VIEWPOINT

Is It Time for Safeguards in the Adoption of Robotic Surgery?

Kyle H. Sheetz, MD, MSc
Department of Surgery, University of Michigan, Ann Arbor; and Center for Healthcare Outcomes and Policy, Ann Arbor, Michigan.

Justin B. Dimick, MD, MPH
Department of Surgery, University of Michigan, Ann Arbor; and Center for Healthcare Outcomes and Policy, Ann Arbor, Michigan.

On February 28, 2019, the US Food and Drug Administration (FDA) released a safety communication that cautioned patients, surgeons, and health care organizations about the use of robotic-assisted surgical systems for the management of breast cancer and other cancers.[1] This safety communication cited concerns that evidence to support the use of robotic-assisted surgery for the management of these cancers was limited and may even be associated with shorter long-term survival compared with other surgical approaches.

Trends in the Use of Robotic-Assisted Surgery

Several broader shifts in surgical practice make this FDA warning particularly timely. The use of robotic-assisted surgery has increased more than 3-fold in the past decade, and the United States is now the largest market for this technology in the world—procedure volumes exceeded 600 000 in 2017 alone.[2] The diffusion of robotic-assisted surgical procedures is concentrated within the fields of urology, gynecology, and general surgery. For these specialties, the technology is often marketed as a tool to mitigate some of the technical or anatomic challenges associated with specific surgical procedures. An additional justification for robotic-assisted surgery is that it increases patient access to safer, minimally invasive operations.

Existing Evidence of Questionable Benefits

To date, most studies demonstrating potential benefits of robotic-assisted surgery have been small, single-centered reports without rigorous controls. There remains little robust evidence to suggest that robotic-assisted surgical procedures are superior to existing open or minimally invasive (laparoscopic) approaches. For example, the ROLARR trial randomized 471 patients to undergo either laparoscopic or robotic-assisted low anterior resection for rectal cancer.[3] This study found no differences in the rates of complications, conversions to open procedures, or the quality of oncologic resection between the groups. A large observational study published in 2017 involving 23 753 patients undergoing radical nephrectomy also found no significant differences in complications, blood transfusions, or length of hospital stay between laparoscopic and robotic-assisted surgery, despite robotic-assisted surgery being associated with almost $3000 higher 90-day direct hospital costs.[4]

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Emerging Evidence of Potential Harm

The FDA's safety communication is also timely in the context of 2 complementary studies published in 2018 (1 randomized trial and 1 observational study) that suggested that minimally invasive radical hysterectomy and robotic-assisted surgery, in particular, were associated with shorter overall survival in patients with cervical cancer.[5,6] Using population-based data, Melamed and colleagues[5] demonstrated that in just 5 years (2006-2010), the rapid adoption of minimally invasive surgery was associated with a significant decline in 4-year relative survival rates for early-stage cervical cancer among all women undergoing radical hysterectomy.

In the FDA's safety communication, the agency encouraged numerous groups, including research institutions, clinical societies, and device manufacturers, to work collaboratively to develop better data on the safety and efficacy of robotic-assisted surgery. The FDA also encouraged patients and surgeons to have more open dialogue about the risks and benefits of robotic-assisted surgery, particularly within the context of surgeon experience with robotic technologies. However, several additional short- and long-term priorities deserve greater attention.

Insurance Coverage

While there is disagreement regarding the benefits of robotic-assisted surgery, considerable evidence suggests that these procedures are more expensive than other approaches. Although some may suggest that these costs are less relevant to patients because they are largely borne by hospitals, it will remain difficult to completely shield patients from higher overall costs as robotic-assisted surgery continues to diffuse at a rapid rate. Higher hospital costs will eventually be transferred to patients in the form of higher insurance premiums.

With unclear clinical benefits and even potential harms, payers should emphasize evidence-based coverage of emerging robotic-assisted procedures. The FDA and the Centers for Medicare & Medicaid Services should exercise their ability to provide coverage with evidence development.[7] This action has been previously applied to unproven procedural interventions, such as carotid artery stenting, when questions about their effectiveness were accompanied by concern for patient harm. This approach could facilitate the creation of registries that could be used to monitor the allocation and safety

Corresponding Author: Kyle H. Sheetz, MD, MSc, Center for Healthcare Outcomes and Policy, University of Michigan, School of Medicine, 2800 Plymouth Rd, NCRC B016, Room 100N-11, Ann Arbor, MI 48109 (ksheetz@med.umich.edu).

of robotic-assisted surgical procedures. It also may allow Medicare and other payers to make coverage decisions that stipulate certain criteria from surgeons and hospitals (eg, proficiency, volume, or participation in clinical trials).

Surgeon Credentialing

Developing clinical registries will take time. For now, the patient safety imperative lies within hospitals that credential surgeons to perform robotic-assisted surgical procedures.[8] At many institutions, surgeons are granted global privileges for robotic-assisted surgery. After voluntary skills courses or hands-on proctoring from other surgeons, they are free to use the robotic surgical technology at their discretion. Historically, surgeons who completed proctoring in as few as 2 robotic-assisted surgical procedures could begin to integrate robotic-assisted surgery into their practice.

This approach to credentialing is problematic for 2 reasons. First, it does not consider the full scope of procedures that surgeons may choose to perform robotically. The training of surgeons generally focuses on individual operations (eg, rectal cancer surgery). As a result, some surgeons may lack sufficient experience in other clinical domains or anatomic regions in which robotic-assisted surgery is technically feasible. Second, this method of credentialing ignores learning curves, which may place patients in unsafe situations if surgeons fail to eclipse their learning curve. It also groups surgeons under common learning curves that do not account for their prior experience with that specific procedure or with minimally invasive surgical techniques in general. To address these issues, hospitals and health care systems should ensure that surgeons are credentialed to perform a narrow scope of robot-assisted surgical procedures for which they have attained proficiency-based benchmarks.

Transparency and Informed Consent

A common trend that is rarely discussed is that when hospitals acquire robotic systems, surgeons will often enhance their robotic surgical skills by "practicing" with less complex procedures. While manufacturers market robotic approaches to more complex operations, such as radical hysterectomy and low anterior resection for rectal cancer, many surgeons apply robot-assisted techniques across myriad procedures.

For example, a general surgeon may earn robotic privileges based on his or her experience performing rectal cancer surgical procedures. To increase skill or broaden the scope of robotic-assisted practice, the surgeon may start to perform other, less complex operations robotically. These procedures might include cholecystectomy, inguinal hernia repair, or appendectomy. Few would argue that there are any real benefits derived from performing these procedures robotically. Aside from the expense, it remains unknown whether this approach increases the risk of harm to the patient.

Within reason, hospitals and health care systems should require procedure-specific training and proctoring for surgeons looking to expand the scope of their robotic-assisted practice. In addition, as written in the FDA safety communication,[1] surgeons should disclose information on the overall effectiveness of robotic procedures relative to other approaches and their specific experience performing robotic surgery to patients when obtaining informed consent.

Conclusions

The FDA's safety communication is particularly important and timely given the rapid diffusion of robotic-assisted surgery. However, several important factors have the potential to diminish the value and safety of common surgical procedures. Payers, hospitals, and surgeons can take immediate steps to ensure that certain safeguards remain in place until the evidence for or against the use of robotic-assisted surgery has time to mature.

ARTICLE INFORMATION

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