Determining the Role of Informed Consent Allegations in Spinal Surgery Medical Malpractice

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Introduction

Predictive factors associated with increased risk of medical malpractice litigation have been identified including severity of injury, physician sex and error in diagnosis. However, there is a paucity of literature investigating informed consent in spinal surgery malpractice. Our objective was to highlight the failure to obtain informed consent as an allegation in medical malpractice claims for patients undergoing spine-surgery.

Methods

This was a retrospective case-control study using a national medico-legal database "westlaw next". We identified a total of 233 patients (80 with no informed consent allegation, 153 who cited lack of informed consent) who underwent spinal surgery and filed a malpractice claim were studied.

Results

The most common informed consent allegations were failure to explain risks/side effects of surgery (30.4%) and failure to explain alternative treatment options (9.9%). In bivariate analysis, patients in the control group were more likely to require additional surgery (56.3% vs 34.6%, P = 0.002) and suffer from more permanent injuries compared to the informed consent group (P = 0.033). On multivariable regression analysis, permanent injuries were more often associated with indemnity payment following a plaintiff verdict (OR 3.12, 95% CI 1.46 - 6.65, P = 0.003) or a settlement (OR 6.26, 95% CI 1.06 - 36.70, P = 0.042). Informed consent allegations were significantly associated with less severe (temporary/emotional) injury (OR 0.52, 95% CI

Control		Informed Consent Malpractice		Total	
State	N (%)	State	N (%)	State	N (%)
California	16 (20.0)	California	29 (19.0)	California	45 (19.3)
Texas	11 (13.8)	Pennsylvania	20 (13.1)	New York	29 (12.4)
New York	9 (11.3)	New York	20 (13.1)	Pennsylvania	27 (11.6)
Pennsylvania	7 (8.8)	Washington	11 (7.2)	Texas	16 (6.9)
Illinois	6 (7.5)	Missouri	7 (4.6)	Washington	15 (6.4)
Washington	4 (5.0)	Florida	6 (3.9)	Missouri	10 (4.3)
Florida	4 (5.0)	Texas	5 (3.3)	Florida	10 (4.3)
Missouri	3 (3.8)	New Jersey	5 (3.3)	Massachusetts	8 (3.4)
Massachusetts	3 (3.8)	Michigan	5 (3.3)	New Jersey	7 (3.0)
New Jersey	2 (2.5)	Massachusetts	5 (3.3)	Illinois	6 (2.6)

Table 1. Summary of the 10 American states with the highest number of malpractice claims.

	Control		Informed Consent Malpractice		Total		P-Value
	Available Data (N)	N (%) (N = 80)	Available Data (N)	N (%) (N = 153)	Available Data (N)	N (%) (N = 233)	
Time Between Surgery and Verdict mean years (st. dev)	62	5.3 (2.5)	139	5.1 (2.6)	199	5.4 (2.5)	0.97
Region							
Northeast	80	24 (30.0)	153	53 (34.6)	233	77 (33.0)	0.30
Midwest		13 (16.3)		31 (20.3)		44 (18.9)	
South		20 (25.0)		23 (15.0)		43 (18.5)	
West		23 (28.8)		46 (30.1)		69 (29.6)	
Patient Demographics							
Female Sex	80	38 (47.5)	152	77 (50.7)	232	115 (49.6)	0.65
Age mean (st. dev)	43	45.8 (12.9)	74	47.9 (13.3)	117	47.1 (13.1)	0.83

Table 2. Bivariate analysis of temporal, geographic, and patient demographic of malpractice cases including informed consent malpractice.

Control Allegation (N = 246)	N (%)	Informed Consent Malpractice Allegation (N = 171)	N (%)
Surgical Negligence	74 (30.1)	Unspecified	75 (43.9)
Failure to diagnose/treat	51 (20.7)	Explanation of risks/side effects	52 (30.4)
General malpractice	30 (12.2)	Explanation of alternative treatment options	17 (9.9)
Unnecessary Surgery	29 (11.8)	Surgeon's surgical experience	5 (2.9)
Hospital malpractice	24 (9.8)	Use of a non-FDA approved device	5 (2.9)

Table 3. Top allegations of both control group and informed consent malpractice cases.

	Verdict in favor of plaintiff		Settlement	
Variable	OR (95% C.I)	P-Value	Odd Ratio (95% C.I)	P-Value
Region				
Northeast vs Midwest	2.05 (0.74 - 5.64)	0.16	2.62 (0.21 - 30.21)	0.45
South vs Midwest	1.41 (0.44 - 4.53)	0.56	1.03 (0.05 - 20.25)	0.98
West vs Midwest	0.79 (0.24 - 2.54)	0.69	4.10 (0.03 - 49.40)	0.27
Age				
>50 y/o vs <50 y/o	1.99 (0.79 - 5.01)	0.14	2.88 (0.05 - 15.59)	0.22
Gender				
Male vs female	0.94 (0.46 - 1.92)	0.88	1.40 (0.03 - 7.07)	0.68
Procedure type				
Fusion vs non-fusion	0.86 (0.36 - 2.09)	0.75	0.09 (0.01 - 0.80)	0.034
Spinal region				
Lumbar vs cervical	0.93 (0.38 - 2.23)	0.87	3.56 (0.05 - 26.80)	0.22
Thoracic vs cervical	0.53 (0.04 - 5.90)	0.61	N/A	N/A
Unspecified vs cervical	1.19 (0.39 - 3.60)	0.76	7.66 (0.72 - 81.51)	0.09
Specialty				
Ortho vs Neuro	0.52 (0.24 - 1.13)	0.10	0.07 (0.009 - 0.68)	0.028
Severity of injury				
Permanent/death vs Temporary/emotional	3.12 (1.46 - 6.65)	0.003	6.26 (1.06 - 36.70)	0.042
Additional surgery needed				
Yes vs No	0.94 (0.45 - 1.95)	0.87	1.61 (0.04 - 7.14)	0.52
Informed consent issue				
Yes vs No	0.41 (0.17 - 0.98)	0.046	0.01 (0.001 - 0.15)	<0.001

Table 4. Multinomial regression analysis of case verdict outcome.

Conclusions

Lack of informed consent is an important cause for medical malpractice litigation. Although associated with a lower rate of indemnity payments, malpractice lawsuits including informed consent allegations still present a time, money, and reputation toll for physicians