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Original article

Endoluminal fundoplication for the treatment of GERD: A preliminary report of a new transoral approach

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SUMMARY

Aim of the study: This is a preliminary report of endoluminal fundoplication (ELF) for the treatment of GERD. Method: Inclusion criteria [age 18-80; BMI < 35; Chronic GERD >6 mo; GERD-health related quality of life score diff ≥ 10 with PPI dependence; DeMeester > 14.7 (after 14 d without PPI); Deteriorated GEV Hill grade ≥ 2 or HH (hiatus hernia) < 2 cm; esophagitis < L.A. (Los Angeles) grade D at time of procedure; acceptable upper GI; acceptable manometry and no visible Barrett's esophagus] are used for enrollment of patients in this protocol. ELF is performed with the use of the EsophyxTM device. Case presentation: Two male patients 37 and 55-years-old with chronic GERD underwent ELF under general anesthesia. Post-procedure period was uneventful and patients were discharged after 24 hours. Cessation of PPIs one week after the procedure was not followed by relapse of GERD symptoms. Conclusion: Current advances in endoscopic treatment of GERD with the development of alternative to surgery endoluminal devices recreating the gastroesophageal valve in a similar pattern as laparoscopic procedures are promising. According to recent studies, reduction of invasiveness, procedural time, adverse effects, hospital stay and need for medical treatment seems to be cost-saving in combination with clinical effectiveness and improved quality of life.

Key words: Gastroesophagel reflux, endoluminal fundoplication, transoral devices

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INTRODUCTION

Gastro-esophageal reflux disease (GERD) is considered as one of the most prevalent upper gastrointestinal (GI) disorders with a varying clinical spectrum.[1] This pathology is currently defined as a condition producing troublesome symptoms (heartburn, chest pain, regurgitation, dysphagia, hoarseness, coughing, wheezing, difficulty in sleeping), impairing quality of life (QoL), leading to mucosal damage of the esophagus or associated with a number of serious complications (esophageal strictures, Barrett's metaplasia, recurrent pulmonary infections, asthma, laryngeal cancer and adenocarcinomas of the esophagus.[2,3]

Treatment modalities for GERD are indented to relieve symptoms, reverse mucosal damage and prevent complications.[4] Pharmacologic gastric acid suppression using proton pump inhibitors (PPIs) is safe and effective in the majority of patients, but is associated with adverse effects, increased healthcare costs and relapse of symptoms after discontinuation, prompting patients to seek alternative therapies. Minimal invasive endoluminal procedures have been currently introduced to provide GERD symptom relief and reduce medication dependency.[5,6] One of these minimal invasive techniques is currently available and called Endoluminal Fundoplication (ELF), involving an endoscopically guided reconstruction of the gastroesophageal valve (GEV) and reduction of hiatus hernia using a new device (Esophyx™, EndoGastric Solutions Inc., Redmond, WA) (Figure 1). This report is a preliminary description of the appliance of this technique in the first two patients in Greece.

METHOD

Criteria

The following inclusion criteria are used to enroll patients into our protocol: age (18-80); BMI (< 35); Chron-

Figure 1. The Esophyx™ Endoluminal Fundoplication device.

ic GERD (>6 mo); GERD-HRQL(health related quality of life) score (diff ≥ 10) with PPI dependence; DeMeester > 14.7 (after 14 d without PPI); Deteriorated GEV Hill grade ≥ 2 or HH (hiatus hernia) ≤ 2 cm; esophagitis ≤ L.A. (Los Angeles) grade D at time of procedure; acceptable upper GI; acceptable manometry and no visible Barrett's esophagus.

Endoluminal Fundoplication Procedure

After a preferable nasotracheal intubation and under general anesthesia the patient is turned on his left side and an initial endoscopy of the upper GI tract for determination of the GEV Hill grade and measurement of the distance of the Z-line from the teeth is performed. The next step involves the placement and securing of the endoscope in the device, which is well lubricated and introduced in the esophagus and subsequently in the stomach. After detaching the endoscope from the device's end (called tissue mold) a retroflex view is produced in order to visualize and assist the whole procedure. Retraction of the endoscope into the device in order to visualize the Z-line, appliance of vacuum and pushing the device distally aims to reduce the coexisting hiatus hernia. After inserting and retroflexing the endoscope in the stomach a helical tissue retractor is pushed through the flexed mold and is inserted in the gastric cardia in distance of 1,5-2 cm from the Z-line and at posterior site close to the greater curve (Figure 2). The gastric fundus is then retracted caudally and the mold flexes and holds tightly this tissue flap, permitting the advancement of a stylet through the flap in order to insert serially two plastic fasteners that approximate the inverted gastric flap (Figure 3). The same procedure is then continued counterclockwisely in order to construct an omega-shaped, 270° in circumference and 3-5 cm in length GEV. Finally, the scope and device are aligned, the stomach deflated and the esophagus inspected.

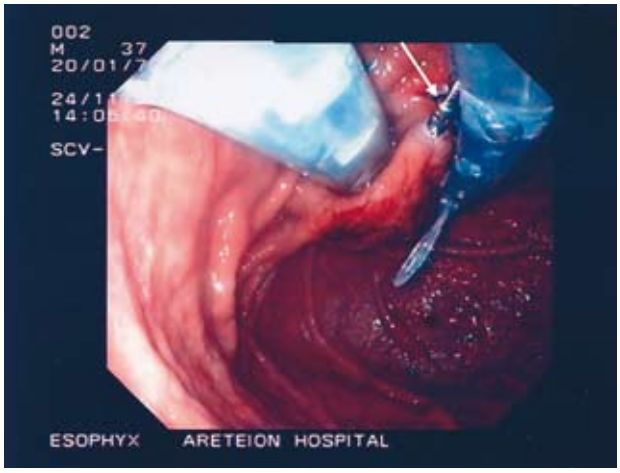


Figure 2. The helical tissue retractor (arrow) holding a tissue flap from gastric cardia.

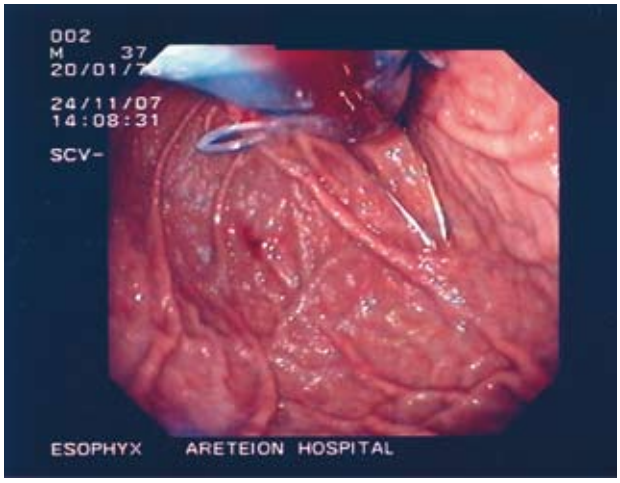
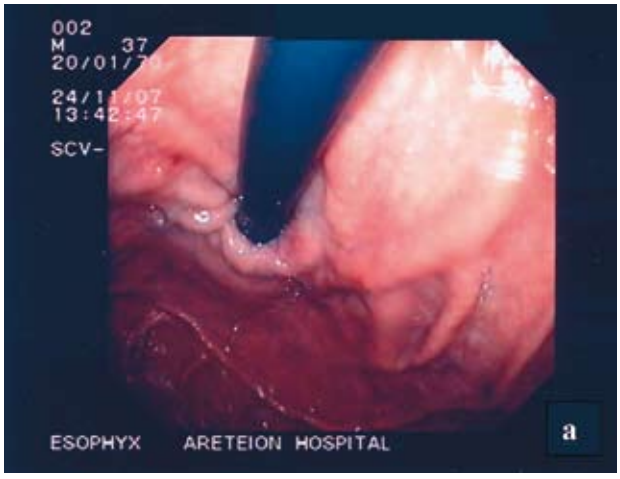


Figure 3. The advancement of both stylets through the flap in order to insert the plastic fasteners.

Case presentation

Two male patients 37 and 55 years-old with chronic GERD (initially presenting before 18 and 10 years respectively) treated by PPIs were the first enrolled in this protocol based on the aforementioned criteria. These patients were admitted in our surgical department in order to be managed with ELF. The patients received general anesthesia for the procedure. Postoperative instructions were the administration of clear fluids on the same afternoon after the ELF and a liquid diet for the first week. The patients were discharged the next day. PPIs were discontinued one week post-procedural. Pre- and post- procedural endoscopic photos are presented in figures 4 and 5. Procedural time ranged from 45 – 70 min. Moderate colicky retrosternal



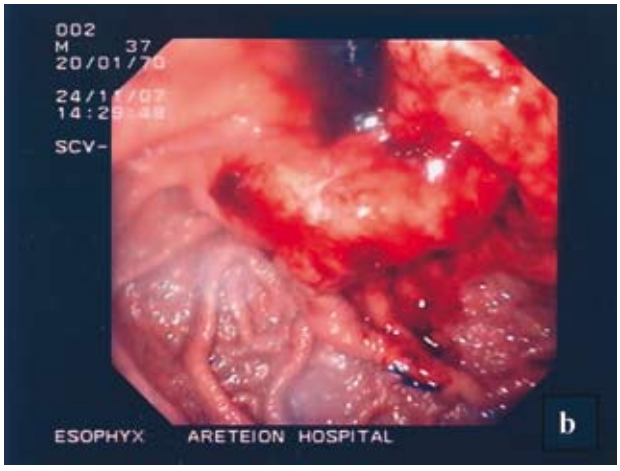
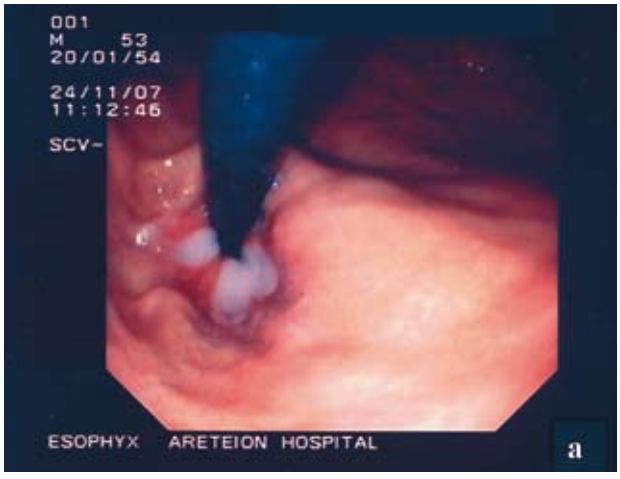


Figure 4. Case # 1: (a) Pre-procedural endoscopic photo, (b) Post-procedural endoscopic photo demonstrating the recreation of the gastro-esophageal valve.



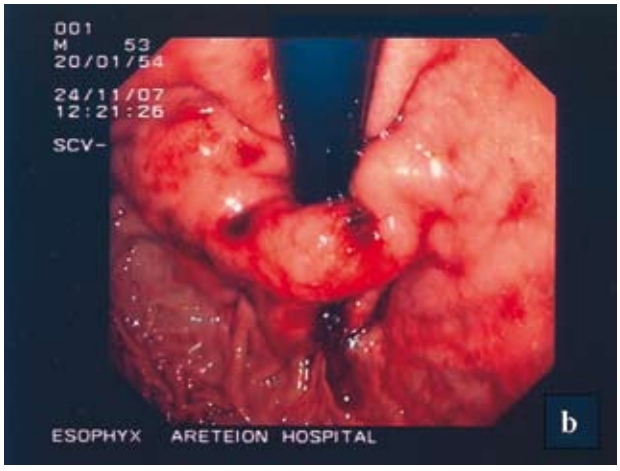


Figure 5. Case # 2: (a) Pre-procedural endoscopic photo, (b) Post-procedural endoscopic photo demonstrating the recreation of the gastro-esophageal valve.

pain on the same afternoon which was relieved by clear fluids was the only postoperative symptom related to the procedure in one of the patients. Both patients reported relief of GERD-related symptoms after gradual re-establishment of normal diet and no recurrence after discontinuation of PPIs at the end of the first week.

DISCUSSION

Gastro-esophageal reflux disease (GERD) is one of the most common disorders of the gastrointestinal (GI) tract.[7,8] Heartburn, the commonest symptom of GERD, is experienced at least once monthly by up to 40% of people in Western countries, while 12% suffer of burning and pain at least once per week and more than 5% on a daily basis.[9,10] Several studies report that up to 77% of patients with GERD symptoms describe a negative impact on everyday quality of life (QoL), while others do not seek medical consultation.[11-15] GERD does not only affect negatively QoL but also impairs work productivity and is associated with substantial costs, both in terms of healthcare and loss of productivity,[16-18] with a total cost of over 24 million USD for year 2000 in the USA.[19]

A wide range of different therapeutic modalities for the treatment of GERD exist. Medical treatment of GERD is based upon proton pump inhibitors (PPIs). However, the relapse of symptoms when medical therapy is discontinued and the fact that PPIs do not stop the reflux, with its possible contribution to the development of cancer of the upper GI tract, lead to the surgical treatment of GERD. Several antireflux operations have been proposed with laparoscopic fundoplications currently being a therapeutic modality with good long-term outcomes (85% patient satisfaction, 5-10% failure rates and less than 10% adverse ef-

fects).20-21 However, evolution in therapeutic endoscopic technology resulted in the development of novel endoluminal procedures, which include tightening of the lower esophageal sphincter (LES) region with sutures or plicators, thermal alteration of the LES using radiofrequency waves (Stretta procedure) and narrowing the gastro-esophageal junction (GEJ) by injecting bulking agents. However, there are no long-term clinical data available on any of the endoluminal therapies and, additionally, their use is limited by the current contraindications for their application (severe esophagitis or Barrett epithelium; morbid obesity; prior antireflux surgery; sizable (> 2 cm) hiatal hernias; and severe dysphagia). Thus, their application is restricted in clinical protocols.

The EsophyXTM EndoLuminal Fundoplication (ELF) is the newest evolution in the treatment of GERD and focuses on restoring the distorted anatomy of the GEJ. Based on the principles of surgical repair (laparoscopic fundoplication), EsophyXTM reduces any existing hiatal hernia, reconstructs a robust gastro-esophageal valve in an omega-shaped fashion, with a 270° circumference and a 3-5cm length and restores the angle of His resembling the laparoscopic Nissen-Toupet procedure. The ELF procedure can also be revised or redone, which is an advantage over the surgical approach. Additionally, it is not time-consuming, is less invasive, is cost-saving, has less adverse effects (dysphagia, bloating) and has a faster learning curve in comparison with the laparoscopic procedure. According to a phase II EU multicenter study (EndoGastric Solutions) regarding clinical effectiveness at 6 months post-procedural there has been recorded a significant improvement of QoL (90%), cessation of PPIs (83%), esophagitis grade downstaging (87%) and reduction of hiatus hernia (88%), while adverse effects were minimal and resolved in 1-2 weeks without use of opiates (left shoulder pain, 18%; abdominal pain, 15%; pharyngitis – nausea, 8%; retrosternal pain, 7%; application site bleeding 6%; dysphagia, 4%; and early satiety 3%). A recently published prospective clinical trial demonstrated technical feasibility and safety of the ELF procedure using the EsophyXTM device. After 12 months, 81% of valves retained their tightness, the hiatal hernias remained reduced in 62% of patients, the median GERD-HRQL scores improved by 67%, 82% of patients were satisfied with the outcome of the procedure, 82% remained completely off PPIs, and 63% had normal pH.[22]

In conclusion, current advances in endoscopic treatment of GERD with the development of alternative to surgery endoluminal devices recreating the gastro-esophageal valve in a similar pattern as laparoscopic procedures are promising. Reduction of invasiveness, procedural time, adverse effects, hospital stay and need for medical treatment seems to be cost-saving in combination with clinical effectiveness and improved quality of life. However, well designed randomized prospective studies comparing all these issues between laparoscopic and endoscopic techniques are necessary to establish firm guidelines for their use in treatment of GERD.

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