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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 $\geq$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%

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