

Drug-Eluting Stents: Worth the Money?

BY BRUCE JANCIN
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STOCKHOLM — Routine use of drug-eluting stents in a real-world patient setting is not good value for money, according to the findings of the first-ever randomized trial that compared drug-eluting stents with bare-metal stents in unselected patients in a study free of industry sponsorship.

The results of the Basel Stent Cost Effectiveness Trial (BASKET) suggest that the use of drug-eluting stents (DESs) could reasonably be restricted to selected high-risk patient subgroups, Matthias Pfisterer, M.D., said at the annual congress of the European Society of Cardiology.

"Based upon these data, we can define some subgroups where these stents are more attractive.

They are more cost effective in patients older than 65 years with three-vessel disease, more than one treated segment, longer lesions, and small treated vessels. This will hold true until the price of drug-eluting stents falls significantly," said Dr. Pfisterer of the University of Basel (Switzerland).

In a typical catheterization laboratory, perhaps two-thirds of patients fit that description, he added.

BASKET involved 826 consecutive patients treated at University Hospital of Basel with angioplasty and stenting for 1,281 de novo coronary lesions. They were randomized to the sirolimus-coated Cypher stent, the paclitaxel-coated Taxus stent, or the cobalt-chromium-based Vision third-generation bare-metal stent (BMS). The study was funded by the university in response to questions from cardiologists and hospital administrators about the impact of the growing use of DESs on the hospital budget.

Unlike previous randomized stent trials that were funded by device manufacturers and featured highly selected patient populations, BASKET was designed to reflect everyday clinical practice in the catheterization laboratory. Three-fifths of the participants presented with acute MI or unstable coronary syndromes. Sixty-nine percent of enrollees had multivessel disease, and one-half of those had involvement of the left anterior

descending coronary artery. Patients received a mean of 1.9 stents with a mean total stent length of 34 mm.

The 6-month combined efficacy end point of cardiac death, MI, or target vessel revascularization occurred in 12.1% of the BMS group and in 7.2% of the DES group. This difference was driven largely by the 43% reduction in target-vessel revascularization in DES-treated patients. There was a consistent trend for fewer major adverse cardiac events with the Cypher, compared with the Taxus DES; however, the sample size was too small to determine statisti-



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cal significance. The cardiac event rate in the BMS group was lower than might be anticipated in such a relatively high-risk population, most likely because the Vision stent is more effective than the earlier-generation steel stents, Dr. Pfisterer said.

The mean 6-month total costs were 10,544 euros per patient with the DESs and 9,639 euros per patient with the BMS. It cost a mean of 18,311 euros to avoid one major adverse cardiac event through the use of drug-eluting rather than bare-metal stents. The estimated cost per quality-adjusted life-year gained through the use of drug-eluting in lieu of bare-metal stents was 55,000-73,000 euros, depending on the quality of life measure that was used. Those estimates fall outside the range of what most health economists define as cost-effective therapy.

Kim M. Fox, M.D., professor of clinical cardiology at Royal Brompton Hospital, London, commented that the rapidly growing use of DESs is a huge issue in the United Kingdom, where there is concern that it is a potential hospital budget buster.

He added that although the BASKET trial provides important information about the limitations of the cost-effectiveness of DESs, interventional cardiologists will point to the devices' superior efficacy and find ways to expand their use. ■

Small Studies Show Carotid Stenting Can Be Safe in Patients Aged 80+

BY MITCHEL L. ZOLER
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STOCKHOLM — Carotid artery stenting can be successfully and safely done in patients in their 80s, according to two reports at the annual congress of the European Society of Cardiology.

But the number of patients in each of the two studies was relatively small—33 patients in one study and 71 in the other—which means that the conclusions must be considered tentative. "I'm concerned about calculating event rates in fewer than 100 patients," commented Antonio Columbo, M.D., director of the cardiac catheterization laboratory at EMO Centro Cuore Columbus in Milan. "There's no question that this is an encouraging experience, but older patients are at higher risk. We need a specific strategy for these patients."

One study, conducted in Buenos Aires, compared the outcomes of carotid stenting in 33 patients aged at least 80 years with those of a concurrent group of 321 younger patients. The second was a registry analyzed in Milan with data on 71 octogenarians who had been treated at four centers in Italy and Germany.

The Argentine study included all patients who had carotid stenting done at Fundacion Favalaro from November 1995 through May 2004. The first patients treated in the series had their carotid stents placed without use of a distal protection device, which is now standard practice. The average age of the octogenarians was 82 years, compared with 66 years in the younger patients.

Angiographic success was achieved in 97% of the octogenarians, and clinical success was achieved in 94%, rates that were similar to those of the younger patients, reported Oscar Mendiz, M.D., chief of interventional cardiology at Fundacion Favalaro. During the first 30 days after treatment, the older

patients had no major or minor strokes, one had a transient ischemic attack, and there were no treatment-related deaths but one nonrelated death. These rates were similar to those of the younger-patient group.

One-year follow-up was available for 32 of the older patients, and they had no additional strokes, deaths, or cases of carotid restenosis.

In the second report, the mean age of the 71 octogenarians was 83 years. Distal protection devices were used on all patients.

Carotid stenting was successful in all but one patient; two patients had nonocclusive dissections during the procedure, but these did not cause neurologic sequelae. During the first 30 days of follow-up, there was one major stroke, which led to the only death. Two patients had transient ischemic attacks, and one patient had a myocardial infarction, reported Ioannis Iakovou, M.D., a cardiologist at EMO Centro Cuore Columbus.

"Carotid stenting with cerebral protection in octogenarians appears to be feasible and safe, with a low rate of major complications," said Dr. Iakovou.

One possible complication with right carotid stenting in very old patients is that the carotid sinus reflex can be triggered, causing a rapid drop in blood pressure, commented Giancarlo Biamino, M.D., director of interventional angiography at the Heart Center in Leipzig, Germany. As a result, "you must be ready to start an infusion of dopamine immediately in these patients," he said. Because many older patients are on a β -blocker, treatment with atropine is not possible.

Another concern with this procedure in octogenarian patients is that their carotid arteries can be heavily calcified. To avoid causing a rupture, Dr. Biamino said he limits his dilating balloon to 4.5 mm, instead of the 6-mm balloon that is often used in younger patients. ■

Carotid Stent Placement Up in Asymptomatic

STOCKHOLM — More than half of the patients who underwent carotid stenting at German hospitals last year were asymptomatic, up from 20% of all carotid stenting in 1996, according to a registry with almost 2,000 patients.

The asymptomatic patients also had somewhat better outcomes than those who had symptoms from carotid stenosis prior to stenting, but the differences were not statistically significant, Bernd Mark, M.D., said at the annual congress of the European Society of Cardiology.

The registry was started in 1996 and includes all patients who undergo carotid artery stenting at 26 German hospitals. By August 2004, a total of 1,954 patients had been entered into the series.

Asymptomatic patients were eligible for carotid stenting if they had a greater than 70% stenosis and if they met at least one of the following criteria: They were scheduled to undergo major surgery such as coronary bypass or valve surgery, there

was evidence of stenosis progression, there was an occlusion of the contralateral coronary artery, or if they had asymptomatic cerebral ischemia documented by CT or MRI.

During the entire series, 910 patients were asymptomatic (47%) and 1,044 were symptomatic. By 2004, asymptomatic patients constituted 54% of all carotid stenting done during the year. The fraction of carotid stenting done in asymptomatic patients at each individual hospital varied widely, from a low of 17% of the procedures to a high of more than 80%. Distal protection devices became routinely used later in the series and were used overall in about 55% of patients.

The incidence of in-hospital complications was 5.2% in the asymptomatic patients and 7% in symptomatic patients, a difference that was not statistically significant, reported Dr. Mark, a cardiologist at the Heart Center in Ludwigshafen, Germany. The incidence of death or stroke during hospitalization was 3% in the

asymptomatic patients and 4.8% in those with symptoms, also not statistically significant difference.

But these complication rates may be inflated because they included many patients who were treated without distal protection devices. "I'd be cautious making conclusions about the complication rates," commented Antonio Columbo, M.D., director of the cardiac catheterization laboratory at the EMO Centro Cuore Columbus in Milan. "During the last 3-4 years, use of distal protection devices has become routine. We penalize ourselves when we include procedures that are not done anymore."

Dr. Columbo also defended the value of carotid stenting in asymptomatic patients.

"Even with the best medical treatment, there is room for improvement" in patients with substantial carotid stenosis, although they're asymptomatic, he said. "We should try to give asymptomatic patients a better prognosis" by offering them carotid stenting.

—Mitchel L. Zoler