Trends in Pain Medicine Liability

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ABSTRACT

Background: The authors examined changes in the frequency of pain medicine malpractice claims and associated treatment modalities and outcomes over time.

Methods: The authors analyzed trends in pain medicine claims from 1980 to 2012 in the Anesthesia Closed Claims Project database by binary logistic regression on year of event. Pain procedures in claims from 2000 to 2012 were compared with the proportion of pain procedures reported to the National Anesthesia Clinical Outcomes Registry in 2010–2014.

Results: Malpractice claims for pain medicine increased from 3% of 2,966 total malpractice claims in the Anesthesia Closed Claims Project database in 1980–1989 to 18% of 2,743 anesthesia claims in 2000–2012 (odds ratio [OR], 1.088 per year; 95% CI, 1.078 to 1.098; $P < 0.001$). Outcomes in pain claims became more severe over time, with increases in death and permanent disabling injury (OR, 1.094 per year; $P < 0.001$). Nonneurolytic cervical injections increased to 27% of pain claims in 2000–2012 (OR, 1.054; $P < 0.001$), whereas National Anesthesia Clinical Outcomes Registry demonstrates that lumbar injections are a more common procedure. Claims associated with medication management increased to 17% of pain claims in 2000–2012 (OR, 1.116 per year; $P < 0.001$).

Conclusions: Pain medicine claims have increased over time and have increased in severity. Claims related to cervical procedures were out of proportion to the frequency with which they are performed. These liability findings suggest that pain specialists should aggressively continue the search for safer and more effective therapies. **(ANESTHESIOLOGY 2015; 123:1133-41)**

CHRONIC pain is one of the most frequent reasons that patients seek medical care[1–3] and is considered a major health and economic problem.[4] Currently, many different medical disciplines practice pain management in the United States, including but not limited to anesthesiology, family medicine, neurology, physical medicine and rehabilitation, and psychiatry. Within this relatively large scope of medical specialties, anesthesiologists represented 44% of all physicians active in pain medicine care in the United States in 2012.[5]

Over the decades, the focus of pain medicine has changed, with emphasis on interventional approaches and interdisciplinary care. The American Board of Medical Specialties approved the American Board of Anesthesiology certification in pain management in 1991 with the first certificates issued in 1993. In March 1998, the American Board of Psychiatry and Neurology, Inc., and the American Board of Physical Medicine and Rehabilitation joined the American Board of Anesthesiology in offering subspecialty certification in pain medicine.

What We Already Know about This Topic

- The number of anesthesiologists practicing pain medicine has expanded over the past two decades, but whether malpractice claims have increased as well is unknown

What This Article Tells Us That Is New

- In a review of the Anesthesia Closed Claims Project database, the proportion of malpractice claims in pain medicine increased from 3% in 1980–1989 to 18% in 2000–2012, accompanied by increasing severity of injury, including death and permanent disabling injury
- Claims related to cervical procedures were out of proportion to the frequency with which they are performed

Central to the practice of pain medicine is the use of analgesic medications and interventional analgesic techniques.[1,6] There are several categories of medications that have proven analgesic efficacy in managing chronic pain, including acetaminophen, nonsteroidal antiinflammatory agents, tricyclic antidepressants, anticonvulsants, and

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opioids. Benzodiazepines and centrally acting muscle relaxants are also frequently prescribed. Technological advances in the 1990s provided extended-release formulations of opioid medications that quickly gained popularity.

Interventional pain treatment involves a wide range of techniques. Since the early 1990s, there has been a significant increase in the use of these modalities to treat painful conditions.[6–8] Among the most common interventional treatments are epidural steroid injections and facet injections for neck and back pain. Furthermore, in the 1990s, implantable therapies such as infusion pumps and spinal cord stimulators became available as technology advanced, allowing for home treatment of patients with very complex pain conditions.[9–11]

Along with this movement toward the use of more potent analgesics and interventional techniques, the proportion of anesthesia malpractice claims associated with pain medicine increased.[12] This earlier review of 284 pain medicine claims from 1970 to 1999 found that epidural steroid injections were the most common treatment, and most injuries were temporary and minor. However, more recent analyses suggested an increase in major adverse outcomes, including deaths from medication overdose and major neurologic injuries associated with cervical procedures.[13,14]

The current study analyzes trends in pain medicine malpractice claims for anesthesiologists from 1980 to 2012. Although the practice of pain medicine in the United States includes many specialties, this report is limited to anesthesiologists practicing pain medicine. We hypothesize that claims for pain medicine have continued to increase as a proportion of anesthesia malpractice claims over time. We also hypothesize that the specific treatment modalities associated with pain medicine anesthesiologist malpractice claims and their outcomes changed over time. We also describe closed anesthesia malpractice pain medicine claims using the Anesthesia Closed Claims Project (CCP) database.

Materials and Methods

The Anesthesia CCP database is a structured collection of closed malpractice claims filed against anesthesiologists as described in detail elsewhere.[15] In brief, on-site anesthesiologist-reviewers abstract data from malpractice claims at professional liability companies throughout the United States. Claims alleging negligence in pain medicine are collected on a specific data collection instrument recording patient characteristics, treatment details, sequence of events, mechanism of injury, outcomes, standard of care, and a narrative description of the claim. Most pain medicine files are reviewed by anesthesiologists who practice pain medicine. Forms and narrative summaries completed by the on-site anesthesiologist-reviewer are subsequently reviewed by three pain-anesthesiologists (J.P.R., D.R.F., and E.M.) for data quality and consistency with project protocols before incorporation into the database.

For this study, we used the Anesthesia CCP database of 10,367 claims. Inclusion criteria were claims for injuries that occurred between 1980 and 2012. Data on selected pain procedures by anesthesiologists were obtained from the National Anesthesia Clinical Outcomes Registry (NACOR) Participant User File through July 2014, by direct query.[16] NACOR contains data from approximately 20% of all anesthesia practices in the United States from 2010 to July 2014. Practices that joined NACOR during the query dates provided retrospective data inclusive of 2010–2014. NACOR was used as a procedural data source to compare the relative proportions of selected pain procedures to the CCP database.

Definition of Variables

Claims in the Anesthesia CCP database were classified as pain medicine if the complication was associated with care provided by an anesthesiologist to treat chronic pain. Pain medicine claims with multiple encounters or treatments were classified into categories based on the treatment encounter associated with the alleged injury. Other claims used in comparison with these pain claims included those associated with surgical anesthesia, postoperative pain management, obstetric anesthesia, intensive care, and resuscitation.

Injections as well as other invasive procedures were classified according to location: cervical; thoracic; lumbar; caudal; unspecified back; head; upper extremity including shoulder; chest; abdomen and groin; lower extremity; multiple locations; or unspecified location. Pain treatments were grouped into the following categories: nonneurolytic cervical injections, nonneurolytic lumbar injections, all other nonneurolytic injections, neurolytic procedures, device management (implantation or removal as well as ongoing management), medication management, other invasive procedures, and other forms of chronic pain care. Injections were classified as neurolytic procedures if any neurolytic chemical or thermal agent was used for the procedure. Examples of neurolytic procedures include injections of alcohol or phenol for chemical neurolysis, cryoablation (destruction of nerves after exposure to extreme cold), and radiofrequency ablation (application of electrical current to provide thermocoagulation and nerve destruction). All other injections were classified as nonneurolytic. Devices included any surgically implanted medication pumps, implanted catheters, or implanted spinal cord or nerve stimulators. Other invasive procedures included any treatment that involved percutaneous access with needles or surgical incision, such as discography, intradiscal electrothermal therapy, discectomy, disc decompression, discoplasty, vertebroplasty, or acupuncture. Other chronic pain care consisted of patient-controlled analgesia management, cupping procedure, and consultations without treatment or the provision of prescriptions.

The severity of injury in each claim was assigned using the National Association of Insurance Commissioners' 10-point scale, which ranges from 0 (no apparent injury) to 9 (death).[17] This scale was collapsed into binary severity outcomes: death and permanent disabling injury (score 6 to 9) and temporary minor injury (score 0 to 5). Pain anesthesia claim clinical outcomes (injuries) were classified as death,

severe nerve injury, temporary minor injuries, and other injuries. Severe nerve injury was defined as permanent disabling injury (score 6 to 8) to the peripheral nerves or spinal cord. The severity of injury represents the assessment at the time the claim was closed. Hence, a claim with severe brain damage resulting in death before claim closure was classified as death.

Appropriateness of care was assessed by the on-site reviewer based on reasonable and prudent criteria for practice at the time of the event. Care was assessed as appropriate, less than appropriate, or impossible to judge. These evaluations were subsequently reviewed for confirmation by the CCP pain-anesthesiologists (J.P.R., D.R.F., and E.M.). The reliability of these evaluations has been judged as acceptable.[18]

National Anesthesia Clinical Outcomes Registry cases were classified by Current Procedure Terminology (CPT) code[19] and grouped by procedure and location using similar classifications as the closed claims groupings: nonneurolytic cervical or thoracic injections; nonneurolytic lumbar injections; device implant, manage, or remove ("devices"); other nonneurolytic injections; and other procedures using the first pain CPT code from the possible five CPT codes available for each record. The NACOR query did not include medication management or CPT codes for evaluation and consultation. To compare approximate proportions of similar procedures between NACOR and the Anesthesia Closed Claims databases, we included only cases classified as cervical nonneurolytic injections, lumbar nonneurolytic injections, and devices.

Statistical Analysis

To assess whether pain medicine claims increased as a proportion of all claims, claims within the Anesthesia CCP database from 1980 to 2012 were analyzed by binary logistic regression on year of event with pain medicine as the indicator *versus* all other claims. To assess whether particular pain treatments and outcomes changed over time, pain procedures and outcomes in 1980–2012 were analyzed by binary logistic regression on year of event with the target procedure or outcome as the indicator *versus* all other pain medicine claims. Bonferroni-adjusted *P* values were calculated in analyses incorporating multiple tests (pain procedures and clinical outcomes in pain claims over years). Trends in patient characteristics and liability were analyzed by binary logistic regression for dichotomous variables and linear regression for continuous variables (age and payment amount) on year.

All payments made to the plaintiff were extracted from the database and adjusted to 2013 dollar amounts with the Consumer Price Index.[20] Because payment amounts were not normally distributed, median and interquartile ranges were reported as descriptive statistics, and payment amounts were transformed by log 10 for regression analysis. Claims with no payment were excluded from calculation of median and interquartile range and from regression analysis of payment amounts over time.

The proportion of cervical injections, lumbar injections, and devices from NACOR were compared with claims data by the chi-square test. Other procedural data from NACOR did not incorporate a formal statistical analysis. All statistical analyses used SPSS 19 for Windows (IBM Corporation, USA) with *P* value less than 0.05 as the criterion for statistical significance and two-tailed tests.

Results

Malpractice claims for pain medicine increased from 1980 to 2012, from 3% of 2,966 total malpractice claims in the Anesthesia CCP database in 1980–1989 to 18% of 2,743 claims in 2000–2012 (odds ratio [OR], 1.088 per year; 95% CI, 1.078 to 1.098; $P < 0.001$). The patient demographic characteristics in pain claims did not change over time. Most patients were relatively young (mean age, 48 yr; SD, 14) and female (60%; table 1).

Outcomes in pain medicine claims were more severe in recent years. Death and permanent disabling injury increased from 21% of 95 pain medicine claims in the 1980s to 55% of 505 pain medicine claims in the 2000s (OR, 1.094 per year; 95% CI, 1.069 to 1.118; $P < 0.001$; table 2). Liability also changed over time, with a decrease in the proportion of pain claims assessed as demonstrating appropriate care in the 2000s (42 *vs.* 56% in the 1980s; OR, 0.948 per year; $P < 0.001$; table 1). Half of recent pain claims resulted in payment (50% in the 2000s; table 1). When payments were made in pain medicine claims, they were greater in the 2000s (median $301,350) compared with the 1980s (median $38,415; regression coefficient, 0.029 [log adjusted 0.069] per year, $P < 0.001$; table 1).

Treatments in Pain Medicine Claims

Among the 1,037 total pain medicine malpractice claims in 1980–2012, the most common treatments were lumbar nonneurolytic injections (n = 273, "lumbar injections"), cervical nonneurolytic injections (n = 211, "cervical injections"), device implantation, management, or removal (n = 146, "devices"), and medication management (n = 115). The types of treatment associated with malpractice claims for pain medicine changed significantly over time. *Cervical* injections increased from 16% of claims in the 1980s to 27% in the 2000s (OR, 1.054 per year; 95% CI, 1.027 to 1.082; Bonferroni-adjusted $P < 0.001$; fig. 1) to become the most common location for nonneurolytic injections since 2000. The most common cervical injections were epidural steroid injections (72%), whereas 16% were stellate ganglion injections (appendix). Permanent disabling nerve injury (generally injury to the cervical spinal cord) associated with cervical injections increased over time (OR, 1.124 per year; 95% CI, 1.064 to 1.188; Bonferroni-adjusted $P < 0.001$) and was the most common complication of cervical injections in the 2000s (54%; table 2).

Medication management and *lumbar* injections were the second most common treatment in claims since 2000 with 87 claims each. Medication management increased from 2% of

Table 1. Characteristics of Pain Medicine Claims

	1980s, n = 95	1990s, n = 437	2000s, n = 505	OR per Year (95% CI)	*P* Value
Female (n = 1,035)	58 (61%)	262 (60%)	301 (60%)	0.995 (0.975 to 1.015)	0.599
Appropriate care (n = 904)	44 (56%)	238 (63%)	191 (42%)	0.948 (0.927 to 0.969)	<0.001
Payment made (n = 991)	55 (60%)	180 (45%)	248 (50%)	0.994 (0.974 to 1.014)	0.539
	n = 95	n = 437	n = 505	Regression Coefficient per Year (95% CI)	*P* Value
Age, mean (SD) (n = 1,023)	48 (15)	48 (14)	48 (14)	0.069 (–0.071 to 0.209)	0.333
Payment amount (n = 483)					
Median	$38,415	$198,275	$301,350	0.029* (0.020–0.039)	<0.001
25th–75th quartile	$19,200–$175,460	$36,625–$721,540	$105,182–$835,312		

P value for regression OR or coefficient. Descriptive statistics based on 1,037 pain medicine claims unless otherwise noted. Claims with missing data excluded. Payment amounts adjusted to 2013 inflation-adjusted dollars. Analysis of payment amount excludes claims with no payment or missing payment data. Because payments were not normally distributed, payment amounts were transformed by log 10 for regression analysis. The effects are presented as the coefficient on the log 10 scale. ORs and regression coefficients were calculated on year. On the average, the odds of the anesthesiologist's care being evaluated as appropriate decreased approximately 1.05-fold each year since 1980. The amount paid for chronic pain claims has increased by approximately 1.069-fold (unstandardized coefficient) for each year since 1980, on the average. *P* values were calculated by logistic regression or linear regression of age and log 10 payment amount respectively on year.

* The relative change is 1.069 ($10^{0.029}$).

OR = odds ratio.

1980s chronic pain claims to 17% in the 2000s (OR, 1.116 per year; 95% CI, 1.074 to 1.159; Bonferroni-adjusted $P < 0.001$; fig. 1). Death was the most common complication of medication management claims in the 2000s, representing 68% of claims.

Lumbar injections decreased from 37% of claims in the 1980s to 17% in the 2000s (OR, 0.931 per year; 95% CI, 0.911 to 0.952; Bonferroni-adjusted $P < 0.001$; fig. 1). Lumbar injections were most commonly epidural steroid injections (84%), whereas sympathetic injections occurred in 7% (appendix). Permanent disabling nerve injury (generally to the lumbar spinal cord) increased to 26% of lumbar injection claims in the 2000s (OR, 1.089 per year; 95% CI, 1.030 to 1.151; Bonferroni-adjusted $P = 0.005$; table 2).

Implantation, management, and removal of devices increased from 3 to 16% of pain medicine claims in the 2000s (OR, 1.051 per year; 95% CI, 1.020 to 1.084; Bonferroni-adjusted $P = 0.005$; fig. 1). Most claims associated with devices (62%) were associated with implantable drug delivery infusion pumps (n = 90). The outcomes in most device claims were temporary and nondisabling (64%), such as an increase in pain or failure to relieve preexisting pain.

The NACOR database of 19,568,058 cases from 2010 to 2014 included 358,521 cases with CPT codes consistent with chronic pain procedures. These data represent 210 practices and 994 facilities. Overall, lumbar nonneurolytic injections accounted for 52% of pain procedures in the NACOR database, whereas cervical or thoracic nonneurolytic injections accounted for another 19% and devices 14% (table 3). A comparison of just these three procedures in NACOR to similar procedures in the Anesthesia CCP database suggests that claims associated with cervical nonneurolytic injections represent nearly twice the claims (44%) as their proportional representation among NACOR procedures (23%, $P < 0.001$; fig. 2).

Table 2. Trends in Outcomes for Most Common Procedures in Pain Medicine Claims

Treatment Groups and Outcomes	1980s, n (%)	1990s, n (%)	2000s, n (%)	OR per Year (95% CI)	*P* Value (Adjusted)
All pain medicine claims (n = 1,037)	n = 95	n = 437	n = 505		
Death and permanent disabling injuries (severity 6–9)	20 (21)	139 (32)	278 (55)	1.094 (1.069–1.118)	<0.001
Cervical nonneurolytic injections (n = 211)*	n = 15	n = 62	n = 134		
Severe nerve injury	2 (13)	18 (29)	72 (54)	1.124 (1.064–1.188)	<0.001
Lumbar nonneurolytic injections (n = 273)*	n = 35	n = 151	n = 87		
Severe nerve injury	3 (9)	21 (14)	23 (26)	1.089 (1.030–1.151)	0.005

Percentage based on number of claims with that treatment within the decade. Denominators for each treatment group (all pain claims, cervical nonneurolytic injections, and lumbar nonneurolytic injections) in each decade are indicated in parentheses. The outcome shown for each treatment group (death and permanent disabling injuries and severe nerve injury) was compared with all other outcomes in that treatment group. *P* values by binary logistic regression on year. The temporal trend (per 1 yr) in the proportion of patients with the outcome shown for each treatment group was analyzed. The odds of death or permanent disabling injury occurring increased 1.094-fold for every year since 1980, on the average. The odds of a severe permanent nerve injury occurring in a cervical procedure increased 1.124-fold for each year since 1980, on the average. The probability of a severe permanent nerve injury occurring in a lumbar procedure increased 1.089-fold for each year since 1980, on the average. Adjusted *P* values based on Bonferroni adjustment for multiple testing for nerve injury within the two injection groups. Most injuries with severity scores of 6 to 9 in these injection groups had severe nerve injury as the clinical outcome. Bonferroni adjustment was based on two tests using raw *P* values to four significant figures to reduce rounding error.

* Nonneurolytic injections only.

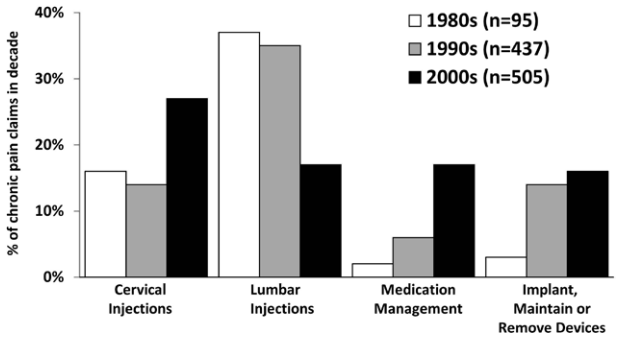

Fig. 1. Trends in treatments in pain medicine malpractice claims. Cervical and lumbar injections are nonneurolytic. Neurolytic injections are not included (see Materials and Methods for definitions). Other treatments are not shown. Claims with missing year of event excluded. For illustration in *bars,* claims from 2010 to 2012 are grouped with other claims from the 2000s due to small numbers. $P < 0.001$ for each treatment by binary logistic regression of treatment (*e.g.*, cervical injections *vs.* all other treatments) on year without correction for multiple testing (Bonferroni-adjusted $P < 0.001$ for cervical and lumbar injections and medication management; $P = 0.005$ for devices).

Discussion

Chronic pain management malpractice claims increased from 1980 and represented nearly one out of every five claims in the Anesthesia CCP database in 2000–2012. The most common chronic pain treatments in claims in the 2000s were associated with severe complications, including permanent severe injury to the spinal cord with cervical and lumbar injections, and death associated with medication management.

Trends over Decades and Liability

Malpractice claims associated with chronic pain treatment have risen markedly during the past 3 decades at a time when interest and involvement in the new subspecialty of pain medicine have grown rapidly. Pain-anesthesiologists represented 2.9 to 4.7% of anesthesiologists in the American Medical Association Physician Master File from 2000 to 2012[5,21–32] (mean 3.6 ± 0.47), whereas pain claims represented 18% of anesthesia claims in 2000–2012, suggesting that liability associated with anesthesiologists subspecializing in pain medicine is now disproportionately high relative to other anesthesiologists in the Anesthesia CCP database. The reason for this is unclear, but one reasonable hypothesis is that the current practice of pain medicine carries greater risk than does the rest of the field of anesthesiology. This hypothesis is supported by surveys of malpractice insurers showing that premiums for pain medicine anesthesiologists are generally 10 to 15% higher than premiums for nonpain-anesthesiologists.[33]

Nonneurolytic Injections

Cervical nonneurolytic injections were the most common treatment associated with claims in 2000–2012, with their proportion far outweighing their representation in the NACOR database of procedures for 2010–2014 (fig. 2). To be clear, a greater proportion of malpractice claims are associated with cervical epidural injections in the CCP database, yet the NACOR database demonstrates that in clinical practice, lumbar epidural injections are carried out with much greater frequency than cervical epidural injections. Although the different time periods used in this comparison (2000–2012 for CCP *vs.* 2010–2014 for NACOR) suggest caution in drawing conclusions, nonetheless this is the first evidence, although indirect, that cervical epidural injections carry greater risk than do lumbar epidural injections. The cervical spinal cord lies in close proximity to the epidural space. Most lumbar epidural injections are carried out below the level of the conus medullaris. Advancing a needle too far anteriorly during lumbar epidural injection will result in dural puncture but is unlikely to result in neural injury. In contrast, advancing a needle too far anteriorly during cervical epidural injection is likely to lead to direct contact with or needle entry into the spinal cord. This anatomic difference may play a role in both the relative overrepresentation of cervical procedures among malpractice claims and the severity of injuries in this group. This overrepresentation of cervical epidural injections in the CCP database may also reflect the severity of injury in these claims, with more than two of three cervical injection claims associated with death or severe permanent nerve injury in the 2000s. In the U.S. medical liability system, plaintiff representation is commonly based on contingency fees, resulting in claims data being skewed toward severe injury. The most common reason plaintiff attorneys do not pursue claims is small recoverable damages (*e.g.*, low awards),[34] and the highest awards are associated with severe injury and substandard care.[15] The high liability profile of cervical injections may reflect the greater potential for severe injury when complications occur with these injections compared with lower severity of complications associated with lumbar injections.

Medication Management

Since 2000, medication management (along with lumbar nonneurolytic injections) was the second most common treatment in pain medicine claims (fig. 1). Proportionally, medication-related claims have increased substantially from 2% of pain medicine claims in the 1980s to 17% since 2000. This finding correlates with national trends regarding opioid prescriptions and likely reflects that pharmacotherapy is considered an integral component of the clinical management of chronic pain.[35–37] Particularly, concerning is the continued trend of deaths associated with medication management claims, with mortality in 68% of claims in the 2000s. This is in contrast to the significant decrease in the proportion of deaths in all claims for anesthesia (including pain claims) from 1975 through 2000.[38] In that study of 6,750 claims from the CCP, the proportion of claims for death and permanent brain damage decreased from 56% of closed claims in

Table 3. Treatments in Claims 2000–2012 *vs.* NACOR Procedures 2010–2014

	Claims 2000–2012, n = 505	NACOR Database 2010–2014, n = 358,521
Cervical nonneurolytic injections	134 (27%)	68,783 (19%)
Lumbar nonneurolytic injections	87 (17%)	185,079 (52%)
Medication management	87 (17%)	NA
Devices	83 (16%)	49,405 (14%)
Other nonneurolytic injections*	43 (9%)	15,834 (4%)
Neurolytic procedures	33 (7%)	11,457 (3%)
Other procedures	38 (8%)†	27,963 (8%)‡

Classification of claims into groups was based on the treatment associated with the alleged injury (see Materials and Methods). NACOR database classifications based on Current Procedural Terminology codes.[19] Cervical injections in NACOR include thoracic injections. Medication management data excluded from NACOR. Devices include insertion, management, and maintenance (see Materials and Methods for types of devices included). A formal statistical analysis of Closed Claims and NACOR procedures was not performed because statistical comparison involving >300,000 procedures risks generating statistical significance when actual clinical differences are trivial.

* Other than cervical or lumbar for claims; other than cervical, thoracic, or lumbar for NACOR. † See Materials and Methods for list. ‡ Mostly joint arthrocentesis.

NA = not available; NACOR = National Anesthesia Clinical Outcomes Registry.

1975 to 27% of claims in the year 2000.[38] Although the cause of death was not evaluated in the current study of pain medicine claims, we previously reported factors associated with medication-related deaths from the late 1990s to 2006.[13] That in-depth analysis found that deaths were associated with prescriptions for long-acting opioids as well as with concomitant use of nonopioid psychoactive medications. Nationally, deaths associated with opioid use plus concomitant psychoactive medications continue to be of major concern.[4] According to the Centers for Disease Control and Prevention, poisoning death rates involving opioid analgesics has more than tripled since 1999, with approximately half of these deaths involving more than one drug.[39] Earlier studies have recommended a high level of vigilance, for example, urine and blood toxicology, behavioral monitoring, and the use of opioid contracts.[40–43] Our data suggest that medication-associated death continues to be a serious issue, and earlier recommendations for vigilance remain appropriate.

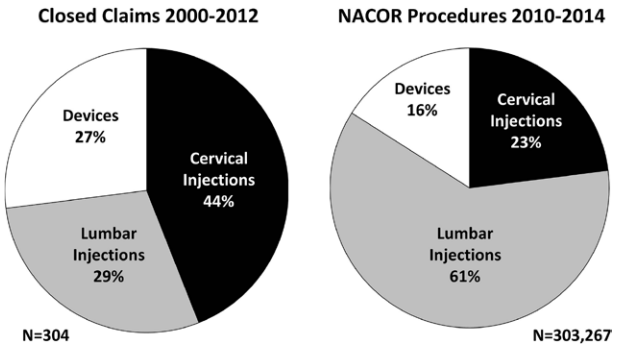

Fig. 2. Comparison of the three most common procedures in claims *versus* National Anesthesia Clinical Outcomes Registry (NACOR) procedures. All other treatments excluded. Cervical injections in NACOR include thoracic injections. All injections are nonneurolytic. Devices include implantation, maintenance, and removal. Claims data from 2000 to 2012; NACOR data from 2010 to 2014. $P < 0.001$ Closed Claims *versus* NACOR by chi-square test.

Implantation, Management, and Removal of Devices

We observed an increase in claims associated with implantation, management, and removal of devices to 16% of pain medicine claims in the 2000s (fig. 1), similar to device representation among NACOR procedures of 14% (table 3). Over 60% of device claims were associated with infusion pumps. An externally programmable implantable drug delivery system pump (SynchroMed®; Medtronic, Inc., USA) was initially released in the United States in 1991. Since then, implantable drug delivery systems and other implantable devices are used more frequently for the management of chronic refractory pain, with continued popularity in recent years.[6] The majority of claims associated with device complications had temporary or nondisabling injuries, reflecting the low mortality associated with devices used for management of chronic pain.[44,45]

Study Limitations

The limitations of closed claims analysis have been previously described, including selection bias, nonrandom retrospective data collection, outcome bias, and possible geographic imbalance in data collection.[46,47] The data are limited to information gathered by insurance companies for claims resolution, and the database lacks a denominator of anesthetics for estimating risk.[46] The Anesthesia CCP database does not include claims for damage to teeth or dentures, which are generally low severity of injury and associated with surgical anesthesia. This exclusion may result in a consistent overestimate of the proportion of chronic pain management malpractice claims in the database.

The NACOR cases come from a more recently compiled registry (2010–2014) and may themselves be subject to selection biases. The CPT codes used to define the relevant NACOR cases combine thoracic and cervical locations, so the comparison with claims for nonneurolytic cervical injections is approximate and should be interpreted with caution. Multiple statistical tests of trends in pain medicine claims

(procedures and outcomes) will have implications for interpretation of statistical significance that should be considered when interpreting the results of this study. For this reason, we have provided *P* values adjusted for multiple testing.

Conclusions

Pain medicine malpractice claims have increased as a proportion of anesthesia malpractice claims and have also increased in severity. Claims related to cervical procedures were out of proportion to the frequency with which they are performed. These liability findings suggest that pain specialists should aggressively continue the search for safer and more effective therapies.

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Competing Interests

Dr. Rathmell serves as a director for the American Board of Anesthesiology, Raleigh, North Carolina. The other authors declare no competing interests.

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Appendix. Types of Pain Procedures Provided by Location of Procedures (n = 763*)

	Lumbar	Cervical	Thoracic	Caudal	Chest	Upper Extremity	Lower Extremity	Unspecified Back	Other
Nonneurolytic blocks/injections (n = 648)	n = 273	n = 211	n = 45	n = 17	n = 28	n = 32	n = 13	n = 7	n = 22
Epidurals	228	151	25	17				4	
Stellate ganglion		34							
Trigger point	4	6	9		5	19	2		
Facet	6	16	2					2	
Sympathetic	18	1							
Subarachnoid block/intrathecal	9	1						1	
Intercostal			7		23				
Interscalene						5			
Other	8†	2‡	2§			8‖	11#		22**
Neurolytic procedures (n = 72)	n = 37	n = 17	n = 6	n = 0	n = 2	n = 0	n = 2	n = 2	n = 6††
Chemical neurolysis	22	3	4		2		2	2	4
Racz procedure	5	2							
Radiofrequency ablation	9	12	1						1
Cryoablation	1		1						1
Other invasive procedures (n = 43)	n = 27	n = 6	n = 1	n = 0	n = 0	n = 2	n = 0	n = 3	n = 4
Discography	9	3						3	
IDET	8								
Discectomy	2	1							
Other	8‡‡	2§§	1‖‖			2##			4***

* Excludes medication management (n = 115), devices (n = 146), consultation and diagnosis only (n = 10), PCA (n = 2), and cupping procedure (n = 1). † One claim each with medial branch, iliopsoas compartment, prolotherapy, and lumbar plexus and four claims with multiple types of blocks or injections. ‡ One claim each for occipital and multiple types of cervical blocks or injections. § One claim each for paravertebral and mylogram. ‖ Three suprascapular, two Bier blocks, two brachial plexus, and one unspecified shoulder block or injection. # Four tendon or joint, three Bier blocks, and one each femoral cutaneous nerve, sciatic, ankle, and unspecified lower extremity block or injection. ** Seven claims were groin procedures including three ilioinguinal, three ilioinguinal and other injections, and one trigger point; six claims were head procedures including two occipital, two multiple types of head blocks/injections, and one each sphenopalatine ganglion and unspecified head block/injection; five claims were for procedures at multiple sites, two abdominal celiac plexus, and two unspecified location trigger point. †† Two claims for chemical neurolysis to an unknown location, one chemical neurolysis each to the abdomen and multiple locations, and one cryoablation and one radiofrequency ablation to the head. ‡‡ Other lumbar invasive procedures including two endoscopic intradiscal decompressions and one each percutaneous disc decompression, one percutaneous disc decompression using nucleoplasty, laser thermal discoplasty, vertebroplasty, nucleoplasty, and acupuncture. §§ Other cervical invasive procedures including one each plasma disc decompression nucleoplasty and acupuncture. ‖‖ One thoracic dry needling. ## One claim each for upper extremity dry needling and phentolamine infusion. *** Other claims for invasive procedures at unknown locations including one each local infiltration and acupuncture. There was also one claim for lumbar and thoracic vertebroplasty and one claim for multiple procedures at multiple locations.

IDET = intradiscal electrothermal therapy; PCA = patient controlled analgesia.