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Adverse Respiratory Events in Anesthesia: A Closed Claims Analysis

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Adverse outcomes associated with respiratory events constitute the single largest class of injury in the American Society of Anesthesiology Closed Claims Study (522 of 1541 cases; 34%). Death or brain damage occurred in 85% of cases. The median cost of settlement or jury award was $200,000. Most outcomes (72%) were considered preventable with better monitoring. Three mechanisms of injury accounted for three-fourths of the adverse respiratory events: inadequate ventilation (196; 38%), esophageal intubation (94; 18%), and difficult tracheal intubation (87; 17%). Inadequate ventilation was used to describe claims in which it was evident that insufficient gas exchange had produced the adverse outcome, but it was not possible to identify the exact cause. This group was characterized by the highest proportion of cases in which care was considered substandard (90%). The esophageal intubation group was notable for a recurring diagnostic failure: in 48% of cases where auscultation of breath sounds was performed and documented, this test led to the erroneous conclusion that the endotracheal tube was correctly located in the trachea. Claims for difficult tracheal intubation were distinguished by a comparatively small proportion of cases (36%) in which the outcome was considered preventable with better monitoring. A better understanding of respiratory risks may require investigative protocols that initiate data collection immediately upon the recognition of a critical incident or adverse outcome. (Key words: Anesthesiology, complications: airway; esophageal intubation; prevention. Monitoring: pulse oximetry; capnometry.)

FOR THE PAST 5 yr, the Committee on Professional Liability of the American Society of Anesthesiologists (ASA) has been engaged in a study of adverse anesthetic outcomes based upon information contained in the closed claims files of a nationwide group of insurance carriers. Since the inception of this project, adverse outcomes involving the respiratory system have comprised the single largest class of injury. The purpose of this paper is to provide an in-depth analysis of adverse respiratory outcomes and to describe potential directions for preventative measures. The availability of a large, standardized collection of cases with similar outcomes offers an important opportunity to identify patterns of liability and causation that otherwise might not emerge from the study of isolated case reports or data obtained under disparate investigative conditions.

Methods

The ASA Closed Claims Study is a structured evaluation of adverse anesthetic outcomes obtained from the closed claims files of 20 U. S. insurance carriers. Claims for dental damage are not included in this project. The database for this study consists of 1541 closed claims collected since 1985, of which 92% occurred between 1975 and 1985.

A detailed description of data collection procedures has been reported recently.[1] In brief, a closed claim for an adverse anesthetic outcome typically consists of relevant hospital and medical records, narrative statements from involved health care personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury award. Each claim is reviewed by a practicing anesthesiologist who has been specifically trained for participation in the Closed Claims Study. The background and qualifications of the reviewers have been described in two related reports.[2,3] A standardized form is used to record detailed information on patient characteristics, surgical procedures, anesthetic agents and techniques, involved personnel, sequence of events, standard of care, critical incidents, clinical manifestations, types of error, responsibility, and outcome. Standard of care is rated as appropriate (standard), less than appropriate (substandard), or impossible to judge, based upon reasonable and prudent practices at the time of the event. Practice patterns that may have evolved at a later date are not retrospectively applied when standard of care is rated. An adverse outcome is deemed preventable with better monitoring if the reviewer finds that the use or better use of any monitor would probably have prevented the outcome, whether or not such monitor was available at the time of the event. An acceptable level of interrater reliability has been established for reviewer judgments on standard of care and preventability of adverse outcomes with better monitoring.[2,4] Adverse outcomes associated with respiratory events are classified by mechanism of injury (*e.g.*, esophageal intubation, difficult tracheal intubation, airway obstruction, unintentional extubation, etc.). The descriptive term inadequate ventilation is assigned to claims in which it is evident that inadequate gas exchange from some cause has produced the adverse out-

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TABLE 1. Distribution of Claims for Adverse Respiratory Events

Event	Number of Cases	Percent of 522 Respiratory Claims	Percent of 1541 Total Claims
Inadequate ventilation	196	38	13
Esophageal intubation	94	18	6
Difficult tracheal intubation	87	17	6
Airway obstruction	34	7	2
Bronchospasm	32	6	2
Aspiration	26	5	2
Premature tracheal extubation	21	4	1
Unintentional tracheal extubation	14	3	1
Inadequate F_{IO_2}	11	2	1
Endobronchial intubation	7	1	<1
Total	522	100%	34%

come, but it is not possible for the reviewer to assign a specific mechanism. Indicators of inadequate ventilation include clinically inappropriate hypercarbia and/or hypoxemia, clinically inappropriate tidal volume and respiratory rate, and related narrative information such as anesthetic care administered by unqualified personnel or unsupervised trainees, patients left unattended while heavily sedated or paralyzed, and the inability to obtain or maintain an adequate mask fit. In most cases of inadequate ventilation, there is sufficient evidence for the reviewer to consider the likelihood of one or more mechanisms (*e.g.*, laryngospasm, airway obstruction from obesity, bronchospasm), but not enough detail to identify a primary mechanism.

Comparison of proportions was made by calculation of confidence limits according to the method suggested by Fleiss.[5] Comparison of payment data was made using the Kolmogorov-Smirnow test. Two-tailed tests and a significance level of 0.05 were used throughout.

Results

A total of 522 claims for adverse respiratory events were identified, representing 34% of the overall database of 1,541 claims. These respiratory events constituted the single largest source of adverse outcomes in the Closed Claims Study. As shown in table 1, three mechanisms of injury accounted for approximately three-fourths of the adverse respiratory events: inadequate ventilation (196; 38%), esophageal intubation (94; 18%), and difficult tracheal intubation (87; 17%). The remaining adverse respiratory events were produced by a variety of low-frequency mechanisms including airway obstruction, bronchospasm, aspiration, premature and unintentional extubation, inadequate inspired oxygen delivery, and endobronchial intubation. Each low-frequency mechanism represented ≤2% of the overall database. Respiratory equipment failures (primarily breathing circuit disconnection or misconnection) represented 1% of the overall database. Claims for adverse respiratory events generally involved healthy adults undergoing nonemergency surgery with general anesthesia (table 2).

Care was judged substandard in 76% of the claims for adverse respiratory events (fig. 1). This is significantly different from nonrespiratory claims (the remainder of the database), in which care was judged substandard in 30% of cases ($P < 0.05$). Anesthetic care was rarely considered appropriate in cases of inadequate ventilation or esophageal intubation. In contrast, care was considered appropriate in one-third of claims involving difficult tracheal intubation.

The reviewers judged that better monitoring would have prevented the adverse outcome in 376 (72%) of the 522 claims for adverse respiratory events (fig. 2). This

TABLE 2. Basic Clinical Features

	All Respiratory Events n = 522	Inadequate Ventilation n = 196	Esophageal Intubation n = 94	Difficult Tracheal Intubation n = 87	All Nonrespiratory Events n = 1019
Age (yr) (mean ± SD)	37 ± 21	35 ± 22	39 ± 17	42 ± 20	41 ± 20
ASA Physical class (median)	2	2	2	2	2
			(Percent of cases)		
Emergency	25	26	21	24	17
Male/female	40/58	45/54	35/63	40/58	40/59
Primary anesthetic					
General	85	81	90	90	63
Regional	11	18	6	1	32
Other*	4	1	3	9	5

Percentages do not always sum to 100 because of missing data and/or rounding.

* Includes combined regional and general techniques, anesthesia standby, monitored anesthesia care, and nonoperative events that involved care by an anesthesiologist.

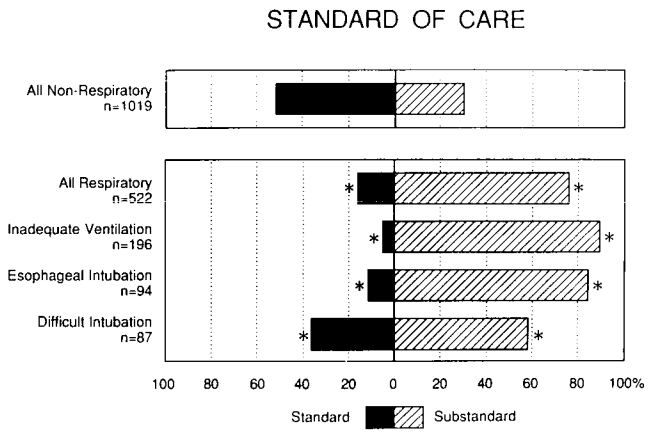

FIG. 1. Percent of cases that the reviewers rated as standard or substandard care in each of the major groups of adverse events. The incidence of "impossible to judge" was 4–8% in the respiratory groups and 18% in the nonrespiratory group. *$P < 0.05$ compared with nonrespiratory claims.

differs from nonrespiratory claims in which only 11% of cases were judged preventable with better monitoring ($P < 0.05$). Almost all (>90%) claims for inadequate ventilation and esophageal intubation were considered preventable with better monitoring as opposed to 36% of claims for difficult tracheal intubation. For the 376 claims considered preventable with better monitoring, the reviewers chose pulse oximetry, capnometry, or both of these devices in 98% of cases. The combination of pulse oximetry and capnometry was the most common choice for esophageal intubation (84%) and inadequate ventilation (50%), but pulse oximetry alone was chosen most often for prevention of adverse outcomes associated with difficult tracheal intubation (74%).

Outcome and payment data are shown in table 3. Death or permanent brain damage occurred in 85% of respiratory-related claims. In the group of nonrespiratory claims, these two outcomes accounted for only 30% of cases ($P < 0.05$). Death and permanent brain damage were more frequent in claims for inadequate ventilation and esophageal intubation (>90%) than in claims for difficult tracheal intubation (56%; $P < 0.05$). Overall, payment for respiratory-related claims ranged from $1,000 to $6,000,000, and 72% of claims resulted in payment. Median payment was highest for inadequate ventilation ($240,000) and lowest for difficult tracheal intubation ($76,000).

Claims for esophageal intubation were usually accompanied by detailed descriptions of the events and actions that accompanied the adverse event. Twenty-two of the 94 claims (23%) contained documentation that intubation had been difficult to perform; the remaining 72 claims (77%) contained no indication that intubation was difficult. In 69 of the 94 claims (73%), there was sufficient information to reconstruct the number of minutes until esophageal intubation was detected. Within this subset, 3% of esophageal intubations were detected before 5 min, 61% were detected in 5–10 min, and 36% were detected after 10 min.

Auscultation of breath sounds was documented in 62 of the 94 claims for esophageal intubation (63%). In three of these cases (5%), breath sound auscultation led to a correct diagnosis of esophageal intubation. In 30 cases (48%), auscultation led to the erroneous conclusion that the endotracheal tube was located in the trachea when it was actually in the esophagus. This result was termed a misdiagnosis of tracheal intubation. The diagnostic error in such cases was recognized in a variety of ways including later re-examination with direct laryngoscopy, absence of any object in the trachea at the time of an emergency tracheostomy (despite ongoing "ventilation" through an endotracheal tube), resolution of cyanosis following reintubation (often by a second participant), and discovery of esophageal intubation at autopsy. In 29 of the 62 claims (47%) in which auscultation was documented, the records did not contain sufficient information to determine how the auscultatory findings were interpreted.

One or more major hemodynamic derangements were recorded in 79 of the 94 claims (84%) for esophageal intubation. In order of frequency, these derangements included bradycardia (57%), asystole (55%), hypotension (49%), unspecified arrhythmia (10%), tachycardia (5%), and ventricular fibrillation (1%). Hemodynamic derangements preceded the recognition of esophageal intubation in 60 claims (65%). Cyanosis was documented in 49 of the 94 claims (52%), and preceded the recognition of esophageal intubation in 32 claims (34%).

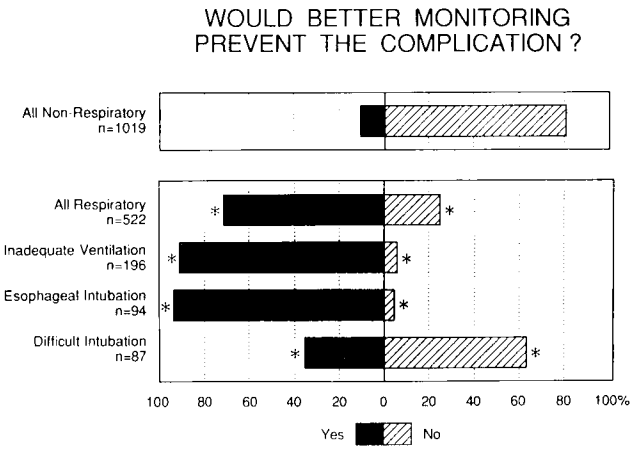

FIG. 2. Percent of adverse outcomes that the reviewers considered preventable or not preventable with better monitoring in each of the major groups of adverse events. The incidence of "impossible to judge" was 1–3% in the respiratory groups and 9% in the nonrespiratory group. *$P < 0.05$ compared with nonrespiratory claims.

TABLE 3. Outcome, Payment, and Payment Frequency

	All Respiratory Events n = 522	Inadequate Ventilation n = 196	Esophageal Intubation n = 94	Difficult Tracheal Intubation n = 87	All Nonrespiratory Events n = 1019
Outcome (percent of cases)					
Death	66*	71*	81*	46*	22
Permanent brain damage	19*	23*	17*	10	8
Other permanent injury	5*	1*	1*	18	25
Temporary injury	9*	4*	1*	24*	39
No injury	1*	1*	0*	1*	6
Payment (in $1,000)					
Range	1–6,000	1.5–6,000	30–3,400	1–4,700	<1–5,400
Median	200*	240*	217*	76*	35
Payment frequency (percent of claims paid)	72*	73*	82*	67*	51

Percentages do not always sum to 100 because of rounding error.

* $P < 0.05$ compared with nonrespiratory events.

Discussion

During the past three decades, outcome studies have repeatedly identified adverse respiratory events as a leading cause of injury in anesthetic practice.[6–12] The predominance of respiratory-related claims in the ASA Closed Claims Study provides additional evidence for the magnitude and persistence of this problem.

The basic limitations of closed claims research have been described in several recent reports.[1,3,13] These limitations include the inability to generate general estimates of risk (due to lack of denominator data), the absence of a rigorous control group, a probable bias toward adverse outcomes, and partial reliance on data from direct participants rather than objective observers. The use of a large group of case reviewers also raises concerns about interrater reliability, but tests designed specifically for the Closed Claims Study have shown that reviewers exhibit statistically significant agreement on basic aspects of clinical care.[2,4] Data on the role of better monitoring in the prevention of adverse outcomes must be interpretated with particular care, as the reviewers were not asked to consider confounding factors such as equipment malfunction, diversion of attention, misinterpretation and misuse of data, or the impact of false-positive and false-negative results. Thus, the reviewers' judgments should be regarded as a near-maximum (and probably unattainable) estimate of the efficacy of better monitoring. A critical analysis of this issue has been prepared by Orkin.[14]

This study provides a quantitative appreciation for the severity and cost of claims for adverse respiratory events. The majority of respiratory-related claims (85%) involved two devastating outcomes: death and permanent brain damage. In addition, most respiratory-related claims (72%) resulted in payment, with a median cost of $200,000. The relative liability posed by adverse respiratory events can be appreciated by a comparison with nonrespiratory claims, the remaining two-thirds of the database. Only 30% of the nonrespiratory claims involved death or brain damage ($P < 0.05$). Payment occurred in a smaller proportion of nonrespiratory claims (51%; $P < 0.05$), and the median payment was considerably lower ($35,000; $P < 0.001$). Although minimization of all forms of injury is a general objective in the practice of anesthesia, these contrasts emphasize the importance of educational strategies and research efforts that focus on respiratory risks.

The largest class of adverse respiratory events was inadequate ventilation. The distinguishing feature in this group of claims was the reviewer's inability to identify a specific mechanism of injury. In part, the inability to assign a mechanism of injury may reflect uncertainty on the part of the original health care providers. Because most adverse events occurred before the widespread use of pulse oximetry and capnometry, the uncertainty may be due to the limitations of traditional clinical signs such as chest excursion, reservoir bag motion, and breath sounds. With increasing use of quantitative measures of ventilation, fewer cases may be assigned to the category of inadequate ventilation. It is also possible that a delayed rather than contemporaneous approach to the investigation of adverse outcomes is not powerful enough to provide an understanding of many events. Research in behavioral psychology has demonstrated that the objectivity of an eyewitness is readily degraded by the passage of time, interaction with other observers, and premature efforts to reach conclusions.[15] The aviation industry uses specific investigative protocols to maximize information retrieval immediately after accidents, and a similar approach is now being explored by the affiliated anesthesia departments at Harvard Medical School.§

Prompt detection of esophageal intubation is a primary concern in anesthetic practice. A disturbing feature in

§ Eichhorn JH: Personal communication.

this series of claims is that the detection of esophageal intubation required 5 min or more in the majority of cases (97%). Incompetence and negligence (*e.g.*, intubation performed by a legally blind practitioner, minimal attention to the patient during the first half hour of the case) provide straightforward explanations for delayed detection. However, we could find only eight claims (9%) in which this type of obviously inadequate behavior played a primary role. We speculate that reliance on indirect tests of ventilation may have been an important factor contributing to delay. For example, cyanosis is an indirect test of ventilation that might be used as a clue of esophageal intubation. This approach, however, is limited by the insensitivity of the human eye to the changes in skin color that occur during arterial desaturation.[16,17] Furthermore, effective preoxygenation before intubation may extend the period of time before significant arterial desaturation develops.[18] In this context, it is not surprising that cyanosis preceded the recognition of esophageal intubation in only 34% of cases. One might also expect cardiovascular clues to accompany hypoxemia or hypercarbia. Indeed, hemodynamic derangements such as bradycardia, hypotension, and asystole occurred before the recognition of esophageal intubation in the majority of cases. Unfortunately, the life-threatening nature of these derangements probably drew effort away from detection of the underlying problem. The severity of the hemodynamic changes also suggests that the respiratory and metabolic consequences of esophageal intubation were so far-advanced that some degree of irreversible damage had already occurred. Thus, from the standpoint of timely detection and intervention, skin color and routine hemodynamic measurements do not seem to provide useful clues of esophageal intubation.

Auscultation of breath sounds is another widely used test of ventilation. In this series, auscultation of breath sounds was employed in over half of the claims for esophageal intubation, but this indirect test of ventilation was associated with misdiagnosis in 48% of cases. Even if one formulates a "best case scenario" by assuming that auscultation led to a correct diagnosis in: 1) the three cases where it actually did so; 2) the 29 cases where the role of auscultation was unclear; and 3) the 32 cases where there was no information about the use of auscultation, then misdiagnosis still occurred at a rate of 32% (30/94). Although the limitations of auscultation have been well described previously,[19] this set of claims provides the first evidence for a recurring pattern of risk: if esophageal intubation has occurred, the use of auscultation to distinguish between tracheal and esophageal location may delay the restoration of effective ventilation by producing a false impression of correct tracheal placement.

We do not wish to imply that the risk of auscultation is related primarily to the mechanical act of listening to breath sounds (which is innocuous by itself) or the simple existence of false-positive and false-negative results (which can occur with any test). We speculate that the risk develops when auscultatory findings are obtained in a clinical environment that promotes misinterpretation. The risk of misinterpretation may be greatest when quantitative data from capnometry and oximetry are unavailable and other indirect clues of esophageal intubation (*e.g.*, gastric distention, cyanosis, hemodynamic changes) are not readily evident or not yet manifest. The most likely setting for misinterpretation of breath sounds is probably the first few minutes following esophageal intubation in the patient who has been adequately preoxygenated during an otherwise uncomplicated induction of general anesthesia. In the context of this transiently benign-appearing state, there may be a tendency to interpret equivocal or ambiguous auscultatory findings as normal. The reasoning process leading to this error might take a course similar to the following: "The breath sounds are somewhat distant, but everything else seems fine. Therefore, I am probably having trouble hearing completely normal breath sounds because the patient is obese, not because of esophageal intubation." Because quantitative data from capnometry and oximetry are also subject to misinterpretation, these monitors cannot be regarded as definitive remedies. The fundamental problem is the potential for error that arises from the interaction between preconceived notions of likelihood, reflex clinical behaviors, conflicting environmental data, and the inherent limitations of all diagnostic tests. The theoretical background for exploring this type of interaction and developing more effective clinical algorithms has been reviewed by Gaba.[20,21]

Payment for claims of difficult tracheal intubation was significantly ($P < 0.01$) lower than payment for either inadequate ventilation or esophageal intubation. Two factors may have contributed to this difference. First, the difficult tracheal intubation group had a lower proportion of high-cost outcomes (permanent brain damage and death), and a higher proportion of low-cost outcomes (temporary injuries such as esophageal and tracheal laceration) than the other two groups. Second, care was more often judged appropriate in cases of difficult tracheal intubation than in cases of inadequate ventilation or esophageal intubation. We have recently shown that claims involving appropriate care are associated with lower median payment than those of comparable severity that involve substandard care.[1]

Outwardly, these comparisons seem to place claims for difficult tracheal intubation in a more favorable light that those for inadequate ventilation and esophageal intubation. From the perspective of risk reduction, however, the comparison is less attractive. If a sizeable proportion of adverse outcomes in the difficult tracheal intubation

group cannot be linked to obvious defects such as inappropriate care or inadequate monitoring, this diminishes the likelihood that claims analysis alone can point to effective or broad-based remedies. In recent years, simulators have attracted considerable attention as educational tools. Simulation routines for difficult tracheal intubation might offer an important opportunity—especially during training years—for clinicians to obtain concentrated exposure to a relatively infrequent event. This approach might provide a useful research environment for educators who wish to devise more effective teaching protocols.

In summary, this analysis of closed claims suggests that adverse respiratory events represent a significant source of patient injury and financial liability in anesthetic practice. Most adverse outcomes were considered preventable with pulse oximetry, capnometry, or a combination of these monitors. Investigative protocols that initiate rigorous data collection immediately upon the recognition of a critical incident or adverse outcome may further improve our understanding of respiratory risks in anesthesia.

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