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Routine Use of Optical Coherence Tomography-Guided Bioresorbable Vascular Scaffold Implantation: Insights on Technique Optimization and Long-Term Outcome

Hesham K Abdelaziz*[1], Hossamaldin Z Abuomara[1], Montasir H Ali[1], Jonas Eichhofer[1], Billal Patel[1] and Marwan Saad[2]

[1]*Lancashire Cardiac Center, Blackpool Victoria Hospital, United Kingdom*

[2]*Division of Cardiovascular Medicine, University of Arkansas for Medical Sciences, United States*

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***Corresponding author:** Hesham K Abdelaziz, Lancashire cardiac center- Blackpool Victoria Hospital, Whinney Heys Road, FY3 8NR, Blackpool- UK

Abstract

Background: Data from prior studies have shown increased risk of adverse outcomes with bioresorbable vascular scaffolds (BVS) compared with drug-eluting stents.

Objective: To study long-term outcomes with routine use of Optical Coherence Tomography (OCT) during BVS implantation.

Method: Clinical, procedural and outcome data were collected for all patients who received ABSORB® BVS between February 2014 and December 2015 in our tertiary center (n=86). Pre- and post-implantation OCT was performed in all cases. Outcomes of interest were acute device success and long-term clinical outcomes including cardiac mortality, target vessel myocardial infarction (TV-MI), ischemia-driven target lesion revascularization (ID-TLR) and scaffold thrombosis (ScT).

Results: A total of 86 patients were included (106 lesions, 115 BVS implanted). Mean age was 59.5 ± 10.9 years, with 66% men. Mean lesion length was 25.2 ± 15.6 mm and mean reference vessel diameter was 3.42 ± 0.45mm. Type B2 and C accounted for 40% of total lesions. Of 115 scaffold analyzed, 11 (9.5%) required further intervention based on OCT review with significant association with type B2/C lesions as compared to those not requiring further OCT optimization (81.9% vs.41.3%, p=0.01). At mean follow-up duration of 31 ± 7.1 months, no cases of cardiac mortality, TV- MI, ID-TLR, or ScT were reported.

Conclusion: The use of PSP technique alone in complex lesions type (B2/C) might be associated with higher rate of suboptimal BVS implantation that is mitigated by the OCT use, and this could be possibly translated into improved clinical outcomes on the long term.

Keywords: Bioresorbable vascular scaffold; optical coherence tomography; Scaffold thrombosis; malapposition

Abbreviations: BVS: Bioresorbable Vascular Scaffolds; OCT: Optical Coherence Tomography; DES: Drug-Eluting Stents; BMS: Bare-Metal Stents; SM: Scaffold Malapposition; ISA: Incomplete Scaffold Apposition; TIMI: Thrombolysis In Myocardial Infarction; TV-MI: Target Vessel Myocardial Infarction; ID-TLR: Ischemia-Driven Target Lesion Revascularization; SCT: Scaffold Thrombosis; ACS: Acute Coronary Syndrome; NSTEMI: Non-St Elevation Mi; STEMI: St-Elevation Mi; Nc: Non-Compliant; QCA: Quantitative Coronary Analysis; IVUS: Intravascular Ultrasound

Introduction

Bioresorbable vascular scaffolds (BVS) were developed to mitigate adverse outcomes related to presence of permanent metallic stent struts. Although second generation drug-eluting stents (DES), including the newer polymer-free DES, are associated with better outcomes compared with first generation DES and bare-metal stents (BMS), they are still associated with a risk of thrombosis and restenosis [1,2]. This may be related to persistent inflammation, loss of normal vessel curvature/vasomotion, strut fracture, and neoatherosclerosis [3]. The complete bioresorption of the BVS over few years after providing the required mechanical support would theoretically avoid these late events [4]. The ABSORB bioresorbable vascular stent (Abbott Vascular Corporation Inc.) is an everolimus BVS that has received a CE mark in Europe in 2011 and approved by FDA in 2016. However, and after initial enthusiasm, sales were halted worldwide by the manufacturer in September 2017 due to an increase in observed target vessel myocardial infarction (MI) and scaffold thrombosis (ScT) [5].

This decision was derived from the 3-year outcome data of ABSORB III trial [6], 4- year outcome of the ABSORB II trial [7], the 2-year data from ISAR-ABSORB registry [8], as well as multiple

meta-analyses [9-11]. Optical coherence tomography (OCT) is a light-based high-resolution intracoronary imaging modality, which allows for better detection and quantification of scaffold malapposition, underexpansion, tissue prolapse, and stent edge dissection, as compared with conventional intravascular imaging modalities [12,13]. Despite their value in optimizing stent implantation, the rate of use of intracoronary imaging modalities in general and OCT in specific were quite low in the previous studies involving BVSs [14]. Given the ongoing development in the biovascular scaffold technology, we sought to study the impact of routine use of OCT during BVS implantation on decision making in regards to the need for further scaffold optimisation as well as on long-term clinical outcomes with BVS.

Methods

Study Design and Patient Population

All patients who underwent OCT-guided ABSORB BVS implantation from February 2014 to March 2016 at our tertiary medical center were reviewed. The number of the patients who did not have OCT guidance were too small (4 patients) to generate control arm for comparison. Exclusion criteria included patients with 1) reference vessel diameter 2.5, and 2) severe vessel calcification (radio-opacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall). All BVS case data were entered prospectively into a local database based on a predetermined data set and was collected by two independent physicians. Data included patient demographics, procedure data, and procedural outcomes.

Procedures

Percutaneous coronary interventions were performed in accordance with the current guidelines for coronary revascularization [15]. All patients were pretreated with aspirin 300 mg and P2Y12 inhibitors (clopidogrel for stable angina and ticagrelor for ACS), and intravenous heparin 70-100 IU/kg was given during the procedure to maintain an activated clotting time >250 seconds. The use of Glycoprotein IIb/IIIa inhibitors were left to operator discretion. All patients underwent baseline OCT imaging of the lesions to determine reference vessel diameters, position of significant side branches, and lesion characteristics. Scaffold post dilatation using non-compliant balloons was performed until angiographic success was achieved. The definition of angiographic success is reported later. Post-deployment OCT was performed to assess scaffold expansion and apposition, minimum in-scaffold diameter and area, diameter stenosis percentage, as well as complications such as tissue prolapse and scaffold edge dissection. Further scaffold optimization was performed if required based on the OCT findings.

Oct Technique and Definitions

OCT acquisition was performed using the C7 Dragonfly™ intracoronary imaging catheter and the ILUMIEN™ PCI Optimization System (Abbott vascular, Santa Clara, California, US). All images were acquired using a non-occlusive technique with injection of non-ionic, low-osmolar iopamidol (Niopam 300™; Bracco UK limited, Buckinghamshire, UK) to limit artefacts from blood. Scaffold under-expansion was defined as minimum scaffold area <80% of the mean proximal and distal reference lumen areas [16]. Scaffold malapposition (SM) was defined as incomplete scaffold apposition (ISA) delineated by the distance between the abluminal side of the frame border of the malapposed struts and the endoluminal contour of the vessel wall [17]. Given the scaffold strut thickness of 156 um, we considered any axial distance > 156 um as significant mal-apposition. Tissue prolapse was defined as any tissue protruding between struts into the lumen at baseline [17]. Scaffold edge dissection was defined using NHLBI classification for coronary artery dissection [18]. The edge dissection was considered significant requiring a second bailout stent if it extended into the medial layer, or extended laterally > 60 degrees, or was > 2 mm in length [19]. For the OCT analysis, all derived measures were based on the abluminal stent contour. Angiographic success was defined as residual diameter stenosis <30% with Thrombolysis In Myocardial Infarction (TIMI) 3 flow by visual assessment [20].

Outcomes and Follow Up

Outcomes of interest were 1) acute device success (defined as residual in-scaffold diameter stenosis < 30% and optimal scaffold apposition by OCT); and 2) long-term clinical outcomes at a minimum follow-up of 24 months, including cardiac mortality, target vessel myocardial infarction (TV-MI), ischemia-driven target lesion revascularization (ID-TLR) and scaffold thrombosis (ScT). The definitions of these outcomes are summarized in the online supplementary appendix 1. Patients were followed up via clinic visits or phone calls. The protocol was performed according to the Declaration of Helsinki and approved by the local ethical committee.

Statistics

Categorical variables are summarized as numbers and percentages and compared using Pearson's X2 test or Fisher's exact test. Continuous variables are presented as mean ± SD and compared with the student's t-test. Statistical significance was accepted as $p<0.05$. Statistical analysis was performed with SPSS version 24.0 (IBM Corporation, Armonk, New York).

Results

Patient Demographics and Angiographic Characteristics

Out of 89 patients initially identified, 3 patients had no follow-up records available, and 86 patients (98 target vessels; 106 lesions) were included in the final analysis. The mean follow-up duration was 31 ± 7.1 months. The mean age was 59.5 ± 10.9 years and males represented around 66% of the cohort. The indications of BVS implantation were stable angina in 58% and acute coronary syndrome (ACS) in 42% of the population (28% and 14% for non-ST elevation MI [NSTEMI], and ST-elevation MI [STEMI] respectively). The left anterior descending artery was the most common target vessel (57.5%) followed by the right coronary artery (22.7%) and the left circumflex / ramus artery (19.8%). De-novo lesions comprised 96.2% of the target lesions. The mean length of lesions was 26.3 ± 14.2 mm and mean reference vessel diameter was 3.42 ± 0.45 mm, with no target vessel less than 2.5 mm in diameter. Around 40% of the lesions were complex (ACC/AHA class B2 or C), and only a small proportion had ≥ moderate calcifications or proximal vessel

tortuosity (22.6% and 21.7% respectively). Baseline characteristics are summarized in Table 1.

Table 1: Baseline characteristics of the study cohort.

Baseline patients' demographics	N=86
Age, years	59.5 ± 10.9
Male	57/86 (66.2)
Diabetes mellitus	46/86 (53.4)
Hypertension	42/86 (48.8)
Smoking history	55/86 (64)
Dyslipidemia	33/86 (38.3)
Family history of premature CAD	18/86 (21)
Prior myocardial infarction	12/86 (14)
Clinical presentation SCAD ACS	 50/86 (58) 36/86 (42)
P2Y12 Clopidogrel Ticagrelor	 50/86 (58) 36/86 (42)
Patients with single target vessel disease	74/86 (86)
Baseline target lesion characteristics	L= 106
Target vessel Left anterior descending Left circumflex/ Ramus Right coronary artery	 61/106 (57.5) 21/106 (19.8) 24/106 (22.7)
Target vessel Reference diameter, mm	3.42 ± 0.45
Target vessel proximal tortuosity* None or Mild ≥ Moderate	 83/106 (78.3) 23/106 (21.7)
Lesion calcification+ None or mild ≥ Moderate	 82/106 (77.4) 24/106 (22.6)
Lesion type Denovo In-stent restenosis	 112/106 (96.2) 4/106 (3.8)
Thrombus	14/106 (13.2)
ACC/AHA lesion classification Class A or B1 Class B2 or C	 63/106 (59.5) 43/106 (40.5)
CTO lesion	2/106 (1.9)
Lesion location Ostial Proximal Mid	 3/106 (2.8) 78/106 (73.6) 25/ 106 (23.6)
Target lesion length, mm	26.3 ± 14.2
Diameter stenosis, %	78.4 ± 13.5
MLD, mm	0.72 ± 0.4
MLA, mm^2	0.56 ± 0.54

Note: Values are expressed as mean ± SD or n (%).

-N= total number of patients; L= total number of lesions; CAD= Coronary artery disease; SCAD= stable coronary artery disease; ACS= acute coronary syndrome; CTO= chronic total occlusion; ACC/AHA= American College of Cardiology/American Heart Association; MLD= minimum lumen diameter; MLA= minimum lumen area

*Tortuosity - mild: one bend > 75° that must be traversed by the balloon or device to reach the target lesion. Moderate: 2 bends > 75° to reach target lesion or one bend > 90°. Severe: 2 bends > 90 ° to reach target lesion.

+Calcification - Readily apparent densities noted within the apparent vascular wall at the site of the stenosis. Moderate: densities noted only during the cardiac cycle prior to contrast injection. Severe: radio-opacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall.

Procedural Outcomes

A total of 115 scaffolds were implanted. OCT was routinely used in all cases prior to implantation to accurately determine vessel size and appropriate scaffold diameter "best fit", and post-implantation to assess for adequate scaffold apposition and expansion and rule out complications such as edge dissection. All patients had adequate lesion preparation with pre-dilatation using semi-compliant or non-compliant (NC) balloons at 1:1 balloon-to-artery ratio. Cutting balloons were utilized in 11.3% of the cases. Post-dilatation with NC balloon (>1:1 balloon-to-scaffold ratio) was used in all cases. Overlapping scaffolds were implanted in third of the cases, and abutting technique was used in around two-third of these cases. Out of the 115 scaffolds analysed, 11 (9.5%) required further intervention following OCT review, despite routine post-dilatation and achieving angiographic success. Of these 11 scaffolds, the reason for further BVS optimisation was scaffold malapposition in five (45.4%), scaffold underexpansion in three (27.3%), and significant distal edge dissection requiring bailout second scaffold in three (27.3%).

Table 2: Procedural outcomes.

Total number of scaffolds	115
Total number of lesions	106
Number of scaffold/patient	1.35 ± 0.6
Predilatation (per lesion) Routine pre-dilatation performed Semi-compliant or compliant balloon Cutting balloon Pre -dilatation balloon diameter, mm	 106/106 (100) 101/106 (88.7) 12/106 (11.3) 2.9 ± 0.4
Post- dilatation (per lesion) Routine post-dilatation performed Balloon/ Scaffold ratio Post-dilatation balloon diameter, mm	 106/106 (100) 1.1 ± 0.2 3.44 ± 0.66
Scaffold implanted (per patient) One scaffold Two or more scaffolds	 59/86 (68.6) 27/86 (31.4)

Overlapping technique Abutting/total number of overlapped scaffolds Overlapping/total number of overlapped scaffolds	36/52 (69.2) 16/52 (30.8)
Acute device success	114/115 (99)
TIMI 3 flow	115/115 (100)
Bailout second scaffold	4
Minimum in-scaffold area, mm^2	6.7 ± 2.2
Mal-apposition	5/115 (4.3)
Scaffold underexpansion	3/115 (2.6)
Edge dissection Total Requiring bailout second scaffold	10/115 (8.7) 3/115 (2.6)
Side branch Jailing Loss	58/115 (50.4) 5/115 (4.3)
Duration of dual antiplatelet, months	12.6 ± 4.2

Note: Values are expressed as mean ± SD or n (%)

TIMI= thrombolysis in myocardial infarction

All the cases of mal-apposition and underexpansion were further treated by more adequate post-dilatation with balloon diameter size which is 0.75 mm larger than the scaffold nominal diameter (N=8). There were no cases of scaffold fracture associated with post-dilatation. Another bailout second BVS was used in one case to treat a guide catheter-induced proximal RCA dissection which was angiographically detected during the procedure. Acute device success was achieved in all cases except one case that showed residual stenosis of 35% despite adequate post-dilatation. In around half of the cases, a side branch was jailed by the scaffold with total loss of this side branch in only 4.3% of the cases but with no clinical or ECG consequences. Table 2 summarizes the procedural outcomes. As compared to scaffolds not requiring further optimisation following OCT, there was a significant association between further OCT-guided scaffold optimization and complex type B2/C lesion (81.9% vs.41.3%, p=0.01) as well as the total length of the procedure (77.4±17.7 min vs. 96±19.1 min, p=0.001), but not fluoroscopy time (22.0±7.1 min vs. 26.2±2.9 min, p=0.07).

There was no association between age, gender or target vessel, lesion length and requirement of OCT-guided optimisation of scaffold placement (Table 3). There were no adverse events associated with OCT imaging in this cohort, despite a total of 176 OCT runs being performed. Within this cohort there was no cases with significant tissue prolapse or acute scaffold thrombosis. All the OCT-derived pre- vs. post-implantation data showed significant improvement in terms of minimum lumen (scaffold) diameter (0.75 ± 0.46 vs. 2.82 ± 0.38 p< 0.001), minimum lumen (scaffold) area (0.62 ± 0.89 vs. 6.4 ± 1., p<0.001) and diameter stenosis (78.8 ± 13.7 vs. 17.1 ± 5.1, p<0.001) (Table 4).

Table 3: Comparison of OCT optimization vs. angiographic success.

	Not requiring OCT Optimisation (n=104)	Requiring OCT optimisation (n=11)	p-value
Age, years	59.2±11.1	63.9±8.9	0.17
Male	63 (60.5)	5 (45.5)	0.33
Target vessel LAD RCA LCX/ Ramus	62 (59.6) 23 (22.1) 19 (18.3)	4 (36.4) 3 (27.2) 4 (36.4)	0.261
Lesion type Type A/ B1 Type B2/C	61 (58.7) 43 (41.3)	2 (18.1) 9 (81.9)	0.01
Lesion length, mm	23.9±15	27.7±16	0.45
Fluoroscopic time, min	22.0±7.1	26.2±2.9	0.07
Length of procedure, min	77.4±17.7	96±19.1	0.001

Note: Values are expressed as mean ± SD or n (%).

LAD= left anterior descending; RCA= right coronary artery; LCX= left circumflex

Table 4: Comparison between pre- and post-procedural OCT guided outcomes.

	Pre-procedure	Post-procedure	p-value
Minimum lumen (or scaffold) diameter, mm	0.75 ± 0.46	2.82 ± 0.38	<0.001
Minimum Lumen (or scaffold) area, mm^2	0.62 ± 0.89	6.4 ± 1.7	<0.001
Diameter stenosis, %	78.8 ± 13.7	17.1 ± 5.1	<0.001

Note: Values are expressed as mean ± SD.

Clinical Outcomes

At mean follow-up duration of 31 ± 7.1 months for the 86 patients, there were no reported cases of cardiac mortality, TV- MI, ID- TLR or ScT. There was one case of recurrent angina with negative inducible ischemia on stress imaging and one case of non-target vessel MI which occurred 23 months after the BVS implantation.

Discussion

In the current article we present the clinical, procedural and outcome data of OCT-guided implantation of ABSORB BVS in 86 patients at our tertiary center. In our study, however, despite following the P-S-P technique (pre-dilation, proper sizing, and post-dilation) with routine use of NC balloon-to-scaffold ratio > 1:1 to optimize scaffold implantation, there were still 8 cases showing either underexpansion or significant mal-apposition as detected by OCT requiring further post-dilation using a larger NC balloon. In addition, the OCT recognized 3 significant outflow edge dissection requiring bailout second scaffold. At a follow up of 31 ± 7.1 months, there were no reported cases of cardiac mortality, TV- MI, ID-TLR

or ScT. The utilization of quantitative coronary analysis (QCA) and angiographic visual estimation may be suboptimal methods to appropriate vessel sizing due to possible underestimation of the vessel diameter as well as wide range of inter- and intra-observer variability [21]. Within modalities of intravascular imaging, OCT has shown to be superior compared with intravascular ultrasound (IVUS) due to a higher axial resolution (10 times) allowing better detection of malapposition, underexpansion, stent-edge dissection and tissue protrusion [22-24].

The use of OCT to optimize metallic stent implantation has been proven to be safe and feasible, with superior clinical outcomes when compared to angiographic guidance alone as shown in a recent large network meta-analysis comparing angiography-, IVUS-, or OCT-guided implantation [25]. Given the inherent biomechanical differences in scaffold structure between BVS and metallic stents, it is imperative to ensure that the scaffold is optimally deployed to maximize chances of successful outcomes in both the short and the long term. In a contemporary review of 100 patients with definite scaffold thrombosis (ScT) (acute and subacute ScT [n=63]; late and very late ScT [n=37]) out of which intracoronary imaging insights were available for 43 cases (OCT [n=38], IVUS [n=5]), mal-apposition was the most frequent imaging finding of ScT, secondary to under-sizing of the device, suboptimal lesion preparation or inadequate post-dilatation [26]. In addition, incomplete lesion coverage, late discontinuity and under-expansion have been implicated as other potential causes [26]. All of these factors were thought to be mitigated by following the P-S-P technique (pre-dilation, proper sizing, and post-dilation) for the implantation procedure [27-30].

However, we have shown in our study that 11 (9.5%) of the scaffolds implanted required further OCT-guided optimization despite following the recommended P-S-P technique. This was more evident with complex lesion (type B2 and C) where one should expect that blinded implantation technique without image guidance might not be enough to achieve proper stent expansion and apposition or might cause inadvertent edge dissection that could adversely affect the outcomes. The poor implantation profile for BVS in such complex lesions could be attributed to the difference in the recoil characteristics between BVS and metallic stents, along with the larger strut size of BVS which could result in the potential for greater scaffold underexpansion and malapposition when BVS are used in such lesions [31]. In an updated meta-analysis evaluating long term outcomes of the 4 largest ABSORB trials, the overall rate of intravascular imaging use was as low as 22% and complex lesion type B2 and C were as high as 50-75% suggesting possible contribution to the higher rate of TV-MI (7.8% versus 4.2%; P=0.0006), ID- TLR (6.6% versus 4.4%; P=0.02) and ScT (2.4% versus 0.6%; P=0.001) associated with BVS compared to cobalt-chromium everolimus-eluting stents [14].

Furthermore, in the ABSORB IV trial, the use of a standardized P-S-P technique seems to have played a role in improving the outcomes of ABSORB compared to XIENCE stent at 30 days. However, the final minimal lumen diameter remained lower (2.66 mm vs. 2.74 mm, $p < 0.0001$) and the rate of ScT remained higher (0.6% vs. 0.2%, $p = 0.06$) in the ABSORB vs Xience arm. Of note, intravascular imaging was only used in 13% of the cases [32]. The long term follow-up data is still awaited. On the other hand, in the ABSORB Japan trial, the 4 cases of very late scaffold thrombosis beyond one year did not occur in the subgroup where post-implantation OCT was performed for proper device apposition [33]. Scaffold overexpansion has been traditionally prohibited and it has been previously advised that the diameter of the post-dilatation balloon should not exceed 0.5 mm above the nominal scaffold diameter in order to avoid acute disruption [34]. Nevertheless, the use of a post-dilatation balloon diameter up to 0.75 mm larger than the nominal scaffold diameter in our small-sized population has resulted in improved struts apposition with no cases of acute scaffold disruption.

This finding is in concordance with a prior study where BVS deployment optimization using high pressure post dilatation (≥24 atmosphere) was not associated with BVS disruption and was rather associated with improved BVS expansion and lower rates of strut mal-apposition [35]. However, our finding needs to be validated in a large scale study. The role of OCT in BVS optimization has previously been highlighted [36]. Nevertheless, the novelty in our observational study is the finding that the more complex the lesion is (type B2/C), the more the use of OCT is encouraged to ensure optimal BVS deployment, while in simpler type A/ B1 lesion, the use of OCT might not be necessary. Compared to prior studies [14], the low rate of adverse events in this study is likely to be multifactorial including the relatively small proportion of complex lesions, larger mean reference vessel diameter and the routine use of use a high resolution OCT to guide the implantation process. The small size of our study could have also contributed to the low rate of events.

The earlier generation of the ABSORB BVS has only initiated the revolution for future BVS technologies. New BVS in development, including the Magmaris (Biotronik), DESolve (Elixir), and MeRes100 (Meril), Fantom (Reva Medical), and Fortitude, Magnitude, and Aptitude (Amaranth) have thinner struts, shorter full resorption time and altered mechanical characteristics with the aim to lower the risks of adverse outcomes and maintain the potential advantages of the BVS. What this small observational study has shown is the possibility that the use of P-S-P technique alone, without image guidance, might not be enough to achieve ideal scaffold implantation outcomes specially in complex lesions despite angiographic success. Therefore, the routine use of OCT-guided implantation at least in the initial experience with these new devices should be encouraged to provide more insight about its biomechanical properties till it is better understood fully. Further larger randomised control trials in the future will be of benefit to define the role of OCT-guided BVS implantation.

Limitations

The current study has several limitations. The study was single-centered, observational study, no control arm, and a small sample size. The lack of OCT images at follow up is another limitation.

Conclusion

In the current limited observational study, we demonstrated that using the PSP technique alone in complex lesions type (B2/C) might be associated with higher rate of suboptimal BVS implantation that is mitigated by the OCT use, and this could be possibly translated into improved clinical outcomes on the long term.

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