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PPM

Cardiopulmonary Sentinel Events During ERCP: Oversedation or Air Embolism?

Introduction

Air embolism during endoscopic retrograde cholangiopancreatography (ERCP) is a rare, but potentially devastating, complication that can cause permanent significant neurological injuries or fatal cardiopulmonary collapse.[1] Due to its rarity and lack of clinical suspicion, air embolism during ERCP is often unrecognized until it is too late for successful treatment.[2] The difficulty in diagnosing air embolism often results in confusing the embolism with poor anesthetic care, or with an acute ischemic or hemorrhagic event.[3] The following case study demonstrates how a sudden cardiovascular collapse during ERCP due to a suspected, undiagnosed air embolism resulted in litigation against the anesthesia providers.

Case Study

A 74-year-old female patient, 155 cm, 72.6 kg, presented to the emergency department with an abrupt onset of diffuse abdominal pain. The patient's medical history included diabetes, chronic renal failure, transient ischemic attacks, coronary artery disease, congestive heart failure, hypertension, and peripheral vascular disease. She had a past surgical history of cholecystectomy, cardiac catheterization with stent placement, coronary artery bypass grafting, below the knee amputation, and stenting of her right femoral artery. The patient was admitted for choledocholithiasis, biliary obstruction and abdominal pain for the purposes of performing an ERCP.

The PPM insured anesthesiologist conducted the preanesthetic evaluation. He noted a history of increased anxiety, but the examination was negative for reasons to delay the procedure. Based on the patient's significant co-morbidities, he classified her as an ASA IV. The anesthetic plan was monitored anesthesia care (MAC) with sedation.

The patient was brought to the endoscopy suite and the case was started by a hospital-employed certified registered nurse anesthetist (CRNA). The patient was attached to electrocardiogram (ECG), blood pressure cuff, pulse oximetry, nasal cannula and placed in the semi-prone position. The CRNA administered 2 mg Versed, 100 mcg fentanyl, 30 mg lidocaine, 0.2 mg Robinul and 15 mg propofol.

Air was used to insufflate the bowel structures. Approximately five minutes into the procedure, the endoscopist noted difficulty identifying the major duodenal papilla. He also documented "a very large periampullary diverticulum" in that area. A few minutes thereafter, the patient became bradycardic and hypotensive. The patient's blood pressure was treated twice with ephedrine, and she was turned supine for mask/bag ventilation. The anesthesiologist was called to assist. Approximately five minutes later, the patient was pulseless with ECG unchanged. CPR was started with chest compressions, 0.5 mg epinephrine was given, the patient was intubated and a pulse was immediately restored. Pulse oximeter readings throughout the case ranged from 92 to 100 percent. The procedure was canceled and the patient was taken to the ICU.

A neurologist consult noted remote ischemic changes in the right parietal-occipital lobe and remote lacunar infarction of the cerebellum on CT scan, which were thought to be chronic changes. Probable anoxic encephalopathy was noted on EEG. The patient never regained any neural function and she expired one week postop.

The patient's husband sued the CRNA, the anesthesiologist, the anesthesia practice group, and the hospital. The patient's husband alleged the patient was oversedated which caused cardiopulmonary depression, arrest and anoxic brain injury. The allegations against the hospital were for vicarious liability for the CRNA's acts and omissions.

The difficulty in diagnosing air embolism often results in confusing the complication with poor anesthetic care…

Plaintiff's expert, Dr. Ronald Wender, Los Angeles, California, opined that the anesthetic was "excessive" and the propofol should not have been administered by the CRNA. He opined further that when the patient first became bradycardic and hypotensive, the CRNA should have called the supervising anesthesiologist, immediately intubated the patient and administered epinephrine. He was also critical that the supervising anesthesiologist was not "carefully and continuously" monitoring the CRNA as he was responsible for the CRNA's actions.

The defense forensic pathology expert, who was retained to provide expert opinion testimony on the life expectancy of the decedent, did not identify any evidence of an anesthetic overdose. No autopsy or toxicology screening were performed so he did not believe the plaintiff's anesthesiology expert had reasonable grounds to conclude the patient received an anesthetic overdose. Because of the

lack of an autopsy and toxicology reports, there was little evidence to determine the exact cause of death.

The defense anesthesiology expert was fully supportive of the care and treatment provided by the anesthesiologist and CRNA. He opined that appropriate doses of anesthesia were utilized in this case. The defense expert noted that the CRNA and anesthesiologist responded to the changes in the blood pressure and heart rate very rapidly. The immediate response to the epinephrine restored blood pressure and provided adequate perfusion for delivery of oxygen. The expert did not believe the documented timeline allowed for anoxia from oxygen deprivation. He opined that the patient's sudden cardiovascular collapse upon being turned supine was the result of an air embolism caused by the ERCP procedure and the gastroenterologist's difficulty finding the hepatopancreatic ampulla. The expert cited numerous cases in the medical literature supporting his causation findings.

Symptoms of air embolism typically appear or become significantly worse when the patient is repositioned from prone to supine at the end of the procedure.

This case was submitted to a mediation panel prior to trial. Following each parties' submission of their respective briefs and exhibits, the panel awarded the patient's husband money damages against both the hospital on behalf of the CRNA and the anesthesiologist. All parties accepted the panel's awards and the hospital settled for a confidential amount. With the PPM's insured anesthesiologist's consent, this case was settled for $10,000.

Discussion

Venous air embolism (VAE) is caused by air bubbles, under pressure, entering the vasculature allowing the passage of air into the systemic circulation.[4] VAE, including intracardiac and intracerebral air embolism, is highly lethal with a mortality rate of up to 21%, according to a recent study.[5]

Different mechanisms causing air inlet to the venous system have been proposed: invasive procedures (e.g., sphincterotomy), prolonged exposure to high air insufflation pressure, intramural dissection by the air blown into the portal vein, and biliary-hepato-venous fistula.[6] Other risk factors for VAE include previous procedures of the bile duct system, abdominal trauma, metal stent placement, and digestive system inflammation.[7]

The use of carbon dioxide (CO2) insufflation, instead of air insufflation during ERCP, can eliminate the risk of VAE, as CO2 gas bubbles are rapidly absorbed from the blood.[8] Significantly, in one of the largest prospective series performed to date assessing for the incidence of VAE in 843 subjects undergoing ERCP, there were no adverse hemodynamic consequences in those patients in which CO2 was used as the insufflating agent and embolism occurred.[9]

VAE can cause cardiovascular, pulmonary, and neurological symptoms.[10] Cardiovascular signs, symptoms, and findings include arrhythmia, hypotension, myocardial ischemia, right heart failure, cardiovascular collapse, and cardiac arrest. Pulmonary signs, symptoms and findings include acute dyspnea, tachypnea, breathlessness, rales, wheezing, decrease in end tidal carbon dioxide (ETCO2) concentration, hypoxia, cyanosis, and respiratory failure. Neurological signs, symptoms, and findings include eye deviation, dilated pupil(s), failure to regain consciousness after anesthesia, hypertonicity, altered mental status, loss of consciousness, hemiparesis, cerebral hypoperfusion, cerebral edema, and coma.[11]

Warning signs of impending cardiovascular collapse may be subtle, but typically the symptoms appear or become significantly worse when the patient is repositioned from prone to supine position at the end of the procedure. This patient deterioration with position change should immediately raise a red flag and trigger suspicion for a VAE as the underlying cause of the patient's symptoms.[12] VAE may be detected by ETCO2 monitoring, and pre-cordial Doppler ultrasound (PDU) should be used in moderate-to-high-risk patients undergoing high-risk procedures, such as ERCP, when air is used instead of CO2.[13] PDU has been shown to be an efficacious, inexpensive, and noninvasive monitoring device for detection of VAE.[14]

To ensure timely management, it is essential to include VAE in the differential diagnosis of adverse events with ERCP, particularly in patients with known risk factors and acute cardiopulmonary impairment exacerbated by a position change. If VAE is suspected, the following steps can have a significant impact on patient outcomes:

1. If possible, immediately stop the procedure.
2. Administer high-flow oxygen at 100% to reduce the air piston size.
3. Place the patient in left lateral decubitus and Trendelenburg position to improve venous return.
4. Perform an emergency echocardiogram.
5. If air is detected on the right side of the heart in the echocardiogram, insert a central catheter.
6. Insert a pulmonary artery catheter, if indicated.
7. Gastrointestinal decompression with nasogastric suction.
8. Start hyperbaric oxygen therapy as soon as the patient's condition allows it, if available.

Once the patient is hemodynamically stable, a brain and thoracic CT scan should be considered to confirm the diagnosis.[15]

Risk Management Analysis

A retrospective review of PPM's loss data identified seven claims involving brain damage or death during ERCP procedures. Six of those claims are closed with total indemnity paid in the amount of $2,215,794. As in the case study above, in several of those claims there was compelling medical evidence and expert opinion to support a defense theory that the complications were caused by air embolism. However, due to the difficulty in timely diagnosing and treating the complications, plaintiffs' experts focused their criticisms on the anesthetic care; frequently testifying that the patients were oversedated and should have been intubated for the procedure. The absence of evidence to support our experts' opinions that an air embolism was caused by the ERCP procedure with air insufflation presents a significant challenge in defending these claims. Timely recognition and diagnosis of air embolism confirmed by pre-cordial Doppler ultrasound, echocardiography or CT scan will not only improve patient outcomes, but provide the necessary evidence to defend PPM's policyholders' care and treatment in these cases.

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PPM Policyholder's Perseverance Prevails After Sixteen Years of Litigation

Dismissal obtained after trial and successful appeal in "Judicial Hellhole™"[1]

The case involved a 71-year-old female who, in 2002, underwent a quadruple coronary bypass. Following the procedure she developed recurrent hypotension and underwent emergency re-exploration in the ICU. It was determined she had a rupture of her right pulmonary artery caused by the Swan Ganz catheter. The patient subsequently experienced cardiac arrest and passed away 10 hours post-procedure.

In 2003, the patient's husband sued the PPM insured anesthesiologist, his anesthesia practice group, the cardiothoracic surgeon, several nurses and the hospital. All of the individual co-defendants were hospital employees.

Plaintiff originally alleged the anesthesiologist negligently failed to obtain consent for pulmonary artery catheterization, and negligently failed to properly and skillfully perform and monitor the Swan-Ganz catheterization. However, with regard to the second allegation, plaintiff could not find a medical expert to support this position, as perforation of the pulmonary artery is a well-known complication. Therefore, plaintiff amended

the complaint, dismissed the negligence claim and alleged medical battery claiming the anesthesiologist did not have a proper consent for the Swan-Ganz catheterization.

During discovery, it was determined that the defendants did not obtain a specific consent for Swan-Ganz catheterization. The patient had signed a consent stating, "I hereby authorize the [physicians] to perform the following procedures: insertion of central venous pressure and/or arterial line."

The defense anesthesiology expert explained that the standard of care does not require an anesthesiologist to obtain consent for procedures that are part and parcel of the heart surgery. The expert's opinion was that the general consent for heart surgery includes consent to all procedures that are a necessary part of the surgery including, but not limited to, general anesthesia, Swan-Ganz catheterization, and arterial line placement. Most importantly, plaintiff could not obtain an expert to offer the opinion that Swan-Ganz catheterization required a specific consent form.

Over the course of the next ten years, the trial court judge granted the plaintiff multiple extensions, trial continuances and unfavorable rulings against the defendants. Throughout this entire time period and despite several attempts by the plaintiff to obtain a settlement, the anesthesiologist maintained his resolve that he was not negligent and he did not wish to consent to settlement.

In 2014, three weeks before trial, the trial court judge granted the plaintiff's motion for summary judgment and ruled as a matter of law that placement of the central venous pressure line was substantially different from placement of the Swan-Ganz catheterization. Accordingly, the judge directed a verdict that a medical battery had occurred, and defense counsel proceeded to prepare the case for trial only on the issues of causation and damages.

One week before trial, defense counsel was notified that the hospital settled on behalf of the cardiothoracic surgeon, the nurses and the hospital for a confidential amount.

On the eve of trial, the judge ruled that the anesthesiologist was not allowed to testify to any opinions—not even the opinions he had expressed in his deposition.

During the three-day trial, the defense was not allowed to present any expert testimony, the anesthesiologist's testimony or any evidence to the jury. The defense was also not allowed to cross examine any of the plaintiff's witnesses.

After the defense rested, plaintiff moved for directed verdict[2] on causation. Defense counsel argued against directed verdict pointing to (and providing the judge with copies of) Illinois case law which holds that causation is an issue of fact for the jury. Despite Illinois case law stating it was reversible error to do so in this situation, the judge granted plaintiff's directed verdict anyway.

During closing arguments, plaintiff requested at least $1,000,000 but "no more than" $2,000,000. In less than three hours, the jury returned a verdict awarding plaintiff $1,000,000 in damages.

The judge denied all of the defendants' post-trial motions and ordered the posting of a $1,200,000 appeal bond. PPM posted the appeal bond and defense counsel proceeded with our appeal.

In March 2015, the Illinois Court of Appeals reversed the trial court, and remanded this case back to the trial court for a new trial. The Appellate Court essentially agreed with all the issues the defense raised on appeal and instructed the trial court multiple times in its decision to follow the law on remand.

A second trial date was set with the same judge for September 2019. Defense counsel recently notified PPM's insured anesthesiologist that the plaintiff had voluntarily dismissed his case.

"This case that dragged on for sixteen years underscores exactly why St. Clair County, Illinois has consistently been ranked in the top ten of Judicial Hellholes. I have never seen anything like the egregious and outrageous disregard for the court's legal and ethical obligations in my entire career," said Shelley Strome, Senior Claims Specialist. Strome continued, "I am just so happy for our insured and thanked him for never bending and defending his care, despite all odds stacked against him in this jurisdiction."

Greg Minana, Esq. of Husch Blackwell, LLP, St. Louis, Missouri, represented PPM's insureds. Shelley Strome, Senior Claims Specialist, and Brian Thomas, JD, Vice President-Risk Management, managed the file on behalf of PPM.

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1. Since 2002, the American Tort Reform Foundation's (ATRF) Judicial Hellholes™ program has identified and documented places **where judges in civil cases systematically apply laws and court procedures in an unfair and unbalanced manner**, generally to the disadvantage of defendants. St. Clair County, Illinois, where this case was venued, has consistently ranked in the top ten of the Judicial Hellholes and was ranked #9 in 2018-2019. Available at: http://www.judicialhellholes.org/wp-content/uploads/2018/11/judicial-hellholes-report-2018-2019.pdf.
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Underwriter's Spotlight

Treating Yourself, Family or Friends? Just Say No

Providing medical treatment to family, friends, colleagues and self-treatment is reportedly widespread among physicians and in most cases it's not illegal, but is it a good idea? PPM continues to defend many policyholders who have come under investigation from state medical licensing boards for informally treating non-patients, especially self-treatment with prescription medications. Sanctions and penalties for treating non-patients or self-treatment can range from public censure, significant fines, and suspension or revocation of the physician's medical license.

PPM has also defended policyholders in medical negligence litigation in which a policyholder treated a partner who experienced a complication or injury. In addition to the potential conflicts these situations may create among the PPM policyholders and their practice groups, defending policyholders in those cases presents unique challenges for PPM. For example, normal recordkeeping and informed consent discussions are frequently abbreviated or omitted altogether based on the personal nature of the relationship.

There are also several ethical guidelines to consider before engaging in self-treatment or treatment of immediate family members. The American Medical Association (AMA) Code of Medical Ethics states, in part, "Physicians generally should not treat themselves or members of their immediate families. Professional objectivity may be compromised when an immediate family member or the physician is the patient." Exceptions include "in emergency settings or isolated settings where there is no other qualified physician available" or "short-term, minor problems. Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members."[1]

Similarly, the American College of Physicians (ACP) Ethics Manual states, in part, "Except in emergent circumstances when no other option exists, physicians ought not care for themselves. A physician cannot adequately interview, examine, or counsel herself or himself, without which ordering diagnostic tests, medications, or other treatments is ill-advised.

"Regarding people with whom the physician has a significant preexisting, nonprofessional relationship, such as family members and close friends, and regarding employees or supervisors, the relationship necessarily adds another layer that may complicate what would become the professional patient–physician relationship.

"While the patient may feel unduly restrained in making choices, or inhibited in speaking about certain matters or in rejecting physician recommendations, the physician may be unduly impaired in maintaining clinical objectivity; inadequate history-taking or physical examination, overtesting, inappropriate prescribing, incomplete counseling on sensitive issues, or failure to keep appropriate medical records are also potential issues. The needs of the patient may not fall within the physician's area of expertise, and emotional proximity may result in difficulties for the patient and/or the physician."[2]

Some state medical boards have additional requirements such as preparing and keeping a proper written record of the treatment, and maintaining records of all written prescriptions or administration of any drugs.[3] Other states prohibit physicians from prescribing controlled substances to themselves, family members or others with whom they have a close personal relationship unless there is an "immediate need."[4]

"Given the significant potential legal and ethical pitfalls from treating non-patients or self-treatment and possible disciplinary actions against the physician's medical license, PPM's advice to our policyholders is to avoid those situations unless it falls within one of the narrow exceptions. In those rare cases, document your treatment and do not prescribe controlled substances," according to John Morhiser, PPM's Vice President-Underwriting.

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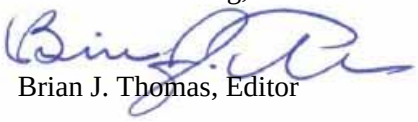

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