Rationale for On-Site Cardiac Surgery for Primary Angioplasty: A Time for Reappraisal

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Since the early 1990s, with significant improvement in the procedural success of percutaneous coronary interventions (PCIs), there has been a concomitant reduction in the need for emergency coronary artery bypass graft surgery. This review article focuses on the need for on-site cardiac surgery in patients with acute myocardial infarction undergoing primary angioplasty at centers without on-site cardiac surgical backup. It gives an overview of the need for emergency bypass surgery in both the large trial setting and the community hospital setting. Special consideration is also given to the risks and benefits of primary angioplasty compared with thrombolytic therapy, transfer to an institution with an on-site cardiac surgical facility compared with primary PCI, the frequency and indications for emergency cardiac surgery related and unrelated to primary angioplasty and the requirements for primary angioplasty that must be met in hospitals without the capability of on-site cardiac surgery. (J Am Coll Cardiol 2002;39:1881–9) © 2002 by the American College of Cardiology Foundation

The initial experience with percutaneous coronary intervention (PCI) was characterized by complications, including coronary dissection, acute recoil, coronary perforation and coronary thrombosis (1). The immediate remedy for many of these complications was emergency coronary artery bypass graft surgery (CABG), and the performance of PCI was predicated on the availability of on-site cardiac surgery. The joint guidelines of the American College of Cardiology and the American Heart Association (ACC/AHA), published in 1996 and updated in 1999, stated that primary PCI in patients with acute myocardial infarction (AMI) who are eligible for thrombolysis should not be performed by a low-volume operator in a laboratory without surgical capability (class III indication) (2,3). In the British Cardiac Society Guidelines, of 20,511 PCI procedures performed in the U.K. in 1996, 1,382 (7%) were performed in six centers without on-site cardiac surgical capabilities (4). Emergency CABG within 24 h was required in 1.5% of patients. Surgical backup, whether on-site or off-site, was recommended for all coronary angioplasty procedures (4). In Canada, the Cardiac Care Network of Ontario (5) recently recommended to the Ontario Ministry of Health that pilot programs be set up in Ontario to perform coronary angioplasty (both primary and elective) at hospitals without on-site surgical backup.

The 2001 ACC/AHA guidelines recommend that primary PCI for patients with AMI (defined as ongoing chest pain and ST-segment elevation or new left bundle branch block) should be performed within 90 min of hospital arrival (class IIa indication) (6). If those prerequisites can be met, PCI without on-site cardiac surgery is regarded as a class IIb indication (the weight of the evidence does not favor performance of the procedure). The continued concerns about performing PCI for patients with AMI without surgical capabilities on-site, as well as the reason it is listed as a class IIb indication, rather than class IIa or class I, relate to patients who may require immediate cardiac surgery after PCI.

Since the early 1980s, the PCI technique, equipment and outcomes have improved significantly (7,8). Since the early 1990s, with improvements in procedural success, there has been a concomitant reduction in complications, especially in the need for emergency CABG (8,9). Selection criteria for PCI have broadened to include high-risk patients, including those who are elderly, those with non-ST-segment elevation coronary syndromes and those in cardiogenic shock (7–11).

In light of this progress, it is the opportune time to re-evaluate the necessity of having an on-site cardiac surgical capability at institutions where PCI is performed in patients with AMI. This review focuses on this need for patients with evolving AMI. In this setting, primary PCI has the greatest potential to reduce mortality, salvage the myocardium and avoid delays incurred by transferring patients to a cardiac surgical facility.
Emergency CABG after primary PCI for patients with AMI. In randomized, controlled trials, the reported rate of emergency CABG for failed primary PCI is low (12–18) (Table 1). In the Primary Angioplasty in Myocardial Infarction–2 (PAMI-2) trial, primary PCI was performed in 982 patients (18). Of these patients, 67 (6.8%) underwent cardiac surgery during the index hospital admission for severe triple-vessel disease or left main coronary artery disease. Only four patients (0.4%) required emergency surgery for a complication resulting from failed PCI. The PAMI-2 investigators concluded that a distinction needs to be made between urgent CABG performed on the basis of “high-risk” coronary anatomic features and true emergency CABG performed after failed PCI. Moreover, the rate of emergency CABG may be higher when the procedure is available on-site (19,20). Based on the low rate of emergency CABG, the PAMI-2 investigators recommended that primary PCI be performed without on-site cardiac surgical capabilities if a protocol exists for the rapid transfer of the patient to a nearby facility with on-site cardiac surgical capabilities. In our review of the combined experience of six major randomized trials comparing primary PCI with thrombolytic therapy, we found that only 6 (0.31%) of 1,953 patients required emergency CABG for failed PCI (Table 1).

Although the risk of an angioplasty-related complication requiring CABG is low, the following points need to be considered when contemplating primary PCI without on-site cardiac surgical capabilities:

1) the risks and benefits of primary PCI versus thrombolytic therapy;
2) the risks and benefits of primary PCI versus transfer of patients to an institution with on-site cardiac surgical capabilities for those not eligible for thrombolytic therapy;
3) the outcome for patients who are treated with the intention that they will receive primary angioplasty, but who do not receive it;
4) the frequency of and indications for emergency CABG unrelated to PCI complications;
5) the management of PCI complications that may be alleviated by emergency CABG;
6) the requirements that must be met in hospitals without on-site cardiac surgical capabilities to perform primary PCI safely and effectively.

**PCI versus thrombolytic therapy.** Randomized studies have demonstrated the safety and efficacy of primary angioplasty for the treatment of AMI in patients eligible for thrombolytic therapy (21–23). A meta-analysis of 2,606 patients enrolled in these trials suggested that primary angioplasty reduces mortality, stroke and recurrent ischemia, as compared with thrombolytic therapy (24). The risk of death was 4.4% for patients treated with primary PCI and 6.5% for patients treated with thrombolysis, which represents 21 lives saved per 1,000 patients treated. The rates of death or nonfatal MI were 7.2% for primary PCI and 11.2% for thrombolytic therapy (40 fewer events per 1,000 patients treated). Pooled data show that the reduction in mortality persists for at least six months. In the Netherlands trial, the mortality benefit favoring primary PCI has persisted for more than three years (25). In one small study in which 71 patients were randomly assigned to receive therapy with a stent and abciximab, and 69 patients to receive therapy with alteplase, the median size of the infarct, as measured by serial scintigraphic studies with technetium-99m sestamibi, was significantly smaller in patients treated with PCI than in those treated with thrombolytic medication (26). Despite the small number of patients, the frequencies of death, reinfarction and stroke were significantly lower in patients assigned to receive therapy with stents and abciximab (8.5%) than in those assigned to receive therapy with alteplase (23.2%) ($p = 0.02$). Primary angioplasty consistently yields higher patency rates in the infarct-related artery at 60 and 90 min, less residual stenoses and lower re-occlusion rates (21,22).

The results of observational registries that may better
reflect the experience of community hospitals do not consistently support the results of the randomized trials favoring PCI over thrombolytic therapy. In the Myocardial Infarction, Triage and Intervention (MITI) registry, the outcomes of 1,050 patients who underwent primary PCI were compared with those of 2,095 patients with ST-segment elevation MI who received thrombolytic therapy within 6 h of admission (27). There was no difference in either in-hospital or long-term mortality during the three-year follow-up. Moreover, the rates of subsequent procedures and costs were lower among patients in the thrombolytic therapy group (27). The second National Registry of Myocardial Infarction (NRMI) analyzed more than 28,000 patients eligible for thrombolytic therapy within 12 h of symptoms, who were treated with either intravenous tissue plasminogen activator or primary PCI (n = 4,052). In-hospital mortality was not statistically different between the two groups (5.2% vs. 5.4%) (28). Similar findings were reported from a large European registry (29).

In contrast to the results of these large registries, analysis of pooled data from the first, second and third NRMIIs showed a greater reduction in early mortality among patients treated with PCI than among those treated with thrombolysis (30). In the Cooperative Cardiovascular Project, a retrospective study of 80,356 elderly North American Medicare beneficiaries who presented with AMI, those undergoing primary PCI versus thrombolytic therapy had lower 30-day mortality (8.7% vs. 11.9%, p = 0.001) and lower one-year mortality (14.4% vs. 17.6%, p = 0.001) (31).

In two German registries—the Maximal Individual TheRapy in Acute myocardial infarction (MITRA) registry and the Myocardial Infarction Registry—the in-hospital mortality rate among patients undergoing primary PCI decreased from 13.9% in 1994 to 3.8% in 1998, whereas mortality remained unchanged for patients treated with lytic agents (10.2% in 1994 and 12.7% in 1998) (32). A recent report from these two registries, which reflect current clinical practice in Germany, demonstrated that primary PCI in patients with AMI who were eligible for thrombolysis was associated with lower hospital mortality than in those who received thrombolytic therapy (33).

The observational results from registries are flawed in that they can never be risk-adjusted: low-risk patients who do well clinically may be more likely to receive thrombolytic therapy, and higher risk patients or those experiencing clinical deterioration or bleeding risks may be more likely to be referred for percutaneous interventions. It should also be noted that the data in some of the older registries, such as MITI, were most likely collected up to 1995, and the MITRA registry and the Myocardial Infarction Registry included more recent outcomes from 1994 to 1998. These more recent registries showed a steady improvement in the outcomes of PCI, but not thrombolytic therapy. Thus, because the outcomes of PCI are steadily improving, data from older registries are less relevant. Although the results of the observational studies vary, overall they support the claim of superiority of primary PCI over thrombolytic therapy.

The superior outcome associated with primary PCI has stimulated interest in expanding its availability to hospitals without on-site cardiac surgery. The paramount question is how to translate the results of large, randomized, controlled trials and observational studies in which primary PCI was almost uniformly performed at centers with on-site cardiac surgery to community hospitals without on-site cardiac surgery.

**PCI versus transfer for PCI for patients who have contraindications to therapy with thrombolysis.** For patients with AMI, pre-hospital triage to chest pain centers allows the reperfusion intervention to be delivered at the time of the initial presentation. Only about one-third of patients presenting with AMI are eligible for thrombolytic therapy (34). Recent data from the NRMI indicate that this remains true today, even with heightened awareness of the benefits of reperfusion therapy and a general lessening of restrictions of or contraindications to thrombolytic treatment (34). However, patients with ongoing chest pain in the absence of ST-segment elevation, patients with ST-segment elevation and an increased risk of bleeding (e.g., recent stroke) and patients with a nondiagnostic ECG, advanced age, cardiogenic shock, late presentation or previous CABG or thrombolytic failure are not eligible to receive thrombolytic therapy. These patients benefit from immediate angioplasty (35). Patients with contraindications to thrombolytic therapy have increased rates of mortality, reinfarction, stroke and heart failure (35). The results from the same registry (MITRA) demonstrated a benefit of primary angioplasty in all subgroups of patients, and as the mortality from AMI increased, the absolute benefit of primary angioplasty also increased (33). Offering primary PCI at the time of the initial presentation, rather than transferring patients, is especially important for patients in cardiogenic shock. In the Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock trial, revascularization within 6 h conferred the best survival advantage of all the descriptors (36).

Patients ineligible to receive thrombolytic therapy should be transferred to a facility where immediate coronary angiography and PCI can be performed, if indicated. However, the delay involved in transporting a patient to another facility increases the risk of adverse outcomes (37,38). In the second NRMI, patients transferred to a tertiary-care center for primary PCI had the procedure 2.3 h later than those who arrived at the tertiary-care center directly. The mortality rate in patients who were transferred was 7.7%, whereas the mortality rate in patients who were not transferred was 5.0% (p = 0.0001) (39). Other studies confirm a relationship between transporting patients to tertiary-care centers and an increased number of adverse cardiac events, which are believed to be the result of reduced myocardial salvage (40).

Several small studies have examined the clinical effect of
transporting patients (either with or without first adminis-
tering thrombolytic drugs intravenously) to hospitals where PCI is performed. A study in Switzerland (n = 146) found similar mortality rates between patients treated at the presenting hospital (7%) and those treated at a nearby tertiary-care center (9%) (41). Another series from the Netherlands (n = 165) showed that transporting patients a short distance (20 miles) could be done safely after the initial administration of intravenous thrombolytic drugs, and early angiography with PCI after thrombolysis showed improved anterograde blood flow in the majority of treated patients (42). One study (Primary Angioplasty in Patients Transferred From General Community Hospitals to Specialized Percutaneous Transluminal Coronary Angioplasty Units With or Without Emergency Thrombolysis) compared three reperfusion strategies in patients who had AMI and presented within 6 h of the onset of symptoms at community hospitals without a catheterization laboratory: 1) immediate thrombolytic therapy (n = 99); 2) thrombo-
lytic therapy during transport for immediate angiography and, as appropriate, angioplasty (n = 100); and 3) imme-
rate transport for primary angioplasty without pretreat-
ment with thrombolysis (n = 101). The combined primary end point (death, reinfarction or stroke within 30 days) was reached less frequently in the third group of patients (8%) than in the first group (23%) or the second group (15%) (p < 0.02). Transferring patients from community hospitals to an angioplasty center during the acute phase of MI has been shown to be safe in this study (43). In contrast, the AIR-PAMI study compared the outcomes of 71 patients who were transferred for PCI with the outcomes of 500 patients enrolled in the PAMI No-Surgery–On-Site regist-
try. There was a trend toward higher 30-day mortality for the transferred patients (8.7% vs. 4.2%, p = 0.13), and one-year mortality was significantly higher in transferred patients (14.8% vs. 6.1%, p = 0.01) (44).

Despite the finding from these studies that patients who are transferred for primary PCI have outcomes superior to those who immediately receive thrombolytic therapy, the data also suggest that patients have an increased frequency of adverse outcomes if reperfusion therapy is delayed. The interval from presentation to an emergency department to performance of PCI (the so-called “door-to-balloon” time) has been shown to be an important correlate of outcome in primary angioplasty. In the Global Use of Strategies To Open occluded arteries (GUSTO-IIIb) study, the time from enrollment to first balloon inflation was an independent predictor of 30-day mortality (37). Similarly, in the second NRMI registry, a door-to-balloon time of more than 120 min increased the adjusted odds rate for mortality by 41% to 62% (38). Transporting patients with AMI to a facility where PCI can be performed probably not only worsens outcomes, but also increases costs and introduces an addi-
tional emotional burden for patients and their families, who generally prefer the continuity of care in their community hospital.

Therefore, the ability to offer prompt primary PCI at the center to which the patient initially presents is appealing. The question of whether PCI conducted at centers without cardiac surgical services is equivalent to PCI performed at centers that do offer such services must be addressed. Even more germane is the question of whether it is superior to the rapid administration of a thrombolytic agent or to the rapid transfer of patients with AMI who are at high risk or ineligible for thrombolysis to an institution with cardiac surgical capabilities.

Studies of primary angioplasty in facilities without on-
site surgery. Relatively few prospective studies have evalu-
ated the outcomes after primary PCI at centers without on-site cardiac surgery. Several observational series and a single randomized trial have directly addressed the issue (45–53) (Tables 2 and 3).

Wharton et al. (48) reported on patients undergoing primary PCI at two community hospitals without on-site cardiac surgery. High-risk patients, including those in cardiogenic shock, and survivors of an out-of-hospital car-
diac arrest were included. The procedural success rate was 94.3%. Angioplasty was not performed in 33.8% of the patients undergoing immediate angiography for suspected AMI, because Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 was present (25.9%), the culprit lesion was technically unsuitable (6.1%) or the infarct-related artery could not be identified (1.8%). Among patients in whom PCI was performed, the median time from arrival in the emergency department to reperfusion was 102 min, which is comparable to the corresponding times in random-
ized trials of PCI versus thrombolytic therapy in which on-site surgery was available. The in-hospital mortality rate for patients undergoing PCI was 5.3%, and no patient required emergency CABG from a procedural complication.

In the PAMI No-Surgery–On-Site registry, in which 500 patients were analyzed, procedural success was achieved in 97% of the patients, and TIMI flow grade 3 was restored in 94.2% of the patients. No patient had a reinfarction, and the in-hospital mortality rate was only 2.8% (46). In the MITI registry of AMI, 233 of 441 patients had primary angio-
plasty performed at hospitals that did not have on-site cardiac surgery (49). The procedural success rate in these patients was 88%, and the in-hospital mortality rate was 5.6%.

We have previously reported the Mayo Clinic’s experi-
ence with primary PCI without cardiac surgery (50). All components of the primary PCI program at the Mayo Clinic, Rochester, Minnesota, where on-site cardiac surgery can be performed, were replicated at a Mayo Health System hospital without on-site cardiac surgery. In addition, a telemedicine system to enable real-time consultation with interventional and cardiac surgical specialists during the procedure is available. Adhering to a strict patient-selection protocol, 50 emergency PCIs (ST-segment elevation AMI or non–ST-segment elevation AMI with ongoing chest pain) have been performed. Procedural success was achieved
in 47 patients (94%); there were 2 in-hospital deaths (4%). No patient required emergency CABG. There were no additional deaths at 30-day follow-up, and none had reinfarction or required repeat target vessel revascularization.

In these studies of PCI at centers without cardiac surgery on-site, the CABG rates during the index hospital period were 5.3% to 7.0%. These rates were not different from the 6.1% rate of cardiac surgery during the index hospital admission in the PAMI-STENT trial at a center with on-site cardiac surgery. In summary, these observational studies demonstrate the safety and efficacy of primary PCI in selected community hospitals without on-site cardiac surgery.

A single, randomized trial directly addressed whether thrombolytic therapy or primary PCI is preferred at hospitals without on-site surgical capabilities. In the Atlantic Cardiovascular Patient Outcomes Research Team trial, which included 11 hospitals where more than one procedure was performed per month, 453 patients with ST-segment elevation or left bundle branch block were randomly assigned to receive either immediate thrombolytic therapy (n = 227) or angiography and PCI if they had suitable coronary anatomic indications (n = 226) (47). Intracoronary stents and glycoprotein IIb/IIIa inhibitors were used in 70% and 75% of the patients, respectively. In the PCI arm, the procedural success rate was 91%. The in-hospital mortality was statistically similar between patients undergoing primary PCI and those receiving thrombolysis (5.5% vs. 7.4%). There was no statistical difference in the individual end points of recurrent MI (5.2% vs. 6.3%) or stroke (1.3% vs. 3.5%). However, the composite end point (death, reinfarction or stroke) occurred in 25.4% of patients receiving thrombolytic therapy, as compared with 15.4% in the primary PCI group (relative risk [RR] reduction 42%, p = 0.03). The patients who benefited the most in this trial were women, those with diabetes mellitus and the elderly. No patient undergoing PCI required emergency CABG. The results of this study favor primary PCI, and although they require confirmation and should be viewed with caution, the data support the safety and efficacy of primary PCI at selected sites without on-site cardiac surgery.

### Table 2. Studies on Primary Angioplasty in Acute Myocardial Infarction at Sites Without On-Site Cardiac Surgery: Baseline Demographic Data

<table>
<thead>
<tr>
<th>Study (Reference)</th>
<th>n</th>
<th>Age (yrs)</th>
<th>Male (%)</th>
<th>Patients With Anterior Infarction (%)</th>
<th>Patients With MVD (%)</th>
<th>Patients Eligible for Thrombolytic Therapy (%)</th>
<th>LVEF (%)</th>
<th>Time From Chest Pain to Presentation in ED (min)</th>
<th>Door-to-Balloon Time (min)*</th>
<th>Patients in Cardiogenic Shock (%)</th>
<th>Patients With Thrombolytic Therapy (%)</th>
<th>Patients With Primary PCI (%)</th>
<th>Time to PCI (%)</th>
<th>Patients Eligible for Thrombolytic Therapy (%)</th>
<th>Patients Eligible for Primary PCI (%)</th>
<th>Median value</th>
<th>25th percentile</th>
<th>75th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wharton et al. (48)</td>
<td>506</td>
<td>61 ± 13</td>
<td>71.1</td>
<td>32</td>
<td>32</td>
<td>11.3</td>
<td>61</td>
<td>90</td>
<td>223</td>
<td>NA</td>
<td>38.7</td>
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<td>90</td>
<td>78</td>
<td>100</td>
<td>105</td>
<td>22</td>
</tr>
<tr>
<td>Weaver et al. (49)</td>
<td>233</td>
<td>58 ± 12</td>
<td>80</td>
<td>32</td>
<td>52</td>
<td>23</td>
<td>90</td>
<td>90</td>
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<td>NA</td>
<td>38.7</td>
<td>49.4</td>
<td>40</td>
<td>90</td>
<td>78</td>
<td>100</td>
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<tr>
<td>Johnston et al. (46)</td>
<td>500</td>
<td>64 ± 12</td>
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<td>70</td>
<td>90</td>
<td>90</td>
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<td>90</td>
<td>78</td>
<td>100</td>
<td>105</td>
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<td>78</td>
<td>100</td>
<td>105</td>
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<td>Brush et al. (52)</td>
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<td>56</td>
<td>61</td>
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<td>90</td>
<td>78</td>
<td>100</td>
<td>105</td>
<td>22</td>
</tr>
</tbody>
</table>

*Interval from presentation in an emergency department to performance of percutaneous coronary intervention. †Median value. 25th percentile, 75th percentile. All other data are presented as the mean value ± SD or percentage of patients.

ED = emergency department; LVEF = left ventricular ejection fraction; MVD = multivessel disease; NA = not available.
for bypass surgery; 3) underwent immediate bypass surgery for anatomic reasons related to the infarct artery; 1 had severe mitral regurgitation that required surgery; and 36 had an infarct-related artery with <70% stenosis or TIMI flow grade 3, or both. For 32 patients, the exact reasons that angioplasty was not performed remain unknown.

**Indications for emergency CABG.** There are two groups of indications for emergency CABG after PCI: 1) documentation of severe disease not suitable for PCI; and 2) a failed coronary intervention requiring emergency CABG.

**DOCUMENTATION OF SEVERE DISEASE NOT SUITABLE FOR PCI.** Severe disease includes: 1) an infarct-related artery not suitable for treatment with PCI because of substantial myocardial jeopardy; 2) a left main coronary artery lesion that precludes PCI or complex triple-vessel disease in which an infarct-related artery cannot be reliably identified; or 3) mechanical complications such as mitral regurgitation, free wall rupture or ventricular septal defect.

**FAILED CORONARY INTERVENTION REQUIRING EMERGENCY CABG.** The complications of PCI that can lead to emergency surgery are: 1) dissection; 2) abrupt closure of the infarct-related artery; 3) occlusion of the large side branch during the procedure, with an inability to restore patency percutaneously; and 4) coronary artery perforation.

In recent years, there has been a steady decline in the frequency of dissections and abrupt closures. The explanations are multifactorial, but the use of coronary artery stents has been the most important factor (54). Glycoprotein IIb/IIIa receptor inhibitors also reduce the need for emergency CABG in patients undergoing PCI (55). In an analysis of pooled data from two trials (Evaluation of Platelet IIb/IIIa Inhibitor for Stenting and Evaluation of Percutaneous Transluminal Coronary Angioplasty to Improve Long-term Outcome With Abciximab Glycoprotein IIb/IIIa Blockade), the incidence of cardiac surgical procedures was 1.28% in patients receiving abciximab, which is substantially lower than the incidence of 2.17% in the placebo group (RR reduction 41%, p = 0.021) (55). Coronary perforations, particularly if they are severe or occur in patients treated with glycoprotein IIb/IIIa inhibitors, may not respond to prolonged balloon inflation or pericardiocentesis and may require emergency CABG, but this complication is rare (56). The recent approval of a coronary stent covered with a polytetrafluoroethylene membrane should reduce the need for CABG in such cases (57).

**Limitations of expanding primary angioplasty to centers without on-site bypass surgery.** There are still many important factors to consider before primary PCI can be recommended in community hospitals without on-site surgical capabilities. More than 800 hospitals in the U.S. have diagnostic catheterization available without on-site cardiac surgery. In the second NRMI, 25.2% of 1,506 participating hospitals were capable of performing cardiac catheterization, and only 39.2% of the hospitals offered on-site cardiac surgery (Fig. 1 (20)).

**Operative competency is an important issue.** There is clearly an association between institutional and individual procedural volumes and clinical outcome, including mortality (58,59). In a recent analysis of the second and third NRMIIs, comprising 62,299 patients with AMI, mortality was lower among patients who received primary PCI than among those who received thrombolysis at hospitals with intermediate PCI volumes (i.e., 17 to 48 primary PCI procedures performed annually) (4.5% vs. 5.9%, p = 0.001) or high volumes (≥49 primary PCI procedures annually) (3.4% vs. 5.4%, p = 0.001) (60). At low-volume hospitals (≤16 primary PCI procedures annually), the mortality was similar between patients treated with primary PCI and those treated with thrombolysis (6.2% vs. 5.9%, p = 0.58). A recent study from the 1995 New York State Coronary

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**Table 3.** Studies on Primary Angioplasty in Acute Myocardial Infarction at Sites Without On-Site Cardiac Surgery: Results of PCI

<table>
<thead>
<tr>
<th>Study (Reference)</th>
<th>n</th>
<th>Procedural Success</th>
<th>TIMI Flow Grade 3</th>
<th>In-Hospital Mortality</th>
<th>Repeat Myocardial Infarction</th>
<th>Stroke</th>
<th>CABG for Failed PCI</th>
<th>CABG During Index Hospital Admission</th>
<th>MACE</th>
<th>Recurrent PCI</th>
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<tr>
<td>Wharton et al. (48)</td>
<td>506</td>
<td>94.3%</td>
<td>94.3%</td>
<td>6.6%</td>
<td>2.5%</td>
<td>0.4%</td>
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<td>8.2%</td>
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<td>Weaver et al. (49)</td>
<td>233</td>
<td>88%</td>
<td>88%*</td>
<td>5.6%</td>
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<td>0.6%</td>
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<td>500</td>
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<td>94.2%</td>
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<td>9.8%</td>
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<td>2.8%</td>
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<td>5.6%</td>
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<td>—</td>
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<td>3.0%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4.0%</td>
<td>5.0%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

TIMI flow grade 2/3. Data are presented as the number or percentage of patients.

MACE = major adverse cardiac event; TIMI = Thrombolysis In Myocardial Infarction trial. Other abbreviations as in Table 1.

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**Figure 1.** Most of the 1,506 hospitals in the National Registry of Myocardial Infarction-2 had the capability to perform coronary angiography (Cath-capable), angioplasty (PTCA-capable) or bypass surgery (CABG-capable). CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty. (From Rogers et al. [20], by permission of the American College of Cardiology.)
Angioplasty Reporting System Registry analyzed the relationship between the number of primary angioplasty procedures performed by physicians in hospitals and in-hospital mortality. Patients who underwent angioplasty procedures within 23 h after the onset of AMI without preceding thrombolytic therapy were included \( n = 1,342 \). In-hospital mortality was reduced by 57% among patients who underwent primary angioplasty performed by high-volume physicians rather than low-volume physicians \( (\text{adjusted RR} \ 0.43, \ 95\% \ CI \ 0.21 \ 0.83) \). When patients with AMI were treated with primary angioplasty in high-volume hospitals rather than low-volume institutions, the RR reduction for in-hospital mortality was 44% \( (\text{adjusted RR} \ 0.56, \ 95\% \ CI \ 0.29 \ 1.1) \). Compared with patients treated at low-volume hospitals by low-volume physicians, patients treated at high-volume hospitals by high-volume physicians had a 49% reduction in the risk of in-hospital mortality \( (\text{adjusted RR} \ 0.51, \ 95\% \ CI \ 0.26 \ 0.99) \) \( (61) \).

### Table 4. Criteria for the Performance of Angioplasty at Hospitals Without On-Site Cardiac Surgery

1. The operators must be experienced interventionalists who regularly perform elective interventions at a surgical center \( (\geq 75 \text{ cases/year}) \). The institution must perform a minimum of 36 primary PCI procedures per year.
2. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They must participate in a 24-h, 365-day call schedule.
3. The catheterization laboratory must be well equipped, with optimal imaging systems, resuscitative equipment, IABP support and a broad array of interventional equipment.
4. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
5. The hospital administration must fully support the program and enable the fulfillment of the aforementioned institutional requirements.
6. There must be formalized written protocols in place for immediate \( (\text{within } 1 \text{ h}) \) and efficient transfer of patients to the nearest cardiac surgical facility, and these protocols should be reviewed and tested on a regular \( (\text{quarterly}) \) basis.
7. Primary intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction to ensure streamlined care paths and increased case volumes.
8. Case selection for the performance of primary angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary angioplasty and for the selection of patients in need of transfer for emergency aortocoronary bypass surgery are shown in Table 5.
9. There must be an ongoing program of outcomes analysis and formalized periodic case review.
10. Institutions should participate in a 3- to 6-month period of implementation, during which time the development of a formalized primary PCI program is instituted that includes establishing standards, training staff, developing detailed logistics and creating a quality assessment and error management system.

From Smith et al. \( (6) \), by permission of the American College of Cardiology and American Heart Association.

IABP = intra-aortic balloon pump; PCI = percutaneous coronary intervention.

### Table 5. Patient Selection for Angioplasty and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:
- Significant stenosis \( (\geq 60\%) \) of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system, which might be disrupted by the angioplasty catheter
- Extremely long or angulated infarct-related lesions with TIMI flow grade 3
- Infarct-related lesions with TIMI flow grade 3 in patients in a stable condition with triple-vessel disease
- Infarct-related lesions of small or secondary vessels
- Lesions in other than the infarct-related artery
- Transfer for emergency aortocoronary bypass surgery of those patients who have:
  - High-grade residual left main or multivessel coronary artery disease and clinical or hemodynamic instability (after angioplasty of occluded vessels and preferably with intra-aortic balloon pump support)

From Smith et al. \( (6) \), by permission of the American College of Cardiology and American Heart Association.

TIMI = Thrombolysis In Myocardial Infarction.

Thus, all these studies suggest a distinct volume–outcome relationship for patients undergoing primary PCI.

The successful performance of primary PCI requires an integrated approach involving physicians, allied health staff and the logistic constraints of the institution. At some centers, a strategy of prompt thrombolytic therapy in the emergency department may be preferable to the adoption of a policy of primary PCI without on-site cardiac surgery. Most likely, the ability to perform primary PCI rapidly and effectively in community hospitals without on-site surgery would be highly variable. A prerequisite for embarking on such a policy should be the development of systems that address the logistic issues, which vary among institutions. Another requirement for the performance of primary PCI without on-site cardiac surgery should be the continuous analysis of all aspects of such a program, including the time to treatment and clinical and procedural outcomes. The recent ACC/AHA guidelines recommend essential components of a successful program of PCI at a hospital without on-site cardiac surgical services \( (6) \) (Tables 4 and 5).

**Conclusions.** Primary PCI in qualified community hospitals without on-site cardiac surgery appears to be safe and effective and may be the best reperfusion therapy. However, it is unknown to what extent this will be a practical and effective approach for the majority of community hospitals in the U.S. and abroad. This area of intervention provides a great opportunity for evidence-based medicine and translational research to determine which method of reperfusion is best suited for a particular institution.

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