Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 62, No. 5, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.03.071



# Cause of Death Within 30 Days of Percutaneous Coronary Intervention in an Era of Mandatory Outcome Reporting

Bhuvnesh Aggarwal, MD,* Stephen G. Ellis, MD,† A. Michael Lincoff, MD,† Samir R. Kapadia, MD,† Joseph Cacchione, MD,† Russell E. Raymond, DO,† Leslie Cho, MD,† Christopher Bajzer, MD,† Ravi Nair, MD,† Irving Franco, MD,† Conrad Simpfendorfer, MD,† E. Murat Tuzcu, MD,† Patrick L. Whitlow, MD,† Mehdi H. Shishehbor, DO, MPH†

*Cleveland, Ohio*

**Objectives** This study sought to ascertain causes of death and the incidence of percutaneous coronary intervention (PCI)-related mortality within 30 days.

**Background** Public reporting of 30-day mortality after PCI without clearly identifying the cause may result in operator risk avoidance and affect hospital reputation and reimbursements. Death certificates, utilized by previous reports, have poor correlation with actual cause of death and may be inadequate for public reporting.

**Methods** All patients who died within 30 days of a PCI from January 2009 to April 2011 at a tertiary care center were included. Causes of death were identified through detailed chart review using Academic Research Consortium consensus guidelines and compared with reported death certificates. The causes of death were divided into cardiac and noncardiac and PCI and non–PCI-related categories.

**Results** Of the 4,078 PCI, 81 deaths (2%) occurred within 30 days. Of these, 58% died of cardiac and 42% of noncardiac causes. However, only 42% of 30-day deaths were attributed to PCI-related complications. Patients with non–PCI-related, compared with PCI-related, death presented with a higher incidence of cardiogenic shock (15 of 47 [32%] vs. 2 of 34 [6%]; $p < 0.01$) and cardiac arrest (19 of 47 [40%] vs. 1 of 34 [3%]; $p < 0.01$). Death certificates had only 58% accuracy (95% confidence interval: 45% to 72%) for classifying patients as experiencing cardiac versus noncardiac death.

**Conclusions** Less than one-half of 30-day deaths are attributed to a PCI-related complication. Death certificates are inaccurate and do not report PCI-related deaths, which may represent a better marker of PCI quality. (J Am Coll Cardiol 2013;62:409–15) © 2013 by the American College of Cardiology Foundation

Public reporting of outcomes after percutaneous coronary intervention (PCI) is likely to be made standard practice as advocated by the Centers for Medicare and Medicaid Services (1). Implementation of this policy will lead to several important consequences. First, Medicare and Medicaid reimbursements for healthcare professionals and institutions will be based on their outcomes (2). Second, mandatory reporting and disclosure of these data will affect the credibility and reputation of a healthcare provider, hopefully helping patients to make informed decisions about their healthcare choices (3). Finally, analysis of the outcomes data will be useful in determining appropriateness and hence cost-effectiveness of performing these procedures (4).

See page 416

Whereas publicly reported outcomes could be considered surrogate markers for healthcare quality, thus far, such disclosures have resulted in mixed reactions from healthcare providers (5–7). In New York and Massachusetts where PCI outcomes were first publicly reported, a strong selection bias toward avoidance of PCI in high-risk patients was subsequently described (8,9). Because of these potentially adverse consequences, many have advocated the importance

From the *Department of Internal Medicine, Medicine Institute, Cleveland Clinic, Cleveland, Ohio; and the †Department of Cardiovascular Medicine, Heart and Vascular Institute, Cleveland Clinic, Cleveland, Ohio. Dr. Cacchione has served as a member of the advisory boards of Humana and UnitedHealthcare. Dr. Nair has received speaker's fees, research support, and honoraria from Boston Scientific, Abbott Vascular, and St. Jude Medical. Dr. Shishhebor has served as an uncompensated consultant and educator for Medtronic, Abbott Vascular, BARD, Bayer HealthCare, and Spectranetics. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received December 12, 2012; revised manuscript received February 15, 2013, accepted March 5, 2013.

**Abbreviations and Acronyms**

**ARC** = Academic Research Consortium
**CI** = confidence interval
**GI** = gastrointestinal
**PCI** = percutaneous coronary intervention
**STEMI** = ST-segment elevation myocardial infarction

of reporting risk-adjusted outcomes, which try to take into account the severity of underlying illnesses (10–14). However, PCI-associated deaths are exceedingly rare, and although risk models are helpful for the majority of patients, their ability to predict the risk of death in very small subgroups (such as PCI patients at very high risk of death) is poor (11). Moreover, the majority of these risk scores were derived from mortality data obtained through death certificates, which are often inaccurate in precisely identifying the cause of death (15–17). Another limitation is lack of data on PCI versus non–PCI-related mortality, which may be a better measure of operator performance and PCI quality. For these reasons, we conducted a detailed chart review to identify the causes of 30-day post-PCI deaths employing standard definitions from globally recognized Academic Research Consortium (ARC) consensus guidelines (18,19).

## Methods

**Study population.** All patients who underwent PCI from January 2009 to April 2011 at a single tertiary care center were identified through the institutional review board–approved institutional PCI registry. Baseline characteristics, cardiac history and risk factors, medications, other chronic medical illnesses, and angiographic and procedural data were prospectively obtained and recorded. Thirty-day deaths after PCI were identified after querying the Social Security Death Index. Circumstances surrounding death such as the decision to withdraw care and site of death were obtained. Medical charts were retrospectively reviewed for cause of death together by 2 clinicians (B.A. and M.H.S.) using standard ARC definitions to prevent any bias. Cause of death by chart review was compared with death certificates when available.

**Definitions.** Cardiogenic shock on presentation was defined as systolic blood pressure persistently <90 mm Hg or the need for inotropic support or intra-aortic balloon pumping to maintain systolic blood pressure >90 mm Hg, in the presence of adequate left ventricular filling pressure and systemic hypoperfusion (18). Neurological dysfunction was defined as Glasgow Coma Scale score <9 or unresponsiveness to any stimuli with absence of brain stem reflexes (in cases were the Glasgow Coma Scale was not checked).

Cause of death was defined as the precipitating factor for the patient's demise, independent of the presenting medical problem on admission (20). There were 19 deaths after initial discharge of whom 8 died after readmission. An attempt to obtain information regarding 11 out-of-hospital deaths was made through a nurse phone call to the patients' families. Of these, no record could be obtained, and the families could not be reached for 5 patients.

The causes of death were divided into cardiac- and noncardiac-related and PCI- and non–PCI-related categories. Cardiac death was defined as any death due to proximate cardiac cause (such as myocardial infarction, low output failure, or fatal arrhythmia), unwitnessed death, death from unknown cause, and all procedure-related deaths, including those related to concomitant treatment. Noncardiac causes were divided into respiratory, infectious, neurological, gastrointestinal (GI), renal and hemato-oncological categories (Table 1). All deaths were considered cardiac unless an unequivocal noncardiac cause could be established. In cases without reasonable clinical evidence toward one or the other, death was determined noncardiac only if stable cardiac pump function was determined by pulmonary artery catheterization.

PCI-related death was defined as death from complication of procedure such as vascular dissection, aneurysm, perforation, bleeding, renal failure, and definite or probable stent thrombosis. Stent thrombosis was defined as "definite" after angiographic confirmation or "probable" in case of any unexplained death within 30 days or any myocardial infarction that was related to documented acute ischemia in the territory of the implanted stent (18). Any bleeding was considered PCI-related if it occurred within 72 h of the procedure, and death from such bleeding was labeled as a complication of PCI (21).

**Statistical analysis.** PCI and non–PCI-related deaths were compared with regard to demographics, past medical history, presenting history, indication for procedure, and the

**Table 1 Definitions of Noncardiac Causes of Death**

| Cause of Death | Definition |
|---|---|
| Infectious | Death from severe sepsis or septic shock as defined by the Society of Critical Care Medicine/American College of Chest Physicians consensus conference guidelines (19). |
| Neurological* | Death due to anoxic brain injury prior to PCI, cerebrovascular accident, or brain death from any cause. |
| Pulmonary | Death after worsening respiratory status due to primary lung pathology including acute respiratory distress syndrome. |
| Gastrointestinal | Death from massive gastrointestinal bleeding, as complication of liver disease, cancer, or gastrointestinal perforation not related to dual antiplatelet therapy. |
| Hemato-oncological | Death from life-threatening hemorrhage (except gastrointestinal and intracranial hemorrhage) or due to an advanced cancer, its complication, or withdrawal of care due to concerns regarding poor prognosis associated with cancer. |
| Renal† | Death due to complication of renal failure such as fluid overload, acidosis, and electrolyte disturbances. |

*In patients with cardiac arrest, death was adjudicated to be neurological only if neurological dysfunction was documented prior to the start of percutaneous coronary intervention (PCI). In addition, the patient was also required to have a successful PCI with restoration of stable cardiac pump function as determined by either a pulmonary artery catheterization or lack of inotropic support. In equivocal cases or if no such data were available, cause of death was considered to be cardiac. †Excluding patients with contrast-induced nephropathy from iodinated contrast administered during PCI.