

Results of IVUS-CTO trial reported at TCT 2014

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A new study found that intravascular ultrasound (IVUS) -guided intervention in patients with chronic total occlusion (CTO) could improve outcomes compared to a conventional angiography-guided approach during percutaneous coronary intervention (PCI). The IVUS-CTO study is the first randomized trial to examine the clinical impact of IVUS guidance for CTO intervention.

Findings were reported today at the 26th 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.

A chronic total occlusion is a complete or nearly complete blockage of a coronary artery that has been present for more than 30 days. PCI of CTO lesions is one of the most challenging forms of PCI, with some of the highest rates of recurrent restenosis due to the complexity of the procedures and lesions. IVUS evaluates coronary arteries using sound waves, and can be used to optimize post-PCI stent results, but whether there is demonstrable efficacy of this technique has not been adequately studied in CTO PCI.

The prospective, multi-center trial randomized 402 patients with CTOs to either the IVUS-guided or angiography-guided groups after successful guidewire crossing. Patients were then additionally randomized to zotarolimus-eluting stents or biolimus-eluting stents. The primary



endpoint was the composite of <u>cardiac death</u>, <u>myocardial infarction</u>, and target-vessel revascularization (TVR) at 12 months. Secondary endpoints included a composite rate of cardiac death or myocardial infarction and individual components of the primary endpoint.

After a 12-month follow up, occurrence of the primary endpoint was significantly lower in the IVUS-guided group compared to the angiography-guided group (2.6 percent vs. 7.1 percent; hazard ratio=0.35, 95% CI=0.13-0.97; p=0.035). Occurrence of the composite of cardiac death and myocardial infarction was also significantly lower in the IVUS-guided group vs. the angiography-guided group (p=0.045). IVUS guidance led to more aggressive balloon inflations during PCI. At follow-up, TVR was non-significantly lower in the IVUS-guided group compared with the angiography-guided group (2.6 percent vs. 5.2 percent; hazard ratio=0.48, 95% CI=0.17-1.42; p=0.186).

Cross-over rates were 2.5 percent from IVUS-guided to the angiography-guided group, and 17.4 percent from angiography-guided to the IVUS-guided group (p

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