However, the distinction between calcified spots and metallic markers with computed tomography is also not easy to determine compared with OCT. The possible advantages of OCT are the ability to: 1) distinguish the MRMs from underlying calcium more clearly than MSCT; 2) measure the embedment of the struts; and 3) evaluate the thickness of neointima because of a higher axial resolution of around 10 to 15 μm as compared with MSCT.

The limitation in this study is that the study result was able to confirm the persistent presence of MRMs only at medium-term follow-up, and the long-term results still require investigation.

In conclusion, MRM recognition by MSCT is critical for precise noninvasive assessment of the coronary location of all MRMs. On the basis of our study criteria, there was no evidence of MRMs dislodgement and embolization 18 months after scaffold implantation.

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REFERENCES

1. Onuma Y, Dudek D, Thuesen L, et al. Five-year clinical and functional multislice computed tomography angiographic results after coronary implantation of the fully resorbable polymeric everolimus-eluting scaffold in patients with de novo coronary artery disease: the ABSORB cohort A trial. J Am Coll Cardiol Intv 2013;6:999–1009.

2. Serruys PW, Onuma Y, Garcia-Garcia HM, et al. Dynamics of vessel wall changes following the implantation of the absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study at 6, 12, 24 and 36 months. EuroIntervention 2014;9:1271–84.

3. Ormiston JA, Serruys PW, Regar E, et al. A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial. Lancet 2008;371:899–907.

4. Abizaid A, Ribamar Costa J Jr., Bartorelli AL, et al. The ABSORB EXTEND study: preliminary report of the twelve-month clinical outcomes in the first 512 patients enrolled. EuroIntervention 2014;10:1396–401.

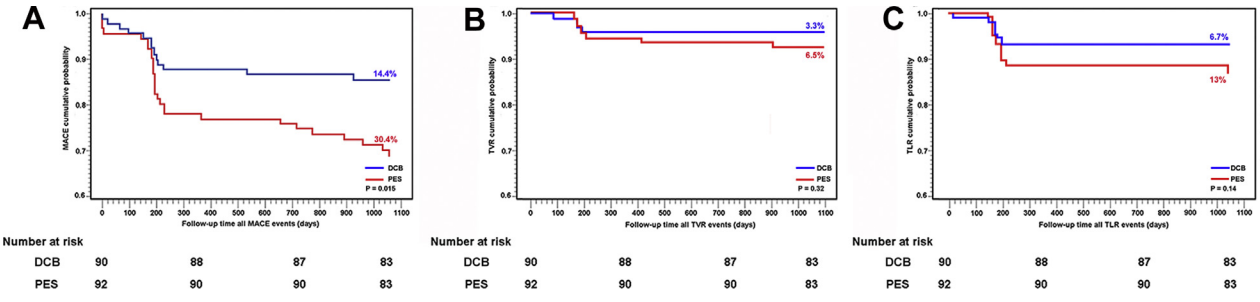
APPENDIX For supplemental methods, statistical analysis, table, and figures, please see the online version of this article.

3-Year Follow-Up of the Balloon Elution and Late Loss Optimization Study (BELLO)

The optimal treatment of de novo small-vessel coronary artery disease remains unclear. The use of drug-eluting stents in this patient group are limited by high rates of restenosis (1) and the requirement of prolonged treatment with dual antiplatelet therapy. The use of drug-coated balloons (DCB) might be an alternative treatment option. There are currently limited data with regard to the long-term efficacy of this strategy (2), and currently no randomized data to support this approach. The BELLO (Balloon Elution and Late Loss Optimization) study (3) was an investigator-initiated, prospective, multicenter, single-blinded, active-treatment controlled clinical trial. In BELLO, 182 patients undergoing percutaneous revascularization of small coronary vessels (reference vessel diameter <2.8 mm by visual estimation) were randomly assigned in a 1:1 ratio to treatments with: 1) In.Pact Falcon paclitaxel DCB (Medtronic, Inc., Santa Rosa, California) dilation and provisional bare-metal stenting; or 2) paclitaxel-eluting stent (PES) (Taxus Liberté, Boston Scientific, Marlborough, Massachusetts) implantation as per standard clinical practice. We have shown that treatment of small-vessel disease with a paclitaxel DCB is associated with less angiographic late loss and similar rates of restenosis and revascularization as PES is at 1 year. Here we report the final pre-defined, protocol-mandated 3-year clinical follow-up results of this study population.

A total of 182 patients were enrolled at 15 Italian centers and randomized to treatment with DCB (n = 90) in 94 lesions or PES (n = 92) in 98 lesions. Patients were eligible if ≥18 years of age, with a diagnosis of stable or unstable angina or documented ischemia and a maximum of 2 angiographically significant de novo lesions <25 mm in length in native coronary arteries with a visually estimated reference

FIGURE 1 3-Year Outcomes Following DCB Treatment for De Novo Coronary Disease in Small Vessels in Comparison With PES Treatment



There was a statistically significant benefit in the drug-coated balloon (DCB) group in comparison with the paclitaxel-eluting stent (PES) group with regard to 3-year composite major adverse cardiac events (MACE) ($p = 0.015$) **(A)**. There were no differences between groups with regard to target vessel revascularization (TVR) ($p = 0.32$) **(B)** and target lesion revascularization (TLR) ($p = 0.14$) **(C)**.

vessel diameter of <2.8 mm. Exclusion criteria and baseline characteristics of patients included in the study have been previously published (3). Of note, there was a high incidence of diabetes mellitus (43.3% in DCB and 38% in PES) and the majority of lesions treated were in vessels <2.5 mm (89.4% vs. 87.8%). The primary endpoint was angiographic in-stent (or in-balloon) late lumen loss at follow-up angiography at 6 months. Secondary endpoints included the occurrence of major adverse cardiac events (MACE), defined as the composite of all-cause death, myocardial infarction, and target vessel revascularization.

A total of 173 patients (95.1%) were included in the final analysis: 166 patients completed 3-year follow-up (83 patients in each group) and 7 patients died: 2 patients in the DCB group (1 sudden cardiac death, 1 following coronary artery bypass graft surgery) and 5 patients in the PES group (3 cancer, 1 respiratory failure, 1 following stroke). Nine patients (4.9%) were lost to follow-up.

The occurrence of the first event of the MACE composite up to 1,100 days was analyzed using the Kaplan-Meier method and showed a statistically significant difference between groups (DCB group: $n = 13$ [14.4%], and PES group: $n = 28$ [30.4%], $p = 0.015$) (**Figure 1A**). Three patients (3.3%) underwent target vessel revascularization in the DCB group and 6 patients (6.5%) in the PES group ($p = 0.32$) (**Figure 1B**). Six patients (6.7%) underwent target lesion revascularization in the DCB group and 12 patients (13%) in the PES group ($p = 0.14$) (**Figure 1C**). There were no reported instances of target stent (or vessel) thrombosis in either group.

In the subgroup of 75 patients with diabetes mellitus, 65 patients completed 3-year follow-up (DCB group: $n = 35$; PES group: $n = 30$), 6 patients died and 4 were lost to follow-up. At least 1 MACE occurred in 6 patients (15.4%) in the DCB group and in 14 patients (38.9%) in the PES group, favoring treatment with DCB ($p = 0.02$). There were no differences between groups with regard to target vessel revascularization (DCB group: $n = 1$; PES group: $n = 2$; $p = 0.51$) or target lesion revascularization (DCB group: $n = 2$; PES group: $n = 6$; $p = 0.11$).

The use of DCB is attractive in the management of de novo coronary disease because it does not require prolonged dual antiplatelet therapy and can be used where vessels are too small to allow for optimal stent implantation. For the treatment of novo disease, a recent meta-analysis concluded DCB use was noninferior to both bare-metal stents and PES (4) and efficacy was further demonstrated in a prospective "all-comer" registry that demonstrated a low MACE and target lesion revascularization rate with DCB use (5).

Data from this extended follow-up suggest the treatment of small vessels with DCB has good efficacy compared with PES treatment at 3-year follow-up in support of our observation at 1 year (3). Interestingly, there was a statistically significant benefit with regard to MACE at 3 years with DCB when compared with PES. Whereas this study was not adequately powered for this endpoint, it does raise the interesting hypothesis that treatment of small vessels with DCB might be associated with an outcome benefit.

In conclusion, the use of DCB in the treatment of de novo coronary lesions in small vessels appears to be an efficacious strategy when compared with PES treatment at 3 years. This holds true in high-risk diabetic patients. Further larger studies are required to evaluate whether there is an additional outcome benefit associated with this approach, especially with new generation limus-eluting stents.

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REFERENCES

1. Kastrati A, Dibra A, Mehilli J, et al. Predictive factors of restenosis after coronary implantation of sirolimus- or paclitaxel-eluting stents. Circulation 2006;113:2293–300.

2. Unverdorben M, Kleber FX, Heuer H, et al. Treatment of small coronary arteries with a paclitaxel-coated balloon catheter in the PEPCAD I study: are lesions clinically stable from 12 to 36 months? EuroIntervention 2013;9:620–8.

3. Latib A, Colombo A, Castriota F, et al. A randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels: the BELLO (Balloon Elution and Late Loss Optimization) study. J Am Coll Cardiol 2012;60:2473–80.

4. Fröhlich GM, Lansky AJ, Ko DT, et al. Drug eluting balloons for de novo coronary lesions — a systematic review and meta-analysis. BMC Med 2013;11:123.

5. Zeymer U, Waliszewski M, Spiecker M, et al. Prospective "real world" registry for the use of the "PCB only" strategy in small vessel de novo lesions. Heart 2014;100:311–6.

Risk Adjusted Mortality Ratings and Public Reporting for High-Risk PCI

We appreciate the perspective of the comments by Drs. Miner and Nield (1) regarding our study (2). As noted by Drs. Miner and Nield (1), there are many limitations to any form of observational risk-adjusted outcomes comparisons. Certainly cardiac arrest or shock patients have a gradient of risk, and certainly providers may have a gradient in who they take to the lab or how they classify and report "high risk." In individual cases, a provider could overcall shock in a lower-risk case and thereby have better observed results than expected. However, the American College of Cardiology-NCDR (National Cardiovascular Data Registry) risk models were developed from real-world data. As such, provider-related factors would have already been incorporated into the models. Thus, such variation in community practice is unlikely to explain why, in aggregate, providers who take on more high-risk cases do better. More importantly, in our analyses of the "concentrated risk year," we used the individual providers themselves as their own control group. We found in such high-risk scenarios, providers' "risk-adjusted" outcome performance was as good or better in high-risk cases than when the provider faced normal-risk or low-risk groups. So, we believe our paper provides compelling evidence that, in aggregate, the NCDR percutaneous coronary intervention risk models adequately assess and compensate providers for taking high-risk cases to the lab.

However, Miner and Nield (1) also raise an important point regarding whether or not public reporting itself is harmful or helpful. To be clear, our paper should not be seen as an endorsement of public reporting, and we agree the assessment of the total impact of public reporting is complex. On the one hand, public reporting does provide consumers with information on provider outcomes as well as give providers an incentive to monitor and hopefully improve their procedural outcomes. Although there is much debate whether consumer choice is improved via public reporting, there has been consistent evidence supporting the value of performance measurement and subsequent provider-led quality improvement, including door-to-balloon times, as well as with the outcomes of acute myocardial infarction, heart failure (3), and stroke (4). On the other hand, public outcome reporting could make certain providers "gun shy" and unwilling to take high-risk cases to the lab, even in situations where revascularization may be beneficial (such as ST-segment elevation myocardial infarction or shock). Previous studies have indicated that states with public reporting use PCI less and perhaps have worse outcomes than do states without (5). However, these studies were the exact motivation for our paper. Risk-averse clinician behavior likely represents the provider's fear that taking on high-risk cases will "hurt"