

The ¹³C-urea blood test is accurate for detecting *Helicobacter pylori* infection

Chey WD, Murthy U, Toskes P, et al. *The ¹³C-urea blood test accurately detects active Helicobacter pylori infection: a United States, multicenter trial.* *Am J Gastroenterol.* 1999 Jun;94:1522-4.

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

Design

Blinded comparison of the ¹³C-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 ¹³C-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 ¹³C-urea blood test did not differ from those for RUT ($p > 0.2$).

Conclusion

The ¹³C-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**

Diagnostic standards	Tests	Sensitivity (95% CI)	Specificity (CI)	+LR	-LR
Histological testing	¹³ C-UBT	89% (85 to 93)	96% (94 to 98)	19.9	0.1
	RUT	87% (75 to 95)†	96% (87 to 99)†	19.4†	0.1†
Histological testing and RUT	¹³ C-UBT	94% (87 to 100)‡	91% (85 to 97)‡	10.4	0.1
	¹³ C-UBT	88% (80 to 96)‡	98% (95 to 100)‡	44.0	0.1

*¹³C-UBT = ¹³C-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.³

Unfortunately, although the absolute values of the performance of the ¹³C-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,⁴ and the absolute difference in sensitivity of the tests is only 5% to 10%.¹ 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 ¹³C-urea-based tests for applying the "test and eradicate" strategy in the office.

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- 4 McColl K, Murray L, El-Omar E, et al. Symptomatic benefit from eradicating *Helicobacter pylori* infection in patients with non-ulcer dyspepsia. *N Engl J Med* 1998;339:1869-74.