Evaluation of an all-in-one hybrid model (EUS Magic Box) for stepwise teaching and training in multiple interventional EUS procedures

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ABSTRACT
Background and study aims While multiple interventional endoscopic ultrasound (EUS)-guided procedures have evolved over the past two decades, there is no model that allows for training in all of these procedures. We aimed to develop and validate an all-in-one hybrid model for stepwise learning in multiple EUS interventions.

Methods A hybrid model was created utilizing a pig esophagus and stomach, a silicon-based duodenum and pancreato-biliary system, a pseudocyst, and biopsy targets. This model was designed to provide hands-on training in multiple interventional EUS procedures, such as EUS-guided fine-needle biopsy (EUS-FNB), biliary drainage (BD), pancreatic duct drainage (PD), pseudocyst drainage (PSD), and gastro-enterostomy (GE). Thirty-six trainees underwent training on this model over 6 days, in two batches. Lumen apposing metal stents were used for PSD and GE. Trainees were assessed for objective criteria of technical difficulties. Subjective assessment by trainees was done via a questionnaire.

Results All the trainees were able to complete the requisite steps for all the procedures under supervision. On subjective assessment, 30 trainees (83 %) graded the model as good or excellent. A total of 107 technical difficulties were noted (scope position 55, duct puncture 27, guidewire-related problems 25). Time taken to complete the requisite steps of biopsy, PSD, and GE (10.5 minutes; range 3.5 to 22) was significantly less than that for BD and PD (28 minutes; range 17 to 40) (P<0.001).

Conclusions The hybrid model provided training for multiple EUS interventions with good acceptance by trainees. Stepwise mentoring with the possibility of performing multiple procedures in a single model with or without X-ray could prove useful in conference as well as institutional settings.

Introduction
Interventional endoscopic ultrasound (EUS)-guided procedures have rapidly evolved over the past two decades. A variety of procedures have shown promise with level I evidence in certain procedures like EUS-guided biliary drainage (EUS-BD), EUS-guided pancreatic fluid collection drainage, and EUS-guided celiac plexus block [1, 2]. The evolution of these procedures is also being facilitated by a parallel evolution in technology. Availability of EUS-specific stents, especially lumen apposing metal stent (LAMS) and bi-flanged metal stents, has helped increase the ease of procedures. While these procedures continue to evolve, an important lacuna is the lack of training opportunities for them. Fellowship programs typically may not provide adequate training in advanced interventional EUS procedures, as most of advanced centers have a limited number of such procedures. In addition, the higher incidence of adverse events reported with some of these procedures makes it pru-
dent to to perform initial learning of basic techniques on models. Models are available for some individual technique, such as EUS-guided fine-needle biopsy (EUS-FNB), EUS-guided pseudocyst drainage (EUS-PSD), and EUS-BD. However, there is no one model that allows training in all these procedures.

We have been attempting to create an interventional EUS model for the last several years. Our first attempt was creation of a 3D-printed model for BD [3]. This was followed by a hybrid model for EUS-BD [4]. One of our aims has always been to explore the possibility of a model that allows training in most if not all interventional EUS procedures. This study evaluated a novel all-in-one model with the possibility of multiple procedures in a single model (EUS magic box). The aims of this study were: 1) creation of a model for multiple interventional EUS procedures such as EUS-guided fine-needle biopsy, EUS-guided hepaticogastrostomy (EUS-HGS), EUS-guided rendezvous biliary drainage (EUS-RV-BD), EUS-guided rendezvous pancreatic duct drainage (EUS-RV-PD), EUS-PSD, and EUS-guided gastroenterostomy (EUS-GE); and 2) assessment of the efficacy of this model (EUS magic box) during training sessions, and associated problems if any.

**Material and methods**

**Creation of EUS magic box**

Based on our experiences with our previous models [3,4], we realized that our previous models needed X-ray, and hence, could be used only in endoscopy theater with X-ray protection. Therefore, we planned to create a model that could be used both with or without X-ray, making it suitable for workshops and conferences.

As mentioned previously in an earlier article, we found it difficult to obtain a suitable artificial material for the stomach, as needle puncture and cautery use through any synthetic material created problems with unsatisfactory end results. Hence, we decided to use a pig stomach and a synthetic duodenum and pancreatic-biliary tree (Fig 1). For the stomach, we utilized disinfected terminal esophagus (distal 5 cm) and pig stomach. The esophagus was used to attach the stomach to the relevant inlet in the magic box through a trocar. The distal end of the stomach was closed with sutures and attached to the side of the EUS magic box. The duodenum with C loop was created using medical grade silicone. Thus, two separate inlets were provided in the magic box, one for the stomach, and one for the duodenum (Fig 1). The need for separate openings for the stomach and duodenum arose from the fact that the papilla in pig duodenum is very high and the bile duct (BD) and the PD configurations are different from humans. Also, our final aim was to create an entirely synthetic model without any pig parts. Because of lack of a suitable material, we created a hybrid model, part synthetic and part porcine. The dimensions of the duodenum were kept slightly larger than normal (4-cm diameter), for ease of procedure during training. A papilla was created on the medial wall of the second part of the duodenum, with separate openings for the BD and PD (Fig 2). The duodenum was provided with openings on the anterior wall for visualization of the guidewire, when X-ray was not being used (Fig 1). The design of the duodenum was such that the C loop of the duodenum ended just underneath the stomach making it possible to do EUS-GE. We intentionally created a markedly dilated biliary and pancreatic ductal system for trainees to learn easily. The BD measured 2 cm, the left intra hepatic bile duct 1 cm, and the PD 1 cm. The right intrahepatic biliary system was kept non-dilated, with the purpose of teaching guidewire manipulation. The BD and PD separately joined the papillary orifice with the help of a narrow plastic valve, thus simulating a stricture.

Multiple pieces of liver tissue were embedded in gelatin, to be used for EUS-guided fine-needle biopsy (EUS-FNB). For pseudocyst we used pig urinary bladder filled with gelatin. The size of the pseudocyst was kept at 6 cm. The pseudocyst and liver tissue were fixed with help of a plastic anchor to the base of model. The positioning of the biopsy target (Fig 1) and pseudocyst is shown in (Fig 1).

The outer box was made up of fine acrylic (5 mm) and measured 37 cm × 29 cm × 32 cm (Fig 1). It had a detachable roof fitted with a camera (standard-definition camera with 2.8-mm lens) with light (DC-12V LED) and external controls (Fig 1). A
12V DC power adapter was used. This allowed projection of the interior of the model on to a TV screen, thus obviating the need for X-ray. However, if the procedure had to be learned under fluoroscopic control, the roof of the model along with the camera could be removed. Electrocautery application was made possible, the cautery pad being kept on the pig stomach or on the gel interface (▶Fig. 1). We used the gel used for electrocardiography/ultrasound (neutralized copolymer of maleic anhydride and a C1-C5 alkyl vinyl ether), as it is cheap, non-degradable and offers excellent acoustic views and electrocautery usage with no problem. The box was filled with gel in such a way that the gel remained just below the level of the inlet ports. This allowed placement of the stomach on the surface of the gel while the biliary system, the PD, the biopsy targets and the pseudocyst were submerged within the gel. The duodenum second part was kept on the surface of the gel, while the third part was submerged in the gel. The position of the left intrahepatic bile duct, biopsy targets and pseudocyst in relation to the stomach is shown in ▶Fig. 1.

Evaluation of the model

We conducted an observational study on this model during two train-the-trainers courses held in September 2019 and January 2020. Thirty-six trainees were chosen from a group of applicants. The criteria for choosing the candidates were: 1) at least 3 years’ experience in gastroscopy and colonoscopy with certification; 2) at least 2 years’ experience in diagnostic EUS; and 3) availability of linear echo-endoscope at the candidate’s institute. The institutional ethics committee approved the study.

A therapeutic linear echo-endoscope (Olympus TGF140, Olympus Inc, Tokyo) was used. A 19-gauge fine-needle aspiration cytology needle (Cook Inc. Bloomington, Indiana, United States) was used for puncture, a 260 cm 0.032″ or a 450 cm 0.035″ guidewire (Terumo, Radifocus, Japan, and Hydra Jag wire, Boston Scientific, Massachusetts, United States) was used for negotiation within ducts or pseudocyst. Tract dilation was done with a 6F cystotome. An Acquire 22-gauge needle (Boston Scientific, Massachusetts, United States) was used to train in EUS-guided biopsy (▶Fig. 3a, ▶Fig. 3b). For pseudocyst drainage and gastroenterostomy, an Axios LAMS (Boston Scientific; Massachusetts, United States) stent was used. For pancreatic and bile duct interventions, plastic stents were used.

Multiple therapeutic EUS procedures (EUS-FNB, EUS-RV-BD, EUS-HGS, EUS-RV-PD, EUS-PSD, EUS-GE,) were taught during the course. No humans or live animals were used. Training was imparted over 3 days in two batches. The first batch (September 2019) had 16 trainees and the second batch (January 2020) had 20 trainees. The training consisted of lectures, demonstra-
tion of live cases of various procedures, and finally training on the model.

**Stepwise training**

The trainees were exposed to technical aspects of various EUS procedures by didactic lectures and live procedures. The hands-on training was divided into three parts over 3 days. On the first day, EUS-FNB (▶Fig. 3, ▶Video 1) and EUS-PSD were taught (▶Fig. 5, ▶Video 4). The trainees performed predefined tasks such as needle puncture and LAMS insertion in the pseudocyst cavity. On the second day, the trainees performed EUS-RV-BD and EUS-HGS on the model (▶Fig. 3, ▶Video 2). They were taught the following steps: 1) appropriate scope position for each procedure; 2) puncture with a 19-gauge needle; 3) guidewire manipulation; 4) tract dilation with 6F cystotome; and 5) stent placement including steps for LAMS placement. On the third day, they were taught EUS-RV-PD (▶Fig. 4, ▶Video 3) and EUS-GE (▶Fig. 6, ▶Video 5).

For EUS-RV-PD, the PD was accessed through the trans-gastric route on the hybrid model. They were taught scope position, needle puncture, and guidewire manipulation across the papilla into the duodenum. They were taught to catch the wire at the papilla with the snare and pull it up into the duodenoscope channel.

For EUS-PSD and EUS-GE, the technique of Hot Axios placement was taught. In addition, for EUS-GE, a nasobiliary drain was placed in the duodenum and water mixed with methylene blue was instilled. A free-hand technique was used for EUS-GE.

A brief description of the individual techniques is as follows.

For EUS-FNB, the echo-endoscope was placed in the stomach and lesions were identified. A 22-gauge EUS-guided biopsy needle was then fixed into the biopsy channel of the echo-endoscope, needle trajectory was assessed and puncture was done through the stomach wall, once in the lesion fanning technique was applied to sample multiple areas within the le-
A slow pull was applied on the stylet to generate gentle negative pressure. The needle was then removed and sample was expressed in a pastry dish filled with saline.

For US-HGS, trainees were taught needle puncture with 19-gauge needle, appropriate scope position, wire manipulation to coil and keep the wire at the liver hilum, track dilation with 6F cystotome, and finally placement of single pigtail plastic stent in left hepatic duct. About 3 cm of stent was left in the stomach.

For the antegrade procedure, trainees were taught appropriate scope position, puncture of the left intrahepatic bile duct with a 19-gauge needle, manipulation of guidewire across the hilum into the duodenum, tract dilation with a 6F cystotome and placement of single pigtail plastic stent in the bile duct and the distal end coming out of the papilla into the duodenum.

For the rendezvous procedure, with both biliary and pancreatic rendezvous, the trainees were taught appropriate scope position (left intrahepatic duct for biliary rendezvous and pancreatic duct in the tail of pancreas for pancreatic rendezvous), guide wire was then manipulated downstream across the papilla into the duodenum. The echo-endoscope was then removed leaving the guide wire in position. The duodenoscope was then introduced through the inlet of the duodenum and guide wire was seen exiting from papilla. The guidewire was caught with a snare and gently pulled into the biopsy channel of the duode-
noscope. Once enough guide wire was available at the biopsy port of duodenoscope a 5F sphincterotome was threaded over it and pancreatic duct or bile duct was cannulated. Once selective cannulation was achieved, the original guidewire was removed and fresh guidewire passed through the sphincterotome into the BD or PD. Finally, a plastic stent was placed over the guidewire.

For EUS-guided pseudocyst drainage, the pseudocyst in relation to posterior wall was identified and measured. A Hot Axios stent was utilized and the stent was deployed in a single step.

For EUS-GE, a naso-duodenal tube was placed in the third part of duodenum which was filled with water mixed with methylene blue. The echo-endoscope was positioned in the stomach to visualize the third or fourth part of the duodenum. Once the position was achieved, a Hot Axios stent was deployed and influx of methylene blue water into the stomach confirmed the successful anastomosis.

Assessment

The experts graded the various aspects of the model as follows: Grade 1 – average, Grade 2 – good, Grade 3 – very good, and Grade 4 – excellent. Objective performance was done. The trainees were assisted in all procedures by an expert who identified their mistakes and corrected them. Assessment parameters were correct scope position, needle puncture and visibility under ultrasound, guidewire manipulation and avoidance of shearing, grasping the guidewire in the duodenum, pulling the guidewire into duodenoscope biopsy channel, plastic stent deployment and LAMS insertion techniques. Deficiencies for each trainee were noted and corrected.

Results

Details of trainee prior experience are shown in Table 1. The expert assessment of the model for various interventional EUS procedures is shown in Table 2. All the trainees were able to complete the requisite steps for all the procedures under supervision. The results of the assessments are shown in Table 3. The success rate in EUS-FNB was high and the trainees also were quick to learn pseudocyst drainage and EUS-GE with LAMS; the success in BD and pancreatic duct drainage (PD) was relatively less. Time taken to complete the requisites step of EUS-FNB, EUS-PSD, EUS-GE was significantly less than for EUS-BD, EUS-RV-PD (mean time 10.5 minutes; range 3.5 to 22 vs 28 minutes; range 17 to 40; P<0.001). A total of 107 technical difficulties (Table 4) were noted while doing interventional procedures on the model: wrong scope position 55, incorrect duct puncture 27, guidewire-related problems 25 (wrong direction 13; shearing 10; slippage during retrieval 2). EUS-FNB and LAMS insertion for pseudocyst and gastroenterostomy showed fewer technical difficulties than bile duct and PD (35 vs 75; P<0.001). On subjective assessment, 30 trainees (83%) graded the model as good or excellent. Six trainees had 10 minor suggestions for improvement (smaller size of papillary orifice 4, thinner wall of the duodenum for easy EUS-GE 4, and use of EUS-specific stents for training in EUS-BD 2).

EUS-guided fine-needle biopsy

Thirty-three of 36 students (92%) were able to achieve appropriate scope position. Thirty-four of 36 were successful with needle puncture. Core obtained from biopsy was adequate. Mean time taken by trainees to complete the procedure was 5.4 minutes (range 3.5 to 10 minutes) (Fig. 3, Video 1).

EUS-guided rendezvous biliary drainage

Appropriate scope position was attained by two-thirds of trainees (n=25, 69%) in the first attempt. Needle puncture was successful by 30 trainees (83%). Twenty-six trainees (72%) and 35 trainees (97%) did successful wire manipulation and tract dilation, respectively. Successful stent placement was done by 32 trainees (89%) on the first attempt. Initially 11 had the wrong scope position, which was corrected by experts. Guidewire shearing was encountered by three trainees. One trainee had guidewire slippage during retrieval. Mean time taken by trainees to complete the procedure was 29.05 minutes (range 24 to 32 minutes).

EUS-guided hepaticogastrostomy

In first attempt, appropriate scope position was attained by 27 trainees (75%). The needle puncture was successful by 31 trainees (86%). Twenty-seven (75%) and 34 (94%) did successful wire manipulation and tract dilation, respectively. Successful stent placement was done by 34 trainees (94%) on the first at-
Table 2: Objective assessment of the model by experts.

<table>
<thead>
<tr>
<th>Score</th>
<th>EUS-RV-BD</th>
<th>EUS-HGS</th>
<th>EUS-PSD</th>
<th>EUS-GE</th>
<th>EUS-RV-PD</th>
<th>EUS-biopsy</th>
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<tr>
<td></td>
<td>Expert 1</td>
<td>Expert 2</td>
<td>Average score</td>
<td>Expert 1</td>
<td>Expert 2</td>
<td>Average score</td>
</tr>
<tr>
<td>Scope position</td>
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<td>3</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>3.5</td>
</tr>
<tr>
<td>Needle visibility (EUS)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3.5</td>
<td>4.75</td>
</tr>
<tr>
<td>Duct visibility (EUS)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3.5</td>
</tr>
<tr>
<td>Duct visibility (X-ray/external camera)</td>
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<td>4</td>
<td>4</td>
<td>4</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Guidewire manipulation</td>
<td>3</td>
<td>3.5</td>
<td>3.25</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Guidewire retrieval (RV)</td>
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<td>4</td>
<td>3.5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Cautery usage</td>
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<td>3</td>
<td>3.5</td>
<td>4</td>
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<td>3.5</td>
</tr>
<tr>
<td>Stent placement</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3.5</td>
</tr>
</tbody>
</table>

Score: Grade 1 – average, Grade 2 – good, Grade 3 – very good, and Grade 4 – excellent

1 Cyst and contents visibility
2 Enteral loop visibility
tempt. Five had incorrect needle puncture and guidewire passage in the wrong direction. Four had guidewire shearing during retrieval. Mean time taken by trainees to complete the procedure was 20.6 minutes (range, 17 to 24 minutes) (▶ Fig. 3, ▶ Video 2).

**EUS-guided rendezvous PD**

In first attempt, appropriate scope position was difficult and attained by only 24 trainees (67%). The needle puncture was successful by 29 trainees (80.5 %). Thirty trainees (83%) and 35 trainees (97 %) did successful wire manipulation and tract dilation, respectively. Successful stent placement was done by 34 trainees (94%) on the first attempt. Seven had an incorrect puncture, two had guidewire passage in the wrong position. Three had guidewire shearing and one had slippage. Mean time taken by trainees to complete the procedure was 34.4 minutes (range, 31 to 40 minutes) (▶ Fig. 4, ▶ Video 3).

**EUS-guided pancreatic pseudocyst drainage**

In 30 trainees (83 %), scope position was appropriate on the first attempt to identify pseudocyst and drain it under EUS guidance. All 36 trainees (100 %) deployed a LAMS stent successfully, free flow of fluid from enteral loop to stomach was noted through the stent. Fourteen trainees had the wrong scope position and five had an incorrect puncture. Mean time taken by trainees to complete the procedure was 15.8 minutes (12–22 minute) (▶ Fig. 6, ▶ Video 5).

**EUS-guided gastroenterostomy**

Twenty-two trainees (61%) were able to identify jejunum with appropriate scope position. All trainees (100%) deployed a LAMS stent successfully, free flow of fluid from enteral loop to stomach was noted through the stent. Fourteen trainees had the wrong scope position and five had an incorrect puncture. Mean time taken by trainees to complete the procedure was 15.8 minutes (12–22 minute) (▶ Fig. 6, ▶ Video 5).

**Durability of the model**

We used the model for two train-the-trainer sessions involving 36 trainees. Our experience indicates that the model is durable even after self-expanding metal stent placement. It can be reused by changing the position of the puncture for at least 25 times. In addition, we also created separate duodenum and bile ducts, which could replace the damaged parts if necessary.

**Discussion**

This is the first report of an all-in-one model with the possibility of performing multiple EUS-guided interventional procedures in a single compact model, which can be utilized in conference as well as institutional settings, with or without X-ray. EUS-guided therapeutic interventions are complex, each having its...
own unique technical challenges. They are currently indicated in a small but growing number of patients, and the case volume remains low even at advanced endoscopy centers, with the probable exception of pancreatic fluid collections [5, 6]. Models for training in EUS-guided interventions are evolving gradually. Separate models have been described for individual procedures like EUS-FNB, EUS-PSD and EUS-BD. [3, 4, 7–12] We are not aware of any model for EUS-GE. We have previously published our experience with a 3D-printed BD model, which appears suitable for teaching the essential basics of EUS-BD [3]. Our subsequent hybrid model for EUS-BD was an improved version with possibilities of cautery as well as two different entry points to facilitate the rendezvous procedure [3, 4]. However, that model was only limited to EUS-BD, needed X-ray, and did not have the possibility of performing other procedures like EUS-FNB, EUS-PSD, and EUS-GE. Our current model is a further improvement, with the addition of multiple procedures in the same model, while also removing the constraints of X-ray.

An ideal synthetic material for the duodenum and pancreatico-biliary system is not yet available. The existing materials tend to be harder, or too soft, thus creating difficulties in puncture or retention of shape. For the past models, we utilized polycarbonate material, which did not allow a good puncture and restricted the movement of the echo-endoscope. For the current model, we settled for thin silicone, as it allows needle puncture, retains its shape, and has good acoustic windows (Fig. 1). We also made the use of fluoroscopy optional by utilizing an internal camera with external control. This along with the compact size of the model allows transportability for use in a conference setting. However, X-ray could still be used for training if needed, by removing the top cover.

The magic box was graded well on most of the parameters by experts as well as the trainees. Our trainees were selected carefully as a part of a train-the-trainer program. Thus, they were well versed with diagnostic EUS and scope maneuvers. This explains the very good success rate in almost all the interventional procedures. However, they did have difficulties, primarily in two broad areas. First, they found it difficult to get a good scope position to puncture. They also found it difficult to hold this position during the procedure. Second, they had difficulties in manipulating the guidewire across a stricture.

Difficulties encountered by trainees did not differ significantly from our earlier studies. Trainees found it relatively easy to learn LAMS insertion and perform EUS-FNB. Time taken and technical difficulties for these two procedures were significantly less as compared to that for EUS-BD and EUS-RV-PD procedures. This could partially be due to the fact that LAMS placement is a single-step procedure and does not require multiple instruments. The BD and PD interventions proved more difficult primarily due to difficulty in maintaining scope position and guidewire manipulation. Trainees found EUS-GE to be relatively easy because of the fixed easily identifiable silicone enteral loop. In real-life situations, locating and fixing the jejunum endosonographically can be challenging. We did try to replicate the technique by placing a nasojejunal tube in the duodenum, and filling the duodenum with water mixed with methylene blue.

There were limitations to this study. The model, although comprehensive, is designed for easy procedures, as evidenced by very dilated common BD and PD, and easily identifiable duodenum for EUS-GE. Thus, the trainees are not exposed to some of the complexities of these procedures. However, this can easily be rectified by creating narrower ducts with strictures, multiple jejunal loops, and complex cysts in future versions. It is also possible to create blood vessels in the vicinity of the ducts or cysts, to make the procedure more challenging. Further, the duodenum and stomach are entered through separate ports. While this distorts the anatomy, it did not preclude the demonstration and performance of the various procedures. Our search for a perfect synthetic material still continues, and while this model is a significant improvement, we realize that we need a better material that simulates the human tissue. There are few interventional EUS procedures that are not included in this hybrid model, such as EUS-guided gall bladder drainage and vascular therapy. These can be added easily with no likely additional technical problems.

Conclusions

In conclusion, the EUS magic box shows good acceptance by experts and trainees for EUS interventions, allowing step-wise learning of multiple procedures in a single model. It can be used with or without X-ray and is a good model to teach the technique of LAMS placement.

Competing interests

The authors declare that they have no conflict of interest.

References


