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COMMENTARY

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Drug-coated balloons for complex coronary de novo lesions

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Key points

- Even complex lesions can be treated with a drug-coated balloon (DCB) alone.
- Debulking followed by DCB in calcified lesions is feasible.
- Future randomized trials should address DCB in more complex lesions.

Although drug-eluting stents (DES) have excellent outcomes, long-term data show that even the latest generation of DES is associated with an annual cardiovascular event rate of 2%–3.3%. The concept of avoiding permanent implants is therefore gaining increased attention. Since bioresorbable scaffolds of the first generation have not yet demonstrated noninferiority to conventional DES, the focus of interest is currently on drug-coated balloons (DCBs). At first, the only indication for DCB that became established was the treatment of in-stent restenosis to prevent multiple metal layers. However, the main advantages of DCB therapy become apparent in de novo lesions. It is not a matter of replacing DES with DCB but is more a question of determining for each individual lesion whether it is suitable for treatment without a stent or in any case requires the radial force and fixation of a severe dissection by the stent. The use of DCB allows the number and length of stents to be reduced. Furthermore, natural vasomotion is restored both in the treated segment and distal to it.[1] A unique feature especially after paclitaxel DCB treatment is late lumen enlargement,[2] which means that a nonstent-like result can be accepted initially and an improvement of the vessel lumen occurs over the course of a few months.

The treatment algorithm is the "DCB-only" concept. The focus is on preparing the lesion and achieving the best possible primary result without causing a flow-limiting dissection.[3] Dissections improve DCB efficacy as long as they do not impair flow and present a risk of vessel closure. Together with dual platelet therapy, this "DCB-only" concept has proven to be safe in many registries and randomized trials.[4] However, the recommendations of the DCB consensus group on lesion preparation and its goals are predominantly expert opinions. Furthermore, clinical evidence from randomized trials (RCT) exists mainly for de novo lesions in small coronary arteries (SVDs).[5]

The present study by Funatsu and colleagues included 934 consecutive patients with 1751 de novo lesions treated with DCB only. Almost half of the lesions were complex (type B2/C), and 27% were heavily calcified. In 64%, intravascular imaging was used without crossover to DES. The high use rate of debulking devices (rotational, orbital, and directional atherectomy) and scoring balloons demonstrate the complexity of the patient group presented here. In the multivariate analysis of the predictors of target lesion revascularization (TLR), only hemodialysis and current smoking had predictive significance. Procedural factors such as the amount of calcification, the length of the lesion or DCB, dilatation time, angiographic success, or the occurrence of a relevant dissection had no significant influence on the occurrence of a TLR. The angiographic and clinical outcomes of non-SVD lesions were similar to SVD lesions. Furthermore, the use of scoring balloons showed no additional benefit.

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One may be disappointed that there were hardly any predictors of outcome. However, this is precisely the good news from these data, as they show that even complex lesions can be treated with DCB alone with similarly good results as simple lesions. The treatment was safe, with acute occlusion occurring in only 0.06% (one lesion). Especially with complex lesions, DCB therapy often simplifies the procedure. There is no need to optimize stent deployment or follow complex bifurcation algorithms. Nonrandomized data such as in the present study cannot, of course, replace RCT, but they do provide information as to which patient groups are eligible for future RCT—including those with complex lesions.

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CONFLICT OF INTEREST STATEMENT

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