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

Evaluation and Outcomes

Eric D. Peterson, MD, MPH, Co-Chair; E. Magnus Ohman, MD, Co-Chair; Ralph G. Brindis, MD, MPH; David J. Cohen, MD, MSc; David J. Magid, MD, MPH

The establishment of systems to improve the quality of care for ST-elevation myocardial infarction (STEMI) patients holds great promise to facilitate patients' access to evidence-based, timely cardiac therapies and, ultimately, to improve patient outcomes. Any evaluation of the quality of STEMI care should be focused squarely on the patient, from initial symptom onset to rapid access to reperfusion therapy and through a coordinated hospital discharge and return to the community. Ideal care therefore requires close collaboration of multiple parties, including the patient, emergency medical services (EMS), emergency physicians, interventional teams, cardiologists, and community-based clinicians. As with any care system, however, attempts to improve the process may not be implemented successfully or, worse, may lead to unintended adverse consequences. As such, it is important to carefully monitor the impact of any new care strategies on clinical outcomes.

Conceptual Model for Evaluation

The overall goal of a proposed STEMI system redesign is to improve quality of care and thereby improve patient outcomes. As defined by the Institute of Medicine, STEMI care should be timely, effective, safe, equitable, patient-centered, and cost-effective.[1] Although there are many approaches to guide evaluation of care, Donabedian's classic triad of structure-process-outcome provides an ideal model.[2] This identifies the major domains of health care and defines the programmatic features needed to achieve success.

Structure

Structure refers to component personnel, equipment, and facilities needed to provide ideal STEMI care. At this conference, several model systems provided examples of EMS, emergency department, percutaneous coronary intervention (PCI)–capable hospital, and regional network features associated with improved reperfusion times (Table 1). Although "structure often drives function," these structural features should be used only as a guide and will often need to be individualized for a particular care setting. Many of these features are described elsewhere in this report, yet 2 require further explanation. First, we believe that providers should participate in national data collection and quality improvement programs. Examples of such programs include those for EMS,[3] myocardial infarction,[4–6] and PCI.[7] Participation in such programs provides caregivers with standardized tools for data collection and risk adjustment, as well as feedback on how their care compares with peers. Such feedback systems are known to be a critical element in continuous quality improvement.[8]

As regional STEMI care delivery systems mature, the model of an individual hospital-centered quality improvement program will need to expand to that of collaborative, community-wide oversight programs. These may include a regional STEMI steering committee and, potentially, a separate data safety monitoring board. Such oversight should have comprehensive representation that includes the region's EMS director and EMS medical director, other emergency services leaders (fire and police), representatives from both the STEMI referral and STEMI-receiving hospitals, and regional

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TABLE 1. Proposed Structural Measures

EMS structural characteristics
Adequate staff, equipment, and training to perform and transmit prehospital ECGs
Single standardized STEMI checklist/algorithm of evaluation and treatment
Prearranged destination protocols
ED structural characteristics
Adequate staff, equipment, and training to perform ED rapid evaluation, triage, and treatment
Single standardized STEMI care pathway
One-contact STEMI hotline
Primary PCI hospital structural characteristics
24/7 PCI capacity
Interventional cardiologist and staff capable of arriving at the laboratory within 30 minutes
Volume/experience characteristics according to ACC/AHA PCI guidelines
For hospitals without cardiac surgery on-site capabilities, a predefined transfer and management plan for emergency coronary artery bypass surgery
Quality assurance system
Participation in national EMS, MI, and PCI data collection and feedback systems
Regional STEMI oversight committee

ED indicates emergency department; 24/7, 24 hours per day/7 days per week; ACC/AHA, American College of Cardiology/American Heart Association; and MI, myocardial infarction.

medical and professional society representatives. These committees should share provider process and outcome data in a transparent manner to ensure access and quality of STEMI care.

Process

Process refers to actions performed in the delivery of care to a patient, including timing and technical competency. Table 2 provides a list of potential process metrics that could be tracked to ensure quality STEMI care. Several of these relate to the timeliness of key steps in the reperfusion process. From a patient perspective, "total ischemic time" (defined as the time from symptom onset to successful PCI) is the most important interval. Yet, the exact onset of symptoms can often be difficult to define. As such, other more quantifiable, intermediate measures (eg, time from 9-1-1 call to hospital arrival and time from hospital to cardiac catheterization laboratory arrival) are also recommended. Beyond timely reperfusion, the importance of providing all evidence-based care, as outlined in the American College of Cardiology/American Heart Association guidelines, to eligible patients is also stressed.[9]

Outcomes

"Outcomes" refers to tangible measures of the consequences of patient care and can be subdivided into categories of mortality, nonfatal adverse events, and patient-reported

TABLE 2. Proposed Process Measures

EMS process characteristics
Time from symptom onset to 9-1-1 call
Time from 9-1-1 call to ambulance arrival
Proportion of patients for whom adequate ECGs were obtained or transmitted
Predictive accuracy (false-positive and false-negative) of field diagnosis
Emergency department process characteristics
Door-to-first ECG time
Proportion of STEMI-eligible patients receiving any reperfusion (PCI or fibrinolytic therapy)
Door-to-catheterization laboratory time (for nontransfer patients) or door-to-disposition time (for patients transferred to PCI center)
The proportion of patients ineligible for lytics but eligible for PCI (eg, cardiogenic shock, bleeding) who are not transferred acutely from the STEMI referral hospital to the STEMI receiving hospital
Primary PCI hospital process characteristics
Door-to-balloon time (from arrival at primary PCI center to balloon inflation, nontransfer patients)
First hospital door-to-balloon time (for transfer patients)
Total patient ischemic time (symptom onset to balloon) stratified by transfer status
Proportion of eligible patients administered guideline-based class I therapies
Proportion of suspected STEMI patients undergoing coronary angiography found not to have STEMI

health status measures (symptoms, functional status, and quality of life). Outcomes assessment should also consider the impact of care on non–health-related measures such as patient satisfaction and economic implications. Finally, outcomes measures may also consider potential unanticipated consequences of care changes. For instance, widespread use of prehospital ECGs and prehospital activation of the cardiac catheterization laboratory may lead to an increase in emergency coronary angiography among patients without acute coronary occlusion; this may lead to increased costs of care and patient risks due to unnecessary procedures. Similarly, a policy that leads to proliferation of low-volume, "stand-alone" primary PCI centers may ultimately result in more procedural complications. A list of potential outcomes metrics is provided in Table 3.

Outcomes represent the aggregate effect of all structure and care processes. Thus, improving this end product is the ultimate goal of successful medical care. The use of outcomes metrics for evaluation, however, also presents challenges. In the case of STEMI care, many adverse events rates tend to be uncommon. Thus, estimates of outcomes performance measures are often unstable at the single-center level, particularly when evaluated over a relatively brief time interval. Moreover, multiple factors beyond provider quality affect patient outcomes and must be accounted for before outcomes comparisons are meaningful. Thus, there is a need for collection of detailed clinical data and rigorous risk adjustment of provider outcomes measurements.[10]

There are several outcomes perspectives that need to be considered. The first is the time frame for evaluation. Data on acute in-hospital STEMI events are the easiest to collect and most directly related to the care delivered; however, it is also likely that longitudinal patient outcomes (ie, 6 months or 1 year) could be impacted if STEMI care were improved. It is often difficult for providers to collect longitudinal data, yet such data collection may be feasible via collaborations with state quality improvement organizations or other payer partners.

Second, changes in STEMI care may have effects on other areas of cardiac care ("halo effects"). On the positive side, the process integration between emergency medicine and cardiology needed to shorten reperfusion times in primary PCI may also stimulate broader improvements in care for all myocardial infarction patients. On the other hand, if a provider focused solely on reperfusion metrics, this could conceivably distract efforts to improve other evidence-based myocardial infarction care processes.

Finally, one must consider the level of aggregation of results. Currently, the standard paradigm of outcome evaluation is generally centered on individual institutional performance; however, in many STEMI situations, patients require timely transport to a center and even transfer between centers to receive reperfusion. Evaluation of such integrated care systems clearly needs to consider the performance of the system as a whole. For example, if the sickest patients with STEMI never reach the tertiary care center, STEMI outcomes for the community may not improve despite measured improvements at an individual center.

Patient Satisfaction and Economic Impact

Nonclinical impacts of programmatic changes must also be considered in the evaluation process. From a patient's perspective, receiving care close to home minimizes the impact on friends and family members and maximizes connection with local care providers. Thus, efforts will be needed to ensure that if patients are diverted or transferred to more distant centers for primary PCI, their subsequent care is coordinated with local providers. Such coordination must occur both at the initial point of contact, as acute treatment plans are formulated, and again at hospital discharge to ensure smooth care transitions and overall patient satisfaction.

Increased delivery of primary PCI will likely have multiple direct and indirect economic impacts. First, the overall cost-effectiveness of such programs should be considered from a societal perspective. Such an evaluation will need to consider the fixed costs associated with implementing

TABLE 3. Proposed Outcome Measures

Hospital STEMI outcome measures
In-hospital (risk-adjusted) mortality
Longitudinal outcomes: 30-day, 1-year (risk-adjusted) mortality
Morbidity events (in-hospital stroke, vascular complications)
PCI procedural success
Regional STEMI outcomes (aggregated across regional hospitals)
In-hospital (risk-adjusted) mortality
Longitudinal outcomes: 30-day, 1-year (risk-adjusted) mortality
"Halo effects" outcome measures
In-hospital, 30-day, and 1-year mortality for all myocardial infarction patients (non-STEMI and STEMI)
In-hospital, 30-day mortality for all PCI patients
Patient satisfaction and resource utilization
Patient's assessment of provider quality and collaboration (eg, Press-Ganey survey)
Changes in individual hospital STEMI charges
Changes in aggregated regional STEMI charges

changes in care (eg, training, equipment, and infrastructure), as well as the variable costs related to the changes themselves (eg, patient transfer and performance of PCI). It is possible (although not assured) that any resulting cost increases may be counterbalanced by savings associated with reduced complications in both the short and long term.

Beyond societal costs, one must also consider the impact of any programmatic changes on the flow of funds at specific institutions. For example, if regionalization results in large shifts in revenue for cardiac care from the local primary care facilities to specialized regional centers, this could have serious adverse consequences on a local hospital's economic viability. Because cardiology care often supports other less-compensated hospital activities, these financial shifts could have broad implications on the health of a community.

Potential Uses of Evaluative Data

The evaluation of STEMI care at the hospital or system level can have several goals. Most importantly, tracking these metrics may help the individual provider or the region to both identify areas that require further improvement and to track trends in care over time as one implements change. As a first step toward this goal, we believe that healthcare systems engaged in STEMI care should develop the collaborative process required for closely following care and outcomes for their patient population. Although some benchmarks may not be readily achieved, by plotting the progress of each quality indicator over time, it should be possible to determine whether the system is moving in the right direction. By using this approach of continuous quality improvement, a community/regional oversight committee can monitor a region's success.

On a second level, certain STEMI metrics could be made public and used for quality assurance or even to alter provider reimbursement rates ("pay-for-quality" programs). When evaluation measures are tied to financial or nonfinancial incentives, such metrics should meet a higher level of rigor and specificity.[11,12] Finally, it must be realized that metrics for evaluating STEMI care will need to evolve as the field evolves. Thus, new therapeutic advances or "out-of-the-box" innovations in care delivery may stimulate a need to reevaluate the tools used in the evaluation process itself.

Summary

The optimization of reperfusion therapy for STEMI patients by developing coordinated care systems that include increased access to primary PCI offers a unique opportunity for collaboration in the delivery of care. If implemented correctly, such coordinated care systems have the potential to improve outcomes substantially for patients with acute myocardial infarction, which is still the leading cause of morbidity and mortality in the United States. Although the opportunities for improvements are vast, these can only be achieved by tracking processes of care and outcomes with standardized quality metrics and careful external oversight. Ensuring that appropriate metrics are implemented in a transparent fashion should help to engage the numerous parties involved in STEMI care and will foster the necessary trust and collaboration that such ambitious changes in care will demand.

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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