Complications and Results of Primary Minimally Invasive Antireflux Procedures: A Review of 10,735 Reported Cases

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The number of antireflux procedures performed for gastroesophageal reflux disease in the United States has increased in the past decade. In a sampling of US hospitals by the National Center for Health Statistics, the number of patients discharged with the International Classification of Disease (ICD-9-CM) classification 44.66 ("Other procedures for creation of esophagogastric sphincteric competence," ie, fundoplication) in the years 1988, 1993, and 1998 was 13,000, 22,000, and 40,000, respectively.[1] It would be safe to say that the majority of these antireflux procedures are now minimally invasive. The trend for more laparoscopic antireflux procedures also has been seen in Europe.[2] The current approach of choice for surgical treatment of gastroesophageal reflux disease is a minimally invasive transabdominal antireflux procedure.[3,4] During this evolution of operational approach there have been untoward events associated with the minimally invasive antireflux operation. There is a growing need to audit the results of minimally invasive antireflux procedures because there has been (in the medical literature) a question of its efficacy,[5-8] and also because of the development of novel endoscopic procedures to reproduce a sphincter mechanism in the lower esophagus,[9,10] which potentially could compete with laparoscopic antireflux surgery. In this review the results of primary laparoscopic antireflux procedures will be examined (international experience, English-language literature) with an emphasis placed on the description of perioperative complications and primary procedure failures. Data on redo procedures also will be analyzed to determine the causes for failure of primary minimally invasive procedures. Recommenda-

tions for avoiding the complications and failure of the primary minimally invasive antireflux procedure will be described.

REVIEW METHOD
A PubMed Medline (National Library of Medicine) search was performed using various combinations of these keywords: "gastroesophageal reflux disease," "antireflux procedure," "Nissen," "laparoscopic," "minimally invasive," "reoperation," and "redo." A full copy of each English-language article identified in this search was obtained. Papers that had the primary intent of describing a clinical series (primary or redo) or trial of antireflux procedures were chosen for the databases (see subsequent text). If an article from a non-English language journal contained sufficient data in its translated abstract, then the abstract was included in the appropriate database. In addition, six major surgery journals (*American Journal of Surgery*, *Annals of Surgery*, *Archives of Surgery*, *British Journal of Surgery*, *Journal of the American College of Surgeons*, and *Surgery*) from 1995 onward were searched manually for relevant articles not found by the electronic search.

Two databases of relevant papers were constructed using Microsoft Excel (Microsoft Corp, Redmond, WA). Database 1 contained data on primary laparoscopic antireflux procedures, and database 2 contained data from redo operations after a primary minimally invasive procedure. The tables of data contained in this review are derived from these two databases. Statistical analysis was performed within the Excel program.

GENERAL CHARACTERISTICS OF THE PAPERS REVIEWED
Database 1
More than 400 papers were identified by electronic and manual searching; ultimately 41 papers, published from 1993 to 2000, were entered into database 1 (primary procedures), as listed in Table 1. The main criteria for a paper to be included in database 1 was that the article

described a series of primary minimally invasive procedures in a reasonably unselected group of reflux patients. Most of the papers identified with the search were not appropriate for database 1 because they were either case reports, small series (<20 procedures), reoperative series, paraesophageal hernia series, earlier updates of a current series, a series with an inadequate description of complications and outcomes, or a series with a selected patient group (eg, patients with only Barrett's esophagus). The problem with including series with a selected patient group (such as those with Barrett's) into this analysis is that such a series usually describes a group of patients that already has been described in a previous publication. Some authors simply divide their total group of reflux patients into subgroups (eg, those with Barrett's) for analysis and additional publication. Including such a series into our analysis would mean that some patients would get counted as having two (or more) primary minimally invasive procedures because we would have already included the primary publication describing the authors' total group of patients into our analysis. Another problem with including series with selected patient groups into our analysis is that this inclusion could introduce more bias into an analysis that already is biased: a retrospective review of published results. We have not included series with selected patient groups into our analysis.

The total number of primary laparoscopic antireflux procedures represented in database 1 was 10,489 (average procedures per article = 272; median = 107; range 22 to 1,470). The study settings in database 1 consisted of 29 academic centers, 8 nonacademic centers, and 4 multicenter studies. The distribution of study design in database 1 was 3 randomized control trials, 5 nonrandomized comparisons, and 33 noncomparative studies (either retrospective or prospective analysis without controls). The study settings of the three randomized control trials[11-13] were two academic centers and one multicenter trial.

Database 2

Database 2 (redo procedures after a primary minimally invasive antireflux operation) contained 246 cases (average procedures per article = 19; median = 14; range 3 to 71) derived from 14 papers published from 1995 to 2000 (see Table 1). The primary procedure had to be minimally invasive to be included in database 2. These cases were all reviewed retrospectively and nearly all were

Table 1. Manuscripts Describing Primary Minimally Invasive Antireflux Procedures and Redo Procedures after a Primary Minimally Invasive Antireflux Operation, 1993–2000

Database*	Reference numbers
1: Primary procedure, n = 41	11–14, 21–27, 33, 34, 45, 49–75
2: Redo procedure, n = 14	70, 76–88

*Two databases (primary and redo procedures) were established to organize the data from these papers.

performed at academic centers. There were some series of redo operations in which it was not clear if the primary procedure was open or laparoscopic; in these cases the article was not included in database 2. If a paper contained sufficient information to determine which approach (open versus laparoscopic) had which finding at reoperation, then this article would be included in database 2.

RESULTS OF PRIMARY MINIMALLY INVASIVE PROCEDURES (DATABASE 1)

Patient characteristics
The age range was 1 to 91 years (17 of 41 papers reporting); the mean of the average age reported in 15 of 41 papers was 47 years (range 40 to 52 years; median = 48). The average male to female ratio was 55:45 (14 of 41 papers reporting). Height and weight data generally were not reported.

Type of primary procedure
The frequency for each type of minimally invasive antireflux procedure performed in the primary setting (34 of 41 papers reporting, representing 6,542 cases) was 61.4% Nissen, 23.8% partial wrap (such as Toupet), 13.4% Nissen-Rossetti, and 1.4% other.

Duration of procedure
The operative time data are given in Table 2. Overall the average of the mean operating room times was 137 minutes (2.3 hours). The shortest duration for a primary minimally invasive antireflux procedure was 11 minutes;[14] what was done in this particular procedure is unclear. A plot of mean operating time versus year of article publication is given in Figure 1. There is a modest trend to a shorter average operating time with progressing year of publication.

Conversion to open procedure
The rate of open conversion during a primary minimally invasive antireflux procedure, as reported in 34 of 41

Table 2. Operating Room Time Data for Primary Minimally Invasive Antireflux Procedures, 1993–2000

Statistic	Minimum operating time (min)	Maximum operating time (min)	Mean operating time (min)
Average	53	307	137
Median	45	303	141
Range	11–120	172–455	59–206
Papers reporting (out of 41) (n)	18	18	26

Typically, a paper would report operating room time data as the mean of all procedure durations along with the range (shortest and longest procedure). The statistics in this table summarize the operating room time data from the papers reporting the data. For example, the average of the mean operating time (137 min) was obtained by tabulating the mean operating time from papers (26 of 41 reporting) in which this mean was available and then calculating the average of the means.

papers (representing 8,620 cases), was 271 (3.14%). The average conversion rate in these 34 papers was 3.70% (median 2.96%, range 0% to 14.3%). A plot of the open conversion rate versus year of article publication is given in Figure 2. There is a modest trend to a lower conversion rate with progressing year of publication, similar to what was demonstrated in Figure 1 with procedure duration.

The cause for conversion of a minimally invasive antireflux procedure to an open operation may be loosely divided into three categories: 1) complication, 2) surgeon comfort, or 3) equipment failure. Surgeon comfort is a broad category that encompasses such problems as adhesions from previous operations, difficult exposure secondary to a large liver, or failure to progress. In addition, the category boundaries are indistinct because surgeon comfort plays a variable role in the decision to convert after most complications or equipment failures.

The distribution among these categories, as reported in 25 of 41 papers (representing 135 open conversions), was 34.1% complication, 59.3% surgeon comfort, and 6.7% equipment failure.

Complications

Frequency data of complications associated with a primary minimally invasive antireflux procedure are given in Table 3. Side effects of the operation (eg, dysphagia, bloating) or late operative failures will be reported in subsequent text. The most common perioperative complication (1.3%) was early wrap herniation, generally defined as occurring within 48 hours of operation. Although considered a complication here, wrap herniation into the chest does not necessarily equate with operative failure. Some authors have described intentional placement of a wrap in the thorax, albeit during open fundoplication, with satisfactory patient outcomes.[15] The next
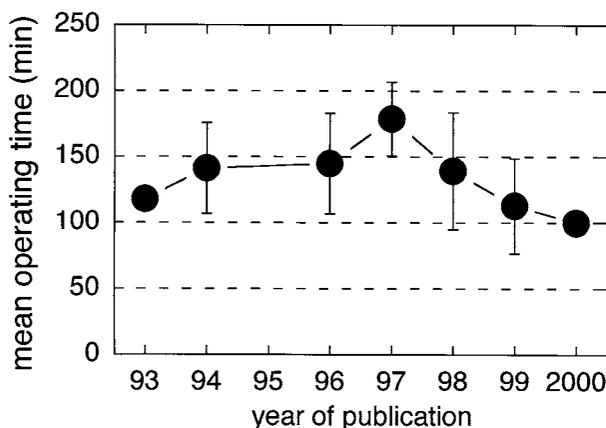

Figure 1. Operating time for primary minimally invasive antireflux procedures versus year of article publication (database 1). Each data point on the plot represents the average ± SD of the mean operating times from the articles published in that year. A data point without an error bar means that there was just one observation in the corresponding year.

Figure 2. Rate of open conversion of primary minimally invasive antireflux procedures versus year of article publication (database 1). Each data point on the plot represents the average ± SD of the mean conversion rates from the articles published in that year. A data point without an error bar means that there was just one observation in the corresponding year.
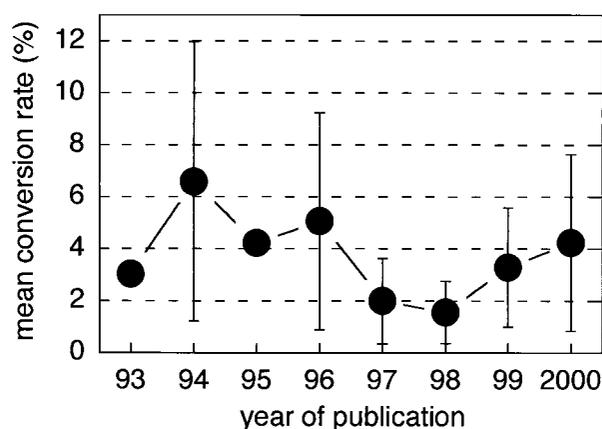
Table 3. Complications During Primary Minimally Invasive Antireflux Procedures, 1993–2000

Complication	Papers reporting (out of 41) (n)	Events (n)	Total procedures	Rate (%)
Wrap herniation (early)	33	85	6,214	1.3
Pneumothorax	33	67	6,543	1.0
Perforation	35	62	7,997	0.78
Hemorrhage	33	49	6,543	0.75
Pneumonia	33	37	6,543	0.57
Abscess	34	18	6,835	0.26
Splenic injury	33	16	6,543	0.24
Trocar hernia	33	12	6,543	0.18
Effusion	33	12	6,543	0.18
Pulmonary embolus	33	11	6,543	0.17
Ulcer	33	10	6,543	0.15
Atelectasis	33	10	6,543	0.15
Wound infection	33	7	6,543	0.11
Myocardial infarction	33	5	6,543	0.08
Splenectomy	33	4	6,543	0.06

Listed in decreasing order of frequency. Data derived from database 1.

most common complication (1.0%) was pneumothorax, which usually was secondary to a pleural tear during mediastinal dissection of a hiatal hernia. Other notable complications were perforation (0.78%), wound infection (0.11%), and splenectomy (0.06%). The location of a typical perforation was in the lower esophagus or gastric fundus and was secondary to manipulation, dissection, or instrumentation of this region. A low wound infection rate has been noted in other areas of minimally invasive surgery and this observation is reinforced here. Dramatically, the incidence of splenectomy with a primary antireflux procedure (0.06%) has dropped to about a hundredth of the incidence generally reported for the open antireflux operation (around 5%).[16-20]

Length of hospital stay

Length of hospital stay after a primary minimally invasive antireflux procedure was usually reported as a mean stay with the range. The average of the mean stay (28 of 41 papers reporting, representing 6,782 cases) was 2.8 days (median = 3.0 days); the shortest and longest mean length of stay were 1.0 and 6.4 days, respectively. A plot of mean length of stay versus year of publication is given in Figure 3. There is no real trend to a decreased length of stay with later publication, as might have been expected.
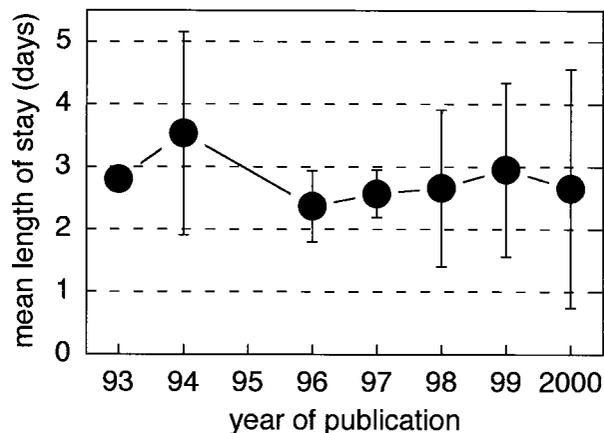

Figure 3. Length of hospital stay after a primary minimally invasive antireflux procedure versus year of article publication (database 1). Each data point on the plot represents the average ± SD of the mean hospital stay lengths from the articles published in that year. A data point without an error bar means that there was just one observation in the corresponding year.

Mortality

The mortality rate for 10,489 primary minimally invasive procedures (41 of 41 papers reporting) was 0.08% (8 deaths). The cause of death was myocardial infarction (n = 3),[21-23] duodenal perforation (n = 1),[24] gastric perforation (n = 1),[8] and unspecified (n = 3).[25-27]

Length of followup

The reporting of followup period after a primary minimally invasive antireflux procedure was variable. Some articles reported a range of followup, minimum followup, average followup, median followup, or a combination of these measures. The average minimum followup period was 5.6 ± 5.4 months (median = 3.0, range 0.5 to 24) in 27 of 41 papers. The mean followup period versus publication year is plotted in Figure 4; unfortunately only 15 of 41 papers reported mean followup data. There appears to be a modest trend to a longer followup period with a later publication year, but there is considerable variability in the data.

Reoperations

One simple method to approximate the failure rate of an operation such as a minimally invasive antireflux procedure, in which functional outcomes with symptom relief are vital, is to record the reoperation rate. In nearly every circumstance a reoperation is not a planned event and indicates that something about the original procedure failed, necessitating an extreme intervention, ie, a reop-
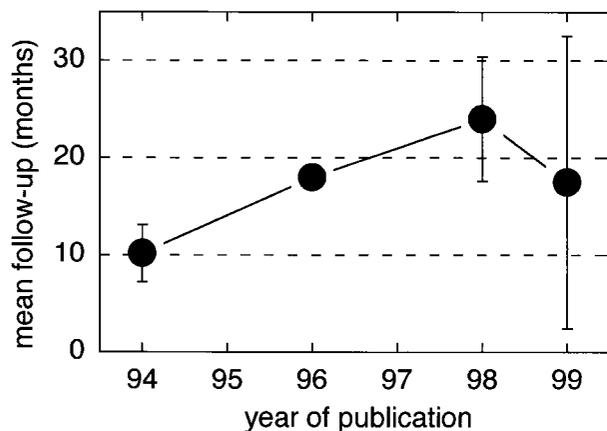
Figure 4. Followup period after a primary minimally invasive antireflux procedure versus year of article publication (database 1). Each data point on the plot represents the average ± SD of the mean followup periods from the articles published in that year.
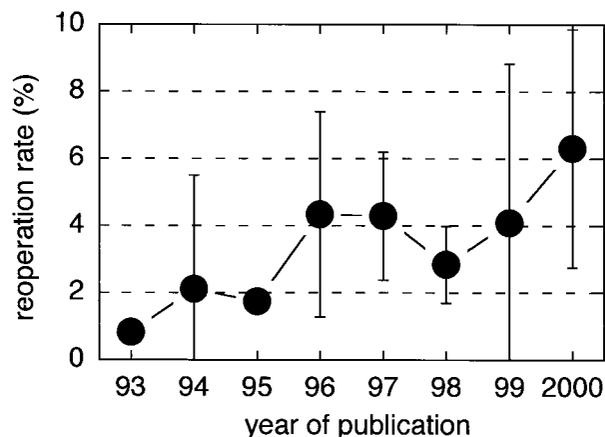

Figure 5. Reoperation rate after a primary minimally invasive antireflux procedure versus year of article publication (database 1). Each data point on the plot represents the average ± SD of the mean reoperation rates from the articles published in that year. A data point without an error bar means that there was just one observation in the corresponding year.

eration. Relying solely on the reoperation rate to determine the failure rate probably will underestimate the true failure rate because some patients have inadequate symptom relief or poor functional outcomes and qualify as an operative failure, yet never undergo reoperation. The reoperation rate for all of the primary minimally invasive antireflux procedures in database 1 (35 of 41 papers reporting on 9,433 procedures) was 2.77% (261 reoperations). The individual reoperative rate of each article ranged from 0% to 15.4% (mean = 3.78%, 3.24%). A plot of the average reoperation rate versus year of article publication is given in Figure 5. If anything, there is a trend to an increasing reoperative rate with progressive year of publication. If this represents a significant finding, one might speculate that it is secondary to more complete followup rather than degradation of operative technique, because the followup in later papers appears to be longer (see preceding text). Assuming that late operative failures occur, then more failures should be observed during a long followup period than a

short one; the occurrence of late failures has been observed, for example, with ventral hernia repair.[28,29]

Indications for reoperation

The indications for reoperation after a primary minimally invasive antireflux procedure (29 of 41 papers reporting on 6,050 primary procedures, of which 162 were reoperated on) are given in Table 4. The most common indication for reoperation in this group of 162 procedures was reflux (43%). The "other" category includes esophageal, gastric, and small bowel perforations, slipped Nissens, hemorrhage, and bloating. The reporting of duration between primary and redo procedure was incomplete.

Postoperative side effects

The postoperative side effects of antireflux procedures are well-described and include dysphagia, bloating, flatulence, and recurrent reflux; this last effect can be better described as a procedural failure rather than a side effect. Whether a side effect is temporary or persistent is an important consideration when determining the operative failure rate. For example, our own experience has indicated that temporary, mild bloating occurs in up to 100% of patients (unpublished results). Temporary side effects generally should not be counted when calculating an operative failure rate. On the other hand, persistent and disabling side effects are the most common cause of procedural failure after an antireflux operation (see sub-

Table 4. Indications for Reoperation after a Primary Minimally Invasive Antireflux Procedure, 1993–2000

Indication	n	%
Reflux	69	43
Dysphagia	40	24
Wrap herniation	29	18
Other	14	14
Total	162	100

Data derived from database 1.

sequent text). The more common side effects after a primary minimally invasive antireflux procedure are given in Table 5; these data represent the persistent (generally > 1 month duration) cases of bloating, recurrent reflux, and dysphagia. The bloating rates ranged from 0% to 45% (median 2.4%), the range for recurrent reflux was 0% to 14% (median 2.1%), and the range for dysphagia was 0.3 to 20% (median 3.4%). The presence or absence of other side effects, such as abdominal or chest pain, diarrhea, or flatulence was not consistently recorded.

The cause of persistent dysphagia after a fundoplication is usually related to the tightness of the fundic wrap around the esophagus. During Nissen fundoplication there might be a tendency to create a tighter wrap if the short gastric vessels are not taken down. Six of the 41 papers (881 cases; 311 Nissen-Rossetti procedures = 35.3%, 570 partial fundoplications = 64.7%) reported that the short gastric vessels were not taken down during the course of fundoplication; the incidence of dysphagia among these cases was 41 of 881 (4.65%). Fourteen of 41 papers (2,486 cases; 2,026 Nissen procedures = 81.5%, 460 partial fundoplications = 19.5%) reported that the short gastric vessels were taken down routinely, and the incidence of dysphagia among these cases was 64 of 2,486 (2.57%). In this uncontrolled comparison the rate of persistent dysphagia after a primary minimally invasive antireflux procedure is less when the short gastric vessels are divided (p = 0.0036, chi-square test). Presumably, ligation of the short gastric vessels allows for the creation of a relatively loose fundoplication.[20] Other factors that could contribute to postoperative dysphagia, such as an inadequately sized esophageal dilator, an overly long wrap, or abnormal preoperative manometry findings, were not adequately reported so no conclusions could be drawn about their role in producing dysphagia.

Rating of operative success and failure: Visick classification

Methods for reporting outcomes after a constructive procedure such as a Nissen fundoplication, in which quality of life is paramount, are not consistent from paper to paper. In this review, the utility of detailing the technique for assessing outcomes after a primary minimally invasive antireflux procedure in each of 41 papers would be questionable. Instead, the results will be analyzed using one standard technique of assessment: the

Table 5. Persistent (>1 = Month Duration) Side Effects of Primary Minimally Invasive Antireflux Procedures, 1993–2000

Side effect	Papers reporting (out of 41) (n)	Events (n)	Total procedures	Rate (%)
Bloating	16	239	2,539	9.41
Reflux	28	206	5,929	3.47
Dysphagia	32	188	7,487	2.51

Data derived from database 1.

Visick classification.[30] Visick followed 500 of his patients who underwent gastrectomy for peptic ulcer disease. His simple classification to assess the severity of symptoms in the followup period is given as follows:

> Grade I: No symptoms.
> Grade II: Mild symptoms relieved by care.
> Grade IIIs: Mild symptoms not relieved by care, but satisfactory.
> Grade IIIu: Mild symptoms not relieved by care. Unsatisfactory.
> Grade IV: Not improved. (Grades IIIu and IV are considered failures.)[30]

This classification system has been in use since its introduction.[31-37] If this system is applied to antireflux procedures, then in addition to relief of reflux symptoms it is important to document that the patient also does not have any new symptoms, such as dysphagia. To be classified as a grade I or II, a patient must have minimal or no recurrent reflux, no new problems such as dysphagia, and no reoperation. A reoperation generally is considered a treatment failure and is classified as grade IV.

The Visick classification after a primary minimally invasive antireflux procedure is given in Table 6. Only a subset of papers from database 1 contained information specific enough to allow Visick classification. Visick grade IIIu has been combined with grade IV in Table 6, so in this review grade IV represents all operative failures. Grades I and II generally are considered as operative successes, and the success rate for primary minimally invasive antireflux procedures in the subset of papers of Table 6 is about 90%. In general, success rates for open antireflux procedures in expert hands have run in the 90% to 95% range,[20,38-40] so the minimally invasive and open approaches appear comparable with regard to outcomes. The failure rate (3.5%) is, as predicted in preceding text, slightly higher than the reoperation rate for database 1 (2.77%, see preceding Reoperations section).

Table 6. Visick Grading[30] of Primary Minimally Invasive Antireflux Procedures, 1993–2000

Visick grade	Papers included (out of 41) (n)	Total procedures	Procedures with Visick grade (n)	Procedures receiving Visick grade (%)
I or II	12	3,008	2,725	90.6
III	7	1,071	69	6.4
IV*	16	4,165	147	3.5

Data derived from database 1.
*Visick grade IIIu and IV have been combined into grade IV.

ANALYSIS OF REDO PROCEDURES (DATABASE 2)

The utility of examining redo antireflux procedures is that the various causes of failure of a primary antireflux procedure are emphasized so a surgeon can "learn from someone else's mistakes." In deference to the purpose of this review, this section will concentrate on the causes of failure of primary minimally invasive antireflux procedures as determined from the findings of redo procedures; the technique and outcomes of redo fundoplication will not be discussed.

Patient demographics in redo operations

Patient age was the most consistently reported demographic, and that only in nine papers. The average of the mean patient age in this subgroup was 50.4 years (median 51.4 years, range 41 to 58 years).

Type of primary procedure in redo operations

The type of primary minimally invasive antireflux procedure performed was specified in 5 of 14 papers in database 2. In this subgroup representing 64 redo antireflux procedures the primary minimally invasive procedure was Nissen fundoplication in 83.3%, partial fundoplication (eg, Toupet) in 6.4%, Nissen-Rossetti fundoplication in 3.8%, and other procedure in 6.4%. In an attempt to determine the "denominator" for these

Table 7. Symptoms Before Redo Operation after a Primary Minimally Invasive Antireflux Procedure, 1993–2000

Symptom	n	(%)*
Dysphagia	66	58.9
Reflux	41	36.6
Paraesophageal hernia	16	14.3
Pain	9	8.0
Bloat	7	6.2
Other	6	5.4

Data derived from database 2. Information obtained from 7 papers (out of 14) of database 2, reporting on 112 redo procedures.
*Rates do not add up to 100% because some patients had more than one symptom.

failure rates and get a procedure-specific failure rate, it might be tempting to look up the raw procedure rates listed for database 1 in the section titled "Type of Primary Procedure." The failure rates just listed do not match the raw procedure rates in database 1; in particular the Nissen procedure appears to be responsible for a disproportionate share of failures. Databases 1 and 2 are not comparable in that the primary procedures in database 1 predominantly were performed at specialized clinics, but the primary procedures in database 2 (which all failed, by definition) were performed at both specialized and nonspecialized clinics. A statistical comparison of the procedure-specific rates between these two databases would not be meaningful and has not been done. The Nissen fundoplication might be the predominant procedure performed at nonspecialized clinics; this might be why the Nissen procedure makes up the vast majority of procedure failures.

Symptoms before redo operation

Preoperative signs and symptoms that led to a redo procedure after a primary minimally invasive antireflux operation are listed in Table 7. Dysphagia was the problem in the majority of patients. This might have been secondary to excessive tightness of the fundoplication or hiatal closure or to inadequately evaluated esophageal dysmotility. Objective preoperative data, such as manometric or pH probe data, were discussed frequently in general terms in the papers of database 2; unfortunately, the data rarely were given as actual numbers so no analysis of objective preoperative data from patients with a failed primary minimally invasive antireflux procedure can be given here.

The principal indication for reoperation in database 1 was recurrent reflux (43% of patients; see Table 4), but the principal indication for reoperation in database 2 was dysphagia (59%; see Table 7). It is difficult to reconcile this discrepancy with the available data. One can speculate that the discrepancy was secondary to the fact

that the primary procedures in database 1 versus 2 were performed by different subgroups of surgeons. That is, the primary procedures in database 1 were performed predominantly by experienced surgeons in tertiary centers, but surgeons of wide-ranging experience and expertise performed the primary procedures (which, by definition, all failed) in database 2. This suggests that the surgeons performing the primary procedure in database 1 were more liable to have an operative failure secondary to a nonfunctioning fundoplication, although the primary surgeons in database 2 had failures that tended to result from fundoplication-induced obstruction. To reduce this more, one could say that the failed wrap of the "expert" tended to be too loose and the failed wrap of the "nonexpert" tended to be too tight; but this would be an oversimplification.

Intraoperative findings at time of redo procedure

The intraoperative findings during a redo procedure after a failed primary minimally invasive antireflux operation are listed in Table 8. In contrast to Table 7 (preoperative symptoms), there was no major intraoperative finding; wrap herniation occurred in a plurality of patients. Taken as a whole the intraoperative findings indicate failure secondary to wrap herniation or to an improperly constructed wrap.

COMMENTS

The fast-paced evolution in the treatment of gastroesophageal reflux disease in the past decade has produced improved medical and surgical therapy. The indications for surgical intervention appear to have broadened and the number of patients undergoing an antireflux procedure has increased (per the CDC; see the introduction). If one uses discussion at national surgical meetings as a soft indicator, then it could be concluded that, with the advent of minimally invasive surgery, patients are undergoing an antireflux procedure earlier in the course of their disease with less reflux-induced pathology present before operation.

It is difficult to know whether this increased use of antireflux procedures is appropriate. Previously, it has been shown that open antireflux surgery is better than medical therapy for complicated gastroesophageal reflux disease. In 1992 a Veterans Affairs cooperative trial demonstrated that open antireflux surgery was more efficacious than medical therapy (antacids and ranitidine) for gastroesophageal reflux disease with peptic esophageal

Table 8. Intraoperative Findings During Redo Operation after a Failed Primary Minimally Invasive Antireflux Procedure, 1993–2000.

Finding	n	%*
Wrap herniation	65	36.3
Tight wrap	30	16.8
Slipped wrap	25	14.0
Disrupted wrap	23	12.8
Malpositioned wrap	19	10.6
Esophageal stricture	10	5.0
Loose wrap	9	2.2
Other	4	5.6

Data derived from database 2. Information obtained from 8 papers (out of 14) of database 2, reporting on 179 redo procedures.
*Rates do not add up to 100% because some patients had more than one finding.

ulcer, stricture, erosive esophagitis, or Barrett's esophagus.[41] In 2000 a controlled trial from Scandinavia of open antireflux surgery versus omeprazole in the treatment of erosive esophagitis demonstrated that surgery was superior for symptom control; if the medical failures subsequently received an increased dose of omeprazole then symptom control became equivalent to surgery.[42] A recent systematic review of medical versus surgical therapy in the treatment of gastroesophageal reflux disease also found the latter to be superior.[43]

The conditions under which antireflux operations currently are performed are different compared with when these trials were conceived because 1) many if not most preoperative patients now have uncomplicated or minimally complicated disease and 2) the operative approach has changed from open to laparoscopic. There is one recent controlled trial that suggests that minimally invasive surgery is superior to proton pump inhibition, but as of this writing this study is only in abstract form.[44] There is inadequate controlled data to determine whether a minimally invasive antireflux procedure is superior to modern medical therapy (ie, proton pump inhibition) for the treatment of uncomplicated gastroesophageal reflux disease. It is unknown whether gastroesophageal reflux patients are benefiting from the considerable increase in minimally invasive antireflux procedures.

Another concern with the increase in minimally invasive antireflux procedures is a possible discrepancy in outcomes between "expert" and "nonexpert" surgeons. The overall Visick rates reported in Table 6 are derived primarily from the data of surgeons heavily experienced in minimally invasive antireflux surgery operating at

specialized centers; beyond noting that the operators in database 1 are heavily experienced it is difficult to quantify their level of expertise with the available information. It is not possible to determine the level of expertise of the operators who performed the primary procedures in database 2 (which all failed). Laparoscopic fundoplications certainly are being performed by surgeons not "expert" in antireflux procedures (the qualifications for "expert" designation being controversial). It is unknown, for instance, what fraction of the 40,000 antireflux procedures performed in 1998 (see the introduction) were done by "nonexpert" surgeons away from specialized centers, nor is it known if the results of the "nonexperts" are similar to those of the "experts." The concern of the referring medical community is that the results of laparoscopic antireflux surgery as practiced outside specialized centers are suboptimal; ie, the perception or hypothesis is that the operative outcomes from a nonexpert surgeon are not as good as the outcomes from the expert surgeon.[5-8] This hypothesis can be neither proved nor disproved with the current data.

Summary of recommendations

The current data are too soft to either 1) define the utility of minimally invasive antireflux surgery in patients with minimal objective pathology or 2) determine whether "expert" versus "nonexpert" outcomes are similar. A summary of the current data may still be helpful. The main purpose of this review was to summarize the published results and complications of laparoscopic antireflux surgery, to describe its efficacy, and to recommend what to do and what to avoid for optimal results. The published results for primary minimally invasive antireflux procedures are good: 90% Visick grade I to II after several years of followup. This approximates the results seen with various open procedures, although the followup with the minimally invasive approach is shorter.

The senior author (CTF) has collected a personal series of 522 primary minimally invasive Nissen fundoplications, of which 95.0% are Visick grade I to II and 2.5% are grade IV; the initial 362 cases from this experience have been published.[45] The technique used is based on the floppy Nissen of Donahue and colleagues.[20] The areas of evaluation and technique that appear to be important in producing the results obtained are discussed; most of these guidelines have strong concurrence

with the literature reviewed in this paper. It should be noted that some of these areas still are controversial.

1. Preoperative evaluation.
Upper gastrointestinal contrast study and esophagoduodenoscopy should be routine. The contrast study evaluates esophageal length, esophageal motility, and hiatal herniation. Endoscopy evaluates for inflammation, ulcers, metaplasia, and comorbid disease. All of this information will impact on management. Ambulatory pH monitoring and esophageal manometry can add vital information in circumstances in which the diagnosis is in question, and certainly the latter should be done if dysphagia is present. We use pH monitoring and manometry selectively; eg, if the diagnosis of reflux is in question or the patient has dysphagia then pH monitoring and manometry would be done. Our selective use of pH monitoring and manometry may be controversial;[38,46] in our hands the selective use of these tests not only has produced satisfactory results, but also has promoted patient compliance with the evaluation while reducing the evaluation cost (unpublished results).

2. Complete fundal and esophageal mobilization.
Complete mobilization of the fundus and lower esophagus (including transection of the short gastric vessels) so that 3 to 4 cm of esophagus is intraabdominal without tension should reduce the risk of wrap herniation into the chest. A mobilized fundus also will permit the construction of loose fundoplication, which will minimize the risk for dysphagia.

3. Routine hiatal closure.
The hiatus should be close around the esophagus to reduce additionally the risk of wrap herniation into the chest. In our practice we consider a PTFE onlay to reinforce the posterior cruroplasty if initially confronted with a large (≥8 cm) hiatal defect.[47,48] Use of prosthetic in this clinical circumstance is not universally recognized as standard treatment. We use prosthetic in large hiatal hernias because our results with prosthetics have been excellent.

4. Fundoplication: short, floppy, and anchored.
It has been demonstrated with the open Nissen fundoplication that excellent results are obtained with a short and floppy wrap. This approach should be applied to minimally invasive Nissen procedures. We construct such a wrap after full gastroesophageal junction mobilization and with a large (54 to 60 Fr, depending on the

size of the patient) intraesophageal dilator in place. Suture anchorage of the wrap to the diaphragm is controversial, but we (and most authors who comment on this topic) prefer anchorage in one form or another to prevent wrap herniation. We do not incorporate the esophagus into the fundoplication sutures, considering that the esophagus lacks a serosal layer, but this again is a controversial topic.

The results of laparoscopic fundoplication as published are satisfactory if compared with previous experience with antireflux surgery. Questions arise about a discrepancy in the results of "expert" versus "nonexpert" surgeons and whether patients with minimal pathology are best treated with proton pump inhibition or a minimally invasive antireflux procedure. These questions obviously could be addressed by carefully planned randomized controlled trials; the feasibility of such trials would need careful consideration. In lieu of such studies a concurrence of management has been produced here from a review of existing data.

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