scaffolds for patients with in-stent restenosis: the RIBS VI study. J Am Coll Cardiol Intv 2017;10:1841–51.

2. Alfonso F, Pérez-Vizcayno MJ, Cárdenas A, et al. A randomized comparison of drug-eluting balloon versus everolimus-eluting stent in patients with bare-metal stent in-stent restenosis: the RIBS V clinical trial. J Am Coll Cardiol 2014;63:1378–86.

3. Alfonso F, Pérez-Vizcayno MJ, Cárdenas A, et al. A prospective randomized trial of drug-eluting balloons versus everolimus-eluting stents in patients with in-stent restenosis of drug-eluting stents. The RIBS IV clinical trial. J Am Coll Cardiol 2015;66:23–33.

4. Moscarella E, Ielasi A, Granata F, et al. Long-term clinical outcomes after bioresorbable vascular scaffold implantation for the treatment of coronary in-stent restenosis: a multicenter Italian experience. Circ Cardiovasc Interv 2016;9:e003148.

5. Puricel S, Cuculi F, Weissner M, et al. Bioresorbable coronary scaffold thrombosis: multicenter comprehensive analysis of clinical presentation, mechanisms, and predictors. J Am Coll Cardiol 2016;67:921–31.

6. Ortega-Paz L, Capodanno D, Gori T, et al. Predilation, sizing and post-dilation scoring in patients undergoing everolimus-eluting bioresorbable scaffold implantation for prediction of cardiac adverse events: development and internal validation of the PSP score. EuroIntervention 2017;12:2110–7.

7. Ali ZA, Serruys PW, Kimura T, et al. 2-Year outcomes with the Absorb bioresorbable scaffold for treatment of coronary artery disease: a systematic review and meta-analysis of seven randomized trials with an individual patient data substudy. Lancet 2017;390:760–72.

REPLY: Bioresorbable Vascular Scaffolds in In-Stent Restenosis

We are most grateful to Dr. Moscarella and colleagues for their interest in our study that sought to assess the value of bioresorbable vascular scaffolds (BVS) compared with everolimus-eluting stents (EES) and drug-eluting balloons (DEB) in patients with in-stent restenosis (ISR) (1). Our trial was initiated before the recommendation to use a "pre-dilation-size-post-dilation" strategy for BVS was established. However, from our previous experience in the treatment of ISR, we were fully aware of the importance of lesion preparation and optimization of final results in these patients (2). Indeed, the study protocol emphasized the relevance of lesion preparation, suggesting aggressively tackling any residual stent under-expansion with noncompliant balloons at high-pressure (1). The maximal pressure used in the BVS arm during either pre-dilation (97% of cases) or post-dilation (66% of cases) was 20 ± 4 bar. In addition, a liberal use of intracoronary imaging was recommended, and eventually, 46% of the patients were treated under intracoronary imaging guidance (optical coherence tomography n = 63; intravascular ultrasound n = 2). However, strict criteria for BVS optimization were not pre-defined, and the potential reaction to the imaging findings was left to the operator's discretion. Despite our optimization efforts, the early and late results of BVS on quantitative coronary angiography were poorer than those obtained with EES. Similar results have been reported in previous studies comparing these devices in de novo lesions (3). Interestingly, some studies suggested that accuracy of edge detection by quantitative coronary angiography differs when polymeric BVS are compared with metallic EES, and this technical issue should be also considered when interpreting angiographic findings (4). Furthermore, although there were some imbalances in baseline characteristics among the 3 therapeutic modalities, the differences detected at late follow-up in the main angiographic outcome measures persisted after careful adjustment for potential confounders, as already explained in our report (1). In the RIBS VI (Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment) study, we used similar inclusion/exclusion criteria to those used in previous RIBS trials. Accordingly, our findings should not be extrapolated to more adverse anatomic scenarios. Whether the relative efficacy of BVS compared with DEB or EES might be different in patients presenting more complex ISR patterns remains speculative. Finally, we are also deeply interested in elucidating whether additional strategies could help to optimize BVS results in ISR(5). The currently ongoing RIBS VI *Scoring* (Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-Dilatation) study (NCT03069066), also including late angiographic surveillance, will determine whether the early and late results of BVS in patients with ISR may be improved by systematic lesion preparation using scoring balloons before BVS deployment.

We fully agree that BVS represent an attractive therapeutic modality for patients with ISR. Our findings suggest that BVS offer an efficacy similar to DEB, a strategy already supported by robust clinical evidence in this anatomic setting. Moreover, we also concur with the idea that BVS iterations might play a major role in the treatment of ISR. Hopefully, our study will pave the way for future initiatives using the "leave nothing behind" strategy in the treatment of these challenging patients.

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REFERENCES

1. Alfonso F, Cuesta J, Pérez-Vizcayno MJ, et al. Bioresorbable vascular scaffolds for patients with in-stent restenosis: the RIBS VI study. J Am Coll Cardiol Intv 2017;10:1841–51.

2. Alfonso F, Byrne RA, Rivero F, Kastrati A. Current treatment of in-stent restenosis. J Am Coll Cardiol 2014;63:2659–73.

3. Stone GW, Gao R, Kimura T, et al. 1-Year outcomes with the Absorb bioresorbable scaffold in patients with coronary artery disease: a patient-level, pooled meta-analysis. Lancet 2016;387:1277–89.

4. Sotomi Y, Onuma Y, Miyazaki Y, et al. Is quantitative coronary angiography reliable in assessing the late lumen loss of the everolimus-eluting bioresorbable polylactide scaffold in comparison with the cobalt-chromium metallic stent? EuroIntervention 2017;13:e585–94.

5. Kufner S, Joner M, Schneider S, et al. Neointimal modification with scoring balloon and efficacy of drug-coated balloon therapy in patients with restenosis in drug-eluting coronary stents: a randomized controlled trial. J Am Coll Cardiol Intv 2017;10:1332–40.

RESEARCH CORRESPONDENCE

Effect of Modern Dose-Reduction Technology on the Exposure of Interventional Cardiologists to Radiation in the Catheterization Laboratory

Interventional cardiologists are exposed to deterministic and stochastic effects of ionizing radiation, as evidenced by their increased risk of developing cataracts and left-sided brain tumors, respectively (1–3). The ClarityIQ dose-reduction system (Philips Healthcare, Amsterdam, the Netherlands) uses advanced real-time image noise reduction algorithms combined with an optimized acquisition chain (as real-time pixel shift and motion compensation algorithms reducing artifacts, image blur in fast moving areas of anatomy, and virtual collimation) that enable dose reduction while providing adequate image quality. This technology has been shown to reduce the dose of radiation received by the patient during invasive cardiology procedures (4). However, the impact of the ClarityIQ system on the exposure of operators to ionizing radiation in invasive cardiology catheterization laboratories (cathlabs) has never been quantified. In this context, we aimed to estimate the percent reduction in the radiation dose received by the operator that could be achieved using ClarityIQ dose-reduction technology in cathlabs. The population for analysis included all invasive coronary procedures performed in our center from March 2017 to June 2017. Four experienced interventional cardiologists are permanent practitioners at our institution, working in 2 cathlabs. Cathlab A is equipped with the Allura Xper FD10 system (Philips Healthcare), in service since January 2011; Cathlab B is equipped with the Allura Xper FD10 Clarity system (Philips Healthcare) inaugurated in March 2015. Both cathlabs are equipped with flat detectors with the same technical characteristics (frame rate of 7.5 fps for coronary angiography and 15 fps for ventricular angiography; 20 cm size of field; 1,024 × 1,024 matrix). The equipment undergoes half-yearly control by the manufacturer, and annual external quality control. The delivered dose and the quality of the image are checked. Tubes are replaced if their performance is <90% of the standard.

TABLE 1 Comparison of Invasive Cardiology Procedures Between Cathlab A (No Dose-Reduction Technology) and Cathlab B (Equipped With ClarityIQ Dose-Reduction Technology)

	Cathlab A (n = 358)	Cathlab B (n = 219)	p Value
Male	249 (70)	152 (70)	0.9
Age, yrs	65.5 ± 13.0	67.8 ± 12.1	0.04
Body mass index, kg/m^2	27.8 ± 4.7	27.3 ± 5.4	0.2
Approach			0.5
Radial	309 (86)	190 (87)	
Femoral	49 (14)	29 (13)	
Procedure with angioplasty of at least 1 lesion	174 (49)	89 (41)	0.1
Total x-ray time, min	8.2 ± 6.7	7.9 ± 6.3	0.5
Operator radiation dose, μSv	7.0 ± 15.8	2.0 ± 3.2	<0.0001
Total air kerma, mGy	379 ± 302	251 ± 202	<0.0001
Total dose area product, cGy.cm^2	3,034 ± 2,480	1,451 ± 1,058	<0.0001

Values are n (%) or mean ± SD.
Cathlabs = catheterization laboratories.

The primary endpoint was operator radiation exposure, as assessed by a personal electronic dosimeter (APVL, Tours, France) with a silicon diode (μSv) located on the operator's left arm. Radiation doses were recorded at the end of each procedure. This measurement corresponds to the dose received at 10 mm under the site of the dosimeter (HP10), and represents the probability of stochastic health effects from radiation. Multivariate analysis was performed using generalized linear regression including all variables related to the primary endpoint with a p value <0.20 by univariate analysis. The multivariate model was adjusted for the operator. Analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, North Carolina). During the study period, there were a total of 577 invasive