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Development of Systems of Care for ST-Elevation Myocardial Infarction Patients The Non-Percutaneous Coronary Intervention-Capable (ST-Elevation Myocardial Infarction Referral) Hospital Perspective

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Developers of systems to improve access to primary percutaneous intervention (PCI) must recognize that most ST-elevation myocardial infarction (STEMI) patients present to hospitals that do not have PCI capability. Indeed, only $\approx 25\%$ of US hospitals are currently capable of delivering this intervention.¹ These non-PCI-capable institutions are often located in rural areas and face real challenges related to distance from PCI centers. In addition, these institutions face significant financial challenges² in pursuing any of the 3 potential strategies to increase timely access to primary PCI. These 3 strategies include the following³: (1) hospitals currently without PCI capability can develop primary PCI services without cardiac surgery on-site (SOS); (2) non-PCI-capable facilities can rapidly diagnose and transfer STEMI patients to primary PCI-capable hospitals and thereby serve as STEMI referral hospitals; or (3) communities can develop systems that bypass non-PCI-capable hospitals.

Each of these strategies is addressed in this article. For each, we review the current status, the ideal system, gaps in and barriers to development of the ideal system, and recommendations.

Develop Primary PCI Capability Without Cardiac SOS

Current Status

Early observational studies from single institutions demonstrated potential efficacy and safety of primary PCI without

SOS. In the Myocardial Infarction, Triage and Intervention (MITI) trial, 233 of 441 primary PCIs were performed at hospitals without SOS. Emergency cardiac surgery was rare (1.4% of patients), and its presence or absence did not affect survival after myocardial infarction.⁴ In another observational study, among 334 patients undergoing primary PCI at a hospital without SOS, there were no deaths, and no patient required emergency coronary artery bypass grafting (CABG).⁵

In a nonrandomized comparison of patients undergoing primary PCI at hospitals without SOS with those undergoing primary PCI after transfer to a tertiary hospital, there was no difference in 30-day or 1-year mortality, although time to reperfusion was significantly shorter, and restoration of Thrombolysis In Myocardial Infarction (TIMI) 3 flow occurred significantly more often in patients undergoing primary PCI without transfer to a tertiary site.⁶ Only 2 patients (0.4%) required emergency CABG.

In a randomized controlled trial in community hospitals, STEMI patients treated with primary PCI had a 42% lower incidence of the composite end point of death, recurrent infarction, or stroke at 6 months (which was driven by a reduced rate of reinfarction), and the median length of stay was reduced by 1.5 days compared with patients treated with accelerated tissue plasminogen activator.⁷ No patient required emergency CABG for PCI-related complications.

In another study,⁸ investigators used the National Registry of Myocardial Infarction (NRFMI) database to compare qual-

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ity of care in 108 132 patients with STEMI treated with primary PCI at 3 different types of hospitals between April 1998 and October 2001: hospitals with diagnostic cardiac catheterization laboratories without SOS, hospitals with PCI capability but without SOS, and those with PCI capability and SOS. Interestingly, door-to-balloon intervals were shorter in hospitals without SOS. In addition, adherence to American College of Cardiology (ACC)/American Heart Association (AHA)-recommended medications, including the use of aspirin, β -blockers, and angiotensin-converting enzyme inhibitors within the first 24 hours, was significantly better in hospitals without SOS. In-hospital mortality rates were comparable between hospital types: 3.2% for diagnostic only, 4.2% for PCI-capable without SOS hospitals, and 4.8% for hospitals with PCI capability and SOS ($P=0.07$). However, because 5% of patients in non-SOS hospitals were transferred to other facilities and lost to follow-up, conclusions concerning mortality cannot be made with certainty.⁸ Of note is the adherence to guideline-directed therapies in the non-SOS facilities. Recently, another large observational study based on Medicare provider analysis and review data confirmed the safety of primary PCI at hospitals without SOS.⁹

Ideal System

It is only possible to highlight some important features of an ideal primary PCI program in a hospital without SOS. A firm commitment to development of a safe, effective, consistently and uniformly applied, and sustainable primary PCI program is an absolute requirement. This commitment must be made at administrative, physician, and nursing levels and involves multiple care areas, including the emergency department (ED), coronary care and step-down units, and the cardiac catheterization laboratory at a minimum. Identification of leaders or "champions" at the administrative, physician, and nursing levels is an important feature of this commitment.

The ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) PCI guidelines¹⁰ describe minimum attributes and requirements of a primary PCI program. These include the setting of standards (for physicians, nurses, technicians, facilities, and treatment), development of logistics, training of staff, and creation of a quality- and error-management strategy (data collection, data review, application of benchmarks, and quality improvement). Furthermore, the physician practitioners should satisfy the ACC/AHA guideline requirements for both initial training and competency maintenance for PCI. Formal affiliation with a temporally close tertiary hospital is important to provide off-site surgical backup, to provide a facility to perform more complex or subsequent nonemergency intervention, and, importantly, to provide a site for initial and continuing observational and hands-on training of catheterization laboratory and postprocedure care staff. It is also critical to develop permanent structures within such institutions to provide regular morbidity and mortality review for physicians, which can be a challenge in low-volume institutions. Furthermore, regular meetings of administrators and physician and nursing representatives from the ED, catheterization laboratory, and coronary care and step-down units are important to review outcomes, identify opportunities for improve-

ment, and modify local practice to reflect the most current evidence-based therapies in this rapidly evolving area.

Gaps and Barriers

Sustaining a stand-alone primary PCI program (ie, without "elective" PCI) is difficult from a fiscal and personnel point of view. Stand-alone primary PCI programs perform a relatively small number of procedures and yet require staffing 24 hours a day, 7 days a week. A sustainable system requires staff to be on call no more than 1 of 3 and preferably no more than 1 of 4 nights and weekends. Single catheterization laboratory facilities are subject to interruption of service during preventive maintenance or if the laboratory fails. In certain areas, there may not be enough experienced interventional cardiologists to cover these laboratories that perform only emergency primary PCI procedures. In addition, if the majority of non-PCI-capable hospitals had the clinical obligation or financial need to develop primary PCI services, there would be the potential for the emergence of multiple hospitals providing a relatively low volume of procedures. Finally, the ACC/AHA/SCAI PCI guideline considers the performance of primary PCI at non-SOS hospitals a class IIb indication (usefulness/efficacy is less well established by evidence/opinion).¹⁰

In addition, a number of STEMI patients have coronary pathology that is not amenable to primary PCI, may be better treated with surgery, or may have a mechanical complication of STEMI that requires cardiac surgery. These patients benefit from prompt surgical evaluation and treatment, including CABG, repair of mechanical defects, and/or insertion of circulatory support devices.

Recommendations

1. Randomized studies comparing the safety and efficacy of nonemergency PCI at hospitals with and without SOS are important. If nonemergency PCI can be performed without colocated cardiac surgery, then this may influence both the viability of and the expertise applied to primary PCI at those facilities.
2. A comparison of outcomes, most likely by use of risk-adjusted registry data, of patients undergoing primary PCI at hospitals with and without nonemergency PCI programs (which usually means with and without colocated cardiac surgery) would be of significant interest. Outcomes should be measured to at least 30 days or more after the index infarction.
3. There is a need for policy reevaluation at the state level, with recognition of the link between higher surgical volumes (both institutional and operator) and better surgical outcomes in most cases.¹¹ A clear need is emerging to limit the proliferation of cardiac surgical programs (to support the creation of additional primary PCI programs) at a time when overall cardiac surgical volumes are decreasing.
4. Healthcare policy makers working together with organizations such as the AHA, ACC, and Joint Commission on Accreditation of Healthcare Organizations must develop criteria for primary PCI centers and determine whether SOS will be required.

Transfer of STEMI Patients From Non-PCI-Capable Hospitals to Primary PCI-Capable Hospitals: The STEMI Referral Hospital

Current Status

The results from recent randomized trials (predominantly from Europe) indicate that outcomes are better when patients with STEMI who present to non-PCI-capable hospitals are transferred to an interventional facility for primary PCI than when they are given fibrinolytic therapy at the local hospital (Figure).¹²⁻¹⁵ The inherent treatment delays associated with primary PCI compared with fibrinolytic therapy in these trials have ranged from 55 to 103 minutes. Unfortunately, in the United States, transfer delays are much longer. Recent data from the NRM found median delays of 180 minutes from arrival at the non-PCI-capable hospital to balloon inflation at the primary PCI-capable hospital, with only 4.2% of transferred patients achieving door-to-balloon times of <90 minutes.¹⁶ The ACC/AHA STEMI guideline recommends primary PCI as the preferred reperfusion strategy for STEMI, but only if it can be performed within 90 minutes of first medical contact. Consequently, most patients presenting to non-PCI-capable hospitals in the United States are not eligible for primary PCI because of the long potential treatment delays. To increase the use of primary PCI as a reperfusion strategy for patients presenting to non-PCI-capable hospitals, much improvement is needed in reducing transfer times.

Ideal System

It has been clearly shown that with well-defined goals, commitment from administrative and clinical leaders, standardized protocols, integrated systems of transfer, and data feedback to monitor progress, door-to-balloon times for patients presenting to non-PCI-capable hospitals can be dramatically reduced and can approach and meet guidelines for timely treatment with primary PCI.¹⁷⁻¹⁹ Time delays in the evaluation, treatment, and transfer of STEMI patients from non-PCI-capable hospitals to tertiary centers can be divided into 3 parts: delays at the non-PCI-capable hospital, transportation delays, and delays before PCI is performed at the tertiary center. Recommended targets for time delays for each of these phases are 30 minutes (the “30-30-30 rule”).

Ideal systems will reduce the in-the-door to out-the-door time to within 30 minutes at the non-PCI-capable hospital. In the 20% to 50% of patients who arrive by emergency medical services (EMS), prehospital 12-lead ECGs should be performed, which can result in early initiation of protocols to facilitate transfer. In patients who arrive by private vehicle, an ECG should be obtained and interpreted by the emergency physician within 10 minutes. If the ECG meets criteria for a STEMI, the emergency physician should be empowered to activate the transfer protocol, which includes simultaneous activation of the catheterization laboratory team at the receiving hospital and paging of the interhospital transport service (EMS). At the receiving PCI center, the batch page goes to notify the catheterization laboratory team, interventional cardiologist, and admissions and bed control personnel.

Death/Reinfarction/Stroke

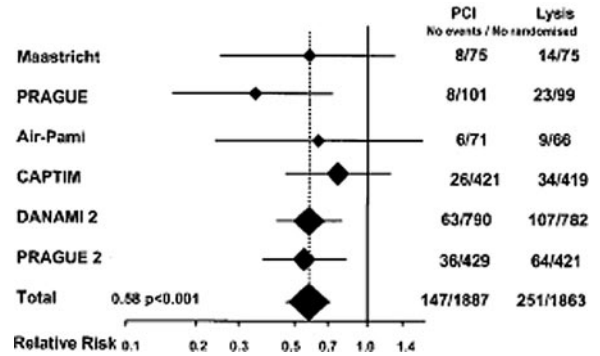


Figure. Relative risks of the composite of death/reinfarction/stroke with thrombolysis and transfer for primary PCI in randomized trials. No indicates number; PRAGUE, PRimary Angioplasty after transport of patients from General community hospitals to catheterization Units with/without Emergency thrombolytic infusion; Air-PAMI, Air Primary Angioplasty in Myocardial Infarction study; CAPTIM, Comparison of Angioplasty and Prehospital Thrombolysis In acute Myocardial infarction; and DANAMI, DANish trial in Acute Myocardial Infarction. Reproduced, with permission, from Dalby et al.²⁰

Standardized written protocols with tools such as posters, pocket cards, and STEMI kits that include all needed medications, equipment, and data forms enable evaluation and treatment to be performed in the minimal amount of time. Patients are treated with oxygen, aspirin, clopidogrel, heparin bolus, intravenous β -blockers, morphine, and nitroglycerin according to the ACC/AHA guidelines and standard protocols, but no drips and pumps are used, and the use of glycoprotein IIb/IIIa inhibitors, if associated with substantial delays, is avoided. Chest radiographs are not routinely essential and may cause additional delays. Transfer data sheets (with pertinent clinical and laboratory information), orders, and ECGs are sent with the patient and also faxed directly to the receiving PCI center’s catheterization laboratory. The goal is an in-the-door/out-the-door time at the non-PCI-capable hospital of within 30 minutes.

Transfer of STEMI patients must be given priority by the EMS system and treated as a 9-1-1 call. If the patient is brought into the non-PCI-capable hospital by ambulance, ideally the same crew should transfer the patient to the PCI center, with the patient remaining on the ambulance stretcher while in the ED. If continuous intravenous infusions are required, they are best administered via saline locks to minimize delays when intravenous tubing is changed. For short transfer distances, heparin and nitroglycerin infusions are not required. Approximately 15 minutes before arrival at the PCI center, the transfer EMS crew should alert the catheterization laboratory team of their impending arrival, and the patient should be taken directly to the catheterization laboratory, bypassing the ED or coronary care unit. The goal for transport time from departure from the non-PCI-capable hospital to the catheterization laboratory is within 30 minutes. This, of course, will depend in part on the distance from the non-PCI-capable hospital to the PCI-capable hospital; in some systems that involve longer distances, air transport will be required.

The catheterization laboratory technicians and nurses and the interventional cardiologist should be waiting for the patient's arrival in the catheterization laboratory. The interventionalist reviews the transfer data sheet and performs a brief examination while the staff prepares the patient. The goal is to perform balloon dilation within 30 minutes of arrival.

Data collection and feedback are essential to a successful transfer program. The interventionalist should call the non-PCI-capable hospital emergency physician at the end of the procedure and the nursing staff at the tertiary hospital should call the non-PCI-capable ED head nurse to discuss times, outcomes, and potential points of improvement. Door-to-balloon times and their component parts, as well as outcomes, should be reviewed by all involved personnel in the non-PCI-capable and PCI-capable hospitals on a regular basis.

Gaps and Barriers

In the United States, there are a number of obstacles that must be overcome to achieve this ideal system:

1. Delays in identifying the patient with STEMI are frequent. The ECG may not be obtained in a timely fashion because of atypical symptoms or a busy and understaffed ED. The ECG may be equivocal for the diagnosis of STEMI. For those patients who arrive by EMS, only a minority (10%) have had a prehospital 12-lead ECG performed.
2. Without prespecified, hospital-specific protocols, delays to reperfusion may occur when ad hoc treatment decisions are being considered. For example, there may be delays in the decision regarding who should be transferred for primary PCI and who should receive fibrinolytic therapy. Some physicians routinely perform a chest radiograph to screen for dissecting aneurysm, which increases transfer delays.
3. There is wide regional variation in interhospital transfer systems. Urban areas have relatively short transfer distances and transfer mostly by ground ambulances, whereas in rural areas, there are much longer transfer distances,²⁰ and many transfers occur by air transport. Unlike the 9-1-1 EMS system, interhospital transfer systems in some regions are not well organized. In some areas of the country, EMS vehicles may not have the staffing and capability to respond to interhospital transfer similar to a 9-1-1 response and may not have the authority to cross county lines. Costs for transport may not be covered by third-party payers, which puts a burden on the patient, and the costs of air transport may be prohibitive.
4. Hospital bed capacity is a major issue in many cities today. Lack of bed availability at the primary PCI hospital may inhibit or delay transfer.
5. Loss of revenue for STEMI patients (and other non-STEMI acute coronary syndrome patients) transferred to the primary PCI-capable hospital may be a disincentive for non-PCI-capable hospitals to participate in transfer protocols.

Recommendations

Further research is needed to better understand which patients under what circumstances are best treated with transfer for primary PCI. Such research should focus on the following areas:

1. Studies are needed to clarify when and in whom the inherent difference between door-to-needle and door-to-balloon times will negate the potential advantage of primary PCI compared with fibrinolytic therapy.
2. The results of ongoing randomized trials are needed to define the role of facilitated PCI in patients presenting to non-PCI-capable hospitals when relatively long delays to primary PCI are anticipated.

Policy and logistical changes are needed to address each of the gaps and barriers outlined above to facilitate development of the ideal system for transport of patients for primary PCI.

1. Well-defined hospital-specific protocols should be developed at each non-PCI-capable hospital to define which patients are candidates for transfer for primary PCI and which patients should be given fibrinolytic therapy on the basis of current guidelines, incorporating patient risk, fibrinolytic risk, time to presentation, and delays to primary PCI. These protocols should be agreed on by all and should eliminate time delays in deciding which patients should be transported for primary PCI. Practical issues, such as keeping patients on their EMS stretchers and rapid decision making (eg, <5 minutes at the non-PCI-capable hospital), which permits EMS personnel to stay with the patient and then transport the patient without waiting for another ambulance, must be addressed.
2. Clinical leadership, visible administrative support, and ongoing commitment to achieving explicit goals for door-to-balloon time will be required at both the non-PCI-capable hospital and the PCI-capable hospital to achieve agreement and implementation of protocols by all parties involved.¹⁹
3. Transport agreements and protocols will need to be negotiated with EMS and other transport systems. Crucial to this is a 9-1-1 type of response to calls for interhospital transfer for STEMI patients.
4. Similar to a level 1 trauma center, primary PCI hospitals will need to accept transfer of STEMI patients regardless of bed availability.
5. For non-PCI-capable hospitals that are not part of the tertiary care system, a legal revenue-sharing arrangement needs to be negotiated between the non-PCI-capable hospital, the primary PCI-capable hospital, and the third-party payers so the financial losses to the non-PCI-capable hospital are minimized.
6. It is critically important that the non-PCI-capable hospital be given incentive to rapidly treat and transfer STEMI patients according to ACC/AHA guidelines and that these hospitals remain an integral part of the STEMI systems of care. They should not be viewed as the "have not" but rather as the "STEMI referral hospital."

Develop Universal Systems in Which EMS Transfers STEMI Patients Directly to Regional Primary PCI-Capable Hospitals (STEMI-Receiving Hospital)

Current Status

Another potential strategy would involve bypassing the non-PCI-capable hospital for direct transfer to a primary PCI-capable hospital. This might allow more timely access to primary PCI for patients arriving via EMS. Nearly 80% of the

adult population in the United States lives within 60 minutes of a PCI-capable hospital, and three fourths of the remainder would experience <30 minutes of additional delay in direct transfer.²¹ Unfortunately, there are few published examples of robust universal transport systems in the United States.

Ideal System

This approach would require paramedic identification of patients with a STEMI in the field and diversion to an appropriate primary PCI-capable hospital. EMS personnel would need to have the training and capability to perform and transmit 12-lead ECGs to the participating primary PCI-capable hospital. Paramedics may accurately acquire such information and identify patients eligible for reperfusion therapy.^{22–27} After appropriate notification, EMS would be empowered to take the patient directly to the cardiac catheterization laboratory at the designated facility. A brief assessment could then be performed by the receiving providers before proceeding with PCI. Such a triage and treatment plan has already been successfully implemented in 1 large urban area.²⁸

Gaps and Barriers

The gaps and barriers to this strategy have been discussed in the EMS and ED perspective in these conference proceedings.²⁹ From the standpoint of the non-PCI-capable hospital, the impact of being bypassed on the hospital's clinical and financial viability is largely unknown. Non-PCI-capable hospitals may experience a negative financial impact from the loss of STEMI patients and the negative "halo effect" on other service lines. It is also unclear whether it is safe to transport patients longer distances (before they receive initial treatment) and whether the added transport time will negatively impact the mortality benefit derived from the primary PCI strategy.

Recommendations

1. EMS and STEMI-receiving primary PCI hospitals will need to monitor treatment times, volumes, patient outcomes, and associated quality indicators.
2. It will be important to ensure that patients without STEMI continue to be transported to the non-PCI-capable hospital.
3. Further study is needed to determine the feasibility of such an approach in suburban and rural settings.

Conclusions

Non-PCI-capable hospitals face significant challenges in improving care for STEMI patients. Many of these hospitals are located in rural areas and have long transport times to primary PCI-capable institutions. These are the hospitals most likely to suffer a significant financial impact with the development of such systems, and their very survival may be threatened.² We have described 3 potential strategies available to these institutions. However, given that approximately 50% to 70% of patients arrive at the local hospital without using EMS, the role of the STEMI referral hospital must be embraced and supported. It is equally important that these institutions and their physicians are reconnected with the

STEMI patient after discharge from the STEMI receiving hospital, to guide patient recovery and to promote continued adherence to secondary prevention measures. The connection between the STEMI referral and STEMI receiving hospitals will promote the overall success of the system of care for STEMI patients.

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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