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ORIGINAL ARTICLE
Valvular Heart Disease

One-Month Dual Antiplatelet Therapy in High Bleeding Risk Asian Patients Undergoing Percutaneous Coronary Intervention

— Onyx ONE Clear 2-Year Results —

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Background: One-month dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients undergoing percutaneous coronary intervention (PCI) with the Resolute Onyx™ zotarolimus-eluting stents (ZES) is safe and effective. Asian patients have a unique ischemia/bleeding risk profile. Here, we compare the outcomes between Asian and non-Asian patients after PCI and 1-month DAPT.

Methods and Results: Onyx ONE Clear was a prospective, multicenter study enrolling HBR patients undergoing PCI with the Resolute Onyx ZES (ClinicalTrials.gov identifier NCT03647475). Event-free patients after 1-month DAPT transitioned to single antiplatelet therapy. Clinical outcomes between 1 month and 2 years were compared between patients from Asian and non-Asian countries after 1:1 propensity score matching accounting for baseline differences. Patients from Asian countries represented 18% (n=273) of the study group (n=1,507). Non-Asian patients had greater clinical complexity; however, these differences were minimal after matching. There were no significant differences in ischemic outcomes between matched cohorts from 1 month to 2 years, including the primary composite endpoint of cardiac death or myocardial infarction (12% vs. 12%; P>0.99). However, there were significantly fewer Bleeding Academic Research Consortium types 3–5 bleeding events in the Asian vs. non-Asian cohort (4% vs. 9%; P=0.007), despite similar bleeding risk profiles after matching.

Conclusions: After propensity score matching, HBR patients from Asian countries undergoing PCI treated with 1-month DAPT had similar ischemic outcomes but fewer bleeding events between 1 month and 2 years compared with patients from non-Asian countries.

Key Words: Asian patients; Drug-eluting stents; High bleeding risk; Percutaneous coronary intervention

A persistent challenge after percutaneous coronary intervention (PCI) using drug-eluting stents (DES) in high bleeding risk (HBR) patients is to carefully balance ischemic and bleeding risks with the appropriate type and duration of antiplatelet therapy. Multiple recent trials assessing 1-month dual antiplatelet therapy (DAPT) following PCI have found that an abbreviated DAPT strategy maintains a low incidence of ischemic events in HBR patients while reducing the incidence of bleeding.[1–3] Onyx ONE Clear, a follow-up, pre-specified analysis of the Onyx ONE US/Japan study and the Onyx ONE randomized control trial, specifically examined outcomes beginning 1 month after PCI in HBR patients on abbreviated DAPT.[4] After implantation of the Resolute Onyx™ zotarolimus-

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eluting stent (ZES), patients who were 'clear' of ischemic events in the first 30 days transitioned from DAPT to single antiplatelet therapy (SAPT) with or without an oral anticoagulant (OAC). The Onyx ONE Clear study met the prespecified performance goal, underscoring the safety and efficacy of an abbreviated DAPT strategy following ZES implantation during PCI.

The safety and efficacy of 1-month DAPT after ZES implantation, in particular HBR subgroups in Onyx ONE Clear, such as patients with diabetes, small coronary vessels, or patients with complex coronary lesions, has recently been demonstrated.[5–7] Asian patients have distinct ischemic and bleeding profiles compared with non-Asian patients, characterized by a reduced ischemic risk but an increased bleeding risk after PCI.[8–11] Bleeding events following stent implantation can be fatal, may occur post-discharge, and have an increased association with mortality beyond 30 days after the procedure.[12,13] Thus, to appropriately balance ischemic and bleeding risks in Asian patients, a reduced DAPT strategy may be warranted. In this post-hoc subgroup analysis, we assess safety outcomes from 1 month to 2 years in Asian vs. non-Asian patients in the Onyx ONE Clear study.

Methods

Design

The Onyx ONE Clear was a prospective, multicenter, single arm, international study including HBR patients enrolled in either the Onyx ONE randomized control trial or the Onyx ONE US/Japan study and who received the Resolute Onyx ZES (ClinicalTrials.gov identifier NCT03647475).[4] To be eligible, patients were required to adhere to 1-month DAPT and be 'clear' of adverse events through the first 30 days after PCI that would otherwise prohibit the discontinuation of DAPT at 1 month. Patients were enrolled if they met a least one of the HBR criteria (**Supplementary Table 1**). The Onyx ONE Clear study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee or institutional review board at each enrollment center.

Procedures

As previously described, patients underwent PCI with implantation of the Resolute Onyx ZES.[4] Following PCI, patients were mandated to adhere to 1-month DAPT, 75–100 mg aspirin and the standard daily dose of $P2Y_{12}$ inhibitor (P2Y12i), followed by SAPT with or without OAC for the duration of the study. Patients already at the time of the procedure were permitted to continue OAC use along with SAPT for the duration of the study. The study only included those who were free of adverse events in the first month that would prevent discontinuation of DAPT, including myocardial infarction (MI; excluding periprocedural MI), repeat PCI or coronary artery bypass graft (CABG), stroke, definite/probable stent thrombosis (ST), or death. Patients receiving a stent other than the Onyx ZES were excluded from the study analysis. Clinical outcomes were assessed from 1-month post-procedure to 2 years.

Endpoints

The primary endpoint of the Onyx ONE Clear study was the composite incidence of cardiac death (CD) and MI from 1 month post-procedure to 1 year. Secondary endpoints were all-cause death, CD, MI, clinically driven target lesion revascularization (TLR), target lesion failure (TLF; composite of CD, target vessel MI, TLR), target vessel failure (TVF; CD, target vessel MI, or clinically driven repeat target vessel revascularization [TVR]), definite/probable ST, stroke, and bleeding. MI was defined according to the Third Universal Definition.[14] Definite/probable ST was defined according to the Academic Research Consortium guidelines.[15] Bleeding events were defined according to the Bleeding Academic Research Consortium (BARC) guidelines.[16] Lesion success was defined as attainment of <30% residual stenosis and Thrombolysis in Myocardial Infarction (TIMI) 3 flow using any percutaneous method.[17] Device success was based on lesion success with the assigned study device. Procedural success was based on lesion success and the absence of in-hospital major adverse cardiac events.

Statistical Analysis

Categorial data are reported as percentages (counts) and were compared between groups using Fisher's exact test. Continuous data are reported as means ± standard deviations and were compared between groups using the two sample t-test. The Kaplan-Meier method was used to generate time-to-first event curves. Propensity score 1:1 matching between groups was performed using a multivariable logistic regression model. The covariates included were the 13 HBR criteria (OAC use at discharge, age ≥75 years, hemoglobin <11 g/dL or transfusion within 4 weeks before procedure, prior intracerebral bleed, stroke in the past 12 months, hospital admission for major bleeding in the past 12 months, non-skin cancer diagnosed or treated within 3 years, nonsteroidal anti-inflammatory drug [NSAID; other than aspirin] or steroids ≥30 days after PCI, planned surgery in the next 12 months requiring interruption of DAPT, creatine clearance >40 mL/min, thrombocytopenia [platelet $<10^5/mm^3$], severe chronic liver disease, and expected non-compliance to prolonged DAPT), as well as sex, body mass index (BMI), previous PCI or CABG, peripheral vascular disease, maximum lesion length, multivessel coronary artery disease, potent P2Y12i use at discharge, and intravascular imaging by intravascular ultrasound (IVUS) or optical coherence tomography (OCT). Patients were matched based on the closest possible value of propensity score (nearest neighbor matching). A logistic regression was performed to compare procedural success based on intracoronary imaging of Asian and non-Asian patients, with a P value <0.05 indicating a statistically significant interaction for procedural success between intracoronary imaging vs. angiography alone and region (Asian vs. non-Asian). Statistical analyses were performed using SAS (version 9.4; SAS Institute, Cary, NC, USA).

Results

Comparison of Asian and Non-Asian Patient Demographics and Procedural Characteristics

Among 1,507 patients in Onyx ONE Clear to 2 years, 273 (18%) patients were from Asian countries (Hong Kong, Japan, Republic of Korea, Malaysia, Singapore, Thailand), while 1,234 (82%) patients were from countries outside of Asia. **Supplementary Table 1** shows the comparison of demographics between Asian and non-Asian patients. Notably, Asian patients were younger, less likely to be female, had a lower BMI, had a lower incidence of hyper-

Table 1. Baseline Characteristics of Propensity Score Matched Asian and Non-Asian Patients

	Asian patients (n=261)	Non-Asian patients (n=261)	P value
Age (years)	71.3±10.9	72.3±10.6	0.30
Female	36.4 (95)	39.5 (103)	0.53
Body mass index (kg/m^2)	24.8±4.0	25.3±4.6	0.13
Hypertension	73.9 (193)	81.2 (212)	0.059
Hyperlipidemia	49.0 (128)	71.6 (187)	<0.001
Previous MI	23.0 (60)	21.5 (56)	0.75
Previous PCI	13.4 (35)	14.9 (39)	0.71
Previous CABG	1.5 (4)	1.9 (5)	>0.99
Atrial fibrillation	19.2 (50)	24.1 (63)	0.20
Chronic obstructive pulmonary disease	3.4 (9)	12.3 (32)	<0.001
Diabetes	43.7 (114)	31.0 (81)	<0.001
Stroke/TIA	8.0 (21)	13.0 (34)	0.086
Peripheral vascular disease	2.7 (7)	3.8 (10)	0.62
Multivessel disease (≥2)	55.2 (144)	53.3 (139)	0.73
Left ventricular ejection fraction ≤35%	11.6 (24)	11.7 (21)	>0.99
Clinical presentation			
Silent ischemia	10.6 (26)	8.9 (22)	0.55
Myocardial infarction	27.2 (67)	31.9 (79)	0.28
NSTEMI	21.5 (53)	27.0 (67)	0.17
STEMI	5.7 (14)	4.8 (12)	0.69

Data are presented as % (n) or mean±SD. Covariates for propensity score matching include 13 high bleeding risk criteria plus sex, body mass index, previous percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), peripheral vascular disease, maximum lesion length, multivessel coronary artery disease, potent P2Y12i use at discharge, and intracoronary imaging. MI, myocardial infarction; NSTEMI, non-ST-elevated myocardial infarction; STEMI, ST-elevated myocardial infarction; TIA, transient ischemic attack.

Table 2. HBR Criteria Among Propensity Score Matched Asian and Non-Asian Patients

HBR inclusion criteria	Asian patients (n=261)	Non-Asian patients (n=261)	P value
Mean number of HBR criteria	1.5±0.7	1.5±0.8	0.77
Age ≥75 years	47.9 (125)	51.7 (135)	0.43
Oral anticoagulation to continue after PCI	24.5 (64)	27.6 (72)	0.49
Hgb <11 g/dL (or transfusion within 4 weeks before procedure)	22.2 (58)	21.1 (55)	0.83
Creatinine clearance <40 mL/min	21.5 (56)	18.4 (48)	0.44
Non-skin cancer diagnosed or treated within 3 years	10.0 (26)	9.6 (25)	>0.99
Planned surgery in next 12 months requiring interruption of DAPT	6.1 (16)	6.5 (17)	>0.99
Expected non-compliance to prolonged DAPT	6.1 (16)	5.7 (15)	>0.99
Hospital admission for major bleeding in prior 12 months	3.8 (10)	4.6 (12)	0.83
Stroke in previous 12 months	2.3 (6)	2.3 (6)	>0.99
NSAID (other than aspirin) or steroids for ≥30 days after PCI	1.1 (3)	1.1 (3)	>0.99
Prior intracerebral bleed	2.7 (7)	1.5 (4)	0.54
Thrombocytopenia (PLT <100,000/mm^3)	1.9 (5)	1.9 (5)	>0.99
Severe chronic liver disease	0.4 (1)	0.4 (1)	>0.99

Data are presented as % (n) or mean±SD. DAPT, dual antiplatelet therapy; HBR, high bleeding risk; Hgb, hemoglobin; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention.

tension, hyperlipidemia and atrial fibrillation, and were less likely to have had previous PCI, CABG and stroke. In addition to these patient demographic differences, the HBR profiles were noticeably different between groups (**Supplementary Table 2**), including fewer Asian patients with planned OAC use to continue after PCI and age ≥75 years.

To account for differences in patient demographics (**Supplementary Table 1**) and HBR differences (**Supplementary Table 2**), Asian and non-Asian patients were matched 1:1 (261 patients from each group) based on propensity scores using 21 different covariates, including 13 HBR covariates (see **Methods**). Although matched patient groups had fewer differences in demographics, Asian patients were significantly less likely to have hyperlipidemia and chronic obstructive pulmonary disease, but more likely to have diabetes (**Table 1**). Between matched cohorts, Asian and non-Asian patients had a similar mean number of HBR

Table 3. Procedural and Lesion Characteristics Among Propensity Score Matched Asian and Non-Asian Patients

	Asian patients (n=261; 334 lesions)	Non-Asian patients (n=261; 378 lesions)	P value
Radial access	30.9 (84)	27.5 (76)	0.40
Staged procedure performed	4.2 (11)	5.7 (15)	0.55
Target vessel			
LAD	70.1 (183)	55.9 (146)	0.001
LCX	17.6 (46)	33.3 (87)	<0.001
RCA	34.5 (90)	38.7 (101)	0.36
Left main	0.4 (1)	0.4 (1)	>0.99
Bypass graft	0.4 (1)	0.0 (0)	>0.99
In-stent restenosis	2.5 (9)	1.6 (7)	0.45
Bifurcation	10.8 (39)	12.0 (51)	0.65
Moderate or severe calcification	61.9 (205)	49.2 (184)	<0.001
Chronic total occlusion	4.7 (17)	0.7 (3)	<0.001
B2/C lesion class	90.4 (302)	81.2 (307)	<0.001
Reference vessel diameter (mm)	2.87±0.43	2.78±0.48	0.010
Percent stenosis (%)	71.0±14.1	67.7±12.6	0.001
Lesion length (mm)	26.71±13.57	22.60±14.34	<0.001
No. treated lesions per patient	1.3±0.5	1.4±0.7	0.003
No. stents per patient	1.7±1.0	1.9±1.3	0.040
Total stent length per lesion (mm)	33.5±16.7	26.2±13.5	<0.001
Total stent length per patient (mm)	46.5±28.9	42.6±30.6	0.141
Lesion success	92.9 (302)	95.5 (358)	0.19
Device success	92.3 (300)	93.9 (352)	0.46
Procedure success	85.4 (216)	88.0 (227)	0.44
Post-procedure hospital length of stay (days)	2.3±2.8	2.1±4.1	0.41

Data presented as % (n) or mean ± SD. Includes procedural data for index and staged procedures. LAD, left anterior descending; LCX, left circumflex; RCA, right coronary artery; RVD, reference vessel diameter.

inclusion criteria (1.5±0.7 vs 1.5±0.8; P=0.77), and differences between individual HBR criterion were similar between the two groups (**Table 2**).

Procedural characteristics on matched cohorts are provided in **Table 3**. There were fewer lesions treated with correspondingly fewer stents implanted among Asian patients compared with non-Asian patients. Asian patients were more likely to have the left anterior descending vessel treated and less likely to have the left circumflex vessel treated than non-Asian patients. In matched cohorts, Asian patients were more likely to have longer lesions, chronic total occlusion, moderate to severe calcification, and modified American College of Cardiology/American Heart Association (ACC/AHA) Lesion Class B2/C compared with non-Asian patients. The preprocedure reference vessel diameter and percent stenosis were also significantly greater in Asian patients than in non-Asian patients. Asian patients were more likely to have undergone intracoronary imaging by IVUS or OCT than non-Asian patients (39.2% vs. 13.3%; P<0.001). However, among matched cohorts, 38.3% of Asian patients and 29.5% of non-Asian patients underwent intravascular imaging during PCI (**Table 3**; P=0.042). Among Asian patients who underwent intracoronary imaging during PCI (n=102), the procedural success rate was 85%. Among non-Asian patients who underwent intracoronary imaging during PCI (n=164), the procedural success rate was 92%. By comparison, among patients who underwent angiography alone during PCI, the procedural success rate in Asian patients (n=163) was 83%, whereas in non-Asian patients (n=1,041) it was 89%. The interaction between intracoronary imaging and procedural success based on region was not statistically significant (P=0.64).

Antiplatelet therapy and oral anticoagulation usage between matched patient cohorts from the index procedure to 2 years are presented in **Figure 1**. Onyx ONE Clear protocol mandated patients transition from DAPT at 1 month after procedure to SAPT. After 1 month, the majority of patients transitioned to SAPT only; however, compared with Asian patients, non-Asian patients were more likely to transition to SAPT plus an OAC. Furthermore, 1 month after the procedure, a greater proportion of Asian patients were prescribed aspirin as SAPT, whereas a greater proportion of non-Asian patients were prescribed P2Y12i (**Supplementary Figure 1**). However, beyond 2 months after the procedure, trends between matched patient cohorts diverged. Among the Asian cohort, the proportion of patients prescribed only aspirin or P2Y12i was maintained to 2 years, with a small increase in transition to DAPT, while at 1 year after the procedure, a small proportion transitioned to OAC only. In comparison, among non-Asian patients, while aspirin only use was more or less maintained to 2 years, the proportion of patients prescribed P2Y12i steadily decreased 2 months after the procedure. Some non-Asian patients similarly transitioned to OAC only use at 1 year. However, the most notable difference in antiplatelet therapy was DAPT usage. At discharge, including OAC use, 99% of Asian patients were on DAPT

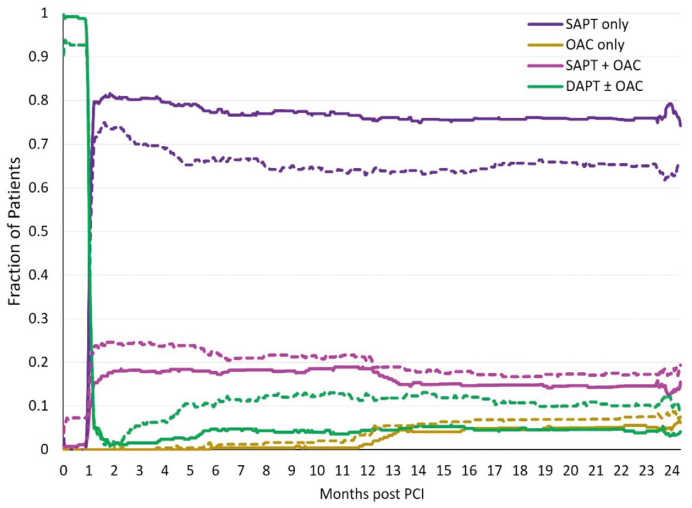

Figure 1. Antiplatelet therapy in propensity score matched Asian and non-Asian patients. Solid lines, Asian patients (n=261); Dashed lines, non-Asian patients (n=261). DAPT, dual antiplatelet therapy; OAC, oral anticoagulant; PCI, percutaneous coronary intervention; SAPT, single platelet therapy (aspirin or $P2Y_{12}$ inhibitors).

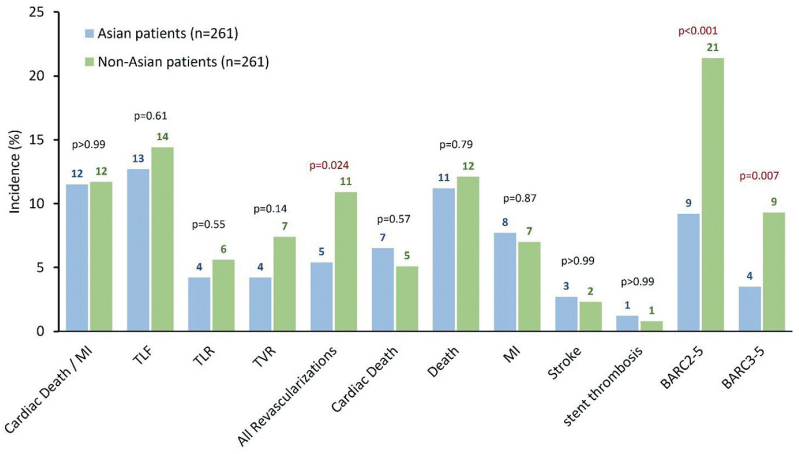

Figure 2. Clinical outcomes from 1 month to 24 months after percutaneous coronary intervention in propensity score matched Asian and non-Asian patients. BARC, Bleeding Academic Research Consortium; MI, myocardial infarction; TLF, target lesion failure; TLR, target lesion revascularization; TVR, target vessel revascularization.

compared with 94% of non-Asian patients (P=0.001). This trend persisted at 1 month after the procedure (P=0.001). A sizeable proportion of non-Asian patients transitioned back onto DAPT for the duration of the follow-up to 2 years. After the protocol-mandated cessation of DAPT at 1 month, few Asian and non-Asian patients were on DAPT (3% vs. 2%; P=0.58). However, even between propensity matched cohorts, significantly fewer Asian patients were on DAPT compared with non-Asian patients at 6 months (4% vs. 10%; P=0.016), 1 year (4% vs. 13%; P=0.002), and 2 years (4% vs. 9%; P=0.034). Potential reasons for the discrepancy in DAPT use to 2 years between cohorts, and the consequences of higher DAPT use in non-Asian patients, is explored further in the Discussion.

Clinical Outcomes to 2 Years

At 2 years, the primary safety endpoint of the composite incidence of CD and MI were comparable between propensity score matched Asian and non-Asian patients (**Figure 2**). Kaplan-Meier rate estimate of CD and MI between 1 month and 2 years was similar for Asian and non-Asian patients (**Figure 3**). Similarly, there were no significant differences in the incidence and Kaplan-Meier rate estimates between Asian and non-Asian patients for CD, TLF, clinically driven TLR, and non-clinically driven TLR (**Figure 3**).

Notably, the incidence of all revascularizations was significantly lower among Asian patients despite TLF and clinically driven TVR being not significantly different between groups (**Figure 2**). Interestingly, the incidence of bleeding (BARC types 2–5 and BARC types 3–5) was significantly lower among Asian patients compared with non-Asian patients (**Figure 2**), as well as by Kaplan-Meier rate estimate (**Figure 3**).

Discussion

Asian patients represented 18% of the total Onyx ONE Clear cohort of HBR patients. Asian patients had several baseline characteristic differences compared with non-Asian patients, including several important differences in HBR. Furthermore, one notable procedural difference between

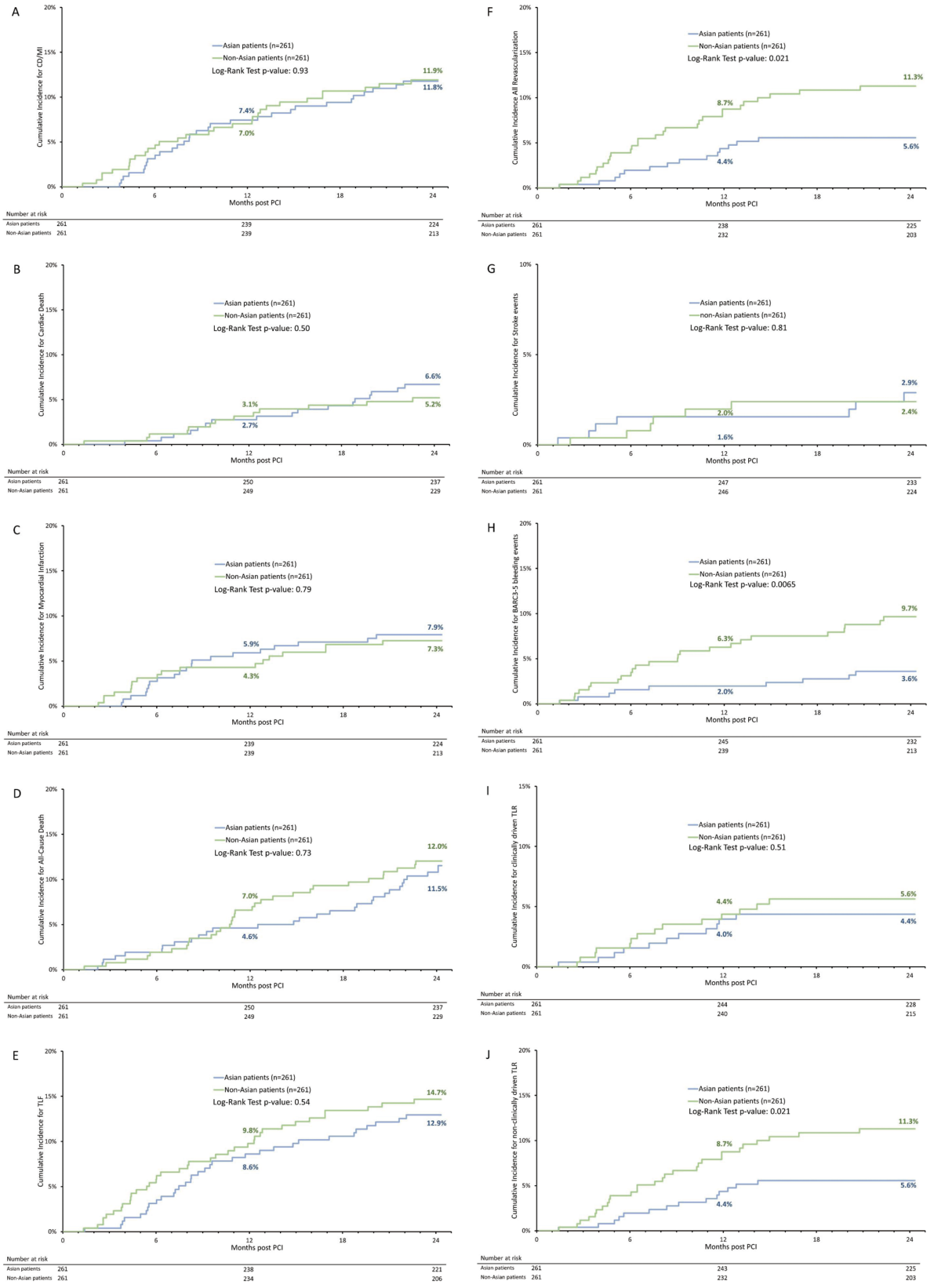

Figure 3. Kaplan-Meier rate estimates for (**A**) CD/MI, (**B**) CD, (**C**) MI, (**D**) all-cause mortality, (**E**) TLF, (**F**) all revascularizations, (**G**) stroke, (**H**) BARC types 3–5 bleeding, (**I**) TLR, and (**J**) non-TLR events in propensity score matched Asian and non-Asian patients. BARC, Bleeding Academic Research Consortium; CD, cardiac death; MI, myocardial infarction; PCI, percutaneous coronary intervention; TLF, target lesion failure; TLR, target lesion revascularization.

Asian and non-Asian cohorts was the higher use of IVUS or OCT during PCI in Asian patients vs. angiography-guided PCI alone. Thus, to compare outcomes from 1 month to 2 years between Asian and non-Asian cohorts, patients were matched 1 : 1 using propensity scores with 21 different covariates including the 13 HBR criteria and intracoronary imaging mentioned in the Methods. The incidence of ischemic events was generally low from 1 month to 2 years in both Asian and non-Asian patients. DAPT and OAC usage were lower among Asian patients, as was the incidence of coronary revascularization. Interestingly, and perhaps paradoxically, the incidence of bleeding events, including BARC types 3–5 events, was significantly lower in Asian patients compared with non-Asian patients.

Asian patients are commonly considered to be at higher risk for bleeding after PCI,[8–11] and subsequent studies have confirmed this finding across East Asian geographies.[18–20] High platelet reactivity has been postulated to be associated with cardiovascular events in Asian patients undergoing PCI.[21] Reducing the dose of antiplatelet therapy has been found to reduce the risk of clinically serious bleeding events without compromising ischemic safety in Asian patients.[22] However, an alternative strategy to appropriately balance ischemic and bleeding risks in HBR patients, including Asian patients, is to shorten the duration of DAPT after PCI before transitioning to SAPT.[4]

In the Onyx ONE Clear study, Asian patients had a significantly lower incidence of clinically serious bleeding events compared with non-Asian patients, even after propensity score matching. Moreover, Asian and non-Asian cohorts were similar in HBR criteria after propensity score matching. We hypothesize multiple factors contributed to this phenomena. First, the significantly higher overall revascularization rate in non-Asian patients and the higher prescription rate of DAPT likely underlies the higher rates of bleeding in that cohort. Additionally, the cumulative incidence of bleeding complications in HBR patients with or without any revascularization during the follow-up period also showed significantly higher bleeding events in those who received revascularization (**Supplementary Figure 2**). Revascularization correlates with the significantly greater use of DAPT in non-Asian patients, possibly increasing the incidence of BARC types 3–5 bleeding events. What explains the lower revascularization rate among Asian patients? One hypothesis is that Asians may have received more aggressive intervention at baseline, which led to lower rates of intervention during follow-up. From the results of the present study, we could see that the total stent length was longer at the index procedure in Asians. Also, during follow-up, clinically driven TLR was similar between Asian patients and non-Asian patients, while non-clinically driven TLR was the main factor for the overall higher revascularization rate in non-Asian patients. Second, Asian patients were prescribed with more 'aspirin' as SAPT, whereas non-Asian patients had more $P2Y_{12}$ receptor antagonists (including potent $P2Y_{12}$ inhibitors) as SAPT. This pattern may be associated with the current knowledge of the impact of CYP2C19 loss-of-function in East Asian patients.[23] Third, the dose of antithrombotic medications could have been different between Asian and non-Asian populations, while Asian patients tend to use lower doses compared with non-Asian patients. This opens the possibility that the higher bleeding events in the matched non-Asian patients may be associated with the higher dose of antithrombotic medications in this population.

Study Limitations

Onyx ONE Clear was a single arm study in which all patients received 1-month DAPT. Thus, different DAPT durations were not assessed in this analysis. Patients only received the Resolute Onyx ZES, and results from this analysis may not be applicable to other drug-eluting stents. This post-hoc analysis was not powered to detect low frequency events, such as ST. Moreover, the present study was not designed to compare outcomes between Asian and non-Asian patients. As such, baseline and procedural characteristics were significantly different between unmatched Asian and non-Asian populations. Propensity score matching mitigates this limitation, in part; however, some characteristic differences remain between matched cohorts. Last, this post-hoc analysis compared results between patients in Asian vs. non-Asian countries; however, patient information on ethnicity and race could not be collected at certain sites. Thus, a few patients of Asian ethnicity may have been included in the non-Asian cohort and vice versa.

Conclusions

In Onyx ONE Clear, both Asian and non-Asian patients had relatively low incidences of ischemic and bleeding events, although Asian patients had a significantly lower incidence of bleeding events compared with non-Asian patients, possibly explained by a lower incidence of revascularization. Overall, however, these data support the safety and efficacy of the Resolute Onyx ZES followed by 1-month DAPT in HBR patients, including Asian HBR patients.

Clinical Perspectives

The ischemic and bleeding risks in patients after PCI with DES must be appropriately balanced. Asian patients present unique challenges, with greater bleeding risks but lower ischemic risks compared with non-Asian patients. Here, we evaluated outcomes between Asian and non-Asian patients from 1 month to 2 years using an abbreviated 1-month DAPT strategy after PCI. Both Asian and non-Asian patients were found to have low ischemic and bleeding risks in Onyx ONE Clear. This suggests abbreviated DAPT is an appropriate strategy post-PCI in Asian patients, who are more susceptible to bleeding events. Asian patients were found to have even lower bleeding risks than non-Asian patients in Onyx ONE Clear; however, this likely stems from differences in residual baseline and procedural characteristics and revascularization rates between propensity score matched patient groups.

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IRB Information

The institutional review board of Seoul National University Hospital approved this study (Reference no. 1802-076-923).

Data Availability

Data from the Onyx ONE Clear study will not be shared.

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Supplementary Files

Please find supplementary file(s);
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