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European PCI guidelines contain key differences from US guidelines

Mar 21, 2005 | Shelley Wood

Munich, Germany - The **European Society of Cardiology** (ESC) has released new practice guidelines for percutaneous coronary interventions (PCI), the first time the ESC has charged a task force with determining the level of evidence supporting benefit and risk associated with the use of PCI in different patient subsets.

Dr Sigmund Silber

As task-force chair, **Dr Sigmund Silber** (Dr Müller Hospital, Munich, Germany) explained to ***heartwire***, the new guidelines have several key differences from US guidelines, which were first created by a joint **ACC**/**AHA** task force as PTCA guidelines in 1993 and updated to be PCI guidelines in 2001.

Silber says the ESC has held off on issuing guidelines, waiting for numerous important trials that have emerged in the past few years. When the task force first set out to evaluate the evidence, Silber says it actually tried to create a joint task force with the ACC/AHA, a union that was to prove impossible. "It became clear from the beginning that it would be very, very difficult to set up any common contents paper between Europe and the US, and one of the issues in the US was legal concerns, not so much what to do or how to do it," Silber says.

Indeed, the ESC guidelines dispense altogether with the topic covered in the American guidelines under "Institutional and Operator Competency." American operators, Silber explains, face medicolegal issues surrounding the concept of PCI clinics without on-site surgery. "We don't even address this issue in our guidelines because we in Europe think this isn't a big deal."

Operator volume is also a big issue in the US, but not in Europe, Silber observed. "If you look very carefully at the analyses of operator volume, there is no clear relationship between minimum volume and outcome. So we didn't touch the subject of minimum volume in our guidelines, either."

Actually reading the guidelines

An interview with Elizabeth Nabel

In a wide-ranging interview, the new director of the NHLBI discusses her thoughts about the NHLBI and the future of cardiovascular medicine in the US.

Features

Bad backs and aching necks: Occupational hazards of the cath lab

The occupational hazards of life in the lab often leave many EPs and interventional cardiologists in pain. For some, orthopedic problems in the back, neck, hips, knees and ankles are a fact of life, but for others, the pain can cut short a career.

Guidewire

Speeding up the treatment of MI: Is prehospital thrombolysis or expanded primary PCI the answer?

Whether primary PCI is always the preferred option for the treatment of ST-elevation-MI patients or whether thrombolysis still has a major role is one of the hottest issues in cardiology at present, and there are some pretty strong views around on the subject.

Features

ESC PCI guidelines and those of the ACC/AHA is that the ESC guidelines are considerably shorter, a feature driven largely by the task force's decision to dispense with the "executive summary" and to drop class-III recommendations from its document.

As a result of these omissions, he says, "the whole paper gets much shorter and more concise. One of the complaints that physicians have is that guidelines are too lengthy, and no one actually reads the whole thing. They just read the executive summary. So our guidelines are approximately half the length of the ACC/AHA guidelines, and we hope, since it's not too lengthy, that people will actually read it."

In the ACC/AHA guidelines, a "class-III" designation refers to "Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful."

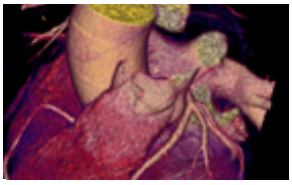
In a sense, says Silber, a class-III recommendation is essentially a "nonrecommendation," and "it's kind of schizophrenic to recommend something that you don't want to recommend," particularly since there is a big difference between something that may be harmful and something that doesn't work. The ESC PCI guidelines thus use a similar classification to the US guidelines—class I, II, IIa, and IIb, and evidence levels of A, B, and C—but omit anything deemed ineffective or harmful.

Specific drug-specific recommendations

Silber says that the primary indications for PCI are more or less similar in both the US and European guidelines, with a heavy emphasis on stenting. Unlike the US document, the ESC guidelines do not dwell on comparisons with medical management or CABG, which he called "just not contemporary any more." What the ESC guidelines do include is a section on drug-eluting stents—which do not appear in the current US guidelines. The ESC guidelines also provide specific recommendations on drugs, rather than just broad drug classes, citing specific randomized clinical-trial evidence.

"This is another interesting difference between the ESC and ACC/AHA guidelines and previous [non-ESC-sanctioned] guidelines in Europe, and that is that we recommend specific drugs. We do not talk in general about GP IIb/IIIa inhibitors, we name them." For example, he says, for upstream GP IIb/IIIa inhibition, the guidelines stipulate that tirofiban and eptifibatide are preferable; but "for GP IIb/IIIa started in the cath lab, we recommend abciximab and eptifibatide, but not tirofiban, because that's what the clinical-trial evidence has shown," Silber explains.

Other key differences, pertaining to adjunctive drug therapy, also distinguish the ACC/AHA and ESC guidelines. Clopidogrel, for one, is recommended in the ESC guidelines to be continued for up to four weeks in patients with stable angina who receive bare-metal stents but for 12 months in people who have undergone brachytherapy and for six to 12 months in patients who have received drug-eluting stents.



Cardiologists and radiologists gear up for CT angiography turf war

Cardiology and radiology practices alike are abuzz over the potential for multidetector CT to replace standard angiography, but many experts say the technology still has many hurdles to overcome, not the least of which is an increasingly bitter feud over who should control it.

Poll

Question Archives

How would you describe your level of concern about the renal safety of nesiritide?
(See: Meta-analysis questions renal safety of nesiritide)

- Very concerned
- Mildly concerned
- Not concerned
- Don't know

Vote

Question Archives

Do you think clopidogrel should become a routine part of the treatment of ST-elevation MI?
(See: CLARITY: Clopidogrel benefits MI patients receiving thrombolysis)

- No
- Yes

Vote

for the direct thrombin inhibitor bivalirudin, stating that it should be used to replace unfractionated or low-molecular-weight heparin to reduce bleeding complications (a class IIa C recommendation) and is "unanimously" recommended to replace heparin in patients with heparin-induced thrombocytopenia (I C recommendation). Bivalirudin is not mentioned in the 2001 US guidelines, and the drug manufacturer (The Medicines Company) is still in discussions with the FDA to approve a labeling change, which would specify a new dose appropriate for use in contemporary PCI. That dose and indication already hold CE Mark approval in Europe.

Thrombolysis vs PCI

Overall, the ESC PCI guidelines specify that PCI "can be considered a valuable initial mode of revascularization in all patients with stable CAD and objective large ischemia in the presence of almost every lesion subset, with the exception of [chronic total occlusions] CTO that cannot be crossed. . . . PCI should be used with reservation in diabetics with multivessel disease and in patients with unprotected left main stenosis," although "the use of drug-eluting stents might change this situation."

In patients with STEMI, PCI should be the treatment of choice in patients admitted to a hospital with a PCI facility, the European guidelines state. Patients admitted to a hospital without on-site PCI who have contraindications to thrombolysis should be immediately transferred, they note. Within the first three hours after onset of chest pain, thrombolysis is a "viable alternative" to PCI, at least in terms of myocardial salvage, but primary PCI appears to have the edge over thrombolysis in preventing stroke, they note.

"Overall, we prefer primary PCI over thrombolysis in the first three hours of chest pain to prevent stroke and in patients presenting three to 12 hours after the onset of chest pain to salvage myocardium and also to prevent stroke," the task force members write.

There is no randomized trial evidence, to date, to support facilitated PCI, the ESC guidelines add; however, in a departure from other published guidelines, the European guidelines specify that all patients who undergo thrombolysis—even apparently successful thrombolysis—should be referred for angiography (by hospital transfer if necessary) and receive revascularization if appropriate.

"The key message from this is, if you're in a hospital that does not have PCI facilities, you should have a network in place so that, if you give the patient thrombolysis, the next day the patient should be transferred for angiography and, if applicable, for PCI," Silber said.

This is *not* the same thing as facilitated PCI, Silber emphasized. "There is a lot of confusion over this, and I want to clarify that before we recommend facilitated PCI, we need studies in which all patients receive PCI with half randomized to thrombolysis and half to no thrombolysis. For now, we do not recommend facilitated PCI. We

thrombolysis within the first three hours, transfer the patient the next day for angiography."

Clear answers on the facilitated-PCI question should come from the **FINESSE** and **ASSENT 4** trials, he added.

Related links

ESC Guidelines for Percutaneous Coronary Interventions

ACC/AHA Guidelines for Percutaneous Coronary Intervention (Revision of the 1993 PTCA Guidelines)

Speeding up the treatment of MI: Is prehospital thrombolysis or expanded primary PCI the answer?
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