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ontraversy continues in the United States over the performance of percutaneous coronary intervention (PCI) at facilities without on-site cardiac surgery. After publication of the quantitative review by Keeley et al in 2003, the superiority of PCI over thrombolytic therapy for the treatment of ST-segment–elevation myocardial infarction (STEMI) was widely accepted. These findings further supported primary PCI programs at hospitals without cardiac surgery in an effort to provide more rapid care for patients with STEMI in their local communities. This strategy was subsequently extended, with good reported results, to non-emergent and elective PCI cases in an attempt to maintain higher PCI volumes and staff expertise. However, controversy continued as the 2005 PCI Guidelines designated primary PCI a class IIb indication (may be considered) but elective PCI a class III indication (not recommended) in hospitals that did not have cardiac surgery on site.

Despite the guideline recommendations, the number of PCI facilities without on-site cardiac surgery in the United States continued to grow. In 2007, the Society for Cardiovascular Angiography and Interventions published an expert consensus document, which reviewed the topic of PCI without on-site surgery and provided recommendations to assure appropriate patient care whenever PCI was performed in this setting. The goal of this document was not to challenge the guideline recommendations, but rather to deal with the reality that primary and elective PCI without on-site surgery was already being performed in 28 states despite the guideline recommendations.

Is PCI Without On-Site Cardiac Surgery Safe?

To answer that question, it is reasonable to separately consider the performance of primary and elective PCI as the risk to benefit ratio is different in each setting. Fortunately, with all the improvements in PCI during the past 32 years, the need for emergency cardiac surgery for a failed PCI is now extremely low, between 0.3% and 0.6%. However, the mortality rate with emergency surgery is approximately 10% to 15% and has not improved since the early days of PCI. In the setting of primary PCI, the risk to benefit ratio is clearly different because rapidly establishing flow in the infarct-related artery is critical for the best outcome. Without question, the more controversial issue is the risk to benefit ratio of elective PCI without on-site surgery. Benefits of this approach have been cited but are more difficult to quantify as hard end points.

Although door-to-balloon times in the United States are improving, important delays still occur when patients are transferred from non-PCI hospitals for primary PCI. The option of PCI in facilities without on-site surgery, especially in rural communities, is one potential way to provide timely access to PCI for patients with STEMI. Developing such programs still raises concerns about maintaining adequate experience and procedure volumes at facilities that only perform primary PCI. Previously reported data from the New York State PCI registry showed that higher volume operators and hospitals have lower risk-adjusted rates of adverse outcomes after PCI, even in the stent era. Therefore, the lingering question of safety and outcomes at low-volume facilities remains and is used as further justification for allowing less urgent and elective PCI at programs without surgery on site. It is important to note, however, that when the expansion of primary PCI to 12 facilities without on-site surgery was allowed in Michigan as part of a demonstration project, the actual improvement in timely access at the 3 most geographically isolated facilities was <10%.

In this issue of Circulation: Cardiovascular Interventions, Hannan et al add to the growing body of evidence that primary PCI for STEMI at facilities without on-site surgery is safe. Starting in 2000, the New York State Department of Health allowed a limited number of hospitals without on-site cardiac surgery to perform primary PCI, and by 2006, 11 hospitals were approved to provide this therapy. Using data collected during a 4-year period, several clinical outcomes for patients with STEMI treated at hospitals with and without on-site surgery were compared. After appropriate exclusions, there remained 1735 patients who had primary PCI at hospitals without on-site cardiac surgery and 8817 patients treated at facilities with on-site surgery. Because patients were not randomized to the 2 types of hospitals and to ensure that the groups ultimately compared were similar in their characteristics, propensity matching was performed. This
resulted in the 2 groups (n=1729 each) compared in this study.

Their data show no significant differences for in-hospital/30-day or 3-year mortality among patients undergoing primary PCI at hospitals with and without on-site cardiac surgery. The very low in-hospital/30-day mortality rates of ≈2% for patients with STEMI should not go unnoticed as it reflects how beneficial primary PCI is as a therapy. Although not “significant” when applying the usual definition of P≤0.05, 3-year mortality was an absolute 1.2% higher (P=0.07) in those receiving PCI at hospitals without on-site surgery. Examination of the Kaplan-Meier curve shows that this small difference exists mainly within the first 3 months after the STEMI. There is no clear explanation for this trend, which may simply be related to how the matching was performed or other variables not accounted for in the statistical models.

Similarly, there was no significant difference in the need for emergency coronary artery bypass grafting surgery immediately after PCI, but a strong trend was evident (P=0.06) showing a lower rate of emergency coronary artery bypass grafting surgery at hospitals without on-site surgery (0.06%) compared with hospitals with on-site surgery (0.35%). A lower rate of emergency coronary artery bypass grafting surgery at hospitals without on-site surgery has been noted in other studies.8 Hospitals without on-site surgery had a lower rate of same or next day coronary artery bypass grafting surgery (0.23% versus 0.69%, P=0.046) compared with hospitals with on-site surgery. One potential explanation is that patients who actually need surgery are not being promptly sent out for a variety of reasons including the logistics of travel to the off-site surgery center. However, if this was true, one might expect a higher in-hospital or 30-day mortality at hospitals without on-site surgery, and this was not observed in the present data or any other study.

One curious observation is the slightly higher rate of repeat target vessel PCI (12.1% versus 9.0%, P=0.003) in patients treated at hospitals without on-site surgery. A propensity match for the use of drug-eluting stents reduced the absolute difference roughly in half (3.1% to 1.6%), but this was still significant. Because all but 3 of the operators at facilities without on-site surgery also performed PCI at facilities with on-site surgery, one potential explanation is that patients who actually need surgery are not being promptly sent out for a variety of reasons including the logistics of travel to the off-site surgery center. However, if this was true, one might expect a higher in-hospital or 30-day mortality at hospitals without on-site surgery, and this was not observed in the present data or any other study.

Their final observation required the incorporation of administrative data from other sources. Patients presenting with STEMI to hospitals without on-site surgery who did not undergo primary PCI had higher in-hospital mortality (28.5%) compared with patients with STEMI treated at hospitals with on-site surgery (22.3%). Although some adjustment for patient risk factors was performed, the characteristics of patients not undergoing PCI are not well described in the article, making any conclusions about this difference difficult.

Several recent studies have also confirmed the safety of PCI performed at hospitals without on-site surgery. The National Cardiovascular Data Registry, in an analysis of just >300 000 patients undergoing either primary or nonprimary PCI, reported no difference in in-hospital mortality between facilities with and without on-site surgery.14 Furthermore, an update of the Mayo Clinic experience and data from the Swedish registry both confirmed the safety of primary and nonurgent PCI performed at hospitals without on-site surgery.15,16 Although the question—Is PCI without on-site cardiac surgery safe?—is appropriate, we believe the answer is now as clear as it has ever been and is—yes.

The Future of PCI Without On-Site Cardiac Surgery

Although the answer about safety may be clear, the practical future of PCI without on-site surgery is uncertain. First, the occurrence of STEMI in the United States is decreasing. From 1988 to 1996, the age-adjusted rate for all STEMI remained steady at ≈108 per 100 000 adults.17 However, from 1996 onward, the age-adjusted incidence of STEMI across various races and genders has steadily decreased to about half the incidence during the previous 8 years. Because the need for primary PCI services has been the driver for many programs and the rate of STEMI is decreasing, is it still necessary to have so many programs? Second, the use of PCI for the treatment of coronary artery disease is also decreasing. Data from the Centers for Medicare & Medicaid Services show a 16% decline in the utilization of PCI during the past 2 to 3 years.18 Third, recent shifts have moved a substantial number of PCI procedures from inpatient to outpatient billing status and this has sharply decreased reimbursement for elective PCIs.19 Declining reimbursements will have a substantial impact on many smaller PCI programs, which tend to be clustered in more rural areas and in community hospitals. PCI programs, which had generated a positive margin for the hospital, may no longer be able to sustain this financial balance and be forced to close. Declining reimbursements will likely continue as more healthcare reform measures occur. Finally, a recent workforce survey commissioned by the American College of Cardiology suggests that there will be a growing shortage of interventional cardiologists during the next 10 years.20 A collision of all these factors will force the interventional cardiology community to ask a very key question—What is the most efficient, patient centered and highest quality system to deliver primary and elective PCI services in the future? “Just because you can do something doesn’t mean you should” is an old expression we have all heard. Having multiple lower volume PCI programs grounded in the desire to provide 24/7 primary PCI services in many local communities may no longer be a viable approach in the changing healthcare environment. Nevertheless, primary PCI programs should exist and be supported if they clearly make rapid reperfusion available to patients who otherwise could not achieve current treatment goals.

The study by Hannan et al further documents the safety of performing primary PCI for STEMI in hospitals without on-site surgery. If such a program is vital to a local community and also needs to perform elective PCIs to remain viable, it should be allowed to function in that capacity and supported by state regulations and recommendations developed by professional organizations. It is critical to emphasize, however, that the New York state experience in PCI facilities...
without on-site surgery occurred as the result of careful planning, logistics, structure, and process with outcomes based feedback. Moreover, these were not low-volume centers or low-volume operators. The favorable results in this important registry study should not be extrapolated to justify the development of off-site PCI programs that do not have a similar process or a strong commitment to provide high-quality evidence-based care.

As stated in the conclusions of the Society for Cardiovascular Angiography and Interventions Expert Consensus document, “In the final 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.”

Disclosures

None.

References


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ST-Segment-Elevation Myocardial Infarction Treated at Hospitals With and Without On-Site Cardiac Surgery: Do We Have the Answer and What About the Future?

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