Characterization of Treatment Practices for Patients with Newly Diagnosed *H pylori* Infection: A US Population-based Study Using Claims and Electronic Medical Record Data

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OBJECTIVES

To determine the demographics, clinical characteristics, and treatment patterns of patients newly diagnosed with *H pylori* infection who undergo first-line (1L) treatment.

RESULTS

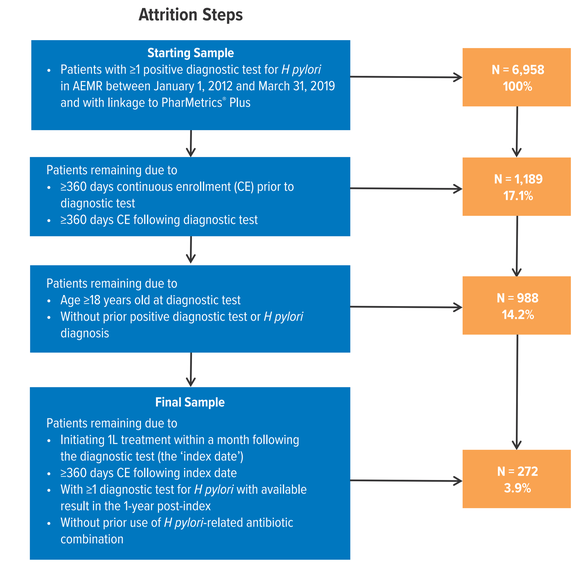
- 988 patients with newly diagnosed *H pylori* infection were identified in the combined dataset who met the eligibility criteria for the initial sample (**Figure 1**).
  - Of this sample, 347 (35.1%) did not initiate any treatment for *H pylori* infection within the pre-defined time window; 49 (5.0%) initiated treatment outside of the ACG treatment recommendations
  - 592 (59.9%) initiated 1L therapy per the study definition within a month of diagnosis irrespective of the availability of a post-treatment test
  - Among the 592 patients initiating 1L therapy, 588 had 1-year continuous enrollment post-index, and of these, 531 (90.3%) had a post-treatment test within 1 year
- The final cohort was composed of 272 1L initiators with post-treatment test results available in AEMR (**Table 1**).
  - Mean (standard deviation [SD]) age was 46.8 (13.2); 68.4% were women; 80.5% had a breath test for diagnosis; patients initiated treatment in a mean (SD) of 5.2 (6.1) days following diagnosis
  - 68% of the 1L treatments initiated were associated with a primary care physician
  - 224 (82.4%) were prescribed a clarithromycin-based regimen. However, 40 (17.9%) of these had a history of macrolide use (i.e., 1L therapy misuse)
  - 161 (59.2%) initiated 1L treatment per guidelines; most common 1L treatment was clarithromycin triple therapy including amoxicillin (n=135, 49.6%) (**Figure 2**)
  - 90 (33.1%) initiated probable 1L treatment per guidelines; most common was clarithromycin triple therapy including amoxicillin (n=46, 16.9%)
  - The remaining 21 patients (7.7%) initiated a 1L regimen outside of treatment guidelines; most common was amoxicillin + metronidazole + PPI (n=4, 1.5%)
  - Only 150 (55.5%) had a post-treatment test with available result within 3 months following end of 1L treatment
    - 30 (20.0%) had a positive test (i.e., 1L treatment failure)
  - 16 patients (53.3%) initiated 2L therapy within a month of the positive post-treatment test. Of these, probable bismuth quadruple therapy (n=7) and probable levofloxacin triple therapy (n=3) were most commonly initiated.

Table 1. Baseline Demographics and Clinical Characteristics

	Final Cohort N = 272	
	n	%
Mean (SD) age (years)	46.8 (13.2)	
Female (n, %)	186	68.4%
Region (n, %)		
Northeast	32	11.8%
Midwest	64	23.5%
South	126	46.3%
West	50	18.4%
Payer type (n, %)		
Commercial	136	50.0%
Medicaid	20	7.4%
Self-insured	116	42.6%
Race/Ethnicity (n, %)		
Caucasian	127	46.7%
African American	25	9.2%
Asian	18	6.6%
Hispanic	11	4.0%
Other	8	2.9%
Unknown	83	80.5%
Comorbidities of interest in the 1-year pre-index period (n, %)		
Dyspepsia	84	30.9%
GERD	83	30.5%
Obesity	49	18.0%
Gastritis	44	16.2%
Iron deficiency anemia	7	2.6%
Peptic ulcer disease	4	1.5%
Allergy to penicillin	4	1.5%
ITP	2	0.7%
Medications of interest in the 1-year pre-index period (n, %)		
NSAIDs	68	25.0%
H2RAs	21	7.7%
PPIs	130	47.8%
Sucralfate	10	3.7%
Antibiotics of interest		
Amoxicillin	43	15.8%
Fluoroquinolones	40	14.7%
Macrolides	52	19.1%
Metronidazole	18	6.6%
Doxycycline	19	17.0%
Type of test (n, %)		
Stool	50	18.4%
Breath	219	80.5%
Biopsy	3	1.1%
1L prescribing physician specialty (n, %)		
PCP[a]	185	68.0%
Gastroenterologist	19	7.0%
Other	68	25.0%

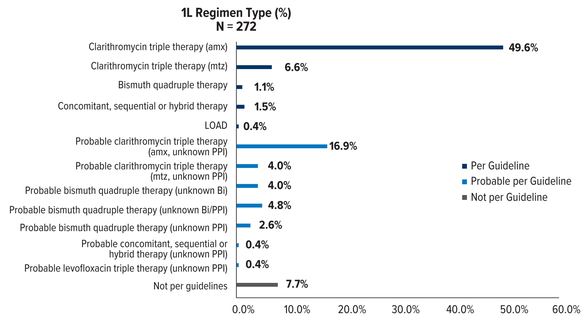
1L, first-line; GERD, gastroesophageal reflux disease; H2RAs, H2 receptor antagonists; ITP, idiopathic thrombocytopenic purpura; NSAIDs, non-steroidal anti-inflammatory drugs; PCP, primary care physician; PPIs, proton pump inhibitors; SD, standard deviation; [a]PCP includes internal medicine, general practice, family practice, physician assistant, and nurse practitioner

Figure 1. Sample Selection



1L, first-line; AEMR, ambulatory electronic medical records; CE, continuous enrollment

Figure 2. First-line (1L) Treatment Regimens



1L, first-line; amx, amoxicillin; Bi, bismuth; LOAD, levofloxacin, omeprazole, nitazoxanide ("Alinia"), and doxycycline; mtz, metronidazole; PPI, proton pump inhibitor

CONCLUSIONS

- This retrospective claims analysis demonstrates that management of newly diagnosed *H pylori* infection is not consistent with clinical guideline recommendations.
  - Among the initial sample, 35.1% did not initiate any *H pylori*-related antibiotic treatment within a month of diagnosis.
  - Testing rates were suboptimal.
  - 82.4% of 1L initiators in the final cohort were prescribed a clarithromycin-based regimen; however, 17.9% had history of macrolide use (i.e., 1L therapy misuse).
  - Among patients who failed 1L, only 53.3% initiated 2L treatment.
- Lack of treatment, suboptimal choice of antibiotics, and inconsistent routine post-treatment testing appear to be major issues in clinical practice.
- Greater adherence to guidelines is needed for the successful treatment of *H pylori* infection and to improve patient outcomes. Efforts in educating clinicians on guideline recommendations is warranted.

BACKGROUND

Helicobacter pylori (H pylori) eradication rates have declined with current treatment regimens, partly attributed to increasing antibiotic resistance and poor treatment adherence. Persistent infection can lead to complications, including peptic ulcer disease (PUD), gastric cancer and gastric mucosa-associated lymphoid tissue (MALT) lymphoma.Consequently, *H pylori* infection remains an important area of unmet need.

METHODS

- A retrospective cohort analysis was conducted using a linked patient population from IQVIA's Ambulatory Electronic Medical Records (AEMR) and PharMetrics® Plus databases in the US using data from January 1, 2011 to March 31, 2020.
  - AEMR was used to identify *H pylori* diagnostic test results while PharMetrics Plus was used to describe baseline patient characteristics and evaluate treatment patterns/prescriptions.
- Adults newly diagnosed with *H pylori* infection between January 1, 2012 and March 31, 2019 were identified from the AEMR database. To ensure patients were newly diagnosed, continuous health plan enrollment in the 1-year pre-index was required. The full study eligibility criteria can be found in **Figure 1**, which included:
  - Positive breath test, stool antigen or gastric biopsy was used to confirm *H pylori* infection.
  - Patients were identified as initiating 1L treatment per the American College of Gastroenterology (ACG) guideline if they received a) ≥1 prescription claim for an *H pylori*-related antibiotic combination (combination product containing ≥2 different antibiotics); b) ≥2 prescription claims within 3 days of each other for different *H pylori*-related antibiotics; or c) ≥1 prescription claim for high-dose amoxicillin, *within a month* following the diagnosis date.
- The date of 1L treatment initiation was termed the "index date".
  - 1L treatment was considered to have a duration of 14 days per ACG guideline, and included observed *H pylori*-related antibiotics, proton pump inhibitors (PPIs), bismuth, and H2 receptor antagonists (H2RAs).
  - "Probable" 1L treatment per guideline was identified for observed 1L regimens if there was an unobserved PPI or other acid suppressant; over-the-counter (OTC) PPI and/or bismuth and/or H2RA use was not captured in the data but assumed.
- Patients with a clarithromycin-based 1L regimen and with a history of prior macrolide use were considered to have 1L therapy misuse.
- Available post-treatment tests were assessed within 3 months of 1L treatment end to determine eradication; a positive diagnostic test was considered as 1L treatment failure.
- For patients with 1L treatment failure, 2L treatment initiation was assessed within a month of the positive post-treatment test following similar rules as 1L.
- Baseline demographics and clinical characteristics were examined over the 1-year pre-index period for the final cohort. Descriptive statistics were reported for all study measures described above.

Disclosures

Colin Howden is a consultant for Phathom Pharmaceuticals.

Eckhard Leifke and Rinu Jacob are employees of Phathom Pharmaceuticals.

Victoria Divino is an employee of IQVIA.

Ronnie Fass is a consultant for Phathom Pharmaceuticals.

Contact

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Meeting details

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