NOTES: Where have we been and where are we going?

SAGES/ASGE Joint Committee on NOTES

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On July 10th, 2008, The Third International Symposium on Natural Orifice Surgery (NOTES) will be held in San Francisco, California. It is worth noting that this meeting will occur almost 3 years to the day after a group of 12 investigators selected by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Gastrointestinal Endoscopy (ASGE) convened in New York City to discuss the feasibility of NOTES and create a plan for its systematic evaluation. A great deal has been accomplished since this group published The ASGE/SAGES White Paper on NOTES [1, 2]. While several highly critical editorials by senior surgeons have decried the futility of pursuing NOTES [3, 4], it is clear that NOTES remains one of the hottest topics in both the gastroenterology and gastrointestinal surgery communities and interest is evolving in the urologic and gynecologic surgery communities as well. The number of NOTES-based abstracts submitted to both the SAGES and DDW annual meetings has increased significantly each year. There is now clinical data demonstrating that basic NOTES procedures in humans are feasible. We believe that at this point NOTES is ready to carefully move from the laboratory to human trials to identify where NOTES approaches might be beneficial and where they are not.

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Looking back to the founding meeting in 2005 there were several fundamental and notable accomplishments. First was the ability of two major national societies from different disciplines to put aside turf issues and work together in a synergistic and collaborative manner. It was clear from the outset that the pioneers in NOTES would require skill sets of both interventional gastroenterologists and laparoscopic surgeons. This collaboration has proven to be very powerful. Most NOTES procedures to date have been performed by multidisciplinary teams, though a few have been performed by surgeons who also possess advanced endoscopic training and skills. With the current equipment it is certainly not possible for a solo practitioner to perform these procedures, and teamwork remains essential for the foreseeable future. Groups in Europe, South America, and Asia seem to be following this collaborative model as well.

The second major accomplishment of the original group was the establishment of the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR). This organization has organized successful international meetings, established a registry for human cases, and most importantly raised and distributed substantial funds for research projects that addressed the eight fundamental problems identified in the original White Paper. So far over 30 grants have been awarded via a rigorous peer review process and the knowledge generated from these studies has moved the field ahead much faster than originally anticipated.

Progress in addressing the eight fundamental problems identified by the original working group (Table 1) has varied. It seems clear that the peritoneal cavity can be accessed safely via a variety of transluminal routes. While each has advantages and disadvantages, access itself seems not to be a problem. The original group

Table 1 Fundamental problems for NOTES identified in the original white paper

Originally identified barriers to NOTES

Access to peritoneal cavity
Gastric (intestinal) closure
Prevention of infection
Development of suturing/anastomotic device
Maintenance of spatial orientation
Development of a multitasking platform
Management of iatrogenic intraperitoneal complications
Identifying physiologic untoward events

identified gastric closure as a fundamental problem based on the pioneering work of the Hopkins group as well as the unpublished case reports of Reddy and Rao (pers. commun.), but most human NOTES procedures have used transvaginal access and vaginal closure has not been a problem. Since transvaginal access is an option in females only, other groups have successfully utilized transgastric access. Nonetheless, the current closure devices are cumbersome and work remains to be done in this critical area. Intraperitoneal contamination and infection appears to be less of a problem than originally feared by the working group as long as the viscerotomy closure is secure. Similarly, concerns about maintenance of spatial orientation appear to have been easily overcome as practitioners gain practical experience.

Some of the eight fundamental problems are heavily dependent on device development. The need for easy-to-use and maneuverable anastomotic and suturing devices remains unmet, although active development is occurring. A robust flexible multitasking platform is currently one of the rate-limiting steps and this too is nearly entirely dependent on industry partners. Commercially available platforms that have been used in humans are helpful, but more versatility is needed before universal application is possible. Promising prototypes of direct drive systems and multitasking flexible endoscopes are now being tested and hopefully will enable more practitioners to acquire the skills needed to perform NOTES. There is a growing body of basic science knowledge generated by NOSCART funding regarding the physiologic impact and possible benefits of natural orifice surgery. Finally there is still almost no information available about the management of intraperitoneal complications.

Several pleasant surprises have occurred in the early human NOTES experience. First, it appears that NOTES procedures can be performed at very low-pressure pneumoperitoneum due to the flexible scopes and their maneuverability. This may have profound impact on physiologic derangements caused by NOTES procedures,

reducing pain related to peritoneal stretch, and perhaps avoid the need for additional CO₂, further minimizing intra and postprocedural pain. While there is still a long way to go, the original vision that NOTES procedures might one day be performed under conscious sedation in an outpatient setting can no longer be dismissed out of hand. Second, there has been uniform reporting of dramatic lack of postoperative pain in patients undergoing NOTES cholecystectomies. There is no published controlled data, but investigators in three different continents have independently observed this phenomenon. Therefore, the original premise upon which NOTES was founded, i.e., less pain and faster recovery, has a reasonable probability of being borne out in practice.

In spite of all that has been accomplished, NOTES is not yet ready for widespread clinical use. While the feasibility question may be answered in some people's minds, healthy skepticism persists. Safety concerns about access and closure need further evaluation. Key questions such as what diseases and conditions are best suited to transluminal approaches beg for answers. With the passage of time, issues that loomed far off in the horizon when NOTES began are now critical. Who will pay for NOTES procedures as they are carefully evaluated in clinical trials? Lack of reimbursement for providers could significantly slow development as much as the device and engineering challenges. Can a worldwide registry be created that would allow us to learn from experience across the globe and will complications be truthfully and fully reported? Can the NOTES community agree on guidelines for the safe introduction of NOTES? It is time to start thinking seriously about what curricula and models need to be included in training programs so that practitioners who want to perform NOTES have the requisite skills and can demonstrate the appropriate competencies. At the Third International NOTES meeting to be held July 10–12, 2008 in San Francisco, investigators from around the world will gather to share experiences and debate these questions. Interested parties will spend a fair portion of this meeting in working groups to try and map out the road forward.

NOTES is now entering a critical phase. Hard questions need to be answered with solid data. The cost and effort of doing so will be significant, but the potential benefit to patients and society could be substantial. At this point in time NOSCART continues to strongly advocate that all human NOTES procedures be performed under IRB oversight to allow for data collection and safety evaluation in a rigorous manner. The Joint Committee on NOTES remains committed to promoting innovative research, objective evaluation of clinical and laboratory studies, and above all patient safety.

References

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