New stent design demonstrates superiority at 6 months; 1 year data to be presented at TCT 2010

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A new drug-eluting stent design demonstrated superiority over a traditional drug-eluting stent at 6 months, according to a study led by Laura Mauri, MD, Associate Professor of Medicine, Brigham and Women's Hospital, Harvard Medical School (Boston, MA.) The study is being presented at the 22nd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

"This new stent proved superior to a traditional drug-eluting stent for the primary endpoint of in-stent late loss at 6 months. This was associated with a trend for better clinical outcomes and an absence of stent thrombosis. The bioresorbable polymer and stent design are targeted to mitigate thrombosis risk without compromising anti-restenotic efficacy," said Dr. Mauri.

Traditional drug eluting stents (DES) deliver an anti-proliferative drug to the vessel wall from a durable polymer which homogeneously covers the outer surface of the stent. The stent used in this study is a sirolimus-eluting coronary stent system that combines a bioresorbable PLGA polymer with the antiproliferative agent sirolimus within a novel reservoir technology on a chromium-cobalt stent platform, reducing spatial and temporal polymer exposure. After drug and polymer reabsorption, all that remains is an inert metallic stent.

Eligible patients had single de-novo lesions ?28mm in native coronary arteries 2.5 - 3.5mm. The primary endpoint was in-stent late loss (LL) at 6 months. Secondary endpoints included death, myocardial infarction (MI), clinically driven target lesion (TLR) and target vessel revascularization (TVR) and the composite endpoints MACE (death, MI, TLR), target lesion failure (cardiac death, target vessel-related MI, TLR), and ARC adjudicated stent thrombosis (ST). IVUS was performed in a subgroup of 100 patients. Clinical follow-up is to be completed at 1, 6, and 12 months and annually to 5 years. Angiographic follow-up was performed at 6 months.

A total of 394 patients were enrolled at 40 sites in 9 countries from March to October 2008. The primary endpoint, in-stent LL at 6 months, (0.13±0.31mm for NEVO™ and 0.36±0.48mm for TAXUS® Liberté) reached statistical significance for the non-inferiority and superiority hypothesis (P 20mm. While not powered for clinical endpoints, 6 month outcomes showed lower event rates for the NEVO™ group: death (0.5% vs. 1.6%, P=0.36); MI (2.0% vs. 2.6%, P=0.75); TLR (1.5% vs. 3.7%, P=0.21); MACE (4.0% vs. 7.9%, P=0.13.) No stent thrombosis was observed for NEVO™, while 2 cases occurred in the TAXUS group. IVUS showed lower neointimal volume for NEVO™ (5.8±11.7mm3 vs 19.5±24.7mm3, P=0.004).

12-month outcome data will be presented be during the Drug-Eluting and Bare Metal Stent Studies I Oral Abstract Session on Wednesday, September 22 in Room 140A at the Washington Convention Center.

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