

Nonsystem Reasons for Delay in Door-to-Balloon Time and Associated In-Hospital Mortality

A Report From the National Cardiovascular Data Registry

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Objectives	The goal of this study was to characterize nonsystem reasons for delay in door-to-balloon time (D2BT) and the impact on in-hospital mortality.
Background	Studies have evaluated predictors of delay in D2BT, highlighting system-related issues and patient demographic characteristics. Limited data exist, however, for nonsystem reasons for delay in D2BT.
Methods	We analyzed nonsystem reasons for delay in D2BT among 82,678 ST-segment elevation myocardial infarction patients who underwent primary percutaneous coronary intervention within 24 h of symptom onset in the CathPCI Registry from January 1, 2009, to June 30, 2011.
Results	Nonsystem delays occurred in 14.7% of patients (n = 12,146). Patients with nonsystem delays were more likely to be older, female, African American, and have greater comorbidities. The in-hospital mortality for patients treated without delay was 2.5% versus 15.1% for those with delay (p < 0.01). Nonsystem delay reasons included delays in providing consent (4.4%), difficult vascular access (8.4%), difficulty crossing the lesion (18.8%), "other" (31%), and cardiac arrest/intubation (37.4%). Cardiac arrest/intubation delays had the highest in-hospital mortality (29.9%) despite the shortest time delay (median D2BT: 84 min; 25th to 75th percentile: 64 to 108 min); delays in providing consent had a relatively lower in-hospital mortality rate (9.4%) despite the longest time delay (median D2BT: 100 min; 25th to 75th percentile: 80 to 131 min). Mortality for delays due to difficult vascular access, difficulty crossing a lesion, and other was also higher (8.0%, 5.6%, and 5.9%, respectively) compared with nondelayed patients (p < 0.0001). After adjustment for baseline characteristics, in-hospital mortality remained higher for patients with nonsystem delays.
Conclusions	Nonsystem reasons for delay in D2BT in ST-segment elevation myocardial infarction patients presenting for primary percutaneous coronary intervention are common and associated with high in-hospital mortality. (J Am Coll Cardiol 2013;61:1688–95) © 2013 by the American College of Cardiology Foundation

Rapid and successful reperfusion with primary percutaneous coronary intervention (PCI) is the goal of initial treatment in patients presenting with ST-segment elevation myocardial infarction (STEMI). Supporting the belief that "time is muscle," previous studies have validated that incremental delays in door-to-balloon time (D2BT) negatively affect clinical outcomes, including both in-hospital (1) and long-

term mortality (2) rates. Correlations between reduced D2BT and reduced mortality (3,4) have prompted primary

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PCI hospitals to adopt strategies for achieving mechanical reperfusion within the recommended 90-min window (5). However,

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real-world registry data reveal that a large proportion of patients continue to fail undergoing PCI within this time frame (6,7).

Determining reasons for D2BT delay in primary PCI for STEMI patients provides an opportunity to improve quality of care for these patients. A number of studies have highlighted certain systems issues and patient demographic characteristics (8,9) as predictors of delay, including need for hospital transfer, non-daytime presentation, low-volume centers, older age, female sex, and nonwhite race (9). In response to these system reasons for delays, a number of organizations have implemented programs to meet the D2BT benchmark of ≤ 90 min and timely access to PCI (10,11), with improvements in D2BT compliance (7).

Although system reasons for delay have garnered attention from a hospital administration and emergency services standpoint, there are limited data on nonsystem reasons for delays. Importantly, nonsystem reasons for delay may account for some of the disparities between guidelines and clinical performance. Examples of nonsystem delays include delays in providing procedure consent, difficult vascular access, difficulty crossing the culprit lesion, and patients who have a cardiac arrest requiring intubation before PCI. The purpose of the present study was to evaluate the frequency and associated mortality of nonsystem delays in D2BT in STEMI patients presenting to hospitals with primary PCI capabilities in the national CathPCI Registry.

We hypothesized that nonsystem delays would be frequent and associated with higher mortality and adverse clinical events based on 2 reasons. First, greater ischemic time as a result of substantial delays in reperfusion would portend a higher mortality (1–4,12). Second, reasons for nonsystem delays are often related to pre-existing patient comorbidities, a higher risk of myocardial infarction presentation, and higher risk coronary anatomy that are surrogate markers for advanced disease and poorer clinical outcomes.

Methods

Data collection. The CathPCI Registry is a large national registry of patients undergoing diagnostic cardiac catheterizations and/or PCI, and details of the registry have been previously described (13,14). The present study used version 4.3 of the CathPCI Registry, in which nonsystem reasons for delays were first collected for analysis.

Study population. A retrospective analysis of CathPCI Registry data was performed to assess nonsystem reasons for delay in D2BT in STEMI patients and the associated in-hospital mortality outcomes between January 1, 2009, and June 30, 2011. We included patients who had electrocardiographic evidence of ST-segment elevations, presented within 12 hours of symptom onset to emergency departments at acute care hospitals with primary PCI capabilities, and subsequently underwent primary PCI with a D2BT < 12 h. Excluded were patients < 18 or > 90 years of age, STEMI transfers, thrombolysed patients, and low-volume centers (average of < 6 primary PCIs for STEMI annually).

Statistical analysis. Nonsystem reasons for delay in primary PCI must be documented in the medical chart to be abstracted into the CathPCI Registry data collection form, and specific nonsystem reasons collected included patient delays in providing consent for the procedure, difficult vascular access, difficulty crossing the culprit lesion during the PCI, and cardiac arrest and/or need for intubation before PCI. Also captured were unclassified nonsystem reasons for delay labeled as “other.” Baseline patient subgroups are presented as counts with percentages for categorical variables and the median with interquartile range (IQR) for continuous variables. An imputation method was used, such that glomerular filtration rate was imputed to the gender-specific and renal failure-specific medians. Likewise, ejection fraction was imputed to medians specific to congestive heart failure (CHF), cardiogenic shock, and previous myocardial infarction. Statistical comparison of between-group differences was performed by using chi-square tests for categorical variables and the Kruskal-Wallis test for continuous variables. Statistical significance was defined as a 2-sided $p < 0.05$ for all comparisons. All statistical analyses were performed by the Duke Clinical Research Institute using SAS version 9.3 (SAS Institute, Cary, North Carolina).

Multivariable logistic regression modeling with generalized estimating equations was performed to evaluate if nonsystem reasons for delay were independent predictors of in-hospital mortality while adjusting for within-hospital correlation by using the CathPCI Registry’s previously validated model for mortality after PCI (15). The reference group consisted of patients with no reported nonsystem delay. Variables in the mortality model included: age, gender, race, cardiogenic shock, previous CHF, valve surgery/procedure, cardiovascular disease, peripheral vascular disease (PVD), chronic lung disease, previous PCI, pre-intra-aortic balloon pump (IABP), ejection fraction, glomerular filtration rate, body mass index, dialysis, New York Heart Association CHF class, highest risk segment category, highest risk lesion pre-Thrombolysis In Myocardial Infarction (TIMI) flow, highest risk Society for Cardiovascular Angiography and Interventions class, PCI status, and diabetes.

Results

Frequency of nonsystem delays and baseline and angiographic characteristics. During the study period, 82,678 STEMI patients presented to 1,172 participating centers after ap-

Abbreviations and Acronyms

CHF	= congestive heart failure
D2BT	= door-to-balloon time
IABP	= intra-aortic balloon pump
IQR	= interquartile range
OR	= odds ratio
PCI	= percutaneous coronary intervention
PVD	= peripheral vascular disease
STEMI	= ST-segment elevation myocardial infarction
TIMI	= Thrombolysis In Myocardial Infarction

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