The Challenges of Success
Maintaining Access to High-Quality Percutaneous Coronary Intervention in the Face of Declining Procedural Volumes

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ver the past several decades, major changes in lifestyle, preventive care, and clinical management have contributed to an impressive reduction in coronary artery disease prevalence, incident acute myocardial infarction, and deaths due to coronary heart disease. As a result, the use of cardiovascular services in the United States has decreased dramatically in recent years. For patients with coronary artery disease, advances in medical management have allowed more and more patients to avoid elective catheterization procedures, whereas the results of recent studies (eg, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation [COURAGE], Fractional Flow Reserve versus Angiography for Multivessel Evaluation [FAME], and Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery [SYNTAX]) have led to the more judicious use of percutaneous coronary intervention (PCI) in patients with chronic coronary artery disease. The combined effect of these trends has been a marked reduction in overall PCI volumes, from a peak of nearly 1 million in the United States in 2006 to ≈600,000 in recent years. At the same time as overall PCI volumes have been decreasing, the number of PCI centers has been increasing as data have emerged indicating that the absence of on-site cardiac surgery does not adversely impact patient outcomes after either emergent or elective PCI. Together, declining PCI volumes and the increasing number of PCI centers has led to a decrease in the volume of PCI procedures at both the center and operator level.

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Common sense dictates that any skill requires adequate experience to ensure optimal results. This holds true for airline pilots, hairdressers, and physicians alike. What differs among the professions is what qualifies as adequate experience. In his book Outliers, Malcolm Gladwell describes the “10,000 hour rule,” in which he posits that it takes 10,000 hours of practice to become a master of any skill. The same principle likely holds true in interventional cardiology, because much research demonstrates a positive association between volume of procedures performed and good patient outcomes. As a result, minimum volume standards for those physicians performing PCI have been established by multiple professional societies. The 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACCF/AHA/SCAI) clinical competence statement on PCI recommended that PCIs be performed only by operators with an annual volume of >75 procedures at hospitals with an annual volume of >400 procedures. In the face of decreasing PCI volumes, however, the 2013 ACCF/AHA/SCAI guidelines were revised and now recommend that PCIs should be performed by operators with an annual volume of >50 procedures averaged over a 2-year period. Despite the wealth of data on the PCI volume-outcome relationship, there are few definitive data on what the threshold for too little volume should be. Consequently, the 2013 ACCF/AHA/SCAI recommendations regarding minimum PCI volumes were based mostly on expert opinion rather than on solid evidence.

In this issue of Circulation, Badheka and colleagues add the largest and most contemporary study to the body of literature regarding the PCI volume-outcome relationship. In this study, they analyzed data on PCI outcomes derived from the National Inpatient Sample database between the years of 2005 and 2009. By using International Classification of Diseases, 9th Revision, Clinical Modification codes, PCI procedures and procedure-related complications were identified and linked to a unique operator identifying number. After restricting the sample to those patients without missing data, a total of 457,498 patients were identified. Using hierarchical mixed-effects models to take into account the effect of clustering within institutions, and geographic region, as well, they identified a clear and robust relationship between institutional and operator PCI volume and in-hospital outcomes, including mortality and periprocedural complications. Spline analyses suggested that the probability of in-hospital mortality and periprocedural complications was minimized at ≈300 PCIs performed per year by an individual operator. Interestingly, they also observed an inverse relationship between operator volume and hospital length of stay and costs (which were estimated from hospital billing data).

Although the findings described by Badheka and colleagues are consistent with many previous studies, their study is not without limitations. First and foremost, the National Inpatient Sample is based entirely on administrative claims data as opposed to clinical data, which are available in other large data sets such as the New York State PCI Registry or the...
NCDR CathPCI Registry. The absence of clinical and procedural data limits the researchers’ ability to adjust for a range of technical factors (eg, patient acuity, lesion complexity, etc) that may influence procedural outcomes. Second, the National Inpatient Sample only collects data on inpatient procedures. As such, any outpatient procedures performed by operators are not included in their calculated procedure volumes, making it difficult to know which operators were truly high versus low volume. The distinction between high- and low-volume operators is made even less reliable when one considers the sampling scheme that underlies the National Inpatient Sample database, and the fact, as well, that nearly half the procedures were excluded from the analysis because of a missing unique operator identifying number.

Notwithstanding these limitations, the general finding of the study—that low-volume operators and institutions are associated with poorer PCI outcomes—is consistent with previous literature.\textsuperscript{13,14,16,19} One of the more sobering, albeit subtle, findings from this study was that the median operator PCI volume was 75 cases per year, with a substantial fraction of operators falling below 50 PCIs per year, a level that barely meets current ACCF/AHA/SCAI recommendations. Although these numbers may have underestimated true operator volume by excluding outpatient procedures as noted above, they nonetheless fall far below the optimal threshold of \textasciitilde300 per year identified in their study. As such, the trend of declining PCI volumes coupled with a clearly defined volume-outcome relationship could spell trouble for PCI patients in the years to come.

In addition to the overall decrease in the number of PCI procedures, one of the key factors leading to the recent decline in operator and institutional PCI volumes has been the proliferation of catheterization laboratories and PCI programs across the country. In some cases, there has been a genuine need for new programs to provide greater availability of primary PCI services in rural and otherwise underserved regions.\textsuperscript{20} In many cases, however, the motivation has been financial with hospitals and health systems seeking to take advantage of the favorable reimbursement for PCI or to add to their cachet as a cardiac or chest pain center. In recent years, this proliferation of operators falling below 50 PCIs per year, a level that barely meets current ACCF/AHA/SCAI recommendations. Although these numbers may have underestimated true operator volume by excluding outpatient procedures as noted above, they nonetheless fall far below the optimal threshold of \textasciitilde300 per year identified in their study. As such, the trend of declining PCI volumes coupled with a clearly defined volume-outcome relationship could spell trouble for PCI patients in the years to come.

In this issue of \textit{Circulation}, Maddox and colleagues have performed one of the first studies to systematically examine the effect of increasing access to PCI on clinical outcomes.\textsuperscript{21} Using data from the Veterans Affairs (VA) Clinical Assessment, Reporting and Tracking program, a clinical database linked to a variety of administrative databases maintained by the VA system, they examined in-hospital and 1-year clinical outcomes among \textasciitilde24,000 patients undergoing PCI at VA facilities with and without on-site cardiac surgery. In a series of carefully constructed analyses, Maddox and colleagues found no significant differences in 1-year clinical outcomes between patients who received PCI at a VA site with on-site cardiac surgery versus a site without on-site cardiac surgery. Moreover, by using geospatial mapping, they found that the availability of PCI centers without on-site cardiac surgery reduced median patient drive time by nearly 90 minutes among patients treated at those facilities. On the basis of these findings, they concluded that, within the VA healthcare system, expanding PCI programs to include facilities without on-site cardiac surgery improved patient access to PCI without compromising clinical outcomes.

The results of this study are both reassuring and concerning at the same time. On the one hand, it is comforting to see that within the VA system, the expansion of PCI facilities has led to enhanced access to services without any detectable compromise in quality. What is disturbing, however, is the fact that the VA experience is unlikely to be generalizable to the United States as a whole. Because the VA is a single payer integrated healthcare delivery system in which patients do not often leave the system for care, the decision to offer PCI programs at facilities without on-site cardiac surgery within the VA system was made in a systematic and organized fashion. Sites for PCI expansion were likely to have been carefully selected so that patient access was maximized. Furthermore, the Clinical Assessment, Reporting and Tracking Program was established concurrently with PCI program expansion to ensure high-quality care. By collecting real-time data on catheterization laboratory procedures, complications, and outcomes, the Clinical Assessment, Reporting and Tracking Program was able to use these data to provide formal site and operator review with the intention of identifying system problems early and addressing them as needed. Unfortunately, this type of quality control program does not commonly exist in health systems outside of the VA, meaning that system and quality issues are harder to diagnose and treat appropriately. Furthermore, there is no centralized body dictating how, where, and when PCI programs are opened at hospitals outside the VA system, with the predictable result that PCI program expansion generally occurs in a haphazard manner.

The question then arises as to the true benefits, risks, and costs of opening new PCI programs. Certainly, if new PCI facilities can improve access to life-saving care (eg, primary PCI) that patients would not be able to otherwise obtain, then the benefits are clear. Unfortunately, the reality is that most new catheterization laboratories in the United States have opened in areas that already have established PCI programs and therefore do not improve access in any meaningful way.\textsuperscript{22,23} Without improving access to PCI, there really is no discernible benefit to society in continuing to develop new PCI centers. In fact, there is likely substantial societal cost, both monetarily (by duplication of services and increased capital expenditures) and clinically (if patient outcomes are compromised by diluting operator and hospital procedure volumes).

Society and the cardiology community are then left with the challenging task of balancing the competing priorities of increasing access to PCI while also maintaining a high-quality service. One approach to this dilemma would be to replicate the VA experience by centralizing decision making for developing and maintaining PCI programs. Certificate of Need regulations, designed to govern the introduction of new medical services to communities, are currently active in 26 states for cardiac catheterization laboratories.\textsuperscript{24} Although
these programs may lead to a more appropriate use of PCI,\textsuperscript{25} they do not necessarily ensure PCI quality, and they may increase costs. Other, less explicit, approaches could also be considered, such as regionalized systems of PCI care (similar to regional ST-segment elevation myocardial infarction networks that have developed endogenously) or economic disincentives (by reducing payments for PCI services to the point where they no longer are viewed as profitable by some hospitals). Unfortunately, none of these methods are without substantial political and operational challenges, and an array of potential unintended consequence, as well.

Improvements in cardiovascular health have created new challenges in the delivery of PCI. A disjointed approach to health services delivery has led to excess PCI capacity and an abundance of low-volume proceduralists without improving access to care, the costs of which will ultimately be borne by patients. The precise solutions to these issues will and should be hotly debated, but are likely to involve a combination of contraction, redistribution, and central coordination. Whatever these solutions may be, they will require courageous leadership by an engaged cardiology community dedicated to the mission of offering PCI that is safe, effective, and accessible.

Disclosures

None.

References


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