

Technology for surgery

Robotics: Little data, much debate

Mention robotics in OR circles, and you're likely to spark a debate. Is robotic surgery an innovative technique with wide application or mainly a marketing ploy to attract patients? Or does the truth lie somewhere between these views?

These questions are far from academic. According to Intuitive Surgical, manufacturer of the da Vinci system, the only robot system currently available in the US, 136,000 da Vinci procedures were performed in 2008, a 60% increase from 2007. With that kind of growth, it's key for OR leaders to understand the state of robotic surgery including outcomes, experience, cost factors, and technical evolution.

Outcomes evidence

Analyzing the evidence for robotic surgery presents challenges, says Diane Robertson, BA, director of the Health Technology Assessment Information Service at ECRI Institute, an independent, nonprofit organization that researches health care technology and services.

Analyzing published data, the institute found a lack of appropriately designed, randomized controlled trials to determine the comparative effectiveness of surgical approaches.

Robertson says that for most clinical applications, the analysis found "little definitive data on the relative effectiveness of robotic-assisted versus standard laparoscopy or open surgery; no conclusive evidence for superior outcomes for robotic-assisted surgery, such as less blood loss, shorter hospital stay, and less pain, over traditional laparoscopy; and longer operative times, which exposes patients to longer anesthesia time."

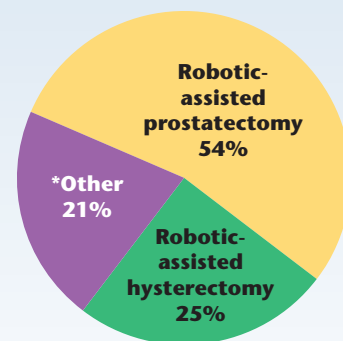
A study in the February 2010 *Journal of Urology* found laparoscopic prostatectomy (with and without robot use) and open radical prostatectomy "have similar rates of postoperative morbidity and additional treatment."

Positive results

Some reports have shown positive results, particularly for prostatectomy, the most common robotic procedure. A widely reported study in *JAMA* in 2009 found men having minimally invasive radical prostatectomy, with or without robotics, had shorter stays and fewer respiratory and other surgical complications compared to those who had retropubic radical prostatectomy surgery. But they had more genitourinary complications and diagnosis of incontinence and erectile dysfunction.

The more frequent diagnoses of these conditions don't necessarily equate to worse urinary and sexual function, the authors said, because men who had higher expectations may be more bothered or engage in rehabilitation that may lead to more frequent diagnoses.

Robotic surgical procedures



**Includes cardiothoracic, general, and other urologic and gynecologic procedures.*

Source: ECRI Institute, 2008.

“The value of the study is that a lot of outcomes in minimally invasive surgery and robotics were coming from single centers, which have observer bias, and in some instances surgeons obtain industry funding for consulting or sponsorship of courses,” says Jim Hu, MD, MPH, division of urologic surgery at Brigham and Women’s Hospital, Boston, and lead author for the study. “The Medicare database (used in the study) is free of these biases.”

Need for logical comparisons

Hiep Nguyen, MD, a surgeon at Children’s Hospital Boston who performs robotic surgery 4 days a week, calls for logical comparisons. He is the robotics program director and runs a research and training lab.

In pediatrics, for example, “We need to compare robotics to open cases because conventional laparoscopy isn’t really an option for what we do. The skill you need to sew isn’t possible through a scope.”

Though most experts agree more research is needed, Dr Nguyen says finding money for research and training is difficult. Donors provide some of the funding, and Dr Nguyen does “a fair amount of fund raising.” He calls for a greater commitment to robotics research.

The experience factor

One possible reason for outcomes variation is surgeon experience.

Dr Hu, who performs 8 robotic-assisted prostatectomies (RAP) a week and uses the robot in many other procedures, says there is a definite learning curve: “Most people doing robotic surgery didn’t learn it in their residency and only took a 2-day course.”

He would like to see credentialing requirements tightened. “When I looked at my own data, my outcomes didn’t really plateau until about 500 cases.” That’s in stark contrast to the 15 to 30 cases required by many hospitals.

Research shows surgeon experience is an important factor in prostatectomy. Researchers at the Memorial Sloan-Kettering Cancer Center in New York City associated surgeon experience with prostatectomy with the risk of recurrence and complications, although RAP wasn’t the only technique examined. The study in the February 2010 *Journal of Urology* found surgeon volume was “inversely related” to hospital stay and genitourinary/bowel complications.

Another issue is that hospitals are buying robots to stay competitive. “Everyone is pressured to buy a robot, so there is pressure to use them,” says Dr Hu. “Maybe pressure to overuse them.”

The cost factor

The cost of robotics is another controversial issue and one of the main reasons, along with surgeon training, that it hasn’t penetrated the market more extensively.

In a January 2010 review article in *Current Opinion in Urology*, Yair Lotan, MD, department of urology at University of Texas Southwestern Medical Center in Dallas, writes, “Robotic application is not cost effective compared with open or laparoscopic approaches, and future studies will need to determine whether there are indirect benefits that will justify its use.”

Dr Lotan, who has published articles on decision analysis, says it’s important to consider all costs, particularly for a procedure that has few demonstrable benefits, such as RAP, with a costly device like a robot. “

“When comparing robotic and open prostatectomy, OR time isn’t shorter, room and board are not that much shorter, and there isn’t that much blood loss with an open procedure,” notes Dr Lotan, who analyzed 640 prostatectomy patients who had open, laparoscopic, and robotic techniques.

He added that there is no added reimbursement to the hospital for robotic-assisted procedures. Savings in pain medication are minimal, ongoing costs of a robot are high, and patients who receive RAP are typically over 65 and not working, so there is no societal economic benefit for returning patients to work.

Dr Lotan says hospitals bear the increased costs: “Surgeons, patients, and insurance companies aren’t affected.”

A different perspective

Dr Nguyen offers a different perspective. When he pushed for Children’s Hospital to purchase the latest da Vinci robot, he says, “The hospital performed an evaluation of the financial impact of the robotic system. I was prepared to present my case that robotic surgery provides a lot of nonfinancial benefits including faster recovery and less pain for the patient to counter the financial report. So I almost fell off my chair when I learned that their results found the robotic cases to be 9% to 10% less expensive.”

He learned that although robotics procedures cost more up front, “We make it up on recovery time and the time the patient is in the hospital.”

The hospital had anticipated it would take 5 to 7 years to pay back the cost of the robot, but Dr Nguyen says in 4 months, “We were at 75% of the number, and we’re predicting 150% of the number in 1 year.”

Managing costs for robotics

Dr Nguyen says his lab is a way to cut costs for robotic surgery. “We can work things out first in the lab before we get into the OR.”

A dedicated team also aids innovation and efficiency, further reducing costs.

“I do not think every surgeon in this country should need to perform robotic surgery,” says Dr Nguyen. “Not every hospital in this country needs a robotic system when the volume does not warrant it.”

Market monopoly

Intuitive’s monopoly of the market likely affects costs. Dr Hu acknowledges the company’s role in innovation, but adds, “It would be healthy for health care in general to have a competitor. One should be rewarded for innovation, but when it’s a monopoly in the face of spiraling health care costs, it’s a problem.”

Dr Nguyen agrees: “This company’s (Intuitive) primary goal is selling the robotic system; all other goals are secondary.” He too would like to see a competitor and notes that his team has used instruments as many as 25 times in the research lab, although the company inactivates them after 10 uses.

Kirby Vosburgh, PhD, an engineer with the Center for Integration of Medicine and Innovative Technology (CIMIT) in Boston and assistant professor at Harvard Medical School, takes a different view.

“Intuitive has done an excellent job of creating a platform for inserting robotics in the OR. In order to go to market at a profitable scale, you end up building walls around a device (in this case the da Vinci robot), which tends

to constrain competition," he says. "On one side, they are doing exactly what they are supposed to—supporting their customers and building their company equity. It would likely be easier to advance the field through newer techniques, but their approach is traditional and has benefits as well."

Factoring in the intangibles

Dr Nguyen points to an example that illustrates the value of robotic surgery. He recently performed a robotic repair of a ureter in a 15-year-old girl. "An open procedure would have meant 4 to 5 days in the hospital, with 3 to 4 weeks of recovery time. Instead, she was up and walking around less than 12 hours after her surgery and went home in not much pain." ♦

—Cynthia Saver, RN, MS

Cynthia Saver, a freelance writer, is president of CLS Development, Inc, in Columbia, Maryland.

ECRI Institute has published a number of evidence reports on robotic surgery and other minimally invasive procedures. Information is at www.ecri.org

References

Hu J C, Gu X, Lipsitz S R, et al. Comparative effectiveness of minimally open radical prostatectomy. *JAMA*. 2009;302:1557-1564.

Lowrance W T, Elkin E B, Jacks LM, et al. Comparative effectiveness of prostate cancer surgical treatments: A population based analysis of postoperative outcomes. *J Urol*. 2010;183:1366-1372.

Savage C J, Vickers A J. Low annual caseloads of United States Surgeons conducting radical prostatectomy. *J Urol*. 2009;182:2677-2681.

Lotan Y. Economics of robotics in urology. *Curr Opin Urol*. 2010;20: 92-97.