—Original Article—

Learning curve for EUS-guided biliary drainage: What have we learned?

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ABSTRACT

Background and Objective: EUS-guided-biliary drainage (EUS-BD) is an efficacious and safe option for patients who fail ERCP. EUS-BD is a technically challenging procedure. The aim of this study was to define the learning curve for EUS-BD. **Methods:** Consecutive patients undergoing EUS-BD by a single operator were included for a prospective registry over 6 years. Demographics, procedural information, adverse events, and follow-up data were collected. Nonlinear regression and CUSUM analyses were conducted for the learning curve. Technical success was defined as successful stent placement. Clinical success was defined as resolution of jaundice and/or at least a 30% reduction in the pretreatment bilirubin level within a week after placement or normalization of bilirubin within 30 days. **Results:** Seventy-two patients were included in the study (53% male, mean age 67 years). Technical success was achieved in 69 patients (96%). Clinical success was achieved in 59/69 patients (86%). Seven patients (10%) had adverse events including bleeding (n = 6) and liver abscess (n = 1). The median procedural time was 59 min (range 36–138 min). This was achieved at the 32nd procedure. Procedural durations were further reduced to 50 min and below after the 50th procedure in a nonlinear pattern. This suggests that procedural durations approach a potential plateau after 100 cases. **Conclusion:** Endoscopists experienced in EUS-BD are expected to achieve a reduction in procedural time over successive cases, with efficiency reached at 59 min and a learning rate of 32 cases. Continued improvement is demonstrated with additional experience, with mastery suggested after approximately 100 cases.

Key words: biliary drainage, biliary stricture, CUSUM, ERCP, EUS-guided, EUS-guided biliary drainage, learning curve

INTRODUCTION

ERCP is the first-line therapy for pancreaticobiliary decompression with success rates >90%. However, failure can occur due to difficult patient anatomy caused by surgical alteration (Whipple, Roux-en-Y gastric bypass, and Billroth surgery), periampullary diverticulum, or malignancies that cause gastric outlet obstruction.[1-7] EUS-guided-biliary drainage (EUS-BD) is an alternative biliary drainage technique after unsuccessful ERCP.

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The procedure was first described in 2001 by Giovannini *et al.* and has since been validated as a safe and efficacious procedure in literature.[5,8,9] There are multiple approaches for EUS-BD, however the overall technique is similar, which involves direct access to the biliary tree via fine-needle aspiration needle, guidewire placement under endosonographic and fluoroscopic visualization, creation of a fistulous tract, and finally stent placement.[6]

Although a minimally invasive procedure, EUS-BD is a highly technical skill that requires specialized training. Adverse event rates have been reported to be between 3.5% and 38.6% due to bile leak, bleeding, cholangitis, perforation, sepsis and peritonitis, and stent migration.[10,11] According to the American Society of Gastrointestinal Endoscopy, proficiency in EUS recommends a minimum of 150 supervised cases to be performed, however no definition for proficiency has been established for EUS-BD. The aim of this study was to define the learning curve for EUS-BD.

METHODS

Study overview

Consecutive patients undergoing EUS-BD by a single endoscopist with expertise in therapeutic EUS and ERCP (MK) were included from a prospective registry over 6 years. The patient demographics, procedural information, adverse events, and follow-up data were collected. Technical success for EUS-BD was defined as successful biliary stent placement. Clinical success was defined as resolution of jaundice and/or at least a 30% decrease in pretreatment bilirubin level within a week after stent placement or normalization of bilirubin within 30 days of stent placement.

Procedural technique

All procedures were done with the patients under general anesthesia. All patients received antibiotics peri-procedurally. A linear echoendoscope was advanced into the stomach or duodenum. Biliary access was obtained either from the stomach into the intrahepatic (IH) biliary tree or from the duodenum into the extrahepatic (EH) biliary tree using an algorithm based on patient anatomy.[12] The biliary tree was accessed by a 19G fine-needle aspiration needle, after which a cholangiogram was obtained. A wire was then advanced into the biliary tree, transpapillary if feasible. Fistula tract creation was performed using a cautery followed by a dilating balloon, after which a stent was deployed. In one case, after the cholangiogram was obtained, the wire was unable to be advanced into the biliary tree. However, conventional ERCP was able to be performed using the cholangiogram.

Statistical analysis

Consecutive patients undergoing EUS-BD drainage by a single operator were included for statistical analyses from a prospective registry over 6 years. Demographics, procedural info, postprocedural follow-up data, and adverse events were collected. Nonlinear regression and CUSUM analyses were conducted for the learning curve using Stata 15 (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC).

RESULTS

A total of 72 patients were included in this study: 53% male, mean age 67 years. Fifty-six patients (78%) had malignant obstruction, 16 (22%) had benign obstruction, and 3 had cholangitis from benign cause [Table 1]. Multiple approaches were performed for biliary stent placement: 32 IH anterograde, 24 EH rendezvous, and 16 hepaticogastrostomies, which also included an indirect

Table 1. Demographics on the study population (*n*=72)

Characteristics	*N* (%)
Age (years), mean (SD)	67.1 (12.4)
Gender - male, *n* (%)	38/72 (53)
Indication for EUS-BD, *n* (%)	
Malignant	56 (78)
Benign	16 (22)
Cholangitis	3 (4)
Technical success, *n* (%)	69/72 (96)
Approach, *n* (%)	
IH antegrade	29/69 (42)
EH Rendezvous	12/69 (17)
Hepaticogastrostomy	16/69 (23)
Choledochoduodenostomy	11/69 (16)
Other	1/69 (1)
Stent placement, *n* (%)	
Transpapillary/transanastomotic	42/69 (61)
Transluminal	27/69 (39)
Stent type, *n* (%)	
Metal	57/69 (83)
Plastic	12/69 (17)
Adverse events, *n* (%)	7/72 (10)
Bleeding - IR embolization	3
Bleeding - conservative	2
Bleeding - death	1
Liver abscess	1
Clinical success, *n* (%)	59/69 (86)
Median procedural time (min)	59

*All Benign. BD: Biliary drainage; IH: Intrahepatic; EH: Extrahepatic; IR: Interventional radiology.

rendezvous when EUS-BD provided a cholangiogram without advancement of the wire after which conventional ERCP was performed. Forty-two stents were transpapillary (61%) and 57 stents were metal (83%).

Technical success was achieved in 69 patients (96%). Clinical success was achieved in 59/69 patients (86%): 28 patients had resolution of jaundice, 26 patients had improvement in bilirubin by 30%, and 5 patients had resolution of initial indication for biliary drainage. Of the ten patients who did not achieve clinical success, five were lost to follow-up or passed away <1 week postprocedure (unrelated to the procedure) and five had no change. Seven patients (10%) had adverse events. Six patients had peri-procedural bleeding, of which three required embolization by interventional radiology, one was managed with clips, one was managed with observation alone, and one died on the procedure table. One patient developed a liver abscess that was drained percutaneously.

The median procedural time was 59 min (range 36–138 min). The CUSUM chart demonstrated that a 59-min procedural time was achieved at the 32nd procedure, indicating efficiency after 32 procedures [Figure 1]. Procedural times further reduced after the 50th procedure, with durations remaining at 50 min or below (nonlinear regression $P < 0.0001$) [Figure 2]. This suggests that a potential plateau may be achieved after about 100 cases, indicating mastery.

DISCUSSION

Currently, there is little data showcasing the learning curve for EUS-BD since its introduction in 2001. However, literature has shown higher technical and clinical success rates and lower complication rates in more experienced endoscopists compared to early endoscopists. In a study comprising of 31 cases, the failure rate of EUS-BD was 38% during the first 3 years of training and 11% in the last 2 years of training.[13] In a Spanish national survey that included data from less experienced endoscopists performing EUS-BD, the technical success rate was 67.2%, which was lower than previously reported data in more experienced endoscopists.[14] In a single-center study on the cumulative experience of EUS-BD by a single operator for obstructive jaundice, there were five procedure-related deaths in the first fifty patients during the first 5 years, and there was one procedure-related death in the last 51 patients during the last 2 years among 101 patients in the 7-year study.[15] Because there is an observed learning curve, Hara *et al.* suggest endoscopists perform at least the first twenty cases under a mentor's supervision.[16] To better define the learning curve for EUS-BD, this study looked at the cumulative experience of a single operator over the course of 6 years.

The overall technical success rate for EUS-BD was 96%, which was comparable to previously reported success rates for EUS-guided hepaticogastrostomy (EUS-HGS) and EUS-guided choledochoduodenostomy (87% and 50%–100%, respectively) and higher than the pooled technical success rate of 89.18%.[10,17,18] Clinical success was achieved in 86% of patients, which is similar to the published clinical success rates in literature (87%–100%).[10,16] The adverse event rate was 10%, which was on the lower end of the reported adverse events in other studies (10%–30%).[5,14,16]

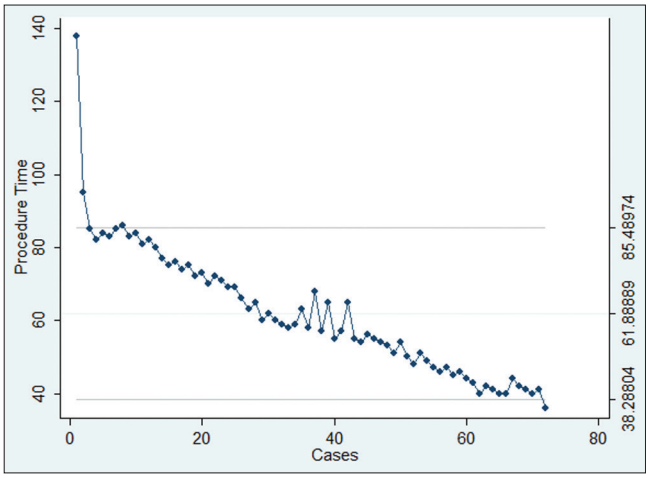

Figure 1. CUSUM chart

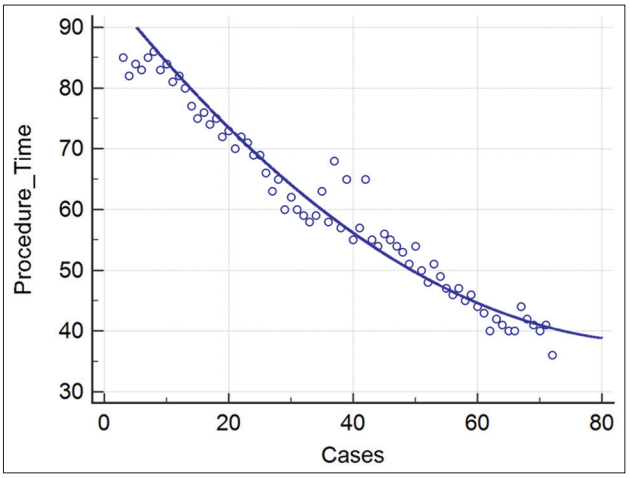

Figure 2. Nonlinear regression

In this study, the single endoscopist's procedural times were correlated with the number of cases performed. On the CUSUM analysis, the single operator achieved efficiency with a procedural time of 59 min after the 32nd case. With cumulative experience, the procedural times eventually reduce in a nonlinear pattern after the 50th procedure, suggesting that there is a potential plateau and achievement of mastery of EUS-BD after approximately 100 cases. This was more than the number of procedures to achieve technical proficiency in Oh *et al.*'s study, which required 24 cases to reduce procedural times to 30.1 ± 13.1 min and 33 cases to stabilize for procedural times.[18] This difference can potentially be attributed to the fact that the study focused on EUS-HGS alone and did not include the other EUS-BD techniques, similar to the current study.

Factors that affect the procedural time and therefore the learning curve include patient factors and operator factors. Patient factors include surgically altered anatomy or complex biliary strictures that make it difficult for the guidewire to pass and insufficient IH bile duct dilatation that may make correct biliary puncture challenging.[15,17] There are multiple endoscopist- and procedure-related factors that contribute to the learning curve. Itoi *et al.* mentioned that although the bile duct appears close to the gastrointestinal wall under EUS, there is some displacement between the puncture site of the gastrointestinal wall and bile duct, potentially resulting in failure of the procedure.[19] The next and most challenging step is guidewire manipulation into the bile ducts, which requires identifying an appropriate plane and insertion into the biliary duct that may have an angular offset.[14,17] If the guidewire is advanced into the peripheral biliary tract, then dilation and stent placement cannot be performed properly.[20] Certain techniques may also be intrinsically more difficult than others, such as EUS-HGS compared to EUS because it requires a relatively stable scope position and a fixed biliary access point.[18] Given the complexity of EUS-BD, repeated number of procedures are needed to familiarize with the technical maneuvers involved.

CONCLUSION

Therapeutic EUS is a highly technical skill that requires specialized training. Proficiency of EUS can only be obtained through execution of numerous cases. In this study, it was determined that endoscopists experienced in EUS-BD are expected to achieve a reduction in procedural time over successive cases, with efficiency reached at 59 min and a learning rate of 32 cases. Continued improvement is demonstrated with additional experience, with mastery suggested after approximately 100 cases.

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Conflicts of interest

There are no conflicts of interest.

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