HHS Public Access

Author manuscript

JAMA. Author manuscript; available in PMC 2020 February 20.

Published in final edited form as:

JAMA. 2019 May 28; 321(20): 1971–1972. doi:10.1001/jama.2019.3736.

Is it time for safeguards in the adoption of robotic surgery?

Kyle H. Sheetz, MD MSc[1,2], **Justin B. Dimick, MD MPH**[1,2]

[1]Department of Surgery, University of Michigan, Ann Arbor, MI

[2]Center for Healthcare Outcomes and Policy, Ann Arbor, MI

On February 28, 2019 the United States 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 treatment of breast and other cancers.[1] This communication cited concerns that evidence to support the use of robotic-assisted surgery for the treatment of these cancers was limited and may even be associated with shorter long-term survival compared to 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 over 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 surgeries 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 surgeries. An additional justification for robotic 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 surgeries are better than existing open or minimally-invasive (laparoscopic) approaches. For example, the ROLARR trial randomized 471 patients to 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 two groups. A recent, large observational study involving 23,753 patients undergoing radical nephrectomy also found no significant differences in complications, blood transfusions, or length-of-stay between laparoscopic and robotic-assisted surgery.[4] This was despite robotic-assisted surgery being associated with almost $3,000 higher 90-day direct hospital costs.

Correspondence: Kyle H. Sheetz, MD, MSc, Center for Healthcare Outcomes & Policy, University of Michigan, School of Medicine, 2800 Plymouth Road, NCRC B016, Room 100N-11, Ann Arbor, MI 48109, Phone: 412-759-5141, ksheetz@med.umich.edu.

This study has not been previously published or presented.

Emerging evidence of potential harm

The FDA's action is also timely in the context of two recent complementary studies (one randomized trial, one observational study) that suggested 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 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 for treatment.[5]

In its communication, the FDA encourage numerous groups – research institutions, clinical societies, and even 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, a considerable body of work suggests that these procedures are more expensive than other approaches. Although some may suggest that that these costs are less relevant 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 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 and Medicaid Services should exercise their ability to provide coverage with evidence development.[7] This action has been previously applied to unproven procedural interventions, like carotid artery stenting, when questions about its 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 of robotic-assisted surgeries. It also may allow Medicare and other payers to make coverage decisions that stipulate certain criteria from surgeons and hospitals (e.g. 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 surgeries. 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. Until recently, surgeons who completed proctoring in as few as 2 robotic-assisted surgeries could begin to integrate robotic-assisted surgery into their practice.

This approach to credentialing is problematic for two reasons. First, it does not consider the full scope of procedures they may choose to perform robotically. The training of surgeons generally focuses on individual operations (e.g. 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. This may place patients in unsafe situations when surgeons fail to eclipse their learning curve. It also groups surgeons under common learning curves that do not account for their prior experience – either with that specific procedure or with minimally-invasive surgical techniques more broadly.

To address this, hospitals and health systems should ensure that surgeons are credentialed to perform a narrow scope of robot-assisted surgeries for which they have attained proficiency-based benchmarks.

Transparency and informed consent

A common trend that is rarely discussed openly 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 like 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 surgery. To increase skill or broaden the scope of robotic-assisted practice, it is common practice for the surgeon to start performing other, less complex operations robotically. These cases might include cholecystectomy, inguinal hernia repair, or appendectomy. Few would argue that there are any real benefits to be derived from doing these cases robotically. Aside from the expense, it remains unknown whether this approach increases the risk of harm to the patient.

Within reason, hospitals and health systems should require procedure-specific training and proctoring for surgeons looking to expand the scope of their robotic-assisted practice. In addition, as in the FDA communication, surgeons should disclose this information to patients at the time of informed consent.

Summary

The FDA's 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.

Acknowledgments

Funding Sources: KHS (AHRQ 2T32HS000053-27); JBD (NIH/NIA R01AG039434, AHRQ R01HS023597).

References

1. Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication [press release]. February 29 2019.
2. Childers CP, Maggard-Gibbons M. Estimation of the Acquisition and Operating Costs for Robotic Surgery. JAMA : the journal of the American Medical Association. 2018;320(8):835–836. [PubMed: 30167686]
3. Jayne D, Pigazzi A, Marshall H, et al. Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer: The ROLARR Randomized Clinical Trial. JAMA : the journal of the American Medical Association. 2017;318(16):1569–1580. [PubMed: 29067426]
4. Jeong IG, Khandwala YS, Kim JH, et al. Association of Robotic-Assisted vs Laparoscopic Radical Nephrectomy With Perioperative Outcomes and Health Care Costs, 2003 to 2015. JAMA : the journal of the American Medical Association. 2017;318(16):1561–1568. [PubMed: 29067427]
5. Melamed A, Margul DJ, Chen L, et al. Survival after Minimally Invasive Radical Hysterectomy for Early-Stage Cervical Cancer. The New England journal of medicine. 2018;379(20):1905–1914. [PubMed: 30379613]
6. Ramirez PT, Frumovitz M, Pareja R, et al. Minimally Invasive versus Abdominal Radical Hysterectomy for Cervical Cancer. The New England journal of medicine. 2018;379(20):1895–1904. [PubMed: 30380365]
7. Daniel GW, Rubens EK, McClellan M. Coverage with evidence development for Medicare beneficiaries: challenges and next steps. JAMA Intern Med. 2013;173(14):1281–1282. [PubMed: 23649323]