

## The light at the end of the tunnel: a single-operator learning curve analysis for per oral endoscopic myotomy

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**Background:** Per oral endoscopic myotomy (POEM) represents a natural orifice transluminal endoscopic surgery approach to Heller myotomy. Our center was the first to offer POEM outside of Japan, allowing us to accumulate what is likely the highest single-operator POEM volume in the United States.

**Objective:** To define the POEM learning curve of a gastroenterologist by using a larger data set and more detailed statistical analysis than used in 2 other reports of POEM performed by surgeons.

**Design:** Prospective cohort study.

**Setting:** Tertiary-care academic medical center.

**Patients:** We analyzed the first 93 consecutive POEMs on patients with achalasia aged > 18 years without contraindications to POEM performed by a single operator from October 2009 to November 2013.

**Interventions:** (1) Efficiency estimation via cumulative sum (CUSUM) analysis, (2) mastery estimation via penalized basis-spline regression and CUSUM analysis, (3) correlation of operator experience with clinical outcomes (Eckardt score improvement, lower esophageal sphincter pressure reduction) and technical errors (accidental mucosotomy rate), and (4) unadjusted and adjusted regression analysis to assess how patient characteristics affected procedure time by using a generalized linear model.

**Main Outcome Measurements:** Clinical outcomes, procedure time, technical errors.

**Results:** Efficiency was attained after 40 POEMs and mastery after 60 POEMs. When we used the adjusted regression analysis, only case number (operator experience) significantly affected procedure time ( $P < .0001$ ). Improvements in clinical outcomes were excellent but not significantly affected by operator experience, as was the case with accidental mucosotomies. Procedure time was not significantly affected by age, sex, achalasia stage, baseline lower esophageal sphincter pressure, baseline Eckardt score, prior treatment of achalasia, prior botulinum toxin injection, incidence of accidental mucosotomies, length of myotomy, or type of knife used (all  $P > .05$ ).

**Limitations:** Our analysis may underestimate the number of POEMs required to achieve mastery for operators with limited or no endoscopic submucosal dissection experience.

**Conclusion:** These results offer thresholds for efficiency and mastery of a single gastroenterologist operator that may guide the efforts of novice POEM operators. (Gastrointest Endosc 2015;81:1181-7.)

*Abbreviations:* AIC, Akaike information criterion; BIC, Bayesian information criterion; B-spline, basis-spline; ESD, endoscopic submucosal dissection; GEJ, gastroesophageal junction; LES, lower esophageal sphincter; NOTES, natural orifice transluminal endoscopic surgery; POEM, per oral endoscopic myotomy; TT, triangular tip.

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Per oral endoscopic myotomy (POEM) represents a natural orifice transluminal endoscopic surgery (NOTES) approach to Heller myotomy for treatment of achalasia. POEM was first performed in 2008, and the excellent initial outcomes by pioneering centers resulted in now rapidly expanding adoption.<sup>1</sup> Defining the learning curve for this novel, challenging, high-risk procedure would be of importance to new physicians as they move from training to early clinical experience. Two prior reports on the POEM learning curve were based on a small number of POEMs (36 and 40, respectively) performed by multiple operators.<sup>2,3</sup> Furthermore, in one of the studies, a simple block analysis was used rather than more detailed statistical techniques such as basis-spline (B-spline) regression and cumulative sum (CUSUM) analysis. Our center was the first to perform POEM after the initial human POEMs by Inoue et al<sup>1</sup> in Japan, allowing us to accumulate what is likely the highest single-operator POEM volume in the United States.<sup>4-6</sup> This substantial number of POEMs was analyzed with both B-spline regression and CUSUM analysis to define the learning curve for POEM.

B-spline regression is a technique used to smooth a regression curves.<sup>7</sup> CUSUM is a useful tool for examining performance improvement in surgical procedures.<sup>8,9</sup> CUSUM analysis examines outcomes like procedure time to assess performance and uses deviations from the median or mean to graph the learning curve.<sup>9</sup> CUSUM analysis has been used previously to examine procedural competence in a variety of procedures including regional anesthesia, endoscopic thyroidectomy, laparoscopic colectomy, endovascular aneurysm repair, video-assisted thorascopic lobectomy, and colonoscopy.<sup>9-14</sup> However, there are no published reports describing a learning curve on POEM by using B-spline regression or CUSUM analysis.

We present our experience in defining the learning curve of POEM. All procedures were completed by one operator (S.N.S.) who had extensive prior experience with endoscopic submucosal dissection (ESD) before initiation of POEM. His first POEM procedure in October 2009 was preceded by live animal laboratory procedures in ESD starting in 2004 and human cases starting in 2006, with approximately 100 hours of ESD training in live animals and 60 human ESD procedures completed before the first POEM.

## METHODS

From October 2009 to November 2013, patients with achalasia aged >18 years, able to consent, and without contraindications to POEM were enrolled in a prospective internal review board–approved study. Data were collected on the first 93 consecutive POEM procedures performed at Winthrop University Hospital by a single operator (S.N.S.).

Efficiency has been defined as the point in the learning curve in which the operator starts engaging in perfor-

mance refinements that lead to gradual decrease in procedure time, whereas mastery is defined as the point at which procedure time becomes consistent, and no further change in mean procedure time is observed.<sup>13</sup> We used a penalized B-spline regression and CUSUM analysis to visually estimate the points at which efficiency and mastery were achieved.

In addition to procedure time, we also included an analysis of technical errors (accidental mucosotomies) and clinical outcomes in our study (Eckardt score improvement and lower esophageal sphincter [LES] pressure reduction). We hypothesized that as the operator gained experience, not only would procedure time decrease but also technical errors would decrease, and the procedure would be performed better in some fashion that would be detectable by improved clinical outcomes.

A secondary objective was to evaluate how certain patient and technique factors affect procedure time. We examined the following variables: age, sex, baseline LES pressure, baseline Eckardt score, achalasia stage, prior treatment for achalasia, prior botulinum toxin treatment, type of knife used, incidence of accidental mucosotomies, and length of myotomy.

This study was a non-randomized, non-blinded, prospective cohort study. Sample size was determined by the number of patients who underwent POEM for achalasia from October 2009 to November 2013. For LES pressures, complete data analyses were done.

## POEM technique

The POEM technique used for our patients was similar to the technique first described by Inoue et al,<sup>1,15</sup> with some important differences described later. A high-definition gastroscope with a straight short transparent distal attachment was used along with CO<sub>2</sub> insufflation.<sup>15</sup> After determining the distance to the gastroesophageal junction (GEJ), we selected a location usually 10 to 15 cm proximal to it as the site of the initial submucosal entry.<sup>15,16</sup> Then, a saline solution containing indigo carmine dye was injected to create a mucosal bleb before the initial 2-cm longitudinal mucosotomy. The submucosal tunnel was extended by using the ESD technique 2 to 3 cm beyond the GEJ into the cardia followed by myotomy and closure of the entry site and any accidental mucosotomies.<sup>1,4,15,16</sup> In our case series, patients 1 to 7 underwent tunnel dissection by using a 12-mm CRE dilation balloon (Boston Scientific, Natick, Mass) followed by use of an Olympus flat knife (Olympus, Center Valley, Pa) to complete the tunnel dissection and the myotomy. This knife was used because of the absence of U.S. Food and Drug Administration–approved specialized ESD knives in the United States in 2009 and 2010. Patients 8 to 18 underwent tunnel dissection and myotomy with the triangular-tip (TT) knife (Olympus) as described by Inoue et al.<sup>1</sup> Patients 19 to 93 underwent tunnel dissection and myotomy with the use

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