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Trends in Anesthesia-related Death and Brain Damage

A Closed Claims Analysis

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Background: **The authors used the American Society of Anesthesiologists Closed Claims Project database to determine changes in the proportion of claims for death or permanent brain damage over a 26-yr period and to identify factors associated with the observed changes.**

Methods: **The Closed Claims Project is a structured evaluation of adverse outcomes from 6,894 closed anesthesia malpractice claims. Trends in the proportion of claims for death or permanent brain damage between 1975 and 2000 were analyzed.**

Results: **Claims for death or brain damage decreased between 1975 and 2000 (odds ratio, 0.95 per year; 95% confidence interval, 0.94–0.96; $P < 0.01$). The overall downward trend did not seem to be affected by the use of pulse oximetry and end-tidal carbon dioxide monitoring, which began in 1986. The use of these monitors increased from 6% in 1985 to 70% in 1989, and thereafter varied from 63% to 83% through the year 2000. During 1986–2000, respiratory damaging events decreased while cardiovascular damaging events increased, so that by 1992, respiratory and cardiovascular damaging events occurred in approximately the same proportion (28%), a trend that continued through 2000.**

Conclusion: **The significant decrease in the proportion of claims for death or permanent brain damage from 1975 through 2000 seems to be unrelated to a marked increase in the proportion of claims where pulse oximetry and end-tidal carbon dioxide monitoring were used. After the introduction and use of these monitors, there was a significant reduction in the proportion of respiratory and an increase in the proportion of cardiovascular damaging events responsible for death or permanent brain damage.**

THE most severe anesthesia-related patient injuries are death or permanent brain damage. We have reported from the American Society of Anesthesiologists (ASA) Closed Claims Project that the proportion of claims for death or permanent brain damage decreased from 44% of 2,904 claims where the injury occurred between 1980 and 1989 to 31% of 783 claims where the injury occurred between 1990 and 1994 ($P \leq 0.05$).[1] In this report, we examined the Closed Claims Database over a 26-yr period (1975–2000) to investigate factors associated with this decrease in the proportion of severe anesthesia-related injuries. We studied the mechanism of injury of these adverse outcomes and explored associated factors such as monitoring that might have affected the observed changes.

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Materials and Methods

The ASA Closed Claims Project is a structured evaluation of adverse anesthetic outcomes collected from the closed anesthesia malpractice insurance claim files of more than 35 professional liability companies throughout the United States. Currently, the Project has 18 insurance organizations in its active panel. A detailed description of the data collection process has been reported.[1,2] In brief, anesthesiologist–reviewers completed a detailed data form plus narrative summary for each claim in which the sequence of events and nature of injury could be determined from the information available in the file. Claims for damage to teeth and dentures were excluded from data collection. Claims with inadequate information were also excluded, which resulted in an approximate 27% file rejection rate of available claims for review before data collection. Standard of care was judged by the on-site reviewer as standard (appropriate), substandard (less than appropriate), or impossible to judge based on reasonable and prudent practice at the time of the event.[2]

Claims in the ASA Closed Claims Project database were categorized according to damaging events and complications. The complications studied were death or permanent brain damage. In cases where brain damage was followed by death, death was considered the complication, so the claims were only counted once. The damaging event was the mechanism by which the complication (injury) occurred. Each claim for brain damage or death was assigned a primary damaging event. Damaging events were grouped into broad categories based on the physiologic system or anesthesia technique implicated in the injury: respiratory system events, cardiovascular system events, medication-related events, equipment problems, regional block–related events, other anesthesia

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events, surgical events, or patient condition. Medication-related events included inhalation anesthetics, and intravenous agents such as hypnotics, induction agents, muscle relaxants, and antibiotics.

For this analysis, the major categories of damaging events were subcategorized into more specific areas, most of which are self-explanatory (table 1). Further definitions of some of the less obvious categories follow. The "other" category in respiratory damaging events included endobronchial intubation, bronchospasm, and inadvertent extubation. In the cardiovascular category, multifactorial/miscellaneous events included arrhythmia and hypotension in circumstances where the primary event causing these cardiovascular system changes was not apparent. Also included in the multifactorial cardiovascular event category were surgical complications and patient conditions such as tamponade, and pathologic abnormalities that were undiagnosed preoperatively but diagnosed at autopsy. This latter category included congenital abnormalities, viral myocarditis, myocardial fibrosis, and unsuspected severe coronary artery disease. Pulmonary embolism included air, blood, and fat.

Anesthetic gas delivery equipment was defined as any device used to convey gas to or from the endotracheal tube or mask.[3] In the regional block–related group, neuraxial cardiac arrest was defined as sudden and unexpected severe bradycardia and/or asystole during neuraxial block, with relatively stable hemodynamic events preceding the event.[4]

At the time of this analysis, there were a total of 6,894 claims in the database. Of this total, there were 6,750 claims where the injury occurred from 1975 through 2000, which were the basis for this report. Claims from 1970–1974 (n = 21) and 2001 (n = 15) were excluded because there were insufficient numbers per year for meaningful analysis. All claims were classified by the

Table 1. Damaging Events Associated with Death and Permanent Brain Damage, 1986–2000 (n = 1,411)

Respiratory Damaging Events	n	% Total Respiratory Events	Less Than Appropriate Care, n (%)
Difficult intubation	115	23	58 (50)
Inadequate ventilation/oxygenation	111	22	82 (74)
Esophageal intubation	66	13	60 (91)
Premature extubation	58	12	47 (81)
Aspiration	50	10	21 (42)
Airway obstruction	47	9	25 (53)
Other respiratory	56	11	29 (52)
Total	503	100	322 (64)*
Cardiovascular Damaging Events	**n**	**% Total Cardiovascular Events**	**Less Than Appropriate Care, n (%)**
Multifactorial/miscellaneous	154	35	28 (18)
Pulmonary embolism	70	16	10 (14)
Inadequate fluid therapy	63	14	48 (76)
Stroke	58	13	14 (24)
Hemorrhage	49	11	9 (18)
Myocardial infarction	48	11	23 (27)
Total	442	100	122 (28)*
Medication-Related Damaging Events	**n**	**% Total Medication-related Events**	**Less Than Appropriate Care, n (%)**
Wrong drug/dose	68	55	52 (76)
Allergic or adverse drug reaction	51	41	12 (24)
Malignant hyperthermia	5	4	4 (80)
Total	124	100	68 (55)
Equipment-Related Damaging Events	**n**	**% Total Equipment-related Events**	**Less Than Appropriate Care, n (%)**
Central lines	54	60	22 (41)
Gas delivery	16	18	13 (81)
Miscellaneous/other	20	22	10 (50)
Total	90	100	45 (50)
Block-Related Damaging Events	**n**	**% Total Block-related Events**	**Less Than Appropriate Care, n (%)**
Neuraxial cardiac arrest	47	53	23 (49)
High spinal/epidural	19	22	12 (63)
Intravenous injection/local absorption	9	10	5 (56)
Other	13	15	10 (77)
Total	88	100	50 (57)

* $P < 0.01$ difference between % less than appropriate care in respiratory *vs.* cardiovascular events (chi-square).

Miscellaneous categories of damaging events are not shown (n = 164).

year the injury occurred rather than when the claim was settled. Claims with unknown year of event (n = 108) were excluded from analysis.

Because pulse oximetry (Spo_2) and end-tidal carbon dioxide ($ETco_2$) monitoring began to appear in a significant number of claims in 1986, we did a further analysis of all claims for specific damaging events and standard of care from 1986 through 2000. In a few of the claims, Spo_2 only was used, but they were grouped in the much larger category of Spo_2 and $ETco_2$. Claims were counted as monitors being present only if this was explicitly noted on the data collection form. Claims where the monitoring information was missing or unknown were designated in the no monitoring category.

Statistical Analysis

Trends over time were analyzed by logistic regression, with years since the index year (1975 or 1986) as the independent variable. Odds ratios (ORs) with 95% confidence intervals (CIs) are therefore odds per year. Comparison of trend lines between 1975–1985 and 1986–2000 was based on the difference in logistic regression coefficients and the estimated SEs of these differences. *P* values were obtained by assuming a normal distribution. The chi-square test was used to compare proportions (less than appropriate care). $P < 0.05$ was required for statistical significance.

Results

There were a total of 6,750 claims where the injury occurred from 1975 through 2000 (fig. 1A), of which 2,613 claims were for death or permanent brain damage (39%). The proportion of total claims for death or brain damage was 56% in 1975 and decreased approximately 1% per year (OR, 0.95 per year; 95% CI, 0.94–0.96; $P < 0.01$) through the year 2000, when death or brain damage represented 27% of total claims (fig. 1B).

The two major damaging events or mechanisms of injury causing death or brain damage were respiratory and cardiovascular, which together made up 68% of damaging events from 1975 through 2000. Respiratory-related damaging events were responsible for approximately 50% or more of claims for death or brain damage before 1986 and did not decrease as a proportion of claims for death or brain damage during this time period (fig. 2). The other major category of damaging event was cardiovascular, which was responsible for 27% or less of the claims for death or brain damage before 1986, without any statistically significant change over time (fig. 2). From 1986 through 2000, respiratory-related damaging events decreased (OR, 0.92; 95% CI, 0.89–0.94; $P < 0.001$), whereas cardiovascular damaging events increased (OR, 1.04; 95% CI, 1.01–1.07; $P = 0.008$). By 1992, the proportions of respiratory and cardiovascular damaging events were both 28%, and each remained near that level through 2000 (fig. 2).

The specific respiratory and cardiovascular damaging events for 1986 through 2000 are shown in table 1. In the respiratory events category, difficult intubation (23% of total respiratory events) and inadequate ventilation/oxygenation (22%) were the most frequent. Esophageal intubation (13%) and premature extubation (12%) were the next most common. The most common cardiovascular damaging event was the multifactorial/miscellaneous category, which accounted for 35% of the total (table 1). The other more specific cardiovascular events included pulmonary embolism (16%), inadequate fluid (14%), stroke (13%), hemorrhage (11%), and myocardial infarction (11%) (table 1).

Medication-, equipment-, and block-related damaging events were far less common and each made up less than 10% of the damaging events in the 26-yr time period. Only medication-related claims showed any statistically significant change over time, and that was an increase from 1975 to 1985 (OR, 1.19; 95% CI, 1.08–1.32; $P = 0.001$). From 1986 through 2000, medication-related damaging events represented 9%, equipment-related damaging events represented 6%, and block-related damaging events represented 6% of the total claims for death or permanent brain damage (table 1).

Monitoring

Before 1984, Spo_2 and $ETco_2$ monitoring were rarely if ever used (fig. 2). In 1985, these monitors were used in 6% of claims for death or brain damage. Use of these monitors suddenly increased to 27% in 1986, 60% in 1987, and 70% in 1989. In subsequent years through 2000, they were used between 63% and 83% of the total claims for death or brain damage (fig. 2). During 1986–2000, Spo_2 and $ETco_2$ monitoring were used in 66% of the respiratory and 77% of the cardiovascular damaging events.

A similar increase in use of Spo_2 and $ETco_2$ was seen starting in 1986 in the nondeath or non–brain damage claims (n = 2,808). Among these claims, use of these monitors was 20% of the total in 1986, 49% in 1987, and 56% in 1988 and 1989. Thereafter through 2000, the monitors were used in 53–69% of the total claims in which death or brain damage did not occur.

Standard of Care, 1986–2000

Anesthesia care was judged by the reviewers to be less than appropriate in 64% of the respiratory-related damaging events *versus* 28% in the cardiovascular event group ($P < 0.001$; table 1). Among the respiratory events, care was most often judged to be less than appropriate in claims for esophageal intubation (91%), premature extubation (81%), and inadequate ventilation/oxygenation (74%) (table 1). The aspiration group had

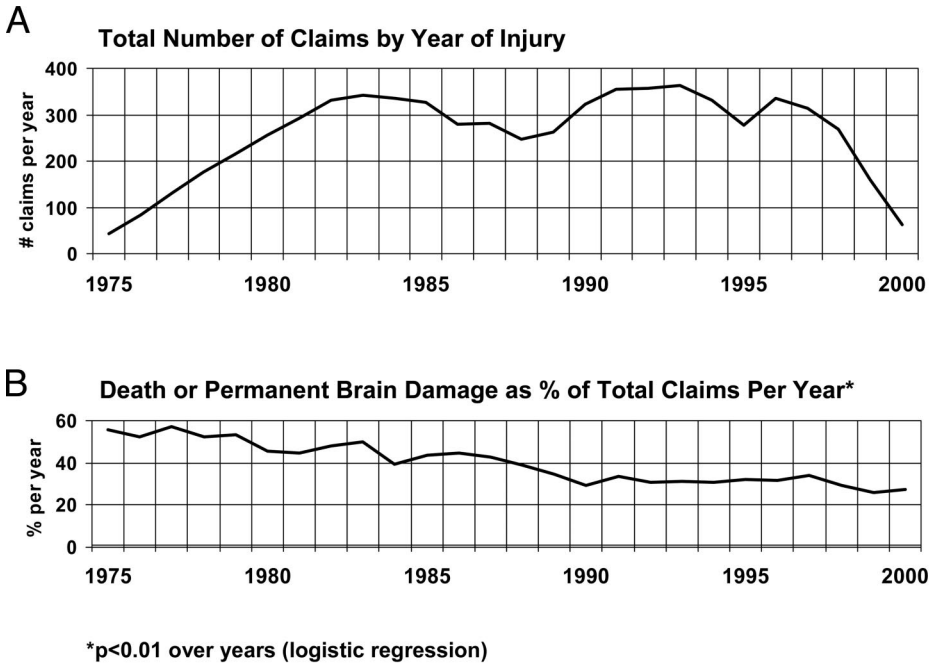

Fig. 1. (*A*) The total number of claims by the year of injury. Retrospective data collection began in 1985. Data in this analysis includes data collected through December 2003. (*B*) Claims for death or permanent brain damage as percentage of total claims per year by year of injury.

the lowest proportion of claims (42%) where the care was judged as less than appropriate.

Among the cardiovascular damaging events, the anesthesia care was judged as less than appropriate in 76% of the inadequate fluid therapy damaging events (table 1). Otherwise, care was judged as less than appropriate in only 18% of the largest category of multifactorial/miscellaneous damaging events (table 1). A judgment of less than appropriate care was made in 18–27% of the other cardiovascular damaging events (table 1). Anesthesia care was judged as less than appropriate in 50–57% of the less frequent categories of medication-related, equipment-related, and block-related damaging events (table 1).

Discussion

The most striking finding of this closed claims analysis was the overall decrease in the proportion of claims for death and brain damage over the 26-yr period of study. The reasons for this decrease are not apparent from our data. Clearly, there was a downward trend in the proportion of these severe injuries before the widespread use of Spo_2 and $ETco_2$ monitors, which began in 1986. Other factors that may have contributed to the overall reduction in the proportion of claims for death or brain damage include improved training of anesthesiologists, use of drugs with fewer adverse effects, and the overall emphasis of the profession on patient safety. Another possibility is that plaintiff's attorneys became more inclined to sue for less serious anesthesia-related injuries during 1975–2000. This latter possibility is unlikely because a national survey of premiums for professional liability insurance (in 2005 dollars) shows a decrease from approximately $30,000 per year in 1985 to $20,000 in 2005.[5] If the total number of claims for death or brain damage had remained constant from 1985 through 2000, it would be expected that this reduction of the inflation-adjusted premium cost would not have occurred.

The sudden increase in the use of Spo_2 and $ETco_2$ monitoring started in 1986 when the monitors were used in 27% of the claims for death or permanent brain

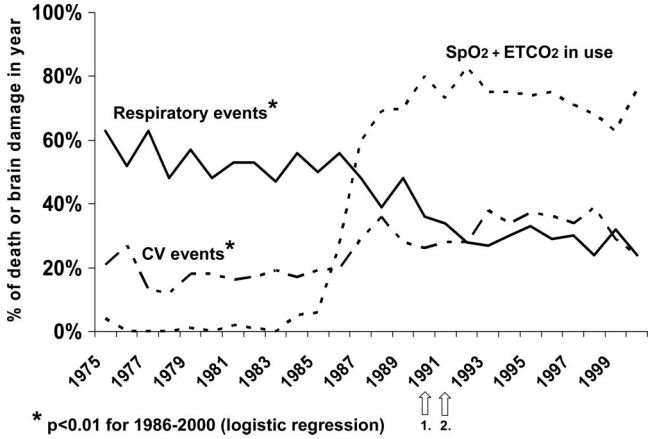

Fig. 2. Respiratory and cardiovascular (CV) damaging events and claims where pulse oximetry (Spo_2) and end-tidal carbon dioxide ($ETco_2$) monitoring were in use as a percent of total claims for death or permanent brain damage by year of injury. Spo_2 became an American Society of Anesthesiologists standard for intraoperative monitoring in 1990 ($\uparrow_1$.) and $ETco_2$ in 1991 ($\uparrow_2$.).

damage (fig. 2). This proportion had reached 70% by 1989, and thereafter use of these monitors varied from 63% to 83% of the total claims for death or brain damage through the year 2000 (fig. 2). There was a similar increase, albeit with a lower proportion, in the remainder of claims during that time period where death or brain damage did not occur. The use of these monitors in the nondeath or non–brain damage claims suddenly increased to 20% in 1986 and plateaued around 56–69% from 1988 through 2000. This lower proportion of claims with monitoring for the nondeath or non–brain damage claims can be explained by the fact that many of these were for injuries such as nerve damage, headache, and other similar injuries where the use of monitoring was not relevant to the claim and hence not recorded in the file.

The increased proportion of claims with Spo_2 and $ETco_2$ monitoring occurred at the same time as a significant decrease in the proportion of respiratory-related and increase in the proportion of cardiovascular-related damaging events during 1986–2000 (fig. 2). Before this time, from 1975 through 1985, the proportion of respiratory and cardiovascular damaging events remained relatively constant, with respiratory damaging events ranging from 47% to 63% and cardiovascular damaging events ranging from 12% to 27% of the total claims for death or brain damage. In 1986, the proportion of respiratory-related damaging events represented 50% and cardiovascular damaging events represented 20% of the claims for death or brain damage (fig. 2). By 1992, each represented 28% of total claims for death or brain damage, and over the ensuing years, through 2000, the proportion of each remained in the range of 27–39%, with cardiovascular events being slightly higher than respiratory (fig. 2).

A possible explanation for the concurrent decreased proportion of respiratory mechanisms for death or brain damage with increased Spo_2 and $ETco_2$ monitoring is that these monitors may have prevented respiratory-related injuries from appearing in the Closed Claims database. Therefore, the cardiovascular events may have increased as a proportion of the total claims for death or brain damage over the same time period. The concurrent increase in proportion of cardiovascular damaging events also suggests that these primarily respiratory monitors did not appreciably affect the cardiovascular mechanism of injury. Another explanation for the relative increase in cardiovascular damaging events is that, before the use of these monitors, injuries related to the onset of arrhythmia, hypotension, or multifactorial cardiac events were attributed to a respiratory mechanism. When these same signs occurred with respiratory monitors in place, indicating the absence of hypoxemia, hypercapnia, or both, then the mechanism of injury was more appropriately attributed to a cardiovascular mechanism.

There are a number of reasons for the absence of Spo_2 and $ETco_2$ monitoring in 17–27% of the claims for death or brain damage after their widespread use became apparent in the late 1980s (fig. 2). These include the fact that the damaging events occurred where Spo_2 and $ETco_2$ are not usually used or available, such as intensive care, the emergency department, the hospital ward, and labor and delivery. In some cases, the monitors had been used during surgery but had been removed for patient transport.

Our data show an increase in the use of Spo_2 and $ETco_2$ monitors in 1986, the same year that Eichhorn *et al.*[6] reported the standards for patient monitoring at Harvard Medical School. In the report of Eichhorn *et al.*, Spo_2 was described as a circulatory monitor, and $ETco_2$ was described as an emerging standard that was "strongly preferred." As shown in figure 2, we found that the use of Spo_2 and $ETco_2$ monitors had already reached a plateau by the time that these monitors became ASA standards of care (1990 for Spo_2 and 1991 for $ETco_2$). These relations suggest that the report from Harvard Medical School may have served as a catalyst for expanding the scope of basic intraoperative monitoring, and the ASA standards may have had a "follow-up" impact that reinforced and sustained this change

The nature of the Closed Claims database is such that we are unable to make any statement about the cause-and-effect relation between the use of Spo_2 and $ETco_2$ monitoring and the reduction in the proportion of respiratory damaging events as the cause of injury. A recent Cochrane Review published in 2003 indicated that pulse oximetry has not been shown to reduce anesthesia-related patient injury.[7] Two of six reports reviewed specifically addressed clinical outcomes. One of these[8] involved study of 20,802 patients where those who had Spo_2 monitoring during surgery and their stay in the postanesthesia care unit were compared with those who did not. There was an equal number of complications (10%) in each group, with seven deaths classified as possibly anesthesia related: three in the Spo_2 group and four in the control group.

It is difficult to make comparisons between prospective population-based studies included in the Cochrane Review and closed claims data, which have a number of limitations, which have been previously described.[1] Because closed claims data are collected from a number of different insurance organizations that insure more than 13,000 anesthesiologists,[1] there is no overall information available as to how many anesthetics or what kind of anesthetic techniques were used by the insured providers. Consequently, denominator data are not available to estimate the relative risks of anesthetic technique or the effects of a monitoring device on patient injury. The data are gathered by insurance organizations for the purpose of resolving malpractice claims, and not patient safety research. The foregoing and other limitations mean that

closed claims data cannot be used to establish conventional or statistical relations between outcomes and preceding events. However, closed claims data are useful in that they provide information on relatively large numbers of rare events and outcomes. When such collections of claims are studied, they may reveal recurrent patterns or associations that would not otherwise be detectible in conventional studies from single or multiple institutions. Although our findings in a closed claims database are in line with those of the Cochrane Review, it may be that a larger sample size is needed for a population-based study to show an effect of pulse oximetry on adverse anesthesia outcomes.

The major difference in reviewer judgments about standard of care between respiratory and cardiovascular damaging events from 1986 through 2000 may reflect the contribution of substandard care to adverse outcomes. Overall standard of care was judged as less than appropriate in 64% of the respiratory-related damaging events compared with 28% of the cardiovascular-related damaging events ($P < 0.001$; table 1). In particular in the respiratory group, inadequate ventilation/oxygenation (74% of the total respiratory events), esophageal intubation (91%), and premature extubation (81%) were most often associated with less than appropriate care. In the cardiovascular group, only inadequate fluid therapy (75%) stood out as being due to less than appropriate care as compared with 28% less than appropriate care for the cardiovascular group as a whole (table 1). Reviewers seemed to judge the care as less than appropriate for damaging events that were presumably under the direct control of the anesthesiologist, such as the respiratory system and fluid management. Less than appropriate care was associated with only 18% of the largest category of cardiovascular damaging events, multifactorial/miscellaneous, where it was difficult to assess the primary cause of the arrhythmia, hypotension, or cardiac arrest that occurred (table 1).

Although reviewer judgments about standard of care may be biased, we have shown that there is fair to good agreement between anesthesiologists judging standard of care from closed claims.[9] Therefore, it might be inferred that there is room for further reduction in the occurrence of severe anesthesia-related adverse outcomes with improvements in the level of care provided for damaging events that are under the direct control of the anesthesiologist.

Conclusion

There has been a significant decrease in the proportion of claims for death or permanent brain damage from 1975 through 2000. Use of Spo_2 and $ETco_2$ monitoring began to appear in 1986, surged to 70% of the total claims for death or brain damage by 1989, and then remained at approximately that level through 2000. The increase in use of these monitors was associated with a decrease in the proportion of claims for respiratory-related damaging events and an increase in the proportion of claims for cardiovascular-related damaging events. We could not find an association between the increase in monitoring and decrease in death or permanent damage.

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