# Drug-Eluting Stents Effective in Complex Lesions

BY MITCHEL L. ZOLER
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ORLANDO — The proven indications for drug-eluting stents in coronary arteries have expanded, based on results from two studies reported at the annual meeting of the American College of Cardiology.

Sirolimus-eluting stents were more effective than bare-metal stents for preventing restenosis and other adverse events in 322 patients with complex lesions, Henning Kelbaek, M.D., reported at the meeting.

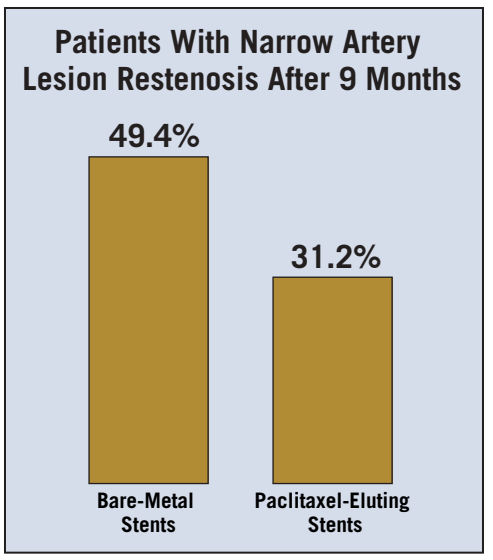
In a separate study, TAXUS-V, paclitaxel-eluting stents also were more effective than bare-metal stents in more than 400 patients with narrow or wide coronaries, said Gregg W. Stone, M.D.

However, when two or more paclitaxel stents were used in an overlapping fashion in long lesions, they led to transient side-branch narrowing that boosted the rate of periprocedural myocardial infarctions, said Dr. Stone, a cardiologist at Columbia University in New York.

"The clinical outcomes of side-branch occlusions tend to be benign," commented Sheldon Goldberg, M.D., director of interventional cardiovascular medicine at Hahnemann University in Philadelphia. "But the increased risk of non–Q-wave myocardial infarctions in patients who got overlapping stents needs further delineation," he said.

The study with paclitaxel-eluting stents enrolled 1,172 patients at more than 20 U.S. centers. Included were more than 700 patients with especially narrow or wide coronary arteries, or with long lesions that required more than one stent. The TAXUS-V study was funded by Boston Scientific, the company that markets the paclitaxel-eluting stent (Taxus).

The study included 379 patients with long lesions—average length of about 25 mm—who received two or more stents in their target artery; 326 of these patients had stents placed in an overlapping fashion. After 9 months of follow-up, the rate of major adverse events was 20.4% in patients who received paclitaxel-eluting stents, and 32.0% in those who received bare-metal stents. Angiography after 9 months in 88% of the patients showed a binary in-segment restenosis rate of 27.2% in patients who got drug-eluting stents and 57.8% in those who got bare-metal stents.




But the 30-day follow-up showed an increased rate of periprocedural MIs among the patients who got multiple paclitaxel-eluting stents, an 8.3% rate, compared with a 3.3% rate among patients who received bare-metal stents. This difference was driven by a 7.3% incidence of non–Q-wave MIs in patients who got paclitaxel-eluting stents. This increased early incidence of MIs was caused by myonecrosis from transient side-branch narrowing and decreased blood flow, Dr. Stone said. This disparity in the rate of MI persisted at 9 months, when there was a cumulative 8.3% rate among patients treated with paclitaxel-eluting stents and a 3.9% rate among patients who received bare-metal stents.

The study subgroup that focused on narrow arteries included a total of 203 patients with an average reference vessel diameter of about 2.1 mm. After 9 months of follow-up, the patients who received paclitaxel-eluting stents had an 18.9% incidence of major adverse coronary events, compared with a 26.9% rate among the patients treated with bare-metal stents. Angiography after 9 months in 88% of these patients showed a binary in-segment restenosis rate of 31.2% in patients who received drug-eluting stents compared with a 49.4% rate in those who got bare-metal stents, reported Dr. Stone, who is a consultant to and receives research support from Boston Scientific.

The subgroup that focused on patients with wide coronary arteries included 202 patients who were treated with 4.0-mm stents. The average reference vessel diameter for patients in this subgroup was about 3.4 mm. After 9 months, the rate of major adverse events was 6.5% among patients who received paclitaxel-eluting stents and 14.9% among the patients who received bare-metal stents.

Angiography after 9 months in 85% of patients showed a binary, in-segment restenosis rate of 3.5% in patients with drug-eluting stents and 14.4% among those with bare-metal stents.

The study using sirolimus-eluting stents in complex lesions, called SCANDSTENT, was done at four centers in Denmark. Although the study received some funding from Cordis, the company that markets sirolimus-eluting stents (Cypher), the study was run independently by Dr. Kelbaek and his associates.

They enrolled 115 patients with a totally occluded coronary artery, 109 with lesions at bifurcations, 73 patients with ostial lesions, and 25 patients with angulated vessels. All affected arteries were native vessels, 2.25-4.0 mm in diameter, with de novo lesions. About half of the patients had non–ST-segment elevation MIs, and 18% had diabetes.

After 6 months, follow-up angiography showed that the binary restenosis rate was 2.0% among the 163 patients who received sirolimus-eluting stents, compared with a 31.9% rate among the 159 patients who received bare-metal stents, said Dr. Kelbaek, a cardiologist at Rigshospitalet in Copenhagen.

After 12 months of follow-up, patients who received drug-eluting stents had a 3.1% rate of major adverse coronary events, including a 2.4% rate of target lesion revascularization. Among the patients who received bare-metal stents the major adverse event rate was 30.2%, including a 29.6% rate of revascularization. The rate of stent thrombosis was 0.6% in patients who received drug-eluting stents, compared with a 3.1% rate among those treated with bare-metal stents. ■

# Off-Pump Coronary Bypass Lowers Mortality Rate in High-Risk Patients

BY MITCHEL L. ZOLER
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NEW YORK — Off-pump coronary surgery cut mortality compared with on-pump surgery in a retrospective assessment of 270 patients with an extremely low ejection fraction.

The study reviewed all 5,765 patients who underwent coronary artery surgery at Lenox Hill Hospital in New York during January 1995-October 2004. The overall in-hospital mortality in all of these patients was 26%, reported Ramachandra C. Reddy, M.D., and his associates in a poster at the annual meeting of the International Society for Minimally Invasive Cardiothoracic Surgery.

The group included 270 patients who had a left ventricular ejection fraction of less than 20% when they were examined prior to coronary bypass surgery. Within this subgroup, 142 patients underwent surgery on cardiopulmonary bypass (on pump), and 128 had their surgery done without bypass (off pump). Assignment to the on-pump or off-pump groups was not done on a randomized basis. Eight of the off-pump patients were converted to on-pump patients during their surgery, but their follow-up results were counted in the off-pump group.

The on-pump and off-pump groups had very similar demographic and clinical profiles. The off-pump patients had a significantly higher prevalence of diabetes, 58%, compared with a 42% prevalence in the on-pump patients. The off-pump group also had a higher prevalence of a history of stroke, though this was not a significant difference—13% off pump and 6% on pump, respectively. The incidence of postsurgical complications was also very similar in the two subgroups. However, postsurgical mortality was 4.7% in the off-pump patients and 11.3% in the on-pump patients, a statistically significant difference, reported Dr. Reddy, a cardiothoracic surgeon at Lenox Hill Hospital.

In a multivariate logistic regression analysis adjusted for baseline differences between groups, on-pump coronary bypass surgery was associated with a 2.6-fold increased risk of death compared with off-pump surgery in this high-risk group.

Another difference between these two techniques of cardiopulmonary bypass was seen in the length of hospitalization following surgery. The on-pump patients had an average, postsurgical length of stay of 13 days, compared with an average of 10 days in the off-pump patients, a statistically significant difference. ■

# *Better Prophylaxis Against GI Bleeding Needed After Stenting*

CHICAGO — Cardiologists might not be adequately protecting their coronary artery–stenting patients against the risk of upper GI bleeding due to antiplatelet therapy, according to a poster presented at the annual Digestive Disease Week.

The study, led by Steven Chang, M.D., was a chart review of 636 randomly selected patients who received cardiovascular stents at three institutions, including Chicago's Northwestern Memorial Hospital. Most patients received aspirin before (n = 459) and/or after (n = 619) stent placement, which increased their risk of peptic ulcer–related bleeding, according to Dr. Chang and his colleagues. After stenting, however, only 155 (24%) were prescribed a proton pump inhibitor (PPI); 14 (2%) were prescribed an H2-receptor antagonist; and 1 patient was prescribed sucralfate, reported Dr. Chang, who is a consultant to Santarus, a manufacturer of omeprazole.

Some of the stent recipients had risk factors for GI bleeding besides aspirin therapy. Three patients had a documented history of upper GI bleeding, 23 had a history of peptic ulcer disease, and 30 were receiving NSAID therapy that was not stopped before stenting.

"Few coronary stent patients who are started on aspirin [therapy] and other antiplatelet agents receive appropriate GI prophylaxis," Dr. Chang wrote. But it might not be cost effective to prescribe a PPI in all patients before stent placement, he added. "We recommend that cardiologists give PPIs to patients at risk [of upper GI bleeding] before stenting."

Outcomes data on GI bleeding were not available in the study. Dr. Chang said a randomized trial of PPI prophylaxis is needed to determine whether PPIs prevent bleeding in this at-risk population.

**—Kathleen Louden**