BACKGROUND While second generation drug-eluting stents (DES) promote more favorable vascular healing, biodegradable polymer containing stents might have a yield in terms of duration of dual antiplatelet therapy (DAPT) than durable polymer stents. We aimed to test whether 6-month DAPT would be non-inferior to 12-month clinical and angiographic outcome to 12-month DAPT with second generation DES, such as biolimus-eluting stent (BES) and Zotarolimus-eluting stent (ZES).

METHODS We compare clinical events and angiographic data between 6- and 12-month DAPT, and between BES and ZES stents. Finally, 1,368 patients were randomly assigned. Optical coherence tomography (OCT) at 6 month was performed in 30 patients of each DES group. The primary end point was major adverse cardiac event (MACE) at 12 months. The secondary end points are target vessel failure, in-segment late loss (LL) at 12 months, and neointimal hyperplasia (NIH) and uncovered stent strut (USS) by OCT at 6 month.

RESULTS n = 72 patients. The primary endpoint was not statistically different between the 6- and 12-month DAPT (MACE: 3.5 vs. 2.5%, p = 0.33), between BES and ZES (MACE: 3.0 vs. 3.0%; p = 1.00). The secondary end points also were not significantly different between the 6- and 12-month DAPT in target vessel failure (1.3 vs. 0.6%, p = 0.25), LL (0.30 ± 0.29 vs. 0.31 ± 0.28, p = 0.61). Similar results showed between BES and ZES in target vessel failure (0.8 vs. 1.1%, p = 0.58), LL (0.56 mm) at 12 months (0.32 ± 0.29 vs. 0.31 ± 0.27, p = 0.61). OCT at 6 month revealed that mean NIH thickness (μm) of BES and ZES were 81.6 ± 57.1, 61.9 ± 39.6, respectively (p = 0.13), and USS percentage (%) of BES and ZES were quite few, as 2.4 ± 5.3, 3.0 ± 5.2, respectively (p = 0.64).

CONCLUSION We suggest that 6 month DAPT might be suggestively safe after 2nd generation DES implantation based on clinical, angiographic, and favorable result of 6 month OCT sub-study.

LATE BREAKING CLINICAL TRIALS

ANTIPATELET AGENTS AND ANTICOAGULANTS (TCTAP A-001)

TCTAP A-001 Outcomes of 6 Months Versus 12 Months Dual Antiplatelet Therapy After Implantation of Biodegradable Polymer Biolimus or Durable Polymer Zotarolimus-eluting Stents: OPTIMTAP A-C Study and Optical Coherence Tomography Sub-study

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BACKGROUND Safety and efficiency of Absorb has been demonstrated in these 450 patients through 2 years after their PCI procedure. The 3-year clinical outcomes will provide the longest term data in the largest single-trial cohort reported to date.

INVASIVE CORONARY IMAGING: IVUS, OCT, SPECTROSCOPY, AND OTHER (TCTAP A-003)

TCTAP A-003 Automated Lipid-rich Plaque Detection with a Novel Optical Coherence Tomography System
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BACKGROUND A large lipid core is one of characteristics of vulnerable coronary plaque. Although optical coherence tomography (OCT) is a very high resolution imaging device, OCT does not facilitate detection of a lipid plaque. The reason is that while commercially-available OCT systems use near-infrared light at 1,300 nm wavelengths, lipid shows characteristic absorption at 1,700 nm, not at 1,300 nm (Figure). Therefore, we developed OCT, short wavelength infraOCT A-red (1,700 nm), spectroscopic optical coherence tomography (SWIR-OCT, Sumitomo Electric Industries, Ltd.) to visualize lipid tissue automatically. The aim of the present study is to investigate the accuracy of SWIR-OCT for identification of lipid tissue within coronary plaques.

METHODS Twenty-nine coronary arteries from 10 cadavers were examined. SWIR-OCT was measured at physiological pressure, and the images were acquired at 94 frames/s and digitally archived. SWIR-OCT generated gray-scale cross sectional images and color tissue maps of a plaque by calculating the obtained spectrum with an original lipid analysis algorithm. After SWIR-OCT imaging, the arteries were pressure-fixed, sliced by a cryostat and stained with H&E and Oil Red O, and then corresponding histology was collected in matched images. Regions of interest, selected from histology, were 108 lipidic and 16 non-lipidic regions. Lipid-enhanced images generated by SWIR-OCT were validated by comparison with histology via selected regions.

RESULTS SWIR-OCT showed high sensitivity (90%) and specificity (94%) for identifying lipid tissue within coronary plaques. The positive predictive value and negative predictive value were 99% and 58%, respectively.

CONCLUSION SWIR-OCT has improved the ability to detect lipid tissue in coronary autopsy specimens compared with conventional OCT. This new technique may hold promise for identifying histopathological feature of coronary plaques at risk for rupture.

LATE BREAKING CLINICAL TRIALS

DRUG-ELUTING STENTS (TCTAP A-002)

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BACKGROUND The safety and performance of the Absorb Biodesorbable Vascular Scaffold (Absorb) (Abbott Vascular, Santa Clara, CA) have been demonstrated in the ABSORB Cohort A, B, and EXTEND trials. Results from the ABSORB Cohort B trial showed 4-year MACE of 10.1%, with no scaffold thrombosis reported. ABSORB EXTEND sought to gain experience with the Absorb in a large population and in different geographies, including the AsiaTCTAP A-Pacific region.

METHODS ABSORB EXTEND is a prospective, single-arm, open-label clinical study that enrolled a total of 812 subjects from 56 global sites. Patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA or IVUS) were included. Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, and long lesions using planned scaffold overlap were permitted.

RESULTS In the first 450 patients enrolled, the mean age at implant was 62 years. Major comorbidities included previous MI (29%), unstable angina (33%), and diabetes mellitus (27%). Lesion locations were 44%, 26%, and 30% for LAD, LCX and RCA respectively. The mean RVD was 2.58 mm and mean lesion length was 11.7 mm. The lesions were 2.5%, 58.4, 34.9%, and 4.2% for Class A, B1, B2 and C respectively. At 2-year, composite endpoints of MACE, TVF, TLF of the first 450 patients were 6.7%, 7.4% and 6.5% respectively. Cumulative scaffold thrombosis (ST) was 1.1% through 2 years, of which 0.2% was very late ST events. The 3-year follow-up data in these 450 patients represents the largest Absorb cohort with long-term safety and performance ever reported from a single trial. Clinical outcomes will be presented at the time of the conference.

CONCLUSION Safety and efficacy of Absorb has been demonstrated in these 450 patients through 2 years after their PCI procedure. The 3-year clinical outcomes will provide the longest term data in the largest single-trial cohort reported to date.