From Concept to Reality: A Decade of Progress in Regional ST-Elevation Myocardial Infarction Systems

Running title: Henry; A decade of progress in regional STEMI

Timothy D. Henry, MD

Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital, Minneapolis, MN

Address for Correspondence:
Timothy D. Henry, MD
Minneapolis Heart Institute Foundation
920 East 28th Street, Suite 100
Minneapolis, MN 55407
Tel: 612-863-7372
Fax: 612-863-3801
E-mail: henry003@umn.edu

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The treatment and outcome of patients with ST-segment elevation myocardial infarction (STEMI) has improved dramatically over the 30 years since I graduated from medical school. In 1982, bed rest, treatment of complications such as ventricular arrhythmias or mural thrombus and prayer (for those so inclined) were the standard of care. In the first decade, pharmacologic therapy was developed, and the open artery hypothesis was confirmed. The Second International Study of Infarct Survival (ISIS-2) trial demonstrated the benefit of not only aspirin, but the combination of aspirin and streptokinase leading to a series of randomized clinical trials to determine the preferred fibrinolytic and adjunctive medications. The second decade was filled with trials that compared fibrinolytic therapy to primary percutaneous coronary intervention (PCI), which ultimately confirmed primary PCI as the preferred method of reperfusion if performed in a timely manner in high-volume centers. European trials extended the benefits of PCI to STEMI patients who presented to non-PCI centers requiring transfer for primary PCI. In particular, the Danish Multicenter Randomized Study on Thrombolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2), a well-designed, multicenter, randomized trial including 24 referral hospitals and 5 PCI centers in Denmark, was stopped early when it demonstrated a significant reduction in the primary endpoint of death, reinfarction and stroke at 30 days (8% for primary PCI vs. 13.7% for fibrinolysis, p<0.001).

These randomized clinical trials stimulated interest in regional STEMI systems in the U.S., but many believed it would be challenging to replicate the results seen in a small European country with short duration transfers (mean 34 miles) and an organized national emergency
medical system (EMS). In 2002, we modeled the Minneapolis Heart Institute’s Level 1 Regional STEMI system after the successful regional trauma systems in the U.S. and the preliminary results from DANAMI-2. Following a presentation of our early results, Henning R. Anderson, MD, the principal investigator of DANAMI-2, wrote an encouraging letter, with this statement: “When I present the DANAMI-2 experience to a U.S. audience, the most frequent comment is that in the U.S. system it is very, very difficult to implement such a strategy.”

The early skepticism and resistance to the development of U.S. regional STEMI systems were indeed challenging at times, but were surpassed by the tangible benefits evident in our patients daily. Benefits that we now know extend beyond the reduction in death, re-infarction and stroke confirmed by randomized clinical trials.

Regional Approach to Cardiovascular Emergencies (RACE)

Expanding on their initial project of 65 hospitals (10 PCI and 55 non-PCI), in this issue of Circulation, the RACE investigators report the results of a statewide STEMI system including all 119 hospitals in North Carolina. The results are based on 6,841 STEMI patients enrolled over an 18-month period, including 3,907 who presented directly to 21 PCI hospitals and 2,933 patients who were transferred from 98 non-PCI hospitals. This is a remarkable accomplishment and even more impressive when you consider the results represent an enhancement to an excellent existing statewide STEMI system.

Benefits of a Statewide STEMI System

A number of noteworthy achievements in North Carolina illustrate the benefits of establishing a regional STEMI system.

Eligible but Untreated

The “eligible but untreated” segment of the STEMI population has been reported to be 25-
35%,\textsuperscript{5,12} but represented only 4% in the RACE registry. The number of “ineligible” patients should also decrease in any well-designed STEMI system. We should expect the number of STEMI patients receiving reperfusion therapy to be >90%. Only patients for whom the therapy would be inappropriate (those with advanced dementia or metastatic cancer) and the rare patient who presents too late (12 or 24 hours after onset) would not undergo reperfusion therapy.

**Time to Treatment**

Consistent with national trends, door-to-device times for patients presenting directly to PCI hospitals continued to improve, achieving the excellent median of 59 minutes.\textsuperscript{13} More importantly, the time from first door-to-device for patients transferred from a non-PCI for PCI improved to 103 minutes with 39% of patients treated within 90 minutes. As expected, the time from first door to device was related to distance.

**Primary PCI Reperfusion**

The number of patients receiving primary PCI as their primary reperfusion method increased from 52% to 66%. Still, 31% of eligible patients were treated with fibrinolytics prior to transfer. It is unclear how many of these patients subsequently underwent cardiac catheterization and PCI (or the timing if they did). Results of recent randomized clinical trials and regional STEMI systems indicate a pharmaco-invasive strategy has the potential to provide a PCI-based reperfusion strategy to almost the entire U.S. population.\textsuperscript{9,14} Data A major challenge to improving the care of STEMI patients in the U.S. has been the lack of accurate and comprehensive data. Data from the Joint Commission, Medicare or registries such as National Cardiovascular Data Registry (NCDR) or National Registry for Myocardial Infarction (NRMI) are highly selective and do not include all STEMI patients.\textsuperscript{15} Incomplete data makes it difficult to understand where improvements need to be made. The availability of complete STEMI results
for an entire state is a tremendous accomplishment for RACE. This was made possible by the fact that all 119 hospitals voluntarily agreed to participate in Acute Coronary Treatment and Intervention Outcomes Network Registry – Get With The Guidelines (AR-G), which will continue to be a challenge nationally.

Limitations & Challenges

One important lesson learned from RACE is that a “mixed” strategy, in which providers could choose PCI or fibrinolysis, may not be the ideal approach. A “mixed” strategy was used in 15 hospitals and resulted in substantially longer first door-to-device times although times did improve from 195 to 138 minutes. It appears preferable to choose a strategy and have a back-up plan. A pharmaco-invasive, PCI-based strategy would theoretically solve this problem.7,9,14

Following the initial RACE publication, questions were raised regarding the lack of clear mortality benefits. Although the authors address this issue in this manuscript, it is worth remembering the proven benefit of primary PCI over fibrinolysis was demonstrated in randomized clinical trials. Therefore, our goal continues to be expanding access to primary PCI. The improvements in RACE were made on top of a preexisting system where primary PCI had already been used for appropriate patients for many years.

The RACE investigators should be congratulated for not only the first successful statewide network and outstanding results, but for successfully obtaining the funding to complete this monumental task. This remains a major challenge for most regions of the U.S. The EMS system in particular is underfunded. Data collection, although invaluable, is also expensive and duplicative in many hospitals. Is it realistic to believe entire statewide systems can be developed throughout the U.S.?
Growth in Regional STEMI Networks

A Mission:Lifeline survey found that in 2010 there were 381 unique STEMI systems including 899 PCI hospitals in 47 states.16 These findings are encouraging and likely underestimate the true extent of growth and development of regional STEMI systems. The survey indicated that the funding was provided by the primary PCI hospital (84%) or cardiology practice (23%) in the majority of cases. The most common barriers to implementation of regional STEMI systems were self-reported to be the hospital administration (37%), cardiology group competition (21%) and emergency medical services (EMS, transport and finances) (26%). The American Heart Association Mission: Lifeline program was designed to increase timely access to PCI for STEMI patients17 and was recently expanded to include patients with out of hospital cardiac arrest. Ideally, regionally STEMI systems of care will be expanded to include all cardiovascular emergencies.18

Lessons Learned from a Decade Developing Regional STEMI Systems

Major advances in healthcare occur not from results of randomized clinical trials or real-world registries, but from the application of those results to complex healthcare systems, which requires the successful interaction of healthcare workers with their patients. The growth and success of regional STEMI systems over the last decade represents such an advance.

Specific lessons learned watching this remarkable achievement are worth noting. The development of a system is based on the use of standardized protocols and order sets designed using guideline-based therapies. Yet the same system needs to allow flexibility to address the individual needs of patients and physicians. The system requires pre-arranged and individualized reperfusion and transfer plans for each community/hospital which necessitates close coordination and communication between EMS, non-PCI centers and PCI centers. Teamwork is essential.
Every member of the team is critical and the improvements require input and leadership at every level. The need for education, training and retraining cannot be underestimated due to the large number of people involved and ongoing changes in both personnel and new data. Feedback is a key component including the transporting paramedics observing the angiogram, the interventional cardiologist calling the ED physician immediately following the procedure and communication the following day between the STEMI coordinator and EMS/ED managers as well as the primary cardiologist with the primary care physician. Monthly, quarterly and yearly quality reports provide ongoing and system-wide quality improvement. Financial and moral support from hospital administration are essential, and if missing can create a major stumbling block. Perhaps the most important link in the chain is a passionate leader at every level.

The growth of regional STEMI systems in the U.S. over the last decade has clearly exceeded our expectations. Seven years ago, we published a manuscript raising the question whether it was time for a national policy concerning the treatment of STEMI patients.5 Today we are no closer to that policy, but I am no longer certain it is either necessary or if it would be helpful. Certainly state and national legislation to support our financially strapped EMS would be welcome, including a 12-lead EKG in each ambulance, AED in all public places as well as support for both EMS training and data collection. Public policy changes to provide financial incentives for more rational use of resources to support regional STEMI systems rather than building more cath labs would also be helpful.19,20 The driving force behind this remarkable improvement in U.S. STEMI care has been passionate individuals dedicated to improving the quality of care for their communities. Individual paramedics, STEMI nurse coordinators, hospital administrations, ED and interventional physicians all are doing their part to improve the entire system.
Ideally, the entire U.S. population will have locally designed regional systems to provide timely access to PCI for all STEMI patients but also to care for all acute cardiovascular emergencies. This lofty goal is not only possible, but within our grasp in the next decade.

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**References:**


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