Results from REVELUTION reported

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A first-in-human study of a new polymer-free drug-filled stent, which provides controlled drug elution from an internal lumen, indicated non-inferior in-stent late lumen loss at nine-months compared with historical zotarolimus-eluting stent (Resolute) data. In addition, there was no binary restenosis, and a high degree of early stent strut coverage with minimal malapposition.

Findings from the REVELUTION study were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in *JACC: Cardiovascular Interventions*.

A polymer-free metal surface stent that is capable of controlled antiproliferative drug elution may avoid the adverse effects of polymer-induced inflammation, thrombosis and non-uniformity, and could potentially allow for shorter durations of dual antiplatelet therapy. The polymer-free drug-filled stent (DFS) used in the study was designed to provide controlled and sustained drug elution from an internal stent lumen without a polymer coating. The DFS is made from a tri-layered continuous wire with an outer cobalt chromium layer, a middle tantalum layer, and an inner lumen coated with sirolimus. Small laser-drilled holes on the abluminal stent surface control drug elution.

The study enrolled 100 patients with de novo coronary lesions 2.25-3.50 mm in diameter and length ? 27 mm in two 50-patient cohorts for angiographic, intravascular ultrasound, and clinical assessment at nine or 24 months, with optical coherence tomography (OCT) performed in a subset of 30 patients at multiple time periods. The primary endpoint was angiographic in-stent late lumen loss at nine months compared with historical data from the zotarolimus-eluting stent (Resolute) as a control. Fifty patients with 56 lesions were treated with DFS in the nine-month cohort.

Researchers found in-stent late lumen loss was 0.26±0.28 mm for DFS and 0.36±0.52 mm for Resolute (Pnoninferiority