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PERIPHERAL

Experience With the Absorb Everolimus-Eluting Bioresorbable Vascular Scaffold in Arteries Below the Knee

12-Month Clinical and Imaging Outcomes

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ABSTRACT

OBJECTIVES The aim of this study was to investigate the midterm performance of an everolimus-eluting, bioresorbable vascular scaffold (Absorb, Abbott Vascular, Santa Clara, California) for the treatment of focal tibial and distal popliteal lesions.

BACKGROUND Drug-eluting stents are used below the knee to improve technical success and durability, but the ongoing presence of a permanent metal scaffold may have deleterious effects on the local vessel.

METHODS Tibial and distal popliteal angioplasty with scaffold placement was performed using an everolimus-eluting, bioresorbable scaffold (Absorb). Clinical and ultrasound follow-up was performed at 1, 3, 6, 12, and 24 months to detect binary restenosis and evaluate safety, restenosis, and clinical improvement.

RESULTS Thirty-eight limbs in 33 patients were treated for critical limb ischemia (68.4%) or severe claudication (31.6%). Fifty scaffolds were used to treat a total of 43 lesions, with a mean length of 19.2 ± 11.6 mm. During a mean follow-up period of 12.0 ± 3.9 months, 5 patients died, and all others were available for follow-up. Among the 38 treated limbs, clinical improvement was present in 30 (79%). Binary restenosis was detected in 3 of 50 scaffolds (6%). Using the Kaplan-Meier method, rates of primary patency were 96% and 84.6% at 12 and 24 months, respectively, and rates of freedom from clinically driven target lesion revascularization were 96% and 96% at 12 and 24 months, respectively. Complete wound healing occurred in 64% of those treated for tissue loss, with no major amputation and a limb-salvage rate of 100%.

CONCLUSIONS Twelve-month follow-up demonstrated excellent safety, patency, and freedom from target lesion revascularization using the Absorb bioresorbable vascular scaffold below the knee. (J Am Coll Cardiol Intv 2016;9:1721–8) © 2016 by the American College of Cardiology Foundation.

Drug-eluting stents (DES) are effective for the treatment of Inter-Society Consensus for the Management of Peripheral Arterial Disease types A and B atherosclerotic arterial disease below the knee, reducing both abrupt closure and restenosis rates in the midterm (1–4). However, the metallic implant has several detrimental effects on the vessel wall, which include the permanent prevention of vasomotion, autoregulation, and adaptive remodeling. Moreover, there is a

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ABBREVIATIONS AND ACRONYMS

BVS = bioresorbable vascular scaffold

CLI = critical limb ischemia

DES = drug-eluting stent(s)

PLLA = poly-L-lactic acid

PTA = percutaneous transluminal angioplasty

TLR = target lesion revascularization

recognized risk for late target vessel failure that may result from incomplete endothelialization, stent fracture, or malapposition (5,6). Even with preserved patency, metallic stents may cause artifacts on noninvasive imaging and act as impediments to future revascularization attempts if required, issues that may be avoided through the use of a fully bioresorbable scaffold.

The Absorb bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, California) has similar mechanical scaffolding and antiproliferative properties to current-generation DES. However, following revascularization and vessel wall stabilization, it is resorbed by the body through the inert process of hydrolysis. The resorbable nature of the device gives it significant potential for positive blood vessel wall remodeling, stabilization of the atheromatous plaque, and return of contractile function, a new paradigm of vascular restorative therapy.

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Following encouraging results from coronary studies (7,8) and our previous published work in the periphery (9), the aim of this study was to examine the midterm performance efficacy of the Absorb BVS in de novo atherosclerotic lesions of arteries below the knee.

METHODS

This single-center study was designed to prospectively evaluate the treatment of patients with chronic lower limb ischemia. It was undertaken to obtain performance data for the treatment of distal popliteal and tibial stenotic lesions treated with an everolimus-eluting BVS system (Absorb). Special access was obtained for the use of the unapproved device through the Australian Therapeutic Goods Administration for 3 attending vascular specialists at our institution. The human research and ethics committee executive assessed and approved the proposed study. All patients provided written informed consent for the procedure, and procedural and demographic data were collected prospectively in an electronic database (Excel 2007, Microsoft Corporation, Redmond, Washington).

INCLUSION AND EXCLUSION CRITERIA. Patients were considered suitable for treatment with a BVS if they had chronic lower limb ischemia (Rutherford-Becker classes 3 to 6) from de novo stenotic lesions >60% of the tibial or distal popliteal arteries with length ≤5 cm and vessel diameters of 2.5 to 4.0 mm in which significant inflow stenoses had been successfully treated, and if they had at least 1 single-vessel outflow to the foot, including that distal to the target lesion.

Patients were excluded if they or their next of kin were unable to give informed consent, they had life expectancy <12 months, they had significant contrast allergy or renal impairment that precluded angiography, or they were known to be intolerant to dual-antiplatelet therapy. Calcified lesions were not excluded.

STUDY DEVICE: THE BVS. The BVS consists of a poly(L-lactic acid) (PLLA) structure coated with a 7-μm poly(D,L-lactide) polymer that controls the release of the antiproliferative drug everolimus at a concentration of 100 μg/mm^2. Both structure and polymer are fully biodegradable. The drug dose density and elution profile are identical to that of the XIENCE Prime DES (Abbott Vascular). As reported previously, the long chains of poly(D,L-lactide) and PLLA are progressively shortened as ester bonds between lactide repeat units are hydrolyzed, and toward the end of the resorption process, small particles <2 μm in diameter are phagocytosed by macrophages (10). Ultimately, both PLLA and poly(D,L-lactide) degrade to lactic acid and are metabolized through the Krebs cycle to form carbon dioxide and water. The design of the current-generation BVS used in this study is shown in **Figure 1** and consists of circumferential hoops connected to one another by straight bridges. The Absorb BVS struts are 157 μm thick, and the scaffold lengths are 4-fold: 8, 18, 23, and 28 mm. Diameters range in 0.5-mm increments between 2.5 and 3.5 mm and can be safely post-dilated 0.5 mm beyond their nominal diameter.

PROCEDURAL DETAIL. All procedures were performed by 1 of 3 endovascular specialists experienced in peripheral intervention. Patients were pre-loaded for at least 1 week with both aspirin (100 mg/day) and clopidogrel (75 mg/day) or alternatively given a loading dose of 300 mg aspirin and 300 mg clopidogrel at the time of the procedure if they were medication naive. After diagnostic angiography, intravenous heparin administration (70 IU/kg), and the treatment of any inflow stenoses, a long sheath was positioned to the level of the knee joint. Each target lesion underwent mandatory pre-dilation with a noncompliant angioplasty balloon (NC Trek, Abbott Vascular), which was chosen to match the size of the disease-free vessel proximal and distal to the lesion. Up to 2 (abutting) balloon-mounted bioresorbable scaffolds were then implanted to treat each suitable lesion according to the manufacturer's instructions for use (**Figure 2**). This involved a slow inflation of 2 atm every 5 s to the desired pressure and related