Drug-Eluting Stents: Worth the Money?

BY BRUCE JANCIN
Denver Bureau

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 unsellected 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, according to Dr. 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 not cost-effective. They are more cost effective in patients older than 65 years with three-vessel disease, more than one segment of long lesion, 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-stent, the paclitaxel-coated stent, the Cypher compared with the Taxus DES; however, the sample size was too small to determine statistically significant results.

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

The mean 6-month total costs were 16,544 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 55,000-75,000 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.

The registry was started in 1995 and includes all patients who underwent carotid artery 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, according to a registry with almost 2,000 patients.

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 included with the follow-up 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 was widely varied from 20% of the procedures to a high of more than 80%.

Distal protection devices became routinely used last year in the series and were used overall in about 55% of patients.

The incidence of in-hospital complications was 5.2% in the asymptomatic patient-related deaths and one non-related 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 or deaths, or cases of carotid restenosis.

In the second report, the mean age of the 71 ocotogenarians 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 the EMO Centro Cuore Columbus in Milan.

“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 Bianimo, M.D., director of interventional angiography at the University of 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. Bianimo said he limits his dilating balloon to 4.5 mm, instead of the 6-mm balloon that is often used in younger patients.

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

BY MITCHEL L. ZOLER
Philadelphia Bureau

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 the EMO Centro Cuore Columbus in Milan.

“The incidence of in-hospital complications was 5.2% in the asymptomatic patient-related deaths and one non-related 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 or 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 the EMO Centro Cuore Columbus.

“We 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. Bianimo 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

BY MITCHEL L. ZOLER
Philadelphia Bureau

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.

Asymptomatic patients were also somewhat better outcomes than those who had symptoms from carotid stenosis prior to stenting, but the differences were not statistically significant, according to a registry with almost 2,000 patients.

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 included with the follow-up 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 was widely varied from 20% of the procedures to a high of more than 80%.

Distal protection devices became routinely used last year in the series and were used overall in about 55% of patients.

The incidence of in-hospital complications was 5.2% in the asymptomatic patient-related deaths and one non-related 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 or 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 the EMO Centro Cuore Columbus.

“We 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. Bianimo said he limits his dilating balloon to 4.5 mm, instead of the 6-mm balloon that is often used in younger patients.

Cardiovascular Medicine

November 15, 2005 • www.familypracticenews.com