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Esophgeal Perforation and Bilateral Empyema Following Endoscopic EsophyX Transoral Incisionless Fundoplication

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Transoral incisionless fundoplication (TIF) has been used for endoscopic treatment of gastroesophageal reflux disease (GERD). TIF using the EsophyX device system (EndoGastric Solutions) was designed to create a full-thickness valve at the gastroesophageal junction through the insertion of multiple fasteners; it improves GERD, reduces proton pump inhibitor use, and improves quality of life. Although TIF is effective in select patients, a significant subset of patients undergoing TIF develop persistent or recurrent GERD symptoms and may need antireflux surgery to control the GERD symptoms. We now report a 48-year-old man with chronic GERD unresponsive to medical management. He underwent TIF complicated by esophageal perforation and developed mediastinitis, left pneumothorax, bilateral pleural effusions, and acute respiratory failure. He required chest tube placement and bilateral decortication for treatment of nonresolving empyemas. Additional postmarketing studies are required to assess the safety, efficacy, and clinical outcomes of this novel procedure, and patients undergoing this procedure need close postprocedural follow-up.

Key Words: Gastroesophageal reflux; Transoral incisionless fundoplication; Esophageal perforation; Empyema; Pneumothorax

INTRODUCTION

Gastroesophageal reflux disease (GERD) develops when the reflux of gastric contents causes troublesome symptoms and/or complications. GERD has a prevalence of 10% to 20% in Western Europe and North America.[1] Proton pump inhibitors (PPIs) effectively treat heartburn and regurgitation secondary to reflux disease, but some patients have persistent symptoms. Antireflux surgery is mainly performed in patients who do not respond to double-dose PPIs, in patients who have PPI intolerance or complications, and in patients who are unwilling to stay on lifelong medication.[2] Some transoral endoscopic techniques have been attempted as alternatives to medical treatment or antireflux surgery but have shown poor long-term results.[3] Transoral incisionless fundoplication (TIF) is a recently introduced endoluminal technique for GERD treatment.[4,5] TIF using the EsophyX device (EndoGastric Solutions, Redmond, WA, USA) was introduced into the United States market in 2008.[6] The effectiveness of TIF as a novel procedure remains under study.

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CASE REPORT

A 48-year-old Caucasian man was diagnosed with GERD and hiatal hernia 15 years before presentation. His symptoms included chronic heartburn and nighttime cough that did not improve with lifestyle modification, histamine 2 blockers, and PPIs. Esophageal 24-hour pH-impedance monitoring confirmed the diagnosis of GERD. He underwent TIF after failing conservative therapy. A few hours after surgery, the patient developed midsternal chest pain. Physical examination revealed a mildly distressed state with rapid shallow breathing. His respiratory rate was 18 breaths per minute, heart rate was 140 beats per minute, O_2 saturation was 88% on a 40% venturi mask, temperature was 36°C, and blood pressure was 154/93 mm Hg. The pulmonary, cardiovascular, and abdominal examinations were normal. Electrocardiogram showed no acute ST/T wave changes. His chest radiograph showed new small bilateral pleural effusions and bilateral lung opacities. The next day, the patient had worsening chest pain, severe back

pain, and shortness of breath. Physical examination revealed decreased breath sounds on the left side. The patient's respiratory status deteriorated, and he was intubated for mechanical ventilation. Another chest radiograph showed a large left-sided pleural effusion and bilateral pulmonary infiltrates consistent with consolidation and/or atelectasis.

Laboratory studies revealed a white blood count of 16.9×10^9/L, a hemoglobin level of 16 g/dL, a blood urea nitrogen level of 22 mg/dL, a serum creatinine level of 1.2 mg/dL, a serum lactate level of 2.7 mmol/L, a total protein level of 5.7 g/dL, and a lactate dehydrogenase (LDH) level of 170 U/L. Arterial blood gases revealed pH 7.27, P_aCO_2 46.7 mm Hg, P_aO_2 53.2 mm Hg, and HCO_3 21 mmol/L. Computed tomography of the chest showed moderate-to-large left-sided and moderate right-sided pleural effusions, a left-sided pneumothorax, and pneumomediastinum, findings consistent with distal esophageal perforation (Fig. 1). Computed tomography of the abdomen showed pneumoperitoneum. The patient was started on vancomycin and ertapenem. A left-sided chest tube was inserted, and purulent, brown-greenish fluid was drained (1,300 mL) during the tube placement. Pleural fluid analysis showed an exudative effusion consistent with esophageal perforation and empyema with a white blood cell count of 1.75×10^9/L (mainly neutrophils), a protein level of 44 g/L, an LDH level of 7,589 U/L, a fluid protein/serum protein ratio of 0.77, a fluid LDH/serum LDH ratio of 4.46, an amylase level of 335 U/L, a lipase level of 1,188 U/L, and a glucose level of 20 mg/dL.

The patient had a fever for 5 days and leukocytosis despite the antibiotic coverage, chest tube placement, and nasogastric decompression. Blood cultures were negative on two occasions; pleural fluid cultures grew coagulase-negative *Staphylococcus* nitric oxide synthase and diphtheroids. On postoperative day 8, a left-sided thoracotomy and decortication for nonresolving empyema was performed. The patient required mechanical ventilation for 12 days. At his most recent follow-up visit, the patient had been hospitalized at another hospital for 2 weeks because of the nonresolving right-sided empyema and had undergone right thoracotomy with decortication.

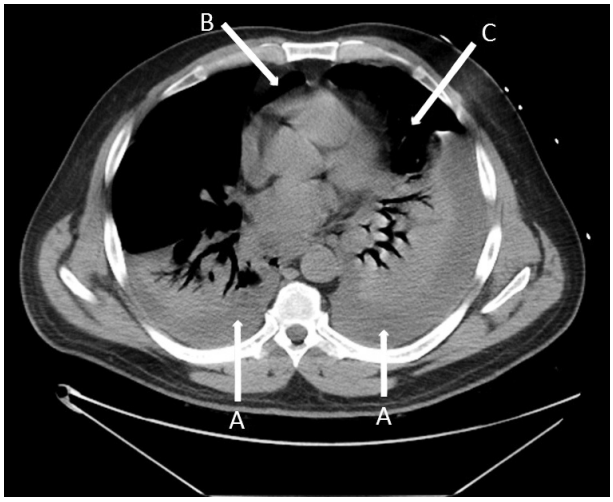

Fig. 1. Computed tomography of the chest shows bilateral pleural effusions greater on the left side (arrow A), pneumomediastinum (arrow B), and anterior left-sided pneumothorax (arrow C). There are compressed and atelectatic lungs at both lung bases.

DISCUSSION

TIF was developed to reconstruct the antireflux barrier and treat GERD. The TIF procedure using the EsophyX system with serosa-fuse fasteners was designed to reconstruct a full-thickness valve at the gastroesophageal junction through tailored delivery of multiple fasteners during a single device insertion (Fig. 2).[5] Some minor and serious adverse events occurred following the use of the EsophyX system. The patient reported in this study developed distal esophageal perforation and left-sided pneumothorax, which were attributed to injury during application of the polypropylene H-fasteners. This injury was complicated by pneumomediastinum, pneumoperitoneum, mediastinitis, empyema, and respiratory failure and required chest tube placement and bilateral thoracotomies with decortications. The patient also developed acute renal injury.

Narsule et al.[7] reviewed the development of endoscopic treatment of GERD and summarized the results from more than 20 surgical studies using the EsophyX system in 2012. The patient follow-up in these studies ranged from 2 to 24 months. Outcomes included discontinuation of PPI therapy in 35% to 85% of patients and significant improvement in GERD-Health Related Quality of Life (HRQL) scores. Bell and colleague[8] reported results in 100 patients in a prospective multicenter registry. GERD-HRQL scores normalized in 73%, and 80% patients were off PPI therapy. There were no complications.

However, other studies have reported serious immediate complications and procedure failures.[7,9,10] A prospective multicenter trial conducted at seven clinical centers enrolled 86 patients in 2006.[5] The inclusion criterion required chronic GERD treated with PPIs; the exclusion criterion was an irreducible hiatal hernia >2 cm. Serious adverse events included two esophageal perforations from device advancement and insertion resulting in procedure discontinuation and surgical suture repair.[5] One patient had postprocedural bleeding and required four units of blood. The risk of esophageal leak can be decreased by deploying the stylet and fastener only once in any given location. If the fastener does not deploy properly, the operator should not reload the fastener and should try to deploy another fastener in the same location, because this may increase the leak potential.[11] Muls et al.[9] reported a multicenter prospective study of TIF with 66 patients; early complications included two esophageal perforations that were attributed to

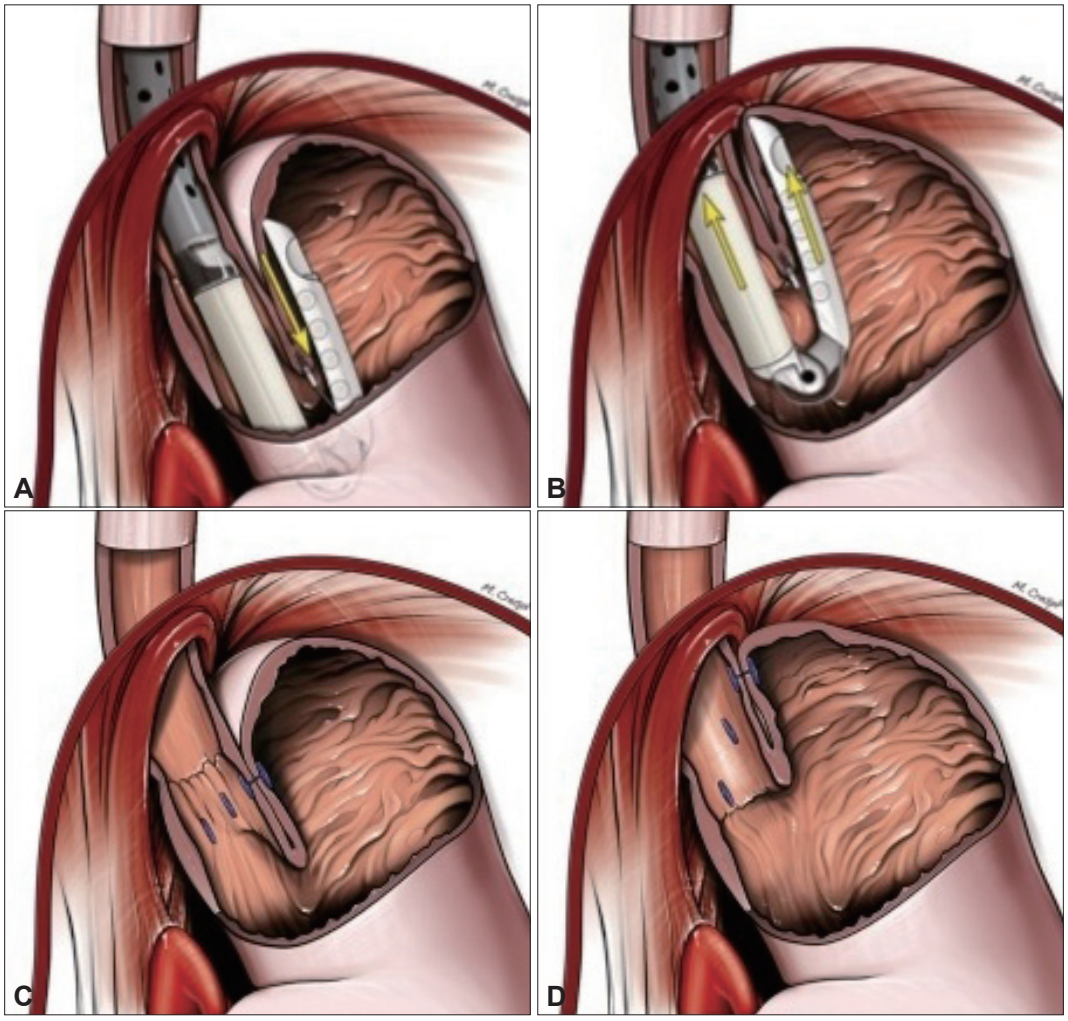

Fig. 2. (A) Transoral incisionless fundoplication procedure with gastrogastric plications placed at the Z-line level. (B) The technique creates an esophagogastric fundoplication proximal to the Z-line. (C, D) Scope withdrawal. This creates partially circumferential fundoplication made of gastric tissue. Available under the terms of a Creative Commons Attribution Noncommercial License. Accessed from Open i beta, TTUHSC Health Sciences Center Library on October 16, 2013. Adapted from Bell et al. Surg Endosc 2011;25:2387-2399, with permission from Springer.[11]

the operators' inexperience. Twelve of these patients required revisional procedures (either repeating TIF or laparoscopic Nissen fundoplication) and were considered failures. Ihde et al.[6] reported a retrospective study in which 47 of 48 patients successfully underwent a TIF procedure with or without laparoscopic hiatal hernia repair in patients with chronic GERD. One procedure could not be completed because of distal esophageal perforation during EsophyX device positioning. This was treated with endoclips to close the mucosal defect followed by a laparoscopic suture repair of the muscular layer with a Nissen fundoplication to patch the repair and control reflux. Bleeding from a suture site during the procedure can occur and is usually controlled with compression using a device for a few minutes.[12] More serious post-TIF intraluminal bleeding requires blood transfusions and the application of endoclips.[5,10,12,13] Respiratory complications include aspiration and pneumothorax.[12,14] Pleural damage is probably related to four-location applications during the procedure and multiple stylet punctures required for deploying the fasteners. The insufflated CO_2 can migrate from the gastric lumen to the mediastinum and pleural space, causing pneumothorax and pneumomediastinum. This procedure has a definite learning curve, and complications may occur more frequently during the introduction of the procedure into new hospitals.[10,12]

In summary, TIF using the EsophyX device is effective and relatively safe for treating GERD and hiatal hernia <2 cm.[7,15,16] It promotes esophagitis healing, reduces PPI use, and improves quality of life. However, the complications with this procedure can be serious and life threatening. These include bleeding at the suture site and esophageal perforation complicated with pneumothorax, empyema, and/or mediastinal abscess.

Conflicts of Interest

The authors have no financial conflicts of interest.

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