The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

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PREAMBLE

The Society for Cardiovascular Angiography and Interventions (SCAI) coauthored and cosponsored with the American College of Cardiology (ACC) and the American Heart Association (AHA) the percutaneous coronary intervention (PCI) guidelines update, released in November 2005 [1]. About 1 year earlier, the SCAI leadership commissioned a working group to examine the current status of PCI without on-site surgical backup. This group, composed of Gregory J. Dehmer, MD (Chair), James Dwyer, MD, Kirk Garrett, MD, Mirle Kellett, MD, Lloyd Klein, MD, Barry F. Uretsky, MD, and Thomas Wharton MD, provided a final report, which was approved by the SCAI Board of Trustees on October 10, 2005. The Board of Trustees then commissioned a writing group to develop an expert consensus document on the current status of PCI without on-site cardiac surgery. SCAI carefully considered and ultimately approved the 2005 PCI guidelines update, which continued to designate elective PCI without on-site surgery as a class III indication and primary PCI for ST-segment elevation myocardial infarction (STEMI) as a class IIb indication in the absence of on-site surgery. Nevertheless, there was a clear opinion within the Society that a comprehensive review of the status of PCI without on-site surgery was warranted.

The performance of PCI without on-site surgical backup is currently the subject of debate [2–5]. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, it must be acknowledged that this debate has the potential to supersede quality of care issues. On one side, opponents of PCI without on-site surgery believe that personal, financial, and market-driven motives have eclipsed quality of care issues and fostered the increased and unregulated growth of this practice. On the opposite side, proponents of PCI with-
out on-site surgery believe that personal, financial, and market-driven motives also exist at PCI centers with on-site surgery where fears of increased competition and loss of market share have promoted unnecessarily restrictive standards and state regulations against a practice that facilitates early and convenient access to PCI services in local communities. It is within this context that SCAI engaged in this effort to determine the current status of PCI without on-site surgery not only in the United States, but globally. The specific goals of this effort were to

1. gather facts and trends on the prevalence of PCI without on-site surgery,
2. review existing guidelines and competency statements related to the performance of PCI without on-site surgery not only in the United States, but also globally,
3. review and summarize literature related to the performance of PCI without on-site surgery,
4. define the best practice methods at facilities that are currently performing PCI without on-site surgery, and
5. make recommendations with universal applicability on the role of PCI without on-site surgery.

This document will not address every possible issue or circumstance related to PCI at facilities without on-site cardiac surgery. Rather, the desired endpoint is to focus on providing the highest quality care to patients.

BACKGROUND

The use of PCI has grown tremendously over the past 20 years. Many factors have contributed to this growth, including equipment improvements, new anticoagulant and antiplatelet therapies, and most recently, the development of the coronary artery stent. These improvements have not only expanded PCI indications, but also improved dramatically procedural safety. In the early days of balloon angioplasty, 1.0%–2.5% of patients died and 1.9%–5.8% required urgent coronary artery bypass graft (CABG) surgery [6–8]. In contrast, recent surveys performed at high-volume centers show an in-lab mortality rate of 0.23% and a 0.3%–0.6% incidence of urgent CABG surgery [9–11]. Although the frequency of emergency CABG has declined, perioperative mortality has remained high and may be increasingly due to an unfavorable shift in patient risk factors and morbidity when urgent surgery is necessary [12].

One of the current PCI indications is acute reperfusion in STEMI patients. Pooled analyses have demonstrated the superiority of primary PCI over thrombolytic therapy [13,14]. However, the superior outcomes of primary PCI are adversely affected by time delays in initiating the PCI procedure [15,16]. Such delays may occur at many levels within the continuum of care, including patient delay from failure to recognize the importance of symptoms, delay in patient transfer to a PCI center, and delay at the PCI hospital once the patient enters the door [17]. Trials combining various pharmacologic agents to improve reperfusion before transfer to a PCI center (so called “facilitated PCI”) have not shown dramatic advantages compared with primary PCI alone [18], but ongoing trials are currently exploring different pharmacologic options [19–21]. Moreover, studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the United States [22,23]. As the advantages of primary PCI became more widely accepted, two separate initiatives developed to deliver this care to as many acute STEMI patients as possible. Efforts to diagnose acute STEMI “in the field” and rapidly transport patients to PCI centers are receiving increasing emphasis, with some suggesting regional MI centers be developed and patterned after the successful trauma center concept [24–26]. Concurrently, efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrated outcomes comparable to facilities that have on-site cardiac surgery [27–32]. The rationale for providing PCI at qualified hospitals without on-site cardiac surgery to support local health needs has been discussed [4,33,34]. Because it is difficult to sustain a PCI program solely on STEMI patients, elective PCIs are also being performed at facilities without on-site surgery [30–32]. Other nonelective subgroups, such as those with high-risk acute coronary syndromes, but with no evidence of myocardial necrosis, may benefit from PCI at local facilities, especially when the distance to a facility with on-site surgery is considerable.

PREVALENCE AND TRENDS OF PCI WITHOUT ON-SITE SURGERY

United States Data

Data on the prevalence of PCI performed without on-site surgical backup are not easily found and are changing rapidly. Data were gathered primarily from a web survey of the SCAI membership and then supplemented and confirmed by several independent sources. These data, which we believe are accurate as of July 2006, indicate primary PCI programs without on-site surgical backup exist in all but 10 states (Alaska, Arkansas, Delaware, Georgia, Mississippi, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming) and the District of Columbia (Fig. 1).
Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. In some states, this situation is allowed only through a controlled demonstration project run by the state’s Department of Health. A large \( n = 18,000 \) randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

### International Data

International data were derived from three sources: a web-based survey of non-US SCAI members; letters of inquiry to leadership of several international interventional cardiology societies; and the medical literature if a study reported PCI without on-site backup in a country. In total, data were available from 39 countries, indicating PCI without on-site surgical backup is being performed in 35 (90%) (Table I).

### PCI Trends in the United States

The number of patients receiving PCI at facilities without on-site surgery is unknown. However, a recent assessment of trends in PCI without on-site surgical backup appears promising. For example, in Georgia, PCI without on-site cardiac surgery is now being performed as part of the CPORT Elective Trial.

### Table I. Status of PCI Without On-Site Surgical Backup, by Country

<table>
<thead>
<tr>
<th>Being performed</th>
<th>Not being performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Israel</td>
</tr>
<tr>
<td>Australia</td>
<td>Italy</td>
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<tr>
<td>Brazil</td>
<td>Japan</td>
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<tr>
<td>Canada</td>
<td>Lebanon</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Mexico</td>
</tr>
<tr>
<td>Egypt</td>
<td>Netherlands(^a)</td>
</tr>
<tr>
<td>England</td>
<td>Norway</td>
</tr>
<tr>
<td>France</td>
<td>Oman</td>
</tr>
<tr>
<td>Germany</td>
<td>Pakistan</td>
</tr>
<tr>
<td>Guatemala</td>
<td>Panama</td>
</tr>
<tr>
<td>India</td>
<td>Phillipines</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Poland</td>
</tr>
</tbody>
</table>

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PCI, percutaneous coronary intervention.

\(^a\)Demonstration project only.
backup was performed using data from the CathPCI Registry of the ACC-National Cardiovascular Data Registry (ACC-NCDR) [35]. From January 2001 to December 2004, 39 facilities without on-site surgical backup submitted PCI data to the ACC-NCDR. These data showed that the number of both primary and elective PCIs with or without on-site surgical backup enrolled in the ACC-NCDR per quarter increased significantly ($P < 0.0001$) from 2001 to 2004. Moreover, the proportion of elective PCIs performed at facilities without on-site surgical backup increased over this time interval. ACC-NCDR data from 2005 show a further increase to 75 facilities performing PCI without on-site surgical backup, with a continued increase in the number of patients receiving PCI in this setting (Fig. 2). These data suggest growth in the performance of PCI without on-site surgery, but are subject to reporting bias since only 463 of $\sim$2,100 cardiac catheterization laboratories in the United States reported data to the ACC-NCDR during this period.

EXISTING GUIDELINES AND COMPETENCY DOCUMENTS

ACC/AHA/SCAI Guidelines
A revision of the 2001 guideline was released in November 2005 [1]. Primary PCI for STEMI without on-site surgical backup remained a class IIb indication and elective PCI without on-site surgery remained a class III indication. Several additional recommendations were made that primary PCI for STEMI be performed by higher volume operators experienced in both elective PCI and primary PCI for STEMI with ongoing activity levels of greater than 75 elective PCI procedures per year and, ideally, annual PCI for STEMI activity levels of at least 11 per year. Numerous other programmatic recommendations were made [1].

European Society of Cardiology Guidelines
In contrast to the ACC/AHA/SCAI guidelines, the 2005 European Society of Cardiology (ESC) guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [36]. Data from our survey of international members indicate that PCI without on-site surgery is performed widely in several European countries and is growing rapidly in the Asia-Pacific rim.

British Cardiac Society and British Cardiovascular Intervention Society Guidelines
Guidelines from these groups were published in 2005 [37]. These guidelines contain a comprehensive discussion of this issue and state the following:

*European practice meantime has continued to evolve with off-site cover being increasingly widespread.*
All centers should be in a position to establish car-
diopulmonary bypass within 90 min of an urgent
treatment. Additional key points in these guidelines are
as follows:

- Although acknowledged to be arbitrary, an annual
  procedure volume of 200 per facility was favored,
  while encouraging individual centers to increase ac-
tivity to a minimum of 400 procedures annually.
  Centers performing fewer than 200 procedures per
  year were encouraged to have a robust plan showing
  how these numbers will be increased in the future to
  achieve the minimum standard.

- The previous guidelines recommendation of 75 pro-
cedures annually for independent operators was reaf-
irmed as appropriate, while encouraging operators
working at this low level to develop a strategy for
increasing their own activity to 150 procedures a
year or more. It was felt that an operator undertaking
fewer than one to two PCI procedures a week will
not be sufficiently skilled to respond appropriately in
an emergency situation. Operators performing fewer
than 75 procedures per year may continue but under
the guidance of a mentor or “buddy” available in the
catheterization laboratory throughout the proc-
dure to offer advice or assistance.

- All facilities should collect data on the intervention
treatments to determine whether the standards of care
are acceptable and to compare results with some form
of benchmark. The BCIS has advocated this approach
for some years and maintains an audit process in which
all interventional cardiologists are expected to partic-
ipate. Rigorous peer review was strongly endorsed.

- All centers should be in a position to establish car-
diopulmonary bypass within 90 min of an urgent
referral being made for cardiac surgery. It was noted
that there was no clear evidence that centers with
on-site surgery will necessarily be in a position to
have the patient on bypass any quicker than the cen-
ter without on-site surgery and sometimes the con-
verse may be true.

Data from 1996 showed that 7% of 20,511 PCI
procedures performed in the United Kingdom were at
facilities without on-site cardiac surgery. The 2004
update from the BCIS (www.bcis.org.uk) PCI registry
shows that 20 (26%) of the 77 PCI centers in the
United Kingdom do not have on-site cardiac surgery.
Of the 62,780 PCI procedures performed in 2004, 15%
were performed at facilities without on-site surgery.

German Guidelines

The only German guidelines found were published in
1987 [38] and thus may not be relevant today. How-
ever, there is substantial evidence that PCI with-
out on-site surgical backup is widely performed in
Germany. An abstract from Germany published in
1994 described 38 sites performing PCI without on-site
cardiac surgery [39].

The Cardiac Society of Australia and New
Zealand Guidelines

A policy statement on support facilities for coronary
angiography and PCI was published (on-line) in 2003
[40]. These state:

The Cardiac Society believes that coronary interven-
tional procedures are preferably performed in hospi-
tals with on-site surgical support. The Council of the
Society believes that the requirements for on-site
cardiac surgical facilities for laboratories performing
coronary interventional procedures may be omitted in
certain circumstances… and that appropriately trained
individuals can perform coronary interventional proce-
dures safely in hospitals without on-site surgical backup.

Additional recommendations included (a) operators
with adequate experience and training be individually
accredited by the hospital; (b) facilities should be per-
forming diagnostic coronary angiography with
acceptable morbidity and mortality before performing
PCI and have a formal written transfer agreement with
a cardiac surgical center; (c) facilities have adequate
equipment and staff capable of maintaining a patient
with intraaortic balloon pump and temporary pace-
maker; (d) careful selection of cases with the statement
that stable patients with high-risk anatomy may be bet-
ter served by performing the procedure in a facility
with on-site surgical backup; (e) patient consent
include an explanation of the potential additional
patient risk as a result of delayed surgical intervention
for a complication due to the time involved in trans-
porting the patient to the surgical facility; and (f)
mandatory careful and complete record keeping and
peer-review auditing of individual and procedural
results as an intrinsic part of quality assurance related
Spanish Society of Cardiology Guidelines

Published in 1999 [42], these guidelines are specific for the PCI performance at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited provided a program meets certain requirements, including (a) dedicated in-house services such as general or vascular surgery, ICU, anesthesia, and blood bank; (b) a formal transfer arrangement with a cardiac surgery center with a travel time less than 1 hr; (c) experienced and proficient operators defined as 50–75 PCI/year; and (d) a laboratory volume of at least 500 diagnostic studies and 100 PCIs annually. It was emphasized that low to moderate risk cases with a reasonable likelihood of success and low likelihood of complications should be the focus of such a program. The consent must include information about the transport to another center should the need for cardiac surgery arise.

Belgian Working Group on Invasive Cardiology Guidelines

Published in 2003, these guidelines acknowledge the increasing safety and diminishing risk of PCI but conclude that “the current standard practice for elective PCI remains the presence of on-site surgical standby” [44].

Operator Competency Documents

There are no publications specifically defining operator competency for PCI performance in facilities without on-site cardiac surgery. However, operator and institutional criteria have been proposed by individual authors [34,45]. Most guideline documents discuss operator competency, but there is no distinction regarding the presence or absence of on-site surgical backup. In general, a minimal annual case load of 50–75 procedures is recommended for operator competency. The 2005 ACC/AHA/SCAI PCI guidelines state that primary PCI for STEMI should be performed by higher volume operators experienced in both elective and primary PCI for STEMI with ongoing activity levels of greater than 75 elective PCI procedures per year and, ideally, an annual STEMI PCI activity level of at least 11 per year [1]. Other publications consistently

to coronary angiography and coronary interventional procedures.

The Cardiac Society of Australia and New Zealand (CSANZ) posted a policy statement on the performance of coronary angiography and PCI at rural sites in 2005 [41]. This document acknowledges that rural patients have reduced access to diagnostic angiography and interventional procedures and further states that providing this service as close to the patient’s place of residence as possible facilitates equity of access that should result in improved quality of care. CSANZ supports the view that it is safe to perform interventional procedures in rural locations remote from surgical units provided certain conditions are met. These conditions include a proper hospital infrastructure and facilities, critical mass of appropriately trained individuals, and formalized links with major tertiary units. In addition, procedure safety requires (a) careful patient selection, (b) comprehensive staff training, (c) structured clinical protocols, and (d) guaranteed priority access to a surgical unit. All patients undergoing coronary angiographic and interventional procedures should be informed that the procedure is being performed without surgery on site, and that access to emergency surgical procedures would likely take additional time. Other management options, including PCI performance in a center with on-site surgery, should be made clear. A minimum case load of 200 procedures annually was recommended.

in 2003, use a classification system similar to the ACC/AHA/SCAI guidelines [1] and state the following:

Percutaneous coronary intervention and surgical backup – In spite of the technical improvements related to the coronary stents, other devices, and new antiplatelet therapy, percutaneous coronary intervention for elective cases is not recommended in centers without an active cardiac surgical service. Primary coronary angioplasty for acute myocardial infarction is an exception for this recommendation. This is a more recent approach, which aims to increase the number of patients treated with mechanical reperfusion during the first hours of an acute myocardial infarction.

Class I – Elective procedures and primary percutaneous intervention for acute myocardial infarction performed in centers with surgical backup (evidence level B).

Class IIa – Primary percutaneous intervention for ST elevation acute myocardial infarction in centers without surgical backup, performed by experienced operator (>35 primary interventions for acute myocardial infarction/year) and possibility for full hemodynamic support during emergency transfer to a center with cardiac surgery (<1 hr) (Evidence level A).

Class III – Elective procedures performed in hospital without surgical backup or primary percutaneous intervention for acute myocardial infarction performed in centers without a transfer plan to a nearby hospital with cardiac surgery (Evidence Level C).

Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista

These guidelines from the Brazilian Society of Cardiac Hemodynamics and Intervention [43], published

Catheterization and Cardiovascular Interventions
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).
emphasize that PCI without on-site cardiac surgery be performed by experienced high-volume interventionalists without providing specific volume or experience requirements.

Developing Countries

PCI is now being used in several developing countries where cardiac surgery is not available and patients are sometimes unable to travel to surrounding nations for care. This document is intended for developed countries and not emerging nations where surgical backup is not possible. Frequently, experienced physicians from developed countries volunteer to perform and teach PCI in this setting.

PEER-REVIEWED LITERATURE OF PCI WITHOUT ON-SITE SURGERY

There are over 30 published papers or abstracts reporting PCI results without on-site surgical backup [27–32,46–73]. Many studies focus on either primary or elective PCI, but several include all PCI patients without on-site surgical backup.

Primary PCI

Publications reporting only primary PCI or data related to primary PCI extracted from mixed studies (primary and elective PCI) are summarized in Table II [27,28,32,46–62]. These studies report retrospective reviews or prospective registries with considerable variation in patient entry criteria. Moreover, these studies span a time period from 1993 to 2006 and thus incorporate changing treatment paradigms, including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors, and coronary artery stents. Accordingly, simple aggregation of outcome data is not appropriate or meaningful. Even total patient number within these reports is not easily derived because some of the studies listed are expanding experiences within the same registry [28,32,54,55], and thus may duplicate early patient experiences. The more recent reports show that primary PCI without on-site surgical backup is performed with a high success rate, low in-hospital mortality rate, and a low rate of urgent cardiac surgery (Table II). The highest mortality rate was reported in a study that included only Medicare patients and is a 30-day rather than in-hospital mortality rate [62]. In this study, the 30-day mortality rate for primary PCI in facilities without on-site backup was not different from that at facilities with on-site backup. Moreover, in this study, the majority of hospitals without on-site cardiac surgery performed ≤25 Medicare PCIs per year, while only a small number of hospitals with on-site cardiac surgery were low-volume hospitals.

Elective PCI

Publications of only elective PCI or data related to elective PCI extracted from mixed studies (primary and elective PCI) are summarized in Table III. [29–32,58,59,62–73] These studies consist of retrospective reviews or prospective registries with considerable variation in the patient entry criteria. They span a time period from 1990 to 2006 and thus reflect therapeutic advances such as glycoprotein IIb/IIIa inhibitors and coronary artery stents. Some studies apply strict screening criteria to identify only low-risk PCI patients while others describe PCI in a broad patient range, including several high-risk subgroups. Therefore, simple aggregation of the outcomes data is difficult to interpret. Recent reports show that elective PCI without on-site surgical backup is performed with a high success rate, low in-hospital mortality rate, and a low rate of urgent cardiac surgery (Table III). The highest mortality rate was observed in a Medicare population, but with 75% of the hospitals performing ≤25 PCI procedures annually on Medicare patients [62].

All published data for both primary and elective PCI were derived from retrospective reviews or registries and thus are subject to unintentional bias and other methodological concerns. The generally favorable reports may also reflect publication bias as there is no requirement for public reporting of programs that have not succeeded at PCI without on-site surgical backup. A well-controlled, properly powered and randomized study has not been performed, but one large study is now underway. Simply showing that the need for urgent CABG following PCI at facilities without on-site surgical backup is low and not different than facilities with on-site surgical backup is insufficient to completely determine the safety of performing PCI without on-site surgery. Since facilities without on-site surgical backup should be performing lower risk cases in the elective setting, it is anticipated that the risk of emergency CABG will be lower than at centers with on-site surgery. It must be shown that the mortality of patients requiring transfer for urgent CABG surgery is no different than the mortality of patients requiring urgent surgery at facilities with on-site cardiac surgery.

BEST PRACTICES FOR PCI WITHOUT ON-SITE SURGERY

Although no randomized or controlled studies exist and despite the current ACC/AHA/SCAI guideline recommendation, PCI without on-site surgery is being
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Country</th>
<th>n</th>
<th>Study type</th>
<th>door-to-balloon time (min)</th>
<th>PCI success (%)</th>
<th>In-hospital mortality (%)</th>
<th>Urgent CABG (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iannone et al.</td>
<td>1993</td>
<td>US</td>
<td>100</td>
<td>Retrospective review</td>
<td>82</td>
<td>5</td>
<td>7</td>
<td></td>
<td>Rescue PCI after SK in 46%; 5 cath. laboratory deaths who had average age of 81 yr and LVEF = 0.23</td>
</tr>
<tr>
<td>Weaver et al.</td>
<td>1995</td>
<td>US</td>
<td>470</td>
<td>Registry</td>
<td>80b (55–126)</td>
<td>88</td>
<td>7</td>
<td>3.8</td>
<td>MITI Registry, 6 sites with on-site surgery treated 592 pts. No difference in mortality with or without on-site surgery</td>
</tr>
<tr>
<td>Brush et al.</td>
<td>1996</td>
<td>US</td>
<td>62</td>
<td>Retrospective review</td>
<td>96</td>
<td>30</td>
<td>3</td>
<td>0</td>
<td>40 pts having primary PCI with cardiogenic shock or rescue PCI were excluded</td>
</tr>
<tr>
<td>Moquet et al.</td>
<td>1997</td>
<td>France</td>
<td>50</td>
<td>Retrospective review</td>
<td>90</td>
<td>10</td>
<td>0</td>
<td></td>
<td>All deaths in pts &gt; 80 yr</td>
</tr>
<tr>
<td>Smyth et al.</td>
<td>1997</td>
<td>New Zealand</td>
<td>71</td>
<td>Retrospective review</td>
<td>72c (60, 90)b</td>
<td>86</td>
<td>9.9</td>
<td>60</td>
<td>Surgical backup 220 miles away. Included only pts with shock, anterior MI, post CABG, lytic ineligible or failure. Two pts transferred for nonurgent CABG</td>
</tr>
<tr>
<td>Wharton et al.</td>
<td>1999</td>
<td>US</td>
<td>335</td>
<td>Registry</td>
<td>109b (87, 148)</td>
<td>94</td>
<td>6.6</td>
<td>25</td>
<td>70% of pts had high-risk clinical and/or angiographic predictors (Killip class 3-4, age ≥ 75 yr, anterior MI, out-of-hospital VF, LM or three-vessel CAD, LVEF &lt; 0.45</td>
</tr>
<tr>
<td>Ribichini et al.</td>
<td>2000</td>
<td>Italy</td>
<td>284</td>
<td>Retrospective review</td>
<td>56 ± 17d</td>
<td>96</td>
<td>8.5</td>
<td>32</td>
<td>55 pts had rescue PCI, with a mortality of 16%</td>
</tr>
<tr>
<td>Aversano et al.</td>
<td>2002</td>
<td>US</td>
<td>171</td>
<td>Randomized PCI vs. lytics</td>
<td>102b (82, 121)</td>
<td>96</td>
<td>4.1</td>
<td></td>
<td>C-PORT Study. Randomized PCI vs. lytics. 225 pts assigned to PCI, 212 received angiography, PCI performed in 171. Improved outcome and shorter LOS with PCI</td>
</tr>
<tr>
<td>Aversano [54]</td>
<td>2003</td>
<td>US</td>
<td>1,103</td>
<td>Randomized vs. lytics Registry</td>
<td>107b (87, 132)</td>
<td>97</td>
<td>3.0</td>
<td></td>
<td>C-PORT Registry (abstract)</td>
</tr>
<tr>
<td>Aversano [55]</td>
<td>2005</td>
<td>US</td>
<td>3,733</td>
<td>Registry</td>
<td>103b (83, 128)</td>
<td>98</td>
<td>3.2</td>
<td></td>
<td>C-PORT Registry including only those treated by PCI. Stents in 93%, GPIIb/IIa inhibitors in 83%</td>
</tr>
<tr>
<td>Politi et al.</td>
<td>2003</td>
<td>Italy</td>
<td>825</td>
<td>Retrospective review</td>
<td>58b (49, 71)</td>
<td>4.9</td>
<td>0.9</td>
<td></td>
<td>Includes rescue PCI in 35 pts (3.2%)</td>
</tr>
<tr>
<td>Singh et al.</td>
<td>2004</td>
<td>US</td>
<td>160</td>
<td>Registry</td>
<td>96</td>
<td>2</td>
<td>0</td>
<td></td>
<td>No difference in outcome compared with 160 pts treated at site with on-site surgery</td>
</tr>
<tr>
<td>Kutcher et al.</td>
<td>2004</td>
<td>US</td>
<td>491</td>
<td>Registry</td>
<td>90</td>
<td>4.9</td>
<td>1.2</td>
<td></td>
<td>ACC-NCDR data. No difference in PCI success, U-CABG or death compared with centers having on-site surgery</td>
</tr>
</tbody>
</table>

Dehmer et al. Catheterization and Cardiovascular Interventions Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Country</th>
<th>n</th>
<th>Study type</th>
<th>Door-to-balloon time (min)</th>
<th>PCI success (%)</th>
<th>In-hospital mortality (%)</th>
<th>Urgent CABG (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foster et al. [59], 28 sites</td>
<td>2005</td>
<td>US</td>
<td>Not stated</td>
<td>Registry</td>
<td>4.6</td>
<td>6,530 pts (primary and elective PCI) without on-site surgery. No mortality difference compared with on-site surgery after adjusting for demographic and clinical characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanborn et al. [60], 97 sites</td>
<td>2004</td>
<td>US</td>
<td>1,874</td>
<td>Registry</td>
<td>110 (107, 113)</td>
<td>3.7</td>
<td>NRMI data. Mortality in hospitals with on-site surgery = 4.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wharton et al. [61], 19 sites</td>
<td>2004</td>
<td>US</td>
<td>440</td>
<td>Registry</td>
<td>105 (80, 139)</td>
<td>96</td>
<td>NRMI data. Mortality in hospitals with on-site surgery = 4.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wennberg et al. [62], 178 sites</td>
<td>2004</td>
<td>US</td>
<td>1,795</td>
<td>Retrospective review</td>
<td>11.3</td>
<td>4.6f</td>
<td>Medicare data from 1999–2001. Only data for primary/rescue PCI shown. No difference in mortality or U-CABG compared with hospitals having on-site surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ting et al. [32], 1 site</td>
<td>2006</td>
<td>US</td>
<td>285</td>
<td>Registry</td>
<td>93</td>
<td>4</td>
<td>Cases matched 1:1 for age, gender, clinical characteristics with data from hospital with on-site backup</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACC-NCDR, American College of Cardiology-National Cardiovascular Data Registry; CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; CHF, congestive heart failure; C-PORT, Cardiovascular Patient Outcomes Research Team; GPIIb/IIIa, glycoprotein IIb/IIIa; HR, heart rate; LM, left main; LVEF, left ventricular ejection fraction; LOS, length of stay; Lytic, fibrinolytic therapy; MI, myocardial infarction; MITI, Myocardial Infarction Triage and Intervention; NRMI, National Registries of Myocardial Infarction; PAMI-No SOS, Primary Angioplasty in Myocardial Infarction—No Surgery On Site; PCI, percutaneous coronary intervention; pts, patients; SK, streptokinase; U-CABG, urgent CABG; VF, ventricular fibrillation.

aTime from presentation in the emergency department to first balloon inflation.
bMedian value (25th percentile, 75th percentile).
cTime from decision to offer primary PCI to first balloon inflation.
dMean ± SD.
ePatients with cardiogenic shock excluded.
Mean value, 95% CI.
fReason for emergency CABG not discriminated between PCI failure and discovery of high-risk anatomy.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Country</th>
<th>n</th>
<th>Study type</th>
<th>Patient criteria</th>
<th>PCI success (%)</th>
<th>In-hospital mortality (total) (%)</th>
<th>Urgent CABG (%)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richardson et al. [63], 1 site</td>
<td>1990</td>
<td>Ireland</td>
<td>540</td>
<td>Retrospective review</td>
<td>Stable, unstable angina, post-AMI</td>
<td>82</td>
<td>0.9</td>
<td>2.2</td>
<td>Primary cause for delay was wait for OR availability, not time to transfer. No primary PCI included</td>
</tr>
<tr>
<td>Meier et al. [64], 1 site</td>
<td>1992</td>
<td>Switzerland</td>
<td>811</td>
<td>Prospective nonrandomized</td>
<td>Excluded pts expected to have large MI if acute occlusion occurred</td>
<td>92</td>
<td>0.1</td>
<td>0.1</td>
<td>Pts scheduled for PCI with or without backup, but at a hospital with on-site surgery. 189 pts done with standby. Primary PCIs excluded. Acute occlusion occurred in 6.9% of no standby group with 1.2% developing q wave MI</td>
</tr>
<tr>
<td>Klinke and Hui [65], 1 site</td>
<td>1992</td>
<td>Canada</td>
<td>847</td>
<td>Retrospective review</td>
<td>All pts, but excluding high-risk clinical or anatomic situations</td>
<td>87</td>
<td>0.9</td>
<td>1.6</td>
<td>Unspecified number of pts with AMI. 42% of U-CABG pts suffered AMI. 2.1% of pts not sent for U-CABG also had AMI managed conservatively</td>
</tr>
<tr>
<td>Iniguez et al. [66], 1 site</td>
<td>1992</td>
<td>Spain</td>
<td>1,014</td>
<td>Retrospective review</td>
<td>Excluded pts expected to have life-threatening MI if acute occlusion occurred</td>
<td>88</td>
<td>0.7</td>
<td>0.1</td>
<td>Pts scheduled for PCI with or without backup, but at a hospital with on-site surgery. 269 PCIs done with standby. AMI (type unknown) in 2.7% of no standby group, not different from standby group 2.9%</td>
</tr>
<tr>
<td>Baduini et al. [67], 1 site</td>
<td>1994</td>
<td>Italy</td>
<td>742</td>
<td>Retrospective review</td>
<td>Not clearly defined, but some pts had AMI</td>
<td>91</td>
<td>0.13</td>
<td>0.8</td>
<td>Mortality rate excludes pts presenting with cardiogenic shock. AMI (type unknown) occurred in 1.2%</td>
</tr>
<tr>
<td>Dellavalle et al. [68], 1 site</td>
<td>1995</td>
<td>Italy</td>
<td>232</td>
<td>Retrospective review</td>
<td>Strict criteria used to select low-risk cases (no PCIs of LAD)</td>
<td>93</td>
<td>0</td>
<td>0</td>
<td>AMI (type unknown) occurred in 1%</td>
</tr>
<tr>
<td>Loubeye et al. [69], multiple sites</td>
<td>1999</td>
<td>France</td>
<td>Not stated</td>
<td>Retrospective review and prospective registry</td>
<td>Included all pts undergoing PCI at registry sites</td>
<td>0.41</td>
<td>0.25</td>
<td></td>
<td>Total experience of French Registry, 62% of sites without on-site surgery. Number of pts undergoing PCI at sites without surgery not reported. Report only details need for U-CABG and outcomes Excludes STEMI</td>
</tr>
<tr>
<td>Dudek et al. [70], 1 site</td>
<td>2003</td>
<td>Poland</td>
<td>479</td>
<td>Retrospective review</td>
<td>ACS and stable pts included</td>
<td>94</td>
<td>0.6</td>
<td>0.4</td>
<td>Stents used in 70% of recent pts</td>
</tr>
<tr>
<td>Turgeman et al. [71], 1 site</td>
<td>2003</td>
<td>Israel</td>
<td>1,016</td>
<td>Retrospective review</td>
<td>All pts, including about 5% primary PCI</td>
<td>Not stated</td>
<td>0.3</td>
<td>0.6</td>
<td>ACC-NCDR data. No difference in PCI success, U-CABG, or death compared with elective pts at sites having on-site surgery (abstract)</td>
</tr>
<tr>
<td>Kutcher et al. [58], 17 sites</td>
<td>2004</td>
<td>US</td>
<td>1,668</td>
<td>Registry</td>
<td>Not defined</td>
<td>92</td>
<td>0.5</td>
<td>0.2</td>
<td>Coronary perforation in 0.9%, all managed without surgery. Peri-procedure MI in 2.1%</td>
</tr>
<tr>
<td>Zavala-Alarcon et al. [30], 1 site</td>
<td>2004</td>
<td>US</td>
<td>1,000</td>
<td>Retrospective review</td>
<td>All pts included</td>
<td>96</td>
<td>0.2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Country</td>
<td>n</td>
<td>Study type</td>
<td>Patient criteria</td>
<td>PCI success (%)</td>
<td>In-hospital mortality (total) (%)</td>
<td>Urgent CABG (%)</td>
<td>Comments</td>
</tr>
<tr>
<td>---------------------------</td>
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<td>----------------------------------</td>
<td>-----------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Wennberg et al. [62], 178 sites</td>
<td>2004</td>
<td>US</td>
<td>6,373</td>
<td>Retrospective review</td>
<td>Not defined</td>
<td>Not stated</td>
<td>4.6</td>
<td>1.2</td>
<td>Medicare data from 1999–2001. Only data for nonprimary/rescue PCI shown. Mortality higher ($P &lt; 0.001$) compared with hospitals having on-site surgery (2.8%). Rate of U-CABG not different</td>
</tr>
<tr>
<td>Foster et al. [59], 28 sites</td>
<td>2005</td>
<td>US</td>
<td>Not stated</td>
<td>Registry</td>
<td>Not defined</td>
<td>Not stated</td>
<td>0.4</td>
<td>Not stated</td>
<td>ACC-NCDR data. 6,530 total pts (primary and elective PCI) without on-site surgery. No mortality difference compared with on-site surgery after adjustment</td>
</tr>
<tr>
<td>Parachos et al. [31], 1 site</td>
<td>2005</td>
<td>US</td>
<td>489</td>
<td>Retrospective review</td>
<td>Only low-risk pts included</td>
<td>98</td>
<td>0.2</td>
<td>0.7</td>
<td>The 1 death was due to renal failure. Mean time from departure to OR was 83 min</td>
</tr>
<tr>
<td>Ting et al. [29,32], 1 site</td>
<td>2006</td>
<td>US</td>
<td>722</td>
<td>Registry</td>
<td>Low-to-moderate risk cases; Mayo Clinic risk score, ≤ 10</td>
<td>97</td>
<td>0.3</td>
<td>0</td>
<td>Cases matched 1:1 for age, gender, clinical characteristics with data from hospital with on-site backup</td>
</tr>
<tr>
<td>Melberg et al. [72], 1 site</td>
<td>2006</td>
<td>Norway</td>
<td>609</td>
<td>Prospective randomized</td>
<td>Only low-risk pts randomized</td>
<td>96</td>
<td>0</td>
<td>0</td>
<td>No differences between low-risk pts having PCI at local vs. regional hospital</td>
</tr>
<tr>
<td>Roussanov et al. [73], 1 site</td>
<td>2006</td>
<td>US VA Hospital</td>
<td>410</td>
<td>Prospective, consecutive</td>
<td>Elective and non-ST elevation ACS pts</td>
<td>97</td>
<td>0</td>
<td>0</td>
<td>Total mortality at 1 and 6 months was 1.5% and 3.5%; repeat TVR 0% and 1.7%</td>
</tr>
</tbody>
</table>

ACC-NCDR, American College of Cardiology-National Cardiovascular Data Registry; ACS, acute coronary syndrome; AMI, acute myocardial infarction; CABG, coronary artery bypass graft surgery; LAD, left anterior descending; MI, myocardial infarction; OR, operating room; PCI, percutaneous coronary intervention; pts, patients; STEMI, ST-segment elevation myocardial infarction; TVR, target vessel revascularization; U-CABG, urgent CABG.
performed in many states and is accepted in many countries throughout the world. Moreover, data from many countries, including the United States, indicate that the use of PCI without on-site surgery is growing [35]. The purpose of this document is neither to challenge the ACC/AHA/SCAI guideline recommendations nor to support PCI without on-site surgical backup. However, with the reality that PCI without on-site surgery is growing, it is both appropriate and necessary to define the best standards of practice such that facilities and physicians operate within the highest possible quality standards. Several prior publications have set forth recommendations for PCI without on-site surgery and have been used in developing the standards recommended by SCAI in this document [27–32,34,45].

Qualifications of the Physician

All prior publications emphasize that PCI without on-site surgery should be performed by “experienced interventionists” but this term is not defined precisely. Simply performing a high volume of cases does not guarantee technical expertise or sound judgment on the part of the physician. More important than a specific case volume threshold is the accurate assessment of complication rates and patient outcomes. Recommendations for physicians performing PCI at facilities without on-site surgery include the following:

a. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures with or without on-site surgery. Although no PCI data registry should be considered comprehensive at this time, for the United States we recommend benchmarks of the most current ACC-NCDR CathPCI RegistryTM be used, including median rates of risk-adjusted mortality, door-to-balloon time ≤90 min, overall vascular complications, angiographic luminal success, urgent revascularization, and periprocedural MI stratified for primary, urgent, and elective PCI. The adverse events tabulated should include events at the original PCI facility and at centers to which the patient may be subsequently transferred. The operator also must actively participate in a facility’s quality improvement program. Participation in a continuous quality improvement program has been suggested to improve selected PCI outcomes [74]. In addition to involvement in local continuous quality improvement efforts, participation in a national data registry, if available, and appropriate continuing medical education are mandatory.

b. A proven record of satisfactory outcomes is of greater importance than simply meeting an arbitrary case volume requirement, but operator outcomes cannot be accurately determined until a substantial number of cases has been completed. Accordingly, operators must have sufficient prior experience to allow assessment of their judgment and quality. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without on-site surgery with <500 cases of lifetime experience should be mentored and monitored by existing physicians until it is determined and certified formally by that hospital that their skills and judgment are excellent and outcomes equivalent or superior to the national benchmarks.

c. Operators performing PCI without on-site surgery should perform ≥100 total PCIs per year, including ≥18 primary PCIs per year. These numbers exceed those currently recommended in the ACC/AHA/SCAI guidelines to reflect the opinion of this writing group that a greater experience level is appropriate for PCI in this setting. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet these annual volume requirements.

d. In the United States, board certification in interventional cardiology by the American Board of Internal Medicine is strongly recommended for all physicians performing PCI. Since 2003, board eligibility can only be obtained by completion of an additional training program in interventional cardiology. It is recognized that a substantial number of experienced interventional cardiologists developed their skills before formal training programs or board certification existed, but this number is gradually diminishing. Individuals who do not possess board certification, but with substantial lifetime experience and monitored outcomes that are within benchmark standards, should continue to perform PCI. Although board certification provides confirmation of a satisfactory knowledge base, it is not a guarantee that an individual can apply that knowledge to obtain satisfactory clinical outcomes in practice. Formal physician certification programs do not exist in many other countries where high-quality PCI is performed. Ultimately, developing benchmark performance metrics is a necessary step to improving the quality of PCI care worldwide.

Facilities and Support Personnel

Requirements for personnel and facilities are listed in Table IV. It is essential that all support personnel have adequate education regarding the management of
TABLE IV. Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

<table>
<thead>
<tr>
<th>Personnel and Facility Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.</td>
</tr>
<tr>
<td>On-call schedule with operation of laboratory 24 hr/day, 365 days/year.</td>
</tr>
<tr>
<td>Experienced coronary care unit nursing staff, comfortable with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.</td>
</tr>
<tr>
<td>Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank, etc.).</td>
</tr>
<tr>
<td>Written agreements for the emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of twice per year.</td>
</tr>
<tr>
<td>Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and intraaortic balloon pump equipment compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup is ideal.</td>
</tr>
<tr>
<td>Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities due to the greater risk of perforation.</td>
</tr>
<tr>
<td>Meticulous clinical and angiographic selection criteria for PCI (Tables V and VI).</td>
</tr>
<tr>
<td>Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked and be &lt;90 min. Outlier cases should be carefully reviewed for process improvement opportunities.</td>
</tr>
<tr>
<td>On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.</td>
</tr>
<tr>
<td>Participation in a national data registry where available, such as the American College of Cardiology-National Cardiovascular Data Registry® in the United States.</td>
</tr>
</tbody>
</table>

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation acute myocardial infarction.

*Required for the United States facilities, but this may not be possible for all facilities world-wide.

Adapted from Ref. 27.

PCI patients before, during, and after the procedure. This knowledge should include potential procedural complications and their management and the drug therapies used in PCI patients.

Much has been written about the association between facility/operator procedure volumes and patient outcomes. Many of the initial studies examining these relationships occurred in an era when balloon angioplasty was the only treatment modality and thus are less meaningful today [75–77]. In the “stent era,” a relationship between procedure volume and patient outcome is apparent in some [78–81], but not all studies [82]. It is important to note that data examining the volume–outcome relationship are derived predominantly from facilities with on-site cardiac surgery and thus are difficult to apply to facilities without on-site surgery because the risk profile of patients treated at such facilities may be different. Moreover, the validity of judging program quality, based on volume data alone, has been challenged not only for PCI, but also for CABG surgery [83–86].

Although the minimal acceptable annual procedure volume for a facility is ill-defined and subject to debate, there must be some minimal threshold below which the experience and proficiency of personnel at a facility would be difficult to maintain. The 2005 ACC/AHA/SCAI guideline update recommends 200 PCIs annually as the absolute minimum number for operation of a facility unless located in an underserved area and defines facilities performing 200–400 PCIs annually to be “low volume” centers [1]. Based on the available data and in concordance with the 2005 ACC/AHA/SCAI guideline update and other guidelines, it is recommended that facilities performing both primary and elective procedures without on-site surgery perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or underserved areas and their performance metrics are equivalent to accepted benchmarks. We recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs and this must include a minimum of 36 primary PCI/year. Programs offering only primary PCIs must perform a minimum of 36 primary PCIs/year to remain operational. At the present time in the United States, there is no justification for a PCI program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hr per day, but such situations may exist in other countries and be appropriate. New programs should have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years should not remain open under any circumstance.

**Patient and Lesion Selection**

Rigorous clinical and angiographic selection criteria are essential for the success of any program, especially programs performing PCI without on-site surgery. These criteria must be developed and documented in each laboratory. Since the clinical situation and risk-to-benefit ratio are different for primary versus elective PCI, different criteria and standards should apply. In the setting of primary PCI for STEMI, the goal is to...
TABLE V. Recommendations for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in:
- Patients with >50% stenosis of left main artery proximal to infarct-related lesion especially if the area in jeopardy is relatively small and the overall LV function is not severely impaired.
- Long, calcified or severely angulated target lesions at high-risk for PCI failure with TIMI grade 3 flow present during initial diagnostic angiography.
- Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing ischemic symptoms).
- Lesions with TIMI grade 3 flow that are not amenable to stenting in patients with left main or three-vessel disease that will require coronary bypass surgery.
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.

Transfer emergently for coronary bypass surgery patients with:
- High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump support.
- Failed or unstable PCI result and ongoing ischemia, with intra-aortic balloon pump support during transfer.

TABLE VI. Recommendations for Patient and Lesion Selection and Backup Strategy for Nonemergent PCI at Hospitals Without On-Site Cardiac Surgery and by Operators Performing ≥ 100 PCIs/year

Patient risk: Expected clinical risk in case of occlusion caused by procedure
- High patient risk: Patients with any of the following:
  - Decompensated congestive heart failure (Killip class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
  - Left ventricular ejection fraction ≤25%
  - Left main stenosis (≥50%) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
  - Single target lesion that jeopardizes over 50% of remaining viable myocardium

Lesion risk: Probability that procedure will cause acute vessel occlusion
- Increased lesion risk: Lesions in open vessels with any of the following characteristics:
  - Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
  - More than moderate calcification of a stenosis or proximal segment
  - Location in an extremely angulated segment (>90°)
  - Inability to protect major side branches
  - Degenerated older vein grafts with friable lesions
  - Substantial thrombus in the vessel or at the lesion site
  - Any other feature that may, in the operator’s judgment, impede successful stent deployment
  - Aggressive measures to open chronic total occlusions are also discouraged because of an increased risk of perforation

Strategy for surgical backup based on lesion and patient risk:
- **High-risk patient with high-risk lesion** should not undergo nonemergent PCI at a facility without on-site surgery
- **High-risk patient with not high-risk lesion** – Nonemergent patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and an operating room are immediately available is necessary.

CVA, cerebrovascular accident; PCI, percutaneous coronary intervention. Adapted from Refs. 27 and 87.

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Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).
TABLE VII. Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
4. Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at that time.
5. Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience.
8. Transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that procedure is being done without on-site surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP, intraaortic balloon pump; PCI, percutaneous coronary intervention. Adapted from Ref. 34.

Cardiologists and cardiac surgeons must be actively involved in the program with attendance at regularly scheduled cardiac catheterization conferences and participation in risk management activities.

In hospitals with on-site surgery, it is no longer standard for a surgical suite to be held open awaiting the completion of a PCI. Should urgent surgery be required, patients are stabilized while awaiting transfer to an open operating room. Because the need for urgent surgery is so infrequent, there are no current data regarding the actual time required to transport a patient to the operating room and initiate cardiopulmonary bypass should the need arise. In one study [11], transport to the operating room within 2 hr was provided to all patients felt to be at increased risk of harm by further delays in transport to the operating room. Should a patient undergoing PCI at a facility without on-site surgery develop a complication requiring urgent transfer for surgery, it is unclear whether or by how much the facility-to-facility transport would add to the time to establish cardiopulmonary bypass in the current practice environment where operating rooms are not held open at on-site facilities. One of the possible reasons for urgent surgery is acute vessel occlusion. Although acute vessel closure occurs less frequently now than in the past, it is a situation similar to primary PCI for STEMI where the goal for door-to-balloon time is ≤90 min. Minimizing the time to the initiation of cardiopulmonary bypass is the goal in this situation and more likely is feasible with on-site cardiac surgery if that surgery is immediately available. There is no acknowledged goal with supporting data similar to a door-to-balloon time for the initiation of cardiopulmonary bypass in this situation, but this should always be accomplished as rapidly as possible, with a goal of <120 min. Operators at facilities without on-site surgical backup should activate the emergency transport system at the first clear signs of a complication even if they attempt to salvage the situation using percutaneous techniques. Coronary vessel perforation is another potential reason for urgent surgery [93,94]. Although the incidence of coronary perforation is low, operators must be familiar with and have access to equipment for the percutaneous management of this complication, including prolonged balloon inflations, covered stent placement, embolization of the affected vessel, and pericardiocentesis.

In addition to hemodynamic support with an intraaortic balloon pump, several percutaneous support devices exist or are in development that may be useful in patients with failed PCI awaiting urgent surgery [95].

Monitoring of Programs

Providing the highest quality PCI services to patients mandates the collection of outcome data and comparison of these data to established benchmarks. Several states now mandate the collection and reporting of PCI outcome data and make these data available to the public. Other independent organizations collect PCI data, sometimes limited to Medicare patients, and issue public reports. Public reporting of outcome data has the potential to drive quality improvement and eliminate programs with poor performance, but may also have unintended negative effects [96,97]. Regardless of the mechanism, all PCI programs, with or without on-site surgical backup, must collect appropriate outcome data and compare their data to state, national or their country’s performance standards. Data submitted must be audited by an independent authority periodically to ensure integrity of the entire process.

With emphasis in the United States shifting to enhancing PCI program quality, and “pay-for-performance” initiatives on the horizon, it will be necessary to have an effective and impartial evaluation of the quality of PCI performance. One of the challenging issues is de-
ciding who should provide oversight of PCI programs. Ideally, each facility should establish an internal, objective, and impartial oversight mechanism, but this approach is infrequently accomplished because of conflicting local issues and financial constraints. External oversight already exists in the United States for hospitals, and oversight of PCI programs will be necessary either through an independent organization, state government agencies, or professional societies. It is critical that such a program be fair, impartial, not burdensome, and focused on providing the best possible PCI care for the locale under consideration. Any program with specified performance metrics below (more than one standard deviation or in the lower quartile) the accepted standards should be on probation pending improvement in the next monitoring period. Programs failing to improve should be closed by the monitoring authority.

**UNRESOLVED ISSUES AND FUTURE DIRECTIONS**

PCI without on-site surgery is a polarizing and emotional issue for many individuals both within and external to the interventional community. Although debate has focused on whether facilities that offer PCI without on-site surgery should exist, a more meaningful approach would focus on the goal of providing the best possible care to patients who require PCI, regardless of the setting. Recent publications suggest that this goal is not being consistently met. For example, door-to-balloon times for primary PCI in patients with STEMI are not optimal. Transfer delays to PCI centers exist [22,98,99] and, in non-STEMI acute coronary artery syndromes, may exceed the optimal interval recommended for treatment [100]. The need to develop a national strategy for the timely treatment of STEMI has recently been highlighted along with the potential barriers to this goal [25,26]. The AHA’s Acute Myocardial Infarction Working Group recommended strategies to increase the number of STEMI patients with timely access to primary PCI [26]. Their strategies included the following:

1. Patient-centered care as the first priority.
2. High-quality care that is safe, effective, and timely.
3. Stakeholder consensus on systems infrastructure.
4. Increased operational efficiencies.
5. Appropriate incentives for quality, such as “pay for performance,” “pay for value,” or “pay for quality.”
7. An evaluation mechanism ensuring that quality-of-care measures reflect changes in evidence-based research, including consensus-based treatment guidelines.

8. A role for local community hospitals so as to avoid a negative impact that could eliminate critical access to local health care.
9. A reduction in disparities of healthcare delivery, such as those across economic, education, racial/ethnic, or geographic lines.

These principles provide an excellent roadmap for the future and are applicable to all PCI programs world-wide. Unresolved is what role facilities without on-site cardiac surgery will play in such a national strategy. Data from facilities participating in the National Registry of Myocardial Infarction (NRMI) 3 and 4 indicate that hospitals performing primary PCI without on-site cardiac surgery have quality-of-care indicators and adherence to ACC/AHA management guidelines that are comparable to hospitals with on-site cardiac surgery [60].

Data indicate that the number of coronary artery bypass operations is declining. This trend is likely to continue. Percutaneous treatments for valvular heart disease may further reduce the number of cardiac surgeries, resulting in the closing of smaller surgical programs and the coalescence of cardiac surgical services to more centralized locations. Data from the National Residency Matching Program indicate that 33% of the thoracic surgery training slots went unfilled for the appointment year beginning 2007 [101]. If cardiac surgery programs begin to shrink, it will become more difficult for all PCI facilities to have on-site cardiac surgery. This situation already exists internationally, where there are fewer cardiac surgery centers per capita, yet substantial portions of the population require revascularization.

Just as it would be inappropriate to open more low-volume cardiac surgery centers if not needed, it likewise is inappropriate to open PCI centers if they are not based on the health needs of the community. Opening a low-volume PCI program within the same geographic area and thereby converting a high-volume program at another facility to a low-volume program is not necessarily in the best interests of patients in the community. There is clearly a potential for unnecessary or inappropriate PCI program development in the same geographic area and this is strongly discouraged. However, the factors that define a geographic area are not consistent throughout the United States or other countries. The level and availability of emergency transport services, response times of emergency medical transport, immediate availability of qualified catheterization laboratory personnel, and coverage by interventional cardiologists must be considered. It was estimated that nearly 80% of the adult population in the United States lived within 60 min of a PCI hospital in

*Catheterization and Cardiovascular Interventions*  
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programs have on-site surgery. It is likely to save more lives than requiring all PCI programs meet appropriate performance metrics to manage individual operator or laboratory outcome equipment and personnel that has careful tracking of satisfactory outcomes in a laboratory with appropriate indications, by a skilled operator with documented This means the PCI is done for appropriate clinical analysis, every PCI procedure regardless of where it is performed should be of the highest possible quality. This means the PCI is done for appropriate clinical indications, by a skilled operator with documented satisfactory outcomes in a laboratory with appropriate equipment and personnel that has careful tracking of patient outcomes and corrective mechanisms in place to manage individual operator or laboratory outcome data that fall below national standards. Ensuring that all PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs have on-site surgery.

RECOMMENDATIONS

1. PCI without on-site surgical backup is being performed with acceptable outcomes and risks in the United States and many other countries. The recommendations outlined in this document are made to ensure patient safety and quality outcomes in such a work environment. This is not an open endorsement of PCI without on-site surgery, and we do not support the wide-spread use of PCI without on-site surgery, especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.

2. The decision to begin or operate a PCI program without on-site surgical backup should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. Rural communities may have different health care delivery needs than urban centers and this should be considered.

3. It is the goal of SCAI to promote the highest possible program quality. Accordingly, PCI programs both with and without on-site surgical backup must evaluate their outcomes against their countries’ benchmark for program performance or other acceptable standard.

4. Operators performing PCI without on-site surgery should perform ≥100 total PCIs per year, including ≥18 primary PCIs per year. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures.

5. Independent program oversight should occur either within the context of a local facility’s quality assurance program or through an independent government or external agency. Any program failing to perform adequately should close.

6. Further data collection and analysis should be done to more completely understand the role of PCI without on-site surgical backup as a strategy for the delivery of care.

REFERENCES


4. Wharton TP Jr. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community? The case for community hospital angioplasty. Circulation 2005; 112:3509–3534.

5. Keeley EC, Grines CL. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community? The case for emergency transfer for primary percutaneous coronary intervention. Circulation 2005;112:3509–3534.


47. Weaver WD, Parsons L, Every N, for the MITI project investigators. Primary coronary angioplasty in hospitals with and without surgery backup. J Invasive Cardiol 1995;7:34F–39F.


APPENDIX. SCAI Writing Committee for Expert Consensus Document Disclosures

<table>
<thead>
<tr>
<th>Name</th>
<th>Do you perform elective PCIs in a hospital that has on-site surgical backup?</th>
<th>Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and has on-site surgical backup?</th>
<th>Do you perform elective PCIs in a hospital that does not have on-site surgical backup?</th>
<th>Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and does not have on-site surgical backup?</th>
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<tr>
<td>Dr. Gregory J. Dehmer</td>
<td>Yes</td>
<td>No</td>
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<td>Dr. James Blankenship</td>
<td>Yes</td>
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<td>Yes</td>
<td>No</td>
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<td>Dr. Ashok Seth</td>
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<td>No</td>
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<td>Yes</td>
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<td>Dr. Carlo DiMario</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>I perform PCI at one hospital with on-site surgery and primary PCI only at a different hospital without on-site surgery.</td>
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<tr>
<td>Dr. David Muller</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>I perform primary PCI at a hospital without on-site surgery.</td>
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<tr>
<td>Dr. Mirle Kellett</td>
<td>Yes</td>
<td>No</td>
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<td>Dr. Barry F. Uretsky</td>
<td>Yes</td>
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PCI, percutaneous coronary intervention.

Percutaneous coronary intervention.