Restenosis in a Bare-Metal Stent
Drug-Eluting Balloon or Drug-Eluting Stent?

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The idea of adding another metallic layer to correct a failed stent is not so appealing; therefore, any attempt to propose a metal-free strategy is laudable. The initial strategy to perform plain balloon angioplasty to treat bare-metal in-stent restenosis (ISR) was inadequate, leaving the remaining options of implanting a drug-eluting stent or using a drug-eluting balloon (DEB).1,2 Pleva et al3 report, in this issue of Circulation: Cardiovascular Interventions, the results of a study randomizing 136 patients with bare-metal ISR to treatment with a DEB (Sequent Please; B. Braun AG, Melsungen, Germany) or an everolimus-eluting stent (EES; Promus Element; Boston Scientific, Marlborough, MA.)

There were 74 ISR lesions (>50% diameter stenosis) in each group. The primary end point was in-segment late lumen loss at 12 months measured by quantitative control angiography. The decision to evaluate late lumen loss as an end point is open to debate because the acute gain, and therefore late loss, is lower with DEB compared with EES. The selection of minimal lumen diameter at follow-up angiography may be viewed as a more appropriate choice. The study was powered for noninferiority with the possibility of demonstrating superiority. Secondary end points included binary restenosis and the overall incidence of 12-month major adverse cardiac events (cardiovascular death, nonfatal acute myocardial infarction, or target vessel revascularization).4 Predilatation was applied in all cases and postdilatation as needed. Dual antiplatelet therapy was prescribed for 3 months after DEB and 6 to 12 months after EES implantation. The investigators succeeded in performing angiographic follow-up in >90% of lesions after a mean time period of 12 months. About the baseline characteristics of the lesions randomized, we would like to highlight that in the EES group, there were 18 versus 10 lesions in the DEB group with unfavorable baseline characteristics (proliferation and occlusive restenosis) and that baseline ISR was more severe for the lesions treated with EES (minimal lumen diameter, 0.79 versus 0.92 mm). These differences in baseline lesion characteristics are important and may explain some unexpected findings.

The main results are as follows:

1. Late loss was lower in the DEB group (primary end point): 0.09 mm for DEB versus 0.44 mm for EES (P = 0.0004). Minimal lumen diameters at 12-month angiographic follow-up were similar (2.09 mm for DEB versus 2.07 mm for EES; P = 0.481).
2. Binary restenosis: 8.7% for DEB versus 19.12% for EES (P = 0.078).
3. Target vessel revascularization: 7.35% for DEB versus 16.18% for EES (P = 0.11).
4. DEB performed better in lesions >10 mm and in vessels <3 mm in diameter.
5. Logistic regression analysis was only positive for DEB versus EES (adjusted odds ratio for diabetes mellitus, renal insufficiency, and type of original lesion: 3.132; 95% confidence interval, 1.058–9.269; P = 0.039).

If we examine the literature searching for similar studies, we will not find much.

The Paclitaxel-Eluting PTCA-Balloon Catheter in Coronary Artery Disease II (PEPCAD II) trial is the study, which comes close to this report as far as the devices evaluated in the setting of bare-metal stent (BMS) restenosis.6 PEPCAD II trial found that the paclitaxel-eluting balloon performed better than paclitaxel-eluting stents for the treatment of BMS restenosis. When EESs were compared with paclitaxel-eluting stents in the treatment of BMS restenosis in a registry, EES performed better in regard to restenosis and the need for revascularization at 1-year follow-up.7 However, when the follow-up extended beyond 1 year, the differences lost statistical significance. A direct randomized comparison between the paclitaxel-eluting balloon and EES for the treatment of BMS restenosis was performed by the Restenosis Intra-Stent of Bare Metal Stents: Paclitaxel-Eluting Balloon Versus Everolimus-Eluting Stent (RIBS V) investigators.8 The results of this study were different from the one reported here. Although the late losses of the DEB groups were similar (0.09 mm in the current study and 0.14 mm in RIBS V), the late loss after EES treatment was much higher in the present study (0.44 versus 0.04 mm in RIBS V). It is not easy to reconcile these opposite findings. A possible explanation is the high prevalence of occlusive and proliferative restenosis in this study (24%), justifying an aggressive late loss in this subset (supported by the 0.73-mm SD), skewing the mean toward this high value.

Are the results of this study going to change our strategy to treat ISR in BMS? Unfortunately, we cannot make a definite
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conclusion because some weaknesses of RIBS V are also present in the current study.

These problems arise when the number of patients evaluated is not sufficiently large, so there is a play of chance, especially when evaluating clinical end points. In addition, the follow-up may need to be extended to 2 years to detect any possible late catchup.

Meta-analyses have been performed mainly comparing balloon angioplasty with DEB or drug-eluting stent, and data are still limited on DEB versus EES.\(^9,10\)

Whatever the conclusions in this debate are, we agree with a valuable statement that the RIBS V Investigators made when commenting on the results of their study: both strategies (DEB or EES) were associated with an excellent 1-year outcome and are effective.

The new side of this debate is that drug-eluting stents have almost replaced BMS and we need to confront a more complex challenge: DES restenosis!

Disclosures

None.

References


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