PROMUS Element Clinical Programs In AMC

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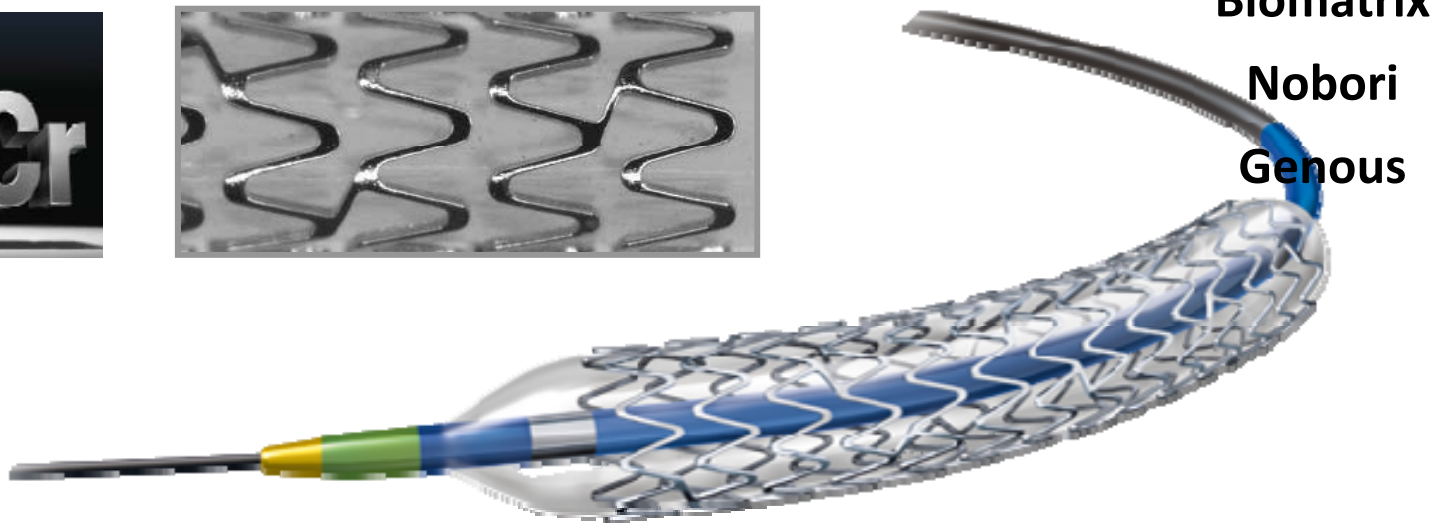
Drug-Eluting Stents

2002	2004	2006	2008	2010
Cypher	Taxus (Liberte)	Pico Elite	Xience V	Xience Prime LL, SV
Taxus (Express)	Endeavor	Coroflex Please	Promus	Promus Element
			Endeavor	
			Resolute	Resolute Integrity
				Biomatrix
				Nobori
				Genous



PROMUS Element Clinical Programs In Asan Medical Center

Left Main Disease

Historical Comparison

of

PROMUS™ Element™
Everolimus-Eluting Stent

Primary Endpoint

Composite of
Death
MI
Stroke
Ischemic –driven TVR
At 12-months

Long Lesion (≥28mm)

RCT

of

PROMUS™ Element™
Everolimus-Eluting Stent

Compared to

Nobori™
Biolimus-Eluting Stent

Primary Endpoint

9 Months In-segment LL

Real World Registry

Registry

of

PROMUS™ Element™
Everolimus-Eluting Stent

Primary Endpoint

Composite of
Death
MI
TVR
at 12-months

PROMUS™ Element™ Stent Implantation for Unprotected Left Main Stenosis:

PRECOMBAT-3 Study

PRECOMBAT-3 Trial

Design

- DESIGN: a prospective, single arm, registry
- OBJECTIVE: To evaluate the outcomes of PCI with PROMUS Element everolimus-eluting stents for patients with ULMCA stenosis, the results were compared with those of patients receiving SES and CABG in the PRECOMBAT trial and those of patients receiving Xience V stent in PRECOMBAT-2 trial.
- PRINCIPAL INVESTIGATOR
  Seung-Jung Park, MD, PhD, Asan Medical Center, Seoul, Korea

Design

Non-randomized Comparison

Historical Control

PRECOMBAT
for unprotected left main disease
In 13 cardiac centers in Korea

PRECOMBAT-2
for unprotected left main disease

PRECOMBAT-3
for unprotected left main disease
In 20 cardiac centers in Korea

Randomization of 600 (1:1)

PCI with
CYPHER Stent
N=300

CABG
N=300

Pre-COMBAT eligible Patients Treated with
Xience V stent
N=300

Pre-COMBAT eligible Patients Treated with
PROMUS Element stent
N=300

NEJM 2011;364:1718-27

JACC Interventions Accepted

Inclusion and Exclusion

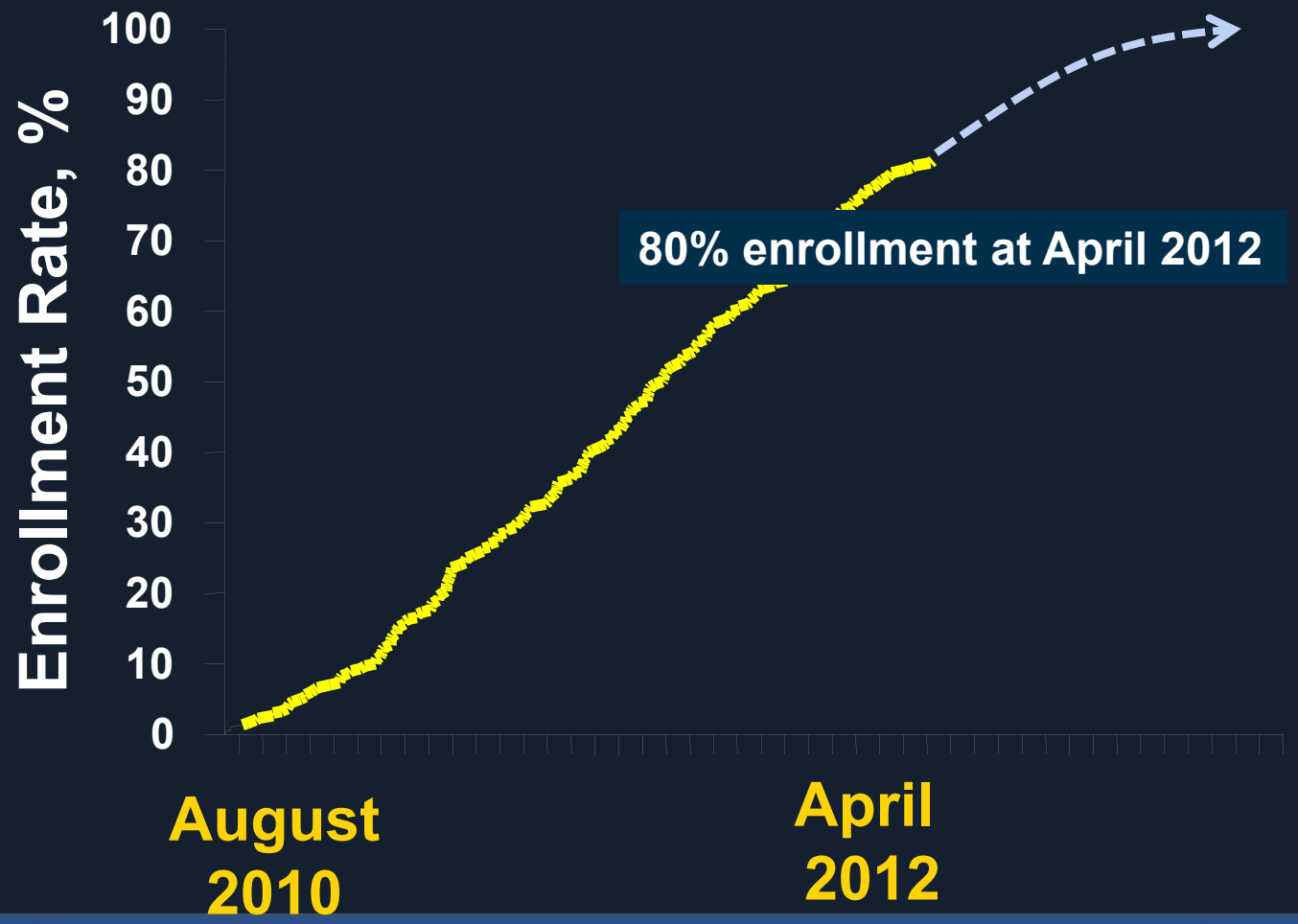
- Same to the PRECOMBAT randomized study
- In brief, patients with angiographic ULMCA stenosis (> 50% stenosis), who had not ST-segment elevation myocardial infarction (MI), cardiogenic shock, other serious comorbidity or contraindication of DES, were included.

End Points

- Definitions of end points were same to those in the PRECOMBAT study.
- **Primary Endpoint (MACCE)**

  Death, MI, stroke and ischemia-driven TVR
- Death included cardiac and non-cardiac deaths.
- MI included Q-MI within 48 hours after procedure and spontaneous MI.
- TVR included ischemia- (symptomatic and stenosis > 70%) and clinical- (symptomatic) driven revascularization.

23 Participating Center in Korea



Comparison of PROMUS™ Element™ Stents and Nobori™ Stents in Patients with De Novo Long Coronary Artery Lesions

A Randomized LONG-DES V Trial

LONG-DES Series

2003	LONG DES I	Registry: SES/PES/BMS
2004	LONG DES II	RCT: SES versus PES
2008	LONG DES III	RCT: SES versus EES
2009	LONG DES IV	RCT: SES versus R-ZES
2010	LONG DES V	RCT: **PROMUS Element** versus Nobori stent

LONG DES V Trial

Design

- DESIGN: a prospective, randomized controlled study
- OBJECTIVE: To compare angiographic and clinical outcomes of PCI using **PROMUS Element Stents** and NOBORI Stents in patients with native long coronary lesions.
- PRINCIPAL INVESTIGATOR
  Seung-Jung Park, MD, PhD, Asan Medical Center, Seoul, Korea

Design

Patients requiring PCI with DES for long coronary lesions:
Lesion length ≥ 25mm (Total stent length ≥ 28mm)

R

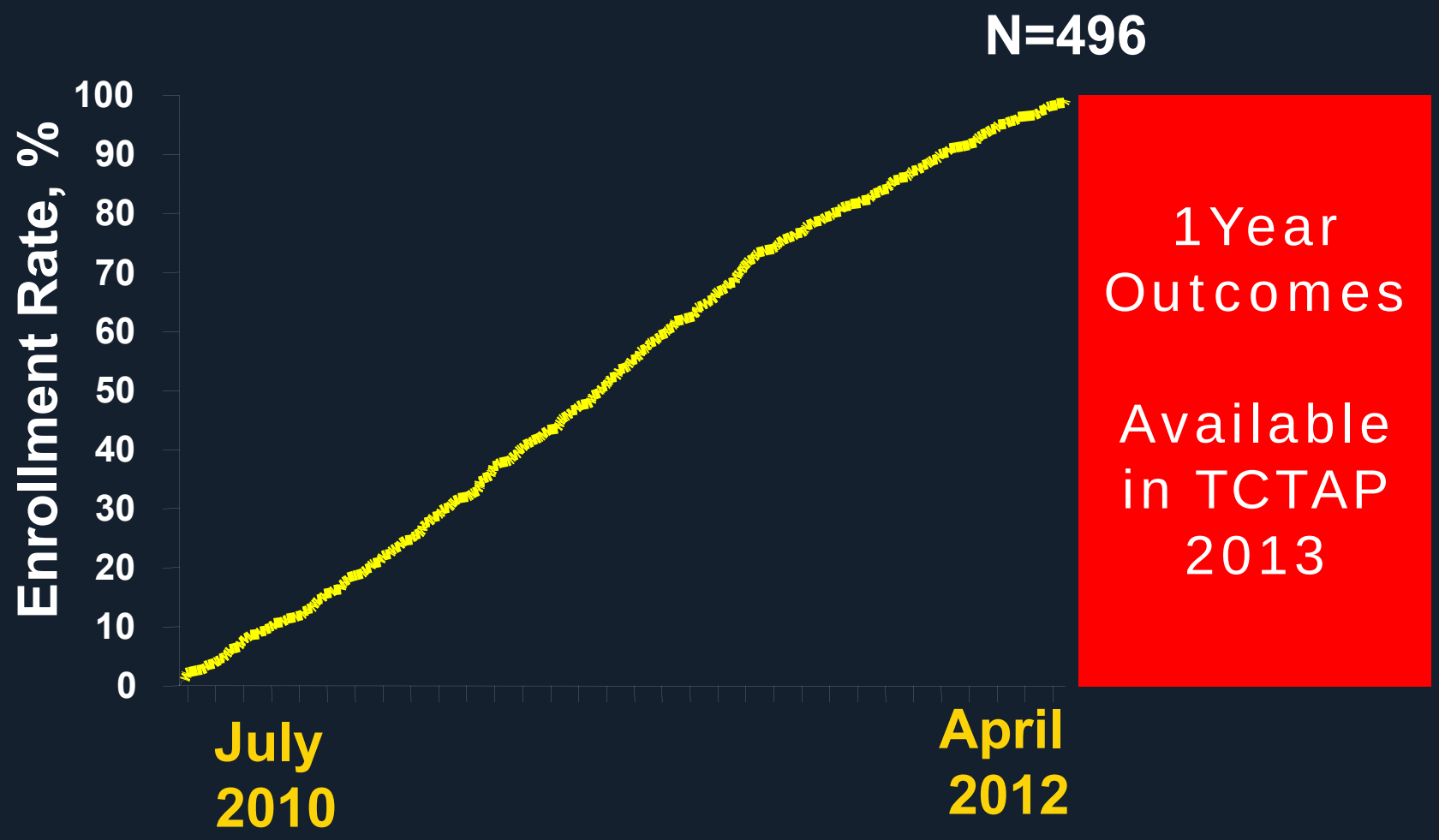
PROMUS Element Stent
(n=250)

NOBORI Stent
(n=250)

9 months Angiographic follow-up
12 months Clinical follow-up

Primary endpoint: In-segment late loss **at 9 months angiographic follow-up**

14 Participating Centers in Korea



Baseline Characteristics

	PROMUS Element (N=243)	NOBORI (N=253)	P Value
Age	62.9±10.5	63.5±10.7	0.51
Male sex	167 (68.7)	183 (72.3)	0.38
Diabetes mellitus	76 (31.5)	87(34.5)	0.48
Hypertension	155 (64.3)	148 (58.7)	0.20
Hyperlipidemia	96 (39.8)	113 (44.8)	0.26
Current smoker	56 (23.2)	69 (27.4)	0.29
Previous coronary angioplasty	13 (5.4)	19 (7.5)	0.33
Previous myocardial infarction	10 (4.0)	6 (2.5)	0.35
Stable angina	125 (51.4)	130 (51.4)	0.99
Left ventricular ejection fraction, %	60.1±7.2	59.9±7.4	0.74
Multivessel disease	117 (48.3)	135 (53.8)	0.23

Lesion & Procedural Characteristics

	PROMUS Element (N=243)	NOBORI (N=253)	P Value
Restenotic lesions	3 (1.2)	1 (0.4)	0.30
Bifurcation	86 (35.7)	83 (33.1)	0.54
preTIMI 0,1	31 (12.8)	33 (13.2)	0.94
Severe Calcification	4 (1.7)	10 (4.0)	0.29
Thrombus	10 (4.1)	13 (5.2)	0.59
No. of stents used at the target lesion	1.6±0.6	1.6±0.7	0.11
Stented length at the target, mm	39.1±14.3	43.5±17.5	0.002
Average stent diameter, mm	3.2±0.6	3.2±0.6	0.83
Maximal pressure, atm	12.8±4.0	13.6±3.1	0.51
Intravascular ultrasound guidance	186 (85.7)	183 (83.6)	0.53

In Hospital Clinical Outcomes

	PROMUS Element (N=243)	NOBORI (N=253)	P Value
Death	1 (0.4%)	1 (0.4%)	0.98
Cardiac	1 (0.4%)	1 (0.4%)	0.98
Noncardiac	0	0	>0.99
Myocardial infarction	8 (3.3%)	22 (8.7%)	0.012

	PROMUS (N=243)	NOBORI (N=253)	P Value
Stented length at target, mm	39.1±14.3	43.5±17.5	0.002
All type	1 (0.4%)	0	0.31
Target-lesion	1 (0.4%)	0	0.31
Target-vessel	1 (0.4%)	0	0.31

Evaluation of Effectiveness and Safety of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice;

IRIS-DES Registry

Consecutive PCI patients receiving New DES without a mixture of other DES

Prospective Enrollment

2007.7 -2010.9	2008.4 -2010.10	2010.5 -2011.12							
DESSIAN Registry	K-XIENCE Registry	IRIS-ELEMENT Registry	IRIS-NOBORI Registry	IRIS-BIOMATRIX Registry	IRIS-GENOUS Registry	IRIS-PRIME Registry	IRIS-RESOLUTE Registry	IRIS-CILOTAX Registry
CYPHER (N=3,600)	XIENCE (N=3,000)	PROMUS ELEMENT (N=3,000)	NOBORI (N=2,000)	BIOMATRIX (N=1,000)	GENOUS STEMI (N=1,000)	XIENCE-PRIME (N=2,000)	RESOLUTE INTEGRITY (N=1,000)	CILOTAX (N=1,000)

Clinical follow-up at 1-, 6-, and 12-months, and annually up to 5 years

*Primary end point: Composite of Death, MI, and TVR at 12-months

CardioVascular Research Foundation

UNIVERSITY OF ULSAN COLLEGE MEDICINE

ASAN Medical Center

IRIS-Element Registry

Design

- **DESIGN**: a prospective, multicenter, single arm, registry
- **OBJECTIVE**: To evaluate the outcomes of PCI with PROMUS Element everolimus-eluting stents in everyday clinical practice
- **PRINCIPAL INVESTIGATOR**
  Seung-Jung Park, MD, PhD,
  Asan Medical Center, Seoul, Korea

IRIS-Element Registry

Inclusion Criteria

- Patients receiving PROMUS Element stents
- ***No limitation of clinical or lesion characteristics***
- Agreement to the study protocol and informed consent

Limited Exclusion Criteria

- Patients with a mixture of other DESs
- Terminal illness with life expectancy < 1 year
- Patients with cardiogenic shock

Study Outcomes

Primary End Points

- Major cardiac adverse events (MACE); a composite of death, non-fatal MI, or TVR at 12 months post procedure

Secondary End Points

- Death
- MI
- Composite of death or MI
- TVR
- Stent thrombosis (ARC criteria)
- Procedural success

41 Participating Centers in Korea

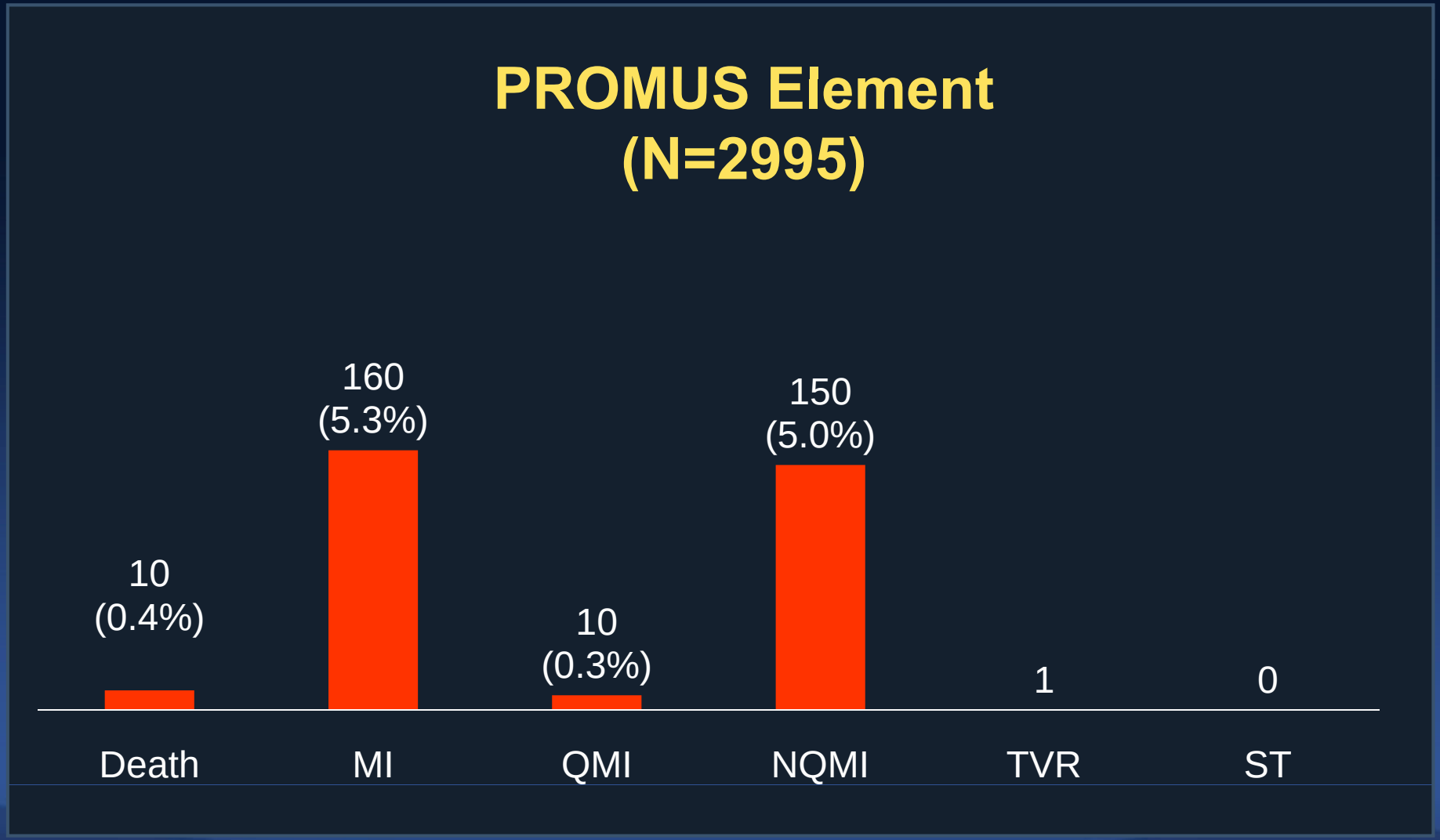
Baseline Characteristics

	PROMUS Element (N=2995)	XIENCE V (N=3081)	CYPHER-S (N=3085)	P Value
Age	63.2±34.6	63.7±10.8	63.5±10.8	0.66
Male sex	2116 (70.7)	2079 (67.5)	2052 (66.5)	0.001
Diabetes mellitus	984 (33.7)	1028 (33.4)	1121 (36.3)	0.022
Hypertension	1784 (61.1)	1924 (62.4)	1923 (62.3)	0.52
Hyperlipidemia	1052 (37.0)	1159 (37.6)	1238 (40.1)	0.03
Current smoker	847 (29.0)	888 (28.8)	841 (27.3)	0.77
Previous coronary angioplasty	309 (10.6)	453 (14.7)	582 (18.9)	<0.01
Previous myocardial infarction	146 (5.0)	158 (5.1)	226 (7.3)	<0.01
Renal Failure	82 (2.8)	105 (3.4)	118 (3.8)	0.092
LVEF%	59.2±10.0	59.4±10.1	59.1±9.9	0.55
ACS	2110 (70.5)	1815 (58.9)	1722 (55.8)	0.86

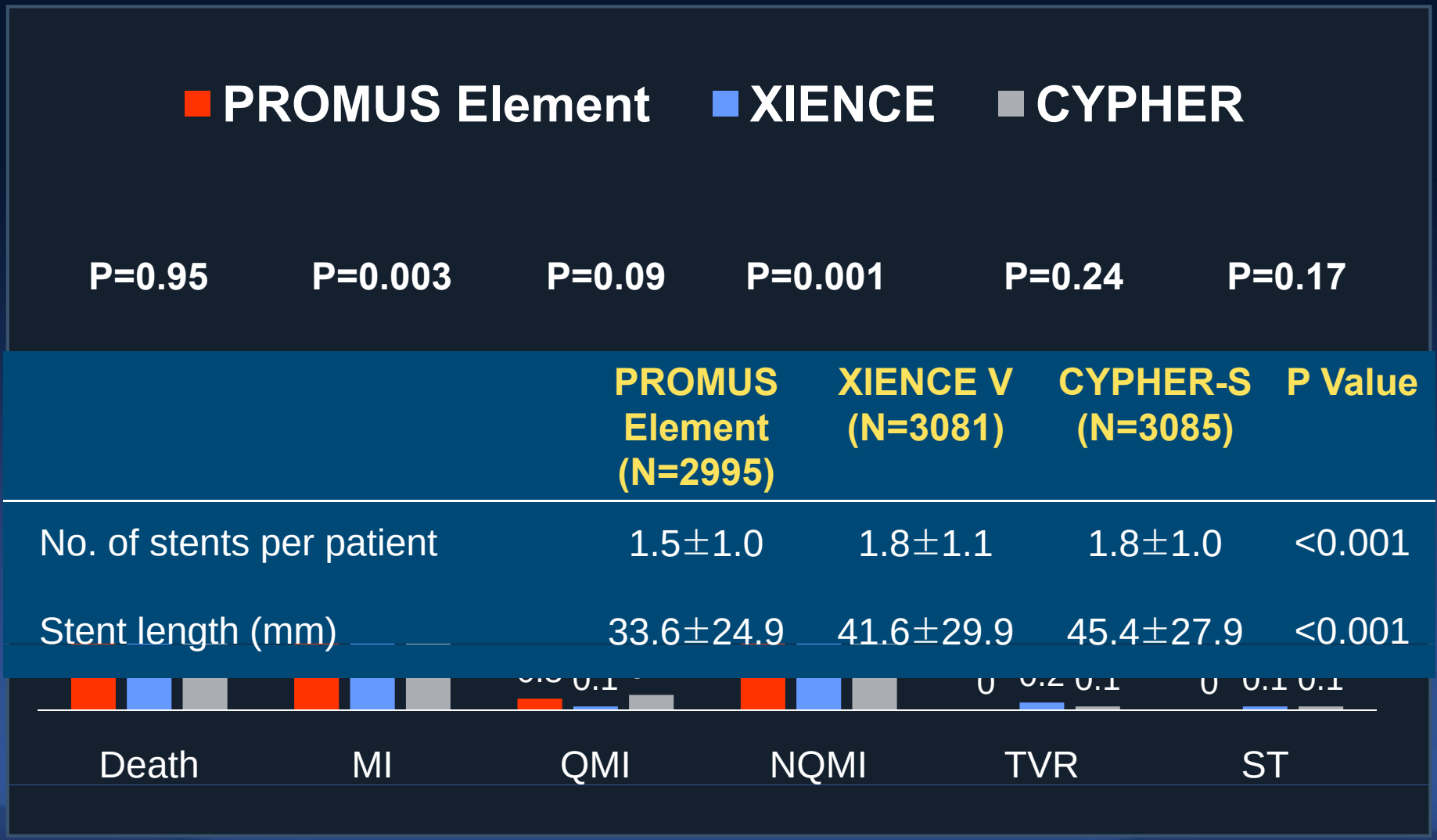
Lesion & Procedural Characteristics

	PROMUS Element (N=2995)	XIENCE V (N=3081)	CYPHER-S (N=3085)	P Value
Multivessel disease	1413 (49.5)	1634 (53.0)	1614 (52.3)	0.016
Left main disease	204 (7.1)	290 (9.4)	154 (5.0)	<0.001
LAD disease	2077 (72.7)	1907 (61.9)	2053 (66.5)	<0.001
Bifurcation disease	827 (29.1)	970 (31.5)	919 (29.8)	0.12
Total obstruction	584 (20.6)	477 (15.5)	430 (13.9)	<0.001
Restenotic lesions	114 (4.0)	186 (6.0)	217 (7.0)	<0.001
No. of lesions treated	1.7±1.0	1.4±0.7	1.4±0.7	<0.001
No. of stents per patient	1.5±1.0	1.8±1.1	1.8±1.0	<0.001
Stent length (mm)	33.6±24.9	41.6±29.9	45.4±27.9	<0.001
Stent diameter (mm)	3.2±0.5	3.2±0.4	3.1±0.3	<0.001

In Hospital Clinical Outcomes



In Hospital Clinical Outcomes, %



	PROMUS Element (N=2995)	XIENCE V (N=3081)	CYPHER-S (N=3085)	P Value
No. of stents per patient	1.5±1.0	1.8±1.1	1.8±1.0	<0.001
Stent length (mm)	33.6±24.9	41.6±29.9	45.4±27.9	<0.001

Conclusion

- PLATINUM trial demonstrated that PROMUS Element stent showed an excellent safety and efficacy profile by 2 year follow-up.

- In Korea, very early outcomes (in-hospital outcomes) of PROMUS element stent appears favorable, but we need long term follow-up clinical outcomes.