

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 PPIs should be considered for helicobacter testing 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 83%) 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 a monoclonal stool antigen test 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), monoclonal stool antigen tests and the urea breath test. Although initial test costs of the stool antigen tests are higher and resources may 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. As more laboratories are transferring to stool antigen tests, the manufacturers are lowering 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, UBT & Stool Antigen Testing

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

	Serology	UBT	Monoclonal Stool Antigen Kits	
			Lowest Price	Highest Price
Cost of test (Appendix 3)	£13.01	£18.68	£12.45	£14.04
Total cost of 5000 tests	£65,050	£93,400	£62,250	£70,200
Total No. of positives	1,788	1,345	1,366	1,366
Specificity (Appendix 1)	83%	95.7%	95.8%	95.8%
No. of false positives detected	638 (36%)	161 (12%)	157 (11%)	157 (11%)
Sensitivity (Appendix 1)	92%	94.7%	96.7%	96.7%
No. of true positives detected	1,150	1,184	1,209	1,209
Lowest possible cost of generic treatment for all positives @ £13.29/patient* (BNF No. 53) <i>Omeprazole, amoxicillin, clarithromycin</i>	£23,763	£17,875	£18,154	£18,154
Total cost of test and treat	£88,813	£111,275	£80,404	£88,354
**Total cost of test and treat using <i>Heliclear</i>	£130,974	£142,990	£112,614	£120,564

*Treatment regimen: Twice daily PPI with amoxicillin 1g bd and clarithromycin 500 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%

Monoclonal Stool Antigen Tests

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

Leodolter A *et al*
Am J Gastroenterol 2002;97:1682-86
(148 patients v UBT)
Dako (Oxoid) Sensitivity: 94.3% Specificity: 93.8%

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

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

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

Zanetti MV & Mucignat G.
Microbiologia Medica 2006;21:N3
(248 adults Meridian monoclonal v Meridian polyclonal v Oxoid monoclonal)
Meridian monoclonal Sensitivity: 97.33 Specificity: 95.89
Oxoid monoclonal Sensitivity: 96.05 Specificity: 94.59

Weighted Mean Values

Serology

Sensitivity: 92%
Specificity: 83%

Monoclonal stool antigen test

Sensitivity: 95.8%
Specificity: 96.7%

Urea Breath Test

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

Sensitivity: 94.7%
Specificity: 95.7%

Urea breath test

Sensitivity: 94.7%
Specificity: 95.7%

APPENDIX 3

COST OF TESTS

	SEROLOGY [#]	MONOCLONAL STOOL ANTIGEN TESTS [#]		BREATH TEST
Kit cost £/no of wells	£343/96	Price range/96		£13.90* single
		Lowest price	Highest price	
		£498	£641	
Cost per test	£3.81	£5.53	£7.12	N/A
Technician time £18/hour	£2.70 (9 min)	£3.60	£3.60 (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 £19/hour	£3.17 (10 min)	N/A	N/A	£4.78 (15 min)
Opportunistic cost				
Transport and handling	£3.20	£3.20	£3.20	N/A
Total	£13.01	£12.45	£14.04	£18.68

*Pylobactell prescription test cost/test to pharmacist is £20.75. £6.85 paid by patient as prescription charge - £13.90 NHS cost.

[#]The costs of the Meridian Premier *H. pylori* serology, Oxoid HpStAR stool antigen and Meridian Premier Platinum Plus stool antigen kits are based on September 2006 UK list prices quoted by the companies. This allows for testing in batches of 30 with 2 controls per batch. Lower prices may be negotiable locally.