

A justification for NOTES—natural orifice transluminal endosurgery

The concept of “incisionless” surgery and a transgastric or even transcolonic approach for intra-abdominal surgery is both attractive and alarming.

Imagine you are a patient and are offered the choice of having an operation that leaves a big scar, hurts a lot, and keeps you in the hospital for a week; a similar operation that leaves you with 5 small scars, is a bit less painful than open surgery, and keeps you in the hospital for a couple of days; and the same operation that leaves you without any incisions on your abdomen and may hurt even less than the more conventional options. Patients are bound to vote for the less invasive, least painful option. They are right to do so, and it is incumbent on us as doctors to try and make their hope for less invasive, less painful surgery a reality.

The 3 main justifications for natural orifice transluminal endoscopic surgery (NOTES) are improved cosmetic appearance, ease of access, and the concept that human ingenuity and technological advance can continue to reduce the trauma and discomfort associated with effective surgery.

The most important of these justifications for the patient is that there is an improved cosmetic result. Women hate scars, as do men, and the scars from laparoscopy are not invisible and can be very unsightly. Surgery that avoids abdominal scars, however small, means that patients do not have a visual reminder of their surgery every time they undress. “Invisible mending” was the title and focus of a recent article in *The Economist* on transgastric surgery.¹ A better postsurgical cosmetic appearance is desired not only by beautiful patients. NOTES procedures do not have to be “better” than laparoscopic or open surgical procedures to be preferable for patients. If the procedures are judged by comparing the cosmetic effect, a NOTES procedure will always be superior to laparoscopic surgery or open surgery because it does not produce scarring while the other procedures always do. It is preferable that such a procedure be as effective and safe as a conventional surgical procedure, and optionally desirable that it offer some noncosmetic advantage to the patient.

What might such advantages be? Obese patients with laparoscopic incisions after bariatric surgery have pain on coughing and may spend more time in the intensive therapy unit because of this disincentive to mobilization. There are patients with abdominal sepsis who need ab-

dominal surgery in whom transgastric surgery would obviously be preferable, but there are not many such patients. Methicillin-resistant *Staphylococcus aureus* and hospital-acquired infections are likely to be reduced if there are fewer skin incisions. Some patients considered unfit for anesthesia might be suitable for less invasive transgastric procedures.

There are real advantages of ease of access. Flexible endoscopy can easily reach, from the inside, structures that are difficult or dangerous to reach with conventional laparoscopes passed through the abdominal wall. The lower esophageal sphincter and the upper stomach (for some bariatric surgical procedures) are obvious anatomic sites

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where a safe transgastric approach might offer substantial advantages over a difficult open or laparoscopic approach. Full-thickness resections of gastric wall cancers and locoregional lymph node excision might allow less-invasive management and better histological assessment of more cancers, provided the technique is safe.

Another argument for boundary breaking in this instance is that it may stimulate a great deal of flexible endosurgical device innovation and development. This is likely to result in the delivery of more effective flexible endosurgical tools, which are frankly poor at present. Suturing is in its infancy, and the devices are difficult to use and are too expensive. Flexible stapling barely exists.

Endoscopic hemostasis methods still mostly involve injection and thermal probe methods, which appear to work in unblinded clinical trials of bleeding ulcers but would be almost totally ineffective if used on large vessels during intra-abdominal surgery. Flexible endoscopic clips mostly have gaps that make them unsuitable for effective compression closure of large intraperitoneal arteries. Even if none of the transluminal procedures become common, endoscopists are likely to be able to perform a variety of

intraluminal procedures by using the tools developed during this period of creativity—tools that are actually effective and will be able to take care of esophageal, gastric, and colonic perforations, stop large-vessel bleeding, and allow easier, precise dissection and remodeling of GI tissue.

This competition may also improve laparoscopic surgery, encourage the development of operations with smaller skin incisions, and combine transgastric surgical procedures with laparoscopic techniques; for example, combining controlled inflation with a Veress needle or a 3-mm or 5-mm grasper passed through the abdominal wall.

Another important advance will be the development of thinner, more effective flexible endoscopic instruments that can be used readily in small children.

We may have to temper this enthusiasm to improve surgery with a cooler realization that there are substantial problems to solve in order to make this flexible endoscopic dream a reality. The tools that can be passed through flexible instruments in order to perform some of the proposed procedures are very poor. We are especially limited in suturing, stapling, achieving effective hemostasis, dissection of tissue planes, and even reaching the gallbladder and the cardioesophageal junction. Will this type of surgery ever be safe enough? Will it be rashly tried out and abandoned before effective devices and safe surgical practices have been developed?

The justification for some of the companies that retail laparoscopic equipment to invest in NOTES may be partly defensive. If a significant percentage of intraperitoneal surgical procedures were performed by NOTES techniques, these companies might lose market share to other companies in the flexible endosurgical market. NOTES is unlikely to increase the number of cholecystectomies performed. The offer from Ethicon Endosurgery of \$1,000,000 for basic research in NOTES is welcome as an unprecedented intervention in experimental surgery.

A glorious period of mad invention seems to be in full swing. The real value of breaking through the boundary of the wall of the GI tract to perform transgastric surgery is uncertain, and the future, as usual, is impossible to predict. It is unclear whether this type of surgery requires complex platforms with large, more effective instruments with more degrees of freedom and triangulating mechanisms, or whether a simple, relatively cheap toolbox of new instruments can be created to deliver effective surgery. Reaching the gallbladder, diaphragm, and lower esophageal sphincter by using a transgastric approach appears difficult when using conventional flexible endoscopes, which are rather floppy and limit the control and exertion of force on instruments during surgical procedures in these areas. The development of more effective endosurgical instruments is likely to help in both flexible and rigid endoscopic surgery and will allow common procedures to be done more easily in the lumen of the GI tract.

In order for NOTES to gather sufficient momentum, the simpler procedures that would be safe to start with, such as diagnostic peritoneoscopy, liver biopsy, and adrenalectomy, are unlikely to have sufficient volume to drive substantial change. Cholecystectomy is arguably the “killer application,” followed by bariatric procedures and, perhaps, fallopian tube ligation.

Although most endoscopists instinctively regard perforating the wall of the GI tract as a disaster, transluminal flexible endoscopic surgery is not new. Flexible endoscopic pseudocyst drainage has been practiced for 30 years,² and PEG has been practiced for 25 years.³ Needle puncture of structures through the wall of the stomach at EUS was introduced more than 12 years ago⁴ and seems safe and useful. Transgastric retroperitoneal necrosectomy has been used for 5 years.⁵ EUS needle-guided transgastric endosurgery has been used for transgastric gastropexy to the diaphragm, hiatus hernia repair, and endosurgical anastomosis of the gallbladder to the stomach.^{6,7} Kalloo et al⁸ reported the use of flexible transgastric peritoneoscopy as a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity in 2004. Rao and Reddy have removed appendices through the mouth in a number of patients. The author of this review thought that future intraperitoneal developments would require needle-based technologies, perhaps guided by EUS, and was initially very doubtful about the potential and safety of transluminal procedures with flexible endoscopes in the peritoneal cavity until he visited the laboratory, in Sweden, of Park and Bergstrom and saw that cholecystectomy⁹ and anastomosis in survival studies was feasible,¹⁰ and that reliable sutured gastric closure was possible based on the work, in London, by Ikeda et al.^{11,12}

A good deal has been achieved in a short time in several experimental surgical laboratories working with pigs. Kantsevoy et al¹³ have also performed anastomosis, and liver biopsy⁸ and fallopian tube ligation¹⁴ have also been performed. Fritscher-Ravens et al¹⁵ have reported removing celiac axis lymph nodes through the stomach wall with closure and identifying and tagging the nodes using EUS in survival studies. A report by Kantsevoy et al¹⁶ suggests that several large-scale abdominal operations are being evaluated for a transgastric approach. Merrifield et al¹⁷ have also reported survival studies of abdominal organs, including transgastric oophorectomy and fallopian tubectomy.¹⁸ Pai et al,¹⁹ with the same group, has recently reported transcolonic cholecystectomy.

It may prove that a transcolonic approach for cholecystectomy is inferior to a transgastric approach. Gastric incisions are very forgiving, whereas colonic incisions may heal less well and feature a much higher count of bacteria than that found in the stomach. The patients would need good colonic preparation for a transcolonic procedure but just an overnight fast for a transgastric approach. Nonetheless, it is easier and quicker to reach the gallbladder by the colonic route than through the wall of the stomach,

and the image is oriented in a fashion that is similar to that seen at laparoscopy. Transgastric endosurgical experience has been reported using a "Shaplock" platform to rigidize the endoscope, especially when operating in the upper abdomen.²⁰ There are hints that transesophageal cardiac procedures, transvaginal, transintestinal, and transvesical approaches are being explored by analogy.

In this issue of *GIE*, there are 2 relevant articles. One describes colonic closure with a new multiple clip applier,²¹ and another describes the use of a suturing device with a curved needle²² (most surgical suturing applications are accomplished using a curved needle). Effective closure of full-thickness incisions is essential if NOTES is to be safe. Improvements in suturing and clipping at flexible endoscopy would be very helpful for a variety of other intra-abdominal procedures. Pham et al²³ and Raju et al,^{24,25} working in the colon, and Bergstrom et al,¹⁰ Ikeda et al,¹¹ and Sclabas et al,²⁶ working in the stomach, have published on closure of full-thickness incisions in the wall of the GI tract—an essential and basic technique for NOTES surgery. A recent change in publishing practice has been the attachment of videos to some scientific journals, including *GIE*, thereby giving an unprecedented opportunity to assess what has been achieved in this field in a short time.

Is transgastric surgery one of those epochal revolutions in surgery to be compared with the advent of anesthesia, anti-septic open surgery, and laparoscopic cholecystectomy? As momentum gathers for NOTES procedures²⁷ and the first human transgastric cholecystectomies (performed initially as a hybrid procedure with a transgastric flexible endoscope and a laparoscope in the peritoneal cavity) have been described, it seems an opportune moment to review the justification for NOTES. Perhaps the strongest justification for doctors and engineers to work in this area is the idea that human ingenuity and invention can continue to deliver more effective treatments by increasingly less invasive means.

DISCLOSURE

Dr Swain acts as a consultant for Ethicon Endosurgery and USGI Medical.

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