A Case Against Low-Volume Percutaneous Coronary Intervention Centers

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Since the publication of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial1 in April 2007, percutaneous coronary intervention (PCI) has received harsh scrutiny in both the scientific and lay press.2,3 The COURAGE investigators concluded that PCI did not reduce chances of death or myocardial infarction (MI) in patients with stable coronary artery disease and mild symptoms. At the same time, enormous controversy and media attention turned to a concern about late stent thrombosis in patients treated with drug-eluting stents. Studies suggested that an excess of deaths occurred 1 to 3 years after drug-eluting stent implantation.4,5 More recently, Tonino et al6 demonstrated in the Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) trial that the risk of MI could be reduced by use of fractional flow reserve measurements during PCI. The FAME trial suggested that patients were benefited by deployment of fewer stents. In 2008, Hannan et al7 found that risk-adjusted mortality was less for coronary artery bypass grafting (CABG) than PCI with drug-eluting stents in the New York State registry. In March 2009, the Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery (SYNTAX) trial was published, and Serruys et al8 concluded that PCI with drug-eluting stents was inferior to CABG in patients with multivessel or left main coronary disease. In June 2009, the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) investigators reported that patients with treated diabetes mellitus had no improvement in survival when they were revascularized with PCI; however, an improvement in survival occurred when patients were treated with CABG.9

In the aggregate, these studies combined with the dramatic decrease of interventions for in-stent restenosis have significantly decreased the growth of PCI use in the United States. Patients and referring physicians will question the need for PCI in patients with mild, stable symptoms. The use of fractional flow reserve will decrease multivessel and multivessel stent implantation. Although it is too soon to tell, it is likely that complex, multivessel PCI will lessen, and more patients who are SYNTAX eligible or diabetic will be referred for CABG.

In the face of this flattening or decline in overall PCI volume, it seems irrational to continue to open more PCI centers in the United States. It is especially irresponsible to open small programs without surgical backup. The study of Khattab et al10 in this issue of Circulation provides compelling evidence for the dangers to patient health posed by low-volume PCI centers.

The authors describe in-hospital and 6-month outcomes for 8201 patients treated with sirolimus-eluting stents (SES) in 51 German centers from April 2002 to September 2005. During this 41-month period, SES use occurred in 10% to 50% of all PCI procedures in these centers. Centers were divided into tertiles of high (>400 patients), medium (150 to 400 patients), and low volume (<150 patients). If you assume a 50% penetration of SES, the overall annualized volume is \( \approx 84 \), 84 to 240, and >240 PCI procedures per year. Outcome data were reported on all patients treated with SES, and an extremely high rate of 6-month follow-up occurred. The main finding from this study is that even when adjusted for baseline differences, an excess of 2 patients per hundred treated died or suffered an MI at 6 months in low-volume centers compared with patients treated in high-volume centers. Baseline differences in patient populations existed. In particular, 62% of patients treated in low-volume centers presented with acute coronary syndromes or MI, whereas only 49% of patients in high-volume centers did so. At first glance, it would appear that much of the outcome difference would be related to the high proportion of patients with acute coronary syndrome treated in the low-volume centers. Strikingly, death/MI or urgent revascularization occurred in 6% of acute coronary syndrome patients in the low-volume centers and only 2.4% of acute coronary syndrome patients treated in high-volume centers (\( P < 0.001 \)). The detailed risk adjustment model demonstrates that severity of illness does not explain the increase in danger for patients undergoing SES implantation in low- and medium-volume centers. Overall, 6-month mortality was significantly higher (\( P = 0.02 \)) in low-volume centers. This concern is especially apparent in patients with an acute coronary syndrome who were treated in low-volume centers.

Differences in lesion selection and stent implantation technique provide some insight into why PCI was safer in high-volume centers. High-volume centers used longer stents, used higher stent implantation pressure, less frequently performed direct stent implantation, and less frequently stented bifurcation- or thrombosis-containing lesions. As a result, fewer residual dissections occurred, and in-hospital major adverse coronary events were dramatically lower. Death, MI,
or urgent revascularization occurred in 1.6% versus 4.4% (P<0.001) of patients.

Why would high-volume centers use better stent implantation technique and treat less risky lesions than low-volume centers? This is the crux of the issue relative to the volume-outcome relation. It is likely that high-volume centers had multiple operators who cross-pollinated information, and more operators allowed for more cross-coverage so that some operators could attend national meetings at which the latest expert evidence is disseminated. Large-volume centers are more likely to participate in ongoing clinical trials. Large-volume centers likely had high-volume surgical programs, and collaboration with surgical colleagues likely enhanced appropriate triage of multivessel disease patients to surgery.

The report of Khattab et al adds to the growing body of evidence that low-volume centers and low-volume operators provide inferior outcomes for PCI-treated patients. McGrath et al\textsuperscript{11} found higher angiographic success and lower referrals for urgent CABG by high-volume operators in New England. Moscucci et al\textsuperscript{12} found a 63% increased odds ratio for major adverse coronary events among low-volume operators in the Michigan Blue Cross/Blue Shield consortium. Epstein et al\textsuperscript{13} analyzed a national database for 362,748 patients treated in the United States from 1998 to 2000. Patients treated in low-volume centers (5 to 199 procedures per year) had a significantly higher mortality than those treated at high-volume centers.

A major argument for opening more centers is the need for expanded coverage for emergency angioplasty therapy of ST-segment elevation MI.\textsuperscript{14} Wharton et al\textsuperscript{15} have demonstrated the safety and success of PCI therapy for ST-segment elevation MI in nonsurgical centers. The added risk posed by low-volume centers is offset by the markedly more rapid reperfusion that occurs in local settings. Wennberg et al\textsuperscript{16} analyzed a national database for 362,748 patients treated in the United States from 1998 to 2000. They found that 178 hospitals in the United States were performing PCI without on-site surgery. Mortality was similar for patients undergoing rescue or primary PCI in either setting. Alarmingly, mortality was significantly higher in the nonsurgical setting. Overall, patients treated in nonsurgical centers had a 6% mortality compared with a 3.3% mortality (P<0.001) in surgical centers. On the basis of these data, the American College of Cardiology/American Heart Association PCI guidelines indicated that performance of nonemergency PCI without on-site surgery was a class III indication.\textsuperscript{17} It is appallingly that, despite these guidelines, performance of PCI without on-site surgery has increased from 2001 to 2004.\textsuperscript{18}

The reasons why low-volume centers have inferior outcome are not complex. With the use of the McGrath definition of low volume (<80 Medicare PCIs per year), a low-volume center does ≈3 PCI procedures per week. Assuming a 4:1 ratio of diagnostic catheterization to intervention, a total of 15 cases per week are done. This averages to 3 cases per day. To be economically viable, these low-volume centers are obligated to cross-utilize staff and imaging laboratories with general radiology. Thus, neither catheterization laboratory imaging nor personnel can be highly specialized in caring for complex, high-risk patients. Catheterization laboratory budgets are tightly constrained so that expensive ancillary equipment such as intravascular ultrasound, fractional flow reserve measurements, and optical coherence tomography are unavailable. Furthermore, even if available, staff are unlikely to be trained to optimally operate this equipment. Similarly, stent inventory is likely to be constrained so that some lengths and sizes of stents are unavailable in stock. Finally, sophisticated support devices such as Tandem Heart or Impella will not be available. Even familiarity and use of intra-aortic balloon counterpulsation are problematic.

The constraints in catheterization laboratory equipment and staff are further compounded by the aftercare of patients. Most low-volume centers do not have dedicated coronary care units but rather small, multipurpose intensive care units. Residents and fellows are unlikely to be present for 24-hour coverage. Intensive care nurses and even step-down nurses cannot be optimally trained in the nuances of postcatheterization care. Care of ST-segment elevation MI patients poses enormous challenges to staff and physicians. The mandate for 24-hour/7 days per week coverage causes rapid burnout of staff. Emergency cases during the day disrupt scheduled cases. Staff will have to have time off the day after nighttime emergencies. It is little wonder that these laboratories rely on temporary agency employees to fill key positions. Vacancies and staff turnover prevent optimal continuing education of a stable work force.

The impediments for staff and equipment are mirrored in physician practices. The worse combination appears to be low-volume operators working at low-volume centers. In this situation, physicians’ inexperience cannot be buffered by institutional support. No “wise gray-haired guru” is available to bail out operators faced with procedural emergencies. A robust, data-driven quality assurance process cannot exist. Because most complication rates are in the single digits, it would take years for an operator to develop statistically significant differences in outcomes. Most low-volume centers are not in academic programs but rather in private practice settings. In this arena, peer review becomes highly political and highly contested. As demonstrated by Khattab, low-volume centers use less optimal stent implantation techniques. This is likely related to lack of current knowledge by low-volume operators. Because low-volume operators must make a living, they are forced to be generalists and noninvasive readers and do not have time to devote to a deep understanding of advances in the interventional field. It is truly not surprising that, in the United States, mortality is higher at low-volume centers that treat non–acute MI patients. The tragedy is that this is completely unnecessary medically.

The reason for the continued opening of unnecessary centers is entirely economic. Every small hospital seems to want a PCI center. The most accepted path to opening a new center in the United States today is by starting an acute MI program. At the start, even robust programs do <100 acute MI interventions per year. Thus, to treat 2 cases per week, the hospital must pay staff for 24 hours/7 days per week, must arrange for physician coverage for 24 hours/7 days per week, and must have trained intensive care nursing for 24-hour/7 days per week coverage. The only way that these programs
can come close to economical viability is to migrate to performance of nonemergency cases. Hospitals are willing to accept these costs because they do not want to lose the ability to accept chest pain patients into their emergency rooms. The strongest argument for opening new centers is patient convenience. Proponents argue that patients prefer to stay locally rather than travel 30 to 60 minutes to a PCI center. In the case of ST-segment elevation MI care, this appears medically appropriate. Patient convenience should never surmount patient safety, as it does in the situation of nonemergency cases performed in local, low-volume centers.

In a brilliant article in the New Yorker magazine, Dr Atul Gawande\(^6\) describes a battle that is raging for the soul of American medicine. This battle is being waged by proponents of appropriate, evidenced-based, high-quality health care against forces pushing to treat more, test more, prescribe more, operate more, and catheterize more for economic gain. It is time for the leadership of the American Interventional Cardiology profession to take a stand. No more low-volume centers! No more low-volume PCI centers performing nonemergency cases! As of 2001, there were 943 PCI centers with surgical programs. These are widely dispersed throughout the country. Access is rapid, and wait times are minimal. Given the flat procedural volumes, opening more centers is doubtfully helpful. First, more low-volume centers will exist; second, they decrease volume and dilute expertise from high-volume centers. If we as a profession cannot alter practices that are placing patients at needless risk of death or major adverse events, then we cannot complain when external regulatory bodies dictate how and where we can practice.

**Disclosures**

Dr O’Neill is a consultant for Medtronic.

**References**


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