Per-Oral Endoscopic Myotomy: A Series of 500 Patients

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BACKGROUND: After the first case of per-oral endoscopic myotomy (POEM) at our institution in 2008, the procedure was quickly accepted as an alternative to surgical myotomy and is now established as an excellent treatment option for achalasia. This study aimed to examine the safety and outcomes of POEM at our institution.

STUDY DESIGN: Per-oral endoscopic myotomy was performed on 500 consecutive achalasia patients at our institution between September 2008 and November 2013. A review of prospectively collected data was conducted, including procedure time, myotomy location and length, adverse events, and patient data with short- (2 months) and long-term (1 and 3 years) follow-up.

RESULTS: Per-oral endoscopic myotomy was successfully completed in all patients, with adverse events observed in 3.2%. Two months post-POEM, significant reductions in symptom scores (Eckardt score 6.0 $\pm$ 3.0 vs 1.0 $\pm$ 2.0, $p < 0.0001$) and lower esophageal sphincter (LES) pressures (25.4 $\pm$ 17.1 vs 13.4 $\pm$ 5.9 mmHg, $p < 0.0001$) were achieved, and this persisted at 3 years post-POEM. Gastroesophageal reflux was seen in 16.8% of patients at 2 months and 21.3% at 3-year follow-up.

CONCLUSIONS: Per-oral endoscopic myotomy was successfully completed in all cases, even when extended indications (extremes of age, previous interventions, or sigmoid esophagus) were used. Adverse events were rare (3.2%), and there were no mortalities. Significant improvements in Eckardt scores and LES pressures were seen at 2 months, 1 year, and 3 years post-POEM. Based on our large series, POEM is a safe and effective treatment for achalasia; there are relatively few contraindications, and the procedure may be used as either first- or second-line therapy. (J Am Coll Surg 2015;221:256–264. © 2015 by the American College of Surgeons)

Achalasia is an esophageal motility disorder of unknown etiology. The histopathology of the disease is characterized by degeneration of the esophageal myenteric plexus; clinically, there is lack of peristalsis of the esophageal body and absent or incomplete relaxation of the lower esophageal sphincter (LES).[1-3] As a result, patients with achalasia have various related symptoms such as dysphagia, regurgitation, and chest pain. The incidence of achalasia is thought to be approximately 1 per 100,000 people,[4] with equal frequency in men and women, and a bimodal age distribution with 1 peak in the third to fourth decades of life and the other after 60 years of age.[5,6]

Until recently, balloon dilatation, botulinum toxin injection, and surgical intervention such as Heller myotomy have been used to relieve symptoms. However, the effectiveness of balloon dilatation and botulinum toxin injection is considered temporary, and repeated treatment is often needed.[7-10] The appropriate timing to repeat therapy or change treatment modalities is still uncertain. Surgical myotomy has long been considered the most definitive treatment for achalasia,[11,12] although Weber and colleagues[13] reported mean 5- and 10-year remission rates after laparoscopic Heller myotomy of only 76.1% and 79.6%, respectively.

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Abbreviations and Acronyms
GEJ = gastro-esophageal junction
IQR = interquartile range
LES = lower esophageal sphincter
POEM = per-oral endoscopic myotomy

Per-oral endoscopic myotomy (POEM) is a novel procedure that was developed and first performed in our center; it has been established as one of the best treatment options for achalasia[14] because it is safe, less invasive than surgery, and expected to offer long-lasting symptom control. Moreover, it can be used as a second-line treatment in patients with recurrent or persistent symptoms after other treatments have been performed.[15-17] However, there are no detailed reports concerning long-term outcomes in a large case series. Therefore, the aim of this study was to present the data we have accumulated at our institution, where POEM was first introduced, and where the largest number of patients have been treated.

METHODS

Patients

In this study, POEM was performed in 500 consecutive achalasia patients at Showa University Northern Yokohama Hospital, a tertiary referral center in Japan, from September 2008 through November 2013. Patients diagnosed with achalasia by established methods (upper gastrointestinal endoscopy, timed-barium swallow, and esophageal manometry) were prospectively included. In our first series of 17 patients (which are also included in this study),[14] the indications for POEM were limited to patients more than 18 years old without S2-sigmoid type achalasia; however, after the success of this series, the indications were extended to include patients with all types of achalasia who were more than 3 years of age and weighed more than 15 kg.[18] Patients were excluded only if their general condition was not favorable for general anesthesia or if they could not stop anticoagulant therapy for the procedure.

Informed consent for POEM was obtained from all patients, and the study was conducted according to the Declaration of Helsinki. This study was conducted as part of a clinical study registered with the University Hospital Medical Information Network (UMIN) (trial ID: UMIN000001901).

Per-oral endoscopic myotomy procedure and in-hospital schedule

According to our standard schedule, patients were admitted the day before POEM. On admission, patients were placed on a liquid diet; if significant retention of esophagus contents was suspected, the esophagus was cleared by endoscopic suction using a 3.7-mm channel endoscope (GIF-1T240, Olympus) under intravenous anesthesia, and no more food was allowed before POEM.

On the day of POEM, patients were placed on NPO status. To reduce the risk of aspiration, endoscopic suction was performed in all patients before induction of general anesthesia. The POEM procedure was performed as previously described, with some minor modifications outlined in Figure 1.[14] Spindle veins at the gastric cardia and narrowing followed by widening of the submucosal tunnel at the gastro-esophageal junction (GEJ) were used as markers of entry into the gastric side.

On the day after POEM, a barium esophagram was performed to confirm smooth passage through the GEJ without leakage, and upper gastrointestinal endoscopy was performed to verify there was no mucosal necrosis and that the retroflexed endoscopic view had appropriately transitioned from a tight GEJ before POEM to a loose GEJ with a visible gap between the endoscope and esophagus after POEM. After confirming these results, water intake was allowed. On postoperative day 2, a liquid diet was started, and on postoperative day 4, patients were typically discharged on a regular diet.

Surveillance schedule

The initial follow-up visit was 2 months postoperatively. Achalasia-related symptoms were postoperatively assessed using the Eckardt score[19,20] and compared with preoperative data. The Eckardt score is the sum of the achalasia-related symptom scores for dysphagia, regurgitation, chest pain, and weight loss, which is used to assess achalasia symptom severity and treatment effectiveness (Table 1). A higher Eckardt score reflects more severe symptoms of achalasia; a lower score indicates improvement. Postoperative testing also included upper gastrointestinal endoscopy, timed-barium swallow, and esophageal manometry. Endoscopic findings of reflux esophagitis were defined using the Los Angeles classification system.[21] Subsequent follow-up was then performed annually and included a detailed interview, with Eckardt score determination, upper gastrointestinal endoscopy, esophageal manometry, and timed-barium swallow.

Outcomes measures

Our primary endpoints were changes in Eckardt score and LES pressure at 2 months (500 patients). Overall success rate was defined as a post-POEM Eckardt score of less than 2 or a reduction of more than 4 points from baseline. The secondary endpoints were changes in Eckardt score and LES pressure in long-term follow-up (1 year and 3