Results from COMBINE (OCT-FFR) reported at TCT Connect

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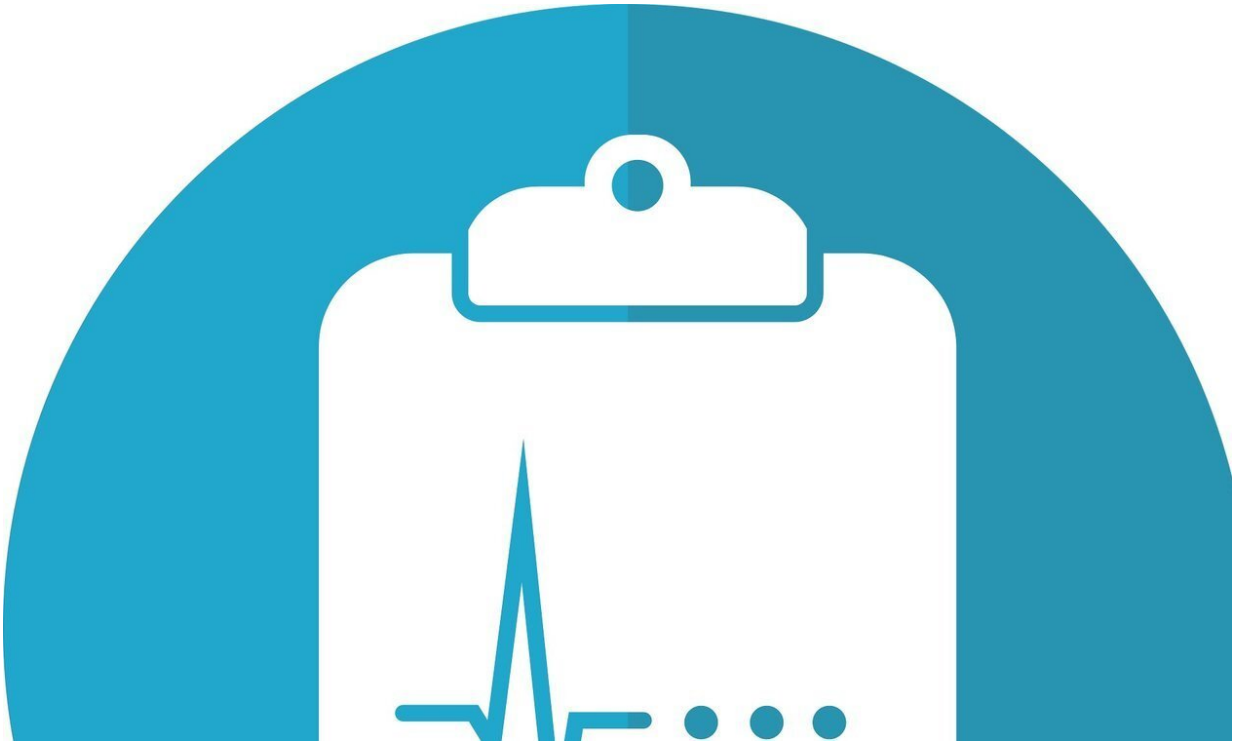

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Data from COMBINE (OCT-FFR) found that the use of FFR combined with OCT imaging can help improve the accuracy of high-risk lesion identification in patients with diabetes.

Findings were reported today at TCT Connect, the 32nd annual scientific

symposium of the Cardiovascular Research Foundation (CRF). TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

Fractional flow reserve (FFR) is widely used to guide the revascularization strategy in the catheterization lab. The FAME I and FAME II trials have shown that stable ischemic heart disease lesions with FFR >0.80 can be safely treated medically, while PCI of lesions with FFR0.80 can have worse outcomes than in patients without DM or ACS, most likely due to plaque instability or rapid progression of atherosclerotic plaque.

Previous studies have shown that lipid-rich plaques with a thin cap fibroatheroma (TCFA) have unfavorable clinical outcomes compared to non-TCFA lesions particularly in DM patients. Optical coherence tomography (OCT) can accurately identify lipid-rich and TCFA lesions. Whether OCT can identify lesions with future unfavorable clinical events despite lack of ischemia has not been studied previously.

The COMBINE (OCT-FFR) trial was a prospective international, natural history study. Patients with DM and with stable or acute coronary syndromes who had one or more non-culprit target lesion(s), with a 40-80% diameter stenosis, underwent FFR assessment. FFR-negative patients underwent OCT assessment and were further medically treated. Depending on the presence or absence of TCFA, patients were divided in two groups: TCFA negative (group A) and TCFA positive (group B). Patients with target lesions with FFR0.80 and TCFA patients (Group B) compared with medically treated patients with FFR>0.80 and no-TCFA (Group A). The secondary endpoint was the incidence of MACE between patients with FFR>0.80 and TCFA (Group B) vs. revascularized lesions that had FFR