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Robot Surgery Damaging Patients Rises With Marketing

By Robert Langreth - Oct 8, 2013

Porter Adventist Hospital in Denver announced last year that Warren Kortz, a general surgeon on the medical staff, was the first in the Rocky Mountain region to use a technique known as robotic surgery to remove gall bladders through one incision in the belly button.

The operation, performed while the doctor sits at a video-game-like console, was “taking advantage of another breakthrough in robotic surgery” and is “easier on the patient,” the hospital said in a press release.

“It’s Star Wars stuff,” Kortz was quoted as saying in another article put out by the hospital touting another operation, robot-assisted parathyroid surgery, in 2010. “My prediction is it will eventually replace everything else.”

What the hospital and Kortz didn’t reveal was the risk. Even as Kortz promoted robotic surgery, 10 patients he treated suffered injuries or complications between 2008 and 2011, according to an April complaint by the Colorado Medical Board. Five had arteries punctured or torn. Objects were temporarily left inside two, and others had nerve damage. One died and another needed cardiopulmonary resuscitation. The complaint charges Kortz with 14 counts of unprofessional conduct, including sometimes not advising patients on alternatives to the robot.

March: [Robosurgery Suits Detail Injuries as Death Reports Rise](#)

Robotic surgeries are on the rise, fueled by aggressive marketing by doctors, hospitals and Intuitive Surgical Inc. (ISRG), which manufactures the \$1.5 million robot. Advertising on hospital and doctor websites, YouTube videos, billboards, and on radio and television has hyped the advantages of robotic surgeries, often claimed fewer complications without proof, and ignored contradictory studies finding no advantage in some cases.

Not Proven

Robot operations haven’t been proven in randomized trials to offer significant health benefits compared to standard, less-invasive surgery and multiple studies show they can cost thousands

of dollars more.

U.S. hospitals used robot-assisted surgery in more than 350,000 operations last year, a 60 percent jump since 2010. Robotic surgery is used to perform hysterectomies, gall bladder removals, prostate cancer treatment, heart valve operations, and many other soft tissue operations. And half of general surgeons plan to add robotic systems within two years in response to general demand, according to a JPMorgan Chase & Co. survey reported Oct. 3.

“If there was a Nobel Prize for marketing, it would go to Intuitive Surgical,” said John Mulhall, an urologist at Memorial Sloan-Kettering Cancer Center in New York, which performs prostate cancer surgery with and without the robot.

FDA Flaws

The rise of Intuitive’s robot surgery also shows flaws in how the U.S. Food and Drug Administration regulates the marketing of medical devices, which includes everything from radiation therapy machines to implanted devices such as artificial hips and cardiac defibrillators to drug infusion pumps to surgical instruments and surgical robots.

The FDA has just two full-time employees dedicated to evaluating medical device ads, including those involving robotic surgery, compared with a full office of more than 60 people watching over prescription drug promotion.

The complexity of medical devices makes safety and efficacy claims hard to evaluate, creating an environment ripe for misleading advertising, including by hospitals, said Robert Steinbuch, a professor of law at the University of Arkansas at Little Rock. “Hospital advertising is essentially a free-for-all,” he said.

70 Deaths

Bloomberg News reported in February that the FDA was surveying surgeons about the robots after an increase in reported adverse events, including 70 deaths since 2009. Reports of injuries linked to robotic surgery have more than doubled in the first eight months of this year, based on when the reports were received by the FDA, compared with the same period last year.

Intuitive Surgical says looking at reporting dates, rather than the dates the incidents occurred, “is likely to seriously misrepresent the true performance of a device.”

While Porter Adventist Hospital cannot comment on the Kortz cases due to privacy laws, safety is its top priority and it responds “with swift and immediate action” to clinical concerns, said Thomas Drake, chief medical officer for the hospital, in a statement. “Our approach to robotic

surgery marketing is focused on consumer awareness,” Drake said.

Warning Letter

In July, the FDA issued a warning letter to Intuitive Surgical after an inspection found the company hadn’t adequately reported device corrections and patient adverse events in some cases. Sales growth slowed in the second quarter on a decline in robot system sales. Since the first Bloomberg report in February, Intuitive Surgical’s shares have fallen 34 percent to \$380.99.

“The marketing material that Intuitive puts out is fair and balanced,” said Myriam Curet, chief medical adviser for Intuitive Surgical. The company has “a robust program where we review all of the marketing material that goes out and we make sure that discussions of alternative procedures are on the marketing materials as well as discussions about risks,” she said.

Intuitive Surgical follows regulatory guidance in every market in which it operates, said Angela Wonson, a spokeswoman for the company. It also continually evaluates and updates the informational materials it provides to medical professionals and the public to ensure they reflect recent research, she said.

“Ultimately, decisions about treatment must be made between the surgeon and the patient during the informed consent process,” Wonson said.

Doctor Proposed

Teresa Hershey, 41, of Bermuda Dunes, California, said she knew nothing about robotic surgery when her doctor proposed it as an alternative to standard hysterectomy.

“It sounded good. She sold me on it,” recalls Hershey, who was impressed with videos on YouTube emphasizing the precision of the robot arms.

Her 2010 operation turned out to be anything but accurate. Doctors punctured her bowel during the procedure, a problem that wasn’t discovered until she had been hospitalized in severe pain for nine days, she said. It took nine operations to fix the problem, keeping her in the hospital for months over multiple stays, and racking up almost \$1 million in medical bills that were paid by her insurance.

“They are deceiving people,” said Hershey, referring to the rosy marketing by doctors and the company. “People don’t hear the cons they only hear the pros.”

Didn’t Mention

A brochure her doctor gave her didn’t mention that the same less-invasive hysterectomy can be

done through small incisions without the robot using a laparoscope, Hershey said. She plans to sue Intuitive Surgical, she said.

Desert Regional Medical Center, where Hershey was treated, puts its marketing materials “through a stringent marketing and advertising review process prior to publication,” Richard A. Ramhoff, a spokesman for the hospital, said in an e-mail.

“Our website, where we feature our robotic surgery offerings, explains that all surgical procedures, including those with robotic options, have risks and benefits,” Ramhoff said.

As a surgeon herself, Curet said she “would never expect a patient to depend on marketing material in terms of making their informed consent.” Wonson said the company has updated language in its newer brochures, which include laparoscopic hysterectomy.

Intuitive Surgical is particularly aggressive in its marketing to hospitals, say doctors and hospital officials.

Sales Pitches

Peter Dunn, executive medical director for perioperative services at Massachusetts General Hospital, said sales representatives for Intuitive Surgical “were constantly coming in” with pitches for how the Boston-based hospital could form a partnership with the company, either providing robot training or by holding symposiums on robot surgery or advertising the benefits of the robot.

“They would go to any avenue they could to infiltrate Mass General,” said Dunn, who declined the partnership. “We absolutely refused.” The company’s marketing “has pushed the limits of truth,” he said. Mass General uses the robot sparingly for urology and gynecology procedures, he said.

Robotic surgery grew out of the U.S. military’s attempts in the late 1980s to design remote-control devices that would enable surgeons at military bases far away from the battlefield to treat wounded soldiers. Intuitive Surgical’s robot was cleared for use by the FDA in 2000.

High-Definition Display

In robot-assisted surgery, a physician sits at a video-game-style console several feet from the patient and peers into a high-definition display. Foot pedals and hand controls maneuver mechanical arms equipped with tools, guided by a 3-D camera that shows the work as it is done inside a patient. This differs from other minimally-invasive operations in which doctors stand over the patient and manually manipulate instruments and a tiny camera through multiple

small incisions.

When a hospital got a robot, Intuitive Surgical provided an extensive marketing kit with everything from material for radio spots to television clips to Web pages the hospital can use in its marketing, said Peter Carnegie, a former Intuitive Surgical cardiothoracic program development manager, who left in 2010 and now provides consulting services for hospitals on complex robotic surgery.

For hospitals, the “primary investment value” of the robot “is growing the hospital’s market share with new surgical referrals,” wrote Ryan Rhodes, an Intuitive executive, and a colleague in a chapter on the economics of robotic surgery in a 2008 book.

Attract Patients

The robot “can attract new patients, new referrals, and new hospital revenue,” they wrote. “We can provide marketing support, including source files for a variety of promotional materials, and we work with hospital and practice marketing staff to coordinate promotional events.”

Marketing materials for robotic hysterectomy often has contained “cherry-picked and very misleading information,” said Barbara Levy, vice president for health policy at the American Congress of Obstetricians and Gynecologists. A September 2012 study by researchers at Columbia University revealed that 44 percent of hospital websites touted robot gynecology surgery, yet only 1.6 percent of the sites mentioned potential complications of the operation.

Websites for hospitals doing robotic prostate surgery often have contained unproven claims of superiority in erectile dysfunction, a study by researchers at Memorial Sloan-Kettering found. In addition, many sites had “generic information copied directly from the website of Intuitive Surgical,” the study, published in 2010, found.

‘Overestimate Benefits’

A 2011 study by doctors at Johns Hopkins School of Medicine also found that 164 hospital robot-surgery websites surveyed “overestimate benefits, largely ignore risks and are strongly influenced by the manufacturer,” according to research in the Journal for Healthcare Quality.

Curet, of Intuitive Surgical, said the study tried to pass judgment on robotic surgery marketing without comparing it to hospital marketing for other devices.

The FDA is “especially weak when it comes to regulating ads for medical devices,” said Diana Zuckerman, president of the National Research Center for Women & Families in Washington.

The FDA is working on a reorganization to increase the number of staff members working on device promotion, and others on limited details are helping in the meantime, said Synim Rivers, a spokeswoman for the agency, in an e-mail.

Intuitive Surgical “like any other medical device manufacturer, provides clinically-supported marketing materials to its customers,” Wonson said in an e-mail. It cannot control how hospitals market the device, she said.

Aggressive Reps

The company’s sales representatives are especially aggressive in marketing the gadget, say former employees and hospital executives.

The sales reps were “masterful at being very aggressive” in playing a hospital off against its local rivals to get them to purchase a robot, said Carnegie, the former Intuitive Surgical program manager.

“They used every ounce of leverage they had in that monopoly to pressure hospitals into purchasing,” Carnegie said.

Once a hospital had one robot, sales people were “trained to drive conflicts” between surgeons so they would start squabbling over who got to use the robot at popular times, Carnegie said. If enough prominent doctors started complaining that they couldn’t schedule robot operations, hospital administrators might have little choice to buy another, he said.

‘Monstrous Leap’

Intuitive Surgical has “great technology” that is “a monstrous leap” over what was available before, said Carnegie, who remains “very positive on the technology.” While the tactics were aggressive, “there is nothing ethically wrong with what they have done when you look at it from a business perspective,” he said.

One time, a sales manager visited Dunn, at Massachusetts General, saying that a senior gynecologist couldn’t get enough operating time on the hospital’s robot, Dunn said. That claim turned out to be incorrect, Dunn said.

Another time, a sales representative told one of his staff surgeons that training on the robot was only worthwhile if the doctor performed a certain number of cases, Dunn said.

Paul MacKoul, director of minimally invasive gynecology surgery at Holy Cross Hospital in Silver Spring, Maryland, has done thousands of minimally invasive operations, and can perform

a hysterectomy without the robotic system through two small incisions in just 45 minutes.

Losing Business

In 2011, he says he started losing business to gynecologists with more limited experience in less-invasive operations who had previously referred patients to him. They were keeping the patients for themselves by adopting the robot, even though the robot operations had more incisions than what he does, he said.

“The marketing has been genius,” MacKoul said. “You’d be surprised how many patients think the robot operates on the patient, not the doctor, and it is very sophisticated and precise and that is why it is better.”

In gynecology, the company “came in and convinced surgeons this new technology is going to take over the market,” said Wendel Naumann, a gynecologic surgeon, at Levine Cancer Institute in Charlotte, North Carolina. “Learn to do this or you can get left behind.” He no longer uses the robot because “it really didn’t add anything.”

Intuitive Surgical’s Curet said that many studies have found that on the robot, surgeons are less likely to run into difficulties that would require them to convert to traditional large incisions, compared with surgeons using standard less invasive methods.

Brings Value

“Where the robot brings value is when you get into more complex procedures” that cannot be done with standard less invasive methods, Curet said. “You are taking a patient who would otherwise have a large incision and now operating minimally invasively.”

Curet said that while randomized, controlled trials comparing surgical techniques are infrequently done, analyses of large patient databases “have shown a definitive advantage” to robotic prostate surgery compared with traditional large-incision prostate removal, including fewer operative complications.

A Stanford University study in the September issue of *Urology* found that men who received robotic prostate operations had shorter hospital stays, needed fewer blood transfusions, and had fewer complications and deaths in the 30 days after surgery.

First Surgeon

In Denver, Porter Adventist Hospital started talking about Kortz’s prowess on the robot as early as October 2009, in a press statement saying he was “the first surgeon in the Rocky Mountain

region” to remove the parathyroid gland with the robot.

A summa-cum-laude graduate of Dartmouth College, Kortz started performing robotic operations in 2005 and by 2012 had done 350 to 400 operations on the robot, according to a court deposition.

In one incident on May 21, 2010, Kortz pierced the aorta of 22-year-old Shanti Lechuga while making an initial incision at the beginning of a planned robotic kidney removal for a donation, necessitating an immediate operation to fix the problem, according to a malpractice lawsuit against Kortz.

A sponge was left inside her body that had to be removed during a second surgery, and she suffered a nerve injury. The litigation was resolved last month, court documents show.

Privileges Suspended

Kortz’s robotic operating room privileges were suspended at Porter Adventist around August 2010. He got them back early in 2011, he said in the 2012 deposition in the Lechuga case, filed as an exhibit to a defense document.

A few months later, Kortz and several other surgeons got together with the hospital to create the Porter Robotics Institute, described in a website as “one off the first robotic surgery programs in the Denver area.”

The expansion of Porter Adventist’s robotic program added nurses dedicated to robotic operations, said Tim Shonsey, a hospital spokesman. While Kortz is on the medical staff at the hospital, he is not an employee, Shonsey said.

In forming the institute, the hospital and Kortz and other doctors signed “a joint marketing agreement” agreeing to split costs of promoting the institute, Kortz said in the deposition. “It’s a contract that allows them and us to do joint marketing.”

Local TV

Kortz and the hospital let a local television station film a segment about new institute. The robot is “decreasing the trauma even further to the patient,” Kortz said in a web article dated May 2011 accompanying the video on www.thedenverchannel.com.

Two months later, another patient of Kortz’s died after his condition worsened following a robotic operation and then a second non-robotic operation that also didn’t solve the problem, according to a wrongful death lawsuit by his widow.

Kortz “strongly denies” unprofessional conduct and his complication rate “is not out of line with those of other experienced general surgeons,” said Lisanne Leasure, a lawyer for Kortz, in an e-mail. “To suggest or imply that it was somehow improper for Dr. Kortz to speak publicly about the proven benefits of robotic surgery even though a very small number of his patients had experienced complications is irresponsible and false.”

The medical board complaint against Kortz is scheduled to be heard in February.

As for Porter Adventist, “our marketing efforts are never meant to interfere with this physician-patient relationship or to supersede a physician’s clinical judgment,” said Drake, the hospital’s chief medical officer, in his statement.

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