Firsthand Experiences: When a Straightforward Case Goes Wrong

Mark H. Wholey, MD, recounts a case in which the right procedure was performed with precise accuracy, but a disappointing outcome resulted in a lawsuit. Dr. Wholey also discusses his methods for averting malpractice litigation.

***Endovascular Today*:** What has been your worst experience in the malpractice arena?

Dr. Wholey: I have only had two experiences with malpractice cases in a long history. One of the patients had a fatal stroke after a carotid stenting procedure. It was a complex situation because the patient had been enrolled in a clinical trial. Two years prior to this event, this patient had a carotid artery stenosis, which was managed effectively with a stent. He did very well for several years and returned with contralateral stenosis; angiographically, it was an ulcerated lesion with 80% to 90% stenosis. It had progressed from 70% 2 years prior. We recommended stenting the lesion.

We discussed the plan of action with the family before the procedure. We are very insistent on informed consent for carotid repair; we explained all the possible outcomes, emphasizing that stroke occurs in 5% or less of the cases and major stroke occurs in 2% or less. We were very confident in our ability to produce a good outcome.

It was a simple procedure. On the final postprocedure angiogram, however, we could see visible clot above the filter. The patient's ACT was 290. The patient became instantly ischemic with left hemispheric symptoms. I had to go out to tell the family that we had a major stroke. The family could not believe what happened because we had talked about the good outcome just 15 minutes before.

I placed a microcatheter at the clot site and administered tPA. The patient responded very nicely to the tPA and returned to baseline. Meanwhile, he had been on effective anticoagulation with heparin, so his ACT was satisfactory. With the tPA, he responded nicely, but in the middle of the night, he had an intracranial bleed and the stroke that had been improving deteriorated very quickly. He had an intraventricular bleed, and by then it was just a matter of time. He was semicomatose, had a major bleed, and ultimately died a few days later. His family filed suit almost 2 years later.

> "I have learned this—I inform in great detail. I insist that the patient understand every possible risk."

***Endovascular Today*:** What was the basis of the lawsuit?

Dr. Wholey: They sued for negligence, inadequate informed consent, inadequate disclosure, and device difficulties.

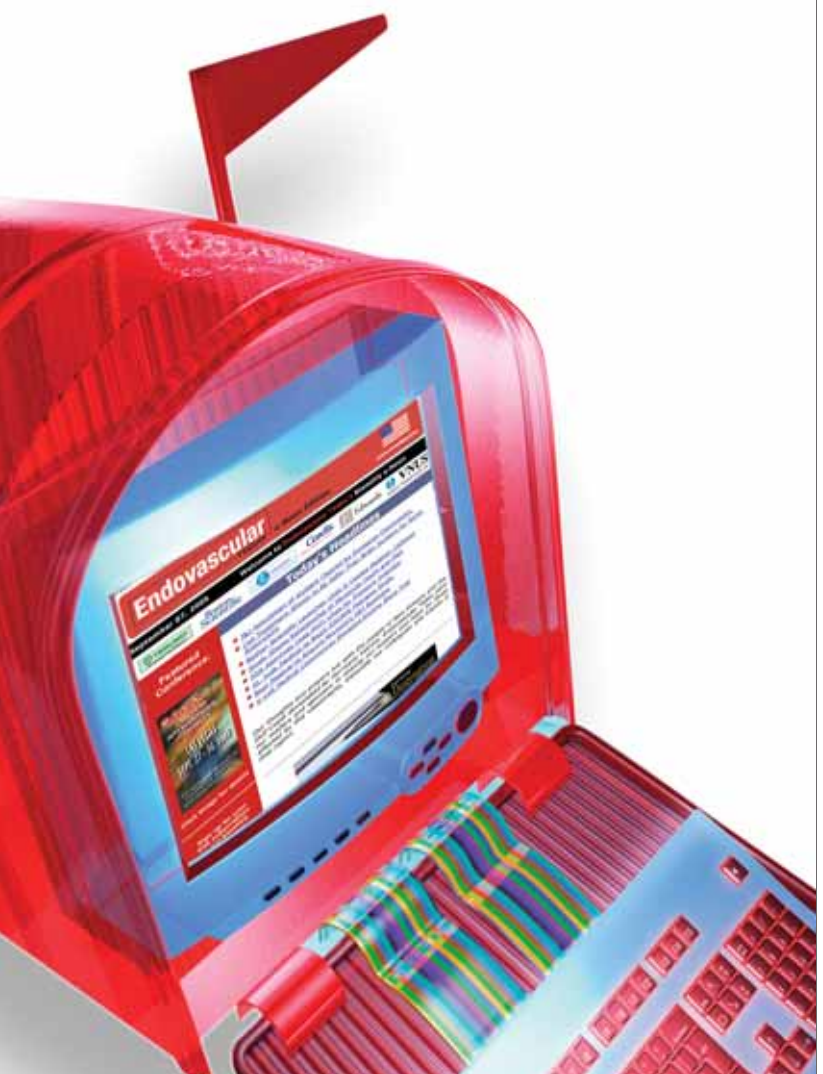
***Endovascular Today*:** Have you learned anything in particular from your malpractice experiences? Is there anything you would do differently today because of what you have been through?

Dr. Wholey: I have learned this—I inform in great detail. I insist that the patient understand every possible risk. Even though we have informed consent provided by the hospital, I never, ever perform any procedure on a patient for whom I did not personally write an informed consent note in my own handwritten signature, documenting that I've talked to the patient, the family, and I have explained every single risk: death, bleed, stroke, amputation—everything. I do not hide anything, and I even tell the patient that I do not like to talk

Subscribe to *Endovascular Today*'s e-News

Our biweekly electronic newsletter can be delivered directly to your e-mail account, bringing you industry and clinical news updates between our print issues. Subscribing is easy and free. Simply e-mail us at EVTeNews@bmctoday.com, type "Subscribe e-News" in the subject line, and include your name in the body of the e-mail. You can unsubscribe at any time by clicking on the "unsubscribe" link in the e-Newsletter.

We look forward to hearing from you!



to them in this manner, but because of our litigious society, I must give them this detailed informed consent even though our results would not indicate that a poor outcome is likely.

***Endovascular Today*:** How is the Pittsburgh litigation environment?

Dr. Wholey: Malpractice cases, rewards, and insurance premiums in Pennsylvania are unreasonably high, and therefore it is very difficult to recruit in Pennsylvania. We have cardiothoracic surgeons with malpractice premiums at $200,000 to $225,000 a year. To counter the threat of being named, at our hospital, we are very thorough with our informed consent. Furthermore, we use extreme judgment in high-risk situations.

> "Physicians are often sued for unfavorable outcomes, and they are forced to practice so defensively that it is beginning to interfere with their judgment."

With someone just beginning, it must be quite intimidating to choose to do carotid stenting procedures. We estimate that 75% or 80% of carotid stenting procedures go without any problem at all, 15% are very difficult, and 5% are extremely difficult. Physicians must take nothing for granted. The simplest type A lesion may have very vulnerable plaque, which will result in a shower of emboli and cause a major stroke. Carotid stenting only has 2% or fewer major strokes, but major stroke is really like Russian roulette; we still do not know when or how they occur.

***Endovascular Today*:** What do you think could or should be done that would help improve our malpractice environment?

Dr. Wholey: We need governmental legislation or assistance, a cap on the premiums, and a review of the cases prior to litigation. Physicians are often sued for unfavorable outcomes, and they are forced to practice so defensively that it is beginning to interfere with their judgment. Presently, physicians are so over regulated, not only with the malpractice crisis, but with regulatory issues that include the FDA, IRBs, CMS, etc., so obviously we have become very cautious about introducing new technology. ■

Mark H. Wholey, MD, is Chairman of the Pittsburgh Vascular Institute in Pittsburgh, Pennsylvania. Dr. Wholey may be reached at (412) 623-2083; wholeymh@upmc.edu.