Use of the Optum Labs Data Warehouse To Assess Test Ordering Patterns for Diagnosis of Helicobacter pylori Infection in the United States

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We surveyed national Helicobacter pylori diagnostic testing practices and diagnoses using commercial and Medicare medical claims data from Optum Labs (Cambridge, MA). Serologic testing for antibodies to H. pylori remains the most commonly ordered diagnostic test despite recent expert recommendations. Changes in reimbursement for serologic testing will likely drive future provider ordering practices.

Helicobacter pylori remains among the most common bacterial infections worldwide. It is estimated that globally one in every two individuals is infected. Local prevalence rates vary, however, with approximately 20 to 40% of individuals in the United States exposed to H. pylori by adulthood (1–5). Despite these infection rates, most individuals remain asymptomatic. A number of well-defined clinical syndromes have been associated with infection, however, including dyspepsia, peptic ulcer disease, gastric adenocarcinoma, and mucosa-associated lymphoid tissue (MALT) lymphoma, with the latter two collectively occurring in <1% of individuals (3). Eradication of H. pylori through appropriate antibiotic regimens leads to a significant reduction of ulcer recurrence and long-term remission of MALT lymphoma for the majority of afflicted patients (6–8). Therefore, accurate and prompt diagnosis of H. pylori infection is essential.

Three noninvasive testing methods are available to detect H. pylori, including serologic assays to measure anti-H. pylori IgM, IgA, and IgG antibodies, H. pylori stool antigen tests (SATs), and urea breath test (UBTs) (9–11). Choosing among these methods requires a thorough understanding of each assay’s clinical utility. Serologic testing shows poor sensitivity (74% to 85%) and specificity (79% to 90%) for active infection, although such testing is not affected by prior intake of protein pump inhibitors (PPIs), bismuth compounds, or antibiotics. Additionally, serologic testing should not be used to document H. pylori eradication due to demonstrable antibody levels for years following the initial exposure (10). Finally, most serologic assays, aside from certain IgG tests, lack Food and Drug Administration (FDA) clearance. Conversely, detection of H. pylori antigen by the SAT or urease activity by the UBT is indicative of active H. pylori infection, and either assay can be applied to confirm H. pylori clearance following completion of antibiotic therapy (9–11). Both methods also have commercially available, FDA-cleared assays that offer high sensitivities and specificities for H. pylori infection (both >95% in pretreatment conditions). Certain drawbacks exist for these two assays, including the generally higher cost compared to that of serologic testing, although this cost is offset by the improved diagnostic accuracy and typically higher reimbursement rates for UBTs and SATs (11, 12). Additionally, due to the specimen collection requirements and assay complexity, UBT availability may be limited to larger hospitals and reference laboratories. Finally, PPIs, bismuth compounds, and antibiotics need to be discontinued 14 to 28 days prior to testing by either the UBT or SAT for result accuracy. Since 2005 and 2007, the American Gastroenterology Association (AGA) and the American College of Gastroenterology (ACG) guidelines have recommended use of either the SAT or UBT as a first-line diagnostic test for suspected H. pylori infection in patients with previously uninvestigated dyspepsia who meet specific criteria (10, 11). They also indicate that serologic testing should be avoided entirely due to poor clinical performance characteristics; if used, however, positive serologic findings should be confirmed by a first-line test to document active infection prior to therapeutic intervention.

We conducted a retrospective study of national H. pylori diagnostic testing practices and the resulting H. pylori diagnoses using medical claims data from the Optum Labs Data Warehouse (OLDW). Briefly, the OLDW is a health care database containing deidentified claims from >100 million individuals enrolled in either commercial insurance or Medicare Advantage plans over a 20-year period (13). For our analysis, we identified first-time tests performed between January 2010 and December 2012 using Current Procedural Terminology, version 4 (CPT-4) codes for H. pylori serology (86677: antibody, H. pylori; the code does not differentiate among IgA, IgM, or IgG serology), SAT (87338: H. pylori, stool), and UBT (83013: H. pylori; breath test analysis for urease activity, nonradioactive isotope). Testing by two different methods was considered the same testing event if tests were performed within 14 days of each other. A diagnosis of H. pylori infection
TABLE 1 Comparison of the number of ordered H. pylori diagnostic tests and the number of H. pylori diagnoses using the Optum Labs Data Warehouse

<table>
<thead>
<tr>
<th>Test name</th>
<th>CPT code</th>
<th>Total no. of patients tested</th>
<th>Normalized patients tested per 10,000 member-months*</th>
<th>Patients with a H. pylori diagnosis†</th>
<th>Patients without a H. pylori diagnosis‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology*</td>
<td>86677</td>
<td>366,846</td>
<td>4.58</td>
<td>15,495 4.2</td>
<td>351,351 95.8</td>
</tr>
<tr>
<td>UBT</td>
<td>83013</td>
<td>81,887</td>
<td>0.75</td>
<td>12,183 18.0</td>
<td>67,141 82.0</td>
</tr>
<tr>
<td>SAT</td>
<td>87338</td>
<td>58,841</td>
<td>1.02</td>
<td>7,666 13.0</td>
<td>51,175 87.0</td>
</tr>
<tr>
<td>Serology + SAT</td>
<td>86677, 87338</td>
<td>4,711</td>
<td>0.06</td>
<td>612 13.0</td>
<td>4,999 87.0</td>
</tr>
<tr>
<td>Serology + UBT</td>
<td>86677, 83013</td>
<td>3,451</td>
<td>0.04</td>
<td>932 27.0</td>
<td>2,519 73.0</td>
</tr>
</tbody>
</table>

* Limited to the first testing event for each individual between 2010 and 2012 (i.e., multiple testing events by the same assay for the same individual were excluded).
† SAT, stool antigen test; UBT, urea breath test.
‡ Based on documentation of the ICD-9-CM 041.86 diagnosis code for H. pylori infection.
§ Serologic testing includes individual or any combination of anti-H. pylori IgM, IgA, and/or IgG antibody testing.

What can be done to encourage proper test utilization for detection of H. pylori? While tailored education regarding the clinical utility of the different methods should continue and target providers who routinely order H. pylori testing, this method alone is unlikely to suffice. A more drastic incentive to alter ordering practices is likely to be changes to test reimbursement rates by insurance providers. Currently, while the Centers for Medicare and Medicaid Services reimburses all three methods (e.g., CPT 86677 at $19.80, CPT 83013 at $91.89, and CPT 87338 at $19.62), an increasing number of private insurers, including Cigna, Geisinger Health Plan, and Aetna indicate that serologic testing is “not medically necessary” and no longer provide reimbursement for such testing.

In conclusion, we show that the OLDW is a powerful tool for examining claims data and have applied it to quantify both H. pylori testing practices and the resulting H. pylori diagnoses at a national level. We confirm that despite current ACG and AGA recommendations, appropriate test utilization for H. pylori remains substandard. Utilization of such databases should be considered an additional means to monitor test utilization, diagnoses, and treatment decisions beyond the local level.

REFERENCES


