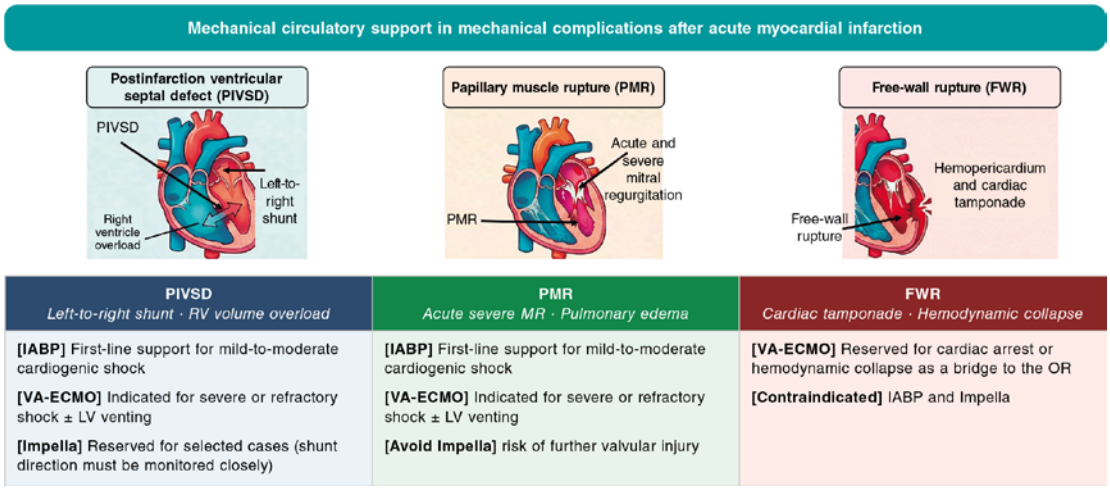
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REVISTA ESPAÑOLA DE CARDIOLOGÍA

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REC: Interventional Cardiology establishes its position as its impact grows

REC: Interventional Cardiology consolida su posición y aumenta su impacto

José M. de la Torre-Hernández,[a,*] Fernando Alfonso,[b] Raúl Moreno,[b] Soledad Ojeda,[b] Armando Pérez de Prado,[b] and Rafael Romaguera[b]

[a] *Editor-in-Chief, REC: Interventional Cardiology*
[b] *Associate Editor, REC: Interventional Cardiology*

Since the launch of *REC: Interventional Cardiology*, the editorial team has pursued the goal of establishing and consolidating the journal, the official publication of the Interventional Cardiology Association of the Spanish Society of Cardiology (ACI-SEC), as one of the leading international journals in the field of interventional cardiology. Its bilingual nature and fully open access to its content are consistent with this objective. However, achieving this goal required attracting high-quality content and ensuring its appropriate visibility in editorial databases and information systems.

Throughout the years, the journal has progressively achieved indexing in several publicly accessible databases, culminating in its inclusion in the most significant of these, PubMed Central (PMC), developed by the US National Library of Medicine and the National Institutes of Health. This milestone has significantly increased the visibility and accessibility of the journal's content worldwide, allowing interested readers to access and cite its articles in their own publications.

As a result of this process, the journal received its first impact factor (IF) in 2024 (2023 IF: 1.2), which increased slightly the following year (2024 IF: 1.3) and rose further in the 2026 edition (2025 IF: 1.5), as shown in figure 1.[1] Despite its well-known limitations, this editorial metric is intended to reflect the impact of a publication.

Although the impact factor is an important metric, increasing it should not be an end per se for a scientific journal. Its primary and essential mission is to publish high-quality scientific research and disseminate relevant review and consensus documents. This is where the journal's true impact lies.

Nevertheless, a higher impact factor can attract higher-quality submissions to the journal, which are more likely to be cited and thus further increase the journal's real impact. Furthermore, authors publishing in *REC: Interventional Cardiology* may benefit from the greater visibility and impact of their article, which has considerable implications for their academic and professional credentials. Indeed, readers and authors are already citing articles from the journal in their own publications, helping to increase its visibility and influence. We expect this trend to continue, supported by the recognition associated with PMC indexing and the journal's current impact factor. Among the articles that have contributed most to the latest impact factor are the ACI-SEC position statement on plaque modification in calcified lesions,[2] the registry by Real et al.[3] on reperfusion therapies in patients with intermediate-high-risk pulmonary embolism, and the ROLLERCOASTR study design published by Jurado-Román et al.[4]

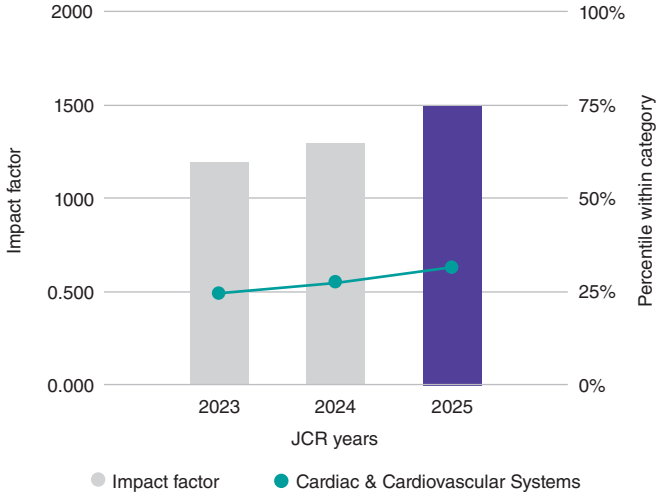


Figure 1. Trends in the impact factor of *REC: Interventional Cardiology*.

EDITORIAL ACTIVITY

Figure 2 illustrates the content published since the journal's launch. The annual number of published articles has declined slightly in recent years, largely due to the discontinuation of case reports in 2024, which had previously been counted as 3 separate items (Case presentation, How would I approach it?, and Case resolution), and the shift to publishing scientific letters and images in cardiology on an as-needed basis.

Over the past year, the journal's quarterly issues have featured original articles, thematic reviews, scientific letters, images, debates, editorial commentaries, and, occasionally, consensus documents endorsed by the ACI-SEC, as well as the abstracts presented at its annual congress.

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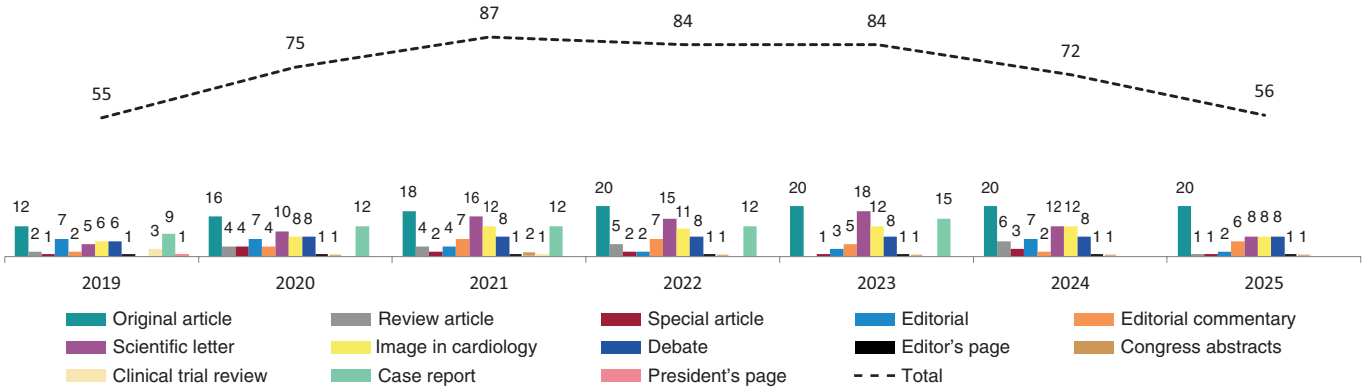
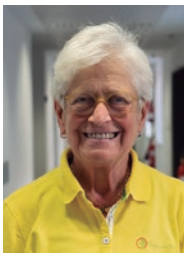


Figure 2. Content published in *REC: Interventional Cardiology*, 2019-2025.



An interview with Camino Bañuelos

Una entrevista con Camino Bañuelos



Pilar Jiménez Quevedo[a,*], and Ana Belén Cid Álvarez[b]

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Figure 3. First article in the interview section of *REC: Interventional Cardiology* (2026).

In 2026, alongside the *Debate* section, we have interspersed interviews with prominent national and international figures in interventional cardiology. This series began with an interview with Camino Bañuelos conducted by Pilar Jiménez Quevedo and Ana Belén Cid Álvarez (figure 3).[5]

The following sections and figures provide statistical data on the different article categories. Information for 2026 refers exclusively to the activity of the first half of the year, reflecting the data available at the time of writing.

Original articles

Original articles are the cornerstone of any scientific publication, and their quality largely determines the journal's overall standing. It is particularly encouraging to see that submissions of original articles have increased steadily since the journal's launch, with a marked rise in 2025 that is likely to be surpassed in 2026. Indeed, submissions received during the first 6 months of 2026 already account for 78% of the total received in 2025 (figure 4). We believe that the journal's inclusion in PCM in 2025 has played an important role in attracting more submissions.

Since 2022, English has become by far the predominant language of original article submissions (figure 5). This trend reflects 2 developments: the journal's growing appeal to international authors, particularly from the Asia-Pacific region, Europe, and Latin America, and an increase in English-language manuscripts submitted by Spanish authors after previous submission to international journals. Both trends suggest that the journal is attracting higher-quality manuscripts, likely encouraged by its PMC indexing and impact factor.

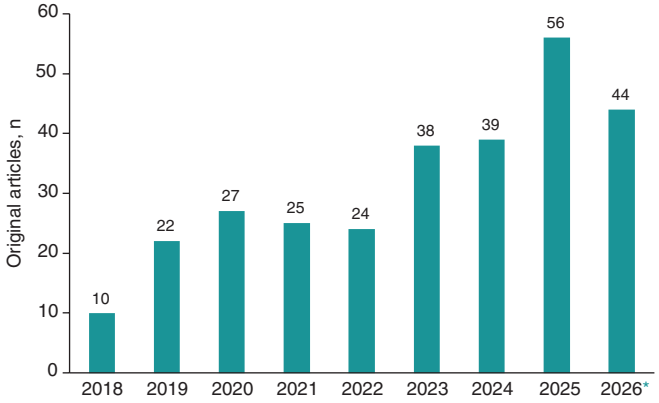


Figure 4. Submission of original articles to *REC: Interventional Cardiology*. *Data through June 30.

Another important consideration for authors is the speed of editorial decision-making, which reflects the efficiency of the journal's editorial processes. Although the mean time to decision has increased slightly in recent years, probably because of the growing volume of submissions, our editorial turnaround times remain highly competitive compared with those of other prestigious journals (figure 6).

As is customary in this *Editor's page*, we encourage readers to submit their original articles to our journal, where they can expect a prompt and efficient editorial review process.

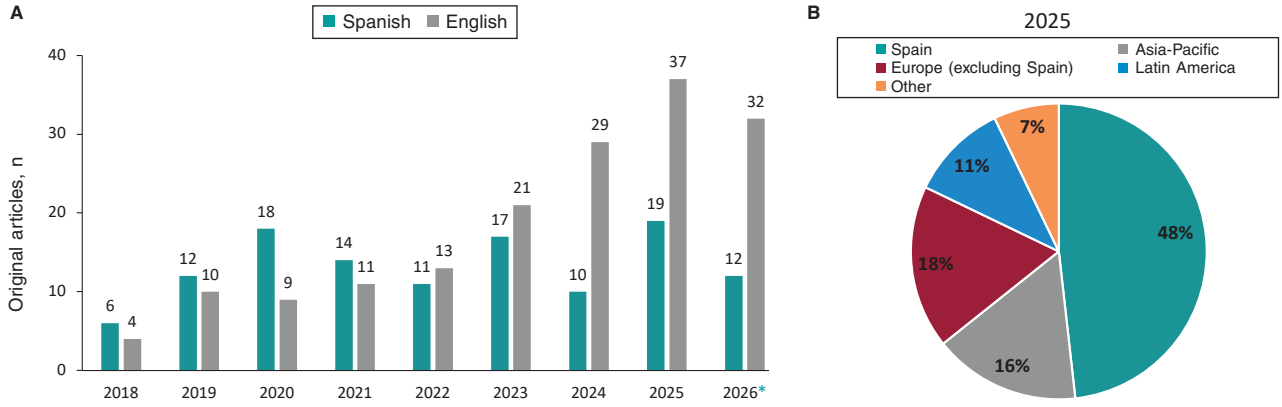


Figure 5. **A:** language of original articles submitted to *REC: Interventional Cardiology*, 2018–2026. **B:** geographic origin of original articles submitted in 2025. *Data through June 30.

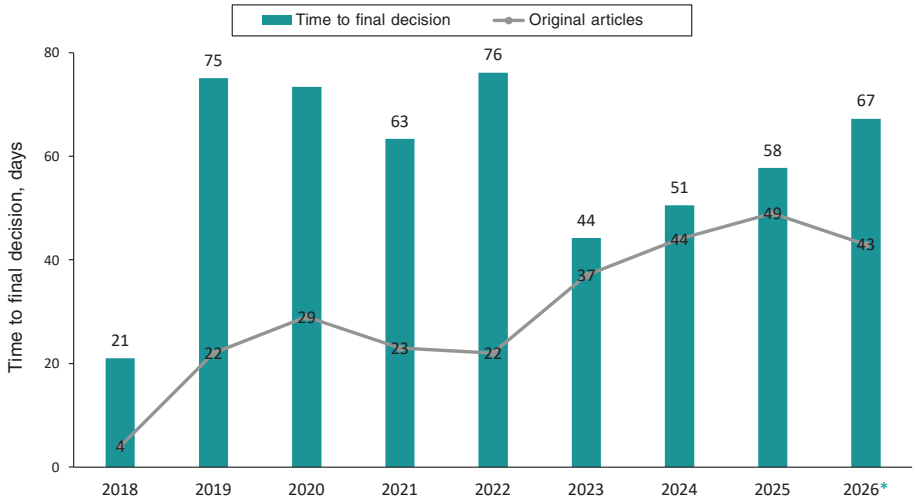


Figure 6. Mean time to final decision on original articles, 2018–2026. The bars represent the mean time to final decision. The gray line indicates the number of articles on which a decision was made each year. *Data through June 30.

Scientific letters

This section includes both original studies presented in a shorter format and small case report series of particular interest. Small case series (1-2 cases) are considered only when they are particularly noteworthy for their originality and novelty. Moreover, scientific letters provide a valuable publication option for original articles that, although not given sufficient priority for publication as full-length articles, remain of interest to the journal.

Figure 7 indicates a recovery in submissions in this category in 2026, with the number of scientific letters received during the first half of the year already exceeding the total for 2025.

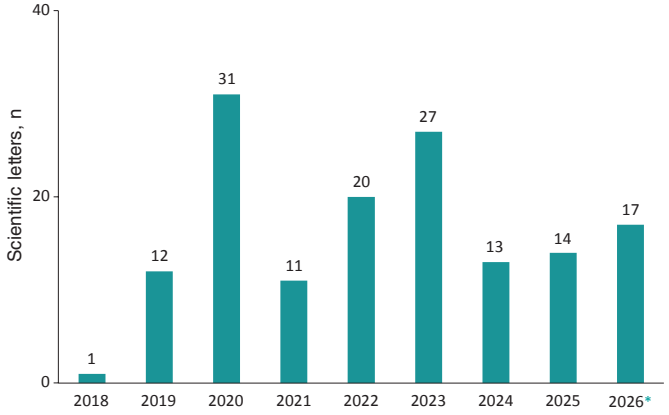


Figure 7. Submission of scientific letters to *REC: Interventional Cardiology*. *Data through June 30.

Images in cardiology

This section is particularly popular, reflecting the central role of multiple imaging modalities in our specialty (figure 8). The substantial backlog of images awaiting publication prompted us to temporarily suspend submissions in this category for several months in 2026, as we had previously done in 2024. The high volume of submissions also means that only a small proportion can be accepted because of space limitations.

Article transfers from *Revista Española de Cardiología*

The established international reputation and high impact factor of *Revista Española de Cardiología* attract a large volume of submissions, resulting in a high rejection rate. Furthermore, as a general

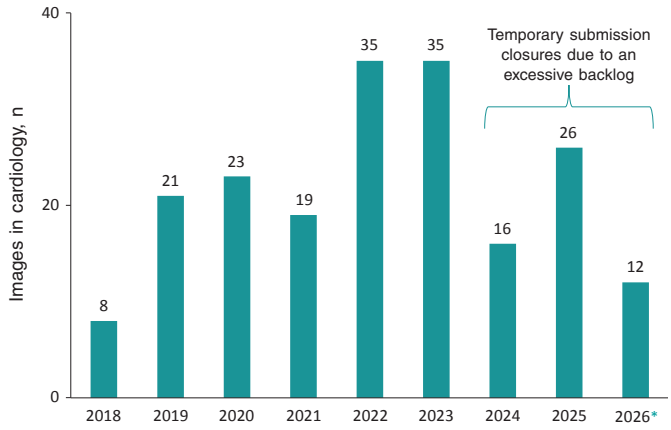


Figure 8. Submission of images in cardiology to *REC: Interventional Cardiology*. *Data through June 30.

cardiology journal, it can devote only a limited proportion of its published content to interventional cardiology.

REC: Interventional Cardiology continues to offer authors the opportunity to transfer original articles and other manuscripts rejected by *Revista Española de Cardiología* (figure 9). Until 2025, the number of transfer offers had increased steadily, although relatively few were accepted. This is understandable, as transferring a manuscript from a higher-impact journal to one with a lower impact factor may lead some authors to pursue other publication options. In 2026, however, transfer activity has declined noticeably (figure 9). We attribute this to 2 factors: more authors are submitting their manuscripts directly to *REC: Interventional Cardiology*, and the growing volume of direct submissions has prompted us to limit transfer offers and adopt a more selective approach.

Special content

As the official journal of the ACI-SEC, *REC: Interventional Cardiology* plays an important role in publishing the association's review articles, position statements, and consensus documents, sometimes developed in collaboration with other scientific societies. As in previous years, issue 3 included the abstracts of presentations delivered at the ACI-SEC annual congress, held in Pamplona (Navarre, Spain) in June 2026. These abstracts were published online ahead of print several days before the congress began.[6]

The studies presented were of high quality, and many are expected to lead to excellent original articles. We therefore encourage their authors to submit their work to the journal, either as original articles or scientific letters.

REVIEWER ACTIVITY: QUALITY, EFFICIENCY, AND COMMITMENT

Peer review is essential to scientific publishing and contributes substantially to the rigor and quality of scientific journals. Nevertheless, we recognize the growing burden placed on reviewers, who are increasingly called upon by numerous journals, particularly those known for their reliability and responsiveness. Peer review is generally performed anonymously and voluntarily, without financial compensation, requiring reviewers to devote valuable time that could otherwise be spent on activities offering greater personal or professional benefits. Recruiting new reviewers and combining different areas of expertise in the assessment of individual manuscripts are therefore essential. Against this backdrop, we are particularly grateful for the commitment of our reviewers, whose excellent turnaround times continue to enable prompt editorial decisions.

As in previous years, we wish to thank everyone who has contributed to the peer-review process (table 1), with special recognition of our 2025 elite reviewers (table 2), selected on the basis of the number of manuscripts reviewed, their responsiveness, and the quality of their evaluations.

DISSEMINATION

The annual presentation of awards for the best articles published in *REC: Interventional Cardiology* is always a highlight of the ACI-SEC annual meeting. The awards carry a total prize fund of €2500 (€1500 for first prize and €1000 for second prize). This year,

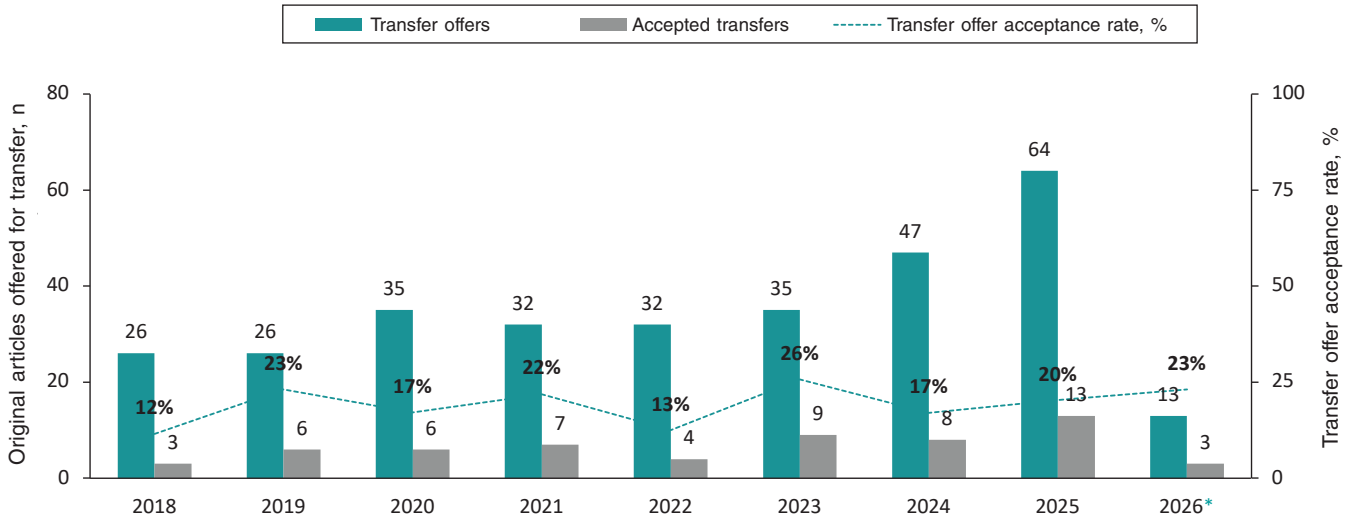


Figure 9. Proposed transfers of original articles from *Revista Española de Cardiología* to *REC: Interventional Cardiology* (2018-2026) and transfer offers accepted during the same period. *Data through June 30.

Table 1. Reviewers of *REC: Interventional Cardiology* who completed peer reviews from 1 July 2025 through 30 June 2026

Omar Abdul-Jawad	Francisco Hidalgo
César Abelleira	Víctor A. Jiménez-Díaz
Guillermo Aldama	Pilar Jiménez-Quevedo
Joaquín Alonso	Santiago Jiménez-Valero
Juan H. Alonso-Briales	Alfonso Jurado
María Álvarez-Fuente	José A. Linares
Ignacio Amat	Ramón López-Palop
Albert Ariza	Íñigo Lozano
Xavier Armario	Antonela Lukic
Eduardo Arroyo	Gerard Martí
Lluís Asmarats	Javier Martín-Moreiras
Pablo Avanzas	Dolores Mesa
Teresa Bastante	Guillem Muntané
José A. Baz	Felipe Navarro
Neus Bellera	Iván Núñez-Gil
Salvatore Brugaletta	Raymundo Ocaranza
Santiago Camacho	Jorge Palazuelos
Berenice Caneiro	Manuel Pan
Pilar Carrillo	Isaac Pascual
Xavier Carrillo	Luis Pérez-Pino
Alberto Cecconi	Javier Portales
Belén Cid	Eduardo Pozo
Juan G. Córdoba	Sergio Raposeiras-Roubín
Carlos Cortés	Ander Regueiro
Ignacio Cruz	Borja Rivero
Javier Cuesta	Fernando Rivero
José A. de Agustín	Jessica Roa
David del Val	Oriol Rodríguez
Raquel del Valle	Sandra Rosillo
José F. Díaz	Gerard Roura
Alejandro Diego-Nieto	Juan M. Ruiz-Nodar
Felipe Díez-Delhoyo	Valeriano Ruiz-Quevedo
José L. Díez-Gil	Eva Rumiz
Agustín Fernández-Cisnal	José R. Rumoroso
Luis Fernández-González	Manel Sabaté
Estefanía Fernández-Peregrina	Luisa Salido
José L. Ferreiro	Pablo Salinas
Xavier Freixa	Ángel Sánchez-Recalde
Guillermo Galeote	Marcelo Sanmartín
Eladio Galindo	Jorge Sanz-Sánchez
Tamara García-Camarero	Ana Serrador
Carmen Garrote	Daniel Tébar
Joan A. Gómez-Hospital	Luis Teruel
Josep Gómez-Lara	Helena Tizón-Marcos
Rafael González-Manzanares	Ramiro Trillo
Alejandro Gutiérrez-Barrios	Cristóbal Urbano
Enrique Gutiérrez-Ibañes	Maite Velázquez-Martín
Federico Gutiérrez-Larraya	David Vivas
Gabriela Guzmán	José L. Zunzunegui

Table 2. Elite reviewers in 2025

Raquel del Valle	Pablo Salinas
Alfonso Jurado	Jorge Sanz-Sánchez
Juan M. Ruiz-Nodar	Ramiro Trillo

first prize went to Cortés et al.[7] for their study on the prognostic value of plaque volume assessed by three-dimensional reconstruction of the coronary tree in patients without significant coronary artery disease. Second prize was awarded to Barreiro et al.[8] for their research on infective endocarditis in surgical vs transcatheter aortic valve implantation (figure 10).

Among the most widely read articles over the past year were the thematic review by Zubiaur et al.[9] examining the implications of the European Medical Device Regulation for research and the study by Martín-Arena et al.[10] on embolization of left atrial appendage occluders.

Among original articles, readers showed particular interest in "Access to transcatheter aortic valve implantation: interregional variability and expert evaluation," by de la Torre-Hernández et al.,[11] the meta-analysis by Sorolla Romero et al.[12] comparing drug-coated balloons vs drug-eluting stents for the treatment of large native coronary artery disease, and "Clinical utility of thrombus aspiration with the Hunter catheter in patients with acute myocardial infarction: the HUNTED registry," by Borraz-Noriega et al.[13]

Moreover, during 2026, we have progressively introduced a requirement for original articles and reviews to include a central illustration. We believe this feature, which many authors already provided voluntarily, will help capture readers' attention and improve communication of the articles' key messages.

Beyond our social media activities through the *REC Publications* accounts on X, Facebook, and Bluesky, using the hashtag #recintervcardiol, the editorial team actively promotes the journal at national and international scientific meetings.[14-16] This year, these have included EuroPCR in Paris, CITIC in Mexico City, the New York Valves congress, and the course on the prevention and management of complications in percutaneous interventional cardiology organized by *Hospital Universitario de Bellvitge* in L'Hospitalet de Llobregat (Barcelona, Spain).

Readers, authors, and reviewers of *REC: Interventional Cardiology* all have a role to play in promoting the journal. Greater visibility helps attract high-quality manuscripts, creates more opportunities for citation, and ultimately strengthens the journal's scientific and editorial impact.

ACKNOWLEDGMENTS

Acknowledgments are a recurring feature of our annual *Editor's page*, and rightly so. The continued success of this journal, its high standards, and its promising future would not be possible without the outstanding dedication of our associate editors: Fernando Alfonso, Raúl Moreno, Soledad Ojeda, Armando Pérez de Prado, and Rafael Romaguera (figure 11).

But equally essential is the exceptional operational support that underpins the work of the editorial team and makes this journal, like all *REC Publications* journals, possible. We wish to express our sincere appreciation for the professionalism and dedication of the *REC Publications* editorial office staff (Iria del Río, Eva M. Cardenal, Belén Juan, and María González-Nogal) (figure 11), our information and communication technology consultant (Juan Quiles), the other departments of *Casa del Corazón*, and the entire Permanyer Publications team.

A defining feature of *REC: Interventional Cardiology*, and one that largely explains its remarkable progress since its foundation, is its role as the official journal of the ACI-SEC. This is a unique strength. Every ACI-SEC board, from the one that established the journal to the most recently elected, has given this project its unwavering support, sustaining it financially with unrestricted contributions from companies in the interventional cardiology sector, to whom we remain deeply grateful. The SEC, meanwhile, covers the operating costs of the editorial office.



Figure 10. Original articles published in *REC: Interventional Cardiology* that received awards at the 2026 annual meeting of the Interventional Cardiology Association of the Spanish Society of Cardiology.



Figure 11. The editorial team of *REC: Interventional Cardiology*, together with members of the *REC Publications* editorial office who attended the 2026 annual meeting of the Interventional Cardiology Association of the Spanish Society of Cardiology in Pamplona. From left to right and top to bottom: Eva M. Cardenal, Armando Pérez de Prado, Iria del Río, José M. de la Torre-Hernández, Belén Juan, Raúl Moreno, Rafael Romaguera, Fernando Alfonso, and Soledad Ojeda.

We traditionally conclude this *Editor's page* with a quotation. This year, we have chosen the words of John Ruskin: "Quality is never an accident; it is always the result of intelligent effort."

FUNDING

None declared.

CONFLICTS OF INTEREST

None declared.

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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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CONFLICTS OF INTEREST

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Editorial

Drug-coated balloon for the treatment of bifurcation lesions: high enthusiasm, but still limited evidence

El balón farmacoactivo en el tratamiento de las bifurcaciones coronarias: mucho entusiasmo y todavía pocas evidencias

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Drug-coated balloon (DCB) is a therapeutic tool that has been available for the treatment of coronary artery disease for more than 20 years. Initially developed for in-stent restenosis,[1,2] its use has expanded given its potential in native coronary lesions. In Spain, annual registry data show a marked increase in DCB utilization, from approximately 4% of percutaneous coronary interventions in 2012 to 15% in the most recent report,[3] accompanied by a parallel decline in drug-eluting stent (DES) use. This growing adoption over the past few years has been driven largely by the "leave nothing behind" concept rather than by robust clinical evidence. Accordingly, American clinical practice guidelines do not recommend DCB over DES,[4] and European clinical practice guidelines restrict their indication to in-stent restenosis.[5] Nevertheless, DCB use has extended to increasingly complex clinical scenarios, including small vessels, diffuse disease, chronic total coronary occlusions, calcified lesions, acute coronary syndrome, patients at high bleeding risk, and bifurcation lesions.

In bifurcation lesions, 2 principal approaches have been described. The pure DCB technique involves treatment of both the main vessel and the side branch (SB) with DCB, and is limited to the SB in Medina 0,0,1 lesions. In contrast, the hybrid technique combines DES implantation in the main vessel with DCB dilation in the SB. Two variants of the hybrid approach exist: SB predilation with DCB before DES implantation in the main vessel, and SB postdilation with DCB after DES deployment in the main vessel through the stent struts. The former allows direct access to the SB with the DCB without compromising drug delivery but may be affected by carina shift following DES implantation, potentially requiring repeat dilation of the new segment treated with DCB. The latter carries the risk of DCB drug loss when crossing the stent struts, and the need to correct the deformation induced in the DES when dilating the SB.

The hybrid strategy has been evaluated in multiple observational studies for years. Its rationale lies in the ability of DCB to reduce late lumen loss through an antiproliferative effect in SB lesions, thereby decreasing restenosis, and the need for repeat revascularization, with a potential reduction in clinical events during follow-up. A reduction in late lumen loss at the SB ostium has indeed been demonstrated in most studies.[6-9] However, the translation of this favorable effect into fewer clinical events is more difficult, with most studies reporting neutral results. The randomized DCB-BIF study, which had sufficient statistical power, compared the hybrid strategy with the provisional stenting technique.[10] Although a significant reduction in events during follow-up was demonstrated, this was driven by myocardial infarction (periprocedural and spontaneous) and not by the need for repeat target lesion revascularization. After excluding periprocedural myocardial infarctions, no significant differences in major adverse events were observed at 1 year (5.1% vs 2.6%; $P = .09$). Although the study concludes that there is a significant reduction of events in the DCB-treated group, the higher incidence rate of periprocedural myocardial infarction in the control group (counted as an event) complicates the interpretation of the results. Although meta-analyses in this field provide another form of evidence, they are strongly influenced by the weight of this study. Thus, although most conclude that the hybrid strategy reduces events compared with the provisional stenting technique,[11-13] these meta-analyses present the same interpretative limitations as the DCB-BIF study.

Regarding the use of the pure DCB strategy, there is still no evidence available, and we will have to wait for the results of the EBC-DCB study [NCT06822322], which is still in the patient inclusion phase.

In a recent article published in *REC: Interventional Cardiology*, Valencia et al. reported a nonrandomized comparison of patients with left anterior descending/diagonal artery bifurcations treated with the hybrid strategy and a DCB in the SB (n = 86) compared with patients treated with the provisional stenting technique (n = 88), with a mean follow-up of 3 years.[14] The study concludes that the strategy of DES in the left anterior descending coronary artery and DCB in the diagonal branch reduced clinical events at the 3-year follow-up compared with the provisional DES strategy.

This study is timely, given the ongoing controversy in this field. However, several limitations warrant consideration beyond those

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already discussed. The use of the proximal optimization technique was notably low, particularly in the control group (only 12%). With the exception of Medina 0,0,1 bifurcations, this maneuver is recommended and generally considered mandatory in current consensus documents from the European Bifurcation Club.[15] The presence of significant differences between the 2 groups penalizes the control group. Another noteworthy finding is the absence of myocardial infarction and target lesion revascularization in the DCB group over a 3-year period. Given the prolonged enrollment period (approximately 6 years), incomplete data capture at the time of analysis cannot be excluded, and some events may have been underreported.

Overall, this study provides relevant insights into a highly topical and debated issue, and the authors should be acknowledged for their effort in comprehensive data collection and long follow-up. Although the impact of DCB on clinical event reduction remains controversial, these findings support the potential clinical utility of this therapeutic strategy in the management of bifurcation lesions.

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CONFLICTS OF INTEREST

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Original article

SELUTION SLR sirolimus-eluting balloon compared with the Pantera Lux paclitaxel drug-coated balloon in the management of de novo coronary lesions

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ABSTRACT

Introduction and objectives: Drug-coated balloons are an emerging stentless therapeutic option for the treatment of de novo coronary artery disease. Although paclitaxel-coated balloons remain the current standard, concerns regarding delayed vascular healing and potential local toxicity have driven the development of sirolimus-eluting balloons (SEB). This study aimed to compare the safety and efficacy profile of the novel SELUTION SLR SEB with the established Pantera Lux paclitaxel-coated balloon in a real-world cohort of patients with de novo coronary artery disease.
Methods: We conducted a prospective, single-center registry included 257 patients with 316 de novo coronary lesions treated with drug-coated balloon–only percutaneous coronary intervention from 2023 through 2024. Patients were treated with either the SELUTION SLR sirolimus-eluting balloon or the Pantera Lux paclitaxel-coated balloon. A 1-year follow-up was conducted to assess major adverse cardiovascular events, target lesion failure (TLF), and target lesion revascularization (TLR), which were descriptively compared across groups.
Results: Baseline clinical and angiographic characteristics were well balanced. At the 1-year follow-up, the overall rate of major adverse cardiovascular events was 5.8%, with no significant differences across treatment groups. The rates of TLF and TLR were low and comparable. However, patients treated with the SELUTION SLR experienced fewer procedural complications, including a lower rate of mild coronary dissections (6.7% vs 14.7%; $P = .043$) and no-reflow events (0.0% vs 2.7%; $P = .036$).
Conclusions: The SELUTION SLR SEB demonstrated efficacy vs the Pantera Lux, with fewer procedural complications. These findings support the selective use of SELUTION SLR as a stentless treatment strategy and highlight the need for larger randomized trials to confirm long-term comparative outcomes.

Keywords: Coronary artery disease. Drug-coated balloon. Percutaneous coronary intervention.

Balón liberador de sirolimus SELUTION SLR frente a balón recubierto con paclitaxel Pantera Lux en lesiones coronarias *de novo*

RESUMEN

Introducción y objetivos: Los balones farmacoactivos representan una alternativa emergente sin *stent* para el tratamiento de la enfermedad coronaria *de novo*. Aunque los balones recubiertos de paclitaxel constituyen el estándar actual, las preocupaciones sobre el retraso en la cicatrización y la toxicidad vascular han favorecido el desarrollo de balones liberadores de sirolimus. El objetivo fue comparar la seguridad y la eficacia del balón liberador de sirolimus SELUTION SLR frente al balón recubierto de paclitaxel Pantera Lux en pacientes con enfermedad coronaria *de novo* en la práctica clínica real.
Métodos: Registro prospectivo y unicéntrico que incluye 257 pacientes con 316 lesiones *de novo* tratados mediante intervención

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coronaria percutánea exclusivamente con balón farmacoactivo entre 2023 y 2024. Los pacientes recibieron SELUTION SLR (sirolimus) o Pantera Lux (paclitaxel). El seguimiento a 1 año evaluó los eventos cardiacos adversos mayores, el fracaso de la lesión diana y la revascularización de la lesión diana, analizados de forma descriptiva.
Resultados: Las características clínicas y angiográficas basales fueron comparables entre los grupos. Al año, la tasa global de eventos cardiacos adversos mayores fue del 5,8%, sin diferencias significativas. El fracaso de la lesión diana y la revascularización de la lesión diana fueron bajos y similares. Sin embargo, el grupo con SELUTION SLR presentó menos complicaciones intraprocedimiento, incluidas disecciones coronarias leves (6,7% frente a 14,7 %, p = 0,043) y fenómenos de no reflujo (0,0 % frente a 2,7 %, p = 0,036).
Conclusiones: El balón liberador de sirolimus SELUTION SLR mostró una eficacia comparable al Pantera Lux, con menos complicaciones intraprocedimiento, lo que apoya su uso selectivo como estrategia sin *stent* y señala la necesidad de ensayos aleatorizados de mayor tamaño.

Palabras clave: Enfermedad coronaria. Balón farmacoactivo. Intervención coronaria percutánea.

Abbreviations

CAD: coronary artery disease. **DCB:** drug-coated balloon. **DES:** drug-eluting stent. **PCB:** paclitaxel-coated balloon. **PCI:** percutaneous coronary intervention. **SEB:** sirolimus-eluting balloon.

INTRODUCTION

Percutaneous coronary intervention (PCI) has revolutionized the treatment of coronary artery disease (CAD), particularly with the advent of drug-eluting stents (DES). However, restenosis, late thrombosis, and very late thrombosis, and the need for prolonged dual antiplatelet therapy have increased interest in no-footprint percutaneous coronary intervention (PCI) strategies like drug-coated balloons (DCBs).[1] Initially developed and widely adopted for treating in-stent restenosis, DCBs have more recently gained acceptance for the management of de novo coronary lesions, particularly in small-vessel disease and in patients at high risk of hemorrhage.[2,3]

Paclitaxel-coated balloons (PCBs) have dominated the field due to drug lipophilicity and potent antiproliferative effect.[4] However, concerns regarding delayed vascular healing, cytotoxicity, and downstream embolization have encouraged the development of newer DCB technologies. Sirolimus, by being cytostatic rather than cytotoxic, offers several theoretical advantages over paclitaxel, including a wider therapeutic window, improved endothelial healing, and reduced inflammatory response. However, its low lipophilicity (making tissue retention difficult) and slow onset of action has limited its use in DCB platforms.

The SELUTION SLR (Cordis, United States) aimed to overcome the unfavorable pharmacodynamics of sirolimus by incorporating microreservoirs and a phospholipid coating designed for controlled, sustained release of sirolimus over 90 days. Preclinical and early clinical evidence suggests favorable vessel healing, drug retention, and patency.[5] However, comparative data vs paclitaxel-based DCBs in de novo lesions remain limited. Given the evolving landscape of interventional cardiology and increasing interest in no-footprint PCI, a direct head-to-head evaluation of the safety and efficacy profiles of these 2 DCB platforms is warranted.

This study provides a real-world comparison between the SELUTION SLR SEB and the Pantera Lux (Biotronik, Germany) PCB in the management of de novo coronary lesions. By analyzing clinical and angiographic outcomes, we aim to determine whether the novel SEB platform offers a feasible and potentially superior alternative to the current standard of care.

METHODS

Study population

We conducted an analysis of a single-center prospective registry of 257 patients and 316 de novo coronary lesions treated with DCBs from January 2023 through December 2024. Patients presenting with chronic or acute coronary syndrome were eligible if at least 1 lesion was treated with either the SELUTION SLR or the Pantera Lux. The selection of the DCB platform was left to the operator's discretion. We excluded patients with cardiac arrest or cardiogenic shock and those in whom > 1 brand of DCB was used. In patients with acute coronary syndrome and multivessel disease, complete revascularization was preferably performed in staged procedures to allow for opportunistic angiographic reevaluation of previously treated lesions. Patients were clinically monitored for 1 year and the rates of all-cause mortality, cardiac death, myocardial infarction (MI), unplanned revascularization, target lesion restenosis, and target lesion revascularization (TLR) were compared between the 2 groups. Target lesion failure (TLF) was determined as a composite endpoint of cardiac death, target lesion MI and TLR. Major adverse cardiovascular events (MACE) were defined as a composite endpoint of cardiac death, any MI and any unplanned revascularization. In patients undergoing opportunistic angiographical follow-up, positive vessel remodeling was defined by a ≥ 50% increment in lumen diameter and restenosis as a ≥ 50% lumen reduction. The protocol of the study was revised and approved by the local ethics committee.

Lesion preparation and DCB deployment

All types of coronary lesions were included and aggressive plaque preparation techniques (using scoring or cutting balloons) were incentivized, as was the use of intracoronary imaging to guide balloon size selection and deployment. Only lesions with residual percent diameter stenosis < 30% after optimal preparation and without significant recoil or flow impairment were eligible for DCB inflation. DCBs were selected according to target vessel reference diameter in a 1:1 ratio and had to be inflated for at least 60 seconds. Only 1 inflation per DCB was allowed. Use of multiple

DCB was allowed only if the same brand was used. In lesions with persistent residual percent diameter ≥ 30% after aggressive preparation, PCI with DES was recommended. Although post-PCB bailout stenting was recommended only in the presence of flow limiting dissections or persistent contrast staining, the final decision was left to the operator's discretion.

Statistical analysis

Continuous variables with normal distribution were expressed as mean ± standard deviation, and categorical ones as absolute count and respective percentages. The 95% confidence intervals (95%CI) of the means of continuous variables and percentages of categorical variables were calculated using *t* tests and Clopper-Pearson (exact) approaches, respectively. The Student *t* and Mann Whitney *U* tests were used to compare variables with normal and non-normal distribution, respectively, while the chi-square test was used to compare prevalences across groups. A subgroup analysis stratified by target vessel diameter was performed using a 3-mm lumen diameter cutoff. Kaplan-Meier survival curves were generated for descriptive time-to-event assessment. Due to the low number of events, propensity score weighting, adjusted Cox proportional hazards models, and other multivariable approaches were not performed, as these approaches would be underpowered and potentially yield unreliable or misleading estimates. All analyses used SPSS v30 (IBM, United States). Although statistical significance was defined as $P < .05$, findings should be interpreted as exploratory.

RESULTS

Study population

A total of 257 patients with 316 coronary lesions were included: 104 patients (133 lesions) treated with SELUTION SLR and 153 patients (183 lesions) treated with Pantera Lux. Baseline demographics and clinical characteristics were balanced across the groups (table 1). There were no significant differences in target vessel location or lesion complexity according to ACC/AHA lesion classification. True bifurcation lesions represented 44.0% of all treated lesions, reflecting the real-world nature and complexity of the cohort (table 2).

Procedural characteristics

Lesion preparation details are shown in table 3. Most lesions were prepared with non-compliant (NC) balloons (82.0%). Intracoronary imaging to guide PCI was used in 25.9% of cases. There were no differences in mean DCB diameter (2.25 [2.00-2.50] vs 2.25 [2.00-2.50] for SELUTION SLR and Pantera Lux, respectively, $P = .205$) and the mean DCB length (20.0 [15.0-25.0] vs 20.0 [15.0-29.0], for SELUTION SLR and Pantera Lux, respectively, $P = .432$). Nearly one-third (n = 100, 31.6%) of all DCB utilization occurred in the setting of hybrid bifurcation PCI (DES in the main branch plus DCB in the side branch), reflecting the increasing adoption of this strategy to avoid 2-stent PCI technique outside of the left main coronary artery. SELUTION SLR was used more frequently than Pantera Lux in pure DCB bifurcation PCI (DCB in both the main and side branches) (15.7% vs 9.8%, for SELUTION SLR and Pantera Lux, respectively; $P = .012$).

Several important differences emerged in procedural findings. Mild coronary dissections, defined as non–flow-limiting dissections of types A–B and considered expected angiographic findings after preparation or DCB inflation, occurred significantly more often in the Pantera Lux than in the SELUTION SLR group (14.7% vs 6.7%; $P = .043$). Severe dissections were rare. There were no-reflow phenomena exclusively in the Pantera Lux group, with 5 cases being reported overall, corresponding to 1.6% of all lesions (0.0% vs 2.7% within each respective treatment group; $P = .036$). There were no periprocedural deaths in either arm.

Table 1. General characteristics of the study population (per patient analysis)

Baseline characteristics	Population (N = 257)	SELUTION SLR (n = 104)	Pantera Lux (n = 153)	*P*
Baseline demographics				
Age (years)	67.3 ± 11.1	67.3 ± 11.4	67.3 ± 10.0	.994
Male	224 (83.7)	91 (87.5)	133 (86.9)	.771
BMI (kg/m²)	27.0 [22.9-29.4]	26.2 [24.5-29.2]	27.0 [24.9-29.6]	.409
Past medical history				
Prior MI	138 (53.7)	54 (51.9)	84 (54.9)	.678
Prior PCI	128 (49.8)	51 (49.0)	77 (50.3)	.839
Prior CABG	9 (3.5)	6 (5.8)	3 (2.0)	.103
Hypertension	192 (74.7)	80 (76.9)	112 (73.2)	.501
Dyslipidemia	200 (77.8)	79 (75.9)	121 (79.1)	.201
Smoker	74 (28.8)	32 (30.8)	42 (27.5)	.564
Congestive heart failure	51 (19.8)	22 (21.2)	29 (18.9)	.512
Diabetes mellitus	102 (39.7)	40 (38.5)	62 (40.5)	.740
Renal dysfunction	52 (20.2)	23 (22.1)	29 (19.0)	.532
Pulmonary disease	12 (4.7)	7 (6.7)	5 (3.3)	.197
Peripheral arterial disease	30 (11.7)	11 (10.6)	19 (12.4)	.652
Atrial fibrillation/flutter	18 (7.0)	7 (6.7)	11 (7.2)	.888
Family history of CAD	21 (8.2)	6 (5.8)	15 (9.8)	.246
Clinical presentation				
STEMI	57 (22.2)	23 (22.1)	34 (22.2)	.984
NSTEMI	77 (30.0)	26 (25.0)	51 (33.3)	.152
Unstable angina	9 (3.5)	3 (2.9)	6 (3.9)	.657
CCS	114 (44.3)	52 (50.0)	62 (40.5)	.113
Procedural characteristics				
Multivessel/segment disease	205 (79.7)	86 (82.7)	119 (77.8)	.650
> 1 lesion treated	181 (70.4)	79 (75.9)	102 (66.7)	.109
No. of treated lesions	1.0 [1.0-2.0]	2.0 [1.0-2.0]	1.0 [1.0-2.0]	.201

BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CCS, chronic coronary syndrome; MI, myocardial infarction; NSTEMI, non-ST segment myocardial infarction; PCI, percutaneous coronary interventions; STEMI, ST-segment elevation myocardial infarction.
Data are express as No. (%), mean ± standard deviation or median [interquartile range].

1-year clinical outcomes

Clinical follow-up at 12 months was available for all patients, whereas angiographic follow-up was performed in 35.4% of

Table 2. General characteristics of the target lesion treated (per lesion analysis)

Vessel/segment	Population (N = 316)	SELUTION SLR (n = 133)	Pantera Lux (n = 183)	*P*
LAD	141 (44.6)	56 (42.1)	85 (46.4)	.331
Proximal LAD	25 (7.9)	10 (7.5)	15 (8.2)	-
Mid LAD	15 (4.7)	6 (4.5)	9 (4.9)	-
Distal LAD	31 (9.8)	11 (8.3)	20 (10.9)	-
First diagonal	59 (18.7)	24 (18.0)	35 (19.1)	-
Second or third diagonal	11 (3.5)	5 (3.8)	6 (3.3)	-
LCx	93 (29.4)	44 (33.1)	49 (26.7)	.109
Proximal LCx	20 (6.3)	8 (6.0)	12 (6.6)	-
Distal LCx	23 (7.3)	12 (9.0)	11 (6.0)	-
First obtuse marginal	37 (11.7)	16 (12.0)	21 (11.5)	-
Second obtuse marginal	11 (3.5)	6 (4.5)	5 (2.7)	-
Third obtuse marginal	2 (0.6)	2 (1.5)	0 (0.0)	-
Intermediate branch	9 (2.8)	3 (2.3)	6 (3.3)	.743
RCA	70 (22.2)	29 (21.8)	41 (22.4)	.828
Proximal RCA	8 (2.5)	3 (2.3)	5 (2.7)	-
Mid RCA	9 (2.8)	2 (1.5)	7 (3.8)	-
Distal RCA	15 (4.7)	6 (4.5)	9 (4.9)	-
PDA	21 (6.6)	10 (7.5)	11 (6.0)	-
Postero-lateral branch	17 (5.4)	8 (6.0)	9 (4.9)	-
CABG	3 (0.9)	1 (0.8)	2 (1.0)	.901
Arterial graft	1 (0.3)	0 (0.0)	1 (0.5)	-
Venous graft	2 (0.6)	1 (0.8)	1 (0.5)	-
Lesion characteristics				
Target vessel diameter ≥ 3 mm	59 (18.7)	23 (17.2)	36 (19.7)	.384
AHA class A	93 (29.4)	39 (29.3)	54 (29.5)	.911
AHA class B1/B2	195 (61.7)	83 (62.4)	112 (61.2)	.873
AHA class C	28 (8.9)	11 (8.3)	17 (9.3)	.795
CTO	29 (9.2)	14 (10.5)	15 (8.2)	.479
True bifurcation	139 (44.0)	61 (45.9)	78 (42.6)	.559

AHA, American Heart Association; CABG, coronary artery bypass graft; CTO, chronic total coronary occlusion; LAD, left anterior descending coronary artery; LCx, left circumflex artery; PDA, posterior descending artery; RCA, right coronary artery.
Data are expressed as No. (%).

Table 3. Lesion preparation, devices used for PCI and procedural results (per lesion analysis)

Devices used and procedural results	Population (N = 316)	SELUTION SLR (n = 133)	Pantera Lux (n = 183)	*P*
Predilatation				
SC balloon	66 (20.9)	29 (21.8)	37 (20.2)	.732
NC balloon	259 (82.0)	110 (82.7)	149 (81.4)	.769
Plaque preparation/calcium modification				
Cutting/scoring balloon	62 (19.6)	27 (20.3)	35 (19.1)	.907
Rotational atherectomy	2 (0.6)	1 (0.8)	1 (0.5)	.820
Orbital atherectomy	9 (2.8)	4 (3.0)	5 (2.7)	.885
IVL	7 (2.2)	3 (2.3)	4 (2.2)	.898
Intracoronary imaging				
IVUS	70 (22.2)	28 (21.1)	42 (23.0)	.792
OCT	12 (3.8)	6 (4.5)	6 (3.3)	.789
PCI				
DCB diameter	2.25 [2.00-2.50]	2.25 [2.00-2.50]	2.25 [2.00-2.50]	.205
DCB length	20.0 [15.0-25.0]	20.0 [15.0-25.0]	20.0 [15.0-29.0]	.432
PCI with DES in a different lesion	181 (57.3)	76 (57.1)	105 (59.7)	.480
Hybrid bifurcation PCI (DES + DCB)	100 (31.6)	43 (32.3)	57 (31.1)	.703
DCB-only bifurcation PCI	39 (12.3)	21 (15.7)	18 (9.8)	.012
Procedural results				
Post-DCB residual percent diameter stenosis > 30%	19 (6.0)	11 (8.4)	8 (4.8)	.201
Mild dissection (type A-B)	36 (11.4)	9(6.7)	27 (14.7)	.043
Severe dissection (type C-F)	3 (0.9)	0 (0.0)	3 (1.6)	.370
Coronary perforation	2 (0.6)	1 (0.8)	1 (0.5)	.820
Coronary rupture	2 (0.6)	1 (0.8)	1 (0.5)	.820
No-reflow	5 (1.6)	0 (0.0)	5 (2.7)	.036
Bailout DES	31 (9.8)	9 (6.8)	22 (12.0)	.121
Procedural mortality	0 (0.0)	0 (0.0)	0 (0.0)	-

DCB, drug-coated balloon; DES, drug eluting stent; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; NC, non-compliant; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; SC, semi-compliant.
Data are expressed as No. (%), mean ± standard deviation or median [interquartile range].

lesions (n = 91) at the operator's discretion and was not protocol mandated. At the patient level, the overall rates of adverse clinical events were low (table 4). All-cause mortality occurred in 2.3% of patients, cardiovascular mortality in 1.6%, and myocardial infarction in 2.3%. The composite MACE rate was 5.8% overall, with no statistically significant difference between SELUTION SLR and Pantera Lux (2.9% vs 7.8%; P = .168). At the lesion level, TLF occurred in 3.8% of lesions, again without significant differences being reported across groups (2.3% vs 5.8%; P = .252). TLR was rare, recorded in 0.9% of lesions, with no difference across devices. Figure 1 illustrates the respective Kaplan-Meier survival curves for MACE, cardiac death and MI.

Among the lesions that underwent repeat angiography, restenosis was diagnosed in 7.7% of cases, with no meaningful differences across the different balloon types. Positive vessel remodeling was numerically more common in SELUTION SLR-treated lesions (35.3% vs 17.5%; P = .097), although the sample was limited due to the opportunistic nature of follow-up.

Table 4. Events at the follow-up

Outcomes	Population	SELUTION SLR	Pantera Lux	*P*
Patient oriented outcomes	N = 257	n = 104	n = 153	
All-cause mortality	6 (2.3)	1 (0.9)	5 (3.2)	.574
Cardiac death	4 (1.6)	1 (0.9)	3 (1.9)	.410
Myocardial infarction	6 (2.3)	1 (0.9)	5 (3.2)	.574
UR for angina	5 (1.9)	1 (0.9)	4 (2.6)	.630
MACE (cardiac death + MI + UR)	15 (5.8)	3 (2.9)	12 (7.8)	.168
Lesion oriented outcomes	N = 316	n = 133	n = 183	
TLF (CV death + target vessel MI + TLR)	12 (3.8)	3 (2.3)	9 (5.8)	.252
Target lesion revascularization	3 (0.9)	1 (0.8)	2 (1.1)	.721
Angiographic control	N = 91	n = 34	n = 57	
Restenosis (> 50% diameter)	7 (7.7)	1 (2.9)	6 (10.5)	.229
Positive remodeling (> 50% lumen gain)	22 (24.2)	12 (35.3)	10 (17.5)	.097

MACE: major adverse cardiovascular events; MI, myocardial infarction; TLR, target lesion revascularization; UR: unplanned revascularization.
Data are expressed as No. (%).

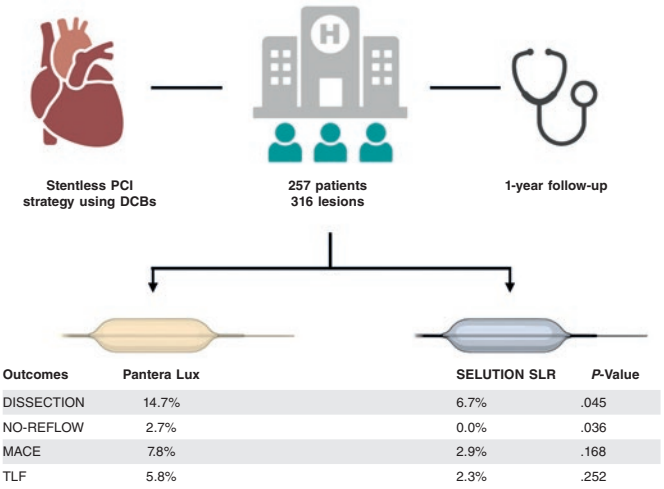


Figure 1. Kaplan Meier survival curves for MACE (**A**), CV death (**B**) and MI (**C**) after 1 year follow-up. CV, cardiovascular; DCB, drug-coated balloon; MACE, major adverse cardiac events; MI, myocardial infarction.

A subgroup analysis according to reference vessel diameter showed that 18.7% of lesions were treated in vessels ≥ 3 mm (table S1). From a procedural standpoint, large arteries did not exhibit higher rates of mild (types A and B) dissections (18.6% vs 10.1%; $P = .066$) but higher rates of bailout stenting (18.6% vs 7.8%; $P = .011$) (reasons for stent bailout are summarized in table S2). Despite this, there were no differences in safety outcomes such as severe dissection, coronary rupture, or no-reflow. Moreover, lesion-oriented outcomes, including TLF and TLR rates, were low and comparable across groups. Of note, only 1 TVF event was registered in the large artery group, in 1 patient treated with Pantera Lux. These subgroup observations should be interpreted as exploratory because the study was not powered for interaction testing and event rates were low.

DISCUSSION

In this prospective, real-world registry comparing the SELUTION SLR sirolimus-eluting balloon with the Pantera Lux paclitaxel-coated balloon for the treatment of de novo coronary lesions, the 2 devices demonstrated low and comparable clinical event rates at 12 months (figure 2). The study population included complex, all-comer patients, and despite the inherent limitations of a single-center observational design, the findings contribute to the growing body of evidence supporting DCB strategies for selected de novo lesions.

The results of our study offer important insights into the real-world performance of sirolimus-DCB, particularly the novel SELUTION SLR platform, in the management of de novo coronary lesions. The findings are 2-fold: first, the SELUTION SLR demonstrated a safety and efficacy profile comparable to that of an established PCB; and second, overall, outcomes were consistent across vessel diameters, with no significant reduction in performance observed between small- and large-caliber arteries.

The principal observation of the present analysis is that SELUTION SLR yielded clinical outcomes similar to those obtained with the Pantera Lux, while being associated with fewer procedural findings such as mild, non–flow-limiting dissections, and no-reflow phenomena. This finding may reflect differences in mechanical interaction or coating characteristics between the 2 platforms. However, because factors such as lesion preparation, severity of calcification, balloon-to-artery ratio, and operator technique strongly influence dissection rates—and were neither controlled nor adjusted for in this analysis—this interpretation remains speculative. Furthermore, mild angiographic type A–B dissections are widely regarded as expected and benign features of DCB angioplasty, provided TIMI grade-3 flow is maintained and no significant recoil is present. Recent consensus documents indicate that such dissections rarely require stenting and may even facilitate drug transfer. Of note, all 5 cases of no-reflow occurred in Pantera Lux–treated lesions, an observation consistent with prior preclinical and clinical work documenting the embolic behavior of crystalline paclitaxel particles.[6] Although this mechanistic explanation is biologically plausible, further studies in humans are required to confirm this association. Given the small number of events observed in both groups, the clinical relevance of these findings remains uncertain.

Paclitaxel has remained the backbone of DCB therapy for CAD for over a decade, primarily due to its lipophilic properties, rapid tissue uptake, and strong antiproliferative effects.[7] However, emerging concerns regarding delayed healing, potential toxicity, and long-term safety have prompted the development of balloons with alternative antiproliferative agents.[8] Sirolimus, although more hydrophilic and requiring innovative delivery systems to ensure sustained arterial wall absorption, has demonstrated superior biocompatibility, endothelial healing properties, and reduced inflammatory responses in both preclinical and early clinical settings. Nonetheless, the results from the TRANSFORM I trial were disappointing.[9] By not being as cytotoxic, it became clear from this trial that platforms using sirolimus had to ensure sustained drug delivery to the artery over a long period of time and become a "drug-eluting balloon" rather than a "drug-coated balloon". Hence, the SELUTION SLR incorporates a proprietary micro-reservoir technology with biodegradable polymers to facilitate sustained sirolimus release over 60–90 days, aiming to mimic the drug release kinetics of second-generation DES, and ensure drug activity over the traditional restenosis cycle period of coronary arteries after balloon barotrauma[9,10].

In our study cohort comprising both small and large vessels, the procedural success and short-term lesion-oriented outcomes, namely TLF and TLR, were low and statistically similar between

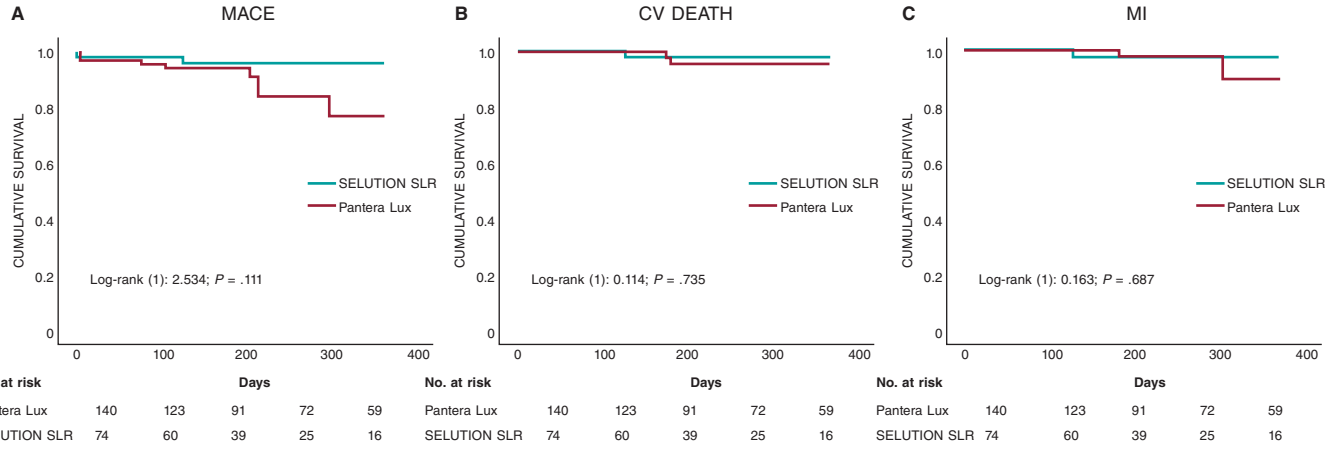


Figure 2. Central illustration. Study design and main outcomes. A total of 257 patients with 316 de novo coronary lesions were treated using a stentless percutaneous coronary intervention strategy with drug-coated balloon and 1-year follow-up. Outcomes were compared between the Pantera Lux (paclitaxel-coated balloon) and SELUTION SLR (sirolimus-eluting balloon). SELUTION SLR was associated with fewer procedural complications, including lower rates of coronary dissection and no-reflow, with comparable clinical outcomes at follow-up. CV, cardiovascular; MI, myocardial infarction; MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention; TLF, target lesion failure.

the SELUTION SLR and the Pantera Lux platforms. These observations are consistent with data from the PRESTIGE trial, which have demonstrated non-inferior late lumen loss (LLL) and binary restenosis rates with SELUTION SLR vs a paclitaxel DCB in a smaller cohort of patients including de novo lesions and in-stent restenosis.[11] We reported very low rates of TLR (0.9% of treated lesions). We believe this finding is likely multifactorial. First, this was a selected population in which most treated vessels were small (< 3.0 mm). In small vessels, the amount of myocardium at risk is limited, and both procedural failures and late vessel occlusions may remain clinically silent and therefore undetected. In our subgroup analysis, we did not find any differences in TLR between small and larger vessels, however, our sample size is underpowered to detect such differences. Notably, in the REC-CAGEFREE I trial, the higher event rates observed in larger vessels ultimately drove the trial results.[12] Second, angiographic follow-up was not mandated by protocol, and we acknowledge that asymptomatic restenosis or late vessel occlusion may have gone undetected and may or may not be equally distributed across treatment groups.

The bulk of the existing evidence favoring PCB comes from large randomized trials such as the PEPCAD II, the FEMPAC, and the BELLO, which provided robust comparative data across various lesion subsets and anatomical territories.[13-15] However, PCB are not without limitations, including concerns regarding late thrombotic events, dose-dependent cytotoxicity, and secondary vasomotor and endothelial dysfunction.[16] In fact, the toxicity profile of PCB was made evident in patients who were treated for chronic total coronary occlusions (CTO) and demonstrated post-PCI late coronary aneurysms, either due to > 1 PCB being applied in the same territory, as paclitaxel has a very narrow therapeutic window, or by having the drug delivered in false lumen segments and being directly applied to the vascular smooth muscle cell layer.[17] Moreover, animal studies have shown that, while PCB and SEB have been shown to equally reduce neointimal formation, medial muscle cell layer loss was greater with PCB, underscoring their higher toxicity profile.[16] Furthermore, various reports have noted the occurrence of paclitaxel crystal embolization into distal vascular territories after balloon inflation both in peripheral and myocardial tissues.[18,19] This phenomenon might help explain the increased occurrence of no-reflow in the PCB group in our study.

The differential performance of DCBs in small vs large coronary arteries is another critical consideration. Traditionally, small vessels have posed a greater challenge for DES due to increased risk of restenosis, higher neointimal proliferation, and limited expansion capacity.[20] By avoiding permanent implants and associated foreign body responses, DCBs are ideally suited for small vessel interventions. Our analysis confirms this advantage, with low rates of TLF and TLR being reported in small arteries, and no significant increase in procedural complications vs larger vessels. In fact, the overall MACE rate at the 1-year follow-up was 5.8%, which is well within the margins of current DES platforms, with 1 exception being the FireBird stent in the REC-CAGEFREE I trial. In this trial, patients with de novo coronary lesions treated with PCB (Swide, Shenqi Medical, China) exhibited a 2-year MACE rate of 6.4%, while patients treated with the FireBird stent, a sirolimus eluting stent, exhibited a 2-year MACE rate of 3.4%, well under the expected rate for DES platforms.[12] The good performance of DES in this study was likely due to the inclusion of simple lesions and high rates of plaque modification techniques before stenting (scoring and cutting balloons being used in > 60% of cases), suggesting that good plaque preparation not only is fundamental for DCB PCI outcomes, but also seems to improve them in the context of DES PCI.

Interestingly, the large vessel subgroup in our cohort demonstrated a higher rate of bailout DES implantation (18.6% vs 7.8%; $P = .011$), despite comparable pre-treatment angiographic severity and lesion characteristics. This finding may reflect either a procedural bias—operators may be more inclined to stent larger vessels when faced with apparently suboptimal DCB results—or true differences in biomechanical response and vessel wall compliance between vessel calibers. Nevertheless, these findings did not translate into differences in safety endpoints or short-term clinical outcomes, highlighting the procedural adaptability and safety of the DCB-only approach in larger arteries when managed judiciously.

In the SELUTION DeNovo trial (NCT04859985),[21] a strategy using the SELUTION SLR sirolimus-eluting balloon with provisional stenting achieved a 1-year TVF rate of approximately 5.3% vs 4.4% in the systematic DES arm, meeting the prespecified non-inferiority margin. Notably, nearly 80% of patients randomized to the SELUTION arm were successfully treated without any stenting, reinforcing the feasibility of a "leave-nothing-behind" approach in appropriately prepared de novo lesions. These results are consistent with the observations of our registry, where SELUTION SLR demonstrated comparable clinical outcomes to its direct PCB comparator, Pantera Lux, along with fewer procedural disturbances such as mild dissections

and no-reflow. While the SELUTION DeNovo findings support the safety and efficacy profile of SELUTION in a controlled randomized environment,[21] it is important to note that the trial included carefully selected patients—excluding left main disease, STEMI, CTO, and other high-risk anatomies—whereas our registry reflects real-world lesion complexity and operator-driven device selection. Consequently, although the procedural and clinical performance of SELUTION in this study appears directionally consistent with DeNovo, extrapolation should remain cautious given differences in inclusion criteria, lesion profiles, and the non-randomized nature of our dataset. Together, both datasets reinforce the potential of SELUTION SLR as a viable stentless strategy, while highlighting the need for further randomized clinical trials with broader inclusion criteria and extended follow-up to determine long-term durability > 1 year. Larger, randomized trials with extended clinical endpoints are essential to confirm the long-term efficacy and durability of SEB, particularly in complex anatomical settings such as bifurcations, diffuse disease, and high-risk diabetic or chronic kidney disease populations.

Limitations

Interpretation of the present results must balance the strengths of an all-comers design with the inherent weaknesses of observational registries. The absence of randomization introduces the possibility of confounding by indication, particularly regarding device selection and bailout stenting decisions. Notably, clinical event rates in this analysis were low across the 2 devices, limiting statistical power to detect small or moderate differences and rendering subgroup analyses descriptive rather than inferential. Given the observational nature of the study and the low number of clinical events, formal propensity score adjustment was not performed, which limits causal inference despite comparable baseline prevalence of key complexity markers. Furthermore, angiographic follow-up was opportunistic rather than protocol-mandated, which may introduce verification bias, as patients returning for angiography may differ meaningfully from those who did not. Despite these constraints, the consistency of the clinical findings, together with the observed procedural advantages, lends support to the feasibility of a sirolimus-eluting balloon strategy in well-prepared de novo lesions. Finally, given the nature of our study, our results are mainly hypothesis generating rather than hypothesis testing and larger studies are required to validate our observations.

CONCLUSIONS

In conclusion, the SELUTION SLR demonstrated comparable 12-month clinical outcomes to the Pantera Lux while showing fewer procedural disturbances and numerically favorable angiographic trends. These results reinforce the role of DCB as a viable stentless strategy in appropriately selected de novo lesions and support continued evaluation of sirolimus-based DCB technologies in larger randomized clinical trials.

ETHICAL CONSIDERATIONS

Ethical approval was obtained from our institutional review board. The study was conducted in full compliance with the principles outlined in the Declaration of Helsinki and follows the SAGER guidelines

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

A large language model was used to improve text readability and fluency.

AUTHORS' CONTRIBUTIONS

D. Faria was responsible for the study design, data collection, statistical analysis and drafting. D. Neves was responsible for review and drafting. L. Hamann was responsible for data collection. J. Guedes, J. Bispo, F. Soares and H. Vinhas were responsible for manuscript review.

CONFLICTS OF INTEREST

D. Faria has received speaker fees from Cordis. H. Vinhas declared to have received speaker fees from Cordis. F. Soares declared to have received consultant fees from Cordis and Biotronik. The remaining authors declared no conflicts of interest whatsoever.

FUNDING

None declared.

SUPPLEMENTARY DATA



Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M26000571.

WHAT IS KNOWN ABOUT THE TOPIC?

- DCBs are an established stentless treatment option for selected coronary lesions, with PCB being supported by extensive clinical evidence.
- More recently, SEB technologies have been developed to address potential limitations of paclitaxel-based platforms, but comparative real-world data in de novo coronary lesions remain limited.

WHAT DOES THIS STUDY ADD?

- In this prospective cohort of 257 patients with de novo coronary artery disease, the SELUTION SLR SEB demonstrated similar 1-year clinical outcomes vs the Pantera Lux paclitaxel-coated balloon, with fewer procedural complications.
- These findings support the safety and feasibility of SEB as a stentless treatment strategy, while underscoring the need for confirmation in randomized clinical trials.

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Original article

Drug-coated balloon for the side branch compared with conventional strategy in left anterior descending-diagonal bifurcation lesions

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ABSTRACT

Introduction and objectives: Drug-coated balloons (DCB) are emerging as a valid alternative for the treatment of coronary bifurcation lesions, particularly in the side branch (SB). Among bifurcation lesions, the left anterior descending (LAD)-diagonal location is the most frequently treated. The aim of this study was to evaluate the long-term effectiveness of a DCB in the SB compared with a conventional strategy in this setting.
Methods: This case-control study compared LAD-diagonal lesions treated in which the SB was treated with a DCB vs a conventional strategy consisting of provisional stenting or a 2-stent technique. The mean follow-up was 3 years. The incidence rates of death, acute myocardial infarction, target lesion revascularization, target vessel revascularization, and the composite of major adverse cardiovascular events were recorded.
Results: A total of 86 patients with LAD-diagonal bifurcation lesions treated with a DCB in the SB were included and compared with a cohort of 88 patients who underwent conventional SB management. The mean follow-up was 1008 days (range, 5-2411 days). In the control group, the strategy consisted of stenting of the main branch only in 76.2% of cases, SB stenting only in 6.8%, and stenting of both branches in 17%. The comparative rate (control vs DCB) of adverse events was as follows: cardiac death, 1.1% vs 2.3% (non-significant); myocardial infarction, 8% vs 0% (P = .014), target lesion revascularization; 9.1% vs 0% (P = .013); target vessel revascularization, 10.2 vs 1.2% (P = .02); and major adverse cardiovascular events, 12.5% vs 3.5% (P = .05).
Conclusions: Treatment of the SB with a DCB in AD-diagonal bifurcation lesions appears to be safe and demonstrates very high long-term effectiveness, with a significantly lower rate of adverse events compared with a conventional strategy. Large randomized clinical trials are needed to confirm these findings.

Keywords: Drug-coated balloon. Coronary bifurcation lesions. Follow-up study.

Balón farmacoactivo en rama lateral frente a estrategia convencional en lesiones de bifurcación descendente anterior-diagonal

RESUMEN

Introducción y objetivos: El balón farmacoactivo (BFA) es una alternativa válida en el tratamiento de las lesiones en bifurcación, en especial en la rama lateral (RL). Dentro de las bifurcaciones, la localización descendente anterior (DA)-diagonal es la más frecuente. Nuestro objetivo fue determinar la efectividad a largo plazo del BFA en la RL en dicho escenario, en comparación con una estrategia convencional.
Métodos: Estudio de casos y controles para comparar lesiones en la bifurcación DA-diagonal con las RL tratadas con BFA o con estrategia convencional de *stent* condicional o 2 *stents*, con un seguimiento medio de 3 años. Se registró la incidencia de muerte, infarto agudo de miocardio, revascularización de la lesión diana, revascularización del vaso diana y la combinación de eventos cardiovasculares adversos mayores.
Resultados: Se incluyó a 86 pacientes con lesión en la bifurcación DA-diagonal en el grupo de tratamiento con BFA y se compararon con una cohorte de 88 pacientes con abordaje convencional de la RL. El seguimiento medio fue de 1.008 días (rango 5-2.411). La estrategia en el grupo control fue *stent* solo en la rama principal 76,2%, *stent* solo en la RL 6,8% y *stent* en ambas ramas 17%. La incidencia comparativa (control frente a BFA) de eventos adversos fue: muerte cardiaca 1,1 frente a 2, 3% (no significativo); infarto de miocardio 8 frente a 0% (p = 0,014); revascularización de la lesión diana 9,1 frente a 0% (p = 0,013); revascularización del vaso diana 10,2 frente a 1,2% (p = 0,02); y eventos cardiovasculares adversos mayores 12,5 frente a 3,5% (p = 0,05).

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Conclusiones: El tratamiento con BFA de la RL en lesiones en la bifurcación DA-diagonal es seguro y presenta una muy alta efectividad a largo plazo, con una incidencia significativamente menor de eventos adversos en comparación con la estrategia convencional. Se requerirían amplios ensayos clínicos aleatorizados para confirmar estos hallazgos.

Palabras clave: Balón farmacoactivo. Lesiones en bifurcación. Estudio de seguimiento.

Abbreviations

DCB: drug-coated balloon. **MACE:** major adverse cardiovascular events. **MB:** main branch. **SB:** side branch. **TLR:** target lesion revascularization. **TVR:** target vessel revascularization.

INTRODUCTION

Coronary bifurcation lesions represent 20% of all lesions treated in the cath lab; among them, left anterior descending coronary artery (LAD)-diagonal lesions are the most frequent (between 50% and 70% according to published series).[1,2] Currently, the most widely accepted strategy is provisional stenting.[3-5] The 2-stent strategy is usually reserved for long lesions in the side branch (SB) or as bailout strategy if the SB worsens after main branch (MB) stenting. Drug-coated balloon (DCB) has emerged as a valid strategy for the treatment of these lesions, both in the MB, mainly in Medina 0,1,1 lesions, and in the SB, which is a much more extensively studied scenario.[6] Studies have demonstrated significant benefit in angiographic parameters; however, controversy remains regarding clinical benefit, and only recently have studies confirmed significant improvements in clinical events. The theoretical advantages[7] of DCB in the management of the SB would mainly be drug delivery at the SB coronary ostium, absence of distortion of its original anatomy, and minimization of strut deformation at the carina if MB stenting is performed.

We present a nonrandomized comparative trial of LAD-diagonal bifurcation lesions with a long-term follow-up (mean 3 years) treated with DCB in the SB vs a control group with conventional SB management.

METHODS

We conducted a comprehensive single-center retrospective registry at *Hospital General Dr. Balmis* (Alicante, Spain), a high-volume center performing > 1200 angioplasties per year including all consecutive LAD-diagonal bifurcation lesions with SB ≥ 2 mm in which the SB was treated with a paclitaxel-coated SeQuent Please NEO DCB (B. Braun, Germany). Procedures had to conclude successfully (including absence of post-DCB dissection requiring stenting, residual percent diameter stenosis < 50%, and final TIMI grade-3 flow). In our cath lab, the routine clinical practice was to use DCB after MB stenting, recrossing and dilating the cell adjacent to the SB coronary ostium before SB treatment (at the operator's discretion, the DCB could be used before stenting if recrossing was anticipated to be difficult).

The inclusion period spanned from October 2018 through July 2024. There were no exclusion criteria. The interventional cardiology team was instructed to adhere to device recommendations, including SB predilatation preferably with a noncompliant or scoring balloon at a vessel/balloon diameter ratio of 0.8–1, and DCB use only if acceptable angiographic results were achieved (including TIMI grade-3 flow, no significant dissection, and residual percent diameter stenosis < 30%). The control group included all consecutive procedures performed during the first half of 2021 in which successful LAD-diagonal bifurcation intervention (diagonal diameter ≥ 2 mm) was performed using the provisional or 2-stent technique at operator discretion.

We analyzed clinical patient variables, lesion anatomical characteristics, and procedural data. Mean clinical follow-up was 3 years, conducted via telephone contact or digital health record review. Clinical events were selected according to the Drug Coated Balloon Academic Research Consortium recommendations.[8] Recorded events included all-cause mortality (cardiac and noncardiac), acute myocardial infarction (elevation of myocardial injury biomarkers > 99th percentile upper reference limit with clinical evidence of ischemia), lesion thrombosis, target lesion revascularization (TLR), and target vessel revascularization (TVR) (revascularization either of the target lesion included in the study or other segments within the same vessel) at the follow-up. The composite endpoint of mayor adverse cardiovascular events (MACE) included TLR, TVR, hospitalization for acute myocardial infarction, and cardiac death. All patients signed informed consent, and the study was approved by *Hospital General Dr. Balmis* ethics committee.

Statistical analysis

Continuous variables were expressed as mean and SD and compared using Student *t* test. Categorical variables were expressed as percentages and were compared using the chi-square test or Fisher's exact test when expected cell counts were < 5. Variables showing significant differences in univariate analysis between the DCB group and the control group were entered into a logistic regression model to determine independent predictors of higher rates of TLR. Similarly, we constructed event-free survival curves using the Kaplan-Meier method, and the log-rank test to compare the DCB treatment group vs the control group.

RESULTS

A total of 86 patients were included in the DCB group and 88 in the control group. The patients' clinical and anatomical characteristics are shown in table 1. The rate of true bifurcations (Medina 1,1,1; 1,0,1; or 0,1,1 with SB diameter ≥ 2.5 mm) was 34.9% in the DCB group and 28.4% in the control group (P = .36). Among such variables, significant differences were observed across groups only in multivessel disease and prior coronary intervention, whose incidence rates were both higher in the DCB group. In-stent restenosis

Table 1. Clinical characteristics of the patients

Clinical characteristics	DCB group (n = 86)	Control group (n = 88)	*P*
Age (years)	67 ± 11	65 ± 13	.28
Male sex	81.8	77.9	.41
Hypertension	60.5	58	.73
Dyslipidemia	75.6	67	.21
Smoking	25.6	31.8	.36
Diabetes	24.4	34.1	.16
Prior PTA	41.9	22.7	< .01
LVEF	54.3	54.4	.96
Indication for coronary angiography			
NSTEACS	38.6	42	
STEACS	19.8	21.6	
Stable angina	25.6	15.9	.61
LV dysfunction	4.7	6.8	
Other	11.6	13.6	
Multivessel disease	67.4	51.1	.029
ISR	15.1	6.8	.079
Medina classification			
1,1,1	38.4	36.4	
0,1,1	14	11.4	
0,0,1	11.6	6.8	
1,1,0	19.8	23.9	.52
0,1,0	5.8	13.6	
1,0,0	7	5.7	
1,0,1	1.7	1.1	
Lesion in the SB			
No lesion	30.2	43.2	
Short, 0–10 mm	50	38.6	.187
Long, > 10 mm	19.8	18.2	

DCB, drug-coated balloon; ISR, in-stent restenosis lesion; LV, left ventricle; LVEF, left ventricular ejection fraction; NSTEACS, non–ST-segment elevation acute coronary syndrome; PTA, percutaneous transluminal angioplasty; SB, side branch; STEACS, ST-segment elevation acute coronary syndrome.
Data are expressed as No. (%) or mean ± SD.

lesions were more than twice as frequent in the DCB group, with borderline statistical significance. Procedural variables are shown in table 2.

In the control group, the predominant strategy was 1 MB stent (76.1%). Stents were implanted in both branches in 17% of the cases and only in the SB in 6.9%. The rates of SB predilatation, MB postdilatation, and use of kissing-balloon or proximal optimization techniques were significantly more frequent in the DCB group. DCB was applied after MB stenting in most cases; pre-stent use occurred in 7 cases (8.1%). The use of intracoronary imaging, such as optical coherence tomography (OCT) or intravascular ultrasound (IVUS) was low in both groups, with a trend toward greater use in the DCB group but remaining < 10%.

The rate of adverse events during follow-up is shown in table 3. After a mean of 3 years, 13 deaths were reported in the DCB group and 11 in the control group, mostly noncardiac. Among the 2 cardiac deaths reported in the DCB group, 1 was due to heart failure progression (after catheterization the patient underwent transfemoral aortic valve implantation and permanent pacemaker implantation), and the other was sudden death at home. No TLR, myocardial infarction, or definite lesion thrombosis occurred in the DCB group. A total of 8 myocardial infarctions were reported in the control group, although only 1 was not target-vessel related (right coronary revascularization in the context of a non-ST-segment elevation acute coronary syndrome). There was 1 case of TVR (figure 1) in the active group in a patient in whom the LAD-diagonal lesion was treated with orbital atherectomy due to severe calcification and who was readmitted 1 year later for unstable angina, without changes on electrocardiogram or echocardiogram and without enzyme elevation. However, repeat catheterization revealed progression of a lesion at the distal margin of the LAD stent, far from the bifurcation treated

Table 2. Procedural characteristics

Characteristics	DCB group (n = 86)	Control group (n = 88)	*P*
Radial access	98.8	96.6	.62
6-Fr	96.5	90.9	.78
Predilatation			
SB	95.3	33	< .01
MB	68.6	58	.14
MB stenting	84.9	93.1	.079
SB diameter ≥ 2.5 mm	65.1	63.1	.84
Postdilatation			
MB	72.1	45.5	< .01
POT	44.2	12.5	< .01
SB	22.1	21.6	.94
Kissing-balloon	37.2	19.3	< .01
OCT/IVUS use	9.3	2.3	.056

DCB, drug-coated balloon; Fr, French; IVUS, intravascular ultrasound; MB, main branch; OCT, optical coherence tomography; POT, proximal optimization technique; SB, side branch.
Data are expressed as percentages.

Table 3. Rate of adverse events during follow-up

Adverse events	DCB group (n = 86)	Control group (n = 88)	*P*
Follow-up days	1009 ± 586	1028 ± 233	.66
Cause of death			
Cardiac	2.3	1.1	.69
Noncardiac	12.8	11.4	
TLR	0	9.1	.013
TVR	1.2	10.2	.02
Lesion thrombosis			
Yes	0	3.4	.15
Possible	1.2	0	
Myocardial infarction	0	8	.014
Major adverse cardiovascular events	3.5	12.5	.05

DCB: drug-coated balloon; TLR: target lesion revascularization; TVR: target vessel revascularization.
Data are expressed as No. (%) or mean ± SD.

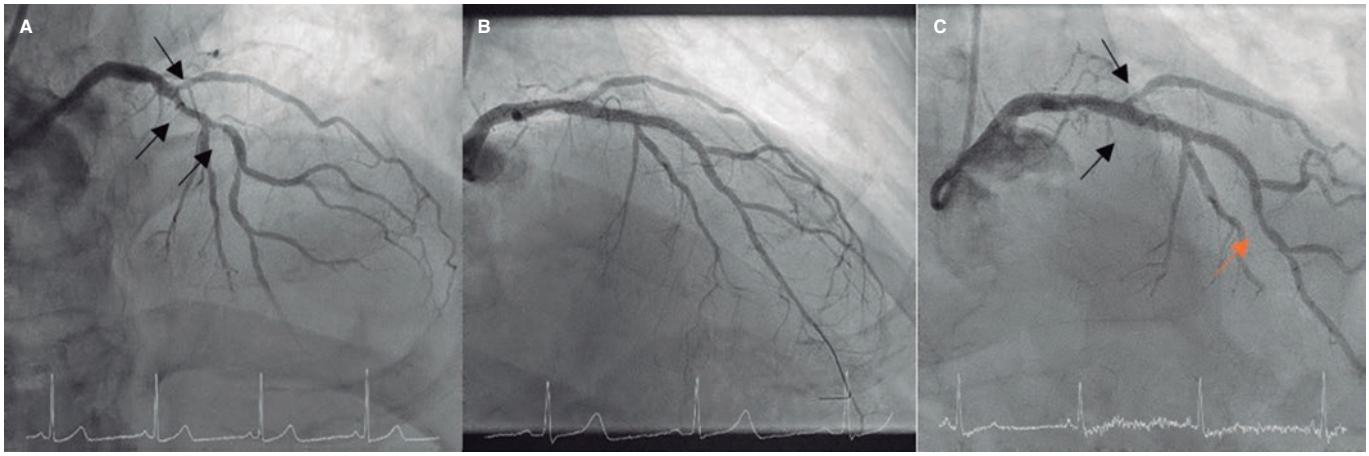


Figure 1. Single case of target vessel revascularization in the drug-coated balloon (DCB) treatment group. **A**: bifurcation lesion with severe calcification in the main branch. **B**: optimal result after orbital atherectomy, stent implantation in the left anterior descending coronary artery, and drug-coated balloon in the diagonal branch. **C**: 1-year follow-up result showing a significant lesion at the distal stent margin (orange arrow), far from the bifurcation treated with DCB (black arrows), which demonstrated sustained procedural success.

with DCB. This revascularization was not ischemia-guided, and the result at the bifurcation was optimal. The rate of TLR in the control group was 9.1%, with the MB responsible in 4 of the 8 cases, the SB in 2 cases, and both branches in the remaining 2. The rates of TLR and TVR were significantly lower in the DCB group (TLR, 0 vs 9.1%; $P = .013$; TVR, 1.2 vs 10.5%; $P = .02$). The logistic regression model (table 4) showed that none of the analyzed variables were independent predictors of events.

The rate of MACE was significantly lower in the DCB group (3.5 vs 12.5%; $P = .05$). Kaplan-Meier curves for primary and secondary endpoints are shown in figure 2.

DISCUSSION

Despite the vast body of literature on coronary bifurcation treatment, the real importance of the SB and its implication in target lesion failure are not well defined; therefore, there are no clear clinical practice guidelines on the optimal therapeutic approach for this branch. Few studies have exclusively analyzed the effectiveness of DCB in SB treatment, although this trend appears to be changing. Early studies published from 2011 onward, such as the DEBIUT,[9] the BABILON,[10] the DEBSIDE,[11] the study by Herrador et al.,[12] the PEPCAD V,[13] the PEPCAD-BIF,[14] and the BEYOND[15] showed discrepant data regarding DCB effectiveness, although generally favorable. These studies demonstrated improved quantitative angiographic parameters in terms of restenosis or late lumen loss; however, this was not always accompanied by lower revascularization rates, and there were concerns on a potential increase in late thrombosis, as suggested by some of them. A meta-analysis including 10 studies evaluating the effect of DCB in the SB concluded that this technique resulted in significantly better angiographic outcomes; however, this did not translate into a significant improvement of the outcomes (mainly target lesion failure), according to the authors, due to the low rate of this adverse event and insufficient statistical power because of small sample size.[16]

The optimal timing for DCB use remains controversial, and no study has demonstrated superiority of its use before or after MB stenting. Although expert consensus recommends its use before stenting, the timing ultimately depends on operator or team experience. Conversely, in the randomized DCB-BIF study[17]—the most relevant to date—the design required DCB application after stenting.

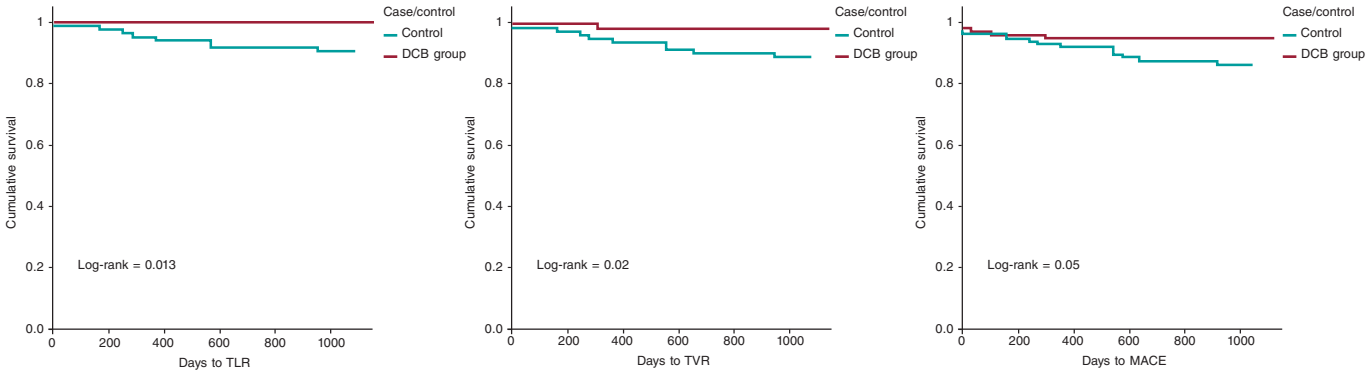
In the present registry, although not randomized, we consider both groups comparable when interpreting differences in the rate of adverse event, which favored the DCB treatment group. Clinical and anatomical differences were unfavorable to the DCB group (higher rate of in-stent restenosis lesions and multivessel disease), and some procedural differences may be explained by the intrinsic characteristics of each approach in each of the groups (such as a higher SB predilatation rate in the DCB group, considered practically mandatory). Furthermore, multivariate analysis including all these factors did not identify any independent predictor of events, thereby minimizing the likelihood of confounding. Despite this, in the study by Oh et al.,[18] treatment of the SB with either a conventional balloon or a stent in 1089 patients with true LAD-diagonal bifurcation lesions, compared with no SB treatment, was associated with a lower rate of target vessel failure. However, this difference did not reach statistical significance overall, although it became significant in the low-risk subgroup.

Very few studies have demonstrated clinical, not only angiographic, benefit after DCB use in the SB. The most relevant one is the 2025 study by Gao et al.,[17] in which DCB in the SB after provisional

Table 4. Logistic regression model for independent predictors of target lesion revascularization

Factors	P	95%CI
Prior PCI	.81	0.13-13.2
Multivessel disease	.45	0.11-2.7
ISR	1	0 – > 30
SB predilatation	.22	0.5-21
MB stent	1	0 – > 30
MB postdilatation	.73	0.2-8.7
POT	.85	0.09-18.2
Kissing-balloon	.85	0.09-18.2
OCT/IVUS	1	0 – ≥ 30

95%CI, 95% confidence interval; ISR, in-stent restenosis; IVUS, intravascular ultrasound; MB, main branch; OCT, optical coherence tomography; PCI, prior coronary intervention; POT, proximal optimization technique; SB, side branch.



Follow-up days	0	200	400	600	800	1000
Cases	86	85	81	71	56	48
Controls	88	81	78	76	74	71

Follow-up days	0	200	400	600	800	1000
Cases	86	85	71	61	46	40
Controls	88	82	77	75	72	69

Follow-up days	0	200	400	600	800	1000
Cases	86	79	71	61	46	39
Controls	88	81	78	75	72	69

Figure 2. Kaplan-Meier curves for adverse-event–free survival. DCB, drug-coated balloon; MACE, major adverse cardiovascular events; TLR, target lesion revascularization; TVR, target vessel revascularization.

stenting resulted in a significant reduction of the composite adverse event driven by fewer myocardial infarctions, although without significant differences in TLR. The cause of these findings remains controversial.[19]

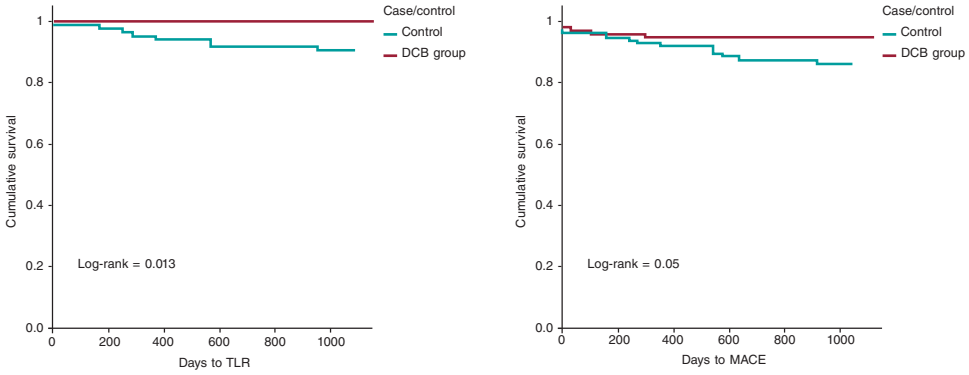
Another study published in 2022 randomized 219 true de novo bifurcation lesions to SB treatment with conventional balloon vs DCB.[20] At the 12-month clinical and angiographic follow-up, significant improvements were observed both in angiographic parameters (lower late lumen loss and greater late minimum lumen diameter) and clinical outcomes, with a lower rate of MACE; however, this improvement did not translate into significant reductions in new revascularizations or target vessel failure.

In the present study, the rate of adverse events at the 3-year follow-up in the DCB group was exceptionally low, with 0% TLR and 1.2% TVR. The 9% TLR rate in the control group is similar to that reported in former studies of high-risk coronary lesions such as bifurcations. In the abovementioned study by Oh et al.,[17] the 3-year rates of TLR went from 6.6% to 9% among > 1000 LAD-diagonal lesions. In another study comparing conventional vs DCB approaches in various complex lesions (including bifurcations: 36% in the first group and 24% in the second), the 2-year rate of TVR was 7.6% in the DCB group and 8.1% in the stent group.[21]

In a very recent Swedish study, the rate of adverse events was compared in nearly 6800 LAD-diagonal bifurcation lesions treated with a simple (MB only) vs complex strategy (both branches, both with balloon and stent).[22] At the 1-year follow-up, the rate of MACE was lower in the complex strategy group (6.2% vs 7.9%; HR, 0.74; 95%CI, 0.59–0.93; $P = .010$), driven by a lower all-cause mortality rate, without differences in TLR. This benefit persisted at 5 years (17% vs 19.8%; HR, 0.83; 95%CI, 0.72–0.96; $P = .010$).

The relative importance of the SB in repeat revascularizations remains controversial. Although some studies, such as the BABILON[10] showed that new revascularizations originated in the MB, in our registry, in the control group, up to 50% of the cases originated in the SB. This supports the need for exhaustive SB treatment during provisional stenting, both with DCB (as suggested by our results) and any other technique (conventional balloon or stent), particularly if significant SB ostial stenosis persists even without flow limitation.

Our group recently published a study analyzing adverse predictors after DCB use in SB bifurcation lesions regardless of location.[23] Only the presence of long SB lesions (> 10 mm) was identified as a negative prognostic factor. Our findings suggest that in the LAD-diagonal location this factor may be less relevant than in other locations, although adequately powered randomized trials are needed to confirm or refute this hypothesis.



Follow-up days	0	200	400	600	800	1000
Cases	86	85	81	71	56	48
Controls	88	81	78	76	74	71

Follow-up days	0	200	400	600	800	1000
Cases	86	79	71	61	46	39
Controls	88	81	78	75	72	69

Figure 3. Central illustration. Kaplan-Meier curves for event-free survival. DCB, drug-coated balloon; MACE, major adverse cardiovascular events; TLR, target lesion revascularization.

Limitations

The main limitations of this study are the lack of randomization, absence of perioperative myocardial infarction recording due to its retrospective design, inability to extract relevant IVUS/OCT data given low usage, relatively small sample size, and lack of systematic angiographic reevaluation, which may have identified subclinical events.

CONCLUSIONS

These results correspond to a single center with a very low long-term rate of adverse events in patients with LAD-diagonal bifurcation lesions whose SB was treated with DCB, significantly lower than in the control group. Currently, this is the first study demonstrating a significant improvement in an important endpoint such as TLR. Therefore, proper lesion selection (possibly those without long SB lesions), meticulous lesion preparation technique, and greater use of IVUS and OCT are essential. Randomized clinical trials with sufficient statistical power are needed to confirm these promising results and definitively establish the superiority of DCB for SB treatment in bifurcation lesions, particularly in the most frequent location, LAD-diagonal.

WHAT IS KNOWN ABOUT THE TOPIC?

- There is a limited number of studies analyzing the role of DCB in SB treatment of coronary bifurcation lesions, particularly in LAD-diagonal.
- Although DCB appears beneficial in angiographic parameters, this has not consistently translated into significant clinical improvement such as target vessel failure or need for repeat revascularization.

WHAT DOES THIS STUDY ADD?

- Experience from a high-volume center with very long-term follow-up representative of real-world practice.
- The favorable results may support DCB as a useful tool to improve long-term outcomes in LAD-diagonal bifurcation intervention.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

The study followed the Helsinki Declaration guidelines and was approved by *Hospital General Dr. Balmis* ethics committee (Alicante, Spain). Informed consent was obtained. SAGER guidelines regarding sex/gender bias were followed.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used in the preparation of this work or manuscript.

AUTHORS' CONTRIBUTIONS

J. Valencia: patient treatment, data collection, manuscript drafting and revision. F. Torres-Mezcua and M. Herrero-Brocal: patient treatment, data collection and revision. P. Bordes, F. Torres-Saura, J. Pineda and J.M. Ruiz-Nodar: patient treatment and revision. All authors approved the final version.

CONFLICTS OF INTEREST

None declared.

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Original article

Immediate versus staged PCI in STEMI and multivessel disease: a systematic review and meta-analysis

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ABSTRACT

Introduction and objectives: To compare clinical outcomes of immediate vs staged multivessel percutaneous coronary intervention (PCI) for non-culprit lesions in hemodynamically stable patients with ST-segment elevation myocardial infarction and multivessel coronary artery disease.
Methods: We conducted this systematic review and meta-analysis according to PRISMA guidelines. PubMed, Embase, and Cochrane databases were searched throughout September 2025. Outcomes included cardiac death, all-cause mortality, reinfarction, acute kidney injury, and stroke. Risk ratios were calculated, and trial sequential analysis, incidence rate ratio (IRR) analyses, and meta-regression were conducted.
Results: Six randomized controlled trials including 4267 patients were analyzed. At the 1-year follow-up, there were no significant differences between immediate and staged PCI regarding cardiac death (RR, 1.26; 95%CI, 0.89-1.79), all-cause mortality (RR, 1.18; 95%CI, 0.93-1.50), acute kidney injury (RR, 0.91; 95%CI, 0.64-1.31), or stroke (RR, 1.17; 95%CI, 0.66-2.05). Immediate PCI was associated with a lower risk of reinfarction (RR, 0.63; 95%CI, 0.40-0.98), a finding confirmed by IRR analysis (IRR, 0.60; 95%CI, 0.39-0.94; $I^2 = 0\%$). Exploratory meta-regression analyses did not identify procedural timing or baseline comorbidities as significant effect modifiers.
Conclusions: In patients with ST-segment elevation myocardial infarction and multivessel disease, immediate PCI was associated with a lower risk of reinfarction, without any significant differences being reported in cardiac death or all-cause mortality compared with staged PCI. Although trial sequential analysis indicates that current evidence remains underpowered for certain outcomes, the consistency of findings across multiple analytical approaches supports the safety profile of immediate complete revascularization, pending confirmation in adequately powered randomized trials. (PROSPERO: CRD42023485163.I).

Keywords: Coronary artery disease. ST-segment elevation myocardial infarction. Multivessel disease. Immediate percutaneous coronary intervention. Staged percutaneous coronary intervention.

ICP inmediata frente a ICP por etapas en el IAMCEST y la enfermedad multivaso: revisión sistemática y metanálisis

RESUMEN

Introducción y objetivos: Esta revisión sistemática con metanálisis evalúa si una estrategia de intervención coronaria percutánea (ICP) multivaso por etapas o inmediata proporciona resultados clínicos superiores en pacientes hemodinámicamente estables con

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infarto agudo de miocardio con elevación del segmento ST y enfermedad coronaria multivaso sometidos a revascularización de lesiones no culpables.
Métodos: Se realizaron búsquedas en PubMed, Embase y Cochrane hasta septiembre de 2025 según las directrices PRISMA. Los resultados incluyeron muerte por causa cardiaca, muerte por cualquier causa, reinfarto, lesión renal aguda y accidente vascular cerebral. Se estimaron los riesgos relativos y se realizó un análisis secuencial de ensayos en desenlaces seleccionados. Además, se calcularon las tasas de incidencia relativa (IRR) y se realizó una metarregresión.
Resultados: Se incluyeron 6 ensayos clínicos aleatorizados con 4.267 pacientes. En el seguimiento al año no se encontraron diferencias significativas entre la ICP por etapas y la inmediata en el riesgo de muerte por causa cardiaca (RR = 1,26; IC95%, 0,89-1,79), muerte por cualquier causa (RR = 1,18; IC95%, 0,93-1,50), lesión renal aguda (RR = 0,91; IC95%, 0,64-1,31) o accidente vascular cerebral (RR = 1,17; IC95%, 0,66-2,05). La ICP inmediata se asoció con un menor riesgo de reinfarto (RR = 0,63; IC95%, 0,40-0,98), confirmado por el análisis de tasa de incidencia relativa (IRR = 0,60; IC95%, 0,39-0,94; I^2 = 0%). La metarregresión no mostró asociación significativa entre el riesgo de reinfarto y el momento de la ICP por etapas o la comorbilidad basal.
Conclusiones: La ICP inmediata en pacientes con infarto agudo de miocardio con elevación del segmento ST y enfermedad multivaso se asoció con un menor riesgo de reinfarto, sin diferencias significativas en la mortalidad por causa cardiaca ni en la mortalidad por cualquier causa frente a la ICP por etapas. Aunque el análisis secuencial de ensayos indicó que la evidencia actual aún carece de suficiente poder estadístico, la consistencia en la dirección del efecto a través de múltiples enfoques analíticos respalda la seguridad y la posible ventaja clínica de la revascularización completa inmediata, lo que justifica su confirmación en futuros ensayos aleatorizados adecuadamente dimensionados. (PROSPERO: CRD42023485163.I).

Palabras clave: Enfermedad coronaria. Infarto agudo de miocardio con elevación del segmento ST. Enfermedad multivaso. Intervención coronaria percutánea inmediata. Intervención coronaria percutánea por etapas.

Abbreviations

AKI: acute kidney injury; **PCI:** percutaneous coronary intervention. **STEMI:** ST-segment elevation myocardial infarction.

INTRODUCTION

Multivessel coronary artery disease is defined as the presence of ≥ 70% luminal stenosis in at least 2 major epicardial coronary arteries due to atherosclerotic plaque. Approximately 40% of patients with ST-segment elevation myocardial infarction (STEMI) exhibit multivessel coronary disease, which is associated with an increased risk of recurrent myocardial infarction and mortality.[1-3] Evidence from randomized controlled trials has underscored the advantages of comprehensive revascularization with multivessel percutaneous coronary intervention (PCI) over culprit-lesion-only PCI, notably reducing the risks of cardiac death, myocardial infarction, and ischemia-driven revascularization at 1 year.[4-6] There are 2 strategies to approach non-culprit lesions: immediate PCI which involves the revascularization of both culprit and non-culprit lesions during the index procedure, and staged PCI, where the treatment of non-culprit lesions is deferred to a later stage.

The 2021 clinical practice guidelines outlined by the American College of Cardiology/American Heart Association (ACC/AHA) acknowledge non-culprit vessel revascularization as a class IIb recommendation for patients with STEMI.[7] However, determining the optimal timing for revascularization of non-culprit lesions remains a clinical challenge[7,8] While PCI for non-culprit lesions has demonstrated superiority over a strategy of treating the culprit lesion alone,[4-6] the timing of intervention, whether immediate or staged, lacks conclusive evidence.[8,9]

The objective of this meta-analysis was to compare staged vs immediate PCI for non-culprit lesions in hemodynamically stable patients with STEMI and multivessel disease. We hypothesize that both the staged and immediate PCI targeting non-culprit vessels will demonstrate comparable levels of safety, efficacy, and rate of complications.

METHODS

We conducted the present study following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[10] All steps were conducted in full compliance with the Cochrane Handbook of Systematic Reviews and Meta-analysis of Interventions (version 6.3).[11] This meta-analysis protocol was registered on PROSPERO on 4 December, 2023, under protocol ID: CRD42023485163.l. During the peer-review process, the literature search was updated using the same search strategy, databases, and eligibility criteria described in supplementary data S1 to identify newly published randomized evidence.

Criteria of the included studies

We evaluated randomized controlled trials comparing immediate vs staged PCI for non-culprit lesions in adults with STEMI and multivessel coronary artery disease. Eligible studies were required to report extractable numerical data for at least 1 prespecified outcome of interest, as defined below. Trials reporting outcomes exclusively as Kaplan-Meier curves without corresponding event counts or effect estimates or reporting outcomes only as composite endpoints without separate data, were excluded from quantitative synthesis. No publication time limit was applied; however, the search was restricted to studies published in Spanish, English, or German. Case-control and cross-sectional studies, systematic reviews, meta-analyses, case reports, basic science research, conference abstracts, and letters to the editor were excluded.

Literature search strategy

We conducted a comprehensive and systematic search across 3 databases (PubMed, EMBASE, and COCHRANE) from their inception until 28 September, 2025. Keywords used for the search

included "coronary artery disease", "immediate multivessel percutaneous coronary intervention", "staged multivessel percutaneous coronary intervention", "acute coronary syndrome", "multivessel disease", "myocardial infarction", "major adverse cardiovascular events", "ST-segment elevation myocardial infarction". These keywords were combined using Boolean operators AND and OR. The search details for each database are available in the supplementary data S1.

Screening of literature search results

All duplicates were removed using Zotero reference manager software. Records were initially screened by title and abstract by one author (E. Andrade-Arbaiza), followed by full-text assessment when potentially eligible. Two independent authors (D. Paulino-González, and L.H. García-Mena) reviewed full-text articles for inclusion and methodological quality, with disagreements being resolved by consensus or third-party adjudication (D.A. Navarro-Martínez). Studies were excluded at the full-text stage if they lacked extractable numerical data for prespecified outcomes or did not report outcomes separately, precluding quantitative synthesis. A detailed list of excluded studies with reasons for exclusion is provided in table S1. References cited in included studies were also manually screened for eligibility.

Data extraction

Data extraction was performed using standardized Excel spreadsheets to collect baseline population characteristics, key study features, outcome measures expressed as risk ratios, and domains for quality assessment. Outcome data were included only when numerical information was directly available or could be reliably derived without reconstruction from survival curves.

Assessing the risk of bias

The risk of bias of included randomized controlled trials was assessed usingvVersion 2 of the Cochrane risk-of-bias tool for randomized trials (ROB 2), in accordance with the Cochrane Handbook of Systematic Reviews of Interventions.[11]

Endpoints

The prespecified endpoints of this meta-analysis were cardiac death, all-cause mortality, stroke, reinfarction, and acute kidney injury (AKI). Given minor variations in endpoint definitions across trials, detailed outcome definitions as reported by each study are summarized in table S2. Outcomes were analyzed as dichotomous variables using event counts and percentages, and risk ratios with 95% confidence intervals (95%CI) were calculated.

Data analysis

Dichotomous outcomes were analyzed using pooled event data from the included studies and are reported as risk ratios with 95%CI. *P* values < .05 were considered statistically significant. Associations between outcomes and immediate vs staged PCI were evaluated using a random-effects model (DerSimonian–Laird method) to account for between-study heterogeneity.[12] Statistical analyses and forest plots were generated using RevMan version 5.4.1 (Cochrane Collaboration) for MacOs.

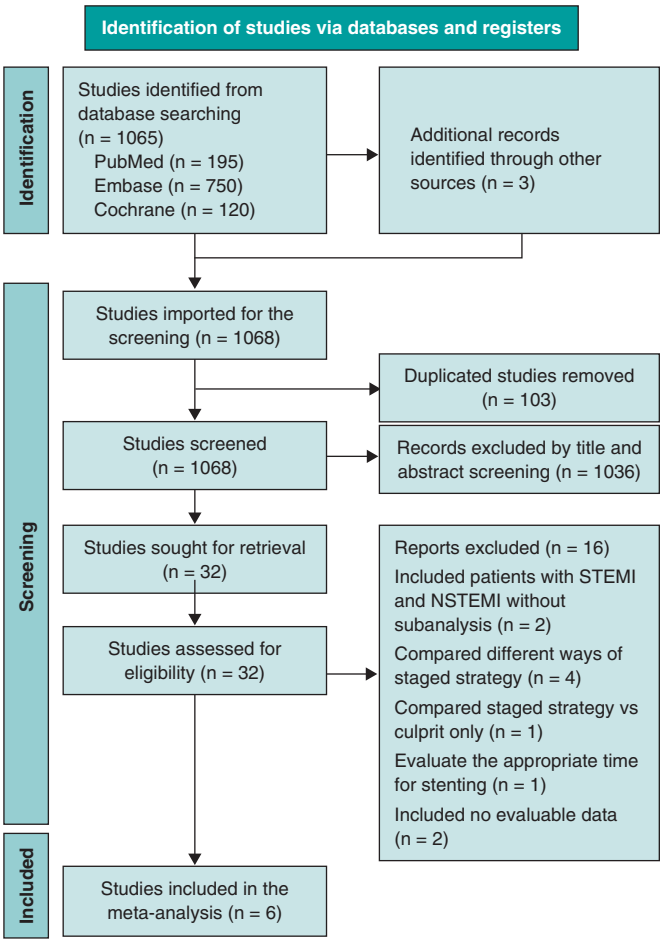


Figure 1. PRISMA flow diagram. The diagram reflects the initial search and the updated search performed during peer review using the same strategy and eligibility criteria (supplementary data S1). NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction.

Statistical analysis

Pooled risk ratios (RR) and incidence rate ratios (IRR) were estimated using random-effects models with appropriate adjustments, and heterogeneity was assessed using the I^2 statistic. Sensitivity analyses, trial sequential analysis, and meta-regression were performed to evaluate the robustness of findings and explore potential effect modifiers. Detailed methodological procedures are shown in the supplementary data S2.

Assessment of heterogeneity

Heterogeneity was assessed using Cochran's Q test ($P < .10$) and quantified with the I^2 statistic, with values > 50% indicating substantial heterogeneity.

RESULTS

A total of 6 studies[13-18] met the predefined inclusion criteria and were included in the analysis. The study selection process is summarized in the PRISMA flow diagram shown in figure 1. All included studies evaluated staged or immediate PCI in non-culprit arteries of patients with STEMI and multivessel disease.

In the staged strategy, PCI of nonculprit lesions was performed a mean of 18.6 days (IQR, 7-34) after the index procedure. The total patient population included in our meta-analysis was 4267 patients, of whom 2479 underwent immediate PCI and 1788, staged PCI. Summary and baseline characteristics are shown in table 1. The characteristics of the included studies are summarized in table 2.

Cardiac death

There were no significant difference between staged and immediate PCI regarding the risk of cardiac death (RR, 1.26; 95%CI, 0.89-1.79; $P = .19$). No heterogeneity was observed among the included studies ($I^2 = 0\%$). These findings are shown in figure 2A.

All-cause mortality

There were no significant differences in the risk of all-cause mortality between patients undergoing staged PCI and those treated with immediate PCI (RR, 1.18; 95%CI, 0.93-1.50; $P = .17$), with no heterogeneity detected among studies ($I^2 = 0\%$) (figure 2B).

Reinfarction

The analysis demonstrated a statistically significant lower risk of reinfarction with immediate vs staged PCI (RR, 0.63; 95%CI, 0.40-0.98; $P = .04$), which amounts to an approximately 37% relative risk reduction with the former. There was no heterogeneity across trials ($I^2 = 0\%$). These findings are shown in figure 3A.

Acute kidney injury

There were no significant differences between the 2 strategies (RR, 0.91; 95%CI, 0.64-1.31; $P = .62$), indicating no clear association between the revascularization strategy and the risk of AKI. There was no heterogeneity among the included studies ($I^2 = 0\%$). These results are shown in figure 3B.

Stroke

Stroke was reported in only 3 of the studies included, and our analysis showed no significant differences between staged and immediate PCI for this outcome (RR, 1.17; 95%CI, 0.66-2.05; $P = .59$). There was no heterogeneity among the included studies ($I^2 = 0\%$). These results are shown in figure S1.

Publication bias was assessed using funnel plots, Egger's regression, and trim-and-fill analyses for reinfarction, cardiac death, and all-cause mortality. There was no visual evidence of funnel-plot asymmetry (figure S2). For reinfarction, trim-and-fill imputed 1 potentially missing study, with the pooled effect remained statistically significant (IRR, 0.59; 95%CI, 0.38-0.90). For cardiac death and all-cause mortality, 2 studies were imputed in each analysis; however, pooled effects remained non-significant, with no heterogeneity detected ($I^2 = 0\%$). Overall, these results suggest no substantial publication bias, although the limited number of included trials reduces the power of formal tests for funnel plot asymmetry.

Sensitivity analyses

Leave-one-out sensitivity analyses confirmed the robustness of the pooled estimates across all primary endpoints (figure S3). For all-cause mortality and cardiac death, exclusion of individual studies did not materially alter the results, with pooled RRs remaining within the confidence intervals of the main models and $I^2 = 0\%$ in all scenarios. For reinfarction, estimates consistently favored immediate PCI (RR range, 0.46-0.75), with $I^2 = 0\%$ supporting the internal consistency of the findings.

Incidence rate ratios

At the 1-year follow-up, IRR analysis showed that immediate PCI was associated with a lower rate of reinfarction vs staged PCI. Under the random-effects model, the pooled IRR was 0.60 (95%CI, 0.39-0.94; $I^2 = 0\%$), which is consistent with the common-effect model (IRR, 0.59; 95%CI, 0.38-0.92), supporting the robustness of this finding (figure S4). In contrast, there were no significant differences between the strategies regarding cardiac death (IRR, 1.26; 95%CI, 0.90-1.77; $I^2 = 0\%$) or all-cause mortality (IRR, 1.17; 95%CI, 0.84-1.64; $I^2 = 0\%$), indicating stable estimates with negligible heterogeneity across studies (figures S5-S6).

Trial sequential analyses

Trial sequential analysis were conducted for cardiac death, all-cause mortality, and reinfarction (figure 4A-C). For cardiac death and all-cause mortality, the accrued sample represented 33% and 58% of the required information size, respectively; in both analysis, the cumulative Z-curves remained within nonsignificant boundaries, indicating insufficient evidence to confirm or exclude a 30% relative risk reduction. For reinfarction, only 3.4% of the required information size was reached, and the Z-curve remained well within the futility zone, showing a non-significant trend favoring immediate PCI. Collectively, these results demonstrate that current data remain underpowered to establish definitive conclusions across outcomes, despite a consistent numerical pattern supporting immediate revascularization.

Meta-regression

Exploratory meta-regression analyses were conducted to assess whether procedural timing or baseline comorbidities influenced reinfarction outcomes. The association between time to staged PCI and reinfarction risk showed a negative but non-significant slope ($\beta = -0.016$ per day; 95%CI, −0.042-0.010; $P = .22$), with no residual heterogeneity ($I^2 = 0\%$), indicating consistent effects across studies (figure S7). Similarly, diabetes prevalence ($\beta = 0.021$ per 1% increase; 95%CI, −0.017 to 0.058; $P = .22$) and hypertension prevalence ($\beta = -0.064$ per 1% increase; 95%CI, −0.214 to 0.085; $P = .40$) were not significantly associated with reinfarction risk, with no evidence of residual heterogeneity ($I^2 = 0\%$ for both) (figures S8-S9). Collectively, these findings suggest that neither procedural timing nor comorbidity burden materially modified the comparative risk of reinfarction between immediate and staged PCI; however, given the study-level and exploratory design of these analyses, results should be interpreted with caution.

Risk of bias assessment

Risk of bias assessment was assessed using version 2 of the Cochrane risk-of-bias tool for randomized trials (ROB 2), as outlined in the Cochrane Handbook of Systematic Reviews of Interventions.[11] Four clinical trials were judged to have a low overall risk of bias, whereas the study by Maamoun et al.[16] was rated as the only clinical trial having some concerns (table 3).

Table 1. Baseline characteristics and treatment of the included studies' populations

Study information				Baseline characteristics								Treatments and following intervention							
Study ID	Country	Total population size	Intervention	Population size	Median [IQR] Age	Gender	Comorbidities	Culprit artery		Non-culprit artery		Access site index	Access site index + staged	Stent used index	Stent used index + staged	Volume of contrast index	Volume of contrast index + staged	Length of stay index	Length of stay index + staged
Kim et al.[18] 2025	Multicenter	994	Immediate	498	66 IQR [57-76]	F: 102 M: 396	Yes	Left main coronary artery	NR NR	Left main coronary artery	NR NR	Radial: 371 Femoral: NR	Radial: 379 Femoral: NR	2	NR	180 (140-225)	NR	4 (3-6)	NR
								Left anterior descending coronary artery	221 234	Left anterior descending coronary artery	222 212								
			Staged	496	65 IQR [58-76]	F: 103 M: 393		Left circumflex artery	62 67	Left circumflex artery	218 215			1	2	130 (100-180)	220 (170-298)	NR	5 (4-8)
								Right coronary artery	215 195	Right coronary artery	162 167								
Stähli et al.[13] 2023	Multicentric	840	Immediate	418	66 IQR [58-74]	F: 97 M: 321	Yes	Left main coronary artery	0 1	Left main coronary artery	1 4	Radial: 301 Femoral: 117	Radial: -- Femoral: 296	3 (2-4)	NR	250 (199-320)	NR	4 (3-6)	NR
								Left anterior descending coronary artery	163 176	Left anterior descending coronary artery	205 180								
			Staged	422	64 IQR [55-73]	F: 81 M: 341		Left circumflex artery	67 77	Left circumflex artery	196 152	Radial: 311 Femoral: 111	Radial: -- Femoral: 90	1 (1-2)	3 (2-4)	170 (130-220)	333 (258-411)	4 (3-6)	5 (4-7)
								Right coronary artery	188 169	Right coronary artery	134 124								
Politi et al.[14] 2010	Italy	130*	Immediate	65	64.5 ± 11.7	F: 15 M: 50	Yes	Left main coronary artery	NR NR	Left main coronary artery	NR NR	NR	NR	NR	NR	NR	NR	4.8 ± 2.6	NR
								Left anterior descending coronary artery	NR NR	Left anterior descending coronary artery	NR NR								
			Staged	65	64.5 ± 11.1	F: 13 M: 52		Left circumflex artery	NR NR	Left circumflex artery	NR NR	NR	NR	NR	NR	NR	NR	5.4 ± 3.1	NR
								Right coronary artery	NR NR	Right coronary artery	NR NR								

(Continues)

Table 1. Baseline characteristics and treatment of the included studies' populations (*continued*)

Study information				Baseline characteristics								Treatments and following intervention							
Study ID	Country	Total population size	Intervention	Population size	Median [IQR] Age	Gender	Comorbidities	Culprit artery		Non-culprit artery		Access site index	Access site index + staged	Stent used index	Stent used index + staged	Volume of contrast index	Volume of contrast index + staged	Length of stay index	Length of stay index + staged
Park et al.[15] 2023	Multicentric	209*	Immediate	103	63.3 ± 10.4	F: 21 M: 82	Yes	Left main coronary artery	1	Left main coronary artery	4	Radial: 27	--	2.58 ± 0.86	--	NR	--	NR	NR
									1		3								
								Left anterior descending coronary artery	45	Left anterior descending coronary artery	79								
									48		82								
			Staged	106	62.2 ± 10.9	F: 18 M: 88		Left circumflex artery	12	Left circumflex artery	60	Radial: 25	NR	2.62 ± 1.00	NR	NR	NR	NR	NR
									17		55								
								Right coronary artery	46	Right coronary artery	78								
									42		80								
									228		65								
Maamoun et al.[16] 2011	Yemen	78	Immediate	36	52.33 ± 7.1	M: 32 F: 4	Yes	NR	NR	NR	NR	Femoral	Femoral	2.38 ± 0.49	2.31 ± 0.47	NR	NR	NR	NR
			Staged	42	54.52 ± 10.3	M: 40 F: 2													
Wood et al.[17] 2019	Canada	4041*	Immediate	1353	61.8 ± 10.5	M: 1079 F: 274	Yes	NR	NR	Left main coronary artery	4	Radial	Radial	NR	NR	NR	NR	NR	NR
											6								
										Left anterior descending coronary artery	683								
											384								
			Staged	663	61.2 ± 11.0	M: 544 F: 119				Left circumflex artery	654								
											294								
										Right coronary artery	463								
											207								

F, female; IQR, interquartile range; M, male; NR, not reported.
* Analysis of a subgroup.

Table 2. Summary of included studies

Author & year	Journal	Country	Study design	Population size (included)	Compared interventions	Timeframe by staged PCI	Mean follow-up	Key findings
Kim et al.[18] 2025	*The Lancet*	South Korea	Ramdomized controlled trial	994	Immediate vs staged revascularization	3 days	1 year	• The rate of the primary composite endpoint (all-cause mortality, nonfatal myocardial infarction, or unplanned revascularization) was similar across groups, being reported in 8.5% of patients from the immediate PCI group and 8.7% from the staged PCI group (RR, 0.98; 95%CI, 0.68-1.42; $P = .015$). • Immediate PCI was non-inferior to staged PCI for the primary endpoint at the 1-year follow-up. • Rates of cardiac death, reinfarction, and stroke were comparable across strategies. • The trial included patients with mild or transient hemodynamic instability, broadening applicability to higher-risk STEMI populations.
Stähli et al.[13] 2023	*New England Journal of Medicine*	Europe	Randomized controlled trial	840	Immediate vs staged revascularization	19-45 days	30 days (± 7 days), 6 months (± 14 days), 1 year (± 14 days)	• The risk of a primary endpoint event was lower in the immediate vs the staged group, with a risk ratio of 0.52 and a 95% confidence interval of 0.38 to 0.72. • Immediate multivessel PCI was noninferior to staged multivessel PCI in terms of the risk of all-cause mortality, nonfatal myocardial infarction, stroke, unplanned ischemia-driven revascularization, or hospitalization for heart failure at 1 year. • Nonfatal myocardial infarction and unplanned ischemia-driven revascularization occurred less frequently in the immediate vs the staged group.
Park et al.[15] 2023	*American Heart Journal*	South Korea	Randomized controlled trial	209	Immediate vs staged revascularization	14 days	7 days 1 month 1 year	• There was no statistically significant difference in MACE within the first year across both groups: 11.6% for immediate revascularization vs 7.5% for staged revascularization, with a HR of 1.60. Of note, the study was completed ahead of schedule due to the development/production of the everolimus-eluting stent.
Wood et al.[17] 2019	*Journal of the American College of Cardiology*	Canada	Randomized controlled trial	4041 (2016)	Immediate vs staged revascularization	23 days (12.5-33.5)	3 years	• For non-culprit lesion PCI planned to occur after hospital discharge (actual time: median 23 days), cardiac death or MI was also reduced with complete revascularization (HR, 0.69; 95%CI, 0.49-0.97; $P = .62$).
Maamoun et al.[16] 2011	*The Egyptian Heart Journal*	Yemen	Randomized controlled trial	78	Immediate vs staged revascularization	7 days	1 year	• A simultaneous multi-vessel strategy during primary PCI is safe and feasible with no clear long-term benefits in MACE rates over staged multi-vessel strategy.
Politi et al.[14] 2010	*Heart*	Italy	Randomized controlled trial	263 (130)	Immediate vs staged revascularization	56.8 ± 12.9 days	2.5 ± 1.4 years	• Specifically, individuals in the SR category demonstrated a 63% reduced likelihood of experiencing MACE, while those in the primary CR category exhibited a 60% decreased risk. • Patients set for staged revascularization encountered a comparable occurrence of MACE or re-PCI vs patients receiving simultaneous complete treatment for non-IRA.

95%CI, 95% confidence interval; CR, complete revascularization; HR, hazard ratio; IRA, infarct-related artery; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; MACE, major adverse cardiovascular events; MI, myocardial infarction; RR, risk ratio; SR, staged revascularization.

DISCUSSION

The present meta-analysis provides a focused comparison of immediate vs staged PCI in patients with STEMI and multivessel disease. By integrating randomized evidence using complementary analytical approaches, our findings offer an updated and clinically relevant synthesis of the safety and efficacy profile of these 2 revascularization strategies in a well-defined population.

Although cardiac death and all-cause mortality are clinically relevant, they are relatively rare outcomes in contemporary STEMI populations undergoing multivessel revascularization. In the

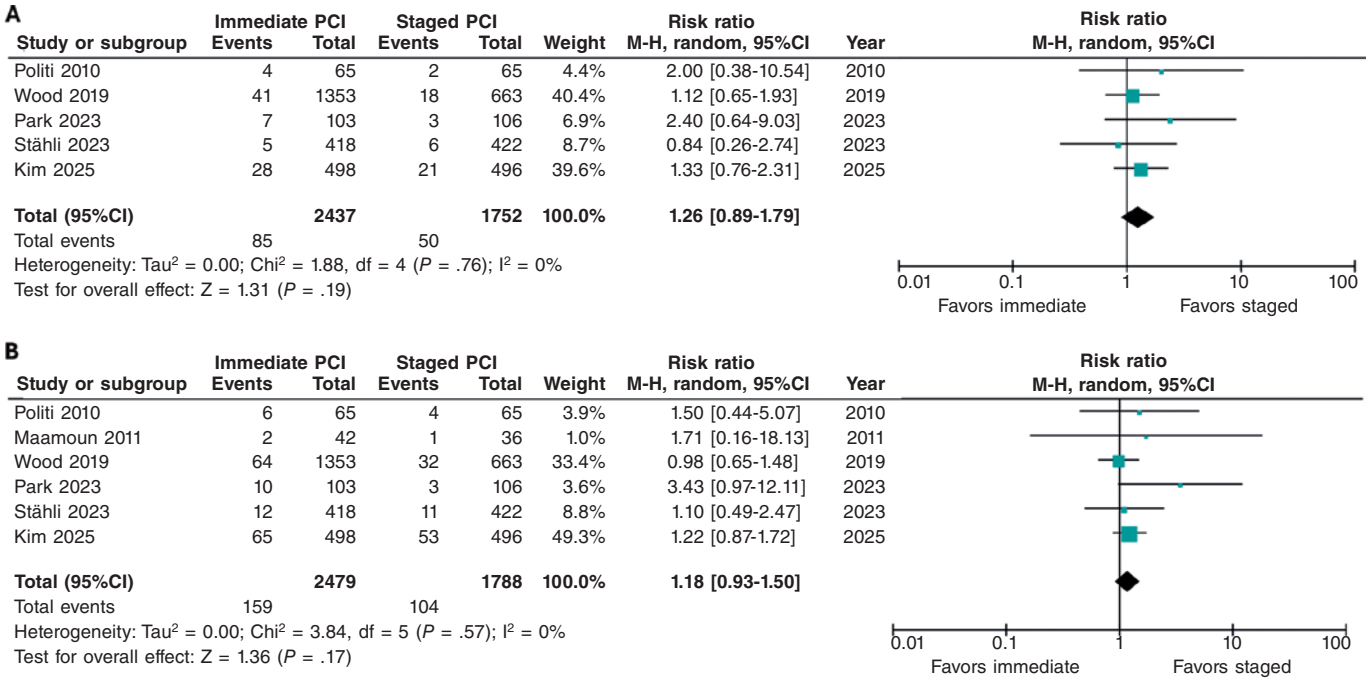


Figure 2. Risk Ratios of cardiac death and all-cause mortality. **A:** cardiac death: risk ratio (RR) across the included trials are represented by solid squares, with horizontal lines indicating 95% confidence intervals (95%CI). **B:** all-cause mortality: RR across trials are shown by solid squares, with 95%CI indicated by horizontal lines. M-H, Mantel-Haenszel; Random, random effects model. The bibliographical references cited in this figure correspond to the following studies: Politi et al.[14] (2010), Maamoun et al.[16] (2011), Wood et al.[17] (2019), Park et al.[15] (2023), Stähli et al.[13] (2023), and Kim et al.[18] (2025).

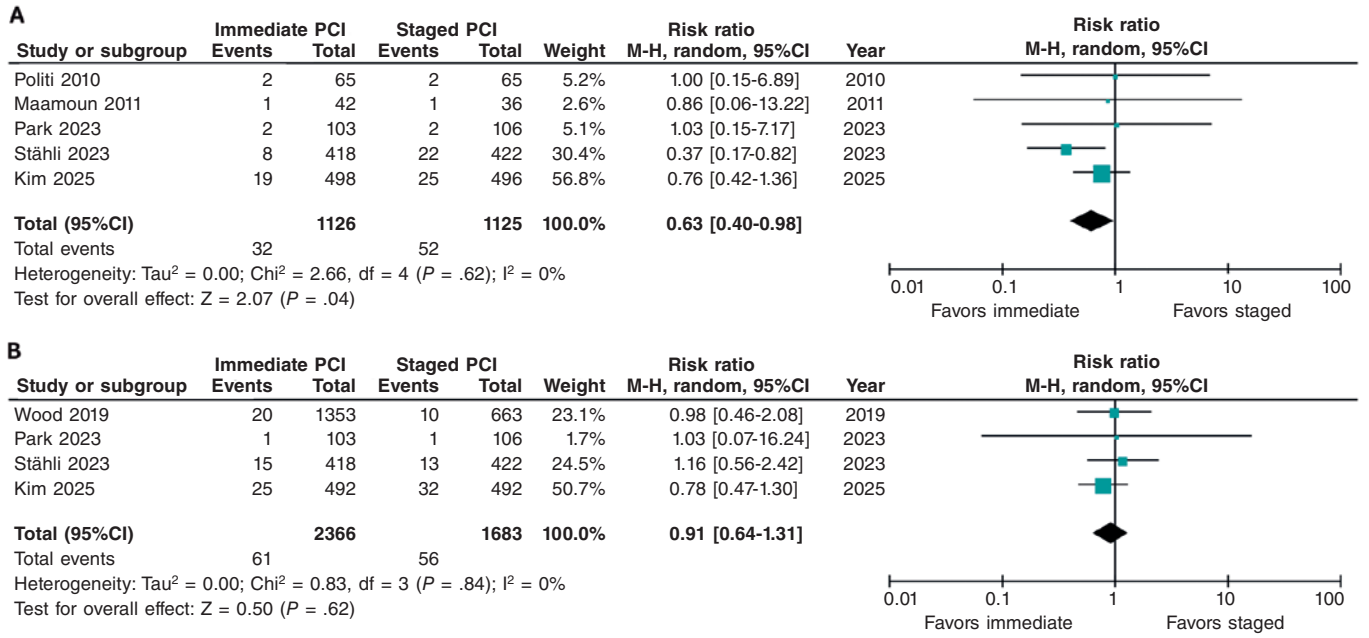


Figure 3. Risk ratios for reinfarction and acute kidney injury. **A:** reinfarction: risk ratio (RR) across the included trials are represented by solid squares, with horizontal lines indicating 95% confidence intervals (95%CI). **B:** acute kidney injury: RR across trials are shown by solid squares, with 95%CI indicated by horizontal lines. M-H, Mantel-Haenszel; Random, random effects model. The bibliographical references cited in this figure correspond to the following studies: Politi et al.[14] (2010), Maamoun et al.[16] (2011), Wood et al.[17] (2019), Park et al.[15] (2023), Stähli et al.[13] (2023), and Kim et al.[18] (2025).

present analysis, there were no statistically significant differences between immediate and staged PCI for either endpoint. These neutral findings should be interpreted in the context of limited statistical power, as reflected by the low cumulative incidence of events and trial sequential analysis indicating that the required information size has not yet been reached.[19,20] Additional IRR analyses yielded consistent results, further supporting the absence of a clinically meaningful survival difference between strategies. Accordingly, mortality outcomes do not appear to discriminate between immediate and staged PCI, and treatment selection should instead be guided by patient-specific clinical stability and procedural considerations rather than isolated mortality endpoints alone.

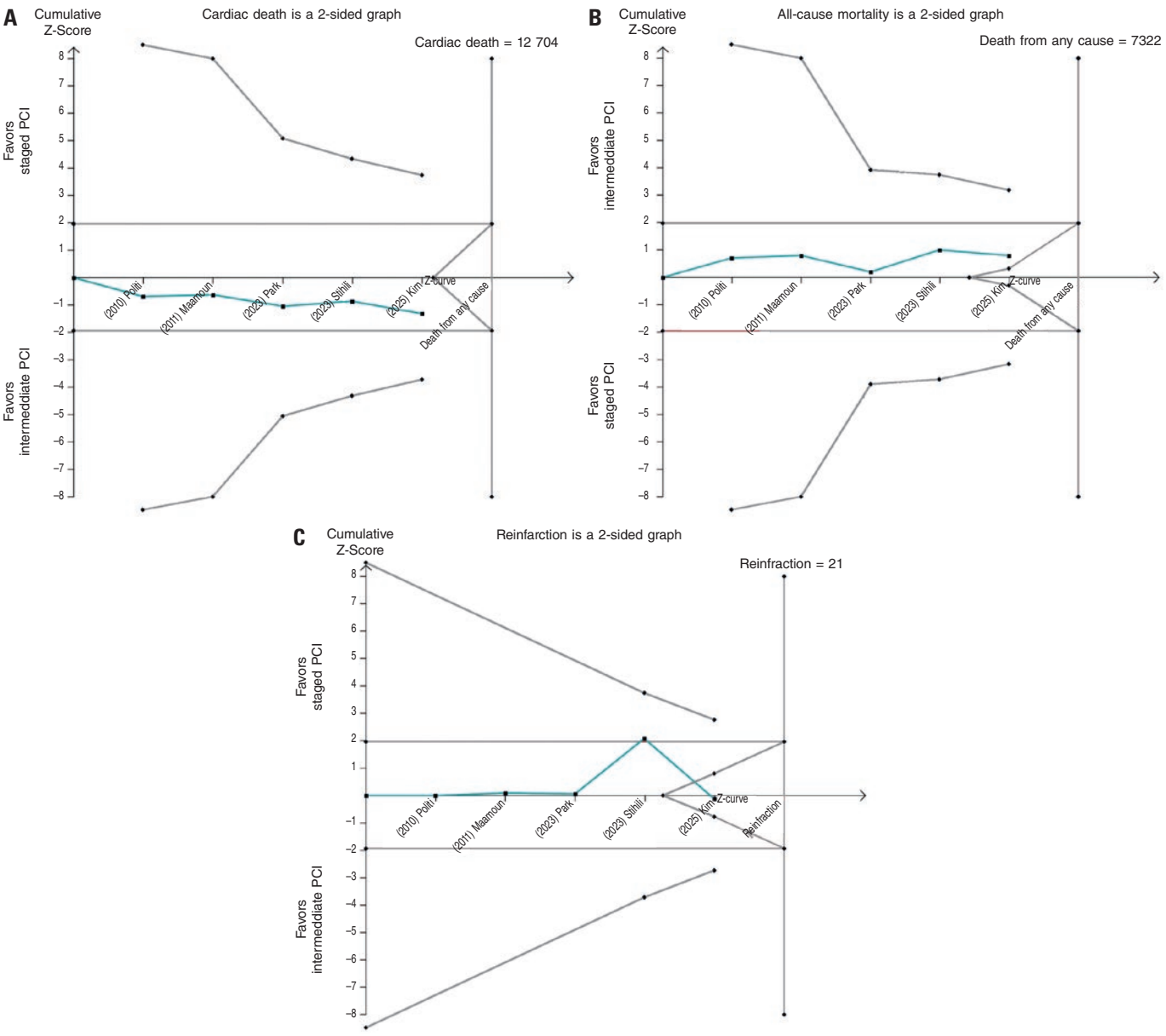


Figure 4. Trial sequential analysis. Trial sequential analysis for (**A**) cardiac death, (**B**) all-cause mortality, and (**C**) reinfarction. In all panels, the cumulative Z-curve is shown in blue, trial sequential monitoring boundaries in red, and conventional significance thresholds as horizontal magenta lines. PCI, percutaneous coronary intervention. The bibliographical references cited in this figure correspond to the following studies: Politi et al.[14] (2010), Maamoun et al.[16] (2011), Wood et al.[17] (2019), Park et al.[15] (2023), Stähli et al.[13] (2023), and Kim et al.[18] (2025).

Table 3. Risk of bias summary for randomized studies (RoB 2)

Study	Bias arising from randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcomes	Bias in selection of the reported results	Overall risk of bias
Politi et al.[14] 2010	Low	Low	Low	Low	Low	Low
Maamoun et al.[16] 2011	Low	Some concerns	Low	Some concerns	Low	Some concerns
Wood et al.[17] 2019	Low	Low	Low	Low	Low	Low
Park et al.[15] 2023	Low	Low	Low	Low	Low	Low
Stähli et al.[13] 2023	Low	Low	Low	Low	Low	Low
Kim et al.[18] 2025	Low	Low	Low	Low	Low	Low

Regarding reinfarction risk, immediate PCI was consistently associated with a significantly lower rate of reinfarction vs staged PCI. Exploratory meta-regression analyses did not identify procedural timing, diabetes, or hypertension prevalence as significant modifiers of this association. Trial sequential and sensitivity analyses showed consistent results across the models, with no evidence of heterogeneity. Although the required information size was not fully reached, the consistency of findings across multiple analytical approaches supports a robust association between immediate PCI and reduced recurrent ischemic events.

Regarding AKI, there were no significant differences between immediate and staged PCI, with low event rates and no heterogeneity across trials. The limited number of events precluded meaningful trial sequential analysis, highlighting insufficient power to detect small differences. Although post-PCI AKI is influenced by multiple factors, including contrast exposure and procedural complexity,[21] current evidence does not support the assumption that staged PCI reduces renal risk by distributing contrast load.[22] None of the included trials were specifically powered for renal outcomes, and AKI definitions varied across studies. Therefore, until adequately powered trials with standardized definitions become available, PCI timing decisions should remain individualized, taking into account baseline renal function and overall procedural risk.[23]

There were no significant differences in the rates of stroke between staged and immediate PCI, with few events being reported across trials, limiting statistical power. Available evidence suggests that stroke risk after PCI in STEMI is more closely related to procedural factors than to the timing of non-culprit revascularization.[15] Accordingly, stroke does not appear to represent a clinically discriminative endpoint when comparing immediate and staged revascularization strategies in this population.

Historically, international clinical practice guidelines favored a staged approach to complete revascularization in STEMI with multivessel disease, largely due to concerns regarding procedural complexity, contrast exposure, and hemodynamic instability during the index intervention. However, cumulative randomized evidence has challenged this paradigm, showing that immediate complete PCI can be performed safely in hemodynamically stable patients, with outcomes comparable or superior to staged strategies.[13,17,24,25] Notably, most prior trials primarily enrolled clinically stable patients following successful reperfusion, which may limit the generalizability of their findings to higher-risk STEMI populations. In this context, the OPTION-STEMI trial extends the available evidence by including patients with transient or mild hemodynamic instability, thereby providing contemporary data that better reflect real-world clinical complexity.[18]

Consistent with our primary findings, immediate and staged PCI did not differ in cardiac death or all-cause mortality at 1 year, while immediate PCI was associated with a lower risk of reinfarction. Beyond clinical outcomes, immediate complete revascularization may offer economic advantages by reducing the length of stay, avoiding repeat cardiac catheterizations, and optimizing resource utilization. In contrast, staged PCI often requires a second procedure and hospitalization, increasing cumulative costs by up to 50% in some analyses,[26,27] and mirroring the additional expenses associated with unplanned readmissions for recurrent ischemia. In this context, a single-session revascularization strategy may provide both clinical and economic value, particularly in health care systems with constrained resources, where contemporary PCI costs remain substantial.[28]

From a safety and efficacy perspective, both staged and immediate PCI represent acceptable revascularization strategies in appropriately selected patients with STEMI and multivessel disease. In the present analysis, immediate PCI was primarily associated with a reduction in recurrent ischemic events, while major adverse cardiovascular events, including cardiac death and all-cause mortality did not differ significantly across strategies. Accordingly, the choice between immediate and staged PCI may increasingly be guided by patient-specific clinical characteristics and logistical considerations rather than concerns regarding procedural safety.

Although not directly assessed in this meta-analysis, emerging evidence suggests that systemic biological factors—such as inflammation, hypercoagulability, and sympathetic activation—may influence recurrent ischemic risk beyond angiographic severity alone.[29,30] In addition, features of plaque vulnerability have been associated with future ischemic events in non-culprit lesions, even when angiographically mild.[31] Integrating biological risk markers and clinical stability into revascularization decision-making, therefore, represents a relevant direction for future research aimed at refining individualized strategies in patients with STEMI and multivessel disease.

Limitations

Several limitations should be acknowledged. First, only 6 randomized controlled trials were included, resulting in limited statistical power, particularly for rare outcomes. Second, this analysis was restricted to patients with STEMI and multivessel disease; therefore, the findings should not be extrapolated to other acute coronary syndrome populations, and the limited number of trials reporting all prespecified outcomes may reduce the robustness of certain estimates. Third, the use of aggregate study-level data precluded adjustment for individual patient characteristics and limited the assessment of patient-level effect modification; accordingly, meta-regression analyses were exploratory and should be interpreted with caution given the small number of included studies and the potential for ecological bias. Finally, variability in the timing of staged PCI across trials may have introduced residual clinical heterogeneity, and formal assessments of publication bias were underpowered due to the limited number of studies.

CONCLUSIONS

This meta-analysis, integrating additional analytical approaches, provides a focused comparison of immediate vs staged PCI in patients with STEMI and multivessel disease. Immediate PCI was consistently associated with a lower risk of reinfarction, without significant differences being reported in cardiac death or all-cause mortality, stroke, or renal injury. Although the cumulative evidence remains below the required information size for certain hard endpoints, the consistency of findings across multiple analyses supports the robustness of the observed reduction in reinfarction events. From a clinical perspective, these results suggest that immediate complete revascularization can be performed safely in appropriately selected patients and may reduce the burden of reinfarction. Accordingly, the choice between immediate and staged strategies should increasingly be guided by patient-specific clinical stability and practical considerations rather than by concerns regarding procedural safety alone. Future research incorporating biological risk markers may further refine individualized revascularization strategies in this population.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

This meta-analysis was based exclusively on data from previously published studies and involved secondary analyses of publicly available information. Therefore, approval by an Ethics Committee or institutional review board was deemed unnecessary. As no individual patient data or case reports were included, informed consent was not applicable. All the studies included were conducted in full compliance with the ethical standards of the respective institutions at the time of their original publication.

In line with the SAGER guidelines, we assessed sex and gender reporting in the included randomized trials. While sex was generally reported at baseline, sex-disaggregated outcome data and gender-related variables were rarely available, precluding analyses by sex or gender. This limitation should be considered when interpreting the results.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

During the preparation of this work the authors used ChatGPT 5.2 to review the syntaxis and grammar of this document. After using this tool/service, the authors reviewed and edited the content as needed and took full responsibility for the content of the published article.

AUTHORS' CONTRIBUTIONS

D. Paulino-González: conceptualization, formal analysis, drafting – review and editing. L.H. García-Mena: formal analysis, investigation, drafting – review and editing. E. Andrade-Arbaiza: methodology, investigation, drafting – review and editing. D.A. Navarro-Martínez: methodology, formal analysis; J.L. Maldonado-García: formal analysis, drafting – review and editing; S.A. Xiloj-López: investigation. C.J. Palomino-Ojeda: investigation, drafting – review and editing, R.M. Arellano-Sánchez: data curating, formal analysis. N.E. Antonio-Villa: data curating, formal analysis, drafting – review and editing. A. Ricalde-Alcocer: drafting – review and editing, supervision. D. Araiza-Garaygordobil: drafting – review and editing, supervision.

CONFLICTS OF INTEREST

None declared.

ACKNOWLEDGEMENTS

The authors respectfully honor, in memory, a beloved family member of one of the coauthors, and gratefully acknowledge the support of Dr. Pavel Pichardo-Rojas.

WHAT IS KNOWN ABOUT THE TOPIC?

- Multivessel disease is present in approximately 40% of patients with ST-segment elevation myocardial infarction and is associated with an increased risk of recurrent myocardial infarction and mortality. Complete revascularization, including both culprit and non-culprit lesions, reduces adverse cardiovascular events compared with culprit-lesion-only PCI. Non-culprit lesions may be treated either during the index procedure or in a staged approach; however, the optimal timing of revascularization remains uncertain.

WHAT DOES THIS STUDY ADD?

- This meta-analysis of 6 randomized controlled trials provides a comprehensive comparison of immediate vs staged PCI for non-culprit lesions in STEMI with multivessel disease. Immediate PCI was associated with a lower risk of reinfarction, without significant differences being reported in cardiac death, all-cause mortality, stroke, or AKI. Exploratory meta-regression analyses did not identify procedural timing or baseline comorbidities as effect modifiers. Overall, these findings support the safety of immediate complete revascularization and suggest a potential clinical and economic advantage by reducing recurrent ischemic events and repeat procedures.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M26000572.

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Original article

Territorial longitudinal strain to predict the location and severity of significant stenosis in stable coronary artery disease

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ABSTRACT

Introduction and objectives: There is limited data on territorial longitudinal strain (TLS) as an echocardiographic marker in stable coronary artery disease (CAD). We evaluated the predictive role of TLS in stable CAD for identifying the location and severity of significant coronary artery stenosis.
Methods: We included patients presenting with chest pain, whereas those with myocardial infarction, arrhythmia, normal coronary angiography, previous percutaneous coronary intervention or coronary artery bypass grafting, and inadequate echocardiographic window were excluded. Among the 738 patients enrolled, a total of 199 study participants with stable CAD were selected and underwent speckle tracking echocardiography.
Results: Regional longitudinal strain (RLS) identified significant stenosis in at least 1 of the coronary arteries with sensitivity and specificity rates of 89.4% and 87.8%, respectively, and an area under curve (AUC) of 0.947 ($P < .001$). Receiver operating characteristic curve comparison demonstrated RLS had the highest predictive value for identifying significant stenosis with an optimal cutoff of ≥ −16% compared with regional radial strain (RRS) (AUC difference, 0.149; 95%CI, 0.132-0.167; $P \leq .0001$), regional wall motion abnormality (RWMA) (AUC difference, 0.277; 95%CI, 0.262-0.293; $P \leq .0001$), and regional circumferential strain (RCS) (AUC difference, 0.348; 95%CI, 0.327-0.368; $P \leq .0001$).
TLS predicted significant proximal left anterior descending coronary artery stenosis when ≥ 4 of 7 territorial segments were impaired, significant proximal left circumflex artery stenosis when ≥ 3 of 5 territorial segments were impaired, and significant proximal right coronary artery stenosis when ≥ 3 of 5 territorial segments were impaired.
Conclusions: TLS predicted the location and severity of significant coronary artery stenosis in patients with stable CAD.
[Trial registration No. Md 110/2021].

Keywords: Coronary artery disease. Echocardiography. Ventricular dysfunction. Global longitudinal strain.

Deformación longitudinal territorial para predecir la ubicación y el grado de estenosis significativa en la enfermedad coronaria estable

RESUMEN

Introducción y objetivos: Existen pocos datos sobre la deformación longitudinal territorial (DLT) como marcador ecocardiográfico en la enfermedad arterial coronaria (EAC) estable. El objetivo fue evaluar el valor predictivo de la DLT en la EAC estable para identificar la localización y el grado de estenosis coronaria significativa.
Métodos: Se incluyó a pacientes con dolor torácico y se excluyó a aquellos con infarto de miocardio, arritmia, angiografía coronaria normal, intervención coronaria percutánea o cirugía de revascularización aortocoronaria previas, o ventana ecocardiográfica deficiente. De los 738 pacientes incluidos se seleccionó a 199 con EAC estable, a los que se realizó una ecocardiografía con rastreo de marcas.
Resultados: La deformación longitudinal regional (DLR) identificó estenosis significativa en al menos 1 de las arterias coronarias, con una sensibilidad del 89,4%, una especificidad del 87,8% y un área bajo la curva (AUC) de 0,947 ($p < 0,001$). La comparación de las curvas ROC mostró que la DLR tenía el mejor valor predictivo para identificar estenosis significativa con un punto de corte ≥ −16% en comparación con la deformación radial regional (DRR) (la diferencia entre las AUC de la DLR y la DRR es 0,149;

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IC95%, 0,132-0,167; p ≤ 0,0001), la alteración de la contractilidad segmentaria (ACS) (la diferencia entre las AUC de la DLR y la ACS es de 0,277; IC95%, 0,262-0,293; p ≤ 0,0001) y la deformación circunferencial regional (la diferencia entre las AUC de la DLR y de la deformación circunferencial regional es de 0,348; IC95%, 0,327-0,368; p ≤ 0,0001). La DLT predijo una estenosis significativa de la arteria descendente anterior izquierda proximal si al menos 4 de los 7 segmentos territoriales estaban afectados, una estenosis significativa de la arteria circunfleja izquierda proximal si al menos 3 de los 5 segmentos territoriales estaban afectados, y una estenosis significativa de la arteria coronaria derecha proximal si al menos 3 de los 5 segmentos territoriales estaban afectados. ***Conclusiones:*** La DLT predijo la ubicación y el grado de estenosis coronaria significativa en pacientes con EAC estable. [Número de registro del estudio: Md 110/2021].

Palabras clave: Enfermedad arterial coronaria. Ecocardiografía. Disfunción ventricular. Deformación longitudinal global.

Abbreviations

CAD: coronary artery disease. **GCS:** global circumferential strain. **GLS:** global longitudinal strain. **RLS:** regional longitudinal strain. **RRS:** regional radial strain. **RWMA:** regional wall motion abnormality.

INTRODUCTION

Coronary artery disease (CAD) is a significant national and global public health concern. In 2021, more than 254 million cases of CAD were diagnosed worldwide, with an incidence rate of 403.89 new cases per 100,000 people and a mortality rate of 113.94 deaths per 100,000. In Egypt, CAD is the most prevalent cardiovascular disease among men and women, with an overall prevalence of 4.27%.[1] Key risk factors for CAD include smoking, gender, diabetes, hypertension, and dyslipidemia, with men experiencing a 2-fold higher rate than women.[2] Computed tomography is the standard diagnostic imaging modality for stable CAD, while high sensitivity C-reactive protein is recommended for predicting stable CAD. Although regional wall motion abnormality (RWMA) is the gold standard echocardiographic marker for stable CAD, it is not effective in detecting subclinical myocardial damage.[3]

Two-dimensional (2D) speckle tracking echocardiography (STE) strain analysis measures myocardial deformation providing a more reliable evaluation of myocardial mechanics and addressing the limitation of RWMA in identifying subtle myocardial damage.[4] Real-world evidence suggests that global (GLS) and regional longitudinal strain (RLS) offer better diagnostic accuracy and reproducibility in detecting stable CAD.[5-7] GLS assesses ventricular shortening from base to apex to estimate overall strain in the left ventricle (LV), whereas RLS focuses on strain in specific LV segments. Other strain analysis methods include global radial strain (GRS), global circumferential strain (GCS), territorial longitudinal strain (TLS), regional radial strain (RRS), and regional circumferential strain (RCS), each measuring different aspects of myocardial strain.[8] Our study aimed to evaluate the predictive role of TLS in stable CAD for identifying significant coronary artery lesions with ≥ 70% diameter stenosis.

METHODS

Study design

We conducted a 24-month cross-sectional, open-label, single-cohort, single-center study was at the cath lab of a tertiary care teaching hospital. Investigators were not blinded to the study group. Prior to conducting the study, its design and protocol were reviewed, approved, and registered with Ain Shams University Hospital Human Ethics Committee on 1 July 2021 under trial registration No. Md 110/2021.

Written informed consents was obtained from all human research subjects and study participants. Participant privacy rights were strictly protected, data were anonymized, and study procedures were conducted in accordance with the Egyptian National Commission for Bioethics statement on ethical conduct in human research. Furthermore, the study adhered to the SAGER guidelines to address potential sex- and gender-related bias.

Study participants

Patients with typical or atypical anginal chest pain evaluated at the outpatient clinic and cath lab of a single tertiary care center between August 2021 and August 2023 were included in the study. Patients with acute coronary syndrome, myocardial infarction, non-sinus rhythm, normal coronary angiography (CAG), prior percutaneous coronary intervention or coronary artery bypass grafting, inadequate echocardiographic window, or valvular or myocardial disease were excluded.

Study procedures

A total of 738 patients were enrolled and undewent history taking and data collection for gender, age, diabetes mellitus, hypertension, smoking, dyslipidemia, chronic kidney disease, peripheral arterial disease, stroke, sedentary lifestyle, myocardial infarction, and family history of CAD. Furthermore, patients undewent blood pressure measurements and comprehensive cardiac examination, including assessment for abnormal auscultatory findings, prior cardiac surgery, cardiomegaly, and heart failure. Moreover, all patients underwent 12-lead electrocardiogram, 2D echocardiography and 2D STE using an IE 33 ultrasound system (Philips, The Netherlands) with an X5-1 phased-array transducer; CAG with digital image acquisition and storage, complete blood count; lipid profile; liver and kidney function tests; coagulation studies (prothrombin time, activated partial thromboplastin time, and international normalized ratio); and serial cardiac enzyme measurements. The 2D echocardiography was conducted before the CAG and the 2D STE after the CAG. The cardiologists performing 2D echocardiography and 2D STE were specialized in

echocardiography, held level III competency according to the European Society of Cardiology Core Curriculum, and were blinded to the coronary angiographic data.[9] Furthermore, the interventional cardiologists, who analyzed the CAGs were blinded to the results of the echocardiographic evaluation. Data documented with CAG included the severity of coronary artery stenosis according to the Coronary Artery Disease-Reporting and Data System and the regional distribution of the area supplied with the epicardial coronary artery according to the 17 LV segment model. A coronary lesion of ≥ 70% diameter stenosis was considered significant, and such patients were classified as having severe stable CAD.[10] A consecutive sample of 199 eligible participants with severe stable CAD was selected, assigned, and allocated to a single group (figure 1). Operators performing 2D echocardiography and 2D STE were blinded to the coronary angiographic data. Data documented with 2D echocardiography and 2D STE included RWMA, wall motion score index (WMSI), and strain analysis. RWMA was categorized into normal with an assigned score of 1, hypokinetic with an assigned score of 2, akinetic with an assigned score of 3, and dyskinetic with an assigned score of 4. The WMSI represents the average RWMA of the 17 analyzed segments in a 17 LV segment model.[11] Myocardial function by strain imaging was evaluated on a frame-by-frame basis by automatic tracking of acoustic markers (speckles) throughout the cardiac cycle in a 17 LV segment model, and GLS was obtained by averaging the myocardial function of all 17 segments. The endocardial borders were traced in the end-systolic frame of the 2D images from the 3 apical views for analyses of longitudinal strains. RCS analysis was obtained from the 3 parasternal short-axis views. RRS analysis from the 3 apical views was conducted manually by tracking the average peak systolic radial excursion for each segment between 2 points (endocardial and epicardial) of 3 levels for each of the 17 segments. Peak systolic strains were obtained for 17 longitudinal, 17 radial, and 16 circumferential LV segments. All segmental values were averaged to GLS and GCS for each study participant and automatically displayed in a bull's-eye plot. TLS measured the number of impaired territories based on the cutoff results of the RLS analysis from the segments supplied with the corresponding coronary arteries in a 17 segment LV model as follows: 7 segments for the left anterior descending coronary artery (LAD), 5 for the right coronary artery (RCA), and 5 for the left circumflex artery (LCx).[12]

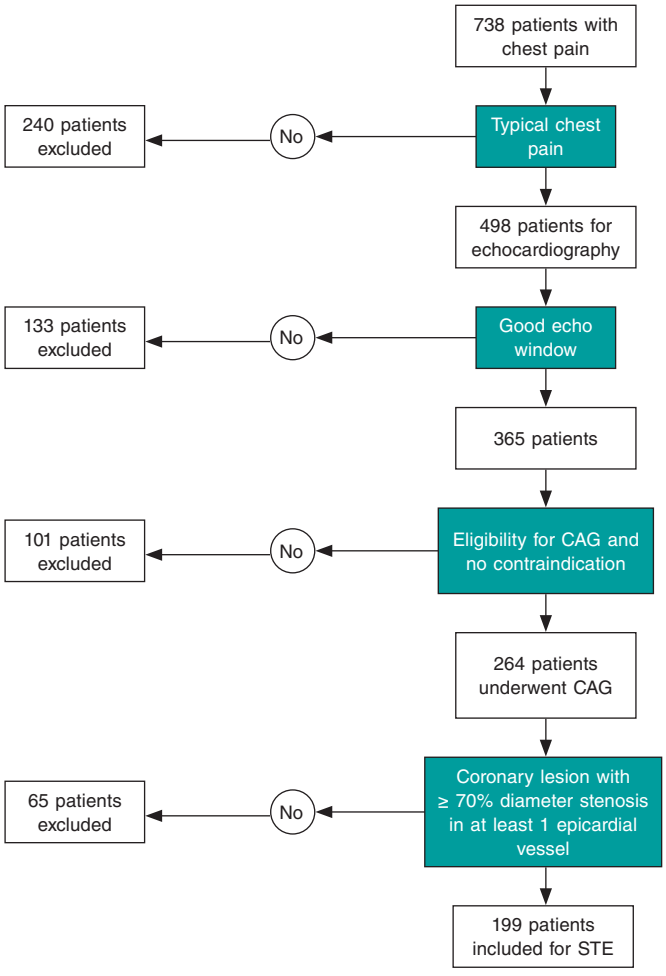


Figure 1. Flow chart of stable coronary artery disease cohort selection. CAG, coronary angiography; STE, speckle tracking echocardiography.

Endpoints

The endpoint of the study was the predictive role of TLS in stable CAD for identifying the location and severity of significant coronary artery lesion with ≥ 70% diameter stenosis.

Statistical analysis

Our study was a cross-sectional, open-label, single cohort, single center study. The echocardiographic assessment outcomes were coded, and data were analyzed with the SPSS v29 software package (IBM, United States). Shapiro-Wilks test was used to assess normality of data. Qualitative data was expressed as frequencies (number of cases) and relative frequencies (percentages), and quantitative data as means, standard deviations, medians, and interquartile ranges. Comparisons of parametrically distributed quantitative variables were performed using the Student *t* test or analysis of variance (ANOVA), whereas nonparametrically distributed quantitative variables were compared using the Mann-Whitney test, and between qualitative variables using the chi-square test or Fishers exact test, as appropriate.[13,14] Inter- and intra-observer variability was assessed by reanalyzing the data of 18 randomly selected study participants and reported as intraclass correlation coefficient (ICC), whose scale ranges from 0 to 1 where 1 represents perfect reliability with no measurement error and 0, no reliability. An ICC value < 0.5 indicates poor reliability; 0.5-0.75, moderate reliability; 0.75-0.9, good reliability; and > 0.90, excellent reliability.[15] The area under the curve (AUC) was constructed to detect the cutoff for optimal sensitivity and specificity of regional strains. Receiver operating characteristic (ROC) curve comparison was performed using MedCalc version 10.3.1.0 (MedCalc Software, United States). Confidence interval was set to 95% and the accepted margin of error at 5%. 01. A *P* value < .05 was considered statistically significant, and a *P* value < .01 was considered highly significant. Final analyses were conducted according to the per-protocol approach.

RESULTS

Baseline characteristics and sociodemographic features

The baseline characteristics and sociodemographic features of the study cohort are shown in table 1. Male predominance was the pivotal sociodemographic characteristic of the enrolled participants (56.5%), and the mean age was 60.4 ± 9.9 years. Baseline risk factors and comorbidities of the study cohort included hypertension in 68.5%, diabetes mellitus in 70%, dyslipidemia in 66%, and smoking in 47%, respectively. There were no withdrawals, and all participants completed the study.

Table 1. Baseline characteristics and sociodemographic features of stable coronary artery disease cohort

Variable	Stable coronary artery disease cohort (No. = 199)	
	Mean ± SD	Range
Age, (years)	60.4 ± 9.9	38-81
Left ventricular ejection fraction	53.9 ± 6.5	40-66
Hypertension	137	68.5
Diabetes mellitus	140	70
Dyslipidemia	132	66
Current smoker	94	47
Gender		
Male	112 (56.6)	–
Female	87 (43.5)	–

Unless otherwise indicated, data are expressed as number (No.) and percentage (%) or mean ± standard deviation (SD).

Table 2. Coronary angiographic characteristics of stable coronary artery disease cohort

Variable	Stable coronary artery disease cohort (No. = 199)					
Site of significant coronary lesions with ≥ 70% diameter stenosis (No., %)	Single-vessel disease		2-vessel disease		3-vessel disease	
	No.	%	No.	%	No.	%
	135	68	45	23	19	10
Level of significant coronary lesions with ≥ 70% diameter stenosis (No., %)	LAD		LCX		RCA	
	No.	%	No.	%	No.	%
Proximal	74	61	40	63	51	52
Mid	42	35	0	0	16	16
Distal	5	4	23	37	31	32
Total	121	100	63	100	98	100

LAD, left anterior descending coronary artery; LCx, left circumflex artery; RCA, right coronary artery.

Coronary angiographic characteristics of stable coronary artery disease cohort

The location and severity of significant coronary lesions with ≥ 70% diameter stenosis is shown in table 2. Most study participants had single-vessel disease (68%). Among significant lesions, 63 (22%) were located in the LCx, 121 (43%) in the LAD, and 98 (35%) in the RCA.

Strain analysis of stable coronary artery disease cohort

The global strain analysis showed a GLS range of –26% to –8%, with a mean value of –16.4 ± 3.6%, and a GCS range of –35% to –10%, with a mean value of –18.4 ± 4.9%. The regional strain analysis (RSA) of 3383 segments showed RWMA in 3378 segments (99.8%), a mean WMSI of 1.3 ± 0.2 with sensitivity and specificity rates of 88% and 61%, respectively, GLS in 3365 segments (99.5%), GCS in 3184 segments (100%), global radial strain in 3352 segments (99%), significant hypoperfusion (coronary lesions with ≥ 70% diameter stenosis) in 1472 segments (43%), and normal perfusion to mild-to-moderate hypoperfusion (coronary lesions with < 70% diameter stenosis) in 1911 segments (57%). The medians and the interquartile ranges of the regional strain parameters for coronary lesions with ≥ 70% diameter stenosis demonstrated significant differences vs the corresponding parameters for coronary lesions with < 70% diameter stenosis. The median RLS was –20% (IQR, –23% to –17%) for lesions < 70% diameter stenosis vs –12% (IQR, –14% to –9%) for lesions ≥ 70% diameter stenosis (P < .001). The median RRS was 40% (IQR, 38%-43%) for lesions < 70% diameter stenosis vs 33% (IQR, 21%-39%) for lesions ≥ 70% diameter stenosis (P < .001) (figure 2). The median RCS was –19% (IQR, –24% to –14%) for lesions < 70% diameter stenosis vs –17% (IQR, –22% to –12%) for lesions ≥ 70% diameter stenosis (P < .001). RWMA were detected in 38% of the segments supplied by significant coronary lesions with ≥ 70% diameter stenosis compared with 6% of the segments supplied by non-significant coronary lesions with < 70% diameter stenosis (P < .001).

Feasibility and reproducibility of stable coronary artery disease cohort

The ICC for inter- and intra-observer variability of segmental strains were measured in 21 of the 199 patients study cohort (11%). The results of the ICC for inter- and intra-observer variability of segmental strains were 0.91 and 0.96 for GLS, 0.94 and 0.97 for GCS, and 0.86 and 0.92 for GRS.

ROC curve and area under the curve analysis in patients with stable coronary artery disease

AUC was constructed to detect the cutoff for optimal sensitivity and specificity of regional strains (table 3). The AUC for RLS was 0.947 (P < .001) which detected a cutoff of ≥ –16% for optimal sensitivity and specificity of RLS. ROC curve comparison showed that RLS exhibited the highest predictive value for identifying significantly hypoperfused segments (with ≥ 70% diameter stenosis) at a cutoff of ≥ –16% vs the RRS (AUC difference, 0.149; 95%CI, 0.132-0.167; P ≤ .0001), RWMA (AUC difference, 0.277; 95%CI, 0.262-0.293; P ≤ .0001), and RCS (AUC difference, 0.348; 95%CI, 0.327-0.368; P ≤ .0001), respectively (figure 3).

ROC curve analysis of regional longitudinal strain in patients with stable coronary artery disease

Guided by the detected cutoff of ≥ –16% for the optimal sensitivity and specificity of RLS, the predictive role of TLS in stable CAD for identifying the location and severity of significant coronary artery lesions with ≥ 70% diameter stenosis was explored (table 4). The ROC curve analysis of the RLS at a cutoff of ≥ –16% demonstrated that the optimal number of impaired segments that could predict the location and severity of significant coronary lesions with ≥ 70% diameter stenosis was ≥ 3 impaired segments out of the 7 territorial segments of LAD to predict proximal or significant lesion in the mid-LAD and ≥ 3 impaired segments among the 5 territorial segments of either the LCx or RCA to predict proximal significant lesion in the LCx or RCA (figure 4).

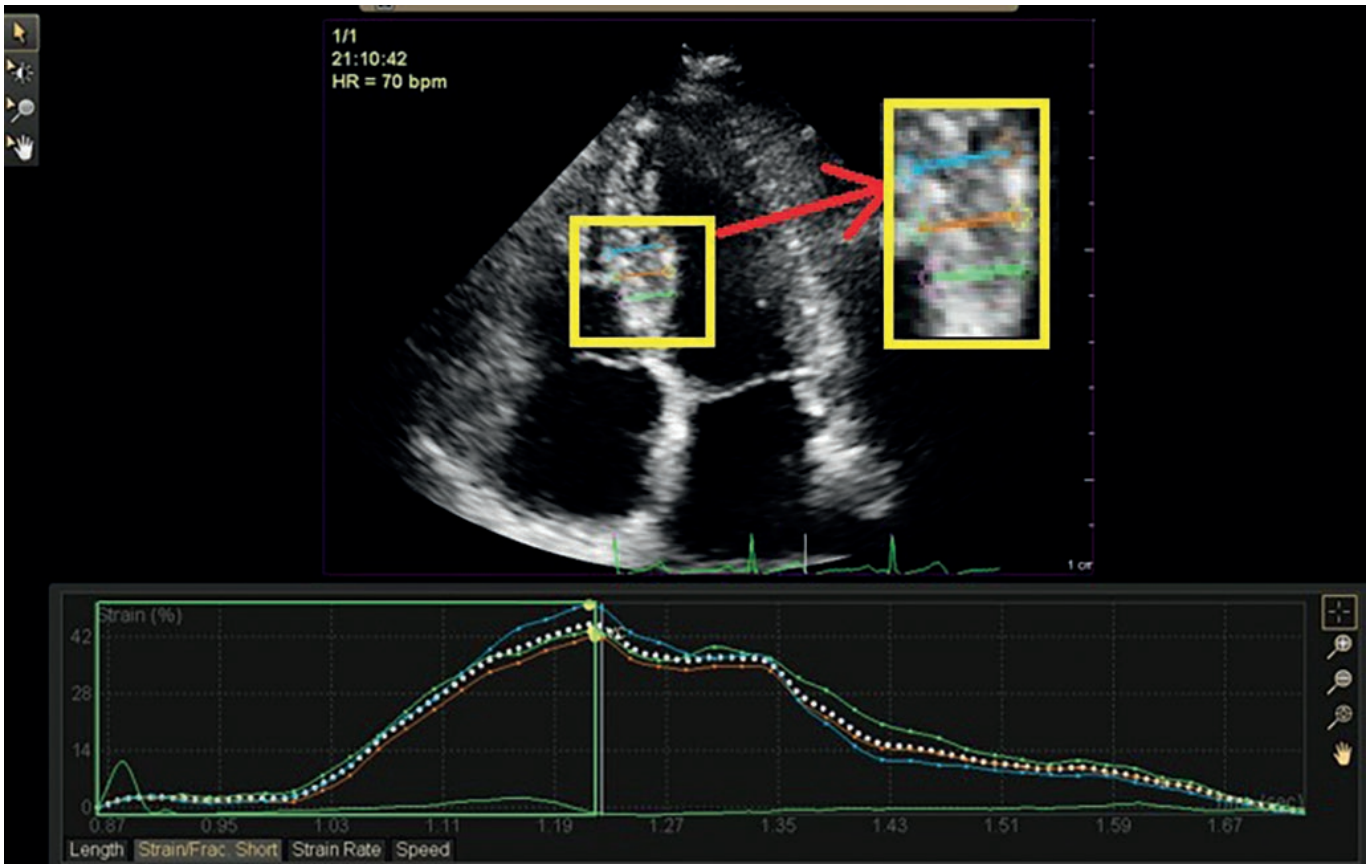


Figure 2. Regional radial strain analysis of a study participant with stable coronary artery disease showing 42% strain of the mid inferoseptal segment.

Table 3. Area under curve for detection of cutoff for optimal sensitivity and specificity of the regional strains

Variable	Cutoff	AUC	95%CI	Sensitivity (%)	Specificity (%)	*P*-value
RLS	≥ –16	0.947	0.938-0.953	89.4	87.8	< .001*
RCS	≥ –19	0.599	0.582-0.617	60.7	54.4	< .001*
RRS	≤ 35	0.8	0.786-0.813	57.8	92.3	< .001*

Data is presented as percentages.
95%CI, 95% confidence interval; AUC, area under the curve; RCS, regional circumferential strain; RLS, regional longitudinal strain; RRS, regional radial strain.
*Statistically significant *P* value.

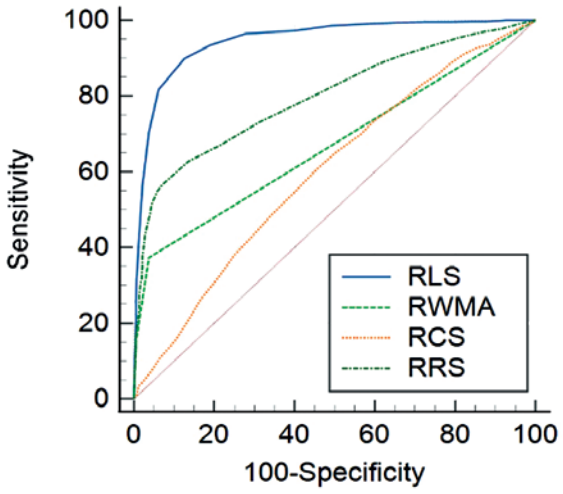


Figure 3. Receiving operating characteristic curve comparison of stable coronary artery disease cohort comparing regional longitudinal strain, regional radial strain, regional circumferential strain, and regional wall motion abnormalities in predicting significant ≥ 70% diameter stenosis. RCS, regional circumferential strain; RLS, regional longitudinal strain; RRS, regional radial strain; RWMA, regional wall motion abnormality.

DISCUSSION

Despite being the gold standard echocardiographic marker for stable CAD, RWMA is ineffective at detecting subclinical myocardial damage.[3] Our study aimed to evaluate the predictive capability of TLS in identifying the location and severity of significant coronary lesions with ≥ 70% diameter stenosis.

Participants in our study had a mean age of 60.4 ± 9.9 years (range, 38-81 years), with 112 men (56.5%). Most participants had single-vessel disease (68%); 45 (23%), 2-vessel disease; and 19 (10%), 3-vessel disease. Significant coronary lesions with ≥ 70% diameter stenosis were located in the LCx, LAD, and RCA in 63 (22%), 121 (43%), and 98 cases (35%), respectively. Similarly, Koulaouzidis et al. found that 57% of their participants had single-vessel disease with ≥ 50% diameter stenosis.[16] Observational studies suggest that most single-vessel coronary occlusions occur in the proximal LAD.[17,18]

Table 4. Receiving operating characteristic curve analysis of regional longitudinal strain

Vessel	Level	No.	AUC	Sensitivity (%)	Specificity (%)	95%CI	*P*-value
LAD (7 segments)	Proximal	≥ 4	0.952	93.20	83.30	0.913-0.977	< .001*
	Mid	≥ 3	0.911	92.20	73.80	0.862-0.946	< .001*
	Distal	≥ 2	0.902	95.80	68.30	0.852-0.939	< .001*
LCx (5 segments)	Proximal	≥ 3	0.897	87.50	85	0.846-0.935	< .001*
	Distal	≥ 2	0.87	92	70.80	0.815-0.913	< .001*
RCA (5 segments)	Proximal	≥ 3	0.928	88.20	83.90	0.883-0.960	< .001*
	Mid	≥ 3	0.942	88	92.50	0.9-0.970	< .001*
	Distal	≥ 2	0.932	91.80	80.40	0.888-0.963	< .001*

Receiving operating characteristic curve analysis of regional longitudinal strain in stable coronary artery disease to explore the role of territorial longitudinal strain in predicting the site and level of significant ≥ 70% diameter stenosis. 95%CI, 95% confidence interval; AUC, area under the curve; LAD, left anterior descending coronary artery; LCx, left circumflex artery; RCA, right coronary artery.
* Statistically significant *P* value.

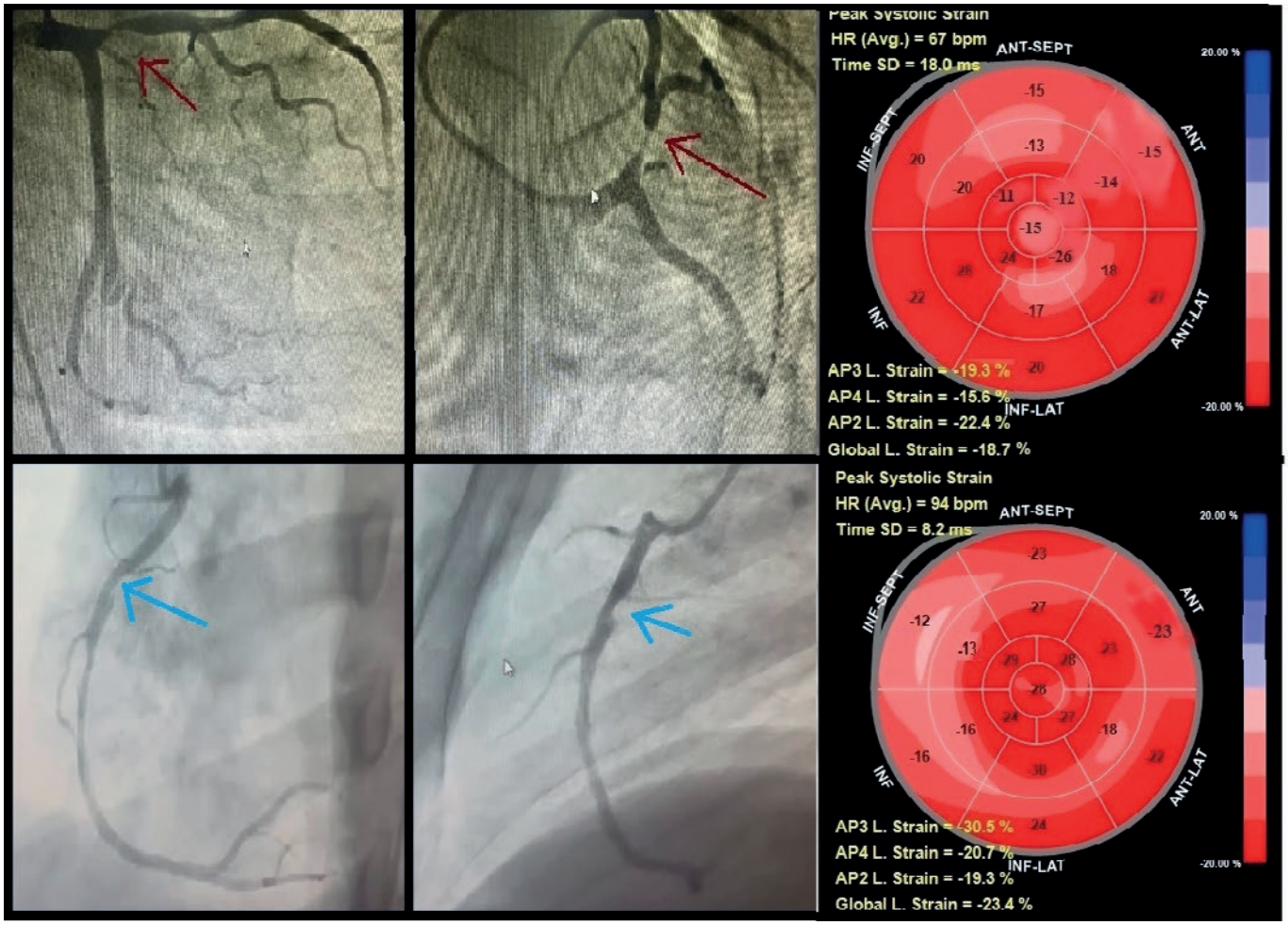


Figure 4. Territorial longitudinal strain of study participants with stable coronary artery disease. Top row: representative study participant with significant proximal left anterior descending coronary artery lesion (≥ 70% diameter stenosis; red arrow). Global longitudinal (L) strain was –18.7%. Seven segments within the left anterior descending coronary artery territory (anteroseptal, anterior regions, and apex) demonstrated impaired strain (≥ –16%), consistent with a true-positive finding, whereas left circumflex and right coronary artery territories showed preserved strain (< –16%), consistent with true-negative findings. Bottom row: representative of a study participant with a significant proximal right coronary artery lesion (≥ 70% diameter stenosis; blue arrow). Global longitudinal strain was –23.3%. Four segments within the right coronary artery territory (mid, basal inferior, and inferoseptal) demonstrated impaired strain (≥ –16%), consistent with a true-positive finding, whereas left anterior descending artery and left circumflex artery territories showed preserved strain (< –16%), consistent with true-negative findings.

In our cross-sectional study, GLS ranged from −26% to −8%, averaging −16.4 ± 3.6%, while RLS for lesions < 70% diameter stenosis was −20% (IQR, −23% to −17%) vs −12% (IQR, −14% to −9%) for lesions ≥ 70% diameter stenosis (P < .001). Norum et al. concluded that a GLS cutoff of −17.4% to −20.3% could predict CAD in patients with chest pain, with sensitivity rates between 51% and 81% and specificity rates between 58% and 81%.[19] There is limited real-world data on RSA in stable CAD. Montgomery et al. found that summed LAD segmental strain demonstrated a sensitivity and specificity of 66% at a cutoff of −20.3% for predicting LAD lesions ≥ 50% diameter stenosis.[20] Shimoni et al. demonstrated that segmental analysis using the least 10-percentile peak systolic strain (PSS) outperformed global PSS and GLS.[21] Biering-Sørensen et al. observed that significant left main stenosis (≥ 70%) affected apical longitudinal strain (ALS) more than significant lesions did in the LAD or LCx, despite similar GLS results.[22] Carstensen et al. studied asymptomatic CAD in patients with aortic stenosis using an 18-segment LV model, finding that only ALS and mid-longitudinal strain were significant independent predictors of asymptomatic CAD, which is consistent with other studies indicating that proximal lesions impact all defined regions.[23-25] Liu et al. showed that a cutoff of ≥ −23.5% for endocardial RLS and GLS of the LAD was higher in identifying significant LAD stenosis (≥ 50%) vs strain values from other layers.[26]

Our findings indicate that at a cutoff of ≥ −16%, TLS can predict the location and severity of significant coronary lesions with ≥ 70% diameter stenosis. Specifically, impairment of ≥ 3 of 7 in the LAD predicted significant proximal or mid lesions, whereas impairment of ≥ 3 of 5 segments in either the LCx or RCA predicted significant proximal lesions. TLS has not been extensively studied in stable CAD. Eek et al. found that at a cutoff of ≥ −14%, impaired blood supply in ≥ 4 segments predicted acute coronary occlusion with improved sensitivity (85%) and specificity (70%) vs the left ventricular ejection fraction.[12] Sarvari et al. noted that although TLS, GLS, and GCS were affected in patients with non-ST-segment elevation myocardial infarction, the differences between GLS and TLS were not statistically significant.[24] Caspar et al. demonstrated that TLS has high predictive value for significant lesions with ≥ 50% diameter stenosis across the 3 major coronary territories.[25]

The takeaway from our study is that TLS enhances the diagnostic capacity of RLS, accurately predicting both the location and severity of significant coronary lesions with ≥ 70% diameter stenosis. While several non-invasive methods show acceptable sensitivity and specificity,[27] they usually face limitations regarding availability and cost. Echocardiography is widely accessible, and strain analysis can be performed offline, making it beneficial for patients with chest pain, allowing for assessment prior to invasive procedures or costly imaging modalities. Further studies are needed to clarify the diagnostic and prognostic significance of TLS in patients with chest pain.

Strengths and limitations

Our study was conducted on a well-balanced cohort with regards to the risk factors and baseline characteristics and did not have missing data allowing robust per protocol analysis, the interventional cardiologists who analyzed the CAGs were blinded to the results of the echocardiographic evaluation, whereas the investigators who performed the 2D echocardiography and the 2D STE were blinded to the coronary angiographic data, hence observer bias was minimized. Despite its strengths, the limitations of the study require consideration. It was a single centre cross-sectional study which didn't allow us to investigate the chronological relationship between the echocardiographic and the coronary angiographic data in stable patients with CAD. There was no invasive functional assessment of the coronary blood flow with fractional flow reserve, RRS was assessed manually, and 36 study participants (18%) with impaired myocardial function (left ventricular ejection fraction ≤ 50%) were selected for the study. Patients with stable CAD patients and coronary microvascular disease (microvascular angina) and normal CAG and patients with stable CAD and abnormal CAG with coronary lesions with < 70% diameter stenosis were excluded from the study cohort overestimating the RLS of the study cohort. Inclusion of patints with stable CAD and abnormal CAG with coronary lesions with ≥ 70% diameter stenosis could only limit the generalizability of the study results to the population with stable CAD. Ultimately, ROC curve analysis of RLS in stable CAD, used to explore the role of TLS in predicting the location and severity of significant ≥ 70% diameter stenosis relied on clinically limited metrics, namely sensitivity and specificity. As a result, the high RLS performance estimate (0.947) may be biased, and the cutoff of ≥ −16% potentially misleading. Consequently, WMSI was not included in the analyss, and no incremental diagnostic value for RLS over WMSI could be established.

CONCLUSIONS

RLS indicated potential clinical relevance in the diagnosis of stable CAD and TLS demonstrated a significant ability to predict the site and level of significant coronary lesion with ≥ 70% diameter stenosis in patients with stable CAD.

DATA AVAILABILITY

Data are available from the corresponding author upon request.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

The study design and protocol were approved by the human ethics committee of the Ain Shams University Hospital before study initiation on 1 July, 2021. The study was registered and assigned trial registration No. Md 110 / 2021. Written informed consent was obtained from all human research subjects and study participants, including consent for publication. Participant privacy was strictly protected, and all data were anonymized, informed consents were signed by study participants for publication, and the study procedures were conducted in full compliance with the Egyptian National Commission for Bioethics statement on ethical conduct in human research, and SAGER guidelines have been followed with respect to possible sex/gender bias.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

The authors declare that they have not used any type of generative artificial intelligence for the drafting of this manuscript, nor for the creation of images, graphics, tables, or their corresponding captions.

AUTHORS' CONTRIBUTIONS

The study was designed by A. Rezq and H. Shaalan, the data was collected, analyzed, and interpreted by M.A. Hashem and A.E. Nayel, the manuscript was drafted by M.A. Hashem and critically reviewed by A. Rezq, A.K. Araquib, A.E. Nayel, and H. Shaalan,

and A. Rezq, A.E. Nayel, A.K. Araquib, and H. Shaalan approved the final manuscript. The authors take full responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

CONFLICTS OF INTEREST

None declared.

WHAT IS KNOWN ABOUT THE TOPIC?

- CAD is the most prevalent cardiovascular condition among Egyptian men and women, with an overall prevalence of 4.27%. Computed tomography is the standard diagnostic imaging modality for stable CAD, while high sensitivity C-reactive protein is the recommended test for predicting stable CAD.
- Although RWMA is the gold standard echocardiographic marker for stable CAD, it is not effective in detecting subclinical myocardial damage.
- Real-world evidence shows that myocardial strain analysis methods with 2D STE, including RLS, GLS, GCS, TLS, and RRS, offer better diagnostic accuracy and reproducibility in detecting stable CAD, provide a more reliable evaluation of myocardial mechanics in stable CAD, and address the limitation of RWMA in identifying subtle myocardial damage.

WHAT DOES THIS STUDY ADD?

- Our study showed that, at a cutoff of ≥ –16%, RLS is the optimal imaging biomarker for predicting significant ≥ 70% diameter stenosis in stable CAD.
- Our study showed that TLS is a promising imaging biomarker for predicting the site and level of significant ≥ 70% diameter stenosis in stable CAD.

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Original article

Outcomes of left ventricular pacing with a pre-shaped guidewire during transcatheter aortic valve implantation

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ABSTRACT

Introduction and objectives: Rapid ventricular pacing is essential to ensure accurate valve deployment during transcatheter aortic valve implantation (TAVI). Although it is traditionally performed via right ventricular (RV) pacing using a temporary pacemaker, left ventricular (LV) pacing with pre-shaped guidewires has emerged as an effective alternative, associated with shorter procedural and fluoroscopy times. There are no data available on the use of the Abbott Circulo guidewire. The aim of this study was to evaluate its safety and efficacy profile for LV pacing during TAVI.
Methods: This was a prospective, multicenter, observational study with patients undergoing transfemoral TAVI with LV pacing using the Circulo guidewire. The primary endpoint was pacing efficacy, defined as a reduction in systolic blood pressure < 60 mmHg. Secondary endpoints included the pacing threshold, crossover to RV pacing, and perioperative complications.
Results: A total of 50 patients were enrolled from March through June 2025 (mean age, 80.56 ± 6.26 years; 62% women). Rapid LV pacing was successful in 100% of cases, with a mean pacing threshold of 7.00 ± 3.48 mV. A total of 3 patients required crossover to RV pacing due to atrioventricular block after balloon predilatation. The overall rate of complications was 14%, with rhythm disturbances being the most common adverse events. There were no complications associated with the use of the Circulo guidewire.
Conclusions: LV pacing using the Circulo guidewire during TAVI is safe and effective, and avoids the routine use of temporary transvenous pacemakers.

Keywords: Transcatheter aortic valve implantation. Left ventricular pacing. Pre-shaped guidewire. Rapid pacing. Pacemaker. Structural heart procedure.

Rendimiento de la estimulación ventricular izquierda con guía preformada durante el implante percutáneo de válvula aórtica

RESUMEN

Introducción y objetivos: La estimulación ventricular rápida es esencial para la correcta colocación de la prótesis durante el implante percutáneo de válvula aórtica (TAVI). Aunque clásicamente se realiza mediante estimulación del ventrículo derecho (VD) con marcapasos transitorio, la estimulación del ventrículo izquierdo (VI) con guías preformadas es una alternativa eficaz, asociada a menor tiempo de procedimiento y de fluoroscopia. No existen estudios publicados sobre el uso de la guía Circulo de Abbott. El objetivo fue evaluar su eficacia y seguridad para la estimulación del VI durante el TAVI.
Métodos: Estudio observacional, prospectivo y multicéntrico que incluyó pacientes sometidos a TAVI transfemoral con estimulación del VI mediante la guía Circulo. El objetivo primario fue la eficacia de la estimulación, definida como una reducción de la presión

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arterial sistólica por debajo de 60 mmHg. Los objetivos secundarios incluyeron el umbral de estimulación, la conversión a estimulación del VD y las complicaciones periprocedimiento.
Resultados: Entre marzo y junio de 2025 se incluyó a 50 pacientes (edad media 80,56 ± 6,26 años; 62% mujeres). La estimulación rápida del VI fue efectiva en el 100% de los casos, con un umbral medio de 7,00 ± 3,48 mV. Un total de 3 pacientes requirieron estimulación del VD por bloqueo auriculoventricular tras la predilatación con balón. La tasa global de complicaciones fue del 14%, principalmente trastornos de la conducción, sin complicaciones atribuibles a la guía Circulo.
Conclusiones: La estimulación del VI con la guía Circulo durante el TAVI es eficaz y segura, y evita el implante sistemático de un marcapasos transitorio.

Palabras clave: Implante percutáneo de válvula aórtica. Estimulación ventricular izquierda. Guía preformada. Estimulación rápida. Marcapasos. Intervención estructural cardiaca.

Abbreviations

AVB: atrioventricular block. **LV:** left ventricle. **RV:** right ventricle. **TAVI:** transcatheter aortic valve implantation.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is one of the treatments that has been shown to improve prognosis and reduce mortality in patients with symptomatic severe aortic stenosis.[1] Currently, according to the clinical practice guidelines outlined by the European Society of Cardiology (ESC),[2] TAVI is the treatment of choice in patients aged ≥ 70 years, while the American Heart Association and the American College of Cardiology (AHA/ACC) clinical practice guidelines indicate that it may be considered from the age of 65 years.[3,4].

Although TAVI is considered a safe procedure, complications may occur;[5] however, their incidence has declined over the years owing, among other factors, to advances in preoperative cardiac imaging, the development of improved models of transcatheter heart valves and delivery sheaths, and the increasing experience of the teams performing the procedure.[6] However, not all complications are directly associated with valve implantation, and some are due to auxiliary devices used perioperatively. One example is the temporary transvenous pacemaker traditionally used for rapid right ventricular (RV) pacing, which requires an additional puncture (generally in the femoral, jugular, subclavian, or brachial vein) and the insertion of a catheter into the RV.

A meta-analysis published in 2019 reported that, even today, despite the availability of imaging modalities that facilitate implantation, transvenous temporary pacing remains associated with complications in 22.9% of patients.[7] Many of these complications could be avoided by performing left ventricular (LV) pacing using the pre-shaped guidewire during TAVI, which eliminates the need for any additional vascular accesses or specific devices.[8] In 2019, the randomized clinical trial EASY TAVI compared both techniques showing a similar safety and efficacy profile, resulting in lower costs and shorter procedural and fluoroscopy times with LV pacing.[9] Although the utility of the SAFARI 2 (Boston Scientific, United States), Confida (Medtronic, United States), Lunderquist (Cook Medical Inc., United States), Amplatz Extra-Stiff (Cook Medical Inc.), Amplatz Super Stiff (Boston Scientific), and SavvyWire (OpSens Inc., Canada) guidewires has already been demonstrated[10,11], there are no studies on the Circulo guidewire (Abbott, United States).[12]

The aim of this study was to evaluate the performance of the pre-shaped Circulo guidewire for LV pacing during TAVI (figure 1A).

METHODS

We conducted an observational, prospective, multicenter study. The primary endpoint was to demonstrate the efficacy of rapid LV pacing, defined as a decrease in systemic systolic pressure < 60 mmHg. Secondary endpoints included pacing threshold, the need for conversion to RV pacing, and safety.

The Circulo guidewire

Circulo is a 275-cm–long polytetrafluoroethylene–coated guidewire. It features a double curve at its distal end, with a circular configuration slightly different from that of other guidewires, which reduces ventricular compression. This characteristic is particularly notable in the smaller curve.

Study population

The study protocol was approved by *Hospital Clínic de Barcelona* Ethics Committee (Barcelona, Spain) in full compliance with the ethical principles outlined in the Declaration of Helsinki. A total of 50 consecutive patients with severe aortic stenosis or regurgitation undergoing TAVI in 8 Spanish centers with the pre-shaped Circulo guidewire for LV pacing were prospectively included. Patients were excluded if, in the investigators' judgment, they required RV pacing, lacked femoral access, or underwent TAVI without the need for rapid pacing.

Baseline characteristics were collected, including sex, age, weight, height, surgical risk, history of pacemaker implantation, atrial fibrillation, ischemic heart disease, or bundle branch block. Echocardiographic characteristics included LV size, LV ejection fraction, and the presence of severe valvular heart disease.

TAVI with left ventricular pacing

TAVI was performed according to the clinical practice of each center. The grounding configuration for LV pacing and the type of TAVI were decided by each center based on patient characteristics (figure 1B-C). During LV pacing, systemic blood pressure and pacing threshold were measured. To determine the LV pacing threshold, pacemaker output was initially increased to the maximum and then gradually reduced until loss of capture was observed. The

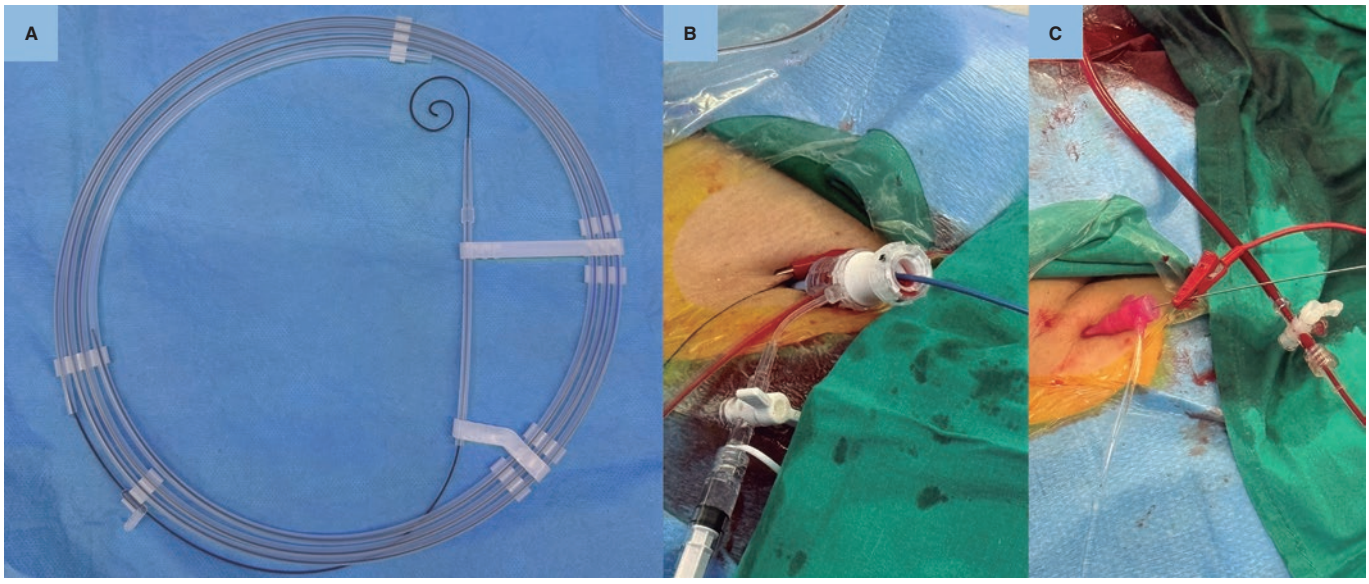


Figure 1. **A:** pre-shaped Circulo guidewire. **B:** grounding for left ventricular pacing through the skin. **C:** grounding for left ventricular pacing through a guidewire.

lowest voltage capable of capturing the ventricle on all beats was selected. Systemic blood pressure was measured using an arterial catheter.

Procedural characteristics were recorded, including venous access, grounding configuration for LV pacing, LV pacing threshold, systemic blood pressure during rapid LV pacing, conversion to pacing using a different LV guidewire or RV pacing, type and size of the transcatheter heart valve, need for balloon pre- or postdilatation, and complications according to the Valve Academic Research Consortium-3 (VARC-3) criteria, including vascular and access-related complications, hemorrhages, neurological events, new conduction disturbances and arrhythmias, acute kidney injury, structural heart complications, length of stay, and mortality.[5]

Follow-up

Follow-up was conducted 30 days after TAVI, either by telephone or in person. Complications were adjudicated according to VARC-3 criteria.[5]

Statistical analysis

Quantitative variables are expressed as mean and standard deviation or median and interquartile range (IQR), depending on whether distribution was normal, as previously assessed using the Kolmogorov–Smirnov test. The qualitative ones are expressed as total number and percentage. Statistical analyses were performed using IBM SPSS Statistics (version 27) and RStudio (version 4.5.1). Depending on the variable, Fisher's exact test, the Kruskal–Wallis test, or ANOVA was applied.

RESULTS

Baseline characteristics

Baseline characteristics are shown in table 1. A total of 50 patients were included in the study, 31 (62%) women and 19 (38%) men. The mean age of the cohort was 80.56 ± 6.26 years. In terms of past medical history, the mean body mass index was 27.38 ± 4.6 kg/m^2; 17 patients (34%) had ischemic heart disease; 12 (24%), atrial fibrillation; 3 (6%), a previously implanted pacemaker; 4 (11.8%), first-degree atrioventricular block (AVB); and 6 (12%), bundle branch block (4 patients had left bundle branch block and 2, right bundle branch block). The PR interval ranged from 140 ms to 240 ms, with a median of 170 ms (IQR, 158-190), and QRS duration ranged from 72 ms to 170 ms, with a median of 90 ms (IQR, 80-110). Median surgical risk, assessed using the EuroSCORE II, was 2.06% (IQR, 1.62-3.36).

Baseline echocardiographic evaluation demonstrated a mean LV end-diastolic diameter of 45.28 ± 7.83 mm, a mean LV ejection fraction of 58.48 ± 8.63%, and a mean transaortic gradient of 47.24 ± 19.25 mmHg. Severe aortic regurgitation was present in 6 patients (12%) and was the primary valvular heart disease in 2 cases (4%). There were no patients with severe tricuspid regurgitation.

Procedural characteristics and performance of the pre-shaped guidewire

LV pacing avoided venous access in nearly half of the patients (n = 24; 48%). Among those requiring venous access, the femoral vein was the most widely used site (n = 20; 77%), followed by the brachial (n = 4; 15%) and jugular veins (n = 2; 8%). Grounding methods for LV pacing varied, with skin grounding being the one most frequently used (n = 22; 44%), followed by grounding to a guidewire via venous access (n = 19; 38%), and needle-based grounding methods (n = 9; 18%) (table 2).

The Navitor valve (Abbott, United States) was the most frequently used transcatheter heart valve (n = 28; 56%), followed by the SAPIEN (Edwards Lifesciences, United States) and the Myval (Meril Life Sciences, India) valves (n = 6; 12%). The least frequently used ones were the Evolut (Medtronic, United States) and the ACURATE (Boston Scientific, United States) (n = 5; 10%). Self-expanding valves accounted for 76% of all implanted transcatheter heart valves. Valve sizes ranged from 23 mm to 34 mm, with a median of 25 mm (IQR, 23-27). Predilatation was performed in most patients (n = 41; 82%), whereas postdilatation was required in only 20% (n = 10) (table 2). The mean LV pacing threshold was 7 ± 3.48 mV,

Table 1. Baseline characteristics of the patients

Variable	Total (n = 50)
Demographic data	
Age (years)	80.56 ± 6.26
Women	31 (62)
Past medical history	
Body mass index (kg/m^2)	27.38 ± 4.6
Ischemic heart disease	17 (34)
Atrial fibrillation	12 (24)
Previous pacemaker	3 (6)
PR duration (ms)	170 [158-190]
QRS duration (ms)	90 [80-110]
First-degree AVB	4 (11.8)
LBBB	4 (8)
RBBB	2 (4)
Surgical risk	
EuroSCORE II (%)	2.06 [1.62-3.36]
Echocardiographic characteristics	
LV ejection fraction (%)	58.48 ± 8.63
LV end-diastolic diameter (mm)	45.28 ± 7.83
Mean gradient (mmHg)	47.24 ± 19.25
Severe aortic regurgitation	6 (12)
Severe tricuspid regurgitation	0 (0)

AVB, atrioventricular block; RBBB, right bundle branch block; LBBB, left bundle branch block; LV, left ventricle.
Data express n (%), mean ± standard deviation, or median [interquartile range].

and in 100% of patients (n = 50), a decrease in systolic blood pressure < 60 mmHg was achieved without loss of capture during rapid LV pacing. Comparative data across the different guidewires are presented in table 3. No patient required conversion to an alternative LV pacing guidewire, and only 3 (6%) required RV pacing, all due to AVB following balloon predilatation or during advancement of the valve into the LV. No guidewire exchange was required to advance the TAVI delivery system (table 2).

Complications

The overall rate of complications was 14% (n = 7), with conduction disturbances being the most frequent. Perioperative AVB requiring temporary pacemaker implantation occurred in 6 patients (12%), 4 of whom (8%) exhibited postoperative persistent complete AVB and eventually required permanent pacemaker implantation. One patient experienced a minor vascular complication in the form of vascular occlusion, which was successfully treated by transcatheter procedure and resolved without sequelae. There were no strokes or other major adverse events. The median length of stay from TAVI to discharge was 3 days (IQR, 2-5). The in-hospital survival rate was 100%, and no readmissions or deaths were recorded at

Table 2. Procedural characteristics and perioperative complications and 30-day follow-up

Procedural characteristics	Total (n = 50)
Venous access	
None	24 (48%)
Femoral	20 (40%)
Jugular	2 (4%)
Brachial	4 (8%)
Grounding for LV pacing	
Needle	9 (18%)
Guidewire	19 (38%)
Skin	22 (44%)
Predilatation	71 (82%)
Systolic blood pressure < 60 mmHg during rapid LV pacing	50 (100%)
LV pacing threshold (mV)	7.00 ± 3.48
Conversion to RV pacing	3 (6%)
Conversion to a different LV guidewire	0 (0%)
Type of transcatheter heart valve	
Navitor	28 (56%)
Evolut	5 (10%)
ACURATE	5 (10%)
SAPIEN	6 (12%)
Myval	6 (12%)
Transcatheter heart valve size	25 [23-27]
Pacing during TAVI	
None	21 (42%)
LV	27 (54%)
RV	2 (4%)
Postdilatation	10 (20%)
Length of stay	3 (2-5)
Total complications	7 (14%)
Stroke	0 (0%)
Vascular	1 (2%)
Bleeding	0 (0%)
Coronary obstruction	0 (0%)
Cardiac tamponade	0 (0%)
Device embolization	0 (0%)
Perioperative AVB	6 (12%)
Permanent pacemaker	4 (8%)
In-hospital mortality	0 (0%)
30-day readmission	0 (0%)
30-day mortality	0 (0%)

AVB, atrioventricular block; LV, left ventricle; RV, right ventricle.

Table 3. Performance of the preformed left ventricular pacing guidewire

Study and guidewire	LV pacing threshold (mV)				Procedural success
	Mean	SD	Median	IQR	n (%)
Circulo (n = 50)	7.00	3.48	7	3.8-9.25	50 (100)
Tamura et al. (2022)[10] (n = 204)					202 (99.02)
CONFIDA (n = 34)	3.36	1.66	3	2-5	34 (100)
SAFARI (n = 163)	5.85	2.68	5	4-7	161 (98.8)
SAFARI Small (n = 110)	5.97	3.01	5	4-7	108 (98.2)
SAFARI Extra Small (n = 53)	5.62	1.96	6	4-7	53 (100)
Lunderquist (n = 7)	7.5	5.94	5	3.25-10.5	7 (100)

IQR, interquartile range; LV, left ventricle; SD, standard deviation.

the 1-month follow-up. Perioperative complications and those occurring within 1 month after the procedure are shown in table 2.

DISCUSSION

The main findings of the study were these: *a)* LV pacing using the pre-shaped Circulo guidewire was effective, achieving a reduction in systolic blood pressure < 60 mmHg in 100% of patients; *b)* no patient required switching to an alternative LV pacing guidewire; *c)* only 3 patients required conversion to RV pacing, all due to AVB following predilatation; *d)* the procedural success rate of TAVI was 100%; and *e)* there were no complications related to the Circulo guidewire. These results demonstrate the safety and efficacy profile of LV pacing using the Circulo guidewire and support its usefulness during transfemoral TAVI.

In this study, the success rate of LV pacing with the Circulo guidewire was comparable to that reported in former studies using other guidewires.[8-11,13,14] Only 4% of patients presented right bundle branch block on baseline electrocardiography, indicating a cohort with a low risk of developing conduction disturbances. No patient required switching to an alternative LV pacing guidewire, and only 3 (6%) required conversion to RV pacing due to the onset of AVB after balloon predilatation or during valve advancement into the LV. In 2 of these 3 cases, LV pacing had been effective, with adequate pacing thresholds of 2.5 mV and 3.0 mV; however, although the procedure could have been continued using LV pacing, the operators decided to implant a transvenous temporary pacemaker before valve implantation, anticipating the need for pacing support after the procedure. In the third case, LV pacing was attempted, but due to the absence of adequate capture, conversion to RV pacing with implantation of a transvenous temporary pacemaker was performed. These patients did not present notable clinical differences, and aside from predilatation, no additional predictive factors were identified. The pacing thresholds recorded were slightly higher than those observed in former studies (7 mV vs 3.36 mV-7.5 mV);[10] however, these discrepancies were not clinically relevant and are plausibly explained by inter-operator variability inherent to the technique.

Because transvenous temporary pacemaker implantation was only required in patients who developed AVB during or after the procedure, LV pacing with the Circulo guidewire avoided the implantation of 44 temporary pacemakers among 50 cases (88%). In former studies, this approach has been shown to reduce both procedural and fluoroscopy times.[9,15,16] Therefore, although LV pacing can be performed in all patients, it is most beneficial in those at low risk of AVB and subsequent pacing requirements. In such cases, transvenous temporary pacemaker implantation can be avoided, a procedure associated with potential complications, such as inadvertent arterial puncture (0.3%), major hemorrhage (2.7%), deep vein thrombosis (0.3%), pulmonary thromboembolism (0.1%), pneumothorax (0.1%), cardiac perforation (0.7%), lead dislodgement (3.4%), pacing failure (7.7%), and the need for multiple placement attempts (0.9%).[7]

Although it is evident that LV pacing reduces most complications associated with transvenous RV temporary pacemaker implantation, the main concerns regarding LV pacing have focused on the risk of aortic bioprosthesis embolization due to loss of capture and the risk of perforation related to advancing the guidewire inside the LV during pacing. However, multiple studies have shown no significant differences in valve embolization rates between the 2 techniques, with some reporting a trend toward a lower risk of cardiac tamponade with LV pacing, likely attributable to the greater myocardial thickness of the LV vs the RV.[9,14,15] In our study, there were no cases of device embolization or cardiac tamponade or LV pacing-related complications.

Study limitations

One limitation of the present study is that guidewire selection was left to the operator's discretion, which may have introduced selection bias. In the cohort presented, only 4% of patients exhibited right bundle branch block on baseline electrocardiography, which is representative of a population at a low risk of developing arrhythmic complications. However, the operator-dependent choice of guidewire enhances the external validity of the results, as it more accurately reflects real-world clinical decision-making. Another limitation is the absence of a comparison group undergoing RV or LV pacing with other guidewires, which limits the ability to directly compare outcomes between techniques. Instead, results were compared with those of previously published studies.

CONCLUSIONS

The use of the Circulo guidewire for LV pacing during TAVI proved to be safe and effective, with a low overall rate of TAVI-related complications and no guidewire-related complications. This approach avoids the need for transvenous temporary pacemaker implantation in most patients at low risk of arrhythmic complications, thus potentially reducing procedural risks and simplifying perioperative management.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

The study protocol was approved by *Hospital Clínic de Barcelona* Clinical Research Ethics Committee in full compliance with the ethical principles outlined in the Declaration of Helsinki. All participants signed informed consent prior to inclusion in the study. No sex-based subgroup analysis was performed, as this could compromise the statistical power of the study and both sexes were adequately represented in the cohort; furthermore, there is no prior evidence suggesting sex-related differences in response to LV pacing using a pre-shaped guidewire.

DECLARATION ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used in the development of this article.

AUTHORS' CONTRIBUTIONS

A. Regueiro designed the protocol, database, and study framework, and coordinated statistical analysis, data interpretation, and manuscript drafting. I. Anduaga contributed to protocol design, database development, and study framework, performed statistical analysis and data interpretation, and drafted the manuscript. A. Ruberti, V. Vilalta, I.J. Amat-Santos, F. Díez-Delhoyo, L.L. Gheorghe, J.A. Baz, J.F. Díaz Fernández, L. Gutiérrez-Alonso, and X. Carrillo participated in data collection and critically reviewed the manuscript. All authors approved the final published version.

CONFLICTS OF INTEREST

A. Regueiro is a consultant for Abbott, Edwards, Haemonetics, Medtronic, and Meril. J.F. Díaz Fernández is a consultant for Abbott, Boston Scientific, and Medtronic. I.J. Amat-Santos is a proctor for Boston Scientific, Medtronic, Meril, and MicroPort. The remaining authors declared no conflicts of interest whatsoever.

WHAT IS KNOWN ABOUT THE TOPIC?

- LV pacing using pre-shaped guidewires has emerged as an effective alternative to RV pacing with transvenous temporary pacemaker implantation.
- LV pacing has been associated with shorter procedural and fluoroscopy times.
- Although LV pacing has proven safe and effective with several guidewires, not all guidewires currently used in TAVI have proven useful for this purpose.

WHAT DOES THIS STUDY ADD?

- The pre-shaped Circulo guidewire, with its circular design, proved to be a highly effective option for LV pacing during transfemoral TAVI.
- The overall TAVI complication rate was low, and no complications attributable to the Circulo guidewire were observed.
- The Circulo guidewire avoids the need for transvenous temporary pacemaker implantation in a considerable proportion of patients and is particularly useful in those at low risk of perioperative conduction disturbances.

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Original article

Spanish cardiac catheterization in congenital heart diseases registry. Fifth official report from the ACI-SEC and GTH-SECPCC (2024)

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ABSTRACT

Introduction and objectives: The Interventional Cardiology Association of the Spanish Society of Cardiology (ACI-SEC) and the Interventional Working Group of the Spanish Society of Pediatric Cardiology (GTH-SECPCC) introduce their annual report on interventional activity in congenital heart diseases in 2024.
Methods: Spanish centers with cath labs performing interventional procedures for congenital heart disease were invited to participate. Data were collected through an online platform and analyzed by an external company in collaboration with members of the ACI-SEC and GTH-SECPCC.
Results: A total of 22 cath lab units from 17 public and 3 private hospitals participated in the registry. Furthermore, the analysis included data on interventional procedures for adult congenital heart disease performed at an additional 98 adult cardiology units reporting activity in congenital heart disease. These units were among the 118 hospitals participating in the 2024 Spanish cardiac catheterization in congenital heart diseases registry of the ACI-SEC. A total of 1888 diagnostic studies were recorded, representing a 67.5% increase compared with 2023, as well as 3711 interventional catheterizations, representing a 3.8% decrease. Of these procedures, 2287 (61.6%) were performed in patients older than 18 years, representing a 6.2% decrease compared with 2023. The most frequent procedures were patent foramen ovale closure (1392 cases) and atrial septal defect closure (641 cases), followed by

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patent ductus arteriosus closure (368 cases), pulmonary artery branch angioplasty (236 cases), angioplasty for aortic coarctation (172 cases), transcatheter pulmonary valve implantation (160 cases), and ventricular septal defect closure (84 cases). Among procedures for which outcomes were reported, the success rate was 96.9%, the major complication rate was 1.9%, and the in-hospital mortality rate was 0.3%.
Conclusions: All interventional procedures showed excellent safety and efficacy outcomes despite a slight reduction in the overall procedural volume compared with 2023.

Keywords: Congenital heart diseases. Cardiac catheterization. Interventional cardiology. Interventional registry.

Registro español de intervencionismo en cardiopatías congénitas. V informe oficial de la ACI-SEC y el GTH-SECPCC (2024)

RESUMEN

Introducción y objetivos: La Asociación de Cardiología Intervencionista de la Sociedad Española de Cardiología (ACI-SEC) y el Grupo de Trabajo de Hemodinámica de la Sociedad Española de Cardiología Pediátrica y Cardiopatías Congénitas (GTH-SECPCC) presentan su informe anual de actividad hemodinámica en cardiopatías congénitas correspondiente al año 2024.
Métodos: Se invitó a participar a los centros españoles con laboratorio de hemodinámica y actividad intervencionista en cardiopatías congénitas. Los datos se recogieron mediante una plataforma telemática y su análisis lo realizó una empresa externa en colaboración con miembros de la ACI-SEC y el GTH-SECPCC.
Resultados: Participaron en el registro 22 unidades de hemodinámica que corresponden a 17 hospitales públicos y 3 privados. Se incorporaron al análisis los datos de intervencionismo en cardiopatías congénitas del adulto aportados por otras 98 unidades de adultos que registraron algún tipo de actividad en enfermedades congénitas, de los 118 hospitales participantes en el registro de hemodinámica y cardiología intervencionista de la ACI-SEC del año 2024. Se registraron 1.888 estudios diagnósticos (un 67,5% más que en 2023) y 3.711 cateterismos intervencionistas (un 3,8% menos que en 2023), de los que 2.287 (61,6%) se realizaron en mayores de 18 años (un 6,2% menos que en 2023). Los procedimientos más frecuentes fueron los cierres de foramen oval permeable (1.392 casos) y de comunicación interauricular (641), seguidos del cierre de *ductus* persistente (368), la angioplastia de ramas pulmonares (236), la angioplastia de la coartación de aorta (172), el implante de válvula pulmonar percutánea (160) y el cierre de comunicación interventricular (84). El porcentaje de éxito en los procedimientos intervencionistas en que se notificó fue del 96,9%, con una tasa de complicaciones mayores del 1,9% y una mortalidad intrahospitalaria del 0,3%.
Conclusiones: Todas las técnicas intervencionistas han mostrado excelentes resultados de seguridad y eficacia, y ha habido una ligera reducción del volumen global de procedimientos intervencionistas respecto a 2023.

Palabras clave: Cardiopatías congénitas. Cateterismo cardiaco. Cardiología intervencionista. Registro de hemodinámica.

Abbreviations

ACI-SEC: Interventional Cardiology Association of the Spanish Society of Cardiology. **ASD:** atrial septal defect. **GTH-SECPCC:** Interventional Working Group of the Spanish Society of Pediatric Cardiology . **PFO:** patent foramen ovale. **VSD:** ventricular septal defect.

INTRODUCTION

This report presents hemodynamic and interventional activity in congenital heart disease in Spain in 2024. Although these data are derived from voluntary participation in a survey conducted for more than a decade by the Interventional Working Group of the Spanish Society of Pediatric Cardiology (GTH-SECPCC), its results have only been published since 2020.[1-4]

In 2020, as a result of collaboration between the Interventional Cardiology Association of the Spanish Society of Cardiology (ACI-SEC) and the GTH-SECPCC, participation was broadened and the results began to be systematically disseminated, leading to the annual publication of the registry. Initially, a total of 12–15 tertiary referral centers participated. These centers were highly representative of pediatric activity but not of overall congenital heart disease activity. Therefore, from 2022 onward, data from adult units participating in the ACI-SEC registry were included, allowing a more accurate estimate of the actual volume of hemodynamic procedures for congenital heart disease across all age groups, with procedures in adults becoming increasingly prevalent.[3,4] The results of this edition were presented on 6 June, 2025, at the ACI-SEC congress held in Santiago de Compostela (A Coruña, Spain) (figure 1).

METHODS

This retrospective, unaudited registry is based on the voluntary submission of data on congenital heart disease procedures from hospitals represented in the GTH-SECPCC, as well as from other hospitals already participating in the ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry.

Each center enters information on its activity, resource use, and outcomes into an electronic database managed by an external company (pInvestiga, Spain). No variables are mandatory, and each center voluntarily provides the data available to it. Data analysis is performed by the same external company in direct collaboration with members of the GTH-SECPCC and the ACI-SEC board. Inconsistent data are reviewed and cross-checked to improve the quality of the publication.

Both absolute (n) and relative (%) data are presented. When data are not available from all centers, percentages are calculated based

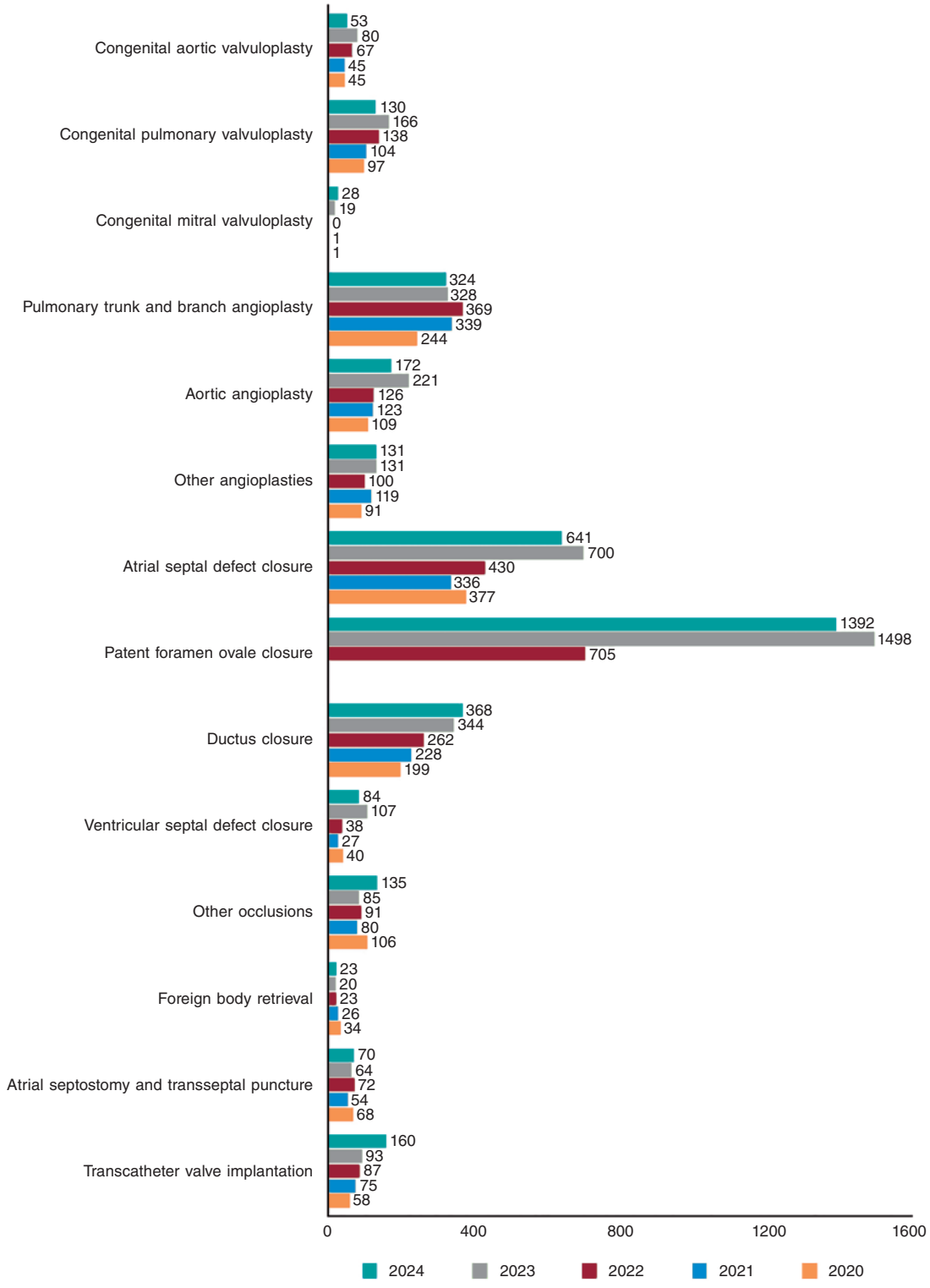


Figure 1. Comparison of the number of interventional procedures during the 2020-2024 period.

on the total number of centers that provided the corresponding variable. Year-to-year comparisons are descriptive, and no hypothesis-testing procedures are performed.

Given the methodological characteristics of the study and because this is solely an activity registry, neither ethics committee approval nor informed consent was required.

RESULTS

Resources and infrastructure

In 2024, a total of 22 cath labs from 20 hospitals participated (2 centers provided separate data for their pediatric and adult sections), which is 1 more hospital compared with 2023. Of these hospitals, 17 belonged to the public health care network and 3 were private

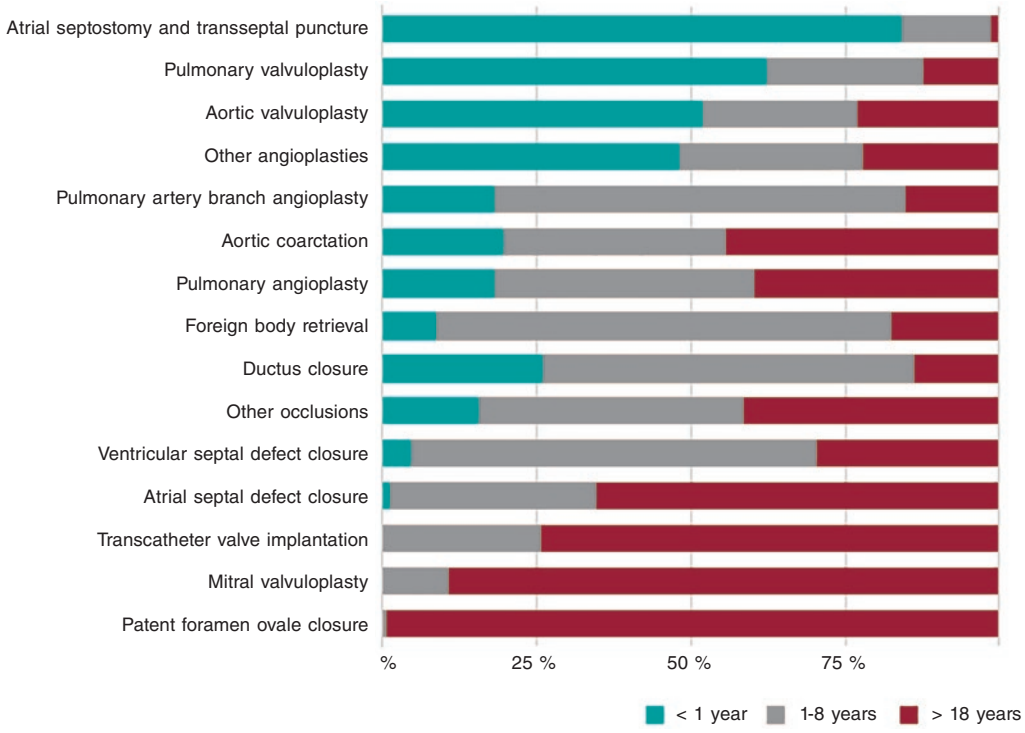


Figure 2. Distribution of interventional procedures by age group.

(table S1). In addition, data on interventional procedures for congenital heart disease provided by another 98 of the 118 adult units participating in the 2024 ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry were included in the analysis.[5]

A total of 39 cath labs routinely performing interventional procedures for congenital heart disease were recorded. Of these, 8 (20.5%) were exclusively pediatric and 23 (59%) were shared for pediatric and adult activity. A total of 11 cath labs (28.2%) had digital imaging, 10 (25.6%) had biplane systems, and 11 (28.2%) used rotational angiography. A median of 12 (1–20) days per month per cath lab were devoted to congenital heart disease interventions, compared with 7 days in 2023. A total of 16 cath labs (72% of the total) provided 24-hour emergency catheterization services, including pediatric emergencies in 14 cath labs at 13 hospitals.

Regarding medical staffing, a total of 70 interventional cardiologists dedicated to this activity were reported, of whom 43 (61.4%) were adult interventional cardiologists and 27 (38.5%) were pediatric interventional cardiologists.

Diagnostic procedures

A total of 1888 diagnostic studies were recorded, representing a 67.5% increase compared with 2023, mainly attributable to the incorporation of activity from the ACI-SEC registry.[5] Distribution by age group was as follows: 19 (1%) procedures were performed in infants younger than 1 month, 102 (5.4%) in patients aged between 1 month and 1 year, 627 (33.2%) in patients aged 1 to 18 years, and 1140 (60.4%) in patients older than 18 years. Of this activity in adults, 66% was reported in the ACI-SEC survey[5] and corresponded to a large number of cath labs, since only 11 cath labs performed > 30 diagnostic procedures in adults.

A total of 60 procedures (3.2%) were classified as emergency procedures. Regarding morbidity, 14 cases (0.7%) of serious complications were reported: 1 cardiac tamponade, 1 severe pericardial effusion without tamponade, 1 hemothorax related to jugular vascular access, 1 cardiac arrest, 6 vascular complications, and 3 other unspecified events. No neurological complications were reported. Only 1 catheterization-related death was reported (0.05%).

Interventional procedures

A total of 3711 therapeutic catheterizations were reported, 3.8% fewer than 2023. These were grouped into 15 categories, and their case volume and age distribution are shown in figure 2 and table 1. Overall, a total of 2287 procedures were performed in patients older than 18 years, of which 1805 (78.9%) derived from the incorporation of data from the ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry (table 2).

A total of 119 catheterizations were classified as emergency procedures (3.2% of the total). In centers corresponding to the GTH-SECPCC, activity was distributed as follows: 5 cath labs (22.7%) recorded > 150 catheterizations, 4 (18.1%) recorded between 75 and 150 interventions, and 13 (59%) recorded < 75 procedures.

The volume of procedures for congenital heart disease, excluding patent foramen ovale (PFO) closure, in the 98 centers corresponding to the ACI-SEC registry was distributed as follows: 2 cath labs performed > 200 interventional catheterizations, 5 performed between 100 and 200 procedures, 6 performed between 50 and 100 interventions, and 87 performed < 50 procedures, 67 of them < 10.

The sum of procedures, excluding PFO closure, performed at the 10 cath labs designated as *Centros, Servicios y Unidades de Referencia* (CSUR) for complex congenital heart disease in pediatric or adult patients accounted for 38.6% of the activity. The overall reported effectiveness of the different interventional techniques was 96.9% (table 3).

Table 1. Number of procedures and distribution by age group

Procedures	Fetal	< 1 month	1 month–1 year	1–18 years	> 18 years	Total
Interventional procedures	1 (0.02)	185 (5)	270 (7.3)	967 (26)	2287 (61.6)	3711
Congenital aortic valvuloplasty	1 (1.9)	14 (26.4)	13 (24.5)	13 (24.5)	12 (22.6)	53
Congenital pulmonary valvuloplasty	–	35 (26.9)	46 (35.4)	33 (25.4)	16 (12.3)	130
Congenital mitral valvuloplasty	–	0	1 (3.5)	2 (7.1)	25 (89.3)	28
Pulmonary angioplasty	–	7 (7.9)	9 (10.2)	37 (42.1)	35 (39.8)	88
Pulmonary artery branch angioplasty	–	7 (3)	36 (15.2)	157 (66.5)	36 (15.3)	236
Aortic coarctation	–	3 (1.8)	31 (18)	62 (36)	76 (44.2)	172
Other angioplasties	–	43 (32.7)	20 (15.3)	39 (29.9)	29 (22.1)	131
Atrial septal defect closure	–	0	8 (1.2)	214 (33.4)	419 (65.4)	641
Patent foramen ovale closure	–	0	0	8 (0.6)	1384 (99.4)	1392
Ductus closure[a]	23 (6.2)	29 (8)	44 (12)	221 (60)	51 (13.8)	368
Ventricular septal defect closure	–	0	4 (4.7)	56 (66.7)	24 (28.6)	84
Other occlusions	–	4 (3)	17 (12.5)	58 (43)	56 (41.5)	135
Foreign body retrieval	–	1 (4.4)	1 (4.4)	17 (73.9)	4 (17.3)	23
Atrial septostomy and transseptal puncture	–	48 (68.6)	11 (15.7)	10 (14.3)	1 (1.4)	70
Transcatheter valve implantation	–	0	0	41 (25.9)	119 (74.1)	160

[a] For ductus closure, the groups are premature infants (fetal), < 6 months (< 1 month), and 6 months to 1 year (1 month to 1 year).
Data are expressed as no. (%).

Transcatheter valvuloplasty

A total of 53 aortic valvuloplasties for congenital aortic stenosis were reported, 36.2% fewer than 2023. Of these, 40 (75.5%) were performed in patients younger than 18 years, with patients younger than 1 year accounting for 51% of the total, and 1 case involved fetal valvuloplasty. Native valves that had not previously been treated were dilated in 83% of procedures.

A total of 130 pulmonary valvuloplasty procedures were recorded, 21.7% fewer than 2023, with 62.3% performed in patients younger than 1 year. Technical data were available for 121 cases: 105 (86.8%) involved native valves, of which 10 (9.5%) were imperforate, and ductal *stent* implantation was additionally performed in 8 of these cases.

Mitral valvuloplasty accounted for 28 cases, 47.4% more than in 2023. This increase was attributable to adult cases, since only 3 procedures were performed in patients younger than 18 years.

Transcatheter angioplasty

A total of 88 right ventricular outflow tract dilations were reported, 18.5% fewer than in 2023. Technical and anatomical data were reported for 74 (84.1%) procedures. Angioplasty of the native outflow tract was performed in 45.9%, whereas the remaining 54.1% involved a surgical conduit. Conventional balloon dilation was used in 47.3%, and a stent was implanted in 52.7%.

Pulmonary artery branch angioplasty accounted for a total of 236 procedures, 20.4% more than in 2023. The vast majority (90.2%) involved proximal branches, and only 9.8% involved peripheral arteries. Stents were implanted in 52.4% of cases, conventional balloon dilation was performed in 47.1%, and cutting-balloon dilation was exceptional (0.9%).

A total of 172 angioplasties for aortic coarctation were recorded, with anatomical information available in 132 (76.7%). Most procedures (60.6%) were reinterventions. The substrate for dilation was the aortic arch or isthmus in all but 5 cases: 4 abdominal aortic dilations and 1 ascending aortic dilation. Stents were implanted in 65%, with balloon dilation used in the remainder; 22% were redilations of previously implanted stents.

Finally, a total of 131 procedures were reported under the category of "other angioplasties," with no change compared with the previous year. Of note, ductal dilation in 47 cases, 62.1% more than in 2023, and surgical shunt dilation in 9. Stent implantation was associated with 67.2% of these procedures.

Shunt closures and other occlusion procedures

In 2024, PFO closure accounted for 1392 procedures, 7.1% fewer than in 2023, of which 1325 (88.7%) derived from the incorporation of data collected in the ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry (table 2). Patients older than 18 years accounted for 99.4% of the total for this technique.

A total of 641 atrial septal defect (ASD) closures were reported, 8.4% fewer than in 2023. Information on defect complexity and procedural imaging guidance was reported only in the GTH-SECPCC registry (48.9%). Complex defects accounted for 33.5%. Transesophageal echocardiography was used in 91% of cases, angiographic balloon sizing in 18.5%, and intracardiac echocardiography in 2.5%.

Persistent ductus arteriosus closure accounted for 368 cardiac catheterizations, 6.9% more than in 2023. Patients aged 1 to 18 years accounted for 60% of this activity, while procedures in premature infants represented 6.2%, with 23 cases, 4.7% more than in 2023.

Table 2. Number of interventional catheterizations in patients older than 18 years and distribution by source registry

Procedures	Total	RICC[a]	RHCI[b]
Congenital aortic valvuloplasty	12	10 (83.3)	2 (16.7)
Congenital pulmonary valvuloplasty	16	7 (43.8)	9 (56.2)
Congenital mitral valvuloplasty	25	0	25 (100)
Pulmonary angioplasty	35	21 (60)	14 (40)
Pulmonary artery branch angioplasty	36	25 (69.4)	11 (30.6)
Aortic coarctation	76	36 (47.4)	40 (53.6)
Other angioplasties	29	20 (69)	9 (31)
Atrial septal defect closure	419	91 (21.7)	328 (78.3)
Patent foramen ovale closure	1384	149 (10.8)	1235 (89.2)
Ductus closure	51	8 (15.7)	43 (84.3)
Ventricular septal defect closure	24	7 (29.2)	17 (71.8)
Other occlusions	56	28 (50)	28 (50)
Foreign body retrieval	4	4 (100)	0
Atrial septostomy and transseptal puncture	1	1 (100)	0
Transcatheter valve implantation	119	75 (63)	44 (37)
Total	2287	482 (21.1)	1805 (78.9)

RHCI, ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry; RICC, GTH-SECPCC Interventional Procedures in Congenital Heart Diseases Registry.
[a] Data provided by centers participating in the 2024 GTH-SECPCC Interventional Procedures in Congenital Heart Diseases Registry.
[b] Data provided by centers to the 2024 ACI-SEC Spanish Cardiac Catheterization in Congenital Heart Diseases Registry.
Data are expressed as no. (%).

Antegrade venous access was used in 61.5% of closures. Occlusion devices were used in 92%, with controlled-release coil-type devices used in the remainder.

A total of 84 ventricular septal defect (VSD) closure procedures were reported, 21.5% fewer than in 2023. Data on the anatomical substrate were reported in 67 cases (79.8%): 52 (77.6%) were perimembranous, 5 (7.4%) muscular, and 9 (13.4%) postsurgical. Occlusion devices were used in 93% of procedures and coil-type devices in the remainder. A hybrid approach was used in 0.2%, while the remaining procedures were transcatheter (99.8%). The retrograde (arterial) approach predominated (79.1%) for closure. Effectiveness, reported in 67 cases, was 95.6%.

The category of "other occlusion procedures" included 135 cardiac catheterizations, 58.8% more than in 2023, due to the addition of cases from the ACI-SEC registry. These involved closure of systemic-to-pulmonary collaterals in 54.2% of cases and occlusion of venous collaterals in 21.5%. The most widely used materials were occlusion devices (43%), followed by coil-type devices (25.2%) and particles (14.9%), either as the sole material or in combination with others.

Atrial septostomy

In 2024, a total of 70 procedures to create or enlarge an interatrial septum were recorded, 9.4% more than in the previous year. Imaging guidance included echocardiography in 24.3% of cases, fluoroscopy in 5.7%, and a combination of both imaging modalities in 68.6%. A total of 70% of the interventions (49) were balloon atrial septostomies (Rashkind procedure). In addition, 8 procedures involving radiofrequency septal perforation and 7 involving needle perforation were reported. Septal stent placement was additionally performed in 13 interventions.

Transcatheter valve implantation

A total of 160 procedures were reported, 72% more than in the previous year, of which 75 (46.9%) were performed in patients older than 18 years. The approach was transcatheter except for 2 cases of hybrid implantation. The pulmonary position predominated (96.8%). The anatomical substrate, reported in 112 procedures, was a native outflow tract in 59 cases (58%), a surgical conduit in 29 (25.9%), and valve-in-valve in 24 (21.4%). In addition, the GTH-SECPCC registry included 4 implantations in the tricuspid position and 3 in the mitral position.

Complications

Morbidity and mortality data were reported for 1897 (51.1%) interventional procedures. A total of 37 serious adverse events were reported (table 4), including 6 deaths, corresponding to a major complication rate of 2% and a mortality rate of 0.3%. The category with the highest morbidity was mitral valvuloplasty (33.3%), followed at a considerable distance by aortic valvuloplasty (3.9%), VSD closure (3.1%), and atrial septostomy (2.8%). The most common complications were device embolizations, which occurred in 9 cases (24.3% overall): 3 during ASD and PFO closures, 2 during persistent ductus arteriosus closure, 2 during VSD closure, and 1 involving a stent during vascular angioplasty. None required surgery. A total of 4 severe arrhythmias were reported, including 1 successfully resuscitated cardiac arrest requiring extracorporeal membrane oxygenation support. Other complications included 2 cases of severe aortic regurgitation, 2 cardiac tamponades requiring pericardiocentesis, and vascular dissection or rupture in 6 interventions.

DISCUSSION

Compared with the previous year's report, 2024 showed relative stability in the number of interventional procedures, with 3.8% fewer procedures than in 2023, although the upward trend compared with years before 2023 was maintained. By category, the procedures showing the greatest reductions, ranging from 18% to 33%, were aortic and pulmonary valvuloplasty, pulmonary outflow tract angioplasty, and aortic angioplasty. The increase in transcatheter VSD closure procedures slowed, with figures below those of 2023 but above those of former registries.

Procedures showing increased volume included ductal stent implantation in congenital heart disease with severe limitation of pulmonary blood flow (62%) and transcatheter pulmonary valve implantation (72%), as well as pulmonary artery branch angioplasty, which showed a slight increase. All these findings reflect the importance of interventional procedures, from neonatal palliation to postoperative optimization, in congenital heart disease involving the right ventricular outflow tract.

A noteworthy finding in this edition is that, as in the previous year, > 60% of the reported diagnostic and therapeutic activity was performed in patients older than 18 years. The increase in interventional procedures for adult congenital heart disease is consistent with international series highlighting the increasing anatomical complexity and the need for specialized teams in this population

Table 3. Summary of reported effectiveness of interventional procedures

Procedures	Total	Cases with success or ineffectiveness data[a]	Success	Ineffective
Congenital aortic valvuloplasty	53	51 (96.2)	48 (94.1)	3 (5.9)
Congenital pulmonary valvuloplasty	130	121 (93.1)	108 (89.3)	13 (10.7)
Congenital mitral valvuloplasty	28	3 (10.7)	3 (100)	0
Pulmonary angioplasty	88	74 (84.1)	69 (93.2)	5 (6.8)
Pulmonary artery branch angioplasty	236	222 (94.1)	212 (95.5)	10 (4.5)
Aortic coarctation	172	130 (75.6)	126 (96.9)	4 (3.1)
Other angioplasties	131	121 (93.9)	114 (94.2)	7 (5.8)
Atrial septal defect closure	641	620 (96.7)	606 (97.7)	14 (2.3)
Patent foramen ovale closure	1392	1270 (91.2)	1258 (99.6)	12 (0.4)
Ductus closure	368	345 (93.7)	343 (99.7)	2 (0.3)
Ventricular septal defect closure	84	71 (84.5)	67 (94.4)	4 (5.6)
Other occlusions	135	105 (77.8)	102 (97.1)	3 (2.9)
Foreign body retrieval	23	23 (100)	20 (87)	3 (13)
Atrial septostomy and transseptal puncture	70	70 (100)	70 (100)	0
Transcatheter valve implantation	160	132 (82.5)	111 (84.1)	21 (15.9)
Total	3711	3358 (90.5)	3253 (96.9)	105 (3.1)

[a] Percentage of success or ineffectiveness calculated from the number of procedures for which these data were available.
Data are expressed as no. (%).

Table 4. Distribution of reported major complications and deaths across interventional procedures

Procedures	Total	Major complications[a]	Deaths
Congenital aortic valvuloplasty	51 (96.2)	1 (1.9) – 1 aortic regurgitation	1 (1.9)
Congenital pulmonary valvuloplasty	120 (92.3)	3 (2) – 3 unspecified	0
Congenital mitral valvuloplasty	3 (10.7)	1 (33.3) – 1 unspecified	0
Pulmonary angioplasty	74 (84.1)	1 (1.3) – 1 pulmonary artery injury	1 (1.3)
Pulmonary artery branch angioplasty	222 (94.1)	4 (1.8) – 1 arterial dissection – 1 stent embolization – 2 arrhythmias	1 (0.5)
Aortic coarctation	130 (75.6)	3 (2.3) – 1 arterial dissection – 1 arrhythmia – 1 unspecified	0
Other angioplasties	121 (92.4)	8 (6.6) – 2 arterial dissections – 6 unspecified	2 (1.7)
Atrial septal defect closure	311 (48.5)	4 (1.3) – 3 embolizations – 1 pericardial effusion	0
Patent foramen ovale closure	152 (10.9)	1 (0.7) – 1 death	1 (0.7)
Ductus closure	318 (86.4)	3 (0.9) – 2 embolizations – 1 tricuspid regurgitation	0
Ventricular septal defect closure	64 (76.2)	2 (3.1) – 2 embolizations	0
Other occlusions	105 (77.8)	2 (1.9) – 1 embolization – 1 aortic regurgitation	0
Foreign body retrieval	23 (100)	0	0
Atrial septostomy and transseptal puncture	71 (100)	2 (2.8) – 2 cardiac tamponades, 1 with cardiac arrest	0
Transcatheter valve implantation	132 (83.5)	3 (2.3) – 1 arterial dissection – 2 pulmonary hemorrhages, 1 requiring ECMO	0
Total	1897 (51.1)	37 (1.9)	6 (0.3)

ECMO, extracorporeal membrane oxygenation.
[a] Percentage of complications or death calculated from the number of procedures for which these data were available.
Data are expressed as no. (%) among procedures for which complication and death were reported.

subgroup.[6] Nevertheless, it should be emphasized that most of the interventional categories recorded had their highest patient volumes in the pediatric age group (figure 2 and table 1).

The reported effectiveness data for the different interventional techniques yielded an overall success rate of 96.9%, compared with 97.9% in 2023, and a mortality rate of 0.3%, compared with 0.05% in 2023. However, the voluntary and unaudited nature of the registry, along with the low reporting rates for effectiveness, morbidity, and mortality, undoubtedly reduces the robustness and reliability of the results. The reported rate of serious adverse events was 1.9%, higher than that recorded in 2023. Device embolizations continued to account for the largest number of cases, representing 23.1% of the total, followed in 2024 by vascular complications at 15.4%. Recent studies conducted in Spain have confirmed the validity and usefulness of specific methodologies for assessing the expected risk of complications according to the different techniques and clinical settings in which they are performed.[7]

Regarding valvuloplasty, only the number of mitral valve dilations increased, driven by the adult population. Currently, three-dimensional imaging modalities provide substantial support for patient selection and procedural guidance.[8] Moreover, in selected patients with congenital heart disease, transcatheter edge-to-edge repair extends structural heart intervention to conditions that have traditionally required surgery.[9]

Aortic and pulmonary valvuloplasty remain predominantly pediatric procedures, particularly within the first year of life. Among pulmonary valvuloplasties, 10 cases involved imperforate pulmonary valves; in selected anatomies, this approach may facilitate progression towards biventricular physiology.[10,11]

Regarding angioplasty, the number of pulmonary artery branch procedures increased compared with the previous year, by 20.4% vs 2023, with most patients younger than 18 years. Cases of aortic coarctation decreased by 22.2% compared with 2023, when they had shown a significant and probably overestimated increase, although they continued to show an upward trend compared with earlier registries. A total of 44.2% involved patients older than 18 years, and stenting has become established as the most frequently used option. The technique is expanding in pediatric patients with increasingly complex anatomy following the availability of lower-profile covered devices and serial stent dilation strategies to adapt them to patient growth.[12]

Atrial septal defect closures remain the highest-volume procedures in the registry, accounting for 57% of all interventional catheterizations. Of the atrial septal defects for which anatomical data were reported, 32.3% were classified as complex, defined by deficient rims or a size > 25 mm. This finding, together with the excellent efficacy (97.7%) and safety results (complication rate, 1.3%), confirms the maturity achieved by the technique.

Atrial septal defect closure remains the most frequently performed intervention in the registry, accounting for 57% of all interventional catheterizations. Among defects with available anatomical data, 32.3% were categorized as complex because of deficient rims or diameters > 25 mm. Together with the high efficacy rate (97.7%) and low complication rate (1.3%), these findings indicate that the technique is well established.

Persistent ductus arteriosus closure remains predominantly a pediatric procedure, with 86.2% of cases performed in patients younger than 18 years. Furthermore, the proportion of procedures in premature newborns increased, from 4.7% in 2023 to 6.2% in 2024, although it remained below the figures reported in 2021 and 2022. Multicenter studies, meta-analyses, and position statements from international scientific societies support the safety and efficacy profile of transcatheter closure in selected premature newborns, as it may reduce morbidity and mortality associated with surgery. However, uptake of this therapeutic option in Spain has slowed.[13,14]

Moreover, the number of VSD closure procedures decreased across all age groups compared with 2023, a year in which there was a marked increase, but remained significantly above the volume recorded in 2022 and earlier years. Safety outcomes continue the improvement observed in former reports: the major complication rate decreased to 3.1%, compared with 3.6% in 2023, and the success rate reached 94.4%, compared with 96.2% in 2023. Occlusion devices were the most frequently used (93%). The introduction of new closure devices (KONAR-MF, Lifetech, China) marked a paradigm shift in this technique in Spain. The retrograde approach now predominates because of its greater simplicity and is being used increasingly in younger patients.[15-17]

Transcatheter valve implantation increased significantly in 2024, by 46.9% compared with 2023. Although the largest number of treated patients came from the GTH-SECPCC registry, 74.1% of procedures were performed in patients older than 18 years, confirming the growth of this technique in interventional treatment of adult congenital heart disease. The activity reported in this registry continues to involve mainly implantation in the pulmonary position, with ongoing expansion of the technique in the native pulmonary outflow tract, which remains > 50% because of the increasing availability of new transcatheter heart valves, both balloon-expandable and self-expanding designs. This has increased the range of anatomical variants amenable to transcatheter valve implantation.[18-21]

Valve implantations in nonpulmonary positions remain uncommon, with only 4 tricuspid and 3 mitral cases. However, the expected growth of transcatheter valve implantation in unconventional positions, such as the atrioventricular position in congenital substrates and transcatheter edge-to-edge valve repair techniques in patients with congenital heart disease, makes it necessary to incorporate these procedures into the registry, as planned for future editions.[22]

Consolidation and methodological improvement of the national registry should address the previously identified need within the Spanish scientific community to standardize activity and quality criteria for interventional procedures in congenital heart disease.[23] Increasing the number of participant centers, harmonizing the variables collected to avoid data duplication, and ensuring continuity over time will improve the quality and reliability of the information generated. Furthermore, the accumulation of reports will facilitate historical comparisons and confirm the maturity of the registry.

Limitations

The inherent characteristics of the registry—retrospective, voluntary, and unaudited—reduce the reliability of its results. Expanding the information collected, including complication, morbidity, and mortality data, would help improve its quality and should therefore be considered in future editions.

CONCLUSIONS

The data obtained provide a realistic estimate of interventional activity for congenital heart disease in Spain across all age groups, with broad hospital participation, thereby consolidating the relevance and usefulness of the registry.

Excellent safety and efficacy outcomes are maintained for most techniques.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

Given the methodological characteristics of the study and because this was solely an activity registry, neither ethics committee approval nor informed consent was required. The characteristics of the study precluded consideration of potential sex and gender variables; therefore, the SAGER guidelines were not followed.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence was not used in the preparation of this study.

AUTHORS' CONTRIBUTIONS

All authors made substantial contributions to data collection and to the critical review and approval of the final version of the manuscript, which was drafted by L. Fernández González and B. Insa Albert.

CONFLICTS OF INTEREST

S. Ojeda is associate editor of *REC: Interventional Cardiology*, and R. Sanz-Ruiz is section editor of *REC: Interventional Cardiology*. In both cases, the journal's editorial procedure to ensure impartial handling of the manuscript has been followed. The remaining authors declared no conflicts of interest whatsoever.

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WHAT IS KNOWN ABOUT THE TOPIC?

- The Spanish cardiac catheterization in congenital heart diseases registry provides an annual report describing national activity in procedures performed across all age groups. The information generated is of great value to professionals involved in this field of cardiology, as well as to patients and their families.

WHAT DOES THIS STUDY ADD?

- This report consolidates the registry in its objective of providing a realistic picture of this activity in patients of all ages.
- A highly significant increase in diagnostic procedures was reported in 2024 due to the addition of cases from the ACI-SEC registry.
- Pulmonary valve implantation procedures increased, with an increasingly high proportion of procedures performed in the native outflow tract using self-expanding valves. VSD closure, PFO-ASD closure, and aortic angioplasty remain among the highest-volume procedures for congenital heart disease.
- Device embolizations and vascular complications were the most frequent procedure-related adverse events this year.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M26000613.

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Review article

Role of mechanical circulatory support in mechanical complications of acute myocardial infarction

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ABSTRACT

Mechanical complications of acute myocardial infarction—ventricular septal rupture, papillary muscle rupture, and free-wall rupture—are rare (< 0.3%) but lethal, with in-hospital mortality rates of 40% to 90%. These conditions may cause cardiogenic shock and require management at high-volume surgical centers by a multidisciplinary heart team. Mechanical circulatory support (MCS), including intra-aortic balloon pump (IABP), Impella, and venoarterial extracorporeal membrane oxygenation (VA-ECMO) may serve as a bridge to hemodynamic stabilization before definitive surgical or percutaneous repair. IABP reduces afterload and shunt fraction, Impella provides active left ventricular unloading, and VA-ECMO provides full cardiopulmonary support in refractory shock. The 2025 American College of Cardiology/American Heart Association guidelines recommend individualized use of short-term MCS (class IIa–IIb; level of evidence, B–C). Randomized trials of cardiogenic shock have excluded these patients; therefore, the available evidence is derived from registries and observational series subject to substantial selection bias. In postinfarction ventricular septal defect, IABP is generally considered first-line support, although VA-ECMO is often required. Delayed surgery (> 7 days) is associated with improved outcomes, although selection bias remains an important confounder. Papillary muscle rupture requires emergency surgery, with IABP used as a bridge; Impella should be used cautiously. Free-wall rupture also mandates emergency surgery; and VA-ECMO may serve as a bridge. MCS may provide time for stabilization and recovery, but no mortality benefit has been conclusively demonstrated. Optimal use requires expert multidisciplinary care.

Keywords: Cardiogenic shock. Mechanical complications. Mechanical circulatory support.

Papel del soporte circulatorio mecánico en las complicaciones mecánicas del infarto agudo de miocardio

RESUMEN

Las complicaciones mecánicas del infarto agudo de miocardio, rotura del septo interventricular, rotura del músculo papilar y rotura de la pared libre, son raras (< 0,3%), pero letales, con una mortalidad hospitalaria del 40-90%. Estas afecciones cursan con *shock* cardiogénico y requieren tratamiento en centros con experiencia quirúrgica cardiaca y equipos multidisciplinarios. El soporte circulatorio mecánico (SCM)—balón de contrapulsación intraaórtico (BCIAo), Impella y oxigenador extracorpóreo de membrana venoarterial (ECMO-VA)—actúa como puente a la estabilización hemodinámica antes de la reparación definitiva. Las guías 2025 del *American College of Cardiology* y la *American Heart Association* recomiendan SCM individualizado (clase IIa-IIb, nivel de evidencia B-C). Los ensayos aleatorizados han excluido estas complicaciones; la evidencia procede tanto de registros como de series observacionales. En la rotura del septo interventricular, el BCIAo es de primera línea, aunque el ECMO-VA suele ser necesario; la cirugía diferida (> 7 días) mejora los resultados. La rotura del músculo papilar requiere cirugía urgente con BCIAo como puente. La rotura de la pared libre exige cirugía urgente; el ECMO-VA puede ser el tratamiento puente. El SCM gana tiempo pero no se ha demostrado su beneficio en cuanto a mortalidad.

Palabras clave: *Shock* cardiogénico. Complicaciones mecánicas. Soporte circulatorio mecánico.

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Abbreviations

AMI: acute myocardial infarction. **IABP:** intra-aortic balloon pump. **LV:** left ventricular. **MCS:** mechanical circulatory support. **PIVSD:** postinfarction ventricular septal defect. **PMR:** papillary muscle rupture. **VA-ECMO:** venoarterial extracorporeal membrane oxygenation. **VSR:** ventricular septal rupture.

INTRODUCTION

Mechanical complications of acute myocardial infarction (AMI)—ventricular septal rupture (VSR), papillary muscle rupture (PMR) causing acute mitral regurgitation, and free wall rupture—are rare but catastrophic events that typically occurr 3 to 7 days after AMI. They present with acute heart failure, cardiogenic shock, a new murmur, or hemodynamic collapse, and are associated with mortality rates of 40% to 90%, depending on the lesion type, severity of shock, and diagnostic delay.[1-3]

Despite advances in reperfusion, their incidence has declined to < 0.3% of AMI cases; however, mortality remains disproportionately high (in-hospital mortality for VSR and PMR: 40%–80%; mortality for free-wall rupture without surgery, nearly 100%).[1-3] Early recognition using echocardiography is critical. Both the European Society of Cardiology and the American College of Cardiology guidelines recommend management at centers with cardiac surgical expertise and heart teams.[4,5] Surgical repair is the definitive treatment, but operative mortality remains high (30%–50%), particularly among patients with shock or multiorgan dysfunction. Delayed surgery (> 7 days) may improve outcomes by allowing maturation of the infarcted tissue, although the apparent survival benefit is confounded by immortal time bias and patient selection.

The central therapeutic challenge is to achieve sufficient hemodynamic stabilization to permit definitive intervention without incurring device-related complications. Mechanical circulatory support (MCS) devices—including intra-aortic balloon pump (IABP), Impella, and venoarterial extracorporeal membrane oxygenation (VA-ECMO)—are the main tools for this purpose (figure 1).[1,3,6]

In mild-to-moderate shock, IABP may provide initial stabilization; in severe or refractory shock, escalation to Impella or VA-ECMO may be required. The 3 complications differ substantially in their pathophysiology and hemodynamic effects, requiring individualized device selection[5] (table 1).

Prolonged MCS is associated with time-dependent increases in major complications including bleeding (30%–50%), limb ischemia, renal failure, stroke, and hemolysis. Complication rates increase with the duration of support and may influence the timing of definitive intervention.[10,11]

Postinfarction ventricular septal defect

Postinfarction ventricular septal defect (PIVSD) occurs in approximately 0.2% to 0.3% of AMI cases. Without repair, 30-day mortality approaches 80%; overall surgical mortality for all-comers remains 30%–50% and is among patients undergoing emergency repair in the setting of shock.[22]

The underlying pathophysiological mechanism is full-thickness septal necrosis with an abrupt left-to-right shunt, resulting in acute right ventricular volume overload, reduced systemic cardiac output, and pulmonary edema. Anterior or apical defects predominate, whereas inferior or posterior defects are more complex and are frequently accompanied by ischemic mitral regurgitation and right ventricular dysfunction.[7,22]

Patients typically present with a new, harsh systolic murmur and rapid hemodynamic deterioration. Diagnosis relies on emergency echocardiography to assess defect location and size, the pulmonary-to-systemic blood flow ratio (Qp:Qs), and biventricular function. Hemodynamic assessment demonstrates a step-up in oxygen saturation at the right ventricular level and elevated pulmonary capillary wedge pressure. Multimodality imaging, including transesophageal echocardiography, computed tomography, and cardiac magnetic resonance imaging, can further define the anatomy and inform the choice between surgical and transcatheter treatment. However, most patients are too unstable to undergo imaging beyond bedside echocardiography.[23,24]

Surgical repair remains the standard of care. Percutaneous closure is an alternative for patients at prohibitive surgical risk or may be used as a temporizing measure. Both approaches are associated with higher mortality when performed during the acute phase (< 7 days). Delayed surgery (> 7 days), which allows maturation of necrotic tissue, has been associated with better outcomes in observational studies. However, this association may reflect patient selection rather than a true treatment effect, because delayed surgery may be a marker of survival to intervention rather the benefit.[12,13] Prolonged MCS as a bridge to definitive treatment carries substantial risks, including hemolysis requiring device removal, limb ischemia in up to 12.5% of patients undergoing femoral cannulation, and progressive organ failure. These complications frequently require earlier intervention than initially intended.[11]

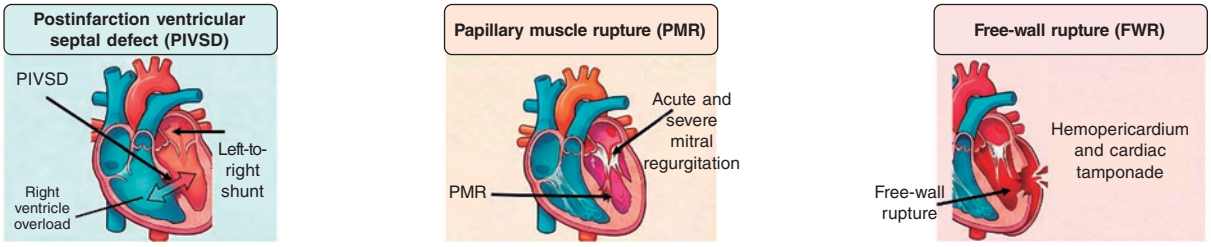
Intra-aortic balloon pump

IABP support reduces systemic vascular resistance by approximately 15%, decreases the left-to-right shunt ratio (Qp:Qs) by 22% (eg, from 3.1 to 2.4), and increases systemic cardiac output by 12% (eg, from 2.1 L/min to 2.4 L/min) in PIVSD.[14] Its mechanism—diastolic balloon inflation to augment coronary perfusion and presystolic deflation to reduce left ventricular (LV) afterload—directly addresses the hemodynamic consequences of VSR. IABP is the recommended first-line MCS device for hemodynamic stabilization in PIVSD.[7,25]

A single-center cohort found that IABP use in patients with shock was associated with lower 30-day mortality than no IABP (61% vs 100%), and all patients who did not undergo repair died within 3 days.[8] However, the 100% mortality observed without IABP in small cohorts likely reflects selection bias and confounding by indication rather than proven IABP efficacy. A systematic review of 2440 patients with PIVSD found that 93% received IABP support and that in-hospital mortality was 52%.[7] No randomized data are available specifically for PIVSD because the IABP-SHOCK II trial excluded patients with mechanical complications.[26]

IABP is often insufficient in patients with severe cardiogenic shock with multiorgan dysfunction. Escalation to higher-level MCS is required when instability persists because of the device's limited effect on cardiac output.

Mechanical circulatory support in mechanical complications after acute myocardial infarction



PIVSD *Left-to-right shunt · RV volume overload*	PMR *Acute severe MR · Pulmonary edema*	FWR *Cardiac tamponade · Hemodynamic collapse*
[IABP] First-line support for mild-to-moderate cardiogenic shock **[VA-ECMO]** Indicated for severe or refractory shock ± LV venting **[Impella]** Reserved for selected cases (shunt direction must be monitored closely) ⚠ *Impella may reverse the shunt from left-to-right to right-to-left if LV pressure falls below RV pressure. Closely monitor oxygen saturation*	**[IABP]** First-line support for mild-to-moderate cardiogenic shock **[VA-ECMO]** Indicated for severe or refractory shock ± LV venting **[Avoid Impella]** risk of further valvular injury ⚠ *Peripheral VA-ECMO increases LV afterload and may worsen pulmonary edema. An LV venting strategy should always be planned*	**[VA-ECMO]** Reserved for cardiac arrest or hemodynamic collapse as a bridge to the OR **[Contraindicated]** IABP and Impella ⚠ *Cardiac tamponade severely restricts venous return. Pericardiocentesis should be performed first. Neither IABP nor Impella relieve tamponade*
▼ **Intervention strategy**	▼ **Intervention strategy**	▼ **Intervention strategy**
PIVSD — intervention strategy ► **Primary goal:** delay surgery > 7 days for tissue maturation ► **Bridge with MCS:** IABP as first-line support; VA-ECMO if refractory ► **Emergency repair:** if refractory shock despite MCS ► **Percutaneous closure:** prohibitive surgical risk or bridge	**PMR — intervention strategy** ► **Primary goal:** emergency surgery within 24 hours ► **Bridge with MCS:** IABP as first-line support; VA-ECMO if refractory ► **Valve repair:** reserved for selected cases of partial PMR (< 25% of cases) ► **TEER:** prohibitive surgical risk with suitable anatomy	**FWR — intervention strategy** ► **Primary goal:** immediate surgical repair—no delay is acceptable ► **Temporary stabilization:** perform pericardiocentesis while activating the cardiac surgical team ► **VA-ECMO:** reserved for patients in cardiac arrest as a bridge to the OR ► **IABP/Impella:** contraindicated and have no role

[IABP] First-line (afterload reduction) **[Impella]** Selective / Caution (active LV unloading) [**VA-ECMO]** Full cardiopulmonary support / Refractory shock **[DEVICE]** Contraindicated / Not indicated.

All patients must be transferred urgently to expert centers with comprehensive cardiac surgical, interventional, and MCS capabilities. All decisions require a multidisciplinary heart team.

Figure 1. Central illustration. Decision algorithm for selecting MCS stratified by the type of mechanical complication and severity of cardiogenic shock. All patients should be transferred urgently to high-complexity centers with comprehensive cardiac surgical, interventional cardiology, and MCS capabilities. Evidence basis: 2025 American College of Cardiology/American Heart Association guidelines (Class IIa–IIb recommendations, Level of Evidence B–C); Ronco et al. 2021[7] (PIVSD systematic review, n = 2440); Kettner et al. 2013[8] (IABP in VSR/PMR); Matteucci et al. 2021[9] (FWR surgical outcomes). FWR, free-wall rupture; IABP, intra-aortic balloon pump; LV, left ventricular; MCS, mechanical circulatory support; MR, mitral regurgitation; OR, operating room; PIVSD, postinfarction ventricular septal defect; PMR, papillary muscle rupture; RV, right ventricular; TEER, transcatheter edge-to-edge repair; VA-ECMO, venoarterial extracorporeal membrane oxygenation.

Impella

Impella-mediated LV unloading reduces LV end-diastolic pressure and afterload, thereby lowering pulmonary capillary wedge pressure and the left-to-right shunt fraction.[25] In the systematic review by Ronco et al., only 17 of 2240 patients with PIVSD received Impella support; the in-hospital mortality rate was 35%, and complications included hemolysis, stroke, and LV thrombus.[7]

An important caveat is that Impella may reduce LV pressure below right ventricular pressure, particularly at excessive pump flow or in the presence of large defects, thereby promoting right-to-left shunting, systemic desaturation, and cerebral or coronary hypoxia.[7] Expert consensus therefore considers PIVSD a relative contraindication to Impella support. Impella may nevertheless be used selectively for temporary LV unloading as a bridge to definitive closure, with careful monitoring of shunt direction and hemodynamic response.

A retrospective case series of 4 patients showed that preoperative Impella 5.5 implantation performed under local anesthesia in 3 patients, permitted a mean time to surgery of 9.8 ± 3.1 days, and 75% of patinets were successfully weaned from support postoperatively.[27]

Venoarterial extracorporeal membrane oxygenation

VA-ECMO provides full cardiopulmonary support and is the only device capable of fully stabilizing patients with refractory cardiogenic

Table 1. Summary of MCS device selection in mechanical complications of AMI

Clinical scenario	PIVSD		PMR		FWR
Intervention	**Surgical repair**	**Percutaneous closure**	**Surgery/MVR**	**TEER (selected)**	**Emergency surgery**
Timing	Delayed (> 7 days) preferred; emergent if refractory shock	Bridge to surgery or alternative in patients at prohibitive surgical risk	Emergency (< 24 h) in most cases	Prohibitive surgical risk and suitable anatomy	Immediate surgery; pericardiocentesis only as temporizing measure
In-hospital mortality	30%–50%[12]	High; limited data[13]	18%–25%[2]	Limited data[17]	> 50% even with surgery[20]
IABP role	**[FIRST-LINE]** Reduces SVR and left-to-right shunting (Qp:Qs reduced by 22%)[7,14]	**[ADJUNCT]** Provides supportive hemodynamic assistance	**[FIRST-LINE]** Reduces the regurgitant fraction and increases CO by approximately 0.5 L/min[8]	**[ADJUNCT]** Provides supportive hemodynamic assistance	**[NOT INDICATED]** Does not address cardiac tamponade[21]
Impella role	**[SELECTIVE]** Active LV unloading; risk of right-to-left shunting if LV pressure falls below RV pressure[7]	**[SELECTIVE]** Requires close monitoring of shunt direction	**[CAUTION]** The inflow cannula may worsen MR or cause chordal injury[18]	**[CONTRAINDICATED]**	**[CONTRAINDICATED]** May increase bleeding through the rupture site[21]
VA-ECMO role	**[REFRACTORY SHOCK]** Provides full cardiopulmonary support; LV venting recommended[7]	**[SALVAGE]** May serve as a bridge to definitive repair	**[SALVAGE]** May serve as a bridge to surgery but is associated with a high complication rate and 39% mortality[19]	**[NOT STANDARD]**	**[BRIDGE TO OR]** Effectiveness may be limited by impaired venous return due to tamponade; independent predictor of operative mortality[9]
MCS complications	Hemolysis, limb ischemia (up to 12.5%), bleeding, AKI; risk increases with support duration[11]		Bleeding, limb ischemia, renal failure; Impella-related mitral valve injury[10,18]		Bleeding, inadequate VA-ECMO flow; high operative mortality with preoperative VA-ECMO[9]
Key evidence	Ronco et al.[7] 2021 Kettner et al.[8] 2013 Ronco et al.[15] 2023	Giblett et al.[13] 2020	Massimi et al.[16] 2025 Kettner et al.[8] 2013	Haberman et al.[17] 2025	Matteucci et al.[9] 2021

AKI, acute kidney injury; AMI, acute myocardial infarction; CO, cardiac output; ECMO, extracorporeal membrane oxygenation; FWR, free-wall rupture; IABP, intra-aortic balloon pump; LV, left ventricular; MCS, mechanical circulatory support; MR, mitral regurgitation; MVR, mitral valve replacement; OR, operating room; PIVSD, postinfarction ventricular septal defect; PMR, papillary muscle rupture; Qp,Qs, pulmonary-to-systemic flow ratio; RV, right ventricular; SVR, systemic vascular resistance; TEER, transcatheter edge-to-edge repair; VA-ECMO, venoarterial extracorporeal membrane oxygenation.
Badge colours: **[FIRST-LINE]** green = first-line; **[SELECTIVE/CAUTION]** orange = selective or caution; **[SALVAGE]** purple = refractory shock/salvage; **[CONTRAINDICATED]** red = contraindicated or not indicated.

shock or multiorgan failure complicating PIVSD.[25] Peripheral VA-ECMO increases mean arterial pressure through retrograde aortic flow but also increases LV afterload, which may exacerbate pulmonary edema and potentially increase the left-to-right shunting. LV venting with an IABP or Impella is recommended in the presence of refractory pulmonary edema, increasing pulmonary capillary wedge pressure, absent aortic valve opening, or a spherically dilated LV on echocardiography.[5,6,10]

In the systematic review, 144 of 2440 patients received VA-ECMO as a bridge therapy to definitive treatment; the in-hospital mortality rate was 29%, and major complications including bleeding, limb ischemia, and coagulopathy.[7] Small case series have demonstrated the feasibility of VA-ECMO as a bridge to delayed repair, typically performed after 5 to 14 days, with survival to hospital discharge in approximately one-half to two-thirds of patients who ultimately underwent repair.[28-30]

ECpella, consisting of combined VA-ECMO and Impella support, can unload the LV while providing full systemic circulatory support. Registry data indicate that ECpella is feasible but associated is with high complication rates and has not demonstrated lower in-hospital mortality compared with VA-ECMO plus IABP or VA-ECMO alone.[3] The European survey by Ronco et al. documented substantial heterogeneity in current management strategies.[15]

PAPILLARY MUSCLE RUPTURE

PMR complicates < 0.1% of AMI cases but is associated with an in-hospital mortality rate of 20% to 40% even with surgical intervention, and 80% without surgery.[2,3,6,31] The posteromedial papillary muscle is more frequently affected because it typically receives its blood supply solely from the posterior descending artery. Complete rupture causes immediate hemodynamic collapse, whereas partial rupture may permit transient stabilization.

The pathophysiological mechanism is acute, severe mitral regurgitation causing sudden volume overload of a normal-sized LV and left atrium, leading to rapid-onset pulmonary edema and reduced cardiac output. Unlike in chronic mitral regurgitation, these chambers cannot accommodate the abrupt increase in volume, resulting in a fulminant clinical presentation.

Diagnosis relies on echocardiography, which may demonstrate a flail mitral leaflet, severe mitral regurgitation, and direct visualization of the ruptured papillary muscle. Mitral valve replacement is the standard treatment. Mitral valve repair may be feasible in selected patients with partial PMR cases but is associated with higher recurrence rates.[16] Emergent surgery within 24 hours is recommended. In patients at prohibitive surgical risk, transcatheter edge-to-edge repair may be considered when the anatomy is suitable.[17]

Intra-aortic balloon pump

IABP is the recommended first-line MCS for PMR. Afterload reduction decreases the regurgitant fraction across the mitral valve and improves forward cardiac output. A cohort study found IABP use was associated with lower 30-day mortality (61% vs 100%; $P = .04$) and lower preoperative mortality (11% vs 88%; $P < .001$) compared with no IABP use among patients with acute mitral regurgitation and cardiogenic shock.[8] These comparisons were observational and subject to selection bias; nevertheless, IABP remains recommended because its mechanism directly reducies regurgitant volume.

Impella

Impella should be used cautiously in patients with PMR. The inflow cannula may directly traumatize the mitral valve apparatus, including the chordae thendineae or papillary muscle structures, potentially worsening regurgitation.[18] In the setting of PMR with mobile or detached fragments, the risk of further structural damage, device malfunction, or embolization is heightened. Evidence is limited to case series and expert opinion.[1,2]

Venoarterial extracorporeal membrane oxygenation

VA-ECMO can stabilize end-organ perfusion in refractory shock as a bridge to surgery. Observational multicenter data indicate VA-ECMO is used preoperatively in approximately 10% of surgically treated patients with PMR; however, in-hospital mortality remains high (39% vs 22% among surgical patients not receiving VA-ECMO).[19,32] The poorer outcomes observed in the VA-ECMO group likely reflect greater baseline severity and higher complication rates, including bleeding, limb ischemia, renal failure. Peripheral cannulation increases LV afterload and may worsen pulmonary edema; therefore, LV venting strategies should be planned when VA-ECMO is initiated.

FREE-WALL RUPTURE

Free-wall rupture is a distinct clinical emergency requiring immediate surgical intervention. It differs fundamentally from PIVSD and PMR because no MCS device can substitute for surgical repair. It typically results from transmural infarction, causing hemopericardium and cardiac tamponade with rapid hemodynamic collapse. In-hospital mortality exceeds 50% even with surgery and approaches 100% without surgical treatment.[20]

Emergency surgery is the only potentially curative intervention. Pericardiocentesis may provide temporary relief of tamponade but must be followed by definitive surgical repair.[3]

Intra-aortic balloon pump and Impella

Neither IABP nor Impella has an established role in free-wall rupture. These 2 devices are designed to treat pump failure rather than structural disruption or cardiac tamponade. Impella is specifically contraindicated in LV rupture because it cannot provide effective support when ventricular chamber integrity is lost and may increase bleeding through the rupture site.[21] IABP may have a very limited temporizing role in subacute or oozing ruptures but is ineffective in classic free-wall rupture with rapid hemodynamic collapse.

Venoarterial extracorporeal membrane oxygenation

VA-ECMO may be used as salvage therapy to maintain end-organ perfusion while emergency surgery is arranged, particularly in patients with cardiac arrest.[33,34] A critical limitation in free-wall rupture is that cardiac tamponade severely restricts venous return, thereby limiting VA-ECMO flow and effectiveness. Inadequate venous drainage through the inferior vena cava cannula may render support partially or completely ineffective. Furthermore, a multicenter study identified preoperative VA-ECMO use in patients with free-wall rupture as an independent predictor of increased operative mortality.[9] In patients presenting with cardiac arrest, VA-ECMO bedside cannulation may nevertheless represent the only means of temporary stabilization before emergency surgical repair.

DISCUSSION

Mechanical complications of AMI remain clinically relevant despite their declining incidence because the associated morbidity and mortality remain extremely high. Several key messages emerge from this review of the available evidence.

First, all patients with suspected mechanical complications should be transferred urgently to high-complexity centers with comprehensive cardiac surgery, interventional cardiology, advanced MCS, cardiac imaging, and intensive care capabilities. Multidisciplinary heart team decision-making is essential and has been associated with improved adherence to clinical guidelines and better outcomes in patiens with cardiogenic shock.[1,5]

Second, in severe refractory cardiogenic shock, VA-ECMO is the only device capable of providing full cardiopulmonary support irrespective of native cardiac function. IABP and Impella provide only partial support and may be insufficient in patients with multiorgan failure. The objective of MCS is to maintain end-organ perfusion as a bridge to definitive repair, not to replace it.

Third, in patients with PIVSD or PMR, appropriate MCS may permit delayed surgical intervention, which has been associated with improved outcomes in observational data. Although the apparent benefit of delayed surgery may partly reflect survivorship bias, there is a plausible biological rationale: maturation of necrotic tissue reduces intraoperative friability and may improve the durability of repair. Future trials should determine whether protocolized MCS-based bridging strategy improve outcomes beyond the effects of patient selection.[12,13]

Fourth, free-wall rupture is a fundamentally different emergency in which surgery is the only potentially lifesaving intervention. VA-ECMO may serve as a bridge in patients with cardiac arrest, although its effectiveness may be limited by impaired venous return due to cardiac tamponade. IABP and Impella have no established role.

The absence of randomized trial evidence in this population is a major limitation. Trials such as IABP-SHOCK II, DANGER-SHOCK, ECLS-SHOCK, and ECMO-CS excluded patients with mechanical complications.[26,35-37] The European survey by Ronco et al.[15] documented substantial heterogeneity in current management, underscoring the need for standardized treatment protocols.

Medical therapy alone is associated with near-universal early mortality. Vasoactive drugs should be used cautiously: dobutamine may worsen VSR progression, whereas noradrenaline may increase the severity of mitral regurgitation. Echocardiography, most often performed at the bedside because of patient instability, remains the principal diagnostic modality.

Future research priorities include: *a)* prospective registries incorporating causal inference methods; *b)* pragmatic registry-based trials

and adaptive platform designs; *c)* definition of optimal patient selection and timing for surgical vs percutaneous repair; *d)* evaluation of emerging percutaneous treatments, including transcatheter edge-to-edge repair for PMR and transcatheter closure of VSR; *e)* development and validation of risk stratification tools; and *f)* investigation of the indications for cardiac transplantation and durable left ventricular assist devices.

CONCLUSIONS

Mechanical complications of AMI are life-threatening emergencies in which MCS may serve as a bridge to hemodynamic stabilization before definitive surgical or percutaneous repair. Device selection must be individualized according to the type of mechanical complication, severity of shock, and degree of organ dysfunction. IABP is the preferred first-line device for PIVSD and PMR; VA-ECMO provides the only full cardiopulmonary support in refractory shock; Impella should be used cautiously in both VSR because of the risk of right-to-left shunting and PMR because of the risk of mitral valve injury; and free-wall rupture is a surgical emergency in which IABP and Impella have no established role. Until high-quality evidence becomes available, the use of MCS should be guided by pathophysiological principles and multidisciplinary expertise rather than device-driven enthusiasm. All patients with these complications should be managed at expert centers with comprehensive cardiac surgical, interventional, and MCS capabilities.

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

During the preparation of this work, the authors used a generative artificial intelligence language model (ChatGPT, OpenAI) to assist solely with minor language editing and stylistic refinement of selected passages. All content was subsequently reviewed and edited by the authors, who take full responsibility for the final manuscript. The tool was not used for study design, data analysis, interpretation of results, or the generation of scientific content; these tasks were performed entirely by the authors.

AUTHORS' CONTRIBUTIONS

F. González-Urbistondo and P. Avanzas shared senior authorship. All authors made substantial contributions to this work; participated in drafting the manuscript and critically revised it for important intellectual content; reviewed and approved the final version; and agreed to be accountable for all aspects of the work by ensuring that questions related to the accuracy or integrity of any part of the work are properly investigated and resolved.

CONFLICTS OF INTEREST

None declared.

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Review article

Drug-coated balloons: from evidence to practice and a proposed antithrombotic therapy algorithm

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ABSTRACT

Drug-coated balloons (DCBs) have emerged as an effective "leave-nothing-behind" strategy in percutaneous coronary intervention, offering the potential to reduce the permanent metallic burden, preserve vasomotion, and shorten the duration of antithrombotic therapy. Current DCB technologies include paclitaxel-coated and sirolimus-coated balloons, which differ in drug delivery, tissue retention, and clinical performance. Evidence from randomized clinical trials and meta-analyses supports the use of DCBs in several coronary settings, particularly in-stent restenosis, small-vessel disease, bifurcation lesions, and patients at high bleeding risk. Optimal lesion preparation is essential to maximize procedural success. Antithrombotic management after DCB-only percutaneous coronary intervention remains insufficiently standardized. Based on the available evidence, abbreviated dual antiplatelet therapy, or even single antiplatelet therapy in selected patients at high bleeding risk, appears feasible and safe. DCBs and drug-eluting stents should therefore be regarded as complementary technologies, with their use tailored to lesion complexity, bleeding risk, and individual patient characteristics.

Keywords: Drug-coated balloon. Drug-eluting stent. Coronary artery disease. Antithrombotic therapy.

Balones farmacoactivos: de la evidencia a la práctica y propuesta de un algoritmo de tratamiento antitrombótico

RESUMEN

Los balones farmacoactivos (BFA) se han consolidado como una estrategia eficaz «sin implante» en la intervención coronaria percutánea, ya que ofrecen la posibilidad de reducir la carga metálica, preservar la vasomotricidad y acortar el tratamiento antitrombótico. Las tecnologías actuales de BFA incluyen balones liberadores de paclitaxel y de sirolimus, que difieren en la liberación del fármaco, la retención tisular y el rendimiento clínico. La evidencia procedente de ensayos aleatorizados y metanálisis respalda el uso de los BFA en varios escenarios coronarios, en particular la reestenosis en el interior del *stent,* la enfermedad de pequeños vasos, las lesiones en bifurcación y los pacientes con alto riesgo hemorrágico. Una preparación óptima de la lesión es esencial para maximizar el éxito del procedimiento. El tratamiento antitrombótico tras una intervención coronaria percutánea únicamente con BFA sigue sin estar suficientemente estandarizado. Según la evidencia disponible, las estrategias abreviadas de tratamiento antiagregante plaquetario doble, o incluso simple en determinados pacientes con alto riesgo hemorrágico, parecen viables y seguras. Por lo tanto, los BFA y los *stents* farmacoactivos deben considerarse tecnologías complementarias, cuya selección debe adaptarse a la complejidad de la lesión, el riesgo hemorrágico y las características individuales del paciente.

Palabras clave: Balón farmacoactivo. *Stent* farmacoactivo. Enfermedad coronaria. Tratamiento antitrombótico.

Abbreviations

ACS: acute coronary syndrome. **CCS:** chronic coronary syndrome. **DAPT:** dual antiplatelet therapy. **DCB:** drug-coated balloon. **DES:** drug-eluting stent. **HBR:** high bleeding risk. **ISR:** in-stent restenosis. **PCI:** percutaneous coronary intervention.

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INTRODUCTION

In contemporary interventional cardiology, drug-coated balloons (DCBs) have emerged as a viable, safe, and effective option for percutaneous coronary intervention (PCI) in selected clinical settings involving coronary artery disease.[1]

The appeal of the "leave-nothing-behind" strategy lies in its potential to reduce the thrombotic and bleeding risks associated with permanent metallic implants and prolonged dual antiplatelet therapy (DAPT), preserve coronary vasomotion, and maintain future revascularization options. These advantages are among the reasons why DCBs have gained an established role in the interventional cardiologist's armamentarium.

DCB TECHNOLOGY AND MECHANISM OF ACTION

The antiproliferative agents used in DCBs can be divided into 2 main classes: paclitaxel and sirolimus.[2] Paclitaxel, a well-established antineoplastic agent, is highly lipophilic, which facilitates rapid cellular uptake and enables a sustained biological effect at low doses. Sirolimus, also known as rapamycin, has potent antiproliferative and immunosuppressive properties. Because sirolimus is less well absorbed than paclitaxel, innovative excipients and delivery systems have been developed to enhance drug transfer, tissue retention, and bioavailability. To overcome these issues, microcarriers are therefore used to facilitate the gradual release and dissolution of sirolimus over time.[2]

In a recent large meta-analysis, paclitaxel-coated balloons (PCBs) were associated with significantly lower late lumen loss (LLL) than sirolimus-coated balloons (SCBs), although no significant difference in TLF was observed.[3]

Because DCBs differ in drug type, formulation, transfer kinetics, excipients, and bioavailability, they are not considered to have a class effect.[1-3] The main differences between the antiproliferative drugs used in DCBs are shown in figure 1.

Future DCB technologies may incorporate novel drugs or combinations of 2 drugs within the same balloon platform.[4] Consequently, different DCBs may be more appropriate for specific lesion types or patient profiles, in accordance with the current precision-medicine paradigm.

LESION PREPARATION AND PROCEDURAL TECHNIQUE

The principal goal of balloon angioplasty is to achieve adequate luminal gain in a stenotic coronary segment. Plaque fracture and vessel dissection caused by stretching of the vessel wall are the main mechanisms responsible for luminal gain, although the risk of acute vessel closure increases with the severity of the dissection.[5]

Dissection may be independently associated with late lumen gain and a lower risk of target lesion failure (TLF) after DCB-only PCI. In a retrospective cohort of 328 de novo coronary lesions treated with DCB-only PCI, the absence of dissection was associated with a significantly higher rate of TLF.[6]

Cortese et al.[7] evaluated a cohort of 156 patients treated with DCBs for native coronary artery disease. Final type A-C dissections without impaired distal flow were observed in 52 patients. No significant differences in MACE rates were found between patients with and without dissection.

DCB	Paclitaxel	Sirolimus
Characteristics	Highly lipophilic Anti-restenotic **Cytotoxic-** Arrests cell in G2/M phase Narrow therapeutic rate Fast tissue absorption Long tissue retention Late vessel remmodeling	Less lipophilic Anti-restenotic + **Cytostatic-** Arrests cell in G1/S phase Wide therapeutic range Poor transfer rate Slow tissue absorption Short tissue retention No late vessel remodeling effect
Clinical outcomes	Limited evidence comparing clinical outcomes between PCBs and SCBs Trends favouring PCBs for angiographic outcomes (PCBs have demonstrated greater minimal lumen diameter in de novo lesions than in ISR)	

Figure 1. Characteristics of paclitaxel-coated and sirolimus-coated DCBs. DCB, drug-coated balloon; ISR, in-stent restenosis; MLD, minimal lumen diameter; PCB, paclitaxel-coated balloon; SCB, sirolimus-coated balloon.

In the TRANSFORM trial, 109 patients were randomized to treatment with an SCB or PCB to demonstrate noninferiority in clinical and angiographic outcomes. Although acute dissection volume showed a slight inverse association with LLL among patients treated with a PCB, this association was not observed among those treated with an SCB.[8] Although no differences in clinical outcomes were found, the greater late lumen loss observed with SCBs, particularly in complex lesions, highlights the importance of adequate lesion preparation when using the less lipophilic sirolimus platform.[9]

The ULTIMATE III trial randomized 260 patients with de novo coronary lesions and high bleeding risk to intravascular ultrasound-guided or angiography-guided DCB-only PCI. The primary endpoint of LLL at 7 months was significantly lower with intravascular ultrasound guidance, whereas target vessel revascularization (TVR) did not differ between groups.[10] Further studies are required to establish the role of intravascular ultrasound and optical coherence tomography (OCT) in DCB-guided PCI.

Lesion preparation may involve semicompliant (SC) or noncompliant (NC) balloons, specialized cutting or scoring balloons, using a 1:1 balloon-to-artery ratio based on the distal reference vessel diameter, or calcium-modification techniques, as recommended by the Academic Research Consortium.[11] An adequate angiographic result should be confirmed before DCB delivery (figure 2).

In the presence of residual dissection or angiographically limited acute luminal gain after predilation, fractional flow reserve has been proposed to provide a more accurate assessment of the functional result. Historical data indicate that a fractional flow reserve > 0.90 after balloon angioplasty is a strong predictor of immediate functional improvement and is associated with low restenosis rates at the 2-year follow-up.[12,13]

Patients with residual percent diameter stenosis > 30% or a National Heart, Lung, and Blood Institute coronary dissection of type C or higher have systematically been excluded from clinical trials because of ethical concerns regarding the risk of procedural failure and subsequent complications.[11]

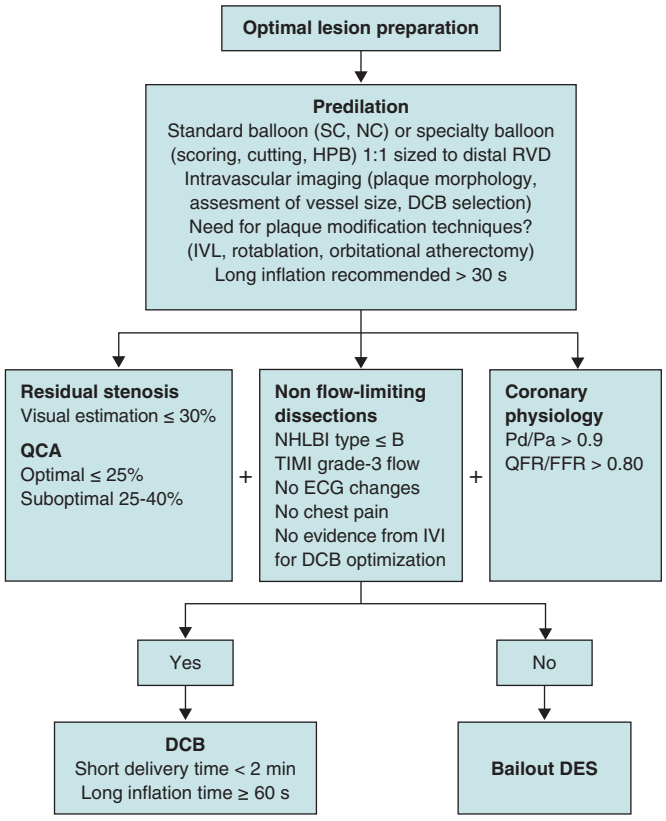


Figure 2. Optimal lesion preparation for drug-coated balloon angioplasty. DCB, drug-coated balloon; DES, drug-eluting stent; ECG, electrocardiogram; FFR, fractional flow reserve; HPB, high-pressure balloon; IVI, intravascular imaging; IVL, intravascular lithotripsy; NC, noncompliant balloon; NHLBI, National Heart, Lung, and Blood Institute coronary dissection classification; Pa, aortic pressure; Pd, distal coronary pressure; QCA, quantitative coronary angiography; QFR, quantitative flow ratio; RVD, reference vessel diameter; SC: semi-compliant; sec, seconds.

CORONARY LESION SUBSETS

In-stent restenosis

Several randomized studies have compared DCBs with plain old balloon angioplasty (POBA) or drug-eluting stents (DESs) for the treatment of in-stent restenosis (ISR), as well as PCBs with SCBs (table 1).[14-25]

The ISAR-DESIRE 3 trial randomized 402 patients with DES-ISR to treatment with POBA, PCB, or paclitaxel-eluting stents (PES). At 10 years, the primary endpoint and major secondary endpoints did not differ significantly between the PCB and PES groups.[18,25]

In the RIBS V trial, the primary endpoint of minimum lumen diameter at 9 months was significantly greater with everolimus-eluting stents than with PCBs ($P < .001$), although clinical outcomes were similar.[15]

In the RIBS IV trial, 309 patients with DES-ISR were randomly assigned to treatment with a PCB or an everolimus-eluting stent. Target lesion revascularization (TLR) rates were significantly lower in the everolimus-eluting stent group at the 1-year ($P = .007$) and 3-year ($P = .015$) follow-up.[20]

In the DARE trial, 278 patients with DES-ISR involving ostial lesions, the left main coronary artery, or bifurcations were randomized to treatment with a PCB or an everolimus-eluting stent. For the primary endpoint of in-segment minimum lumen diameter at 6 months, PCB treatment was noninferior to DES implantation (P for noninferiority $< .0001$). TLR rates were similar at 12-month follow-up.[23]

DAEDALUS was a patient-level meta-analysis of 710 patients from 10 randomized clinical trials comparing DCB angioplasty with repeat DES implantation for ISR. Among patients with bare-metal stent ISR (BMS-ISR), no significant differences were observed between treatments in the primary efficacy or safety endpoints. Among patients with DES-ISR, the risk of the primary efficacy endpoint was significantly higher with DCB angioplasty, whereas the risk of the primary safety endpoint was numerically lower.[26]

In a recent cohort of 160 patients with ISR treated with SCB-based PCI and followed for a median of 1 year, no cardiac deaths were reported. The rates of myocardial infarction (MI), TLR, and TVR were 3.4%, 2.5%, and 6.3%, respectively, which were lower than the 11.1% event rate reported in the DAEDALUS meta-analysis at 1 year.[27]

According to the European clinical practice guidelines on chronic coronary syndromes (CCS), DES implantation is preferred over DCB angioplasty for the treatment of DES-ISR.[28] However, an initial DCB strategy may be preferable in selected cases, reserving implantation of an additional DES layer for DCB treatment failure. A DCB-first approach is particularly appealing for patients with BMS-ISR, multiple pre-existing stent layers, ISR in small vessels, or ISR involving bifurcations. The recommended duration of DAPT after DCB-PCI for ISR is 4 weeks.[29]

All available evidence should be considered when selecting a treatment strategy for ISR. The theoretical advantages of DCBs—avoiding additional metallic layers and shortening antithrombotic therapy—must be balanced against their potentially lower long-term efficacy in this setting.

De novo lesions

Small-vessel de novo disease

The first randomized trials comparing DCBs with DESs for de novo coronary lesions focused on small-vessel disease (table 2).[30-34]

A recent meta-analysis included 4 randomized clinical trials that assigned 1414 participants with vessels < 3 mm to treatment with either a PCB or a DES. No significant differences in MACE rates were observed at 1- or 2-year follow-up.[35] Furthermore, the BASKET-SMALL 2 trial reported no significant differences at 3 years. TVR rates at the 3-year follow-up were likewise similar between groups. Major bleeding was evaluated only in BASKET-SMALL 2 and was significantly less frequent with the PCB strategy at the 2-year follow-up ($P = .03$).[35]

In all trials except RESTORE SVD, antiplatelet therapy consisted of 1 month of DAPT for patients with CCS undergoing PCB-PCI, 3 months for patients undergoing BMS implantation, and 6-12 months for those undergoing DES implantation. All patients with acute coronary syndrome (ACS) received 12 months of DAPT.

Although different DAPT regimens were used after PCI with BMSs or DESs, 3 randomized clinical trials (RCT) used 1 month of DAPT after DCB-PCI in patients with CCS. None showed a statistically significant difference in MACE or TLR between treatment groups, supporting the safety of abbreviated DAPT after DCB-PCI.

Table 1. Randomized controlled trials evaluating drug-coated balloons for in-stent restenosis

Trial	N	Design	Primary endpoint	TLR
BMS-ISR				
PEPCAD II[14]	56	PCB vs PES	LLL: PCB (0.17 ± 0.42 mm) vs PES (0.38 ± 0.61 mm); *P* = .03	PCB (7.6%) vs PES (16.9%); *P* = .17
RIBS V[15]	189	PCB vs EES	MLD: PCB (2.01 ± 0.6 mm) vs EES (2.36 ± 0.6 mm); *P* < .001	PCB (6%) vs EES (1%); *P* = .09
TIS[16]	136	PCB vs EES	LLL: PCB (0.09 ± 0.44 mm) vs EES (0.44 ± 0.73 mm); *P* = .0004	PCB (7.3%) vs EES (16.2%); *P* = .11
SEDUCE[17]	50	PCB vs EES	Percentage of uncovered struts per patient: PCB (1.4%) vs EES (3.1%); *P* = .025	PCB (4.2%) vs EES (8%); *P* = .57
DES-ISR				
ISAR DESIRE 3[18,25]	402	POBA vs PCB vs PES	MACE: POBA (72%) vs PCB (55.9%) vs PES (62.4%); *P* < .0001	POBA (58%) vs PCB (43.9%) vs PES (38.6%); *P* < .0001
PEPCAD-China ISR[19]	220	PCB vs PES	LLL: PCB (0.46 ± 0.51 mm) vs PES (0.55 ± 0.61 mm); *P* noninferiority = .0005	PCB (15.6%) vs PES (12.3%); *P* = .48
RIBS IV[20]	309	DCB vs EES	MLD: DCB (1.80 ± 0.6 mm) vs EES (2.03 ± 0.7 mm); *P* < .01	DCB (20%) vs EES (7%); *P* = .007
RESTORE[21]	172	PCB vs EES	LLL: PCB (0.15 ± 0.49 mm) vs EES (0.19 ± 0.41 mm); *P* = .54	PCB (7.0%) vs EES (4.7%); *P* = .51
SELUTION SLR[22]	418	SCB vs control (80% DES or 20% POBA)	TLF: SCB (15.3%) vs DES control (7.1%); *P* = .02	SCB (12.9%) vs DES control (7.1%); *P* = .07
BMS-ISR/DES-ISR				
DARE[23]	278	PCB vs EES	MLD: PCB (1.71 ± 0.51) vs EES (1.74 ± 0.61); *P* for noninferiority < .0001	PCB (8.8%) vs EES (7.1%); *P* = .65
BIOLUX[24]	229	PCB vs SES	LLL: PCB (0.03 ± 0.40 mm) vs SES (0.20 ± 070); *P* = .398	PCB (12.5%) vs SES (10.1%); *P* = .82

DCB, drug-coated balloon; DES, drug-eluting stent; EES, everolimus-eluting stent; LLL, late lumen loss; MLD, minimal lumen diameter; PCB, paclitaxel-coated balloon; PES, paclitaxel-eluting stent; POBA, plain old balloon angioplasty; SES, sirolimus-eluting stent; TLR, target lesion revascularization.

Table 2. Randomized controlled trials evaluating drug-coated balloons for de-novo small vessel disease

Trial	N	Design	Primary endpoint	TLR
PICCOLETO[30]	57	PCB vs PES	DS: PCB (43.6%) vs PES (24.3%); *P* = .029	Not reported
BELLO[33]	182	PCB vs PES	LLL: DCB (0.08 ± 0.38 mm) vs DES (0.29 ± 0.44 mm); *P* for noninferiority = < .001; *P* for superiority = .001)	PCB (4.4%) vs PES (7.6%); *P* = .37
RESTORE SVD[31]	230	PCB vs ZES	DS: PCB (29.6 ± 2.0%) vs ZES (24.1 ± 2.0%); *P* < .001)	PCB (4.4%) vs ZES (2.6%); *P* = .72
PICCOLETO II[32]	232	PCB vs EES	LLL: PCB (0.04 ± 0.28 mm) vs EES (0.17 ± 0.39 mm); *P* for noninferiority = .001; *P* for superiority = .03	PCB (5.6%) vs EES (5.6%); *P* = .8
BASKET SMALL 2[34]	758	PCB vs EES	MACE at 12 months: PCB (7.3%) vs EES (7.5%); *P* = .92	PCB (3.4%) vs EES (4.5%); *P* = .43

DCB, drug-coated balloon; DES, drug-eluting stent; DS, diameter stenosis; EES, everolimus-eluting stent; LLL, late lumen loss; MACE, major cardiovascular adverse events; PCB, paclitaxel-coated balloon; PES, paclitaxel-eluting stent; SVD, small vessel disease; TLR, target lesion revascularization; ZES, zotarolimus-eluting stent.

Large-vessel de novo disease

Evidence regarding DCB use in large-vessel disease is derived from several trials conducted in different clinical settings (table 3).[36-42]

The REC-CAGEFREE I trial investigated the efficacy of PCB angioplasty compared with sirolimus-eluting stent (SES) implantation in 2272 patients with de novo, noncomplex coronary lesions without restrictions on vessel size.[35] At the 3-year follow-up, no significant differences were observed between the PCB and SES groups in cardiovascular death or target vessel myocardial infarction (TVMI). However, clinically driven TLR was significantly more frequent after PCB treatment at 1 year (*P* = .002) and 3 years (*P* < .001). Notably, subgroup analysis according to small- vs nonsmall-vessel disease showed a significant interaction. Among patients with nonsmall-vessel disease, SESs were associated with fewer device-oriented composite endpoint events (*P* < .0001). Among patients with small-vessel disease, PCB and SES strategies produced similar device-oriented composite endpoint rates through 3 years. Major bleeding was numerically less frequent in the PCB group but did not differ significantly between groups.[37]

Table 3. Randomized controlled trials evaluating drug-coated balloons for de-novo large vessel disease

Trial	N	Design	Primary endpoint	TLR
REVELATION[36]	120	PCB vs SES	FFR: PCB (0.92 ± 0.05) vs SES (0.91 ± 0.06); *P* = .27	PCB (3%) vs SES (2%); *P* = 1.0
REC-CAGEFREE-I[37]	2902	PCB vs SES	DoCE: PCB (6.4%) vs SES (3.4%); *P* for noninferiority = .65	PCB (3.1%) vs SES (1.2%); *P* = .0021
SELUTION[38]	3341	SCB vs DES strategies	TVF: SCB (5.3%) vs DES (4.4%); *P* for noninferiority = .02	TVR: SCB (3.3%) vs DES (2.1%); *P* = .04
REC-CAGEFREE-II[39]	1948	PCB only: stepwise DAPT vs standard DAPT	NACE: stepwise DAPT (8.9%) vs standard DAPT (8.6%); *P* for noninferiority = .013	Stepwise DAPT (3.8%) vs standard DAPT (3.6%); *P* = .76
DEBUT[40]	220	PCB vs BMS	MACE: PCB (1%) vs BMS (14%); *P* for noninferiority < .00001; *P* for superiority = .00034	PCB (0%) vs BMS (6%); *P* for noninferiority < .0001; *P* for superiority = .0003
Yu et al.[41]	170	PCB vs DES	LLL: PCB (-0.19 ± 0.49 mm) vs DES (0.03 ± 0.64); *P* for noninferiority = .019	PCB (1.2%) vs DES (3.8%); *P* = .36
PEPCAD NSTEMI[42]	210	PCB vs stent treatment (BMS/DES)	TLF: PCB (3.8%) vs stent treatment (6.6%); *P* = .53; *P* for noninferiority = < .003	PCB (1%) vs stent treatment (1%); *P* = 1.0

BMS, bare-metal stent; DCB, drug-coated balloon; DoCE, device-oriented composite endpoint. DES; drug-eluting stent, FFR; fractional flow reserve; LLL, late lumen loss; MACE, major adverse cardiovascular events; NACE, net adverse clinical events; NSTEMI, non-ST-segment elevation myocardial infarction; PCB, paclitaxel-coated balloon; SCB, sirolimus-coated balloon; SES, sirolimus-eluting stent; TLF, target lesion failure; TLR, target lesion revascularization; TVF, target vessel failure TVR, target vessel revascularization.

The SELUTION trial, recently presented at a major scientific conference, randomized 3341 patients eligible for PCI to an SCB strategy using the SELUTION SLR device or a DES strategy, with randomization performed before lesion preparation.[38] All participants had a de novo lesion in a vessel measuring between 2.0 mm and 5.0 mm. Crossover to DES implantation occurred in 20% of patients assigned to the SCB strategy.

The primary composite endpoint of target vessel failure (TVF) at 1 year comprised cardiac death, TVMI, and clinically driven TVR. Noninferiority was demonstrated in the intention-to-treat analysis. Although the trial had broad inclusion criteria, patients with ST-segment elevation myocardial infarction, chronic total occlusions, ISR, or left main coronary lesions were excluded. Significant interactions were observed according to sex, with worse outcomes for SCB treatment in women; moderate-to-severe calcification, with better outcomes for SCB treatment in calcified lesions; and high bleeding risk, with better outcomes for the SCB strategy.

A recent systematic review and meta-analysis of randomized clinical trials comparing DCBs with DESs in 2961 patients with de novo large-vessel disease found that DCB treatment was associated with risks of TLR, all-cause mortality, cardiac death, MI, and MACE similar to those observed with DES implantation. However, DCB treatment was associated with a higher risk of TVR.[43]

All studies included in this meta-analysis evaluated PCB-based PCI, and the criteria for adequate lesion preparation, balloon inflation time, and angiographic and clinical outcomes varied across studies. Target vessel thrombosis was not reported in these trials and is considered one of the most important safety considerations when deciding whether to use DCB-PCI for large-vessel disease. These methodological differences highlight important areas for future randomized clinical trials.[44]

Bifurcation lesions

DCBs offer several theoretical advantages in bifurcation lesions, particularly when used within a provisional stenting strategy. These advantages include targeted delivery of antiproliferative therapy to the side branch (SB), a lower risk of carina shift and stent thrombosis, and avoidance of stent malapposition and polymer deformation.

Regarding the benefit of DCB treatment of the SB during provisional stenting, the PEPCAD-BIF trial randomized 64 patients with bifurcation lesions and a SB reference diameter of 2.0 mm to 3.5 mm to DCB angioplasty or POBA of the SB. The primary endpoint of LLL and the binary restenosis rate were significantly lower in the DCB group.[45]

Gao et al. conducted the DCB-BIF trial, which compared DCBs with NC balloons for SB treatment in 784 patients with true bifurcation lesions undergoing main-vessel stenting and presenting with a severely compromised SB. The primary composite endpoint of cardiac death, TVMI, or clinically driven TLR was significantly less frequent in the DCB group (*P* = .013), primarily because of a lower rate of TVMI.[46]

In the SPACIOUS trial, Zhou et al. enrolled 230 patients with de novo, non-left-main true bifurcation lesions and randomized them to SCB or PCB angioplasty of the SB. LLL did not differ significantly between groups, whereas binary restenosis was significantly less frequent in the sirolimus group (*P* = .043). Clinical outcomes, including death, MI, and revascularization, were similar between groups.[47]

A meta-analysis by Zheng et al., which included 934 patients from 10 studies, showed that DCB treatment of the SB was associated with lower LLL and a lower rate of binary restenosis than POBA. The rate of MACE at 12 months was also significantly lower in the DCB group.[48] Notably, the DCB-BIF trial was not included in this meta-analysis.

Chronic total coronary occlusions

The treatment of chronic total coronary occlusions has gained increasing clinical importance over the past decade, with growing evidence suggesting that successful PCI may improve symptoms and reduce ischemic burden.[49] DES implantation has potential limitations, and alternative strategies that avoid permanent coronary implants have therefore attracted increasing interest.[50]

In a retrospective analysis of the PROGRESS-CTO Registry, DCBs were used in 454 patients (3.7%). A DCB-only strategy was used in 48.4% of cases. Patients in the DCB-only group had more favorable

angiographic characteristics and a technical success rate similar to that of patients treated with a hybrid DES-DCB strategy. During a median follow-up of 323 days, the DCB-only group had a lower rate of MACE ($P = .032$).[51]

Yan et al.[52] conducted a retrospective analysis of patients with successfully revascularized chronic total coronary occlusions and diffuse distal disease who were treated with either a DES-only or a hybrid DES-DCB strategy. At 24 months, the DES-DCB group had significantly lower MACE rates ($P = .008$) and greater improvement in anginal symptoms ($P < .001$).

In the PICCOLETO X study, Cortese et al.[53] conducted a multicenter registry including 938 patients and compared DCB-only and DCB plus DES strategies. At 12 months, the primary endpoint of TVF occurred in 9.5% of the overall population, with no significant differences between groups.

Panuccio et al.[54] conducted a meta-analysis of 6 observational studies including 2221 patients undergoing PCI for chronic total coronary occlusions and compared DCB-only and hybrid strategies. The primary endpoint of TLR at a mean follow-up of 2.8 years did not differ between groups. Secondary endpoints, including MACE, cardiovascular mortality, TVR, and TVMI, were also similar.

Several RCTs evaluating the use of DCBs in chronic total coronary occlusions are ongoing and should provide more robust evidence in this setting.[55,56]

CLINICAL SCENARIOS

Acute coronary syndrome

Patients with acute coronary syndrome (ACS) have a higher ischemic risk, and concerns remain regarding the feasibility of DCB-PCI in lesions with a high thrombus burden. However, adequate lesion preparation and restoration of Thrombolysis in Myocardial Infarction grade-3 flow may facilitate DCB use in this setting.

The PEPCAD NSTEMI trial evaluated 210 patients with non–ST-segment elevation MI. The PCB-only strategy was noninferior to BMSs and DESs for TLF at 9 months. The overall MACE rate was 6.7% with PCB treatment vs 14.2% with DES implantation. TLR and LLL did not differ significantly between groups. All patients received DAPT for 1 year.[42]

The REVELATION study randomized 120 patients presenting with ST-segment elevation MI and < 50% residual percent diameter stenosis after thrombus aspiration to treatment of the culprit lesion with either a PCB or a SES. During 2-year follow-up, MACE rates did not differ significantly between groups. All patients received DAPT for 1 year.[36]

The REC-CAGEFREE II trial specifically evaluated DAPT duration in patients with ACS treated with PCB-only PCI.[39] Conducted at 41 centers in China, the trial randomized 1948 patients with ACS to either stepwise DAPT de-escalation DAPT, consisting of DAPT for 1 month with ticagrelor, followed by 5 months on ticagrelor monotherapy, and then 6 months of aspirin monotherapy or a standard 12-month regimen of DAPT consisting of aspirin plus ticagrelor. Stepwise DAPT de-escalation was noninferior to 12-month DAPT for the primary composite endpoint of Bleeding Academic Research Consortium (BARC) type 3 or 5 bleeding, all-cause mortality, stroke, MI, and revascularization at 12 months (P for noninferiority = .01). The composite of all-cause mortality, stroke, MI, and revascularization was similar between groups, whereas BARC type 3 or 5 bleeding was less frequent in the de-escalation group.

Notably, only 44% of patients presented with ST-segment elevation or non–ST-segment elevation MI; the remaining patients had unstable angina. The mean PCB diameter was 2.72 mm, placing most treated lesions within the small-vessel category. In addition, only 1 lesion was treated in most patients. These findings suggest that the trial population was highly selected and that the results should not be generalized to the broader ACS population. Nevertheless, this was one of the first RCTs to evaluate DAPT duration in patients treated with DCBs and supports the hypothesis that an abbreviated antiplatelet regimen may be appropriate in selected patients with ACS.

Regarding future perspectives, the ongoing COPERNICAN trial is a Spanish study enrolling patients with ST-segment elevation MI who are randomized to PCB or SES treatment of culprit and suitable nonculprit lesions, either during the index PCI or as part of a staged strategy. The primary endpoint is a 12-month composite of TLF. The antithrombotic regimen is left to the operator's discretion; therefore, prespecified subgroup analyses of the different treatment strategies should provide additional insights. The trial is intended to support the expanding use of DCB-PCI in ACS by evaluating the safety and efficacy profile of this metal-sparing strategy.[57]

Currently, the generally recommended duration of DAPT after either DES implantation or DCB-PCI in patients with ACS remains 12 months.[58]

Patients at high bleeding risk

High bleeding risk (HBR) is an increasingly common clinical scenario among patients undergoing PCI. Increased life expectancy has resulted in a proportional rise in PCI procedures among older patients and those requiring long-term oral anticoagulation.

Patients who experience bleeding after PCI have significantly higher rates of all-cause mortality and adverse outcomes, including nonfatal MI, stroke, and prolonged hospitalization, compared with patients without bleeding.[59]

In the DEBUT trial, 220 patients at HBR were randomized to treatment with a PCB or BMS.[40] At 9 months, the primary endpoint occurred in 14% of patients in the BMS group and 1% of those in the PCB group (P for superiority = .00034). Both groups received only 1 month of DAPT, regardless of whether the clinical presentation was CCS or ACS.

A subgroup analysis of the HBR population in the BASKET-SMALL 2 trial included 758 patients who were randomized to PCB or DES treatment of de novo lesions in small native coronary vessels.[60] MACE rates did not differ significantly between PCB and DES treatment, irrespective of bleeding risk. Although the differences were not statistically significant, major bleeding was less frequent with PCB than with DES treatment among patients without HBR (0.9% vs 3.8%), whereas the corresponding rates among patients with HBR were 4.5% and 3.4%. The numerical increase in bleeding among DES-treated patients without HBR was probably related to the longer duration of DAPT.

In the REC-CAGEFREE II trial described above, 20.6% of patients met HBR criteria. In the stepwise de-escalation group, BARC type 3 or 5 bleeding was significantly less frequent than in the standard-treatment group, while noninferiority was maintained for the primary endpoint. These findings suggest that abbreviated DAPT in patients at HBR may reduce bleeding without increasing ischemic events.[39]

In addition, single antiplatelet therapy (SAPT) has been evaluated in patients at HBR. In a Finnish study, 172 patients, 87% of whom

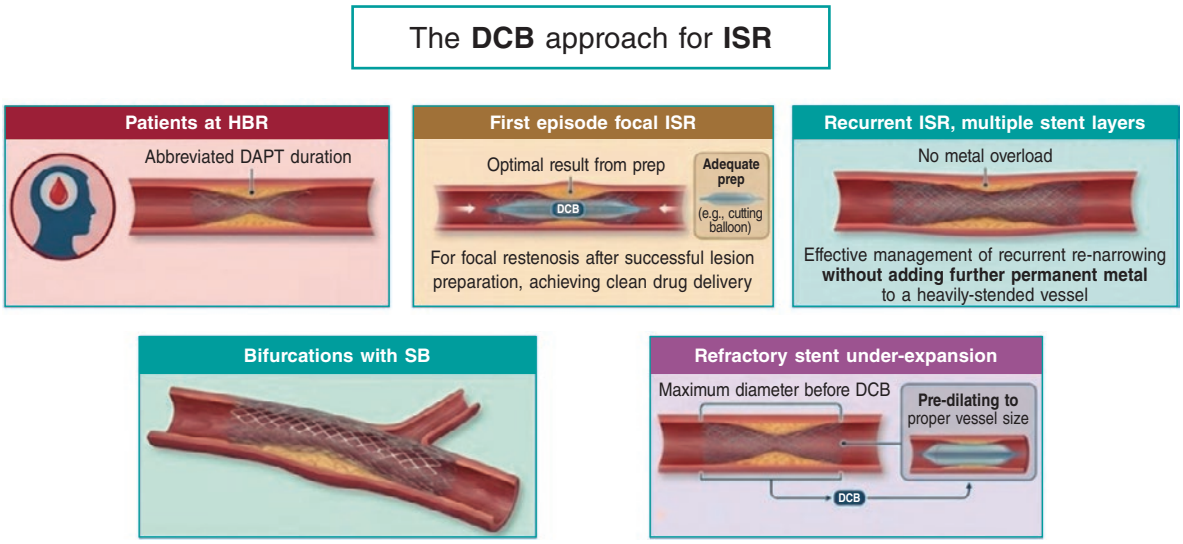


Figure 3. Recommended indications for DCB treatment of ISR. DAPT, dual antiplatelet therapy; DCB, drug-coated balloon; HBR, high bleeding risk; ISR, in-stent restenosis; SB, side branch.

met HBR criteria, underwent DCB-only PCI and were discharged on SAPT.[61] At 1 year, MACE and all-cause mortality rates were 1.4% and 4.1%, respectively, among patients with CCS and 7.1% and 12.1%, respectively, among those with ACS. The rate of clinically relevant bleeding, defined as BARC type 2-5 bleeding, was 10.5% despite the advanced age and high comorbidity burden of the population.

Cortese et al.[62] evaluated 107 patients at HBR who underwent DCB-only PCI and were discharged on SAPT, comparing them with patients treated with DAPT for 6 months. At 1 year, MACE rates did not differ significantly between groups, whereas the cumulative incidence of BARC type 2-5 bleeding was significantly lower in the SAPT group ($P = .04$).

In the EASTBOURNE registry, 2123 patients underwent DCB-PCI for de novo lesions (56.3%) or ISR (47.7%). A subgroup of 113 patients (5.8%) received SAPT.[63] No TLR or abrupt vessel closure occurred in the SAPT group. At 1 year, MACE and TLR rates did not differ between SAPT and DAPT regimens.

Additional details of these 3 studies are shown in table S1.

In conclusion, in patients at HBR undergoing DCB-only PCI, an abbreviated 1-month DAPT regimen may be considered. SAPT may also be considered in selected patients at very high bleeding risk.

The main findings from randomized clinical trials evaluating DCB angioplasty in patients with large-vessel disease, ACS, or HBR are summarized in table 3.

Patients with diabetes and diffuse or multivessel disease

Patients with diabetes often present with complex, diffuse coronary artery disease and a higher risk of restenosis, particularly in small vessels and bifurcation lesions. The stent-sparing nature of DCBs, together with their favorable outcomes in small-vessel disease, suggests that they may be beneficial in this high-risk population. DCBs and DESs should therefore be regarded as complementary devices that can be combined in hybrid strategies to reduce total stent length.

In a retrospective study, 254 patients with multivessel disease successfully treated with DCBs alone or in combination with DESs were included in a DCB-based treatment group and compared with 254 propensity score-matched patients treated with second-generation DESs. The DCB-based strategy was associated with a lower rate of MACE.[64]

In a 3-year subgroup analysis of the BASKET-SMALL 2 trial, TVR rates were significantly lower among patients with diabetes mellitus treated with PCBs ($P = .036$), whereas no significant difference was observed among patients without diabetes.[65] The DAPT strategy used in this study consisted of 1 month of DAPT after PCB-PCI. However, patients with insulin-dependent diabetes mellitus represented only 12.6% of the study population; therefore, no firm recommendation can be made because of the limited sample size.

CURRENT INDICATIONS FOR DCB USE

Based on the evidence and knowledge accumulated in recent years, our recommendations for DCB use are summarized below (figure 3 and figure 4).[66]

In-stent restenosis

We recommend considering DCB treatment in the following settings: *a)* a first episode of focal in-stent restenosis (ISR) with an optimal result after adequate lesion preparation; *b)* recurrent ISR with multiple stent layers; *c)* refractory stent underexpansion; *d)* bifurcation lesions with side-branch involvement. *e)* patients at HBR.

De novo lesions

We recommend considering DCB treatment in the following settings: *a)* small vessels with a reference diameter of < 2.75 mm; *b)* ostial or proximal SB treatment during provisional stenting; *c)* very diffuse disease or long lesions > 25 mm, using a hybrid DCB-DES strategy when appropriate; *d)* lesions in vessels of any size in patients at HBR, particularly those at very HBR.

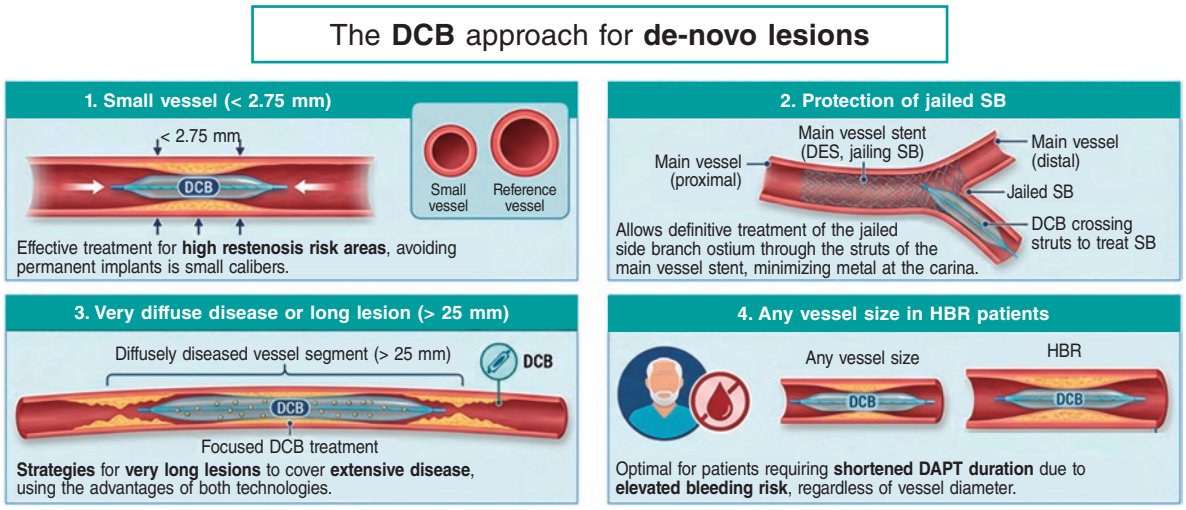


Figure 4. Recommended indications for DCB treatment of de novo lesions. DAPT, dual antiplatelet therapy; DCB, drug-coated balloon; DES, drug-eluting stent; HBR, high bleeding risk; SB, side branch.

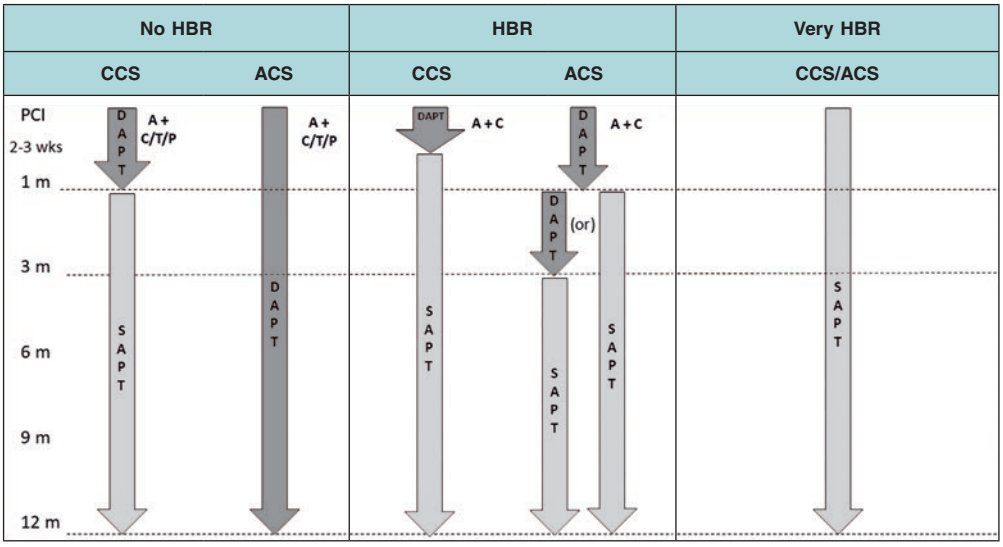


Figure 5. Antiplatelet therapy during the first year after DCB-only PCI in patients without an indication for oral anticoagulation. A, aspirin; ACS, acute coronary syndrome; C, clopidogrel; CCS, chronic coronary syndrome; DAPT, dual antiplatelet therapy; DCB, drug-coated balloon; HBR, high bleeding risk; M, months; P, prasugrel; PCI, percutaneous coronary intervention; SAPT, single antiplatelet therapy; SB, side branch; T, ticagrelor; wk, weeks.

A PROPOSED ANTITHROMBOTIC THERAPY ALGORITHM AFTER DCB-ONLY PCI

The Third Report of the International DCB Consensus Group, published in 2020, was developed in response to the lack of standardization and comparability among DCB studies.[10] The group proposed 4 weeks of DAPT for ISR and de novo lesions in patients with CCS treated with DCB-only PCI. The authors also noted that DAPT duration after DCB treatment could potentially be shortened further in patients at HBR and that oral anticoagulation could be combined with SAPT in selected patients.[10]

According to current European clinical practice guidelines, DAPT after DCB angioplasty is recommended for 6 months in patients with CCS and 12 months in those with ACS. In patients at HBR, 3 months of DAPT is considered appropriate, whereas a 1-month regimen may be considered as an alternative.[28,58]

Our proposed antiplatelet strategy for patients treated with DCB-only PCI is based on a personal interpretation of the reviewed evidence and acknowledges the lack of robust randomized clinical trial data (figure 5 and figure 6).

Bleeding risk is not dichotomous but exists along a continuum and may be divided into at least 3 categories. The PRECISE-HBR score stratifies bleeding risk as follows: very high bleeding risk, defined by a 1-year Bleeding Academic Research Consortium (BARC) type 3 or 5 bleeding rate of ≥ 6% and a score of ≥ 27; HBR, defined by a 1-year rate of ≥ 4% but < 6% and a score of 23-26; and non-HBR, defined by a 1-year rate of < 4% and a score of ≤ 22.[67]

The first consideration is whether the patient requires oral anticoagulation and the degree of bleeding risk, classified as low bleeding risk, HBR, or very HBR. The second consideration is the clinical presentation, namely CCS or ACS.

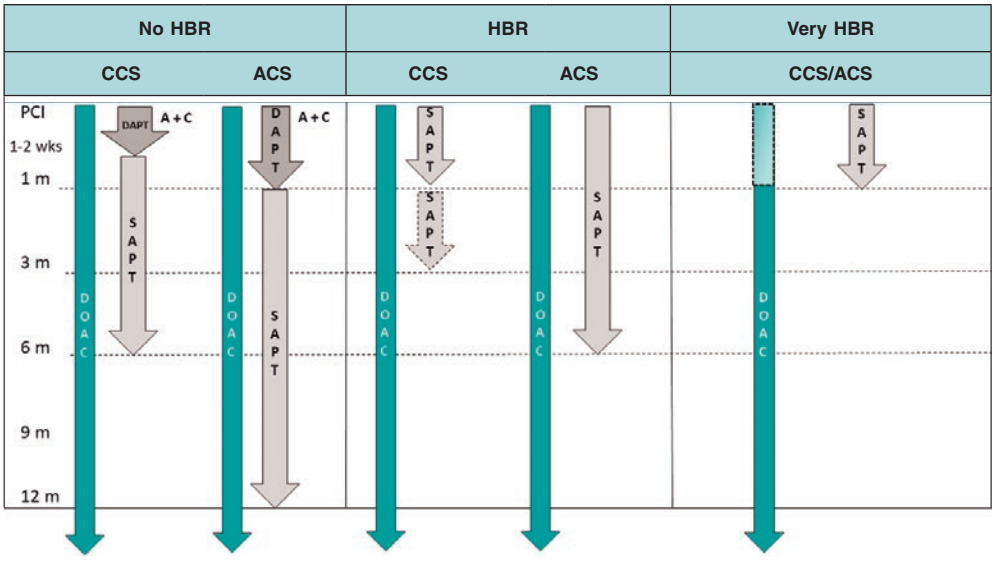


Figure 6. Antithrombotic therapy during the first year after DCB-only PCI in patients with an indication for oral anticoagulation. A, aspirin; ACS, acute coronary syndrome; C, clopidogrel; CCS, chronic coronary syndrome; DAPT, dual antiplatelet therapy; DCB, drug-coated balloon; DOAC, direct oral anticoagulant; HBR, high bleeding risk; M, months; PCI, percutaneous coronary intervention; SAPT, single antiplatelet therapy; wk, weeks.

Recommendations when oral anticoagulation is not required

In patients without HBR, DAPT should be administered for 1 month after DCB-only PCI for CCS and for 12 months after ACS. Any oral $P2Y_{12}$ inhibitor may be used.

Among patients at HBR, those with CCS may receive DAPT for 2-3 weeks followed by SAPT, whereas patients with ACS may receive DAPT for 1-3 months according to individual clinical characteristics. Clopidogrel should be used as the $P2Y_{12}$ inhibitor. The complex group of patients at very HBR may be treated with SAPT alone from hospital discharge, preferably with clopidogrel (figure 5).

Recommendations when oral anticoagulation is required

In patients without HBR, we propose triple therapy with a direct oral anticoagulant (DOAC + DAPT) for 1-2 weeks after PCI for CCS and for 1 month after ACS. This should be followed by dual therapy (DOAC + clopidogrel) for up to 12 months, after which DOAC monotherapy should be continued.

Among patients at HBR, dual therapy with a DOAC plus clopidogrel may be administered for 1-3 months after PCI for CCS and for up to 6 months after ACS. Thereafter, DOAC monotherapy is recommended.

The very challenging group of patients at very HBR may receive dual therapy for 1 month followed by DOAC monotherapy. Alternatively, SAPT may be considered during the first month, followed by DOAC monotherapy (figure 6).

Because evidence in this area remains extremely limited, these recommendations should be regarded as provisional proposals pending validation in future studies.

CONCLUSIONS

Overall, DCBs and DESs should be considered complementary rather than competing technologies. Reducing the permanent metallic burden in complex multivessel disease is an appealing strategy, and hybrid approaches incorporating DCBs are increasingly used in clinical practice.

Current evidence particularly supports DCB use in ISR, small-vessel disease, bifurcation lesions, and patients at HBR, in whom a "leave-nothing-behind" strategy may reduce the metallic burden and permit shorter antithrombotic regimens. Optimal lesion preparation and careful patient selection remain essential to achieve favorable outcomes.

A class effect should not be assumed because individual DCB platforms differ substantially in design, drug formulation, excipient, and delivery characteristics, all of which may influence clinical performance.[68]

Although evidence regarding antithrombotic therapy after DCB-only PCI remains limited, emerging data suggest that abbreviated DAPT, and even SAPT in selected patients at HBR, may be feasible and safe. Future randomized trials are needed to better define the role of DCBs in large-vessel disease and to establish individualized antithrombotic strategies.

In conclusion, DCB angioplasty is an alternative when DES implantation is considered problematic because of anatomical or clinical factors.

Figure 7 provides a comprehensive visual summary of this review as the central illustration.

DCB therapy is currently receiving substantial attention. Over time, the field is likely to reach a more balanced position, consolidating the most appropriate indications and optimal methods of use.[69]

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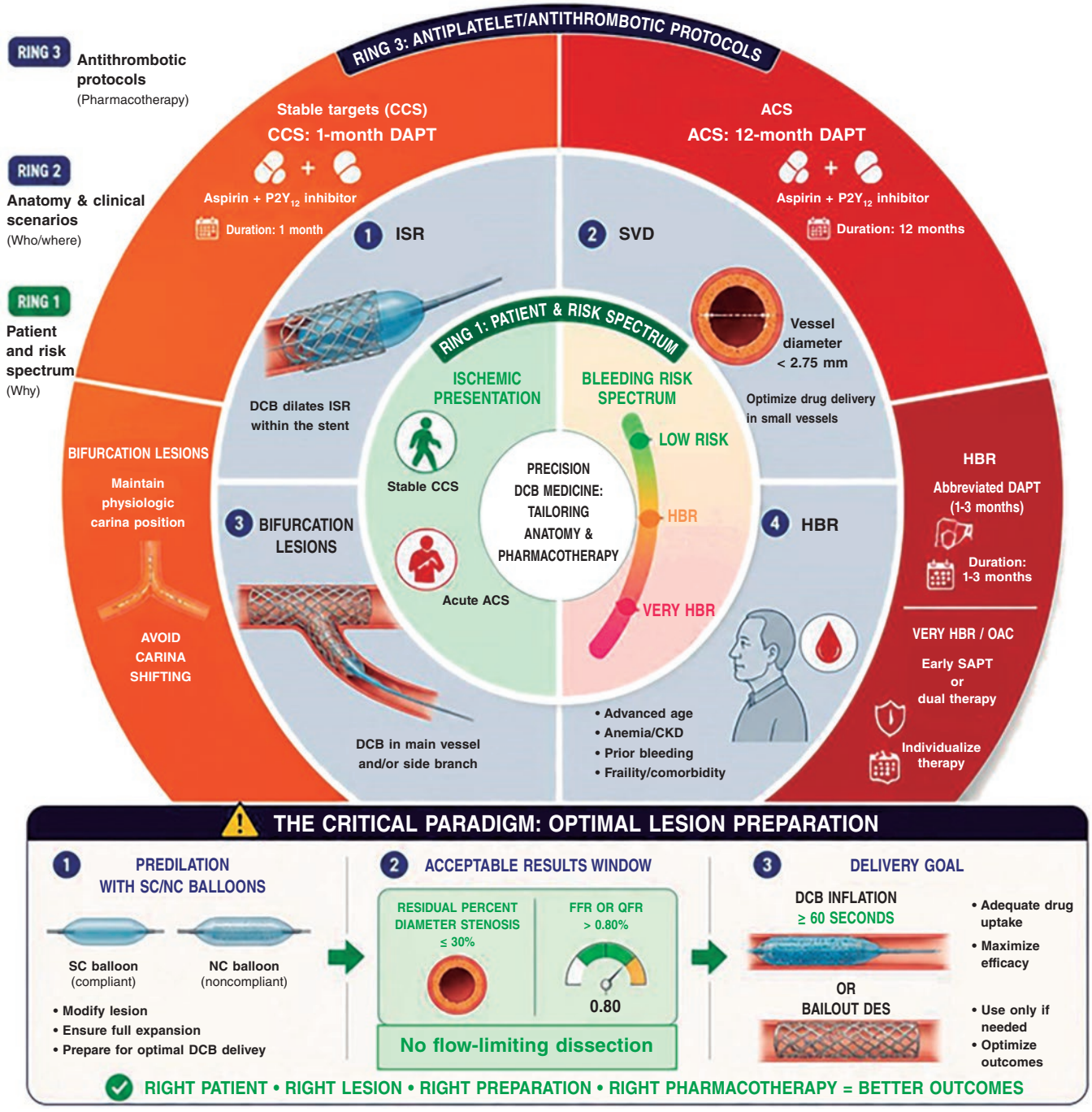


Figure 7. Central illustration. The wheel integrates 3 levels of decision-making: the patient and bleeding-risk profile (ring 1), the anatomical target lesion or high bleeding risk (ring 2), and the corresponding antithrombotic strategy (ring 3). The lower panel summarizes the critical lesion-preparation strategy required to optimize outcomes. ACS, acute coronary syndrome; CCS, chronic coronary syndrome; CKD, chronic kidney disease; DAPT, dual antiplatelet therapy; DCB, drug-coated balloon; DES, drug-eluting stent; FFR, fractional flow reserve; HBR, high bleeding risk; ISR, in-stent restenosis; NC, noncompliant balloon; DOAC, direct oral anticoagulation; QFR, quantitative flow ratio; SAPT, single antiplatelet therapy; SC, semicompliant balloon; SVD, small-vessel disease.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

The authors used Google Gemini solely to develop representative figures illustrating the different applications of drug-coated balloons in clinical settings involving in-stent restenosis and de novo lesions. Canva was used to assist with the design of the central illustration. After using these tools, the authors reviewed and edited the resulting content as necessary and take full responsibility for all content included in the publication.

AUTHORS' CONTRIBUTIONS

J.M. de la Torre-Hernández and R.R. Hernández Caballero conceived the topic and designed the structure of the review. J.M. de la Torre-Hernández, R.R. Hernández Caballero, and S. Siliano performed the literature search and extracted data on coronary drug-coated balloons. R.R. Hernández Caballero and S. Siliano drafted the sections on current clinical evidence and compiled the data presented in the tables. R.R. Hernández Caballero and J.M. de

la Torre-Hernández developed and organized the figures used for the lesion preparation flowchart and the proposed antithrombotic therapy algorithms. All authors critically reviewed and edited the manuscript and approved the final version.

CONFLICTS OF INTEREST

J.M. de la Torre-Hernández is editor-in-chief of *REC: Interventional Cardiology*. The journal's editorial procedure to ensure impartial handling of the manuscript has been followed. J.M. de la Torre-Hernández reports receiving payments from Abbott, Medtronic, Philips, Biotronik, Amgen, Daiichi Sankyo, Boston Scientific, and Novartis for participation as a speaker or advisory board member. R.R. Hernández Caballero and S. Siliano declared no conflicts of interest whatsoever.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M26000610.

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Scientific letter

Late functional gain after drug-coated balloon treatment for de novo coronary lesions

Mejora funcional tardía tras el tratamiento con balón farmacoactivo para lesiones coronarias de novo

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To the Editor,

Drug-coated balloon (DCB) angioplasty has been associated with late lumen enlargement (LLE), a phenomenon in which vessel dimensions increase over time in the absence of permanent scaffolding.[1] Although this angiographic observation is well-documented, the temporal evolution of coronary physiology after DCB treatment remains incompletely characterized. Previous studies have shown that fractional flow reserve improves from baseline to the postoperative period and remains stable at the follow-up;[2,3] however, paired functional improvement from post-procedure to follow-up has not been specifically documented. We therefore performed a paired temporal assessment of late functional gain (LFG), defined as progressive physiological improvement occurring after completion of the index procedure, in patients undergoing DCB angioplasty for de novo coronary lesions.

This study analyzed consecutive patients who underwent DCB treatment for de novo coronary lesions between January 2018 and December 2024 from the CARDIO-FR registry (NCT04185285), a single-center prospective registry that systematically enrolls all consecutive patients undergoing percutaneous coronary intervention at Hospital & University Fribourg. The study protocol was approved by the local ethics committee and conducted in full compliance with the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all patients. Eligible patients aged ≥ 18 years and had available baseline, postoperative, and follow-up coronary angiography performed ≥ 7 days after the index procedure, with adequate image quality for Murray's law-based quantitative flow ratio (μQFR) analysis at all time points. Follow-up angiography was not protocol-mandated in the CARDIO-FR registry; however, for the present analysis, only patients with a follow-up angiography after a DCB angioplasty were included. μQFR assessment was performed using AngioPlus Gallery (Pulse Medical Imaging Technology, China) by 2 independent blinded analysts. For each lesion, the angiographic projection that best visualized the vessel from ostium to distal segment was selected, minimizing overlap and foreshortening. The same projection was used for μQFR assessment at all 3 time points to ensure reproducibility. Lesions with inadequate image quality or inability to match projections across time points were excluded. DCB procedures followed standardized institutional protocols, with lesion preparation at the operator's discretion. Statistical analyses included paired tests for temporal comparisons and regression analyses to identify predictors of functional improvement.

Between January 1, 2018, and December 31, 2024, 4725 patients were included in the registry, of whom 120 underwent DCB-only percutaneous coronary intervention for de novo coronary lesions. Among these, 59 patients (66 lesions) met all inclusion criteria and were included in the analysis. We analyzed a total of 132 angiograms from these 59 patients (age 70 ± 8 years; 22%, women; 37%, diabetic) with 66 de novo lesions (reference vessel diameter. 2.5 [interquartile range (IQR) 1.8-2.8] mm). Lesion preparation used semi-compliant (88%), non-compliant (62%), cutting balloons (28.8%), and intravascular lithotripsy (5.1%). DCB platforms comprised SELUTION SLR (M.A. Med Alliance, Ireland; n = 46, 78.0%, sirolimus-coated), Prevail (Medtronic, United States; n = 10, 16.9%, paclitaxel-coated), MagicTouch (Concept Medical, United States; n = 2, 3.4%, sirolimus-coated), and AGENT DCB (Boston Scientific, United States; n = 1, 1.7%, paclitaxel-coated). At a median angiographic follow-up of 8.5 months [IQR, 6.2-12.3 months], target lesion revascularization (TLR) occurred in 14 (21.2%) of 66 lesions. μQFR improved significantly from 0.88 ± 0.08 at baseline to 0.90 ± 0.07 at follow-up (+0.02; 95%CI, 0.00-0.04; P = .007). Minimal luminal diameter increased from 1.68 ± 0.40 mm to 1.78 ± 0.40 mm (+0.09 mm; 95%CI, 0.01-0.18; P = .036) (figure 1). Physiological trajectories were heterogeneous, with functional improvement predominantly observed in lesions without TLR. After excluding TLR, LFG was even more pronounced at +0.04 (95%CI, 0.01-0.06; P < .001), with minimal luminal diameter increasing by +0.05 mm (95%CI, 0.01-0.18; P = .034).

Higher DCB diameter-to-vessel ratio and longer inflation time predicted functional improvement (+0.01 per 0.1 ratio increase, P = .015; +0.0041 per second, P = .011; respectively). The predilatation maximal diameter-to-vessel ratio emerged as the strongest binary predictor (odds ratio [OR], 17.23; P = .006), followed by DCB maximal diameter-to-vessel ratio (OR, 14.38; P = .011). Exploratory thresholds were identified at DCB balloon-to-vessel ratio > 1.31 (95%CI, 1.03-1.45) and inflation time > 72 seconds, both of which were associated with greater functional gain (+0.05 vs +0.02; P = .012; +0.04 vs +0.02; P = .008, respectively). Lesion preparation characteristics beyond diameter-to-vessel ratio, including

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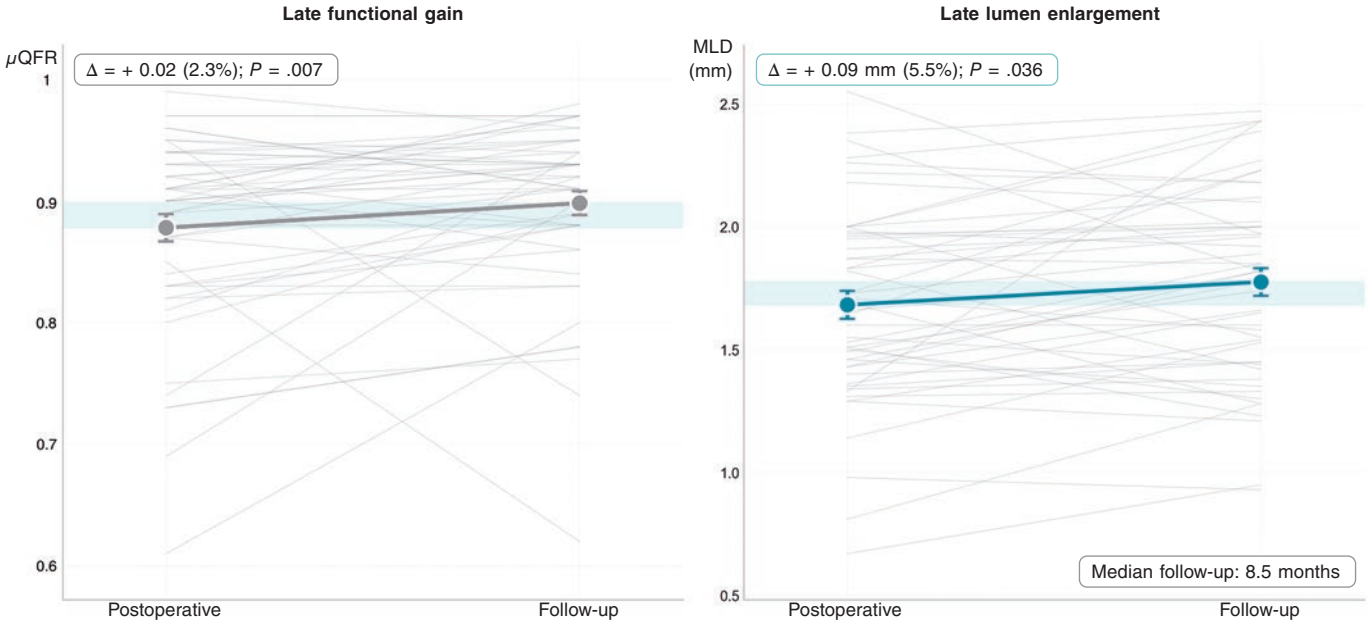


Figure 1. Paired analysis of minimum lumen diameter and Murray's law-based quantitative flow ratio from the postoperative period to follow-up (n = 66 paired lesions). Individual patient trajectories are shown in grey lines and mean values with standard error bars in grey (LFG, left) and green (LLE, right). Absolute and relative changes are displayed. LFG, late functional gain; LLE, late lumen enlargement; μQFR, Murray's law-based quantitative flow ratio.

specialty balloon type, showed no predictive value for functional improvement (all $P > .20$). For LLE, only DCB inflation time predicted enlargement (+0.011 mm per second; $P = .015$). The use of sirolimus-coated balloons showed a trend toward lower likelihood of lumen gain (OR, 0.22; 95%CI, 0.04-1.10; $P = .07$).

This exploratory study reports a paired temporal μQFR assessment of LFG following DCB angioplasty, suggesting progressive coronary physiological improvement from the postoperative period to mid-term follow-up in lesions without revascularization. LFG refers to continued functional recovery beyond the acute procedural result, conceptually distinct from, yet complementary to the established angiographic phenomenon of LLE.[1] The temporal association between anatomical LLE and functional improvement suggests a potential mechanistic relationship; however, the observational design precludes definitive causal inference. Previous physiological assessments using μQFR in the PICCOLETO II trial showed comparable functional performance between DCB and drug-eluting stents at follow-up, with DCB showing relative functional recovery over time.[4] Recent data have also described heterogeneous late physiological trajectories after DCB treatment, including late QFR deterioration in a subset of patients.[5] Our findings extend these observations by identifying procedural determinants associated with functional improvement within a paired within-patient design. This hypothesis-generating observation provides further insight into the biological effects of DCB therapy, suggesting that vascuular healing may continue beyond the index procedure.[6] In contrast to drug-eluting stents, where fractional flow reserve may deteriorate over time, and plain balloon angioplasty, which is often associated with functional decline, DCB treatment may promote progressive physiological improvement, potentially through antiproliferative effects, positive vessel remodeling,[1] and restoration of endothelial function.

Our findings identify 2 procedural determinants associated with functional improvement. First, adequate lesion preparation induces plaque disruption, facilitating optimal drug penetration into the vessel wall. Second, optimized DCB delivery, through appropriate sizing and prolonged inflation, provides mechanical support that prevents elastic recoil and stabilizes dissection planes, thereby reducing the need for bail-out stenting. While drug transfer from sirolimus-coated balloons occurs within 30–45 seconds, prolonged inflation likely provides an additional mechanical benefit beyond drug delivery. Current consensus recommends DCB sizing with a balloon-to-vessel ratio of 0.9–1.3.[6] Our results suggest that ratios toward the upper range may be associated with greater functional gain; however, these findings remain exploratory and should be individualized according to vessel anatomy, lesion characteristics, and operator experience.

Several limitations warrant consideration. The observational single-center design and modest sample size limit the generalizability of these findings, which should be considered hypothesis-generating. Second, the cohort included heterogeneous DCB platforms with different drug coatings, limiting the ability to draw conclusions regarding drug-class effects. The observed trend toward a lower likelihood of LLE with sirolimus-coated balloons may reflect device-specific differences in drug formulation, coating technology, or release kinetics rather than a true drug-class effect. As no class effect has been established among DCBs, caution is warranted when extrapolating these findings, and device-specific analyses were limited by the small sample size. Third, the absence of an independent imaging core laboratory may have introduced variability in image acquisition and μQFR analysis. Fourth, the observed TLR rate exceeds rates typically reported in randomized DCB clinical trials, which likely reflects the study's inclusion criteria and limits the generalizability of the observed physiological findings. Finally, because follow-up angiography was not protocol-mandated, the study introduced inherent selection bias toward individuals with clinical indications for repeat imaging, resulting in heterogeneous clinical indications and variable follow-up timing.

In conclusion, this study provides evidence of LFG assessed by μQFR, suggesting progressive physiological improvement from the postoperative period to mid-term follow-up after DCB angioplasty.

FUNDING

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ETHICAL CONSIDERATIONS

This study was conducted in full compliance with the principles outlined in the Declaration of Helsinki and was approved by the local ethics committee (analysis from the CARDIO-FR registry, ClinicalTrials.gov identifier: NCT04185285). Written informed consent was obtained from all participati patients prior to enrollment. The SAGER guidelines were considered throughout the design, analysis, and reporting of this study. However, sex- and gender-based subgroup analyses were not performed due to the limited sample size, which precluded meaningful comparisons. Sex and gender distribution of participants is reported in the baseline characteristics.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence-based tools were used solely for English language proofreading during the preparation of this manuscript. All aspects of the study, including conception, design, data collection, analysis, interpretation of results, and manuscript drafting, were performed entirely by the authors without the assistance of artificial intelligence. The authors take full responsibility for the content and integrity of the work.

AUTHORS' CONTRIBUTIONS

D. Garin conceived and designed the study. D. Garin and R. Mohand Saidi performed data collection, data analysis, and drafted the manuscript. J.F. Iglesias and C. Seydoux contributed to data interpretation and critically revised the manuscript for relevant intellectual content. M. Togni and S. Cook provided senior supervision, contributed to study design, and critically revised the manuscript. D. Garin supervised the overall project, contributed to data interpretation, and provided critical revision of the manuscript. All authors read and approved the final version of the manuscript.

CONFLICTS OF INTEREST

J.F. Iglesias reports having received speaker fees or honoraria from Abbott Vascular, Biotronik, Biosensors, Bristol Myers Squibb/Pfizer, Cordis, Concept Medical, Medtronic, Penumbra Inc., and ReCor Medical, and consulting fees from Biotronik, ReCor Medical, Cordis, and Medtronic. J.F. Iglesias's institution received unrestricted research grants from Biotronik, Concept Medical, Terumo Corp., and SMT. None of these relationships influenced the design, conduct, or reporting of this research. The remaining authors declared no conflicts of interest whatsoever.

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Scientific letter

Ultra low-dose fluoroscopy in chronic total occlusion PCI: a preliminary feasibility study

Fluoroscopia de dosis ultrabaja en la ICP de oclusión total crónica: un estudio preliminar de viabilidad

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To the Editor,

Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is among the most radiation-intensive coronary procedures, owing to high lesion complexity, use of dual injections, and prolonged wire manipulation and/or retrograde techniques, all of which increase fluoroscopy time and cine acquisition. Contemporary data indicate that median patient radiation exposure, measured as air kerma (AK) remains substantial in CTO PCI (median, 2.3 Gy); however, this has been in decline recently due to improvements in equipment and procedural techniques.[1] From the patient standpoint, transient tissue reactions usually occur when absorbed radiation skin dose exceeds 2 Gy while permanent effects occur in absorbed doses > 5 Gy.[2] For operators, cumulative scatter radiation exposure to the eyes, head, and torso underscores the need to improve shielding and workflow to reduce occupational exposure.[3] Importantly, a large multicenter analysis showed that education, equipment optimization, and procedural discipline can significantly decrease radiation exposure without compromising procedural success.[4] Similarly, a previously published report from our research group showed that an ultra-low-dose (ULD) fluoroscopy protocol significantly reduces radiation exposure during CTO PCI.[5] Accordingly, we sought to evaluate the feasibility of implementing a ULD fluoroscopy workflow during CTO PCI procedures at a single-center institution.

We conducted a retrospective analysis of 88 consecutive patients referred to our single-center catheterization laboratory for elective PCI CTO over a 3-year period (January 2021 to October 2023). Because of the use of solely retrospective and anonymized data for this manuscript, Ethical Committee approval was deemed unnecessary as per our local institutional practices. All procedures were performed by the single operator, and in all patient cases we employed an ULD fluoroscopy workflow featuring routine fluoroscopy at 3.75 frames per second (FPS) and cine acquisition limited to 7.5 FPS. In addition to reduced frame rates, the workflow routinely emphasized tight collimation, minimation of magnification, preferential use of stored fluoroscopy in place of cine acquisition when clinically appropriate, avoidance of unnecessary repeat acquisitions, and attention to shielding and operator positioning. The equipment used in the study was a single-plane suspended C-arm angiographic system (Shimadzu Corporation, Trinias C8, Model DAR 9500f). As this was a retrospective analysis, detailed dose-escalation logs, dose-area product (DAP), and vendor-specific radiation output variables such as pulse width and tube current were not systematically available for all cases and are therefore not reported.

Most patients were male (81.8%) with a mean body mass index of 28.9 ± 5.4 kg/m^2. The median J-CTO score was 2.0 (interquartile range [IQR], 1-3) points while nearly 40% of cases had a J-CTO score of 0 to 1 (N = 35). Median CTO length per QCA analysis was 15 mm [IQR, 10-20], interventional CTO approach was primarily antegrade in 83% of cases (N = 73), and target CTO vessel was approached via radial access in most cases (94.3%). Median CTO crossing time was 6.5 [2.0-15.0] minutes with a mean of 10.9 ± 16 minutes. The most widely affected CTO artery in our dataset was the right coronary artery (59%), followed by the left circumflex (22%) and left anterior descending coronary arteries (19%). Ten out of 88 patients (10.2%) had a previous CTO recanalization attempt while the mean eGFR at baseline was 70.6 ± 23.1 mL/min/1.73 m^2. The median contrast volume used was 210 mL (152-260), the median total procedural time was 70 minutes (45-120), and procedural success and Thrombolysis in Myocardial Infarction grade-3 flow were achieved in 75 out of 88 patients (85.2%). No adverse events were observed including death, perioperative myocardial infarction, stroke, coronary perforation, flow-limiting dissection, or bleeding.

Importantly, our data show that median AK at the interventional reference point was 715 mGy (369-1116) with a total fluoroscopy time of only 27 minutes (16-41), as shown in figure 1. This yielded a normalized AK/fluoroscopy-time ratio of approximately 26.5 mGy/min. Within this cohort, the low-frame-rate workflow was feasible and adopted as a routine practice without apparent compromise in procedural conduct. However, given the absence of a contemporary control group and the lack of formal image quality assessment, no comparative inference can be made regarding procedural time, contrast volume, or visualization relative to standard fluoroscopy settings.

This feasibility study bears important implications for clinical practice since it demonstrates that, in a cohort with a median J-CTO score of 2 and predominantly antegrade procedures, CTO PCI can often

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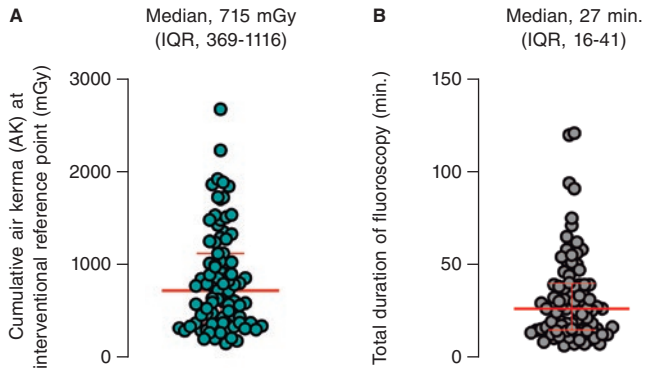


Figure 1. **A**: median cumulative air kerma at interventional reference point (in mGy); **B**: median total fluoroscopy time (minutes). IQR, interquartile range.

be performed with cumulative radiationa exposure < 1 Gy and total fluoroscopy times < 30 minutes. These absolute AK values are directionally similar to those reported with other structured protocol-based approaches and lower than those described in standard CTO practice, including multicenter PROGRESS-CTO data; however, such cross-study comparisons should be interpreted with caution.[1,6] Given that most cases procedures were antegrade, median lesion length was modest, and re-attempts were infrequent, this workflow may be easiest to implement initially in lower- to intermediate-complexity CTO before broader adoption in more complex retrograde or reattempt cases. Importantly, the use of normalized radiation metrics, such as AK per minute of fluoroscopy, may facilitate benchmarking across centers and offer better comparability among institutions employing similar radiation-reduction protocols.

Several limitations should be acknowledged. First, our results may not be generalized to other CTO centers with different operator experience, case selection, or equipment-specific programming because this work is limited to a single center. Furthermore, no standardized universal definition of ULD fluoroscopy currently exists; for this study we used a cumulative procedural AK < 1 Gy as a pragmatic descriptive benchmark rather than a universally accepted threshold. More broadly, our ULD protocol reflects a combination of low frame-rate acquisition (3.75 frames/s fluoroscopy and 7.5 frames/s cine) and systematic dose-reduction strategies, including collimation, minimal magnification, and restriction of cine acquisitions. Our analysis also lacks a contemporary non-ULD comparator cohort. In addition, several potentially relevant variables relevant for external benchmarking— including operator experience, frequency of temporary dose escalation, dose-area product, and vendor-specific radiation output parameters— were not systematically captured in this retrospective dataset. Accordingly, comparison with PROGRESS-CTO[1] or other observational series should be considered contextual only rather than a formal control analysis. The protocol described in this report remains in routine use at our center; however, larger datasets and prospective comparative analyses are warranted.

In conclusion, reducing radiation exposure during CTO PCI is essential both for patient safety and operator occupational exposure, especially in CTO. We suggest that interventional cardiologists performing CTO procedures should consider adopting structured radiation-sparing workflows tailored to local expertise and equipment, particularly as part of broader dose-optimization programs. This protocol might be particularly feasible for non-overly complex CTO lesions. Larger comparative studies are needed to define which CTO subsets derive the greatest benefit and to validate these findings across operators, centers, and imaging platforms.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

Under the applicable institutional framework governing this type of research (HR-OBC-71023-2016-04-18), this study was exempt from local ethics committee approval and did not require formal institutional review board oversight. The study was conducted in full compliance with institutional requirements and with the principles outlined in the Declaration of Helsinki. Informed consent was waived due to the retrospective design of the study and the use of fully anonymized data, where applicable. SAGER guidelines were followed with respect to possible sex/gender bias.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence software or services were used while drafting this manuscript.

AUTHORS' CONTRIBUTIONS

M. Kovacic and J.A. Borovac conceived the idea and wrote the original first draft. M. Ostricki, G.L. Gasparini contributed with important intellectual content, as well as with manuscript drafting and revision. All authors reviewed and approved the final version of the manuscript for publication.

CONFLICTS OF INTEREST

None declared.

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Scientific letter

Artificial intelligence-assisted detection of marker band detachment during laser atherectomy

Detección basada en inteligencia artificial del desprendimiento de la banda marcadora durante la aterectomía con láser

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To the Editor,

Excimer laser coronary atherectomy (ELCA) is a plaque-modification technique used in the treatment of heavily calcified coronary lesions.[1,2] Although recommendations favor saline infusion, contrast-enhanced ELCA is still used for resistant lesions despite higher dissection and perforation risk.[3] It remains unclear whether laser activation in the presence of contrast may also lead to specific and reproducible device-failure events, as existing literature reports safety and complications without linking events to specific hardware failure.[2] Therefore, we queried publicly available narratives from the United States Food and Drug Administration (US FDA) Manufacturer and User Facility Device Experience (MAUDE) database for ELCA (product code "LPC") from 1 January 2016 through 31 May 2025. MAUDE is a passive FDA repository of device adverse events comprising mandatory reports from manufacturers and user facilities as well as voluntary reports from clinicians. We implemented a 2-stage large language model (LLM) workflow to screen narratives and extracted event-action sequences. All analyses used performed using the Gemini 2.5 Pro model with temperature = 0 and top-p = 1 to ensure deterministic outputs. In stage 1, rules-assisted screening with negation handling was used to identify candidate reports describing laser activation in the presence of contrast (eg, "contrast present," "lased in contrast," "before flushing"). In stage 2, the full free text of all narratives was analyzed to extract event sequences and device-outcome relationships without predefined labels. Prompts required structured outputs (presence/absence labels and an ordered action-outcome sequence) and mandated inclusion of verbatim supporting phrases from each narrative for all key labels. Two interventional cardiologists independently adjudicated all cases, with disagreements (2 of 120) resolved by consensus. We applied an explicit case definition for distal marker-band detachment. Reports were classified as "explicit detachment" only when the narrative clearly indicated that the marker band had separated, fractured, or become dislodged. "Activation in contrast" was defined as *a)* activation during active contrast injection, *b)* activation immediately after contrast delivery without documented saline flushing, or *c)* activation after incomplete flushingwith probable residual contrast at the catheter tip.

Within MAUDE (16 756 924 total entries across all device categories during the study period, not limited to ELCA procedures), the product-code query ("LPC") retrieved 120 unique ELCA narratives. As a passive repositoru, MAUDE does not allow inference of incidence or causality. Distal marker-band detachment was reported in 27 of 120 narratives. Seven reports explicitly described laser activation in the presence of iodinated contrast (5.8%), of which 5 reported detachment. Across these 5 detachment narratives with confirmed contrast-time activation, the LLM identified a recurring narrative pattern: recent contrast injection or likely residual contrast at the catheter tip, laser activation before documented saline flushing (off-instructions for use [IFU]), and subsequent report of distal marker-band detachment. Among the remaining 113 narratives without explicit contrast-time activation, detachment was reported in 22. This signal is mechanistically plausible: since contrast media acts as a powerful chromophore, activating ELCA in its presence significantly amplifies local energy absorption and cavitation. This enhanced photomechanical effect, intended to modify resistant plaque, creates an omnidirectional stress wave that may inadvertently exceed the structural tolerance of the catheter's distal tip assembly, resulting in marker-band detachment. In clinical series, the most frequently described complications of contrast-enhanced ELCA are coronary perforation and dissection, whereas this MAUDE-based analysis highlights a device-component failure—distal marker-band detachment—consistent with tip damage in the setting of incomplete saline flushing[4,5] (figure 1).

Our findings, grounded in real-world adverse-event narratives, organize these concerns into an explicit hypothesis-generating pattern that may be modifiable through technique and adherence to the saline-flush IFU recommendations. Beyond this specific mechanism, the same LLM-assisted workflow can be extended across intracoronary atherectomy modalities to systematically map associations among lesion substrate, procedural technique, and device-failure modes. Viewing each MAUDE report as a sequence of actions and consequences rather than a single coded term enables comparative signal detection and hypothesis generation for device-specific guardrails and training strategies.

The practical implications of these findings are hypothesis generating and primarily focused on awareness: *a)* contrast-time ELCA may be associated with distal marker-band detachment through 2 potential mechanisms: first, the chromophore effect that amplifies photomechanical shockwaves; second, the use of contrast may

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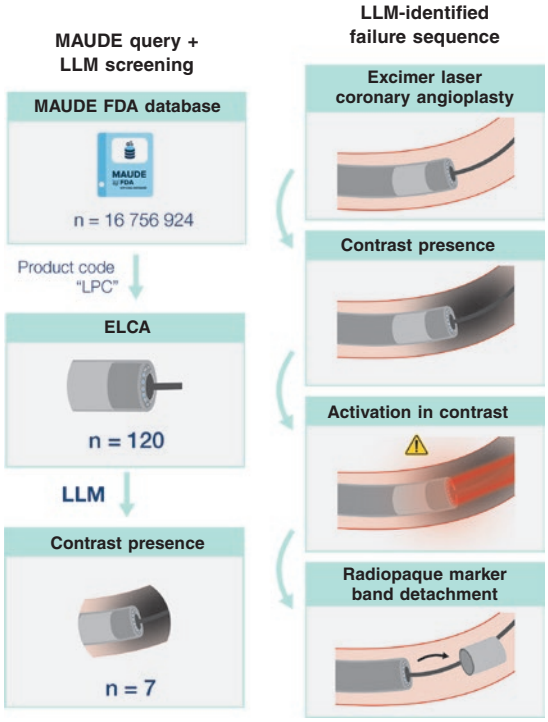


Figure 1. MAUDE query (LPC) with LLM-assisted screening identified 120 ELCA narratives (not a procedural denominator), including 7 with explicit contrast-time activation. A hypothesis-generating signal was observed, characterized by a recurring narrative pattern of recent contrast administration followed by activation before documented saline flushing, culminating in distal marker-band detachment (5 or 7 cases). ELCA, excimer laser coronary atherectomy; FDA, Food and Drug Administration; LLM, large language model; MAUDE, Manufacturer and User Facility Device Experience.

simply signal resistant or 'uncrossable' lesions requiring stationary activation, where focal energy concentration compromises the structural integrity of the catheter tip; *b)* recognition of this potential failure mode may enhance intraoperative vigilance and prompt systematic inspection of the catheter tip; and *c)* LLM-assisted analysis of MAUDE narratives can identify low-frequency, mechanism-specific device failure patterns that may inform refinement of practice, operator training, and device design.

The principal limitations of this analysis include potential underreporting inherent to the MAUDE database, narrative heterogeneity across reports, and the absence of exposure denominators, which preclude accurate estimation of event incidence. Signal detection relies on the linguistic structure of individual reports, raising the possibility of misclassification, particularly when key procedural details are not documented. Moreover, the LLM-derived event sequences reflect associative rather than causal relationships. MAUDE reports are unverified and narratives may be incomplete or biased by reporting from clinicians or manufacturers.

In conclusion, LLM-assisted analysis of MAUDE narratives revealed a consistent, small signal linking contrast-time laser activation to device-specific failure, most notably distal marker-band detachment. This observation is hypothesis-generating and warrants vaildation in prospective registries and, ideally, bench testing. This workflow illustrates how scalable LLM pipelines can transform passive adverse-event repositories into comparative, technology-agnostic maps of device-specific risk.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

This study analysed publicly available, de-identified reports from the US FDA MAUDE database; therefore, ethics committee approval and informed consent were deemed unnecesary. The SAGER guidelines were considered; however, sex/gender analyses were not feasible because MAUDE narratives do not provide reliable patient-level sex or gender data for analysis.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

During manuscript preparation, the authors used a large language model (Gemini 2.5 Pro) to assist with narrative screening and sequence extraction as described in the manuscript, and minor language edits. All outputs were reviewed and edited by the authors, who take full responsibility for the content.

AUTHORS' CONTRIBUTIONS

A. Fernández-Cisnal: conceptualization, clinical adjudication, MAUDE query, methodology (LLM workflow), data analysis, drafting of the manuscript. A. Jurado-Román: interpretation, critical revision of the manuscript. G. Miñana: clinical adjudication, interpretation, critical revision of the manuscript. All authors approved the final version.

CONFLICTS OF INTEREST

None declared.

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Selective orbital atherectomy avoiding injury to adjacent vulnerable structures

Aterectomía orbitacional selectiva para evitar estructuras adyacentes vulnerables

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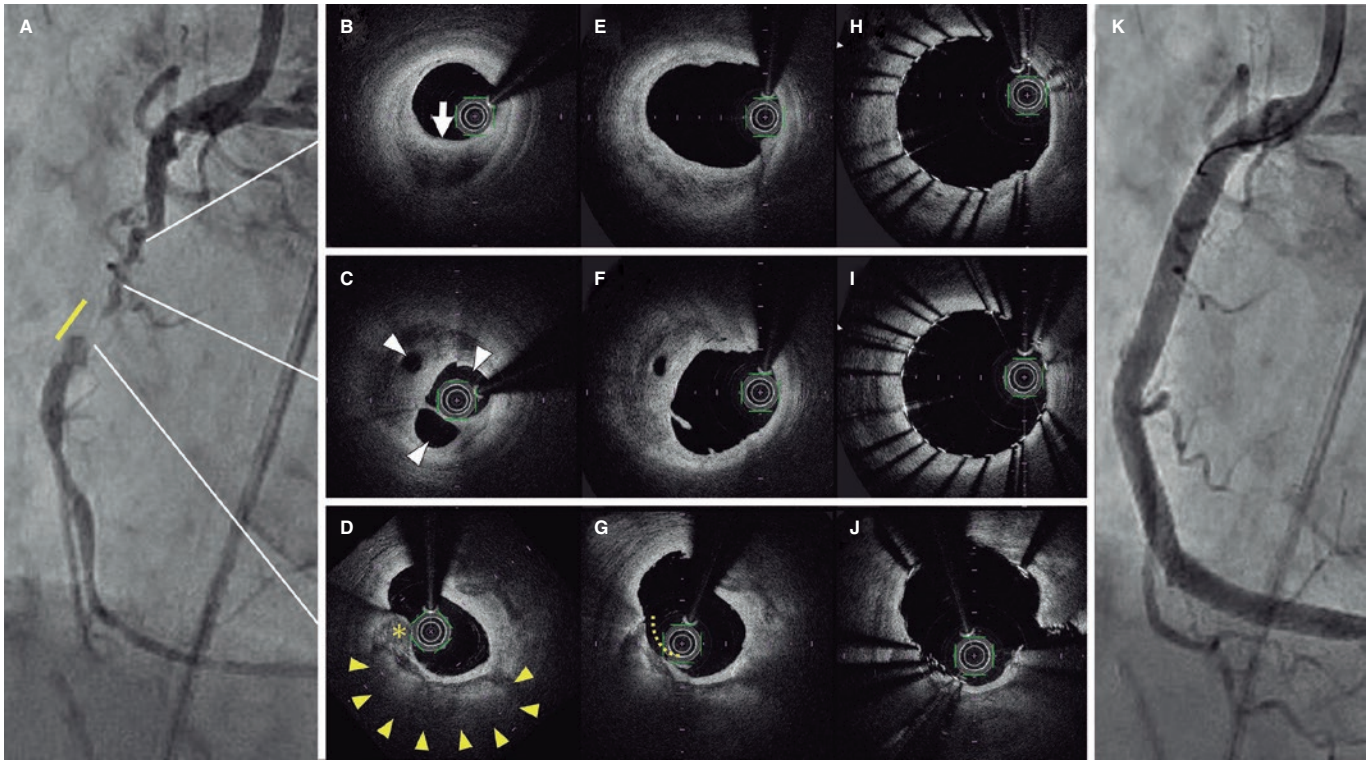


Figure 1.

An 80-year-old man with maintenance hemodialysis presented with exertional angina. Coronary angiography demonstrated a subtotal occlusion with severe calcification (figure 1A, yellow line) of the right coronary artery. After predilation with a 1.5-mm balloon, optical frequency domain imaging (OFDI; Terumo, Japan) identified layered plaque (LP) (figure 1B, arrow), honeycomb-like structures (HLS) (figure 1C, arrowheads), and a calcified nodule (CN) with a thick calcified plate (figure 1D, asterisk and arrowheads). Because LP and HLS may contain organized thrombi, conventional rotational atherectomy (RA) could disrupt these vulnerable structures, resulting in distal embolization and no-reflow. Therefore, we performed selective orbital atherectomy (OA) using the Diamondback 360 system (Abbott Vascular, United States). A 1.25-mm crown was advanced toward the distal calcified segment without use of the glide-assist mode. OA was performed using a controlled pullback technique, focusing selectively on the calcified lesion while preserving adjacent vulnerable structures. Afterward, the treated segment was dilated with a 2.5-mm scoring balloon. OFDI confirmed no severe damage to the LP (figure 1E) or HLS (figure 1F), with successful calcified nodule debulking (figure 1G, dotted line). No distal embolization or no-reflow occurred. Two drug-eluting stents were implanted, followed by postdilatation with a 3.5-mm high-pressure balloon. Final OFDI (figure 1H-J) and angiography (figure 1K) confirmed excellent stent expansion. Informed consent was obtained.

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When treating calcified lesions, the choice between RA and OA can be challenging. This case demonstrates the unique advantages of OA, which allows selective debulking using a controlled pullback technique that targets only the calcified lesion while carefully avoiding the adjacent vulnerable areas.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

Informed consent was obtained from the patient for tests and publication of this case. Because this is a single case report, most SAGER guideline recommendations do not apply. The patient's gender (man) has been specified. However, as this is a case report rather than a research study, further considerations were deemed unnecessary.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence has been used in the preparation of this article.

AUTHORS' CONTRIBUTIONS

S. Koga drafted the initial version of the manuscript and selected and edited the images that would later be used. M. Kunimoto and K. Isoda collaborated in the manuscript critical review and approved its final version.

CONFLICTS OF INTEREST

None declared.

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Neonatal coronary thrombosis successfully treated with local fibrinolysis

Trombosis coronaria neonatal resuelta con fibrinolisis local

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Instituto Pediátrico del Corazón, Instituto de Investigación Sanitaria 12 de Octubre (imas12), Hospital Universitario 12 de Octubre, Madrid, Spain

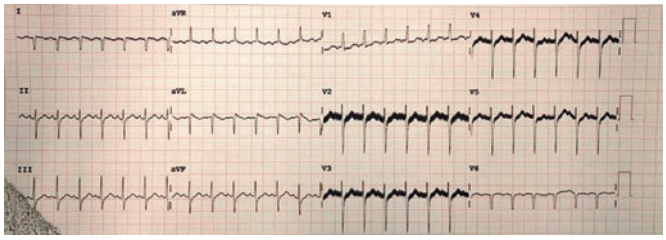


Figure 1.

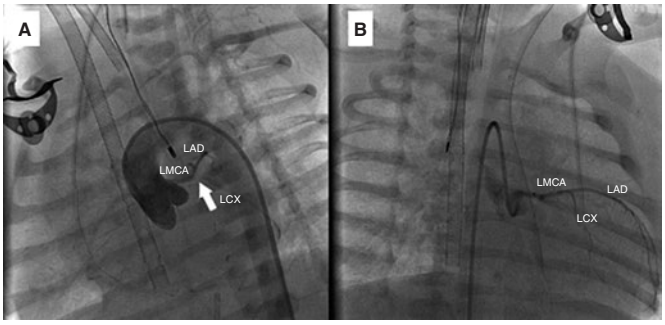


Figure 2.

A 12-hour-old neonate, with no relevant prenatal history, presented with an episode of irritability, peripheral hypoperfusion, and metabolic acidosis.

Given the suspicion of sepsis, empirical antibiotic therapy was initiated. The electrocardiogram revealed a QS pattern in leads I and aVL (figure 1), and the lab test results showed a significant elevation of troponins. Echocardiography demonstrated severe biventricular dysfunction with more pronounced hypokinesia in the left ventricular anterolateral region (videos S1-S2), without visualization of the course of the left coronary artery.

Due to hemodynamic instability despite intubation and vasoactive support, we performed cannulation for extracorporeal membrane oxygenation and cardiac catheterization to rule out coronary artery disease. A normal origin of the left coronary artery was found, with lack of contrast opacification at the junction of the left anterior descending (LAD) and left circumflex (LCX) coronary arteries, and slow distal filling of both vessels (figure 2A and videos S3-S4; LMCA, left main coronary artery). We performed local fibrinolysis using a microcatheter with administration of 2 boluses of alteplase (0.8 mg and 0.4 mg), achieving recanalization of the LCX and the origin of the LAD (figure 2B).

We performed a second cardiac catheterization at 72 hours after a failed extubation attempt that confirmed adequate coronary flow (video S5). The favorable clinical course allowed weaning from extracorporeal membrane oxygenation and discharge at 44 days of life, with treatment for chronic heart failure (table 1S) and progressive functional recovery (videos S6-S7).

Although the incidence rate of neonatal acute myocardial infarction is extremely low, its high mortality rate underscores the importance of early diagnosis and prompt treatment.

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ETHICAL CONSIDERATIONS

The patient's parents gave their informed consent for publication of this case. As this is a single-patient case report, approval by an ethics committee and consideration of SAGER guidelines were deemed unnecessary.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tools were used in the preparation of this manuscript.

AUTHORS' CONTRIBUTIONS

C. Santos Lorente, A. Mendoza Soto, M. Flores Fernández, L. Albert de la Torre, and D. Herrera Linde were directly involved in the drafting of this article and have read and approved its final version for publication.

CONFLICTS OF INTEREST

None declared.

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.24875/RECICE.M25000563.

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Interview



An interview with Augusto D. Pichard

Una entrevista con Augusto D. Pichard

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Augusto D. Pichard graduated with honors in Medicine from Universidad Católica de Chile (Santiago, Chile) and completed his fellowship in Cardiology at Cleveland Clinic (Ohio, United States) (1971–1973), where he remained until 1975. That year, he was appointed director of the cath labs at Mount Sinai Hospital in New York, where he performed the institution's first angioplasty in 1979. After spending a year in Chile, where he introduced angioplasty, he was appointed director of the cath labs at MedStar Washington Hospital Center in 1983. Under his leadership, the center became one of the world's leading institutions in interventional cardiology, training generations of interventional cardiologists who now hold leadership positions worldwide. He was Professor of Medicine at Georgetown University and received the Alexander J. Lindsay Award for Excellence in Teaching. He has authored more than 800 scientific publications. Augusto D. Pichard is a cofounder of the Transcatheter Cardiovascular Therapeutics (TCT) and Cardiovascular Research Technologies (CRT) conferences, as well as a founding member and Master of the Society for Cardiovascular Angiography and Interventions (SCAI). From 2017 to 2021, he served as Medical Director of Abbott's Structural Heart Division and Global Director of its TAVI program.

Although you are regarded as one of the pioneers of interventional cardiology, the early stages of that career path must not have been easy. Could you describe how you came to join Cleveland Clinic and what ultimately led you toward interventional cardiology?

I was a Cardiology fellow in Santiago (Chile), and had absolutely no intention of moving to the United States. F. Mason Sones, the father of coronary arteriography and head of the department at the Cleveland Clinic, personally called me to offer me a fellowship in cardiology and cardiac catheterization. I thanked him and declined. He then asked me to speak with my supervisors before turning down the offer, and that is exactly what I did: they sent me to Cleveland!

At the time, coronary artery bypass surgery—which René Favaloro had developed at that same institution—was highly controversial. Most centers did not yet accept it as a valid treatment option, and the evidence supporting it was still very limited. I presented a study at the American Heart Association meeting showing, for the first time, that surgery provided better outcomes than optimal medical therapy in patients with left main coronary artery disease. The audience strongly challenged the findings. I learned a great deal in that room. The clinical volume was extraordinary. Every evening, I reviewed the day's cases, photographed the coronary angiograms, and eventually published them as an atlas. I remained on the faculty for another 2 years, training fellows and performing a great deal of catheterizations.

Before establishing a world-renowned referral center in Washington, you worked at Mount Sinai Hospital in New York, where you directed the cath lab. What were the main lessons you learned from that period, and how did they shape your future career?

I moved to New York at the invitation of Richard Gorlin, from Harvard, who was joining Mount Sinai Hospital with his team and asked me to go with them to direct the cath lab. Academic life was extremely demanding: clinical conferences began at 7 in the morning, followed by lectures and meetings throughout the day. When I arrived, cardiac catheterizations were being performed in a room borrowed from the radiology department. I had to build the service from the ground up, establish dedicated cath labs, and launch clinical and experimental research programs.

That was where I first heard about Andreas Grüntzig and angioplasty. We immediately initiated an animal protocol to study the effects of balloon dilation on the artery and myocardium, which allowed us to introduce the technique into clinical practice at a very early stage. Those first 10 years in the United States taught me the importance of working within large teams, rigorously validating every advance scientifically, and allowing intellectual satisfaction to be the main driving force. Nobody thought of maximizing revenue, and everyone focused on advancing the specialty.

In Washington, you recruited professionals who would later achieve major international recognition, such as Gregg Stone, Martin Leon, Ron Waksman, Ran Kornowski, Gary Mintz, Jeff Popma, Roxana Mehran, Alexandra Lansky, and George Dangas. What do you remember about that group, and what advice would you give about surrounding yourself with talent in an environment in which some leaders may perceive their brightest collaborators as a threat?

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After a period at the Universidad Católica de Chile, I moved to Washington Hospital Center, which at the time was a private hospital with very limited interventional activity, performing only 3 to 5 catheterizations per day. I reorganized the service, built new cath labs, established a prospective database, introduced coronary angioplasty and mitral and aortic valvuloplasty, and organized our first live-case course, devoted to aortic valvuloplasty, along with Alain Cribier.

The program grew rapidly. Once I reached a volume of 1000 procedures per year, I decided to build a group. Many colleagues advised me to recruit people who would not threaten my position. I did exactly the opposite: I looked for the most talented people I could find. That is how Martin Leon, Kenny Kent, and Lowell Satler came to join us, with the rest of the group following later. We divided income equally to eliminate financial competition, declined industry benefits, and decided not to patent our innovations. Eventually, we were performing more than 15,000 procedures per year and producing the highest volume of publications in the United States. Team spirit made everything possible: listening to every member of the group and working without internal rivalry, always keeping the patient at the center of everything we did.



Washington Hospital Center team in 1997. Bottom row, from left to right: Augusto D. Pichard, Martin Leon, Lowell Satler, and Kenneth Kent. Top row: Andrea Abizaid (first), Alexandra Lansky (third), Gary Mintz (fourth), Jeffrey J. Popma (fifth), Alexandre Abizaid (sixth), Ran Kornowsky (seventh), Ron Waksman (eleventh), and Roxana Mehran (fourteenth), together with their colleagues.

Teaching has been a focal point of your career. What did you try to instill in the fellows you trained?

Our fellows were essential to the success of the group. We structured the fellowship as 1 year devoted to research followed by 1 clinical year, so that they would leave with a strong methodological foundation from which they could continue to develop independently. It worked well. Many of them are now leaders in the specialty in their own institutions and countries. Beyond technical skills, what I tried to instill in them was rigor, curiosity, and a permanent desire to learn. And perhaps the idea that medicine is not an individual pursuit.

How was TCT created, and what role has it played in the global dissemination of cardiovascular intervention?

The idea came from Martin Leon and Kenny Kent. The first meeting was held in 1988, with fewer than 200 attendees and a single live case transmitted from Georgetown Hospital. In 1989, with the establishment of the Washington Cardiology Center, we took responsibility for continuing the meeting and developed a format centered on the presentation of rigorous scientific data and the real-time demonstration of the technologies we were developing. We invited the world's leading experts to participate as panelists, and the meeting rapidly became a major international reference point in interventional cardiology. From the outset, what set it apart was the opportunity for direct interaction among cardiologists, researchers, and industry representatives. It remains a highly relevant meeting today, and its format has expanded considerably to include workshops, hands-on training, live cases, and presentations of emerging technologies.

You have always emphasized that every member of the cath lab team—physicians, nurses, technicians, and support staff—is essential. Why is team culture so important in interventional cardiology?

From the very first day, I made it clear that every member of the team, from those responsible for cleaning the area to the department chiefs, had a role in decisions concerning the cath lab. We held weekly meetings to review how the system was functioning, and anyone could give their opinion. Decisions were not made simply because the chief said so; they were made because the group had reached a consensus. Moreover, we organized social events for the entire staff, including a Thanksgiving lunch in which everyone contributed in their own way. A team that feels valued works differently, and that ultimately has an impact on patient outcomes.

Throughout the course of a long career, complications are inevitable. How does one learn to deal with them?

By documenting them, analyzing them as a group, and publishing them. That is the best way to learn how to prevent them from happening again and how to respond when they occur. In our department, we consistently emphasized reviewing every complication collectively and sharing the results, even when the outcomes were unfavorable. Currently, we have an annual meeting and a monthly publication devoted specifically to this topic. High-volume practice was essential too. Being in the cath lab every day allowed us to develop the skills required to manage complex situations without increasing the rate of complications.

Interventional cardiology requires extraordinary dedication. What place should personal life have within that career?

At the beginning of my career, I made one decision: I would be home for dinner with my family at 7 every evening. I later extended that principle to the entire staff. To make this compatible with clinical work, we progressively moved the start of procedures earlier until we were beginning at 6:30 in the morning, with the patient already on the table at 6:00 sharp. After 6 in the evening, I did not accept any more medical commitments. Family dinner was sacred: no television, all of us sitting together in the dining room, talking about our day. My children and I did homework together after dinner. I could never go to their weekday games, but I was there on the weekend ones. When I traveled to conferences, I always returned as soon as possible. On three occasions, I traveled to Japan and Australia and returned without staying overnight. You cannot get your personal life back. The hospital is always there.

You retired from active clinical practice approximately 5 years ago. How did you experience that process, and what would you recommend to those approaching that stage?

My advice is to retire at the peak of your career, without waiting for your technical skills, energy, or physical endurance to begin to decline.



Augusto D. Pichard performing back-strengthening exercises between cases.

I would not recommend either a gradual withdrawal involving 1 procedure per week. Interventional cardiology requires high-frequency practice to maintain proficiency. When you stop, you are done.

That said, what comes afterward is fascinating. A medical career is a life of service, and my recommendation is to find a way to continue serving the community in a different capacity. There is a huge world outside the hospital setting, equally fascinating, that for decades you simply have not had the time to explore it.

What message would you give to the new generations of interventional cardiologists?

That this is an extraordinary career. It is certainly demanding, but the satisfaction of restoring a patient's cardiovascular health has no equivalent. As I used to tell my team in the cath lab, it is like running a marathon: you may be exhausted, but reaching the finish line makes all the effort worthwhile. Work as a team. This is not a specialty to practice in isolation. Do not hesitate to refer a patient to someone with greater experience in that particular case, whether at your own center or elsewhere. Start doing back-strengthening exercises from day one. I have done them throughout my life and, despite spending decades in the cath lab, I have no functional limitations. And assess the whole patient: their emotional state, diet, physical activity, inflammatory profile, and physical examination findings. Angiography is only one side of the whole story.

FUNDING

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence was not used in the preparation of this manuscript.

CONFLICTS OF INTEREST

None declared.

ABOUT THE AUTHOR

Rafael Romaguera is associate editor of *REC: Interventional Cardiology* and Head of the Interventional Cardiology Section at Hospital Universitari de Bellvitge (Barcelona, Spain). Augusto D. Pichard was his mentor during his training period in Washington, DC.

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Letter to the Editor

Beyond "leave nothing behind": reconsidering biological restoration after drug-coated balloon coronary intervention

«*No dejar nada atrás*»: *una nueva perspectiva sobre la restauración biológica en la intervención coronaria con balón farmacoactivo*

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https://doi.org/10.24875/RECICE.M26000603

To the Editor,

In their insightful editorial discussing the evolving "leave nothing behind" philosophy, Colombo et al.[1] highlight one of the most compelling conceptual shifts in contemporary interventional cardiology. With the progressive development of drug-coated balloon (DCB) technologies, minimizing permanent metallic implantation has emerged as an increasingly attractive therapeutic concept. Nevertheless, equating the absence of a permanent metallic scaffold with genuine vascular restoration may oversimplify the inherently complex biology of coronary healing.

Undoubtedly, DCB-based approaches reduce metallic burden and may preserve a more physiological vascular geometry. However, vascular restoration cannot be defined solely by the absence of metal within the vessel wall. Endothelial integrity, vasomotor responsiveness, vessel wall biology, local inflammatory signaling, and microvascular adaptation remain among the most critical, yet incompletely understood, determinants of postinterventional recovery. Therefore, the concept of "less metal" should not automatically be interpreted as synonymous with physiological vascular normalization.

Perhaps the more fundamental question is not how little metal we leave behind, but to what extent vascular biology is truly restored. Although the "leave nothing behind" strategy may reduce the burden of permanent implants, balloon-induced vascular trauma, endothelial disruption, vessel wall stress responses, and biological remodeling do not entirely disappear. In other words, leaving no metal behind does not necessarily mean leaving no biological footprint behind.

Importantly, the expanding DCB literature reflects not only the evolution of device technology, but also the emergence of a distinct procedural philosophy.[2,3] Yet, the conceptual boundaries of what truly constitutes a "DCB strategy" remain insufficiently defined. Lesion preparation intensity, acceptable recoil thresholds, bailout stenting criteria, dissection tolerance, inflation duration, and hybrid transition algorithms vary considerably across studies.[2-4] Consequently, substantially different procedural paradigms are frequently grouped under the same therapeutic label, potentially complicating the interpretation of pooled and metaanalytic outcomes.

For this reason, future DCB research may need to move beyond the binary question of "metal vs no metal" and instead focus on defining what genuine vascular restoration actually means. Studies integrating coronary physiology, endothelial function, vascular imaging, and biological healing parameters may ultimately clarify whether the "leave nothing behind" philosophy represents merely a form of mechanical minimalism or a truly physiological model of vascular recovery.

Perhaps the next major transformation in interventional cardiology will not be defined by the disappearance of metal, but by the emergence of biology-guided vascular restoration.

FUNDING

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tools were used in the preparation of this manuscript.

AUTHORS' CONTRIBUTIONS

All authors contributed to the conceptualization, drafting, critical revision, and final approval of the manuscript.

CONFLICTS OF INTEREST

The authors declared no conflict of interest whatsoever.

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Letter to Editor

Beyond "leave nothing behind": reconsidering biological restoration after drug-coated balloon coronary intervention. Response

«*No dejar nada atrás*»: *una nueva perspectiva sobre la restauración biológica en la intervención coronaria con balón farmacoactivo. Respuesta*

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To the Editor,

We thank Astan et al. for their thoughtful letter and for emphasizing the inherent complexity of coronary vascular healing.[1] Their central argument, that the absence of a permanent metallic scaffold should not be equated with true biological restoration, is one that we fully endorse.

We agree that the potential to preserve adaptive remodeling and vasomotor reactivity, both of which are constrained by a permanent metallic cage, does not in itself imply recovery of normal vascular biology. Endothelial integrity, inflammatory signaling within the vessel wall, and microvascular adaptation remain only partially captured by current available metrics. Nevertheless, we would argue that preserving these physiological attributes represents an important first step in that direction.[2] Atherosclerosis is a diffuse and progressive disease that is unlikely to be abolished by any mechanical intervention, regardless of how little it leaves behind.[3] Reducing the permanent implant burden while preserving the vessel's capacity to remodel and vasodilate should therefore be regarded as a step toward, rather than a guarantee of, physiological normalization. This response may also vary according to other factors, such as the drug used to coat the balloon[4] or the patient's sex.[5]

Bioresorbable vascular scaffolds were conceived on precisely the premise that removal of the permanent implant would restore, among other physiological function, vasomotion. However, when this mechanistic hypothesis was prospectively evaluated in ABSORB II,[6] an everolimus-eluting scaffold failed to demonstrate superior vasomotor reactivity compared with a metallic everolimus-eluting stent at 3 years. The anticipated biological restoration was not achieved simply by removing the metal. We therefore share the authors' view that future research should more clearly define what genuine vascular restoration entails by integrating coronary physiology assessment, endothelial function testing, intracoronary imaging, and markers of biological healing into appropriately designed studies with long-term follow-up. Whether a drug-coated balloon strategy can fulfill this physiological promise remains a hypothesis that must be proven.

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used for the development of this work.

AUTHORS' CONTRIBUTIONS

A. Colombo: conceptualization, methodology, investigation, data curation, formal analysis, validation, visualization, writing—original draft, writing—review and editing, supervision, project administration. P.P. Leone: conceptualization, methodology, investigation, data curation, visualization, writing—review and editing, supervision, project administration.

CONFLICTS OF INTEREST

The authors declare there are no relationships relevant to the contents of this paper to disclose.

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