Natural Orifice Transluminal Endoscopic Surgery: Reality or Myth?

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Introduction

Access to the abdominal cavity is required for the surgical treatment and diagnosis of diseases affecting the abdominal organs. Traditional methods of accessing the abdominal cavity have involved incision of the abdominal wall, which has been the source of complications such as infection, scarring and post-operative pain. The smaller incisions required for performing laparoscopic surgery have reduced these incision-related complications, but have not entirely eliminated them [1]. More recently, technological advances have allowed the extension of endoscopy into the peritoneal cavity via a transvisceral incision, created with endoscopic equipment inserted through a natural orifice [2, 3]. These developments have led to the development of Natural Orifice Transluminal Endoscopic Surgery (NOTES), which has the potential to revolutionize abdominal surgery through the elimination of all abdominal wall incision-related complications. Proponents and researchers in this field recognize the potential of this technique to revolutionize the field of minimally invasive surgery by eliminating abdominal incisions. NOTES could be the next major paradigm shift in surgery, just as laparoscopy was the major change during the 1980s and 1990s [3].

Endoscopy and Genesis of NOTES

Considering the continued evolution of flexible endoscopy into more of a therapeutic tool and at the same time, the growing awareness that the degree of invasiveness of surgery has a large impact on patient outcomes, it was perhaps inevitable that endoscopy and surgery would eventually work together [4]. The potential of flexible endoscopy to perform therapeutic procedures beyond the wall of the gastrointestinal tract

was recognized as early as 1980 when the first transluminal feeding gastrostomy was described by Gauderer et al [5]. Kozarek et al [6] published the first report of successful endoscopic drainage of pseudocyst in 1985. On the surgical side, the established benefits of laparoscopic procedures over conventional laparotomy in terms of patient recovery and perioperative morbidity, the increasing skill set of advanced laparoscopists and the comfort of practitioners in performing complex surgeries using video imaging and pneumoperitoneum raised the possibility of replicating such operations endoscopically. The first report of oral peritoneoscopy done in animals was published by researchers at Johns Hopkins University [2]. Though initially greeted with skepticism - some even called it blasphemy - the medical community and the general public was captivated with the idea of “no-scar” abdominal surgery. This earmarked the birth of NOTES. Since then, multiple investigators have used transluminal flexible endoscopy in animal models to perform various intraperitoneal procedures, ranging from tubal ligation to splenectomy [7, 8]. The bettering technologies and the skills have made the progress from animals to humans a definite inevitability. NOTES seemed to have gained the light of the day, in 2004, when a case of first transgastric appendectomy in a human subject was presented during the annual meeting of the American Society of Gastrointestinal Endoscopy (ASGE) [9]. This prompted the ASGE and the Society of Gastrointestinal Endoscopic Surgeons (SAGES) to arrange for a conference in 2005 to develop a consensus among endoscopists and surgeons on the ideal way to proceed with this procedure. Finally, in 2007 Hazey et al [1], described the safety and feasibility of NOTES in the first human pilot trial.

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Advantages

The idea of NOTES was developed in response to the concepts that patients would realize the benefits of less invasive surgery, faster recovery time, experience less physical discomfort and would not have any visible scar.

When the laparoscopic approach was introduced, it was initially argued that it might not provide any benefit other than better cosmesis. Since then, multiple benefits of laparoscopic surgery, including a decreased neurohumoral stress response [11], decreased immunosuppression [12], less pain, faster recovery [13], and a decreased incidence of wound-related and pulmonary complications, have been recognized [14, 15]. In spite of initial skepticism then, today laparoscopy has become a standard approach for most general surgical, gynecologic and urologic procedures. NOTES should provide all of the above-mentioned advantages of laparoscopic surgery. In addition, the elimination of abdominal wall incisions results in elimination of wound infection, incisional hernias and decreased rates of adhesive small bowel complications. Other potential benefits that NOTES has been theorized to offer are decreased postoperative pain, less need for postoperative analgesia, shorter hospital stay, faster recovery and the potential for “scarless” abdominal surgery. Additionally, NOTES may have several advantages in specific subpopulations. It may provide an easy alternative access to the peritoneal cavity in morbidly obese patients, in whom traditional open or laparoscopic access can be difficult because of abdominal wall thickness [4].

Challenges

Although NOTES appears to offer definite patient benefits, several critical issues must be resolved before it can be successfully and responsibly used in clinical care.

Making the viscerotomy and accessing the abdomen is feasible using standard endoscopic equipment, but beyond those steps, technical advances are imperative for the success of NOTES. A stable operating platform is necessary to safely conduct precise abdominal operations. The flexibility of the endoscope provides the ability to maneuver to the organ of interest. However, the flexibility also precludes stabilization of the tip of the scope. A stiffening overtube might solve this problem [16].

One of the basic tenets of laparoscopy is triangulation of optics and instrumentation. The current version of end-viewing endoscopes precludes such triangulation in natural orifice surgery. The working channels are in line with the optical view, limiting range of motion of instruments and obscuring the view of the operative field.

There is unanimous consensus among experts regarding the critical nature of the need for secure enterotomy closure, understanding the physiologic consequences of NOTES and the need for adequate training. In the various animal experiments, several different techniques, such as suturing, clips, T-fasteners, and novel closure devices have been employed by different investigators to obtain a secure closure of the enterotomy. It is very important that the closure device and the technique be easy to use and provide a nearly 100% secure closure of the enterotomy site. Complications of enterotomy leakage will create a big hurdle to the safe clinical use of NOTES. It is widely accepted that given the safety of laparoscopic approach, an enterotomy leak rate of even 1% would be unacceptable [4].

The physiologic consequences of pneumoperitoneum for various organ systems have been extensively studied in laparoscopic surgery. However, it is not known whether the pneumoperitoneum created during NOTES will behave in the same fashion. Initial reports suggest difficulties maintaining a controlled pressure or required flow rates through flexible endoscopes. Investigators have reported difficulties in maintaining tight seals around the enterotomy that can effectively prevent backflow of carbon dioxide into the stomach. Additionally, leakage of gas into the gastrointestinal tract can lead to loss of domain within the peritoneal cavity. Finally, there is the danger inherent in using current flexible endoscopic insufflators, which are not pressure regulated. These technologic hurdles must be resolved before NOTES can be successfully used in clinical practice [4].

Lastly the most important aspect for a safe clinical application of NOTES is the availability of effective training programs and practicing guidelines. Because NOTES requires surgeons to be adept in both minimally invasive surgery as well as advanced flexible endoscopy and therefore may involve both surgeons and gastroenterologists, multidisciplinary training programs will be necessary [16].

The Instruments

Currently available flexible endoscopes are inadequate for performing complex transluminal surgical procedures. Issues with current flexible scopes include the lack of a multitasking platform, the number and size of access channels, the inability to position and then fix or “stiffen” the endoscope to allow robust retraction and exposure, the inability to control insufflation pressures, fixed visual horizons that force the surgeon to adjust to tilted or inverted views and inadequate suction/irrigation capabilities. These problems can be resolved to some extent with scope-handling expertise and by altering the

surgical approach. However, a better long-term solution will be to redesign the endoscopic access device itself. Several prototype endoscopes are being tested, including the Transport (Figs.1,2) (USGI Medical, San Juan Capistrano, CA), the R scope (Olympus, Center Valley, PA), and the robotic Endovia (Hansen Medical, Mountain View, CA), all designed to resolve these issues. The Transport and Cobra devices adapted an existing design of a locking overtube (Shape Lock, USGI Medical), adding independent steering of the tip, four channels and an insufflator connection. The Transport is a 16-mm flexible device with four large channels. One of the channels is designed for a standard 6-mm flexible endoscope, which can be locked into position but also can be torqued independently to correct the horizon. The Transport is capable of 180° retroflexion as well as lateral movements and can be frozen in place by closing a lever, whereas the tip still has independent four-way movement for fine surgical maneuvers. It also provides connection to a standard laparoscopic insufflator for an effective, controlled carbon dioxide pneumoperitoneum. The large 4 and 6 mm channels allow passage of the new stronger and flexible surgical tools. The Cobra and Endovia devices are designed to provide triangulation, thought by many surgeons to be an essential feature. The R scope is a traditional-size scope with an extra flexion point for better tip positioning and two access channels (3.8 mm) with horizontal and vertical lifters, which offer a reasonable simulation of triangulation. At present only a limited number of flexible endoscopic

Fig. 1 : The Transport advanced operating endoscope

Fig. 2 : The Cobra triangulating scope

instruments are available. Owing to the small channel size of currently available endoscopes, the end effectors of most of these instruments are small and feeble. This makes tissue grasping and manipulation challenging. Ideally, instruments for flexible endoscopic surgery should replicate the designs of laparoscopic instruments to permit true surgeries. The newer prototype scopes, which have large working channels and are being tested, have allowed the creation of 4.5 mm graspers with 2.5 cm jaws that are similar to laparoscopic tools. There is need for further development of improved energy sources for dissection and haemostasis in a flexible format, including some that would be an alternative to bipolar circumactive probe cautery, the needle knife and the sphincterotome. Of primary importance is the need for easy-to-use tissue approximation devices that can provide secure full-thickness closures of inadvertent perforations or intentional enterotomies, as well as anastomosis and bleeding control. Many devices designed to achieve these goals and to enable the use of NOTES are in development (Fig. 3). The Eagle Claw (Olympus) and the Swain closure system (Ethicon, Cincinnati, OH) seem to answer many of these requirements and are nearing commercial readiness. The Eagle Claw, developed in collaboration between the Apollo Group and Olympus, is a simple grasping and needle-driving device that fits on the end of a standard endoscope. It is capable of grasping large amounts of tissue and taking substantial bites with the needle. The needle delivers a pretied monofilament suture with a sliding lock that can be cinched down with a separate device. The Swain system has two T-fasteners attached together with a sliding lock on the connecting suture. This system is flexible and easy to apply but has been associated with risk of injury to adjacent structures because the extramural deployment is blind. The g-Prox Tissue Grasper from USGI Medical allows the surgeon to grasp a full-thickness bite of tissue and then perforate it

Fig. 3 : Visceral closure system

perpendicularly with a 19-gauge needle. The needle is preloaded with a suture with two expandable baskets. The first basket is expelled on one side of the grasped tissue, which is then released, allowing the grasper to either be reversed for a figure-of-eight suture or used again the same way for a simple stitch. The second bite is pierced again with the needle and the second basket is deployed. A one-way cinching device approximates the two baskets, creating a tight, imbricated closure of the enterotomy edges. This device has achieved closure of gastrostomies as securely as hand sutures [4].

NOTES: moving forward

Undoubtedly the technology and data needed to support the practice of NOTES will continue to evolve, driven by innovation, a rapid growth in animal experimentation and human trials to investigate the benefits, physiologic impact, complications, safety, cost, training and long-term outcome of NOTES. The future promise relies on the analysis of the deficiencies of current endoscopes and the review of future endoscopes, as well as the development and investigation of current tissue approximation systems. This new experimental field may in the near future, establish itself as a viable alternative to open and laparoscopic surgery for the treatment of many gastrointestinal and abdominal conditions [16]. When and if this occurs, the implementation of NOTES will have numerous ramifications at several levels, including those of the patient, health care systems, insurance companies, state and national governments, legislative organizations, and professional societies [4].

Conclusions

Surgery is evolving beyond current flexible endoscopic and laparoscopic approaches. NOTES may represent the next phase of minimally invasive surgery and early clinical experience shows that intra-abdominal surgery using flexible endoscopes is indeed possible. Because of the immaturity of the instrumentation, early cases demand a technical virtuosity that probably precludes a widespread application of this approach. This balance will shift as enabling technologies are developed. Nevertheless, NOTES will always be more technically demanding than open or laparoscopic surgery. If definite patient benefits are documented and if the public begins to demand "incisionless" surgery, practitioners will need to master these techniques. An issue yet to be resolved is who will perform NOTES: gastroenterologists or surgeons or a new breed of surgical endoscopists?

Conflicts of Interest

None identified

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