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Anesthesiology
1999; 91:552-6
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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?

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IN the early 1980s, the medical profession underwent a "crisis of affordability" in professional liability insurance coverage. Anesthesiologists were perceived as especially bad risks, representing only 3% of insured physicians but 11% of total dollars paid for patient injury, and this risk was reflected in soaring insurance premiums. Prevention of patient injury should decrease claims and resultant payments, which would be expected to lead to a reduction in premiums. In 1984, the president of the American Society of Anesthesiologists (ASA), Ellison C. Pierce, Jr, M.D., initiated a number of programs to improve patient safety and prevent anesthetic injury, one of which was the Closed Claims Project. This project was assigned to the ASA Committee Professional Liability, of which the author was then chairman.

In 1984, there was little comprehensive information on the scope and cause of anesthetic injury in the United States. Because significant anesthesia injury is a relatively rare occurrence, it is difficult to study prospectively or by retrospective medical record review, even from mul-

iple institutions. The study of insurance company closed claims provided a cost-effective approach to data collection in that extensive data on injuries that occurred in many different institutions have been gathered in a centralized location. Typically, a closed claim file consists of the hospital record, the anesthesia record, narrative statements of the involved healthcare personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury awards. Therefore, these files provide a concentrated collection of information on the relatively rare events leading to anesthesia-related injury. The task was to gain access to and collect information from professional liability organizations throughout the United States. Thus, the ASA Closed Claims Project was initiated for the purpose of identifying the major areas of anesthesia-related patient injury. The major objective was to provide data for the design of strategies to improve patient safety.

Although the use of closed claims circumvents the problem of gaining access to low-frequency adverse events, this approach does have inherent limitations that must be considered when interpreting the data. Although the Closed Claims Project has successfully recruited companies insuring approximately 14,500 of the 23,000 or so practicing anesthesiologists in the United States, there is not information as to how many anesthetics were administered by these providers. Therefore, closed claims data does not provide a denominator for calculating the risk of anesthetic injury. In addition, some injured patients do not file claims, whereas others without any apparent injury do file claims. Therefore, the study of closed claims data

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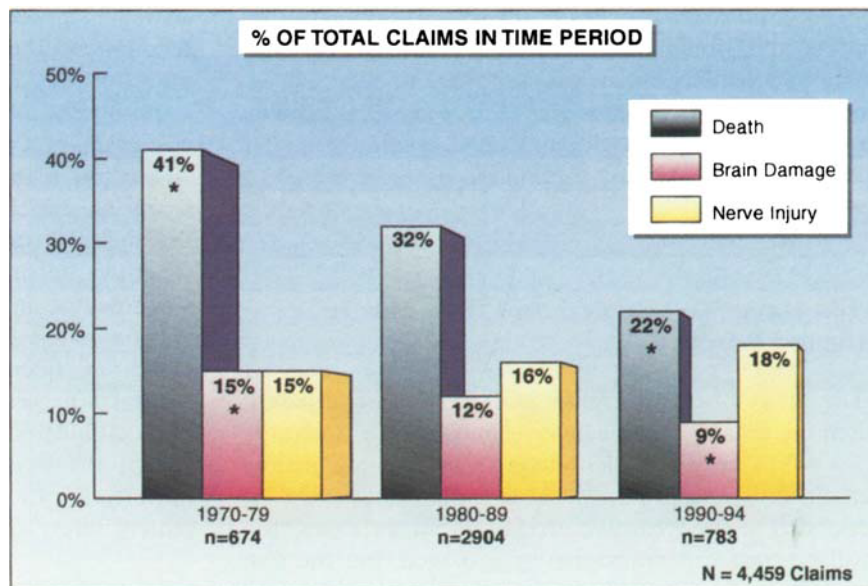
Received from the Department of Anesthesiology, University of Washington School of Medicine, Seattle, Washington. Submitted for publication October 14, 1998. Accepted for publication March 16, 1999. Supported by the American Society of Anesthesiologists. The opinions expressed herein are those of the author and do not represent the policy of the American Society of Anesthesiologists.

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Key words: Cardiac arrest; monitoring; nerve injury.

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Fig. 1. The incidence of death, brain damage, and nerve injury as a percentage of total claims in a given time period. A significant reduction in the proportion of claims for death and brain damage occurred between 1970–1979 and 1990–1994 ($*P \leq 0.01$, Z test).



provides a snapshot of anesthesia *liability*, but is not a comprehensive picture of all anesthetic *injury*. Injuries leading to claims are not a random sample of all injuries, and we do not know how closely this snapshot resembles the whole picture of anesthetic injury.

Another limitation of closed claims analysis is the retrospective nature of data collection. The information was gathered by the insurance companies for the purpose of resolving the claims, not for patient safety research. Data from different sources may be conflicting, and some data may be missing. Closed claims analysis is useful for generating hypotheses about the mechanism and prevention of anesthetic injury, but cannot be used for testing of those hypotheses. As a retrospective study, it cannot establish a cause-and-effect relationship of previous events, nor of changes in claim experience.

There are currently more than 4,000 claims in the database, collected from 35 insurance organizations throughout the United States. Dental injuries were excluded from review because the pathogenesis of these injuries is well understood, and insurance com-

panies usually do not gather much information about these claims. The majority of adverse events leading to these claims occurred in the 1980s, although there are a substantial number of claims from the 1970s and more than 700 claims from 1990–1994 (fig. 1). All claims in the database were reviewed on site at the respective insurance companies by volunteer practicing anesthesiologists using a standardized data collection form with specific detailed instructions. Claims submitted to the database undergo further review by the project investigators and staff for consistency and completeness. Assessments regarding the cause of injury and appropriateness of anesthesia care are reviewed by an anesthesiologist investigator, who refers the claim to a second anesthesiologist investigator if the on-site reviewer's assessment is questioned. If disagreement persists, the claim is discussed by the three anesthesiologist investigators, and a final judgment is made. The reliability of this review process has been established to be within the accepted range.¹ Claims are entered into the database on an anonymous basis such that there is no identification of defendants, plaintiffs, institutions, companies, or location, and there is no way to match claims in the database to their source files at the participating companies. Funding for project activities is provided entirely by the ASA.

Ongoing analysis of the database is conducted by project investigators, and as significant patterns of injury emerge, a manuscript is prepared and submitted to peer-

† Dr. Frederick W. Cheney is the Project Director. Other members participating include Dr. Robert Caplan, Associate Project Director, Dr. Karen Domino, and Dr. Karen Posner, Project Coordinator. Requests for data should be addressed to Dr. Karen Posner at the author's address. Abstracts of the peer-reviewed publications and full text of the *ASA Newsletter* articles can be accessed on the Closed Claims Project website: <http://depts.washington.edu/asaccp>.

reviewed journals to ensure scientific integrity. Brief reports and preliminary analysis of emerging patient safety and liability issues are reported in meeting abstracts and the *ASA Newsletter*. A free customized data analysis service is provided to ASA members under guidelines established by Committee on Professional Liability.†

What Have We Learned and How Has It Affected Practice

The utility of closed claims analysis became apparent when the first 900 claims in the database were analyzed. A set of 14 claims was identified in which young healthy patients undergoing surgery during spinal anesthesia experienced sudden cardiac arrest.² In all 14 cases, the cardiac arrest was appropriately managed, but the outcomes were severe, including death in six patients and permanent brain damage in the remainder. From patterns analyzed in this set of extremely rare adverse events, we hypothesized that the poor outcome may have been a result of the poor cerebral perfusion pressures engendered by closed chest cardiac massage in the presence of high sympathetic blockade. Therefore, we advocated the early administration of epinephrine in response to the severe bradycardia and hypotension that can occur during spinal anesthesia. Since this initial analysis, a number of reports have appeared in the literature that have confirmed the suddenness of the onset of bradycardia and hypotension during neuraxial block and the efficacy of early pharmacologic intervention.³⁻⁵

Further investigation of major trends in the Closed Claims Project database showed that respiratory system events accounted for a large share of all claims, and an especially large percentage of claims for death and brain damage.⁶ The most common events leading to injury were inadequate ventilation, esophageal intubation, and difficult tracheal intubation. These findings were considered by the ASA Committee on Standards in the formulation of standards requiring the use of pulse oximetry intraoperatively,⁷ the use of end-tidal CO₂ for the verification of endotracheal intubation,⁶ and the use of pulse oximetry in the postanesthesia care unit. This is not to imply that the standards would not have been written without these data, but at the time, closed claims data were the only substantive supporting evidence that was national in scope. Analysis of closed claims for injury caused by difficult tracheal intubation indicated the need for improved strategies for management of the difficult

airway.⁶ This led the ASA Committee on Patient Safety to recommend the formulation of the ASA practice guidelines for management of the difficult airway.⁸

Closed claims data are now being used to analyze the role of the ASA guideline for management of the difficult airway on patient safety and anesthesia liability. Currently closed claims involving difficult tracheal intubation are evaluated in a structured fashion with regard to whether the practice guidelines were followed and, if so, how the injury occurred. Because it usually takes approximately 5 yr from the date of injury for a claim to close and become part of the database, it will take several more years before enough postguideline data will be accumulated for any meaningful conclusions to be drawn. However, this sort of analysis provides a unique opportunity to evaluate the role of these guidelines in patient safety and liability.

Future Trends

Because pulse oximetry and capnography have been in clinical use since the mid-1980s, we analyzed data from the project to determine whether these monitoring modalities were correlated with improvements in patient safety. Two trends were apparent. The first is that the severity of injury in malpractice claims is decreasing, as indicated by the incidence of claims for death and brain damage (fig. 1). In the 1970s, 56% of claims were for death and brain damage compared with only 31% in the 1990s ($P \leq 0.01$). The incidence of claims for nerve injury, a far less serious complication, has remained relatively constant over the years (fig. 1). Unfortunately, it cannot be determined from claims whether the actual incidence of severe injuries is decreasing or is simply offset by an increase in claims for minor injuries. The fact that professional liability premiums for anesthesiologists have decreased significantly since the mid-1980s would imply an overall reduction in severe injuries.

The second trend is that the major category of damaging event or mechanism responsible for severe injuries (death and brain damage) has changed over time (fig. 2). The occurrence of respiratory system events has decreased primarily in claims for injuries due to inadequate ventilation and, to a lesser extent, esophageal intubation. Inadequate ventilation and esophageal intubation were two of the three most common respiratory system events before the use of pulse oximetry and capnography. Whether this reduction in claims for injuries caused by inadequate ventilation and esophageal intubation is

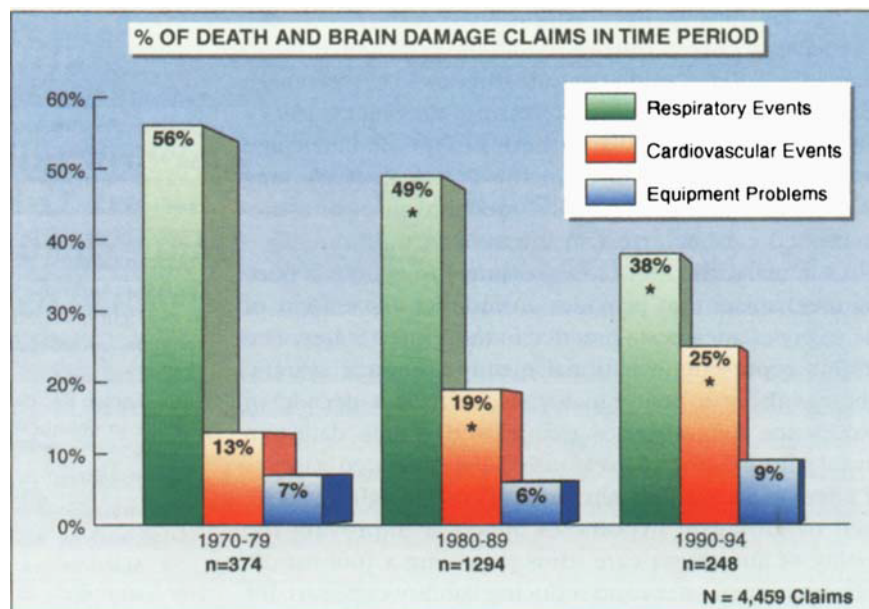


Fig. 2. The incidence of respiratory, cardiovascular, and equipment-related damaging events as a percentage of the total claims for death and brain damage in each time period (* $P \leq 0.05$, Z test) (compared with 1970–1979).

actually a result of better monitoring cannot be determined by retrospective analysis afforded by the Closed Claims Project. However, the occurrence of difficult tracheal intubation, the third most common respiratory-related event that would not be expected to be affected by improved monitoring, has remained relatively constant. With the decrease in respiratory events leading to death and brain damage comes an increase in cardiovascular events. In the 1970s, cardiovascular events accounted for 13% of death and brain damage claims, and in the 1990s, they accounted for 25% ($P \leq 0.01$; fig. 2). This trend may reflect more accuracy in diagnosis of the damaging event afforded by monitoring with pulse oximetry and capnography, changing legal strategies, patient characteristics, or other factors.

Although claims for death and brain damage are decreasing, nerve injury may well assume the position as a leading cause of anesthesia-related injury for which a malpractice claim is made. The finding that most injuries to the ulnar nerve and brachial plexus seem to occur in the presence of adequate positioning and padding suggests that the mechanisms of such injuries are not well known.⁹ Because preventive strategies for these nerve injuries are not apparent, no reduction in claims for

these injuries may be expected. A surprising finding is that among claims for nerve damage in which the injury occurred in the 1990s, injury to the spinal cord was the most frequent.⁹ This seems to be related to injuries from neuraxial block in anticoagulated patients and blocks for chronic pain management.⁹

Because of the low frequency of occurrence of severe anesthesia-related patient injuries, prospective studies of their incidence and strategies for their prevention require large numbers of patients. Therefore, these studies would have to be multi-institutional. An example of such a prospective study suggested by recent closed claims data⁹ involves the use of neuraxial block anesthesia in patients undergoing vascular surgery requiring systemic heparinization. The question is whether the occurrence of spinal cord injury is higher in patients who receive neuraxial block than in those who do not.

An example of an ongoing multi-institutional effort (albeit retrospective) is the Pediatric Perioperative Cardiac Arrest (POCA) Registry, which was formed in 1994 under the combined auspices of the Closed Claims Project and the Quality Assurance Committee of the American Academy of Pediatrics Section on Anesthesiology.[‡] When the pediatric claims from the Closed Claims Project database were analyzed,¹⁰ it was noted that the specific mechanism of cardiac arrest was not apparent in a large number of claims. Therefore, the POCA Registry was formed specifically to examine this phenomenon. Currently, 63 partici-

‡ The POCA Registry is directed by Dr. Jeffrey Morray. Other members of the committee include, in addition to the Closed Claims Project Committee, Dr. Jeremy Geiduschek, Dr. Charles Haberkern, Dr. Alvin Hackel, and Dr. Chandra Ramamoorthy. Further information is available on the Closed Claims Project website.

pating institutions have submitted nearly 300 cases that have occurred during the administration of more than one million pediatric anesthetics. This gives an incidence of cardiac arrest during the years 1994-1997 of 2.7 per 10,000 anesthetics in the pediatric age group. Analysis of data from the POCA Registry may provide new insights into the mechanism of anesthesia-related cardiac arrest in infants and children.

In summary, the ASA Closed Claims Project is a reporting mechanism that provides an indirect assessment of the safety of anesthesia practice in the United States. The project represents a national quality-assurance system, albeit without a denominator. More than a decade of experience demonstrates that closed claims data can reveal important and previously unappreciated aspects of adverse anesthetic outcomes. These insights can be used to formulate hypotheses aimed at improving the quality of anesthesia care, thus providing a tool for advancing patient safety and reducing liability exposure for the anesthesiologist.

References

1. Posner KL, Sampson, PD, Caplan RA, Ward RJ, Cheney FW: Measuring interrater reliability among multiple raters: An example of methods for nominal data [published erratum appears in *Stat Med* 1992; 11:1401]. *Stat Med* 1990; 9:1103-15
2. Caplan RA, Ward RJ, Posner K, Cheney FW: Unexpected cardiac arrest during spinal anesthesia: A closed claims analysis of predisposing factors. *ANESTHESIOLOGY* 1988; 68:5-11
3. Frerichs RL, Campbell J, Bassell, MB: Psychogenic cardiac arrest during extensive sympathetic blockade. *ANESTHESIOLOGY* 1988; 68:943-4
4. Chester, WL: Spinal anesthesia, complete heart block, and the pericardial chest thump: An unusual complication and a unique resuscitation. *ANESTHESIOLOGY* 1988; 69:600-2
5. Liguori GA, Sharrock NE: Asystole and severe bradycardia during epidural anesthesia in orthopedic patients. *ANESTHESIOLOGY* 1997; 86:250-7
6. Caplan RA, Posner KL, Ward RJ, Cheney FW: Adverse respiratory events in anesthesia: A closed claims analysis. *ANESTHESIOLOGY* 1990; 72:828-33
7. Tinker JH, Dull DL, Caplan RA, Ward RJ, Cheney FW: Role of monitoring devices in prevention of anesthetic mishaps: A closed claims analysis. *ANESTHESIOLOGY* 1989; 71:541-6
8. American Society of Anesthesiologists Task Force on Guidelines for Management of the Difficult Airway: Practice guidelines for management of the difficult airway. *ANESTHESIOLOGY* 1993; 78:597-602
9. Cheney FW, Domino KB, Caplan, RA, Posner KL: Nerve injury associated with anesthesia: A closed claims analysis. *ANESTHESIOLOGY* 1999; 90:1062-9
10. Morray JP, Geiduschek JM, Caplan RA, Posner KL, Gild WM, Cheney FW: A comparison of pediatric and adult anesthesia closed malpractice claims. *ANESTHESIOLOGY* 1993; 78:461-7