Liability in robotic gyn surgery

Surgeon tells patient, "I have done a few" robotic hysterectomies before performing robotic-assisted total laparoscopic hysterectomy and bilateral salpingo-oophorectomy. What's the verdict after complications ensue?

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IN THIS ARTICLE

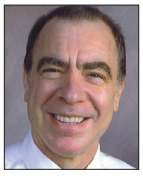
The approach to hysterectomy has been debated, with the need for individualization case by case stressed, and the expertise of the operating surgeon considered.

CASE Was surgeon experience a factor in case complications?

VM is a 46-year-old woman (G5 P4014) reporting persistent uterine bleeding that is refractory to medical therapy. The patient has uterine fibroids, 6 weeks in size on examination, with "mild" prolapse noted. Additional medical diagnoses included vulvitis, ovarian cyst in the past, cystic mastopathy, and prior evidence of pelvic adhesion, noted at the time of ovarian cystectomy. Prior surgical records were not obtained by the operating surgeon, although her obstetric history includes 2 prior vaginal deliveries and 2 cesarean deliveries (CDs). The patient had an umbilical herniorraphy a number of years ago. Her medications include hormonal therapy, for presumed menopause, and medication for depression (she reported "doing well" on medication). She reported smoking 1 PPD and had a prior tubal ligation.

VM was previously evaluated for Lynch Syndrome and informed of the potential for increased risks of colon, endometrial, and several other cancers. She did not have cancer as of the time of planned surgery.

The patient underwent robotic-assisted total laparoscopic hysterectomy and bilateral salpingo-oophorectomy. The operating surgeon did not have a lot of experience with robotic hysterectomies but told the patient preoperatively "I have done a few." Perioperatively, blood loss was minimal, urine output was recorded as 25 mL, and according to the operative report there were extensive pelvic adhesions and no complications. The "ureters were identified" when the broad ligament was opened at the time of skeletonization of the uterine vessels and documented accordingly. The intraoperative Foley was discontinued at the end of the procedure. The pathology report noted diffuse adenomyosis and uterine fibroids; the uterus weighed 250 g. In addition, a "large hemorrhagic corpus luteum cyst" was noted on the right ovary.



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*The case presented is hypothetical. The facts are a composite of several cases.

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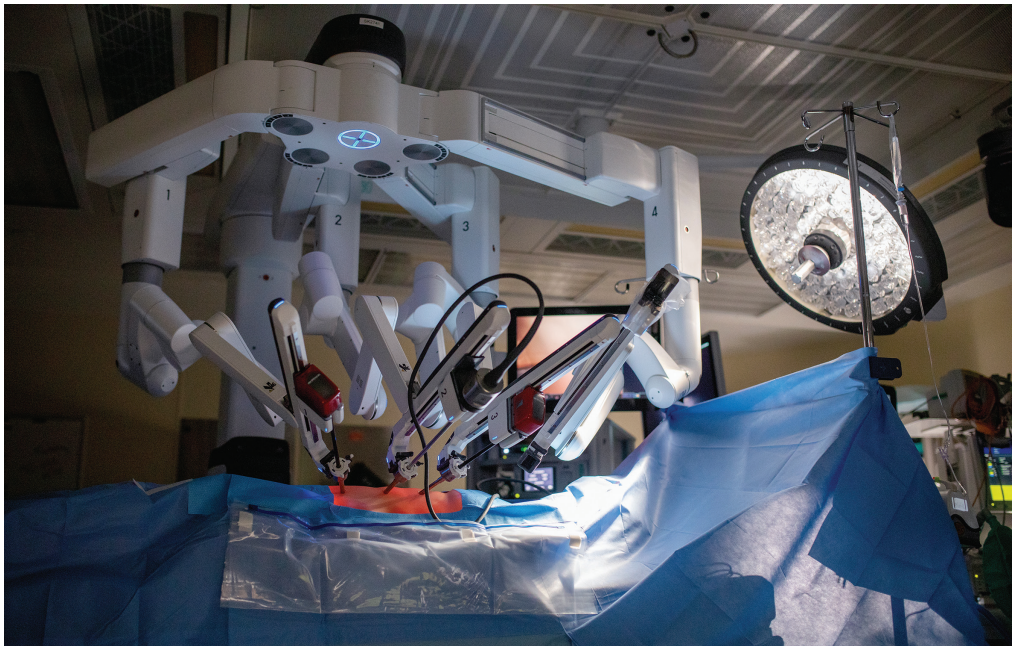

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The patient presented for a postoperative visit reporting "leaking" serosanguinous fluid that began 2.5 weeks postoperatively and required her to wear 3 to 4 "Depends" every day. She also reported constipation since beginning her prescribed pain medication. She requested a copy of her medical records and said she was dissatisfied with the care she had received related to the hysterectomy; she was "seeking a second opinion from a urologist." The urologist suggested evaluation of the "leaking," and a Foley catheter was placed. When she stood up, however, there was leaking around the catheter, and she reported a "yellowish-green," foul smelling discharge. She called the urologist's office, stating, "I think I have a bowel obstruction." The patient was instructed to proceed to the emergency department at her local hospital. She was released with a diagnosis of constipation. Upon follow-up urologic evaluation, a vulvovaginal fistula was noted. Management was a "simple fistula repair," and the patient did well subsequently.

The patient brought suit against the hospital and operating gynecologist. In part the hospital records noted, "relatively inexperienced robotic surgeon." The hospital was taken to task for granting privileges to an individual that had prior privilege "problems."

Medical opinion

This case demonstrates a number of issues. (We will discuss the credentials for the surgeon and hospital privileges in the legal considerations section.) From the medical perspective, the rate of urologic injury associated with all hysterectomies is 0.87%.[1] Robotic hysterectomy has been reported at 0.92% in a series published from Henry Ford Hospital.[1] The lowest rate of urologic injury is associated with vaginal hysterectomy, reported at 0.2%.[2] Reported rates of urologic injury by approach to hysterectomy are[1]:

- robotic, 0.92%
- laparoscopic, 0.90%
- vaginal, 0.33%
- abdominal, 0.96%.

Complications by surgeon type also have been addressed, and the percent of total urologic complications are reported as[1]:

- ObGyn, 47%
- gyn oncologist, 47%
- urogynecologist, 6%.

Intraoperative conversion to laparotomy from initial robotic approach has been addressed in a retrospective study over a 2-year period, with operative times ranging from 1 hr, 50 min to 9 hrs of surgical time.[1] The vast majority of intraoperative complications in a series reported from

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The rate of urologic injury associated with hysterectomy is less than 1%, with vaginal hysterectomy the lowest reported rate and abdominal the highest

Finland were managed "within minutes," and in the series of 83 patients, 5 (6%) required conversion to laparotomy.[2] Intraoperative complications reported include failed entry, vascular injury, nerve injury, visceral injury, solid organ injury, tumor fragmentation, and anesthetic-related complications.[3] Of note, the vascular injuries included inferior vena cava, common iliac, and external iliac.

Mortality rates in association with benign laparoscopic and robotic procedures have been addressed and noted to be 1:6,456 cases based upon a meta-analysis.[4] The analysis included 124,216 patients. Laparoscopic versus robotic mortality rates were not statistically different. Mortality was more common among cases of undiagnosed rare colorectal injury. This mortality is on par with complications from Roux-en-Y gastric bypass procedures. Procedures such as sacrocolpopexy are equated with higher mortality (1:1,246) in comparison with benign hysterectomy.[5]

Infectious complications following either laparoscopic or robotic hysterectomy were reported at less than 1% and not statistically different for either approach.[6] The series authored by Marra et al evaluated 176,016 patients.

Overall, robotic-assisted gynecologic complications are rare. One series was focused on gynecological oncologic cases.[7] Specific categories of complications included[7]:

- patient positioning and pneumoperitoneum
- injury to surrounding organs
- bowel injury
- port site metastasis
- surgical emphysema
- vaginal cuff dehiscence
- anesthesia-related problems.

The authors concluded, "robotic assisted surgery in gynecological oncology is safe and the incidence of complications is low."[7] The major cause of death related to robotic surgery is vascular injury–related. The authors emphasized the importance of knowledge of anatomy, basic principles of "traction and counter-traction" and proper dissection along tissue planes as key to minimizing complications. Consider placement of stents for ureter identification, as appropriate. Barbed-suturing does not prevent dehiscence.

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The following factors have been identified as important for minimizing complications in robotic surgery: knowledge of anatomy, understanding of basic principles of "traction and counter-traction," and proper dissection along tissue planes

Legal considerations

Robotic surgery presents many legal issues and promises to raise many more in the future. The law must control new technology while encouraging productive uses, and provide new remedies for harms while respecting traditional legal principles.[8] There is no shortage of good ideas about controlling surgical robots,[9] automated devices more generally,[10] and artificial intelligence.[11] Those issues will be important, and watching them unfold will be intriguing.

In the meantime, physicians and other health care professionals, health care facilities, technology companies, and patients must work within current legal structures in implementing and using robotic surgery. These are extraordinarily complex issues, so it is possible only to review the current landscape and speculate what the near future may hold.

Regulating surgical robots

The US Food and Drug Administration (FDA) is the primary regulator of robots used in medicine.[12] It has the authority to regulate surgical devices, including surgical robots—which it refers to as "robotically-assisted surgical devices," or RASD. In 2000, it approved Intuitive Surgical's daVinci system for use in surgery. In 2017, the FDA expanded its clearance to include the Senhance System of TransEnterix Surgical Inc. for minimally invasive gynecologic surgery.[13] In 2021, the FDA cleared the Hominis Surgical System for transvaginal hysterectomy "in certain patients." However, the FDA emphasized that this clearance is for benign hysterectomy with salpingo-oophorectomy.[14] (The FDA has cleared various robotic devices for several other areas of surgical practice, including neurosurgery, orthopedics, and urology.)

The use of robots in cancer surgery is limited. The FDA approved specific RASDs in some "surgical procedures commonly performed in patients with cancer, such

as hysterectomy, prostatectomy, and colectomy."[15] However, it cautioned that this clearance was based only on a 30-day patient follow up. More specifically, the FDA "has not evaluated the safety or effectiveness of RASD devices for the prevention or treatment of cancer, based on cancer-related outcomes such as overall survival, recurrence, and disease-free survival."[15]

The FDA has clearly warned physicians and patients that the agency has not granted the use of RASDs "for any cancer-related surgery marketing authorization, and therefore the survival benefits to patients compared to traditional surgery have not been established."[15] (This did not apply to the hysterectomy surgery as noted above. More specifically, that clearance did not apply to anything other than 30-day results, nor to the efficacy related to cancer survival.)

States also have some authority to regulate medical practice within their borders.[9] When the FDA has approved a device as safe and effective, however, there are limits on what states can do to regulate or impose liability on the approved product. The Supreme Court held that the FDA approval "pre-empted" some state action regarding approved devices.[16]

Hospitals, of course, regulate what is allowed within the hospital. For example, it may require training before a physician is permitted to use equipment, limit the conditions for which the equipment may be used, or decline to obtain equipment for use in the hospitals.[17] In the case of RASDs, however, the high cost of equipment may provide an incentive for hospitals to urge the wide use of the latest robotic acquisition.[18]

Regulation aims primarily to protect patients, usually from injury or inadequate treatment. Some robotic surgery is likely to be more expensive than the same surgery without robotic assistance. The cost to the patient is not usually part of the FDA's consideration. Insurance companies (including Medicare and Medicaid), however, do care about costs and will set or negotiate how much the reimbursement will be for a procedure. Third-party payers may decline to cover the additional cost when there is no apparent benefit from using the robot.[19] For some institutions, the public perception that it offers "the most modern technology" is an important public message and a strong incentive to have the equipment.[20]

There are inconsistent studies about the advantages and disadvantages of RADS in gynecologic procedures, although there are few randomized studies.[21] The demonstrated advantages are generally identified as somewhat shorter recovery time.[22] The ultimate goal will be to minimize risks while maximizing the many potential benefits of robotic surgery.[23]

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There was a 250% increase in the total number of malpractice claims for robotic surgery in 2014-2021 versus 2006-2013

Liability

A recent study by De Ravin and colleagues of robotic surgery liability found a 250% increase in the total number of robotic surgery–related malpractice claims reported in 7 recent years (2014-2021), compared with the prior 7 (2006-2013).[24] However, the number of cases varied considerably from year to year. ObGyn had the most significant gain (from 19% to 49% of all claims). During the same time, urology claims declined from 56% to 16%. (The limitations of the study's data are discussed later in this article.)

De Ravin et al reported the legal bases for the claims, but the specific legal claim was unclear in many cases.[24] For example, the vast majority were classified as "negligent surgery." Many cases made more than 1 legal claim for liability, so the total percentages were greater than 100%. Of the specific claims, many appear unrelated to robotic surgery (misdiagnosis, delayed treatment, or infection). However, there were a significant number of cases that raised issues that were related to robotic surgery. The following are those claims that probably relate to the "robotic" surgery, along with the percentage of cases making such a claim as reported[24]:

- **"Patient not a candidate for surgery performed"** appeared in about 13% of the cases.[24] Such claims could include that the surgeon should have performed the surgery with traditional laparoscopy or open

technique, but instead using a robot led to the injury. Physicians may feel pressure from patients or hospitals, because of the equipment's cost, to use robotic surgery as it seems to be the modern approach (and therefore better). Neither reason is sufficient for using robotic assistance unless it will benefit the patient.

- **"Failure to calibrate or operate robot"** was in 11% of the claims.[24] Physicians must properly calibrate and otherwise ensure that surgical equipment is operating correctly. In addition, the hospitals supplying the equipment must ensure that the equipment is maintained correctly. Finally, the equipment manufacturer may be liable through "products liability" if the equipment is defective.[25] The expanding use of artificial intelligence in medical equipment (including surgical robots) is increasing the complexity of determining what "defective" means.[11]
- **"Training deficiencies or credentialing"** liability is a common problem with new technology. Physicians using new technology should be thoroughly trained and, where appropriate, certified in the use of the new technology.[26] Early adopters of the technology should be especially cautious because good training may be challenging to obtain. In the study, the claims of inadequate training were particularly high during the early 7 years (35%), but dropped during the later time (4%).[24]
- **"Improper positioning"** of the patient or device or patient was raised in 7% of the cases.[24]
- **"Manufacturing problems"** were claimed in a small number of cases—13% in 2006-2013, but 2% in 2014-2021.[24] These cases raise the complex question of products liability for robotic surgery and artificial intelligence (AI). Products liability has been part of surgical practice for many years. There usually will be liability if there are "defects" in a product, whether or not resulting from negligence. What a "defect" in a computer program means is a complicated issue that will be significant in future liability cases.[27]

Several other cases reported in the De Ravin study were probably related to robotic surgery. For example, *Informed Consent* and *Failure to Monitor* each appeared in more than 30%, of 2014-2021 cases, and *Failure to Refer* in 16% of the cases.[24,27]

The outcomes of the reported cases were mostly verdicts (or trial-related settlements) for defendants (doctors and hospitals). The defense prevailed 69% of the time in the early period and 78% of the time in 2014-2021. However, there were substantial damages in some cases. The range of damages in 2006-2013 was $95,000 to $6 million (mean, $2.5 million); in 2014-2021, it was $10,000 to $5 million (mean, $1.3 million).[24]

An earlier study looked at reported cases against Intuitive Surgical, maker of the daVinci system, from 2000-2017.[28] Of the 108 claims in the study, 62% were gynecologic surgeries. Of these claims, 35% were dismissed, but "no other information regarding settlements or trial outcomes was available." The study did not report the basis for the lawsuits involving gynecologic surgeries.

We should exercise caution in reviewing these studies. Although the studies were of considerable value, the authors note significant limitations of the databases available. The database was Westlaw in the first study discussed ("Robotic surgery: the impact"[24]) and Bloomberg in the second ("Robotic urologic"[28]). For example, the "impact" study was based on "jury verdict reports" excluding settlements, and the latter excluded class actions and cases settled. Thus the studies undoubtedly understated the number of claims made (those that resulted in settlement before a lawsuit was filed), cases filed but abandoned, and settlements made before trial.

Despite these limitations, the studies provide valuable insights into current malpractice risks and future directions. It is worth remembering that these cases nearly all involved a single robot, the daVinci, produced by Intuitive Surgical. It is not a "smart" robot and is commonly referred to as a "master-slave" machine. With much more intelligent and independent machines, the future will raise more complex problems in

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In one study, "failure to calibrate or operate robot" was identified as a cause of liability in 11% of robotic surgery cases

the FDA approval process and malpractice and product liability claims when things go wrong.

What's the verdict?

The case of VM and operating surgeon Dr. G illustrates several important legal aspects of using surgical robots. It also demonstrates that the presence of the robot assist still requires the surgeon's careful attention to issues of informed consent, adequate specific training, and thorough follow up. In the following discussion, we divide the case review into the elements of negligence-malpractice (duty and breach, causation, and damages) and conclude with a thought about how to proceed when things have gone wrong.

Dr. G's statement, "I've done a few," is indefinite, but it may suggest that Dr. G. had not received full, supervised training in the robotic assist he was planning to use. That problem was underlined by the conclusion that Dr. G was a "relatively inexperienced robotic surgeon." If so, that failure could constitute a breach of the duty of care to the patient. In addition, if it is inaccurate or did not provide information VM reasonably needed in consenting to Dr. G proceeding with the surgery, there could be an issue of whether there was a partial failure of fully informed consent.

The hospital also may have potential liability. It was "taken to task for granting privileges to an individual that had prior privilege 'problems,'" suggesting that it had not performed adequate review before granting hospital privileges. Furthermore, if Dr. G was not sufficiently practiced or supervised in robotic surgery, the hospital, which allowed Dr. G to proceed, might also be negligent.

VM had a series of problems postsurgery that ultimately resulted in additional care and "simple fistula repair." Assuming that there was negligence, the next question is whether that failure caused the injury. Causation may be the most difficult part of the case for VM to prove. It would require expert testimony that the inadequate surgery (inappropriate use of robotic surgery or other error during surgery) and follow up resulted in the formation or increase in the likelihood of the fistula.

VM would also have to prove damages. Damages are those costs (the economic value) of injuries that would not have occurred but for negligence. Damages would include most of the cost of the follow-up medical care and any related additional future care required, plus costs that were a consequence of the negligence (such as lost work). In addition, damages would include pain and suffering that resulted from the negligence, subject to caps in some states.

When the patient was dissatisfied and reported a postsurgical problem, the hospital and Dr. G may have had an opportunity to avoid further dissatisfaction, complaints, and ultimately a lawsuit. Effective approaches for dealing with such dissatisfaction may serve the institution's and physician's values and financial best interests.

The jury verdict was in favor of the plaintiff. Jurors felt the operating surgeon should have conveyed his experience with robotic surgery more clearly as part of the informed consent process.

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In the opening case, the verdict was in favor of the plaintiff; the jury felt the operating surgeon should have conveyed his experience more clearly as part of the informed consent process

"Hey Siri! Perform a type 3 hysterectomy. Please watch out for the ureter!"[29]

Medicine is still at the frontier of surgical robots. Over future decades, the number and sophistication of these machines will increase substantially. They likely will become much more like robots, guided by AI, and make independent judgments. These have the potential for significant medical progress that improves the treatment of patients. At the same time, the last 20 years suggest that robotic innovation will challenge medicine, the FDA and other regulators, lawmakers, and courts. In the future, regulators and patients should embrace genuine advances in robotic surgery but not be dazzled by these new machines' luster (or potential for considerable profits).[30]

The public may be wildly optimistic about the benefits without balancing the risks. The AI that runs them will be essentially

invisible and constantly changing. Physicians and regulators must develop new techniques for assessing and controlling the software. Real surgical robots require rigorous testing, cautious promotion, disciplined use, and perpetual review. ●

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