

Placement of Gastric Calibration Tubes Inflates Anesthesiologists' Liability Exposure

In the past several years, PPM has identified a developing loss trend involving patient injuries and litigation arising from anesthesiologists placing gastric calibration tubes. Similar adverse outcomes and injuries related to gastric calibration tube placement have been reported to the Federal Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.

Anesthesiologists may be asked to place gastric calibration tubes to assist surgeons even though placement of the tubes are part of the surgical procedure and not the anesthetic care. Anesthesiologists working at the direction of the surgeon may believe the surgeon remains ultimately responsible for the care provided at the surgeon's direction, but this is often not the case, as highlighted in the following case summaries. In the event of an adverse outcome related to the calibration tube placement or use, surgeons are typically not named as defendants and often blame the anesthesia provider for the patient's injuries.

One recent case involved a 40 year-old female patient who underwent a laparoscopic gastric sleeve resection with general anesthesia. During surgery, after the sleeve had been created, the surgeon asked the PPM insured anesthesiologist to introduce air through the calibration tube to check for a leak in the anastomosis. Instead of introducing air through the fenestrated suction port in the stomach, he used the balloon port and inflated the balloon causing injury to the gastric sleeve. The surgeon closed the injured muscle layers and performed an endoscopy to check for a leak. Another surgeon was consulted and it was decided that the patient required gastric bypass.

Following the gastric bypass, the patient required a lengthened hospital stay (10 days) and multiple evaluations to ensure there was no leaking or any evidence of perforation. Treatment was conservative bowel rest and nasojejunal feedings. The patient was discharged with home health and tube feedings.

The patient retained an attorney who filed a claim against the PPM insured anesthesiologist. The patient alleged that the anesthesiologist was negligent in inflating the balloon port instead of the fenestrated suction port. The surgeon was not named in the claim.

The patient testified in her deposition that after the incident the anesthesiologist explained to her that he inflated the incorrect port of the calibration tube. The surgeon did not accept any responsibility for the miscommunication with the anesthesiologist regarding use of the correct port to inflate the gastric sleeve. The surgeon also wrote a note in the patient's chart blaming the anesthesiologist for the patient's injury.

The anesthesiology defense expert opined the surgeon shared responsibility for the injury due to the surgeon's failure to carefully instruct the anesthesiologist when asking him to introduce air into the calibration tube. This was particularly true in this case as it was the first gastric sleeve procedure in which the anesthesiologist had been involved. This was also the first time the anesthesiologist had worked with this particular surgeon.

During mediation, the patient asserted a claim in the amount of \$690,240 for past and future medical expenses, pain and suffering and loss of enjoyment of life. The PPM insured anesthesiologist consented to settlement and the claim was resolved for \$250,000 based on the recommendations of defense counsel and PPM.

In another case, a 33 year-old female patient presented for laparoscopic banding and hiatal hernia repair. During the case, the surgeon requested the PPM insured anesthesiologist to pass a calibration tube to determine if there was sufficient space in the stomach. The anesthesiologist encountered light resistance when he attempted to pass the tube per the surgeon's request. The surgeon was informed about the resistance and made some adjustment and then asked the anesthesiologist to try again. This time the tube passed without difficulty. At the surgeon's direction, the calibration tube was passed up and down several more times during the procedure. The surgeon then requested 180 mls of methylene blue dye to be administered and no leaks were detected.

The following day the anesthesiologist was informed the patient was tachycardic and was being taken back to surgery. No leaks were found, but an x-ray showed a pneumothorax that was suspected to be the source of the patient's problems. A CT scan was obtained and demonstrated a 20 cm esophageal tear. The tear was repaired surgically and the patient's postoperative course was complicated by respiratory failure, mediastinitis and sepsis. The patient was eventually discharged but continued to complain of long term sequelae, including emesis, pain, nausea and dysphagia.

The patient sued the surgeon and the anesthesiologist. The patient alleged the anesthesiologist caused a significant tear to her esophagus when he passed the calibration tube. The patient initially alleged the surgeon caused weakness in the muscle layer of her esophagus from an errant stitch that predisposed her to a linear tear in her esophagus.

Plaintiff's anesthesiology expert, William Mazzei, MD, San Diego, California, testified that the patient's injury likely occurred during the anesthesiologist's advancement of the calibration tube, coupled with him using too much force in the process of advancement. He also testified that the injury could have been caused by the anesthesiologist inappropriately withdrawing the calibration tube while the balloon was inflated. Finally, he testified that the errant stitch placed by the surgeon was a "red herring" and had nothing to do with the tear in the esophagus.

The defense anesthesiology expert testified that it was not realistically possible to cause a 20 cm tear in the esophagus using the calibration tube. He testified further that he could not envision an anesthesiologist forcing a calibration tube down the throat with the amount of force it would take for the calibration tube to cause a "through and through" injury. The defense expert testified that there is a very small, but well-recognized, risk of perforation every time you insert a tube into the stomach.

The PPM insured anesthesiologist testified in his deposition that this was only the first or second time he had used this particular tube. The anesthesiologist noted he had no formal training regarding this surgical procedure, although the tube was similar to other tubes he had previously used. He also conceded that it is possible that placement of the calibration tube was the cause of the patient's injury.

The case settled prior to trial for \$125,000 on behalf of PPM insured anesthesiologist. The surgeon was eventually dismissed with no payment.

In addition to surgeons blaming anesthesia providers for injuries caused by the placement of gastric calibration tubes, PPM faces several other challenges defending these lawsuits. According to Arik Worsfold, Claims Attorney, "In most cases, the PPM insured anesthesiologist typically had to concede they lacked formal training regarding the surgical procedure, were unfamiliar with the equipment and its proper use, and there was a lack of communication between the surgeon and the anesthesiologist regarding the appropriate use of the calibration tube." Given those facts, PPM's defense counsel have recommended settlement rather than defending these cases at trial. ❖

Risk Management Tips for Preventing Injury from Calibration Tube Placement

- Proactively engage hospitals and facilities regarding involvement in these surgical procedures and obtain appropriate credentialing for these procedures.
- Ensure proper training and familiarity with the calibration tube and its use prior to the procedure, or require surgeons to specifically instruct on the use of the calibration tube if you are unfamiliar with the device or procedure.
- Discuss with surgeon or independently determine any contraindications during pre-operative assessment – e.g. patients with: inflammatory diseases of the gastrointestinal (GI) tract, congenital or acquired anomalies of the GI tract, potential upper GI bleeding conditions, etc.
- Ask the surgeon to visually direct the placement via EGD.
- Document surgeon's request and direction to use the calibration tube and note any "off-label" manner inconsistent with the manufacturer's Directions of Use (DOU).

Underwriter's Spotlight

Ethical and legal guidelines for treatment of non-patients or self-treatment

Providing medical treatment to family, friends, colleagues and self-treatment is reportedly widespread among physicians, but is it a good idea? PPM has defended 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 to 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 obvious conflicts these situations 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."

Similarly, the American College of Physicians (ACP) Ethics Manual states, "Except in emergent circumstances when no other option exists, physicians ought not care for themselves. A physician cannot adequately interview, examine, or counsel herself; without which, ordering diagnostic tests, medications, or other treatments is ill-advised. Regarding people with whom the physician has a prior, nonprofessional relationship, including family members, friends or acquaintances, colleagues, and employees, the physician's prior emotional or social relationship complicates what would become the professional patient-physician relationship."

"Given the morass of potential legal and ethical pitfalls that might arise from treating non-patients or self-treatment, PPM's advice to our policyholders is to avoid those situations unless it falls within one of the exceptions," according to John Morhiser, PPM's Underwriting Supervisor. ❖

References:

1. AMA Code of Medical Ethics, Opinion 8.19 <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page>
2. ACP Ethics Manual https://www.acponline.org/running_practice/ethics/manual/manual6th.htm

PPM has Moved

On August 20, 2015, PPM moved to a new location. Please update your records with our new address.

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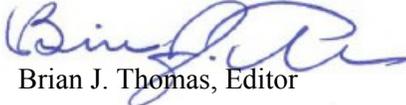
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In This Issue

We examine a developing loss trend involving patient injuries and litigation arising from anesthesiologists' participation in a surgical procedure, specifically placing gastric calibration tubes. Complications resulting in significant patient injuries include over-inflation of the balloon port causing injury to the gastric sleeve and esophageal perforation. We highlight two case summaries and offer some risk management strategies to assist PPM policyholders in avoiding and minimizing patient injuries and potential liability resulting from the placement of gastric calibration tubes. Finally, in the Underwriter's Spotlight, we address some ethical and legal guidelines and potential pitfalls surrounding providing medical treatment to yourself, family, friends and colleagues.

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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