Meta-analysis of randomized clinical trials comparing open and laparoscopic anti-reflux surgery


CRD summary
This review compared laparoscopic anti-reflux surgery and open anti-reflux surgery for proven gastro-oesophageal reflux disease, concluding that laparoscopic anti-reflux surgery was an effective and safe alternative. Although this was a generally well-conducted review, the findings were limited by a lack of good-quality data, significant variation across trials and publication bias; the authors' conclusions should be interpreted with some caution.

Authors' objectives
To compare laparoscopic anti-reflux surgery and open anti-reflux surgery for proven gastro-oesophageal reflux disease.

Searching
MEDLINE, EMBASE, Science Citation Index and Current Contents were searched from 1990 to 2007 for peer-reviewed English language-studies; search terms were reported. Reference lists of relevant articles were manually searched to identify additional articles.

Study selection
Randomised controlled trials (RCTs) comparing laparoscopic anti-reflux surgery with open anti-reflux surgery in adult or paediatric patient populations, with no restriction on trial size, were eligible for inclusion. Unpublished studies and abstracts were excluded, as were non-randomised trials.

Outcomes considered included operating time, hospital stay, return to normal activity, perioperative complications, treatment failure, and requirement for further surgery, as were rates of conversion to an open procedure.

For the majority of included trials open anti-reflux surgery and laparoscopic anti-reflux surgery were undertaken using a loose 360 degree Nissen fundoplication technique, with a 250 to 270 degree wrap used for one trial. Variability amongst trials was reported for the division of the short gastric vessels, performance of hiatoplasty, and calibration using either a bougie or gastric tube.

Determinants of gastro-oesophageal reflux disease in included trials comprised variable use of upper gastrointestinal endoscopic investigation, barium swallow, 24 hour oesophageal manometry and pH studies. All but one of the included trials were in adult patients.

The authors did not state how the papers were selected for review, or how many reviewers performed the selection.

Assessment of study quality
Trial quality was assessed using the 5-point Jadad scale, which assessed randomisation, blinding, withdrawals and drop-outs. High-quality trials were defined as those that scored at least 3 points and low-quality trials those scoring less than 3.

The authors stated that four reviewers independently assessed validity; discrepancies were resolved by consensus.

Data extraction
Data for dichotomous outcomes were extracted to calculate odds ratios (OR). Means and standard deviations were extracted for continuous outcomes. Where mean changes and standard deviations were not reported, estimates were calculated from medians, ranges and sample sizes using the methods of Hozo et al.

The authors stated that four reviewers independently extracted data; discrepancies were resolved by consensus.
Methods of synthesis
Pooled odds ratios and weighted mean differences (WMDs), and their 95% confidence intervals, were calculated using a random-effects model. The odds ratio was amended to avoid the computation of the reciprocal of zeros among observed values for the calculation of the original odds ratio. Statistical heterogeneity was assessed using the Cochran Q statistic and the $I^2$ statistic. Significant heterogeneity was defined as $p \leq 0.05$. Publication bias was assessed using funnel plots. Subgroup analyses were undertaken to compare 'high quality' with 'low quality' trials.

Results of the review
Twelve RCTs were included in the review (n=1,041 patients, range 20 to 192; 503 patients underwent open anti-reflux surgery and 538 laparoscopic anti-reflux surgery). There was some discrepancy in patient numbers between the tables and the text. Where stated, the duration of follow-up ranged from three to 137 months. The quality score was 1 point in one trial, five trials each had quality scores of 2 and 3 points, and one trial scored 5 points; the average quality score was 2.6. Funnel plots indicated the presence of publication bias.

Compared with open anti-reflux surgery, the laparoscopic anti-reflux surgery group had significantly shorter hospital stays (WMD -2.68 days, 95% CI -3.54 to -1.81; nine RCTs), quicker return to normal activity (WMD -7.75 days, 95% CI -14.37 to -1.14; six RCTs) and reduced complication rates (OR 0.35, 95% CI 0.16 to 0.75; 11 RCTs). Operating times were significantly longer in the laparoscopic anti-reflux surgery group (WMD: 39.02 min, 95% CI 17.99 to 60.05; nine RCTs). Treatment failure rates were comparable between the two groups, but the requirement for further surgery was significantly greater in the laparoscopic anti-reflux surgery group (OR 1.79, 95% CI 1.00 to 3.22; 10 RCTs). Significant heterogeneity was present for these comparisons. Subgroup results were reported.

Authors' conclusions
Laparoscopic anti-reflux surgery was an effective and safe alternative to open anti-reflux surgery for the treatment of proven gastro-oesophageal reflux disease. Laparoscopic anti-reflux surgery enabled a faster convalescence and return to productive activity, with a reduced risk of complications and a similar treatment outcome, than an open approach. There was a significantly higher rate of re-operation (79%) in the laparoscopic anti-reflux surgery group.

CRD commentary
The review question and inclusion criteria were clear. The authors searched a small number of appropriate sources, but the search was restricted to publications in English and it was unclear whether unpublished studies were sought; consequently, language bias could have been present and some studies may have been missed. Publication bias was assessed and found to be present. With the exception of study selection, all stages of the review process appeared to have been conducted by multiple reviewers, reducing the potential for error and bias.

Appropriate criteria were used to assess the quality of the included trials; all but one of which achieved a Jadad score of 3 or less, indicating that the included trials were not of the highest quality. Suitable methods were used for the meta-analysis. Heterogeneity was assessed and found to be significant for significant results.

Generally, this was a well-conducted review, but the findings were limited by a lack of good-quality data, significant variation across trials and the presence of significant publication bias. In light of these shortcomings, the authors' conclusions should be interpreted with some caution.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

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None.

Bibliographic details
**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.