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Association of preoperative workup and comorbidities with risk of gastroesophageal surgery failure

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Abstract

Background While surgical failure rates for fundoplication and hiatal hernia repair are low, there has been no clear evaluation of the preoperative risk factors associated with surgical failure. This study aimed to identify risk factors predisposing patients to surgical failure.

Methods Patients who underwent antireflux surgery during a 3-year period were evaluated for evidence of surgical complications and placed accordingly into the failure or control group. Demographic data, comorbidities, clinical presentation, preoperative evaluation, and surgical data were collected and compared between the groups.

Results In total, 86 patients with failure and 42 controls were identified among our cohort. No significant differences were found between groups based on sex (P=0.640). However, patients with failure were younger than controls (57.0 vs. 64.7 years, P=0.0001). Body mass index, tobacco use and alcohol use did not differ significantly between the groups (P=0.189, P=0.0999, P=0.060). Notably, psychiatric illness was more common in the failure group (P=0.0086). Neither hypertension (P=0.134) nor diabetes (P=0.335) had significant differences between groups. For procedures, no significant differences were found for the frequencies of preoperative imaging (P=0.395) or manometry (P=0.374), but pH/BRAVO studies (P=0.0193) and endoscopy (P<0.001) were both performed more frequently in the failure group.

Conclusions Patients with psychiatric comorbidities are at higher risk of surgical failure. Alcohol use trended toward significance, which warrants further investigation. We also noted an increase in rates of preoperative pH and endoscopy studies, contrary to the prior literature; this is likely due to more complex cases requiring additional workup.

Keywords Gastroenterology, general surgery, fundoplication, hiatal hernia, surgical failure

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Introduction

Fundoplication (FO) and hiatal hernia repair (HHR) are well-established treatments for gastroesophageal reflux disease (GERD). Up to 27% of North Americans are impacted by GERD, with the disease being the top gastrointestinal diagnosis in the United States, resulting in 1 million visits annually [1]. First-line treatments are typically medications such as proton-pump inhibitors (PPI), on which approximately $10 billion are spent per year [1,2]. Despite this, a multitude of patients are left without symptom resolution. In such cases, FO and HHR are surgical alternatives to medical therapy. Some studies have even suggested that asymptomatic patients younger than 50 should undergo surgery [3,4]. Given such significant commonality of GERD, it is no surprise that FO and HHR have become increasingly frequent in practice; therefore, their failures are a major concern.

Though the failure rates of FO and HHR are variable, they are not negligible and should thus be investigated. FO failure

in previous studies has been defined as a need for a revisional antireflux operation, patient dissatisfaction with the outcome, or the presence of at least 1 severe symptom post-surgery [5]. Failure rates are quite variable in the literature, ranging between 2% and 50% at 5-year follow up [1,6]. Others have noted a need for antisecretory medications in 50% of patients up to 10 years post-operation [7].

Given the increasing need for FO and HHR, along with the variable failure rates, it is important to identify any factors that predispose patients to operation failure. A few studies have investigated preoperative risk factors in relation to failure; however, the data are currently limited. Morgenthal *et al* [5] investigated several preoperative factors, including symptomatology, body mass index (BMI), sex, prior surgeries, preoperative workup studies, and comorbidities (e.g., psychiatric illness, hiatal hernia, Barrett's esophagus). Their study found that morbid obesity and atypical reflux symptoms were associated with a greater failure rate, while a history of psychiatric illness trended toward significance at P=0.06. Other studies have noted similar findings correlating BMI to failure rates [8]. Female and elderly patients have also been shown in 1 study to have a higher incidence of FO migration; however, sex and age have not correlated with failure rates in other investigations [9]. Interestingly, it has even been suggested that frequent belching and gagging may lead to higher rates of FO failure [10]. The only other article that noted a statistically significant correlation between psycho-neural impairment and failure rate was by Pacilli *et al* in 2007, in which the authors investigated only children [11].

Aside from the abovementioned publications, the relationship between psychiatric illness and FO failure has not been well defined. Other comorbidity clarification would also benefit from further data collection. As FO and HHR become more frequent, it is essential to further understand what puts a patient at risk of failure. The aim of this study was to determine any preoperative comorbidities that predispose to foregut surgery failure.

Patients and methods

Study design

A retrospective study was conducted at Wake Forest Baptist Medical Center over a 3-year period. Approval from our medical institution's Institutional Review Board was first obtained. A database was then created to collect information on patients. This database was designed to investigate the correlation between preoperative comorbidities and gastroesophageal surgery failure. The study included patients undergoing either FO or HHR over a 3-year period at our institution. No specific exclusion criteria were defined.

Surgical failure was defined as a need for either reoperation or high-dose PPIs, recurrence of or new onset of hiatal hernia, or evidence of new Los Angeles grade C or D erosive esophagitis, following surgery. Patients who did not exhibit any of these criteria were allocated to the control group with successful surgeries.

Data collection

We used a retrospective approach to collect data via chart review. Once patients who underwent FO or HHR were identified and age-matched, further information was compiled. A statistical power of 80% to detect an alpha value of 0.05 was used to dictate our sample size, and for this reason not all FO patients were included in the study. The following data were recorded: surgery type, demographics, BMI, diagnosis, comorbidities, preoperative symptoms, preoperative workup, procedural information, and postoperative symptoms. All information was stored in the same database and each patient was de-identified.

Statistical analysis

Biostatisticians from Wake Forest Baptist Medical Center were recruited for the statistical analysis. Chi-square and *t*-tests were performed to compare variables between the failure group and the control group (e.g., prevalence of diabetes in the study group vs. controls).

Results

A total of 86 patients were deemed to have surgical failure and 42 patients were age-matched as the control group, having not met the criteria for surgical failure (Table 1). No significant differences were noted in surgical failure rates between males and females, or in relation to BMI (P=0.64, P=0.189, respectively). The surgical failure group was noted to be significantly younger than the controls, with the average age being 57 compared to 64.7 years (P<0.001). Regarding social factors, alcohol use trended toward significance, but did not meet the criterion (P=0.060). Tobacco use did not correlate with surgery failure (P=0.999).

Comorbidities were also investigated as risk factors for surgical failure. Interestingly, patients with underlying psychiatric illnesses were more likely to have treatment failure (P=0.0086; Fig. 1). These psychiatric diagnoses were predominantly anxiety or depression; however, several patients exhibited other processes, such as somatoform disorder (SD), schizophrenia, bipolar disorder, etc. (Table 2). Other comorbidities, such as hypertension and diabetes, did not correlate with outcomes (P=0.134, P=0.335, respectively). Asthma, chronic obstructive pulmonary disease, and liver disease also did not correlate with treatment outcomes.

The preoperative workup, including radiologic imaging, manometry, endoscopy and pH/BRAVO studies was also studied in relation to surgical failure (Fig. 2). There was no significant correlation between preoperative imaging or manometry and the failure group (P=0.395, P=0.374, respectively). However, patients who underwent either a pH/BRAVO study or preoperative endoscopy were more likely to have surgical failure than those who did not (P=0.0193, P<0.001, respectively) (Table 3).

Table 1 Preoperative demographics of all patients, showing the frequency of various comorbidities and preoperative workup procedures. A total of 128 patients were included in the study.

Variable	Sample size (N)	Results (%)
Age (mean; range)	128	60.8 (13-94)
Male: female ratio	127	24.0%
BMI (mean; range)	128	30.1 (18.1-48.1)
Alcohol use	127	27.6%
Tobacco use	128	45.3%
Hypertension	128	57.0%
Diabetes mellitus	128	9.4%
Psychiatric illness	128	45.3%
Imaging performed	128	87.5%
Manometry performed	128	23.4%
pH study performed	128	15.6%
Endoscopy performed	128	35.2%

BMI, body mass index

Table 2 Distribution of psychiatric comorbidities in patients undergoing FO or HHR. Overall, 58 of the 128 patients had a psychiatric diagnosis. In particular, a predominance of anxiety and depression disorders was observed (32.8%, 24.2% respectively). Several patients had other comorbidities, including somatoform disorder, bipolar disorder, schizophrenia, etc.

Diagnosis	# in FG (N, %)	# in CG (N, %)	Total # (N, %)
Anxiety	33 (25.8%)	9 (7.0%)	42 (32.8%)
Depression	23 (18.0%)	8 (6.3%)	31 (24.2%)
Bipolar disorder	3 (2.3%)	0 (0%)	3 (2.3%)
Schizophrenia	2 (1.6%)	0 (0%)	2 (1.6%)
Drug abuse	3 (2.3%)	1 (0.8%)	4 (3.1%)
PTSD	3 (2.3%)	0 (0%)	3 (2.3%)
ADHD	1 (0.8%)	0 (0%)	1 (0.8%)
Somatoform	3 (2.3%)	1 (0.8%)	4 (3.1%)
Pseudo-seizure	1 (0.8%)	0 (0%)	1 (0.8%)

FO, fundoplication; HHR, hiatal hernia repair; FG, failure group; CG, control group; PTSD, post-traumatic stress disorder; ADHD, attention deficit hyperactivity disorder

Table 3 Comparison of demographics, comorbidities, and preoperative testing between the failure and control groups. The average age was lower in the failure group than in the control group (57 vs. 65.7 years; P<0.001). Alcohol use trended toward significance, in that more patients in the failure group consumed alcohol (32.9% vs. 16.7%; P=0.06). Psychiatric comorbidities were present in 53.5% of the failure group compared with 28.6% of the control group (P=0.0086). Both pH studies and endoscopy for surgical workup were used more in the surgical failure groups (P=0.0193, P<0.001)

Variable	Failure group	Control group	P-value
Age (mean; SD)	57.0 (14.5)	65.7 (10.2)	<0.001
Sex			
Male	18 (21.2%)	7 (16.7%)	0.640
Female	67 (78.8%)	35 (83.3%)	
BMI (mean; SD)	31.8 (7.53)	34.0 (10.1)	0.189
Alcohol use			
No	57 (67.06%)	35 (83.3%)	0.060
Yes/Former	28 (32.94%)	7 (16.7%)	
Tobacco use			
No	47 (54.7%)	23 (54.8%)	0.999
Yes/Former	39 (45.4%)	(19 (32.2%)	
Hypertension			
No	41 (47.7%)	14 (33.3%)	0.134
Yes	45 (52.3%)	28 (66.7%)	
Diabetes mellitus			
No	76 (88.4%)	40 (95.2%)	0.335
Yes	10 (11.6%)	2 (4.8%)	
Psychiatric illness			
No	40 (46.5%)	30 (71.4%)	0.0086
Yes	46 (53.5%)	12 (28.6%)	
Imaging			
No	9 (10.47%)	7 (16.7%)	0.395
Yes	77 (89.5%)	35 (83.3%)	
Manometry			
No	62 (72.1%)	36 (85.7%)	0.120
Yes	24 (27.9%)	6 (14.3%)	
pH/BRAVO study			
No	68 (79.1%)	40 (95.2%)	0.0193
Yes	18 (20.9%)	2 (4.8%)	
Endoscopy			
No	45 (52.3%)	38 (90.5%)	0.001
Yes	41 (47.7%)	4 (9.5%)	

BMI, body mass index; SD, standard deviation

Discussion

FO procedures and HHR have well-established results as regards benefiting patients with acid reflux. For laparoscopic FO, up to 90% of patients may see improvement in symptoms [7]. Despite these successes, it is important to have proper selection criteria for candidates. Historically, the patients most fit for FO are those who show partial relief from medicine, have established GERD, with or without hiatal hernia, observed esophagitis, abnormal pH studies and normal esophageal motility studies [7,12,13].

As FO and HHR become more common, it is essential to better understand the risk factors that may lead to surgical failure. Some literature has investigated preoperative risk factors, but there is currently a shortage of cumulative data. Morgenthal *et al* [5] investigated the correlation of various factors with Nissen FO failure rates. In this retrospective study, 175 patients who underwent Nissen FO from 1992-1995 were identified. Patients were put in the failure group if they had revisional operations, were dissatisfied with treatment results, or developed severe symptoms at follow up.

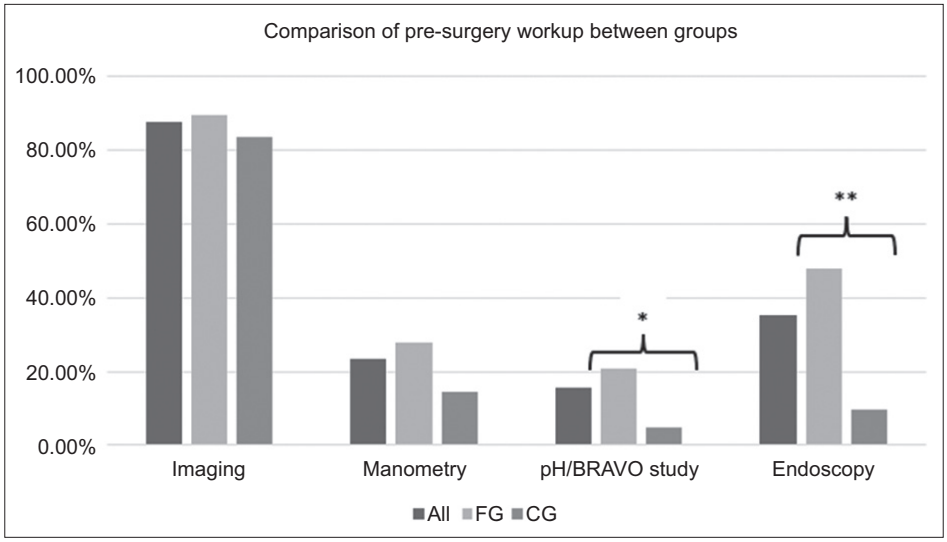

Figure 1 Comparison of presurgical workup between the failure (FG) and control groups (CG)
**pH studies were performed 4.5 times more frequently in the FG compared to the CG (P=0.0193)*
***Endoscopy was performed 5.02 time more often the FG compared to the CG (P<0.001)*

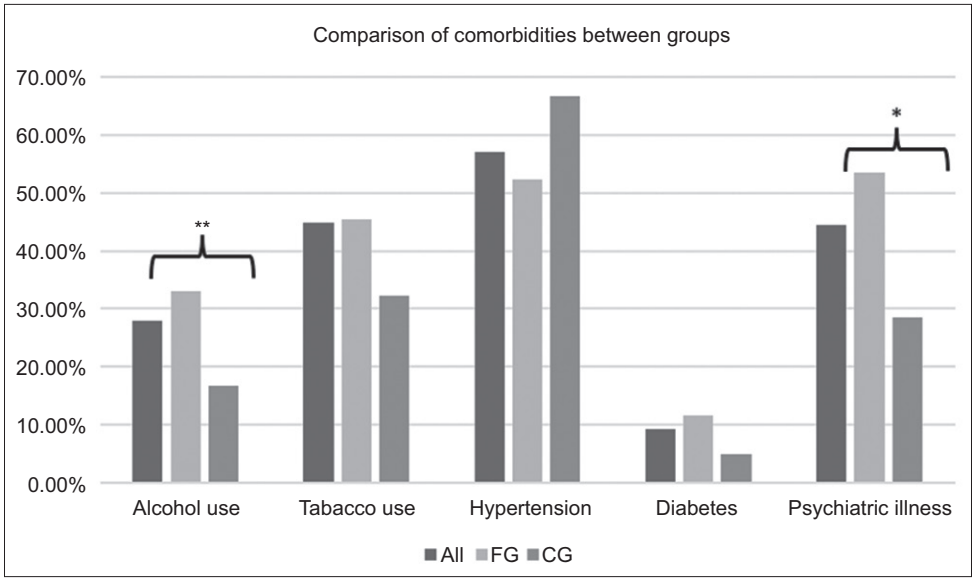

Figure 2 Comparison of comorbidities between the failure (FG) and control groups (CG)
**Psychiatric illness observed 1.87 times more in the surgical FG compared to the CG (P=0.0086)*
***Alcohol use trended toward significance, being 1.97 times more common in the FG (P=0.06)*

The following preoperative predictors were evaluated: sex, age, weight, BMI, prior abdominal surgery, psychiatric history, atypical vs. typical symptoms, hiatal hernia, observed esophagitis, Barrett's esophagus, prior dilation for esophageal strictures, manometry, and pH [5]. When comparing the success group to the failure group, they found patients with atypical symptoms or morbid obesity, as well as patients with no response to medications, had a significantly higher chance of failure. Interestingly, patients with a psychiatric illness trended toward statistical significance for a higher rate of surgical failure (P=0.064). Specifically, psychiatric patients were more likely to be dissatisfied with the FO results than those without psychiatric comorbidities (P<0.01). However, the authors reported this finding as a secondary endpoint, and did not believe it to be clinically relevant.

A few other articles have investigated particular psychological states and their correlation to laparoscopic FO outcomes. One prospective study compared SD to procedure outcomes [12,13]. According to the Diagnostic and Statistical Manual of Mental Disorders, SD is defined as a somatic symptom that is thought to be disproportionately serious, and which must last longer than 6 months [14]. In Fuchs' research, patients were given a standardized somatoform symptom index (SSI) to determine if any somatic disorders were present. These preoperative results

were then correlated with the postoperative SSI scores. They found that patients without SD had a significant improvement of symptoms after laparoscopic FO (P<0.001). Patients with SD also had a significant improvement, with a P-value of 0.0043. The study did not specifically compare postoperative results of SD vs. non-SD patients, but did imply that SD patients may not benefit so much, given the different P-values between individual groups.

It is clear that a few studies have investigated the correlation between psychiatric disease and laparoscopic FO outcomes. So far, a trend has been identified indicating that patients with psychiatric illness, be it SD or other, have lower success rates after FO procedures [5,12,13]. Our study provides the first statistically significant evidence for a true correlation between psychiatric disease and a higher risk of foregut operation failures, for both FO and HHR. Many of the psychiatric diagnoses observed were anxiety or depression; however, a handful of patients had comorbidities such as SD, bipolar disorder, schizophrenia, etc. Our study included patients undergoing laparoscopic FO, as in prior publications, but has also extended the correlation to other types of surgery, namely HHR.

Several theories can be derived as to why psychiatric illness correlates with lower surgical success rates. It is possible that the symptoms reported by psychiatric patients are somatoform in nature and not strictly gastrointestinal. FO and HHR are well-known for improving gastrointestinal symptoms, but they would not improve symptoms due to somatoform etiologies. Surgical failure in our study was defined by patients' need for reoperation or high-dose PPIs, recurrence of a hiatal hernia, or Los Angeles grade C or D erosive esophagitis. Assuming these patients reported ongoing somatoform symptoms, they would have a higher likelihood of being started on PPIs or requiring reoperation. It would be worthwhile investigating their relation to the strictly objective surgical failure data, such as recurrence of hiatal hernias or erosive esophagitis. Currently, the literature notes that a large amount of surgical failure is due to transdiaphragmatic herniation and hernia recurrence [15-17]. Comparing prior findings to failure causes in psychiatric patients may shed more light on the mechanism behind surgical failures.

These results can better determine patients who will benefit from these foregut operations compared to those who will not. The patient selection criteria for FO typically include those with partial relief from medicine, established GERD, with or without hiatal hernia, observed esophagitis, abnormal pH studies and normal esophageal motility studies [7,12,13]. Even with these criteria, other authors have noted there is room for selection improvement, especially in the psychiatric population. "Even if patients might otherwise be candidates for surgical treatment … they should be approached with great trepidation" [18]. The findings of our study, in combination with prior observed trends, suggest that adding psychiatric illness to the selection criteria would also lead to better patient selection, and ultimately a lower surgical failure rate.

Our study also demonstrated a higher rate of surgical failure in younger patients. In particular, the failure group's average age was 57±14 years, while the control group's average age was 64.7±10 years. Given that the difference is only 7 years, and both standard deviations are relatively large, we believe these findings to be clinically irrelevant to the general population. It is important to note that the prior literature has also been inconsistent regarding the correlation between age and failure rates. One study demonstrated that older patients had a greater chance of FO migration; however, this has not been successfully replicated [9]. Given the variation in our findings and the current literature, further investigation still needs to be carried out before a true correlation between age and surgical failure rates can be established.

Alcohol use trended toward statistical correlation when the failure and control groups were compared (P=0.06). We noted a 1.97-fold greater level of alcohol consumption in patients who failed surgery compared to those with successful surgeries. Currently, there is no substantial literature linking alcohol use to surgical outcomes. One article investigated both tobacco and alcohol use as possible risk factors for FO failure requiring PPIs; however, no correlation was found [19]. Another editorial suggested there is a relationship between post-FO alcohol use and intestinal motility alterations [20]. They reported that some patients had an abnormally slowed motility observed on gastric emptying studies, which may correlate to ongoing symptoms. If a true relationship between alcohol use and anti-reflux surgery failure is to be found in the future, investigating changes in gastrointestinal motility at a larger scale may prove beneficial.

We also noted that presurgical pH studies and endoscopy were significantly correlated with FO and HHR failure. Interestingly, pH studies were performed 4.5 times more often on patients who failed surgery, while endoscopy was performed 5.02 times more frequently in the failure group compared to the control group. Though previous research has not strictly correlated these studies with surgical failure, some articles have noted that patients with advanced disease on these workup studies have had higher surgical failure rates [21].

In further support, the Lyon consensus helps define the use of pH studies and endoscopy to stratify GERD as proven and unproven [22]. As a result, pH studies have increasingly been enrolled to investigate unproven GERD diagnoses vs. proven GERD (Los Angeles grade C or D erosive esophagitis). Ultimately, pH impedance testing is frequently used for complex unproven reflux cases. It is likely that the correlations we observed were linked with the fact that the inclusion of pH studies in the presurgical workup mainly involved patients with unproven disease, who thus possibly represented a group with more convoluted cases of GERD. Our study did not investigate a correlation with individual pH study and endoscopy results, an area where further research is needed.

Our study does have several weaknesses that need to be noted. This was a single-center study, and as such it is not so generalizable to the general population as is multicenter research. Furthermore, the overall sample size was 128 patients. This was sufficient to begin correlating risk factors to surgical failure; however, future studies would benefit from expanding the sample size to improve the statistical power. A multicenter review could also help substantiate the external validity and relate the findings to the general population. A 3-year follow-

up period was used in our study, whereas a longer follow-up period could also substantiate the long-term results. Future directions of our study will be to include a larger cohort and a longer follow-up period. We also hope to investigate the pH studies and endoscopy results to determine the correlation between disease severity and surgical failure.

Note that our study does not reflect the true FO failure rate. Our control group was selected as age-matched controls and were not sequential cases. Our institution had more successful FO cases that were not included in the study; thus, not all cases were accounted for. Considering the entire cohort at our facility, we estimated the FO failure rate to be 18.9%.

Our sample size was aimed to be age-controlled and meet a statistical power of 80% at an alpha value of 0.05. Future studies would benefit by expanding the sample size beyond this to further strengthen the data.

In conclusion, the major finding from our study is that patients with psychiatric illnesses were more likely to have FO or HHR failure compared to those without psychiatric comorbidities. In addition, patients whose preceding workup included pH studies and endoscopy tended to have higher failure rates, though this could be due to more severe disease. Patients using alcohol also trended toward a significant association with a higher risk of surgical failure. As FO and HHR have become such common procedures, it is essential to understand the factors predisposing to surgical failure. This study highlights several aspects, particularly psychiatric comorbidities, that should be considered prior to FO and HHR.

Summary Box

What is already known:

- As fundoplication and hiatal hernia repairs become increasingly more common, so do their surgical complications
- Surgical failure rates tend to be highly variable; however, none are negligible
- There is limited evidence as to the risk factors for failure of fundoplication and hernia procedures

What the new findings are:

- Psychiatric illness is a risk factor for failure of fundoplication and hernia repair
- Alcohol use trended toward being a risk factor for gastroesophageal surgical failure
- Preoperative endoscopy and pH studies were utilized more in the failure group, probably because of the need for workup of complex cases

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