Results of the TRYTON trial presented

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A clinical trial designed to measure the effectiveness of using a dedicated side branch-covering bare metal stent in true bifurcation coronary lesions found that that the strategy was safe, but the results did not establish non-inferiority compared to the currently accepted strategy of using a single stent with provisional use of a second side branch stent when indicated.

The findings of the TRYTON trial were presented today at the 25th 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.

Coronary bifurcation lesions are caused from a build-up of plaque in the heart at a location where one artery branches from another. Currently, a provisional side-branch stent strategy is the recommended practice in patients with coronary bifurcation lesions. (In provisional stenting strategy, stenting of the side branch is performed only when absolutely necessary.) However, in true bifurcation lesions (disease affecting the origin of both branches), this approach can lead to suboptimal results and even closure of the non-stented branch. The TRYTON trial compared a new specially-designed bare metal bifurcation stent to standard practice. The Tryton stent is placed in the proximal main vessel extending into the side branch. A standard drug-eluting stent (DES) is then placed in the main vessel through the proximal portion of the bifurcation stent into the distal main vessel.

The multicenter international study randomized 704 patients with true coronary bifurcation lesions to receive the new bifurcation stent (355 patients) or provisional stenting (349 patients). The primary endpoint was target vessel failure (TVF), a composite of cardiac death, target vessel myocardial infarction, or target vessel revascularization at nine months.

At nine months, TVF was 12.8 percent in the provisional stenting group, and 17.4 percent in the Tryton stent group.

However, the strategy met the secondary superiority endpoint, improving the percent diameter stenosis of the side branch at nine months. In the provisional group, the percent diameter stenosis was 38.6 and in the bifurcation stent group, the percent diameter stenosis was 31.6. In a post-hoc analysis, the Tryton stent demonstrated improved angiographic outcomes with the bifurcation stent in larger side branches (> 2.25 mm side branches = 39 percent of enrolled patients). Interestingly, the study demonstrated a striking disparity between binary restenosis and clinically-driven TVR for both arms, indicating that side branch angiographic restenosis is uncommonly expressed clinically.

"The two-stent strategy in true bifurcations compared with the provisional strategy did not meet the non-inferiority clinical endpoint (TVF), largely due to a relatively higher frequency of peri-procedural CK-MB elevations," said lead investigator Martin Leon, MD. Dr. Leon is Professor of Medicine at Columbia University College of Physicians and Surgeons and Director of the Center for Interventional Vascular Therapy (CIVT) at NewYork-Presbyterian Hospital/ Columbia University Medical Center. He is also Founder and Chairman Emeritus of CRF.

"However, both strategies were safe resulting in rare clinically significant MIs and stent thrombosis. Both also had low nine-month clinically-driven TVR, with 3.6 percent occurring in the provisional

group and 4.7 percent in the bifurcation stent group."

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