A trial of a test-and-treat strategy for Helicobacter pylori positive dyspeptic patients in general practice


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 (HP) test-and-treat strategy based on HP serological testing in general practice. The test was undertaken using the HP serological testing kit (Helisal).

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients under the age of 45 presenting with persistent (more than 4 weeks) ulcer-like dyspeptic symptoms, without the alarm symptoms specified by the British Society of Gastroenterology and others, and in whom the GP considered further investigation appropriate.

Setting
Primary care and hospital. The economic study was carried out in London, UK.

Dates to which data relate
No dates were specified for the effectiveness and resource use data. The cost data were obtained from 1996 to 1999 sources.

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

Link between effectiveness and cost data
Costing appears to have been undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The intervention group (test-and-treat) consisted of a total of 165 patients from 6 intervention practices comprising 31 GPs; of these patients, 141 with a mean age of 33.1 years had 12-month follow-up data. The control group (endoscopy) comprised 92 patients with a mean age of 34.1 years from 9 practices consisting of 33 GPs.
**Study design**
A multi-centred randomised controlled trial, carried out in the Lewisham area of South London. The duration of the follow-up was 12 months. Loss to follow-up was 15% in the intervention group (lacked 12-month follow-up data) and 0% in the control group. The general practice was the unit of randomisation. All general practices served by the study hospital were stratified for size and location. Practices willing to participate in the study after being contacted by letter were randomised to the intervention or control groups. A trained practice nurse performed the Helisal test as a side-room procedure with the result being available to the doctor in about 15 minutes. HP eradication therapy was prescribed for patients with a positive result. No specific eradication regimen was determined for positive cases in order to replicate usual practice; an emphasis was placed on triple therapy for at least one week, and on a proton pump inhibitor-based triple therapy regimen being likely to be more effective than a traditional bismuth-based combination.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was treatment completers only. The main clinical outcomes included the mean GP consultation rate, the mean number of prescriptions for GI drugs, the percentage of patients with HP positive and negative, referral rates, and adverse events. The comparability of the two groups of patients was not discussed.

**Effectiveness results**
It was reported that the majority of clinical outcomes in the three groups (the control group and the subgroups of intervention patients with HP positive and HP negative results) were comparable. It was also reported that there were no serious adverse clinical events in either the study or control group. Although a few patients (5) in the HP positive group receiving eradication therapy experienced side effects of antibiotics.

In the intervention group, 41% were HP positive and 59% HP negative. No ulcers or erosive oesophagitis were found in the control group who were referred for endoscopy by the control practices. The number of endoscopies performed in the intervention group in the 12-months follow-up period was 17; 7 (10%) in the HP positive patients and 10 (10%) in the HP negative patients; none of these endoscopies revealed peptic ulcer or cancer. All patients in the control group, by definition, underwent endoscopy.

The hospital referral rate was 30% in the intervention group versus 16% in the control group (p=0.025). It was noted that, after exclusion of referrals for urea breath tests, there was no significant difference between referral rates.

**Clinical conclusions**
There is no evidence that, after one year, a non-endoscopy (test-and-treat) approach has missed any serious lesions. In the 14 endoscopies performed in the study group patients, no serious mucosal lesions were identified and there was no evidence of adverse clinical effects in the remaining patients.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and since the clinical outcomes were deemed largely comparable, the economic analysis performed most closely resembles a cost-minimisation analysis.

**Direct costs**
Costs were not discounted in view of the one-year follow-up period of the study. Quantities were reported separately from the costs and cost items were reported separately. Cost analysis covered the costs of drug prescriptions, investigations, visits to general practice, consultations with specialists and other medical events, and treatment. The perspective adopted in the cost analysis was that of a general practice. Note audit was the main source used for gathering information on resource use. The prescription data were extracted both from the routine clinical notes and prescribing registers. Cost data were obtained from the British National Formulary, Trust hospitals and other sources. The dates of the price data appeared to be 1996 to 1999.
Statistical analysis of costs
The student’s t test was used to compare the groups in terms of total costs and cost components.

Indirect Costs
Not included.

Currency
UK pounds sterling (€).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable. See effectiveness results above.

Cost results
The total cost of patient management for one year was 404.31 in the control group versus 205.67 in the intervention group (p<0.0001). When the costs of HP eradication therapy were excluded, the corresponding values were 329.42 in the control group and 114.20 in the intervention group (p<0.0001).

Synthesis of costs and benefits
Costs and benefits were not combined since the economic analysis was performed on a cost-minimisation basis.

Authors’ conclusions
A HP test-and-treat strategy for dyspeptic patients aged under 45, employing office-based serology testing, appears to be associated with substantially lower costs than initial endoscopy and with similar clinical outcomes.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (direct access to endoscopy at a local hospital). It was reported that GPs were used to having access to this service in the study area. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results is likely to be high due to the rigorous approach to data collection, although it was not shown whether randomisation at the level of clinical practice could achieve comparability of patient characteristics at baseline between the study groups. The study was a cost-minimisation analysis and in this respect the principal benefit would be derived from the avoidance of hospital-based endoscopies.

Validity of estimate of costs
Quantities were reported separately from the costs and adequate details of the methods of cost estimation were given. It was noted that, with the exception of drug costs (which were deemed unlikely to vary within the UK), other main cost components (costs of endoscopy, referral and investigations) might vary between hospitals and health authority districts.

Other issues
Given the uncertainties in the data, the authors' conclusions appear to be justified. The issue of generalisability in costs was addressed by stressing that the costings used in this study need to be carefully scrutinised before the results can be generalised to other health-care settings. Regarding the effectiveness results, it was noted that the test characteristics attributed to the Helisal test might not be sufficiently robust for routine use as a basis for clinical management. Appropriate comparisons were made with other studies, principally that the results compare favourably with other modelled studies.

**Implications of the study**
The use of the intervention as an office-based test has not yet been established due to uncertainties about the sensitivity, specificity and predictive values of the Helisal test. These findings therefore clearly require replication in other settings, where the costs and patterns of health-care may be different. They also need to be considered in relation to emerging concern about the effect of HP eradication on the development of gastro-oesophageal reflux disease and the possible increased risk of oesophageal cancer.

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