Failure to diagnose epidural abscess

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Presentation
An 80-year-old man was admitted to the emergency department on December 16 complaining of severe right lower extremity pain. His medical history included severe peripheral vascular disease, coronary artery disease, COPD, diabetes and hypertension. He had previously undergone a femoral bypass, coronary angioplasty, and thrombectomy. He was admitted to the hospital by his primary care physician who initiated intravenous heparin and warfarin therapy.

Physician action
On December 18, the patient’s care was transferred to Internist A who continued the heparin and warfarin therapy. On December 20, blood cultures indicated gram positive cocci and clusters in the blood, and the patient was given levofloxacin. On December 21, the patient developed fever and complained of back pain. Urine and blood cultures and a chest x-ray were ordered on December 22. The patient was started on vancomycin. A chest CT revealed left lower lobe pneumonia, which the internist thought was likely responsible for the fever and complaints of pain.

Since the patient continued to complain of pain, a neurology consultation was requested on December 23 at approximately 10:30 a.m. At that time Internist A wrote “abscess?” in the medical record; however, he indicated that he did not consider an epidural abscess likely based on the patient’s symptoms and lack of neurological deficit. The neurologist examined the patient the afternoon of December 23, and obtained a history of severe middle and upper back pain with no radiation to the arms or legs. On examination, he found no evidence of weakness in the extremities, bowel or bladder dysfunction, and normal knee jerk reactions. He felt the most likely causes of the pain were compression fracture, hematoma, or osteomyelitis. On December 24, blood culture reports indicated a staphylococcus infection sensitive to levofloxacin and vancomycin which had already been given. Internist A visited the patient in the morning of December 24, at which time the patient’s family requested care be transferred to Internist B who had previously cared for the patient. The neurologist indicated that he examined the patient at approximately 12 p.m. on December 24; however, there was no documentation in the record reflecting the visit or the examination. On examination, the neurologist found no change in the patient’s condition and no evidence of neurological deficit. Internist B continued to see the patient and his treatment remained unchanged.

On the morning of December 25, the patient, for the first time, began to exhibit neurological deficits with weakened grip and weakness in his lower extremities. The neurologist came to the hospital, examined the patient, and ordered an MRI of the cervical and thoracic spine. The MRI revealed mild to moderate degenerative disc disease with no significant lesions in the thoracic spine, and severe spondylolysis and stenosis in the cervical spine with mild spondylolisthesis of C6 into C5. The results were not reported to the neurologist who had left the hospital and returned home after examining the patient and ordering the MRI. Early in the evening of December 25, he returned to the hospital, personally reviewed the MRI, and examined the patient. Examination revealed significant neurological changes. He subsequently ordered a neurosurgical consultation at 10:00 p.m. The neurologist discussed the patient’s condition with the neurosurgeon by telephone. He advised he did not feel the patient was a surgical candidate for the following reasons: warfarin therapy, elevated WBC with possible sepsis, and heart block with AV dissociation. The neurosurgeon did not go to the hospital to examine the patient.

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This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians’ defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material more difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.
On December 26, the neurosurgeon examined the patient and discovered he had neither feeling nor movement in his lower extremities. A MRI performed on January 2 revealed an anterior epidural fluid collection at C6-7. After examining the patient and reviewing the films, the neurosurgeon elected not to drain the abscess because it was small and could be treated medically. The patient was discharged to an acute long-term care facility on January 17, and subsequently a nursing home on January 29. He remained in a nursing home at the time the claim was filed with C-6 quadriparesis.

**Allegations**

A lawsuit was filed against Internist A and the neurologist, alleging that they were negligent in failing to timely diagnose and treat the patient’s epidural abscess resulting in quadriplegia.

**Legal implications**

TMLT consultants reviewing this case were generally supportive of the care and treatment rendered by Internist A and the neurologist, noting there was little reason to suspect an abscess. The outcome would have been unchanged since the patient was not a surgical candidate due multiple pre-existing medical conditions. Additionally, the only available neurosurgeon in this rural hospital declined to perform surgery for those reasons.

In testimony, the neurologist insisted that he saw the patient on December 24. However, he stated that the chart was unavailable as the internist was reviewing it, and therefore he made no entry in the medical record. The plaintiff attorney used this to indicate there was no examination on December 24 because there was no documentation in the record.

TMLT consultants were critical of the neurologist for the delay in obtaining the MRI. Additionally, it was noted in Internist A’s differential diagnosis that the patient had an infection, and yet he ordered no further testing.

The neurosurgeon in this case testified he would not have agreed to perform surgery on the patient at anytime during his hospitalization since he was not a surgical candidate. One TMLT consultant indicated the neurosurgeon should have come to the hospital to examine the patient and evaluate him for surgery since the radiological diagnosis of spinal stenosis did not explain the clinical symptoms.

**Disposition**

This case was settled on behalf of Internist A and the neurologist.

**Risk management considerations**

Situations such as this, involving an elderly patient with multiple pre-existing medical conditions, present challenges for physicians in determining the most appropriate course of action and treatment.

Documentation of medical decision-making and treatment plans is important. When multiple physicians and providers are involved, the medical record serves as a mechanism for communication regarding the patient’s condition and treatment. Additionally, Texas Medical Board rules list the requirements for an “adequate medical record.” These include the reason for the encounter and relevant history, physical examination findings, assessment, clinical impression or diagnosis, plan for care, and the date and legible identity of the observer.1 The neurologist stated that he saw the patient on December 24, but did not document his visit in the medical record. The lack of documentation to that effect was used by the plaintiff’s attorney. It led to conjecture and became an obstacle in the defense of the physician.

The MRI was not performed until December 25. One might question the lack of timeliness in ordering the MRI. A consultant was critical of the neurologist for the delay in obtaining the study in view of the fact the internist indicated he was considering an abscess as a differential diagnosis. Additionally, the results of the MRI were not communicated promptly to the neurologist. Rather, the neurologist reviewed the study when he returned to the hospital that evening at which time significant neurological changes had already occurred in the patient. It is important for physicians to rely on practices to timely receive test results and respond accordingly. Improved communication with the radiology department may have expedited obtaining the results with a more prompt assessment by the neurologist.

With hindsight it may have been prudent for the neurosurgeon to come to the hospital to examine the patient, especially since clinical symptoms did not correspond with the radiological diagnosis. Physicians should use caution when making treatment decisions without physical examinations especially in situations involving a patient as this with deteriorating neurological status.

Gadolinium, renal failure, and NSF: a potentially dangerous combination

by Jay Henderson, JD

Physicians and patients are familiar with the imaging modality we know as magnetic resonance imaging (MRI). MRI is an imaging technique in which radio waves and a powerful magnet linked to a computer are used to create detailed images of areas inside the body. MRI images are often enhanced by the use of a contrast media, which is injected in the body to permit greater visualization of the organs and structures under scrutiny.

Gadolinium is a paramagnetic metal ion contrast agent that was developed in the 1980s. Gadolinium has been used in imaging procedures since 1988, when the first gadolinium-based contrast agent (GBCA) was approved for use in the United States. Gadolinium provides improved lesion sensitivity and improved lesion characterization. Millions of patients have received injections of GBCAs, including patients on dialysis or with compromised renal function.

GBCAs were historically thought to be safe for use in patients with renal compromise. There was no indication in the medical literature or the product labeling that use of gadolinium in these patients might result in a systemic autoimmune disorder. As of 2004, the American College of Radiology (ACR) observed that “Gadolinium agents are considered to have no nephrotoxicity at approved dosages for MR imaging.” The 2006 ACR Practice Guidelines and Technical Standards offered numerous scenarios in which “intravenous contrast may be useful,” including vascular abnormalities, infections, masses, and tumors. As a result, millions of imaging procedures were performed using this presumably safe agent.

The first public indication that GBCAs might pose a potential health hazard in susceptible patients occurred in June 2006. At that time, the Food and Drug Administration (FDA) obtained reports of an unusual cluster of adverse events from Europe. The disease in question was known as Nephrogenic Systemic Fibrosis (NSF). The FDA issued a Public Health Advisory on this subject. The advisory offered two recommendations to health care professionals and patients: (1) gadolinium-containing contrast agents, especially at high doses, should be used only if clearly necessary in patients with advanced kidney failure; and (2) it may be prudent to institute prompt dialysis in patients with advanced kidney dysfunction who receive a gadolinium contrast Magnetic Resonance Angiography (MRA). Thus, this first advisory was limited in scope and contrary to two decades of experience of physicians familiar with this compound.

Many physicians, including radiologists, did not become aware of this initial advisory. Among those who did, the prevailing view was that the FDA advisory did not warrant a drastic change in existing medical practice. There was no definitive guidance from industry or professional organizations initially, which left practitioners to their own devices. As a result, most physicians continued to order contrast-enhanced studies in the same circumstances as they had for years.

The FDA issued a second Public Health Advisory in December 2006. This second advisory stated: “When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.” Again, the information in this advisory did not initially gain wide distribution or acceptance.

One critical flaw in our drug and medical device regulatory system is that there was no reliable way to ensure that information on NSF would come to the attention of physicians. The FDA advisories were not widely circulated. Manufacturers of GBCAs did not revise their labeling to reflect the contents of the advisory. Communications from industry and professional associations were not well disseminated and were vulnerable to subjective interpretations. The practical effect of this divergence of information was that practice standards varied dramatically among prescribers and radiologists. This was not an urban-rural dichotomy or one dictated by the sophistication of the practice. The author has first-hand knowledge that tertiary care centers in major metropolitan areas of Texas did not begin to screen patients for renal dysfunction until the spring and summer of 2007 or thereafter. In any event, many radiology centers did not alter their gadolinium screening protocols in response to the FDA advisories.

In May 2007, the FDA announced that it would require a black box warning for all marketed GBCAs to alert prescribers to the risk of NSF in patients with renal compromise. The product labeling for GBCAs was not modified until after this announcement, and the revised labeling was not formally distributed to the medical community until September 2007. This series of events explains why many physicians did not implement new gadolinium protocols in the early days of this episode.

Today, all marketed GBCAs are subject to a black box warning. This warning states that gadolinium-based contrast agents increase the risk for nephrogenic systemic fibrosis (NSF) in susceptible patients. The ACR issued formal screening recommendations on gadolinium-based MR contrast agents in July continued on page 4
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2007. GBCA product labeling also contains screening criteria for physician consideration.

Physicians who order contrast-enhanced MRIs, as well as radiologists, must take heed of the new black box warning that accompanies gadolinium-based contrast agents. While its occurrence is rare, nephrogenic system fibrosis is a tragic disease for which there currently is no cure. GBCAs remain a useful tool for the vast majority of patients undergoing MRIs, but candidates who are susceptible to NSF should be screened and assessed under current medical guidelines. In the end, the appropriate course of care is left to the sound discretion of the physician and should include the informed consent of the patient.

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