



“What’s the Risk?” Assessing and Mitigating Risk in Cardiothoracic Surgery

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Not everything that counts can be counted, and not everything that can be counted counts.—William Bruce Cameron, *Informal Sociology*, 1963

To increase awareness and improve safety, quality, and value in cardiothoracic surgery, we provide a synopsis of risk, risk assessment methods, and considerations for mitigating modifiable risks associated in the cardiothoracic surgery patient. Definitions of risk include (1) the possibility or danger of injury or loss; (2) a person or thing that creates a hazard; and (3) the chance of financial loss. One way to quantify risk is to sum the product of consequences and probabilities. A common example of risk, in which the potential outcomes and probability are known, would be the flip of a coin. In surgery, however, quantifying risk becomes much more challenging, and all of the possible outcomes and the exact probabilities of each are difficult to forecast for an individual patient.

Risk management involves assessing and mitigating risk through avoidance, modification of risk (eg, altering timing or procedure type, cancellation, modifications in host, and other factors), as well as the acceptance of risk. An effective surgical risk management strategy requires an objective comparison of risk exposure to the anticipated value of an operation for each patient. Fundamental characteristics of risk models include calibration, namely, the level of agreement between observed and expected outcomes, and discrimination, which is the ability to distinguish between high-risk and low-risk patients [1]. Additionally, surgical risk scoring systems can be static (eg, a snapshot of a patient's risk before operative intervention) or dynamic—which factor in the unique pathophysiological changes associated with the planned procedure through defined phases of care with variation of risk over time [1, 2].

The Society of Thoracic Surgeons (STS) Adult Cardiac Database, established in 1989 and utilized by approximately 1,100 participants in the United States, leads other clinical disciplines in risk assessment and transparency of methodology [3]. Risk algorithms for adult cardiac surgery have been created, are regularly updated with demographic and clinical data, and are currently available for coronary artery bypass grafting (CABG),

cardiac valve surgery, and CABG plus valve surgery. The online STS risk calculator (available at <http://riskcalc.sts.org>) provides a statistical assessment of the patient's risk of mortality and postoperative morbidities. Surgeons are strongly encouraged to use the calculated risk profile in assessing an individual patient's risks and as a starting point for discussing expectations of surgery and informed consent. It should be noted, however, that despite robust standards, data acquisition methods, and validated statistical models, the coding process may complicate reporting [4].

The reporting of outcomes includes a composite rating system and the opportunity for voluntary public reporting (and soon, reports for individual surgeons). The National Quality Forum has developed national voluntary consensus standards for cardiac surgery to foster quality improvement and transparency to promote the highest quality of care for cardiac surgery patients (available at <http://www.qualityforum.org>).

Burden of Cardiac and Thoracic Disorders

Acquired heart disease affects 27.6 million adults in the United States, is the leading cause of death (611,106 estimated for 2016), and is projected to result in 3.7 million hospitalizations annually [5]. Approximately 600,000 adult cardiac surgical procedures are expected to be performed in 2016 [6]. In addition, congenital heart disease affects approximately 1% of live births (40,000 per year in the United States), and approximately 25% of those require surgery in their first year of life [7]. Cancer is the second most common cause of death in the United States, and the American Cancer Society estimates 224,390 new cases of lung cancer in the United States for 2016 [8]. Lung cancer causes approximately one in four cancer deaths [9]. The American Cancer Society also estimates 16,910 new cases esophageal cancer in the United States for 2016.

When assessing and categorizing surgical risk, one can utilize a variety of measures such as percentage mortality and relevant statistical information such as standard deviation from the mean, and so forth [10]. Risk assessment may include measuring physiologic determinants such as anaerobic threshold, functional capacity and frailty, and serum biomarkers. In addition, surgical risk and indicators of inferior quality correlate with elevated total costs, as shown by the Virginia Cardiac Surgery Quality

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Initiative and others, reinforcing the incremental costs of complications in CABG [11–14]. Importantly, the Centers for Medicare and Medicaid Services has proposed bundled payment models for CABG in which the hospital or health system will accept financial risk for the cost and quality of care during an entire episode of care for as long as 90 days after discharge [15].

Host Factors

Surgical risk should be assessed and mitigated where possible across all phases of patient care. Risk is increased when a mismatch exists between the physiologic demand of the procedure and the patient's functional reserve. Age is consistently an important risk factor, and elderly patients incur added risk associated with the potential for frailty, falls, infection, and pulmonary complications [16, 17]. At the other end of the spectrum, prematurity also confers risk, with one study reporting 43% mortality for surgical corrections using cardiopulmonary bypass [18]. Increased body mass index (BMI) in adult patients elevates the risk of wound problems, such as dehiscence and infection, deep venous thrombosis, and prolonged recovery. Surprisingly, moderately overweight cardiac surgery patients have lower operative mortality, reduced hemorrhage and transfusions, and better 5-year survival than patients with a normal BMI [19, 20]. This paradox has also been described for other procedures, such as lung resection surgery [21]. Conversely, lower than normal BMI has consistently been shown to increase surgical risk.

Hypothermia is associated with a lower metabolic rate, immunologic changes that increase the risk of surgical site infections, and delays in postoperative recovery and separation from mechanical ventilation. Therefore, measures to maintain normothermia, including control of room temperature, patient draping, warming of intravenous solutions, blood products, ventilator circuits, and blankets, are important components in risk reduction. The STS guidelines on temperature management in patients undergoing cardiopulmonary bypass are readily available [3].

Because the risk of stroke with CABG increases with severity of carotid disease, particularly with complete occlusion, a thorough evaluation for cerebrovascular disease is important [22]. Additional risk factors for neurologic injury include age more than 60 years, ascending aortic disease, poor left ventricular ejection fraction, and peripheral vascular disease. The use of neuraxial and opioid anesthesia may reduce operative mortality and should be strongly considered in appropriate cases [23].

Chronic respiratory insufficiency can increase operative risk and complicate postoperative care. Prudent pulmonary evaluation should be coupled with smoking cessation at least 30 days before operation in conjunction with patient counseling and, if necessary, nicotine replacement. Smoking cessation within 7 days of surgery increases the risk of pulmonary complications due to airway inflammation and excessive secretions [24].

Preoperative pulmonary rehabilitation appears to be beneficial in reducing pulmonary risk [25]. In thoracic surgery, dependent living correlates with increased surgical risk [26]. Modifiable risk factors include weight loss, smoking cessation, and a multidisciplinary approach toward optimizing lung function, including exercise, patient education, and treatment of bronchorrhea and bronchospasm [27]. Postoperative lung dysfunction is related to mechanical ventilator support, higher inspired oxygen fraction, and intravenous crystalloids, as well as to blood product transfusions [28]. Early extubation after surgery, particularly for patients with preexisting lung disease, correlates strongly with improved outcomes [29]. The STS provides education on avoiding prolonged ventilation through its webinar series [3].

Preoperative evaluation should also include assessing the risk of myocardial ischemia, ventricular dysfunction, rhythm abnormalities, and pulmonary hypertension during the perioperative period. The right ventricular failure risk score is a simple and useful clinical tool to quantify the risk of postoperative right ventricular dysfunction in left ventricular assist device candidates. An elevated right ventricular failure risk score can suggest a need for postoperative inhaled nitric oxide, inotropic support, and mechanical support of the right side of the heart [30].

Furthermore, nutritional status, weight loss, skeletal myoatrophy, and peripheral edema need to be fully evaluated. Nutritional support should be strongly considered for at-risk patients whenever feasible. Liver dysfunction can confer considerable risk as it is associated with coagulopathy and hemorrhage, sepsis, cardiomyopathy with both systolic and diastolic dysfunction, peripheral vasodilation, and pulmonary and renal dysfunction [31]. The Model for End-Stage Liver Disease (MELD) categorizes patients by bilirubin, creatinine, international normalized ratio, and etiology of the underlying liver dysfunction [32, 33]. Both diabetes mellitus and hyperglycemia are linked with death, surgical site infection, and atrial fibrillation in the cardiac surgical patient. Although various glycemic control protocols have been developed, optimal management strategies continue to be debated [34]. A comprehensive review of glycemic control in cardiac surgery is included in the STS Task-force for Quality Improvement Webinar Series [3].

Renal risk should be quantified given that acute kidney injury correlates with the magnitude of insult; and acute kidney injury is strongly linked to mortality, longer length of stay, and readmission in adult cardiac surgery [35]. Acute renal failure complicates 2.1% of the CABG population and carries a high association with failure to rescue, at 22.3% [36]. Risk models (including <http://riskcalc.sts.org>) commonly contain factors such as age, BMI, hypertension, peripheral vascular disease, chronic pulmonary disease, serum creatinine concentration, anemia, previous cardiac surgery, emergency operation, and operation type [37, 38]. Acute kidney injury risk mitigation strategies include the avoidance of nephrotoxic agents and goal-directed hemodynamic therapy [39–41]. General, cardiac, and renal biomarkers

may predict acute kidney injury and aid in mitigating its risk [42].

Another important perioperative consideration is venous thromboembolic disease and pulmonary thromboembolism after surgery [43]. The deep venous thrombosis Geneva and Caprini risk scoring systems correlate patient factors with the risk of deep venous thrombosis and pulmonary thromboembolism [44, 45]. The incidence of bleeding complications from acquired coagulopathy is increasing with the introduction of various newer anticoagulants for treating atrial fibrillation and coronary and cerebrovascular disease, as well as the use of nontraditional medical remedies [46, 47]. The surgical team must be familiar with the effects of common drugs that may alter coagulation, including their pharmacokinetics as well as bridging and reversal strategies. The HAS-BLED (acronym for hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile international normalized ratio, elderly, drugs/alcohol concomitantly) bleeding risk score is useful, and includes age, liver dysfunction, renal dysfunction, bleeding tendency, warfarin and antiplatelet drug use, and alcohol excess [48]. The STS has created a valuable review of antiplatelet agents for cardiac and noncardiac operations [3].

Hospital-acquired infections are common and costly [49]. Risk factors include age, being female, increased BMI, and having comorbidities. Inherited and acquired immune deficiencies must be considered and managed during the perioperative period and beyond. Many options exist for skin antisepsis, draping, and wound closure. The role of rigid sternal fixation hardware rather than sternal wires to prevent dehiscence and infection remains undefined. Negative pressure wound therapy has simplified and improved the management of open and infected wounds [50, 51] and is commonly used to help prevent wound infections associated with delayed sternal closure.

Non-Host Factors

In delivering the best possible care, surgeons must choose the appropriate procedure for each individual patient and intervene in a timely fashion. Each patient's values and constraints, pathologic anatomy, and physiology will challenge surgical decision making and the system of health care delivery. In cardiac surgery, for example, procedural considerations tailored to risk profiles include on-pump CABG versus off-pump CABG, CABG versus minimally invasive CABG, total arterial revascularization CABG versus CABG with the use of vein grafts, and surgical aortic valve replacement versus transcatheter replacement or sutureless replacement [52–57]. Even seemingly less critical portions of operations, such as sternal closure techniques, can have an impact on risk and outcomes [58, 59]. Similar constraints and considerations of risks affect minimally invasive pulmonary and esophageal surgery [60, 61]. Novel performance scores have been developed to forecast

outcomes in cardiac surgery [62, 63], and these concepts are worthy of further consideration.

To evaluate methods that optimize outcomes and to define best practices, cardiac surgery collaboratives and multicenter quality improvement programs have reported, on average, a 20% to 24% reduction in mortality rates, with one institution demonstrating a 40% reduction in risk-adjusted mortality, decreased morbidity, and increased success with early extubation and glycemic control [64–66]. TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) and other training programs that incorporate human factors principles have demonstrated that surgical teams that train together develop effective leadership and communication skills, and use of briefings and debriefings can produce better outcomes [67, 68]. "Failure to rescue" patients from complications is a core quality measure endorsed by the National Quality Forum in 2012 [69]. Failure-to-rescue rates in cardiac and lung surgery have been found to be higher at high-mortality hospitals [70, 71]. A 10-year review of Medicare data determined that postoperative readmissions to the index hospital are associated with 26% lower 90-day mortality than when a patient is readmitted to a nonindex facility [72]. The STS recently produced a webinar entitled "Readmissions After CABG" that highlights important administrative issues as well as successful strategies to mitigate the risk of readmission [3].

Issues regarding pharmacology and blood management are critical considerations during the perioperative period. Aprotinin, the serine protease inhibitor (which decreased red blood cell transfusion after CABG), is perhaps the archetype for the complexity of a pharmacologic agent's efficacy and risks—which include death, cardiac, renal, and neurologic events—and is now only available as an investigational drug under a special treatment protocol [73]. Angiotensin-converting enzyme inhibitors have been associated with the challenging problem of vasoplegia associated with cardiac surgery and cardiopulmonary bypass [74]. The combination of aprotinin and angiotensin-converting enzyme inhibitors and the risk of acute kidney injury is illustrative of the potential of drug combinations to create additive risk [75]. According to the STS Workforce on Evidence-Based Surgery, surgical procedures in the United States result in the transfusion of 15 million units of packed red blood cells annually, and cardiac surgery accounts for 10% to 15% of all blood product consumption [3]. A total of 43% of CABG patients receive transfusions according to STS Adult Cardiac Database 2015 report. The deleterious consequences of blood transfusion include transmission of infections, immunologic reactions, and increase in morbidity and mortality, among others [76, 77]. The STS provides a thorough review of the safety, quality, and value implications associated with blood management in its webinar series [3].

Systems of Care

Important in the discussion of optimizing the delivery of surgical care has been the influence of the health care

facility and the relationship between surgical volume and clinical outcomes [78]. Market concentration and individual hospital volumes contribute to declining mortality associated with esophagectomy and pulmonary lobectomy [79]. Reductions in mortality rates with cardiovascular procedures have been associated with factors not related to volume, although increased institutional volume may be a surrogate for greater experience associated with patient selection and operative and perioperative management and may diminish risk for complex procedures, such as left ventricular assist device implantation, orthotopic heart transplantation, and congenital cardiac surgery [80, 81].

From a comprehensive patient care perspective, early patient and family engagement promotes smoking cessation, education, exercise training, and weight reduction [82]. Proactive risk mitigation strategies include exercise and inspiratory muscle training and “prehabilitation” [83–85]. More expansive programs include the entire continuum of surgical care (“surgical home”) and detailed pathways promoting early recovery after surgery [86]. Many consider the current efforts pivotal to creating a broadly networked, decentralized “periprocedural home” in cardiothoracic surgical care [87, 88]. The evolving redesign of health care delivery around service lines mirrors that of “focus factories” in other industries and have demonstrated improvement in efficacy and efficiency [89].

Because as much as 85% of error in delivering care is attributable to communication failures, goal sheets for each patient create a shared mental model among health care workers, resulting in shorter length of stay in the intensive care unit [90]. Moreover, memory aids such as checklists, hand-off tools, and structured communication strategies have reduced complications and hospital and intensive care unit readmissions [91, 92]. Multidisciplinary rounds—which involve patients, their families, and the entire health care team—mitigate mortality risk in critically ill patients [93, 94]. Organizational staffing of critical care units with “closed” management by dedicated critical care trained providers, in contradistinction to an “open” model of non-critical care-trained providers, as well as the use of tele-intensive care unit technology also correlates with lower mortality, morbidity, and shorter length of stay [95, 96].

Goal-directed therapy is a process in which a variety of physiologic goals are elucidated and actions are taken to mitigate risk, although controversy persists around which specific variables, goals, and associated therapeutic strategies have positive effects in cardiac surgery [97]. Various other modifiable factors in processes of care, such as the incremental risk associated with late-in-day cardiac operations and low staffing patterns, have surfaced as opportunities for reducing risk [98, 99].

The introduction of innovative and potentially “disruptive” technology has the potential to transform the care of cardiothoracic surgical patients. For example, the evolution of wearable biosensors can generate valuable monitoring data across the continuum of health care.

These and other Internet-based technologies enhance the development of proactive strategies to contain risk by providing early warning systems. Technologies such as biomarkers, proteomics, and genomics, consistent with the Precision Medicine Initiative (<https://www.nih.gov/precision-medicine-initiative-cohort-program/scale-scope>), complement the rapidly improving risk assessment methods. The IBM Corporation’s Watson computer illustrates the promise of harnessing “big data” to transform decision making in the health care environment.

Conclusion

The considerable global burden of surgery, combined with evidence of considerable variability in cardiothoracic surgical outcomes, and its associated costs create a “burning platform” to improve the delivery of health care. An important component of this effort involves a systematic, prioritized approach to risk assessment and management to improve safety, quality, and value in all aspects of surgical care. Each facility, health system, and individual practitioner has unique and important opportunities to learn, improve, and address these risks. Improvements in risk assessment and mitigation are founded on improved data mining, management, analysis, and widespread access by frontline health care professionals. Parallel improvements in technology and communication will enhance multidisciplinary teamwork and accelerate the transformation of networked, decentralized surgical care.

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