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
Study compares laparoscopic Nissen fundoplication (LFN) technique with a drug (omeprazole) in the treatment of patients with gastroesophageal reflux disease (GERD).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
A hypothetical cohort of 10,000 patients were followed for 5 years. The study focused on a 45-year-old male with moderate to severe esophagitis caused by GERD with no significant co-morbid conditions.

Setting
Hospital and the community. The economic study was carried out in Alabama, USA.

Dates to which data relate
Effectiveness data were derived from studies conducted between 1988 and 1994. Costs were derived from data published in 1995.

Source of effectiveness data
Effectiveness data were derived from a review of the literature and a panel of experts. The panel consisted of three practicing gastroenterologists, one practicing general internist, and a clinical psychologist and obtained estimates for utilities and probabilities.

Modelling
A Markov tree simulation model was used to compare the two strategies in terms of cost and Quality-Adjusted Life Years (QALYs). Patients were followed for 5 years, with each year divided into 3-month periods for a total of 20 cycles. A decision tree (semi-Markov tree) was also used to represent healing and maintenance, which relates to the two strategies above.

Outcomes assessed in the review
The outcomes assessed in the review were the probabilities of LFN failure (rate, year), surgical death, OME healing (short), OME healing (mid), OME healing (long), OME healing (ultralong), OME healing (high), low OME
maintenance (5 year), high OME maintenance (year); Quality of life for surgery (short term), and OME chronic use.

**Study designs and other criteria for inclusion in the review**
Not stated.

**Sources searched to identify primary studies**
Not stated.

**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**
The review included approximately 12 studies.

**Methods of combining primary studies**
Not stated.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
The probabilities (range in parentheses) derived were:

- LNF failure (rate, year) = 0.01 (0.005-0.04),
- surgical death = 0 (0.0-0.01),
- OME healing (short) = 0.64 (0.5 - 0.8),
- OME healing (mid) = 0.18,
- OME healing (long) = 0.13,
- OME healing (ultralong) = 0.04,
- OME healing (high) = 0.01,
- low OME maintenance (5 year) = 0.47 (0.24 - 0.7),
- high OME maintenance (year) = 0.9775,
- quality of life for surgery (short term) = 0.5,
- OME chronic use = 1.0 (0.98 - 1.0).
These data were used as input parameters to the Markov model.

**Methods used to derive estimates of effectiveness**
The panel of experts used a modified Delphi technique to obtain estimates for utilities and probabilities not available from the literature.

**Estimates of effectiveness and key assumptions**
The probabilities derived were:

- redo LNF rate was (range in parenthesis) 0.01 (0.005-0.004),
- quality of life for reflux symptoms (short/long term) = 0.82 (0.5-0.95),
- quality of life for surgery (long term) = 1.0 (0.9-1.0).

These data were also used as input parameters to the Markov model.

**Measure of benefits used in the economic analysis**
The benefit measure was the QALY. A decision tree was used to highlight the healing and maintenance compartments. The authors used a Markov model to extrapolate outcome results from one duration (5 years) to another (10 years) for surgical and medical management strategies. The simulation model used accrued utility (quality of life) for each patient in a given health state.

**Direct costs**
Overall costs associated with the healing and maintenance were calculated using reimbursement figures from Blue Cross/Blue Shield of Alabama for medications, office visits and procedures. To obtain costs of LNF, average wholesale prices for medications and published charge estimates were used. In the healing phase costs were based on initial endoscopy for diagnosis and monthly omeprazole use as determined by the probabilities of being healed after 30-120 days on 40 mg/day of omeprazole. The same procedure was used to calculate costs for both medical and surgical strategy. A 3% discount rate was used.

**Statistical analysis of costs**
The authors did treat the costs as stochastic.

**Indirect Costs**
These were not considered as the study was carried out from a third party payer perspective (Blue Cross and Blue Shield)

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analysis was carried out with the simulation model. This was done by varying the ages to include 35 and 55 year old males in addition to the 45 year old. The number of cycles was varied to include 5 years and 10 years, to understand better the trade off between upfront surgical costs and length of follow-up. Both one-way and two-way sensitivity analyses were carried out.
Estimated benefits used in the economic analysis
The number of QALYs per patient slightly favoured the LNF strategy compared with an up-front PPI (4.334 versus 4.332), an improvement of 18 hours over a 5 year period. Both strategies showed similar QALYs at 35 years (4.51) and 55 years (4.27).

Cost results
The cost per patient when using omeprazole first was $6,043 compared with $9,426 if surgery was considered first (a 36% saving).

Synthesis of costs and benefits
In the base-case analysis, the PPI first strategy was as effective and less expensive than LNF strategy. The average cost-effectiveness (cost per QALY) favoured PPI over the LNF strategy by $788 (1,398/QALY versus 2,186/QALY, respectively). Varying the starting age of the cohort did not change the main effectiveness results, with both strategies showing similar QALYs at 35 years (4.51) and 55 years (4.27). Although PPIs remained the preferred strategy in terms of cost, the percentage difference between PPI and LNF changes slightly for the different age cohorts: for the 35 year cohort the reduction in cost was 35% while for the 55 year cohort the reduction was 38% favouring PPI over LNF.

Authors' conclusions
Medical therapy is the preferred treatment strategy for most severe erosive esophagitis. Individuals with a long life expectancy are good candidates for LNF if postoperative morbidity is low and GERD symptoms remain abated for many years.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of comparators was clearly stated.

Validity of estimate of measure of benefit
The benefit measure was derived from a review of the literature and estimates based on expert opinion. It is not clear from the study whether or not the review of literature was systematic, although the authors did carry out sensitivity analyses to test the robustness of the results over plausible ranges.

Validity of estimate of costs
Detail was rather lacking as far as costs were concerned and it was stated that average costs and information from the third party payer were used.

Other issues
The authors' conclusions were justified based on the fact that they used a simulation model. The study was more focused on the clinical effectiveness of the intervention and more detail could have been given on the cost analysis. The authors did however indicate the areas in which the study did not provide sufficient information.

Implications of the study
The lack of existing information implied that not much research had been done in this area, especially in regard to the costs therefore this study raises many questions and could be used as a baseline study.

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None stated.

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