

A Training Model for Introducing a Novel Surgical Procedure into Clinical Practice: Our Experience on Peroral Endoscopic Myotomy for Achalasia

Dear Editor,

Peroral endoscopic myotomy (POEM) is a treatment for achalasia which can potentially obviate the need for intra-abdominal surgery, whilst at the same time, deliver the same effective treatment as the current standard of care – surgical myotomy. Although POEM has shown encouraging 1-year success rates of more than 90%,¹⁻³ it remains a technically demanding procedure. In the absence of local experts in the field, our unit came up with a structured training programme to ensure that a new procedure can be offered safely and efficaciously. This article illustrates our journey in adopting POEM as a therapeutic procedure, including its safe introduction into clinical practice, and presents a series of our first 20 experiences with this procedure.

Materials and Methods

This was a prospective study documenting our experiences in the inception of this new modality from training until the completion of our first 20 patients who had this procedure performed on them. We obtained approval from the Institutional Review Board (IRB) for the conduct of this study.

Data collected included patient demographics as well as disease characteristics. The Eckardt⁴ and dysphagia⁵ scores were also obtained from patients at 1 month and 6 months after discharge. Intraoperative details including procedure duration, length of submucosal tunnelling and myotomy length were collected. Postoperatively, the patients' pain scores were collected on postoperative day 1 and on discharge. Length of hospital stay (LOS) as well as any perioperative complications were also documented. Student's paired t-test was used for statistical analysis of pre- and post-procedural comparison of Eckardt and dysphagia scores.

Training for POEM

All procedures were performed by the senior author. Training for POEM commenced 6 months before the first patient underwent the procedure. A self-structured training programme was created by our department. Initial training for the procedure was via attending a hands-on workshop which was conducted overseas. In-house training was then

commenced using both explanted porcine models and live porcine models. Explanted porcine models were ordered from the local abattoir on each training session and fixed to a white box (Fig. 1). Professor Philip Chiu, who has had extensive personal experience with this procedure,⁶ proctored our unit in the procedure and the necessary set-up. In total, 8 training sessions, each lasting about 4 hours, were organised prior to our first experience on patients, with 2 of these being on live porcine models.

Upon completion of animal training, we obtained the institutional approval for Implementation of New Surgical Device and Interventional Procedure for Clinical Service (NSIPC) prior to our first clinical case. The first patient was performed by the overseas expert with the series author assisting in the procedure. The subsequent 2 cases were performed by the series author, with Professor Chiu observing and mentoring in the procedure. From case 4 onwards, the series author was able to perform the procedure independently.



Fig. 1. Explanted porcine model, placed within a plastic box, with an endoscope in the stomach during the practice session.

Results

Our experience with POEM thus far includes 20 consecutive patients, all of which have been reported in this study. Ten of our patients were male, with a median age of 50.5 (range, 39 to 68) years. The most common complaint amongst our patients was dysphagia. Median procedural duration was 150 (79 to 294) minutes, and median length of stay was 4 (range, 1 to 50) days (Table 1).

Pain score as measured on a Visual Analogue Scale (VAS) showed a mean of 2.9 on postoperative day 1,

which declined to 1.1 by the day of discharge. Out of our 20 patients, 1 suffered a myocardial infarction and required percutaneous coronary intervention. The patient was eventually discharged well. There were no other complications in this series. Patients underwent a routine gastrograffin study and gastroscopy the day after, and as all the studies did not show any leak of contrast, all patients commenced a liquid diet on post-procedure day 1.

Excluding a patient who was eventually found to have pseudoachalasia and underwent definitive total gastrectomy,

Table 1. Preoperative, Perioperative and Postoperative Findings

Patient No.	Age (Years)	Duration of Symptoms (Years)	Previous Interventions	No. of Previous Intervention(s)	Achalasia Type	Myotomy Length (cm)	Duration of Procedure (minutes)	Length of Stay (Days)	Complications
1	39	1	Balloon dilatation	1					
2	62	0.25	Nil	0					
3	44	20	Balloon dilatation	2	1	10	95	5	Nil
			Botox injection	3					
4	63	0.67	Nil	0	2	10	195	6	Nil
5	55	10	Balloon dilatation	1	3	13	122	4	Nil
6	62	45	Surgical myotomy	1	2	13	153	2	Nil
			Balloon dilatation	3					
7	52	1	Nil	0	2	14	140	4	Nil
8	53	2	Nil	0	2	13	161	4	Nil
9	33	1	Nil	0	2	15	101	1	Nil
10	51	2.5	Nil	0	2	12	94	3	Nil
11	68	30	Botox injection	1	3	15	134	2	Nil
12	67	0.875	Nil	0	3	13	150	50	ST elevation myocardial infarction
13	23	3.5	Balloon dilatation	2	1	7	218	5	Nil
			Botox injection	1					
14	34	3	Nil	0	1	10	294	5	Nil
15	33	5	Nil	0	2	14	92	2	Nil
16	38	4	Nil	0	2	14	163	3	Nil
17	49	4	Nil	0	2	14	140	3	Nil
18	50	4.5	Nil	0	3	16	214	4	Nil
19	49	10	Nil	0	1	10	192	4	Nil
20	68	15	Balloon dilatation	3	1	10	133	3	Nil

19 patients were reviewed at 1 month, and 8 at 6 months. A statistically significant decrease was noted for the Eckardt score from 5.6 to 1.3 ($P < 0.001$) at 1 month and 0.9 ($P = 0.002$) at 6 months (Fig. 2). There was also a statistically significant decrease in the dysphagia score from 2.8 to 1.1 ($P < 0.001$) at 1 month and to 1.1 ($P = 0.014$) at 6 months. Our intraoperative experience varied most with our initial few cases. Our third case required 258 minutes for completion largely because of difficulty in approximating the mucosal edges of the incision. We needed to use an absorbable looped suture (Loop MAJ254; Olympus, Singapore) to close the mucosal defect. In our fourth case, the distal cap attachment dislodged during the procedure and again, we used the endoscopic biopsy forceps to retrieve the cap.

Discussion

A structured training and proctorship programme can be implemented for new procedures with successful results. We utilised a stepwise progressive approach from attending hands-on workshop, to training on animal models and proctoring in order to bring a new procedure to our institution. Our initial results with POEM have been encouraging.

The authors believe that a comprehensive training programme is key to ensuring that the introduction of a new procedure would be safe and successful. The use of simulation-based training prior to performing a procedure in a live patient has been described in a recent review published by Dawe et al.⁷ After evaluating the outcomes in both laparoscopic and endoscopic surgery, the authors concluded that there was strong evidence that preparatory simulation-based training improved overall outcomes. Bench-top training models in the form of explanted porcine models and anaesthetised animals were also suggested as suitable modes of training to reduce the learning curve in undertaking laparoscopic Roux-en-Y gastric bypass.⁸

Our training programme was designed specifically to achieve this. A two-pronged strategy was used to familiarise our unit with the procedure. We engaged the help of foreign experts through a mentorship programme on the setup and techniques in performing POEM. This was critical as POEM is a new technique in Singapore and no one else had expertise to perform this procedure. We also made use of animal models in our training, starting with porcine organs to practise on, graduating to live and anaesthetised animals. Sufficient time was also given to our unit to work as a team in performing this new procedure and to familiarise with the instruments and equipment used. We believe that this programme can be applied to the learning of other procedures and surgeries, not just for POEM.

We were able to achieve outcomes comparable to other

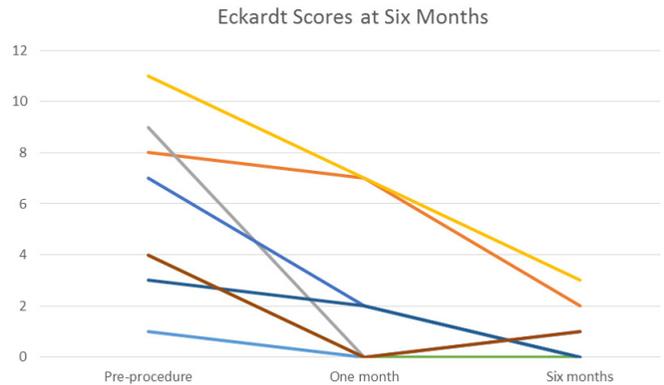


Fig. 2. Comparison of pre-, 1- and 6-months Eckardt scores. There was a statistically significant decline in the score from 5.6 to 1.3 ($P < 0.001$) and then to 0.9 ($P = 0.002$).

centres globally. At 6 months, most patients achieved improvement in their symptoms. This is concordant with other large volume centres which have achieved 98% to 100% success rates.⁹⁻¹¹ Only 1 of our patients (5.0%) suffered a serious adverse event. Our journey in the introduction of this new procedure showed that we encountered some technical difficulties in our first few cases, as well as an incorrect diagnosis of achalasia which was only discovered after POEM was performed. In spite of these initial difficulties in the first few cases, we were able to learn from these difficulties and subsequent cases were performed smoothly.

Conclusion

A structured training programme can be implemented in a safe and effective fashion to improve the outcomes of the surgical procedures in general. Our initial experience with POEM has been encouraging and should be considered in the treatment armamentarium of achalasia.

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