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Impact of Prehospital Electrocardiogram Protocol and Immediate Catheterization Team Activation for Patients With ST-Elevation–Myocardial Infarction

David M. Nestler, MD, MS; Roger D. White, MD; Charanjit S. Rihal, MD, MBA;
Lucas A. Myers, NREMT-P; Christine M. Bjerke, RN, BSN; Ryan J. Lennon, MS;
Jeffery L. Schultz, NREMT-P; Malcolm R. Bell, MBBS, FRACP; Bernard J. Gersh, MB, ChB, DPhil;
David R. Holmes, Jr, MD; Henry H. Ting, MD, MBA

Guidelines recommend implementing prehospital electrocardiograms (PH ECG) into systems of care for patients with suspected ST-elevation–myocardial infarction to reduce door-to-balloon time (DTB). We developed a PH ECG protocol with an affiliated emergency medical service, combining 4 features: (1) PH ECG acquisition; (2) emergency medical service interpretation without PH ECG transmission; (3) prehospital activation of the cardiac catheterization team; and (4) emergency department bypass. We compared data from June 1, 2006, to August 31, 2007 (preimplementation group, n=50), with data from October 1, 2007, to June 30, 2010 (postimplementation group, n=82), analyzing all patients with ST-elevation–myocardial infarction transported by an affiliated EMS and treated with primary percutaneous coronary intervention. PH ECGs were acquired in 33 (66%) and 67 (82%) patients in the preimplementation and postimplementation groups, respectively ($P=0.041$). Median DTB was 59 and 57 minutes for the preimplementation and postimplementation groups, respectively ($P=0.28$). In a pre-specified subgroup analysis of postimplementation patients (n=38) who had prehospital activation of catheterization team and emergency department bypass, median DTB was 32 minutes ($P<0.001$ compared with preimplementation group). Our PH ECG protocol increased the frequency of PH ECG acquisition and decreased DTB for patients when all 4 features of our PH ECG protocol were carried out.

Prehospital electrocardiograms (PH ECG) can decrease reperfusion times for patients with ST-elevation–myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).^{1–16} However, even when PH ECG are acquired, they may not be optimally utilized and integrated. A recent scientific statement by the American Heart Association (AHA) stated, “the central challenge for health-

care providers is not to simply perform PH ECG, but to use and integrate the diagnostic information from a PH ECG with systems of care.”¹⁷

The American College of Cardiology/AHA (ACC/AHA) guidelines for STEMI encourage a first medical contact-to-balloon time (FMCTB) within 90 minutes for patients undergoing primary PCI.¹⁸ These recommendations encourage an “as-soon-as-possible” strategy for primary PCI, citing improved survival for every 30-minute decrement in door-to-balloon time (DTB).¹⁹ Despite a class I recommendation for PH ECG acquisition, prehospital identification of STEMI, and prehospital activation of the cardiac catheterization laboratory for these patients, current studies show that PH ECG are performed on less than 30% patients with STEMI in the United States.^{5,8,20}

We developed and implemented a comprehensive PH ECG protocol for patients in Olmsted County, Minnesota, who were transported by Gold Cross Rochester (GCR), an affiliated emergency medical service (EMS). Our PH ECG protocol consisted of the following 4 features: (1) PH ECG acquisition; (2) PH ECG interpretation by paramedics without wireless transmission; (3) prehospital activation of the cardiac catheterization laboratory; and (4) patient bypass of the emergency department (ED). To test the hypothesis that our protocol would improve timeliness of reperfusion therapy for STEMI patients, we assessed time intervals preimplementation and postimplementation of the PH ECG protocol.

Methods

Study Design

A prospective, observational study design was used to collect demographic, prehospital, and in-hospital data on all patients transported by GCR EMS with STEMI and treated with primary PCI. All

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From the Departments of Emergency Medicine (D.M.N.) and Anesthesiology (R.D.W.), the Division of Cardiovascular Diseases (C.S.R., C.M.B., M.R.B., B.J.G., D.R.H., H.H.T.), Mayo Medical Transport (L.A.M., J.L.S.), and the Department of Health Sciences Research, Division of Biomedical Statistics and Informatics (R.J.L.), Mayo Clinic College of Medicine, Rochester, MN.

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Correspondence to Henry H. Ting, MD, MBA, Mayo Clinic, 200 First St SW, Rochester, MN 55905. E-mail ting.henry@mayo.edu

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patients had a final hospital discharge diagnosis of STEMI, based on ECG findings, preintervention angiography, and reperfusion with primary PCI. The preimplementation group consisted of STEMI patients from June 1, 2006, to August 31, 2007, and the postimplementation group consisted of STEMI patients from October 1, 2007, to June 30, 2010. The month of September 2007 was designated the implementation and communication period. The primary end point is reperfusion time, measured as DTB and FMCTB, for all patients transported by GCR that had a final hospital diagnosis of STEMI during the preimplementation versus postimplementation time periods. For our primary end point, patients who had protocol exclusions and protocol violations and patients who did not have ST-elevation on PH ECG but developed ST-elevation on subsequent ECG in the ED were included in our analysis. In an attempt to learn the impact on DTB and FMCTB when the PH ECG protocol was fully executed, we also undertook a prespecified analysis of the preimplementation group versus the postimplementation subgroup who had all aspects of the PH ECG protocol performed, including prehospital activation of the catheterization laboratory and ED bypass. This study was conducted with institutional review board review approval.

Setting and Participants

Saint Mary's Hospital is an academic tertiary care hospital and part of Mayo Clinic in Olmsted County, Minnesota (population, 141 360). We implemented the PH ECG protocol with GCR ambulance service, an affiliated EMS. GCR is an advanced cardiac life support (ACLS) ambulance service that provides services to Olmsted County, Minnesota, and employs approximately 67 Nationally Registered Emergency Medical Technician-Paramedics. There are other ambulance services based in outlying areas of or in proximity to Olmsted County that transported patients to Saint Mary's Hospital. They were excluded from this study because they represent a small percentage of our regional EMS coverage, only serve outlying areas of Olmsted County, and are staffed by basic life support personnel who frequently call for an ACLS intercept when transporting critically ill patients. Inclusion criteria included any patient during the study period that were transported by GCR EMS to Saint Mary's Hospital, who had a final clinical diagnosis of STEMI and was treated with primary PCI. Patients with STEMI transferred to Saint Mary's Hospital from a regional, STEMI-referral hospital were excluded from this analysis.

Intervention

In September 2007, our PH ECG protocol (available in the online-only Data Supplement) was implemented, after receiving input from a multidisciplinary group consisting of physician and allied health members from Emergency Medicine, Cardiology, Cardiac Catheterization Laboratory, and EMS. Patients transported during this month were excluded from this analysis to allow for education of EMS personnel, communication to stakeholders, and protocol implementation.

During the preimplementation phase, GCR personnel acquired PH ECG ad hoc, without any specific guidelines or protocols outlining when to acquire PH ECG, how to interpret, or how to utilize the information in the prehospital setting or at the hospital. Our PH ECG protocol included 4 features: (1) PH ECG acquisition; (2) PH ECG interpretation by paramedics without wireless transmission; (3) prehospital activation of the cardiac catheterization laboratory; and (4) patient bypass of the ED. We equipped 8 ambulances with Zoll M-Series monitor-defibrillators with 12-lead capability (Zoll Medical Corporation, Chelmsford, MA). All GCR paramedics underwent a 3-hour training session on the PH ECG protocol, including details of the protocol, PH ECG acquisition, and interpretation and were required to pass a test on the materials presented.

According to the protocol, if the PH ECG computer algorithm interpretation displayed *****Acute Myocardial Infarction***** and GCR paramedics agreed that there was ≥ 1 mm of ST-segment elevation in 2 contiguous leads, then paramedics classified the PH ECG as a PH STEMI activation. If either the computer algorithm or the paramedic interpretation did not indicate STEMI, then the PH ECG was categorized as no PH STEMI activation. Our protocol did

not involve wireless transmission to a central monitoring station for physician interpretation and over-read of the PH ECG.

The PH ECG protocol included specific criteria for conditions when EMS should not activate the catheterization team or bypass the ED even when a STEMI is suspected in the prehospital setting. These included (1) left bundle-branch block on PH ECG; (2) need for head CT or neurological evaluation; (3) need for emergent intubation; (4) need for immediate hemodynamic stabilization; (5) chest trauma or motor vehicle collision victims; or (6) do-not-resuscitate status.

The postimplementation group consisted of 2 subgroups: a PH STEMI activation subgroup when all 4 features of the PH ECG protocol were carried out (ie, PH ECG acquired, PH ECG interpreted as STEMI, catheterization team activated from the field, and patient bypassed the ED) and a no PH STEMI activation subgroup. To activate the catheterization laboratory, paramedics made a single call to the Saint Mary's Hospital Emergency Communications Center (ECC) to activate the cardiac catheterization laboratory team without needing approval by the ED or Cardiology physician. The ECC coordinates and dispatches ground and air ambulances for 30 regional hospitals in Minnesota, Wisconsin, and Iowa.²¹ The catheterization team was expected to arrive at the hospital and begin the procedure within 20 to 30 minutes of activation. The patient would bypass the ED and was transported directly to the cardiac catheterization laboratory. If the case occurred during off-hours and catheterization team members were still en route, the patient was transported to the Coronary Care Unit (CCU), which is across the hall from the catheterization laboratories on the Fourth floor of Saint Mary's Hospital, in an effort to avoid any unnecessary delays in the ED. The paramedics and CCU providers kept the patient on the ambulance gurney, and acute therapies including defibrillation and medications were immediately available. The paramedics and CCU providers cared for the patient until the catheterization team arrived. If the patient was in the "no PH STEMI activation" subgroup, the patient was taken to the ED for a standard evaluation.

To encourage continuous quality improvement, we instituted feedback within 24–48 hours to all clinicians involved in each patient's care. The feedback, in the form of electronic mail, included DTB, FMCTB, specific time intervals, and a copy of the PH ECG for every prehospital STEMI activation. This document was also sent to all 67 GCR paramedics, regardless of whether they participated in the case, to foster learning from each case. A sample of the feedback electronic mail is shown in the online-only Data Supplement Figure.

Variables and Data Sources

We prospectively collected data on all patients transported by GCR to Saint Mary's Hospital who had STEMI and were treated with primary PCI. These data included time of ambulance arrival on scene (first medical contact time), time that PH ECG was acquired, length of time on scene, time of patient arrival at hospital (door time), and time of first device used to open the coronary artery, including balloon, stent, or thrombectomy device (balloon time).

Statistical Methods

Discrete data are summarized with frequency and group percentage and group comparisons are tested with Pearson χ^2 test. GCR transport time intervals are summarized using median and interquartile range and compared using a Mann-Whitney-Wilcoxon test. Kaplan-Meier methods are used to estimate time-to-balloon distributions, with group comparisons assessed using a log-rank test. Pairwise log-rank tests were adjusted for multiple tests using a permutation algorithm to simulate the test statistic distribution under the null hypothesis. Probability values < 0.05 were considered statistically significant. All analyses were conducted using SAS 9.2 (SAS Institute, Cary, NC).

Results

Participant Flow and Baseline Demographic Data

We identified a total of 135 STEMI patients who were transported by GCR to Saint Mary's Hospital and underwent

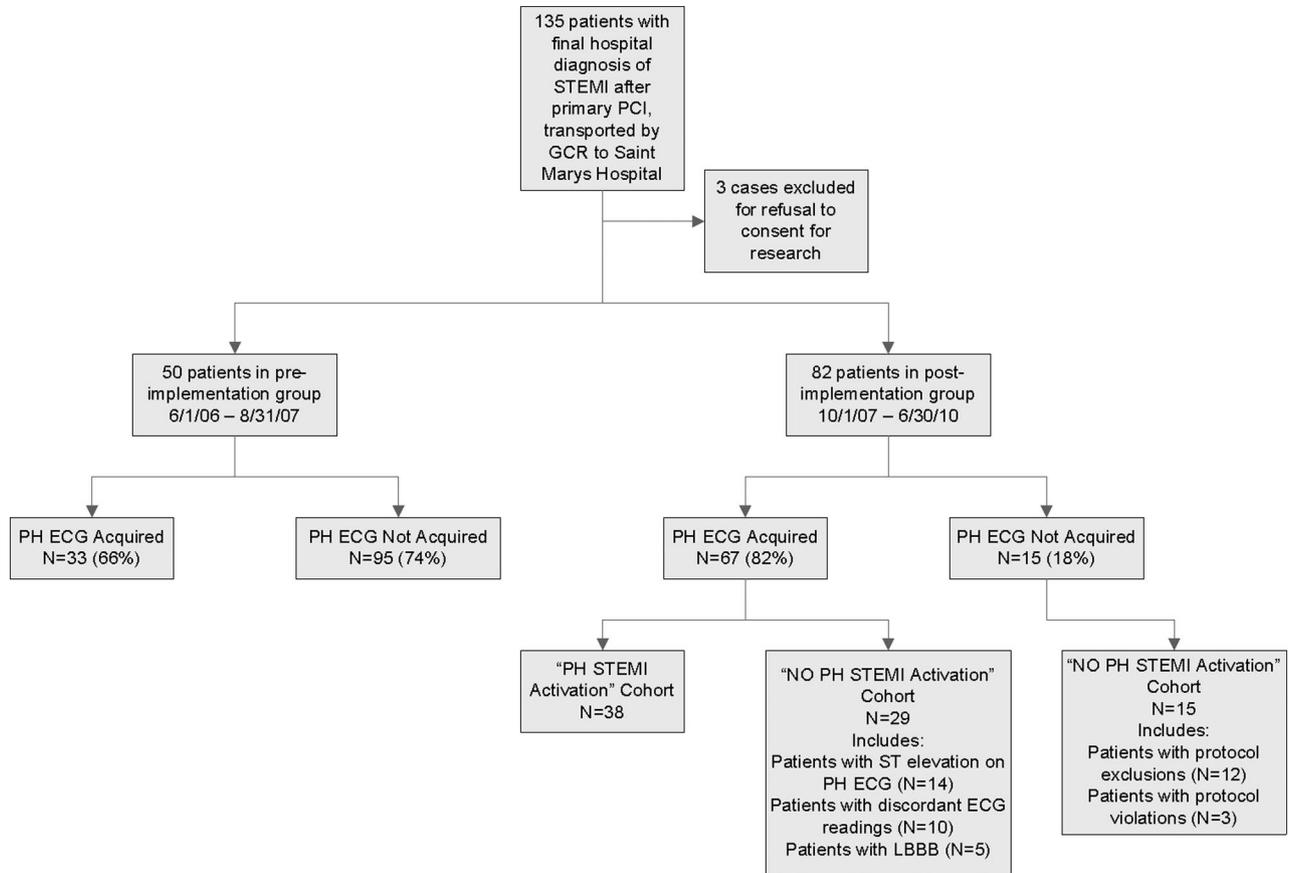


Figure 1. Patient population. PH ECG indicates prehospital electrocardiogram; PH STEMI, prehospital ST-elevation–myocardial infarction.

primary PCI (Figure 1). Three were excluded because they refused consent for research use of their medical records, leaving 132 patients for analysis.

The preimplementation phase included 50 patients. Of these, 33 (66%) had a PH ECG performed. Because there was no PH ECG protocol in place and no plan for what to do with the PH ECG information, none of these patients had a “PH STEMI activation,” and they were all taken to the ED for further treatment.

The postimplementation phase included 82 patients with a final hospital diagnosis of STEMI, 67 (82%) of whom had a PH ECG performed ($P=0.041$ compared with the preimplementation group). Of these, 38 (46%) were classified as PH STEMI activation. Of the remaining 44 of 82 patients, who comprised the no PH STEMI activation group: (1) 15 patients did not have a PH ECG acquired. Of these, 12 had protocol exclusions including out-of-hospital cardiac arrest or shock, and 3 were protocol violations, as a PH ECG was not acquired; (2) 29 patients did have a PH ECG acquired. Of these, 14 patients did not have ST-elevation on their PH ECG but developed ST-elevation on a subsequent ECG in the ED; 6 patients had ST-elevation but the computer algorithm did not interpret as ***Acute Myocardial Infarction***; 5 patients had left bundle-branch block and were excluded; and 4 patients had a computer algorithm of ***Acute Myocardial Infarction*** but the paramedics failed to agree with the computer interpretation. During this same period, there were

4 false-positive activations. These were attributed to protocol violations, in which GCR activated the catheterization laboratory and bypassed the ED, but the computer interpretation did not read ***Acute Myocardial Infarction***, and the patient was not diagnosed with STEMI. These cases were not included in this analysis because we analyzed patients with a final hospital diagnosis of STEMI. Baseline demographic data for all STEMI patients in this analysis are presented in Table 1. Patient demographics were similar between all preimplementation and postimplementation patients, as well as between all preimplementation patients and the prespecified postimplementation PH STEMI activation group.

Preimplementation Phase: Effect of PH ECG Acquisition on Reperfusion Times

During the preimplementation phase, we analyzed whether ad hoc acquisition of a PH ECG, without any formal protocol to guide its interpretation or use, led to a decrease in DTB or FMCTB. We found no difference in DTB or FMCTB between patients who did and did not receive a PH ECG during the preimplementation phase (Table 2). Median (interquartile range) DTB for patients with PH ECG acquired was 61 (49, 80) minutes, compared with 59 (43, 74) minutes for those without PH ECG acquired ($P=0.61$). Median (interquartile range) FMCTB for patients with PH ECG acquired was 90 (78, 111) minutes, compared with 91 (79, 112) minutes for those without PH ECG acquired ($P=0.81$).

Table 1. Baseline Demographic Data

Variable	All Preimplementation (n=50)	All Postimplementation (n=82)	P Value	Postimplementation PH STEMI Activation (n=38)	P Value†
Age, y	65.9±15.7	66.8±13.6	0.74	67.0±11.6	0.73
Male, n (%)	36 (72)	61 (74)	0.76	27 (71)	0.92
Hypertension, n (%)	29 (58)	54 (68)	0.27	26 (70)	0.24
Diabetes, n (%)	9 (18)	18 (22)	0.56	9 (24)	0.51
Smoking status, n (%)			0.95		0.57
Never	19 (38)	32 (40)		14 (37)	
Former	16 (32)	23 (29)		9 (24)	
Current	15 (30)	25 (31)		15 (39)	
Hyperlipidemia, n (%)	28 (56)	52 (65)	0.30	23 (62)	0.56
History of CAD, n (%)	19 (38)	26 (32)	0.49	14 (37)	0.91
Cardiogenic shock,* n (%)	8 (16)	24 (29)	0.08	9 (24)	0.37
Creatinine	1.0±0.3	1.1±0.8	0.37	1.0±0.3	0.29

PH STEMI indicates prehospital ST-elevation–myocardial infarction; CAD, coronary artery disease.

*Cardiogenic shock, at or immediately after admission to the hospital, was defined as a persistent systolic blood pressure ≤ 85 mm Hg that was unresponsive to fluid administration and required vasopressors or placement of an intra-aortic balloon pump.

†P value for comparing postimplementation PH-STEMI activation group versus all preimplementation group.

Postimplementation Phase: Effect of PH ECG Protocol on Reperfusion Times

The median DTB was 59 (47, 76) minutes for the entire preimplementation group, compared with 57 (36, 72) minutes for the entire postimplementation group ($P=0.28$) (Table 3). The median FMCTB was 90 (78, 111) minutes for the preimplementation group compared with 88 (63, 114) minutes for the postimplementation group ($P=0.87$).

The postimplementation phase subgroup (n=38) who had PH STEMI activation had shorter median DTB 32 (27, 55) minutes compared with median DTB 59 (47, 76) minutes for the preimplementation group ($P<0.001$) (Table 3). Similarly, median FMCTB was 58 (51, 87) minutes for the postimplementation PH STEMI activation subgroup compared with 90 (78, 111) minutes for the preimplementation group ($P=0.001$). The median and variance for DTB and FMCTB for the preimplementation group, postimplementation group, and postimplementation PH STEMI activation subgroup are shown in Figure 2.

Discussion

The present study shows that our PH ECG protocol significantly reduced median DTB and FMCTB for patients with STEMI when all 4 features of our PH ECG protocol were carried out, including (1) PH ECG acquisition; (2) EMS

interpretation without PH ECG transmission; (3) prehospital activation of the cardiac catheterization team; and (4) ED bypass. The median DTB decreased from 59 to 32 minutes ($P<0.001$) for patients with STEMI who had all 4 features of the PH ECG protocol performed.

Although DTB has been the traditionally reported time metric for STEMI patients, this measure does not account for the time spent with medical personnel in the prehospital setting. In 2007, the guidelines called for a FMCTB of less than 90 minutes for patients with STEMI, with first medical contact being defined as EMS arrival for patients calling 911.¹⁸ As most centers have achieved DTB of 90 minutes in 75% of patients with STEMI,²² prehospital transport time and delay are gaining increasing importance and focus. To encourage rapid FMCTB, guidelines noted “an underutilized but effective strategy for improving systems of care for STEMI patients is to expand the use of prehospital 12-lead ECG programs by EMS that provide advanced life support.”¹⁸ This study also demonstrated that median FMCTB decreased from a median of 90 to 58 minutes ($P=0.001$) when all 4 features of the PH ECG protocol were performed.

Although there was no significant difference in the entire preimplementation and postimplementation comparison of DTB and FMCTB times, it should be noted that these analyses include all patients with a final hospital diagnosis of STEMI who were transported by GCR. Most of the postimplementation patients that did not have PH STEMI activation and ED bypass included protocol exclusions when the patient was too sick to acquire a PH ECG, patients who did not have ST elevation on the PH ECG but developed ST elevation after arrival to the ED, or cases in which there was no agreement by the paramedic and computer algorithm on the presence of ST elevation on the PH ECG. These situations contributed to the lack of significant difference in reperfusion times between the entire preimplementation and postimplementation groups.

Table 2. Effect of PH ECG Acquisition on Reperfusion Times

	Preimplementation With PH ECG Acquired (n=33)	Preimplementation Without PH ECG Acquired (n=17)	P Value
Median DTB, min (interquartile range)	61 (49, 80)	59 (43, 74)	0.61
Median FMCTB, min (interquartile range)	90 (78, 111)	91 (79, 112)	0.81

PH ECG indicates prehospital electrocardiogram; DTB, door-to-balloon time; and FMCTB, first medical contact-to-balloon time.

Table 3. Effect of PH ECG Protocol on Reperfusion Times

	All Preimplementation (n=50)	All Postimplementation (n=82)	P Value*	Postimplementation PH STEMI Activation (n=38)	P Value†
Median DTB, min (interquartile range)	59 (47, 76)	57 (36, 72)	0.28	32 (27, 55)	<0.001
Median FMCTB, min (interquartile range)	90 (78, 111)	88 (63, 114)	0.87	58 (51, 87)	0.001

PH ECG indicates prehospital electrocardiogram; PH STEMI, prehospital ST-elevation–myocardial infarction; DTB, door-to-balloon time; and FMCTB, first medical contact-to-balloon time.

*Postimplementation versus pre-implementation comparison.

†Postimplementation PH STEMI activation versus pre-implementation comparison.

Several studies in the literature have shown improved reperfusion times in patients with STEMI when PH ECG is acquired.^{1–16} LeMay et al¹¹ instituted a citywide protocol in Ottawa for STEMI management. They included paramedic interpretation, activation, and direct patient transport to the city’s cardiac care center rather than any of the city’s 4 hospital EDs, with a median DTB of 69 minutes. Rao et al¹⁵ published a report on a prehospital STEMI protocol using wireless transmission, in which the ED physician interpreted the ECG and activated the catheterization laboratory before patient arrival, and their median DTB was 60 minutes. Camp-Rogers et al³ reported a mean DTB of 49 minutes when paramedics reviewed electronic ECG interpretations and activated the laboratory in the prehospital setting, but they did not bypass the ED for any patients.

Patients with STEMI who presented directly to Saint Mary’s Hospital already have rapid DTB times of 67 minutes

from 2004 to 2008.²¹ The Mayo PH ECG protocol extended these findings and integrated 4 key features, including (1) PH ECG acquisition; (2) EMS interpretation without PH ECG transmission; (3) prehospital activation of the cardiac catheterization team; and (4) ED bypass which resulted in a median DTB and FMCTB times of 32 minutes and 58 minutes, respectively. No other significant changes occurred with treatment of STEMI patients, either in the prehospital setting or in the ED, during this study period.

For our protocol to be successful, we wanted several things to occur before the patient’s arrival at the hospital. First, we wanted to increase the percentage of STEMI patients who had a PH ECG collected in the prehospital setting, and we wanted to have paramedics interpret that PH ECG without wireless transmission for physician overread. During the preimplementation phase, 66% patients with STEMI had PH ECG acquired without any protocol to guide how to use that diagnostic information. We found that DTB and FMCTB

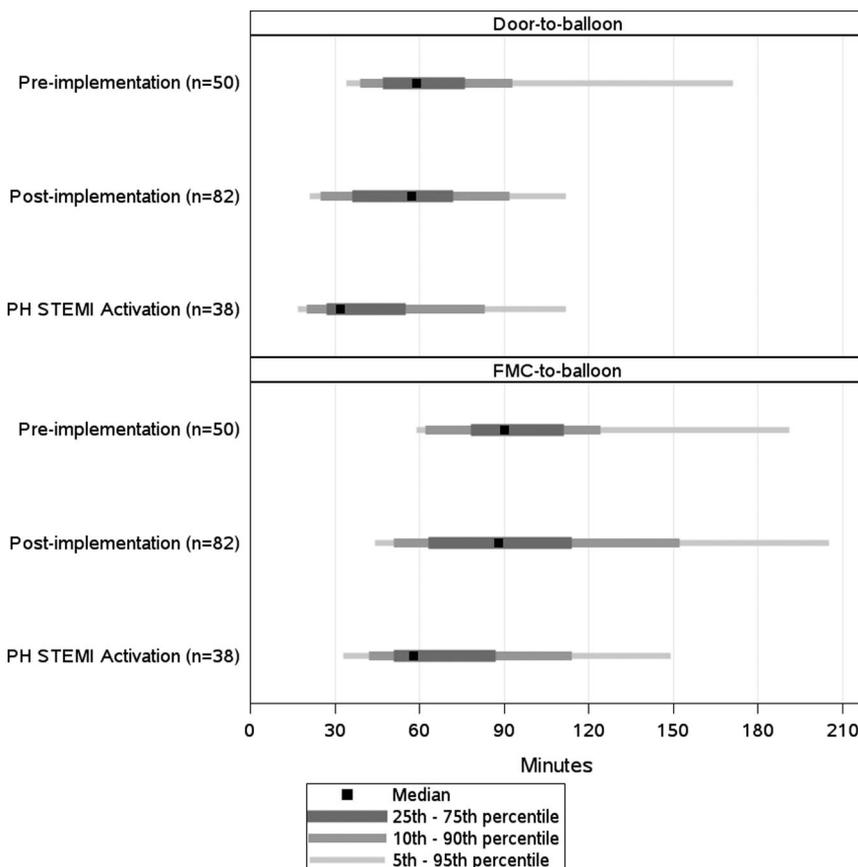


Figure 2. Door-to-balloon time and first medical contact-to-balloon time by study group. PH STEMI indicates prehospital ST-elevation–myocardial infarction.

were similar for all patients in the preimplementation phase, regardless of whether a PH ECG was acquired. This is seemingly because we treated all patients similarly during this time period, regardless of whether they had a PH ECG collected. This highlights that acquiring a PH ECG is necessary but not sufficient to improve reperfusion times. Specific protocols must be implemented to integrate the diagnostic information from a PH ECG with downstream systems of care to decrease reperfusion times.

To institute our protocol, we implemented a standardized training curriculum and competency examination for our paramedic staff that was required and completed over a half-day. In addition, we instituted feedback for all paramedics employed by our affiliated EMS, to encourage discussion and provide frequent reminders of our protocol. Also, we were able to avoid costly and complex technology, potential wireless transmission failures that have been reported as high as 20%, and physician staffing requirements that would otherwise be necessary if we instituted wireless PH ECG transmission.^{17,20,23,24} We believe that the training, competency examination, and protocol can be generalizable to larger populations with greater number of EMS personnel but may be limited to paramedic-level providers, given the complexity of decision-making.

Once the PH ECG was collected and interpreted, we allowed paramedics to place a single call to activate the cardiac catheterization laboratory. A single-call paging system has been recommended by the D2B Alliance as a key strategy for hospitals to reduce DTB.²⁵ We had already been using a single-call system for ED STEMI activations,²¹ and we simply enabled paramedics to call the same telephone number for prehospital activations. Finally, once the paramedics had activated the cardiac catheterization laboratory, the patient bypassed the ED entirely and went directly to the laboratory. When we instituted our protocol, we strived to remove any unnecessary patient hand-offs or delays in the ED for patients that were hemodynamically stable and did not have other reasons for an ED evaluation. This is supported by a recent analysis of prehospital time intervals for STEMI patients, noting that the time from scene departure to arrival at the cardiac catheterization laboratory is the greatest predictor of achieving timely primary PCI.²⁶

It is important to note that not all patients can, or should, bypass the ED. For those patients with hemodynamic or respiratory compromise, for example, ED evaluation and initial stabilization is beneficial. This can lead to a selection bias, in which more stable patients are included in prehospital activation and ED bypass protocols such as ours.²⁷ In our study, we saw longer DTB with patients who were not taken directly to the catheterization laboratory, with a median DTB of 67 minutes in this postimplementation population. We think that the DTB was longer for this population because this subgroup included a concentration of patients who had out-of-hospital cardiac arrest, shock, and other patient factors in which ED bypass was not performed because the patient had protocol-defined conditions requiring ED evaluation. However, we do note that our postimplementation PH STEMI Activation group had cardiac risk factors and similar prevalence of cardiogenic shock when compared with all preimple-

mentation patients (as noted in Table 1), suggesting that the difference in reperfusion times between these groups may not be due to patient selection bias alone. Larger analyses will be required to control for all predictors of stability, while still looking for reperfusion time benefits.

Hospital systems that do not already meet the DTB goals set for by the D2B Alliance recommendations²⁵ may not be able to reproduce the reperfusion times seen in this study, even with PH ECG protocol implementation. However, this protocol provides a framework for designing and implementing an efficient and safe prehospital system of care. Future work will focus on increasing the number of patients that can be identified as STEMI in the prehospital setting and taken directly to the catheterization laboratory by exploring collaborations with other ambulance systems and other levels of EMS providers. In addition, we are interested in exploring whether allowing paramedics to activate the catheterization laboratory without computer interpretation of ***acute myocardial infarction*** may safely increase the number of patients identified in the prehospital setting, since we had an additional 6 cases that may have been captured in our study if this protocol requirement was changed.

Conclusion

An EMS-based PH ECG protocol involving prehospital interpretation without physician oversight, direct cardiac catheterization laboratory activation, and ED bypass resulted in significant reductions in median DTB and FMCTB intervals for those identified as STEMI in the prehospital setting. Future work will focus on applying the protocol to more patients, other EMS systems, and assessing the impact on clinical outcomes.

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Disclosures

None.

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