Study finds everolimus-eluting stent safer, more effective than paclitaxel-eluting stent

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Results from the SPIRIT IV clinical trial, which were first presented at the Transcatheter Cardiovascular Therapeutics (TCT) 2009 scientific symposium, were published today in the *New England Journal of Medicine*.

Data from the trial, a large-scale multi-center study of nearly 4,000 patients in the U.S., showed that everolimus-eluting stents demonstrated enhanced safety and efficacy in the treatment of de novo native coronary artery lesions when compared to paclitaxel-eluting stents. The trial, which was powered for superiority for clinical endpoints without angiographic follow up, also examined the differences in performance of the two stents in patients with diabetes.

"The data published in today's New England Journal of Medicine, and first reported at TCT, demonstrate enhanced safety and efficacy of the everolimus-eluting stent compared to the paclitaxel-eluting stent in this large-scale study without routine angiographic follow-up. The study results also suggest that minimal late loss may be achieved with drug-eluting stents without sacrificing safety," said principal investigator Gregg W. Stone, MD, Professor of Medicine at Columbia University College of Physicians and Surgeons, Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and Co-Director of the Medical Research and Education Division at the Cardiovascular Research Foundation.

The primary endpoint of the trial was target-lesion failure (TLF) at one year, a composite measure of cardiac death, target-vessel heart attack or ischemia-driven target-lesion revascularization (TLR). Major secondary endpoints of the trial were ischemia-driven TLR at one year, and the composite rate of cardiac death or target-vessel heart attack at one year.

For everolimus-eluting stents, TLF at one year was 4.2 percent, and for paclitaxel-eluting stents, TLF was 6.8 percent, a significant 38 percent reduction.

At one-year, ischemia-driven TLR was 2.5 percent for everolimus-eluting stents and 4.6 percent for paclitaxel-eluting stents, a significant 45 percent reduction.

The composite rates of cardiac death or target-vessel myocardial infarction through one year were not statistically different with the 2 stents (2.2 percent for everolimus-eluting stents and 3.2 percent for paclitaxel-eluting stents). The one-year rates of myocardial infarction and stent thrombosis, however, were also lower with everolimus-eluting stents than with paclitaxel-eluting stents (1.9 percent vs. 3.1 percent for myocardial infarction and 0.17 percent vs. 0.85 percent stent thrombosis.)

The results were consistent regardless of lesion length, vessel size and the number of lesions treated. However, in the diabetic-patient subgroup, the study found a comparable rate of TLF with both stents, whereas in patients without diabetes, everolimus-eluting stents reduced TLF by 53 percent compared to paclitaxel-eluting stents.

"Outcomes in patients with diabetes may still be improved, and should represent an area of focus for future development of novel drugs and enhanced stent design," Dr. Stone said.