

EDITORIAL

Imaging Bioresorbable Vascular Scaffolds – at the Border between Science and Technology

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PERCUTANEOUS CORONARY REVASCULARIZATION – FROM BALLOON TO BIORESORBABLE SCAFFOLDS

Coronary artery disease (CAD), in its various forms of clinical presentations, including acute coronary syndromes and stable CAD, continues to negatively impact the quality of life, mortality and morbidity, while concomitantly increasing healthcare costs. As the number of patients with CAD increases, the need for optimal revascularization strategies rises, both in the area of interventional cardiology and in coronary artery by-pass grafting techniques, which have substantially developed during the last decades.¹

Percutaneous coronary revascularization techniques have undergone considerable progress in the last four decades, from the first use of balloon angioplasty, which provided a mechanical vascular patency but with a high risk of early recoil, to the introduction of the first metal stents that were able to provide better long-term results compared to balloon dilation. In spite of this, bare metal stents presented several disadvantages, including high rates of in-stent restenosis, therefore a need for an upgrade emerged that led to the development of drug-eluting stents (DES). The main advantage of DES consisted in being coated with anti-proliferative pharmacological agents that inhibit neointimal proliferation, thus preventing restenosis. However, there were major concerns regarding the increased risk of late in-stent thrombosis which was higher in DES, meaning longer dual-antiplatelet therapy regimens, with their associated adverse effects.^{2–5}

Newer-generation DES have been shown to present lower rates of late and very late thrombosis if associated with prolonged double-antiplatelet therapies. Their remaining main disadvantages include the failure to restore the native vascular motricity, architecture, and physiological function due to implantation of a rigid metallic cage-like structure at the site of the coronary lesion.⁶ The development of bioresorbable vascular scaffolds (BVS) has revolutionized percutaneous coronary revascularization procedures, as they provide proper radial support

for early recoil prevention while releasing an anti-proliferative substance which delays neointimal hyperplasia and eventually resorbs, thus restoring the vascular function otherwise impaired by the presence of a metallic device within the coronary artery.⁶⁻⁹

BIORESORBABLE VASCULAR SCAFFOLDS – PROS AND CONS

The short-term scaffolding of the arterial wall and the early healing and restoration of arterial wall motility seemed to overcome the limitations of BMS and DES. Promising early studies reported low restenosis rates, with major adverse cardiovascular event (MACE) rates around 3–6%, but the 5-year follow-up studies found a 11% MACE rate, with 7.8 to 12.5% binary restenosis rates.^{10,11} In an Italian registry, Moscarella *et al.* investigated the use of BVS for BMS and DES restenosis with a median follow-up of 15 months and reported a 6.2% restenosis rate for BVS. The results of the large ABSORB III trial concluded that BVS were not inferior to third-generation everolimus-eluting stents (Xience, Abbott Vascular, Santa Clara, CA, USA), but they were associated with higher thrombosis rates (1.5% vs. 0.7%, $p = 0.13$), leading to cessation of sales of this stent type on the European market.

IMAGING TECHNIQUES FOR BVS EVALUATION

Invasive intracoronary imaging

Several imaging techniques have been used for the assessment of the safety, efficiency, and long-term follow-up of BVS. The follow-up studies used invasive imaging methods such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT) for the assessment of procedural outcomes (under/overexpansion of the stent, dissection etc.), scaffold degradation, vascular healing response, vasomotion restoration, and for prediction of stent thrombosis. Both animal and human studies were conducted for the evaluation of BVS strut degradation, and follow-up studies proved that complete histological resorption of the stent struts takes up to 4 years. In a 2-year OCT follow-up study as many as 80% of the stent struts were still visible, which may explain the late or very late occurrence of thrombotic events, following the discontinuation of dual antiplatelet therapy in these patients.¹² The endothelial coverage of the struts has also been the subject of studies evaluating BVSs. Long-term follow-up studies also concluded that at the 2- or 3-year follow-up, 98 to 99% of the stent struts were covered by endothelium.¹³ OCT and IVUS studies also

evaluated the luminal changes after BVS angioplasty. The implantation of BVS was associated with increased luminal area and dynamic changes in the follow-up period. The first 6 months were associated with a decrease in the mean and minimal luminal area, with significant increases from 6 months to 5 years due to the resorption of the stent struts and reduction (–14%) of the plaque area.^{10,12,14}

Noninvasive imaging methods

With the emerging number of implanted BVS, there is an urging need for an accurate noninvasive imaging method for the evaluation of these scaffolds. Coronary computed tomography angiography (CCTA) has already been proved as a liable imaging method for the analysis of both native and stented coronary arteries. In a recent study, Collet *et al.* assessed the accuracy of CCTA at 3 years after BVS implantation and established a 100% specificity and 80% sensitivity with area under the curve 0.88 (95% confidence interval 0.82 to 0.92) for stenoses greater than 50%, which were validated by quantitative coronary angiography and IVUS.¹⁵

In the current number of JIM, Ferent *et al.* published the results of a follow-up study, which included 30 patients, 1 to 2 years after BVS implantation using this emerging imaging method for the assessment of BVS. The study did not only target the evaluation of luminal volumes ($100.8 \pm 33.68 \text{ mm}^3$ vs. $128.2 \pm 37.38 \text{ mm}^3$, $p = 0.01$) and degree of stenosis ($61.63\% \pm 12.6$ vs. $23.41\% \pm 12.48$, $p < 0.0001$) pre- and post-implantation, but also aimed higher by assessing the technical aspects of the implantation, which may be the key for avoidance of late or very late thrombotic events, which represent the main concern of these stent scaffolds. Furthermore, the workgroup analyzed plaque composition and demonstrated a significant decrease of the fibro-fatty tissue after BVS implantation ($10.31\% \pm 6.24$ vs. $6.46\% \pm 6.14$, $p = 0.01$) and regression of the vulnerability degree of coronary plaques (with significant decrease of low attenuation plaques [37.5% vs. 20.83% , $p = 0.01$] and significant increase of spotty calcifications after BVS implantation [66.66% vs. 79.16% , $p = 0.05$]).^{16,17}

The result of this study aids in the understanding of vascular and plaque changes following BVS implantation and further enhances the role of CCTA in the evaluation of BVS. The authors succeeded to make a big step forward in order to validate CCTA as the method of choice for imaging-based follow-up of patients with BVS.

CONFLICT OF INTEREST

Nothing to declare.

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