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LETTER TO THE EDITOR

In Response to: Methodological Considerations on the Design of the DCB-DCS Registry

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We would like to thank the author for the careful evaluation of our design paper and for the thoughtful comments. The observations raised are constructive and provide an opportunity to further clarify several methodological aspects of the drug-coated balloons-drug-coated stents (DCB-DCS) registry. Because the published article was intended to describe the rationale and design of the registry rather than report clinical outcome data, several of the comments naturally concern the interpretation of the final analyses and will therefore be addressed in greater detail in the primary results manuscript. Our point-by-point responses are provided below.

Comment 1. Primary Endpoint

We appreciate this important observation. The apparent inconsistency reflects a distinction between the procedural and clinical outcome domains rather than conflicting study objectives. Procedural success was defined as the primary procedural endpoint, whereas 12-month target lesion failure was defined as the primary clinical endpoint. These endpoints assess complementary aspects of DCB treatment and were not intended to be mutually exclusive. To avoid potential ambiguity, the distinction between the procedural and clinical endpoints will be described more explicitly in the primary results manuscript.

Comment 2. Follow-up Strategy and Ascertainment Bias

We agree that clinically driven angiographic follow-up may introduce ascertainment bias, which is an inherent limitation of pragmatic, real-world registries. However, clinically indicated repeat angiography was prospectively defined in the study protocol, and angiographic outcomes, including late lumen loss, were prespecified as exploratory endpoints. Our intention was to capture routine contemporary clinical practice rather than impose protocol-mandated surveillance. We will further emphasize these methodological considerations in the primary results manuscript and discuss their potential implications when presenting the final registry results.

Comment 3. Suggested Surveillance Strategy

We appreciate these thoughtful suggestions. Although standardized angiographic or functional surveillance could reduce ascertainment bias, mandatory protocol-driven follow-up would substantially alter the pragmatic design of the registry and potentially limit its applicability to real-world clinical practice. The DCB-DCS registry was intentionally designed to reflect routine clinical practice across participating centers. We therefore consider these proposals to be valuable methodological considerations for future dedicated studies rather than essential components of the present registry.

Comment 4. Follow-up Terminology

We thank the author for highlighting this point. We agree that the terminology should accurately reflect the planned follow-up duration and will revise the wording accordingly to ensure consistency throughout the manuscript.

Comment 5. Heterogeneity of Clinical Scenarios

We appreciate this important comment. The inclusion of different clinical scenarios was intentional and represents one of the principal strengths of the registry, as it allows assessment of DCB use across the spectrum of contemporary clinical practice. As outlined in the Statistical Analysis section, predefined subgroup analyses, multivariable adjustment, sensitivity analyses, and appropriate modeling strategies have already been incorporated into the study design. Detailed scenario-specific analyses, including interaction testing where appropriate, will be presented in the primary results manuscript.

Comment 6. Comparison of Paclitaxel- and sirolimus-coated Balloons

We agree that comparisons between different DCB technologies in an observational registry require careful adjustment for potential confounding. Such analyses are not a primary objective of the registry. If undertaken, these comparisons will be considered exploratory and performed using appropriate statistical methods, with cautious interpretation of the findings.

We once again thank the author for these constructive comments. We believe that the suggested clarifications will improve the presentation of the study design while preserving the original objectives and pragmatic methodology of the DCB-DCS registry. We are grateful to the Editor for the opportunity to address these methodological points.

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