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Review

Evaluating Quality in Adult Cardiac Surgery

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National and institutional quality initiatives provide benchmarks for evaluating the effectiveness of medical care. However, the dramatic growth in the number and type of medical and organizational quality-improvement standards creates a challenge to identify and understand those that most accurately determine quality in cardiac surgery. It is important that surgeons have knowledge and insight into valid, useful indicators for comparison and improvement. We therefore reviewed the medical literature and have identified improvement initiatives focused on cardiac surgery. We discuss the benefits and drawbacks of existing methodologies, such as comprehensive regional and national databases that aid self-evaluation and feedback, volume-based standards as structural indicators, process measurements arising from evidence-based research, and risk-adjusted outcomes. In addition, we discuss the potential of newer methods, such as patient-reported outcomes and composite measurements that combine data from multiple sources. ***(Tex Heart Inst J 2021;48(1):e197136)***

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The concept of healthcare outcome research and quality improvement (QI) was introduced by Codman,[1] who in 1918 recommended "End Results Cards" to document and enable a systematic review of outcomes. Donabedian[2] later advanced an approach for evaluating healthcare quality from 3 vantage points: structure, process, and outcome. Despite the intuitive desire everywhere to promote quality care, it was not until 1999 that focus on patient safety was reinvigorated, when the Institute of Medicine detailed the prevalence and the lack of awareness of preventable medical errors.[3]

Since then, the number of contemporary quality measurements has expanded, so defining which ones truly identify high-quality care is challenging. In this review, we provide a basic framework for surgical QI and discuss examples of existing QI standards, focusing on cardiac surgery.

National Registries and Regional Consortia

Cardiac surgery has a rich history of QI, thanks to pioneers who systematically collected and analyzed performance data for monitoring quality of care, developed follow-up methods, and identified learning opportunities to prompt clinical improvement. The considerable progress during the last 30 years is indicated by the development of large multi-institutional databases.

Veterans Affairs Cardiac Surgery Advisory Group

The first broad monitoring of cardiac surgical quality began with the United States Veterans Administration, now the U.S. Department of Veterans Affairs (VA), in 1971. This prospective monitoring of outcomes in cardiac surgery initially used volume and unadjusted operative mortality data to measure quality. The first comprehensive report of identifiable hospital death rates was published in 1986 by the Health Care Financing Administration.[4] These unadjusted death rates were widely criticized for inadequate risk adjustment. Thereafter, the VA developed a risk model for coronary artery bypass grafting (CABG) and for valvular and other surgical procedures, presenting its first report in 1990.[5] Since 1987, the VA has continued to analyze mortality and

morbidity data to provide feedback to each VA cardiac center.[6] In 2009, the VA Surgical Quality Improvement Program was established as a risk-adjusted database intended to serve as a benchmark for quality assurance and improvement in all surgical specialties.

Society of Thoracic Surgeons Registry

The idea of a national database for comparing national outcomes was proposed in 1984. In 1988, an ad hoc committee was entrusted with developing a risk-adjusted national database benchmark for thoracic surgery. In 1990, the software for data storage and risk-stratification models was developed,[7] and the Society of Thoracic Surgeons (STS) National Database enrolled 50 participants.[8]

The STS Congenital Heart Surgery Database was begun in 1994, and the STS General Thoracic Surgery Database, in 2002. The STS National Database includes these functional task forces: Quality Measurement, Quality Initiatives, Public Reporting, Informatics, and Patient-Reported Outcomes. The database has provided a source for identifying variations in care processes and has stimulated important QI efforts. Cardiac surgical centers submit data to the STS and receive quarterly reports that show their performance in relation to peer institutions nationwide. This risk-adjusted feedback—a comparison with national and regional averages—is important for self-monitoring, for focusing quality initiatives on areas of concern, and as a benchmark for best practice. After 3 decades, the STS National Database is the foundation for measuring performance, QI, public reporting, and research in cardiothoracic surgery.

Statewide and Regional Collaboration

State and regional collaboration for continuous QI in cardiac surgery has a long history. Groups include the Virginia Cardiac Services Quality Initiative,[9] the Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative,[10] the Northern New England Cardiovascular Disease Study Group,[11] and the Surgical Care and Outcome Assessment Program in Washington state.[12] These surgical QI consortia collect more data than do individual hospitals and have central data registries, thus enabling more meaningful comparison and broader improvement in care.

Once in place, a registry-based system can provide anonymous, risk-adjusted comparative reports that enable surgeons and hospitals to compare their processes of care with others and learn from institutional and surgeon-dependent disparities in care. Systematic sharing of knowledge improves quality by reducing variations in outcomes and processes of care at every participating hospital.

National databases are often criticized because the data reports are perceived to focus more on hospitals than on surgeons. Regional collaboration engenders a strong sense of ownership, including confidence in the quality and value of the data being collected and the content of the subsequent reports. Smaller regional groups can then lead research and quality projects, promoting a joint purpose that may be more difficult to achieve in one national consortium.

Metrics for Evaluating Quality of Care

Donabedian[13] described 7 attributes of health care: efficacy, effectiveness, efficiency, equity, optimality, acceptability, and legitimacy. These principles highlight the importance of patient and social preferences when assuring health care. Donabedian's definition of quality of care encompasses structure, process, and outcome.

Structural Measurements

Healthcare structure refers to fixed attributes of the system in which patients receive care. Structural measurements apply to the infrastructure of a healthcare environment, including material resources (such as electronic health records), human resources (such as staff expertise), and organizational format (such as hospitals or clinics).

Case volume is the structural factor evaluated most often. It became an established part of healthcare discussion after a seminal publication that showed an association between higher case volume and lower rates of perioperative mortality.[14] The association between hospitals' CABG volume and outcome has been investigated.[14,15] Hospital volume was proposed as an indicator of CABG quality by the Center for Medicare & Medicaid Services (CMS). These data are easy to collect and interpret and accompany a belief that "practice makes perfect."

National Medicare claims data from 1994 through 1999 and the New York Cardiac State registry showed that high-volume hospitals had lower mortality rates than did low-volume hospitals.[14] Furthermore, in a review of the STS database of more than 26,000 patients who underwent CABG, procedural volume was modestly associated with outcomes.[15]

However, the association of CABG outcomes with volume is weak. An analysis of the National Inpatient Sample revealed that 85% of low-volume and 89% of medium-volume hospital-years showed risk-standardized mortality rates that were statistically lower than or comparable to those expected, and only 6% of high-volume hospital-years had outcomes statistically better than expected.[16] Patients experience increased travel and discontinuity in postoperative care.[17] Hence, CABG volume might be a surrogate for other process or structural measurements, and adherence to evidence-based metrics is more important than volume alone.[17] However, the volume-outcome relationship has been found to be

important in other cardiac operations, such as transcatheter valve replacement.[18] Evidence shows that this relationship is stronger for procedures that are newer, but that it weakens as technology matures.[18] Moreover, individual operator volume might be more important than institutional volume.[19]

Process Measurements

Processes, referring to services provided to the patient, are evidence-based best practices. Adhering to them leads to improved care.

Process factors for CABG endorsed by the National Quality Forum (NQF) include perioperative β-blockade; internal mammary artery use; and β-blockade therapy, lipid-lowering therapy, and antiplatelet medications given patients before their discharge from the hospital.[20] These data, all collected by STS, are included in a CABG bundle of care, and STS uses them to calculate a CABG Composite Score. Results of extensive studies support the benefit of applying these factors to CABG and to the prevention or progression of coronary atherosclerosis.[21,22] These factors are included in the American College of Cardiology/American Heart Association Guidelines for Secondary Prevention for patients with coronary and other atherosclerotic vascular disease.[23]

Outcome Measurements

Outcome measurements have been defined as the "measure of the end result of what happens to patients as a consequence of their encounter(s) with the healthcare system,"[24] and healthcare institutions therefore seek to develop and apply them.

Risk-Adjusted Mortality

All STS databases define operative mortality as all deaths occurring during the hospitalization in which the operation was performed, even after 30 days, and all deaths occurring after discharge from the hospital through the 30th postoperative day.[25] The risk-adjusted observed-to-predicted mortality ratio is frequently used for comparison in STS databases.[26]

The STS Predicted Risk of Mortality score has been validated for predicting short-term morbidity and death after typical cardiac operations. However, the STS mortality risk and other risk algorithms, for example the European System for Cardiac Operative Risk Evaluation (EuroSCORE), do not evaluate relevant anatomic factors such as porcelain aorta, a patent internal mammary artery crossing the sternotomy, frailty, or the patient's age. Concomitant with the increase in minimally invasive and transcatheter cardiac interventions, expanding risk scores to include frailty and disability enables incremental prognosis, especially in elderly populations. This is highly relevant in patients considered for transcatheter intervention.[27] In addition, all-cause mortality measurements do not provide information about preventable deaths, which are the focus from a QI perspective.[28]

Risk-Adjusted Morbidity

In 2007, the STS Quality Measurement Task Force bundled NQF morbidity factors into a separate outcome domain.[20] By combining multiple quality indicators for a single operation (for example, risk-adjusted mortality and risk-adjusted morbidity), this approach strengthens the quality signal and improves reliability. Five postoperative complications from the NQF cardiac surgery measurement that are considered as a bundle include stroke, renal insufficiency (defined as a new requirement for dialysis or an increase in serum creatinine level to more than 2 mg/dL), deep sternal wound infection, repeat exploration for any cause, and prolonged intubation or ventilation (>24 hr).[29] Complications are associated with reduced survival[30,31] and lead to poor quality of life.[32] Retrospective analysis of the general risk factors associated with these complications helps to identify patients at risk for prolonged length of stay and readmissions.[33] These factors have been the focus in continuous QI projects, which in turn have led to improvement in other quality metrics.[34,35]

For meaningful comparison, the risk adjustment incorporates case-mix adjustment for procedural and patient-level factors. However, the calculation depends on accuracy and inclusion of crucial data, which need constant updating.

Readmissions

The rate of early unplanned hospital readmissions after cardiac surgery varies widely, from 8% to 24%. Interest is high in the readmission rate as a quality-care indicator, because some readmissions are avoidable.[36,37]

Results of a prospective multicenter study showed an 18.7% overall rate of readmission after CABG; the chief causes were infection, arrhythmia, and volume overload. Almost 80% of these readmissions occurred within 30 days of discharge from the hospital.[38] Focusing resources on high-risk patients during this crucial time period and exploring predictive models for readmission risk have potential value.[39] However, these models usually do not consider socioeconomic factors[40] such as household environment, family support, and cultural norms, all of which affect readmission risk after CABG.[41] Of note, not all early unplanned readmissions result from poor care; only about 25% are classified as potentially avoidable.[42]

Failure to Rescue

Failure to rescue (FTR) is defined as the rate of death after adverse occurrences, such as postoperative complications.[43] Because FTR indicates how a system deals with potentially modifiable complications in a timely and appropriate manner, this measure may reliably re-

flect quality. In addition, FTR is independently associated with hospital characteristics and is less sensitive to errors in severity adjustment and patient-specific factors that affect other outcome measures, such as morbidity and death.[44] In an analysis of a large Medicare population of patients who underwent 6 major cardiac operations that included valve replacement and CABG, complication rates were similar between the best- and worst-performing hospitals, but the hospitals with a higher mortality rate had significantly higher FTR rates, overall and when individual surgical operations were compared.[44] A statewide review of 33 hospitals in Michigan showed that low-mortality-rate hospitals had not only low complication rates, but also superior ability to rescue patients from complications when they occurred.[45] An analysis of the STS database, intended to calculate FTR rates for 4 complications after CABG (stroke, reoperation, prolonged intubation, and renal failure), revealed similar results, with mortality rates varying directly with FTR rates.[46]

The STS model to predict a patient's risk of FTR after CABG considers age, preoperative predicted risk of death, and complications.[46] These FTR rates, derived from the STS National Database, can serve as a benchmark for comparing programs.

Quality of Life and Patient-Reported Outcomes

Surgical outcomes are increasingly quantified in terms of the effect that surgery has on patients' daily functional status. Patient-reported outcome measurements (PROM) involve using generic or disease-specific structured questionnaires that convert the patient's own perception of physical and mental health into an objective numerical score. These directly reported scores may provide insight into the patient's response to treatment and thus be a more patient-centered way of comparing the effectiveness of treatments. The NQF and CMS have both endorsed the use of PROM as a performance measurement for QI,[47] and the U.S. Food and Drug Administration has recommended that PROM be incorporated into trials of new devices and drug therapies. Indeed, PROM capture is becoming obligatory because payers demand to understand the value of the healthcare that they purchase. This trend has subsequently mandated PROM reporting as a criterion for payment by CMS in transcatheter aortic valve replacement (AVR). The PROM Task Force was established by the STS in April 2016 to incorporate PROM data into the STS National Database. The result is the Patient-Reported Outcomes Measurement Information System (PROMIS).[48]

Using PROM in routine patient care, however, presents challenges, including managing resources, expertise, time, and clinical workflow concerns, accurately interpreting data from standardized questionnaires, matching domains to clinical situations, not adjusting for risk, and linking measurements to clinical outcomes.[49]

Public Reporting and Surgeon Scorecards

New York was among the first states to begin public reporting of outcomes in cardiac surgery, in 1990.[50] In 2010, the STS began voluntary public reporting of outcomes of isolated CABG by using a composite score.[29] Subsequently, the initiatives have expanded to include isolated AVR,[51] combined AVR and CABG,[52] isolated mitral valve replacement and repair (MVR),[53] and combined MVR and CABG.[54] Amid these investigations, the STS developed an individual composite measurement, surgeon "report cards," based on a 3-year period of major surgical procedures, such as CABG and valve replacement.[55]

Public reporting initially sounds beneficial. Investigators compared in-hospital and 30-day risk-adjusted mortality rates for CABG from 1994 through 1999 between states and regions of the U.S. that had public reporting or formal QI programs and those that did not, and found benefit when programs existed.[56] In-hospital mortality rates for CABG were significantly lower in New York state with its mandated public reporting and in STS programs that voluntarily participated than in programs with other protocols.[57] A systematic review and meta-analysis showed a relative risk reduction of 0.85 (95% CI, 0.79–0.92) in the rate of adverse events when public reporting was performed.[58]

On the other hand, despite the availability of report cards for surgeons, few cardiologists used them as a basis for referral, and fewer shared these reports with their patients during decision-making.[59] Denial of care to high-risk patients is a serious consequence of public reporting.[60] When cardiac surgeons in New York state were surveyed, 62% of respondents said that they had declined to perform CABG in at least one high-risk patient after public records of their performance became available.[61] In addition, these data can be used to compare the performance of 2 hospitals without considering the case mix.[62] Poor interrater reliability between hospital rating systems has been found, as well as poor correlation between private media organizations' findings and the STS adult cardiac surgery database.[63] The impact on surgical training is not fully understood.[64] Surgeon-specific mortality data inaccurately apply to patients undergoing multidisciplinary care.[65]

In summary, public reporting—although imperfect—is a new reality that can help patients make informed decisions regarding their care. However, the data must be meaningful, risk-adjusted, easily understood, and properly interpreted.

Value-Based Care

Consequent to the institution of STS quality metrics and tracking of outcome data, the mortality rate for car-

diac surgery has been steadily declining; however, costs have increased proportionately,[66] prompting a transition from volume-based to value-based models. Such a change is thought to encourage patient-centered care, which would enable high-quality care at lower cost. Value is defined as health outcomes achieved relative to the costs of care.[67] However, the financial charges differ substantially from the actual costs of care delivery, and few institutions have adequate tools to measure value.[68] The University of Utah Health Science Center uses a Value-Driven Outcome (VDO) management and reporting tool to help analyze actual system costs and outcomes.[69] By using VDO and identifying institution- and patient-specific metrics of "perfect care" and appropriate clinical pathways, the University substantially lowered the cost of CABG and improved its outcomes.[70]

Establishing a Culture of Safety and Quality

Supportive leadership,[71] emphasis on safety and QI as organizational priorities,[72,73] and systemwide QI leadership development are important in making substantive changes.[71] Open communication, including sharing results with stakeholders in specifying purpose and strategy[74] and being open to concerns and criticisms throughout the process of change,[75] is important. Other positive factors are having multidisciplinary teams, using proven methodologies for QI, following evidence-based practice, standardizing care processes, and sharing continuous feedback from collected data.[76,77]

Conclusion

The contributions of the cardiothoracic surgeons who established the VA and STS registries in cardiac surgery cannot be overstated, within the medical specialty itself and healthcare nationally. The data generated, questions answered, and programs developed from the STS database use have had substantial impact on the way cardiac surgery is practiced. Although the traditional standards based on morbidity and mortality remain useful, newer concepts such as FTR and PROM are important additions to quality and safety measurement. Finally, a transition from focusing strictly on outcomes to the broader value of care may enable more nuanced QI evaluation in modern health care.

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