Session 6: Navigating Toward Relief: A Case-Based Approach to Treating GERD and Peptic Ulcer Disease

Learning Objectives

- List risk factors and current strategies for treating patients with gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD).
- Identify proton pump inhibitor (PPI) administration options and the rationale(s) for their use in patients with acid-related disorders.

Faculty

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Dr Fugit received his doctor of pharmacy degree from the University of New Mexico, Albuquerque. Upon graduation, he completed a clinical pharmacy practice residency at the Albuquerque Veterans Affairs Medical Center, with a focus on internal medicine and ambulatory care. He is a board-certified pharmacotherapy specialist and maintains an active clinical practice in the Department of Internal Medicine at the Denver VA Medical Center.

Dr Fugit focuses on pharmacoeconomics and outcomes research, including clinical pathway development; is involved in the management of both acute and chronic disease states in gastroenterology, cardiology, and infectious diseases; and has authored and coauthored numerous publications on these areas. He is currently coauthoring the upper gastrointestinal disorders chapter in Applied Therapeutics: The Clinical Use of Drugs. Dr Fugit also lectures extensively as a national speaker on these topics.

Faculty Financial Disclosure Statement

The presenting faculty report the following: Dr Fugit has nothing to report.

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Drug List

<table>
<thead>
<tr>
<th>Generic</th>
<th>Trade</th>
<th>Generic</th>
<th>Trade</th>
</tr>
</thead>
<tbody>
<tr>
<td>alendronate</td>
<td>Fosamax</td>
<td>fenoprofen</td>
<td>Nalfon</td>
</tr>
<tr>
<td>amoxicillin</td>
<td>Amoxil</td>
<td>flurbiprofen</td>
<td>Ansaid</td>
</tr>
<tr>
<td>aspirin</td>
<td></td>
<td>hydrochlorothiazide</td>
<td>Ocu fen</td>
</tr>
<tr>
<td>bismuth subcitrate, tetracycline, metronidazole (combination)</td>
<td>Pylera</td>
<td>ibuprofen</td>
<td>various</td>
</tr>
<tr>
<td>celecoxib</td>
<td>Celebrex</td>
<td>indomethacin</td>
<td>Indocin</td>
</tr>
<tr>
<td>clarithromycin</td>
<td>Biaxin</td>
<td>ketoprofen</td>
<td>Actron, Orudis,</td>
</tr>
<tr>
<td>clopidogrel</td>
<td>Plavix</td>
<td>ketorolac</td>
<td>Torad ol</td>
</tr>
<tr>
<td>diclofenac</td>
<td>Arthrotec, Cataflam, Solaraze, Voltaren</td>
<td>lansoprazole</td>
<td>Prevacid</td>
</tr>
<tr>
<td>esomeprazole</td>
<td>Nexium</td>
<td>levofloxacin</td>
<td>Iquix, Levaquin</td>
</tr>
<tr>
<td>etodolac</td>
<td>Lodine</td>
<td>Levothyroxine</td>
<td>Synthroid, Levoxyl,</td>
</tr>
<tr>
<td>famotidine</td>
<td>Pepcid</td>
<td></td>
<td>Levothroid,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unithroid</td>
</tr>
</tbody>
</table>
### Suggested Reading List


Today’s Focus
• Discuss risk factors and current strategies for treating patients with gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD)
• Compare and contrast the efficacy of proton pump inhibitors (PPIs) and histamine-2 receptor antagonists (H2RAs) for the treatment of GERD and PUD
• Evaluate issues surrounding the long-term use of PPIs and their potential to cause adverse effects
• Discuss pharmacogenomics, drug interactions, and dosing associated with PPI therapy
• Identify PPI administration options and the rationale(s) for their use in patients with acid-related disorders

Section 1: An Overview of GERD

Case: Daniel
• 55-year-old attorney presents with heartburn that has occurred on and off for the past year
  - Heartburn occurs 3 to 5 times a week
• Symptoms primarily occur after eating and when lying down
• Initially treated with lansoprazole 30 mg twice daily for Los Angeles (LA) Grade C esophagitis
• Prescribed lansoprazole 30 mg once daily, but admits he takes medication only as needed and that he sometimes takes an H2RA instead of his PPI
• Often eats high-fat meals
• Takes theophylline daily for asthma

Audience Question
• Which of the following most likely contributed to Daniel’s recurrent heartburn?
  1. Takes PPI only when needed
  2. Tolerance to antisecretory effect of PPI
  3. Timing of PPI dose in relationship to meals
  4. Genetic polymorphism related to PPI

GERD Is a Heterogeneous Disorder

- 60% - 70%1,2 of GERD patients are diagnosed with nonerosive reflux disease (NERD)
- 20% - 30%1 of GERD patients are diagnosed with erosive esophagitis (EE)
- 6% - 10%1,2 of GERD patients are diagnosed with Barrett’s esophagus

The Prevalence of GERD Is Increasing Across Different Geographic Regions

- Patients worldwide are reporting more GERD symptoms over the last 2 decades
- Overall, GERD symptoms increased approximately 4% per year worldwide
  - 5% in North America (P = 0.0005)
  - 27% in Europe (P = 0.0001)
  - 1% in Asia (P = 0.49)

Prevalence of GERD Symptoms in 17 Studies from 1980-2005

Factors Responsible for the Changing Epidemiology of GERD

- Increasing longevity
  - Increased acid exposure occurs more in older patients
- Obesity epidemic
  - Changes in lower esophageal sphincter (LES) pressure
  - High-fat diet, delayed gastric emptying, visceral obesity
- Comorbid conditions affecting the esophagus
  - Diabetes, Parkinson disease, Alzheimer disease, amyotrophic lateral sclerosis
- Use of drugs that affect LES pressure and gastric emptying
  - Theophylline, calcium antagonists, benzodiazepines, nitrates, anticholinergics, antidepressants

The Prevalence of Severe Erosive Esophagitis Increases Among Older Patients with Severe Heartburn

A post hoc analysis of the baseline characteristics from 9 prospective, randomized, controlled clinical trials assessing effect of PPIs on healing of erosive esophagitis (N = 11,945)

Poor Control of Intragastric pH Is a Risk Factor for Persistent Erosive Esophagitis

Double-blind, multicenter, 4-week, proof-of-concept study of adults (N = 103; mean age 48.7 years; 65% men) with endoscopically verified LA grade C or D esophagitis

Comparison of Maintenance Therapies for Erosive Esophagitis

- 38 randomized controlled trials
- Follow-up time 24 – 52 weeks
Audience Question

• Which of the following is a misconception about appropriate dosing patterns for PPIs?

1. On-demand therapy is effective in patients with severe esophagitis
2. The ideal BID dosing schedule for PPIs is 30 minutes before breakfast and 30 minutes before evening meal
3. Taking a PPI when eating a high-fat meal may reduce its bioavailability
4. PPI dosing more than once per day may decrease adherence

Compliance with Medications

Coping with GERD Internet Survey (n = 587)

- Regularly as prescribed by their physician: 55%
- As needed: 17%
- Do not take medication: 22%
- Fairly regularly but sometimes forget: 6%


Maintenance Treatment of GERD With PPIs Taken on Demand*

On-demand PPI therapy is effective in the long-term management of patients with NERD or mild GERD1

† Symptom load: heartburn, acid regurgitation, pain in swallowing

Dosing

Administer PPI1,2

QD
30 minutes before breakfast
or 30 minutes before evening meal

BID
30 minutes before breakfast and evening meal

PPIs are only able to bind to proton pumps when the pumps are active (about 75% of pumps are activated after stimulation, usually meal-related)3

Dietary and Lifestyle Modifications in the Management of GERD

Dietary Factors to Avoid

- Alcohol
- Fatty Foods
- Spicy foods
- Chocolate
- Caffeine, coffee
- Peppermint
- Citrus, fruit juices
- Carbonated beverages

Lifestyle

- Smoking/tobacco cessation
- Do not eat at least 3 hours before bedtime
- Weight
- Elevate head of bed
- Avoid LES-relaxing medications
- Nitrates
- Calcium channel blockers

Evidence to support these measures is limited

• Alone, they are unlikely to control symptoms in patients with moderate to severe GERD
• Recommend in conjunction with medical therapy.
Case Follow-up: Daniel

- Takes lansoprazole 30 mg once daily
- Importance of compliance to drug regimen discussed as well as when to take dose in relationship to meal
- Heartburn symptoms have been reduced to once a month
- Pharmacist recommends that Daniel avoid eating 2 to 3 hours before bedtime and modifying his diet to decrease high-fat foods
- Pharmacist requests Daniel keep a diary for one week on dietary and lifestyle triggers that exacerbate his heartburn, and requests he return one week later to review these triggers

Case: Martin

- 69-year-old retired accountant, was diagnosed with nonerosive reflux disease 6 months ago
- Treated with once-daily PPI
- About 3 months ago, he began to complain of coughing and wheezing (asthma-like) as well as nocturnal heartburn to the point that the heartburn woke him up 3 or 4 nights a week
- Pantoprazole 40 mg once daily has not relieved his nocturnal heartburn or his coughing and wheezing

Nighttime Heartburn Versus No Nighttime Heartburn in GERD

- Nighttime heartburn is associated with excessive gastroesophageal reflux

Persistent Symptoms Are Common on PPIs After 4 Weeks of Treatment

- Symptom response to PPI therapy among patients with NERD and EE

Audience Question

- Which of the following is an “atypical” or extraesophageal manifestation of GERD?
  1. Chronic cough
  2. Chronic hoarseness
  3. Asthma
  4. Chronic sinusitis
  5. All of the above

Atypical or Extraesophageal Manifestations of GERD

- Pulmonary
  - Asthma
  - Chronic bronchitis
  - Aspiration pneumonia
  - Idiopathic pulmonary fibrosis
- Ear, Nose, and Throat
  - Hoarseness
  - Chronic cough
  - Chronic laryngitis
- Other
  - Noncardiac chest pain
  - Atypical loss of dental enamel
  - Sudden infant death
  - Hallitosis
  - Sleep apnea

References

Effect of PPI Therapy in Patients with GERD-Related Asthma and Cough

**Expert’s Algorithm for Treating Mild and Moderate/Severe GERD**

**Case: Margaret**

- 48-year-old woman diagnosed with *H. pylori*-positive duodenal ulcer
  - Presents with gnawing, burning epigastric pain that occurs daily
  - Symptoms frequently occur several hours following a meal
- Allergic to penicillin - hives
- Admits to being noncompliant with medications
- Currently takes calcium carbonate, levothyroxine for hypothyroidism, hydrochlorothiazide and lisinopril for hypertension

**Case Follow-up: Martin**

- Pantoprazole increased to 40 mg twice daily with second dose to be taken at dinner
- Nocturnal heartburn has been resolved and patient is asymptomatic during the night
- Cough and wheezing decrease after 3 months of empiric treatment with twice-daily pantoprazole
- Referral to ENT for further evaluation

**Section 2: Exploring Peptic Ulcer Disease**

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Denver, CO

**Audience Question**

Which of the following is the preferred eradication regimen for treating this patient?

1. PPI + clarithromycin
2. PPI + clarithromycin + metronidazole
3. PPI + metronidazole + tetracycline + bismuth subsalicylate
4. 2 and 3
5. All of the above
### Helicobacter pylori

- Most people infected with *H. pylori* are asymptomatic.
- Associated with chronic gastritis, duodenal ulcer, gastric ulcer, gastric cancer, and gastric B-cell lymphoma.
- Association between *H. pylori* and GERD remains unclear.
- *H. pylori* eradication heals ulcers and decreases ulcer recurrence.
- Up to 20%-40% of patients fail eradication therapy.

### Effect of PPIs on Thyrotropin Values in Patients With Hypothyroidism

<table>
<thead>
<tr>
<th>Medication</th>
<th>Antimicrobial Resistance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole</td>
<td>25.1</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>12.9</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>0.9</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>None</td>
</tr>
</tbody>
</table>

### Factors That May Affect Treatment Success

- Selection of eradication regimen
- Antibacterial resistance
- Side effects
  - Nausea
  - Diarrhea
  - Short-term use of metronidazole can cause a disulfiram-like reaction when taken with alcohol
  - Pseudomembranous colitis and allergic reactions (rare)
- Nonadherence to drug regimen
- Drug interactions
- Duration of treatment
  - 10-day treatment associated with lower treatment failure than 7-day treatment
  - 14-day treatment associated with lower treatment failure than 7-day treatment

### Sequential Therapy

- Rationale:
  - Initial treatment with drugs that rarely promote resistance
  - Reduce bacterial load and preexisting resistant organisms
  - Follow with different antibiotics to kill remaining organisms
- Regimen (dual treatment followed by triple therapy):
  - Days 1 through 5: PPI + amoxicillin 1 g, both taken twice daily
  - Day 6: Discontinue amoxicillin; add clarithromycin + tinidazole
  - Days 7 through 10: PPI + clarithromycin 250-500 mg + tinidazole 500 mg, all taken twice daily

### Recommended Treatment Plan for *H. pylori* Infection

- First line of defense
  - PPI + clarithromycin + amoxicillin
  - (For penicillin-allergic patients) PPI + clarithromycin + metronidazole
- Second line of defense
  - PPI + amoxicillin + metronidazole
  - PPI (H2RA) + bismuth + clarithromycin + tetracycline
- Third line of defense (rescue treatment)
  - PPI + amoxicillin + rifabutin
  - PPI + amoxicillin + levofloxacin

### H. pylori Antimicrobial Resistance in Adults

<table>
<thead>
<tr>
<th>Medication</th>
<th>Antimicrobial Resistance (%)</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>Tetracycline</td>
<td>None</td>
</tr>
</tbody>
</table>

Case: Veronica

- 72-year-old woman with chronic osteoarthritis and a history of ulcer-related bleeding
  - Takes naproxen twice daily
  - Also takes aspirin 81 mg daily for cardioprotection post–myocardial infarction
- Other medications include:
  - Over-the-counter omeprazole 20 mg per day (but stopped taking medication 2 weeks ago because she read a newspaper article questioning the long-term safety of PPIs)
  - Alendronate weekly
  - Calcium plus vitamin D
- Because it is easier for her to swallow liquid than to take a tablet or capsule, she wants to know if PPIs come in a liquid form.

Risk Factors for Serious Upper GI Events with NSAID Use

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior ulcer or complicated ulcer</td>
<td>Multiple NSAID use</td>
</tr>
<tr>
<td>Advancing age (&gt; 65 years)</td>
<td>High-dose NSAIDs</td>
</tr>
<tr>
<td>Concomitant anticoagulant use</td>
<td>Selection of NSAID (eg, etodolac or nabumetone vs ketorolac, indomethacin, or piroxicam)</td>
</tr>
<tr>
<td>Concomitant corticosteroid use</td>
<td>Concomitant SSRI use</td>
</tr>
<tr>
<td>Concomitant aspirin use (including low-dose)</td>
<td></td>
</tr>
</tbody>
</table>

Gastroprotection Strategies for Patients Taking Chronic NSAIDs

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol</td>
<td>- FDA labeled for reducing risk of gastric ulcers &lt;sup&gt;1,3&lt;/sup&gt; - Reduces ulcer complications</td>
<td>- Poor compliance - Diarrhea in 20% of patients - Contraindicated in women of childbearing age</td>
</tr>
<tr>
<td>H&lt;sub&gt;R&lt;/sub&gt;As</td>
<td>- Alleviate dyspeptic symptoms - Heal active ulcers only if NSAID is discontinued</td>
<td>- Double dosages (eg, famotidine 40 mg BID) required to reduce risk of gastric ulcer - Less effective than standard PPI dosages</td>
</tr>
<tr>
<td>PPIs</td>
<td>- FDA labeled for reducing risk of gastric ulcers - Alleviate dyspeptic symptoms - Heal active ulcers even when NSAID is continued</td>
<td>- Fewer years on the market than H&lt;sub&gt;R&lt;/sub&gt;As - Cost</td>
</tr>
</tbody>
</table>

Underutilization of Gastroprotective Measures in Patients Receiving NSAIDs

Concurrent use of traditional NSAIDs and gastroprotective drugs among study cohort

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Traditional NSAIDs (n = 71,839)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antulcer therapy</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>48,182 (67%)</td>
</tr>
<tr>
<td>Recommended protection</td>
<td>7322 (10%)</td>
</tr>
<tr>
<td>Less than recommended protection</td>
<td>16,335 (23%)</td>
</tr>
</tbody>
</table>

Specific therapy

| Less than recommended dose of H<sub>R</sub>As | 16,395 (23%) |
| Less than recommended dose of PPIs | 51 (1%) |
| Less than recommended dose of misoprostol | 517 (1%) |

**Increasingly COX-2 Selective**

- Omeprazole
- Lansoprazole
- Esomeprazole
- Pantoprazole
  - > 50-fold COX-2 selective
  - 5- to 50-fold COX-2 selective

**Long-Term PPI Use and Hip Fractures**

- Nested case-control study of patients aged > 50 years
- 13,556 patients with hip fracture and 135,386 controls

**Exposure Group**

<table>
<thead>
<tr>
<th>Adjusted Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 1 year of PPI therapy</td>
<td>1.44 – 1.99</td>
</tr>
<tr>
<td>Long-term high-dose PPI therapy</td>
<td>2.65 – 3.00</td>
</tr>
</tbody>
</table>

- Association stronger in men than women
- Possible mechanisms:
  - Calcium malabsorption secondary to acid suppression
  - Reduction in bone resorption through inhibition of osteoclastic vascular protein pumps
- Did not include information on OTC calcium and vitamin D use

**Use of PPIs and Risk of Osteoporosis-Related Fractures**

- 15,792 patients with osteoporosis-related fracture (hip, vertebra, or wrist) matched against 47,289 controls
- Adjusted odds ratios (OR)
- For the risk of all osteoporosis-related fractures calculated for duration of PPI exposure ranging from ≥ 1 year to ≥ 7 years

**PPIs and Risk of Community-Acquired *Clostridium difficile*–Associated Disease**

**Long-Term Use of PPIs and Risk of Colorectal Cancer (CRC)**

**Study**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Adjusted OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever vs never or rare PPI users</td>
<td>1.11</td>
<td>0.97-1.27</td>
</tr>
<tr>
<td>Short-term vs never or rare users</td>
<td>1.07</td>
<td>0.86-1.34</td>
</tr>
<tr>
<td>Long-term vs never or rare users</td>
<td>1.09</td>
<td>0.58-2.06</td>
</tr>
</tbody>
</table>

- No statistically significant increase in CRC after ≥ 5 years of PPI use (adjusted OR 1.1; 95% CI, 0.7-1.9)†
- Recent studies show that the long-term use of PPI therapy does not have an association with a significantly increased risk of CRC‡

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*Adjusted for income, region of residence, depression, schizophrenia, dementia, home care use, and multiple medications
† Not FDA approved
‡ Antibiotic Exposure
§ Adjusted OR for PPI exposure: ≥7 years = 1.92 (95% CI, 1.16-3.18; P = 0.0011)
**Not FDA approved
†† Adjusted OR for PPI exposure (years)
‡‡ Long-term = > 1 year of PPI therapy
§§ Short-term = < 7 years of PPI use
No Current CV Risk in PPI Use of Omeprazole and Esomeprazole

• The FDA recently reviewed a 14-year omeprazole study and 5-year ongoing analysis of esomeprazole
  – Patients randomly received treatment with either PPI versus those who received surgery for severe GERD
  – Initial results raised concerns that long-term use may increase the risk of heart attack, heart failure, and heart-related sudden death compared to patients receiving surgery
• Supported data via patient follow-up and studies (including 2-year placebo-controlled trials) concluded there was no such related CV risk of either PPI

“The FDA does not believe that health care providers or patients should change either their prescribing practices or their use of these products at this time”


Audience Question

• Which of the following is an FDA-approved alternative PPI formulation that you could recommend for this patient?
  1. Pantoprazole granules sprinkled on soft foods
  2. Omeprazole capsule opened and chewed followed by a full glass of water
  3. Rabeprazole oral suspension
  4. Lansoprazole orally disintegrating tablet

When Additional PPI Formulations May Be Needed

• Difficulty swallowing tablets or capsules
  – As high as 22% in patients aged > 50 years
  – Up to 60% of the nursing home population
  – Causes: stricture, esophageal motility disorders, strokes
• Aversion to swallowing tablets or capsules
• Nothing by mouth (NPO) patients
  – In hospital
  – Tube feedings
• High-risk bleeding ulcers
• Children

FDA-Approved Alternative PPI Formulations and Administration Options

<table>
<thead>
<tr>
<th>PPI</th>
<th>Esomeprazole</th>
<th>Lansoprazole</th>
<th>Omeprazole</th>
<th>Pantoprazole</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule granules sprinkled on selected soft foods</td>
<td>Applesauce</td>
<td>Applesauce</td>
<td>Applesauce</td>
<td>Applesauce</td>
</tr>
<tr>
<td>Capsule granules mixed into selected beverages</td>
<td>Apple sauce</td>
<td>Apple sauce</td>
<td>Apple sauce</td>
<td>Apple sauce</td>
</tr>
<tr>
<td>Nasogastric (NG) tube administration</td>
<td>Capsule granules in water</td>
<td>Capsule granules in apple juice or ODT in water (≤ 8 Fr)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>IV formulation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Packet for oral suspension</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Orally disintegrating tablet (ODT)</td>
<td>Orally with or without water or dispersed in water through NG tube or oral syringe</td>
<td>Orally with or without water or dispersed in water through NG tube or oral syringe</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Rabeprazole is available in tablet form only

Contents of PPI capsules are delayed-release and should not be chewed or crushed


Case Summary: Veronica

• After speaking with her physician about the benefits versus risks of PPI therapy, Veronica agrees to resume taking PPI
• Options such as oral PPI tablets and capsules discussed with patient
• Veronica decides to try an alternative form of PPI
• Pharmacist instructs Veronica on properly preparing and administering orally disintegrating tablet formulation of lansoprazole

Clinical Pearls

• PPIs are effective for GORD treatment and maintenance therapy, *H. pylori* ulcers (when combined with antimicrobials), and the treatment and prophylaxis of NSAID ulcers and ulcer-related bleeding
  – Should only be used when indicated, in the lowest effective dose and for shortest period of time
• PPIs are superior to H2RAs in relieving symptoms, preventing and healing NSAID ulcers and esophagitis, and tolerance does not develop to antisecretory effect
• Patients must be educated on the proper usage and timing of PPIs
• There are many PPI dosing and formulation options to meet every patient’s needs
• Drug interactions, side effects, pharmacogenomics, and dosing should be considered with PPI therapy