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The American Society of Anesthesiologists Closed Claims Project

The Beginning

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Unexpected cardiac arrest during spinal anesthesia: A closed claims analysis of predisposing factors. By Robert A. Caplan, Richard J. Ward, Karen Posner, and Frederick W. Cheney. ANESTHESIOLOGY 1988; 68:5–11. Abstract used with permission.

Abstract: Fourteen cases of sudden cardiac arrest in healthy patients who received spinal anesthesia were discovered in a preliminary review of 900 closed insurance claims for major anesthetic mishaps. All patients were resuscitated from the intraoperative cardiac arrest, but six suffered such severe neurologic injury that they died in hospital. Of the eight survivors, only one patient exhibited sufficient neurologic recovery to allow independence in daily self-care. In view of the unexpected nature of these cardiac arrests—as well as the ultimate severity of injury—the cases were analyzed in detail to determine whether there were recurring patterns of anesthetic management

that may have contributed to patient morbidity and mortality. Two patterns were identified. The first was the intraoperative use of sufficient sedation to produce a comfortable-appearing, sleep-like state in which there was no spontaneous verbalization. Cyanosis frequently heralded the onset of cardiac arrest in patients exhibiting this degree of sedation, suggesting that unappreciated respiratory insufficiency may have played an important role. The second pattern appeared to be an inadequate appreciation of the interaction between sympathetic blockade during high spinal anesthesia and the mechanisms of cardiopulmonary resuscitation. Prompt augmentation of central venous filling through the use of a potent α -agonist and positional change might have improved organ perfusion, shortened the duration of cardiac arrest, and lessened the degree of neurologic damage.

THIS paper was the first publication from the American Society of Anesthesiologists (ASA) Closed Claims Project database.¹ The Project was initiated in 1984 by the ASA during the presidency of Ellison (Jeep) Pierce, Jr., M.D., a highly visible leader in the field of anesthesia patient safety. The idea of analyzing closed malpractice claims as a method of improving patient safety was that of Dr. Pierce and Richard (Dick) J. Ward, M.D., Professor Emeritus, who was then a professor of anesthesiology at the University of

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Washington in Seattle. Dick had done an analysis of closed malpractice claims from Washington state with Richard J. Solazzi, M.D., who was then an anesthesiology resident at the University of Washington and had first proposed studying closed claims.² Dick convinced Jeep Pierce that a national study sponsored by the ASA might yield valuable information about the prevention of anesthesia-related injuries.

Dr. Pierce assigned the project to the Committee on Professional Liability, to which I had just been appointed Chair in 1985. Dick and I began the process of gaining access to the closed claims of anesthesiologists from various malpractice insurance companies. This was not an easy task because insurance carriers were concerned about confidentiality—and the fact that we were trying to do something new. Jeep Pierce paved the way with several companies in the Northeast. A major source of claims became available unexpectedly when we discovered that St. Paul Fire and Marine Insurance Company of St. Paul, Minnesota, which insured anesthesiologists in many states, was actually looking for help from the profession because the severity of anesthesia injuries resulted in much higher total expenditures for anesthesiologists' claims than for those in other specialties.

Dick and I, and a number of other dedicated committee members, went to various insurance organizations who had agreed to participate. We collected standardized data on each claim, which included a summary of the events leading to the injury. Dick Ward was by far the most productive reviewer and at one point spent a whole week reviewing claims in person at the St. Paul company.

As the data started to accumulate, we felt it important that it be published in the peer-reviewed literature so that it might receive maximal acceptance from the medical, risk management, and legal communities. At that time, there was not much in the way of peer-reviewed publications from malpractice claims and we became increasingly concerned about how to analyze and present the data. We, therefore, sought the advice of Edward Perrin, M.A., Ph.D., Professor Emeritus and then-Chair of the Department of Health Services at the University of Washington School of Public Health, with whom we had previously consulted on other research. Dr. Perrin was nationally recognized and had been director of the National Center for Health Statistics in the 1970s. After reviewing the data we had collected, his opinion was that they were unique and had great value. He ended our discussion with the unforgettable lines: "Fred, the only problem here is that you don't know what you are doing. This isn't 10 dogs and a *t* test. I will see if I can get one of my graduate students to help you out." He was correct in his assessment of my expertise. I had been continuously funded by the National Institutes of Health for 18 yr for laboratory research, but I had no idea how to handle the data we were collecting. The graduate student he recruited for us was Karen L. Posner, Ph.D., who joined the project and has been one of the major contributors to it ever since. Her immediate contributions were to tell us where we could and could not use statis-

tics, how to organize the data, and how to assess the reliability of the judgments that reviewers were making about the standard of care provided.

As we continued to collect data, we saw an unexpected group of claims that involved sudden cardiac arrest in relatively healthy patients who had received spinal anesthesia. When I saw the first claim, I thought there was some grave error that was not apparent in the records. The second such claim raised questions in my mind. When I encountered two similar claims at one insurance company, I asked to take copies of all the relevant records back to University of Washington for further analysis. We then asked our group of reviewers to copy and send us all relevant records if they ran into similar claims during their on-site visits.

After gathering a number of such cases, we thought this surprising finding merited a peer-reviewed paper. Robert (Bob) A. Caplan, M.D., then an assistant professor in our department who had been working in my research laboratory, volunteered to help with the project. I warned him that the research laboratory was a surer path to academic advancement, but fortunately he ignored my advice. He agreed to organize the cases of cardiac arrest under spinal anesthesia for a peer-reviewed publication.

The initial attempt at writing a closed claims paper included 11 cases written in the format of a case series and a review of the literature. The manuscript was sent to *Anesthesia and Analgesia* because the editor was a recognized expert in the field of spinal anesthesia. The manuscript was rejected with many negative comments including: "We believe it fair to say that the only thing the reader is left with is the fact that spinal anesthesia can be dangerous if not lethal. This is certainly not news." The reviewers also rightly criticized the length and complexity of the manuscript.

At this point Dr. Caplan suggested we use the concept of a sentinel event, which is defined as an unusual or unexpected outcome that should not occur under the prevailing conditions of health care.³ The cardiac arrests were approached as sentinel events, and the paper was reoriented in this direction. The new approach became highly significant not only for this paper but also for future analysis and the presentation of closed claims data. The paper was shortened considerably, and three cases were added.

We now had an analysis of 14 of the first 900 claims in the Project database. In all 14 cases, the patients were relatively young and healthy, undergoing relatively minor operations, and the standard of care was considered appropriate in all cases. The key finding was the sudden appearance of bradycardia and hypotension, which rapidly progressed to asystole. Despite seemingly appropriate pharmacologic therapy and chest compressions (fig. 1),¹ there were six deaths in the hospital and seven patients with severe brain damage. Only one patient recovered to the point of independent self-care.

On the basis of our analysis, we made recommendations that included the use of pulse oximetry (which was then just coming into widespread use), the early use of epinephrine for the treatment of bradycardia when it was not immediately

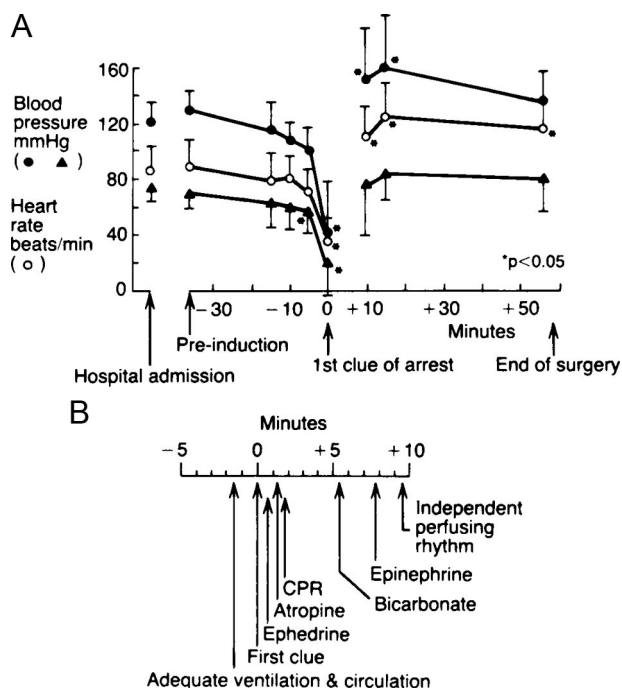


Fig. 1. Composite display of vital signs (A) and key events (B) in 14 cases of cardiac arrest during spinal anesthesia. Events are shown in relation to the first clue of impending cardiac arrest (located at 0 min on the time scale). The values for systolic blood pressure (closed circles), diastolic blood pressure (closed triangles), and heart rate (open circles) are mean \pm SD. $*P < 0.05$ versus hospital admission values. Used with permission, from 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.

responsive to atropine and ephedrine, and, most importantly, immediate use of a full resuscitation dose of epinephrine if asystole occurred. We hypothesized that chest compressions in the presence of high sympathetic blockade were not effective in delivering adequate perfusion to the heart and brain. Thus, increasing peripheral vasoconstriction was a key element in providing perfusion to vital organs.

As the revision of the paper progressed, I received a call from Lawrence (Larry) J. Saidman, M.D., then-Editor-in-Chief of *ANESTHESIOLOGY*, who asked whether I would be interested in a position on the editorial board. I declined his invitation because my hands were full with the closed claims study, as it was then called, and asked, by the way, if he would be interested in looking at our first paper. He replied that he would be happy to peer review “anything.” Thus, the revised manuscript was submitted to *ANESTHESIOLOGY*.

† ASA Closed Claims Project. Available at: <http://www.asaclosedclaims.org>. Accessed June 11, 2010.

‡ Statement on respiratory monitoring during endoscopic procedures. Approved by ASA House of Delegates on October 21, 2009. Available at: <http://www.asahq.org/publicationsAndServices/standards/52.pdf>. Accessed May 25, 2010.

When the paper was published in 1988, it was accompanied by a glowing editorial by Arthur S. Keats, M.D. (1923–2007), a former Editor-in-Chief of *ANESTHESIOLOGY* and a highly regarded patient safety advocate.⁴ He pointed out the limitations of the database, which included a biased sample of all adverse events, no control group for comparison, and an inability to derive an incidence. However, he heaped praise on the value of closed claims analysis for rare events.

After publication of the article, skepticism was expressed in letters to the editor about both the suddenness of the onset of the bradycardia and hypotension and the adequacy of the level of vigilance we described. However, there were subsequent reports in the literature confirming the sudden onset of the phenomena and the efficacy of early pharmacologic intervention.^{5–7}

This first peer-reviewed publication opened other avenues for dissemination of closed claims data. Erwin Lear, M.D. (Professor Emeritus, Department of Anesthesiology, Beth Israel Medical Center, New York, New York), then-Editor of the *ASA Newsletter*, had been pressing us to report our data in that publication. We initially declined due to concerns about the effect it might have on our eligibility for subsequent publications in the peer-reviewed literature. Larry Saidman at *ANESTHESIOLOGY* informed us that he considered Newsletter articles the same as abstracts from scientific meetings. From that point forward, in addition to scientific meeting abstracts, we presented emerging patient safety and liability issues in the *ASA Newsletter*. When sufficient data had been accumulated on a given subject, we then prepared a paper for peer review. Since 1988 there have been 63 newsletter articles and 33 peer-reviewed manuscripts published, all of which can now be accessed on the ASA Closed Claims Project Web site.[†]

Subsequent to publication of the first paper, we turned our attention to the less surprising finding that respiratory system events were the major source of anesthesia-related injury, especially death and brain damage. These findings were considered by the ASA Committee on Standards in formulating the standards requiring use of pulse oximetry intraoperatively⁸ and the use of end-tidal carbon dioxide for verification of tracheal intubation.⁹ Closed claims data on difficult intubation⁹ led to formulation of the ASA Practice Guidelines for Management of the Difficult Airway (1993).¹⁰ Closed Claims Project data have also been used to develop a Practice Advisory for the Prevention of Perioperative Peripheral Neuropathies (2000),¹¹ a Practice Advisory for Perioperative Visual Loss Associated with Spine Surgery (2006),¹² as well as an ASA-approved Statement on Respiratory Monitoring During Endoscopic Procedures (2009).[‡] Ultimately, the Project stimulated similar review of closed claims in anesthesia care in other countries (e.g., United Kingdom)¹³ and other areas of medicine in the United States (e.g., general surgery).^{14,15}

The experience we gained from our in-depth analysis of claims for sudden cardiac arrest during spinal anesthesia was helpful as we subsequently developed additional registries for

pediatric perioperative cardiac arrest,¹⁶ postoperative visual loss,¹⁷ and anesthesia awareness.¹⁸ The Pediatric Perioperative Cardiac Arrest Registry was organized by Jeffrey P. Morray, M.D. (currently President-Elect of the Phoenix Children's Medical Staff, Phoenix Children's Hospital, Phoenix, Arizona), when he was at University of Washington.¹⁶ This registry did not use closed claims data because it was a multi-institutional effort for which practitioners provided standardized data from their individual hospitals. The Postoperative Visual Loss Registry includes some closed claims data, but data are also acquired from other sources such as individual practitioners and patients. The Anesthesia Awareness Registry collects data from patients who have experienced awareness during general anesthesia.

In 2002, I handed the reins of the Closed Claims Project to my University of Washington colleague Professor Karen B. Domino, M.D., M.P.H., who had become chair of the ASA Committee on Professional Liability. Although her scientific background, like mine, was pulmonary-related laboratory research, she was better prepared in that she had obtained an M.P.H. in Health Services in 1998. She did an outstanding job of taking the Closed Claims Project to the next level.

Today, the Project is run by Dr. Domino; Karen L. Posner, Ph.D., Laura Cheney Professor in Anesthesia Patient Safety; and Lorri A. Lee, M.D., Associate Professor of Anesthesiology and Director of the Postoperative Visual Loss Registry.

Bob Caplan moved to Virginia Mason Clinic in Seattle in 1988, where he is Clinical Professor of Anesthesiology and remains involved with the Project as a senior advisor. Dick Ward retired from practice in 1990 and became a Jesuit priest. He is now semiretired but, at last report, still active in performing celestial duties. I attribute his career change to the fact that he looked at one malpractice claim too many (over 800) and needed to do something else. I gave up laboratory research in 1989 and now act as a senior advisor to the Project. I still work part time in the operating room to maintain my eligibility as a closed claims reviewer, and I remain fascinated by this endeavor.

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