New Revision to PCI Guidelines Stirs Rancor

Critics question the need for on-site surgical backup and volume requirements, both cited in the guidelines.

BY BRUCE JANCIN
Denver Bureau

DALLAS — Newly updated joint national percutaneous coronary intervention guidelines have some cardiologists seeing red.

The major point of contention regarding the first update of the guidelines since 2001 concerns the use of PCI in centers without on-site surgical backup.

"Of all the areas we covered in the guidelines, this is the area that's going to raise the most controversy and interest," William W. O'Neill, M.D., predicted at a press conference announcing release of the guidelines during the annual scientific sessions of the American Heart Association.

As in the 2001 guidelines, the new version nixes elective PCI at centers without on-site surgical backup. Primary PCI for patients with ST-segment elevation MI, when done in experienced centers lacking on-site surgical backup, gets a class IIb recommendation—the weakest possible endorsement—meaning there is divergent expert opinion and "less well established" supporting evidence.

Sidney C. Smith Jr., M.D., who headed the guideline writing committee, said the group was persuaded to retain the recommendation against elective PCI in the absence of on-site surgical backup chiefly by a large study of the Medicare database that showed worse outcomes in such settings.

"That carried the weight," according to Dr. Smith, professor of medicine and director of the Center for Cardiovascular Science and Medicine at the University of North Carolina, Chapel Hill.

"There is no access-to-care issue in the U.S. about angioplasty. We have minimal waiting times," added Dr. O'Neill, corporate chairman of cardiology for the William Beaumont Hospital System, Royal Oak, Mich. "There really is no proof that we could see right now that doing these procedures [without on-site backup] enhances the value to the patient or makes it safer—if anything, it could make it worse."

But Thomas P. Wharton Jr., M.D., said in an interview that since the 2001 guidelines there have been 15 new studies of PCI at hospitals without on-site backup; the committee failed to cite or apparently consider 12 of them, all of which were positive, a deficiency he termed "not fathomable." Collectively these large studies boost primary PCI without on-site backup into a legitimate class IIa procedure and make a strong case for elective PCI as a class IIb recommendation, he said.

Among these studies was one presented at the same AHA meeting that involved more than 660,000 consecutive PCIs included in the American College of Cardiology's rigorous prospective National Cardiovascular Data Registry. In-hospital mortality in the 6,530 patients who underwent primary or nonemergent PCI without on-site backup was comparable with that in patients who had PCI with on-site backup. The guidelines task force was provided with the results of this and the other studies, said Dr. Wharton of Exeter (N.H.) Hospital.

"PCI is underutilized in acute MI and other high-risk acute coronary syndromes, most of which present to hospitals without PCI—a definite access problem." Providing PCI at such hospitals will improve access and thereby could lower mortality rates. This far outweighs the downside risk of 1-2 patients per 1,000 experiencing a PCI complication requiring emergency bypass surgery within 2 hours, which with good transfer planning in place can be accomplished off-site, he added.

"Performance of PCI at qualified hospitals with off-site surgical backup is a growing grassroots movement. It's being done in 36 states. More states are changing their regulations to allow it. The ACC should recognize and help guide this growing movement," Dr. Wharton said.

Among the other key recommendations in the new guidelines:

► **Volume requirements.** As in 2001, the 2005 guidelines recommend that elective PCI be performed by physicians who do at least 75 PCI procedures per year, and in centers where more than 400 per year are done. But the institutional volume requirement may be headed for the scrap heap. In another report from the ACC National Cardiovascular Data Registry presented at the AHA meeting, William S. Weintraub, M.D., and his coinvestigators found no evidence of a relationship between institutional PCI volume and in-hospital mortality in a series of nearly 668,000 patients who underwent PCI in the contemporary era of improved stents and antiplatelet regimens.

"The task force is aware of our data," Dr. Weintraub said in an interview. "I think before they change their recommendations, they're going to want to see our final results in print. The next version of the guidelines will probably get away from the institutional volume requirement," predicted Dr. Weintraub, director of outcomes for the Christiana Care Health System, Newark, Del.

► **Left main coronary artery disease—a new PCI target.** Considered the exclusive domain of surgeons since the inception of bypass surgery, left main disease is for the first time deemed reasonably addressed via PCI provided the patient is a poor surgical candidate.

The guidelines go on to state that completion of ongoing clinical trials will be required before it's known whether PCI is also appropriate for left main disease in good candidates for coronary artery bypass graft, according to Ted Feldman, M.D., professor of medicine at Northwestern University, Chicago, and past president of the Society for Cardiovascular Angiography and Interventions (SCAI), which developed the new PCI guidelines together with the AHA and ACC.

► **Distal embolic protection devices.** These devices have been declared essential whenever technically feasible in patients undergoing PCI of saphenous vein grafts. However, the devices haven't as yet been shown to be beneficial in patients undergoing primary PCI for acute MI.

► **An expanded role for interventionalists in postprocedural patient management.** Aggressive LDL-cholesterol lowering to a target below 70 mg/dL is recommended in very high risk patients. The guidelines also emphasize the role of specific antiplatelet regimens involving aspirin plus clopidogrel, as well as the use of ACE inhibitor and β-blocker therapy. And all diabetic patients need to have an hemoglobin A_{1c} below 7%.

"Interventional cardiologists are already awfully busy, and we don't expect them to take on the management of diabetes. But Hb A_{1c} is a pretty good indicator of diabetic control, and it's an easy test for the interventional cardiologist to draw in the hospital. If better control is needed, they can refer the patient back to the primary care physician. We really think it's an opportunity for the interventionalist to get the patient off in the right direction," Dr. Smith said.

The full 122-page guidelines with their 109 recommendations are available on the Web sites of the ACC (www.acc.org), AHA (www.my.americanheart.org), and the SCAI (www.scai.org). The guidelines will be published in print form in early 2006. ■

Registry Shows Little Difference Between Drug-Eluting Stents

BY ALICIA AULT
Contributing Writer

WASHINGTON — Data from a U.S. registry of drug-eluting stent use suggest that there is little difference between the two commercially available models, Charles Simonton, M.D., said at a symposium sponsored by the Cardiovascular Research Foundation.

Dr. Simonton reported on interim results of the Strategic Transcatheter Evaluation of New Therapies (STENT) registry, which aimed to track patterns of use and the comparative safety and efficacy of the Cypher, a sirolimus-eluting stent made by Cordis Corp., and the Taxus, a paclitaxel-eluting stent made by Boston Scientific.

The registry was supported by unrestricted grants from Boston Scientific, Cordis Corp., Possis Medical, and The Medicines Company. The two drugs have different mechanisms of action, but the STENT data "would suggest the actual clinical outcome for the patients is identical," said Dr. Simonton, director of adult cardiology research at Carolinas Heart Institute (Charlotte, N.C.) and a principal investigator in the study.

The data for the registry were entered into a secure Web site by each of eight participating coronary interventional centers. The goal was to prospectively enroll between 8,000 and 10,000 consecutive cases per year. The data had to be entered within 60 days of each predetermined time period: in-hospital, 3- and 9-month data; and key events, such as stent thrombosis and target vessel revascularization (TVR), were adjudicated by physicians.

From May 2003 through September 2004, 8,013 patients who had primary coronary interventions were eligible for the registry, and 6,659 (83%) of those consented to inclusion. At 9 months, there was complete follow-up on 6,336. Not all the patients received drug-eluting stents; of those who did, there were complete data on 2,282 patients who received the Cypher and 1,476 who received the Taxus.

The two drugs have different mechanisms of action, but the STENT data suggest that the actual clinical outcomes for the patients are identical.

Among those who received stents, the major adverse cardiac events (MACE) rate was 7.9% for Cypher and 6.8% for Taxus. The death rate was 2.7% for Cypher and 2.1% for Taxus. Myocardial infarction rates were also similar, at 2.2% for Cypher and 1.8% for Taxus. Just under 4% of Cypher patients had a second procedure in the target vessel, compared with 2.8% of Taxus patients.

The TVR rates were very close, with 95 (4.2%) Cypher patients and 50 (3.4%) Taxus patients requiring revascularization. There was a low rate of subacute stent thrombosis: 0.7% for Cypher and 0.5% for Taxus.

There was no statistically significant difference between the two for time to TVR or MACE, said Dr. Simonton.

The Taxus group might have been at a slight disadvantage because it was a little older and had more incidents of acute coronary syndrome and a marginally lower preprocedure Thrombolysis in Myocardial Infarction Study Group (TIMI) grade flow, he said. But the majority of the baseline characteristics were similar between the two groups, and a risk-adjusted multivariable analysis for MACE and TVR showed no significant differences.

The results so far argue for both stents to stay in the catheterization lab, said Dr. Simonton. The choice on which one to use may in part be decided by price and deliverability, he said.

"If the clinical outcomes look the same, it comes down to deliverability—how easy [it is] to use the stent," he said. But, he added, there are no objective ways to measure that deliverability. ■