TCT-521
Clinical outcomes after bioresorbable scaffold implantation in patients with a high prevalence of complex lesions: the Milan experience
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BACKGROUND Bioresorbable scaffolds (BRS) have the potential to revolutionize the treatment of coronary artery disease. To date, limited trial data have demonstrated favorable short- and longer-term clinical outcomes up to a maximum of 5 years. However, these observations have been limited to patients presenting with simple coronary lesions. Outcomes following BRS use in complex lesions have been described by a few registries but remain poorly characterized. We report the clinical outcomes of our “real-world” experience following BRS implantation in a patient cohort that includes a high prevalence of complex lesions.

METHODS A retrospective analysis of consecutive patients who underwent percutaneous coronary intervention (PCI) with BRS (ABSORB; Abbott Vascular, Santa Clara, CA) in 2 centers in Milan between May 2012 and April 2015.

RESULTS The mean age was 63.8±10.7 years. The prevalence of diabetes mellitus, chronic kidney disease, and left main coronary artery was 22.7%, 25.8%, and 2.6%, respectively. The mean target vessel was the left anterior descending artery (61.7%). The average SYNTAX score was 17.3±10.4. Meticulous lesion preparation and aggressive post-dilatation were recommended for all cases with pre- and post-dilatation performed in 99.8% and 99.7%, respectively. A scoring balloon was utilized in 14.6%. Intravascular ultrasound (IVUS) was utilized in 83.7% of patients to guide therapy. The median follow-up period was 441 days (interquartile range 150 to 503 days). The incidence of major adverse cardiac events (MACE; defined as a combination of all-cause death, follow-up myocardial infarction and target vessel revascularization) occurred in 10.1% at 1-year follow-up (calculated with Kaplan-Meier analysis). All-cause death occurred in 2 patients (non-cardiac death). The incidence of target lesion revascularization (per lesion) and vessel revascularization were 6.3% and 8.9%, respectively. Definite scaffold thrombosis occurred in 2 patients (1.2%), the first following BRS implantation for the treatment of ST-elevation MI and the second was late scaffold thrombosis in a patient that prematurely stopped clopidogrel 2 months after BRS implantation.

CONCLUSIONS Our “real-world” BRS experience that included a high prevalence of complex lesions demonstrated excellent clinical outcomes. The incidence of scaffold thrombosis was low (1.0% at 1-year). Meticulous lesion preparation with non-compliant or scoring balloons and IVUS-guided BRS implantation are likely to be important factors in optimizing outcomes and reducing clinical events.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-522
Impact of Strut Distribution on Neointimal Coverage of Everolimus-Eluting Bioresorbable Scaffolds: An Optical Coherence Tomography Study
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BACKGROUND The number and distribution of stent struts has been previously reported to affect neointimal coverage of metallic drug-eluting stents (DES), and stented areas with fewer struts and larger inter-strut angles have been associated with excess neointimal hyperplasia compared to areas with more crowded struts. Everolimus-eluting bioresorbable scaffolds (BRS) are novel coronary implants that may show better neointimal vascular scarring compared with drug delivery capability. However, the thicker struts of current generation BRS create areas of low endothelial shear stress, which may contribute to neointimal formation. The aim of the present study is to investigate the relationship between the number and distribution of BRS struts and neointimal coverage using optical coherence tomography (OCT).

METHODS This study includes 35 patients (42 lesions) treated with BRS and followed-up with coronary angiography and OCT at 12 (11.8 ± 2.6) months after the index procedure. All patients were prescribed lifelong aspirin (100 mg/day) and prasugrel (10 mg/day) for 6 months according to local institutional guidelines. Cross sectional areas (CSA) of OCT images were analyzed at 1-mm intervals. Scaffold area and neointimal thickness were evaluated. Additionally, scaffold eccentricity (SE) was defined as follows: maximum diameter (mm)/minimum diameter (mm). To assess the impact of strut distribution, CSAs of BRS were divided into four regions. The average neointimal thickness (ANT) and the number of struts in each region were measured. The number of struts in each region was classified into 1, 2, 3 and > 4. The ANT acquired in each area was divided by the ANT of all struts in the same CSA to describe an ANT unevenness score, and its maximum and minimum values were defined as maximum and minimum unevenness score.

RESULTS The mean age of the study population was 58±10 years and 23 (65%) were males. Mean scaffold diameter and length were 3.7±0.37 and 19.9±5.2 mm, respectively. Pre-dilatation was performed in almost all lesions (90%) and post-dilatation rate was 72%. There was a significant difference in the unevenness score between regions with different strut numbers (unevenness score = 1.04±0.34 in regions with 1 strut (n=401); 0.97±0.25 in regions with 2 struts (n=512); 0.96±0.25 in regions with 3 struts (n=664); and 1.04±0.20 in regions with > 4 struts (n=691); p<0.01). A positive significant correlation was observed between SE in each CSA and the dispersion (heterogeneity) of neointimal proliferation in the same CSA, which was expressed as maximum unevenness score - minimum unevenness score (n=651; R=0.10, p<0.02).

CONCLUSIONS Unlike metallic DES, not only sparse distribution of struts but also crowding of struts is associated with increased neo-intimal proliferation after BRS implantation. In addition, SE is associated with uneven neointimal proliferation. Adequate lesion preparation prior to BRS implantation is therefore recommended so that BRS can expand as evenly as possible.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Neointimal coverage, OCT

TCT-523
Percutaneous Coronary Intervention For Chronic Total Coronary Artery Occlusion With The Implantation Of Bioresorbable Everolimus-Eluting Scaffolds: Poznan CTO-Absorb Pilot Registry
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BACKGROUND The data concerning the use of bioresorbable vascular scaffolds (BVS) for coronary chronic total occlusion lesions (CTO) are limited. The aim of the study was to evaluate the early and long-term clinical outcomes of CTO stenting with BVS.

METHODS The study is a prospective, nonrandomized clinical pilot registry of patients with CTO lesion located in a major coronary artery, treated with everolimus-eluting scaffolds. Patients were eligible if they had symptoms and/or documented reversible myocardial ischemia, with the presence of viable myocardium in territory supplied by the occluded vessel, assessed by cardiac magnetic resonance imaging (CMRI). Patients with reference vessel diameter above 4 mm, metallic stents in the target vessel, excessive calcium and tortuosity were excluded. Subjects were followed after 1 month by CMRI and 6 months, then by CMRI every 3 months. To assess the impact of strut distribution, CSAs of BRS were divided into four regions. The average neointimal thickness (ANT) and the number of struts in each region were measured. The number of struts in each region was classified into 1, 2, 3 and > 4. The ANT acquired in each area was divided by the ANT of all struts in the same CSA to describe an ANT unevenness score, and its maximum and minimum values were defined as maximum and minimum unevenness score.

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