

Natural Orifice Transluminal Endoscopic Surgery: “NOTES”

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Advanced practitioners of laparoscopy and endoscopy are developing an exciting new concept that may represent a paradigm shift in how operative interventions are carried out. Natural Orifice Transluminal Endoscopic Surgery (NOTES) is an operative procedure that utilizes an existing body opening for the initial point of access to the abdomen. Rather than transgressing the abdominal wall, an existing orifice, such as the mouth, vagina, or rectum, is used to deliver a flexible endoscope near the peritoneal cavity. A gastrotomy, opening in the vaginal canal, or colotomy is then fashioned to access the abdominal cavity.

Once intraabdominal entrance of the endoscope is achieved and pneumoperitoneum established, various maneuvers can be performed. These procedures range from making a diagnosis to therapeutic interventions, such as biopsy, enteroenterostomy, hollow viscus surgery (appendectomy, cholecystectomy, tubal ligation, and others), and solid organ surgery including splenectomy, oophorectomy, and liver resection.¹⁻⁸ The procedures that can be performed will be limited only by our technology and our imagination.

At first glance, it might seem heresy to deliberately puncture the stomach, vagina, or colon just to access the abdomen. But, is that so very different from transgressing the abdominal wall, subcutaneous tissue, fascia, muscle, and peritoneum—all comprise the abdominal wall—just to gain access to the same body cavity?

Several circumstances might recommend themselves to a NOTES approach. These would include patients with extensive abdominal scarring from previous procedures, morbidly obese persons, those with abdominal wall infection, and those with diminished abdominal wall integrity, such as patients with burns and skin grafting. No abdominal wall incision is made with a NOTES procedure.

Another important consideration might be cosmesis.

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Some patients just do not want to have a scar if it can be avoided. NOTES provides another option.

Investigation of natural orifice procedures is in its infancy and the procedures reported to date essentially explore proof of the concept. Natural orifice transluminal surgery can be done, but should it be done and under what circumstances. These are issues yet to be resolved.

To avoid some of the misunderstandings, missteps, and complications that occurred with the introduction of laparoscopic surgery, responsible leaders in surgical laparoscopy and gastrointestinal endoscopy have begun to confer and define the major issues that confront NOTES intervention. Training, credentialing, privileges, new instrumentation, intellectual property of original ideas, national registry of outcomes, and oversight are just some of the matters that must be studied. One of the main lessons learned from the introduction of laparoscopic surgery is that these issues should be addressed before widespread introduction of a new technology.

A working group on natural orifice transluminal endoscopic surgery composed of ASGE and SAGES members developed a White Paper in October 2005 that helped define the issues confronting NOTES.⁹ Potential barriers to clinical practice with NOTES methodology include the following:

- (1) Access to the peritoneal cavity,
- (2) Gastric (intestinal, vaginal) closure,
- (3) Prevention of infection,
- (4) Development of suture and anastomotic devices,
- (5) Spatial orientation, development of an endoscopic multitasking platform,
- (6) Management of intraperitoneal complications,
- (7) Physiologic untoward events, compression syndromes, training,
- (8) And other issues currently not apparent.

There should be zero tolerance of complications in closure of the stomach, colon, or vaginal access sites.

All of the above challenges must be addressed *before* widespread adoption of natural orifice surgical interventions. Current laparoscopic surgery and endoscopic techniques provide a standard of care with a very low rate of complications. To abandon these techniques to explore a

new paradigm before thorough laboratory and animal testing of NOTES would be reckless and foolhardy.

It is important to recognize that there has been a blurring of the borders between GI surgery and gastrointestinal endoscopy. Surgeons and gynecologists routinely perform endoscopic examinations. Gastrointestinal endoscopists routinely perform therapeutic procedures in the GI tract. This trend will likely continue and is not unnecessarily undesirable. It may be that one day digestive tract specialists will meld surgical and endoscopic training into one specialty. Until then, the initial development of NOTES should involve input from both GI tract surgeons and gastroenterological endoscopists. Teamwork in the lab and in the OR should be encouraged and nurtured.

Initial training of surgeons and endoscopists in natural orifice interventions must involve laboratory and animal models. Training should involve a team approach that takes advantage of the unique skills of endoscopists and laparoscopic surgeons. Appropriate laboratory experience and establishing supportive data are important to gain IRB approval for NOTES intervention in human subjects. After a team has learned and taught one another fundamental skill sets, it is imperative that IRB oversight be obtained before interventions in human subjects are attempted.

Finally, human procedures involving natural orifice surgery should be recorded in a national registry. For this potentially valuable new paradigm to be safely introduced in medical practice, it is necessary to prospectively record the good and bad results of the technique. Only in this manner can potentially harmful trends be identified and corrective measures taken in a timely fashion.

As with the introduction of laparoscopy, there will be a learning curve for NOTES. This and other hurdles remain to be surmounted. The hard-learned lessons of the lapa-

roscopic revolution must not be neglected. Lets not forget history, lest we repeat it.

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