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EUS-guided gallbladder drainage: is it so easy?

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Over the last few years, we have seen an increasing number of reports about use of endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) as an option for drainage of the gallbladder in patients suffering from acute cholecystitis who are at high risk for cholecystectomy [1]. Other indications for the procedure include conversion of permanent cholecystostomy to internal drainage or drainage of the biliary tract when endoscopic retrograde cholangiopancreatography and EUS-guided biliary drainage fails [2–4]. Multiple studies and meta-analyses have shown that the procedure is associated with reduced adverse events (AEs), reinterventions and re-admissions [5–9]. Nevertheless, the procedure is still mostly performed in tertiary centers with vast experience in interventional EUS and the learning curve for it is still undefined.

In the current study by Tyberg et al [10], outcomes in 48 patients who received US-GBD by a single operator over a 5-year period were reported. The gallbladder was drained using a variety of stents including lumen-apposing stents (LAMS) (37.77 %), fully-covered self-expanding metal stents (FCSEMS) (19 %) or plastic stents (4 %). AEs occurred in 19 % of patients and evenly throughout the study period. Median procedural time was 41 minutes and was achieved on the 19th procedure. Procedural duration declined further, with the last 10 procedures taking 20 minutes or less. The authors concluded that the learning curve for EUS-GBD should be around 19 cases.

The amount of experience required to obtain competency with a procedure is an important concept, as it is vital for standardization and credentialing purposes. However, many factors could influence the learning curve for a procedure, including the endoscopist's prior experiences, institutional volume, presence of prior training on models, and availability of dedicated devices. Thus, to measure what makes the individual competent for a procedure is extremely difficult, given that many of these factors may introduce different biases. Hence, investigators often have to resort to measuring surrogate outcomes like procedure time and AEs to quantify the learning curve for a procedure.

In another recently published manuscript on the learning curve of gallbladder drainage, the authors attempted to quantify the number of procedures required to gain competency by comparing outcomes of EUS-GBD in endoscopists experienced with fewer than 25 versus 25 or more procedures [11]. The authors also had an interesting outcome parameter that is known as unplanned procedural events (UPE). UPEs were defined as any deviations of the procedure from the planned steps. These events include dislodged guidewires or mis-deployment of the stents, where subsequent proper placement of the stent may not lead to any clinical sequalae. UPEs are a new classification of events that are particular to interventional EUS procedures and do not occur in other endoscopic procedures. In this study, UPEs were significantly more common in patients with EUS-GBD performed for conversion of cholecystostomy ($P<0.001$); and by endoscopists with experience with fewer than 25 procedures ($P=0.033$). Both presence of clinical failure ($P=0.014$; RR 8.69 95 %CI [1.56–48.47]) and endoscopist experience with fewer than 25 procedures ($P=0.002$; RR 4.68 95 %CI [1.79–12.26]) were significant predictors of 30-day AEs. Presence of 30-day AEs was a significant predictor of mortality ($P<0.001$; RR 103 95 %CI [11.24–944.04]). The authors concluded that the number of cases required to gain competency with EUS-GBD by experienced interventional endosonographers was 25 procedures.

Both of the above studies have flaws in the method of measuring learning curves. The procedures were also performed by highly experienced and specialized endoscopists, and outcomes reported may not be applicable to those just beginning the procedure. Nevertheless, they still provide some guidance as to the minimal number of procedures required to gain competency with EUS-GBD. In those already experienced in interventional EUS, the number should be around 19 to 25 proce-

dures. However, apart from mere numbers, when learning a new procedure, perhaps the more important aspect is to follow a standard protocol. An example could be starting with understanding background about the procedure, followed by hands-on training in ex-vivo or animal models, and then observing the procedure being performed in humans, followed by performing the procedure under supervision by those experienced in the procedure [12]. Only by introducing new procedures in a stepwise manner can we continue to educate our junior colleagues without jeopardizing patient safety.

In conclusion, EUS-GBD is gaining popularity as the procedure of choice in treatment of acute cholecystitis in patients who are at very high risk of surgery. To introduce the technique effectively and safely to the wider endoscopic society, a standardized training program is essential. Thereafter, we should validate the numbers required to gain competency by trainees who have undergone these training programs.

Competing interests

Prof. Teoh is a consultant for Boston Scientific, Cook, Taewoong and Microtech Medical Corporations.

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