

# The fate of coronary dissections left after sirolimus-coated balloon angioplasty: A prespecified subanalysis of the EASTBOURNE study

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## Abstract

**Objectives:** We sought to understand the clinical outcomes of dissections left untreated after sirolimus drug-coated balloon (DCB) angioplasty.

**Background:** DCB may be a valuable alternative to stents for the treatment of native coronary lesions, but the risk of having a dissection after DCB-angioplasty is not negligible. While type A and B dissections can be safely treated conservatively, some debate exists regarding type C dissections. We previously showed the safety of dissections left untreated after second-generation paclitaxel-DCB. However, the fate of dissections after sirolimus-DCB angioplasty has not been investigated so far.

**Methods:** EASTBOURNE is a prospective, multicenter, international, investigator-driven study aiming to explore the safety and efficacy of a novel sirolimus-DCB. This study enrolled a consecutive, all-comer population of coronary artery disease patients and is the largest prospective study on DCB so far. Primary endpoints of the study, target-lesion revascularization (TLR), and other clinical endpoints at 12 months, have been presented elsewhere. This is a prespecified subgroup analysis of the patients left with not-flow limiting dissection after DCB angioplasty, with complete 12 months follow-up and comparison between patients left with a dissection versus patients with DCB used for de novo lesions.

**Results:** Between September 2016 and November 2020, a total of 2123 patients were enrolled at 38 study centers. Seventy-three patients were left with nonflow limiting dissections (43 type A, 27 type B, 3 type C) and underwent complete 1-year clinical follow-up. In the nondissection group, 1110 patients had de-novo coronary artery disease while 900 had in-stent restenosis. Baseline characteristics were similar between the groups, while the dissection group was associated with longer lesions (23.8 vs. 18.4 mm,  $p < 0.001$ ) and more frequent use of predilation (100 vs. 91.4%,  $p = 0.016$ ). At 12-month follow-up, no significant differences among the groups were found, with a total of 1.25% TLR in the dissection cohort versus 5.6% in the de-novo cohort ( $p = 0.13$ ), and an overall rate of major adverse cardiovascular events of 4.4% versus 10.1% ( $p = 0.18$ ). Total death (1.5 vs. 2.6,  $p = 0.87$ ), cardiac

death, myocardial infarction (0% vs. 2.5%,  $p = 0.35$ ), and bleedings did not differ significantly among the groups as well.

**Conclusions:** In this subgroup analysis of the EASTBOURNE study of consecutive patients treated with new-generation sirolimus DCB, dissections left untreated after angioplasty did not lead to an increase in adverse events.

#### KEYWORDS

bailout stenting, drug-coated balloon, EASTBOURNE registry, residual dissection

## 1 | INTRODUCTION

Drug eluting stents (DES) remain the default revascularization strategy for patients with coronary artery disease and are considered class I recommendations for patients with de novo lesions and in-stent restenosis according to the European Society of Cardiology revascularization guidelines.<sup>1</sup> However, drug-coated balloons (DCB) are now emerging as a safe and efficient alternative to stent implantation, mainly for in-stent restenosis,<sup>2</sup> for which the European Society of Cardiology has granted a class IA recommendation. What is more, this approach is currently being used as a routine strategy for small coronary vessels and for high-bleeding risk patients that cannot tolerate long-term antiplatelet therapy as well.<sup>3</sup> DCB share the peculiarity of delivering an antirestenotic drug without the need for prosthesis implantation.<sup>4,5</sup> As it is well recognized from the early era of interventional cardiology, one of the direct consequences of balloon dilatation of a vessel could be the occurrence of an angiographically visible coronary dissection.<sup>6</sup> The decision if to stent a coronary dissection after DCB angioplasty or not is still under debate, and is often left at the personal experience of every single operator. After angioplasty with paclitaxel-DCB the safety of leaving a not flow-limiting dissection without stenting has already been proved.<sup>6</sup> On the other hand, information on the outcome of dissections left untreated after sirolimus-DCB (SCB) is still scarce and anecdotal. We here report a prespecified analysis of the prospective EASTBOURNE registry aiming to discover the fate of dissections left untreated after Magic Touch SCB (Concept Medical, USA).

## 2 | METHODS

### 2.1 | Study design and population

EASTBOURNE ([clinicaltrials.gov](https://clinicaltrials.gov) I.D.: NCT03085823) is a prospective, investigator-driven multicenter study including 38 international centers from Europe and Asia. The clinical setting is an all-comer PCI population treated with Magic Touch SCB. We enrolled patients with symptomatic coronary artery disease, both stable angina and acute coronary syndromes with clinical indications for percutaneous coronary intervention and  $\geq 18$  years, where the Operator had

decided to use the study DCB. To be invited to participate in the study, investigators had to certify good expertise with the DCB procedure with usage of at least 30 DCB per year in the last 5 years.

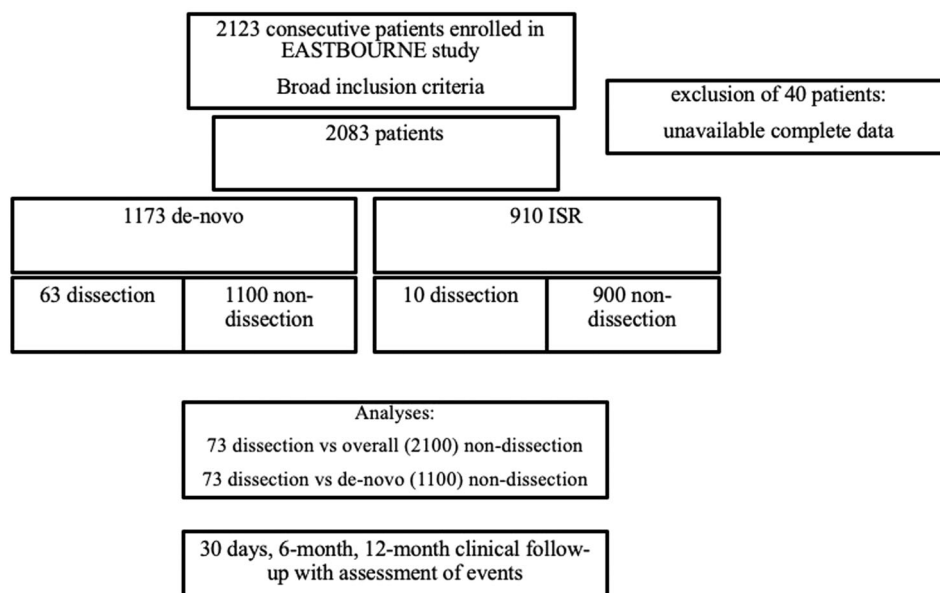
The study excluded patients with unsuccessful predilatation with residual stenosis  $>50\%$ , severe calcifications, high tortuosity of the vessel and visible thrombus.<sup>7</sup> Study primary endpoint was target-lesion revascularization (TLR) at 12 months. Secondary endpoints were procedural success and major adverse cardiac events (MACE) throughout the 36 months. Procedural success was defined as angiographic success in the absence of in-hospital major events including death, myocardial infarction (MI), need for TLR, stroke, vascular access site complications, and contrast agent nephropathy. Angiographic success was defined as successful balloon delivery with a residual diameter stenosis value of  $<50\%$  without procedural complications. MACE was defined as a composite of all-cause death, spontaneous MI, and TLR.

Cardiovascular risk factors were defined as follows: arterial hypertension as systolic blood pressure  $>140$  mmHg and/or diastolic blood pressure  $>90$  mmHg or treated hypertension; diabetes mellitus as glycosylated hemoglobin level  $\geq 6.5\%$  and/or fasting glucose level  $\geq 126$  mg/dL or the use of antidiabetic drugs; dyslipidemia as low-density lipoprotein cholesterol  $>130$  mg/dL and/or triglycerides  $>150$  mg/dL or treated dyslipidemia.

STEMI was defined as continuous typical chest pain that lasted more than 30 min associated with an ST-segment elevation of at least 0.1 mV in 2 or more contiguous leads or a new left bundle branch block on the 12-lead electrocardiogram and elevated cardiac biomarkers (high-sensitivity cardiac troponin I, creatin kinase, creatin kinase-MB). NSTEMI was defined as ischemic symptoms with elevated cardiac enzymes in the absence of persistent ST-segment elevation on the electrocardiogram, whereas UAP was defined as ischemic symptoms at rest in the absence of ST-segment elevation or positive cardiac biomarkers. Multivessel disease was diagnosed in the presence of a significant stenosis in any of the nonculprit vessels or LM disease.

All patients underwent clinical follow-up following the index procedure at 30 days, 6 months, and 12 months, respectively, via telephone survey and outpatient clinical visits.

In this article, we are reporting the 12-month outcome of patients left with coronary dissection without stent implantation and compared their outcome with the one of the overall study population (Figure 1, Study flowchart).



**FIGURE 1** Study flowchart.

## 2.2 | Main study results

The main results of the EASTBOURNE study have been reported elsewhere.<sup>7,8</sup> Briefly, the study enrolled a total population of 2123 patients with 2440 lesions treated. Fifty-five percent of the patients had de-novo lesions and 45% ISR. After 12 months, TLR occurred in 5.9% of the lesions, MACE in 9.9% of the patients, and the rate of all cause death was 2.5%, while the main determinant for the occurrence of the primary endpoint after multivariate analysis was ISR (OR 5.5, IC 3.382–8.881).

## 2.3 | Device description

Magic Touch SCB contains a nanocarrier that is able to carry a dose of 1.27 mg of sirolimus/mm<sup>2</sup>.<sup>2</sup> The device is available in multiple dimensions ranging from 10 to 40 mm in length and 1.5 to 4 mm in diameter. The surface of the balloon, when exposed to blood, is able to create pores and connections that will allow a faster release of the drug on the targeted area.

## 2.4 | Procedure

Proximal and distal references were identified as sites with the largest lumen diameter proximal and distal to the plaque, but within a 10 mm segment. The average between the proximal and distal references was calculated (reference vessel diameter- RVD). Minimal lumen diameter (MLD) was defined as the smallest diameter in the lesion segment.

The procedure was performed according to international guidelines.<sup>1</sup> Heparin was given after sheath insertion with the addition of loading doses of antiplatelets (aspirin 100–325 mg and loading dose of ticagrelor [180 mg] or prasugrel [60 mg] or clopidogrel [300/600 mg] depending on the presentation of the patient). Aspirin was continued lifelong and the second antiplatelet drug for up to 1 month postprocedure in case of absence of additional stenting, and for 6–12 months in case of DES implantation or presentation with acute coronary syndrome. DCB was inflated to its nominal pressure and was maintained for a minimum of 30 s. DCB diameter was adapted to the RVD with a balloon-to-vessel ratio of 0.8–1.0/1.0, while balloon length was chosen to exceed both lesion ends with at least 3 mm. The placement of a stent post-DCB in a bailout fashion was decided by the operator and suggested in the case of coronary dissection of type >B and in case of impaired coronary flow. The protocol also suggested not to stent small and uncomplicated dissections of type A and B.

## 2.5 | Statistical analysis

Patient characteristics are summarized using descriptive statistics. Mean (SD), median (IQR) were used for continuous variables with normal or nonnormal distributions. Percent absolute frequency was used for categorical variables. Continuous variables were compared using t test and Mann–Whitney *U* test, and categorical variables using  $\chi^2$  test.

All tests were two-sided and *p* value < 0.05 was considered significant. All statistical analyses were performed using R version 4.0.2 (R Core Team 2022: A language and environment for statistical computing. R Foundation for Statistical Computing, URL <https://www.R-project.org/>).

**TABLE 1** Initial classification of patients.

Variable	Patients			Lesions		
	Overall	DL	IR	Overall	DL	IR
	2083	1173	910	2339	1284	1055
Final dissection (%)						
No	2010 (96)	1110 (95)	900 (99)	2266 (97)	1221 (95)	1045 (99)
Yes	73 (4)	63 (5)	10 (1)	73 (3)	63 (5)	10 (1)
Final dissection type (%)						
A	43	39	4	43	39	4
B	21	15	6	21	15	6
C	3	3		3	3	
NA	6	6		6	6	

Abbreviations: DL, de novo lesions; IR, intrastent restenosis.

**TABLE 2** Baseline characteristics of patients.

	Overall (N = 2083)	Final dissection, yes (N = 73)	Final dissection, no (N = 2010)	<i>p</i> *
Gender (male), <i>n</i> (%)	1690 (81.1)	61 (83.6)	1629 (81.0)	0.698
Age, mean (SD)	66.61 (11.27)	64.58 (13.91)	66.37 (12.90)	0.245
Diabetes mellitus, <i>n</i> (%)	864 (41.5)	31 (42.5)	833 (41.4)	0.957
Insulin-dependent diabetes, <i>n</i> (%)	283 (13.6)	8 (11.0)	275 (13.7)	0.622
Hypercholesterolemia, <i>n</i> (%)	1496 (71.8)	54 (74.0)	1442 (71.7)	0.777
Hypertension, <i>n</i> (%)	1604 (77.0)	51 (69.9)	1553 (77.3)	0.182
Congestive heart failure, <i>n</i> (%)	170 (8.2)	6 (8.2)	164 (8.2)	>0.999
Previous myocardial infarction, <i>n</i> (%)	894 (42.9)	34 (46.6)	860 (42.8)	0.602
Previous CABG, <sup>a</sup> <i>n</i> (%)	244 (11.7)	6 (8.2)	238 (11.8)	0.447
Previous PCI, <i>n</i> (%)	1380 (66.3)	38 (52.1)	1342 (66.8)	0.013
Multivessel disease, <i>n</i> (%)	1235 (59.3)	46 (63.0)	1189 (59.2)	0.591
Creatinine, median [IQR]	1.00 [0.83, 1.20]	1.00 [0.84, 1.17]	1.00 [0.83, 1.20]	0.93
Hemoglobin, mean (SD)	13.39 (2.14)	13.34 (2.88)	24.58 (501.57)	0.848
Clinical indication to PCI, <i>n</i> (%)				
Non-STEMI <sup>b</sup>	445 (21.4)	17 (23.3)	428 (21.3)	0.787
Silent ischemia	409 (19.6)	12 (16.4)	397 (19.8)	–
Stable angina	706 (33.9)	25 (34.2)	681 (33.9)	–
STEMI < 12 h <sup>c</sup>	91 (4.4)	5 (6.8)	86 (4.3)	–
STEMI > 12 h	68 (3.3)	1 (1.4)	67 (3.3)	–
Unstable angina	364 (17.5)	13 (17.8)	351 (17.5)	–

\**p* Values from: *t* test (mean (SD)); Mann–Whitney *U* test (median [IQR]);  $\chi^2$  test (*n* (%)) or Fisher's exact test (*n* (%), when some of the cell have counts fewer than 5).

<sup>a</sup>Coronary artery bypass graft.

<sup>b</sup>Non ST-elevation myocardial infarction.

<sup>c</sup>ST-elevation myocardial infarction.

### 3 | RESULTS

Between September 2016 and December 2020, a total of 2083 patients were included in the dissection subanalysis of EASTBOURNE study. Overall, a total of 73 patients (3%) were left with dissections without further stenting, following judgment of the operator (Table 1). As expected, in only 10 cases dissections left untreated occurred in the ISR group (1% of all the lesions). The type of dissection left was type A or B, following the suggestions by study protocol and international position papers, although also 6 type C dissections were left unstented for clinical decision by the local Investigator. Bailout stenting occurred in 7.7% of cases in the overall population.

Within the entire cohort of EASTBOURNE patients, we made a comparison between patients and lesions left or not with a dissection. Table 2 provides the baseline characteristics of patients with and without dissections, and shows that the patients were equally matched in terms of baseline profile. The mean patient age was 66 years, while the majority were male (81%). There was a high prevalence of hypertension and hypercholesterolemia (77% and 72%, respectively). Patient clinical presentation was heterogeneous and more than half of the patients had previous PCI history and multivessel CAD.

The characteristics of lesions, such as number, length, and calcification level, are also presented in Table 3. The average lesion length as well as predilatation balloon length in the dissection group were longer, 24 and 26 mm vs. 18 and 22 mm in the nondissection group ( $p < 0.001$ ). All patients with dissection were treated with predilatation, as

compared with only 91.4% of patients without dissection ( $p = 0.016$ ). RVD, predilatation balloons diameter were smaller and pressure of inflation was lower in the dissection group compared with the nondissection group (2.35 vs. 2.56 mm,  $p = 0.011$ ; 2.4 vs. 2.65 mm,  $p = 0.001$ ; 8.4 vs. 10 atm,  $p = 0.002$ ). Interestingly, the type of balloon used (noncompliant, semicompliant, or scoring) did not affect the occurrence of dissection.

One-year follow-up was available for 92.5% of the patients. We could not find significant differences in terms of hard clinical endpoints between the dissection cohort and the overall population (Figure 2).

As per the primary endpoint TLR, we only observed one case in the dissection group, with no significant differences with the overall de novo group (1.25% vs. 5.6%,  $p = 0.127$ ). MACE rate occurred in 4.4% of patients with a dissection left versus 10.1% of the whole population ( $p = 0.182$ ) (Figure 1). Interestingly, we did not observe any MI or acute vessel closures in the dissection cohort.

Figures 3 and 4 describe the Kaplan–Meier curves for the occurrence respectively of MACE ( $p = 0.32$ ) and TLR ( $p = 0.21$ ), which were not significantly different.

### 4 | DISCUSSION

The main findings of EASTBOURNE-DISS study are the following:

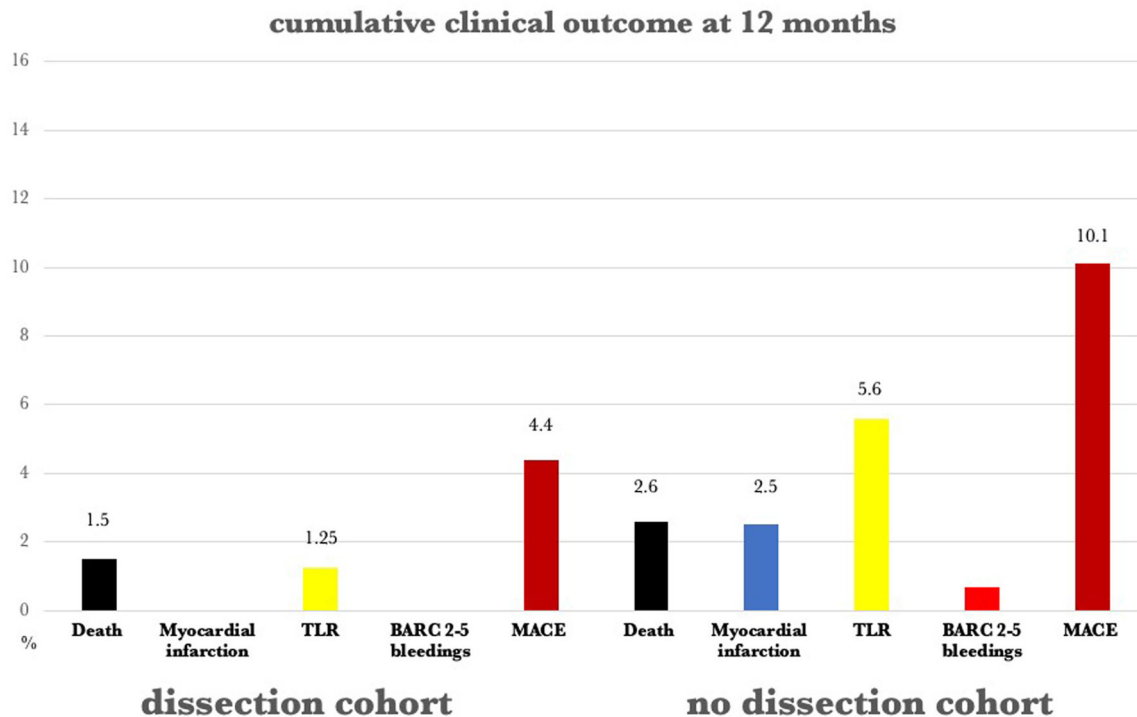
1. The rate of dissections left untreated after SCB angioplasty is relatively low in experienced hands.

**TABLE 3** Procedural characteristics.

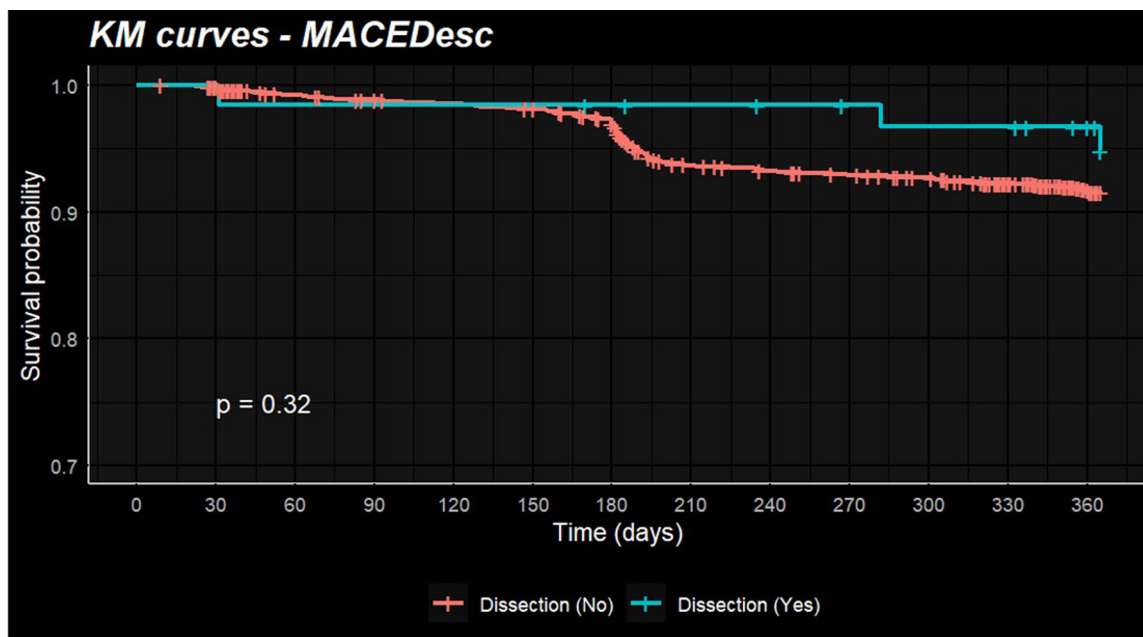
	Overall (N = 2083)	Final dissection, yes (N = 73)	Final dissection, no (N = 2010)	<i>p</i> *
Multivessel PCI, n (%)	873 (41.9)	27 (37.0)	846 (42.1)	0.455
RVD, mean (SD)	2.55 (0.70)	2.35 (0.49)	2.56 (0.71)	0.011
Calcification, moderate–severe, n (%)	1049 (52.3)	51 (70)	998 (49.6)	0.001
Lesion Length, mean (SD)	18.71 (9.17)	23.83 (14.68)	18.46 (8.91)	<0.001
MLD, mean (SD)	0.63 (0.51)	0.88 (2.20)	0.75 (0.91)	0.279
Predilatation, n (%)	1910 (91.7)	73 (100.0)	1837 (91.4)	0.016
Predilatation balloon length, mean (SD)	22.18 (7.51)	26.10 (8.66)	22.03 (7.43)	<0.001
Predilatation balloon diameter, mean (SD)	2.64 (0.56)	2.42 (0.43)	2.65 (0.56)	0.001
Pressure of inflation, atm., mean (SD)	9.90 (4.38)	8.36 (3.14)	9.95 (4.41)	0.002
Inflation balloon time, mean (SD)	57.77 (19.52)	60.62 (17.26)	57.67 (19.59)	0.205
Use of semicompliant balloon, n (%)	1235 (59.2)	42 (57.5)	1102 (54.8)	0.54
Use of noncompliant balloon, n (%)	990 (47.5)	32 (43.8)	1021 (50.8)	0.41
Use of scoring balloon, n (%)	182 (8.7)	10 (13.7)	172 (8.6)	0.16
Final dissection after DCB, n (%)	73 (3.5)	73 (100.0)	0 (0.0)	<0.001
Angiographic success, n (%)	2032 (97.6)	71 (97.3)	1961 (97.6)	>0.999

Abbreviations: DCB, drug-coated balloon; MLD, minimal luminal diameter; RVD, reference vessel diameter.

\**p* Values from: *t* test (mean (SD)); Mann–Whitney *U* test (median [IQR]);  $\chi^2$  test (*n* (%)) or Fisher's exact test (*n* (%), when some of the cell have counts fewer than 5).



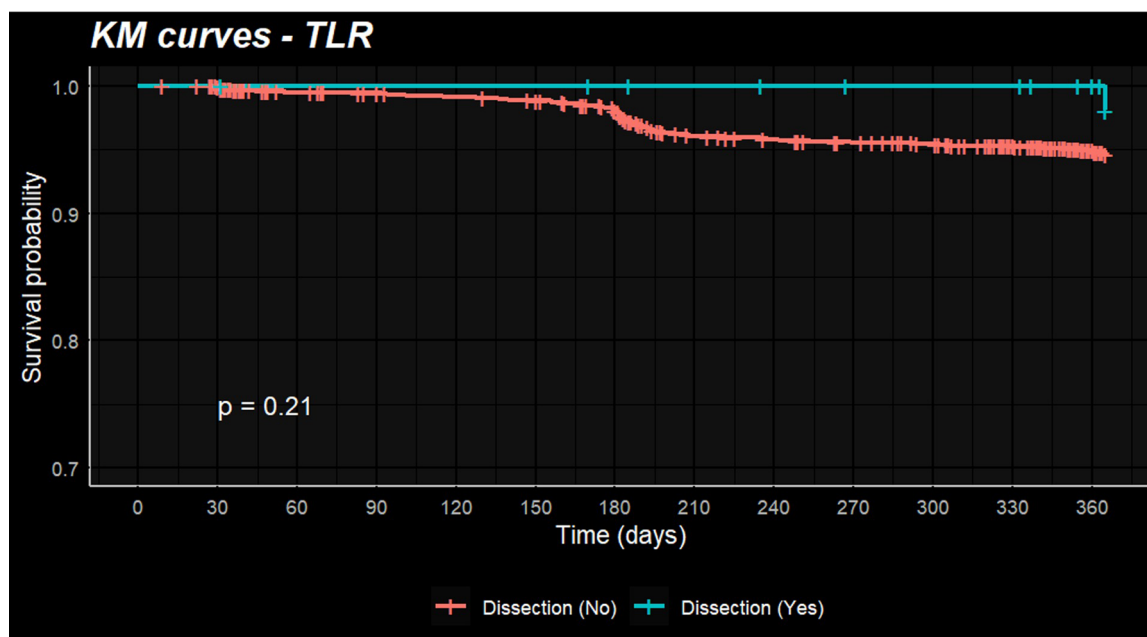
**FIGURE 2** Cumulative clinical outcome at 12 months. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 3** The Kaplan–Meier curves for the occurrence of major adverse cardiac event. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

- The clinical outcome of dissections left untreated after SCB is similar to that of the overall and de novo population at 12 months.
- In patients treated with SCB, a type A-B, not-flow limiting dissection can be safely left unstented.

The first experiences of leaving a dissection untreated after DCB derives from peripheral studies. In a subanalysis of the Thunder trial, patients that had a coronary dissection post-DCB were compared with patients treated with stenting in terms of late lumen loss (LLL). At 6-month angiographic follow-up, patients left with dissection as



**FIGURE 4** The Kaplan–Meier curves for the occurrence of target-lesion revascularization. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

compared with patients left with dissection after POBA had lower LLL (0.4 vs. 1.9 mm,  $p=0.001$ ) and binary restenosis (20 vs. 51%,  $p=0.003$ ). Interestingly, also the rate of TLR after 2 years was lower (10 vs. 56%,  $p=0.002$ ).<sup>9,10</sup>

Regarding coronary artery disease, our group previously showed that leaving a dissection after paclitaxel-DCB was associated with good clinical outcomes. Out of the 48 dissections left, 45 had complete healing at 6-month angiographic follow-up, and 3 chronicized.<sup>6</sup> Interestingly, we did not observe any acute occlusion in the whole cohort of patients, and the clinical outcome was similar to the cohort of patients left without dissection after DCB-angioplasty.<sup>4</sup>

Another study published in 2020 conducted by Hui et al. studied the impact of dissection after DCB treatment of de novo coronary lesions in 227 patients with coronary artery disease and showed that the presence of dissection post DCB treatment was not associated with increased risk of LLL and target vessel revascularization at 6 months follow up confirming the safety and efficacy of DCB.<sup>11</sup> Additionally, the DCB group had a lower rate of TLR and a higher rate of clinical improvement compared with the POBA group. The safety profile of DCB was also favorable, with no significant difference in the incidence of adverse events between the two groups.

Since no data have been presented on the outcome of dissections left after SCB so far, the findings of EASTBOURNE study are particularly interesting because derive from a prospective, multicenter investigator-driven registry with all of the clinical events adjudicated by an independent CEC, from the largest prospective study ever performed with DCB.

As expected, dissections were more common in de novo lesions with a rate of 2.97% versus 1.1% in the ISR group

(Table 2). As suggested by the protocol, only types A and B (and few types C) dissections were left untreated, and despite the lack of routine angiographic follow-up, we can argue that most of them underwent a healing process during the 12-month follow-up, since we did not observe any case of MI in this cohort of patients. Also, the analysis of mortality data are showing four cases in the whole population and one in the dissection cohort without significant differences.

This substudy of EASTBOURNE has some limitations. Despite a prespecified analysis of the EASTBOURNE study, the number of patients left with a dissection was relatively low. There are some differences among the compared populations, which cannot be modified by means of statistical maneuvers (e.g., propensity matching) because of the limited population. Another important point to underline is that the fate of dissections left after angioplasty is related to many factors, including some operations performed by the physician when a dissection is discovered (prolonged balloon inflations, use of long and larger balloons). Finally, angiographic or intravascular imaging follow-up was not available, rendering our results hypothesis generating. Nevertheless, our study provides clinical follow-up through hard endpoints that are equally as important and can be regarded as surrogates to angiographic endpoints.

## 5 | CONCLUSION

The results of this subanalysis of the EASTBOURNE study showed how type A-B dissections left untreated after sirolimus-DCB were safe at 12-month clinical follow-up.



## ACKNOWLEDGMENTS

The study was an independent, investigator-driven study.

## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict 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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