Vanish-trial to investigate MBF and CFR early after BVS vs. DES implantation.

Methods: Sixty patients (45 men (75%), 55 ± 7 years) with a documented single vessel type A or B1 lesion, either stable or unstable angina without biochemical signs of myocardial infarction, were included in this single blind randomized clinical trial. Patients were randomized to implantation of a DES or BVS (Xience Prime or Abbott Vascular, respectively) in a one-to-one fashion. Approximately 1 month after percutaneous coronary intervention patients underwent H215O PET to assess (hyperemic) MBF, cold pressor test MBF, and CFR.

Results: Lesions were predominantly located in the LAD (n=36, 60%) and less frequently in the RCA (n=14, 23%) orCx (n=10, 17%). One patient refused PET perfusion at 1 month follow-up (DES arm). MBF of the treated myocardial territory during rest, CPT, and hyperemia of DES was comparable with the BVS arm (0.96 ± 0.24 vs. 1.02 ± 0.28 mL.min⁻¹.g⁻¹, p=0.38, 1.08 ± 0.23 vs. 1.20 ± 0.38 mL.min⁻¹.g⁻¹, p=0.16, and 3.32 ± 0.77 vs. 3.04 ± 0.80 mL.min⁻¹.g⁻¹, p=0.16, respectively). CFR of the treated territory was significantly lower in the BVS arm compared to DES (3.09 ± 0.94 vs. 3.57 ± 0.85, p<0.05). No significant differences in (hyperemic) MBF, CPT, and CFR were documented in remote areas between treatment arms. Also, a trend toward an attenuated remote CFR was observed in the BVS treatment arm (3.03 ± 0.86 vs. 3.48 ± 0.96 mL.min⁻¹.g⁻¹, p=0.06).

Conclusions: CFR is attenuated one month after implantation of a BVS compared with a DES, although, quantitative hyperemic MBF was not different between both treatment arms.

Categories: Coronary: Stents: Bioresorbable Vascular Scaffolds Keywords: Bioresorbable scaffold, PCI - Percutaneous Coronary Intervention, PET imaging

TCT-504: Bioresorbable Scaffold As Option For The Treatment Of Coronary In-Stent Restenosis: Result From Single-Centre Prospective Observational Study With Angiographic Follow-Up

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Background: The aim of this single center observational study was to investigate the feasibility of bioresorbable vascular scaffold (BVS) in treatment in-stent restenosis lesions. In stent restenosis is still a relatively common problem in daily practice. Existing solutions were not fully effective so far. The use of drug-eluting stents (DES) is related with increased thrombosis risk, also drug-eluting balloon has disadvantage because the eluted-drug stays in the arterial wall only for few weeks, which is not sufficient to eliminate the risk of restenosis. Bioresorbable scaffolds could be possible solution of this issue. The BVS has a number of proposed advantages over current metallic stent technology which could be helpful in providing short-term vessel scaffolding and capability of prolonged drug delivery.

Methods: Between October 2013 and January 2015, 53 Patients (61 lesions) were enrolled in single arm prospective open label study in which in stent restenosis lesions was suitable for BVS implantation. Primary endpoints were procedural success of deployment of the BVS at the target lesion and absence of in-hospital major adverse events (death, Q-wave myocardial infarction, stroke or any repeat target lesion revascularization). The mean patient age was 64±12 years and 78% patients were male, 93% suffered from hypertension and 31% from diabetes. PCI procedures were performed in 87% patients presenting with stable CAD and 15% with acute coronary syndrome. According to the angiographic ISR pattern 45% lesions were focal and 55% were diffuse, the majority of the lesions was post DES ISR (79%). Procedural OCT evaluation was performed in all lesions (100%) before and post-BVS implantation. Estimate the size of the BVS was made on the basis of the IVUS examination just after first balloon predilatation. Lesion predilatation was mandatory and post dilatation was needed in 92% of cases. After 6 month of BVS implantation clinical evaluation was made, the next 6 month patients had performed control angiography with OCT.

Results: Procedural success was obtained in all cases. No in-hospital clinical events and intra-procedural or acute BVS-in-stent thrombosis were reported. Mean BVS implanted length was 30.5 mm. A number of 1.6 stents were implanted per lesion. At a median of 6 months follow up 2 clinically-driven TLR (3.8% per patient) were reported due to recurrent ISR at the BVS-in-stent implantation site. No cardiac death, Q-wave MI occurred at follow-up. Re-evaluation by angiography with OCT will be obtained in next 12 months follow-up after procedures.

Conclusions: The results of our study suggest that BVS is safe and technically feasible for the treatment of ISR in patients presenting with both stable CAD and ACS with reasonable midterm outcomes. Moreover, follow-up revealed a very low rate of adverse events in patients treated by BVS implantation in the context of treatment of in-stent restenosis.

Categories: Coronary: Bioabsorbable Vascular Scaffolds Keywords: Bioabsorbable scaffolds, In-stent restenosis

TCT-505: Comparative Clinical Resource Utilization With Bioresorbable Everolimus-eluting Scaffolds Vs. Metallic Everolimus-eluting Stent With Abolunimal Polymer In Contemporary Clinical Practice

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Background: Bioresorbable everolimus-eluting scaffolds (BVS) and the P-CT everolimus eluting stent with abulaminial polymer (Synergy™) have shown positive clinical results in trials. However, there are important differences in the respective platforms which could impact on clinical performance during implantation.