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Controversies in the management of the pylorus among patients undergoing robotic-assisted minimally invasive esophagectomy

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Abstract

Bilateral truncal vagotomies are intrinsic to nearly all esophagectomies, rendering patients susceptible to delayed gastric emptying. The question of whether, how, and when to perform pyloric drainage is essential and remains controversial in the era of robotic-assisted minimally invasive esophagectomy. While a variety of pyloric intervention techniques have been described, selective endoscopic pyloromyotomy for post-esophagectomy patients with durable signs of delayed gastric emptying is an attractive option, given its low morbidity rate, particularly its low incidence of dumping.

Keywords: Robotic-assisted surgery, esophagectomy, pyloromyotomy

INTRODUCTION

While there is no agreed-upon single best approach for esophagectomy, bilateral truncal vagotomies are intrinsic to nearly all esophagectomies, rendering patients susceptible to impaired gastric emptying. The question of whether, how, and when to perform pyloric drainage is thus essential, yet remains controversial as it has been unaddressed by randomized trials. Indeed, the literature has yet to definitively support any strategy over another[1-3]. Several management strategies have been proposed: surgical pyloromyotomy, surgical pyloroplasty, endoscopic pyloric dilatation, chemodenervation with onabotulinum toxin, and (most

recently) endoscopic pyloromyotomy. Intervention can be performed preoperatively, at the time of esophagectomy, routinely in the postoperative phase, or selectively in the postoperative phase in response to specific obstructive complications.

The many and varied techniques and strategies for pyloric drainage have developed and evolved alongside the approach to the esophagectomy itself - chiefly from conventional open two- or three-field approaches to hybrid and even completely minimally invasive approaches. The historical context of pyloric drainage is inseparable from the advent of minimally invasive and robotic-assisted minimally invasive surgery, and thus, an understanding of the approach to pyloric drainage in the era of robotic-assisted minimally invasive surgery requires an exploration of the history of all aspects of the esophagectomy.

THE CONTROVERSY: THE EFFECT OF PYLORIC DRAINAGE ON GASTRIC CONDUIT FUNCTION AFTER ESOPHAGECTOMY

Proponents of pyloric drainage during or immediately after esophagectomy invoke surgical dogma from the era prior to anti-secretory medications when peptic ulcer disease was common. One common operation for peptic ulcer disease was a bilateral truncal vagotomy, which necessitated pyloric drainage. Because bilateral truncal vagotomies are intrinsic to nearly all esophagectomies, the gastric conduit demands the same consideration. Indeed, pyloric drainage yields decreased rates of delayed gastric emptying when compared to the absence of an emptying procedure (10% and 50%)[1-7]. Purported downstream clinical effects include a decreased rate of morbidity, particularly aspiration pneumonia and anastomotic leakage[8]. However, the literature has not consistently supported these theoretical benefits. A retrospective cohort study conducted by Antonoff *et al.* found that routine pyloric drainage was associated with a lower need for postoperative pyloric dilatation during the index hospitalization and a reduced risk of postoperative aspiration[9]. In contrast, a meta-analysis by Urschel *et al.* demonstrated pyloric drainage did not reduce the risk of aspiration with statistical significance[10]. In addition, long-term morbidity (including anastomotic leakage) and mortality were not influenced by pyloric drainage, a finding corroborated by Antonoff *et al.*' study[9,10].

Critics of pyloric drainage highlight that the procedure is not without consequences. It is associated with a 10% to 20% risk of postoperative dumping and a 5% risk of bile reflux, which can be challenging to manage[2,4,5,9,11]. Though pyloric drainage is designed to facilitate conduit emptying, subsequent postoperative edema at the level of the pylorus may have a transient paradoxical effect, impairing drainage until the edema resolves. Indeed, Lanuti *et al.* found, in a retrospective review, that delayed gastric emptying (defined for their purposes as the presence of symptoms, radiographic evidence of delayed emptying on barium swallow, persistently dilated conduit with air-fluid level, or retained food on esophagoscopy) occurred at a higher rate after pyloric drainage (18.2%) than without (9.6%)[11]. Finally, pyloroplasty and pyloromyotomy are associated with a risk of a leak, albeit rare: Antonoff *et al.* reported major complications directly related to pyloromyotomy or pyloroplasty in two of their cohort of 293 patients, one of whom died as a result of those complications[9].

Further reservations include the small effect size of pyloric drainage on the rates of gastric conduit dysfunction. While the Urschel meta-analysis demonstrated a trend favoring pyloric drainage as protective against delayed gastric emptying, this trend did not reach significance. Fritz *et al.* omitted pyloric drainage in 170 consecutive patients undergoing esophagectomy and found similar rates of gastric conduit dysfunction (16.5%) as those who undergo pyloric drainage[12]. Another meta-analysis by Akkerman *et al.* in 2014 corroborated this result[7].

These discordant findings must be interpreted in historical context, as the method of gastric conduit construction confounds some of the findings in the literature. Early esophagectomy series often used the whole stomach for esophageal replacement, which has inherently worse emptying than a tubularized conduit[7,13]. A whole intrathoracic stomach is more distensible than a tubularized conduit, and is, therefore, more prone to dysfunction in part by virtue of the law of LaPlace: the pressure within the stomach (which resides within the negatively pressurized thoracic cavity after esophageal reconstruction) may not surpass the pressure of the pylorus[4,14,15]. Furthermore, though the preservation of the lesser curvature preserves some degree of gastric motility, it also sometimes permits gastroptosis, in which the pylorus lies more cephalad than the lowest point of the conduit[16]. A retrospective study conducted by Shu *et al.* in 2013 found that intrathoracic stomach syndrome occurred with whole stomach reconstruction approximately 10% of the time, compared to an incidence of 3.3% with tubularized conduit reconstruction[17]. A prospective study by Zhang *et al.* in 2011 found similar rates (6%) of delayed gastric emptying yet a significantly higher rate of reflux esophagitis (21%) among patients who underwent whole stomach, as compared with gastric tube reconstruction (6%)[18]. The Akkerman meta-analysis also established the tubularized stomach as superior with respect to gastric emptying[7]. Of note, the studies analyzed within the Urschel meta-analysis - each conducted in the 1990s - largely comprised patients who underwent whole stomach reconstruction, but this practice is now much less commonplace.

In parallel, the surgical approach for esophagectomy has evolved towards minimally invasive and robotic-assisted minimally invasive techniques. In 1992, Dallemagne *et al.* described one of the first cases of a three-field esophagectomy performed with the assistance of laparoscopy and thoracoscopy, and DePaula *et al.* described one of the first cases of a transhiatal esophagectomy in 1995, each of which incorporated a conventional hand-sewn cervical esophagogastrostomy[19,20]. Watson *et al.* followed in 1998, describing one of the first cases of a conventional minimally invasive Ivor Lewis esophagectomy (ILE) using laparoscopy and thoracoscopy, in which the esophagogastrostomy was hand-sewn intrathoracically[21]. Soon after, Horgan *et al.* described their experience with one of the first robotic-assisted minimally invasive esophagectomies in 2003 via a transhiatal approach, extolling such benefits as the three-dimensional field of view, additional degrees of motion, and longer reach of the robotic instruments compared to that of conventional laparoscopy[22]. Early reports of robotic-assisted minimally invasive ILE soon followed. Of note, each of these case reports states that pyloric drainage was not routinely performed, and a tubularized gastric conduit was employed for reconstruction.

Trends in pyloric drainage have similarly evolved over time, and thus, the effect of pyloric drainage on outcomes - particularly gastric conduit dysfunction - is inextricably confounded by several technical aspects of esophagectomy, including the approach. For example, the choice of anastomotic level (cervical *vs.* intrathoracic) and route of reconstruction (posterior mediastinal *vs.* retrosternal) each concomitantly alter the configuration of the gastric conduit in three-dimensional space. Additionally, no level 1 evidence exists to support any given approach (transhiatal *vs.* transthoracic, hybrid *vs.* minimally invasive, *etc.*) over another. Though these variables may be considered when deciding whether to perform a gastric emptying procedure, the literature does not provide conclusive evidence that either level of the anastomosis or route of reconstruction independently affects gastric conduit function[7]. Consequently, we also seek high-quality evidence on the management of the pylorus during and after robotic-assisted minimally invasive esophagectomy.

COMMON TECHNIQUES FOR PYLORIC DRAINAGE DURING ROBOTIC-ASSISTED MINIMALLY INVASIVE ESOPHAGECTOMY

Robotic-assisted laparoscopic pyloroplasty

When performed robotically, a Heineke-Mikulicz pyloroplasty should follow the same principles as when the operation is performed via an open approach[23]. After placing stay sutures through the pyloric ring superiorly and inferiorly, a longitudinal incision is made to expose and divide the pyloric ring completely; we prefer to use monopolar cautery. Though running closures have been described, we prefer to use an interrupted 2-0 braided polyester suture, taking care to take separate bites of the serosa and mucosa on the gastric side of the pylorus. We cover the completed closure with a loose tongue of omentum. Whereas pyloric drainage has been touted by some to have greater technical difficulty with a conventional laparoscopic approach[24], robotic assistance arguably re-simplifies surgical pyloromyotomy and pyloroplasty to a degree of technical complexity comparable to the traditional open approach; indeed, the additional degrees of motion and dexterity afforded by robotic instrumentation decrease operative times for a surgical pyloroplasty as compared with those of traditional laparoscopy[25]. The primary limitations of robotic pyloroplasty include the limited availability of robotic surgical systems in some hospitals and the cost of the platform and disposable equipment.

Pyloric chemodenervation

Chemodenervation, a temporary method of pyloric drainage, is performed by injecting a small aliquot of onabotulinum toxin into the subserosal space of the pylorus. The most frequently described dose and technique is 100 units of toxin diluted in 5cc saline injected into each quadrant of the pylorus, approximately 20-25 units per quadrant. This is accomplished via either an external approach (i.e., intraoperatively, using a 22G spinal needle) or an endoscopic approach (e.g., with a 26G injection needle). The toxin facilitates pyloric drainage by decreasing pyloric smooth muscle contractility both directly and via inhibition of acetylcholine release at the neuromuscular junction[26], and its pharmacologic duration is approximately 90 to 120 days. Cerfolio *et al.* reported favorable results with this technique: patients who underwent chemodenervation at the time of esophagectomy experienced lower rates of radiographic delayed gastric emptying (59%, *vs.* rates surpassing 90% for patients who underwent surgical pyloric drainage or no intervention)[2]. Importantly, patients who underwent pyloric chemodenervation had lower rates of biliary reflux symptoms (6%) than those treated with pyloroplasty, which carries a rate of bile reflux up to 20% to 38%.

A recently published large single-center retrospective analysis by Saeed *et al.* demonstrated the overall safety and efficacy of chemodenervation, with several important caveats[27]. Patients who underwent chemodenervation at the time of esophagectomy had similar rates of anastomotic leak (approximately 17%-19%) as those who underwent surgical pyloric drainage (pyloroplasty or pyloromyotomy). While the chemodenervation group had a shorter length of hospital stay (9.8 *vs.* 12.1 days), this came at the expense of a greater rate of delayed gastric emptying (15.9% *vs.* 9.3%). However, the authors note that this effect is largely driven by a low rate of delayed gastric emptying among the subset of surgical drainage patients who specifically underwent pyloroplasty as opposed to pyloromyotomy. Chemodenervation was also associated with a lower rate of bile reflux (0.4% *vs.* 2.8%) and postoperative weight loss (9.8 *vs.* 11.4 kg after six months) than pyloroplasty. Crucially, the chemodenervation group was more likely to have undergone esophagectomy via a fully robotic-assisted Ivor Lewis approach, whereas the surgical pyloric drainage group was more likely to have undergone a hybrid laparotomy/robotic-assisted thoracoscopic approach.

Endoscopic pyloromyotomy

Gastric peroral endoscopic myotomy (G-POEM) [also known as per oral pyloromyotomy (POP)] was first described as a novel therapeutic technique for refractory gastroparesis, but has since garnered attention as a

potential therapy for delayed gastric emptying following esophagectomy[1,28-31]. As its name suggests, G-POEM was derived from the technique of peroral endoscopic myotomy (POEM), which is well-described for the treatment of achalasia. Via an endoscopic approach, a longitudinal or transverse mucosotomy is made approximately 5 cm proximal to the pylorus (posteriorly and slightly towards the lesser curve) and a submucosal tunnel is created with electrosurgical dissection. After extending the submucosal tunnel into the duodenal bulb and completely exposing the pyloric ring, the pylorus is divided longitudinally. The mucosotomy is closed with either through-the-scope clips or endoscopic suture. It should be noted that while it is easier to enter the submucosal plane through a transverse mucosotomy, a longitudinal mucosotomy is easier to close.

A separate but related technique has been described wherein the muscularis of the pylorus and the overlying mucosa are incised directly via an endoscopic approach at the time of esophagectomy[30]. Comparative data are yet lacking for the application of G-POEM specifically to pyloric drainage after esophagectomy, but Nammour *et al.* reported a series of 11 patients with delayed gastric emptying after esophagectomy who experienced favorable results with G-POEM, with patients reporting a lower burden of symptoms and gastric scintigraphy demonstrating improvement or normalization of gastric emptying in 87.5% of examined patients after the procedure[29]. Notably, 81.8% of the cohort (9 of 11) had previously undergone pyloric chemodenervation and were experiencing recurrent or recalcitrant symptoms.

DOGMATIC *VS.* SELECTIVE PYLORIC DRAINAGE

The advent of robotic-assisted surgery has undeniably revolutionized the care of patients undergoing esophagectomy. What was formerly a procedure that mandated large incisions in two or three body cavities can now be performed in a hybrid or even exclusively minimally invasive fashion. Moreover, endoscopic techniques for managing postoperative complications including delayed gastric emptying have since been developed since the introduction of minimally invasive approaches. Dogmatic pyloroplasty and pyloromyotomy arose in an era when a redo laparotomy, which confers a significant risk of complications and need for recovery in immunocompromised cancer patients, was the primary option for patients with delayed gastric emptying after esophagectomy who did not undergo pyloroplasty or pyloromyotomy at the index operation. Since then, robotic-assisted laparoscopic pyloric drainage in a separate setting and endoscopic therapies including pyloric chemodenervation with onabotulinum toxin[2], endoscopic balloon dilatation[14], and G-POEM[1] have emerged as minimally invasive options, which has subsequently enabled a more selective approach to pyloric drainage after esophagectomy.

When comparing dogmatic *vs.* selective pyloric drainage, several clinical outcomes warrant consideration. Directly related functional outcomes include gastric outlet obstruction, dumping syndrome, and bile reflux. Indirectly related clinical outcomes (e.g., those suggestive of or caused by conduit distension) include postoperative aspiration, anastomotic leak, and acid reflux. With increased attention on quality-of-life outcomes, the influence of pyloric drainage on postoperative dysphagia, odynophagia, nausea and vomiting, reflux, regurgitation, cough, and weight loss also warrants consideration[32]. Nevertheless, the presence or absence of any of the above signs or symptoms may be confounded by numerous other factors. Particularly troublesome to parse out are symptomatic reflux and esophagitis, which may be due to either reflux of bile (to which pyloric drainage may contribute) or the inadequate clearance of swallowed material (to which the lack of pyloric drainage may contribute); indeed, patient questionnaires have reported both higher and lower rates of reflux after pyloric drainage[15].

Study design further complicates interpretation of the available literature. Among retrospective studies and meta-analyses, pyloroplasty and pyloromyotomy are often combined, yet they may have different outcomes,

as demonstrated by Saeed *et al.* in their retrospective review[27]. The two most recently published meta-analyses grouped all patients who undergo a pyloric drainage procedure, whether permanent (pyloromyotomy and pyloroplasty) or temporary (dilatation and chemodenervation)[6,7,9,10]. Moreover, gastric conduit dysfunction - including the closely related clinical entities of gastric outlet obstruction, delayed gastric emptying, acquired pyloric stenosis, and intrathoracic stomach syndrome - is variably defined in the body of literature (whether by subjective symptom profile, a radiologist's impression of a barium esophagram, or quantitative gastric scintigraphy), complicating objective comparison and meta-analysis[8,11,14,33].

The transience of the newer alternatives to surgical pyloric drainage is worth further consideration. Most episodes of gastric conduit dysfunction occur within the first 30 days of the index operation when postoperative edema may be a significant contributing factor[11]. The effects of chemodenervation and dilatation are temporary, whereas surgical pyloromyotomy or pyloroplasty and endoscopic pyloromyotomy (i.e., G-POEM or POP) permanently alter the patient's anatomy. Lanuti *et al.* employed selective endoscopic balloon dilatation ad hoc when there was symptomatic, endoscopic, or radiographic evidence of gastric conduit dysfunction, touting an impressive 95% success rate in resolution[4]. Repeat intervention was not described within the same cohort, and only five patients within the cohort of 98 patients developed gastric conduit dysfunction beyond one year after their index operation. Taken together, these data suggest that endoscopic balloon dilatation or chemodenervation could adequately address early (i.e., within 30 days) gastric conduit dysfunction with minimal risk of late gastric conduit dysfunction. With translational studies drawing increased attention to the regenerative potential of the gastric myenteric plexus (and hence gastropyloric motility) after esophagectomy[33,34], a selective temporary pyloric drainage procedure, rather than a permanent pyloroplasty or pyloromyotomy, is an appealing strategy for those with early signs of gastric conduit dysfunction. In addition, G-POEM is emerging and is our preferred selective approach to pyloric drainage for the minority of patients with durable signs of delayed gastric emptying after esophagectomy. We have adopted this approach to manage the pylorus in a selective fashion with G-POEM and have anecdotally noted a very low risk of functional side effects as compared with surgical pyloroplasty. Though studies have established the safety and efficacy of G-POEM, comparative studies have not yet been conducted[1,28-31]. Impedance planimetry [EndoFLIP™ (endoluminal functional lumen imaging probe), Medtronic, Minneapolis, MN] utilizes an endoscopically placed catheter equipped with a cylindrical balloon that can be inflated to various diameters to allow dynamic assessment of sphincter distensibility. While its use in assessing esophageal motility and lower esophageal sphincter distensibility is becoming increasingly commonplace, its use to assess abnormal pyloric distensibility is under investigation. In the future, it may help individualize management of the pylorus after esophagectomy.

CONCLUSION

Though more than a century has passed since the first esophagectomy, controversy remains regarding many technical details, including management of the pylorus. In particular, the debates regarding the optimal technique to manage the pylorus and whether a pyloric intervention should be performed dogmatically at the time of esophagectomy or selectively for symptomatic post-esophagectomy patients have yet to be resolved. While addressing these debates, a standardized definition and classification of gastric conduit dysfunction after esophagectomy is critical to allow proper analyses in future comparative effectiveness studies. The contemporary era of robotic-assisted surgery has facilitated the performance of pyloric drainage via pyloroplasty and pyloromyotomy, and advanced third-space endoscopy now provides the option of selective pyloric drainage via a G-POEM. Given the rising incidence of esophageal cancer and the growing adoption of robotic-assisted minimally invasive esophagectomy, high-quality prospective studies are needed to settle one of the most enduring debates in thoracic surgery. Until then, we suggest a selective approach to pyloric drainage.

DECLARATIONS

Authors' contributions

Contributed equally to the organization and writing of this manuscript, agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: Creden SP, Groth SS

Availability of data and materials

Creden SP and Groth SS had full access to all data and materials.

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Both authors declared that there are no conflicts of interest.

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Not applicable.

Consent for publication

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