

ORIGINAL ARTICLE - GASTROINTESTINAL ONCOLOGY

## Esophagojejunal Reconstruction After Total Gastrectomy for Gastric Cancer Using a Transorally Inserted Anvil Delivery System

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### ABSTRACT

**Introduction.** Total gastrectomy (TG) is commonly performed for the treatment of patients with gastric cancer. However, reconstruction of the esophagojejunal (EJ) anastomosis can be technically demanding, with reported anastomotic leak rates in the Western world still approaching 10–15 %. We report our experience using the transoral anvil delivery system (OrVil<sup>TM</sup>) for creation of the EJ anastomosis after TG.

**Methods.** From 2007 to 2011, 48 consecutive patients with gastric cancer underwent open ( $n = 31$ ) or laparoscopic ( $n = 17$ ) TG. EJ reconstruction was performed with the transoral anvil delivery system (OrVil<sup>TM</sup>) in an end-to-side fashion. Demographic, clinic, and perioperative data were obtained from a prospectively maintained database.

**Results.** Of the 48 patients, 83 % were male. Median age at resection was 64 years. Median body mass index was 27.1 kg/m<sup>2</sup>. Seventy-nine percent ( $n = 38$ ) of patients had at least one comorbidity. Fifteen patients (31 %) had at least one perioperative complication. There was one perioperative death (2 %) following a duodenal stump leak. There were four EJ leaks (8 %) and two EJ stenoses (independent of leak; 4 %). There was one EJ leak (6 %) and one EJ stenosis (6 %) following a case that was first attempted laparoscopically. There were no deaths as a consequence of an EJ leak.

**Conclusions.** The use of the transoral anvil delivery system during EJ reconstruction is a safe and effective option for reconstruction after open or laparoscopic TG with acceptable mortality and morbidity. The anastomotic leak rate appears to be comparable to that of other techniques.

Total gastrectomy (TG) is utilized for prophylactic management of high-risk patients (i.e., those with *CDH1* mutations) as well as treatment for gastric carcinomas arising diffusely, from the middle and proximal stomach, or from some tumors of the gastroesophageal junction (GEJ). Recent advances in perioperative management have decreased postoperative mortality from TG. Complication rates, though, still range from 20 to 40 % in most Western specialized centers.<sup>1–3</sup> A significant proportion of the postoperative morbidity and mortality after TG has been attributed to complications associated with the esophagojejunal (EJ) anastomosis.<sup>4,5</sup>

This anastomosis has been perceived as technically demanding due to the intrinsic structure of the esophageal wall and technical issues of exposure of the esophageal stump, particularly when addressing GEJ tumors via the transabdominal approach. Complications have limited the development of minimally invasive approaches. Currently no method is widely accepted as superior for EJ reconstruction after TG.

The transoral anvil delivery system was introduced as a means of facilitating the difficult reconstruction and anastomosis in open and laparoscopic TG. The objective of this prospective study is to present the first American experience about the use of this technology for a circular-stapled EJ anastomosis after TG. We hypothesize that use of this system to perform stapled, circular anastomosis during TG can be performed safely with acceptable outcomes.

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## METHODS

### Patient Selection

Patients who underwent laparoscopic or open TG for gastric carcinoma or *CDH1* mutation at Memorial Sloan-Kettering Cancer Center from June 2007 through February 2011 and who did not have a history of prior gastric surgery were identified from a prospectively maintained gastric database. The study was conducted according to the institutional human research committee procedures. Laparoscopic surgery was offered to patients regardless of stage. Tumors with extensive serosal involvement or bulky nodal disease were generally resected by open approach. Patients were included if they were reconstructed with an end-to-side EJ using the transorally inserted anvil delivery system. All surgeries were performed by a single, high-volume gastric surgeon.

Demographic, histopathologic, perioperative, and follow-up information were collected. Pathologic staging is based on 7th edition AJCC staging of the postoperative pathologic evaluation. Analysis was performed as an intent-to-treat analysis; laparoscopic converted to open TG were analyzed as laparoscopic TG. Thirty-day perioperative outcomes are reported. Postoperative leak and stenoses were determined by radiologic, endoscopic, or operative findings; workups were performed based on the patient's clinical status. Resection margins were defined as R0 (negative), R1 (microscopically positive), and R2 (macroscopically positive). Ranges are reported as interquartile ranges (IQR) unless otherwise specified.

### Surgical Technique

The OrVil<sup>TM</sup> system includes an anvil with an orogastric tube attached to the central rod by a connecting thread. The head of the anvil comes tilted to facilitate the passage through the pharynx and upper esophagus. The rod of the anvil is connected to a DST series<sup>TM</sup> EEA<sup>TM</sup> XL 25 staple device (Covidien, USA), which allows tissue approximation.

After entering the abdomen, the gastrocolic ligament was divided to include the greater omentum in the specimen. The dissection was directed toward the pylorus with division of the inferior gastroepiploic vessels. The hepatoduodenal ligament was dissected, and the right gastric artery was divided. Circumferential dissection of the duodenum was completed and transected distal to the pylorus using a 35-mm linear stapler. Dissection continued along the gastrohepatic ligament until the hiatus was reached. Splenectomy was avoided unless surgical margins were compromised or macroscopic nodal disease was present at the splenic hilum. The abdominal esophagus was circumferentially mobilized to a length thought to prevent undue tension. At this point,

the esophagus was transected with a 35-mm linear stapler. The proximal margin was sent for intraoperative frozen section; additional resection of esophagus was performed if necessary. Patients with the diagnosis of gastric cancer underwent standard D2 lymphadenectomy; D1 dissection was performed in patients with a *CDH1* mutation who did not have a diagnosis of cancer.

The orogastric tube was introduced in the esophagus, and the tip was identified at the esophageal stump (Fig. 1). The tube was exteriorized through a small hole created on the anterior esophageal wall adjacent to the staple line and extracted until the rod of the attached anvil reached the hole. The connecting thread was divided allowing the tube to be removed. A 50-cm Roux-en-Y loop was created and the EEA<sup>TM</sup> XL 25 stapler device was introduced through the jejunal loop end. The EEA<sup>TM</sup> was then connected to the anvil and fired (Fig. 2). The enterotomy was closed with a 35-mm linear stapler.

Patients receive postoperative care according to the MSKCC TG treatment pathway. If the patient's clinical status allows, a clear liquid diet is started on postoperative day 2, and diet is advanced to a postgastrectomy diet as tolerated. Workup, including upper GI studies, is reserved for patients in whom there is a clinical concern for a leak. Standard management for EJ leaks includes nonoperative intervention for hemodynamically stable patients without peritonitis and with contained or small leaks. However, reexploration is indicated in the setting of hemodynamic instability, peritonitis, or a failure of nonoperative management. This study was funded by internal sources and was not funded by Covidien.

## RESULTS

### Patient Characteristics

Forty-eight consecutive patients underwent laparoscopic or open TG with this technique. No patient was excluded. Patient characteristics are summarized in Table 1. Forty (83 %) patients were male. Median age at resection was 64 years (IQR 55–70). Median body mass index (BMI) was 27.1 kg/m<sup>2</sup> (IQR 24.0–30.5). Thirty-eight patients (79 %) had at least one comorbidity, which most commonly included hypertension (44 %), obesity (29 %), and cardiac disease (27 %).

### Pathologic Characteristics

Pathologic characteristics are summarized in Table 1. Pathologic diagnosis was gastric carcinoma in 46 cases (96 %), high-grade dysplasia (2 %), and low-grade dysplasia (2 %). Tumors were most commonly located at the GEJ (37 %), middle third (33 %), upper third (23 %), and

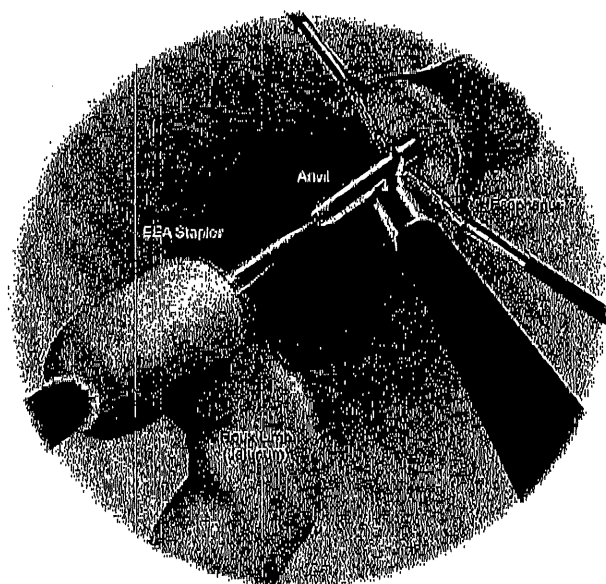


**FIG. 1** Insertion and positioning of the transoral anvil delivery system

diffusely (6 %). Median tumor diameter was 3.2 cm (IQR 1.5–6.0). Median number of harvested lymph nodes was 22 (IQR 17–28). Forty-five cases had negative margins (R0; 94 %); three cases had R1 resections (6 %). Stage II lesions were most common (35 %), followed by I (33 %), III (21 %), 0 (8 %), and IV (2 %).

#### *Perioperative Characteristics*

Perioperative characteristics are summarized in Table 1. Open TG was the most commonly performed procedure ( $n = 31$ , 65 %), followed by laparoscopic (35 %). Six laparoscopic cases were converted to open (35 %); three



**FIG. 2** Docking of the circular stapling device to the transoral anvil delivery system

(18 %) were converted to laparoscopically assisted. Conversion indications include: unfavorable tumor characteristics ( $n = 5$ , 56 %), positive esophageal margin (2 %), splenic hemorrhage (2 %), adhesions (2 %), and device failure (2 %). Median operative time was 230 min (IQR 190–277). Estimated blood loss was 250 mL (IQR 150–450). Median hospital stay was 8 days (IQR 6–9). Anvil passage through the pharynx and esophagus was uneventful in all cases.

### Perioperative Outcomes

Perioperative outcomes are summarized in Table 1. There was one perioperative death (2 %) in a patient with a cT2N1 tumor undergoing open TG after neoadjuvant chemotherapy. The patient developed a duodenal stump leak, necessitating reexploration. The EJ anastomosis was found to be intact. There were no perioperative deaths due to EJ leak.

One of more complications occurred in 15 patients (31 %). Two patients developed a duodenal stump leak (4 %); one developed hemorrhage at the EJ (2 %). Four patients (8.3 %) developed a postoperative EJ leak. Three of the EJ leaks followed open TG; one was associated with a laparoscopic-assisted TG. No leaks occurred in cases that were performed totally laparoscopically. Because postoperative studies to evaluate anastomotic leak are only obtained in the setting of a clinical suspicion, it is possible that we are underreporting clinically occult anastomotic leaks. However, the presence of these clinically inapparent leaks does not require additional treatment.

**TABLE 1** Demographics, pathologic, and perioperative characteristics of patients undergoing esophagojejunal reconstruction with transoral anvil delivery system after total gastrectomy

<b>Patient characteristic</b>	
No. of patients ( $n$ )	48
Gender ( $n$ , %)	
Male	40 (83)
Age at resection, year (median, IQR)	64 (55–70)
Body mass index ( $\text{kg}/\text{m}^2$ ; median, IQR)	27.1 (24.0–30.5)
Comorbidities ( $n$ , %)	
Hypertension	21 (44)
Obesity (BMI $>30 \text{ kg}/\text{m}^2$ )	14 (29)
Diabetes mellitus	5 (10)
Cardiac disease <sup>a</sup>	13 (27)
COPD <sup>b</sup>	7 (15)
ASA grade (median, IQR)	2 (2–3)
<b>Pathologic characteristic</b>	
<b>Preoperative diagnosis (<math>n</math>, %)</b>	
Gastric carcinoma	46 (96)
High-grade dysplasia	1 (2)
Low-grade dysplasia	1 (2)
<b>Tumor location (<math>n</math>, %)</b>	
Gastroesophageal junction	18 (37)
Upper third	11 (23)
Middle third	16 (33)
Distal third	0 (0)
Diffuse	3 (6)
Tumor size (cm), median (IQR)	3.2 (1.5–6.0)
Lymph nodes harvested, median (IQR)	22 (17–28)
<b>AJCC staging, 7th edition</b>	
Stage 0	4 (8)
Stage I	16 (33)
Stage II	17 (35)
Stage III	10 (21)
Stage IV	1 (2)
<b>Perioperative characteristic</b>	
<b>Type of total gastrectomy (<math>n</math>, %)</b>	
Open	31 (65)
Laparoscopic <sup>c</sup>	17 (35)
Operative time (min), median (IQR)	230 (190–277)
Estimated blood loss (mL), median (IQR)	250 (150–450)
Length of stay (days), median (IQR)	8 (6–9)
<b>Perioperative outcomes</b>	
Mortality ( $n$ , %)	1 (2)
EJ leak $\pm$ stricture ( $n$ , %)	4 (8)
EJ stricture ( $n$ , %)	2 (4)
Duodenal stump leak ( $n$ , %)	2 (4)
EJ hemorrhage ( $n$ , %)	1 (2)

IQR interquartile range

<sup>a</sup> Coronary artery disease, arrhythmia, angina, or valvular heart disease

<sup>b</sup> COPD and asthma

<sup>c</sup> Includes totally laparoscopic, laparoscopic-assisted, and laparoscopic converted to open

Patient 1 underwent a laparoscopic converted to laparoscopic-assisted TG and was diagnosed with an EJ leak on an upper GI swallow performed on the seventh postoperative day after developing a left pleural effusion. The study demonstrated a small, contained area of extravasation. The patient was managed conservatively, and the leak had resolved on the planned study 3 weeks later. Oral diet was resumed, and the patient was discharged after a 30-day stay.

The second case was diagnosed on a computed tomography (CT) scan performed on the third postoperative day due to persistent abdominal pain and tachycardia after an open TG. Imaging revealed pooling of oral contrast around the EJ anastomosis. Reoperation with irrigation and drainage was performed. Intraoperatively, the leak could not be identified. The patient recovered and was discharged 40 days later.

The third patient developed cardiopulmonary decompensation, distension, and hypotension on the ninth postoperative day after open TG. The patient was reexplored and found an EJ dehiscence. The EJ was taken down, and cervical esophagostomy with feeding jejunostomy tube was performed. The patient was discharged on hospital day 51.

The final case occurred in a patient who underwent an open TG. On postoperative day 10, the patient developed peritonitis and was taken to the operating room, where a 5- to 7-mm defect at of anterior aspect of the EJ anastomosis was identified. Management was similar to third patient with discharge on day 59.

Two patients (4 %) developed EJ stenoses, independent of EJ leak. Patient 1 underwent a laparoscopic converted to open TG after frozen section confirmed a positive esophageal margin. The patient developed a stenosis after completing locoregional radiotherapy. Patient 2 developed an EJ stenosis after open TG. No EJ stenoses occurred after a totally laparoscopic TG. There was one additional EJ stenosis that developed after an EJ leak. All stenoses were treated with endoscopic dilations (median; 3 dilations).

The median follow-up since time of resection was 18 months (IQR 11–34). At last follow-up, 32 patients had no evidence of disease, 9 had died of disease, 5 were alive with disease, and 1 each had died of other causes or of unknown causes.

## DISCUSSION

Open, and more recently, laparoscopic TG serve as the mainstays of gastric cancer management for tumors at the GEJ, upper, or middle third of the stomach, or diffusely. Reconstruction with an EJ anastomosis can be technically difficult, due to both patient and tumor characteristics. A

number of series have reported on the use of the circular stapler in the setting of open TG (Table 2). However, a widely accepted method for EJ reconstruction after laparoscopic TG has not yet been developed. Some authors recommend assistance by a minilaparotomy, but this approach may compromise the advantages that laparoscopic surgery provides.<sup>6–9</sup> Reported alternatives for EJ reconstruction after laparoscopic TG include linear and circular stapled techniques (Table 3). Although they seem safe in experienced hands, complex and time-consuming maneuvers are necessary to complete the anastomosis. With the increasing application of laparoscopic TG, the current technique may facilitate intracorporeal creation of the EJ anastomosis in all patient and tumor types.

Traditionally, creation of stapled circular EJ anastomosis involves a pursestring suture to insert the anvil. In some circumstances, such as a narrow esophagus, a large, obese patient, or a higher resection of the esophagus, creation of the pursestring may pose a great challenge. This is an important issue in Western countries where GEJ cancers and obese patients are more common.<sup>10</sup> Alternatively the placement of the pursestring sutures may be incomplete because of lack of adequate visualization, leaving portions of the esophageal wall not included in the anastomosis.<sup>11</sup> These technical difficulties are minimized with this system.

This study is the first American series to report use of the transoral anvil delivery system for the EJ anastomosis after TG for gastric cancer. In the 11 (predominantly Eastern) published studies in which BMI was evaluated in the setting of laparoscopic TG, the median BMI was 22.4 kg/m<sup>2</sup>; the mean BMI was similarly low at 23.0 kg/m<sup>2</sup> (Table 3). Additionally, a Korean, randomized, controlled trial evaluating laparoscopic versus open distal gastrectomy reported a mean age of 55 years and mean BMI of 23.5 kg/m<sup>2</sup>. Thirty-seven percent of patients had a comorbid condition; less than 10 % had an ASA class of 3.<sup>12</sup> Unlike Eastern series<sup>13</sup> that traditionally report on a young and healthy population, this report notes a high-risk population; median age at resection was 64 years and median BMI was 27.1 kg/m<sup>2</sup>. Additionally, 79 % of patients had at least one preoperative comorbidity (29 % with morbid obesity) and 37 % (*n* = 18) had an ASA class of 3. Additionally, unlike the Eastern series in which tumors may have a more favorable location and biology, tumors in this series are commonly located at the GEJ (37 %).

The presence of comorbidities, obesity, and advanced age are associated with reduced postoperative outcomes after both open and laparoscopic gastrectomy.<sup>14–26</sup> Despite features that increase morbidity and mortality in the current series, we report an acceptable incidence of EJ anastomotic leak. Reported leak rates after open and laparoscopic TG range from 0.5 to 13 % (Tables 2, 3). In the current series,

**TABLE 2** Relevant series reporting postoperative results after open total gastrectomy and esophagojejunal reconstruction with a circular staple technique

Author	Year	Method of anvil insertion	N	Mortality (%)	EJ leak rate (%)	EJ leak lethality (%)	EJ stenosis rate (%)
Habu et al. <sup>34</sup>	1989	Handsewn pursestring	94	0	7.4	0	1.1
Seufert et al. <sup>35</sup>	1990	Pursestring clamp	40	2.5	2.5	0	0
Fujimoto et al. <sup>36</sup>	1991	Handsewn pursestring	199	N/R	3.5	N/R	3
Isozaki et al. <sup>27</sup>	1997	N/R	207	N/R	9.7	30.3	N/R
Pol et al. <sup>28</sup>	1997	Pursestring clamp	176	8	2.8	0	0
Nomura et al. <sup>37</sup>	2000	N/R	943	N/R	2.9	N/R	1.2
Takeyoshi et al. <sup>29</sup>	2000	Pursestring clamp	324	N/R	3.1	0	4.9
Pesko et al. <sup>32</sup>	2002	Handsewn pursestring	148	2.9	1.4	0	0
Doglietto et al. <sup>30</sup>	2004	N/R	237	0.8	6.3	13.3	N/R
Lamb et al. <sup>31</sup>	2004	N/R	76	9	11	50	N/R
Hyodo et al. <sup>38</sup>	2007	Automatic pursestring	390	N/R	0.5	0	1
Sierzega et al. <sup>3</sup>	2010	N/R	690	3.9	5.9	27	N/R

N/R not reported

**TABLE 3** Relevant series reporting results after laparoscopic total gastrectomy grouped by the technique of esophagojejunal reconstruction

Author	Year	Gastrectomy technique	N	BMI (kg/m <sup>2</sup> )	Mortality (%)	EJ leak rate (%)	EJ stenosis rate (%)
End-to-side linear stapler anastomosis							
Huscher et al. <sup>6</sup>	2007	TLTG	11	N/R	18.1	0	0
Ziqiang et al. <sup>8</sup>	2008	TLTG	14	N/R	0	0	0
Okabe et al. <sup>7</sup>	2009	TLTG	16	20.8 <sup>a</sup>	0	0	0
Shinohara et al. <sup>9</sup>	2009	TLTG	55	N/R	0	3.6	N/R
Bracale et al. <sup>39</sup>	2010	TLTG	67	N/R	1.5	6	3
Inaba et al. <sup>40</sup>	2010	TLTG	53	22.0 <sup>a</sup>	0	3.8	N/R
Tsujimoto et al. <sup>41</sup>	2012	TLTG	15	21.7 <sup>b</sup>	0	0	0
End-to-side circular stapler anastomosis with hand sewn/clamped/stapled pursestring							
Carboni et al. <sup>42</sup>	2005	TLTG	8	N/R	0	12.5	N/R
Dulucq et al. <sup>43</sup>	2005	TLTG	8	N/R	0	0	0
Ibañez Aguirre et al. <sup>44</sup>	2006	TLTG-LATG	63	N/R	N/R	4.8	0
Kim <sup>45</sup>	2008	LATG	27	22.6 <sup>b</sup>	0	0	N/R
Mochiki et al. <sup>46</sup>	2008	LATG	20	N/R	0	10	5
Topal et al. <sup>47</sup>	2008	TLTG	38	24.0 <sup>a</sup>	2.6	5.3	N/R
Usui et al. <sup>48</sup>	2008	LATG	23	23.7 <sup>a</sup>	0	0	N/R
Allietta et al. <sup>49</sup>	2009	TLTG-LATG	16	N/R	6.3	6.3	0
Jeong et al. <sup>50</sup>	2009	LATG	131	23.0 <sup>b</sup>	0	2.3	0
Lee et al. <sup>51</sup>	2009	LATG	67	22.9 <sup>b</sup>	0	1.5	9
Kinoshita et al. <sup>52</sup>	2010	TLTG	10	22.4 <sup>a</sup>	0	0	0
End-to-side circular stapler anastomosis with OrVii™							
Jeong et al. <sup>53</sup>	2009	TLTG	16	23.0 <sup>b</sup>	0	0	0
Sakuramoto et al. <sup>33</sup>	2010	LATG	26	24.0 <sup>b</sup>	0	0	3.8
Kachikwu et al. <sup>54</sup>	2011	TLTG	16	24.9 <sup>a</sup>	0	0	18.8
Kunisaki et al. <sup>55</sup>	2011	LATG	30	23.0 <sup>b</sup>	3.3	3.3	N/R
Marangogi et al. <sup>56</sup>	2012	TLTG	13	N/R	7.7	0	N/R
Current series	2012	TLTG	17	27.1 <sup>a</sup>	0	5.9	5.9

TLTG totally laparoscopic total gastrectomy, LATG laparoscopically assisted total gastrectomy, N/R not reported

<sup>a</sup> Median<sup>b</sup> Mean

the EJ leak rate is 8.3 %; in the setting of laparoscopic (but ultimately converted to open) TG, this incidence is reduced to 5.9 %. The leak rate, in this series, is 0 % after totally laparoscopic TG.

EJ leak is associated with considerable mortality. Overall perioperative mortality in the setting of open and laparoscopic TG ranges for 0–18 % (Tables 2, 3). Some reports have attributed up to a 50 % mortality directly resulting from a postoperative leak. In the current series, one patient with an EJ leak after laparoscopic-assisted TG was managed conservatively; three after open TG were managed with reoperation and diversion. Though three of the four leaks required reoperation, there were no deaths as a consequence of an EJ leak, demonstrating that early detection and aggressive management of a postoperative EJ leak is critical. Additionally, it is of the utmost importance to limit tension on the esophagus during mobilization and to ensure a tension-free EJ anastomosis creation, as minimize the risk of EJ leak and stenosis.

Finally, previous reports have estimated a risk of EJ stricture to be 0–19 % (Tables 2, 3). In the current series, we identified two early postoperative EJ strictures, and we estimate an early stenosis risk, independent of leak, to be 4 %. This stricture rate is comparable to previously published studies. Additionally, when strictures do develop, management is generally successful with endoscopic balloon dilations.

A potential drawback of this system is contamination of the abdomen that occurs when the orogastric tube is extracted through the esophageal stump. Intra-abdominal collections attributed to this have been reported.<sup>27</sup> Although we did not experience this problem, we advise proper measures to decrease infectious complications, including perioperative antibiotics and local irrigation after the anvil positioning. If the procedure is being performed laparoscopically, the orogastric tube should be extracted through an inserted port. Another concern using this system is the possibility of damaging the pharynx or the esophagus while the anvil is passed.<sup>28,29</sup> Although this complication is at least theoretically possible, it has not been reported in any previous studies.<sup>27,30–32</sup> Sakuramoto et al.<sup>33</sup> reported one patient in which passage of the anvil was not possible due to an esophageal stenosis caused by ulceration. This was detected due to unexpected resistance during the extraction of the orogastric tube. The anvil was removed with intraoperative endoscopy. Preemptive steps should be taken to avoid potential difficulties during the passage of the anvil: manual guidance at the pharynx, deflation of the cuff of the endotracheal tube and gentle traction of the orogastric tube. Extraction should be halted and endoscopy performed if resistance is encountered. This group also recommended that esophagotomy is better done at the center of the staple line due to tissue lacerations when performed on the

anterior or posterior wall. This has not been described by other authors or by our group. In any case, careful extraction and manipulation of the anvil is always required to avoid this potential intraoperative complication.

TG, both laparoscopic and open, can be performed safely and effectively in high-volume, specialized centers. Recent reports on outcomes are derived predominantly from Eastern centers. In this first American series, which includes a representative Western population of older, sicker patients with tumors demonstrating a more aggressive biology, we demonstrate that TG, using the transoral anvil delivery system can be performed safely and effectively, with acceptable morbidity and mortality. Leak and stricture rates appear to be comparable to that seen using other techniques.

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