Drug-Eluting Stents Cut Mortality in Diabetes

BY BRUCE JANCIN

NEW ORLEANS — Diabetic patients treated with drug-eluting stents showed impressive reductions in mortality, acute MI, and repeat revascularization during the subsequent 3 years compared with bare-metal stent recipients in a large real-world Massachusetts registry featuring mandatory reporting and follow-up.

The mortality benefit for drug-eluting stents (DES) relative to bare-metal stents (BMS) in this consecutive series of more than 5,000 diabetic patients was surprising. The study was conducted to address safety concerns that have arisen regarding DES in the last couple of years. It turned out that in a diabetic population, DES were not associated with increased hazard; indeed, the opposite proved true, Dr. Laura Mauri reported at the annual scientific sessions of the American Heart Association.

This is an important finding because diabetic patients now account for roughly one-third of all angioplasties performed in clinical practice. This is a population that tends to have very aggressive coronary disease with high rates of restenosis, MI, and cardiac death, both periprocedurally and long term, explained Dr. Mauri of Brigham and Women's Hospital and Harvard Medical School, Boston.

The Massachusetts Data Analysis Center Registry (Mass-DAC) includes all patients undergoing percutaneous coronary intervention at nonfederal hospitals statewide. During the 18-month study period beginning in April 2003, there were 3,341 diabetic patients who underwent DES-only PCI and 1,710 who received only BMS with subsequent complete 3-year follow-up data.

The unadjusted differences in 3-year mortality, MI, and target-vessel revascularization (TVR) were strikingly in favor of DES. However, because this was an observational study and the DES and BMS groups differed in key ways at baseline, the investigators performed a logistic regression propensity score-matched analysis involving 1,476 DES recipients and an equal number of BMS recipients matched according to 67 patient, procedural, and hospital variables. Clinical outcomes in the DES group remained significantly better. (See box.)

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DR. MAURI

The mortality curves for the DES- and BMS-treated patients separated in the first month and stayed roughly parallel from the 6-month mark through the full 3 years of follow-up, showing the durability of the DES survival benefit, she noted.

Discussant David O. Williams said the clinical implication of the Massachusetts study is that DES are the preferred PCI option whenever possible in diabetic patients. "Probably the selection of a bare-metal stent over a drug-eluting stent will be based on a patient's inability to take dual antiplatelet therapy for a sustained period of time," added Dr. Williams, professor of medicine at Brown University, Providence, R.I.

He noted that he and his coinvestigators in the National Heart, Lung, and Blood Institute Dynamic Registry recently reported a lower 1-year risk of TVR in 1,749 DES-treated diabetic participants than that of 817 in the BMS group. They also found a 43% reduction in the risk of death or MI with DES in non–insulin-treated diabetics, but no difference in the insulin-dependent patients (J. Am. Coll. Cardiol. Intv. 2008;1:139-47).

The randomized trials that led to regulatory approval of the DES have not shown mortality or MI benefits over BMS with several years' follow-up. That may be because the early trial participants had uncomplicated disease, Dr. Williams explained, adding that the benefits may show up only in higher-risk patients, such as those with diabetes.

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Dr. Mauri speculated that the mortality reduction observed with DES in diabetic patients in the Massachusetts study was probably due to a combination of three factors. For one, it wasn't possible to adjust for the duration of dual antiplatelet therapy with aspirin and a thienopyridine, yet the DES-treated group was likely on dual antiplatelet therapy longer, since the standard regimen during the study period was 3-6 months for DES compared with 1 month for BMS.

Also, DES patients tended to have more complete revascularization, which may have reduced late coronary events. Finally, by preventing restenosis and thus avoiding the invasive procedures employed to treat restenosis, some periprocedural MIs and deaths were averted.

Roughly three-quarters of DES implanted in study participants were sirolimus eluting, since those stent types reached the U.S. marketplace earlier than did paclitaxel-eluting stents. No difference in the study end points was seen between the two DES types.

The study was funded by the Massachusetts Department of Public Health. Dr. Mauri has received honoraria from Abbott Vascular, Boston Scientific, Cordis, and Medtronic Vascular. ■

Clinical Outcomes in Diabetic Patents

Unadjusted

	DES	BMS
Death	14.4%	22.2%
MI	13.4%	17.1%
TVR	19.1%	23.1%

Adjusted

	DES	BMS
Death	17.5%	20.7%
MI	13.8%	16.9%
TVR	18.4%	23.7%

Note: Data are based on a study of 5,051 patients.
Source: Dr. Mauri

ELSEVIER GLOBAL MEDICAL NEWS

At-Home INR Monitoring Safe for Patients on Warfarin

BY MITCHEL L. ZOLER

NEW ORLEANS — Patients taking warfarin who regularly self-tested their level of anticoagulation at home had outcomes that were at least as good as, and in some cases better than, patients who were monitored by regular monthly visits to an anticoagulation clinic.

This good performance by patient self-testing of their international normalized ratio (INR) suggests that "home self-testing is an acceptable alternative to high-quality clinic care and may be preferable when patient access [to a clinic] is difficult," Dr. Alan K. Jacobson said at the annual scientific sessions of the American Heart Association.

Expanded home INR monitoring could "lead to an improvement in quality, particularly with an appropriate infrastructure. I'm hopeful this will be an option for a lot of patients," Dr. Alan S. Go, assistant director for clinical research for Kaiser Permanente of Northern California in Oakland, said in an interview.

Home monitoring of INR levels may now be particularly attractive for insurers and physicians because Medicare began last March to allow reimbursement for home monitoring of patients with atrial fibrillation or venous thromboembolism, noted Dr. Go, who was not involved with the study.

"Patients in the self-testing group had a higher rate of time in their target INR range, and they liked using the [home-monitoring] device," said Dr. David B. Matchar, director of the Duke Center for Clinical Health Policy Research in Durham, N.C., and cochair of the study. The results show that "home testing provides another option for high-quality anticoagulation."

The Home INR Study (THINRS) was run at 28 Veterans Affairs medical centers, each of which had an anticoagulation clinic that met the 2002 guidelines of the Managing Anticoagulation Services Trial (Am. J. Med. 2002;113:42-51). The study used the ProTime device and system made by International Technidyne Corp. The INR-measuring devices and kits used in the study were purchased by the VA through the federal bid process, and the study received no commercial support, said Dr. Jacobson, who disclosed that he has received research support (for other studies) from International Technidyne and several other manufacturers of INR measurement devices. Dr. Matchar said that he had no financial relationships to disclose.

The study initially enrolled 3,644 patients who required warfarin treatment because of either atrial fibrillation or a mechanical heart valve. Patients received training in using the home monitor, which took about 30 minutes, and then used the device at home for 2-4 weeks. They then returned to their local center for an assessment of how well they had monitored their INR level, either completely on their own or with the assistance of a caregiver at home.

Of the initial 3,644 patients, more than 700 patients dropped out, failed training, or failed to adequately monitor themselves, but 2,922 patients (80% of the original group) demonstrated that they could successfully handle home monitoring and progressed to the randomized part of the study. Their average age was 67 years, with a range of 23-99. About two-thirds of the patients had atrial fibrillation.

The patients were randomized to either continue weekly INR self-testing at home or come to the clinic for monthly INR testing (control group). The at-home patients called in their test results each week and if necessary were given instructions by telephone for dosage adjustment. Home-monitored patients were seen in the clinic when required by changes in their status. Patients remained on their monitoring schedules for 2-5 years.

The study's primary end point was the combined rate of stroke, major bleeding, or death during the study. This rate was 8.9% in the control patients and 7.9% in the self-monitored patients, a difference that was not statistically significant but did show that home monitoring was not harming patients, said Dr. Jacobson, a cardiologist and associate chief of staff for research at the Loma Linda (Calif.) VA Medical Center.

A secondary end point was the time each patient spent within their INR therapeutic range. The average rate was 62% in the control patients and 67% in the home-monitored patients, a statistically significant difference. ■

A related interview with Dr. Matchar can be seen at www.youtube.com/InternalMedicineNews (search for 63081).