

# **Randomized clinical trial of laparoscopic versus open fundoplication for gastro-oesophageal reflux**

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This is a paper from the University of Lund in Sweden giving the long term results of a prospective randomized trial of laparoscopic versus open fundoplication for gastro-oesophageal reflux.

The authors randomized 60 patients with gastro-oesophageal reflux disease (GORD) to open or laparoscopic fundoplication. Subject of evaluation using disease specific and generic questionnaires and structured interviews and objective evaluation by endoscopy, oesophageal manometry and 24 hour pH monitoring were performed before operation and one month, six months and five years after surgery.

Two patients in the laparoscopic group had re-operation for hiatal stricture, 18 and 19 months after surgery. These two patients were not included in the five year follow up. One patient in the open operation group underwent a gastrectomy for gastric cancer three years after the fundoplication and this patient was also excluded from further examination in the five year follow up. Two patients underwent surgery for intestinal obstruction, one three months after open fundoplication and the other 24 months after laparoscopic fundoplication. Another patient from the open group had a repair of incisional hernia 21 months after surgery. One patient in each group died from malignant melanoma after open surgery and from gastric cancer after laparoscopic surgery.

In all 22 patients in the laparoscopic group and 28 in the open group (plus five patients whose laparoscopic procedure was converted to open operation) were followed up at five years.

There was no significant difference between the two groups in frequency or severity of heartburn or regurgitation six months after surgery and these results were maintained at five years. There was a tendency towards a higher frequency of mild dysphagia in the laparoscopic group after six months but this was not statistically significant and after five years there was no difference between the two groups. Difficulty in belching was reported at five years by eight of 17 patients after laparoscopic and 10 of 23 patients after open operations. There was no difference between the groups. Increased flatulence was described by 13 of 17 patients in the laparoscopic group and 17 of 23 in the open group after five years.

The only difference seen in this study concerned complaints about the scar which were reported only after open fundoplication. Otherwise no significant differences between the procedures were identified after five years in either the per protocol or intention to treat analyses. In this investigation the incidence of sleep disturbance was significantly lower in the open surgery group after six months but after five years there were no differences between the groups.

It is unclear why the difference was seen only in the short term as the greatest impact on sleep results from the disappearance of nightly reflux symptoms. Benefits from laparoscopic fundoplication were seen in the immediate post-operative period but at long term follow up there was little if any difference between open and laparoscopic surgery.

The authors conclude that patients should be informed of the results of this analysis so that expectations of the outcomes of surgery are realistic. It is a very useful analysis however given that there are known benefits in the short term in favour of laparoscopic surgery and now that long term results can be seen to be equally as good as open surgery this is most useful in allowing patients to determine their choice of operation.

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