Surgical outcomes research

The incidence and nature of surgical adverse events in Colorado and Utah in 1992

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Background. *Despite more than three decades of research on iatrogenesis, surgical adverse events have not been subjected to detailed study to identify their characteristics. This information could be invaluable, however, for guiding quality assurance and research efforts aimed at reducing the occurrence of surgical adverse events. Thus we conducted a retrospective chart review of 15,000 randomly selected admissions to Colorado and Utah hospitals during 1992 to identify and analyze these events.*
Methods. *We selected a representative sample of hospitals from Utah and Colorado and then randomly sampled 15,000 nonpsychiatric discharges from 1992. With use of a 2-stage record-review process modeled on previous adverse event studies, we estimated the incidence, morbidity, and preventability of surgical adverse events that caused death, disability at the time of discharge, or prolonged hospital stay. We characterized their distribution by type of injury and by physician specialty and determined incidence rates by procedure.*
Results. *Adverse events were no more likely in surgical care than in nonsurgical care. Nonetheless, 66% of all adverse events were surgical, and the annual incidence among hospitalized patients who underwent an operation or child delivery was 3.0% (confidence interval 2.7% to 3.4%). Among surgical adverse events 54% (confidence interval 48.9% to 58.9%) were preventable. We identified 12 common operations with significantly elevated adverse event incidence rates that ranged from 4.4% for hysterectomy (confidence interval 2.9% to 6.8%) to 18.9% for abdominal aortic aneurysm repair (confidence interval 8.3% to 37.5%). Eight operations also carried a significantly higher risk of a preventable adverse event: lower extremity bypass graft (11.0%), abdominal aortic aneurysm repair (8.1%), colon resection (5.9%), coronary artery bypass graft/cardiac valve surgery (4.7%), transurethral resection of the prostate or of a bladder tumor (3.9%), cholecystectomy (3.0%), hysterectomy (2.8%), and appendectomy (1.5%). Among all surgical adverse events, 5.6% (confidence interval 3.7% to 8.3%) resulted in death, accounting for 12.2% (confidence interval 6.9% to 21.4%) of all hospital deaths in Utah and Colorado. Technique-related complications, wound infections, and postoperative bleeding produced nearly half of all surgical adverse events.*
Conclusion. *These findings provide direction for research to identify the causes of surgical adverse events and for targeted quality improvement efforts. (Surgery 1999;126:66-75.)*

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THERE ARE NOW MORE THAN 3 decades of studies on adverse events in medicine, but only recently has the potential to use these results to guide quality improvement and research efforts been appreciated. The first large scale study of iatrogenesis was done in the early 1970s, when the California Medical Association reviewed records from nearly 21,000 hospital admissions and found that adverse events had occurred in 4.6%.[1] However, it was not until the 1991 publication of the Harvard Medical Practice Study, which analyzed 30,000 hospital records from 1984 and found that the adverse event incidence rate had actually decreased to 3.7%, that attention shifted from the medical malpractice considerations to studying how to further reduce the occurrence of adverse events.[2] It was

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noticed that drug-related errors constituted an unexpectedly high proportion—19%—of adverse events,[3] and this spurred a flurry of research into the mechanisms behind such errors.[4-6] This research recently has paid dividends with the development of practical solutions, such as computerized physician order entry systems, that have been shown to markedly reduce drug-related errors.[7-9] Similar research on human factors in anesthesia mishaps has led to changes in equipment, standards, and training that have reduced the mortality rate from general anesthesia from 1 in approximately 10,000 cases during the 1970s to 1 in more than 200,000 cases.[10]

Taking a systematic approach to studying the nature and patterns of adverse events in surgical practice could be similarly fruitful. As yet, these events are poorly understood. We know surgical adverse events—unhappy outcomes resulting from surgical management, not disease—are not infrequent and are often avoidable. In 1981 Couch et al[11] found that avoidable surgical mishaps occurred in more than 1% of admissions to their academic general surgery service; 55% of these complications had resulted in death. The Harvard Medical Practice Study found that operative adverse events accounted for 48% of all adverse events, occurred in approximately 2% of all hospitalized patients, and were preventable 74% of the time.[2,3,12] Much greater detail about surgical adverse events has been missing, however.

Surgeons currently have 2 sources of information about the nature of surgical adverse events: our enduring institution of morbidity and mortality conferences[13] and large population studies of surgical outcomes such as Great Britain's national registry of perioperative deaths[14,15] and the National Veterans Affairs Surgical Risk Study.[16] Both continue to provide invaluable insights for surgical care. However, neither is able to provide a complete and accurate picture of surgical adverse events. Morbidity and mortality conferences and other forms of incident reporting miss 65% to 91% of adverse events detected by other methods,[17-19] and the large outcomes studies, not being designed to investigate adverse events, do not separate complications resulting from management from those resulting from disease.

METHODS

We sought to provide a detailed analysis of surgical adverse events through a retrospective chart review of 15,000 randomly selected admissions to Colorado and Utah hospitals during 1992 with use of the techniques of previous adverse event studies.[20] Specifically, in addition to estimating the incidence, morbidity, and preventability of surgical adverse events, we sought to characterize their distribution by type of injury and by physician specialty and to determine incidence rates by procedure. This study was part of a broader study designed to inform physicians, hospitals, and malpractice insurers in Colorado and Utah who are considering a "no-fault" alternative to the tort system for compensating injured patients and deterring substandard medical practice. Each participating hospital approved in advance the study design and publication of the data, as did the Human Subjects Committee at the Harvard School of Public Health.

Sample definition. We cooperated with the Utah Health Data Committee and the Colorado Hospital Association to sample 1992 discharges. First, we characterized all hospitals in each state according to size (fewer than 8000 discharges per year or greater than or equal to 8000 discharges per year), location (urban or rural), teaching status (major, minor, or nonteaching), and ownership (for profit, nonprofit, or government). Next, we created strata representing all possible combinations of these characteristics, and every hospital in each state was assigned to its appropriate stratum (filling 11 strata in Utah and 15 in Colorado). Psychiatric, rehabilitation, and drug-alcohol treatment Diagnostic Related Groups and hospitals that exclusively provide these services were excluded, as were Veterans Administration Hospitals.

At least 1 hospital from each stratum was then invited to participate on the basis of its appropriateness for a subsequent no-fault medical malpractice demonstration project. Hospitals did not volunteer, none of the invited hospitals refused to participate, and the investigators had no knowledge of the hospitals' adverse event rates. This resulted in a sample of 13 Utah hospitals from which 5000 calendar year 1992 discharge records were randomly selected and 15 Colorado hospitals from which 10,000 calendar year 1992 discharge records were randomly selected. This represented 2.6% of all discharges from Colorado and Utah hospitals in 1992. The number of records sampled from each hospital was proportional to the hospital's share of all discharges in the 28 hospitals.

Record review. First, nurses trained by us screened charts for any of 18 indicators associated with an adverse event, defined as an injury caused by medical management (rather than the disease process) that resulted in a prolonged hospital stay, disability at discharge, or death. Charts screened positive were then reviewed by a local physician trained to use a standard adverse event analysis

form. This form has a series of questions to facilitate reliable detection of adverse events and was identical to those used in previous studies, except for slight modifications.[2] We sought to detect adverse events of both surgical and medical care across all specialties. Thus we used board-certified family physicians and internists as reviewers and made appropriate specialist consultation available to them. Because judgments about adverse events may be complex, we used a 6-point confidence scale: 1, little or no evidence that medical management caused the event; 2, slight evidence; 3, not quite likely; 4, more likely than not; 5, strong evidence; and 6, virtually certain evidence. We required a confidence score of 4 or more to determine that an adverse event had occurred. The reviewers made a written description of the event and recorded specific characteristics of care, including the specialty of the caregiver who provided the injury-related care and the location of that care. Reviewers documented patient gender, race, age, and comorbid illnesses with use of the Charlson comorbidity index.[22] We obtained International Classification of Diseases, 9th revision (ICD-9), procedure codes from hospital discharge datasets in each state.[23]

Reviewers classified the type of event by choosing 1 of 10 mutually exclusive categories: operative complications (adverse events related to an operation or occurring within 30 days after an operation), adverse drug event, anesthesia related, fall related, fracture related, incorrect or delayed diagnosis, incorrect or delayed therapy, medical procedure complication, neonatal related, and postpartum related. They subclassified operative complications into one of 13 additional categories: acute myocardial infarction, bleeding, congestive heart failure, deep venous thrombosis, dysrhythmia, nonwound infection, other nontechnical event, other wound problems, pneumonia, pulmonary embolism, stroke, technique-related complication, and wound infection.

For the purposes of this study, 1 investigator reviewed case summaries for all events involving technique-related complications and identified those resulting from failure of the surgery (eg, fracture nonunion after open reduction with internal fixation) as opposed to complications of an otherwise successful operation (eg, bladder laceration during hysterectomy). We combined "other nontechnical" and "fracture-related" events as "other" events.

Quality control. This process for adverse event determination was extensively studied during the Harvard Medical Practice Study and was determined to be valid and reliable.[19,24] However, outlier physician reviewers with high false-negative rates were recognized. To address this problem, a study investigator rereviewed 50 randomly selected records of physician reviewers whose adverse event detection rate was 2 SDs below the mean for the group of reviewers in their respective states. If 10% or more of the records were classified as an adverse event by the investigator, the outlier physician's reviews were substituted with rereviews by a different reviewer who was blinded to the purpose of the rereview. To address false-positive reviews, 2 investigators reviewed all adverse event data forms and excluded adverse events that did not meet the study definition. At the end, a final rereview was performed on a random selection of 500 of the 15,000 original records. Reviewers achieved 79% agreement and acceptable interrater reliability (κ 0.4).

Disability and preventability estimation. Disability ratings were first made by the physician chart reviewers with use of the National Association of Insurance Commissioners severity-of-injury scale.[25] Next, 2 study investigators reviewed all available information about each adverse event and corrected disability scores in cases in which reviewers clearly misapplied criteria. These scores were then reviewed by 4 medical malpractice insurance claims adjusters from Utah and 6 from Colorado, and consensus was reached on a final disability score for each patient. All adjusters had prior training and experience applying these scores to medical injury cases as part of their responsibilities for the medical malpractice insurers who employed them.

Preventability was estimated with methods similar to those of previous studies.[26,27] An adverse event was considered preventable if it was avoidable by available means unless those means were not considered the standard of care. Two study investigators reviewed each of the adverse events and graded on a 6-point scale their confidence that the event was preventable. Specialty consultation was available as needed. Reviewers achieved 91% agreement (κ 0.81). The reviewers reached consensus on cases in which they disagreed.

Definition of surgical adverse events. For this study we defined surgical adverse events as adverse events related to an operation or a surgeon's nonoperative care or occurring within 30 days after an operation. One investigator reviewed all surgical adverse events to ensure the ICD-9 procedure code recorded the operation that resulted in an adverse event and not a subsequent reoperation. With use of ICD-9 codes, we then defined 15 types of operations that each accounted for 1% or more of all surgical adverse events: abdominal aortic aneurysm

Table I. Surgical adverse events in Colorado and Utah, by type of injury and preventability

Type of event	*Percent of surgical events (95% confidence interval)*	*Percent preventable*
Technique-related complications	24.2 (20.3-28.6)	68
Wound infection	11.2 (8.5-14.7)	23
Postoperative bleeding	10.8 (8.1-14.2)	85
Postpartum/neonatal related	8.3 (5.9-11.4)	67
Other infection	7.0 (4.9-10.0)	38
Drug-related injury	6.5 (4.5-9.4)	46
Wound problem (noninfectious)	4.0 (2.4-6.4)	53
Deep venous thrombosis	3.7 (2.3-6.1)	18
Nonsurgical procedure injury	2.6 (1.4-4.7)	59
Diagnostic error/delay	2.6 (1.4-4.7)	100
Pulmonary embolism	2.3 (1.2-4.3)	14
Acute myocardial infarction	2.1 (1.1-4.1)	0
Inappropriate therapy	2.0 (1.0-3.9)	100
Anesthesia injury	1.6 (0.8-3.5)	45
Congestive heart failure	1.2 (0.5-2.9)	33
Stroke	1.2 (0.5-2.9)	0
Pneumonia	0.9 (0.3-2.5)	65
Fall	0.3 (0.0-1.8)	50
Other	5.5 (3.6-8.2)	32
Injury not classified	2.1 (1.1-4.1)	73
Total	100.0	54

(AAA) repair, appendectomy, arthroscopy, cesarean section, cholecystectomy, colon resection, coronary artery bypass graft or heart valve replacement (CABG/valve surgery), hysterectomy, lower extremity bypass graft (BPG), oophorectomy or salpingectomy (without hysterectomy), open reduction with internal fixation of a fracture (ORIF), prostatectomy, spinal laminectomy or discectomy, total knee or hip replacement, and transurethral resection of the prostate or bladder tumor (TURP/TURBT). We placed all other surgical adverse events in 1 of 3 categories: other operations, vaginal child deliveries, and nonoperative admissions.

Population estimate calculations and statistical analysis. To avoid overrepresentation and underrepresentation of patients from particular types of hospitals, we report population estimates of adverse events, which were calculated by weighting the observed data according to standard methods.[28] For each of the sample hospitals, weights were calculated by dividing the number of discharges in its stratum during 1992 by the total number of records reviewed in the stratum. Adverse event rates are reported as the observed percentage of discharges with adverse events.

As in previous studies,[2] in calculating annual incidence rates we counted only events discovered during the sampled hospitalizations. Events that were detected during a subsequent hospitalization were excluded to avoid overstating incidence. We included all cases in the sample, however, when analyzing the nature of surgical adverse events. We calculated 95% confidence intervals for population estimates and *P* values for simple and multivariate analysis with use of weighted logistic regression. We performed all analyses with the SAS statistical software package, version 6.12.[29]

RESULTS

Patient characteristics. We completed initial review of 14,700 of 15,000 records (98.0%) in the original random sample. Patients were 38.9 years old on average in our sample compared with 38.2 years for all discharges, women were 61% of our sample and 59% of all discharges, Medicare beneficiaries were 24% of both groups, Medicaid beneficiaries were 15% of both groups, the privately insured were 47% of our sample and 46% of all discharges, managed care enrollees were 8% versus 11%, and the uninsured were 6% versus 5%. Whites were 72% of our sample.

Incidence, morbidity, and preventability. Among the 14,700 records in our sample, we identified 402 surgical adverse events. This was 66% of all adverse events. Three hundred fifteen events were attributable to surgical care that was provided in 1992. This represented 11,087 (confidence interval 9868 to 12,457) surgical adverse events in Utah and Colorado in 1992, producing an annual incidence rate of 1.9% (confidence interval 1.7% to 2.1%) of 1992 hospital admissions. Among patients coded as

Table II. Incidence of surgical adverse events among Colorado and Utah inpatients by type of injury, 1992

Type of event	*Incidence per 10,000 operations (95% confidence interval)*
Technique-related complications	90 (71-114)
Postoperative bleeding	47 (34-65)
Other infection	28 (18-42)
Wound infection	27 (17-42)
Drug-related injury	27 (17-41)
Deep venous thrombosis	14 (8-26)
Postpartum/neonatal related	11 (6-22)
Wound problem (noninfectious)	10 (5-21)
Acute myocardial infarction	10 (5-21)
Nonsurgical procedure injury	10 (5-20)
Diagnostic error/delay	9 (4-19)
Injury not classified	8 (4-19)
Pulmonary embolism	8 (4-18)
Inappropriate therapy	6 (3-16)
Anesthesia injury	6 (2-15)
Congestive heart failure	6 (2-15)
Stroke	6 (2-15)
Pneumonia	3 (1-11)
Fall	1 (0-10)
Other	19 (12-32)

having had an operation or childbearing during their 1992 admissions, the incidence of surgical adverse events was 3.0% (confidence interval 2.7% to 3.4%). Among nonsurgical patients, the likelihood of an adverse event was not significantly different.

We determined that 54.0% (confidence interval 48.9% to 58.9%) of surgical adverse events were preventable. The preventable surgical adverse event incidence rate among operative admissions was 1.9% (confidence interval 1.6% to 2.2%). We also found that 5.6% (confidence interval 3.7% to 8.3%) of surgical adverse events resulted in death, accounting for 755 deaths (confidence interval 481 to 1185 deaths) in Colorado and Utah in 1992. This represented an estimated 12.2% (confidence interval 6.6% to 22.4%) of all hospital deaths in the 2 states. Fifteen percent (confidence interval 11.8% to 18.9%) of surgical adverse events resulted in permanent disability or death in patients.

In multivariate analysis adjusting for age, gender, race, and Charlson score, increased risk of surgical adverse events was associated with older age (odds ratio 5.0 age 64 years versus age <15 years, confidence interval 3.0 to 8.4) and Charlson score more than 4 (odds ratio 1.57 versus score 0, confidence interval 1.03 to 2.39). Race and gender had no effect. Only age correlated significantly with an increased risk of a preventable adverse event.

Results by injury type, hospital location, and specialty. We studied the characteristics of all 402 surgical adverse events, which included injuries attributable to care that took place in another year. This represented an estimated 13,886 (confidence interval 13,014 to 14,707) surgical adverse events. The reviewer's level of confidence that injury was the result of medical management was "more likely than not" in 39% of cases, "strong evidence" in 45%, and "virtually certain evidence" in 16%. Charts for 85% of these cases contained a note acknowledging that management had caused the injury (but not necessarily that it was unavoidable).

Table I shows the types of injuries involved and their preventability. Three categories accounted for nearly half of all surgical adverse events: technique-related complications (24.2%), wound infections (11.2%), and postoperative bleeding (10.8%). Among the technique-related complications, 35% were the result of failure of the surgery to accomplish its intended purpose (for example, postoperative thrombosis of a lower extremity bypass graft, failed tubal ligation, or fracture nonunion after ORIF). The remainder were the results of complications of an otherwise successful surgery (for example, bladder laceration during hysterectomy or popliteal vessel injury during arthroscopy). Table II shows the incidence rates among operative admissions in the 2 states for specific complications severe enough to cause prolonged hospital stay, disability, or death. Serious technique-related complications occurred in 90 cases per 10,000 (of which 68% were preventable), wound infections in 27 cases per 10,000 (23% preventable), and postoperative bleeding in 47 per 10,000 (85% preventable).

In terms of location, patients were injured in the operating room or labor and delivery room in an estimated 74.1% (confidence interval 69.6% to 78.1%) of surgical adverse events. In terms of specialty, 3 types of surgeons—general surgeons, obstetrician-gynecologists, and orthopedists—accounted for 66.9% (confidence interval 62.2% to 71.4%) of surgical adverse events. Among nonsurgeons routinely involved in surgical care, management provided by anesthesiologists resulted in 0.9% (confidence interval 0.3% to 2.4%), and by nurses 0.2% (confidence interval 0% to 1.8%) of surgical adverse events.

Results by operative type. We identified 15 types of operations (Table III) that each resulted in at least 1% of surgical adverse events. Together these 15 accounted for 58% (confidence interval 53% to 63%) of surgical adverse events in Colorado and Utah (Table III). This group represented 20% (confidence interval 19% to 21%) of all admissions (including those to 2 hospitals that did not per-

Table III. Incidence and preventability of surgical adverse events in Colorado and Utah by type of operation, 1992

Type of operation	*Incidence of surgical adverse events (%)**	*Incidence of preventable surgical adverse events (%)†*
AAA repair‡	18.9 (8.3-37.5)	8.1 (2.2-25.5)
Lower extremity BPG‡	14.1 (6.0-29.7)	11.0 (4.2-26.1)
CABG/valve replacement‡	12.3 (7.9-18.7)	4.7 (2.3-9.7)
Colon resection‡	6.8 (2.9-14.8)	5.9 (2.4-13.8)
Cholecystectomy‡	5.9 (3.7-9.3)	3.0 (1.6-5.8)
Prostatectomy§	5.9 (2.3-14.3)	2.0 (0.4-9.5)
TURP/TURBT‡	5.5 (2.7-10.7)	3.9 (1.7-8.7)
Knee/hip replacement§	4.9 (2.9-8.4)	2.6 (1.2-5.5)
Spinal surgery§	4.5 (2.8-7.3)	1.6 (0.7-3.6)
Hysterectomy‡	4.4 (2.9-6.8)	2.8 (1.6-4.7)
ORIF	4.4 (2.2-8.7)	2.0 (0.7-5.6)
Cesarean section	3.1 (1.9-5.0)	1.7 (0.8-3.3)
Appendectomy‡	3.0 (1.4-6.6)	1.5 (0.5-4.5)
Oophorectomy-salpingectomy	2.9 (1.2-6.5)	2.0 (0.7-5.4)
Other operations	2.3 (1.9-2.8)	1.3 (1.0-1.7)

*Variation in surgical adverse event incidence was significant ($P = .0001$).

†Variation in preventable surgical adverse event incidence was significant ($P = .0001$).

‡Incidence rate for both surgical adverse events and preventable surgical adverse events significantly different from "other operations" ($P < .05$).

§Incidence rate for surgical adverse events significantly different from "other operations" ($P < .05$).

form any of these operations) and produced 37% (confidence interval 33% to 41%) of all adverse events. Preventability, permanent disability, and death resulting from these operations were not significantly different from other operations taken as a group.

Overall, the incidence of surgical adverse events ranged from 2.3% (of "other operations") to 19.0% (of arthroscopies) in 1992 in the 2 states (Table III and Figure). However, because it was unclear whether any uncomplicated arthroscopies were being performed on an outpatient basis in the 2 states in 1992, we do not present the results for arthroscopies in our incidence tables and figures. The incidence of preventable surgical adverse events that year ranged from 1.3% (of "other operations") to 11.0% (of lower extremity bypass grafts). The variation for both measures was statistically significant ($P = .0001$). All but 3 of the 15 operative types (oophorectomy-salpingectomy, cesarean section, and ORIF) had a higher incidence of adverse events than other operations ($P < .05$). When the operations were divided into 3 groups, the odds of a surgical adverse event for the tercile of operations with the highest incidence rates were 2.5 times that of the middle tercile (confidence interval, odds ratio 1.7 to 3.6); the odds of such events for the middle tercile were 2.1 times that of the tercile with the lowest incidence rates (confidence interval, odds ratio 1.6 to 2.7).

Compared with patients admitted for other operations, patients undergoing 8 of the 15 operations had a significantly higher incidence of preventable surgical adverse events in 1992 in the 2 states ($P < .05$): AAA repair, lower extremity BPG, CABG/valve surgery, colon resection, cholecystectomy, TURP/TURBT, hysterectomy, and appendectomy. In terms of the burden of injury, 4 operations accounted for just over a fourth of all surgical adverse events—hysterectomy, spinal surgery, CABG/heart valve replacement, and vaginal delivery (Table IV).

DISCUSSION

Contrary to a perhaps-common perception, our study of hospitalized patients in Colorado and Utah in 1992 found that adverse events resulting in death, disability, or a prolonged hospital stay were no more likely to occur in surgical care than in nonsurgical care. Overall, such adverse events occurred in approximately 3% of admissions in the 2 states in 1992. How much the incidence of adverse events varies by region is unknown, but this could represent a decline from previous incidence rates of 3.7% of New York admissions in 1984 and 4.6% of California hospital admissions in 1972 obtained in studies that used similar methods.

Nonetheless, admitted patients were highly likely to see a surgeon for at least part of their care. Thus two thirds of all adverse events were surgical. Consistent with previous findings,[12] more than half of surgical adverse events were preventable and

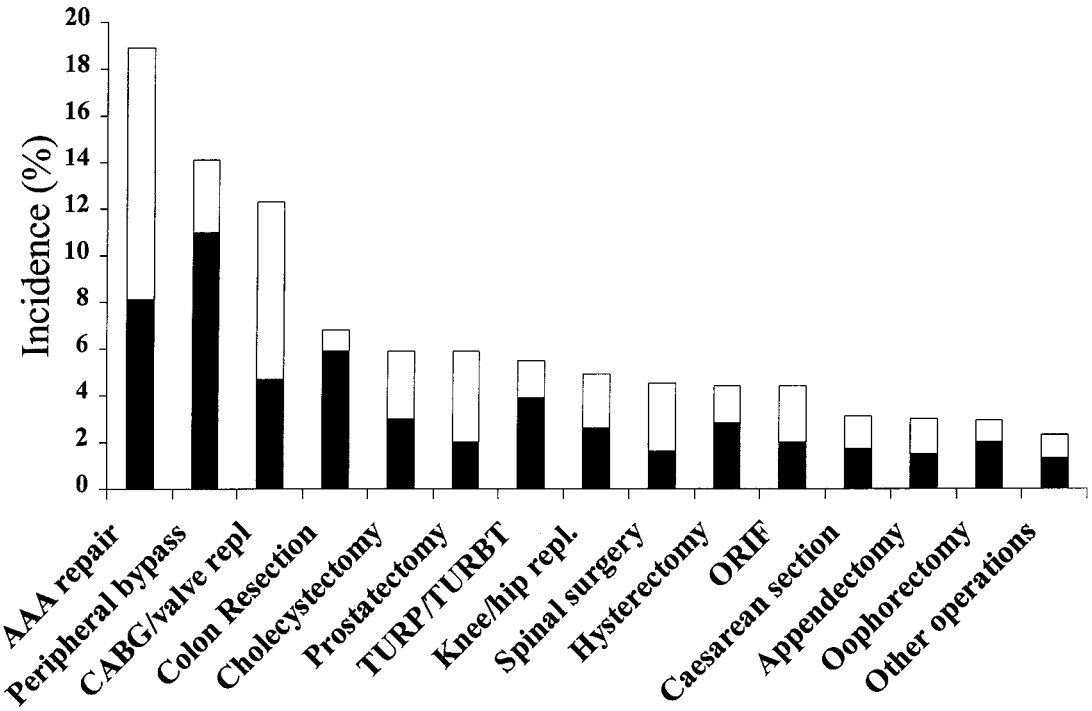

Fig 1. 1992 Incidence of surgical adverse events in Colorado and Utah by type of operation. Bar height indicates incidence rate for any surgical adverse event for inpatients who received that type of operation. Shaded portion indicates incidence rate for preventable surgical adverse event.

Table IV. Distribution of surgical adverse events in Colorado and Utah by type of operation or procedure

Type of operation	*Percent of all surgical events*
Hysterectomy	7.7 (5.5-10.7)
Spinal surgery	6.6 (4.5-9.5)
CABG/valve replacement	6.0 (4.1-8.8)
Vaginal child delivery	5.8 (3.9-8.5)
Cholecystectomy	5.1 (3.3-7.7)
Knee/hip replacement	5.1 (3.3-7.7)
Nonoperative surgical care	4.7 (3.0-7.3)
Cesarean section	4.6 (3.0-7.2)
Appendectomy	3.3 (1.9-5.5)
TURP/TURBT	2.8 (1.6-5.0)
ORIF	2.8 (1.6-4.9)
Oophorectomy-salpingectomy	2.4 (1.3-4.4)
Arthroscopy	2.3 (1.2-4.3)
Colon resection	1.7 (0.8-3.6)
Lower extremity BPG	1.7 (0.8-3.6)
Prostatectomy	1.7 (0.8-3.5)
AAA repair	1.5 (0.7-3.3)
Other operations	34.2 (29.7-38.9)

nearly 1 in 7 resulted in permanent disability or death. Overall, the burden from these iatrogenic injuries was substantial: 12.2% of hospital deaths were associated with adverse events arising from surgical care. These data suggest that efforts to better understand surgical adverse events, to identify their patterns and risk factors, and ultimately to develop strategies to reduce their incidence could be important. Our findings provide direction for such efforts and, for the first time, reveal some of the patterns.

The results showed that, not surprisingly, most surgical adverse events involve complications of intraoperative management. Technique-related complications constituted the largest proportion—nearly a fourth—of surgical adverse events. This is something of a catch-all category, however, and what factors contribute to technical complications is currently not well understood. Adverse events related to nonoperative aspects of the care of surgical patients proved surprisingly important as well. Drug-related errors, diagnostic errors, and errors in choice of therapy accounted for 12% of surgical adverse events. Further work is needed to discover how both nonoperative and operative injuries occur, what the primary contributing factors are, and the approaches most likely to produce improvement.

The incidence rates for individual complications may appear to be lower than in other series. For example, wound infections are estimated to occur in 2% of clean cases,[30] whereas we found that adverse events resulting from wound infection

occurred in 0.3% of operations. The discrepancy likely occurs, however, because we have only sought to detect serious complications—that is, those that result in prolonged hospital stay, disability, or death.

We found that just 15 types of operations accounted for 58% of surgical adverse events and for 37% of all hospital adverse events. In some cases, adverse event rates were unexpectedly high, such as in AAA repair (18.9%), lower extremity BPG (14.1%), CABG/valve surgery (12.3%), colon resection (6.8%), and cholecystectomy (5.9%). For 8 of these operations (AAA repair, appendectomy, CABG/valve surgery, cholecystectomy, colon resection, hysterectomy, lower extremity BPG, and TURP/TURBT), the rate of preventable adverse events was significantly elevated as well. It is not clear why some operations result in high rates of injury. Surgical complexity may be an influence. For example, it may not be all that surprising that vascular and cardiac operations had high rates. Also, patient characteristics seem to be a factor. We found that age more than 64 years and an elevated Charlson comorbidity score significantly increased the risk of a surgical adverse event for patients. This may reflect greater exposure to riskier surgeries and an inability to weather complications as readily as others. However, operations such as hysterectomy and cholecystectomy carry high adverse event rates yet do not seem unusually complex or prone to involving older, less healthy patients.

Our civil liability system and the media—and sometimes even morbidity and mortality conferences—have traditionally treated adverse events as the failings of individual physicians, the "Theory of the Bad Apples."[31,32] However, a different approach focusing on systemic causes has proved successful in several arenas of surgery. Goldman et al[33] showed that postoperative cardiac complications often can be predicted in advance and spurred research showing that the risk of such complications could be reduced through modifications in patient management before, during, and after surgery.[34-36] Research first done by Luft et al[37] showing the relationship between hospital volume and surgical mortality led to a reduction of complications in high-risk procedures through regionalization.[38-40] Complementing these traditional epidemiologic studies, some investigators have advocated the use of human factors techniques to identify causes of suboptimal performance in the operating room.[41,42] Such approaches have led to strategies that have produced substantial reductions in accidents in drug administration[7-9] and in anesthesia.[43]

Although we have identified important patterns of iatrogenesis in surgical care, it is clear that surgical adverse events arise in a diversity of ways. Thus future efforts will need to identify not just how to improve particular operations and aspects of care but also how surgeons and systems that perform well across the full range of surgical tasks differ from those that perform less well. A large variety of factors have been asserted to cause poor surgical outcomes: inexperience of the surgeon,[44-46] subspecialty training,[47] low hospital volume for the surgery in question,[37,48,49] lack of optimal technology,[15] inadequate hospital systems,[50] poor communication among staff,[51] time of day,[15] insufficient staffing,[52] and the effects of managed care and for-profit enterprises,[52-54] among others. Nonetheless, surgeons remain uncertain about the importance of individual and organizational factors. As 1 small example, subspecialization within surgery has been proposed as a method to improve patient outcomes. However, it remains unclear whether subspecialization or regionalization is more important. Further research is needed to identify the systems strategies that will most effectively reduce surgical adverse events. Our findings identify a group of operations with a high incidence of adverse events that should be the first target of improvement efforts both by researchers and by individual surgical departments.

The reliability of judgments about adverse events is an important concern for this study. A previous analysis of the Harvard Medical Practice Study methods found that nurse screening of charts for possible adverse events was highly reliable (the negative predictive value was 92%).[24] The more complex determination, however, is the physician reviewer's judgment about whether an adverse event occurred. We found that the reliability of physician determinations was only moderate (κ 0.4). However, this was similar not only to results of previous studies[2,21] but also to the reliability of commonly used diagnostic tests such as screening mammography (κ 0.47).[55] As in other studies,[27] physician judgments of the preventability of adverse events had excellent reliability (κ 0.81), indicating that determinations of whether an iatrogenic injury was preventable are generally more clear cut.

The use of inpatient medical records to identify adverse events has other limitations. Given the growth of ambulatory surgery, we may have missed a subset of surgical adverse events. We also missed adverse events in patients who received care at a sample hospital but then went to a nonsample hospital for care of complications. Furthermore, record review captures only adverse events documented in patient records. All these factors can lead to an underestimate of adverse events.

Our hospital selection ensured a representative sample of patients, but the hospitals within each stratum were not randomly selected. Therefore selection bias could have altered our estimates of adverse event rates if hospitals with poor or high quality of care did not participate. However, all the hospitals approached agreed to participate and the investigators had no prior knowledge of any hospital's adverse event rate. Because our data are from hospitalizations in 1992, changes in the health care system and surgical practices since then may have altered the incidence and nature of surgical adverse events. Finally, results from Colorado and Utah may not be generalizable to the country as a whole.

In summary, we found that surgical adverse events are often morbid, preventable, and concentrated in a few common types of operations. After recent successes in research and development to reduce anesthesia deaths and drug-related adverse events, surgical adverse events are logically the next "frontier" for efforts to improve quality and performance in medical care. Our findings provide an initial understanding of the characteristics of these events. They also provide direction to focus future quality assurance efforts and research programs.

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