Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022) 100003

Contents lists available at ScienceDirect

Journal of the Society for Cardiovascular Angiography & Interventions

journal homepage: www.jscai.org

Editorial

We Now Have a Tool to Optimally Implant Stents

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Stent implantation with intravascular ultrasound (IVUS) guidance has been shown to lower follow-up adverse events including death.[1] The same is true for optical coherence tomography (OCT).[2] Thus, systematic use of intravascular imaging has been strongly advocated when treating calcific lesions.[3] Indeed, not only can intravascular imaging accurately assess the baseline severity and extent of calcifications,[4] but it is also crucial for stent optimization by detecting under-expansion and malapposition, well-known mechanisms of in-stent restenosis (ISR). Notwithstanding these advantages, the use of intravascular imaging to guide percutaneous coronary interventions (PCIs) and to help interventionalists select proper plaque modification devices remains negligible. A few key reasons help explain the underuse of intravascular imaging. First, despite significantly lowering adverse events, IVUS-guided PCI has a modest impact on the reduction of absolute number of these events.[1] In addition, it is difficult to achieve "truly optimized PCI" based on imaging criteria—optimal IVUS-guided stent implantation, defined as a minimal stent cross-sectional area >5.5 mm^2, is reached in just about 50% of the lesions,[5] with severely calcific and fibrotic lesions being more challenging for achieving optimal final results. Finally, assessment of adequate lesion preparation before stenting is rarely performed, although further modification of a fibrocalcific plaque after stenting may be challenging, especially when using techniques relying on mechanical tissue injury by physical interaction.

Intravascular lithotripsy (IVL) may effectively improve the final lumen after stenting in lesions known to be associated with a suboptimal result. The publication of the short-term results of Disrupt CAD III[6] in 2020 that introduced IVL was the first step forward. This prospective, single-arm, multicenter study enrolled 384 patients with severely calcified coronary lesions (radio-opacities on both sides of the artery during still frames), with a total lesion length <40 mm. The study showed good acute success with IVL (residual stenosis <50% without in-hospital major adverse cardiovascular events [MACE] in 92.4% and successful IVL delivery in 98.2%). An OCT substudy enrolled 97 patients and confirmed 102 ± 29% stent expansion (OCT was used to document the result, not to guide the procedure). The study reported a very low rate of complications (0.3% perforation, no slow flow).

These promising short-term outcomes are consistent with the recent patient-level pooled analysis of the Disrupt CAD I, II, III, and IV studies.[7] Although these data are encouraging, they need to be replicated in a more real-world population, as these studies excluded a number of clinically high-risk patients and complex lesions (unprotected left main stenosis, ostial lesions, severe tortuosity, ISR).

The publication of the 1-year outcomes of Disrupt CAD III[8] represents a second step forward. At 1-year follow-up, available in 97.1% of the patients, the rate of MACE was 13.8% (1.1% cardiac death, 10.5% myocardial infarction [MI] [3.2% after 30 days], and 6% ischemia-driven target vessel revascularization), the target vessel failure was 11.9%, and the stent thrombosis was 1.1% (just 1 event after 30 days). The adverse event rate was higher in patients with longer lesions (MACE 9% if <25 mm and 17.6% if >25 mm). Prior MI and bifurcation lesions were predictors of MACE.

Notably, the lack of intravascular imaging guidance for stent implantation may have negatively affected these results. Indeed, despite the remarkable rate of balloon postdilatation (99%), the extensive use of IVUS and OCT may help recognize suboptimally expanded areas and lead to the use of larger final postdilation balloons, thus improving the final minimal stent cross-sectional area and reducing the likelihood of events (both hard, such as stent thrombosis, and soft, such as ISR).

Are these results better than expected?

In a large study evaluating the impact of moderate/severe calcifications after PCI at 5-year follow-up,[9] target lesion failure occurred in 16% of patients, MI in 7%, target lesion revascularization in 9.4%, and stent thrombosis in 2.9%. Comparisons with the present study are difficult, as moderate calcified lesions were included and follow-up was extended to 5 years.

How these data compare with those from the use of other lesion modification devices?

Lesion preparation with upfront mechanical atherectomy, laser atherectomy, or IVL has been encouraged as the strategy of choice

DOI of original article: https://doi.org/10.1016/j.jscai.2021.100001.
Keywords: Stent; Calcium; Lithotripsy.
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https://doi.org/10.1016/j.jscai.2021.100003
Received 18 November 2021; Accepted 29 November 2021

when treating lesions with multiple complex calcium imaging features.[3] Comparisons with previous trials evaluating rotational atherectomy (RA) may not be appropriate, considering the different design of the studies and angiographic exclusion criteria. Nevertheless, the ORBIT II trial,[10] which evaluated orbital atherectomy in severely calcified lesion and had similar inclusion and exclusion criteria to the present study, reported MACE in 16.9%, cardiac death in 3.2%, MI in 10.6%, and target lesion revascularization in 4.7% of patients at 1-year follow-up.

These data suggest that "new generation" devices may produce similar results in terms of lesion preparation and technical success. We believe that the procedural simplicity, quick learning curve, and low rates of procedural complications (especially slow flow and perforations) are the main strengths and unique features of IVL. Furthermore, IVL may become the first choice when treating calcific lesions involving bifurcations, as it allows the operator to keep a wire in both branches and minimizes the risk of side branch occlusion. Conversely, RA and orbital atherectomy are still better choices for uncrossable lesions. While evidence supporting RA for unprotected left main lesions and calcified ostial right coronary artery lesions is available, evidence for IVL use in these settings is lacking. Finally, the combined use of different tools, although promising, is still not fully studied.

Both short- and long-term results after IVL represent important evidence helping interventional cardiologists to consciously select the right device in each setting of calcific lesions. The fact that early positive results are now sustained at 1 year is confirmation that we are moving in the right direction. Indeed, we now have intravascular imaging to help us identify and evaluate calcific lesions and plaque modification devices such as IVL to better expand stents even in settings traditionally considered unsuitable for optimal stenting. Although more expensive and time consuming, we believe this is the right way to implant stents and, ultimately, minimize complications.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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