



Catastrophic Complications During Endoscopy

Traditionally, endoscopy was performed with conscious sedation typically with the administration of a benzodiazepine and a narcotic by the endoscopist or a nurse. However, in the past decade, anesthesia-administered deep sedation with propofol for endoscopy has increased. Benefits associated with deep sedation with propofol include, but are not limited to: decreased surgical stimulation and pain, shorter recovery time, and increased patient satisfaction. However, the administration of deep sedation also potentially increases the risk for adverse events and catastrophic complications.

As highlighted in the following cases, endoscopic anesthesia claims and litigation often involve allegations of inappropriate patient assessment and selection. Another common allegation is over-sedation causing bradycardia and adverse respiratory events resulting in brain damage and death.

Case #1

- A 64 year-old male patient, ASA III, with a medical history including morbid obesity (BMI 44), hypertension and diabetes presented for an elective colonoscopy. The patient's wife reported her husband snored and obstructed during sleep; however, he had not been diagnosed with obstructive sleep apnea (OSA). General anesthesia with propofol (400 mg), lidocaine and oxygen (O₂) via nasal cannula at 4 liters/min was administered. Lights in the procedure room were dimmed. Approximately 15 minutes into the procedure, the endoscopist noted intermittent ectopy with bigeminy and hypotension followed by bradycardia. The patient's heart rate (HR) dropped into the 50s and remained there until the colonoscopy was finished.

When the lights were turned back on, the patient was noted to be "ruddy with a darkened complexion." The O₂ saturation (sat) was 75% with HR of 49. The O₂ was increased to 8 liters/min and mask ventilation was initiated. The O₂ sat dropped to 49% and bradycardia turned to asystole. A code blue was called and resuscitation measures were employed, but the patient eventually went into ventricular fibrillation (v-fib). The patient was defibrillated twice before return of spontaneous circulation. The patient was intubated and acidotic with a pCO₂ = 90.

The patient was transferred to ICU and cooling protocol was initiated. CT scan confirmed diffuse brain swelling. The patient never regained consciousness. The patient's family withdrew supportive measures and the patient expired one week post-procedure.

The patient's wife and three adult children sued the PPM insured anesthesiologist and the anesthesia practice group. The patient's family alleged the anesthesiologist was negligent for failing to place an airway for the colonoscopy procedure based on the patient's history that included an ASA III physical status classification, short neck, BMI = 44 (5' 10", 310 lbs.) and self-reported suspected OSA. The patient's family also alleged the anesthesiologist was negligent in the administration of propofol resulting in over-sedation, bradycardia and pulseless electrical activity (PEA). The patient's family further alleged the anesthesiologist was negligent in failing to recognize evolving respiratory depression, hypercarbia and respiratory acidosis.

Plaintiff's anesthesiology expert, Corey A. Burchman, MD, York, Pennsylvania, testified selecting intravenous anesthesia (IVA) with propofol for this patient was in compliance with the standard of care. However, when the patient started having problems, the anesthesiologist should have taken action such as placement of a face mask, a laryngeal mask airway (LMA) or intubation. Plaintiffs' expert testified further the anesthesiologist was not vigilant and failed to (1) observe the patient's

chest rise and fall, (2) use capnography (there were no ETCO₂ readings or notes recorded in the anesthesia record), and (3) pay attention to alarms or the patient's skin color and overall appearance.

Plaintiffs' initial settlement demand was \$1.8 million. PPM's defense counsel's evaluation of the potential jury verdict exposure was \$1.4 million with a recommended settlement value of \$1 million. With the PPM's insured anesthesiologist's consent, PPM negotiated a \$970,000 settlement.

Case #2

- A 46 year-old female patient with a medical history significant for morbid obesity, hypertension, asthma, abnormal cardiac rhythm and diverticulitis presented for an elective colonoscopy. A PPM insured certified registered nurse anesthetist (CRNA) assessed the patient and designated her as an "ASA I." The CRNA provided monitored anesthesia care (MAC) with sedation with 2 mg Versed and 100 mg propofol at the start of the case.

The patient tolerated the procedure and anesthetic without any initial complications. However, O₂ via nasal cannula was increased twice and additional propofol was administered in response to the patient moving. Immediately thereafter, the patient started snoring with a partially obstructed airway.

As the endoscopist was finishing the procedure, he announced he forgot to check something and retroflexed the colonoscope looking for internal hemorrhoids. At that moment, the patient experienced profound bradycardia, then asystole. A code blue was initiated, the CRNA intubated the patient and the supervising anesthesiologist was called to assist. When the anesthesiologist arrived, it was noted the esophagus was intubated; however, a second laryngoscopy resulted in tracheal intubation. The patient was transferred to the ER where echocardiography showed a lack of right-sided heart contractility. The patient was transferred to another hospital via life flight and was diagnosed with severe and permanent brain damage.

Following the code, the endoscopist authored an operative note indicating the patient suffered respiratory arrest or distress caused by "over-sedation." The endoscopist's operative note failed to mention reintroduction of the scope may have precipitated the bradycardia and cardiac arrest.

The patient's husband and minor son sued the PPM insured CRNA and the anesthesia practice group. The patient's family alleged the CRNA negligently administered an excessive amount of anesthesia without timely, adequate or appropriate monitoring. The patient's family alleged further the CRNA failed to maintain the patient's O₂ saturation and airway, and also failed to timely and appropriately perform resuscitative measures to prevent the patient from suffering catastrophic and permanent brain damage.

The plaintiffs' anesthesiology expert, James Pepple, MD, Havre de Grace, Maryland, and two CRNA experts testified the PPM insured CRNA breached the standard of care. The experts testified the CRNA was negligent in failing to fully appreciate and appropriately assess the patient's various medical conditions and history. The experts testified further the patient should have been designated an ASA III, rather than an "ASA I." The experts also testified an appropriate assessment of the patient should have resulted in a higher degree of vigilance when monitoring the patient's respiratory effort (there were no ETCO₂ readings or notes recorded in the anesthesia record), heart rate, and pulse.

Several expert anesthesiologists retained by the defense were unable to support the anesthetic care in this case. PPM's defense counsel evaluated this as a case of liability with significant damage exposure, including past medical expenses in excess of \$600,000 and future medical expenses in the millions of dollars. Based on the lack of expert support and defense counsel's recommendation for settlement, the anesthesia practice group consented and PPM resolved this case for \$1.7 million.

Case #3

- A 76 year-old male patient with a medical history significant for obesity, probable OSA, orthopnea, dyspnea upon exertion, atrial fibrillation, coronary artery disease, myocardial infarction, ischemic cardiomyopathy (ejection fraction = 35%), congestive heart failure, hypertension, chronic renal insufficiency, adult onset diabetes, anemia, and status post coronary bypass surgery presented for an elective esophagogastroduodenoscopy (EGD) and colonoscopy. On admission to the endoscopy center, the patient's O₂ saturation was 86%. However, this abnormal O₂ saturation was not evaluated further or communicated to the PPM insured anesthesiologist. The patient was designated an ASA III by the anesthesiologist following his pre-anesthesia evaluation.

Prior to the start of the case, the anesthesiologist discussed the patient's multiple co-morbidities and risks with the endoscopist. The endoscopist assured the anesthesiologist it was "safe to proceed."

Soon after the case started, the patient was given two 40 mg doses of propofol and within a few minutes he became hypoxic and bradycardic. The anesthesiologist administered ephedrine to treat the bradycardia, but it quickly progressed to PEA. A code was called and resuscitation was attempted with atropine and epinephrine. The patient was transported to the hospital with CPR in progress. Spontaneous circulation was restored en route to the hospital. However, the patient never regained consciousness and was diagnosed with profound hypoxic brain damage. Two weeks post-procedure, the patient's family withdrew mechanical ventilation and the patient expired.

The patient's wife sued the PPM insured anesthesiologist, the endoscopist and the endoscopy center. The patient's wife alleged the patient's procedure should have been performed in a hospital, if at all, and should have been deferred because of the low O₂ saturation (86%) noted on admission that persisted despite supplemental O₂.

The plaintiff's unnamed anesthesiology expert (in some states plaintiffs are not required to identify their experts until the time of trial) submitted an affidavit with the filing of the lawsuit. The plaintiff's expert opined that because of the patient's complex medical history, including ischemic cardiomyopathy, the patient was not an acceptable patient for a freestanding endoscopy center. Furthermore, when it was discovered his baseline oxygen saturation was only 86%, the procedure should have been cancelled and an evaluation of his respiratory and cardiac status initiated. The expert also opined the patient's low baseline O₂ saturation placed him at grave risk of becoming hypoxic. The expert further opined one of the effects of propofol is to lower the respiratory rate. Therefore, it was medically probable the patient would become hypoxic. According to the expert, a baseline O₂ saturation of only 86% provided no safe margin for an additional drop in O₂ saturation, which is a common response to propofol. The expert concluded the hypoxia and cardiac arrest that occurred were the predictable consequences of sedation, which ultimately led to the patient's death.

The defense anesthesiology experts who reviewed this case conceded the PPM insured anesthesiologist did not adequately assess the patient's significant co-morbidities and history and should have designated the patient as an ASA IV, not an ASA III. The experts further opined the anesthesiologist should not have relied on the endoscopist's assurances that it was "safe to proceed" and delayed or cancelled the procedure. Ultimately, none of the defense experts could support the anesthesiologist's pre-anesthesia evaluation and care in this case.

The initial settlement demand to all defendants was \$1,750,000. All parties participated in mediation and the case was settled globally for \$750,000. PPM contributed \$390,000 to the settlement on behalf of the PPM insured anesthesiologist.

In each of the cited cases, allegations against the anesthesia providers included a failure to recognize increased risk factors presented by the patient. Such allegations, along with PPM loss data suggesting an expanded use of anesthesia-administered deep sedation with propofol for patients with an ASA greater than II, form the basis for PPM's patient safety and risk management recommendations. "The increased number of morbidly obese patients with OSA and other co-morbidities elevates the importance of proper assessment and selection, especially in non-hospital settings. Our patient safety and risk management recommendations are a reminder of the importance of identifying patients at higher risk and then tailoring the anesthesia care to reduce the risk," according to Tracey Dujakovich, PPM Senior Claims Attorney.

Risk Management Tips for Preventing Injury During Endoscopy with Deep Sedation

When high-risk patients (e.g. morbid obesity with untreated or suspected OSA, pulmonary disease, and/or heart failure) are identified during the pre-anesthesia evaluation, PPM policyholders should consider:

- Whether the patient is an appropriate candidate for the planned procedure and facility; document the discussion with the endoscopist in the medical record
- Delaying or canceling the procedure for further evaluation and treatment, if medically indicated
- Prophylactic vagolytic therapy – e.g. atropine, glycopyrrolate to reduce incidence of bradycardia
- Avoiding IV general anesthesia with an unprotected airway and instead administer minimal or moderate sedation or general anesthesia via endotracheal tube or LMA
- Oxygen delivery via non-rebreathing mask with a sampling device used for qualitative ETCO₂ measurement
- Aggressive treatment of bradycardia

References

1. Fisher D, Dominitz JA, et al. Complications of Colonoscopy, *Gastrointestinal Endoscopy* 2011;74:745-752.
2. *Journal Watch Gastroenterology* April 2012.
3. Cooper GS, Kou TD, Rex DK, Complications Following Colonoscopy With Anesthesia Assistance: A Population-Based Analysis, *JAMA Internal Medicine*;2013; 173(7):551-556.
4. Khalid-de Bakker CA, Jonkers DM, et al. Cardiopulmonary events during primary colonoscopy screening in average risk population. *Neth J Med.* 2011 Apr; 69(4):186-91.
5. Koehler U, Becker HF, et al. Relations among hypoxemia, sleep stage, and brady arrhythmia during obstructive sleep apnea. *AM Heart J.* 2000 Jan; 139 (1 PT 1):142-8. ❖

Underwriter's Spotlight

The Dark Side of the Moon: Moonlighting may increase anesthesia practice group's liability exposure

Moonlighting, or practicing outside of an anesthesiologist's primary practice group, may appeal to PPM policyholders for many reasons. Anesthesiologists may be looking for ways to pay off medical school debt, increase their income, teach or volunteer. There are, however, several important questions and factors for the individual anesthesiologist to consider before entering into a moonlighting arrangement. There are also potential liability exposures for anesthesia practice groups that allow their physicians to moonlight.

For the individual PPM policyholder:

- **Review your contract.** Most anesthesia practice groups require new employees to execute an employment contract as part of the hiring process. PPM policyholders should review their employment contract for terms and conditions that could impact their ability to moonlight. Employment contracts may require the anesthesiologist to obtain written permission from the anesthesia practice group before engaging in moonlighting positions. Other employment contracts may disallow employees to engage in moonlighting practice.
- **Insurance.** If the employment contract allows employees to moonlight, PPM policyholders should make sure they fully understand their professional liability insurance coverage while moonlighting. PPM policyholders may believe they are covered by the facility or entity that hires them to moonlight; however, that may not be the case. Additionally, insurance coverage under the individual's PPM policy requires notifying PPM and having the moonlighting practice location endorsed on the PPM policy.

For the anesthesia practice group:

PPM insured anesthesia practice groups may have potential liability exposure arising from moonlighting employees. Most states recognize common law agency principles that allow employers to be sued for the acts or omissions of their employees. Even if the employee is not officially acting on behalf of the employer, if the patient reasonably believes or relies on certain representations that the employee is acting on behalf of the employer, most states will allow those patients to sue the employer for injuries allegedly caused by the employee. These legal claims are typically referred to as apparent or ostensible agency claims.

Courts will look at several factors to determine if an employee was acting on behalf of the employer or as an independent contractor if the alleged injury arises when the employee is moonlighting. Those factors include, but are not limited to:

- Did the anesthesia practice group control the physician's time, place and manner of employment?
- Did the physician hold him or herself out to the patient as being an employee of the anesthesia practice group when engaging in moonlighting activities?
- Did the physician wear any clothing, badges, scrubs, etc. identifying the anesthesia practice group when engaging in moonlighting activities?
- Did the physician use any documents, letterhead, business cards, materials or equipment belonging to or identifying the anesthesia practice group when engaging in moonlighting activities?

Typically, no single factor will determine whether the court will allow a plaintiff to sue the anesthesia practice group based on a theory of apparent or ostensible agency. However, in PPM's experience, the more factors that exist increase the likelihood that the court will allow the plaintiff to add the anesthesia practice group as a defendant.

According to Patsy Kremer, Senior Underwriter, "If a PPM anesthesia practice group allows their employees to moonlight or is aware their employees are moonlighting, we recommend the group contact PPM's Underwriting Department so we can discuss any issues and address any potential liability exposure those moonlighting arrangements might create." PPM also has sample language to include in the practice group's employment contract or moonlighting agreement to help protect the anesthesia practice group from potential liability exposure created by moonlighting activities. ❖

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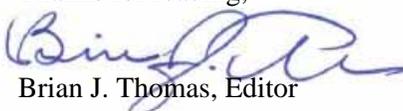
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In This Issue

Over the past five years, PPM has identified a developing loss trend involving anesthesia-administered sedation/general anesthesia for endoscopic procedures, including catastrophic complications resulting in brain damage and death. To date, PPM has paid losses approaching \$5 million from endoscopic anesthesia claims. Additional cases involving significant injuries from endoscopic anesthesia procedures are pending. In this issue, we highlight several cases involving allegations against PPM insured anesthesia providers for injuries resulting from the administration of deep sedation/general anesthesia with propofol. We also offer some risk management strategies to avoid and minimize patient injuries and potential liability resulting from the administration of endoscopic anesthesia. Finally, in the Underwriter's Spotlight, we address the potential increased liability exposure to anesthesia practice groups whose anesthesia providers practice outside of the group, often described as "moonlighting."

Thanks for reading,


Brian J. Thomas, Editor

Note: The purpose of this newsletter is to provide information to policyholders and defense counsel regarding professional liability issues. Risk management analysis is offered for general guidance and is not intended to establish a standard of care or to provide legal advice.

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