Study: Robotic Surgery Complications Underreported

Despite widespread adoption by hospitals of surgical robot technology over the past decade, a "slapdash" system of reporting complications paints an unclear picture of its safety, according to Johns Hopkins researchers.

In a report published online in the *Journal for Healthcare Quality*, the Johns Hopkins team says that of the 1 million or so robotic surgeries performed since 2000, only 245 complications -- including 71 deaths -- were reported to the U.S. Food and Drug Administration. When an adverse event or device malfunction occurs, hospitals are required to report these incidents to the manufacturer, which in turn is required to report them to the FDA. But this doesn't always happen, the researchers say.

"The number reported is very low for any complex technology used over a million times," says Martin A. Makary, M.D., M.P.H., an associate professor of surgery at the Johns Hopkins University School of Medicine. "Doctors and patients can't properly evaluate safety when we have a haphazard system of collecting data that is not independent and not transparent. There may be some complications specific to the use of this device, but we can only learn about them if we accurately track outcomes."

As part of their study, the researchers found several incidents reported in the national news media that were not reported to the FDA until after the stories appeared in the press, even though the incidents took place long before the media exposure. Makary says it's likely many other incidents go unreported, never to be captured by research like his or by the FDA.

"We need innovation in medicine and, in this country, we are tremendously good at introducing new technologies," he says. "But we have to evaluate new technology properly so we don't over-adopt -- or under-adopt -- important advances that could benefit patients."

Robot-assisted surgery is a minimally invasive technique employed in a variety of operations from hysterectomy to removal of the gallbladder to repair of the mitral valve of the heart. To perform the surgery, small incisions are made through which remote-controlled instruments are inserted into the body. The surgeon directs the movement of the instruments via console, possibly from another room. Such devices can get into smaller spaces than human hands and fingers can. Some surgeons complain that the robot reduces tactile sensations, making it difficult to be certain they are making appropriate incisions, but recent studies have found that patient outcomes after robot-assisted surgery are the same as with laparoscopic procedures, albeit more expensive.

In his study, Makary explains how the use of robots in surgery has skyrocketed in

recent years. Between 2007 and 2011, the number of procedures performed using them increased by more than 400 percent in the United States and more than 300 percent internationally. At the end of 2011, there were 1,400 surgical robots installed in American hospitals, up from 800 just four years before.

For their study, Makary and his colleagues reviewed the FDA adverse events database from Jan. 1, 2000, to Aug. 1, 2012. They also searched legal judgments and adverse events using LexisNexis to scan news media, and PACER to scan court records. The cases were then cross-referenced to see if they matched. They found that eight cases were not appropriately reported to the FDA, five of which were never filed and two of which were filed only after a story about them appeared in the press.

The researchers also reviewed all reported complications. The procedures most commonly associated with death were gynecologic (22 of the 71 deaths), urologic (15 deaths) and cardiothoracic (12 deaths). The cause of death was most often excessive bleeding. In cases where patients survived, hysterectomy by far had the most complications (43 percent of injuries).

A previous study found that nearly 57 percent of surgeons anonymously surveyed reported irrecoverable operative malfunction while using the robotic system and had to convert to laparoscopic or open surgery as a result.

Makary says there needs to be standardized reporting of adverse events related to robotic devices. One rare complication that occurs, he says, is that a surgeon can accidently cut the aorta because the surgeon cannot feel its firmness. For reporting purposes, however, it's unclear whether such an event is surgeon error or device-related error.

Makary argues that these errors, although preventable with proper technique, should be tracked as device-related because they are more common with robotic surgery compared to conventional surgery. Without better reporting standards, he says, these complications are less likely to be reported to the FDA at all, and thus cannot contribute to understanding or identifying safety problems. The FDA, in this scenario, is only collecting device-related complications.

He suggests one solution may be to use a database like the one maintained by the American College of Surgeons in which independent nurses identify and track adverse events and complications of traditional operations.

Good information on robotic surgery is not only needed for research, but also to ensure patients are fully informed about potential risks. Right now, Makary says, it is too easy for a surgeon to say there are no additional risks related to robotic surgery because the evidence is nowhere to be found. "Decisions should not be made based on the information in the FDA database," he says. "We need to be able to give patients answers to their questions about safety and how much risk is associated with the robot. We have all suspected the answer has not been zero. We still don't really know what the true answer is."

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