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Thirty-Day Postoperative Death Rate at an Academic Medical Center

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Objective

To improve understanding of perioperative deaths at an academic medical center.

Summary Background Data

Because published data have typically focused on specific patient populations, diagnoses, or procedures, there are few data regarding surgical deaths and complications in institutional or regional studies. Specifically, surgical adverse events and errors are generally not studied comprehensively. This limits the overall understanding of complications and deaths.

Methods

Data from all operations performed in the main operating suite of the University of Virginia Health Sciences Center from January 1 to June 30, 1999, were compared with state death records to gain a dataset of patients dying within 30 days of surgery. All clinical records from patients who died were screened for adverse events and subsequently reviewed by three surgeons who identified adverse events and errors and performed comparisons with survivors.

Results

One hundred nineteen deaths followed 7,379 operations performed on 6,296 patients, yielding a patient death rate of 1.9%. Patients dying within 30 days of surgery were older and had higher American Society of Anesthesiologists scores. Of 119 deaths, 86 (72.3%) were attributable to the patient's primary disease. Twenty-three patient deaths (19.3% of all deaths, 0.37% of all patients) could not be attributed to the patient's primary disease and thus were suspicious for an adverse event (AE) as the cause of the death. Of the 23 deaths suspicious for AE, 15 (12.6% of all deaths, and 65.2% of AE deaths) followed an error in care and thus were classified as potentially preventable, affecting 0.24% of the study population.

Conclusions

Overall, the 30-day postoperative death rate was low in the total surgical population at an academic medical center. Errors and AEs were associated with 12.6% and 19.3% of deaths, respectively. Retrospective review inadequately characterized the nature of AEs and failed to determine causality. Prospective audits of outcomes will enhance our understanding of surgical AEs.

Published surgical reports and clinical presentations at the meetings of surgical organizations usually include death and complications data only concerning the disease or operation under study. Further, detailed and comprehensive information that focuses on global adverse events after operations in institutional, regional, or national populations is lacking. Several factors contribute to the limited study of this important matter, including the difficult, time-consuming, and costly collection of prospective surgical complications, death, and outcome data; an unclear taxonomy for the classification of adverse events (AEs) and errors; and the difficulty inherent in determining the relationship between the disease, an AE, an error, and death and complications.

Although many healthcare organizations maintain elaborate systems for tracking revenue, billing, collections, monitoring costs, and accounting, few if any devote comparable

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resources to quantifying quality of care. In addition, social, political, and legal factors impede the study and reporting of complications, deaths, errors, and AEs because of the associated discomfort of disclosure, fear of litigation, and the prospect of unfavorable comparison with peers.

However, improvements in our understanding of surgical AEs and errors will improve the quality of surgical care. Recent studies have documented the incidence and role of AEs in medical and surgical practice by analyzing the results from multiple hospitals within a region or from national databases.[1–3]

Our research focused on defining AEs and errors during the perioperative period. This study reviewed 30-day postoperative deaths, as this represented a definitive endpoint for study. We defined the incidence of postoperative deaths in an institutional surgical population rather than in a mixed medical and surgical population or in a disease-defined group of patients. Further, we defined factors associated with death in this population, including the preventability of AEs and errors.

METHODS

Databases

After approval from our Human Investigation Committee, we queried the institutional Clinical Data Repository, an electronic patient database including demographic, financial, and clinical information, to assemble a list of all patients undergoing an operation during the study period January 1 to June 30, 1999. This patient list was cross-referenced with all patients dying within 30 days of their procedure during the study period, as reported from state death records. Only operations performed in the main operating room, but not in the separate obstetrics operating rooms, endoscopy suites, ambulatory surgery center, or other nonoperative procedure areas, were selected for analysis. An additional separate institutional database provided demographic information of patients undergoing operations. The populations of survivors and patients dying within 30 days after surgery were compared in subsequent analyses. When necessary, the institutional electronic document delivery system provided clinic notes, operative notes, discharge summaries, consultations, and diagnostic studies. Logs of morbidity and mortality conference proceedings captured four additional deaths not gained through other sources.

Chart Audit

The charts of patients previously identified as dying within 30 days of surgery were initially screened by trained reviewers (M.J.O., V.C.), who made an assignment regarding the occurrence of an AE, defined in similar previous studies as "unintended injury [death in this case] caused by medical treatment, and thus not primarily attributable to the patient's primary disease process."[4] Three physician reviewers (J.F.C., R.B.A., R.S.J.) subsequently reviewed all charts assigned any score other than "no suspicion for AE" by the screeners. To assess the validity of the screener assignments, a random sample of 10% of the low-suspicion records were rescreened by a physician reviewer (J.F.C.), who found 100% blinded concordance with screener assignments.

All potential AEs were reviewed blindly by each physician reviewer and assigned a subjective score (based on a 5-point ordinal scale) as to the likelihood that death was attributable to some factor other than the patient's primary disease. Each of these charts also was scored using a 5-point scale as to the likelihood that the AE was the result of an error. Errors were defined as "episodes in care in which a planned sequence of mental or physical activities failed to achieve its intended outcome, and this failure could not be attributed to chance occurrence."[5] No strict criteria for the certainty of errors or AEs were defined before the study. Rather, the strength of the likelihood of an error was based on each individual reviewer's interpretation of the material available in the medical record. Discordant scores were subsequently reconciled through in-depth review and discussion to obtain a final consensus-based score.

Statistics

Statistical analysis was done using STATA 6.0 (College Station, TX). All 95% confidence intervals (95% CI) and *P* values are two-tailed. *P* values were derived from chi-square testing, Wilcoxon rank-sum, or multivariate logistic regression where appropriate.

RESULTS

All operations in the University of Virginia Health Systems' main operating room from January 1 to June 30, 1999, were selected for initial review, involving 6,380 patient records. Eighty-four records (involving 1.1% of all procedures performed) were excluded for cases solely involving dental extractions, podiatric procedures, organ donations, for which there were no relevant periprocedural deaths observed, or because no data were available. These patients are not included in subsequent analyses. Thus, the records of 6,296 patients who underwent 7,379 operations were reviewed in detail (Table 1). Individual data points for some patients were not available, accounting for the variable numbers in the accompanying figures of age and American Society of Anesthesiologists (ASA) score distribution. One hundred nineteen patients (1.9%) died within 30 days of surgery. These patients were older ($P < .0001$), had higher ASA scores ($P < .0001$), and were more likely to have undergone an emergency procedure. They also were more likely to have had their index primary operation performed at night or on a weekend ($P < .0001$). Thirty-five percent of patients dying within 30 days of surgery, but only 17.0% of

Table 1. DEMOGRAPHICS

	Survivors (N = 6,177)	Deaths (N = 119)
Mean age ± std dev (yrs)	47.4 ± 22.7	56.2 ± 24.5†
% Female	48.0%	45.4%
Emergency	8.9%	54.5%‡
Median ASA	2	4†
Procedures (average per patient)	7225 (1.2)	154 (1.3)
Service		
General surgery	1380 (22.3%)	35 (29.4%)
Orthopedics	984 (15.9%)	10 (8.4%)
Thoracic/cardiovascular Services	874 (14.1%)	34 (28.6%)
Neurosurgery	839 (13.6%)	17 (14.3%)
Urology	450 (7.3%)	4 (3.4%)
Gynecology	464 (7.5%)	3 (2.5%)
Otolaryngology	408 (6.6%)	2 (1.7%)
Plastics/Burn Services	271 (4.4%)	8 (6.7%)
Ophthalmology	298 (4.8%)	1 (0.8%)
Pediatric Surgery	178 (2.9%)	5 (4.2%)
Other	31 (0.5%)	0 (0%)
% Weekend	4.2%	13.4%‡
Time: 8 PM to 6 AM	3.27%	14.29%‡
Pre-/post-operative LOS§ (days)	1/5	5/10

† $P < 0.0001$ Wilcoxon Rank Sum (Mann-Whitney U Test).
‡ $P < 0.0001$ Chi-square Analysis.
§ LOS = Length of stay.

survivors, were older than 70 years (Fig. 1). The lowest ASA score in the death group occurred in a single patient with an ASA of 2 (Fig. 2).

Surgical Volumes and Thirty-Day Death Rates

Real and relative operative volumes and deaths were highest on the general surgery and thoracic/cardiovascular services (Fig. 3). The operative volume was higher on the thoracic/cardiovascular services compared with orthopedics, despite the overall higher number of orthopedic patients, because several of the thoracic/cardiovascular patients underwent multiple procedures. Death rates were higher on the thoracic/cardiovascular and plastics/burns services (3.9% and 2.9%, respectively; Fig. 4). The lowest observed 30-day death rates were those after otolaryngology and ophthalmology procedures (0.5% and 0.3%, respectively). Ninety-six of 119 deaths occurred in the hospital (80.7%), 10 (8.4%) patients died at home, and 13 (10.9%) died in nursing homes, skilled nursing facilities, or other unidentified out-of-hospital locations (Fig. 5). Although procedures performed at night or on weekends had significantly higher postoperative death rates, they were not independent predictors of death after multivariable logistic regression analysis adjusting for ASA score and status as elective or emergent ($P = .97$ and $P = .26$, respectively).

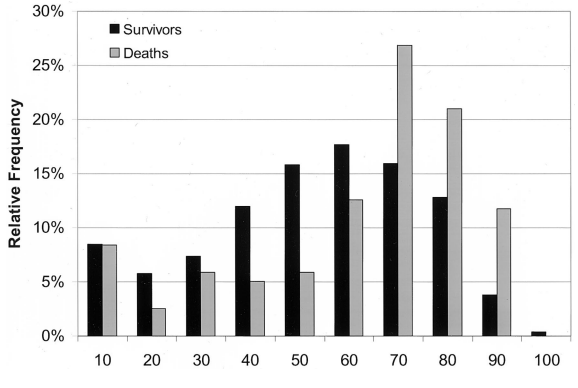

Figure 1. Ages stratified by decade for patients dying within 30 days of an operation (gray bars, n = 119 deaths) are compared with those in patients who survived procedures beyond 30 days (black bars, n = 6,177 survivors).

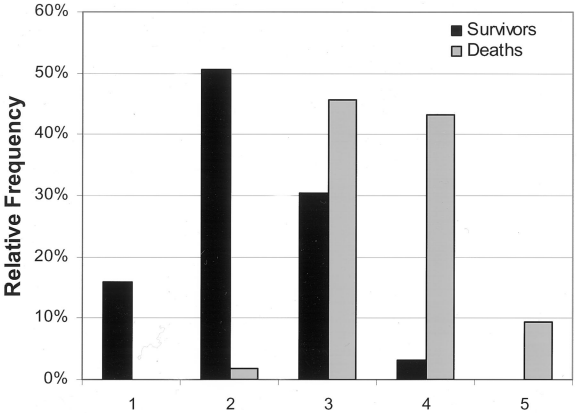

Figure 2. American Society of Anesthesiologists preoperative risk assessments for procedures performed on patients dying within 30 days of an operation (gray bars, n = 119 patients who died) are compared with those assigned to patients surviving beyond 30 days (black bars, n = 6,075 patients who survived).

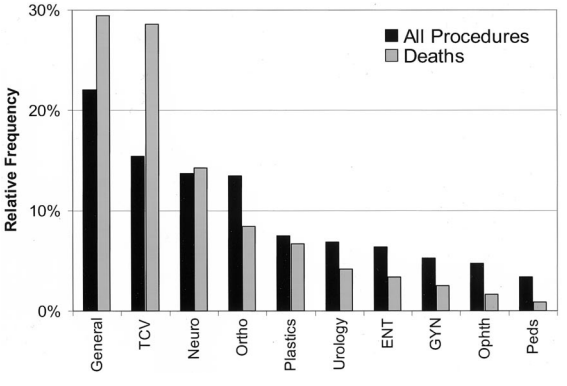

Figure 3. Frequency of cases (number of service cases/total operative cases) by service are denoted by black bars. General, general surgery including oncology, transplantation, and trauma surgery; TCV, thoracic and cardiovascular surgery; Neuro, neurologic surgery; Ortho, orthopedic surgery; Plastics, plastic surgery and burn services; ENT, otolaryngology; Gyn, gynecology; Peds, pediatric surgery; Ophth, Ophthalmology. Total number of procedures, 7,379.

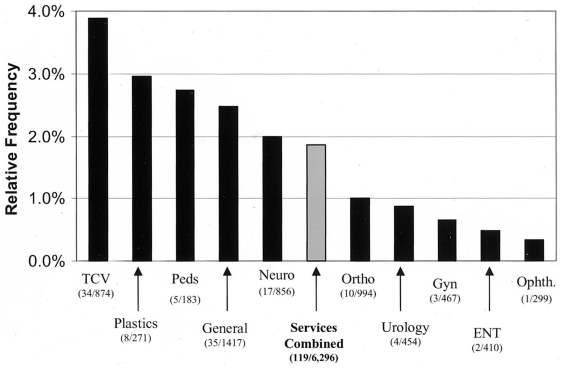

Figure 4. Death rates (total number of service deaths/total number of service patients) are portrayed by service. Numbers in parenthesis are total deaths per service/total patients per service. General, general surgery including oncology, transplantation, and trauma surgery; TCV; thoracic and cardiovascular surgery; Neuro, neurological surgery; Ortho, orthopedic surgery; Plastics, plastic surgery and burn services; ENT, otolaryngology; Gyn, gynecology; Peds, pediatric surgery; Ophth, ophthalmology. Total deaths, 119; total patients, 6,296.

Adverse Events

Twenty-three (19.3%) of the 119 deaths had a strong likelihood of resulting from unintended injuries associated with medical treatment (AEs) rather than the patient's primary disease (Fig. 6). The cause of death was indeterminate in 10 (8.4%) patients. Hemorrhage, observed in eight (34.8%) patients in the AE group (6.7% of all deaths), was the most common complication observed (Fig. 7), followed by infection (5 patients, 21.7% of AEs), cardiovascular complications (4 patients, 17.4% of AEs), and stroke (4 patients, 17.4% of AEs). There were single cases involving respiratory failure and a technical complication (1 patient each, 4.3% of AEs respectively).

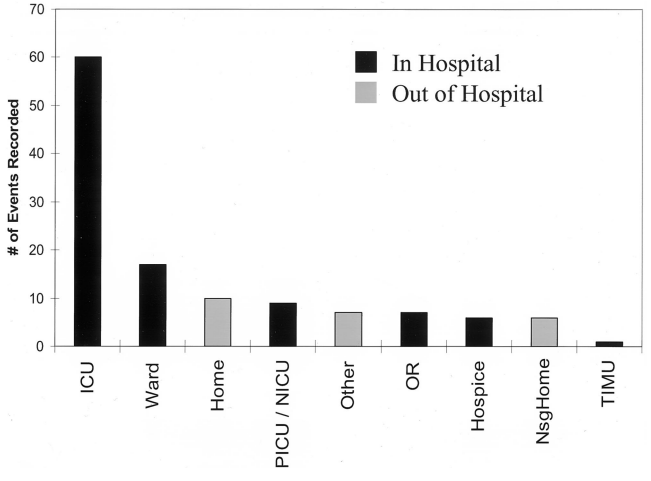

Figure 5. Physical location at time of death (n = 119). ICU, intensive care unit; Ward, acute care nursing unit; Home, patient's home; PICU/NICU, pediatric intensive care units; Other, unidentified location out of the hospital; OR, operating room; Hospice, hospice care unit; NsgHome, nursing home or other skilled nursing facility; TIMU, thoracic intermediate care unit.

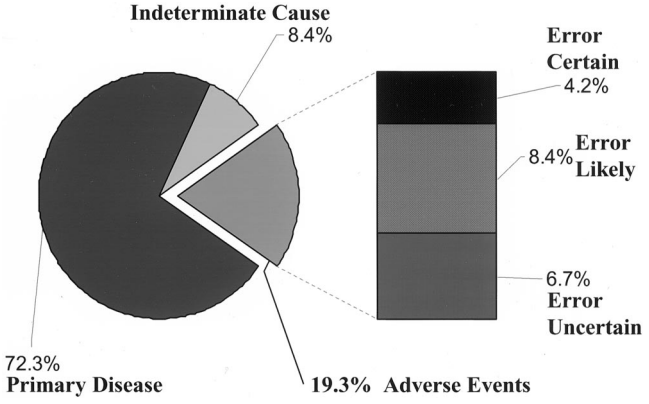

Figure 6. Deaths attributable to the primary diseases, those of indeterminate origin, and deaths related to adverse events. Adverse events are further broken down by the presence of an error and the likelihood that the error contributed to death. Total adverse events, 23; total errors, 17.

Errors

The deaths of 15 patients (12.6% of all deaths and 65.2% of AE deaths) were associated with an error in care, affecting 0.24% of the surgical population. Seventeen errors occurred in 15 patients; 2 patients experienced multiple errors. None of the patients scored by reviewers as "likely" or "certainly" experiencing AEs had sufficient data in the records to exclude completely an error as the cause of their AE, and were thus assigned an indeterminate error designation. Figure 8 illustrates error types and shows that technical errors prevailed as the most common error recorded: they were associated with death in six patients (26.1% of patients with AEs and 40.0% of cases involving errors). Errors associated with death occurred most frequently in the operating room, followed by patient rooms and the intensive care unit (Fig. 9).

Preventability

As reported above, 65.2% of patient deaths were not attributable to their primary diseases and had at least one

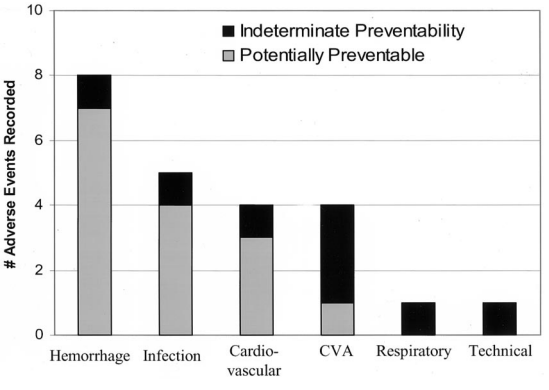

Figure 7. Observed number of adverse events (n = 23) by category (total bar height) and their judged preventability. Preventable, gray; indeterminate, black.

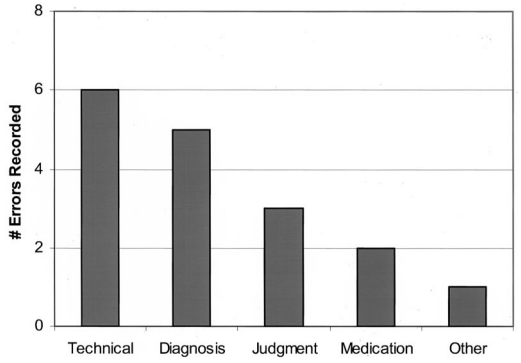

Figure 8. Types of errors associated with death (n = 19 errors in 15 patients).

error identified in their records. Defined by coexistence of an AE and an identifiable error, the most common potentially preventable AEs identified were intra- and postoperative hemorrhage, deemed potentially preventable in seven of eight instances (81.5%). Infections and cardiovascular complications were other common AEs identified; they were judged potentially preventable in 80.0% and 75.0% of instances, respectively (see Fig. 7).

Documentation Quality

The ability to determine, qualitatively and quantitatively, the occurrence of an AE or error depends on the medical documentation at present. The quality of the documentation by the primary surgical team was judged adequate in 15.7% of instances at the time of the AE itself and in 21.0% of instances for the follow-up investigation of the AE. In most situations, the primary surgical team did no follow-up documentation. In many situations, detailed documentation of the AE was derived from the written notes of the nursing staff and consultants.

DISCUSSION

Understanding surgical AEs associated with surgical procedures will improve efforts to decrease surgical errors and improve patient care. This study is unique from others investigating surgical AEs in its approach to the question. To our knowledge, this is the first study to have examined all operations conducted at a single, academic institution in which a detailed audit was made of all procedures resulting in patient death within 30 days of the procedure. Each death was graded for the likelihood that an AE had occurred and the possibility that an error had occurred in conjunction with the AE. As an initial effort to categorize and study surgical AEs at our institution, we chose postoperative death as the endpoint because the unambiguous nature of death can be verified using death certificates. In addition, we hypothesized that AEs related to postoperative deaths would be readily identifiable.

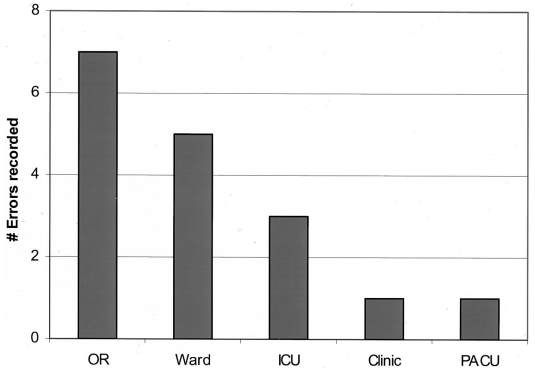

Figure 9. Site of error occurrence associated with death (n = 19 errors in 15 patients).

These results illustrate the overall 30-day postoperative death rate in an institutional surgical patient population. Seventy-two percent of patients died as a result of their diseases. Statistically, the risk of postoperative death, although small overall, is increased with age, ASA score, and the need for an emergency procedure. This is not surprising and confirms in a mixed patient population the results from other disease- and procedure-specific reports. Our finding that nights and weekends are not independent predictors of death on multivariate analysis may be attributable to subtle differences in patients with similar ASA scores or differences in night and weekend case mix, or our analyses may have lacked sufficient power to detect a difference. Surgical services that performed larger, complex, or more physiologically disruptive procedures also were more likely to have higher associated postoperative death rates.

Although physician reviewers agreed on most of the assessments regarding the presence of an AE or an error, there was some disagreement. In addition, considerable time was spent reviewing all aspects of the chart to make this assessment, indicating the difficulty in finding adequate documentation to support or refute an AE or error. Consequently, several instances were coded as indeterminate as to whether an AE or an error had occurred. In assessable charts, an AE occurred in one fifth of the patients dying within 30 days of their procedure. However, the overall incidence of a postoperative AE was small (0.4%). Of the AEs, 65% were associated with errors and thus were potentially preventable. Finally, it is clear that poor documentation of potential AEs and errors is a significant problem for these types of studies, making this and similar efforts likely fraught with error.

Findings in Context

The results of this study are not directly comparable with other reports of surgical AEs in the absence of risk adjustment. However, the largest study to date investigating the incidence of surgical AEs reported a 3% rate in patients undergoing a surgical procedure or childbirth.[1] Of those surgical AEs (defined by these authors as related to a surgeon's operative or nonoperative care), 5.6% resulted in

death. This equated to an overall associated death rate of approximately 1.7 cases per 1,000 episodes of surgical care.[1] In our study, fatal AEs were judged likely to have occurred in 23 of 6,296 patients undergoing 7,379 operations, for an overall fatal AE rate of 3.1 cases per 1,000 cases performed, resulting in death in 1:275 patients. If the nonfatal-to-fatal AE ratios established in previous studies have validity in our institution, then we would expect to see nonfatal AEs in 8% to 24% of patients if such a rate was measured.[1,6]

One potential issue is whether data from Gawande et al[1] captured patients who died outside the index hospital. If not, this could underestimate the number of deaths associated with a surgical AE. We searched state death records as well as hospital records and morbidity and mortality reports in an effort to identify all postoperative deaths. An alternative cause of the somewhat higher-than-expected death and AE rates in this study compared with other retrospective studies was that our chart audit and event review was performed exclusively by experienced surgeons. Thus, data extraction and analysis may have been subjected to scrutiny more attuned to subtleties in the care and documentation that resulted from intra- and perioperative care. That underestimation of the true AE and death rates after retrospective reviews occurs is suggested by the results reported from the National Surgical Quality Improvement Project.[2] Although these data were restricted to Veterans Administration hospitals, they reported all-cause complication and death rates of 10.0% and 2.8%, respectively, but did not address AE or error rates.[2]

Although this relationship has been shown in a similar previous study, we were surprised to find a correlation between day and time of service and outcome.[7] Even though the starting time and day of the week were not independent predictors of postoperative death, reexamination of these factors with a larger study population is warranted. Although several factors, including fatigue, staffing density and experience, and level of physician experience, have been suggested as possible contributors to this effect, our study was not designed to answer this question, and we cannot comment on possible causative factors.

Our 0.37% fatal AE rate is less than the overall AE rates published in previous studies.[1,6,8,9] This is not surprising because other reports investigated all adverse events in a population, most of which were not fatal. With errors observed in 15 of 23 AEs, this yields a potential preventability rate of 65.2%, which also is in concordance with other reports.[1,6,8,9]

Limitations

The results of this study are limited primarily by several factors: its retrospective nature; an absent, well-established taxonomy of error classification; and the subjective nature of AEs and error assignment, again due to lack of a recognized standard. The uniformly poor level of documentation compounds all of these in general in medical charts and, in particular, in reference to possible AEs or errors. A second major and unexpected issue was the inability to assess critical information because requested charts were unavailable, missing in their entirety, or missing entire data sections needed for review. Consequently, 33 of the 119 (27.7%) conventional written care records requested for an in-depth review of postoperative death were subject to this potential source of error. This necessitated the use of more limited data sources, such as electronic operative reports, discharge summaries, and death certificates, to make determinations of AEs and errors. Twenty-five of the 33 charts (76%) with missing data were assigned indeterminate or nonsuspicious codes for AE likelihood, thus raising the possibility that our analysis underestimated the true incidence of AEs in this cohort of patients with 30-day postoperative death.

Underestimation of the postoperative death rate also occurred in this study because we chose to limit our analysis to the 30-day postoperative period. We found 18 additional in-hospital deaths that occurred after the 30-day study period. If included in the analysis, the observed crude death rate would have been 2.2%, closer to that reported by Khuri et al.[2] This also suggests that additional AEs and errors would be identified in this cohort and therefore are underestimated.

This study also does not address the question of patient survival had care been optimal. Recently published work by Hayward and Hofer[10] raises the question, among others, of whether surgical AEs or errors are less meaningful when they occur in a patient with an expected survival of less than 90 days. The merit of this question has been debated, and we have chosen not to focus on it in our studies. Instead, we devoted our investigation to understanding the factors affecting the safety of care using all data available to us, ever mindful that an increasing proportion of our patients will possess the comorbidities and frail health common to the aged.[11]

Study Implications

This study illustrates several important points with considerable implications for research in this area. First, considerable work remains to be done concerning this topic; it is evident that we have a very limited understanding of the nature of surgical AEs and the factors that contribute to them. Even less clear is how to characterize them in an effort to develop strategies to minimize AEs and errors. Second, fundamental changes will be required to improve our understanding of these issues. Two critical issues must be addressed in this regard. The development of a standardized taxonomy for AEs and errors in surgery will allow standardization within the field and facilitate a common language for discussion and reporting by investigators. Prospective databases focused on AE and error documentation must be developed to allow timely data utilization. Ideally,

trained, independent evaluators would collect accurate data enrollment to provide information to improve care. The development of institutional complete electronic patient records coupled with electronic AE data sets will improve the quality of surgical care.

At present, individual and groups of surgeons function with very little capacity to develop institutional memory or cross-discipline understanding of how system and human factors affect surgical outcomes. Collecting and reporting this type of information is important, decreases variance in care, and ultimately improves patient outcomes.[2] Although recurring themes were found in the preventable complications we observed, each possessed nuances that made it unique, allowing the relevant clinicians to reassure themselves that the death was anomalous with regard to their general outcomes. Standardized data sets regarding these issues will allow individuals a basis for comparing their own results, as well as facilitating the development of systematic approaches to reducing surgical AEs and errors.

CONCLUSIONS

Periprocedural death, although uncommon, is not rare. Most of these deaths can be attributed to the patient's primary diseases. In some patients, however, death cannot be solely attributed to their disease, raising the concern that an AE had occurred. Despite a detailed review of available data, a conclusive cause of death and its contributors often cannot be discerned in surgical patients, given current record-keeping methodology. These data suggest that posthoc analysis is limited in its utility to define and identify potential contributors to perioperative complications and death. Clinicians and patients are likely to benefit substantially from systematic prospective and multidisciplinary examination.

Acknowledgments

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Discussion

DR. MURRAY F. BRENNAN (New York, NY): Thank you for the kind invitation to discuss this paper. The title clearly underestimates and understates the significant content of the manuscript.

Most clinicians are averse to the appellation of errors, seeing such a statement as a form of personal attack on their manhood or womanhood and a threat to surgical hierarchy. Airline pilots, however, diligently address any issue of potential hazard in a proactive fashion. This is an area where, as Dr. Jones says, we have much to learn and a great deal to gain.

The important features of the manuscript are that 20% of the deaths were questionable and 15% had an identifiable error in care and were potentially preventable. It is important to emphasize that this is a retrospective review and almost certainly underestimates the potentially preventable events. As you will hear later this morning, the standard of complication reporting in the surgical literature is poor even in prospective, randomized control trials. We recently reviewed all surgical procedures for cancer in the New York City greater metropolitan area from a database freely available to the insurance carrier. For approximately 100,000 operations, mortality within institutions varied by a factor of fourfold (i.e., you can decrease your risk of dying from surgical operation from malignancy by 200% to 400% by choosing your hospital or surgeon)—a personal and politically unacceptable observation.

An important contribution of this manuscript is the use of trained nonphysician observers to record the data, something shown to work in the national VA Surgical Quality Improvement Project.

The major prevalent errors identified were related to hemorrhage and infection, and the hemorrhage was predominantly technical. My first question, therefore: was this related to the experience of the operator? As there were greater deaths related to operations at night and on weekends, not surprisingly, are we remiss in the senior supervision that we provide?

My second question relates to follow-up. With increasing emphasis on early discharge, many infections present following discharge rather than during the admission; the prevalence, therefore, of infectious complications must be higher. The authors did find, by examining postdischarge mortality, that that increased from 1.9% to 3% when postdischarge mortality was included.

Presumably, the same is true of the nonfatal complications and errors, and this is clearly understated.

Finally, the paper itself is much more important for what it portends rather than what it presents. Unless surgeons take the leadership in quality improvement in a nonpejorative manner, then others will. We will be left to respond to administrative terrorism, often defined in New York City as

oversight, a process in which there can be no winners, and the greatest loser will be the patient.

DR. MARK A. TALAMINI (Baltimore, MD): I appreciate the opportunity to review this manuscript and ask a few questions.

Dr. Jones and his group have analyzed perioperative deaths over a 6-month period for an entire academic hospital to detect adverse events and errors in care. The analysis is exhaustive and contains an impressive system of checks and balances designed to catch all possible events. They are to be commended for their courage and compulsiveness in both performing the analysis and reporting the results. I have the following questions.

First, the actual detected rate of errors leading to death was quite small, at 0.24% of the entire patient population. I am sure many nonmedical personnel would claim that surgeons analyzing their own results would be an example of the fox guarding the hen house. Is it appropriate for surgeons to analyze their own data in this manner? If not, who should be, quote, watching our results?

Second, in the manuscript the suggestion is made that this type of analysis will increase the quality of surgical care. How does this data actually lead to such an improvement? Also, how does this sort of analysis fit in with our time-honored tradition of the morbidity and mortality conference?

In this analysis, adverse event reporting detailed by physicians was poor. How would you suggest that the details of such events be reported more effectively?

Finally, similar to Dr. Brennan's comments, how can we shine the light of day on the arena of surgical errors without further eroding the overall morale of surgeons, who already feel as though they have lost much of the control of the surgical profession?

DR. JAMES C. THOMPSON (Galveston, TX): The information we have received here is invaluable. I don't think any of us appreciate fully how hard these data are to put together and what tender bunions you may step on if you attempt to do this in your own hospital.

We all have to know what happens, exactly, to our patients. The Institute of Medicine has been requested by Congress to develop a systems approach to error reduction in medicine. The Institute of Medicine recently had a symposium on informatics. Now, I always thought of informatics as a bunch of techno-geeks sort of nosing into our business. And I was surprised—stunned would be a better word—to learn that some hospitals in this country already are putting in place programs in which the computer printout of the admitting history and physical examination is placed in some central facility, and whenever orders for studies or medications are requested by the attending physician, these requests are matched with a diagnostic coding for the patient and the appropriateness of each order is graded on a scale, say 1 to 5, on the degree of appropriateness. If a wound culture is sent to the lab, the report goes not only to the patient's record but also to the pharmacy, which then communicates appropriate therapeutic suggestions. This is also true for any diagnostic studies that may be ordered. Now, the physician in charge is not required to follow the suggestions, but he or she ignores them at his or her peril.

This will all result in the establishment of guidelines, firm guidelines, and I hope that these guidelines and pathways are made for us, by us, in surgery, and not by outside agencies. The validity of these guidelines will depend on hard data. This paper and the papers from Memphis and Atlanta and the paper to be given from Sloan-Kettering, plus the VA studies, all illustrate the importance of arriving at accurate hard data.

In the field of informatics, we exist far behind business, especially airlines. We can no longer depend on carrying around information accrued over a lifelong period, on carrying that information just in our heads.

And in answer to President Britt's and Dr. Sharp's earlier question about judgment versus algorithms, the goal, perhaps ephemeral, is to keep surgeons so well informed from readily available data that the algorithms will coincide with good judgment.

Now, as we speak, there are some guidelines already firmly in effect. For example, a patient in many institutions with chronic congestive failure cannot be discharged from the hospital without receiving an order for a beta-blocker, and if the physician fails to so order, the patient's discharge will be delayed until that prescription is written.

Make no mistake. We are at a watershed. If we fail to make sure that our best judgment is fully attended to the best evidence, someone else will do it for us. Probably gently, at first, but we will be told.

DR. F. DEAN GRIFFEN (Shreveport, LA): I would like to know how Dr. Scott feels about privilege versus disclosure in terms of peer review. What is the answer to obtaining errors for review with which to improve patient safety without enhancing liability? Second, how do the authors reconcile our current teaching that implicates systems failure as the source of errors with the data they have just presented, showing that individuals fail more commonly?

DR. GRACE S. ROZYCKI (Atlanta, GA): I congratulate the authors on an outstanding paper. How many of the patients had postmortem examinations? And how did this impact the results?

DR. MAX R. LANGHAM, JR. (Gainesville, FL): This is a pioneering piece of work, one of the first serious clinical studies of error in medicine. As has been alluded to by other discussants, error analysis in the aviation industry is fairly advanced compared with ours, and it has been a clear finding that it is usually a string of errors, not a single error, that ends up in a catastrophe.

One of the things the aviation industry has just begun to do, interestingly enough, is to look at black box recordings of flights that do not end in disaster for errors, trying to improve or reduce the error rate in flights. I am curious as to whether Dr. Jones' unique database at Charlottesville will allow them to look at errors that end up in nonfatal cases and to try to differentiate what interrupted a potential string of errors and prevented death, or, alternatively, whether the concept of a string of sequential errors causing death is valid in surgical services.

DR. JOSEPH B. COFER (Chattanooga, TN): I would like to ask Dr. Jones if the impending HIPAA regulations will influence databases like this in the future. Have the lawyers at the University of Virginia looked at what the HIPAA regulations are going to do to your database and other databases that we might try to construct involving basically confidential patient records?

DR. BARBARA L. BASS (Baltimore, MD): I enjoyed this paper greatly as well. My concern has to do with the cost of accumulating this fabulous data. We all know that the quality of the conclusions we make depends on the quality of the data we get. To get good data you have to pay for the people and the systems to support the effort. I wonder if you could give us an estimate, Dr. Jones, as to how much this study cost in terms of manpower, data processing, information management, and other expenses; and, further, if you might speculate as to how much it might cost to do this on an annual continuing basis for your surgical program.

DR. BASIL A. PRUITT, JR. (San Antonio, TX): One of the problems with the IOM study is that the reviewers knew the outcome. I suppose that the assessment of technical errors is pretty straightforward and that prior knowledge of outcome has little effect on that assessment. In assessing judgment errors, however, prior knowledge of outcome is a real problem. How did you avoid that complicating feature in your study?

DR. GENE BRANUM (Harrisonburg, VA): Most of my questions were answered. But I recall vividly a patient I did a Whipple on a few years ago who had a bit of a rocky postoperative course but went home after about 3 weeks. At 6 weeks home from the hospital he suffered a fatal pulmonary embolism. And the fact that he was past 30 days in the mortality data didn't make me or his family feel any better. What is magic about 30 days? And how are we going to deal with, as you mentioned in your manuscript—which is excellent, by the way—mortality down the road after 30 days? Isn't this just an arbitrary number?

DR. J. FORREST CALLAND (Charlottesville, VA): Again, thank you, members and guests of the Southern Surgical Association, for the opportunity to present our work. I will now address each question in turn.

First, Dr. Brennan asked the question of was hemorrhage related to the experience of the operators that we observed in our database. We did not grade the experience of the operators when we looked at our individual complications. In addition, he asked the question of how are we to avoid additional oversight that could emerge as our errors and complication rates become delineated. This question was answered, in part, by some of the other discussants. It is going to be very important that we do this work

ourselves in order to avoid people from Washington and other places coming in and doing it for us.

Dr. Talamini asked how our data could lead to improved care. I think that the salient point there is that at least 10% of our cases had indeterminate outcomes and a substantial portion of the written records were unavailable for review, necessitating review of electronic records. This shows us that prospective review of our outcomes will be very, very important, and there is clear evidence from the National Surgical Quality Improvement Project that prospectively reviewing outcomes and reporting those to clinicians in a risk-adjusted manner improves future outcomes.

Dr. Talamini also asked a question about the morbidity and mortality conference. We found that less than half of the patients who died within 30 days of an operative procedure on the general surgery services underwent any review at our morbidity and mortality conference.

To address the question of how can we avoid this data actually decreasing the morale of our hard-working and sometimes beleaguered surgeons: if anything, surgeons who feel empowered to improve the safety and quality of the care they deliver may actually feel a higher sense of morale about the work they do rather than lower. Having prospective data available to these people to improve the quality of care they deliver will augment this.

I appreciate the comments of Dr. Thompson.

With regard to Dr. Griffen's questions of privilege and disclosure, all of our studies are put through review of our Human Investigation Committee, which has a university lawyer as a standing member, who determines whether the research that we propose falls within the bounds of HIPAA regulations.

Ensuring that we can use quality assurance data solely for quality assurance and not for litigation or administrative purposes is our personal responsibility as surgeons, both at our home institutions and perhaps also at a legislative level.

Dr. Griffen also addressed the question of how do we make sure that we utilize a systems approach rather than one of individual blame. Perhaps one of the most important aspects of our work is that we do work very closely with systems engineers and human factors experts.

And to move forward on that question a little bit, how do we address the idea of errors not caused by individuals but by a chain of errors in systems? It all begins with objective, dispassionate examination of outcomes. Clearly, with hindsight bias, knowing the outcomes before reviewing these cases, it is incredibly easy to assign blame where none exists. I believe that we are extremely conservative in our assignments of error and "blame." If anything, these data should lead us to perform more prospective data collection not only in terms of outcomes but also in terms of black box recorders doing video-based research, which we currently are undertaking at the University of Virginia, to look at how systems errors contribute to adverse outcomes in the operating room.

Dr. Rozycki asked the question of how autopsy rates contributed to adverse events. I believe that our autopsy rate is no different than what has been observed elsewhere, occurring in less than 10% of the patients studied. Very clearly, this severely limits our ability to do adequate assessments of outcomes.

Dr. Langham, from Gainesville, I think I addressed his questions about the error chain and doing systems analysis in the operating room.

Dr. Cofer also asked about HIPAA regulations. As I said, these things don't really go into effect for another year or two, and we still have time to work hard at a local, national, and legislative level to ensure that quality data are used only for quality assurance and not for litigation.

Dr. Bass asked the question of how much do we estimate this work costs to do and what were our personnel needs to do it. We had two medical students and six undergraduate research assistants who did the screening of the charts, and probably put in over 100 hours' work, probably closer to 200 hours' work each, on that portion. We also had three surgeons. One of those surgeons put in easily over probably 300 hours, and two of the others put in somewhere around 50 hours each. This work was funded by the National Patient Safety Foundation.

In terms of what this would cost to do on an institution-wide level, that is really hard to say. I do know that the National Surgical Quality Improvement Project claims that each patient is prospectively entered into their database for a cost of about $12 per patient.

I believe I addressed Dr. Pruitt's question of hindsight bias. And, of course, that is why prospective databases and prospective research will be important.

Finally, Dr. Branum, how do we address this question about 30-day mortality? That is, are deaths any less meaningful if they occur on the 35th day or the 60th day rather than the 30th day? I truthfully don't have a great answer for that question. I will say that we can start with 30-day and in-house mortality as beginning points. Recently I spoke with Dr. Nugent from the Northern New England Cardiovascular Research Group, and he pointed out that using a combination of in-house mortality and 30-day should gain us over 90% capture for all of our deaths. From that point, we would have to extrapolate.