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SURGICAL ENDOSCOPY
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Comparison of patient satisfaction after redo and primary fundoplications

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Abstract
Background: Although much has been written about the results and patient satisfaction with fundoplication for the treatment of gastroesophageal reflux disease, the reports have focused primarily on surgical successes. With the growing number of fundoplications being performed, more patients are requiring reoperation because of recurrent symptoms or side effects. Reports of success rates for reoperation are available, but information regarding patient satisfaction is limited.
Methods: All the patients undergoing fundoplication at our institution were sent short-form health surveys (SF-12), Gastroesophageal reflux disease–specific quality-of-life questionnaires (QOLRAD), and queries regarding long-term satisfaction.
Results: Between November 1992 and July 2000, 221 patients (198 primary and 23 redo) underwent fundoplication. There were 19 open cases (3 primary and 16 redo). In the primary group, 173 patients underwent Nissen, 23 underwent Toupet, and 2 underwent Collis fundoplications. In the redo group, 12 patients underwent Nissen, 9 underwent Toupet, 1 underwent Collis, and l underwent Belsey fundoplications. Follow-up surveys were completed for 130 patients (112 primary and 18 redo) at a mean of 32.6 months (range, 0.8–98 months). In the primary group, 87% of the patients were satisfied with their operation, as compared with 75% in the redo group. There was a trend toward higher SF-12 mental scores (46 ± 12 vs 40 ± 14; $p = 0.07$) and QOLRAD scores (6.2 ± 1.3 vs 5.2 ± 2.0; $p = 0.07$) in the primary fundoplication group. There was a significant difference in the SF-12 physical scores between the groups (32 ± 13 for the primary group vs 18.5 ± 11 for the redo group; $p = 0.0002$). Additionally, 61% of the patients in the redo group were again using antireflux medications, whereas only 24% of the patients in the primary group were using medications again.
Conclusion: Gastroesophageal reflux disease symptom scores and quality-of-life scores for patients undergoing redo fundoplication are lower than the scores of patients having primary fundoplication. Quality of life is similar between primary and redo fundoplication patients in the mental component. However, redo patients do not do as well physically more than 2 years after surgery.

Key words: Redo fundoplication — Patient satisfaction

Over the past decade, patient quality of life (QOL) after surgical procedures and related medical conditions has received greater attention. Gastroesophageal reflux disease (GERD) is one health condition that has been studied extensively both subjectively and objectively. Over the past decade, the number of people with a diagnosis of GERD has increased. With the introduction of minimally invasive surgical options for the treatment of GERD, the percentage of individuals opting for operative treatment of the disease has grown [1, 11, 12]. Data suggest that GERD has an adverse impact on patient quality of life [4, 6, 8], and that fundoplication can have a positive impact for patients with GERD [9]. Quality of life has become increasingly important in guiding patient treatment. Ideally, it is measured before and after treatment using validated questionnaires that reflect general or health-related quality of life. Although literature exists for patients who have undergone fundoplication, more studies to assess quality of life in patients who have failed their initial antireflux procedure is needed.

In this retrospective study, comparisons between outcomes after primary and redo antireflux procedures are evaluated using validated quality-of-life questionnaires. Also, an attempt is made to identify factors predictive of patient satisfaction so that optimal outcomes can be achieved in the future.

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Methods

All adult patients who underwent a fundoplication at the Vanderbilt University Medical Center between November 1992 and July 2000 were identified. The charts of all the patients were retrospectively reviewed by a single reviewer for information regarding the preoperative evaluation, the perioperative care, and the postoperative course. All the patients were mailed short-form health surveys (SF-12, on which a higher score reflects an improved quality of life; the normal score for the general population is 45) and GERD-specific QOL questionnaires (QOLRAD, with a scale of 0 to 7, on which a higher score reflects an improved quality of life). The patients who did not return the survey after the initial mailing were contacted by telephone and asked to return the questionnaire. They were contacted three times. Then they were given the option of completing the survey over the telephone. Data collected from the patients undergoing primary fundoplication were compared with the data for patients undergoing redo fundoplication. Preoperative factors including indication for procedure, pH studies, manometry findings, endoscopic findings, and patient symptoms were analyzed to determine factors that may be predictive of patient dissatisfaction.

All the collected data were stored in a database and analyzed using STATA statistical software (College Station, TX, USA). Chi-square analysis, Fisher's exact test, and Mann–Whitney tests were used where appropriate for comparisons between groups. Univariate and multivariate analyses were performed. Statistical significance was reported for p values less than 0.05. Data are reported as mean ± SD.

Results

During the study period, 221 patients underwent fundoplication. Of these patients, 198 had primary and 23 had redo procedures. These two groups provided comparative measures for the remaining analyses. All but one patient in the redo group were referred to Vanderbilt by outside physicians. Most of the patients were referred for a second operation. However, two patients had undergone two previous procedures. The patients presented anytime from 6 days to 20 years after their previous procedure.

Preoperatively, the patients were evaluated with upper endoscopy and manometry. If no esophagitis was evident on endoscopy, the patients underwent 24-h pH study. Between groups, endoscopic findings were similar, with similar proportions having hiatal hernia (22% in the primary group vs 26% in the redo group) and esophagitis (25% in the primary group vs 26% in the redo group). In the redo group, however, a higher proportion of the patients had Barrett's esophagus (6% in the primary vs 13% in the redo group) and a higher proportion had strictures (3% in the primary group vs 17% in the redo group). The manometry findings showed a trend toward higher esophageal sphincter pressure (LESP) in the redo group: 13 ± 11 in the primary group and 18 ± 14 in the redo group ($p = 0.11$). However, the percentage of normally propagated peristaltic swallows measured in each group was significantly different, with 94 ± 14% peristaltic swallows in the primary group and only 74 ± 41% peristaltic swallows in the redo group ($p = 0.0005$).

Primary indications for the procedure were esophageal symptoms (heartburn and regurgitation) in 76% of the patients undergoing their first antireflux procedure. Extraesophageal symptoms such as asthma, cough, and aspiration pneumonia were the primary problems reported by the remaining 24%. In the redo group, 78% of the patients continued to have primarily esophageal symptoms, and 22% had extraesophageal symptoms. Presenting symptoms in the redo group differed, with a higher percentage of patients describing dysphagia ($n = 12$, 52%) and noncardiac chest pain ($n = 9$, 39%). Three patients had excessive nausea and vomiting, resulting in significant weight loss.

Of the total 221 patients, 19 had their procedures performed in an open manner: 3 primary procedures (3/198, 2%) and 16 redo procedures (16/23, 70%). In the primary group, 173 patients underwent Nissen fundoplication, 23 patients had a Toupet fundoplication, and 2 patients had a Collis-Nissen fundoplication. In the reoperative group, 12 patients underwent Nissen fundoplication, nine had a Toupet fundoplication, one patient had a Collis-Nissen fundoplication, and one patient had a Belsey fundoplication. Of the redo procedures performed by open surgery, only seven were started as open procedures, and nine were converted from laparoscopic to open procedures, for a conversion rate of 56%. In the redo group, the intraoperative findings confirmed a slipped Nissen in five patients, a paraesophageal component in two patients, and malformation or angulation of the wrap in seven patients. In three patients, the wrap had herniated into the chest, and six had fundoplication disruptions.

After the procedure, the hospital stay was 1.8 ± 1.6 days in the primary group, as compared with 5.3 ± 3.6 days in the redo group ($p < 0.0001$). Intraoperatively, the redo procedures were complicated by excessive bleeding in three patients (more than expected, but not requiring transfusion in any patient) and splenectomy in two patients. In the primary group, four patients had intraoperative pneumothoraces, which were treated nonoperatively, one patient had an enterotomy, and one esophageal perforation was identified. The enterotomy and perforation were recognized and treated at the time of procedure. Within 30 days of the procedure, two patients in the primary group required endoscopic esophageal dilation, whereas none required this in the redo group. One patient in the primary group had a breakdown in their wrap caused by postoperative emesis, which was repaired immediately. There were no perioperative mortalities in either group.

Follow-up surveys were completed by 130 patients (response rate, 59%) during a mean follow-up period of 32.6 months (range, 0.8–98 months). The respondents were classified as patients who underwent a primary procedure (112 patients) and those who had a redo procedure (18 patients). The results from the quality-of-life questionnaires are shown in Table 1. The patients in the primary group scored higher on all the parameters. The only statistically significant difference was noted in the SF-12 physical score (32 ± 13 in the primary group vs 18.5 ± 11 in the redo group; $p = 0.0002$). No significant differences could be demonstrated in the SF-12 mental scores or QOLRAD scores between the two groups. However, there was a trend toward higher scores in the primary group (Table 1). A correlation between patient symptoms and patient quality of life could not be demonstrated. In the redo group, 61% of

Table 1. Comparison of quality-of-life outcomes between the patients who underwent primary fundoplication and those who underwent redo fundoplication

	SF-12 MCS	SF-12 PCS	QOLRAD
Primary (n = 18)	46 ± 12	32 ± 13	6.2 ± 1.3
Redo (n = 112)	40 ± 14	18.5 ± 11	5.2 ± 2.0
p	0.07	0.0002	0.07

SF-12, short-form health survey; MCS, mental composite score; PCS, physical composite score; QOLRAD, gastroesophageal reflux disease–specific quality-of-life questionnaire

the patients were again using antireflux medications at the time of survey, whereas in the primary group, only 24% of the respondents were using anti-reflux medications again.

When asked if they were satisfied with their procedure, 87% of the patients in the primary group were satisfied with their operation and would have it performed again, as compared with 75% of the patients in the redo group. The results of the preoperative studies and perioperative measures were compared between the patients who were satisfied with their procedure and those who were not satisfied. When these measures were evaluated for all patients, no significant differences were found between the groups, and no predictors of outcome could be identified. Similarly, when the patients who had a primary fundoplication and those who had a redo fundoplication were analyzed separately, no preoperative findings were predictive of patient satisfaction. No differences were noted in relation to the procedure performed (Nissen, Toupet, or Collis) or the perioperative complications. When postoperative quality-of-life measures were evaluated, no differences were noted in the primary fundoplication group. In the redo group, the QOLRAD and SF-12 physical scores were comparable. The SF-12 mental composite score was significantly higher for the satisfied patients (43.3 ± 13.9) than for the dissatisfied patients (28.5 ± 5.6; p = 0.01).

Discussion

In this study, the quality of life was compared between patients who had primary fundoplication and those who had redo fundoplication, using validated questionnaires. The patients who underwent primary fundoplications, had better scores on the GERD symptom questionnaires that approached statistical significance. The results for the mental component of the SF-12 were similar. The number of patients was small and revealed trends, but these did not reach statistical significance. When general health-related quality of life was measured, statistically significant differences were noted between groups in the physical score. This may be attributable to the fact that most of the redo procedures were performed in an open manner (2% in the primary group vs 70% in the redo group). When the redo patients alone were evaluated, the dissatisfied patients had a much lower mental score than the satisfied patients. No predictors of dissatisfaction were identifiable in this study. This also may be related to the small number of patients in the study.

The rate of laparoscopic fundoplication failures has been reported to range from 2% to 17% [5]. An estimated 1.5% to 9% of patients require a revision operation [2, 10]. The success rate with reoperation in patients with failures is 75% to 85%, and decreases with each subsequent operation. Reoperation also has an increased morbidity rate of approximately 25% and a mortality rate exceeding 1% [13]. The types of failures have been described by previous investigators [5]. Similar to these results, most of the patients referred for a redo procedure in this study had some type of anatomic failure: a slipped Nissen in five patients, malformed angulation of the wrap in seven patients, three herniations of wraps into the chest, and six fundoplication disruptions. These failures were particularly notable in the patients returning for revision within 1 year of their previous procedure.

In this study, patient quality of life was measured at a mean of 2.7 years follow-up evaluation using the validated SF-12 and QOLRAD surveys. These surveys have not been used previously to evaluate outcomes in patients undergoing repeat operations for failed antireflux procedures. The results from these surveys among patients undergoing a repeat procedure were compared directly with those for patients undergoing a primary fundoplication. The results show that primary fundoplication patients fared slightly better on the GERD-related quality-of-life score (6.2 vs 5.2). The general health-related quality of life was equal in the mental component between the two groups. The SF-12 physical component scores were significantly higher in the primary group. Other groups have used other measures to assess quality of life, and also found that good patient outcomes can be achieved after a redo operation [3, 7].

We realize that this study had several limitations. First is the small number of patients in the study. The differences in the QOLRAD and SF-12 scores were noted, but they did not reach statistical significance. There is a strong possibility of a type 2 error in this study. If the numbers of subjects in each group had been larger, perhaps these differences could be stated with confidence. Another limitation of the study was the response rate of only 59%. When the respondents are broken down into redo and primary groups, the findings show that 78% of the redo patients responded, as compared with only 51% of the primary patients. In the group of less satisfied patients (redo group), a much higher percentage (78% vs 51%) responded to the questionnaires.

Still another shortcoming of this study was the fact that quality-of-life questionnaires were not used at this institution until 1999, so preoperative quality-of-life evaluations were not available for this group of patients. One group administered a different validated quality-of-life questionnaire, the Gastrointestinal Quality of Life Index (GIQLI), to patients undergoing redo fundoplications before, 3 months after, and 1 year after surgery. It was noted that the scores improved markedly from 87 points before surgery to 123 points 1 year after surgery, which is comparable with the population mean (122.6

points) [7]. In this study we did not have the benefit of preoperative measures. However, the scores on the QOLRAD surveys for the redo group were comparable with those for the primary group, and most of the patients (74%) were satisfied with their procedure.

Satisfaction with the procedure in this study is similar to the findings in other studies [5, 9]. Among the patients undergoing a primary fundoplication 87% were satisfied with their procedure, and only 24% of these patients were again using antireflux medications. In the redo group, the satisfaction rate was slightly lower (75%), and 61% were using medications again. The reason for the resumption of medications is not known. However, none of the respondents admitted to objective measurement of acid exposure in the esophagus before resumption of medications. Patients who were dissatisfied had a significantly lower mental composite score on the SF-12, but their GERD-related symptoms on the QOLRAD were similar to those of the patients who were satisfied with their treatment. Such data have not been identified previously, and this group of patients needs to be examined more closely in prospective studies. In this study, no significant predictors of dissatisfaction could be identified.

Many groups have demonstrated the feasibility of the laparoscopic approach to repeat antireflux operations, showing a 79% success rate [3, 7, 14]. Most of the redo procedures in our series were performed using an open approach. In fact, slightly more than half of 16 procedures begun laparoscopically were converted to open surgery. The amount of scarring noted intraoperatively in these patients was variable. The high number of open procedures in this series may explain the lower physical composite scores among the patients undergoing the redo operations.

According to the findings of this study, redo fundoplication can be an effective procedure with reasonable patient satisfaction. However, most patients undergoing a redo procedure will have a quality of life that is inferior to that of patients undergoing an initial procedure. Patients and physicians need to acknowledge that redo procedures have lower success rates than primary procedures with regard to patient quality of life and satisfaction. Another realistic expectation for the outcomes of redo procedures is that patients may continue to require medical treatment for symptomatic control. Every effort should be made to perform the initial fundoplication correctly so that patients can have satisfactory results. However, a cohort will remain dissatisfied, and further prospective studies are needed to find predictors of poor outcome.

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