

Cell-coated stent as effective as drug-coated ones but needs less meds

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A stent that entices artery-lining cells to coat it works as well or better than drug-eluting stents in keeping arteries open in coronary heart disease patients, according to two research studies presented at the American Heart Association's Scientific Sessions 2008.

The new endothelial progenitor cell-capturing (EPC) stent is coated with an antibody that binds endothelial progenitor cells circulating in the blood. A number of smaller, randomized studies have shown that the stent is effective in carefully selected patients.

The new findings came from real-world patients who typically receive stents to restore adequate blood flow to the heart instead of carefully selected trial patients.

"Randomized trials have the advantage of a very good control group, but they usually have very restrictive exclusion and inclusion criteria; so results from randomized trials cannot be extrapolated to everyday patients," said Sigmund Silber, M.D., chief of cardiology at Müller Hospital Munich in Munich, Germany, and the first author of the large, multicenter stenting study.

In one study (abstract 6000), Silber and colleagues reported the one-year outcomes of 1,640 patients treated with the stent in an international study conducted outside the United States.

"The most significant finding was that the rate of stent blockage was

really low," Silber said. "The number of patients who needed another catheterized heart intervention within a year was also low."

Patients were treated at 144 sites around the world and entered into an electronic registry. Their average age was 62.8 years, 78.7 percent were males, 25.0 percent had diabetes, and 36.7 percent had suffered a prior heart attack.

Based on results of previous studies, physicians pretreated 73.8 percent of the patients with statin drugs, which increase the number of endothelial progenitor cells in the blood.

Most patients received two anti-clotting drugs, generally aspirin and clopidogrel, for one month.

Researchers found that one year after stenting:

- Only 1.0 percent of the patients suffered a stent-related blood clot.
- 2.1 percent of the patients died of cardiac causes; 1.8 percent of those were heart attacks.
- 5.4 percent required a revascularization procedure on the treated artery; a catheter-based procedure was used in 5.1 percent to restore blood flow.
- 9.3 percent experienced major adverse cardiac events (MACE), which included heart attacks, unexpected bypass surgery, treatment-related catheter-based revascularization, and cardiac death.
- Among diabetic patients, 4.7 percent had undergone revascularization procedures, the MACE rate was 10.3 percent, and 1.1 percent had stent-related blood clots.

"The stent appears very safe, even in diabetics," Silber said. "I don't think EPC-capturing stents will replace drug-eluting stents, but whenever you decide not to use a drug-eluting stent, this stent is a good

alternative."

In a separate study (abstract 4491), researchers reported the one-year clinical outcome of 236 mainly high-risk patients treated with an EPC-capturing stent at the Academic Medical Center of the University of Amsterdam in The Netherlands.

Until recently, two types of stents were used in daily practice; the bare-metal stent and the drug-eluting stent. The latter is coated with an antiproliferative drug to reduce the risk of restenosis (reblockage).

"The long-term safety concerns of the drug-eluting stent are late stent thrombosis (stent-related blood clots) and an associated increased risk of bleeding, due to long-term dual antiplatelet therapy." said Margo Klomp, M.D., first author of the Amsterdam study and a medical fellow at the Academic Medical Center.

In the single-center Dutch study, Klomp and her colleagues reported on patients with mainly complex lesions who were stented at the Amsterdam center between September 2005 and March 2007. The patients' averaged 65 years old, 72 percent were male, and 14 percent had diabetes.

The researchers' one-year follow-up findings included:

- 3.0 percent of the patients died, of whom 0.8 percent died of cardiac causes.
- 10.2 percent required a repeat revascularization procedure of the treated vessel.
- 1.2 percent (3 patients) had suffered stent thrombosis, which were angiographically documented and occurred within 24 hours, at seven days, and at 18 days, respectively.
- The MACE rate, composed of cardiac death, target lesion

revascularization and myocardial infarction, was 13.6 percent.

"Further research on the stent is being performed in a two-armed study, the TRIAS Program, at the Academic Medical Center," Klomp said. "In one arm, TRIAS LR, the EPC-capturing stent is being compared with the bare-metal stent in patients with a low risk of develop a new blockage. In the other arm, TRIAS HR, the EPC-capturing stent is being compared with conventional drug-eluting stents in people with a high risk of restenosis."

Source: American Heart Association

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