

NOTES: Gathering Momentum

It has been several years since Kalloo in Baltimore and Reddy and Rao in Hyderabad, India began accessing the peritoneal cavity via a transgastric route. Though initially greeted with skepticism- some even called it blasphemy- the idea that intraperitoneal surgery might be performed without an abdominal incision appears to be worth pursuing. In a relatively short time span, the Hopkins group demonstrated the feasibility of performing a gastrojejunostomy via a totally endoscopic/transgastric route. Even more stunning are the reports from Hyderabad of a series of 7 transgastric human appendectomies with good results.

Acknowledging the potential of this novel approach, the leadership of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Gastrointestinal Endoscopy (ASGE) appointed a group of 14 members to study and comment on this new technique. This group met in New York City in July 2005 and published its deliberations as the NOTES Working Group White Paper (citation for each pub). The White Paper delineated the anticipated technical barriers to further development of NOTES, emphasized the need for development to be carried out by interdisciplinary teams of surgeons and gastroenterologists and emphasized that any human procedures be performed only with IRB approval. Since the White Paper was authored by a small group, it also mandated that a next step should be a larger and more inclusive gathering of interested parties to challenge the tenets put forth in the White Paper and to create a roadmap for NOTES development.

The first international conference on NOTES was held in Scottsdale, Arizona March 9-11, 2006. One hundred forty physicians from 11 countries came as teams (each team had at least one gastroenterologist and one surgeon with access to animal lab facilities). After a morning of lectures describing accomplishments to date as well as the challenges anticipated to move the field forward, participants were assigned to eight separate working groups with the task of developing a detailed roadmap for overcoming the eight technical barriers that had been identified in the original White Paper. The roadmaps from the Working Groups were presented at the closing session the following day. These presentations as well as the White Paper and other related resources have been posted on a Web site, www.noscar.org, for interested parties to see. Equally important was the launch of NOSCAR-the Natural Orifice Surgery Consortium for Assessment and Research.

NOTES is an emerging transdisciplinary therapy based upon a disruptive technology. If NOTES is to reach a stage of widespread clinical applicability there will need to be further innovation and true collaboration on multiple fronts. Experimental work needs to be done to understand the physiologic disruption and infectious complications of NOTES. Better devices are needed for gastric closure, suturing, tissue grasping and manipulation, and anastomosis. Further research is needed to optimize procedure performance. Ultimately, there will be a need for collaborative clinical trials to test the value of NOTES. The establishment of NOSCAR represents a collaborative vision built on the strength and leadership of two strong innovative organizations-

SAGES and ASGE. It is our hope that NOSCART can provide leadership as well as a collaborative common ground to prospectively shape this emerging therapeutic discipline. In short, The NOSCART group is a rare attempt to prospectively manage a disruptive technology.

We see NOSCART as the appropriate vehicle for the following tasks:

- 1) Produce White Papers that define the large challenges needing thought and research.
- 2) Track portfolios - i.e. groups of similar research projects that address challenges laid out in the White Paper.
- 3) Provide organization for research projects in such a way as to enhance collaboration and attract funding to key areas of study.
- 4) Collect (and, in fact, require) submission of data to build a robust outcomes database.
- 5) Foster collaborative clinical trials.

We anticipate that SAGES and ASGE will establish a joint committee that will guide NOSCART to identify and foster needed research directions. NOSCART, through its parent societies is likely to establish a request for proposal process, raise research funds, vet grant applications and oversee a consortium of labs and clinical study groups. In this fashion, NOSCART should become the repository for maintaining a portfolio of research projects from interested groups around the world.

As NOTES matures and enters clinical trials it is envisioned that NOSCART will create and maintain a clinical case registry. Ad hoc NOTES meetings seem likely in the future and NOSCART, under societal guidance, would organize such meetings. Down the road, if NOTES is shown to be a beneficial technology, NOSCART might help define scope of practice, competency measures, and work with regulatory agencies on reimbursement issues.

All this is heady talk given the paucity of data currently available. However, the overwhelming sense among the 140 physicians in Scottsdale was that NOTES will develop into a mainstream clinical capability in the near future. Times have changed since the introduction of laparoscopic cholecystectomy nearly two decades ago. The public and profession are no longer willing to accept indiscriminate introduction of new technology, and physicians are focused on keeping quality patient care first. By creating NOSCART, we hope to introduce NOTES in a safe and responsible way that will provide an even less invasive way of undergoing surgical procedures.