TCT-50

Peri-strut Low Intensity Area Assessed By Mid-term Follow-up Optical Coherence Tomography May Predict Target Lesion Revascularization After Stent Implantation

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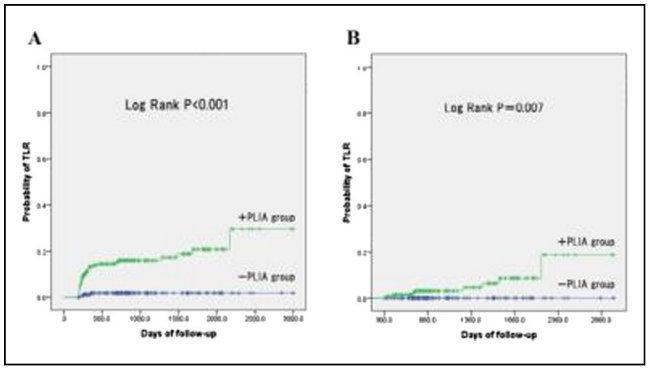
BACKGROUND According to recent studies, the presence of peri-strut low intensity area (PLIA) detected by optical coherence tomography (OCT) has been described as a potential marker of abnormal neointimal healing such as continuous inflammation, fibrin deposition, and extracellular matrix accumulation. However, the impact of PLIA presence on clinical events and its risk factors remain unknown.

METHODS From the Kobe University OCT registry, we enrolled a total of 382 lesions treated with coronary stents (BMS: n=23, 1st generation DES: n=186, 2nd generation DES: n=249) from 289 patients that underwent mid-term follow-up OCT 6-12 months after stent implantation. In addition to standard OCT parameters, PLIA was evaluated with the definition of homogenous low-intensity area around a stent strut without significant signal attenuation behind the area. Clinical follow-up was performed to evaluate target lesion revascularization (TLR) for a median duration of 2.7±1.9 years after stenting.

RESULTS PLIA was identified in 205 lesions (54%) on the follow-up OCT (PLIA+ group). The remaining 177 lesions did not exhibit PLIA (PLIA- group). The incidence of smoking habit, unstable angina pectoris or acute myocardial infarction, BMS and paclitaxel eluting stents use was significantly higher in the PLIA+ group. Also, the rate of dyslipidemia and dual antiplatelet therapy at the timing of follow-up OCT was significantly lower in the PLIA+ group than PLIA- group. In multivariate logistic analysis, smoking habit, BMS and paclitaxel eluting stents use were independently associated with the presence of PLIA (odds ratio [OR]: 1.64, P=0.026, OR: 25.77, P= 0.002, OR: 5.10, P<0.001 respectively). Moreover, patients with PLIA had a higher incidence of TLR during the clinical follow-up (PLIA+: 16.6% vs. PLIA-: 1.7%, P<0.01 Figure A). Multivariate logistic regression analysis showed that , in addition to statin use, the presence of PLIA was an independent risk factor for TLR (OR: 7.36, P = 0.001). A landmark analysis at one year after stent implantation showed that the presence of PLIA was associated with higher incidence of late TLR (TLR>1year) after stenting (Figure B).



CONCLUSIONS The presence of PLIA on mid-term OCT imaging was associated with TLR after stent implantation. Detailed stent assessment by mid-term follow-up OCT may help predict future stent failure in patients with coronary artery disease.

CATEGORIES IMAGING: Intravascular

KEYWORDS Coronary artery disease, Optical coherence tomography, Target lesion revascularization

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TCT-51

The Tendyne Transcatheter Mitral Valve Implantation (TMVI) Global Feasibility Trial

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BACKGROUND Severe mitral regurgitation (MR) is the most prevalent valve disorder. It is associated with a high morbidity and need for hospitalization, and a 5yr mortality >50%. Options for management in the high surgical risk population are limited. Transcatheter mitral valve implantation (TMVI) is a promising alternative to conventional surgery in high-risk patients. The Global Feasibility Trial aims to evaluate the Tendyne TMVI prosthesis in a population of patients with severe mitral regurgitation at high risk for surgical repair.

METHODS The trial is a prospective, non-randomised, open-label study designed to evaluate the safety and efficacy of a novel mitral valve prosthesis implanted via an intercostal, trans-apical route. The device consists of a D-shaped outer frame, a circular inner frame and a symmetrical porcine pericardial trileaflet valve that is deployed within the mitral annulus and tethered to the apex of the left ventricle. The valve can be fully recaptured, repositioned, and if necessary, fully retrieved. Up to 30 patients with severe, symptomatic MR who are considered poor candidates for surgical valve repair will be included in the Feasibility Trial. Patients are considered ineligible for the trial if they have LVEF<30%, LVEDD >7.0cm, prior mitral or aortic valve surgery, severe coronary disease, heart failure requiring inotropic support, severe tricuspid valve regurgitation or severe RV dysfunction. Anatomic suitability is evaluated by transthoracic and transesophageal echo, and full cycle CT angiography. The primary efficacy endpoint for the trial is MR grade<2 at 90days. The primary safety endpoint is a composite of freedom from cardiovascular death, stroke, myocardial infarction, or surgical intervention for valve-related dysfunction.

RESULTS To date, 6 patients (5M, 1F; age 75.8±3.4yrs) have been treated at two study sites. All patients had severe (4+) MR (5 secondary, 1 primary MR), and all were symptomatic (3pts NYHA class III, 3pts NYHA class IV). The LVEF was 40.8±11.0% (range 30-61%) and the mean STS score was 8 (range 2-16). In 5 patients, the device was successfully deployed with no residual MR, no paravalvular leak, MV gradient 2.2±0.7mmHg, and no adverse events. In one pt, deployment of the device resulted in a significant LV outflow gradient and hypotension. The device was removed without adverse sequelae. Each pt was discharged home between post-operative day 5 and day 7. All remain alive. The 5 with successful implants are all in NYHA class I or II.

CONCLUSIONS The preliminary results from this Feasibility Trial suggest that the Tendyne device can be used to effectively treat MR with a low peri-procedural complication rate in a high-risk population. 30day outcomes for pts enrolled in the trial will be presented.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

KEYWORDS Heart failure, Mitral regurgitation, severe, Mitral valve replacement