

## Development of Systems of Care for ST-Elevation Myocardial Infarction Patients

### Current State of ST-Elevation Myocardial Infarction Care

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Advances in the treatment of ST-elevation myocardial infarction (STEMI) over the past 20 years have resulted in dramatic reductions in death attributable to STEMI. In large part, this reduction has been due to early reperfusion and advances in medical therapy.<sup>1</sup> The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines and the European Society of Cardiology guidelines for STEMI are in agreement that early and complete reperfusion is optimal, with the goal of door-to-balloon times within 90 minutes and door-to-needle times within 30 minutes.<sup>2,3</sup> Most disturbing is that as many as one third of patients do not receive any reperfusion therapy in the absence of contraindications to its use.<sup>1,4</sup> In the group of patients who do not receive any reperfusion, both short- and long-term outcomes are significantly worse. Advances in medical therapy, including use of aspirin, heparin,  $\beta$ -blockers, and angiotensin-converting enzyme inhibitors, have also dramatically improved outcomes. Hospitals that are most compliant with the guideline recommendations have better outcomes than those that follow the guidelines less well.<sup>5-7</sup>

In addition, one of the major delays in patients receiving rapid reperfusion is the delay in the patient seeking care and arrival at the emergency department.<sup>8</sup> The National Heart, Lung, and Blood Institute, the AHA, and others have initiated a number of programs to attempt to improve public awareness of this problem and to reduce the time between symptom onset and hospital arrival. Despite these programs, little progress has been made.<sup>9</sup> The European Society of Cardiology has identified the need for the establishment of networks

for reperfusion at regional and national levels with the ready availability of primary percutaneous coronary intervention (PCI) and adequate quality control.<sup>10</sup> Although there are some differences in the delivery of STEMI care between the United States and Europe, both locations are characterized by wide variability in care that would be improved by a more effective and uniform system of care

#### Treatment Rates in the United States and Europe

The most comprehensive source of information concerning the “real world” treatment of patients with STEMI comes from large registries. The National Registry of Myocardial Infarction (NRMI) is an ongoing voluntary registry that was established in 1990 and has collected data on >2.3 million patients from >1600 hospitals in the United States (<http://www.nrmi.org>). Over time, there has been a substantial reduction in the use of fibrinolytic therapy, from 34% in 1990 to 20% in 1999, and an increase in primary PCI, from 2.45% to 7.3% during the same time period.<sup>1</sup> Concomitant with this change, door-to-needle times improved from 61 minutes to 37.5 minutes. Disappointingly, a more recent study from the NRMI showed little change in these rates between 1999 and 2002, with 46% of patients in the fibrinolytic therapy cohort treated within the 30-minute goal, and 35% of the patients in the PCI cohort treated within the 90-minute goal.<sup>11</sup> The reasons for a lack of further improvement are unclear but were not related to hospital characteristics other than hospital volume and a New England location. Hospitals performing

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>50 PCI procedures per year had better door-to-balloon times over the 4-year period. Variability in care has been seen in relationship to payer status, with Medicare and Medicaid patients receiving reperfusion therapy less frequently.<sup>12</sup> Likewise, black patients have been less likely to receive reperfusion than nonblacks,<sup>13</sup> and significant regional differences in care are also evident, particularly among those located in a rural setting.<sup>14,15</sup> Not surprisingly, hospitals with cardiac catheterization laboratories compared with those without are more likely to perform primary PCI.<sup>16</sup> Considerable regional variation in the use of invasive strategies has been seen in the Medicare population.<sup>17,18</sup> In those regions that provide the highest rates of invasive and medical management strategies, there was an improved 7-year survival rate, averaging 6.2%. In addition, greater compliance with the recommended medical therapy was associated with improved outcomes that helped to explain these regional differences.<sup>19</sup> The limited on-site availability of cardiac procedures in the highly regionalized Veterans Affairs (VA) health system has been cited as the reason for the underuse of needed angiography after STEMI in the VA compared with the Medicare systems.<sup>20</sup> The availability of invasive facilities is often stated as one of the reasons for regional variability, but studies show that nearly 80% of patients live within 60 minutes of a PCI-capable hospital.<sup>21</sup> Rural hospitals may be an exception where long distances make transport difficult. Care in these hospitals has also been shown to be inferior to that in more urban settings.<sup>15</sup>

The information available from large registries outside of the United States confirms the findings seen inside the United States, with significant variation in practice from country to country and from region to region.<sup>22</sup> In Europe, the distances between tertiary medical centers and community hospitals are substantially shorter, which makes it possible to develop regional care more easily. The shorter distance to the hospital may be one reason for a shorter time from the onset of symptoms to hospital presentation in Europe; however, the use of reperfusion therapy in Europe is similar to that in the United States. In a contemporary Euro Heart Survey, 55% of patients received some form of reperfusion therapy, with 35% receiving fibrinolysis and 21% receiving primary PCI.<sup>23</sup> These rates are lower than those reported in the multinational Global Registry of Acute Coronary Events (GRACE).<sup>4,24</sup> GRACE is an observational registry involving centers in Australia, New Zealand, Canada, Argentina, Brazil, the United States, and Europe. In these countries, the use of reperfusion with PCI and lytic therapy varied tremendously, with primary PCI varying from 1.1% for Australia, New Zealand, and Canada to 16.2% in Europe.<sup>4</sup> Although the use of primary PCI has significantly increased in all countries over the past few years, these regional differences likely are still present. The registry also showed that there were significant geographic variations in the integration of new guidelines into practice.<sup>25</sup> For instance, the use of low-molecular-weight heparin was more common in Europe (63%) than in the United States (20%). In addition, the use of PCI in STEMI was highly related to the presence of on-site catheterization facilities (61% for those with versus 5.8% for those without). However, in this registry of patients with acute coronary

syndromes, there was no difference in short-term or 6-month mortality in 9833 patients with STEMI admitted to hospitals with or without catheterization facilities.<sup>26</sup> This differs from an earlier study from the NRMI performed in the United States in a larger number of patients.<sup>27</sup>

### Models of Successful Systems

A number of systems have been developed to improve the acute care of STEMI patients. An initial experience with the ACC "Guidelines Applied in Practice" program in Michigan has been shown to be highly effective in achieving treatment goals and reducing mortality.<sup>7</sup> The AHA's secondary prevention program, "Get With The Guidelines," has shown similar success.<sup>28</sup> The ACC/AHA guidelines recommend PCI as the preferred strategy in STEMI, particularly in those patients presenting after 3 hours of chest pain; however, implementation has been difficult given the limited number of PCI-capable hospitals in the United States.<sup>2</sup> It is estimated that only 1200 hospitals in the United States are PCI capable among 2200 hospitals with cardiac catheterization laboratories and nearly 5000 acute care hospitals.<sup>29</sup> To convert all hospitals that have catheterization capability to PCI-capable hospitals would only increase the number of patients receiving primary PCI minimally given the geographic location of these hospitals. In addition, the cost of establishing PCI centers at most hospitals is prohibitively expensive. Therefore, a system of referral to a PCI-capable hospital is necessary. Even in those patients in whom fibrinolysis is chosen, the availability of rescue angioplasty at a referral hospital is often needed. Two models for transfer are most common: the emergency medical services bypass model and the hospital transfer model.

The emergency medical services bypass model is being actively used in a number of cities in the United States. One system in Boston, Mass, is part of an active study to investigate the benefit of ambulance bypass of non-PCI-capable hospitals. This pilot study is ongoing, and results are not yet available. Another approach is to transfer patients from community hospitals to a hospital that has 24-hours-per-day/7-days-per-week primary PCI capabilities. This model has been implemented successfully in the Minneapolis/St. Paul, Minn, area, where patients as far as 200 miles away have door-to-balloon times <100 minutes.<sup>30</sup> Strict protocols and efficient communication have enabled this system to be successful. In North Carolina, the Reperfusion of Acute myocardial infarction in Carolina Emergency departments (RACE) project involves 70 hospitals with strict protocols and timely transfer to regional centers.<sup>31</sup> In Europe, it is easier to implement such a system because the distances between PCI centers and community hospitals are shorter; also, in many countries, socialized care makes implementation easier. National networks have been established in Denmark and in the Czech Republic in which reperfusion therapy is organized in predefined areas with rapid transport to PCI-capable hospitals. In the DANish multicenter randomized study on fibrinolytic therapy versus acute coronary angioplasty in Acute Myocardial Infarction (DANAMI-2) trial, outcomes were better in those receiving primary PCI, but the study was able to achieve door-to-balloon times of <120 minutes.<sup>32</sup> In

the PRimary Angioplasty in patients transferred from General community hospitals to specialized PTCA Units with or without Emergency thrombolysis (PRAGUE) study, a system of transport from surrounding communities to Prague, Czech Republic, was effective in achieving door-to-balloon times of 96 to 106 minutes.<sup>33,34</sup>

Such a triage system is not unlike the trauma system in the United States, where hospitals that meet certain criteria are certified to accept patients with severe trauma. The criteria vary by state but are based on guidelines established by the American College of Surgeons Committee on Trauma. These centers are certified in 3 levels, with level I designated for the most critically injured. As of January 2005, there were 190 level I, 255 level II, and 258 level III trauma centers in the United States. A number of studies have shown this system to be highly effective in reducing mortality.<sup>35</sup> There are, however, a number of limitations to the current system. Factors such as a higher volume of trauma and effective quality assurance processes are related to improved outcomes.<sup>36</sup> One of the most notable problems is that access is not readily available for all residents. A recent survey determined that only 69% of all US residents had access to a level I or II trauma center, and the majority of those who did not lived in rural areas.<sup>37</sup> These same limitations will apply for any system that requires transport for STEMI care in the United States.

### Conclusions

The effective treatment of STEMI requires an improvement in the current system of care in the United States. Considerable variability in the use of reperfusion and in compliance with guidelines has limited the benefit of these treatments. An organized strategy to make access and therapy more unified is needed. As suggested by others, the organization of networks at both the regional and national levels is key to success.<sup>10</sup> There are many factors that influence the development of an optimal system of care of STEMI patients in the United States beyond the establishment of high-volume skilled centers. Geographic location, particularly in rural areas, presents challenges given the transportation issues and less favorable outcomes seen in patients in this setting.<sup>15</sup> In addition, socioeconomic factors are important, with race, sex, and insurance status also playing a role.<sup>12,14</sup> Any program that is suggested to improve care for patients with STEMI needs to address these considerations in addition to the type of system, its cost, and its feasibility.

### Disclosures

Potential conflicts of interest for members of the writing groups for all sections of these conference proceedings are provided in a disclosure table included with the Executive Summary.

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