Esophageal Perforation and Bilateral Empyema Following Endoscopic EsophyX Transoral Incisionless Fundoplication

Hawa Edriss, Amal El-Bakush and Kenneth Nugent
Department of Internal Medicine, Texas Tech University Health Sciences Center, Lubbock, TX, USA

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

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. Endoscopic evaluation 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, 

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\text{O}_2\text{ saturation was 88\% on a 40\% venturi mask, temperature was 36\degree 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.}
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The patient was admitted to the intensive care unit for further evaluation. Chest computed tomography (CT) scan showed bilateral pleural effusions with small bilateral pneumothoraces. He was managed with chest tube placement and 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.

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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. Proton pump inhibitors (PPIs) effectively treat heartburn and regurgitation secondary to reflux disease, but some patients have persistent symptoms. Antireflux surgery is primarily 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. Some transoral endoscopic techniques have been attempted as alternatives to medical treatment or antireflux surgery but have shown poor long-term results. Transoral incisionless fundoplication (TIF) is a recently introduced endoluminal technique for GERD treatment. Using the EsophyX device (EndoGastric Solutions, Redmond, WA, USA) was introduced into the United States market in 2008. The effectiveness of TIF as a novel procedure remains under study.

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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\textsubscript{CO}_2 46.7 mm Hg, P\textsubscript{O}_2 53.2 mm Hg, and HCO\textsubscript{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.

**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). 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

**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.
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The operators’ inexperience. Twelve of these patients required revisional procedures (either repeating TIF or laparoscopic Nissen fundoplication) and were considered failures. Ihde et al. 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. More serious post-TIF intraluminal bleeding requires blood transfusions and the application of endoclips. Respiratory complications include aspiration and pneumothorax. Pleural damage is probably related to four-location applications during the procedure and multiple stylet punctures required for deploying the fasteners. The insufflated CO₂ 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.

In summary, TIF using the EsophyX device is effective and relatively safe for treating GERD and hiatal hernia <2 cm. 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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