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The STAT-MI (ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction) Trial Improves Outcomes

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Objectives The goal of this study was to evaluate the impact of the STAT-MI (ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction) network on outcomes in the treatment of patients presenting with ST-segment elevation myocardial infarction (STEMI).

Background Shortening door-to-balloon (D2B) time remains a national priority for the treatment of STEMI. We previously reported a fully automated wireless network (STAT-MI) for transmission of electrocardiograms (ECGs) for suspected STEMI from the field to offsite cardiologists, allowing early triage with shortening of subsequent D2B times. We now report the impact of the STAT-MI wireless network on infarct size, length of hospital stay (LOS), and mortality.

Methods A fully automated wireless network (STAT-MI) was developed to enable automatic 12-lead ECG transmission and direct communication between emergency medical services personnel and offsite cardiologists that facilitated direct triage of patients to the cardiac catheterization laboratory. Demographic, laboratory, and time interval data of STAT-MI network patients were prospectively collected over a 33-month period and compared with concurrent control patients who presented with STEMI through non–STAT-MI pathways.

Results From June 2006 through February 2009, 92 patients presented via the STAT-MI network, and 50 patients presented through non–STAT-MI pathways (control group). Baseline clinical and demographic variables were similar in both groups. Overall, compared with control subjects, STAT-MI patients had significantly shorter D2B times (63 [42 to 87] min vs. 119 [96 to 178] min, $U = 779.5$, $p < 0.00004$), significantly lower peak troponin I (39.5 [11 to 120.5] ng/ml vs. 87.6 [38.4 to 227] ng/ml, $U = 889.5$, $p = 0.005$) and creatine phosphokinase-MB (126.1 [37.2 to 280.5] ng/ml vs. 290.3 [102.4 to 484] ng/ml, $U = 883$, $p = 0.001$), higher left ventricular ejection fractions (50% [35 to 55] vs. 35% [25 to 52], $U = 1{,}075$, $p = 0.004$), and shorter LOS (3 [2 to 4] days vs. 5.5 [3.5 to 10.5] days, $U = 378$, $p < 0.001$).

Conclusions A fully automated, field-based, wireless network that transmits ECGs automatically to offsite cardiologists for the early evaluation and triage of patients with STEMI shortens D2B times, reduces infarct size, limits ejection fraction reduction, and shortens LOS. (J Am Coll Cardiol Intv 2011;4:222–7) © 2011 by the American College of Cardiology Foundation

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The benefit of decreasing door-to-balloon (D2B) times in acute ST-segment elevation myocardial infarction (STEMI) has previously been widely reported (1–5). Shortening D2B time remains a national priority for the treatment of STEMI. Strategies to decrease D2B times are often limited by multiple time-intensive steps. National registries have demonstrated a linear correlation between D2B times and mortality (6,7). We previously reported on the STAT-MI (ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction) network that we established that allows for immediate and automatic transmission of high-resolution electrocardiograms (ECGs) from the field directly to smart phones worn by cardiologists (8). We now present outcome data including infarct size, length of hospital stay (LOS) and mortality that resulted from the implementation of our STAT-MI network. In addition, new data on D2B and other times that have accrued from our continued use of the network are presented.

Methods

The STAT-MI network was developed by a collaborative task force including cardiology, emergency medical services (EMS), emergency department (ED), hospital administration, information health technology and telecommunications, and the New Jersey State Department of Health. This project was undertaken at the New Jersey Medical School University Hospital, an inner city safety-net hospital for Newark, New Jersey.

Network. The STAT-MI network and initial data have previously been described (8). Bluetooth-enabled LIFEPAK 12 defibrillators (Medtronic, Minneapolis, Minnesota) automatically transmitted the 12-lead ECG to Bluetooth-enabled phones worn by EMS personnel. These phones in-turn automatically transmitted the 12-lead ECGs to the LifeNet Receiving Station (Medtronic), which automatically printed the ECG for local review, converted the ECG to a PDF file, sent the ECG via the University Hospital secure intranet to pre-specified e-mail addresses of the cardiologists and sent an audible text page to the on-call cardiologist. No intervening action by any personnel was required once EMS activated the system in the field. On-call cardiologists accessed the PDF ECG file via their handheld smartphones. The ECGs were transmitted with an embedded telephone number for the en route EMS personnel allowing for direct communication between the cardiologist and EMS before hospital arrival. The ECG could be magnified and manipulated on the smartphone screen allowing for detailed ST-segment and other waveform analyses. On the basis of the ECG and en route discussion with EMS, a decision for primary percutaneous intervention (PCI) was made. During regular hours (7:00 AM to 5:00 PM, Monday to Friday), the patient was brought directly to the cardiac catheterization laboratory. During off hours (5:00 PM to 7:00 AM and weekends), the catheterization laboratory team was notified, and the patient was delivered to the ED if the catheterization laboratory team had not yet arrived.

Data collection. From June 2006 to February 2009, all patients identified by EMS personnel in the field with suspected STEMI were triaged with the STAT-MI network. All patients confirmed to have STEMI were brought to the cardiac catheterization laboratory for primary PCI. Demographic and clinical data were prospectively collected on all patients. Door-to-arterial access (D2A) time was the time between hospital arrival and femoral arterial access. The D2B time was defined as the time between hospital arrival and first intervention (balloon angioplasty, stenting, or mechanical thrombectomy) that restored patency of the culprit vessel. The STAT-MI–treated patients were compared with other STEMI patients who presented either as walk-ins or via ambulance services not equipped with the STAT-MI system (control group).

Data including peak troponin I and creatine phosphokinase-MB (CPK-MB), post-intervention (within 24 to 48 h) left ventricular ejection fractions (LVEFs), hospital LOS, and mortality were collected to assess the impact of the STAT-MI pathway on patient outcomes. Troponin I and CK-MB microparticle enzyme immunoassays were used to assess infarct size. Levels were drawn every 8 h from admission until a downward trend was noted. The LVEF was obtained by 2-dimensional echocardiography and determined by visual estimate on the basis of assessment of left ventricular contractile function in multiple echocardiographic views. The accuracy and reproducibility of visual estimates of LVEF has been previously established (9). Left ventricular internal dimensions and wall thicknesses were measured at end diastole and end systole according to the American Society of Echocardiography recommendations at or just below the tips of the mitral valve leaflets in the parasternal long- or short-axis views (10). Wall motion was assessed in the parasternal long- and short-axis views and apical 2-, 3-, and 4-chamber views.

Primary end point. The primary end point was to compare D2B times for primary PCI in STEMI patients treated via the STAT-MI pathway versus STEMI patients treated via non–STAT-MI pathways. Patients with suspected STEMI who underwent diagnostic catheterization only (without an intervention) were included in the D2A analysis only. Time interval data were further analyzed comparing the

Abbreviations and Acronyms

CABG = coronary artery bypass graft surgery
CPK-MB = creatine phosphokinase-MB
D2B = door-to-balloon
E2B = emergency medical services-to-balloon
ECG = electrocardiogram
EMS = emergency medical services
LOS = length of hospital stay
PCI = percutaneous intervention
STEMI = ST-segment elevation myocardial infarction

STAT-MI network with control subgroups ("walk-ins" and non–STAT-MI EMS) for pre-hospital transport, door-to-ECG acquisition, and door-to-cardiology notification times.

Secondary end points. The secondary end points were to assess the impact of the STAT-MI pathway on outcomes including infarct size (as assessed by peak troponin I, peak CPK, and peak CPK-MB), LVEF after intervention, and hospital LOS.

Statistical analysis. Analyses included descriptive statistics, *t* test for independent means, chi-square, and Fisher exact test for categorical analysis. Other measurements of time interval are presented as means with SDs in minutes. Normality of distribution of all variables was checked with Kolmogorov-Smirnoff tests. Mann-Whitney *U* test for comparisons was used for nonparametric data. Analysis of variance with treatment groups (STAT-MI or concurrent control subjects) and time of presentation (day or night/weekends) as fixed factors examined independent and interaction effects when looking at key time measures. Statistical analysis was conducted with Statistica 8 for Windows (StatSoft, Tulsa, Oklahoma). Statistical significance was set at $p < 0.05$.

Results

Study flow. Between June 2006 and February 2009 (33 months), 330 ECGs were transmitted by EMS through the STAT-MI network (Fig. 1). Ninety-two (28%) were interpreted by the cardiologist on-call as consistent with STEMI, and these patients were triaged directly from the field to the catheterization laboratory for primary PCI. The remaining 238 patients (72%) had ECGs not consistent with STEMI (including prior bundle branch block, left ventricular hypertrophy, early repolarization, nonspecific ST and T wave abnormalities, ST depressions, supraventricular tachycardia, and paced rhythm) and were triaged to the ED. None of the patients triaged to the ED were subsequently found to have STEMI. Of the 92 patients triaged for primary PCI, 72 patients (78%) underwent primary PCI to the culprit lesion, whereas 20 patients (22%) had either noncritical coronary stenosis (n = 17) or were referred for coronary artery bypass graft surgery (CABG) (n = 3). These patients were compared with the 50 control non–STAT-MI network STEMI patients, 43 (86%) of whom were treated with primary PCI and 7 (14%) who were referred for CABG. Of the 50 control patients, 20 (40%) were ED "walk-ins," and 30 (60%) were non–STAT-MI EMS patients (both advanced life support and basic life support).

Baseline characteristics. The baseline characteristics of the STAT-MI pathway patients were similar to the control patients except for higher self-reported cocaine use in the control group ($p = 0.005$) (Table 1). Of note, control patients who used cocaine on presentation had a similar distribution of typical symptoms compared with those who did not use cocaine (83.3% vs. 74.4%, $p = 0.7$). Both the STAT-MI network and control groups were predominantly male (71% and 54%, respectively) with mean ages of 56 and 55 years, respectively, and similar prevalence of cardiovascular risk factors.

Primary end point. Median D2B time was significantly less in the STAT-MI group (n = 72) compared with control subjects (n = 43) (63 [42 to 87] min vs. 119 [96 to 178] min, $U = 779.5$, $p < 0.00004$) (Fig. 2). Improvement in D2B time was seen, regardless of time of day (peak hours vs. off hours). Nonparametric analysis with analysis of variance

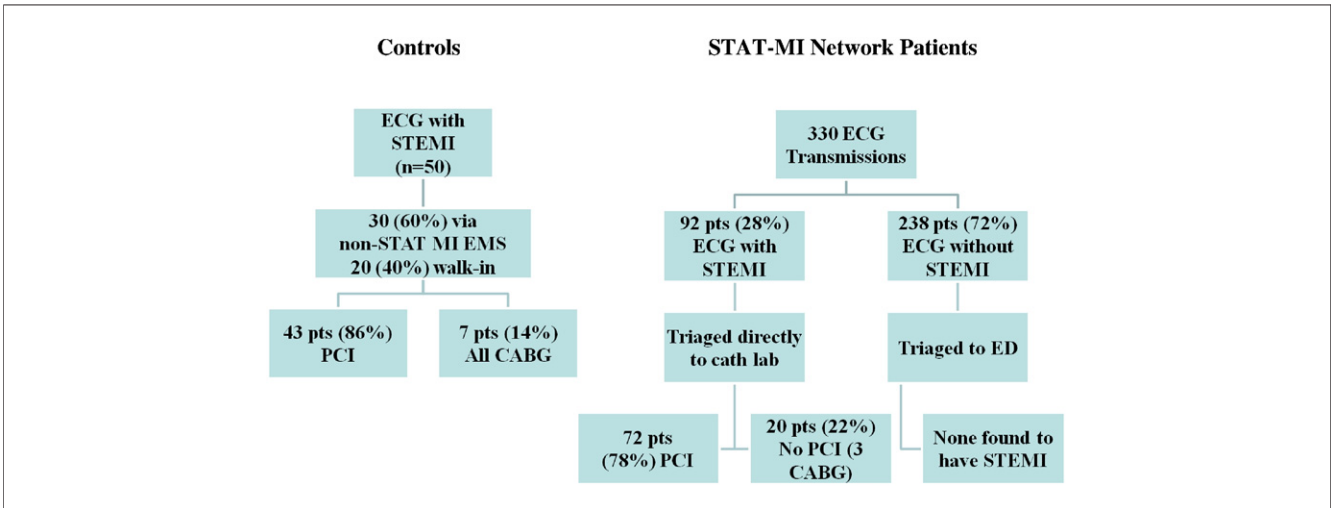

Figure 1. Study Flow Comparing STAT-MI Network and Concurrent Control Patients

CABG = coronary artery bypass graft surgery; ECG = electrocardiogram; ED = emergency department; EMS = emergency medical services; PCI = percutaneous intervention; STAT-MI = ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction; STEMI = ST-segment elevation myocardial infarction.

Table 1. Baseline Characteristics

	Control Subjects (n = 50)	STAT-MI (n = 92)
Age (yrs)	54.5 ± 11.6	56.1 ± 14.3
Male	54% (27)	71% (65)
Hypertension	58% (29)	68% (63)
Tobacco use	36% (18)	52% (48)
Diabetes	28% (14)	31% (29)
Family history	30% (15)	20% (18)
Previous CAD	20% (10)	28% (26)
Cocaine*	22% (11)	6% (6)
Mean LDL (mg/dl)	110.9 ± 34.5	107.0 ± 52.2
Mean HDL (mg/dl)	46.2 ± 15.5	46.1 ± 15.7

Values are mean ± SD or % (n). The p value is nonsignificant between comparisons unless otherwise specified. *p = 0.005.

CAD = coronary artery disease; HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol; STAT-MI = ST-segment Analysis Using Wireless Technology in Acute Myocardial Infarction.

revealed an observed interaction between group assignment and time of presentation such that STAT-MI patients presenting during regular hours had the shortest D2B time and control patients presenting during off hours had the longest D2B time (p = 0.005). These results are depicted in Figure 2, showing median D2B times overall, and regular versus off hours. The D2A time was similarly less in the STAT-MI group (n = 92) when compared with control subjects (n = 50) (42 [23 to 59] min vs. 96 [72 to 157] min, U = 428.5, p < 0.001 = 0.01^{-5}). Although pre-hospital transport times were similar between STAT-MI network and control EMS patients, door-to-ECG acquisition and door-to-cardiology notification times were significantly and similarly prolonged in the control subgroups (control EMS and walk-ins) compared with STAT-MI network patients (Table 2).

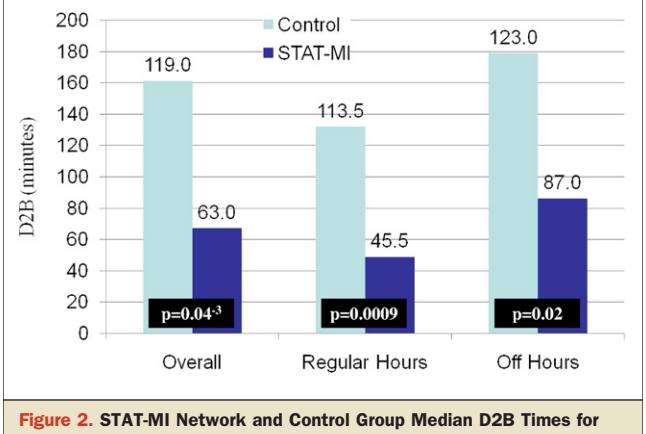

Figure 2. STAT-MI Network and Control Group Median D2B Times for Overall and Regular Versus Off Hours

D2B = door-to-balloon; STAT-MI = ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction.

Table 2. Time Interval Data

	Walk-In	Control EMS	STAT-MI EMS
Pre-hospital transport	NA	32.8 ± 16.0	36.7 ± 11.6
Door-to-ECG*	20 (11.46)	11 (6.25)	−23 (18.29)
Door-to-cardio*	36 (28.60)	26 (14.72)	−16 (22.10)

Values are mean ± SD or n (%). Data shown in minutes. The p value is nonsignificant unless otherwise specified. *p < 0.001 for walk-in versus STAT-MI (ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction) network emergency medical services (EMS) and control EMS vs. STAT-MI network EMS.

Door-to-cardio = door-to-cardiology notification; ECG = electrocardiogram.

Secondary end points. Peak troponin I (39.5 [11 to 120.5] ng/ml vs. 87.6 [38.4 to 227] ng/ml, U = 889.5, p = 0.005) and CPK-MB (126.1 [37.2 to 280.5] ng/ml vs. 290.3 [102.4 to 484] ng/ml, U = 883, p = 0.001) were significantly lower in patients treated via the STAT-MI network compared with control subjects (Table 3). Post-infarction LVEFs (50% [35% to 55%] vs. 35% [25% to 52%], U = 1,075, p = 0.004) were greater and LOS (3 [2 to 4] days vs. 5.5 [3.5 to 10.5] days, U = 378, p < 0.001) was less in STAT-MI patients compared with control subjects. The overall mortality in the STAT-MI group was 1.1% (n = 1) versus 6% (n = 3) in the control subjects (p = 0.125).

Discussion

Primary PCI remains the therapy of choice for STEMI if performed in a timely fashion. The American College of Cardiology and American Heart Association guidelines for the management of acute myocardial infarction have established a D2B time of 90 min as a gold standard for primary PCI (11). A meta-analysis of trials comparing primary PCI and fibrinolysis showed that every additional 10-min delay in D2B time beyond door-to-needle time for fibrinolytic therapy resulted in a reduction in absolute benefit (combined end point of death, reinfarction, and stroke at 4 to 6 weeks) of primary PCI (12). We have previously reported that using our STAT-MI network resulted in a significantly

Table 3. Outcome Data

	Control Subjects (n = 43)	STAT-MI (n = 72)	p Value
Peak troponin, ng/ml	87.6 [38.4, 227]	39.5 [11,120.5]	0.005
Peak CPK-MB, ng/ml	290.3 [102.4, 484]	126.1 [37.2, 280.5]	0.001
Ejection fraction, %	35 [25, 52]	50 [35, 55]	0.004
Length of stay, days	5.5 [3.5,10.5]	3 [2, 4]	<0.001
Mortality	6.0	1.1	0.125

CPK-MB = creatine phosphokinase-MB; STAT-MI = ST-Segment Analysis Using Wireless Technology in Acute Myocardial Infarction.

shortened D2B time (8). The initial 20-patient cohort treated via our protocol showed a reduction of D2B time from 145 to 80 min.

The current report expands our initial observation and demonstrates the impact of this network on outcomes. The 92 patients treated via the STAT-MI network had a median D2A time of 42 min, and the 72 patients who went on to primary PCI had a median D2B time of 63 min. This D2B time is significantly shorter than the D2B time of the control patients who presented to the hospital as walk-ins or via other ambulance services during the same time period. Time delays in patient evaluations and ECG acquisition and transmissions in busy EDs delays the timely management of STEMI patients (7). Our study took advantage of wireless technology by completely automating the process of ECG acquisition and transmission from the field to handheld smartphones worn by cardiologists and eliminated many intermediary personnel-induced time delays in treating acute myocardial infarction patients.

Steen et al. (13) showed that troponin levels correlate with infarct size and cardiac function in both STEMI and non-STEMI. Troponin and CPK-MB were significantly lower in the STAT-MI–treated patients compared with control subjects. Consistent with smaller infarct size were the significantly higher post-infarct ejection fractions and shorter LOS in patients treated via the STAT-MI network. The trend toward a lower mortality seen in the STAT-MI patients is consistent with national registry observations (6).

Since the American College of Cardiology launched the D2B alliance (2006), nationwide efforts have been made to decrease D2B times to <90 min in >75% of the population (14). However, progress has been slow, and most hospitals in the U.S. continue to fall short of this benchmark. Although, a recent consensus statement (15) supports the use of pre-hospital ECGs to facilitate timelier triage of STEMI patients, a recent study by Diercks et al. (16) shows that only 27% of patients from the National Cardiovascular Data Registry Acute Coronary Treatment and Intervention Outcomes Network received them. Median D2B time in patients with a pre-hospital ECG was 61 min, with 82.3% having a D2B <90 min, compared with 75 min ($p < 0.0001$) and 70.0% ($p < 0.0001$) in patients receiving an in-hospital ECG (16). Pre-hospital ECG use was associated with a greater use of reperfusion therapy, faster reperfusion times, and a trend for lower adjusted in-hospital mortality.

Rokos et al. (17) reported on a pooled analysis (2,712 patients diagnosed with STEMI with pre-hospital ECG) of 10 observational, collaborating STEMI Receiving Center Network hospitals. They showed 86% of patients achieved a D2B time of ≤90 min, with 50% having a D2B time of ≤60 min, 25% having ≤45 min, and 8% having ≤30 min. Both this study (17) and that by Diercks et al. (16) correlate well with our STAT-MI network patients in which 78% had a D2B time of <90 min with similar reperfusion times (63 min). Rokos et al. reported on EMS-to-balloon (E2B) times in addition to D2B times, for which 68% of the STEMI patients had an E2B time of ≤90 min. Our data are similar, with E2B times of 82.7 ± 30.2 min and 57% having an E2B time of <90 min in the last year (18).

The rate of false-positive activations in our study was 24%, with the most common ECG abnormalities in this group being left bundle branch block, previous myocardial infarction, and early repolarization. Other studies report a false-positive activation rate of 4% to 19% (19–23). Davis et al. (22) compared EMS with emergency physician ECG interpretation as related to the positive predictive value of appropriate catheterization laboratory activation for STEMI and showed a difference of 78% vs. 96% ($p < 0.01$), respectively. Carstensen et al. (23) reported in using field-based triage a 7% to 9% false positive catheterization laboratory activation rate, for which 7 of their 440 patients (1.6% false negative rate) triaged from the field to the ED were later found to have STEMI. In our study, no STEMI patients were missed. Given the clinical importance of STEMI treatment, the expected range of false positive catheterization laboratory activation would be justifiably wide. In review of our false positive activations, we noted that these included left bundle branch block or early repolarization in the setting of chest pain (n = 9), previous CABG (n = 3), previous STEMI with persistent ST elevations (n = 3), and Takatsubo Syndrome (n = 2).

Study limitations. Comparison with walk-ins, who are generally more "stable" than ambulance-arrived patients, might be flawed by a selection bias against early recognition of STEMI in these "more stable" patients. However, D2B times were equally prolonged in both the walk-ins and other ambulance-arrived patients, suggesting that bias against walk-ins did not play a role in their delayed D2B times.

Conclusions

A fully automated wireless network that transmits ECGs from the field directly to cardiologists for the early evaluation, triage, and treatment of patients with STEMI decreases D2B times to <90 min, reduces infarct size, limits ejection fraction reduction, and shortens LOS. Continued efforts to eliminate unnecessary intermediate steps in the treatment of patients who present with STEMI are crucial in the design of STEMI pathways. The STAT-MI network facilitates accurate STEMI patient triage in the field by bringing the interventional cardiologist to the patient's "door." The improved outcomes that we have observed reinforce development of pathways that concentrate on eliminating unnecessary intermediary steps.

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Key Words: angiography ■ door-to-intervention time ■ electrocardiography ■ infarct size ■ troponin ■ wireless technology.