Use of Direct Angioplasty for Treatment of Patients With Acute Myocardial Infarction in Hospitals With and Without On-Site Cardiac Surgery

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Background. In the Myocardial Infarction, Triage, and Intervention (MITI) registry of acute myocardial infarction, 441 (12%) of 3750 patients had direct angioplasty as initial treatment. Approximately half (233) were performed in hospitals with no on-site surgery.

Methods and Results. Procedure success rates, use of emergent surgery, and factors influencing outcome were compared in both angioplasty groups as well as with 653 patients treated with thrombolytic therapy in the same hospitals. There was no difference in baseline characteristics between patient groups treated by angioplasty in the two types of hospitals. Patency was established in 88% of patients. Only 1.4% underwent emergent surgery. Overall, survival was 93% but was significantly worse after a failed procedure in all ECG and hemodynamic subsets as well as in those with prior bypass surgery. In a multivariate analysis, age, initial heart rate, blood pressure, and prior bypass surgery but not type of hospital were predictive of survival. Survival rates were similar, but there tended to be fewer strokes (0.6% versus 2.1%, P=.12), shorter hospital stays (7.0 versus 8.1 days, P<.001), and less recurrent ischemia (20% versus 30%, P=.009) in patients treated by angioplasty compared with thrombolysis. Readmission and reinfarction rates were similar for both treatments.

Conclusions. Observations from this community registry suggest that mortality after direct angioplasty is low and the use of emergent surgery is infrequent. Outcome in this registry study was dependent on initial hemodynamic findings and infarct location but not on the presence of on-site surgery. Compared with thrombolytic therapy, the incidence of complications was the same or lower, but this needs confirmation in randomized trials. (Circulation. 1993;88[part 1]:2067-2075.)

Key Words  •  myocardial infarction  •  coronary angioplasty  •  thrombolytic therapy

There is considerable controversy regarding the optimal approach to reestablish perfusion in patients with acute coronary thrombosis and myocardial infarction.1-4 Several controlled trials have shown a reduction in mortality in selected patients with acute myocardial infarction treated with thrombolytic therapy.5-8 However, similar controlled evaluations of outcome of patients treated by emergent direct coronary angioplasty have been few in number and small in size.9-11 Proponents of direct angioplasty point out that this procedure leads to more rapid and complete coronary reperfusion, that there may be a lower risk of serious bleeding, particularly intracranial hemorrhage and stroke, and furthermore, that this approach may be more cost-effective than medical treatment, since early definition of the coronary anatomy and ventricular function may obviate the need for much noninvasive testing and reduce the length of hospitalization. Also, reports of patients with shock and who are treated by direct angioplasty suggest that this means of reperfusion may be particularly effective in this subset.12-16 On the other hand, the routine use of direct angioplasty to treat patients with acute myocardial infarction is inherently limited; even in the United States, no more than 50% of moderate-sized hospitals (200 beds or more) have angiography laboratories, and still fewer are prepared with experienced support staff to provide this treatment in a timely and safe manner on a 24-hour basis. Although the use of direct angioplasty for treatment of acute myocardial infarction appears promising, inherently complex logistics associated with this approach, the possible need for additional procedures to treat restenosis, the lack of long-term outcome, and cost comparisons for this treatment versus thrombolytic drug treatment have tempered enthusiasm for this approach.

Over the past decade, as the population in suburban areas has increased, there has been a proliferation of diagnostic coronary angiographic facilities in medium-sized hospitals, many of which do not have on-site cardiac surgical capability. Emergent direct angioplasty has been used to treat patients with acute myocardial infarction in many such hospitals despite the small
number of studies assessing either safety or efficacy of this approach. This approach has been justified because of the general perception that direct angioplasty, like thrombolytic therapy, should be carried out as rapidly as possible to maximize its potential benefit in reducing the extent of infarction and complications after acute infarction. Also, treatment by direct angioplasty may be more effective with fewer complications, most notably, fewer strokes, than treatment with thrombolytic drugs. Last, there is a general belief that if the artery is occluded, there is minimal likelihood of making the situation worse. It has been assumed that the requirement for emergent surgery is unusual after direct angioplasty, being primarily used to treat residual high-risk anatomy, but not because direct angioplasty has made the condition worse.

Clearly, these perceptions may be incorrect, and results of direct angioplasty in general clinical practice may not be typical of those published from large centers with highly experienced operators. Although regulatory constraints have required the conduct of large controlled studies of thrombolytic drugs and thereby enhanced our understanding of their effectiveness for treatment of acute infarction, the use of direct coronary angioplasty has instead been driven by promising results of small published series and regional standards of care.

The Myocardial Infarction, Triage, and Intervention (MITI) Project includes a registry of consecutive patients with acute myocardial infarction admitted to hospitals in the Seattle metropolitan area. The purpose of this study is to describe the frequency, results, and outcome of patients treated by direct angioplasty in hospitals with and without on-site surgery and to contrast these findings to those in patients treated in the same hospitals with thrombolytic drugs.

**Methods**

*Data Acquisition and Characteristics of the Project*

The MITI Project, initiated in 1988, includes baseline and outcome data on all patients with suspected acute myocardial infarction admitted to hospitals in the Seattle metropolitan area (population approximately 1.7 million). Both coronary care unit and emergency department patient admission logs are reviewed frequently to identify all patients with suspected myocardial infarction. The collaborative efforts by the individual hospitals and practitioners in these 17 hospitals provide data on approximately 8000 admissions each year, of which approximately 2200 have evidence of acute infarction. From this point of entry, all subsequent data retrieval (prehospital and hospital medical records, ECG, survival, and readmission data) are tracked by a unique computerized method enabling several sources of data, including readmissions to other hospitals, to be identified and added to the patientspecific file. Research assistants independent of the hospitals review each record to determine patient demographics and, in the subset of patients with hospital evidence of acute infarction, to abstract detailed clinical histories, treatments delivered, complications, and mortality. Details of this project, the data abstraction process, and accuracy, have been reported previously.17-19

**Patients in This Study**

This report includes all patients admitted to the 10 hospitals having coronary angiography facilities. Five of the hospitals have coronary angiography laboratories but no on-site cardiac surgery. In these hospitals, diagnostic angiography is done routinely and coronary angioplasty done only in the setting of acute myocardial infarction. Five other hospitals have the capability for both angiography and cardiac surgery on site. The cardiologists who perform direct angioplasty in the former type of hospital also perform elective coronary angioplasty in tertiary facilities and therefore are familiar with the operation, logistics, and personnel in the nearby tertiary facilities, which are no more than 10 miles away. Both types of hospitals have intra-aortic balloon pumps. Investigational angioplasty catheters and devices were generally not available. The period of study includes 36 months, ending in December of 1990. Survival data are available through December 1991 (follow-up available in 97%). All patients admitted for suspected myocardial infarction and who received either thrombolytic therapy or direct angioplasty within 6 hours of admission in these 10 hospitals are considered in this report. Patients with myocardial infarction as a consequence of other hospital illnesses, eg, after surgery, as well as those developing myocardial infarction after hospitalization for unstable angina are not considered. In addition, patients who were initially treated with thrombolytic therapy and who also underwent angioplasty within 6 hours of admission are not included in the direct angioplasty groups. Patients receiving treatment with thrombolytic drugs (within 6 hours of admission) in those 10 hospitals are included in this analysis for the purpose of comparison.

Each hospital record was reviewed to determine age, sex, and history of myocardial infarction, congestive heart failure, angina, hypertension, coronary bypass surgery, the type of treatment delivered after admission, the use of emergent coronary surgery or other procedures, and hospital length of stay. In addition, vital signs at the time of admission were tabulated for all patients. The admitting ECG was reviewed, and the type and location of ST abnormalities were recorded. ST elevation in leads II, III, and aVF was designated inferior; whereas ST elevation in V1-V3, was designated anterior infarction. In cases with ST elevation in I, aVF, or V1-V6, the location was designated anterior unless ST elevation was also present in II, III, or aVF, in which case it was designated inferior. The angiographic results were reviewed and coronary patency was classified successful when TIMI 2 or 3 flow was present in the infarct artery at the termination of the procedure.20

In patients in whom coronary surgery was subsequently performed, the time from a decision to transfer the patient from the cardiac catheterization laboratory to arrival in the operating room was recorded. The former was retrieved from the laboratory procedure logs and the latter from the anesthesia and surgical records.

**Analyses**

Differences in continuous variables were assessed using two-sided Student's t tests, and discrete variables were compared using \( \chi^2 \) (Yates' continuity correction
TABLE 1. Characteristics of Patients Treated With Direct Angioplasty in the Two Types of Hospital Facilities and in Patients Treated With Thrombolytic Therapy in the Same Group of Hospitals

<table>
<thead>
<tr>
<th></th>
<th>No On-Site Surgery (n=233)</th>
<th>Direct Angioplasty On-Site Surgery (n=208)</th>
<th>All (n=441)</th>
<th>Thrombolytic Drug Treatment (n=653)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y (X±SD)</td>
<td>59±11</td>
<td>59±11</td>
<td>59±11</td>
<td>59±11</td>
<td>.80</td>
</tr>
<tr>
<td>Men, %</td>
<td>80%</td>
<td>76%</td>
<td>78%</td>
<td>80%</td>
<td>.61</td>
</tr>
<tr>
<td>Prior cardiac histories, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina</td>
<td>31%</td>
<td>31%</td>
<td>31%</td>
<td>40%</td>
<td>.005</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>18%</td>
<td>21%</td>
<td>19%</td>
<td>24%</td>
<td>.09</td>
</tr>
<tr>
<td>Congestive failure</td>
<td>2%</td>
<td>6%</td>
<td>4%</td>
<td>5%</td>
<td>.43</td>
</tr>
<tr>
<td>Hypertension</td>
<td>36%</td>
<td>37%</td>
<td>41%</td>
<td>39%</td>
<td>.48</td>
</tr>
<tr>
<td>Coronary Surgery</td>
<td>7%</td>
<td>9%</td>
<td>8%</td>
<td>8%</td>
<td>.96</td>
</tr>
<tr>
<td>Duration of symptoms before admission, h (median, 25th, and 75th percentiles)</td>
<td>1.5, 0.9-2.3</td>
<td>1.6, 1.0-2.6</td>
<td>1.6, 1.0-2.5</td>
<td>1.5, 1.0-2.3</td>
<td>.78</td>
</tr>
<tr>
<td>Heart rate, bpm (X±SD)</td>
<td>77±20</td>
<td>76±18</td>
<td>76±19</td>
<td>76±17</td>
<td>.57</td>
</tr>
<tr>
<td>Systolic blood pressure, bpm (X±SD)</td>
<td>137±31</td>
<td>135±31</td>
<td>136±31</td>
<td>133±28</td>
<td>.11</td>
</tr>
<tr>
<td>Hypotensive on admission, % (BP &lt;100 mm Hg)</td>
<td>13%</td>
<td>15%</td>
<td>14%</td>
<td>13%</td>
<td>.68</td>
</tr>
<tr>
<td>Shock on admission, %</td>
<td>4.7%</td>
<td>3.8%</td>
<td>4.3%</td>
<td>2.6%</td>
<td>.12</td>
</tr>
<tr>
<td>Electrocardiographic findings, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior ST elevation</td>
<td>32%</td>
<td>34%</td>
<td>33%</td>
<td>38%</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Inferior ST elevation</td>
<td>47%</td>
<td>53%</td>
<td>50%</td>
<td>55%</td>
<td></td>
</tr>
<tr>
<td>Bundle branch block</td>
<td>4%</td>
<td>3%</td>
<td>3%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Other abnormality</td>
<td>17%</td>
<td>11%</td>
<td>13%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Thrombolyis eligible†</td>
<td>82%</td>
<td>74%</td>
<td>78%</td>
<td>87%</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Admission to treatment time, min (median, 25th, and 75th percentiles)</td>
<td>77, 54-135</td>
<td>80, 54-122</td>
<td>79, 55-129</td>
<td>39, 15-70</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>103±73</td>
<td>101±72</td>
<td>102±72</td>
<td>54±58</td>
<td></td>
</tr>
</tbody>
</table>

BP indicates blood pressure and bpm, beats per minute.
*Based on comparison of 441 angioplasty patients with 653 thrombolysis patients.
†Excludes patients without ST elevation or history of bypass surgery.

was used where appropriate). Multivariate logistic regression analysis was used to adjust for possible differences in baseline clinical characteristics to determine the effect of on-site surgery on outcome. Life table survival analysis was used to assess outcome differences between treatment groups in the year after admission.

Results

Characteristics of the Treatment Groups

Four hundred forty-one (12%) of 3750 consecutive patients admitted with acute myocardial infarction in these hospitals underwent direct angioplasty. In addition, 653 (17%) patients in these same 10 hospitals were initially treated for acute myocardial infarction using thrombolytic therapy. The use of direct angioplasty to treat acute infarction among individual hospitals ranged from 1% to 45% of patients. The use of thrombolytic drug treatment exhibited an inverse relation to direct angioplasty in these same hospitals—ranging from a high of 32% in one hospital where thrombolytic therapy was the preferred treatment to a low of 5% in a hospital where angioplasty was preferred. Table 1 shows the baseline characteristics of patients undergoing direct angioplasty at the two institution types as well as in the reference group of patients treated with thrombolytic drugs. The median age for the three groups of patients was essentially the same, about 59 years. The proportion of women (20%) in the three treatment groups was also similar. Likewise, the median duration (+/− 75% CI) of symptoms until hospital admission was almost identical (median of 1.6 [1.0 to 2.5] hours) for angioplasty-treated patients and 1.5 (1.0 to 2.3) for those treated with thrombolytic drugs. The incidence of prior myocardial infarction, congestive heart failure, and previous coronary bypass surgery was also similar for both groups treated by angioplasty and the group treated with thrombolysis. There was no significant difference in baseline hemodynamic findings between groups; about 1 in 6 patients had hypotensive (blood pressure <100 mm Hg) on admission. A history of angina was more common in the thrombolysis-treated group (40% versus 31%, P=.005). Approximately one third of patients had
Procedure with cardiogram. There was a somewhat higher proportion of patients with initial nondiagnostic ECGs in the group treated by direct angioplasty (Table 1). Although the majority of patients receiving both treatments would meet the past strict eligibility criteria for thrombolytic trials, there was a somewhat more heterogenous population of patients treated by angioplasty. Sixty-two percent of those treated by angioplasty and 76% treated by thrombolysis were ≤75 years of age, had ST elevation, and were hemodynamically stable (no shock or systolic blood pressure ≤100 mm Hg) at the time of admission (P<.001). Using less selective criteria, 78% of those treated by angioplasty and 87% of those treated with thrombolytic drugs had ST elevation on the initial ECG and no history of bypass surgery.

Procedure Success Rates and Outcome

The median time from admission until direct angioplasty was 80 minutes in hospitals without and 77 minutes in hospitals with on-site surgery (Table 1). These times were significantly longer than the time to administration of the first bolus of thrombolytic therapy (39 minutes) in the 653 patients treated with drug therapy (P<.01).

The overall procedural success rate (TIMI 2 or 3 flow) was 88% (84% in those patients whose initial blood pressure was ≤100 mm Hg). The angioplasty success rates averaged 93% for inferior infarction, 85% for anterior infarction, and 92% for patients with nondiagnostic ECG changes. Procedure success rates were considerably lower (68%) in patients with prior coronary bypass graft surgery.

Table 2 shows 30-day and 1-year survival rates for patients treated by direct angioplasty and compares the outcome in patients with successful and failed direct angioplasty in the subsets with initial ST elevation, those with nondiagnostic ECG changes, and in patients with a history of bypass surgery. Failure to reestablish patency was associated with worse outcome in each group, including both anterior and inferior infarction. Thirty-day mortality rates for all patients undergoing direct angioplasty were 7%; 4% in patients having a successful procedure and 28% mortality in the 53 patients who failed to reperfuse (P<.0001, Fig 1). It is noteworthy that almost a third (29%) of the failed procedures occurred in patients with a history of coronary surgery.

The outcome of patients with initial nondiagnostic ECGs treated by direct angioplasty was similar to patients with inferior ST segment elevation (Table 2). The overall 30-day survival rates for anterior infarction were 91%; for inferior infarction, 96%; and for those with nondiagnostic ECGs, 95%. Fig 1 shows 30-day outcome for patients treated with direct angioplasty by initial hemodynamic findings (tachycardia and hypotension). Eighty percent of patients who were initially hypotensive and who had failed direct angioplasty died compared with only a 10% mortality rates when the procedure was successful (P<.0001).

Outcome in Patients Treated at the Two Types of Hospitals

The overall hospital mortality rate for the 233 patients undergoing direct angioplasty in hospitals with no on-site surgery was 5.6% (95% CI, 2.6% to 8.6%)
compared with 8.2% (95% CI, 4.6% to 10%) in the patients treated in tertiary cardiac hospitals. As there may have been reluctance to transfer patients to a tertiary hospital from those sites without surgical backup, which in turn could have influenced survival in the days after the procedure, 1-year survival analysis was performed in an effort to detect any evidence of late mortality in the group of patients treated in hospitals with no on-site surgery (Fig 2). There was no difference in immediate or 1-year survival between the two groups of patients.

There was also no difference in outcome between the two treatment groups after covariate adjustment for baseline characteristics by multivariate logistic regression. In fact, the baseline characteristics were remarkably similar (Table 1). Clinical factors associated with in-hospital death after direct coronary angioplasty included older age, higher heart rate, and lower blood pressure (Table 3). After adjusting for these baseline characteristics, the absence of on-site surgery had no independent effect on survival.

The short- and long-term outcomes of patients meeting typical eligibility criteria for thrombolysis (ST elevation, no prior coronary surgery or shock) who were treated by direct angioplasty were remarkably similar to those in patients treated with thrombolytic therapy. The 1-year survival rates for both treatments (with and without adjustment for baseline characteristics) were virtually identical (Fig 3). There was a trend toward fewer strokes after direct angioplasty (0.6%; 95% CI, 0 to 1.4) compared with thrombolytic therapy (2.1%; 95% CI, 0.9 to 3.3) (P=.12); however, the confidence limits overlap and the incidence of stroke in thrombolysis-treated patients is somewhat higher than in previous reports. The incidence of recurrent ischemia was 20% in those treated by direct angioplasty compared with 30% in those treated with thrombolysis (P=.009). In the small subset of patients at high risk (age >75 years, shock or systolic pressure <100 mm Hg, or prior bypass surgery), mortality was 18% in patients treated by angioplasty and 16% in those treated with thrombolytic drugs.

The median hospital stay for patients treated by direct angioplasty was 7.0 days (95% CI, 6.6 to 7.4) and 8.1 days (95% CI, 7.6 to 8.6) in patients treated with thrombolysis (P<.001). During the year of follow-up, there was no significant difference in the number of admissions for either suspected or documented myocardial infarction in the comparable thrombolysis-eligible patients treated by direct angioplasty and thrombolytic drugs (see Figs 4 and 5).
TABLE 3. Multivariate Analysis of Factors Associated With In-Hospital Mortality in All Patients Treated by Direct Angioplasty for Acute Myocardial Infarction

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds of Death</th>
<th>95% Confidence Interval</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age per 10-γ Increase</td>
<td>2.4</td>
<td>1.4, 4.0</td>
<td>.001</td>
</tr>
<tr>
<td>Heart rate &gt;100 bpm</td>
<td>3.2</td>
<td>1.0, 10.0</td>
<td>.04</td>
</tr>
<tr>
<td>Systolic BP ≤100 mm Hg</td>
<td>8.0</td>
<td>3.0, 21.5</td>
<td>.0001</td>
</tr>
<tr>
<td>Prior coronary surgery</td>
<td>6.4</td>
<td>2.0, 20.3</td>
<td>.002</td>
</tr>
<tr>
<td>Location of Infarct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior ST elevation</td>
<td>2.5</td>
<td>0.6, 10.6</td>
<td>.22</td>
</tr>
<tr>
<td>Inferior ST elevation</td>
<td>1.4</td>
<td>0.3, 6.0</td>
<td>.63</td>
</tr>
<tr>
<td>Direct angioplasty without on-site surgery</td>
<td>0.8</td>
<td>0.3, 2.0</td>
<td>.63</td>
</tr>
</tbody>
</table>

n=441. BP indicates blood pressure and bpm, beats per minute.

Use of Emergent Surgery and Procedure-Related Mortality

Of those treated with direct angioplasty, only 6 (1.4%) patients underwent emergent surgery (performed within 6 hours of catheterization): 1 from a hospital without on-site surgery and 5 in tertiary cardiac facilities. For reference, in the group of patients treated with thrombolytic therapy, 18% of patients had emergent angiography, 6% had "rescue" angioplasty, and less than 1% of those treated were sent for emergent surgery. Of the 6 patients receiving emergent coronary surgery after direct angioplasty, 3 patients had multi-vessel coronary disease and continued to be symptomatic after coronary patency had been reestablished with angioplasty. The other 3 failed to maintain perfusion after several balloon inflations, including 1 who had severe acute mitral regurgitation. One patient was pulseless during attempted angiography and angioplasty. He underwent surgery (at the same hospital) after receiving cardiopulmonary resuscitation throughout the procedure and never recovered. In assessing the circumstances in the other 49 patients who failed to reperfuse and who did not receive emergent surgery, the stated reasons for not pursuing emergent surgery were the absence of severe symptoms at the end of the procedure (patients with relatively small myocardial areas at risk) or less commonly, the presence of severe disease and large areas of myocardial compromise but no obvious distal vessels to bypass, so that surgery was considered to be inappropriate. There did not appear to be any difference in immediate mortality in the laboratory or before discharge in patients treated at the two types of facilities to suggest that on-site surgery might have influenced outcome; in fact, it was uncommonly used in both settings. For those requiring emergent surgery, the time from the decision to transfer the patient from the laboratory to arrival in the operating room averaged 45 minutes (range, 23 to 120). The time to surgery was 43 minutes in the one patient transferred for surgery from a hospital without on-site surgery. There were 10 (2%) deaths that occurred during angiography and angioplasty: 4 in the hospitals without on-site facilities and 6 in the hospitals with on-site surgery. Nine of these 10 patients were in shock at the time of admission to hospital. Direct angioplasty failed

Fig 3. Graph of 1-year survival in patients with ST segment elevation treated by direct angioplasty (n=344) or thrombolytic therapy (n=569) (patients with prior coronary surgery and nondiagnostic ECGs are excluded). Short- and long-term outcomes are almost identical for both treatments.

Fig 4. Bar graph of in-hospital events in the comparable groups of patients treated by direct angioplasty and thrombolytic drugs (see legend, Fig 3). Complication rates were similar for both treatments. There was a trend toward a reduction in the incidence of all-cause stroke (P=.12) and a significant reduction in recurrent angina (P=.009) in patients treated by direct angioplasty.
to reestablish coronary perfusion in all nine. One other patient who died was also admitted with hypotension and pulmonary congestion but improved after successful restoration of coronary flow. Almost immediately after the procedure and upon admission to the coronary care unit, he developed recurrence of chest pain and hypotension and died within a few minutes.

Discussion

In the past 15 years, many suburban hospitals have established diagnostic angioplasty laboratories, and many cardiologists use these hospitals to perform diagnostic angiography and use tertiary facilities to perform coronary angioplasty procedures in patients transferred for this purpose. These “secondary” hospitals are often closest to the population that develops acute infarction and therefore important “front line” facilities. Since publication of the joint AHA-ACC guidelines for the performance of coronary angioplasty, which suggested that this procedure should only be done in hospitals with on-site surgery (even in emergent situations), there has been considerable concern that the additional delay associated with transfer may put these patients at risk to greater harm.25 During the period of study, direct angioplasty was performed in Seattle area hospitals with and without on-site surgery. The metropolitan area spans 40 miles in one direction and tertiary hospitals are within 10 miles of each hospital not having on-site surgery. It is also important to note that the operators in these latter facilities also perform elective angioplasty at one or more of the tertiary hospitals and thus are familiar with both the surgical staff and logistics of these sites. No one confined their use of angioplasty solely to the setting of emergent cases. Although highly variable, each operator performed an average of 67 angioplasty procedures each year (range, 29 to 200). The indications for direct angioplasty sometimes included initial hemodynamic instability or contraindicating factors for treatment with thrombolytic drugs. Such complicating factors were present in 31% of the patients treated by direct angioplasty. In the majority of instances, however, the procedure was performed simply because of physician preference for this treatment. That is, about three quarters of patients treated by angioplasty appeared also to be eligible to receive thrombolytic drugs.

The baseline characteristics of the two patient groups (on-site and no on-site surgery) were remarkably similar. Fourteen percent of patients treated by direct angioplasty had evidence of profound hypotension on admission to hospital. Indeed, many of these attempts were aimed at salvaging life, and frequently (84% of the time in hypotensive patients) they were successful, with 90% survival. Whether any of those hypotensive patients who survived would have in turn been lost because of the delay associated with transfer to a tertiary facility is unknown. Mortality in the angiographic laboratory was 3% and occurred exclusively in patients presenting with hypotension and shock. There was also no apparent difference in mortality at the end of 1 day, at the time of discharge, or at 1 year between patients treated with direct angioplasty in the two types of centers, suggesting that appropriate initial triage to surgery was equally provided and not withheld from patients treated at the facilities with no on-site surgery. Overall procedure success rates were 88%, although considerably less in patients with prior bypass surgery. Failure to reestablish coronary perfusion with direct angioplasty was associated with much higher mortality rate in both patients with anterior and inferior ST segment elevation as well as in those with initial nondiagnostic ECG changes. Angioplasty failure was particularly associated with high mortality in patients with prior bypass surgery and in those who were hypotensive at the time of admission.

In a multivariate analysis of outcome after direct angioplasty, age, initial heart rate and blood pressure at the time of admission, and prior bypass surgery were each independent predictors of in-hospital mortality. There was, however, no independent effect of the type of hospital facility (with or without on-site surgery) on the outcome of patients having direct angioplasty. Although these data support the contention that direct angioplasty for treatment of acute infarction without on-site surgery is feasible, the size of the study is inadequate to detect very small differences in mortality rates. On the other hand, the study is large enough to detect a 6% excess in mortality for those institutions without surgical standby.

Emergent surgery in patients treated with direct angioplasty was infrequent (1.4%). This rate is consistent with many other reports in which surgery was immediately available on site.26-33 It was primarily performed to treat patients with continued symptoms and multivessel coronary disease after a successful angioplasty or in patients with failed angioplasty who continued to be compromised and had anatomy potentially suitable for bypass. It was not used because of complications induced by the procedure.

Long-term outcome for patients treated with direct angioplasty with ST segment elevation was as good as or equal to that in patients treated with thrombolytic therapy. In the subset of patients treated by direct angioplasty meeting typical thrombolytic eligibility criteria, there was a reduction in the incidence of spontaneous recurrent ischemia after direct angioplasty compared with treatment with thrombolytic therapy. This is
consistent with the findings of others.9,10 The length of hospital stay was also shorter for patients treated by direct angioplasty. The reasons for this difference are unknown. It could be the result of fewer episodes of spontaneous ischemia, which in turn prolonged hospitalization, or possibly that there was less subsequent diagnostic testing in the angioplasty group in which coronary anatomy and left ventricular function were already known. This current study is limited in our ability to control for all factors associated with thrombolysis eligibility such as a detailed assessment of prior bleeding or neurologic illness, which could influence the results of the treatment comparisons presented. Our primary interest was evaluating direct angioplasty in the two types of hospitals, and the observational outcomes for thrombolysis are presented to help reference event rates in unselected patients. More appropriately designed studies are required that ensure case equivalence and that attempt to control for the possible bias attendant with an open study to accurately measure the initial and subsequent costs and needs for hospitalization for the two treatments.

It should be recognized that the comparisons of outcome in the two types of sites and between the two types of reperfusion methods are observational in nature. Although we adjusted for all possible known differences in baseline characteristics by multivariate analysis, it is possible that other unrecognized factors could have influenced outcome. The results in this study, however, are consistent with other small randomized trials.9,10 Larger studies will be required to accurately assess whether there are advantages afforded by direct angioplasty with regard to death, stroke, and other less common clinical events.

The role of direct angioplasty for treatment of acute myocardial infarction in sites without on-site surgery may be most important in the subset of patients admitted with congestive heart failure, hypotension, and nondiagnostic ECG, or in those with findings typical of acute coronary thrombosis but who are at apparent risk for serious bleeding if treated with thrombolytic drugs. Case series of patients admitted to hospitals with hypotension and shock and treated with direct angioplasty suggest that emergent direct angioplasty may be superior to treatment with thrombolytic drugs in this subset.14-17 There are now initial reports comparing direct angioplasty with thrombolytic therapy in patients eligible for both treatments, but no controlled evaluations of direct angioplasty have been carried out in patients with acute myocardial infarction who are not typical thrombolysis candidates. These patients account for at least half of all patients admitted with acute infarction and therefore seem particularly well suited for investigation into the treatment effectiveness of direct angioplasty. If direct angioplasty is to be used and time to treatment is an important determinant of myocardial salvage and mortality, it seems counterintuitive to defer treatment of patients admitted to hospitals without coronary surgery backup until they can be transferred to a tertiary facility unless, of course, there is an inadequately trained staff at the admitting hospital to care for the patient and perform the procedure or if surgery would be required in a substantial proportion of patients in order to ensure safety. The delay with transfer might be particularly important for patients who are initially hypotensive and unstable. Also, in many instances, tertiary centers and laboratories are frequently full with elective cases, so that the delay associated with emergent transfer is not inconsequential. For many cases undergoing direct angioplasty in tertiary centers, the provision for surgery is relatively informal. Serious complications after elective coronary angioplasty cannot be accurately predicted for individual patients and frequently are due to acute occlusion in patients whose coronary anatomy suggested low risk.21-24 Thus, some delay until surgery is almost inevitable, even when available on-site. In the setting of emergent angioplasty, the delay associated with inter-hospital transfer may not be substantially longer, provided a plan enabling immediate transfer to surgery is in place.

Conclusions

These data show that direct angioplasty is a feasible treatment for patients with acute infarction admitted to hospitals with and without on-site surgery. The use of emergent surgery is infrequent after direct angioplasty and when used is primarily for the treatment of multi-vessel disease associated with hypotension that fails to respond to attempts at reperfusion by direct angioplasty. It is important to note, however, that these secondary care hospitals were staffed by operators who performed direct angioplasty in these hospitals and also routinely performed elective angioplasty at nearby tertiary centers. Thus, these cardiologists were not only experienced but were familiar with the logistics and surgical personnel at the tertiary sites. Provided operators are experienced, practice in a similar setting, and have a plan for emergent transfer if needed, direct angioplasty in hospitals without on-site surgery is feasible and may be beneficial, particularly in patients with hypotension or nondiagnostic ECG abnormalities or patients with contraindications to treatment with thrombolysis. These findings should not be used to support the use of direct angioplasty by operators who might do only emergent procedures or in sites that have no close liaison with a nearby surgical facility. Unless angioplasty is consistently shown to be superior to treatment with thrombolytic drugs, it would also seem that in sites not having immediate surgical backup, angioplasty should be reserved for the treatment of hemodynamically compromised patients or those who are not eligible for treatment with thrombolytic drugs. It may be in the patient's best interest to permit the use of angioplasty in these selected circumstances rather than developing more low-volume surgical programs in order to permit the use of angioplasty in these settings.

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