

Robotic Hysterectomy Takes Off, Causing Concern

BY CHRISTINE KILGORE

A recent explosion of interest in robotic surgery for routine hysterectomies and treatment of other nononcologic gynecologic conditions is raising concern about the cost and comparative value of the robot over conventional laparoscopy, as well as the future of vaginal hysterectomy and current and future training needs.

In 2010, for the first time, more hysterectomies were performed with the da Vinci Surgical System than any other procedure, including prostatectomy. The number of robotic-assisted hysterectomies performed worldwide grew to 110,000 in 2010, from approximately 69,000 the year before.

Approximately 32,000 of these hysterectomies were for treatment of cancer, and the remaining 78,000 were related to benign conditions, according to Chris Simmonds, senior director of marketing for Intuitive Surgical, which makes the da Vinci, the only such system currently on the market.

Gynecologic oncologists swiftly embraced the robotic surgical system after it was approved in 2005 for gynecologic surgical procedures because it enabled them to perform minimally invasive endometrial cancer staging – something most surgeons found too technically challenging with pure laparoscopy.

While issues of cost and training have been part of an ongoing debate in gynecologic oncology, such issues have taken on new meaning – and more urgency – with the more recent rise in robotically assisted routine hysterectomy. It can be argued, some experts explain, that an advantage exists for robotics in gynecologic oncology that, overall, does not exist for benign disease.

“Robotics will probably be the future of surgery,” said Dr. Resad P. Pasic, professor of obstetrics and gynecology and director of operative gynecologic endoscopy at the University of Louisville (Ky.). “We need to [better understand] what the real advantages are, however, especially for routine laparoscopic hysterectomies, because the cost is higher than tradition-

al laparoscopy and vaginal surgery.”

Robotic assistance “is great for some procedures, like myomectomies, where there is more suturing. But I really don’t see a huge benefit overall for less complex, benign cases,” he said in an interview. “We’re even seeing supracervical hysterectomies being done [robotically] – that doesn’t make any sense.”

A study published last year, which Dr. Pasic coauthored, found higher per-case hospital costs with robotic-assisted hysterectomies, compared with conventional laparoscopic hysterectomies, with-



‘Are we killing the art with the new technology we’re using for laparoscopy and now robotics?’

DR. PASIC

out any significant differences in complications, postsurgical infections, or frequency of hemorrhage.

Robot-assisted hysterectomies were associated with longer surgical times and cost an average of \$2,600 more, the investigators reported (J. Minim. Invasive Gynecol. 2010;17:730-8).

Using the Premier hospital database, they analyzed patient records and billing and insurance data for more than 36,000 women who received minimally invasive hysterectomy during 2007-2008 in more than 350 hospitals. Their cost analysis reflected the cost of the robotic procedure to the hospital but did not include the acquisition or maintenance costs of the robotic device over time.

The robotic unit costs between \$1 million and \$2.3 million and is associated with annual maintenance costs of \$100,000-\$170,000 a year, and instrumentation/accessories costs of \$1,300-\$2,200 per procedure, according to Intuitive Surgical.

“Further decisions regarding the diffusion of robot technology in routine laparoscopic hysterectomy,” they concluded, must be informed by random-

ized controlled studies of comparative effectiveness.

At the annual meeting of the American Association of Gynecologic Laparoscopists last month, the paper won the organization’s Robert Hunt Award for the “best article” published in the Journal of Minimally Invasive Gynecology in the past year. The study may cause some to pause, however, in that it was funded by Ethicon Endo-Surgery, and because three of the six coauthors have notable ties with Ethicon – one is employed by the company, one is a consultant, and Dr. Pasic is a speaker for the company.

Dr. Pasic, who said he uses the da Vinci for about 10% of his procedures, dismissed any suggestions of bias. “We’re not the only paper concluding there is a high cost to robotics, and we made every effort to be as impartial as possible,” he said.

Authors of a broader recently published analysis of robotic-assisted surgery and health care costs drew similar conclusions about comparative value. The investigators examined all the cost studies of robot-assisted procedures published since 2005 and reported that, on average, “across the full range of 20 types of surgery for which studies exist,” the additional cost of using a robot-assisted procedure was about \$1,600, or



‘The increase of robotic hysterectomy so far has decreased the number of laparotomies, which is very good.’

DR. MAGRINA

about 6% of the cost of the procedure in 2007 (N. Eng. J. Med. 2010;363:701-4).

There have not been any large-scale randomized trials of robot-assisted surgery, and the “limited observational evidence fails to show that the long-term outcomes of robot-assisted surgery are superior to those of conventional procedures,” said Dr. Gabriel I. Barbash of the medical school at Tel Aviv University and Sherry A. Glied, Ph.D., of the school of public health at Columbia University, New York.

With hysterectomy, a pure vaginal approach has long been viewed by many experts as the preferable approach whenever possible – the most cost-effective minimally invasive method – and some experts are concerned that the growing popularity of robotics may chip away at its use.

“Vaginal hysterectomy is an art, so the question is, are we killing the art with the new technology we’re using for laparoscopy and now robotics? Maybe ... there are some studies suggesting [this], but we have no definitive data,” Dr. Pasic said.

Dr. Javier Magrina, a professor of obstetrics and gynecology and director of gynecologic oncology at the Mayo Clinic in Scottsdale, Ariz., who has written and lectured extensively on robotic

surgery from the standpoint of both benign and malignant disease, said that so far, vaginal hysterectomy rates appear to be “stable in spite of robotics,” comprising about 20%-25% of all hysterectomies. “The increase of robotic hysterectomy so far has decreased the number of laparotomies, which is very good,” he said in an interview.



‘General ob.gyns. don’t want to be the only physicians in the community not offering [robotic surgery].’

DR. DELMORE

Dr. Jed Delmore and his colleagues at the University of Kansas in Wichita found just this when they compared the types of hysterectomy performed at their teaching hospital and two outpatient surgery centers during two periods of time: before robotic surgery became locally available (2006-2007) and 2 years after it arrived (2009-2010).

Using electronic medical record and billing data to identify hysterectomies, they found that the number of abdominal hysterectomies decreased significantly, while the number of vaginal hysterectomies remained relatively constant. The unpublished findings were presented at the American Congress of Obstetricians and Gynecologists District VII meeting in Kansas City in September.

“At least in our community of 400,000 women, there was a positive shift,” Dr. Delmore said in an interview.

Still, he said, the potential longer-term impact of robotics on vaginal hysterectomy is a concern. “If there’s a big shift from abdominal surgery to robotic surgery, that will be cost effective. ... But if it turns out that over time fewer women end up having vaginal hysterectomies, and have robotic hysterectomies instead, there will be greater expense to individuals and society,” said Dr. Delmore, professor of obstetrics and gynecology and director of gynecologic oncology at the university.

An even larger concern, he noted, is “whether robotic surgery, as it becomes more and more available, will increase the total volume of hysterectomies – in women who would have previously been treated with hormone therapy or [other modalities].”

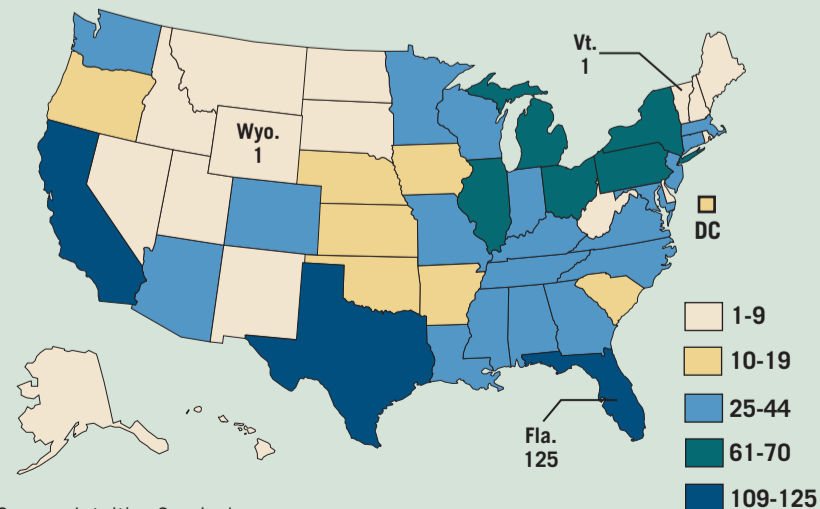
Such a trend may be occurring with prostatectomy, note the authors of the New England Journal of Medicine cost analysis, with robotic technology possibly contributing to the substitution of surgical for nonsurgical treatments for prostate cancer.

This does not appear to be happening with hysterectomy in the Kansas City area thus far, Dr. Delmore said.

The undercurrents may already exist, however. Gynecology is one of Intuitive Surgical’s five main “target markets,”

Continued on following page

da Vinci Robotic Surgical Systems Installed per State



Continued from previous page

according to a company investor presentation, and hysterectomy is one of four “target” gynecologic procedures, along with sacral colpopexy, myomectomy, and endometrial resection.

With an estimated 600,000 hysterectomies being performed each year in the United States, Intuitive sees potential for growth. As of this fall, the 2011 surgical volume with the da Vinci had increased 30% over 2010 volume across all types of procedures, said Intuitive Surgical’s Mr. Simmonds.

Having a surgical robot has become a status symbol of sorts for hospitals in many urban areas – as of September, Intuitive had installed 1,478 da Vinci surgical systems in the United States – and ob.gyns. may feel compelled to keep up with market demands.

“General ob.gyns. don’t want to be the only physicians in the community not offering it,” said Dr. Delmore, who teaches robotic surgery as a proctor for Intuitive Surgical.

Many ob.gyns., moreover, find robotic-assisted laparoscopy much easier than conventional laparoscopy to learn and adopt. Suturing is easier, and

‘If it turns out that over time fewer women end up having vaginal hysterectomies, and have robotic hysterectomies instead, there will be greater expense to individuals and society.’

Dr. Magrina and other proponents of robotics maintain that the advantages of instrument articulation and steady three-dimensional vision have proven even higher than expected – for hysterectomies as well as more complex gynecologic procedures.

While the learning curve for robotics is said to be relatively short, Dr. Pasic and his coauthors caution that robotic assistance should not be used by physicians who are unwilling to invest time and effort into laparoscopic training. Exuberance for the da Vinci could have an “unintended negative effect on resident and fellow training as it relates to overall laparoscopic competencies,” they said.

Institutions, in the meantime, are individually attempting to determine how best to train residents in robotic-assisted surgery. The University of Kansas is implementing a training model for ob.gyn. residents that includes an online tutorial, training with inanimate objects, animal lab training, and bedside assistance in real robotic-assisted hysterectomies.

Dr. Delmore and his colleagues have a study underway to look at how graduate ob.gyns. utilize this training. “What if residents go somewhere afterward where there isn’t a robot, for instance? Will [they have learned enough] to safely operate?” he said.

Dr. Magrina said he had no relevant financial disclosures. Dr. Delmore teaches robotic surgery as a proctor for Intuitive Surgical. Dr. Pasic is a speaker for Ethicon Endo-Surgery. ■

Postpartum Perineal Clinic: When Pelvic Floor Complaints Just Can’t Wait

BY AMY ROTHMAN
SCHONFELD

FROM THE ANNUAL MEETING OF THE
AMERICAN UROGYNECOLOGIC SOCIETY

PROVIDENCE, R.I. – A postpartum perineal clinic staffed by urogynecologists has been established at the University of Michigan to expedite the assessment and treatment of pelvic floor disorders resulting from maternal birth injuries, according to Dr. Cynthia Brincat, who described the clinic in an oral poster presentation at the meeting.

“About 10% of women develop complications associated with childbirth. We are a one-stop location for these women to be seen during a very busy and very stressful time in their lives,” Dr. Brincat said in an interview. “We provide focused, problem-based, short-term therapy. Patients then can go back to their regular providers, often with a care plan that can be carried out in that setting.” Dr. Brincat worked at the clinic as a fellow in female pelvic medicine and reconstructive surgery at the University of Michigan Medical Center, and is now with the University of Wisconsin–Madison.

At the Michigan Healthy Healing After Delivery Program, patients are seen within 2 weeks of requesting an appointment. It offers its services to women with such symptoms as fecal or urinary incontinence, painful or nonhealing episiotomy, anal fissures, third- or fourth-degree lacerations, rectovaginal fistulas, postpartum urinary retention, pelvic organ prolapse, and painful intercourse.

The clinic provides a range of services. “Some of the treatments we provide center around asking the right questions and uncovering what is going on. We do a lot of patient education. Once a patient understands what has happened to her, she can take better care of herself,” said Dr. Brincat. “For example, if she has a third- or fourth-degree laceration, she

can understand how important it is to keep her stool consistency soft.” Patients can consult with a PhD nurse continence expert and physical therapists who can develop a pelvic floor muscle-strengthening program or provide advice concerning diet and lifestyle changes to promote healthy living and prevent future incontinence problems. Counseling in the clinic deals with the patient’s emotional well-being and fears about future pregnancies.

More focused interventions include cauterization of granulation tissue, application of nitroglycerin paste for anal fissures, trigger-point injections for pain relief, or estrogen application for atrophic vaginal tissue. Biofeedback is commonly used for helping patients visualize the most effective ways to perform pelvic floor muscle contraction exercises. Other services provided include endoanal ultrasound for the assessment of sphincter anatomy and multichannel urodynamics to assess bladder function. MRI studies, performed under approved research protocols, are useful for detailing birth trauma such as injury to the levator ani and can help physicians establish a plan for avoiding injuries with subsequent births. Some patients require surgical management for incontinence, anal sphincter repair, or debridement.

Now in its fourth year, the practice has been steadily growing. Total new patient visits increased 35% from year 1 to year 2 (from 40 to 62) and 7.5% between year 2 and year 3 (62 to 66). “This year we are on track to see 80 new patients,” said Dr. Brincat. The most common presenting problems were follow-up of third-degree lacerations, urinary incontinence, and perineal pain.

Analysis of referral distribution indicated that less than one-third of referrals were from the University of Michigan’s in-house generalist practice. Thirty-one percent came from the resident practice,

and 41% were referred from family medicine practice, certified nurse-midwife practice, outside physician referrals, and self-referrals.

“We knew we had to build a broad referral base to be successful,” said Dr. Brincat. To accomplish this, the nurse coordinator and staff members undertook direct patient marketing via Web search engines, YouTube videos, podcasts, and distribution of printed patient education materials. Peer-to-peer programs targeted nurses and other obstetric providers. All referrals are cleared through one point of entry, a knowledgeable nurse who can triage patients and serve as an ongoing contact.

Although there was some initial reluctance among generalists to refer patients, that no longer holds true. “Patients often don’t see us more than once – our average number of visits is about 1.6,” said Dr. Brincat. Once a primary provider sees that the patient returns to his or her practice, the provider is less reluctant to refer the next patient. In fact, she said, the bond with the primary provider is often strengthened once the patient realizes that the provider values the patient’s outcome enough to send the patient for specialized treatment when necessary.

“In the United Kingdom and most European countries, anyone who has undergone a traumatic birth injury is seen in a follow-up clinic right away. In the United States, that’s not the standard of care. What we’re trying to do is change that,” said Dr. Brincat. “In general, the assessment and treatment of women with birth injuries is not given enough attention. If this was about professional football players or baseball players, and we said 1 in 10 of them would experience a traumatic injury and not be seen for weeks afterwards, I think the issue would get a lot more attention.”

Dr. Brincat said she had no relevant financial disclosures. ■

Hip Fracture Risk Rose at Start of Loop Diuretics

BY BRUCE JANCIN

FROM THE ANNUAL MEETING OF THE
AMERICAN SOCIETY FOR BONE AND
MINERAL RESEARCH

SAN DIEGO – The risk of hip fracture nearly doubles during the week following a new prescription for a loop diuretic.

In contrast, there is no spike in the risk of hip fracture in the 7 days following a new prescription for other classes of diuretics or for ACE inhibitors, according to an analysis of the massive The Health Improvement Network (THIN) database involving more than 400 U.K. primary care practices.

The most likely explanation for the short-term jump in risk of hip fracture may be related to the prominent urinary symptoms that often accompany a

new prescription for loop diuretics. The resultant rush to the bathroom could lead to an increased rate of falls during that initial adjustment period, Dr. Sarah D. Berry speculated at the meeting.

She reported on 28,703 subjects who experienced an incident hip fracture and more than 2 million others who did not during 15.1 million person-years of follow-up recorded in the THIN primary care database. In a nested, case-crossover study, she and her coworkers compared the occurrence of new diuretic prescriptions in the 7 days prior to the hip fracture to the occurrence of new diuretic prescriptions during the control period 31-37 days before the fracture.

The adjusted odds ratio of an incident hip fracture was significantly increased by 80% during the 7 days following a

new prescription for a loop diuretic. That being said, it needs to be emphasized that the absolute risk during this week-long window of increased vulnerability remained low: 2.9 hip fractures per 100,000 new loop diuretic prescriptions, according to Dr. Berry of the Hebrew SeniorLife Institute for Aging Research and Beth Israel Deaconess Medical Center, Boston.

Counseling vulnerable older adults and their caregivers about the need for increased awareness and careful ambulation to the bathroom during the 7 days after going on a loop diuretic might help reduce hip fractures, she added.

Dr. Berry declared having no financial conflicts regarding the study, which was supported by the National Institutes of Health and Hebrew SeniorLife. ■