Complications in Surgical Patients

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Hypothesis: Complications are common in hospitalized surgical patients. Provider error contributes to a significant proportion of these complications.

Design: Surgical patients were concurrently observed for the development of explicit complications. All complications were reviewed by the attending surgeon and other members of the service and evaluated for the severity of sequelae (major or minor) and for whether the complication resulted from medical error (avoidable) or not.

Setting: University teaching hospital with a level I trauma designation.

Patients: All inpatients (operative or nonoperative) from 4 different surgical services: general surgery, combined general surgery and trauma, vascular surgery, and cardiothoracic surgery.

Main Outcome Measures: Total complication rate (number of complications divided by the number of patients) and the number of patients with complications. Complications were separated into those with major or minor sequelae and the proportion of each type that were due to medical error (avoidable). Rates of complications in a recent Institute of Medicine report were used as a criterion standard.

Results: The data for the respective groups (general surgery, vascular surgery, combined general surgery and trauma, and cardiothoracic surgery) are as follows. The number of patients was 1363, 978, 914, and 1403; number of complications, 413, 409, 295, and 378; total complication rate, 30.3%, 42.4%, 32.3%, and 26.9%; minor complication rate, 13.3%, 19.9%, 13.5%, and 13.0% (percentage of minor complications that were avoidable, 37.4%, 59.0%, 51.2%, and 49.3%); major complication rate, 16.2%, 21.1%, 18.1%, and 12.9% (percentage of major complications that were avoidable, 53.4%, 60.7%, 38.8%, and 38.7%); and mortality rate, 1.83%, 3.33%, 2.28%, and 3.34% (percentage of mortality that was avoidable, 28.0%, 44.1%, 19.0%, and 25.0%).

Conclusions: Despite mortality rates that compare favorably with national benchmarks, a prospective examination of surgical patients reveals complication rates that are 2 to 4 times higher than those identified in an Institute of Medicine report. Almost half of these adverse events were judged contemporaneously by peers to be due to provider error (avoidable). Errors in care contributed to 38 (30%) of 128 deaths. Recognition that provider error contributes significantly to adverse events presents significant opportunities for improving patient outcomes.

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A RECENT Institute of Medicine (IOM) report has suggested that as many as 98000 patients die annually in the United States as a result of medical error.1 This report has been criticized because of its reliance on retrospective review of medical records by outside reviewers several years after the hospital admissions.2-4 Some5-8 have suggested that the report significantly overestimates the rate of medical error. Most literature reporting complication rates does not differentiate complications due to medical error from those due to patient disease.

This work was undertaken to determine the incidence of complications in surgical patients at our institution and to ascertain the proportion of these that result from medical error. To do this, we used a prospectively designed method to concurrently screen all surgical patients for explicit complications.

We hypothesized that some of the complications occurring in surgical patients are due to medical error. We further hypothesized that by separating complications into disease related (unavoidable) and provider related (avoidable) and by determining factors contributing to errors, it would be possible to identify areas for improvement in surgical care.

RESULTS

The rate of compliance with the protocol for data completion varied between 96% and 100%; and for assessment of out-
This project was performed in compliance with the Investigational Review Board of the University of Vermont, Burlington. From January 1, 2000, to June 30, 2001, patients treated by 4 representative surgical services of the University of Vermont Teaching Hospital/Level I Trauma Center were prospectively monitored for the development of complications. The 4 services were as follows: general surgery, composed of 4 general surgeons with specialty interest in colorectal surgery, bariatric surgery, and hepatobiliary surgery; vascular surgery, composed of 5 board-certified vascular surgeons with practices confined to vascular surgery; combined general surgery and trauma, a trauma/burn/emergency and general surgery service with 3 fellowship-trained trauma surgeons with added qualifications in surgical critical care; and cardiothoracic surgery, a cardiothoracic service with 4 board-certified cardiothoracic surgeons performing approximately 800 cardiac procedures per year and thoracic and thoracic aortic surgery.

At admission, each patient had a data sheet initiated by the house staff (data available from the authors). The patient was assessed daily for complications chosen from a service-specific list. At hospital discharge, the data were entered into the Surgical Activity Tracking System (SATS) database. This database contains patient demographics, a unique identifier for the patient admission, and information about complications that occurred. To capture all complications, the SATS database was cross-referenced with 2 additional databases: the hospital discharge database, to identify those patients admitted to a surgeon; and the billing database, to identify all patients (inpatient or outpatient) undergoing a surgical procedure. Any patients missing from the SATS database were thereby identified, and a data entry sheet was forwarded to the appropriate service for completion.

For all patients with complications, a second data sheet was generated (available from the authors), which was then completed by the attending surgeon in collaboration with his or her peers. The complication was evaluated for duration of sequelae (temporary or permanent), severity (major or minor), causation, and mitigating or extenuating factors. Complications were considered major if they caused or prolonged hospitalization, required an invasive procedure to treat, or resulted in a change of functional status. The same complication could be considered major in one patient and minor in another. For example, cellulitis of the leg that required hospital admission, intravenous antibiotics, and immobilization following a varicose vein excision would be considered a major complication. On the other hand, a patient who had experienced multiple trauma who is intubated, bedridden, and already receiving appropriate antibiotics for other indications would sustain little additional impact from leg cellulitis, and the complication would be considered to have minor sequelae.

Complications were deemed avoidable when there were deficiencies in care as assessed by the surgeon’s own peer.
The cardiothoracic surgery service is a contributing member of the Northern New England Cardiovascular Disease Study Group, which is a multicenter study group that monitors risk-adjusted mortality rates for each of its 9 centers. This group has published aggregate data indicating better outcomes than previously published. During the study period, the risk-adjusted morbidity and mortality rates for the patients admitted to the cardiothoracic surgery group at our institution were not statistically different from those of the other hospitals in the group (Bruce Leavitt, FACS, unpublished data, 2001).

The IOM report suggested raw complication rates for hospitalized patients of 2.9% to 3.7%. Our patient complication rates are 4 to 6 times higher than this. The reasons for this difference are as follows.

For the entire cohort, 46% of the complications were assessed as minor, and 49% of these were felt to be avoidable, although the rates varied by service (Table 5). The most common cause of an avoidable minor complication was technical error (Table 5).

For the entire cohort, 52% of the complications were assessed as major. Of these, 49% were judged to be avoidable. The most frequent cause of an avoidable major complication was technical error (68% overall) (Table 6). Deaths in each group were classified as either avoidable or unavoidable (Table 7). Preventable and potentially preventable deaths were combined under the avoidable or unavoidable.
They provide a single retrospective review by a team of outside reviewers. Although our outcomes compare favorably with those from studies used as criterion standards, our method differs in several important respects. The large, retrospective, population-based studies that form the basis of the IOM report were not confined to surgical patients. First, the 2 studies that formed the basis of the IOM report were not focused on surgical patients. In both of these studies, the rates of complications in surgical patients were much higher than in the overall group. Brennan et al reported a mean adverse event rate of 7.0% ± 0.5% for patients undergoing general surgery, 10.8% ± 2.4% for patients undergoing cardiothoracic surgery, and 16.1% ± 3.0% for patients undergoing vascular surgery. Second, both studies used a more narrow definition of complication, defining an adverse event as an “injury caused by medical management (rather than the disease process) that resulted in either a prolonged hospital stay or disability at discharge.” This corresponds to our subset of major complications. Their patients included those with both avoidable and unavoidable adverse events. For instance, a postoperative patient with a PE was considered to have an adverse event caused by medical management regardless of whether prophylaxis was provided. Third, both of the IOM quoted studies looked only at the patient complication rate rather than the total complication rate. Our patient complication rate was approximately two thirds of the total complication rate, and only half of these complications were major (Table 3). Therefore, if we use the same definition of adverse event as these 2 studies, our approximate adverse event rate is 9% for general surgery, 9% for cardiothoracic surgery, and 11% for vascular surgery, compared with 7%, 11%, and 16%, respectively, cited by Brennan et al.

Criticism that the IOM report overestimates complication rates is, therefore, not supported by our findings in surgical patients. Work by others confirms a high adverse event rate in general medical populations as well. Bates et al reported an adverse event rate of 11%...
on a medical service of an urban US hospital. Using the same method as used in the IOM cited studies, Wilson et al.\textsuperscript{15} found an adverse event rate of 16.6\% in 14,000 patients admitted to 28 Australian hospitals. Taken together, the available literature suggests that the IOM estimate of adverse event rates is actually an underestimate.

By using a broader definition of complication, the present study identifies total complication rates that exceed adverse event rates quoted by the IOM.\textsuperscript{2,4} We believe the definition of adverse event used in the studies\textsuperscript{2,4} cited in the IOM report is too narrow because it ignores minor complications. Not all errors or complications result in long-term sequelae, but they remain important. The detection of minor complications presents significant opportunities for quality improvement without the occurrence of a major adverse outcome. We believe it is important to monitor the total complication rate in addition to the patient complication rate because patients at high risk for developing one complication may be at high risk for developing multiple complications. Tracking the number of complications may allow the detection of more subtle QA problems in this sickest subset of patients.

We also believe it is important to distinguish between complications due to patient disease and those due to provider error. To our knowledge, this distinction has not been previously reported in a nonhomogeneous surgical population. Provider- and disease-related compli-
In contrast, some complications occur because of provider error. Error in this context refers to a spectrum of deficient provider or system performance. It ranges from obvious technical blunder to missed opportunities to deliver optimal care. In this study, we have referred to these as provider-related complications. An example would be a patient at increased risk for postoperative deep venous thrombosis who developed deep venous thrombosis but did not receive prophylaxis. Some complications are arbitrarily attributed to the provider. An example is a pneumothorax secondary to the placement of a central catheter. Presumably, some patients will always develop this complication, but for any given patient, it should not be an expected outcome. Therefore, regardless of preventability, it is a provider-related complication. By intentionally erring toward provider related in ambiguous cases, we feel we can maximize opportunities for improvement in care and outcomes. Our finding that approximately half of the complications are avoidable given our current cognitive and technical expertise. Thus, a patient with significant underlying physiologic derangement or multiple comorbidities may develop complications despite optimal care by current standards. Such complications must be recorded and tracked to identify priorities for research into the pathogenesis of disease and permit the development of new evidence-based therapies.

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In comparison, only 30% of our deaths were felt to be potentially preventable because of care that was suboptimal. Substandard care was observed much less frequently.

In many instances, there are no published standards of care. Historically, this has given surgeons substantial latitude in what is considered to be appropriate clinical pathways for their patients. We believe that this contributes to the underreporting of complications and to underestimates of provider contribution. Surgeons have long recognized this tendency and have widely instituted morbidity and mortality conferences to subject individual cases to scrutiny by colleagues who are able to provide a local standard of care. The standard of care that is outlined in such conferences typically exceeds the minimum acceptable standard used to identify negligent care in the studies previously cited. Until evidence-based standards of care become widely available for the myriad surgical conditions encountered, this local standard will serve as the best measure of compliance with optimal diagnostic and therapeutic strategies.

Unfortunately, time constraints prevent surgeons from presenting most complications at the morbidity and mortality conferences. We believe that a strength of the presented method is the provision of peer review for all complications. Importantly, this review is performed concurrently, by surgeons in the same discipline, and with the attending surgeon present and able to present the full details of any extenuating circumstances. This differs from the method used in the IOM study, in which medical records were reviewed retrospectively, long after the admission, by outside evaluators without knowledge of many of the details of the case and not possessing the clinical expertise of subspecialists.

We believe that regular review of complications by all services contributes to active reporting. When a group of colleagues convenes regularly to review complications, it is difficult for one or more members to fail to report them.

**Table 7. Assessment of Deaths**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Gen Surg</th>
<th>Vascular</th>
<th>Trauma</th>
<th>CT Surg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of deaths</td>
<td>25</td>
<td>34</td>
<td>21</td>
<td>48</td>
</tr>
<tr>
<td>Mortality rate</td>
<td>1.83</td>
<td>3.33</td>
<td>2.28</td>
<td>3.34</td>
</tr>
<tr>
<td>% Unavoidable†</td>
<td>72.0</td>
<td>55.9</td>
<td>81.0</td>
<td>75.0</td>
</tr>
<tr>
<td>% Avoidable†</td>
<td>28.0</td>
<td>44.1</td>
<td>19.0</td>
<td>25.0</td>
</tr>
<tr>
<td>% Technical error</td>
<td>42.9</td>
<td>40.0</td>
<td>25.0</td>
<td>58.3</td>
</tr>
<tr>
<td>% Patient disease</td>
<td>0</td>
<td>26.7</td>
<td>50.0</td>
<td>25.0</td>
</tr>
<tr>
<td>% Judgment error</td>
<td>0</td>
<td>13.3</td>
<td>0</td>
<td>16.7</td>
</tr>
<tr>
<td>% Delay</td>
<td>14.3</td>
<td>6.7</td>
<td>25.0</td>
<td>0</td>
</tr>
<tr>
<td>% Multiple</td>
<td>28.6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Patient noncompliance</td>
<td>0</td>
<td>13.3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% No cause provided</td>
<td>14.3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Diagnostic error</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Medication</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Policy or process</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Equipment failure</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Omission</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% Environment</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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*Data are given as percentage unless otherwise indicated. Abbreviations are explained in the first footnote to Table 2.
†Individual percentages may not total 100 because of rounding.
report their complications while rendering judgments on the appropriateness of care by their peers. Underreporting by an entire division will manifest as an atypically low complication rate relative to other divisions. This should be easily detected by monitoring for unusually high or low complication rates across divisions. A weekly review by peer groups allows early identification of common complications, allowing targeted quality improvement initiatives. Outliers can be quickly identified. Where complication rates are unusually high, immediate input from a group of peers is available for improvement. Where complication rates are unusually low, and this is not due to underreporting, an opportunity for rapid recognition of and dissemination of superior management techniques is possible.

Our study has limitations inherent to this field of research. The definitions of complications, their sequelae, and causation were locally and somewhat arbitrarily defined. We believe it is incumbent on surgeons to develop explicit definitions of specific complications and to adopt consistent methods for tracking, adjudicating, and reporting these complications. It is our belief that surgeons should not relinquish this task to nurses or hospital administration but should take a leadership role in developing national standards. Despite the checks and balances previously mentioned, a potential limitation of this method is underreporting. We are addressing this by the placement of a QA nurse who performs functions analogous to a trauma nurse coordinator. This person will be trained in the recognition of complications and their sequelae and will monitor the patients to ensure that all adverse events are captured. This has several potential benefits. First, it reduces underreporting. Second, it allows an important opportunity to move away from merely reporting complications to reporting and tracking errors regardless of whether these result in a complication. Errors occur much more frequently than complications and provide greater opportunity for improvement in process, with consequent improvements in efficiency, outcome, and cost. Last, it provides a workable method for the assessment of an institution by an accrediting body. It will be possible for them to randomly assess patients for the completeness of data entry by the QA nurse. If this audit reveals that data entry meets defined standards, then the institution's database can be used as an accurate reflection of patient outcomes, complications, and medical error rates.

We believe that this method for surgical QA is sustainable and accurate and provides immediate feedback to the providers. It is outcome related and permits continuous performance improvement by serving the functions of problem recognition, performance monitoring, and rapid dissemination of information about improvements in outcomes. It permits some standardization of care, where outcomes deviate negatively from local standards, while allowing for differences in practice patterns, where outcomes are equivalent. It also allows rapid adoption of techniques associated with improved outcomes. The method may also answer the growing need for ways to perform an objective outcome-based assessment of the clinical component of surgeon competence.

This study was presented at the 82nd Annual Meeting of the New England Surgical Society, Providence, RI, September 21, 2001.

We thank Peggy Lesage, who manages the SATS database and performs data extraction; and the chief surgical residents, who diligently recorded the complications as they occurred during the study period.

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REFERENCES


DISCUSSION

Joseph Civetta, MD, Farmington, Conn: “Truth is right and science is but a synonym of truth. Efficiency must acknowledge truth. Secrecy is the peculiar disease of efficiency. Publicity is the cure of the disease secrecy.” Many in the audience will recognize the quotation from E. A. Codman’s A Study in Hospital Efficiency. His report covered 337 cases from 1912 to 1916. His classification system, updated for our current processes of care, is remarkably similar to the classification used by Dr Healey. I did a quick scan of the first 100 patients and about 50% had either errors or patient problems and the other 50% were classified as okay. The split between errors and pa-
tient problems was also 50:50; therefore, he recorded an error rate in the early 1900s of 25% compared to 32% in this study.

When I was a resident, the MGH [Massachusetts General Hospital] used 4 of Codman’s errors: judgment, diagnosis, management, and technique, and patient’s disease. Dr Oliver Cope became the visiting professor on the East Surgical Service one month. He announced that the only patient who he would consider for patient’s disease would be a trauma patient brought to the emergency room in 2 ambulances. In all other cases, he said he would find an error. Dr Healey and Dr Shackford are nearly as stringent. I believe, as they stated, that opportunities for improvement only could be found if processes are critically analyzed. The differences between their rates and the Institute of Medicine rates reflect that they looked just at surgery (known to have higher rates), they used broader definitions, and, of the greatest importance, the data were collected prospectively by people involved in their care. I compliment them on their methodology and their vision. I have just 2 questions.

First, have you established consequences for failure to comply with reporting requirements and judgments?

Second, have you planned any quality improvement projects based on the errors identified?

At this vital juncture, we all have a choice. We will either lead or we will be led. I join the authors in hoping we pick the former for our credibility, to preserve the medical care system, and, of greatest importance, for our patients.

Walter Goldfarb, MD, Portland, Me: I want to thank Dr Healey. He has quantified what I have long known as the rule of Moshkowitz regarding the causes of surgical complications, which espoused the theory that there are 3 main causes of surgical complications: (1) the right operation done incorrectly; (2) the wrong operation done correctly; and (3) most frequently, the wrong operation done incorrectly. We have come a long way from that to the quantification, and I appreciate it.

Peter Baute, MD, Warwick, RI: I want to compliment the authors on an impressive effort in quality improvement. I have 2 questions, essentially 1 question of 2 parts.

How difficult would it be to apply this kind of a study to the community hospital setting in which there are multiple independent practitioners? And how expensive is it to carry out this kind of a study over an extended period of time?

Lenworth Jacobs, MD, Hartford, Conn: This is a very important paper, specifically the trauma cohort. Your data show a long way from that to the quantification, and I appreciate it.

Frederick Bagley, MD, Rutland, Vt: Dr Healey, many of these would qualify as sentinel events under the new JCAHO [Joint Commission of Accreditation for Health Care Organizations] reporting criteria. Do you have plans to integrate this into an administrative reporting system, as we all might be required to do?

Dr Healey: Dr Civetta asked if we had established consequences and Dr Bagley asked about administrative implications. The entire SATS database and reporting mechanism is integrated with our morbidity and mortality conference, and we are presently working to develop—in fact, we will have the first one available later this year—an annual report card that evaluates each division and each individual surgeon’s performance according to the 6 domains of competence described recently in the American College of Surgeons’ bulletin. Reappointment to surgical staff will be based on professional competence. A surgeon’s complication rates will form part of that evaluation and will be provided by these data. Compliance with the data collection will fall under the rubric of professional behavior and also communication skills and will form part of this evaluation as well.

What projects have we identified? Several projects have come to the fore based on observing recurrent themes. One of the nice things about integrating this with the morbidity and mortality conference is that you are able to pick up patterns that might otherwise be missed. For instance, at the beginning of the M&M [morbidity and mortality] conference, we show a list of all the complications that have been turned back by the SATS database. Just last month, we noticed that there seemed to be a lot of pulmonary emboli occurring. We quickly checked in the SATS database for the last 8 years and found that our annual rate is about 4 pulmonary emboli and we already have 14 this year, so clearly there is a new problem that we are now investigating and this is one of the initiatives. Another example would be the incidence of saphenous vein harvest infections. From the SATS database, we started doing peripheral venous studies preoperatively and switching over to endoscopic harvest and we have decreased the infection rates.

Thank you for your comments, Dr Goldfarb.

Dr Baute, how difficult would this be in a community hospital setting? I go into this a little bit in the manuscript, but I think this method with some modification would be sustainable even in the community hospital. For a hospital without residents, it may require a switch over to relying on the ICD-9 [International Classification of Diseases, Ninth Revision] discharge database, but as my colleague, Dr Osler, demonstrated earlier, the accuracy of this discharge data is quite good. Specialized nurses could also assist with data collection. I think it would require about a half-time equivalent for a busy surgical service, or in this case we could easily do this with 2 nurse equivalents. I believe it may be possible to develop, similar to a trauma nurse coordinator, a “quality” nurse coordinator who would be trained in the recognition of complications and the recording of complications and how to adjudicate those complications.

Dr Jacobs, did we stratify technical errors? No, we did not. That is an excellent suggestion. The technical errors are important. Many of the technical errors were sort of clear-cut mistakes: an anastomotic leak, a bile leak following surgery, wound dehiscence. They actually tend to be the most clear-cut things that most of us would agree on as a provider-related complication.