Cost-effectiveness analysis of two management strategies for dyspepsia
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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.

Health technology
The health technologies considered for the treatment of dyspepsia were empirical proton-pump inhibition (PPI) and endoscopy-guided therapy (EGT). Empirical PPI treatment consisted of 40 mg omeprazol for 2 weeks with referral for endoscopy if symptoms persisted. A recurrence of symptoms in patients aged 45 years or older resulted in referral for endoscopy. Patients aged younger than 45 years who were Helicobacter pylori (H. pylori)-positive received eradication therapy. Those who were H. pylori-negative with reflux received an additional 2 weeks of PPI therapy, while those without reflux were referred for endoscopy. EGT consisted of endoscopy within 2 weeks, with patients treated according to findings. Patients with ulcus duodeni and H. pylori-positive ulcus ventriculi were given eradication therapy, while those with H. pylori-negative ulcus ventriculi or oesophagitis were given 4 weeks of 40 mg omeprazol.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients (aged 18 years or older) with dyspepsia.

Setting
The study setting was (outpatient) primary care. The geographical setting was Aarhus County, Denmark.

Dates to which data relate
The clinical effectiveness and resource use data were collected between 2000 and 2003. The price year was 2006.

Link between effectiveness and cost data
The cost data were collected prospectively from the same patients who provided the clinical effectiveness evidence.

Study sample
A total of 368 patients were included in the study. Of these, 184 were allocated to the PPI group and 184 were assigned to the EGT group. Consecutive patients presenting to general practices were recruited to the study. The authors did not report whether any patients refused to participate in the study. No sample size or power calculations were reported in the paper.

Study design
The study was a multi-centre RCT. Thirty-two general practices participated in the study. The randomisation method
was not reported in the paper. Blinding was not possible in this study. The patients were followed up for 1 year and 18 patients were lost to follow-up (10 from the PPI group and 8 from the EGT group). Response rates for the 1-year follow-up questionnaire were 90% for general practitioners (GPs) and 86% for patients.

**Analysis of effectiveness**
The primary health outcomes used were the number of days with dyspepsia symptoms, and whether patients and their GPs considered that they were free from symptoms at the 1-year follow-up. The authors stated that an intention to treat analysis was undertaken, but the 18 patients lost to follow-up were excluded.

**Effectiveness results**
In the first 3 months, the number of days without dyspepsia was 75.7 in the PPI group and 76.7 in the EGT group.

Between months 9 and 12, the number of days without dyspepsia was 76.8 in the PPI group and 77.1 in the EGT group.

At 1 year, 21% of patients in the PPI group and 24% of patients in the EGT group indicated that they were free of symptoms.

GPs assessed that 55% of patients in the PPI group and 61% in the EGT group were free from their predominant symptoms.

**Clinical conclusions**
The authors concluded that EGT was more clinically effective than PPI, but the difference was not statistically significant.

**Measure of benefits used in the economic analysis**
The health benefit used in the economic analysis was symptom-free days. These data were taken from the RCT.

**Direct costs**
The direct costs to the health care payer and the patient were included in this study. These covered the costs of diagnostic procedures, H. pylori tests, drugs, GP consultations and patient travel. The resource use data were collected prospectively from the patients included in the RCT. The unit costs of diagnostic procedures and tests were taken from the National Board of Health in Denmark. The unit costs of the drugs were taken from Laegemiddelfortegnelsen (Drug information, Denmark). The unit cost for transport was calculated using a government rate per km. The source of the unit cost of GP consultations was not reported. A breakdown of unit costs and resource use was given in the paper. The price year was 2006.

**Statistical analysis of costs**
The differences in costs were assessed using t-tests.

**Indirect Costs**
Productivity costs due to endoscopy, consultations and sick leave were included in this study. Only the costs of those in employment were considered. The resource use data were taken from the study outlined above. The unit costs were derived using mean national wages from Statbank Denmark. A breakdown of the unit costs and resource use was given in the paper. The price year was 2006.

**Currency**
Euros (EUR).
Sensitivity analysis
Non-parametric bootstrapping (10,000 iterations) was used to assess the impact of uncertainty in the data.

Estimated benefits used in the economic analysis
Over the year, there were 205.0 dyspepsia-free days in the PPI group compared with 207.6 in the EGT group.

Cost results
The total cost was EUR 488 in the PPI group compared with EUR 887 in the EGT group.

Synthesis of costs and benefits
The incremental cost effectiveness ratio was EUR 154 per day without dyspepsia (95% confidence interval: -989 to 1,012).

Bootstrapping indicated that the 95% confidence interval was from EUR -951 to EUR 1,071.

Authors' conclusions
Endoscopy-guided therapy (EGT) was slightly more clinically effective, but was not cost-effective.

CRD COMMENTARY - Selection of comparators
This study compared EGT and PPI for the treatment of adult patients diagnosed with dyspepsia. The authors did not clearly identify either treatment option as a comparator, but they noted that PPI was the usual treatment in a primary care setting. Before applying the results of this study, you should consider how these options compare with usual practice in your own setting.

Validity of estimate of measure of effectiveness
The clinical effectiveness estimate was taken from an RCT. The length of follow-up and loss to follow-up were reported, which suggest good internal validity. However, blinding was not performed and the method of randomisation was not reported. Since no sample size or power calculations were reported, it was not clear whether the study had sufficient power to identify a difference between the two groups. No details of the study sample were given in the paper, so it was unclear whether the sample was representative of the wider population with dyspepsia. An intention to treat analysis was undertaken. However, a small number of patients who were lost to follow-up were not included in this analysis.

Validity of estimate of measure of benefit
The measure of health benefit used in the study was taken directly from the RCT. It was not clear exactly what the measure of benefit in the cost-effectiveness ratio represented. It was the incremental proportion free of dyspeptic symptoms at 1 year.

Validity of estimate of costs
A societal perspective was adopted and all the relevant costs appear to have been included. The impact of uncertainty in the cost data was examined using appropriate multivariate sensitivity analyses. A breakdown of resource use and unit costs was provided in the paper. These factors add to the generalisability of the study findings. A clear price year was reported, which will enable future reflation exercises.

Other issues
The authors do not appear to have presented their results selectively and their conclusions reflected their analysis. They compared their findings with other similar studies and considered reasons for differences in the results. The authors suggested that the lack of a clinical difference between the two treatments might have been due to the inclusion of a high proportion of patients with functional dyspepsia which was difficult to treat.
Implications of the study
The authors recommend that EGT is not implemented in general practice.

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