Primary Percutaneous Coronary Intervention at Hospitals Without On-Site Cardiac Surgery

Expanding the Use of Mechanical Reperfusion for Acute Myocardial Infarction*

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Mechanical reperfusion was introduced as a reperfusion strategy for ST-segment elevation acute myocardial infarction (AMI) in the mid- and late 1980s and offered advantages over thrombolytic therapy in achieving higher infarct artery patency rates with less re-occlusion. With the publication of the Zwolle and PAMI trials in 1993 (1,2), which documented superior outcomes with primary percutaneous coronary intervention (PCI) over thrombolytic therapy, primary PCI became a legitimate competing reperfusion strategy at interventional facilities with experienced operators. There are now over 23 randomized trials documenting the superiority of mechanical reperfusion over thrombolytic therapy (3), and primary PCI has become the preferred reperfusion strategy when experienced operators can perform it in a timely manner. However, the use of primary PCI has been limited owing to the lack of interventional facilities at most hospitals and the reluctance of physicians to transfer patients with AMI who present at community hospitals to interventional facilities because of concerns about the deleterious effects of treatment delay on myocardial salvage and clinical outcomes. This has stimulated new strategies to provide primary PCI to patients presenting to non-interventional hospitals.

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In this issue of the Journal, Wharton et al. (4) present data from a prospective multi-center registry in high-risk patients with AMI, presenting to hospitals with catheterization facilities but no cardiac surgery on site (no-SOS), who were treated with primary PCI. Outcomes in this registry were compared with outcomes of patients enrolled in the Air PAMI randomized trial who presented to non-interventional hospitals, had identical high-risk inclusion criteria, and were randomized to transfer to a tertiary center for primary PCI. Time to treatment (symptom onset to balloon inflation) was 67 min shorter for patients treated at no-SOS hospitals than for patients transferred to interventional facilities in the Air PAMI trial, and outcomes at 30 days were similar between the two groups. Unadjusted one-year mortality was lower in the no-SOS group, but after adjusting for differences in baseline variables, there were no differences in mortality. The need for emergency surgery for failed PCI was very low (0.4%), although surgical availability was still important because 5% of patients required transfer for surgery when critical coronary anatomy was found at angiography. The investigators emphasized the importance of adhering to stringent guidelines to achieve optimal results, including the following: 1) experienced interventionalists who regularly perform elective interventions at a surgical center; 2) an experienced catheterization laboratory team available 24 hours a day, seven days a week; 3) a well-equipped catheterization laboratory with digital imaging equipment and a full array of interventional equipment; 4) formalized protocols for rapid transfer to a surgical center when necessary; and 5) rigorous, ongoing quality/assurance and outcomes monitoring.

This study is the largest multi-center registry of primary PCI performed at hospitals with interventional capabilities but without on-site surgery. Although the study does not provide randomized data comparing outcomes with primary PCI at no-SOS hospitals with outcomes in patients transferred to tertiary hospitals for primary PCI, the comparative data with similar patients transferred for primary PCI in the Air PAMI trial put these outcomes into perspective and provide strong support for the use of primary PCI at centers without on-site surgery.

The safety and efficacy of primary PCI for AMI at no-SOS hospitals have also been supported by the results of the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trial and data from the National Registry of Myocardial Infarction. The C-PORT trial (5) evaluated primary PCI at hospitals with catheterization laboratories but without cardiac surgery or elective PCI. Using skilled operators who performed PCI at nearby tertiary centers, the C-PORT investigators documented superior outcomes with primary PCI versus lytic therapy. The National Registry of Myocardial Infarction investigators (6) evaluated outcomes in 1,935 patients treated with primary PCI at 97 no-SOS hospitals and compared them with outcomes in patients treated at hospitals with on-site surgery and found similar outcomes in both groups.

Thus, it appears clear from the data of Wharton et al. (4) and others that primary PCI can be performed safely and effectively at hospitals that do elective catheterization but do not have cardiac surgery on site, if rigorous guidelines are followed. A more difficult question is whether this experience can be duplicated at other hospitals that perform primary PCI without on-site surgery. Some have argued...
that the requirement for cardiac surgery on site acts as a surrogate for an experienced team and comprehensive support services, which are necessary to ensure optimal outcomes. There remain a number of unanswered questions. How difficult will it be to find interventionists with experience at tertiary hospitals to staff these no-SOS hospitals, and where will the technicians get their experience, when only as few as 36 interventions may be performed per year at these hospitals? Is it feasible to have all the catheters, wires, balloons, and stents in stock and available for sometimes-complex interventions when only a small number of interventions are performed per year? Will these low-volume hospitals be able to adapt to rapidly changing technologies such as distal protection? And who will assume the responsibility for monitoring quality assurance and outcomes data from these hospitals? These questions and more will need to be addressed as we embark on this new frontier.

The study by Wharton et al. is extremely relevant because currently there is great debate regarding the appropriateness of performing primary PCI at hospitals without on-site surgery. Current American College of Cardiology/American Heart Association guidelines permit the performance of primary PCI at hospitals without on-site cardiac surgical back-up if procedures can be performed by experienced operators (>75 procedures/year) in a timely fashion (90 ± 30 min of arrival), if at least 36 primary PCI procedures are performed per year at the hospital, and if stringent guidelines are in place similar to those described above (7). Primary PCI at no-SOS hospitals have a class IIb indication, which means that the usefulness and efficacy are less well established by current evidence and opinion. This study documents that superb outcomes can be achieved at hospitals that do not offer on-site cardiac surgery. Emergency surgery for failed PCI is very infrequent and can be managed effectively with proper protocols for transfer to a tertiary facility. Therefore, despite the questions posed above, I believe the data presented by Wharton et al. provide sufficient evidence to revise these guidelines to provide a class IIa indication (weight of evidence/opinion is in favor of usefulness/efficacy) for primary PCI at hospitals with catheterization laboratories but without on-site surgery. It will then be our responsibility as a cardiology community to ensure that these procedures are performed according to the guidelines outlined above and that outcomes are monitored.

The use of primary PCI at hospitals without on-site cardiac surgery is part of a greater movement, that of expanding primary PCI to a larger segment of our AMI population. Recently, the results of two randomized trials have added momentum to the expansion of primary PCI. The large Danish Multicenter Randomized Study on Fibrinolytic Therapy versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2) and PRAGUE-2 trials (8,9) have documented superior outcomes in patients with AMI transferred from community hospitals to interventional facilities for primary PCI compared with local treatment with lytic therapy, despite additional treatment delays of 60 to 90 min in the PCI group. This has spawned the concept of heart attack centers, similar to trauma centers, in which patients with AMI would be transferred directly to high-volume centers of excellence with mechanical reperfusion. In this “hub-and-spoke” model, all patients presenting at outlying hospitals would be transferred to interventional centers for primary PCI. Ideally, patients brought to the hospital by ambulance would be routed directly to the heart attack center, as has been often done in Europe and is done with trauma patients in this country. Unfortunately, this has not worked very well in this country, because of the small proportion of patients brought to the hospital by ambulance and the lack of centralized emergency transport systems to facilitate this process. Most patients present directly to the community hospital (not by ambulance) and, unfortunately, hospitals in this country have not yet been able to duplicate the rapid triage and transport seen in the European trials. Despite current limitations, the hub-and-spoke model may be an effective approach. Treatment delays do not appear as critical with primary PCI as with thrombolytic therapy (10) and, as the results of DANAMI-2 and PRAGUE-2 show, do not appear to greatly compromise outcomes. An exception is the group of patients who present very early when delays in treatment with primary PCI may compromise outcomes. In PRAGUE-2, patients randomized at less than three hours had no mortality benefit with primary PCI over thrombolytic therapy. In these patients “facilitated PCI,” the use of pharmacologic reperfusion therapy followed by rapid transport for facilitated PCI, may allow for earlier reperfusion with improved outcomes and may prove to be the optimal approach. Facilitated PCI is currently being tested in several randomized trials and, if effective, would work well with the hub-and-spoke model.

The National Registry of Myocardial Infarction has shown modest trends for increased use of primary PCI over the past decade, but in 2001 only 20% of patients with ST-segment elevation AMI were treated with primary PCI compared with 50% treated with thrombolytic therapy (11) (Fig. 1). The expanded use of primary PCI at hospitals without on-site cardiac surgery and the development of acute MI centers with protocols for rapid transport of patients presenting at non-interventional hospitals will both help expand the use of primary PCI to a larger proportion of our AMI population. Currently, the hub-and-spoke approach appears to have a wider application, but in the future primary PCI at no-SOS hospitals may play a larger role. The use of elective revascularization with PCI is increasing rapidly, whereas the use of coronary artery bypass grafting is declining. Rather than opening new surgery centers to compliment new PCI centers, it is likely that there will be increasing pressure to “uncouple” cardiac surgery and PCI. This would result in a large number of free-standing PCI centers performing elective PCI without on-site cardiac
surgical back-up, and these hospitals would be capable of performing primary PCI.

The differences in outcomes between mechanical reperfusion strategies and pharmacologic reperfusion strategies are not trivial. It should no longer be acceptable in most patients to give only thrombolytic therapy when mechanical reperfusion is available. And we, as a cardiology community, should vigorously promote making mechanical reperfusion more available. The performance of primary PCI at facilities with interventional capabilities but without on-site cardiac surgery will help us toward this goal.

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REFERENCES