CLINICAL JURISPRUDENCE COLUMN

Lost needle tip during hysterectomy

Is the surgeon liable for patient's related injuries?

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CASE* Lost needle tip

A 36-year-old woman (G3 P2012) with stress urinary incontinence (SUI) and abnormal uterine bleeding presented to a gynecologist. She had explored medical therapy for her SUI with no symptom improvement. She had a previous tubal ligation, and the gynecologist ordered urodynamic testing, the results of which led to a discussion of vaginal hysterectomy; anterior, posterior colporrhaphy; and mesh placement. It was felt that the patient had a number of risk factors for incontinence (including pregnancy with vaginal delivery, well-controlled diabetes mellitus, and obesity). She had a long-standing history of chronic pelvic pain, with an established diagnosis of diverticulosis with episodes of diverticulitis in the past.

The gynecologist had the patient keep a bladder diary for 1 week. When asked, the patient reported no problems with sexual dysfunction, stating that her quality of life was "fine" except for the vaginal bleeding and loss of urine refractory to medical therapy. The Urogenital Distress Inventory was administered, and it identified frequent urination, leakage, and incontinence related to activities. An Incontinence Impact Questionnaire also was administered. Physical examination included cotton-tipped swab urethral, or Q-tip, test and cough stress test as part of POP-Q (Pelvic Organ Prolapse Quantification system) evaluation. Urinary tract infection was ruled out. The gynecologist counseled the patient about possible medical therapies for urinary incontinence, and she requested definitive surgery.

The gynecologist obtained informed consent for surgery that included preoperative discussion of potential surgical complications, including bleeding, infection, trauma to surrounding structures, and the possibility of additional surgical procedures secondary to complications. The gynecologist also discussed transvaginal tape versus transobturator tape (TOT) placement, including potential complications and sequelae. The final planned procedure, which was performed by the gynecologist, included vaginal hysterectomy, anterior colporrhaphy, and TOT placement.

Intraoperatively, the patient was identified

In this quarterly column, these medical and legal experts and educators present a case-based* discussion and provide clear teaching points and takeaways for your practice.

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*The "facts" of this case are based on actual cases but are a composite of several events and do not reflect a specific case.

(upon entering the operating room [OR]); time-out occurred, and the gynecologist proceeded with surgery. During the procedure, the tip of a needle broke off. The gynecologist noted the broken tip as he removed the needle and handed it to the surgical technician. The gynecologist palpated the sidewall in the presumed area of the needle tip and felt it easily. He attempted to remove the tip, but his effort was fruitless. He made the intraoperative decision to leave the tip in situ. A needle and sponge count was performed, reported as correct, and it was felt there was no indication for imaging of the pelvis. The circulating nurse filled out an incident report immediately following the surgery, noting the missing needle tip. The occurrence was discussed by the surgical committee at the hospital.

Postoperatively, while the patient was in the hospital, she was informed of the intraoperative incident.

Three months later, the patient reported vaginal and pelvic pain on the sidewall in the area of the lost needle tip, with radiating pain down the involved extremity. A segment of the TOT was noted to be protruding into the vagina, and this was addressed in the OR with "trimming of such."

Postoperatively, again the patient reported pain on the involved side. She sought the opinion of another gynecologist, who subsequently performed surgical intervention to remove the needle tip. Her symptoms improved.

The patient sued the original gynecologic surgeon, alleging pain and suffering from the surgery involving the lost needle tip.

FAST TRACK

Use of a surgical material that is associated with significant complications can raise a liability flag

WHAT'S THE VERDICT?

A defense verdict was awarded.

Medical teaching points

Medical evaluation seemed appropriate. Parity is associated with SUI (but not urge incontinence). In general, urinary incontinence is more commonly associated with a history of lower urinary tract infections. The patient in this case was asked about and evaluated for:

- stress incontinence (associated with loss of urine with sneezing, coughing, and exercise)
- urge incontinence (inability to reach the bathroom in time)
- frequency of urination, especially while sleeping
- overflow incontinence
- overall loss of bladder control.

Was information on the broken needle handled appropriately? This case explores the question of what, if any, obligation the surgeon and hospital system have to the patient when informing her of a broken needle and the intraoperative decision-making process that led to its staying in place. When such a situation occurs, which is very uncommon, should an intraoperative x-ray be performed to assess the location of the needle tip? Should the patient automatically be brought back to the OR for removal?

The surgeon's concern was a legitimate one—that additional attempts at removal could lead to complications far worse than having a small segment of a needle left in place. After all, shrapnel, bullets, etc, remain lodged in various locations throughout the body without subsequent ill effects. He did discuss with the patient the fact that a needle segment was left in the muscle wall. But how do you assess postoperative pelvic pain in a patient who had preoperative chronic pelvic pain? These are questions we as clinicians ask. Clearly, there are no black-and-white answers, and we will call upon our legal consultants for their expertise in addressing these queries.

From the gynecologic perspective, however, it is of paramount importance to address the patient's postoperative vaginal pain and determine the best management approach. In this case the TOT, and its association with a 21.5% complication rate, including reported vaginal extrusion, introduces a whole new set of concerns.[1] The TOT use in itself raises the question of liability on the part of the surgeon. This mesh has more than 150 associated complications, including obturator nerve injuries, extensive blood loss, and ischiorectal fossa abscesses.[2] Once a device comes upon the radar screen of the US Food and Drug Administration for

significant complications, where does that leave the clinician in regard to litigation? Let's look to our legal colleagues for their insight and expertise.

Legal considerations

Given the facts in this case, it is not surprising that it resulted in a defense verdict. The majority of cases filed are ultimately disposed of in favor of the medical defendants, and the majority of medical malpractice cases that go to trial result in defense verdicts.

Medical malpractice, or "professional negligence," consists of a claim that a medical professional had a duty of care to the patient, a breach of that duty, injury to the patient, and a causal connection ("causation") between the breach of duty and the injury. It is the obligation of the plaintiff to prove the elements of negligence by a preponderance of the evidence.

Were the surgeon's actions in line with other surgeons' expected actions? The issue of the breach of the duty of care essentially is the question of whether the physician acted similarly to a reasonably careful practitioner of the same specialty under the same circumstances. Doctors are not held to a standard of perfection. That is, not every injury or bad outcome is negligence—only those injuries that result from actions, or inactions, that were not within the level of care acceptable in the profession.

Why would this patient file a lawsuit? The injury was not trivial (it had both pain and cost associated with it), but it was not catastrophic, and the negligence was going to be difficult to prove. Furthermore, lawsuits are expensive in terms of time, energy, and emotional commitment—few people file them for the fun of it. We can only speculate on the answer to the question but, frequently, such claims are a search for the answer to "What happened, and why?" or a reaction to feeling ignored or disrespected. There is little in the case facts that we have to work with to indicate what the communication was between the gynecologist and the patient and her family. The statement of facts, however, leaves the impression that communication deteriorated as the postoperative pain endured.

Some additional areas of potential claims for liability in this case include:

- The explanation for the needle breaking during surgery is unclear from the brief statement of case facts. There might be malpractice liability if the surgeon was unreasonable in how the needle was used, used the wrong needle, or ignored defects in the needle.
- The surgeon tried unsuccessfully to retrieve the needle during the original surgery. If the surgeon's failure to retrieve the needle was because of inadequate training, lack of care or the like, it might be seen as the "cause" of the patient's injuries.
- The fact that a second surgeon was able to remove the needle tip, which resolved the patient's pain, may raise the question of whether the first surgeon's decision not to seek to remove it in response to the continuing pain was reasonable. If the first surgeon did not want to remove the needle tip, a question might be raised about whether that surgeon should have referred the patient to another surgeon. (The patient ultimately found another surgeon on her own.)
- Regarding use of TOT: A 21.5% complication rate ordinarily would be a significant factor to consider in a decision to use the tape. Physicians are responsible for keeping up with current developments in the devices and pharmaceuticals they use. Therefore, if information on the complication rate was available, the surgeon's documentation should reflect the basis for choosing to use the tape. More important, the surgeon should document a conversation with the patient about the risks and benefits of using the TOT and the discussion of alternatives to its use.

What factors could have tipped the case toward the defense?

The defense verdict indicates that the jury determined there was no negligence, or that the patient could not prove any of these potential bases of liability. As noted above, what may have helped the defense is the fact

FAST TRACK

The plantiff is charged with proving that professional negligence resulted in a breach of care and caused patient injury

that the surgeon documented the details of the informed consent conversation, including that "discussion was carried out regarding" the tape. The informed consent process is an important opportunity for communication with the patient, and a chance to make sure that expectations are reasonable. Liability for the failure of informed consent is not common. When something has gone wrong, however, it can matter whether the problem was something mentioned in the informed consent process. In addition, it was positive that postoperatively the patient was informed of the broken needle—although it is not clear who informed her about it.

A couple of other legal issues are worth noting. From our fact scenario we do not know what was documented in the incident report filed by the circulating nurse and reviewed by the surgical committee. We also do not know whether the plaintiff was privy to the incident report document. The surgical committee is likely a peer-review committee, and most states provide some privilege for such committees (to avoid disclosure of committee information for discovery or at trial). The deliberations and conclusions of the committee, therefore, were likely privileged. However, incident reports are frequently used for other purposes, such as administrative reports, that are not privileged—so the incident report often is determined to be discoverable depending on the interpretation of the state's law.

No winner in this case

Despite the defense verdict, the physician was not really the "winner" after having spent a great deal of time, energy, money, and emotion defending this suit. Ultimately, the goal is not to win malpractice cases but to avoid them—in this case, among other things, by being frank with patients about expectations, keeping an open line of communication with patients when they are concerned with an outcome that is less than ideal, and referring a patient when it may be appropriate.

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