2014 SSAT PLENARY PRESENTATION



# End of the Road for a Dysfunctional End Organ: Laparoscopic Gastrectomy for Refractory Gastroparesis

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#### Abstract

*Introduction* Gastroparesis is a functional disorder resulting in debilitating nausea, esophageal reflux, and abdominal pain and is frequently refractory to medical treatment. Therapies such as pyloroplasty and neurostimulators can improve symptoms. When medical and surgical treatments fail, palliative gastrectomy is an option. We examined outcomes after gastrectomy for postoperative, diabetic, and idiopathic gastroparesis.

*Methods* A prospective database was queried for gastrectomies performed for gastroparesis from 1999 to 2013. Primary outcomes were improvements in pre- versus postoperative symptoms at last follow-up, measured on a five-point scale. Secondary outcome was operative morbidity.

*Results* Thirty-five patients underwent laparoscopic total or near-total gastrectomies for postoperative (43 %), diabetic (34 %), or idiopathic (23 %) gastroparesis. Antiemetics and prokinetics afforded minimal relief for one third of patients. There were no mortalities. Six patients suffered a leak, all treated with surgical reintervention. With a median follow-up of 6 months, nausea improved or resolved in 69 %. Chronic abdominal pain improved or resolved in 70 %. Belching and bloating resolved for 79 and 89 %, respectively (p<0.01).

*Conclusions* Regardless of etiology, medically refractory gastroparesis can be a devastating disease. Near-total gastrectomy can ameliorate or relieve nausea, belching, and bloating. Chronic abdominal pain commonly resolved or improved with resection. Despite attendant morbidity, gastrectomy can effectively palliate symptoms of gastroparesis.

 $\label{eq:construction} \begin{array}{l} \textbf{Keywords} & \textbf{Gastrectomy} \cdot \textbf{Gastroparesis} \cdot \textbf{Surgery} \cdot \\ \textbf{Resection} \cdot \textbf{Refractory} \end{array}$ 

## Introduction

Gastroparesis is a functional gastrointestinal disorder characterized by nausea, gastroesophageal reflux,

N. H. Bhayani · A. M. Sharata · A. A. Kurian Providence Cancer Center, Portland, OR, USA vomiting, and abdominal pain.<sup>1–3</sup> Medical management included antiemetics, prokinetics, neuropsychic medications, and dietary management. Surgical management, typically after the failure of medical management, includes venting gastrostomies, enteral feeding tubes, gastric stimulators, and pyloroplasty to facilitate gastric emptying.<sup>4</sup> In the subset of patients where all of these measures fail and in the face of continued debilitating symptoms, radical resection may be considered.<sup>5</sup> The risks and benefits of employing gastrectomy for refractory gastroparesis have not been well described.

Our study reports on our experience with laparoscopic total or near-total gastrectomy for refractory diabetic, postsurgical, and idiopathic gastroparesis at a tertiary foregut referral center. We propose that surgical resection of a dysfunctional end organ can ameliorate symptoms such as nausea, abdominal pain, belching, and bloating. Herein, we present the potential benefits of gastrectomy and the operative risks and morbidity.

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## Methods

## Population and Data

We examined all gastrectomies performed for gastroparesis between 1999 and 2013 found in our prospectively collected, clinical database. The database comprises demographics, previous surgical and medical history, symptoms, operative details, and pre- and postoperative objective testing. The diagnosis was made by the primary surgeon, based on nuclear medicine gastric emptying study, using either the " $t_{\frac{1}{2}}$ " (previously) or "4-h emptying" (current) based on the evolution in the field. At pre- and postoperative visits, patients reported symptoms of abdominal pain and nausea on a standardized questionnaire using a five-point scale: 0 = none, 1 =occasional, 2 = weekly, 3 = daily noncontinuous, and 4 = daily continuous. Symptoms of bloating and belching were recorded as "any" or "none" using the same tool. The questionnaire was administered by a trained provider. The symptom scores at last follow-up were considered to be the final, postoperative symptom scores. The database, questionnaire, and this study have been approved by the institutional IRB. Two boardcertified surgeons performed all surgeries with the assistance of a surgery resident or fellow in a private teaching hospital setting.

## Operation

All surgeries were performed laparoscopically. A standard five-port approach was used. Intact fundoplications were left in situ, and the gastric pouch was created by dividing just below them. Disrupted or herniated fundoplications were reduced and reversed, and hiatal hernias were repaired. In general, a near-total (90 %) gastrectomy was performed with a lesser curve-based vertical pouch. Hand-sewn or circular stapler gastrojejunostomies were performed in a standard fashion. Total gastrectomies were reconstructed with a peroral circular stapled esophagojejunostomy. An ante-colic Roux limb was used in all cases. A 40-cm Roux limb was used for normal or underweight patients. A 100-cm limb was used for patients who were obese or morbidly obese. Patients had a Gastrografin swallow on post-op day 1 and were discharged when tolerating a pureed diet-usually on PODs 3 and 4.

## Outcomes

Clinical outcomes were selected in order to present the benefits and risks of gastrectomy for gastroparesis. The primary outcome was patient-reported improvement in symptoms. For symptoms of bloating and belching, success was defined as the absence of postoperative symptoms. To account for patients who developed symptoms, the overall impact of surgery on abdominal pain and nausea was defined using several different metrics: (a) the absence of any postoperative symptoms, (b) the absence of  $\geq$  weekly symptoms, and (c) the absence of  $\geq$  daily symptoms. To hone down on the efficacy of surgery to treat preoperative symptoms, we assessed resolution of symptoms and improvement in symptoms by greater than or equal to two points on our scale. These metrics were chosen because they reflect clinically significant improvement, not mere numerical changes in symptom scores. Secondary outcomes were operative morbidity: major if reoperation was required and minor otherwise. Requirements for nutritional monitoring and supplementation (vitamin B<sub>12</sub>, etc.) are deferred to the gastroenterologist or primary care physician.

## Analysis

All statistical analyses were performed using Stata 64-bit, version 12, SE (College Park, TX). The Wilcoxon signed-rank test was used to compare ordinal symptom scores. McNemar's exact test for matched pairs was used for comparisons of matched dichotomous symptoms.

#### Results

#### Population Description

During the study period, 35 patients underwent gastrectomy for refractory gastroparesis (Table 1). The median age was 50 years, and 30 patients (86 %) were female. The median BMI before surgery was 32.9 (range 20.2-49.9). The etiology of their gastroparesis was evenly distributed between postsurgical (n=15, 43%), diabetic (n=12, 34%), and idiopathic (n=8, 34%). 23 %). Patients had a diagnosis of gastroparesis for a median of 6.5 years (standard deviation 0.73 years) prior to surgery. The most common presenting complaints were reflux, nausea, and abdominal pain. Previously attempted medical therapies included prokinetics (erythromycin, metoclopramide, and domperidone) and antiemetics (prochlorpromazine, ondansetron, and promethazine). These medications partially ameliorated symptoms for approximately two thirds of patients. Previous surgeries in this patient population were common. Sixteen patients (46 %) had prior pyloroplasties to facilitate gastric emptying, and 19 patients (54 %) had previous fundoplications, most frequently for overflow reflux possibly secondary to gastroparesis or from iatrogenic, vagal nerve injury that led to a postprocedure gastroparesis. Two patients had existing jejunostomy tubes to provide nutrition due to poor oral intake, while another two patients had venting gastrostomies for severe vomiting. Eight patients had prior gastric stimulators. The median duration between previous

#### Table 1 Population description

Baseline characteristics	N=35
Age, median (years)	50
Male	5 (14)
Female	30 (86)
Primary symptom	
Nausea	11 (31)
Abdominal pain	10 (29)
Gastroesophageal reflux	14 (40)
Duration of symptoms, median (years)	6.5
Comorbid diseases	
Irritable bowel syndrome	3
Depression	6
Etiology	
Diabetic	12 (34)
Idiopathic	8 (23)
Postfundoplication	15 (43)
Response to medical treatment	
Prokinetics	21/30 (70)
Antiemetics	18/30 (60)
Previous procedures	
Pyloroplasty	16 (46)
Pyloric botox	4 (11)
Stimulator	8 (23)
Fundoplication	19 (54)
Enteral tubes	4 (11)
Time to surgery	
Median, months	11.4
Range, months	2.5-60.8

intervention or initial consultation and gastrectomy was 11.4 months.

## Operative and Postoperative Outcomes

All surgeries were performed laparoscopically. Six patients had a total gastrectomy with esophagojejunostomy, and the other 29 had near-total gastrectomies (Table 2). Intraoperative endoscopy revealed retained gastric contents in 100 % of patients despite of a protocol of 24–48 h of clear liquids followed by 12 h of nil per os. Despite routine intraoperative anastomotic leak testing, postoperative leaks occurred in six patients (17%). Clinical symptoms warranted reoperation and revision for all leaks, all of which were performed laparoscopically: esophagojejunostomy (n=2), gastrojejunostomy (n=1), duodenal stump (n=2), and jejunojejunostomy (n=1). Wound infections and a hematoma occurred in three and one patient, respectively. Overall patients did well, and the median length of hospitalization was 4.5 days (range 2–16 days). There were no deaths.

 Table 2
 Surgery and morbidity

Perioperative outcomes	N=35
Surgical reconstruction	
Esophagojejunostomy	6 (17)
Gastrojejunostomy	29 (83)
Major morbidity	
Esophago/gastrojejunostomy leak	3 (9)
Duodenal stump leak	2 (6)
Jejunojejunostomy leak	1 (3)
Reoperation	6 (17)
Minor morbidity	
Wound infection	3 (9)
Hematoma	1 (3)
Length of stay, median days (SD)	4.5 (3.3)

#### Symptoms

Preoperatively, nausea and abdominal pain were two of the primary complaints. Nausea was present at least occasionally in 29 patients (83 %), at least weekly in 26 patients (74 %) and daily in 19 (54 %). Similarly, chronic abdominal pain was reported at least occasionally in 20 patients (57 %), at least weekly in 16 patients (46 %), and at least daily in 8 patients (23 %). Belching and bloating were present in 12 (44 %) and 16 (59 %) patients, respectively.

Follow-up occurred at a median of 6 months postoperatively (range 1 month to 5 years). The median symptom score for nausea improved markedly after surgery (3 vs. 1, p=0.002). Because abdominal pain was less common and less severe preoperatively, there was no significant change after surgery (1 vs. 1, p=0.3) (Table 3). The proportion of patients with any, weekly, or daily abdominal pain diminished, though without statistical significance (Fig. 1a). The proportion of patients with weekly or daily nausea improved significantly (Fig. 1b). There was a substantial reduction in the proportion of patients with symptoms of bloating (p=0.0005) and belching (p=0.03) after surgery (Table 3).

Outcomes for patients with preoperative chronic abdominal pain or nausea are shown in Fig. 2. Of the 20 patients with any abdominal pain, ten (50 %) had complete resolution. Of the 29 patients with nausea, 21 (72 %) had improvement or resolution. The benefits of surgery for abdominal pain were more pronounced in patients whose preoperative symptoms were the most severe. The benefit of surgery for nausea was consistent, regardless of preoperative symptoms. Of the 14 patients with preoperative belching, 11 patients (79 %) had complete resolution of symptoms; bloating resolved in 16 of 18 patients (89 %).

Most patients lost some weight following the surgery. All patients, including those requiring preoperative tube, which delivered nutritional supplementation, resumed a complete oral

Table 3	Pre- and	postoperative	symptoms

	Preoperative score (median)	Postoperative score (median)	p value
Abdominal pain	1	1	0.3 <sup>a</sup>
Nausea	3	1	$0.002^{a}$
Any symptoms, n (	%)		
Belching	14 (40)	6 (17)	0.03 <sup>b</sup>
Bloating	18 (51)	4 (11)	0.0005 <sup>b</sup>

<sup>a</sup> Wilcoxon signed-rank p value

<sup>b</sup> McNemar's *p* value

diet within 6 months. Most commonly, this occurred within 1 month. Postoperative BMI was significantly reduced, median 25.0 (range 19.1–47), p<0.0001. Preoperative BMI was >30 in 67 % of patients, but this proportion was significantly reduced (39 %) postoperatively (McNemar's exact test, p=0.008).

#### Discussion

Gastroparesis, particularly in nondiabetics, is a relatively new diagnosis. For severe cases, it can be a devastatingly morbid condition and it is always a frustration for care providers and an enormous financial burden on the healthcare system. For patients with gastroparesis of any etiology, therapy begins with dietary and lifestyle modification, usually combined with medical therapy. The goal, of course, is management of their chronic symptoms to enable them to have a reasonable quality of life and to keep them out of the emergency room. Symptoms of gastroparesis can often mimic or cause a multitude of other foregut symptoms, and we have found that a majority of these patients end up having surgery (explorations, cholecystectomy, fundoplications, etc.) which usually fail because they fail to address the underlying cause—poor gastric emptying. We have found that when patients fail all attempts to pharmacologically or surgically manage their symptoms of nausea, abdominal pain, belching, and bloating, a total and near-total gastrectomy will give good symptomatic outcomes, particularly for nausea, bloating, and belching. We report on a series of patients with a mixture of etiologies for their gastroparesis, with a median follow-up of 6 months, and nausea completely resolved in 28 % of patients and improved in another 41 %. Bloating and belching resolved in >78 % of patients. Chronic abdominal pain associated with gastroparesis is poorly understood and is often the most challenging symptom to treat. By the time patients are seen by tertiary specialists, they are often heavily addicted to pain meds or other class II drugs and this further complicates their management. Our data demonstrated a reduction in frequency of abdominal pain in 20 % of patients and a complete resolution in 50 %. In patients with debilitating and refractory disease, despite the failure of previous therapies, total or near-total gastrectomy, to remove the diseased organ can palliate symptoms and ameliorate their quality of life.

Despite careful patient selection, disease optimization, and preoperative preparation, 17 % of these patients suffered postoperative major morbidity requiring surgical reintervention. While the benefits demonstrated previously may be substantial, the operative morbidity cannot be underestimated and should prompt a frank conversation with the patient. There are many potential causes of this high morbidity. Malnutrition or poor nutrition is not uncommon among patients with gastroparesis, making for tenuous anastomotic healing.<sup>6</sup> Often, these patients have had previous surgery, mandating adhesiolysis, increasing operative times and potential for injury. Retained gastric contents, present at surgery, may also play some role. Technical error always remains a possibility, despite our practice of routine intraoperative endoscopy and leak testing.

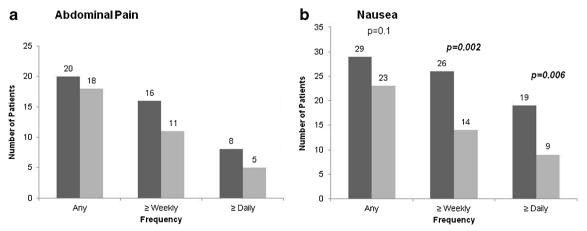
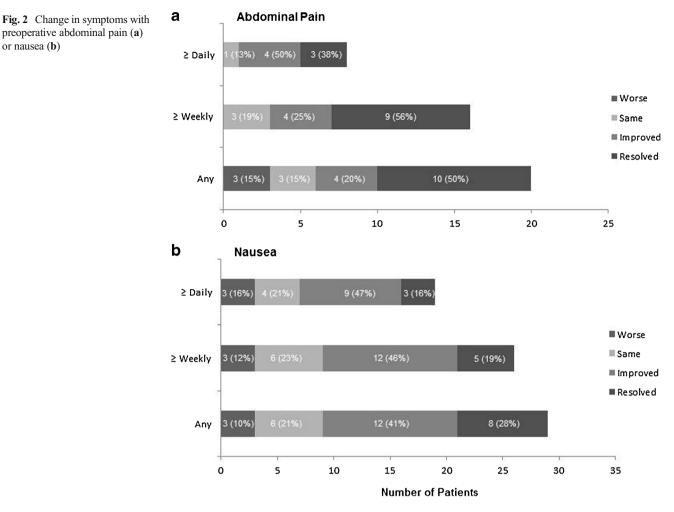


Fig. 1 Comparison of symptoms before surgery (dark bars) and after surgery (light bars)



It cannot be overstated that gastrectomy is the final option for refractory gastroparesis and is appropriate for only a subset of patients. Medical therapies, such as antiemetics and prokinetics, adequately control symptoms for many patients.<sup>7</sup> Initially, surgical options may include gastric stimulators which has been shown to reduce nausea/vomiting and ameliorate chronic pain.<sup>8,9</sup> Both our group and others have demonstrated that surgical pyloroplasty facilitates gastric emptying and often reduces vomiting and bloating, with excellent overall symptom control.<sup>10,11</sup> When these options fail, it is appropriate to consider gastrectomy if the patient continues to be symptomatic and is willing to accept the risks. While we normally consider gastric resection the final option, a recent study has demonstrated that gastrectomy is superior to gastric stimulation in the primary treatment of gastroparesis.<sup>12</sup> More studies are needed to promote early gastrectomy for gastroparesis.

Literature on gastric resection for gastroparesis is limited. Most studies consist of small series. Watkins et al. reported seven patients undergoing near-total gastrectomy without any perioperative complications.<sup>13</sup> Vomiting was nearly extinguished in six of the seven patients, and most patients were able to resume a normal quality of life. Recently, Clark et al. reported nine patients with postfundoplication gastroparesis but concluded that patient outcomes were "variable."<sup>4</sup> In a series of 44 gastrectomies for postsurgical gastroparesis, Speicher et al. reported that 78 % of patients had improvements in health and function scores after surgery despite 36 % perioperative morbidity.<sup>14</sup> Forstner et al. reported an early experience of 62 gastric resections, demonstrating that 43 % of patients experienced improvement in "all or most symptoms."<sup>5</sup> Our 35 patients with postsurgical gastroparesis had outcomes similar to those with other etiologies. Our sample size is not sufficient to provide a statistical comparison of outcomes by etiology, though differences in symptoms and treatment response may exist.<sup>15</sup> Based on our data, there is no need to treat postsurgical gastroparesis.

Our study does have limitations. Obtained from a prospectively collected database, the data is of good quality. However, our database did not include quality of life parameters or nutritional variables to allow more thorough interpretation. In addition, because we use a standardized data collection tool, if new symptoms occurred postoperatively that were not on the tool, these symptoms, such as dumping, would not be collected or observed. As a referral center for foregut surgery, our practice will be biased in so far that we frequently see a high proportion of the most clinically challenging patients. Symptomatic and operative outcomes may actually be better in a more general setting. The above-average operative morbidity may raise questions of external validity. Specifically, the leak rate of 17 % that we describe is higher than in the oncologic gastrectomy literature. We believe that the diagnosis of refractory gastroparesis, and the attendant clinical situation, carries an elevated risk for surgical complications. These patients often have severe gastritis, retained food in the stomach, and in general, are not healthy. This certainly puts them in a category with gastrectomy for malignancy or reoperative surgery with regard to complication risk.<sup>16</sup> While trainees are routinely involved in cases, it is impossible to assess the role of the learning curve of either trainee or attending in the morbidity. In addition, with a cohort of 35 patients, there is a higher risk of false-negative results and trends that do not reach a statistical significance. This does not, however, detract from our positive findings.

Even with these study weaknesses in mind, it remains difficult to discount the substantial reduction and resolution of patient symptoms that we describe. For a patient population facing the debilitating consequences of recalcitrant gastroparesis, this radical laparoscopic approach may offer the best hope for a normal existence when the alternative is to continue to suffer debilitating symptoms.

## Conclusion

Gastroparesis is a chronic debilitating condition that is best treated following a progressive algorithm: starting with medical/dietary management and progressing to surgical options like pyloroplasty or gastric neurostimulation when symptoms become untenable. As a final option, gastrectomy can afford substantial improvement and even resolution of their nausea, belching, and bloating. Abdominal pain due to gastroparesis can improve or resolve but with varying results. However, gastrectomy in this population has substantial risks for operative morbidity, perhaps due to concomitant malnutrition or other factors. Nonetheless, we show that surgical removal of the diseased end organ is an effective treatment of gastroparesis.

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#### Discussant

**Dr. Steven R. DeMeester (Los Angeles, CA):** I would like to congratulate the authors on a very interesting study on a difficult topic. I have several questions. The first is on the definition of delayed gastric emptying. Given the duration of the study with patients dating back some 15 years or so, how has the definition of delayed gastric emptying changed, and do you think that impacted the results?

Secondly, what did you do with the remnant stomach in these patients? Was it left intact similar to a bariatric procedure, or was it removed? If it was done differently in patients, did it seem to make a difference whether it was removed or left in place?

The third question relates to the patients that had prior fundoplications. Did you ever leave the fundoplication in place and do the gastrojejunostomy just below the intact fundoplication? If not, and the fundoplication was removed and an esophagojejunostomy performed, did these patients have difficulties with regurgitation given the presumably weak or absent lower esophageal sphincter at that point?

Lastly, I have a question about the outcome in these patients. While most of the patients were females, there were some men. It has been my personal experience that men are much less happy without a stomach, whereas oftentimes, women do not seem to be as troubled. Did you note any differences in satisfaction or outcome between men and women after gastrectomy?

Thank you and, again, congratulations on a very interesting study.

**Dr. Bhayani:** Thank you for the excellent questions and the opportunity to elaborate on some of our data. In our database, the means of diagnosing gastroparesis is not specified. The patients were evaluated in our specialized foregut referral practice. Their diagnosis was assigned by our physicians after verifying or repeating previous diagnostics. However, as the criteria for diagnosing gastroparesis has evolved from using the " $t_{1/2}$ " to using the "4-h emptying" metrics, our practice has followed.

In all these patients, we performed a resection of the stomach. Regardless of total or subtotal, the remnant was removed. Relatedly, we tended to leave intact fundoplications alone and transect the stomach below the fundoplication. If the fundoplication was not intact, it was taken down prior to resection. Because we try to avoid the morbidity of an esophagojejunostomy, most patients had a subtotal gastrectomy. Unfortunately, we do not have the sample numbers to compare regurgitation or reflux between patients who underwent total versus subtotal gastrectomy with fundoplication.

Our population of refractory gastroparetics was predominantly female. There were no apparent differences between genders in symptom scores or symptom resolution. However, due to the limited numbers of men, it would not be an adequately powered comparison.

Thanks again to the society, the moderator, and my coinvestigators for the privilege to present our data and findings.