PPM ANESTHESIA MALPRACTICE INSURANCE

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PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP, INC.

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Risk Management for Postoperative Vision Loss

Postoperative vision loss (POVL) after spine surgery is one of the more serious complications reported to Preferred Physicians Medical (PPM) and the number of POVL cases is on the upswing. In an ongoing effort to identify developing anesthesia malpractice loss trends, PPM has been closely monitoring these cases and the developing body of medical literature.

In conjunction with ongoing risk management efforts, PPM recently conducted a retrospective study of 17 recent cases of POVL. This study has been helpful in improving our ability to manage ongoing POVL litigation files, and provides the basis for our preliminary risk management recommendations. At the same time, we note that this particular injury is currently under review by the American Society of Anesthesiology (ASA). The ASA Committee on Professional Liability established a Postoperative Visual Loss Registry in 1999 and has now collected detailed data on more than 75 cases. While POVL has now garnered increased attention, to date, no comprehensive conclusions have been reached. More importantly, given the preliminary nature of the research, no specific methodologies for reducing the risk of POVL have been introduced. While the medical community will ultimately need to provide anesthesiologists with concrete protocols for reducing the risk of POVL, in the interim, PPM offers the following risk reduction strategies.

The importance of informed consent

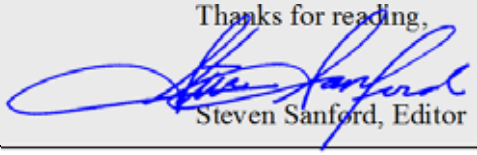
First, because the underlying causes of POVL are still under investigation, PPM initially recommends revising informed consent documents to include vision loss as a general risk on all standardized anesthesia informed consent documents. A nationwide cross-section of informed consent forms reviewed by Preferred Physicians Medical demonstrates that vision loss is not routinely included as a generalized risk of anesthesia. In fact, our own recommended informed consent document did not mention any risk of vision loss until just this year. This revised informed consent document is now available from PPM's Claims Department.

In addition to addressing POVL on routine informed consent documents, PPM recommends additional steps for any anesthesiologist whose practice includes a significant number of spine surgeries. The anesthesiologist, in conjunction with orthopedic and neurosurgeons, should collaborate to insure that both anesthesia and surgical consents for spine surgery provide more detailed disclosures regarding the risk of POVL. We also encourage surgeons to review and update any patient literature that is routinely provided to spine surgery patients. Such literature should include a detailed discussion of the risk of POVL. Anesthesiologists practicing in facilities that perform a significant number of spine surgeries should likewise be familiar with the most recent medical literature regarding POVL and prepared to discuss this risk with patients. In this regard, Preferred Physicians Medical has included in this newsletter, a recent article by Dr. Lorri A. Lee, the Director of the ASA POVL Registry. In addition, at the conclusion of this article is a reference list of related medical articles.

In this Issue

Preferred Physicians Medical has noted an increase in the number of claims involving post-operative vision loss (POVL) following spine surgeries performed using controlled hypotension. In this issue, we discuss recent cases of POVL and provide preliminary information from the ASA's POVL Registry. Unfortunately, until the medical community is better able to understand the causes of POVL and develop prevention protocols, this devastating and costly injury will continue to impact anesthesia malpractice rates. In the interim, based on our experience defending POVL litigation, we offer some preliminary risk management suggestions.

Thanks for reading,



Steven Sanford, Editor

We should note that during several recent on-site risk management seminars, anesthesiologists have indicated that orthopedic surgeons in their facilities have resisted recommendations to bring the risk of vision loss to the patient's attention on the day of surgery. Unfortunately, many of these same orthopedic surgeons also refuse to specifically address this risk with their patients during earlier visits where it could be addressed in a more detailed and less anxiety-prone manner. For this reason, we encourage anesthesiologists to bring this issue to the attention of the hospital or health care facility and request that steps be taken to implement a comprehensive approach based on input from surgeons, anesthesiologists and the nursing staff. PPM has and will continue to assist its policyholders in these efforts. Also, by creating a paper trail for our POVL recommendations, PPM is in a better position to defend its policyholders in cases where the surgeons and/or facilities have refused to adequately address this issue.

It should be noted that in the litigation setting, orthopedic surgeons routinely testify that the issues surrounding POVL are a complication associated with anesthesia care and therefore the anesthesiologist, not the orthopedic surgeon, is responsible for discussing this risk with the patient. With such litigation posturing in mind, it is essential that anesthesiologists insist that the risk of POVL be appropriately addressed by their health care facilities.

Addressing the medical causes of POVL

Litigation involving vision loss or eye injuries has been familiar territory for PPM. Past cases have focused on actual trauma to the eye (corneal abrasion, globe puncture caused by retrobulbar or peribulbar blocks) or vision loss in prone patients where improper positioning of the head resulted in central retinal artery occlusion. Today, vision loss cases are more often cases of POVL following spine surgery. In these cases, the patient's vision impairment is typically diagnosed as ischemic optic neuropathy (ION). In earlier years, incidents of ION were more typically associated with cardiopulmonary bypass or other procedures with extensive blood loss and long periods of hypotension. In more recent years, the majority of cases involving ION are now associated with lengthy spine surgeries, especially those that utilize controlled hypotension.

While the exact mechanism of injury is not known, recent studies, including those of the ASA, point to a number of risk factors, including the length of surgery, long periods of low blood pressure (controlled hypotension), low hemoglobin levels, and prolonged periods in the head-down position.[1-7] Other factors may also have inadvertently increased the number of patients at risk. Conservative transfusion policies designed to address concerns with transfusion borne infections like HIV, may have both increased the number of patients undergoing surgery with marginal hemoglobin levels and also deterred anesthesiologists from treating anemia as quickly.[8] Based on our handling of litigation files, we offer the following preliminary risk management suggestions:

- Review and re-evaluate transfusion policies for patients undergoing spine surgery. The risk-benefit analysis should consider the increased risk of POVL as a factor in determining whether to transfuse a patient scheduled for a lengthy spine procedure. Anesthesiologists should also consider how quickly to treat perioperative anemia given its suspected role in POVL. In this regard, more aggressive blood replacement may be indicated, rather than relying primarily on crystalloid.
- Adjust the level of controlled hypotension to reflect individual patient characteristics. Our litigation files suggest that a "cookie-cutter" approach may be partly responsible for adverse outcomes. Thoughtful adjustments in the controlled hypotension technique, according to the experts, are indicated in patients with low hemoglobin levels, hypertension or hypotension, atherosclerosis, diabetes mellitus, etc.
- Staging spine surgery. A number of the experts consulted during litigation have suggested the idea of staging especially long surgeries or limiting the period of controlled hypotension by bringing the blood pressure back up at regular intervals or during a pause in the surgical procedure.

While these preliminary recommendations are modest, PPM remains hopeful that such recommendations, along with increased attention to the risk of POVL, will help anesthesiologists to avoid this particular adverse outcome.

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ASA Postoperative Visual Loss Registry: Preliminary Analysis of Factors Associated With Spine Operations

Lorri A. Lee, M.D.

Postoperative visual loss is a devastating perioperative complication that has received increased attention by anesthesiologists, spine surgeons and ophthalmologists over the last five to 10 years. Despite this increased awareness, physicians remain helpless in preventing its occurrence because most of the cases have no proven etiology.

The ASA Committee on Professional Liability established the ASA Postoperative Visual Loss (POVL) Registry in July 1999 to collect detailed information on these cases obtained through anonymous submissions. The goal of the ASA POVL Registry is to collect 100 cases of postoperative visual loss and search for common patient characteristics and/or perioperative events that may be associated with the development of this complication. As of this writing, 79 cases of postoperative visual deficits after nonophthalmologic surgery have been submitted to the ASA POVL Registry.

Preliminary Data From ASA Postoperative Visual Loss Registry: Associated Factors From Spine Cases*

	Ischemic Optic Neuropathy (n=43)	Central Retinal Artery Occlusion (n=7)
Age-years, median (range)	49 (19-73)	49 (35-71)
Headrest:		
Mayfield tongs	8 (18%)	0
Horseshoe	0	2 (29%)
Foam	33 (77%)	3 (43%)
Unknown	2 (5%)	2 (29%)
Prone time-hours, median (range)	8 (3-24)	5.5 (3.4-9)
EBL† liters, median (range)	2.3 (0.2-20.0)	0.7 (0.5-1.3)
Lowest Hct percentage, median (range)	25.5 (19-40)	33(29-38)
Bilateral disease	25 (58%)	0
No vision recovery	24 (56%)	7 (100%)

* Three cases with unknown diagnosis for vision loss not shown. † EBL = estimated blood loss

Table 1

Preliminary analysis of the database indicates that the majority of cases are associated with spine operations (67 percent) followed distantly by cardiac bypass procedures (10 percent). The remaining 23 percent of cases are composed of liver transplants, thoracoabdominal aneurysm resections, peripheral vascular procedures, head and neck operations, prostatectomies and miscellaneous cases. Because spine operations comprised such a large percentage of the ASA POVL Registry, these cases were analyzed separately.

Of the 53 cases of postoperative visual loss associated with spine surgery in the registry, ophthalmologic diagnoses included ischemic optic neuropathy (n = 43, 81 percent), central retinal artery occlusion (n = 7, 13 percent) and unknown diagnosis (n = 3, 6 percent). Potential associated factors for spine operations with ischemic optic neuropathy were compared to those for spine operations with central retinal artery occlusion [Table 1]. Patients were similar in age but had striking differences between groups for other factors.

Eight of 43 patients who developed ischemic optic neuropathy had their heads positioned in Mayfield tongs with their faces free from external pressure, whereas none of the patients who developed central retinal artery occlusion was positioned in Mayfield tongs. Two patients from the central retinal artery occlusion group were positioned in a horseshoe headrest. Patients in the ischemic optic neuropathy group had longer periods in the prone position (eight hours) with larger estimated blood loss (2.3 liters) compared to the central retinal artery occlusion group (5.5 hours and 0.7 liters). Consistent with the estimated blood loss, the median lowest hematocrit was lower in the ischemic optic neuropathy group (25.5 percent) compared to the central retinal artery occlusion group (33 percent).

More than half of the ischemic optic neuropathy group had both eyes affected, whereas none in the central retinal artery occlusion group demonstrated bilateral disease. Recovery of vision occurred in 44 percent of the ischemic optic neuropathy group compared to 0 percent recovery in the central retinal artery occlusion group.

This preliminary analysis of potential associated factors in ischemic optic neuropathy spine patients compared to central retinal artery occlusion patients from the ASA POVL Registry supports previously published literature reviews and case reports. The etiology of central retinal artery occlusion is thought to be caused by direct pressure on the globe from face masks, or cushions in the prone position, by emboli or by low perfusion pressure in the retina.[1] The findings of low estimated blood loss, lack of anemia, shorter duration of prone position, unilateral disease and no vision recovery are all consistent with these proposed etiologies. Unilateral periorbital bruising, proptosis, paresis of extraocular eye muscles and/or supraorbital paresthesias may be found in association with central retinal artery occlusion when it is caused by direct pressure on the globe.

In contrast, the etiology for ischemic optic neuropathy is unknown and possibly multifactorial. It has been associated with large blood loss, hypotension, anemia, the prone position and/or vaso-occlusive disease, though specific etiologies for anterior and posterior ischemic optic neuropathy may differ.[1,2] The preliminary data in Table 1 demonstrate a relatively large blood loss, presence of a moderate anemia and long duration in the prone position in the ischemic optic neuropathy group. The occurrence of this disease in eight spine surgery patients whose heads are suspended in Mayfield tongs strongly supports the theory that ischemic optic neuropathy is not caused by direct pressure on the globe. Moreover, the high percentage of patients with bilateral disease makes direct globe pressure an unlikely etiology.

Although the preliminary data suggest unique etiologies for different types of ophthalmologic lesions causing postoperative visual loss, larger numbers of cases will be required before a meaningful statistical analysis can be performed. Collection and analysis of these cases will provide insight into the perioperative events surrounding the development of this complication. For example, as discussed above, the ASA POVL Registry now contains strong evidence that the most commonly reported form of postoperative visual loss, i.e., ischemic optic neuropathy, occurs in the absence of direct pressure on the globe. The data refute a misperception commonly held by surgeons, patients and even many anesthesiologists, and it broadens the potential for research into this perplexing perioperative complication. More definitive data on postoperative visual loss will be gained by obtaining the goal of 100 patients in the ASA POVL Registry. For more information, please visit our ASA POVL Registry Web site at www.asaclosedclaims.org.

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ASA Postoperative Visual Loss Registry: Preliminary Analysis of Factors Associated With Spine Operations (2003) is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068-2573 and its author Lorri Anne Lee, MD. ❖

POVL: Michigan Defense Verdict

Plaintiff, a 51 year-old male, underwent a lumbar laminectomy with fusion and instrumentation. The procedure was performed under general anesthesia with controlled hypotension. Anesthesia time was almost 9 hours, with the patient in the prone position for slightly more than 8 hours. The patient's history included smoking one pack per day for over 30 years, obesity, blood pressure of 124/80 and a pre-operative hemoglobin/hematocrit (H&H) of 12.5/35.9. During the course of the case, the patient's blood pressure was reduced, at its lowest point, to 90/52. Throughout the case the patient's mean arterial blood pressure (MAP) was maintained at approximately 70mmHg and never fell below a MAP of 65.

H&H levels during the surgery were recorded as 10.1/28.2 and in PACU the H&H was 10.3/28.9. The anesthesiologist administered approximately 7000cc of lactated ringers and recorded urine output of 1000cc.

Following surgery the patient complained of visual impairment and later filed a lawsuit claiming he was unable to see with his left eye and had approximately 10 percent vision in his right eye.

Plaintiff's anesthesia expert, William Berger, MD, focused mainly on the issue of fluid management and opined that fluid overload resulted in ischemic optic neuropathy and POVL (Note: Dr. Berger ranked as the third most prolific plaintiff's expert against PPM according to figures from December, 2002, see Anesthesia & the Law, Issue 13). According to Dr. Berger the patient's injury was caused by edema resulting from excess fluid that was administered. Dr. Berger testified that no more than 3 or 4 liters of fluid should have been given, not the 6 to 7 liters actually administered in this case. Dr. Berger also testified that eye checks were not performed during the course of the procedure, as this was not noted on the anesthesia record, and contributed to the patient's injury.

Plaintiff's neurology expert, Steven Newman, MD, testified that a post-operative MRI showing fluid build-up in the patient's sinus was evidence of a fluid overload that caused the injury to the optic nerve. Dr. Newman's independent examination of the patient confirmed that there was complete vision loss in the left eye and a significant impairment of the right eye.

PPM's anesthesia experts were Steven Roth, MD from the University of Chicago and Kevin Tremper, MD from Michigan. Dr. Roth conceded that the patient probably did experience a posterior ischemic optic neuropathy, but indicated that such injuries can occur without negligence. According to Dr. Roth the controlled hypotension was properly managed and that a decrease of approximately 35 percent in the patient's MAP was not significant. Dr. Roth also found that a hematocrit of 28 was also not a significant change. In addition, Dr. Roth testified that the fluid administered was appropriate at 6.8 liters in this particularly long surgery. Dr. Tremper testified that the anesthesiologist in this case had complied with the standard of care with respect to the level of controlled hypotension and the need to transfuse the patient, and that eye checks had indeed been performed based on the testimony of the anesthesia providers. The expert anesthesia testimony was bolstered by a defense neurologist who indicated that post-operative fluid in the sinuses was a normal MRI finding, especially in a patient with longstanding sinusitis, and not an indicator of fluid overload.

Despite the fact there was contradictory expert testimony; the jury was perhaps most persuaded by evidence provided by the patient himself. After initially claiming in discovery documents and at his earlier deposition that he was unable to work, drive or help around the house, the patient's testimony at trial changed after the defense revealed that it had conducted videotaped surveillance. At trial, the plaintiff conceded that has been able to drive on a limited basis and had resumed hunting. PPM's defense counsel then showed the videotape to the jury which included footage of the patient engaged in activities that were inconsistent with his claims of significant vision impairment.

The jury deliberated for one hour prior to returning a unanimous defense verdict. Prior to trial settlement discussions had taken place at the request of PPM's insured, but the plaintiff attorney was unwilling to accept an amount that PPM deemed reasonable. At trial, the plaintiff's attorney asked the jury to award $700,000.

This case was tried by Art Jalkanen of Schwartz & Jalkanen in Southfield, Michigan in February, 2004. Wade Willard, Senior Claims Attorney managed the file on behalf of Preferred Physicians Medical. ❖

PPM Aggressively Pursues Recovery of Costs

Given an increase in the number of cases tried to jury verdicts over the last three years, PPM has embarked on an aggressive attempt to recover litigation costs that are permitted following a successful defense verdict. While the laws allowing recovery vary greatly from state to state, PPM believes that our cost recovery efforts are an important tool in the success of the Company.

As attorney and expert witness fees continue to escalate, the total cost of defending a malpractice case to a jury verdict typically ranges between $50,000 and $200,000 depending on the complexities of the medical issues, the number of defendants and the jurisdiction in which the lawsuit is filed. Pursuing a recovery of costs is just one method that PPM utilizes to help minimize the cost of malpractice insurance for our policyholders.

During the course of the last 18 months, Preferred Physicians Medical has secured judgments of $527,004.38 back against the plaintiffs. "While the amounts awarded can be significant, such award may not necessarily be collected in full, or even at all" according to Brian Thomas, Senior Claims Attorney at PPM. "The amount of money awarded by the court following a defense verdict is a judgment imposed on the actual plaintiff, not his/her attorney. Such awards may be uncollectible if the plaintiff has little money, or decides to simply avoid the judgment by filing for bankruptcy protection."

Despite the difficulty of collecting a cost recovery judgment, Mr. Thomas, indicates that the "mere entry of a cost collection judgment is a powerful tool, even when the judgment cannot be collected. Such a judgment can provide the basis for avoiding a threatened appeal, it may help dissuade other attorneys and litigants from pursuing frivolous cases, and it can assist us in negotiating a more favorable settlement." According to Mr. Thomas, "plaintiffs tend to be far more reasonable in settlement discussions, once we explain our intention to pursue a judgment against them following a defense verdict. Given that plaintiff attorneys work on a contingency fee, it is often the first time the plaintiff has had to consider the possibility of not only losing the case, but actually owing PPM a considerable amount of money."

Wade Willard, another Senior Attorney at PPM, went on to remark that "a judgment, even if it is not collectible, creates a serious inconvenience for the plaintiff. By securing a cost recovery judgment against the plaintiff, at a minimum PPM may be able to place a lien on the plaintiff's home. This by itself will prevent the plaintiff from selling the house without satisfying the lien. The judgment will also be reflected on credit reports and is often enough to prevent the plaintiff from refinancing an existing loan, obtaining a home equity loan, or even obtaining advantageous financing arrangements on household furniture or automobile purchases." During settlement negotiations, Mr. Willard indicates that he "will typically inform the plaintiff that PPM intends to aggressively pursue the collection of costs, especially in those situations where plaintiffs have not been reasonable in their settlement negotiations."

Over the last year, PPM has actually collected approximately $253,787 from plaintiffs. Judgments recovered to date have ranged from $2,172.05 to $150,000. ❖

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Catch the latest risk management trends, read recent jury verdicts and learn more about Preferred Physicians Medical on our website – www.ppmrrg.com. Several past issues of Anesthesia & the Law are also available on-line. ❖

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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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