



A contemporary medicolegal analysis of implanted devices for chronic pain management



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Background

Analyses of closed malpractice claims allow the study of rare but serious complications.

The Controlled Risk Insurance Company (CRICO) was founded as a captive professional liability insurer for hospitals in the Harvard medical community. The CRICO Strategies Comparative Benchmarking System (CBS), in turn, is a database containing over 300,000 malpractice claims from over 400 academic and community institutions, representing approximately thirty percent of malpractice cases in the United States. CBS is used by CRICO's Risk Management Foundation and other insurers across the country to study patient and provider risk, using a standardized methodology.

Methods

We queried the CRICO CBS database for the period 01/01/2009 through 12/31/2013 for cases with pain medicine as the primary service. Pain medicine represented 1% of claims from this period.

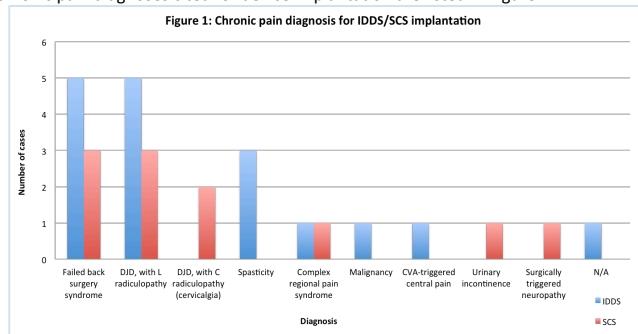
Each case included a detailed narrative summary of the case compiled by CRICO, including testimony of the expert witnesses for the defense and the prosecution, as well as many coded variables.

Table 1: IDDS and SCS patient and claim overview

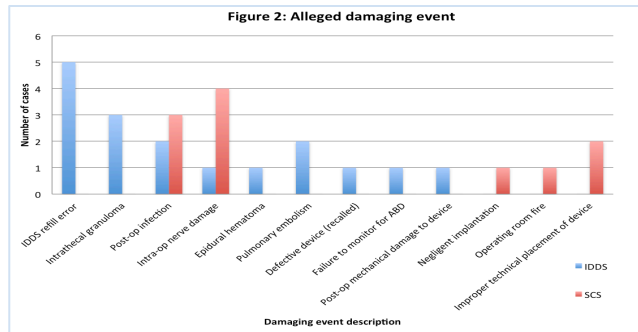
	IDDS	SCS
Case total	17	11
Mean patient age, years	51	53
Male patient	8 (47%)	6 (54%)
High severity outcome	5 (30%)	3 (27%)
Medium severity outcome	12 (70%)	8 (73%)
Low severity outcome	0 (0%)	0 (0%)
Settled cases (i.e., claim paid)	5 (29%)	6 (54%)
Median total incurred	\$17,425	\$74,627
Range	0-\$398,832	\$250-\$1,144,954
Mean total incurred	\$91,481	\$303,173
95% confidence interval	(\$16,957, \$166,005)	(\$18,191, \$588,155)

Results

The chronic pain diagnoses cited for device implantation are listed in Figure 1.



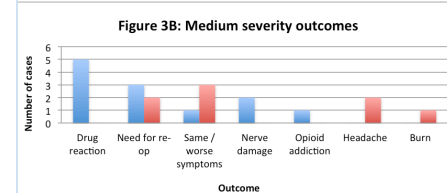
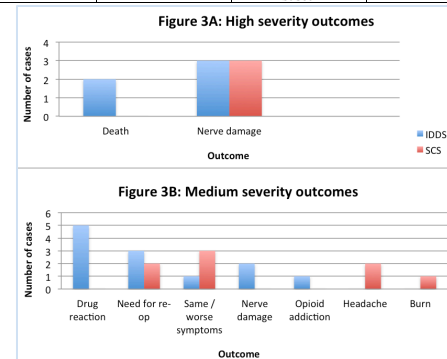
The alleged damaging events are listed in Figure 2.



E.g.: accidental subcutaneous injection of sufentanil 100 mcg/mL by a registered nurse in an obese patient with abdominal scar tissue; an accidental 20-fold IDDS dose increase by a physician; traumatic lead insertion of SCS in a patient under monitored anesthesia care; failure to administer pre-operative antibiotics; failure to diagnose intrathecal granuloma.

The CRICO-determined contributing factors to patient injury are listed in Table 2; the high and medium severity outcomes are listed in Figure 3.

Contributing factor category	IDDS		SCS	
	Present in % of claims (n)	Contributing factor category	Present in % of claims (n)	Contributing factor category
Technical skill	47% (8)	Technical skill	64% (7)	Technical skill
Clinical judgment	29% (5)	Clinical judgment	54% (6)	Clinical judgment
Communication	12% (2)	Communication	27% (3)	Communication
Documentation	12% (2)	Documentation	9% (1)	Documentation
Patient behavior	12% (2)	Patient behavior	45% (5)	Patient behavior
Supervision of staff or supervision of trainees	12% (2)			
Equipment related	17% (3)			
No risk management issue identified	6% (1)			
		Health care system-based	9% (1)	



Discussion

Implanted devices used for pain management involve a significant risk of morbidity and mortality. Proper education of providers and patients is essential. Providers must acquire the technical skills required for implantation and refilling of these devices and the clinical skills required for the identification and management of complications, such as intrathecal granuloma formation. Proper patient selection is crucial as is clear communication between the provider and the patient about the possibility of complications.