Case Analysis:

Negligent Diagnostic Cerebral Angiogram During Endovascular Cerebral Aneurysm Repair

BY THE *ENDOVASCULAR TODAY* STAFF

CASE: Harden, 2004 Ohio 5548; 2004 Ohio App. LEXIS 4951, (2004)
JURISDICTION: Court of Appeals of Ohio, Tenth Appellate District, Franklin County
DISPOSITIVE ISSUES: Instead of testifying to a generally applicable standard of medical care, the plaintiff's expert testified to a personal standard of care, which was inapplicable under the law.

FACTS

In 1994, a neurosurgeon diagnosed Gretchen Harden with an aneurysm in the left internal carotid artery located in the cavernous sinus. The aneurysm was initially asymptomatic and was difficult to repair or remove surgically due to its location. Harden did not require treatment until 1997, when she began to experience severe pain and double vision in the area of the aneurysm. On July 16, 1997, her neurosurgeon admitted Harden, who was then 60 years old, to the hospital for treatment. He referred Harden to an interventional radiologist who recommended that Harden undergo a balloon occlusion procedure that was being conducted as part of a study.

The interventional radiologist and his assistants performed the procedure on Harden on July 18, 1997. Four days after the procedure, Harden experienced sudden left-side paralysis and changes in her pupils that indicated she had suffered a stroke on the right side of her brain. An emergency angiogram revealed a large dissection in Harden's right carotid artery, not the left carotid artery on which the procedure was performed, that nearly completely occluded the anterior circulation on the right side of her brain. Her neurosurgeon's attempt to surgically bypass the occluded right carotid artery eventually failed, and Harden suffered permanent injuries from lack of sufficient blood flow to the brain, requiring constant nursing care for the rest of her life.

Harden filed a medical malpractice action against the interventional radiologist and hospital alleging in relevant part that the interventional radiologist rendered negligent medical care and treatment to Harden. The court dismissed the case against the interventional radiologist on the basis of statutory immunity (as a state employee) but proceeded against the hospital.

At the trial in 2002, the interventional radiologist described how the balloon occlusion procedure was performed on Harden. Before placing and inflating the balloons in Harden's left internal carotid artery, the interventional radiologist performed a diagnostic angiogram to determine if sufficient blood flowed through the cerebral arteries. He inserted a guidewire into the left femoral artery and threaded through the aorta up to the left carotid artery; a catheter was then advanced over the wire to the left arteries. Another guidewire and catheter were similarly threaded through the right femoral artery and positioned into the vessels on the right side of Harden's neck to study the collateral circulation on the right side of her brain.

Next, he positioned a catheter into Harden's right internal carotid artery and injected contrast to determine the nature and health of the vessel, including whether other aneurysms, disease processes, or dissections were present in the vessel that could impact blood circulation to the brain. The angiogram showed the right carotid artery was open

and had no dissections, but a small aneurysm was detected in the artery that previously had not been discovered. Angiography was then performed in Harden's common carotid artery and left carotid artery, which confirmed the presence of the large, previously diagnosed aneurysm in the left internal carotid artery. Notes of the procedure reflect that Harden's arteries were markedly tortuous.

The interventional radiologist next performed a temporary balloon occlusion test to make sure the brain had enough collateral circulation to adequately perfuse the entire brain even if the left internal carotid artery were occluded. For the temporary balloon occlusion test, a balloon was inflated at the site of the aneurysm in the left internal carotid artery. While the left carotid artery was temporarily occluded, a catheter was reinserted into Harden's right carotid artery for another angiogram, which again confirmed good blood flow through the artery, with no dissections shown. Angiograms were then obtained in Harden's left and right vertebral arteries. No dissections were observed in the vertebral arteries, and Harden's collateral circulation was determined to be good. Performance of a hypotensive challenge test, to see if any symptoms developed when Harden's blood pressure was decreased, confirmed good collateral circulation in the brain.

After the hypotensive challenge test, and while the balloon was still temporarily inflated, Harden underwent a single positive electron computed tomography (SPECT) study that verified that she had sufficient perfusion to both hemispheres of the brain from the right side during occlusion of the blood flow through the left internal carotid artery. Having established good collateral circulation in the temporary balloon occlusion and SPECT tests, the interventional radiologist proceeded with permanent balloon occlusion and released three inflated balloons in Harden's left internal carotid artery, permanently occluding the left anterior circulation in Harden's brain.

After permanently occluding the left internal carotid artery, he opted to obtain an angiogram of Harden's right vertebral artery to see if other aneurysms existed in addition to the previously diagnosed aneurysm in the left internal carotid artery and the recently discovered aneurysm in the right internal carotid artery. The angiogram revealed that blood flow through the right vertebral artery was good, but that a dissection had occurred in that artery.

The interventional radiologist explained that he did not perform completion angiography on the right internal carotid artery after permanent balloon occlusion because reinserting the guidewire and catheter into the right internal carotid artery to again examine the artery would have added a risk of further injury. He further explained the procedure would have produced no appreciable benefit where the artery had already been examined and good collateral flow had been demonstrated during the temporary balloon occlusion and SPECT tests. Instead, he chose to terminate the procedure, which lasted approximately 8 hours, and Harden was transported to the ICU for monitoring during her recovery. The interventional radiologist advised the neurosurgeon and Harden's family of the dissection in Harden's right vertebral artery.

The interventional radiologist testified that Harden was treated with heparin and underwent two more SPECT studies, on July 19 and July 21, which showed continued adequate perfusion to both hemispheres of her brain. Then, early on the morning of July 22, 1997, Harden suffered a sudden onset of symptoms of a stroke, which an emergency angiogram showed was caused by a large dissection in the right internal carotid artery that nearly completely occluded circulation through the artery.

THE LAWSUIT

The plaintiff Harden alleged that the defendant provided negligent care in the treatment of the aneurysm. On January 12, 2004, the trial court issued its decision and judgment entry in favor of the hospital on all of Harden's claims.

THE EXPERT REPORTS

The experts in this case agreed that in the vast majority of the cases where a dissection occurs, the dissection is asymptomatic and heals on its own, but the possibility remains that a dissection can progress and cause partial or complete blockage of an artery.

Plaintiffs' experts (an interventional radiologist and a neurosurgeon) testified at trial that the standard of care obligated the defendant physician to obtain a completion angiogram after permanent balloon occlusion to check for dissection in plaintiff's vessels, specifically the right internal carotid artery. The plaintiff's expert acknowledged a right internal carotid artery dissection was not evidenced on any of numerous films taken of the area prior to permanent occlusion, and conceded nothing in the plaintiff's medical records or in observations of her condition suggested the second dissection occurred prior to the stroke which the plaintiff's expert characterized as a "sudden-onset event."

The plaintiff's expert maintained, however, that dissection does not happen spontaneously, and that the dissection in the right internal carotid artery must have occurred at some point during the balloon occlusion procedure. He further opined that the dissection probably occurred as the result of manipulation of the guidewire or the catheter, and that plaintiff's history of cigarette smoking may have been an aggravating factor in causing the vessel damage. He also testified that each pass of a guidewire or catheter

through the vessel offers a chance for injury to the vessel and stated that tortuous vessels increase the risk of injury. Nevertheless, he opined that after the plaintiff's left internal artery was permanently blocked with balloons to prevent rupture of the aneurysm, the risk of injury to the right carotid artery by reinserting the guidewire and catheter and re-injecting dye into that vessel was outweighed by the need to verify that the plaintiff's remaining carotid artery was uninjured and had good blood flow.

> "the physician . . . is required to exercise the average degree of skill, care, and diligence exercised by members of the same medical specialty community in similar situations."

The defense also offered the expert testimony of an interventional radiologist and a neurosurgeon. In contrast to the plaintiff's experts' opinions, the defense experts claimed that the standard of care did not require the defendant to perform a completion angiogram after permanent occlusion took place. The defense expert testified that the accepted standard of care is to check the adequacy of collateral circulation during the temporary balloon occlusion and, if the circulation provides adequate perfusion to the brain, to detach the balloons and end the procedure. He further stated that the defendant not only met the standard of care, but he did some "extra" things during temporary balloon occlusion by performing the hypotensive challenge test, conducting contrast dye injection tests on the plaintiff's right side, performing the SPECT study to confirm adequate blood flow, and performing a neurological assessment of the patient.

According to the defense expert, dissections can begin very slowly and develop over time, and an injury to the lining of a blood vessel may be initially undetectable. The films taken during temporary balloon occlusion showed equal and adequate blood flow to the anterior and posterior portions of the plaintiff's brain and no obstruction of flow on the plaintiff's right side, despite the small dissection detected in the plaintiff's right vertebral artery.

All experts agreed that after the defendant recognized the dissection in the right vertebral artery, he responded appropriately and within the accepted standard of care by placing the plaintiff on an anticoagulant and by ordering repeated SPECT scans, which verified blood perfusion to both hemispheres of the brain. Both sides were in further agreement that whether there was one dissection or two, the anticoagulation therapy remains the same. The defense expert testified that since the presence of a second dissection might be undetectable, and adequate perfusion had been documented during the temporary occlusion of the plaintiff's left carotid artery, it was unnecessary to recheck the plaintiff's collateral perfusion after permanent occlusion; that to do so would pose a needless risk to the patient without appreciable benefit.

AT TRIAL

The trial court determined that Harden's expert's testimony constituted his "own personal standard" of care, rather than the appropriate, legal standard of care for interventional neuroradiologists performing the balloon occlusion procedure. During cross-examination, the plaintiff's expert agreed to differences among practitioners about how best to perform the balloon occlusion procedure, including practitioners' use of different techniques for evaluating the adequacy of contralateral flow during temporary occlusion. He testified, however, that he would still "blame" other practitioners if they performed a SPECT study without also performing a contrast study and would "consider it to be below standard of care." Defense counsel then questioned the plaintiff's expert as follows:

Q. When you use the term "standard of care" what do you mean by it, doctor?

A. What I do in the best interest of the patient.

The court found that Hardens failed to prove the hospital's negligence in the care or treatment and that the standard of care did not require the treating to do a completion angiogram on Harden to ensure adequate blood flow through the right internal carotid artery after permanent balloon occlusion was completed on her left internal carotid artery.

ON APPEAL

The plaintiff appealed the finding of the trial court and claimed that the trial court misinterpreted the expert testimony regarding standard of care. To determine the applicable "standard of care," Ohio courts have held that "the test is whether the physician, in the performance of his service, either did some particular thing or things that physicians and surgeons, in that medical community, of ordinary skill, care, and diligence would not have done under the same or similar circumstances, or failed or omitted to do some particular thing or things which physicians and surgeons of ordinary skill, care, and diligence would have done under the same or similar circumstances. He is required to exercise the average degree of skill, care, and diligence exercised by members of the same

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medical specialty community in similar situations." The court found that the record supported the trial court's conclusion that the plaintiff's expert testified to his own, personal standard of care rather than the standard of care set forth previously.

On direct and cross-examination, the plaintiff's expert acknowledged that other practitioners may perform techniques and procedures differently than he does. However, his testimony consistently reflected his belief that he considered his own protocol to constitute "the" standard of care and that any deviation from his protocol fell below the "standard of care." Further, the appellate court found that the plaintiff's expert seemed to equate "standard of care" with the highest, or virtually perfect, standard of care in a given situation, rather than the standard of what a medical professional of "average" degree of skill, care, and diligence in the same medical specialty would do in similar circumstances. As an example, while the plaintiff's expert testified that an arterial dissection is a known risk of angiography and can happen even in the exercise of reasonable caution by a skilled physician performing a cerebral arteriogram, he also testified that he considers it to be a mistake and below the "standard of care" if he creates a dissection.

RESULT

The defense verdict was upheld on appeal. The appellate court found that the testimony of expert witnesses provided substantial, credible evidence to support the trial court's finding that the applicable standard of care did not require that the defendant perform a completion angiogram after permanent balloon occlusion.

DISCUSSION

As happens in many medical malpractice cases, this case revolved around the battle of the experts. Both the plaintiff and the defendant had an interventional radiologist and neurosurgeon to testify on their behalf. It appears from the record that the underlying case was a "bench trial," a case tried before a judge, without a jury, so that the judge sits as both the finder of both fact and law. The judge's findings of law are able to be questioned on appeal, while the judge's findings of fact may not be disturbed.

The standard of care applied by the Ohio court is similar to that used in almost every jurisdiction. The trial court found that the plaintiff's expert did not testify to the standard that should be employed by a physician of *ordinary* skill, care, and diligence under the same or similar circumstances, but to the level of skill that the expert would have demanded of himself. As the court held, failure to meet that higher standard is not malpractice. ■