Patterns of Technical Error Among Surgical Malpractice Claims

An Analysis of Strategies to Prevent Injury to Surgical Patients

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Objective: To identify the most prevalent patterns of technical errors in surgery, and evaluate commonly recommended interventions in light of these patterns.

Summary Background Data: The majority of surgical adverse events involve technical errors, but little is known about the nature and causes of these events. We examined characteristics of technical errors and common contributing factors among closed surgical malpractice claims.

Methods: Surgeon reviewers analyzed 444 randomly sampled surgical malpractice claims from four liability insurers. Among 258 claims in which injuries due to error were detected, 52% (n = 133) involved technical errors. These technical errors were further analyzed with a structured review instrument designed by qualitative content analysis.

Results: Forty-nine percent of the technical errors caused permanent disability; an additional 16% resulted in death. Two-thirds (65%) of the technical errors were linked to manual error, 9% to errors in judgment, and 26% to both manual and judgment error. A minority of technical errors involved advanced procedures requiring special training ("index operations"; 16%), surgeons inexperienced with the task (14%), or poorly supervised residents (9%). The majority involved experienced surgeons (73%), and occurred in routine, rather than index, operations (84%). Patient-related complexities—including emergencies, difficult or unexpected anatomy, and previous surgery—contributed to 61% of technical errors, and technology or systems failures contributed to 21%.

Conclusions: Most technical errors occur in routine operations with experienced surgeons, under conditions of increased patient complexity or systems failure. Commonly recommended interventions, including restricting high-complexity operations to experienced surgeons, additional training for inexperienced surgeons, and stricter supervision of trainees, are likely to address only a minority of technical errors. Surgical safety research should instead focus on improving decision-making and performance in routine operations for complex patients and circumstances.

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The morbidity and cost of medical injuries have inspired broad interest in strategies to reduce preventable adverse events. Research showing that between one-half and two-thirds of hospital adverse events are attributable to surgical care[1–3] has brought the need for safety interventions in surgery to the forefront.[4,5] The design and success of such efforts, however, depend on improving our understanding of the etiology of surgical error.

The causes of error in medical care[6–8] may not be easily generalized to surgery because these specialties differ in important ways. In particular, most surgical errors occur in the operating room[1,3,9] and are technical in nature.[2,3,9] Technical errors are defined to include direct manual errors (such as transection of the ureter during hysterectomy) as well as judgment and knowledge errors leading to performance of an inappropriate, inadequate, or untimely procedure (for example, performing simple cholecystectomy for invasive adenocarcinoma of the gallbladder, or failing to intervene promptly in a patient with a leaking aortic aneurysm). They can occur in any phase of care, and are pervasive in surgery.

The key causes of technical error in surgery remain poorly understood, although a number of factors have been identified. Surgical complications and adverse outcomes have been linked to lack of surgeon specialization,[10,11] low hospital volume,[12–15] communication breakdowns,[3,15a,16–18] fatigue,[19] surgical residents and trainees,[20] and numerous other factors. Research linking surgical volume to patient outcomes in high-complexity operations[11,21–25] implies that low-volume surgeons or younger, inexperienced surgeons[23,26] are an important source of error.

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The importance of risk adjustment in comparisons of postoperative mortality rates suggests that patients' comorbidities and operative complexity are key factors.[27,28]

Each of these factors leads to hypotheses about the causes of surgical error, and suggest a variety of specific interventions, such as mentoring, consultation, and extended training for young surgeons,[26] selective referral to high-volume providers,[12] restrictions on privileging for high-complexity operations,[26] or development of specific risk-reduction strategies for high-risk circumstances. Prioritization, however, depends on understanding which contributing factors are most important, and this has remained unknown for several reasons. Studies of surgical complications using administrative data have lacked sufficient clinical detail,[29,30] and chart reviews,[2] observational studies,[31,32] and "root cause analyses"[33] have proved too time- and labor-intensive to replicate on a large scale.

To date, closed malpractice claims have been rarely used because of concerns about confidentiality, unfounded litigation, and generalizability.[34] Yet, this data source offers a very broad catchment point for studying serious injuries, and the claim records supply detailed clinical and contextual information about the care provided.[35–37] In this study, we used a large national database of surgical malpractice claims[9] to identify and analyze a set of technical errors that resulted in serious injury to surgical patients.

METHODS

Derivation of Study Sample

Data for this analysis came from a previous study, in which surgeons reviewed 444 closed surgical malpractice claims and identified 258 in which an error resulted in injury to a surgical patient. In 135 of these 258 claims (52%), reviewers judged that technical error was a contributing factor. We excluded 2 claims in which the technical error was attributed to an anesthesiologist. The remaining 133 "study cases" constitute the sample used for this secondary analysis (Fig. 1).

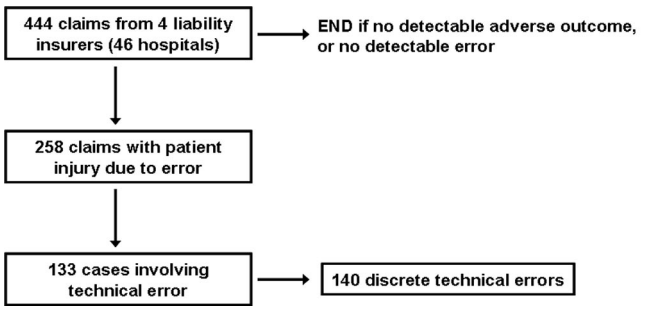

FIGURE 1. Case selection. In the Malpractice Insurers Medical Error Prevention Study, 444 randomly selected closed malpractice claims involving surgical care were reviewed, and 258 were found to involve 1 or more errors (according to the Institute of Medicine definition[6]) resulting in patient injury.[9] Of those claims, there were 133 cases of technical error. In this study, those 133 cases were reviewed, and 140 discrete technical errors were identified for analysis.

The methods for the parent study are described in detail elsewhere.[9] We summarize them briefly here, and then describe in detail the methods associated with the secondary analysis.

Study Sites and Primary Review of Claim Files

The sample of closed malpractice claims for the parent study came from 4 malpractice insurance companies based in 3 US regions (Northeast, Southwest, and West). The participating insurers covered approximately 21,000 physicians, 46 acute care hospitals (20 academic and 26 nonacademic), and 390 outpatient facilities. The claims were closed between 1986 and 2004 and alleged injuries sustained between 1980 and 2002. Eighty-eight percent of the claims were closed in 1994 or later, and 80% of the injuries occurred in 1990 or later.

Each insurer's administrative database was used to identify surgical claims, defined as those claims alleging substandard care in or related to an operation, or failure to provide a timely and appropriate operation. We sampled randomly among claims meeting this definition, with each insurer contributing to the overall study sample in proportion to its annual claims volume.[38] Senior surgical residents, surgical fellows, and board-certified surgeons from each insurer's locale conducted on-site reviews of the claim files. The claim files included medical records associated with the episode of care in dispute. The reviewers used a structured review instrument. They were oriented to claim files and trained in the use of the instrument in 1-day training sessions run by the investigators.

Definitions of Key Variables

Error was defined according to the Institute of Medicine definition: "the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (ie, error of planning)."[6] Technical errors were those for which reviewers believed that an error of operative technique contributed to the adverse outcome, either because of manual error (error of execution with a direct physical act causing injury to viscera, vasculature or other tissue, inadequate repair, or failure to relieve symptoms) or judgment or knowledge error (error of planning such as wrong timing or selection of procedure, failure to diagnose complications, or wrong site surgery).

The primary reviewers rated injury severity according to the National Association of Insurance Commissioners' Injury Severity Scale.[39] In the secondary review, we defined "index operations" as high-complexity, subspecialty operations for which additional training and specialization beyond a standard residency and/or fellowship is usually required (eg, esophagectomy for a general surgeon, radical hysterectomy for an obstetrician-gynecologist, or multilevel laminectomy for an orthopedic surgeon). We classified as urgent any unscheduled operation for an acute condition in which intervention was required promptly; the rest were classified as elective or scheduled.

In the primary review, the physician-reviewers typically recorded information on the experience level of the surgeon(s) involved in technical errors, such as number of

years in practice, specialty training, and/or volume of experience with the specific procedure. This information came from a combination of evidence from the claims file and—because reviewers were recruited from among clinical staff at insured institutions and were not blinded to personnel identifiers in the review—local knowledge of the practitioners, institutions, and care context. In the secondary review, we used this information to examine the role of experience in technical error. Otherwise experienced surgeons were considered to be operating outside their area of expertise if they lacked significant experience with the particular operation, diagnosis, or situation in which the error occurred.

The secondary review also examined 2 contributing factors whose definition is not self-evident: handoffs and ambiguity of responsibility. A handoff in care occurs when there is complete transfer of care from one provider to the next and the first agent physically leaves the scene.[40] Ambiguity of responsibility refers to a situation in which duty assignments for patient care have not been clearly defined.

Secondary Review and Analysis

To evaluate the factors contributing to technical errors, we used directed qualitative content analysis techniques[41] to compose a structured review instrument using a list of human and system factors that have been documented in the literature as important contributors to technical error.[4,5,16,31,32,42–44] Because of their relevance to prevailing hypotheses about the causes of technical error,[3,12,26,45] we focused on the relative frequency of the following variables: index versus routine operations, the relative contribution of experienced versus younger and/or lower-volume surgeons, and the frequency of trainees' contribution to failures.

For each study case, 2 surgeon-reviewers (S.E.R. and C.C.G.) independently reviewed the data extracted in the primary review, including a series of text fields describing the nature of the clinical circumstances, error, and injury.[9] We allowed each study case to have more than 1 technical error, providing that the errors were discrete. Secondary reviewers characterized each technical error according to the a priori definitions and classifications described earlier. At the completion of the independent review, the reviewers discussed discrepancies and reached consensus. The original classifications were retained for purposes of reliability testing.

Statistical Analysis

Our study was primarily descriptive, with each discrete technical error as the unit of analysis. We compared frequencies of categorical variables using χ^2 tests. We measured interrater reliability for the secondary review by pairing the reviewers' judgments and calculating unweighted kappa statistics.[46] Because some cases included more than 1 error, we used generalized estimating equation techniques[47] to account for clustering, but the results were almost identical to those generated by standard analyses assuming independence. For simplicity, only the standard analysis is presented here. All analyses were performed using the SAS 9.1 statistical software package (SAS Institute, Cary, NC).

RESULTS

Characteristics of Cases and Errors

Among the 133 study cases, we identified 140 discrete technical errors (range 1–2 per case; Fig. 1). Characteristics of the errors are displayed in Table 1. Attending surgeons were responsible for 97 (69%) of the errors, and another 38 (27%) involved both attending physicians and trainees. Only 5 errors (4%) were attributed to surgical residents or fellows alone. The most common types of operations associated with the errors were general or gastrointestinal surgery (31%), spine surgery (15%), gynecologic surgery (12%), and nonspine orthopedic surgery (9%).

Most of the technical errors caused serious injury to patients. Forty-nine percent resulted in permanent disability (68 of 140), and an additional 16% resulted in death (22 of 140).

Ninety-one percent of the technical errors involved manual error and 35% involved judgment or knowledge error (Table 2). Nearly two-thirds (65%) of the technical errors

TABLE 1. Characteristics of the 140 Technical Errors

Case Characteristics	N	%
Clinician(s) responsible for failures		
Attending surgeons only	97	69
Residents or fellows only	5	4
Both attending surgeons and residents or fellows	38	27
Specialty of operation		
General and gastrointestinal surgery	44	31
Spine surgery	21	15
Gynecologic surgery	17	12
Nonspine orthopedic surgery	12	9
Cardiothoracic surgery	11	8
Otolaryngology	10	7
Plastic surgery	7	5
Urology	5	4
Nonspine neurosurgery	5	4
Ophthalmology	4	3
Vascular surgery	3	2
Oral and maxillofacial surgery	1	1
Status of operation		
Elective/scheduled	116	83
Urgent/emergency	24	17
Type of operation		
Index operation (advanced, high-complexity)	22	16
Routine operation	118	84
Type of technical error involved		
Manual error only	91	65
Knowledge/judgment error only	13	9
Both manual and knowledge/judgment errors	36	26
Severity of injury		
Temporary minor disability	22	16
Temporary major disability	28	20
Permanent disability	68	49
Death	22	16

TABLE 2. Subtypes of Manual Versus Judgment/Knowledge Errors

Description of Event	N	%*
Manual errors	127	91
Incidental injury to viscera or other anatomy	48	34
Breakdown of repair or failure to relieve condition	23	16
Hemorrhage	22	16
Peripheral nerve injury	20	14
Misplacement or improper choice of prosthesis	10	7
Retained surgical equipment, due to error of technique	4	3
Judgment/knowledge errors	49	35
Delay or error in intraoperative diagnosis and/or treatment	23	16
Incorrect procedure or technique chosen	13	9
Wrong site of operation	10	7
Failure to change operative plan in light of contraindication or intraoperative findings	3	2

*Percentages total more than 100% because 36 errors involved both manual and judgment/knowledge errors.

involved manual error only; 26% had both manual and judgment or knowledge components; few involved solely knowledge or judgment errors (9%).

The specific types of errors are arrayed in Table 2. The most common type of manual error involved incidental visceral injury (34%), followed by breakdown of operative repair or failure to relieve the disease (16%), hemorrhage (16%), and peripheral nerve injury (14%). The most common type of judgment or knowledge error was delay or error in intraoperative diagnosis or management (16%), which often consisted of failure to recognize an intraoperative complication. Other relatively frequent judgment or knowledge errors included incorrect choice of procedure or technique (9%) and wrong operative site (7%).

Operative Complexity and Surgeon Experience Level

A minority of the technical errors involved index operations (16%), inexperienced surgeons (8%), surgeons operating outside their area of expertise (5%), or unexpected events that required skills outside a surgeon's area of expertise (1%) (Fig. 2). Eighteen failures (13%) were attributed to surgical trainees, but only 13 (9%) occurred in the absence of adequate supervision by an attending surgeon.

A majority (84%) of the technical errors involved routine operations, and 73% involved experienced surgeons operating within their area of expertise and training. When stratified by complexity of the operation, experienced surgeons accounted for 68% of technical errors among index operations and 74% of errors among routine operations. This difference was not statistically significant ($P = 0.59$).

Contributing Factors in Technical Errors

Overall, 69% of technical errors involved complicating factors (Table 3), related either to the patient (61%) or to human or systems factors (21%). The leading patient-related complexities were difficult or unusual anatomy (25%), reoperation (20%), and urgent or emergency operations (17%). Equipment-use problems (16%) accounted for the majority of human or systems factors.

These complicating factors occurred with equal frequency among technical errors at the hands of experienced surgeons and those at the hands of inexperienced surgeons or trainees (69% vs. 71%; $P = 0.78$). Experienced surgeons' technical errors were significantly more likely to involve difficulties because of repeat operations (25% vs. 8%; $P = 0.03$) and were significantly less likely to involve equipment-use problems (12% vs. 29%; $P = 0.01$). Otherwise, there were no significant differences in the distribution of contributing factors.

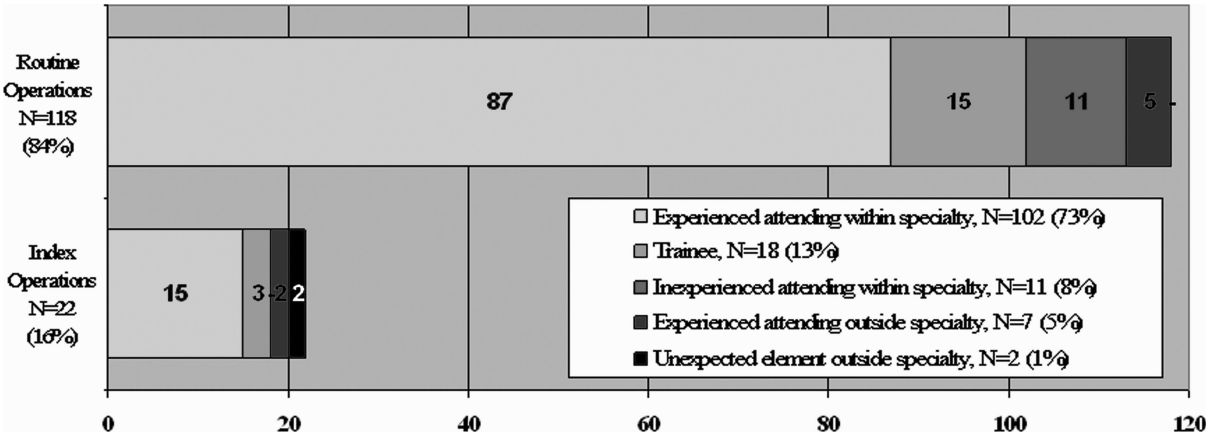

FIGURE 2. Surgeon experience level in 140 technical errors among index operations (advanced procedures requiring special training) versus routine operations. Index operations are high-complexity, subspecialty procedures for which additional training and specialization beyond a standard residency and/or fellowship is usually required. All other operations are considered routine. Surgeons' experience level was ascertained from their number of years in practice, specialty training, and volume of experience with the specific procedure.

TABLE 3. Contributing Factors in Technical Errors

Contributing Factor	Total N = 140, N (%)	Experienced Surgeons N = 102, N (%)	Others* N = 38, N (%)	$P^{\dagger}$
Patient-related complexity	85 (61)	64 (63)	21 (55)	0.42
Difficult or unusual anatomy or operative findings	35 (25)	24 (24)	11 (29)	0.51
Reoperation	28 (20)	25 (25)	3 (8)	0.03
Urgent/emergency operation	24 (17)	15 (15)	9 (24)	0.21
Medical comorbidity	8 (6)	8 (8)	0 (0)	0.08
Human/systems factors	29 (21)	16 (16)	13 (34)	0.02
Equipment-use problems	23 (16)	12 (12)	11 (29)	0.01
Ambiguity of responsibility	6 (4)	4 (4)	2 (5)	0.73
Handoff of care	6 (4)	4 (4)	2 (5)	0.73
Any of the above	97 (69)	70 (69)	27 (71)	0.78

Data are presented as frequencies and column percentages.
*Includes residents, fellows, inexperienced surgeons, and surgeons operating outside their area of expertise.
$^{\dagger}\chi^2$ test.

Interrater Reliability Measures

The kappa statistics measuring interrater reliability of the secondary reviewers' judgments on contributing factors ranged from 0.69 to 0.98, indicating very good to excellent overall agreement.[46]

DISCUSSION

Focusing on technical errors discovered in surgical malpractice claims, we have identified important underlying patterns that can inform injury prevention efforts in surgery. Almost three-fourths of technical errors in this study involved fully trained and experienced surgeons operating within their area of expertise and 84% occurred in routine operations, for which advanced expertise beyond a standard training program is not required or expected. These errors occurred predominantly in situations complicated by comorbidity, complex anatomy, repeat surgery, or equipment problems.

These findings advance a different set of surgical safety priorities from those suggested by other lines of health services research in surgery. For example, the volume-outcome relationship demonstrated in large database studies of high-complexity operations[11,13,15,22,48] has been taken to imply that poor outcomes are primarily the result of inexperience. However, lower-complexity operations are far more common than the advanced procedures for which the strongest volume-outcome relationships have been shown. Accordingly, the overall burden of technical errors in this study sample was heavily concentrated among routine operations. Further, among both routine and index operations in our sample, the surgeons responsible for technical errors were well-experienced in more than two-thirds of the cases. Neither selective referral,[14] nor regionalization,[12] nor limitation of privileging[26] for high-complexity operations would be expected to directly address errors in these more common situations.

To have a major initial impact, strategies to reduce patient harm from surgical error must address the most prevalent types of failures. Our findings suggest that significant potential may reside in strategies to improve decision-making, operative planning, and team performance for common operations, particularly under high-risk circumstances such as emergencies, reoperation, or patients with unusually difficult anatomy. There is, unfortunately, little evidence to guide interventions in this area, because management of the high-risk surgical patient has received comparatively little attention.[49,50] In obstetrics, recognition of a similar difficulty led to the creation of Maternal-Fetal Medicine, a specialty focused on the management of complicated pregnancy.[51] Surgery could follow suit—perhaps a natural role for the nascent specialty of "acute care surgery"[52]—or could investigate strategies such as peer consultation and collaboration,[53] implementation and standardization of evidence-based perioperative processes of care,[54] team training,[55] and simulation[56,57] for difficult circumstances.

There are several limitations to our study. We cannot determine the relative incidence of the contributing factors—only their prevalence within our claims sample—because we lack a denominator (ie, the total quantity of cases from which these claims were derived). Our findings are, however, consistent with a previous study from our group, showing that a majority of surgical adverse events occur among a set of just 15 common operations.[2] Patterns of error in malpractice claims could differ from those in a broader sample of surgical adverse events, although we know of no reason why they would. Malpractice claims are known to over-represent severe injuries and younger patients.[36] However, the main causal pathways in the subset of surgical errors that proceed to litigation are unlikely to be systematically different from those in surgical errors that go unlitigated. In addition, the over-representation of teaching hospitals and academic surgeons in our study sample may have led to an underestimate of the role of inexperienced surgeons in technical errors as a whole, and an overestimate of the prevalence of index operations.

Nevertheless, there are several reasons to think that the errors identified in malpractice claims are of particular concern. First, to prevent the largest number of injuries, we must address the most prevalent contributors to harmful technical errors, not necessarily the operations with the highest error rates. Second, cases identified from malpractice claims typically involve serious injury[9,35,37]—16% of errors in this study

(as well as 23% of the total sample from which they were drawn[9]), resulted in death, and an additional 49% caused permanent disability—precisely the cases we most want to prevent. Third, because large malpractice insurers cover thousands of physicians and reflect upon the care provided to hundreds of thousands of patients, they represent a powerful catchment point for information on errors. This highly enriched source of technical errors would be extremely difficult to accrue by any other means. Finally, by drawing together documentation from both formal legal documents, such as depositions and interrogatories, and confidential internal investigations, claim files present a substantially richer body of information about the antecedents of medical injury than the medical record alone.[37]

In summary, we have used surgical malpractice claims data to inform priorities for improving surgical safety. We find that technical errors resulting in serious injury to surgical patients occur most often in routine operations conducted by experienced surgeons, but with complex patients and/or circumstances. Volume- or experience-based restrictions on privileging for high-complexity operations, expanded training for young surgeons, and limitations on the practice of surgical residents each address only a minority of the errors we observed. Although these interventions may have broad effect in combination, our data suggest that to prevent the largest number of injuries and make greatest improvements in surgical safety, further research should focus on designing targeted interventions to improve decision-making and performance in routine operations for high-risk patients and circumstances.

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