Injury and Liability Associated with Cervical Procedures for Chronic Pain

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ABSTRACT

Background: Prompted by an increase in interventional pain treatments performed at the level of the cervical spine, we investigated the characteristics and patterns of injury in malpractice claims collected from January 1, 2005 to December 31, 2008.

Methods: We compared claims arising from cervical pain treatments with all other chronic pain claims collected from the American Society of Anesthesiologists' closed claims database between 2005 and 2008. Claims for spinal cord injury underwent in-depth analysis for mechanisms of injury and use of sedation during the procedure.

Results: Claims related to cervical interventions represented 22% (64/294) of chronic pain treatment claims. Patients who underwent cervical procedures were healthier (American Society of Anesthesiologists' score, 1–2; $P < 0.001$) and were more often women ($P = 0.011$). Of the patients who underwent a cervical procedure, 59% experienced spinal cord damage compared with 11% of patients with other chronic pain ($P < 0.001$), with direct needle trauma as the predominant cause (31%). General anesthesia or sedation was used in 67% of cervical procedure claims associated with spinal cord injuries but in only 19% of cervical procedure claims not associated with spinal cord injuries ($P < 0.001$). Of the patients who underwent cervical procedures and had spinal cord injuries, 25% were nonresponsive during the procedure compared with 5% of the patients who underwent cervical procedures and did not have spinal cord injuries ($P < 0.05$, $\kappa = 0.52$).

Conclusions: Injuries related to cervical interventional pain treatment were often severe and related to direct needle trauma to the spinal cord. Traumatic spinal cord injury was more common in patients who received sedation or general anesthesia and in those who were unresponsive during the procedure. Further studies are crucial to define the usefulness of cervical interventions and to improve their safety.

What We Already Know about This Topic

- Cervical interventions for the treatment of pain, including epidural injections, are commonly used; however, little is known about their safety.

What This Article Tells Us That Is New

- In the American Society of Anesthesiologists' closed claims database, claims related to procedures performed at the level of the cervical spine composed 22% (64/294) of all claims related to chronic pain treatment.
- Injuries were often severe, permanent, and disabling; were related to direct needle injury to the spinal cord; and were associated with sedation or general anesthesia used during the procedure.

INTERVENTIONAL pain treatment refers to a wide range of specific therapies aimed at treating chronically painful disorders. Most common among interventional pain treatments are the use of epidural injection of steroids to treat acute radicular pain associated with disk herniation or spinal stenosis and facet injection to treat chronic neck or low-back pain associated with facet degeneration. There has been a dramatic increase in the use of interventional pain treatment

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in recent years. In a 10-yr evaluation of Medicare beneficiaries, between 1996 and 2006, there was an overall growth in interventional pain treatment of 197%, with much of the growth because of an exponential increase in the use of facet injections to treat chronic spinal pain.[1] Despite the upsurge in use of interventional pain treatments, recent systematic reviews, meta-analyses, and practice guidelines[2–4] reveal the extreme dearth of evidence regarding their safety and effectiveness.

As interventional pain treatment has become more common, unforeseen complications have been reported. Foremost among these complications is the occurrence of devastating neurologic injuries, including spinal cord infarction and stroke, associated with the intravascular injection of particulate steroids.[5–8] Significant uncertainty and disagreement remain regarding the safety of performing these techniques using deep sedation[9,10] and the role of radiographic guidance in reducing complications.[11] The direct proximity of the spinal cord during interventions performed at cervical spinal levels and the severity of sequelae that follow injury to the cervical spinal cord raise specific concerns about the safety of cervical interventions. We used the American Society of Anesthesiologists' (ASA) closed claims database to review adverse complications of cervical spine pain procedures.

Materials and Methods

The ASA's Closed Claims Project is a structured evaluation of adverse anesthetic outcomes obtained from the closed claims files of 35 US professional liability insurance companies. The data collection process has previously been described in detail.[12,13] In response to an increase in chronic pain claims since the 1990s, a revised Institutional Review Board–approved form, designed specifically to collect detailed information on chronic pain claims, was used for review of closed malpractice claims for chronic pain management, collected from 2005 onward. Each chronic pain management claim file was reviewed by a practicing anesthesiologist (55% of the files were reviewed by a specialist in chronic pain management) who completed the standardized form and narrative summary. Information was recorded concerning patient characteristics, treatment details, sequence of events, critical incidents, mechanism of injury, clinical manifestations of injury, outcomes, and standard of care.

Specific details on claims alleging injury after a range of procedures were added to the data collection instrument and included information on the use of radiographic guidance, the locations or sites of the originating pain, the performed injection or other procedure, the subsequent injury, and the space, mechanism, and manifestations of any neuraxial injuries. Forms and summaries completed by the on-site anesthesiologist reviewer were subsequently reviewed by three pain management anesthesiologists (J.P.R., E.M., and D.R.F.) before incorporation into the database. The current analysis involved chronic pain claims collected from January 1, 2005 through December 31, 2008 from the ASA closed claims database of 8,954 claims.

Inclusion criteria for this report were chronic pain management claims collected between 2005 and 2008 for the ASA's Closed Claims Project. These included all chronic pain treatments and consultations that were alleged to result in injury, whether invasive procedures, medication management, or consultation only.

Definition of Variables

All chronic pain claims were classified based on the location of the procedure as indicated by the on-site reviewer and grouped into the following categories: lumbar, thoracic, cervical (including neck), and other procedure locations. All claims involving procedures in the cervical location (including neck) were classified as cervical procedures for comparison with all other chronic pain claims in the study period. If the procedure in the cervical region was a block, injection, radiofrequency ablation, epidural lysis of adhesions (Racz procedure), or plasma disk decompression, it was classified as a cervical procedure claim. If the cervical injection was an epidural, the specific route (interlaminar, transforaminal, or unknown) was determined. Cervical procedures adjacent to the spine, such as stellate ganglion blocks or trigger-point injections, were included in the category of cervical procedure claims.

The primary diagnosis in each cervical procedure claim was identified as cervical radicular pain with or without radiculopathy, neck pain, spinal stenosis, degenerative disk disease, spondylolisthesis, or complex regional pain syndrome (CRPS).

Damaging events are defined as the mechanism by which an injury or complication occurred or allegedly occurred. These events can be classified as directly related to the procedure (including needle trauma to the nerve or cord, inadvertent intravascular injections, cord infarction/stroke after intraarterial injection, dural punctures, high block/total spinal, pneumothorax, compressive hematoma events, infections or abscesses, or other procedure-related events) or damaging events not directly related to the performed procedure (including failure to diagnose, positioning, patient falling, wrong procedure, patient's condition deteriorated, and patient's expectations for the procedure were not met). Patient expectations for the procedure were classified as not met when the patient alleged the treatment provided inadequate pain relief or made the pain worse.

The severity of the injury was ascertained using the National Association of Insurance Commissioners' 10-point scale, ranging from 0 (no obvious injury) to 9 (death).[14] For this analysis, severity was divided into the following four categories: none or emotional only (score, 0–1); minor severity (score, 2–5), including all temporary injuries and nondisabling permanent injuries; permanent disabling injury (score, 6–8), from incomplete loss of motor or sensory function in one area to injuries that require lifelong care; and death (score, 9). *Permanent severe brain damage* was defined as brain damage scored between 6 and 8 on the insurance commissioners' scale.

If a neuraxial injury occurred, the anatomic location where the injury occurred (including epidural, intrathecal, or other areas) and the mechanism of the injury (including compressive, ischemia/infarction, direct trauma, or other mechanism) were determined. Manifestations of neuraxial injuries consisted of quadriplegia or quadriparesis, paraplegia or paraparesis, tract signs unilateral (including corticospinal tract [ipsilateral hemiparesis], spinal thalamic tract [contralateral pain or temperature loss], or dorsal column [ipsilateral proprioception]), tract signs bilateral reticulospinal, and gray matter injuries.

Three pain management anesthesiologists (J.P.R., E.M., and D.R.F.) conducted a secondary review of the data forms to determine whether the patient was responsive during the procedure. Patients were considered responsive during the procedure if no sedation or only light sedation was used. If moderate or deep sedation or general anesthesia was used during the procedure, the patient was considered not responsive.

The use of radiographic guidance was evaluated through questions on whether it was used during the procedure. If it was used, the following were determined: type of radiographic guidance, whether contrast was used, and whether images were taken in multiple planes.

The appropriateness of pain management care was rated as appropriate (standard), substandard, or impossible to judge by the on-site reviewer on the basis of reasonable or prudent practice during the event. The appropriateness of pain management care refers to the decision to perform the intervention (*i.e.*, indication) and how the procedure was performed. A previously published study[15] found the reliability of reviewer judgments to be acceptable. Payments were adjusted to 2007 dollar amounts using the Consumer Price Index.#

Statistical Analysis

Cervical procedure claims were compared with all other chronic pain claims (both invasive and noninvasive) by χ^2 analysis, Fisher exact test, *t* test, and Kolmogorov–Smirnov test using $P < 0.05$ for statistical significance. All hypothesis testing was performed using two-tailed tests. Because payments were not distributed normally, the median and range were reported for all cases for which a payment was made. The κ value was used to assess agreement among three of us (J.P.R., E.M., and D.R.F.) on the secondary assessment of whether the patient was responsive. All statistical analysis was conducted with SPSS 16.0.2 for Windows (SPSS Inc., Chicago, IL).

Results

Overview of Cervical Procedure Claims

In the total ASA Closed Claims Project database of 8,954 claims, the period under study included 1,627 claims. Among these 1,627 claims, there were 294 (18%) for chronic pain management. There were 64 claims related to cervical procedures, representing 22% of the 294 chronic pain claims and 4% of all 1,627 claims collected during the study period. Most (74%) of the chronic pain claims during the study period cited events that occurred in 2000 or later, with 83% of the claims related to cervical procedures occurring from January 1, 2000 to December 31, 2006 (table 1).

Table 1. Patient and Case Characteristics

Characteristics	Cervical Procedures (n = 64)	Other Pain Claims (n = 230)	*P* Value
Age, yr*	49 ± 13	46 ± 14	0.773
Female sex	47 (73)	130 (57)	0.011
ASA physical status 1–2	54 (89)	151 (66)	< 0.001
Year of event			
1991–1999	11 (17)	64 (28)	0.0063
2000–2006	52 (83)	166 (72)	
Substandard care	30 (52)	107 (52)	0.558
Payment made	30 (51)	99 (43)	0.183
Payment amount, $†			
Median	388,600	242,850	0.146
Range	642–2,681,720	5,500–2,967,000	

N = 294 total patients studied. Data are given as number (percentage) of each group unless otherwise indicated. Missing data were excluded. *P* values were determined by *t* test (age), Kolmogorov–Smirnov test (distribution of payments), or Fisher exact test (all others).

* Data are given as mean ± SD. † Payment amounts adjusted to 2007 dollars using the Consumer Price Index. Claims with no payment were excluded.

ASA = American Society of Anesthesiologists.

Compared with other patients receiving chronic pain management, those receiving care for cervical procedures tended to be healthier (ASA score, 1–2; $P < 0.001$) and women ($P = 0.011$, table 1). All claims were associated with chronic noncancer pain. The pain provider's care was considered less than appropriate in 52% of cervical procedure and noncervical chronic pain claims (table 1). Payment was made in 51% of cervical procedure claims, with a median payment of $388,600 (table 1).

Compared with patients with other chronic pain, patients whose pain was associated with cervical procedures were less likely to die (6–21%) but more likely to have permanent disabling injuries (58–33%) ($P < 0.001$, fig. 1).

Indications and Procedures in Cervical Procedure Claims

There were 64 claims associated with cervical procedures. Of cervical procedure claims, the primary diagnosis was cervical radicular pain in 50%, neck pain of musculoskeletal origin in 28%, CRPS in 11%, and spinal stenosis in 5% (table 2). Of the cervical procedures, 58 (91%) were blocks or injections, with 43 epidurals (67%), 7 stellate ganglion blocks (11%), 6

Bureau of Labor Statistics, US Department of Labor. Consumer Price Index inflation calculator. Available at: http://www.bls.gov/data/home.htm. Accessed May 30, 2008.

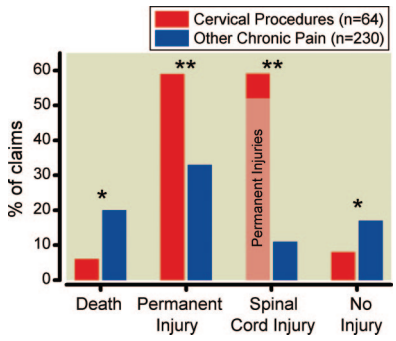

Fig. 1. Cervical procedure outcomes compared with other chronic pain treatment. Patients who underwent cervical procedures were more likely to have spinal cord injury and less likely to die than other chronic pain claim patients. Most spinal cord injuries (87%) were permanent; one patient with a spinal cord injury after a cervical procedure died. *$P < 0.01$, and **$P < 0.001$.

trigger-point injections (9%), and 2 intraarticular facet injections (3%) (table 2). Forty-one (95%) of the cervical epidurals were steroid injections. Twenty-nine (91%, table 2) of the patients who presented with cervical radicular pain had treatment with epidurals. Of those 18 patients who presented with neck pain, 8 (44%) were treated with epidurals, 5 (28%) were treated with trigger-point injections, 2 (11%) were treated with intraarticular facet injections, and 3 (17%, table 2) were treated with facet radiofrequency ablation. All seven patients who presented with CRPS received stellate ganglion blocks (table 2).

Most Common Events and Outcomes in Cervical Procedures

Of the damaging events in cervical procedure claims, 80% were directly related to the procedure performed (table 3). The most common procedure-related events were direct needle trauma to a nerve or the spinal cord (31%), cord infarction/stroke after intraarterial 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%) (table 3).

Table 3. Damaging Event for Cervical Procedure Cases

Variable	Primary Damaging Event
Procedure related	51 (80)
Needle trauma to nerve or cord	20 (31)
Cord infarction/stroke after intraarterial injection	9 (14)
Dural puncture	4 (6)
Hematoma caused by spinal cord compression	3 (5)
Infection/abscess	3 (5)
High block total spinal	3 (5)
Unintentional intravascular injections of local anesthetic	2 (3)
Pneumothorax	2 (3)
Other procedure related*	5 (8)
Other damaging events	13 (20)
Failure to diagnose	3 (5)
Patient expectations of treatment not met	3 (5)
Patient fell	2 (3)
Positioning	1 (2)
Patient condition	1 (2)
Wrong procedure	1 (2)
Peripheral intravenous catheter	1 (2)
No damaging event	1 (2)

Data are given as number (percentage) of the 64 cases.

* Consist of direct injection into the spinal cord during trigger-point injections over the high cervical facet joints, performed with fluoroscopy; persistent neck and shoulder pain, with facial numbness after cervical facet injections (mechanism unknown); a new C5–C6 disk extrusion on magnetic resonance imaging 2 days after plasma disk decompression, attributed to instrumentation of the disk; subarachnoid injection of hypertonic saline during epidural lysis of adhesions; and a large volume of injectate placed into the epidural catheter, resulting in spinal cord compression.

There were nine cervical procedure claims associated with cord infarction or stroke after intraarterial injection (table 3). In five of these cases, spinal cord infarction followed cervical transforaminal injection of particulate steroid (three triamcinolone, one methylprednisolone, and one unspecified). In three other claims, cervical transforaminal injection of particulate steroid (methylprednisolone) resulted in stroke, pre-

Table 2. Diagnosis and Procedure Type

Procedure	Cervical Radicular Pain (n = 32)	Neck Pain (n = 18)	CRPS (n = 7)	Spinal Stenosis (n = 3)	Degenerative Disk Disease (n = 2)	Spondylolisthesis (n = 1)	Total (N = 64)
Epidural*	29 (91)	8 (44)	0 (0)	3 (100)	1 (50)	1 (100)	43 (67)
Stellate ganglion	0 (0)	0 (0)	7 (100)	0 (0)	0 (0)	0 (0)	7 (11)
Trigger points	1 (3)	5 (28)	0 (0)	0 (0)	0 (0)	0 (0)	6 (9)
Intraarticular facet	0 (0)	2 (11)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Other procedures†	2 (6)	3 (17)	0 (0)	0 (0)	1 (50)	0 (0)	6 (9)

Data are given as number (percentage) of each group.

* One steroid epidural injection was excluded, with missing diagnosis. Of 43 epidurals, 41 were steroid injections, 1 was a local only, and 1 was unknown. † Other procedures include 4 radiofrequency ablation, 1 lysis of adhesions, and 1 plasma disk decompression. CRPS = complex regional pain syndrome.

sumably *via* injection of particulate steroid into the vertebral artery. The final case was spinal cord ischemia, possibly resulting from direct intraarterial injection during stellate ganglion block. This patient had difficulty moving the right arm and right lower extremity immediately after the block; the weakness in both upper and lower extremities was permanent. A magnetic resonance image revealed subtle patchy areas of increased T2-weighted signal intensity within the cervical spinal cord, suggesting ischemic injury. There was no evidence of direct spinal cord trauma. The mechanism proposed in the claim file was composed of spinal cord blood flow during injection. There was no information regarding the medications administered, but this may have involved the direct intraarterial injection of particulate steroid.

Seven claims arose from use of stellate ganglion block for the treatment of CRPS of the upper extremity. The most common claim associated with stellate ganglion block (2 [29%]) was failure to diagnose a condition that was later the cause of ongoing upper-extremity pain. In one patient, the subsequent diagnosis was lung cancer affecting the brachial plexus; and in the other patient, carpal tunnel syndrome was diagnosed and treated.

Other procedure-related events are described in table 3. The most common damaging events that were considered not directly related to the procedure included three claims (5%) for which there was a failure to diagnose the underlying problem causing the pain under treatment, three claims (5%) for which the patients' expectations for pain relief from the procedure were not met, and two claims (3%) that resulted from a fall (table 3).

Spinal Cord Injury Associated with Cervical Procedures

Of patients whose claims arose from a procedure done at the level of the cervical spine, 59% experienced spinal cord injury compared with 11% of patients whose claims arose from other pain treatments ($P < 0.001$, fig. 1). Of the 38 cervical procedure claims associated with an injury to the spinal cord, 87% resulted in permanent disabling injuries, whereas in 8% of claims associated with spinal cord injury, the pain and or paresthesia resolved within weeks of treatment (table 4). The cause of the injury to the spinal cord was related to the procedure in 95% of the claims, with 53% of the injuries resulting from direct needle trauma to the spinal cord and 16% related to cord infarction/stroke after intraarterial injection (table 4). For one of the two injuries not related to the procedure, a hematoma appeared a month after the procedure and was determined not to be procedure related. In the second non–procedure-related claim, the patient's pain increased in the months after cervical radiofrequency facet treatment but not in close temporal relationship to the procedure. Of the patients with permanent disabling spinal cord injuries, 27% were quadriplegic, 18% were paraplegic, and 9% were hemiplegic (table 4).

Of spinal cord injuries associated with cervical procedures, 91% occurred during epidural procedures compared with 50% of non–spinal cord injuries associated with cervical procedures ($P < 0.01$, table 5). The 31 cervical epidural procedures associated with spinal cord injury included 20 interlaminar and 10 transforaminal injections (1 unknown route). Trigger-point, stellate ganglion, and facet procedures were each associated with one claim of spinal cord injury. In 58 of the 64 cervical procedure–related claims, the use of sedation or general anesthesia could be determined (table 5). General anesthesia or sedation was used in 67% of cervical procedure claims with spinal cord injuries but in only 19% of cervical procedure claims without spinal cord injuries ($P < 0.001$, table 5). In 54 of the 64 cervical procedure–related claims, the level of responsiveness at injury could be determined (table 5). Of patients who underwent cervical procedures and had spinal cord injuries, 25% were nonresponsive during the procedure compared with 5% of patients who underwent cervical procedures and did not have spinal cord injuries ($P < 0.05$, $\kappa = 0.52$, table 5). In claims with information on whether radiographic guidance was used, it was used in 76% of cervical procedure claims with spinal cord injury ($P < 0.05$, table 5). There was evidence that contrast was used with radiographic guidance in 57% of claims with spinal cord injury compared with 17% of claims without spinal cord injury after a cervical procedure ($P < 0.05$, table 5). On-site reviewers indicated that the appropriate use of radiographic guidance would have prevented the injury in

Table 4. Characteristics of Spinal Cord Injury

Characteristics	Value
Severity of injury	
No injury or emotional only*	1 (3)
Temporary injuries†	3 (8)
Permanent disabling injuries	33 (87)
Death	1 (3)
Cause of injury	
Procedure related	36 (95)
Needle trauma	20 (53)
Cord infarction after intraarterial injection	6 (16)
Hematoma caused by cord compression	3 (8)
Dural puncture	2 (5)
High block/total spinal	1 (3)
Other procedure related	3 (8)
Undetermined	1 (3)
Patient condition	1 (3)
Patient expectations not met	1 (3)
Permanent injury manifestations	
Quadriplegia/quadriparesis	9 (27)
Paraplegia/paraparesis	6 (18)
Hemiplegia/hemiparesis	3 (9)
Other injuries‡	15 (45)

Data are given as number (percentage) of 38 injuries.

* Spinal cord injury was the result of the patient's deteriorating condition. † Three claims in which paresthesia and/or pain occurred that resolved within weeks. ‡ Twelve involved injury to one limb: 10 at a new site (not the presenting site) and 2 at a preexisting site of pain.

Table 5. Characteristics of Cervical Procedure–related Claims: Comparison of Claimants Sustaining Spinal Cord Injury *vs.* No Spinal Cord Injury

Characteristics	Spinal Cord Injury (n = 38)	No Spinal Cord Injury (n = 26)	*P* Value
Types of blocks or injections (n = 58)			0.004
Epidural	31 (91)	12 (50)	
Facet	1 (3)	1 (4)	
Stellate ganglion	1 (3)	6 (25)	
Trigger point	1 (3)	5 (21)	
Epidural type/route (n = 43)			0.074
Interlaminar	20 (65)	7 (58)	
Transforaminal	10 (32)	2 (17)	
Unknown	1 (3)	3 (25)	
General anesthesia or sedation used (n = 58)			0.001
Neither	12 (33)	18 (82)	
Sedation only	23 (64)	3 (14)	
General anesthesia	1 (3)	1 (5)	
Patient responsive during procedure (n = 54)*			0.049
Yes	24 (75)	21 (95)	
No	8 (25)	1 (5)	
Radiographic guidance used (n = 45)			0.031
Yes	22 (76)	7 (44)	
No	7 (24)	9 (56)	
Contrast used (n = 33)			0.027
Yes	12 (57)	2 (17)	
No	9 (43)	10 (83)	
Radiographic guidance would have prevented injury (n = 40)†			0.053
Yes	10 (45)	3 (17)	
No	12 (55)	15 (83)	

Data are given as number (percentage) of each group. Missing data were excluded.

* κ Score = 0.520. † Judged by an on-site reviewer.

45% of cervical procedure claims with spinal cord injury compared with 17% of cervical procedure claims without spinal cord injury (table 5).

Discussion

Claims related to interventional pain treatment performed at the level of the cervical spine (including procedures adjacent to the spine, such as stellate ganglion blocks and trigger-point injections) represented 22% (64/294) of the claims associated with chronic pain treatment in the ASA closed claims database collected between 2005 and 2008. Injuries were often permanent and disabling, and one-third of cases were caused by direct needle trauma to the spinal cord and occurred with both the interlaminar and transforaminal approaches to epidural injection. Traumatic spinal cord injury was more common in patients who received sedation or general anesthesia and in those who were unresponsive when the procedure was conducted.

Factors Associated with Cervical Claims

Claims associated with interventional pain treatment performed at the level of the cervical spine were more frequent in healthy (ASA score, 1 or 2) middle-aged women than claims associated with other chronic pain treatments. Neck pain was more prevalent among women, and the occurrence of neck pain was highest in middle age, matching the characteristics of plaintiffs in this study.[16,17] The most common diagnoses were cervical radicular pain and chronic neck pain, and the most common treatment was cervical epidural steroid injection for cervical radicular pain, matching the epidemiological features of painful cervical disorders.[16,17]

Cervical Interlaminar and Transforaminal Injections

Much recent attention has focused on embolization of particulate steroid during cervical transforaminal injection of steroid,[5,7,18] and this complication occurred in eight patients in our series (table 3). Five were cases of spinal cord infarction after cervical transforaminal injection of particulate steroid, and three were strokes associated with cervical transforaminal injection of particulate steroid. Although direct needle trauma to the spinal cord occurred with the transforaminal approach, direct needle trauma was far more common during a cervical interlaminar injection. The cervical epidural space lies just a few millimeters from the cervical spinal cord, and textbook descriptions of cervical interlaminar epidural injection invariably include a discussion of the possibility of direct spinal cord injury.[19] Indeed, direct trauma to the spinal cord has been reported infrequently in association with cervical epidural steroid injection *via* the interlaminar route, often with minimal sequelae.[20,21] It is tempting to conclude that the higher number of direct spinal cord injuries associated with the interlaminar technique in our study stems from a greater risk associated with this technique. However, anesthesiologists are trained in identifying the epidural space using the loss-of-resistance technique and may inherently have more comfort with the interlaminar approach and, thus, use this approach more often. We do not know the overall frequency of use of either technique and cannot draw any conclusion about the relative safety of one technique over another. The many cases in the current series are alarming and suggest that direct spinal cord trauma and catastrophic neural injury may be more common than previously reported.

Stellate Ganglion Block. The most common claim arising from use of stellate ganglion block was failure to properly diagnose the underlying painful disorder. This emphasizes the fact that CRPS remains a diagnosis of exclusion, and a search for other causes for neuropathic pain should be exhausted before adopting this diagnosis and proceeding with sympathetic blockade for treatment.[22] Direct intravascular

injection of particulate steroid and subsequent spinal cord infarction may have occurred in one stellate ganglion block case. The rationale for use of steroid during stellate ganglion block is unclear; to our knowledge, there are no published reports providing such a rationale. However, the proximity of the vertebral artery and the risk of direct intraarterial injection have long been known.[23] Indeed, direct injection of particulate steroid into the vertebral artery and subsequent stroke have been reported during cervical transforaminal injection of steroid[5] and cervical facet injection.[6] In the absence of any sound rationale for the use of particulate steroid as a part of stellate ganglion block during the treatment of CRPS, it seems prudent to avoid its use altogether.

Trigger-point Injections. One case of direct injection into the spinal cord and resultant hemiplegia resulted from placement of 20 separate cervical trigger-point injections using a 22-gauge 3-inch spinal needle and fluoroscopic guidance. The description of this claim was verified as accurate by a pain medicine specialist, who commented that use of fluoroscopic guidance to conduct trigger-point injections is uncommon. This case emphasizes that neither the intent to conduct a superficial procedure nor the use of fluoroscopy can absolutely ensure that injection into the spinal cord is avoided. Trigger-point injections are typically limited to the superficial soft tissues and, thus, are generally considered inherently safer than neuraxial injections, carrying less risk of spinal cord injury. We opted to include trigger-point injections in this analysis because we had a case in which the trigger-point injection was performed with fluoroscopic guidance and the needle entered the spinal cord, causing a permanent spinal cord injury. If these more superficial trigger-point injections were indeed safer, their inclusion in this analysis would dilute our findings, decreasing the apparent incidence of spinal cord injury. Yet, our findings remain robust: spinal cord injury occurred with alarming regularity even when the analysis included both superficial and deep procedures performed at cervical spinal levels.

Sedation or General Anesthesia. Sedation or general anesthesia was used in 67% of cervical procedures associated with spinal cord injuries but in only 19% of cervical procedures not associated with spinal cord injuries ($P < 0.001$, table 5). From the available records, it was sometimes impossible to discern the level of responsiveness of the patient at injury. Nevertheless, in a subset of patients (n = 54) in whom the level of responsiveness could be determined, 25% with spinal cord injuries were judged nonresponsive during the procedure compared with 5% without spinal cord injuries ($P < 0.05$, table 5).

The use of deep sedation or general anesthesia, during which the patient becomes briefly nonresponsive to verbal commands, has come under much scrutiny.[10,24] Advocates state that sedation allays anxiety, allowing treatment in a population that could not otherwise receive treatment; and renders patients temporarily immobile during these procedures and reduces the risk of sudden movement, thereby potentially decreasing the risk of neural injury.[10,24–26] Opponents cite ample anecdotes in the form of case reports, in which a responsive patient reported symptoms as a needle contacted a peripheral nerve or the spinal cord itself, allowing the procedure to be discontinued and causing no permanent neural injury.[10,24,25,27,28] Indeed, a recent consensus group concluded that warning signs, such as paresthesia or pain on injection of a local anesthetic, inconsistently herald needle contact with the spinal cord; however, some patients do report warning signs of needle-to-neuraxis proximity. The group warned that general anesthesia or heavy sedation removes any ability for the patient to recognize and report warning signs; they recommended that neuraxial regional anesthesia should rarely be performed in adult patients whose sensorium is compromised by general anesthesia or heavy sedation.[10] Although imperfect, the current analysis supports the notion that use of sedation or general anesthesia and conduct of cervical procedures in unresponsive patients are associated with a significant increase in the likelihood of permanent spinal cord injury.

Radiographic Guidance. Despite strong advocates,[29–31] there is little scientific evidence to judge the impact of radiographic guidance on the safety of pain interventions. In many of the cases examined for this study, it was not possible to discern whether radiographic guidance and/or radiographic contrast was used to assist in determining needle location. In those claims in which it was possible to discern this information, radiographic guidance was used in 76% of cervical procedures associated with spinal cord injury ($P < 0.05$), with evidence that contrast was used in 57% of these claims with spinal cord injury, compared with contrast used in 17% of claims in which no spinal cord injury occurred (table 5). Thus, claims resulting from spinal cord injury occurred more often when radiographic guidance was used. However, without knowing the overall rate of use of radiographic guidance, the temptation to conclude that use of radiographic guidance increased the risk of cervical interventions should be avoided. It is equally plausible that, at the time of this study, most practitioners were using radiographic guidance for cervical procedures. Thus, the higher incidence of claims may simply reflect the more common use of radiographic guidance during cervical procedures, particularly cervical epidurals (compared with lower-risk stellate ganglion blocks and trigger-point injections), rather than any improvement in safety.

Alternatively, it is possible that radiographic guidance was used incorrectly, giving practitioners a false sense of security that, in itself, increased the risk of spinal cord injury. Indeed, without disciplined use of fluoroscopy using images taken in multiple planes, the exact needle location cannot be determined with precision. After their review of all available records for each case, the on-site reviewers indicated the appropriate use of radiographic guidance would have prevented the spinal cord injury in 45% of claims with injury compared with 17% of claims without injury (table 5). Although most reviewers were experts in chronic pain, no specific rationale

was given for how each reviewer reached this decision; thus, it is impossible to judge how much weight to place on their conclusions. The current analysis sheds little light on the role for radiographic guidance in the safety of cervical interventional pain treatment. We must emphasize that our results neither support nor refute the notion that use of radiographic guidance can improve the safety of cervical interventional pain treatments. Nevertheless, recent expert guidelines argue strongly for the routine use of radiographic guidance.[2–4]

Limitations of the Closed Claims Analysis

The analysis of closed claims has several well-described limitations.[13] Because of the lack of denominator data for number of procedures performed, the closed claims database can only provide an indirect assessment of safety and liability risks of interventional cervical pain procedures within the United States. The analysis was conducted on data that were transcribed to data sheets by anesthesiologist reviewers, who depended on the information contained in the insurance company file. Therefore, specific detailed information regarding signs and mechanisms of injury may have been incomplete compared with a prospective study. Data concerning the degree of patient responsiveness and radiologic guidance were incomplete in some claims. Malpractice claims are also biased by the presence of more severe and costly injuries and nonrandom geographic distribution. Claims spanned a period during which practice patterns changed. As a retrospective study, it cannot establish a cause-and-effect relationship between previous events or between changes in claims experience.

Our analysis focuses largely on the complications that can arise when various interventional pain treatment techniques are conducted at the level of the cervical spine. However, whenever complications are discussed, it is critical to remember that patient selection is as important as the description of the technique. There were three cases for which a claim arose regarding failure to diagnose a condition; all three cases involved patients who had received interventional treatments that were later deemed inappropriate. In most cases in this analysis, there was insufficient information regarding the clinical history, physical examination findings, and laboratory and imaging results to make any judgment about the appropriateness of patient selection.

In summary, despite limited evidence for the usefulness of many interventional pain treatments,[2,3,32] their use has increased dramatically in recent years in the United States.[1] We found that injuries related to cervical interventional pain treatment were often severe and frequently related to direct needle trauma to the spinal cord. Traumatic spinal cord injury was more common in patients who received sedation or general anesthesia and in those who were unresponsive when the procedure was conducted. Further studies are crucial to understand whether and when the use of these interventions is warranted and to establish techniques that can ensure that the risk of these devastating injuries is minimized.

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