Randomized clinical trial and follow-up study of cost-effectiveness of laparoscopic versus conventional Nissen fundoplication


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 laparoscopic Nissen fundoplication (NF) versus conventional NF for the treatment of gastro-oesophageal reflux disease (GORD).

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised the patient populations (n=224) included in a published randomised controlled trial (RCT) (Bais et al. 2000, see ‘Other Publications of Related Interest’ below for bibliographic details) and a follow-up cohort study (reference not given). Patients in the RCT (n=103) either underwent conventional NF or laparoscopic NF. All patients in the follow-up study (n=121) were operated on using laparoscopic NF. The characteristics of the patients were reported in the current study.

Setting
A secondary care provider delivered the interventions in an inpatient setting. The economic study was set in the Netherlands.

Dates to which data relate
The effectiveness data used to populate the model came from an RCT published in 2000 and from a consecutive cohort study (which was not referenced). The price year was not explicitly reported, but it appears to have been 2004.

Source of effectiveness data
The clinical parameters in the model that were associated with the procedures performed included:

the probability of death,
the probability of complications necessitating re-operation,
the probability of success after re-operation,
the probability of complications manageable with non-surgical treatment,
the probability of no complications, and
the probability of success without complications.

Modelling
A decision tree was constructed to model the treatment pathways, which ended in mortality, treatment success or treatment failure. The time horizon of the model was 1 year. The probabilities used to populate the model were reported.

Sources searched to identify primary studies
The parameters for the conventional treatment were derived from an RCT (Bais et al. 2000) and a follow-up cohort study. The parameters for the laparoscopic treatment were taken from a cohort study.

Methods used to judge relevance and validity, and for extracting data
There was no systematic review of the literature. The studies selected were recent and the setting, populations and interventions were appropriate. Further, economic measurements were made alongside the studies. It was only towards the end of the paper that the authors justified using data from the cohort study rather than the RCT to inform the model parameters for the intervention. The justification was that the surgeons were more experienced when the cohort study was performed than when the RCT was performed.

Measure of benefits used in the economic analysis
The measure of benefit used was the quality-adjusted life-years (QALYs). Utility values were estimated using a visual analogue scale (VAS, 0 - 100). These were measured before surgery and at 3, 6, 9 and 12 months after surgery, in all patients according to success or failure of each treatment within each study. The QALYs were then calculated by estimating the area under the curve.

Direct costs
Health service costs were included in the analysis. These were for pre- and postoperative visits, diagnostics and screening, operation and re-operation (including cost of personnel, materials, depreciation and interest costs of equipment, overhead costs), hospitalisation, additional procedures and consultations, and in-hospital and after discharge complications. Resource use was determined using a micro costing methodology, on clinical studies identified from the literature. The costs were reported as the mean cost per patient for each cost category. The price year was not explicitly reported.

Statistical analysis of costs
The cost data appear to have been treated deterministically.

Indirect Costs
The costs for productivity losses were estimated using the friction cost method and were based on the assumption that productivity losses will have a limited duration, that is, the time needed for the company to adapt to the patient’s absence (the friction period). The friction period was estimated to be 123 days (2003 - 2004 data). The mean costs and quantities per patient were reported. Friction costs were obtained from an official source published in 2000. The price year was not explicitly reported.

Currency
Euros (EUR).

Sensitivity analysis
Parameter uncertainty was investigated through numerous one-way sensitivity analyses. The parameters investigated and the ranges used were reported. The ranges were obtained from published studies. In addition, two-way sensitivity analyses were performed on varying combinations of specific parameters (the total cost of the operation, duration of sick leave, and re-operation rate).

**Estimated benefits used in the economic analysis**

For the patient population in the RCT, the mean number of QALYs after 12 months was 0.63 for the laparoscopic NF group and 0.59 for the conventional NF group. For the patient population from the cohort study (laparoscopic NF), the mean number of QALYs at the end of the first year after surgery was 0.66.

The authors reported that the differences in quality of life between studies or individual groups were not statistically significant.

**Cost results**

The mean total costs per patient (including productivity losses) at the end of the first year were:

- EUR 15,447 for patients who underwent laparoscopic NF in the RCT,
- EUR 14,342 for patients who underwent laparoscopic NF in the cohort study, and
- EUR 13,940 for patients who underwent conventional NF in the RCT.

**Synthesis of costs and benefits**

An incremental analysis was performed.

The incremental cost-utility ratio for laparoscopic LNF in the cohort study compared with conventional NF in the RCT was EUR 40,254 per QALY gained.

The sensitivity analyses demonstrated that the results were sensitive to variations in the total cost of laparoscopic NF, the re-operation rate after laparoscopic NF and the mean duration of sick leave. When changing these parameters for the laparoscopic NF group while holding them constant for the conventional NF group, laparoscopic NF became less costly than conventional NF.

The two-way sensitivity analyses demonstrated that, when the total costs of laparoscopic NF were less than EUR 950 and the duration of sick leave after laparoscopic NF was less than 52.8 days (baseline 67.2 to 71.8 days), laparoscopy could become cost-saving.

**Authors’ conclusions**

When accounting for re-interventions, clinical outcomes at 1 year after surgery were similar for conventional Nissen fundoplication (NF) and laparoscopic NF, while laparoscopic NF proved to be more costly.

**CRD COMMENTARY - Selection of comparators**

Laparoscopic NF would appear to be one of the main treatment options for GORD that seem to substitute for the former routine surgical treatment, conventional NF. You should decide if this represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**

The authors combined data from a published RCT and an unpublished cohort study. They did not justify using the cohort study, rather than the RCT, to inform the intervention parameters for the cost-effectiveness analysis until the 'Discussion' section of the paper. The authors did not explicitly justify their selection of the primary studies. However,
the appropriate setting, sample size, interventions and economic measurements were likely reasons.

**Validity of estimate of measure of benefit**
The authors used QALYs as the measure of benefit in the economic analysis. The methods used to estimate the utility weights were described.

**Validity of estimate of costs**
The analysis of the costs was performed from a societal perspective. As such, all the relevant categories of costs appear to have been included in the analysis. It was reported that where cost data were not available, charges were used to proxy prices. This was not appropriate given the societal perspective of the study, as prices do not reflect true opportunity costs. The price year was not explicitly reported and, although the cost data related to different dates, adjustments for inflation were not reported. Resource use was measured using microcosting methodology, consequently the costs and the quantities were not reported separately. Uncertainty surrounding the cost estimates was investigated in sensitivity analyses.

**Other issues**
The authors mentioned previous studies, alluding to methodological shortfalls that preclude direct comparisons of the results. The issue of the generalisability of the results to other settings was not directly addressed. The authors reported only limited results of their sensitivity analyses, and they did not justify why these particular results had been selected for reporting. The study considered patients with GORD who underwent either laparoscopic or conventional NF, and this was reflected in the authors’ conclusions. The authors did not report or discuss any limitations to their study.

**Implications of the study**
The authors did not make explicit recommendations for changes in policy or practice, or for further research.

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None stated.

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**Other publications of related interest**
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Subject indexing assigned by NLM

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