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[Intervention Review]

Laparoscopic fundoplication surgery versus medical management for gastro-oesophageal reflux disease (GORD) in adults

Sushil K Garg¹, Kurinchi Selvan Gurusamy²

¹Department of Medicine, University of Minnesota, Minneapolis, MN, USA. ²Department of Surgery, Royal Free Campus, UCL Medical School, London, UK

Contact address: Sushil K Garg, Department of Medicine, University of Minnesota, Minneapolis, MN, USA. sushilaiims@gmail.com, skg@umn.edu.

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ABSTRACT

Background

Gastro-oesophageal reflux disease (GORD) is a common condition with 3% to 33% of people from different parts of the world suffering from GORD. There is considerable uncertainty about whether people with GORD should receive an operation or medical treatment for controlling the condition.

Objectives

To assess the benefits and harms of laparoscopic fundoplication versus medical treatment for people with gastro-oesophageal reflux disease.

Search methods

We searched the Cochrane Upper Gastrointestinal and Pancreatic Diseases Group (UGPD) Trials Register (June 2015), Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 6, 2015), Ovid MEDLINE (1966 to June 2015), and EMBASE (1980 to June 2015) to identify randomised controlled trials. We also searched the references of included trials to identify further trials.

Selection criteria

We considered only randomised controlled trials (RCT) comparing laparoscopic fundoplication with medical treatment in people with GORD irrespective of language, blinding, or publication status for inclusion in the review.

Data collection and analysis

Two review authors independently identified trials and independently extracted data. We calculated the risk ratio (RR) or standardised mean difference (SMD) with 95% confidence intervals (CI) using both fixed-effect and random-effects models with RevMan 5 based on available case analysis.

Main results

Four studies met the inclusion criteria for the review, and provided information on one or more outcomes for the review. A total of 1160 participants in the four RCTs were either randomly assigned to laparoscopic fundoplication (589 participants) or medical treatment with proton pump inhibitors (571 participants). All the trials included participants who had had reflux symptoms for at least six months and had received long-term acid suppressive therapy. All the trials included only participants who could undergo surgery if randomised to the



surgery arm. All of the trials were at high risk of bias. The overall quality of evidence was low or very low. None of the trials reported long-term health-related quality of life (HRQoL) or GORD-specific quality of life (QoL).

The difference between laparoscopic fundoplication and medical treatment was imprecise for overall short-term HRQOL (SMD 0.14, 95% CI -0.02 to 0.30; participants = 605; studies = 3), medium-term HRQOL (SMD 0.03, 95% CI -0.19 to 0.24; participants = 323; studies = 2), medium-term GORD-specific QoL (SMD 0.28, 95% CI -0.27 to 0.84; participants = 994; studies = 3), proportion of people with adverse events (surgery: 7/43 (adjusted proportion = 14.0%); medical: 0/40 (0.0%); RR 13.98, 95% CI 0.82 to 237.07; participants = 83; studies = 1), long-term dysphagia (surgery: 27/118 (adjusted proportion = 22.9%); medical: 28/110 (25.5%); RR 0.90, 95% CI 0.57 to 1.42; participants = 228; studies = 1), and long-term reflux symptoms (surgery: 29/118 (adjusted proportion = 24.6%); medical: 41/115 (35.7%); RR 0.69, 95% CI 0.46 to 1.03; participants = 233; studies = 1).

The short-term GORD-specific QoL was better in the laparoscopic fundoplication group than in the medical treatment group (SMD 0.58, 95% CI 0.46 to 0.70; participants = 1160; studies = 4).

The proportion of people with serious adverse events (surgery: 60/331 (adjusted proportion = 18.1%); medical: 38/306 (12.4%); RR 1.46, 95% CI 1.01 to 2.11; participants = 637; studies = 2), short-term dysphagia (surgery: 44/331 (adjusted proportion = 12.9%); medical: 11/306 (3.6%); RR 3.58, 95% CI 1.91 to 6.71; participants = 637; studies = 2), and medium-term dysphagia (surgery: 29/288 (adjusted proportion = 10.2%); medical: 5/266 (1.9%); RR 5.36, 95% CI 2.1 to 13.64; participants = 554; studies = 1) was higher in the laparoscopic fundoplication group than in the medical treatment group.

The proportion of people with heartburn at short term (surgery: 29/288 (adjusted proportion = 10.0%); medical: 59/266 (22.2%); RR 0.45, 95% CI 0.30 to 0.69; participants = 554; studies = 1), medium term (surgery: 12/288 (adjusted proportion = 4.2%); medical: 59/266 (22.2%); RR 0.19, 95% CI 0.10 to 0.34; participants = 554; studies = 1), long term (surgery: 46/111 (adjusted proportion = 41.2%); medical: 78/106 (73.6%); RR 0.56, 95% CI 0.44 to 0.72); participants = 217; studies = 1) and those with reflux symptoms at short-term (surgery: 6/288 (adjusted proportion = 2.0%); medical: 53/266 (19.9%); RR 0.10, 95% CI 0.05 to 0.24; participants = 554; studies = 1) and medium term (surgery: 6/288 (adjusted proportion = 2.1%); medical: 37/266 (13.9%); RR 0.15, 95% CI 0.06 to 0.35; participants = 554; studies = 1) was less in the laparoscopic fundoplication group than in the medical treatment group.

Authors' conclusions

There is considerable uncertainty in the balance of benefits versus harms of laparoscopic fundoplication compared to long-term medical treatment with proton pump inhibitors. Further RCTs of laparoscopic fundoplication versus medical management in patients with GORD should be conducted with outcome-assessor blinding and should include all participants in the analysis. Such trials should include long-term patient-orientated outcomes such as treatment-related adverse events (including severity), quality of life, and also report on the social and economic impact of the adverse events and symptoms.

PLAIN LANGUAGE SUMMARY

Keyhole surgery versus medical treatment for adults with heart burn or acid regurgitation

Review question

Is laparoscopic fundoplication (keyhole surgery which involves wrapping the top end of the stomach around the bottom of the oesophagus (food pipe or gullet) to form a new valve) beneficial or harmful when compared to medical treatment in adults with heartburn or acid regurgitation (gastro-oesophageal reflux disease (GORD))?

Background

Gastro-oesophageal reflux disease or GORD is a condition which develops when stomach contents regurgitate into the oesophagus causing troublesome symptoms such as heartburn (burning sensation at the lower end of the breastbone) or regurgitation (perception of flow of stomach content into the throat or mouth). Long-term complications of GORD include reflux oesophagitis (injury to lining of oesophagus), bleeding from the oesophagus, narrowing of the oesophagus, change in the nature of the lining of the oesophagus which can sometimes give rise to oesophageal cancer. Approximately 3% to 33% of people have GORD around the world. The risk factors for GORD include a family history of reflux disease in immediate relatives, pregnancy, older age, obesity, cigarette smoking, and excessive alcohol drinking. Apart from lifestyle changes (such as cessation of smoking) and diet changes (avoiding food that causes heartburn), the major forms of treatment for GORD are medical and surgical. The medical treatment is usually aimed at decreasing acidity in the stomach. Currently a group of drugs which suppress acid secretion, called proton pump inhibitors, are considered the best in decreasing acid secretion. The main surgical treatment is fundoplication which involves wrapping around the lower part of the food pipe with stomach. This can be performed by traditional open surgery, keyhole surgery or surgery that is performed without making any cut from within the stomach with the help of an endoscope (in this context, a flexible tube introduced through the mouth to give a view of the food pipe and stomach). The benefits and harms of laparoscopic fundoplication compared to medical treatment in people with GORD is not known. We sought to resolve this issue by searching for existing studies on the topic. We included all studies whose results were reported until 1st October 2014.

Study characteristics



Four studies met the inclusion criteria for the review, and provided information for the review. A total of 1160 participants received either laparoscopic fundoplication (589 participants) or medical treatment (571 participants). The decision on whether a participant received surgery or medical treatment was made using methods similar to tossing a coin, ensuring that the participants in the two groups were similar. All the trials included people who had had reflux symptoms for at least six months, had received long-term acid suppressive therapy, and could undergo laparoscopic fundoplication if necessary.

Key results

None of the trials reported long-term health-related quality of life (HRQoL) or GORD-specific quality of life (QoL). The difference between laparoscopic fundoplication and medical treatment was imprecise for overall short-term HRQOL, medium-term HRQOL, medium-term GORD-specific QoL, percentage of people with adverse events, long-term dysphagia (difficulty in swallowing), and long-term acid regurgitation. The short-term GORD-specific quality of life was better in the laparoscopic fundoplication group than in the medical treatment group. However, it was not clear how much this improvement benefited the patient. The proportion of people with serious adverse events, short-term dysphagia, and medium-term dysphagia was higher in the laparoscopic fundoplication group than in the medical treatment group. The proportion of people with heartburn at short term, medium term, and long term, and those with acid regurgitation at short term and medium term was less in the laparoscopic fundoplication group than in the medical treatment group. The severity of difficulty in swallowing, heartburn, or acid regurgitation was not reported. There is considerable uncertainty in the balance of benefits versus harms of laparoscopic fundoplication compared to long-term medical treatment with proton pump inhibitors. Due to the poor quality of the trials, future high-quality studies are needed in this field.

Quality of the evidence

The quality of evidence was low or very low. As a result, there is a lot of uncertainty regarding the results.