Transgastric cholecystectomy: transgastric accessibility to the gallbladder improved with the SEMF method and a novel multibending therapeutic endoscope

Kazuki Sumiyama, MD, PhD, Christopher J. Gostout, MD, Elizabeth Rajan, MD, Timothy A. Bakken, RN, Mary A. Knipschield, Sydney Chung, MD, Peter B. Cotton, MD, Robert H. Hawes, MD, Anthony N. Kalloo, MD, Sergey V. Kantsevoy, MD, Pankaj J. Pasricha, MD

Rochester, Minnesota, USA

Background: Transgastric cholecystectomy is thought to technically and anatomically challenge a single entry flexible endoscopic approach.

Objectives: To examine the feasibility of a transgastric-only cholecystectomy, endoscope performance in an upper-abdominal operation, and the usefulness of an offset gastrotomy.

Study Design: Animal survival study.

Setting: Animal research laboratory.

Patients: Six domestic pigs.

Main Outcome Measurements: Transgastric access to the gallbladder and technical feasibility of unassisted transgastric cholecystectomy.

Interventions: A cephalad submucosal tunnel was created in the anterior gastric wall with a high-pressure CO_2 injection. An EMR-cap myotomy was performed distally within the submucosal space and created an offset gastrotomy. An endoscope was inserted into the peritoneal cavity through the myotomy. Access to the gallbladder was compared by using a multibending therapeutic endoscope (R-scope), with a standard double-channel endoscope. A cholecystectomy was performed by using both types of endoscopes. The myotomy site was sealed with the overlying mucosal flap. The mucosal entry point was closed with clips or tissue anchors.

Results: A standard double-channel endoscope could access the gallbladder in 2 of 4 attempts. A multibending endoscope accessed the gallbladder in all 4 attempts, including 2 pigs in which the standard scope failed to access the gallbladder. In 4 pigs, a cholecystectomy was completed. Two pigs died during surgery, with air embolization observed in 1. Two pigs survived a planned 1-week survival period.

Conclusions: Transgastric cholecystectomy is technically feasible. Transgastric access to the gallbladder may be improved by using submucosal endoscopy with an offset exit gastrotomy by means of the mucosal flap safety-valve technique and a multibending gastroscope. (Gastrointest Endosc 2007;65:1028-34.)

A cholecystectomy is the most prevalent laparoscopic surgery and is a consideration for natural orifice transluminal endoscopic surgery (NOTES).[1-3] A peroral transgastric route was used as an access to the peritoneal cavity for NOTES in initial trials.[1,2,4-13] However, access to the upper-abdominal cavity, higher than the level of the stomach, requires retroflexion of an endoscope.[1-3,14] Access to the gallbladder is restrictive because of the distance and the angle of approach from an anterior gastrotomy site. Therefore, the gallbladder is not consistently identified via a single gastrotomy approach.[3] Although Swanstrom et al[2] reported a new shape lockable overtube that provided consistent access to the gallbladder, a cholecystectomy succeeded in only 1 of 3 attempts. Park et al[1] reported the use of 2 endoscopes and percutaneously

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inserted forceps as a hybrid procedure in anticipation that a single endoscope unassisted cholecystectomy may be overwhelming. In an effort to improve access to the gallbladder for NOTES, approaches from the lower abdominal cavity, such as transcolonic, transvesical, and even transvaginal routes, were reported and offered as more ideal than a transgastric route.[3,12,14,15] These alternative routes emphasize a straight access to the upper abdominal cavity, maintaining scope functionality by avoiding retroflexion. However, a peroral transgastric route has advantages over these alternative routes. Peroral gastric preparation may be easier and more acceptable for patients. The stomach is relatively cleaner and may provide better endoluminal anatomical orientation with discriminating anatomic landmarks. There may also be a lower risk for surrounding organ injury with the anterior wall PEG-style gastrotomy.[16-18]

In this study, we primarily attempted to perform exclusive transgastric cholecystectomy and compared our standard 2-channel gastroscope used for NOTES procedures with a therapeutic multibending endoscope.[19-21]

We reported submucosal endoscopy with a mucosal flap safety valve technique (SEMF) as a safer methodology to access the peritoneal cavity for NOTES.[22] SEMF requires the submucosa to be separated with a high-pressure CO_2 injection followed by balloon dissection to create a working space. Access to the peritoneal cavity is established by myotomy distally within the submucosal space. The submucosal space can provide a protective offset entry to the peritoneal cavity, which may minimize peritoneal soiling by using the overlying mucosa as a sealant flap. The SEMF technique allows safe transesophageal access into the mediastinum.[23] In this study, we examined this approach but modified it to create a cephalad submucosal tunnel at the anterior gastric wall to directly lead an endoscope to the upper-abdominal cavity.

Capsule Summary

What is already known on this topic

- A peroral transgastric route has been used to access the peritoneal cavity for natural orifice transluminal endoscopic surgery, but access to the abdominal cavity higher than the level of the stomach requires retroflexion of an endoscope.

What this study adds to our knowledge

- By using a cephalad submucosal tunnel in 6 pigs, a multibending therapeutic endoscope could access the gallbladder in 4 pigs, including 2 in which a standard endoscope failed access, and cholecystectomy was completed in 4 pigs.

MATERIALS AND METHODS

Instruments

Multibending endoscope. The endoscope used (XGIF-2TQ260ZMY, R-scope; Olympus Optical Co, Ltd, Tokyo, Japan) has 2 bending sections: the proximal section can be deflected in a single plane (up–down); the distal section can be deflected in 2 planes (up-down, right-left). There also are 2 actuated instrument channels: 1 allows vertical elevation, the other allows a horizontal ‘‘swing’’ movement (Fig. 1, Table 1).

CO_2 tissue separation. For CO_2 injection, a commercially available CO_2 cylinder (CO_2 Duster; American Recorder Technology Inc, Simi Valley, Calif), used to clean electronic equipment, was used (Fig. 2). The published pressure of the cylinder is 70 to 140 psi, with an average of 100 psi or 7 Bars. The CO_2 is released into a standard needle catheter (23-gauge, 4-mm-long Injector Force catheter; Olympus America, Center Valley, Pa).

Transgastric cholecystectomy procedure

Six domestic 30- to 40-kg pigs were approved by the institutional animal care and use committee research section for use in this study.

SEMF technique

First, the gastric mucosa was lavaged with sterilized water and 20 mL 10% povidone iodine via the endoscope channel. A high-pressure millisecond (estimated) CO_2 burst was injected into the submucosa at the anterior wall of the mid body or the antrum. The CO_2 injection was performed with the maximum pressure of the cylinder and a quick full squeeze and release of the handle. A mucosal incision (10 mm) was made at the closest margin of the gas submucosal cushion with a standard needle knife (KD-1L-1; Olympus Optical). A standard double-channel endoscope (GIF 2T100B; Olympus America), with an attached 19-mm EMR cap (Olympus America) was inserted into the submucosal space. A standard 15-mm-diameter ERCP occlusion balloon catheter (Olympus America) was used to dissect the submucosal space if complete separation of the mucosa from the submucosa was not obtained by gas dissection. Opposite the mucosal entry point and within the submucosal space, a myotomy was made by an EMR cap. Either endoscope was used, with the tip retroflexed to create a cephalad submucosal tunnel.

After entry into the peritoneal cavity, air was instilled via the endoscope channel to maintain a pneumoperitoneum. The pneumoperitoneum was not measured with a Verres needle. It was monitored as per prior protocol by maintaining a soft abdomen to manual palpation and by closely following the respiratory rate, oxygen saturation, and

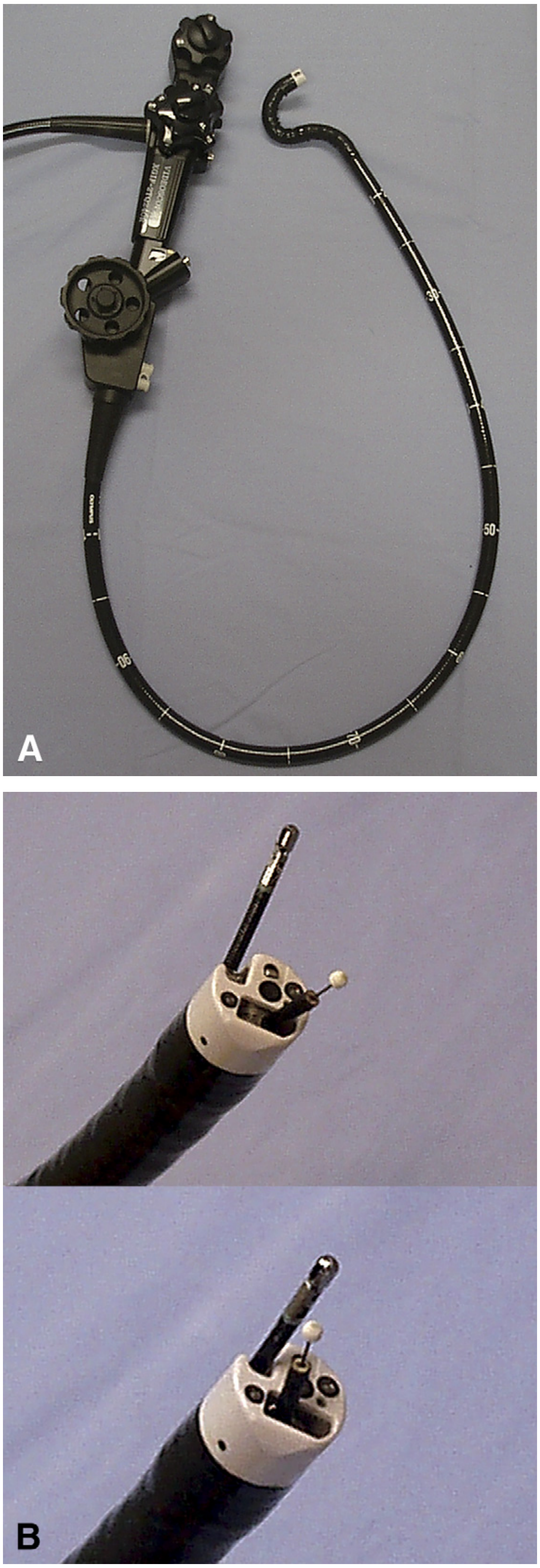

Figure 1. Multibending therapeutic endoscope, **A,** Entire view of the scope. The dial at the top of the control arm controls the proximal bending portion. The second dial controls the distal bending portion. The third dial is for the horizontal ''swing'' function. **B,** Tip of the endoscope. A ball tip knife swung to left and forceps elevated (*above*), and knife swung to right and forceps at the regular position (*below*).

TABLE 1. Comparison between a therapeutic multibending endoscope (XGIF-2TQ260ZMY: R-scope) and a standard double channel endoscope (GIF-2T100B)

	XGIF-2TQ260ZMY	GIF-2T100B
Channel size, mm	2.8/2.8	3.7/2.8
Outer diameter, mm	14.3	13.2
Field of view	140° in wide position; 75° in tele position	120°
Angulation range		
Distal	Up, 180°; down, 100°; right, 100°; left, 100°	Up, 210°; down, 90°; down right, 100°; left, 100°
Proximal	Up, 90°; down, 90°	NA

NA, Not applicable.

Figure 2. CO_2 cylinder.

heart rhythm. Each pig was placed in a reverse Trendelenburg position.

Evaluation of gallbladder access and technical feasibility of ''single-scope'' transgastric cholecystectomy

Controlled access to the gallbladder was evaluated by touching the cystic duct (Fig. 3A) and the fundus of the gallbladder (Fig. 3B) with the endoscope tip. The

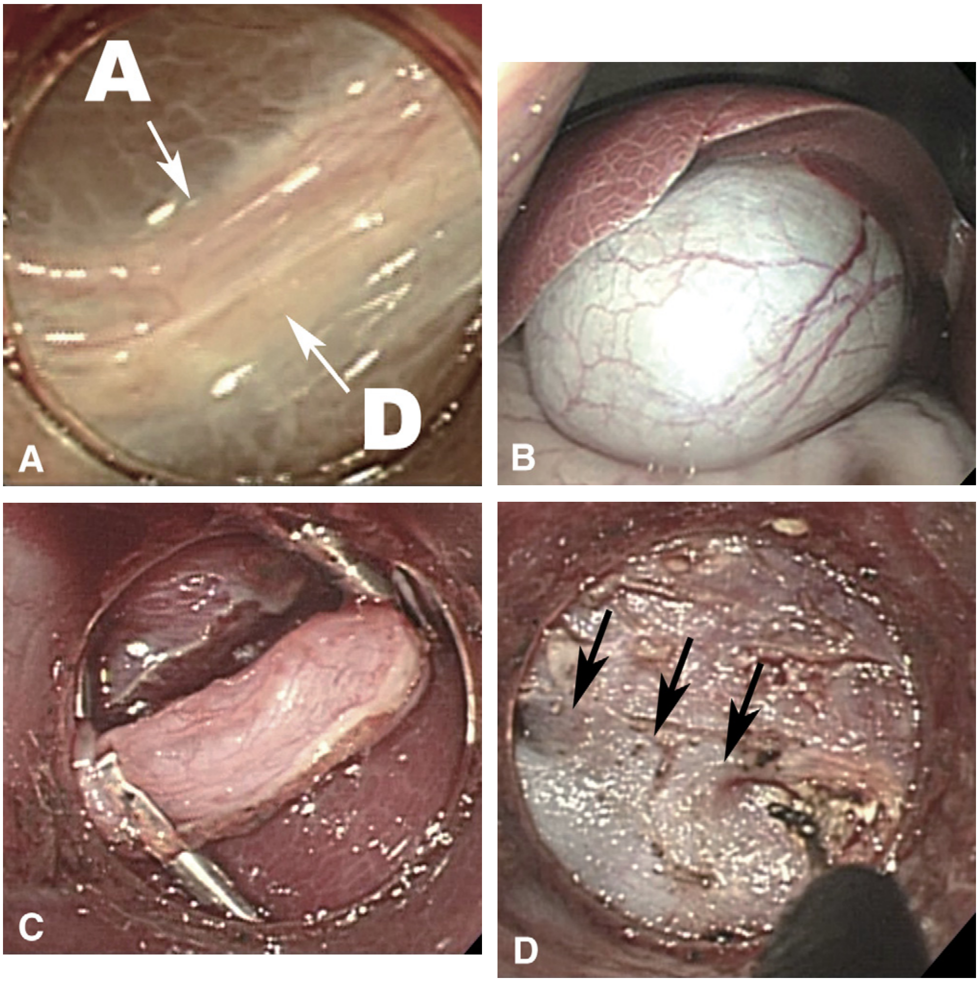

Figure 3. Cholecystectomy procedural steps. **A,** Cystic duct (*A*, the cystic artery; *D*, the cystic duct). **B,** The fundus of the gallbladder. **C,** Isolated cystic duct and artery clamped with 4 clips. **D,** Endoscopic dissection of gallbladder from liver (*arrows*).

procedure started with the double-channel endoscope for 4 pigs and with the R-scope for 2 pigs. The transparent EMR cap was used to create an instrument working space, albeit small, for either endoscope. If either the cystic duct or the fundus of the gallbladder could not be accessed with the initial endoscope, then it was switched to the other endoscope and access was evaluated similarly. A cholecystectomy was attempted by using the endoscope that provided access to the 2 contact locations.

The cystic duct and artery were isolated by dissection off the liver surface with a hook knife (Hook knife; Olympus Optical). The cystic artery and cystic duct were clipped together with 4 standard hemoclips (QuickClip2; Olympus America) and then divided between the clips (Fig. 3C). To dissect the gallbladder from the liver bed, the gallbladder was retracted toward the fundus to expose posteroinferior attachments of the gallbladder by pushing with the EMR cap. The tissue plane between the gallbladder and the liver was dissected with a hook knife. Blended current was used to prevent oozing from the liver bed (Fig. 3D). When the R-scope was used, both the horizontal ''swing'' function and the vertical elevator were used to position the knife for the most ideal dissection. The excised gallbladder was perorally retrieved from the body via the SEMF gastrotomy without any prior drainage of the organ.

After the cholecystectomy, the peritoneal cavity was lavaged with 5% povidone-iodine. The gastrotomy was sealed with the overlying mucosal flap. The mucosal incision was apposed with either hemoclips or tissue anchors (Olympus Optical). T-tag tissue anchors attached by a bifurcated suture were deployed into the submucosal space by using needle delivery systems at both sides of the edges of the mucosal incision. Then, a proximal moveable T-tag was slid forward to cinch the 2 distal submucosal tags by using a pusher sheath advanced over a forceps grasping the proximal end of the moveable tissue anchor. The details of this procedure were previously reported.[24]

The pigs were on a liquid diet for 48 hours, a softened diet on day 3, and then a normal diet as tolerated. They also received antibiotics for 5 days (enrofloxacin

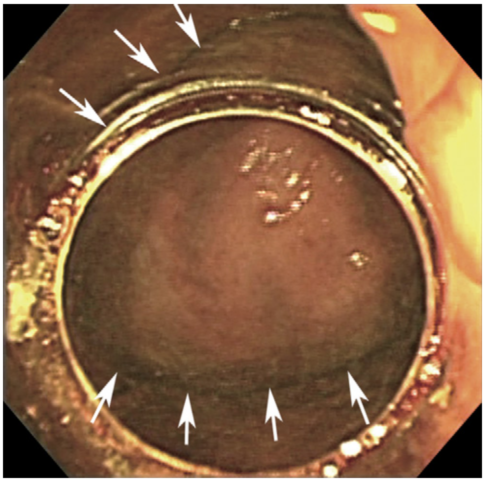

Figure 4. A bowl-shaped gas submucosal bleb approximately 10 cm in diameter at the anterior wall of the stomach (*arrows*).

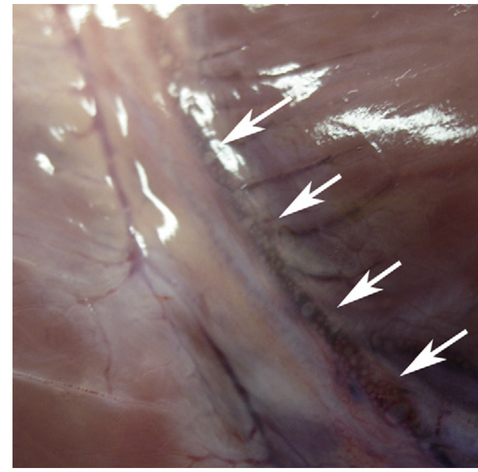

Figure 6. The coronary vein filled with microbubbles (*arrows*).

Figure 5. A resected gallbladder.

10 mg/kg once a day [Baytril]; Bayel Co, Shawnee Mission, Kan), and antacid therapy for 7 days (esomeprazole Mg 40 mg twice a day [Nexium]; AstraZeneca Pharmaceuticals LP, Wilmington, Del). One week after the procedure, an endoscopy and a necropsy were performed with examination of the abdomen.

RESULTS

SEMF with CO_2 insufflation

A bowl-shaped giant submucosal bleb over 8 cm in diameter was created by several milliseconds (estimated only) of CO_2 injection for 5 animals (Fig. 4), completely separating the submucosal layer from the mucosa, thereby forming a true space (Fig. 5). In 1 pig, a complete submucosal dissection failed, despite CO_2 injections in 5 different locations. The submucosal space was eventually created with supplemental balloon dissection.

Gallbladder access

Myotomies with the attached serosa could be performed inside the submucosal space and provided ready access to the peritoneal cavity in all the pigs. In all of them, the cephalad insertion of the endoscope into the upper abdominal cavity was guided by the submucosal space. The gallbladder was easily identified in all pigs with both types of endoscopes. The time for visualization of the gallbladder from insertion of the endoscope into the peritoneal cavity was 166.7 ± 91.6 seconds (mean ± standard deviation), from 6 to 255 seconds (range), and was not different between the 2 endoscopes. However, the standard 2-channel endoscope could not reach the gallbladder fundus in 1 pig (1/4) and the cystic duct in 2 pigs (2/4), 1 of which included the pig in whom the fundus could not be accessed. The scope was switched to the R-scope for these 2 pigs. The R-scope could access the fundus and the cystic duct of the gallbladder in a total of 4 pigs, including the 2 pigs that the standard dual-channel endoscope failed to access.

Technical feasibility of the cholecystectomy

In 4 of the 6 pigs, the gallbladder was successfully removed and perorally retrieved (Fig. 5). In 2 of the 4 removed gallbladders, a small perforation occurred during the dissection from the liver bed. The R-scope and the double-channel endoscope were used for 2 pigs each. The average operating time was 103.75 minutes (range 70-125 minutes). There was no difference between the 2 scopes in their performance during the dissection. There was minimal oozing during the dissection process, which could be cleared from the field with irrigation. Two pigs died from sudden cardiac arrest and hypoxemia during the operation. Acute necropsy revealed that micro air bubbles had filled the coronary veins (Fig. 6), the right atrium and the ventricles of the heart, and the inferior vena cava in 1 of the 2 pigs.

Outcome of survival study

In 4 surviving pigs after cholecystectomy, the mucosal entry was apposed with clips or tissue anchors for 2 pigs each. Two pigs survived for 1 week after the procedures, without any clinical complication. They were eating normally and gained weight (2 kg) during the survival period. Necropsy revealed that clips still remained at the cystic-duct stump, and there was no finding of bile leakage (Fig. 7). The other 2 pigs were euthanized because of severe peritonitis from gastric contents leakage. In 1 pig, clip mucosal apposition failed, and the mucosal entry site remained open. In the other pig, a hole on the overlying mucosal flap at a different location from the mucosal entry point suture line was found.

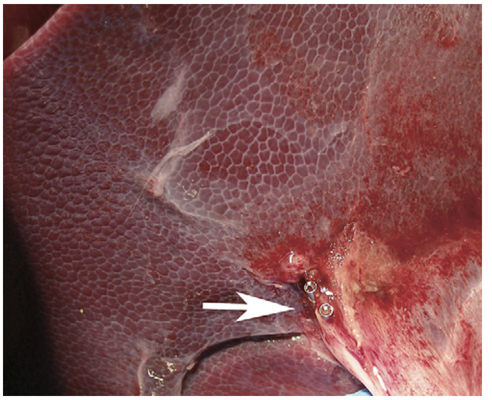

Figure 7. The liver bed of the gallbladder after cholecystectomy during necropsy. Two clips still remained on the cystic duct after the 1-week survival period (*arrow*).

DISCUSSION

A pure transgastric cholecystectomy is feasible when using a cephalad directional exit from the stomach to allow access to the gallbladder. Although the overall outcomes may not have been ideal, they proved instructional with regard to moving forward with NOTES research and development.

Modifying the anterior gastric exit with the SEMF technique directed cephalad could effectively create a biologic endoscope and instrument guide for the upper abdominal cavity. Furthermore, the R-type endoscope design allowed predictable access to the gallbladder by providing additional angulation and ''reach'' from the proximal bending portion. This multibending feature may have other applications during NOTES.

Despite the failure of the SEMF approach to seal the offset gastrotomy in 2 of the pigs, we remain encouraged about its overall value, although comparison with direct PEG-type gastrotomy techniques with balloon dilation is necessary to validate this technique in future studies. The technique was modified to deliver a more robust injection of CO_2 to create an immediate open submucosal space and to avoid tedious dissection with balloons. The large-sized mucosal flap formed during this study may have been excessive and created a risk for mucosal necrosis. The robust gas submucosal dissection interrupts the submucosal vasculature. To prevent necrosis of the mucosal flap, it is necessary to identify the ideal width and length of the submucosal tunnel to preserve a microvascular blood supply for the overlying mucosal flap and to prevent peritoneal contamination. It is possible that the defect encountered in one of the mucosal flaps may have been because of unrecognized mechanical trauma and not because of a presumptive focal ischemic necrosis. Also, it may be imperative to close the mucosal entry site into the submucosal space with minimal tension on the overlying mucosal flap to avoid occlusion of the capillary network of the flap. In preceding studies, the SEMF technique was used to access the mediastinum via the esophagus. The submucosal tunnel was longitudinally created with a 15-mm biliary occlusion balloon, and the thin esophageal mucosa at the mucosal entry site could be easily closed by simple clip application. Ulceration of the mucosal flap and mediastinal soiling have not been observed in this location.[23]

Entry into the peritoneal cavity was accomplished by a snare myotomy, excising the muscularis and the serosa. Although this creates a convenient access to the peritoneum, it is not mandatory. Simple balloon dilation through the muscularis and the serosa may minimize the risk for peritoneal soiling and enhance the healing process with the mucosal flap. Our developmental endoscopy unit is working to develop practical closure devices and a sealant to adhere the mucosal flap onto the muscular layer.

Pneumoperitoneum for NOTES is currently maintained out of convenience with simple air insufflation via the endoscope, because there is no readily available pressure-regulated air insufflator for NOTES adapted to the flexible endoscopic system. Until this study, we were performing less-complex procedures without the use of a Verres needle laparoscopic-gas monitoring system and by closely monitoring the pig clinically, as described above. Maintaining the pneumoperitoneum within accepted pressure ranges is an established standard of practice during laparoscopic surgery. We fully anticipated that this standard would inevitably be required as our own NOTES development progressed further. This ultimately became challenged by the fatal complication of air embolism documented in 1 of the 2 pigs' sudden fatalities. Room air is 34 times less soluble in blood than CO_2 used in most laparoscopic surgery for pneumoperitoneum.[25] Room air pneumoperitoneum, therefore, is recognized as the risk for gas embolism and is currently obsolete in laparoscopic surgery.[26] We surmise that a massive air infusion into the systemic circulation occurred in one of the pigs through opened venous channels during prolonged gallbladder dissection and caused fatal pulmonary embolization. To minimize risks of the gas embolism, pneumoperitoneum should be established with CO_2 or other soluble gases, and intra-abdominal pressure should be maintained lower than the venous blood pressure, as is the practice in laparoscopic surgery. This outcome emphasized that NOTES requires a standard surgical environment for safe surgery under pneumoperitoneum.

A standard EMR cap was used to provide a mini-working space for manipulating the devices and for performing the dissections. Although this worked, both the operative field of view provided by the endoscope and the limited working space challenge organ removal when the target tissues and organs already are in a confined location. Minor bleeding that occurred during the dissection, which may not be uncommon, stressed the already-limited field of view. This could be a norm for early-generation NOTES procedures, but, based upon our experience creating a model for appendicitis and a NOTES appendectomy, this is not a universal problem.

This study demonstrated the technical feasibility of the transgastric cholecystectomy. The access to the gallbladder for a transgastric route could be improved with the combined use of the upward submucosal tunnel with the SEMF technique and a multibending endoscope. Further innovation with NOTES-specific surgical devices is mandatory for efficiencies, success, and safety of these evolving procedures.

DISCLOSURE

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Current affiliations: Developmental Endoscopy Unit, Division of Gastroenterology and Hepatology, Mayo Clinic College of Medicine, Rochester, Minnesota, USA (K.S., C.J.G., E.R., M.A.K., T.A.B.), Division of Gastroenterology and Hepatology, Johns Hopkins University, Balti*more,* Maryland, USA (A.N.K., S.V.K.), Division of Gastroenterology and Hepatology, University of Texas Medical Branch, Galveston, Texas, USA (P.J.P.), Division of Surgery, University of Papua New Guinea, Port Moresby, Papua New Guinea (S.C.), The Digestive Disease Center, The Medical University of South Carolina, Charleston, South Carolina, USA (R.H.H., P.B.C.).

Reprint requests: Christopher J. Gostout, MD, Developmental Endoscopy Unit, Charlton 8, Mayo Clinic, 200 First St SW, Rochester, MN 55905.