Focus on Evidence-Based Medicine

In this issue, two of our leading robotic surgeons—a gynecologist and gynecologic oncologist—tackle the difficult issue of morcellation in gynecology.

Because a patient, who also happens to be a physician in Boston, had deadly sarcoma spread following surgery, the media suggests that gynecologists are causing harm by morcellating uteri.

While unarguably unfortunate, this is not a new problem. We have been publishing about it and discussing it for years. Because sarcomas, in general, are rare and resistant to treatment, it is difficult to get quality research. All the recent problems, decisions and FDA reviews are based on five papers that show retrospective data on sarcomas and survival. Only one (Park et al.) has any comparison on survival with more than 30 patients. In this Robotic Surgery Advantage, Nicholas Lambrou, M.D., and Jason James, M.D., tackle this dilemma, as we continue to research it and look at our data.

Recently a patient and her attorney husband came into my office and did not want robotic surgery because of reports that they had read and cases he had consulted on. Despite concerns in the general public, the data is clear. There is not one single paper that has a higher rate of complications using robotic surgery compared with those found in laparoscopic surgery, even at the beginning of the surgeon’s robotic experience. What is also clear is that robotic surgery has the same complications as laparoscopic surgery, yet without the 25 percent conversion rate, as seen in the LAP2 GOG trial. Further, more complex cases can be done robotically than laparoscopically with the same low complication rate.

In this issue, we also highlight how Baptist Health surgeons are successfully using robotic technology to perform traditionally difficult surgeries with positive outcomes.

We don’t go to attorneys’ offices to tell them how to do their job, or go to the mechanic and tell them what tools to use to fix our cars. Why would anyone take a chance and tell their surgeon what tools to use to do their surgery? We should encourage patients to choose their surgeons based on experience and reputation. Patients should then allow those surgeons to do what they think is best. As surgeons, we should base our decisions on true, concrete, evidence-based medicine, not media hype.

Ricardo Estape, M.D.
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In April 2014, the Food and Drug Administration issued a communication highlighting the risks of laparoscopic power morcellation during hysterectomy or myomectomy for women with uterine fibroids. This guidance was spurred by the discovery that the incidence of uterine sarcoma may be much higher than previously thought—as high as one in 350 patients. When using power morcellation for such patients, there is a risk of spreading neoplastic cells to adjoining sites, likely worsening the patient’s prognosis. And no imaging or diagnostic tool exists to differentiate a fibroid from a sarcoma.

These concerns are significant and warrant additional caution and education when considering fibroid morcellation. However, Baptist Health South Florida’s Center for Robotic Surgery believes that the technique can still play an important role in appropriately selected patients. By restricting it to patients with low risk for uterine cancer and using intraoperative diagnostic techniques, the power morcellator can be used safely.

“There needs to be a deliberate process and appropriate workup of patients to ensure that we decrease the likelihood of an undiscovered sarcoma,” said obstetrician-gynecologist Jason James, M.D., chair of the Department of Obstetrics and Gynecology at Baptist Hospital of Miami. “At the same time, we are hesitant to abandon this technique for appropriate patients, as the outcomes—decreased hospital stays, shorter recovery periods, less pain—are clearly superior to alternative methodologies.”

REDUCING RISK

While it is not possible to eliminate the risk of an undiscovered sarcoma, physicians can take steps to significantly reduce it.

“The instrument remains a good option for the right patient,” said Nicholas Lambrou, M.D., gynecologic oncologist and medical director of minimally invasive gynecologic surgery at South Miami Hospital. “I reserve it for young women at the low end of the spectrum for cancer risk—for example, patients who need a myomectomy for fertility reasons. For women closer to menopause or with a larger uterus, I look to alternatives.”

INTRA-OPERATIVE DIAGNOSIS

Surgeons also take steps during surgery to reduce risk. “We can test a section of the fibroid during the procedure to confirm it is negative for cancer before using the morcellator,” said Dr. Lambrou.

In all cases, it is essential to have a thorough informed consent discussion with the patient. It also is important to note that even when power morcellation cannot be used, surgeons do not necessarily need to revert to a total abdominal hysterectomy.

“Our health system has been proactive in taking the lead to educate surgeons about fibroid morcellation, improve our informed consent to more accurately reflect the potential risks and provide alternative minimally invasive approaches to fibroid removal,” said Dr. Lambrou. “The safety of our patients is our number one goal.”
HELPING Pancreatic Cancer Patients Get to Chemotherapy Faster

Most pancreatic cancers are unresectable by the time of diagnosis, either because the disease has metastasized or because the tumor is too locally advanced. Even among the minority of patients with resectable tumors, most of which occur in the head of the pancreas, surgical treatment requires a lengthy, multi-organ Whipple procedure. Surgeons at Baptist Health South Florida are the first in the state to offer a fully robotic Whipple, which aims to improve cancer outcomes by boosting patients’ ability to recover from the surgery.

“Our goal is to get patients to chemotherapy or radiation therapy as quickly as possible,” said Omar Llaguna, M.D., a surgical oncologist at the Center. “Because a Whipple is such a complex procedure, the complication rate is high—about 40 percent nationwide. Patients tend to be more robust after a robot-assisted Whipple, compared with an open procedure. If complications occur, patients seem to tolerate them better and recover from them faster.”

Refining the Whipple

A Whipple procedure involves resection of the head of the pancreas. Because the pancreas is so closely integrated with nearby structures, the surgeon must also remove the duodenum, gallbladder, distal common bile duct and distal stomach. Then the surgeon must reconnect the pancreas, common bile duct and stomach to the small bowel. The process takes four to eight hours. Baptist Health surgeons perform about 100 Whipples per year—a high volume for this demanding procedure.

A robotic Whipple involves the same steps as an open procedure, but they are performed in a minimally invasive fashion using robot-assisted technology. “This technology provides a three-dimensional, high-definition view that is magnified 10 times,” said Jorge Rabaza, M.D., chief of surgery at South Miami Hospital. “The superior visualization is critical in such a delicate surgery. For example, when you are dissecting the neck of the pancreas from the underlying portal vein, you can actually see the space between the structures—something that isn’t visible looking down with the naked eye. The improved visualization has also been linked to a reduction in operative blood loss.”

Moving Beyond Surgery

A robotic Whipple requires five 8-mm incisions, versus what is typically a 254-mm midline or subcostal incision for open surgery. “Because the incisions are much smaller, postoperative pain and risk of wound infection are much lower,” said Dr. Llaguna. “Patients are able to get up sooner after surgery, which may reduce pneumonia and ileus.” Other possible complications of a Whipple, whether performed robotically or conventionally, include anastomotic leak and pancreatic fistula, gastroparesis and gastroduodenal artery stump blowout.

“If such complications arise, patients may have more left in reserve for dealing with them after robotic surgery,” said Dr. Llaguna. “Anything that helps patients move on faster to the next stage in their cancer treatment is going to have a positive impact on their disease.”

Jorge Rabaza, M.D. (left), and Omar Llaguna, M.D., confer with Whipple patient Judy Ramiro.
Pushing the Boundaries of Robot-Assisted Hernia Repair

Robot-assisted laparoscopy is now used for an ever-growing range of surgical procedures. One area where Baptist Health South Florida surgeons have made major strides in expanding the field is hernia repair.

INGUINAL HERNIA REPAIR

David Edelman, M.D., was among the first surgeons in South Florida in 1990 to employ robot-assisted laparoscopy for inguinal hernias. Since then, he has performed more than 2,000 such procedures.

As general surgeon for the Miami HEAT and a consulting surgeon with other area sports teams, Dr. Edelman prefers a robotic approach for sports hernias when possible, as it provides a more natural means of manipulating surgical instruments and much greater magnification and visibility of the surgical site.

He also highlights robotic outcomes: “A standard laparoscopic repair has three to four weeks recovery time,” he said. “In my experience, using the robot, we can bring that down to a week to 10 days.”

VENTRAL HERNIA REPAIR

Baptist Health surgeons also are using robot-assisted surgery to revolutionize the repair of ventral hernias, associated with defects in the abdominal wall. Surgeons have struggled to find optimal methodologies to treat these hernias, as patients receiving traditional laparoscopic approaches have a relatively high likelihood of recurrence and of seromas forming at the site due to fluid accumulation after surgery.

“The ideal solution is to close these holes and place a mesh over them, but when you are working with conventional laparoscopic instrumentation, the angles needed to do this are nearly impossible,” said Anthony Gonzalez, M.D., chief of surgery at Baptist Hospital of Miami.

Dr. Gonzalez was among the first to perform ventral hernia repair robotically in 2008. His team has found that, compared with the standard laparoscopic protocol, using the robot to repair the abdominal defect along with the hernia yields significantly better outcomes. “These patients stayed in the hospital an average of one day less, recurrence dropped by a third, and complications and conversions were significantly reduced,” he said.

These findings were published in the *Journal of Medical Robotics and Computer Assisted Surgery* in September 2014. Dr. Gonzalez’s group has performed hundreds of these procedures and trained more than 100 surgeons in the technique.

“For patients with very small or very large hernias, this approach is not necessarily applicable,” he said. “But for the great majority of ventral hernia patients, it is an excellent option.”

To reach Dr. Edelman or Dr. Gonzalez, call the Baptist Health Center for Robotic Surgery at 786-662-8877.