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The Trials and Tribulations of Percutaneous Coronary Intervention in Hospitals Without On-site CABG Surgery

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Historically, on-site coronary artery bypass grafting (CABG) surgery was not only required for percutaneous coronary angioplasty but operating rooms were also usually on standby until the angioplasty procedure was deemed successful.¹ In the 1980s, abrupt and subacute closure of the coronary artery at the angioplasty site due to dissection and associated thrombus, were not uncommon and 5% to 10% of patients required emergency CABG or CABG surgery within 24 hours.²

Bail-out coronary stenting, for which stents are used to treat a dissection or abrupt closure after balloon angioplasty, revolutionized percutaneous coronary interventions (PCIs) by preventing periprocedural myocardial infarction and reducing the need for emergency CABG surgery. Subsequent randomized trials showed that primary stenting (stenting as a primary strategy) offered greater procedural success and lower rates of restenosis than balloon angioplasty and bail-out stenting.^{3,4} More recently, with primary stenting, the risk of requiring emergency CABG surgery is now 10 times lower than it was in the early balloon angioplasty era (<0.5%).^{5,6} Events are rare, because stents and other technologies successfully treat all but the most catastrophic complications of PCI.

The move to establish PCIs in hospitals without on-site CABG surgical facilities started with several trials that showed better outcomes with primary PCI than with thrombolytic therapy for ST-elevation myocardial infarction (STEMI).⁵ These benefits were expected because PCI is a more definitive treatment for the culprit coronary lesion and because thrombolytic therapy has defined risks of hemorrhagic stroke. Initial studies demonstrated that a strategy of transferring patients to centers with CABG surgery for primary PCI resulted in better outcomes than local treatment with thrombolysis.⁷ Subsequently, in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) study,⁸ better outcomes were achieved with local PCI in centers without CABG surgery than with thrombolytic therapy. Although no randomized trial tested primary PCI in centers without CABG surgery vs transfer for PCI in centers with CABG surgery, supporters argued that local PCI would permit more rapid and greater access to primary PCI for patients with STEMI.⁹

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However, transportation time is less of an issue for PCI among the much larger pool of patients with non-STEMI and stable angina. For these patients, PCI in hospitals without on-site CABG surgery is based on patient convenience and the low absolute risk of death and emergency CABG surgery in carefully selected patients. Also, providing PCI services offers other benefits for an institution such as prestige in the community and the promise of handsome remuneration from procedural, professional, and hospitalization fees.

Numerous registry studies comparing PCI outcomes in centers with or without CABG surgery show similar rates of in-hospital mortality and emergency CABG surgery.¹⁰⁻¹⁴ In this issue of *JAMA*, Singh and colleagues¹⁵ report on a meta-analysis of largely observational studies that extends the results of earlier meta-analyses from these and other authors.^{16,17} The studies included in this analysis span the pre-STEMI era (before 1994), the bare-metal stent era (1994-2004), and the drug-eluting stent eras (after 2004). Despite outcomes differing substantially over these periods, the pooled estimates of in-hospital mortality and emergency CABG surgery for primary and nonprimary PCI are low in absolute terms.

Observational studies and registries are not immune to bias, which limits their evaluation of the need for on-site CABG surgery. Hospitals without CABG surgical facilities may (appropriately) be more inclined to avoid performing PCI in higher-risk patients or in someone with higher-risk coronary anatomy, particularly in the non-STEMI setting in which PCI is more elective. Evidence to support this is circumstantial but could be inferred from the lower PCI rates among patients presenting with STEMI and non-STEMI in hospitals without CABG surgery.^{12,13} Also, it is unclear how deaths after transfer from a non-CABG surgical hospital are counted. Some registries try to ascertain deaths after nonemergency transfers for CABG surgery¹¹; however, this is not the rule. Similarly, deaths occurring among patients with successful PCI after transfer to a tertiary hospital for complications (eg, heart failure) may not be counted as in-hospital deaths for the referring non-CABG surgical hospital. Risk adjustment to account for sicker patients is imperfect and raises concern, particularly with public reporting.¹⁸

Overall, prior studies and the meta-analysis by Singh et al suggest that the current patterns of judicious PCI by operators in hospitals without CABG surgery leads to risks that are similar to those of hospitals with CABG surgery. Because the incidence of adverse events is low, future studies should assess differences in absolute risk rather than relative risk or hazard ratios. Identifying the magnitude of risk avoidance (by ascertaining eligible patients not receiving PCI), as well as risk shifting (patients transferred to other hospitals with complications after technically successful PCI) would also add valuable data. Randomized studies of elective PCI (not STEMIs), such as the MassCOMM study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01116882) identifier: NCT01116882) or the CPORT-E study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00549796) identifier: NCT00549796) may be helpful, although these trials may only recruit lower-risk patients limiting the statistical power to detect differences in adverse events; this is supported by the initial results of the CPORT-E study, which demonstrated that procedural success was very high, death rates were very low, and CABG surgery or subsequent unplanned PCI were rarely required.¹⁹

The most recent PCI guideline released in November 2011, avoids making recommendations about performing PCI in hospitals without CABG surgery.²⁰ This omission reflects the residual uncertainty of expanding PCI to smaller more remote hospitals. Recommendations for annual PCI volume limit the spread of PCI services to smaller institutions but are largely based on data from the pretest era.^{5,21} Annual PCI volume may be less important than total lifetime number of PCI cases, which arguably reflects the experience an operator uses to recognize patterns of presentation or coronary anatomy that portend higher risk for emergency CABG surgery or death.

Most importantly, performance of PCI in hospitals without CABG surgery requires a structured program with several key features. These include experienced operators, experienced nursing staff, and clear plans and agreements for rapid transport of patients to a facility with CABG surgery.⁹ Quality assurance for all hospitals providing PCI is an important objective, and participation in national clinical registries (eg, those run by the American College of Cardiology, American Heart Association, and Veterans Affairs Clinical Assessment, Reporting, and Tracking [VA-CART] program), and arguably public reporting will help evaluate and perhaps modulate PCI practice in order to keep adverse events low. In clinical practice, statistical adjustment of adverse risks to compare hospitals may be less valid for determining which hospitals should perform PCI. Rather registries can identify sentinel adverse events for independent review—a process instituted by the VA-CART system to assess outcomes in catheterization laboratories in VA hospitals throughout the nation.²²

The current practice of PCI offers a safe mode of coronary revascularization for many patients with lifestyle-limiting symptoms or acute coronary syndromes. The prevention of adverse events is arguably less dependent on the presence of on-site CABG surgery and more dependent on an operator's skill to select appropriate patients, their technical skill to complete PCI, and their commitment to maintain skills through continued education and participation in quality assurance programs.

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