DES Safety Shown in Massachusetts Database

BY MITCHEL L. ZOLER
Philadelphia Bureau

ORLANDO — The safety of drug-eluting coronary stents, compared with bare-metal stents, received a substantial boost in an analysis of data from more than 10,000 patients who received coronary stents in Massachusetts during 2003-2004.

Data collected by the Massachusetts Department of Public Health, which sponsored the study, on all patients who received a coronary stent in the state showed that use of drug-eluting stents (DES) was associated with a significantly lower risk of death or need for revascularization and a similar incidence of myocardial infarctions, compared with patients treated with bare-metal stents (BMS), Dr. Laura Mauri reported at the annual scientific sessions of the American Heart Association.

"The results are very reassuring" regarding the relative safety of DES, said Dr. Mauri, a cardiologist at Brigham and Women's Hospital in Boston. These are the first large-scale registry data that compare DES with BMS using exclusively patients treated in the United States. In addition, because the study, called MASS Stent, used data collected from nearly 19,000 patients, Dr. Mauri and her associates were able to use an extensive propensity-score analysis that closely matched patients in the DES and BMS groups using 63 clinical and demographic variables.

The new findings "are reassuring for patients who have or may get drug-eluting stents," Dr. Robert O. Bonow commented in an interview.

"Data like these may lead to a resurgence in DES use," said Dr. Bonow, professor of cardiology and chief of cardiology at Northwestern University in Chicago. Use of coronary DES in the United States (and elsewhere) dropped substantially this year following several reports during the past 15 months that raised questions about their safety, compared with BMS.

The Massachusetts Department of Public Health requires reporting on all patients who receive coronary stents in the state. The new study used data collected by the department for more than 21,000 patients who received one or more coronary stents during April 1, 2003–Sept. 30, 2004. This period was selected for the analysis because DES first went on sale in the United States in April 2003, and because all patients in this group had at least 2 years of follow-up data.

The analysis included more than 11,000 patients who received exclusively DES, and more than 6,000 patients who received only BMS. The analysis excluded more than 1,000 patients who received both DES and BMS. Also excluded were about 1,500 patients who were not Massachusetts residents, and about 600 patients who could not be linked to data collected in administrative files.

During the early portion of the study period, about 90% of patients received BMS and about 10% received DES. This ratio shifted over the next 18 months, so that by September 2004 the situation was reversed and about 90% of patients who got coronary stents received DES and about 10% got BMS. Throughout the entire period, about 65% of the patients got DES and about 35% received BMS.

This level of DES use was substantially higher than in other registry data that have been reported for coronary stents, in which DES were about 30%-40% of all stents used. This includes data from the Swedish national registry that were published early this year, in which about 30% of patients received DES. In the Massachusetts data, about 70% of the DES used were sirolimus-eluting stents (Cypher). The other 30% of the DES used were placitaxel-eluting stents (Taxus).

The high rate of BMS use early on and the high rate of DES use later were strengths of the new study. This information meant that a broad population of patients received each stent type, which helped the investigators when they attempted to match very similar patients in the two groups, Dr. Mauri said.

Application of the propensity-score analysis, which matched patients from the two groups based on 63 variables, led to a final-analysis group of 5,441 patients treated with one or more DES and an equal number of patients who received one or more BMS.

The incidence of death during 2 years of follow-up was 9.4% in the DES group and 11.9% in the BMS group, a difference that was highly statistically significant. The total revascularization rate was 20.1% in the DES group and 23.9% in the BMS group, also a highly significant difference. Rates of nonfatal myocardial infarction were 10.8% in the DES patients and 11.8% in the BMS recipients, a difference that was not statistically significant.

The revascularization rate for the DES patients may seem unexpectedly high, but was probably caused by a very liberal approach in which any additional coronary stenting that patients received was counted. Many of the subsequent stenting procedures done in the DES recipients involved lesions that had not been treated initially, Dr. Mauri said.

The analysis has not yet specifically compared the rates of stent thrombosis in the DES and BMS groups. A major concern about DES safety has been that they might cause a higher incidence of stent thrombosis than BMS. Any clinically significant, in-stent thrombotic events would manifest as either death or myocardial infarction, she noted. During most of the study period, patients receiving DES were routinely treated with dual antiplatelet therapy—both aspirin and clopidogrel—for 3-6 months. Today, the recommended length of dual therapy is 1 year.

Dr. Mauri has received honoraria from Abbott Vascular, Boston Scientific, Cordis, and Metronic Vascular. ■

Statewide Program Cuts Time to Reperfusion in STEMI

BY MARY ANN MOON
Contributing Writer

Delays in reperfusion were substantially reduced for patients with ST-segment elevation myocardial infarction after a statewide program was introduced in North Carolina.

The results of the program were announced on Nov. 4 at the annual scientific sessions of the American Heart Association in Orlando and simultaneously published online (JAMA 2007 Nov. 4 [Epubdoi:10.1001/jama.298.20.joc70124]).

Described as "one of the largest and most extensive regional systems …for the reperfusion of STEMI developed in the United States," the program was modeled on systems for general trauma care. The program streamlined protocols and coordinated emergency medical services, hospital emergency departments, catheterization labs, and interhospital transfer, according to Dr. Christopher B. Granger of the division of cardiology at Duke University, Durham, N.C., and his associates.

After this program was instituted, the proportion of PCI patients who achieved door-to-device times of 90 minutes or less increased from 57% to 72%, and the median interval decreased from 85 minutes to 74 minutes, the researchers noted.

For patients who presented to hospitals that didn't perform PCI and therefore had to be transferred, the median door-to-device time dropped from 165 minutes to 128 minutes. Median door-in to door-out times decreased from 120 minutes to 71 minutes, "one of the greatest reductions observed in the study," Dr. Granger and his associates said.

For patients undergoing fibrinolysis, the proportion who achieved door-to-needle times of less than 30 minutes rose from 35% to 52%, and the median interval decreased from 35 minutes to 29 minutes.

The program shaved times by eliminating waits for a cardiology consultation and by having an on-call interventional cardiologist identified at all times.

The emergency physician or paramedic could activate the nearest catheterization laboratory at any hour on any day of the week with a single phone call. Emergency department physicians or medical technicians were allowed to start treatment without waits for a cardiology consultation.

The on-call interventional cardiologist eliminated delays that result when "trying to determine which cardiologist from several competing groups would intervene." Time to treatment was trimmed in remote areas by encouraging the use of local ambulances rather than helicopters or mobile critical care units. Other strategies included leaving patients "on the stretcher" when appropriate for more rapid evaluation and transfer.

Since STEMI "was a relatively infrequent event for most emergency personnel" to encounter, the program established a specific reperfusion plan that would cover most patients and would sidestep clinician delays that resulted from "indecision" and the need to develop individualized treatment plans.

ICU nurses staffed catheterization labs on an emergency basis, when night and weekend coverage by the usual staff couldn't be arranged. Certain procedures conducted by paramedics and medical technicians were modified to save time. For example, use of intravenous drips such as heparin or nitroglycerin were minimized because substantial delays were associated with establishing and changing infusion lines.

Additionally, the program addressed the limitations of regions with severe restrictions on available equipment and personnel. In resource-poor regions, intermediate-level emergency medical technicians were allowed to perform electrocardiograms. Paramedics were sometimes allowed to interpret ECGs, sometimes with the aid of computer algorithms or via electronic transmission to a physician. ■