Laparoscopic Nissen fundoplication: cost, morbidity, and outcome compared with open surgery

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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
Laparoscopic Nissen fundoplication, alone or in combination with other surgical procedures, for the treatment of reflux oesophagitis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing Nissen fundoplication.

Setting
Hospital. The economic study was carried out in Utah, USA.

Dates to which data relate
The resource use data were recorded from January 1990 to December 1993. The price dates were not stated, but would appear to be those prevailing at the time of data recording.

Source of effectiveness data
Based on opinion.

Study sample
The study included 232 patients, who underwent NFP over the study period. 72 (31%) patients underwent Lap NFP and 160 (69%) underwent open NFP. 13 staff surgeons performed the procedures. Power calculations were not used to determine sample size.

Study design
The study was a retrospective cohort study, based at a single centre.

Analysis of effectiveness
The analysis of the retrospective cohort study was based on a complete set of computerised patient records. The primary health outcome used for the retrospective analysis was inpatient morbidity, measured by perioperative
complications. The groups were shown to be comparable in terms of demographic, but not of clinical, characteristics.

**Effectiveness results**
In the retrospective analysis, the complication rate was 11.1% in the lap NFP group and 37.5% in the open NFP group (p<0.0001).

**Clinical conclusions**
Open Nissen fundoplication was associated with significantly greater in-hospital morbidity than was the laparoscopic procedure.

**Methods used to derive estimates of effectiveness**
Estimates of effectiveness were based on the authors' assumptions.

**Estimates of effectiveness and key assumptions**
The authors implicitly assumed that the effectiveness was at least equivalent to that of the open NFP group. In-hospital perioperative complications were reported, although length of stay varied significantly between the groups. The complication rate was 11.1% in the lap NFP group and 37.5% in the open NFP group (p<0.0001).

**Measure of benefits used in the economic analysis**
The measure of benefit included number of days to return to general health, number of days to return to work, number of days to return to moderate activity and number and type of postoperative complications. The values for these measures were obtained from a postal questionnaire, sent to 187 patients, who had undergone lap or open NFP at the study hospital. The link between those patients receiving the questionnaire and those in the cost analysis is unclear. The proportion of surveys sent to each group was not specified. The overall response rate was 52% and loss to follow up for reporting of complications was 70%.

**Direct costs**
Some quantities were analysed separately. Costs were measured from the perspective of the hospital and included operating room costs, the cost of NFP (excluding surgeons' fees) and the cost of additional simultaneous surgical procedures. The cost of complications was not included in the analysis. Resource use data and charges were taken from the hospital's computerised files and related to the period from January 1990 to December 1993. The price dates were not reported. Costs were not discounted.

**Statistical analysis of costs**
Means were reported and comparisons were made by the student's t-test.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis was not performed.
Estimated benefits used in the economic analysis
The average number of days to return to general health was 16 days in the lap NFP group and 43 days in the open NFP group, (p<0.005). The average number of days to return to work was 19 days in the lap NFP group and 34 days the open NFP group, (p<0.01). The average number of days to return to moderate activity was 5 days in the lap NFP group and 14 days the open NFP group, (p<0.001). Of those completing the complications section of the survey (Lap NFP, n=28, Open NFP, n=30), 77% of the open NFP subgroup reported postoperative complications, compared to 29% in the LAP subgroup (p<0.001).

Cost results
In the lap NFP group, the average hospital cost was $4,331 and in the open NFP group it was $8,616 (p<0.001). The OR cost for the lap group was $2,324 and for the open group was $1,287 (p<0.001). The total average per patient cost was therefore $6,655 in the lap NFP group and $9,903 for the open NFP group. The statistical significance of this result was not reported.

Synthesis of costs and benefits
The laparoscopic Nissen fundoplication strategy was shown to be the optimal strategy, therefore no synthesis was necessary.

Authors' conclusions
"The results of this study confirm that patients benefit from laparoscopic Nissen fundoplication with shorter length of stay, overall reduced hospital costs, and decreased in-hospital complications. Patients undergoing laparoscopic Nissen fundoplication subjectively feel better, are able to return to normal activity sooner, and have a lower perceived complication rate after undergoing laparoscopic Nissen fundoplication."

CRD Commentary
The procedures' effectiveness was not demonstrated, although perioperative complications were reported. Instead, the authors implicitly assumed that the laparoscopic procedure would be at least equivalent in its effectiveness, relative to open NFP. The measures of benefit were based on a sample with a low response rate, which may have introduced biases into the results. The link between survey respondents and patients analysed in the cost study was not stated. Details about the way the choice of surgical procedure was made were not reported. Since this decision was guided by the individual surgeon's preference, there would seem to be important potential biases that could not be controlled for with a retrospective analysis of medical and billing records. Moreover, the groups were not shown to be comparable in terms of clinical characteristics, and it is possible that the lower complication rate and superior health benefits observed are attributable to patients' health states before surgery. It is also possible that those surgeons performing laparoscopy were more skilled than were those undertaking open surgery. These factors limit the interpretation of the results. The cost analysis was limited in coverage and did not include the cost of informal care, a higher level of which might have been required for those in the laparoscopic group. The costs of the laparoscopic option may therefore have been underestimated. The cost of complications was not included in the analysis, which may have underestimated the cost of open NFP. The authors' conclusions regarding cost savings are therefore uncertain.

Implications of the study
A randomised, controlled trial, comparing the effectiveness of the two procedures and including the cost of informal care and of complications, would give a more reliable assessment of the cost-effectiveness of laparoscopic Nissen fundoplication.

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