

PCI Effective as Surgery in Diabetes in Small Trial

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Body

MUNICH - Patients with diabetes who received coronary stents fared just as well as similar patients who underwent coronary bypass surgery in a randomized study with 510 patients with 1 year of follow-up.

The results seemed to disprove the conventional wisdom that percutaneous coronary intervention (PCI) is not a good option for patients with diabetes because of their greater risk of restenosis, compared with nondiabetic patients, Dr. Akhil Kapur said at the annual congress of the European Society of Cardiology.

But some experts were skeptical of the finding, saying that a study with a total of 510 patients wasn't large enough to definitively address the issue. "Five hundred patients is small for any comparison" of PCI and coronary surgery in patients with diabetes, commented Dr. Spencer B. King III, executive director of Academic Affairs at the Saint Joseph Health System in Atlanta. He recommended that physicians await results from the Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) study, which is planned to enroll 2,400 patients and have results reported in 2012.

"The 1-year follow-up is very short, the study was very underpowered, and the results are inconclusive," commented Dr. Valentin Fuster, professor of medicine and director of the cardiovascular institute at Mount Sinai Hospital in New York. He also suggested waiting for the FREEDOM results.

The Coronary Artery Revascularization in Diabetes (CARDIA) trial was done at 24 hospitals in the United Kingdom and Ireland. It randomized patients with diabetes and either multivessel coronary disease or complex single-vessel disease who were suitable for either PCI or coronary artery bypass grafting (CABG). When the study began in 2002, bare-metal stents were used, but this changed once sirolimus-eluting coronary stents (Cypher) came on the market. The patients' average age was 64 years, and about 31% were on insulin treatment.

The study received support from Cordis, the company that markets Cypher stents, as well as many other device and drug companies. The study's primary sponsor was Hammersmith Hospitals NHS Trust, London. Dr. Kapur said he had no relevant disclosures.

The study's primary end point was the combined rate of death, nonfatal myocardial infarction, or nonfatal stroke after 1 year. The rate was 10.2% in 245 patients treated with CABG, and 11.6% in the 251 patients treated with

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PCI, a difference that was not statistically significant, reported Dr. Kapur, a cardiologist at the London Chest Hospital.

As in the other major comparison of PCI and CABG presented at the meeting, the SYNTAX study, the rate of stroke was significantly lower in patients treated with PCI (0.4%) than in patients treated with CABG (2.5%). On the other hand, the PCI patients had a higher rate of nonfatal MIs (8.4%), although not significantly higher than the CABG patients (5.7%). Also as in SYNTAX, the rate of repeat revascularizations was significantly higher in the PCI patients (9.9%) than in the CABG patients (2.0%), but unlike SYNTAX, the **CARDIA study** did not include repeat revascularization in the primary end point.

When the analysis was confined to the 179 PCI patients who received a drug-eluting coronary stent (71% of the PCI patients), the results shifted a little more in favor of PCI. The rate of death, MI, or stroke in this PCI subgroup was 10.1%, including no strokes. The rate of repeat revascularization fell to 7.3%.

"There was always a fear that PCI did not perform well in patients with diabetes. What we're impressed by is the improvement in both techniques," PCI and CABG, said Dr. Kapur. "All the data suggest that drug-eluting stents have reduced the need for repeat revascularization in patients with diabetes. I have plenty of patients who do not want surgery and are prepared to have a second procedure" if they develop restenosis. "But other patients want it over and done with" and choose CABG, Dr. Kapur said.



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