Robotic vs laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease: systematic review and meta-analysis

Markar SR, Karthikesalingam AP, Hagen ME, Talamini M, Horgan S, Wagner OJ

CRD summary
The review concluded that robotic Nissen fundoplication was comparable to standard laparoscopic Nissen fundoplication, but was associated with increased operative time and procedure cost. The authors’ conclusion is supported by the results presented, but should be interpreted with some degree of caution due to the small number of included trials of generally poor quality.

Authors' objectives
To determine the effects of robotic Nissen fundoplication compared with standard laparoscopic Nissen fundoplication on clinical outcomes for gastro-oesophageal reflux disease.

Searching
MEDLINE, EMBASE, the Cochrane Library and the Current Controlled Trials Register were searched up to September 2009. Search terms were reported. A handsearch of published abstracts in six key journals was also performed. References of relevant studies were checked.

Study selection
Prospective, controlled trials that assessed robotic or laparoscopic Nissen fundoplication were eligible for inclusion. Trials that focused on paediatric populations and reported an alternative anti-reflux procedure were excluded.

The primary outcomes of interest were the requirement for re-operation, postoperative mortality and postoperative dysphagia (inability to swallow that was present at the first follow-up). Secondary outcomes included operative time, hospital stay, operative complications (within the first month of the operation as a direct result of the initial operation), and cost.

In included trials, the mean age of participants ranged from 38 to 50.5 years in the laparoscopic group and 40 to 49.6 years in the robotic surgery group; the mean body mass index (BMI) ranged from 24.8 to 28.5 (where reported). The percentage of males ranged from 30 to 89%.

Two reviewers selected studies for inclusion in the review.

Assessment of study quality
The quality of the included trials was assessed using the Jadad criteria (randomisation, blinding, and description of withdrawals and drop-outs), and a summary score was awarded for each trial.

The authors did not state how many reviewers performed the validity assessment.

Data extraction
Data permitting the calculation of weighted mean differences (WMD) and odds ratios (RRs), with their associated confidence intervals (CIs), were extracted.

The authors did not state how many reviewers performed the data extraction.

Methods of synthesis
Trials were combined in a meta-analysis using a random-effects model. Summary estimates were reported as weighted mean differences for continuous outcomes (e.g. operating time and hospital stay) and odds ratios for dichotomous outcomes (e.g. postoperative complications, the requirement for re-operation, the development of postoperative
dysphagia, and postoperative mortality), with 95% confidence intervals.

Statistical heterogeneity was assessed using the Cochran's Q.

Publication bias was assessed using funnel plots and the Egger test.

**Results of the review**

Six randomised controlled trials (RCTs) were included in the review (n=221 patients). Sample sizes ranged from 20 to 50 patients. The Jadad scores ranged from 1 to 3 points, with two trials scoring 3.

No significant difference was found between robotic Nissen fundoplication and the standard laparoscopic approach for requirement for re-operation (six RCTs), occurrence of postoperative dysphagia (three RCTs), operative complications (six RCTs), and duration of hospital stay (five RCTs). Evidence of statistical heterogeneity was found for hospital stay (p<0.0001).

Laparoscopic surgery was associated with a significant reduction in operation time compared with robotic surgery (WMD 4.145, 95% CI 1.932 to 6.375; six RCTs); evidence of significant heterogeneity was found (p<0.0001).

No deaths occurred in any of the included trials.

A fixed effect model was used for operation time; all other analyses used a random effects model.

No evidence of publication bias was found for requirement for re-operation or hospital stay, but there was some evidence of publication bias for operative time (Egger test=8.89, p=0.03).

**Cost information**

The mean cost of robotic surgery was from 501 Euros to 1,806 Euros more expensive than the mean cost of laparoscopic surgery (based on data from two trials).

**Authors’ conclusions**

Robotic Nissen fundoplication was comparable to standard laparoscopic Nissen fundoplication, but was associated with increased operative time and procedure cost.

**CRD commentary**

The review question was supported by defined inclusion criteria. A number of different sources were searched for relevant literature (it was not clear whether this search was restricted by language), but no specific attempts were made to locate unpublished studies, increasing the possibility of publication bias. Publication bias was assessed, but the small number of included trials meant that this assessment may not be reliable. Two reviewers selected studies for inclusion in the review, but it was not clear whether this procedure was carried out independently. It was unclear whether appropriate steps were taken to minimise reviewer error and bias for data extraction or validity assessment.

Trial quality was assessed using appropriate criteria, but only a summary score was presented; in general, the quality of the included trials was low. Few participant characteristics were reported, which made it difficult to judge generalisability. Appropriate methods appeared to have been used to pool trials. Statistical heterogeneity was assessed.

The authors' conclusion is supported by the results presented, but should be interpreted with some degree of caution due to the small number of generally poor quality trials and lack of reported review process.

**Implications of the review for practice and research**

**Practice:** The authors stated that laparoscopic Nissen fundoplication should remain the gold standard surgical treatment for gastro-oesophageal reflux disease. The technical advantages of robotic surgery may offer a clinical benefit for 'high-risk' patients with more complex anatomy.
Research: The authors stated that larger scale trials with a formal assessment of postoperative quality of life and detailed health economic assessment are required.

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