BIORESORBABLE VASCULAR SCAFFOLDS

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TCT-397

Effect of post-dilatation on device expansion and arterial healing following Everolimus-eluting bioresorbable stent (Absorb BVS) versus durable polymer everolimus-eluting metallic stent (EES) implantation in STEMI patients: substudy of ABSORB STEMI TROFI II

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BACKGROUND Post-dilatation (PD) of Absorb BVS has been proposed to improve post-procedural angiographic and subsequent device related clinical outcomes. Whether this recommendation is also applicable among patients undergoing BVS implantation in the setting of primary PCI (PPCI) remains unknown.

METHODS In the ABSORB STEMI TROFI II trial, 191 patients with STEMI undergoing PPCI were randomly assigned to treatment with Absorb BVS (N=95) or EES (N=96). Post-procedural minimal lumen diameter (MLD) as assessed by QCA and minimal intra-scaffold lumen area and healing score as assessed by OCT at 6 months were compared between Absorb BVS- and EES-treated patients stratified according to PD status.

RESULTS PD was performed in 47 (50%) of Absorb BVS- and in 25 (26%) EES- treated patients. There were no difference in clinical characteristics including age, diabetic status, culprit vessel localization and pre-PPCI TIMI flow between Absorb BVS and EES or according to PD status. Similarly, no difference in terms of angiographic lesion length and pre-procedural MLD was noted. Direct stent implantation was less frequent in patients with PD (Absorb BVS: 25% vs 64%, P<0.001; EES 28% vs 56%, P=0.02). Post-procedural in-stent MLD was similar among patients with vs without PD (Absorb BVS: 2.44±0.33mm vs 2.48±0.33mm, p=0.54; EES: 2.46±0.50mm vs 2.47±0.37mm, P=0.93). OCT follow-up at 6 months was available in 84 Absorb BVS- (PD: N=41) and 86 EES-treated patients (PD: N=23). No difference in minimal in-stent lumen area and healing score was observed in patients with versus without PD at 6 months (Absorb BVS: 5.07±1.68mm2 vs 5.72±1.77mm2, p=0.09 and 1.55±2.61 vs 1.92±2.17, p=0.48; EES: 5.46±2.18mm2 vs 5.55±1.77mm2, p=0.85 and 2.50±3.33 vs 2.90±4.80, p=0.72).

CONCLUSION Post-dilatation was not associated with improved device expansion or arterial healing parameters following primary PCI with either Absorb BVS or EES in ABSORB STEMI TROFI II.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT-398

Impact of scaffold oversizing, underexpansion and postdilatation on acute angiographic and one year clinical outcomes in patients with ACS treated with bioresorbable vascular scaffolds. A pooled analysis from BVS STEMI First and BVS EXPAND studies

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BACKGROUND Implantation of bioresorbable vascular scaffold (BVS) in acute coronary syndromes (ACS), with the presence of vasoconstriction and thrombotic material, might be associated with device undersizing and malapposition after thrombus dissolution. On the other hand, the implantation of oversized BVS has been reported to increase the risk of acute and late adverse events. The study aims to assess the impact of scaffold oversizing, underexpansion and postdilatation on acute angiographic and one year clinical outcomes in patients with ACS treated with bioresorbable devices.

METHODS Patient data were pooled from the BVS STEMI First and BVS Expand studies. Scaffold oversizing was defined as scaffold-to-vessel diameter ratio >1.2. Scaffold underexpansion was evaluated analyzing final MLD, %scaled residual diameter stenosis (%scDS), maximal footprint (MFP). Procedural characteristics and one-year clinical outcomes were reported.

RESULTS A total of 285 ACS patients treated with BVS implantation were evaluated. Scaffold oversizing was present in 159 patients (185 lesions). In the oversizing group was observed a higher rate of underexpansion in terms of final MLD (2.2±0.4 vs 2.5±0.4, p=0.0001), %scDS (28.1%±9.7 vs 21.1% ±11.3, p=0.0001) and MFP (37.4%±7.0 vs 33.6%±6.0, p=0.0001) as compared to non-oversizing group (126 patients, 151 lesions). In the oversizing group a higher relative gain (0.7±0.3 vs 0.6±0.2, p=0.003) was observed indicating stronger vessel wall stretching. Scaffold oversizing was associated with a higher rate of MACE (8.2% vs. 1.6%, p=0.013), myocardial infarction (6.9% vs. 1.6%, p=0.032), target lesion revascularization (5.0% vs. 0.8%, p=0.044) and target lesion failure (6.9% vs. 0.8%, p=0.011) at one-year follow-up. On the contrary, there was no impact of postdilatation on the clinical outcomes in this population.

CONCLUSION Oversized scaffold implantation in patients with ACS is often associated with both increased vessel injury and underexpansion as expressed by scaled residual diameter stenosis, scaffold maximal footprint and minimal lumen diameter and could be related to a higher rate of adverse clinical events at one year.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-399

Impact of post-dilatation on angiographic and clinical outcomes of patients undergoing bioresorbable scaffold implantation in clinical practice

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BACKGROUND Post-dilatation may improve stent deployment after bioresorbable scaffold (BRS) implantation but its impact on clinical outcomes is poorly defined. We aimed to evaluate angiographic and clinical outcomes after BRS implantation in patients with and without post-dilatation.

METHODS Consecutive patients treated with BRS during routine practice at 2 centers in Munich, Germany were enrolled. Patients were classified according to whether or not they underwent post-dilatation after scaffold implantation. Angiographic surveillance was scheduled at 6-8 months and clinical follow-up was performed up to 24 months. The main angiographic parameter of interest was in-stent late lumen loss. The primary clinical endpoints of interest were the composite of death/myocardial infarction/target lesion revascularization, target lesion revascularization and definite scaffold thrombosis.

RESULTS A total of 292 patients who underwent post-dilatation were compared with 127 patients without post-dilatation. Baseline patient characteristics were comparable in both groups. Baseline angiography showed a higher proportion of B2/C lesions (51.7 vs. 42.0%; p=0.04), a larger reference vessel diameter (2.94 vs. 2.79mm; p=0.003), and a larger minimal lumen diameter (0.96 vs. 0.78mm; p<0.001) in patients undergoing post-dilatation. After BRS implantation minimal lumen diameter was larger in the post-dilatation group

(2.62 vs. 2.52mm; p=0.009). At angiographic surveillance, in-stent late lumen loss was higher in the post-dilatation group (0.28 vs. 0.20mm, p=0.02) though in-segment minimal lumen diameter did not differ significantly (2.34 vs. 2.33mm; p=0.53). After 2 years, the rate of the composite endpoint (25.0 vs. 16.1 %, p=0.83), target lesion revascularization (18.7% vs. 11.6%, p=0.17) and scaffold thrombosis (4.3 vs. 3.2%, p=0.92) was comparable in both groups.

CONCLUSION Post-dilatation after implantation of BRS was more often performed in complex lesions and resulted in greater minimal diameter post procedure. However, overall clinical outcomes at 2 years were comparable in patients with and without post-dilatation after stenting with BRS.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-400

The importance of implantation technique in ensuring optimal outcomes after bioresorbable scaffold implantation: implications from a real-world cohort

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BACKGROUND Bioresorbabale scaffold (BRS) are increasingly being used for the treatment of coronary artery disease due to the potential advantages. However, it has become clearly apparent that current BRS requires specific implantation techniques. The objective of this study was to investigate outcomes following BRS implantation using a dedicated implantation strategy.

METHODS 447 consecutive lesions (291 patients) treated with Absorb BRS between May 2012 and December 2015 were analyzed. The primary endpoint was target lesion failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction (MI), and target lesion revascularization (TLR). Other endpoints including scaffold thrombosis (ST) were also investigated.

RESULTS The majority of target lesions (76.0%) were type B2 or C lesions. Pre-dilation (97.1%) and post-dilation (99.8%) were performed in almost all cases. The mean post-dilation pressure was 21±4 atm, and the total scaffold length per patient was 54.3±33.7mm. Intravascular imaging was performed in the majority of cases (85.9%), and a further intervention was required in 23.9% of lesions when utilized after post-dilatation. The median patient follow-up was 554 days (interquartile range 360-856 days). The cumulative TLF rates were 8.2% at 1 year and 12.7% at 2 years. The rates of cardiac death were 1.1% at 1 year and 1.7% at 2 years, target vessel MI 1.9% at 1 year and 2.4% at 2-years, and TLR 7.1% at 1 year and 11.7% at 2 years. Definite or probable ST occurred in 4 patients (1.4% at 1- and 2-years).

CONCLUSION Clinical outcomes following current BRS implantation are acceptable in a real-world population with high prevalence of complex lesions. These results are most likely achieved by utilizing a consistent implantation and optimization strategy. It is imperative that we acknowledge that in comparison to metallic DES, current generation BRS are less forgiving to suboptimal implantation and requires a dedicated strategy to ensure good clinical outcomes.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-401

Bioresorbable Scaffolds And Thrombosis: Insights From The GHOST-EU (Gauging coronary Healing with biOresorbable Scaffolding plaTforms in Europe) Registry

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BACKGROUND Potential advantages of bioresorbable scaffolds (BRS) include restoration of vasomotor function, endothelial function, and positive remodelling following their complete resorption. Whilst safety and efficacy have been demonstrated in early pivotal studies, there are concerns that BRS are associated with an increased risk of scaffold thrombosis (ST). We aim to identify associations and predictors of ST following BRS implantation in a 'real world' clinical patient population.

METHODS The GHOST-EU registry was an 'all-comer' registry and included patients with both 'simple' and 'complex' lesions. All patients underwent single- or multi-vessel percutaneous coronary intervention for both stable and acute coronary syndromes with the current generation everolimus-eluting BRS device (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) between November 2011 and September 2014. ST was defined according to the definitions proposed by the Academic Research Consortium.

RESULTS 1,477 patients (1,736 lesions) were included. 52.8% of patients were treated for stable angina or silent ischemia with 47.2% of patients treated for acute coronary syndrome (ACS). Median follow-up was 384 days. Definite or probable ST occurred in 36 patients (2.44%). There were no differences in baseline characteristics between patients that suffered a ST and those that did not. ST was more common in patients treated for NSTEMI (p=0.04) and less common in patients treated for stable angina or silent ischemia (p=0.01). Univariate analysis identified ACS (HR:2.84, CI:1.39-5.81, p=0.004), thrombotic lesions (HR: 2.38, CI:1.19-4.77, p=0.02) and ostial lesions (HR:3.28, 1.36-7.95, p=0.01) as predictors for ST. A multivariable model identified diabetes mellitus (p=0.02) and ostial lesions (p=0.01) as independent risk factors for ST.

CONCLUSION ST rates in this 'real-life' registry are higher than would be expected if treated with contemporary metallic DES. The treatment of patients with BRS with diabetes mellitus or presenting with ostial lesions should be considered carefully with meticulous attention paid to technical factors to ensure optimal procedural results and possible more aggressive antiplatelet therapy in a bid to minimize ST.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-402

Relationship between Bioresorbable Scaffold Sizing and Scaffold Thrombosis: a Pooled Analysis of ABSORB Trials

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BACKGROUND Scaffold/stent thrombosis (ST) is a multifactorial event. Inappropriate device sizing is a common factor which may contribute to ST. This analysis will investigate the relationship between scaffold sizing and ST with Absorb Bioresorbable Scaffold (BVS).

METHODS A patient level pooled analysis of Absorb BVS treated patients will be performed from four ABSORB trials: ABSORB Cohort B (N=101), ABSORB EXTEND (N=812), ABSORB II (N=335), and ABSORB Japan (N=266). Patients will be evaluated according to the size of implanted scaffold and vessel diameter.

RESULTS At the time of the TCT presentation, data will be presented on a total of 1514 patients pooled from the four ABSORB trials.

CONCLUSION The results will help understand the relationship between scaffold sizing and ST.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds