SURGICAL ADVANCES

Points of Entry

Is natural orifice surgery the way of the future?

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Consider the most minimally invasive surgery of all: the future of some abdominal procedures may be virtually incisionless, with surgical aims accomplished by way of a patient’s natural orifices. Research currently being conducted by members of the American Society for Gastrointestinal Endoscopy and the Society for American Gastrointestinal and Endoscopic Surgeons may pave the way to that future. Here’s how.

Notes on NOTES™

The two societies are studying this potentially revolutionary technique under the aegis of the Natural Orifice Surgery Consortium for Assessment and Research™ (NOSCAR™), a joint working group they’ve founded to further the exploration of natural orifice translumenal endoscopic surgery (NOTES) — a title they’ve trademarked.

So what, exactly, does NOTES entail? Picture organ surgery without cutting the skin and without laparoscopic ports. Surgical instruments and a small camera gain access to the abdominal cavity through the mouth and esophagus
to the stomach, through the rectum, through the vagina, perhaps even through the urethra to the bladder. Small incisions made in the digestive or urogenital tracts allow physicians to reach and treat or remove organs.

When the idea of natural orifice surgery was first proposed during the late 1990s, in a clinical working group that sought ways to push the endoscopic envelope, the new idea was viewed with some skepticism. Now, however, medical facilities worldwide are experimenting with the technique in animal and human studies. Last year U.S. hospitals saw several patients’ gallbladders successfully removed through their mouths, while surgeons at New York-Presbyterian Hospital performed what was believed to be the first transvaginal cholecystectomy. NOTES stands to create a revolution in surgical care, but the technique still involves challenges for surgeons to overcome.

**Advantages and applications**

Natural orifice surgery offers clear benefits to both patients and physicians. Perhaps the most obvious advantage from a patient’s perspective is its incisionlessness: it leaves no visible scarring.

That’s a cosmetic benefit, to be sure, but the absence of a painful incision, a less invasive surgery, is said to reduce or eliminate post-operative pain as compared to traditional open procedures. This big plus can result in shortened recovery times, in which a patient might be up and around from what was once a demanding procedure in a relatively short time.

For physicians, natural orifice techniques could realign where and how
certain procedures might be performed. Once-open, once-inpatient surgeries could migrate to the ambulatory setting, of course, but anesthesia services may also see the change. If procedures that once required general anesthesia could be performed with a lesser degree of anesthesia, perhaps nothing more than deep sedation, NOTES would have a radical impact on the economics of patient care.

While we’ve already seen the possibility that transgastric and transvaginal cholecystectomies might improve on their laparoscopic counterpart, it is as yet unclear what else might be replaced by natural orifice surgery. Some likelihoods, however, have been suggested:

- **Diagnostic staging.** When imaging such as a CT or PET scan is indeterminate in detecting the presence or spread of a malignancy, a transgastric peritoneoscopy — using a small caliber endoscope to biopsy the liver or abdominal lymph nodes — could be easily accomplished. This could be one of the first natural orifice possibilities to go mainstream.

- **Appendectomy.** One might ask, if appendectomies are so successfully done laparoscopically, why risk them any other way? But consider performing natural orifice appendectomies with deep sedation, after which you prescribe a painkiller and a course of antibiotics and discharge the patient. It could be done in an emergency room. That would be a tremendous paradigm shift in patient care.

- **Hernia repair.** Not only would natural orifice hernia repair be easy to accomplish, it would also remove many concerns about post-operative stress on
a patient’s incisions.

• **Gynecological applications.** The interdisciplinary nature of NOTES makes it an ideal technique for fallopian tubal ligation, removal of the ovaries and other gynecological surgeries. This advance might require some diplomacy, though, in terms of turf issues: while gastroenterologists could easily cross over into the specialty, gynecologists don’t often work with flexible endoscopy, so some synergy would be necessary.

• **Chest surgery.** A more distant possibility, currently under consideration, would involve tunneling through the layers of the esophageal wall to enter the chest cavity and perhaps even reach the surface of the heart. That would offset the major exposure of open chest surgery, but since the threat of infection presents serious concerns, everything depends on how well the esophageal incision can be sealed off.

**Challenges and concerns**

The safe and reliable closing of natural orifice surgery’s internal incisions is, in fact, one of the main challenges the technique’s practitioners face, largely on account of infection concerns. Exiting into the peritoneal cavity from any site, particularly the intestinal tract, presents a major risk of bacterial spread and the onset of infection.

Anyone involved in NOTES is asking, how are we planning to prevent infection? The answer seems to be a combination of patient preparation, antibiotic administration and precise instrumentation. In the latter case, one
medical manufacturer has reported its development of the first device that can swiftly and confidently close an incision in the stomach wall.

The limitations of available technology are another big challenge. It should be noted that many of the natural orifice surgeries that have made news headlines have actually been hybrid procedures, NOTES with laparoscopic assistance, due to the limitations of existing technology. At present, the success of natural orifice surgery depends on the use of traditional flexible endoscopes and laparoscopic tools, but the effectiveness of pure NOTES is waiting on the development of a new, unique toolbox specific to the one hole, one exit site, one scope technique.

What’s needed? First and foremost, a redesigned endoscope. Unlike laparoscopy, which uses multiple ports to give the surgeon a global view, a small caliber endoscope such as the type used in NOTES has a single, limited eye. Oblique side views will be needed in addition to the straight ahead one. The flexible scope will need to be able to bend in more ways than just a U-turn as well, and its channels have to be able to accommodate the tools that will be working through them. The scopes may even become primarily a carrying device for the instruments inside.

Those instruments are another focus of development. Cutting devices and graspers will need to be longer and smaller in diameter for greater reach, while electrocauterities must be made more precise to prevent unintended burn injuries. NOTES instrumentation must provide a high level of control in order to, for instance, be able to secure, maintain and correct a complicated bleeding
situation quickly and effectively.

Additionally, ports to maintain the access site — like laparoscopic ports, except providing the way to the abdominal cavity through orifices instead of through the skin — will be needed, as will internal retractors and like devices to prepare and maintain the surgical site itself, for example, by holding organs out of the way.

**Rules of research**

It’s important to emphasize that natural orifice surgery is still highly experimental. As mentioned above, the ideal instrumentation is not yet available and the technique has by no means been accepted into the mainstream yet.

A relatively small number of natural orifice procedures have been performed in American ORs to date, and those trials that have been conducted were done under tightly controlled circumstances and cautious supervision by NOSCAR. The working group’s logic in such oversight is to ensure that the technique’s future practitioners develop and release NOTES to clinical practice carefully and correctly, with the outcomes thoroughly monitored, to avoid ruining what could be an excellent surgical advance through potential misuse.

In its introductory literature, NOSCAR cites the lessons learned from the rise of minimally invasive surgery in the 1980s and the later adoption of laparoscopic cholecystectomy, when demand for the procedures outnumbered the supply of surgeons skilled enough to safely undertake them, resulting in an inexcusable amount of patient complications and poor outcomes.
They’ve openly admitted that natural orifice procedures are more difficult than the traditional surgeries they’re improving upon, and that they demand specialized training. To that end, the results of NOTES efforts are being reported to a general database for SAGES and ASGE members for continued clinical reference and research.

The surgery is under similar strict controls in Europe, but is attracting much attention in South American medical facilities. The continent’s natural orifice surgeons may become world leaders in the field, if a well-attended conference on the subject held in Rio de Janeiro is any evidence.

Could it eventually reach domestic outpatient surgery facilities? It certainly seems like it could eventually be a good fit and transform itself into the ambulatory setting, but it may be a long time in coming. Beyond the challenges of technique and instrumentation, reimbursement stands between a potentially outpatient procedure and mainstream use. Any new technology or procedure is highly dependent on reimbursement, of course, and natural orifice surgery isn’t even on Medicare’s or private insurers’ radar screens yet. It’s a limit for outpatient NOTES, but NOTES is perfectly suited for outpatient ORs.

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