

TEST & TREAT HELICOBACTER MANAGEMENT OF DYSPEPSIA

COST COMPARISON OF SEROLOGY TO STOOL ANTIGEN & BREATH TEST

Recently published dyspepsia guidelines suggest that all patients, irrespective of age, with uncomplicated dyspepsia unresponsive to lifestyle changes or acid reducing agents should be tested for helicobacter and treated accordingly.

The most commonly used non-invasive test in the UK for helicobacter is laboratory-based serology, which is significantly less specific than breath test or stool antigen test. At a prevalence of 25%, 36% of patients positive by serology (assuming specificity 81%) will be incorrectly diagnosed with helicobacter and receive inappropriate treatment. (Appendix 2) The stool antigen or breath tests lead to much less inappropriate helicobacter antibiotic treatment and thus less confusion in post treatment follow-up. With the monoclonal stool antigen test (DakoCytomation) or urea breath test approximately 12% of positive patients will be incorrectly treated (Appendix 2).

We enclose the cost comparison of serology (currently being used by most microbiology laboratories), the stool antigen kit and the urea breath test. Although initial test costs of the stool antigen tests are higher and resources need to be transferred to microbiology laboratories, the treatment and follow-up costs are significantly lower, especially if Heliclear rather than generic treatment is used. It is also likely that as we transfer to stool antigen tests the manufacturers will lower the costs.

Considering a population of 500,000

- 4% of general practice consultations are for dyspepsia = 16,000
- Approximately 10% of these will be referred for further investigation
- Current GP serology testing rate in microbiology laboratories varies from 0-56/1000 GP practice population, mean 5/1000 GP practice population. We anticipate testing rates increasing to 10/1000

Test & Treat Management of Dyspepsia Cost Comparison of Serology & Stool Antigen Testing

Approximate number of patients for test and treat/annum 5000
Prevalence rate of helicobacter (%) 25

	Serology	UBT	Monoclonal Stool Ag (DakoCytomation)	Polyclonal Stool Ag (Meridian)
Total No. of positives	1,788	1,345	1,374	1,459
Specificity (Appendix 1) %	83	95.7	95.9	91.9
No. of false positives detected	638 (36%)	161 (12%)	154 (11%)	304 (20%)
Sensitivity (Appendix 1) %	92	94.7	97.6	92.4
No. of true positives detected	1,150	1,184	1,220	1,155
Cost of test (Appendix 3) £	9.45	18.65	11.65	11.43
Total cost of 5000 tests £	47,250	93,250	58,250	57,150
Lowest possible cost of generic treatment for all positives @ £19.16/patient* £	34,258	25,170	26,326	27,954
Total cost of test and treat £	81,508	119,020	84,576	85,104
**Total cost of test and treat using <i>Heliclear</i>	113,174	142,840	108,909	110,943

*Treatment regimen: Twice daily PPI with clarithromycin 250 mg bd and metronidazole 400 mg bd

** Prescribing information suggests that *Heliclear* is the most commonly prescribed treatment at £36.87/patient

NICE guidance suggests that post treatment tests are unnecessary.

APPENDIX 1

PERFORMANCE OF TESTS

Serology Tests

Evaluation of commercially available *Helicobacter pylori* serology kits: A Review

Laheij RJF, Straatman H, Jansen JBMJ, Verbeek ALM *J Clin Microbiol* Oct 1998;36:2803-09 (26,812 patients, 177 tests, 36 kits)

Sensitivity: 92%
Specificity: 83%

Performance of DakoCytomation Hp StAR Stool Antigen Test

Malfertheiner *et al*
GUT Sept 2001; 49 (Supplement II): Abstract A97 (256 adults v histo/culture. Sensitivity better than Meridian)
Sensitivity: 95.5%
Specificity: 97.8%

Leodolter A *et al*
Am J Gastroenterol 2002;97:1682-86 (Comparison of 2 stool Ag to UBT. 148 patients. Dako more sensitive than Meridian)

Sensitivity: 94.3%
Specificity: 93.8%

Makristathis A *et al*
J Clin Microbiol Oct 2000;38:3710-14 (49 children versus UBT)
Sensitivity: 98.2%
Specificity: 98.1%

Koletzko S *et al*
GUT 2003;52:804-6 (302 children v histo/culture)
Sensitivity: 98%
Specificity: 99%

Andrews J *et al. J Clin Pathol* 2003;56:769-71. (111 adults v histo/culture. More sensitive than Meridian)
Sensitivity: 88%
Specificity: 97.6%

Performance of Meridian HpSA Stool Antigen Test

Gisbert *et al*
Am J Gastroenterol 2001;96:2829-38 (4769 patients, 43 studies. 2078 patients, 25 studies test for confirmation of eradication at ≥ 4 weeks)

Sensitivity: 92.4%
Specificity: 91.9%

Urea Breath Test

Vaira D.
GUT 2001;48:287-89 (3,643 patients)

Sensitivity: 94.7%
Specificity: 95.7%

Weighted Mean Values

Serology

Sensitivity: 92%
Specificity: 83%

DakoCytomation stool antigen

Sensitivity: 95.9%
Specificity: 97.6%

Meridian stool antigen

Sensitivity: 92.4%
Specificity: 91.9%

Urea breath test

Sensitivity: 94.7%
Specificity: 95.7%

APPENDIX 3

COST OF TESTS

	SEROLOGY [#]	STOOL ANTIGEN TESTS [#]		BREATH TEST
Kit cost £/no of wells	£123.38/96	Monoclonal (Dako) £480/96	Polyclonal (Meridian) £225/48	£14.35* single
Cost per test	£1.37	£5.33	£5.11	N/A
Technician time £15/hour	£2.25 (9 min)	£3.00	£3.00 (12 min)	N/A
Needle/vacutainer or stool collection vial	£0.07	£0.12	£0.12	N/A
Syringe	£0.06	N/A	N/A	N/A
Practice Nurse £15/hour Opportunistic cost	£2.50 (10 min)	N/A	N/A	£4.25 (15 min)
Transport and handling	£3.20	£3.20	£3.20	N/A
Total	£9.45	£11.65	£11.43	£18.65

*Pylobactell prescription test cost/test to pharmacist is £20.75. £6.40 paid by patient as prescription charge - £14.35 NHS cost.

[#]The cost of the serology and stool antigen kits is based on February 2005 UK prices quoted by the companies. This allows for testing in batches of 30 with 2 controls per batch. Lower prices may be negotiable locally.