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Drug-Coated Balloons Versus Second-Generation Drug-Eluting Stents for the Management of Recurrent Multimetal-Layered In-Stent Restenosis

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ABSTRACT

OBJECTIVES This study aimed to investigate the clinical outcomes of patients presenting with recurrent drug-eluting stent (DES) in-stent restenosis (ISR) treated with a second-generation DES or with a drug-coated balloon (DCB).

BACKGROUND To date, there are no reports of DCB treatment and limited data with regard to the efficacy of further DES implantation for recurrent ISR.

METHODS Between January 2008 and December 2013, 171 lesions were assessed for eligibility (82 lesions in the second-generation DES group and 89 lesions in the DCB group).

RESULTS Acute gain was greater in the second-generation DES group (second-generation DES, 2.09 ± 0.53 mm vs. DCBs, 1.60 ± 0.62 mm, $p < 0.001$). The rates of major adverse cardiac events were comparable (at 1 year, DES 14.0% vs. DCBs 12.3%; at 2 years, DES 28.8% vs. DCBs 43.5%, $p = 0.21$). Major adverse cardiac event rates were mainly driven by target lesion revascularization (at 1 year, DES 12.5% vs. DCBs 10.9%; at 2 years, DES 27.7% vs. DCBs 38.3%; $p = 0.40$). Definite scaffold thrombosis occurred in 2 patients (1 patient in each group). Multivariable analysis revealed ISR recurrence within 1 year (hazard ratio: 2.43, 95% confidence interval: 1.14 to 5.18, $p = 0.02$) and lesion length (per 10-mm increase) (hazard ratio: 1.15, 95% confidence interval: 1.00 to 1.32, $p = 0.049$) to be independent predictors of TLR.

CONCLUSIONS The results after both treatments were equivalent. ISR recurrence within 1 year of the first reintervention and lesion length were independent predictors of future target lesion revascularization. Larger studies are required to confirm the late (>1 year) differences with regard to clinical outcomes. (J Am Coll Cardiol Intv 2015;8:1586–94)

Percutaneous coronary intervention (PCI) with drug-eluting stents (DES) has dramatically reduced the rate of in-stent restenosis (ISR) (1), and clinical outcomes have further improved with the advent of second-generation DES. However, the widespread use of second-generation DES has resulted in a large number of patients (in absolute terms) presenting with DES failure (2). The optimal management for DES-ISR lesions is not currently established. Repeat DES implantation has been reported to be superior to conventional balloon angioplasty in several studies (3–6). However, ~10% to 20% of these patients experience recurrent ISR (7,8). In addition, multimetal layers on the vessel wall have the increased potential risk of stent thrombosis (ST) and the requirement for prolonged dual antiplatelet therapy (DAPT) (9). There are only a few studies investigating outcomes after repeated DES treatment of recurrent multimetal-layered ISR (10,11), and the optimal management of these patients remains unknown.

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The drug-coated balloon (DCB) is an attractive option in the management of this patient group. DCB use avoids an additional metal layer at the site of ISR, which may reduce the risk of future ST or bleeding due to the requirement for shorter DAPT compared with DES. DCBs have already been associated with more favorable outcomes compared with conventional balloon angioplasty (12–14) in the treatment of bare-metal stent (BMS) or DES ISR. However, the use of a DCB to treat recurrent multilayered-metal ISR has not been reported.

The aim of this study was to investigate the efficacy, safety, and clinical outcomes associated with DCB use for the treatment of recurrent DES-ISR with multimetal layers compared with additional DES implantation.

METHODS

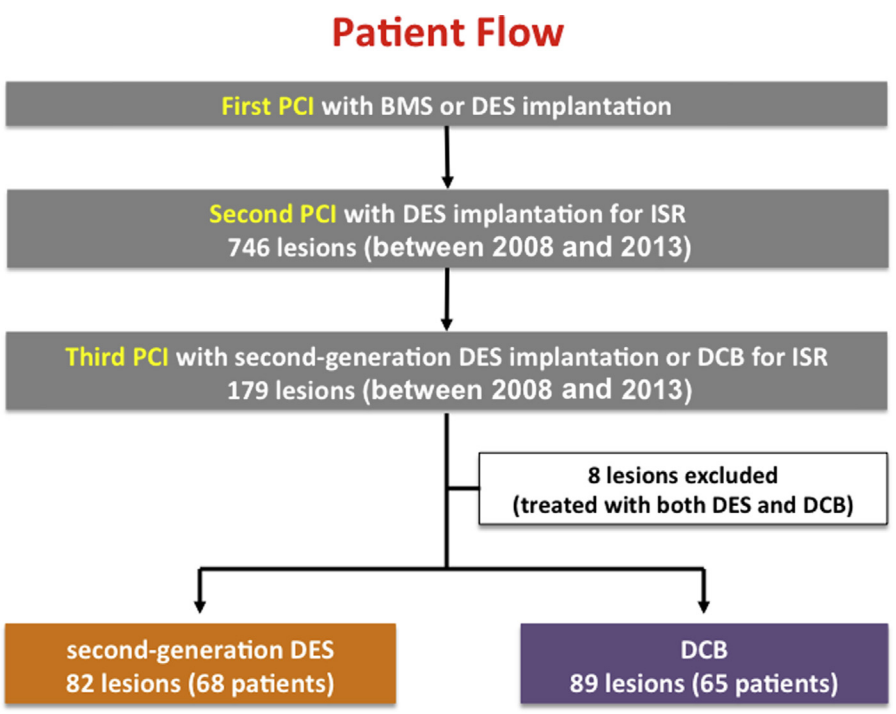
STUDY POPULATION. We analyzed all PCI procedures between January 2008 and December 2013 at 2 centers (San Raffaele Scientific Institute and EMO-GVM Centro Cuore Columbus, Milan, Italy). A total of 746 lesions were treated with DES implantation for BMS- or DES-ISR during the study period. Of these, 179 lesions were recurrent ISR lesions and were treated by DCB and/or second-generation DES implantation. The patient flow is illustrated in Figure 1. Of the total 179 lesions, we excluded 8 lesions that were treated with both a DCB and DES; therefore, we analyzed 171 lesions (82 lesions [n = 68] in the second-generation DES group, and 89 lesions [n = 65] in the DCB group). Each patient provided written informed consent for data collection and analysis, according to the Declaration of Helsinki. All clinical follow-up was conducted via hospital visits or telephone consultations.

STUDY DEVICES. The second-generation DES in this study included everolimus-eluting stents (Xience V, Xience Prime, Abbott Vascular, Santa Clara, California; PROMUS and PROMUS ELEMENT, Boston Scientific Corp., Natick, Massachusetts), zotarolimus-eluting stent (Endeavor Resolute, Medtronic Vascular, Santa Rosa,

ABBREVIATIONS AND ACRONYMS

BMS = bare-metal stent(s)
CI = confidence interval
DAPT = dual antiplatelet therapy
DCB = drug-coated balloon
DES = drug-eluting stent(s)
HR = hazard ratio
ISR = in-stent restenosis
IVUS = intravascular ultrasound
MACE = major adverse cardiac event(s)
PCI = percutaneous coronary intervention
ST = stent thrombosis
TLR = target lesion revascularization

FIGURE 1 Chart Demonstrating the Study Design and Inclusion Criteria



Between January 2008 and December 2013, 171 lesions were assessed for eligibility (82 lesions in the second-generation DES group, and 89 lesions in the DCB group). BMS = bare-metal stent(s); DCB = drug-coated balloon; DES = drug-eluting stent(s); ISR = in-stent restenosis; PCI = percutaneous coronary intervention.