Background: Outcomes in patients having surgery for gastroesophageal reflux disease are most commonly determined by symptomatic assessment. Objective testing is usually reserved for symptomatic patients.

Hypothesis: To evaluate the relationship between symptomatic and objective outcomes after antireflux surgery.

Design: Retrospective analysis of prospectively collected data.

Setting: A tertiary care teaching hospital with a comprehensive esophageal physiology laboratory.

Interventions: A 360° (Nissen) fundoplication or a 270° (Toupet) posterior fundoplication was performed based on esophageal motility. Twenty-four–hour pH monitoring was used as a gold standard for assessing postoperative acid reflux.

Patients: Two hundred nine consecutive patients with preoperative and postoperative symptomatic and objective testing performed between January 1, 1996, and June 15, 2001.

Main Outcome Measures: Data on preoperative and postoperative symptoms, DeMeester scores, and esophageal motility were prospectively collected. Objective testing was performed after at least 6 months.

Results: The preoperative median DeMeester score was 50.0 (interquartile [IQ] range, 30.3-87.0). One hundred eighty patients had a Nissen and 29 patients had a Toupet fundoplication. After a median postoperative interval of 7.7 months (IQ range, 6.7-9.5 months), 174 patients (83.3%) had normal DeMeester scores (median, 2.2; IQ range, 0.8-5.0; P<.001). Of 58 patients (27.7%) who had reflux symptoms after surgery, only 17 (29.3%) had abnormal DeMeester scores (median, 36.9; IQ range, 748.4-20.0; P=.001). Eighteen (11.9%) of the 151 asymptomatic patients had abnormal DeMeester scores (median, 32.5; IQ range, 22.2-57.5; P=.006).

Conclusions: There is poor correlation between postoperative reflux symptoms and actual reflux (abnormal DeMeester scores). Surgeons must be careful to define their terms when reporting success or failure rates after antireflux surgery. Routine use of medical therapy for suppressing postoperative gastroesophageal reflux disease symptoms is not supported by these data, and postoperative therapy should be based on objective testing only.

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Gastroesophageal reflux disease (GERD) is the most common upper gastrointestinal tract disorder in the United States.1 Most patients with symptomatic GERD are treated empirically with anti-peptic medication. Patients who fail or refuse medical therapy, or those with severe mucosal injury, are usually considered to be possible candidates for surgical treatment.2

Laparoscopic antireflux surgery (ARS) is currently the most common operative approach for the treatment of patients with GERD. Referrals for surgery have dramatically increased since the introduction of laparoscopic approaches for fundoplication. The continued popularity of laparoscopic ARS depends on documentation of good outcomes. Patients and referring physicians have been encouraged by early studies2-5 from specialty centers that describe an 87% to 98% success rate. There remains some skepticism in the medical community, however, regarding such excellent outcomes. Specifically, questions are raised about the ability to replicate these results outside of high-volume specialty centers,6 whether early results will translate into long-term success, and whether the outcomes reported by the investigator are accurate.7 Recent studies that show a high number of postoperative patients returning to chronic medical therapy are widely cited in the
medical community and lay press and underscore the need for a better understanding of postsurgical outcomes. Most studies on outcomes after laparoscopic ARS have been based on symptomatic assessment. Objective postsurgical testing is not considered part of routine follow-up because of its cost, the time involved, and, partly, the patient’s resistance to these uncomfortable tests. Postoperative testing, therefore, is typically applied only to patients with persistent or recurrent symptoms after surgery or those with preoperative documentation of severe mucosal injury or Barrett esophagus and is usually confined to a single test—usually upper GI tract endoscopy. It is common for symptomatic failures to be reported as “surgical failures” without confirmation using 24-hour pH testing despite the fact that similar symptoms are associated with most upper GI tract disorders.

The aim of the present study is to evaluate the accuracy of symptomatic assessment in predicting true failure of surgical treatment.

PATIENTS, MATERIALS, AND METHODS

PATIENTS

Patients were selected from a prospective database of individuals who underwent antireflux procedures between January 1, 1996, and June 15, 2001, at the Department of Minimally Invasive Surgery, Legacy Health System, Portland, Ore. Only patients with typical symptoms of GERD (heartburn, acid reflux, or both), preoperative objective testing confirming GERD, and postoperative objective follow-up with 24-hour pH testing of at least 6 months’ duration were included in the study. Patients undergoing antireflux procedures for pure paraesophageal (type II) hernia, mixed paraesophageal (type III) hernia with no preoperative subjective or objective documentation of GERD, achalasia, and a history of a previous fundoplication were excluded. A total of 209 consecutive patients were identified who satisfied inclusion criteria.

OUTCOME MEASURES

All preoperative, intraoperative, and postoperative data were recorded prospectively on standardized data collection forms, which were transferred into an electronic database system (Microsoft Access 97; Microsoft Corp, Redmond, Wash). All of the patients were interviewed by one of us (L.L.S.). Baseline demographics and preoperative clinical data were obtained at the first office visit. Symptoms of GERD were recorded on a scale from 0 to 4, with higher values representing greater frequency of symptoms (0 indicates never; 1, once or twice a month but not weekly; 2, once or twice a week but not daily; 3, daily but not continuously; and 4, daily and continuously [all the time]). Data were also recorded on preoperative 24-hour pH testing, manometry, upper GI tract endoscopy, and upper GI tract series. Data on operative time, intraoperative complications, American Society of Anesthesiologists grade, surgeon, and type of procedure performed were acquired at the time of surgery.

Patients were followed up after the first week and again at 2 to 6 weeks. At 3 months, patients were asked to complete a symptom assessment form and quality-of-life questionnaire (36-Item Short-Form Health Survey). Six months after surgery, all patients were asked to undergo esophageal manometry and 24-hour ambulatory pH testing at no charge. Symptom assessment forms were administered at each visit. Long-term follow-up of all patients was performed by telephone interview every year using the standardized symptom form, and symptomatic patients returned for further testing.

Twenty-four-hour pH testing was used as the gold standard to determine failure of surgical treatment. DeMeester scores greater than 14.7 were considered abnormal. Sensitivity, specificity, and positive and negative predictive values of symptomatic assessment in predicting postoperative acid reflux were determined for typical GERD symptoms. Likelihood ratios for negative and positive symptomatic assessment were calculated to determine the odds of ruling out or ruling in true pathologic reflux. Only symptoms of heartburn or acid reflux or a combination of both were considered typical GERD symptoms as these have been shown to have a significant correlation with the results of 24-hour pH testing. Esophageal manometric data were used to further characterize the outcomes.

The means of all continuous variables were compared using appropriate parametric or nonparametric tests. Categorical variables and proportions were compared using the x² test or the Fisher exact test. A P<.05 is considered statistically significant. All data are reported as percentage of patients, mean±SD, or median (interquartile [IQ] range).

INTERVENTIONS

All procedures were performed by or under the supervision of one of the senior investigators (P.D.H. or L.L.S.). Five trocars were placed in the upper abdomen. The gastroesophageal junction and mediastinal esophagus were widely mobilized while preserving both vagus nerves. The short gastric vessels were routinely divided. Both crura were approximated posteriorly, and a floppy Nissen fundoplication (360°) was performed if preoperative esophageal motility was normal. In patients with impaired esophageal motility (>50% dropped peristalsis or peristaltic amplitudes <30 mm Hg in all manometry leads), a posterior Toupet fundoplication (270°) was considered. All wraps were fashioned around the esophagus after carefully advancing a 54-58 French bougie into the stomach.

Esophageal manometry was performed using an 8-channel water-perfused catheter. The lower esophageal sphincter (LES) was located using a stationary pull-through technique, and the resting LES pressure, LES relaxation, and esophageal body contractility were determined for a minimum of 10 wet swallows. A commercial software program (Synectics/Medtronics, Stockholm, Sweden) was used for the interpretation of manometry tracings and for data analysis.

Twenty-four-hour pH testing was performed after discontinuation of all peptic medications for 5 days and by positioning the pH electrode 5 cm above the upper border of the LES. The data were recorded by a portable digital data-logger for 24 hours while the patient was ambulatory and were analyzed for calculating the DeMeester score using a standard software program (GastroSOFT; Synectics/Medtronics).

RESULTS

Of 209 patients, 109 (52%) were men. The mean patient age and weight were 52±13 years and 85±14 kg, respectively. All of the patients had “typical” symptoms (heartburn and reflux) of GERD before surgery and abnormal 24-hour pH scores. The median preoperative symptom scores for heartburn and acid reflux were 3 (IQ range, 2-4) and 2 (IQ range, 0-3). The median preoperative DeMeester score was 50.0 (IQ range, 30.3-87.0), and the median preoperative LES pressure was 9 mm Hg (IQ range, 5-15 mm Hg). Twenty-seven patients (12.9%) had poor esophageal body motility documented by having more than 50% dropped peristalsis. Four patients had severely hy-
patients, No.

A Nissen fundoplication was performed in 180 patients (86.1%), and 29 (13.9%) underwent posterior Toupet repair. Mean operative time was 146.7 ± 57.0 minutes, and mean intraoperative blood loss was 66.2 ± 52.0 mL. There were no conversions to open surgery in the series, but 2 patients sustained gastric injuries during surgery. Both injuries were repaired with laparoscopic sutures, and there were no sequelae in either patient. Another patient had blood loss of more than 500 mL from a liver retraction injury but did not require a transfusion.

Median follow-up duration for objective testing was 7.7 months (IQ range, 6.7-9.5 months). After surgery, 174 patients (83.3%) had normal DeMeester scores (median, 7.7 months; IQ range, 6.7-9.5 months). After surgery, 174 patients (83.3%) had normal DeMeester scores (median, 0.8-5.0). One patient (86.1%), and 29 (13.9%) underwent posterior Toupet repair. Mean operative time was 146.7 ± 57.0 minutes, and mean intraoperative blood loss was 66.2 ± 52.0 mL. There were no conversions to open surgery in the series, but 2 patients sustained gastric injuries during surgery. Both injuries were repaired with laparoscopic sutures, and there were no sequelae in either patient. Another patient had blood loss of more than 500 mL from a liver retraction injury but did not require a transfusion.

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Figure 1. A, Proportion of patients with normal (n=41) and abnormal (n=17) DeMeester scores among postoperative symptomatic patients (n=58). B, Proportion of patients with normal (n=133) and abnormal (n=18) DeMeester scores among postoperative asymptomatic patients (n=151).

Table 1. Preoperative Subjective and Objective Data in 209 Patients*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Median (Interquartile Range)</th>
<th>Patients, No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Heartburn Score</td>
<td>Reflux Score</td>
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<tr>
<td>True positive</td>
<td>3 (2-4)</td>
<td>2 (1-3)</td>
</tr>
<tr>
<td>False positive</td>
<td>3 (2-4)</td>
<td>2 (0-3)</td>
</tr>
<tr>
<td>True negative</td>
<td>3 (2-4)</td>
<td>2 (0-3)</td>
</tr>
<tr>
<td>False negative</td>
<td>3 (2-4)</td>
<td>2.5 (1-3)</td>
</tr>
<tr>
<td>Nissen Fundoplication</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Toupet Fundoplication</td>
<td>37</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>119</td>
<td>14</td>
</tr>
</tbody>
</table>

*LES indicates lower esophageal sphincter. †Value is significantly higher than the true-negative (P<.001) and false-positive (P<.001) groups. ‡Value is significantly higher than the true-negative (P=.02) and false-positive (P=.01) groups.
(daily, grades 3 and 4) were considered; however, sensitivity actually decreased to 0.15 in this case (Table 2). The odds of having pathologic reflux were better when patients having only daily symptoms were considered (likelihood ratio of positive symptoms, 2.85) compared with patients with symptoms of all grades (likelihood ratio of positive symptoms, 2.06). However, the likelihood of ruling out the disease was worse when only patients having daily symptoms were considered (likelihood ratio of negative symptoms, 0.89 vs 0.67) (Table 2).

**COMMENT**

Heartburn and acid regurgitation are considered to be the cardinal symptoms of GERD. However, these symptoms have been found to have a low specificity and sensitivity for the actual diagnosis of GERD. Long-term pH monitoring of the lower esophagus is the best objective tool for measuring abnormal esophageal mucosal acid exposure and is the most recommended test for confirming the diagnosis of GERD.

A 24-hour esophageal pH monitoring system quantifies esophageal mucosal acid exposure and provides this information as several variables. The composite scoring system developed by Johnson and DeMeester and the total time that the pH is less than 4 provides the best assessment for esophageal acid exposure. We used the composite DeMeester scoring system as a gold standard to evaluate our patients because of its higher accuracy and its applicability to both men and women.

In this review of 209 patients with GERD—all with classic symptoms and documented acid reflux—70% of the patients who complained of continued GERD symp-

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**Figure 2.** Median preoperative and postoperative DeMeester scores in the 4 groups. Preoperative DeMeester scores were significantly higher in the true-positive ($P < .001$) and false-negative groups ($P = .01$), and there was no statistically significant difference in the postoperative values between these 2 groups ($P = .88$). Error bars represent interquartile range.

**Figure 3.** Preoperative and postoperative DeMeester scores for individual patients in the 4 groups. A, True-positive patients ($n = 17$). B, False-positive patients ($n = 41$). C, False-negative patients ($n = 18$). D, True-negative patients ($n = 133$). $P < .001$ for all.
toms at intermediate follow-up, in fact, had perfectly normal 24-hour pH values. Furthermore, 18 (11.9%) of the 151 asymptomatic patients had significantly higher DeMeester scores, and no statistically significant difference was found in the mean DeMeester score between this group and the symptomatic patients with abnormal DeMeester scores ($P = .88$).

This study shows that symptomatic assessment has relatively high specificity and a high negative predictive value but low sensitivity and a low positive predictive value for abnormal 24-hour pH study findings in the postoperative setting. Our data demonstrate that postoperative symptomatic assessment is an insensitive tool to diagnose failure of the laparoscopic ARS and has a low predictive value of positive assessment and poor diagnostic accuracy. Specifically, symptoms incorrectly identified many patients as having recurrent or residual GERD who had normal pH values on objective testing. This represents approximately 20% of the patients (n = 41) in our study population with postoperative symptoms suggestive of GERD but normal 24-hour pH test results. There were no statistically significant differences in the postoperative symptom frequency scores between false-positive and true-positive groups. All of the patients in these 2 symptomatic groups demonstrated a decrease in the severity of symptoms and a significant improvement in their resting LES pressure, suggesting good surgical correction.

Although the role of 24-hour pH testing has been well recognized as the absolute best test to demonstrate pathologic reflux, recurrent or persistent symptoms after surgery are frequently regarded as failures by surgeons (and more so by their patients) without any objective testing to confirm acid reflux. Most surgeons believe that the primary goal of ARS is to improve quality of life and eliminate the symptoms of GERD. Postoperative testing is usually recommended only in patients with persistent or recurrent symptoms after ARS. It is not offered to asymptomatic patients, as routine testing of these patients seems to be unreasonable, particularly in this era of cost containment. In addition, it is commonly presumed that asymptomatic patients have good physiologic control of acid reflux irrespective of the fact that postoperative GERD-specific symptoms and quality of life have poor correlation with the results of postoperative pH testing. Our results suggest that this approach is not appropriate, since most symptomatic patients after surgery will have no pathologic reflux as determined by pH study, whereas a portion of asymptomatic patients will actually have significant pathologic reflux.

The present study is not an outcomes analysis, and the higher subjective and objective failure rates do not represent true outcomes of ARS at Legacy Health System. Although we routinely attempt to have all of our patients return for postoperative objective testing after 6 months, it is our experience that symptomatic patients and patients with severe complicated GERD are more likely to return for postoperative objective testing than asymptomatic patients. There is therefore a selection bias in this study for a group of patients with complicated GERD and recurrent symptoms. It is uncertain what the utility of routine objective assessment might be in the entire population of patients with postoperative GERD.

Another drawback of the study is that median follow-up was short (7.7 months). This might explain, however, why postoperative symptoms were noted to be more frequent in patients with worse preoperative disease, which could result from residual or healing esophagitis in patients with severe disease in the short term. With time, such symptoms might resolve or dramatically improve. Regardless of the short follow-up in the present study, early pH testing should still distinguish between such patients and those with inadequate antireflux barriers, and could guide further treatment and minimize the time before appropriate treatment can be initiated.

One explanation for at least a portion of patients who are symptomatic with negative pH study findings might be the presence of alkaline reflux. We did not use bili-rubin probes to determine whether duodenogastroesophageal reflux might be a component of disease in such

![Figure 4. Median preoperative and postoperative resting lower esophageal sphincter (LES) pressures in the 4 groups. There was significant improvement in each group ($P < .001$), and there was no significant difference in the postoperative mean LES pressure among the 4 groups ($P = .06$ for true positive vs true negative; $P = .09$ for true positive vs false positive; $P = .65$ for false negative vs true negative; $P = .06$ for false negative vs false positive). Error bars represent interquartile range.](image)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Specificity</th>
<th>Sensitivity</th>
<th>Predictive Value</th>
<th>Likelihood Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>For Negative Symptoms</td>
<td>For Positive Symptoms</td>
</tr>
<tr>
<td>All patients (grades 1-4)</td>
<td>0.77</td>
<td>0.48</td>
<td>0.29</td>
<td>0.88</td>
</tr>
<tr>
<td>Patients having daily symptoms only (grades 3-4)</td>
<td>0.94</td>
<td>0.15</td>
<td>0.35</td>
<td>0.85</td>
</tr>
<tr>
<td>Nissen fundoplication patients only</td>
<td>0.77</td>
<td>0.38</td>
<td>0.19</td>
<td>0.88</td>
</tr>
</tbody>
</table>

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patients, but such a tool might be well applied to this subset of patients. At the very least, outcomes studies using endoscopy in this and other subsets of patients might define the degree to which an incompetent antireflux mechanism or complications such as wrap herniation or slipped Nissen fundoplication contribute to their symptoms.

Of greater concern are the 12% of patients who are asymptomatic but who had significantly high DeMeester scores after surgery. These patients are certainly at risk of disease progression. Symptomatic assessment does not identify this subgroup, whereas routine postoperative objective testing would allow for early identification of such patients before the onset of severe complications of GERD.

Our results, therefore, argue for the use of routine objective testing in the postoperative setting for symptomatic patients, many of whom will not have abnormal reflux on pH testing, and for asymptomatic patients, some of whom will have significant reflux. In addition, these results act as an important guide for physicians involved in the follow-up of patients after ARS. Symptomatic assessment is not an accurate predictor of the presence or absence of recurrent or persistent reflux disease, and it is important for physicians caring for such patients to realize this and to alter diagnostic workup appropriately rather than starting antipeptic medications empirically. Finally, these data have important implications for analysis of the literature addressing the efficacy of ARS. Investigators typically use symptomatic assessment as a primary outcome measure of the competency of the antireflux mechanism after fundoplication. These data suggest that symptomatic assessment is inaccurate and that objective testing should be applied more liberally in the analysis of outcomes after ARS.

In conclusion, based on these data, symptomatic assessment seems to be a poor predictor of true pathologic reflux in patients who have had ARS. Postoperative GERD symptoms actually indicate acid reflux in only 30% of patients and are not even accurate to rule out acid reflux in patients who are completely free of symptoms after surgery. This is critical information for all involved in the care of these patients. Surgeons should keep this in mind when interpreting their own results and outcomes literature, most of which relies on symptomatic follow-up. Gastroenterologists and primary care physicians also need to understand that most patients who complain of postoperative reflux or heartburn do not have pathologic reflux. These patients need objective testing to determine the actual cause of their symptoms, with treatment directed specifically to the test findings.

This paper was presented at the 73rd Annual Meeting of the Pacific Coast Surgical Association, Las Vegas, Nev, February 16, 2002, and is published after peer review and revision. The discussions are based on the originally submitted manuscript and not the revised manuscript.

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REFERENCES


DISCUSSION

Peter F. Crookes, MD, Los Angeles, Calif: I have 4 comments and 4 questions for the authors. The first thing that I would like to do is commend the authors for having studied 209 patients with 24-hour pH after surgery. Anybody who has tried to do this type of work will know what a praiseworthy achievement that is. Many of our patients will say when they are coming back for follow-up that the 24-hour pH was the most horrific component of their entire experience, even worse than the operation itself, and it is difficult to persuade them to un-
dergo it. Maybe in the future the new Bravo probe, which is a wireless 24-hour pH monitor, will make this a little easier for us, but for the time being this is all we have, and I commend the authors for having studied the patients so intensively.

The second thing is that this message ought to be carried not just to surgeons but to the wider community of gastroenterologists and family practitioners. It is a very common thing, as the authors probably have found out, for patients to return for follow-up already back on proton pump inhibitors. This seems to be something of a knee-jerk response in the gastroenterology community. The patients go back to their family doctor and they are immediately restarted on Prilosec or Prevacid. Even in my own institution I have had a patient with a total gastrectomy who was put back on Prevacid by one of my colleagues!

So this message ought to be carried back to a wider community and when it is published in the Archives of Surgery it should be extended or summarized in some of the other AMA journals as well because the striking message is that most people who come back with so-called reflux symptoms do not in fact have failure of the operation due to recurrent reflux.

Now the third point I want to make is that even in those patients with postoperative reflux, the reflux that was objectively detected was very much reduced from the reflux they started with preoperatively. These true positives were by and large the most severe refluxers with the lowest sphincter pressures and the highest DeMeester scores, sometimes even 2-300. I don't think I have ever seen a DeMeester score of 300, but obviously those are the worst refluxers. One of the things that interested me in the paper is that if you looked in the tables, you had 180 Nissens and 29 Toupetts. But only 8 of the Nissens were in this false-positive group; that was 8 out of 180, which is about a 5% risk, whereas 8 of the 29 Toupetts were in the positive refluxing group, which means that if you do a Toupet, there is about a 30% chance that they will come back with reflux. I think this emphasizes the inferior protective ability of partial wraps in patients with severe reflux.

I was provided with a copy of the printed paper and I note that you speculate about the possibility of bile reflux. I would just like to make the point that bile reflux on its own as an explanation for symptoms when the 24-hour pH is negative is an unlikely explanation. It is very rare to get bile reflux on its own in the absence of concomitant severe acid reflux.

So here are my questions for the authors. If the symptoms of heartburn and regurgitation are so hopelessly inaccurate for diagnosing true reflux postoperatively, is there any symptom which can help you? I would speculate, and I ask if you have data to comment on this, that if patients complain that they are totally unable to belch or unable to vomit, probably they are not going to be refluxers and they will have a negative DeMeester score. I don't know if you have data to support that, but it would be interesting to know.

The second thing is if you successfully exclude reflux, which you did in 90 out of your 37 symptomatic patients, the patient may then inquire, “Well, if it isn’t reflux, what is it?” You show them this beautiful flat tracing and say, “Look—you have no reflux.” I would ask you, what was the cause of their symptoms?

My third question is, “Was there any anatomical recurrence? Did any studies, short of having to subject them to 24-hour pH, such as endoscopy or barium studies, tell you the reason why they were having symptoms?”

The last thing is that if you are faced now with a patient with extremely severe reflux, for example, with a DeMeester score of more than 100, will you now, as a result of this study, warn the patient ahead of time that they are perhaps going to need to remain on medical treatment afterward? Perhaps they will need to continue their proton pump inhibitor afterward or they will need a Nissen rather than a Toupet. Will the presence of that extremely severe reflux change your operative strategy? These are my questions.

Dr Hansen: Dr Swanstrom, who was going to be answering the questions, was unavailable to be here today. Because I am not a member, Dr Susan Orloff has kindly agreed to come up and formally close the paper. I would like to thank Peter for his very insightful and kind comments, and I will do my best to answer his 4 questions.

The first question is, if symptoms such as heartburn and reflux are not terribly helpful, are there other symptoms which are more helpful, and the answer to that is, that is not something that we have evaluated yet. We have a tremendous amount of data in the database. We prospectively collected a series of 30 questions on preoperative symptoms on these patients, and I certainly would agree that an inability to either vomit or to burp is probably an indication that their wrap is mechanically intact, and that may be a clue but we don't have any better symptoms at this point.

Second question: If we excluded reflux, then what is causing their symptoms? This is going to be one of our next topics for evaluation. Most of these patients are evaluated. As soon as we hear about a patient who is again refluxing, we bring them back in; we usually go ahead and perform the pH manometry fairly quickly on them. If that looks like it is intact, we would move on to an EGD to look anatomically again at whether or not the wrap looks like it is intact internally. We would probably also move on to studies such as gastric emptying studies and find out if there are other mechanical problems or functional problems which are causing their symptoms. One of the issues may be that certain of these patients, especially the patients who had DeMeester scores in the 200 and 300 range, their esophagi may have been sensitized in a way where they just have very severe symptoms with the smallest amount of acid reflux. They may behave differently than say a patient who has had a DeMeester score of 40 and hasn't had such longstanding or severe disease. Again, that is a question we don't know yet. We may find this out in a future study.

Other studies again to look at symptoms postoperatively, again as I have just mentioned would be EGD and gastric emptying and in patients who have quite severe reflux, DeMeester's of 2 and 300, do we warn the patients preoperatively? The answer is yes. We definitely feel that those are the patients who are going to be at the highest likelihood for recurring. If you look at the mean DeMeester scores postoperatively in the patients who were true failures, the average preoperative DeMeester score for those patients was around 80 to 90. The average postoperative score was around 40. So we are making an anatomic improvement in those patients, but it is not enough to get them to be symptom free or into the nonrefluxing category. I hope that answers your question.