Acute Coronary Syndromes

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 Cath-PCI 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

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

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

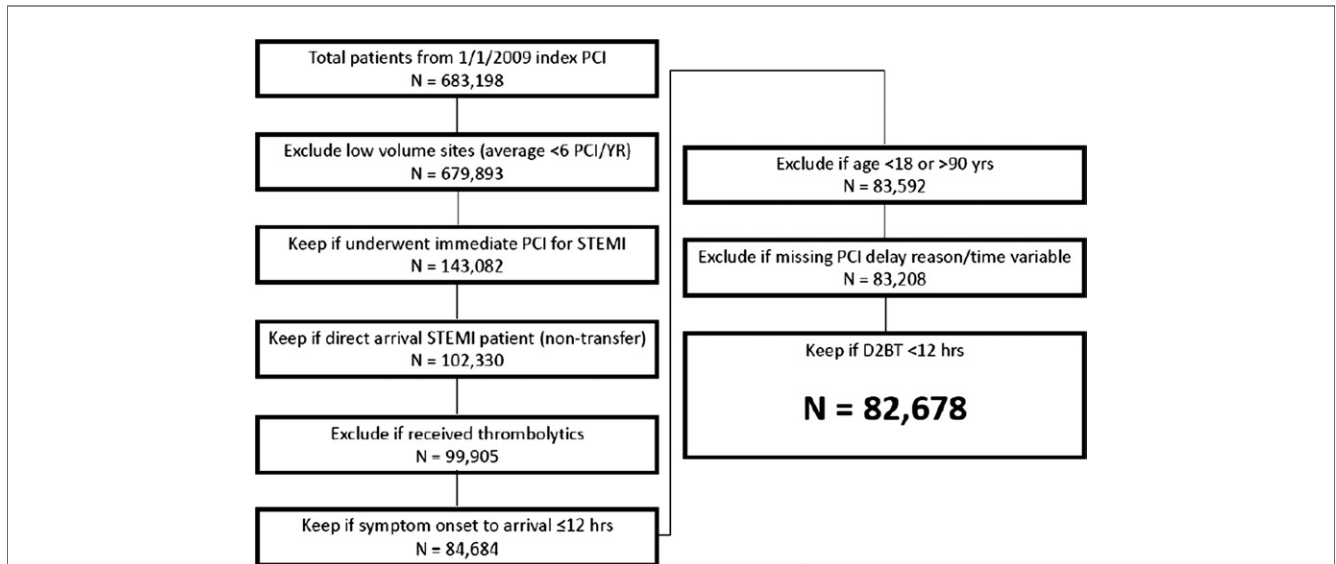**TIMI** = Thrombolysis In Myocardial Infarction

Figure 1   Study Population

Flowchart of study patients. D2BT = door-to-balloon time; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

plication of inclusion and exclusion criteria to the CathPCI Registry database (Fig. 1). Median D2BT was 65 min (IQR: 50 to 83 min), with 18.9% of patients having D2BT ≥90 min. Of these 82,678 patients, 14.7% (n = 12,146) were reported to have nonsystem reasons for delay. D2BTs were longer (median: 92 min; IQR: 70 to 115 min) for patients with nonsystem delays compared with patients not reporting delays (median: 63 min; IQR: 48 to 78 min).

The nonsystem reasons for delay and frequency of each occurrence were as follows: delays in providing procedure consent (4.4% [n = 535]), difficult vascular access (8.4% [n = 1,017]), difficulty crossing lesion (18.8% [n = 2,289]), other (31.0% [n = 3,761]), and cardiac arrest/need for intubation (37.4% [n = 4,544]). Table 1 summarizes the frequency of each nonsystem delay and baseline characteristics.

Overall, patients with nonsystem delays were more likely to be older, female, or African American, and have a history of hypertension, diabetes, previous myocardial infarction, previous CHF, previous coronary artery bypass graft, dialysis, cerebrovascular disease, PVD, or chronic lung disease compared with nondelayed patients. Patients with delayed D2BT due to delays in providing consent were more likely to be older, female, and nonwhite compared with other nonsystem reasons for delay. Patients delayed due to difficult vascular access were more likely to be smokers and have PVD. Patients delayed due to difficulty in crossing the culprit lesion were more likely to be male and to have a history of dyslipidemia, previous PCI, and previous coronary artery bypass graft. Delays in primary PCI due to cardiac arrest/intubation included patients with less frequent cardiovascular risk factors of hypertension, dyslipidemia, and diabetes.

Table 2 summarizes angiographic and procedural characteristics associated with nonsystem delays. Patients delayed due to difficult vascular access had a greater frequency of radial and brachial entry sites relative to femoral access. Delays due to difficulty in crossing the culprit lesion were more frequent in left circumflex arteries and associated with longer lesion length. In this group, the presence of thrombus and complete post-procedure TIMI flow grade 3 were less frequent. Patients with cardiac arrest/intubation delays more frequently had left main and left anterior descending artery culprits, presence of thrombus, cardiogenic shock before PCI, and placement of an IABP or other mechanical ventricular support placed before PCI.

D2BT for nonsystem delays. Patients with nonsystem delays did not necessarily all have a D2BT >90 min (Table 3). Patients with delays due to providing consent had a median and a 25th to 75th percentile D2BT range of 100 min and 80 to 131 min, respectively. This represented the longest time delay and resulted in 67% of patients missing the recommended American College of Cardiology/American Heart Association 90-min D2BT guideline (5). Patients with delays due to cardiac arrest/need for intubation had a median and a 25th to 75th percentile D2BT range of 84 min and 64 to 108 min, respectively. This represented the shortest time delay. Although the time to device deployment was "delayed" due to each nonsystem reason, 47% of patients reported to have nonsystem delays still met D2BT guidelines of ≤90 min.

Mortality outcomes and adverse events. The overall, in-hospital mortality for patients without reported nonsystem delays was 2.5% compared with 15.1% (p < 0.0001) for those with a reported nonsystem delay (Fig. 2A). Mortality rates for each nonsystem delay were as follows: difficulty crossing lesion (5.6%), other (5.9%), difficult vascular access

Table 1	Baseline Characteristics and Frequency of Patients With and Without Nonsystem Delays							
Patient Characteristic	No Report of Nonsystem Delay	Nonsystem Delay	p Value	Delays in Consent	Difficult Access	Difficulty Crossing Lesion	Cardiac Arrest/ Intubation	Other
Patients	70,532 (85.3)	12,146 (14.7)		535 (4.4)	1,017 (8.4)	2,289 (18.8)	4,544 (37.4)	3,761 (31.0)
Age (yrs)	60.3 ± 12.4	62.9 ± 13.1	<0.001	67.9 ± 14.9	63.6 ± 12.8	64.2 ± 12.9	61.9 ± 12.7	62.5 ± 13.2
Male	52,022 (73.8)	8,338 (68.6)	<0.001	310 (57.9)	653 (64.2)	1,666 (72.8)	3,155 (69.4)	2,554 (67.9)
Race/ethnicity								
White	62,036 (88.0)	10,520 (86.6)	<0.001	443 (82.8)	903 (88.8)	2,010 (87.8)	3,908 (86.0)	3,256 (86.6)
Black	5,619 (8.0)	1,123 (9.3)	<0.001	54 (10.1)	83 (8.2)	197 (8.6)	439 (9.7)	350 (9.3)
Asian	1,914 (2.7)	337 (2.8)	0.703	32 (6.0)	21 (2.1)	58 (2.5)	130 (2.9)	96 (2.6)
Hispanic	4,231 (6.0)	783 (6.5)	0.055	32 (6.0)	60 (5.9)	144 (6.3)	286 (6.3)	261 (6.9)
Body mass index (kg/m^2)	29.1 ± 6.0	29.0 ± 6.5	0.0001	27.6 ± 6.5	29.9 ± 8.0	29.2 ± 6.1	29.0 ± 6.6	28.9 ± 6.2
Smoker	30,686 (43.5)	4,900 (40.3)	<0.0001	178 (33.3)	488 (48.0)	818 (35.7)	1,947 (42.9)	1,469 (39.1)
Hypertension	45,304 (64.2)	8,332 (68.6)	<0.0001	390 (72.9)	751 (73.8)	1,678 (73.3)	2,908 (64.0)	2,605 (69.3)
Dyslipidemia	44,199 (62.7)	7,427 (61.2)	0.001	324 (60.6)	658 (64.7)	1,545 (67.5)	2,543 (56.0)	2,357 (62.7)
Diabetes	15,605 (22.1)	3,185 (26.2)	<0.0001	159 (29.7)	293 (28.8)	600 (26.2)	1,159 (25.5)	974 (25.9)
Family history of CAD	15,343 (21.8)	2,182 (18.0)	<0.0001	74 (13.8)	210 (20.7)	447 (19.5)	688 (15.1)	763 (20.3)
Previous MI	13,348 (18.9)	2,619 (21.6)	<0.0001	107 (20.0)	254 (25.0)	595 (26.0)	848 (18.7)	815 (21.7)
Previous CHF	2,604 (3.7)	894 (7.4)	<0.0001	50 (9.4)	67 (6.6)	182 (8.0)	371 (8.2)	224 (6.0)
Previous PCI	15,165 (21.5)	2,656 (21.9)	0.363	92 (17.2)	260 (25.6)	622 (27.2)	880 (19.4)	802 (21.3)
Previous CABG	3,743 (5.3)	1,099 (9.1)	<0.0001	43 (8.0)	107 (10.5)	308 (13.5)	292 (6.4)	349 (9.3)
Dialysis	523 (0.7)	221 (1.8)	<0.0001	14 (2.6)	18 (1.8)	38 (1.7)	89 (2.0)	62 (1.7)
Cerebrovascular disease	4,320 (6.1)	1,148 (9.5)	<0.0001	74 (13.8)	99 (9.7)	222 (9.7)	418 (9.2)	335 (8.9)
Peripheral vascular disease	3,608 (5.1)	1,162 (9.6)	<0.0001	53 (9.9)	277 (27.2)	184 (8.0)	368 (8.1)	280 (7.4)
Chronic lung disease	6,237 (8.8)	1,526 (12.6)	<0.0001	78 (14.6)	146 (14.4)	271 (11.8)	600 (13.2)	431 (11.5)

Values are n (%) or mean ± SD. Frequency of all combined nonsystem delays and each separate nonsystem reason for delay in door-to-balloon time and associated baseline characteristics.

CABG = coronary artery bypass graft; CAD = coronary artery disease; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention.

(8.0%), delay in providing consent (9.4%), and cardiac arrest/intubation (29.9%) (Fig. 2B). All mortality rates associated with each nonsystem reason for delay were significantly higher compared with nondelayed patients (p < 0.0001).

After adjustment for baseline characteristics in a multivariable regression model, risks of in-hospital mortality were calculated for cardiac arrest/intubation versus no delay and for all other combined nonsystem delays versus no delay (Table 4). In this model, the adjusted odds of mortality remained significantly higher for patients with a cardiac arrest/intubation delay compared with those with no delay (odds ratio [OR]: 3.4 [95% confidence interval: 3.1 to 3.8]) and for all other combined nonsystem delays versus no delay (OR: 1.7 [95% confidence interval: 1.5 to 1.9]). Adjusted in-hospital mortality was also analyzed after stratifying patients according to D2BT (≤90 min or >90 min). The mortality OR was similar for all other combined nonsystem delays regardless of D2BT (Table 4).

Post-procedure adverse events (cardiogenic shock, CHF, cerebrovascular accident/stroke, renal failure, any vascular complications, and bleeding events within 72 h) were also more common in patients delayed for nonsystem reasons compared with nondelayed patients (Table 5).

Discussion

To the best of our knowledge, this is the first report of the frequency, magnitude, and associated mortality for nonsystem reasons for a delay in PCI for STEMI patients presenting to centers with primary PCI capabilities. Our

hypothesis that nonsystem delays would be frequent and associated with higher mortality and adverse events was supported by this analysis and was related to patient comorbidities and higher risk presentation rather than greater ischemic time from a substantial delay in reperfusion. This is in contrast to other analyses on system delays and D2BT, which report an increase in associated mortalities with incremental time delays in D2BT (1–4,8).

Cardiac arrest/intubation delays. We found that the most frequent nonsystem delay was in patients presenting with a cardiac arrest requiring intubation before PCI (37.4%). As expected, this group had the highest in-hospital mortality rate (30%). This figure is similar to that of a large prospective, single-center observational study which found that STEMI cardiac arrest patients requiring transfer to a PCI hospital had a mortality rate of 30.6% at the index hospital and 44.2% at the PCI center (16). Internationally, investigators have found that resuscitated cardiac arrest STEMI patients requiring intubation is an independent predictor of both in-hospital and long-term mortality (17). Interestingly, baseline characteristics of patients in this group did not include an increased relative frequency of smokers, chronic lung disease, or previous CHF compared with other nonsystem reasons for delay. Instead, these patients were more likely to have anterior wall injury (left main or left anterior descending lesions) and cardiogenic shock requiring IABP or other mechanical support, indicating that left ventricle pump failure and acute CHF were the main reasons for intubation. The median D2BT of 84 min

Table 2	**Angiographic and Procedural Characteristics of Patients With and Without Nonsystem Delay**							
Angiographic/Procedural Characteristic	**No Report of Nonsystem Delay (n = 70,532)**	**Nonsystem Delay (n = 12,146)**	**p Value**	**Delays in Consent (n = 535)**	**Difficult Access (n = 1,017)**	**Difficulty Crossing Lesion (n = 2,289)**	**Cardiac Arrest/ Intubation (n = 4,544)**	**Other (n = 3,761)**
Culprit lesion								
Left main	291 (0.4)	277 (1.9)	<0.0001	4 (0.8)	4 (0.4)	13 (0.6)	156 (3.4)	50 (1.3)
LAD	26,932 (38.2)	4,864 (40.1)	<0.0001	228 (42.6)	366 (36.0)	798 (34.9)	2,018 (44.4)	1,454 (38.7)
Circumflex	10,105 (14.3)	1,989 (16.4)	<0.0001	90 (16.8)	159 (15.6)	399 (17.4)	713 (15.7)	628 (16.7)
RCA	32,877 (46.6)	4,998 (41.2)	<0.0001	209 (39.1)	481 (47.3)	1,065 (46.5)	1,634 (36.0)	1,609 (42.8)
Lesion length (mm)	20.9 ± 10.9	21.0 ± 11.9	0.0018	20.6 ± 12.1	21.0 ± 11.5	20.7 ± 12.8	21.3 ± 11.8	20.8 ± 11.6
Bifurcation	7,792 (11.1)	1,482 (12.2)	0.0002	60 (11.2)	108 (10.6)	280 (12.2)	591 (13.0)	443 (11.8)
Thrombus present	39,178 (55.6)	6,592 (54.3)	0.0098	288 (53.8)	570 (56.1)	1,103 (48.2)	2,599 (57.2)	2,032 (54.0)
Post-procedure	67,406 (95.6)	10,588 (87.2)	<0.0001	491 (91.8)	927 (91.1)	1,745 (76.2)	3,935 (86.6)	3,490 (92.8)
TIMI flow (complete)								
Percutaneous entry site*								
Femoral	68,567 (97.2)	11,709 (96.4)	<0.0001	519 (97.0)	859 (84.5)	2,227 (97.3)	4,459 (98.1)	3,645 (96.9)
Brachial	76 (0.1)	100 (0.8)	<0.0001	2 (0.4)	76 (7.5)	3 (0.1)	14 (0.3)	5 (0.1)
Radial	1,857 (2.6)	328 (2.7)	<0.0001	14 (2.6)	80 (7.9)	56 (2.5)	69 (1.5)	109 (2.9)
Contrast volume (cc)	198.1 ± 80.5	219.4 ± 99.2	<0.0001	201.4 ± 87.8	237.5 ± 107.9	257.2 ± 112.1	205.0 ± 92.4	211.4 ± 90.8
Fluoroscopy time (min)	12.4 ± 9.0	17.4 ± 13.1	<0.0001	14.8 ± 9.9	20.2 ± 13.5	25.7 ± 16.7	15.3 ± 11.2	14.7 ± 10.6
IABP (any)	5,428 (7.7)	2,795 (23.0)	<0.0001	47 (8.8)	89 (8.8)	304 (13.3)	1,842 (40.5)	513 (13.6)
At start of procedure	102 (1.9)	128 (4.6)	—	3 (6.4)	1 (1.1)	5 (1.6)	100 (5.4)	19 (3.7)
During procedure, before PCI	1,066 (19.6)	1,033 (37.0)	—	12 (25.5)	24 (27.0)	64 (21.1)	717 (38.9)	216 (42.1)
After PCI	4,257 (78.4)	1,634 (58.5)	—	32 (68.1)	64 (71.9)	235 (77.3)	1,025 (55.7)	278 (54.2)
Other mechanical ventricular support	431 (0.6)	408 (3.4)	<0.0001	2 (0.4)	15 (1.5)	24 (1.1)	318 (7.0)	49 (1.3)
Cardiogenic shock at start of PCI	3,974 (5.6)	3,176 (26.2)	<0.0001	50 (9.4)	101 (9.9)	164 (7.2)	2,396 (52.7)	465 (12.4)

Values are n (%) or mean ± SD. Angiographic and procedural characteristics associated with all combined nonsystem delays and each separate nonsystem reason for delay in door-to-balloon time. *Primary location of percutaneous entry; site used to perform a majority of the procedure if more than 1 site was used.

IABP = intra-aortic balloon pump; LAD = left anterior descending; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction; other abbreviation as in Table 1.

suggests that a significant number of these patients were still treated expeditiously within the 90-min D2BT, suggesting that the intubation process occurred quickly.

Delays due to difficulty in obtaining vascular access and crossing the culprit lesion. The next most frequent nonsystem reasons for delay were due to difficult vascular access (8.4%) and difficulty crossing the culprit lesion (18.8%). Together, these accounted for 3,306 patients over the study period. Interestingly, although the delay for each reason resulted in a similar median and 25th to 75th percentile range for D2BT, the associated mortality between the 2 was significantly different (8.0% vs. 5.6%, respectively; p = 0.02). This finding suggests that the higher mortality associated with patients who have difficult vascular access may be independent of D2BT. The patients delayed for difficulty with vascular access had a higher prevalence of
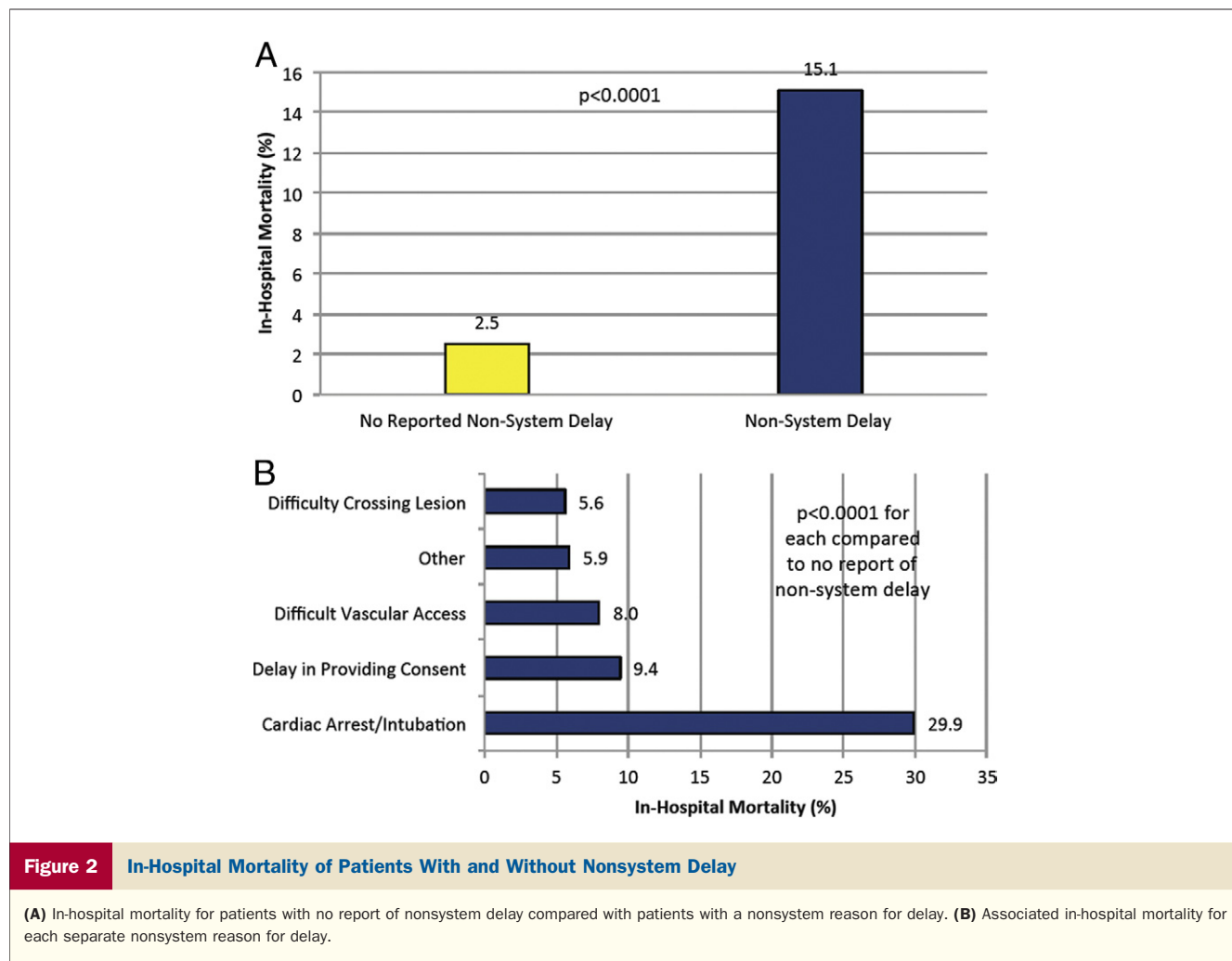
PVD (27.2%), which may explain the higher mortality seen in this group because patients with PVD are more likely to have a greater degree of systemic and coronary atherosclerosis. Previous data support that PVD in patients with acute coronary syndromes undergoing PCI is an independent predictor of in-hospital death (18–22). In 1 study, the adjusted mortality OR of PVD patients presenting with STEMI was 2.6 (95% confidence interval: 1.23 to 5.65) compared with patients without PVD (23). In our study, we found a higher frequency of use of nonfemoral access sites in the delay due to difficult vascular access group. This finding may be due to a failed femoral attempt, with conversion to either a radial or brachial approach.

We found that the timing of IABP placement, when operators had difficulty crossing the culprit lesion, was more

Table 3	**Door-to-Balloon Times of Patients With and Without Nonsystem Delay**						
D2BT Variable (min)	**No Report of Nonsystem Delay (n = 70,532)**	**Nonsystem Delay (n = 12,146)**	**Delays in Consent (n = 535)**	**Difficult Access (n = 1,017)**	**Difficulty Crossing Lesion (n = 2,289)**	**Cardiac Arrest/ Intubation (n = 4,544)**	**Other (n = 3,761)**
Median	63.0	92.0	100.0	92.0	92.0	84.0	99.0
25th percentile	48.0	70.0	80.0	74.0	72.0	64.0	76.0
75th percentile	78.0	115.0	131.0	110.0	109.0	108.0	130.0
>90 min	13%	53%	67%	54%	53%	43%	62%

Median, 25th to 75th percentile range, and overall percentage of patients in each delay category that missed the American College of Cardiology/American Heart Association–recommended 90-min door-to-balloon time (D2BT) as a result of nonsystem delays. p < 0.0001 for differences in the distribution of D2BT for each nonsystem reason for delay compared with no delay.

Figure 2   **In-Hospital Mortality of Patients With and Without Nonsystem Delay**

(A) In-hospital mortality for patients with no report of nonsystem delay compared with patients with a nonsystem reason for delay. **(B)** Associated in-hospital mortality for each separate nonsystem reason for delay.

likely to be after PCI, as opposed to patients with cardiac arrest/intubation who had a relatively higher frequency of IABPs implanted before the start of the PCI. Patients with difficult-to-cross culprit lesions were less likely to have TIMI flow grade 3 post-procedure, which may explain the IABP placement at that time. The timing of IABP placement likely had no significant impact on overall D2BT

given the pre-PCI placement in the cardiac arrest/ intubation group, which had the shortest median D2BT among nonsystem delay groups. Furthermore, our multivariable regression model adjusted for pre-operative IABP (in place at the start of the procedure), and a significantly higher mortality OR was found for all nonsystem delay groups regardless of overall D2BT.

Table 4   **Risk-Adjusted In-Hospital Mortality**

D2BT	Category	Unadjusted				Adjusted			
		Mortality OR	Lower (95% CI)	Upper (95% CI)	p Value	Mortality OR	Lower (95% CI)	Upper (95% CI)	p Value
All times	Cardiac arrest delay (vs. no delay)	16.8	15.5	18.3	<0.001	3.4	3.1	3.8	<0.001
	All other delays (vs. no delay)	2.7	2.4	3.0	<0.001	1.7	1.5	1.9	<0.001
If D2BT ≤90 min	Cardiac arrest delay (vs. no delay)	14.2	12.9	15.7	<0.001	3.0	2.6	3.5	<0.001
	All other delays (vs. no delay)	2.7	2.3	3.1	<0.001	1.7	1.5	2.1	<0.001
If D2BT >90 min	Cardiac arrest delay (vs. no delay)	17.9	15.2	21.1	<0.001	3.8	3.1	4.8	<0.001
	All other delays (vs. no delay)	2.2	1.9	2.7	<0.001	1.6	1.3	1.9	<0.001

In-hospital mortality odds ratio (OR) in a multivariable analysis stratified according to door-to-balloon time (D2BT) after adjustment for age, gender, race, cardiogenic shock, previous congestive heart failure, valve surgery/procedure, cardiovascular disease, peripheral vascular disease, chronic lung disease, previous PCI, pre-IABP, ejection fraction, glomerular filtration rate, body mass index, dialysis, New York Heart class, highest risk segment category, highest risk lesion pre–Thrombolysis In Myocardial Infarction flow, highest risk Society for Cardiovascular Angiography and Interventions class, PCI status, and diabetes.

CI = confidence interval; OR = odds ratio; other abbreviations as in Tables 1 and 2.

| Table 5 | In-Hospital Adverse Outcomes of Patients With and Without Nonsystem Delay |

Adverse Outcomes	No Report of Nonsystem Delay (n = 70,532)	Nonsystem Delay (n = 12,146)	p Value	Delays in Consent (n = 535)	Difficult Access (n = 1,017)	Difficulty Crossing Lesion (n = 2,289)	Cardiac Arrest/ Intubation (n = 4,544)	Other (n = 3,761)
Cardiogenic shock	1,990 (2.8)	840 (7.3)	<0.0001	22 (4.2)	75 (7.5)	104 (4.6)	449 (11.0)	190 (5.1)
CHF	1,755 (2.5)	676 (5.9)	<0.0001	20 (3.8)	46 (4.6)	94 (4.2)	346 (8.5)	170 (4.6)
CVA/stroke	263 (0.4)	120 (1.0)	<0.0001	3 (0.6)	10 (1.0)	16 (0.7)	67 (1.7)	24 (0.7)
Renal failure	225 (0.3)	160 (1.4)	<0.0001	2 (0.4)	6 (0.6)	16 (0.7)	100 (2.5)	36 (1.0)
Any vascular complications	384 (0.6)	128 (1.1)	<0.0001	3 (0.6)	22 (2.2)	25 (1.1)	43 (1.1)	35 (0.9)
Bleeding event within 72 h	2,375 (3.4)	796 (6.9)	<0.0001	35 (6.7)	70 (7.0)	138 (6.1)	377 (9.3)	176 (4.8)

Values are n (%). In-hospital adverse outcomes for all combined nonsystem delays and each separate nonsystem reason for delay.

CHF = congestive heart failure; CVA = cerebrovascular accident.

Delays in providing consent. This nonsystem reason resulted in the longest delays among those evaluated, and two-thirds of these patients missed the recommended 90-min D2BT. The in-hospital mortality rate for this group was 9.4%. Unlike the aforementioned nonsystem delays that are generally surrogates for advanced disease and cannot be modified, the consenting process may provide an opportunity for substantial improvement and reduction in delays. For example, healthcare providers initially treating and triaging patients should be permitted to begin conversations regarding the procedure with the patient and family so as to expedite obtaining the informed consent by a member of the PCI team. Given more lead time to think about these issues while en route to the primary PCI center may help expedite the consenting process on arrival. Interestingly, our study also showed that Asian patients with nonsystem delays were more likely to be delayed for not providing timely consent. Perhaps a cultural bias or language barrier led to the delay in obtaining informed consent in a subgroup of these patients. This possibility raises the notion that a system solution to making interpreters rapidly available may help reduce the delays in obtaining consents for emergent PCI.

Mortality outcomes and D2BT. Nonsystem reasons for delay were associated with higher mortality outcomes even after adjustment for baseline characteristics. Interestingly, we noted that a similar mortality risk existed in nonsystem delay groups regardless of whether the D2BT was ≤90 min. This raises the question: Would further improvements in D2BT measures actually improve mortality? A recent analysis of STEMI patients in Michigan showed significant reductions in D2BT over 5 years, yet in-hospital mortality remained unchanged at approximately 4% (24). Differences in clinical risk presentation and symptom onset-to-door time may explain why mortality does not always correlate with D2BT. In our study, patients with a cardiac arrest requiring intubation fell in the highest risk category and had the highest mortality despite a shorter D2BT. Patients with nonsystem delays related to consent might also have delayed their presentation to hospitals from the time of symptom onset due to hesitancy in seeking medical attention and treatment. The benefit of reperfusion decreases with time such that there may be no mortality benefit even if treated within 90 min if the symptom onset-to-door time is already substantial. This highlights the importance of

public education for seeking rapid medical attention at the onset of typical chest pain symptoms.

Study limitations. The CathPCI Registry is an ideal, real-world registry used to study the frequency of nonsystem delays and associated mortality. The registry includes data collected from approximately 60% of the cardiac catheterization laboratories in the United States (25). Nevertheless, there are limitations to the database. CathPCI Registry data are retrospective and observational. Because the registry encapsulates all-comers, there is the possibility of unmeasured confounding. The data are abstracted from a heterogeneous mixture of facilities that vary in the types and numbers of procedures performed. We tried to limit this bias by excluding low-volume centers. Individual operator experience may have affected the ability to obtain access or cross a difficult lesion, which was not controlled for in this study. Version 4.3 of the CathPCI Registry form classified 4 nonsystem reasons for delay in D2BT. The other group was unclassified and accounted for 31% of patients who were delayed for nonsystem reasons. We were limited in our understanding of this unclassified group, because the form did not require specific descriptions for the "other" reason.

Conclusions

Nonsystem reasons for delay in D2BT are common and associated with high in-hospital mortality. The frequency of nonsystem reasons for delay may account for disparities seen between guidelines and clinical practice. Some nonsystem reasons for delay may have system solutions to improve quality of care, such as adjustments to the consenting process. These system solutions to nonsystem reasons for delay should be scrutinized to discern any potential improvements in the quality of care delivered to this high-risk group of patients.

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