The clinical and economic impact of competing management strategies for gastro-oesophageal reflex disease
Ofman J J, Dorn G H, Fennerty M B, Fass R

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 interventions examined in the study were two management strategies for patients with gastro-oesophageal reflex disease (GERD):

- the conventional 'step-up' management strategy consisting of incrementally more intensive medical therapy, beginning with the least costly and the least potent therapy (usually H2RA therapy) and reserving diagnostic testing for unresponsive patients or those presenting with symptoms indicating more serious pathologies; and

- the more innovative 'proton pump inhibitor test' approach, which included an initial proton pump inhibitor test (based on seven days of omeprazole as diagnostic test: 40 mg AM + 20 mg PM), followed by less intensive therapeutic trials in those testing positive ('step-down' approach) with sequentially invasive diagnostic testing if required.

Type of intervention
Treatment and diagnosis.

Economic study type
Cost-effectiveness analysis; Cost-utility analysis.

Study population
The study population comprised patients presenting to a primary care provider with typical GERD symptoms, such as heartburn and/or acid regurgitation. Patients with specific symptoms, such as dysphagia, weight-loss, anaemia, or extra-oesophageal manifestation of GERD (chest pain, cough, asthma, hoarseness) were not included in the analysis.

Setting
The setting was primary care. The economic study was carried out in the USA.

Dates to which data relate
Data on effectiveness and resource use were derived from studies published between 1981 and 1999. The price year was 1998.

Source of effectiveness data
Data on effectiveness were derived from a systematic review of the literature, augmented by authors’ assumptions.

Modelling
A decision analytic model was constructed to estimate costs and clinical outcomes of the two management strategies for GERD over a period of one year. A real-world assumption in the model was that physicians were not aware of
definitive diagnosis while patients progressed through the decision tree.

Outcomes assessed in the review
The outcomes estimated in the review were prevalence of GERD in patients with heartburn, spontaneous symptom resolution rate in patients with GERD, percentage of patients who achieved symptom relief who were successfully 'stepped-down' to less intensive therapy; sensitivity and specificity of proton pump inhibitor test, upper gastrointestinal endoscopy, and ambulatory 24 hour oesophageal monitoring; and symptom response to 'on-demand' H2Ras, regular dose of H2Ras, 'high-dose' of H2RA, regular dose of proton pump inhibitor, high-dose of proton pump inhibitor, and surgical intervention after failure of medical therapy. A range of utility weights for moderate heartburn was also estimated from a published study based on an expert panel.

Study designs and other criteria for inclusion in the review
The authors did not report the inclusion criteria used in the review but stated that some of the primary studies were randomised controlled studies. In particular, one study was a large placebo controlled, double blind trial.

Sources searched to identify primary studies
The MEDLINE and HEALTHSTAR databases were reviewed from 1980 in order to identify relevant English-language articles. Articles identified by reviewing selected bibliographies were also included in the review.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Thirty-one studies were used in the review to derive the effectiveness data.

Methods of combining primary studies
Primary studies were combined using narrative methods.

Investigation of differences between primary studies
Not stated.

Results of the review
The results of the review were as follows:

the prevalence of GERD in patients with heartburn was 80%.

the spontaneous symptom resolution rate in patients with GERD was 20%;

the percentage of patients who achieved symptom relief who were successfully 'stepped-down' to less intensive therapy was 50%;

the sensitivity (sens) and specificity (spec) of proton pump inhibitor test were 80% (sens) and 57% (spec);
the sensitivity and specificity of upper gastrointestinal endoscopy were 40% (sens) and 95% (spec);

the sensitivity and specificity of ambulatory 24 hour oesophageal monitoring were both 80%;

the symptom response was 30% for 'on-demand' H2Ras, 50% for regular dose of H2Ras, 50% for 'high-dose' of H2RA, 70% for regular dose of proton pump inhibitor, 80% for high-dose of proton pump inhibitor, and 90% for surgical intervention after failure of medical therapy; and

the range of utility weights for moderate heartburn was 0.82 to 0.95.

**Methods used to derive estimates of effectiveness**
The authors made some assumptions used in the decision model.

**Estimates of effectiveness and key assumptions**
The spontaneous symptom resolution rate in patients without GERD was 50%.

The percentage of people who failed medical therapy and who received endoscopy as the first diagnostic test was 85%.

The percentage of people who had positive proton pump inhibitor test and who were immediately 'stepped-down' to H2Ras was 100%.

**Measure of benefits used in the economic analysis**
The main outcome measure was symptom-free patients over the period of one year. Quality-adjusted life-years (QALYs) were also estimated on the basis of utility weights derived from a published study, as reported above.

**Direct costs**
No discounting was performed as costs were incurred over a period of one year. Unit costs were reported but quantities of resources were not. The health services included in the economic evaluation were procedure costs (upper gastrointestinal endoscopy, ambulatory 24 hour oesophageal pH monitoring, and laparoscopic Nissen fundoplication) office visit costs (specialty office visit, primary care office visit, and surgical evaluation), and drug costs (omeprazole and ranitidine). The cost/resource boundary adopted was that of the third-party payer. The estimation of costs was based on actual data as Medicare reimbursement costs and drug acquisition prices were used. The estimation of quantities of resources used was derived from published studies and assumptions. All costs were reported in 1998 values.

**Statistical analysis of costs**
Costs were treated deterministically.

**Indirect Costs**
Indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were conducted to assess the impact of variations in baseline cost and effectiveness estimates used in the decision model over values ranging from 0 to 100%. Two-way sensitivity analyses and threshold
analyses were also performed on some crucial variables.

Estimated benefits used in the economic analysis
The rate of symptom-free patients at one year was 75% with proton pump inhibitor test and 50% with traditional management. The proton pump inhibitor test led to a 0.01-0.05 gain in QALYs over the traditional management strategy.

Cost results
Total costs were $1,172 with the proton pump inhibitor test and $1,045 with traditional management. Thus the proton pump inhibitor test cost $127 more than the traditional approach.

Synthesis of costs and benefits
Average and incremental cost-effectiveness and cost-utility analyses were performed to combine costs and benefits of the two management strategies.

The average cost per symptom-free patient was $1,565 with proton pump inhibitor test and $2,089 with traditional management.

The resulting incremental cost per symptom-free patient with proton pump inhibitor test over traditional management was $510.

The incremental cost per QALY gained with proton pump inhibitor over traditional management therapy ranged from $2,822 to $10,160.

Sensitivity analyses showed that cost and sensitivity of pump proton inhibitor were the variables that most affected the base case results. In particular, the cost of pump proton inhibitor would need to fall below the threshold of $521 and its sensitivity below the value of 23% for the decision to switch and the traditional approach to become more cost-effective.

Authors’ conclusions
The authors concluded that the strategy based on proton pump inhibitor test for the management of patients with GERD proved to be a cost-effective option in comparison with the traditional approach, with a cost per QALY well below the threshold used to assess the cost-effectiveness of health interventions. The economic convenience of the proton pump inhibitor test was based on a reduced number of invasive diagnostic tests.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The two strategies were selected as they represented, respectively, the traditional approach and a newly available procedure for patients with GERD. You, as a user of this database, should decide whether they are widely implemented in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on data derived from a systematic review of the literature. Search sources were reported, but other details of methodology and conduct of the review were not given. Above all, inclusion criteria were not reported and evidence appears not to have been exclusively derived from randomised studies. Additionally, primary study estimates were combined using narrative methods and it was not clear whether the authors considered differences between the studies when estimating effectiveness. Effectiveness data were also based on authors’ assumptions. When results from the literature review were equivocal, conservative estimates favouring the traditional approach were applied. The authors performed sensitivity analyses to investigate the robustness of the study findings to variations in most of the model inputs derived from the literature and in some assumptions used in the analysis.
Validity of estimate of measure of benefit
The proportion of symptom-free patients and QALYs were selected as benefit measures in the economic analysis. Although the use of QALYs enhances the comparability of the intervention under study with those of other strategies implemented in the health care system, utility weights were based on a panel of experts and were not investigated in the sensitivity analysis.

Validity of estimate of costs
The analysis of costs was conducted from the perspective of the third-party payer and it appears that all relevant categories of costs were included in the study. Costs were somewhat specific to the study setting, but both unit costs and price year were reported, thus making the reproducibility of the economic analysis in other settings easier. Costs were treated deterministically in the base case, but sensitivity analyses were conducted on cost data. A cost-to-charge ratio was employed to convert charges into costs in the Medicare system.

Other issues
The authors did not compare their findings with those from other studies, and commented that the generalisability of the study findings to other settings could be limited by differences in clinical patterns when managing patients with GERD.

Implications of the study
The authors recommend that the proton pump inhibitor test should be implemented for the management of patients with GERD as it achieved rapid symptom control and avoided unnecessary invasive diagnostic tests at an acceptable cost from the perspective of the third-party payer. These results should be confirmed in a prospective randomised trial.

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