

**ROUNDTABLE DISCUSSION**

# Avoiding legal pitfalls of hysteroscopy

Attorneys and Ob/Gyns trade views on informed consent, documentation, and other vulnerable areas.

**O**ver the course of our careers, at least 75% of Ob/Gyns will have 1 or more medical liability claims filed against us. This naturally makes us cautious, sometimes overly so.

Though hysteroscopy is usually an effective—as well as safe—alternative to hysterectomy, many Ob/Gyns have not yet integrated this technology routinely into patient care, partly because of the fear of litigation.

In this roundtable, legal and medical experts comment on ways to minimize legal risks in 3 hypothetical cases.

**CASE 1: FLUID OVERLOAD**

“Abby” is a 30-year-old nulligravida who presents with menometrorrhagia and symptomatic anemia. Sonohysterography reveals a 3-cm submucous fibroid. After 3 months of pretreatment with a GnRH agonist to decrease the size of the fibroid and relieve her anemia, Abby undergoes hysteroscopic resection of the fibroid with a monopolar instrument and 1.5% glycine as the distention medium. The surgery is prolonged, and the fluid deficit at the end of the case is 1,700 mL.

Serial labs are drawn in the recovery room, and Abby is hospitalized overnight for observation. Her fluid intake is restricted and a diuretic is administered. The next day her electrolytes are normal, and she is discharged from the hospital.

**When assessing clinical risk, watch fluid deficit, large myomas**

**DR. LINDHEIM:** Clinically speaking, the choice of distention fluid in this case is appropriate, since the surgeon is using monopolar electrical current, and glycine has low molecular viscosity. However, it is imperative to strictly monitor the fluid deficit and, whenever possible, limit infusion pressure to 60 to 75 mm Hg and keep operating time below 1 hour.

Also be aware that larger submucosal myomas may have sizeable venous channels. When these channels are opened dur-

**OUR EXPERT PANELISTS**

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**FAST TRACK**

**Pick up the phone and call a patient who feels wronged. It may be the single most effective way to prevent lawsuits**

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## Should a physician say "I'm sorry"?

**Dr. Lindheim:** As a front-page article in the *Wall Street Journal*<sup>8</sup> observed, a doctor's best tool in fighting lawsuits may simply be owning up to errors. Yet this concept has been somewhat taboo in the medical community. What are your thoughts on a physician giving a simple apology?

**Mr. Lindheim:** It is in the heat of passion, usually involving anger, that families seek vindication against a physician simply because the physician wasn't nice or failed to address questions posed by the family about an unfortunate outcome. In everyday life, when emotion clouds reason, it is hard to think logically and understand complex explanations. When a physician comes across as arrogant at such a time, the patient and her family are often motivated to contact an attorney to evaluate the standard of care.

Of course, an unfortunate outcome is not always the result of medical negligence. This is difficult to

explain to a family angered by a doctor's "attitude." An apology may somewhat soothe the anger that drives many lawsuits, but it may not be enough to deflect litigation unless the physician is prepared to take responsibility for the adverse outcome.

**Mr. Newman:** Patients usually seek the advice of a lawyer out of anger or mistrust. They may believe their doctor has been evasive or inaccessible.

In cases where medical negligence may have caused injury to the patient, or complications associated with the nature of the procedure result in injury, it is my opinion that the treating doctor should forthrightly address any questions and concerns the patient has. This includes making oneself available in person or by telephone on a daily basis. In fact, picking up the phone and calling a patient who feels "wronged" may be the single most effective tool the doctor has to prevent a medical malpractice lawsuit.

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## Only the risks and complications listed on the form can be assumed to have the patient's consent

ing resection, significant fluid intravasation can result.

Complications associated with glycine solution include water intoxication with hypervolemia and hyponatremia. Once a fluid deficit reaches 750 mL, the surgeon should check electrolytes, give a diuretic, and complete the procedure as soon as possible. When deficits exceed 1,500 mL, stop the procedure immediately (assuming adequate hemostasis) and give another diuretic.

When using bipolar technology, isotonic distention media is suitable, and the deficit can safely reach up to 2,000 mL.<sup>1-3</sup>

### Managing water intoxication

Treating patients with water intoxication involves removing excess fluid and correcting serum sodium levels.

Some experts have argued the case for expectant management, which consists of water restriction and spontaneous diuresis. Others counter that patients with severe hyponatremia warrant immediate therapy, since they can deteriorate rapidly with little warning of seizures and respiratory arrest.

### Legal outlook: Informed consent, thorough documentation are key

**MR. LINDHEIM:** I assume a proper informed consent document has been signed. Only the risks and complications listed on that document can be assumed to have the patient's consent.

To avoid a claim associated with the consent process, the form should describe the exact procedure and alternatives, as well as the potential risks and complications, and it should be signed by the patient. Remember that informed consent is not just the physician's recitation of this information, but the patient's articulation of her understanding in response.

In this case, the facts surrounding all events should be well documented. The OR nurse should record the time, amount, and concentration of distention media given, preferably initialized by the person actually administering the medium. If this is not possible, the nurse should note that she was present at the time of administration and observed the medium being given. If a nurse or physician is later asked to explain what medications or fluids were

**FIGURE**

## Which complications are most common? Bleeding and perforation lead the pack, but others warrant vigilance, too

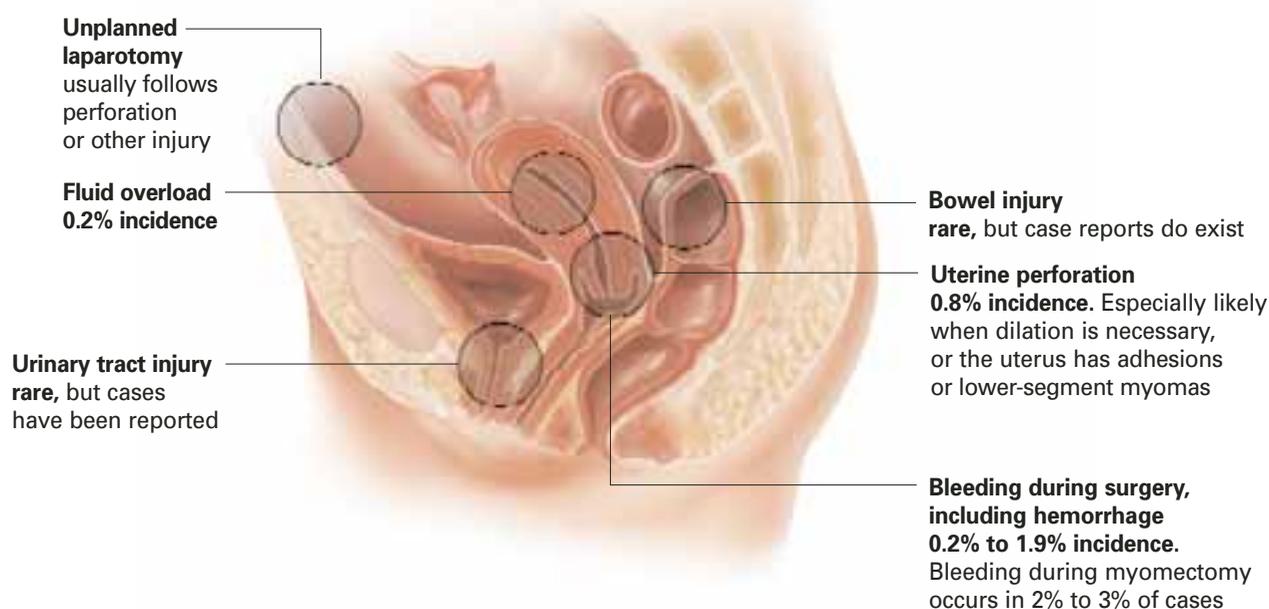


IMAGE: JENNIFER FAIRMAN

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## **Tampering with a patient's chart is a surefire way to incur punitive damages**

administered, and this information was not documented, it opens the door to fanciful speculation on their part and cross-examination by the plaintiff's attorney.

Do not attempt to insert these entries later. Handwriting specialists and other experts can detect when a record has been altered. Never try to change entries or erase them—by hand or using correction fluid. The chart is the first thing the plaintiff's attorney will request and receive once a suit is initiated. Tampering with it is a surefire way to incur punitive damages.

Since this patient was kept for observation, the reasons for doing so may warrant an entry (eg, to monitor fluid intake and output [I/O]). If serial labs are drawn, each one should find its way into the chart.

Thorough recordkeeping is essential. Any time an item is lost or not included, the plaintiff's attorney will argue that something is being hidden. Fluid levels are just as important as lab studies. Make sure the I/O chart is properly filled in, especial-

ly when fluid overload could give rise to litigation. These I/O sheets and medication (diuretic) forms should include the time of each assessment or administration.

### **Key ingredients of informed consent**

**DR. WILLIAMS:** Could you describe an adequate informed consent form?

**MR. LINDHEIM:** In general, the body of the document should list all benefits and risks of the procedure, including anesthetic risk, infection, injury to organs and the need to repair them surgically, fluid overload and specific complications related to the type of distention media to be used, air emboli and their treatment, and long-term complications such as scarring and infertility.

Consent forms are usually signed at the end of the document, but you may want to insert a line next to each risk for initialing or signing by the patient, as well as a witnessing line at the end. This would make it clear the patient agreed to the procedure and was aware of all benefits and

risks, and would present a strong defense to a later claim of lack of consent. I also recommend a notation in the progress records reemphasizing the consent process.

### Provide patient-education articles

**MR. WEITZ:** Another effective technique is to mail or provide the woman with patient-oriented articles about the procedure and risks. Since most patients undergo hysteroscopy on a scheduled basis rather than emergently, they have an opportunity to read these articles before signing the consent form. Reference to these materials in the form is also an effective way to minimize medicolegal risk.

### Factors leading to litigation

**DR. LINDHEIM:** Under what conditions would a legal action be initiated?

**MR. WEITZ:** All negligence claims require 4 elements:

- duty arising out of the physician-patient relationship,
- a breach of that duty (ie, deviation from the accepted standard of care),
- a link between that breach of duty and
- a specific harm.

**MR. NEWMAN:** In this case I believe the standards of care have been met. There is no legal case here.

**MR. WEITZ:** I agree. The complications that occurred did not result from deviation from the standard of care, but from the patient's reaction to the procedure.

Should a law firm decide to proceed with this case, which seems doubtful, it would be hard to show any damage the patient suffered as a result of any alleged improper conduct.

### CASE 2: LATER FINDING OF BOWEL INJURY

"Cathy" is a 40-year-old mother of 2 who is found to have a 10-mm polyp as part of her evaluation for abnormal uterine bleeding. She is scheduled to undergo hysteroscopic removal of the polyp with endometrial ablation. However, her uterus is severely retroverted, making serial cervical dilation necessary for entry. During the surgery, a pressure of 90 mm Hg is

required for optimum visualization. The polyp is easily removed with a grasping instrument, and endometrial ablation is performed with a monopolar rollerball using 2.7% sorbitol for distention. Cathy is discharged the same day without complications.

Two days after the surgery, she calls with complaints of nausea, vomiting, and abdominal distention. She is told to go to the emergency room, where upright abdominal radiography shows free air in the abdomen. Cathy undergoes an exploratory laparotomy for small bowel perforation with end-to-end anastomosis and is discharged 1 week later without sequelae.

### Factors that raise risk of perforation

**DR. WILLIAMS:** Uterine perforation is the most common complication of operative hysteroscopy. It is especially likely with cervical stenosis or severe anteversion or retroflexion of the uterus; with lower-segment myomas or intrauterine synechiae; and when the operator is inexperienced.<sup>3-5</sup>

When perforation occurs without an electrical source, hysteroscopy usually is discontinued because of the inability to achieve uterine distention.

Terminate the procedure even if the perforation is small and distention is possible, since fluid will be lost into the peritoneal cavity. Usually, the patient can be observed and discharged home if there is no vaginal or intraperitoneal bleeding.<sup>3,4</sup>

When perforation occurs during use of electrical energy, laparoscopy is advised to rule out bowel injury.

Patients with unrecognized bowel injury after hysteroscopy frequently are not symptomatic until 2 to 10 days after the procedure due to the thermal nature of the injury, as this case illustrates.

### Value of a photographic record

In this case, unrecognized perforation with later bowel injury could raise questions about adequate visualization throughout the case. Use of video or photography may be helpful to document that visualization.

Bowel injury also can occur in the

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absence of uterine perforation. With lower coagulating currents, it may take longer to achieve the desired endometrial effect, and this can sometimes lead to transmural thermal damage. This heat effect has been reported to cause bowel injury.<sup>6,7</sup>

#### **Justify procedures in advance**

**DR. LINDHEIM:** An expert also might question whether the ablation was necessary. Was the option of doing a simple polypectomy versus doing both a polypectomy and ablation discussed and documented?

**DR. WILLIAMS:** With such a small polyp, it was reasonable to perform the ablation, provided consent was given and recorded.

**DR. LINDHEIM:** What is the legal perspective on this issue?

**MR. LINDHEIM:** The physician will have to explain why it was necessary to perform an ablation when the treatment possibly required only simple polyp removal. Is it documented that the patient was refractory to medical therapy?

Whenever surgery entails any complication or additional procedures that could have been treated with simpler, less invasive methods, the surgeon is exposed to scrutiny, questioning, and accountability. For this reason, more is better than less when it comes to documentation.

**MR. WEITZ:** Most juries weighing treatment options are sympathetic when the patient testifies that she chose the procedure recommended by her physician. Thus, the doctor may be held accountable if something goes wrong with a riskier procedure.

If the physician wants to use informed consent as a defense, he or she should consider giving all patients articles about the various procedures so a woman cannot complain she was inadequately informed.

**MR. NEWMAN:** In a case like this, the plaintiff's attorney likely would focus on documentation in the operative report as well as in the operative, anesthesia, postoperative-care, and pathology records.

#### **Does the case have merit?**

It depends on the type of injury and when it was found.

The location, size, and nature of the perforation, as described by pathology, may be pivotal in determining whether this case has merit. If the perforation can be described as a hole, tear, or laceration and is larger than a few millimeters, the doctor will have a harder time defending this case, since no perforation was discovered at surgery or before the patient's discharge.

Following the surgery, all health-care providers should document abdominal examinations and findings at regular intervals, and should note that the patient was assessed and offered no complaints of nausea, vomiting, abdominal pain, or fever.

Should a perforation occur, finding and repairing it at the time of the original surgery is critical in preventing a lawsuit, since, in these cases, no additional injuries would be sustained by the patient—hence, no legally cognizable damages.

**DR. LINDHEIM:** Is our liability different if a bowel perforation is detected postoperatively within the standard of care?

**MR. WEITZ:** Some physicians do not believe perforation of the bowel itself is negligent, but a failure to identify and remedy it prior to completing the original procedure is.

Of course, the timing of identifying the bowel perforation after surgery may determine whether any damage can be attributed to the delay. If the perforation is identified soon after surgery and easily repaired, it will not be easy for the patient to establish a case of additional harm.

#### **Listen to a patient's complaints**

Another important point: Many plaintiffs complain that when they called their physician with postoperative complaints, they were ignored. One of the best liability-avoidance measures is to actively listen to patients and be responsive to their needs, even if treatment will remain the same.

As for the use of photos and video as defense, wholesale reliance on them and pathology reports is risky. Depending on how this evidence is presented, a jury may conclude the physician chose not to photograph the site where the injury occurred or intentionally took tissue samples from a

#### **FAST TRACK**

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different area. If a jury senses a cover-up, the defense can be undermined.

### CASE 3: AIR EMBOLISM

“Elaine” is a 35-year-old mother of 1 with secondary amenorrhea for 6 months. She delivered her son vaginally at term, but had bleeding 5 weeks postpartum that required D&C for retained placenta. After a hysterosalpingogram reveals severe Asherman’s syndrome, she is scheduled for hysteroscopic adhesiolysis.

At surgery, the cervical canal is serially dilated. On entry into the uterine cavity with a 5-mm hysteroscope, severe adhesions are visible throughout the entire cavity. Through the operating channel of the hysteroscope, a bipolar tip is used for lysis, with saline distending medium.

Shortly into the procedure, the anesthesiologist observes a decrease in oxygen saturation and a drop in end-tidal CO<sub>2</sub>, as well as hypotension. An air embolism is suspected. The gynecologist immediately stops the procedure while the anesthesiologist repositions Elaine in the left lateral decubitus position and administers 100% oxygen. The cardiac team is called, and Elaine requires invasive monitoring and catheterization of the subclavian vein. She fully recovers within 24 hours and is discharged from the hospital.

### Clinical signs of collapse

**DR. WILLIAMS:** The most common sign of impending cardiovascular collapse is a sudden drop in end-tidal carbon dioxide, as seen in this case. Both the surgeon and the anesthesiologist acted properly.

**MR. WEITZ:** I assume the procedure was thoroughly discussed with the patient during the consent process, with the risk of gas emboli emphasized, and that this discussion was documented.

### Advise the patient of risky techniques

If hysteroscopic placement or repetitive removal and replacement of the hysteroscope can create air bubbles, the physician should clearly document why the patient should be exposed to this risk. Most times,

as in this case, there are valid explanations, but without a notation in the record, the physician is exposed to legal risk.

### Standards are a double-edged sword

Perhaps industry organizations such as the American College of Obstetricians and Gynecologists should consider creating industry-wide standards for the proper use of hysteroscopes. Even with a negative outcome, including significant injury, it is difficult to prosecute a case when the medical community recognizes that the steps followed by the physician adhered to the standard of care.

Another benefit of industry-wide standards is that they provide practitioners and health-care insurers with a common framework by which to evaluate the necessity and effectiveness of hysteroscopic procedures.

**MR. LINDHEIM:** There are both positive and negative aspects to standards. When they exist, they increase the level of expectation, usually thought of as a minimum. When this minimum is adhered to, the risk of medicolegal liability is low. But when care deviates from it—regardless of the reason—the patient can argue that malpractice occurred. Conversely, without standards, the physician’s actions are viewed as a “judgment call,” and it is harder to argue that a deviation occurred. ■

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The most common sign of impending cardiovascular collapse is a sudden drop in end-tidal carbon dioxide