Clinical outcomes in patients with calcified lesions, treated with bioresorbable vascular scaffolds

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Background: To date no data exist on clinical outcomes of patients with calcified lesions treated with bioresorbable vascular scaffolds (BVS).

Methods: We analyzed 8-month clinical outcome data of consecutive patients with at least one calcified lesion (defined as calcium arc >60° on IVUS) performed in 76% of cases or in the absence of IVUS at least moderate lesion calcification on angiography) treated with BVS between May 2012 and May 2014. Primary outcome was major adverse cardiovascular event (MACE: defined as all-cause death, myocardial infarction (MI) and target-vessel revascularization (TVR)) rate, at median follow up time.

Results: Out of a total of 163 patients treated with BVS, 62 (38%) had at least one calcified lesion. Mean age of the latter was 63±8.10 years and 54% (87.1%) were men. The number of patients were 22 (35.5%) patients with diabetes, 3 (4.8%) patients with previous CAGB and 31 (50%) with previous PCI. Mean SYNTAX score was 18.89±9.27, whereas left ventricular ejection fraction was 55.5±7.8%. Mean total stent length per patient was 53.3±29.33. Of a total of 76 calcified lesions 82.9% were AHAs type B2/C, 3.9% were in-stent restenosis, 5.3% were chronic total occlusions and 1.3% were acute coronary occlusion in 19.7%. Right coronary artery in 11.8% and left main in 3.1%. Predilation was performed in all cases, and at conventional balloons whereas a scoring balloon was used in 26.3% of cases and rotablation in 11.8%. Postdilatation was used in all but one case (98.7%), with an average maximum pressure of 20.7±5.14 atm. Minimal luminal area (MLA) increased from 3.18±1.34 pre-procedure to 6.4±1.65 mm²(minimum stent area) post BVS implantation, p<0.001. At median follow up of 8.7 (4.9 to 13.4) months 4 (6.5%) MACE occurred. There were no deaths observed, one MI (1.6%), 3 (4.8%) cases of TLR, 4 (6.5%) of TVR and one case (1.6%) of definite late stent thrombosis.

Conclusion: Excellent short term results are observed in patients with calcified lesions treated with BVS. Meticulous lesion preparation is essential.

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The morphological assessment was performed with optical coherence tomography (OCT, St Jude).

Results: 71 Patients (77 lesions, 60+/−13 years old, 57 males, 7 diabetics) underwent coronary angiography at 12 months after BVS implantation for acute coronary syndromes (42 NSTEMI, 29 STEMI). OCT was performed in 65 lesions; endoluminal function (intracoronary inflations of three different doses of acetylcholine) and endothelial independent vasodilatation (intracoronary nitroglycerin, 200microgr) were tested in 54 patients. Results The culprit lesion was identified in all cases with OCT. The minimum thickness of the fibrous cap covering the lesion was 0 to 550 micro-meter (mean 232+/−139microm). Incomplete BVS expansion was evidenced in 20 cases and malposition in 15. The minimum lumen area was 2 to 11 mm². There were 3 cases of in-BVS restenosis, maximal neointima thickness was 370+/−220(microinm), uncovered struts were observed in 12 lesions. Vasodilation beyond the minimum resolution of angiography was observed in 40% of the lesions, and vasoconstriction in 30%.

Conclusions: 12 months after BVS implantation, the presence of a fibrotic cap and of phsiologic vasodilation in response to endothelium-dependent acetylcholine confirm an effective stabilization of the culprit plaque. These data provide a rationale for the use of BVS in the setting of culprit lesions and the basis for a long-term randomized study comparing BVS with traditional metal stents.

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Detailed Morphologic Characterization of the Strut Composition Following Absorb Scaffold Placement in a Porcine Coronary Artery Model Through 48 Months

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Background: The process of bioreosorption following Absorb™ bioresorbable vascular scaffold (Absorb, Abbott Vascular) placement has been investigated by optical coherence tomography (OCT) and intravascular ultrasound imaging modalities; however, the details of histomorphological changes within the strut remain poorly characterized. We present detailed histological characterization of the strut composition in porcine coronary arteries from 6 to 48 months (mo).

Methods: A total of 32 Absorb in swine coronary arteries (29 animals) from 8 time points (6, 12, 18, 24, 30, 36, 42, and 48 mo, 4 Absorb from each time point) were evaluated using histologic and immunohistological stains (Figure).

Results: Struts are of stable morphology through 18 mo, being unstained and easily identified under polarized light (Figure). Thereafter, there is rapid decline in birefringence of strut sites and color changes marked by increased proteoglycan staining by Movat and Alcian blue (blue-green, ≥24 mo) and increasing eosinophilia by H&E (≥30 mo). These changes correspond to the absorption and inspissation of proteins (presence of albuim). Strut sites are eventually composed of a provisional matrix that matures from collagen Type III integration (36 mo) to eventual replacement by smooth muscle cells and collagen Type I at 42 to 48 mo, demonstrating an increasing integration of scaffold into the arterial tissue.

Conclusions: Detailed histological characterization of the Absorb struts provides insight into the process of bioreosorption and integration that may be correlated to changes observed by in vivo imaging modalities such as OCT.