

Title: Long-Term Outcomes of Re-intervention for Failed Fundoplication: Redo Fundoplication versus Roux-en-Y Reconstruction

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Short running head: Redo vs RNY for failed fundoplication

Category: Original article

Keywords: Recurrent reflux, Re-operative, Redo fundoplication, Roux-en-Y,
Failed fundoplication

Presented at: SAGES2013, Apr. 2013. Baltimore, MD, USA

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Background: Redo fundoplication (RF) is the mainstay of treatment for failed fundoplication. A subset of patients with failed fundoplication requires Roux-en-Y reconstruction (RNY) for symptom relief. The aim of this study was to compare the long term subjective outcomes between RF and RNY in patients with failed fundoplication.

Methods: After Institutional Board Review approval retrospective review of a prospective database identified 119 RF (mean 54.1 years, 78 women) and 64 RNY (mean 54.8 years, 35 women) patients who underwent re-operative surgery between December 2003 and September 2009. Data variables analyzed included demographics, esophageal manometry, 24h pH study, type of procedure, peri-operative findings, complications, pre and post symptom (heartburn, regurgitation, dysphagia and chest pain) scores (scale 0-3), and patients' satisfaction score (scale 1-10). Patients with grade 2 and 3 scores were considered to have significant symptoms.

Results: Patients undergoing RNY had a significantly higher BMI, higher mean number of risk factors, and higher preoperative severity of heartburn and regurgitation compared to the RF group. Of the 183 patients, long term (>3 years) follow-up was available for 132 (89 RF and 43 RNY) patients. Symptom

severity significantly improved after both procedures, with the exception of dysphagia in the RNY group. Overall, there was no significant difference in patients' satisfaction between the RF and RNY groups. In subset analysis, patients with morbid obesity, esophageal dysmotility, or ≥ 4 risk factors have better satisfaction with RNY compared to RF ($p=0.027$, 0.031 and 0.045 , respectively).

Conclusions: Redo fundoplication and RNY have equally good patient satisfaction at 3 years follow-up. Roux-en-Y reconstruction may have improved outcomes in patients with morbid obesity, esophageal dysmotility, or in the presence of more number of risk factors.

Introduction

Gastroesophageal reflux disease (GERD) is a common disease of the Western world with symptoms affecting up to 40% of the population [1]. Anti-reflux surgery (ARS) for advanced gastroesophageal reflux disease is a safe and effective treatment. Laparoscopic nissen fundoplication is the gold standard for definitive management of pathological reflux disease and excellent 5-10 year symptom resolution has been reported [2–4]. However, there has been a cumulative increase in the number of patients reporting dissatisfaction with symptom control. Recurrence or persistence of symptoms and/or new undesirable symptoms have been reported in up to 15% of patients on long term follow-up [5]. Revisional surgery may be necessary in 3-6% of patients undergoing ARS [6-8].

Outcomes after re-operative anti-reflux surgery (Re-ARS) show decreased symptom resolution compared to primary ARS [9, 10]. Most commonly, these patients undergo redo fundoplication (RF), but it was previously reported that morbid obesity, esophageal dysmotility, short esophagus, severe preoperative dysphagia, and extraesophageal GERD symptoms were factors which contribute to poor outcomes after Re-ARS [11-13]. Roux-en-Y (RNY) gastric

bypass is the gold standard for primary and remedial control of GERD in morbidly obese patients. Several studies have shown that RNY reconstruction has good short term success, even in non-obese patients undergoing remedial anti-reflux surgery [14-17]. We have previously reported that patients with more complex pathology (≥ 4 risk factors) who underwent RNY had better short term outcomes than those who had RF [18].

Over the years our practice has changed. Earlier in the study period we invariably proceeded with redo fundoplication unless a devitalized fundus precluded it. With a greater understanding of the factors which contributed to poor patient outcomes and satisfaction after redo fundoplication, a shift to more liberal use of RNY reconstruction occurred.

The aim of this study was to assess >3 years outcomes for redo fundoplication and Roux-en-Y reconstruction in patients with failed fundoplication.

Methods

All patients undergoing anti-reflux surgery at the Esophageal Center at Creighton University Medical Center (CUMC) were entered in a prospectively maintained database. After Institutional Review Board approval the database

was queried to identify patients who underwent re-operative intervention between December 2003 and September 2009 after one or more previous anti-reflux procedures. Data on patient demographics, history of previous operations, preoperative symptoms and evaluation, operative course, peri-operative outcomes and subsequent follow-up data were extracted into a Microsoft Excel database. Patients who underwent esophagectomy as the re-operative procedure were excluded from this study.

Preoperative work-up

Patients presenting for Re-ARS were evaluated with a detailed history including a standardized esophageal questionnaire. Inquiry was made regarding original symptoms, workup before the previous surgery, immediate outcomes after primary surgery, and the timing of symptom occurrence prompting Re-ARS evaluation. Efforts were made to obtain previous operative reports. Preoperative workup included esophagogastroduodenoscopy, barium swallow, esophageal manometry, and gastric emptying study. Twenty-four hour pH monitoring was done as indicated. Esophageal dysmotility was defined as more than 20% ineffective peristalsis (dropped waves, simultaneous waves, or waves with peristaltic amplitudes less than 30 mmHg in the distal channels) with 10ml

liquid swallows. Patients with an intrathoracic fundoplication, a large (>5 cm) hiatal hernia, and/or a slipped fundoplication were considered to be at risk for short esophagus.

Surgical technique

The choice of procedure was individualized based on the preoperative assessment and intraoperative findings. Our surgical planning evolved during the course of the study. In the early part of the study, a redo fundoplication was the objective in surgery unless a devitalized fundus precluded it. With more experience and a better understanding of risk factors which lead to poor outcomes in RF patients, a shift to performing more RNY reconstructions occurred. At present we continue to individualize the decision after looking at pre-operative and intra-operative findings, and gauging the patient's ability to adapt to life with a RNY reconstruction.

Regardless of the approach, the essential steps of re-operative intervention were as follows: (1) takedown of the previous fundoplication and mediastinal mobilization of the esophagus, (2) repair of the hiatus defect as needed, and (3) an anti-reflux procedure. The anti-reflux procedure was either RF (with or without esophageal lengthening) or RNY (with or without distal gastrectomy). The

procedures have been described previously in detail [19]. Briefly in the RNY group, the goal was to preserve the distal stomach (i.e bypass) especially in patient's with severe esophageal dysmotility and/or Barrett's esophagus, who may require esophageal resection and gastric pull-up in the future. However, in patients with severe delayed gastric emptying, a redo fundoplication with distal gastrectomy and RNY Gastro-Jejunostomy was preferred. In some cases the decision to proceed with RNY reconstruction was made pre-operatively (i.e. morbidly obese, severe dysmotility, multiple previous fundoplications, or previous Collis gastroplasty). However, not infrequently the decision was made intra-operatively after take down of fundoplication when a devitalized fundus or presence of short esophagus precluded a redo fundoplication – particularly in the presence of other risk factors for failure which on their own may not have been enough to warrant RNY.

Previous laparotomy was not a contraindication to attempt laparoscopic surgery for re-operative intervention. Occasionally patients underwent trans-thoracic or thoraco-abdominal procedures.

Follow-up

Patients were followed-up with a standardized questionnaire (Appendix 1) either

by mail or telephone interview and the results were entered into our database. Patients were asked to assess the presence and severity of heartburn, chest pain, dysphagia and regurgitation, applying a 4 point symptom severity scale (0-none, 1-minimal, 2-moderate, 3-severe). The presence of other symptoms such as gas bloat and epigastric pain was recorded, as well as the use of medications. Patients with postoperative symptoms of grade 2 or 3 were considered to have a poor outcome. Patients were asked to score their satisfaction with outcomes on a scale of 1 to 10 with 1 being least satisfaction and 10 highest. Additionally patients were asked whether they would recommend a re-operative procedure to a friend if needed.

Statistical analysis

The data were presented as mean \pm standard deviation. The chi-square test was used to compare categorical data sets. Unpaired data were compared using the Student's t-test and Mann-Whitney *U* test. Paired data were analyzed using the Wilcoxon signed-ranks test. A $p < 0.05$ was considered significant.

Results

One hundred and eighty two patients underwent 183 Re-ARS from December

2003 to October 2008. One patient first underwent redo Collis fundoplication and subsequently a RNY conversion during the study period. One hundred and nineteen RF with or without Collis gastroplasty and 64 RNY with or without gastric resection were included in this study. Three patients who underwent esophagectomy were excluded.

Demographics are shown in Table 1. There were no significant differences in age and gender between the two groups. However, patients in the RNY group had a significantly higher mean body mass index (BMI). The RNY group was noted to have a higher proportion of patients with morbid obesity (BMI > 35 kg/m²), esophageal dysmotility, delayed gastric emptying, short esophagus, and more than one previous hiatal surgery. Patients who underwent RNY had a significantly higher mean number of risk factors than those who had RF (Table 2).

Preoperative symptoms are shown in Figure 1. Significantly higher heartburn and regurgitation severity scores were seen in the RNY group compared to the RF group (p=0.038, 0.049 respectively).

Re-operative surgery and complications

The majority of procedures were performed laparoscopically in both groups.

Fifteen procedures (8.2%) were converted from laparoscopic to open (8 patients (6.7%) in RF and 7 patients (10.9%) in RNY). The details of the re-operative surgery performed are presented in Table 3. Patients in the RF group had a significantly shorter mean operative time (202.9 ± 66.1 vs. 252.4 ± 64.0 min, $p < 0.001$) and mean hospital stay (6.62 ± 8.49 vs. 8.70 ± 11.78 days, $p < 0.001$) than those in the RNY group. Median hospital stay was 3 days in the RF group and 5.5 days in the RNY group, respectively.

There was no in-hospital or 30-day postoperative mortality. Early complications were observed in 42 (23.0%) patients, 13 of these underwent another surgical intervention within the same hospitalization (7.1 %). Details were given in our previous publication [18]. Late complications were observed in 61 patients (33.3%) (Table 5). In the RF group, dysphagia was the most common ($n=22$) complication and patients underwent endoscopy with dilation. In the RNY group, anastomosis related complications (anastomotic stricture, ulcer, and bleeding) were the most common ($n=9$). Three additional patients presented with acute bowel obstruction due to internal hernia and underwent laparoscopic repair. Four patients have had difficulty in maintaining oral nutrition due to dumping syndrome with one patient requiring long term parental nutrition. Another patient

has presented with recurrent heartburn and regurgitation and found to have a pathologically elevated 24 hour pH score presumably due to a relatively large pouch (100cc) created at the time of RNY reconstruction.

Symptom outcomes

Long-term follow-up was completed in 132 patients (72.1%) with a mean follow-up of 53.5 months (± 17.9 months). The mean follow-up time in the RF group (89/119, 74.8%) was 57.7 months (± 18.0 months) and in the RNY group (44/64, 68.8%) it was 41.8 months (± 11.5 months). A significantly higher reported weight loss was noted in the RNY group than the RF group (18.1 vs. 5.9 kg, $p < 0.001$). There was significant improvement in all symptom severity scores after Re-ARS. All symptoms significantly improved in both groups except for dysphagia, which was significantly improved only in the RF group (Fig. 2). Eighty patients (65.6%) had complete resolution of symptoms or had only minimal symptoms at follow-up. There was no significant difference in symptom control among patients who underwent RF or RNY. However, patients who had ≥ 4 risk factors and underwent RNY had better symptom outcomes than those who had ≥ 4 risk factors and underwent RF (18.2% vs. 66.7%, $p = 0.031$). Among patients with esophageal dysmotility, the incidence of postoperative dysphagia

among patients who underwent RF was higher compared to those who had RNY (58 % vs. 31 %, $p=0.07$).

Overall, mean satisfaction score was 7.8 and 87% of patients graded their satisfaction as good (6-7) or excellent (8–10). There was no significant difference in mean satisfaction score between RF and RNY. In subgroup analysis, patients with morbid obesity, esophageal dysmotility and ≥ 4 risk factors, who underwent RNY reported a significantly higher mean satisfaction score than those who underwent RF (9.46 vs. 7.25, $p=0.027$, 8.93 vs. 6.91, $p=0.031$, 9.44 vs. 7.25, $p=0.045$, respectively) (Fig. 3). Ninety percent of patients would recommend the surgery to a friend if needed.

Discussion

Re-operative intervention after failed fundoplication is technically challenging and reported to produce 81% patient satisfaction [20]. Re-operative anti-reflux surgery is a complicated procedure with high morbidity and even mortality. These surgeries should be performed in centers with dedicated foregut surgeons.

In the present study an overall satisfaction of 87% is consistent with that reported in literature. Surgical options after failed anti-reflux surgery include a

redo fundoplication, esophagectomy, and Roux-en-Y reconstruction. We have previously reported good patient satisfaction with both redo fundoplication and RNY reconstruction at one year of follow-up [18]. In this study, we compared long term outcomes after the two most commonly performed Re-ARS. After a mean follow-up of 53.5 months, the overall outcome of patients who underwent RNY were similar to those who underwent RF despite a significantly higher mean number of risk factors in the RNY group. These findings highlight the importance of identifying risk factors for poor outcomes in patients undergoing Re-ARS, as operative technique may be altered in “high risk” patients to achieve better outcomes.

Several investigations in the literature including our prior reports have implicated certain risk factors for poor outcomes in patients undergoing re-operative intervention for failed fundoplication. A lack of appreciation of these factors in patients may be a reason for the higher morbidity and poorer patient satisfaction seen in a certain subset of the population undergoing Re-ARS. Morbid obesity, poor esophageal motility, delayed gastric emptying, and multiple previous surgeries at the hiatus are some of the risk factors proposed behind poor satisfaction after failed fundoplication.

In obese patients with failed anti-reflux procedures, conversion to a RNY has been reported to be feasible and associated with significant reduction of reflux symptoms [21, 22]. It is clearly evident from the bariatric literature that the weight loss after RNY can lead to significant improvement in GERD symptoms [23, 24]. In this study, we identified that patients with morbid obesity who underwent RNY have better symptomatic outcomes compared to those who underwent RF. The RNY group also reported significant weight loss, which could be a factor in symptomatic improvement and better satisfaction. However, we have reported improved outcomes with RNY reconstruction even in non-obese patients, particularly those who have other risk factors for failure of RF.

Furnee et al. documented that impaired esophageal motility was one of the predictors of a poor symptomatic outcome after re-operative intervention [11]. Our present study showed that patients with impaired esophageal motility who underwent RNY had better satisfaction scores than those who had RF. The present study also shows that it is also important to identify the number of risk factors for poor outcomes in patients. We previously reported that patients with ≥ 4 risk factors who underwent RNY had better short term outcomes than those who had RF [18]. The current study reconfirms that these patients (with ≥ 4 risk

factors) undergoing RNY continue to have better long term satisfaction compared to those undergoing RF. Overall, our results show that RNY is a better alternative to RF in this subset of patients with morbid obesity, esophageal dysmotility or more than 4 risk factors.

Our data showed that 39 % (25/64) of patients with RNY had complications after long term follow-up. Of these, anastomotic strictures at 28% (7/25) were the most common. However, all of these were managed with endoscopic dilation with good long term success. The incidence of anastomosis related complications was relatively high in the RNY group. Multiple previous interventions at the hiatus could be a possible reason for the higher incidence of anastomosis related complications in the RNY group, which were seen more in patients with smaller gastric pouches. Additional complications unique to RNY reconstruction such as dumping syndrome and internal hernias have also been noted.

Since incorporating RNY reconstruction into our armamentarium we have been leaning towards increasing the gastric pouch size (from 15-30 to 70-100 cc) either due to necessity, when there is significant devascularization of the lesser curvature (a more oblong pouch similar to a vertical gastropasty is created

maintaining vascularity) or to allow for a larger meal size. However, this has resulted in one patient having a pathologically elevated 24 pH score. These issues highlight that though RNY reconstruction is a viable alternative for a subset of patients undergoing re-operative intervention, it comes at a higher “cost” and the need for long term follow-up.

This study along with others showing good outcomes in “at-risk” patients with RNY reconstruction raise the possibility of using RNY reconstruction as a primary rather than remedial modality in a select group of patients. As mentioned above, in morbidly obese patients RNY reconstruction is superior to primary fundoplication. Additionally, Kent et al have reported superior outcomes with RNY reconstruction compared to partial fundoplication when used as primary treatment in patients with scleroderma who have severe esophageal dysmotility [25]. Therefore, an argument can be made for identifying patients who are at high risk for poor or failed outcomes after fundoplication, and directly proceed with RNY reconstruction as primary treatment.

In this present study, the overall outcome of patients who underwent RNY was similar to that of those who underwent RF even though they had more complex disease pathology. However, RNY may not be the better option for all patients.

Deschamps et al. [26] reported that RNY with truncal vagotomy was performed when the fundus was found to be inadequate for any type of repair. Several other studies have also concluded that RNY was an acceptable treatment option for patients with risk factors such as multiple previous fundoplications and morbid obesity [16, 27]. Patients undergoing re-operative intervention should be thoroughly investigated and a procedure offered only if the anatomic derangements and physiologic findings explain the patient's symptoms, and that these symptoms are not amenable to medical therapy. The exact operative approach and technique needs to be individualized. RF should be the first choice in most patients, and RNY preferred for a subset of patients at high risk of poor outcomes after RF. Our data demonstrates that in patients with morbid obesity, poor esophageal motility, or ≥ 4 risk factors RNY resulted in better patient satisfaction at long term follow-up.

Conclusion

Reoperation provides good subjective outcomes when may measured more than 3 year after surgery. Both RF and RNY showed equally good patient

satisfaction, even though patients undergoing RNY had a higher severity of disease. RNY be considered a preferred surgical option in patients with morbid obesity, esophageal dysmotility and more complex pathology.

Disclosures

Drs. Se Ryung Yamamoto, Masato Hoshino, Amith V. Reddy, Kalyana C. Nandipati, Tommy H. Lee and Sumeet K. Mittal have no conflict of interest or financial ties to disclose.

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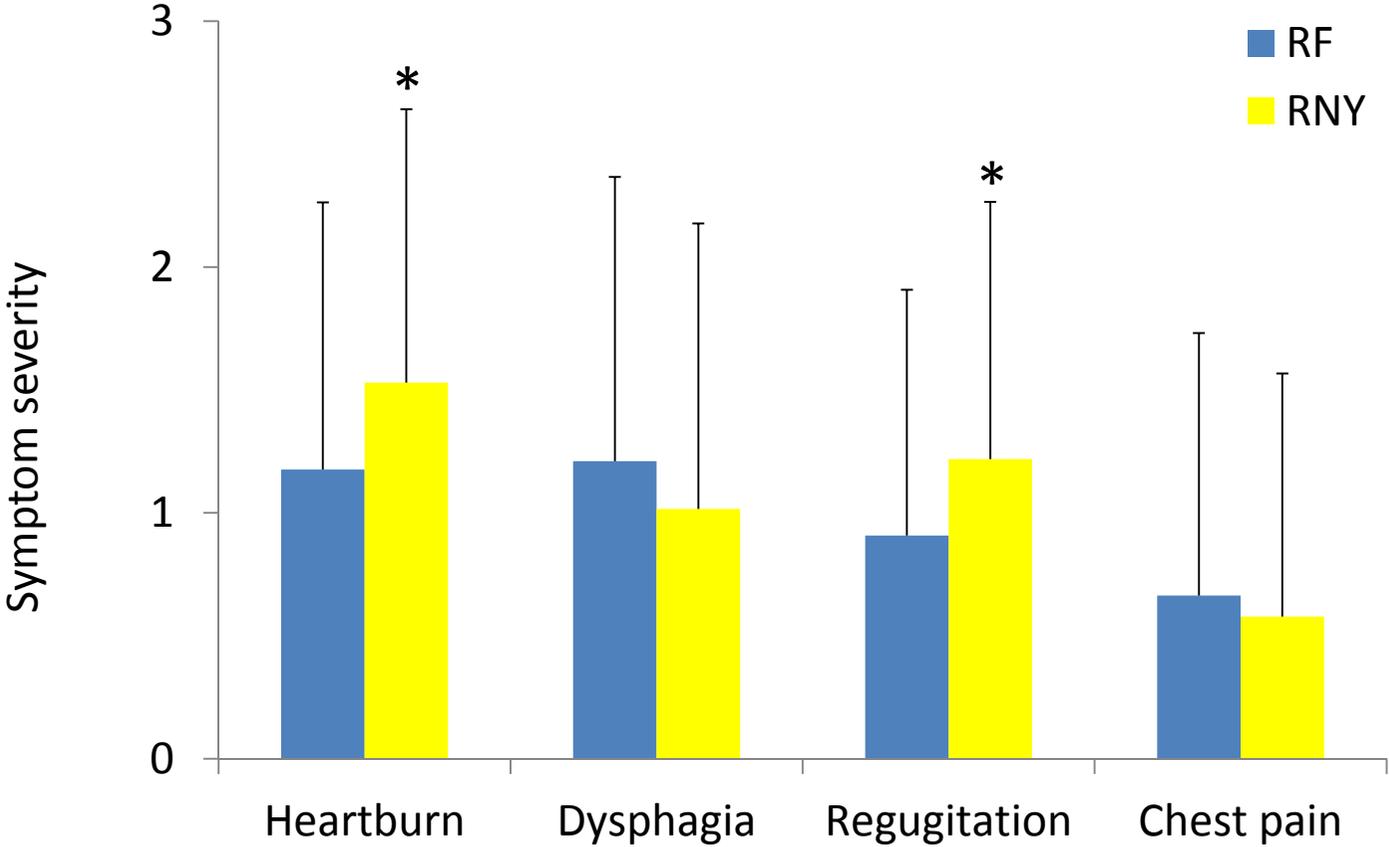
Legend

Figure 1: Preoperative symptoms

Figure 2: Pre- and Postoperative symptoms

Figure 3: Patients satisfaction

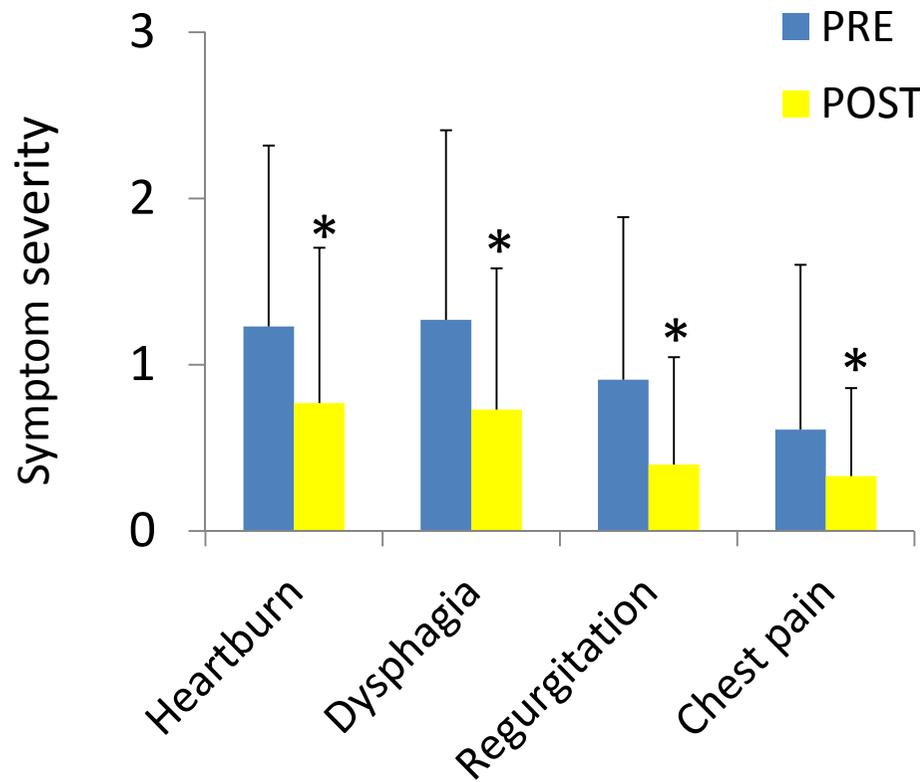
Figure 1



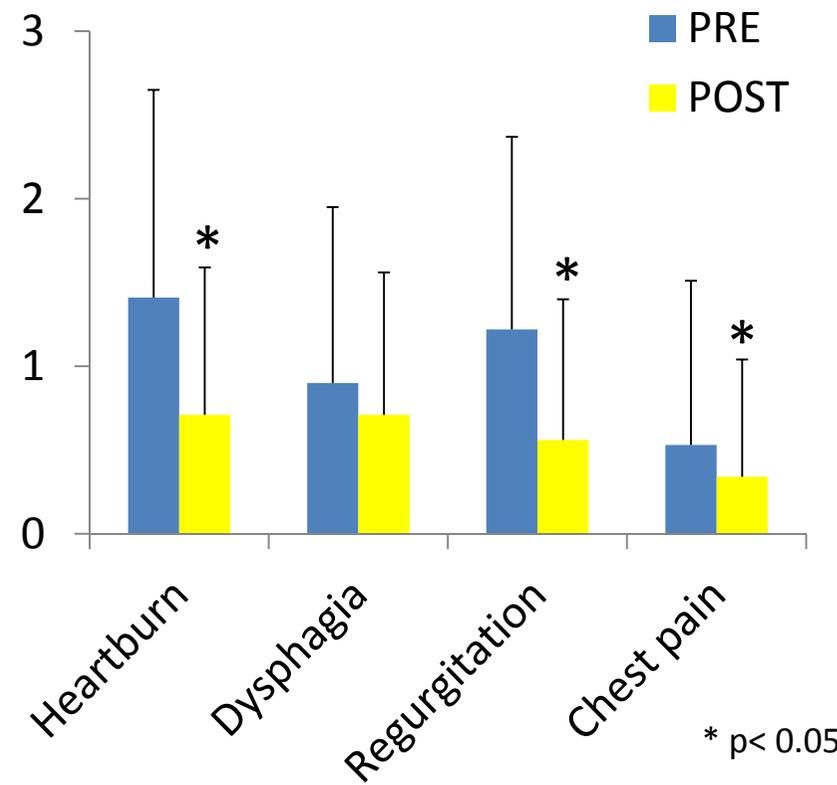
RF: redo fundoplication, RNY: Roux-en-Y reconstruction

* p < 0.05

Figure 2



Redo fundoplication



RNY reconstruction

* p < 0.05

Figure 3

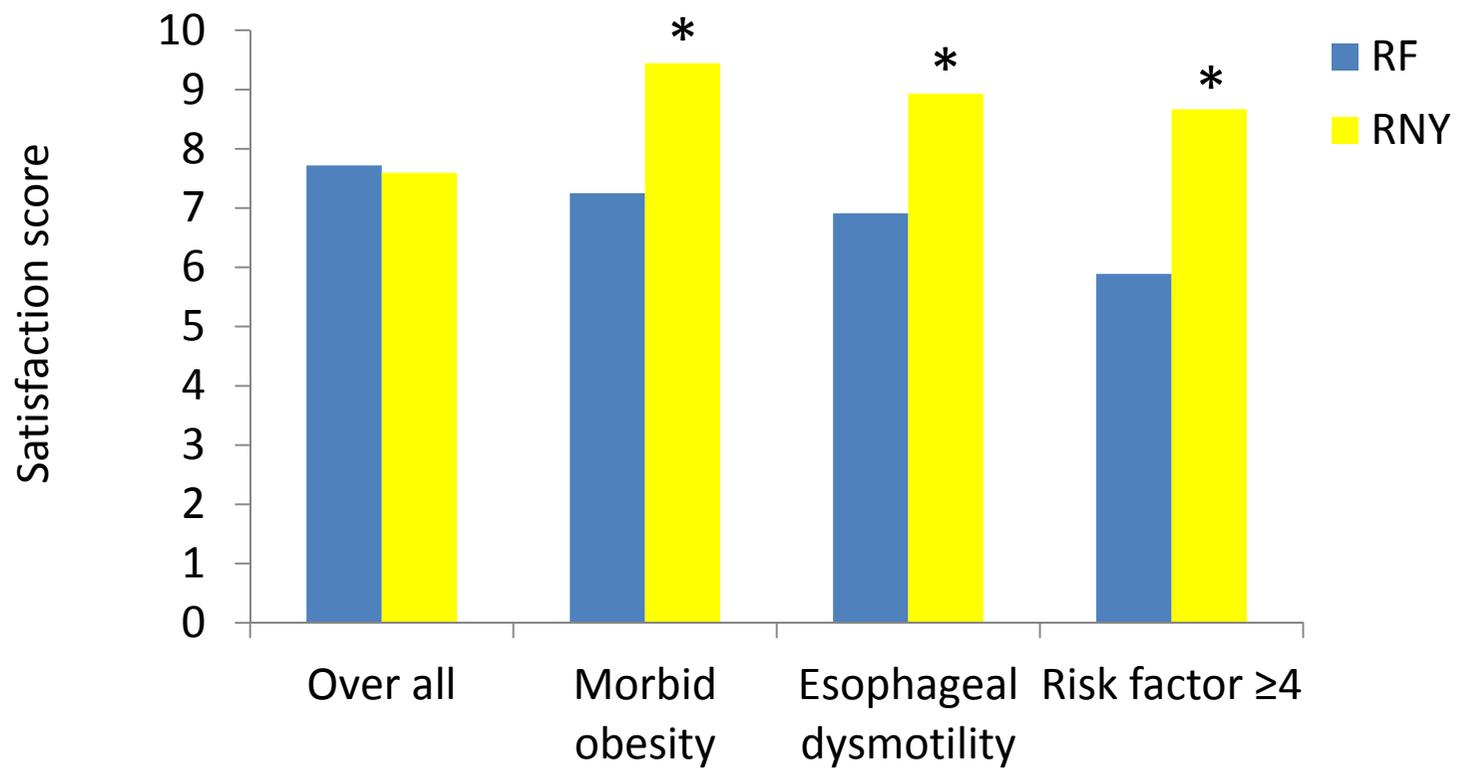


Table 1 Patient Characteristics

	RF (n=119)	RNY (n=64)	<i>p</i> Value
Male:Female	41:78	19:35	0.51
Age, mean (range)	54.1 (25-85)	54.8 (26-84)	0.71
BMI, mean (\pm SD)	29.6 \pm 4.9	31.5 \pm 5.7	0.023
Number of previous surgeries			
1	109 (91.6%)	47 (73.4%)	<0.001
2	10 (8.4%)	13 (20.3%)	0.04
≥ 3	0	4 (6.3%)	0.005

Table 2 Risk factors

	RF (n=119)	RNY (n=64)	<i>p</i> Value
BMI > 35 Kg/m ²	16 (12.6%)	17 (26.6%)	0.018
≥ 2 previous surgery	10 (8.4%)	17 (26.6%)	<0.001
Esophageal dysmotility	32 (26.9%)	26 (40.6%)	0.028
Delayed gastric emptying	28 (23.5%)	24 (37.5%)	0.058
Significant dysphagia	58 (48.7%)	25 (39.1%)	0.24
Respiratory symptom	37 (29.4%)	23 (35.9%)	0.035
Short esophagus	17 (14.3%)	22 (34.4%)	0.002
Mean no. of risk factors	1.8	2.6	<0.001

Table 3 Operations performed

Redo fundoplication (n=119)		Roux-en Y reconstruction (n=64)	
Laparoscopic	81	Laparoscopic	37
Lap to open	8	Lap to open	7
Open	30	Open	20
Laparotomy	7	Laparotomy	18
Thoracotomy	23	Thoracolaparotomy	2
Nissen	64	Gastrojejunostomy	59
Toupet	41	Esophagojejunostomy	5
Dor	6		
Belsey	4	Stomach	
Adhesiolysis and HH repair	3	in situ	47
Take down fundoplication	1	resected	17

Table 4 Late complications

Redo fundoplication (n=119)

Small bowel obstruction	1
Dysphagia requiring dilation	22
Gas bloat syndrome	12

Roux-en-Y reconstruction (n=64)

EGJ stricture	2
Anastomotic stricture	7
Anastomotic ulcer	3
Anastomotic bleeding	2
Internal hernia	3
Ventral hernia	6
Small bowel obstruction	2
Cholelithiasis	2
Dumping syndrome	4

Appendix

Symptoms	Heartburn	Dysphagia
Grading	0 None	0 None
	1 Minimal - episodic, no treatment is required	1 Minimal - once a week or less
	2 Moderate - controlled with medication	2 Moderate - more than once a week, requiring dietary adjustment
	3 Severe - interferes with daily activity or not controlled with medication	3 Severe - preventing ingestion of solid food
	Regurgitation	Chest pain
	0 None	0 None
	1 Mild - after straining or large meal	1 Minimal - episodic
	2 Moderate - positional	2 Moderate - reason for visit
	3 Severe - constant regurgitation with or without aspiration	3 Severe - interferes with daily activity
	Nausea/Vomiting	Abdominal bloating
	0 None	0 None
	1 Occasional episodes of nausea	1 Present
	2 Frequent nausea or episodic vomiting	
	3 Continuous nausea or frequent vomiting	
	Other symptoms	

Medications

Name:

Dose:

Weight

How satisfied are you with your surgical outcome?

(Scale 1-10, 1-worse/10-best)

Would you recommend this procedure to a friend? Yes/No