Randomised controlled trial of Helicobacter pylori testing and endoscopy for dyspepsia in primary care

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Helicobacter pylori testing and endoscopy for dyspepsia in primary care.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients, 18 to 50 years of age, presenting with dyspepsia of longer than four weeks duration. Patients were excluded if they had had an endoscopy or positive barium meal examination in the last 3 years, were unable to give informed consent or were unfit for endoscopy.

Setting
The setting was primary and secondary care. The economic evaluation was carried out in Birmingham, UK.

Dates to which data relate
Effectiveness and resource use data were collected from May 1995 onwards. The end date of the data collection was not specified. The price year was 1998.

Source of effectiveness data
The evidence/estimate for final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. It was not stated whether this was done prospectively or retrospectively.

Study sample
Baseline characteristics were given. Therefore one can see if the initial study sample was appropriate for the clinical study question. Power calculations were conducted based on a power of 90% at the 5% significance level and a loss to follow up assumed to be 25%. 478 patients entered the trial, 285 were randomised to 'test and endoscopy' and 193 to usual management. The percentage of patients invited to participate who refused was not reported. The percentage of subjects excluded from the initial sample was not reported.
Study design
The study design was a randomised controlled trial. 31 practices participated in the study. The duration of follow up of the cohort was 15 to 18 months. Patients were randomised individually using sealed, opaque, sequentially numbered envelopes. The randomisation schedule was carried out on a 60:40 basis (study control) and used a computerised random number sequence without blocking or stratification. A log of numbers issued to practices was maintained. 284 (99.6%) out of 285 patients completed the trial in the study group and 191 (99%) patients out of 193 completed the trial in the control group. Assessment of outcomes was not blinded. The authors stated that ‘evaluable symptom scores and quality of life scores were obtained from 290 (183 versus 107) (61%) patients’. 273 patients (57%) returned satisfaction questionnaires, although the division between treatment arms was not stated.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat, but there was loss to follow-up, the data for which was effectively censored. The primary health outcomes used in the analysis were: a measure of dyspepsia symptoms, a measure of quality of life in terms of pain, emotion and social function and patient satisfaction. Symptoms were measured using the Birmingham dyspepsia symptom score, a postal measure previously validated in the local population. Quality of life was measured using a questionnaire derived from a validated measure for patients with peptic ulcer disease. Patient satisfaction was assessed by a validated measure of satisfaction with the primary care consultation supplemented with additional questions relating to secondary care and endoscopy. The baseline characteristics of the patients entered into the analysis were stated to be similar in the two randomised groups, although no statistical test was carried out and some data were missing. However, a multiple logistic regression showed that non respondents (of symptom and quality of life questionnaires) were more likely to smoke and were younger than respondents, but no difference by sex or baseline symptoms was observed. It was stated that analysis of covariance found that age and smoking had no significant effect on symptoms or quality of life, although no results were reported. Compared with the control patients, fewer patients in the study group had oesophagitis (17% versus 31%, p=0.04) and more had duodenitis (19% versus 6%, p=0.04). Among the patients who underwent endoscopy, significantly more peptic ulcers were detected by the test and endoscopy strategy than by standard management (21 (7%) versus 4 (2.1%), p=0.011).

Effectiveness results
The mean (standard deviation) improvement in symptom scores from baseline to 18 months was 3.8 (4.8) in the study group and 3.5 (4.5) in the control group. The mean difference in change between the two groups was 0.3 (95% CI: -0.9 - 1.5, p=0.61).

The mean (standard deviation) improvement in the quality of life pain score from baseline to 18 months was 16.9 (25.3) in the study group and 14.3 (21.5) in the control group. The mean difference in change between the two groups was 2.5 (95% CI: -3.5 - 8.6, p=0.41).

The mean (standard deviation) improvement in quality of life social score from baseline to 18 months was 9.6 (18.4) in the study group and 10.3 (17.3) in the control group. The mean difference in change between the two groups was 0.7 (95% CI: -3.9 - 5.2, p=0.78).

The mean (standard deviation) improvement in quality of life emotion score from baseline to 18 months was 5.4 (18.6) in the study group and 7.2 (18.0) in the control group. The mean difference in change between the two groups was 1.8 (95% CI: -2.8 - 6.4, p=0.44).

Patient satisfaction scores were not reported but the authors reported that no significant differences were observed between the two groups.

Clinical conclusions
Symptom scores and quality of life improved over time for all patients with no clear difference between groups.
Measure of benefits used in the economic analysis
No summary benefit measure was reported and therefore this was a cost consequences analysis.

Direct costs
Costs were not discounted which was appropriate, given the 12-month follow up period. Quantities and costs were reported separately. The quantities measured included number of endoscopies, barium meal examinations, primary care consultations, outpatient appointments, in-patient episodes, H. pylori test, and drugs prescribed (in terms of individual daily doses). The quantity/cost boundary adopted was that of the health service. The estimation of quantities was based on primary care case records. Unit costs were derived from official publications or obtained from the relevant laboratory (Public Health Laboratory Service) or company (Cortecs Diagnostics). The price year was 1998.

Statistical analysis of costs
Resource use was compared using t tests.

Indirect Costs
Indirect costs were not included in the analysis.

Currency
UK pounds sterling ( ).

Sensitivity analysis
A sensitivity analysis was not conducted.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
The mean total costs for the test and endoscopy strategy was 367.85 and 253.16 for usual management.

The incremental cost per patient was 114.69. The duration of follow up was 12 months for costs.

A comparison of mean (SD) resources used per patient revealed:
endoscopy: study: 0.59 (0.76) versus control: 0.28 (0.49), p<0.0001;
H.Pylori test: study: 1.35 (0.78) versus control: 0.74 (0.73), p<0.0001.

All other resource consumption, except for antacids was in the opposite direction, but all with p values greater than 0.11.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The test and endoscopy strategy increases endoscopy rates over usual practice in primary care. The additional cost is not offset by benefits in symptom relief or quality of life.
CRD COMMENTARY - Selection of comparators
The choice of the comparator was justified as it was usual management for patients presenting with symptoms of dyspepsia. You, as a user of the database, should decide if this is a widely used health technology in your own setting.

Validity of estimate of effectiveness:
The analysis was based on a randomised controlled trial, which was appropriate for the study question. There are some doubts as to whether the study sample was representative of the study population given that some baseline data were missing, particularly regarding symptoms of dyspepsia. Patients appeared to be comparable at baseline within the caveat above. Appropriate statistical analyses (analysis of covariance) were undertaken to take account of potential bias arising from non-responding, although the results were not shown. However, parametric tests were used for ordinal data on quality of life and symptoms, which could have masked a bigger difference, should it have been skewed. Also there were statistically significant differences in pathology found by endoscopy; i.e., more peptic ulcers in the intervention group, which was not controlled for.

Validity of estimate of measure of benefit
Estimation of benefits was obtained directly from the effectiveness analysis. This choice of estimate was justified.

Validity of estimate of costs
Positive features of the cost analysis were that all relevant categories of cost for the perspective adopted appear to have been included in the analysis, costs were reported separately from quantities, and a statistical analysis of quantities was conducted. However, neither a sensitivity analysis of prices nor statistical analysis of costs was reported.

Other issues
The authors made appropriate comparisons of their findings with those from other studies but did not address the issue of generalisability to other settings. It would have been better had the results of the covariance test been given, and it might have been possible to have carried out intention to treat analysis. The study considered patients between 18 and 50 presenting with symptoms of dyspepsia, although the authors missed the bottom limit in their conclusions.

Implications of the study
It is unclear whether a strategy to test for H. pylori and then eradicate is cost-effective as an initial management strategy in primary care. Future trials should evaluate the cost-effectiveness of this strategy compared with empirical prescribing.

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None stated.

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