneumonia may be multifactorial, but is thought to stem from compromising the stomach's "acid mantle" against gastric colonization of acid-labile pathogenic bacteria which then may be aspirated. A secondary postulate is that PPIs, through their inhibition of extra-gastric H^+/K^+-ATPase enzymes, may reduce the acidity of the upper aerodigestive tract, thus resulting in increased bacterial colonization of the larynx, esophagus and lungs. To date, several retrospective case control studies have been published looking at the association between PPI use and CAP. Some studies found a temporal relationship between PPI exposure and the incidence of pneumonia, but only two could define a dose-response re-

ICU patients showed an increased risk of HAP with PPIs, but not with H_2RAs. In conclusion, the current literature shows a slight trend toward an association between PPI use and pneumonia and an increased risk with PPIs over H_2RAs, but the findings are not consistent across all studies. Larger controlled trials still need to be done to better identify the risk that PPIs impart towards patients contracting CAP or HAP. Until these are completed, we will have to continue to extrapolate across smaller controlled trials to predict the associated risks in our respective patient populations. In the interim, it appears prudent to limit the use of PPIs to situations where they are clinically indicated and, in such cases, use them at the lowest effective dose. In the case of prescribing for stress ulcer prophylaxis in ICU patients, perhaps H_2RAs should be used as the preferred agents over PPIs.

Key words: Proton pump inhibition; Pneumonia; Pharmacotherapy; Gastroesophageal reflux disease; Gastric acid

Peer reviewers: Dr. Andreas Marc Palmer, PhD, Department of Medicinal Chemistry, Nycomed GmbH, Byk Gulden Str. 2, Konstanz 78467, Germany; Mark Anthony A De Lusong, MD, Associate Professor, Section of Gastroenterology, University of the Philippines-Philippine General Hospital, Taft Avenue, Ermita, Manila 1200, Philippines

Fohl AL, Regal RE. Proton pump inhibitor-associated pneumonia: Not a breath of fresh air after all? *World J Gastrointest Pharmacol Ther* 2011; 2(3): 17-26 Available from: URL: http://www.wjgnet.com/2150-5349/full/v2/i3/17.htm DOI: http://dx.doi.org/10.4292/wjgpt.v2.i3.17

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META-ANALYSIS

Proton pump inhibitors therapy and risk of *Clostridium difficile* infection: Systematic review and meta-analysis

This meta-analysis of fifty-six studies (40 case-control and 16 cohort) involving 356,683 patients provides further evidence that PPI use is associated with an increased risk for development of *Clostridium difficile* infection.

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Author contributions: Trifan A and Stanciu C designed the study, contributed to the selection of studies, analyzed the data and wrote the manuscript; Stoica OC, Maxim R, Singeap AM, Girleanu I, Chiriac SA and Ciobica A were involved in the acquisition of data and contributed to the analysis and interpretation of data; Girleanu I, Stoica OC, Maxim R and Singeap AM drafted the manuscript; Boiculese L and Girleanu I contributed to the statistical analysis; all authors have read and approved the final version of the manuscript; all authors accept responsibility for its content.

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Abstract

AIM

To perform a systematic review and meta-analysis on proton pump inhibitors (PPIs) therapy and the risk of *Clostridium difficile* infection (CDI).

METHODS

We conducted a systematic search of MEDLINE/PubMed and seven other databases through January 1990 to March 2017 for published studies that evaluated the association between PPIs and CDI. Adult case-control and cohort studies providing information on the association between PPI therapy and the development of CDI were included. Pooled odds ratios (ORs) estimates with 95% confidence intervals (CIs) were calculated using the random effect. Heterogeneity was assessed by I^2 test and Cochran's Q statistic.

Case Study: PPI Withdrawal

Difficulties & Challenges

Case Study: PPI Withdrawal

- 70 y/o male presented to my office with acid reflux, 20 lbs. weight loss, and loss of appetite.
- PMHx: Lifetime suffering with IBS + upset stomach
- For the last 18 months: PPI-dependent to control his symptoms.
- Rx: Protonix 40mg once daily
- 2 weeks prior to this appmt: tried stopping PPI + took Tagamet 200mg BID, but not strong enough to control his symptoms
- Patient says: “I feel like a prisoner to the PPI now.”

Case Study: 70 y/o male wants to get off PPI

- Very High Stress Job; now retired
- For 35 – 40 years, his job involved traveling all over the U.S. Flew at least 4 – 5 days per week.
- Retired: 2008
- Other PMHx:
  - Hypothyroidism (2008): 1st tx'd w/ Synthroid; now WP Thyroid (since 2015)
  - High cholesterol (diet-managed)
  - Enlarged prostate

Case Study: 70 y/o male wants to get off PPI

- Social History:
  - Divorced at 32 y/o. Never remarried.
  - Moved to NYC in 2015 to be closer to his daughter / grandchildren
  - Feels a sense of emptiness
- Other symptoms:
  - Constant sense of unease (anxiety)
  - Episodes of dysthymia (predates PPI usage)
  - Low libido

Case Study: 70 y/o male wants to get off PPI

- Diet:
  - Gluten-free
  - Dairy-free
  - Avoiding red meat, because of his cholesterol and it sits too heavy in his stomach
  - Believes he is avoiding acid reflux triggers, but still symptomatic
- Exercise:
  - Regular cardio
  - Light weights
- Mindfulness:
  - Trained in TM, but not regular with it

Case Study: 70 y/o male wants to get off PPI

- Supplements:
  - 5-MTHF
  - Chewable B12
  - L-glutamine
  - Trimethylglycine
  - Krill oil
  - Prostate support (working with a Naturopath specializing in men's health)
  - Many more (*Polynutraceuticology?*)

Case Study: Treatment Plan (1st visit)

- Acid Reflux Diet:
  - Slow down; chew food thoroughly
  - Dinner > 3 hrs before bedtime
  - Foods to Avoid…

Case Study: Treatment Plan (1st visit)

- Acid Reflux Diet:
  - ➢ Foods to Avoid:
    - Alcohol
    - Caffeine
    - Carbonated beverages
    - Fried foods
    - Processed foods
    - Chocolate
    - Dairy products
    - Vegetable oils, including canola oil
    - Spicy foods
    - Tomatoes, tomato products, onions
    - Citrus fruits and juices
    - Cream-based salad dressings
    - Mint and peppermint
    - Processed grains

Case Study: 1st visit Plan (continued…)

- Supplements:
  - Reduced to the essentials (avoid too many supplements sitting in the stomach)
  - Slippery elm bark powder (made into a porridge) once or twice daily
  - DGL chewables – before each meal
  - Zinc carnosine 30mg once daily
  - Aloe vera juice
  - Comprehensive Digestive enzyme – before each meal
  - Betaine-HCl (only with protein-rich meals) – start with lowest dose and titrate up slowly after testing each dose over 2 – 3 days

Case Study: 1st visit Plan (continued…)

- PPI: Taking Protonix 40mg once daily

  → Reduce to alternating dose 40mg / 20mg every other day x 2 – 4 wks

Gut-Healing Supplements

Slippery Elm Bark

History:

- Deciduous tree native to North America
- Traditional remedy for Native Americans
- Word “slippery” comes from the mucilaginous inner bark of slippery elm
- Used for intestinal complaints, fevers, and as a poultice for wounds

Benefits:

- Demulcent (soothing)
- Aids in the expulsion of mucous
- Used in traditional medicine to soothe multiple GI complaints (incl. IBS, colitis, diarrhea, GERD)

Forms:

- Powder – can be made into a porridge or mixed with water

DGL (deglycyrrhizinated licorice)

Benefits:

- Licorice has been used for centuries in Chinese medicine
- Glycyrrhizin removed (< 1- 2 %) – less concern for BP elevation, but monitor
- Anti-inflammatory
- Demulcent (soothing)
- Rich in flavonoids – help maintain a healthy mucosal barrier in the stomach and intestines
- Effective against functional dyspepsia[1]
- Natural remedy for nausea, indigestion, and stomach pain

1. Raveendra, et al. An Extract of *Glycyrrhiza glabra* (GutGard) Alleviates Symptoms of Functional Dyspepsia: A Randomized, Double-Blind, Placebo-Controlled Study. Evid Based Complement Alternat Med. 2012; 2012: 216970. Published online 2011 Jun 16. doi: 10.1155/2012/216970

DGL (deglycyrrhizinated licorice)

Forms:

- Chewable, capsule, or powder
- Often combined with other demulcent herbs
  - Marshmellow root
  - Slippery elm bark
  - Aloe vera leaf extract

Dose: 400 – 800 mg per serving
Frequency: 1 – 5 x/day before and after meals (for symptoms)

Zinc carnosine

Benefits:

- Essential trace mineral – involved in over 300 proteins in the body
- Carnosine is an amino acid, primarily from meat and animal sources
- Supports enzymatic and structural functions
- Important for healthy cell membranes
- Chelate supports adaptive Heat Shock Protein expression (needed for a healthy response to inflammation, immune challenges, and stress)
- Stabilizes intestinal permeability and stimulates repair of gut mucosa[1]

1. Gut. 2007 Feb;56(2):168-75. Epub 2006 Jun 15.

Zinc carnosine

Form: capsule, chewable tablet

Dose: 15 – 30 mg per dose; up to 75mg

Frequency: once (or divided) daily

Aloe vera

History:

- Perennial, succulent plant with thick, fleshy leaves
- More than 75 active components (enzymes, minerals, antioxidants…)
- Believed to have originated from Sudan; then, introduced to the rest of the world

Benefits:

- Anthraquinones – act as laxatives
- Cape aloe, the solid residue obtained by evaporating liquid aloe vera, has been shown to promote colon peristalsis
- Helps with wound healing; anti-inflammatory properties
- Aides in healing chronic stomach ulcers[1]

1. Iran J Med Sci. 2016 May; 41(3 Suppl): S30.

Aloe vera

Form: capsule, softgel, liquid

Dose: 250 - 450mg per dose

Frequency: once (or divided twice) daily

Betaine-HCl + Pepsin

Benefits:

- Supports normal, healthy acid levels in the stomach
- Supports protein breakdown
- Improves absorption of amino acids
- Aids in fat breakdown
- Protects against bacterial infections
- Prevents yeast colonization in the intestines

Betaine-HCl + Pepsin

Form: capsule

Dose: 500 – 1000 mg per dose; up to 2500 mg

Frequency: at the beginning/middle of every protein-rich meal

Case Study: 2nd visit (4 weeks later)

- Reports doing well on protocol
- Diet: compliant with anti-GERD/Paleo-style plan
- Supplements:
  - Continue prior supplements
  - Add mastic gum to protect gastric lining
  - Betaine-HCl – taking 2 capsules with protein-rich meals; no symptoms; may advance dose to 3 capsules w/ protein meals

- PPI: Taking Protonix 40/20mg alternating days →
  Reduce to alternating 20mg once daily for next 2 weeks; then reduce to 20mg QOD, adding H2-blocker on the days off as needed

Case Study: 3rd visit (4 weeks later)

- Flare-up! ☹ Experiencing lots of anxiety over his symptoms.
- Old symptoms back: hoarse voice, constant need to clear the throat, and chest pain
- Diet: compliant with anti-GERD/Paleo-style plan
- Supplements:
  - Betaine-HCl – says he stopped tolerating it, so he went back to taking a prior digestive enzyme. He is afraid the Betaine-HCl may have damaged his esophagus.

- PPI: Had tapered off the PPI, and was taking the H2-blocker, but increased it to 2x/day. Then, 2 weeks prior to appmt restarted Protonix 20mg once daily ☹

Case Study: 3rd visit Plan

- Stress relief: Daily meditation
- Breathing exercises: 4—4—8—4; or 5—5—10—5
- Vagus nerve stimulation: gargling; singing
- Reassurance
- Diet: continue acid-reflux diet + lifestyle
- EGD: referral for endoscopy to rule out esophageal damage

- PPI: Protonix 20mg once daily ☹ (compromise)

Case Study: 4th visit (6 weeks later)

- EGD results: No ulcer. No esophagitis. No Barrett's esophagus. Mild gastritis. Biopsies neg. for H. pylori
- What a relief! ☺ Patient is ready to proceed with taper.
- Diet: compliant with anti-GERD/Paleo-style plan
- Supplements:
  - Betaine-HCl – reintroduce with 1 capsule 2x/day with protein meals. He is now able to tolerate eating salmon.
  - DGL – additional doses as needed for symptomatic relief

Case Study: 4th visit (6 weeks later)

- PPI: Protonix 20mg every other day; alternating with H2-blocker for 2 – 4 weeks, then H2-blocker as needed.
  - Patient is reminded that symptoms may worsen as he tapers off
  - Remember to use breathing exercises if symptoms arise

Case Study: 5th visit (6 weeks later)

- Diet: compliant with anti-GERD/Paleo-style plan
- Supplements:
  - Betaine-HCl – taking 1—2 capsules 2x/day with protein meals. Asymptomatic. At this point he may add grass fed beef.
- Weight gain! ☺ Increased 4 lbs.

- OFF PPI!!! Stopped Protonix; taking H2-blocker every other day
  - He has a better understanding of the connection between his “acid reflux” symptoms and his anxiety.

Case Study: Final (6th) visit (6 weeks later)

OFF PPI & H2-blocker!!!!

- Diet: adding more grass fed beef and wild salmon to the diet.
  - Loves the Paleo protocol – asks if he can stick with it.
- Weight gain! ☺ Increased another 6 lbs. (10 lbs. total)
- Supplements:
  - Betaine-HCl – forgetting to take it. Asymptomatic.
  - DGL – no longer taking
  - Comprehensive digestive enzyme – as needed
  - Probiotic – daily

Conclusions

- PPIs are physiologically addictive medications
- PPI use is confounded by psychological dependence factors
- PPI withdrawal is challenging
- There is no one right way to wean a patient off of a PPI

Conclusions

- Frequent monitoring and support is necessary when helping patients wean off of PPIs
- Supplement support is often needed when weaning PPIs
- Not all factors are lifestyle-based or dietary
- Stress is a huge contributor to symptomatic “acid reflux”

Questions & Answers

THANK YOU!

Vincent Pedre M.D.
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