procedural characteristics between the 3 groups. Well-established confounding factors such as diabetes mellitus II, ostial lesions, and lesion length emerged have predictors of adverse events at the multivariate analysis and, obviously, were significantly more frequent in patients treated with ≥60 mm of BVS. Third, this finding is not new. A recent study showed that patients and lesions complexity impact on major adverse cardiac events (MACE) in patients treated with new-generation drug-eluting stents (DES) exactly in the same way (2). As correctly showed by authors in Table 6, the MACE rate in the ≥60-mm group is superimposable with one of the previous trials with DES. Thus, the difference in the outcome is attributable to patient and lesion complexity rather than to the use of a specific device.

A really important issue raised by authors is the unacceptably high rate of scaffold thrombosis (3.8% at 1 year) in the ≥60-mm group. Their worrisome results have been recently reinforced by presented and published data (3,4) confirming that BVS are more prone to device thrombosis than DES are. However, we have no information on how overlap was performed in the study and no standard implantation technique was implemented (namely aggressive pre-dilatation, sizing, post-dilatation). Previously published data have shown that with a systematic correct implantation technique imaging-guided, overlapping BVS could be comparable to second-generation DES (5).

In conclusion, we think that given the recent amount of worrisome results on BVS, it is of paramount importance to wait for a greater body of evidence coming from big populations with standardized procedures rather than to raise further question marks on small unmatched populations.

*Simone Biscaglia, MD
Gianluca Campo, MD
*Cardiovascular Institute
Medical Sciences Department
Azienda Ospedaliero-Universitaria S. Anna
Via Aldo Moro 8
44124 Cona, Ferrara
Italy
E-mail: bscsmn@unife.it

http://dx.doi.org/10.1016/j.jcin.2017.04.001

Please note: Both authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Geraci S, Kawamoto H, Caramanno G, et al. Bioresorbable everolimus-eluting vascular scaffold for long coronary lesions: a subanalysis of the international, multicenter GHOST-EU registry. J Am Coll Cardiol Intv 2017;10:560–8.

2. Koskinas KC, Taniwaki M, Rigamonti F, et al. Impact of patient and lesion complexity on long-term outcomes following coronary revascularization with new-generation drug-eluting stents. Am J Cardiol 2017;119:501–7.

3. Wykrzykowska JJ, Kraak RP, Hofma SH, et al. Bioresorbable scaffolds versus metallic stents in routine PCI. N Engl J Med 2017 Mar 29 [E-pub ahead of print].

4. Ellis SG, Kereiakes DJ, Stone GW. Everolimus-eluting bioresorbable vascular scaffolds in patients with coronary artery disease: ABSORB III trial 2-year results. Presented at: American College of Cardiology Annual Scientific Session (ACC 2017); March 18, 2017; Washington, DC.

5. Biscaglia S, Ugo F, Ielasi A, et al. Bioresorbable scaffold vs. second generation drug eluting stent in long coronary lesions requiring overlap: a propensity-matched comparison (the UNDERDOGS study). Int J Cardiol 2016;208:40–5.

REPLY: Bioresorbable Everolimus-Eluting Vascular Scaffold for Long Coronary Lesions

A Subanalysis of the International, Multicenter GHOST-EU (Gauging coronary Healing with bioresorbable Scaffolding plaTforms in EUrope) Registry

Drs. Biscaglia and Campo argue against the conclusions of our study that "treatment of very long coronary lesions (scaffold length ≥60 mm) with BVS [bioresorbable vascular scaffolds] was associated with a high target lesion failure [TLF] rate" (1). Indeed, the rate of TLF at 12 months in our study was as high as 14.3%. In their letter, Biscaglia and Campo raise a number of "straw man" arguments, refuting conclusions we did not advance. This is particularly reflected in their observation that the difference in the outcomes of longer and shorter lesions with BVS in our study was "attributable to patients and lesions complexity rather than to the use of a specific device," the latter being an interpretation we did not even consider in our report, because of lack of a drug-eluting stent (DES) comparator. The comparative efficacy of BVS and DES in long lesions is a question for ongoing randomized clinical studies (i.e., ABSORB-LONG [Everolimus-Eluting Bioresorbable Scaffolds Versus Everolimus-Eluting Metallic Stents for Diffuse Long Coronary Artery Disease; NCT02831205], Compare Absorb [ABSORB Bioresorbable Scaffold vs. Xience Metallic Stent for Prevention of Restenosis in Patients at High Risk of Restenosis; NCT02486068]).

GHOST-EU (Gauging Coronary Healing With Bioresorbable Scaffolding Platforms in Europe) was an early experience with the Absorb BVS in a large, real-world population (2). The retrospective and multicenter nature of the registry, with absence of a pre-specified implantation technique, implied substantial differences in scaffold implantation techniques and imaging use among the centers. To support the concept that treatment of long lesions with overlapping BVS achieves outcomes comparable

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10, NO. 12, 2017
JUNE 26, 2017:1273–9

with DES when using systematic implantation technique and imaging guidance, Biscaglia and Campo reference their published registry of 162 patients treated with BVS matched with DES control subjects (UNDERDOGS) (3), but they should note that in that study, the mean scaffold length was on average 30 mm shorter than in our group of lesions with scaffold length ≥60 mm (54 ± 15 mm vs. 85.9 ± 7.2 mm, respectively), preventing any meaningful comparison. Conversely, consistent with the UNDERDOGS study, overlapping BVS did not appear to have an impact on clinical outcomes of GHOST-EU patients compared with no-overlapping bioresorbable scaffolds (4), and the rate of TLF in patients with scaffold lengths between 30 and 60 mm was more reassuring (4.5%). Accordingly, we reiterate our conclusion that "treatment of very long coronary lesions (scaffold length ≥60 mm) with BVS was associated with a high TLF rate" (1). Whether this is the consequence of issues related to patient selection, implantation technique, or the device itself cannot be addressed by our or the UNDERDOGS study and is open to future investigations.

*Salvatore Geraci, MD
Hiroyoshi Kawamoto, MD
Davide Capodanno, MD
Giuseppe Caramanno, MD
Azeem Latib, MD

*San Giovanni di Dio Hospital
Interventional Cardiology
Contrada Consolida
92100, Agrigento
Italy
E-mail: dr.geraci.cardio@gmail.com

http://dx.doi.org/10.1016/j.jcin.2017.05.013

Please note: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

REFERENCES

1. Geraci S, Kawamoto H, Caramanno G, et al. Bioresorbable everolimus-eluting vascular scaffold for long coronary lesions: a subanalysis of the international, multicenter GHOST-EU registry. J Am Coll Cardiol Intv 2017;10:560–8.

2. Capodanno D, Gori T, Nef H, et al. Percutaneous coronary intervention with everolimus-eluting bioresorbable vascular scaffolds in routine clinical practice: early and midterm outcomes from the European multicentre GHOST-EU registry. EuroIntervention 2015;10:1144–53.

3. Biscaglia S, Ugo F, Ielasi A, et al. Bioresorbable scaffold vs. second generation drug eluting stent in long coronary lesions requiring overlap: a propensity-matched comparison (the UNDERDOGS study). Int J Cardiol 2016;208:40–5.

4. Ortega-Paz L, Capodanno D, Giacchi G. Impact of overlapping on 1-year clinical outcomes in patients undergoing everolimus-eluting bioresorbable scaffolds implantation in routine clinical practice: insights from the European multicenter GHOST-EU registry. Catheter Cardiovasc Interv 2017;89:812–8.

Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement

The introduction of transcatheter aortic valve replacement (TAVR) as an alternative to open surgery in high-risk patients has been increasing steadily across the United States since the Food and Drug Administration approval of the Edwards Lifesciences SAPIEN device (Edwards Lifesciences, Irvine, California) for inoperable patients in 2011 (1). As the use of this technology continues to expand, interest in the use of TAVR for treatment of intermediate- and low-risk patients with aortic stenosis has also grown. However, several complications associated with TAVR, such as the need for permanent pacemakers (PPMs), have not been fully evaluated and their long-term clinical consequences remain unclear.

The recent publication by Fadahunsi et al. (2) used a novel approach to answer this question by using the STS/ACC TVT (U.S. Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy) registry to identify 9,785 TAVR patients and the Centers for Medicare & Medicaid Services (CMS) database to follow patients through 1-year post-implantation. Their results indicate that PPM placement within 30 days post-TAVR is found in 6.7% of patients undergoing either balloon-expanding Edwards SAPIEN valve or self-expanding Edwards SAPIEN valve, and is associated with increased mortality and hospitalizations. This study also sought to understand the impact of PPMs in TAVR patients using CMS Medicare claims.

This study contains 14,305 TAVR patients whose index hospitalization occurred between January 2011 and December 2013. TAVR patients were identified using Common Procedural Terminology (CPT) codes, and PPMs were identified using previously validated International Classification of Diseases-9th Revision- Clinical Modification (ICD-9-CM) procedure codes present within 30 days post-TAVR. Using MEDPAR (Medicare Provider Analysis and Review) files, patient follow-up was recorded through December 2014. Similar to Fadahunsi et al. (2), patients with previous PPMs were excluded from this study.

The results of Fadahunsi et al. (2) indicate that 6.7% of all TAVR patients received PPMs within