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, hypertension, chronic kidney disease, and current smoking were 25.8%, 57.9%, 12.0%, and 30.7%, respectively. The median number of diseased vessels was 3 (interquartile range 2 to 3). The incidence of target lesion revascularization (per lesion) was 1.04 ± 0.34 in regions with 1 stent (n = 401); 0.97 ± 0.25 in regions with 2 stents (n = 512); 0.90 ± 0.25 in regions with 3 stents (n = 664); and 1.04 ± 0.20 in regions with ≥4 stents (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 = 661, 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 neointimal 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

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 coverage of metal and vascular scaffolds combined 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) and prasugrel (60 mg) for at least 3 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 (maximal strut diameter/minimum strut diameter). 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 the area 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 3.71 ± 0.37 and 19.9 ± 5.2 mm, respectively. Pre-dilation was performed in almost all lesions (90%) and post-dilation 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 stent (n = 401); 0.97 ± 0.25 in regions with 2 stents (n = 512); 0.90 ± 0.25 in regions with 3 stents (n = 664); and 1.04 ± 0.20 in regions with ≥4 stents (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 = 661, 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 neointimal 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 enrolled after DAPT completion, with lifelong on aspirin alone. Clopidogrel was used until March 2014, when it was replaced with degarelor for at least three months post procedure.
RESULTS: Forty consecutive patients (male 78%, mean age 59.9 ± 8.3, diabetics 30%) with CTO treated with BVS were enrolled. A total of 63 BVS were implanted with the average number of 1.6 per patient, and the scaffold length of 42.4 ± 21.5 mm. Mean J-CTO score was 1.6. Antegrade approach was used in 38 patients (95%), and retrograde, after failed antegrade, in the remaining two (5%). High pressure post-dilatation was performed in 38 patients. Procedural success was achieved in all patients with no device-related complications. IVUS was used in two, whereas OCT in ten patients. On QCA the mean in-scaffold final MLD was 2.13 ± 0.31 mm and residual stenosis 13.90 ± 7.59%. In OCT analysis, performed in 10 patients, the minimal in-scaffold luminal diameter was 2.65 ± 0.45 mm, minimal luminal area 6.15 ± 0.20 mm2, and lumen area stenosis 17.7 ± 11.1%. At follow-up (median time 434 days), there were no deaths, one patient experienced subacute and late scaffold thrombosis (ST), another one developed symptomatic in-scaffold focal restenosis treated with repeat PCI. At control angiography, performed at the median time of 264 days in 23 patients (58%), the mean in-scaffold diameter stenosis was 22.42 ± 12.74, and the mean late lumen loss was 0.24 ± 0.55 mm. No more restenosis or vessel reocclusion was found.

CONCLUSIONS: Stenting of coronary CTO lesions with bioresorbable everolimus-eluting scaffolds is feasible with excellent acute performance and good early and long-term clinical outcomes. Adequate stenting technique and optimal DAPT is of crucial importance. The results of our study represent a major step forward towards more complete implementation of BVS to coronary interventions.

CATEGORIES: Coronary: Bioresorbable Vascular Scaffolds

KEYWORDS: Bioabsorbable scaffolds, Drug-eluting stent, everolimus

TCT-524

Should Bioresorbable Scaffold Stents be Considered Non-inferior to Drug Eluting Stents for Treatment of Ischemic Coronary Artery Disease?: A Meta-analysis of RCTs

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BACKGROUND: The bioresorbable vascular scaffold (BVS) is a new therapy that provides transient vessel support with drug delivery capability, potentially without the limitations of permanent metallic implants. It can be an alternative option to currently used drug eluting stents (DES) for percutaneous coronary intervention (PCI) of ischemic coronary artery disease (CAD). We aimed to compare the non-inferiority of BVS use to DES.

METHODS: We searched Pub Med and Cochrane through June 2015 for all randomized clinical trials (RCTs) that directly compared BVS and DES for ischemic CAD. Primary outcome was target vessel revascularization (TVR). Secondary outcomes included cardiac death, acute myocardial infarction, and definite or probable stent thrombosis (ST). We used Fixed or Random Effect analysis using the Cochrane Handbook of Systematic Reviews and RevMan 5.2 for statistical analysis.

RESULTS: Out of 257 articles, four randomized trial studies were included. The pooled data provided 3873 patients; 2024 treated with BVS and 1849 with Everolimus drug-eluting stent. Mean follow-up was 12 months. There was a trend towards lower TVR in BVS group compared to Everolimus group (2.7% vs. 4.5%, p = 0.1) (Figure 1). There was no difference in cardiac death (0.7% vs. 0.7%, p = 0.8), AMI (3.4% vs. 3.4%, p = 0.9) and ST (0.6% vs. 0.7%, p = 0.9) between the two groups (Figure 2).

CONCLUSIONS: Our analysis showed similar outcomes between two treatment modalities. This suggests that BVS might not be inferior to DES for PCI of ischemic CAD. Further randomized trials should be pursued to confirm those findings.

CATEGORIES: Coronary: Bioresorbable Vascular Scaffolds

KEYWORDS: Bioabsorbable scaffolds, Drug-eluting stent, everolimus

TCT-525

Clinical outcomes following percutaneous coronary intervention using small bioresorbable scaffolds

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BACKGROUND: Bioresorbable scaffolds (BRS) are an attractive option for the percutaneous treatment of coronary artery disease due to the potential advantages associated with its complete absorption within 3-4 years of implantation. However, due the current design of BRS with thicker struts compared to contemporary metallic stents, some concern remains that this property may be associated with adverse events including thrombosis and restenosis when using small BRS.

METHODS: Among 350 consecutive lesions treated with Absorb BRS during May 2012 - Apr 2015 at 2 high volume centers in Milan, 116 lesions were treated using 2.5 mm BRS (small BRS group) and 234 lesions were treated with BRS ≥2.5 mm BRS (large BRS group). Outcomes including target lesion revascularization (TLR) per lesion and definite stent thrombosis were investigated.

RESULTS: The number of BRS was higher and the total BRS length was longer in the small BRS group when compared to the large BRS group (1.7 ± 0.8 vs 1.4 ± 0.6; p < 0.001, and 42.3 ± 22.6 mm vs 30.7 ± 15.0 mm; p < 0.001, respectively). As expected, the post procedural minimum lumen diameter was significantly smaller in the small BRS group (2.36 ± 0.43mm vs 2.82 ± 0.44mm; p < 0.001). TLR- free rate (median