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Scientific letter

Drug-coated balloons across different scenarios. Long-term single center experience

Balón farmacoactivo en diferentes escenarios. Experiencia a largo plazo en un centro

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To the Editor,

Currently, drug-coated balloons (DCBs) are used across many different scenarios.[1] There is solid evidence supporting their use in any type of in-stent restenosis (ISR), whether related to bare metal or drug-eluting stents (DES). Other studied settings include small vessels, diffuse disease, and bifurcations.

As there is the need for real-world data with long term follow-up, we sought to conduct a retrospective assessment on the long-term outcomes (1-year follow-up) of patients treated with DCB in our center. The use of DCBs was left to the physician's discretion, provided good lesion preparation was achieved, with < 30% residual percent diameter stenosis and no flow-limiting dissections.

Patients were categorized into 4 groups based on their anatomical context: ISR, small vessels ([SV] reference diameter ≤ 2.5 mm), bifurcations ([Bif], whenever the operator wired the side branch, even if ≤ 2.5 mm) and others (lesions outside the previous groups, where a good angiographic result was achieved with lesion preparation).

We attempted percutaneous coronary intervention (PCI) with DCB was attempted in 298 lesions in 290 patients (table 1). Bailout stenting was performed in 9 procedures. One DCB was not delivered due to proximal tortuosity. Only 5 patients received sirolimus-eluting balloons, all others were paclitaxel-eluting. There were no cases of death or clinically meaningful myocardial infarction related to the procedure. Median follow-up was 3.1 years [1.42-6.61] (a mean of 4.2 ± 3.34 years).

Target lesion failure (TLF) (defined as a composite of clinically driven target-lesion revascularization [TLR], lesion-related death or myocardial infarction [MI]) was observed in 22 (7%) patients, 15 (12%) of whom were ISR; 4 (5%), Bif; 3 (6%), SV; and 0, others. Coronary angiography was performed at the follow-up in 105 patients: in 30 after a scheduled follow-up or PCI, in 39 for stable angina or other stable context, in 8 for unstable angina, in 21 for non-ST-segment elevation myocardial infarction (NSTEMI), and in 7 for ST-segment elevation myocardial infarction (STEMI). Binary restenosis (> 50% percent diameter stenosis) was found in 33 (11%) patients, 18 (6%) of whom underwent TLR (figure 1A) (13 for ISR (10%); 3 for Bif (4%); 2 for SV (4%); and 0 others without statistically significant inter-group differences (figure 1B). Acute myocardial infarction occurred in 25 patients at the follow up. In only 4 of these patients, the AMI was related to the DCB-treated lesion (3 NSTEMIs, 1 inferior STEMI). A total of 84 patients (30%) died (5 during the index admission), 3 had a stroke (1%) and 7 (2%) experienced severe bleeding.

A total of 37 chronic total coronary occlusions (CTOs) were also treated with DCBs, 1 of which required bailout stenting. There were 2 TLFs (6%), both with TLR.

This study has unavoidable caveats related to its retrospective design, such as the lack of detailed information on the optimal medical therapy and out-of-hospital outcomes.

However, this is a real-world study, with updated results that allow us to draw conclusions to some extent. First, the use of DCBs is technically feasible in most cases, provided that a good lesion preparation is achieved (only in 1 case the DCB could not be delivered). Second, it has a low rate of procedural events (3% bailout stenting, no significant procedural clinical complications). Third, the 6% TLR rate observed at the > 3-year follow-up demonstrates that long-term results are very good. The classic ISR indication had non-statistically significant worse results.

In ISR, the TLR rate of 10% observed in our cohort is consistent with the previously described (6.3% up to to 33.3% at 36 months).[2]

Of note, these patients had generally very advanced disease and comorbidities, which probably contributed to an increased incidence of adverse clinical outcomes, especially all-cause mortality.

Regarding bifurcations, DCBs have proven to be a good option, alone or in combination with a DES in the main branch—with a reported TLR of 2% up to 12% at the 6-12-month follow-up[3]—which is also consistent with our observed 4% in a longer follow-up.

In SV, there is strong evidence pointing to a benefit of DCB when compared to POBA and results, at least, as good as full-DES. In fact, irrespectively of vessel diameter, DCBs may allow for a shorter DES need, with similarly good outcomes.

In CTO patients, previously published data report a 8.3% rate of major adverse cardiovascular events and a 11% rate of major adverse cardiovascular and cerebrovascular events 1 year after DCB delivery. Only 2 TLRs were reported in CTO cases in our cohort, giving a 2/36 (5.6%) TLR ratio, which is, at least, equally good as

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Table 1. Patient and procedural characteristics

Patient characteristics			
Patients	290	**Clinical context**	
Male	201 (69)	*Stable angina/Silent ischemia*	115 (40)
Age, years	68 ± 11.0	*Unstable angina*	32 (11)
Diabetes	116 (40)	*NSTEMI*	46 (16)
Type II, non-insulin	102 (34)	*STEMI (culprit in PCI)*	46 (16)
Type II, insulin	13 (5)	*Staged after ACS*	51 (18)
Type I	1 (0)	**CTO**	37 (12)
Dyslipidemia	195 (67)	**Severe calcification**	24 (8)
Hypertension	254 (88)	**Significant thrombus**	9 (3)
Smoking	101 (35)		
Active	53 (18)		
Former	48 (17)		
Previous AMI	152 (52)		
Previous PCI	187 (64)		
Previous CABG	31 (11)		

Lesions		**DCB diameter, mm**	**DCB length, mm**	**Predilation balloons**			**IC imaging**	**Bailout stenting**
				SC	**NC**	**cutting**		
Total	298 (100)	2.8 ± 0.57	20,5 ± 5.63	100 (34)	139 (47)	155 (52)	61 (20)	9 (3)
In-stent restenosis	127 (43)	3.2 ± 0.50	23.6 ± 8.19	32 (25)	72 (57)	80 (63)	44 (35)	0 (0)
Bifurcations	83 (28)	2.6 ± 0.55	18.4 ± 5.60	27 (32)	29 (35)	50 (60)	14 (17)	4 (5)
SV	51 (17)	2.2 ± 0.22	20.0 ± 4.47	28 (55)	22 (43)	9 (18)	2 (4)	2 (4)
Other	37 (12)	2.7 ± 0.40	20.2 ± 5.54	13 (35)	16 (43)	16 (43)	1 (3)	3 (8)

ACS, acute coronary syndrome; AMI, acute myocardial infarction; CABG, coronary artery bypass graft; CTO, chronic total occlusion; DCB, drug-coated balloons; IC, intracoronary; NC, non-compliant; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; SC, semi-compliant; STEMI, ST-segment elevation myocardial infarction; SV, small vessels.
Data are expressed as no. (%) or mean ± standard deviation.

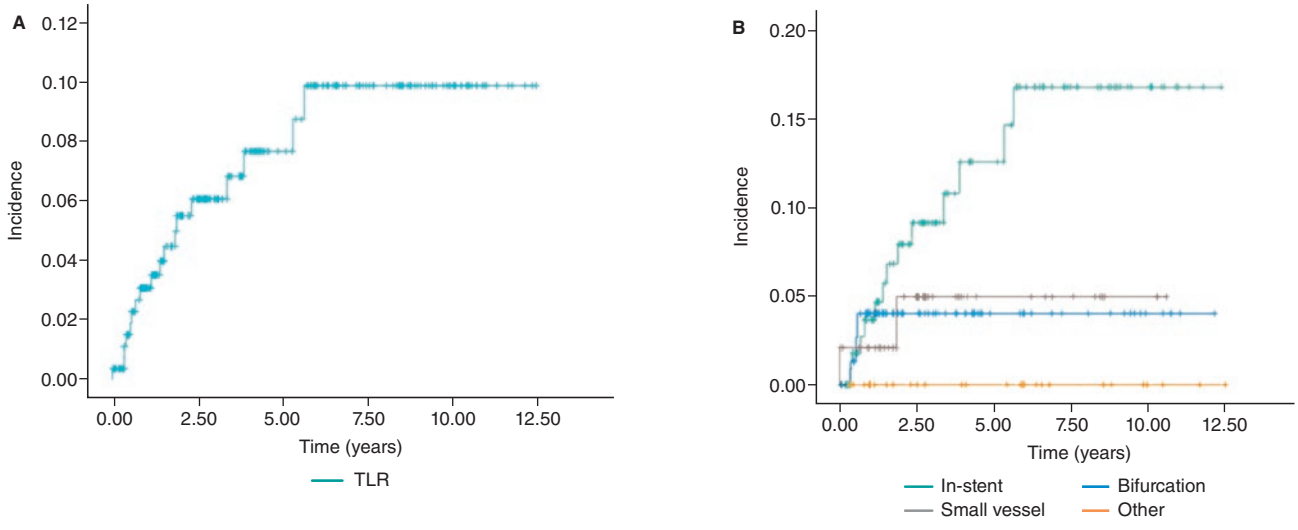

Figure 1. A: Kaplan Meyer cumulative incidence curve for target lesion revascularization (TLR) in all patients. B: Kaplan Meyer cumulative incidence curve for target lesion revascularization in patients based on their anatomical setting.

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the 11.8% and 27.7% reported at the above-mentioned 1- and 6-month follow-ups.[4]

Provided that a good lesion preparation is achieved, and in the absence of structural compromise to the vessel, the lack of a metal stent will be of benefit for any type of lesion (such as those included in "others"). It will contribute to late lumen enlargement (LLE), which can happen in 40%-56% of lesions treated with DCB and is associated with layered plaques by OCT and medial dissection after lesion preparation.

Our results refer to paclitaxel-eluting balloons almost exclusively, although the early experience with sirolimus seems to be similar. In the PREVENT trial,[5] PCI with DES in vulnerable lesions proved to improve prognosis. The drug eluted by the DES also has anti-inflammatory properties, thus significantly contributing to the stabilization of de novo atherosclerotic plaques. Therefore, the question of whether a DCB could have even better long-term results remains, given its greater LLE potential. The nature of the plaque probably impacts the DCB outcomes significantly, as demonstrated by its association with LLE. In the future it would be useful to predict the DCB long-term success through imaging modalities before any DCB vs DES (vs other) decisions are made, for example, with intravascular imaging and computed tomography angiography.

FUNDING

None declared.

ETHICAL CONSIDERATIONS

This work was approved by the local ethics committee; all patients signed an informed consent form and the SAGER guidelines were followed at all times.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence tools were used.

AUTHORS' CONTRIBUTIONS

All authors contributed to the patients' clinical management and follow-up, and the proofreading and optimization of the manuscript; D. Neves: study design and drafting; M. Sousa: statistics.

CONFLICTS OF INTEREST

None declared.

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