Editorial

All Hospitals Are Not Equal for Treatment of Patients With Acute Myocardial Infarction

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Over the past several years, mounting evidence has shown that emergent angiography and primary angioplasty (or perhaps more appropriately named primary percutaneous coronary intervention [PCI]) are superior to treatment with thrombolytic therapy and watchful waiting for treatment of acute myocardial infarction (AMI). This is particularly true for patients at high risk for death (e.g., those >70 years of age), those who present to hospital late (≥4 hours after AMI), and those with prior myocardial infarction or diabetes. 

Primary PCI has advantages of higher initial TIMI 3 flow rates, less reocclusion, and less recurrent ischemia and reinfarction when compared with thrombolytic drug treatment and watchful waiting. Emergent angiography also permits early risk stratification, assessment of left ventricular function, and identification of other complications. In addition, early intervention has also been shown to be the best therapeutic option in patients with moderate and high-risk features who have non-ST-elevation infarction.

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Today, in this country as well as in others, most patients with AMI are admitted to suburban or rural hospitals, many without catheterization labs and many more without angioplasty facilities. Although long ago, we decided that the treatment of serious trauma was best done in specialized centers, patients with AMI, despite an overall mortality rate of ≥10%, are managed in any hospital with a coronary care unit. Few are transferred at the time of admission, and most receive thrombolytic therapy and then watchful waiting for complications. First, it has been generally held that the delay in transferring a patient to a tertiary center for primary PCI would more than offset any treatment advantage favoring emergent catheterization. Second, both physicians and hospital administrators in these smaller centers are reluctant to close their doors to patients with acute infarction, as it makes the hospital appear "second rate," and many patients simply prefer to be treated locally, close to their homes, families, and family physicians, unless they have an unusual and complicated illness. Third, the logistics of transfer, in and of themselves, are often cumbersome, can further delay treatment, and in some cases, can be a great imposition on the community’s emergency medical system and interfere with its ability to respond to additional emergencies. These issues are not trivial, but they now must be addressed. Too often in cardiology, we generate evidence to support a new treatment but fail to effectively implement it. This cannot be another such example!

There have been several recent clinical trials that have compared the outcomes of patients receiving up-front thrombolytic treatment at the primary hospital versus transfer to a regional center for primary PCI. Most sizable ones have been done outside the United States, in countries where the healthcare system is more integrated, and often the studies have not employed the latest thrombolytic drugs or done follow-up angiography on days 2 and 3 and, therefore, may make inferences in countries like the United States more difficult. In the present issue of Circulation, Daly and colleagues performed a meta-analysis of the available transfer studies, which number some 3750 patients. They found highly significant reductions in recurrent nonfatal infarction (1.5% versus 5.1%), stroke (0.6% versus 1.9%), and a trend toward lower mortality (7.8% versus 10.0%; P=0.086) favoring transfer, despite 1 to 3-hour delays. The mortality rates in these trials are not low for primary PCI (6.3%), and the difference in mortality rates between the two strategies was 1.4% despite the delay and similar to that seen when there are no delays (2%). We may continue to debate whether the findings are typical of those in our own communities, where second- and third-generation thrombolytic drugs are routinely used, and the use of rescue and follow-up angiography is almost done routinely after thrombolysis. In the largest of the comparative studies (Danish Multicenter Randomized Study on Thrombolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction [DANAMI]-2) done in Denmark, rescue PCI was done in only 1.9% of patients, and only 10% were revascularized by 30 days; a rate considerably lower than in the United States. Although further study of the influence of this and other factors on the outcomes and additional large trials would be of interest, we have to cope now with the fact that most cardiologists currently favor emergent angiography and the use of primary PCI for treatment of AMI, except when it is not readily available, when it is done in small centers by low-volume operators, or when treatment delays would be 2 to 3 hours or more. Time to treatment is very important for patients receiving thrombolysis, but the effect of time on survival is greatest only during the first "golden" hour (a time in which only 10% to 15% of patients seek care) and is less important thereafter.
When patients present later, the delay for the performance of primary PCI seems to be obviated by the higher rate of reperfusion and hence better results. This is not to say we shouldn’t monitor and minimize the time to PCI, because the currently available data support an expeditious approach.11–14

So, What Do We Do?

Currently, there are three possible strategies to make emergent angiography and primary PCI more readily available and timely: (1) to establish primary PCI programs in all free-standing cath labs having suitable case volumes and skilled personnel, (2) to regionalize the care of patients with AMI by transferring those with ST-elevation myocardial infarction within 2 to 3 hours to cardiac centers, and (3) to initiate thrombolysis at facilities without cath labs and even longer transfer delays and then transfer them for emergent angiography/PCI (“facilitated” PCI). There are problems with each approach, but each is needed if we are to fully implement this strategy.

Build More Cath Labs-Allow Primary PCI in Existing Free-Standing Labs

First, it would seem terribly unwise, impractical, and expensive to build cardiac catheterization labs for the sole purpose of doing primary PCI. Many such hospitals are relatively small, and case volumes would likewise be small. Albeit sparse, there are data suggesting that when the annual primary PCI patient volume is ≤36 per year, outcomes are worse.2,15 The current American College of Cardiology/American Heart Association Guidelines for PCI recommend an institutional volume of 200 to 400 cases per year and an operator volume of ≥75 interventions.16 Although these criteria need to be regularly reevaluated, there is little reason to begin cath laboratory programs that can’t meet these requirements, and there are data that support these volumes.17–19 There are, however, many hospitals with free-standing labs currently staffed by interventional cardiologists who perform the requisite case numbers in other facilities. Among these hospitals that have suitable volumes plus a committed staff and where regulations are not an impediment, several have switched from using thrombolytic therapy to the emergent angiography/primary PCI strategy. Some states, however, have regulations that do not permit the performance of PCI without on-site surgery. To get around the regulation, more and more of these hospitals are establishing cardiac surgical programs to enable elective and primary PCI programs. These new surgical programs are likely to remain small and further diffuse an already diminishing annual surgical volume in other large centers in a metropolitan area. It seems clear that in many instances, these new surgical programs exist solely to enable emergent and elective PCI. In my mind, these restrictive regulations must be changed, as they are promulgating new, small surgery programs that are increasing cost and very likely will lead to worse surgical outcomes throughout.20–22

In the past year, with the continued expansion of PCI, we have observed a 10% to 15% fall in cardiac bypass surgery—we simply do not need more surgical programs for the sole purpose of supporting PCI. The need for “backup” surgery for angioplasty has become unusual with the advent of stents. Although there have been no randomized trials evaluating outcome in hospitals doing elective PCI in settings with and without on-site surgical backup, many states and now many countries are permitting or initiating angioplasty programs in centers without surgery backup, as long as the PCI case numbers justify it and formal relationships for transfer exist with tertiary cardiac centers. This category now includes at least 19 states and countries such as England, Germany, Australia, Italy, France, Canada, and Sweden. Because it is important for the team to be familiar with the procedure and patient needs at the time of emergent PCI, these hospitals perform both elective and emergent angioplasty procedures to insure adequate case volumes and quality. This seems wise; except where there are exceptional motivation and sufficient case numbers to provide only primary PCI, it is far more practical to make the PCI procedure more of a routine. Patients with AMI can be critically ill at the time of the procedure, requiring physician, nursing, and technical expertise. A stand-alone PCI laboratory is not the ideal setting for building a competent PCI team. Hospital programs that exist without on-site surgery, however, need to be accountable by doing monthly quality assessments of their procedures and by participating in the American College of Cardiology National Cardiovascular Data Registry so that they can track their performance against others. I also believe that until we have more data, they also need to be monitored by either their own Institutional Review Board or an external oversight body. These hospitals must also have formal relationships and transfer policies that facilitate any need for emergent transfer to a site with on-site surgery. It is my belief that the current need for emergent surgery is low enough that such “stand-alone” centers should do both elective and primary PCI, as the time for transfer is typically not the limiting step in getting a patient to the operating room.

Transfer to Cardiac Centers

In urban areas, there are often hospitals minutes from each other, some with full tertiary cardiac facilities and others without. In this situation, protocols should be put in place to triage patients with chest pain and ST-elevation myocardial infarction first evaluated by emergency medical services to a hospital staffed and dedicated to provide 24/7 emergent angiography and primary PCI capability, even if it means driving beyond the first hospital. This requires that paramedic teams be equipped and trained to do 12-lead electrocardiography. As only half of patients with AMI seek 9-1-1 care, there also need to be protocols and relationships put in place that expedite the transfer of appropriate patients from hospitals that can’t to hospitals that can perform emergent angiography and primary PCI. This change may require emergency medical services directors to establish permissive protocols for paramedics to transfer and for hospitals to have effective communications with a cardiac center so there is no delay, as well as a transport plan that can be responsive within 30 minutes. Bottom line: In urban and suburban centers with primary PCI capability, transfer all patients with ST-elevation myocardial infarction to a tertiary center with which a
transferred protocol has been established (within a 2-hour travel radius). The Table lists the minimum requirements for primary and tertiary PCI centers.

### Hospitals With Delays of ≥2 Hours

The more difficult situation includes those facilities hours away from tertiary hospitals. In these hospitals, thrombolysis should be used. It is a good treatment and one for which we have an abundance of evidence favoring its use. Patients without ECG evidence of reperfusion or those with recurrent spontaneous or inducible/recurrent ischemia should be transferred for emergent angiography. An alternative approach is to treat each patient initially with a thrombolytic drug and then transfer for emergent angiography (facilitated PCI). For now, the value of this approach is unknown and the subject of ongoing trials. I encourage those centers with the will and capability to participate in such studies to help answer this question.

### So, What Should We Do?

These recommendations have many implications and accountabilities. First, they may lead to new cath labs and permit the performance of angioplasty in centers where it is not currently done, providing that minimal PCI volume and reporting requirements are met. I personally feel this is better than establishing more surgical programs. Second, they would classify hospitals as capable of emergent angiography/PCI or not and accordingly change current emergency triage and transfer protocols. Although this represents a major change for how AMI is routinely managed in this country, it is better than the current situation of no organized plan, no overall measure of quality, and a fragmented approach to this serious illness. These recommendations are not complete and satisfactory answers for patients, many of whom desire treatment as close as possible to their homes and families and by their usual physicians—but they do provide for the best possible outcomes.

Should thrombolysis be used initially before transfer to facilitate the procedure by causing earlier coronary reperfusion? The answer is unclear and needs further study. There are rural hospitals without the option of nearby (<2 hours) transfer; in these patients at such hospitals, thrombolytic therapy should be initially used.

Geography should not determine the type of treatment we receive for life-threatening conditions such as AMI. We currently have the means by these two strategies to provide for emergent angiography and PCI for the majority of patients, and it is time we address it.

### References


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