1-or 3-Month DAPT in Patients With HBR With or Without Oral Anticoagulant Therapy After PCI

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One or three-month dual antiplatelet therapy in high bleeding risk patients with or without oral anticoagulant therapy after coronary stenting

Abstract (Word count: 248)

Background: The optimal duration of dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI) in patients on chronic oral anticoagulant (OAC) therapy is still matter of debate.

Methods: The XIENCE Short DAPT program enrolled high bleeding risk (HBR) patients who underwent successful PCI with a cobalt-chromium everolimus-eluting stent. DAPT was discontinued at 1 or at 3 months in patients free from ischemic events and adherent to treatment. The effect of 1- vs 3-month DAPT was compared in patients with and without OAC using propensity score stratification. The primary endpoint was all-cause death or any myocardial infarction (MI). The key secondary endpoint was Bleeding Academic Research Consortium (BARC) type 2 to 5 bleeding. Outcomes were assessed from 1 to 12 months after index PCI.

Results: Out of 3,364 patients, 1,462 (43%) was on OAC. Among OAC patients, the risk of death or MI was similar between 1- and 3-month DAPT (7.4% vs 8.8%; adj. HR 0.74, 95% CI 0.49-1.11, p-value 0.139), whereas BARC 2-5 bleeding was lower with 1-month DAPT (adj. HR 0.71, 95% CI 0.51-0.99, p-value 0.046). These effects were consistent in patients with or without OAC (p of interaction >0.05). In OAC patients, all-cause death was reduced with 1- as compared to 3-month DAPT.

Conclusions: After PCI, 1- compared with 3-month of DAPT was associated with a similar rate of all-cause death or MI and reduced rates of BARC 2-5 bleeding, irrespective of OAC treatment. Among OAC patients, all-cause death was reduced with 1-month DAPT.

Key words: DAPT; everolimus-eluting stent; high bleeding risk; oral anticoagulant therapy; percutaneous coronary intervention; outcomes

Introduction

Dual-antiplatelet therapy (DAPT), consisting of the combination of aspirin and a $P2Y_{12}$ receptor inhibitor, is indicated to prevent recurrent ischemic events following percutaneous coronary intervention (PCI) (1,2). However, this benefit is offset by the occurrence of bleeding complications, whose impact on morbidity and mortality is comparable to that of ischemic events (3-6). Therefore, assessment of bleeding risk and adoption of bleeding avoidance strategies including modulation of antiplatelet treatment are pivotal in patients undergoing PCI (7).

Chronic oral anticoagulation (OAC) is indicated in roughly 10% of patients undergoing PCI mostly, because of atrial fibrillation (8,9). OAC increases the risk of bleeding, especially when associated with DAPT (8,10,11) and it is one of the major high bleeding risk (HBR) criteria according to the Academic Research Consortium (ARC) (12).

Discontinuation of $P2Y_{12}$ inhibitor at 6-week after PCI while continuing OAC and aspirin resulted in similar net adverse events when compared to 6-month of triple therapy in one small randomized controlled trial (RCT) (13). International guidelines recommend aspirin discontinuation at 1- to 4-week after PCI while maintaining preferably a nonvitamin K antagonist oral anticoagulant (NOAC) and a $P2Y_{12}$ inhibitor, in order to maximize bleeding prevention(1,14-16). However, recent meta-analyses of RCTs demonstrated an increased risk of stent thrombosis and myocardial infarction (MI) with this strategy (17-19). Therefore, the optimal antiplatelet regimen after PCI in patients on OAC remains unclear.

In a pooled dataset of three prospective studies enrolling HBR patients undergoing PCI (XIENCE Short DAPT program), 1- compared with 3-month DAPT followed by a single

antiplatelet agent (mostly aspirin) was associated with lower bleeding complications and no ischemic harm (20).

In this analysis, we sought to assess the effects of 1- versus 3-month DAPT in patients with or without concomitant OAC included in the XIENCE Short DAPT program.

METHODS

Study Design

The XIENCE Short DAPT program consisted of three prospective, multi-center, single-arm studies, of which the rationale, design, and principal results have been previously reported (20,21). Sponsored by Abbott, the studies explored two different DAPT durations in patients undergoing PCI with implantation of a fluoropolymer-based cobalt-chromium everolimus-eluting stent (XIENCE, Abbott). The 1-month DAPT program consisted of the XIENCE 28 USA study (NCT03815175), which was conducted at 58 sites in the United States and Canada, and the XIENCE 28 global study (NCT03355742), which was conducted at 52 sites in Europe and Asia. Despite being conducted separately, the XIENCE 28 studies were prespecified as being pooled together for the statistical analysis. The 3-month DAPT program consisted of the XIENCE 90 study (NCT03218787), which was conducted at 101 sites in the United States. The principal investigators with members of the executive and steering committees and the sponsor designed the protocol. National regulatory agencies and institutional review boards or ethics committees of participating sites approved the study protocol. An independent data monitoring committee provided external oversight to ensure public safety. All enrolled patients provided written informed consent.

Study population and treatment

The protocols of the XIENCE 28 and 90 studies were nearly identical, except for the DAPT duration. Patients were considered eligible if they underwent successful PCI with the implantation of fluoropolymer-based cobalt-chromium everolimus-eluting stent (XIENCE, Abbott) and met at least one of the following HBR criteria: age ≥75 years, indication for chronic

(at least 6 months) anticoagulant therapy, history of major bleeding within 12 months of the index procedure, history of ischemic or hemorrhagic stroke, renal insufficiency (creatinine ≥2.0 mg/dL) or failure (maintenance dialysis), anemia (hemoglobin <11 g/dL), and systemic conditions associated with an increased risk for bleeding, including hematologic disorders such as thrombocytopenia (platelet count <100,000/mm^3) and coagulation disorders. The treatment of up to 3 target lesions, with a maximum of 2 target lesions per epicardial vessel, and of bifurcation lesions without 2-stent techniques during index PCI were allowed. Key exclusion criteria included presentation with ST-segment elevation myocardial infarction (MI), left ventricular ejection fraction (LVEF) <30%, implantation of a DES other than a cobalt-chromium everolimus-eluting stent in the previous 12 months, target lesion located in the left main, arterial or saphenous vein graft, in a previously implanted stent (in-stent restenosis), chronic total occlusion (CTO), and target lesion treated with overlapping stents (**Supplemental Table 1**). All patients received after index PCI open-label aspirin of 75-100 mg plus a $P2Y_{12}$ inhibitor, preferably 75 mg of clopidogrel, especially in presence of a concomitant oral anticoagulation (OAC) therapy. Eligibility to discontinue DAPT was assessed at 1 month after index PCI in XIENCE 28 and at 3 months in XIENCE 90. Patients who had been adherent to treatment and free from MI, repeat coronary revascularization, stroke, or stent thrombosis discontinued the $P2Y_{12}$ inhibitor and continued aspirin until the end of the study. Follow-up occurred in-person or via telephone at 1, 3, 6, and 12 months after index PCI in XIENCE 28, and at 3, 6, and 12 months in XIENCE 90. Given that eligibility to discontinue DAPT was assessed at different time points in the 2 studies, patients from XIENCE 90 who were event-free and adherent to treatment at 1 month were retrospectively selected to mimic the patients' selection of the XIENCE 28 program.

Clinical endpoints

The primary endpoint was the composite of all-cause death or MI. The key secondary endpoint was Bleeding Academic Research Consortium (BARC) type 2 to 5 bleeding. Other outcomes were: individual components of the primary endpoint; target lesion failure (TLF), a composite of cardiovascular death, target vessel MI, or clinically indicated target lesion revascularization (TLR); stroke; ischemic stroke; cardiovascular death; definite or probable stent thrombosis; TLR; target vessel revascularization (TVR); and BARC 3 to 5 bleeding. Outcomes were assessed between 1 and 12 months after the index procedure. All clinical events were adjudicated by an independent external committee. MI was defined in accordance with the Academic Research Consortium 2 definition (22). The definitions used for the outcomes are provided in **Supplemental Table 2**.

Statistical analysis

This analysis was designed to compare the effect of 1- versus 3-month DAPT on clinical outcomes in patients taking OAC and patients not taking OAC at hospital discharge.

Baseline and procedural continuous variables were summarized by means and standard deviations, categorical variables by counts and percentages. Chi-square and Student's t-test were used to compare data, as appropriate. Outcome incidence was calculated with the Kaplan-Meier method and compared between groups using the log-rank test for the time to first event. Cox proportional hazard models were used to compare the unadjusted risk for the primary and secondary outcomes.

Because treatment arms were not randomized, adjusted risks for all endpoints were estimated using propensity score stratification into quintiles, consistently with the main study design. Propensity scores (patients' estimated probability of receiving 1- or 3-month DAPT) were derived using a logistic regression model that included the study group as the outcome and the following baseline demographic, clinical, and procedural covariates as the predictors: sex, body mass index (BMI), hypertension, hypercholesterolemia, diabetes, prior PCI, prior CABG, prior MI, history of stroke, history of major bleeding, baseline serum creatinine, platelet and hemoglobin counts, acute coronary syndrome, multi-vessel disease, B2/C lesion, total lesion length, mean pre reference vessel diameter (RVD), mean pre diameter stenosis (DS), bifurcation lesion, number of lesion treated, number of vessel treated, number of stent, total stent length, PARIS risk score, PRECISE DAPT risk score, $P2Y_{12}$ at discharge, anticoagulation therapy.

The Markov Chain Monte Carlo multiple imputation method was used to handle missing data in the propensity score building. The Rubin's combination rule was used to integrate the final analysis with each of the 10 imputed data sets. All endpoints were tested for superiority with the Farrington-Manning method and a 1-sided alpha of 0.025. The stratification weight was based on the total sample size in each stratum relative to the overall sample size for both arms. Heterogeneity of treatment effects was assessed across prespecified subgroups using a generic version of the meta-analysis where each subgroup contributes a normalized treatment effect and its standard error. All statistical analyses were performed with the R software, version 3.6.2 (R Foundation for Statistical Computing), or the SAS software, version 9.4 (SAS Institute).

RESULTS

Population characteristics

Between July 19, 2017 and February 7, 2020, 3,652 patients were enrolled in the XIENCE Short DAPT program. The final cohort included 3,364 patients free of ischemic events and adherent to treatment at 1 month, of which 1,462 (44%) with OAC (OAC group), and 1,902 (56%) without OAC at discharge (no OAC group). A total of 644 patients received 1-month and 818 patients received 3-month DAPT in the OAC group, whereas the corresponding figures in the no-OAC group were 748 and 1,154, respectively **(Figure 1).**

Patients on OAC were younger, more likely male, Caucasian, with prior CABG and were less likely with chronic kidney disease (CKD), anemia, history of major bleeding compared with the no-OAC group. OAC patients had a higher number of HBR criteria but lower PRECISE-DAPT and PARIS bleeding risk score than no-OAC patients; they were also more likely to be discharged on clopidogrel (**Supplemental Tables 3 and 4**).

In both OAC and no-OAC groups, patients with 1-month DAPT were older, more likely Asian or Hispanic, to have CKD, NSTEMI at clinical presentation, clopidogrel at discharge, higher number of HBR criteria and higher PRECISE-DAPT bleeding risk score; patients on OAC had less frequently hypertension, dyslipidemia or prior CABG (**Table 1 and Table 2**).

Patients on OAC were more adherent to the study antiplatelet regimen than patients without OAC, since they were less likely to continue the DAPT beyond 1-month (1.7% vs 4.3%, p= 0.006) or 3-month (7.7% vs 19.4%, p-value <0.001) (**Table 3**).

Mortality and ischemic outcomes

Rates of death or MI or any of the ischemic outcomes were similar in OAC and no-OAC patients (**Figure 2**).

Death or MI occurred in 43 (7.4%) OAC patients with 1-month DAPT and in 66 (8.8%) OAC patients with 3-month DAPT and in 60 (8.4%) no-OAC patients with 1-month DAPT and in 79 (7.3%) no-OAC patients with 3-month DAPT. After PS-adjustment, the risk of death or MI did not differ between 1- and 3-month DAPT in both the OAC (adj. HR 0.74, 95% CI 0.49-1.11, p-value 0.139) and no-OAC (adj. HR 1.17, 95% CI 0.82-1.65, p-value of 0.390) groups (p-value of interaction 0.162) **(Figure 3)**.

All-cause death occurred in 24 (4.2%) OAC patients with 1-month DAPT and 44 (6.0%) OAC patients with 3-month DAPT, and in 40 (5.5%) no-OAC patients with 1-month DAPT and 44 (4.1%) no-OAC patients with 3-month DAPT. One-month DAPT was associated with a lower risk of all-cause death compared with 3-month DAPT in the OAC group (adj. HR 0.58, 95% CI 0.34-0.98, p-value 0.043), but not in the no-OAC group (adj. HR 1.33, 95% CI 0.85-2.08, p-value of 0.206; p-value of interaction 0.031). Risk of MI did not differ with 1- vs. 3-month DAPT in both OAC (3.4% vs 3.5%; adj. HR 0.93, 95% CI 0.51-1.71, p-value 0.814) and no-OAC (3.5% vs 3.0%; adj. HR 0.72, 95% CI 0.42-1.23, p-value of 0.226) patients (p-value of interaction 0.416) (**Figure 3**).

Ischemic stroke was reduced with 1- vs. 3-month DAPT in OAC patients (0.8% vs 1.5%, Adj. HR 0.20, 95% CI 0.05-0.79, p-value 0.021) whereas, in no-OAC patients it did not significantly differ between the two DAPT groups (0.8% vs 1.8%, Adj. HR 0.47, 95% CI 0.18-1.21, p-value 0.119; p of interaction 0.624). In OAC and no-OAC patients, there were no differences between 1- and 3-month DAPT with respect to TLF, cardiovascular death, stroke, define or probable ST, TVR or TLR (interaction p-values >0.05) (**Table 4**).

Bleeding outcomes

For the follow-up period from 1 to 12 months after index PCI, BARC 2-5 (12.5% vs 6.8%, HR 1.81, 95% CI 1.43-2.29, p<0.001) and BARC 3-5 bleeding (6.2% vs 3.0%, HR 2.04, 95% CI 1.43-2.29, p<0.001) were higher in OAC than no-OAC patients (**Figure 2**).

BARC 2-5 bleeding was observed in in 62 (10.7%) OAC patients taking 1-month DAPT group and 103 (14.0%) OAC patients on 3-month DAPT; in the no-OAC group it occurred in 40 (5.5%) and 79 (7.3%) patients in the two DAPT groups, respectively. The adjusted risk of BARC 2-5 bleeding was lower with 1- than with 3-month DAPT in OAC patients (adj. HR 0.74, 95% CI 0.51-0.99, p-value 0.046) but it did not significantly differ in the no-OAC group (adj. HR 0.74, 95% CI 0.50-1.09, p-value of 0.124; p-value of interaction 0.812) **(Figure 3)**. The risk of BARC 3-5 bleeding did not differ between 1- and 3-month DAPT in both OAC (5.5% vs 5.6%, adj. HR 0.76, 95% CI 0.48-1.21, p-value 0.252) and no-OAC (2.2% vs 2.4%, adj. HR 0.68, 95% CI 0.38-1.24, p-value of 0.212) patients (p-value of interaction 0.828) **(Figure 3)**.

DISCUSSION

We compared the effects at 1-year of 1- vs 3-month DAPT followed by a single antiplatelet agent (aspirin in >90% of cases) in 3,364 patients undergoing successful PCI with or without chronic OAC in a large, international prospective study with central events adjudication (XIENCE Short DAPT program).

The main findings can be summarized as follows:

1) OAC patients comprised 44% of the study population and they were younger, mostly man, Caucasian, less likely with comorbidities (i.e. CKD, anemia, prior major bleeding) and incurred 2-times higher risk of bleeding than no-OAC patients

2) While 1- or 3-month DAPT were associated with a similar risk of death or MI in both OAC groups, OAC patients experienced lower risks of all-cause death and stroke with 1- than 3-month DAPT
3) The risk of BARC 2 to 5 was decreased with 1- compared with 3-month DAPT in OAC patients but not significantly reduced in no-OAC patients; BARC 3 to 5 rates were numerically but not significantly lower with 1- vs. 3-month DAPT irrespective of concomitant OAC.

DAPT for at least 6 months is the standard of care in patients undergoing PCI (1,2,16). To reduce bleeding complications, current guidelines propose to shorten DAPT duration in presence of HBR features and not to exceed 4 weeks of DAPT in patients on OAC (triple therapy) (1,14-16). This last recommendation is partially based on the results of four recent RCTs, showing that aspirin discontinuation early after PCI is associated with lower bleeding risk (23-26); however, this strategy might increase the risk of stent thrombosis or MI (17,19). Early $P2Y_{12}$ inhibitor discontinuation after PCI was not associated with clear benefit in one small RCT (13). The MASTER DAPT trial randomized HBR patients after biodegradable polymer sirolimus-eluting stent implantation, including patients with OAC, to receive 1- or 3-month DAPT and showed bleeding risk reduction and no excess of ischemic events with abbreviated compared to standard DAPT regimen (27-29).

In this analysis, we assessed the effect of 1- vs 3-month DAPT followed by single antiplatelet agent (aspirin in >90% of cases) in HBR patients with or without OAC undergoing successful PCI. The study population was mostly at low risk of ischemic events, since patients

with STEMI or complex PCI features (i.e. PCI involving the left main artery, arterial or saphenous vein graft, chronic total occlusion, bifurcation with 2-stent techniques, in-stent restenosis or overlapping stent) were excluded. Despite the younger age and lower likelihood of comorbidities, OAC patients incurred a 2-fold higher rates of clinically relevant or major bleeding but similar rates of death and ischemic events compared with no-OAC patients. DAPT discontinuation was more likely to occur earlier and according to the study protocol in OAC than no-OAC patients. Irrespective of concomitant OAC, 1- versus 3-month DAPT consistently reduced the risk of clinically relevant (BARC 2 to 5) bleeding (interaction p-value 0.812). Major bleeding (BARC 3 to 5) was numerically but not significantly lower with 1- vs 3-month DAPT (absolute risk reduction ≈1%). The benefits of a shorter DAPT are consistent with the findings of four recent RCTs (23-26). However, the increase in stent thrombosis and MI with up to 1-week DAPT, which was found in two meta-analyses (17,19), was not observed in our analysis with 1- compared with 3-month DAPT. Interestingly, in OAC patients, the risk of all-cause death and stroke were reduced with 1-month DAPT. These different results might be related to several factors, including the lack of power to detect small differences in ischemic events in our study, the exclusion of patients with high ischemic risk (i.e. presenting with STEMI or complex PCI features) or the more prolonged DAPT regimen in the abbreviated group (up to 1-week vs. 1-month). A lower risk of ischemic stroke in OAC patients with an abbreviated DAPT was consistently found in the WOEST (What is the Optimal Antiplatelet and Anticoagulant therapy in patients with oral anticoagulation and coronary stenting) and MASTER-DAPT (Management of High Bleeding Risk Patients Post Bioresorbable Polymer Coated Stent Implantation With an Abbreviated Versus Standard DAPT Regimen) trials (27,30).

Bleeding reduction was not statistically significant when one antiplatelet agent was discontinued earlier in patients on triple therapy included in the ISAR-TRIPLE (Intracoronary Stenting and Antithrombotic Regimen–Testing of a 6-Week Versus a 6-Month Clopidogrel Treatment Regimen in Patients With Concomitant Aspirin and Oral Anticoagulant Therapy Following Drug-Eluting Stenting) and MASTER-DAPT trial (13,27). The ISAR-TRIPLE did not show differences with respect to the composite endpoint of death, MI, stent thrombosis, stroke or TIMI major bleeding between $P2Y_{12}$ inhibitor discontinuation at 6-week and at 6-month while maintaining VKA and aspirin; clinically relevant bleeding (BARC ≥2) was numerically lower in the former group but not significantly reduced (13). The small sample size (n=614) of the ISAR-TRIPLE trial probably prevented the detection of significant difference in bleeding events. The MASTERDAPT is the only RCT that compared 1-month (median DAPT duration from index PCI 33 days) with 3-month (median DAPT duration 96 days) DAPT in HBR patients on chronic OAC. In this study, an abbreviated DAPT was associated with consistent reduction of clinically relevant bleeding events (BARC 2, 3, or 5) (27). In our study, as well as in several previous studies on HBR patients (13% to 62% on OAC) mostly at low ischemic risk, there was no signal potentially indicating a higher risk of ischemic complications with 1-month DAPT followed by aspirin monotherapy (31-35). Aspirin or $P2Y_{12}$ inhibitor monotherapy after a short course of DAPT immediately after PCI were not yet compared in a randomized study.

Our analysis suggests that 1-month DAPT followed by a single antiplatelet therapy (in most cases aspirin monotherapy) might be a suitable option in HBR patients at low ischemic risk, especially if on chronic OAC treatment to maximize bleeding protection without trade-off of ischemic events. This strategy is being investigated in an ongoing RCT (NCT04436978).

Limitations

The results of this analysis have to be interpreted in light of some limitations. First, due to the nonrandomized design, there exists a risk for residual unmeasured confounders. The study was not powered to detect differences for single ischemic endpoints such as myocardial infarction, stent thrombosis or stroke. Patients in the 1-month study (XIENCE 28) were evaluated and characterized as event free at 1-month while patients in the 3-month study (XIENCE 90) did not have a follow up at 1-month. The retrospective identification of 1-month event-free patients in XIENCE 90 resulted in poorer adherence to the antiplatelet regimen in this cohort. Indeed, in case of ischemic events between 1 and 3-month, DAPT discontinuation was unlikely to occur at 3-month. Further, the results of this study may not apply to patients who did not meet the inclusion and exclusion criteria of the study, such as those presenting with STEMI or requiring complex PCI.

CONCLUSIONS

Among HBR patients undergoing non-complex PCI with a cobalt-chromium everolimus-eluting stent, 1-month compared with 3-month DAPT was associated with a similar risk of death or MI and lower rates of BARC 2-5 bleeding, irrespective of concomitant OAC treatment. In the OAC group, 1-month DAPT was associated with lower mortality and stroke rates compared with 3-month DAPT.

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Figure 1. Patient flow diagram.
DAPT= dual antiplatelet therapy; OAC= oral anticoagulation
** 1 duplicate subject enrolment, 12 missed 1-month visit*

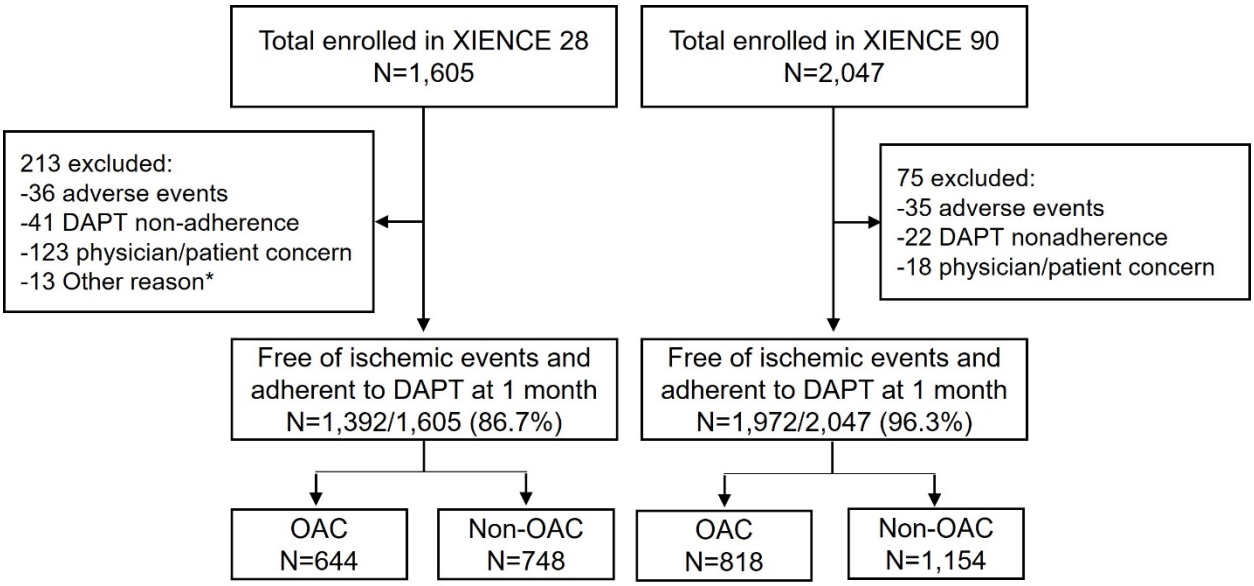
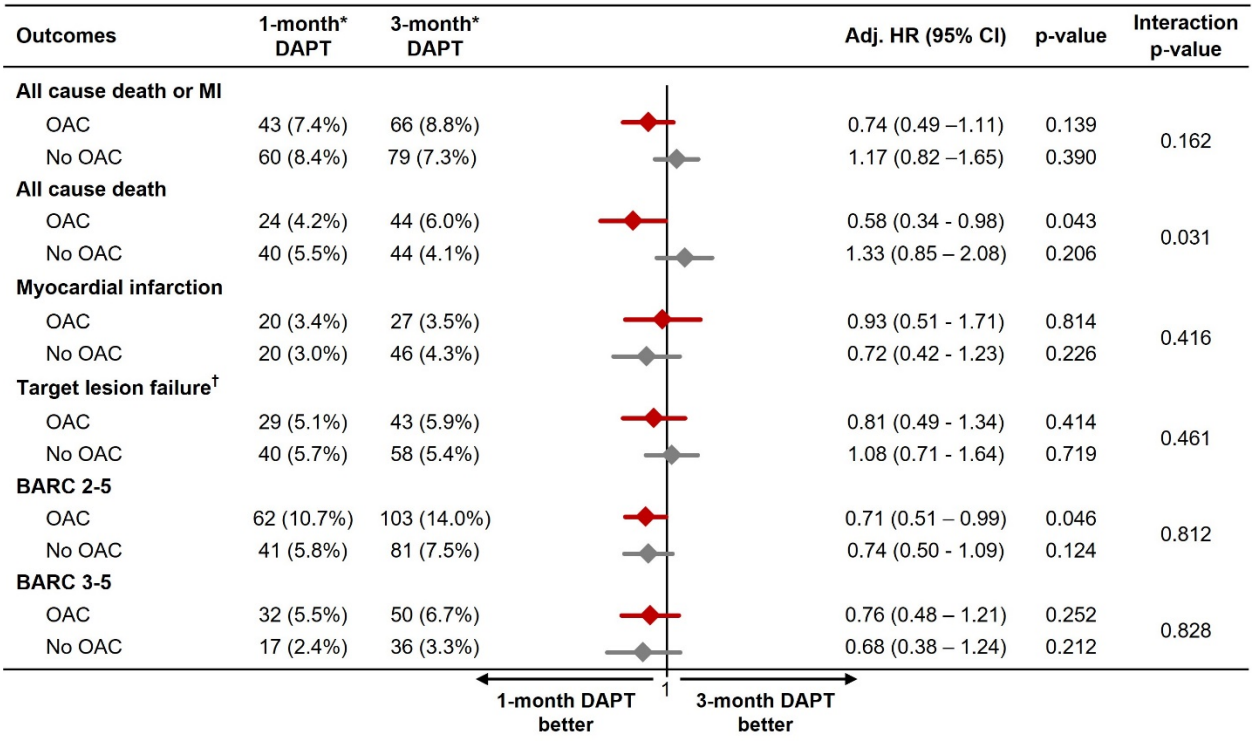


Figure 2. Rates and risk of adverse events from 1 to 12 months after PCI in patients with and without OAC.

BARC: Bleeding Academic Research Consortium; MI: myocardial infarction; OAC: oral anticoagulation; ST: Stent thrombosis.

Outcomes	OAC N=1,462	No OAC N=1,902	Hazard ratio (95% CI)	p-value
All-cause death, or MI	109 (8.2%)	139 (7.8%)	1.03 (0.80 - 1.32)	0.846
All-cause death	68 (5.2%)	84 (4.7%)	1.06 (0.77 - 1.46)	0.722
Cardiovascular death	36 (2.9%)	45 (2.5%)	1.05 (0.68 - 1.62)	0.836
MI	47 (3.5%)	66 (3.8%)	0.93 (0.64 - 1.35)	0.707
Definite or probable ST	5 (0.4%)	5 (0.3%)	1.32 (0.38 - 4.55)	0.664
Stroke	17 (1.4%)	27 (1.5%)	0.82 (0.45 - 1.51)	0.529
Ischemic stroke	14 (1.2%)	25 (1.4%)	0.73 (0.38 - 1.41)	0.350
Target lesion failure	72 (5.5%)	98 (5.5%)	0.96 (0.71 - 1.30)	0.804
Target lesion revascularization	18 (1.4%)	26 (1.5%)	0.91 (0.50 - 1.66)	0.752
Target vessel revascularization	26 (2.1%)	49 (2.8%)	0.69 (0.43 - 1.12)	0.131
BARC 2-5 bleeding	165 (12.5%)	122 (6.8%)	1.81 (1.43 - 2.29)	<.001
BARC 3-5 bleeding	82 (6.2%)	53 (3.0%)	2.04 (1.45 - 2.89)	<.001

Figure 3. Propensity score adjusted risk of adverse events from 1 to 12 months after PCI with 1- vs 3-month DAPT in patients with and without OAC.



BARC: Bleeding Academic Research Consortium; DAPT: dual antiplatelet therapy; HR: hazard ratio; MI: myocardial infarction; OAC: oral anticoagulation.
*Among OAC patients, 644 received 1-month DAPT and 818 3-month DAPT; among no OAC 748 received 1-month DAPT and 1,154 3-month DAPT
†Composite of cardiovascular death, target vessel MI, or clinically indicated target lesion revascularization

Table 1. Baseline characteristics.

	OAC (N=1,462)			No OAC (N=1,902)		
	1-month DAPT N=644	3-month DAPT N=818	p-value	1-month DAPT N=748	3-month DAPT N=1,154	p-value
Age, years	74.2±8.5	73.1±9.3	0.022	77.5±7.9	76.5±9.2	0.011
Female sex	178 (27.6%)	247 (30.2%)	0.285	275 (36.8%)	454 (39.3%)	0.259
Race						
White	418 (89.3%)	760 (92.9%)	0.025	389 (77.3%)	979 (84.8%)	<.001
Hispanic or Latino ethnicity	50 (8.4%)	15 (1.8%)	<.001	88 (12.3%)	41 (3.6%)	<.001
Black or African American	14 (3.0%)	32 (3.9%)	0.392	22 (4.4%)	85 (7.4%)	0.023
Asian	34 (7.3%)	7 (0.9%)	<.001	92 (18.3%)	38 (3.3%)	<.001
American Indian or Alaskan Native	2 (0.4%)	4 (0.5%)	1.000	0 (0.0%)	7 (0.6%)	0.109
Native Hawaiian or Pacific Islander	0 (0.0%)	2 (0.2%)	0.537	0 (0.0%)	3 (0.3%)	0.558
Hypertension	554 (86.0%)	746 (91.2%)	0.002	625 (83.6%)	1025 (88.8%)	<.001
Dyslipidemia	433 (67.2%)	682 (83.4%)	<.001	506 (67.6%)	940 (81.5%)	<.001
Diabetes mellitus	235 (36.7%)	322 (39.4%)	0.292	277 (37.4%)	465 (40.4%)	0.194
Chronic kidney disease	230 (37.3%)	244 (30.0%)	0.004	401 (56.2%)	557 (48.7%)	0.002
Prior PCI	183 (28.4%)	243 (29.7%)	0.590	207 (27.7%)	364 (31.5%)	0.072
Prior CABG	59 (9.2%)	121 (14.8%)	0.001	53 (7.1%)	125 (10.8%)	0.006
Prior MI	116 (18.2%)	130 (16.1%)	0.301	111 (14.9%)	187 (16.4%)	0.368
Chronic coronary syndrome	430 (66.8%)	536 (65.5%)	0.618	487 (65.1%)	747 (64.7%)	0.867
Acute coronary syndrome	214 (33.2%)	282 (34.5%)	0.618	261 (34.9%)	407 (35.3%)	0.867
NSTEMI	102 (15.8%)	54 (6.6%)	<.001	143 (19.1%)	87 (7.5%)	<.001
High bleeding risk criteria						
Age ≥75 years	341 (53.0%)	404 (49.4%)	0.176	608 (81.3%)	888 (76.9%)	0.024
Chronic anticoagulant therapy	617 (95.8%)	805 (98.4%)	0.002	0 (0%)	0 (0%)	N.A.
History of stroke	74 (11.5%)	87 (10.6%)	0.604	71 (9.5%)	136 (11.8%)	0.119
Renal insufficiency	27 (4.2%)	27 (3.3%)	0.369	89 (11.9%)	130 (11.3%)	0.665
Anemia	68 (10.6%)	90 (11.0%)	0.786	133 (17.8%)	223 (19.3%)	0.407
Thrombocytopenia	13 (2.1%)	10 (1.3%)	0.211	18 (2.5%)	28 (2.5%)	0.977
History of major bleeding	11 (1.7%)	17 (2.1%)	0.608	35 (4.7%)	40 (3.5%)	0.182
Number of HBR criteria	1.8±0.8	1.8±0.8	0.510	1.3±0.6	1.3±0.5	0.372
Bleeding risk scores						
PARIS	6.3±2.4	6.4±2.3	0.310	5.9±2.2	5.7±2.2	0.032
PRECISE-DAPT	24.3±11.2	22.6±11.9	0.008	30.6±10.5	28.8±10.8	<.001

CABG: coronary artery bypass grafting, DAPT: dual antiplatelet therapy, HBR: high bleeding risk, MI: myocardial infarction, NSTEMI: non-ST segment elevation myocardial infarction, OAC: oral anticoagulation, PCI: percutaneous coronary intervention

Table 2. Procedural characteristics.

	OAC (N=1,462)			No OAC (N=1,902)		
	1-month DAPT N=644	3-month DAPT N=818	p-value	1-month DAPT N=748	3-month DAPT N=1,154	p-value
Procedural characteristics						
Radial access	458 (71.1%)	444 (54.3%)	<.001	528 (70.6%)	584 (50.6%)	<.001
Multivessel disease	281 (43.6%)	381 (46.6%)	0.262	292 (39.0%)	537 (46.5%)	0.001
Number of lesions treated (IQR)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.783	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.784
Number of vessels treated (IQR)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.676	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.090
B2/C lesion	256 (39.8%)	282 (34.5%)	0.038	242 (32.4%)	405 (35.1%)	0.218
Bifurcation	78 (12.1%)	60 (7.3%)	0.002	83 (11.1%)	93 (8.1%)	0.026
Number of stents per subject (IQR)	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.354	1.0 (1.0-1.0)	1.0 (1.0-1.0)	0.629
Total stent length, mm	27.8±14.8	24.7±12.6	<.001	26.7±14.1	26.2±14.6	0.419
Pre-procedure RVD, mm	3.0±0.5	3.0±0.5	0.654	3.0±0.5	3.0±0.5	0.422
Pre-procedure % DS	82.4±10.4	84.1±9.6	0.002	82.6±10.2	83.8±9.5	0.008
Antiplatelet therapy at discharge						
Aspirin	387 (60.1%)	647 (79.1%)	<.001	745 (99.6%)	1154 (100%)	0.061
Clopidogrel	591 (91.8%)	707 (86.4%)	0.001	613 (82.0%)	905 (78.4%)	0.061
Prasugrel	8 (1.2%)	19 (2.3%)	0.128	6 (0.8%)	27 (2.3%)	0.012
Ticagrelor	45 (7.0%)	94 (11.5%)	0.004	129 (17.2%)	223 (19.3%)	0.254

DS: diameter stenosis; IQR: interquartile range; RVD: reference vessel diameter

Table 3. Proportion of patients on dual antiplatelet therapy (DAPT) at different timepoints. In XIENCE 28, DAPT discontinuation was mandated at 1 month after PCI (A), whereas in XIENCE 90 at 3-month (B). Reported rates refer to the antiplatelet therapy taken by the patient until the study visit (and not the new prescribed regimen).

A

XIENCE 28	**30 days**	**45 days**	**90 days**	**180 days**	**365 days**
OAC	67.9%	1.7%	0.9%	1.4%	1.4%
No OAC	71.3%	4.3%	4.1%	4.3%	5.9%
p-value	*0.169*	*0.006*	*<0.001*	*0.002*	*0.011*

B

XIENCE 90	**30 days**	**45 days**	**90 days**	**180 days**	**365 days**
OAC	70.7%	66.3%	52.8%	7.7%	6.1%
No OAC	99.7%	98.3%	82.2%	19.4%	17.1%
p-value	*<0.001*	*<0.001*	*<0.001*	*<0.001*	*<0.001*

DAPT: dual-antiplatelet therapy, OAC: oral anticoagulant

Table 4. Rates and adjusted risk of other outcomes from 1 to 12 month after PCI. The reported percentages represent Kaplan-Meier rates.

Outcomes	Group	1-month DAPT	3-month DAPT	Adjusted Hazard ratio† (95% CI)	p-value	Interaction p-value‡
Cardiovascular death	OAC	11/644 (2.0%)	25/818 (3.6%)	0.52 (0.25 - 1.09)	0.085	0.055
	No OAC	21/748 (2.9%)	24/1154 (2.2%)	1.26 (0.69 - 2.33)	0.453	
Stroke	OAC	4 (0.9%)	13 (1.8%)	0.26 (0.08 - 0.86)	0.028	0.624
	No OAC	7 (1.0%)	20 (1.9%)	0.55 (0.22 - 1.33)	0.181	
Ischemic stroke	OAC	3 (0.8%)	11 (1.5%)	0.20 (0.05 - 0.79)	0.021	0.643
	No OAC	6 (0.8%)	19 (1.8%)	0.47 (0.18 - 1.21)	0.119	
Definite or probable ST	OAC	3 (0.5%)	2 (0.3%)	2.03 (0.31-13.22)	0.459	0.278
	No OAC	1 (0.1%)	4 (0.4%)	0.49 (0.05 - 4.59)	0.536	
Target vessel revascularization	OAC	11 (2.3%)	15 (2.0%)	0.96 (0.42 - 2.19)	0.926	0.971
	No OAC	18 (2.7%)	31 (2.9%)	0.96 (0.53 - 1.75)	0.893	
Target lesion revascularization	OAC	9 (1.7%)	9 (1.2%)	1.35 (0.51 - 3.57)	0.542	0.499
	No OAC	9 (1.2%)	17 (1.6%)	0.85 (0.37 - 1.96)	0.699	

DAPT: dual-antiplatelet therapy, OAC: oral anticoagulation ST: stent thrombosis

† Propensity stratified outcomes according to gender, baseline serum creatinine, anticoagulation therapy, stroke, history of major bleeding, baseline platelet, baseline hemoglobin, BMI, hypertension, hypercholesterolemia, prior PCI, prior CABG, prior MI, multi-vessel disease, acute coronary syndrome, diabetes, B2/C lesion, total lesion length, mean pre RVD, mean pre DS, bifurcation lesion, number of lesion treated, number of vessel treated, number of stents, total stent length, $P2Y_{12}$ on discharged, PARIS risk score for major bleeding, PRECISE DAPT risk score for bleeding

‡ P value is obtained from the interaction test between anticoagulant at discharge and DAPT after applying multiple imputation and propensity score stratification

SUPPLEMENTARY APPENDIX

Supplemental Table 1. Inclusion and exclusion criteria of the XIENCE 90 and XIENCE 28 studies. Any differences in the inclusion/ exclusion criteria for the trials have been italicized.

XIENCE 90	XIENCE 28 Global	XIENCE 28 USA
General Inclusion Criteria: 1. Subject is considered at high risk for bleeding (HBR), defined as meeting one or more of the following criteria at the time of registration and in the opinion of the referring physician, the risk of major bleeding with > 3-month DAPT outweighs the benefit: a) ≥ 75 years of age. b) Clinical indication for chronic (at least 6 months) or lifelong anticoagulation therapy. c) History of major bleeding which required medical attention within 12 months of the index procedure. d) History of stroke (ischemic or hemorrhagic). e) Renal insufficiency (creatinine ≥ 2.0 mg/dl) or failure (dialysis dependent). f) Systemic conditions associated with an increased bleeding risk (e.g. hematological disorders, including a history of or current thrombocytopenia defined as a platelet count <100,000/mm^3, or any known coagulation disorder associated with increased bleeding risk). g) Anemia with hemoglobin < 11g/dl. 2. Subject must be at least 18 years of age. 3. *Subject or a legally authorized representative must provide written informed consent as approved by the Institutional Review Board (IRB)/Ethics Committee (EC) of the respective clinical site prior to any study related procedure*.	**General Inclusion Criteria:** 1. Subject is considered at high risk for bleeding (HBR), defined as meeting one or more of the following criteria at the time of registration and in the opinion of the referring physician, the risk of major bleeding with > 1-month DAPT outweighs the benefit: a) ≥ 75 years of age. b) Clinical indication for chronic (at least 6 months) or lifelong anticoagulation therapy. c) History of major bleeding which required medical attention within 12 months of the index procedure. d) History of stroke (ischemic or hemorrhagic). e) Renal insufficiency (creatinine ≥ 2.0 mg/dl) or failure (dialysis dependent). f) Systemic conditions associated with an increased bleeding risk (e.g. hematological disorders, including a history of or current thrombocytopenia defined as a platelet count <100,000/mm^3, or any known coagulation disorder associated with increased bleeding risk). g) Anemia with hemoglobin < 11g/dl. 2. Subject must be at least 18 years of age. 3. *Subject must provide written informed consent as approved by the Ethics Committee (EC) of the respective clinical site prior to any trial related procedure*. 4. Subject is willing to comply with all protocol requirements, including agreement to stop	**General Inclusion Criteria:** 1. Subject is considered at high risk for bleeding (HBR), defined as meeting one or more of the following criteria at the time of registration and in the opinion of the referring physician, the risk of major bleeding with > 1-month DAPT outweighs the benefit: a) ≥ 75 years of age. b) Clinical indication for chronic (at least 6 months) or lifelong anticoagulation therapy. c) History of major bleeding which required medical attention within 12 months of the index procedure. d) History of stroke (ischemic or hemorrhagic). e) Renal insufficiency (creatinine ≥ 2.0 mg/dl) or failure (dialysis dependent). f) Systemic conditions associated with an increased bleeding risk (e.g. hematological disorders, including a history of or current thrombocytopenia defined as a platelet count <100,000/mm3, or any known coagulation disorder associated with increased bleeding risk). g) Anemia with hemoglobin < 11g/dl. 2. Subject must be at least 18 years of age. 3. *Subject must provide written informed consent as approved by the Institutional Review Board (IRB) of the respective clinical site prior to any trial related procedure.* 4. Subject is willing to comply with all protocol requirements, including agreement to stop

4. Subject is willing to comply with all protocol requirements, including agreement to stop taking P2Y12 inhibitor at 3 months, if eligible per protocol. 5. *Subject must agree not to participate in any other clinical trial for a period of one year following the index procedure.* **Angiographic Inclusion Criteria:** 1. Up to three target lesions with a maximum of two target lesions per epicardial vessel. Note: • The definition of epicardial vessels means left anterior descending coronary artery (LAD), left circumflex coronary artery (LCX) and right coronary artery (RCA) and their branches. For example, the patient must not have >2 lesions requiring treatment within both the LAD and a diagonal branch in total. • If there are two target lesions within the same epicardial vessel, the two target lesions must be at least 15 mm apart per visual estimation; otherwise this is *considered as a single target lesion.* 2. *Target lesion ≤ 32 mm in length by visual estimation.* 3. Target lesion must be located in a native coronary artery with visually estimated reference vessel diameter between 2.25 mm and 4.25 mm. 4. Exclusive use of XIENCE family of stent systems during the index procedure. 5. Target lesion has been treated successfully, which is defined as achievement of a final in-stent residual diameter stenosis of <20% with final TIMI-3 flow assessed by online quantitative angiography or visual estimation, with no residual dissection NHLBI grade ≥ type B, and no transient or sustained	taking P2Y12 inhibitor at 1 month, if eligible per protocol. 5. *Subject must agree not to participate in any other clinical trial for a period of one year following the index procedure.* **Angiographic Inclusion Criteria:** 1. Up to three target lesions with a maximum of two target lesions per epicardial vessel. Note: • The definition of epicardial vessels means left anterior descending coronary artery (LAD), left circumflex coronary artery (LCX) and right coronary artery (RCA) and their branches. For example, the subject must not have >2 lesions requiring treatment within both the LAD and a diagonal branch in total. • If there are two target lesions within the same epicardial vessel, the two target lesions must be at least 15 mm apart per visual estimation; otherwise this is considered as a single target lesion. 2. Target lesion must be located in a native coronary artery with visually estimated reference vessel diameter between 2.25 mm and 4.25 mm. 3. Exclusive use of XIENCE family of stent systems during the index procedure. 4. Target lesion has been treated successfully, which is defined as achievement of a final in-stent residual diameter stenosis of <20% with final TIMI-3 flow assessed by online quantitative angiography or visual estimation, with no residual dissection NHLBI grade ≥ type B, and no transient or sustained angiographic complications (e.g., distal embolization, side branch closure), no chest	taking P2Y12 inhibitor at 1 month, if eligible per protocol. 5. *Subject must agree not to participate in any other clinical trial for a period of one year following the index procedure, except for cases where subject is transferred to the XIENCE 90 study after the 1-month visit assessment.* **Angiographic Inclusion Criteria:** 1. Up to three target lesions with a maximum of two target lesions per epicardial vessel. Note: • The definition of epicardial vessels means left anterior descending coronary artery (LAD), left circumflex coronary artery (LCX) and right coronary artery (RCA) and their branches. For example, the subject must not have >2 lesions requiring treatment within both the LAD and a diagonal branch in total. • If there are two target lesions within the same epicardial vessel, the two target lesions must be at least 15 mm apart per visual estimation; otherwise this is considered as a single target lesion. 2. Target lesion must be located in a native coronary artery with visually estimated reference vessel diameter between 2.25 mm and 4.25 mm. 3. Exclusive use of XIENCE family of stent systems during the index procedure. 4. Target lesion has been treated successfully, which is defined as achievement of a final in-stent residual diameter stenosis of <20% with final TIMI-3 flow assessed by online quantitative angiography or visual estimation, with no residual dissection NHLBI grade ≥ type B, and no transient or sustained angiographic complications (e.g., distal embolization, side branch closure), no chest

angiographic complications (e.g., distal embolization, side branch closure), no chest pain lasting > 5 minutes, and no ST segment elevation > 0.5 mm or depression lasting > 5 minutes.	pain lasting > 5 minutes, and no ST segment elevation > 0.5mm or depression lasting > 5 minutes.	pain lasting > 5 minutes, and no ST segment elevation > 0.5mm or depression lasting > 5 minutes.
General Exclusion Criteria: 1. Subject with an indication for the index procedure of acute ST-segment elevation MI (STEMI). 2. Subject has a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, P2Y12 inhibitors (clopidogrel/prasugrel/ticagrelor), everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated. 3. Subject with implantation of another drug-eluting stent (other than XIENCE) within 9 months prior to index procedure. 4. Subject has a known left ventricular ejection fraction (LVEF) <30%. 5. Subject judged by physician as inappropriate for discontinuation from P2Y12 inhibitor use at 3 months, due to another condition requiring chronic P2Y12 inhibitor use. 6. Subject with planned surgery or procedure necessitating discontinuation of P2Y12 inhibitor within 3 months following index procedure. 7. Subject with a current medical condition with a life expectancy of less than 12 months 8. *Subject intends to participate in an investigational drug or device trial within 12 months following the index procedure.* 9. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure. Female subjects of	**General Exclusion Criteria:** 1. Subject with an indication for the index procedure of acute ST-segment elevation MI (STEMI). 2. Subject has a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, P2Y12 inhibitors (clopidogrel/prasugrel/ticagrelor), everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated. 3. Subject with implantation of another drug-eluting stent (other than XIENCE) within 12 months prior to index procedure. 4. Subject has a known left ventricular ejection fraction (LVEF) <30%. 5. Subject judged by physician as inappropriate for discontinuation from P2Y12 inhibitor use at 1 month, due to another condition requiring chronic P2Y12 inhibitor use. 6. Subject with planned surgery or procedure necessitating discontinuation of P2Y12 inhibitor within 1 month following index procedure. 7. Subject with a current medical condition with a life expectancy of less than 12 months 8. *Subject intends to participate in an investigational drug or device trial within 12 months following the index procedure.* 9. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure. Female subjects of	**General Exclusion Criteria:** 1. Subject with an indication for the index procedure of acute ST-segment elevation MI (STEMI). 2. Subject has a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, P2Y12 inhibitors (clopidogrel/prasugrel/ticagrelor), everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated. 3. Subject with implantation of another drug-eluting stent (other than XIENCE) within 12 months prior to index procedure. 4. Subject has a known left ventricular ejection fraction (LVEF) <30%. 5. Subject judged by physician as inappropriate for discontinuation from P2Y12 inhibitor use at 1 month, due to another condition requiring chronic P2Y12 inhibitor use. 6. Subject with planned surgery or procedure necessitating discontinuation of P2Y12 inhibitor within 1 month following index procedure. 7. Subject with a current medical condition with a life expectancy of less than 12 months. 8. *Subject intends to participate in an investigational drug or device trial within 12 months following the index procedure. Transferring to the XIENCE 90 study will not be an exclusion criterion.* 9. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure. Female subjects of

child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test. **Note**: Female patients of childbearing potential should be instructed to use safe contraception (e.g., intrauterine devices, hormonal contraceptives: contraceptive pills, implants, transdermal patches, hormonal vaginal devices, injections with prolonged release.) It is accepted, in certain cases, to include subjects having a sterilized regular partner or subjects using a double barrier contraceptive method. However, this should be explicitly justified in special circumstances arising from the study design, product characteristics and/or study population. 10. *Subject is part of a vulnerable population, defined as subject whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples of populations which may contain vulnerable subjects include: individuals with lack of or loss of autonomy due to immaturity or through mental disability, persons in nursing homes, children, impoverished persons, subjects in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, and those incapable of giving informed consent. Other vulnerable subjects include, for example, members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the sponsor, members of the armed forces, and persons kept in detention.*	child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test. **Note**: Female subjects of childbearing potential should be instructed to use safe contraception (e.g., intrauterine devices, hormonal contraceptives: contraceptive pills, implants, transdermal patches hormonal vaginal devices, injections with prolonged release.) It is accepted, in certain cases, to include subjects having a sterilized regular partner or subjects using a double barrier contraceptive method. However, this should be explicitly justified in special circumstances arising from the trial design, product characteristics and/or trial population. 10. *Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results.*	child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test. **Note**: Female subjects of childbearing potential should be instructed to use safe contraception (e.g., intrauterine devices, hormonal contraceptives: contraceptive pills, implants, transdermal patches, hormonal vaginal devices, injections with prolonged release.) It is accepted, in certain cases, to include subjects having a sterilized regular partner or subjects using a double barrier contraceptive method. However, this should be explicitly justified in special circumstances arising from the trial design, product characteristics and/or trial population. 10. *Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results.*

11. Subject is currently participating in another clinical trial that has not yet completed its primary endpoint. **Angiographic Exclusion Criteria:** 1. Target lesion is in a left main location. 2. Target lesion is located within an arterial or saphenous vein graft. 3. Target lesion is restenotic from a previous stent implantation. 4. *Target lesion is a total occluded lesion (TIMI flow 0).* 5. *Target lesion contains thrombus as indicated in the angiographic images (per SYNTAX score thrombus definition).* 6. Target lesion is implanted with overlapping stents, whether planned or for bailout. **Note**: If there is more than one target lesion, all target lesions must satisfy the angiographic eligibility criteria. Non-target lesion (i.e., lesions that do not meet the angiographic criteria listed above) treatments are not allowed during the index procedure.	11. Subject is currently participating in another clinical trial that has not yet completed its primary endpoint. **Angiographic Exclusion Criteria:** 1. Target lesion is in a left main location. 2. Target lesion is located within an arterial or saphenous vein graft. 3. Target lesion is restenotic from a previous stent implantation. 4. *Target lesion is a chronic total occlusion (CTO, defined as lesion with TIMI flow 0 for at least 3 months).* 5. Target lesion is implanted with overlapping stents, whether planned or for bailout. **Note:** If there is more than one target lesion, all target lesions must satisfy the angiographic eligibility criteria. Non-target lesion (i.e., lesions that do not meet the angiographic criteria listed above) treatments are not allowed during the index procedure.	11. Subject is currently participating in another clinical trial that has not yet completed its primary endpoint. **Angiographic Exclusion Criteria:** 1. Target lesion is in a left main location. 2. Target lesion is located within an arterial or saphenous vein graft. 3. Target lesion is restenotic from a previous stent implantation. 4. *Target lesion is a chronic total occlusion (CTO, defined as lesion with TIMI flow 0 for at least 3 months).* 5. Target lesion is implanted with overlapping stents, whether planned or for bailout. **Note**: If there is more than one target lesion, all target lesions must satisfy the angiographic eligibility criteria. Non-target lesion (i.e., lesions that do not meet the angiographic criteria listed above) treatments are not allowed during the index procedure.

Supplemental Table 2. Outcomes definitions.

DEATH (Per ARC Circulation 2007; 115: 2344-2351)	
All death	All deaths are considered cardiac unless an unequivocal non-cardiac cause can be established. Specifically, any unexpected death even in patients with coexisting potentially fatal non-cardiac disease (e.g. cancer, infection) should be classified as cardiac.
Cardiac death	Any death due to proximate cardiac cause (e.g. MI, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, all procedure related deaths including those related to concomitant treatment.
Vascular death	Death due to non-coronary vascular causes such as cerebrovascular disease, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular cause
MYOCARDIAL INFARCTION (MI)	
MI (Modified ARC)	Patients present any of the following clinical or imaging evidence of ischemia: • Clinical symptoms of ischemia; • ECG changes indicative of new ischemia - new ST-T changes or new left bundle branch block (LBBB), development of pathological Q waves*; • Imaging evidence of a new loss of viable myocardium or a new regional wall motion abnormality) AND confirmed with elevated cardiac biomarkers** per ARC criteria (Circulation 2007; 115: 2344-2351): • Periprocedural MI: • Within 48h after PCI: CK-MB >3 x URL or Troponin > 3 x URL with baseline value < URL • Within 72h after CABG: CK-MB >5 x URL or Troponin > 5 x URL with baseline value < URL • Spontaneous MI (> 48h following PCI, > 72h following CABG): CK-MB > URL or Troponin > URL with baseline value < URL * Pathologic Q waves may be defined according to the Global Task Force, Minnesota code, or Novacode **The assessment of CK-MB is preferred over the assessment of troponin for the diagnosis of peri-procedural MI, if possible. Baseline biomarker value requiring before study procedure and presumes a typical rise and fall.
Electrocardiographic Classification	
Q-wave MI [QMI]	Development of new pathological Q waves in 2 or more contiguous leads with or without post- procedure CK or CK-MB levels elevated above normal.
Non Q-wave MI [NQMI]	All MIs not classified as Q waves.
STENT THROMBOSIS (Per ARC Circulation 2007; 115: 2344-2351)	
Timing	
Acute*	0 - 24 hours post stent implantation
Subacute*	>24 hours. 30 days post stent implantation
Late†	30 days - 1-year post stent implantation

Very late† >1-year post stent implantation

** Acute/subacute can also be replaced by early stent thrombosis. Early stent thrombosis (0 - 30 days) - this definition is currently used in the community.*

† Including "primary" as well as "secondary" late stent thrombosis; "secondary" late stent thrombosis is a stent thrombosis after a target segment revascularization.

Categories

Definite Definite stent thrombosis is considered to have occurred by either angiographic or pathologic confirmation.

Angiographic confirmation of stent thrombosis*

The presence of a thrombus† that originates in the stent or in the segment 5 mm proximal or distal to the stent and presence of at least 1 of the following criteria within a 48-hour time window:

- Acute onset of ischemic symptoms at rest
- New ischemic ECG changes that suggest acute ischemia
- Typical rise and fall in cardiac biomarkers (refer to definition of spontaneous MI)
- Non-occlusive thrombosis
    - Thrombus Intracoronary thrombus is defined as a (spheric, ovoid, or irregular) non-calcified filling defect or lucency surrounded by contrast material (on 3 sides or within a coronary stenosis) seen in multiple projections, or persistence of contrast material within the lumen, or a visible embolization of intraluminal material downstream.
- Occlusive thrombus
    - TIMI 0 or TIMI 1 intrastent or proximal to a stent up to the most adjacent proximal side branch or main branch (if originates from the side branch).

Pathological confirmation of stent thrombosis

Evidence of recent thrombus within the stent determined at autopsy or via examination of tissue retrieved following thrombectomy.

**The incidental angiographic documentation of stent occlusion in the absence of clinical signs or symptoms is not considered a confirmed stent thrombosis (silent occlusion)*

† Intracoronary thrombus.

Probable Clinical definition of probable stent thrombosis is considered to have occurred after intracoronary stenting in the following cases:

- Any unexplained death within the first 30 days‡
- Irrespective of the time after the index procedure, any MI that is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause

‡ For studies with ST-elevation MI population, one may consider the exclusion of unexplained death within 30 days as evidence of probable stent thrombosis.

Possible Clinical definition of possible stent thrombosis is considered to have occurred with any unexplained death from 30 days after

intracoronary stenting until end of trial follow-up.

STROKE

An acute symptomatic episode of neurological dysfunction attributed to a vascular cause lasting more than 24 hours or lasting 24 hours or less with a brain imaging study or autopsy showing new infarction. an event that last < 24 hours may be adjudicated as a stroke if the following treatments were used: Pharmacologic, i.e., thrombolytic drug administration, or non-pharmacologic, i.e., neurointerventional procedure (e.g., intracranial angioplasty)

Categories

Ischemic Stroke	An acute symptomatic episode of focal cerebral, spinal, or retinal dysfunction caused by an infarction of central nervous system tissue.
Hemorrhagic Stroke	An acute symptomatic episode of focal or global cerebral or spinal dysfunction caused by a non-traumatic intraparenchymal, intraventricular, or subarachnoid hemorrhage.
Undetermined Stroke	A stroke with insufficient information to allow categorization as ischemic or hemorrhagic.

BLEEDING (Per BARC, Circulation 2011; 123: 2736-2747)

Categories

Type 0	No bleeding
Type 1	Bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional
Type 2	Any overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for type 3, 4, or 5 but does meet at least one of the following criteria: (1) requiring nonsurgical, medical intervention by a healthcare professional, (2) leading to hospitalization or increased level of care, or (3) prompting evaluation
Type 3	
Type 3a	• Overt bleeding plus hemoglobin drop of 3 to < 5 g/dL* (provided hemoglobin drop is related to bleed) • Any transfusion with overt bleeding
Type 3b	• Overt bleeding plus hemoglobin drop ≥ 5 g/dL*(provided hemoglobin drop is related to bleed) • Cardiac tamponade • Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid) • Bleeding requiring intravenous vasoactive agents
Type 3c	• Intracranial hemorrhage (does not include microbleeds or hemorrhagic transformation, does include intraspinal) • Subcategories confirmed by autopsy or imaging or lumbar puncture • Intraocular bleed compromising vision
Type 4: CABG-related bleeding	• Perioperative intracranial bleeding within 48 h • Reoperation after closure of sternotomy for the purpose of controlling bleeding • Transfusion of ≥ 5 U whole blood or packed red blood cells within a 48-h period†

	• Chest tube output ≥ 2L within a 24-h period
Type 5: fatal bleeding	
Type 5a	Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
Type 5b	Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation
CABG related	CABG indicates coronary artery bypass graft. Platelet transfusions should be recorded and reported but are not included in these definitions until further information is obtained about the relationship to outcomes. If a CABG-related bleed is not adjudicated as at least a type 3 severity event, it will be classified as not a bleeding event. If a bleeding event occurs with a clear temporal relationship to CABG (i.e., within a 48-h time frame) but does not meet type 4 severity criteria, it will be classified as not a bleeding event. * Corrected for transfusion (1 U packed red blood cells or 1 U whole blood=1 g/dL hemoglobin). † Cell saver products are not counted.
REVASCULARIZATION (Per ARC Circulation 2007; 115: 2344-2351)	
Target Lesion Revascularization (TLR)	TLR is defined as any repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel performed for restenosis or other complication of the target lesion. All TLR should be classified prospectively as clinically indicated [CI] or not clinically indicated by the investigator prior to repeat angiography. The target lesion is defined as the treated segment from 5 mm proximal to the stent and to 5 mm distal to the stent.
Target Vessel Revascularization (TVR)	TVR is defined as any repeat percutaneous intervention or surgical bypass of any segment of the target vessel. The target vessel is defined as the entire major coronary vessel proximal and distal to the target lesion which includes upstream and downstream branches and the target lesion itself
Clinically Indicated [CI] Revascularization (TLR/TVR)	A revascularization is considered clinically indicated if angiography at follow-up shows a percent diameter stenosis ≥ 50% and if one of the following occurs: • A positive history of recurrent angina pectoris, presumably related to the target vessel; • Objective signs of ischemia at rest (ECG changes) or during exercise test (or equivalent), presumably related to the target vessel; • Abnormal results of any invasive functional diagnostic test (e.g., Doppler flow velocity reserve, fractional flow reserve); • A TLR/TVR with a diameter stenosis ≥70% in the absence of the above-mentioned ischemic signs or symptoms.

TARGET LESION FAILURE (TLF)

TLF is defined as a composite of all cardiac death, myocardial infarction attributed to target vessel or clinically-indicated TLR.

Supplemental Table 3. Baseline characteristics and therapy at discharge in patients with and without oral anticoagulation.

	OAC N=1,462	No OAC N=1,902	P-Value
Age, years	73.6±9.0	76.9±8.7	<.001
Female sex	425 (29.1%)	729 (38.3%)	<.001
Race			
White	1178 (91.6%)	1368 (82.6%)	<.001
Hispanic or Latino ethnicity	65 (4.6%)	129 (6.9%)	0.005
Black or African American	46 (3.6%)	107 (6.5%)	<.001
Asian	41 (3.2%)	130 (7.8%)	<.001
American Indian or Alaskan Native	6 (0.5%)	7 (0.4%)	0.858
Native Hawaiian or Pacific Islander	2 (0.2%)	3 (0.2%)	0.868
Hypertension	1300 (88.9%)	1650 (86.8%)	0.058
Dyslipidemia	1115 (76.3%)	1446 (76.0%)	0.871
Diabetes mellitus	557 (38.2%)	742 (39.2%)	0.548
Chronic kidney disease	474 (33.2%)	958 (51.6%)	<.001
Prior PCI	426 (29.1%)	571 (30.0%)	0.578
Prior CABG	180 (12.3%)	178 (9.4%)	0.006
Prior MI	246 (17.1%)	298 (15.8%)	0.344
Chronic coronary syndrome	966 (66.1%)	1234 (64.9%)	0.470
Acute coronary syndrome	496 (33.9%)	668 (35.1%)	0.470
NSTEMI	156 (10.7%)	230 (12.1%)	0.200
High bleeding risk criteria			
Age ≥75 years	745 (51.0%)	1496 (78.7%)	<.001
Oral anticoagulant therapy at enrolment	1422 (97.3%)	0 (0.0%)	N.A.
History of stroke	161 (11.0%)	207 (10.9%)	0.910
Renal insufficiency	54 (3.7%)	219 (11.5%)	<.001
Anemia	158 (10.8%)	356 (18.7%)	<.001
Thrombocytopenia	23 (1.6%)	46 (2.5%)	0.091
History of major bleeding	28 (1.9%)	75 (3.9%)	<.001
Number of HBR criteria	1.8±0.8	1.3±0.6	<.001
Bleeding risk scores			

PARIS	6.4±2.4	5.8±2.2	<.001
PRECISE-DAPT	23.3±11.6	29.5±10.7	<.001

CABG: coronary artery bypass grafting, DAPT: dual antiplatelet therapy, HBR: high bleeding risk, MI: myocardial infarction, NSTEMI: non-ST segment elevation myocardial infarction, OAC: oral anticoagulation, PCI: percutaneous coronary intervention

Supplemental Table 4. Procedural characteristics and therapy at discharge in patients with and without oral anticoagulation.

	OAC N=1,462	No OAC N=1,902	P-Value
Procedural characteristics			
Radial access	902 (61.7%)	1112 (58.5%)	0.058
Multivessel disease	662 (45.3%)	829 (43.6%)	0.327
Number of lesions treated [IQR]	1.0 [1.0-1.0]	1.0 [1.0-1.0]	0.183
Number of vessels treated [IQR]	1.0 [1.0-1.0]	1.0 [1.0-1.0]	0.998
B2/C lesion	538 (36.8%)	647 (34.0%)	0.094
Bifurcation	138 (9.4%)	176 (9.3%)	0.854
Number of stents per subject [IQR]	1.0 [1.0-1.0]	1.0 [1.0-1.0]	0.481
Total stent length, mm	26.0±13.7	26.4±14.4	0.453
Pre-procedure RVD, mm	3.0±0.5	3.0±0.5	0.164
Pre-procedure % DS	83.4±10.0	83.3±9.8	0.931
Antiplatelet therapy at discharge			
Aspirin	1034 (70.7%)	1899 (99.8%)	<.001
Clopidogrel	1298 (88.8%)	1518 (79.8%)	<.001
Prasugrel	27 (1.8%)	33 (1.7%)	0.808
Ticagrelor	139 (9.5%)	352 (18.5%)	<.001

DS: diameter stenosis, OAC: oral anticoagulation, RVD: reference vessel diameter

Supplemental Table 5. Outcomes from 1 to 12 months after PCI in patients with or without oral anticoagulation.

Outcomes	OAC N=1,462	No OAC N=1,902	Hazard ratio (95% CI)	p-value
All-cause death, or MI	109 (8.2%)	139 (7.8%)	1.03 (0.80 - 1.32)	0.846
All-cause death	68 (5.2%)	84 (4.7%)	1.06 (0.77 - 1.46)	0.722
Cardiovascular death	36 (2.9%)	45 (2.5%)	1.05 (0.68 - 1.62)	0.836
MI	47 (3.5%)	66 (3.8%)	0.93 (0.64 - 1.35)	0.707
Definite or probable ST	5 (0.4%)	5 (0.3%)	1.32 (0.38 - 4.55)	0.664
Stroke	17 (1.4%)	27 (1.5%)	0.82 (0.45 - 1.51)	0.529
Ischemic stroke	14 (1.2%)	25 (1.4%)	0.73 (0.38 - 1.41)	0.350
Target lesion failure	72 (5.5%)	98 (5.5%)	0.96 (0.71 - 1.30)	0.804
Target lesion revascularization	18 (1.4%)	26 (1.5%)	0.91 (0.50 - 1.66)	0.752
Target vessel revascularization	26 (2.1%)	49 (2.8%)	0.69 (0.43 - 1.12)	0.131
BARC 2-5 bleeding	165 (12.5%)	122 (6.8%)	1.81 (1.43 - 2.29)	<.001
BARC 3-5 bleeding	82 (6.2%)	53 (3.0%)	2.04 (1.45 - 2.89)	<.001

BARC: bleeding academic research consortium, MI: myocardial infarction, OAC: oral anticoagulation, ST: stent thrombosis,