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Rise of the Machines: Robotic Surgery, Patient Safety, and Liability

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The turn of the 21st century was witness to a significant technological milestone in American healthcare — the approval of the first robotic surgical system by the U.S. Food and Drug Administration (FDA). Now, almost two decades later, robotic-assisted surgery (RAS) is used for hundreds of thousands of procedures each year, and the number continues to grow.[1]

Unlike in traditional laparoscopy or open surgery, in which a surgeon uses his/her hands to operate the surgical instruments, RAS uses a computer-assisted robot as an intermediary in the surgical process. The surgeon sits at a console and uses hand and foot controls to maneuver instruments and a small camera on thin robotic arms through small incisions in the patient. The surgeon is able to monitor progress using a three-dimensional viewer on the console.

During RAS, the surgeon typically is in the operating room, but removed from the patient. However, the technology also offers the possibility of robotic telesurgery, in which the surgeon operates the robot from a remote location.[2]

Since its inception, RAS has been lauded as a "symbol of medical progress" and featured prominently in print and electronic media.[3] Healthcare organizations of all sizes have invested in robotic surgical technology, and the number and types of procedures done using robots have expanded over the years, reaching various specialties such as general surgery, urology, gynecology, cardiology, otolaryngology, and orthopaedics. With time, more applications for robotic surgery will most certainly emerge. For example, in 2017, a robot performed dental implant surgery without direct human assistance — the first surgery of this kind.[4]

However, despite RAS's growing popularity and proven and purported benefits — such as greater precision and visualization, smaller scars, faster recovery, lower infection rates, and less pain — many questions have arisen about patient safety, long-term outcomes, and the appropriate use of this technology.

This article examines various patient safety and risk management concerns associated with RAS — such as training, competency, credentialing, learning curves, proficiency, patient selection criteria, and informed consent — and offers strategies to help healthcare organizations, surgeons, and surgical staff minimize potential risks.

Reconciling Business With Safety and Efficacy

For many healthcare organizations, the incentive to invest in robotic surgical systems is significant. Robots have been marketed as a way to increase revenue and capture market share. The technology can offer a state-of-the-art advantage over competitors and provide an enticing recruitment tool for sought-after surgeons.

Further, direct-to-consumer marketing of RAS to patients has resulted in increasing pressure for hospitals to offer the technology as a means to satiate patient demand and boost satisfaction. An Agency for Healthcare Research and Quality (AHRQ) case commentary notes that "The idea of robotic surgery is very enticing to patients and has influenced the growth of robotics in the United States."[5] Further, a *Healthline* article explains that hospitals react to patient demand through increased advertising because "They see the robots as a way to bring more patients through their glass doors rather than their competitors."[6]

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However, as RAS has made its impressive ascent, concerns have been raised. For example, in 2013, the Massachusetts Board of Registration in Medicine issued a robotic surgery advisory to its hospitals. The board acknowledged that RAS offers numerous technical advantages, but it cautioned that large-scale, high-quality, prospective studies had not yet been done.[7]

In the same time period, the number of RAS-associated adverse events reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database more than doubled.[8] This increase in reports was accompanied by a proliferation of media stories detailing deaths and injuries following robotic surgery as well as law firms seeking to represent clients who had suffered complications or poor outcomes following robotic surgery, such as burns, tearing of the intestines and arteries, organ and nerve damage, excessive blood loss, and bowel injuries.

Those who are cautious about RAS point to limited research on the long-term benefits of this technique and insufficient data about surgical complications and adverse patient outcomes. The absence of such research and data highlights the need for healthcare organizations and surgeons using RAS to evaluate risks and take necessary precautions to maximize patient safety and minimize liability exposure.

Evaluating Robotic-Assisted Surgery From a Risk Management Perspective

As the market for robotic surgical systems continues to surge and patient demand grows, more healthcare organizations will likely invest in these systems. Further, because the robots carry a hefty price tag — costing between $1.5 and $2 million[9] — it will be important for organizations to see a return on their investments, which may result in increased pressure on surgeons to use RAS.[10]

RAS potentially offers benefits for both patients and surgeons; however, like any medical technology, it also presents safety challenges. Examples of these challenges include ensuring appropriate training, overcoming learning curves, evaluating for proficiency, determining patient selection criteria, and providing appropriate informed consent for patients having robotic procedures.

Training

Since the time RAS was initially approved until present day, training has persistently been a top risk concern, in part because no universal consensus has been reached on the appropriate type and duration of training or credentialing standards. Although some professional organizations have made recommendations, others are still working to define standards for this fairly new technology.

Because of the lack of consensus, individual healthcare organizations are "responsible to develop and implement training and credentialing processes that are medically sound, that promote patient safety, and that protect the organization from undue risk."[11]

Although product and technical training is offered through the device manufacturer, literature suggests that this training alone may not sufficiently prepare surgeons to perform surgery using a complex robotic system.[12] Thus, healthcare organizations must define rigorous curricula and specific standards for clinical training, proctoring and oversight, competency, and credentialing to ensure that surgeons and the entire surgical team are prepared to undertake RAS.

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Guidance from professional associations and information from robotic surgery research studies and literature can help healthcare organizations establish appropriate training and credentialing criteria. Several research studies and systematic reviews focusing on robotic surgery call for training that (a) is based on competency rather than time or quantity, (b) uses graduated learning objectives, with assessment at each level, (c) involves simulation/virtual training, and (d) sets minimum criteria for demonstrating competency.[13]

Since 2007, a consensus statement from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotics Association (MIRA) has served as a fundamental resource on training standards for organizations developing RAS programs. The statement describes a broad twofold approach to training that involves technical and capability instruction as well as training for specific procedures.

The SAGES-MIRA statement further explains that surgeons must have a thorough knowledge base and practical experience, understand standard operating procedures and emergency protocols, and be able to anticipate risks and develop appropriate responses.[14] For example, surgeons must be prepared to convert to traditional laparoscopy or an open procedure in the event of technical problems or certain clinical complications.[15]

A study examining 14 years of FDA MAUDE data to determine adverse events associated with RAS (a total of 10,624 events) noted that, on average, device malfunctions led to surgical conversions in 7.3 percent of cases, with some specialties closer to a rate of 14–17 percent (e.g., urology and cardiothoracic surgery).[16]

For doctors whose primary surgical experience is using a robotic surgical system, conversion to open surgery might be problematic. In these cases, another surgeon who is experienced with open surgery should be available to assist if necessary.[17] Surgeons and surgical team members also must be aware of the risks that can occur as a result of conversion — such as issues related to patient positioning and prolonged use of anesthesia — and have plans in place to manage those risks.[18]

Case Example

The complexities involved in converting from RAS to laparoscopic or open surgery can increase patient risks. For example, in one case, surgeons performed a robot-assisted hysterectomy on a patient who was morbidly obese. Complications during the surgery forced the doctors to convert to traditional laparoscopy and then to open surgery.

Following the surgery, the patient complained of arm pain, weakness, and numbness, and she was diagnosed with brachial plexus injuries. A review of the case determined that the lengthy duration of the procedure, the patient's obesity, and her positioning prior to the open surgery (in a steep head-down position) contributed to her injuries.

In 2013, the Fundamentals of Robotic Surgery consensus conference convened numerous professional organizations and developed a list of 25 outcome measures that surgeons seeking RAS privileges should attain in preoperative, intraoperative, and postoperative categories. Examples included system settings, ergonomic positioning, operating room setup, energy sources, instrument exchange, multi-arm control, and undocking. The conference statement also discussed creating a curriculum for teaching those skills via didactic lecture, psychomotor skills labs, and team training activities.[19]

Other professional associations also have published recommendations for RAS training, curricula development, and credentialing/privileging standards, which healthcare

organizations can use to guide development of RAS-related policies, procedures, and standards. Examples include the American Urological Association, the American College of Obstetricians and Gynecologists (ACOG), the American Association of Gynecologic Laparoscopists, the Society of Laparoendoscopic Surgeons, the Society of Thoracic Surgeons, and more.

In addition to comprehensive training for surgeons, healthcare organizations should consider essential training for other members of the surgical team, such as the anesthesiologist, assisting surgeon, and nurses. The ECRI Institute explains that using RAS "alters the circumstances of surgery for everybody involved,"[20] thus requiring a comprehensive approach to training that takes into account the various technical, clinical, and interpersonal skills required for performing safe and effective robotic procedures.

In addition to training considerations for surgeons, healthcare organizations should consider essential training for other members of the surgical team, such as the anesthesiologist, assisting surgeon, and nurses."

One training strategy is running drills with the surgical team that simulate various clinical situations and the appropriate steps to take during an emergency. Drills and simulations can help prepare team members to handle a range of situations that might arise. Further, lessons learned from evaluation of drills and proctored surgeries can provide the foundation for the development of RAS best practices and protocols.

Learning Curve

Along with training considerations, surgeons should be aware of the steep learning curve associated with using robotic surgical systems. Proficiency with these complex systems "is a major factor affecting whether a robotic surgical system can be used safely."[21]

Surgeons must master use of the platform's functions — such as camera controls, foot pedals, robotic arm movements, and instrument operations — as well as the surgical techniques for the procedures they plan to perform.

Unfortunately, attaining proficiency with a robotic surgical system is not a one-size-fits-all formula. The number of procedures required to demonstrate proficiency varies based on the type of procedure, and no firm standards have been set. Some estimates suggest that it may take hundreds of surgeries to attain high proficiency, while other estimates are lower.[22] In an FDA survey of a sample of surgeons who are experienced with robotic surgery, all participants stated that they had to perform numerous surgeries using the robot before achieving proficiency.[23]

Case Example

Lack of defined training standards and limited awareness of the learning curve for RAS have played a role in malpractice lawsuits. In one case, a surgeon performed an unsupervised prostate surgery on a patient after completing only two previous supervised robotic prostate surgeries.

The surgery took more than 13 hours and resulted in multiple injuries and severe blood loss, as well as the need to convert to open surgery during the process. The complications from the surgery were alleged to have contributed to the patient's death several years later.

Further, various other factors also contribute to proficiency, such as basic skill, experience and comfort level with technology, familiarity with the procedures being performed, frequency of cases, and type of training. Just as with other surgical techniques, robotic surgery skills are honed over time. For less experienced surgeons, procedures might take longer, associated costs might be higher, and the risk of complications might be greater.[24] A study assessing the effect of the learning curve on robotic-assisted radical prostatectomies showed that key measurements — such as conversion rates, surgery time, hospital stays, and complication rates — improved within surgeons' initial 100 cases, as well as beyond 100 cases.[25]

Proctoring and mentoring opportunities, established as part of each healthcare organization's credentialing guidelines, can help contribute to patient safety initiatives and address risks related to learning curve and proficiency. Additionally, organizational policies should establish criteria for maintaining proficiency over time, such as performance monitoring, continuing education, training, and recredentialing.

Patient Selection Criteria

One of the driving factors in the rise of robotic surgery is patient demand; however, some patients who are eager for this technology might not be ideal candidates due to comorbidities or other factors. For example, in the prostate surgery case mentioned previously, the patient was obese, diabetic, and had a history of heart surgery. These health conditions, combined with the surgeon's limited RAS experience, ultimately might have contributed to the patient's poor outcome.[26]

To counter increasing patient pressure, a crucial strategy for managing robotic surgery risk is careful consideration of patient selection criteria. All surgeons in the aforementioned FDA survey felt that appropriate selection criteria played a pivotal role in successful patient outcomes. Although they noted that criteria may vary across specialties, standards were primarily based on maintaining patient safety.[27]

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The Massachusetts Board of Registration in Medicine's robotic surgery advisory also emphasized the importance of establishing patient selection criteria, noting that "Careful preoperative assessment of patient risk is critical for preventing perioperative complications. Both the patient's comorbidities and the complexity of the robotic surgical case are important risk factors that should be considered."[28]

By developing greater awareness of potential risk factors and contraindications for robotic surgery, healthcare organizations and surgeons can create and implement patient selection guidelines and assessment protocols, as well as reinforce or improve quality measures.[29] Further, documenting the assessment of patient risks in accordance with established selection criteria supports the clinical decision-making process.

Beyond establishing patient selection criteria, it is also crucial to manage patients' expectations related to RAS. This may prove challenging for surgeons because the technology is complex, and direct claims about benefits and safety can be difficult to make.

Compounding this challenge are aggressive marketing from the device manufacturer and idealistic hospital advertising that might overestimate benefits, overpromise results, and/or fail to define specific risks, leading to inflated patient perceptions.[30] The result of these efforts might "help drive the perception that robots make the best surgeons."[31]

A study that examined robotic surgery information on 400 U.S. hospital websites concluded that hospital marketing of robots touted benefits, often ignored risks, and was strongly influenced by the manufacturer. Of the 41 percent of hospital websites that included robotic surgery information, 73 percent used manufacturer-provided stock images and text. Eighty-six percent made statements about the clinical superiority of robotic surgery, but few provided comparative data.[32]

The study's authors explained that "Because patients regard information on hospital websites as medical opinion of the physicians working at that hospital, hospital website information carries credibility that can influence patient choice."[33]

These same concerns prompted ACOG to release a statement addressing robotic surgery for hysterectomies, in which the organization's president stressed the necessity of providing patients with factual information and education about their treatment options.[34] The Massachusetts Board of Registration in Medicine's advisory echoed this sentiment and encouraged

Case Example

Accurately portraying the benefits and risks of treatment is vital for patients to make informed decisions about their care. Failure to do so might result in patients feeling misled, which could potentially lead to a malpractice claim.

For example, in an OB/GYN case, a doctor proposed a robot-assisted hysterectomy as an alternative treatment option for a woman who knew little about the procedure. The patient agreed to the surgery based on the doctor's recommendation and YouTube videos that extoled the precision of surgical robots.

Unfortunately, during the course of the procedure, the surgeon punctured the patient's bowel. The costly injury required nine operations to fix, and the patient had to be hospitalized multiple times. Following the incident, the patient stated that she felt deceived by the optimistic marketing of the robot from her doctor and the manufacturer.

hospitals to pay attention to whether their marketing efforts have influenced how they select patients.[35]

A careful review of advertising and marketing efforts promoting RAS might help healthcare organizations and medical staff pinpoint potentially misleading statements and identify opportunities for clarity. Ultimately, these strategies might assist patients in making more educated and informed decisions about their care.

Informed Consent

Concerns about aggressive advertising and marketing not only point to the need for accurate and objective verbal and written information, but they also highlight the essential role of informed consent in RAS. Just like with any other type of surgery, informed consent for RAS should involve a process undertaken by the treating surgeon to educate the patient about his/her procedure.

The informed consent process should include disclosure of standard consent information — e.g., and explanation of the procedures, the healthcare providers who will be involved in the procedures, potential risks and benefits, alternative options, etc. — as well as information specific to RAS. For example, surgeons should educate each patient about:

- The procedure he/she is having and how it is performed
- The potential risks of robotic surgery in relation to equipment failures and malfunctions, such as:
    - System errors
    - Video imaging problems
    - Broken components
    - Electrical arcing, sparking, and charring
    - Unintended instrument movements[36]
- The potential risks of robotic surgery in relation to the patient's specific condition and comorbidities

- The surgeon's past experience with RAS in general and with the recommended robotic procedure specifically
- Alternative options or techniques for treatment and any information about how those techniques compare to RAS
- What will happen in the event of an emergency or complication (e.g., the surgeon will switch to open surgery or traditional laparoscopy), as well as any related risks

Taking the time to provide patients with these details and answer any questions can help ensure that they have the appropriate information to make informed decisions about their treatment. Following the informed consent process, surgeons should document these discussions in patients' health records and include copies of any related consent forms.

Take-Away Message

Over the past two decades, RAS has continued to gain momentum and establish a foothold in modern surgery. Many factors have contributed to the rise of this technology, including the pursuit of new minimally invasive treatment options, strategic healthcare decisions, savvy marketing, and patient demand.

Although the concept and potential benefits of RAS are exciting, they should not overshadow patient safety and risk concerns. Healthcare organizations, surgeons, and surgical team members that offer, or who use, this technology should be aware of key risk areas related to robotic surgery, such as training, credentialing, proficiency, patient selection, and informed consent.

Developing greater awareness of the risks and establishing training and credentialing guidelines, patient selection criteria, emergency protocols, detailed informed consent processes, and performance monitoring standards can help enhance safety initiatives and minimize liability exposure.

Endnotes

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