JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. ■, NO. ■, 2017

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER
https://doi.org/10.1016/j.jacc.2017.09.1106

Effect of Technique on Outcomes Following Bioresorbable Vascular Scaffold Implantation

Analysis From the ABSORB Trials

Gregg W. Stone, MD,[a,b] Alexandre Abizaid, MD,[c] Yoshinobu Onuma, MD, PhD,[d] Ashok Seth, MD,[e] Runlin Gao, MD,[f] John Ormiston, MD,[g] Takeshi Kimura, MD,[h] Bernard Chevalier, MD,[i] Ori Ben-Yehuda, MD,[a,b] Ovidiu Dressler, MD,[b] Tom McAndrew, PhD,[b] Stephen G. Ellis, MD,[j] Dean J. Kereiakes, MD,[k] Patrick W. Serruys, MD, PhD[l]

ABSTRACT

BACKGROUND Procedural technique may affect clinical outcomes after bioresorbable vascular scaffold (BVS) implantation. Prior studies suggesting such a relationship have not adjusted for baseline patient and lesion characteristics that may have influenced operator choice of technique and outcomes.

OBJECTIVES This study sought to determine whether target lesion failure (TLF) (cardiac death, target-vessel myocardial infarction, or ischemia-driven target lesion revascularization) and scaffold thrombosis (ScT) rates within 3 years of BVS implantation are affected by operator technique (vessel size selection and pre- and post-dilation parameters).

METHODS TLF and ScT rates were determined in 2,973 patients with 3,149 BVS-treated coronary artery lesions from 5 prospective studies (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, and ABSORB Extend). Outcomes through 3 years (and between 0 to 1 and 1 to 3 years) were assessed according to pre-specified definitions of optimal technique (pre-dilation, vessel sizing, and post-dilation). Multivariable analysis was used to adjust for differences in up to 18 patient and lesion characteristics.

RESULTS Optimal pre-dilation (balloon to core laboratory-derived reference vessel diameter ratio ≥1:1), vessel size selection (reference vessel diameter ≥2.25 mm and ≤3.75 mm), and post-dilation (with a noncompliant balloon at ≥18 atm and larger than the nominal scaffold diameter, but not by >0.5 mm larger) in all BVS-treated lesions were performed in 59.2%, 81.6%, and 12.4% of patients, respectively. BVS implantation in properly sized vessels was an independent predictor of freedom from TLF through 1 year (hazard ratio [HR]: 0.67; $p = 0.01$) and through 3 years (HR: 0.72; $p = 0.01$), and of freedom from ScT through 1 year (HR: 0.36; $p = 0.004$). Aggressive pre-dilation was an independent predictor of freedom from ScT between 1 and 3 years (HR: 0.44; $p = 0.03$), and optimal post-dilation was an independent predictor of freedom from TLF between 1 and 3 years (HR: 0.55; $p = 0.05$).

CONCLUSIONS In the present large-scale analysis from the major ABSORB studies, after multivariable adjustment for baseline patient and lesion characteristics, vessel sizing and operator technique were strongly associated with BVS-related outcomes during 3-year follow-up. (ABSORB II Randomized Controlled Trial [ABSORB II]; NCT01425281; ABSORB III Randomized Controlled Trial [RCT] [ABSORB-III]; NCT01751906; A Clinical Evaluation of Absorb Bioresorbable Vascular Scaffold [Absorb BVS] System in Chinese Population—ABSORB CHINA Randomized Controlled Trial [RCT] [ABSORB CHINA]; NCT01923740 ABSORB EXTEND Clinical Investigation [ABSORB EXTEND]; NCT01023789 AVJ-301 Clinical Trial: A Clinical Evaluation of AVJ-301 [Absorb BVS] in Japanese Population [ABSORB JAPAN]; NCT01844284) (J Am Coll Cardiol 2017;■:■–■)

From the [a]New York Presbyterian Hospital, Columbia University Medical Center, New York, New York; [b]The Cardiovascular Research Foundation, New York, New York; [c]Instituto de Cardiologia Dante Pazzanese, Sao Paulo, Brazil; [d]Thoraxcenter, Erasmus Medical Center and Cardialysis, Rotterdam, the Netherlands; [e]Fortis Escorts Heart Institute, New Delhi, India; [f]Fu Wai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences, Beijing, China; [g]University of Auckland School

ABBREVIATIONS AND ACRONYMS

BVS = bioresorbable vascular scaffold(s)

DES = drug-eluting stent(s)

ILSD = intraluminal scaffold dismantling

PSP = optimal pre-dilation, vessel and device sizing, and post-dilation

ScT = scaffold thrombosis

TLF = target lesion failure

Bioresorbable vascular scaffolds (BVS) are intended to provide early mechanical support and antiproliferative drug delivery similar to metallic drug-eluting stents (DES), but then completely resorb within several years, normalizing vascular adaptive responses and improving late outcomes (1). The poly-L-lactic acid-based everolimus-eluting Absorb BVS (Abbott Vascular, Santa Clara, California) was the first scaffold to be approved in both the United States and European Union, and is the most widely used resorbable device with approximately 150,000 coronary implants globally to date. Randomized trials and observational registries performed in patients undergoing percutaneous coronary intervention have demonstrated higher 1-year and midterm rates of device thrombosis and adverse events with Absorb compared to contemporary DES (2-6), leading to reduced device use and the recent decision by the manufacturer to halt production. However, most early protocols emphasized a cautious approach to BVS implantation to avoid strut fracture (7-9). Recent studies have suggested that adverse events after BVS may be more frequent with either undersizing or oversizing the scaffold relative to the vessel diameter, as well as with implantation in small vessels and suboptimal angiographic results (10,11). This has led to the concept of "PSP" (optimal *p*re-dilation, vessel and device *s*izing, and *p*ost-dilation) to optimize BVS outcomes (12). However, the criteria for PSP have varied from study to study, and prior investigations of the relationship between PSP and BVS results have not adjusted for baseline patient and lesion characteristics, which may have influenced operator choice of technique and outcomes (11-14). In addition, the effect of a specific technique may vary before 1 year (the period during which strut endothelialization occurs and neointimal hyperplasia develops) and between 1 and 3 years (just prior to complete scaffold bioresorption, and during which structural discontinuities are more likely to clinically manifest).

We therefore performed a comprehensive analysis of the effect of procedural technique on early and late BVS outcomes from the ABSORB clinical trials.

METHODS

The present study represents an academic collaboration between the study chairs and principal investigators of the ABSORB II, ABSORB Japan, ABSORB China, and ABSORB III randomized trials, as well as the ABSORB Extend nonrandomized registry (15-19). The study designs for the 4 randomized trials have been recently summarized (3), and the ABSORB Extend protocol has been described (19). The number of sites, number of patients, and principal lesion and vessel inclusion criteria for the 5 studies are shown in Online Table 1. Each study was performed after institutional review board or ethics committee approval, and all patients signed informed, written consent.

The data from the 5 studies were pooled at the Cardiovascular Research Foundation. The present analysis population consists of all patients treated with the first-generation BVS. At the time of the present report, clinical follow-up is complete through 3 years in all 5 studies. The sponsor (Abbott Vascular) provided funding for the present analyses, but was otherwise uninvolved in data analysis or manuscript preparation.

DEFINITIONS AND ANALYSIS PLAN. Prior to any data analysis, the investigators pre-specified by consensus the parameters to define optimal technique. Given the availability of Absorb scaffold sizes during enrollment of these studies, and consistent with the protocol directives, optimal vessel sizing was pre-specified to be present when the reference vessel diameter (RVD) of the target lesion was ≥2.25 mm

of Medicine, Auckland, New Zealand; [h]Kyoto University Hospital, Kyoto, Japan; [i]Institut Cardiovasculaire Paris Sud, Massy, France; [j]Cleveland Clinic, Cleveland, Ohio; [k]The Christ Hospital, Heart and Vascular Center, Lindner Research Center, Cincinnati, Ohio; and the [l]International Centre for Circulatory Health, National Heart and Lung Institute, Imperial College London, London, United Kingdom. Dr. Stone is a consultant for Reva Medical; and his employer, Columbia University, receives royalty payments from Abbott Vascular for sale of the MitraClip. Dr. Abizaid has received research grants from Abbott Vascular, Elixir Medical, Reva Medical, and Meril Life Science. Drs. Onuma, Seth, Chevalier, and Serruys have served as consultants to and/or as members of the advisory board of Abbott Vascular. Dr. Seth has received a minor speaking honorarium from Abbott Vascular. Dr. Gao has received a research grant from Abbott Vascular. Dr. Ormiston has served as a consultant to Boston Scientific; and has received minor honoraria from Boston Scientific. Dr. Kimura has received research grants from Abbott Vascular. Dr. Ellis has served as a consultant to Abbott Vascular, Boston Scientific, and Medtronic; and has received research funding from Abbott Vascular. Dr. Kereiakes has served as a consultant to Boston Scientific, Abbott Vascular, Svelte Medical Systems, Inc., Micell Technologies, Inc., and Sino Medical Sciences Technology, Inc. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received September 8, 2017; revised manuscript received September 25, 2017, accepted September 26, 2017.