

Selective Use of Esophageal Manometry and 24-Hour pH Monitoring before Laparoscopic Fundoplication

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- BACKGROUND:** Preoperative esophageal manometry and 24-hour pH monitoring commonly are used in preoperative evaluation of patients undergoing fundoplication. Here we review our experience with the selective preoperative workup of patients undergoing fundoplication to treat gastroesophageal reflux disease.
- STUDY DESIGN:** A series of 628 consecutive antireflux procedures was reviewed. History and physical examination, upper endoscopy, and upper gastrointestinal videofluoroscopy were obtained preoperatively on all patients; the first 30 patients also underwent esophageal manometry and pH monitoring (routine evaluation group). Thereafter, pH monitoring only was performed for atypical reflux symptoms, and manometry only was performed for a history of dysphagia, odynophagia, or for abnormal motility on videofluoroscopy (selective evaluation group). All patients underwent a laparoscopic floppy Nissen fundoplication, and then endoscopy and fluoroscopy at 3 months and 12 months postoperatively.
- RESULTS:** Eighty-five of the patients in the selective evaluation group (14%) required manometry, and 88 (15%) underwent pH monitoring. Eighteen of the 115 patients who underwent manometry (16%) had evidence of dysmotility. None of these 18 patients had increased dysphagia postoperatively; 8 of 18 reported improvement with swallowing. Five patients in the selective group (0.8%) had persistent postoperative dysphagia caused by technical error (four patients) or with no identifiable cause (one patient). The estimated charge or collection reduction with use of the selective evaluation was \$1,253,100 or \$395,000, respectively.
- CONCLUSIONS:** Selective use of manometry and pH monitoring was cost effective and safe in this series. Although esophageal manometry and 24-hour pH monitoring might be necessary with abnormal findings on videofluoroscopy or atypical symptoms, in our experience, their routine use is not essential in preoperative evaluation of patients undergoing fundoplication for gastroesophageal reflux disease. (*J Am Coll Surg* 2003;197:358–364. © 2003 by the American College of Surgeons)

Routine esophageal manometry and 24-hour pH monitoring have been advocated in evaluating patients being

considered for an antireflux procedure.^{1,2} The most sensitive test to diagnose gastroesophageal reflux disease (GERD) is 24-hour pH monitoring;³ but the value of pH monitoring is debatable in the patient whose heartburn and esophagitis already provides strong evidence of GERD. Esophageal manometry can be important to identify patients with various dysmotility disorders that might have an impact on the planned operation (eg, partial versus complete fundoplication);⁴ it could be argued, though, that the vast majority of patients with an esophageal dysmotility disorder could be identified on the basis of symptomatology, by the results of upper gastrointestinal videofluoroscopy, or both.^{5,6}

We believe that patients with GERD can be selected

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Abbreviations and Acronyms

EGD = esophagogastroduodenoscopy
 GERD = gastroesophageal reflux disease
 UGI = upper gastrointestinal videofluoroscopy

(based on symptomatology, upper endoscopy, and upper gastrointestinal videofluoroscopy) to undergo pH monitoring, manometry, or both, and that such an approach would yield patient outcomes comparable with those with routine use of these preoperative tests, and cost savings with respect to routine use. Here we present a review of this selective approach to preoperative evaluation of patients with GERD.

METHODS

This retrospective review consisted of a consecutive series of primary antireflux procedures, all performed under the supervision of the first author. This review did not include data on redo procedures or patients refused a primary operation (eg, because of test results). A thorough history and physical examination, esophagogastroduodenoscopy (EGD), and upper gastrointestinal videofluoroscopy (UGI) were obtained preoperatively on all patients. All patients were instructed to be off medications for at least 1 month before endoscopy. Esophagitis was graded according to the method of Sa-

vary and Miller.⁷ The first 30 patients underwent preoperative pH monitoring and manometry (routine evaluation group). For patients 31 to 628 (selective evaluation group), an algorithm (Fig. 1) was used to determine whether pH monitoring and manometry would be performed.

The algorithm specified that patients with typical reflux symptoms (pyrosis, regurgitation) and objective evidence of GERD (esophagitis on EGD, reflux on UGI, or both) would not undergo pH monitoring or manometry. Patients with atypical symptoms or no objective evidence of GERD underwent pH monitoring; any history of dysphagia or odynophagia, or any evidence of abnormal motility on fluoroscopy, prompted esophageal manometry. The results of manometry or pH monitoring directed further management, as indicated in Figure 1.

The techniques of esophageal manometry,⁸ ambulatory 24-hour pH monitoring,⁹ and laparoscopic floppy Nissen fundoplication¹⁰⁻¹² have been described. Technical highlights of our antireflux procedure include: complete mobilization of the esophagus so that at least 5 cm lie intraabdominally; routine and careful closure of the crura with generous suture bites, and with a large bougie (up to 60 Fr) in the esophagus to avoid constriction; reinforcement of the crural closure with an onlay of polytetrafluoroethylene mesh if the bial defect is

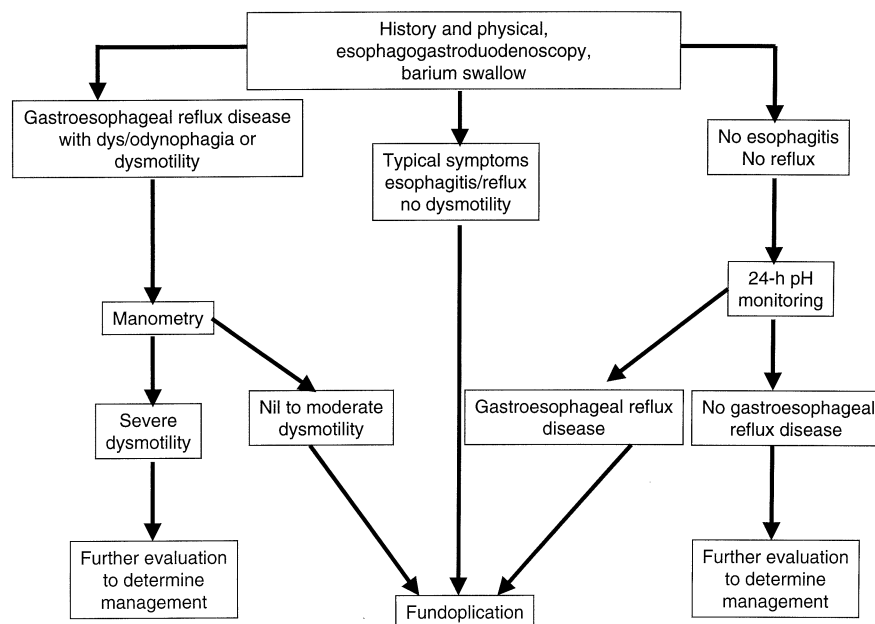


Figure 1. Algorithm for the selective use of preoperative esophageal manometry and 24-hour pH monitoring.

Table 1. Questionnaire Administered at Each Followup Visit

1. Do you have difficulty swallowing? If so, does the difficulty seem to be in the upper or lower chest? Is the difficulty with solids or liquids or both?
2. Do you experience heartburn? How often?
3. Do you experience pain during swallowing?
4. Do you experience chest pain when not swallowing?
5. Do you vomit? How often?
6. Do you experience nausea?
7. Do you have dry heaves and/or hiccups?
8. Do you regurgitate liquids, solids, or both?
9. Do you have a morning cough?
10. Do you have difficulty breathing or asthma?
11. Do you have voice hoarseness?
12. Do you have bloating and/or flatulence (gas from below)?
13. Do you get full with small portions of food?
14. Do you have diarrhea? How often?
15. Do you have constipation?
16. Do you have indigestion? How often?

large;¹³ fundus mobilization with ligation and division of the short gastric vessels; and a 3-stitch, 2-cm, floppy fundoplication anchored to the anterior arch of the crura (not to the esophagus).

During the first 3 months after the operation, all patients were instructed to avoid carbonated beverages and gas-producing foods, and to take small bites of food while chewing very well. The diet was advanced to unrestricted after 3 months. Postoperative clinic visits were scheduled at 1 week, 1, 3, 6, and 12 months, and then yearly. Patients were seen in clinic or contacted by phone; in a few cases, followup information had to be obtained from the referring physician. A questionnaire was administered to each patient at each followup visit (see Table 1). EGD and UGI were performed 3 and 12 months after the procedure. Recurrences, conversions, mortality, followup, and the presence of postoperative side effects were recorded.

RESULTS

During 1991 to 2000, 628 primary laparoscopic floppy Nissen fundoplications were performed. The average patient age was 42 years (range 11 to 92 years); there were 283 men (45%). The average duration of preoperative symptoms was 3.5 years (SD \pm 1.5 years, range 0.5 to 26 years). All patients underwent preoperative upper endoscopy. Mild, moderate, and severe esophagitis was found in 144 (14%), 327 (52%), and 69 (11%) of patients, respectively; no esophagitis was found in 88 patients (14%).

Table 2. Patients Undergoing Esophageal Manometry or pH Monitoring

Test	Routine group (n)	Selective group (n)	Total (n)
Manometry	30	85	115
pH monitoring	30	88	118

The breakdown of patients undergoing manometry or pH monitoring is shown in Table 2. Only patients selected for operation are represented in Table 2; so by definition, 100% of the pH tests in Table 2 were positive. Eighteen of the 115 patients (16%) who underwent manometry had evidence of dysmotility; the causes were scleroderma (3), severe erosive esophagitis (6), and indeterminate (9). All patients in this series, including those with scleroderma or mild-to-moderate esophageal dysmotility, underwent laparoscopic floppy Nissen fundoplication: patients with severe dysmotility or no objective evidence of GERD did not undergo operation (data not shown).

There were four conversions (0.6%) secondary to perforation (3) and adhesions (1); there was no mortality. None of 19 patients with esophageal dysmotility on preoperative manometry had worse symptoms postoperatively; on the contrary, 8 of these patients reported improvement of dysphagia. Temporary postoperative dysphagia (duration 3 months or less) and temporary odynophagia occurred in 201 and 18 patients (32% and 2.9%), respectively. Five patients (0.8%) had persistent postoperative dysphagia (duration greater than 3 months) from slipped fundoplication (2), excessively tight cruroplasty (1) or fundoplication (1), or no identifiable cause (1); these five patients were in the selective evaluation group. The patient with postoperative dysphagia of no identifiable cause underwent postoperative esophageal manometry, which did not demonstrate esophageal dysmotility. This patient subsequently was reoperated on by another surgeon who performed a partial fundoplication; unfortunately, the patient still complained of dysphagia after reoperation. The three scleroderma patients had postoperative improvement in their symptoms and did not suffer from operative side effects.

The average followup period was 4.3 years (range 0.5 to 9 years); ie, all patients had a minimum followup (either clinic visit, phone call, or communication with the referring physician) of 6 months. A minimum followup of 1 year was obtained in 615 patients (98%). Sixteen patients (2.5%) out of the entire group

Table 3. Charge Reduction Secondary to the Use of Selective Preoperative Evaluation

Test	Billing cost per test (\$)	Billing for selective utilization (\$)	Billing if routine evaluation was used (\$)	Savings based on selective utilization (\$)
Manometry	1,200	102,000 (n=85)	717,600 (n=598)	615,600
pH monitoring	1,250	110,000 (n=88)	747,500 (n=598)	637,500
Total savings				1,253,100

The estimated billing cost (in 2002) for manometry and pH monitoring was obtained from the University of Nebraska Medical Center, and is the sum of the professional fee and hospital charge. The patient numbers (n) are from the selective evaluation group.

(n = 628) had recurrent reflux from hiatal hernia recurrence, “slipped” fundoplication, or an ineffective valve. Fourteen of the patients with recurrent reflux (88%) developed symptoms within the first 6 months after the procedure; the other two patients with recurrent reflux presented within 12 months. Good-to-excellent patient outcomes (Visick I-II)¹⁴ in the selective evaluation group were recorded in 568 of 598 patients (95.0%). The estimated charge reduction secondary to the use of the selective algorithm was estimated to be \$1,253,100 (see Table 3). This charge reduction translated into an estimated reduction in collection of \$395,000.

DISCUSSION

Selective use of preoperative testing resulted in an acceptable rate of good-to-excellent patient outcomes compared with published results of minimally invasive antireflux surgery.¹⁵ There were no treatment failures that could be attributed to the nonperformance of either esophageal manometry or pH monitoring. The selective algorithm yielded a substantial cost savings compared with theoretical routine use; additionally, an immeasurable degree of patient inconvenience and discomfort was avoided by the selective algorithm. Selective use of pH monitoring and esophageal manometry was an acceptable method of preoperative evaluation in our series of laparoscopic funduplications.

The rates of persistent dysphagia and recurrent reflux in this series were 0.8% and 2.5%, respectively; these rates are somewhat lower than those cited in the recent literature.¹⁵ The low rate of persistent dysphagia might be attributable to the technique of floppy fundoplication¹⁰ and wrap anchorage, which was routinely used (see Methods section). We anchor the wrap only to the crura; ie, the esophagus is not incorporated. If the fundoplication is kept free from the esophagus, then an assessment of the looseness of the completed wrap can be performed. We believe this assessment is vital in preventing postoperative dysphagia. The low rate of recurrent

reflux might, in part, be secondary to the use of prosthetic reinforcement of hiatal herniorrhaphy in patients with a large hiatal defect.¹³ Recurrent hiatal herniation is a main cause of failure for antireflux procedures.¹⁵ Our recurrence rate after hiatal herniorrhaphy with prosthetic onlay has been zero.

The diagnosis of GERD is fraught with difficulties, and a misdiagnosis can lead to improper therapy, such as an ill-advised antireflux procedure. Routine preoperative manometry and pH monitoring have been advocated to prevent misdiagnosis of GERD. Perdakis and colleagues¹⁶ concluded that pH monitoring and esophageal manometry altered clinical decisions in the management of GERD, and Campos and associates¹⁷ found, in a retrospective review of antireflux procedures, that a positive 24-hour pH test was most predictive of a good postoperative outcome. Waring and coworkers⁶ reported that approximately 10% of patients had their surgical procedure altered because of manometry; patients with impaired esophageal clearance underwent a partial fundoplication. These nonrandomized studies evaluated the use of pH monitoring and manometry, and found these tests helpful; our nonrandomized study evaluated the nonuse of these tests based on an algorithm, and we found that the tests did not appear necessary within the boundary of the algorithm. The theoretical concern for misdiagnosis of GERD was not seen in our series. We attribute this primarily to adherence to the algorithm in Figure 1.

Patients with abnormal esophageal body motility can suffer from dysphagia after a 360-degree fundoplication.¹⁸ Notwithstanding these observations of others, we chose to perform a floppy 360-degree fundoplication on all patients in our series, and we observed an acceptable 0.8% rate of persistent postoperative dysphagia. We concluded that the presence of mild-to-moderate esophageal dysmotility might not be a strict contraindication for a complete, floppy fundoplication. Based on our series, it might be argued that manometry has little value in the

preoperative evaluation of patients with GERD because the manometry results did not seem to affect our operative treatment. Such a conclusion would ignore the small subset of patients with severe esophageal dysmotility (Fig. 1), whom we would not operate on (data on these patients were not recorded for this manuscript). Manometry would be relevant in identifying these patients.

Although patients with atypical symptoms might have their surgical plan altered because of pH monitoring and manometry, our data demonstrate that patients with typical symptoms do not routinely need these studies. Tefera and colleagues¹⁹ found that a diagnosis of GERD could be established in patients with moderate-to-severe symptoms and endoscopic evidence of esophageal injury without further testing. Although pH monitoring is a sensitive test for acid reflux,²⁰ some false negatives will occur secondary to duodenogastroesophageal reflux.²¹ Manometry can identify other diseases that might have symptoms that overlap with GERD; a detailed history, however, should alert the examiner to the possibility of diagnoses such as achalasia, scleroderma, and “end-stage” GERD.^{22,23} These latter diagnoses also have a characteristic appearance on EGD and UGI.^{24,25} It has been our experience that an experienced and skilled gastrointestinal radiologist can identify clinically important esophageal dysmotility on videofluoroscopic UGI examination; this situation would make routine manometry somewhat redundant. We would not recommend following the algorithm in Figure 1 if the surgeon did not have access to expertise in gastrointestinal radiology. Drawing from the data in the literature and from our own series, a case can be made for selective use of preoperative manometry and pH monitoring, as summarized in Figure 1.

The results of our series indicate that selective use of preoperative pH monitoring and esophageal manometry in patients with GERD might be cost effective and safe. Our patient outcomes with selective test use were comparable with other published results of laparoscopic fundoplication. Although 24-hour pH monitoring and esophageal manometry might be useful in the patient with atypical symptoms or abnormal findings on upper gastrointestinal fluoroscopy, our position is that routine use of these tests is not necessary. It would be irresponsible of us to advocate complete abandonment of these tests; we merely want to examine the necessity of their routine use.

Author Contributions

Study conception and design: Frantzides, Carlson, Madan, Stewart, Smith

Acquisition of data: Frantzides, Carlson, Madan, Stewart, Smith

Analysis and interpretation of data: Frantzides, Carlson, Madan

Drafting of manuscript: Frantzides, Carlson, Madan

Critical revision: Frantzides, Carlson

Supervision: Frantzides

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Invited Commentary

Carlos A Pellegrini, MD, FACS
Seattle, WA

Dr Frantzides and his colleagues have told us that manometry and 24-hour pH monitoring should be used in only a small proportion of selected patients; they used it in 14% of their patients. They told us that the use of this selective approach did not appear to alter the end results of operations. Indeed, they report an impressive 97.5% cure rate for gastroesophageal reflux disease (GERD) at a mean followup of 4.3 years, with recurrent reflux in 2.5% of their patients.

I have recommended almost routine use of these tests in evaluating patients with GERD, which results in about 90% of our patients being tested. So we are pretty much at the other end of the spectrum. Perhaps we might agree that, in patients with typical symptoms, excellent response to proton pump inhibitors, and esophagitis grade II and above on endoscopy, the indication for operation will not be changed by the findings of

24-hour pH monitoring, but the majority of patients we see do not fit this description. My first question to the authors has to do with patients they decided not to operate on. How many patients, of those in whom you had doubt and were tested with 24-hour pH monitoring, were found to have normal acid exposure and not operated on? This is an important issue, because many of our patients are referred to us having failed proton pump inhibitor therapy, and we find that they do not have reflux. I am afraid that without measuring reflux objectively—we know that endoscopy is very subjective, particularly in grade I esophagitis, and biopsy does not help—they might have operated on a number of patients who did not need the operation. In fact, most previous reports have noted that symptoms alone often fail to differentiate true refluxers from those without reflux.

I am also concerned with their results. Again, a great number of papers now report that 15% to 30% of patients are back on proton pump inhibitors 5 years after the operation. What is so different about your results? Because there is no measurement of postoperative reflux, I am afraid most of us cannot accept the results you have shown.

The issue of testing becomes quite important, not only pre- but also postoperatively, particularly now when we are evaluating so many new techniques to control reflux. Unless we can define objectively and determine the magnitude of reflux preoperatively, I am afraid a number of patients with symptoms but without reflux are going to end up being treated. Similarly, it will be impossible to evaluate the result of the intervention because a number of these patients might experience simple placebo effects. In summary, I believe that we should encourage, rather than discourage, the objective determination of reflux before and after operation in these patients. It is the only way to make our practice credible to the rest of the gastroenterology community.

Reply

Constantine T Frantzides, MD, PhD, FACS
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We would like to thank Dr Pellegrini for his thoughtful reading of our paper, and we would like to take this opportunity to respond to his critiques.

Dr Pellegrini inquired about the group of patients we

did not operate on. We cannot answer this question directly, because we recorded data only on patients selected for operation. Nevertheless, we still would like to emphasize the importance of preoperative testing (manometry and pH monitoring), which, in our hands, is used selectively. Patients in whom a diagnosis was unclear after history and physical examination, endoscopy, and contrast fluoroscopy underwent manometry and pH monitoring so that appropriate management could be instituted. It was not our intent in this manuscript to discredit manometry and pH monitoring, which we rely on heavily, but to suggest a refinement in the use of these tests.

Dr Pellegrini was concerned that we might have operated on a number of patients in whom an operation might have not been indicated. He indicated that reliance on symptomatology, endoscopy, and contrast fluoroscopy alone for the diagnosis of gastroesophageal reflux disease (GERD) would result in an unacceptable rate of false positives. It is conceivable that operating on patients with a false-positive diagnosis of GERD would improve the operative outcomes, which might explain our excellent results. The response rate in our series, however, argues against the possibility that we were operating on patients with a false-positive diagnosis of GERD, because many of these hypothetical patients eventually would return with symptoms of whatever process they originally were afflicted with (ie, an antireflux procedure would not have been therapeutic). We have not noted failures in followup (average period, 4.3 years) attributable to a misdiagnosis of GERD.

Dr Pellegrini also inquired about patients who have failed proton pump inhibitor therapy. For practical purposes, the symptomatic patient who has failed proton pump inhibitor therapy either has a misdiagnosis of GERD or has been noncompliant with the medication

regime. If the patient has a misdiagnosis of GERD, then endoscopy presumably would not demonstrate esophagitis, so this patient would be referred for pH monitoring (according to our algorithm). If noncompliance is an issue, but the endoscopy is negative, this patient also would be referred for pH monitoring. It would seem that Dr Pellegrini's main concern involved the specificity of our routine preoperative evaluation (history and physical, endoscopy, and contrast fluoroscopy) in establishing the diagnosis of GERD. Because we have not noted failures in our followup period (see above) attributable to a misdiagnosis of GERD, we have been confident in our diagnosis of GERD using our routine preoperative evaluation.

In addition, Dr Pellegrini seemed to have difficulty believing our success rate (95% overall) during the 4-year followup period. Similar to Dr. Pellegrini, we have noted increasing reports about the failures of antireflux procedures during intermediate and longterm followup.¹ One of the primary causes of failure in these cases is recurrence of hiatal hernia. We have minimized such recurrence in our patients with selective use of prosthetic reinforcement of hiatal herniorrhaphy in patients who have had a large hiatal defect.² In all likelihood, our success rate after minimally invasive fundoplication for GERD would have been substantially lower if we had not used this reinforcement.

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