



Successful Design and Implementation of a POEM Program for Achalasia in an Integrated Healthcare System

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Abstract

Background Per Oral Endoscopic Myotomy (POEM) is a minimally invasive treatment for achalasia with results comparable to laparoscopic Heller myotomy (LHM). Studies have described the development of proficiency for endoscopists learning to perform POEM, and societies have defined educational and technical objectives for advanced endoscopy fellows in training. However, there is limited guidance on the organizational strategy and educational plan necessary to develop an achalasia service with POEM expertise.

Aims We aim to outline the steps for design and implementation of a successful POEM program.

Methods We reported our experience developing a multi-disciplinary clinical program for POEM and the steps taken to achieve procedural proficiency. We also reported our technical success (successful tunneling into the gastric cardia and myotomy of LES muscle fibers) and clinical success (post-procedure Eckardt score ≤ 3) at 3–6 months and 12 months post-procedure. Adverse events were classified per the ASGE lexicon for endoscopic adverse events.

Results After creating a multi-disciplinary clinical program for achalasia and completing procedural proficiency for POEM, our technical success rate was 100% and clinical success rate 90% for the first 41 patients. One adverse event (2.4%) occurred, moderate in severity per the American Society of Gastrointestinal Endoscopy (ASGE) lexicon for adverse endoscopic events.

Conclusion In this study, we outlined the steps involved to establish a POEM service in a large integrated healthcare system. Prior competency in interventional endoscopy, procedural training models, POEM observation and education, proctorship, and interdisciplinary patient care are recommended.

Keywords Achalasia · Peroral endoscopic myotomy · Implementation · Competency · Integrated healthcare system

Introduction

Achalasia is an esophageal motility disorder characterized by the inability to mobilize food and liquid into the stomach during swallowing [1–3]. The incidence is approximately 1.63 in 100,000 people while the prevalence is 10.82 in 100,000 people [4]. Achalasia is further categorized into 3 distinct subtypes based on high-resolution manometry patterns in the esophageal body: type I with minimal to no esophageal body contraction, type II with recurrent panesophageal pressure, and type III with spastic esophageal contractions [1, 5, 6]. The Eckardt Score determines severity of achalasia by assessing frequency of dysphagia, regurgitation and chest pain while accounting for extent of weight loss. [7]

Achalasia treatment options include medications to induce lower esophageal (LES) relaxation, endoscopic

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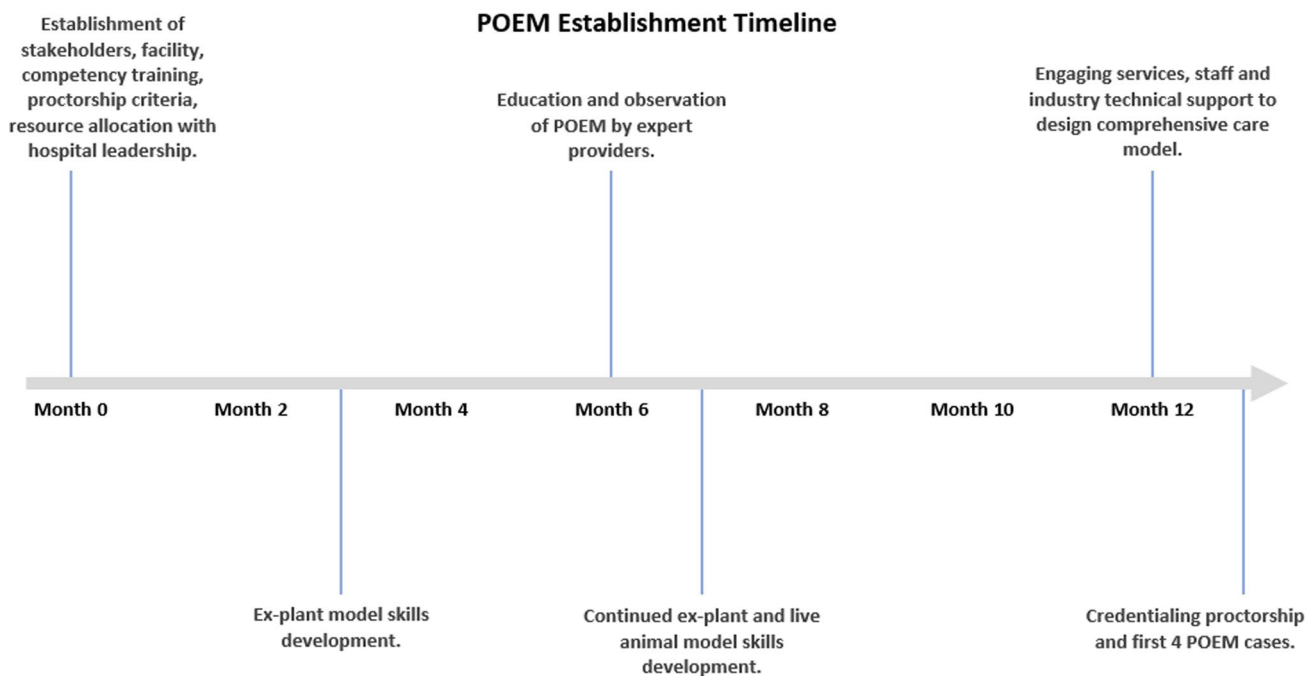


Fig. 1 POEM establishment timeline

botulinum toxin injection (BTX) to the LES, pneumatic balloon dilation (PBD) to disrupt the LES muscle fibers, and surgical and endoscopic myotomy [5]. Laparoscopic Heller myotomy (LHM) has been the definitive treatment for achalasia until Inoue performed the first peroral endoscopic myotomy (POEM) in humans in 2008 [8, 9]. POEM has since been shown to be non-inferior to LHM [10] and possibly superior to PBD for definitive achalasia treatment [11]. In addition, POEM is capable of performing a longer myotomy in the esophagus, with potentially better clinical response than LHM for achalasia type III [12], and is recommended as the preferred intervention for this subtype. [5]

POEM requires advanced endoscopic skills and the ability to recognize and manage adverse events [5, 13, 14]. The requirements for achieving procedural competency in POEM remains undefined; and the steps to create and the outcomes of a multidisciplinary POEM program in a community health system have not been reported [5, 15–19]. In this retrospective evaluation, we describe the process of developing a comprehensive POEM service in an integrated healthcare system and its clinical results.

Methods

Study Population and Eligibility Criteria

Kaiser Permanente Northern California (KPNC) is a large integrated healthcare system with 4.3 million members who have access to ambulatory and hospital facilities throughout Northern California. Patients within the KPNC region diagnosed with achalasia with an Eckardt score > 3 (greater than 3) were given the option to undergo a POEM procedure. We catalogued patients who underwent POEM at Kaiser Permanente Oakland Medical Center from January 2019 to December 2020. This retrospective evaluation was approved by the KPNC Institutional Review Board.¹

Establishment of a POEM Service

Based on prior population studies [4], we estimated the incidence of achalasia in our enrolled membership to be between 45 and 72 patients annually. The process to start a POEM service was formally initiated in 2018 and was a multi-step

¹ The Research Determination Committee for the Kaiser Permanente Northern California region has determined the project does not meet the regulatory definition of research involving human subjects per 45 CFR 46.102(d).

process, culminating in the first POEM procedures in late January of 2019 (Fig. 1).

A hospital facility with thoracic and foregut surgical expertise was designated as the location for POEM procedures. The hospital facility (Oakland) had an experienced surgeon (JS) routinely performing a high volume of LHM, and served as a referral center for interpretation of esophageal high-resolution manometry (HRM). We engaged hospital leadership—requesting support from anesthesia, nursing, and technicians for pre-, peri-, and post-POEM care for up to 30 patients annually. The Permanente Medical Group leadership provided resources to support instruction from experts in POEM and to achieve procedural competency under supervised proctorship.

Two gastroenterologists (H.C. and T.L.J.) underwent POEM training. They (H.C. and T.L.J.) did not have prior POEM experience. One (H.C.) had experience in endoscopic mucosal resection (EMR) procedures, and the other (T.L.J.) had performed nearly 100 endoscopic submucosal dissection (ESD) and over 200 EMR procedures. A third gastroenterologist (G.K.M.) who was fellowship trained in POEM joined later (proctored in January 2020). He (G.K.M.) had performed 21 POEM procedures during his interventional endoscopy fellowship prior to joining. In April 2018, technical education commenced by performing POEM on an ex-plant porcine model supported by industry (ERBE, Marietta, GA, USA). In June 2018, observation of an expert endoscopist (N.F.) performing two POEM procedures, and their post-procedural care took place. A formal course in POEM (The Foundation for Surgical Innovation & Education (FSIE), Portland, OR, USA), which consisted of lectures, hands-on simulation with ex-plant and living porcine models, and observing live procedures was attended in August.

Before the first POEM cases, patient-centered multidisciplinary collaborations were established. Radiologists implemented protocols for timed-barium esophagram (TBE) as a measure of severity of achalasia, and also post-POEM esophagram for detection of leaks. Surgical services, in conjunction with their residency program, agreed to provide inpatient post-POEM care. In December we presented a lecture to a team of designated anesthesiologists on POEM, with specific focus on the risks of pneumomediastinum, pneumoperitoneum, and peri-procedural physiologic manifestations [14]. Nurses and technicians skilled with EMR procedures in Oakland were designated to assist with POEM. To prepare them for submucosal dissection techniques, they traveled to observe a nurse and technician assist an endoscopist (T.L.J.) performing ESD.

The first POEM cases were performed in January of 2019. We performed 4 cases over two days. A highly experienced expert in POEM (N.F.) served as a proctor. A second endoscopist (M.X.) proficient in POEM also proctored, as

her medical license in our state allowed her to intervene with direct hands-on endoscopic assistance and intervention if necessary. Nursing and technician staff skilled in assisting with ESD came to supervise the designated staff in Oakland. Industry representatives were on site to assist with devices and electrosurgical generator settings unique to POEM. The first candidates for POEM were evaluated in an outpatient, ambulatory setting. Patients were counseled on the treatment options for achalasia, including the risks, benefits, and comparative advantages and limitations of LHM, POEM, and PBD. Patients not previously seen by surgery were provided the opportunity for consultation for LHM. After the first 4 POEM procedures in January of 2019, subsequent patients were offered telehealth consultations for pre-procedural and post-procedural ambulatory encounters; thereby facilitating care when patients would otherwise need to travel long distances [20]. With the declaration of the coronavirus disease 2019 pandemic (COVID-19) in March of 2020, telemedicine was utilized exclusively for outpatient care.

POEM Procedural Techniques

All POEM procedures were performed in the endoscopy suite by 3 gastroenterologists (T.L.J., H.C., and G.K.M.). Patients were administered general anesthesia and positioned in a supine position, with head slightly turned left to facilitate passage of the endoscope. Broad spectrum intravenous antibiotics were given. During POEM, anesthesia providers brought attention to any increased difficulty in ventilation or change in vital signs, which is associated with pneumomediastinum or pneumoperitoneum. Nursing staff also examined the abdomen every 10 min to check for increased distension.

Standard diagnostic adult gastroscopes (GIF-H190; Olympus, Tokyo, Japan) fitted with a transparent distal cap attachment (12.4 mm D-201-11804; Olympus, Tokyo, Japan) were used. Endoscopic carbon dioxide (CO₂) insufflation was administered using low flow settings (ECO2 7913-1000, ERBE Inc, Marietta, GA, USA), with room air insufflation turned off. A baseline measurement of lower esophageal sphincter distensibility index (the GEJ cross sectional area divided by the balloon median pressure, with units in mm²/mm Hg) [21] was determined using an 8 cm endoluminal functional lumen imaging probe (EndoFLIP, EF-200, EF-325N, Medtronic, Minneapolis, MN, USA). The probe was carefully advanced under direct visualization across the LES and left in place as the endoscope was removed. The distensibility index was recorded with the balloon at 30 mL, 40 mL, and 50 mL. To orient the endoscope within the esophagus, the posterior wall was identified by identifying the imprint of the spine against the esophagus and by observing the gravitational effect on water injected from the endoscopic knife (HybridKnife, I-Type, I-Jet, 2.33 mm, product 20150-261, ERBE Inc).

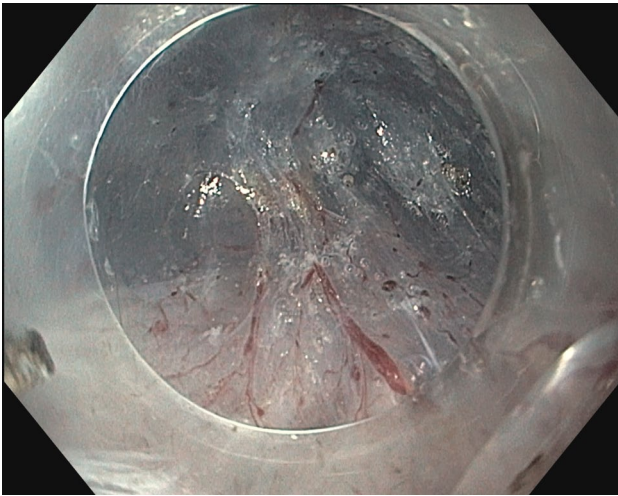


Fig. 2 Submucosal spindle vessels indicative of the cardia

All POEM tunneling and myotomy procedures were performed in the posterior right esophagus – endoscopically at the 4 or 5 o’clock position with the spine acting as a reference at 6 o’clock. To initiate mucosotomy, the endoscopic knife was used to make a diminutive mucosal incision, just into the submucosa, followed by injection (ERBEjet2, ERBE Inc) of several mL of a solution of saline and indigo carmine to lift the mucosa distally. A 2 cm longitudinal mucosal incision (Endocut I 3-3-1, VIO3/300D, ERBE Inc) created the mucosotomy, followed by submucosal tunneling (Spray Coag Effect 1-2 50 W, VIO300D; preciseSECT 5.6 VIO3 ERBE, Inc) into the cardia.

For Types 1 and 2 achalasia, a 2 cm mucosotomy was initiated 6 cm proximal to the gastroesophageal junction. The width of the submucosal tunnel was created to be one-third the circumference of the esophagus, and extended to the cardia, 2 to 3 cm beyond the lower esophageal sphincter (LES). Hemostasis and treatment of large submucosal vessels was performed using either the HybridKnife with forced coagulation (Effect 1, 10 W VIO300D or 0.5 VIO3, ERBE Inc) or electro-surgical hemostatic forceps (FD-410LR, Olympus, Tokyo, Japan using Soft Coagulation (Effect 5, 80 W VIO300D or 5.0 VIO3 ERBE Inc). The cardia was recognized by passage of the scope beyond an “increased pressure zone” just proximal to the LES—as noted by the resistance of advancing the endoscope—to an area of decreased resistance. Palisading submucosal vessels (Fig. 2), and the loss of circular distribution of the muscularis propria fibers were typically observed in the cardia, as well as penetrating gastric vessels. Adequate length of tunnel creation was also confirmed by removing the scope from the tunnel back into the lumen, and with the scope in a retroflexed position in the stomach demonstrating the presence of blue dye with submucosal lift in the cardia.

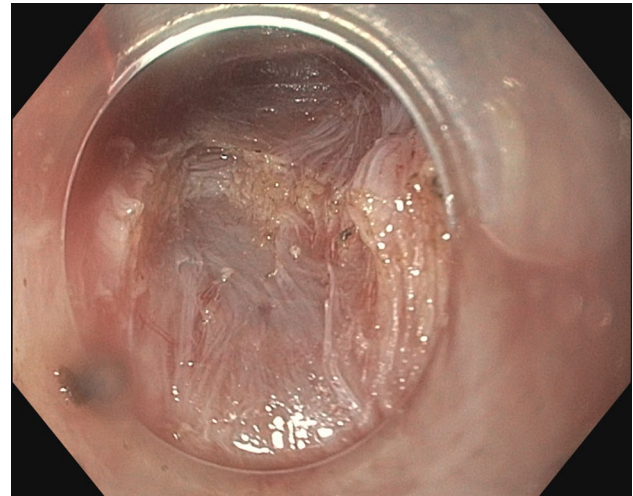


Fig. 3 Myotomy of inner circumferential esophageal muscularis propria with intact longitudinal outer muscularis propria

For Types 1 and 2 achalasia, a 3 cm long myotomy was then performed of the inner, circumferential muscle layer of the lower esophagus and then a 2 to 3 cm myotomy at the LES and gastric cardia (Endocut I, 3-3-1) with care to cut through the entire circular layer while trying to avoid cutting through the outer longitudinal muscle fibers (Fig. 3). For Type 3 achalasia, myotomy length proximal to the LES was determined by review of the esophageal HRM, which defines the extent of esophageal spasticity proximal to the LES. The mucosal incision was created 4 cm proximal to where myotomy would begin.

After completion of myotomy, the scope was withdrawn and the endoluminal functional lumen imaging probe was again carefully advanced under direct endoscopic visualization within the lumen and across the LES, with care to avoid accidentally entering or creating a mucosal injury of the submucosal tunnel; or tearing the mucosal incision. Measurements were repeated to confirm successful myotomy, as noted by an increase in distensibility index versus baseline. If the distensibility index was not increased by at least 1 mm²/mm Hg versus baseline, or to at least 2.0 mm²/mm Hg, we ensured all circular muscle fibers were cut and considered extension of the length of myotomy. After increase in distensibility was confirmed, the endoluminal probe was carefully removed and the endoscope reintroduced. The submucosal tunnel was inspected once more to treat any delayed bleeding, and the mucosa carefully examined within the lumen to check for mucosal injury that places the patient at risk for leak into the mediastinum. Endoscopic clips (Resolution 360, M00521240, Boston Scientific, USA) were then placed to close the mucosal defect, placing them in a distal to proximal sequence.

After extubation, patients had nothing by mouth while hospitalized overnight on the surgical service. As our facility is affiliated with an academic general surgery program, residents managing the patients were educated about and observed POEM procedures. The following morning an esophagram was performed. If no leak was seen on esophagram, then patients would start a clear liquid diet and the patient discharged with instructions to start a full liquid diet in two days before resuming soft foods for at least 2 days and then gradually advancing as tolerated to a regular diet. Due to the need to maximize hospital bed availability during the COVID-19 pandemic, beginning in the summer of 2020 we performed same-day discharge after POEM in patients with minimal or no pain who did not have advanced, chronic medical conditions [22, 23]. Follow up telehealth encounters took place at 3–6 months and at one year after POEM to determine clinical response and to inquire about symptoms of gastroesophageal reflux.

Outcomes of Interest

Pertinent information including achalasia subtype and prior treatments were recorded. Primary outcome measures include technical success (successful tunneling into the gastric cardia and myotomy of LES muscle fibers), clinical success (post-procedure Eckardt score ≤ 3) at 3–6 months and 12 months post-procedure. Adverse events were classified per the ASGE lexicon for endoscopic adverse events [24].

Statistical Analysis

Primary outcome measures of technical success, clinical success at 3–6 months post-procedure, clinical success at 12 months post-procedure, and adverse events were evaluated and further stratified by achalasia subtype and by whether prior surgical and endoscopic therapies had been performed.

Results

During our study period, we performed 41 POEMS in 41 individuals with achalasia; most of which were type 2 (46.3%) and type 3 (46.3%), followed by type 1 (7.3%). The mean age of our cohort was 57.7 years (SD = 18); most were males and the average Eckardt score pre-procedure was 6.2 (SD = 1.84) (Table 1). A few of the patients had prior interventions, including LHM (17%), Nissen fundoplication (2.4%), BTX (9.8%), and PBD (4.9%) (Table 2). Follow up was attempted at 3–6 months and 12 months for all 41 patients, of which 1 (2.4%) was lost to follow up. Therefore, nearly all of the patients had at least one follow up within a year. 34 of the 41 patients (82.9%) of the patients had follow

Table 1 Patient demographic and characteristics

Demographics/Characteristics	
<i>Age at POEM (Years)</i>	
Mean (SD)	57.7 (18.0)
Median	62
Range	61
<i>Sex, n (%)</i>	
Male	28 (68.3%)
Female	13 (31.7%)
<i>Achalasia subtype, n (%)</i>	
Type 1	3 (7.3%)
Type 2	19 (46.3%)
Type 3	19 (46.3%)
<i>Eckardt score, mean (SD)</i>	
Pre-procedure (<i>n</i> = 41)	6.20 (1.84)
Post-procedure 3–6 months (<i>n</i> = 34)	1.31 (1.62)
Post-procedure 12 months (<i>n</i> = 33)	1.81 (1.56)
<i>Clinical nonresponders n (Post-procedure time)</i>	
Achalasia Subtype 1	1 (3–6 months) ⁺
Achalasia Subtype 2	1 (3–6 months) [#]
Achalasia Subtype 3	2 (3–6 and 12 months)
<i>Technical success, n (%)</i>	41 (100%)
<i>Adverse events, n (%)</i>	1 (2.4%)

⁺One patient with prior LHM + Dor

[#]One patient with concomitant myasthenia gravis, responded well initially at 3–6 months. Second patient with prior nissen with no response at both 3–6 and 12 months

Table 2 Patient prior interventions

Prior interventions	
<i>Surgery, n (%)</i>	
Laparoscopic Heller Myotomy + Dor Fundoplication (LHM + Dor)	7 (17%)
Nissen Fundoplication (Nissen)	1 (2.4%)
<i>Endoscopy, n (%)</i>	
Botulinum toxin (BTX)	4 (9.8%)
Pneumatic balloon dilation (PBD)	2 (4.9%)

Table 3 Patient follow up

Follow up	
<i>Total (n = 41)</i>	
3–6 months	34 (82.9%)*
12 months	33 (80.5%)*
Lost to follow up	1 (2.4%)

*Some patients at 3–6 months and 12 months are not the same. Overall, only 1 patient did not have any form of follow up

Table 4 Clinical success

Clinical success (%)	
<i>Post-procedure</i>	
3–6 Months (<i>n</i> = 34)	31 (91.2%)
12 months (<i>n</i> = 33)	31 (93.9%)
<i>Achalasia subtype 1 (n = 3)</i>	
3–6 Months (<i>n</i> = 3)	2 (66.7%)
12 months (<i>n</i> = 2)	2 (100%)
<i>Achalasia subtype 2 (n = 19)</i>	
3–6 Months (<i>n</i> = 15)	14 (93.3%)
12 months (<i>n</i> = 16)	16 (100%)
<i>Achalasia subtype 3 (n = 19)</i>	
3–6 Months (<i>n</i> = 15)	15 (93.8%)
12 months (<i>n</i> = 16)	13 (86.7%)
<i>LHM + Dor (n = 7)</i>	
3–6 Months (<i>n</i> = 5)	4 (80%)
12 months (<i>n</i> = 5)	5 (100%)
<i>Nissen (n = 1)</i>	
3–6 Months (<i>n</i> = 1)	0 (0%)
12 months (<i>n</i> = 1)	0 (0%)
<i>BTX (n = 4)</i>	
3–6 Months (<i>n</i> = 3)	3 (100%)
12 months (<i>n</i> = 3)	3 (100%)
<i>PBD (n = 2)</i>	
3–6 Months (<i>n</i> = 1)	1 (100%)
12 months (<i>n</i> = 2)	2 (100%)

up at 3–6 months and 33 of the 41 (80.5%) had follow up at 12 months (Table 3).

Technical success was achieved in 100% of our patients (Table 1). 31 of the 34 (91.2%) patients who followed up at 3–6 months post-procedure had clinical success and 31 of the 33 (93.9%) had clinical success at 12 months post-procedure (Table 4). Average Eckardt score 3–6 months post-procedure was 1.31 (SD = 1.62) and 12 months post-procedure 1.81 (SD = 1.56) (Table 1). Stratifying by achalasia subtype, technical success remains 100% for subtype 1 (*n* = 3), 2 (*n* = 19), and 3 (*n* = 19). Clinical success at 3–6 months for subtype 1 is 66.7% (*n* = 3), subtype 2 is 93.3% (*n* = 15), and subtype 3 is 93.8% (*n* = 16), whereas at 12 months for subtype 1 is 100% (*n* = 2), subtype 2 is 100% (*n* = 16), and subtype 3 is 86.7% (*n* = 15) (Table 4). Notable is that some patients at 3–6 months and 12 months are not the same. Overall, only 1 patient did not have any form of follow-up.

One adverse event occurred (2.4%). This adverse event occurred with our first patient. Advancement of the endoluminal functioning lumen imaging probe to measure post-myotomy distensibility caused a mucosotomy when the tip went through the mucosa into the submucosal tunnel. This required closure by clips, and a submucosal hematoma later

Table 5 Clinical success by providers

G.K.M. (<i>n</i> = 10)	3–6 months (<i>n</i> = 10)	10 (100%)
	12 months (<i>n</i> = 6)	6 (100%)
H.C. (<i>n</i> = 16)	3–6 months (<i>n</i> = 13)	12 (92.3%)
	12 months (<i>n</i> = 15)	15 (100%)
T.L.J. (<i>n</i> = 15)	3–6 months (<i>n</i> = 11)	9 (81.8%)
	12 months (<i>n</i> = 12)	10 (83.3%)

formed that was confirmed on EGD. The patient recovered uneventfully and responded to POEM, with sustained response at 2 year follow up. The severity of the event was moderate per the ASGE Lexicon. Adverse event rate is 0% for subtype 1 (*n* = 3) and subtype 3 (*n* = 19); and 5.26% (*n* = 19) for subtype 2.

Stratifying by providers, clinical success was achieved in over 80% at both 3–6 months and at 12 months of follow-up (Table 5), reflecting high success beginning with the earliest POEM procedures by all three endoscopists. Most POEM procedures for patients with type 3 achalasia and who had prior surgical interventions were assigned to T.L.J. given his third space experience and the anticipated level of procedural difficulty. Also, at times, T.L.J. took the scope to assist with POEM procedures performed by H.C. or G.K.M. We did not track how often this assistance occurred.

Discussion

POEM is an effective alternative to surgical treatment [5, 12, 25]. Our high technical (100%) and clinical success (91.2%) rates with only one adverse event (2.4%) coincides with results from high volume expert centers. Clinical nonresponders to POEM included those who underwent prior foregut surgery, except for one patient with relapse of advanced myasthenia gravis. A multicenter study comparing LHM and POEM in those with achalasia subtype 3 concluded that POEM might provide better clinical outcomes due to a longer achievable myotomy [12]. Our study included 19 patients with subtype 3, 93.8% of which are clinically successful at 3–6 months and 86.7% at 12 months.

The development of a program begins with estimating the number of achalasia referrals and deciding whether the volume of POEM procedures is adequate to produce consistent successful outcomes. Although achalasia is not common, a prevalence rate of 10.82 in 100,000 people [4] may provide significant demand for specialized care at tertiary medical centers serving a large population. KPNC both insures and provides health care to 4.3 million members. Consequently, the number of individuals affected by achalasia who would

prefer POEM is significant and warranted developing a comprehensive clinical service.

After determining that a need exists for achalasia treatment by POEM, a clinical service line should be created. Collaboration between providers who perform Heller myotomy and POEM is essential. Surgeons and interventional gastroenterologists may develop proficiency in POEM, and availability of both surgical and advanced endoscopic skills are necessary to address emergent complications. Gastroenterology expertise in esophageal motility is also required for accurate diagnosis of achalasia and longitudinal clinical care. Interdisciplinary education supporting expertise in gastrointestinal motility, interventional endoscopy, radiology, thoracic surgery, and anesthesia supported our excellent POEM outcomes. As achalasia is uncommon, and myotomy a nonemergent intervention, we centralized our services at one facility with the goal of honing experience and producing consistent excellent results. In addition to developing multidisciplinary physician expertise in POEM, we trained technicians and nursing staff to assist with POEM by having them observe assistance with ESD, and then providing them with on-site mentorship by nurses and technicians proficient in assisting ESD during the first POEM cases. Medical industry specialists were also present for several of the first POEM procedures to support proper use of electro-surgical generator settings and devices. Although an outline for developing proficiency in POEM for those in advanced endoscopy fellowships has been published [26], no standardized training and credentialing criteria for endoscopists in practice have been defined [5]. We believe expertise in endoscopic resection, particularly ESD, eases the learning curve for POEM. Needle knife submucosal dissection techniques for resection are comparable to tunneling for POEM. Knife control for incision around a lesion for ESD is analogous to creating a mucosotomy. ESD requires recognition of the mucosal, submucosal, and muscularis propria planes, and this recognition is essential for successful POEM. To develop procedural competency in POEM, an interventional gastroenterologist skilled in ESD helped lead the development of our POEM service. We completed hands-on practice with animal models, were mentored and proctored by POEM experts, participated together in dedicated instructional courses, and observed several POEM procedures at high volume tertiary centers.

We wanted maximal preparation prior to our first patient since POEM has the potential for significant morbidity and mortality and a successful program requires safe and quality outcomes from inception. Our training components included animal models, mentorship and proctoring by experts, instructional courses, and observation of POEM at an existing center. We believed all components were vital to the success of our program. Working with animal models allowed the development of a framework for a successful POEM,

including the creation of the initial mucosotomy incision, tunneling within the submucosal layer, recognizing tunnel landmarks such as the transition from the lower esophagus to the cardia, and performing the myotomy. Animal models provided the opportunity to hone essential skills ahead of the first human POEM. Mentorship and proctorship by an experienced POEM expert are essential for feedback on case selection, short- and long-term post-POEM care, and additional questions that may arise. Additionally, having an expert proctor in the initial patient cases ensured safety by having someone able to intervene if complications occurred. Instructional courses provided additional opportunities to practice POEM on live animal models and observe live cases. The FSIE POEM course was taught by thoracic surgeons highly facile with third space endoscopy and provided an opportunity to learn from operators capable of performing both POEM and Laparoscopic Heller Myotomy. The course was vital because it provided a structured, proven approach to POEM. Observation of POEM at an expert center was essential to learn the workflow and logistics. This includes the reasoning and nuances behind room set up, peri-procedural patient care, equipment logistics and troubleshooting, and the responsibilities of the ancillary staff. While instructional courses were helpful, they accommodate many learners. Observing at a center allows for dedicated time to learn all aspects of pre-, intra-, and post-procedural care and logistics. There were many subtle details to care that would otherwise not have been recognized without direct, in-room observation.

The introduction of telehealth for video consultations in 2019 was integral for the development of the POEM clinical service as the KPNC network covers a large geographic area. In 2020, the COVID-19 pandemic and social distancing requirements accelerated adaptation of this technology. Beginning in the summer of 2020, to minimize risk of COVID-19 exposure and preserve hospital beds, we identified patients who might meet criteria for same day discharge after POEM, as described in the literature [23]. These POEM procedures were performed in the morning, with plan for possible same-day esophagram and then discharge.

Limitations of our data include short duration of follow up. We also did not measure the time elapsed for our procedures. This data would be helpful in describing the learning curve for achieving POEM proficiency, including for endoscopists skilled in ESD, as well as those trained in POEM during advanced endoscopy fellowship. The single adverse event happened with passage of the functional luminal imaging probe to measure distensibility after myotomy. The tip of the probe punctured the mucosa overlying the submucosal tunnel, requiring closure by clips. The site developed a hematoma which later resolved. To prevent future adverse events with passage of the probe, we gently folded its tip into the biopsy channel at the end of the endoscope

before passing it back down into the gastrointestinal tract under direct observation.

The role of EndoFlip was not certain at the initiation of our program in 2018. We used the EndoFLIP as a qualitative measure to ensure that there was improvement in the measurement without any defined threshold of improvement. Analysis of pre- and post- procedure EndoFLIP measurements and their ability to predict clinical response to POEM was beyond the scope of this study. Generally, we aimed to achieve distensibility indices of more than 2.5 mm²/mmHg and tried to correlate the EndoFLIP results with endoscopic findings. There were some cases that the distensibility index did not reach > 2.5 mm²/mmHg yet we could not identify any more circular muscle to cut. The GEJ tightness felt with passage of the scope across the lower esophagus into the stomach pre-mytomy was no longer evident. Our decision was to trust the endoscopic findings since the value of EndoFlip was still controversial.

This program was created in the context of our providers' resources and experiences. Accurate self-assessments would be different for each new program. We recognize that our lead had extensive experience in third space endoscopy, while another had POEM training in fellowship, and the third had extensive esophageal experience.

As POEM becomes increasingly adopted as a minimally invasive treatment for achalasia, determining how to deliver successful, safe, and consistent care is essential. We outlined the steps involved to establish a POEM service in a large integrated healthcare system, and highlighted criteria for optimal success and minimal adverse events. Prior competency in interventional endoscopy, utilizing procedural training models, POEM observation and education, proctorship, and interdisciplinary patient care are recommended.

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Declarations

Conflict of interest All authors declare that they have no conflict of interests.

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