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, Chronic total occlusion

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

Daniel C. Garcia,1 Mohammad M. Ansari,2 Rhanderson N. Cardoso,3 Carlos Alfonso7

1Ochsner Clinic Foundation, New Orleans, LA; 2University of Miami-Jackson Memorial Hospital, New York, NY; 3University of Miami/Jackson Memorial Hospital, Miami, FL; 4University of Miami, Miller School of Medicine, Miami, FL

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

Akihito Tanaka,1 Azeem Latib,1 Neil Ruparelia,1 Hiroyoshi Kawamoto,1 Francesco Giannini,1 Alessandro Sticchi,1 Mauro Carlino,1 Alaide Gheiffio,1 Matteo Montorfano,2 Antonio Colombo2

1San Raffaele Scientific Institute, Milan, Italy
2University of Milan, Italy

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 ± 15.0mm; 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
follow-up; 44 days, interquartile range-150-503 days) did not differ between the two groups (p<0.59). One-year TLR free rate was 95.7 ± 2.1% in the small BRS group and 92.5 ± 2.1% in the large BRS group. There were no differences between groups with regards to definite stent thrombosis with was 1 late thrombosis in the small BRS group and 1 acute thrombosis in the large BRS group.

CONCLUSIONS Percutaneous coronary intervention using small BRS was associated with comparable outcomes when compared to larger BRS with no observed increase in adverse events.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds
KEYWORDS Bioresorbable scaffold, Small coronary vessels, Target lesion revascularization

TCT-526
An in-vivo multi-modality imaging study of the Absorb everolimus-eluting bioresorbable scaffold in complex coronary bifurcations
Johan Bennett,1 Nina Vanden Driessche,2 Maarten Vanhaverbeke,3 Walter Desmet,4 P. Sinnaeve,5 Tom Adriaensen,6 Christophe Dubois7 UZ Leuven, Leuven, Belgium; 2Catholic University of Leuven, Leuven, Belgium; 3Catholic University of Leuven, Leuven, Belgium; 4Catholic University of Leuven, Leuven, Belgium; 5Catholic University of Leuven, Leuven, Belgium; 6Catholic University of Leuven, Leuven, Belgium; 7University Hospital Leuven, Leuven, Belgium

BACKGROUND This in-vivo study sought to provide insights regarding the feasibility and safety of performing complex bifurcation techniques with the Absorb everolimus-eluting bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA). Inclusion criteria were patients presenting with NSTEMI, stable, unstable angina, or silent ischemia caused by a de novo stenotic lesion in a native previous untreated coronary artery. Lesions with a Dmax (proximal and distal mean lumen diameter) within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online QCA were obligatory. Exclusion criteria were patients with a history of CABG, presentation with cardiogenic shock, bifurcation lesions requiring kissing balloon post-dilatation, STEMI patients requiring immediate stent implantation, allergies or contra-indications to antipatele therapy, female patient with bearing potential not taking adequate contraceptives or currently breast-feeding, expected survival of less than one year. Procedural outcomes and clinical outcomes were assessed.

RESULTS From September 2012 to January 2015, 250 patients with 335 lesions were enrolled in this study. A total of 445 BVS were placed in 271 lesions. The number of implanted scaffolds was 1.37. Pre-dilation was performed in 89.8%. Predilation balloon; artery ratio was 1.05±0.23. Post-dilation was performed in 54.3%. In 14.5% baseline imaging using IVUS was used; OCT in 24.9%. Bifurcation was present in 21.4%, calcification in 42.2% and total occlusions in 4.2%. In 38.0% there were AHA classification type B2/ C lesions. Mean lesion length was 22.10±13.90 mm. Pre-procedural reference vessel diameter (RVD) was 2.42±0.74mm, minimal lumen diameter (MLD) 0.91±0.45mm and percentage diameter stenosis (%DS) 59.13±7.02. Pre-procedural QCA characteristics were as followed: RVD 2.77±0.46 mm, MLD 2.30±0.42 mm and %DS 16.90±4.04. Median follow-up period was 559 days (interquartile range [IQR], 371-733 days). Up to 12 months three patients died (all cardiac death) with a Kaplan Meier estimate of 1.4% at one year. Rate of all myocardial infarction (MI) was 4.1%, definite scaffold thrombosis (ST) 1.4%, target lesion revascularization (TLR) and target vessel revascularization (TVR) were 3.7%. Non-target vessel revascularization (non-TVR) was 3.8%. Major cardiac adverse events (MACE, a composite endpoint of cardiac death, TLR and all MI) at one year was 5.5%.

CONCLUSIONS Long-term results in a mixed group of patients imply that BVS usage is associated with favorable clinical outcomes.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds
KEYWORDS Bioabsorbable scaffolds, Coronary artery disease, PCI - Percutaneous Coronary Intervention

TCT-528
Bioabsorbable Vascular Scaffold Overexpansion: Insights from in-vitro post-expansion experiments
Nicolas Foin,1 Renick D. Lee,1 Alessio Mattesini,2 Jing Ni Chan,3 Yingying Huang,4 Gianluca Caiazzo,5 Enrico Fabris,6 Ismail D. Kilic,7 Subbu S. Venkatraman,8 Carlo Di Mario,9 Philip Wong,9 Holger Nef10 National Heart Centre Singapore, Singapore, Singapore; 2Careggi Hospital, Florence, Italy; 3Nanyang Technological University, Singapore, Singapore; 4Nanyang Technological University, Singapore, Singapore; 5S. Giuseppe Moscati Hospital, Naples, Italy; 6BRU, Royal Brompton NHS Trust, London, United Kingdom; 7Royal Brompton NHS Trust, London, United Kingdom; 8Imperial College London, London, United Kingdom; 9Justus-Liebig University of Giessen, Giessen, Germany

BACKGROUND While Bioresorbable Vascular Scaffolds (BVS) are increasingly used in clinical practice, behavior when post-dilated beyond their recommended maximum over-expansion diameter remains sparsely documented.

METHODS We examined the post-expansion behavior of the Bioresorbable Vascular Scaffold (3.0mm and 3.5mm Absorb BVS; Abbott Vascular, Santa Clara, CA) after over-expansion with Non-Compliant (NC) balloons of increasing diameters. After each oversizing step, the scaffolds were measured and inspected for strut disruption using...