Randomized clinical trial of robot-assisted versus laparoscopic Nissen fundoplication
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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
Robot-assisted surgery was compared with traditional laparoscopic Nissen fundoplication surgery for patients with gastro-oesophageal reflux disease (GORD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with GORD who were scheduled for laparoscopic antireflux surgery according to the criteria of Hinder et al., and an American Society of Anaesthesiologists (ASA) score of I-II. Exclusion criteria included giant hiatal hernia (larger than 6 cm on preoperative barium meal), ASA score of III-IV, previous upper abdominal surgery and contraindications to pneumoperitoneum.

Setting
The setting was secondary care. The economic study was carried out in Italy.

Dates to which data relate
The effectiveness and resource use data were obtained from February 2002 to February 2004. The price year was not stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Although power calculations were carried out, they were not reported in the present paper. The authors reported that the required sample size was based on two assumptions: a 30% difference in costs between robot-assisted and standard laparoscopic fundoplication, and a 20% difference in skin-to-skin and total operating times. The sample was selected from patients with GORD who underwent laparoscopic fundoplication. Of the 88 patients undergoing surgery, 38 were excluded for various reasons. The total number of participants was thus 50, of whom 25 were in the study group (19 men) and 25 in the control group (18 men). The mean age of the participants was 43.0 years in the study group and 46.3
years in the control group.

**Study design**
The study was a single-centre, randomised controlled trial. Randomisation was performed on the day before surgery by means of sealed envelopes containing computer-generated random numbers. The follow-up period was 12 months.

**Analysis of effectiveness**
The basis of the clinical analysis was intention to treat. The primary health outcomes were skin-to-skin and total operating times. Patients also completed the Gastro-oesophageal Reflux Health-Related Quality of Life scale (GORD-HRQOL) questionnaire at each follow-up interview (3, 6 and 12 months after surgery). In addition, hospital stay and postoperative complications were compared between the two groups. The groups were shown to be comparable at baseline.

**Effectiveness results**
The average operating time was 131.3 minutes (range: 90 to 162) for robot-assisted surgery and 91.1 minutes (range: 72 to 106) for traditional surgery. The difference was statistically significant, (p<0.001).

The average skin-to-skin time was 78 minutes (range: 48 to 104) for robot-assisted surgery and 63.5 minutes (range: 46 to 84) for traditional surgery. The difference was statistically significant, (p=0.001).

There were no clinical differences between the two groups in the GORD-HRQOL questionnaire at 3, 6 and 12 months (actual scores were not reported).

There were no postoperative complications with either approach.

Mean hospital stay was 2.9 days (range: 2 to 6) in the standard laparoscopy group and 3.0 days (range: 2 to 7) in the robot-assisted group, (p=0.588).

**Clinical conclusions**
The authors concluded that there were no significant differences in clinical, endoscopic and functional outcomes between groups. However, robot-assisted surgery was associated with longer operating times than traditional surgery.

**Measure of benefits used in the economic analysis**
No measure of benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

**Direct costs**
Discounting was not relevant as the costs were incurred during less than 12 months. The costs were limited to those associated with the operating room (nursing and technical staff, surgical devices and maintenance), surgical tools and hospital stay. The source and dates of the cost data were not reported. The costs and the quantities were not reported separately. The price year was also not reported.

**Statistical analysis of costs**
The costs were compared using Student’s t-test or the Mann-Whitney U-test, depending on the distribution.

**Indirect Costs**
Indirect costs were not included in the study.
Currency
Euros (EUR).

Sensitivity analysis
A sensitivity analysis was not undertaken.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average cost was EUR 3,157 for robot-assisted surgery versus EUR 1,527 for laparoscopic surgery, (p<0.001).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The current robotic systems are not of significant benefit to routine surgical practice as they prolong operating time and increase the costs.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparators was clear. Robotic technology has recently been introduced into laparoscopic clinical practice with the aim of improving surgical performance. This was compared with traditional surgical methods.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was a single study. The study design, a randomised controlled trial, was appropriate for the hypothesis. Power calculations were performed although they were not reported. The authors did not clearly state whether the study sample was representative of the study population. The patient groups were shown to be similar at baseline, with no significantly different characteristics. There were no other sources of effectiveness data.

Validity of estimate of measure of benefit
No summary benefit was used so, in effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The authors limited the analysis to the direct costs of the operations. Future costing would be improved by establishing, a priori, a perspective from which the costs are to be estimated, for instance that of the health care provider. The unit costs were reported, but their source was not. The reporting of the unit costs and quantities would be very useful in terms of enhancing the readers' understanding of key cost-drivers. In addition, since the initial cost of the robot was not included in the model, the model will have underestimated the costs of robot-assisted surgery. No statistical or sensitivity analysis of the costs or prices was undertaken. Discounting was not relevant, as all the costs were incurred during a short time (less than one year), discounting was unnecessary, and was not carried out. No price year was reported, which will hinder any future inflation exercises.

Other issues
The authors made appropriate comparisons with other relevant studies. They also addressed the issue of generalisability
to other settings, commenting on robot-assisted surgery for other types of surgery. The authors did not present their results selectively and their conclusions appear to have reflected the scope of the analysis. The authors acknowledged that the small number of patients included in the analysis was a limitation of their study.

Implications of the study
The authors did not make any recommendations. However, developments in robotic technology such as new instruments, additional but smaller robotic arms, and tactile feedback could prompt a re-evaluation of its use in antireflux surgery.

Source of funding
None stated.

Bibliographic details

PubMedID
16552744

DOI
10.1002/bjs.5325

Other publications of related interest
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Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Female; Follow-Up Studies; Fundoplication /methods; Gastroesophageal Reflux /surgery; Humans; Hydrogen-Ion Concentration; Laparoscopy /methods; Length of Stay; Male; Middle Aged; Quality of Life; Robotics

AccessionNumber
22006001040

Date bibliographic record published
30/09/2007

Date abstract record published
30/09/2007