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Gastroenterology & Hepatology
Advanced Practice Providers

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H. Pylori Diagnosis and Therapies What's New?

Carol Antequera, MMS, PA-C

University of Miami Miller School of Medicine

Department of Medicine

Division of Gastroenterology

Disclosures

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Disclosures

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No financial relationships to disclose.

Objectives

- Epidemiology of *H. pylori*
- Bacteriology
- Clinical presentation
- Indication for testing
- Diagnosis
- Treatments

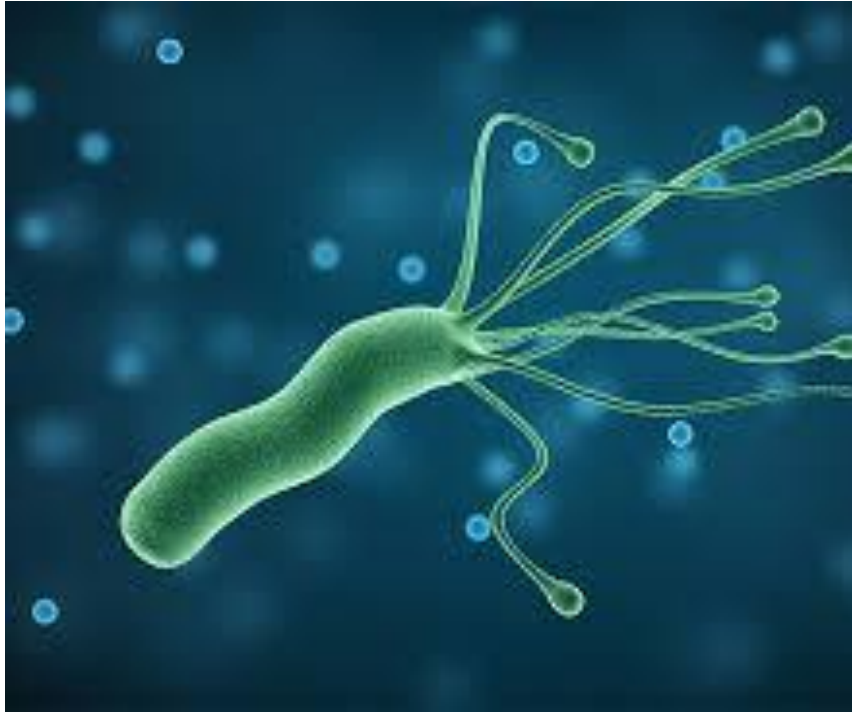
Epidemiology

- *H. pylori* colonizes the gastric mucosa of ~50% of the World's population
- 70-80% in developing countries
- Estimated to colonize 30-40% of the U.S. population

Bacteriology

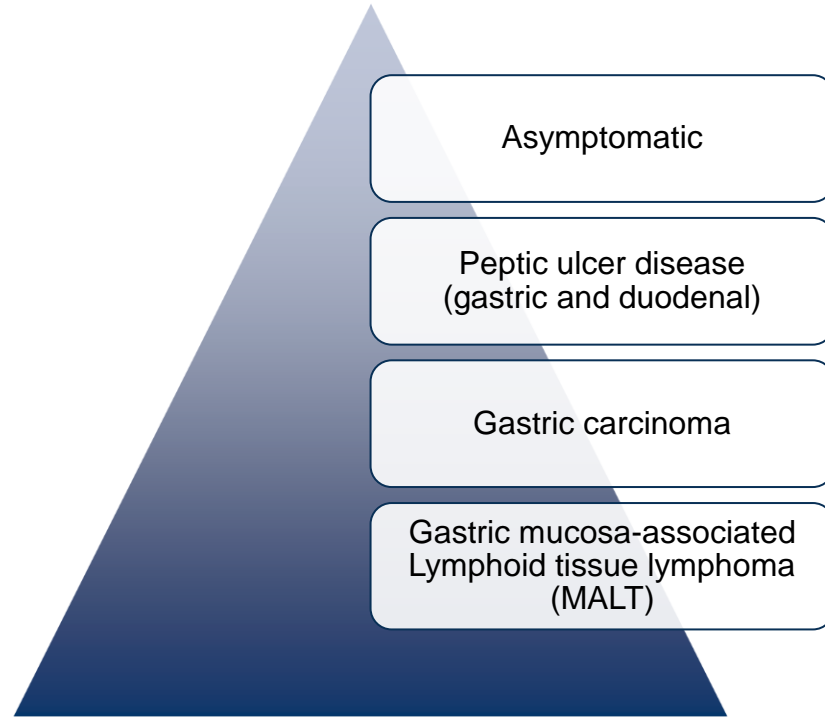
- Gram negative bacillus
- Urease-producing
- Humans are the only known host
- Person-to-person transmission

Virology

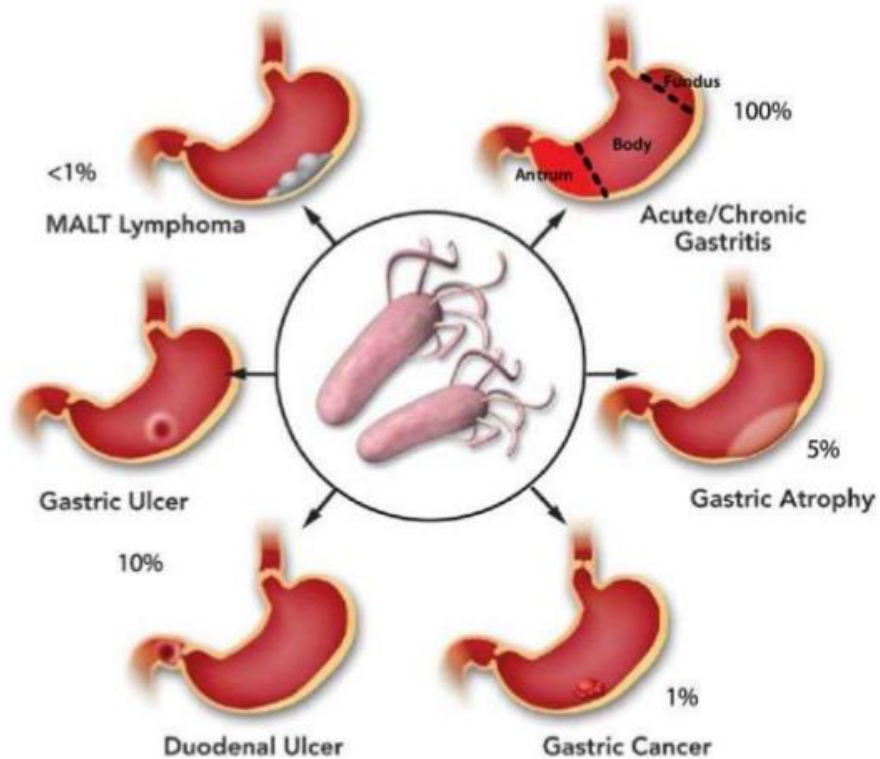


- The bacteria has flagella which allows mobility in the viscous mucus
- Secretion of urease enzyme converts urea into ammonia and carbon dioxide
- Damage is caused by toxins secreted

Clinical Presentation



Conditions Arising From *H. pylori*



How Common Is Gastric Cancer?

- Gastric carcinoma is, worldwide the second leading cause of cancer related mortality
- May present as abdominal pain, weight loss, early satiety and anemia
- Upon diagnosis most patients have advanced, incurable disease
- 95% of gastric cancer is adenocarcinoma
- Screening is only performed in countries with high incidence (Japan, Chile, Venezuela)

Gastric Cancer

- 1 in 12 of all oncological deaths are attributable to gastric cancer
- Gastric cancer has the fifth highest incidence among cancers, with 5.7% of all new cases attributable to the disease
- The 5-year survival rate for gastric cancer is 31% in the United States

Indications for Testing

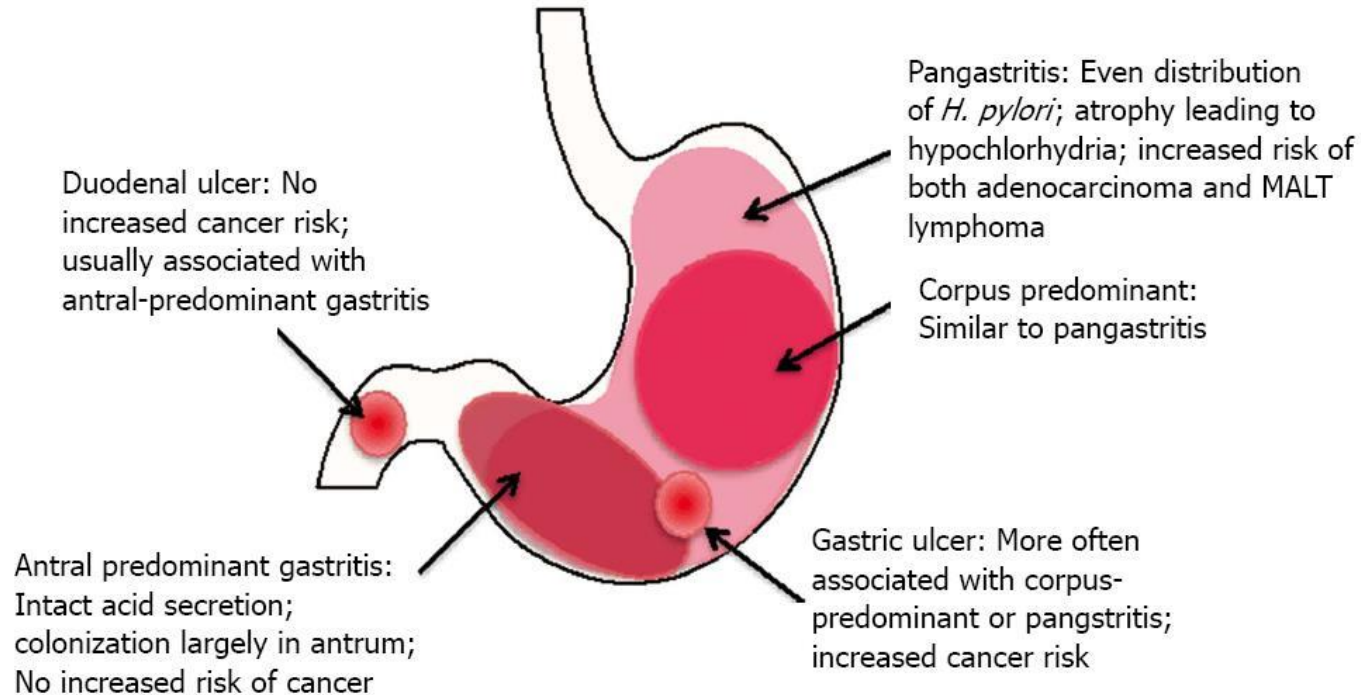
Active peptic
ulcer disease or
history of peptic
ulcer disease

Long-term
NSAID use

Unexplained
iron deficiency
anemia

Dyspepsia

H. pylori-Associated Gastritis



H. pylori Testing

Noninvasive Testing

- Stool PCR – predicts *H. pylori* Clarithromycin susceptibility or resistance
- Stool antigen
- Urea breath test

Invasive testing

- Gastric biopsy (Antrum preferred)
- Rapid urease test
- Culture

H. pylori Stool PCR

- Stool PCR
 - Predicts *H. pylori* clarithromycin susceptibility or resistance

Stool Antigen Testing

- Advantage

- Tests for active infection only
- Sensitivity and specificity near 100%
- Must stop PPIs 14 days prior to testing
- Cheaper and requires less equipment than breath test

- Disadvantages

- Stool collection may be distasteful for patient

Urea Breath Test

- Advantages

- Only detects active infection
- Sensitivity and specificity near 100%
- Must stop PPIs 14 days prior to testing
- More expensive than stool testing

- Disadvantages

- False negative results can occur with use of PPI or recent antibiotic use
- Resources and personnel required to perform testing
- C¹⁴ radiation exposure

Serology Testing (IgG Antibody)

- Cannot detect active vs. past infection
- No longer used
- Can be useful in research

Gastric Biopsy

- Advantages

- Sensitivity and specificity 95-99%
- Provides additional information about gastric mucosa

- Disadvantages

- Expensive
- Requires endoscopy and sedation
- May be less accurate with use of PPI

Rapid Urease Test

- Advantages

- Rapid results
- Sensitivity and specificity 93%
- Accurate in patients off PPIs or antibiotics

- Disadvantages

- Requires a high density of bacteria in the specimen
- Requires endoscopy

Cultures

- Advantages

- Provides *H. pylori* isolate which is subjected to amoxicillin, levofloxacin, clarithromycin, metronidazole, and tetracycline susceptibility testing
- Sensitivity and specificity 100%

- Disadvantages

- Requires trained staff and properly equipped facilities
- Expensive
- Requires endoscopy
- Not done at all facilities

When Is Endoscopy Indicated

- Age 60 or older
- Under age 60 with high risk of gastric cancer (eg, Southeast Asian descent)
- Under age 60 with more than one alarm feature

Alarm Features

- New onset of symptoms age 60+
- Unexplained weight loss
- Progressive dysphagia
- Odynophagia
- Persistent vomiting
- Overt GI bleeding
- Palpable mass
- Iron deficiency anemia
- Jaundice
- Fam history of GI cancer

Treatment regimens: First-line therapies

Regimen	Drugs (doses)	Dosing Frequency	Duration (days)	FDA Approval
Clarithromycin triple*	PPI (standard or double the standard dose) Clarithromycin 500mg Amoxicillin 1 gram or metronidazole 500 mg	BID BID BID or TID	14	Yes
Bismuth quadruple	PPI (standard dose) BSS 120 to 300 mg ^a or 420 mg ^b or BSS 300 or 524 mg Tetracycline 500 mg Metronidazole 250 to 500 mg	BID QID TID to QID TID to QID	10 to 14 ^o	No
Clarithromycin -based concomitant*	PPI (standard dose) Clarithromycin 500 mg Amoxicillin 1 gram Metronidazole or tinidazole 500 mg	BID BID BID BID	10 to 14	No
Clarithromycin -based sequential**	PPI (standard dose) plus amoxicillin 1 gram for 5 days followed by PPI, clarithromycin 500 mg plus either metronidazole or tinidazole 500 mg for more 5 days	BID	10 to 14	No

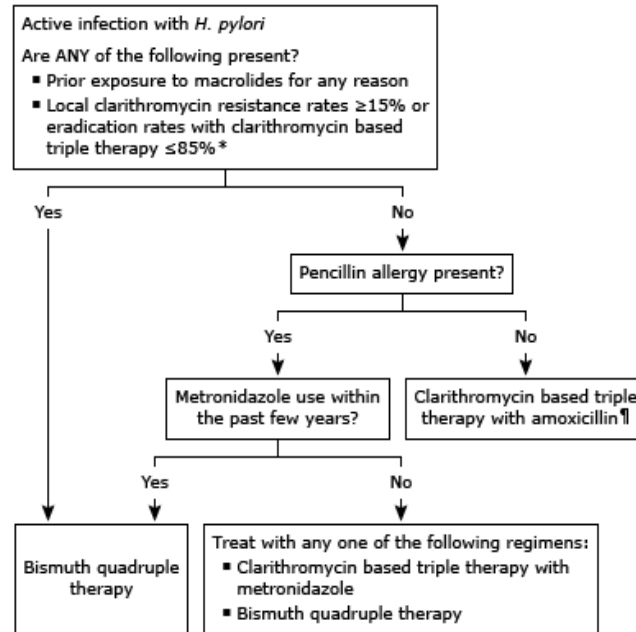
BSS, bismuth subsalicylate; PPI, proton pump inhibitor.

^aNot available in US;

^bavailable in North American and elsewhere as part of Pylera® combination pill.

Initial Approach to Antibiotic Treatment

Initial approach to antibiotic treatment for *Helicobacter pylori* infection



Clarithromycin Based Therapy

- Amoxicillin 1 Gram BID
- Clarithromycin 500 mg BID
- Omeprazole 20 mg BID
- Treatment duration 14 days
- Penicillin allergy:
 - Metronidazole 500 mg BID
- Eradication rates with clarithromycin-based therapy are below 80%
- Therapy should be reserved for geographic areas where resistance to clarithromycin is less than 15% and for patients without previous macrolide exposure
- FDA-approved treatment regimen

Bismuth Quadruple Therapy

- Tetracycline 500 mg QID
- Metronidazole
250-500 mg QID
- Bismuth QID
- Omeprazole 20 mg
- Treatment duration
10-14 days
- Eradication rates with
Quadruple therapy
average 91%

Levofloxacin Based Therapy

- Levofloxacin
500 mg QD
- Amoxicillin 1
Gram BID
- Omeprazole
20 mg BID
- Eradication rate
of 81%
- Can also be used with
Quadruple therapy

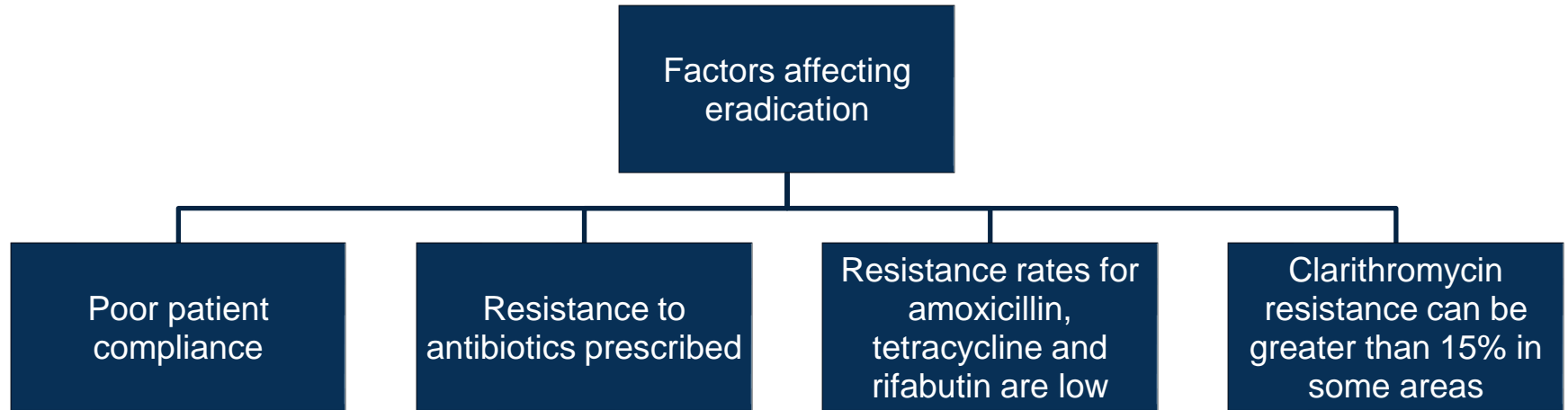
Sequential Therapy

- Amoxicillin 1 Gram BID + omeprazole 20mg BID for 5-7 days
- Clarithromycin 500mg BID + metronidazole 500 mg BID+ omeprazole 20 mg BID for 5-7 days
- Not endorsed by guidelines as first line therapy due to its complexity

Salvage Therapy

- Amoxicillin 1 Gram BID
- Rifabutin 300 mg QD
- Omeprazole 20 mg BID
 - Moxifloxacin 400 mg QD can be used for PCN allergy
- 20% of patients fail initial attempt at *H. pylori* eradication

Predictor of Treatment Success



Test for Eradication

- Urea breath test
- Fecal Antigen testing
- Must wait at least 4 weeks after completing treatment
- Stop PPI 14 days prior to testing for eradication

Key Points

- Emerging evidence suggests an association between *H. pylori* and unexplained iron deficiency anemia
- In populations with a low pretest probability of *H. pylori* infection, non-endoscopic tests such as the urea breath test and fecal antigen test offer superior positive predictive value compared with antibody tests
- Eradication rates with a PPI, clarithromycin, and amoxicillin are decreasing worldwide

Key Points

- Fourteen-day courses of therapy are more effective than 7-days treatment regimens
- Newer treatments such as sequential therapy require validation in the United States before they can be recommended as a standard first-line therapy (not FDA approved)
- A PPI, levofloxacin, and amoxicillin for 10 days appear to be more effective and better tolerated than a PPI, bismuth, tetracycline, and metronidazole in patients with persistent *H. pylori* infection but require validation in North America

Questions and Comments

