Comparison of new faecal antigen test with ^{13}C-urea breath test for detecting *Helicobacter pylori* infection and monitoring eradication treatment: prospective clinical evaluation

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The ^{13}C-urea breath test is currently regarded as the best non-invasive diagnostic method for detecting *Helicobacter pylori* infection, even when monitoring efficacy of treatment.[1–2] Serological methods are not appropriate for such monitoring as antibodies stay for months after successful eradication.[3] A newly developed immunoassay that detects bacterial antigens in a faeces specimen might constitute a non-invasive technique for evaluating the efficacy of eradication regimens shortly after treatment is stopped.

In this prospective study we compared a new antigen test for *H pylori* in faeces[4] with the reference method of monitoring treatment, the ^{13}C-urea breath test. We intended to evaluate the clinical validity of the test for first diagnosis of *H pylori* infection and for monitoring efficacy of eradication treatment.

Participants, methods, and results

Ninety participants (46 men, 44 women; age range 18-82 years) complaining about dyspeptic symptoms were screened for *H pylori* infection with both the ^{13}C-urea breath test and the *H pylori* antigen test in faeces.

In another part of this study, 115 participants (62 men, 53 women; 18-78 years) with *H pylori* infection (according to positive breath test results) were treated with a triple therapy (omeprazole 20 mg twice daily, clarithromycin 250 mg twice daily, and metronidazole 400 mg twice daily for seven days). At least four weeks after the end of treatment the participants were retested with the breath test and the antigen detection test.

For the breath test, the participants ingested 75 mg ^{13}C-urea (99% atom percent excess) dissolved in 200 ml of 0.1N citric acid. *H pylori* infection was indicated by a delta over baseline value $>5\delta$‰ after 30 minutes.[2]

The faecal test is based on a sandwich enzyme immunoassay with *H pylori* antigen detection (HpSA test, Meridian Diagnostics, Cincinnati, OH). An optical density $OD_{450} > 0.140$ indicates the presence of *H pylori* antigens.[5]

The table shows the findings of the analysis of the test results. Fifty one (57%) of the 90 participants who presented for the first time due to dyspeptic symptoms were positive for *H pylori* (positive breath test), and in 47 of these the *H pylori* antigen could be detected in the faeces (sensitivity 92.2%). Thirty eight of the 39 participants with negative breath test results were *H pylori* negative in the antigen test (specificity 97.4%). Among the antigen test results, we observed four false negatives (5.82δ‰ (breath test) *v* OD_{450} 0.033 (antigen test); 16.25δ‰ *v* 0.072; 16.55δ‰ *v* 0.09; 18.13δ‰ *v* 1.12) and one false positive (3.88δ ‰ *v* 0.188).

Of the 115 *H pylori* positive participants who were treated with the triple regimen, 92 (80%) presented with a negative breath test. Among these 92 participants we observed two false negative and five false positive antigen test results (false negatives: 8.34δ‰ *v* 0.072, 11.42δ‰ *v* 0.086; false positives: 3.2δ‰ *v* 0.402, 3.55δ‰ *v* 0.969, 4.21δ‰ *v* 0.144, 4.33δ‰ *v* 0.407, 4.55δ‰ *v* 0.738). With reference to the breath test this accounts for a sensitivity of 91.3% and a specificity of 94.6%.

The results in these 205 participants showed that the overall sensitivity and specificity of the antigen faecal test were 91.9% and 95.4% respectively.

Sensitivity, specificity, and predictive values (95% confidence intervals) for faecal antigen test for *Helicobacter pylori*

	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
First diagnosis (n=90)	92.2 (81.1 to 97.8)	97.4 (86.5 to 99.9)	97.9 (88.9 to 99.9)	90.5 (77.4 to 97.3)
Control of eradication (n=115)	91.3 (72.0 to 98.9)	94.6 (87.8 to 98.2)	80.8 (60.6 to 93.4)	97.8 (92.1 to 99.7)
Total (n=205)	91.9 (83.2 to 96.9)	95.4 (90.3 to 98.3)	91.9 (83.2 to 96.9)	95.4 (90.3 to 98.3)

Comment

The new enzyme immunoassay HpSA is a highly sensitive and specific, non-invasive diagnostic tool for the qualitative detection of *H pylori* infection, even for monitoring efficacy of treatment. It is not time consuming (taking about 90 minutes), and, at about £19, it is cheaper than the ^{13}C-urea breath test. The analytical technique is easily performed in any laboratory. Although some patients may be reluctant to collect a faecal specimen, specimens can usually be obtained easily, even in very young children.

Contributors: BB initiated and designed the study; coordinated the testing of participants, data collection, and analysis; interpreted the data; and wrote the manuscript. GT assisted in the design and execution of the study and in writing the manuscript. CFD helped to design the study, collected data, and participated in the analysis, data documentation, interpretation of the data, and writing of the paper. WFC initiated the research, discussed core ideas, and contributed to the study design, interpretation of the data, and editing of the paper. BL participated in the design of the study protocol, collected data, and contributed to the statistical analysis, interpretation of the findings, and writing of the paper. BB is the guarantor for the paper.

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