Natural Orifice Translumenal Endoscopic Surgery May Allow Incisionless Operations
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Natural orifice translumenal endoscopic surgery (NOTES®) allows for appendectomy through the mouth as well as for other procedures through natural orifices without making abdominal incisions, although laparoscopic assistance is used as a precautionary measure. This advance in minimally invasive surgery was showcased last week at the Natural Orifice Surgery Consortium for Assessment and Research's (NOSCAR®) 3rd International Conference on NOTES, held in San Francisco, California.

Santiago Horgan, MD, director of the University of California San Diego Center for the Future of Surgery, used the EndoSurgical Operating System (EOS; USGI Medical, Inc) to perform an appendectomy on a pig without using abdominal incisions or laparoscopic assistance. EOS has not yet been approved by the US Food and Drug Administration (FDA).

Using EOS instrumentation delivered through the mouth, Dr. Horgan was also able to close the gastrotomy incision from inside the stomach, which has been considered the major obstacle to widespread implementation of incisionless NOTES procedures.

"Appendectomies in patients so far have been transgastric with laparoscopic guidance, because we couldn't get sufficient traction on the appendix to remove it," Dr. Horgan told Medscape General Surgery. "This was the first time this has ever been done — using new technology, we were able to do the entire operation through the stomach without anything in the abdomen, which was a real turning point."

Dr. Horgan performed the incisionless appendectomy before 300 NOSCAR attendees and has now performed the procedure on a total of 5 pigs with "very good results." As soon as the FDA approves the EOS technology, Dr. Horgan plans to perform this procedure on the first human patient. He attributes the success of the procedure to the innovative technology.

"When we operate, we like to use both our left and our right hand in triangulation fashion, moving at 45 degree angles toward the target. If the instruments are parallel, we can't operate, because we can't grab tissue," Dr.
Horgan said, "One of the issues with the endoscope is that we were not able to control the instruments the way we do the instruments used in laparoscopic surgery."

The EOS developed by USGI allows instruments to be placed through the operating platform allowing triangulation, with a 1 to 1 relationship between movements of the handles of the instruments outside the patient and the operating end of the instruments within the patient.

"If I move the handle 1 degree, the operating end moves 1 degree," Dr. Horgan said. "With the old technology, in order to move the operating tip 1 degree, I would have to move the handle 5 to 20 degrees, so it was not very accurate. The new technology allows us to have more control over the tip of the instrument, as we do in open or laparoscopic surgery."

In late March, Dr. Horgan became the first US surgeon to remove a patient's appendix through the mouth, which was his twenty-second incisionless surgery procedure, although it was done with laparoscopic guidance. His case series now consists of 26 patients who have had transvaginal or transgastric procedures.

"The drawback of transgastric surgery clearly is, can we close the stomach safely in all the patients?" Dr. Horgan said. "For transvaginal surgery, there is no doubt that this is better, with much less postoperative pain and better cosmetic results than laparoscopic surgery."

Other NOTES procedures have included cholecystectomy using a vaginal approach and sleeve gastrectomy. The rationale behind this surgical method is that surgery performed through the body's natural orifices, unlike traditional and laparoscopic surgery, eliminates the need for external incisions, with the potential for less postoperative pain, shorter hospitalization, reduced healthcare costs, and no external scars.

David W. Rattner, MD, chief of general gastrointestinal surgery at Massachusetts General Hospital and professor of surgery at Harvard Medical School in Boston, provided independent commentary for MedScape General Surgery and said that results to date were "excellent." Reported complications have included 1 or 2 reported abscesses.

"In a relatively large series from Brazil with about 180 patients, there were minor wound infections, 1 take-back hemorrhage, 1 take-back leak — not much different than what you would expect from laparoscopic cholecystectomies," Dr. Rattner told MedScape General Surgery. "What's been reported to date has been favorable, although we don't know if there are complications that are not being
reported. In the United States, where everything has been done under [institutional review board] scrutiny, there have been no complications, but the volume of cases here has been much lower than in South America.”

Anecdotal reports cited by Dr. Rattner suggest that in the Brazil series, there was definitely much less use of pain medicine by the NOTES patients than by the patients undergoing laparoscopic surgery. He believes it is "promising" that patients will recover faster but also noted that a proper study has not yet been done.

"It's a little more risky than a laparoscopic procedure for the transgastric approach, certainly, but the transvaginal approach seems to be relatively benign, because there are very few complications from the access itself," Dr. Rattner said. "At this point it's considered investigational — obviously, people have concerns about poking a hole that wouldn't ordinarily be made. We need to consider whether the risks of that extra puncture outweigh the benefits or vice versa, and at this point, it looks favorable — like the benefits outweigh the risks."

Dr. Horgan believes that operative costs for these procedures will be no more expensive than for laparoscopic surgery. Dr. Rattner pointed out that costs would vary from hospital to hospital, and that third-party payers have had a mixed response, with some saying that NOTES is an experimental procedure and is therefore not reimbursable.

Although Dr. Horgan thought that all surgeons would readily embrace these new procedures, only about 80% have expressed approval so far. However, more come on board once they appreciate the good results seen in his growing case series.

"I have residents in my service who have said, 'I'm not having the operation that way,' but when they see the outcomes, they change their mind, so I think the lack of knowledge creates the difference in opinion." Dr. Horgan said. "Interestingly, every time we offer this procedure to patients in the emergency room for transvaginal or transgastric appendectomy, all of them say 'yes.' The younger generation especially understands that pain, cosmesis, and improvement in ventral hernias as an outcome is much better for them."

In terms of additional research, Dr. Horgan is eager not only to expand his case series but also to have better technology developed.

"We've been using what I call first-century instruments to do 22nd-century surgery," Dr. Horgan said. "We have far fewer dollars today than we did 20 years ago to invest in research. Good companies like USGI and others are coming up
with new technology that will clearly help the advancement of this type of surgery."

Dr. Rattner explained that all the procedures done in humans to date have been hybrid procedures, using some laparoscopic tools either for visualization or guidance, requiring anywhere from 1 to 3 trochars with some access for flexible laparoscopic tools, through either the vagina or the stomach. Some transgastric work has been done using a transport device, which is a flexible tube that can stay locked in almost any position, acting as a conduit to deliver the instruments in and out.

"The transvaginal procedures are often done with off-the-shelf, flexible fiber optic instruments, and there are some custom-made instruments, but we really at this point are waiting for some better devices to make it easier to do these procedures," Dr. Rattner said.

Device manufacturers are developing tools now in the pipeline, and Dr. Rattner believes that it will soon be time for comparative, multicenter, human clinical trials.

"NOTES offers a lot of potential to get people back to work faster — undoubtedly it's been established that this is feasible, and now we need to delve into is it risky or not, and what are the benefits: are they real or imagined?" Dr. Rattner said. "What I'm most afraid of is that this would be done in a less than careful fashion, and that something would go wrong, and that these procedures would be shut down by regulatory agencies before they would have a chance to be evaluated in a fair manner. I believe there is an opportunity here that we could do minimally invasive surgery and improve on what we're doing, so those are my hopes and fears."

Dr. Horgan is a consultant for USGI. Dr. Rattner has received honoraria from Carl Storz Endoscopy and from Olympus.

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