

# EUS-guided pancreatic drainage: A steep learning curve

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## ABSTRACT

**Background and Objective:** EUS-guided pancreatic drainage (EUS-PD) is an efficacious, acceptable risk option for patients with pancreatic duct obstruction who fail conventional ERCP. The aim of this study was to define the learning curve (LC) for EUS-PD. **Methods:** Consecutive patients undergoing EUS-PD by a single operator were included from a dedicated registry. Demographics, procedural info, adverse events, and follow-up data were collected. Nonlinear regression and cumulative sum (CUSUM) analyses were conducted for the LC. **Results:** Fifty-six patients were included (54% of male, with a mean age of 58 years). Technical success was achieved in 47 patients (84%). Stent placement was antegrade in 36 patients (77%) and retrograde in 11 (23%). Clinical success was achieved in 46/47 (98%) patients who achieved technical success. Adverse events were seen in 13 patients (6 of whom did not achieve technical success) and included bleeding requiring embolization ( $n = 5$ ), bleeding treated with clips peri-procedurally ( $n = 1$ ), pancreatitis ( $n = 5$ ), and a pancreatic fluid collection drained via EUS-drainage ( $n = 2$ ). The median procedural time was 80 min (range 49–159 min). The CUSUM chart showed that 80-min procedural time was achieved at the 27<sup>th</sup> procedure. Durations further reduced 40<sup>th</sup> procedure onward, reaching a plateau indicating proficiency (nonlinear regression  $P < 0.0001$ ). **Conclusion:** Endoscopists experienced in EUS-PD are expected to achieve a reduction in procedural time over successive cases, with efficiency reached at 80 min and a learning rate of 27 cases. Continued improvement is demonstrated with additional experience, with plateau indicating mastery suggested at the 40<sup>th</sup> case. EUS-PD is probably one of the hardest therapeutic endosonographic procedures to learn.

**Key words:** EUS-guided pancreatic drainage, pancreatic stricture, pancreaticogastrostomy, pancreatico-jejunostomy, therapeutic EUS

## INTRODUCTION

EUS-guided pancreatic drainage (EUS-PD) is a minimally invasive alternative for patients who fail conventional endoscopic retrograde pancreatography (ERP).<sup>[1-6]</sup> EUS-PD has gained increasing recognition as an alternative to surgery or percutaneous interventions for patients who fail conventional ERP.<sup>[7-16]</sup>

EUS-PD is a challenging procedure that requires access to the main pancreatic duct (MPD), creation of a fistulous tract, and deployment of a decompressing stent across the tract.<sup>[8]</sup> Numerous technical challenges have been identified in performing EUS-PD.<sup>[17,18]</sup>

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Accessing the MPD requires traversing fibrotic changes in the pancreatic parenchyma.<sup>[19,20]</sup> Other technical challenges identified are the lack of stability of the EUS endoscope in the stomach, the ability to move a guidewire through a needle to create a fistulous tract, and the ability to dilate the fistulous tract with either a balloon-dilating catheter or cautery.<sup>[19,21,22]</sup> No study has been performed on the learning curve (LC) for performing EUS-PD. The aim of this study is to define the LC for performing EUS-PD based on a single-operator experience.

## METHODS

### *Study overview*

Over a 14-year span, 56 patients underwent EUS-PD by a single endoscopist (MK) with expertise in therapeutic EUS and ERCP. All patients were included in a prospective registry. Data on patient demographics, clinical indications for procedure, procedural techniques, and follow-up information were collected. Technical success was defined as successful stent placement. Clinical success was defined as resolution of procedural indication. Adverse effects including bleeding, pancreatic fluid collections, and pancreatitis were recorded.

### *Procedural technique*

All patients were done under general anesthesia and using CO<sub>2</sub> insufflation. Antibiotics were given to all patients peri-procedurally.

A linear echoendoscope was advanced into the stomach or small bowel. Following localization of the MPD and the use of color Doppler imaging to identify regional vasculature, the MPD was punctured with a 19G fine-needle aspiration needle. A pancreatogram was performed by injecting contrast through the 19G needle, and wire access was obtained by advancing a guidewire through the EUS needle into the MPD under fluoroscopic guidance. A 0.035" hydrophilic wire was used in all cases. Fistula track creation and dilation was performed using cautery with a needle-knife catheter or 10 Fr cystotome followed by a 4-mm dilating balloon after which a stent was deployed.

### *Stent placement*

The terminology and techniques used to describe stent placement have been previously reported by our group.<sup>[17]</sup> Antegrade stent placement is in the direction toward the head of the pancreas and retrograde is toward the tail of the pancreas. In the majority of

cases, one plastic double-pigtail stent was deployed; in several cases, a fully covered metal stent was deployed.

### *Statistical analysis*

Nonlinear regression was performed to evaluate the effect of number of procedures on procedural time. LC-Cumulative sum (CUSUM) analysis was used to assess the LC for performing EUS-PD. LC-CUSUM analysis was performed similar to the modeling demonstrated by Biau *et al.*<sup>[23]</sup>

The following parameters were applied to this series: for the LC, the hypothesis H<sub>0</sub> was set with P<sub>0</sub> = 0.175 (failure rate 17.5%; process out of control) and H<sub>1</sub> with P<sub>1</sub> = 0.1 (failure rate 10%; process in control) as per standard ERCP failures rates. Type I ( $\alpha$ ) and Type II ( $\beta$ ) error rates were set at 0.1. A control limit of  $b = 2.0$  was chosen. All descriptive and statistical analyses were conducted using MedCalc V18.9 (MedCalc Software, Ostend, Belgium).

## RESULTS

In total, 56 patients (54% men; mean age, 58.0 ± 18.2 years) were included. The majority of patients ( $n = 48$ , 86%) had benign disease: 26 patients (46%) had chronic pancreatitis, 16 patients (29%) had a surgical stricture, and 6 patients (11%) had pancreatic divisum [Table 1]. The remaining eight patients (14%) had malignant obstruction. Twenty-five patients (45%) had undergone prior surgical intervention (Whipple  $n = 22$ , Roux-en-Y  $n = 3$ ). The procedures were evenly spread over the 14-year period.

### *Technical success*

Technical success was achieved in 84% of patients ( $n = 47$ ) [Table 1]. MPD was accessed in a transgastric orientation in 38 patients (81%) and a transduodenal orientation in 5 patients (11%). The stent was deployed in an antegrade manner in 36 of the 47 patients (77%): 4 antegrade transpapillary or transanastomotic and 32 antegrade transgastric. The stent was deployed in a retrograde manner in 11 patients (23%), with 5 retrograde transgastric and 6 retrograde transenteric. Except for one metal stent, all stents were double-pigtail plastic stents (range 5 F–10 F). Two patients who did not achieve technical success had a repeat attempt at EUS-PD and achieved technical success (not included in this article's technical success rate); one patient underwent surgery and four patients underwent celiac plexus block for symptom

control. All the technical failures were attempted via transgastric puncture.

### Clinical success

Clinical success was achieved in 84% of the total patients (46/56) and in 98% of patients who achieved technical success (46/47) [Table 1]. Two patients required reintervention due to stent migration with successful repeat EUS-PD. The median follow-up period was 13 months (range 1–41), with 50% of patients having follow-up for  $\geq 12$  months.

### Adverse events

The overall adverse event rate was 24% ( $n = 13$ ). Six of the 13 patients who experienced adverse effects did not achieve technical success. Adverse events included bleeding requiring embolization ( $n = 5$ ), bleeding requiring peri-procedural clips ( $n = 1$ ), pancreatitis ( $n = 5$ ), and a pancreatic fluid collection requiring EUS-guided drainage ( $n = 2$ ).

### Learning curve

The median procedural time was 80 min (range 49–159 min). The CUSUM plot showed a progressing reduction in procedural time, indicating that performance proficiency consistently improved. At the

27<sup>th</sup> procedure, a total procedural time of 80 min was achieved, indicating procedural efficiency.

Figure 1 shows the nonlinear regression curve between procedural time and number of cases. The downward slope of the curve shows progressive reduction in procedural time. Procedural durations further reduced 40<sup>th</sup> procedure onward, reaching a plateau indicating proficiency (nonlinear regression  $P < 0.0001$ ).

## DISCUSSION

EUS-PD has been described as a potential alternative for patients who fail conventional ERCP. Initial studies demonstrated a wide range of efficacy and adverse effect rates, ranging from 50% to 100% and 7% to 55%, respectively.<sup>[1-16]</sup>

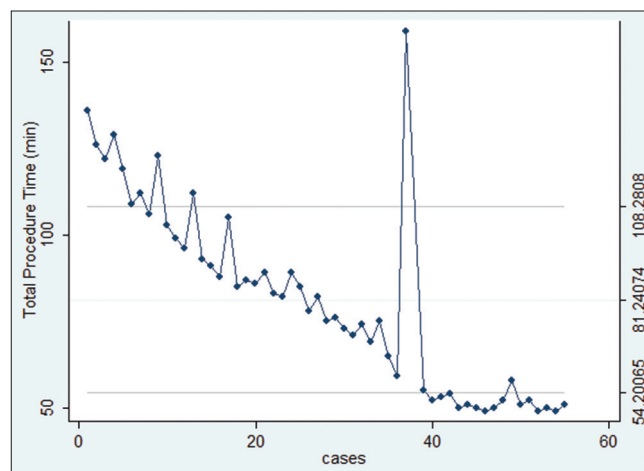
With technological improvement and increasing operator experience, EUS-PD's efficacy and safety rates have increased as well. A large, international multicentric study reported a technical success of 89%, a clinical success of 81%, and an overall adverse effect rate of 20% in eighty patients undergoing EUS-PD.<sup>[17]</sup> Chen *et al.*'s study compared EUS-PD with enteroscopy-assisted ERP in patients with post-Whipple anatomy and reported a technical success of 92.5%, clinical success of 87.5%, and an overall adverse effect rate of 35% in forty patients undergoing EUS-PD.<sup>[18]</sup>

Despite improvements in technology and increased time spent doing therapeutic EUS procedures, EUS-PD remains a technically challenging procedure for proficient echoendoscopists. Limited data exist on the LC associated with technically difficult

**Table 1. EUS-pancreatic drainage learning curve (n=56)**

Characteristic	n (%)
Age, mean (SD)	58 (18.2)
Gender - male, n (%)	29/56 (54)
Indication for EUS-PD, n (%)	
Chronic pancreatitis	26 (46)
Surgical stricture	16 (29)
Malignant stricture	8 (14)
Pancreas divisum	6 (11)
Technical success	47/56 (84)
Approach, n (%)	
Antegrade	36 (77)
Retrograde	11 (23)
Type of stent	
Plastic	46/47
Metal	1/47
Adverse events, n (%)	13/56 (24)
Bleeding	6
Pancreatitis	5
PFC with cystogastrostomy	2
Clinical success, n (%)	46/47 (98)
Procedural time (min)	80
Reintervention required	2
Mean follow-up time (months)	13.2

PD: Pancreatic drainage; SD: Standard deviation; PFC: Pancreatic fluid collection



**Figure 1.** Nonlinear regression curve of EUS-PD between procedural time and number of cases

advanced endoscopy procedures, including EUS-PD. Fujii *et al.* reported a procedural duration mean of 142 min (standard deviation [SD]: 59 min) in 32 patients who underwent successful stenting with EUS-PD and 154 min (SD: 54 min) in 11 patients who failed stenting, although the authors suggested that the reported duration times may be an overestimate due to limitations of their procedural database.<sup>[6]</sup> In their report, it was suggested that increasing experience of the endoscopists led to increasing technical success and fewer adverse effects.<sup>[6]</sup> Chen *et al.* reported a procedural duration of 55.1 min in forty patients with post-Whipple anatomy undergoing EUS-PD in an international, multicentric study.<sup>[18]</sup> In our study, CUSUM analysis showed a reduction in procedural time over successive cases, with efficiency achieved at around the 27<sup>th</sup> case. In addition, continued improvement was demonstrated with additional experience, with proficiency reached around 40 cases. CUSUM analysis has been used to evaluate the LC for trainees performing ERCP, trainees performing EUS in gastric cancer T staging, and an advanced endoscopist performing EUS-guided hepaticogastrotomy with transmural stenting.<sup>[24-27]</sup>

Our study has a few limitations. This study reports the LC of a single operator with expertise in both EUS and ERCP at a large tertiary academic center. Our study also does not separately assess the LC between patients who had benign indication for the procedure and those with malignant disease and between patients with normal anatomy and those with surgically altered anatomy based on the stent placement technique, as the procedural duration times are directly impacted by disease indication, stent placement technique, and anatomy.

## CONCLUSION

In conclusion, our study is the first study to assess the LC of therapeutic EUS of PD for various indications. Our data may form the basis for recommending the minimum number of EUS-PD procedures needed to achieve competency and mastery. Further studies with more operators, and further separation of LC s by disease indication, would help produce competency estimates and form a credentialing standard for EUS-PD training.

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## Conflicts of interest

There are no conflicts of interest.

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