



# Long-term clinical outcomes after intrathoracic stomach surgery: a decade of longitudinal follow-up

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Received: 6 June 2017 / Accepted: 13 September 2017 / Published online: 19 October 2017 © Springer Science+Business Media, LLC 2017

#### **Abstract**

Background A subset of patients with large paraesophageal hernias have more than 75% of the stomach herniated above the diaphragm; such cases are referred to as intrathoracic stomach (ITS). Herein, we report longitudinal symptomatic outcomes over a decade after surgical ITS repair in a large patient cohort.

Methods Patients who underwent surgical treatment for ITS from 01/2004 to 05/2016 were studied. Preoperative and follow-up data were prospectively collected. Patients completed a standardized symptom questionnaire 1 year postoperatively and at 2-year intervals thereafter.

Results In total, 235 patients were reviewed. The mean age was  $70.0 \pm 11.6$  years; 174 patients (74.0%) were women. Surgical procedures included 7 transthoracic repairs and 228 transabdominal repairs (222 laparoscopic, 2 open, 4 laparoscopic-to-open conversions). Anti-reflux procedures were performed in 173 patients (73.6%). 33 patients (14.0%) had mesh reinforcement of hiatal closure; 11 (4.7%) underwent Collis gastroplasty. Follow-up symptom questionnaires at 1, 3, 5, 7, 9, and 11 years were available for 81, 48, 47, 30, 33, and 38% of patients, respectively. Significant and lasting symptom improvement was reported at all follow-up time points. Mean satisfaction scores of 9.3, 9.1, 9.3, 9.0, 9.5, and 9.8 on a 1–10 scale were recorded at the aforementioned intervals.

Conclusions Long-term clinical outcomes confirm that laparoscopic ITS repair is safe and durable, and is associated with a high degree of patient satisfaction and symptom resolution.

**Keywords** Clinical outcomes · Fundoplication · Hiatal hernia · Intrathoracic stomach · Mesh · Paraesophageal hernia

Paraesophageal hernias (PEH) account for roughly 5% of all hiatal hernias (HH), and are more likely to be symptomatic and require surgical intervention than Type I HH. Although many definitions have been used to describe a large PEH, it is most consistently defined as an HH larger than 5 cm, or more than 33% of the stomach herniated above the hiatus. Patients whose PEH involves more than 75% of the stomach herniated can more aptly be described as having an intrathoracic stomach (ITS). This condition usually presents with obstructive symptoms and is associated with a higher risk of volvulus and strangulation. Given the complications associated with nonoperative management of ITS and the high morbidity of emergent surgery, elective repair has been widely recommended [1, 2].

Laparoscopic repair of PEH was pioneered in the 1990s; the feasibility and safety of this technique have been well reported [3–5]. Laparoscopic repair is associated with lower rates of perioperative morbidity and a shorter hospital stay compared with open procedures, but has a steep learning curve. Excellent short-term and mid-term outcomes have been reported in the literature, including a 2011 study by our group [6–8]. However, some have reported high recurrence rates associated with laparoscopic PEH repair, and mesh use has been advocated to decrease recurrence [8–11]. Mesh has

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also been associated with catastrophic complications, and its routine use remains controversial [12].

Routine fundoplication, though traditionally recommended for reflux, has been suggested to decrease the likelihood of PEH recurrence. However, Svetanoff et al. [13] recently questioned the need for routine fundoplication in patients with ITS after finding that patients whose ITS was repaired without fundoplication had outcomes comparable to those repaired with fundoplication. However, they also noted that these findings are limited to patients with ITS (who generally present with obstructive symptoms) and do not apply to patients with smaller, Type III HH (who more often present with reflux symptoms).

Several techniques—namely, the use of mesh, fundoplication, and lengthening procedures—are still controversial. We have previously reported 1- and 5-year outcomes for primary ITS repair [3, 6]. Herein, we report our long-term findings (i.e., > 10 years of longitudinal clinical outcomes) after repair of ITS.

#### Materials and methods

# Study design

This study was approved by the Institutional Review Board at Creighton University Medical Center. All patients who undergo foregut surgery at Creighton University Esophageal Center are entered into a prospectively maintained database containing operative and perioperative data. A nurse navigator contacted patients in this study 1 year after surgery and then at 2-year intervals for subjective follow-up. A standard symptom questionnaire was administered pertaining to foregut symptoms, use of medications, and satisfaction with surgical outcomes. The database was queried to identify patients who underwent primary repair of ITS between January 1, 2004 and May 30, 2016 by a single surgeon. ITS was defined as more than 75% of the stomach above the hiatus based on barium swallow or computed tomography (CT). Patients with smaller Type III PEH and recurrent HH were excluded. Perioperative and questionnaire data were analyzed.

## Preoperative work-up

All patients scheduled for primary repair of ITS underwent a preoperative upper endoscopy (by the operating surgeon), manometry, and a barium swallow in the elective or semi-elective setting, as well as cardiopulmonary evaluation for surgical risk assessment. The barium swallow was carried out according to standard protocol. Upright contrast film or CT (if done) was used to estimate the percentage of stomach that had herniated above the hiatus. Patients presenting to

the emergency department underwent emergent ITS repair only if there was evidence of acute perforation. Patients without perforation were managed with endoscopic decompression and nasogastric tube placement. These patients subsequently underwent semi-urgent repair at the same admission. Patients were offered surgery if their symptoms were obstructive in nature or were not amenable to medical therapy. Not infrequently, these patients downplay their symptoms, but upon closer questioning, they reveal that they have been eating progressively smaller meals to avoid postprandial symptoms. Patients were also administered a structured questionnaire pertaining to foregut symptoms.

## Surgical technique

The operative repair of ITS has been previously described in great detail [6, 14–17]. After complete hernia sac excision and mediastinal mobilization for hiatus closure, we use interrupted 0 Ethibond figure of eight sutures (Ethicon, Somerville, NJ) beginning posteriorly and proceeding anteriorly. If further posterior closure would significantly angulate the esophagus at the hiatus and additional crural closure is needed, more sutures are placed anterolaterally at the 2 o'clock position (Fig. 1). Mesh is used only if excessive tension is noted at the crural closure; this decision is subjective and is made intraoperatively. If planned, a fundoplication is created with or without Collis gastroplasty. We presently prefer a posterior partial fundoplication to a total fundoplication. We also prefer to avoid any degree of

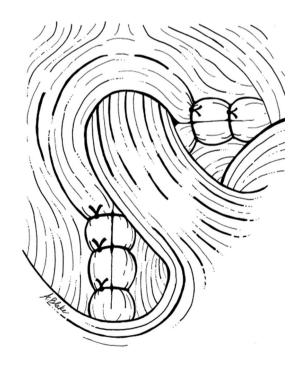


Fig. 1 Primary suture closure of the crus



fundoplication in debilitated patients, especially those without extensive preexisting reflux symptoms; and in patients who have extremely poor esophageal motility, especially in the setting of short esophagus. We are liberal in our use of percutaneous gastrostomy tube placement, mainly for more facile gastric decompression to aid in patient comfort. It also serves as a convenient way to administer medications or hydration, if necessary, in these often-debilitated patients.

Figure 2 shows our treatment algorithm that guides intraoperative decision-making in patients undergoing surgical ITS repair. It is neither comprehensive nor dogmatic, and intraoperative decisions are ultimately based on each patient's clinical situation and intraoperative findings. Over the years, we have decreased our use of mesh and Collis gastroplasty, and have increased our anterolateral crus closure and our utilization of temporary percutaneous gastrostomy tubes.

## Perioperative care

Patients who have undergone open procedures receive postoperative analgesia via an epidural. Patient-controlled analgesia is used after laparoscopic procedures. In all cases, early ambulation is encouraged. Gentle diuresis is initiated on the first postoperative day to decrease the incidence of volume-associated complications (e.g., cardiac arrhythmia). Perioperative swallow studies are performed in patients who have Collis gastroplasty or as indicated by clinical scenario. In patients who have undergone laparoscopy, diet is started on postoperative day 1 and patients are instructed to vent the tube if there is significant bloating not amenable to medical management. Patients are discharged after bowel function has returned and after adequate oral fluid intake (net of fluid lost with decompression, if needed) is achieved. The gastrostomy is removed in an outpatient setting if it has not

been used for at least 1 week. This usually occurs 2–3 weeks postoperatively.

# Postoperative follow-up

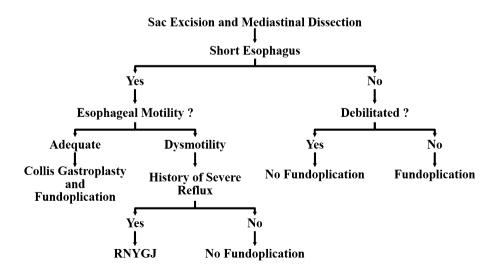
Patients were contacted at 1, 3, 5, 7, 9, and 11 years after surgery and a standard foregut symptom questionnaire was administered (Appendix 1). Patients were asked to grade foregut symptoms (i.e., heartburn, regurgitation, dysphagia, chest pain) on an analog scale of 0–3. Pro-kinetic, anti-gas, and acid-suppressing medication use was recorded. Overall outcome satisfaction was reported on an analog scale of 1–10, with 10 being the most satisfied.

## **Results**

# **Demographics**

A total of 852 patients underwent primary hiatal hernia/anti-reflux surgery from 01/01/2007–05/30/2016. Of these, 235 (27.6%) patients had ITS; these patients form the cohort for this study. 2/235 cases (1%) were done emergently. The mean age was  $70.0 \pm 11.6$  years (range 38–96 years) and 174 patients (74.0%) were women. 22 patients (9.4%) did not have any follow-up; the remaining 213 patients had one or more follow-ups at the aforementioned time periods. The patients in this cohort often presented with more than one symptom: 78% of patients presented with obstructive symptoms, 61% presented with postprandial epigastric fullness/pain/inability to belch, and 17% presented with dysphagia. Still others had reflux symptoms as the primary presenting symptoms (12% heartburn, 10% regurgitation).

Fig. 2 Intraoperative treatment algorithm for repair of intrathoracic stomach





**Table 1** Operative details of 235 patients who underwent surgical PEH repair

Variable	n (%)				
Surgery type					
Laparoscopic	226 (96.2)				
Conversion to open	4 (1.7)				
Open	9 (3.8)				
Laparotomy	2 (0.85)				
Transthoracic	7 (3.0)				
Collis gastroplasty	11 (4.7)				
Percutaneous endoscopic gastronomy	132 (56.2)				
Mesh reinforcement	33 (14.0)				
Anti-reflux surgery $(n=173)$					
Nissen fundoplication	87 (50.3)				
Toupet fundoplication	81 (46.8)				
Roux-en-Y gastrojejunostomy	3 (1.7)				
Dor fundoplication	2 (1.2)				

#### Procedure

Operative details are presented in Table 1. Most patients (n = 226, 96.2%) underwent laparoscopic repair; four of these required conversion to open procedures due to intraoperative bleeding. Of the remaining nine patients, seven underwent a primary transthoracic procedure due to anticipated hostile abdomen. Primary laparotomy was performed in two patients: one with compromised cardiopulmonary status who would not tolerate pneumoperitoneum, and one as an emergency procedure for suspected gastric perforation. Fundoplication was performed in 170 patients (72.3%), and 11 of these patients also required Collis gastroplasty for a short esophagus. Three patients underwent Roux-en-Y gastrojejunostomy with or without gastrectomy. One of these patients demonstrated extensive gastric erosions and polyps, one presented emergently with perforation and abscess surrounding an ITS, and one had a body mass index over 40 kg/m<sup>2</sup>. 33 patients (14.0%) received mesh reinforcement. Two patients treated early in the study period received nonabsorbable mesh; the remaining 31 patients received biosynthetic mesh, most of which (21/31) were Veritas mesh (Baxter International, Deerfield, IL, USA) cut into a U-shape. A gastrostomy tube was placed intraoperatively in 132 patients (56.2%). This was most commonly a percutaneous gastrostomy; however, a laparoscopic G-tube with anchoring sutures was used for patients who had Collis gastroplasty. The average operative time was  $155 \pm 54$  min and mean blood loss was 73.8 mL (range 10-1250 mL).

#### Morbidity and mortality

Operative and postoperative complications were noted in 54 patients (Table 2). Two patients were taken back to

the OR for bleeding and were managed with washout and transfusions (no specific source of bleeding was identified in either patient). One additional patient required transfusion only. Minor cardiac complications were the most common postoperative complication, followed by symptomatic pneumo-, hydro-, or hemothoraces. Median hospital stay was 2 days (mean  $13 \pm 5$  days for open procedures versus  $4 \pm 4$  days for laparoscopic procedures; p < 0.05) and 29 patients required care in the intensive care unit (median length of stay: 1 day; range 1–10 days). There was one intraoperative death secondary to bleeding and coagulopathy after blood transfusion. Overall 30- and 60-day mortality rates were 1 and 2.5%, respectively.

## Subjective follow-up

Subjective symptom and satisfaction scores of patients who were alive and with capacity were analyzed (Table 3; Fig. 3). Of these, 81, 48, 47, 30, 33, and 38% completed foregut symptom questionnaires at 1, 3, 5, 7, 9, and 11 years postoperatively, respectively. Compared to preoperative symptom

**Table 2** Peri- and postoperative complications of 235 patients who underwent surgical PEH repair

Complication	n (%)			
Intraoperative complications				
Bleeding	6 (2.6%)			
Esophageal myotomy	5 (2.1%)			
Gastrotomy	4 (1.7%)			
Esophageal mucosal tear	2 (0.9%)			
Liver injury	1 (0.4%)			
Perioperative complications				
Atrial fibrillation	6 (2.6%)			
Other arrhythmia	5 (2.1%)			
Pneumo-/hemothorax requiring CT	5 (2.1%)			
Urinary tract infection/urinary retention	5 (2.1%)			
Reintubation	4 (1.7%)			
Aspiration/pneumonia	3 (1.3%)			
Hemorrhage requiring return to OR	2 (0.9%)			
Acute renal failure	1 (0.4%)			
Bile leak	1 (0.4%)			
Chyle leak	1 (0.4%)			
Dysphagia requiring dilation	1 (0.4%)			
Gastric content leak	1 (0.4%)			
Gout exacerbation	1 (0.4%)			
Hemorrhage resulting in death	1 (0.4%)			
Pericardial effusion	1 (0.4%)			
Postoperative myocardial infarction	1 (0.4%)			
Prolonged ileus causing SBO	1 (0.4%)			

CT computed tomography, OR operating room, SBO small bowel obstruction



scores, postoperative symptom scores were reduced in every category, and this improvement was stable over time. Satisfaction scores were also consistent at 9.0–9.8 for the duration of follow-up, with >85% patients reporting excellent satisfaction (>8 out of 10) at all time points.

No significant differences in patient-reported symptoms and satisfaction scores were observed between patients with fundoplication and patients without; similarly, no significant differences in symptoms or satisfaction were observed between patients with mesh reinforcement at the hiatus and patients without (Fig. 4). Fifty-seven percent of patients were on proton pump inhibitors preoperatively, while 23, 20, 17, 21, and 33% of patients were on these medications at 1, 3, 5, 7, and 9 years postoperatively (Table 3).

# Objective follow-up

In addition to the foregut symptom questionnaires, patients were objectively assessed 1 year postoperatively. Recurrence was defined as either the need for reoperation, or radiographic evidence of a hiatal hernia ≥ 2 cm. In total, 212 patients were eligible for 1-year follow-up, but 10 of these patients died within the first year and 3 lacked capacity due to advanced dementia. Of the remaining 199 patients, 127 (63.8%) completed objective follow-up. Within the first postoperative year, 2/127 patients (1.6%) required reoperation, and 3/127 (2.4%) had recurrent hiatal hernias ≥ 2 cm. 11 patients (8.7%) had hiatal hernias < 2 cm. Given the low number of recurrences and the infrequent use of mesh, potential statistical significance of mesh reinforcement or fundoplication on recurrence rate could not be determined.

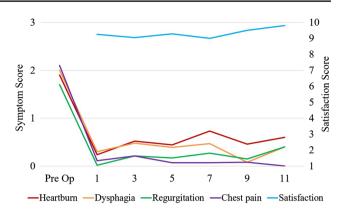


Fig. 3 Mean symptom (left axis) and satisfaction (right axis) scores over time

## Discussion

Since the first elective HH repair was described by Mayo in 1911, the operative approach for this indication has continued to evolve. Initially, most cases were performed open from a thoracic or abdominal approach, and repair was limited to anatomic reduction with simple gastropexy, which was associated with high recurrence rates [18, 19]. Later, hernia sac excision was found to be critical in preventing recurrence, and was added to gastropexy as the treatment of choice [20]. Lal et al. advocate routine fundoplication to prevent postoperative reflux and to decrease recurrence by achieving intra-abdominal gastric fixation [21]. The dispute over open versus minimally invasive repair commenced with the description of the laparoscopic technique in 1992

Table 3 Symptom and satisfaction scores

Variable	Follow-up duration						
	Preop	1 year	3 years	5 years	7 years	9 years	11 years
Patient response		158/195 (81.0%) <sup>a</sup>	69/145 (47.6%)	50/107 (46.7%)	18/61 (29.5%)	13/40 (32.5%)	5/13 (38.4%)
Symptom <sup>b</sup>							
Heartburn	1.9(2)	0.24(0)	0.52(0)	0.44(0)	0.73(0)	0.46(0)	0.60(0)
Dysphagia	2.0(2)	0.30(0)	0.48 (0)	0.39(0)	0.47(0)	0.08(0)	0.40(0)
Regurgitation	1.7(2)	0.016(0)	0.21(0)	0.17(0)	0.27(0)	0.15(0)	0.40(0)
Chest pain	2.1(2)	0.11(0)	0.21(0)	0.07(0)	0.07(0)	0.08(0)	0 (0)
Satisfaction score <sup>c</sup>	N/A	9.3 (2-10)	9.1 (3–10)	9.3 (6-10)	9.0 (6-10)	9.5 (8-10)	9.8 (9-10)
Satisfaction≥8, %	N/A	86	88	86	94	85	100
Medication use							
Proton pump inhibitor, %	57	23	20	17	21	33	_
Histamine H2 blocker, %	2	3	5	13	14	11	-

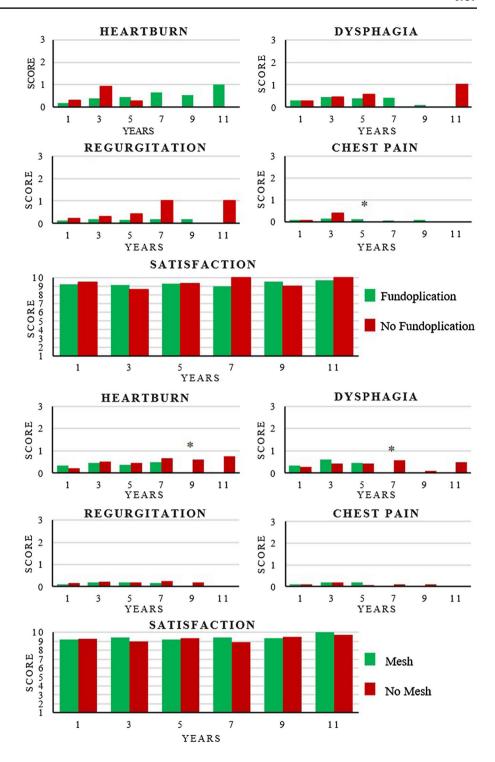
<sup>&</sup>lt;sup>a</sup>Of the 212 patients who originally would be included in the 1-year follow-up, 10 died, 3 lacked capacity due to advanced dementia, and 4 underwent surgery for other procedures and were therefore excluded from the questionnaire component of this study

<sup>&</sup>lt;sup>c</sup>Values expressed as mean (range)



<sup>&</sup>lt;sup>b</sup>Values expressed as mean (mode)

Fig. 4 Comparison of symptom and satisfaction scores over time between patients who received fundoplication versus no fundoplication (above) and mesh reinforcement versus no mesh reinforcement (below). \*p value  $\leq 0.05$ 



[5]. A 2005 systematic review concluded that most published reports now recognize the laparoscopic approach as the safer technique that offers decreased morbidity (median morbidity of open and laparoscopic repairs: 16.2 and 4.3%, respectively) and lower recurrence rates (open and laparoscopic repairs: 9 and 7%, respectively) [11]. In several early laparoscopic series, however, recurrence rates of up to 66% were reported, igniting the debate over which intraoperative

approach would result in fewer recurrences with appropriately low complication rates [8, 9].

Several factors are believed to contribute to recurrence, including primary failure of the crural closure and high axial tension resulting from a shortened esophagus and increased transdiaphragmatic pressure gradient at the gastroesophageal junction. At the same time, widespread use of mesh for inguinal and ventral hernias had been shown to be safe and

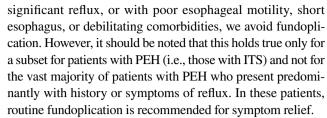


efficacious. Collis gastroplasty and mesh reinforcement at the hiatus are generally suggested for recurrence prevention.

Collis gastroplasty is intended for use in patients with a short esophagus, the existence of which is itself controversial, especially in the era of widespread proton pump inhibitor use [22]. Clinical outcome studies of Collis gastroplasty have reported mixed results [23–25], and the potential for preventing recurrence must be weighed against the increased morbidity and mortality associated with this procedure. In our experience, improved laparoscopic skills allow for more extensive esophageal mobilization and increased confidence in foregoing fundoplication in select patients have led to decreased need for Collis gastroplasty.

Tension-free closure with mesh reinforcement has been widely recommended in the literature. Several randomized clinical trials comparing crural closure techniques have reported reduced short-term recurrence rates when mesh is used [26–28]. However, mesh repair has not been universally supported because the disastrous complications associated with mesh potentially outweigh any reduction in recurrence [12, 29]. Over time, we have significantly decreased use of mesh and, as shown by the data presented here, this does not affect patient-centered outcomes. This may be in part due to additional crural sutures placed anterolaterally, which allow us to decrease tension on the posterior sutures (Fig. 1).

More recently, the routine use of fundoplication has been called into question. Although gastroesophageal reflux is common in patients with PEH, it is not universal, and dysphagia is often the primary complaint, especially in patients with ITS. The benefits of fundoplication in patients without reflux are unclear [30], and it has not been shown to reduce recurrence rates [10], therefore, it should only be considered when required based on preoperative symptoms (including remote history). Recently, our group showed that addition of fundoplication in patients undergoing surgery for ITS does not appear to significantly improve quality of life [13]; this finding was supported by Williamson et al. [31], who reported no significant difference in the development of esophagitis based on whether fundoplication was performed. Boeckxstaens [32] demonstrated that the "acid pocket" created by a PEH, and the disruption of the anatomic continuity of the lower esophageal sphincter with the hiatus, are responsible for the increased risk for gastroesophageal reflux associated with PEH. It stands to reason, therefore, that reduction of the gastroesophageal junction to its proper location below the hiatus would itself decrease the risk of gastroesophageal reflux and obviate the need for fundoplication. Fundoplication is also associated with increased incidence of dysphagia, with rates as high as 50% reported after PEH repair [33]. Several publications have argued against routine fundoplication, and the results of the present study further support this movement [10, 13, 20, 34, 35]. With this evidence in mind, our group assesses each patient individually, and in patients without history of



Much of the existing literature on PEH repair as it relates to ITS focuses on patients with large or giant PEH. ITS, however, is a unique subgroup of PEH with a distinct presentation and an increased morbidity and mortality due to the high risk of acute gastric volvulus. Most patients with smaller PEH may be safely watched, but elective repair of ITS is recommended to avoid the 20-fold increase in mortality associated with emergent surgical repair [36].

A major strength of this study is the prospective nature of all data collection. However, there was no randomization, and the operating surgeon made treatment decisions somewhat subjectively, which may limit external validity. This is especially true with respect to our determination of debilitation, which was assessed on a case-by-case basis. A fragility index may resolve this issue in future investigations. The results in this study are primarily based on subjective patient reports; however, we report more than 10 years follow-up in 38% of patients—more than what has been reported previously. Another limitation of the study is lack of objective follow-up (i.e., 64% objective follow-up at 1 year). Although a greater amount of objective follow-up would be desirable, the existing literature has extensively reported that symptoms do not correlate with recurrence. We have observed that insurance companies are increasingly denying coverage for contrast studies if the patient is asymptomatic, and we also concur that routine contrast studies in an asymptomatic patient may be of academic import only.

Although there are reports of short- and mid-term follow-up of patients with ITS, long-term follow-up is notably absent. This large, single-center longitudinal study addresses this deficiency. Our data show that surgical ITS repair conveys long-lasting reduction in clinical foregut symptoms—outcomes that are stable over time, and that confer a high degree of patient satisfaction. Similar results can be obtained without the routine use of gastroplasty, mesh, or fundoplication, and the decision to perform these adjunct procedures should be made on a case-by-case basis.

**Acknowledgements** We wish to thank Janese D. Gerhardt and Kim McKinley, RNs at the esophageal center at CUMC for their assistance with data collection, and Clare Prendergast for her assistance with manuscript preparation.

#### Compliance with ethical standards

**Disclosures** A. Blake and S. K. Mittal have no conflicts of interest or financial ties to disclose.



# **Appendix**

#### POST - PROCEDURE OUESTIONNAIRE

hone Number those Number	Sex: Data Sheet #:  Duration since Surgery:  Date of Procedure				
HEARTBURN: times a day/week/m  0 - None  1 - Minimal – episodic, no treatment i  2 - Moderate – controlled with medica  3 - Severe – interferes with daily activ  DYSPHAGIA  0 - No dysphagia  1 - once a week or less  2 - more than once a week, requiring  3 - Severe, preventing ingestion of so  REGURGITATION: times a day/we  0 - None  1 - Mild – after straining or large mea  2 - Moderate – positional  3 - Severe – constant regurgitation with	Date of Procedure				
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<ul> <li>□ 1 - Mild – after straining or large mea</li> <li>□ 2 - Moderate – positional</li> <li>□ 3 - Severe – constant regurgitation with</li> </ul>	eek/month				
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CHEST PAIN: times a day/week/mo	th or without aspiration				
	onth				
□ 0 – None					
□ 1 – Minimal – episodic	1 – Minimal – episodic				
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□ 1 – Minimal – episodic					
□ 2 – Moderate – reason for visit					
☐ 3 – Severe – interfere with daily active	ity				
ABDOMINAL BLOATING: YES	NO				
OTHER SYMPTOMS:					
MEDICATIONS:					
□ None					
□ Antacids Name Dose	Started by/on				
☐ H2 Blockers Name Dose					
	e Started by/on				
	Started by/on				
WEIGHT:					
GRADING RATE:					
How satisfied are you with your surgical outc					

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