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Biodegradable-polymer versus durable-polymer drug-eluting stents in left main percutaneous coronary intervention: final results of the randomised IDEAL-LM trial

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The optimal strategy for patients with left main (LM) coronary disease and an indication for revascularisation is uncertain. Previous studies, including the EXCEL and NOBLE trials, have shown that percutaneous coronary intervention (PCI) is an acceptable alternative to coronary artery bypass graft (CABG) surgery, with comparable outcomes. However, the optimal PCI strategy has yet to be determined[1,2]. The IDEAL-LM trial randomised 818 patients undergoing LM PCI in a 1:1 ratio to treatment with either a durable-polymer (DP) drug-eluting stent (DES) and 12 months of dual antiplatelet therapy (DAPT) or a biodegradable-polymer (BP) DES with 4 months of DAPT. After 2 years of follow-up, clinical outcomes were similar in both groups[3]. Here, we report the final 5-year outcomes.

In brief, the IDEAL-LM trial was an investigator-initiated, international, multicentre, open-label, randomised clinical trial. The primary objective was to establish non-inferiority of the BP platinum-chromium everolimus-eluting stent (BP-PtCr-EES; SYNERGY [Boston Scientific]) group to the DP cobalt-chromium everolimus-eluting stent (DP-CoCr-EES; XIENCE [Abbott]) group for the composite endpoint of major adverse cardiovascular events (MACE) – defined as all-cause death, myocardial infarction (MI), and ischaemia-driven target vessel revascularisation (TVR) at 2 years after PCI. Secondary endpoints included the individual components of the primary endpoint, a device-oriented composite endpoint (DOCE) defined as cardiac death, MI not clearly attributable to a non-treated vessel and clinically-indicated target lesion revascularisation (TLR), a patient-oriented composite endpoint (POCE) defined as a composite endpoint of all-cause death, any stroke, and any MI, and any revascularisation, stent thrombosis, and bleeding as per the Bleeding Academic Research Consortium (BARC) criteria. The final study results were assessed at 5 years after PCI.

The 5-year results are summarised in the **Central illustration**. From December 2014 to October 2016, 818 patients were enrolled (BP-PtCr-EES: n=410; DP-CoCr-EES: n=408). Baseline characteristics are summarised in **Supplementary Table 1**. The original protocol mandated follow-up for 5 years, but a combination of the COVID-19 pandemic and limited funding meant this was not possible in some patients. Ultimately, 4-year follow-up data were available for 382 (93.0%) patients in the BP-PtCr-EES group and 379 (92.9%) patients in the DP-CoCr-EES group, while 5-year follow-up data were available for 183 (44.6%) patients and 178 (43.6%) patients in the respective groups **(Supplementary Figure 1)**.

At 5 years, the primary endpoint of MACE occurred in 24.1% (89 events) of the BP-PtCr-EES group and in 22.5% (81 events) of the DP-CoCr-EES group (Kaplan-Meier estimates; p=0.50) **(Supplementary Figure 2)**. Landmark analysis showed no significant differences between groups either up to 1 year or from 1 year to the end of follow-up **(Supplementary Figure 3)**. There were no significant differences between groups in any of the secondary endpoints, including TVR **(Supplementary Figure 4)**. Landmark analysis at 1 year demonstrated a higher incidence of TVR in the BP-PtCr-EES group compared to the control group (5.5% vs 2.3%; p=0.02); however, this difference was not observed during the 1- to 5-year follow-up period **(Supplementary Figure 5)**. The

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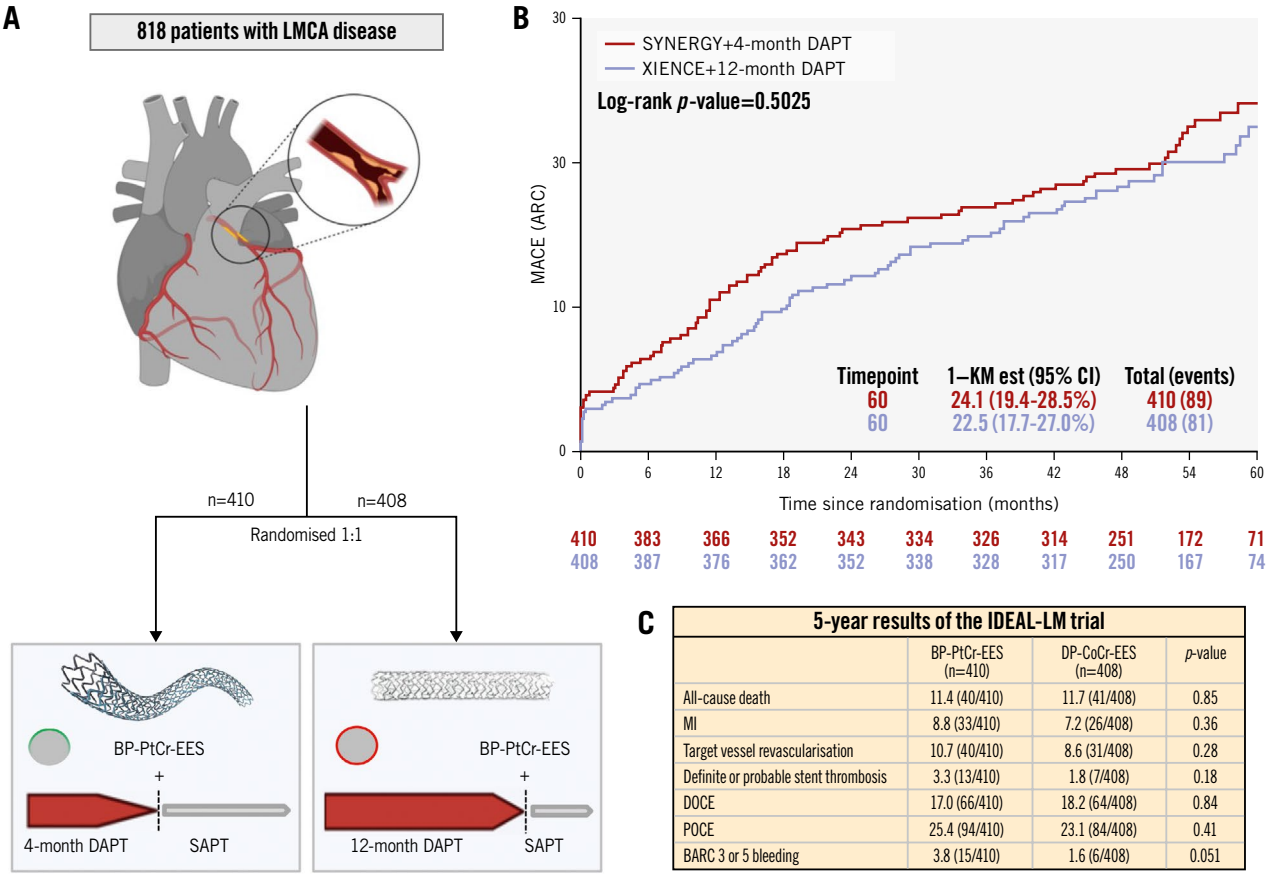
Overview of the IDEAL-LM trial.



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5-year results of the IDEAL-LM trial

	BP-PtCr-EES (n=410)	DP-CoCr-EES (n=408)	*p*-value
All-cause death	11.4 (40/410)	11.7 (41/408)	0.85
MI	8.8 (33/410)	7.2 (26/408)	0.36
Target vessel revascularisation	10.7 (40/410)	8.6 (31/408)	0.28
Definite or probable stent thrombosis	3.3 (13/410)	1.8 (7/408)	0.18
DOCE	17.0 (66/410)	18.2 (64/408)	0.84
POCE	25.4 (94/410)	23.1 (84/408)	0.41
BARC 3 or 5 bleeding	3.8 (15/410)	1.6 (6/408)	0.051

BP-PtCr-EES with 4 months of DAPT does not confer any advantages over DP-CoCr-EES with 12 months of DAPT

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A) Flowchart of study design; (B) incidence of MACE by stent type; (C) 5-year results of the IDEAL-LM trial. ARC: Academic Research Consortium; BARC: Bleeding Academic Research Consortium; BP-PtCr-EES: biodegradable-polymer platinum-chromium everolimus-eluting stent; CI: confidence interval; DAPT: dual antiplatelet therapy; DOCE: device-oriented composite endpoint; DP-CoCr-EES: durable-polymer cobalt-chromium everolimus-eluting stent; LMCA: left main coronary artery; MACE: major adverse cardiovascular event; MI: myocardial infarction; POCE: patient-oriented composite endpoint; SAPT: single antiplatelet therapy

incidence of definite/probable stent thrombosis between the BP-PtCr-EES and DP-CoCr-EES groups was not significantly different over the entire period of follow-up (3.3% vs 1.8%; p=0.18) nor in the landmark analysis (0-12 months: 1.7% vs 1.2%; p=0.57; 12-60 months: 1.6% vs 0.5%; p=0.16) **(Supplementary Figure 6, Supplementary Figure 7).** There was no significant difference between groups with respect to BARC 3 or 5 bleeding (3.8% vs 1.6%; p=0.05) **(Supplementary Table 2)**. There was no significant subgroup difference in the association between treatment strategy and MACE at 5 years **(Supplementary Figure 8)**.

At the time this study was designed, the standard of care after LM PCI was 12 months of DAPT, except in patients at high bleeding risk. Accordingly, the experimental arm in our study, utilising BP-PtCr-EES with only 4 months of DAPT, was considered highly novel. Since then, as evidence has accumulated, the use of shorter-duration DAPT, even after complex PCI, has increased. As a result, the 2024 European Society of Cardiology guidelines on the management of chronic coronary syndromes recommend 3-6 months of DAPT in patients undergoing high thrombotic risk PCI, which includes LM PCI[4]. In addition, no convincing data have emerged to support the hypothesis that BP-DES are inherently safer than DP-DES, particularly in the context of short-duration DAPT. The results of IDEAL-LM support this conclusion. Despite the difference in DAPT duration between the two groups in IDEAL-LM, there was no difference in major bleeding. This may reflect the fact that we did not study an exclusively high bleeding risk population, and further studies are required to assess strategies utilising very short (1 month) durations of

DAPT in patients undergoing LM PCI. Overall, both groups in this study showed excellent long-term outcomes with respect to cardiac death, MI and TVR, comparable to the 5-year results from the CABG arms in major clinical trials of PCI versus CABG[5,6]. Although a significant number of patients (approximately half) were lost to follow-up between years 4 and 5, this was, to some extent, mitigated by the use of Kaplan-Meier methodology to estimate event rates.

In conclusion, the use of BP-PtCr-EES followed by 4 months of DAPT in patients undergoing LM coronary artery PCI did not confer any advantages over treatment with a durable-polymer stent followed by 12 months of DAPT after 5 years of follow-up.

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Conflict of interest statement

R.-J.M. van Geuns reported grants and personal fees from Boston Scientific, Abbott, AstraZeneca, and Amgen; and grants from InfraRedx. M. Lesiak reported being on the speaker bureau for Abbott and Boston Scientific. P. O'Kane reported speaker fees from Abbott and Boston Scientific. E. Bressolette reported being a consultant for Boston Scientific. K.G. Oldroyd reported being an employee for Biosensors. The other authors have no conflicts of interest to declare.

References

1. Stone GW, Sabik JF, Serruys PW, Simonton CA, Généreux P, Puskas J, Kandzari DE, Morice MC, Lembo N, Brown WM 3rd, Taggart DP, Banning A, Merkely B, Horkay F, Boonstra PW, van Boven AJ, Ungi I, Bogáts G, Mansour S, Noiseux N, Sabaté M, Pomar J, Hickey M, Gershlick A, Buszman P, Bochenek A, Schampaert E, Pagé P, Dressler O, Kosmidou I, Mehran R, Pocock SJ, Kappetein AP; EXCEL Trial Investigators. Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease. *N Engl J Med*. 2016;375:2223-35.

2. Mäkikallio T, Holm NR, Lindsay M, Spence MS, Erglis A, Menown IB, Trovik T, Eskola M, Romppanen H, Kellerth T, Ravkilde J, Jensen LO, Kalinauskas G, Linder RB, Pentikainen M, Hervold A, Banning A, Zaman A, Cotton J, Eriksen E, Margus S, Sørensen HT, Nielsen PH, Niemelä M, Kervinen K, Lassen JF, Maeng M, Oldroyd K, Berg G, Walsh SJ, Hanratty CG, Kumsars I, Stradins P, Steigen TK, Fröbert O, Graham AN, Endresen PC, Corbascio M, Kajander O, Trivedi U, Hartikainen J, Anttila V, Hildick-Smith D, Thuesen L, Christiansen EH; NOBLE study investigators. Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial. *Lancet*. 2016;388:2743-52.

3. van Geuns RJ, Chun-Chin C, McEntegart MB, Merkulov E, Kretov E, Lesiak M, O'Kane P, Hanratty CG, Bressollette E, Silvestri M, Wlodarczak A, Barragan P, Anderson R, Protopopov A, Peace A, Menown I, Rocchiccioli P, Onuma Y, Oldroyd KG. Bioabsorbable polymer drug-eluting stents with 4-month dual antiplatelet therapy versus durable polymer drug-eluting stents with 12-month dual antiplatelet therapy in patients with left main coronary artery disease: the IDEAL-LM randomised trial. *EuroIntervention*. 2022;17:1467-76.

4. Vrints C, Andreotti F, Koskinas KC, Rossello X, Adamo M, Ainslie J, Banning AP, Budaj A, Buechel RR, Chiariello GA, Chieffo A, Christodorescu RM, Deaton C, Doenst T, Jones HW, Kunadian V, Mehilli J, Milojevic M, Piek JJ, Pugliese F, Rubboli A, Semb AG, Senior R, Ten Berg JM, Van Belle E, Van Craenenbroeck EM, Vidal-Perez R, Winther S; ESC Scientific Document Group. 2024 ESC Guidelines for the management of chronic coronary syndromes. *Eur Heart J*. 2024;45:3415-537.

5. Stone GW, Kappetein AP, Sabik JF, Pocock SJ, Morice MC, Puskas J, Kandzari DE, Karmpaliotis D, Brown WM 3rd, Lembo NJ, Banning A, Merkely B, Horkay F, Boonstra PW, van Boven AJ, Ungi I, Bogáts G, Mansour S, Noiseux N, Sabaté M, Pomar J, Hickey M, Gershlick A, Buszman PE, Bochenek A, Schampaert E, Pagé P, Modolo R, Gregson J, Simonton CA, Mehran R, Kosmidou I, Généreux P, Crowley A, Dressler O, Serruys PW; EXCEL Trial Investigators. Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease. *N Engl J Med*. 2019;381:1820-30.

6. Holm NR, Mäkikallio T, Lindsay MM, Spence MS, Erglis A, Menown IBA, Trovik T, Kellerth T, Kalinauskas G, Mogensen LJH, Nielsen PH, Niemelä M, Lassen JF, Oldroyd K, Berg G, Stradins P, Walsh SJ, Graham ANJ, Endresen PC, Fröbert O, Trivedi U, Anttila V, Hildick-Smith D, Thuesen L, Christiansen EH; NOBLE investigators. Percutaneous coronary angioplasty versus coronary artery bypass grafting in the treatment of unprotected left main stenosis: updated 5-year outcomes from the randomised, non-inferiority NOBLE trial. *Lancet*. 2020;395:191-9.

Supplementary data

Supplementary Table 1. Baseline characteristics.
Supplementary Table 2. Five-year clinical outcomes.
Supplementary Figure 1. Flowchart of the study population.
Supplementary Figure 2. Cumulative event rate plot for the primary endpoint of MACE during 5-year follow-up.
Supplementary Figure 3. Landmark analysis from 0-12 months and 12-60 months for the primary endpoint of MACE.
Supplementary Figure 4. Cumulative event rate plot for TVR during 5-year follow-up.
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Supplementary Figure 6. Cumulative event rate plot for definite/probable stent thrombosis during 5-year follow-up.
Supplementary Figure 7. Landmark analysis from 0-12 months and 12-60 months for definite/probable stent thrombosis.
Supplementary Figure 8. Stratified analyses of the primary endpoint at 5 years across subgroups.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00918

Supplementary data

Supplementary Table 1. Baseline characteristics.

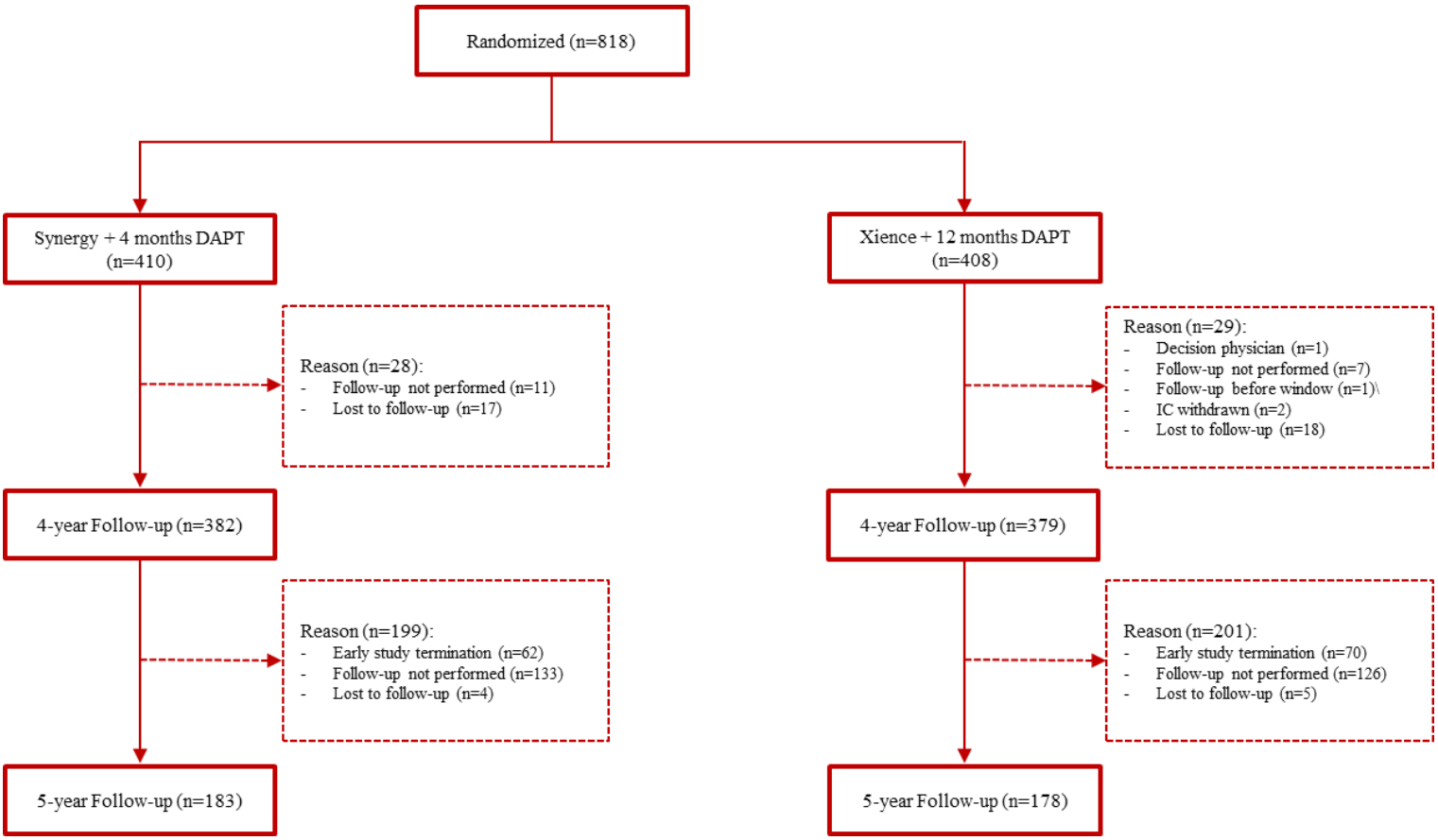
	BP-PtCr-EES (n = 410)	DP-CoCr-EES (n = 408)	Total (n = 818)
Patient characteristics			
Age (years) (±SD)	66.8 (±10.2)	66.0 (±10.5)	66.4 (±10.3)
Male, n (%)	338/410 (82.4)	313/408 (76.7)	651/818 (79.6)
Body mass index (kg/m^2) (±SD)	28.1 (±4.8)	28.6 (±5.2)	28.3 (±5.0)
Current smoker, n (%)	86/410 (21.0)	94/408 (23.0)	180/818 (22.0)
Diabetes mellitus, n (%)	87/410 (21.2)	93/408 (22.8)	180/818 (22.0)
Hypertension, n (%)	315/410 (76.8)	308/408 (75.5)	623/818 (76.2)
Hypercholesterolaemia, n (%)	319/410 (77.8)	293/408 (71.8)	612/818 (74.8)
Family history of coronary artery disease, n (%)	146/410 (35.6)	166/408 (40.7)	312/818 (38.1)
Previous ACS, n (%)	163/409 (39.9)	155/407 (38.1)	318/816 (39.0)
Previous PCI, n (%)	150/410 (36.6)	121/408 (29.7)	271/818 (33.1)
Previous CABG, n (%)	29/410 (7.1)	29/408 (7.1)	58/818 (7.1)
Previous cerebrovascular accident, n (%)	34/410 (8.3)	31/408 (7.6)	65/818 (8.0)
Clinical presentation			
Stable coronary artery disease, n (%)	243/410 (59.3)	244/408 (59.8)	487/818 (59.5)
ACS, n (%)	167/410 (40.7)	164/408 (40.2)	331/818 (40.5)
Unstable angina, n (%)	30/410 (7.3)	33/408 (8.1)	63/818 (7.7)
Non-ST-elevation MI, n (%)	59/410 (14.4)	69/408 (16.9)	128/818 (15.7)
ST-elevation MI, n (%)	78/410 (19.0)	62/408 (15.2)	140/818 (17.1)
Angiographic and procedural characteristics			
Syntax score (±SD)	21.6 (±9.0)	20.9 (±9.1)	
Left main, n (%)	95/410 (23.2)	104/408 (25.5)	
Left main + one vessel disease, n (%)	171/410 (41.7)	175/408 (42.9)	
Left main + two vessel disease, n (%)	106/410 (25.9)	87/408 (21.3)	
Left main + three vessel disease, n (%)	38/410 (9.2)	42/408 (10.3)	
Number of stents used (±SD)	1.3 (±0.6)	1.2 (±0.5)	
Number of stent used in the left main, n (%)			
1	317/410 (77.3)	334/408 (81.8)	
2	76/410 (18.5)	59/408 (14.5)	
DAPT at discharge, n (%)			
Clopidogrel	259/410 (63.2%)	263/407 (64.6%)	
Ticagrelor	52/410 (12.7%)	60/407 (14.7%)	
Prasugrel	28/410 (6.8%)	29/407 (7.1%)	
Monotherapy (±(N)OAC), n (%)	69/410 (16.8)	53/407 (13.0%)	
OAC	21/410 (5.1%)	27/408 (6.6%)	

Data are mean (±SD) or counts (percentage). ACS: acute coronary syndrome; BP-PtCr-EES: biodegradable polymer platinum-chromium everolimus-eluting stent; CABG: coronary artery bypass graft; DAPT: Dual Antiplatelet Therapy, DP-CoCr-EES: durable polymer cobalt-chromium everolimus-eluting stent; MI: myocardial infarction; OAC: Oral anticoagulation, PCI: percutaneous coronary intervention; SD: standard deviation

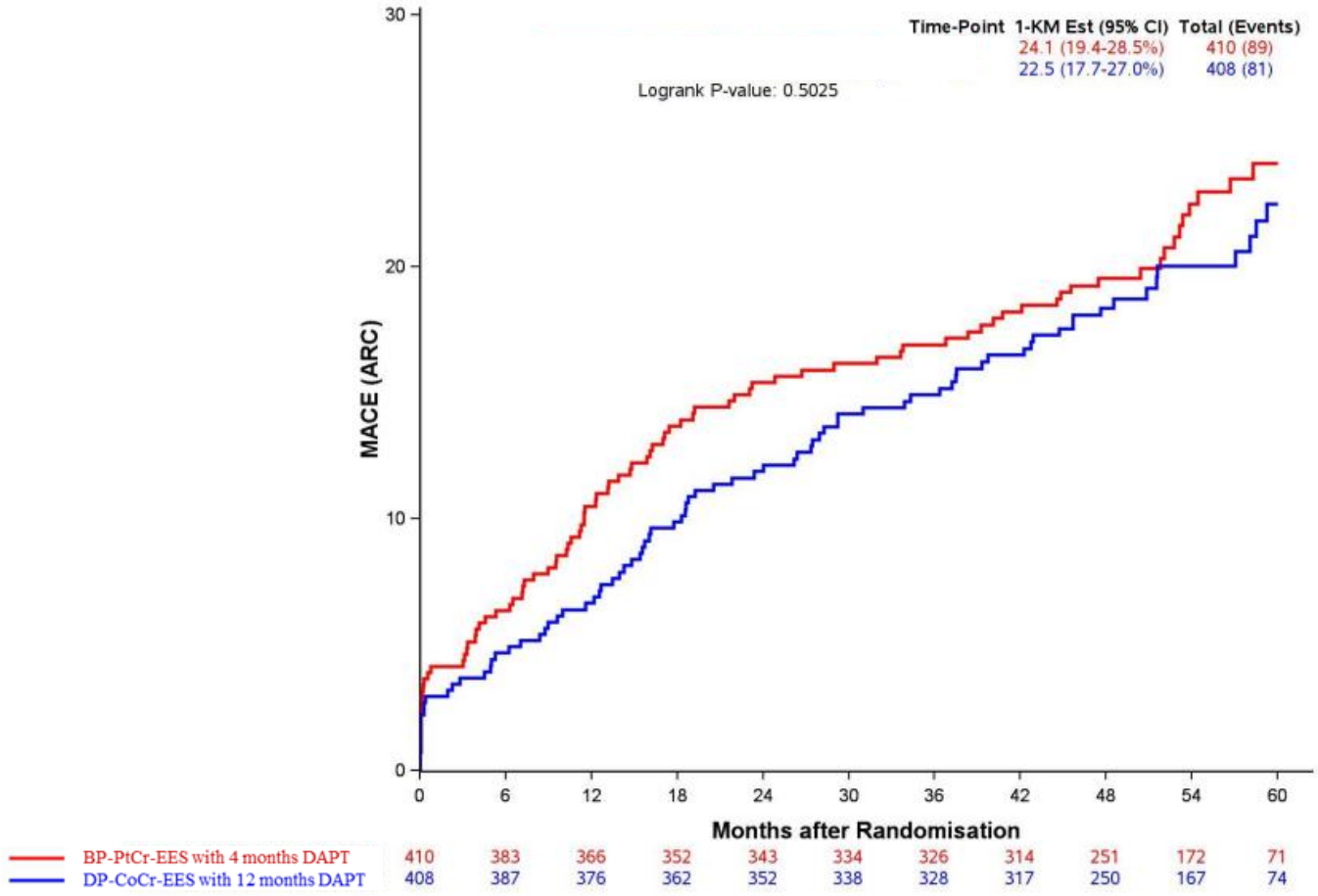
Supplementary Table 2. Five-year clinical outcomes.

	BP-PtCr-EES (n = 410)	DP-CoCr-EES (n = 408)	p-value
Primary outcome			
MACE*	24.1 (89/410)	22.5 (81/408)	0.50
Individual endpoints of the primary outcome			
All-cause death	11.4 (40/410)	11.7 (41/408)	0.85
MI	8.8 (33/410)	7.2 (26/408)	0.36
Target Vessel Revascularization	10.7 (40/410)	8.6 (31/408)	0.28
Secondary outcome			
Cardiac Death	5.2 (20/410)	6.9 (23/408)	0.61
Non-periprocedural MI	6.4 (23/410)	5.2 (18/408)	0.45
Target Lesion Revascularization	8.9 (33/410)	7.9 (28/408)	0.53
Target Lesion Revascularization LM	7.7 (30/410)	6.6 (23/408)	0.33
Definite or probable stent thrombosis	3.3 (13/410)	1.8 (7/408)	0.18
DOCE**	17.0 (66/410)	18.2 (64/408)	0.84
POCE***	25.4 (94/410)	23.1 (84/408)	0.41
BARC 3	3.3 (13/410)	1.3 (5/408)	0.06
BARC 5	0.8 (3/410)	0.3 (1/408)	0.32
BARC 3 or 5 bleeding	3.8 (15/410)	1.6 (6/408)	0.05

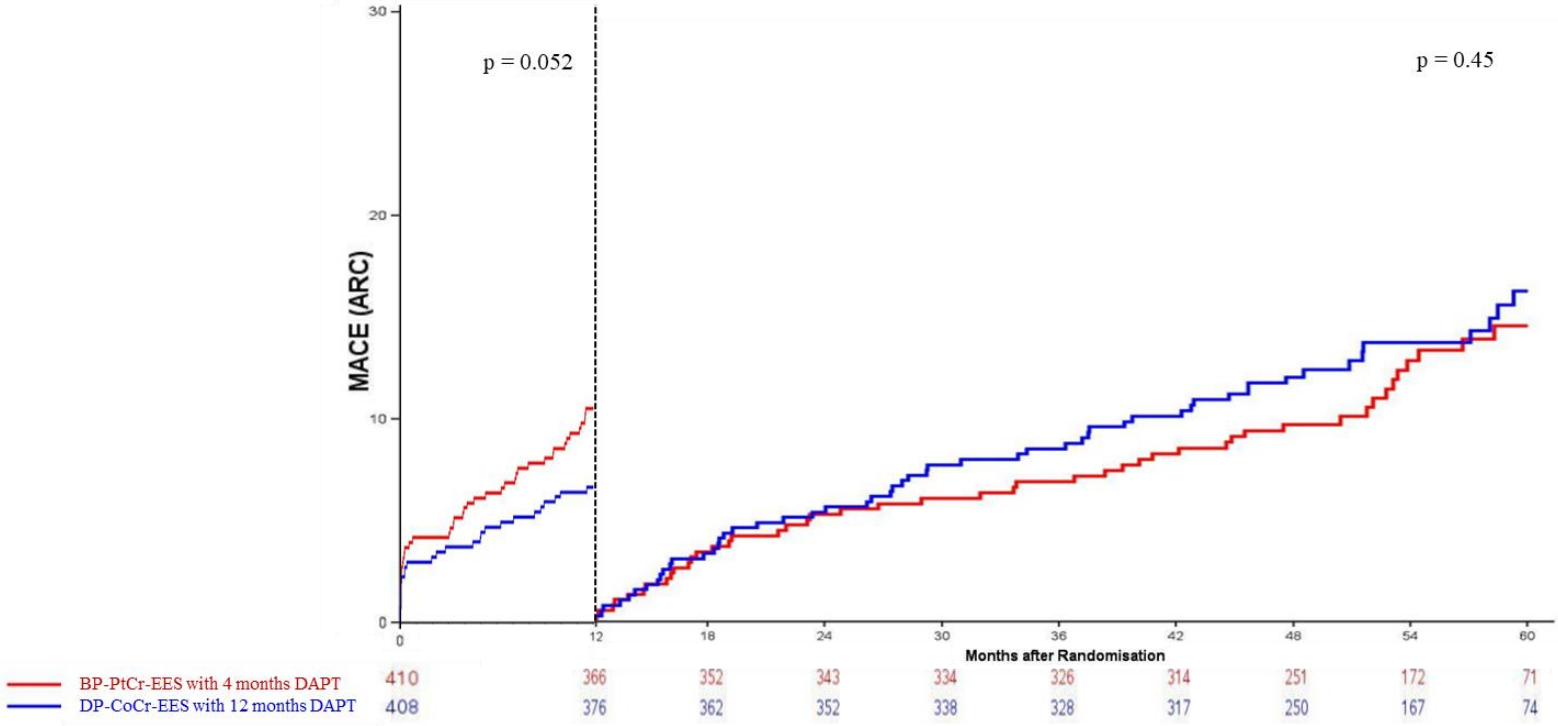
Data are percentages (counts), based on Kaplan-Meier estimates. *All-cause death, myocardial infarction, target vessel revascularization. **Cardiac death, target vessel myocardial infarction, or target lesion revascularization. ***All-cause death, any stroke, any MI, any revascularization. BARC: Bleeding Academic Research Consortium criteria. BP-PtCR-EES: biodegradable polymer platinum-chromium everolimus-eluting stent; DOCE: device-orientated cardiac events; DP-CoCr-EES: durable polymer cobalt-chromium everolimus-eluting stent; LM: left main; MACE: major cardiovascular events; MI: myocardial infarction; POCE; patient-orientated cardiac events



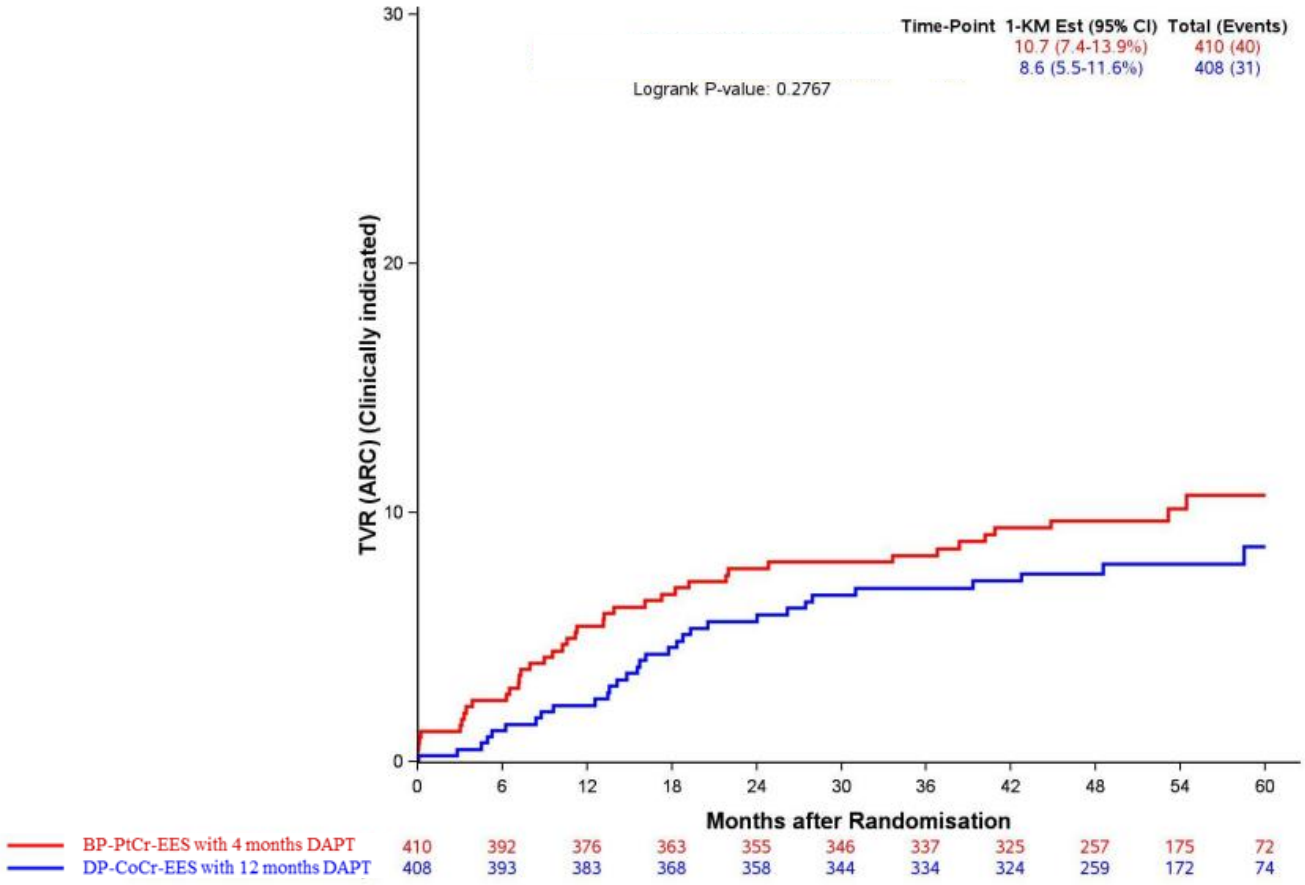
Supplementary Figure 1. Flowchart of the study population.



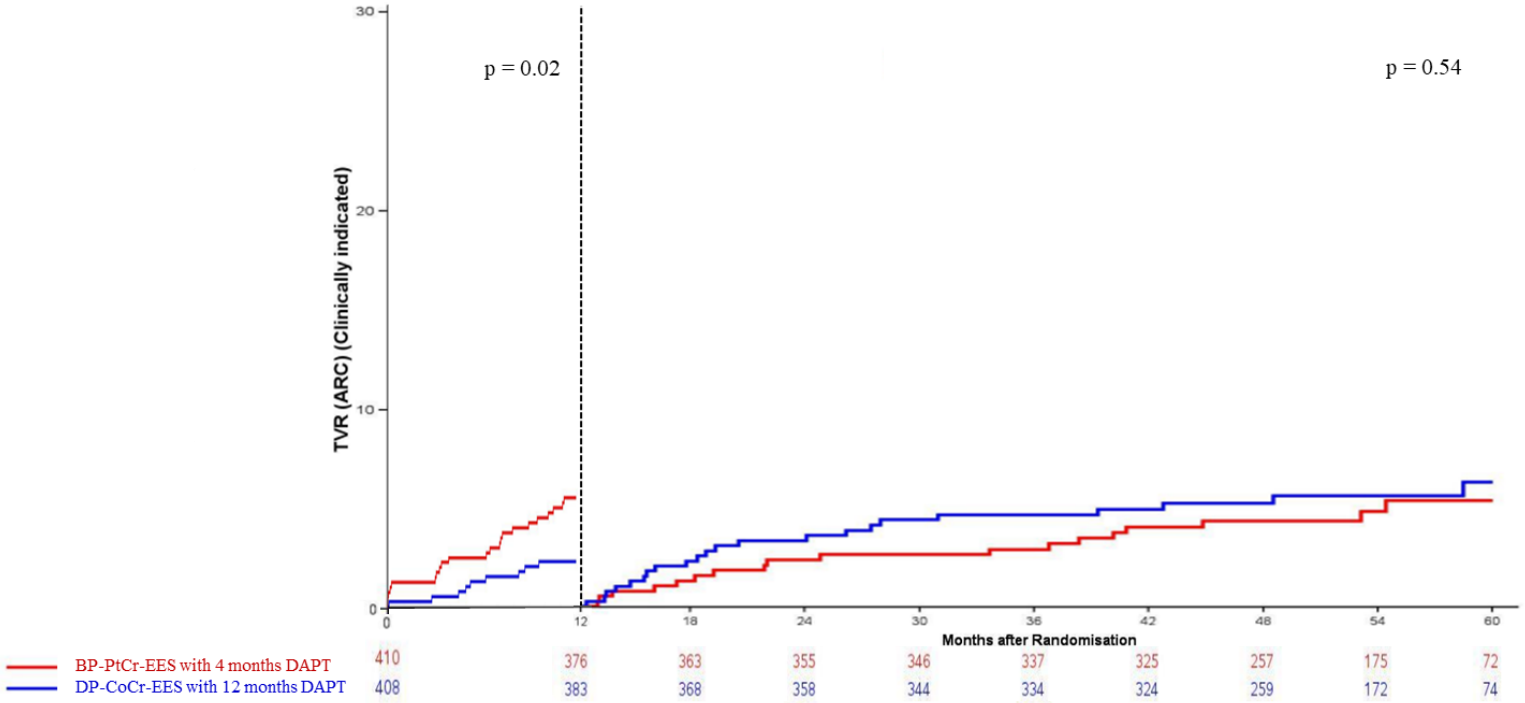
Supplementary Figure 2. Cumulative event rate plot for the primary endpoint of MACE during 5-year follow-up.



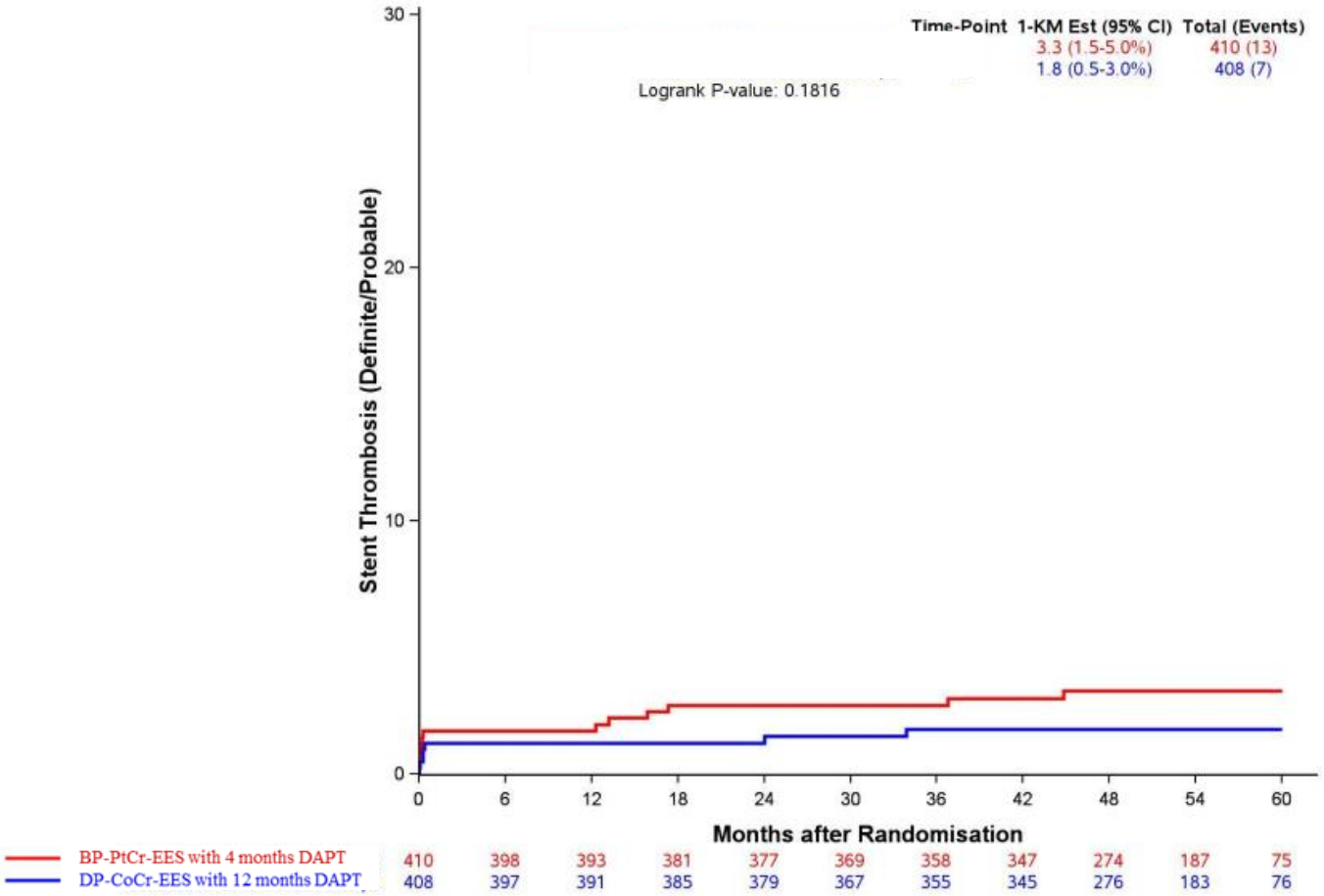
Supplementary Figure 3. Landmark analysis from 0-12 months and 12-60 months for the primary endpoint of MACE.



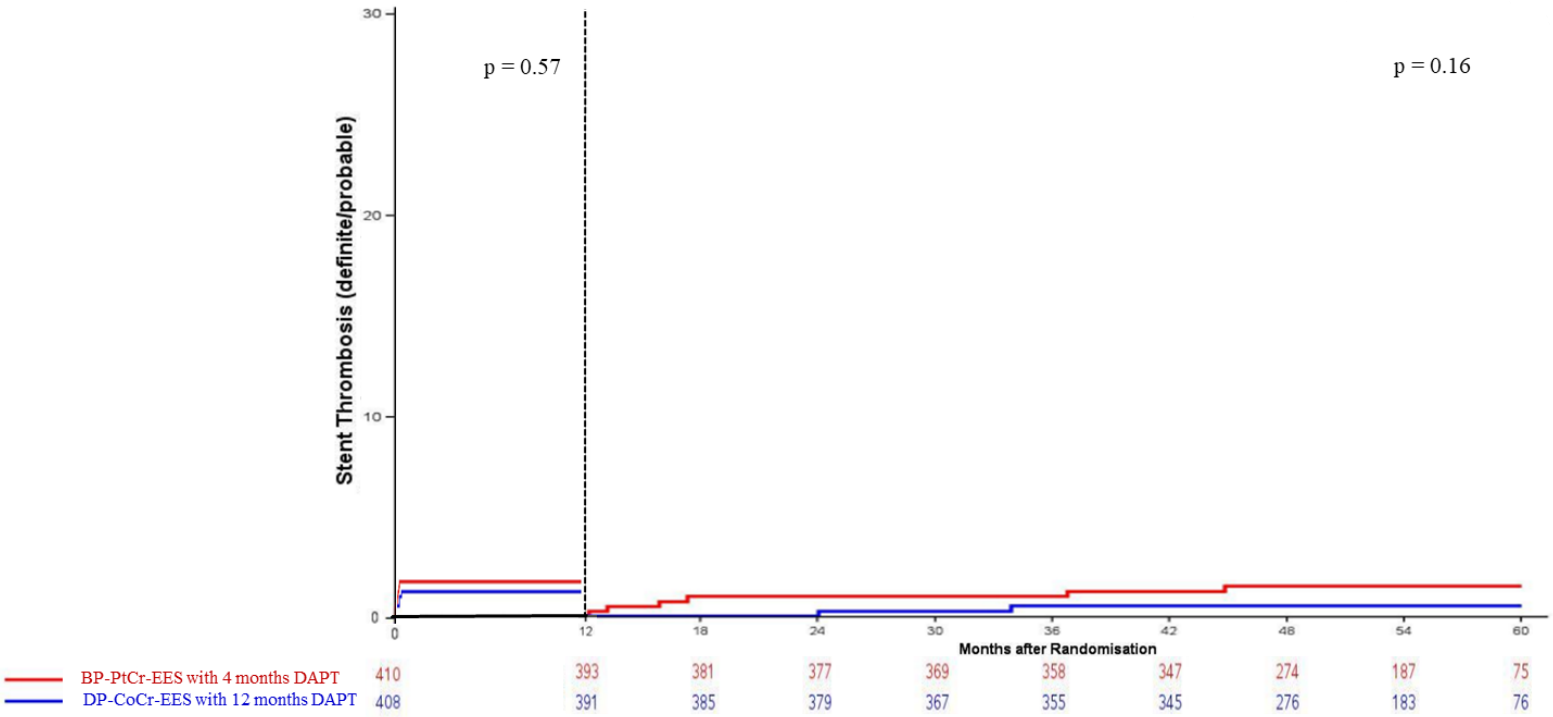
Supplementary Figure 4. Cumulative event rate plot for TVR during 5-year follow-up.



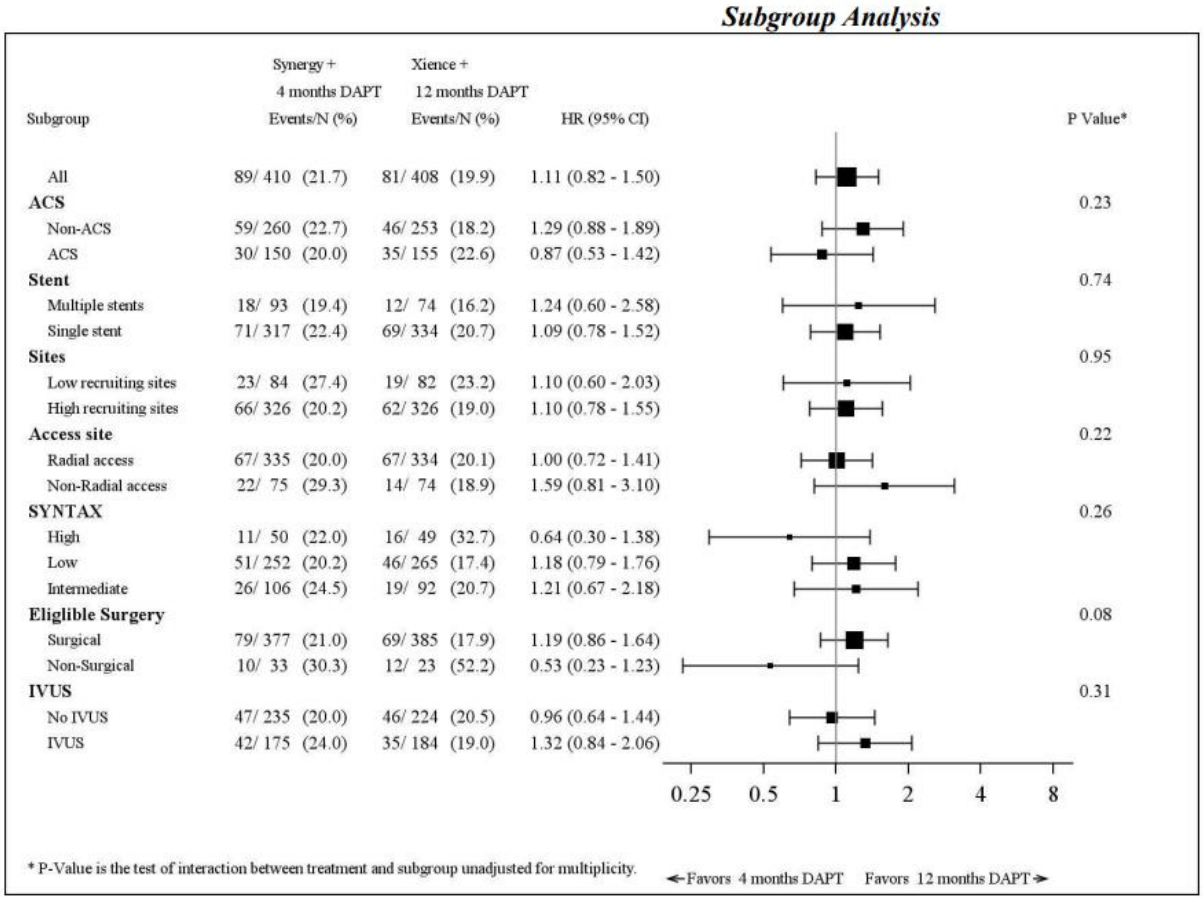
Supplementary Figure 5. Landmark analysis from 0-12 months and 12-60 months for TVR.



Supplementary Figure 6. Cumulative event rate plot for definite/probable stent thrombosis during 5-year follow-up.



Supplementary Figure 7. Landmark analysis from 0-12 months and 12-60 months for definite/probable stent thrombosis.



Supplementary Figure 8. Stratified analyses of the primary endpoint at 5 years across subgroups.