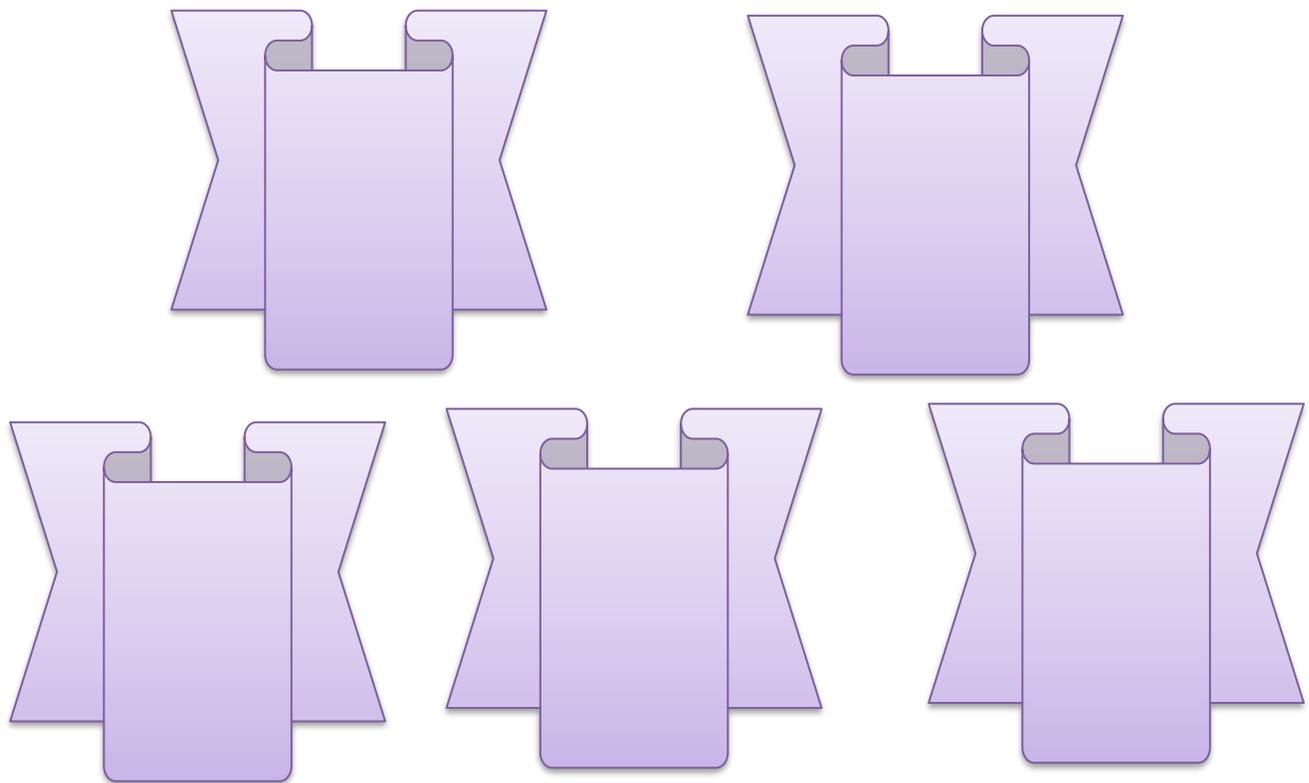


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## Original Article

# Predictors of Outcome after Laparoscopic Nissen Fundoplication

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## ABSTRACT

### Article information

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**Background:** Laparoscopic Nissen fundoplication with posterior hiatal repair is now thought to be the best way to treat severe Gastroesophageal Reflux Disease with surgery [GERD]. Long-term studies have shown that it gives most patients good control of their reflux symptoms and good clinical outcomes.

**Aim of the work:** This study aims to identify the predictive factors of the surgical outcomes of laparoscopic Nissen fundoplication.

**Patients and Methods:** A prospective study that was carried out at the department of surgery, Faculty of Medicine, Al-Azhar University [Damietta] on 30 patients with GERD and or hiatal hernia. Laparoscopic Nissen Fundoplication was described for all patients and the possible complications [including pain, wound complications, recurrence, dysphagia, bleeding and esophageal or gastric injury] were discussed.

**Results:** The mean age of the studied cases was 37.5±11.29 years. As regards their gender, 53.3% were females and 46.7% were male. In terms of BMI, the mean body mass index was 27.0±3.39, with 26.7% of the cases being over-weight and 26.7% being obese. We found a significant association between the patient's satisfaction and the psychiatric disorders [P= 0.18], in which 50% of the patients who are unsatisfied or partially satisfied had positive psychiatric disorders. We also found a significant association between the patient's response to surgery and their satisfaction at all follow-up periods [P = 0.001]. We found that Positive psychiatric disorders are the only statistically significant predictor of poor response. The patients with positive psychiatric disorders have a risk of developing poor outcomes 10.55 times more risk than cases with negative psychiatric disorders [odds ratio =10.55;95% CI: 1.61-69.12].

**Conclusion:** Psychiatric disorders are the most important predictor for poor outcomes after laparoscopic fundoplication.

**Keywords:** Laparoscope; Nissen fundoplication; GERD; Psychiatric disorders.



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## INTRODUCTION

One-third of healthy people have heartburn at least once a month and 7% experience heartburn and other symptoms of uncomplicated GERD as frequently as once a day. It is estimated that 2% of adults have a complicated GERD with macroscopic or microscopic esophageal changes [1].

Hiatus hernia can be caused by different mechanisms such as widening of the esophageal opening in the diaphragm, shortening of the esophagus or increased intra-abdominal pressure [2].

Several studies reported the relationship between the incidence of GERD and psychiatric problems. In addition, some drugs used in the treatment of psychiatric disorders may predispose to GERD through their effect on the lower esophageal sphincter tone, salivation, and esophageal motility [3].

Other studies reported the relationship between the incidence of GERD and obesity through increasing intra-abdominal pressure and diminished lower esophageal sphincter pressure [4].

Laparoscopic Nissen fundoplication with posterior hiatal repair is now thought to be the best way to treat severe Gastroesophageal Reflux Disease with surgery [GERD]. Long-term studies have shown that it gives most patients good control of their reflux symptoms and good clinical outcomes [5, 6].

It is becoming more and more apparent that 30–40% of people using chronic acid suppression therapy are unhappy with the level of symptom control they have achieved. Approximately 40% of these people will not have GERD by objective testing, hence it is important to confirm the diagnosis. In these cases, an alternative cause should be explored for the symptoms [7].

Despite these encouraging studies of the fundoplication, there can be a poor improvement, recurrence, or complications that can necessitate a second intervention [8].

So, this study aims to identify the predictive factors of the surgical outcomes of laparoscopic Nissen fundoplication.

## PATIENTS AND METHODS

This is a prospective study that was carried out at the department of surgery, Faculty of Medicine, Al-Azhar University [Damietta] on 30 patients with GERD and or hiatal hernia. Our study followed the Helsinki declaration principles. Informed consent was taken from every patient in the study. Also, Ethical approval was taken from the Institutional Review Board of the Damietta faculty of Medicine [Al-Azhar university]. Recruitment of the studied patients was done as regards the following criteria:

The Inclusion criteria were 1] Patients with proven gastro-esophageal reflux disease either complicated or not complicated. 2] Age ranges from 17-60 years old.

The Exclusion criteria were 1] Patients with recurrence following anti-reflux surgery. 2] Patients suffering from esophageal motility disorders. 3] Patients with biliary reflux. 4] Patients with the conversion from laparoscopic to open Nissen fundoplication.

### Data collection

Complete medical history [age, sex, BMI, lifestyle, smoking, alcohol intake, previous use of anti-reflux medications], physical examination, routine laboratory investigations [blood picture, liver, and renal function tests], radiological investigations [barium swallow and meal], and esophagogastroduodenoscopy were to each patient upon enrollment. Fundoplication was described for all patients and the possible complications [including pain, wound complications, recurrence, dysphagia, bleeding and esophageal or gastric injury] were discussed.

Psychological disorders were considered positive when the patient had been already diagnosed by a psychiatrist according to the standard Diagnostic and Statistical Manual of Mental Disorders-V.

### Surgical procedure

The patient was placed in the reverse Trendelenburg position under complete general anesthesia. Insufflation was achieved with the Veress needle technique and direct entrance to the peritoneal cavity, the intra-peritoneal pressure allowed was 14 mm/Hg. A camera port [10 mm] was placed supra-umbilicus at the junction between the upper two-thirds and the

lower one-third of a line connecting the umbilicus and the xiphoid. Each of the remaining ports [right 5 mm subcostal mid-clavicular line, left 5 mm subcostal mid-clavicular line, and left 5 mm subcostal anterior axillary line] was inserted using direct vision. A liver retractor was placed in the sub-xiphoid position. Then the patient was placed in a steep reverse Trendelenburg position.

We started by dissection of the lesser omentum, then pars flacida, and then above the hepatic branch of the vagus in the pars condense, the phrenico-esophageal membrane is then divided. This was followed by Left crural dissection, Division of the short gastric vessels, Right crural dissection, Esophageal mobilization, Crural approximation posteriorly, Creation of the wrap, and finally fascial closure which was done at the 10-mm port sites. Skin closure will be done at all sites. Without a nasogastric tube, all patients were taken to the operating room. The morning after surgery, patients were given clear liquids, followed by a soft diet, and told to stay away from meat, bread, and carbonated drinks for two weeks. In the absence of complications, patients were usually discharged between 24 and 48 hours after their hospital stay.

### Follow-up

At three, six and 12 months after surgery, postoperative GERD symptom resolution was scored as poor, good, or excellent for typical symptoms [heartburn and regurgitation] and atypical symptoms [hoarseness, chronic cough, chronic laryngitis, chest pain, nausea, and chest pain]. We regarded the good response as partial control of symptoms, and the excellent response as complete control of the symptoms. Symptom control was defined as the complete recovery of all GERD symptoms [Typical and Atypical]. However, partial control was defined as the disappearance of one of the 2 types of symptoms. The poor response was defined as if neither of the two improves.

### Statistical analysis

Statistical analysis was performed by SPSS statistical software, version 28 [IBM, Chicago, Illinois, USA]. Categorical data were presented as numbers and percentages and were compared using the Chi-Square Test. The normality of continuous data was initially checked by the Kolmogorov-Smirnov test. Mann-Whitney U test to detect pair-wise comparison. Binary

stepwise logistic regression analysis was used for the prediction of independent variables of a binary outcome. Significant predictors in the Univariate analysis were entered into a regression model. Significant P value if less than 0.05.

## RESULTS

Our study included 30 patients with gastroesophageal reflux disease and or hiatal hernia. Table 1 shows the Socio-demographic characteristics of the studied cases. The mean age of the studied cases was  $37.5 \pm 11.29$  years. As regards their gender, 53.3% were females and 46.7% were male. In terms of BMI, the mean body mass index was  $27.0 \pm 3.39$ , with 26.7% of the cases being over-weight and 26.7% being obese.

According to the response to medical treatment of GERD, 50% of the included patient were with poor response, 26.7% were with good response, and 23.3% were with a moderate response. Twenty percent of the studied cases have a positive history of taking psychiatric drugs and 26.7% have positive psychiatric disorders. In our study, we found that 43.3% had a typical presentation of GERD, with a median duration of symptoms of 3 years ranging from 1 to 17 years. The endoscopic examination of the studied patients revealed that 73% of the studied patients had incomplete cardia and gastritis [Table 2].

The patient's response to surgery was assessed at 3, 6, and 12 months postoperative, and we found that the excellent response was 63.3% at one month, 60% at six months, and 56.6% at 12 months [Table 3].

In our study we reported only three cases with complications, two of them were with persistent dysphagia to solids, and the third was with gas bloating. In terms of patient satisfaction, 80% of patients were satisfied and partially satisfied with surgery, however, 20% were unsatisfied. We found a significant association between the patient's satisfaction and the psychiatric disorders [ $P = 0.18$ ], in which 50% of the patients who are unsatisfied or partially satisfied had positive psychiatric disorders. We also found a significant association between the patient's response to surgery and their satisfaction at all follow-up periods [ $P = 0.001$ ] [Table 4].

During three months follow-up period, we found a statistically significant association between the result of surgery, and the psychiatric state [P = 0.02], with a statistically significant difference, is detected between good and excellent response [P = 0.04]. Also, at 6- and 12-months follow-up periods, we found a statistically significant association was detected between response [P = 0.05, and 0.02 respectively], and psychiatric disorders with a statistically significant difference detected between poor and excellent response [P = 0.04, and 0.01 respectively]. Cases with a positive

psychiatric state have higher poor response frequency.

Binary logistic regression analysis was done for the detection of the predictors of poor response after 12 months, and we found that Positive psychiatric disorders are the only statistically significant predictor of poor response. The patients with positive psychiatric disorders have the risk of developing poor outcomes 10.55 times more risk than cases with negative psychiatric disorders [odds ratio =10.55;95% CI: 1.61-69.12] [Table 5].

**Table [1]:** Socio-demographic characteristics of the studied cases

Variables	Results
Age [years]	Mean ± SD 37.5±11.29
Body mass index [Kg/m <sup>2</sup> ]	Mean ± SD 27.0±3.39
Gender, n [%]	Male 14 [46.7 %]
	Female 16 [53.3%]
Body mass index, n [%]	Normal 14 [46.7%]
	Overweight 8 [26.7%]
	Obese 8 [26.7%]
Smoking, n [%]	Negative 22 [73.3%]
	Positive 8 [26.75]

**Table [2]:** History and clinical presentation among studied cases

Variables	Results
Duration of symptoms [years]	Median [range] 3 [1-17]
Response to Anti-Reflux drugs, n [%]	Poor response 15 [50.0%]
	Moderate response 7 [23.3%]
	Good response 8 [26.7%]
Patients on psychiatric drugs, n [%]	Negative 24 [80.0%]
	Positive 6 [20.0%]
Psychiatric disorders, n [%]	Negative 22 [73.3%]
	Positive 8 [26.7%]
Presentation, n [%]	Typical 13 [43.3%]
	Both [Typical and Atypical] 17 [56.7%]
Endoscopy, n [%]	Incompetent cardia 1 [3.3%]
	Incompetent cardia gastritis 22 [73.3%]
	Incompetent cardia, gastritis and esophagitis 7 [23.4%]

**Table [3]:** Follow up results of the studied cases

Follow Up period [No.=30]	No. [%]
After 3 months	Poor 3 [10%]
	Good 8 [26.7%]
	Excellent 19 [63.3%]
After 6 months	Poor 5 [16.7%]
	Good 7 [23.3%]
	Excellent 18 [60%]
After 12 months	Poor 8 [26.7%]
	Good 5 [16.7%]
	Excellent 17 [56.6%]

**Table [4]:** Factors affecting patient satisfaction

		No or partially satisfied [n=12]	Satisfied [n=18]	P value
Age [years]	Mean ± SD	41.67±10.36	34.72±11.29	0.09 <sup>a</sup>
Body mass index [Kg/m <sup>2</sup> ]	Mean ± SD	34.72±11.29	27.50±3.54	0.332 <sup>a</sup>
Gender, n [%]	Male	6 [50%]	8 [44.4%]	0.765 <sup>b</sup>
	Female	6 [50%]	10 [55.6%]	
Body mass index, n [%]	Normal	8 [66.7%]	6 [33.3%]	0.119 <sup>b</sup>
	Overweight	1 [8.3%]	7 [38.9%]	
	Obese	3 [25%]	5 [27.8%]	
Smoking, n [%]	Negative	8 [66.7%]	14 [77.8%]	0.678 <sup>c</sup>
	Positive	4 [33.3%]	4 [22.2%]	
Response to Anti-Reflux drugs, n [%]	Poor response	6 [50%]	9 [50%]	0.448 <sup>b</sup>
	Moderate response	4 [33.3%]	3 [16.7%]	
	Good response	2 [16.7%]	6 [33.3%]	
Patients on psychiatric drugs, n [%]	Negative	8 [66.7%]	16 [88.9%]	0.184 <sup>c</sup>
	Positive	4 [33.3%]	2 [11.1%]	
Psychiatric disorders, n [%]	Negative	6 [50%]	16 [88.9%]	0.018* <sup>c</sup>
	Positive	6 [50%]	2 [11.1%]	
Presentation, n [%]	Typical	3 [25%]	10 [55.6%]	0.141 <sup>c</sup>
	Both [Typical and Atypical]	9 [75%]	8 [44.4%]	
Duration of symptoms [years]	Median [range]	2 [1-10]	2 [1-10]	0.561 <sup>d</sup>
Follow Up after 3 months, n [%]	Poor	3 [25%]	0	0.001* <sup>b</sup>
	Good	7 [58.3%]	1 [5.6%]	
	Excellent	2 [16.7%]	17 [94.4%]	
Follow Up after 6 months, n [%]	Poor	5 [41.7%]	0	0.001* <sup>b</sup>
	Good	6 [50%]	1 [5.6%]	
	Excellent	1 [8.3%]	17 [94.4%]	
Follow Up after 12 months, n [%]	Poor	8 [66.7%]	0 [0%]	0.001* <sup>b</sup>
	Good	4 [33.3%]	1 [5.6%]	
	Excellent	0 [0%]	17 [94.4%]	
Complications. N [%]	Negative	9 [75%]	18 [100%]	0.025* <sup>b</sup>
	Positive	3 [25%]	0 [0%]	

a: Independent t test. b: Chi square test. c: Fisher exact test. d: Mann Whitney U test. \*: statistically significant.

**Table [5]:** Predictors of poor outcome at 12 months follow up

Variables	p-value	Odds ratio [92%CI]
Age/years	0.192	1.05 [0.975 - 1.14]
Sex [Male]	0.546	r 1.67 [0.318-8.74]
BMI	Normal	0.710
	Overweight	0.999
	Obese	0.407
Smoking	0.423	r 2.04 [0.356-11.67]
Response	Poor	0.538
	Moderate	0.272
	Good	0.782
Psychiatric drugs	0.164	r 3.8 [0.580-24.88]
Psychiatric disorders	0.014*	r 10.55 [1.61-69.12]
Presentation	Typical	0.698
	Both	0.698
Duration of symptoms /years	0.240	1.16[0.902-1.51]

## DISCUSSION

Laparoscopic Nissen fundoplication is still the best surgery for treating acid reflux, with high patient satisfaction and few problems after the surgery [9]. Several previous studies have tried to identify what factors affect the outcome after laparoscopic Nissen fundoplication [4]. The overall patient satisfaction after surgery in our study was 80% including patients who are completely and partially satisfied and only 20% were unsatisfied with the results one year after surgery. Based on prior studies, this result was deemed favorable. In particular, the majority of our patients presented with unusual symptoms, and many of them did not react to proton pump inhibitor medication, both of which have been documented as predictors of unsatisfactory surgical results.

In our study, there was no statistically significant association between the demographic factors and the outcome after laparoscopic Nissen fundoplication. This is in line with **Ip et al.** [10] who confirmed that the demographic factors don't predict the laparoscopic Nissen fundoplication outcomes, and also agree with **Addo et al.** [11] who reported that postoperative outcomes and complication rates were parallel among all age groups and the age of patients is not a predictor of the outcomes after Nissen fundoplication. However, these results disagree with **Cowgill et al.** [12] who concluded that Safe laparoscopic fundoplication improves GERD symptoms in the elderly, with outcomes similar to or better than those found in younger patients.

In other studies, the demographic factors appeared to have an impact on the outcome of Nissen fundoplication, there is a recent study that recommends the selection of young patients for good outcomes after Nissen fundoplication and considered aging as a relative contraindication to Nissen fundoplication [9]. Also, **Shukla et al.** [13] declared that the male gender is a good predictor of good outcomes after laparoscopic Nissen fundoplication. Similarly, **Beck et al.** [14] reported that the outcome for women is poorer than in males after laparoscopic Nissen fundoplication.

As regards the BMI, we found no significant association between it and the fundoplication outcomes. So, obesity is not considered a predictor of fundoplication outcomes. This agreed with **Tolone et al.** [15] who reported that morbid obesity does not affect the fundoplication adversely. Also, **Sanford et al.** [16] reported that

laparoscopic anti-reflux surgery in overweight, obese, and morbidly obese people may have the same value as in normal-weight people when it comes to treating pathological reflux symptoms and improving quality of life without adding morbidity or mortality.

A similar study was done by **Abdelrahman et al.** [17] lend support to anti-reflux surgery, regardless of BMI, and suggest that laparoscopic anti-reflux surgery can be done safely on obese people, and there's a lot of evidence that their outcomes will be the same as those of normal-weight people. On the other hand, **Morgenthal et al.** [4] stated that patients with morbid obesity are at a high risk of failure after Nissen fundoplication.

Smoking in our study had no significant effect on the outcome of laparoscopic Nissen fundoplication. In similar studies, there was no important effect on the outcome of anti-reflux surgery, **Wang et al.** [18] reported that Five years after surgery, smokers report the same rates of symptom improvement, PPI abstinence, and surgical satisfaction as nonsmokers. The long-term symptomatic outcomes following laparoscopic anti-reflux surgery do not appear to be negatively impacted by active smoking.

In terms of anti-reflux drugs, there is a concept that patients with poor response to anti-reflux drugs will have a poor outcome after laparoscopic Nissen fundoplication [13]. In our study there was no difference in outcome between patients with good responses to anti-reflux drugs and others with poor responses to these drugs. Similar to our results, **Schwameis et al.** [19] reported that response to anti-reflux drugs is not a predictor of outcome after laparoscopic Nissen fundoplication.

Also, **Shedeed et al.** [20] conducted a recent study done on patients with GERD who are not responding to medical treatment and proved that laparoscopic Nissen fundoplication done to this group of patients had a good outcome and laparoscopic Nissen fundoplication is a safe and effective procedure for gastroesophageal reflux disease in patients with poor response to anti-reflux drugs. There is a considerable incidence of anxiety and depression among GERD patients so all GERD patients should carefully be screened for psychiatric disorders [21].

The most important predictive factor determining the outcome of laparoscopic Nissen

fundoplication in our study was the psychiatric factor, out of six patients reported unsatisfied with surgery, there were four of them with psychiatric disorders one with anxiety disorder, and three had chronic depression with statistical significance, so in our study, we found that the psychiatric disorders are a significant factor in predicting poor out-come after Nissen fundoplication.

The majority of the recent studies prove the relation between the poor outcome after laparoscopic Nissen fundoplication and psychiatric disorders. **Holcomb et al.** [22] conducted a study about the Impact of psychiatric disorders on patient satisfaction after Nissen Fundoplication and concluded that anxiety and depression affect the patient's satisfaction on the long term follow up. Similarly, **Grimsley et al.** [23] reported that psychological disorders, such as anxiety and depression, can also lead to poor out-come after Nissen fundoplication.

**Statz et al.** [24] recommended that Strong social support and psychiatric well-being appear to be crucial predictors of the outcome following laparoscopic Nissen fundoplication. Optimizing social support and treating depression preoperatively and postoperatively may improve outcomes for laparoscopic anti-reflux surgery.

### Conclusion

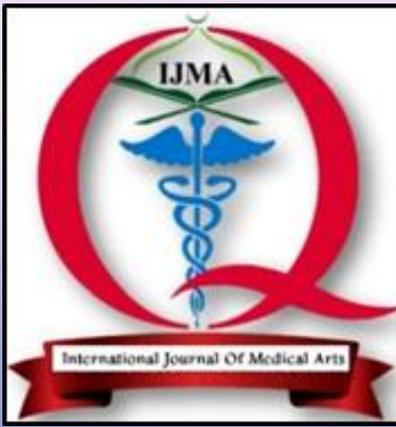
Laparoscopic fundoplication is effective for controlling GERD symptoms. Psychiatric disorders are the most important predictor for poor outcomes after laparoscopic fundoplication. Good pre-operative assessment of the patient's psychiatric state is crucial in planning for laparoscopic Nissen fundoplication.

**Conflict of Interest and Financial Disclosure:** None.

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