New PCI Safety Standards at Odds With Guidelines

Controversy has greeted the release of standards for performing PCI without on-site surgical backup.

BY BETSY BATES
Los Angeles Bureau

The Society for Cardiovascular Angiography and Interventions took the dramatic step in early February of introducing "best practice" recommendations for physicians and institutions offering percutaneous coronary intervention without on-site surgical backup, a move that failed to gain the support of the American Heart Association or the American College of Cardiology.

Current guidelines endorsed by all three organizations in November 2005 classified elective percutaneous coronary intervention (PCI) without on-site cardiac surgery a Class III indication, meaning it is considered "not useful/effective and in some cases may be harmful" (Circulation 2006;113:156-75).

Primary PCI without surgical backup was ranked in the 2005 ACC/AHA/SCAI guideline update as a Class IIb indication, for which there is conflicting evidence and/or divergence of opinion and the absence of well-established suggestions of usefulness or efficacy.

Pragmatism was the driving force behind the SCAI's decision to issue structured safety recommendations for the controversial practice, said Dr. Gregory J. Dehmer, president of SCAI, at a press teleconference.

He insisted that the SCAI was "not in any way promoting PCI without surgical backup," and maintained that the group still stands behind the joint guidelines of 2005, but he said it was time to establish quality standards for an increasingly common practice.

"The reality is that despite the guidelines, this practice is going on in this country and it's growing," said Dr. Dehmer, professor of medicine at Texas A&M University, College Station, and director of cardiology at the Scott & White Clinic in Temple, Tex.

An SCAI Web survey completed in July found that primary PCI programs without on-site surgical backup exist in 40 states. Elective PCI without on-site surgical backup is being performed in 28 states.

Around the world, the practice is also increasing, said Dr. Dehmer, with 35 of 39 developed countries reporting the performance of PCI without on-site cardiac surgery backup.

"We want to be sure that if this is being done, it is being done with the highest quality," Dr. Dehmer said during the teleconference.

The SCAI consensus statement, which was developed by a nine-member international committee and endorsed by many international cardiology societies, recommends that PCI programs without on-site cardiac surgery should meet certain standards, including the following:

- Institutional case volumes of at least 200 PCIs a year.
- Thresholds for interventional cardiologists, including career case volumes of more than 500 PCIs and annual case volumes of more than 100 PCIs, including at least 18 primary PCIs per year.
- A "strong recommendation" that interventional cardiologists performing PCI without surgical backup be board certified in interventional cardiology.
- Independent review of outcomes, comparing institutions and cardiologists against state or national benchmark standards for success rates and complications.
- "Rigorous clinical and angiographic selection criteria" of patients to minimize the risk of complications.
- Appropriate equipment, staffing, and training surrounding PCI; a "close alliance" with cardiovascular surgeons; and formalized, tested procedures for emergency transport of patients at the first sign of a complication.

The American College of Cardiology is concerned that endorsing the new recommendations would promote PCI without surgical backup.

Both the ACC and the AHA pointedly declined to endorse the SCAI's document.

Dr. Steven Nissen, president of the ACC, said the college was concerned that the endorsement of best-practice recommendations would lead to promotion of PCI without surgical backup and "contradict our own guidelines."

"When we say it's Class III, we're telling people that it shouldn't be done. I don't see how you can have it both ways: It's not indicated but here's how you do it," said Dr. Nissen, medical director of the Cleveland Clinic Cardiovascular Coordinating Center, in an interview.

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"Despite the guidelines, this practice is going on in this country and it's growing," SCAI President Gregory J. Dehmer said.

Dr. Raymond J. Gibbons, president of the AHA, concurred with that view.

"We have existing guidelines that attempt to discourage angioplasty without surgical backup. The SCAI statement is inconsistent with those guidelines," he said in an interview.

"The consistency of our statements is critical to their credibility," said Dr. Gibbons, professor of cardiology at the Mayo Medical School, Rochester, Minn.

An executive summary of the SCAI document acknowledged that PCI without surgical backup is "a polarizing and emotional issue for many individuals both within and external to the interventional community."

However, the SCAI report contends that burgeoning growth of the practice, coupled with a decline in cardiac surgical services at many hospitals, suggests that on-site surgical capability during PCI will be increasingly difficult to achieve.

The safety rate of PCI is high and improving, with urgent cardiac surgery required in 3-6 cases per 1,000 at high-volume hospitals, according to SCAI data sheets.

Many small, retrospective studies have concluded that PCI can be performed safely and with a very low rate of complications at individual institutions.

The "fly in the ointment" came in a 2004 study of 1,121 hospitals. The study found that there were higher mortality rates among nonprimary PCI cases performed in hospitals without surgical backup, especially those that performed a small number of the procedures each year, said Dr. Michael Cowley, professor of medicine at Virginia Commonwealth University, Richmond, during a January conference in Snowmass, Colo., sponsored by SCAI and the ACC (JAMA 2004; 292:1961-8).

Dr. Dehmer said in his press briefing that the safety issue will become clearer with the first large randomized trial comparing PCI rates at hospitals with and without surgical backup.

That trial, the Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study (CPORT), will enroll 18,000 patients.

In the meantime, the SCAI safety guidelines "focus on the goal of providing the best possible care to patients who require PCI, regardless of the setting."

"Ensuring that all PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs have on-site surgery," noted the society's executive summary.

The summary acknowledged there is "clearly a potential for unnecessary or inappropriate PCI program development in the same geographic area."

In addition, it stressed that such actions driven by financial or market gain are "strongly discouraged."

In his President's Page to members, Dr. Dehmer said that "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."

He also said cardiologists may need a "dose of reality" in recognizing that some patients may place a higher priority on "personal rather than medical considerations" when it comes to moving to a different facility for PCI.

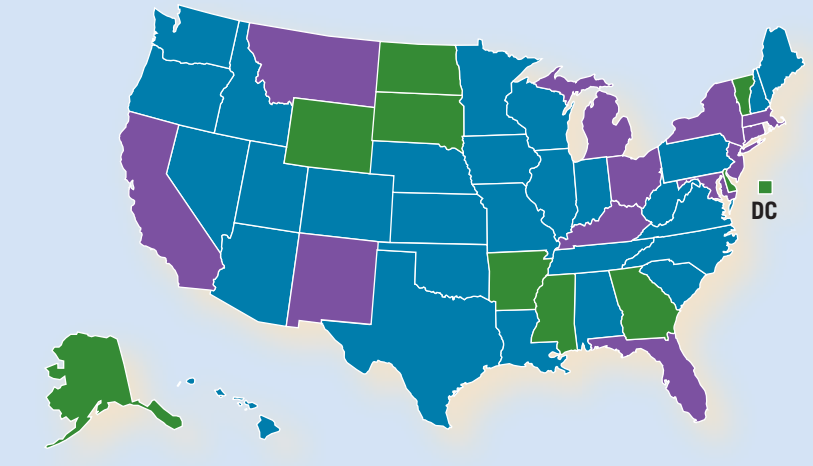
"Having a surgeon on-site and just waiting for a failed PCI may be ideal, but it is not a realistic solution for the foreseeable future," he wrote.

Finally, Dr. Dehmer said a larger message "not meant to be hidden" within the document is that ideal quality standards are not being met at every institution or by every interventional cardiologist.

"The message is QUALITY and promoting quality among all PCI facilities," he told members in his president's message online.

The SCAI report, as well as the president's message, are available online at www.scai.org. ■

PCI Is Performed Without On-Site Surgical Backup in Most States



Note: Based on July 2006 data from the Society for Cardiovascular Angiography and Interventions.
Source: Catheter. Cardiovasc. Interv. 2007 (available at scai.org/pdf/PCI-SOS-full.pdf)

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