Risk of Intraoperative Injury of Nearby Structures: National Trend, Distribution, and Burden

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BACKGROUND: Accidental injury of a nearby structure during surgical operations carries a risk of serious morbidity and mortality. Furthermore, it represents a medico-legal liability. We aimed to examine the national distribution, cost, and trend of accidental intraoperative injuries.

STUDY DESIGN: We performed a cross-sectional study using the Nationwide Inpatient Sample database. The study population consisted of patients who encountered intraoperative injuries between 2003 and 2010. Controls were randomly selected from patients who underwent similar procedures during the same period. Cost was adjusted for inflation rate to reflect 2015 dollar values.

RESULTS: A total of 61,667 cases with intraoperative injuries and 430,424 controls were included. Intraoperative injuries were most common in procedures that involved the digestive system (38.0%), female reproductive organs (21.4%), and musculoskeletal system (12.2%). There was a significant increase in those injuries from 161.3 cases/100,000 procedures in 2003 to 254.9 cases/100,000 procedures in 2010 ($p < 0.001$). Female sex, pediatric and older populations, overweight, trauma and teaching hospital were all independent risk factors of injuries in the multivariate model ($p < 0.05$ for all). Intraoperative injuries were associated with a higher risk of concomitant complications (odds ratio [OR] 2.44, 95% CI 2.36, 2.54, $p < 0.001$) and hospital mortality risk (OR 2.33, 95% CI [2.15, 2.51], $p < 0.001$). Nationally, it is estimated that injuries of nearby structures resulted in an annual average of 84,708.7 days of excess hospital admission days and $426.33 million excess cost.

CONCLUSIONS: Certain demographic and clinical factors influence the risk of intraoperative injury of nearby structures. The prevalence of intraoperative injuries is increasing at the national level, and these injuries are associated with increased mortality and pose substantial clinical and financial burdens. (J Am Coll Surg 2016;222:624−631. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Adverse events during a hospital stay constitute a considerable cause of disability and are a source of malpractice litigation.[1,2] It is estimated that 39.6% of in-hospital adverse events are related to surgical procedures.[1] Intraoperative misadventure includes a wide range of adverse events, among which is the risk of injury of nearby structures. The literature contains a plethora of cases and case-series reports on such injuries.[3-11] However, very few large scale studies have focused specifically on intraoperative injuries. In the United States, the most prominent pursuit of this topic came in 1991 from the Harvard Medical Practice Study,[2,12] which investigated all adverse events that could arise from medical and surgical management.[12] Operation-related events were reported in 41.0% of the sample, with 15.5% related to technical complication or surgical failure.[12] The most recent study that investigated misadventures during hospital stays was from the United Kingdom,[13] in which the authors reported that surgical and medical misadventures are a significant cause of harm and mortality; however, it lacked a focused assessment of iatrogenic intraoperative injuries.[13]

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Abbreviations and Acronyms

CCIS = Charlson Comorbidity Index Score
CCS = Clinical Classifications Software
HCUP = Healthcare Cost and Utilization Project
LOS = length of stay
NIS = Nationwide Inpatient Sample
OR = odds ratio

In this study, we aimed to specifically investigate the incidence of accidental intraoperative injury in the United States and across all clinical surgical disciplines. We also sought to investigate patient and setting characteristics associated with unintentional injuries and to assess clinical and financial outcomes related to intraoperative misadventures.

METHODS

This study is a cross-sectional analysis using the Nationwide Inpatient Sample (NIS) database for the years 2003 to 2010. The NIS is part of the Healthcare Cost and Use Project (HCUP), sponsored by the Agency for Healthcare Research and Quality. This is the largest all-payer inpatient care database publicly available in the United States. It contains data from approximately 8 million hospital stays from about 1,000 hospitals sampled to approximate a 20% stratified sample of US community hospitals. The NIS database consists of publicly available de-identified data that are exempt from Institutional Review Board approval.[14]

Clinical Classifications Software (CCS) was used to classify the site/system of the primary procedure,[15] and the International Classification of Disease, 9th Revision (ICD-9) was used in defining the other parameters of the study. The CCS is a diagnosis and procedure categorization scheme developed by HCUP and based on the ICD-9; it provides a smaller number of clinically meaningful categories that are more useful for presenting descriptive statistics than are individual ICD-9 codes.[15]

A total of 63,865,171 inpatient records were surveyed for patients who developed a secondary diagnosis of accidental cut, puncture, perforation, or hemorrhage during a surgical operation (ICD-9: E87.00). Then, based on the site/system of the primary procedure, controls were randomly selected from those who underwent similar procedures with a control-to-case ratio of 7-to-1. Assessment of characteristics of patients and settings in relation to iatrogenic intraoperative injuries was performed. Factors of interest included: age: < 18, 18 to 30, >30 to 60, and >65 years old; sex; BMI: <25 kg/m^2 and ≥25 kg/m^2; trauma status at admission: nontrauma, trauma; hospital location: rural, urban; and hospital teaching status: nonteaching, teaching.

The second objective of the study was to assess the outcomes associated with intraoperative injury. Those outcomes included: postoperative complications: none vs 1 or more cardiovascular, pulmonary, urinary, bleeding, infectious, or wound complications; in-hospital mortality; length of stay (LOS), categorized based on quartile classification into: short stay (≤75th percentile, ≤6 days) vs long stay (>75th percentile, >6 days); and cost of health services, adjusted for inflation rate to reflect 2015 US dollar values and categorized based on quartile classification into low cost (≤75th percentile, ≤$16,713.19) vs high cost (>75th percentile, >$16,713.19).

Excess LOS was determined by subtracting the average LOS of cases from that of controls. Similarly, excess cost on the health system produced by the cases was defined as the average cost difference between cases and controls.

Other independent factors considered for their confounding effect included: site/system of primary procedure: nervous system, endocrine, eye, ear, nose, mouth, pharynx, respiratory, cardiovascular, lymphatic, digestive, urinary, male reproductive organs, female reproductive organs, and musculoskeletal; modified Charlson Comorbidity Index Score (CCIS): low (0 to 1), intermediate (2 to 3), high (≥4)[16]; admission status: nonelective, elective; hospital region: Northeast, Midwest, West, South; and hospital bed size: small, medium, large.[17]

Statistical analysis used weighted data reflecting a national estimate. The records' weights are available in the NIS data and calculated based on stratification variables that were used in sampling methodology. These variables included hospital geographic region, urban/rural location, teaching status, bed size, and ownership.[14]

Cross-tabulation and chi-square tests were used to examine the association between each of the independent factors and the outcomes of interest. Factors with significant association were considered possible confounders and were included in multivariate logistic regression models. Multivariate logistic regression models were used to calculate the odds ratio (OR) and 95% CI. Additionally, because literature review showed a higher incidence of injury associated with gastrointestinal and gynecologic procedures, a subpopulation analysis for the procedures that involved the digestive tract and female reproductive organs was performed. Linear regression model was applied to determine the incidence growth rate for 8 years beyond the study period. Significance level was set as ($\alpha = 0.05$). All data analyses were performed using SAS 9.3 for Windows (SAS Institute Inc).