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>RUT</td>
<td>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
(continued from page 30)

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, and the absolute difference in sensitivity of the tests is only 5% 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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