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ORIGINAL ARTICLE

Everolimus-eluting Bioresorbable Vascular Scaffold Implantation in Real World and Complex Coronary Disease: Procedural and 30-day Outcomes at Two Australian Centres

Daniel Robaei, FRACP [a,b,c*], Liam M. Back, MBBS [a], Sze-Yuan M. Ooi, FRACP [a,c], Mark R. Pitney, FRACP [a,b,c], N. Jepson, FRACP [a,c]

[a]Eastern Heart Clinic, Prince of Wales Hospital, Sydney, Australia
[b]Sutherland Heart Clinic, Sutherland Hospital, Sydney, Australia
[c]University of New South Wales, Sydney, Australia

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Background The Absorb BVS is a new generation of coronary stent designed to provide coronary arteries with mechanical support of a temporary nature, following balloon angioplasty. Clinical trials of the device have shown promising results thus far, however concern surrounds the deliverability of the device in real-world and complex coronary disease, and the possible higher incidence of early scaffold thrombosis when compared to conventional metallic drug-eluting stents.

Methods Implantation of the Absorb BVS was attempted in 152 lesions in 100 patients at two Sydney teaching hospitals, as part of a prospective registry. Lesions treated reflected a wide spectrum of real-world disease. Young patient age, long lesion length and involvement of the mid-portion of the left anterior descending artery were the strongest factors likely to influence the decision to use the Absorb BVS over conventional metallic stents. There were no restrictions on the lesion length, or on the number of lesions or vessels treated. Type C lesions made up 37% of all lesions treated with 64% of these being long lesions (>20mm). The Absorb BVS was successfully implanted in 98.8% of cases. Post-dilatation was performed in 95% of scaffolds. Peri-procedural non-ST elevation myocardial infarction occurred in four cases. Scaffold thrombosis did not occur in any patient at 30 days follow-up. There was no death, or need for target lesion revascularisation in-hospital or at 30 days.

Conclusions High rates of procedural success were achieved with minimal complications with use of the Absorb BVS in real-world coronary disease, including complex disease. These results suggest that the reduced deliverability of the device can be largely overcome by meticulous lesion preparation, and that early scaffold thrombosis may be minimised through scaffold post-dilatation.

Keywords Coronary artery disease • Percutaneous coronary intervention • Bioresorbable scaffolds • Drug-eluting stents

*Corresponding author at: Eastern Heart Clinic, Prince of Wales Hospital, Barker St, Randwick NSW 2031 AUSTRALIA. Tel.: +612 93820700; fax: +612 93820799, Email: daniel.robaei@unsw.edu.au

Introduction

Permanent metallic stents have significantly improved outcomes following percutaneous coronary intervention (PCI) when compared to balloon angioplasty alone [1]. The Absorb bioresorbable vascular scaffold (BVS) has been developed as an alternative to a permanent metallic stent, to provide temporary mechanical support to coronary arteries with drug delivery capability following balloon angioplasty. The Absorb BVS consists of a framework of poly-L-lactide (PLLA) struts coated with a thin layer of poly-D, L-lactide (PDLLA) polymer containing the anti-proliferative drug everolimus [2]. Over time the PLLA and PDLLA components of the BVS are hydrolysed to lactic acid resulting in complete resorption of the device in approximately two to three years. Polylactide polymers have been safely used for many years in a wide range of medical applications including bioresorbable sutures, surgical mesh, and orthopaedic plates and screws [3]. The dose and release rate of everolimus integrated into the BVS is the same as that for the Xience V metallic stent, shown to be effective in reducing the incidence of in-stent re-stenosis [4,5].

The Absorb BVS was investigated in the Absorb Cohort A and B studies and found to be safe and effective with low rates of major adverse cardiac events (MACE) during follow-up [2,6–8]. Alterations in scaffold design in the revision 1.1 device first used in the Absorb Cohort B study increased the duration of radial support, while maintaining the same strut thickness of 150 µm, resulting in improved luminal late loss compared to the original 1.0 device [6]. The Absorb EXTEND trial broadened the use of the device to include target vessel diameters of 2.0-3.3mm as well as longer lesions (up to 28mm). The Absorb device was found to be safe and effective with high rates of device success and low rates of MACE in follow-up to date [9].

While the performance of the Absorb device in these early studies has been promising, data evaluating the device in real-world and complex disease subgroups has, until recently, been limited.

Since December 2010 our two sites in Sydney have utilised the Absorb 1.1 BVS for coronary revascularisation. As experience with use of the device has increased its use has been expanded to include complex coronary disease previously excluded from trials of the device.

Methods

Use of the Absorb BVS at our two centres was undertaken as part of a Human Ethics Research Committee approved single-arm, prospective, open-label registry of a nationally non-approved device. Specific written informed consent was provided by all enrolled patients. All patients in whom treatment with a BVS was attempted at our institutions between December 2010 and October 2013 are included in this series. Patient and lesion complexity for BVS implantation occurred at the discretion of the interventionalist and featured a wide spectrum reflecting real world clinical practice. Patients in whom a temporary bioresorbable scaffold was thought to provide the most theoretical advantage in comparison to a permanent metallic stent were preferentially selected. This included younger patients (<70 yrs), patients with long segment disease (>28mm), those with disease involving the mid-portion of the LAD (the site of future attachment of a left internal mammary artery graft) and a life expectancy of at least five years. No limits were set on the number of treated vessels or lesions, or on the lesion length. Only the following factors were considered to preclude use of a BVS: in-stent re-stenotic lesions, extreme proximal vessel tortuosity, extreme calcification, residual unexpanded lesion >50% after preparation, contraindication to prolonged dual antiplatelet therapy, or high likelihood of non-compliance with dual antiplatelet therapy, planned major surgery within six months, and participation in another trial. Target vessels treated were required to be compatible with the available scaffold sizes, specifically 2.5, 3.0 or 3.5mm diameter scaffolds in 18mm or 28mm length, or 3.5mm diameter scaffolds in a shorter 12mm length.

Procedures

The Absorb BVS, an everolimus-eluting bioresorbable stent, by Abbott Vascular (Santa Clara CA, USA) was used for revascularisation of de novo disease in the setting of stable angina or acute coronary syndrome.

Patients were pre-treated with aspirin and a P2Y12 inhibitor. Full anti-coagulation was obtained during intervention with use of unfractionated heparin or bivalirudin. The PCI strategy and use of GPIIb/IIIa inhibitors was left to the discretion of the interventionalist. Lesion pre-dilation was considered mandatory and aggressive vessel preparation prior to scaffold deployment was strongly advocated. Deployment of the scaffold was undertaken using the manufacturer's recommendation of 2 atm pressure increase every five seconds. Scaffolds were to cover 2mm of non-diseased vessel proximal and distal to the target lesion. Intracoronary imaging (OCT or IVUS) was non-mandated and performed at the operator's discretion. Dual antiplatelet therapy with aspirin combined with clopidogrel, prasugrel or ticagrelor was prescribed in all patients on discharge with a plan to continue for a minimum duration of 12 months.

Outcomes

In-hospital and 30-day outcome data were collected via review of clinical notes, reporting by the treating cardiologist, phone call follow-up, and completion of a patient questionnaire. Clinical endpoints assessed were the need for target and non-target lesion revascularisation, scaffold thrombosis (definite/probable/possible), and cardiac death as defined by the Academic Research Consortium criteria [10] as well as myocardial infarction as defined by the more recent universal criteria [11]. Post-procedure troponin levels were routinely measured on day 1 by means of a high sensitivity assay.