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Prevalence of parameters of suboptimal scaffold deployment following angiographic guided bioresorbable vascular scaffold implantation in real world practice - an optical coherence tomography analysis

Vijayakumar Subban [a,*,1], Gunasekaran Sengottuvelu [b,1], Kalaichelvan Uthayakumaran [a,1], Ravindran Rajendran [b,1], Ezhilan Janakiraman [a,1], Balaji Pakshirajan [a,1], Jose G. Thenpally [a,1], Latchumanadhas Kalidoss [a,1], Suma M. Victor [a,1], Mathew Samuel Kalarickal [b,1], Mullasari S. Ajit [a,1]

[a] Institute of Cardiovascular Diseases, The Madras Medical Mission, Chennai, India
[b] Department of Cardiology, Apollo Hospitals, Chennai, India

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ABSTRACT

Aim: To assess the prevalence of suboptimal bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, California) deployment in real world practice with intracoronary optical coherence tomography (OCT) imaging.
Methods: Consecutive patients who underwent percutaneous coronary intervention using BVS and the final optimization assessed with OCT imaging in two tertiary care centers between December 2012 and February 2015 were evaluated for parameters of suboptimal scaffold deployment by OCT.
Results: Overall, 36 scaffolds were implanted in 27 patients during this period. Mean age of the population was 54.7 ± 8.2 years and 19 (70.4%) were type B2/C lesions. The prevalence of parameters of suboptimal scaffold deployment were: underexpansion-22(61.1%), geographic miss-3(8.3%), tissue prolapse-7(25.9%), scaffold pattern irregularity-1(2.8%), longitudinal elongation-7(38.8%). Of the 7 overlaps imaged: excessive overlap was observed in 3 and scaffold gap in one. The median duration of follow up was 679 days (range 193–963 days). There were four events during this period. None were associated with suboptimal scaffold deployment.
Conclusion: OCT based parameters of suboptimal scaffold deployment are common in real world scenario and were not associated with adverse outcomes on long term follow up. These findings need to be confirmed in larger studies.

1. Introduction

Bioresorbable vascular scaffold (BVS, Absorb, Abbott Vascular, Santa Clara, California) is a new generation device and considered as the fourth revolution in the evaluation of coronary stent technology. BVS is made up of bioresorbable polymer (poly-L-lactic acid) backbone and coated with bioresorbable polymer (poly-DL-lactic acid) and anti-proliferative drug, everolimus. The scaffold is completely resorbed over a period of 24–48 months and leaves the vessel free of permanent metallic caging. This offers a number of advantages over the current generation drug eluting stents (DES) and may potentially alleviate most of the long term problems associated with them. Similar to DES, the scaffold provides mechanical support to counteract the acute vessel recoil post angioplasty and the drug elution limits excessive neointimal growth. In contrast, its flexibility and conformability preserves the vessel geometry and bioresorption restores vasomotion, prevents permanent jailing of the side branch ostium, and frees the segment for late bypass grafting and also results in late luminal gain and expansive remodeling. In addition, it may eliminate the risk of very late stent thrombosis and the need for long term dual anti-platelet therapy [1]. With promising outcomes from the first in man study [2] and subsequent registries [3,4], BVS is currently being implanted in more complex clinical subsets and the acute performance and the clinical outcomes have been shown to be comparable to that of DES [5,6].

Though BVS promises numerous improvements over DES, it may not be totally immune to the acute and late failures (stent thrombosis and restenosis) associated with DES. With increasing usage of BVS in the real world scenarios and complex lesion subsets, the scaffold failures are increasingly being recognized [7]. Importantly, the main mode of failure was scaffold thrombosis and the most of the events clustered

* Corresponding author at: Institute of Cardiovascular Diseases, The Madras Medical Mission, 4A, Dr. JJ Nagar, Mogappair, Chennai 600037, India.
E-mail address: drkumarvijay@gmail.com (V. Subban).
[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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to the early period following scaffold implantation. This implicates suboptimal scaffold implantation as the possible pathological mechanism of scaffold thrombosis [7]. In addition, intravascular imaging studies have shown the same pathologic mechanisms of DES failure, such as underexpansion, gross malapposition and geographic miss in patients presenting with scaffold thrombosis [8,9]. Similarly, there was evidence of suboptimal scaffold implantation in patients with scaffold restenosis [10,11]. Further, unlike metallic stents, the scaffold is prone to deformation with overexpansion [12] and longitudinal elongation [13] with high pressure dilatation in the presence of resistant plaques. Importantly, poor angiographic visibility of BVS, makes it difficult to recognize these abnormalities with angiography alone.

The current study retrospectively analyzed in detail the prevalence of such markers of suboptimal scaffold deployment with optimal coherence tomography (OCT) and correlates them with clinical outcomes during follow up.

2. Methods

The study population included consecutive patients who underwent percutaneous coronary intervention (PCI) using BVS and the final optimization assessed with OCT imaging in two tertiary care centers (the Madras Medical Mission, and the Apollo hospital) in Chennai, India between December 2012 and February 2015. There were no specific exclusion criteria except for the angiographic vessel size assessed visually by the operator not suitable for the currently available scaffold sizes.

All the scaffolds were implanted by 4 experienced operators. Aggressive lesion preparation was recommended and the strategy was left to operator's preference. There was no routine preprocedural QCA or OCT assessment. Scaffold selection was based on visual assessment of vessel size by the operator. All the scaffolds were implanted as per manufacturer's recommendation. Routine post dilatation was recommended with noncompliant balloon sized to the scaffold or within the expansion range of the particular scaffold. When overlapping of scaffolds was required, marker-to-marker or scaffold-to-scaffold technique was used. In case of bifurcation lesions, either provisional technique with or without snuggle balloon dilation or two scaffold T technique with final kissing balloon dilatation was used. Once optimal scaffold deployment was confirmed angiographically, OCT imaging was obtained. Further scaffold optimization based on the OCT findings were allowed and a final OCT imaging was acquired in the end. All the OCT imaging were performed with either Ilumien™ or Ilumien™ Optis™ PCI optimization system (St. Jude Medical, Minneapolis, Minnesota) using DragonFly™ imaging catheter (St. Jude Medical) at a pullback speed of either 10 mm or 20 mm per second with manual contrast flushing. Imaging was repeated when the pullback was not optimal and additional imaging was performed when the pullback was not enough to cover the full length of the scaffold.

Baseline demographic and clinical data and the procedural details such as type of the pre-dilatation/post-dilatation balloons used, the maximal diameter and maximal inflation pressure were collected from the case records.

All the angiographic and OCT data were collected retrospectively and analyzed by two independent observers at a core laboratory (Indian Cardiology Research Foundation, Chennai, India). The angiographic analysis was performed with CASS 5.10.2 software (Pie Medical BV, Maastricht, Netherlands). Lesions were categorized into different types based on ACC/AHA task force criteria for coronary lesion classification [14]. The minimal lumen diameter (MLD, smallest diameter in the lesion segment), angiographic percentage diameter stenosis (DS, [reference lumen diameter − minimal lumen diameter/reference lumen diameter] × 100), the interpolated reference vessel diameter (RVD, predicted reference diameter at the site of MLD), maximal vessel diameter (Dmax, largest reference diameters proximal and distal to the lesion) and the length of the obstruction were obtained in the preprocedural angiogram [15]. Post procedure QCA analysis included the lesion as a whole rather than individual scaffolds in patients with overlapping scaffolds. The treated segment and the peri-scaffold areas (5 mm both proximal and distal to the scaffold) were analyzed in the final angiogram and MLD, DS and acute lumen gain were obtained. Epicardial flow in the target artery was categorized as per TIMI flow grading criteria [14].

OCT analysis was performed offline using a dedicated OCT work station (Ilumien™ Optis™, St. Jude Medical) as per previous recommendations [16]. Cross sections were analyzed at 1 mm intervals in the scaffold segment and 5 mm proximal and distal to the scaffold. The frames where $>90^0$ of the circumference was not suitable for analysis, were excluded. The scaffold struts are translucent and appear as black boxes with high back-scattering borders that allow the assessment of the vessel wall behind the struts. In each frame, observation was made for presence of malapposition (lack of contact between scaffold and vessel wall), tissue prolapse (plaque or thrombus protruding between the struts) and scaffold pattern irregularity/fracture (SPI/F, presence of a 2nd strut overhanging in the same angular sector or a free floating strut close to the center of the lumen). The total number struts and those with malapposition in each scaffold were counted and the percentage of malapposed struts per scaffold was then calculated. In each frame, the lumen area, scaffold area, maximal and minimal diameter were obtained. The lumen area was traced at the tissue border behind the scaffold in the absence of tissue prolapse and is equal to the scaffold area in the absence of malapposition and larger than the scaffold area in the presence of malapposition. In the areas of tissue prolapse, the lumen area was traced along the tissue inside the scaffold. Tissue prolapse area was derived from subtracting the lumen area from the scaffold area. Optimal scaffold expansion was defined as scaffold minimal cross sectional area (CSA) of more than 80% of the maximum expected area for the scaffold used. For 2.5 mm, 3 mm and 3.5 mm scaffolds the optimal areas were 4 mm^2, 6 mm^2 and 8 mm^2 respectively [17]. Scaffolds not meeting these criteria were defined as underexpanded. Malapposition was classified into following types: under-deployment related (malapposition resulting from correctly sized scaffold deployed at low pressure), under-sized scaffold related (malapposition resulting from undersized scaffold), plaque related (fibro-calcific plaque preventing strut apposing to the vessel wall), ectasia related (malapposition resulting from large lumen dimensions at the ectatic segment), overhang/protrusion related (malapposition resulting from scaffold overhang in to the proximal main vessel), side branch related (malapposition at the site of side branches), scaffold fracture related (malapposition related to scaffold fracture – malapposed overhanging or free strut). Side branch related malapposition was excluded from the analysis. Presence of >5% of the struts with malapposition in a scaffold was considered significant. Tissue prolapse occupying >10% of the scaffold area was considered abnormal. The proximal and distal edges were assessed for the presence of dissection (breach in the endoluminal continuity), intramural hematoma (accumulation of blood in the medial space) and geographic miss (Inadequate lumen area - <4 mm^2/large uncovered plaque or dilated segment at the scaffold edges). Edge dissection was defined as major when it occupies >60% of the lumen circumference and the residual lumen area < 4 mm^2 [18]. In case of overlapping scaffolds, presence of excessive overlap (stacking of struts of adjacent scaffolds for >1 mm length) or scaffold gap (gap between the scaffolds at the overlapping site) was noted. For scaffolds implanted in the ostial position, the length of overhang was measured. Overhang of >1 mm was considered excessive. The scaffolds where there was no overlap and both proximal and distal edges clearly visible were assessed for elongation (measured length longer than the predicted length). The scaffold edge was defined as the first frame with <3 quadrants of scaffold identified in a cross section at either ends. The calibration was adjusted before each measurement [13]. All the length measurements were done thrice by each examiner and the average value was taken. In addition, symmetry