Yes, We Can! (Should We?)

Running title: Aversano; Yes, we can! (Should we?)

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Historically, percutaneous coronary intervention (PCI) was relegated to hospitals with co-located cardiac surgery because of the potential need for emergent surgical treatment of PCI-related complications. In the current issue of Circulation, Lee and colleagues\(^1\) compare outcomes of PCI at hospitals with and without on-site cardiac surgery and show that emergency cardiac surgery is, in fact, rarely needed (<1%). This meta-analysis summarizes 23 studies that include over one million patients and demonstrates the incidence of other PCI-related complications including myocardial infarction, stroke, cardiogenic shock, aortic dissection, and tamponade, as well as early (within 30 days) and late (after 30 days) all-cause mortality, are not different at hospitals with and without co-located cardiac surgery\(^1\).

Because of inconsistencies among the studies, other outcomes indicators of quality, including the need for target vessel revascularization (TVR) could not be evaluated in detail. However, combining results from the two randomized controlled trials (RCT) reporting TVR, (CPORT-E\(^2\) and MASS COMM\(^3\)), rates of TVR were similar at hospitals with and without on-site cardiac surgery.

This important contribution confirms and puts on a more sound evidence-based foundation current guideline recommendations that allow for performance of primary and non-primary PCI at hospitals without surgery on-site\(^4\).

Like all important studies, this report raises a number of questions. While PCI at hospitals without on-site cardiac surgery is safe and effective, what is the motivation for extending non-primary PCI at these facilities? What are the consequences of extending PCI to more hospitals? How should the extensive research knowledge base summarized by Lee and colleagues be applied to development of PCI programs at hospitals without on-site cardiac surgery?
Why extend PCI to hospitals without on-site cardiac surgery?

The cynical view is that performance of PCI at hospitals without on-site cardiac surgery is all about money and market share. Economic motivations certainly exist and are understandable, given that those entrusted with the well-being of a hospital, be it for-profit or non-profit, are stewards of its financial health. But this kind of motivation is a given, is reasonable, and is not particularly interesting or illuminating.

The motivation for providing primary PCI at hospitals without on-site cardiac surgery is the survival advantage with which it is associated; non-primary PCI is associated with no such advantage. Lee and colleagues\(^1\) suggest the reason for extending non-primary PCI to hospitals without on-site cardiac surgery is patient convenience and continuity of care. While these are reasonable goals, the strongest motivation for extending non-primary PCI to hospitals without on-site cardiac surgery is to sustain primary PCI programs. Because of the financial and human resource commitment required, it is at best difficult to sustain stand-alone primary PCI programs that have a low procedure volume and yet must have staff available 24/7/365. If non-primary PCI also can be performed at these hospitals, then case volume increases which, in turn, allows hiring additional staff, could lower per case cost and reduce the on-call burden for physician, nurse and technician providers. A second important motivation is evidence that in the absence of a common treatment (PCI) for a ubiquitous disease (coronary artery disease), outcomes for patients with acute coronary syndromes treated at hospitals without revascularization capability may be suboptimal\(^5,6\). Therefore another reason to allow for non-primary PCI at hospitals without surgery on-site is to improve the outcomes of patients with coronary artery disease who present to those institutions. Finally, by allowing PCI at hospitals without on-site cardiac
surgery, the pressure to develop new cardiac surgery programs at a time when cardiac surgical volume is flat or declining could be minimized.

**How are safe and effective PCI services extended to hospitals without on-site cardiac surgery?**

To avoid application of study results to an inappropriate (i.e. unstudied) population requires careful attention to methodological detail. In a meta-analysis, this kind of detail can be obscured. In the report by Lee and colleagues\(^1\), the “population” studied involves not only patients, but institutions, nursing and physician staff in every care area including the emergency department, cardiac catheterization laboratory and post-procedure care area and even PCI equipment. For example, in the two largest RCTs high risk patients (those with an unprotected left main lesion or who those with very poor LV function (EF < 20%)) were excluded. All hospitals participating in CPORT E and some of the MASS COMM hospitals, participated in a three to six month PCI development program that included training of staff and development of logistics, order sets and critical pathways in the emergency department, cardiac catheterization laboratory and post-procedure care areas. Interventional cardiologists had to meet ACC/AHA competency criteria to participate and institutions had to achieve certain volume requirements. Use of devices that might be associated with higher complications rates, such as rotational and directional atherectomy, was not allowed. Finally, outcomes of sites participating in these studies was reported and monitored, an activity that encourages prudent patient selection and temperate procedures, which can importantly contribute to good outcomes. To what extent these specific patient, institution, device and provider criteria and training program influence outcome is not clear. But failure to incorporate them into a PCI program at a hospital without on-site cardiac surgery, makes outcomes comparable to those reported by Lee\(^1\) less assured.
What are the consequences of extending PCI to more hospitals?

Negative consequences

Perhaps the single, most problematic consequence of extending PCI to hospitals without on-site cardiac surgery is the effect on institutional procedure volume. Thus, while non-primary PCI programs may help sustain primary PCI programs, the potential reduction in human and financial resource utilization has probably not diminished and could increase if more programs develop.

Because volume is traditionally used as a surrogate for quality, a major concern is that quality will decline as a relatively fixed PCI volume is diluted among more facilities. The contemporary move away from using volume as a quality surrogate and toward using outcomes measures of quality may help address this problem. Questions are frequently raised about how well outcomes measures can be identified and defined, and how reliably they can be measured, but rarely addressed is that accurate, meaningful measurements of quality requires a certain volume. Particularly with infrequent events (such as death), it may take many years to identify sub-standard outcomes in hospitals performing low procedure volumes because of the wide confidence intervals around that outcome estimate. While volume may not equal quality, measurement of quality requires volume.

Low procedure volume also makes difficult the maintenance of physician and nurse complication management competency, made still more problematic because complications in the cardiac catheterization laboratory and in the post-procedure care areas are infrequent.

While we tend to focus on the effect of lower procedure volume in hospitals without on-site cardiac surgery, there can be important effects in tertiary and academic medical centers as well. Reducing the volume of “bread-and-butter” PCI procedures at tertiary hospitals may affect
their financial viability, reduce their ability to support newer minimally-invasive treatments of structural heart, and adversely affect research and training of interventional cardiology fellows.

*Positive consequences*

The ability to treat STEMI patients with prompt PCI is undoubtedly a positive consequence of extending primary PCI to hospitals without co-located cardiac surgery and has been life-saving for many. While not directly reducing morbidity and mortality, there are, nevertheless, positive consequences of extending non-primary PCI to these hospitals, as well.

Although the convenience of patients and continuity of care were not specific motivations for the CPORT primary or non-primary PCI projects, they are reasonable motivations for performing PCI at hospitals without cardiac surgery on-site. Those who work exclusively in large tertiary or academic facilities can underestimate the emotional and financial burden imposed not only on the patient, but on the patient’s support structure, his family and friends, of moving from a community hospital to a larger, more distant institution. The argument that if people can drive 20 miles to buy a car or to have a great dinner, they can drive that distance to have an angioplasty, is specious: comparing consumerism to treatment of a disease that for most is frightening, life threatening and life changing is fatuous. Being able to remain in one’s community hospital for a treatment that is as safe and effective there as it is at a distant, tertiary center is good medicine.

The experience of hospitals participating in CPORT projects was that the development of PCI services raised the standard of care not just for patients with coronary artery disease, but for all hospital patients. Perhaps the positive effect of a PCI program is best revealed by examining what happens in hospitals without such a program. In many regions, selective triage transports suspected ACS patients only to PCI-capable hospitals. In hospitals that cannot perform PCI,
cardiac catheterization services are frequently abandoned because most physicians do not want to submit patients to diagnostic catheterization without the option for PCI. Domino-like, once cardiac catheterization services are abandoned, other invasive services are increasingly difficult to obtain, such as pericardiocentesis and right heart catheterization. This limited selection of cardiac services makes the facility’s environment less attractive to cardiologists, in general. As time goes on, the extent and even the quality of cardiac services in that facility can decline, potentially affecting patient care on all medical and surgical services. In community hospitals with internal medicine residency programs, the absence of patients with acute ischemic heart disease, one of the most common diseases in the United States, is a major deficiency. The hospitals without co-located cardiac surgery who have a PCI program avoid the atrophy of their cardiac services, can better serve their general hospital patient population and provide a better learning environment for trainees.

Balancing act

Clearly, there are important positive and negative consequences of extending PCI capability to hospitals without on-site cardiac surgery. The report by Lee and colleagues in this issue of Circulation says we can safely perform PCI in this setting. The question is, while we can, should we? And if we do, how should we?

To balance the myriad factors the influence the potential benefits and harms extending PCI capability, State Departments of Health, in concert with physicians and citizens, can develop evidence-based policies that simultaneously allow for rational distribution of high-quality PCI services without excessive restriction. For example, the Maryland Health Care Commission which regulates cardiovascular services in the State of Maryland has modified the State’s health plan to accommodate first primary PCI and more recently non-primary PCI as routine clinical
procedures performed at hospitals without on-site cardiac surgery. The plan specifies licensure requirements that include the need for formal program development, institutional and operator volume benchmarks, data reporting, outcomes monitoring and peer review for performance of PCI at all hospitals, regardless of cardiac surgery. The plan is evidence-based and represents a collaborative effort among Commission staff, local physician and nursing experts, regional representatives of national cardiovascular organizations and citizen stakeholders. It can be reviewed on-line (Code of Maryland Regulations COMAR 10.24.17)\(^7\).

Performing PCI at a hospital without on-site cardiac surgery is not simply a matter of stocking a catheterization laboratory with angioplasty equipment, recruiting interventional cardiologists and applying national care guidelines. Rather development of such programs should replicate, to the extent possible, the research methods on which their safety and efficacy is based.

Ideally, all PCI programs regardless of co-located cardiac surgery, fit into an overall plan for regional cardiovascular services, that provides for optimal access to the highest quality care at sustainable cost, and is concordant with and supportive of the multifaceted missions of community, tertiary and academic hospitals.

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**References:**


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