Intraindividual Comparison of Everolimus-Eluting Bioresorbable Vascular Scaffolds Versus Drug-Eluting Metallic Stents

Salvatore Cassese, MD, PhD; Petra Hoppmann, MD; Sebastian Kufner, MD; Robert A. Byrne, MB, BCh, PhD; Jens Wiebe, MD; Roisin Colleran, MB, BCh; Daniele Giacoppo, MD; Yukinori Harada, MD; Karl-Ludwig Laugwitz, MD; Heribert Schunkert, MD; Massimiliano Fusaro, MD; Adnan Kastrati, MD

Background—The performance of everolimus-eluting bioresorbable vascular scaffold (BVS) versus drug-eluting metallic stent (DES) in the same individual receiving multilession percutaneous coronary intervention (PCI) remains poorly studied. This report investigates the intraindividual performance of BVS and DES in patients receiving multilession PCI and follow-up angiography.

Methods and Results—Data of patients undergoing BVS implantation for de novo lesions from 2012 to 2014 at 2 centers in Munich, Germany, were prospectively collected. Individuals receiving multilession PCI with BVS and DES and follow-up angiography at 6 to 8 months were studied. Primary end point was in-device late lumen loss. Secondary end points were binary restenosis, target lesion revascularization, and definite stent/scaffold thrombosis. A total of 90 PCI patients with 239 lesions received BVS (n=112) and DES (n=127). Follow-up angiography after a median of 6.6 months (5.8–7.1) showed a higher degree of late lumen loss in lesions treated with BVS versus DES (0.30±0.59 versus 0.22±0.48 mm; P=0.035). However, the adjustment for baseline angiographic imbalances discarded an influence of stent type on late lumen loss (P=0.82). At the same time point, binary restenosis was comparable between BVS and DES (7.8% versus 8.9%; P=0.90). After a median of 13.2 months (9.2–17.6), target lesion revascularization (9.8% versus 10.2%; P=0.97) and definite stent/scaffold thrombosis (2.7% versus 1.6%; P=0.48) did not differ between BVS and DES.

Conclusions—In patients receiving multilession PCI, BVS displays acceptable intraindividual performance compared with DES. Larger trials, extended follow-up, and continuous device iteration remain essential to improve BVS technology. (Circ Cardiovasc Interv. 2016;9:e003698. DOI: 10.1161/CIRCINTERVENTIONS.116.003698.)

Key Words: angiography ■ bioresorbable vascular scaffold ■ coronary artery disease ■ drug-eluting stent ■ everolimus ■ percutaneous coronary intervention

Guideline-writing authorities support the use of newer drug-eluting metallic stents (DES) as first-line revascularization option for patients with obstructive coronary artery disease (CAD) because of superior angiographic and clinical outcomes as compared with earlier stent platforms.1 Notwithstanding this, fully bioresorbable stents eluting antirestenotic drugs have emerged as a technology alternative to that of metallic DES.2

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Among bioresorbable stents, the everolimus-eluting bioresorbable vascular scaffold (BVS - Absorb; Abbott Vascular, Santa Clara, CA) has been the first platform approved for medical use in Europe.3 Preliminary data,4 and recent randomized trials suggest overall acceptable performance of BVS in comparison to that of DES.5

Studies comparing intrapatient differences in stent outcomes remain an important tool for assessing comparative device efficacy: indeed, by excluding the baseline variability between patients (not completely eliminated even with a random allocation), the intraindividual design offers the advantage of a net-effect analysis of treatments.6,7 Previous intraindividual studies of DES efficacy have generally shown similar outcomes to randomized trials comparing stents.6–8 However, angiographic and clinical outcomes of BVS and DES in the same individual receiving multilession percutaneous coronary intervention (PCI) have yet to be investigated.

Against this background, the current report investigated the intraindividual performance of BVS and DES in patients receiving routine surveillance angiography after multilession PCI.
WHAT IS KNOWN

• Recent randomized trials support the favorable outcome of bioresorbable vascular scaffold (BVS) in comparison to that of drug-eluting metallic stent (DES).
• The performance of BVS and DES in the same individual receiving multilesion percutaneous coronary intervention and surveillance angiography has yet to be investigated.

WHAT THE STUDY ADDS

• In patients receiving multilesion percutaneous coronary intervention, a revascularization strategy with BVS showed acceptable midterm intraindividual performance compared with DES.
• Despite more aggressive lesion preparation as compared with DES, BVS displayed technical shortcomings such as adverse edge effect and recoil.
• The continuous iteration of BVS technology, longer-term follow-up, and future randomized trials remain instrumental to definitively address the role of BVS as compared with current high-performance DES.

Methods

Study Design and Population
Clinical, angiographic, and procedural data for all consecutive PCI patients treated with BVS for symptomatic obstructive CAD because of de novo stenosis at 2 high-volume centers in Munich, Germany, were prospectively collected. There was no need for institutional review board approval because all procedures were part of the standard medical care, and nothing special was done for the purposes of this study. We just searched our patient database for data of individuals receiving multilesion intervention with BVS and DES. The type of stent to be implanted (BVS versus DES) was left to the discretion of the operator. Interventions were performed according to standard of care, with predilation and BVS implantation not exceeding the burst pressure rate. Intravascular imaging guidance and postdilation were left to the discretion of the operator. In all cases, anticoagulation was accomplished with either unfractionated heparin or bivalirudin. Antithrombotic therapy consisted of 500 mg aspirin as a loading dose, followed by 100 to 200 mg aspirin per day indefinitely. Patients received a loading dose of thienopyridines before PCI followed by a maintenance dose for a minimum of 6 months depending on stent type and clinical indication. Other cardiac medications were prescribed as per standard of care. All patients were scheduled for repeat coronary angiography at 6 to 8 months.

Data Management
All data relevant to the present study were entered into a computer database by a specialized personnel of the Clinical Data Management Center (ISARESEARCH Center, Munich, Germany). Baseline, postprocedural, and follow-up coronary angiograms were digitally recorded and assessed off-line in the quantitative coronary angiography core laboratory (ISARESEARCH Center, Munich, Germany) with an automated edge-detection system (CMS version 7.1; Medis Medical Imaging Systems) by independent, experienced operators. Qualitative, morphological lesion characteristics were defined according to standard criteria. Measurements were performed on cineangiograms recorded after the intracoronary administration of nitroglycerine using the same single worst-view projection at all times. The contrast-filled nonpneumatic catheter tip was used for calibration. Quantitative analysis was performed on both the in-device (stent/scaffold) and in-segment area (including the treated segment and both 5-mm margins proximal and distal to the stent/scaffold).

End Points and Definitions
The primary end point of the current analysis was in-device late lumen loss (LLL), defined as the difference between the minimal lumen diameter (MLD) at the end of the procedure and the MLD at follow-up angiography after 6 to 8 months. Secondary end points were restenosis (angiographic or binary), defined as diameter stenosis ≥50% in the in-segment area at follow-up angiography after 6 to 8 months, target lesion revascularization (TLR), and definite stent/scaffold thrombosis (ST) at the longest available follow-up. TLR was defined as any repeat PCI of the target lesion. Definite ST was defined according to the Academic Research Consortium criteria.

Statistical Analysis
The statistical software package R (version 2.15.1; R Foundation for Statistical Computing, Vienna, Austria) was used for analyses. Continuous data are presented as mean (SD) or median (25th–75th percentiles). Categorical data are presented as counts or proportions (%). For lesion-level data, the differences between groups were checked for statistical significance using generalized estimating equations to address the intrapatient correlation in patients with multilesion interventions. Depending on the nature of the dependent variable, we used the gaussian and the binomial family for continuous and discrete variables, respectively. We used the exchangeable link function (correlation structure). A multivariate analysis explored whether the stent type (BVS versus DES) influenced LLL after adjustment for baseline angiographic differences (namely, vessel type, bifurcation, calcification, reference vessel diameter, lesion length, predilation, maximal stent diameter, and postdilation), and P values were derived from a generalized estimating equation model.

Results
Between September 2012 and June 2014, a total of 419 patients (527 lesions) with symptomatic obstructive CAD received a PCI with at least 1 BVS: baseline clinical and angiographic features of these patients have been previously described. Among these participants, 90 cases with 239 lesions underwent multileision PCI with BVS (n=112) and DES (n=127) and were selected for further analyses (Figure 1). In the overwhelming majority of cases (90.0%), the DES platform implanted consisted of everolimus-eluting metallic stent (Xience V/Xience Prime; Abbott Vascular).

Baseline clinical characteristics of patients receiving a PCI with BVS only or multilesion PCI with BVS and DES are presented in the Table 1. Patients receiving multilesion PCI with BVS and DES were aged 69.4 years (61.7–73.7), predominantly males and in one-third of cases diabetics. Patients receiving multilesion PCI with BVS and DES showed a higher proportion of multivesSEL CAD as compared with those treated with BVS only (88.9% versus 72.6%; P<0.001). Overall, 39.0% of patients with acute coronary syndrome received multileision PCI with BVS and DES.

Angiographic and procedural characteristics of lesions treated with BVS and DES are summarized in Table 2. Stenting of left main coronary artery was performed exclusively with DES. Lesions treated with BVS as compared with those treated with DES presented a lower proportion of moderate-to-severe calcification (15.2% versus 29.1%; P<0.001), involved less frequently a bifurcation (14.3% versus 40.1%;
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BVS Versus DES in Multilesion PCI

P<0.001), presented a smaller reference vessel diameter pre-PCI (2.90±0.48 versus 3.03±0.75; P<0.001), and were longer (17.4±10.1 versus 15.5±9.7; P=0.044). Baseline MLD and percentage of stenosis were comparable between groups. The proportions of predilation (98.2% versus 83.5%; P=0.02) and postdilation (85.7% versus 73.2%; P=0.01) were higher among lesions treated with BVS compared with those treated with DES. Final MLD and percentage of stenosis were comparable between groups. Angiographic success was achieved in all lesions treated.

Scheduled repeat angiography was obtained in 71 patients (80.0%) with 191 lesions treated (BVS, n=90 and DES, n=101) after a median of 6.6 months (5.8–7.1). Quantitative measures at angiographic surveillance are summarized in Table 3.

In-Device Angiographic Measures
Mean LLL, the primary angiographic end point, was 0.30±0.59 mm versus 0.22±0.48 mm for BVS versus DES (P=0.035; Figure 2A). The adjustment for baseline angiographic variables displaying significant differences showed that the stent type (BVS versus DES) did not influence LLL (P=0.82). Notably, mean LLL of patients receiving PCI with BVS only (266 lesions, 0.25±0.48 mm) was comparable to that of patients treated with BVS in the context of multilesion PCI (P=0.25). Lesions treated with BVS as compared with those treated with DES displayed a higher diameter stenosis (22.7±19.8% versus 20.0±14.6%; P=0.03) and a smaller MLD (2.33±0.74 versus 2.56±0.73 mm; P=0.02).

In-Segment Angiographic Measures
The rate of binary restenosis, the secondary angiographic end point, was 8.4% (16 lesions) and did not differ between BVS and DES (7.8% and 8.9%, respectively; P=0.90; Figure 2B). Notably, the rate of binary restenosis of patients receiving PCI with BVS only (7.4%) was comparable to that of patients treated with BVS in the context of multilesion PCI (P=0.72). Interestingly, mean LLL was significantly higher for BVS versus DES (0.26±0.56 versus 0.12±0.49 mm; P=0.044).

Clinical Outcomes
Clinical follow-up was available for all patients (median 13.2 months [9.2–17.6]). Overall, the rate of TLR was 10.0% (24 lesions) and was comparable between BVS and DES (9.8% and 10.2%, respectively; P=0.97; Figure 3). The rate of definite ST was 2.1% (5 lesions) and not significantly different between BVS and DES (2.7% and 1.6%, respectively; P=0.48; Figure 3).

Discussion
The present analysis reports for the first time the intraindividual performance of BVS and DES in a patient population receiving surveillance angiography after multilesion PCI. The major findings are that: (1) BVS displays a generally acceptable midterm angiographic result as compared with that of current metallic DES; (2) the rates of TLR and ST after a median follow-up of 13.2 months are in line with previous studies performing surveillance angiography in patients treated with BVS in routine clinical practice.

Despite the unprecedented safety and efficacy of contemporary metallic DES, the permanent nature of these implants make the elution of antirestenotic drugs from transient platforms intuitively attractive. Indeed, bioresorbable stents eluting antiproliferative substances offer a temporary scaffolding of the vessel until the antirestenotic function is served, than degrade into inert breakdown products after a certain amount of time. This bioresorption process avoids the permanent vascular caging from metallic frames.

The everolimus-eluting BVS is the bioresorbable stent platform with the largest available preclinical and clinical evidence. Recent randomized trials suggest acceptable angiographic results with BVS against current DES. On the one hand, the use of angiographic surveillance remains important...
in investigations of coronary stents. On the other hand, the complex interplay between baseline comorbidities, lesion features, and vessel response after stenting makes comparisons of technologies in different individuals more effortful.

Studies with intraindividual design are a valuable adding to investigations of device efficacy. To the best of our knowledge, studies exploring BVS and DES in the same patient receiving multilesion PCI have not been performed. Against this background, this report investigates the intraindividual performance of BVS and DES in patients receiving multilesion PCI and subsequent angiographic surveillance. The results of this analysis merit careful evaluation.

At first, we displayed a generally acceptable intraindividual antirestenotic efficacy of BVS versus DES in the routine practice. The findings of this study are in line with previous angiographic observations of BVS implantation in patient populations with similar follow-up duration; indeed, in-device LLL after BVS implantation ranged between 0.28 mm and 0.16 mm, depending on the complexity of treated lesions. In addition, Puricel et al have recently reported a rate of binary restenosis at 6 to 9 months after BVS implantation ranging between 0.28 and 0.16 mm, depending on the complexity of treated lesions. In addition, Puricel et al have recently reported a rate of binary restenosis at 6 to 9 months after BVS implantation ranging between 0.28 and 0.16 mm, depending on the complexity of treated lesions.

Second, the in-segment analysis at angiographic surveillance found significantly higher LLL with BVS versus DES, supporting the existence of adverse device edge effects, likely attributable to a transient constrictive remodeling at the margins of BVS. This phenomenon has been noted in patients with metallic DES platforms. On the one hand, angiographic parameters measured in-segment are less robust markers of device efficacy than those collected in-device; in addition, in-segment LLL is regarded as more sensitive but more complex and less reliable measure because the accurate identification of BVS edges may be challenging. On the other hand, this edge vascular response deserves future investigation to fully disclose incidence, time course, and possible clinical sequelae of this phenomenon.

Third, some reports describe that the refinement of the implantation technique at time of index PCI improves the performance of BVS. In the current report, the fairly high proportions of predilation and postdilation of lesions treated with BVS led to final MLD and diameter stenosis similar to

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### Table 1. Patients Characteristics According to Stent Therapy

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BVS Only, n=329</th>
<th>BVS and DES, n=90</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>68.4 (59.1–74.4)</td>
<td>69.4 (61.7–73.7)</td>
<td>0.61</td>
</tr>
<tr>
<td>Male sex</td>
<td>248 (75.4)</td>
<td>73 (81.1)</td>
<td>0.25</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>100 (30.4)</td>
<td>32 (35.5)</td>
<td>0.35</td>
</tr>
<tr>
<td>Insulin treated</td>
<td>33 (10.1)</td>
<td>10 (11.1)</td>
<td>0.76</td>
</tr>
<tr>
<td>Hypertension</td>
<td>283 (86.1)</td>
<td>78 (86.7)</td>
<td>0.87</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>225 (68.4)</td>
<td>56 (62.2)</td>
<td>0.27</td>
</tr>
<tr>
<td>Current smoker</td>
<td>71 (21.6)</td>
<td>19 (21.1)</td>
<td>0.92</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>27.0 (24.7–30.4)</td>
<td>27.1 (24.5–30.1)</td>
<td>0.70</td>
</tr>
<tr>
<td>Previous MI</td>
<td>81 (24.6)</td>
<td>28 (31.1)</td>
<td>0.21</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>14 (4.3)</td>
<td>4 (4.4)</td>
<td>0.93</td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>239 (72.6)</td>
<td>80 (88.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Clinical presentation</td>
<td></td>
<td></td>
<td>0.29</td>
</tr>
</tbody>
</table>

Data are represented as median (25th–75th) or n (%), unless otherwise indicated. BMI indicates body mass index; BVS, bioresorbable vascular scaffold; CABG, coronary artery bypass graft; CAD, coronary artery disease; DES, drug-eluting stent; MI, myocardial infarction; NSTEMI, non-ST-segment–elevation myocardial infarction; and STEMI, ST-segment–elevation myocardial infarction.

### Table 2. Angiographic and Procedural Characteristics of Lesions Treated With BVS and DES

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BVS, n=112</th>
<th>DES, n=127</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target vessel</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LAD</td>
<td>54 (48.2)</td>
<td>54 (42.5)</td>
<td></td>
</tr>
<tr>
<td>LCx</td>
<td>23 (20.5)</td>
<td>32 (25.2)</td>
<td></td>
</tr>
<tr>
<td>RCA</td>
<td>35 (31.3)</td>
<td>34 (28.6)</td>
<td></td>
</tr>
<tr>
<td>LMCA</td>
<td>0 (-)</td>
<td>7 (5.5)</td>
<td></td>
</tr>
<tr>
<td>B2/C type</td>
<td>66 (58.9)</td>
<td>92 (72.4)</td>
<td>0.17</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>16 (14.3)</td>
<td>51 (40.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Calcification</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Data are mean (SD) or n (%), unless otherwise indicated. Denominators have been provided when they differ from the total number of lesions. ACS indicates acute coronary syndrome; BVS, bioresorbable vascular scaffold; DES, drug-eluting stent; LAD, left anterior descending artery; LCx, left circumflex; LMCA, left main coronary artery; and RCA, right coronary artery.
that reported in lesions treated with DES. Interestingly, we found at repeat angiography a smaller MLD and a higher diameter stenosis after BVS implantation than after DES, likely because of late recoil. Preclinical studies have reported dynamic changes of vessel wall and instances of chronic recoil after BVS implantation. In particular, the smaller MLD at control angiography at the level of BVS suggests that the properties of vessel scaffolding of this stent platform could not be halted for a long period as with metallic stents, even with similar acute results after deployment. The differences in material components likely play a pivotal role; polymeric backbones are more prone to be stressed from plaque features and elastic properties of the arterial wall as compared with metallic implants. In addition, the progressive self-degradation of BVS may alter its own structural integrity and diminish the radial strength over time, which in turn may be responsible for late adverse events.

Finally, after a median of 13.2-month follow-up, TLR and definite ST rates after BVS were 9.8% and 2.7%, respectively. The TLR rate is higher than that in some other studies investigating this bioresorbable stent platform in more selected CAD populations but comparable to that observed in all-comer studies with per-protocol angiographic follow-up. The differences between studies can likely be accounted for to some extent by the impact of routine invasive surveillance on the rates of re-PCI. In addition, a possible interaction of interlesion dependence with angiographic results cannot completely be discarded. The definite ST rate is in line with other reports investigating BVS implantation in routine practice but higher than that described in registries of contemporary metallic DES. Although in this report definite ST was numerically higher with BVS, we did not find a significant difference in comparison to DES, likely because of the limited number of events. As the iteration of BVS technology goes on, it is desirable that next-generation platforms will ensure durable radial strength, thinner struts, and improved expansion characteristics, to improve outcomes compared with the device investigated in this study, and current metallic DES platforms.

Study Limitations
This report has several important limitations. First, this study has no randomized design: intraindividual comparisons eliminate the intrinsic disparities associated with different patient groups, but we observed some imbalances in baseline angiographic features. Despite statistical adjustment, we are unable to account for unmeasured confounders. Second, the particular design of this study limits the comparison of different stent strategies in terms of clinical end points. As a consequence, the analyses of TLR and definite ST, performed at lesion level, should be intended as exploratory in nature. Third, angiographic follow-up data were missing in 20% of patients: although these data are deemed missing not at random, it is a consistent feature of angiographic follow-up studies. However, numerous studies have shown that angiographic surrogates are robust markers of device efficacy and that the validity of such data is high when rates of angiographic

| Table 3. Quantitative Measures at Surveillance Angiography for Lesions Treated With BVS and DES |
|-----------------------------------------------|-----------------|-----------------|-----------------|
| In-device analysis                           | BVS, n=90       | DES, n=101      | PValue          |
| MLD, mm                                      | 2.33±0.74       | 2.56±0.73       | 0.02            |
| Diameter stenosis, %                         | 22.7±19.8       | 20.0±14.6       | 0.03            |
| LLL, mm (87)                                 | 0.30±0.59       | 0.22±0.48       | 0.035           |
| In-segment analysis                          |                 |                 |                 |
| MLD, mm                                      | 2.14±0.68       | 2.26±0.71       | 0.34            |
| Diameter stenosis, %                         | 29.3±18.1       | 30.0±14.4       | 0.93            |
| LLL, mm (87)                                 | 0.26±0.56       | 0.12±0.49       | 0.044           |
| Restenosis, n (%)                            | 7 (7.8)         | 9 (8.9)         | 0.90            |

Data are mean (SD) or n (%), unless otherwise indicated. Denominators have been provided when they differ from the total number of lesions. BVS indicates bioresorbable vascular scaffold; DES, drug-eluting stent; LLL, late lumen loss; and MLD, minimal luminal diameter.

Figure 2. Primary and secondary angiographic end points with bioresorbable vascular scaffold (BVS) vs drug-eluting stent (DES). Cumulative distribution of in-device late lumen loss (A) and cumulative rates of restenosis (B) at follow-up angiography after a median follow-up of 6.6 months.
follow-up approach 80%. Fourth, patient enrollment was limited to just 2 high-volume centers. This may affect the generalizability of the present findings. Fifth, because intravascular imaging during implantation of BVS and DES was not mandatory, the association of further lesion-specific factors on subsequent angiographic results cannot be completely assessed. Finally, angiographic follow-up was limited to 6 to 8 months. Previous observations1,2 and a recent meta-analysis5 suggest a possible time dependence of angiographic outcome with BVS versus metallic DES. Ongoing studies with late angiographic surveillance are eagerly awaited to address this issue.2,6

Conclusions

In patients receiving multilession PCI, a revascularization strategy with BVS displays acceptable midterm intraindividual antirestenotic efficacy compared with DES. A meticulous lesion preparation; the refinement of the biocompatibility of current BVS technology, angiographic, and clinical data at longer-term follow-up; and future randomized trials with intraindividual design remain instrumental to definitively address the role of BVS technology as compared with current high-performance metallic DES.

Disclosures

Dr Kastrati reports patent applications related to drug-eluting stent coatings. Dr Byrne reports receiving lecture fees from B. Braun Melsungen AG, Biotronik, and Boston Scientific and scientific support from the Irish Board for Training in Cardiovascular Medicine sponsored by MSD. Dr Giacoppo is the recipient of a research fellowship grant funded by European Association of Percutaneous Cardiovascular Interventions (EAPCI). The other authors report no conflicts.

References


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