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Rise of the Machines: Robot-Assisted Surgery, Patient Safety, and Liability

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Since its inception, robot-assisted surgery (RAS) has been lauded as a symbol of medical progress and a revolutionary advancement in surgical treatment. Now, more than 20 years after the first robotic surgical system was approved in the United States, RAS is used for more than a million procedures each year, and the number continues to grow.[1] A study published in the *JAMA Network Open* notes that RAS accounted for slightly more than 15 percent of all general surgeries in 2018 — an eightfold increase from 2012.[2]

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, orthopaedics, and even dentistry.

For many healthcare organizations, the incentive to invest in robotic surgical systems is significant. Robots have been marketed as a way to increase revenue, capture market share, and recruit sought-after surgeons. Additionally, direct-to-consumer marketing of RAS has resulted in increasing pressure for hospitals to offer the technology as a means to satiate patient demand, boost satisfaction, and eclipse competitors.[3]

RAS and Malpractice

Reports of adverse events linked to RAS have resulted in law firms seeking to represent clients who have 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. Lawsuits have been brought against device manufacturers, healthcare providers, and healthcare facilities — some of which have resulted in substantial settlements.

However, despite RAS's impressive ascent 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, research quality, associated costs, and the appropriate use of this technology. These concerns highlight 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 Robot-Assisted Surgery From a Risk Management and Patient Safety Perspective

As the market for robotic surgical systems continues to expand and patient demand for less invasive treatment options persists, healthcare organizations will continue to invest in these systems. Further, because the robots carry a hefty price tag, organizations will want to see a return on their investments, which may result in increased pressure on surgeons to use RAS.[4]

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

Training and Credentialing

Since the time RAS was initially approved until present day, appropriate training has persistently been a top risk concern. Even though more than two decades have passed, a standardized training curriculum and unified credentialing standards for RAS remain elusive.[5] As a result, each healthcare organization that offers, or plans to offer, RAS is "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."[6]

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Although product training and technical training are offered through the device manufacturer, literature suggests that this training alone may not sufficiently prepare surgeons to perform

surgery using a complex robotic system.[7] Thus, healthcare organizations must define rigorous and specific standards for clinical training, proctoring and oversight, competency, and credentialing to ensure that the entire surgical team is prepared to undertake RAS.

Some experts recommend that organizations set up robotic steering committees or robotic credentialing committees that include surgeons and other stakeholders to help determine appropriate standards.[8] Additionally, 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.[9]

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.[10] 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 also states that surgeons must:

- Have a thorough knowledge base and practical experience
- Understand standard operating procedures and emergency protocols
- Be able to anticipate risks and develop appropriate responses

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.[11] A study to determine adverse events associated with RAS 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).[12]

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.[13] 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.[14]

Case Example

The complexities involved in converting from RAS to laparoscopic or open surgery can increase patient risks. 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.

Five years after the SAGES-MIRA statement was published, numerous multidisciplinary subject matter experts convened to come to a consensus about the critical skills and tasks that should be included in a comprehensive basic curriculum for RAS. The group developed a list of 25 outcome measures that surgeons seeking RAS privileges should attain in preoperative, intraoperative, and postoperative categories. Examples of these measures include system settings, ergonomic positioning, operating room setup, energy sources, instrument exchange, multi-arm control, and undocking.

Two more consensus conferences followed, and the group ultimately developed Fundamentals of Robotic Surgery (FRS), a "multi-specialty, proficiency-based curriculum of basic technical skills to train and assess surgeons to safely and efficiently perform robotic-assisted surgery."[15] However, the American Board of Surgery notes that FRS — unlike Fundamentals of Endoscopic Surgery and Fundamentals of Laparoscopic Surgery — is not a requirement for completion of a general surgery residency.[16]

Various other professional associations also have published recommendations for RAS training, curriculum 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, 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. Using RAS "alters the circumstances of surgery for everybody involved,"[17] 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.

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The lessons learned from various types of training, including coursework, simulation drills, and proctored surgeries, can provide the foundation for a strong training and credentialing program as well as the development of RAS best practices and protocols.

Learning Curve and Proficiency

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."[18]

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 competency 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.[19] In a U.S. Food and Drug Administration (FDA) survey of a sample of surgeons who had experience with robotic surgery, all participants stated that they had to perform numerous surgeries using the robot before achieving proficiency.[20]

Beyond quantity of procedures, 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.[21] 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.[22]

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.

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 competency. 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 growth of robotic surgery over the past two decades 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, should have raised red flags about whether the patient was an appropriate candidate for RAS.[23]

To counter patient pressure, a crucial strategy for managing robotic surgery risk is careful consideration of patient selection criteria."

To counter 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.[24]

A robotic surgery advisory issued a number of years ago from the Massachusetts Board of Registration in Medicine 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."[25]

In 2019, the FDA issued a notice cautioning that the safety and effectiveness of using RAS to perform mastectomies and other cancer-related treatments have not been established.[26] Thus, in addition to patient-specific factors, surgeons also should consider evidence related to effectiveness and clinical benefit for various types of procedures.

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.[27]

Additionally, 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 and idealistic marketing and advertising that might overestimate benefits, overpromise results, and/or fail to define specific risks, leading to inflated patient perceptions.[28] The result of these efforts might "help drive the perception that robots make the best surgeons."[29]

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.[30] 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."[31]

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 online 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.

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., an explanation of the procedure, the healthcare providers who will be involved in the procedure, 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:[32]
    - System errors
    - Video imaging problems
    - Broken components
    - Electrical arcing, sparking, and charring
    - Unintended instrument movements
- 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 critical 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.

In Summary

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 use this technology should be aware of key risk areas related to robotic surgery, such as training and credentialing, proficiency, patient selection, and informed consent. Developing greater awareness of the risks and establishing standards and best practices can help enhance safety initiatives and minimize liability exposure.

Endnotes

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