Robotic Surgery: Risks vs. Rewards

February 1, 2016
Kirkpatrick T, LaGrange C. Robotic Surgery: Risks vs. Rewards. PSNet [internet]. 2016.
https://psnet.ahrq.gov/web-mm/robotic-surgery-risks-vs-rewards

Case Objectives

- Discuss the background and current trends in robotic surgery.
- Identify the benefits of robotic surgery as well as potential disadvantages.
- Discuss the potential complications directly related to robotic malfunction and the current system for reporting these errors.
- Examine potential solutions to improve the safety of robotic assisted surgery in the future.

The Case

A 66-year-old man was seen by a urologist for difficulty urinating and diagnosed by biopsy with localized prostate cancer. The urologist recommended a radical prostatectomy (removal of the prostate). The urologist stated that the best and safest way to remove the prostate was with a minimally invasive robotic surgery. The robotic surgery, he explained, would involve a few small incisions, performed by a surgeon seated at a computer console in the operating room. The procedure would be carried out using robotic arms and surgical instruments. The urologist went on to say that the robotic technology would allow for smaller incisions, better control of the instruments, lower risk of complications, and faster return of erectile function.

During the procedure, there were mechanical problems as the robotic arms were not responding as expected. The urologist persisted in using the robotic technology and ultimately was able to complete the procedure. The operation took twice as long as expected, but the urologist felt it had been successful.

Postoperatively, the patient developed serious bleeding requiring multiple blood transfusions. He was taken back to the operating room where it was noted the inferior epigastric artery (a key artery in the pelvis) had been damaged during the original procedure. The injury was repaired but this second operation was prolonged and complicated due to the degree of bleeding. The patient ultimately required several additional surgeries and a prolonged hospital stay.

The Commentary

Background and Prevalence of Robotics in Surgery

The use of robotic assistance in surgery has expanded exponentially since it was first approved in 2000.(1,2) It is estimated that, worldwide, more than 570,000 procedures were performed with the da Vinci robotic surgical system in 2014, with this figure growing almost 10% each year.(2) Robotic-assisted surgery (RAS) has found its way into almost every surgical subspecialty and now has approved uses in urology, gynecology, cardiothoracic surgery, general surgery, and otolaryngology.(2,3) RAS is most commonly used in urology and gynecology; more than 75% of robotic procedures performed are within these two specialties.(2) Robotic surgical systems have the potential to improve surgical technique and outcomes, but they also create a unique set of risks and patient safety concerns.

RAS is a derivative of standard laparoscopic surgery and was developed to overcome the limitations of standard laparoscopy. Like traditional laparoscopy, RAS uses small incisions and insufflation of the anatomical operative space with carbon dioxide. The robotic camera and various instruments are placed through the ports into the body and can be manipulated by the surgeon performing the operation. In the case of RAS, though, the surgeon, seated at a computer console in the operating room, uses robot assistance to utilize the tools (instead of doing it himself or herself directly at the bedside). In RAS, a bedside assistant exchanges the instruments and performs manual tasks like retraction and suction. The da Vinci robotic surgical system, made by Intuitive Surgical, Inc., is the only robotic system on the market today (Figure). There are three major components of the system including:

- The robot, which is a mobile tower with four arms, including a camera arm and three instrument arms.
- The bedside cart, consisting of the image processing equipment and light source, which is transmitted to monitors in the operating suite and sends the image to the surgeon console.
- The console, at which the surgeon sits to operate; there are two binocular lenses that magnify and create a three-dimensional image for the surgeon. Two handpieces transmit the surgeon's hand movements to the instruments within the patient, manipulating the surgical instruments to perform the operation. A built-in motion filtration system minimizes tremor, and foot pedals at the console control different types of energy and also allow for movement of the different robotic components within the patient.(3-5)

Benefits of Robotic-assisted Surgery

In theory, RAS marries the benefits of laparoscopic surgery with that of open techniques by combining a minimally invasive approach with the additional benefit of a three-dimensional, magnified image. In addition, RAS offers improved ergonomics and dexterity compared to traditional laparoscopy, and these advantages may lead to a shorter learning curve for surgeons. The purported benefits of RAS also include smaller incisions, decreased blood loss, shorter hospital stays, faster return to work, improved cosmesis, and lower incidence of some surgical complications.(1,2,6)

While we appreciate these advantages of RAS, most of these benefits are short term and limited to the acute perioperative period. In fact, there is little evidence demonstrating that robotic surgery provides any long-term benefits over open techniques.(6) Taking the above case as an example, robotic-assisted laparoscopic prostatectomy (RALP) has been one of the most commonly adopted robotic procedures; more than 85% of all prostatectomies are now performed with robotic assistance in the United States.(7) Multiple, well-validated studies have shown that RALP has significantly less blood loss, with much lower transfusion rates, and shorter hospital stays than with open approaches. In addition, the rates of some complications—deep vein thrombosis, wound infections, lymphoceles and hematomas, anastomotic leaks, and ureteral injuries—appear to be slightly lower than with open approaches.(8-10) RALP appears to have similar advantages over laparoscopic prostatectomy, although the difference is less pronounced. When compared to standard laparoscopic prostatectomy, robotic assistance has been shown to have decreased blood loss, lower rates of blood transfusion, and slightly shorter hospital stays.(8) Like with robotic assistance, pure laparoscopic techniques share a significant learning curve.(5) While some studies have also suggested that robotic surgery may be more effective at total removal of cancerous tissue in prostate surgery (i.e., lower positive surgical margin rates) than with open and pure laparoscopic procedures (11), large systematic reviews and well-validated meta-analyses have shown similar rates of oncologic control.(5,7-9,12)

Interestingly, the proponents of RALP frequently boast improved urinary continence and sexual function after surgery (or at least equivalent rates) when compared to open prostatectomy. The data has generally been equivocal in this area; standardized, comparable, long-term data are lacking.(10) A study using surveillance, epidemiology, and end results Medicare claims data compared open to minimally invasive prostatectomy (laparoscopic and robotic). Their results supported previous findings of lower transfusion rates, shorter hospital stays, similar oncologic control, and fewer miscellaneous complications. On the other hand, they discovered that men who had undergone robotic prostatectomy had higher rates of post-prostatectomy incontinence and erectile dysfunction than men who had an open procedure.(13) It may be a matter of experience: many of RALP proponents have performed thousands of procedures, which may lead to improved outcomes in their hands but may not be generalized to other, less experienced, urologists.

Risks of Robotic-assisted Surgery

RAS shares the same risks of open and laparoscopic surgery, including the potential for infection, bleeding, and the cardiopulmonary risks of anesthesia. On top of that, there are additional risks that are unique to the robotic system.(14) Not only is there potential for human error in operating the robotic technology, but an added risk of mechanical failure is also introduced. Multiple components of the system can malfunction, including the camera, binocular lenses, robotic tower, robotic arms, and instruments. The energy source, which is prone to electric arcing, can cause unintended internal burn injuries from the cautery device. Arcing occurs when electrical current from the robotic instrument leaves the robotic arm and is misdirected to surrounding tissue. This can cause sparks and burns leading to tissue damage which may not always be immediately recognized. There is a small risk of temporary, and even permanent, nerve palsies from the extreme body positioning needed to dock the robot and access the pelvis adequately to perform RALP. Direct nerve compression from the robotic arms can also lead to nerve palsies.(14,15) RAS has also been shown to take significantly longer than nonrobotic procedures when performed at centers with lower robotic volume and by surgeons with less experience, and, overall, it is more expensive than open surgery.(6,9)

As mentioned earlier, the outcomes in RAS seem to correlate with individual surgeon experience.(5,6) For example, in cancer surgery, surgeons with more experience are more likely to have clean margins.(7,11,16) Other studies have documented lower complication rates with an increasing number of procedures.(14) These findings of practice makes perfect are not specific to robotic surgery; such findings have been seen in many procedures. There are varying reports of exactly how many cases are required to master the robotic learning curve, and the number varies by surgical procedure. For RALP, the range has been reported from as low as 40 to as many as 250.(16,17) For hysterectomies, the literature reports a range of 20–50 cases to master the operation and reports that less experienced surgeons have significantly longer operative times.(6,18)

Notwithstanding the concerns, RAS has been accepted as generally safe. RALP has reported complication rates (including all grades of perioperative complications, from minor to life-threatening) of around 10%.(9,12-15) Multiple risk factors can increase the possibility of complications and errors: patient factors (i.e., obesity or underlying comorbidities), surgeon factors (training and experience), and robotic factors (i.e., mechanical malfunction). The reported complication rate related directly to robotic malfunction is very low (approximately 0.1%–0.5%).(19,20) However, when robotic errors do occur, the rates of permanent injury have been reported anywhere from 4.8%–46.6% (19-21), and this literature may suffer from underreporting.(20,22) Although fewer than 800 complications directly attributable to the robotic operating system have been reported to the FDA over the past 10 years (21-23), in a web-based survey among urologists performing RALP, almost 57% of respondents had experienced an irrecoverable intraoperative malfunction of the robot. The most common areas of complications were malfunction of the robotic arms, joint setup and camera, followed by power error, instrument malfunction, and breakage of the handpiece.(22)

Preventing Complications of Robotic-assisted Surgery

Standardized Credentialing and Training

Currently, there are no universal standard guidelines on appropriate training or credentialing for robotic surgery.(17,24) Some organizations have made progress in this area. The American Urological Association has made recommendations for training and credentialing procedures consisting of specific online curriculum, testing, case load requirements, and also recommendations that all physicians complete the da Vinci online robotic safety training course on set-up, draping, specific safety features, and trouble shooting.(24) Training in robotics is still a relatively new field, and there is not a strong body of evidence to support a specific training and credentialing model. Various authors have developed different curriculums and simulation models, but an ideal model has yet to be found, as this is a new and developing field.(17,20,24) Until well-validated credentialing and training models can be developed, hospitals should require a basic robotic safety curriculum, such as provided by the American Urological Association, for any surgeons using the surgical robot, and require case logs be supplied or case proctoring prior to granting robotic privileges.

Stricter Reporting Guidelines

Developing a more uniform system of error reporting and tougher penalties for noncompliance may potentially help capture a more accurate representation of the true incidence of adverse events. It is important to determine the true incidence of different complications and the surrounding circumstances.

The goal should be to identify key risk factors for errors and complications with a focus on those that are modifiable. This ideally would lead to improved outcomes and fewer complications. There are clearly gaps with the current FDA device tracking system, as many more robotic errors are experienced than are ever reported to the FDA.(21-23) There needs to be a more rigorous reporting effort by individual hospitals to capture the true incidence of robotic malfunction. These institutional reports can be submitted to the FDA so that recurrent mechanical problems can be more easily and rapidly recognized and addressed by the manufacturer.

Appropriate Risk Disclosure to Patients

The idea of robotic surgery is very enticing to patients and has influenced the growth of robotics in the United States. However, Schroeck and colleagues (25) found that men undergoing robotic prostatectomy were more likely to express "regret" and "dissatisfaction" than men undergoing open surgery, which was attributed to unrealistic patient expectations associated with the robot. Kaushik and colleagues found that less than 70% of patients were appropriately counseled preoperatively on the potential risks specific to robotic surgery, including possible robotic malfunction or potential conversion to an open procedure.(22) The direct-to-consumer marketing phenomenon could be used to improve safety in robotics by appropriately educating patients. Institutions should ensure appropriate patient counseling and informed consent for RAS is happening consistently. This tracking could be accomplished through auditing of informed consent materials as well as intermittent patient interviews.

While RAS has many potential benefits for patients and providers, the case above clearly demonstrates that the technology itself may place patients at risk. National organizations and individual institutions should ensure appropriate training and credentialing, accurate and timely error reporting, and consistent informed consent for patients. Discussions about robotic surgery—both with individual patients and at the policy level—should appropriately balance the advantages and potential with the real risks and limited evidence of major advantages in terms of long-term outcomes.

Take-Home Points

- Robotic surgery is a rapidly expanding technology that has found a niche in multiple different surgical specialties worldwide.
- Although robotic-assisted surgery shows some short-term benefits surrounding the direct perioperative period, it has fairly equivalent long-term outcomes when compared to open surgery.
- Robotic surgery is generally safe with low overall complication rates, but adding the robot to the surgical equation inserts another potential entry point for error into an already complex and risk-fraught arena.
- In general, surgical outcomes are ultimately a direct manifestation of the skill and experience of the surgeon, not the technology or approach used.
- Potential areas for improvement and reduction of error in robotic surgery include more standardized training and credentialing practices, improved reporting systems for robotic-associated adverse events, and enhanced patient education.

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Faculty Disclosure: Dr. Kirkpatrick and Dr. LaGrange have declared that neither they, nor any immediate member of their families, have a financial arrangement or other relationship with the manufacturers of any commercial products discussed in this continuing medical education activity. In addition, the commentary does not include information regarding investigational or off-label use of pharmaceutical products or medical devices.

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Figure

Figure. Components of the Robotic Operating System: the Console, the Robot, and the Bedside Cart. Image ©2016 Intuitive Surgical, Inc. Used with permission.

This project was funded under contract number 75Q80119C00004 from the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. The authors are solely responsible for this report's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this report as an official position of AHRQ or of the U.S. Department of Health and Human Services. None of the authors has any affiliation or financial involvement that conflicts with the material presented in this report. *View AHRQ Disclaimers*