INTRODUCTION

Report on Emerging Technology: a guide to the future

In this issue of *Gastrointestinal Endoscopy*, the American Society for Gastrointestinal Endoscopy (ASGE) introduces a new series of concise reviews designed to familiarize the reader with novel endoscopic technologies likely to have an impact on patient care as the technology progresses. Like the familiar Technology Status Evaluation Reports, these reviews are generated by the ASGE Technology Committee and are edited and approved by the ASGE Governing Board. Topics will generally include devices or techniques not yet approved by the U.S. Food and Drug Administration or widely available in clinical practice. The goal is to provide a brief overview of the technology, the current status of concept or clinical data, current obstacles to dissemination into practice, and proposals for future studies. It is anticipated that many of these technologies will eventually become integrated into the practice of GI endoscopy, and the reviews serve as an educational platform from which to follow future developments. As with any pioneering venture, the frontier is harsh. Some technologies will fall short, and these eventual failures may be anticipated based on some of the obstacles presented. The overriding goal of any emerging endoscopic technology is to improve technical performance, safety, and clinical outcomes relative to contemporary systems. Adoption of any of these technologies in routine practice will eventually require evidence based on these principles. Although numerous technologies are in the experimental or proof-of-concept stage, the Report on Emerging Technology reviews will focus on devices and techniques with the greatest and the most immediate potential to impact the practice of GI endoscopy. As the leader in the practice of GI endoscopy, the ASGE will strive to monitor these emerging technologies by providing these concise and directed reviews so that clinicians, researchers, and endoscopists ot the future can direct their perspective on the respective field as it matures. It is often stated that the future is bright. However, as all endoscopists realize, it is not only important for it to be bright—the future must also be in focus.

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REPORT ON EMERGING TECHNOLOGY

Natural orifice translumenal endoscopic surgery

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of new or emerging endoscopic technologies that have the potential to impact the practice of GI endoscopy. Evidence-based methodology is used, by performing a MEDLINE literature search to identify pertinent preclinical and clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but, in many cases, data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. For this review, the MEDLINE database was searched through March 2008 by using the keywords "natural orifice translumenal endoscopic surgery" and "NOTES."

Reports on Emerging Technologies are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. These reports are scientific reviews provided solely for educational and

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TABLE 1. Animal NOTES™ procedures reported

Technical aspects of NOTES™ procedures
Peritoneoscopy
Gallbladder surgery
Pelvic organs surgery
Gastrojejunal anastomosis
Abdominal-wall hernia repair
Splenectomy
Lymphadenectomy
Pancreatic resection
Appendectomy
Diaphragmatic pacing

informational purposes. Reports on Emerging Technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

Natural orifice translumenal endoscopic surgery (NOTES™)[1] is a term that describes novel endoscopic interventions on internal organs performed through natural orifices, with the goal of avoiding skin incisions. This term was invented during the first meeting of the Natural Orifice Surgery Consortium for Assessment and Research™ (NOSCAR™) in July 2005.[1]

The first translumenal procedures were performed in a porcine model and were reported in 2000, followed by a full-length publication in 2004.[2,3] Since that time, multiple translumenal interventions have been completed in animal experiments and reported in abstracts and full-length articles. The most common interventions include gastrojejunostomy, cholecystectomy, ligation and resection of pelvic organs, and abdominal-wall hernia repair (Table 1).[4-41]

Human transgastric intraperitoneal interventions were initiated in India in 2003.[42] At the time of this writing, only a limited number of human NOTES™ procedures have been reported in the United States.[43-48] Additional translumenal human procedures have been done around the world.[49-53]

POTENTIAL APPLICATIONS

Animal NOTES™ procedures reported in full-length publications are summarized in Table 1. All animal NOTES™ procedures were completed in small feasibility studies on a limited number of animals (usually 5-7). At the time of this writing, a total of 226 nonsurvival and survival animal procedures were performed.[2-41] The majority of these animal experiments studied various technical aspects of translumenal procedures (eg, access to the peritoneal cavity, closure of the translumenal access site). The most commonly performed NOTES™ interventions have been translumenal peritoneal exploration, gallbladder surgery, interventions on pelvic organs, and the creation of gastrojejunostomy. Less commonly investigated procedures include ventral hernia repair, splenectomy, abdominal lymphadenectomy, appendectomy, pancreatic resection, and diaphragmatic pacing.

The first published human NOTES™ procedure described transgastric rescue of a prematurely dislodged PEG tube.[43] The intervention started with peroral endoscopic dilation of the previous gastrostomy site by using an esophageal dilating balloon. The endoscope was then advanced through the gastrostomy into the peritoneal cavity, free fluid was aspirated from the peritoneal cavity, and a guidewire was passed through the external PEG site into the peritoneal cavity and grasped with an endoscopic snare. The endoscope, snare, and guidewire were withdrawn into the stomach and out of the mouth. The new PEG was inserted over the guidewire by using the standard pull technique.

Transvaginal purely endoscopic appendectomies (n = 2) were recently reported by 2 independent groups of investigators from Germany and India.[52,53] Each group performed an appendectomy by using a standard flexible gastroscope and endoscopic accessories (hot biopsy forceps, needle-knives, endoclips, endoscopic detachable loops, etc). There were no complications, and both patients recovered quickly, with an uneventful follow-up.

Other reported human NOTES™ interventions were done as hybrid procedures with translumenal incision and advancement of the flexible endoscope into the peritoneal cavity, along with direct laparoscopic visualization. These include transvaginal (n = 2) and transgastric appendectomy (n = 1), transvaginal (n = 7) and transgastric cholecystectomy (n = 3), transgastric diagnostic peritoneoscopy (n = 10), and liver biopsy (n = 3).[44-53]

Transgastric peritoneoscopy and liver biopsy were technically simple and safe, and provided information comparable with laparoscopic abdominal exploration.[46,47] In addition to laparoscopic observation, the transvaginal and transgastric cholecystectomies in human beings also used laparoscopic instruments for gallbladder traction or to facilitate access to the cystic artery and cystic duct.[44,45,49-51] The duct and artery were ligated with laparoscopic or endoscopic clips, the gallbladder was dissected by using endoscopic accessories (eg, needle-knives, scissors, and monopolar round-tip electrodes) and extracted through the vagina or the mouth. To date no complications have been reported during or after human NOTES™ procedures.[42-53]

AREAS FOR FUTURE RESEARCH

More systematic studies are necessary before translumenal procedures can be recommended as an acceptable

alternative in clinical practice. Many issues remain unanswered or need clarification, including:[1]

- What is the safest way to traverse the lumenal wall for organ access
- How to improve spatial orientation
- How to recognize and control intraprocedural complications
- What is the best way to close the translumenal access site
- How to prevent procedure-related infection and control complications
- How to remove resected organs
- What is the optimal procedure-specific instrumentation
- What level of anesthesia is required for specific procedures

The physiologic impact of NOTES™ is still largely unknown. On-demand peritoneal cavity insufflation through the flexible endoscope has led to wide fluctuations of intra-abdominal pressure, which can potentially lead to undesired systemic effects (hemodynamic instability, respiratory compromise, etc).[32-35] Use of standard autoregulated laparoscopic insufflators and feedback pressure valves on flexible endoscopes can resolve this problem.[32-35] More studies of systemic consequences of NOTES™ procedures and its impact on the human immune system are still necessary to determine the potential advantages and disadvantages of translumenal interventions relative to traditional surgical and laparoscopic approaches.

It is also unclear who will be best qualified to perform translumenal procedures: gastroenterologists or surgeons. The appropriate training and level of competency required to perform NOTES™ procedures should be addressed.

SUMMARY

Translumenal endoscopic surgery is currently at a very early stage in its development. NOTES™ has the potential to decrease the invasiveness of surgical and laparoscopic interventions by eliminating skin incisions, potentially reducing anesthesia requirements, and improving cosmetic results. Numerous issues must be resolved before NOTES™ can be integrated into clinical practice.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; NOTES, natural orifice translumenal endoscopic surgery.

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