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Role of Monitoring Devices in Prevention of Anesthetic Mishaps: A Closed Claims Analysis

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Anesthesiologist-reviewers examined 1,175 anesthetic-related closed malpractice claims from 17 professional liability insurance companies. The claims were filed between 1974 and 1988. The reviewers were asked to determine if the negative outcome was preventable by proper use of additional monitoring devices available at the time of the review even if not available at the time the incident occurred, and if so, which devices could have been preventative. In 1,097 cases sufficient information was available to make a judgment regarding preventability of the morbidity or mortality by application of additional monitoring devices. It was determined that 31.5% of the negative outcomes could have been prevented by application of additional monitors. Using the insurance industry's scale of 0 (no injury) to 9 (death), the median severity of injury for incidents deemed preventable was 9 compared with 5 for those deemed not preventable ($P < 0.01$, scale detailed in text). The severity of injury scores were the same for preventable mishaps occurring during regional or general anesthesia, suggesting that additional monitoring devices may be equally efficacious in preventing serious negative outcomes during either regional or general anesthesia. The judgments or settlements of the incidents judged preventable by additional monitoring were 11 times more costly ($P < 0.01$) than those mishaps not judged preventable. The monitors determined by the reviewers to be most useful in mishap prevention were pulse oximetry plus capnometry. Applied together, these two technologies were considered potentially preventative in 93% of the preventable mishaps. These results demonstrate that a large number of anesthetic mishaps resulting in negative outcomes sufficiently serious to engender malpractice actions may be preventable by the proper use of pulse oximetry and capnometry. (Key words: Anesthesia: complications. Monitoring: Capnometry; pulse oximetry.)

RAPID DEVELOPMENT and widespread use of sophisticated monitoring technology is one of the changes that has characterized the past decade of anesthetic practice. Improved patient safety is, of course, the goal. Often the introduction of new technology has been accompanied by the contention that monitoring some particular physiologic variable, heretofore difficult or impossible to monitor, makes it imperative not to await validation studies, but rather to use the new technology as soon as possible. Indeed, predictions by "experts" that a particular piece of new technology will "soon become standard of care" have often pushed new technology ahead of, or perhaps instead of, validation. Dr. Arthur Keats, in his 1983 Rovenstine Lecture to the American Society of Anesthesiologists,[1] objected to this commonly used justification for new technology or new methods, *i.e.*, the concept that if something seems logical, we should go ahead and use it while we await validation studies. To date, there have been no definitive studies that have validated or refuted the putative link between additional monitoring and critical incident reduction or decreased morbidity or mortality. Additionally, studies evaluating the efficacy of individual monitors in preventing anesthetic complications or even evaluating which complications may be preventable are currently lacking. Despite the paucity of data on the role of monitoring in prevention of anesthetic complications few have questioned their utility[2] and have recently suggested the addition of several monitors to currently accepted standards for routine monitoring during anesthesia.[3–8,**,††]

An opportunity to explore the role of monitoring technology in the prevention of anesthetic complications has recently been afforded by the American Society of Anesthesiologists Professional Liability Committee's Closed Claims Study. As part of an ongoing review of major anesthetic mishaps, practicing anesthesiologists were asked to review closed malpractice claims to determine which, if any, monitoring techniques available as of the time of the review might have prevented the morbidity and/or mortality that occurred, even if that technology was not available at the time of the incident. Using this data base we addressed the issue of whether additional monitoring technology, if employed, interpreted and acted upon properly, would have prevented the negative outcome that actually occurred in each case.

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TABLE 1. Severity of Injury Score (SIS)

	SIS	Example
0	No obvious injury	—
1	Emotional only	Awareness during anesthesia
Temporary		
2	Insignificant	Contusion, no recovery delay
3	Minor	Fall in hospital, delayed recovery
4	Major	Nerve damage, unable to work
Permanent		
5	Minor	Organ damage, nondisabling
6	Significant	Loss of an eye, kidney, lung, or deafness
7	Major	Paraplegia, blindness, brain damage
8	Grave	Severe brain damage, lifelong care, fatal prognosis
9	Death	—

Materials and Methods

The American Society of Anesthesiologists Closed Claims Study is an ongoing review of closed malpractice claims against anesthesiologists. The cases were obtained from 17 professional liability insurance companies who consented to participate in the review. The involved insurance companies include both private and physician-owned corporations. The percentages of anesthesiologists insured by these companies is unknown. However, one of the companies represents anesthesiologists in over 40 states. The cases were settled or adjudicated between 1974 and 1988, although the patient care activities involved occurred between 1962 and 1987.

The review process required that one or more anesthesiologist-reviewers visit each insurance company to review anesthesia-related closed malpractice claims. Each case was summarized by a single reviewer on a standardized data collection instrument according to a written set of instructions. Cases were excluded if inadequate information existed to reconstruct the most probable sequence of events, the reviewer was unable to make a determination of probable cause of the injuries; or the injury was limited to dental damage.

Each closed claim file typically contains copies of the hospital records, anesthesia records, narrative statements from involved health care personnel, summaries of depositions, testimony at deposition and/or trial from material and expert witnesses, patient outcome reports, and dollar amounts of settlements or jury awards. The reviewer produced a written summary of each case and completed a detailed questionnaire about monitoring devices employed, critical incidents, premonitory clinical signs present, complications, and outcome. The data collection instrument then required the reviewer to render a judgment as to whether additional monitoring, available as of the time of the review, could have prevented the mishap even if the technology was not clinically available at the time the mishap actually occurred. The reviewer also judged which specific monitoring technologies would have been efficacious in preventing the complication. The judgments regarding preventability and the efficacy of specific monitors in preventing the mishap were made based on the reviewer's understanding of the sequence of events that preceded the injury as well as the reviewer's understanding of the probable cause of injury. Pertinent clinical signs, if noted in the records and/or testimony, were recorded as a routine part of the review and were later correlated with overall preventability of the mishap. All judgments were reviewed by the Closed Claims Committee.

Each case was also assigned a severity of injury score (SIS) by the reviewer based on the insurance industry's 10-point scale:[9,10] 0 = no physical injury, 1–4 = temporary injury, 5 = permanent but non-disabling injury, 6–8 = permanent disabling injuries, 9 = death (table 1).

The individuals involved in the on-site reviews were 15 anesthesiologists, 14 of whom were Diplomates of the American Board of Anesthesiology. Data were collected by the physicians themselves, not summarized for them by assistants. The reviewers came from both private and academic practice and had been in practice between 6 and 37 years. All reviewers had prior experience with claims review.

Statistical significance was tested using the median test for all data and the Kolmogorov-Smirnov two-sample test for all data except the regional anesthesia subset, which was too small to be tested using the Kolmogorov-Smirnov two-sample test. The median was used as the measure of central tendency for data that were ordinal in nature or that showed nonnormal distribution. The value of $P \leq 0.05$ was chosen as the level of statistical significance for all data.

Results

A total of 1,175 claims from 17 insurance companies were reviewed by the 15 anesthesiologist-reviewers. The mean age of the patients was 39 yr with a range from newborn to 87 yr. Forty-one percent were males, 57% were females, and in 2% no gender was specified by the reviewer. The median ASA physical status was 2, with 75% of the patients classified as ASA physical status 1 or 2. In 1,097 cases (93% of the data base), sufficient information was available for the reviewer to determine the cause of injury or death, to determine the sequence of events that led to it, and to make a judgment, based on the above determinations, as to whether additional monitoring technology would have prevented the negative outcome. The reviewers judged that in 346 of the 1,097 cases (31.5%), the injuries or deaths could have been prevented by use of one or more additional monitoring de-

vices available as of the review, assuming proper application, interpretation, and intervention. In the remaining 751 cases (68.5%), the reviewers judged that the injuries or deaths were not preventable by application of additional monitors. There was considerable differences between the subsets in the percentage of cases considered preventable. For the general anesthesia subset 37.1% of the 773 injuries or deaths were deemed preventable by application of additional monitors. In contrast, in the regional anesthesia subset only 17.7% of the 288 injuries or deaths were judged preventable.

There was also a considerable difference between the SIS for cases that were judged preventable compared with those that were judged not preventable by application of additional monitors. For cases in which additional monitoring would likely have been efficacious, the median SIS was 9 for the overall data, as well as for both the regional and general anesthesia subsets. Where additional monitoring was judged not to be preventative, the median SIS was 5 for the overall data base and for the general anesthesia subset. This score was even lower, namely, 4, for the regional anesthesia subset in which monitoring would not have been preventative. The differences were significant for all three groups of data ($P < 0.01$).

The median total cost of settlement or judgment was 11 times greater for those injuries judged preventable by additional monitoring compared with those judged not preventable. The median payment for cases deemed preventable by additional monitoring was $250,000, whereas the median payment for cases deemed not preventable was $22,500 ($P \leq 0.01$).

The reviewers identified 1,087 pertinent clinical signs present in the 1,097 case records in which the efficacy of monitoring could be assessed. Multiple signs were noted in some cases. Seven hundred fifty-one signs (69.4% of the total) were noted in the records or testimony of the 346 cases judged preventable by additional monitoring. In contrast, only 332 such signs (30.6% of the total) were noted in the 751 cases judged nonpreventable. There was at least one clinical sign noted in 305 of 346 cases judged preventable. By comparison, in only 190 of 751 cases judged not preventable were clinical signs noted. The most common signs were bradycardia, asystole, hypotension, and cyanosis (table 2). The most frequent complications were death, nerve damage, and brain damage. Nearly 60% of the instances of death and brain damage were considered preventable by application of additional monitors. In contrast, less than 1% of instances of nerve damage were considered preventable by application of additional monitors (table 3).

The monitors judged most useful in preventing anesthetic mishaps were pulse oximetry and capnometry (table 4). The reviewers judged that pulse oximetry, if applied without capnometry, would have been efficacious in preventing injury in 138 cases (40% of the 346 cases judged preventable). The reviewers also determined that capnometry applied without pulse oximetry would have been useful in prevention of anesthetic mishaps in only eight cases (2% of the preventable cases). In contrast, if applied together, these two monitors would have potentially prevented an additional 176 negative outcomes (51% of the preventable cases). Thus, the reviewers determined that for the entire data base, application of either or both pulse oximetry and capnometry would have prevented a total of 322 injuries or deaths, or 93% of the total number of complications deemed preventable. In only 24 cases (7% of the preventable injuries or deaths) were monitors other than pulse oximetry and capnometry considered potentially preventative.

The efficacy of pulse oximetry and capnometry varied between the regional and general anesthesia patients.

TABLE 3. Most Frequent Complications

Complication	Negative Outcome Considered Preventable by Additional Monitors (no. of cases)	Negative Outcome Considered Not Preventable by Additional Monitors (no. of cases)
Death	241 (57.1%)	158 (37.4%)
Nerve damage	1 (0.6%)	164 (92.1%)
Brain damage	83 (58.4%)	51 (35.9%)

Percentages do not necessarily add to 100 because of cases in which there was insufficient information to judge preventability.

TABLE 2. Most Common Clinical Signs Noted in the Record

Clinical Sign	Negative Outcome Considered Preventable (no. of cases)	Negative Outcome Considered Not Preventable (no. of cases)
Cyanosis	142 (81.6%)	29 (16.7%)
Bradycardia	182 (77.4%)	50 (21.3%)
Hypotension	157 (66.2%)	75 (31.6%)
Asystole	170 (65.1%)	81 (31.0%)

Percentages do not necessarily add to 100 because of cases in which there was insufficient information to judge preventability.

TABLE 4. Monitors Deemed Useful in Cases of Preventable Injuries or Deaths

Monitors	Overall (n = 346)*	Regional (n = 51)	General (n = 290)
Pulse oximetry	138 (40%)	41 (80%)	93 (32%)
Capnometry	8 (2%)	1 (1%)	7 (2%)
Pulse oximetry plus capnometry	176 (51%)	8 (16%)	168 (58%)
Other	18 (5%)	0 (0%)	17 (6%)
Not specified	6 (2%)	1 (1%)	5 (2%)

* In five cases the type of anesthesia employed was not specified.

Pulse oximetry alone was considered preventive in 80% of the preventable regional anesthesia cases but was preventative in only 32% of the preventable general anesthesia cases. Capnometry with or without pulse oximetry was deemed useful in 17% of the preventable regional anesthesia cases compared with 60% of the preventable general anesthesia cases.

Discussion

This report is a retrospective review of anesthetic management associated with closed malpractice claims from 17 insurance companies. To date it is the only study in which entire confidential closed claim files of a large number of carriers were reviewed by physician anesthesiologists.

Inherent in this study are several limitations. First, it was assumed that monitors would be applied correctly and would function continuously. It was assumed that the output from the monitoring devices would be assimilated, interpreted, and acted upon correctly. We are *not* stating that the technology would inherently prevent anything. It was also assumed that the monitors themselves would not have caused additional complications, either directly or by unduly diverting the anesthesiologists' attention from the patient. As a result of the above assumptions, the derived efficacy may be an unachievable maximum efficacy.

Second, the reviewers represented a broad base of clinical experience from diverse geographic locations and practice situations. Despite the diversity of experience, or perhaps because of it, the committee was concerned that the reviewers' assessments and judgments might be subject to variability sufficient to render the study unreliable. Therefore, a reliability study was performed and recently reported by Caplan *et al.*[11] The interrater reliability study involved distribution of a stratified sample of the entire closed claims study data base to a group of 42 independent anesthesiologist-reviewers who were not part of the closed claim study. These reviewers were asked to make the same judgments as the closed claims reviewers. The interrater reliability study demonstrated that independent reviewers and the Closed Claims Committee exhibited significant interrater reliability in the analysis of closed claims data ($P < 0.001$). Their findings indicate that practicing anesthesiologists can produce a cohesive set of judgments when asked to review anesthetic mishaps for basic aspects of clinical care.

Third, this is a retrospective study with all the inherent limitations (and advantages) of such. These patient care activities all occurred prior to 1988 (89% of the cases occurred prior to 1984), and might not reflect the current situation. Clearly, use of sophisticated monitoring, especially pulse oximetry and capnometry, is increasingly prevalent, perhaps because it seems "logical." This study, we believe, adds some validity to that logic. If pulse oximetry and capnometry continue to be widely utilized, then these results may be superseded by future decreases in preventable, catastrophic injuries. Cohen *et al.*[12] are less than optimistic in this regard because they did not demonstrate such a trend for the period 1975–1978 compared with 1979–1983, despite increased intraoperative monitoring. Nonetheless, neither capnometry nor pulse oximetry was in widespread use during their study period. Their findings may reflect a more seriously ill patient population in the latter period, or there may have been "improved" monitoring, but not of variables that would reliably prevent negative outcomes.

Fourth, this data base includes only cases wherein plaintiff's attorneys decided that the negative outcome was serious enough and there was sufficient grounds for a claim of negligence to justify filing a lawsuit. There is little doubt that during the same period a large number of anesthetic-related mishaps did not result in completed litigation. Thus, perhaps our data base contains a "reverse bias" in that it may contain a disproportionately large number of serious negative outcomes. We were unable to determine incidence or frequency of anesthetic-related mishaps because we cannot estimate the denominator of the fraction. Finally, it is impossible to determine what percentage of practicing anesthesiologists were represented by the insurance companies involved, to know how many of the involved anesthesiologists were board-certified, or to know how many anesthesiologists had more than one action against them.

Because of the nonnormal distribution of the cost data, the median was used as the measure of central tendency. If the mean had been used, instead of the median, the difference between the cost of preventable and nonpreventable injuries would have been narrowed. However, using mean costs of the preventable ($494,000 ± $737,000) *versus* nonpreventable ($170,000 ± $520,000) cases, the results were still significantly different ($P < 0.01$ unpaired t test). The total costs of preventable death or injury and death or injury not preventable by application of additional monitors were not reported because the nonnormal distribution would potentially bias the results as it does in the presentation of mean costs.

The results of this study are important because they demonstrate that about one third of the malpractice cases actually carried to judgment or settlement, and a majority of the deaths (57%) might have been prevented if additional monitoring, available currently, had been applied. These results are thus in agreement with previous anesthetic mortality studies, which have suggested that greater than 50% of deaths judged due to anesthesia were preventable.[13–15]

This study is unique in that although numerous studies have suggested that additional monitoring would improve patient safety,[3-5,††,15-19] except for the investigation by Cooper *et al.*[17] and Eichhorn,[18] no prior series has been specifically designed to make that judgment and no series has involved cases that all resulted in litigation.

This study is also the first to individually evaluate severity and costliness of anesthetic complications and to quantitatively report that there was a relationship between resultant severity of outcome and preventability by application of additional monitors. These data demonstrate that injuries preventable by additional monitoring devices were much more serious in terms of resultant negative outcome (SIS 9.0 *vs.* 5.0) and also payment for settlement or judgment ($250,000 *vs.* $22,500).

Although regional anesthesia is viewed by some as less likely to be associated with major complications, this study has demonstrated that when preventable negative outcomes occurred during regional anesthesia, the severity and costliness was not better than (or different from) those associated with general. Our study also provides support for the efficacy of modern monitoring during regional anesthesia. The median SIS for regional anesthetic-associated complications judged preventable by additional monitoring was the same as that for preventable general anesthesia-associated complications. Thus, the utility of additional monitors in preventing costly injuries was consistent and similar for patients undergoing both regional and general anesthesia. The utility of the individual monitors, however, did vary between the regional and general anesthesia groups with pulse oximetry judged to be of greater usefulness and capnometry judged of less utility for regional *versus* general anesthesia. The incidence of preventable complications as a percent of the subgroup total complications was lower for regional (17.9%) *versus* general (37.5%) anesthesia. These data do not provide evidence that regional anesthesia is inherently safer or less safe than general anesthesia. It does demonstrate that additional monitoring should be of value in prevention of serious injury whether regional or general anesthesia is chosen.

The reviewers found that considerably more clinical signs were recorded in cases that they deemed preventable. The presence of these signs in the records may indicate that reasonable vigilance was often present in these cases. We wonder whether these results suggest that vigilance alone was not sufficient to prevent at least some of the complications. We cannot prove that the recorded clinical signs noted retrospectively by the reviewers were missed intraoperatively, implying a lack of vigilance, or that improper interpretation or action occurred, implying something other than lack of vigilance. We wonder if additional monitors, especially pulse oximetry and capnometry, would have forced earlier and/or more appropriate intervention. This speculation is in agreement with the contentions of Keenan and Boyan[15] and of Cote[5] that vigilance can be supplemented by addition of monitoring devices.

The reviewers judged, in a majority of cases preventable by application of additional monitors, the combination of pulse oximetry and capnometry to be more efficacious than either monitor alone. We suspect that this is because this monitoring combination may allow the anesthesiologist to most quickly identify that a problem existed and narrowed the differential diagnosis. Examples of conditions where this combination would be especially useful would be hypoxia due to pulmonary embolus, venous air embolus, or partial airway obstruction.

The fact that monitors other than pulse oximetry and capnometry were judged useful only infrequently should not be misinterpreted. It may be that these other monitors were already in place and thus could not have been "added" by the reviewer. Certainly, pulmonary artery catheters, EEG monitors, and automated blood pressures devices were clinically available during the period of this study. Nonetheless, addition of such monitors when one was not in use was judged important in only 24 cases.

In summary, the anesthesiologist-reviewers judged that application of pulse oximetry and capnometry can prevent nearly one third of anesthetic-related negative outcomes considered serious enough to result in claims of malpractice and that these two monitors would have been efficacious in prevention of complications during regional and general anesthesia. These data are supportive, therefore, of the concept that patients undergoing either general or regional anesthesia would benefit from continuous monitoring with pulse oximetry and/or capnometry.

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