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Risk Management Review

Patient Sues Surgeon Following Difficult Mastectomy; Nonclinical Factors Impede Defense of Case

Theodore Passineau, JD, HRM, RPLU, FASHRM

Introduction

All medical surgery requires careful attention, sound judgment, and precise technical performance. In addition, appropriate attention must also be paid to other nonclinical responsibilities. This interesting case from the Northwest illustrates how the failure to attend to these responsibilities can make acceptable clinical care difficult to defend within the legal process.

Facts

The patient was a 42-year-old female who had long-standing bilateral fibrocystic breast disease. She consulted Dr. J, a MedPro-insured general and vascular surgeon, because of a painful and enlarging right breast mass that was discharging blood-tinged fluid. Before consulting Dr. J, other surgeons had removed numerous benign tumors and fibroids from both of her breasts. Neither the patient nor her family had any history of breast cancer.

The patient's surgical history also included an appendectomy, cholecystectomy, hysterectomy (with one ovary removed because of concern for cervical cancer), tubal ligation, laparoscopic right knee surgery (x4), and excision of muscle tissue from her right breast. She was 5'8" and weighed 253 pounds, and she had a 17-year history of smoking one pack of cigarettes per day. She also had a history of mental health treatment, primarily for anxiety-related issues.

The patient began treatment with Dr. J in May of Year 1 in relation to the aforementioned right breast mass. Dr. J performed an excisional biopsy of the mass later that month. The pathology was negative for malignancy.

The patient continued to have discomfort in the area of the breast mass. In August, it was decided that a subcutaneous (nipple-saving) mastectomy would be performed to alleviate the continuous pain from the fibrocystic disease. This surgery occurred in early September, and the pathology was again negative for malignancy. Dr. J contends that he and the patient discussed the alternatives, risks, and anticipated benefits of a complete mastectomy before the surgery; however, very little of this was documented in the patient's health record. No formal informed consent process occurred prior to surgery either.

Later in September, Dr. J determined that the nipple also needed to be removed so he did so. In early October, Dr. J identified grossly infected tissue at the surgical site that required debridement. Because of slow healing, later in October, a wound vacuum was required for about 2 weeks. In December, the patient consulted her psychiatrist regarding the extreme anxiety she was suffering as a result of these complications. She was prescribed alprazolam.

In January of Year 2, the patient’s bra prosthesis caused an area of dehiscence that became infected with methicillin-resistant Staphylococcus aureus (MRSA), and a peripherally inserted central catheter (PICC) line was placed to facilitate antibiotic therapy. The treatment (including home healthcare) continued into April. The wound continued to reopen throughout May, and in June, another debridement was performed.

A hematoma developed at the surgical site in August, resulting in an additional debridement and insertion of a drain, which was removed later that month. Because Dr. J relocated his practice shortly thereafter, this was the last contact he had with the patient.

Because of continued problems with healing, the patient came under the care of another surgeon who continued antibiotic therapy. In November of Year 2, this surgeon performed another debridement. During this procedure, a 10 cm-long piece of gauze was identified and removed (it was completely covered by healed skin). Internally, nonviable tissue was encountered all the way down to the intercostal muscles. Following this surgery, healing took place slowly, and the patient was able to have several reconstructive surgeries in August through October of Year 3.

Later in Year 3, a medical malpractice lawsuit was commenced against Dr. J. After investigation and expert review, Dr. J consented to settle the case. The settlement resulted in a

payment in the midrange, with defense costs in the high range.

Discussion

MedPro sent this claim to experts in general and plastic surgery for their review. Both experts opined that the hands-on technical surgery could be supported as within the standard of care.

At first blush, the retained piece of gauze could have been very problematic for the defense of the case. This is because, generally, when foreign material (instruments, needles, gauze, etc.) is left behind in the surgical site, the legal doctrine of *res ipsa loquitur* (Latin for "the thing speaks for itself") may be appropriate to invoke. The rule of *res ipsa loquitur* can be stated as follows:

> When an event occurs, which would not normally occur in the absence of negligence, and the mechanism of injury was under the defendant's exclusive control, the jury may (but is not required to) infer that the defendant was negligent. (author's definition)

Fortunately, in this case, there was a reasonable explanation for the presence of the gauze (other than negligence on the part of Dr. J). The particular type of gauze that was removed was not used by Dr. J in his practice; however, it is commonly used by home healthcare providers. Since the patient was assisted by home healthcare providers during the time of her recovery (including them cleaning and repacking her wounds), it was reasonable to assume that this is when the retention occurred. Given the timing, it was also reasonable to assume that home healthcare was responsible for the hematoma developing.

However, this case had other issues. The complete lack of a formal informed consent process is hard to understand. The absence of a signed consent form (accompanied by appropriate conversation prior to surgery) left the patient in a position to claim that she had no idea that a complete mastectomy was being proposed, and that she would have refused it if it had been offered.

As mentioned above, Dr. J contended that he and the patient had discussed reasonable alternatives, risks, and expected benefits of the procedure prior to its performance; however, his documentation of this conversation was very sparse, and its timing was suspicious. Dr. J also contended that he had offered the patient referral to pain management and endocrinology services, which she refused. No documentation exists of these conversations.

It was generally accepted that the patient's obesity and continued smoking contributed to her slow healing, and that this should have been brought to her attention. Dr. J contended that he did so on numerous occasions, to the point that it was upsetting the patient and he was asked to not bring it up any more. However, his complete lack of documentation of these conversations could have reasonably led to the conclusion that they did not happen.

In the end, this case was likely defensible from a clinical standpoint. However, Dr. J's inattention to risk management fundamentals, such as informed consent to treatment and documentation of several critical events, rendered the case indefensible.

Summary Recommendations

The following recommendations may be beneficial when planning pre- and postsurgical care:

- Prior to the performance of a major, irreversible procedure, all reasonable alternatives should be carefully considered, discussed, and documented.
- When major, irreversible surgery is recommended, a best practice is to offer the patient the option of a second opinion prior to moving forward.
- When possible, physicians should only perform procedures with which they are thoroughly familiar and that they perform regularly.
- Except in emergencies, a surgical procedure should not begin until the patient has been engaged in an appropriate informed consent process. This process should include direct discussion with the patient about benefits, risks, and alternatives (including doing nothing. The process should be thoroughly documented in the patient's record, including related signed consent forms. See MedPro's *Checklist: Informed Consent*.
- Clinically significant conversations with patients, which are important elements of the patient's treatment experience, should always be documented in sufficient detail in the patient's health record. See MedPro's *Checklist: Documentation Essentials*.
- When it is known that the patient suffers from mental/emotional health issues (such as anxiety), they should be observed for signs of destabilization and, if appropriate, referred to a mental health professional for evaluation.

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Conclusion

Medical treatment — particularly surgery — is never “cookie-cutter,” but adherence to established protocols and best practices can increase the likelihood of a favorable outcome and minimize the practitioner’s professional liability risk.

In addition, careful attention to the nonclinical aspects of care further enhances the likelihood of a favorable result.