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Original Article

Low major adverse cardiac event rates following bioresorbable vascular scaffold implantation: Impact of implantation technique on treatment outcomes

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ABSTRACT

Background and objective: Studies conducted across the world have reported that the rates of major adverse cardiac events (MACE) following the use of bioresorbable vascular scaffolds (BVS) are comparable to that noted with traditional drug eluting stents (DES). However, there is limited data on the immediate and medium-term clinical outcomes following the use of the Absorb BVS (Abbott Vascular, Santa Clara, SA) in the Indian context. This study was conducted to determine real-world evidence on the immediate and medium-term clinical outcomes in all patients undergoing percutaneous coronary intervention (PCI) with the Absorb BVS.

Methods: Data of all patients who were treated with Absorb BVS at our center were evaluated. Between December 2012 and October 2016, 142 patients underwent PCI with BVS. The MACE rates during hospitalization, at 30 days, 3 months, 6 months after PCI, and every 6 months thereafter were the primary endpoints evaluated with median follow up of 13 months.

Results: Mean age of the study participants was 53.7 ± 11.8 years. Intravascular ultrasound imaging was performed in 15.34% of patients. Predilatation and postdilatation were performed in 81.8% and 84.6% of scaffolds, respectively. There were no episodes of MACE during hospitalization. However, 1 BVS-related MACE was observed at the 1-month (0.7%) as well as at the ≥12 month (0.8%) follow up visits. At the 6- and 12-month follow up visits, 2 (1.5%) and 3 (2.5%) non-BVS-related MACEs, respectively, were recorded.

Conclusion: The use of Absorb BVS in this real-world experience was associated with very good immediate and medium-term clinical outcomes.

1. Introduction

The advent of coronary stent implants has revolutionized the percutaneous treatment of coronary artery disease (CAD), with significant improvement in in-hospital morbidity and mortality compared with plain old balloon angioplasty.[1] Coronary artery stenting with a metallic stent, especially a drug-eluting stent (DES), may be regarded as the gold standard treatment for patients with obstructive CAD, ranging from stable angina to acute coronary syndrome.[2,3] However, metallic stents are associated with several disadvantages such as permanent implants, vessel caging, side branches jailing, impaired vasomotion, and impossibility of late lumen enlargement.[2] Bioresorbable vascular scaffolds (BVS) represent a novel strategy that provide the possibility of transient vessel scaffolding to prevent acute vessel closure and recoil.[4,5] Additionally, the drug delivery capability of BVS counteracts the constrictive remodelling and excessive neointimal hyperplasia, while preserving vasomotion.[4,5]

However, there is limited evidence on the short- and long-term clinical outcomes with the use of Absorb (Abbott Vascular, Santa Clara, SA) BVS in a real-world population from India despite BVS being launched in India since December 2012. This study aimed to report the immediate and medium-term clinical outcomes of BVS implantation performed at a single, intravascular ultrasound (IVUS) imaging-experienced center in India.

2. Methods

One hundred and forty-two consecutive patients who underwent PCI with BVS implantation at the Dr. L H Hiranandani Hospital, Mumbai, India, between December 2012 and October 2016 were included in this single-center, retrospective study.

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The doctors and staff at the center were formally trained on the recommended technique for Absorb BVS implantation. The recommended technique included Adequate Lesion Preparation (P), Appropriate Sizing (S) and Post Dilatation (P) with an objective to achieve final diameter stenosis of <10% with a +0.5 mm non-compliant balloon to high pressure (>16 atm). The primary objective of the study was to assess major adverse cardiac event (MACE) rates during hospitalization, at 30 days after PCI, at 3 months after PCI, at 6 months after PCI, and every 6 months thereafter. The median follow up was 13 months. The MACE was defined as the composite of allcause mortality, follow-up myocardial infarction, and target vessel revascularization.[6]

During the initial learning curve of using the BVS, IVUS or optical coherence tomography (OCT) was used more often to assess the target and lesion vessel characteristics and the scaffold expansion and apposition before and after implantation. However, subsequently with experience, these imaging modalities were used at the discretion of the operator. Clinical device success was defined as successful delivery and deployment of the scaffold at the intended target lesion and successful withdrawal of the delivery system with attainment of a final residual stenosis of <30%, as evaluated by quantitative coronary angiography. Procedural success was defined as clinical device success without the occurrence of major peri-procedural complications or in-hospital MACE.[7]

3. Results

A total of 214 Absorb BVS were successfully implanted in 176 vessels in 142 patients. There was one case of device failure in which we could not implant the device since the proximal LAD had a type B2 lesion with moderate calcium. Despite the use of a 1:1 cutting balloon, the Absorb BVS could not be tracked into the vessel and hence we had to use a metallic DES in this patient. The baseline characteristics and clinical presentation of the patients who were treated with the Absorb BVS are presented in Table 1 and Table 2, respectively. Majority of the patients were men (83.8%). There was a relatively high incidence of recent myocardial infarction (43%), followed by left ventricular dysfunction (39.71%). The incidence of ST-elevation myocardial infarction and multiple vessel disease was equally distributed among the study participants.

A total of 177 vessels were treated (left anterior descending artery: n = 102; left circumflex artery: n = 23; right coronary artery: n = 37; and other vessels: n = 15). Diffuse stenosis was noted in 95 vessels (54%), and tubular stenosis was noted in 71 vessels (40.3%). Diffuse or long lesions refer to lesions more than 20 mm, tubular stenosis refers to lesions which are 10–20 mm and discrete lesions refer to lesions which measure less than 10 mm. Though 61.4% of the patients had type B2 or type C lesions, out of which 10.2% were calcific lesions, none of them required rotablation and could be managed with a scoring balloon. In-stent restenosis was noted in one cases (0.6%) and tortuosity was noted in one case (0.6%). Cutting balloon/scoring balloon was required in 15 cases (8.5%). The lesion characteristics are presented in Table 3.

Overall, IVUS/OCT imaging was used in 20.45% of the cases, with a majority of the cases requiring the imaging guidance only during the initial learning period. After the initial learning period, IVUS/OCT imaging was used only at the sole discretion of the operator. Thus, subsequently, 78.98% of the cases were performed without

Table 2
Clinical presentation of study participants.

Presentation	Total number of patients; n = 142 (%)
Recent myocardial infarction	61 (43%)
Chronic stable angina/positive stress test	32 (22.5%)
Unstable angina	48 (33.8%)
ST-elevation myocardial infarction	37 (26.1%)
Non-ST-elevation myocardial infarction	21 (14.8%)
Multiple vessel disease	37 (26.1%)
Left ventricular dysfunction	56 (39.4%)
Left main vessel affected	00 (00%)

Table 3
Lesion characteristics.

Lesion characteristics	Number of patients (%)
De novo lesions	175 (99.4%)
B2 or C type of lesions	108 (61.4%)
Diffuse or long lesions	27 (15.3%)
Calcified lesion	18 (10.2%)
Chronic total occlusion	11 (6.3%)
Bifurcation lesion	7 (4%)
Ostial/LMCA lesion	0 (0%)
Lesion site	
Proximal LAD	46 (45.1%)
Mid LAD	54 (52.9%)
Distal LAD	5 (2%)
Proximal LCX	10 (43.5%)
Mid LCX	10 (43.5%)
Distal LCX	3 (13%)
Proximal RCA	10 (27%)
Mid RCA	21 (56.8%)
Distal RCA	6 (16.2)
Proximal OM	12 (80.0%)
PDA	1 (6.7%)
Mid PLV	1 (6.7%)
Mid ramus	1 (6.7%)
Bifurcation classification	
1,0,1	2 (1.1%)
1,1,1	5 (2.8%)
None	169 (96%)

LAD: Left anterior descending; LCX: Left circumflex; RCA: Right coronary artery; OM: Obtuse marginal branch; PDA: Posterior descending artery; PLV: Posterior left ventricular branch.

Table 1
Patient characteristics at baseline.

Characteristics	Total number of patients; n = 142 (%)
Age (years)	53.7 ± 11.8
Male	119 (83.8%)
Female	23 (16.2%)
Family history of coronary artery disease	9 (6.3%)
Previous history of percutaneous coronary intervention	2 (1.4%)
Previous history of coronary artery bypass grafting	1 (0.7%)
Hypertension	72 (50.7%)
Diabetes mellitus	59 (41.5%)
Dyslipidemia	11 (7.7%)
Primary percutaneous coronary intervention	37 (26.1%)
Ejection fraction	54% ± 9%

any imaging guidance. An overlap strategy was used in 29 cases, while most of the cases required no overlap strategy.

Only 5 lesions required provisional one-stent strategy as part of the bifurcation strategy. One hundred and seventy-five (81.8%) scaffolds required predilatation and 181 scaffolds (84.6%) required postdilatation. The ratio between the largest post-dilatation balloon at its maximum inflation pressure divided by reference vessel diameter was >0.9 in 176 vessels. The procedural characteristics are presented in Table 4. Anticoagulants were used in all the patients. Antiplatelets were used on loading as well as at discharge in all the patients. Wire-induced perforation was reported in one patient where 2 BVS were used in the LAD. This patient required pericardiocentesis and mechanical sealing of the perforation using a glue. Once this was done, the circumflex vessel was subsequently treated in the same setting. There were no other treatment-related complications.

The minimum scaffold length used was 12 mm, while the maximum length used was 28 mm. The other scaffold characteristics are presented in Table 5.

One hundred and forty patients completed the follow-up at 3 months, 127 patients completed follow-up at 6 months, and 110 patients completed follow-up at 12 months in the outpatient department. The median follow-up period was 395 days (ranging from 31 to 397 days). A 100% clinical follow up was recorded. Patients who were found to be symptomatic at follow up were subjected to a treadmill test. A CT angiography/conventional angiography was performed only in patients who had angina, or suspicion of angina, or who were positive for inducible reversible ischemia on treadmill test.

The in-hospitalization (acute) MACE rate was zero. One patient who received a BVS in the proximal LAD as primary PCI strategy for ST-elevation anterior wall myocardial infarction and was on ticagrelor was switched over to clopidogrel due to intolerance to ticagrelor (after a loading dose of clopidogrel) on the day of discharge (i.e. day 4). However, this patient presented to the emergency department with ST-elevation myocardial infarction, within 24 h of discharge. A check angiography confirmed scaffold thrombosis, which was again treated with balloon angioplasty (use of high pressure non-compliant balloon) and the patient was administered prasugrel; subsequently, the patient remained uneventful. There were no other complications reported at the 3-month or 6- month follow-up visit. One patient died in-hospital due to carcinoma of the colon after 8 months of BVS implantation. The treatment outcomes are presented in Table 6.

4. Discussion

Our study demonstrated that the use of Absorb BVS is associated with low MACE rates at immediate and medium-term follow-up visits. We achieved 99.3% device success and 100% procedural success. These results can be attributed to several reasons (Box 1). Coronary artery disease is associated with significant morbidity and mortality in both developed and developing countries. In India, CAD is the leading cause of mortality. Indians are affected by CAD at a younger age compared to their western counterparts.[8] Given that CAD exerts a profound impact on morbidity and mortality, it is imperative to develop improved therapies for this condition.[3]

Bioresorbable vascular scaffolds were launched in India in December 2012. The method of implanting the BVS was a learning curve across Europe and India during the initial period. The BVS scaffolds offer several advantages over the bare metal stents, including reduction in late luminal enlargement and late or very late stent thrombosis and restoration of vasomotion and adaptive shear stress. They also facilitate non-invasive assessment of coronary arteries during follow-up since the metallic stents are associated with the production of excessive artefacts. Additionally, if required, coronary percutaneous or surgical revascularization can be performed in the future since the BVS scaffolds do not leave behind a metallic cage once they are completely resorbed.[9]

Majority of evidence on BVS is from studies which have used the Absorb BVS.[10] Globally, more than 1,50,000 patients have been treated with the Absorb BVS.[11] The Absorb cohort A and cohort B of the first-in-man Absorb trials have demonstrated the safety and performance of the Absorb BVS system.[12] After initial encouraging results from the Absorb cohort A and cohort B trials, several registries and randomized trials have been conducted.[10] The Absorb II was a single-blind, multicenter, randomized trial that compared the Absorb BVS with a metallic everolimus-eluting stent. According to an interim 1-year analysis of the Absorb II study, the secondary clinical outcomes (cardiac death, all myocardial infarction, clinically indicated target-vessel revascularization) of the Absorb BVS were similar to that of its metallic counterpart (5% vs. 5%, p = 0.78). The 1-year composite device-oriented endpoint (cardiac death, target-vessel myocardial infarction, or clinically indicated target-lesion revascularization) was similar between the Absorb BVS and the metallic stent group (5% vs. 3%, p = 0.35).[4] The preliminary report of the 12-month clinical outcomes in the first 512 patients enrolled in the Absorb EXTEND trial has reported an ischemia-driven MACE of 4.3% and ischemia-driven target vessel failure of 4.9%.[12] Another single-center study in India included a real-world population of patients with a high proportion of diabetes and complex lesions. The primary outcomes (cardiac death, target lesion failure, and myocardial infarction) with BVS implantation were 7.6% at 30 days and 9.8% at 1 year.[13]

The Gauging coronary Healing with biOresorbable Scaffolding plaTforms in EUrope (GHOST-EU) registry, which represents the largest contemporary registry of the Absorb BVS, has demonstrated

Table 4
Procedural characteristics.

Image-guided procedure	
Intravascular ultrasound	27 (15.34%)
OCT	9 (5.11%)
None	139 (78.98%)
Overlap strategy	
Distal first	26 (14.9%)
Proximal first	3 (1.7%)
None	146 (83.4%)
Bifurcation strategy	
Provisional one-stent	5 (2.9%)
None	170 (97.1%)

Table 5
Scaffold characteristics.[a]

Scaffold characteristics	Mean	SD	Median	Min	Max
Scaffold length	22.90	5.8	28	12	28
Reference vessel diameter (Yes/No)	3.1	0.4	3	2.5	3.5
Predilatation balloon length (mm)	14.7	6.9	15	10	27
Predilatation balloon diameter (mm)	2.9	1.2	3	2	3.5
Predilatation balloon pressure (atm)	14.5	6.3	14	6	28
Pre-procedure % DS	86.3	10.5	90	70	100
ABS length (mm)	22.9	5.8	28	12	28
ABS diameter (mm)	3.1	0.4	3	2.5	3.5
Maximum diameter (mm)	3.2	0.4	3.25	2.5	4
ABS pressure (atm)	13.7	3.0	14	9	19
Postdilatation balloon length (mm)	14.3	6.8	15	8	27
Postdilatation balloon diameter (mm)	3.2	1.2	3	2.5	4
Postdilatation balloon pressure (atm)	18.0	7.6	18	10	30

[a] Post 1:1 dilatation, no one had >10% residual diameter stenosis.

Table 6
Treatment outcomes.

Follow-up	Follow-up completed	BVS-related MACE	Non BVS-related MACE	Comments
One month	141	1 (0.7%)	0	Patient developed scaffold thrombosis due to change from ticagrelor to clopidogrel; we suspect clopidogrel resistance
3 months	141	0	0	
6 months	136	0	2 (1.5%)	Angina due to ISR in metallic DES and not in BVS (BVS patent)
12 months or more	118	1 (0.8%)	3 (2.5%)	One BVS-related MACE: • ISR OF BVS in OM which was subsequently treated with metallic DES Three non BVS related MACE: • Target vessel failure of LAD, patent BVS in proximal LAD, new mid-LAD lesion at 16 months was treated with a metallic DES • Previously received 2 BVS, one in LAD and one in RCA; LAD patent BVS, RCA target vessel failure, proximal RCA patent BVS, new distal RCA was treated with a metallic DES • One patient died due to carcinoma of the colon after 8 months of BVS implantatio

Box 1. Probable reasons contributing to low MACE rates.

1. Appropriate selection of patients and proper assessment of lesion characteristics: After the initial experience with BVS and abundant use of imaging modalities, we selected younger patients. We excluded highly calcified lesions and complex bifurcation lesions which require a two-stent strategy. We also excluded ostial lesions since according to our initial learning with the device, the radial strength of the BVS may not be sufficient for ostial lesions. None of our patients received a scaffold which was smaller than the vessel size. For e.g. There was no single case of a left main PCI as we believe that a 3.5 mm scaffold (the maximum size of Absorb BVS available in the market), is inadequate for a left main which usually has a diameter >4 mm. We performed pre-dilatation and post-dilatation in majority of the cases; and cases which did not require pre- and post-dilatation were mainly primary PCI situations. We performed direct stenting without pre-dilatation only in young patients who presented with myocardial infarction with a large thrombus burden due to plaque rupture.
2. Use of imaging during the initial learning curve: During the initial learning curve, we received a lot of anecdotal cases from our colleagues about scaffold thrombosis. We believe inadequate lesion preparation/inappropriate sizing (i.e. smaller scaffold for a bigger lesion) prior to implantation contributes to majority of the cases of scaffold thrombosis. Given that ours is an IVUS-experienced center, we used IVUS imaging initially to avoid such mistakes. Subsequently, with experience, we gained eyeball sizing that matches the IVUS sizing.
3. All patients received either ticagrelor or prasugrel in addition to aspirin; none of the patients received clopidogrel: One patient however was changed to clopidogrel due to intolerance to ticagrelor (developed skin rash) and was therefore changed to clopidogrel with a loading dose of clopidogrel. However, this patient presented with a scaffold thrombosis within 24 h, and subsequently clopidogrel was changed to prasugrel.
4. Training of the catheterization laboratory personnel in addition to doctors: In general, each BVS implantation was planned well in advance by the catheterization laboratory personnel and doctors. None of the cases were performed in a hurry, which is the usual practice in high-volume centers. Sufficient planning and discussion amongst the attending laboratory personnel and doctors may have eliminated the risk of underdoing a BVS implantation.

higher MACE rates when compared to findings from small, randomized trials.[14] The GHOST-EU registry included 1189 patients who underwent PCI with one or more BVS at 10 European centers and reported a cumulative incidence of target lesion failure of 2.2% at 30 days and 4.4% at 6 months. The annualized rate of target lesion failure was high at 10.1%. Pre-dilation was performed in 98% of cases, while post-dilation was performed in only 49% of lesions.[15] During a mean follow-up of 211 ± 136 days, the rates of MACE were higher among patients who had possible BVS undersizing (7.9% vs. 4.6%; p = 0.015). As per the multivariate Cox regression, BVS undersizing (Hazard ratio [HR] 2.65, 95% CI: 1.27–5.53, p = 0.009) and number of implanted scaffolds (HR 1.33, 95% CI: 1.04–1.70, p = 0.024) were independent predictors of MACE, with a significant trend also emerging for diabetes mellitus (HR 1.93, 95% CI: 0.98–3.79, p = 0.056).[14] The high MACE rates could also be attributed to lack of consistent use of Absorb optimal implantation techniques across various centers participating in the trial.[11] Furthermore, there was a clustering of definite/probable scaffold thrombosis during the early period (1.5% at 30 days) suggesting the need for scrupulous lesion selection and optimal implantation techniques, and the need for systematic post-implantation assessment.[11,14] Shortly after the GHOST-EU data were published, several physicians who were part of the GHOST-EU registry published a paper detailing the standard operating protocol for use of Absorb BVS. This paper, which was intended to serve as a practical guide for new users of Absorb, focused on the use of intravascular imaging or use of pre-dilatation balloon for appropriate vessel sizing, good lesion preparation and use of high pressure post-dilatation with a non-compliant balloon.[11]

The low MACE rates noted in our study are in contrast with the high MACE rates observed in the GHOST-EU registry. Although there could be several reasons for the contrasting findings, the positive outcomes in our study could be attributed to meticulous lesion preparation, accurate sizing of the scaffolds, and prior experience with IVUS imaging for appropriate scaffold expansion. It is notable that such excellent outcomes could be achieved despite the several technical limitations associated with bioresorbable scaffolds, such as low radial support, poor visualization and deliverability, larger strut size, and complex implantation technique.[16]

A study of BVS implantation using imaging (IVUS/OCT) along with an OCT/multi-slice computed tomography follow up of long lesions treated with overlapped scaffolds is being considered as a part of multicentric evaluation in India. This is expected to further

provide insights to better comprehend this technology for long-term outcomes.

5. Conclusion

The use of Absorb BVS in this real-world population is associated with low acute MACE rates and good medium-term clinical outcomes. Future randomized controlled trials using DES as a comparator will provide more insights on the role of BVS in the real-world scenario to improve PCI outcomes.

Conflict of interest

None.

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