

## Results from the ULTIMATE trial reported

## September 24 2018

September 24, 2018—The first study designed to determine the benefits of intravascular ultrasound (IVUS) guidance over angiography guidance during drug-eluting stent (DES) implantation in all-comer patients found that IVUS improved clinical outcomes by lowering the rate of target vessel failure at one year.

Findings from the ULTIMATE trial were reported today at the 30th 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 the *Journal of the American College of Cardiology* (*JACC*).

IVUS is an intravascular imaging modality that provides detailed anatomic information about reference vessel dimensions and lesion characteristics, including severity of diameter stenosis, lesion length, and morphology (vulnerable plaque), which is less well-detected by coronary angiography. Whether the routine use of IVUS is associated with improved outcomes in all-comer patients is not known.

From August 2014 to May 2017, a total of 1,448 all-comer patients from eight centers in China who were undergoing DES implantation were randomly assigned (1:1) to either IVUS guidance (n=724) or angiography guidance (n=724). Multi-vessel disease was seen in 54.9% of patients. Mean lesion length was 34.5 mm, and 66.9% of lesions were classified as Type B2/C lesions. IVUS-guided procedures were longer in



duration, and on a per-lesion basis used slightly greater stent diameters and stent lengths.

The primary endpoint was target vessel failure (TVF) at 12 months, defined as the composite of cardiac death, target vessel myocardial infarction (TVMI), and clinically driven target vessel revascularization (TVR). At 30-day follow up, primary and secondary endpoints were comparable between the two groups.

One year after PCI, a total of 60 (4.2%) TVFs occurred, with 21 (2.9%) in the IVUS group and 39 (5.4%) in the angiography group (HR 0.530; 95% CI: 0.312-0.901; p=0.019). In lesion-level analyses, the IVUS group had a lower rate of target lesion revascularization (TLR) compared with the angiography group (0.9% vs. 2.3%, p=0.02). Despite the use of IVUS, 53% of patients met prespecified optimal criteria for stent implantation; in this group, TVF was 1.6%, compared with 4.4% in patients who failed to achieve all optimal IVUS criteria (HR 0.349; 95% CI: 0.135-0.898; p=0.029).

"The study demonstrated that IVUS-guided stent implantation significantly improved <u>clinical outcomes</u> in all-comers, particularly for patients who had an IVUS-defined optimal procedure, compared to <u>angiography</u> guidance," said Junjie Zhang, MD, Vice Director of the Cardiovascular Department at Nanjing First Hospital in Nanjing Medical University (Nanjing, China). "While previous studies and this trial have demonstrated the overall favorable effect of IVUS <u>guidance</u> for <u>patients</u> with particular lesion subsets, this study further reports that achievement of IVUS-defined optimal PCI improves clinical outcomes for all-comers."

Provided by Cardiovascular Research Foundation



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