Different Harm and Mortality in Critically Ill Medical vs Surgical Patients: Retrospective Analysis of Variation in Adverse Events in Different Intensive Care Units

Ko Un Park, MD; Michael Eichenhorn, MD; Bruno DiGiovine, MD; Jennifer Ritz, RN; Jack Jordan; Ilan Rubinfeld, MD, MBA

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ABSTRACT

Background: Institutional harm reduction campaigns are essential in improving safe practice in critical care. Our institution embarked on an aggressive project to measure harm. We hypothesized that critically ill surgical patients were at increased risk of harm compared with medical intensive care patients.

Methods: Three years of administrative data for patients with at least 1 Intensive Care Unit day at an urban tertiary care center were assembled. Data were accessed from the Henry Ford Health System No Harm Campaign in Detroit, MI. *Harm* was defined as any unintended physical injury resulting from medical care. Patients were deemed surgical if they had at least 1 procedure in the operating room. Univariate analysis was used to compare surgical patients with nonsurgical. Logistic regression was used for risk adjustment in predicting harm and death.

Results: The study included 19,844 patients, of whom 7483 (37.7%) were surgical. The overall mortality was 7.8% (n = 1554). More surgical patients experienced harm than did nonsurgical patients (2923 [39.1%] vs 2798 [22.6%], odds ratio [OR] = 2.2, $p < 0.001$). Surgical patients were less likely to die (6.2% vs 8.8%, $p < 0.001$). Surgical patients were more likely to experience harm (OR = 2.1) but had lower mortalities (OR = 0.45) vs other harmed patients (OR = 3.8; all $p < 0.001$).

Conclusion: Most harm in surgically critically ill patients is procedure related. Preliminary data show that harm is associated with death, yet both surgical and African American patients experience more harm with a lower mortality rate.

INTRODUCTION

The 1999 Institute of Medicine report, *To Err is Human*, led to an intense focus on reducing harm at health care organizations throughout the US.[1] One of the report's main conclusions was that most medical errors occur not from individual recklessness or the actions of a particular group. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Much like in Reason's Swiss Cheese model of accident causation, used in aviation safety, mistakes can best be prevented by designing the health system so that it is harder for people to do something wrong and easier for them to do it right.[2]

Thus, institutional harm reduction campaigns have become essential in our improvement of safe practice in critical care. Our institution embarked on an aggressive project to measure harm in our patients, called the No Harm Campaign.[3] The No Harm Campaign uses initiatives such as Michigan Health & Hospital Association's Keystone Center for Patient Safety and Quality initiatives in Detroit, MI, the Institute for Healthcare Improvement's "Saving 100,000 Lives" and "5 Million Lives" campaigns' evidence-based interventions, and the American College of Surgeons' National Surgical Quality Improvement Program to build an infrastructure for systemwide harm reduction efforts. One of the key objectives of this campaign was to build an error management system that begins with accurate harm measurements. To achieve this objective, we defined 27 major types of harm in 6 broad categories.

Many studies have demonstrated that to improve patient safety, different methods other than voluntary adverse event (AE) reporting systems are required.[4] Depending on the method of record review and identification of AEs, there is a wide range of reported AEs in the literature. In the Intensive Care Unit (ICU), it has been reported that approximately 20% of patients experience an AE.[5] The most common AEs involve procedural complications, nosocomial infections, and adverse drug events. Almost 20% of ICU patients who died during or shortly after ICU care experienced AEs. Despite the impact of AEs on mortality and morbidity, there is no comprehensive set of harm measures for US hospitals.

Because the ICU is traditionally the unit with the highest mortality in the hospital and a likely site of medical error given the complexity of care,[6-8] we studied the patterns of harm in critically ill patients. We hypothesized that critically ill surgical patients were at more risk of harm compared with medical intensive care patients. To test this hypothesis, we used the No Harm Campaign data, which uses a variety of sources to capture the various types of AEs in the health care setting.

Ko Un Park, MD, is a Breast Surgical Oncologist at The Ohio State University Wexner Medical Center in Columbus (koun.park@osumc.edu). **Michael Eichenhorn, MD,** is a Specialist in Pulmonary Disease, Critical Care Medicine at Henry Ford Hospital in Detroit, MI (meichen1@hfhs.org). **Bruno DiGiovine, MD,** is a Specialist in Pulmonary Disease, Critical Care Medicine at Henry Ford Hospital in Detroit, MI (bdigiov1@hfhs.org). **Jennifer Ritz, RN,** is a General Surgery Nurse at Henry Ford Hospital in Detroit, MI (jritz1@hfhs.org). **Jack Jordan** is an Analyst in Clinical and Quality Analytics at Henry Ford Hospital in Detroit, MI (jjordan1@hfhs.org). **Ilan Rubinfeld, MD, MBA,** is the Director of the Surgical Intensive Care Units, a Trauma Surgeon, and an Associate Professor in the Department of Surgery in the Division of Trauma and Acute Care Surgery at the Henry Ford Hospital and the Center for Health System Research at the Henry Ford Health System in Detroit, MI (irubmd@gmail.com).

METHODS

With the approval of the institutional review board, 3 years of administrative data from 2009 through 2011 at a single urban tertiary care center were collected. Patients with at least 1 ICU day were included in the study. The hospital is a Level 1 trauma center and tertiary care academic center with 802 beds, which includes 168 ICU beds with dedicated intensivists. The medical ICU and coronary care unit have a closed-unit attending model with hospital-based intensivists and cardiologists assuming primary patient responsibility.[4] The surgical ICU, cardiothoracic ICU, and neurologic ICU have an open ICU model with the surgical team assuming primary patient responsibility with a mandatory intensivist consultation. If the primary team in the neurologic ICU is not the neurosurgery team but the neurology team, then it is a closed unit.

Data Collection

Harm data was accessed from the Henry Ford Health System No Harm Campaign. According to this campaign, *harm* is defined as "any unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment, or hospitalization or that results in death. Such injury is considered harm whether or not it is considered preventable, resulted from a medical error, or occurred within a hospital."[3] Patients were deemed surgical if they had at least 1 procedure in the operating room. A *surgical patient,* for the purposes of the study, was defined not by the patient's location or primary care team but by the presence of a procedure performed in the operating room. This was to capture the harms that are unique to surgical patients.

The No Harm Campaign groups harm into the following categories: Infection related, medication related, procedure related, care delivery harm (falls and pressure ulcers), employee harm, and other harm (health care-acquired acute renal failure, code blue alert, deep vein thrombosis, and obstetrics harm). Infection-related harm data (ie, bloodstream infection, ventilator-associated pneumonia, urinary tract infection, *Clostridium difficile,* surgical site infection, and sepsis) were collected from chart review by the hospital's Infection Control Surveillance Committee or from administrative data, including coded data (ie, International Classification of Disease, Ninth Revision [ICD-9] Codes 599.0 and 996.64 for urinary tract infection). *Surgical site infection* was defined as a surgical wound infection (purulent drainage, organism isolated from aseptic culture from incision, symptoms of infection, incision opened by surgeon because of concern for infection) that occurred within 30 days after a procedure. *Medication-related harm* (blood glucose level < 40 mg/dL, international normalized ratio < 5, narcotics) was defined as ICD-9 code beginning with the E code related to medication. *Procedure-related harm* was defined as ICD-9 Codes E998.0 to E999.99 or ICD-9 codes related to procedures (ie, coded complications, procedural harm recorded in the National

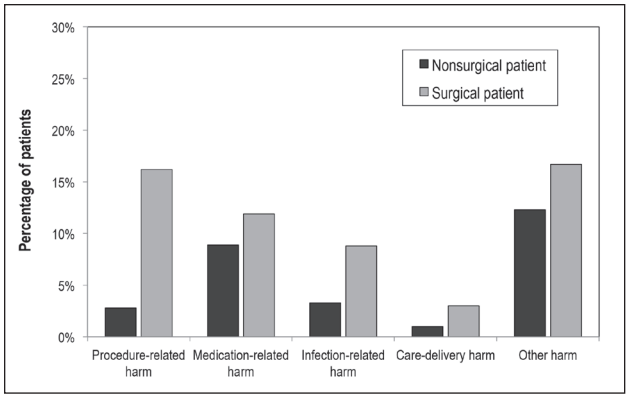

Figure 1. Different categories of harm in nonsurgical and surgical patients. Percentage was calculated by dividing number of nonsurgical or surgical patients harmed by total number of nonsurgical or surgical patients.

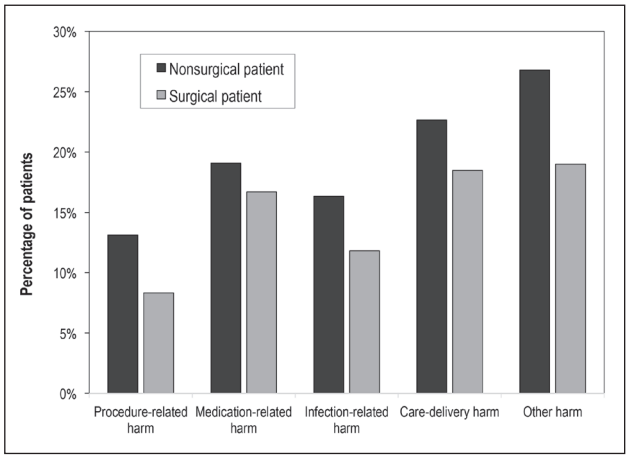

Figure 2. Mortality in surgical and nonsurgical patients who experienced various categories of harm. Percentage was calculated by dividing number of patients with harm who died by total number of patients who experienced that harm.

Table 1. Characteristics of study patients

Characteristic	Number
Study group totals	
All patients	19,844
Nonsurgical	12,361
Surgical	7483
Mean age, years	
All patients (25th-75th percentile)	52.5 (41-70)
Nonsurgical	48.7
Surgical	58.8
Mean Elixhauser score	
All patients (range)	5.88 (0-10)
Nonsurgical	5.63
Surgical	6.29
Mean ICU stay, days	
All patients (range)	4.79 (1-249)
Nonsurgical	3.78
Surgical	6.46

ICU = intensive care unit.

Surgical Quality Improvement Program, and pneumothorax). *Patient falls* were defined as ICD-9 Codes E880.9 to E884.6 related to falls, and pressure ulcer data were obtained from nursing skin audits. *Acute renal failure harm* was defined as ICD-9 codes beginning with 584. *Code blue alert events* were defined as all patients with recorded blue alert with documented zero pulse, shock delivery, or epinephrine administration. Venous thromboembolism events were based on ICD-9 Codes 415, 451, and 453. Employee-related harm, which includes needle-sticks and job-related musculoskeletal back injuries, was excluded from the analysis to focus on harms to patients.

Statistical Analysis

Univariate analysis was used to compare surgical patients with nonsurgical using the occurrence of various harms grouped by category. Logistic regression was used to attempt risk adjustment in predicting a harm event and in predicting death. Elixhauser scores were calculated for each group. The Elixhauser Comorbidity Index is a single score that summarizes a patient's disease burden on the basis of 30 comorbidities from administrative data. This score has been tested in previous studies to adequately predict hospital mortality.[9] Statistical analysis was performed using statistical software (SPSS Version 21, IBM Corp, Armonk, NY).

RESULTS

A total of 19,844 patients met eligibility criteria, with 7483 surgical patients (37.7%) and 12,361 (62.3%) nonsurgical patients. Operative procedures included all surgical specialties, including general, cardiothoracic, vascular, otolaryngology, transplant, neurosurgery, urology, and orthopedic surgery. The mean age of the patients was 52.5 years. The mean length of stay in the hospital was 9.26 days. There were no statistically significant differences in age, length of stay in the ICU, ventilator days, or Elixhauser score between the surgical and nonsurgical groups (Table 1). The overall mortality was 7.8% (n = 1554), and the overall harm rate was 28.8% (n = 5721).

In general, more surgical patients experienced harm than did nonsurgical patients (2923 [39.1%] vs 2798 [22.6%], odds ratio = 2.2, p < 0.001). Across all harm categories, surgical patients experienced more harm than did nonsurgical patients (Figure 1). Not surprisingly, procedure-related harm was one of the most common types of harm for surgical patients.

Overall, patients were more likely to die if they experienced harm: 912 patients with harm who died (57.7%) vs 642 without harm who died (41.3%). Interestingly, harmed surgical patients had decreased mortality (6.2% vs 8.8%, p < .001), and this was also true when stratified by harm (Figure 2, Table 2). Regression analysis showed that among harmed patients, the risk of mortality in nonsurgical patients was higher than in surgical patients (relative risk = 1.7, confidence interval = 1.49-1.92, p < 0.001). Even among the 14,123 patients who experienced no harm, the mortality rate among the surgical patients was lower than in the nonsurgical patients (113 [2.5%] vs 529 [5.5%], p < 0.001). Regardless of the type of patient, the "other harm" category was the most common harm type among those who died.

Table 2. Risk of experiencing a specific type of harm in surgical versus nonsurgical patients who died[a]

Category of harm	Odds ratio	95% Confidence interval
Procedure-related harm	6.5	4.51-9.47
Medication-related harm	2	1.58-2.59
Infection-related harm	3.2	2.24-4.49
Care delivery-related harm	3.6	2.19-5.84
Other harm	1.8	1.44-2.23
Total harm	2.9	2.27-3.68

[a] All p < 0.001.

Table 3. Multivariate logistic regression predicting harm

Variable	Odds ratio	95% Confidence interval	p value
Male sex	1.0	0.93-1.06	< 0.001
African American	1.2	1.12-1.28	0.915
Elixhauser score	1.06	1.059-1.070	< 0.001
Surgical patient	2.2	2.08-2.37	< 0.001

Table 4. Multivariate logistic regression predicting mortality

Variable	Odds ratio	95% Confidence interval	p value
Male sex	1.2	1.08-1.34	< 0.001
African American	0.88	0.79-0.98	0.02
Elixhauser score	1.1	1.08-1.10	< 0.001
Surgical patient	0.5	0.41-0.53	< 0.001
Harmed	3.8	3.40-1.25	< 0.001

Surgical patients were more than twice as likely to experience harm than nonsurgical patients, and there was a trend toward greater harm in African Americans (odds ratio = 1.2, p = 0.915; Table 3). Interestingly, multivariate logistic regression analysis showed that surgical and African American patients had the lowest odds of a fatal outcome (Table 4).

DISCUSSION

Our study demonstrates the high rate of AEs in the ICU and its association with mortality. In general, those who were harmed were 3.8 times more likely to die. We report an overall harm of 28.8%. The sensitivity of the No Harm Campaign to capture an AE regardless of preventability likely contributed to the higher rate of AEs in our study compared with the literature.

Although procedure-related harm was one of the most common types of harm for surgical patients, across all the harm categories, surgical patients experienced more harm than did nonsurgical patients. Previous study findings have shown that intrahospital transport of the patient for diagnostic studies or surgical intervention outside the ICU is associated with a higher rate of adverse drug events.[10] Furthermore, the difference in ICU models may have also contributed to the difference in the rate of harm.[11,12] For instance, Ghorra et al[12] reported a decrease in overall complication and mortality rates in a closed unit vs an open ICU.

Our study results show that patients undergoing surgery experience fewer fatal outcomes. Even though the surgical patients

were more likely to experience harm, they were less likely to die. The way we defined a patient as surgical may be a contributing factor to this result. A surgical patient was not defined by the patient's location or primary care team but by the presence of a trip to the operating room. Only those who received a surgical intervention outside the ICU were categorized as a surgical patient. Thus, even those with a surgical problem under the care of the surgical ICU but who were too sick to receive an operation were grouped as a nonsurgical patient. Furthermore, most of the surgical patients were those undergoing surgical interventions who were postoperatively admitted to the ICU. Elective surgical patients would have undergone perioperative risk assessment and been deemed to have adequate functional reserve to endure the operation.

There are several limitations of our study. First, this is a single-institution study from an urban care center. Although the data were collected prospectively, the analysis was retrospective Additionally, we did not collect data regarding the reason for admission to the ICU. Furthermore, the actual contribution of harm to the patient's mortality was unclear because we did not grade the severity of the harm.

CONCLUSION

The No Harm Campaign at the Henry Ford Health System offers a comprehensive method of measuring the diverse types of health care-related harm. Our study shows that harm is associated with mortality. Although surgical patients experienced more harm than nonsurgical patients did, harmed surgical patients had a lower mortality rate than harmed nonsurgical patients. The next step is to identify ways to reduce the harms that were identified. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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Care

Care more particularly for the individual patient than for the special features of the disease.

— William Osler, MD, 1849-1919, physician, pathologist, teacher, diagnostician, bibliophile, historian, classicist, essayist, conservationalist, organizer, manager, and author