

## **From Medscape General Surgery**

# **An Insider's Note on NOTES: The Dawn of Prime Time**

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NOTES (Natural Orifice Transluminal Endoscopic Surgery) is a rapidly growing new surgical technique with many different clinical applications. This innovative, minimally invasive method of performing intra-abdominal surgery by accessing the abdominal cavity through a natural orifice (eg, the stomach, vagina, or rectum) is being assessed in many ongoing research studies. Low complication and conversion rates seem to be indicative parameters of the benefits of NOTES. Adding these to the undeniable benefits of no visible scars, less pain, and faster recovery clearly makes NOTES a viable, attainable, and attractive surgical alternative for all appropriate patients.

At this time, 26 NOTES studies registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) are actively recruiting patients in the United States. Nationwide NOTES databases in Germany<sup>[1]</sup> and South America<sup>[2]</sup> support and exceed the expectations of the proponents of this innovative, minimally invasive approach. In the United States, the highly anticipated NOSCAR (Natural Orifice Surgery Consortium for Assessment and Research) initiated a multicenter randomized controlled study comparing traditional cholecystectomy with NOTES cholecystectomy. The outcomes of this trial will be crucial for assessing the advantages and disadvantages of NOTES in a regulated, unbiased clinical trial. When these studies are combined with the results of the German and South American trials, it will be possible to conclusively demonstrate whether NOTES is a viable alternative to standard surgical approaches for a variety of common procedures.

The undeniable benefits of NOTES reported around the world,<sup>[1,2]</sup> along with the results of our 33 transvaginal surgeries (appendectomies and cholecystectomies) performed at Yale-New Haven Hospital, lend strong supportive evidence to the efficacy of this new innovative technique and its tangible readiness for widespread clinical application.

In our experience, the ability to have a laparoscopic transvaginal cholecystectomy on a Thursday or Friday and return to work on Monday is a convincing benefit for most patients. About 50% of female patients in our hospital opt for a transvaginal cholecystectomy or transvaginal appendectomy when offered. This is a remarkable percentage, given that this procedure is relatively new and is only now receiving interest in the lay press. Based on the success of the procedure, a growing number of patients come into the office well educated about NOTES and request to have their gallbladder removed via the vaginal approach even before NOTES has been offered as an alternative to conventional methodologies.

There can be no question about the fact that every new surgical technique has to follow medicine's utmost important creed: *Primum non nocere*. Before a final shift in paradigm can occur, adequate training in minimally invasive surgery for surgeons performing NOTES and randomized controlled studies are needed. With that being said, however, new advances in surgery have always happened under the critical eyes of the proponents of old established techniques.<sup>[3]</sup> The controversies surrounding laparoscopic cholecystectomies in the late 1980s and 1990 are still well remembered. To date, the results of studies and multicenter trials evaluating NOTES procedures are very promising, but once again it will be the patients who ultimately drive surgeons to adopt this new surgical technique.

At the American College of Surgeons' 96th Annual Clinical Congress in October 2010, Dr. Kai Lehmann presented very encouraging data obtained from the German National NOTES Registry (GNR).<sup>[4]</sup> Between

March 2008 and September 2010, the GNR included 1328 patients. Of these, 1318 were women and almost all of them underwent a hybrid transvaginal cholecystectomy. In total, 38 (2.9%) conversions to laparoscopy or laparotomy were seen due to technical or other complications. A total of 56 documented complications (22 intraoperative and 34 postoperative) translates into a complication rate of 4.2%. No mortality was reported. In August 2010, Lehmann and colleagues published the report of the first 551 patients of the GNR and concluded that NOTES hybrid cholecystectomy is a safe and practicable alternative to laparoscopic cholecystectomy even in older and obese patients.<sup>[1]</sup> Since August, the number of patients opting for the procedure has increased from 551 to 1328, while the conversion rate (from 4.9% to 2.9%) and the complication rate (from 3.1% to 4.2%) have remained astonishingly low for a new surgical technique. These data strongly support the assumption of many NOTES surgeons: this innovative technique is indeed the new promised approach that combines patients' safety with the benefits of no scars, less pain, and faster recovery.

A second major registry, the International Multicenter Trial on Clinical Natural Orifice Surgery (NOTES IMTN study) is currently being conducted in South America.<sup>[2]</sup> In 2010, Zorrón and colleagues published the results of the first 362 patients. A total of 66.3% of the NOTES procedures were transvaginal cholecystectomies, with a complication rate of 6.7%. He concluded that results of clinical applications of NOTES reported in the IMTN study have shown the feasibility of this new minimally invasive technique.

Our own 33 vaginal NOTES operations (18 transvaginal appendectomies and 15 transvaginal cholecystectomies) have resulted in statistically significantly less pain ( $P < .05$ ), faster return to normal activity ( $P < .05$ ), and faster return to work ( $P < .05$ ) compared with traditional transabdominal laparoscopic surgeries. Of all these procedures, we have experienced 3 complications to date: one intra-abdominal abscess after gangrenous appendicitis at the site of the caecum, one dislodged intrauterine device, and one case of postoperative urinary retention. In our experience, the benefits of NOTES clearly outweigh the risks.

Without any doubt, data from extensive randomized controlled studies, such as the highly anticipated NOSCAR, are required to compare NOTES with laparoscopic surgeries and to ensure patient safety, monitor clinical outcomes, and identify new complications. However, the data collected to date, along with the growing patient demand for NOTES, seem to point in one clear direction: This is the dawn of the prime time for NOTES.

The first uses of NOTES have been predominantly in females, due to the anatomic access. We would predict that the rise in implementation will be based on women demanding surgical procedures using this technology. Before we see widespread application of NOTES in the male population, some additional skills need to be developed, and new instrumentation suited for the entry route in the male anatomy must be tested and evaluated. This being said, NOTES is on the verge of becoming the greatest advancement in the surgical venue since laparoscopic surgery. We only need to remember the skepticism that came with the introduction of laparoscopic surgery to realize that the final operative note on NOTES remains to be written.

## References

1. Lehmann KS, Ritz JP, Wibmer A, et al. The German Registry for Natural Orifice Transluminal Endoscopic Surgery: report of the first 551 patients. *Ann Surg.* 2010;252:263-270. [Abstract](#)
2. Zorrón R, Palanivelu C, Galvao NM, et al. International Multicenter Trial on Clinical Natural Orifice Surgery -- NOTES IMTN Study: preliminary results of 362 patients. *Surgical Innovation.* 2010;17:142-158. [Abstract](#)
3. Cameron JL, Gadacz TR. Laparoscopic cholecystectomy. *Ann Surg.* 1991;213:1-2. [Abstract](#)

4. Keller D. Note to surgeons: NOTES not ready for widespread use. Medscape 2010. Available at: <http://www.medscape.com/viewarticle/730139> Accessed May 15, 2011.

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