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Long term clinical outcome of sirolimus drug coated balloons in large coronary vessels

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Abstract

Background: Studies evaluating the safety and efficacy of drug coating balloons (DCB) for the treatment of lesions in large coronary vessel are limited.

Aims: Our study aimed to evaluate the performance of a sirolimus DCB in large coronary arteries.

Methods: We analyzed all the procedures included in the EASTBOURNE Registry (NCT03085823) enrolling patients with a clinical indication to percutaneous coronary intervention performed by a sirolimus DCB according to investigator judgment. In the present analysis, a cut-off of 2.75 mm was used to define large coronary arteries. Primary endpoint of the study was clinically driven target lesion revascularization (TLR) at 24 months whereas secondary endpoint included procedural success, myocardial infarction (MI), cardiac death and total mortality.

Results: Among the 2123 patients and 2440 lesions enrolled in the EASTBOURNE study between 2016 and 2020, 757 patients/810 lesions fulfilled the criteria for the present analysis. Mean reference vessel diameter was 3.2 ± 0.3 mm with mean lesion length of 22 ± 7 mm. Procedural success was high (96%) and at 2-year follow up the device showed a good efficacy with a TLR rate of 9%. There were 34 deaths (4.5%), 30 MIs (4%) and 8 BARC type 3–5 bleedings (1.1%). In-stent restenosis (629 lesions) and de novo lesions (181) were associated with 11% and 4% rates of TLR at 2 years, respectively ($p = 0.003$).

Conclusions: Clinical performance of a sirolimus DCB in large coronary artery vessels shows promising signals at 2-year follow up, both in de novo and in-stent restenosis lesions.

KEYWORDS

drug coated balloon, large coronary arteries, long term follow up, PCI, sirolimus

1 | INTRODUCTION

Drug coated balloon (DCB) may represent a valid alternative to stenting for the treatment of coronary artery disease in several clinical situations, including in-stent restenosis (ISR) and small coronary vessel disease.[1–4]

The role of DCB in the treatment of large coronary arteries is less defined but potentially appealing as the lack of a permanent cage in the vessel allows the maintenance of a regular vasomotion and may reduce the duration of dual antiplatelet therapy. Previous studies showed the feasibility of DCB in the treatment of large vessel disease but most of the data come from studies enrolling a small number of patients with short follow up.[5,6]

DCB is a semi-compliant angioplasty balloon coated with different antiproliferative drugs that are released into the vessel wall upon inflation. The most largely studied drug in the setting of DCB is paclitaxel, introduced in 2007, but sirolimus became available as well since 2016. If several trials have shown the superiority of sirolimus compared to paclitaxel as regards drug eluting stents (DES),[7] only few designed comparative randomized trials between paclitaxel or sirolimus DCB are available,[8,9] and a class effect cannot be assumed for this technology. Recently, the safety and efficacy of a sirolimus DCB in a broad population of coronary artery disease patients has been demonstrated in the EASTBOURNE study.[10]

Aim of this study is to confirm the efficacy and safety of a sirolimus DCB in the treatment of large vessel in terms of acute and long-term outcome.

2 | METHODS

2.1 | Study design and population

The EASTBOURNE (All-Comers Sirolimus-Coated Balloon European Registry; NCT03085823) registry is a prospective, multicentre investigator-driven clinical study aimed to evaluate the performance of the MagicTouch (Concept Medical) sirolimus DCB for the treatment of any type of coronary lesion. Globally, 38 Centers located in Europe and Asia with experienced operators using DCB were included, enrolling real-world coronary artery disease patients. All patients with a clinical indication to PCI with DCB following the investigator judgment could be enrolled. Being this an all-comer study, only exclusion criteria were severe calcification of the vessel, high tortuosity and visible thrombus of the culprit vessel. The procedural strategy as well the pharmacological therapy during the procedure and at follow up were left to operator discretion. Lesion preparation was mandatory and bailout stenting was discouraged unless significant flow-limiting dissections or acute vessel recoil were observed. The study device has been described elsewhere.[11]

After discharge patients were followed clinically at 6, 12, 24, and 36 months after the index procedure.

For the sake of the current analysis (a post hoc analysis not prespecified), we stratified patients according to their vessel diameter. Since no general accepted definition is available, we chose a cut-off of 2.75 mm to define large coronary arteries as documented in previous studies.[12,13] Procedures included in this sub-study were subsequently divided in two groups according to the treatment of "de novo" lesions or ISR.

The study received the approval of the ethical committee of each participating center.

2.2 | Endpoint of the study

Primary endpoint of the study was clinically driven target lesion revascularization (TLR) at 24 months. TLR was defined as re-intervention of the culprit lesion in case of a >70% angiographic stenosis associated with symptoms or ischemia documented by stress test or functional assessment. Secondary endpoints included angiographic success (final stenosis <50% without flow-limiting dissection), procedural success (angiographic success without in-hospital complications), myocardial infarction (MI), cardiac death and major adverse cardiac events (MACE) defined as a combination of TLR, MI and cardiac death during the 24-month follow up. "Device malfunctioning" was defined as any case in which the device did not work as expected during or after its use in accordance with its function and when used in accordance with the instructions for use.

2.3 | Statistical analysis

Patient characteristics are summarized using descriptive statistics. Continuous variables are reported as mean and standard deviation for variables normally distributed and as median with interquartile range for variable not-normally distributed and were compared between de novo and ISR group using the *t*-test and Mann–Whitney *U*-test. Categorical variables are presented as absolute numbers and percent and were compared using the Pearson Chi square test or the Fisher exact test (if the number of cases was fewer than 5). All tests were two-tailed and a $p < 0.005$ was considered significant. All statistics were performed using R version 4.0.1 (R Foundation for statistical Computing).

3 | RESULTS

From a total of 2123 patients and 2440 lesions enrolled in 38 Centers in Europe and Asia between September 2016 and November 2020 in the EASTBOURNE study, 757 patients and 810 lesions fulfilled the inclusion criteria for large coronary arteries in the present analysis and have been analyzed here. One-hundred-and-eighty-one patients were treated with DCB for "de novo," and 629 for ISR lesions.

3.1 | Procedural and clinical characteristics

Baseline clinical characteristics are presented in Table 1. The majority of patients treated were males (81%) with a median age of 69 years. More

TABLE 1 Clinical characteristics.

	Entire population (*n* = 757)	De novo lesions (*n* = 171)	In-stent restenosis (*n* = 586)	*p*
Age (years)	68 ± 11	65 ± 12	69 ± 10	<0.001
Male	616 (81)	140 (82)	476 (81)	0.911
Height (cm)	169 ± 9	169 ± 9	169 ± 8	0.729
Weight (Kg)	78 ± 14	78 ± 16	78 ± 14	0.889
Body mass index	27 ± 4	27 ± 5	27 ± 4	0.882
Smoking habitus	193 (26)	60 (35)	133 (23)	0.001
Diabetes	314 (42)	52 (30)	262 (45)	0.001
Dyslipidemia	570 (75)	112 (66)	458 (78)	0.001
Chronic kidney disease	108 (14)	22 (13)	86 (15)	0.620
Previous stroke	42 (6)	10 (6)	32 (6)	0.850
Congestive heart failure	68 (9)	8 (5)	60 (10)	0.023
Previous MI	397 (52)	60 (35)	337 (58)	<0.001
Previous PCI	652 (86)	88 (52)	586 (100)	<0.001
Previous CABG	113 (15)	12 (7)	101 (17)	0.001
Peripheral vascular disease	314 (42)	52 (30)	262 (45)	0.001
Multivessel disease	477 (63)	93 (54)	384 (66)	0.009
Left ventricular EF (%)	51 ± 11	52 ± 14	51 ± 10	0.828
Creatinine (mg/dL)	1.3 ± 1.3	1.2 ± 1.3	1.3 ± 1.3	0.593
Hemoglogin (g/dL)	13 ± 2	14 ± 2	13 ± 2	0.052
Treatment at discharge				
Aspirin	657 (87)	129 (75)	528 (90)	<0.001
Clopidogrel	231 (31)	45 (26)	186 (32)	0.187
Prasugrel	13 (2)	0 (0)	13 (2)	0.048
Ticagrelor	82 (11)	26 (15)	56 (10)	0.049
Statin	523 (69)	92 (54)	431 (74)	<0.001
Clinical indication				<0.001
NSTEMI	140 (19)	26 (15)	114 (20)	
Silent ischemia	139 (18)	38 (22)	101 (17)	
Stable angina	272 (36)	61 (36)	211 (36)	
STEMI <12 h	26 (3)	11 (6)	15 (3)	
STEMI >12 h	16 (2)	9 (5)	7 (1)	
Unstable angina	164 (22)	26 (15)	138 (24)	

Note: Results expressed as mean ± standard deviation or absolute number and percent in bracket. *Median with interquartile range.

Abbreviations: ACS, acute coronary syndrome; CABG, coronary artery by pass; CAD, coronary artery disease; EF, ejection fraction; MI, myocardial infarction; NSTEMI, non-ST elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST elevation myocardial infarction.

than 40% of the patients enrolled had diabetes mellitus and more than 75% had hypercholesterolemia. Acute coronary syndrome was the clinical indication for PCI in more than 45% of patients with 5% of patients with acute or sub-acute ST elevation acute myocardial infarction.

As depicted in Table 1, there were significant differences between the "de novo" and ISR groups. Patients with ISR were older and with higher rate of diabetes and previous MI compared to patients with de novo lesions.

Procedural characteristics are shown in Table 2. Mean reference vessel diameter was 3.2 ± 0.3 mm with mean lesion length of 22 ± 7 mm. A large proportion of patients had an American College of Cardiology/American Heart Association type B2 or C stenosis (43%). Lesion preparation occurred more frequently in the de novo group (84% vs. 96%, $p < 0.001$), despite it was strongly recommended by study protocol. Predilatation before DCB has been mostly performed by semi-compliant (52%) or non compliant balloons (40%) and only in few cases by scoring balloons (8%). A moderate (49%) or severe (9%) calcification of the lesion treated has been reported by the operators and in 145 cases a bifurcation lesion has been treated. Most of the procedures has been performed through transradial approach (79%) and imaging was employed in a minority of patients (9%). Procedural success was high (96%) with post-procedural TIMI III flow observed in 98% of cases. A DES was implanted in a bailout fashion in 7% of the procedures.

Reference vessel diameter was significantly larger in ISR (3.3 ± 0.3 mm) compared to de novo lesions (3.1 ± 0.3 mm, $p < 0.001$) whereas there were no significant differences in terms of lesion length (21 ± 7 mm in the ISR group and 23 ± 8 mm in the de novo group, $p = 0.08$).

3.2 | Clinical endpoints

At 2-year follow up, this DCB showed a good efficacy with a TLR rate of 9% (75 lesions). MACE occurred in 111 patients (15%) with 30 MIs (4%) and 34 cardiac deaths (4.5%) (Figure 1).

TLR occurred more frequently in ISR as compared to de novo lesions (11% and 4%, respectively, $p = 0.003$, Figure 2). Target vessel

TABLE 2 Procedural characteristics.

	Entire population (n = 810)	De novo lesions (n = 181)	In-stent restenosis (n = 629)	p
Diameter stenosis (%)	81 ± 14	82 ± 13	80 ± 15	0.07
Reference vessel diameter (mm)	3.3 ± 0.3	3.1 ± 0.3	3.3 ± 0.3	<0.001
Lesion length (mm)	22 ± 7	23 ± 8	21 ± 7	0.073
Lesion type				0.001
Type A	165 (20)	24 (13)	141 (22)	
Type B1	293 (36)	87 (48)	206 (33)	
Type B2	176 (22)	33 (18)	143 (23)	
Type C	176 (22)	37 (20)	139 (22)	
Predilatation	752 (93)	151 (84)	601 (96)	<0.001
IVUS	47 (6)	5 (3)	42 (7)	0.048
OCT	23 (3)	5 (3)	18 (3)	1.000
Bailout stent implantation	57 (7)	20 (11)	37 (6)	0.069
Final dissection left (type B)	15 (2)	7 (4)	8 (1)	0.054
Device malfunction	2 (0.2)	1 (0.6)	1 (0.2)	0.397

Note: Results expressed as mean ± standard deviation or absolute number and percent in bracket.

Abbreviations: DCB: drug coated balloon; IVUS, intravascular ultrasonography; OCT, optical coherence tomography.

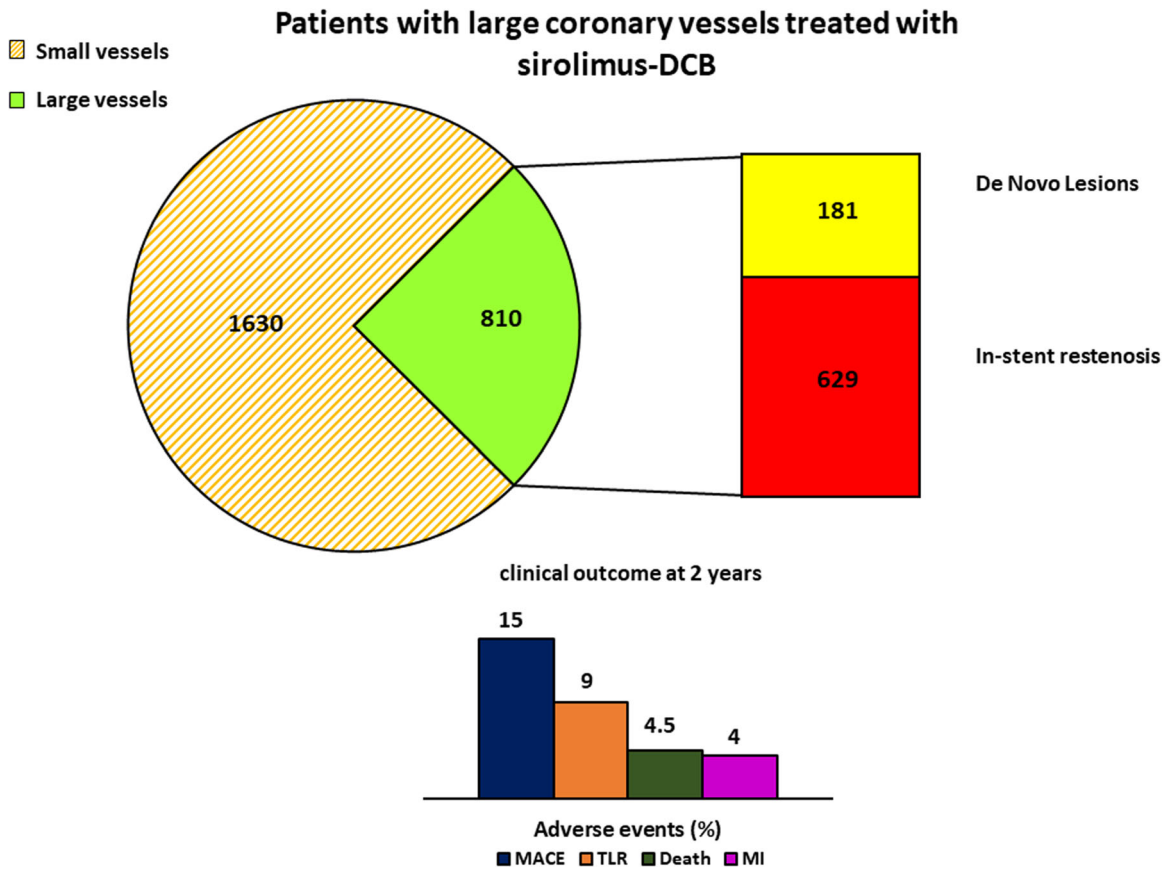

FIGURE 1 Procedures and clinical events. A total of 810 procedures were included in this study (181 de novo lesions and 629 in-stent restenosis). At 2-year follow up, the studied device showed a good efficacy with a target lesion revascularization rate of 9% (75 lesions) and a death rate of 4.5%. MACE, major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularization. [Color figure can be viewed at wileyonlinelibrary.com]

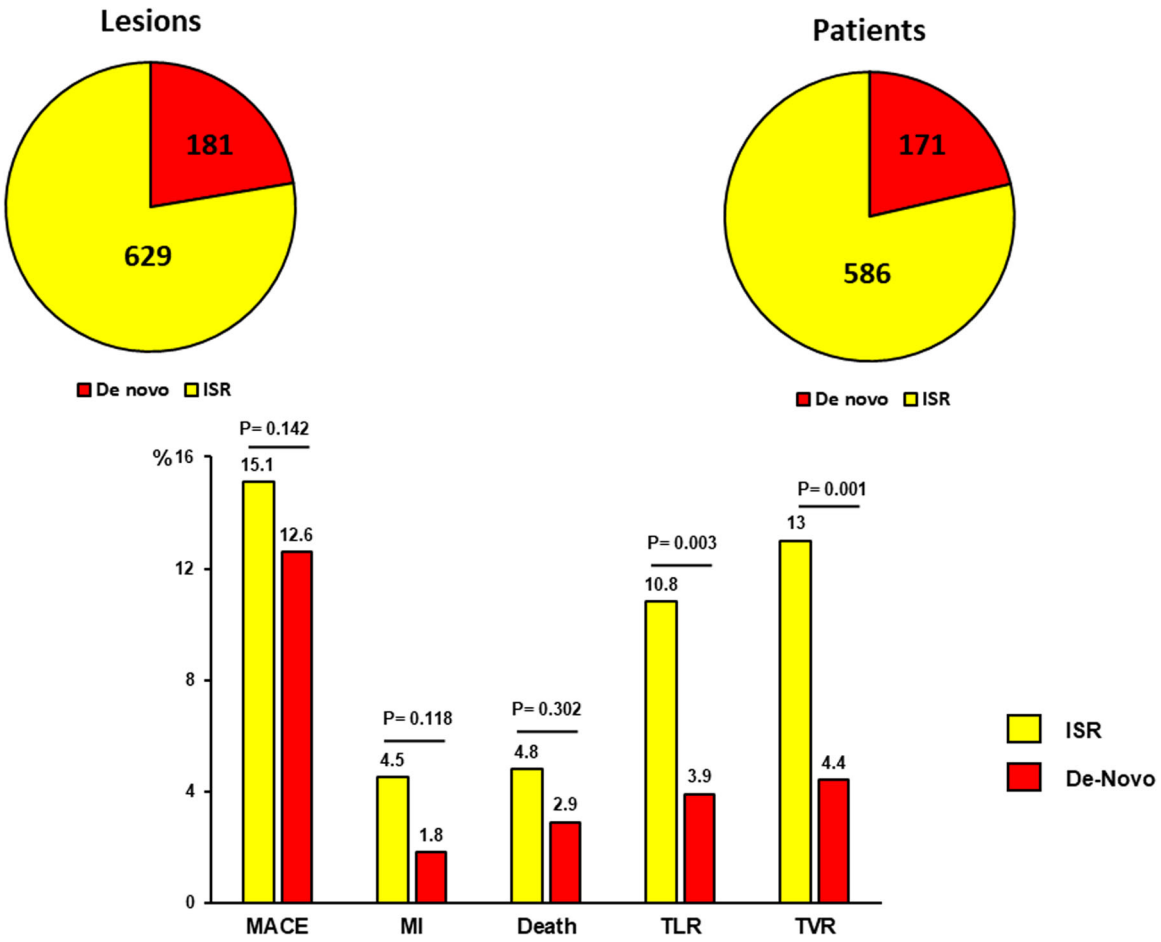

FIGURE 2 Clinical endpoints at 2-year follow up comparing in-stent restenosis and de novo lesions. At 2-year follow up, target lesion revascularization and target vessel revascularization were significantly lower in patients in the de novo group compared with patients with in-stent restenosis. ISR, in-stent restenosis; MACE, major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization. [Color figure can be viewed at wileyonlinelibrary.com]

revascularization was also significantly lower in de novo lesions (4%) compared to ISR (12%, $p = 0.002$). No significant differences in MACE (15.7% in ISR and 11.1% in de novo lesions, $p = 0.142$), death rate (4.9% in ISR and 2.9% in de novo lesions, $p = 0.302$), and MI (4.6% in ISR and 1.8% in de novo lesions, $p = 0.118$) were observed between the two groups.

4 | DISCUSSION

The main finding of our study is that DCB angioplasty is safe and effective for the treatment of large coronary vessels, with data deriving from a large prospective registry with external clinical events assessment. Interesting, this information can be applied either to ISR and de novo lesions.

DCB allows, after the achievement of good lesion preparation by means of plain balloon angioplasty or other dedicated tools, the local delivery of antiproliferative drugs without leaving a metal scaffold behind. In this way, DCB could reduce some complications associated with the use of stents such as late stent thrombosis and allows only short-term dual antiplatelet therapy (usually 1–3 months) which is useful in patients with a high bleeding risk.[1] Several studies showed the efficacy of DCB for the treatment of small vessel disease with a comparable effect to DES, with some initial signals of lower events on the long term.[4,14] DCB have been also tested in large vessels but in these studies the number of patients enrolled is limited.[5,6] Recently, Leone et al.[15] tested a strategy of DCB in 100 large vessels, showing a target lesion failure of 5.1% at 12-month follow up which is similar to the 4% TLR rate observed in de novo lesions of our study even though at 2-year follow up. In that study different types of DCB have been used including paclitaxel-DCB as well sirolimus-DCB limiting the understanding of the results because the two drugs have different pharmacological characteristics (paclitaxel binds irreversibly to the microtubes whereas sirolimus blocks cell cycle progression between G1 and S phases) that exclude a class effect. For example, in the setting of DES, sirolimus and its analogues showed a significant superiority compared to paclitaxel[7] and currently only limus-eluting stents are available. Differently, the majority of currently available DCB are coated with paclitaxel whereas data on sirolimus-DCB are limited with few direct comparison between the two drugs.[8] Recently

a small randomized trial comparing paclitaxel versus sirolimus DCB using the same sirolimus balloon tested in our study has been published showing that the sirolimus DCB failed to demonstratenon-inferiority as per angiographic net lumen gain at 6 months in the treatment of small vessel disease, without differences in clinical events even though the study was not powered for clinical events.[16,17] Our study, including only Magic Touch sirolimus-DCB, allows to clarify the efficacy and safety of this type of DCB for the treatment of large coronary vessel including ISR.

Data on the long-term efficacy of DCB in large coronary vessels are scantbecause in most of the studies the follow up is lower than 1 year. A longer follow up (2 years) is available in the study of Hu et al.[18] that evaluated the efficacy of a paclitaxel-coated DCB in de novo lesions ≥2.75 mm showing a TLR of 3.4%, similar to the one observed here in the cohort of de novo lesions. In our study too, the follow up was extended up 2 years demonstrating a TLR of 9% in the whole population but only a 4% rate in the de novo sub-group, representing the largest registry with the longest follow up testing a sirolimus DCB in the treatment of large coronary vessel.

Some studies have shown the superiority of DCB in terms of clinical and angiographic outcome for de novo lesions compared to ISR using paclitaxel-DCB.[19] In the study by Widder et al.[20] in more than 800 lesions treated by paclitaxel-DCB, a TLR rate of 7.5% has been observed in the ISR group and only 4.9% in the de novo lesions group. In our study too, a sirolimus-DCB showed higher efficacy and better clinical outcome for the treatment of de novo lesions compared to ISR appearing an attractive alternative for the interventional, stentless treatment of suitable de-novo coronary lesions.

In our study, we report a 24 months cardiac death rate of 5% which is higher compared to that observed in previous studies.[14,15] However, the risk profile of our patients is substantially higher compared to previous registries, including 25% of patients with acute MI and more than 40% patients with diabetes. At the same time, our mortality rate is similar to that observed by Rosenberg et al.[19] that analyzed a comparable high risk population of patients with large vessel disease.

We would like to acknowledge some important limitations for the current study. First, the study lacks of a control group due to the observational design and possible selection biases cannot be excluded and the ongoing TRASFORM II study comparing a sirolimus-DCB with DES[21] will clarify this point. Moreover, there was no routine angiographic follow up probably reducing the rate of restenosis even though we considered more important clinical outcomes as death and MI that were low despite the elevated risk profile of the patients enrolled. Finally in the "de novo" large vessel group there was a suboptimal rate of predilatation that could have impaired our results since any DCB is only a drug delivery device and not a dedicated balloon for dilatation: unfortunately, according to the observational design of the study, even though predilatation was strongly indicated, it was left to operator discretion and our results express the real world practice.

5 | CONCLUSIONS

In conclusion, our study shows that sirolimus-DCB is safe and effective on the long term in the treatment of lesions (either de novo as well ISR) in large coronary vessels. Larger and randomized studies are necessary to confirm our preliminary results.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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