Impact of Delays to Cardiac Surgery After Failed Angioplasty and Stenting

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OBJECTIVES
This study was designed to determine the likelihood of harm in patients having additional delays before urgent coronary artery bypass graft (UCABG) surgery after percutaneous coronary intervention (PCI).

BACKGROUND
Patients who have PCI at hospitals without cardiac surgery have additional delays to surgery when UCABG is indicated.

METHODS
Detailed chart review was performed on all patients who had a failed PCI leading to UCABG at a large tertiary care hospital. A prespecified set of criteria (hemodynamic instability, coronary perforation with significant effusion or tamponade, or severe ischemia) was used to identify patients who would have an increased likelihood of harm with additional delays to surgery.

RESULTS
From 1996 to 2000, 6,582 PCIs were performed. There were 45 patients (0.7%) identified to have UCABG. The demographic characteristics of the UCABG patients were similar to the rest of the patients in the PCI database, except for significantly more type C lesions (45.3% vs. 25.0%, p < 0.001) and more urgent cases (66.6% vs. 49.8%, p = 0.03) in patients with UCABG. Myocardial infarction occurred in eight patients (17.0%) after UCABG, with a mean peak creatine kinase of 2,445 ± 1,212 IU/l. Death during the index hospital admission occurred in two patients. Eleven of the 45 patients (24.4%) were identified by the prespecified criteria to be at high likelihood of harm with additional delays to surgery. The absolute risk of harm is approximately one to two patients per 1,000 PCIs.

CONCLUSIONS
Approximately one in four patients referred for UCABG would be placed at increased risk of harm if delays to surgery were encountered. (J Am Coll Cardiol 2004;43:337–42) © 2004 by the American College of Cardiology Foundation

The role of percutaneous coronary intervention (PCI) in the management of cardiac patients has expanded tremendously since its introduction in 1977. Improvements in both operator experience and techniques have led to a significant reduction in failed or complicated PCI leading to urgent coronary artery bypass graft (UCABG) surgery (1,2). However, the acuity and risk profile of patients undergoing PCI have also increased, resulting in more cases of cardiogenic shock, non–ST-elevation acute coronary syndromes, acute myocardial infarctions (AMIs), and elderly patients with extensive co-morbidities (3).

With the availability of stents and the increased demand for coronary interventions, there has been growing interest in stand-alone angioplasty for primary and elective cases (4). However, the current standard of practice in North America and the most recent American College of Cardiology/American Heart Association (ACC/AHA) guidelines clearly advocate the presence of on-site surgical services for performance of PCI. Evidence of harm has been suggested for patients undergoing elective PCI in centers without cardiac surgical availability (5).

The published literature reviewing the impact of on-site surgical availability for patients who require UCABG after failed PCI is limited (6–8). More recent data from large European registries and primary angioplasty trials suggest acceptable risk with stand-alone angioplasty in selected patients (9). However, several important subgroups of patients requiring UCABG, including the severely hemodynamically compromised, only have a chance at survival in centers with on-site cardiac surgery (10,11). Patients transferred for UCABG from community PCI programs without on-site surgical services have significant delays to surgery (6,9). An increased incidence of perioperative infarction and death has been reported with delays to surgery for failed PCI (12,13).

Data recently presented in more than 100,000 consecutive patients undergoing PCI from the ACC–National Cardiovascular Data Registry (ACC–NCDR) revealed that “the need for UCABG after failed PCI is still unpredictable” (14). Therefore, controversy continues about the safety and logistics of allowing elective angioplasty in centers without cardiac surgery (15,16). In this study, we have undertaken a review of all our PCI procedures in the current era of high stent availability to assess the potential number
of patients referred for UCABG after failed PCI who would have been adversely affected by delays related to transfer.

**METHODS**

From April 1996 to December 2000 in the University Health Network in Toronto, Canada, clinical and procedural data of all patients (n = 6,582) who had undergone PCI were prospectively collected and entered into a database. All clinical events after the index PCI were documented until hospital discharge. All patients (n = 47) who had cardiac surgery in the same admission as the index PCI had a detailed review of their medical and operative notes. We will use the term UCABG (n = 45) to refer to patients who met the ACC/AHA classification of urgent or emergent need for bypass surgery after failed PCI (ongoing ischemia despite maximal medical therapy with or without intra-aortic balloon pump, AMI within 24 h of PCI, cardiogenic shock, or minimal chance of further clinical deterioration). Two patients who had CABG during their index PCI did not qualify for the ACC/AHA UCABG definition. In these two patients, CABG was done for convenience rather than to "minimize further clinical deterioration."

To determine the potential risk of not having immediate surgical availability, a prespecified set of criteria was designed to identify patients that would have a high likelihood of harm from the additional delay related to transfer. The prespecified criteria were hemodynamic instability (blood pressure <90 mm Hg or blood pressure ≥90 mm Hg with inotropic support), severe ischemia (new ST-elevation or persistent ST-depression ≥1 mm), and coronary perforation with effusion or tamponade. We designed the prespecified criteria after reviewing the published literature related to complications of PCI patients who had CABG (17,19). Patients who became hemodynamically unstable after a failed PCI generally have a limited reserve to withstand delays to surgery.

Hemodynamic instability has been shown to be the most important predictor of survival after failed PCI in patients having UCABG (17,19). Patients who become hemodynamically unstable after a failed PCI generally have a limited reserve to withstand delays to surgery.

All patients who died as a complication of PCI were also reviewed to exclude the possibility of a death occurring before a planned surgical intervention or referral. No deaths occurred before surgery among patients felt to be suitable for UCABG.

Complications of UCABG that were uniformly recorded were MI and death. Patients with creatine kinase (CK) ≥5 times the upper limit of normal or new Q waves (≥0.04 s duration in two leads) within 24 h of the urgent bypass surgery were defined as having had an MI. In-hospital death was defined as death occurring during hospitalization for the index UCABG.

**Statistical analysis.** Continuous variables are presented as means ± SD and categorical data as frequencies and percentages. The chi-square test was used to assess statistical significance between categorical variables and the paired t test was used for continuous variables. A p value <0.05 was used for statistical significance.

**RESULTS**

A total of 6,582 PCIs were completed from April 1996 to December 2000. Forty-five patients (0.7%) required UCABG after failed PCI. Clinical and angiographic characteristics of PCI patients are shown in Table 1 and Figure 1. The clinical characteristics of patients who had UCABG after failed PCI were similar to patients without UCABG, except for significantly more urgent PCI cases (66.6% vs. 49.8%, p = 0.03) and a trend of fewer prior CABG (4.4% vs. 16.0%, p = 0.06).

Patients who subsequently had UCABG after a failed PCI were more likely to have increased lesion complexity. The UCABG group had significantly more Type C lesions (45.3% vs. 25.0%, p < 0.001) and fewer Type A lesions (0% vs. 6.7%, p = 0.03) compared with controls. Stent deployment increased from 60.0% in 1996 to 90.2% in 2000.

By comparison with the UCABG definition, the prespecified criteria identified 11 (24.4%) of the 45 patients to be at high likelihood of harm with additional delays to surgery. The UCABG patients with the prespecified criteria had more ECG changes, chest pain, inotropic use, type B2/C lesions, and surprisingly, more cases of elective PCI (45.4% vs. 19.4%) (Table 2). Nineteen patients were taken to the OR within 2 h, and 15 waited at least 12 h (Fig. 2).
The majority (55.6%) of patients with UCABG had surgery started within 4 h of consultation. In particular, all 11 patients who met the prespecified criteria were taken to the operating room within 2 h of consultation. The median and maximum CK were also higher in the group with the prespecified criteria (2,910, 4,680 IU/l vs. 2,335, 2,890 IU/l).

The reasons for inclusion into the prespecified criteria included severe ischemia (n = 4), effusion or tamponade (n = 3), and hemodynamic instability (n = 4). As expected, this number is a more conservative estimate of risk than the urgent/emergent status used by the ACC/AHA classification (UCABG). Therefore, even when a relatively conservative risk is estimated, one-quarter of patients who are referred for PCI are at significant risk with additional delays to surgery.

The primary indication for surgical referral is shown in Table 3. Dissection was the most common referral indication. He was stable after his attempted PCI and surgery was started hastily because of the patient’s rapid clinical deterioration. Both patients survived and were subsequently discharged home. Two further patients required inotropic support before the start of anesthetic induction for surgery. However, all patients survived their operations and were transferred to the cardiovascular intensive care unit.

Myocardial infarction occurred in eight patients (17.8%) after UCABG with a mean peak CK of 2,445 ± 1,212 IU/l. Death during the index hospital admission occurred in two patients. The first patient had an angioplasty of a mid-right coronary artery lesion that was abandoned because of severe calcification. He was stable after his attempted PCI and underwent CABG two days later. However, he deteriorated

Table 2. Clinical, Lesion, and Outcome Characteristics of Patients With and Without the Prespecified Criteria

<table>
<thead>
<tr>
<th>Variable</th>
<th>PSC (n = 11)</th>
<th>No PSC (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest pain</td>
<td>8 (72.7%)</td>
<td>14 (38.9%)</td>
</tr>
<tr>
<td>ECG changes</td>
<td>7 (63.6%)</td>
<td>14 (38.9%)</td>
</tr>
<tr>
<td>IABP</td>
<td>9 (72.7%)</td>
<td>23 (63.9%)</td>
</tr>
<tr>
<td>Time to operating room</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 2 h</td>
<td>11 (100%)</td>
<td>8 (23.5%)</td>
</tr>
<tr>
<td>2–4 h</td>
<td>0</td>
<td>4 (11.8%)</td>
</tr>
<tr>
<td>&gt; 4 h</td>
<td>0</td>
<td>22 (64.7%)</td>
</tr>
<tr>
<td>Lesion classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B1</td>
<td>0</td>
<td>6 (11.1%)</td>
</tr>
<tr>
<td>B2</td>
<td>9 (64.3%)</td>
<td>23 (64.2%)</td>
</tr>
<tr>
<td>C</td>
<td>5 (35.7%)</td>
<td>25 (46.3%)</td>
</tr>
<tr>
<td>MI [median CK (range)]</td>
<td>2,910 (1,495–4,680)</td>
<td>2,335 (1,308–2,890)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (9.1%)</td>
<td>1 (2.8%)</td>
</tr>
</tbody>
</table>

*Mean age with standard deviation in parentheses.

CABG = coronary artery bypass grafting; CK = creatine kinase; ECG = electrocardiographic; IABP = intra-aortic balloon pump; MI = myocardial infarction; PCI = percutaneous coronary intervention; PSC = prespecified criteria; UCABG = urgent coronary artery bypass surgery.
significantly several hours post-operatively. Surgical exploration at the time of his deterioration in the cardiovascular intensive care unit revealed diffuse coronary spasm with all grafts patent. Despite extensive resuscitative efforts, he died. The second patient had severe three-vessel disease with left ventricular hypertrophy and developed severe ischemia during routine coronary angiography. Percutaneous coronary intervention was done to stabilize him for more elective surgical referral. However, during the PCI he deteriorated rapidly and was transferred to the operating room, requiring intermittent cardiopulmonary resuscitation with chest compressions. He died the following day in the cardiovascular intensive care unit of disseminated intravascular coagulation and multi-organ failure.

**DISCUSSION**

In line with recent reports and trends, the rate of UCABG at our center has been consistently below 1% for the time periods evaluated (20). Importantly, the conservative estimate derived from the prespecified criteria used in this study demonstrates that there is a potential risk of serious harm in approximately 25% of patients referred for UCABG after failed PCI if there are additional delays leading to surgery. In absolute terms, the risk of causing significant harm from transfer delays relating to offsite PCI could be estimated at one to two patients per 1,000 angioplasties (25% of the 0.7% transfer delays relating to offsite PCI could be estimated at approximately 25% of the patients referred for UCABG after failed PCI if there are additional delays leading to surgery.

In their consecutive series of more than 100,000 angioplasties, UCABG occurred with elective cases, low-angiographic-risk cases, and even “safe” total occlusions. The group reaffirmed the ACC/AHA policy that on-site emergency surgical “back-up” should remain the standard of care (14).

Several groups have previously published their experience with PCI without on-site surgical back-up (6,8,9,22,23). The early studies (1990 to 1992) had small numbers of patients and do not reflect current PCI management. The larger registry data have significant selection bias, as noted by the increased prevalence of patients with three-vessel disease and higher mortality in the centers with on-site PCI (9). The voluntary reporting and absence of data auditing also limit the generalizability of the results.

By contrast with elective PCI, several centers have reported an acceptable risk associated with primary PCI in AMI without on-site surgical back-up (24). However, the risk–benefit analysis is different in this setting than in non-primary PCI, especially with more data revealing improved outcomes with PCI versus thrombolysis for AMI (25). This has led to the revisions in the most recent ACC/AHA guidelines allowing primary PCI to be done in hospitals without on-site cardiac surgery if certain conditions are met (5). Controversy over the strict requirement of on-site surgical availability for elective PCI has promoted further research on the impact of this strategy in an era of cost containment (26). Recently, Ting et al. (27) reported their findings in 196 patients who underwent elective PCI without on-site surgical availability in the U.S. Ryan (28), in the accompanying editorial, comments that the model seen in this study is “unlikely to be replicated anywhere” and that this lack of feasibility of the structure and process of care “renders this report to be of extremely little value to health policy decision-making.” His comments are related to the three helicopters, one fixed-wing aircraft, two land ambulances, and the $200,000-a-year sophisticated telemedicine system designed for direct surgical consultation. Also, only patients of the lowest risk were accepted, leading to a 99.5% success rate and no cases of UCABG. Therefore, this study does not address the impact of on-site surgical availability for the majority of the patients who need UCABG.

Our analysis adds to the current literature in several ways. Importantly, all of the patients that were reviewed had full availability of stent use, which represents current-day prac-
tic. Published data looking at UCABG after failed PCI in an era of high stent availability is limited. Shubrooks et al. (8) recently published the “first analysis of the need for UCABG in a large population of U.S. patients” having PCI in an era of routine stent use. However, the majority (80%) of their procedural data are derived from patients having PCI during 1992 to 1996, whereas stent use became standard practice in PCI chiefly after 1996. Also, stent technology has significantly advanced since 1996, and thus some patients may have been managed with PCI only. Subsequently, Seshadri et al. (20) reported their experience with UCABG after failed PCI revealing a similar decline in the rates of UCABG over an eight-year period (1992 to 2000). Increasing stent use (5% to 81%) during the time period studied was associated with a significant decrease in UCABG rates. However, a broader definition of emergency CABG including “indications warranting CABG that was not electively scheduled” decreases the specificity of identifying patients who may have derived harm from additional delays related to transfer. Thus, the impact of having on-site bypass surgical availability was not specifically addressed. Finally, reports from large U.S. interventional registry databases have been recently presented, revealing similar declines in UCABG rates, but the impact or risk estimate of on-site surgical availability was not addressed.

There are several limitations that need to be noted in our study. It is an observational clinical study limited by selection bias. Patients with a decreased chance of survival or increased likelihood of post-operative complications may not have been referred for surgery. To minimize the bias, we reviewed the charts of all patients who died as a result of a PCI to make sure there were no attempts made to refer for surgery prior to the patient’s death. No deaths occurred before surgery among patients felt to be suitable for UCABG.

To further enhance the specificity of our study to identify harm caused by additional delays in UCABG patients, a set of prespecified criteria focusing on the highest risk patients were developed. These criteria were derived chiefly from the published literature of UCABG patients. All patients who had the prespecified criteria in our study were taken to the operating room within 2 h of consultation, which emphasized that most of these patients truly required immediate intervention. These prespecified criteria helped to identify the subset of patients labeled as UCABG who are more likely to be adversely affected by additional delays to surgery, such as those requiring transfer to a surgical hospital. In our study, it is likely that at least two further deaths may have occurred if immediate surgical intervention were not available.

The risk estimates relating to delays associated with transfer may be conditional on the settings of this study. However, our center represents a typical tertiary care center in North America with experienced, high-volume operators with similar patient profiles. The relatively small sample size of the UCABG patients in our study, specifically those with the prespecified criteria, is another limitation. However, a multi-center study will be required to generate sufficiently large numbers of UCABG patients to generate more accurate risk estimates. Also, the data may not be generalizable to other institutions with less experience or lower volumes. It is likely that the risks would be higher than our conservative estimate in the latter setting if an unselected cohort of elective PCIs were done.

Conclusions. The rates of UCABG associated with failed PCI have significantly declined over that last decade. The 0.7% rate of UCABG seen at our center is in line with other large academic centers (20). This is the first study that has attempted to approximate a risk estimate for PCI patients who need UCABG if delays are encountered. From this study population, approximately 25% of these UCABG patients had potential for serious harm if additional delays to surgery were introduced, representing an absolute risk of one to two patients per 1,000 PCI.

However, it is clear from recent registry data that selected patients can have PCI in high-volume centers without on-site surgery with acceptable risk (9). The concern arises when the data from large-volume experienced centers are taken as the risk estimate, when in fact many of the centers interested in developing new PCI programs are low-volume centers with less experienced operators. Therefore, in some patient groups (i.e., AMI), the risks that we have estimated for delays relating to transfer can be justified if the infrastructure is properly planned. Our study supports the unpredictability of the need for UCABG and shows that certain patients will undoubtedly be put at increased risk without the immediate availability of cardiac surgery. The cardiology community should develop monitoring strategies to ensure that patients are not being placed at increased risk of adverse events in PCI programs without on-site surgery.

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REFERENCES