Door-to-Balloon Time in Primary Percutaneous Coronary Intervention
Is the 90-Minute Gold Standard an Unreachable Chimera?

Mauro Moscucci, MD; Kim A. Eagle, MD

Over the past decade, primary percutaneous coronary intervention (PCI) has emerged as an effective treatment strategy for acute ST-segment–elevation myocardial infarction (STEMI). Compared with thrombolytic therapy, the benefits of primary PCI include a reduction in the frequency of total stroke and hemorrhagic stroke, a reduction in the frequency of reinfarction, and an increase in the frequency of infarct-related artery patency, resulting in improved in-hospital and long-term survival. In addition, the availability of primary PCI provides a valid alternative for patients who have contraindications to thrombolytic therapy.

These observations have led many institutions to select primary PCI as the preferred treatment strategy for patients with acute STEMI. In addition, after the publication of several reports on the safety and efficacy of primary PCI in centers without cardiac surgery on site, several state regulatory agencies have changed local regulations by allowing primary PCI for acute STEMI in centers without cardiac surgery on site. Thus, it is likely that the next decade will be characterized by further expansion of primary PCI for acute STEMI in hospitals with cardiac catheterization laboratories.

As previously shown for thrombolytic therapy, time to treatment also plays a key role in survival with primary PCI. In the Global Use of Strategies to Open Occluded Arteries in Acute Coronary Syndromes (GUSTO-IIb) substudy, the lowest 30-day mortality rate was observed in patients undergoing primary PCI within 60 minutes from presentation to the emergency room, whereas the highest mortality rate was observed in patients undergoing PCI >90 minutes from presentation (1.0% versus 6.4%). Similar compelling data were reported in an analysis of data from the National Registry of Acute Myocardial Infarction (NRMI). In that analysis, which included 27,080 patients, the lowest mortality rate again was observed in patients undergoing PCI within 60 minutes from presentation, whereas significantly higher mortality rates were observed in patients undergoing PCI beyond 120 minutes.

The importance of door-to-balloon time as a correlate of mortality is further underscored by additional analysis that have shown an inverse relationship between door-to-balloon time and mortality benefit of primary PCI over thrombolysis. Thus, given the time dependency of survival in patients with STEMI undergoing primary PCI, the American College of Cardiology and American Heart Association guidelines for the management of acute myocardial infarction have established a door-to-balloon time of 90 minutes as a new gold standard for primary PCI. Furthermore, door-to-balloon time would appear to meet all the criteria for a valid performance measurement. These criteria include a measurement that is meaningful, valid, and reliable; that can account for patient variability; and that is feasible and can be modified by improvements in the healthcare system. As such, door-to-balloon time has been adopted as a key performance measurement for quality of care of patients with STEMI.

Unfortunately, in the same analysis of NRMI data that highlighted the importance of door-to-balloon time for survival, the overall median door-to-balloon time was 116 minutes. Only 29.3% of patients underwent PCI <90 minutes from presentation, whereas 46% of patients underwent PCI >120 minutes. Thus, the 90-minute standard seems an ambitious goal, given the current levels of performance.

Factors that have been found to be associated with delays in door-to-balloon time include female gender, contraindication to thrombolytic therapy, age >65 years, atypical symptoms or absence of chest pain at presentation, and additional “environmental” challenges represented by providing timely care on weekends, holidays, and off-hours. Furthermore, coronary reperfusion with primary PCI requires the complex integration of multiple units and healthcare providers within a given hospital system. Thus, it depends on the function of what could be characterized as a complex system—a system that constantly evolves over time, a system with an evolution that is very sensitive to small changes, a system with a large number of independent interacting components, or a system that can evolve through multiple pathways. This complexity further enhances the challenge of achieving timely reperfusion with primary PCI and raises the question of how institutions can succeed in achieving such a goal.

In this issue of Circulation, Bradley and colleagues provide a qualitative analysis of 11 hospitals participating to the NRMI that had median door-to-balloon times of ≤90 minutes during 2001 to 2002 and had substantial improvement since 1999. Poorly performing centers were excluded from the study. Using a methodology including interviews...
with clinical and administrative staff, they were able to identify 8 themes that were characteristic of the experiences of top performing hospitals: commitment to an explicit goal to improve door-to-balloon time motivated by internal and external pressures, senior management support, innovative protocols, flexibility in refining standardized protocols, uncompromising individual clinical leaders, collaborative teams, data feedback to monitor progress and identify problems and successes, and an organizational culture that fostered resilience to challenges or setbacks in improvement efforts. Taken together, their results summarize and apply to the specific issue of door-to-balloon time the elements that have previously been shown to play an important role in improving overall quality of care for patients with acute coronary syndromes.

In the National Cooperative Cardiovascular Project, one of the first studies addressing the issue of practice variations and quality of care for acute myocardial infarction, data collection at baseline was followed by an intervention that included data feedback. At follow-up, significantly higher rates of aspirin use during the same hospitalization and of β-blockers use on discharge were observed. These improvements in key measures of care processes were associated with a reduction in 30-day and 1-year mortality. Other studies have suggested that more aggressive interventions beyond data feedback alone might result in further improvement in quality of care. In 1 study evaluating the effectiveness of a structured approach to quality improvement, hospitals were randomized to either simple performance feedback mailed to clinical leaders or a systematic intervention including the identification of barriers to change in approaches to care for patients with acute myocardial infarction; data collection, distribution of comparative performance reports, and identification of opinion leaders responsible to influence their peers through small- and large-group discussions, informal consultation, revision of hospital protocols and clinical pathways, distribution of comparative performance reports, and identification of barriers to change in approaches to care for patients with acute myocardial infarction. At follow-up, the hospitals randomized to the systematic intervention had a higher increase in use of aspirin and β-blockers compared with the hospitals randomized to data feedback alone.

In a more recent regional Guidelines Applied to Practice (GAP) intervention aimed at improving quality of care for patients with acute coronary syndromes, baseline data collection was followed by an intervention including hospital site visits by project leaders, the development of standing orders and tool kits, simple hospital discharge contracts designed to ensure that patients left the hospital having received essential medications and education, and systematic data feedback on performance on key quality indicators. Data from 10 intervention hospitals were compared with data from a control group of 11 hospitals that were not selected for participation. Confirming the results of prior studies, a significant improvement in quality of care was observed in the intervention hospitals compared with the control hospitals, and more recently, an association between the intervention performed and a reduction in 30-day and 1-year mortality for patients with myocardial infarction was reported. However, the GAP initiative was unsuccessful in improving door-to-balloon time for primary PCI, perhaps because the effort did not focus sufficient attention on the key factors influencing initial triage and therapy as patients entered emergency departments.

Caputo et al reported the effect of a detailed quality improvement intervention aimed at reducing door-to-balloon time in a single institution. The intervention included avoidance of pre-evaluation by referring cardiologists; education of emergency room staff, transport personnel, and cardiology staff on the importance of rapid diagnosis of myocardial infarction and rapid transport to the catheterization laboratory; immediate activation of the cardiac catheterization laboratory on notification of a patient with suspected acute myocardial infarction; requirement for the catheterization laboratory staff to be in the hospital within 30 minutes; and target time of 30 minutes for interventional staff for first balloon inflation after xylocaine administration. A significant reduction in door-to-balloon time, and in particular a marked reduction for “after hours” cases, was observed after implementation of the intervention. Thus, as a group, these studies suggest that action through systematic interventions can result in significant improvement in care for patients with acute myocardial infarction and that door-to-balloon time can be favorably influenced if the complex system surrounding it is understood and modified.

In the study of Bradley and colleagues, the exclusion of poorly performing hospitals from the analysis does not allow assessment of which cultural factors were most important for reaching optimal performance. Although the “self-reported” interview approach can be perceived as an additional limitation, their report does provide us with 8 important themes that indicate institutional “preparedness” for improving door-to-balloon times. Actual improvement must move beyond preparedness to action such as the one described by Caputo et al in which targeting 5 specific steps led to substantial improvement. We believe that a substantial reduction in door-to-balloon time can be achieved through multi-institutional collaborative initiatives in which institutions and caregivers work together to create a culture of change like the one described by Bradley and colleagues to identify local action items on which to focus, to implement systems to measure process and outcomes, and to provide timely feedback. Achieving the 90-minute gold standard is possible, but it will require sustained investment on the part of institutions and caregivers alike.

Disclosures
None.

References


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