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## Learning models for endoscopic ultrasonography in gastrointestinal endoscopy

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### Abstract

Endoscopic ultrasonography (EUS) has become a useful

diagnostic and therapeutic modality in gastrointestinal endoscopy. However, EUS requires additional training since it requires simultaneous endoscopic manipulation and ultrasonographic interpretation. Obtaining adequate EUS training can be challenging since EUS is highly operator-dependent and training on actual patients can be associated with an increased risk of complications including inaccurate diagnosis. Therefore, several models have been developed to help facilitate training of EUS. The models currently available for EUS training include computer-based simulators, phantoms, *ex vivo* models, and live animal models. Although each model has its own merits and limitations, the value of these different models is rather complementary than competitive. However, there is a lack of objective data regarding the efficacy of each model with recommendations on the use of various training models based on expert opinion only. Therefore, objective studies evaluating the efficacy of various EUS training models on technical and clinical outcomes are still needed.

**Key words:** Endoscopic ultrasonography; Training; Phantom; Computer simulation; Animal model

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**Core tip:** The present review offers a summary of learning models for endoscopic ultrasonography (EUS). The models currently available for EUS training include computer-based simulators, phantoms, *ex vivo* models, and live animal models. Although each model has its own merits and limitations, the value of these different models is complementary than competitive. However, there is a lack of objective data regarding the efficacy of each model with recommendations on the use of various training models based on expert opinion only. Therefore, objective studies evaluating the efficacy of various EUS training models on technical and clinical outcomes is needed.

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## INTRODUCTION

Endoscopic ultrasonography (EUS) has evolved from a diagnostic tool to one that provides a wide range of therapeutic capabilities<sup>[1,2]</sup>. EUS is often used as the initial tool for diagnosis and staging in the multidisciplinary approach to gastrointestinal cancers, and the advent of EUS-guided fine-needle aspiration (EUS-FNA) provides an alternative approach to traditional percutaneous computerized tomography-guided or ultrasonography-guided biopsies. Furthermore, EUS has been employed in the treatment of pancreatic cancer with EUS-guided injection of anti-tumor agents<sup>[3]</sup> as well as EUS-guided drainage of pancreatic pseudocyst and obstructed bile duct<sup>[4,5]</sup>. The main characteristic of EUS, the combination of endoscopy and ultrasonography, has enabled its application to extend to oncology as well as treatment of various benign conditions such as pseudocyst drainage. EUS requires a cognitive and technical skill set combining endoscopic manipulation and ultrasonographic interpretation, which makes this a highly operator-dependent procedure<sup>[6,7]</sup>. The complexity of instrument handling to generate adequate ultrasound imaging has resulted in the use of EUS only in limited facilities unlike esophagogastroduodenoscopy and colonoscopy. Although the number of EUS examinations including interventional EUS has increased, centers that have adequate volumes of cases to train endoscopists to perform EUS remains limited.

To achieve a certain level of competency for EUS, additional training is required with numerous studies demonstrating the importance of the learning curve in improving EUS accuracy<sup>[8]</sup>. Generally it is recommended that luminal gastrointestinal EUS (staging of luminal cancers and evaluation of subepithelial masses) requires at least 3-6 mo of intensive training to establish competency (150 supervised cases), whereas pancreatobiliary EUS may require training for up to 1 year (a minimum of 75 cases)<sup>[9-11]</sup>. For EUS-FNA, at least 120-150 supervised examinations and 25-75 FNA procedures are considered to be the requirement to reach competence<sup>[11-15]</sup>. However, learning EUS, especially interventional EUS on actual patients, is associated with an increased risk of complications and posed ethical concerns. Therefore, effective EUS training models have the potential to improve training outside of the patient and decrease the number of supervised examinations in actual patients needed to achieve competence in performing EUS. The aim of this review is to evaluate the current EUS training models.



Figure 1 GI-Mentor system.

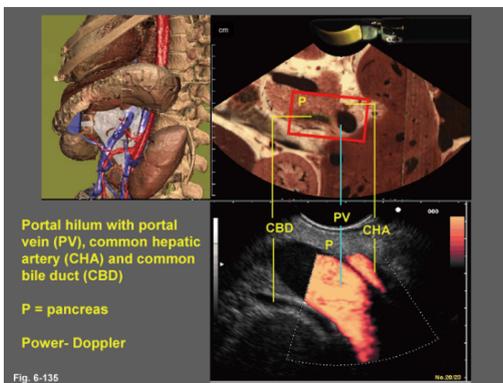
## COMPUTER-BASED SIMULATORS

Simulation means the imitation or modeling of a real-life situation for training or instruction. Several computer-based endoscopic simulators for gastrointestinal endoscopy have been developed. The GI-Mentor (Simbionix, Tel Hashomer, Israel), is the first reported simulator<sup>[16]</sup>, which is based on flight simulator technology. It consists of a plastic mannequin on a wheeled trolley (Figure 1). On the mannequin, are a mouth for upper endoscopy and an anus for lower endoscopy. Sensors that enable haptic feedback to the user are included in interior of the mannequin. A LCD touch screen for image display and system operation is attached to the trolley base on a movable arm. This simulator comes with several modified endoscopes according to the object of examination. The simulator endoscope tip has a sensor which allows the computer to generate a dynamic real-time endoscopic view according to the user's movements. The master tool handle portion is designed to be similar to that of standard endoscopic devices, but contains sensors on the handle to simulate the procedure being performed. This simulator has the following characteristics<sup>[17]</sup>; force feedback with an air pumping system, alert functions when the pressure against the gut wall is too high or if too much air has been insufflated, virtual skill tests, and an automatic back-up log system for each user.

A module for EUS (EUS Mentor) is available on the GI-Mentor<sup>[18]</sup>. EUS Mentor represents an addition to a computer-based endoscopic simulator platform and was developed for radial and linear-array EUS<sup>[16]</sup>. It provides a realistic linear or radial real-time ultrasound display based on human anatomy. The trainee gains experience in correct scope maneuvering, interpretation of EUS images and landmark identification, and receives



**Figure 2** Radial endoscopic ultrasonography image and anatomical 3-dimensional view of pancreas on endoscopic ultrasonography Mentor.



**Figure 3** Atlas image of right abdomen on endoscopic ultrasonography Meets VOXEL-MAN (permitted by Dr. Eike Burmester).

immediate objective feedback on performance. On-screen visual assistance with side-by-side, split-screen EUS/3-dimensional (3D) mapping is also provided (Figure 2). There are more than 30 individual EUS tasks incorporated in the radial and linear EUS simulator, and post-procedural review of saved images, indication of anatomy and land-marks not properly identified is possible. However, natural resistance for the tools through the working channels is not currently available. This function is needed for effective simulation of interventional EUS such as EUS-FNA.

EUS Meets VOXEL-MAN is an interactive 3D anatomic simulation program that has been developed for linear-array EUS training using the real anatomy of cadavers<sup>[19]</sup>, and has been recently revised (2<sup>nd</sup> version). This interactive simulation system allows basic anatomic structures to be learned for linear EUS even on a standard personal computer (Figure 3). In the 2<sup>nd</sup> version, it is possible to choose the orientation of EUS images. However, there is no function for scope or needle manipulation.

## PHANTOMS

Olympus (Tokyo, Japan) has developed EUS and EUS-FNA phantoms, which consist of a longitudinal body

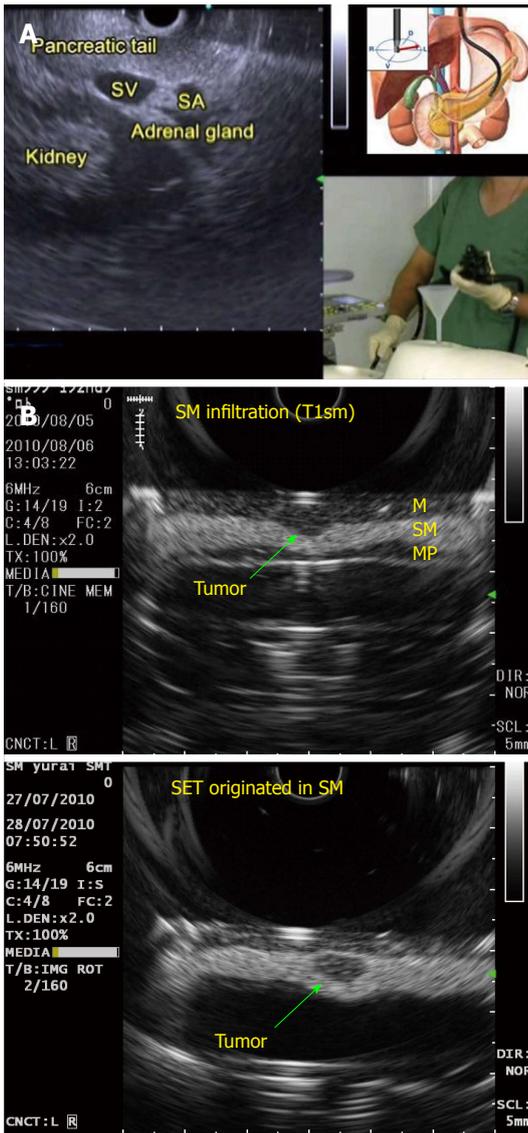


**Figure 4** Models of endoscopic ultrasonography phantom. A: A model for pancreatobiliary system; B: A model for gut wall.

with a hole in the center to simulate the esophagus and different types and sizes of silicon block to simulate lymph nodes or cystic lesions (Figure 4). These phantoms have been usually used in hands-on-courses for EUS. The advantage of this model is that it is simple, easy to use and transport, and has various models such as subepithelial tumors, various cancer invasion depths, radial and linear EUS models for the pancreatobiliary system, and EUS-FNA (Figure 5). Another type of phantom using commonly available materials such as bags filled with barium, plastic tubes, or standard agar has also been reported<sup>[20]</sup>. This phantom is low cost, reusable, and designed for learning EUS-FNA. Both phantoms can aid in learning the basic techniques of EUS and EUS-FNA - especially manipulation and positioning of the echoendoscope and needle relative to the target lesion. However, these phantoms do not adequately simulate actual *in vivo* anatomy or conditions (e.g., blood flow, respiratory motion, etc.).

## EX VIVO ANIMAL MODELS

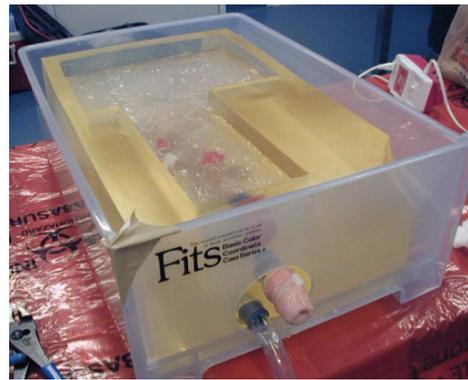
*Ex vivo* animal models are made from a combination of explanted animal organs and plastic parts to overcome some limitations of live animal models. The most well-known *ex vivo* model for endoscopy is the Erlangen Active Simulator for Interventional Endoscopy (EASIE) (ECETraining GmbH, Erlangen, Germany)<sup>[21,22]</sup>. This was the first model to simulate spurting blood in a realistic manner and was developed



**Figure 5** Endoscopic ultrasonography images using endoscopic ultrasonography phantom. A: Linear endoscopic ultrasonography (EUS) image of pancreas; B: Radial EUS image of submucosal cancer and subepithelial tumor (permitted by Dr. Mitsuhiro Kida).

for training of therapeutic endoscopy in 1997<sup>[23]</sup>. The EASIE model is a human-shaped mannequin consisting of anatomical torso, a pivotal suspension frame with an external perfusion system. This mannequin is adapted to connection devices and fixation elements for topographically implanting the prepared special swine organs. Advantages of these *ex vivo* models are a more realistic feeling, the opportunity to practice therapeutic endoscopy in a controlled setting, and lower cost compared with computer-based simulators<sup>[18]</sup>. Disadvantages are lengthy preparation time, disposal of tissue, and unfavorable tissue characteristics compared with vital tissue.

This model can be also modified for use in training EUS (EUS RK model) (Figure 6)<sup>[17,24,25]</sup>. For using this model for EUS training, additional preparation for



**Figure 6** EUS RK model (permitted by Dr. Koji Matsuda).

providing extraluminal structures made from silicon, gelatin, tubing, and/or other materials for ultrasound imaging is needed<sup>[17,24]</sup>. Constructing this model takes approximately 6 h in addition to preparation of the swine organs, and can last 2-3 d if refrigerated. The merits of this model are as follows<sup>[17]</sup>; (1) it can simulate EUS as well as EUS-FNA; (2) normal EUS equipment can be used; and (3) modification of this model, especially for therapeutic EUS applications, is possible. Because the EUS RK model is the most realistic simulator of EUS-FNA besides the live swine model and real-time EUS imaging of tissue is possible, this model has been used in the learning center at many EUS symposiums and hands-on training courses in Asia, United States and Europe.

Development in 3D technology has enabled bioprinting of numerous human body parts for a wide range of medical conditions. Recently, a 3D printing bile duct prototype model, which was incorporated into pig/goat liver, was developed for training in EUS-guided biliary drainage<sup>[26]</sup>. Studies with a large number of trainees are required to determine the usefulness of a 3D printing bile duct prototype model; however, further development in EUS training models using 3D printing technology could be used in the near future

## LIVE ANIMAL MODELS

Live animal models are the most realistic endoscopy simulators. Although the orientation and thickness of various organs are different, the haptic feedback is nearly identical to human tissue. The swine has been used most commonly as a live model for teaching EUS (Figure 7). Its anatomy is similar to that of the human in the following points<sup>[27-29]</sup>: (1) the five layers of the gut wall can be displayed; (2) the liver presents a similar echostructure; (3) the pancreas, left kidney and celiac axis are easily identifiable; and (4) it provides the possibility of identifying vascular structures by Doppler. In addition, these models are reported to be useful in identifying subepithelial lesions after injection of substances to simulate lesions, and



Figure 7 Hands-on-course of endoscopic ultrasonography using a live swine.

in the training of some therapeutic techniques such as FNA, pancreatic pseudocyst drainage, or neurolysis of the celiac plexus<sup>[2,28,30]</sup>. However, live animal models can be difficult to acquire and are expensive. In addition, live animal experimentation should be carried out according to the ethical principles and laws of the country where the work is conducted<sup>[31]</sup>, which often limits their availability.

The efficacy of the swine model has been reported not only for teaching diagnostic EUS<sup>[27]</sup>, but also for teaching interventional EUS by making pseudo-lesions with the injection of saline<sup>[28]</sup>. This model is helpful for understanding manipulation of the scope and needle. If well-controlled facilities for animal laboratories are available, this model is an excellent modality for teaching EUS to beginners. However, there are some limitations such as cost for routine use and the need for a relatively large investment in equipment and the need for specialized laboratory space.

## EFFICACY OF EACH MODEL

For evaluating the efficacy of each model, 2 types of studies are needed: validation studies and clinical trials<sup>[18]</sup>. Validation studies assess whether a model can distinguish between beginners and experts as measured by various parameters such as procedure time, extent of procedure achieved, and recognition of pathology. For initial evaluation of each model, validation studies are important. Later, clinical trials including the outcome of EUS are needed to determine whether use of the model decreases the number of supervised cases needed to achieve competence in performing clinical EUS. However, there have been few validation studies or clinical trials for evaluation of EUS training models to date. Furthermore, cost-effectiveness studies may be added to determine whether models decrease training time and subsequent procedure time enough to compensate for their cost.

Although not shown in randomized trials, these models, especially live animal models, is likely to improve training and shorten the learning curve in patients. The studies about the usefulness of live

animal models in training courses are as follows. On a study based on questionnaires completed by students who attended EUS training courses sponsored by the American Society of Gastrointestinal Endoscopy (1997 and 2000) using live swine models, 95% of attendees in 1997 found the course to be useful and 85% particularly valued the live-animal, hands-on aspect of the course<sup>[29]</sup>. More than 90% of respondents in 2000 stated that participation in the course had improved their skills and 88% thought that they would be likely to perform EUS in the future. A designed study evaluating a 17-d training course for EUS-FNA using hilar lymph nodes in live swine models showed that procedural times were significantly reduced and accuracy was increased after the training course<sup>[30]</sup>. Another study using live animal models for training EUS-FNA also showed improved performance and student confidence when performing the procedure in real patients<sup>[32]</sup>. Recently many emerging EUS-guided procedures such as portal vein access<sup>[33,34]</sup>, intratumoral injection of anti-neoplastic agents<sup>[35-37]</sup>, radiofrequency ablation<sup>[38,39]</sup>, and photodynamic therapy<sup>[40,41]</sup> are still under investigation and have been performed only in animal models. Models play a critical role in the development and evaluation of new EUS-based procedures and techniques prior to clinical implementation<sup>[2,42]</sup>.

## WHICH MODEL IS MORE APPROPRIATE?

As stated above, there are several options available to help trainees approach the systematic learning of EUS. The advantages and disadvantages of each model are summarized in Table 1<sup>[17,43]</sup>. Phantoms are easy to use and require minimal preparation, but lack realism. *Ex vivo* animal models are easy to use but require more extensive preparation and disposal after use. Live animal models are the most realistic but much more expensive than *ex vivo* animal models. In addition, use of live animals requires special facilities and equipment. Computer-based simulators have the advantage of prolonged use at minimal additional expense after a one-time startup cost. However, the startup cost is often too expensive, and these simulators also lack realism. In a survey to assess the impact of 4 models as a learning tool by 8 EUS experts<sup>[43]</sup>, the EUS Mentor was recommended highest when "doing EUS without FNA", followed by "before starting EUS fellowship", whereas the EUS RK model and phantom was recommended most in "just before starting EUS-FNA". The animal model was recommended throughout the training process.

Generally, the following sequence is recommended for learning EUS: (1) acquisition of EUS knowledge *via* books, videos, lectures and other media such as on-line content; (2) computer-based simulation; (3) use of phantoms; and (4) use of *ex vivo* and/or live animal models. The values of the different models

**Table 1** Advantages and disadvantages of learning models for endoscopic ultrasonography and endoscopic ultrasonography-guided fine-needle aspiration

	Advantages	Disadvantages
Computer-based simulator	Easy to use Reusable Feedback and alert function Various EUS tasks are possible	High startup cost Not realistic for anatomy Not realistic for needle manipulation
Phantom	Simple, easy to use and transport Minimal preparation Reusable Various EUS models are possible	Not actual <i>in vivo</i> anatomy or conditions Not realistic for scope manipulation
<i>Ex vivo</i> model	Realistic Low cost Some interventional EUS procedures are possible	Lengthy preparation No vital tissue characteristics
Live animal model	Most realistic Closest resemblance to human structure Realistic for scope and needle manipulation Interventional EUS procedures are possible	High cost Ethical problem about animals Needs special facilities and equipment

EUS: Endoscopic ultrasonography.

are complementary and not necessarily competitive. Although the use of the above mentioned models improves EUS training, these models cannot replace supervised clinical training by EUS experts<sup>[8]</sup>.

## CONCLUSION

There are several learning models to achieve competency in EUS and EUS-guided therapeutic procedures. Although most studies assessing their efficacy on training consistently concluded that training in these models improves skills, only a few studies showed that the training on live animal models facilitates the application of certain techniques in clinical practice and increases self-confidence of the trainees<sup>[2]</sup>. Therefore, the efficacy of each model is reported principally on the basis of the experts' recommendations without objective evidence. Although the development of more ideal models for learning EUS is necessary, more objective evaluation of existing models, including how these models effect the overall learning curve of EUS and whether they improve clinical outcomes, is also necessary.

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