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 study compared surgical and medical therapy in patients with gastroesophageal reflux disease (GERD) and severe oesophagitis. The medical strategy involved the use of the proton-pump inhibitor (PPI) omeprazole. All patients receiving the medical strategy initially received 40 mg/day, although the dosage, which varied between 20 and 60 mg/day, was dependent on how symptoms responded over time. The surgical strategy involved the use of laparoscopic Nissen fundoplication (LNF).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised a hypothetical 45-year old patient with moderate to severe oesophagitis secondary to GERD, and no significant co-morbid conditions.

Setting
The setting was secondary care. The economic study was conducted in Alabama and Texas, USA.

Dates to which data relate
The effectiveness and resource use data were obtained from studies published between 1994 and 2003. The price year was 2002.

Source of effectiveness data
The effectiveness data were derived from a review of published studies.

Modelling
A decision tree analysis was undertaken, based on evidence from trials and assumptions, to calculate the costs and benefits of the two strategies. A two-compartment simulation model, which comprised a "healing phase" and a "maintenance phase", was designed. The "healing phase" was designed as a standard decision tree and modelled the costs and effectiveness of each treatment strategy in rendering a patient asymptomatic from GERD symptoms. The "maintenance phase" was designed as a Markov cycle tree. Patients could reside in a number of mutually exclusive health states dependent on the medical or surgical management strategy. These states included medical therapy with controlled symptoms, medical therapy with uncontrolled symptoms, postsurgery with controlled symptoms, postsurgery with uncontrolled symptoms, and death.
Outcomes assessed in the review
The main outcomes assessed were the transition probabilities for the healing and maintenance phases of the model. These included:

- the surgical death rate,
- the rate of recurrent symptoms (per year),
- the LNF failure rate (after 5 years),
- the redo LNF failure rate (after 5 years),
- the proportion of patients in whom medical therapy was initiated after surgery, and
- the failure rates of low-dose (20 mg/day) and high-dose (40 mg/day) omeprazole after 5 years.

Study designs and other criteria for inclusion in the review
None stated.

Sources searched to identify primary studies
MEDLINE was searched for relevant studies. No other information on the search strategy was provided.

Criteria used to ensure the validity of primary studies
None stated.

Methods used to judge relevance and validity, and for extracting data
None stated.

Number of primary studies included
Nine primary studies were used to derive effectiveness data.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The surgical failure rate after 5 years was 0.05 (range: 0.025 - 0.25).
The redo LNF failure rate after 5 years was 0.05 (range: 0.025 - 0.20).
The surgical death rate was 0 (range: 0.0 - 0.01)
The rate of recurrent symptoms (per year) was 0.062 (range: 0.05 - 0.074).
The proportion of symptomatic patients that received PPI therapy was 0.52 (range: 0.25 - 0.75).
The low-dose PPI failure rate after 5 years was 0.47 (range: 0.24 - 0.7).

The high-dose PPI failure rate after 5 years was 0.1125.

**Measure of benefits used in the economic analysis**

The benefit measure was the quality-adjusted life-years (QALYs). The utility estimates were derived from published studies and authors’ assumptions. The published studies evaluated the long-term health status in individuals who had undergone medical versus surgical therapy. Utilities were derived by incorporating scores from Short Form 12 (SF-12) and Short-Form 36 (SF-36). Authors’ assumptions were the basis for the estimate of the utility of surgery over the short term, but no further information was provided.

**Direct costs**

All future costs were discounted at a rate of 3% per year. Resource use data were not provided. The cost boundary adopted was that of the hospital. Included in the analysis were the costs of LNF, open fundoplication, omeprazole (annual; based on 20 mg/day), H2-receptor antagonists (annual), the PH study/manometry, upper endoscopy, and an office visit. The costs were based on average Medicare reimbursement rates at the University of Alabama. Drug costs represented the average wholesale price. The average costs were reported and the price year was 2002.

**Statistical analysis of costs**

The costs were treated stochastically.

**Indirect Costs**

No indirect costs were included in the analysis.

**Currency**

US dollars ($).

**Sensitivity analysis**

A one-way sensitivity analysis was undertaken on the three variables found to be the most sensitive in the original model. More specifically, the length of follow-up, surgical success and utility estimates. The cost of PPI, medication and the therapeutic success of medication were also varied. A two-way sensitivity analysis, which combined variations in the length of follow-up with utilities associated with surgical success, was also undertaken.

**Estimated benefits used in the economic analysis**

After 10 years, the undiscounted analysis demonstrated that medical therapy was associated with a gain of 5.246 QALYs per patient, whereas surgery was associated with a gain of 5.232 QALYs per patient. The corresponding discounted analysis demonstrated that medical therapy was associated with a gain of 4.59 QALYs per patient, whilst surgery yielded a gain of 4.55 QALYs per patient.

**Cost results**

The surgical strategy was more expensive than medical therapy over a 10-year period.

In the undiscounted analysis, the average cost per patient was $10,178 for medical therapy and $12,793 for surgery.

In the discounted analysis, the average cost per patient was $8,798 for medical therapy and $10,475 for surgery.
Synthesis of costs and benefits
The authors did not combine the costs and benefits since medical therapy was the dominant strategy. Medical therapy was more effective and less expensive than surgery (4.59 versus 4.55 QALYs per patient and $8,798 versus $10,475 per patient, respectively).

In the sensitivity analysis, varying the length of follow-up affected the results. With a time period of less than 3.5 years, the surgical strategy was associated with a higher QALY gain per patient than medical therapy (1.56 versus 1.53 QALYs). At 3.6 years the QALYs associated with each strategy were equal. The analysis demonstrated that medical therapy was consistently more effective than surgery over a follow-up period greater than 3.6 years. Medical therapy remained the least expensive strategy up to 27 years, although over time the cost differential between the two strategies decreased.

The model was also sensitive to the utility associated with the health state of recurrent GERD symptoms after surgery. At a value of 0.7 (baseline 0.62), the surgical strategy became more effective than the medical strategy (4.65 versus 4.59 QALYs gained per patient). The resulting marginal cost-effectiveness ratio of the surgical strategy compared with medical therapy was $59,980 per QALY.

The model was also sensitive to the utility of long-term medication usage. When this value reached 0.58 (baseline 0.64) the surgical strategy became more effective than medical therapy, with a resulting marginal cost-effectiveness ratio of $50,500 per QALY.

The two-way sensitivity analysis, which linked length of follow-up with utility value associated with surgical success, demonstrated that the surgical strategy was more effective between 2.5 and 6 years of simulation.

Varying the cost of PPI to reflect the average cost associated with recently available generic preparations ($250 per year) increased the cost differential in favour of medical therapy from $1,677 (baseline) to $6,762.

Authors' conclusions
At a time horizon of 10 years, the medical treatment of patients with moderate to severe GERD dominated initial fundoplication, because medical therapy was both less expensive and more effective in improving health-related quality of life. The authors also concluded that the study demonstrated the value of using primary data collection and the results of published studies to enhance the accuracy and generalisability of a cost-utility analysis.

CRD COMMENTARY - Selection of comparators
The comparator was chosen to reflect current practice in the authors' setting. The reader should consider whether this comparator reflects current practice in their own setting.

Validity of estimate of measure of effectiveness
There was little information on how the review of the literature was conducted. The authors did not state that a systematic review had been undertaken, and it was unclear whether the review had been conducted systematically to identify relevant research and minimise bias. Further, it was unclear how data from the available studies were combined to derive estimates of effectiveness, and whether the authors considered the impact of differences between the primary studies when estimating effectiveness. Appropriate sensitivity analyses, however, were included and this will enhance the internal and external validity of the results.

Validity of estimate of measure of benefit
The measure of benefit used was the QALYs. The utilities were derived from published studies and authors' assumptions. The authors acknowledged that the derivation of utilities by incorporating scores from the SF-12 and SF-36 were not ideal and that the use of preference-based measures, such as standard gamble and time trade-off, would have been more appropriate. In addition, the authors acknowledged that the utilities associated with the surgical strategy, were derived from patients who had undergone open fundoplication, rather than LNF. The validity of the
estimate of the utility of surgery over the short term is questionable since it was based on authors' assumptions, with no further information being provided.

Validity of estimate of costs
The authors limited their analysis to direct costs. The categories of cost included in the analysis were relevant to the hospital perspective adopted by the study. The costs and the quantities were not reported separately. The prices were derived from a published source and were based on average Medicare reimbursement rates at the authors' own setting, rather than actual costs. A sensitivity analysis of the price of PPI was conducted. The costs were discounted, which was appropriate given the long time horizon of the study. The date to which the costs referred was reported.

Other issues
Although the authors stated that there was a lack of evidence on the long-term outcomes associated with medical and surgical therapy for GERD, they did compare their results with the findings of other studies. The issue of generalisability to other settings or older or younger patients was not addressed. The authors do not appear to have presented their results selectively. The study aimed to compare the use of surgical and medical therapy for patients with GERD and severe oesophagitis and this was reflected in the conclusions. The main limitations of the study were the lack of information surrounding the derivation of the estimates of effectiveness, and the sensitivity of a number of the components of the model.

Implications of the study
Following this study, the authors advocated the use of medical therapy for patients with GERD and severe oesophagitis over a 10-year time period. The previous study had advocated its use for only a 5-year period.

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Other publications of related interest

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