Clinical trial: a randomized trial of early endoscopy, Helicobacter pylori testing and empirical therapy for the management of dyspepsia in primary care

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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.

CRD summary
This study examined the cost-effectiveness of endoscopy, Helicobacter pylori (H. pylori) test and refer or treat, and empirical acid suppression for patients with dyspepsia in primary care. The authors concluded that the most cost-effective strategy was to test and treat, although early endoscopy might be the preferred strategy in older patients, due to their greater risk of malignant disease. On the whole, the study was well conducted and satisfactorily reported. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to examine the cost-effectiveness of endoscopy, Helicobacter pylori (H. pylori) test and refer or treat, and empirical acid suppression, for adult patients with dyspepsia in primary care.

Interventions
The four strategies were early endoscopy, test-and-refer, test-and-treat, and empirical therapy.

In early endoscopy, the procedure was used to establish a diagnosis.
In test-and-refer, testing for H. pylori was followed by referral to endoscopy, for those who tested positive.
In test-and-treat, testing for H. pylori was followed by eradication therapy, for those who tested positive.
In empirical therapy, pragmatic treatment with a proton pump inhibitor (PPI) was given without testing.

In both the test-and-refer and test-and-treat strategies, patients who tested negative, and all patients in the empirical therapy group, were prescribed lanzoprazole 30mg daily for one month (the PPI). In the test-and-treat strategy, those who tested positive received omeprazole 20mg, metronidazole 400mg, and clarithromycin 250mg twice daily for one week (eradication treatment).

Location/setting
UK/primary care.

Methods
Analytical approach:
This economic evaluation was based on a single study with a one-year time horizon. The authors stated that the perspective of the health service provider was adopted.

Effectiveness data:
The clinical evidence came from a multi-centre (43 practices in Nottingham, UK), randomised controlled trial (RCT). A sample of 762 patients (411 men) was enrolled in the study, with 187 early endoscopy, 199 test-and-refer, 198 test-and-treat, and 178 empirical therapy patients. The patients in all groups were similar in terms of their demographic and clinical characteristics. The first-year clinical data were available for 186 early endoscopy, 196 test-and-refer, 195 test-and-treat, and 176 empirical therapy patients. The length of follow-up was one year. The primary clinical outcome was symptom response which was assessed using a five-point Likert Scale.
Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The summary benefit measures were symptom response and patient satisfaction, which were assessed by means of a patient questionnaire administered at two and 12 months. Other clinical endpoints were also reported.

Cost data:
The economic analysis included the costs of H. pylori test, H. pylori eradication, drugs, out-patient visits, barium meal, and urea breath test. The unit costs were reported. The one-year resource use data were derived from the whole sample of patients enrolled in the clinical trial, using their general practitioner records and hospital notes. The costs were obtained from the British National Formulary, the Queen’s Medical Centre’s pharmacy and finance department, and national guidelines on dyspepsia. The price year was 2004 and all costs were in UK pounds sterling (£).

Analysis of uncertainty:
The authors carried out a bootstrapped simulation to calculate the proportion of time, for which each strategy had the highest net monetary benefit (NMB), for different willingness-to-pay values. Cost-effectiveness acceptability curves were generated. The impact of varying the cost of endoscopy was specifically investigated.

Results
At 12 months, the proportions of patients reporting no or minimal symptoms were 55% in the early endoscopy group, 53% in the test-and-refer group, 52% in the test-and-treat group, and 50% in the empirical therapy group (53% overall).

In general, patients in the early endoscopy group reported less frequent or severe symptoms and greater satisfaction, but the differences that were significant at two months, did not reach statistical significance at 12 months. Similarly, by 12 months there were no differences in patient satisfaction among the groups, although those receiving empirical therapy were less satisfied than the other groups at two months.

The total health care costs were £265 in the early endoscopy group, £199 in the test-and-refer group, £159 in the test-and-treat group, and £174 in the empiric treatment group. Those in the early endoscopy group had higher intervention costs, compared with the other groups, which were partly offset by a reduction in subsequent costs. However, these differences in total costs did not reach statistical significance.

The costs and benefits were synthesised by means of their NMB. At a value for a symptom-free day of between £0 and £6,000, the test-and-treat strategy was the most frequently cost-effective option while, above the threshold of £6,000, test-and-refer was the preferred strategy. Reductions in the cost of endoscopy made the latter strategy more attractive.

Authors’ conclusions
The authors concluded that the most cost-effective strategy was test-and-treat, although early endoscopy might be the preferred strategy in older patients, due to their greater risk of malignant disease. These findings supported the guidelines provided by the National Institute for Clinical Excellence (NICE).

CRD commentary
Interventions:
The authors provided a justification for the selection of the comparators, which represented the four main strategies available for the initial management of patients presenting in primary care. Details of the four strategies were given.

Effectiveness/benefits:
The clinical data were derived from an RCT, which is usually considered to be a valid source of evidence given its robust design. The details of the inclusion and exclusion criteria, power calculations for determining the appropriate sample size, randomisation procedures, and follow-up were reported. The baseline comparability of the groups strengthened the validity of the clinical comparison. Overall, the clinical analysis was carried out in a credible and transparent fashion. The benefit measure was derived directly from the RCT and was an intermediate, although
relevant, outcome for this specific disease.

Costs:
The analysis of costs was consistent with the perspective. The unit costs and quantities of resources used for each study group were presented separately. The economic study was well presented. The sources of costs were reported and they reflected the economic viewpoint of the analysis. The price year was given, which will allow reflation exercises for other time periods.

Analysis and results:
The synthesis of costs and benefits was appropriately performed. The issue of uncertainty was appropriately addressed, using a comprehensive approach. The findings were clearly reported and discussed. The authors highlighted the strengths of their study, such as the direct and simultaneous comparison of the four strategies in a single trial, and its generalisability to other primary care practices. They acknowledged that their study had several limitations, such as the limited accuracy of the near patient (results at the point of testing) H. pylori test.

Concluding remarks:
On the whole, the study was well conducted and satisfactorily reported. The authors’ conclusions appear to be valid.

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