

Cutting the legal risks of laparoscopy

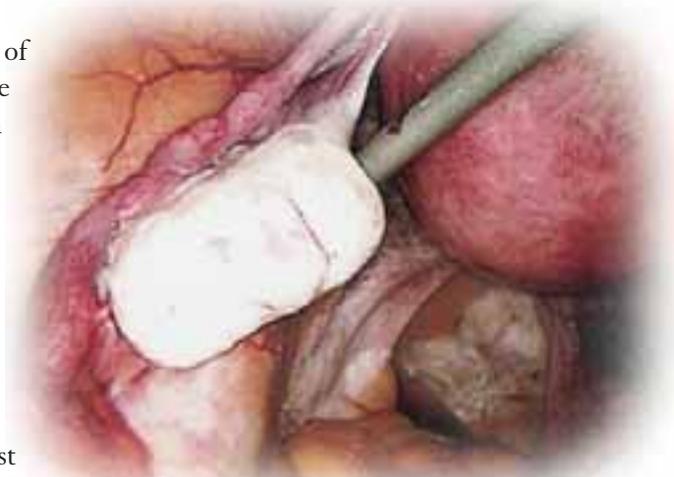
Despite laparoscopy's increasingly broad application, safety and efficacy data for this modality have accumulated in a piecemeal fashion. An attorney surveys the field and offers recommendations on avoiding medicolegal claims.

In December 1995, a 37-year-old mother of 2 entered a Michigan hospital to have her gallbladder removed. The surgeon made a small incision above the umbilicus and inserted a laparoscope to begin the operation. When he viewed the peritoneal cavity, the physician observed "a little bleeding," which he assumed was a result of the initial trocar insertion.

The woman's blood pressure dropped to 105/52 mm Hg from 126/66 mm Hg. Unfortunately, the anesthesiologist did not inform the surgeon of this drop or ask if there was any bleeding. When the patient's blood pressure dropped again—to 85/50 mm Hg—and her heart rate accelerated to 120 bpm, the anesthesiologist assumed she was suffering from a pulmonary embolism. He instructed the surgeon to step away from the table so that the patient could be repositioned. During the 10 minutes spent searching for emboli, the patient bled to death.

What went wrong? At the onset of the procedure, during insertion of the first trocar, the iliac artery had been severed. Not surprisingly, the claim resulting from this incident

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was settled for a substantial sum of money.

By analyzing this and other cases, and by reviewing the medical literature, we can get a clearer picture of the types and causes of injuries most commonly associated with laparoscopic procedures. The Ob/Gyn can

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KEY POINTS

- In a recent review of medical liability claims for laparoscopy, women were claimants in 95% of cases, and most were under the age of 40. OBG was the physician specialty involved in the majority of these claims.
- Absolute contraindications to laparoscopy include hypovolemic shock, intestinal obstruction with extensive bowel distention, a large pelvic or abdominal mass, and severe cardiac decompensation.
- The most critical aspect of laparoscopy is the placement of the first trocar and sleeve through the incision near the umbilicus. For this reason, it is the most legally defensible.

reduce the likelihood of complications—and the risk of related litigation—by remaining vigilant for circumstances that may lead to such injuries, planning accordingly, and training staff properly.

A relatively new technology

Until the mid-1980s, laparoscopy was used primarily as a diagnostic tool or to perform sterilization.¹ Indeed, the first reported appellate case involving laparoscopy was a failed tubal ligation in 1974. That year, 9 appellate cases involving failed tubal laparoscopic surgery were initiated and lost by the plaintiffs.²

We must recognize the paucity of large clinical studies that have examined the safety and efficacy of many current laparoscopic applications.

In 1986 in Germany, Mühe reported the first laparoscopic cholecystectomy,³ and in 1989 the first laparoscopic vaginal hysterectomy was performed.³ Now, scarcely more than a decade later, we have come to take much of laparoscopic technology and application for granted. That may prove to be a mistake.

When assessing the safety and efficacy of laparoscopic diagnostics and surgical procedures, we must take into account the relative newness of the procedure as well as the availability of alternative technologies (e.g., ultrasound, magnetic resonance imaging [MRI], medications) as competing diagnostic and treatment modalities. We also must recognize the paucity of large clinical studies that have examined the safety and efficacy of many current laparoscopic applications. Unfortunately, there is no national reporting mechanism for laparoscopic-associated morbidity and mortality, and published data tend to come from university settings rather than field operators.

Think defensively

One of the best ways to avoid litigation is to anticipate it routinely. By that I mean that the clinician should regularly consider whether his or her management decisions could inadvertently lead to legal claims. When it comes to laparoscopy, the first consideration should be whether the minimally invasive surgery is indeed the best approach.

The benefits most commonly cited in support of laparoscopy include a shorter operative time, hospital stay, and convalescence; earlier diagnosis; less pain; fewer complications; improved cosmetic results; and lower costs. But not all of these benefits routinely apply. Many depend on the specific laparoscopic procedure being considered.

For example, laparoscopic diagnosis and surgery generally do result in shorter hospital stays and a quicker return to work, but thanks to new technologies—particularly in the realm of imaging—diagnosis can sometimes be achieved earlier with an alternative method than is possible with laparoscopy. In addition, variables such as operative time, complications, costs, and use of pain medication vary according to procedure.

When they compared the safety and efficacy of laparoscopic and abdominal hysterectomy, Nezhat et al found that women undergoing the laparoscopic approach spent more time in surgery (160 versus 120 minutes) but had significantly shorter hospital stays (2.4 versus 4.4 days). Laparoscopic hysterectomy also allowed for a shorter convalescent period (3 versus 5 weeks) and fewer complications. Although these results are preliminary (due to the small number of subjects), the authors concluded that, in the hands of experienced laparoscopists, laparoscopic-assisted vaginal hysterectomy is preferable to abdominal hysterectomy for select candidates.⁴

The data on other procedures, however, paint a different picture. In a 1996 study in men, laparoscopic appendectomy required significantly longer anesthetic (72.5 minutes

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versus 55 minutes) and operative times (45 minutes versus 25 minutes) than open appendectomy, and there were no apparent benefits

In the most recent study of laparoscopy by the PIAA, Ob/Gyns were involved in more claims than any other specialist.

in terms of postoperative pain, recovery of bowel function, or length of hospital stay (4.9 days for laparoscopy versus 5.3 days for open surgery).⁵

Another comparison of laparoscopic and open appendectomy found no significant dif-

ferences in the length of stay or complications between the 2 groups.⁶ The need for postoperative pain medication was lower in the laparoscopic group, while operative time was significantly longer. The investigators concluded that the greatest benefits of laparoscopic appendectomy are less trauma (evidenced by less postoperative analgesia), improved diagnostic accuracy, and a better cosmetic result than with the conventional operation.⁶

When comparing laparoscopic to open hernia repair, Millikan et al found that surgical complications, hospital stay, time off from work, and use of medication all were significantly less with laparoscopy. In addition, operative times were roughly equivalent. However, the costs of instrumentation and technology made laparoscopic hernia repair more expensive than open repair.⁷

TABLE 1

Laparoscopic surgical injuries leading to liability claims*

LOCATION	NUMBER OF CLAIMS
Common bile duct (perforation, lacerations, punctures, leakage)	197
Hepatic duct (same injuries as above)	45
Bowel area (same injuries as above)	38
Arteries and veins (punctures, tears)	32
Fistulae	8
Equipment burns	7
Retained gallstones	3
Retained surgical foreign body	2
Other injuries	15

*For general and gynecologic surgeries combined. Reprinted with permission from *Laparoscopic Procedure Study*. Rockville, Md: Physician Insurers Association of America; May 1994.

ferences in the length of stay or complications between the 2 groups.⁶ The need for postoperative pain medication was lower in the

What recent litigation reveals

An analysis of liability insurance claims provides us with an interesting look into laparoscopy-related safety, demographics, complications, and outcomes. In short, it offers a snapshot of some of the most common legal pitfalls.

In the most recent study of laparoscopy conducted by the Physician Insurers Association of America (PIAA), 31 member companies reported 615 claims for 13 different types of procedures.⁸ The highest percentage of these reported claims involved cholecystectomy (54%). Tubal-ligation failures were next, making up

another 25% of the claims. With the exception of hernia repair, appendectomy, and a few diagnostic laparoscopies, the majority of

the remaining claims involved gynecologic diagnostic procedures.

Women were claimants in 95% of cases, and most were under the age of 40. Not surprisingly, Ob/Gyns were involved in more of these claims (over 90%) than any other specialist. General surgeons were named in a smaller number of cases, most involving hernia repair and appendectomy.

Across all of the procedures, the most common injury involved the common bile duct (TABLE 1). In gynecologic claims, it was injury to the ureter. In more than 80% of all claims, an additional surgical procedure was necessary—usually an open procedure to repair the punctured, lacerated, or perforated organ or vessel.

What does this mean? It suggests that Ob/Gyns are particularly vulnerable to legal claims, especially those involving complications to the bowel or ureter. It also reveals that young women are the most likely to sue—perhaps because their reproductive ability is at stake.

Complications and their causes

Similarly, an analysis of the complications cited in recent legal cases gives us a window into the most common patterns of error. An awareness of these patterns can help the Ob/Gyn sidestep many potential problems.

The learning curve. Learning-curve errors can be expected with any new technology,^{1,9} and laparoscopy, which remains in its infancy, is no exception. Beyond a knowledge of basic anatomy and familiarity with the equipment and techniques to be used, laparoscopists must have adequate training that includes preceptorship with an experienced surgeon; supervision by a teaching surgeon; and the performance of multiple procedures. Physicians must also maintain an awareness of standards of care, so they can identify the indications, contraindications, and applications of laparoscopic technology to specific diagnostic and treatment modalities.

Anatomy. Surprisingly, knowledge of human anatomy is a major factor in many laparoscopic complications: There are many important blood vessels (not counting ducts, organs, and nerves) for the anatomically challenged, unwary, or unlucky operator to hit.

The most critical aspect of laparoscopy is the placement of the first trocar and sleeve through the incision near the umbilicus—as our opening case demonstrates—since this positioning carries the greatest risk of lacerating internal organs and blood vessels. The

Because the first trocar is inserted somewhat “blindly,” complications associated with its insertion are the most legally defensible.

angle of trocar placement, the shape of its tip (i.e., conical or pyramidal), and the force of insertion all are technical variables and have great potential for injury when coupled with anatomic carelessness.

In many laparoscopic procedures, more than 1 trocar is used. Because the first trocar is inserted somewhat “blindly,” it carries the greatest risk of harm. For this reason, complications associated with its insertion are the most legally defensible. Conversely, injuries caused by second or third trocar insertions are largely indefensible, since visualization through the first trocar should bring the anatomic structures at these sites into view.

Equipment and technique failures. Although equipment failures are sometimes caused by product defects, they are more commonly associated with improper assembly, maintenance, and utilization. For example, electrical malfunction frequently is caused by poor cable connection or operator error. Accordingly, insulated surfaces should be inspected prior to each procedure to minimize inadvertent burns.

A failure of technique usually involves the inability to attain an initial pneumoperi-

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toneum.¹⁰ Extraperitoneal placement of inflating gas is another common complication and is frequently due to operator inexperience, faulty equipment, or poor patient selection. As one textbook notes, testing intraperitoneal placement with fluid in a syringe prior to gas insufflation is “mandatory.”¹¹ In addition, the amount and type of gas insufflated should be monitored and recorded. Room air, carbon dioxide, and nitrous oxide are common insufflation gases, each carrying its own risks and benefits.

The selection of unipolar or bipolar electrogenerators is another important decision. Because unipolar currents must return to ground electrodes, the risk of arcing to unin-

Surprisingly, thin, athletic, nulliparous women face an even higher risk of complications from laparoscopy than obese patients.

tended anatomic structures is increased—if that route proves to be more direct than the approach that is intended. Because a bipolar system develops current at a lower voltage and only between the jaws of the forceps, it offers greater safety, including a decreased risk of thermal damage to surrounding tissue.

The repair of burns or lacerations is more difficult when they are caused by unipolar current because the damage margins are larger and not always readily apparent. For this reason, suture repairs and anastomosis of defects caused by unipolar current require the clinician to take larger margins to insure that healthy tissue is sutured.

Patient selection. As in any surgical intervention, patient selection is critical. Individuals who have undergone a previous laparotomy face an increased risk of complications.¹ In addition, emergent, older, or acutely medically impaired patients may be unable to tolerate the challenges of laparoscopy, including its profound effects on

hemodynamics and respiration.¹⁰ Obesity, multiple previous surgeries, chronic pulmonary disease, diaphragmatic hernia, septic peritonitis, and an intolerance to positioning also constitute relative contraindications to laparoscopy.¹⁰

Surprisingly, thin, athletic, nulliparous women face an even higher risk of complications from laparoscopy than obese patients. Levy suggests that the reason for this is that “the fascia is not pliable enough...to facilitate safe trocar insertion.”¹²

Absolute contraindications to laparoscopy include hypovolemic shock, intestinal obstruction with extensive bowel distention, a large pelvic or abdominal mass, and severe cardiac decompensation.¹⁰ As information accumulates from larger studies, criteria for patient selection will be further refined.

Repositioning the patient. When the patient is repositioned—after insufflation but before all trocars are placed, or by the anesthesiologist or surgeon during the surgical procedure—organs, instrumentation, and other anatomic structures may shift into harm’s way. As Levy cautions, “Moving the patient...or even tucking the arm can change the anatomy so much that the planned puncture becomes dangerous.”¹²

Infection. Because reports of infection are rare following laparoscopy, even with complicated and lengthy cases, establishing liability is almost impossible.¹⁰

Planning for complications

Complications are predictable. For this reason, the surgical team must be prepared to perform a laparotomy if one becomes necessary. The surgeon also should obtain the proper informed consents in anticipation of laparotomy and have extra equipment available in case of mechanical failure. Moreover, he or she should be prepared to stop the procedure and exhaustively search for perforations, burns, or other injuries rather than ignore any problems

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that arise. Also crucial are adequate blood products and specialized personnel.¹⁰

As the science of laparoscopy develops and the various surgical colleges and professional organizations establish standards of

The surgeon should be prepared to stop the procedure and exhaustively search for injuries.

practice, including criteria for the education and training of surgeons, laparoscopy should become safer. And, as the number of laparoscopic procedures increases, safety and efficacy data should accumulate on a procedure-specific basis, further advancing the technology. ■

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