Injury and Liability Associated with Implantable Devices for Chronic Pain

Dermot R. Fitzgibbon, M.D., Linda S. Stephens, Ph.D., Karen L. Posner, Ph.D., Edward Michna, M.D., J.D., James P. Rathmell, M.D., Kelly A. Pollak, M.D., Karen B. Domino, M.D., M.P.H.

ABSTRACT

Background: Due to an increase in implantable device–related anesthesia pain medicine claims, the authors investigated anesthesia liability associated with these devices.

Methods: After institutional review board approval, the authors identified 148 pain medicine device claims from 1990 or later in the Anesthesia Closed Claims Project Database. Device-related damaging events included medication administration events, infections, hematomas, retained catheter fragments, cerebrospinal fluid leaks, cord or cauda equina trauma, device placed at wrong level, stimulator incorrectly programmed, delay in recognition of granuloma formation, and other issues.

Results: The most common devices were implantable drug delivery systems (IDDS; 64%) and spinal cord stimulators (29%). Device-related care consisted of surgical device procedures (n = 107) and IDDS maintenance (n = 41). Severity of injury was greater in IDDS maintenance claims (56% death or severe permanent injury) than in surgical device procedures (26%, $P < 0.001$). Death and brain damage in IDDS maintenance claims resulted from medication administration errors (n = 13; 32%); spinal cord injury resulted from delayed recognition of granuloma formation (n = 9; 22%). The most common damaging events for surgical device procedures were infections, inadequate pain relief, cord trauma, retained catheter fragments, and subcutaneous hygroma. Care was more commonly assessed as less than appropriate (78%) and payments more common (63%) in IDDS maintenance than in surgical device procedure claims ($P < 0.001$).

Conclusions: Half of IDDS maintenance claims were associated with death or permanent severe injury, most commonly from medication errors or failure to recognize progressive neurologic deterioration. Practitioners implanting or managing devices for chronic pain should exercise caution in these areas to minimize patient harm. **(ANESTHESIOLOGY 2016; 124:1384-93)**

IMPLANTABLE technology for chronic pain is primarily intended to reduce afferent nociceptive activity within pain pathways (neuromodulation) by targeted electrical neurostimulation (peripheral or central) or drug delivery into cerebrospinal fluid (CSF). Neuraxial or peripheral nerve targets for implanted neurostimulators include spinal cord stimulation, deep brain stimulation, or peripheral nerve stimulation. Implantable neuraxial infusion pumps deliver drugs to intrathecal or intracerebroventricular sites.

Spinal cord stimulators (SCS) were approved by the Food and Drug Administration in 1989 to relieve pain from nerve injuries in the trunk and extremities. They are used to treat radiculopathies refractory to conservative or surgical treatment, peripheral neuropathies, complex regional pain syndrome, and other selected conditions.[1]

Intrathecal drug delivery systems (IDDS) using implantable pumps and catheter systems have been used since the 1980s to treat chronic pain[2] and since 1992 to treat spasticity. There are two methods for delivering intrathecal medications: external pump or fully implantable devices. IDDS are either mechanical constant flow delivery systems or electronically variable flow programmable devices with the option for patient-controlled bolus administration. Battery-powered IDDS pumps allow for noninvasive medication

What We Already Know about This Topic

- The use of implantable pain management technology has increased since the 1990s
- Malpractice claims related to the implantation and maintenance of these devices have also increased

What This Article Tells Us That Is New

- Claims related to surgical implantation of devices involved infection, inadequate pain relief, trauma to the cord or cauda equina, and retained catheter fragments
- Claims related to implanted drug delivery system maintenance tended to involve more serious outcomes associated with medication administration errors and failure to recognize granuloma formation

Preliminary findings were published for the American Society of Anesthesiologists annual meeting in San Diego, California, October 24–28, 2015 (Pollack KA, Stephens L, Fitzgibbon DR, Posner K, Rathmell JP, Michna E, Domino KB: Injury and liability associated with implantable devices for chronic pain. Abstract A1006).

Submitted for publication December 14, 2015. Accepted for publication March 3, 2016. From the Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington (D.R.F., L.S.S., K.L.P., K.A.P., K.B.D.); Pain Management Center, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts (E.M.); and Department of Anesthesia, Critical Care, and Pain Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts (J.P.R.).

 Anesthesiology 2016; 124:1384-93

<zdoi;10.1097/ALN.0000000000001122>

dose changes using an external programmer. Advances in IDDS accommodate a range of medications. Intrathecal opioid administration is effective at lower doses compared to other routes,[3] and the highly localized drug results in maximal analgesic efficacy at the targeted area (neuraxis).[4]

There are a number of potential safety hazards associated with IDDS, including medication errors,[5,6] granuloma formation,[7] and device product performance events.[8] Turner *et al.*[9] reported that one in three patients undergoing SCS implantation experienced adverse complications, although very few of these complications were life threatening. Complications associated with SCS implantation included infections, both deep and superficial, dural punctures, equipment failures, surgical revision, and new or ongoing pain.

Due to the increase in implantable device–related anesthesia pain medicine claims from 3% in the 1980s to 16% of pain medicine claims in the 2000s,[10] we analyzed liability associated with these devices in the Anesthesia Closed Claims Project database.

Materials and Methods

The Anesthesia Closed Claims Project database is a structured evaluation of adverse anesthetic outcomes obtained from the closed malpractice claims files of U.S. professional liability insurance companies. The data collection process has previously been described in detail.[11,12] Claims alleging negligence in pain medicine were 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 events involved in the claim. Most pain medicine files were reviewed by anesthesiologists who practice pain medicine. Forms and narrative summaries completed by the on-site anesthesiologist-reviewer were subsequently reviewed by three pain anesthesiologists (D.R.F., E.M., and J.P.R.) for data quality and consistency with project protocol. For this study, we used the Anesthesia Closed Claims Project database of 10,546 claims for injuries between 1990 and 2013. Inclusion criteria were claims for pain medicine that occurred in 1990 or later. There were no exclusions.

Definition of Variables

All pain medicine claims in the Anesthesia Closed Claims Project database were classified by the type of pain medicine care provided by the anesthesiologist, including device-related care, consultations, medication management, nonlytic blocks and injections, lytic chemical procedures, lytic thermal procedures, acupuncture, discography, intradiscal electrothermal therapy, and other invasive procedures.[10] If more than one type of care was provided, the care was classified by the type of care associated with the injury or alleged injury.

Device-related care was initially categorized by type of device: implantable drug delivery systems (IDDS), tunneled catheters, SCS, and peripheral nerve stimulators, and by type of care provided: implant, replace, remove, or maintain the device. After initial analyses, the damaging events and outcomes associated with implanting, replacing, and removing all four types of devices were found to be similar to each other, and consequently, they were grouped together as "surgical device procedures."

Damaging events were defined as the mechanism by which a complication or injury occurred or allegedly occurred. Device-related damaging events were grouped into the following categories: medication administration events, device-related infections, device-related hematomas, retained catheter fragments, CSF leaks, needle, catheter, or lead trauma to the cord or cauda equina, device placed at wrong level, stimulator incorrectly programmed, delay in recognition of granuloma formation (soft tissue masses resulting from an inflammatory reaction at the level of the catheter tip), failure to diagnose presenting condition or cause for new symptoms (excludes granuloma formation), patient did not cooperate in his/her own care (taking additional opioids not prescribed by the plaintiff anesthesiologist), inadequate pain relief or pain made worse, and other issues. Medication administration events were further subclassified as programming errors, side port-fill or pocket-fill of medication (accidental injection during a refill procedure of all or some of the prescribed drug into the patient's subcutaneous tissue, which includes the pump pocket, instead of into the pump), inappropriately high doses of medication on an outpatient basis, wrong drug administered, adverse drug reactions, equipment malfunction, and other medication issues. Inadequate pain relief events consisted of claims where no relief was ever experienced after insertion of the device, claims where the insertion of the device immediately increased the level of pain, and claims where there was an initial improvement in pain, but the pain returned at a later time.

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).[13] This scale was collapsed into three severity outcomes: death, permanent disabling injury (score, 6 to 8) and temporary minor injury (score, 0 to 5). The severity of injury was based on the patient's status at the time the claim was closed. A claim with severe brain damage resulting in death before claim closure was classified as death. Because death and severe permanent brain damage were often associated with the same damaging events, some results are reported for patients experiencing either death or severe brain damage. Severe nerve injury was defined as permanent disabling injury (score, 6 to 8).

Appropriateness of care was assessed by the on-site reviewer based on reasonable and prudent criteria for anesthesia practice at the time of the event. Standard of care was assessed as appropriate, less than appropriate, or impossible to judge. The reliability of these evaluations has been judged as acceptable.[14]

Statistical Analysis

Device-related claims were compared to other pain medicine claims by chi-square analysis, Fisher exact test, Student's *t* test, and Mann–Whitney U test using $P < 0.05$ for statistical significance. Claims for IDDS maintenance and surgical device procedures were also compared by the same statistical tests. All payments made to the plaintiff were extracted from the database and adjusted to 2014 dollar amounts with the Consumer Price Index.[15] Because payment amounts were not normally distributed, median and interquartile ranges were reported as descriptive statistics. Claims with no payment were excluded from calculation of median and interquartile range. All statistical analyses were conducted using SPSS 19.0.0 for Windows (IBM Corporation, USA).

Results

Device-related versus *Other Pain Medicine Claims*

Most (97%, n = 144) device-related claims involved management of nonmalignant chronic pain. Two devices were for management of cancer-related pain and two for spasticity. Injuries in device-related claims occurred between 1990 and 2011. Implantable device–related claims (n = 148) were similar to other pain medicine claims (n = 822) with a few exceptions: device-related claims were more likely to occur on an inpatient basis (40%, n = 53, *vs.* 7%, n = 54, $P < 0.001$; table 1), and patients in device-related claims had more medical issues than patients in other pain medicine claims (46%, n = 60, *vs.* 29%, n = 191, American Society of Anesthesiologists 3 to 5, $P < 0.001$; table 1). The injuries that resulted from device-related claims were more likely to be temporary and/or minor than the injuries that resulted from other pain medicine claims (66%, n = 97, *vs.* 54%, n = 439, $P = 0.02$; table 1). Serious injuries occurred with death in 9% (n = 14) of device-related claims and permanent disabling injury in 25% (n = 37). Standard of care and payments did not differ between device-related and other pain medicine claims (table 1).

The most common devices in the device-related claims were IDDS (n = 94, 64%) and SCS (n = 43, 29%). Device-related care provided by anesthesiologists consisted of surgical device procedures (n = 107, 72%) and maintenance of IDDS (n = 41, 28%; table 2). There were no claims for maintenance of SCS, peripheral nerve stimulators, or tunneled neuraxial catheters.

IDDS Maintenance versus *Surgical Device Procedure Claims*

The severity of patient injury was greater in claims related to IDDS maintenance compared to claims related to surgical device procedures (fig. 1). Fifty-six percent of IDDS maintenance patients experienced death or severe permanent injury (n = 23), whereas 26% (n = 28) of surgical device procedure patients experienced death or severe permanent injury ($P < 0.001$). Severe permanent injuries included brain damage and injury to the spinal cord and cauda equina.

Damaging events differed between IDDS maintenance and surgical device procedure claims. While 61% (n = 25) of IDDS maintenance claims were associated with medication management issues, only 7% (n = 8) of surgical device procedure claims had events related to medication administration (table 3). Delay in recognition of granuloma formation occurred in 22% (n = 9) of IDDS maintenance claims. The most common damaging events for surgical device procedures were infections (23%, n = 25), inadequate pain relief

Table 1. Patient and Claim Characteristics of Device-related and Other Chronic Pain Claims*

	Device-related Claims (n = 148), n (%)	Other Chronic Pain Claims (n = 822), n (%)	*P* Value
Patient was female (n = 967)	86 (58)	492 (60)	0.359
Mean age of patient, SD (n = 957)	47 (13)	49 (14)	0.217
Patient was obese (n = 439)	27 (42)	149 (40)	0.449
ASA 3–5 (n = 784)	60 (46)	191 (29)	< 0.001
Patient was inpatient (n = 901)	53 (40)	54 (7)	< 0.001
Severity of injury (n = 968)			0.020
Death	14 (9)	125 (15)	
Permanent disabling injuries	37 (25)	256 (31)	
Temporary or minor injuries	97 (66)	439 (54)	
Severe permanent nerve injury	27 (18)	197 (24)	0.075
Severe permanent brain damage	8 (5)	25 (3)	0.116
Standard of care was inadequate (n = 855)	70 (54)	341 (47)	0.091
Claim was paid (n = 928)	59 (41)	374 (48)	0.081
Median payment made (2014$)	$274,000	$276,650	0.746
25th quartile	$64,500	$75,175	
75th quartile	$920,000	$756,000	

*N = 970 chronic pain claims, where event occurred in 1990 or later unless otherwise indicated. Independent samples Mann–Whitney U test was used for comparison of median payments. Chi-square test was used for comparison of severity of injury and Student's *t* test for mean age. All other comparisons use Fisher exact test.

ASA = American Society of Anesthesiologists.

Table 2. Device-related Care by Types of Device in Claims (n = 148)*

	n (%)
Maintain IDDS (n = 41)	41 (28)
Surgical device procedures (n = 107)	
Implant IDDS	45 (30)
Implant spinal cord stimulators	42 (28)
Implant tunneled catheters	7 (5)
Implant peripheral stimulators	3 (2)
Remove IDDS	8 (5)
Remove spinal cord stimulators	1 (1)
Remove tunneled catheters	1 (1)

*Event occurred in 1990 or later.
IDDS = implantable drug delivery systems.

(15%, n = 16), trauma to cord or cauda equina (9%, n = 10), and retained catheter fragments (9%, n = 10).

The standard of care and the proportion of claims with payments also varied with the type of device-related care. The care provided by the pain medicine anesthesiologist was judged as less than appropriate in 78% (n = 32) of the IDDS maintenance claims and in 43% (n = 38) of the claims for surgical device procedures ($P < 0.001$; table 3). Payments were made in 63% (n = 25) of IDDS maintenance claims *versus* 33% (n = 34) of surgical device procedure claims ($P = 0.001$; table 3). The payment amount was not different in IDDS maintenance and surgical device procedure claims (table 3).

Specific Damaging Events and Outcomes in Device-related Claims

Medication administration damaging events (n = 33) were associated with 64% of all device-related death or severe permanent brain damage claims (fig. 2). The most common mechanisms for these dosage-related damaging events during IDDS maintenance were programming errors (n = 7), pocket-fill and side port-fill (n = 6 and 2, respectively), and wrong drug administered (n = 3; table 4). Six deaths, five cases of permanent brain damage, and one case of a patient requiring permanent ventilator support occurred in the claims for drug dosage errors. In another five claims, the dose given was assessed as too high to be given on an outpatient basis during the initial placement of the IDDS device or during maintenance of the IDDS device.

For all device-related claims, the most common reasons for severe permanent injury to the spinal cord or cauda equina (n = 27) were delay in recognition of granuloma formation (33%, n = 9), needle trauma to the spinal cord or caudal equina (26%, n = 7), and epidural hematoma (11%, n = 3; fig. 2). Overall, there were nine claims for delay in recognition of granuloma formation at the tip of the catheter during the maintenance of IDDS (table 3), all resulting in paraplegia. Patients typically presented complaining of increased back pain at the site of the catheter tip and/or had new or increasing lower extremity weakness. Six of the nine cases first presented with either paralysis or increasing lower extremity weakness, and five cases initially presented with either new-onset back pain or increasing back pain. Six cases presented 2 yr after implantation of the device, one case presented after 3 months, and one case presented 8 yr after implantation. In all nine cases, providers failed to recognize the development of the granuloma until there was permanent severe disabling neurologic injury affecting the spinal cord or cauda equina. Opioids were implicated in all nine cases (hydromorphone in four claims, morphine in three claims, and an unspecified opioid in two claims). There were 10 claims for needle (n = 8), catheter (n = 1), or lead (n = 1) trauma to the cord. Seven of the 10 claims resulted in permanent severe nerve injuries including paraplegia, cauda equina syndrome, and hemiparesis secondary to injury to the corticospinal tract on 1 side; 1 claim resulted in death. Of the seven claims that reported the use of radiographic guidance, one used guidance only after multiple needle sticks and only one of the seven used multiple-plane imaging.

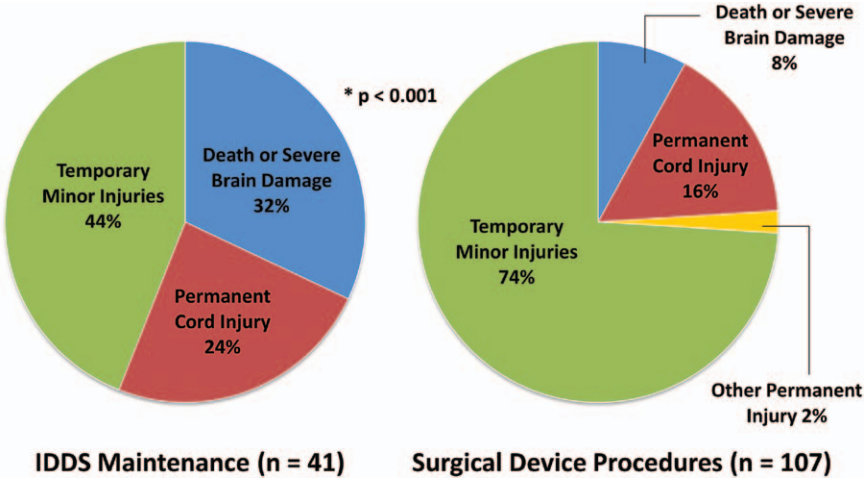

Fig. 1. Permanent severe injuries and death were more common in implantable drug delivery systems (IDDS) maintenance claims than surgical device procedure claims ($P < 0.001$).

Table 3. Damaging Events and Claim Liability by Type of Device-related Care*

	Surgical Device Procedures (n = 107), n (%)	Maintenance of IDDS (n = 41), n (%)	*P* Value
Damaging events			
Medication administration issues	8 (7)	25 (61)	
Device-related infections	25 (23)	0 (0)	
Inadequate pain relief	16 (15)	1 (2)	
Needle/catheter/lead trauma to cord/cauda equina	10 (9)	0 (0)	
Retained catheter fragments	10 (9)	0 (0)	
CSF leaks resulting in lumbar subcutaneous hygroma	9 (8)	0 (0)	
Delay in recognition granuloma formation	0 (0)	9 (22)	
Other†	29 (27)	6 (15)	
Care was less than appropriate (n = 130)	38 (43)	32 (78)	< 0.001
Claim was paid (n = 144)	34 (33)	25 (63)	0.001
Median payment (2014$)	$149,650	$334,526	0.177
25% quartile	$61,110	$89,540	
75% quartile	$693,165	$1,206,700	

Independent samples Mann–Whitney U test was used for comparison of median payments. All other comparisons use Fisher exact test.

*n = 148 device-related chronic pain claims, where event occurred in 1990 or later unless otherwise indicated. †See table 4 for details on other damaging events.

CSF = cerebrospinal fluid; IDDS = implantable drug delivery systems.

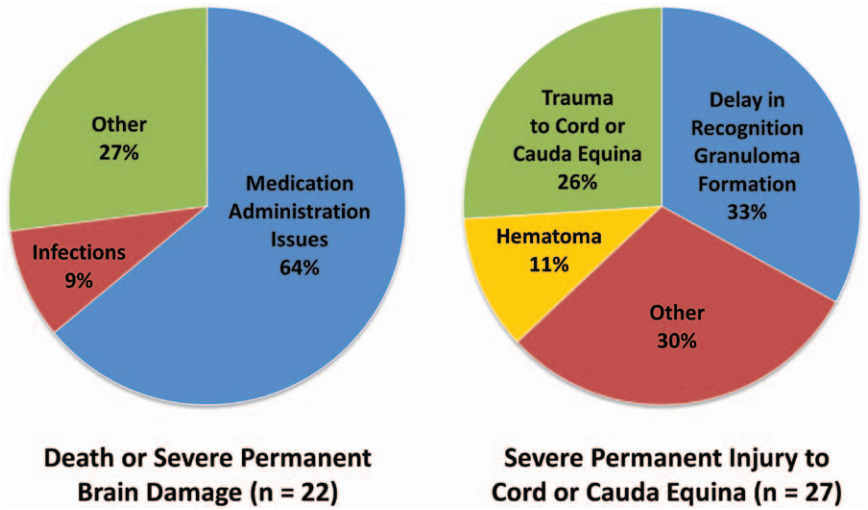

Fig. 2. The most common cause of death and severe permanent brain damage was medication administration problems, frequently associated with implantable drug delivery systems. Severe permanent injury to the spinal cord or cauda equina was most commonly associated with delay in recognition of granuloma formation; needle, catheter, or lead trauma; or hematoma.

Procedure-related infections associated with surgical procedures occurred in 25 of 107 claims-related surgical device procedures (23%; table 3). Seven of the 25 infections were associated with retained foreign bodies, *e.g.*, sponges and leads (table 4). The injuries were either temporary or minor for all but 3 of the 25 procedure-related infections. The three claims with permanent severe injuries resulted in one claim each for finger amputation, severe brain damage, and death.

In nine claims, a CSF leak occurred resulting in formation of a lumbar subcutaneous hygroma (table 3), with one resulting in death. There were also 10 claims for retained portions of catheters (with none resulting in infection) and 4 claims for the device being placed at the wrong level or in the wrong space (table 4), which resulted in 2 patients with permanent paraplegia and 1 with hemiparesis secondary to injury to the corticospinal tract on one side.

Of the 17 claims for inadequate pain relief or an increase in pain after the device was implanted, 11 were associated with SCS (table 4). Three of the 10 SCS never provided any relief of pain, and 1 was associated with an immediate increase in pain. For 7 of the 11 stimulator claims, the patient initially reported pain relief for a period of time before the spinal cord stimulator failed to provide relief. In three of those claims, the leads had migrated; in one claim, the patient experienced a fall just before the failure; in three claims, there was no obvious reason why the relief had subsided.

Of note, in four device-related claims, the patient did not cooperate in his or her own care by taking opioids and other

Table 4. Types of Damaging Events by Device-related Care (n = 148)

	Implant/Replace IDDS or Catheters (n = 52), n (%)	Maintain IDDS (n = 41), n (%)	Remove Device* (n = 10), n (%)	Implant/Replace/Stimulators† (n = 45), n (%)
Medication administration issues (n = 33)	8 (15)	25 (61)	0 (0)	0 (0)
Programming error	n = 1	n = 7		
Pocket-fill of medication		n = 6		
Side port-fill of medication		n = 2		
Inappropriately high dose on outpatient basis	n = 2	n = 3		
Wrong drug administered	n = 2	n = 3		
Adverse drug reaction	n = 3			
Other‡		n = 4		
Device-related infections (n = 25)	13 (25)	0 (0)	1 (10)	11 (24)
Associated with retained sponges, leads, and other parts	n = 2		n = 1	n = 4
Patient condition (n = 7)§	3 (6)	0 (0)	0 (0)	4 (9)
Retained catheter fragments (n = 10)	4 (8)	0 (0)	6 (60)	0 (0)
CSF leaks resulting in lumbar subcutaneous hygroma (n = 9)	8 (15)	0 (0)	0 (0)	1 (2)
Delay in recognition of granuloma formation (n = 9)	0 (0)	9 (22)	0 (0)	0 (0)
Trauma to cord or cauda equina (n = 10)	9 (17)	0 (0)	0 (0)	1 (2)
Inadequate pain relief or pain made worse (n = 17)	4 (8)	1 (2)	1 (10)	11 (24)
Never provided pain relief	n = 1			n = 3
Initially provided pain relief‖	n = 1	n = 1	n = 1	n = 7
Immediate increase in pain	n = 1			n = 1
Initially no relief until dose increased	n = 1			
Device placed at wrong level or space (n = 4)	1 (2)	0 (0)	0 (0)	3 (7)
Failure to diagnose presenting condition or cause for new symptoms (n = 5)	1 (2)	1 (2)	0 (0)	3 (7)
Device-related hematomas (n = 5)	1 (2)	0 (0)	0 (0)	4 (9)
Patient did not cooperate in his/her care (n = 4)	0 (0)	1 (2)	2 (20)	1 (2)
Stimulator incorrectly programmed (n = 2)				2 (4)
Other (n = 8)#	0 (0)	4 (10)	0 (0)	4 (9)

*Devices removed consisted of implantable drug delivery systems (IDDS), spinal cord stimulators, and tunneled catheters. †Stimulators were for spinal cord and peripheral nerves. ‡Other medication administration issues consisted of one claim each for equipment malfunction, failure to purge a pump, wrong volume administered, and patient sent home with pump known to be nonfunctioning. §Other patient condition issues after implantation or replacement of IDDS or catheters consisted of one claim each for postprocedure addiction, cardiovascular accident, and unexplained seizures. Other patient condition issues after implantation or replacement of stimulators consisted of one claim each for areflexic bladder, hypotension and hypoxemia, progression of degenerative disc disease, and unexplained respiratory event. ‖An IDDS pump stopped providing relief after catheter migration. Three spinal cord stimulators stopped providing relief after lead migration, one after patient fell, and three had no obvious reason why they stopped providing pain relief. #Other damaging events for IDDS maintenance consisted of one claim each for cerebrospinal fluid (CSF) leak, patient's care not transferred to new physician, insurance issues, and one unknown damaging event. Other damaging events for implant/replace stimulators consisted of one claim each for patient fell off procedure table, stimulator manufacturer sent wrong part, surgical technique of another physician working with the anesthesiologist, and anesthesiologist supervising sedation and implanting pump at the same time.

medications not prescribed by the defendant anesthesiologist (table 4). This included one claim where it was discovered that the patient was self-filling the pump reservoir with phencyclidine and methamphetamine.

Discussion

This is the first study of liability associated with implantable devices for treatment of chronic pain. Severe injuries were more commonly associated with IDDS maintenance than with surgical device procedures (66 *vs.* 26%; fig. 1). Severe injuries with IDDS maintenance were associated with medication administration errors and failure to recognize granuloma formation. Severe injuries from surgical device procedures involved needle trauma to the spinal cord or cauda equina or surgical site infections.

Implantable Devices for Chronic Pain Management

Implantable devices such as SCS and IDDS for chronic pain management represented 93% of device-related claims in the Anesthesia Closed Claims Project database. These devices require surgical procedures for implantation/replacement or removal, regular monitoring of use, replacement over time, and refilling of pumps at regular intervals.[16] Surgical procedures and device medication refills have the potential for serious complications. According to the Implantable Systems Performance Registry Report from Medtronic (USA) in 2014, 60% of reported events were non-product performance events including implant site infection, pump inversion, therapeutic product ineffective, drug toxicity, and drug withdrawal syndrome.[8] Fifty-nine percent of all reported events resulted in patient death; no deaths were assessed as the direct result of device failure or infusion therapy failure. However, the Food

and Drug Administration recently issued a consent decree limiting the manufacture and distribution of certain IDDS related to over- and underinfusion,[17] and there are reports of IDDS failures resulting in deaths[18] and life-threatening complications.[19–21] Turner *et al.*[22] noted that while life-threatening complications were rare, adverse occurrences (*e.g.*, pump malposition, catheter-related problems, wound infection, drug side effects) occurred relatively frequently. Rare, but serious, complications included intrathecal catheter tip granulomas.[22]

IDDS Medication Administration Events

Opioid overdose in patients with IDDS can occur for various reasons including pocket fills,[5,23] changes in intrathecal opioid medication,[24] programming errors,[6] flushing the line accidentally with morphine rather than saline after catheter placement,[25] and pump refill *via* the side port instead of the drug reservoir port resulting in opioid administration directly into the CSF.[6] Our closed claims review found that programming errors, pocket fills, inappropriately high doses of opioids without proper initial in-house monitoring, wrong drug, adverse drug reactions, and side port injections were the causes of medication errors. Half of these events resulted in catastrophic outcome (death and brain damage), suggesting the need to improve IDDS medication safety.

Outpatient IDDS management typically involves simultaneous medication prescription, dispensing, and administration in one step by a single provider, potentially increasing the probability of error. A mechanism to prevent such errors might include two person checks for appropriateness of dosing, programming, and refill procedures with detailed accounting to the patient and the patient's family of potential adverse events and the changes made during the visit. At each refill, patients should be instructed about possible symptoms of a medication error and to seek immediate assistance should any of these symptoms occur.[26]

Potentially catastrophic pocket fills occur during IDDS refill if the needle is not inserted through the refill port septum until it has reached the metal bottom of the refill port or the needle is moved outside the refill port. This can result in placement of a large amount of drug outside the pump (in subcutaneous tissue) where it can be rapidly absorbed into the systemic circulation, leading to serious morbidity/mortality. Symptoms usually occur immediately or within several hours. To prevent pocket fills, the leading IDDS manufacturer produced guidelines for critical actions to be taken during the pump refill procedure.[27]

Accidental side port injections can result in direct injection of highly concentrated opioids or other drugs into the CSF with life-threatening consequences. Our study identified two deaths from side port injections. Both occurred before 2004 and were likely related to older pump refill or side port template design that allowed for potential side port injection during refill. Voluntary manufacturer withdrawal of these older devices in 2007 and device redesign appear to have addressed the side port injection problem.

Delay in Recognition of Granuloma Formation

Delays in recognition of granuloma formation with IDDS were associated with severe permanent injury to the spinal cord or cauda equina in our claim series (fig. 2). The development of a granuloma from subarachnoid infusion of morphine was first recognized in 1991.[28] The most common agents associated with granulomas are morphine and hydromorphone[29] although there are cases associated with intrathecal baclofen as the sole agent.[30–32] Administration of high concentrations or high doses of opioids has been associated with formation of granulomas,[33] with some authors recommending maximum doses of intrathecal morphine at 10 mg/day and concentration of 15 mg/ml.[34] Opioids at equianalgesic doses present different risks for granuloma formation. Opioids were implicated in all cases in our review.

The time required for human granuloma development is uncertain, and times reported vary from 0.5 to 72 months with an average of 24 months until clinical symptoms are identified.[35] Animal studies suggest that a mass may begin to form proximal to the catheter tip in just 10 days; termination of morphine infusion resulted in progressive reduction in mass size over the ensuing 14 days.[36] In our closed claims review, cases presented 3 months to 2 yr after device implantation.

Asymptomatic lesions may exist for years before signs or symptoms appear.[37] In all nine claims in our review, providers failed to recognize the development of the granuloma until there was permanent disabling neurologic injury. The most frequently reported symptoms associated with inflammatory mass are decreased therapeutic response/inadequate pain relief, pain, and neurologic deficit/dysfunction.[7,38] Consistent with this description, our closed claims patients presented complaining of increased back pain and/or had new or increasing lower extremity weakness. Loss of analgesia accompanied by new, gradually progressive neurologic symptoms and signs may aid in the diagnosis of granulomas.[39] Patients receiving intrathecal opioid therapy should be monitored at each visit for changes in motor or sensory function or increased back pain. The diagnostic test of choice is magnetic resonance imaging with and without gadolinium with closely spaced images through the level of the catheter tip. If there is evidence of neural compression, consultation with a neurosurgeon is needed. In symptomatic patients, treatment strategies are based on degree of symptomatology. Loss of motor function will usually require surgical relocation or removal of the catheter.[29,40]

Complications Associated with Device-related Surgical Procedures

In our analysis, surgical procedures for devices involved 72% of all claims (n = 107) with temporary or minor complications in 74%. These findings appear consistent with other reports[9,41,42] noting that major complications were rare and minor complications were associated with SCS during placement or removal and superficial infections.

There are reports of traumatic syrinx formation due to spinal cord penetration by the intrathecal catheter during placement[43] and intracranial subdural hematoma after IDDS procedures.[44] In our series, there were 10 claims with needle, catheter, or lead trauma resulting in severe injuries including lower extremity paralysis and cauda equina syndrome in 7 and 1 death. If general anesthesia is used for surgical device procedures, patients will be unable to provide input about potential problems, so extra vigilance is indicated at the time of needle placement and at catheter/lead advancement to avoid spinal cord trauma.[26]

Neurologic injury from catheter/lead placement is rare and can occur directly from needle or catheter/lead trauma during insertion or from epidural hematoma or infection.[41] Insertion of intrathecal needles or catheters above L2 increases the risk of spinal cord injury.[45] Placing the intrathecal catheter under fluoroscopic guidance is standard for positioning the tip at the desired vertebral level. Fluoroscopy using multiple planes, *e.g.*, anteroposterior and lateral images, has been recommended as a means to improve the safety of spinal injections.[46,47] Use of the anteroposterior view during initial needle placement allows selection of a vertebral interspace below L2 to avoid entering the thecal sac above the termination of the conus medullaris where direct trauma to the cord may be more likely; this view also allows the practitioner to keep the needle directed toward the midline, avoiding potential injury to the spinal nerves. Use of the lateral view established the depth of needle advancement and can be used to position the catheter tip at the desired vertebral level.[46,47] Multiple-plane imaging was rarely used in claims with spinal cord trauma in our series.

Device-related Infections

Bolash *et al.*[48] reported infection in 38 of 365 patients over a 14-yr period. The majority of these patients (74%) required inpatient admission for intravenous antibiotic therapy. Although most SCS infections can be adequately managed either with antibiotic therapy or complete removal of the device, life-threatening infections can occur.[49] In our closed claims review, surgical procedure–associated infections occurred with IDDS, tunneled epidural catheters, SCS, and peripheral stimulators. One third of the device-related infections were related to retained sponges, anchoring devices, or other parts. Some of these infections were not referred for appropriate consultative services or were inappropriately managed, such as primary closure of an infected wound. Recommendations for prevention and management of device-related infections are available.[50] Standard infection control measures, aseptic surgical techniques, and appropriate monitoring of wound healing with appropriate training for management of infectious complications are essential. Introduction of infection control measures for implantable devices has been associated with a reduction in the incidence of infection.[51]

Study Limitations

The limitations of closed claims analysis have been previously described, including selection bias, nonrandom retrospective data collection, and possible geographic imbalance in data collection.[11,12] Data collected by anesthesiologist-reviewers are limited to information gathered for claims resolution. Lawsuits form a small proportion of adverse events, with a bias toward severe outcomes and substandard care. The database lacks a denominator of procedures for estimating rates of complications for the various procedures. Despite these limitations, the database provides detailed information on rare adverse events and outcomes that are otherwise difficult to study prospectively.

Conclusions

Serious outcomes including death or permanent brain damage resulted from medication administration errors, primarily during maintenance of IDDS. Permanent neuraxial injuries were primarily caused by trauma during device placement and failure to recognize granuloma formation during IDDS maintenance. Clinicians involved with implantation and ongoing care of patients receiving these therapies require a high level of expertise. Morbidity and mortality can be minimized using optimal surgical technique, establishing protocols for refilling and reprogramming, and appropriate patient follow-up with rapid recognition of evolving complications and implementation of appropriate treatment.

Acknowledgments

The authors acknowledge the closed claims reviewers from the American Society of Anesthesiologists and participation of the following liability insurance companies who have given permission to be acknowledged: Anesthesia Service Medical Group, Inc., San Diego, California; COPIC Insurance Company, Denver, Colorado; Department of Veterans Affairs, Washington, D.C.; ISMIE Mutual Insurance Company, Chicago, Illinois; MAG Mutual Insurance Company, Atlanta, Georgia; Medical Liability Mutual Insurance Company, New York, New York; Medical Professional Mutual Insurance Company, Boston, Massachusetts; Midwest Medical Insurance Company, Minneapolis, Minnesota; NORCAL Mutual Insurance Company, San Francisco, California; Pennsylvania Medical Society Liability Insurance Company, Mechanicsburg, Pennsylvania; Physicians Insurance A Mutual Company, Seattle, Washington; Preferred Physicians Medical Risk Retention Group, Overland Park, Kansas; Risk Management Foundation, Cambridge, Massachusetts; State Volunteer Mutual Insurance Company, Brentwood, Tennessee; The Doctors' Company, Napa, California; The University of Texas System, Austin, Texas; Utah Medical Insurance Association, Salt Lake City, Utah.

Supported in part by the American Society of Anesthesiologists (ASA), Schaumburg, Illinois, and the Anesthesia Quality Institute (AQI), Schaumburg, Illinois. All opinions expressed are those of the authors and do not reflect the policy of the ASA or AQI.

Competing Interests

The authors declare no competing interests.

Correspondence

Address correspondence to Dr. Fitzgibbon: Department of Anesthesiology and Pain Medicine, University of Washington, 1959 NE Pacific Street, Box 356540, Seattle, Washington 98195. dermot@uw.edu. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue. ANESTHESIOLOGY's articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

References

1. American Society of Anesthesiologists Task Force on Chronic Pain Management: Practice guidelines for chronic pain management: An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. ANESTHESIOLOGY 2010; 112:810–33
2. Penn RD, Paice JA, Gottschalk W, Ivankovich AD: Cancer pain relief using chronic morphine infusion. Early experience with a programmable implanted drug pump. J Neurosurg 1984; 61:302–6
3. Nordberg G, Hedner T, Mellstrand T, Dahlström B: Pharmacokinetic aspects of intrathecal morphine analgesia. ANESTHESIOLOGY 1984; 60:448–54
4. Bernards CM: Cerebrospinal fluid and spinal cord distribution of baclofen and bupivacaine during slow intrathecal infusion in pigs. ANESTHESIOLOGY 2006; 105:169–78
5. Coyne PJ, Hansen LA, Laird J, Buster P, Smith TJ: Massive hydromorphone dose delivered subcutaneously instead of intrathecally: Guidelines for prevention and management of opioid, local anesthetic, and clonidine overdose. J Pain Symptom Manage 2004; 28:273–6
6. Sauter K, Kaufman HH, Bloomfield SM, Cline S, Banks D: Treatment of high-dose intrathecal morphine overdose. Case report. J Neurosurg 1994; 81:143–6
7. Medtronic: Medical Device Correction: Inflammatory Mass (Granuloma) at or Near the Distal Tip of Intrathecal Catheters (Product Advisory). Minneapolis: Medtronic, 2008
8. Weaver T, Wells M, Schiller K, Roediger M, Stromberg K, Van Dorn B: Medtronic 2014 Product Performance Report: Data Through July 31, 2014. Minneapolis: Medtronic, 2014
9. Turner JA, Loeser JD, Deyo RA, Sanders SB: Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. Pain 2004; 108:137–47
10. Pollak KA, Stephens LS, Posner KL, Rathmell JP, Fitzgibbon DR, Dutton RP, Michna E, Domino KB: Trends in pain medicine liability. ANESTHESIOLOGY 2015; 123:1133–41
11. Cheney FW, Posner K, Caplan RA, Ward RJ: Standard of care and anesthesia liability. JAMA 1989; 261:1599–603
12. Cheney FW: The American Society of Anesthesiologists Closed Claims Project: What have we learned, how has it affected practice, and how will it affect practice in the future? ANESTHESIOLOGY 1999; 91:552–6
13. Sowka M, ed.: Malpractice Claims: Final Compilation. Brookfield, National Association of Insurance Commissioners, 1980
14. Posner KL, Sampson PD, Caplan RA, Ward RJ, Cheney FW: Measuring interrater reliability among multiple raters: An example of methods for nominal data. Stat Med 1990; 9:1103–15
15. Bureau of Labor Statistics, US Department of Labor: Consumer Price Index Inflation Calculator. Available at: http://www.bls.gov/data/home.htm. Accessed March 3, 2015
16. Turk DC, Wilson HD, Cahana A: Treatment of chronic noncancer pain. Lancet 2011; 377:2226–35
17. U.S. Food and Drug Administration: FDA Enters Consent Decree with Medtronics, Inc.: Company Cited for Manufacturing Violations. FDA, April 27, 2015. Available at: http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm444690.htm. Accessed December 9, 2015
18. Burton TM: Medtronic in FDA consent decree over its SynchroMed infusion pump. The Wall Street Journal April 27, 2015
19. Maino P, Koetsier E, Perez RS: Fentanyl overdose caused by malfunction of SynchroMed II intrathecal pump: Two case reports. Reg Anesth Pain Med 2014; 39:434–7
20. Riordan J, Murphy P: Intrathecal pump: An abrupt intermittent pump failure. Neuromodulation 2015; 18:433–5
21. Sgouros S, Charalambides C, Matsota P, Tsangaris I, Kostopanagiotou G: Malfunction of SynchroMed II baclofen pump delivers a near-lethal baclofen overdose. Pediatr Neurosurg 2010; 46:62–5
22. Turner JA, Sears JM, Loeser JD: Programmable intrathecal opioid delivery systems for chronic noncancer pain: A systematic review of effectiveness and complications. Clin J Pain 2007; 23:180–95
23. Perruchoud C, Bovy M, Durrer A, Rosato M, Rutschmann B, Mustaki JP, Buchser E: Severe hypertension following accidental clonidine overdose during the refilling of an implanted intrathecal drug delivery system. Neuromodulation 2012; 15:31–4; discussion 34
24. Kamran S, Wright BD: Complications of intrathecal drug delivery systems. Neuromodulation 2001; 4:111–5
25. Groudine SB, Cresanti-Daknis C, Lumb PD: Successful treatment of a massive intrathecal morphine overdose. ANESTHESIOLOGY 1995; 82:292–5
26. Prager J, Deer T, Levy R, Bruel B, Buchser E, Caraway D, Cousins M, Jacobs M, McGlothlen G, Rauck R, Staats P, Stearns L: Best practices for intrathecal drug delivery for pain. Neuromodulation 2014; 17:354–72; discussion 372
27. Medtronic: Clinical Actions in the Pump Refill Procedure: Clinician Refill Reference Card. Medtronics, Inc., 2013. Available at: https://professional.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@neuro/documents/documents/pa-refill-guide.pdf. Accessed August 21, 2015
28. North RB, Cutchis PN, Epstein JA, Long DM: Spinal cord compression complicating subarachnoid infusion of morphine: Case report and laboratory experience. Neurosurgery 1991; 29:778–84
29. Deer TR, Levy R, Prager J, Buchser E, Burton A, Caraway D, Cousins M, De Andres J, Diwan S, Erdek M, Grigsby E, Huntoon M, Jacobs MS, Kim P, Kumar K, Leong M, Liem L, McDowell GC II, Panchal S, Rauck R, Saulino M, Sitzman BT, Staats P, Stanton-Hicks M, Stearns L, Wallace M, Willis KD, Witt W, Yaksh T, Mekhail N: Polyanalgesic Consensus Conference—2012: Recommendations to reduce morbidity and mortality in intrathecal drug delivery in the treatment of chronic pain. Neuromodulation 2012; 15:467–82; discussion 482
30. Murphy PM, Skouvaklis DE, Amadeo RJ, Haberman C, Brazier DH, Cousins MJ: Intrathecal catheter granuloma associated with isolated baclofen infusion. Anesth Analg 2006; 102:848–52
31. Deer TR, Raso LJ, Garten TG: Inflammatory mass of an intrathecal catheter in patients receiving baclofen as a sole agent: A report of two cases and a review of the identification and treatment of the complication. Pain Med 2007; 8:259–62
32. Narouze SN, Mekhail NA: Intrathecal catheter granuloma with baclofen infusion. Anesth Analg 2007; 104:209; author reply 209–10
33. Coffey RJ, Burchiel K: Inflammatory mass lesions associated with intrathecal drug infusion catheters: Report and observations on 41 patients. Neurosurgery 2002; 50:78–86; discussion 86–7
34. Duarte RV, Raphael JH, Southall JL, Baker C, Ashford RL: Intrathecal granuloma formation as result of opioid

delivery: Systematic literature review of case reports and analysis against a control group. Clin Neurol Neurosurg 2012; 114:577–84

35. Deer TR: A prospective analysis of intrathecal granuloma in chronic pain patients: A review of the literature and report of a surveillance study. Pain Physician 2004; 7:225–8
36. Allen JW, Horais KA, Tozier NA, Wegner K, Corbeil JA, Mattrey RF, Rossi SS, Yaksh TL: Time course and role of morphine dose and concentration in intrathecal granuloma formation in dogs: A combined magnetic resonance imaging and histopathology investigation. Anesthesiology 2006; 105:581–9
37. Deer TR, Prager J, Levy R, Rathmell J, Buchser E, Burton A, Caraway D, Cousins M, De Andrés J, Diwan S, Erdek M, Grigsby E, Huntoon M, Jacobs MS, Kim P, Kumar K, Leong M, Liem L, McDowell GC II, Panchal S, Rauck R, Saulino M, Sitzman BT, Staats P, Stanton-Hicks M, Stearns L, Wallace M, Willis KD, Witt W, Yaksh T, Mekhail N: Polyanalgesic Consensus Conference—2012: Consensus on diagnosis, detection, and treatment of catheter-tip granulomas (inflammatory masses). Neuromodulation 2012; 15:483–95; discussion 496
38. Allen JW, Horais KA, Tozier NA, Yaksh TL: Opiate pharmacology of intrathecal granulomas. Anesthesiology 2006; 105:590–8
39. Hassenbusch S, Burchiel K, Coffey RJ, Cousins MJ, Deer T, Hahn MB, Pen SD, Follett KA, Krames E, Rogers JN, Sagher O, Staats PS, Wallace M, Willis KD: Management of intrathecal catheter-tip inflammatory masses: A consensus statement. Pain Med 2002; 3:313–23
40. Tomycz ND, Ortiz V, McFadden KA, Urgo L, Moossy JJ: Management of symptomatic intrathecal catheter-associated inflammatory masses. Clin Neurol Neurosurg 2012; 114:190–5
41. Cameron T: Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: A 20-year literature review. J Neurosurg 2004; 100(3 suppl Spine):254–67
42. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J: Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. Pain Pract 2011; 11:148–53
43. Harney D, Victor R: Traumatic syrinx after implantation of an intrathecal catheter. Reg Anesth Pain Med 2004; 29:606–9
44. Velarde CA, Zuniga RE, Leon RF, Abram SE: Cranial nerve palsy and intracranial subdural hematoma following implantation of intrathecal drug delivery device. Reg Anesth Pain Med 2000; 25:76–8
45. Reynolds F: Damage to the conus medullaris following spinal anaesthesia. Anaesthesia 2001; 56:238–47
46. Rathmell JP, Benzon HT, Dreyfuss P, Huntoon M, Wallace M, Baker R, Riew KD, Rosenquist RW, Aprill C, Rost NS, Buvanendran A, Kreiner DS, Bogduk N, Fourney DR, Fraifeld E, Horn S, Stone J, Vorenkamp K, Lawler G, Summers J, Kloth D, O'Brien D Jr, Tutton S: Safeguards to prevent neurologic complications after epidural steroid injections: Consensus opinions from a multidisciplinary working group and national organizations. Anesthesiology 2015; 122:974–84
47. Neal JM, Kopp SL, Pasternak JJ, Lanier WL, Rathmell JP: Anatomy and pathophysiology of spinal cord injury associated with regional anesthesia and pain medicine: 2015 update. Reg Anesth Pain Med 2015; 40:506–25
48. Bolash R, Udeh B, Saweris Y, Guirguis M, Dalton JE, Makarova N, Mekhail N: Longevity and cost of implantable intrathecal drug delivery systems for chronic pain management: A retrospective analysis of 365 patients. Neuromodulation 2015; 18:150–5; discussion 155–6
49. Torrens JK, Stanley PJ, Ragunathan PL, Bush DJ: Risk of infection with electrical spinal-cord stimulation. Lancet 1997; 349:729
50. Follett KA, Boortz-Marx RL, Drake JM, DuPen S, Schneider SJ, Turner MS, Coffey RJ: Prevention and management of intrathecal drug delivery and spinal cord stimulation system infections. Anesthesiology 2004; 100:1582–94
51. Burgher AH, Barnett CF, Obray JB, Mauck WD: Introduction of infection control measures to reduce infection associated with implantable pain therapy devices. Pain Pract 2007; 7:279–84