NOTES: Issues and Technical Details With Introduction of NOTES Into a Small General Surgery Residency Program

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ABSTRACT

Background and Objectives: Natural orifice transluminal endoscopic surgery (NOTES) is a development of recent origin. In 2004, Kalloo et al first described NOTES investigation in an animal model. Since then, several investigators have pursued NOTES study in animal survival and nonsurvival models. Our objectives for this project included studying NOTES intervention in a laboratory environment using large animal (swine) models and learning to do so in a safe, controlled manner. Ultimately, we intend to introduce NOTES methodology into our surgical residency training program. The expertise of an experienced laparoscopic surgeon, fellowship-trained laparoendoscopic surgeon, and veterinarian along with a senior surgical resident was utilized to bring the input of several disciplines to this study. The Institutional Animal Care and Use Committee (IACUC) of Northeastern Ohio Universities College of Medicine and Pharmacy (NEOUCOM/COP) approved this study.

Methods: A series of 5 laboratory sessions using mixed breed farm swine varying in weight from 37 kg to 43.1 kg was planned for the initial phase of NOTES introduction into our residency program. Animals were not kept alive in this investigation. All animals were anesthetized using a standard swine protocol and euthanized following guidelines issued by the American Veterinary Medical Association Panel on Euthanasia. Equipment included a Fujinon EVE endoscope 0.8 cm in diameter with a suction/irrigation channel and one working channel. Initially, a US Endoscopy gastric overtube, 19.5 mm OD and 50 cm in length, was used to facilitate passage of the endoscope. However, this device was found to have insufficient length. Subsequently, commercially available 5/8” diameter clear plastic tubing, 70 cm to 80 cm in length, was adapted for use as an overtube. Standard endoscopic instruments included Boston Scientific biopsy forceps, needle-knife, papillotome, endoscopic clip applier, and Valley Lab electrosurgical unit. A Karl Storz laparoscope and tower were used for laparoscopic observation of NOTES maneuvers. Necropsy was performed to determine specific details of surgical intervention.

Results: NOTES intervention is feasible in an animal model. Insight into the potential of NOTES was obtained in this investigation.

Conclusions: NOTES investigation in a controlled, laboratory setting using an animal model proved to have value for our program. A steep learning curve was encountered despite the availability of an investigator familiar with elementary NOTES procedures. The authors strongly suggest investigators adopt the ASGE/SAGES working group recommendations for a multidisciplinary team possessing advanced therapeutic endoscopic and advanced laparoscopic skills to study NOTES before human investigation. Animal laboratory facilities to perform research and training should be available to the multidisciplinary team for exploration of NOTES techniques and procedures. Institutional Review Board (IRB) approval must be obtained before introduction of NOTES procedures in human patients.

Key words: Natural Orifice Transluminal Endoscopic Surgery, Endoscopy, Laparoscopy, Surgical residency.

INTRODUCTION

An unprecedented revolution occurred in general surgery with Reddick and Olsen’s, McKernan and Saye’s, (and others) introduction of laparoscopic cholecystectomy in the United States in 1988. Since that time, many operative interventions in the abdominal and thoracic cavity have been adapted to a laparoscopic approach. Less invasive methods of diagnosis and therapy have been applied to a
wide variety of diseases. It has become apparent that minimally invasive surgery has been associated with faster recovery, earlier return to full activity, less suppression of the immune system, and fewer adhesions. In addition, most would agree that the small incisions of laparoscopic surgery are associated with a more cosmetic outcome than is possible with open laparotomy. A similar revolution has quietly been going on in the field of flexible intralumenal endoscopy. Initially, endoscopic evaluation of the GI tract was one of diagnosis and very limited therapy. However, endoscopic biopsy and the snaring of polyps was a marked advance over previous methods of management, which often involved open exploration. Interventional endoscopists have recently broadened the indications for endoscopic therapeutic manipulation, and there seems to be a convergence of the once separate paths of endoscopy and gastrointestinal surgery. Endoscopists now perform procedures once solely reserved for the gastrointestinal surgeon.

Further convergence of the gastrointestinal interventionist and GI tract surgeon may involve a melding of the endoscopic and laparoscopic experience. Natural orifice translumenal endoscopic surgery (NOTES) offers the potential to utilize the expertise of gastroenterologists and surgeons to develop a new, more minimally invasive approach to intercavitary operative intervention. There are no abdominal incisions with NOTES. Access to the peritoneal cavity is gained by transgressing a hollow viscus, which may include the stomach, colon, vagina, or urinary bladder. The elimination of abdominal incisions may lessen return to full activity, lessen up-regulation of the immune response, reduce abdominal wall incisional hernias, and improve cosmesis of the operative procedure. In addition, there may be benefits to be gained from not transgressing a scarred or obese abdominal wall and avoiding the necessity of incurring a surgical wound in the presence of abdominal wall infection.

Leaders of the American Society of Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) formed a working group called the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) of which the senior author is a member. NOSCAR identified challenges that NOTES practitioners would have to address before NOTES could be addressed in clinical practice. The challenges or potential barriers to NOTES adoption in clinical practice include:

- Access to the peritoneal cavity
- Gastric (intestinal) closure
- Prevention of infection
- Development of a suturing device
- Development of an anastomotic (nonsuturing) device
- Development of a multitasking platform to accomplish procedures
- Control of intraperitoneal hemorrhage
- Management of iatrogenic intraperitoneal complications
- Physiologic untoward events
- Compression syndromes
- Training other providers

Several studies have now demonstrated that NOTES can be performed. But, there is a question of whether NOTES procedures can be performed safely. Also, specific issues exist that concern the NOTES practitioner regarding secure closure of the translumenal access site and development of endoscopic instrumentation suitable for surgical procedures.

With the above in mind, the authors determined to explore NOTES technology and determine whether now is the time to introduce this concept into a small general surgery residency program.

METHODS

Approval for this project was obtained from the Northeastern Ohio Universities College of Medicine and Pharmacy (NEOUCOM/COP) IACUC (Institutional Animal Care and Use Committee). St. Elizabeth Health Center (SEHC) is one of several major teaching facilities for NEOUCOM, a medical school comprising a consortium of 3 state universities in northeast Ohio. All animal laboratory experiments were conducted in the NEOUCOM/COP Comparative Medicine Unit.

From January 2007 through July 2007 at approximately monthly intervals, a large animal laboratory session was conducted at NEOUCOM/COP to study NOTES intervention.

Five female mixed breed farm swine were selected for the experimental model because of their size and close approximation of human anatomy. The swine varied in weight from 37 kg to 42.1 kg. Animals were fasted for 24 hours before the laboratory procedure, but allowed water
ad libitum. Swine were preanesthetized with Telazol administered intramuscularly at a dose of approximately 6.6 mg/kg and atropine at a dose of approximately 0.04 mg/kg. Animals were subsequently intubated, and anesthesia was maintained with isoflurane delivered at 1% to 2% of inspired gas (pure oxygen). Animals were ventilated at a rate of 10 breaths per minute using a tidal volume of approximately 11 mL/kg and an inspiratory ratio of 1:2.

Endoscopic equipment was supplied by the Fujinon Corporation (Omiya, Japan) and consisted of a 0.8-cm Fujinon EVE endoscope with one working channel and an irrigation/suction channel. The control module was set for 12:00 orientation. Surgical images were captured on a 512 MB memory card and saved in JPEG format.

A Karl Storz (Tuttlingen, Germany) laparoscope, insufflator, light source, and display were used for laparoscopic monitoring of the NOTES procedure and also used for a “hybrid” (NOTES and laparoscopic techniques) intervention. Five-mm trocars and cannula were used for laparoscopic visualization of NOTES maneuvers.

A commercial US Endoscopy (Mentor, OH) esophageal overtube (19.5 mm OD, 50 cm length) for human use was initially used to facilitate repeat passage of the endoscope. This overtube was found to lack sufficient length for NOTES studies in a large animal model. Clear plastic tubing 5/8” in diameter was substituted for the US Endoscopy overtube and cut to 70 cm to 80 cm lengths depending on animal size and anatomy. The proximal obturator of the US Endoscopy tube was taped to the longer clear plastic tube to prevent egress of insufflated air and GI content.

A Jorgensen 24 Fr veterinary oral gastric tube (ID 14 Fr, OD 23 Fr, length 76 cm) (Jorgensen Laboratories, Loveland, CO) was used to decompress the stomach. In our swine model, the oral gastric tube served as a guide for overtube passage. A long suture was affixed to the proximal end of the oral gastric tube and secured distally to a long, straightened coat hanger. Once it was determined to pass the overtube, the straightened coat hanger was passed through the overtube. The overtube was advanced over the oral gastric tube, and the oral gastric tube was removed by withdrawing the long suture that had been previously attached to its proximal end.

Chlorhexidine solution diluted to 0.5% was used to wash and cleanse the oropharynx (130 mL) and stomach (200 mL). Each site was washed and suctioned 3 times during the preoperative preparation. Aerobic and anaerobic cultures were taken after preparation.

Boston Scientific (Natick, MA) Glidewires, 450 cm in length and 0.035” in diameter, were used to guide passage of endoscopic instruments and dilators. Boston Scientific microvasive C-R-E balloon dilators were capable of dilating the gastric track 10 mm to 12 mm in diameter. Lubrication of all channels was secured with sterile water or saline. Water-soluble gel was used to lubricate the overtube.

Boston Scientific provided biopsy forceps and endoscopic clips.

“Safe tract” passage of a spinal needle with attached syringe was used to rule out the presence of a hollow viscus anterior to the anterior gastric wall.15 Anterior abdominal pressure with a 20 mL syringe barrel was used to help determine endoscopic orientation within the gastric lumen. Pressure was maintained to help orient the operator to the anterior surface of the stomach. A mound of stomach mucosa was produced with anterior abdominal wall pressure and helped provide a “target” for the needle knife. In addition, abdominal wall/stomach pressure provided counterresistance for advancement of the needle knife and application of electrosurgical energy.

An overtube was used to guide the needle knife to the target site on the anterior gastric wall. The overtube supplies necessary rigidity for the flexible endoscope to appropriately address the stomach wall. A Boston Scientific needle knife was used to perform all gastrotomies. After safe tract maneuvers suggested that no visceras intervened between the anterior abdominal wall and stomach, a mound of gastric mucosa was developed as described above. Under direct visualization of the gastric mound by the endoscopist, the endoscope, made rigid at its distal end by the overtube, was guided to the gastric mound (Figure 1). Contact was then made with the gastric mound. Electrosurgical energy was supplied to the needle knife, and the needle knife wire and knife body were thrust through the gastric wall. Immediately prior to gastric wall penetration, electrical surgical power was discontinued and the needle knife wire withdrawn. Failure to perform this maneuver in a precise fashion can cause inadvertent injury to the anterior abdominal wall, mesentery, intestine, or viscera (Figure 2).

A 450-cm glidewire was then advanced through the needle knife (Figure 3). It is important to have sufficient length of glidewire to enable passage of endoscopic instruments. A dilating balloon was then exchanged over
the glidewire and the gastrotomy site dilated to 12 mm (Figure 4).

The endoscope was advanced through the dilated gastrotomy site and intraabdominal endoscopic examination was performed (Figure 5). At this point, it is important to monitor intraabdominal pneumoperitoneum to avoid excessive abdominal pressures. A 5-mm trocar and cannula were effective in monitoring intraabdominal pressure and evacuation of pneumoperitoneum as required.

It was noted that during prolonged periods of gastric insufflation, air passed through the pylorus and distended the entire small bowel. Dilatation of the small bowel from this cause limited intraabdominal examination and could hamper endoscopic intraabdominal procedures. A pyloric obturator using a human baby nipple and plastic skirt was fashioned, but proved to be difficult to pass down the confines of an overtube (Figures 6 and 7). Further work to develop an appropriate obturator is ongoing in our lab.

Solid organ biopsy was performed during our studies along with attempted endoscopic clip closure of the gastrotomy site and simulated appendectomy (fallopian tube model). (Figure 8).

RESULTS

Preprocedure placement of an oral gastric tube (Jorgensen 24 Fr, Jorgensen Laboratories, Loveland, CO) was useful in decompressing the stomach. In addition, placement of
an oral gastric tube facilitated passage of the overtube. Use of an overtube in this animal model reduced operator-induced trauma to the oral pharynx and esophagus and reduced the potential for transporting oropharyngeal bacteria into the abdominal cavity.

Chlorhexidine solution (0.5%) wash of the oral pharynx and stomach was efficient in cleansing these areas and providing asepsis. No aerobic or anaerobic organisms were retrieved on culture.

In the 5 animals studied, 4 had normal swine anatomy. Gastric perforation with a needle knife and dilation of the gastrotomy tract was accomplished in these animals (#1 – 4). Intraabdominal exploration with the flexible endoscope was similarly successful.

Animal #5, however, had extensive adhesions in the epigastrium and left upper quadrant. These adhesions were of undetermined origin. In this animal, adhesions hindered adequate abdominal access and visualization. There was extensive distortion of intraabdominal anatomy. The spleen was tethered to the greater curvature of the stomach. Because the spleen was also fixed to the mid epigas-
trium, inadvertent injury to the spleen occurred with passage of the needle knife, glidewire, and endoscope.

A steep learning curve was encountered with the initial laboratory experiments. Four to 5 hours were required in the initial studies to gain endoscopic access to the intra-abdominal cavity. Because of the lengthy time required to actually perform NOTES maneuvers, the authors learned to withhold anesthetizing animals until all members of the team were present and all instruments checked and made ready. With practice and experience, time to gain intra-abdominal endoscopic access was reduced to less than one hour.

“Safe tract” proved to be a useful maneuver. It was, however, not foolproof in our experience. Other techniques such as ultrasound or CT would facilitate the determination of intraabdominal visceral relationships. Palpation on the anterior abdominal wall after endoscopic access to the stomach and gastric insufflation helped orient the operator to the anterior stomach wall and provided a “target” (gastric mound) for penetration by the needle knife. Additionally, the resistance afforded by anterior abdominal/stomach wall pressure enabled the operator to more easily thrust the needle knife through the gastric wall.

However, the supposed midgastric position of gastrotomy was frequently inaccurate. Most of our gastrotomies were sited closer to the GE junction than anticipated.

Intraabdominal orientation of the gastroscope proved to be difficult. To visualize the liver and gallbladder, the endoscope had to be “J’ed” back upon itself. This maneuver caused several authors to feel as if they were operating “over their shoulders.” Electronic image inversion (conversion to a familiar 12:00 o’clock orientation) reduced this problem.

The presence of one endoscopic operating channel precluded all but the most simple of diagnostic and therapeutic procedures. Two channels would have allowed for grasping a target tissue, fixing it, and performing other maneuvers (cutting, coagulation, biopsy, and others) through the second channel. A limitation of this setup, however, would be the small amount of distance between the 2 channels hindering appropriate triangulation of the instruments. Most of the time, the 2 channels would require that endoscopic instruments be passed just about parallel with one another making manipulation at the target site difficult. “Sword fighting,” as noted when laparoscopic trocars are spaced close together, would result between the instruments. A potential solution to this problem would be the development of articulating endoscopic instruments that could oppose one another with a reasonable degree of separation.

Secure closure of the gastrotomy site is relatively straightforward if a PEG device is used. However, this type of closure is limited by subsequent fixation of the stomach to the undersurface of the abdominal wall and formation of adhesions. The stomach being fixed to the anterior abdominal wall would compromise future NOTES procedures.

Interestingly, the endoscopic clip applier used to close the gastrotomy site was found to be difficult to manipulate. The clips are approved for hemostasis of mucosal and submucosal defects <3 mm, bleeding ulcers, polyps <1.5 mm in diameter, and securing colonic diverticula. They are also approved as a supplementary method to close GI track luminal perforations <20 mm that can be treated conservatively. In our hands, it was difficult to place the endoscopic clips with accuracy in relationship to the gastrotomy site. In addition, it was difficult to manipulate ends of the endoscopic clips on the gastrotomy site to oppose one side of the gastrotomy incision to the other (Figures 9 and 10).

During the course of our studies, several glidewires and endoscopic instruments were used more than once. We found that it was very important to lubricate all channels used to pass instruments with the appropriate agent, water-soluble gel or liquid. The close tolerances of endoscopic instruments and operating channels mandated that generous lubrication be used and that the operating chan-

Figure 9. Open endoscopic clip.
nels be kept as straight as possible to facilitate instrument passage.

Because of the unanticipated steep and prolonged learning curve, all animals were euthanized at the conclusion of the NOTES procedure while still under anesthesia. Subsequent necropsy revealed the soundness of this decision as many relationships, particularly orientation and spatial relationships, became apparent only after open exploration of the abdominal cavity and 3-dimensional visualization.

**DISCUSSION**

Despite the long, steep learning curve, difficulties with operative orientation, and inadequate instrumentation, this laboratory study was found to be instructive and useful in introducing the concept of NOTES intervention to a small general surgery residency program. There were several lessons learned, many of which have been articulated by the early NOSCAR enthusiasts.13

Perhaps the most important lesson relearned was that the initiation of a NOTES program requires the special skills and experience of both surgeons and therapeutic endoscopists. Each group has particular expertise specific to that specialty, and this combined expertise is necessary for the successful development of translumenal, intercavitary surgery.

The matter of endoscopic orientation was an issue from the very first. It was interesting to find that palpation of the anterior abdominal wall and safe tract maneuvers resulted in the anterior stomach wall appearing in many positions other than a 12:00 o’clock orientation. Orientation was further challenged when the endoscope was J’ed to look back at the liver and gallbladder from an anterior gastrotomy site. In this position, the 12:00 o’clock and 6:00 o’clock positions were frequently reversed, and it was difficult to torque the endoscope around to right matters. Future instrument development should incorporate endoscopic electronic readjustment capability to “normalize” the visual field for proper triangulation of operative or diagnostic interventions.

Chlorhexidine (0.5%) wash of the oral pharynx and stomach after intubation appeared to be successful in removing particulate matter and providing an aseptic state. Although aerobic and anaerobic cultures of these areas were negative after cleansing, it will be necessary for animal survival studies to show whether dislodgement of bacteria from the oral pharynx during passage of endoscopic instruments is a factor of clinical significance.

The nonsurvival mode of the animal study benefited the development of our NOTES skill. There is a long and steep learning curve for NOTES methodology. By performing an immediate necropsy, we were able to correlate endoscopic impressions with actual anatomic reality.

We found that an in situ oral gastric tube served as an excellent guide for passage of the overtube. Because of the short commercial overtubes available, we utilized commonly available thin-walled clear plastic tubing of 5/8” diameter cut to a length of 70 cm to 80 cm. An overtube of clear plastic was of value in subsequent passage(s) of the endoscope because esophageal and gastric anatomy could be identified through the clear plastic wall. The gastroesophageal junction, an important anatomic landmark and reference point, was easily identified through the overtube. However, we found that an overtube in the porcine, large animal model must be at least 70 cm long to assist in positioning and stabilizing the endoscope for gastric procedures.

The use of an overtube allows for repeated passage of the endoscope with minimal potential for injury to the oral pharynx and esophagus. In addition, there is a decreased risk of dislocating bacteria from the oral cavity and oral pharynx to the operative site(s). It was necessary to secure the open end of the improvised overtube with the obturator available on commercial overtubes. The makeshift obturator prevented efflux of insufflated air and gastric content (Figure 11).

Our improvised overtube was stiff and had a small amount of curve inherent in the plastic material (Figure 11). These qualities augmented our ability to direct the

![Figure 10. Endoscopic clip closure of gastrotomy site.](image-url)
endoscope to a target site and to stabilize it during thrusting and retraction maneuvers. In effect, the overtube stiffened the flexible tip of the distal endoscope and allowed us to have more control when thrusting and manipulating endoscopic instruments was necessary. However, a “soft” tip applied to the distal end of the overtube will help prevent unnecessary trauma to the gastric wall.

During the course of our exercises, we consistently performed the gastrotomy puncture closer to the GE junction than anticipated. The more proximal position of the gastrotomy incision suggested the use of a longer overtube and positioning safe track pressure in a more caudal site on the abdominal wall (between the third and fourth nipple) to the right of the midline.

Besides helping orient our team to endoscopic findings, postprocedure necropsy revealed needle knife superficial injuries to the anterior abdominal wall, mesentery, and small bowel that might have been missed if the animal had been allowed to survive the initial procedure.

We also observed that concurrent 2-mm or 5-mm laparoscopic surveillance was an aid to selecting a gastrotomy site and monitoring passage of the glidewire and endoscope. It was our impression that laparoscopic visualization improved the ease and safety of gastric wall penetration and intraabdominal visceral manipulation. Laparoscopic surveillance, initiated by the Hasson technique, may also aid in safe passage of the endoscope through the stomach wall in those patients suspected of having abdominal adhesions. The addition of small 1-mm or 2-mm laparoscopic ports can allow for laparoscopic instrument introduction to assist NOTES procedures in a “hybrid” manner.

Retroflexion of the endoscope introduced through a gastrotomy site caused difficulty with targeting and triangulating an organ in the upper abdomen. In many instances, it was difficult to obtain proper image orientation and perform subsequent instrument manipulation. Because of these challenges, it may be more advantageous to perform NOTES procedures in the upper abdomen by accessing the abdominal cavity from a more caudal site in the colon, vagina, or urinary bladder.

Interestingly, the development of pneumoperitoneum after hollow viscus penetration may improve safety and deter glidewire or endoscopic instrument injury to intraabdominal content by increasing the distance from the stomach gastrotomy site to these structures.

**CONCLUSION**

Our study suggests that NOTES intervention is a feasible and appropriate “next step” in the evolution of minimally invasive surgical access. There was, however, a long and steep learning curve for our team. We conclude that any investigation of NOTES should involve a multidisciplinary approach with experienced laparoendoscopic surgeons and interventional gastroenterologists collaborating together. These investigations should begin in a controlled, laboratory environment before procedures are attempted on human patients. Finally, we conclude that NOTES investigation is beneficial for a small general surgery residency program to stimulate creativity, explore the limits of technology, gain insight into the design and use of improved NOTES surgical instrumentation, and improve the diffusion of surgical knowledge.

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