



Anesthesiology Clin N Am  
20 (2002) 485–501

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ANESTHESIOLOGY  
CLINICS OF  
NORTH AMERICA

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## The Closed Claims Project Has it influenced anesthetic practice and outcome?

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The Closed Claims Project was established by the American Society of Anesthesiologists to identify anesthetic-related complications and their mechanism of occurrence with the goal of improving patient safety. Although the Closed Claims Project has inherent biases, it has provided information that has influenced the standards for the practice of anesthesia and stimulated research in problem areas. The decrease in severity of injury in anesthesia malpractice claims over the last 3 decades suggests that anesthesia safety improved during the 1990s.

The American Society of Anesthesiologists (ASA) Closed Claims Project was established in 1984 in response to rapidly escalating professional liability insurance premiums [1]. Anesthesiologists were considered high insurance risks because 11% of total dollars paid for patient injury were caused by anesthetic-related complications, despite anesthesiologists accounting for only 3% of total physicians insured. The Closed Claims Project collects detailed information on adverse anesthetic outcomes obtained from the closed claims files of professional liability insurance companies in the United States. Although this is a cost-effective method of studying rare anesthetic complications, there are multiple limitations to the use of closed malpractice claims for outcome assessment. This article will review these limitations of closed claims analysis, describe trends in outcome and anesthetic injury in the closed claims database over the last three decades, and assess the impact of the Closed Claims Project on patient safety and outcome.

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### **The ASA Closed Claims Project design**

The ASA Closed Claims Project is designed to systematically evaluate adverse anesthetic outcomes derived from the closed claim files of 35 professional liability insurance companies in the United States. Some companies may insure anesthesiologists in more than 40 states. Other sources are mainly statewide organizations that include both physician-owned and private companies. These organizations insure approximately 14,500 anesthesiologists, which is approximately 60% of the practicing anesthesiologists in the United States [1]. The database contains a total of 5,480 claims for adverse outcomes that originated between 1961 and 1999. Twelve percent of the claims occurred before 1980; 54% occurred between 1980 and 1990. Because 2 to 5 years elapse between the occurrence of an adverse event and the closure of its associated claim, only 33% of the claims are from the 1990s. Dental injury claims are excluded from the database.

Claims data are collected by one or more trained practicing anesthesiologists who visit each insurance company office to review all files for claims against anesthesiologists at periodic intervals. Inclusion criteria are based on the availability of specific information. Claims with enough information to reconstruct the sequence of events and to determine the nature and causation of injury are included. The closed claim files typically consist of relevant hospital and medical records, narrative statements from involved healthcare personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury award. Detailed instructions are given to reviewers to complete a standardized form with information on patient characteristics (age, sex, weight, and physical status), date of procedure, surgical procedures, anesthetic agents and techniques, monitors employed, sequence and location of events, critical incidents, clinical manifestations of injury, complications and outcomes, severity of injury, whether or not a lawsuit was filed, and the amount of the award. Reviewers assess the overall appropriateness of anesthetic care and its contribution to the injury. Each claim is assigned a severity of injury score that is designated by the onsite reviewer using the insurance industry's 10-point scale. This ordinal scale rates injury severity from 0 (no injury) to 9 (death). A value of 1 represents emotional injury; 2–4 reflect temporary injuries; 5 reflects permanent, nondisabling injuries; and 6–8 reflect permanent and disabling injuries. The sequence of events in each case is summarized by the onsite reviewer. Data collection forms and summaries are sent to the three practicing anesthesiologists of the Closed Claims Project Committee in Seattle. A minimum of two Committee members review each claim. Any discrepancies between members in their assessment of the claim and appropriateness of care are resolved by a third member.

Data are then analyzed according to decade, appropriateness of care, severity of injury, and many other factors. For purposes of analysis, injuries are grouped into two categories for severity: temporary/nondisabling (0–4) and disabling/permanent/death (5–9).

### Limitations of closed claim analysis

There are multiple sources of bias in closed claims analysis such as incomplete information on the total number of adverse events and the total number of anesthetics performed (unknown numerator, denominator, and incidence); lack of inter-observer agreement regarding appropriateness of care; bias from retrospective review of cases; and outcome bias in which more severe injuries tend to be judged more negatively than less severe injuries despite the same error (Box 1) [2–6].

#### Box 1. Limitations of closed claim analysis

1. Subset of adverse outcomes
  - a. Few adverse outcomes end in malpractice claims
  - b. Bias toward more severe injuries
2. Inability to calculate incidence
  - a. Lack of denominator data
  - b. Geographic imbalance
3. Miscellaneous sources of bias
  - a. Changes in practice patterns
  - b. Partial reliance on direct participants
  - c. Retrospective transcription of data
  - d. Absence of rigorous comparison groups
  - e. Judgment of appropriateness of care
  - f. Poor prediction of quality of care

#### *Unknown incidence*

The incidence of anesthetic-related adverse outcomes is indeterminate in the closed claims analysis for several reasons: 1) all adverse outcomes do not result in a malpractice claim; 2) there are only 35 professional liability insurance companies that participate in the Closed Claims Project, and they insure approximately half of all practicing anesthesiologists in the United States; and 3) there is no information on the total number of anesthetics performed by the insured physicians. Only a small percentage of adverse outcomes result in a claim being filed and malpractice litigation for reasons discussed below. The Harvard Medical Practice Study published in 1991 identified 280 patients who sustained iatrogenic injuries involving medical negligence [2]; less than 3% of these patients filed malpractice claims [3]. The investigators estimated that in New York State only 1 out of 8 adverse events associated with negligence, and only 1 out of 25 adverse events not necessarily associated with negligence, resulted in a medical malpractice claim [3,4].

The relationship between malpractice claims and adverse outcomes is depicted in Fig. 1. Area A represents all medical injuries among hospitalized patients,

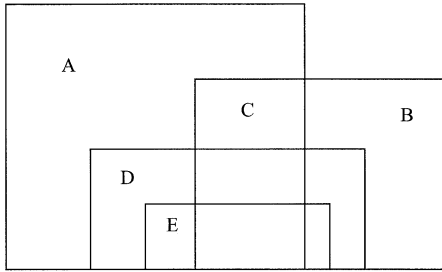


Fig. 1. Relationships among adverse outcomes, errors during medical care, and malpractice claims. (A) Incidence of patient injuries. (B) Incidence of errors during medical care. (C) Patient injuries due to errors during medical care. (D) Filed malpractice claims. (E) Filed claims resulting in claimant compensation. (From Morlock LL, Lindgren OH, Mills DH. Medical malpractice and clinical risk management. In: Goldfield N, Nash DB, (editors). Providing quality care: future challenges. 2nd edition. Ann Arbor (MI): Health Administration Press; 1995. p. 163–83; with permission.)

estimated at approximately 4% of all patient admissions [2,3]. Area B represents all errors by healthcare providers, the extent of which is unknown. Area C represents the subset of adverse patient outcomes due to error or negligence (about 1% of all hospital admissions) [2]. The fraction of outcomes represented by medical malpractice claims is represented in area D. A small percentage of adverse events due to error end in a malpractice claim, and many of the claims filed are associated with care that was deemed inappropriate [3]. Area E signifies filed claims resulting in claimant compensation, estimated at about 1 in 25 patients who experience an injury [6]. Therefore, although malpractice claims provide useful information about adverse outcomes, they are comprised of a highly selective subset that is not necessarily a representative cross-section of all adverse outcomes.

From the time a patient sustains an adverse outcome, multiple factors influence the potential filing of a malpractice claim [7–13]. Physician–patient rapport has been cited in multiple studies as a key determinant of future litigation. An inverse relationship between time spent with patients and number of malpractice suits per physician has been documented [7,12]. In a prospective study by Huycke and Huycke, approximately half of patients that sought malpractice litigation reported a poor physician–patient relationship [11]. The physician’s failure to stay informed, to refer when needed, and to be available when needed were common concerns of the potential plaintiffs. Many families that filed a medical malpractice claim following perinatal injuries were concerned that there was a cover-up (24% of respondents), wanted more information (20%), and wanted revenge or to protect others (19%) [10]. Physicians were criticized for not talking openly (32%), not listening (13%), or being misleading about long-term disabilities (70%). Other factors that influenced patients’ decisions to seek legal recourse for adverse outcomes in this study were television advertising by law firms (73%), inability to pay medical bills (36%), and explicit recommendations by other health care providers (frequently the post-adverse outcome

consultant) to seek legal counsel (27%) [8,11]. Patients typically consult with family members, friends, lawyers, and medical professionals to decide whether to pursue a lawsuit [10,11]. Contrary to popular opinion, low-income and uninsured patients, as well as the elderly, are 5 to 10 times less likely to file malpractice claims than their higher income cohorts based on a case-control study of malpractice claims in New York State [9].

Once the injured party has decided to seek legal recourse, the attorney decides whether or not a claim is worth pursuing. Huycke and Huycke reported an average of 12 calls per day to 6 law firms in 5 states regarding malpractice litigation, but only one in 30 calls resulted in filing a malpractice lawsuit [11]. Screening criteria for filing a successful lawsuit by attorneys include evidence of negligence and causation, and potential damages. The most common reason for attorneys to decline a potential lawsuit was a projected insufficient compensation for damages. Claims with potentially recoverable damages of less than \$50,000 were usually rejected [11]. As many as one quarter of claims may be rejected for failure to demonstrate negligence [11].

After a malpractice lawsuit has been filed and a claim made, many factors will determine whether or not the case will be settled before trial and thus influence payment amount. Cheney and colleagues have demonstrated that increasing severity of injury correlates with higher claim payments, making the Closed Claims Project database biased toward more severe injuries [14]. Substandard care also increases the frequency of successful claim payment and interacts with severity of injury for the amount of payment [14]. Defendant attorneys may want to avoid a trial because of poor projected appearance of the physician or projected jury awards greater than the settlement amount. Therefore, claim payment amount may not correlate with evidence of negligence.

Malpractice claims clearly represent only a small subset of adverse outcomes. Some injured patients do not file claims, whereas others file claims without any apparent injury. Moreover, the Closed Claims Project draws from only 35 professional liability companies insuring only half of the working anesthesiologists in the United States. These companies are located predominately in the Northeast, upper Midwest, and West Coast. Therefore, geographic variations in anesthesia practice may influence the number and types of adverse events found in the Closed Claims Project database.

In addition, professional liability companies do not maintain records of the total number of anesthetics that their insured anesthesiologists provide. Therefore, neither numerator data on the total number of adverse events nor denominator data on the total number of anesthetics provided can be determined for calculating incidence.

#### *Other sources of bias*

##### *Changing patterns of practice and standard of care*

Cases span a considerable amount of time during which anesthetic agents and practice patterns change. Reviewers may develop a bias by citing standards of

care that were not in practice at the time of the adverse event. In addition, it may take many years to detect a change in outcome with changes in practice patterns. For instance, the Closed Claims Project is just now beginning to evaluate a significant number of claims in the 1990s, when new monitoring standards were universally employed.

#### *Retrospective bias and nonpartial participants*

The Closed Claims Project data also relies partially on data obtained from direct participants rather than impartial observers, because plaintiff and physician correspondence and depositions are the sources of information used by reviewers. Information about the outcomes is recorded retrospectively and is limited to that transcribed on a data sheet by the reviewers, who, in turn, depend on the information contained in the insurance company file. Important medical records, such as anesthesia records, may be missing from insurance company files. In addition, there is an absence of rigorous comparison groups.

#### *Poor interrater reliability*

There are also ambiguities surrounding the judgment of the appropriateness of care. Appropriate or standard care has been defined as “that which met the standard for a prudent anesthesiologist practicing anywhere in the United States at the time of the event” [14]. Substandard care has been defined as “that below the standard of practice (ie, negligence)” [14]. Examples of substandard care included cases in which the patient was not appropriately monitored, in which shortcuts in care were taken, or in which serious errors in judgment were made, or if there was a poor choice or conduct of anesthesia. The standard of care was designated as “impossible to judge” if there was not enough information in the file for the reviewer to make a judgment about standard of care [14]. Interrater reliability is relatively low in the complex judgment of standard of care [15,16]. Anesthesiologist reviewers agreed on the standard of care in 62% of claims and disagreed in 38% of claims [16]. This bias raises several concerns about peer review and suggests that divergent opinions may be easily found among multiple experts. This concept is clearly evident during most malpractice cases in which both the plaintiff and the defendant have expert witnesses with divergent opinions.

#### *Outcome bias*

Is the judgment of the appropriateness of care influenced by the severity of the outcome? Caplan et al [15] studied this question by asking 112 practicing anesthesiologists to rate the appropriateness of care in 21 cases involving adverse anesthetic outcomes. The original case involved either a temporary or permanent outcome. An alternate case identical to the original case was constructed, except that a plausible outcome of opposite severity was substituted. A typical set of matched cases might involve a patient who coughs on the endotracheal tube during general anesthesia while the surgeons are operating on the eye under the microscope. In one case, the patient may suffer a corneal abrasion that heals

within 3 days. In the alternate scenario with opposite severity of outcome, the patient may suffer permanent visual loss. Reviewers were blinded as to the intent of the study. Knowledge of the severity of injury resulted in a significant inverse effect on judgment of the appropriateness of care in 15 of the 21 cases. The proportion of ratings for appropriate care decreased by 31% when the outcome was changed from temporary to permanent and increased by 28% when the outcome was changed from permanent to temporary [15].

These biases inherent in closed claim analysis are numerous. The Closed Claims Project provides a snapshot of anesthesia liability, but not a comprehensive view of anesthetic injury [1]. Therefore, findings from the Closed Claims Project can only give an indirect and imperfect measure of outcome in anesthesia.

## **ASA Closed Claims Project**

### *General description*

The majority of the claims in the Closed Claims Project involve relatively healthy adults undergoing nonemergency surgery. Fifty-nine percent are female, 91% are adults (> 16 years), 69% are ASA 1–2 physical status, 75% are non-emergency and 67% involve general anesthesia. Thus, the database is not a collection of critically ill patients in whom underlying disease plays a major role in outcome; it predominantly reflects the process of anesthesia care. Twelve percent of the claims are from the 1970s, 54% are from the 1980s, and 33% are from the 1990s.

The claims are separated into two categories: complications and damaging events. A complication refers to the injury that the patient sustained; the damaging event is the specific incident that led to the injury. Three injuries account for one half of all complications: death (30%), brain damage (12%), and nerve damage (18%) (Table 1). Claims for low severity injuries account for approximately 15% of the claims and include headache (4%), emotional distress (4%), back pain (3%), pain during surgery (2%), and awareness (2%), (Table 1). Thus the database demonstrates that patients are more likely to sue for adverse outcomes with higher severity.

Three damaging events account for nearly one half of all claims: respiratory system (24%), cardiovascular system (11%), and equipment problems (11%). Less frequent damaging events include wrong drug or dose (4%), surgical (4%), and block needle trauma (3%). This clustering of damaging events and complications by the Closed Claims Project suggests that risk management strategies directed at just a few areas of clinical practice can result in large improvements in patient safety and professional liability. In addition, pinpointing specific injuries with high frequency and high payment amounts for further study also may improve outcome and professional liability. The subsequent sections outline how the Closed Claims Project has affected outcome after anesthesia.

Table 1  
Most common adverse outcomes in the Closed Claims Project database

Adverse outcome	Percentage of claims	Median payments (\$)	Range of payments (\$)
Death	30	210,000	250–14,700,000
Nerve damage	18	47,000	188–8,425,000
Brain damage	12	700,000	2,750–23,200,000
Airway trauma	7	30,000	15–1,500,000
Aspiration	4	195,327	390–14,500,000
Eye injury	4	67,500	25–2,900,000
Headache	4	15,000	752–825,000
Pneumothorax	4	35,000	500–9,000,000
Back pain	3	30,000	2,000–1,150,000
Fetal/newborn injury	3	352,221	18,248–7,000,000
Stroke	3	204,000	5,000–8,900,000
Awareness	2	18,000	1,000–750,000
Myocardial infarction	2	125,000	5,000–1,150,000
Burns	2	30,000	3,500–600,000

n = 5,480.

### Trends in outcomes

#### Decreasing severity of injury

The severity of injury in anesthesia malpractice claims has decreased since the 1970s. In the 1970s, 65% of the claims were for permanent/disabling injuries compared to 42% of the claims in the 1990s ( $P < 0.05$ ) (Fig. 2). The proportion of claims for death and brain damage has also decreased ( $P < 0.05$ ) in the 1990s (Fig. 3). In the 1970s, 41% of the claims were for death and 15% were for brain damage, whereas in the 1990s, only 22% of the claims were for death and 10% were for brain damage. In contrast, the proportion of claims for nerve injury, a

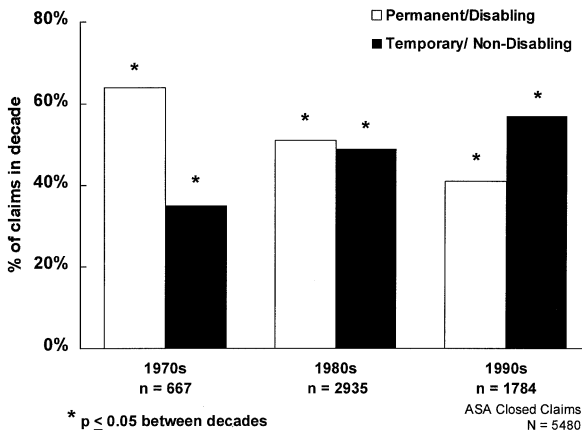


Fig. 2. Trends in outcome over time. The proportion of claims for permanent or disabling injuries in each decade has decreased from the 1970s to the 1990s.



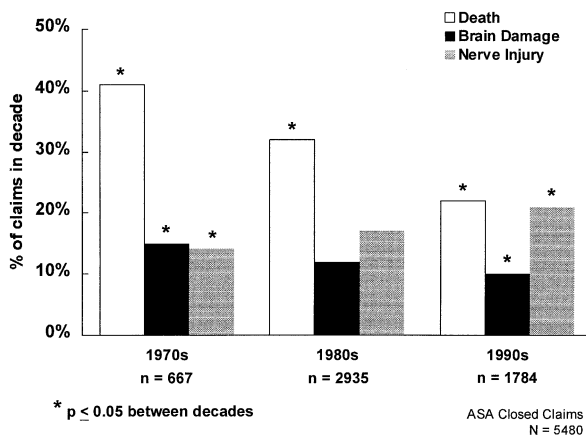


Fig. 3. Trends in the most common complications in anesthesia malpractice claims. The proportion of claims for death and brain damage has decreased in the 1990s compared with earlier decades. The proportion of claims for nerve injury has increased in the 1990s compared with the 1970s.

less severe injury, has increased in the 1990s compared with the 1970s (Fig. 3). Unfortunately, the closed claims study cannot determine whether the actual incidence of severe injuries is decreasing or the number of claims for minor injuries is increasing; however, there is a decrease in the proportion of claims with a payment in the 1990s (50%) compared with the 1970s (70%,  $P < 0.05$ ), suggesting an overall reduction of severe injuries. In addition, the fact that professional liability premiums for anesthesiologists have also decreased since the mid-1980s also suggests an improvement in anesthesia safety.

### Respiratory adverse events

Shortly after the Closed Claims Project database was established in 1984, adverse events involving the respiratory system were found to account for 34% of claims, and 85% of these claims involved brain damage or death [17]. Three mechanisms of injury accounted for almost three quarters of the adverse respiratory events: inadequate ventilation (38%), esophageal intubation (18%), and difficult tracheal intubation (17%). In 1989, the Closed Claims Project data provided substantive, national-based evidence that many of these injuries were preventable by pulse oximetry and capnography monitoring, although these monitoring devices may not have been available at the time of the adverse event [18]. These findings, among others, were considered by the ASA Committee on Standards in formulating new monitoring standards in the OR and Postanesthesia Care Unit [1]. The ASA Committee on Patient Safety recommended the formulation of the ASA practice guidelines for management of the difficult airway [19], partially in response to the Closed Claims Project data on difficult intubation [1]. Pulse oximetry and capnography monitoring gained widespread acceptance in the mid- to late 1980s. Interestingly, respiratory system adverse events decreased from 36% of the claims in the 1970s to 14% of the claims in the 1990s ( $P < 0.05$ )

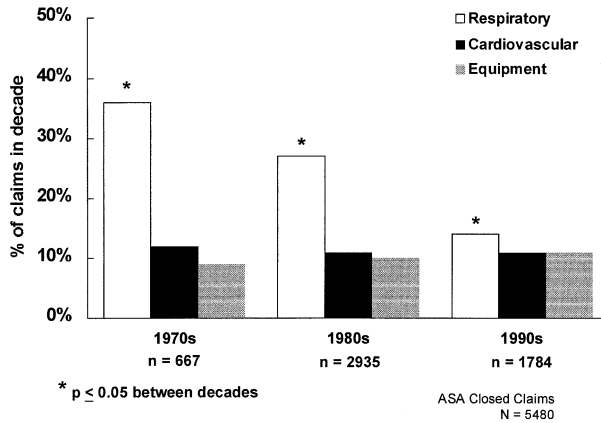


Fig. 4. Trends in the most common damaging events in anesthesia malpractice claims. The proportion of respiratory system damaging events decreased in the 1990s compared with earlier decades. The decrease was predominantly due to a reduction in claims involving inadequate ventilation.

(Fig. 4). Over 55% of claims related to death and brain damage in the 1970s involved damaging events to the respiratory system, compared with 28% for severe injuries in the 1990s. This decrease is due primarily to increased adequacy of ventilation (Fig. 5). The Closed Claims Project cannot determine whether or not the reduction in claims for injuries caused by inadequate ventilation is actually a result of better monitoring; however, the importance of pulse oximetry and end-tidal capnography in improving anesthesia safety is suggested by a reduction in the proportion of claims that are potentially preventable by monitoring (Fig. 6). Only 9% of the claims from the 1990s were preventable by monitoring, in contrast to 39% of the claims from the 1970s ( $P < 0.05$ ). In

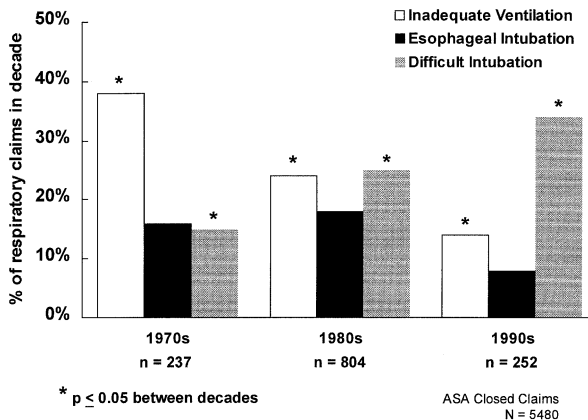


Fig. 5. Trends in the most common causes of respiratory events. The percentage of respiratory events caused by inadequate ventilation has decreased from the 1970s to the 1990s.

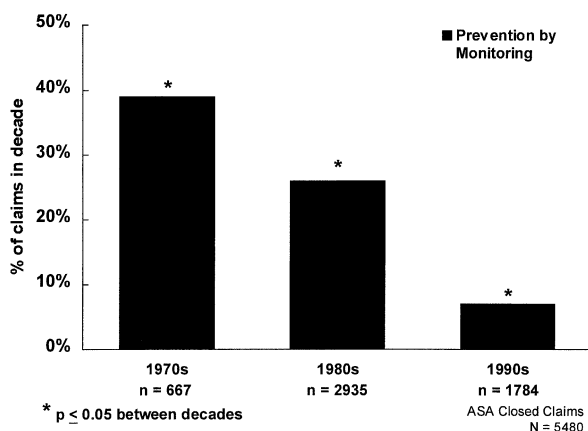


Fig. 6. Trends in prevention by monitoring. There has been a marked decrease in the proportion of claims deemed preventable by additional monitoring in the 1990s compared with earlier decades.

addition, the proportion of claims for difficult intubation, which would not be expected to be affected by improved monitoring, has increased (Fig. 5).

#### *Cardiovascular adverse events*

The decrease in respiratory events leading to death and brain damage is accompanied by an increase in cardiovascular events. In the 1970s, cardiovascular events accounted for 18% of claims for severe injuries; in the 1990s they accounted for 25%. This trend may reflect more accurate diagnoses afforded by monitoring with pulse oximetry and capnography, changing legal strategies, patient characteristics, or other factors.

In summary, the decrease in severity of anesthesia malpractice claims and the decrease in respiratory-related events that are preventable by monitoring suggest an improvement in anesthesia safety since the adoption of pulse oximetry and capnography in the mid-1980s.

#### *Specific patterns of injury*

The Closed Claims Project has focused on many specific adverse outcomes that, though infrequent, are of special interest. Some of these injuries of special interest include: sudden cardiac arrest during spinal anesthesia, ulnar and spinal cord nerve injury, airway trauma, injuries from office-based anesthesia and monitored anesthesia care (MAC), and postoperative visual loss. Other patterns of injury that have been examined but are not discussed in this article include nonoperative pain management injuries, regional anesthesia injuries, other nerve injuries, obstetric anesthesia claims, pediatric cardiac arrest claims, and intra-operative awareness claims. Although it is impossible to assess its impact on anesthesia safety and outcome, the Closed Claims Project has heightened

anesthesia practitioner awareness of these problems and stimulated research into the mechanisms for some of the injuries.

### *Neuraxial cardiac arrest*

The first paper published by the Closed Claims Project identified 14 cases of sudden cardiac arrest in young, healthy patients undergoing spinal anesthesia [20]. The cardiac arrest was appropriately managed in all cases, but the outcome was severe, involving death in six patients and brain damage in eight patients. The study hypothesized that the poor outcome was the result of poor cerebral perfusion in the presence of high sympathetic blockade. Early administration of epinephrine in response to severe bradycardia and hypotension was advised. Several other reports confirmed this newly identified mechanism of anesthesia injury and the efficacy of early pharmacological treatment of bradycardia and hypotension during neuraxial block [21–23].

Neuraxial cardiac arrest remains the leading cause of death in regional anesthesia claims in the 1990s, accounting for 32% of deaths associated with regional anesthesia. This is in contrast to 61% in the 1970s and 40% in the 1980s. Of the 13 deaths from neuraxial cardiac arrest in the 1990s, three were obstetrical patients, five were undergoing orthopedic surgery, and two were undergoing brief urological surgery. Care in 9 of the 13 cases was deemed inappropriate. Neuraxial cardiac arrest is not only a problem in the young athletic patient; eight cases occurred in patients who were above 55 years of age. These data suggest that neuraxial cardiac arrest remains a significant cause of death in current anesthetic practice.

### *Ulnar nerve injury*

The Closed Claims Project found that 27% of injuries to the ulnar nerve occurred in the presence of adequate positioning and padding, 62% had a delayed onset postoperatively (median: 3 days; range: 1–28 days) and 7% occurred during neuraxial regional anesthesia in awake or sedated patients [24,25]. In contrast to claims for other nerve injuries, ulnar nerve injuries had a male predominance (75%). These findings cast doubt on the assumption that compression of the ulnar nerve at the elbow is the mechanism of nerve injury, and stimulated research into the causes of ulnar nerve injury. Recent research by Warner and colleagues at the Mayo Clinic has confirmed that ulnar neuropathy is most common in middle-aged men [26–28]. Gender-related anatomical differences at the elbow may contribute to the male predominance of ulnar neuropathy. The neuropathy is generally not symptomatic until several days after surgery [28]. Medical (nonoperative) patients can also develop symptoms of ulnar neuropathy during hospitalization [26]. These findings suggest that the symptoms of ulnar neuropathy may be related to prolonged periods of bed rest in the supine position in the postoperative period [26–28]. Hospitalized patients who rest in the supine position commonly flex their elbows and rest their hands on their upper abdomen or chest. This position may cause external compression of the ulnar nerve and its vascular supply in the

postcondylar groove of humerus or the subtubercular groove of the coronoid process of the ulna. Although the mechanism of ulnar nerve injury is not completely understood, the proportion of this claim to total nerve injury claims decreased from 37% between 1980 and 1984 to 17% in the 1990s. This decrease may reflect changing legal strategies or an increase in claims for other types of nerve injury.

### *Spinal cord injury*

Unlike ulnar nerve injury, the proportion of claims for spinal cord injury in the Closed Claims Project database has increased in the 1990s, representing 27% of all nerve injury claims in the 1990s compared with 8% of these claims between 1980 and 1984 [24]. A mechanism of injury was identified in only 48% of these claims. Regional neuraxial anesthesia was administered in 68% of spinal cord injury claims. Nineteen percent (14 of 73) of claims were associated with blocks for chronic pain management, including eight cases for lumbar epidural steroid injection. Eighteen percent of cases were associated with intraoperative administration of heparin in the presence of a neuraxial block and resulted in paraplegia. In many of these claims, there was a delay in the diagnosis of an epidural hematoma. These findings suggest that any patient receiving anticoagulation after a neuraxial block should be monitored carefully postoperatively and that any unexpected motor or sensory changes should be strongly considered as potential evidence of an epidural hematoma. The Closed Claims Project findings also suggest that a prospective study involving the use of neuraxial block anesthesia in patients undergoing vascular surgery requiring systemic heparinization is warranted. Other causes of spinal cord injury were chemical injury (7%), anterior spinal artery syndrome (5%), meningitis (5%), trauma from fall from the operating table (4%), epidural abscess (3%), and intradural or intraspinal hematoma (1%).

### *Airway trauma*

Although many case reports have been published, including during routine anesthesia care, pharyngoesophageal perforation remains an underappreciated complication of endotracheal intubation [29]. Perforation of the pharynx or esophagus is a serious, life-threatening injury. In the Closed Claims Project database, 14 out of 62 (23%) patients filing claims for pharyngoesophageal perforation died [29]. Difficult intubation (odds ratio = 4.53, 95% CI = 2.36, 8.71), age older than 60 years (odds ratio = 2.97, 95% CI = 1.51, 5.87), and female gender (odds ratio = 2.43, 95% CI = 1.09, 5.42) were associated with claims for pharyngoesophageal perforation. The mechanism for the possible increased risk of injury in elderly women is unknown and deserves further study.

The Closed Claims Project data also suggests that prompt diagnosis of pharyngoesophageal perforation may be difficult. Early signs of perforation (eg, pneumothorax and subcutaneous emphysema) were present in only 51% of perforation claims, whereas late sequelae (eg, retropharyngeal abscess and

mediastinitis) occurred in 65%. Therefore, a delay in diagnosis was associated significantly with the development of late infectious sequelae and may have exacerbated patient morbidity and mortality. The mortality of mediastinitis from pharyngoesophageal perforation is 25%.

The clinical implication of the findings is that patients in whom tracheal intubation has been difficult should be observed for and be told to watch for the development of symptoms and signs of retropharyngeal abscess or mediastinitis. Symptoms such as severe sore throat, deep cervical or chest pain, and fever should be thoroughly investigated after difficult endotracheal intubation or difficult insertion of a nasogastric tube. Surgeons should also be alerted to the possibility of such a complication after a difficult intubation, so they can respond appropriately if the patient contacts them initially.

#### *Office-based anesthetic injuries*

Because of the 2 to 5 year delay for claims to be resolved and appear in the Closed Claims Project database, only 14 of the 5,480 claims in the current database are related to office-based anesthesia practice [30]. The majority of patients were middle-aged (median: 45 years), female (64%), or ASA 1–2 physical status (89%) patients having elective surgery under general anesthesia (71%) or monitored anesthesia care (14%). These demographics are similar for claims of patients in ambulatory anesthesia settings ( $n = 753$ ). The most common procedure in the office-based anesthesia setting was plastic surgery (64%), followed by dental procedures (21%) and miscellaneous procedures (14%). In contrast, the claims for ambulatory anesthesia involved only 32% of plastic surgery cases, 3% dental cases, and 64% miscellaneous cases.

Although denominator data is lacking, the office-based anesthesia claims had a significantly higher proportion of deaths (64%) compared with the ambulatory anesthesia claims (21%;  $P < 0.01$ ). The most common damaging event was the respiratory system (50%) and drug-related events (25%). Respiratory system events included bronchospasm, airway obstruction, inadequate oxygenation or ventilation, and esophageal intubation. Drug-related damaging events included wrong dose or drug, malignant hyperthermia, and allergic reaction. Because of the low number of office-based claims in the database, there were no statistical differences between the types of damaging events in this group compared with ambulatory anesthesia claims.

Forty-six percent of the office-based anesthesia claims were deemed preventable by better monitoring compared with 13% of ambulatory anesthesia claims ( $P < 0.01$ ). All of these injuries were due to adverse respiratory events in the recovery or postoperative periods and were thought to be preventable by pulse oximetry monitoring. Payment was made in 92% of the office-based anesthesia claims compared with 59% of ambulatory anesthesia claims. Median payment was also higher in the office-based anesthesia claims versus ambulatory anesthesia claims (\$200,000 vs \$85,000, respectively). These preliminary data suggest that office-based anesthesia quality improvement should focus on better monitoring in the recovery and postoperative periods.

### *Monitored anesthesia care claims*

Although the denominator data is lacking, claims for MAC (3%) are far less common than for general anesthesia (67%) or regional anesthesia (24%); however, the proportion of claims for MAC has increased from 1% in the 1970s to 4% in the 1990s [31]. This may reflect an increase in number of MAC anesthetics or a decreasing proportion of claims for other anesthetics, rather than a true increase in the incidence of adverse events during MAC. Monitored anesthesia care claims, when compared with general or regional anesthesia claims, exhibited a greater proportion of permanent injuries and a lower proportion of temporary injuries ( $P < 0.05$ ), a higher proportion of eye injury (24% vs 4%, respectively), a lower proportion of nerve injury (6% vs 17%, respectively), and similar proportions of death (24% vs 32%, respectively) and brain damage (15% vs 12%, respectively) [31]. Other adverse outcomes for MAC claims included stroke, burns, gastric aspiration, myocardial infarction, and emotional distress or fright.

Patients in MAC claims tended to be older and a higher ASA physical status than other anesthesia claims [31]. The mechanism of injury was 25% respiratory and 14% cardiovascular, which is similar to other anesthesia claims. Other damaging events that were more common in MAC than other types of anesthesia claims included intravenous catheter problems, burns, equipment problems, patient condition, and incorrect doses or drugs.

Standard of care was deemed appropriate in half of the MAC claims, which is similar to that of claims for general or regional anesthesia [31]. Better monitoring would not have prevented most of the injuries associated with MAC in the 1990s. The proportion of claims paid and median payment amount were similar for MAC claims and other anesthesia claims [31]. Although MAC injuries represent a small proportion of the total claims in the Closed Claims Project database, they tend to have similar damaging events with higher severity injuries, and similar payment proportion and amount compared with general or regional anesthesia claims. This is somewhat surprising given the older, sicker population, who are less likely to sue [9].

### *Postoperative visual loss*

Due to a perceived increase in the incidence of postoperative visual deficits, the ASA Committee on Professional Liability established the Postoperative Visual Loss Registry in June of 1999. A preliminary report published on the first 23 cases found that most cases were associated with spine surgery in the prone position (56%), followed by cardiopulmonary bypass procedures (22%) [32]. Forty-eight percent of the lesions were diagnosed as posterior ischemic optic neuropathy; 35% were diagnosed as anterior ischemic neuropathy. Median operative time was 9.9 hours (range: 5.8–18 hours) and median estimated blood loss was 2.2 liters (range: 0.1 to >12 liters). Hypotension was documented in half of the patients, and the lowest hematocrit was 25% (range: 13%–40%). Approximately half of the visual deficits were bilateral, and 39% of patients showed some improvement over time. Vaso-occlusive disease was present in

about half of the patients. The etiology of postoperative visual loss is most likely multifactorial and may depend on the position of the patient and the type of procedure. Suggested risk factors include prolonged hypotension, severe anemia, vaso-occlusive disease, venous congestion, and individual variation in the ocular vascular anatomy. The increase in the number of cases in the prone position may also reflect an increase in the number of prolonged spine operations with instrumentation performed in the 1990s. The Closed Claims Project is still collecting detailed information from cases of visual loss. A data form is available via the Closed Claims Project website (<http://depts.washington.edu/asaccp/>).

## Summary

Although there are intrinsic limitations in the analysis of closed malpractice claims, the Closed Claims Project has identified important anesthetic complications and mechanisms of injury and stimulated research in problem areas. The decrease in severity of injury in anesthesia malpractice claims suggests that anesthesia safety has improved since the establishment of monitoring standards using pulse oximetry and end-tidal capnography.

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