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SCAI President's Page

PCI Without On-Site Surgical Backup

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In this issue of *Catheterization and Cardiovascular Interventions*, SCAI is publishing an Expert Consensus document titled, "The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup" [1]. Because of the document's length, only the Executive Summary appears in print, but you are strongly encouraged to obtain the full document, which is available online at *www.scai.org*. It is not my purpose to review the content of the document in this President's Page. Rather my goal is to provide answers to several key questions you will likely ask as you read this document.

Why Did SCAI Undertake This Effort?

Without question, percutaneous coronary intervention (PCI) without on-site surgical backup is a controversial issue. In fact, the controversial nature of this topic is exactly why the Society embarked on this effort. The performance of PCI without on-site surgery has been the focus of debates at national meetings and many published editorials, both in support of and opposed to this practice [2,3]. Lawsuits now exist in some states over this issue [4]. Respected academic institutions such as the Mayo Clinic and Duke have supported such programs and published their results in peer-reviewed journals [5,6]. If PCI without on-site surgery is wrong, then why are these well-known institutions engaged in this process? If PCI without on-site surgery is right, then why are the current practice guidelines so restrictive?

It is a fact that PCI without on-site surgery is more widely accepted and practiced outside the United States. Does this mean our respected international colleagues worry any less about the care that their patients receive or are more willing to put their patients at risk of

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harm? During my year as President, I have had the privilege to meet interventional cardiologists from around the world and none could be characterized as having that attitude. What I have observed is the universal commitment of our interventional colleagues worldwide to provide high-quality care for their patients. There are differences in healthcare delivery systems and physician reimbursement models around the world. In some situations abroad, PCI without on-site surgical backup is a necessity as surgery is simply not available. In other situations, there are no financial incentives to physicians or hospitals to engage in this practice, and it is done because it is the best way to deliver PCI services to the population.

To provide this international perspective and develop a document that would have more universal application, we specifically included SCAI members from several countries outside the United States and closely reviewed guidelines from other professional organizations. As of this writing, 12 other Societies have endorsed this document and thereby support our findings and recommendations for their countries or international regions. Critics of this process have commented that healthcare delivery and access are different in other countries so, just because PCI without on-site surgery is performed abroad, does not mean it is correct for the United States. We agree, and our purpose is not to imitate what is done in other countries, but rather to focus on providing high-quality PCI in all settings. Although we would like to believe that everyone in the United States has equal and rapid access to PCI services, access to healthcare in the United States is not nearly as uniform as we would like to believe. Distance alone is not the only factor to consider, and other less obvious barriers exist.

Whether you, as an individual, agree or disagree with the performance of PCI without on-site surgery, it must be acknowledged that this is occurring, not only in the United States, but also in many other countries. Given the controversial and sometimes acrimonious debate, it was SCAI's goal to conduct an *objective* evaluation of this practice and make appropriate recommendations. Some have suggested the Society was touching the dreaded "third rail" by attempting to examine this highly charged issue and encouraged us to back away. Nevertheless, the leadership of the Society unanimously felt that as a professional organization we needed to "step to the plate" and address this important issue. After all, we are "the" Society representing the majority of interventional cardiologists in the United States and we have a growing representation globally. Third rail or not, SCAI believed it was appropriate to establish some structural recommendations for such programs. This effort should not be interpreted as a judgment about the current quality of any individual PCI program without on-site surgical backup. In fact, many model programs exist with outcome metrics as good as programs with on-site surgery, and we used experiences from such programs to prepare our recommendations. However, we must also be realistic. At the core of the debate over this issue are arguments that this practice is all being driven by desire for financial gain and market share. Some accuse those developing such programs of simply wanting a piece of the financial pie; in contrast, others say facilities that have programs with on-site surgery do not want their slice of the pie to disappear even if it is best for patient care. Although these debates may have an entertaining quality, the Society feels the focus should be redirected toward providing quality PCI care to all patients and developing a delivery model that is best for the patients of each individual community. With these guiding principles, the Society engaged in this challenging—but necessary—effort.

Does This Document Mean SCAI No Longer Supports the Guidelines?

The answer to that question is *absolutely not*. The 2005 PCI guideline update is a tremendous resource to clinicians and should be used as a guide in providing the best therapy to their patients. As described in our Expert Consensus document, the Society's effort to examine this topic began over two years ago, well before the 2005 Update of the Guidelines for PCI was published [7]. The Society participated in the development of the 2005 update of the guidelines and is proud to have coauthored that update in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). We hope to continue this important collaboration on further updates to the PCI guideline and other guidelines in the future.

The strongest recommendations within any of the existing guidelines are derived from large, randomized, controlled trials of a specific therapy. For guidelines to change, there must be new, convincing information to support a change. Since balloon angioplasty was first performed, almost all research has been directed toward developing better devices, drugs, and techniques to use during PCI so that the procedure produces improved outcomes for patients. Although there are many single-center reports of PCI without on-site backup, a large properly designed, randomized study examining this delivery model has not been performed. An 18,000-patient study, conducted by the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT), is currently underway and hopes to have its conclusions by 2008

[4]. In the absence of any randomized trials and given the controversial nature of this topic, one can understand why the writers of the most recent guideline update adopted a conservative approach and did not change their recommendations about PCI without on-site surgery.

However, despite what the guidelines have consistently recommended in 1993 [8], in 2001 [9], and most recently in 2005 [7], PCI without on-site surgery is being performed with increasing frequency. If one acknowledges the reality that PCI without on-site surgery is occurring despite the guideline recommendations, what is the best course of action for a professional organization like SCAI that represents the physicians who actually perform these procedures? The leadership of SCAI felt the answer was clear: it was the belief of the Society that remaining silent in the face of this growing practice simply avoided the issue, and would not be the correct course. The SCAI Board of Trustees unanimously approved this effort and publication of the Expert Consensus document published in this issue.

The main interest of SCAI is to promote the highest possible quality in the delivery of invasive cardiology services and PCI. Before publication of this Expert Consensus document, we solicited endorsements of many international organizations dedicated to interventional cardiology. PCI without on-site surgery is also rapidly expanding abroad. Many of these international societies appreciated the recommendations set forth in this document and believed they would be useful in improving the quality of PCI care in their countries. We also shared this document with the AHA and ACC and engaged in several discussions with the leadership of these organizations. Ultimately, both of these organizations declined to endorse this document. Concerns were expressed that our document appeared to contradict the guidelines and, in reality, was a veiled approval of PCI without on-site surgery. Moreover, there was concern that publication of this document could "open the door" to the widespread use of PCI without on-site surgery. The view of SCAI is quite different. We believe the door has already opened and this viewpoint is documented by data we collected as part of our examination of this issue. This door is not only open, but it is open fairly widely as indicated by the rapid growth of PCI without on-site surgery both in the United States and globally.

As said earlier, SCAI advocates for the highest possible quality in the delivery of PCI care whether it occurs at facilities with or without on-site surgery. We all recognize that the need for emergency coronary artery bypass surgery following PCI is now very infrequent, although it is not zero. If our goal is to promote the highest possible quality in PCI care, should the sole metric for this determination be whether or not a facility has on-site cardiac surgery to address a complication that occurs in roughly 2 per 1000 patients? SCAI believes there are many important issues to address that could improve the quality of PCI care and outcomes for patients. For example, a major national effort, the D2B Alliance, was recently launched by the ACC to improve door-to-balloon times for patients with acute ST-segment elevation MI. This is being done because of the realization that many facilities are failing to meet this important metric known to be associated with improved outcomes. Meeting the door-to-balloon metric should be an expectation of a quality PCI program. This is just one example of a quality initiative, but one could list many others related to PCI. In the final analysis, working toward goals that help *all* PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs to have on-site surgery.

SCAI is not promoting PCI without on-site surgery, but we do acknowledge that this can and is being performed well at many facilities. Our goal is to make structural and operational recommendations that should be used to insure such programs are of high quality. At the present time, SCAI believes it would not be appropriate for the practice guidelines to formally address any of the recommendations found in our Expert Consensus document and, likewise, it is not appropriate for anyone to construe that our Expert Consensus document is a contradiction of the practice guidelines.

Would You Want Your PCI at a Facility Without On-Site Surgical Backup?

This was the question I was frequently asked by many of my colleagues during this process. Whether you choose to call me old-fashioned, traditional, or conservative, I have been performing interventional procedures for over 25 years and thus am a child of an era when performing PCI without a surgeon "standing by" was simply unthinkable. So, I must admit that as this effort started, my personal bias was against PCI without on-site surgery. Nevertheless, having heard all the rhetoric on this topic and believing that SCAI would perform a valuable service by objectively evaluating this issue, I promised myself, more than anyone else, to keep an open mind. As this effort proceeded, this question became a daily haunting reminder of the seriousness of this project. Just what would I do if I were in this situation? What are the things most important to me if I ever needed a PCI? What would I want? What would you want?

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First, I want an operator who has great interventional skills and excellent clinical judgment. Second, I want my procedure in a laboratory that has a terrific crew of nurses and technologists supporting the operator. Third, I want my procedure in a facility dedicated to providing high-quality care and thus actively engaged in benchmarking outcomes and continuous quality improvement. Finally, I want the support and love of my family and friends through this process. These would be on my list before thinking about whether a cardiac surgeon was on-site. All other factors being equal, of course I want the best cardiac surgeon and cardiac anesthesiologist in the world standing by during my procedure and a fully staffed operating room immediately available just waiting for my arrival should my procedure fail. I suspect that most reading this list would want these same things, but in reality we and our patients may not always have these choices.

We should reexamine this list with a dose of reality and from the perspective of the average patient. While I may be able to choose my operator in some circumstances, what happens if I am on vacation and develop an acute coronary syndrome or suffer an acute ST-segment elevation myocardial infarction? I likely will not be able to choose my operator, laboratory, or facility and I, like many patients, will rely on "the system" to insure my operator and facility meet appropriate performance standards. Should I need an elective PCI, I could likely travel to any place in the country to get it done, but realistically few of our patients have this option. While I might be able to use my privileged status as a physician to "pull some strings" and have a surgeon and operating room actually waiting for me, this is not how PCI programs operate today. Physicians should be focused on what they believe is important in the care of a patient, but our patients do not always have the same focus and may place a higher value on personal rather than medical considerations. Although we may think moving a patient to another facility is no big deal, patients sometimes see things differently. This statement is not meant to be a justification for PCI without on-site surgical backup just because it is convenient for patients, but rather an acknowledgement that for patients sometimes the things that are most important cannot be quantified with a "*p* value." Having a surgeon on-site and just waiting for a failed PCI may be ideal, but it is not a realistic solution for the foreseeable future.

Is There a Hidden Message Here?

This document is not meant to be like an old Beatles' tune that when played backwards has a hidden message. There is a much larger issue here than simply an opinion about whether a PCI can be done in a facility without on-site surgery. Over my years of involvement with the Society and in academic medicine, I have participated in the peer-review of many PCI programs and individual cases. When you are sent cases to review, it is not because they were a smashing success; it is usually because there was a disaster and someone is questioning the actions of a physician or the quality of a facility. Without question, I believe the vast majority of interventional cardiologists are dedicated, hard-working, skilled individuals who have nothing but the best interests of their patients as their goal. Yes, these same physicians sometimes have disastrous complications despite their best efforts; this is not an easy profession and there is little margin for error. Unfortunately, not every PCI program or interventional cardiologist meets the ideal quality standards. There is a larger message in this document, but it is not meant to be hidden. The message is QUALITY and promoting quality among all PCI facilities.

Basically, two models of PCI delivery are emerging. One is the "spoke-and-hub" model, where outlying patients are transported to a centrally located center. The other model is to develop PCI centers in community hospitals to provide services locally. Both have advantages and disadvantages and neither can be ignored. Rather than make this a contest pitting one against the other, would it not be better to acknowledge that there may be a role for both models in the United States? It is clearly not necessary for every hospital to provide PCI services and thus in some areas the spoke-and-hub model is appropriate to develop. However, the community hospital model or a combination of these models may be appropriate in other situations.

Although the title of this document places a focus on facilities without on-site surgery, the not-so-hidden message throughout the document is really on QUALITY. Whether you are involved in a PCI program with or without on-site surgical backup, providing quality services should be the highest priority. This SCAI document establishes quality operating parameters for PCI programs without on-site surgery. Rather than focusing on the presence or absence of on-site cardiac surgery, SCAI believes there is much more to be gained by promoting a quality agenda in *all* PCI facilities, wherever they exist.

As always, I welcome hearing what you think. Please send your comments to me at president@scai.org; I will try to respond to every comment received.

REFERENCES

1. Dehmer GJ, Blankenship J, Wharton TP, Jr., Seth A, Morrison DA, DiMario C, Muller D, Kellett M, Uretsky BF. The current

status and future direction of percutaneous coronary intervention without on-site surgical backup. Catheter Cardiovasc Intervent 2007;69. DOI 10.1002/ccd.21097.
2. Wharton TP, Jr. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community: the case for community hospital angioplasty. Circulation 2005;112:3509–3534.
3. Keeley EC, Grines CL. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community: the case for emergency transfer for primary percutaneous coronary intervention. Circulation 2005;112:3509–3534.
4. Aversano T. Angioplasty waiver controversy. Physicians News Digest, November 2006. [Available at: http://www.physiciansnews.com/cover/1106csnj.html].
5. Ting HH, Raveendran G, Lennon RJ, Hall Long KH, Singh M, Wood DL, Gersh BL, Rihal CS, Holmes DR Jr. A total of 1,007 percutaneous coronary interventions without onsite cardiac surgery. Acute and long-term outcomes. J Am Coll Cardiol 2006; 47:1713–1721.
6. Paraschos A, Callwood D, Wightman MB, Tcheng JE, Phillips HR, Stiles GL, Daniel JM, Sketch MH Jr. Outcomes following elective percutaneous coronary intervention without on-site surgical backup in a community hospital. Am J Cardiol 2005;95: 1091–1093.
7. Smith SC Jr., Feldman TE, Hirshfeld JW Jr., Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). Available at: http://www.acc.org/clinical/guidelines/percutaneous/ update/index.pdf
8. Ryan TJ, Bauman WB, Kennedy JW, Kereiakes DJ, King SB III, McCallister BD, Smith SC Jr., Ullyot DJ., Guidelines for percutaneous transluminal coronary angioplasty. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on percutaneous transluminal coronary angioplasty). J Am Coll Cardiol 1993;22:2033–2054.
9. Smith SC Jr., Dove JT, Jacobs AK, et al., ACC/AHA guidelines of percutaneous coronary interventions (revision of the 1993 PTCA guidelines)—executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (committee to revise the 1993 guidelines for percutaneous transluminal coronary angioplasty). J Am Coll Cardiol 2001;37:2215–2239.