

SPECIAL ARTICLE

Pre-Hospital 12-Lead Electrocardiography Programs

A Call for Implementation by Emergency Medical Services Systems Providing Advanced Life Support—National Heart Attack Alert Program (NHAAP) Coordinating Committee; National Heart, Lung, and Blood Institute (NHLBI); National Institutes of Health

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Emergency medical services (EMS) providers who administer advanced life support should include diagnostic 12-lead electrocardiography programs as one of their services. Evidence demonstrates that this technology can be readily used by EMS providers to identify patients with ST-segment elevation myocardial infarction (STEMI) before a patient's arrival at a hospital emergency department. Earlier identification of STEMI patients leads to faster artery-opening treatment with fibrinolytic agents, either in the pre-hospital setting or at the hospital. Alternatively, a reperfusion strategy using percutaneous coronary intervention can be facilitated by use of pre-hospital 12-lead electrocardiography (P12ECG). Analysis of the cost of providing this service to the community must include consideration of the demonstrated benefits of more rapid treatment of patients with STEMI and the resulting time savings advantage shown to accompany the use of P12ECG programs. (J Am Coll Cardiol 2006; 47:485–91) © 2006 by the American College of Cardiology Foundation

Coronary heart disease, the single largest cause of death in U.S. men and women, was responsible for more than one in every five deaths in 2002. According to the latest estimates, as many as 1.2 million Americans experience an acute myocardial infarction (AMI) each year, resulting in over 494,300 deaths (1).

A decade has passed since a working group of the National Heart Attack Alert Program (NHAAP) published “60 Minutes to Treatment,” a position paper on rapid identification and treatment of patients with AMI (2). This statement challenged the U.S. health care system to provide definitive artery-opening (reperfusion) treatment (notably

fibrinolytic) to eligible AMI patients within 60 min of symptom onset, and within 30 min of arrival at the hospital. These benchmarks are critical because the benefits of AMI treatment diminish rapidly over time (3). Early reperfusion treatment for eligible AMI patients has a significant impact on morbidity and mortality (4). The benefit of a shorter time to artery-opening treatment with fibrinolytics and percutaneous coronary intervention (PCI) has been conclusively shown for patients with ST-segment elevation myocardial infarction (STEMI) (4–7). For fibrinolytic therapy, the beneficial effects are substantially greater in patients treated early after symptom onset than in those treated later, and mortality reduction is greatest among patients presenting to the hospital within 1 h of symptom onset. The benefit of fibrinolytic therapy initiated within 30 to 60 min after the onset of symptoms is estimated to result in 60 to 80 additional patients alive, at one month, per 1,000 patients treated with conventional therapy (8). These data support the well-known concept of a “golden hour” for AMI. The importance of total ischemic time has also been described for artery-opening treatment by PCI (6,9–11). The length of time from symptom onset to balloon inflation has been shown to be significantly correlated with one-year mortality (6). While PCI confers a higher rate of reperfusion, notably in patients presenting later in the course of infarction, myocardial necrosis is related to the duration of occlusion of the infarct-related artery, particularly in patients at greater risk (6). Thus, the time to opening of the infarct-related artery is important for patients who receive PCI as well as fibrinolysis (12).

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Abbreviations and Acronyms

ACC	= American College of Cardiology
ACI-TIPI	= acute cardiac ischemia time-insensitive predictive instrument
ACS	= acute coronary syndromes
AHA	= American Heart Association
AHRQ	= Agency for Healthcare Research and Quality
ALS	= advanced life support
AMI	= acute myocardial infarction
ED	= emergency department
EMS	= emergency medical services
EMT-P	= emergency medical technician-paramedic
PCI	= percutaneous coronary intervention
P12ECG	= pre-hospital 12-lead electrocardiography
STEMI	= ST-segment elevation myocardial infarction

The use of measurable time intervals (e.g., from arrival at the emergency department [ED] ["door"] to the initial electrocardiogram ["data"], and from the decision to treat ["decision"] to fibrinolytic drug administration time ["drug"]) has been promoted as a means for individual hospitals to study their system of care, implement changes in their processes, and improve performance relative to these benchmarks (2). Many hospitals can now state that definitive care is provided to STEMI patients within the benchmark time interval starting with arrival at the ED, but the proportion of patients treated within 60 min of symptom onset is only 4% for fibrinolytics and less than 1% for PCI (E. Stoehr, National Registry of Myocardial Infarction, personal communication, July 2004). Given the previously published time-to-treatment goals and the increased availability of PCI as an option for these patients, the American College of Cardiology (ACC) and the American Heart Association (AHA) recommend that after eligible STEMI patients present to the "medical system" (either emergency medical services [EMS] or the ED), they should receive fibrinolytic therapy within 30 min or PCI within 90 min (13).

For these benchmarks to be met, emphasis on further improvements in the time to definitive care for patients with STEMI must look to pre-hospital factors. Patient and bystander delays are responsible for the greatest proportion of delay before treatment (14). Major clinical trials show that the median time from symptom onset to treatment of persons with STEMI is approximately 2 to 3 h (15-17). Patient-related delay in seeking treatment has remained largely unchanged over the last decade, even though studies have shown that the effectiveness of reperfusion therapy depends on timely intervention (16,18-20). The full potential of current artery-opening treatments has not been realized because many patients are not seen in the hospital in time to fully reap their benefits (18,21).

Patients' recognition of symptoms, their motivation to seek care very early in the course of symptoms, and their use of EMS to provide immediate care will ultimately increase the number of persons receiving care within 60 min of

symptom onset (22). Two educational initiatives, the National Heart, Lung, and Blood Institute's "Act in Time to Heart Attack Signs," campaign (23,24) and the Society of Chest Pain Centers' "Early Heart Attack Care" program (25,26), target educating potential patients (and others who may be in a position to help patients act quickly) to recognize and respond to symptoms associated with acute coronary syndromes (ACS). Community intervention and educational campaigns may promote the appropriate use of EMS by potential AMI patients (27).

The use of EMS in itself has been shown to be associated with earlier evaluation in the ED, wider use of acute reperfusion therapies, and less time between arrival at the ED, to fibrinolytic therapy or urgent PCI (17,28-32). Even though use of EMS is associated with earlier evaluation and treatment in the hospital setting, only 10% to 59% of patients with chest pain use such services for treatment and transportation to the hospital (17,29,30,33,34). Most patients are driven by someone else (about 60%) or drive themselves to the hospital (nearly 16%) (29,33). Emergency medical services is the only means by which patients can obtain the earlier evaluation and treatment benefit associated with pre-hospital 12-lead electrocardiography (P12ECG).

Pre-hospital electrocardiographs are usually sold as additional modular components or integrated into monitor-defibrillator devices. Pre-hospital 12-lead electrocardiography entails application of recording electrodes, capture of electrocardiographic data, automated interpretation using diagnostic algorithms within the device, transmission capability, and the option for over-read of the output by paramedics. The quality of P12ECG data has been shown to be equal to that obtained in the hospital (35,36). Pre-hospital 12-lead electrocardiographic data are readily obtained at the point of care of the patient in the pre-hospital environment, without undue delay in transportation to the hospital (35,37-39). Although a longer time from symptom onset to hospital presentation for the P12ECG group was reported in one series (40), the time to in-hospital reperfusion was significantly less in the P12ECG group. Printable copies of P12ECG data can be sent to hospital EDs via cellular telephone, or direct medical oversight physicians can discuss the paramedic's interpretation and other relevant aspects of the patient's symptoms, risk profile, and response to initial therapy. While many EMS providers are trained in the interpretation of 12-lead electrocardiography, and computerized algorithms provide diagnostic statements that paramedics can over-read, it is also possible to receive real-time remote interpretation of pre-hospital 12-lead electrocardiograms by expert physician electrocardiographers (41). The pre-hospital 12-lead electrocardiogram should be expeditiously over-read by a qualified physician.

Benefits of a P12ECG. The pre-hospital 12-lead electrocardiogram has favorable diagnostic and clinical impact ratings. The Agency for Healthcare Research and Quality (AHRQ) included P12ECG in its assessment of a wide

range of technologies used for identification of patients with acute cardiac ischemia in EDs (42,43). The AHRQ review found P12ECG to be moderately sensitive (76%) and specific (88%) for the diagnosis of ACS (36,44-48), and 68% sensitive and 97% specific for the diagnosis of AMI (36,44-47,49-54). The same report (42) found that the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI), which prints the patient's probability of having ACS on the electrocardiogram header, improved the diagnosis of ACS. Further research is needed to test the potential impact of ACI-TIPI on EMS-based identification of ACS (55).

Pre-hospital 12-lead electrocardiography acquisition has been shown to be feasible and to result in earlier identification of patients with STEMI (39,56-59). Pre-hospital 12-lead electrocardiography has been shown to reduce the median time to fibrinolytic therapy in the hospital by 32 to 62 min (58,60,61). According to a study that examined a large registry of STEMI patients, activation of the cardiac catheterization laboratory using P12ECG data was shown to reduce the mean time to PCI by an average of 23 min (92 vs. 115 min, $p < 0.001$) (40). The P12ECG group was more likely to receive fibrinolytic therapy (43% vs. 37%, $p < 0.001$) and to undergo PCI (11% vs. 7%, $p < 0.001$). Also, the P12ECG group was more likely to undergo coronary arteriography (55% vs. 40%, $p < 0.001$), angioplasty (24% vs. 16%, $p < 0.001$), or bypass surgery (10% vs. 6%, $p < 0.001$). The influence of other factors in addition to P12ECG was not completely controlled for in this report, but the authors emphasized the importance of P12ECG in effecting wider, faster utilization of reperfusion strategies, greater usage of invasive procedures, and lower in-hospital mortality (8% vs. 12%, $p < 0.001$) for STEMI patients who received P12ECG versus those who did not (40).

One study of the use of P12ECG by paramedics (53) demonstrated a nonsignificant trend toward lower all-cause mortality among the P12ECG patients directly admitted for treatment to the hospital coronary care unit ($p = 0.22$). This was in addition to the main findings of 1 h reductions in both the EMS-call-to-fibrinolysis interval, and the door-to-drug interval, for the patients with P12ECG and direct coronary care unit admission by paramedics.

The clinical impact associated with use of P12ECG has been largely addressed by comparing the initiation of pre-hospital fibrinolysis, with hospital initiation of fibrinolysis (42,43). The outcomes of these randomized trials and prospective, nonrandomized studies have been reported in terms of time savings, early differences in left ventricular function, hospital mortality, and long-term mortality (42,43). In these studies where P12ECG was used in conjunction with a pre-hospital fibrinolysis program, it is not possible to attribute clinical impact effects associated solely with P12ECG versus that of pre-hospital fibrinolysis. Pre-hospital fibrinolysis alone has been shown in a meta-analysis to significantly decrease the time to fibrinolysis and all-cause hospital mortality (62). Pooled results of six

randomized trials ($n = 6,434$ patients) showed a significantly decreased all-cause hospital mortality among patients treated with pre-hospital fibrinolysis compared with hospital fibrinolysis (odds ratio, 0.83; 95% confidence interval, 0.70 to 0.98). The estimated time from symptom onset to fibrinolysis was 104 min for the pre-hospital group and 162 min for the in-hospital fibrinolysis group (62). The Myocardial Infarction Triage and Intervention trial (61) did not find a pre-hospital fibrinolytic strategy superior to a hospital-based strategy, but did demonstrate the overriding benefit of early reperfusion with fibrinolytics for patients in either group who were treated within 70 min. Advance notification of the hospitals of a STEMI patient resulted in expedited care once the patient arrived, compared to the usual ED care the patient would have received without the advance notification afforded by P12ECG.

IMPLEMENTING AN EFFECTIVE P12ECG PROGRAM

Despite reports of the utility of P12ECG, particularly its effectiveness in reducing time intervals to treatment and a trend toward lower short-term mortality of STEMI patients, this strategy has been incompletely adopted by EMS agencies in the U.S. According to a survey that collected data on EMS systems in 200 U.S. cities (63), 67% of those systems had P12ECG as part of their available equipment and procedure capability (the average total population served by the survey respondents was 459,804; the average geographic coverage area was 294 square miles). Less populous cities and rural regions may have even fewer systems incorporating P12ECG. Nationally standardized data on the actual use of P12ECG by these systems are unavailable.

Because of the advantage gained by P12ECG with advance ED notification in rapid diagnosis and treatment of ACS, in particular, STEMI, the ACC/AHA recommend that "It is reasonable that all advanced cardiac life support providers perform and evaluate 12-lead ECGs routinely on chest pain patients suspected of STEMI (level of evidence B, based on data from a number of nonrandomized studies)" (13). Pre-hospital 12-lead electrocardiography programs employing urban and suburban paramedics have previously been strongly encouraged by the AHA (64), the ACC (65), the National Association of EMS Physicians (66), as well as the ACC/AHA Guidelines for Management of Patients with ST-Elevation Myocardial Infarction (13). See Table 1 for a description of the benefits of P12ECG for AMI patients and EMS providers (67,68).

Barriers to the implementation of P12ECG programs include the costs of device acquisition and replacement, paramedic training, and ongoing competency assessment. Integrated devices (pre-hospital 12-lead electrocardiograph with monitor-defibrillator) now cost \$9,000 to \$25,000 each, but the expense of the equipment is likely to decrease in the future as it becomes more standard (as has occurred with automated external defibrillators, for example). Re-

Table 1. Benefits of Pre-Hospital 12-Lead Electrocardiography Programs

For AMI patients
Earlier evaluation in the field and in the hospital
Earlier treatment with fibrinolysis and PCI
Triage in the field, sending high-risk patients to tertiary hospitals
Improved outcomes in terms of:
Reduction in short-term mortality
Longer-term survival benefit (reported in some studies but not all)
For EMS providers
Enhanced skill acquisition in pre-hospital electrocardiography and opportunities to use that technology
Improved pre-hospital detection accuracy in chest pain patients
Detection of transient pre-hospital ischemia that may be resolved by the time of hospital arrival
Acquisition of a 12-lead electrocardiogram for comparison with the first ED electrocardiogram
Potential to differentiate more accurately pre-hospital cardiac arrhythmias (e.g., wide complex tachycardias)
Advance notice of STEMI patient en route for ED staff and cardiac catheterization team
Potentially improved process of care and treatment measures monitored by quality improvement organizations

Modified from Auffderheide et al. (67) and Urban et al. (68).

AMI = acute myocardial infarction; ED = emergency department; EMS = emergency medical services; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

placement or upgrade costs of current integrated devices may be less. A formal cost effectiveness of P12ECG has not been published (69).

Advanced life support (ALS) providers are the focus of this paper because these individuals are trained and equipped to identify and manage patients with ACS symptoms and, as such, are essential to the implementation of P12ECG programs. The *EMS Agenda for the Future* (70) calls for EMS to work with national organizations and associations to help determine its role in enhancing identification and treatment of various clinical conditions (e.g., myocardial infarction). The *agenda* advocates that EMS clinical care be subjected to ongoing evaluation to determine its impact on patient outcomes and that changes in clinical care should be justifiable based on community health care needs.

Paramedic education in electrocardiography is currently a component of 1998 Emergency Medical Technician-Paramedic (EMT-P): National Standard Curriculum by the National Highway Traffic Safety Administration (71), but it is considered “enhanced” rather than “core” education content. Those EMT-P professionals requiring specific training in P12ECG typically undergo up to 12 h of classroom and practical training. Competency assessments are routine components of the administration of EMS agencies, and inclusion of P12ECG for proficiency testing should not significantly increase this cost. The P12ECG program should be implemented with qualified medical oversight.

Implementing a P12ECG program represents a significant investment of time, effort, personnel, and resources. Implementation has three phases: phase I is a retrospective baseline analysis; phase II, a feasibility and safety assess-

ment; and phase III, the implementation of accurate and routine pre-hospital identification of fibrinolytic or PCI candidates to facilitate hospital-based definitive therapy (67,72). Pre-hospital 12-lead electrocardiography and advance ED notification may utilize verbal notification or transmission of the electrocardiogram. In the latter form of notification, it is important to ensure that transmitted electrocardiograms are identified with the appropriate patient; P12ECG identification forms can facilitate this goal. Fibrinolytic and PCI eligibility can be determined by means of a paramedic-generated checklist, the results of which can then be conveyed to either the base or receiving physician. Members of the medical community should be educated about the P12ECG program and how to effectively use the advance notification of diagnostic information to deliver more time-effective interventions. A written protocol, including clinical algorithms for pre-hospital personnel, should be established (67,72). Finally, an effective quality assurance and improvement program should be initiated in advance of implementing a P12ECG program, and is fundamental to P12ECG implementation and ongoing evaluation. Pre-hospital 12-lead electrocardiography with advance ED notification has the greatest potential for patient benefit when the information is utilized as a key component of significant patient care improvements through a well-planned and coordinated program (67,72,73). When considering implementation of a P12ECG program, EMS system administrators need to identify and inform key participants, address political issues, and find alternative sources of funding to cover costs, both direct (e.g., equipment, training, supplies) and indirect (e.g., hospital, EMS system, program infrastructure, and organization). People who will be involved in program coordination, training and competency evaluation, and communication mechanisms should be identified along with those involved in program implementation. Pre-hospital 12-lead electrocardiogram programs should be strongly considered by all EMS systems with ALS capability. Ultimately, the decision to implement a P12ECG program in a community should be based on an evaluation of resources available and public health priorities. Pre-hospital 12-lead electrocardiogram programs should be implemented through a systematic process that encompasses all facets of the EMS system and under the supervision of the EMS physician medical director (74).

The ACC/AHA (13) has specified the conditions under which a pre-hospital fibrinolysis program is reasonable: 1) when physicians are present in the ambulance; or 2) in well-organized EMS systems with full-time paramedics capable of acquiring pre-hospital 12-lead electrocardiograms and interpreting or reading software through initial and ongoing training in P12ECG interpretation and myocardial infarction treatment, direct medical oversight, a medical director with training/experience in STEMI management, and an ongoing continuous quality improvement program. However, the strategy of P12ECG alone (without

immediate fibrinolytic therapy) is a simpler approach and has established benefits (67). This approach may be further augmented by use of pre-hospital electrocardiographs that have the thrombolytic predictive instrument, although prospective validation of its benefits in the out-of-hospital setting remains untested (75).

Creation of local or regional cardiac destination hospitals, facilities capable of cardiac catheterization and rapid revascularization has been proposed as a means for improving outcomes for patients with STEMI (76-78). Availability of pre-hospital electrocardiography is intrinsic to this proposal. Current guidelines (13) recommend that STEMI patients with cardiogenic shock, or with contraindications to fibrinolytic therapy, should be brought immediately to facilities capable of cardiac catheterization and rapid revascularization with PCI or coronary artery bypass grafting (13). Discussions about regionalization should not eclipse the issue of a continued shortfall in care of the 30% of eligible STEMI patients who do not receive any reperfusion therapy (79,80). Pre-hospital 12-lead electrocardiography, with advance notice of STEMI patients en route to an ED, can optimally be used to prompt action before the patient's arrival. A variety of strategies have been employed, all with the goal of rapidly instituting therapy to reestablish perfusion of the culprit infarct-related artery. Activation of a cardiac response team will have care providers and medical decision makers ready for the arrival of a STEMI patient. Additional hospital-based resources (e.g., nursing, radiology) acting as a team can rapidly accomplish tasks according to a prearranged design (81). Decisions about a patient's treatment and disposition can be made quickly.

In summary, use of P12ECG with advance ED notification in patients with symptoms suggestive of ACS will allow a greater number of STEMI patients to receive definitive care more quickly. Pre-hospital 12-lead electrocardiography with advance notification has the greatest potential for shortening the time to definitive treatment when the information is utilized as a key component of a well-planned and coordinated program. Use of this technology is supported by evidence suggesting improved treatment outcomes, but P12ECG programs are underutilized in the U.S. The National Heart, Lung, and Blood Institute's National Heart Attack Alert Program Coordinating Committee believes the collective evidence demonstrating benefit of this approach supports implementation of P12ECG programs in ALS systems.

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