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CORONARY ARTERY DISEASE

Editor's Choice

A Hospital-Wide System to Ensure Rapid Treatment Time Across the Entire Spectrum of Emergency Percutaneous Intervention

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Objectives: This study's aim was to describe a hospital-wide system to deliver rapid door-to-balloon time across the entire spectrum of emergency percutaneous intervention. Background: Many patients needing emergency PCI are excluded from door-to-balloon public reporting metric; these groups do not achieve door-to-balloon times ≤90 min and have increased mortality rates. Methods: We prospectively implemented a protocol for patients with STEMI or other emergency indication for catheterization mandating (1) emergency department physician or cardiologist activation of the catheterization lab and (2) immediate patient transfer to an immediately available catheterization lab by an in-house nursing transfer team. Results: From September 1, 2005 to December 31, 2008, 526 consecutive patients underwent emergency PCI. Median door-to-balloon time was 68 min with 85.7% ≤90 min overall. Important subgroups included primary emergency department (62.5 min), cardiorespiratory arrest (71 min), cardiogenic shock (68 min), need for temporary pacemaker or balloon pump (67 min), initial ECG without ST-elevation (66.5 min), transfer from another ED (84 min), in-hospital (70 min), and activation indications other than STEMI (68 min). Patients presenting to primary ED and in transfer were compared to historical controls. Treatment ≤90 min increased

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(28%–85%, $P < 0.0001$). Mean infarct size decreased, as did hospital length-of-stay and admission total hospital costs. Acute myocardial infarction all-cause 30-day unadjusted mortality and risk-standardized mortality ratios were substantially lower than national averages. Conclusion: A hospital-wide systems approach applied across the entire spectrum of emergency PCI leads to rapid door-to-balloon time, reduced infarct size and hospitals costs, and low myocardial infarction 30-day all-cause mortality.

Key words: angioplasty and stenting; quality improvement; percutaneous coronary intervention; stents; healthcare costs; public reporting

INTRODUCTION

The importance of time to reperfusion in primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI) has been clearly demonstrated with a powerful relationship between delays in door-to-balloon time and increased mortality [1]. Intense focus on door-to-balloon time by cardiologists and hospitals has led to a substantial increase in the proportion of STEMI patients with door-to-balloon times $\leq$90 min from 44.2% in 2005 to 91.4% in 2010 in a Medicare public reporting database [2]. The Medicare public reporting database, however, only includes a small minority of patients undergoing emergency percutaneous intervention (Fig. 1). In one series, the public reporting measure only included 13% of STEMI patients as STEMI patients with an initial ECG without ST elevation and in-hospital and transfer STEMI patients are all excluded [3]. In addition, public reporting of door-to-balloon time has been associated with an increase in patients excluded due to "acceptable" nonsystem delays from 3.7% in 2005 to 8.1% in 2010 [2]. Finally, many emergency percutaneous intervention patients with indications other than ST-elevation such as refractory unstable angina, NSTEMI, and cardiac arrest are not included within systems to improve door-to-balloon time. In contrast to improvements in the Medicare public reporting database, patients with reported nonsystem delays as well as in-hospital and transfer STEMI fail to achieve a median door-to-balloon time $\leq$90 min and have a substantially higher mortality [4–7]. A comprehensive hospital-wide system to ensure timely reperfusion within 90 min in all emergency PCI patients is needed and may be a novel strategy to reduce myocardial infarction mortality. Therefore, we present the impact on door-to-balloon time and mortality of a strategy of emergency department physician or cardiologist one-call activation of the catheterization lab combined with immediate physical transfer of the patient to an immediately available catheterization lab by in-house nursing staff prospectively applied across the entire spectrum of emergency PCI.

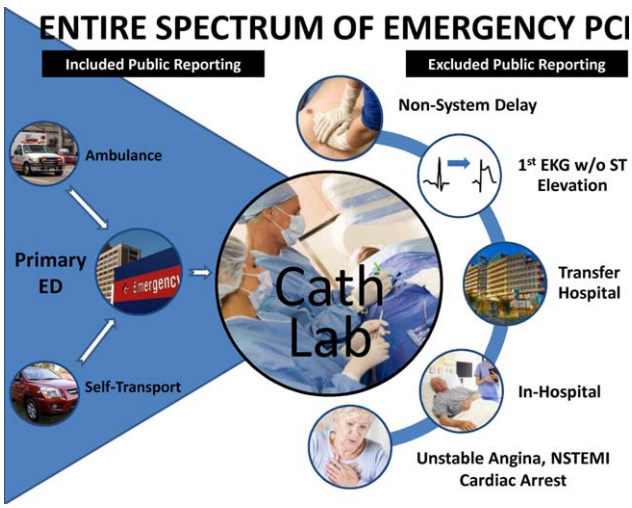

Fig. 1. The entire spectrum of emergency percutaneous intervention. Emergency status defined as a patient of sufficient acuity that PCI is to be performed immediately (cancelling elective case) in next available room during regular hours or activation of on-call cath lab team during off-hours. [Color figure can be viewed at wileyonlinelibrary.com.]

METHODS

Study Design and Protocol Description

This prospective study was conducted between October 1, 2004 and December 1, 2008 at St. Francis Hospital and Health Center (Beech Grove and Indianapolis, IN), a 591-bed tertiary care community hospital consisting of two campuses 7 miles apart. Details of the hospital system, the protocol during the historical control period (October 1, 2004–August 31, 2005) and characteristics of the enrolled patients during the historical control period have been previously reported [8]. Beginning September 1, 2005, we prospectively enrolled a consecutive series of patients with emergency catheterization lab activation irrespective of clinical indication, manner or timing of presentation, activating physician, or location within the hospital. We mandated the ED physicians to activate the catheterization lab for STEMI in the emergency department; cardiologists could activate the catheterization lab for any patient requiring emergent catheterization independent of indication (i.e., STEMI, refractory unstable angina, NSTEMI,

cardiogenic shock, or cardiac arrest) or location (i.e., emergency department, inpatient floor, or intensive care unit; Fig. 2). The emergency department physician or cardiologist contacted the hospital operator to activate the catheterization lab. The operator subsequently paged the cardiology physician assistant, catheterization lab coordinator, and a critical care unit nurse during regular hours or the on-call cardiologist, interventional cardiologist, critical care unit nurse, chest pain unit nurse, and the on-call catheterization team during off-hours. Four catheterization staff members take home call during off-hours and are expected to arrive to the hospital within 30 min of laboratory activation.

Following catheterization lab activation, the in-house Emergency Heart Attack Response Team (EHART^{TM}), consisting of an emergency department nurse, a critical care unit nurse, and a chest pain unit nurse initiated a policy of immediate transfer of the patient to an immediately available catheterization lab. The critical care unit nurse proceeded to the patient's location and initiated a standard resuscitation order set with the emergency department or bedside nurse (if patient was not in the emergency department). The nurses then proceeded to immediately transfer the patient to the catheterization lab. The only exceptions to immediate transfer by the nursing staff included hemodynamic compromise (requiring vasopressors, temporary pacing, or balloon pump) and ongoing CPR; these patients were prepared for immediate transfer but transferred by the nursing staff with the cardiologist. The critical care unit nurse could administer dopamine or norepinephrine intravenous drips, perform defibrillation, and direct intubation by respiratory therapy all without prior physician approval in case of sustained hypotension or arrest. The Critical Care Unit modified the work requirements for the EHART^{TM} nurse by assigning the nurse one patient instead of two patients.

To make the cath lab immediately available during regular hours, the catheterization lab coordinator identified a room and staff for the patient. The lab coordinator could remove an elective patient from the lab if the case had not started (defined as cardiologist fully scrubbed at bedside obtaining access). If all rooms were occupied with cases in progress, then the STEMI patient went to the first available room. Upon patient placement on the catheterization lab table, the Emergency Heart Attack Response Team members transferred the patient's nursing care to the catheterization team.

To make the cath lab immediately available during off-hours, the chest pain unit nurse proceeded to the catheterization lab, activated the catheterization lab imaging equipment, and confirmed that the temporary pacemaker, balloon pump, defibrillator, and activated clotting time machine were in working order. This individual subsequently assisted the critical care unit nurse and emergency department nurse in the initial setup of the patient including placement on the catheterization table, monitoring equipment setup, prepping of groins, and assistance with the sterile catheterization lab table. The emergency department nurse and critical care nurse monitored the patient until the third and fourth catheterization staff members arrived and subsequently transferred nursing care to the catheterization team. If the patient was unstable, all staff attended to the patient until safe transfer of care was possible.

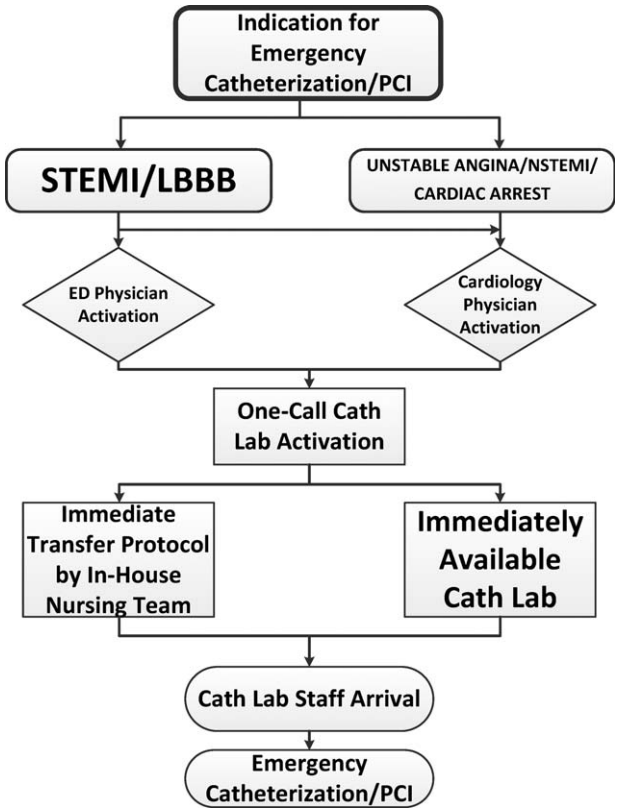

Fig. 2. Protocol design for standardized treatment of all emergency percutaneous intervention patients. Emergency department physicians or cardiologists identified all patients needing emergency cardiac catheterization/PCI with subsequent immediate transfer protocol by in-house nursing staff to catheterization lab. PCI = Percutaneous Coronary Intervention.

For cath lab activations by emergency department (ED) physicians, all activities in the emergency department, during the transfer to the catheterization lab, and during initial setup in the catheterization lab did not require cardiologist presence or input. The cardiologist evaluated the patient and confirmed the appropriateness for emergency catheterization in the emergency department, en route to the catheterization lab, or in the catheterization lab.

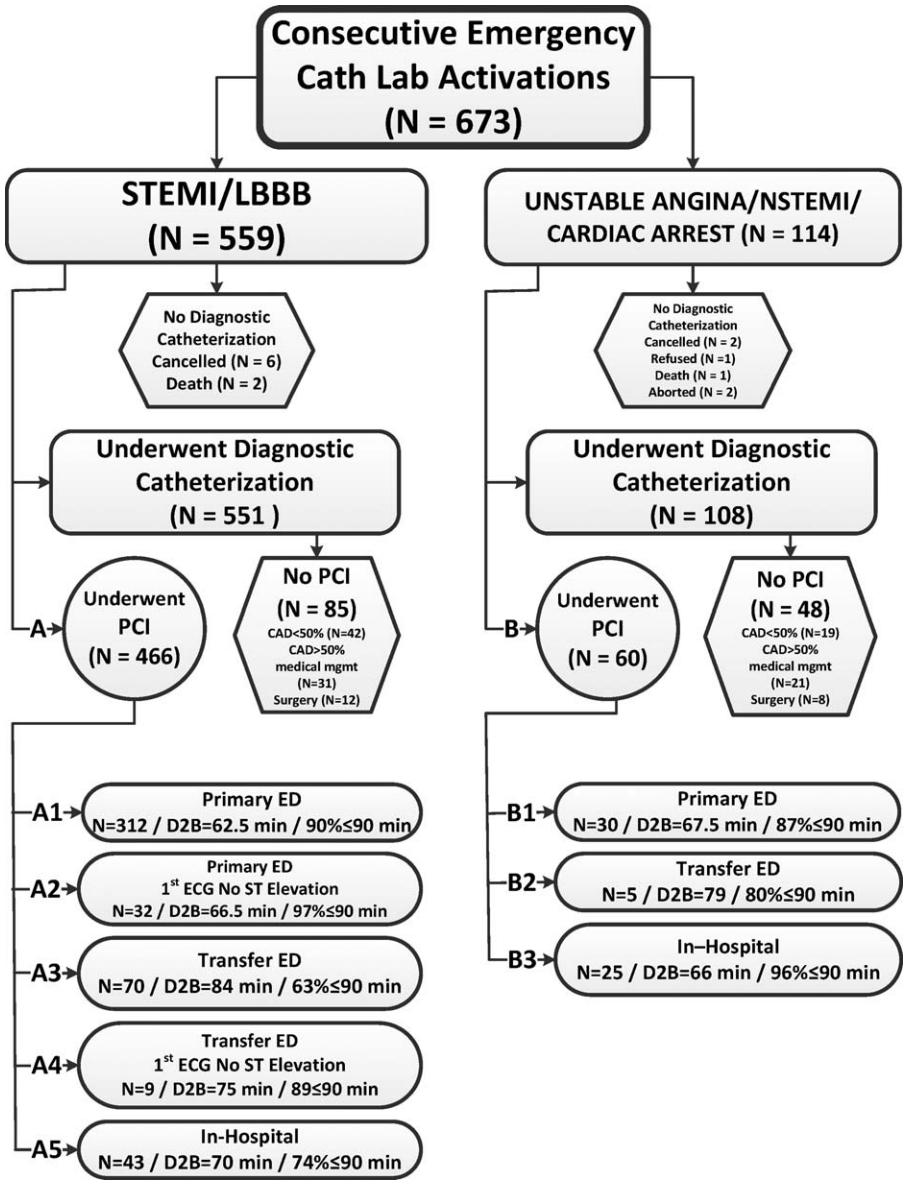

Fig. 3. Summary of 679 consecutive emergency catheterization lab activations according to indication and origin of patient. ECG = Electrocardiogram, STEMI = ST-Elevation Myocardial Infarction.

Study Endpoints and Statistical Analysis

Median door-to-balloon time was the primary endpoint and was defined as follows: [1] door-to-balloon time for primary emergency department patients, [2] first door-to-balloon time for transfer patients, [3] activating ECG-to-balloon time for patients without ST-elevation on first ECG and in-hospital, and [4] activation-to-balloon time for patients with activating indication other than STEMI. Secondary endpoints included the proportion of door-to-balloon times $\leq$90 min, infarct size measured by peak creatinine kinase within the first 24 hr [9–11], hospital costs (total, direct, and indirect), and hospital length of stay. Hospital cost data reflect the actual costs involved in the delivery of care to each patient and were determined by the hospital's cost-accounting software (Alliance for Decision Support, Avega Health Systems. El Segundo, CA). Mortality was determined by hospital medical record review and via query of Social Security Death Index. Using a national mortality database, we analyzed 30-day all-cause unadjusted mortality and 30-day all-cause risk-standardized mortality ratios for patients diagnosed with acute myocardial infarction for our hospital compared to national averages for the time periods

TABLE I. Demographics, Initial Presentation Characteristics, and Treatment Outcomes in STEMI and Emergent Activation Patients Undergoing PCI

	STEMI activation + PCI ($N = 466$)	Emergent indication activation + PCI ($N = 60$)	P value
Age, y	60 ± 13	59 ± 13	0.449
Female gender	148 (31.8)	13 (21.7)	0.136
Health insurance			
Private	241 (51.7)	35 (58.3)	0.7368
Medicare	160 (34.3)	19 (31.7)	...
Medicaid	15 (3.2)	1 (1.7)	...
Self-pay	50 (10.7)	5 (8.3)	...
Medical history			
Current smoker	228 (48.9)	23 (38.3)	0.132
Diabetes	85 (18.2)	11 (18.3)	1
Hypertension	273 (58.6)	32 (53.3)	0.488
Hypercholesterolemia	240 (51.5)	34 (56.7)	0.494
Family history of CHD	156 (33.5)	28 (46.7)	0.061
Congestive heart failure	21 (4.5)	5 (8.3)	0.203
COPD	45 (9.7)	3 (5)	0.340
Prior carotid disease	7 (1.5)	2 (3.3)	0.274
Prior PCI	113 (24.2)	18 (30)	0.343
Prior CABG	24 (5.2)	9 (15)	0.0076
PVD	29 (6.2)	10 (16.7)	0.0078
Stroke	15 (3.2)	1 (1.7)	1
Initial presentation			
Regular hours	159 (34.1)	8 (13.3)	0.0010
Transferred to PCI	79 (17)	5 (8.3)	0.094
Symptom onset to arrival			
≤1 h	183 (46.2)	16 (38.1)	0.0240
>1–2 h	96 (24.2)	5 (11.9)	...
>2–6 h	74 (18.7)	11 (26.2)	...
>6–12 h	25 (6.3)	4 (9.5)	...
>12 h	18 (4.5)	6 (14.3)	...
Unknown	70 (15)	18 (30)	0.0056
Chest pain at presentation	423 (90.8)	56 (93.3)	0.636
Prehospital ECG	120 (25.8)	9 (15)	0.079
Ambulance arrival	207 (44.4)	13 (21.7)	0.0007
Field defibrillation	17 (3.6)	0 (0)	0.240
Field CPR	13 (2.8)	0 (0)	0.379
Field intubation	7 (1.5)	0 (0)	1
Heart rate, bpm	78 ± 21[a]	81 ± 20	0.294
Systolic blood pressure, mm Hg	139 ± 41	139 ± 33	0.987
Diastolic blood pressure, mm Hg	81 ± 22	82 ± 19	0.761
Location of infarct			
Anterior	153 (32.8)	N/A	...
Inferior	278 (59.7)	N/A	...
Lateral (isolated)	31 (6.7)	N/A	...
LBBB	4 (0.9)	N/A	...
ECG leads with ST-elevation			
2	84 (18.1)	N/A	...
3–4	241 (52.1)	N/A	...
≥5	138 (29.8)	N/A	...
Elevated cardiac troponin	459 (98.5)	53 (88.3)	<0.0001
Cardiogenic shock	83 (17.8)	8 (13.3)	0.471
Cath lab activation			
ED physician	378 (81.1)	7 (11.7)	<0.0001
Cardiologist	88 (18.9)	53 (88.3)	...
Medical therapy			
Aspirin	449 (96.6)[a]	59 (98.3)	1
Beta blocker	382 (82.2)[a]	53 (88.3)	0.4597
Heparin	447 (95.9)	56 (93.3)	0.092
Glycoprotein llb/llla inhibitor	442 (94.8)	54 (91.5)[b]	0.357

TABLE I. *Continued*

	STEMI activation + PCI ($N = 466$)	Emergent indication activation + PCI ($N = 60$)	P value
Bivalirudin	4 (0.9)	1 (1.7)	0.456
Thrombolytics	14 (3)	0 (0)	0.386
In-hospital cardiopulmonary arrest	46 (9.9)	3 (5)	0.342
In-hospital defibrillation before PCI	27 (5.8)	0 (0)	0.060
In-hospital CPR prior to PCI	17 (3.6)	1 (1.7)	0.708
In-hospital intubation prior to PCI	29 (6.2)	2 (3.3)	0.561
Temporary pacemaker before PCI	29 (6.2)	0 (0)	0.063
IABP before PCI	5 (1.1)	0 (0)	1
IABP after PCI	46 (9.9)	6 (10)	1
Catheterization results			
Infarct-related artery			
Left main	2 (0.4)	2 (3.3)	0.0056
Left anterior descending	170 (36.5)	17 (28.3)	...
Left circumflex	59 (12.7)	16 (26.7)	...
Right coronary	225 (48.3)	23 (38.3)	...
Bypass graft	10 (2.1)	2 (3.3)	...
Treatment			
Balloon angioplasty only	61 (13.1)	15 (25)	0.1085
Balloon angioplasty/stent	401 (86.1)	45 (75)	...
Balloon angioplasty/angiojet	3 (0.6)	0 (0)	...
Balloon angioplasty/rotoblation/stent	1 (0.2)	0 (0)	...
Type of stent			
Bare metal stent	218 (54.2)	21 (46.7)	0.080
Drug-eluting stent	181 (45)	22 (48.9)	...
Bare metal stent and drug-eluting stent	3 (0.7)	2 (4.4)	...
Interventional cardiologist experience, years	11 ± 10	11 ± 10	0.828
Mean infarct size, peak creatinine kinase IU/L	$1{,}683 \pm 2{,}494$[c]	$975 \pm 1{,}656$[d]	0.0378
Mean DRG relative weight	2.6806 ± 1.605	2.8054 ± 2.6235	0.603
Mean total hospital costs, $	$20{,}408 \pm 16{,}830$	$20{,}197 \pm 13{,}833$	0.926
Mean direct hospital costs, $	$13{,}853 \pm 11{,}960$	$13{,}624 \pm 9{,}879$	0.887
Mean indirect hospital costs, $	$6{,}554 \pm 4{,}993$	$6{,}574 \pm 4{,}066$	0.977
Mean hospital length of stay, day	4 ± 4	5 ± 4	0.412
Mean time in coronary care unit, h	58 ± 74	58 ± 72	0.976
All cause in-hospital mortality	23 (4.9)	2 (3.3)	0.756
All cause 30 day mortality	27 (5.8)	2 (3.3)	0.761
All cause 180 day mortality	31 (6.7)	3 (5)	0.785
All cause 1 year mortality	36 (7.7)	3 (5)	0.604

Values are expressed as mean ± SD or n (%). ED, emergency department; CHD, coronary heart disease; COPD, chronic obstructive pulmonary disease; PCI, percutaneous intervention; CABG, coronary artery bypass grafting; PVD, peripheral vascular disease; ECG, electrocardiogram; CPR, cardiopulmonary resuscitation; LBBB, left bundle branch block; cath lab, catheterization laboratory; IABP, intra-aortic balloon pump; and DRG, diagnosis-related group.

[a] $n = 465$.

[b] $n = 59$.

[c] $n = 446$.

[d] $n = 57$.

of July 2008 and June 2008 and July 2006 to June 2009. All patients provided informed consent, and our institutional review board approved the study.

Time values are presented as medians with interquartile ranges and were analyzed using one sample Wilcoxon signed rank test against a median value of 90 min. The proportion of patients with door-to-balloon $\leq$90 min was compared to the goal of 75% by the binomial test. Continuous data are presented as means ± standard deviation and were analyzed by two sample t-tests. Categorical data are presented as proportions and were analyzed by Fisher's exact test. $P < 0.05$ was considered statistically significant. Stata Software (version 8.2, College Station, TX) and Prism (version 6.0d, La Jolla, CA) were used for statistical analyses.

TABLE II. Door-to-Balloon Time, Infarct Size, Hospital Length of Stay, Costs, and All-Cause Mortality Before and After Process Change in Primary and Transfer ED Patients

	Cardiology only activation/ routine transfer October 1, 2004–August 31, 2005 ($N = 60$)	ED physician + cardiologist activation/immediate transfer September 1, 2005–December 31, 2008 ($N = 382$)	P value
Door-to-balloon (min)			
≤45	1 (1.7)	65 (17)	<0.0001
46–60	5 (8.3)	77 (20.2)	
61–90	11 (18.3)	184 (48.2)	
91–120	15 (25)	38 (9.9)	
>120	28 (46.7)	18 (4.7)	
Mean infarct size, peak creatinine kinase, IU/L	2,623 ± 3,329	1,677 ± 2,585	0.0123
Mean hospital length of stay, days	6 ± 7	4 ± 3	0.0153
Mean DRG relative weight	3.67 ± 2.52	2.67 ± 1.57	<0.0001
Mean total hospital costs, $	26,826 ± 29,497	19,712 ± 15,338	0.0043
Mean direct hospital costs, $	19,585 ± 21,946	13,395 ± 11,002	0.0006
Mean indirect hospital costs, $	7,240 ± 7,571	6,317 ± 4,471	0.184
All-cause in-hospital mortality	3 (5.0)	16 (4.2)	0.732
All-cause 30-day mortality	3 (5.0)	20 (5.2)	1
All-cause 180 day mortality	4 (6.7)	24 (6.3)	0.782
All-cause 1 year mortality	4 (6.7)	29 (7.6)	1

RESULTS

STEMI accounted for 83.1% of 673 consecutive emergency catheterization lab activations (Fig. 3). The proportion undergoing diagnostic catheterization was slightly higher in the STEMI activation group compared to indications other than STEMI (98.6% vs. 94.7%, $P = 0.0194$) while the proportion undergoing PCI was markedly higher in the STEMI group (83.4% vs. 52.6%, $P < 0.0001$).

STEMI patients had lower rates of prior CABG and peripheral vascular disease compared to patients with indications other than STEMI (Table I). Patient with indications other than STEMI were more likely to have off-hours cath lab activations, self-transportation, and left circumflex involvement as the infarct-related artery. Emergency department physicians accounted for 81.1% of cath lab activations for STEMI but only 11.7% of activations for indications other than STEMI.

Compared to historical controls, the clinical profile of STEMI patients undergoing PCI originating from the primary emergency department and in transfer (Groups A1 and A3 from Fig. 3) was similar (Supporting Information, Appendix). The proportion treated within 90 min increased from 28.3% to 85.3% ($P < 0.0001$; Table II). There was a 10-fold increase in the treatment within 45 min and a nearly 10-fold reduction in treatment requiring >120 min ($P < 0.0001$). Mean infarct size, hospital length of stay, total and direct hospital costs all decreased. PCI unadjusted all-cause in-hospital, 30-day, and 1 year mortality were unchanged.

For all patient types, median door-to-balloon time was 68 min with 85.7% of patients treated within 90 min (Table III). For STEMI patients presenting to the primary emergency department (Fig. 3, Group A1), a median door-to-balloon time less than 90 min was achieved overall and in every subgroup. Similarly, the goal of 75% of patients to be treated within 90 min was achieved except in patients with prior CABG and patients presenting without chest pain. Furthermore, all emergency PCI patient subgroups achieved a median door-to-balloon time ≤90 minute; nearly all achieved the goal of 75% of patients within 90 min except for STEMI transfer patients and those with STEMI in-hospital.

Compared to national averages, there were substantially lower unadjusted 30-day all-cause mortality for acute myocardial infarction and 30-day all-cause risk-standardized mortality ratios for the time periods of July 2008 and June 2008 and July 2006 to June 2009 (Fig. 4).

DISCUSSION

Our study is the first description of a hospital-wide systems approach to achieve rapid door-to-balloon time by implementing a uniform strategy across the entire spectrum of emergency PCI. This consistent

TABLE III. Median Door-to-Balloon and Proportion of Door-to-Balloon Times Within 90 min

Group (Fig. 2)	Category	*N*	Median Door-to-balloon	Median≤90 min *P* value	% (*N*) ≤90 min	75% door-to-balloon ≤ 90 min *P* value
A+B	STEMI and emergent overall	526	68 (53.75,82)	<0.0001	85.7% (451)	<0.0001
A	STEMI overall	466	68 (53,82)	<0.0001	85.2% (397)	<0.0001
A1	STEMI primary ED	312	62.5 (47.25,76)	<0.0001	90.4% (282)	<0.0001
A1 Subgroups	Regular hours	113	48 (43,62)	<0.0001	94.7% (107)	<0.0001
	Off hours	199	69 (59,79)	<0.0001	87.9% (175)	<0.0001
	Female	99	66 (50,78)	<0.0001	88.9% (88)	0.0010
	Male	213	61 (47,75)	<0.0001	91.1% (194)	<0.0001
	Ambulance arrival	174	61 (46,74)	<0.0001	93.7% (163)	<0.0001
	Nonambulance arrival	138	65.5 (49,80.25)	<0.0001	86.2% (119)	0.0016
	<65 years	201	61 (47,74.5)	<0.0001	93% (187)	<0.0001
	≥65 years	111	66 (48,81)	<0.0001	85.6% (95)	0.0084
	Prior CABG	16	83 (69,108.3)	0.4874	68.8% (11)	0.5669
	No prior CABG	296	61 (47,74.75)	<0.0001	91.6% (271)	<0.0001
	Chest pain on presentation	286	62 (47,75)	<0.0001	92.3% (264)	<0.0001
	No chest pain on presentation	26	72.5 (48.75,94)	0.0456	69.2% (18)	0.4992
	Symptom onset to presentation known	275	62 (48,75)	<0.0001	92.4% (254)	<0.0001
	Symptoms onset to presentation unknown	37	71 (43.5,91)	0.0035	75.7% (28)	>0.9999
	Field cardiopulmonary arrest	13	50 (41,73)	0.0024	92.3% (12)	0.2069
	No field cardiopulmonary arrest	299	63 (48,76)	<0.0001	90.3% (270)	<0.0001
	In-hospital cardiopulmonary arrest prior to PCI	27	71 (45,77)	0.0020	81.5% (22)	0.5130
	No in-hospital cardiopulmonary arrest prior to PCI	285	62 (47.5,76)	<0.0001	91.2% (260)	<0.0001
	Temporary pacemaker/IABP prior to PCI	20	67 (45.75,74.25)	0.0002	95% (19)	0.0382
	No temporary pacemaker/IABP prior to PCI	292	62 (47.25,76)	<0.0001	90.1% (263)	<0.0001
	Cardiogenic shock	49	68 (49.5,75.5)	<0.0001	87.8% (43)	0.0461
	No cardiogenic shock	263	62 (47,76)	<0.0001	90.9% (239)	<0.0001
	Interventionalist experience <3 years	68	70.5 (55.75,87.75)	<0.0001	80.9% (55)	0.3267
	Interventionalist experience 3-10 years	127	57 (45,72)	<0.0001	93.7% (119)	<0.0001
	Interventionalist experience >10 years	117	64 (47.5,75)	<0.0001	92.3% (108)	<0.0001
A2	STEMI primary ED 1st ECG No ST elevation	32	66.5 (54.25,77)	<0.0001	96.9% (31)	0.0012
A3	STEMI transfer ED	70	84 (74,98.25)	0.1659	62.9% (44)	0.9917
A4	STEMI transfer ED 1st ECG No ST Elev	9	75 (62,83.5)	0.0117	88.9% (8)	0.3003
A5	STEMI in-hospital	43	70 (63,92)	<0.0001	74.4% (32)	0.6145
B	Emergent overall	60	68 (57,81.5)	<0.0001	90% (54)	0.0031
B1	Emergent primary ED	30	67.5 (56.5,80.5)	0.0021	86.7% (26)	0.0979
B2	Emergent transfer ED	5	79 (69.5,94)	0.4375	80% (4)	0.6328
B3	Emergent in-hospital	25	66 (55,81)	<0.0001	96% (24)	0.0070

Door-to-balloon defined (1) conventionally for primary ED patients, (2) first door-to-balloon for transfer patients, (3) activating ECG-to-balloon for 1st ECG without ST elevation, and (4) activation to balloon for emergency activations for indications other than STEMI.

performance in door-to-balloon time was evident in patients at high risk for delayed door-to-balloon time, transfer patients, and patients requiring emergency PCI for indications other than STEMI (Fig. 5). Important secondary benefits included a 35% reduction in myocardial infarct size, a decrease in hospital length of stay by 2 days, and a more than $7,000 reduction in total costs for the hospital admission. Most importantly, although PCI-related mortality did not change, both unadjusted and risk-adjusted mortality for all acute myocardial infarction patients at 30 days were dramatically lower than national averages.

Delays in door-to-balloon time can be ascribed to either system-centered delays or patient-related reasons [12]. System-centered delays, such as delay in cath lab staff arrival, are believed to be amenable to process improvement. Patient-related reasons, such as cardiac arrest or the need for additional procedures, are believed to be appropriate justifications for delayed door-to-balloon times. However, our data indicate that virtually every patient subgroup including cardiorespiratory arrest, cardiogenic shock, and the need for additional procedures, can have PCI performed within a median door-to-balloon ≤90 min and even the more stringent criteria of 75% within 90 min. These findings refute the belief that delays in door-to-balloon time are inevitable in high-risk patients for patient-related reasons.

The applicability of our protocol extends beyond the focused population of patients who present to emergency departments with STEMI and underscores the heterogeneity of clinical presentations of patients needing emergency PCI (Fig. 1). Nearly 10% of all STEMI

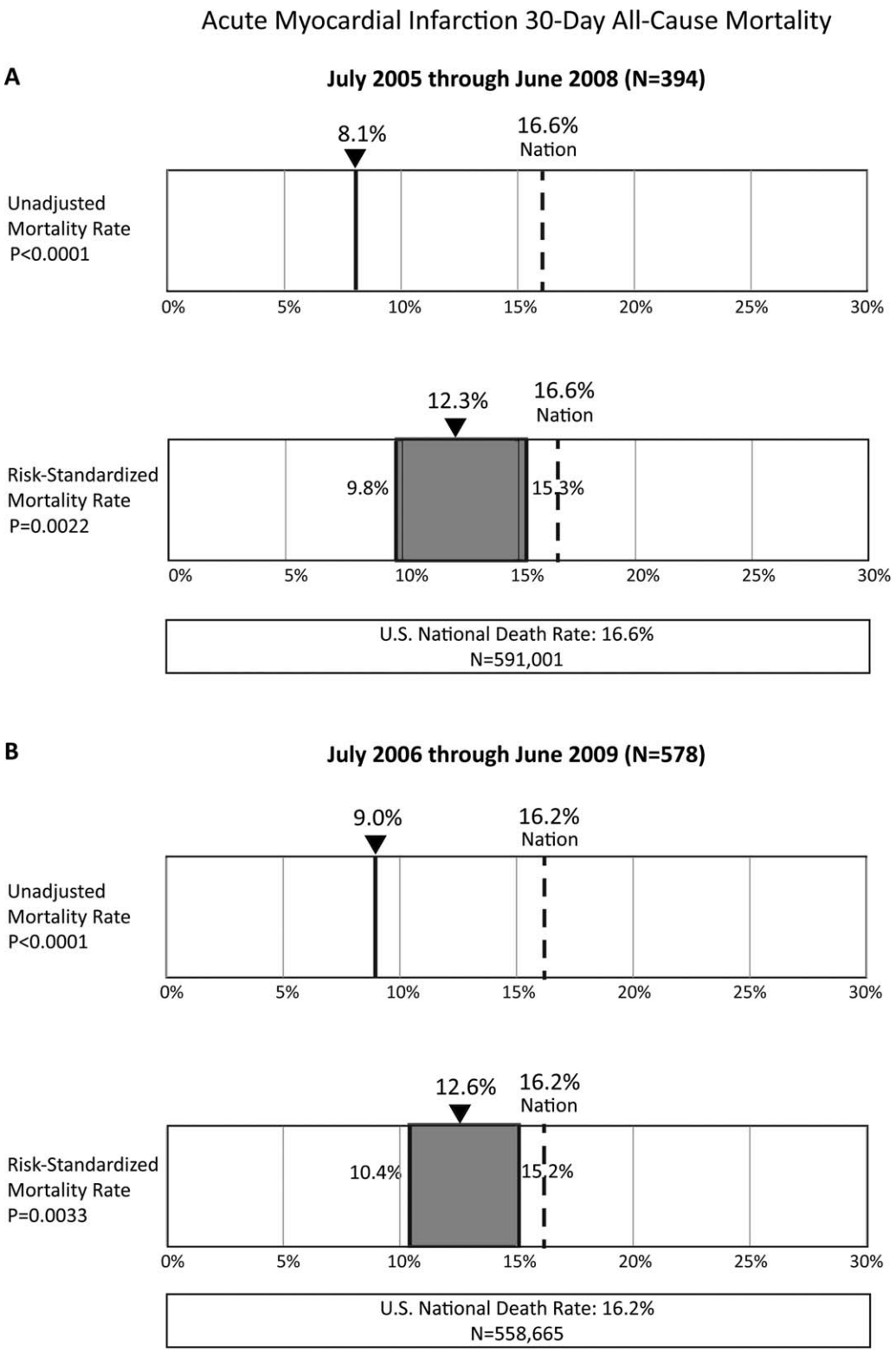

Fig. 4. All-cause 30-day mortality rate during the time period of this study compared to national averages. The protocol led to a substantial reduction in unadjusted mortality and risk-standardized mortality ratios for all-cause 30-day mortality compared to national averages in both 2005–2008 and 2006–2009.

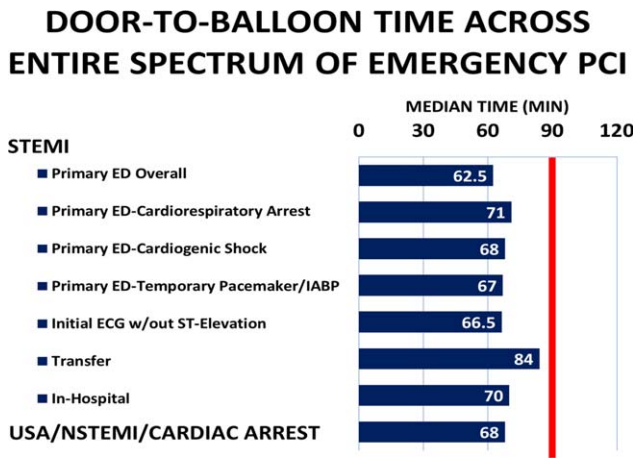

Fig. 5. Achieving rapid door-to-balloon time across the entire spectrum of emergency percutaneous intervention. ECG = Electrocardiogram, IABP = Intra-Aortic Balloon Pump, NSTEMI = Non-ST-elevation myocardial infarction, PCI = Percutaneous Coronary Intervention, STEMI = ST-elevation myocardial infarction, USA = Unstable Angina. [Color figure can be viewed at wileyonlinelibrary.com]

presentations have an initial ECG without ST-elevation [13]. The in-hospital development of STEMI is also an important source of patients needing emergency PCI with a very high mortality rate [6,12,14]. In fact, our study is the first study to demonstrate the ability to provide reperfusion to in-hospital STEMI within 90 min from detection. We also included patients who require emergency catheterization for reasons other than STEMI including unstable angina/non-ST-elevation myocardial infarction complicated by refractory angina, hemodynamic or electrical instability, cardiac arrest, and cardiogenic shock. Attention to all of these patients extends the focus of timely reperfusion from the emergency department STEMI populations to the broader population of all patients who require emergency catheterization and revascularization.

A Michigan study revealed that the decrease in door-to-balloon time led to no improvement in PCI in-hospital mortality [15]. Furthermore, at a national level, improvements in door-to-balloon time also led to no temporal improvement in PCI in-hospital or 30-day mortality [16]. Current public reporting criteria and national clinical registries allow for exclusion of patients for CPR, defibrillation, and intubation within 90 min of arrival or those with clinical reasons documented within the medical record (i.e., difficulty with access, the need for additional workup or procedures prior to PCI, or time required for patient). These allowances have led to "erosion of the denominator" of the public reporting door-to-balloon metric as the number of patients excluded for nonsystem delays has increased from 3.7% to 8.1% between the years 2005 and 2010 [2]. The potentially excluded populations account for only 18.1% of patients but 54% of deaths [4]. Similarly, in the United States CathPCI registry, in-hospital mortality for patients without reported nonsystem delays was 2.5% compared with 15.1% for those with a reported nonsystem delay [5]. As the benefits of improved door-to-balloon time are concentrated in high-risk subgroups [17], public reporting and clinical registries should require reporting of door-to-balloon times for all patients undergoing emergency PCI.

Hospitals typically require STEMI patients to wait in the emergency department until a certain number of catheterization staff have arrived and for the catheterization lab to be ready prior to transfer [18]. Time spent within the emergency department and transferring to the catheterization lab is the largest component of door-to-balloon time. Immediate transfer to an immediately available cath lab by an in-house nursing staff is one of the most effective steps to reduce door-to-balloon time. This process has now been validated by our experience, in academic medical settings, and outside the United States [8,19,20]. Widespread adoption clinically and within the guidelines should be strongly encouraged.

There has been considerable focus on prehospital identification of STEMI. However, only 36% of emergency PCI patients in our study were eligible for prehospital identification and treatment. Of note, self-transportation is a common mode of presentation by STEMI patients occurring approximately 50%–70% of the time—a figure which is consistently seen worldwide [21]. Thus, systems of care like ours that ensure equally rapid treatment for patients presenting via ambulance or self-transportation should be instituted.

LIMITATIONS

Although the historical and process improvement cohorts were clinically similar, baseline differences cannot be completely accounted for because of our study's nonrandomized nature. Our before and after outcome and cost comparisons (Table II) are limited to primary and transfer ED STEMI patients; data from the other emergency PCI patient populations in this study (i.e., initial ECG without ST-elevation, in-hospital, and activation indications other than STEMI) were not collected during the historical time period. However, these primary and ED transfer patients did account for more than 70% of the patients treated with PCI. Our study describes a cohort of patients from 2004 to 2008; however, we believe that the system design remains relevant today particularly given ongoing challenges with rapid treatment of in-hospital and transfer STEMI. Our study reflects a single center

United States experience and may not be applicable outside the United States. Our acute myocardial infarction mortality data reflect only our Medicare population. We could not analyze mortality data prior to July 2005 as it is not available from the Centers of Medicare and Medicaid Services. The start date of the public reporting mortality data (July 2005) do not identically match the start date for our process improvement (September 2005) as the two projects were performed independently. Our mortality findings were statistically and clinically significant, but the study was not primarily designed to measure mortality.

CONCLUSION

Optimal door-to-balloon times can be achieved across a hospital system by broad implementation of ED physician or cardiology one-call activation of the catheterization lab and immediate transfer protocol by an in-house nursing staff. The strategy can be further extended to patients who do not have ST-elevation on initial ECG, to in-hospital STEMI, and to patients who undergo emergency catheterization for clinical indications other than STEMI. Ultimately, this system can align improvements in door-to-balloon time with reduced myocardial infarction mortality rates. Widespread adoption of this comprehensive strategy can substantially improve the care of a broad population of patients undergoing emergency PCI worldwide.

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Editorial Comment

Come One, Come All. . .the Sooner the Better!

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Key Points:

- This study demonstrates improved clinical outcomes with reduced D2B times in an "all-comers no exclusion" population.
- Implementation of systematic, hospital wide protocols to reduce D2B times consistently across a heterogeneous population may improve clinical outcomes and reduce costs.
- These results should encourage registry reporting "without exclusions" and inclusion of challenging subgroups such as in-hospital STEMI, transfer patients, and cardiac arrest.

Door to balloon (D2B) times are subject to intense scrutiny in the context of primary percutaneous coronary intervention (PCI), for ST elevation myocardial infarction (STEMI). Current guidelines recommend the D2B time for patients with STEMI presenting to a PCI facility be ≤ 90 min and ≤ 120 min for patients transferred from a non-PCI facility. Public reporting and national initiatives such as the NCDR CathPCI registry, ACC D2B Project, and AHA Mission:Lifeline have focused attention on D2B and STEMI systems and enabled assessment of changes in outcome following implementation of novel strategies or therapies. However, national registry data includes only STEMI patients undergoing PCI and frequently excludes challenging subpopulations such as in-hospital STEMI, transfer patients, pharmacoinvasive-treated patients, and cardiac arrest [1]. In addition, accurate reporting is limited by exclusion of patients due to perceived acceptable non-system delays, thereby not necessarily providing a true measure of D2B times in "all-comers" due to "erosion of the denominator" [2].

In this issue of *CCI*, Khot et al. describe the impact of a hospital-wide system to deliver rapid D2B time

Conflict of interest: Nothing to report.

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