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Editorial

PCB vs SCB: has the balance begun to shift?

BFA de paclitaxel o de sirolimus: ¿ha empezado a cambiar el equilibrio?

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Paclitaxel-coated balloons (PCB) have long dominated the drug-coated balloon (DCB) landscape, supported by favourable pharmacokinetics and extensive randomised evidence.[1] Sirolimus, by contrast, is inherently less lipophilic and biologically dependent on sustained arterial wall exposure, rendering simple balloon-coating strategies suboptimal. Consequently, early-generation sirolimus-coated balloons (SCB) were met with skepticism regarding effective drug transfer and durable tissue retention. Signals of attenuated late lumen gain with SCB in early randomised comparisons, including the TRANSFORM I, highlighted these limitations.[2] However, subsequent randomised trials in both de novo lesions and in-stent restenosis have failed to demonstrate a meaningful difference in late lumen loss versus PCB.[3] Crucially, in contemporary meta-analyses, even when modest angiographic differences are observed, these have not translated into significant differences in clinically relevant outcomes, including target lesion failure, repeat revascularisation, or myocardial infarction.[4,5]

The SELUTION SLR platform (Cordis, United States) is a deliberate evolution in this field, incorporating a proprietary phospholipid carrier and micro-reservoir architecture designed to enable controlled and prolonged sirolimus release with minimal drug loss.[6] The key question is whether this technological maturation translates into meaningful therapeutic equivalence.

In a recent paper published in *REC: Interventional Cardiology*, Faria et al. present a prospective single-center registry of 257 patients with 316 de novo lesions and provide a contemporary head-to-head comparison between the SELUTION SLR and the established Pantera Lux (Biotronik, Germany) PCB.[7] The authors are to be congratulated for assembling a real-world cohort that included both acute and chronic coronary syndromes, a high prevalence of bifurcation disease, and frequent hybrid strategies. At 12 months, clinical outcomes were reassuringly low and statistically similar between devices, with a MACE rate of 5.8% and a target lesion failure rate of 3.8% overall. Target lesion revascularisation occurred in fewer than 1% of lesions.

Several aspects of the study merit recognition. The registry was prospective with complete 1-year follow-up. The investigators appropriately avoided multivariable or propensity modelling in the setting of low event counts, thereby avoiding the risk of statistical overreach. Lesion preparation was systematic, imaging use was encouraged, and bailout criteria was clearly defined, reflecting thoughtful procedural strategy.

Nevertheless, these findings do require careful interpretation. The treated population was predominantly small-vessel disease, with a mean DCB diameter of 2.25 mm and only 18.7% of vessels ≥ 3.0 mm. As such, these findings primarily reinforce the established role of DCB in small-calibre arteries rather than expanding indications into larger vessels. Although subgroup analysis in larger vessels did not reveal excess adverse events, bailout stenting was notably higher in ≥ 3 mm arteries (18.6%), suggesting that operator thresholds for permanent scaffolding may differ by vessel calibre. The observed reduction in mild, non–flow-limiting dissections with the SELUTION SLR (6.7% vs 14.7%) warrants careful interpretation. Types A-B dissections are expected following DCB angioplasty and are typically benign when TIMI 3 flow is preserved.[8,9] Whether this difference reflects intrinsic coating behaviour, mechanical interaction, lesion preparation variability, or simply procedural nuance cannot be determined in the absence of randomisation or imaging adjudication. Similarly, the absence of no-reflow events in the SCB arm compared with 2.7% in the PCB group is hypothesis-generating but numerically small. The small number of events precludes definitive mechanistic interpretation.

Taken together, what conclusion can be reasonably drawn from these data? This study demonstrates that the SELUTION SLR platform is safe and clinically comparable to an established PCB in a predominantly small-vessel, real-world population. It does not demonstrate superiority in clinical endpoints. The procedural signals—fewer mild dissections and less no-reflow—are intriguing but remain angiographic observations rather than outcome-altering findings.

In this context, the evolution of sustained-release technology appears incremental rather than revolutionary. Importantly, these findings sit alongside a growing body of randomised evidence. In SELUTION DeNovo RCT, a sirolimus-eluting balloon strategy demonstrated non-inferiority to contemporary drug-eluting stents in selected de novo lesions, supporting the feasibility of a "leave-nothing-behind" approach.[10] Whether such platforms will ultimately displace paclitaxel balloons or simply broaden therapeutic choice, remains to be determined by longer-term and adequately powered comparative trials.

For now, the balance has not decisively shifted—but the field is more competitive.

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