Results of the ROTAXUS trial reported at TCT 2011

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A clinical trial testing the efficacy of rotational atherectomy (or rotablation, a process of drilling through plaque deposits) prior to implantation of a drug-eluting stent found that the process was not superior to standard balloon angioplasty and decreased the efficacy of the stent in reducing new tissue growth within the blood vessel.

Results of the ROTAXUS (A Prospective, Randomized Trial of High-Speed Rotational Atherectomy Prior to Paclitaxel-Eluting Stent Implantation in Complex Calcified Coronary Lesions) trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Drug-eluting stents (DES) are liberally used in complex lesions and patients. Heavily calcified stenoses have not been adequately studied, and form a challenge for immediate and late outcomes. Rotational atherectomy has been shown to effectively modify calcified plaques and facilitate stent delivery and expansion. However, in the DES era, data concerning rotational atherectomy are scarce. In patients with complex calcified lesions, rotablation followed by DES seems a rational combination, but is not supported by randomized studies.

ROTAXUS is a randomized active-controlled superiority trial in patients with documented myocardial ischemia and complex calcified native coronary lesions. Eligible patients who met all clinical and angiographic inclusion criteria and gave written informed consent were randomized

1:1 to a strategy of rotablation followed by stenting, or stenting without prior rotablation (standard therapy). Stenting was performed using the polymer-based slow-release paclitaxel-eluting stent. The primary endpoint of the trial was the in-stent late lumen loss at nine months as measured by follow-up angiography.

240 patients with complex calcified coronary artery disease were enrolled at three investigator sites in Germany, and were assigned to be treated with rotablation followed by stenting (n=120) or stenting without rotablation (n=120).

At nine months, in-stent late lumen loss in the rotablation group was 0.44 mm and 0.31 mm in the standard therapy group. The rotablation group performed better than the standard therapy group in some areas, including acute lumen gain and strategy success (i.e. angiographic success without stent loss or cross-over).

"The superior acute gain obtained by rotablation counterbalanced the increased late loss resulting in a neutral effect on restenosis," said Gert Richardt, MD, PhD, the Study Chair. Dr. Richardt is a Professor at the Heart Center, Segeberger Kliniken in Germany.

"Rotablation remains an important bail-out device for uncrossable or undilatable coronary lesions but does not improve efficacy of DES in complex calcified lesions." Dr. Richardt said.

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