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#### Introduction

The practice of pain medicine has continued to evolve and contemporary care is characterized by multimodal treatment incorporating medical, psychological, physical and interventional modalities. The past decade has witnessed significant growth in the treatment of pain and in the type and volume of interventional procedures used to address chronic pain conditions. In some cases, inadequate treatment response has fostered the search for new treatment modalities and expanded use of imaging techniques has facilitated the development and performance of new interventional pain procedures. While new interventional techniques have improved outcomes in some patients, they have also been associated with previously unreported 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, granuloma development, direct neural trauma, stroke and death. This refresher course will address complications related to interventional pain medicine and suggest methods for their avoidance when appropriate.

#### **Scope of the Problem**

The practice of interventional pain medicine is associated with risk, but until recently the relative risk associated with this practice had not been described. In a recent publication derived from data maintained within the American Society of Anesthesiologists Closed Claims Project, Fitzgibbon et al.<sup>1</sup> identified and described issues and trends in liability related to chronic pain management by anesthesiologists. The authors reviewed the closed claims database between 1979 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 was the most common complication related to implantation or removal of devices, while the most common outcome of claims related to maintenance of devices was death or brain damage. Although the data is limited to that available from closed claims, the trends identified by the authors are extremely valuable and provide insight into the larger picture of significant complications associated with the practice of interventional pain medicine.

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

This category of procedures is performed with the greatest frequency and has been associated with the greatest number of complications. Trigger point injections are commonly performed using a variety of injectate solutions, most of which are parochial and have limited evidence to support their selection. Although seemingly simple and safe, they have nonetheless been associated with a variety of significant complications including, bleeding, local infection, epidural abscess,<sup>2</sup> seizure, myotoxicity<sub>3</sub> and pneumothorax.<sup>4</sup> Facet injections are performed less commonly, but have been associated with significant complications as well. Those reported in the medical literature include infections<sup>6</sup> and pneumothorax.<sup>1</sup> 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 recent cases series of transforaminal injections using both fluoroscopy and contrast confirmation

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identified 0/322 procedures with dural puncture, although the incidence of transient headache in the same study was reported at 3.1%.<sup>7</sup> 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.<sup>8</sup> Epidural hematoma has been reported at all levels of the spine following epidural injections and has an estimated incidence of 1:150,000.9 There have been numerous reports of epidural hematoma occurring after epidural steroid injection.<sup>10,11,12,13</sup> In general, if anticoagulant agents are avoided as described in the ASRA guideline for neuraxial anesthesia or limited to NSAID's alone, the risk of epidural hematoma is felt to be unchanged from the norm.<sup>8,9</sup> Infection involving the epidural space, discitis, meningitis and osteomyelitis has been reported following epidural steroid injection.<sup>15</sup> Epidural abscesses occur spontaneously with an incidence that has been reported as 0.33-1.96:10,000 admissions per year<sup>14</sup> or related to epidural catheterization with a reported incidence of 1:1930 catheters.<sup>16,17</sup> Although an incidence of epidural abscess development related to performance of epidural steroid injections has not been reported, there are numerous case reports identifying epidural abscess development.<sup>18,19,20,21,22,23,24</sup> 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.<sup>25</sup> 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.<sup>26</sup> Those cases associated with demonstrable spinal cord injury have been associated with permanent neurological injury. A variety of methods to avoid this type of devastating complication including avoiding sedation, using imaging, contrast or 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.<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup> Twelve of 13 cases involved the use of fluoroscopy. In recent years, transforaminal approaches to epidural steroid injections have been associated with severe complications including blindness, stroke, spinal cord injury and death. <sup>30,31,32,33,34,35</sup> The exact etiology of these devastating injuries has not been elucidated, but is theorized to be the result of radicular artery spasm, vascular injury or intravascular injection of particulate steroid into radicular or vertebral arteries. The hazards of this technique were not immediately apparent and now that numerous severe complications have been reported, there have been calls to abandon the technique. At the present time, the most appropriate response may be that suggested in an editorial by Rathmell and Benzon, which calls for further studies and advises those who continue to use the transforminal approach to carefully study the anatomy and adopt a technique that can detect intra-arterial injection before particulate steroid is administered.<sup>36</sup> Finally, the 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.<sup>1</sup>

## 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.<sup>37,38,39,40,41</sup>

### **Diagnostic Procedures (Discography)**

The increased use of interventional pain procedures as well as certain new surgical treatments for low back pain has produced an increased demand for diagnostic discography. While the performance, interpretation and utility of this diagnostic procedure remain 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

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and infection. <sup>42,43,44,45,46,47</sup> 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.<sup>48</sup> The role of intravenous or intradiscal antibiotics as infection prophylaxis is still debated although their use is still recommended.

## Ablative Procedures (Radiofrequency ablation, IDET, 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. The most commonly reported complications related to IDET include disc herniation and nerve root injury.<sup>49,50</sup> In addition, a case report of a broken IDET catheter migrating intradurally, producing radiculopathy and requiring surgical removal has been published. 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.<sup>51</sup> The mechanism may be related to vascular injury, vascular injection of neurolytic agent or direct neural trauma.<sup>52,53,54,5</sup>

## 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.<sup>56,57</sup> 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.<sup>58</sup> 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.<sup>1,59,60,61,62,63,65</sup> 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. Regular evaluation of equipment performance, patient function and response to treatment to facilitate detection and treatment of complications at the earliest opportunity is important.

### Conclusions

Interventional pain procedures provide hope for relief in some of our most complicated patients, but are accompanied by the opportunity to produce disastrous consequences. It is critical that we continue to develop clear criteria for patient selection that will provide us with the greatest potential to produce the desired outcomes. We must be meticulous in learning and performing interventional pain procedures in order to minimize risk. 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 can promptly seek appropriate medical care and long term consequences may be minimized. Finally, we must continue to encourage reporting of complications in the medical literature and systems like the ASA closed claims database so that awareness may be raised and disturbing patterns recognized and addressed.

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