Failure to adequately maintain patient’s blood pressure

By Robin Desrocher
Risk Management Representative

Presentation
A 45-year-old woman with a history of a cervical fusion at C6-7 and L3-4, L4-5 interbody fusion continued to have pain. She sought an evaluation by an orthopedic surgeon specializing in reconstructive spine surgery. The patient’s medical history included hypertension, smoking (self-reported as ½ pack per day “on and off” for thirty years), mild chronic renal insufficiency, and hepatitis C. A work-up demonstrated an annular tear at L5-S1, with luencies of the allograft at L3-4, suggesting pseudo-arthritis. The orthopedic surgeon recommended surgical exploration and revision of the previous lumbar fusion. The patient was scheduled for spine revision surgery.

Physician action
A certified registered nurse anesthetist (CRNA) provided the anesthesia care for the surgery, under the supervision of an anesthesiologist. The procedure lasted approximately 12 hours. At the beginning of the case, an arterial line and central line were placed followed by induction of general anesthesia. The patient was placed in a Cloward frame in the prone position with her face down on a pillow with no pressure points on the eyes and nose.

At the beginning of the procedure, the patient’s blood pressure was recorded as 181/92 mm/Hg. Her blood pressure was deliberately lowered and maintained at approximately 110/60 mm/Hg for the first three hours. The patient’s blood pressure then began to fluctuate for one hour, with readings between 110/70 mm/Hg and 100/55 mm/Hg. Over the next hour, her blood pressure was consistently maintained at 95/55 mm/Hg and then began to decrease. Almost one hour later, the lowest blood pressure reading was recorded to be 90/50 mm/Hg. The systolic pressure for the next 3 hours remained at a range between 95 and 105 mm/Hg. The systolic pressure then dropped to a low of 85 mm/Hg and stayed between 80 and 90 mm/Hg. The diastolic pressure remained between 45 and 55 mm/Hg for the remainder of the procedure.

Estimated blood loss during the procedure was 2000 ccs, and the patient received one liter of cell saver along with some packed red blood cells. The supervising anesthesiologist was present at several points during the procedure as documented in the medical record. She did not note any problems and did not return to the operating room during the last two hours of the surgery.

The patient was taken to the post anesthesia care unit (PACU) and was noted to be very combative and uncooperative. Massive orbital edema and a hard, red area on her chin were also noted. Two hours later, the patient was transferred to the floor.

The next morning, the patient was able to open her eyes, but she reported that she could not see anything. Blood pressure readings were within the normal range. The patient was found to be in renal failure with a high potassium level of 9. Her pupils were documented as non-reactive to direct light. A consultation with an ophthalmologist confirmed that the patient had no light perception vision in both eyes. The ophthalmologist concluded that the patient had suffered posterior ischemic optic neuropathy (ION) in both eyes. The patient was discharged. A follow-up appointment three weeks later confirmed this finding. The blindness has not improved and is permanent.

Allegations
A lawsuit was filed against the anesthesiologist and the CRNA. The allegations included failure to adequately maintain the patient’s blood pressure, causing her to sustain intra-operative ION resulting in permanent blindness in both eyes.

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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.
Legal implications

The CRNA was an employee of the anesthesiology practice, and the anesthesiologist was vicariously liable for her actions or omissions.

The plaintiffs retained credible experts who asserted that the defendant and co-defendant failed to meet the standard of care by maintaining the patient’s blood pressure at no less than 25% of her pre-operative blood pressure. This breach of the standard of care resulted in significantly decreased perfusion to the patient’s optic nerve and organ systems, resulting in the ION and acute renal failure.

Two physicians who reviewed this case for the defense were supportive of the actions of the CRNA and the anesthesiologist, asserting that they did not deviate from the standard of care. The pre-operative anesthesia assessment specifically addressed the risk of acute renal failure and ION. This was discussed with the patient before the procedure. However, one consultant did believe that the anesthesiologist should have been more directly involved during the last few hours of the case.

Disposition

This is an unfortunate case involving a young woman with permanent blindness following a lengthy spine surgery. This case was settled on behalf of the anesthesiologist and the CRNA.

Risk management considerations

“Vision loss after non-ocular surgery is a rare but potentially devastating surgical complication that is usually the result of cortical blindness, ischemic neuropathy or retinal vascular occlusion. Due to its rare and unexpected occurrence, the origin of perioperative vision loss (POVL) is poorly understood.”

“Because the number of POVL cases from a single institution is very low, a multi-institutional database is required to obtain sufficient numbers for meaningful analysis of common perioperative characteristics or events. In response to this problem, the American Society of Anesthesiologists (ASA) Committee on Professional Liability established the ASA POVL Registry in 1999 to collect detailed information on cases of POVL occurring after nonocular surgery. More than two thirds of the cases in the ASA POVL Registry were related to spine surgery in the prone position, and 89% of these cases were associated with ION. Most spine surgery patients with ION were relatively healthy and had a wide range of nadir hematocrits and blood pressure management that may reflect a multifactorial etiology. Estimated blood loss of 1,000 ml or greater or anesthetic duration of 6 hours or longer was present in 96% of these cases. For patients undergoing lengthy spine surgery in the prone position, the risk of visual loss should be considered in the discussion of perioperative risks.”

The anesthesia preoperative note indicated that the anesthesiologist did discuss the risk of vision loss with the patient. The American Society of Anesthesiologists also published a Practice Advisory 2006. In this advisory, task force members and consultants agreed that “Vascular risk factors increase the risk of perioperative visual loss. In addition, they agree that the preoperative presence of anemia, prolonged procedures, substantial blood loss, and prolonged procedures combined with substantial blood loss all increase the risk of perioperative visual loss.”

An immediate evaluation by an ophthalmologist for a patient with visual complaints at any time after surgery is critical. Although POVL is a rare complication, the possibility that it can occur exists. It is recommended the possibility of POVL be discussed with patients before undergoing anesthesia. This discussion should be clearly documented in the medical record.

With low systolic blood pressures, dropping central venous pressures and tachycardia during the last several hours of the surgery, an anesthesiology consultant for the defendant indicated that the anesthesiologist should have been more directly involved during that time period to ensure adequate perfusion and possibly prevent the prolonged hypotension, tachycardia and falling central volume. He further stated that the relative hypotension and reduced perfusion to the head — particularly in light of the fact the patient already had compromised optic nerve perfusion secondary to diabetes, hypertension and smoking — may have contributed to the ION resulting in permanent blindness. He opined the anesthesiologist should have used vasopressors or volume loading to support cerebral and optic nerve perfusion to maintain the blood pressure. He also indicated it would likely have been beneficial to limit the surgeon to a shorter procedure time for this patient.

Anesthesiologists supervising CRNAs should be mindful of cases of this magnitude — especially related to the length of surgery and the patient’s pre-existing conditions — and provide close supervision and intervention when indicated. The ASA Statement of the Anesthesia Care Team addresses this model of anesthesia delivery and defines the roles of both physician and non-physician personnel. It states “...[the Anesthesia Care Team] involves the delegation of monitoring and appropriate tasks by the physician to non-physicians. Such delegation should be specifically defined by the anesthesiologist and should also be consistent with state law and regulations and medical staff policy. Although selected tasks of overall anesthesia care may be delegated to qualified members of the Anesthesia Care Team, overall responsibility for the Anesthesia Care Team and the patients’ safety rests with the anesthesiologist.”

Further defining the responsibilities of the anesthesiologist related to management of the anesthetic the statement indicates, “The management of an anesthetic is dependent on many factors including the unique medical conditions of individual patients and the procedures being performed... The anesthesiologist may delegate specific tasks to qualified non-anesthesiologist members of the Anesthesia Care Team providing that quality of care and patient safety are not compromised, but should participate in critical parts of the anesthetic and remain immediately physically

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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.
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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 systemic 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.

Jay Henderson, JD is a partner in the law firm of Cruse, Scott, Henderson and Allen in Houston. He can be reached at jhenderson@crusescott.com.

Sources


Robin Desrocher can be reached at robin-desrocher@tmlt.org.

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available for management of emergencies regardless of the type of anesthetic.”

Sources


Robin Desrocher can be reached at robin-desrocher@tmlt.org.