Implementation of Regional ST-Segment Elevation Myocardial Infarction Systems of Care

Successes and Challenges

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KEYWORDS

- ST-segment elevation myocardial infarction • Reperfusion • Systems
- Primary percutaneous coronary intervention • Emergency medical services

KEY POINTS

- Timely reperfusion for acute myocardial infarction with ST-segment elevation is the most important treatment to improve early survival.
- Primary percutaneous coronary intervention is the ideal method of reperfusion but availability is a challenge in many areas of the United States.
- Providing patients with the earliest reperfusion calls for organized regional systems of care that include emergency medical services, non-PCI-capable hospitals, and PCI-capable hospitals working with regional protocols and continuously measuring and improving performance.
- Barriers to successful implementation of ST-segment elevation myocardial infarction (STEMI) systems include hospital and physician competition, system funding, EMS transport and finances, and inadequate data collection and feedback.
- Expanding STEMI systems throughout the world remains an important goal as well as expansion to other cardiovascular emergencies, such as out-of-hospital cardiac arrest, stroke, aortic dissection, and pulmonary embolism.

INTRODUCTION

Rapid coronary artery reperfusion is the foundation of treatment to improve survival for acute ST-segment elevation myocardial infarction (STEMI). Current guidelines strongly recommend that each community create and maintain a regional system of STEMI care that includes assessment and continuous quality improvement of emergency medical services (EMS) and hospital-based activities.[1] In this setting, primary percutaneous coronary intervention (PCI) is the preferred method of revascularization for acute STEMI, provided that it is performed promptly by skilled personnel.[1] Among patients undergoing PCI, clinical practice guidelines recommend first medical contact to device (FMC)-to-device time of less than 90 minutes for patients presenting to PCI-capable hospitals, and FMC-to-device time of less than 120 minutes for patients presenting to PCI-noncapable hospitals.[1] Standardization of regional STEMI reperfusion algorithms, consistent rapid identification of

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patients with STEMI using prehospital electrocardiograms, and expedited interfacility transfer using standardized protocols are methods that have all been shown to reduce FMC-to-device times.[2–4]

How have guidelines evolved to support STEMI regionalization, including timely primary PCI for an increasing proportion of patients with STEMI, and how successful has implementation of STEMI systems of care been? This article reviews clinical trial data supporting the use of primary PCI as the optimal reperfusion strategy, and fibrinolysis (ideally as part of a pharmacoinvasive strategy) as an option when this is not possible; describes the outcomes of regional systems of STEMI care, particularly in the United States; and discusses ongoing challenges for STEMI system implementation.

SUCCESSFUL ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION REGIONALIZATION

Clinical Trial Evidence Supporting Primary Percutaneous Coronary Intervention as the Optimal Reperfusion Strategy

In the 1990s, trials comparing fibrinolytic therapy with primary PCI showed that primary PCI, if performed in a timely manner in high-volume centers, results in better survival than fibrinolysis.[5] At the same time, a meta-analysis demonstrated the superiority of transferring patients with STEMI who presented to non-PCI-capable centers for primary PCI, compared with on-site fibrinolysis.[6] The Danish Multicenter Randomized Study on Thrombolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2) trial, a well-designed, multicenter, randomized trial with 1572 patients including 24 referral hospitals and five PCI centers in Denmark, was stopped early when it demonstrated a significant reduction in the primary outcome of death, reinfarction, and stroke at 30 days (8% for primary PCI vs 13.7% for fibrinolysis; $P<.001$).[7] For those patients who were transferred for primary PCI from a non-PCI-capable site, the median time between randomization and arrival in the catheterization laboratory was 67 minutes, with 96% arriving within 120 minutes and the median time from first door to primary PCI was about 114 minutes (providing the basis for the current guideline recommendations). Importantly, the mortality benefit was most evident in the subgroup of high-risk patients (TIMI risk score $\geq$5 at presentation),[8] but the difference in the primary outcome favoring PCI remained significant at up to 7.8 years (11.7% vs 18.5%), driven mostly by reinfarction.[9] Similarly, the PRAGUE-2 trial randomized 850 patients with acute STEMI to onsite fibrinolysis at a non-PCI-capable hospital versus transfer to a PCI-capable hospital, and also found a nonsignificant mortality reduction at 30 days. Primary PCI was associated with a nonsignificant trend toward lower mortality at 30 days (6.8% vs 10.0% with fibrinolysis) and benefits persisted at 5 years.[10,11]

Clinical Trial Evidence Supporting Fibrinolysis as a Viable Reperfusion Option

Ischemic time (time from symptom onset to reperfusion) drives the relative benefit of primary PCI compared with fibrinolysis. As ischemic time increases, outcomes are worse irrespective of reperfusion strategy. However, the benefits from reperfusion are lost more quickly with fibrinolytic therapy.[12]

Indeed, fibrinolytic therapy is most effective in less than or equal to 3 hours of symptom onset.[12,13] Evidence for which patients derive comparable benefits from fibrinolytic therapy to primary PCI comes from the STREAM study, which included 1892 patients with STEMI who presented within 3 hours after symptom onset and who were unable to undergo primary PCI within 1 hour.[14] These patients were randomized to undergo either primary PCI or fibrinolytic therapy with bolus tenecteplase (amended to half dose in patients $\geq$75 years of age), clopidogrel, and enoxaparin before transport to a PCI-capable hospital. There was no difference in the primary composite end point (death, shock, congestive heart failure, or reinfarction up to 30 days) between the fibrinolytic and PCI groups (12.4% vs 14.3%, respectively; relative risk, 0.86; 95% confidence interval, 0.68–1.09), and no difference in all-cause mortality at 1-year of follow-up.[15] Although the efficacy outcomes seemed similar to primary PCI, there was an increased rate of intracranial hemorrhage (1.0% vs 0.2%) for patients greater than or equal to 75 years old, resulting in a protocol amendment that called for a lower dose of fibrinolytics in this group. There is also reasonably strong evidence for benefit of routine transfer to receive urgent angiography $\pm$ PCI (a form of pharmacoinvasive therapy) within 3 to 24 hours.[16,17]

Implementation of Regional ST-Segment Elevation Myocardial Infarction Systems in the United States

Despite the promising results of DANAMI-2 and PRAGUE-2, many believed it would be challenging to replicate these results in North America with fragmented EMS systems and longer