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TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

Complications in Interventional Pain Medicine

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Introduction

Contemporary pain management is founded on appropriate diagnostic evaluation followed by multimodal treatment incorporating medical, psychological, physical and interventional modalities. The use of interventional therapies in this context has seen meteoric growth in both the type and volume of interventional procedures used to treat chronic pain conditions. Incomplete or inadequate treatment responses to current treatment modalities have fostered ongoing research and the introduction of many new treatment modalities. While new interventional techniques have improved outcomes in some patients, they have also been associated with severe complications. These include commonly reported complications such as pneumothorax, headache, back pain, bleeding, drug toxicity and infection as well as reports of catheter, lead or device breakage, methylmethacrylate migration, granuloma development, direct neural trauma, stroke and death. This refresher course addresses complications related to interventional pain treatments and suggests methods for their avoidance when appropriate.

Scope of the Problem

The relative risk associated with interventional pain therapies has been steadily increasing in concert with the increase in medical judgment and technical skill required to use them effectively. In a 2004 publication derived from data maintained within the American Society of Anesthesiologists Closed Claims Project, Fitzgibbon et al.¹ identified and described issues and trends in liability related to chronic pain management by anesthesiologists. The authors reviewed the closed claims database between 1970 and 1999 to identify liability related to chronic pain management. They excluded all claims related to acute pain management. They compared outcomes and liability characteristics of 284 pain management claims to 5,125 surgical/obstetric claims. Claims related to chronic pain management increased over time in concert with the growth in pain medicine. They accounted for 2% of the claims in the 1970's, 3% in the 1980's and 10% of all claims in the 1990's. Payments for chronic pain management claims were lower than surgical/obstetric claims from 1970-1989. During the 1990's, there was no difference in size of payments between chronic pain management and surgical/obstetric claims. Almost one-third of chronic pain management claims resulting in payment in the 1990's involved a permanent and disabling injury as compared to only 17% from 1979-1989 although this difference was not considered statistically different. In 64% of chronic pain management claims, the injury became apparent after discharge from the treatment facility. Of the 284 chronic pain management claims in the database, 276 involved invasive procedures. Epidural steroid injections accounted for 83% of injections and 40% of all chronic pain management claims. Peripheral and autonomic blocks accounted for 36% of the block claims. The most common complication of blocks was pneumothorax. The most common complications involving epidural steroids were nerve injury, infection and headache. Claims related to ablative procedures involved unintentional nerve injury in 47% of the cases. Infection or retained catheter fragments were the most common complications related to implantation or removal of devices, while the most common outcome of claims related to maintenance of devices was death or brain damage. In 2010, Rathmell et al.,² compared cervical procedures to other chronic pain claims collected from 2005 through 2008 in the ASA Closed Claims Database. The data in this manuscript is notable not only for the dramatic number of claims related to cervical procedures, but the fact that there were more claims entered for chronic pain in a four year period than the entire previous review of chronic pain claims for a 30 year period. There were 64 cervical procedure claims (22%) among 294 chronic pain claims. Cervical procedure claims occurred more often among women and in healthier individuals. The most common diagnoses included cervical radicular pain (50%) and neck pain of musculoskeletal origin (28%), CRPS (11%) and spinal stenosis (5%). Ninety-one percent of the cervical procedures were blocks with (67%) being epidurals, (11%) stellate ganglion blocks, (9%) trigger point injections and (3%) intra-articular facet injections. In

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ANESTHESIOLOGY 2012

TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

eighty percent of the cases, the damaging event was directly related to the procedure; needle trauma to the cord (31%), cord infarction/stroke after intra-arterial injection (14%), dural puncture (6%), compressive hematoma (5%), infection or abscess (5%), high block/total spinal (5%), inadvertent intravascular injections of local anesthetic (3%) and pneumothorax (3%). General anesthesia or sedation was used in (67%) of cervical procedure claims with spinal cord injuries, but only (19%) of cervical procedure claims without spinal cord injuries. In claims with information regarding radiographic guidance, it was used in (76%) of cases with spinal cord injury. The authors found evidence of contrast use with radiographic guidance in (57%) of claims with spinal cord injury compared with (17%) of claims without spinal cord injury after a cervical procedure. Further study is needed to develop approaches to prevent catastrophic neurologic injuries occurring during pain procedures at the cervical level and to clarify the role that general anesthesia and/or sedation may have in the occurrence and severity of injury. Although data in these studies is limited to that available from closed claims, the trends identified provide valuable insight into the larger picture of significant complications associated with interventional pain procedures and in particular cervical interventional pain procedures that have limited evidence to support their use.

Injections (Trigger Point, Facets, Epidural Steroid ± Associated Agents, Other)

Injections are performed with the greatest frequency and have the greatest number of complications. Trigger point injections have been associated with a variety of significant complications including, bleeding, local infection, epidural abscess,³ seizure, myotoxicity⁴ and pneumothorax.⁵ Facet injections are performed less commonly, but have been associated with significant complications as well. Those reported in the medical literature include infection,^{6,7} pneumothorax¹, spinal cord injury and death.^{8,9,10} The medical literature is sparse concerning other complications that may have occurred in association with facet injection, but hematoma and nerve injury would not be unexpected. The largest and most devastating group of complications has been associated with performance of epidural steroid injections. Although common, the occurrence of accidental dural puncture is less threatening than other reported complications. Some practitioners have advocated the use of the transforaminal approach as a means of avoiding dural puncture. A cases series of transforaminal injections published in 2000 using both fluoroscopy and contrast confirmation identified 0/322 procedures with dural puncture, although the incidence of transient headache in the same study was reported at 3.1%.¹¹ Another prospective series performed at two academic medical centers using an interlaminar approach reported a 0.8% incidence of dural puncture with only 25% of cases being performed with fluoroscopy and contrast confirmation.¹² Epidural hematoma has been reported at all levels of the spine following epidural injections and has an estimated incidence of 1:150,000.¹³ There have been numerous reports of epidural hematoma occurring after epidural steroid injection.^{14,15,16,17} In general, if anticoagulant agents are avoided as described in the ASRA guideline for neuraxial anesthesia or limited to NSAIDs alone, the risk of epidural hematoma is felt to be unchanged from the norm.^{12,13} Infection involving the epidural space, discitis, meningitis and osteomyelitis has been reported following epidural steroid injection.¹⁸ Epidural abscesses occur spontaneously with an incidence that has been reported as 0.33-1.96:10,000 admissions per year¹⁹ or related to epidural catheterization with a reported incidence of 1:1930 catheters.^{20,21} The incidence of epidural abscess development related to performance of epidural steroid injections has not been reported. However, there are numerous case reports identifying epidural abscess development.^{22,23,24,25,26,27,28} This complication is more insidious as it develops after the patient has left the treatment facility and may not be promptly discovered or reported by the patient. Underlying medical illnesses and impaired immune function may increase the risk of this complication, which is most commonly produced by *Staphylococcus aureus* species. In those with significant immune compromise, prophylactic antibiotics at the time of the procedure may be warranted. Neuropathic pain may develop following epidural steroid injection and has been hypothesized to be the result of nerve root irritation caused by the steroid solution or damage to the spinal cord or nerve roots without dural puncture by minor compression of neural elements.²⁹ Direct trauma to the spinal cord in association with performance of cervical, thoracic and lumbar epidural steroid injections has been reported in procedures performed with and without fluoroscopic imaging.³⁰ Those cases associated with demonstrable spinal cord injury have been associated with permanent neurological injury. A variety of methods to

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ANESTHESIOLOGY 2012

TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

avoid this type of devastating complication including avoiding sedation, using imaging, contrast or a local anesthetic test dose have been suggested, although significant injury has occurred despite use of all currently recommended safety measures. Tripathi et al., reported a case of paraplegia after intracord injection during attempted epidural steroid injection in an awake patient under fluoroscopic guidance.³¹ In the case report, they comment “it seems fluoroscopy guidance may not prevent intrathecal perforation or spinal cord penetration.” In a letter to the editor regarding this article published in May 2006, Drs. Munir, Rastogi and Nedeljkovic comment that the implications of this statement cannot be understated and reiterate the fact fluoroscopy does not protect patients from injection related complications.³² This is corroborated in the Anesthesia Patient Safety Foundation newsletter published in 2005 that analyzed 13 claims related to complications after cervical epidural steroid injections.³³ Twelve of 13 cases had been performed with fluoroscopic guidance. In recent years, transforaminal approaches to epidural steroid injections including both lumbar and cervical approaches have been associated with a growing number of severe complications including blindness, stroke, spinal cord injury and death.^{34,35,36,37,38,39} The exact etiology of these devastating injuries is not clear, but has been variously theorized to be the result of radicular artery spasm, vascular injury or intravascular injection of particulate steroid into medullary or vertebral arteries. Although an outright recommendation to abandon this approach has not been advocated, modifications in needle choice, needle location, imaging and drug administration have all been proposed. At the present time, needle placement in a dorsal portion of the foramen where medullary vessels are less likely to be located is being proposed as one means of reducing risk. Other imaging approaches to reduce the risk include the use of live fluoroscopy during injection of contrast at a minimum along with digital subtraction angiography (DSA) if it is available. The use of DSA will improve the sensitivity for detecting intravascular injection.⁴⁰ Some clinicians have advocated injecting local anesthetics prior to injecting a steroid medication and the use of non-particulate steroids such as Dexamethasone as a means of avoiding these complications. Initial outcome data examining the use of this Dexamethasone is limited and suggests that it may not work as well as traditional long lasting preparations.^{41,42} A 2011 dose-response trial for Dexamethasone demonstrated meaningful improvement in radicular pain at 12 weeks after injection with parallel improvements in disability, impression of change and satisfaction measures. There was no difference in efficacy for Dexamethasone 4 mg compared to 8 or 12 mg. (Ahadian 2011 RAPM)⁴³ In addition, there have been some reports of flushing after the use of Dexamethasone in this setting with the occurrence more common in females than males.⁴⁴ The frequency of complications related to transforaminal steroid injections has garnered the attention of the FDA and there is an ongoing effort on their part to understand the problem and collaborate with physicians to develop recommendations to reduce the risk of complications. Finally, co-administration of opioids, local anesthetic or both occurred in 61% of claims reported in the ASA closed claims epidural steroid injection cases and death or brain damage occurred only in epidural steroid injection cases that involved local anesthetics with or without opioids in the injection.¹

Blocks (Peripheral, Axial, Neuraxial, Autonomic)

The most common complication following the performance of blocks is pneumothorax and accounted for 51% of all block claims in the ASA closed claims database. Other complications include infection, nerve injury, dural puncture, vascular injury, hematoma, seizure and death.^{45,46,47,48,49}

Diagnostic Procedures (Discography)

Diagnostic discography continues to be used as a diagnostic procedure. While the performance, interpretation and utility of this diagnostic procedure remains controversial, the technical performance of the procedure has been associated with complications. These include direct neural trauma, dural puncture, vascular injury, drug reaction, disc herniation and infection.^{50,51,52,53,54,55} Of these, infection is the most common complication. Meticulous technique and the use of a two-needle technique are well accepted means of reducing infectious risk.⁵⁶ Both intravenous or intradiscal antibiotics have been utilized as infection prophylaxis although the relative success of using either approach individually or in a combined fashion has not been defined.

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ANESTHESIOLOGY 2012

TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

Ablative Procedures (Radiofrequency ablation, IDET, Coblation, Chemical)

The performance of neuroablative procedures has been associated with a variety of complications. The common complications of infection, hematoma and direct nerve injury as reported with other nonablative procedures are expected. However, complications reported with ablative techniques may also be produced by heat injury outside of the desired area of effect in the case of radiofrequency ablation or IDET and unexpected spread of the neurolytic agent in the case of chemical denervation.⁵⁷ The most commonly reported complications related to IDET include disc herniation and nerve root injury.^{58,59} In addition, a case report of a broken IDET catheter migrating intradurally, producing radiculopathy and requiring surgical removal has been published. There have also been reports of spinal cord injury due to inappropriate lead placement. Major neurologic injury has been reported in relation to the performance of neurolytic celiac plexus blocks with both alcohol and phenol and in one series had an incidence of 1:683.⁶⁰ The mechanism of injury may be related to vascular injury, vascular injection of the neurolytic agent or direct neural trauma.^{61,62,63,64}

Disc Decompression, Nucleoplasty and Laser Discectomy

There is growing interest in the use of devices to reduce disc volume as an alternative to microdiscectomy or open discectomy in patients with contained disc herniation. A variety of techniques have been used including mechanical devices that remove small amounts of disc material, lasers and plasma-mediated ablation. Complications following the performance of these procedures have included mechanical failure of a Dekompressor unit resulting in four inches of the probe remaining in the patient after removal of the probe and epidural fibrosis.^{65,66} As with any percutaneous procedure, complications such as localized pain, infection, bleeding and nerve injury have also been reported.^{67,68}

Vertebroplasty and Kyphoplasty

Despite the controversies surrounding the use of vertebroplasty and kyphoplasty, these techniques are still in widespread use and for well selected patients, the outcomes are excellent. These procedures have been associated with a wide variety of devastating complications including; spread into the spinal canal, late collapse after vertebroplasty,⁶⁹ migration of cement mass,⁷⁰ pulmonary migration of cement,⁷¹ and lumbar artery pseudoaneurysm.⁷² These procedures require great care in patient selection and technique to optimize outcomes.

Implantation, Maintenance or Removal of Devices (Intrathecal, Epidural, Spinal Cord Stimulation)

The use of devices to facilitate drug delivery into the epidural or subarachnoid spaces or provide analgesia via electrical stimulation of the spinal cord has seen significant growth related to the treatment of both non-cancer and cancer related pain. Complications have resulted from implantation, maintenance and removal of these devices. Nerve injury, infections, retained catheter fragments or equipment failure are the most common complications related to implantation and removal of devices.^{73,74} A prospective study by Follett and Naumann identified frequent procedure related complications and underscored the need for careful surgical technique and adherence to implant guidelines.⁷⁵ Complications occurring with maintenance of devices were related to pump programming errors, drug overdose, drug error, concomitant administration of other central nervous system depressants and toxicity or granuloma formation related to chronic intrathecal drug administration.^{1,76,77,78,79,80,81} The incidence of granuloma formation has not been reported, but may be much higher than expected as a result of slow growth and lack of immediate symptom development. In addition, a recent study has suggested that non-cancer pain patients receiving intrathecal opioids have an increased risk of mortality.⁸² Regular evaluation of equipment performance, patient

ANESTHESIOLOGY 2012

TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

function and response to treatment to facilitate detection and treatment of complications at the earliest opportunity is important.

Training in Pain Medicine and Interventional Procedures

The role of training in the incidence and severity of complications related to interventional pain procedures has not been examined. The range of training received prior to the performance of interventional procedures is highly variable and ranges from fellowship trained pain medicine physicians with board certification to physicians with some exposure during residency to physicians from non-interventional specialties taking weekend courses to learn interventional procedures to improve the revenue stream of their practice. In addition, there are non-physician providers with no formal pain training or certification who are performing the entire range of interventional pain procedures including vertebroplasty and spinal cord stimulation. In most cases, the public lacks sufficient sophistication to inquire about the extent of training or board certification prior to undergoing procedures. In other cases, there may be active misrepresentation of credentials. In the case of free standing offices, there may be no mechanism to examine the training or certification of individuals providing pain care. In the hospital setting, the credentials committee may choose to establish a low or high standard in granting privileges to perform interventional pain procedures. In addition, various states have established certain criteria through the medical boards to regulate pain medicine or establish standards. The net effect of these efforts to improve care and reduce complications remains to be seen.

Avoiding Complications

The ability to avoid complications prospectively is a desirable goal for pain medicine. This includes the need to maintain high standards throughout our practices and to participate in ongoing education. There are fundamentals such as using good sterile technique for the handling of medications and performance of interventional procedures. We need to examine new procedures from multiple perspectives including anatomy, physiology, pharmacology and others prior to performing them on humans to determine what complications might occur and how best to avoid them. We also need to develop consistent approaches that represent best practices in order to reduce the risks to our patients. This may include the use of algorithms or checklists to standardize approaches. However, even if these are developed and used, we must constantly question each step along the way and look for ways to improve further. In most cases, if an unusual circumstance is encountered such as aspiration of blood or vascular runoff during injection of contrast, it is reasonable to consider stopping the procedure and either performing it again later the same day or rescheduling for another day. There is no substitute for good judgment and few chronic pain procedures are emergent.

Conclusions

Interventional therapies provide pain relief to some of our most complicated patients, but are accompanied by the opportunity to produce disastrous consequences. It is critical that we continue to examine the complications associated with these procedures and develop clear criteria for patient selection, training and technical performance to provide the greatest potential to produce the desired outcomes. We must be acutely aware of unusual or unexpected symptoms or images before, during or after procedures and aggressive in diagnosing and treating complications as they arise. Furthermore, we must educate our patients about the potential complications that may develop following discharge so that they may promptly seek appropriate medical care. Finally, we must systematically examine treatment outcomes and complications in our own practices, through reports in the medical literature and through systems like the ASA closed claims database so that awareness may be raised, disturbing patterns recognized and improvements in patient selection and technique promoted to the medical community.

ANESTHESIOLOGY 2012

TRANSFORMING PATIENT SAFETY THROUGH EDUCATION AND ADVOCACY

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ANESTHESIOLOGY 2012

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ANESTHESIOLOGY 2012

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ANESTHESIOLOGY 2012

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ANESTHESIOLOGY 2012

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