

Standardising the complexity of contemporary PCI

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The field of percutaneous coronary intervention (PCI) has evolved substantially over the last 3 decades¹. Initially performed mostly among patients with single, focal coronary lesions, PCI is now being applied across the entire spectrum of coronary artery disease complexity¹. Technological innovations and iterations in drug-eluting stent platforms, intravascular imaging, plaque modification, antithrombotic therapies, and mechanical circulatory support have made this possible². Currently, it is estimated that approximately 30% of patients undergo complex PCI procedures. However, a universally accepted definition of “complex PCI” does not exist. About 10 years ago, at a time when there was intense debate on the optimal duration of dual antiplatelet therapy post-PCI, we first proposed an intuitive and easy-to-use definition of “complex PCI” to try to identify patients at higher risk of ischaemic events who may derive a greater benefit from prolonged or more intense antithrombotic therapies³. Since then, the criteria for complex PCI have been evaluated in many subsequent observational studies and subgroup analyses of randomised controlled trials and have been endorsed by the European Society of Cardiology (ESC) and the Japanese Society of Cardiology in their respective guidelines^{4,5}.

In this issue of EuroIntervention, Piccolo et al⁶ contribute a large, comprehensive meta-analysis, including more than 290,000 patients, that evaluates the association of PCI complexity with ischaemic and bleeding outcomes. A total of 36 studies were included, and among the study population, features of complex PCI were present in 33% of patients. The definition of complex PCI varied among studies but had to include at least 2 of the following criteria: ≥ 3 stents implanted, ≥ 3 vessels treated, ≥ 3 lesions treated, bifurcation lesions requiring implantation of ≥ 2 stents, a total stent length

>60 mm, PCI of a chronic total occlusion (CTO), left main PCI, in-stent restenosis, or use of atherectomy. The authors should be congratulated for applying very robust and rigorous analytical methods. At a median follow-up time of 1 year, in adjusted analyses, complex PCI compared with non-complex PCI was associated with a higher risk of cardiac ischaemic events including myocardial infarction (hazard ratio [HR] 1.71, 95% credible interval [CrI]: 1.49-1.96), stent thrombosis (HR 1.71, 95% CrI: 1.45-2.04), and target lesion or vessel revascularisation (HR 1.99, 95% CrI: 1.58-2.49). On the other hand, complex PCI was also associated with a higher risk of major bleeding events (HR 1.24, 95% CrI: 1.14-1.35). It should be noted that the magnitude of the association of complex PCI with adverse outcomes was substantially greater for ischaemic events rather than for bleeding events. For instance, the HRs for myocardial infarction, stent thrombosis, and repeat revascularisation ranged from 1.71 to 1.99, compared with 1.24 for major bleeding. Results were largely consistent in sensitivity analyses and in subgroup analyses, with consistent effects across observational studies, randomised controlled trials, and in patients with or without acute coronary syndrome.

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Defining PCI complexity in clinical practice is important for multiple reasons. First, it allows for risk stratification with implications for prognostication, longitudinal clinical follow-up, and the tailoring of more aggressive pharmacological therapies. In addition, it is relevant for operator training, reimbursement, credentialing, and shared decision-making with patients and for multidisciplinary Heart Team discussions. The definition utilised by Piccolo et al across the literature convincingly captures most of the elements that constitute a complex PCI and quantifies its associated risks compared with non-complex

procedures⁶. The limitations of the current analysis are the lack of patient-level data, the inability to evaluate the individual effects of each subset of complex PCI (e.g., bifurcation with ≥ 2 stents vs CTO PCI), and the incremental effect of multiple complex PCI components in an individual patient.

While the benefits of coronary artery bypass surgery are undeniable in patients with complex multivessel coronary artery disease who are surgical candidates¹, as a field, we need to continue to push our limits to improve the short- and long-term outcomes of complex PCI. First, we need better and more consistent training requirements to ensure that contemporary PCI operators can safely perform complex PCI. While technical complexity can be relative (what is difficult for one operator may not be for another), it is important to ensure that minimum standards are met (e.g., ability to perform atherectomy, a bifurcation with ≥ 2 stents, or obtaining large-bore access for the use of percutaneous mechanical circulatory support). Second, trade-offs between ischaemic and bleeding risks continue to be challenging, as complex PCI patients are inherently at higher risk for both complications due to a greater prevalence of comorbidities, usually more diseased peripheral vasculature, and the use of more intense antithrombotic therapies⁷. Addressing the residual atherothrombotic risk and developing novel pharmacological approaches that can reduce ischaemic events without increasing bleeding are warranted⁷⁻¹⁰. Third, the use of intravascular imaging is even more important in complex PCI for baseline lesion assessment, guiding the optimal plaque modification tool, and optimising stent implantation, all of which impact both short- and long-term outcomes^{11,12}. Again, ensuring appropriate and consistent training in using and interpreting intravascular imaging during these procedures is of paramount importance. In fact, it has been shown that operator experience and intravascular imaging use are strongly associated with improved outcomes, with the beneficial effects of imaging being more pronounced among less experienced operators¹³. Finally, continuing iterations in percutaneous device-based therapies driven by industry are welcomed, but they require critical and careful appraisal of their efficacy and safety in contemporary practice, beyond the data from randomised controlled trials in selected patient populations.

It is time to move beyond debating what constitutes complex PCI. This meta-analysis is a welcome contribution to the literature, confirming a decade of data evaluating the impact of PCI complexity. We now need to act to further improve its efficacy, safety, and long-term patient outcomes.

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Conflict of interest statement

G. Giustino has been a proctor and consultant for Edwards Lifesciences, Medtronic, and Shockwave Medical; and is a founder and shareholder of Antegrade Medical.

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