Postendoscopic Zenker Esophagodiverticulostomy Leaks Associated With a Specific Stapler Cartridge

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Objective: To determine the cause of postoperative leaks in 2 patients with Zenker diverticula treated with endoscopic staple-assisted esophagodiverticulostomy.

Design: Medical chart review and simulated surgery.

Setting: Teaching hospital.

Patients and Methods: Two case reports of postoperative leaks in patients treated with endoscopic staple-assisted esophagodiverticulostomy and experimental simulated surgery to investigate the possible cause of this complication. Use of a TR45B, 3.5-mm cartridge for an Endopath ETS Flex45 Endoscopic Articulation Linear Cutter stapler was associated with complications, whereas use of a TR45W, 2.5-mm cartridge in the same stapler was not.

Results: In a simulated surgery model, the 3.5-mm cartridge staple line leaked from the incision apex with pressure of less than 20 cm H₂O, whereas the apex remained dry when using the 2.5-mm cartridge. When pressure was increased to 30 cm H₂O, the staple line of the 2.5-mm cartridge had diffuse weeping of fluid but no focal, apical leak.

Conclusions: Endoscopic staple-assisted esophagodiverticulostomy continues to be a relatively safe procedure; however, to provide maximum safety at the apex, the surgeon needs to be aware of stapler cartridge differences.


UNDREDs of cases treating Zenker diverticula using endoscopic staplers have been reported in the United States and Europe. The staplers, invented for general and thoracic surgery, have been widely accepted by head and neck surgeons. The technique, endoscopic staple-assisted esophagodiverticulostomy (ESED), has been celebrated for its simplicity and safety. We recently observed postoperative leaks in 2 patients associated with a specific stapler cartridge, different from staplers that were originally reported in the literature. The first studies of ESED in the United States and Europe used an Endo-GIA-30 stapler (US Surgical Corp, Norwalk, Conn). The experience reported herein is with the Endopath ETS Flex45 Endoscopic Articulation Linear Cutter stapler (Ethicon Endo-Surgery Inc, Cincinnati, Ohio) using a TR45B, 3.5-mm stapler cartridge without modifications.

RESULTS

In the first glove, the 3.5-mm cartridge suture line appeared to leak from the apex with pressure of 17 to 20 cm H₂O (Figure 2). No leak could be detected from the suture line produced by the 2.5-mm cartridge under similar conditions. The second glove was then sealed in the cuff area with a plastic disk, and additional hydrostatic pressure was added by attaching tubing to the closed system. Once pressure exceeded 30 cm H₂O, diffuse weeping of fluid was observed from each staple hole of the 2.5-mm cartridge suture line. In this glove, the apex did not leak as a focal area as it did with the lower pressure–stressed suture line of the 3.5-mm cartridge.

COMMENT

The experience of Cook et al has shown that ESED is safe and effective in treating Zenker diverticula, and the postoperative complications of these 2 patients are unique in our experience to this point. The only potential leak from a distal pouch laceration was identified and repaired endoscopically as reported previously. It is possible that the mechanism of pouch laceration from the stapler anvil was responsible in the patients reported herein, but careful inspection of the pouch at the end of each procedure did not identify a laceration. Especially careful was our inspec-
PATIENTS AND METHODS

PATIENT 1

A 73-year-old woman with radiological evidence of a Zenker diverticulum had a small, easily identified pouch at surgery. Endoscopic visualization and video control were maintained throughout the procedure. A retraction suture was placed using an endoscopic suture (Endostitch; US Surgical Corp) and was used to retract the parting wall between the small diverticulum and the esophagus. Firm retraction allowed entry of the tissue into the stapler reloaded with the 3.5-mm, standard cartridge and subsequent division of the cricopharyngeus. The surgery went uneventfully, and the patient was discharged from the hospital the following morning eating a full diet. On postoperative day 3, the patient presented with dysphasia and odynophagia. A computed tomographic scan showed gas and fluid in the retropharyngeal space, and 4 mL of purulent material was drained through the neck. The patient, treated with antibiotics and drainage, was discharged after a 4-day hospitalization with no other adverse effects and persistently improved swallow.

PATIENT 2

A 53-year-old man with a moderate-sized Zenker diverticulum pouch had difficult exposure owing to the small transverse diameter of his jaw. Once the laryngoscope was positioned, the esophagus and pouch were identified and monitored as described previously. The Endopath ETS Flex45 Endoscopic Articulation Linear Cutter (stapler) was reloaded with the 3.5-mm, standard cartridge, and subsequent division of the cricopharyngeus was carried out without difficulty. The patient initially complained of tongue and throat pain. Two days after surgery he continued to have symptoms of odynophagia. Plain radiographs showed air at the level of the pouch, and a computed tomographic scan showed evidence of inflammation but no abscess. He was treated with antibiotics for 5 days, and his symptoms resolved uneventfully with improved swallowing.

At the time of surgery, both patients bled more from the stapled edges than at a previous experience of one of us (W.J.R.) with the EndoGIA-30 stapler. In both circumstances, a 3.5-mm, standard cartridge was used. In 12 other patients, the TR45W, 2.5-mm, vascular/thin stapler cartridge was used in the Endopath ETS Flex45 Endoscopic Articulation Linear Cutter (stapler) with no clinical evidence of leak. All 12 patients ate a normal diet and were discharged from the hospital the following morning without antibiotic treatment. In 1 patient, the initial cut was made using the 3.5-mm cartridge, and then the difference between the staple cartridges was discovered. In the same procedure, a second cut was performed through the apex using a second cartridge loaded with the 2.5-mm cartridge. There was no adverse postoperative clinical outcome.

The Endopath ETW-45 stapler (Ethicon Endo-Surgery Inc), in common use at Bassett Healthcare Cooperstown, NY, is supplied with a 2.5-mm stapler cartridge referred to as “vascular/thin” by the manufacturer. The conformation of that staple cartridge is shown in Figure 1A. Refills for that staple can include a 3.5-mm cartridge, referred to as “standard” by the manufacturer, the conformation of which is shown in Figure 1B. The 3 rows of staples and the extension of the staples directly beyond the incision of the 2.5-mm stapler cartridge is similar to the staple arrangement of the EndoGIA-30 stapler. The 3.5-mm cartridge has 3 distinct characteristics: only 2 rows of staples and the extension of the staples directly beyond the incision of the 2.5-mm cartridge is similar to the staple arrangement of the EndoGIA-30 stapler. The 3.5-mm cartridge has 3 distinct characteristics: only 2 rows of staples, a greater distance between the medial staple line and the incision, and the arrangement of the most distal medial staple and the end of the incision.

METHODS

Because of differences in the staple configuration of the cartridges, an experiment was undertaken to test the potential leak of the ETS45, 3.5-mm cartridge. A glove made of natural rubber coated with neoprene (Magla Products LLC, Morristown, NJ) was used as the experimental model. The stapler was introduced in a fashion somewhat similar to that used for ESED, where the anvil of the stapler was placed into the thumb of the glove and the cartridge into the index finger. Care was taken to keep the material corresponding to the web space of the fingers so as not to allow it to bunch up and leak from the initiation point of the incision because of redundant material. The stapler was fired in the usual manner as recommended by the manufacturer for each staple cartridge. The glove, turned inside out for contrast (blue on white), was then filled with methylene blue–dyed water and observed at the various water levels above the apex of the suture line.

In similar experiments, 4 gloves were stapled with both cartridges, placing the anvil of the ETS45 into the long finger and alternating one cartridge into either the index finger or the ring finger. The gloves were then observed at 22-cm H2O pressure. There was 1 misfire of the stapler in which the last 2 rows of staples were not pressed into the glove material using the 2.5-mm cartridge. The staples could be palpated and seen in the end of the stapler, but the glove did not leak when subjected to 22-cm H2O pressure. In each glove, a leak was observed from the apex of the staple line closed by the TR43B cartridge, but no leak was observed from the TR45W staple line.
port herein. Using the ATW-45 stapler with the vascular/thin conformation of the 2.5-mm staple length has not yielded any evidence of leaks in our small series of patients. Although this experience does not ensure safety, it is our current instrument of choice.

In contrast to the 2 post-ESED leaks reported herein, Feeley et al\(^8\) reported 2 fistulas in 24 patients treated with the open, transcervical approach. In their review, 9 of 24 patients developed significant complications. The 2 patients described herein are unique in the hundreds of reported treated patients with ESED without such complications.

The ETS45 stapler has the advantage of being 15 mm longer than the EndoGIA-30, allowing a longer cut without repositioning of the stapler. Fewer stapler firings provides less chance of laceration of the pouch with the anvil. By using the 2.5-mm cartridge, the ETS45 is nearly the same in stapler configuration, especially at the end of the razor cut. We believe that the arrangement of the 2.5-mm cartridge is similar to that of the EndoGIA-30, and when using the Ethicon staplers for ESED, it is the stapler cartridge of choice. Because the cephalad part of the incision can be made without repair, as in the Dolhman procedure, it is the relationship between the distal staple line and the incision that is critical.

In our experiments, the difference in leak pressures between the 2 staplers suggests that the 3.5-mm cartridge should not be used for ESED in Zenker diverticula if maximum safety of the apex is a concern. A second staple line fired through the apex of the first incision using a different stapler secures the distal cut (apex) and renders the initial cut and staple configuration moot. The pressure in the pharyngoesophageal segment during swallow is estimated to be 40 to 120 mm Hg.\(^9,10\) far

**Figure 1.** The staple conformation of 2 cartridges that fit the Endopath ETS Flex45 Endoscopic Articulation Linear Cutter system (Ethicon Endo-Surgery Inc, Cincinnati, Ohio). A, The TR45W, 2.5-mm, vascular/thin cartridge. B, The TR45B, 3.5-mm, standard cartridge. The TR45G, 4.1-mm-thick cartridge has a staple arrangement similar to the 3.5-mm cartridge.

**Figure 2.** A glove made of natural rubber coated with neoprene was stapled using the Endopath ETS Flex45 Endoscopic Articulation Linear Cutter system (Ethicon Endo-Surgery Inc, Cincinnati, Ohio). The staple anvil was placed into the thumb and the cartridge into the index finger, simulating the Zenker pouch and the esophagus, respectively. The glove was then filled with water containing methylene blue for contrast. A, The suture line created using the TR45B, 3.5-mm cartridge leaked with less than 20-cm H\(_2\)O pressure. B, No leak was observed in the TR45W, 2.5-mm cartridge suture line under similar circumstances. In both photographs, the distal thumb is retracted with a clamp to view the area immediately below the apex of the staple line.
higher than the 20–cm H₂O (1.5–mm Hg) pressure seen in our experiments, which yielded a leak. Although the relatively thin glove used in our experiment does not accurately recreate human tissues, it allows comparison of the 2 staple conformations as far as preventing a leak from the apex of the incision. The vascular/thin cartridge may staple the thin glove more tightly than the standard cartridge throughout the suture line and is a source of leak artifact.

A major safety aspect of the ESED approach depends on the staple line existing beyond the razor cut. The 3.5-mm cartridge fits the ATW45 stapler and is routinely used in gastrointestinal tract surgery. The obvious difference in the staple arrangement between available cartridges for the ETS45 system is evident on the cartridge surface but is not obvious from the cartridge package. The package insert for the Ethicon stapler system clearly states the differences in the staple conformation of the cartridges available. There is no marking on the packages of any of the cartridge inserts other than to indicate the difference in staple length between the TR45W (2.5 mm) and the TR45B (3.5 mm). Surgeons who perform Zenker endoscopy should be aware of these differences and should check the specific stapler cartridge conformation before use in pharyngeal surgery.

In conclusion, ESED continues to be a relatively safe, efficient, and simple procedure for Zenker diverticula. Surgeons should be aware of stapler cartridge differences, the potential for leaks, and the need to inform patients of possible transcervical surgery to treat complications.

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REFERENCES