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Original article

Safety and efficacy of the Essential Pro paclitaxel drug-coated balloon in de novo coronary lesions

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ABSTRACT

Introduction and objectives: Drug-coated balloons (DCBs) are an increasingly used therapeutic strategy for the treatment of de novo artery lesions (DNLs). This study aimed to assess the safety and efficacy profile of a new DCB in patients with DNLs.
Methods: This is a prospective, single-center, consecutive cohort study of patients with DNL undergoing coronary angioplasty with a new second-generation paclitaxel-coated balloon. The 3 main endpoints were myocardial infarction, target lesion revascularization, and target vessel revascularization. Baseline variables, including patient and procedural characteristics, were collected.
Results: This study included a total of 185 consecutive patients with 211 treated lesions (mean age, 68.4 ± 11.5 years; 8.7% women) undergoing a percutaneous coronary intervention with a DCB for DNLs. Device delivery was successful in 100%. Final angiographic assessment showed final dissection in 2.4%, TIMI grade < 3 flow in 1.4%, residual percent diameter stenosis > 10% in 14.4%, and residual percent diameter stenosis > 30% in 7.7%. Bailout stenting was required in 12.4%. A suboptimal DCB result occurred in 13.7%. At the 30-day follow-up, there were no deaths, 1 myocardial infarction (0.5%), no target lesion revascularization, target vessel revascularization in 1.1%, and 2 patients (1.1%) were readmitted to hospital due to a coronary syndrome. At 617 days, corresponding to the 75th percentile of follow-up, there were no deaths, and Kaplan-Meier estimates for myocardial infarction, target lesion revascularization, and target vessel revascularization were 2.2% (95%CI, 0-4.7%), 1.1% (95%CI, 0-2.7%), and 4.5% (95%CI, 1.2-7.8%) respectively. The most common indications were small vessel disease (66.8%), high bleeding risk (36.6%), and bifurcation lesions (11.4%). Patients at high bleeding risk had a more adverse clinical profile. No statistical differences in outcomes were observed according to indication.
Conclusions: Among patients with DNLs, the use of the Essential Pro DCB (iVascular, Spain) was associated with high device deliverability and low rates of adverse clinical events during follow-up. Outcomes were consistent across the main clinical indications evaluated. These findings support the feasibility and safety of DCB angioplasty in this real-world cohort.

Keywords: De novo coronary lesions. Drug-coated balloon. Paclitaxel.

Eficacia y seguridad del balón recubierto con paclitaxel Essential Pro en lesiones coronarias *de novo*

RESUMEN

Introducción y objetivos: Los balones farmacoactivos (BFA) constituyen una terapia en expansión para el tratamiento de las lesiones coronarias *de novo* (LDN). El objetivo fue evaluar la eficacia y la seguridad de un nuevo BFA en pacientes con LDN.
Métodos: Cohorte prospectiva, unicéntrica y consecutiva de pacientes con LDN sometidos a angioplastia coronaria con un nuevo balón recubierto con paclitaxel de segunda generación. Los 3 objetivos principales fueron infarto de miocardio, revascularización de la lesión diana y revascularización del vaso diana.
Resultados: Se incluyeron 185 pacientes consecutivos con 211 lesiones tratadas (68,4 ± 11,5 años; 8,7% mujeres). La tasa de éxito de liberación del dispositivo fue del 100%. La angiografía final mostró disección en el 2,4% de los pacientes, un grado de flujo TIMI < 3 en el 1,4% y un porcentaje de estenosis residual por diámetro > 10% en el 14,4% y del > 30% en el 7,7%. Se requirió implante de *stent* de rescate en el 12,4% y hubo un resultado subóptimo del BFA en el 13,7% de los casos. A los 30 días no ocurrieron muertes, se registró un infarto de miocardio (0,5%), no se produjo ninguna revascularización de la lesión diana, la

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revascularización del vaso diana fue del 1,1% y 2 pacientes (1,1%) fueron rehospitalizados por presentar síndrome coronario. A los 617 días (percentil 75) no hubo ninguna muerte. Las tasas de Kaplan-Meier para el infarto de miocardio, la revascularización de la lesión diana y la revascularización del vaso diana fueron del 2,2% (IC95%, 0-4,7%), el 1,1% (IC95%, 0-2,7%) y el 4,5% (IC95%, 1,2-7,8%), respectivamente. Las principales indicaciones fueron enfermedad coronaria de pequeño vaso (66,8%), alto riesgo hemorrágico (36,6%) y bifurcación (11,4%). No se encontró ninguna diferencia significativa en los desenlaces según la indicación.

Conclusiones: En pacientes con LDN, el BFA Essential Pro (iVascular, España) mostró una alta capacidad de liberación del dispositivo y tasas bajas de episodios clínicos durante el seguimiento. Los resultados fueron consistentes entre las principales indicaciones clínicas, lo que respalda la factibilidad y la seguridad de esta estrategia en una cohorte del mundo real.

Palabras clave: Lesiones coronarias *de novo*. Balón farmacoactivo. Paclitaxel.

Abbreviations

DCB: drug-coated balloon. **DNL:** de novo coronary artery lesion. **TLR:** target lesion revascularization. **TVR:** target vessel revascularization.

INTRODUCTION

The use of drug-coated balloons (DCBs) has been extensively investigated and adopted for the treatment of in-stent restenosis, primarily to avoid multiple stent layers.[1,2] However, there is growing interest in the use of DCBs for treatment of native coronary artery disease unrelated to in-stent restenosis, referred to as de novo coronary lesions (DNLs).[3] DNL scenarios that may be particularly suitable for treatment with DCBs include those in which coronary stenting is considered suboptimal, such as small-vessel disease, high bleeding risk, and side-branch lesions in bifurcation disease.[3] Former studies, including randomized trials comparing DCB angioplasty with coronary stenting for DNLs, have demonstrated the noninferiority and in some settings, superiority.[4] These findings support the conduct and publication of randomized clinical trials and real-world studies evaluating the use of DCBs for DNLs, particularly studies of newer-generation devices incorporating technological advancements that may translate into improved clinical outcomes. This analysis aimed to describe the indications, safety, and efficacy of DCB angioplasty for DNLs using Essential Pro (iVascular, Spain), a second generation DCB.

METHODS

Design and population

This is a prospective, single-center cohort of consecutive patients undergoing DCB angioplasty with the Essential Pro. During the study period, from January 2020 through May 2024, a total of 6246 percutaneous coronary interventions were performed at our center, most of which involved the implantation of drug-eluting stents. The 2 inclusion criteria for this analysis were: *a)* use of an Essential Pro DCB and *b)* use of the device to treat a DNL. A DNL was defined as a coronary lesion unrelated to in-stent restenosis that was treated by percutaneous coronary intervention. There were no exclusion criteria. Patients could also undergo coronary stent implantation because of suboptimal results or for the treatment of other lesions during the same or a separate procedure. Small-vessel disease was defined as the presence of a coronary artery lesions with a reference vessel diameter of ≤ 2.5 mm.[5] High bleeding risk was defined as the presence of 1 major criterion or 2 minor criteria according to the Academic Research Consortium for High Bleeding Risk.[6]

Drug-coated balloon characteristics

The Essential Pro is a DCB with a uniform drug eluting formulation of 3 μg/mm^2 comprising paclitaxel (80%) and a biocompatible amphiphilic excipient (20%).[7] The balloon incorporates proprietary TransferTech technology, which is based on the ultrasonic deposition of nanodroplets followed by a dying process, resulting in a homogenous microcrystalline drug coating. This technology allows more uniform and complete delivery of the antiproliferative drug to the vessel wall. The microcrystalline structure, together with the lipophilic nature of both paclitaxel and the excipient, facilitates drug transfer within 45 to 60 seconds. The Essential Pro balloon has been designed with a smooth transition and a very low tip profile of 0.016 inches to enhance flexibility, trackability, and lesion-crossing capability. The balloon is compatible with 5-Fr introducer sheaths across all available diameters.

Procedures

All the procedures and clinical decisions in this study reflected routine clinical practice. Therefore, the clinical indication, decision to use a DCB, device selection, procedural steps, and optimal medical therapy were decided by the treating physicians without adherence to study-specific guidance. All coronary angiograms obtained during follow-up as part of routine clinical practice were reviewed by the research team when available. Baseline and follow-up data was collected in a dedicated anonymized database. Procedural characteristics, and baseline and follow-up angiograms were independently evaluated once by 3 interventional cardiologists. Physicians were instructed to consult senior staff in cases of uncertainty regarding the assessment of angiograms or clinical records. Follow-up information was obtained from clinical records. Patients who did not attend an on-site clinical visit during follow-up were contacted by telephone in accordance with routine clinical practice at our institution. This study was approved by the local institutional review board and all patients provided informed consent for the use of their anonymized information for research purposes before inclusion. This was an investigator-initiated study with no external sponsoring or funding.

Outcome definitions

Device delivery success was defined as successful inflation of the DCB in the target coronary segment. Procedural, angiographic, and

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other standard outcomes were defined according to the Second Academic Research Consortium consensus document.[8] Cardiovascular death was defined as any death without a clearly established noncardiovascular cause. Acute myocardial infarction was defined as any myocardial infarction meeting the criteria of the Fourth Universal Definition of Myocardial Infarction.[9] Target lesion revascularization (TLR) was defined as any repeat revascularization performed within the treated segment or within 5 mm proximal or distal to it.[8] Target vessel revascularization (TVR) was defined as any repeat revascularization of the index treated vessel.[8] Coronary-related hospitalization was defined as any repeat hospitalization for which a coronary cause was considered the primary reason for admission. The 3 main efficacy outcomes were myocardial infarction, TLR and TVR. A suboptimal result after DCB angioplasty was defined as residual percent diameter stenosis > 30%, Thrombolysis in Myocardial Infarction (TIMI) grade < 3 flow, or the need for bailout stenting.

Statistical analysis

Categorical variables are expressed as percentages, and continuous variables as mean and standard deviations (SDs) when appropriate. Because the same patient could receive > 1 DCB, either in the same or a different coronary territory, the denominators for balloon-level variables were based on the total number of DCBs used. These variables included the treated vessel, reference vessel diameter, and DCB diameter and length, By contrast, the denominators for patient-level variables, such as age, sex, and clinical outcomes, were based on the number of individual patients. Clinical outcomes during follow-up are reported at 30 days, at 1 year, and over the entire follow-up period. The Kaplan-Meier method was used to estimate the 75th percentile of follow-up duration and to generate survival curves. Data were analyzed using IBM SPSS Statistics, version 25.0 (IBM Corp).

RESULTS

Between January 2020 and May 2024, a total of 430 patients with 495 coronary lesions were treated with a DCB. Of these, 185 patients with 211 lesions underwent DCB angioplasty for DNLs. Baseline patient characteristics are summarized in table 1. Mean age was 68.4 years (SD, 11.5), 8.7% of patients were women, and 24.9% had diabetes mellitus. The clinical presentation was stable angina in 20.7% of patients, unstable angina in 30.4%, non–ST-segment elevation myocardial infarction in 10.9%, ST-segment elevation myocardial infarction in 8.7%; the remaining 29.3% were asymptomatic.

Table 1. Baseline characteristics

Variables	Overall	Small vessel	HBR	Bifurcation
Patient characteristics				
Age, y	68.4 (11.5)	67.9 (10.5)	72.2 (11.3)	65.6 (10.1)
Female sex	15 (8.7)	9 (8.5)	8 (11.9)	1 (5.9)
BMI, kg/m^2	27.2 (3.84)	27.0 (3.95)	27.2 (4.0)	27.7 (3.28)
Hypertension	141 (76.6)	94 (80.3)	60 (84.5)	13 (76.5)
Current smoking	18 (9.8)	12 (10.3)	5 (7.0)	2 (11.8)
Diabetes mellitus	46 (25)	32 (27.4)	20 (28.2)	3 (17.6)
Previous MI	60 (32.6)	39 (33.3)	32 (45.1)	8 (47.1)
Previous PCI	123 (66.8)	79 (67.5)	56 (78.9)	17 (100)
Previous CABG	28 (15.2)	19 (16.2)	23 (32.4)	1 (5.9)
Reduced LVEF (< 30%)	11 (6)	4 (3.4)	6 (8.5)	1 (5.9)
Atrial fibrillation	20 (10.9)	14 (12)	18 (25.4)	1 (5.9)
Laboratory parameters				
Hemoglobin, g/dL	13.9 (1.5)	13.8 (1.53)	13.2 (1.72)	14.3 (1.15)
GFR, mL/min/1.73 m^2	82.7 (25.1)	83.6 (24.2)	77.6 (26.7)	82.8 (23.9)
Current medication				
Aspirin	115 (84.7)	96 (82.1)	58 (81.7)	15 (88.2)
Clopidogrel	70 (38)	44 (37.6)	32 (45.1)	5 (29.4)
Ticagrelor	12 (6.5)	8 (6.8)	0 (0)	3 (17.6)
Prasugrel	18 (9.8)	14 (12)	5 (7.0)	2 (11.8)
Anticoagulation	23 (12.5)	18 (15.4)	20 (28.2)	1 (5.9)
Clinical presentation				
Silent ischemia	54 (29.3)	33 (28.2)	14 (19.7)	6 (35.3)
Stable angina	38 (20.7)	21 (17.9)	12 (16.9)	4 (23.5)
Unstable angina	56 (30.4)	41 (35)	24 (33.8)	5 (29.4)
NSTEMI	20 (10.9)	14 (12)	10 (14.1)	1 (5.9)
STEMI	16 (8.7)	8 (6.8)	10 (14.1)	1 (5.9)

BMI, body mass index; CABG, coronary artery bypass grafting; GFR, glomerular filtration rate; HBR, high bleeding risk; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.
Data are expressed as No. (%).

Procedural characteristics

The most frequently treated vessel was the left anterior descending coronary artery (48.3%), followed by the left circumflex artery (30.9%), and the right coronary artery (16.4%) (table 2). Lesion preparation was performed in 92.4% of lesions, with a noncompliant balloon used in 70.6%. Intracoronary imaging was used in 8.1% of patients. Rotational atherectomy was performed in 1 case (0.5%) whereas intravascular lithotripsy was not used before DCB delivery. Mean reference vessel diameter was 2.5 mm (SD, 0.57 mm). Mean DCB diameter and length were 2.5 mm (SD, 0.58 mm) and 22.2 mm (SD, 6.6 mm), respectively. Mean DCB diameter was 2.20 mm (SD, 0.27 mm) in small vessels and 3.05 mm (SD, 0.61 mm) in non-small vessels (P < .001). A DCB diameter of < 2.5 mm was used in 48.3% of lesions, a 2.5-mm DCB in 25.2%, and a DCB > 2.5 mm in 26.5%. The largest DCB used was 4.5 mm.

Device delivery was successful in all cases. Final angiography showed residual dissection in 2.4% of lesions, final Thrombolysis in Myocardial Infarction grade < 3 flow in 1.4%, residual percent diameter stenosis > 10% in 14.4%, and residual percent diameter stenosis > 30% in 7.7%. A suboptimal angiographic result after DCB treatment was observed in 13.7% of lesions, and bailout stenting was required in 12.4% (figure 1).

Clinical outcomes

Clinical follow-up after discharge was available for 98.4% of patients. Median follow-up was 506 days (interquartile range 397

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Table 2. Characteristics of the treated lesion

Variable	Overall	Small vessel	HBR	Bifurcation
Treated vessel				
LAD	100 (48.3)	69 (50)	37 (53.6)	8 (34.8)
LCx	64 (30.9)	44 (31.9)	19 (27.5)	10 (43.4)
RCA	34 (16.4)	25 (18.1)	6 (8.7)	5 (21.7)
LMCA	0 (0)	0 (0)	0 (0)	0 (0)
Bypass graft	0 (0)	0 (0)	0 (0)	0 (0)
Procedural characteristics				
IVUS-guided PCI	17 (8.1)	10 (7.1)	8 (11.3)	3 (12.5)
Lesion predilatation	195 (92.4)	131 (92.9)	66 (93)	24 (100)
Predilatation with a NC balloon	149 (70.6)	97 (68.8)	48 (67.6)	16 (66.7)
Rotational atherectomy	1 (0.5)	0 (0)	0 (0)	0 (0)
DCB diameter, mm	2.49 (0.58)	2.20 (0.28)	2.58 (0.62)	2.56 (0.45)
DCB length, mm	22.2 (6.6)	22.4 (6.4)	22.8 (6.6)	20.2 (5.6)
Angiographic results after DCB angioplasty				
Residual vessel dissection	5 (2.4)	3 (2.1)	3 (4.3)	0 (0)
TIMI grade-3 flow	203 (98.6)	141 (100)	69 (97.2)	24 (100)
Residual percent diameter stenosis > 10%	30 (14.4)	18 (12.9)	10 (14.5)	1 (4.2)
Residual percent diameter stenosis > 30%	16 (7.7)	8 (5.7)	7 (10.1)	1 (4.2)
Bailout stenting	23 (12.4)	11 (7.8)	8 (11.3)	1 (4.2)
Suboptimal DCB result	25 (13.7)	12 (10.3)	11 (15.9)	2 (11.8)

DCB, drug-coated balloon; HBR, high bleeding risk; IVUS, intravascular ultrasound; LAD, left anterior descending coronary artery; LCx, left circumflex artery; NC, noncompliant; PCI, percutaneous coronary intervention; RCA, right coronary artery; TIMI, Thrombolysis in Myocardial Infarction.
Data are expressed as No. (%).

and 617), including censored patients. At 30 days, there were no deaths, 1 patient experienced myocardial infarction (0.5%), no TLRs were recorded, TVR occurred in 1.1%, and 2 patients (1.1%) were readmitted because of an acute coronary syndrome. At 1 year, there were no deaths. The rates of myocardial infarction, TLR, TVR, and coronary-related rehospitalization were 1.1%, 1.1%, 2.7%, and 9.3%, respectively. At 617 days, corresponding to the 75th percentile of follow-up, no deaths had occurred. Kaplan-Meier estimates were 2.2% (95%CI, 0%-4.7%) for myocardial infarction, 1.1% (95%CI, 0%-2.7%) for TLR, and 4.5% (95%CI, 1.2%-7.8%) for TVR (figure 2). No patient required surgical coronary revascularization during follow-up. All myocardial infarctions, TLRs, and TVRs occurring within the first year were recorded in patients who initially presented with an acute coronary syndrome. Compared with patients without an acute coronary syndrome, these patients more frequently developed angina during follow-up (14.3% vs 4.4%; $P = .023$) and showed numerically higher rates of hospitalization (12.1% vs 6.7%; $P = .211$), repeat coronary angiography (16.5% vs 7.8%; p = 0.070), and suboptimal DCB results (17.8% vs 10.0%; $P = .131$).

Outcomes according to treatment indication

The 3 most common indications for DNL angioplasty were small-vessel disease (66.8%) high-bleeding risk (36.6%) and bifurcation lesions (11.4%). Only 29 patients (15.9%) underwent DCB angioplasty in the absence of small-vessel disease, high bleeding risk, or bifurcation anatomy. None of the evaluated indications was significantly associated with clinical outcomes (all $P > .05$). Patients treated for small-vessel disease showed no major differences from those treated for non-small-vessel disease. However, they more frequently underwent treatment of the right coronary artery (18.1% vs 13.0%; $P > .001$), required bailout stenting less often (7.8% vs 18.6%; $P = .02$), more frequently achieved final TIMI grade-3 flow (100% vs 95.7%; $P = .013$), and received smaller-diameter DCBs (2.20 mm vs 3.05 mm; $P > .001$).

Compared with patients without high-bleeding, those with high bleeding risk were older (72.1 vs 65.1; $P > .001$), and more frequently had hypertension (84.5% vs 71.4%; $P = .04$), previous myocardial infarction (45,1% vs 25.7%; $P = .08$), previous coronary angioplasty (78.9% vs 59%; $P = .006$), previous coronary artery bypass grafting (32.4% vs 4.8%; $P > .001$), and atrial fibrillation (25.4% vs 1.9%; $P > .001$). They were less frequently treated with potent antiplatelet therapy, including ticagrelor (0% vs 11.4%; $P > .001$) and prasugrel (7% vs 11.4%; $P = .02$), and more frequently received oral anticoagulants (28.2% vs 2%; $P > .001$). Moreover, they less frequently presented with silent ischemia (19.7% vs 33.3%; $P = .048$), had lower hemoglobin levels (13.2 vs 14.3; $P < .001$), and had poorer renal function (77.5 vs 87.0; $P > .001$).

Compared with patients without a bifurcation indication, those treated for bifurcation lesions more frequently had a history of percutaneous coronary intervention (100% vs 63.5%; $P = .002$), and received shorter DCBs (20.2 mm vs 22.5 mm; $P = .026$).

DISCUSSION

In this contemporary real-world cohort of patients with DNLs treated with the second-generation paclitaxel-coated Essential Pro DCB, device deliverability was high, bailout stenting was infrequent, and final angiographic results were favorable. At a median follow-up of 506 days, cardiovascular event rates remained low. Importantly, outcomes were broadly consistent across the 3 main treatment indications—small-vessel disease, high bleeding risk, and bifurcation lesions—despite marked baseline differences in baseline clinical characteristics.

The current clinical adoption of paclitaxel-coated balloons has largely been based on a class effect rather than on evidence specific to individual devices since the lipophilic properties of paclitaxel enable rapid tissue uptake and prolonged retention within the vessel wall, contributing to broadly consistent biological effects across different DCB platforms.[7] Nevertheless, contemporary devices differ in coating technology, excipients, and drug-delivery mechanisms, which may affect deliverability, coating stability, and drug-transfer efficiency. Essential Pro uses an ultrasonic nanodrop deposition process that produces a homogeneous microcrystalline coating intended to optimize drug transfer while preserving a low crossing profile. These characteristics may have contributed to the high deliverability and low bailout-stenting rates observed in this cohort. However, direct comparative studies are required before any superiority over other contemporary paclitaxel-coated balloons can be established.

The included population had a mean age between 65 and 70 years, nearly one-quarter of patients had diabetes mellitus, and a high proportion presented with an acute coronary syndrome. The clinical

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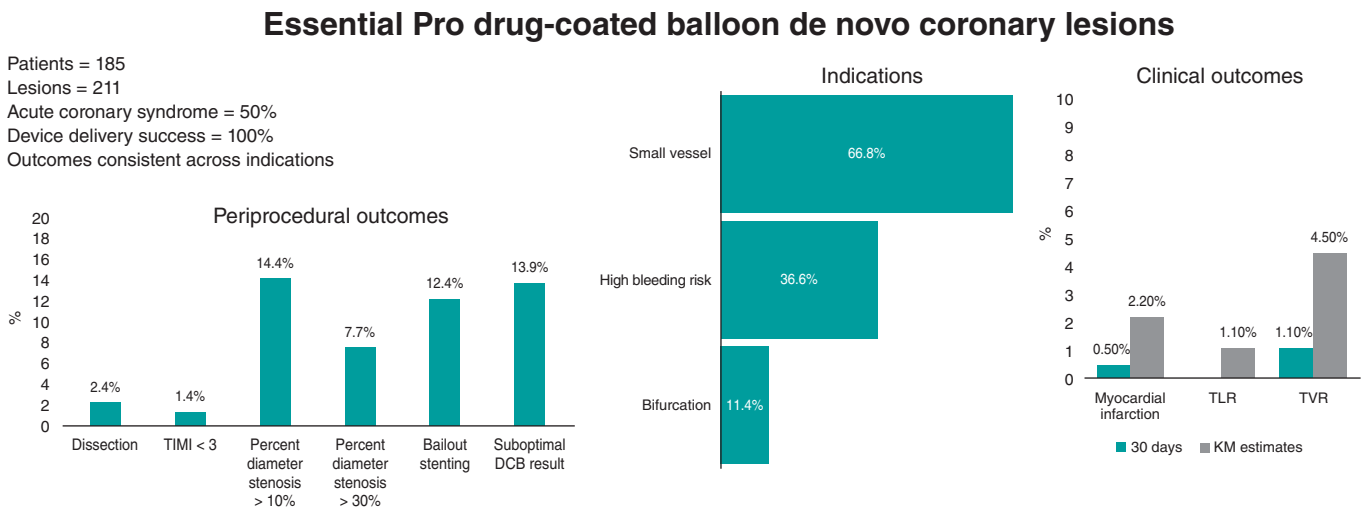

Figure 1. Central illustration. Essential Pro drug-coated balloon de novo coronary lesions. KM, Kaplan Meier; TLR, target lesion revascularization; TVR, target vessel revascularization.

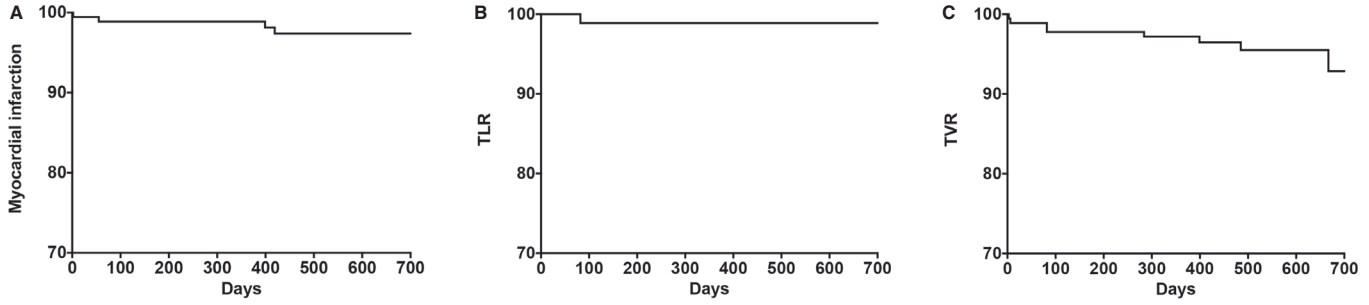

Figure 2. Survival curves of the main clinical outcomes. Kaplan Meier estimates of survival free from myocardial infarction (**A**), target lesion revascularization (**B**), and target vessel revascularization (**C**) with follow-up expressed in days. 95%CI, 95% confidence interval; TLR, target lesion revascularization; TVR, target vessel revascularization.

profile is broadly consistent with that reported in previous DCB studies, including the PEPCAD I/II and BELLO trials, which also enrolled older patients with comorbidities.[10-12] However, our cohort included a large proportion of patients with acute coronary syndrome (nearly 50%) compared with previous series.[4,12] This difference may partly reflect the declining use of percutaneous coronary intervention in patients with chronic coronary syndromes. Moreover, it is possible that patients with acute coronary syndrome have softer plaques and are particularly suitable for a stentless strategy.

Women were underrepresented, as is common in interventional cardiology studies. This finding may limit the generalizability of DCB findings across sexes. The prevalence of diabetes mellitus in our population was comparable to that reported in previous DCB studies, in which approximately 20% to 30% of patients had diabetes.[4,13] Some reports support a higher risk of restenosis compared with non-diabetic cohorts.[14] In contrast, our results suggest a preserved safety and efficacy profile in diabetic patients that may be due to technological advances in DCB design that may mitigate some of these concerns.

The angiographic success in our study was high, with a final TIMI grade-3 flow achieved in 98.6% of lesions, and a relatively low need for bailout stenting (12.4%). These findings are consistent with those of the PEPCAD II trial, which demonstrated favorable procedural success with paclitaxel-coated balloons, although bail-out-stenting rates were generally higher in earlier DCB studies.[11] Our findings highlight the advantages of contemporary DCB platforms, including lower crossing profiles and improved drug transfer, which may account for better procedural performance. The low event rates reported suggest that meticulous lesion preparation and appropriate balloon sizing remain the cornerstone of successful DCB angioplasty.

Two-thirds of procedures accounted for DCB use due to small-vessel disease in our cohort. The BELLO and the more contemporary BASKET-SMALL 2 trials demonstrated that DCB angioplasty was noninferior to DES (drug-eluting stent) implantation in small coronary vessels.[4,12] In the PICCOLETO II trial, DCB treatment not only performed similarly to coronary stenting in late lumen loss but was also associated with fewer major coronary adverse events at 3 years.[13] Our findings extend this evidence by showing a sustained safety and efficacy profile with the second generation Essential Pro DCB in real-world practice as a feasible alternative to DES in small-vessel lesions.

High bleeding risk was the second most frequent indication. The use of DCB in this population is particularly attractive to mitigate the risk of early discontinuation of dual antiplatelet therapy. These patients had a more unfavorable baseline profile, including atrial fibrillation and previous coronary bypass grafting. Although DES combined with abbreviated dual antiplatelet therapy regimens has been evaluated in patients at high bleeding risk, evidence supporting DCB angioplasty in this setting remains more limited.[15] The low ischemic event rate and absence of an apparent excess of repeat revascularization in this subgroup suggest that DCB angioplasty

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may be a useful strategy in this particularly vulnerable subgroup. Furthermore, the use of DCBs may be a useful strategy when treating side branches primarily to avoid excessive metal deployment in bifurcations. We reported low event rates when treating bifurcations with DCBs, echoing smaller registries that highlighted the versatility of DCBs in complex anatomies.[16]

In our cohort, all myocardial infarctions and repeat revascularization events occurring during the first year were observed in patients who initially presented with an acute coronary syndrome. In addition, the acute coronary syndrome presentation was associated with higher rates of recurrent angina, repeat coronary angiography, and numerical higher rates of hospitalization and suboptimal DCB results. Most randomized DCB trials in de novo disease, including BELLO, BASKET-SMALL 2, and PICCOLETO II, predominantly enrolled stable or mixed populations, with fewer patients with unstable presentation compared with real-world cohorts. Therefore, the greater event burden observed in patients with acute coronary syndrome in our study may therefore reflect the underlying biological and clinical complexity of this subgroup, including greater plaque vulnerability, thrombotic burden, and diffuse coronary disease, rather than an intrinsic limitation of the DCB strategy.

Limitations

This single-center real-world study lacked a standardized protocol, core laboratory adjudication, and systematic intracoronary imaging. Most treated vessels were of small caliber, which may limit the generalizability of the findings to larger coronary vessels. Finally, the low number of events limits the precision of the outcome estimates.

CONCLUSIONS

Among patients with DNL, use of the Essential Pro DCB was associated with high device deliverability and low rates of adverse clinical events during follow-up. Outcomes were broadly consistent across the main clinical indications evaluated. These findings support the feasibility and safety of DCB angioplasty in this real-world cohort.

FUNDING

This study received no industry sponsoring or external funding.

ETHICAL CONSIDERATIONS

This study was approved by the local institutional review board of the *Instituto Cardiovascular de Buenos Aires* (Buenos Aires, Argentina). Before enrollment, all patients provided written informed consent for the use of their anonymized clinical information for research purposes. Possible sex- and gender-related biases were considered in the preparation of this manuscript.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

We used artificial intelligence to improve reporting readability and grammar.

AUTHORS' CONTRIBUTIONS

L. Padilla conceived and supervised all stages of the research. F. Liberman, J. Tello, P. Rosas, P. Spaletra, G. Pedernera, P. Mascolo, S. Ordoñez, P. Santilli, and A. Candiello collected the data and analyzed the coronary angiograms. F. Cura and J. Belardi provided senior scientific and clinical advice. P. Lamelas performed the statistical analysis and prepared the first draft of the manuscript.

CONFLICTS OF INTEREST

L. Padilla has received proctoring and consulting fees from Terumo and Boston Scientific. P. Spaletra has received honoraria from Boston Scientific. F. Cura received honoraria from Medtronic, Boston Scientific, Terumo and Meril. P. Lamelas has received proctoring and consulting fees from Medtronic, Boston Scientific, Meril, and Microport. The remaining authors declared no conflicts of interest whatsoever.

WHAT IS KNOWN ABOUT THE TOPIC?

- Drug-coated balloons (DCBs) are an established therapy for in-stent restenosis and have recently gained interest for treating de novo coronary lesions. Randomized trials and registry studies suggest that DCB angioplasty may be noninferior—and in some cases comparable—to drug-eluting stent implantation, particularly in small vessels and patients at high bleeding risk.
- By avoiding permanent metallic scaffolds, DCB angioplasty may reduce complications related to stent implantation and the need for prolonged dual antiplatelet therapy.
- However, real-world evidence on newer-generation DCBs for the treatment of de novo coronary lesions remains limited.

WHAT DOES THIS STUDY ADD?

- This prospective cohort specifically evaluated the second-generation paclitaxel-coated Essential Pro DCB in patients with de novo coronary lesions.
- The device showed high deliverability, a low rate of bailout stenting, and favorable final angiographic results.
- Clinical events (MI, TLR, TVR) remained low at short- and mid-term follow-up, and no deaths were recorded.
- Outcomes were broadly consistent across the main treatment indications, including small-vessel disease, high bleeding risk, and bifurcation lesions, supporting the feasibility and safety of this DCB in contemporary real-world practice.

REFERENCES

1. Alfonso F, Byrne RA, Rivero F, et al. Current Treatment of In-Stent Restenosis. *J Am Coll Cardiol*. 2014;63:2659-2673.
2. Padilla L, Liberman F, Tello J, et al. Safety and efficacy of the Essential Pro paclitaxel drug-eluting balloon for the treatment of coronary in-stent restenosis. *REC Interv Cardiol*. 2024;6:166-171.
3. Fezzi S, Serruys PW, Cortese B, et al. Indications for Use of Drug-Coated Balloons in Coronary Intervention: Academic Research Consortium Position Statement. *J Am Coll Cardiol*. 2025;86:1170-1202.

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4. Jeger RV, Farah A, Ohlow MA, et al. Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial. *Lancet*. 2018;392:849-856.
5. Sanz-Sánchez J, Chiarito M, Gill GS, et al. Small Vessel Coronary Artery Disease: Rationale for Standardized Definition and Critical Appraisal of the Literature. *J Soc Cardiovasc Angiogr Interv.* 2022;1:100403.
6. Urban P, Mehran R, Colleran R, et al. Defining high bleeding risk in patients undergoing percutaneous coronary intervention: a consensus document from the Academic Research Consortium for High Bleeding Risk. *Eur Heart J.* 2019;40:2632-2653.
7. Pérez de Prado A, Pérez-Martínez C, Cuellas Ramón C, et al. Safety and Efficacy of Different Paclitaxel-eluting Balloons in a Porcine Model. *Rev Esp Cardiol.* 2014;67:456-462.
8. Garcia-Garcia HM, McFadden EP, Farb A, et al. Standardized end point definitions for coronary intervention trials: The academic research consortium-2 consensus document. *Circulation.* 2018;137:2635-2650.
9. Domienik-Karłowicz J, Kupczyńska K, Michalski B, et al. Fourth universal definition of myocardial infarction. Selected messages from the european society of cardiology document and lessons learned from the new guidelines on st-segment elevation myocardial infarction and non-st-segment elevation-acute coronary syndrome. *Cardiol J.* 2021;28:195-201.
10. Unverdorben M, Kleber FX, Heuer H, et al. Treatment of small coronary arteries with a paclitaxel-coated balloon catheter in the PEPCAD I study: are lesions clinically s from 12 to 36 months? *EuroIntervention.* 2013;9:620-628.
11. Unverdorben M, Vallbracht C, Cremers B, et al. Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis. *Circulation* 2009;119:2986-2994.
12. Latib A, Colombo A, Castriota F, et al. A randomized multicenter study comparing a paclitaxel drug-eluting balloon with a paclitaxel-eluting stent in small coronary vessels: the BELLO (Balloon Elution and Late Loss Optimization) study. *J Am Coll Cardiol* 2012;60:2473-2480.
13. Cortese B, Di Palma G, Guimaraes MG, et al. Drug-Coated Balloon Versus Drug-Eluting Stent for Small Coronary Vessel Disease: PICCOLETO II Randomized Clinical Trial. *JACC Cardiovasc Interv.* 2020;13:2840-2849.
14. Wilson S, Mone P, Kansakar U, et al. Diabetes and restenosis. *Cardiovasc Diabetol* 2022;21:23.
15. Garot P, Morice M-C, Tresukosol D, *et al.* 2-Year Outcomes of High Bleeding Risk Patients After Polymer-Free Drug-Coated Stents. *J Am Coll Cardiol*. 2017;69:162-171.
16. Mathey DG, Wendig I, Boxberger M, et al. Treatment of bifurcation lesions with a drug-eluting balloon: the PEPCAD V (Paclitaxel Eluting PTCA Balloon in Coronary Artery Disease) trial. *EuroIntervention.* 2011;7 Suppl K:K61-K655.

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