

Choosing the right patient for laparoscopic fundoplication: a narrative review of preoperative predictors

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Objective: To determine the best preoperative predictors for a successful outcome after primary laparoscopic fundoplication.

Background: Anti-reflux surgery is a proven treatment modality for patients with debilitating reflux symptoms, or those with breakthrough symptoms or an intolerance to medical therapy. Studies show that 3–6% of patients undergoing primary anti-reflux surgery will ultimately need a revisional procedure, and this carries a higher morbidity and mortality rate than primary surgery. Given the risks associated with laparoscopic revisional fundoplication, it is imperative to select the right patient for a primary laparoscopic fundoplication.

Methods: A literature search was conducted of MEDLINE, Embase, Cochrane and ClinicalKey databases using the search terms “fundoplication”, “recurrent reflux”, “predictors of success” with “AND” and “OR” selected. English-written papers published between 1995 to 2020 were included. Abstracts and case reports of patients less than 18 years of age were excluded. Only studies with laparoscopic fundoplication were included. Open, endoscopic and revisional fundoplication studies were excluded, as well as any paper discussing hiatus hernias greater than 5 cm in size.

Conclusions: Best predictors for a good outcome after anti-reflux surgery include: male gender, BMI under 30 kg/m², typical reflux symptoms, responders to anti-reflux medication, and abnormal reflux on 24-hour pH monitoring with positive symptom indices.

Keywords: Recurrent reflux; laparoscopic fundoplication; predictors of success

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Introduction

Gastro-esophageal reflux disease (GERD or reflux disease) is defined by the Montreal consensus as a condition that develops when the reflux of gastric content into the esophagus causes troublesome symptoms or complications (1).

According to a review by Nirwan *et al.*, GERD has a global prevalence of 14% with significant variations between regions and countries. Whilst the prevalence of GERD in Australia and the United Kingdom is 10–15%, the prevalence in the United States of America is higher, at 30–35% (2).

Laparoscopic anti-reflux surgery is an accepted

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treatment for GERD (3-7). However, the published failure rate from laparoscopic fundoplication ranges from 10% to 20% (8-10), of which 3–6% of patients will require a revisional surgery (5,11-17). This small percentage of patients undergoing revisional fundoplication is significant considering the large number of fundoplication undertaken since the advent of laparoscopic anti-reflux surgery. A revisional fundoplication not only poses a greater technical challenge than a primary fundoplication, but it also results in higher complication rates ranging from 0–44% (18), and higher risk of mortality (1%) (19). As well, a further 10% of patients undergoing laparoscopic re-operative anti-reflux surgery may require another revisional procedure (20,21).

Given the risks associated with laparoscopic revisional fundoplication, it is imperative to select the right patient for a primary laparoscopic fundoplication. We aim to determine the best preoperative predictors which correspond to a successful outcome following laparoscopic fundoplication and will present the article in accordance with the Narrative Review reporting checklist (available at <http://dx.doi.org/10.21037/aoe-21-19>).

Methods

GERD is one of the most common benign disorders of the upper gastro-intestinal tract with non-specific symptoms, heterogeneous clinical presentation, and a varied diagnostic differential. Hence, making the correct diagnosis of reflux, and then making the correct treatment choice (i.e., medical versus surgical therapy) are both of the utmost importance.

An extensive literature search was conducted of MEDLINE, Embase, Cochrane and ClinicalKey databases using the search terms “fundoplication”, “recurrent reflux”, “predictors of success” with “AND” and “OR” selected. English-written papers published between 1995 to 2020 were included. Abstracts and case reports of patients less than 18 years of age were excluded. Only studies with laparoscopic fundoplication were included, and of those, only studies which focused on pre-operative patient predictors or investigations were included. Open, endoscopic and revisional fundoplication studies were excluded, as well as any paper discussing hiatus hernias greater than 5 cm in size.

Discussion

Pre-operative patient predictors

Age

Age as a predictor of outcome after laparoscopic

fundoplication for GERD patients has contradictory findings. Addo *et al.* in a retrospective study, demonstrated improved long-term quality of life amongst elderly patients undergoing laparoscopic fundoplication, even though the risk of intra-operative complications, length of stay, and re-operation rates were all higher compared to the younger age group (22). In a study involving review of a Californian database of 13,050 patients, multivariate analysis demonstrated significantly higher rates of re-operation among younger patients (hazard ratio, HR =3.56 for <30 years old; HR 1.89 for 30–50 years old; HR 1.65 for 50–65 years old) and female patients (HR =1.35) (23). Older patients had greater symptom improvement, a finding which is consistent across multiple studies (24–26).

Large population database studies have also revealed higher rates of re-operation in younger patients compared to patients more than 70 years of age (23,27). Although a large Swedish study, with up to 5 years follow-up, found older age was a risk factor for reflux recurrence (HR 1.41 for >61 years compared to <45 years). Though the redo fundoplication rate was similar in both groups (2.7% *vs.* 2.6%), the percentage of patients with post laparoscopic fundoplication recurrence treated with medication was higher in elderly group (19.2%) compared to the younger aged group (10.8%) (28). The Adelaide group reported similar findings of frequent anti-reflux medication use and re-operation rate (11%) with increasing age (29). In a multivariate analysis, age (<50 years), typical symptoms, and response to PPI had an exponential effect on positive outcome after laparoscopic fundoplication compared to outcome for older persons, age >50 years (30).

Gender

The likelihood of a successful outcome following laparoscopic fundoplication for women may be lower than for men, although most will still have a good outcome. In a large prospectively collected database study, females were less satisfied with the outcomes after fundoplication, consequently having more revisional procedures compared to males (24). Observational studies confirm that female gender (OR 1.56, $P < 0.0001$) is associated with increased risk for re-operation after fundoplication (23,27). In a Swedish study involving 2,655 patients, the overall recurrence rate of reflux symptoms in female patients was 22% *vs.* 14% in males, and the rate of redo fundoplication was 4% *vs.* 2% for males. The majority of patients with reflux recurrence were treated with medication with a median follow-up of 5.6 years (28).

Body mass index (BMI)

Obesity is a recognized risk factor for the development for reflux. Studies evaluating BMI as a predictor for fundoplication outcome have classified patients into 3 categories: BMI <30 kg/m², ≥30 to <35 kg/m², and ≥35 kg/m². While patients with a BMI ≥35 kg/m² are best suited to bariatric surgery (31), treatment for moderate obesity (middle BMI group) is more controversial. Poorer outcomes after laparoscopic fundoplication were seen in obese patients in some studies (32-35), whereas other studies found similar outcome regardless of patient BMI (36-43). Schietroma *et al.* compared outcomes for 201 patients based on BMI and found that although short term outcomes were similar for all groups, long term outcomes were not. After more than 10 years, reflux control was worse in the obese group compared to the non-obese group (44). A recent meta-analysis by Abdelrahman *et al.* concluded that although laparoscopic fundoplication can be safely performed in an obese patient, higher reflux recurrence is a risk (45). In a study analysing patterns of re-operation for failed fundoplication in 9,462 patients, the majority of patients (86%) who underwent conversion to Roux-en-Y gastric bypass were obese, whereas only 8% redo fundoplication patients were obese (27).

Typical vs. atypical symptoms

Laparoscopic fundoplication achieves excellent outcomes in over 90% of GERD patients with typical symptoms, namely heartburn and acid regurgitation (11,33,46-48). However, the effectiveness of anti-reflux surgery for the resolution of atypical symptoms (i.e., cough, hoarseness, globus, odynophagia, sore throat, etc.) is less predictive (46,49,50). Therefore, patients with atypical reflux symptoms should have a concrete diagnosis of pathological reflux through validated objective tests to qualify for surgery and elevate the likelihood of good outcome post-surgery. A recent large retrospective study of patients with objectively diagnosed reflux associated with atypical symptoms (difficulty breathing, chronic cough, hoarseness, and globus sensation), with follow-up of 19±17 months after laparoscopic anti-reflux surgery, found significant post-operative benefits as assessed by four quality of life validated instruments (51). In the same cohort of study, complete resolution of chronic cough was found in 77% of respondents at follow-up (52).

Response to anti-reflux medication

The majority of patients with reflux have resolution of reflux

symptoms with proton pump inhibitor (PPI) therapy and are termed as good responders. However, about 17–45% of patients complain of persistent reflux symptoms despite maximal PPI therapy, and are deemed poor responders (53-56). PPI response is predictive. Patients classified as PPI responders is one of the best predictors for an excellent outcome post laparoscopic fundoplication (11,57), while PPI non responders are considered as poor candidates for laparoscopic anti-reflux surgery. Hence, these patients form an important subgroup of GERD patients to be considered for further investigation prior to laparoscopic fundoplication. Studies comparing these two groups, indicate that the non-responders may still benefit from laparoscopic anti-reflux surgery, though not as much as PPI responders (58-60). Other smaller prospective studies report similar findings, with a fundoplication success rate averaging 85% for PPI non-responders (48,61,62).

PPI non responders constitute the most common group of patients referred for laparoscopic fundoplication (39,63). A systematic review on PPI-refractory GERD patients found that at 10 years post laparoscopic fundoplication, nearly 35% of patients experienced recurrent heartburn, 30% reported regurgitation, and PPI use increased from 9% at 1 year to 18% at 10 years. Additionally, 10% of patients with PPI-refractory GERD required surgical intervention within 10 years of follow-up (64). The degree of circumferential extent of fundoplication failed to alter the outcomes for GERD patients refractory to PPI undergoing laparoscopic fundoplication (65-67). Frazzoni *et al.* found that for PPI-refractory GERD patients confirmed by impedance pH-study, cure of GERD was achieved in 34 of 38 patients (89%), in which 11 patients had an abnormal number of total reflux events as the only preoperative abnormality on ambulatory impedance-pH testing, suggesting weakly acidic reflux can play a role in the pathogenesis of PPI-refractory GERD (62). In 2018, an expert panel recommended that in PPI-refractory GERD patients undergoing impedance-pH monitoring while on PPI therapy, laparoscopic anti-reflux surgery should only be considered if there is abnormal reflux burden in the form of elevated distal esophageal acid exposure or regurgitation with positive symptom-reflux association and a large hiatus hernia (68). Future studies based on these indications for PPI-refractory GERD patients may help reduce the burden of revisional fundoplication.

Pre-operative investigations

Endoscopy

Patients with reflux are divided into erosive and non-

erosive reflux disease based on endoscopy findings. Up to 70% of patients with reflux symptoms have no evidence of esophagitis at endoscopy (69). However, the pre-operative severity of esophagitis does not influence the outcomes of laparoscopic fundoplication (70,71). Studies comparing the outcomes of patients with or without erosive esophagitis, found a similar reduction in symptoms and anti-reflux medication use in both groups (72,73). However, another comparative study indicated that quality of life outcomes after laparoscopic fundoplication are worse in patients with non-erosive reflux disease, and one third of these patients will continue anti-reflux medication after surgery (74).

Endoscopy remains a vital investigation prior to revisional fundoplication (19,75). Ideally, it should be undertaken by the operating surgeon as it provides a blueprint for the mechanism of failure and a management plan (76).

pH studies

Ambulatory pH or pH-impedance monitoring is the gold standard for quantifying esophageal acid exposure and establishing a relationship with symptoms in patients with GERD (77,78). In a multivariate analysis conducted by Campos *et al.* for 199 GERD patients who underwent a laparoscopic Nissen fundoplication, the strongest predictor of good or excellent outcome was the 24-hour pH monitoring score with an odds ratio of 5.4. In contrast, patients with typical symptoms, responsive to anti-reflux medications, but with normal pH score had only a fair or poor outcome after surgery (39). The value of routine preoperative pH testing was confirmed in another study in which significantly worse subjective outcomes after Nissen fundoplication were found in patients with normal compared with abnormal preoperative 24-hour pH test results (79). In cases of a strong clinical suspicion yet previous negative reflux pH testing, prolonged 48-hour Bravo™ wireless pH monitoring can be considered to improve the diagnostic yield (80-83). The subgroup of patients diagnosed with esophageal hypersensitivity to acid reflux (i.e., those with a positive symptom association probability but physiological levels of esophageal acid exposure) are equally good candidates for laparoscopic anti-reflux surgery as patients with pathological acid exposure (84).

Postoperatively, pH monitoring can also be used to identify fundoplication failures for patients with recurrent symptoms. Esophageal multichannel intraluminal impedance (MII) monitoring in combination with pH monitoring (MII-pH) in patients either on or off acid

suppression medications can detect all types of reflux events (acidic, weakly acidic or non-acidic) recording the retrograde movement of refluxate by impedance and degree of acidity by pH (85). The role of ambulatory impedance monitoring in selecting patients for anti-reflux surgery is evolving. A study by Glasgow *et al.* urged caution in the use of abnormal impedance values in the context of normal esophageal acid exposure for the selection of patients for anti-reflux operation. The study found that patients who underwent anti-reflux surgery who had abnormal impedance monitoring but physiologically normal esophageal acid exposure (DeMeester score <14.7), post-operatively had poor control of heartburn; more frequent new onset dysphagia (23% *vs.* 5%); and significantly more likelihood of continuing PPI medications after surgery (86). In a study by Francis *et al.* of 27 patients with pathological GERD but atypical symptoms refractory to PPI who underwent LARS, predictors of improvement of atypical symptom post-operatively were the presence of heartburn with or without regurgitation concomitant to their primary extra-esophageal symptom and distal esophageal pH <4 more than 12% over 24 hours. The probability of extra-esophageal symptom improvement was 90% if both conditions were present. Impedance-pH parameters performed on PPI therapy were not predictive of improvement of atypical symptom after fundoplication (87).

Manometry

(I) Esophageal motility: manometric assessment of esophageal motility is considered standard practice for pre-operative work-up of GERD patients being considered for primary or revisional anti-reflux surgery (88-90). Abnormalities of motility may contraindicate or modify planned anti-reflux surgery. The importance of undertaking preoperative manometry is shown by Chan *et al.*, who found 2.5% of 1,081 patients referred for anti-reflux surgery had obstructive lower esophageal sphincter (LES) pathophysiology (1% achalasia and 2.5% incomplete LES relaxation) and 4.5% had significant esophageal body hypomotility, which included aperistalsis in 3.2% and severe hypomotility in 1.3% of patients (91). Impaired esophageal motility is a frequent finding on manometry in GERD patients, however it is not a disease specific finding (92-98). Tailoring of the fundoplication in patients with ineffective esophageal motility and GERD has long been debated, yet several studies show that esophageal motility does

Table 1 Predictors assessed for laparoscopic fundoplication outcome

Pre-operative factors	Predictive strength for a good outcome
1. Age	None
2. Gender	Male gender*
3. Body mass index	BMI <30 kg/m ² *
4. Typical vs. atypical symptoms	Typical symptoms***
5. Response to anti-reflux medications	Good responder***
6. Endoscopy	None
7. pH studies	Positive pH study***
8. Manometry studies	None
9. Barium esophagogram	None

Legend: strength of predictor: *, some evidence; ***, strong evidence.

not influence the outcome after laparoscopic anti-reflux surgery (99-102). Randomized controlled trials comparing laparoscopic Nissen *vs.* Toupet in patients with GERD based on esophageal body motility, failed to find any differences in symptomatic outcomes (103,104). Some patients with GERD and ineffective esophageal motility show normalization of peristalsis and increase in gastro-esophageal junction (GEJ) pressure after laparoscopic fundoplication (105-107). A cohort study using a large database comparing the outcomes of 2,040 patients based on the wrap type and preoperative motility with a follow-up of 5 years demonstrated that ineffective esophageal motility based on conventional manometry did not predict postoperative dysphagia; and tailoring the degree of fundoplication based on preoperative motility had no impact on long-term postoperative dysphagia (108). Nevertheless, current common practice is to perform a partial fundoplication in patients with poor preoperative motility as this yields good post-operative reflux control with high patient satisfaction (109).

- (II) GEJ: the GEJ consists of the intrinsic LES pressure and extrinsic crural diaphragm pressure. For many years, manometric studies reported findings for LES luminal pressure before and/or after fundoplication, failing to recognize the contribution of crural diaphragm pressure. Regardless, many GERD patients show mechanically impaired LES competence with or without low crural diaphragm pressure, in the presence

or absence of a hiatus hernia (110-112). Other studies show that normotensive or increased LES or GEJ pressure in GERD patients prior to surgery, has no effect on the outcome after laparoscopic total or partial fundoplication (33,111,113-115). However, one study with a median follow-up of 14 months (6–81 months) found that patients with a normal LES had a six-fold increase in the risk of developing dysphagia compared to those with an abnormal LES (relative risk 5.8) (116). A small minority of patients with GERD have a hypertensive LES. Studies, albeit with smaller samples, have confirmed that this subset of patients have a good outcome after laparoscopic fundoplication (117-119).

Barium esophagogram

Studies to date indicate a limited role for barium esophagogram (or barium swallow) in the preoperative work up of GERD patients (120,121). However, the Esophageal Diagnostic Advisory Panel recommends barium studies in all patients during the work-up for laparoscopic fundoplication (88). Preoperatively, barium esophagogram is used to differentiate between a type III paraesophageal (mixed) hernia and the more common type I sliding hernia, as endoscopy can be inaccurate in this context (122). Barium swallow may identify a foreshortened esophagus associated with a large (>5 cm) hiatus hernia; a non-reducible hiatal hernia (i.e., does not reduce when the patient is upright); and a distal esophageal stricture.

In symptomatic post fundoplication patients, barium esophagogram is essential in predicting the anatomical cause of a failed fundoplication. It provides information concerning the integrity of the fundoplication, the state of motility, and the presence of reflux in GERD patients with recurrent symptoms post fundoplication (123). The role of barium is useful for planning primary or redo fundoplication, as a road map for operative intervention for large hiatal hernia or laparoscopic revisional fundoplication (124).

Conclusions

Table 1 summarizes the findings from our literature review. Best predictors for a good outcome after anti-reflux surgery include: male gender, BMI under 30 kg/m², typical reflux symptoms, responders to anti-reflux medication, and abnormal reflux on 24-hour pH monitoring with positive symptom indices.

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