New *ex-vivo* porcine model for endoscopic ultrasound-guided training in transmural puncture and drainage of pancreatic cysts and fluid collections (with videos)

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ABSTRACT

Background and Objectives: Endoscopic transmural puncture cysts and drainage pancreatic fluid collections are an important part of endoscopic ultrasound practices, but can be technically difficult to master, particularly with regards to placing stents. We developed an *ex-vivo* model that is inexpensive and can be used for cyst puncture and fluid collection drainage. **Methods:** Over the last 5 years, we have perfected the creation of this *ex-vivo* model. The model is easy and inexpensive to create and multiple aspirations and device placements and removals into a single cavity with decompression. The model allows the use of cautery devices and placement of expandable metal stents. Additionally, the contents in the model can be altered to appear as walled-off necrotic collections endosonographically. **Results:** The model can be created for <300 US dollars. It has been used at multiple international conferences for teaching purposes and can withstand up to 10 puncture and drainages without having to replace the "cyst." The cyst can easily be exchanged for other prepared cysts. Preliminary surveys obtained from users show ratings that are realistic. **Conclusions:** A new *ex-vivo* model can be easily and economically created, is realistic and can be used multiple times during the single training session.

Key words: Drainage/methods, endoscopic ultrasound, pancreatic cyst, pancreatic pseudocyst, simulator, walled off pancreatic necrosis

INTRODUCTION

Endoscopic ultrasound (EUS) has proven to play an invaluable role in the diagnosis and treatment of gastrointestinal and extra-gastrointestinal disorders. The learning curve for EUS training is steep and

Access this article online

Quick Response Code:

Website:
www.eusjournal.com

DOI:
10.4103/2303-9027.151326

hands-on experience is essential for learning. For the augmentation of hands-on experience, simulators may be useful. In many specialties both within[1-3] and outside of gastrointestinal endoscopy simulators have been used and validated to improve real-life skills. Virtual simulators either lack haptic feedback or cannot recreate realistic haptics. Use of live animals is costly and carries ethical concerns. In addition, a live animal is not useful for training and assessing new devices for cystic puncture and drainage other than the gallbladder, though more than one gallbladder puncture is not feasible. *Ex-vivo* animal models have been used for endoscopic retrograde cholangiography trainees at all levels of experience. Prior *ex-vivo* tissue models for EUS puncture of pseudocysts have been described.[2,4] In this article, we describe how to create and use a reliable,

inexpensive *ex-vivo* tissue simulator (TDSimulator®) for EUS-guided puncture and drainage of cystic lesions that can incorporate cautery devices and "vasculature," as needed.

CREATION OF THE MODEL

The model was created in a manner similar to the "Erlangen Biosimulation Model" and was created by one of the authors (DeSimio TM) to provide an option for repetition and practice of translumenal EUS procedures. Existing commercial models lacked durability, being useful for only the first intervention, and were not satisfactory for performing multiple procedures during the same session without irreparable damage to the model. We evolved the "fluid" of EUS targets from water to gelatin, creating a durable sample that could withstand multiple repetitions of puncture and stenting.

DESCRIPTION OF THE MODEL

Items needed
The following items and necessary for the creation of the model and are shown with approximate costs (US dollars).
1. Fresh porcine abdominal organs, which are available from food processing facility. These include esophagus, stomach, liver, gallbladder, pancreas, small and large bowel. An intact entire sample intact is preferred. Ideally, the tissue is obtained shortly after the animal's expiration. $105.00
2. Gelatin, 1 large box lemon, 1 small box lime. $2.00
3. Stainless steel steam table "half pan," 4″ deep. $10.00
4. Plastic bus pan, minimum 6″ deep. $6.00
5. Assorted plastic cable ties (tie-wraps), 6-8″ lengths One package contains approximately 100 units. $5.00
6. Copper cable clamps, 3/4″, 10 each. $10.00
7. Small roll of Mason twine. $3.00
8. Esophageal overtube, to accommodate a therapeutic echoendoscope. $100.00
9. 12″ bar clamp (Irwin Quick-Grip®, Huntersville, NC). $12.00
10. Latex tubing: 1/8″ and 3/8″ diameter, 6″ lengths. $10.00
11. Submersible, disposable fountain pump (Beckett™ 7062110 PUMP-DP80, Irving, TX). $25.00.

Tissue dissection
The *ex-vivo* model consists of porcine esophagus, stomach, duodenum, and liver. Porcine abdominal organs are procured from a rendering facility. Dissection of the organs is performed retaining 20-25 cm of esophagus with intact stomach and approximately 30 cm of small bowel distal to the pylorus. The liver with intact gallbladder is separated from the stomach.

Disposable medical scissors are used for the dissection process. The small bowel is carefully dissected from the large bowel being careful not to perforate the large bowel. The colon is transected between the splenic flexure and the sigmoid, discarding the proximal colon from the ileocecal valve to the splenic flexure. The latter step is because the right colon is a major source of odor and contamination. The remnant between the rectum and the anus is transected and discarded. The small bowel can be used to recreate dilated extrahepatic bile ducts and gallbladders, while the sigmoid colon is used for recreation of pancreatic pseudocysts and fluid collections.

All animal parts are then thoroughly rinsed with tap water. A thin incision is made in the gastric fundus approximately 4-5 cm in length and the stomach is inverted and thoroughly rinsed to remove any food or exudate and to clear the mucosa. The gastric "incision" is closed with 8″ cable tie, cinching it tightly and hence that the stomach will remain airtight during insufflation.

Creation of the cyst, gallbladder and bile duct
The sigmoid colon is copiously rinsed and reserved for the creation of pancreatic fluid collections. The small bowel is transected into 1-1.5 m sections, carefully trimming the mesentery from the section as needed while avoiding perforation. Each meter provides enough tissue to create about eight gallbladders or five dilated extrahepatic bile ducts. The remaining portion of the small bowel is used as filler material in the EUS field.

Plastic cable ties and gelatin are used to create the specimens. Lemon flavored gelatin with a pinch of lime yields a bilious color. Instructions are followed on the gelatin package with the exception that 10% less volume of water is used to allow the gelatin to completely solidify. The gelatin is allowed to cool to room temperature before filling the specimens as hot liquid deteriorates the tissue and causes it to rupture easily during the filling process. Care is taken to avoid the introduction of air into the samples as subsequent air-trapping will decrease EUS image quality.

One end of a bowel section is closed by tightly applying a cable-tie. To create pseudocysts, each section of colon is filled with about 200 mL of gelatin using

the cable ties to create "sausages" along the length of the colon. Each sample should be about 10 cm long. Squeezing the top of the fluid column will distend the tissue, ideally to at least 5 cm. Leave a 3-4 cm gap between each sample allows room for separating the segments while allowing formation of a convenient tab for affixation to the stomach with cable clamps as described later. The addition of tapioca pudding to the gelatin simulates the presence of necrotic debris (walled-off necrosis) within the cystic cavity. The cyst contents then appear heterogeneous with hypo- and hyperechoic areas.

Small bowel tissue is used to recreate gallbladder and bile duct samples. For gallbladders, the specimens are about 10 cm long. For bile ducts, the samples are about 20 cm long. Gallbladders are best made by holding the length of bowel vertically when filling the bowel with gelatin and applying the cable ties. The bowel will distend to a diameter of about 30-35 mm. For bile ducts, it is best to keep the specimen on a horizontal surface to prevent the tissue from distending during filling, thus making the diameter <20 mm. As with pseudocysts, a 3-4 cm gap is made between the samples to allow for separation of each segment and creating a tab for affixation in the final model. Placing 2-5 dried garbanzo beans or black beans into each specimen will appear sonographically hyperechoic with shadowing to mimic stones.

All specimens are refrigerated for at least 3-4 h before using. The bile duct samples must be handled carefully to avoid distending the tissue. The samples are placed in a covered plastic container (i.e., Tupperware®, Orlando, Florida) to congeal.

Creation of blood vessels
Latex tubing provides a conduit for water flow via pump. Use of a Y tubing adapter allows various tubing diameters to be utilized. The pump should have a variable flow adjustment to optimize the Doppler Effect.
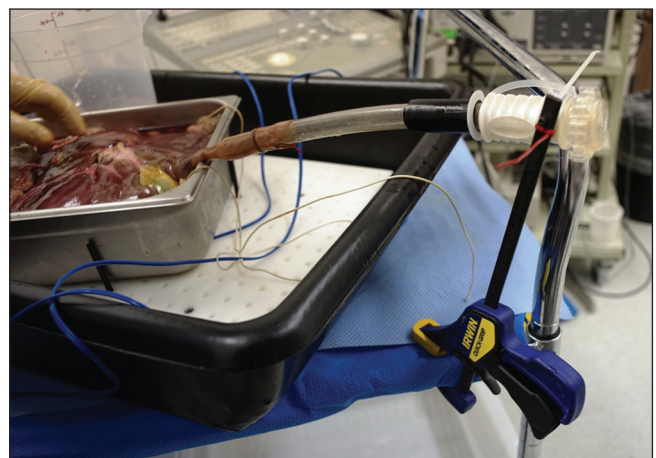
Assembly
A fixture consisting of the plastic and stainless pans is used to maintain the porcine organs in position throughout the simulation. An over tube is secured to the clamp (Irwin Quick-Grip®) to facilitate intubation. Copper wire clamps with a lanyard, connecting several points of the stomach to a plastic tub keep it immobile. Accessory organs such as the pancreas,

spleen and small intestines are used to aid in target organ positioning as well as for providing good EUS images.

Instructions for assembly of the model are as follows
1. Place a grounding pad on the outside of the stainless steel pan prior to organ assembly. This will keep it dry and provide a reliable connection for the duration of the session;
2. Place the stainless pan into the plastic bus tub: Prepare the bus tub to hold a metal pan by cutting small notches in pairs around the perimeter of the tub;
3. Place the unused small bowel (and any other organs that may have been obtained with the sample from the meat processor, such as spleen, pancreas and kidneys) into the pan;
4. Position the stomach sample flat on top of the other organs. Orient it such that the esophagus is towards the "head" of the pan, the position the operator will stand during the simulation. The pylorus should be to the right as observed from the head;
5. Place a cable tie approximately 5 cm from the distal portion of the overtube and pull it tightly;
6. Use the index finger to dilate the os of the esophagus, so that the overtube can be inserted easily. Pull the esophagus above the cable tie by at least 2 cm;
7. Place a cable tie around the esophagus, above the first one, to prevent the esophagus from sliding off the overtube during simulator usage;
8. Attach the clamp to the front edge of the table. Use 8″ cable tie to fasten the overtube to the upright post of the clamp [Figure 1];

Figure 1. Initial assembly of simulator. The stainless steel pan contains the small bowel at the bottom. The stomach is suspended and secured with copper clamps and twine attached to the plastic tub. Note the esophagus is attached to the overtube using cable ties. The blue cord of the grounding pad can be seen at the upper left portion of the tube (grounding pad attached to pan but not visible)

9. Secure an 18″ lanyard of Mason twine to the set screw of 4 copper wire clamps;
10. Clip the wire clamps onto the stomach;
11. Pull gentle traction on the twine lanyards and secure them to the notches of the bus pan. This will keep the stomach immobile during simulator use [Figure 2];
12. Place the desired specimen (simulated gallbladder, pseudocyst, or bile duct) or any combination thereof into the pan on top of the stomach [Figure 3]. Position them such that they are in line with the axis of the esophagus. Clamp the tissue tab of the specimen to the margin of the stomach to keep them in a stable position during instrumentation;
13. Connect a length of latex tubing to the fountain pump output. Use at least one liter container as the water reservoir, placing the pump and the return loop into the container. Loop sections of the latex are tubing to course in the direct vicinity of the samples [Figures 3 and 4]. Using ice water in the reservoir helps preserve the samples and decrease odor formation. Maintain the ice water if the simulator is to be used for extended periods of time or if it is on successive days. Keeping the tissues cold is significant for the longevity of the samples;
14. Place the liver on top of the organ collection [Figure 4]. Be aware that the native gallbladder may be used for imaging, but will only tolerate one puncture and bile will leak into the pan. Thus, it is often preferable to orient the liver with the gallbladder upwards [Figure 4];
15. Intubate the overtube and echoendoscope ad lib. Connecting the grounding pad to a cautery source provides conduction to all items in the pan. Care must be taken to avoid contact with the stainless pan to prevention electrical shock. Electrocautery settings are adjusted as necessary for intended applications.

Miscellaneous aspects

Complete set up of the system can be achieved in 20-30 min after completion of organ preparation. Organs can be prepared a day in advance if properly cleaned and refrigerated (34-38°F) in a covered container. The specimens should not be allowed to dehydrate as this decreases tactile sensation.

Proficiency with the system set up is possible after two to three assemblies.

Costs include "hardware" and "software" and total approximately $300. The hardware is a one-time expense since these items (pans, clamps, overtube, pump, latex tubing, twine) are reusable. Hardware can
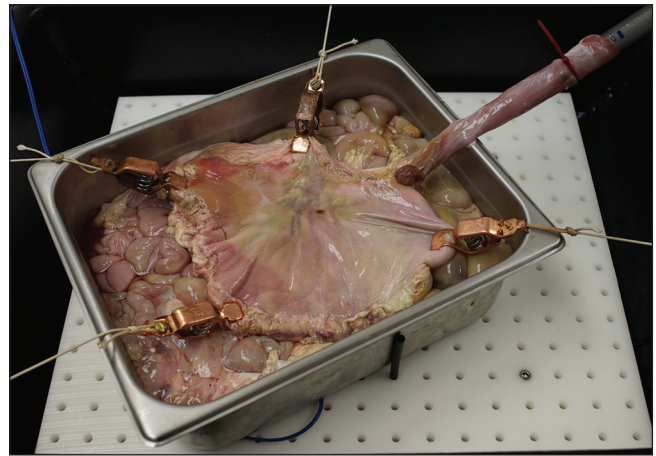
Figure 2. Copper clamps applied to the stomach and tied to the bus tub notches
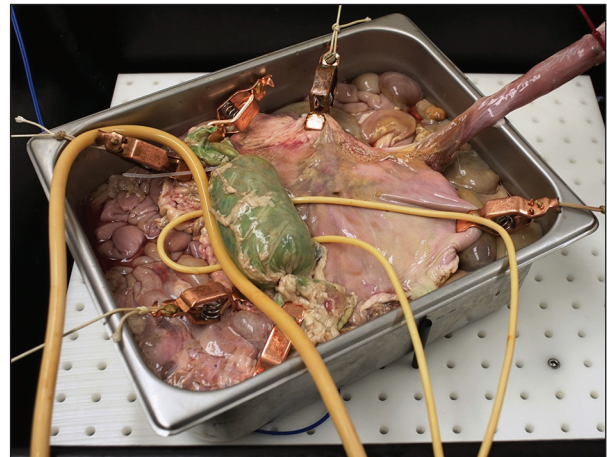
Figure 3. Pseudocyst is placed onto the stomach. Latex tubing has been placed underneath and over the top of the cyst to create Doppler images with water infusion
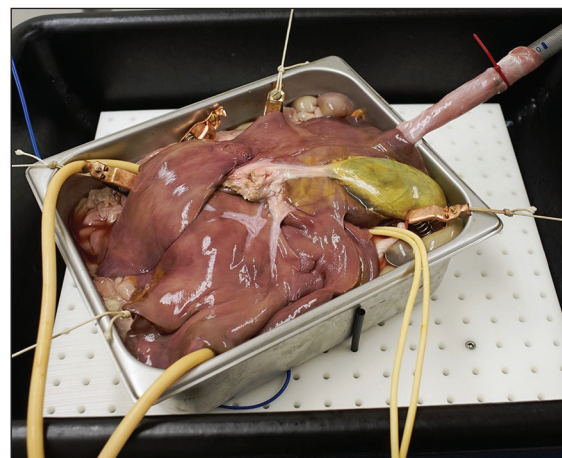
Figure 4. Final assembly with liver placed over the top of the tissue. Gallbladder is facing upward. Overtube clamped to table top using cable ties. The prepared model is seen to the left

be procured for approximately $180. The software includes the disposable components (porcine organs,

gelatin and cable ties) and can be purchased for approximately $115. Thus, total cost for initial set up is about $300 with a cost of $115 for subsequent uses.

PERFORMANCE OF THE MODEL

The model has been used during more than 8 hands-on courses throughout the world including American Society for Gastrointestinal Endoscopy hands-on courses during Digestive Disease Week in 2012 (San Diego, California, USA) and 2013 (Chicago, IL, USA). It has been used in EndoLive Roma 2013 (Rome, Italy), Hong Kong Interventional Endoscopy at the Chinese University of Hong Kong Prince of Wales Hospital 2013 (Hong Kong, China) and Orlando Live EUS 2013 (Orlando, FL).

We recently administered a questionnaire to seven echoendoscopists before and after use of the simulator during a hands-on training course in Italy. The mean EUS experience was 5 years (range: 1-10) and the mean number of EUS procedures performed per year was 201 (range: 30-350). All but one endoscopist rated the model ≥8 on a scale of 1-10 for the following parameters: Overall satisfaction, ease of use, realistic feel, and ability to image. Although we believe the model is beneficial for training purposes results and ease of use by trainees are not yet available.

Echovideos taken during various procedures using the model are shown [Videos 1-7]. During puncture, the "cyst" does not move away from the gastric wall even when the Seldinger technique (without electrocautery) is used. The images and tactile feel are similar to that found in pseudocyst and cyst puncture.

We have found the model to be quite durable. The cyst can withstand 5-10 punctures with and without cautery and does not collapse during this period. In addition, the stomach can be rotated so that the puncture sites are on the opposite gastric wall, allowing it to be repeatedly punctured and maintain the ability hold air for insufflation. In addition, despite insertion and removal of stents (including large bore self-expandable metal stents) from the "cyst" it does not collapse until an average of seven interventions due to the high viscosity of the contents [Figure 5].

Aside from practicing access of fluid collections, the model is useful for practicing access to other fluid filled targets, such as gallbladders and dilated bile ducts. The opportunity to practice guidewire exchanges is quite
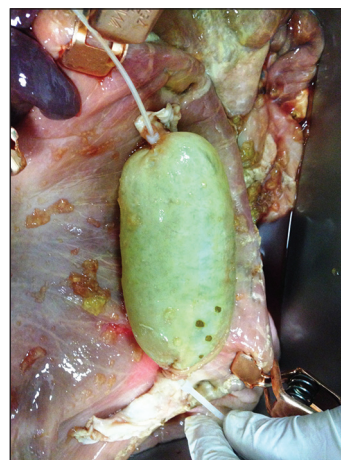
Figure 5. Inspection of "pseudocyst" after multiple punctures, insertions, and removal of large diameter self-expandable metal stents. Note the cyst has not collapsed, and puncture sites are visible toward the bottom of the cyst

valuable, as this is a frequent root cause of failure of complex interventions. Fine-needle aspiration (FNA) technique can also be practiced. Unfortunately, the model cannot be used to recreate normal sized bile ducts and thus is a minor limitation.

Since the entire contents of the stainless pan are grounded, any procedure utilizing cautery can be performed. The users and any personnel are protected from electrical conduction as the stainless pan sits deeply on an insulated tub.

DISCUSSION

In this report, we describe the creation and use of an inexpensive *ex-vivo* model for EUS-guided puncture and practicing transmural drainage techniques of cystic structures, particularly for simulated pancreatic cysts and pseudocysts and walled-off necrosis. The model has been used for a hands-on demonstration at national and international society meetings around the world. The addition of artificial blood vessels in the form of water-filled tubing allows the user to become familiar with using echoendoscopic Doppler and to use techniques to avoid puncture of such "blood vessels."

The advantages of this model are its low cost, relatively easy set up, and its durability that allows one to puncture cystic structures multiple times without having to change any components of the model.

Endoscopic ultrasound models have been previously described. For example, in 2003 a simple phantom

model was created for training in EUS-FNA puncture of solid and cystic lesions.[5] The authors used a modified barium enema bag filled with agar and which contained suspended vegetables, macaroni, and water-filled latex spheres to simulate solid and cystic lesions. Intravenous tubing was connected to a water pump and placed into the enema bag to simulate blood flow. However, this model does not create a realistic tissue effect.

Itoi *et al*. created an inanimate mechanical model for testing physical properties of various EUS needles, though it is not designed to simulate the human experience.[6]

Other *ex-vivo* simulators have been used. Only one formal publication of the Erlanger training model has been described.[4] This model uses a porcine gallbladder attached to the duodenum. However, only one puncture and drainage can be performed since bile is quickly evacuated from the gallbladder.

We are aware of the variation in which the porcine urinary bladder was attached to the posterior wall of the stomach to simulate a cystic structure (unpublished). However, during use by one author (Baron TH) the porcine bladder wall was quite firm and somewhat difficult to puncture. This caused some separation of the cystic structure from the gastric wall. The durability of the model is not known.

Limitations of the present system are the need for dedicated animal echoendoscopes due to concern for transmission of animal-related diseases and breakage of clinical endoscopes. Provision of such nonclinical equipment is expensive and can be prohibitive for many endocenters and training programs. In addition,

the model does not replicate true anatomy, particularly the orientation of biliary structures in live porcine anatomy. Finally, the stainless pan precludes the use of fluoroscopy, though the model could potentially be modified for such use.

We believe this model described here is useful for endoscopists with an interest in training in EUS-guided FNA, and aspiration and placement of prosthesis transmurally into pancreatic cysts and pancreatic fluid collections as well into simulated bile ducts and gallbladders. It is also useful for the development and testing of accessories for transmural puncture and drainage of pancreatic collections. Studies are needed to validate its use as a method to enhance learning of EUS-guided techniques.

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