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Novel DES Aims at Full Thromboresistance: Another Promising Player on the Field?



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Over the years, technical innovations have refined various aspects of coronary drug-eluting stents (DES), which resulted in excellent clinical results after treatment with new-generation DES [1,2]. The overall low adverse event rates with several contemporary DES in all-comer patients suggest that there may be little room for further improvement, which could diminish interest in further DES refinement. Yet, we were pleasantly surprised to learn about a novel device that combines several favorable features of previous and current "gold-standard DES." The ithDestiny sirolimus-eluting stent (SES) (Iberohospitex S.A., Llica de Vall, Spain) utilizes four principal elements of DES innovation: (I) reduction in strut thickness to increasingly thin dimensions; (II) reshaping of struts to more "streamlined" cross-sections; (III) use of polymers renowned for low thrombogenicity; and (IV) delivery of an antithrombotic drug besides the anti-proliferative drug. The PROMETHEUS study, a first-in-man assessment of this new DES, is reported by de la Torre Hernandez et al. in the current issue of the journal [3].

In fact, the novel SES has ultrathin struts that facilitate stent endothelialization and have been linked to better clinical outcomes as compared to DES with thicker struts [4-7]. In addition, the oval strut shape of this SES may be somewhat similar to the strut shape of the most recent iteration of the zotarolimus-eluting stent [8,9], which has a very low acute stent thrombosis risk [8] and is suitable for onemonth dual antiplatelet therapy (DAPT) in high-bleeding-risk patients [10]. The more streamlined strut shapes are thought to reduce local flow turbulence around stent struts, facilitate stent endothelialization, and prevent the formation of microthrombi around struts [3]. Furthermore, an abluminal fluoropolymer coating is utilized in the new SES. Fluoropolymer coating has previously been used in well-known everolimus-eluting stents that in preclinical studies showed low thrombogenicity [11] and only few coating defects after aggressive (oversized) postdilation [12]. Moreover, a network analysis of clinical studies revealed that fluoropolymer-coated cobalt chromium-based everolimus-eluting stents were associated with a low rate of definite

stent thrombosis at long-term follow-up [13]. Finally, the novel SES releases not only the established anti-proliferative drug sirolimus but also triflusal – a platelet aggregation inhibitor with effects similar to aspirin [14]. This drug, which is released, during a period of 2 years might help prevent thrombus formation, yet the potential benefit of such slow release is unclear.

The PROMETHEUS study revealed favorable angiographic results, including a low mean late lumen loss of 0.11 mm at 9-month follow-up [3]. In addition, optical coherence tomography (OCT) analysis showed no subclinical stent thrombosis and low rates of malapposed or uncovered struts (1.1% and 2.5%, respectively). The incidence of repeated target lesion revascularization was also low (3.0%). While the development of in-DES restenosis may not be fully completed at 9 months, choosing this time for the OCT analysis is suitable to compare the present findings with the results of previous OCT studies [15].

The featured study is a well-executed first-in-man study, and the acquisition of an OCT follow-up in 58 out of 65 patients is very reasonable especially when considering the challenging circumstances of clinical research during the ongoing COVID-19 pandemic. Nevertheless, some critical comments can be made. Surprisingly, DAPT was prescribed for at least 9 months in all study participants, while one in four patients was treated for stable angina, for which international guidelines generally recommend 6 months of DAPT [16]. The 9-month duration of DAPT is even more surprising when considering that the novel SES combines several anti-thrombotic features that could make this DES very suitable for short-term DAPT. Another issue is the radiopacity of the novel SES. Allegedly, the stent combines the best features of current DES [3], but x-ray visualization of ultrathin-strut cobalt chromium stents is rather difficult, especially compared to stents that are made from more dense alloys (e.g., containing platinum) [17,18] or from struts with a platinum core [9,19]. Limited stent visibility may be an issue when stenting ostial lesions or implanting overlapping stents. As outlined by the authors, the occurrence of periprocedural myocardial infarction may have been underestimated because routine serial assessment of cardiac markers









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was not performed. Yet, this approach represents real-world practice in which serial assessment of cardiac markers may often not be done. Furthermore, the authors point out that during the index PCI, no systematic assessment with OCT was required. Nevertheless, this may actually be preferable, as this approach reflects routine clinical practice and makes study findings more applicable to real-world scenarios.

All in all, we congratulate Dr. de la Torre Hernandez and his coworkers on a well-performed first-in-man study of a novel DES that shows promising initial results. Yet, future randomized comparisons against current "gold-standard DES" in all-comers are required before the clinical value of this novel device can ultimately be determined.

Declaration of competing interest

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