The $^{13}$C-urea blood test is accurate for detecting Helicobacter pylori infection


**QUESTION:** How accurate is the $^{13}$C-urea blood test for detecting Helicobacter pylori infection?

**Design**

Blinded comparison of the $^{13}$C-urea blood test with tests based on endoscopic biopsy.

**Setting**

5 centres in the United States (Ann Arbor, Michigan; Syracuse, New York; Gainesville, Florida; Savannah, Georgia; and Los Angeles, California).

**Patients**

121 patients (mean age 49 y, 51% men) who were referred for endoscopy. Exclusion criteria included treatment for $H. pylori$ infection in the previous year or use of antibiotics or bismuth in the previous month or proton-pump inhibitors in the previous 7 days.

**Description of tests and diagnostic standards**

Patients received $^{13}$C-urea, 125 mg dissolved in 75 ml of water. 30 minutes later, a 3-ml blood sample was obtained by venipuncture and analysed by gas isotope ratio mass spectrometry. The 3 diagnostic standards were histological evidence of $H. pylori$ infection in biopsies obtained from the body and antrum of the stomach, a positive result for both histological and rapid urease testing (RUT) (patients with discordant histological and RUT results were considered uninfected), and a positive result for either histological testing or RUT.

**Main outcome measures**

Sensitivity and specificity for detecting $H. pylori$ infection.

**Main results**

The table shows sensitivities, specificities, and likelihood ratios. Results for the $^{13}$C-urea blood test did not differ from those for RUT ($p > 0.2$).

**Conclusion**

The $^{13}$C-urea blood test was similar to rapid urease testing and had high sensitivity and specificity for detecting Helicobacter pylori infection.

**Test characteristics for detecting Helicobacter pylori infection**

<table>
<thead>
<tr>
<th>Diagnostic standards</th>
<th>Tests</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (CI)</th>
<th>+LR</th>
<th>−LR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Histological testing</td>
<td>$^{13}$C-UBT 89% (85 to 93)</td>
<td>96% (94 to 98)</td>
<td>19.9</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RUT 87% (75 to 95)†</td>
<td>96% (87 to 99)†</td>
<td>19.4†</td>
<td>0.1†</td>
<td></td>
</tr>
<tr>
<td>Histological testing and RUT</td>
<td>$^{13}$C-UBT 94% (87 to 100)‡</td>
<td>91% (85 to 97)‡</td>
<td>10.4</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>Histological testing or RUT</td>
<td>$^{13}$C-UBT 88% (80 to 96)‡</td>
<td>98% (95 to 100)‡</td>
<td>44.0</td>
<td>0.1</td>
<td></td>
</tr>
</tbody>
</table>

$^{13}$C-UBT = $^{13}$C-urea blood test; RUT = rapid urease testing. LRs defined in glossary and calculated from data in article.

†Calculated from data supplied by author.

‡CIs provided by author.

**COMMENTARY**

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The combination of reference standard error, spectrum bias, and a greater potential for operator error means that caution should be used when extrapolating these results to the office setting.1

Unfortunately, although the absolute values of the performance of the $^{13}$C-urea blood test are greater than the whole-blood antibody tests, the confidence intervals overlap, which means that we cannot be certain that the difference is robust. In any case, clinical differences between the 2 types of tests will be small because, at most, only 20% of patients will benefit from the “test and eradicate” strategy,2 and the absolute difference in sensitivity of the tests is only 0% to 10%. Only 2 patients in 100 might be missed with the antibody test. An evaluation of the tests in the office setting with larger samples and a health economic analysis are needed before an informed choice can be made between whole-blood tests and $^{13}$C-urea–based tests for applying the “test and eradicate” strategy in the office.

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