



Patient Safety in Neurosurgical Practice: Physician and Patient Factors that Contribute to Patient Injury

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■ **BACKGROUND:** Recommendations that may help reduce adverse events outside the perioperative period are uncommon. We identified the primary factors that contributed to patient injury in neurosurgical practice both within the perioperative period and outside the perioperative period.

■ **METHODS:** Medical malpractice claims ($n = 355$) from The Doctors Company that were closed over 7 years were reviewed by neurosurgical medical experts. Objective neurosurgical expert analysis of the cases identified patient injuries and the primary factor that contributed to the patient injury.

■ **RESULTS:** Continued pain, nerve damage, and need for additional surgery were the most common injuries. In 145 cases (40.8%), the primary factor that contributed to patient injury occurred outside the perioperative period: assessment (evaluation and diagnosis), selection and management of therapy, and communication between the physician and patient/family. In 138 (38.9%) cases, the primary factor that contributed to patient injury occurred within the perioperative period. Surgical complication (a known risk of the procedure) was the primary factor in 99 cases (27.9%), and technical performance of surgery was the primary factor in only 39 cases (11.0%).

■ **CONCLUSIONS:** In addition to excellent surgical technique, checklists, teamwork, outcomes measurement, and regionalization of subspecialty care, improving patient safety in neurosurgical practice requires careful attention to care provided outside the perioperative period. Differential diagnosis, consideration of all relevant clinical data, active pursuit of good physician—patient relationships, and

adequate monitoring of patients receiving nonsurgical treatment may also help improve patient safety in neurosurgical practice.

INTRODUCTION

Patient safety is important. Widely publicized studies have identified a surprisingly high incidence of harm caused to patients by medical treatment, or the lack thereof.^{1,2} Minimizing the risk of these adverse events is especially important in neurosurgery because many of the diseases that we treat already threaten significant disability, and all of the treatments that we use carry some risk of complication.

The number of studies on patient safety in neurosurgery is substantial, and several comprehensive reviews have been performed. However, these studies primarily focus only on injuries that occur within the operating room. Wong et al.³ identified the most common neurosurgical adverse events from existing studies and categorized them by likely contributing factors, aside from patient condition. The categories that were identified were all related to the perioperative period. For example, the sole potential communication error identified in tumor surgery was wrong-site surgery. Another group who reviewed patient safety stated that “Adverse events in neurosurgery can be defined as both the unexpected perioperative complications as well as the anticipated neurologic or general deterioration related to surgical approach or other known causative factors.”⁴ Adverse events occurring outside the perioperative period were not explicitly included in the definition. Patient care in neurosurgical practice outside the perioperative period occurs before surgery or other invasive treatment, after surgery or other invasive treatment, or during medical management. Recommendations that may help reduce adverse events outside the perioperative period are sparse

Key words

- Adverse events
- Complications
- Liability
- Medical error
- Neurosurgery
- Patient safety

Abbreviations and Acronyms

QOD: Quality Outcomes Database

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but include outcomes monitoring and regionalization of subspecialty care.^{3,5}

However, neurosurgical practice is not limited to the operating room. In some cases, the severity of injury from an inadequate differential diagnosis may match that caused by poor surgical technique. A recent study of litigation⁶ showed that nonsurgical treatment is a common, and perhaps underrecognized, source of liability in neurosurgical practice. In the current study, we considered patient safety broadly and sought to identify all aspects of neurosurgical practice that contributed to patient injury.

METHODS

Medical malpractice claims from The Doctors Company in which a neurosurgeon was named as the primary defendant and that were closed between 1 January 2007 and 31 December 2013 were included in the study. Closed claims are lawsuits that have been given up by the plaintiff, settled, or have completed trial. Cases with insufficient or missing data for analysis were excluded. Neurosurgical procedures were categorized according to the classification scheme used in the American Association of Neurological Surgeons National Neurosurgical Procedural Statistics 2012 Survey Based on 2011 Data.⁷ Cases were designated medical management when a neurosurgical procedure was not performed or when the neurosurgical procedure was unrelated to the primary allegation and patient injury.

For each case, all available information, including medical records, imaging, and depositions, was reviewed by a neurosurgical medical expert. Neurosurgical experts were generally chosen by the defense attorney and approved by The Doctors Company. All neurosurgical expert reviewers were certified by the American Board of Neurological Surgery and were practicing independently at the time of their review. Most claims have more than 1 allegation and some patients claimed more than 1 injury. The primary allegation and patient injury or injuries were determined from the claim by the reviewer.

The reviewers were asked to provide objective analysis of each case. Identification of patient injuries, the primary factor that contributed to the patient injury, and patient comorbid factors that were directly related to the injury were determined by the expert reviewer assigned to the case. For example, diabetes mellitus with proper management does not necessarily contribute to patient injury in neurosurgical patients. However, in a patient with wound infection and poor blood sugar control before surgery, diabetes mellitus was identified as a patient comorbid factor that contributed to patient injury. The Doctors Company started capturing comorbidities in 2010. Therefore, the analysis of patient comorbid factors that contributed to patient injury is based on a subset of the entire cohort.

Because the study data are based on the date that the claim closed and not the date that the incident occurred, it is impossible to determine the number of neurosurgeons insured and the number of years of practice that generated these claims. To protect anonymity, demographic data of patients and neurosurgeons are not provided. Furthermore, The Doctors Company does not collect exposure data; therefore, it is impossible to determine the incidence of claim by procedure. The Doctors Company is the largest physician-owned medical practice insurer in the United States,

providing medical malpractice coverage to more than 77,000 physicians and surgeons nationwide.

RESULTS

Between 1 January 2007 and 31 December 2013, The Doctors Company closed 15,636 claims for all medical specialties. During this period, The Doctors Company closed 361 claims (2.31%) in which a neurosurgeon was the primary physician defendant. Six cases had insufficient or missing data for analysis and were excluded from the study, leaving 355 cases for analysis of associated procedures, primary allegations, patient injuries, and primary factors that contributed to patient injuries. Case type by neurosurgical procedure is shown in **Table 1**. Spine procedures were the most common, occurring in 185 cases (52.1%). Nonsurgical management was second most common, occurring in 104 cases (29.3%).

The top 7 allegations represent 86% of the claims made and are shown in **Table 2**. Improper performance of surgery was the most common allegation by plaintiff, occurring in 193 cases (54.4%). All other allegations were each made in 5 or fewer cases (1.4% or less). “Improper performance of surgery”, “improper management of surgical patient,” and “improper management of treatment plan” are plaintiff allegations that the treating neurosurgeon did not exercise the degree of skill and expertise normally possessed and exercised by a reasonable and prudent practitioner with the same level of training in similar circumstances. That is, the patient argues that the neurosurgeon failed to meet standard of care. Patient injuries as determined by the neurosurgical expert reviewer are shown in **Table 3**. For all claims, continued pain (23.9%), nerve damage (23.1%), and need for additional surgery (18.0%) were the most common injuries. The total adds to more than 100% because some patients sustained more than 1 injury.

The primary factors that contributed to patient injury as determined by the neurosurgical expert reviewer are shown in **Table 4**. Assessment (evaluation and diagnosis), selection and management of therapy, and communication between the physician and patient/family (all factors that are controlled primarily by the neurosurgeon and occur primarily outside the operating room) were the primary factors that contributed to

Table 1. Case Type by Neurosurgical Procedure Associated with Patient Claims

	Number (%)
Spine	185 (52.1)
Cranial	30 (8.5)
Cerebrospinal fluid shunting	7 (2.0)
Peripheral nerve	12 (3.4)
Functional/pain/interventional	10 (2.8)
Endovascular/catheter/percutaneous	7 (2.0)
Extracranial cerebrovascular	0
Medical management	104 (29.3)

Table 2. Top 7 Primary Allegations by Plaintiff

	Number (%)
Improper performance of surgery*	193 (54.4)
Diagnosis-related (failure, delay, wrong)	40 (11.3)
Improper management of surgical patient*	33 (9.3)
Improper management of treatment plan*	17 (4.8)
Unnecessary surgery	8 (2.3)
Retained foreign body	7 (2.0)
Delay in surgery	6 (1.7)

*The plaintiff (patient) alleges that the neurosurgeon did not exercise the degree of skill and expertise normally possessed and exercised by a reasonable and prudent practitioner with the same level of training in similar circumstances.

injury as determined by the neurosurgical expert reviewer in 145 cases (40.9%). Patients alleged failure to diagnose, delayed diagnosis, or wrong diagnosis in 11.3% of claims (Table 3). This closely matched the neurosurgery expert reviewer findings of inadequate assessment in 14.9% of claims (Table 4). Inadequate assessment included failures to order diagnostic tests, factor in available clinical information, address abnormal findings, and establish a differential diagnosis. Complication (a known risk of the procedure), was the primary factor as determined by the neurosurgical expert reviewer in 99 cases (27.9%). Technical performance of surgery was the primary factor as determined by the neurosurgical expert causing patient injury in only 39 cases (11.0%).

Between 2010 and 2013, 262 cases were closed and included patient comorbidity data. A total of 71 comorbid factors contributed to patient injury as determined by the neurosurgical expert in 49 patients (18.7%). Table 5 shows the patient comorbid factors that occurred in more than 1 patient and contributed to patient injury as determined by the neurosurgery expert reviewer.

Table 3. Patient Injuries as Determined by Neurosurgical Expert Reviewer

	Number (%)
Continued pain	85 (23.9)
Nerve damage	82 (23.1)
Need for additional surgery	64 (18.0)
Condition severity worsened with treatment	57 (16.1)
Mobility dysfunction	57 (16.1)
Death	46 (13.0)
Infection	43 (12.1)
Partial paralysis	21 (5.9)

The total adds to more than 100% because some patients sustained more than 1 injury.

DISCUSSION

There was an approximately equal distribution of primary factors contributing to injury as determined by the neurosurgery expert reviewer between the perioperative period (complication and technical performance) and outside the perioperative period (assessment, selection and management of therapy, and communication). This suggests that to improve patient safety in neurosurgery we must look both within and outside the operating room. Time-outs and checklists can reduce adverse events during procedures. Careful differential diagnosis, attention to all relevant clinical information, and good communication are some factors under control of the surgeon that may reduce adverse events in the clinic and on the ward.

Diagnostic failures (assessment) may be conceptually and practically different in the preoperative period compared with the postoperative period. For example, failure to review a radiology report that identifies a lung nodule on a preoperative chest radiograph is different from failure to recognize the clinical symptoms and signs of a postoperative pulmonary embolism. Our data do not allow distinction into these categories.

In more than a quarter of patients claiming medical negligence, a known complication of the procedure was the primary factor contributing to patient injury. Complication was about 2.5 times more likely to contribute to patient injury than was technical performance of surgery.

The fact that known risks of surgery generated claims of negligence calls into question the efficacy of the consent process.

Table 4. Primary Factors that Contributed to Patient Injury as Determined by Neurosurgical Expert Reviewer

	Number (%)
Assessment	53 (14.9)
Includes failure or delay ordering diagnostic tests, failure to establish a differential diagnosis, failure to consider available clinical information, and failure to address abnormal findings	
Selection and management of therapy	46 (13.0)
Includes selection/management of surgical/invasive procedure, selection and management of medical treatment, and failure to order medication	
Communication between physician and patient/family	46 (13.0)
Includes inadequate informed consent for surgical or invasive procedure, poor rapport (includes unsympathetic response to patient), and patient not informed of adverse event	
Technical performance	39 (11.0)
Includes poor technique, incorrect body site, misidentification of anatomic structure, and incorrect body position	
Complication (known risk of procedure)	99 (27.9)
Patient factors/behaviors	60 (16.9)
Includes seeks other providers and not compliant with treatment plan	
No identified factors	12 (3.4)

Table 5. Patient Comorbid Factors that Contributed to Patient Injury as Determined by Neurosurgical Expert Reviewer

	Number (%)
Obesity	21 (8.0)
Diabetes	13 (5.0)
Smoking	13 (5.0)
Hypertension	7 (2.7)
Psychiatric history/substance abuse	6 (2.3)
Cerebrovascular disease	3 (1.1)
Chronic pulmonary disease	2 (0.8)
Malignancy	2 (0.8)

Bhattacharyya et al.⁸ reviewed closed claims in orthopedic surgery and identified several features of the consent process that, if present, were associated with decreased indemnity. However, more important may be the findings of behavioral scientists showing that many people do not understand the predictive value of numerical probabilities.^{9,10} When surgical complications occur, patients often have a misunderstanding of the causes of their condition. This shows the importance of conversations between physicians and patients after surgery linking the complication and its causes with the informed consent discussion.

Patient factors or behaviors were the primary factor contributing to patient injury in 16.9% of cases. These results need to be interpreted carefully. A significant percentage of patient factors was related to patients seeking other providers because of dissatisfaction. This may have been related to poor rapport or inadequate communication between physicians and patients. Neurosurgeons should actively pursue good physician–patient relationships. Patients should not delay necessary treatment when time is of the essence and should be encouraged to comply with appropriate treatment regimens. However, the fundamental right of autonomy allows competent patients to make decisions that are seemingly against their best interests. Patient comorbidities were not the primary factors but contributed to patient injury in 18.7% of cases and should not be ignored in patient management.

Most claims occurred after spine surgery. Medical management was the next most common case category. These findings are consistent with a previous study⁶ showing that claims are statistically less likely after cranial surgery compared with spine surgery and that nonsurgical treatment is a common source of liability in neurosurgical practice. Patients who do not receive surgery require adequate monitoring of their symptoms, response to therapy, and disease progression.

The Quality Outcomes Database (QOD, formerly known as the National Neurosurgery Quality and Outcomes Database, aka N²QOD), a project of NeuroPoint Alliance, may be an important step toward improving patient safety.^{11,12} Outcomes are measured at 1 year and, therefore, account for all aspects of the treatment regimen, not simply the technical prowess of the surgeon. QOD is intended to establish national benchmarks for common neurosurgical procedures and practice patterns. QOD includes surgical

treatment, interventional procedures, and medical management of neurosurgical patients.

A weakness of this study is our reliance on closed claims as a convenience sample for patients injured while undergoing neurosurgical treatment. Previous studies^{13,14} have shown that many medical injuries caused by negligence do not result in claims, and that a substantial proportion of claims are brought when the plaintiff is theoretically not entitled to compensation. However, a recent study of joint replacement surgery¹⁵ found statistically significant correlations between claims and revision surgeries and between claims and infections. There is also evidence that physicians with better patient relationships have fewer lawsuits.¹⁶ Therefore, the overall contribution of poor communication may be overemphasized in this study.

Closed claims in neurosurgery have been studied previously. Rovit et al.¹⁷ reviewed 280 cases from New York state and found that the chance of being sued was related to the types of cases in which the physician was involved. They also found that elective spinal surgery cases constitute most neurosurgical litigation. Scarrow et al.¹⁸ reviewed 90 cases and found that improperly performed surgery was the allegation in 70% of cases but that in 87% of cases factors other than the defendant's actions contributed to generation of a claim.

Another potential weakness of this study is our reliance on experts for determination of patient injury and contributing factors. The legal designation of expert¹⁹ is different from the more familiar expertise level of skill acquisition identified in the Dreyfus model.²⁰ Independent review of records involved in negligence claims, corrected for chance correlations, have shown slight to fair agreement between experts in bile duct injury cases²¹ and poor to good agreement in anesthesia cases.²² In a review of 51 litigated claims followed over a 10-year period, Brennan et al.²³ found that “In most cases, our initial assessments of the medical records agreed with the expert assessments....” In addition, a recent review of neurosurgical cases found that witnesses testifying on behalf of defendants (similar to those used in this study) had significantly higher scholarly impact and were more likely to practice in an academic setting.²⁴ Although the accuracy of expert review is open to debate, it is a necessary component of our current civil litigation process and is unlikely to be replaced in the foreseeable future. Clinical practice guidelines may help to define standard of care in some cases.²⁵ However, guidelines often fail to address salient questions in individual cases.

CONCLUSIONS

The primary factors that contribute to patient injury in neurosurgical practice are evenly divided between the perioperative period and outside the perioperative period. Patient care in neurosurgical practice outside the perioperative period occurs before surgery or other invasive treatment, after surgery or other invasive treatment, or during medical management. Assessment (evaluation and diagnosis), selection and management of therapy, and communication are just as likely to be the primary contributor to patient injury as are surgical complication and technical performance of surgery. To improve patient safety, we must look both within and outside the operating room.

In slightly more than a quarter of cases, the primary factor contributing to patient injury was a known complication of the procedure. The fact that these cases led to claims of negligence should prompt evaluation of our current consent process in a search for better ways of helping patients to understand the possible outcomes of surgery. Patient factors and comorbid conditions are the primary causes of patient injury in a few cases but should not be ignored.

In addition to excellent surgical technique, checklists, teamwork, outcomes measurement, and regionalization of subspecialty care, improving patient safety in neurosurgical practice requires careful attention to care provided outside the perioperative period. Differential diagnosis, consideration of all relevant clinical data, active pursuit of good physician–patient relationships, and adequate monitoring of patients receiving nonsurgical treatment may also help improve patient safety in neurosurgical practice.

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