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A Simple Strategy Improves Prehospital Electrocardiogram Utilization and Hospital Treatment for Patients with Acute Coronary Syndrome (from the ST SMART Study)

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Although the American Heart Association recommends a prehospital electrocardiogram (ECG) be recorded for all patients who access the emergency medical system with symptoms of acute coronary syndrome (ACS), widespread use of prehospital ECG has not been achieved in the United States. A 5-year prospective randomized clinical trial was conducted in a predominately rural county in northern California to test a simple strategy for acquiring and transmitting prehospital ECGs that involved minimal paramedic training and decision making. A 12-lead ECG was synthesized from 5 electrodes and continuous ST-segment monitoring was performed with ST-event ECGs automatically transmitted to the destination hospital emergency department. Patients randomized to the experimental group had their ECGs printed out in the emergency department with an audible voice alarm, whereas control patients had an ECG after hospital arrival, as was the standard of care in the county. The result was that nearly 3/4 (74%) of 4,219 patients with symptoms of ACS over the 4-year study enrollment period had a prehospital ECG. Mean time from 911 call to first ECG was 20 minutes in those with a prehospital ECG versus 79 minutes in those without a prehospital ECG ($p < 0.0001$). Mean paramedic scene time in patients with a prehospital ECG was just 2 minutes longer than in those without a prehospital ECG (95% confidence interval 1.2 to 3.6, $p < 0.001$). Patients with non-ST-elevation myocardial infarction or unstable angina pectoris had a faster time to first intravenous drug and there was a suggested trend for a faster door-to-balloon time and lower risk of mortality in patients with ST-elevation myocardial infarction. In conclusion, increased paramedic use of prehospital ECGs and decreased hospital treatment times for ACS are feasible with a simple approach tailored to characteristics of a local geographic region. © 2011 Elsevier Inc. All rights reserved. (Am J Cardiol 2011;107:347–352)

Acquisition of a prehospital 12-lead electrocardiogram (ECG) in patients with ST-elevation myocardial infarction (STEMI) has been shown to result in greater use of reperfusion therapy, faster reperfusion times, and a trend for lower mortality.¹ Despite these benefits, <1/4 of patients with STEMI transported by emergency medical services (EMSs) in the United States receive a prehospital ECG.¹ Our goal was to select a county that was not providing prehospital ECG, develop a tailor-made program for this county, and evaluate its effectiveness in a prospective randomized clinical trial. The tailor-made prehospital electrocardiographic program we developed involved synthesis of

a 12-lead ECG from a 5-electrode configuration with continuous ST-segment monitoring and automatic cell phone transmission of ECGs to the destination emergency department (ED) when ST-segment events occurred in the field. Our intervention was termed “Synthesized Twelve-lead ST Monitoring and Real-time Tele-electrocardiography” (ST SMART) and we implemented it in a county in northern California. An aim of the present analysis was to determine whether the ST SMART prehospital electrocardiographic program would result in better paramedic use of prehospital ECG than the National Registry–reported use of 24.7%.¹ Additional aims were to compare patients with and without a prehospital ECG in paramedic scene time, hospital time to treatment (STEMI, door to balloon; non-STEMI and unstable angina pectoris, door to first intravenous acute coronary syndrome [ACS] drug), and survival over the 5-year span of the study.

Methods

The ST SMART study was a prospective randomized clinical trial in Santa Cruz County, California from June 2003 to June 2009. We purposely chose to implement the ST SMART program in Santa Cruz County because it is representative of counties across the United States without prehospital electrocardiographic programs. The county has

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Figure 1. Lead configuration for synthesized 12-lead electrocardiogram used in the ST SMART trial. A standard 5-electrode patient cable was used in which the right arm (RA), left arm (LA), and right leg (RL) electrodes were placed in the usual Mason-Likar torso positions. The left leg (LL) electrode was placed in the sixth intercostal space at the left midclavicular line; the chest (C) electrode was placed in the fourth intercostal space midway between the left midclavicular line and the left sternal border. Paramedics used 2 familiar landmarks to locate the left leg and chest electrodes. Namely the left leg electrode was placed at a level just below the xiphoid process (landmark used for finding chest compression site in cardiopulmonary resuscitation) and the chest electrode was placed on an imaginary line between the left leg electrode and the suprasternal notch (used with permission from Drew et al²).

no large academic medical centers, consists of just 445 square miles with a limited EMS budget, and has geographic challenges for rapid ambulance transport. The county is mostly coastal mountain range with about 25% of the 255,602 residents living in rural areas served by a network of fragile roads that are likely to be closed periodically each winter due to flooding, washouts, mudslides, and falling trees. When the study began in 2003, median time from 911 call to ED arrival was 39.5 minutes, which makes electrocardiographic transmission from the field a logical choice to investigate for decreasing hospital time to treatment.

The county has 2 community hospitals in small cities located 10 miles apart and these hospitals participated in the study. The larger of the 2 hospitals (admission capacity 232) had full cardiac services including cardiac surgery and a cardiac catheterization laboratory providing percutaneous coronary intervention. However, catheterization laboratory personnel were not on-site at night or on weekends so they had to be called to the hospital if a patient required primary percutaneous coronary intervention for acute MI. The pre-study door to balloon time for this hospital was 105 minutes (National Registry of Myocardial Infarction database). The second hospital (admission capacity 102) in an agricultural region serves a population that is 75% Latino with a low rate of health insurance and the county's highest rate of unemployment. Because this hospital did not have primary percutaneous coronary intervention capability, patients with STEMI were usually transferred to the larger hospital.

All 26 paramedic-staffed emergency vehicles responding to 911 calls in the county were equipped with portable monitor-defibrillators (Lifepak12, Physio-Control, Red-

Table 1

Guide for paramedics to transmit a prehospital electrocardiogram in ST SMART study

Patients who call 911, are ≥ 30 years old, are not in cardiac arrest, and have any of the following

1. Chest pain or pressure, arm or jaw pain
2. New-onset shortness of breath, not due to asthma
3. Syncope, not due to drug overdose or intoxication

If accompanied by nausea/vomiting or sweating, electrocardiogram should definitely be transmitted

mond, Washington) that were modified with special study software to (1) synthesize a 12-lead ECG from 5 electrodes, (2) measure ST amplitudes in all 12 leads every 30 seconds, and (3) automatically transmit an ECG to the destination ED if there was a change in ST amplitude of 0.2 mV in ≥ 1 lead or 0.1 mV in ≥ 2 contiguous leads lasting 2.5 minutes. The 5-electrode lead configuration that was developed for the ST SMART study is shown in Figure 1. The synthesized 12-lead ECG was validated in a study reported previously.²

The ST SMART portable monitor-defibrillator device collected 20 seconds of electrocardiographic data and then selected the 10 seconds with the best signal-to-noise ratio for developing a noise-free median beat, from which ST-segment measurements were made in all 12 leads. If 1 20-second sample was unacceptably noisy, the device did not use it for ST-segment measurements but rather analyzed the subsequent 20 seconds of data. The ST SMART device used a bandwidth of 0.05 to 150 Hz, which is the filtering recommended for diagnostic standard 12-lead ECGs.

All 83 county paramedics were taught to apply the 5

Figure 2. Enrollment summary for ST SMART study.

electrodes and manually transmit an initial ECG for patients who had symptoms of ACS (Table 1). This initial manual electrocardiographic transmission activated the continuous ST-segment monitoring software that was otherwise inactive for routine rhythm monitoring of patients without ACS. All subsequent transmissions of ST-event ECGs occurred automatically without paramedic decision making. If transmission failed because of poor cell phone coverage, the software would automatically redial up to 3 attempts to transmit an ECG. Paramedics were instructed not to delay at the scene but rather to allow the device to transmit the ECG while traveling to the hospital. They visualized a single limb lead for routine rhythm monitoring and did not see the synthesized 12-lead ECG in the field.

A central computer received transmitted ECGs and special software randomized the patient to an experimental or control group. Patients randomized to the experimental group had their initial and any subsequent ST-event ECGs printed out in the destination ED with an audible voice alarm stating "incoming ECG from the field." Patients in the control group had an ECG after hospital arrival, which was the standard of care in the county.

Emergency physicians examined incoming ECGs from the field to determine whether the patient had a STEMI. If so, the cardiologist on call was alerted and the cardiac catheterization laboratory personnel were called in. If personnel were on-site and ready at the time the patient reached the hospital, the patient bypassed the ED and went directly to the cardiac catheterization laboratory for primary percutaneous coronary intervention. Because the synthesized

ECG was investigational, a standard 12-lead ECG was required in the hospital to confirm the diagnosis.

Institutional review boards of the University of California at San Francisco and the 2 hospitals approved the study with a waiver of consent in the field to avoid delays in patients reaching the hospital due to the study. Community consent was obtained by a front-page report in the county's newspaper (*Santa Cruz Sentinel*) and by posting information on hospitals' and EMS agencies' Web sites, including the fire department and American Medical Response ambulance company. Patients were invited to participate in the study by a research nurse after they reached the hospital or, if discharged from the ED, by a letter followed by a telephone call from the research nurse. If patient consent was not obtained, their prehospital electrocardiographic data that had already been collected were not used in the analysis.

American College of Cardiology key data elements for measuring clinical management and outcomes of patients with ACS were used to define variables for the study, including patient characteristics (demographics, coronary risk factors, cardiac history), clinical presentation, diagnostic tests, percutaneous coronary intervention or other procedures, medications, and patient outcomes.³ Electrocardiographic criteria for STEMI and non-STEMI were defined by new universal criteria for MI.⁴ These criteria included ST-segment elevation at the J-point with cut-off points ≥ 0.2 mV in men and ≥ 0.15 mV in women in leads V_2 to V_3 and/or ≥ 0.1 mV in other leads, or horizontal or downsloping ST-segment depression ≥ 0.05 mV and/or T-wave in-

Table 2
Comparison of experimental and control groups

Variable	Control Group (without prehospital ECG) (n = 391)	Experimental Group (with prehospital ECG) (n = 403)	p Value
Age (years)	71 ± 14	70 ± 15	0.176
Women	49%	47%	0.523
Previous angina pectoris	31%	35%	0.201
Previous myocardial infarction	19%	25%	0.050
Previous heart failure	21%	17%	0.278
Previous percutaneous coronary intervention	19%	22%	0.331
Previous coronary bypass surgery	13%	14%	0.675
Previous stroke	8%	8%	0.798
Previous peripheral arterial disease	9%	10%	0.807
Diabetes mellitus	24%	22%	0.674
Hypertension	65%	65%	0.941
Current smoker	13%	14%	0.438
Hyperlipidemia	39%	41%	0.470
Chronic lung disease	18%	13%	0.049
Killip classification of heart failure			0.338
I	86%	90%	
II	12%	9%	
III	1%	1%	
IV	0.3%	0%	
Mean admission heart rate (beats/min)	84 ± 26	85 ± 25	0.693
Mean admission systolic blood pressure	142 ± 30	143 ± 32	0.608
Ejection fraction (n = 90)	58% ± 18	53% ± 22	0.266

version of ≥ 0.1 mV. All electrocardiographic criteria had to be present in 2 contiguous leads.

Unstable angina pectoris was defined as angina or equivalent without biomarker evidence of necrosis with any 1 of the 3 following features: (1) angina occurring at rest and prolonged, usually >20 minutes, (2) new-onset angina with Canadian Cardiovascular Society classification $\geq$ III severity, or (3) recent acceleration of angina reflected by an increase in severity of ≥ 1 Canadian Cardiovascular Society class to class $\geq$ III.³

Because patient report of symptom onset is often unreliable and is missing or variable between EMSs and hospital records for the same patient, we used 911 call time as a surrogate for symptom onset. The 911 call time was time stamped by the computer when the call was picked up by the dispatcher at an EMS call center. These times could not be edited after the call was closed. Computer time was automatically synchronized with official Greenwich Time every day.

To determine the true denominator of ACS cases over the study period, electronic databases from the 2 hospitals were analyzed for all patients during the 5-year enrollment period who were transported by EMSs and who had an *International Classification of Diseases, Ninth Revision*

code of MI or unstable angina pectoris. Then, to confirm that the MI or unstable angina pectoris was a “presenting” condition, rather than a complication after hospital admission, all EMS prehospital care reports were reviewed. After determining the true denominator of total ACS cases in the county over the 5-year period, we determined EMS use by calculating the proportion of patients with ACS who had a prehospital ECG transmission.

Because key time variables (911 call to first ECG, door to balloon, door to drug) were skewed, a log-transformation of these times was applied to normalize the distribution and 2-tailed *t* tests for independent samples were used to compare control and experimental groups. Mann-Whitney nonparametric test was also used for all time comparisons between groups. Survival analysis with log-rank Mantel-Cox test was used to test differences between control and experimental patients’ survival over the 5-year follow-up period.

Results

A summary of study enrollment is shown in Figure 2. Total number of patients who called 911 for symptoms suggestive of ACS, were ≥ 30 years of age, were not in cardiac arrest at EMS arrival, had a prehospital ECG transmitted, and consented to participate in the study was 794. Ethnicity included 86% White, 9% Latino, 2% Asian, 1% Black, and 2% mixed/unknown. There were 215 patients with ACS—50 with STEMI, 63 with non-STEMI, 5 with uncertain type (left bundle branch block), and 97 with definite/probable unstable angina pectoris.

Patients randomized to having a prehospital ECG printed out in the ED (experimental group, n = 403) were not different from those without a prehospital ECG (control group, n = 391) except for 2 baseline characteristics (Table 2). These 2 differences were that a larger proportion of experimental patients had a previous MI and a larger proportion of control patients had a history of chronic lung disease.

The experimental patients’ first ECG was the ECG manually transmitted by paramedics from the field and printed out in the destination ED. The control patients’ first ECG was the ECG recorded after hospital arrival. Mean times from 911 call to first ECG were 20 ± 10 minutes in the experimental group and 79 ± 149 minutes in the control group. This average 59-minute decrease in time to first ECG in the experimental group was statistically significant ($p < 0.0001$).

Paramedic use of prehospital ECG was determined for all patients with ACS symptoms and for all patients who had a confirmed diagnosis of ACS. First, we determined the proportion of patients who called 911 with symptoms of ACS that were appropriately identified by paramedics, as evidenced by their manual transmission of an ECG from the field. As shown in Figure 2, of the 4,219 patients who called 911 with ACS symptoms over the 5-year span of the study, paramedics transmitted a prehospital ECG in 3,103 (74%). Second, to compare our EMS use to the National Registry, we determined the proportion of patients who “ruled in” with a final diagnosis of ACS who had a prehospital ECG. The true denominator of patients with ACS transported by EMS to 1 of the 2 hospitals over the 5-year enrollment

period was 563. Of these, paramedics appropriately transmitted a prehospital ECG in 320 (57%).

To compare EMS scene time with and without a prehospital ECG, we analyzed the EMS computer log for all consecutive 911 calls for a 1-year period in the middle of the study (2007) when paramedics were comfortable with the new equipment and lead configuration. In total 406 patients met study inclusion criteria, of which 128 had a prehospital ECG and 278 did not. Mean scene time in those with a prehospital ECG was 18 ± 6 minutes compared to 16 ± 6 minutes in those without a prehospital ECG. This average 2-minute increase in scene time was statistically significant (95% confidence interval 1.2 to 3.6, $p < 0.001$); however, it was less than our definition of a "clinically" significant increase in scene time (≥ 5 minutes).

Mean door-to-balloon time in the 42 patients with STEMI who received primary percutaneous coronary intervention was 78 ± 22 minutes in the experimental group compared to 101 ± 56 minutes in the control group. This 23-minute difference was not statistically significant. Proportions of patients with STEMI who had reperfusion within 90 minutes of ED arrival were 76% in the experimental group and 56% in the control group ($p = 0.197$).

Time from ED arrival to first drug was determined as recommended by American College of Cardiology/American Heart Association 2007 guidelines for management of patients with unstable angina/non-STEMI.⁵ These drugs included intravenous glycoprotein IIb/IIIa inhibitors, intravenous or subcutaneous antithrombotic agents (heparin, etc.), intravenous nitroglycerin, or intravenous β blockers. Four patients with "do not resuscitate" orders were excluded from this time-to-treatment analysis. Mean door-to-drug time was 23 ± 12 minutes in the experimental group compared to 31 ± 16 minutes in the control group ($p = 0.043$).

Follow-up response rates for the total sample of 794 were 95% for 30 days, 93% for 1 year, 88% for 2 years, 82% for 3 years, and 76% for 4 years. In patients with STEMI, there were 5 deaths in the control group and 2 deaths in the experimental group; however, this difference was not statistically significant ($p = 0.083$, Fisher's exact 2-sided test). Likewise, in the entire sample of patients with ACS, there was not a statistically significant difference in survival over the span of the study between those with and without a prehospital ECG.

Discussion

Our study is the first to evaluate prospectively time to reperfusion and outcomes in patients randomized to prehospital ECG versus no prehospital ECG. Previous studies examining time to reperfusion after implementation of a prehospital electrocardiographic program have compared postintervention to preintervention historic data. Therefore, the decrease in reperfusion time reported in these studies may have occurred over time regardless of prehospital electrocardiographic program because of growing pressure on hospitals for more timely treatment.

Findings from our study indicate that a simple strategy can improve paramedic use of prehospital ECGs in patients with ACS. Our intervention involved synthesizing a 12-lead ECG using 1/2 the number of electrodes required for a

standard ECG and transmitting prehospital ECGs in patients who had dynamic ST-segment changes using ST-segment monitoring software with automatic cell phone transmission. As a result, paramedics transmitted a prehospital ECG in nearly 3/4 of patients (74%) who called 911 for symptoms of ACS and in 57% of patients with actual ACS. Our results are in sharp contrast with the low (24.7%) paramedic use of prehospital ECGs in 7,098 patients with STEMI transported by EMSs in the United States reported by the National ACTION Registry investigators.¹

Our strategy also led to an average 59-minute decrease in time from 911 call to first ECG in those with versus without a prehospital ECG. In a county where EMS transport from rural areas may result in longer times from 911 call to ED arrival, this nearly 1-hour advance notice of a patients with ACS en route has the potential to shorten hospital time to treatment. We found faster time (about 8 minutes faster) to first intravenous drug for patients with non-STEMI or unstable angina pectoris and a trend toward faster door-to-balloon times (23 minutes faster) in patients with STEMI. We also observed a trend toward lower mortality in patients with STEMI with versus without a prehospital ECG; however, this was not statistically significant, most likely due to the small sample.

Our increased paramedic use of prehospital ECG did not come at the expense of significantly longer scene times. We found an average 2-minute increase in scene time for those with versus without a prehospital ECG. Although this slight difference was statistically significant, it is not clinically significant, especially when shorter hospital time to treatment cancels out this small time increase in the field. Most studies have shown an average increase of 5 to 6 minutes in EMS scene time with acquisition of a standard 12-lead ECG.⁶ One study using data from the National Registry of Myocardial Infarction from 1994 to 1996 showed that patients with prehospital ECGs had an average 20-minute longer time from symptom onset to hospital arrival.⁷ Our minimal increase in scene time was likely due to the less cumbersome 5-electrode ECG configuration and automatic cell phone transmissions without the need for paramedic ECG interpretation in the field.

Findings from our study agree with the American Heart Association's initiative to improve systems of care for patients with STEMI that encourage strategies tailored to the unique characteristics of each geographic region.⁸ Clearly, there is no "one-size-fits-all" solution for removing barriers to widespread implementation of prehospital ECGs.

A limitation of our study was that our sample of 794 (215 with ACS) provided insufficient power to detect a statistically significant difference in survival between patients with and without a prehospital ECG. Although it was necessary to waive consent in the field to avoid delays in reaching a hospital, the result was that fewer patients consented to be in the study because they were often discharged by the time the research nurse contacted them. However, despite the limited sample, we found that a simple strategy for acquiring and transmitting 12-lead ECGs from the field to the hospital was associated with greater paramedic prehospital ECG use without clinically significant increases in scene time. It also resulted in faster time to first ECG in patients with symptoms of ACS, faster time to first drug in patients with non-STEMI or unstable angina pectoris, and a sug-

gested trend for faster door-to-balloon times and lower mortality in patients with STEMI.

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