

# Two-Year Outcomes After PCI in High Bleeding Risk Asian Patients: The Onyx ONE Clear Study

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# Disclosure

Within the past 12 months, I, [Jeehoon Kang](#) or my spouse/partner, have had a financial interest/arrangement or affiliation with the organization(s) listed below.

- Nothing to disclose

# Introduction

- Along with the improvement of PCI techniques and devices, more vulnerable patients are receiving PCI.
- **High Bleeding Risk (HBR)** patients represent a high-risk population, who are gaining attention.
- The Onyx ONE RCT was the first trial comparing DES versus DCS in HBR patients.
- Nowadays, we no longer use DCS in those who are at need of a shorter DAPT duration.
- Asians are known to have a **unique ischemia/bleeding risk profile** compared to Westerns.
- Whether there may be a difference in safety and efficacy of short DAPT between **Ethnicity** should be evaluated.

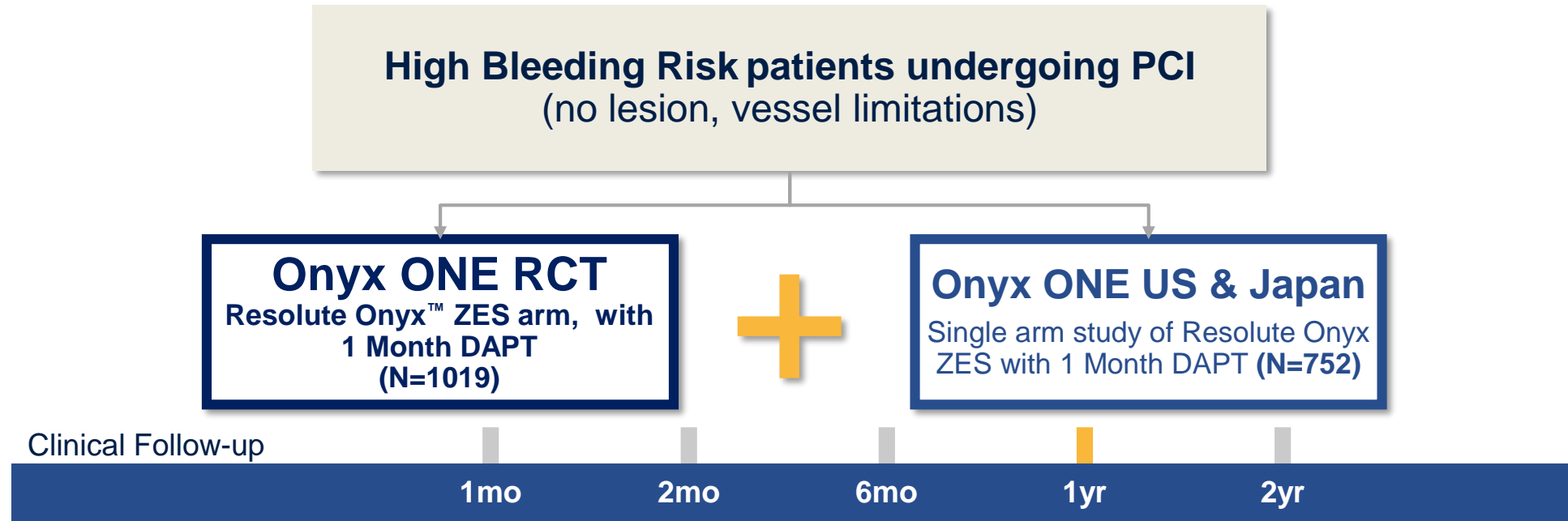


# Study Purpose

- To evaluate the efficacy and safety of short DAPT between Asians and non-Asians with HBR.
- The efficacy and safety events were defined as a composite of Cardiac death / MI and BARC3, 5 bleeding events, respectively.
- The Onyx ONE clear study was used for analysis

# Onyx ONE Clear Study Design

Prospective, Multicenter, Single-arm Study



**Primary efficacy endpoint:** Cardiac death/MI assessed in **“1-month clear”\*** patients from 1-24 Mo

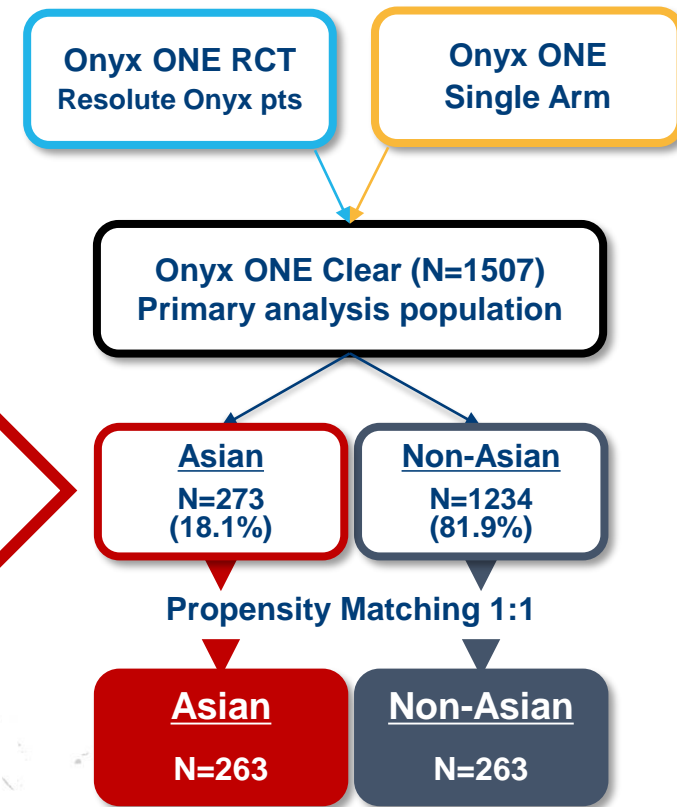
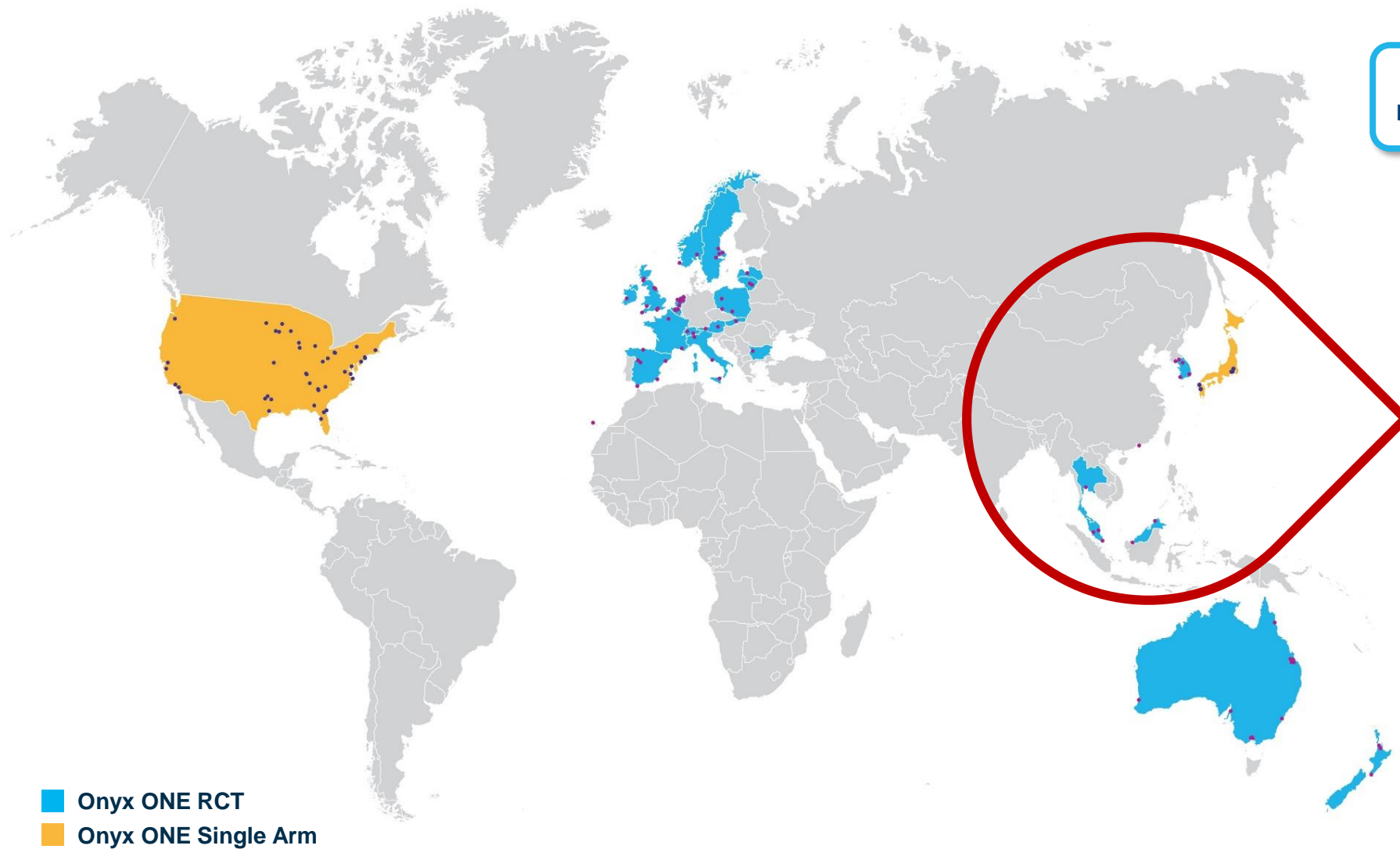
**Primary safety endpoint:** BARC 3-5 bleeding assessed in **“1-month clear”\*** patients from 1-24 Mo

**Methods current analysis:** Compared outcomes between patients from Asian countries and non-Asian countries using **propensity score matching** to adjust for baseline differences\*\*

\* “1-month clear” defined as patients who were adherent to DAPT within 1<sup>st</sup> month after PCI and free of events that would preclude 1-month DAPT cessation

\*\* Optimal fixed ratio matching 1:1 following propensity score calculation based on age, sex, BMI, DM, previous PCI, previous CABG, hyperlipidemia, hypertension, stroke/TIA, COPD, PVD, smoking (ever smoking vs never), Hb level, creatinine level, multivessel CAD, target vessel location in LAD, maximum lesion length, minimum MLD, OAC usage (at discharge), potent P2Y12 inhibitor usage (at discharge) as the confounding variables

# Patient Flowchart

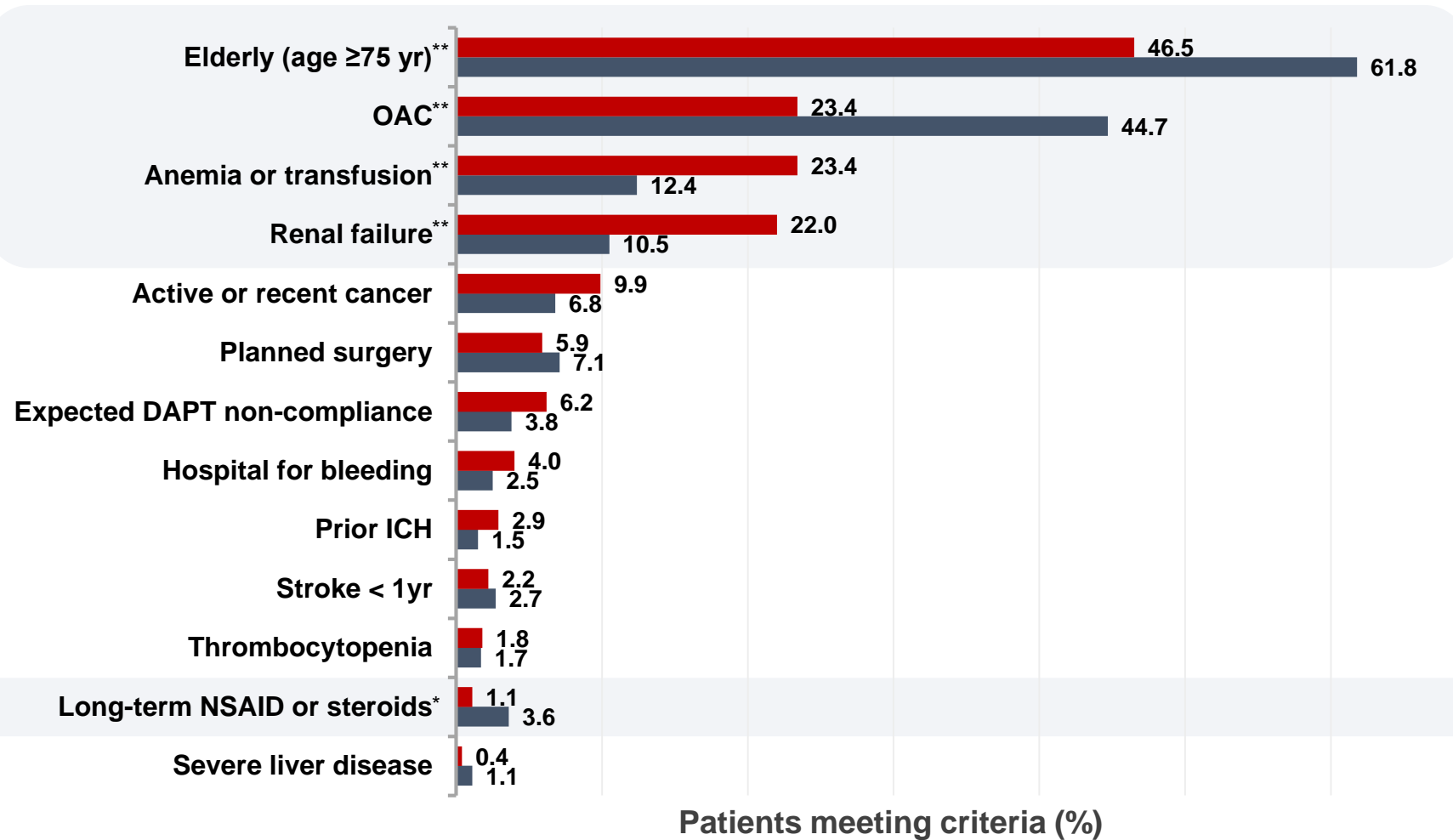


\* “1-month clear” defined as patients who were adherent to DAPT within 1<sup>st</sup> month after PCI and free of events that would preclude 1-month DAPT cessation

# Baseline Patient Characteristics (unmatched)

% or mean ± SD	Asian Cohort (N=273 pts)	Non-Asian Cohort (N=1234 pts)	P
Age (yrs)	70.8 ± 11.3	74.7 ± 9.0	<0.001
Female	36.6	31.3	0.10
BMI	24.6 ± 4.1	29.0 ± 5.7	<0.001
Diabetes	44.3	38.4	0.08
Insulin dependent	13.6	13.5	1.00
Hypertension	74.7	86.1	<0.001
Hyperlipidemia	49.8	77.6	<0.001
Previous MI	23.1	26.9	0.22
Previous PCI	12.8	33.9	<0.001
Previous CABG	1.5	15.4	<0.001
Stroke/TIA	8.4	15.3	0.003
A-Fib	18.7	39.3	<0.001
LVEF	54.5 ± 13.4	52.2 ± 12.0	0.020
ACS	48.4	48.8	0.95
OAC usage (at discharge)	15.0	40.4	<0.001
Potent P2Y12 usage (at discharge)	8.4	16.6	<0.001

# HBR Inclusion Criteria (unmatched)



## Mean # HBR criteria

Asian vs. Non-Asian  
**1.5** vs. **1.6** (p=0.052)

■ Asian Cohort (N=273)  
 ■ Non-Asian Cohort (N=1234)

\* P-value < 0.05  
 \*\* P-value < 0.01



# Baseline Lesion & Procedure Characteristics

(unmatched)

% or mean ± SD	Asian (N=273 pts, 353 lesions)	Non-Asian (N=1234 pts, 1613 lesions)	P
Multivessel disease	56.8	48.2	<b>0.011</b>
Target vessel: - LAD	70.0	48.6	<b>&lt;0.001</b>
- LCx	17.9	30.3	<b>&lt;0.001</b>
- RCA	35.5	34.0	0.62
- Left main	0.7	1.3	0.76
- Bypass graft	0.4	4.8	<b>&lt;0.001</b>
Calcification mod/sev	61.1	47.6	<b>&lt;0.001</b>
Bifurcation	11.0	11.4	0.86
CTO	4.7	1.9	<b>0.003</b>
In-stent restenosis	2.3	3.3	0.42
B2/C lesion class	89.2	76.2	<b>&lt;0.001</b>
RVD (mm)	2.86 ± 0.43	2.81 ± 0.49	<b>0.048</b>
% Diameter stenosis	70.7 ± 14.0	67.8 ± 13.0	<b>&lt;0.001</b>
Lesion length (mm)	27.0 ± 14.2	19.4 ± 12.2	<b>&lt;0.001</b>

% or mean ± SD	Asian (N=273 pts, 353 lesions)	Non-Asian (N=1234 pts, 1613 lesions)	P
Radial access	66.5	65.9	0.89
IVUS/OCT usage	39.2	13.3	<b>&lt;0.001</b>
# Vessels treated / pt	1.2 ± 0.5	1.2 ± 0.4	0.051
# Lesions treated / pt	1.3 ± 0.5	1.3 ± 0.6	0.62
# Stents implanted / pt	1.8 ± 1.0	1.7 ± 1.0	0.11
Total stent length / lesion	33.8 ± 17.5	23.9 ± 12.4	<b>&lt;0.001</b>
Total stent length / pt	47.4 ± 29.6	34.6 ± 24.9	<b>&lt;0.001</b>
Acute gain (in-stent)	1.76 ± 0.49	1.68 ± 0.49	<b>0.003</b>
Procedure time	49.8 ± 31.4	39.8 ± 28.5	<b>&lt;0.001</b>
Post-PCI hospital stay (days)	2.3 ± 2.8	1.8 ± 3.8	<b>0.007</b>
Lesion success <sup>1</sup>	92.4	95.2	<b>0.045</b>
Device success <sup>2</sup>	91.8	93.7	0.23
Procedure success <sup>3</sup>	84.2	89.5	<b>0.019</b>

<sup>1</sup> The attainment of <30% residual stenosis by QCA (or <20% by visual assessment) and TIMI flow 3 after the procedure, using any percutaneous method.

<sup>2</sup> The attainment of <30% residual stenosis by QCA (or <20% by visual assessment) and TIMI flow 3 after the procedure, using the assigned device only.

<sup>3</sup> The attainment of <30% residual stenosis by QCA (or <20% by visual assessment) and TIMI flow 3 after the procedure, using any percutaneous method without the occurrence of MACE during the hospital stay.



# 1:1 Matched Patient Analysis

## Variables Included in Propensity Score

% or mean ± SD	Asian (N=263)	Non-Asian (N=263)	Absolute Standardized Difference
Age (yrs)	71.4 ± 11.0	73.4 ± 9.9	0.191
Female	36.9	39.5	0.055
BMI	24.7 ± 4.1	25.2 ± 4.3	0.116
Diabetes	43.3	41.1	0.046
Hypertension	74.5	76.4	0.044
Hyperlipidemia	51.0	57.4	0.13
Smoking (ever)	41.1	40.7	0.008
Previous PCI	12.9	15.6	0.076
Previous CABG	1.5	1.5	0.000
Stroke/TIA	8.7	9.5	0.026

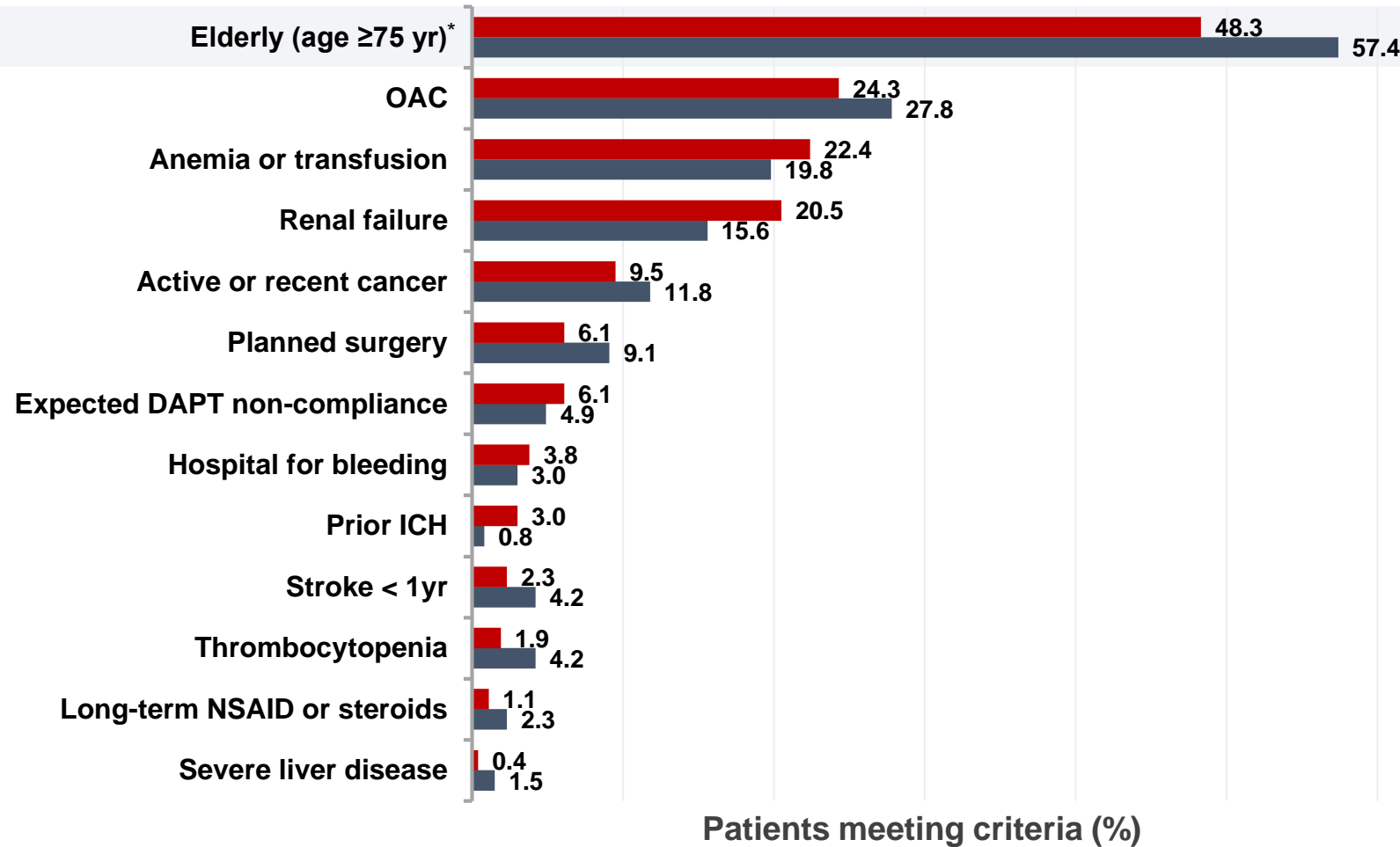
% or mean ± SD	Asian (N=263)	Non-Asian (N=263)	Absolute Standardized Difference
COPD	3.4	5.7	0.109
Peripheral vascular disease	2.7	3.0	0.023
Hemoglobin level	12.3 ± 1.9	12.5 ± 2.0	0.094
Creatinine level	149.9 ± 188.6	140.1 ± 245.8	0.045
Multivessel CAD	55.5	52.9	0.053
LAD lesion	69.6	68.4	0.025
Max lesion length	27.3 ± 14.0	25.7 ± 15.1	0.110
Minimal luminal diameter	0.8 ± 0.4	0.8 ± 0.4	0.097
OAC usage (discharge)	15.6	17.9	0.061
Potent P2Y12 usage (discharge)	8.4	11.8	0.114

Variables with missing values were imputed before propensity score calculation

Matching was performed based on age, sex, BMI, DM, previous PCI, previous CABG, hyperlipidemia, hypertension, stroke/TIA, COPD, PVD, smoking (ever smoking vs never), Hb level, creatinine level, multivessel CAD, target vessel location in LAD, maximum lesion length, minimum MLD, OAC usage (at discharge), potent P2Y12 inhibitor usage (at discharge)

# HBR Inclusion Criteria

## (1:1 Matched Patient Analysis)



### Mean # HBR criteria

Asian vs. Non-Asian  
**1.5** vs. **1.6** ( $p=0.08$ )

■ Asian Cohort (N=263)  
 ■ Non-Asian Cohort (N=263)

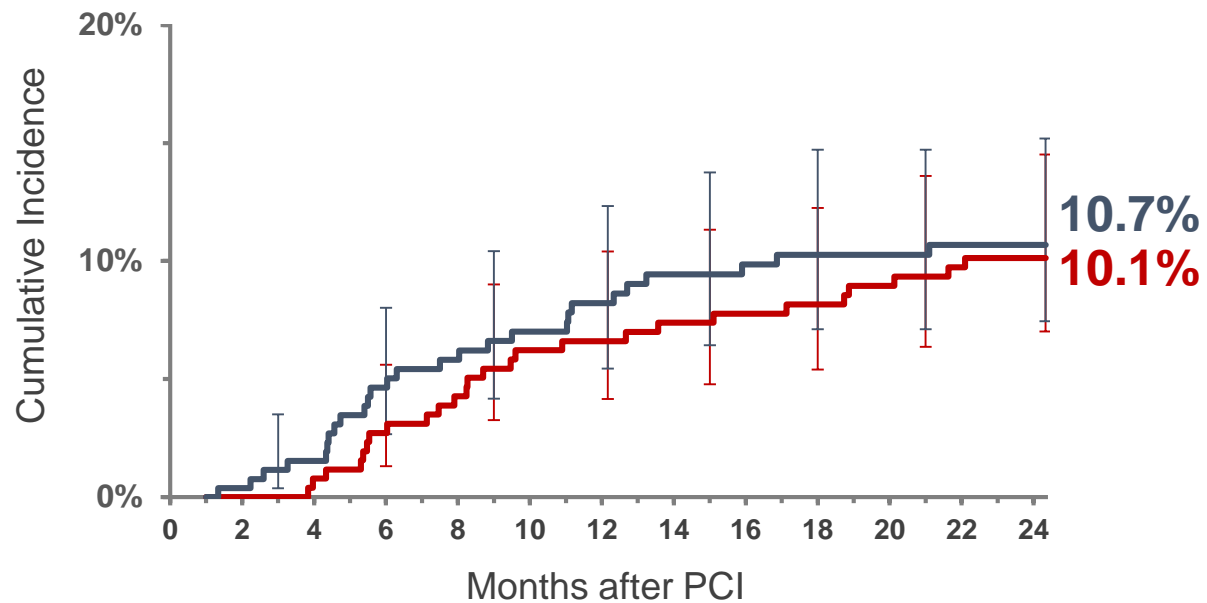
\*  $P$ -value = 0.04

# 1:1 Matched Patients KM Estimates

From Time of SAPT Initiation



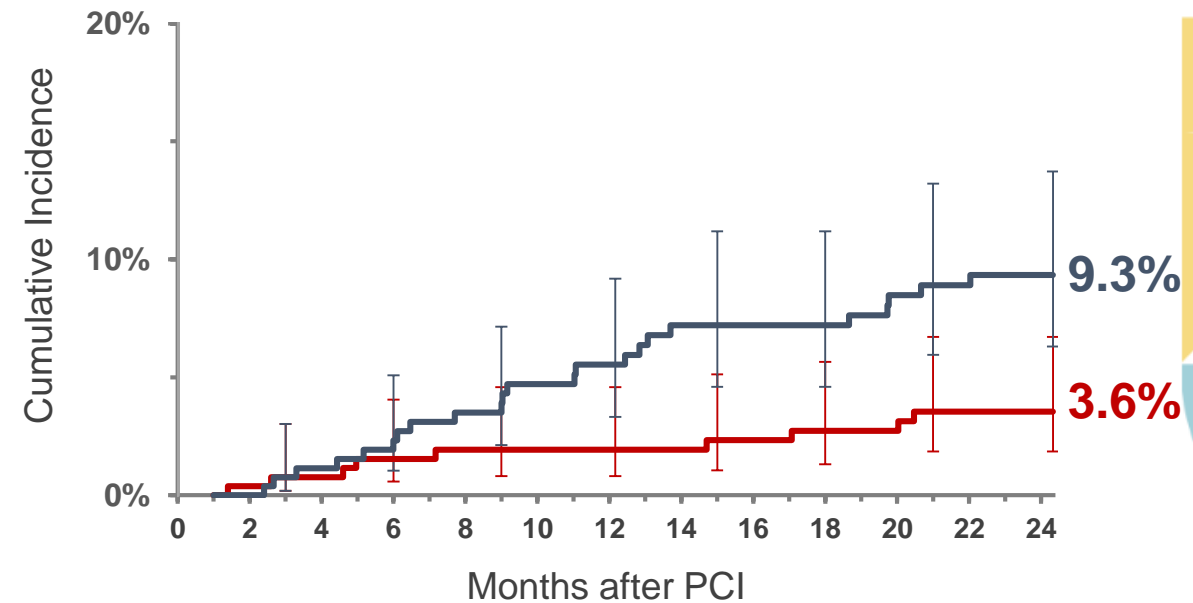
## Cardiac Death / MI



Number at risk

Asian	263	260	243	238	230
Non-Asian	263	257	235	221	214

## BARC 3-5



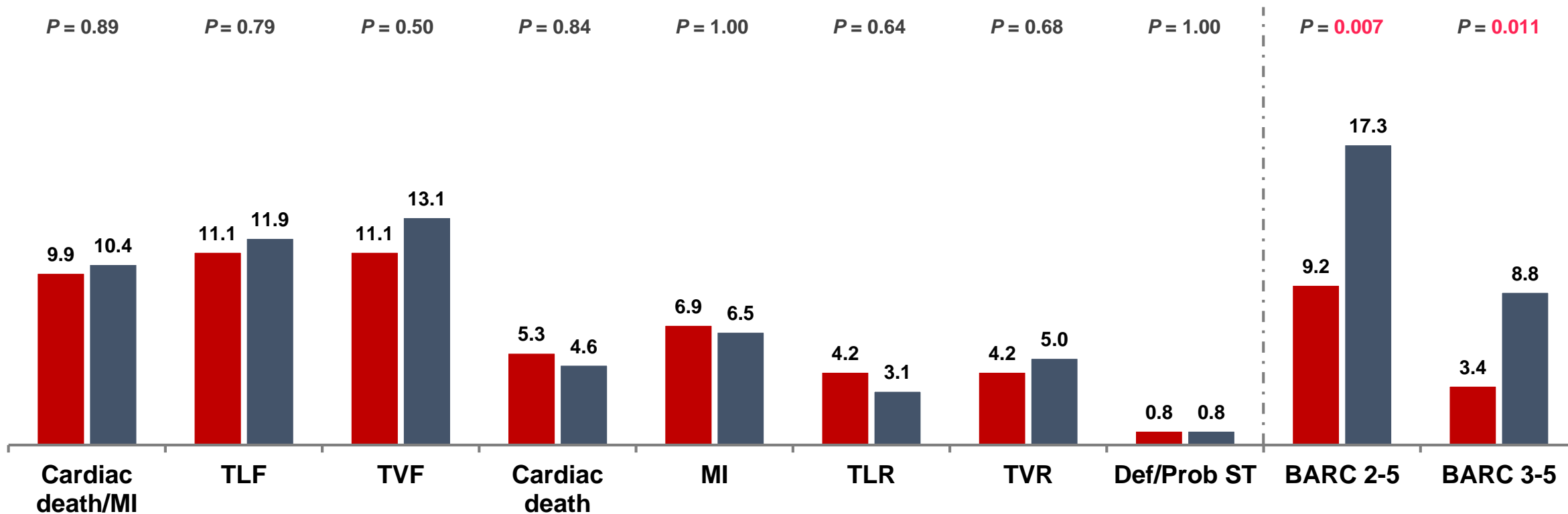
Asian	263	258	248	244	237
Non-Asian	263	257	239	221	213

# 1:1 Matched Patients Clinical Outcomes (%)

Between 1 – 24 Months

■ Asian Cohort (n=262/263)

■ Non-Asian Cohort (n=260/263)



# Conclusions

- There were **significant differences in baseline characteristics between HBR patients from Asian countries vs non-Asian countries**, which we addressed by propensity score matching leading to small standardized differences in potential baseline confounding covariates.
- Asian patients receiving the Resolute Onyx ZES during PCI treated with 1-month DAPT had **similar ischemic outcomes but fewer bleeding events** between 1 month and 24 months compared with patients from non-Asian countries.

# Important Points for interpretation

- **This cohort was a 1-month event free population, who were stable on single antiplatelet agents.**
  - The most vulnerable phase was excluded from analysis.
- **Although the propensity score matching method was used, we still observe difference between the Asian and non-Asian population.**
  - The higher clinical complexity in non-Asians and higher lesion/procedural complexity in Asians should be considered.



# Summary

- In the current analysis, we evaluated the ethnic difference in HBR patients who received the Resolute Onyx ZES during PCI, treated with 1-month DAPT.
- Asian patients **similar ischemic outcomes but fewer bleeding events**, implying that short term DAPT may be safer in Asian HBR patients, once stabilized during the first month post-PCI.

**Thank you for your kind attention**