

REVIEW AND COMMENTARY

The Public Health Hazards of Risk Avoidance Associated With Public Reporting of Risk-Adjusted Outcomes in Coronary Intervention

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Public reporting of risk-adjusted outcomes for percutaneous coronary intervention (PCI) procedures has been mandated in New York State for more than a decade. During that time there has been a significant decline in the unadjusted mortality after such procedures. Massachusetts joined New York in 2003 as only the second state to require case level reporting of every coronary interventional procedure performed. In this review, we explore the differences in the populations reported by the 2 states and consider possible risks of public reporting of clinical outcomes after PCI procedures, including the risk of increasing conservatism in the treatment of the sickest patients. We offer a conceptual framework to understand the potential risk-averse behavior of interventional cardiologists subject to public reporting, and offer several proposals to counteract this potential deleterious effect of reporting programs. (J Am Coll Cardiol 2009;53:825–30) © 2009 by the American College of Cardiology Foundation

With the recent publication of hospital-specific mortality outcomes of isolated coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI), Massachusetts joined a growing number of states in publicly reporting risk-adjusted cardiac outcomes (1). Although there are a number of reasons to enthusiastically support public reporting, there are potential risks that should be considered when evaluating the overall benefits and costs of such programs.

The most compelling justification for the public reporting of clinical outcomes is the public's right to know about the care that they are likely to receive from hospitals and physicians they use. Such transparency of information should allow patients to make better informed decisions about their health care choices. Implicit in this reasoning is that the public be provided with accurate and meaningful data and that access to care remains unchanged. As will be described in the following text, these goals may be more elusive to achieve than hoped by the designers of public reporting programs.

Beyond the right to know, important potential additional benefits of public reporting include accelerating the adoption of “best practices” from successful medical centers, as well as leveraging the scrutiny of performance, which typically increases attention to process and quality improvement (the Hawthorne effect) (2). As a result of mandated reporting efforts, high quality datasets have been established and used for critical outcomes research (3–5). Importantly, public reporting provides accountability and transparency in regard to quality assurance, and thereby enhances trust between patients, regulators, payors, and providers (6).

Alongside these clear benefits of public reporting, however, there are several limitations to current programs and concerns regarding unintended consequences of these efforts. Developing optimal data collection instruments and assuring adequate data quality from participating centers are significant challenges. In addition, it has been difficult to develop risk adjustment methods that adequately account for the severity of illness in extremely sick patients (7–9). Although these risk-adjustment models have demonstrated excellent discrimination, calibration, and goodness-of-fit in the overall patient populations studied, there are concerns that these models do not adequately address the patients at highest risk (8). Finally, as demonstrated in recent surveys of interventional cardiologists, performing physicians may not fully accept the accuracy of risk adjustment (10), leading to avoidance of higher-risk patients, and providing perverse incentives to perform procedures in lowest-risk patient populations.

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Abbreviations
and Acronyms**CABG** = coronary artery
bypass grafting**PCI** = percutaneous
coronary intervention**STEMI** = ST-elevation
myocardial infarction**The Massachusetts
Experience With Public
Reporting of PCI Outcomes**

The first Massachusetts public report of PCI risk-adjusted mortality was released in 2005 for cases performed during 2003; it demonstrated comparable performance by all Massachusetts

hospitals, as measured by the “Standardized Mortality Incidence Rate” (11). The statewide unadjusted in-hospital mortality after PCI was 1.71% (n = 12,657 total PCI cases for the last 9 months of 2003). Results from this report indicated that Brigham and Women’s Hospital outcomes were within expectations given our case-mix, although higher-risk patients appeared to experience slightly worse outcomes compared with statewide averages than the lower-risk population (neither difference was statistically significant). Given the impact of the report on external assessment of the quality of care at our institution, we undertook a detailed exploration of the factors associated with mortality after PCI. Between January 2003 and December 2005, there were 85 in-hospital deaths among 5,050 patients receiving PCI performed at Brigham and Women’s Hospital, with an unadjusted mortality rate of 1.68%. Although only 2.69% of patients had presented in cardiogenic shock, these patients represented more than 54% of the mortality after PCI, with such patients experiencing a 68-fold increase in the risk of death as compared with patients not presenting in shock.

As shown in Table 1, 44.7% of patients who died before hospital discharge had at least 1 severe acute medical condition present before the index PCI procedure that was not accounted for in the data collection instrument used by the state mandated effort (the American College of Cardiology–National Cardiovascular Data Registry) (12). Typical examples of such severe acute comorbidities included advanced malignancy, active infection, acute stroke, perioperative myocardial infarction after major noncardiac surgery, and anoxic brain injury.

We sought to examine the mortalities further through detailed review of the clinical record and angiograms in an effort to classify the deaths into 1 of 3 categories: 1) no complication of the procedure thought to have contributed to death; 2) complication of procedure possibly related to

patient’s death; and 3) procedural complication materially contributing to the patient’s death. Charts and films were reviewed independently by 2 board-certified interventional cardiologists blinded to both the identity of the patient and the performing interventional cardiologist. Determinations of causality were made based on major neurologic, vascular, or cardiac complications occurring during the procedure or during the hospitalization after the PCI. Examples include intracerebral hemorrhage, major vascular complications requiring surgery or leading to hemodynamic instability, coronary complications including dissection and loss of vessel, or acute or subacute stent thrombosis. Of the 85 deaths, 11 (13%) were categorized as being related to a complication of the PCI procedure. An additional 7 (8%) were determined to be possibly related to the PCI procedure. The majority of deaths (67 of 85, 79%), however, had no identifiable complication of the procedure that was plausibly related to the patient’s death. Implicit in the rationale for using mortality as an end point of quality is that deaths are a reasonable surrogate for the overall quality of the care being provided. These data, however, illustrate that less than one-quarter of all deaths were possibly related to the PCI procedure itself.

Based on this analysis, we sought to improve the performance of the standard risk prediction model by adding available pre-procedural data elements including presentation with neurologic compromise after a presenting cardiac arrest, history of malignancy, in-hospital onset of acute coronary syndrome (e.g., after noncardiac surgery), and presentation to hospital with sepsis. The revised model was then tested using a backward selection algorithm on a boot-strap developed multivariate risk model using our single center PCI experience since 2005. This analysis of 4,921 consecutive PCI cases demonstrated that the addition of the 4 additional covariates modestly improved the discrimination of the model, with an improvement in the area under the receiver-operating characteristic curve from 0.919 to 0.937. However, this improvement was not statistically significant, with a pair-wise comparison for improvement in model discrimination having a p value of 0.171, despite adequate power (>80%) to detect a difference between the 2 models.

Although inconclusive, this initial analysis suggests that there may be additional value to expanding the existing risk prediction models to include high risk markers available at case presentation. In support of this hypothesis is the evidence from Massachusetts, which has recently begun to use a composite additional risk factor (“compassionate use PCI”) in the risk adjustment model for Massachusetts PCI outcomes for 2006. The “compassionate use” variable was developed to identify uniquely high-risk cases that were taken for PCI when the long-term prognosis of the patient was unclear to the operator, but when there was a class I indication for emergent revascularization. These included survivors of cardiac arrest with neurologic impairment in the setting of ST-segment elevation myocardial infarction

Table 1 Characteristics of Patients Who Died After PCI at Brigham and Women’s Hospital From 2003 to 2005

Characteristic	n	% of Deaths
Post-PCI deaths (of 5,050 patients)	85	100
Elective PCI	3	3.5
Pre-procedure cardiogenic shock	46	54.1
STEMI	47	55.3
Simultaneous acute medical event	38	44.7
Noncardiac cause of death	36	42.4

PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

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