Laparoscopic Nissen fundoplication: a curative, safe, and cost-effective procedure for complicated gastroesophageal reflux disease


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 for complicated gastroesophageal reflux disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Men and women aged 32-77 years, suffering from intractable disabling symptoms.

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

Dates to which data relate
Effectiveness data were collected during the period October 1992 to January 1994. The cost data source was not stated. The price year was not stated.

Source of effectiveness data
The evidence for effectiveness was derived from a single study.

Link between effectiveness and cost data
It was not stated whether the costing was undertaken on the same patient sample as that used in the effectiveness study. Nor was it stated whether the costing information was gathered prospectively or retrospectively.

Study sample
52 patients were studied with gravity ratings from 1 (minimal inflammation) to grade 4 (associated stricture). Of these, 49 cases were completed laparoscopically. 3 patients were allocated to the open technique (control) group because they were not suitable for laparoscopy treatment. No power calculations were stated in determining the sample size. Many patients were excluded from surgical consideration (no figures stated) due to a failure to meet intractability criteria or due to gastroesophageal reflux disease complications, whilst 2 were eliminated following manometry and ph testing.

Study design
The study was a non-randomised trial with concurrent controls. The duration of follow up was up to 14 months after treatment. No loss to follow up was reported.

**Analysis of effectiveness**
The primary health outcomes used were control of symptoms, level of medical management, complications and return to a normal lifestyle.

**Effectiveness results**
Three patients (5.7%) were converted to the open procedure because of unforeseen complications. 90% of those cured returned to preoperative activities: 10% had significant improvements. Two patients (3.8%) suffered major complications whilst nearly all patients reported at least one minor side-effect, although none were reported after 2 months. One side effect of the procedure, long term gassiness, was reported by 12 individuals (25%) from the laparoscopic surgery group. The mean hospital stay periods for the laparoscopic and open groups were 2.3 and 8.3 days respectively. The mean return to work periods for the laparoscopic and open groups were 15 and 42 days respectively. No confidence intervals were stated.

**Clinical conclusions**
Laparoscopic Nissen fundoplication was effective and leaves the patient in less pain than does the open technique.

**Measure of benefits used in the economic analysis**
Control of symptoms, complications, reduced hospital stay and return to work time periods were measured as health benefits.

**Direct costs**
No discounting or prices were stated. The mean hospital charge for both treatment groups was included although the source was not specified.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
Three patients (5.7%) were converted to the open procedure because of unforeseen complications. 90% of those cured returned to preoperative activities: 10% had significant improvements. Two patients (3.8%) suffered major complications whilst nearly all patients reported at least one minor side-effect, although none were reported after 2 months. One side effect of the procedure, long term gassiness, was reported by 12 individuals (25%) of the laparoscopic surgery group. The mean hospital stay periods for the laparoscopic and open groups were 2.3 and 8.3 days respectively. The mean return to work periods for the laparoscopic and open groups were 15 and 42 days respectively.

**Cost results**
The mean hospital charges for the laparoscopic and open groups were $6870 and $11990 respectively.

**Synthesis of costs and benefits**
The laparoscopic Nissen fundoplication treatment was the dominant strategy.

**Authors' conclusions**
Laparoscopic Nissen fundoplication was as safe and effective as the open technique whilst also reducing hospital costs, in-patient time, and employment.

**CRD Commentary**
Power calculations were not used to determine sample sizes: the control group had only 3 subjects receiving open surgery, over 16 times smaller than the laparoscopic group (49). Treatments were not allocated randomly and therefore effectiveness data may involve bias. No discounting or sensitivity analysis was performed. 28% of those undergoing laparoscopic surgery experienced complications, and extra expense incurred as a result was not accounted for. Inadequate (direct) cost descriptions were given, i.e. individual cost items, dates, etc. It is not clear to what the mean hospital charges refer, for example, does the mean charge for the laparoscopic group include the costs of conversion to open surgery for the 3 patients for whom this was required?

**Implications of the study**
A well designed randomised control trial comparing these two techniques is required.

**Source of funding**
None stated.

**Bibliographic details**

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