Design and validation of a therapeutic EUS training program using a live animal model: Taking training to the next level

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ABSTRACT

Background and Objectives: EUS has evolved into a therapeutic modality for gastrointestinal disorders. Simulators, ex vivo models, and phantoms are the current teaching methods for therapeutic EUS (TEUS). We create and evaluate a high-fidelity simulated live animal model (HiFi SAM) for teaching endoscopists TEUS. Materials and Methods: Designing a curriculum that uses HiFi SAM and enables trainees to perform realistic procedures with expert mentors. Results: Twenty-seven trainees participated in a 3-day program with 6 h of theoretical and 14 h of hands-on using life HiFi SAM. Eighteen experts participated. Twenty-two (20–25) TEUS were defined for each HiFi SAM, and 616 were performed in all. Of 616/264 (43%) were evaluated with a mean of 88 per course (ranging between 80 and 95). Ninety-one percent (240/264) of the procedures were completed successfully. In 24, success was not achieved due to technical and/or model problems. Student rating of HiFi SAM was: 71% excellent rating (scale 8–10) and 95% excellent/good. The HiFi SAM procedure evaluation was (scale 1–5): fine-needle biopsy: 4.79, radiofrequency: 4.76, common bile duct and gallbladder drainage: 4.75, cystic drainages: 4.72, neurolysis: 4.55, microbiopsy: 4.50, and hepatogastric drainage: 4.04, with an overall satisfaction rate of 4.56 (91%). A short survey showed: 83% would recommend absolutely (17% most likely), 33% think that ITEC training was sufficient for their practice, and 66% would like additional training, especially more practice in specific techniques rather than more clinical case discussion. Regarding impact on their practice, 66% of the trainees started a new procedure and/or noted improvement in previous ones. Conclusion: HiFi SAM is a complex model; however, experts and trainees are satisfied with the training this new curriculum provided.

Key words: education, EUS, FNA, fine-needle biopsy, radiofrequency, teaching, training

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INTRODUCTION

First used as a diagnostic tool for local tumor staging and the characterization of mucosal and submucosal lesions, 30 years on EUS has evolved into a valuable therapeutic modality for gastrointestinal and nondigestive disorders, transforming many surgical procedures into minimally invasive endoscopic treatments. With the development of more specific accessories, its applications have extended to all the digestive areas and organs in the mediastinum, the abdomen, the retroperitoneum, and the pelvic space.[1-4]

Because cases are concentrated in tertiary referral centers, the therapeutic EUS (TEUS) learning process is difficult and costly as the physician is required to spend several weeks at the teaching hospital to gather experience, which is often only observational due to regulation policies in each country.

Simulators, ex vivo models, and phantoms are the current teaching methods for TEUS training. Many short courses, sometimes conducted by endoscopic societies at international congresses, train using porcine ex vivo models. This results in limited learning of diagnostic and TEUS applications such as EUS-guided fine-needle aspiration (FNA)/fine-needle biopsy (FNB), radiofrequency, and EUS-guided cystic drainage. It is evident that such courses contribute little to get practitioners beyond the learning curve. In 2001, the American Society for Gastrointestinal Endoscopy (ASGE) advocated that the minimum number of supervised pancreatic EUS was 150 with 50 FNAs to achieve proficiency in this technique. Different guidelines for EUS qualifying training have also been proposed. Ten years later, the British Society of Gastroenterology recommended to add 100 cases to the ASGE suggestion, thereby proposing that 250 cases were necessary for good quality training when starting with EUS with: 80 endoluminal cancers, 20 gastrointestinal submucosal tumors, and 150 pancreatic biliary lesions. Currently, 75 FNAs are recommended, including 45 pancreatic carcinomas. However, the number of assisted FNA has been linked to the initial number of complications. Doubling from 100 to 200 procedures showed a decrease in complications, therefore many advocates for more mentored biopsies before starting alone.[5-13]

Moreover, in 2006, EUS training centers showed a range of 50–1100 procedures performed by their fellows with a mean of 200; at that time, 48% had achieved the ASGE-recommended 150 examinations.

In TEUS, one problem is where, when, and how does one access appropriate training? Training centers remain scarce in the United States and in each European country; most are booked in advance for fellowship programs in relation to their university teaching courses. Few centers teach with live animal models. Generally, they use a normal pig to allow endoscopists to familiarize with normal EUS features and to perform biopsies (FNA/FNB) among normal liver and pancreatic tissue and some celiac reactive lymph nodes. Some centers have created biliary dilation for certain types of drainage, with a few descriptions available in current literature. Live models are very expensive and life is precious, so every living model must be used to the maximum. Therefore, more workshops with teaching platforms for TEUS with ex vivo porcine models are being proposed for participants. However, these courses are not widespread and regular training is required. Furthermore, there are many endoscopists in the world performing endosonography and/or interventional endoscopy without TEUS because their training took place when EUS had just been introduced to postgraduate courses, mainly as a diagnostic tool.[11,14-16]

A live standardized simulated model for TEUS has not been established. Learning EUS depends on numbers, techniques, indications, contraindications, and adverse events. Experts recommend at least 6–24 months of hands-on experience to achieve proficiency.

We report on the design and validation of a high-fidelity simulated live animal model (HiFi SAM) for teaching experienced interventional endoscopists from diagnostic EUS to TEUS during an international TEUS course (ITEC).

MATERIALS AND METHODS

We designed a training curriculum for TEUS that uses HiFi SAM and enables trainees working in paired groups per EUS working station to perform many realistic procedures during 3 days with expert mentors selected from different countries to represent worldwide approaches.[17,18]

Materials and Methods

1. EUS workstation: One video processor with an EG38-J10UT (PENTAX Medical, Europe) echoendoscope (4.0-mm diameter working channel), one console of Ultrasound Arietta V70 (HITACHI
Medical, Europe), and one X-ray Cios FUSION mobile C-arm (Siemens Inc., USA). Four workstations were used for each course.

2. Participant doctor (trainee): endoscopists, gastroenterologists, or surgeons with at least 3 years of EUS diagnostic FNA and/or FNB experience and one optional accompanying nurse or doctor who will observe and assist all procedures.

3. HiFi SAM: Is a live high fidelity simulated (modified) porcine model with:
   - Biliary tract obstruction: The model was operated 48 h prior to the course. Under anesthesia, in 20–30 min with a colonoscope (KARL STORZ flexible silver scope® series, CA, USA) fixation of the major biliary papillae was performed using several metallic hemostatic clips achieving a long-lasting extrahepatic dilation (EHBO-bile duct/cystic duct and gallbladder) [Figure 1].
   - Submucosal fake tumor: Endoscopic preparation at noon, each swine had three submucosal pseudotumors (fake) created and used for FNB. A 22-g EUS-guided needle was used to inject 1 cc of saline solution and then 15 cc of a hydrogel preparation (Science et d’Ingénierie Supramoléculaires ISIS, University of Strasbourg, Prof. Luisa De Cola) into the submucosal space.
   - Ex vivo and in vivo intra-abdominal collections: Three meters of swine intestine with long meso was harvested before the training session and were cleaned with drinking water and frozen. Twenty-four hours before preparation, the intestines were defrosted and prepared with a special author liquid recipe. They were placed on the posterior gastric wall, each 3–5 cm long and liquid filled without air to be used for endoscopic cystic drainages. During swine surgery, 40 cm of a defunctionalized distal ileum loop was raised to the greater curvature of the stomach, filled with a special author liquid recipe, and fixed to be used for endoscopic cystic drainages.
   - Intra-abdominal reactive lymph nodes were used for fiducial placements, FNB biopsy, and radiofrequency endoscopic ablation.

Animals and ethics
A domestic Swine (Sus scrofa domesticus) was used as a live animal model. All animals are under general anesthesia during experiments and euthanized/sacrificed at the end of the hands-on session. They were manipulated according to the European Directive 2010/63 and French laws concerning animal protection in laboratories. Procedures were approved by the local Ethical Committee and authorized by the French Ministry of Education, Research and Innovation under protocol notification number: 16259-2018072416083965 v1.

Animal preparation and drug administration
Five days prior to the hands-on session, animals are prepared according to the following instructions: (a) Reception from the breeder and acclimation in laboratory animal facilities under veterinarian supervision. (b) Controlled diet with water and standard pellets. (c) 48 h prior to the hands-on session, they only received liquid food (Fortimel), sucralfate, 40 mg of omeprazole, and ursodeoxycholic acid. (d) Before surgical procedures, animals are sedated in their pen with IM injection of tiletamine + zolazepam and transferred to the operative room. Anesthesia is induced by IV injection of propofol 3 mg/kg (Propofol Lipuro 1%, B. Braun, Germany) and rocuronium 0.8 mg/kg (Esmeron ND, MSD France, France) to allow intubation and mechanical ventilation. General anesthesia is then maintained by inhalation of isoflurane 2%–3% (Isoflurin® ND, Axience, France) in a mix of O2/NO2 50%/50% 2 L/min. Perfusion of NaCl...
0.9% 10 mL/kg/h is continuously infused through the marginal ear vein. Antibiotics and analgesics are injected before the beginning of the surgical procedures on hands-on day. Animals are monitored during the experiment for temperature, heart rate, oxygen saturation, and capnography, to adapt anesthesia and pain management.

**Surgical preparation**
The swine was ready for the course after 2 days and was prepared in 45 min by a team of two surgeons. Preparation consisted of:
1. Ligation of the left ureter;
2. Placement and attachment of *ex vivo* collections posteriorly to the stomach;
3. Placement and attachment of *in vivo* collections lateral to the stomach;
4. Fixing the stomach;
5. Cystic duct ligature;
6. Closure of the abdominal wall;
7. Swine in left lateral decubitus position, gastroscopy to identify possible complications, and overtube (Steris Endoscopy, USA) introduction to protect esophagus during further training procedures;
8. Before hands-on session, gastric mucosa and localization of collections are controlled by EUS (expert). Then, to simulate real clinical practice, a contrast multi-slide scan with arterial and early venous portal phase was performed and showed to the doctor trainees before starting all procedures. This image shows a 3D reconstruction performed by Visible Patient® after scan to evaluate the models:

**The following EUS-guided interventions were performed**
1. EUS-guided biliary drainage with direct transgastric or transesophageal (hepaticogastrostomy or hepatoesophageogastrostomy or choledochogastrostomy) routes involves stenting for transmural biliary drainage, avoiding biliary access via the papillae (clipped 24–48 h before)
2. EUS-guided transgastric gallbladder drainage
3. EUS-guided enteral-enteral anastomosis (gastroenteroanastomosis)
4. EUS-guided drainage of abdominal perigastric fluid collections (cyst gastrostomy)
5. Through-the-needle intracystic microbiopsy forceps technique in the gallbladder or the collections
6. Lymph nodes and pancreatic fiducial placement
7. Celiac plexus interventions
8. EUS-guided radiofrequency ablation (coagulative necrosis)
9. EUS-guided intravascular coil and glue placements
10. FNA and FNB of lymph nodes, pancreas, liver, and gastric submucosal fake tumor [Figures 2-8].

**Quality analysis of the course**
During all TEUS courses, participants and experts analyzed each procedure in terms of quality and educational satisfaction. Each intervention was evaluated simultaneously using a structured survey administered by a nonexpert observer. Data included demographics and procedure details as well as the value and quality ranked using a Likert scale. A global evaluation of the procedures, including realism and the use of simulation-based education, was recorded by the trainees and experts in the form of written comments. All data were registered and analyzed by two blinded surgical educators. Experts and trainees used two scales: from 1 to 5 in the course evaluation form and from 1 to 10 in procedure skills assessment form.

**Course structure**
The course consists of a half-day theoretical session and two and a half days of practical sessions. First, 3 h of *ex vivo* training took place with four participants and two experts using EndoSim systems for lumen apposing metallic stent training as well as plastic stents with cystic drainage from the stomach of a porcine model. Next, each two participants were attributed a mentoring expert in TEUS and performed procedures over 2 days with each 7 h of hands-on training. Experts rotated in the morning and in the afternoon for different stations while participants worked at the same station without rotating for the entire day using one HiFi SAM to accomplish a maximum number of the procedures that had been assigned.

**Figure 2.** In green color, you see the extrahepatic biliary tree dilation (common bile duct = 20 mm). In yellow color, few *in vivo* collections with red vessels at the greater curvature and without vessels the *ex vivo* collections located at the posterior gastric wall. In blue color, the esophagus-the stomach and the duodenum. In purple color, the pancreatic gland.
The same model was used for all procedures. Procedures were performed in order of difficulty and of risk of complications for the swine. First cystogastrostomy was done through the posterior wall of the stomach using metal and plastic stents, then microbiopsy of the gallbladder and drainage were performed and thereafter, hepaticogastrostomy or hepaticoesophagostomy drainage (swine anatomy), going from simplest to the hardest. In the afternoon, FNB of gastric submucosal tumors that were created at noon was performed and also procedures from numbers 6–10 were done including more cystogastrostomy drainage. When the left kidney drainage was possible it was used to simulate an intrahepatic bile duct drainage. All materials were supplied by: Starmed – Taewoong Medical, South Korea; Cousin – Endosurg, France; Cook Medical, Europe; Boston Scientific, USA; Steris Endoscopy, USA; ERBE Elektromedizin, Europe; Life Partners, France; and M.I. Tech, South Korea.

At the end of the hands-on session, animals were sacrificed with a lethal IV injection of pentobarbital 40 mg/kg (Hexagon ND, Axience, France).

RESULTS

Three ITEC courses were run between May 2019 and February 2020. A total of 27 trainees participated in the 3-day programs. Each program had 6 h of theoretical conferences with prerecorded clinical cases and 14 h of hands-on training using: an ex vivo models from Endo Sim® for 2 h and HiFi SAM (IHU-Strasbourg) model for 12 h, all in our experimental platform. Eighteen experts participated in these training courses: 16 of them were international faculty from the USA, France, Belgium, Italy, Denmark, Ecuador, and Venezuela and 2 were local. In total, 28 HiFi SAM weighing 45–50 kg were prepared: 10 for two courses and 8 for one course [Figure 3 – February course].

All experts and trainees found the course interesting and interactive. The average age range was 35–58 years old for participants and 45–64 for experts. The procedure median time was 22 min (5–48 min). Participants had different backgrounds in EUS: 60% performed both radial and linear techniques, 35% only linear, and 5% only radial. The participant average EUS diagnostic experience was 4.43 years and FNA experience 3.9 years. Needle preference was 58% for 22 g and 42% for 20 g; all used 19 g and only 17% used other sized needles. Some trainees had performed EUS therapeutic procedures before the course: half of them drainage type, a quarter necrosectomies, and less than one-sixth biliary drainage. Regarding their expectations: all expected to perform FNB, cystic
A total of 22 (20–25) TEUS procedures were possible in each HiFi SAM, therefore, 616 TEUS were performed. The 22 TEUS procedures included: 6 collections for drainages, 1 distended gallbladder, 1 dilated common bile duct (CBD), 1 left intrahepatic biliary dilation, 1 left pyelocalyceal kidney dilation, 4 radiofrequency targets, 1 fiducial placement, 6 FNB targets, and 1 glue ± coil embolization. The simulated lesions planned were: 182 collections (6–7 per swine), 28 gallbladders, 28 CBDs, 28 left livers and left kidneys to drain and 84 gastric submucosal tumors with hydrogel, 154 (5–6 per swine) reactive lymph nodes to treat or biopsy, 28 pancreas for 28 fiducial placements, and 84 FNB. A mean of 26 TEUS per day per station was performed; in some stations, two swine were used in 1 day due to swine complications and early euthanasia. Of 616 procedures, 264 (43%) were independently evaluated by an assistant doctor–endoscopist with little or no experience in EUS [Figure 1 not for publishing]. Each course had a mean of 88 procedures (ranging between 80 and 95) evaluated, 11 ± 2 procedures per trainee had a main operator, and 11 ± 2 procedures more as an assistant, therefore, a total of 22 ± 2 procedures per participating...
team of 2 trainees (there were a 3-trainee team in each course with fewer procedures than average per trainee = 7).

Overall, 91% (240/264) of the procedures were completed successfully. In 24 procedures, success was not achieved due to technical and/or model problems. Results of the questionnaires were: general quality of HiFi SAM: 71% excellent rating (scale 8–10), 24% good (scale 7–4), and 5% poor (scale 1–3). The quality of the models was judged excellent or good in 95% of the assessment forms. In 12 (5%) assessment forms, the HiFi SAM was rated poor in some swine because the sausages used as targets had a high-fat content (too white to see), the collections were not well attached to the stomach wall (very loose), normal pancreatic duct was not accessible (not visible), no rendezvous due to clipped papillae was always the case, no gastrojejunal anastomosis was possible due to bowel movements (instability), left kidney drainage was not possible due to gastric movements (untargeted kidney), difficult collections due to increased echogenicity (great heterogenicity), difficult gallbladder drainage due to intrahepatic position, and finally, insufficient intrahepatic left ductal dilatation was achieved.

The global evaluation (trainee and expert) of the course was collected using a 7-category questionnaire with scores on a scale from 1 to 5: recommendation: 4.91, appreciation: 4.73, presentations-lectures-cases: 4.72, satisfaction: 4.71, HiFi SAM: 4.40, ex vivo model: 4.39, and useful techniques: 4.08. Successfully completed procedures by participants were cystic (collections), gallbladder, and CBD drainage: 100%; radiofrequency: 100%; FNB: 100%; hepatic gastric drainage: 70%; intracystic microbiopsy: 70%; and neurolysis: 50%. However, when questioned as to what procedures they felt, they had learned: cystic drainage: 94%, FNB-radiofrequency and microbiopsy: 88%, CBD and gallbladder drainage: 83%, hepatogastric drainage: 71%, and neurolysis: 53% with an overall learning satisfaction of 81%.

The HiFi SAM evaluation in terms of procedures was (scale 1–5): FNB: 4.79, radiofrequency: 4.76, CBD and gallbladder drainage: 4.75, cystic drainages: 4.72, neurolysis: 4.55, microbiopsy: 4.50, and hepatogastric drainage: 4.04, with an overall satisfaction rate of 4.56/5.00 (91%). Useful imaging techniques were evaluated from 1 to 5 as follows: doppler: 4.94 and elastography: 2.92 Sonovue contrast media was not always evaluated. Other parameters were also evaluated:
quality of technical assistance: 4.83, resources facilities: 4.76, endoscopic accessories: 4.60 and needle-type selection: 4.66. February course example is shown in Figures 4 and 8.

After the COVID-19 pandemic, we send a short survey to our trainees for follow-up. Thirty percent of them responded. Eighty-three percent recommended the course absolutely (17% most likely). 33% thought that ITEC training itself was sufficient for their practice, and 66% would like additional training, specifically more practice in specific techniques rather than more clinical case discussion. Half of the trainees are doing more than 10 TEUS procedures per month and the other half less than 10 TEUS per month in their hospitals. The course helped decrease referrals to other centers and increase patient recruitment and broaden therapeutic options and vision for patient care in 40% of the trainees. One felt much more confident with TEUS. Gallbladder drainage, radiofrequency ablation, and glue embolization were new procedures. FNB was ameliorated technically. 66% of the trainees started a new procedure and/or improved their practice of established ones. The group from the February course had no opportunity to do any cases due to COVID-19 pandemic in their countries.

DISCUSSION

EUS is difficult to learn and has a steep learning curve. Author Mohamad A. Eloubeidi described the link between EUS-guided FNA of solid pancreatic masses and defined a learning curve of 300 consecutive procedures to meet qualification requirements. Learning TEUS is equally difficult, and the problem is compounded by the ever-growing list of new EUS-guided therapeutic procedures. We describe our HiFi SAM that allowed endosonographers and/or interventional endoscopists to learn TEUS procedures during a 3-day training course, with the goal of helping them to shift from mostly diagnostic EUS to more interventional practices. The HiFi SAM was used to access and drain biliary ducts (intra- and extrahepatic), gallbladder, liquid perigastric collections of different echogenicity (in vivo and ex vivo), celiac plexus neurolysis, fiducial marker placement, radiofrequency ablation of pancreatic tissue or lymph nodes, and vascular coil and glue embolization. All TEUS procedures represent the standard of care today.[12,19,27]

In comparison to other ex vivo models and in vivo models used for EUS teachings,[12,26,27] our model is complex to prepare (two interventions and medical treatment), but this allowed us to reproduce pathological conditions found in patients. Furthermore, our course had available imaging modalities such as multi-slice contrast-enhanced scanner and 2D radiology C-arm images as would be used in clinical interventions. From 616 procedures performed, 264 were evaluated for success, quality of the model, and difficulties. All of our parameters scored above 4.2 points in a scale from 1 to 5 by all experts and trainees. We demonstrated with this study that training in TEUS is possible with high-fidelity modified (simulated) swine model allowing a high number of procedures in short period of time under the tutoring of a EUS expert.

Today, the availability of expert mentors is not easy due to cost and access. For TEUS training, certain doctors will go to referral centers for observational training with an expert for several months, and this is probably one of the most widespread learning methods in interventional endoscopy. Accessibility to hands-on clinical training is more and more scarce due to increasingly restrictive laws worldwide. Finally, most of the official university programs are already full and are mainly aimed at newly qualified endoscopic gastroenterologists or surgeons who have just completed their residency program.[28-32]

The HiFi SAM was used in the context of a 3-day training curriculum called the ITEC targeted to doctors who would benefit from an international faculty’s expertise and a high-fidelity hands-on experience during a 3-day program. The major drawback to this program is its cost and resource-heavy nature that may not be universally transferable. For each workstation, a minimum of 6 persons is required: one expert, two doctor trainees, a radiology technician, a specialized assistant nurse, and an endoscopist doctor to collect all the evaluation data, without counting the important participation of endoscopic companies’ staff assisting with material supplies and providing advice on the use of equipment in relation to the various procedures. During the preparation of the models, issues such as improper positioning of the collections or poorly attached collections to the stomach would happen sometimes, as is seen in Figure 9.

The objective was to develop a new teaching aid for interventional endoscopy and EUS as a tool, thereby allowing experienced endosonographers and interventional endoscopists to learn on live models, to
use different EUS approaches to be able to progress toward better technique, and to have the opportunity of discovering the amazing range of EUS therapeutics to date.

TEUS is the result of a significant evolution of diagnostic EUS, and this type of teaching will provide a valuable resource to the next generation of future endosonographers. As illustrated in the management of pancreatic pathologies, it is highly likely that no interventional endoscopist will be able to work without mastering TEUS procedures in future. Training under conditions that directly mimic human procedures with expert mentoring is fundamental to achieving this goal. At the IHU-Strasbourg, the HiFi SAM was integrated with a training curriculum called the “EUS Therapeutic Program (ITEC)” and received a good reception over the last 2 years.

CONCLUSIONS

We present a new training paradigm aimed at current practitioners of EUS who wish to advance their practice by introducing more complex therapeutic procedures. The course includes a variety of procedures with expert doctors and students, didactics, and a very high-definition simulated live animal model that allows many realistic interventions to be performed. The students and the experts reported high satisfaction with the course and the model, and most importantly, the majority reported introducing new procedures into their practice or improving older ones. However, we recommend that this type of training should be limited to endoscopists experienced in endoscopic retrograde cholangiopancreatography and EUS to achieve complete training.

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Conflicts of interest

Carlos Robles-Medranda, Peter Vilmann, Alberto Larghi and Mouen Khashab are Editorial Board Members of the journal. The article was subject to the journal’s standard procedures, with peer review handled independently of these editors and their research groups.

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