Early clinical experience with the POEM procedure for achalasia

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This paper was presented at the Canadian Surgery Forum, Vancouver, BC, Sept. 17–21, 2014.

Accepted for publication
 May 19, 2015

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DOI: 10.1503/cjs.017214

Background: Per oral endoscopic myotomy (POEM) is a viable alternative to standard Heller myotomy for surgical treatment of achalasia. Outcomes from the United States, Europe and Asia have been reported. We sought to report data after the initiation of POEM in a Canadian centre.

Methods: We enrolled patients with achalasia in a research ethics board–approved pilot study. Surgeons learned the POEM procedure in a systematic manner that included visiting experts in POEM, practice in an animal laboratory and mentoring from POEM experts. Preoperative evaluation included manometry, 24-hour pH, barium swallow, endoscopy and Eckhardt Symptom Score. All patients underwent gastrografin swallow on postoperative day 1. Patients were re-evaluated using the Eckhardt score on postoperative day 14.

Results: Ten patients underwent POEM. Seven patients had previous endoscopic treatments: 6 had balloon dilatation and 1 had botulinum toxin injection. Mean pre-operative Eckhardt score was 8.1 ± 2.4 . Mean preoperative lower esophageal sphincter resting and residual pressure was 32.3 ± 9.2 and 20.8 ± 5.3 , respectively. Mean duration of surgery was 141.3 ± 43.7 minutes. Mean length of hospital stay was 1 day. No major perioperative complications occurred. On postoperative day 14, the mean Eckhardt score was 1 ± 1.2 .

Conclusion: Our approach to POEM introduction was systematic and deliberate. The procedure is safe, feasible and has good perioperative outcomes. Our early results are consistent with current literature.

Contexte : La myotomie perorale endoscopique (POEM) est une solution de rechange viable à la myotomie de Heller standard pour le traitement chirurgical de l'achalasie. Des rapports ont fait état de résultats enregistrés aux États-Unis, en Europe et en Asie. Nous avons voulu faire le point après l'instauration de la méthode POEM dans un centre canadien.

Méthodes : Nous avons inscrit des patients atteints d'achalasie à une étude de recherche pilote, approuvée par le comité d'éthique. Les chirurgiens se sont initiés à la technique POEM de façon systématique auprès d'experts de cette technique, en s'exerçant sur des animaux de laboratoire et ensuite auprès d'experts-mentors. L'examen préopératoire incluait : manométrie, pH des 24 heures, repas baryté, endoscopie et score d'Eckardt (pour les symptômes). Tous les patients ont subi un transit du grêle avec Gastrografin au jour 1 postopératoire. Le score d'Eckardt des patients a été réévalué au jour 14 postopératoire.

Résultats : Dix patients ont subi la technique POEM. Sept avaient déjà reçu des traitements endoscopiques : 6 avaient subi une dilatation par ballonnet et 1 avait reçu une injection de toxine botulique. Le score d'Eckardt préopératoire moyen était de $8,1 \pm 2,4$. La pression préopératoire moyenne du sphincter œsophagien inférieur au repos et résiduelle était de $32,3 \pm 9,2$ et de $20,8 \pm 5,3$, respectivement. La durée moyenne de la chirurgie a été de $141,3 \pm 43,7$ minutes. La durée moyenne du séjour hospitalier a été d'un jour. Aucune complication périopératoire majeure n'est survenue. Au jour 14 postopératoire, le score d'Eckardt moyen était de $1 \pm 1,2$.

Conclusion : Notre approche à l'instauration de la technique POEM a été systématique et délibérée. L'intervention s'est révélée sécuritaire, réalisable et a procuré des résultats périopératoires positifs. Nos résultats préliminaires concordent avec ceux de la littérature actuelle.

Achalasia is a rare disease characterized by nonperistaltic esophagus and incomplete relaxation of the lower esophageal sphincter (LES). These 2 characteristics are the basis of the symptoms of achalasia that include dysphagia, regurgitation, reflux, vomiting and weight loss.

Treatments for achalasia include medical, endoscopic and surgical therapy. Medications, such as calcium channel blockers and nitrates, are generally ineffective and poorly tolerated.¹ Endoscopic treatments include botulinum toxin injections and balloon dilatation. Endoscopic botox injections are usually recommended for elderly patients and poor operative candidates. Endoscopic balloon dilatation is an effective treatment for achalasia; however, it is associated with a relatively high perforation rate and may require repeated treatments.² The main surgical therapy is a Heller myotomy with a partial fundoplication. Several studies have shown this to be an effective treatment for achalasia.^{3–6} The newest surgical treatment for achalasia is per oral endoscopic myotomy (POEM), an endoscopic treatment that divides the circular esophageal muscle fibres through a submucosal tunnel in the esophagus. The muscle fibre division includes the LES and at least 2 cm into the stomach. Small case series from various institutions have shown POEM to be safe and viable.^{7–10} To our knowledge, there have been no studies from a Canadian institution.

The objective of this study was to assess the safety, feasibility and observed perioperative outcomes of POEM as a treatment for achalasia in a Canadian institution.

METHODS

Our research ethics board (REB) approved a pilot study offering POEM for the treatment of achalasia to patients who met the inclusion criteria. Exclusion criteria were previous esophageal or mediastinal surgery, pregnancy, age younger than 18 years, inability to tolerate general anesthesia, a body mass index (BMI) greater than 40, presence of a hiatal hernia (> 3 cm) or a need for an associated intra-abdominal procedure. Previous endoscopic dilation or botulinum toxin injection was not an exclusion criterion.

Preoperative assessment included the Eckhardt questionnaire, upper endoscopy, barium swallow, esophageal manometry and 24-hour pH when feasible. Patients were instructed to consume only clear liquids for 48 hours before their surgery date. A 5-day course of nystatin (500 000 units 3 times/d, swish and swallow) was given before their surgery. Only a mechanical compressive device was used for deep vein thrombosis prophylaxis. A second-generation cephalosporin was given preoperatively.

Surgical technique

Patients were under general anesthesia and placed in the supine position with the left arm tucked. A single-channel high-definition flexible gastroscope (GIF-H180, Olympus Canada) with carbon dioxide insufflation was used. An oblique dissecting cap was fitted onto the gastroscope. Gastroscope was performed and the esophagus suctioned clear. A submucosal lift (10–15 mL of a mixture of 0.2 mg/mL indigo carmine, 5 µg/mL epinephrine and 0.9% saline) was performed 10 cm above the gastroesophageal junction on the anterior surface of the esophagus (Fig. 1A). A triangle-tip endoscopic knife (Olympus Canada) was used to make a 2 cm longitudinal mucosotomy (Fig. 1B). The endoscope was manoeuvred into the submucosal space. The submucosal tunnel was created using the triangle-tip knife (Fig. 1C). The submucosal tunnel extended 2 cm distal to the gastroesophageal junction onto the lesser curvature of the stomach (Fig. 1D). After completion of the submucosal tunnel, the gastroscope was removed and inserted into the gastric lumen to confirm adequate extent of the submucosal tunnel. Presence of gastric mucosal blanching identified on a retroflexed endoscopic view in the stomach indicated adequate submucosal tunnel. After confirmation, the gastroscope was reinserted into the submucosal tunnel, and a selective myotomy of only the inner, circular muscle fibres was performed using the triangle-tip knife (Olympus Canada; Fig. 1E). The myotomy was started 2–3 cm distal to the mucosotomy site. After successful completion of the myotomy the mucosotomy was closed using endoscopic clips (QuickClip, Olympus, Canada; Fig. 1F).

Postoperative routine

We performed a water-soluble contrast study on postoperative day 1. A clear liquid diet was started after the contrast study was read. Narcotic usage was recorded. Patients were scheduled for a follow-up appointment 2 weeks postsurgery. A dietician instructed the patients on diet advancement before discharge from hospital.

RESULTS

We included 10 patients in our pilot study. All patients underwent successful POEM. Preoperative patient and manometric characteristics are shown in Table 1. Seven (70%) patients had prior endoscopic treatments for achalasia. We found that performing POEM in the patient who had a previous botulinum toxin injection was more technically challenging owing to scarring in the submucosal layer at the level of the LES. The duration of surgery for this patient was 182 minutes compared with a mean duration of 141 minutes for the

group. Patients who underwent previous balloon dilatation were technically equivalent to patients who did not have previous treatments. Seven (70%) patients had an American Society of Anaesthesiologists (ASA) physical status score of 3, and 3 (30%) patients had an ASA score of 2.

There were no deaths or morbidities among our patients. One patient had clinically important intraoperative capnoperitoneum that required decompression via a Veress needle placed in the left upper quadrant. Another patient experienced a transient, intraoperative episode of hypotension that resolved with endoscopic decompression of the stomach. A third patient had a fever (38° C) on postoperative day 1 that resolved spontaneously.

All patients had a normal water-soluble gastrografin swallows on postoperative day 1. Perioperative outcomes

are shown in Table 2. Six (60%) patients took no narcotics postoperatively. Three (30%) patients took 1 dose of narcotic and 1 (10%) patient took 3 doses of narcotics. Nine (90%) patients were discharged on postoperative day 1, and 1 patient stayed in hospital 2 days. No complications were reported by patients during their 2-week follow-up visit. All patients reported substantial symptomatic improvement.

DISCUSSION

The first endoscopic division of the lower esophageal sphincter was described by Ortega and colleagues in 1980.¹¹ However, it wasn't until Pasricha and colleagues¹² described an endoscopic submucosal myotomy in a pig model and, subsequently, Inoue and colleagues¹³

Fig. 1: Steps of the per oral endoscopic myotomy (POEM) procedure.

described the first human study of endoscopic submucosal myotomy for achalasia that interest in this technique gained attention. Since the first human report, investigators from the United States, Europe and Asia have reported their results using the POEM technique.

Most published outcomes using POEM have been positive. Several recent reviews have shown excellent operative and short-term outcomes.^{14–16} No deaths from POEM have been reported in the more than 1000 cases performed. We had no clinically important complications in our pilot study. We did have 1 patient with intraoperative capnoperitoneum that required decompression, and several patients showed a small capnoperitoneum on postoperative day 1 water-soluble contrast. This highlights the need to use carbon dioxide insufflation, as air does tract beyond the thin longitudinal muscle fibres of the esophagus and stomach. If regular air is used for insufflation, a clinically important pneumothorax, pneumomediastinum or pneumoperitoneum may occur. These excellent outcomes are likely a result of careful patient selection, surgeons and gastroenterologists who are expert endoscopists and physicians undergoing a rigorous systematic approach to learn POEM.

POEM is an advanced therapeutic endoscopic procedure requiring advanced endoscopic skills. Our group had previous advanced endoscopic skills, including stent placement, advanced clipping and endoscopic mucosal resection. In preparation for undertaking the POEM study, we were deliberate, conservative and systematic in

our approach. One of us (D.H.) travelled to the institution of a high-volume POEM surgeon (Dr. Lee Swanstrom, Portland, Oregon, USA) to observe how the team was set up and to learn technical skills. He then completed a formal course in POEM (American Society for Gastrointestinal Endoscopy, 2013). We then performed 2 animal models to familiarize ourselves with the submucosal anatomy and master instrumentation. We obtained REB approval for our pilot study, and an expert (Dr. Lee Swanstrom) who had performed more than 100 POEM procedures assisted us in our first 2 cases. Other investigators have followed similar, systematic approaches to introducing POEM at their institution.¹⁷ We feel participation in animal laboratories and expert mentoring are necessary when introducing new, technically demanding procedures, such as POEM.

A criticism of POEM has been the potential risk of reflux. Unlike Heller myotomy, the angle of His and esophageal attachments are not disrupted in POEM, obviating the need for an antireflux procedure. Data suggest that a limited hiatal dissection with preservation of hiatal anatomy may result in lower reflux.¹⁸ Bhayani and colleagues¹⁹ recently described their comparative study on laparoscopic Heller myotomy plus fundoplication versus POEM. At 6 months, they found no statistical difference in abnormal acid exposure between the 2 procedures. Some have criticized the high percentage of POEM patients with abnormal acid exposure on 24-hour testing (39%) in their study. A second comparative study between POEM and laparoscopic Heller myotomy plus fundoplication found similar rates of reflux postoperatively.²⁰ Advocates of POEM have suggested that the rates of reflux following a Heller myotomy plus fundoplication are just as high as the rates found following POEM.^{21,22} This would suggest that, in the short-term, POEM produces the same rates of reflux as a Heller myotomy with fundoplication.

Another concern has been that division of only the circular muscle fibres in the POEM procedure may limit its effectiveness in alleviating the symptoms of achalasia as compared with division of all muscle fibres in a standard Heller myotomy. Yet a recent comparative study on endoscopic full-thickness myotomy versus circular muscle myotomy found no clinical or manometric differences.²³ This suggests that circular muscle myotomy alone is sufficient for excellent outcomes.

Limitations

Our study has some limitations. The first is our small sample of 10 patients. Low prevalence of achalasia will require several institutions specializing in esophageal motility disorders to collaborate to achieve adequate numbers. Another limitation is the lack of longer-term data regarding the rate of reflux. We will continue to

Table 1. Patient and manometry characteristics

Characteristic	Mean $\pm$ SD or no. (%)
Age, yr	53.8 $\pm$ 10.8
Male sex	7 (70%)
Previous treatment	
None	3 (30%)
Balloon dilatation	6 (60%)
Botulinum toxin	1 (10%)
Preoperative Eckhardt scores (< 3 is normal)	8.1 $\pm$ 2.4
LES resting pressure	32.3 $\pm$ 9.2
LES residual pressure	20.8 $\pm$ 5.3

LES = lower esophageal sphincter; SD = standard deviation.

Table 2. Perioperative outcomes of POEM

Outcome	Mean $\pm$ SD
Duration of surgery, min	141.3 $\pm$ 43.7
Submucosal tunnel length, cm	12 $\pm$ 1.1
Myotomy length, cm	8.9 $\pm$ 1.1
No. of clips to close mucosotomy	7.5 $\pm$ 2.1
LOS, d	1.1 $\pm$ 0.3
Postoperative (2 wk) Eckhardt score (< 3 is normal)	0.9 $\pm$ 1.2

LOS = length of stay in hospital; POEM = per oral endoscopic myotomy; SD = standard deviation.

accrue patients prospectively and are currently obtaining esophageal manometry, 24-hour pH, barium swallow and upper endoscopy at 6 months for all patients.

CONCLUSION

To our knowledge, this is the first published series of POEM in Canada. Even in the early learning curve, POEM is safe and feasible to treat esophageal achalasia. Multi-institutional, collaborative studies are required to assess the long-term results of POEM.

Affiliations: All authors are from the Department of Surgery, McMaster University, Hamilton, Ont.

Competing interests: None declared.

Contributors: D. Hong, R. Pescarus and M. Anvari designed the study. D. Hong, R. Khan, L. Ambrosini and M. Cadeddu acquired the data, which D. Hong and M. Anvari analyzed. D. Hong and L. Ambrosini wrote the article, which all authors reviewed and approved for publication.

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