Elective PCI Without On-Site Cardiac Surgery: Standard of Care?

The performance of PCI without on-site cardiac surgery remains controversial and continues to be debated in the US.

BY GREGORY J. DEHMER, MD

The use of percutaneous coronary intervention (PCI) has grown dramatically during the past 30 years. Several developments have led to the growth of PCI, including improved equipment, new anticoagulant and antiplatelet drugs, and the evolution of coronary artery stents. Simultaneous with these improvements, the indications for PCI have expanded, and the safety and outcomes of the procedure have steadily improved. During the early days of balloon angioplasty, procedure mortality was 1% to 2.5%, and up to 5% of patients required urgent coronary artery bypass graft (CABG) surgery.[1,2] In comparison, in-lab mortality at high-volume centers is now approximately 0.2%, and <0.5% of patients require urgent CABG surgery.[3,4]

PCI is now the preferred therapy for patients with ST-segment elevation myocardial infarction (STEMI).[5,6] However, the superior outcomes of primary PCI are adversely affected by time delays that may accumulate before the patient arrives in the cardiac catheterization laboratory at a PCI-capable facility.[7,8] Studies showed that door-to-balloon times for primary PCI were not optimal but could be decreased by 30 to 40 minutes in some settings by offering PCI at facilities without on-site surgery.[9-11] To avoid the inherent delays that occur when transferring patients, and to extend this therapy to a larger number of patients, some facilities began to perform primary PCI for STEMI in the absence of on-site surgery and reported excellent outcomes.[12] Because the actual number of patients with STEMI at any location is relatively small, many of these facilities also started performing elective PCIs in an effort to maintain proficiency among the support staff and have adequate procedure volumes to justify the operation of such programs.[13-15] Although it is accepted in many countries abroad, the performance of PCI without on-site cardiac surgery remains controversial in the US.[16]

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THE STANDARD OF CARE

In legal terms, the "standard of care" is defined as the level at which the average, prudent provider in a given community would practice. It describes how similarly qualified practitioners would have managed the patient's care under the same or similar circumstances. The standard of care is not simply what the majority of practitioners would have done. The courts recognize the respectable minority rule. This rule allows the practitioner to show that although the course of therapy followed was not the same as other practitioners, it would be accepted by a respectable minority of practitioners. The jury is not bound to accept the majority standard of care and may, in fact, decide that a minority standard is the proper standard and that a physician following the majority standard was negligent. The medical malpractice plaintiff must establish the appropriate standard of care and demonstrate that the standard of care has been breached. Based on this definition, should elective PCI without on-site cardiac surgery now be considered the standard of care?

THE USE OF PCI WITHOUT ON-SITE CARDIAC SURGERY IN THE US

One factor to consider in determining whether elective PCI without on-site cardiac surgery is the standard of care is to ascertain how commonly it is being performed in the US. Data on PCIs performed at facilities without on-site surgical backup in the US are not easily found. In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document on this topic, which contained survey data collected by the SCAI on the use of PCI without on-site surgery.[17] This is a dynamic situation, with some states currently considering changes in their statutes. Updated survey data indicate there are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) in which neither primary nor elective PCI are performed without on-site surgery (Figure 1). There are 10 states in which only primary PCI is performed and 33 states in which both primary and elective PCI are being performed without on-site surgical backup. However, in seven of these 33 states, primary and elective PCI are only allowed as part of a research study or controlled demonstration project.

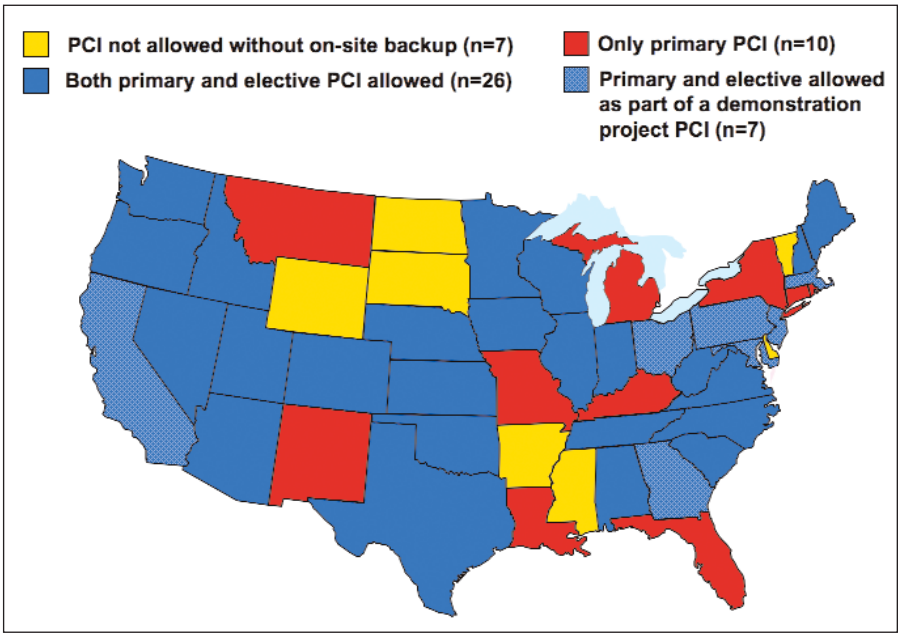

Figure 1. Status of PCI without on-site cardiac surgery backup in the US. There are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) in which PCI without on-site cardiac surgery is not performed. Legislation is pending in California to allow a monitored demonstration project of elective PCI without on-site backup. Primary PCI without on-site surgery was allowed in Washington but not elective PCI. However, Washington has a liberal definition of emergency PCI so that patients with acute coronary syndromes and non-STEMI who have stabilized are allowed to undergo PCI at facilities without on-site surgery. Florida is also considering rule changes to allow both primary and elective PCI at selected facilities without on-site surgery. (Adapted from Dehmer GJ, Blankenship J, Wharton TP, et al. Executive Summary. 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. Catheter Cardiovasc Interv. 2007;69:471-478.[17])

The number of patients receiving PCI at facilities without on-site surgery in the US is unknown. Recent data from the CathPCI Registry of the National Cardiovascular Data Registry (NCDR) show an increasing use of PCI without on-site surgical backup, but even in this registry, the number of patients having PCI without on-site surgery is small.[18] The most recent NCDR report listed 60 of 405 (14.8%) sites without on-site cardiac surgery and 8,736 of the 308,161 patients (2.8%) undergoing PCI at such facilities.[19] However, these data are subject to bias because reporting to the NCDR is not mandatory, and some facilities only report data because they are required by the state as part of their approval to perform PCI without on-site surgical backup.

Data from outside the US show a greater use of PCI without on-site surgery. For example, the 2006 update from the British Cardiovascular Interventional Society PCI registry shows that 42% of the 91 PCI centers in the United Kingdom do not have on-site cardiac surgery, and these centers performed 21% of the total annual PCIs in 2006.[20] Likewise, data from the Swedish Coronary Angiography and Angioplasty Registry show that 58% of the 24 PCI centers in Sweden do not have on-site cardiac surgery, and these centers performed 26% of all PCIs.[21]

THE SAFETY OF PCI WITHOUT ON-SITE CARDIAC SURGERY

A prerequisite for evaluating whether PCI without on-site cardiac surgery is the standard of care is to deter-

mine if it is safe compared with PCI performed at centers with on-site cardiac surgery. Obviously, if this practice were hazardous, it could not be considered the standard of care.

The first reports of PCI performed without on-site surgical backup appeared in the literature in the early 1990s, and there are now nearly 40 published reports describing experiences with PCI without on-site cardiac surgery.[11-15,17,20-25] Simple aggregation or meta-analysis of these data are difficult because some studies apply strict screening criteria to identify only low-risk PCI patients, whereas others describe PCI in a broad patient range, including several high-risk subgroups. Some studies examine either primary or elective PCI performed without on-site surgical backup, whereas others include all PCI patients. Moreover, these studies span a time period from 1990 to 2008 and thus incorporate the changing treatments used, such as glycoprotein IIb/IIIa inhibitors and coronary artery stents. Even the total patient number in some of these studies is difficult to assess because they describe expanding experiences within the same registry and thus include some duplication of patient experiences. Because coronary artery stents resulted in a substantial decrease in the number of patients requiring emergency CABG surgery, it is a logical point of separation for examining these studies, but the use of stents is not consistently reported among these studies.

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More recent reports show that PCI performed without on-site cardiac surgery backup has a high success rate, a low in-hospital mortality rate, and a low rate of urgent cardiac surgery.[19-22,24,25] The highest mortality rate reported in a contemporary study was based on administrative data that included only Medicare patients and reported a 30-day rather than in-hospital mortality rate.[23] In this study, the 30-day mortality rate for primary PCI was similar, but an increase in mortality for elective PCI was observed at sites without on-site surgery backup. However, the majority of hospitals without on-site cardiac surgery in this study performed fewer than 25 Medicare PCIs per year, whereas only a small number with on-site cardiac surgery were low-volume hospitals.

CONTEMPORARY STUDIES OF PCI WITHOUT ON-SITE CARDIAC SURGERY

Table 1 summarizes the results from several contemporary studies that compare PCI performed at facilities without on-site cardiac surgery to PCI performed at centers with on-site cardiac surgery. Included are the large experiences of the The British Cardiovascular Interventional Society, the Swedish Coronary Angiography and Angioplasty Registry, and the CathPCI Registry of the NCDR (a total of 416,216 patients).[19-21] In these registries, the rates of emergency CABG surgery and in-hospital mortality at facilities without on-site cardiac surgery were uniformly low and not different from facilities with on-site cardiac surgery. Moreover, there was no difference in the success of the PCI procedure among facilities, although selection criteria and clinical judgment were used to avoid high-risk procedures at facilities without on-site cardiac surgery.

Single-center experiences from the Mayo Clinic, Duke University, Mid America Heart Institute, a VA hospital, and Norway are also included in Table 1.[13,14,22,24,25] The US studies report the results of PCI in large healthcare systems in which a satellite program was supported at a community hospital without on-site cardiac surgery. As in the large registries, all of these studies report excellent patient outcomes and a low incidence of urgent cardiac surgery. Uniformly, programs at these satellite facilities emphasize the importance of using experienced interventionists, technicians, and nurses; a tested emergency transport protocol; a well-equipped catheterization laboratory; a thorough quality assurance process; and the avoidance of obvious high-risk cases. A more comprehensive summary of studies related to PCI without on-site surgical backup and recommendations for the structure and operation of such programs is beyond the scope of this article but can be found in the SCAI Expert Consensus document.[17]

All published data for PCI without on-site cardiac surgery are derived from retrospective reviews or prospective registries and thus are subject to unintentional bias and other methodological concerns. The favorable reports may also reflect publication bias because there is no requirement for public reporting of programs that have not succeeded. A well-controlled, properly powered, and randomized study has not been performed, but a study with these characteristics is under way.

IS PCI WITHOUT CARDIAC SURGERY THE STANDARD OF CARE?

PCI without on-site cardiac surgery is being performed in the majority of states and in many countries, including Canada, the United Kingdom, Germany, France, Italy,

TABLE 1. SELECTED CONTEMPORARY STUDIES OF PCI WITHOUT ON-SITE CARDIAC SURGERY

Study	Total Number of PCIs	Number of PCIs Performed Without On-Site Surgery	Proportion of Sites Without On-Site Cardiac Surgery	Emergency CABG Needed		Mortality	
				With On-Site Surgery	Without On-Site Surgery	With On-Site Surgery	Without On-Site Surgery
BCIS[20]	73,692	15,539	42%	0.1%	0.05%	0.73% not separated by site	
SCAAR[21]	34,363	8,838	58%	0.2%	0.1%	2.2%	1.4%*
NCDR[19]	308,161	8,736	14.8%	0.4%	0.3%	No difference in risk-adjusted mortality	
Duke[14]	562	562	No comparison group		0.8%		0.18%
Mayo[13]	1,007	1,007	50%†	0%	0.1%	0.5%	1.2%
Mid America Heart[22]	1,009	1,090	50%†	0.3%	0.2%	0.8%	0.1%
VA study[25]	401	401	No comparison group		0%		0%
Norway[24]	609	305	50%†	0%	0%	0%	0%

BCIS, British Cardiovascular Interventional Society; NCDR, National Cardiovascular Data Registry; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; VA, Veterans Administration.
**30-day unadjusted mortality.*
†Only two sites reported, one with and one without on-site cardiac surgery.

Mexico, Sweden, and Norway. In many countries outside the US, the healthcare delivery system provides no financial motives to stimulate the performance of PCI without on-site cardiac surgery. Therefore, it seems reasonable to assume that PCI without on-site cardiac surgery backup is performed in these countries because the health authorities believe it is safe and an appropriate situation for the delivery of PCI services to the largest number of patients. Although existing data evaluating the delivery of PCI in this manner are imperfect, it seem reasonable to conclude that there are many patients who can safely be treated by PCI in the absence of on-site cardiac surgery if "best-practice" standards are applied to the operation of such programs.[17]

Most individuals in healthcare equate the phrase "standard of care" with the use of a particular treatment rather than the setting in which a particular treatment is used. The standard of care describes how similarly qualified practitioners, in this case interventional cardiologists, would have managed the patient's care under the same or similar circumstances. Most would agree that elective PCI is appropriate and thus is the standard of care for a patient with severe, limiting angina despite good medical therapy, evidence of stress-induced myocardial ischemia, and single-vessel disease that is correctable by stent placement. However, there are

many other clinical scenarios in which opinions would vary and the use of PCI for revascularization would be debated. Likewise, the performance of PCI at facilities without on-site cardiac surgery is a situation in which opinions continue to vary.[26-28] Regardless of what is done in other countries or individual opinions about PCI without on-site cardiac surgery, a more important question is, how can the US develop the best possible delivery system for PCI that provides the best care to the largest number of patients? At the present time, this issue mainly revolves around providing rapid care for patients with STEMI.[26-29]

THE FUTURE OF PCI WITHOUT ON-SITE SURGICAL BACKUP IN THE US

Despite the demonstrated advantage of primary PCI, access to this service in the US remains limited, with only 25% of acute care hospitals capable of providing PCI.[28,30] Although data from the Global Registry of Acute Coronary Events show an increase in the use of reperfusion therapy among patients with myocardial infarction, only 44% of patients undergo primary PCI.[31] One possible interpretation of these data would be that more primary PCI centers are needed. However, the impact of opening more PCI centers at facilities without on-site surgery is questionable. Using census data from 2000, it was estimated that nearly 80% of the adult population lives within 60 minutes of a PCI hospital and among those living closer to non-PCI hospitals, almost three-fourths would experience <30 minutes of additional delay with direct referral to a PCI hospital.[30] Furthermore, a recent study examined data from Michigan and estimated that providing PCI without on-site backup improved access to <5% of the population.[32]

At the present time, there are three models for the delivery of PCI care in patients with STEMI. One model is to develop PCI programs at community hospitals without on-site surgery in an attempt to provide rapid primary PCI to patients in their local community.[16,33] Although several reports document the safety of this approach, it requires a high level of physician and facility support, a commitment to maintain high standards of quality, and by necessity, the need to also perform elective PCIs to maintain adequate procedure volumes and experience. Opening a low-volume PCI program in close proximity to a high-volume program, thereby degrading the high-volume program, is not necessarily in the best interest of patients or the community. However, many factors besides distance can define a geographic area, including the level and availability of emergency transport services, response times of emergency medical transport, immediate availability of qualified catheterization lab personnel, and coverage by interventional cardiologists.

An alternative model is the "hub-and-spoke model" in which a referral network is established to transfer all STEMI patients to a central high-volume facility.[34,35] In this model, the central hospital works closely with the outlying hospitals to develop treatment and transfer protocols designed to standardize care and minimize transfer delays. This model has been promoted successfully at a state-wide level.[36-38] A variant of the hub-and-spoke model is the so-called "bypass model." In the bypass model, there is an enhanced effort to recognize patients with STEMI "in the field" and then transport patients directly to PCI-capable facilities, thereby bypassing facilities without PCI capability.[39]

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.[29,34] 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. In some areas, the appropriate solution may be the development of a "hub-and-spoke" or bypass system for the efficient transfer of patients to a PCI facility. However, in other areas, developing a PCI program at a hospital without on-site surgery may be preferable.

CONCLUSION

In the final analysis, every PCI procedure, regardless of where it is performed, should be performed on patients with appropriate indications by a skilled operator with documented satisfactory outcomes and in a manner consistent with the highest possible quality standards. This should be the standard of care for all PCI procedures. If the local environment dictates the need for PCI without on-site cardiac surgical backup because the service is otherwise unavailable, it is likely a similarly qualified and prudent interventional cardiologist would proceed in this setting and, by definition, PCI without on-site cardiac surgical backup could be considered the standard of care. However, if the local environment suggests that the performance of PCI at a facility without on-site surgery is simply a duplication of existing services that provide little to improve access to care in the community and is being performed mostly for financial motives, it is unlikely it could be considered the standard of care. ■

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