

# The Per Oral Endoscopic Myotomy (POEM) technique: how many preclinical procedures are needed to master it?

## Authors

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## Bibliography

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**Background and study aim:** Per oral endoscopic myotomy (POEM) is a complex technique used in achalasia. Preclinical training is essential but little is known about the number of procedures needed. The aim of this study was to determine the number of procedures required to master POEM in an animal model.

**Patients and methods:** This prospective comparative study was conducted in two swine models at a single institution in Mexico City between November 2012 and October 2014: Group 1 (G1)=30 ex vivo and Group 2 (G2)=20 live swine models. POEM was mastered after finishing the five steps without complications. Time, characteristics, and complications were recorded. Velocity of tunnelization and myotomy (VTM) was determined. Ex vivo analysis was done in G1 immediately after finishing POEM and at day 30 in G2.

**Results:** A total of 50 POEM were done in both groups (G1=30, G2=20). The mean times were 90.17 min (G1) and 89.50 min (G2) ( $P=0.92$ ). Myotomy was faster in G2 (21.10 vs 27.97 min;  $P=0.009$ ) with a slightly slower tunnelization (40.35 vs 41.13 min;  $P=0.86$ ). Myotomy was longer in G2 (9.25 vs 8.83 cm;  $P=0.26$ ). VTM between the groups was similar (G1=0.159 vs G2=0.157 cm/min;  $P=0.925$ ). Complications were: mucosotomy (G1=18%, G2=8%;  $P=0.430$ ), mediastinal perforation (G1=12%, G2=8%;  $P=1.0$ ), and perforation at the gastroesophageal junction (GEJ) level (G1=16%, G2=4%;  $P=0.149$ ). Seven models in G2 presented minor bleeding and there was one death not attributed to the procedure. Mastery was obtained after 26 cases.

**Conclusions:** We suggest that centers interested in learning POEM consider 26 procedures in animal models to master it before performing it in patients with achalasia.

## Introduction

Esophageal achalasia is an uncommon primary motor disorder that affects men and women equally and at all ages including children and elderly people, but more frequently between 25 and 60 years of age [1]. Its annual incidence is 1–2 cases per 100 000 [2,3]. Although the specific cause of lower esophageal sphincter dysfunction is unknown, an autoimmune component in the myenteric plexus seems to play an important role [3]. Dysphagia is the most common symptom (90% of cases) but other symptoms include pyrosis, thoracic pain, and weight loss [4]. Esophageal manometry detects body aperistalsis with an impaired relaxation of the lower esophageal sphincter [5].

Esophageal achalasia can be treated with medication, endoscopy or surgery [6]; among them, Laparoscopic Heller Myotomy (LHM) with a partial fundoplication is considered to be the gold

standard, because of its efficacy [7]. However, for those non-candidates to this treatment or who failed with it, the endoscopic options are: pneumatic dilation and botulinum toxin application; unfortunately, with only temporary results [8–10].

POEM is a new endoscopic treatment developed to treat esophageal achalasia. It was first practiced in an animal model in 2007 by Pasricha et al. [11] and then applied in humans in 2008 with its first publication in 2010 by Inoue et al. [12]. Up to the present time, more than 2000 patients have been treated with this new technique with a safety and short-term efficacy similar to LHM [13]. The potential advantages over LHM are: it is less invasive, cheaper, it allows a longer proximal esophageal myotomy, fewer postoperative side effects, faster return to normal activities, and a better acceptance from the cosmetic point of view [14].

## License terms



However, the POEM technique requires rigorous technical preparation. It is necessary to have an excellent knowledge of esophageal anatomy, of the equipment used in this procedure, and knowledge of advanced endoscopy specifically in endoscopic submucosal dissection (ESD) [15, 16]. Furthermore, serious complications include perforation, bleeding, and sepsis, however, no death has been reported so far. Hence, the endoscopist must be prepared to diagnose and treat patients correctly [17].

To meet these challenges, before performing POEM in esophageal achalasia, a learning program has been suggested and this includes: (1) Theoretical knowledge of the procedure. (2) Observation of it when done by an expert. (3) Practice in a preclinical setting (animal or cadaver model). (4) Finally, practice POEM in humans proctored by an expert [18]. Kurian et al. [19] conducted an analysis of the POEM learning curve, concluding that 20 procedures are necessary to master the technique. However, findings in regard to mastery of POEM reported by other research groups vary from 7 to 60 procedures [20].

Due to the difficulty of the technique and the increasing interest among hospitals in the implementation of a POEM training program, it is necessary to determine the number of procedures necessary for an endoscopist to be considered fully qualified. The aim of the present study was to document the learning process of the POEM procedure in order to define the number of pre-clinical procedures needed to master it before its implementation in patients with esophageal achalasia.

## Materials and methods



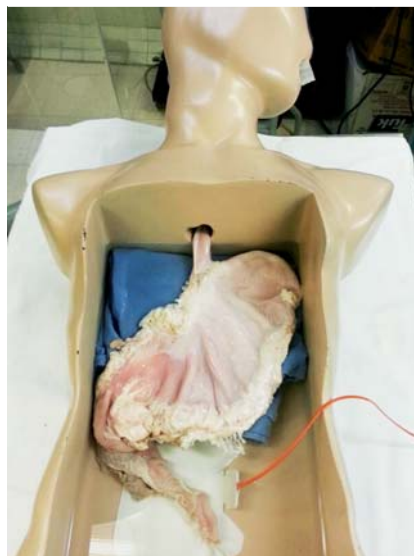
This was a prospective experimental study carried out in the Bioterium of the Department of Veterinarian Surgery, Specialties Hospital at the National Medical Center Century XXI in Mexico City, Mexico. All of the POEMs were performed in an operating room which had a temperature between 16 and 27°C, with a relative humidity of 40–70%. The Research and Ethics Committee of the institution approved the procedures herein used for the handling and care of animals.

The study consisted of three steps:

- ▶ Step 1 (preclinical): one of the authors (OVHM) performed all of the procedures aided by two fellows. He had experience in therapeutic endoscopy and had performed over 100 ESD procedures. He took two short courses to learn the POEM technique, supervised by medical experts, and then conducted an extensive review of videos and the literature in regard to this procedure.
- ▶ Step 2 (ex-vivo model): POEM was performed in 30 blocks (esophagus, stomach, and duodenum) of an ex-vivo swine model (G1).
- ▶ Step 3 (in vivo model): POEM was performed in 20 live swine models (G2).

## Equipment

(1) Fujinon endoscope model EG-530FP of 9.8 mm (Fujinon, Tokyo, Japan), which had an external diameter of 9.8 mm and a working channel of 2.8 mm. (2) Transparent cap model DH-28GR (Fujinon, Saitama, Japan) attached to the tip of the endoscope. (3) Electrosurgical unit model ERBE ICC 200 (ERBE Elektromedizin, Tübingen, Germany) employed in monopolar “auto-cut” mode with cutting power at 50 W (effect 3) and coagulation at 30 W (effect 2). For coagulation of vessels, soft coagulation mode at 50 W. (4) A water irrigation pump (Endogator) model EGP-100 (Medi-



**Fig. 1** Ex vivo model: After being prepared, the swine esophagus and stomach are attached to a dummy to simulate the normal anatomic position.

vators, Minneapolis, MN, United States). (5) CO<sub>2</sub> insufflator model Endostratus (Medivators, Minneapolis, MN, United States) used at a flow of 1.2 L/min. (6) Flush knife model BT 2.0 (Fujinon, Tokyo, Japan). (7) Coagrasper forceps (Olympus, Tokyo, Japan) for coagulation of vessels. (8) Resolution clip (Boston Scientific, Natick, MA, United States) to close the entry site. (9) Injection needle model interject 23 g (Boston Scientific, Natick, MA, United States).

## Animal models

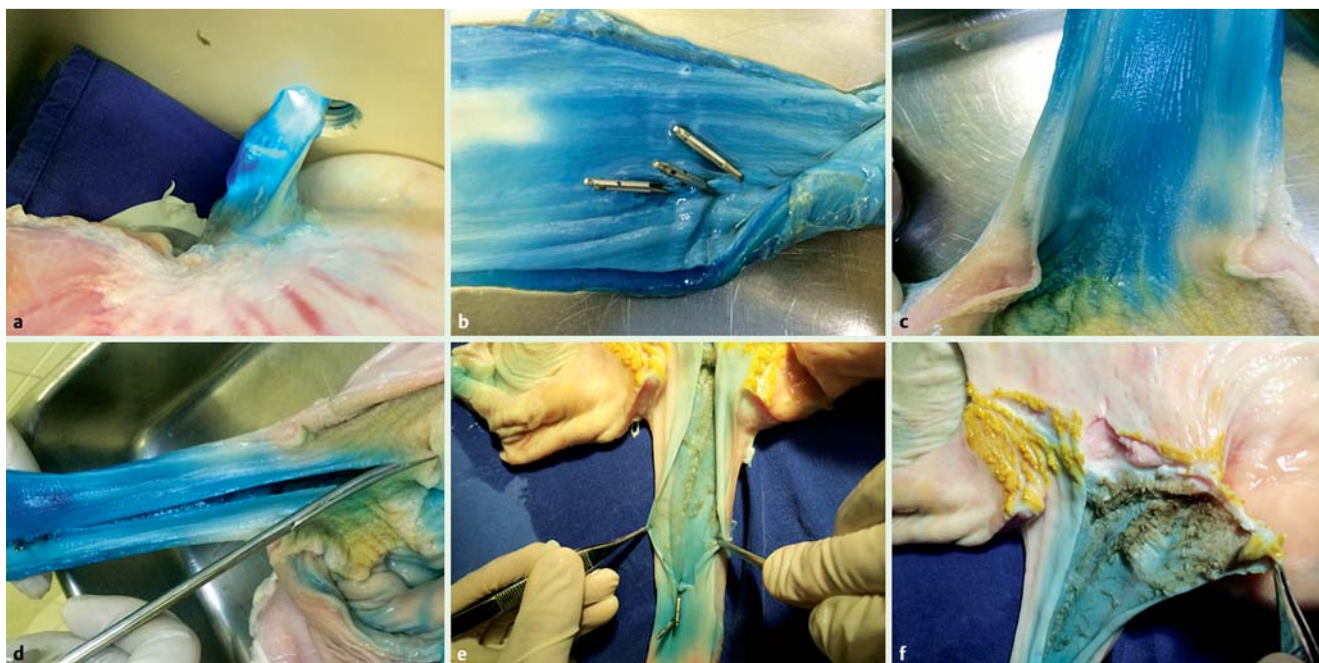
### Group 1

In total, 30 blocks of a swine model (including esophagus, stomach, and duodenum) were prepared. Each block was frozen at –17.8°C before use and for thawing, it was placed in a rectangular container (25×15 cm) with a mixture of water with 10 g of sodium chloride at 25°C. The blocks were submerged for 45 min to preserve the elasticity. Then they were washed with 8 L of tap water to remove mucous and other remnants. The block was fixed in a mannequin to simulate a normal anatomical situation, sewing it in place with a 2-0 silk thread (● Fig. 1).

Immediately after finishing POEM, the organs were meticulously inspected to analyze the characteristics of the procedure. All of these data were recorded and photographs were taken. After finishing the procedure, all of the waste biologic and inorganic material were disposed of according to the norms for dangerous biological/infectious residues (The Mexican Official Norm NOM-087-ECOL-94, as well as the Law of Ecological Balance and Environmental Protection) (● Fig. 2).

### Group 2

The POEM procedure was performed on 20 live swine – male or female Landrages breed between 3 and 8 months old and weighing 40 to 50 kg. All animals had a health certificate. A liquid diet was given for 48 hours before the procedure, followed by 8 hours of fasting. Then the animals were medicated with ketamine at a dose of 15 mg/kg by the intramuscular route and then a bolus of midazolam at a dose of 5 mg/kg with a maintenance dose of 2 mg/kg by the auricular route. The animals were orointubated and buprenorphine (0.01–0.04 mg/kg) as analgesic was administered as well as antibiotic (ceftiofur sodium 50 mg/16 kg/24 h) which was continued until 5 days after POEM.



**Fig. 2** Analysis of the ex vivo model. **a** Trans-illumination at the level of the distal esophagus and gastroesophageal junction (GEJ); no perforation was seen. **b** Examination of the three clips placed at the entry site in the proximal esophagus. **c** Exposure of the mucosa at the GEJ, showing indigo carmine dye in the submucosal space and no mucosotomies. **d** Longitudinal dissection of the submucosal tunnel. **e** Exposure of the tunnel. **f** Analysis of the myotomy length.



**Fig. 3** In vivo model and operation room.

Once the POEM was finished, the animal was taken to the recovery area. During the first 24 hours, it was fasted and then a liquid diet was begun; if no clinical signs of complication were observed, a normal diet was given. A weekly check-up was carried out until day 30 when it was sacrificed by pharmacologic methods. Death was verified by the absence of vital signs and then an analysis of the block of swine esophagus and stomach was carried out as in the ex vivo group. The handling of the animal was in accordance with the Mexican Official Norm NOM-087-ECOL-94, as well as the Law of Ecological Balance and Environmental Protection (● Fig. 3).

### POEM procedure

The five steps of the POEM technique [12] were performed on groups G1 and G2. Air was used for the ex vivo model, while CO<sub>2</sub> at 1.2 L/min was used for the in vivo model. The steps are outlined in ● Fig. 4.

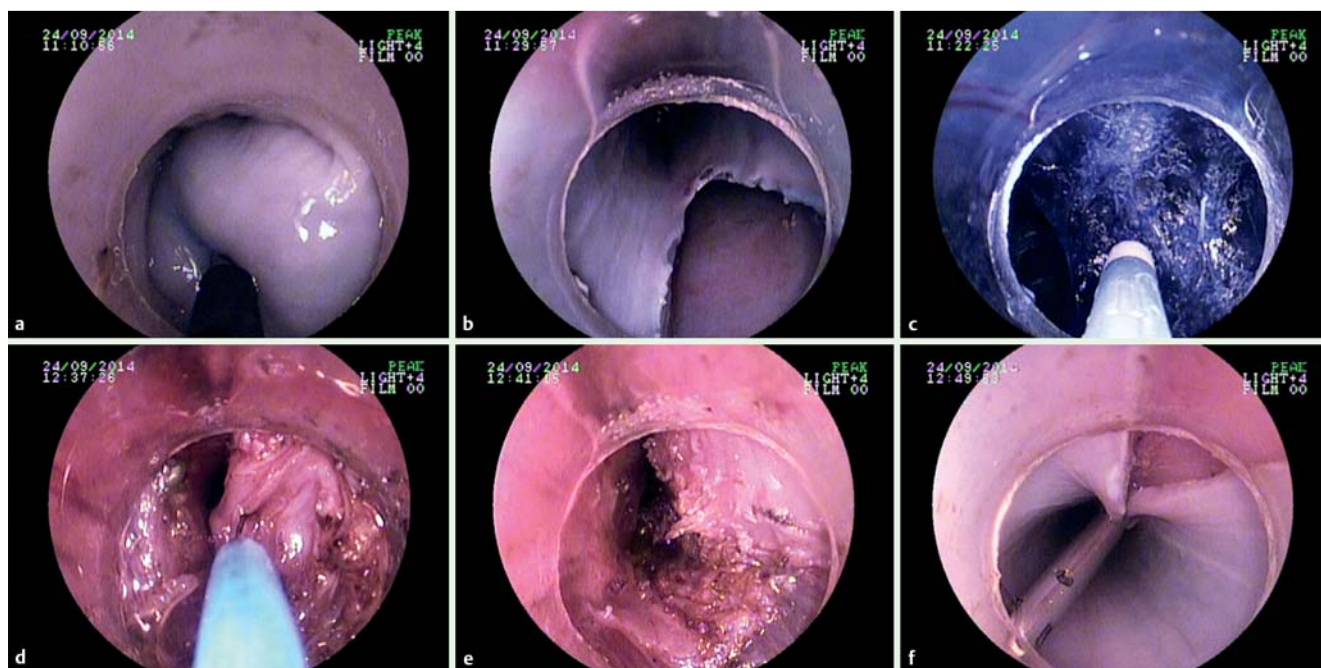
All of the procedures were recorded on a DVD and the duration of each step was calculated as well as the length of the myotomy and the presence of complications. Back-up images were made in JPG or TIFF format.

For the purposes of the present study, the learning process was defined as the acquisition of the necessary abilities for performing the five steps of POEM, while mastery of the technique was considered when it could be performed without complications. Complications were defined for G1 as follows: mucosotomy (communication between the submucosal space and esophageal or gastric lumen through an inadvertent or accidental orifice) or perforation (defined as the accidental or inadvertent communication between the submucosal space and the mediastinum or peritoneal cavity during the procedure). In G2, they were: mucosotomy, perforation, post-POEM hemorrhage, or death attributed to the procedure (defined after autopsy of the swine). Subcutaneous emphysema, pneumomediastinum, pneumoperitoneum, or bleeding during the procedure were considered to be adverse events, and were defined as complications only if any could not be controlled by endoscopic methods or other medical maneuvers.

Animals used in both models were excluded when they were not suitable for the performance of POEM. In G1 blocks that presented lesions not attributable to POEM were eliminated, as were those which had any condition that impeded the realization of the procedure in G2.

### Statistical analysis

The velocity of the procedure for each group was used as an objective indicator of the POEM learning process (quantitative continuous variable) and it was calculated with the basic physics for-



**Fig. 4** POEM procedure. **a** Injection: 15 cm proximal to the gastroesophageal junction (GEJ), 5–10 mL of a combined solution of saline at 0.9% (100 mL) with indigo carmine at 0.3% (5 mL) are injected until a submucosal bleb is seen. **b** Incision: A longitudinal incision of 2 cm is made at this level and the submucosal space is exposed. **c** Tunnelization: A proximal to distal dissection of the submucosal fibers is made up to 2 cm after the GEJ. **d** Myotomy of the circular muscle of the esophagus. **e** Myotomy at the level of the lower esophageal sphincter and 2 cm of the gastric side. **f** Closure: Clips are placed at the entry site.

mula velocity = distance/time. A Gaussian distribution ( $P > 0.05$ ) was determined with Shapiro Wilk and Kolmogorov Smirnov normality tests as indicated in G1 ( $n = 30$ ), G2 ( $n = 20$ ), or both groups ( $n = 50$ ). Homoscedasticity of variances between groups was determined after Levene's test was applied and assumed when  $P < 0.05$ . After determining this normality in our sample, the Student's  $t$  test was used to compare differences between groups. In order to evaluate mastery of the procedure, we divided each group into two subgroups (complicated and non-complicated cases) and these were compared using the Student's  $t$  test. Mean and SD were used to express the results of VTM. To evaluate complications between groups (nominal qualitative variable), Chi Squared analysis ( $\times 2$ ) was used and expressed as percentages. A statistically significant difference was defined when  $P < 0.05$  and results were expressed with their corresponding 95%CI intervals.

To analyze the VTM in each group, SigmaXL graphs were used which provide a visual representation of the behavior of the POEM process in each group. In these graphs, four different limits can be seen: upper and lower limits which represent the maximum and minimum expected velocity if the process had a mean increasing constant velocity with 1SD (68% population), and the upper control limit (UCL) and lower control limit (LCL) which includes 95% of the cases. The graphs do not allow a  $P$  value or a 95%CI to be calculated. They only show the progress of velocity in each group as a direct indicator of acquisition of the ability to perform POEM and a red line divides the group into those who had or who did not have complications. Data were analyzed with SPSS version 21 for MAC.

## Results

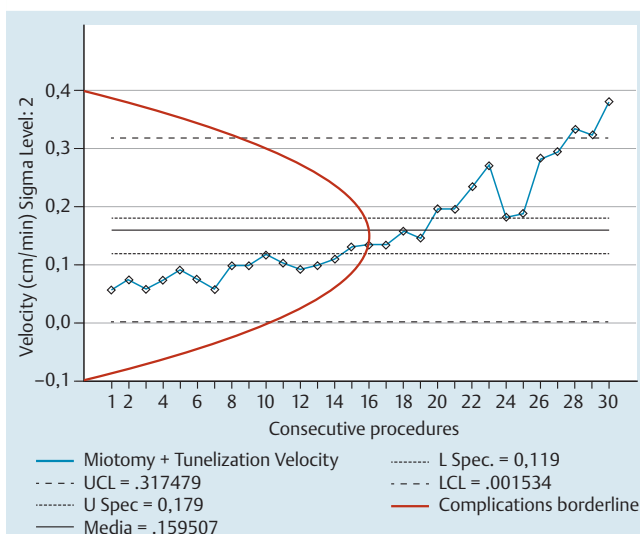


A total of 50 POEM procedures were carried out between November 2013 and October 2014: 30 ex vivo blocks in G1 and 20 live swine models in G2. Mean total time for POEM was  $90.17 \pm 10.13$  min (G1) vs.  $89.50 \pm 13.25$  min (G2) ( $P = 0.92$ ). The five steps of POEM were successfully performed in all cases.

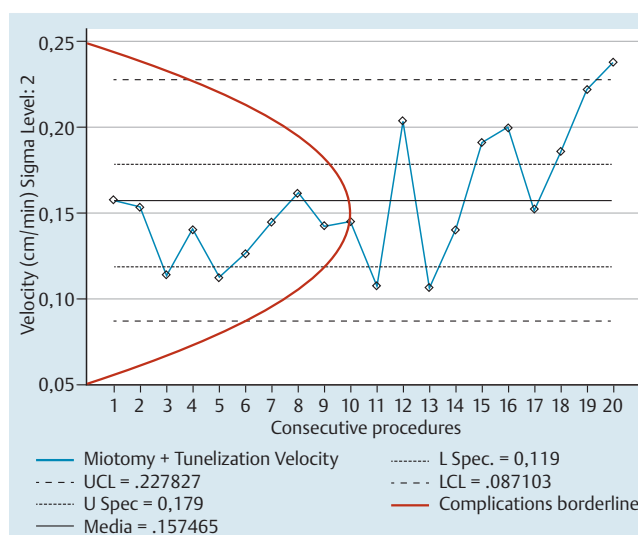
Tunnelization was the most time consuming step in both groups ( $41.13 \pm 5.81$  min for G1 and  $40.35 \pm 6.41$  min for G2;  $P = 0.86$ ). Myotomy was the second most time consuming step, taking significantly less time in G2 ( $21.10 \pm 3.82$  min) compared with G1 ( $27.97 \pm 4.10$  min) ( $P = 0.009$ ). These steps are the most difficult and important, so the majority of complications are present in them. The other steps did not show any statistically significant difference between both groups in regard to the time required. The length of the myotomy was slightly greater in G2 ( $9.25 \pm 2.21$  cm) compared with G1 ( $8.83 \pm 1.9$  cm) ( $P = 0.26$ ).

To calculate the velocity of the procedure, we considered distance as the total length of the myotomy and time as the number of minutes required to perform the two most important steps of POEM (myotomy and tunnelization). It was found that the VTM increased with a greater number of procedures performed. For these two steps, the mean velocity in the ex vivo group was  $0.159 \pm 0.914$  cm/min ( $0.056 - 0.379$  cm/min). The live model had a mean velocity of  $0.157 \pm 0.038$  cm/min ( $0.107 - 0.238$  cm/min). There was no statistically significant difference in the mean VTM between both groups ( $P = 0.925$ ).

Mastery of the procedure was found when no complications were observed in each group and the increase or maintenance of VTM was observed. So when both subgroups (complicated and non-complicated cases) were compared in G1, after 16 cases, the increase in VTM was maintained and the final difference between groups favoring non-complicated cases was  $0.140$  cm/min ( $P < 0.001$ ; 95%CI  $0.10 - 0.18$ ). In G2, when comparing both sub-



**Fig. 5** Control chart of speed behavior in subsequent procedures of ex vivo model. UCL, upper control limit; LCL, lower control limit; U Spec, upper specification; L Spec, lower specification.



**Fig. 6** Control chart of speed behavior in subsequent procedures of porcine model. UCL, upper control limit; LCL, lower control limit; U Spec, upper specification; L Spec, lower specification.

groups after 10 cases, the difference in the increase in VTM in favor of the non-complicated cases was 0.032 cm/min ( $P=0.05$ ; 95%CI 0.005–0.067). We did not find an association between the increase in VTM and the degree or type of complications during the procedure (• Figs. 5 and 6).

The complications are detailed in • Table 1. Bleeding was present in seven cases and all were endoscopically controlled and no clinical signs of bleeding were detected during follow-up. Subcutaneous emphysema was self-limited in less than 48 hours in all cases. Pneumoperitoneum was present in two cases in G2 and did not require any type of intervention. The only death was due to a cardiac arrhythmia, attributed to anesthetic agents administered 3 hours before the procedure. During the autopsy, no complications from the POEM were detected.

**Table 1** Distribution of complications and adverse events in both groups.

Complication/adverse event	Group 1 (n=30)	Group 2 (n=20)	P value
Mucosotomy	9 (18%)	4 (8%)	0.430
Perforation of mediastinum	6 (12%)	4 (8%)	1.0
Perforation in the GEJ or stomach	8 (16%)	2 (4%)	0.149
Bleeding	–	7 (35%)	–
Death at 72 h	–	1 (5%)	–
Subcutaneous emphysema	–	4 (20%)	–

Nonparametric test: Chi Squared analysis ( $\times 2$ ); GEJ, gastroesophageal junction.

In all cases, the closure of the entry site was successful. The mean number of clips used in both groups was  $5 \pm 2$ , and in G2, 90% of clips were not found at the point of analysis of the block.

## Discussion

POEM is a complex technique which has been the attention of growing interest among different hospitals worldwide. This is because of its safety and efficacy as well as the fact that its results are comparable to the gold standard (LHM) [13]. In addition, POEM has other potential advantages. It is less invasive, more economical, gives faster recovery, and offers the possibility that it can be performed on patients who have already received some type of previous treatment including LHM and did not respond adequately [14,21].

However, the diffusion of POEM has been limited by a number of factors, including the fear of manipulating the esophagus and the potential for complications in the mediastinum (however, no deaths have been reported until now) [22]. It is unquestionable that POEM has many technical challenges and requires special training. However, only a few recommendations have been released by hospital centers with the greatest experience in POEM [23].

As stated before, all of the endoscopists interested in performing this procedure should: (1) Have experience with therapeutic endoscopy and ESD. (2) Acquire knowledge of the diverse aspects of the POEM procedure including observation of each step, know the different instruments used to perform it, and have a detailed understanding of intraluminal, extraluminal, and mediastinal anatomy as well as the vascular and nerve structures. Acquire the capacity to detect and treat potential complications during or after the procedure. (3) Begin with a preclinical practice on animal models or cadavers. (4) Perform the first POEM procedures on patients under the strict supervision of an expert in the field [24]. All of the steps are important, but particularly the practice in an animal model (first ex vivo and later in vivo), in an attempt to reproduce conditions similar to patients with esophageal achalasia and with virtual simulators for endoscopic training. This allows a better understanding of the POEM procedure in order to acquire sufficient ability to master it before performing it on patients. Because proficiency has been acquired for each of the distinct steps, the risk of complications is minimized, and the ability to respond to them is adequate [25].

The present study concludes that 26 procedures are sufficient to master the POEM technique. This number is given by the sum of 16/30 (53%) procedures done in the ex vivo model and 10/20 (50%) with the in vivo model. We observed that, after this number of procedures in both groups, the endoscopist should

perform the procedures without complications and speed will gradually improve without sacrificing safety. This was confirmed after analyses of both subgroups (complicated vs. non-complicated); in the ex vivo group, after 16 cases, the VTM showed a continuous increase without complications defining mastery of the procedure, and in the vivo group besides the fact that the VTM is more heterogeneous, this phenomenon is also observed after 10 cases, both showing a statistically significant difference. These results represent an important contribution to answering the question about how many procedures are needed to master this technique, on account of the great discrepancy related to this number in the literature (7 to 60) [18–20], which could be explained by the diverse forms of evaluating the learning process of this technique.

Kurian et al., who used a concept of evaluation similar to that employed in the present study, performed 30 procedures on animals and cadavers, before moving on to humans. Later, after performing POEM in patients with esophageal achalasia, they concluded that 20 procedures were sufficient to master this technique and that after this number, there was not a significant decrease in the time taken to perform the myotomy or an increase in the number of mucosotomies [19]. Two other studies, by Patel et al. [20] and Teitelbaum et al. [18], tried to evaluate the learning process for this technique; both were retrospective and performed on humans. Patel et al. concluded that 40 procedures were required to reach efficiency and 60 to master it; however, they mentioned that gastroenterologists with limited experience in ESD could underestimate this number of procedures. However, this number is very different from that obtained by Teitelbaum et al. In an analysis of 36 procedures, they found that the “learning rate” for the procedure was seven POEMs. Although great discrepancy exists in this topic, there is general agreement about the importance of preclinical training before it can be applied to patients. In fact, in a recent survey (IPOEMS) performed in 16 centers that have the greatest experience in POEM procedure around the world, it was found that 10 undertook extensive preclinical training before moving on to humans [26].

We decided to evaluate the learning process to master the POEM technique in animal models because: (1) The ex vivo model has great similarity to the human esophagus, but is not so expensive to perform and is easy to handle. (2) The different steps of POEM are well understood. (3) In the swine model, there is another level of difficulty because of the risk of bleeding (present in seven cases in our group G2) and perforation with its clinical consequences. We observed an important decrease in the mean VTM when we changed from the last case in G1 (0.379 cm/min) to the first case in G2 (0.157 cm/min).

Mediastinal perforation was more common during myotomy and occurred just before dissection of the gastroesophageal junction (GEJ), perhaps because of narrowing of the tunnel at this level, so it must be done carefully. In the ex vivo model, we observed more perforations at the gastric side, probably due to harder tissue. Finally, as reported by other authors, mucosotomies were found during tunnelization and solved by placing a clip over the mucosa.

We used SigmaXL graphs because these provided a visual representation of the results for each procedure and for the model as a whole. In both graphs, it can be seen that the velocity was ascendant. In G1, the velocity of the procedure was increasing in a homogeneous manner without complications after case 16 and only with a relative decrease in cases 24 and 25, but never below the first sigma level or the median line (0.179 cm/min); however,

G2 showed a heterogeneous behavior with a median VTM of 0.119 cm/min. This was because of the latent possibility of bleeding that could delay the procedure. After 10 procedures, we did not find any complications but we could not predict the VTM behavior unless more procedures on live models were included. The mean total time between both procedures was almost the same. This is because, although the myotomy was faster in G2, tunnelization was slower in G2 than in G1 and there were not differences in the other steps, so we concluded that the mean time for the POEM procedure was 90 min. This is similar to the mean time reported when POEM was performed in a patient with esophageal achalasia [12, 14, 16, 26].

The results from this model of learning are not distinct from those found with other models used for learning complicated procedures such as ESD and LHM, in which a set of steps must be practiced to acquire the necessary competence before operating on patients. For ESD and LHM, it has been determined that between 20 and 35 procedures are necessary to master the technique [27, 28].

Our study has several limitations. First, although the ex vivo swine esophagus is cheap, the live swine model is not and has difficult logistics requirements and ethical concerns. Additionally, it does not have the same characteristics as the achalasic one, the first having a thinner muscular layer and softer less vascularized submucosal space [21] so it does not replicate entirely the challenges of performing POEM in a patient with esophageal achalasia where there could be distension of the distal esophagus, scarring from prior endoscopic procedures, and a tight GEJ. For these reasons, we cannot extrapolate the current results to patients with achalasia. This may represent an important challenge for the practitioner who is attempting to learn this technique and therefore it could result in perhaps an increased mean time for the procedure when done on patients with esophageal achalasia, mostly during tunnelization and myotomy, probably because of a potential increased risk of bleeding. However, we consider that this transition from an in vivo swine model to patients with esophageal achalasia should not be so different as the changes we found when transitioning from G1 to G2 in terms of velocity and complications. But it would be necessary to include a group of patients with esophageal achalasia to evaluate this topic. Hence, patient selection and proctoring are extremely important when moving from the preclinical to the clinical stage of setting up a POEM program.

A second limitation is that the process of learning and mastery of the technique were evaluated with only one endoscopist, which means that the results cannot be generalized. Endoscopists with different experience and skills may require substantially diverse procedural numbers, so a future study including a greater number of endoscopists should be done to evaluate the current findings.

A third limitation is the lack of clinical data in humans with esophageal achalasia. However, with regard to this topic, in our earlier experience in eight patients (not shown), the differences between G2 and patients with esophageal achalasia are minimal in terms of velocity of the procedure and complications. For example, we have found a mean VTM of 0.215 cm/min, which is within the range of the G2 velocities (0.107–0.238 cm/min), and the efficacy in these patients in clinical and manometric terms has been 100%. Based on this, we can preliminarily suggest that the model of training and number of procedures proposed herein are effective for mastery of the POEM technique.

Despite these limitations, this is the first study whose principal focus was to determine the number of preclinical procedures necessary for learning and mastering the POEM technique before performing it on patients. Hence, our proposal of 26 preclinical procedures offers a guideline for optimization of resources in different centers that wish to begin this procedure, especially taking into account that the present finding is similar to previous recommendations made by some experts.

In conclusion, POEM is an arduous and technically difficult procedure that requires an excellent preclinical learning process before attempting it on patients with esophageal achalasia. The swine model appears to be good for this purpose and any center interested in implementing this model should consider having a bioterium capable of housing and caring for at least 26 swine models (16 ex vivo and 10 in vivo), for the practice of these procedures. Based on the results of the present study, we suggest that 26 preclinical POEMs are sufficient for mastery of this technique and after that, POEM could be safely performed on patients with esophageal achalasia. Although further research is necessary to validate the current findings, we consider that it can serve as a guideline for establishing a training program for the POEM technique in centers around the world.

**Competing interests:** None

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