

NOTES: of caution

Jeffrey L. Ponsky · Michael J. Rosen ·
Benjamin K. Poulouse

Published online: 28 May 2008
© Springer Science+Business Media, LLC 2008

Not since the introduction of laparoscopic cholecystectomy has the development of a new surgical technique generated as much excitement and enthusiasm as the concept of natural orifice transluminal endoscopic surgery (NOTES). First described by Kalloo et al. [2], the idea of performing surgery in a body cavity through a natural orifice has rapidly expanded from simple transgastric peritoneoscopy to interventions performed through the rectum, vagina, and bladder.

The initial work, performed with porcine models, sought to describe the technique, its feasibility, and its limits. Further studies, most supported by generous grants from industry, helped to define the physiologic, infectious, and immunologic implications of the method [5, 6]. New instrumentation specifically addressing the needs and unique problems of natural orifice surgery has been emerging, offering promise for this technique as well as for traditional endoluminal therapy.

With the enthusiastic reception of NOTES came the vision for an entirely new approach to human surgical therapy offering improved cosmetic results and potentially less pain. The video demonstration of a NOTES appendectomy, performed in India, has electrified the surgical world and offered great promise. Human NOTES

procedures have been anecdotally reported at meetings, in the media, and by word of mouth. Performed in the United States and other parts of the world, NOTES procedures have included peritoneoscopy, cholecystectomy, tubal ligation, and percutaneous endoscopic gastrostomy “rescue” [1, 3, 4].

Recognizing the great excitement surrounding NOTES and the potential for errant development of procedures, members of the Society of American Gastrointestinal and Endoscopic Surgeons and the American Society for Gastrointestinal Endoscopy met for the Natural Orifice Consortium for Assessment and Research (NOSCAR). The NOSCAR meeting provided a forum for discussing areas of research and clinical practice with regard to NOTES and issued a paper outlining the perceived areas for research and practice of the method [7]. An overriding principle established early on was the protection of patients by the assurance that all initial procedures would be performed under the auspices of institutional review board (IRB) oversight.

Most of the NOTES procedures in the United States have been performed under IRB protocol. In other parts of the world, IRB protocols also are used to ensure patient protection and safety. Unfortunately, some cases are being performed off protocol, and reports of patient injury and even death have surfaced, but in unpublished form. In our zeal to develop this new area of surgery, we must ensure that patient safety is at all times paramount and that results are honestly and clearly presented. Work presented in journals or at meetings should represent only the results of IRB-approved protocols, and videos or reports of non-IRB approved work should be avoided. This exciting new area offers much potential for the future and must not be discredited by misadventures with patients unaware of the procedure’s potential risks.

J. L. Ponsky (✉) · M. J. Rosen · B. K. Poulouse
Department of Surgery, University Hospitals Case Medical
Center, Lakeside 7th Floor, Mailstop 5047, Cleveland,
OH 44106, USA
e-mail: jponsky@yahoo.com

M. J. Rosen
e-mail: michael.rosen@uhhospitals.org

B. K. Poulouse
e-mail: Benjamin.Poulouse@UHhospitals.org

References

1. Hazey JW, Narula VK, Renton DB, Reavis KM, Paul CM, Hinshaw KE, Muscarella P, Ellison EC, Melvin WS, Hazey JW, Narula VK, Renton DB, Reavis KM, Paul CM, Hinshaw KE, Muscarella P, Ellison EC, Melvin WS (2008) Natural orifice transgastric endoscopic peritoneoscopy in humans: initial clinical trial. *Surg Endosc* 22:16–20
2. Kalloo AN, Singh VK, Jagannath SB, Niiyama H, Hill SL, Vaughn CA, Magee CA, Kantsevov SV (2004) Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointest Endosc* 60: 114–117
3. Marescaux J, Dallemagne B, Perretta S, Wattiez A, Mutter D, Coumaros D (2007) Surgery without scars: report of transluminal cholecystectomy in a human being (see comment). *Arch Surg* 142:823–826, discussion 826–827
4. Marks JM, Ponsky JL, Pearl JP, McGee MF, Marks JM, Ponsky JL, Pearl JP, McGee MF (2007) PEG “rescue”: a practical NOTES technique. *Surg Endosc* 21:816–819
5. McGee MF, Marks J, Onders R (2007) Infectious complications of natural orifice transluminal endoscopic surgery with percutaneous endoscopic gastrotomy tube closure: a quantitative bacteriologic study in the porcine model. *Surg Endosc* 21:S333
6. McGee MF, Schomisch SJ, Marks JM, Delaney CP, Jin J, Williams C, Chak A, Matteson DT, Andrews J, Ponsky JL (2008) Late-phase TNF-alpha depression in natural orifice transluminal endoscopic surgery (NOTES) peritoneoscopy. *Surgery* 143: 318–328
7. Rattner D, Kalloo A, Group ASW (2006) ASGE/SAGES Working Group on Natural Orifice Transluminal Endoscopic Surgery. October 2005. *Surg Endosc* 20:329–333