

Redefining the way to perform percutaneous coronary intervention: a view in search of evidence

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Graphical Abstract

Drug-coated balloon strategy



Pros

May simplify the procedure

Short DAPT or single antiplatelet

Allows for positive remodeling

Limit stent layers at long-term



Cons

Specific operator skills

Need to evaluate dissections

Less appealing immediate result

Need to build evidence

Metal-limited PCI. Pros and cons of a drug-coated balloon strategy. DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention.

Percutaneous coronary intervention (PCI) has long been conceived as optimal stent implantation since introduction of the first stents and even more so with drug-eluting stents (DES), second and third generation DES.

Results from several trials support the conclusion that stent implantation is superior to plain balloon angioplasty (POBA) to prevent restenosis.^{1,2} There was no reason to conceive a study to evaluate whether stent implantation was superior to POBA when dealing with occlusive, or almost occlusive, dissections. Indeed, the advantage of stenting was so clear to make such a trial inappropriate.

Subsequently, superiority of DES to bare metal stent in terms of restenosis prevention was proven.³ Availability of second-generation

DES, whose implantation was so safe and quite reliable to prevent restenosis, contributed to conversion of what was born as a rescue approach to treat impending vessel closure, into a default strategy to perform PCI.

The logic behind this conduct is clear and supported by many studies. What is also clear is that, despite all refinements, PCI including DES implantation performs inferiorly to coronary artery bypass grafting (CABG) in moderately to highly complex lesions.^{4,5} Imaging-guided DES implantation and optimal lesion preparation including better handling of calcified lesions are possible solutions, although not free of complexity, risk of complications, and cost. Solid evidence comparing such an approach vs. CABG is though still lacking.

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Finally, the persistent risk of late stent thrombosis and restenosis after DES implantation, with a 2% hazard per year, is a concern, regardless of lesion complexity.⁶

We invite the Interventional Community to a look back, with the aim to offer our forecast to the field of PCI, rather than proposing an immediate change.

We envision that the following concept has the potential, if supported by adequate studies, to reshape the way to perform PCI: 'Performance of optimal lesion dilatation with an adequate result should not be considered a straightforward justification to carry on with DES implantation.'

Indeed, why do we implant DES? If the result after lesion dilatation appears angiographically poor due to recoil or dissection judged unstable, DES implantation should follow to avoid impending vessel closure and, possibly, restenosis. If the result after lesion dilatation is satisfactory, why cannot we opt to deliver an anti-restenotic medication via drug coated balloon (DCB) angioplasty rather than proceeding with DES implantation?

Given the above suggestions, two important questions arise when picturing such metal-limited PCI strategy:

- (1) How can we be safe (both patient and operator) that the result of lesion preparation will not lead to acute or sub-acute vessel occlusion?
- (2) Why should the proposed approach including DCB angioplasty be superior to DES implantation?

The first question is about safety

In our experience, we have witnessed that results after pre-dilatation fall into three groups, and a dedicated approach may follow:

- Group 1: optimal result (residual diameter stenosis <30%) without or with minimal dissection—we suggest DCB.
- Group 2: poor result with recoil or occlusive dissection—we suggest DES.
- Group 3: intermediate result with good lumen gain with a dissection leading to uncertainty about stability of the result. In these situations, we suggest evaluation of the pressure in the vessel distal to the lesion (Pd) compared to the aortic pressure (Pa): the Pd/Pa gradient. Our experience has been positive, with no vessel occlusion, whenever the Pd/Pa gradient is 10 mm Hg or less.⁷ In case of diffuse disease, our approach entails starting from the very beginning with a pressure wire to monitor the dilatation procedure via the Pd/Pa gradient. In some long lesions, proximal implantation of a short DES, in combination with DCB angioplasty addressing the remaining disease, appears a reasonable solution.

The second question leads us to discuss about reasons to try avoiding stenting

Although fully aware of the value of stenting, limiting this approach may have immediate, medium-term, and long-term advantages:

- Immediate: the procedure can be simplified—indeed, stent delivery is not always a straightforward procedure.
- Medium-term: dual antiplatelet therapy can be shortened or, possibly, avoided.⁸

- Long-term: absence of a persistent foreign body may limit vessel wall reactivity and lower the risk of neoatherosclerosis. Positive vessel remodelling and lumen gain could also be achieved.

Presently, we have several observational and randomized studies giving some evidence about the safety and effectiveness of DCB treatment mainly in *de novo* lesions located in small vessels.^{9–12} On the other hand, randomized evidence addressing usage of DCB in *de novo* lesions located in large vessels is limited.¹³ Similarly, the REvascularization With PaclitaxEL-Coated Balloon Angioplasty Versus Drug-Eluting Stenting in Acute Myocardial Infarction Trial¹⁴ is among the few studies evaluating usage of DCB in large vessels in the context of acute myocardial infarction; therefore, a solid base to support usage of DCB in acute coronary syndromes is today lacking. Recently, a DCB-based treatment approach was shown to lead to reduced stent burden and lower risk of major adverse cardiac events when compared with DES-only treatment in multi-vessel coronary artery disease.¹⁵ We recognize that large, randomized studies with long-term follow-up will be needed to appropriately answer this question. We hereby provide some images (*Graphical Abstract*) to highlight the metal-limited PCI strategy we propose, which is being evaluated in many trials in progress (NCT04859985, NCT05550233, NCT04893291, NCT05209412).

Finally, we would like to stress that, although the terminology 'DCB' has been adopted in a generic fashion, these devices do not have a class effect. Data regarding performance of each specific DCB are needed.

Data availability

No new data were generated or analysed in support of this research.

Conflict of interest

All authors declare no conflict of interest for this contribution.

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