

VIEWPOINT FROM THE INTERVENTIONAL COUNCIL

Implications of Public Reporting of Risk-Adjusted Mortality Following Percutaneous Coronary Intervention

Misperceptions and Potential Consequences for High-Risk Patients Including Nonsurgical Patients



Anuj Gupta, MD,^a Robert W. Yeh, MD,^b Jacqueline E. Tamis-Holland, MD,^c Shalin H. Patel, MD,^a
Robert A. Guyton, MD,^d Lloyd W. Klein, MD,^e Tanveer Rab, MD,^d Ajay J. Kirtane, MD, SM^f

ABSTRACT

Assessment of clinical outcomes such as 30-day mortality following coronary revascularization procedures has historically been used to spur quality improvement programs. Public reporting of risk-adjusted outcomes is already mandated in several states, and proposals to further expand public reporting have been put forward as a means of increasing transparency and potentially incentivizing high quality care. However, for public reporting of outcomes to be considered a useful surrogate of procedural quality of care, several prerequisites must be met. First, the reporting measure must be truly representative of the quality of the procedure itself, rather than be dominated by other underlying factors, such as the overall level of illness of a patient. Second, to foster comparisons among physicians and institutions, the metric requires accurate ascertainment of and adjustment for differences in patient risk profiles. This is particularly relevant for high-risk clinical patient scenarios. Finally, the potential deleterious consequences of public reporting of a quality metric should be considered prior to expanding the use of public reporting more broadly. In this viewpoint, the authors review in particular the characterization of high-risk patients currently treated by percutaneous coronary interventional procedures, assessing the adequacy of clinical risk models used in this population. They then expand upon the limitations of 30-day mortality as a quality metric for percutaneous coronary intervention, addressing the strengths and limitations of this metric, as well as offering suggestions to enhance its future use in public reporting. (J Am Coll Cardiol Intv 2016;9: 2077-85) © 2016 by the American College of Cardiology Foundation.

Calls for public reporting of cardiovascular outcomes have been growing, with transparency touted as a fundamental component of quality improvement in an emerging era of value-based health care (1). Public reporting of outcomes following coronary revascularization procedures is already available in several states, with a number of proposals for its expansion looming (2,3). As an

example, the American College of Cardiology has announced plans for voluntary public reporting of process-related institutional data for limited metrics as a first step toward public reporting within the National Cardiovascular Data Registry (4). Increasingly, regulators are legislating public reporting, while payers may use these data to rank physicians (5). These efforts stem from a desire for transparency in

From the ^aUniversity of Maryland School of Medicine, Baltimore, Maryland; ^bBeth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts; ^cMount Sinai Saint Luke's Hospital, New York, New York; ^dEmory University School of Medicine, Atlanta, Georgia; ^eRush Medical College, Chicago, Illinois; and the ^fColumbia University Medical Center/New York-Presbyterian Hospital, New York, New York. Dr. Guyton is a principal investigator for Edwards Lifesciences TMVR trial (no compensation). All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. The views expressed in this manuscript by the American College of Cardiology's (ACC) Interventional Council do not necessarily reflect the views of JACC: Cardiovascular Interventions or the ACC.

Manuscript received May 20, 2016; revised manuscript received August 5, 2016, accepted August 11, 2016.

ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass
grafting

PCI = percutaneous coronary
intervention

RAMR = risk-adjusted
mortality reporting

STEMI = ST-segment elevation
myocardial infarction

outcomes to both ensure and incentivize high-quality care and to guide patients in their selection of providers and hospitals. However, fair comparisons among hospitals and physicians require accurate risk assessment and/or risk adjustment in the reporting process by accounting for case selection and case mix at the levels of both hospitals and physicians. In addition, it is imperative that data collection be accurate and that the

reporting measure being publicly reported be truly representative of the quality of the procedure rather than be dominated by other underlying conditions of the patient.

Risk-adjusted mortality reporting (RAMR) following percutaneous coronary intervention (PCI) has been used as a conventional metric for evaluating the quality of PCI. If an adequate number of PCI procedures are performed, the use of RAMR can be useful for the identification of outlier hospitals and operators and as a base to anchor quality improvement processes. Mortality represents an easily ascertained endpoint of indisputable importance to patients. However, the use of RAMR as a surrogate comparative metric of PCI quality may be misleading, because mortality at 30 days following PCI is frequently not directly related to procedural quality itself (6). Herein lies a fundamental dichotomy related to the use of this metric: although there can be utility in the identification of hospital and physician outliers through examination of 30-day mortality rates, lesser degrees of variability encompassed within comparisons of these rates may have little to do with actual differences in PCI quality, and when taken out of context, these perceived differences can be inappropriately magnified.

Risk adjustment may be one way to address the variability in patient and procedure selection. Yet although the underlying risk of patients undergoing PCI bears a strong influence upon the subsequent occurrence of 30-day mortality, the methodology for risk adjustment varies across state and national registries, with no clear consensus favoring a particular risk adjustment model or strategy. Inadequate accounting of risk in RAMR assessments can inadvertently—when these data are either used as part of a quality improvement initiative or publicly reported—impugn the quality of care offered by providers and hospitals. Particularly for higher risk patients, concerns about how public reporting of RAMR might affect the reputation of a physician and/or hospital can lead to “nonclinical” influences during case selection (such as risk aversion) (7) which may run contrary to the best interest of patients being assessed for treatment.

The conundrum of how to incentivize high-quality care while minimizing the untoward potential impact of public reporting upon the care of high-risk patients is of critical concern to the interventional cardiology community. In this viewpoint, we review in particular specific high-risk patient populations currently treated with PCI procedures, assessing the adequacy of risk models assessing mortality used in this population. We then expand upon the limitations of 30-day mortality as a quality metric for PCI, addressing the implications of public reporting of this metric. We finally offer potential solutions to address the limitations of this metric if used for public reporting, particularly in the context of preserving and enhancing the assessment of PCI-related quality.

HIGH-RISK PATIENT POPULATIONS

Several subgroups of patients have traditionally been considered to be at high risk for adverse outcomes following PCI. These include patients with cardiogenic shock or the resuscitated cardiac arrest patients with post-arrest anoxic encephalopathy. Additionally, patients indicated for complex revascularization but who are deemed nonsurgical—because of extremely high surgical risk, unfavorable anatomy, or other factors precluding surgical revascularization—represent a subset of “high-risk” patients for whom there is increasing interest in the potentially less morbid revascularization afforded by PCI. In these high-risk populations, the increased mortality risk is frequently due to elevated baseline mortality risk, not the actual quality or complexity of the percutaneous revascularization procedure (8).

PCI IN PATIENTS FOLLOWING CARDIAC ARREST.

Observational studies suggest better outcomes when early coronary angiography and revascularization are performed for patients post-arrest (9). In the INTCAR (International Cardiac Arrest Registry) registry of comatose post-cardiac patients, 80% of patients with ST-segment elevation myocardial infarction (STEMI) present on electrocardiography and 33% of patients without STEMI on electrocardiography had evidence of a culprit lesion (mostly total occlusions) on angiography; functional status among comatose patients even without evidence of STEMI was improved in those who underwent coronary angiography (10). Mortality rates for patients with out-of-hospital cardiac arrest remain high even in contemporary trials, approaching 50%, with two-thirds of these deaths a result of neurological causes and occurring irrespective of whether coronary angiography and PCI are performed (11). When PCI is performed in these

high-risk patients, it may have a significant impact on PCI-related outcomes for both the physician and institution performing these procedures if reported outcomes are not adequately risk adjusted. For example, in Washington State, although only 2% of patients undergoing PCI initially presented with out-of-hospital cardiac arrest statewide, these patients accounted for >10% of the case volume at low-volume centers (12).

PCI IN PATIENTS WITH CARIOGENIC SHOCK.

Patients in cardiogenic shock represent another high-risk category. A landmark randomized trial demonstrated that shock patients are among those with the most to gain from invasive management and coronary revascularization, with 62% of hospital survivors assigned to early revascularization alive at 6 years, compared with only 44% of patients managed conservatively (13). As a result of these data in addition to corroborative observational data, revascularization of patients with myocardial infarction complicated by shock is viewed as current standard of care, with a class I recommendation in current clinical guidelines (14). Given the high mortality, however, shock patients can be disproportionally represented in an individual physician's and institution's count of mortalities occurring after PCI, which is why some states current exclude these patients in public reporting.

PCI AS AN ALTERNATIVE TO SURGERY OR IN "NONSURGICAL" PATIENTS.

Patients who merit revascularization for anatomically severe or complex coronary artery disease but are not offered coronary artery bypass grafting (CABG) represent another distinct high-risk subgroup often considered for PCI. Notably, the determination of high surgical risk and/or nonsurgical status may be institution and operator dependent and may be difficult to standardize. Thus, in accordance with current guidelines, these evaluations are ideally made in a heart team-based approach to possible coronary revascularization, considering the relative risks and benefits of medical therapy, PCI, and CABG. In a typical clinical scenario for a patient with symptomatic and severe coronary artery disease, CABG is deemed too high risk for the patient, and PCI is offered as an alternative because revascularization is indicated (either for symptoms or for prognosis). Sometimes PCI is conducted with possible CABG as a "safety net" in the event that PCI causes additional ischemia or poorly controllable hemodynamic deterioration. In other situations, the risk of CABG is truly prohibitive compared with medical therapy, and PCI is performed without the possibility of bail-out CABG. However, the patient's

risk for death with PCI in many cases may be due to the same comorbidities that precluded conventional CABG surgery.

CURRENT RISK ADJUSTMENT MODELS

Risk prediction and risk stratification are critical components in the evaluation and management of patients undergoing revascularization. Many variables (clinical presentation, comorbid risk factors, noninvasive testing including functional testing, and anatomic delineation of coronary artery disease) inform the overall risk assessment of patients with coronary artery disease. Ideally, if risk assessment is performed pre-procedure, diagnostic and therapeutic strategies can usually be tailored by weighing the anticipated benefits of treatment against an individual's predicted risk for adverse events. However, there may be factors that contribute to procedural risk that are not captured in validated risk calculators (15,16). In addition, there are conflicting data on the accuracy of these risk assessment tools in the highest risk patients undergoing PCI (17,18). There may be individual variability in levels of accepted and/or tolerated risk by both patients and providers, and some of this may be due to lack of confidence in RAMR methodology.

The current assessment of PCI-based procedural risk has involved modeling risk on the basis of coronary anatomy, patient clinical characteristics, and in some cases a combination of the 2 factors. The major limitation with all purely anatomic and functional scores is the lack of clinical variables and acuity of clinical presentation in modeling, which reduces their overall predictive ability. In addition, angiography-based scores such as the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score require rigorous and systematic assessments of the coronary angiogram, which can lead to substantial interreader variability (19), particularly if these scores are applied in real time at the point of care. This is particularly relevant when considering the use of such scores (which are not routinely calculated in clinical practice) within larger observational registries. Clinically based risk scores have the advantage of being easier to calculate (20-24). While strengthening their ease of use, the omission of angiographic criteria within some of these scores may limit their predictive performance. In further attempts to increase predictive power and to combine the prognostic importance of clinical and angiographic characteristics, several hybrid anatomic and clinical risk scores have also been developed (25-27).

Procedural registries, such as the National Cardiovascular Data Registry's CathPCI Registry and New York State's Percutaneous Coronary Interventions Reporting System, provide large enough populations enabling the robust derivation and validation of risk models suitable for discriminating patients on the basis of predicted risk (23,28). These risk models depend on the breadth, depth, and accuracy of the data collected and may have limited mechanisms for auditing and overall quality control. In addition to capturing clinical and angiographic data (although not to the extent encompassed by the SYNTAX score), these models further incorporate patient-, operator-, and institutional-level variables, enabling the comparison of outcomes across institutions or operators while normalizing for potential differences in case mix. These scores can additionally be iteratively updated to incorporate information from the growing number of procedures performed in the registries and changes to the variables collected.

POTENTIAL INADEQUACIES OF RISK ADJUSTMENT

Valid comparisons of hospital and operator outcomes are dependent on the methods used for risk adjustment. Factors that might determine whether risk adjustment methodologies have adequately addressed potential confounding due to differences in case mix include: 1) whether all characteristics that influence the risk for mortality after PCI are collected in the dataset used for risk adjustment; and 2) whether these characteristics substantially differ in prevalence among patients treated by different physicians and hospitals (29). Although no model can perfectly adjust for risk, adequate risk assessment (particularly when public reporting is present) engenders confidence among physicians that influences their willingness to perform revascularization procedures in the highest risk/benefit scenarios. This is critically important to avoid perpetuating a treatment-risk paradox, in which treatment is delivered to the patients with the lowest risk (and lower absolute benefit) and withheld from high-risk patients (with a higher absolute benefit).

Because hospitals and operators may care for patients that differ in the severity of coronary disease and underlying comorbidities, as well as the technical complexities of the procedures performed, the possibility exists that comparisons of outcomes could be confounded. For example, elective or urgent patients who are transferred from a hospital with elective PCI capabilities but without cardiac surgery backup to a hospital performing PCI with cardiac surgery backup

are likely to be at elevated risk compared with those for whom operators felt comfortable performing PCI at the original hospital (30). In contrast, some of these referring centers may have greater proportions of patients with emergent STEMI and/or shock relative to their overall volume. If variability in case mix at a given hospital leads to PCI in a greater number of high-risk patients with unmeasured variables, such a hospital may have an RAMR that is increased compared with regional or national benchmarks despite having similar or better quality. In the setting of public reporting that often emphasizes summary statistics, these subtleties may be overlooked.

Inadequate risk adjustment emerges in part from the fact that the majority of patients included in most PCI registries are at low risk for serious adverse events, with only a small minority of patients falling in the intermediate- and high-risk ranges (31). As such, these intermediate- and high-risk patients, and their associated high-risk comorbidities, are under-represented in the sample used to construct the risk model, leading to models that may not fully account for factors that may be rare but highly prognostic. Importantly, because rare but highly prognostic variables may not be captured in registry data collection forms, the influence of their omission can be challenging to evaluate. Notably, in an analysis of 6 different risk models applied to patients undergoing high-risk PCI with hemodynamic support, all assessed risk models were reasonably correlated but had poor discriminatory capacity for overall mortality (17). Efforts have been made to add additional covariates to strengthen the performance of risk models (32). In a recent analysis using data from the CathPCI Registry, RAMR was reported to be well calibrated among registry-defined high-risk patients, and those hospitals treating the largest number of such patients actually had better risk-adjusted outcomes than those treating patients with lower severity of illness (18). However, because high-risk patients in this internally validated study were necessarily defined by the variables collected in the dataset, such an analysis provides little assurance that unaccounted for markers of risk, such as frailty, will not distort comparisons in a manner that falsely impugns those providers and hospitals accepting the highest risk patients. Procedural registries not capturing these factors have no ability to assess the influence of their omission on public reporting metrics.

Finally, in a detailed observational registry study evaluating patients referred for elective PCI of an unprotected left main coronary artery, one-half of the patients were considered to be surgically "ineligible." Among the patients who were deemed unsuitable for

cardiac surgery, three-quarters had at least 1 risk factor not captured on the CathPCI Registry form that contributed to a high risk for CABG (16). Notably, when compared with patients who underwent elective PCI of the left main coronary artery who were also “eligible” for CABG, these CABG-“ineligible” patients had a >6-fold increased risk for death at 1 year. After adjusting for European System for Cardiac Operative Risk Evaluation score, Society of Thoracic Surgeons score, or National Cardiovascular Data Registry-based predicted mortality, the mere presence of surgical ineligibility remained an independent predictor of 1-year mortality. Thus the bedside evaluation of such patients was able to identify important prognostic clinical factors that greatly increased patient risk and were not accounted for using conventional risk adjustment methodology. Because surgical “ineligibility,” in most circumstances, involves evaluation by a cardiac surgeon, it could be expected that such high-risk patients would be concentrated at tertiary care referral centers with cardiac surgical programs, fulfilling the preconditions for introducing statistical bias into the public reporting measure.

The majority of current PCI registries do not collect specific data concerning patient frailty, patient preferences, or extenuating circumstances that may be highly relevant to the decisions being made for choice of revascularization. Physician’s judgment that a patient is “nonsurgical” is an important prognostic factor that is independently associated with a high likelihood for a poor outcome; however, this remains a difficult variable to reliably and consistently record. This is especially important when considering the notion of “gaming the system” by the up-coding of variables defining high risk; independent evaluation by a cardiac surgeon may help mitigate this risk. Overestimation of patient risk, termed “coding creep,” was suggested as early as 1995 in the Cardiac Surgery Reporting System in New York in the setting of CABG, for which the incidence of high-risk variables increased >10-fold when reporting was analyzed (33). Separately, an audit of high-risk variables in PCI found these factors overreported compared with independent adjudication (34). In this analysis, there were consistent differences between reported data and audited data, especially in cases with shock or salvage PCI or emergent cases in which acuity was in fact reassigned by the auditing committee, ranging from 15% to 43% of cases.

When adjustment is applied to procedural-based registries, rather than disease-based registries, even the most accurate forms of procedural risk adjustment cannot take into account the clinical

consequences of risk avoidance behaviors (or cases that never enter the procedural database because they are simply not performed). Despite the importance placed on risk-adjusted PCI mortality as a quality measure, it is not clear to what extent PCI mortality truly reflects the quality of the procedure. Because the “optimal RAMR” for any given case mix is largely unknown, RAMR can be used to identify “outliers” above the 90th percentile of RAMR to screen for variability in overall interventional program quality. However, in a review of PCI mortality over an 8-year period at a single center, 3 physicians reviewing all PCI-related deaths found that 93% of all deaths were either mostly or entirely unpreventable, and only 7% of total deaths appeared to be directly related to the PCI procedure (6). As a result, in circumstances in which RAMR identifies an outlier, the outlying institution or provider may have been singled out because of differences in patient selection and the willingness to perform high-risk procedures, rather than differences in quality of the procedure itself. Nonetheless, case selection itself is an important cognitive component of interventional quality, and it is important to audit this aspect of interventional management in addition to the technical performance of the procedure.

UNINTENDED CONSEQUENCES OF PUBLIC REPORTING OF PCI OUTCOMES

Public reporting of PCI outcomes such as RAMR after PCI has been available in several states and amid increasing calls for transparency of outcomes has been proposed to become more widely available. The advantages to public reporting of procedural outcomes include further stimulation and adoption of rigorous quality improvement programs and institutional protocols, facilitating decision making among patients, and the establishment of preferred providers and institutions by payers. However, public reporting and external scrutiny of outcomes such as mortality following PCI may unintentionally result in risk-averse behavior at both the physician and hospital levels (35). Interventional cardiologists, often under real or perceived pressure from hospitals and a growing number of other influencers, may alter their behavior because of a lack of confidence in the accuracy of RAMR methodology, whether justified or not, to the detriment of the most critically ill patients, who may have the most to gain from a revascularization procedure (36).

Several studies have suggested that avoidance of PCI in high-risk patients may be more common in states with public reporting. RAMR for PCI was first

introduced in New York State in 1995. An analysis of 545 patients with acute myocardial infarction and cardiogenic shock who were enrolled in the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) registry demonstrated a lower rate of coronary angiography and PCI for patients with acute infarction and shock who were admitted to a hospital in New York State compared with their out-of-state counterparts (37). Another study comparing PCI indications and outcomes for patients in New York State with patients undergoing PCI in Michigan (a state that does not publically report PCI outcomes) demonstrated that patients in Michigan more frequently underwent PCI for acute myocardial infarction or cardiogenic shock than patients in New York State (38), despite having a higher rate of comorbidities, including a history of congestive heart failure, extracardiac vascular disease, and pre-procedural cardiac arrest. Similar findings were noted when evaluating PCI indications for patients treated in hospitals in Massachusetts, another state with RAMR (39).

As another example of this problem of “risk aversion” behavior, a review of 7 years of PCI data involving more than 100,000 PCI procedures in non-federally funded hospitals in Massachusetts examined the effects of public reporting on PCI mortality in hospitals identified as outliers (7). The 4 hospitals identified as negative outliers were higher volume institutions performing more PCI for shock and patients with STEMI. Once identified as outlier hospitals, these institutions had a subsequent drop in the predicted mortality of patients undergoing PCI over the ensuing years. However, the improvement in mortality at follow-up for these hospitals was 18% greater than the overall secular trend in mortality reduction for all hospitals in Massachusetts. The investigators suggest that outlier hospitals may have either identified ways to further improve their mortality or alternatively may have selected a lower risk cohort of patients for PCI in the subsequent years to improve mortality data.

A recent study using the Nationwide Inpatient Sample compared outcomes among all patients with diagnoses of acute myocardial infarction in public reporting states compared with non-public reporting states (40). In this sample of more than 84,000 patients from the Northeast and Mid-Atlantic regions between 2005 and 2011, patients who presented with acute myocardial infarction and underwent PCI had a lower mortality rate in public reporting states compared with those patients who underwent PCI for acute myocardial infarction in states without public reporting. However, there was a 19% lower chance of

undergoing revascularization in a public reporting state, with even stronger effects observed in high-risk presentations such as STEMI, cardiogenic shock, or cardiac arrest. Notably, among the broader population of all patients with acute infarction, irrespective of whether they underwent PCI, the risk for dying in public reporting states was significantly higher, driven by a greater risk for mortality in patients who did not undergo PCI in public reporting states.

This is of critical importance when considering public reporting of PCI-related outcomes. In an extreme example, an operator could have outstanding overall mortality (and RAMR) if he or she were simply to refuse all high-risk cases, particularly those whose true risk was not well accounted for by risk adjustment models. However, patients who ought to have been treated with PCI (e.g., patients with myocardial infarction or shock) would not even be offered PCI by this operator, which is a clear disservice to these patients, whose data will never enter a procedure-based PCI registry. Without information regarding the relative case mix (in a disease-based analysis) and the expected mortality rate for that specific case mix, assessing data based on procedural RAMR can be fraught with error. Although an examination of expected mortality rates for specific operators may provide indirect evidence of this effect, particularly for operators with smaller overall numbers, this approach is by no means definitive.

POSSIBLE REMEDIES RELATED TO CONCERNS ABOUT PUBLIC REPORTING

Because RAMR is sensitive only to the covariates specifically included in the derivation of the risk adjustment models used to calculate RAMR, it is important to recognize that behavior driven by inadequate risk assessment can have unintended consequences for patient care. One possible solution that is already being used in specific high-risk scenarios is to introduce further captured variables into the databases used for the risk modeling. This might involve specific modeling for identified high-risk patient features. For example, a series of data fields that can assess surgical eligibility as part of a heart team-based approach (requiring documentation of the specific reasons for considering a patient too high risk for surgery, for example in Table 1), could capture those reasons that rendered a patient ineligible for CABG, and these could be used in subsequent risk modeling. The most recent proposed update to the data collection form within the CathPCI Registry contains several elements specifically designed to implement this approach (Table 2).

TABLE 1 Factors That Can Result in Nonsurgical Categorization of Patients Otherwise Suitable for Revascularization

Patient cachexia/frailty (e.g., 5m walk distance (seconds), activities of daily living)
Active malignancy
Severe aortic calcification
Inadequate conduits
Hostile chest from radiation or multiple previous operations
Extensive vascular calcification
Chronic kidney disease \geq stage 3
Cirrhosis
Encephalopathy or previous stroke with persistent disability
Hematologic abnormality or immunosuppressed
Severe pulmonary hypertension
Gastrointestinal bleeding
Extensive nonviable myocardium

However, it is important to also accept that no risk adjustment model will perfectly adjust for all possible risk variables. Therefore, other potential solutions, such as the exclusion of specific subtypes of high-risk cases from mortality reporting, should be considered. Exclusions for specific high-risk features are already present in certain (although not all) publicly reported registries. For example, in New York State, patients undergoing PCI who have refractory cardiogenic shock (using a clear definition) have been excluded from the publicly reported outcomes data since 2006. Additionally, patients with cardiac arrest who die of neurological causes following PCI are also excluded from public reporting. Two parallel analyses have recently examined the temporal effects of PCI use among patients with acute myocardial infarction complicated by cardiogenic shock in New York State before and after the 2006 exclusion of shock patients. After 2006, there was a clear increase in the use of PCI for this condition, with commensurate declines in overall mortality (41,42). Despite this exclusion, however, the rates of PCI for cardiogenic shock complicating acute myocardial infarction still lagged

TABLE 2 New Elements on the CathPCI Registry Data Collection Form Related to High-Risk Patients

Valvular heart disease with severity
Life-threatening arrhythmia and type
SYNTAX score (if calculated)
Concomitant intervention (peripheral, valvuloplasty, alcohol septal ablation)
Frailty (ADLs, kyphosis, neurocognitive impairment, 5-m walk test)
Cardiac arrest (location, who performed CPR, treatment with hypothermia)
Surgical turnaround (with or without surgical consultation)

ADL = activity of daily living; CPR = cardiopulmonary resuscitation;
SYNTAX = Synergy Between PCI With Taxus and Cardiac Surgery.

behind nonreporting states, suggesting residual risk aversion associated with public reporting.

There is a groundswell of support for excluding high-risk patients from public reporting among interventional cardiologists. In a recent electronic survey distributed to members of the American College of Cardiology's interventional cardiology section, 86% of 1,297 respondents stated that public reporting of mortality following PCI should exclude patients with cardiac arrest, and 76% stated that public reporting of mortality following PCI should exclude patients with cardiogenic shock following acute myocardial infarction. This concern is not limited to interventional cardiologists: in a survey in which 73% of all eligible cardiac surgeons in the United Kingdom participated, 58% of cardiac surgeons were against public reporting of surgeon-specific mortality because of concerns regarding risk aversion, gaming, and misinterpretation and favored instead team-based result reporting (43).

Other states (e.g., Massachusetts) use external peer reviews to assess selected cases deemed to be of extreme risk. Although labor intensive and costly, this allows the more detailed assessment to ensure the accurate assessment of patient risk and the exclusion of selected cases deemed exceptional on the basis of pre-defined criteria. In Maryland, external peer review is already required for randomly selected PCI procedures to judge appropriateness. External peer review can provide a nuanced evaluation of both appropriateness and outcomes and reduce the ability to "game" the system. Furthermore, external peer review, if correctly implemented, could encourage interventional cardiologists to potentially revascularize high-risk patients who might have the greatest possible benefit, with the knowledge that rather than a statistical adjustment, their practicing interventional cardiology peers would review interventions in a blinded fashion and reintroduce clinical judgment into the evaluation of outcomes. Mechanisms for administration, cost allocation, and decisions on how cases would be selected for review (randomly selected procedures, procedures with complications, or other criteria), are still to be made, and whether the states themselves or state-specific chapters of societies will be able to take on the charge to lead these processes is uncertain.

RECOMMENDATIONS

Devising solutions aimed at addressing objective outcomes assessment in high-risk patients is critically important in order to avoid scenarios in which patients are not being offered revascularization strategies that may substantially improve their quality of

TABLE 3 Potential Solutions to Risk Avoidance in High-Risk Patients

Exclusion of higher-risk patients (patients with cardiac arrest, cardiogenic shock, and salvage patients such as those declined by or considered high risk for cardiac surgery) from public reporting
External peer review of procedure-related deaths with specific exclusions from public reporting if procedural causes are absent
Inclusion of high-risk variables in standard registries and risk adjustment such as cardiac arrest patients, cardiogenic shock patients, and salvage patients such as patients declined by or considered high risk for cardiac surgery
Reporting system-based or hospital-based outcomes rather than individual scores for PCI performed for cardiac arrest, cardiogenic shock, and salvage patients such as patients declined by or considered high risk for cardiac surgery
Reporting of process-oriented rather than outcomes measures
Reporting of disease-based outcomes rather than procedure-based outcomes

PCI = percutaneous coronary intervention.

life and/or cardiovascular outcomes (Table 3). As a result, we are fully in support of recent efforts to capture previously unmeasured covariates that capture nontraditional elements of high patient risk and to include them in risk adjustment. Additionally, we propose the development of a mechanism to accurately characterize high-risk clinical scenarios, including patients with cardiac arrest, patients in cardiogenic shock, and nonsurgical patients. Definitions should be selective enough to avoid over-inclusion of patients into the metric, while allowing acceptable parameters to identify patients appropriate for this classification. Using these universal definitions of a high-risk patient, reporting registries can generate several outcomes values for each institution and operator: 1 report would summarize the

overall outcomes for each institution and operator inclusive of all patients, 1 report would provide a summary of outcomes for usual-risk patients, and 1 might report the outcomes for the high-risk patients. Finally, although challenging, we believe that it will be important to move toward disease-based registries, in which patients who do not undergo procedures are also included, as a more accurate assessment of overall quality delivered for a particular condition and a check against risk-averse behavior that can harm patients. Another approach would be to deemphasize outcomes measures such as RAMR and instead report on more process-oriented measures, as has been already established through the CathPCI Registry's reporting of discharge medication use.

In the interim, absent improved models of risk, only data on RAMR for usual-risk patients should be considered for public reporting; the outcomes reported for high-risk patients would not generally be relevant to the public's need when selecting providers and hospitals and therefore need not be available for the public to scrutinize. Either high-risk patients should be excluded from the metric used to report overall outcomes to the public, or registry agencies should institute a process to allow external peer review of all mortality cases prior to potential public reporting, excluding cases if the deaths that occur are clearly unrelated to the PCI procedure or hospital quality of care.

REPRINT REQUESTS AND CORRESPONDENCE: Dr. Ajay J. Kirtane, Herbert Irving Pavilion, 161 Fort Washington Avenue, 6th Floor, New York, New York 10032. E-mail: akirtane@columbia.edu.

REFERENCES

- Totten AM, Wagner J, Tiwari A, O'Haire C, Griffin J, Walker M. Closing the quality gap: revisiting the state of the science (vol. 5: public reporting as a quality improvement strategy). *Evid Rep Technol Assess (Full Rep)* 2012;1-645.
- Dehmer GJ, Drozda JP Jr., Brindis RG, et al. Public reporting of clinical quality data: an update for cardiovascular specialists. *J Am Coll Cardiol* 2014;63:1239-45.
- Bhatt DL, Drozda JP Jr., Shahian DM, et al. ACC/AHA/STS statement on the future of registries and the performance measurement enterprise: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and The Society of Thoracic Surgeons. *J Am Coll Cardiol* 2015;66:2230-45.
- Dehmer GJ, Jennings J, Madden RA, et al. The National Cardiovascular Data Registry Voluntary Public Reporting Program: an interim report from the NCDR Public Reporting Advisory Group. *J Am Coll Cardiol* 2016;67:205-15.
- Wasfy JH, Borden WB, Secemsky EA, McCabe JM, Yeh RW. Public reporting in cardiovascular medicine: accountability, unintended consequences, and promise for improvement. *Circulation* 2015;131:1518-27.
- Valle JA, Smith DE, Booher AM, Menees DS, Gurm HS. Cause and circumstance of in-hospital mortality among patients undergoing contemporary percutaneous coronary intervention: a root-cause analysis. *Circ Cardiovasc Qual Outcomes* 2012;5:229-35.
- McCabe JM, Joynt KE, Welt FG, Resnic FS. Impact of public reporting and outlier status identification on percutaneous coronary intervention case selection in Massachusetts. *J Am Coll Cardiol Interv* 2013;6:625-30.
- Resnic FS, Welt FG. The public health hazards of risk avoidance associated with public reporting of risk-adjusted outcomes in coronary intervention. *J Am Coll Cardiol* 2009;53:825-30.
- Rab T, Kern KB, Tamis-Holland JE, et al. Cardiac arrest: a treatment algorithm for emergent invasive cardiac procedures in the resuscitated comatose patient. *J Am Coll Cardiol* 2015;66:62-73.
- Kern KB, Lotun K, Patel N, et al. Outcomes of comatose cardiac arrest survivors with and without ST-segment elevation myocardial infarction: importance of coronary angiography. *J Am Coll Cardiol* 2015;8:1031-40.
- Nielsen N, Wetterslev J, Cronberg T, et al. Targeted temperature management at 33 degrees C versus 36 degrees C after cardiac arrest. *N Engl J Med* 2013;369:2197-206.
- Maynard C, Rao SV, Gregg M, et al. The role of out-of-hospital cardiac arrest in predicting hospital mortality for percutaneous coronary interventions in the Clinical Outcomes Assessment Program. *J Invasive Cardiol* 2009;21:1-5.
- Hochman JS, Sleeper LA, Webb JG, et al. Early revascularization and long-term survival in

cardiogenic shock complicating acute myocardial infarction. *JAMA* 2006;295:2511-5.

14. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013;127:e362-425.

15. Waldo SW, Secemsky EA, O'Brien C, et al. Surgical ineligibility and mortality among patients with unprotected left main or multivessel coronary artery disease undergoing percutaneous coronary intervention. *Circulation* 2014;130:2295-301.

16. McNulty EJ, Ng W, Spertus JA, et al. Surgical candidacy and selection biases in nonemergent left main stenting: implications for observational studies. *J Am Coll Cardiol Interv* 2011;4:1020-7.

17. Henriques JP, Claessen BE, Dangas GD, et al. Performance of currently available risk models in a cohort of mechanically supported high-risk percutaneous coronary intervention—from the PROTECT II randomized trial. *Int J Cardiol* 2015;189:272-8.

18. Sherwood MW, Brennan JM, Ho KK, et al. The impact of extreme-risk cases on hospitals' risk-adjusted percutaneous coronary intervention mortality ratings. *J Am Coll Cardiol Interv* 2015;8:10-6.

19. Genereux P, Palmerini T, Caixeta A, et al. SYNTAX score reproducibility and variability between interventional cardiologists, core laboratory technicians, and quantitative coronary measurements. *Circ Cardiovasc Interv* 2011;4:553-61.

20. Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart-disease. *Circulation* 1989;79:3-12.

21. Singh M, Rihal CS, Lennon RJ, Spertus J, Rumsfeld JS, Holmes DR. Bedside estimation of risk from percutaneous coronary intervention: the new Mayo Clinic risk scores. *Mayo Clin Proc* 2007;82:701-8.

22. Romagnoli E, Burzotta F, Trani C, et al. EuroSCORE as predictor of in-hospital mortality after percutaneous coronary intervention. *Heart* 2009;95:43-8.

23. Peterson ED, Dai D, DeLong ER, et al. Contemporary mortality risk prediction for percutaneous coronary intervention: results from 588,398 procedures in the National Cardiovascular Data Registry. *J Am Coll Cardiol* 2010;55:1923-32.

24. Wykrzykowska JJ, Garg S, Onuma Y, et al. Value of age, creatinine, and ejection fraction

(ACEF Score) in assessing risk in patients undergoing percutaneous coronary interventions in the "all-comers" LEADERS trial. *Circ Cardiovasc Interv* 2011;4:47-56.

25. Singh M, Rihal CS, Selzer F, Kip KE, Detre K, Holmes DR. Validation of Mayo Clinic risk adjustment model for in-hospital complications after percutaneous coronary interventions, using the National Heart, Lung, and Blood Institute dynamic registry. *J Am Coll Cardiol* 2003;42:1722-8.

26. Garg S, Sarno G, Garcia-Garcia HM, et al. A new tool for the risk stratification of patients with complex coronary artery disease: the clinical SYNTAX score. *Circ Cardiovasc Interv* 2010;3:317-26.

27. Farooq V, van Klaveren D, Steyerberg EW, et al. Anatomical and clinical characteristics to guide decision making between coronary artery bypass surgery and percutaneous coronary intervention for individual patients: development and validation of SYNTAX score II. *Lancet* 2013;381:639-50.

28. Wu C, Camacho FT, King SB III, et al. Risk stratification for long-term mortality after percutaneous coronary intervention. *Circ Cardiovasc Interv* 2014;7:80-7.

29. Krumholz HM. Mathematical models and the assessment of performance in cardiology. *Circulation* 1999;99:2067-9.

30. Dehmer GJ, Blankenship JC, Cilingiroglu M, et al. SCAI/ACC/AHA expert consensus document: 2014 update on percutaneous coronary intervention without on-site surgical backup. *J Am Coll Cardiol* 2014;63:2624-41.

31. Klein LW, Maroney J. Risk-adjusted models of 30-day mortality following coronary intervention: how can they be made more clinically relevant? *J Am Coll Cardiol Interv* 2013;6:623-4.

32. Brennan JM, Curtis JP, Dai D, et al. Enhanced mortality risk prediction with a focus on high-risk percutaneous coronary intervention: results from 1,208,137 procedures in the NCDR (National Cardiovascular Data Registry). *J Am Coll Cardiol Interv* 2013;6:790-9.

33. Green J, Wintfeld N. Report cards on cardiac surgeons. Assessing New York State's approach. *N Engl J Med* 1995;332:1229-32.

34. Barringhaus KG, Zelevinsky K, Lovett A, Normand SL, Ho KK. Impact of independent data adjudication on hospital-specific estimates of risk-adjusted mortality following percutaneous coronary interventions in Massachusetts. *Circ Cardiovasc Qual Outcomes* 2011;4:92-8.

35. Narins CR, Dozier AM, Ling FS, Zareba W. The influence of public reporting of outcome data on medical decision making by physicians. *Arch Intern Med* 2005;165:83-7.

36. Rab T, Interventional Council, Wilson H, Board of Governors. Public reporting of mortality after PCI in cardiac arrest and cardiogenic shock: an opinion from the Interventional Council and the Board of Governors of the American College of Cardiology. *J Am Coll Cardiol Interv* 2016;9:496-8.

37. Apolito RA, Greenberg MA, Menegus MA, et al. Impact of the New York State Cardiac Surgery and Percutaneous Coronary Intervention Reporting System on the management of patients with acute myocardial infarction complicated by cardiogenic shock. *Am Heart J* 2008;155:267-73.

38. Moscucci M, Eagle KA, Share D, et al. Public reporting and case selection for percutaneous coronary interventions: an analysis from two large multicenter percutaneous coronary intervention databases. *J Am Coll Cardiol* 2005;45:1759-65.

39. Joynt KE, Blumenthal DM, Orav EJ, Resnic FS, Jha AK. Association of public reporting for percutaneous coronary intervention with utilization and outcomes among Medicare beneficiaries with acute myocardial infarction. *JAMA* 2012;308:1460-8.

40. Waldo SW, McCabe JM, O'Brien C, Kennedy KF, Joynt KE, Yeh RW. Association between public reporting of outcomes with procedural management and mortality for patients with acute myocardial infarction. *J Am Coll Cardiol* 2015;65:1119-26.

41. McCabe JM, Waldo SW, Kennedy KF, Yeh RW. Treatment and outcomes of myocardial infarction complicated by shock after policy changes in New York State public reporting. *JAMA Cardiol* 2016;1:648-54.

42. Bangalore S, Guo Y, Xu J, et al. Invasive management of cardiogenic shock before and after exclusion of cardiogenic shock from public reporting. *JAMA* 2016;1:640-7.

43. Jarral OA, Baig K, Pettengell C, et al. National survey of UK consultant surgeons' opinions on surgeon-specific mortality data in cardiothoracic surgery. *Circ Cardiovasc Qual Outcomes* 2016;9:414-23.

KEY WORDS CABG, cardiac arrest, high risk, mortality, National Cardiovascular Data Registry, PCI, public reporting, RAMR, shock