Cholecystectomy with no external incisions

For the first time in the US, surgeons at New York-Presbyterian Hospital/ Columbia University Medical Center in July removed a woman’s gallbladder without any external incisions. Using the technique called NOTES (natural-orifice transluminal endoscopic surgery), a team of surgeons led by Marc Bessler, MD, inserted a flexible endoscope into the woman’s abdomen through a 1-inch incision behind her uterus and removed her gallbladder.

The 3-hour outpatient procedure was part of an ongoing clinical research trial at the hospital. The surgeons performed the same procedure in April 2007 using a flexible endoscope, aided by several external incisions for added instrumentation. (See July 2007 OR Manager.)

NOTES refers to intra-abdominal surgery through the wall of an abdominal organ. Abdominal surgery through a natural orifice is the culmination of minimally invasive surgery’s progression to smaller and fewer incisions, says Dr Bessler, director of laparoscopic surgery and director of the Center for Obesity Surgery at New York-Presbyterian Hospital/Columbia University Medical Center and assistant professor of surgery at Columbia University College of Physicians and Surgeons in New York City.

What’s new?

For the most recent procedure, the team used the same long flexible endoscope as for the 2007 procedure, Dr Bessler told OR Manager. The scope is similar to a gastroscope with 2 channels for instrument insertion. As with laparoscopic surgery, the abdomen was expanded by insufflation with carbon dioxide gas.

New for this procedure was a semi-rigid articulating instrument (RealHand, Novare) to hold up on the gallbladder that was inserted alongside the scope via a second small incision.

The team used the same techniques for dissection and cutting through the flexible scope as they did last year, but this year they also used clips through the scope instead of through a trocar port in the abdomen.

Also, this time they did not use an abdominal port for visualization as they entered the abdomen through the vagina. Instead, they used direct vision through the vagina to make the incision into the pelvic floor and watched as they made the incision going forward rather than watching it from the inside coming in.

“As we became more comfortable with our technique, we started to remove abdominal ports, eventually getting to none,” Dr Bessler says.

What’s coming?

Companies are working on new instruments and scopes with 3-dimensional views for the NOTES procedure. The instruments and flexible endoscope used today will not be the same in a few years, says Dr Bessler.

Flexible endoscopes were developed for use in the stomach, not the sterile abdomen, and there have been some problems with reprocessing them between cases in the past, he says. For this reason, his team gas-sterilizes the flexible endoscope. As more of these cases are performed, hospitals will need more than 1 scope to allow time for aeration after gas sterilization.

“Right now, we’re doing 1 case a month, so 1 scope is enough,” he says.

Some 300 NOTES procedures have been performed worldwide. In the US, 4 cen-
ters are now performing NOTES procedures, and many more are preparing to do them, says Dr Bessler.

“The technology is rudimentary right now, and the data doesn’t yet exist to support this procedure as beneficial,” he says. “It’s going to take us a couple of years to generate the data, and if the data is positive, it’s going to take a couple of years to train other physicians. I think we’re looking at 3 to 5 years before this becomes routine.”

In April 2008, NOTES was discussed at a University of Minnesota conference on the design of medical devices, according to St Paul’s Pioneer Press. Boston Scientific’s endoscopy business and a unit of New Jersey-based Johnson & Johnson are among companies working with a nonprofit group coordinating research to produce new instruments for NOTES.

**NOTES not just for women**

The NOTES procedures are not just for women, says Dr Bessler. Three centers in the US are offering the transgastric approach to men as well.

Dr Bessler presently is only doing the transvaginal approach because surgery through the vagina does not pose a greater infection risk than a procedure through the abdominal wall. Both can be prepped with povidone-iodine or other prep solutions.

He and other researchers are developing ways to prep the stomach, though the stomach is already relatively sterile because of the acids.

In general, the problem isn’t in opening the stomach, it is in the closure, he says. If the stomach incision doesn’t heal and continuously leaks nonsterile or acidic contents into the peritoneal cavity, it can become a significant problem. Dr Bessler noted that leaks in the stomach incision have occurred in patients in South America.

“I figure that while we’re waiting to prove the benefit of this procedure, we shouldn’t take any more risks than we need to. Therefore, going vaginally makes the most sense,” he says.

“If patients are hurt early on without knowing there’s a benefit because their stomachs don’t heal well, then I think this could hurt the field. But if things go well in the stomach, we’ll be ahead of the game, knowing the procedure is beneficial for patients both transvaginally and transgastrically,” he says. “It’s experimental right now, so it’s hard to know what the right answer is.”

In addition to gallbladder surgery, the New York-Presbyterian/Columbia clinical trial offers the transvaginal NOTES procedure for appendectomy, abdominal exploration, and biopsy.

Dr Bessler is recruiting patients for the clinical trial. Those interested may contact his office at 212/305-9506.

—Judith M. Mathias, RN, MA

**References**
