



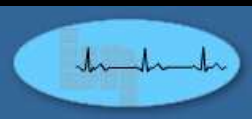
Safety Assured

Global RESOLUTE Data

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ASEAN Federation of Cardiology



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RESOLUTE Global Clinical Program

7618 Patients Included in Current Analysis

Latest
Available
Follow Up

RESOLUTE¹	Non-RCT First-in-Human (R=139)		5 yr
RESOLUTE AC^{2,3}	1:1 RCT vs. Xience V™ EES (R=1140; X=1152)		5 yr
RESOLUTE Int^{4,5}	Non-RCT Observational (R=2349)		3 yr
RESOLUTE US⁶	2.25 – 4.0 mm Non-RCT vs. Hx Control (R=1402)		4 yr
RESOLUTE Japan	2.5 – 3.5 mm Non-RCT (R=100) vs. Hx Control		4 yr
R-Japan SVS	2.25 Non-RCT vs. PG (R=65)		3 yr
R-US 38mm⁷	38 mm sub-study Non-RCT vs. PG (R=114)		3 yr
R-China RCT⁸	1:1 RCT vs. Taxus™ PES (R=200; T=200)		2 yr
RESOLUTE Asia⁷	Non-RCT Observational (R=312)		2 yr
R-China Registry⁹	Non-RCT Observational (R=1800)		2 yr

¹ Meredith IT, et al. *EuroIntervention*. 2010;5:692-7. ² Serruys PW, et al. *N Engl J Med*. 2010;363:136-46.

³ Silber S, et al. *Lancet*. 2011;377:1241-47. ⁴ Neumann FJ, et al. *EuroIntervention*. 2012;7(10):1181-8. ⁵ Belardi JA, et al. *J Interv Cardiol*. 2013;26(5):515-23. ⁶ Yeung AC, et al. *JACC*. 2011;57:1778-83. ⁷ Lee M, et al. *Am J Cardiol*. 2013;112(9):1335-41. ⁸ Xu B, et al. *JACC Cardiovasc Interv*. 2013;6(7):664-70. ⁹ Qiao S, et al. *Am J Cardiol*. 2013. doi: 10.1016/j.amjcard.2013.10.042. [Epub ahead of print]



**PCI of Small Vessels (≤ 2.5 mm) in
the RESOLUTE
Global Clinical Program:
The Impact of Diabetes Mellitus**

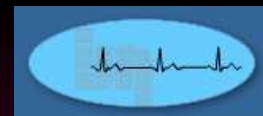
RESOLUTE Pooled – Small Vessel DM



Baseline Patient Characteristics

%	<i>Non-Diabetic</i> <i>n = 1764 pts,</i> <i>2741 lesions</i>	<i>Non-IDDM</i> <i>n = 725 pts,</i> <i>1104 lesions</i>	<i>IDDM</i> <i>n = 233 pts,</i> <i>336 lesions</i>	<i>P-value</i> <i>Non-DM</i> <i>vs NIDDM</i>	<i>P-value</i> <i>Non-DM</i> <i>vs IDDM</i>
Age (yr)	63.7 ± 11.3	65.1 ± 10.1	64.8 ± 10.0	0.003	NS
Men	75.1	69.8	56.2	0.008	<0.001
Hypertension	69.7	83.7	92.3	<0.001	<0.001
Hyperlipidemia	63.9	70.3	81.5	0.002	<0.001
Current smoker	24.6	19.7	15.9	0.009	0.003
Family history of CAD	32.2	26.1	39.7	0.006	0.046
Prior MI	28.9	29.9	32.3	NS	NS
Prior PCI	27.4	30.8	38.2	NS	<0.001
Prior CABG	6.1	8.3	9.9	NS	0.035
<i>Cardiac status</i>				NS	<0.001
Silent Ischemia	2.3	3.2	4.3		
Stable Angina	36.1	36.1	51.0		
Unstable Angina	35.7	41.6	26.0		
Myocardial Infarction	25.9	19.1	18.8		
ACS	50.3	52.7	35.6	NS	<0.001
STEMI	6.9	4.5	1.0	0.035	<0.001

RESOLUTE Pooled – Small Vessel DM Lesion and Procedure Characteristics



%	<i>Non-Diabetic</i> <i>n = 1764 pts,</i> <i>2741 lesions</i>	<i>Non-IDDM</i> <i>n = 725 pts,</i> <i>1104 lesions</i>	<i>IDDM</i> <i>n = 233 pts,</i> <i>336 lesions</i>	<i>P-value</i> <i>Non-DM</i> <i>vs NIDDM</i>	<i>P-value</i> <i>Non-DM</i> <i>vs IDDM</i>
<i>Lesion location (lesion level):</i>					
LAD	43.8	40.3	41.9	NS	NS
LCx	31.7	33.2	27.4	NS	NS
RCA	23.3	25.1	28.6	NS	NS
Left main	0.7	0.5	0.9	NS	NS
Bypass graft	0.5	0.8	1.2	NS	NS
B2/C Lesion class ACC/AHA	65.6	67.2	64.2	NS	NS
Bifurcation	15.0	14.3	11.2	NS	NS
In-stent restenosis	3.7	3.4	6.3	NS	NS
RVD ¹	2.4 ± 0.4	2.5 ± 0.4	2.4 ± 0.4	NS	0.007
MLD	0.6 ± 0.4	0.6 ± 0.4	0.6 ± 0.4	NS	NS
Diameter stenosis	74.8 ± 16.3	76.0 ± 16.0	72.9 ± 16.0	0.047	0.05
Lesion length (mm)	16.4 ± 10.1	17.9 ± 12.0	16.0 ± 10.1	<0.001	NS
Lesions treated per patient	1.6 ± 0.8	1.6 ± 0.8	1.4 ± 0.7	NS	0.005
Number of stents per patient	1.8 ± 1.1	1.8 ± 1.1	1.6 ± 1.0	NS	0.010
Stent length per patient (mm)	36.6 ± 25.2	38.4 ± 27.5	31.7 ± 21.6	NS	0.002
Complex patients²	46.4	42.9	37.8	NS	0.014

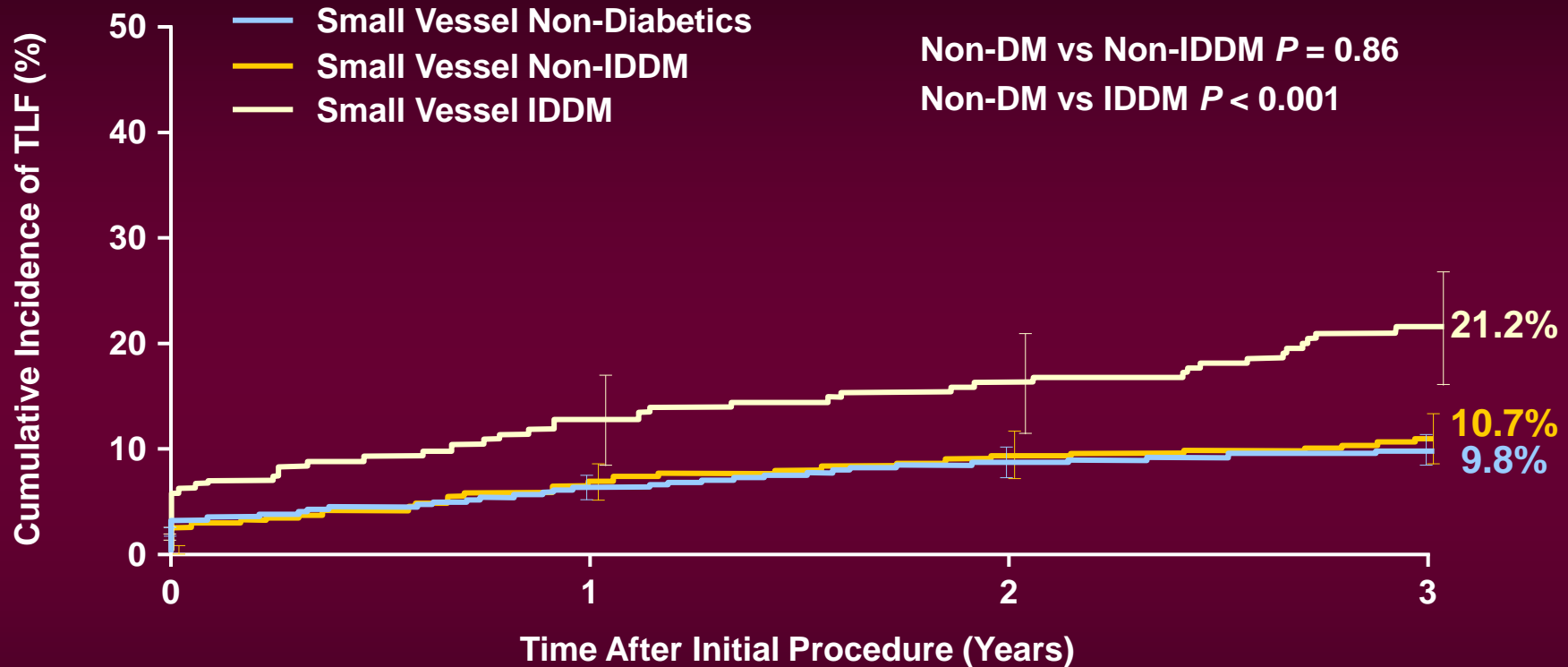
¹ RVD of *all* treated lesions of patients who have at least one small vessel (RVD ≤ 2.5mm) stented.

² Complex patient definition: Bifurcation, Bypass grafts, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 μmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0).

RESOLUTE Pooled – Small Vessel DM



Target Lesion Failure to 3 Years



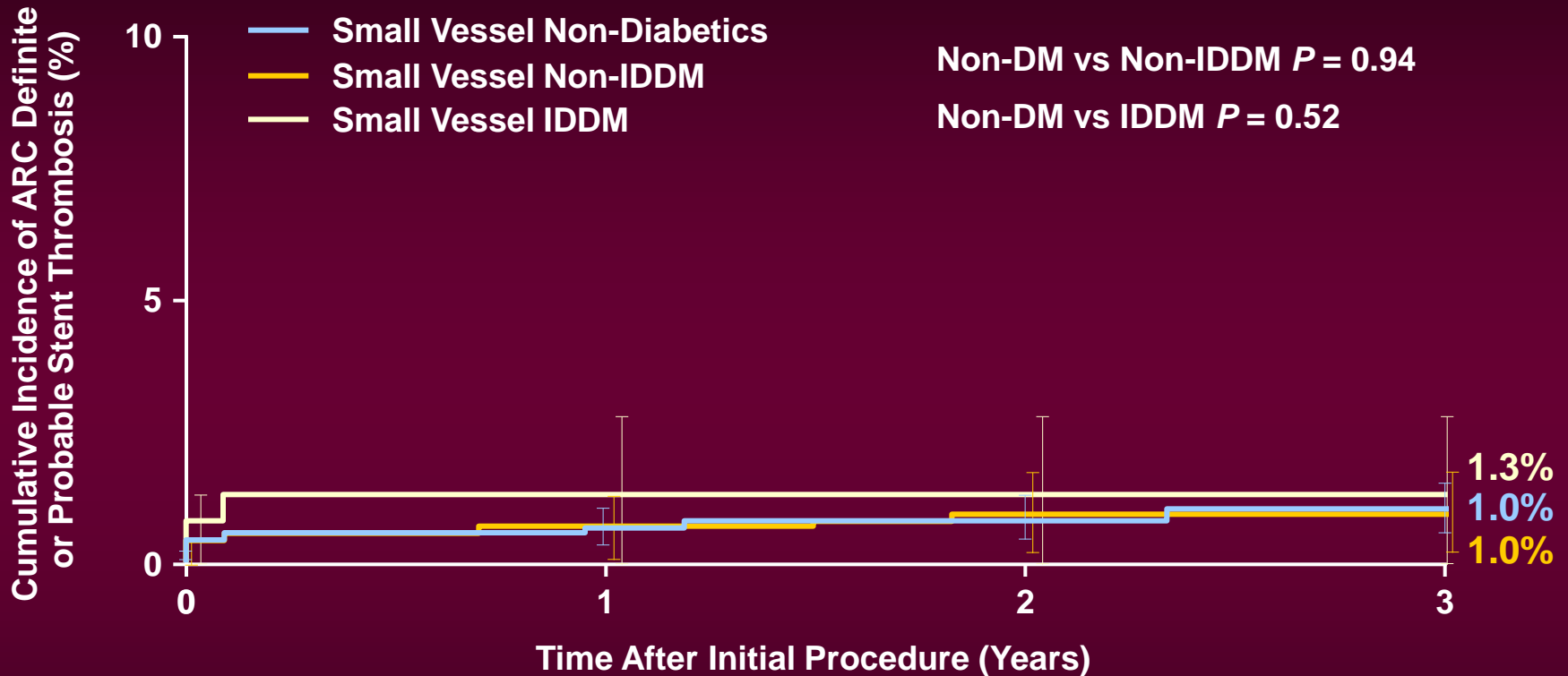
No. at risk

	0	1	2	3
Non-Diabetics	1764	1734	1614	1169
Non-IDDM	725	722	667	448
IDDM	233	226	201	178

RESOLUTE Pooled – Small Vessel DM



Stent Thrombosis (ARC Def/Prob) to 3 Years



No. at risk

	0	1	2	3
Non-Diabetics	1764	1763	1702	1264
Non-IDDM	725	724	699	474
IDDM	233	232	223	205



PCI of Very Small Vessels (≤ 2.25 mm) in the RESOLUTE Global Clinical Program

RESOLUTE Pooled – Small Vessel

Baseline Patient Characteristics



%	XS Vessel ≤ 2.25 mm N = 1204	Small Vessel 2.25 – 2.75 mm N = 2773	P-value
Age (yr)	64.3 ± 10.7	63.6 ± 11.0	0.07
Men	71.4	73.0	0.33
Diabetes mellitus	35.5	33.0	0.12
IDDM	7.6	8.0	0.65
Hypertension	78.3	72.0	<0.001
Hyperlipidemia	69.6	63.3	<0.001
Current smoker	21.3	24.6	0.03
Family history of CAD	32.4	29.1	0.06
Prior MI	28.8	30.0	0.47
Prior PCI	32.6	25.7	<0.001
Prior CABG	8.2	5.8	0.005
<i>Reason for Revascularization:</i>			<0.001
Silent Ischemia	2.0	2.9	
Stable Angina	40.7	34.4	
Unstable Angina	36.9	36.9	
Myocardial Infarction	20.4	25.7	
STEMI	4.7	6.4	0.04

RESOLUTE Pooled – Small Vessel Lesion and Procedure Characteristics



%	XS Vessel N = 1204 pts, 1929 lesions	Small Vessel N = 2773 pts, 3902 lesions	P-value
Lesion location (lesion level):			0.83
LAD	42.5	44.9	
LCx	33.8	27.6	
RCA	22.4	26.3	
Left main	0.5	0.8	
B2/C Lesion class ACC/AHA	67.2	67.0	0.88
TIMI 3 flow	85.7	78.0	<0.001
Bifurcation	12.0	15.5	0.005
RVD¹	2.3 ± 0.4	2.7 ± 0.3	<0.001
MLD	0.6 ± 0.4	0.6 ± 0.4	0.002
Diameter stenosis	71.6 ± 16.4	77.3 ± 15.8	<0.001
Lesion length (mm)	15.2 ± 10.3	18.4 ± 11.2	<0.001
Lesions treated per patient	1.6 ± 0.8	1.4 ± 0.7	<0.001
Multi-vessel treatment	35.0	24.6	<0.001
Number of stents per patient	1.9 ± 1.2	1.7 ± 1.0	<0.001
Stent length per patient (mm)	37.4 ± 27.2	34.7 ± 23.5	0.002
Complex patients²	40.9	45.4	0.009

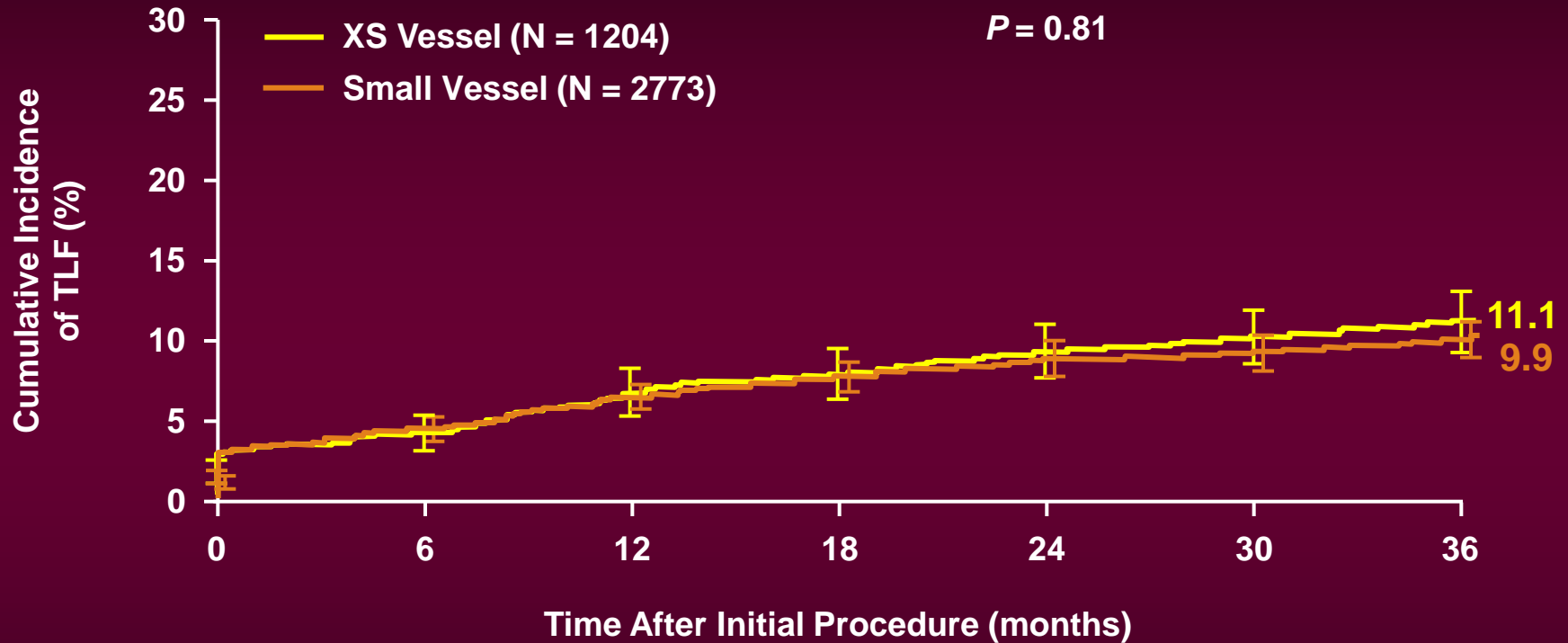
¹ RVD of all treated lesions of patients who have at least one XS vessel (RVD ≤2.25mm) stented.

² Complex patient definition: Bifurcation, Bypass grafts, ISR, AMI <72 hr, LVEF <30%, unprotected LM, >2 vessels stented, renal insufficiency or failure (creatinine >140 µmol/L), lesion length >27 mm, >1 lesion per vessel, lesion with thrombus or TO (preprocedure TIMI = 0).

RESOLUTE Pooled – Small Vessel



Target Lesion Failure to 3 Years



No. at risk

XS vessel	1204	1183	1144	1096	1074	817	799
Small vessel	2773	2742	2635	2550	2475	1757	1726



**Multi-Vessel Versus Single-Vessel
Treatment with Resolute Zotarolimus
Eluting Stent in the RESOLUTE
Global Clinical Program**

RESOLUTE Pooled – Multi-Vessel

Baseline Patient Characteristics

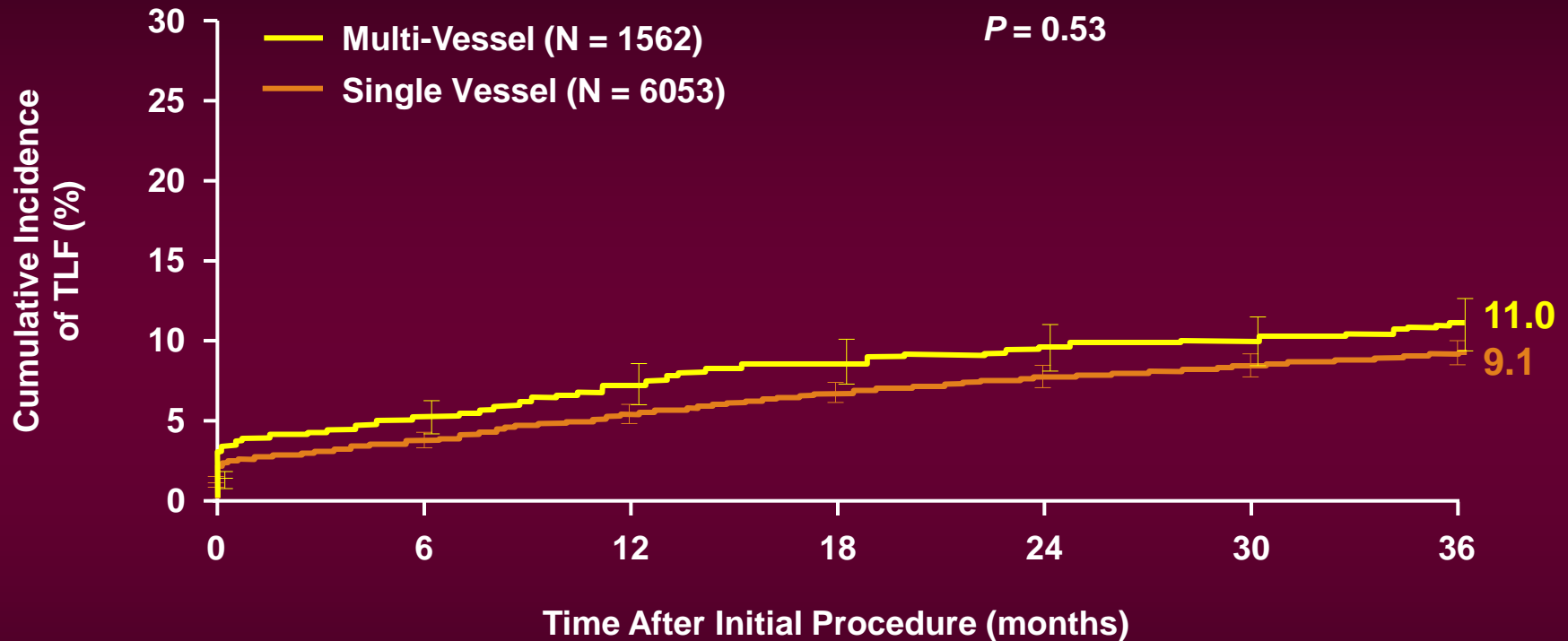


%	Single Vessel N = 6053	Multi-Vessel N = 1562	P-value
Age (yr)	63.0 ± 11.1	63.0 ± 10.6	0.99
Men	74.7	78.4	0.003
Diabetes mellitus	29.6	33.6	0.002
IDDM	6.9	6.1	0.31
Hypertension	71.0	70.7	0.80
Hyperlipidemia	63.8	56.5	<0.001
Current smoker	26.4	26.5	0.92
Family history of CAD	30.5	24.0	<0.001
Prior MI	29.0	30.0	0.47
Prior PCI	28.1	17.1	<0.001
Prior CABG	6.9	3.8	<0.001
<i>Reason for Revascularization:</i>			
Acute Coronary Syndrome	51.8	55.1	0.022
STEMI	7.9	6.0	0.017



RESOLUTE Pooled – Multi-Vessel

Target Lesion Failure to 3 Years



No. at risk

Multi vessel	1562	1543	1469	1421	1386	702	687
Single vessel	6053	5986	5771	5605	5447	4042	3957

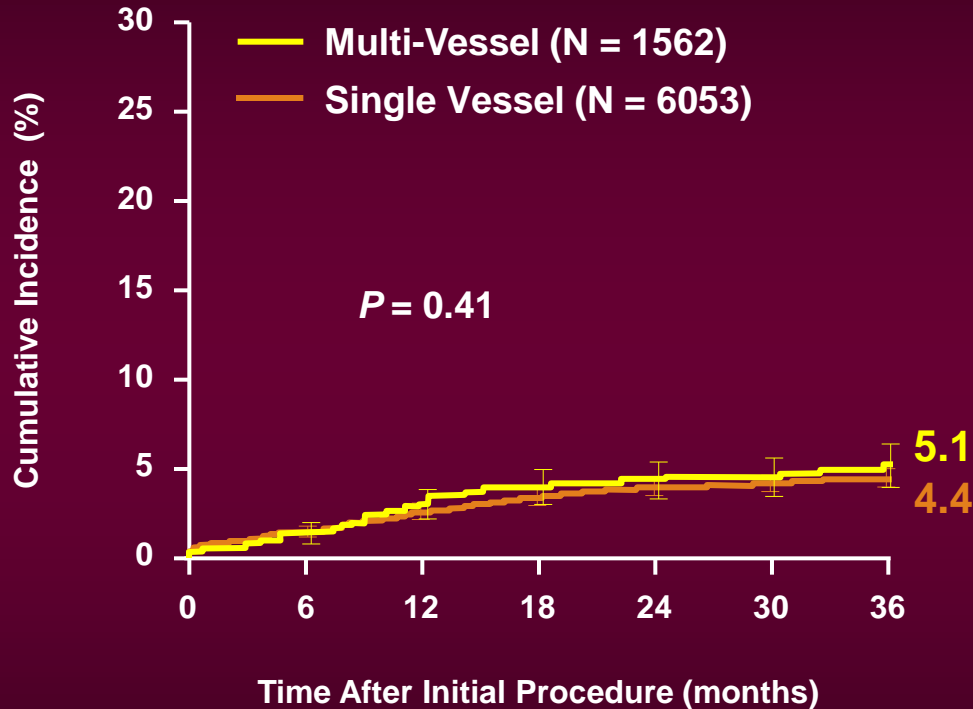
P-value adjusted by propensity score for differences in baseline characteristics



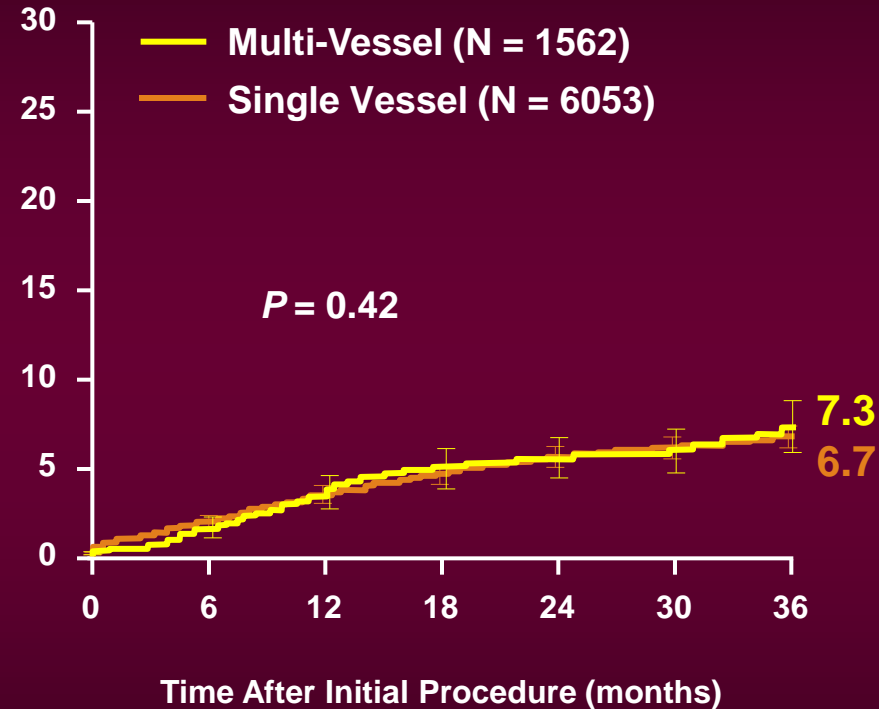
RESOLUTE Pooled – Multi-Vessel

Revascularization to 3 Years

TLR



TVR



No. at risk

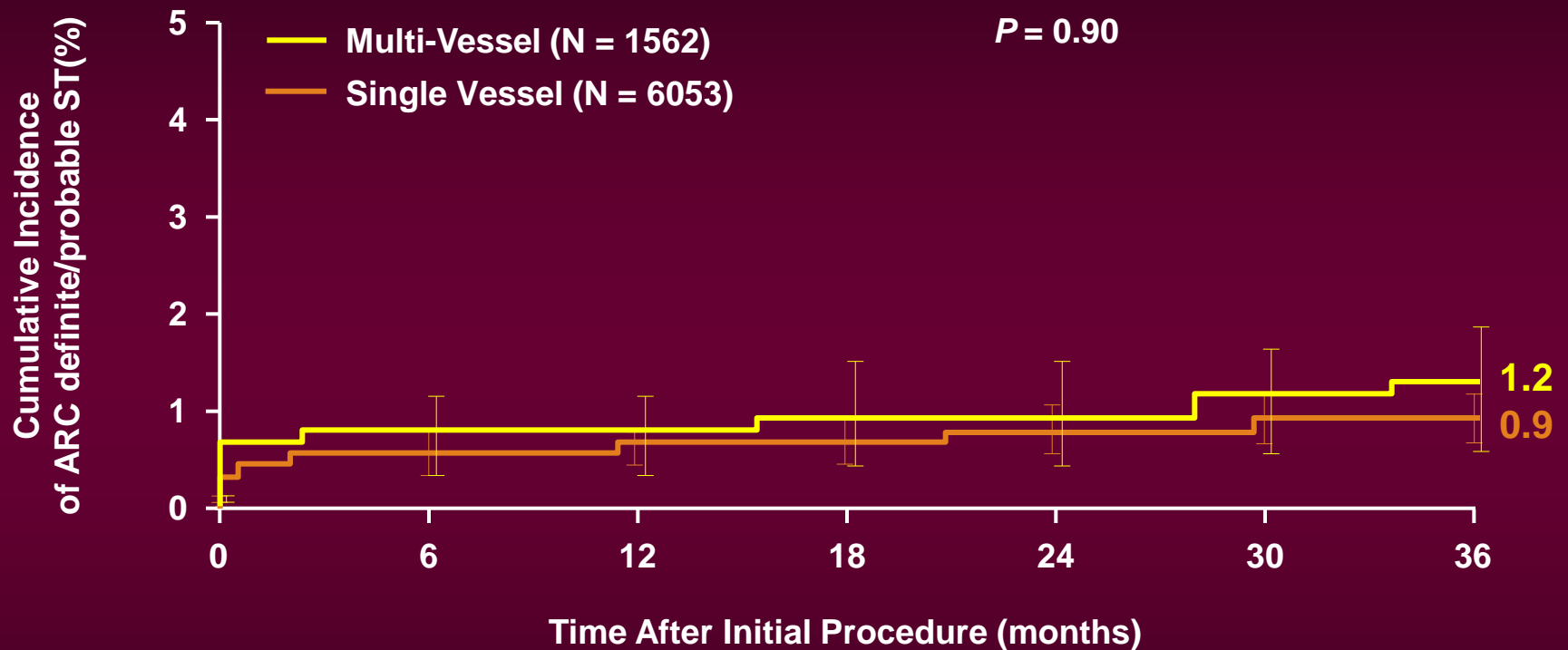
Multi vessel	1562	1562	1518	1468	1434	727	712
Single vessel	6053	6043	5884	5722	5565	4144	4060

1562	1562	1513	1458	1418	716	700
6053	6043	5848	5666	5489	4055	3961

P-value adjusted by propensity score for differences in baseline characteristics



RESOLUTE Pooled – Multi-Vessel Stent Thrombosis to 3 Years



No. at risk

	0	6	12	18	24	30	36
Multi vessel	1562	1560	1530	1506	1485	763	747
Single vessel	6053	6047	5937	5836	5723	4312	4229

P-value adjusted by propensity score for differences in baseline characteristics



Long-Term Clinical Outcomes For Primary Angioplasty with Resolute Zotarolimus Eluting Stent in Acute ST-Segment Elevation Myocardial Infarction

RESOLUTE All Comers: STEMI Subgroup

Baseline Characteristics

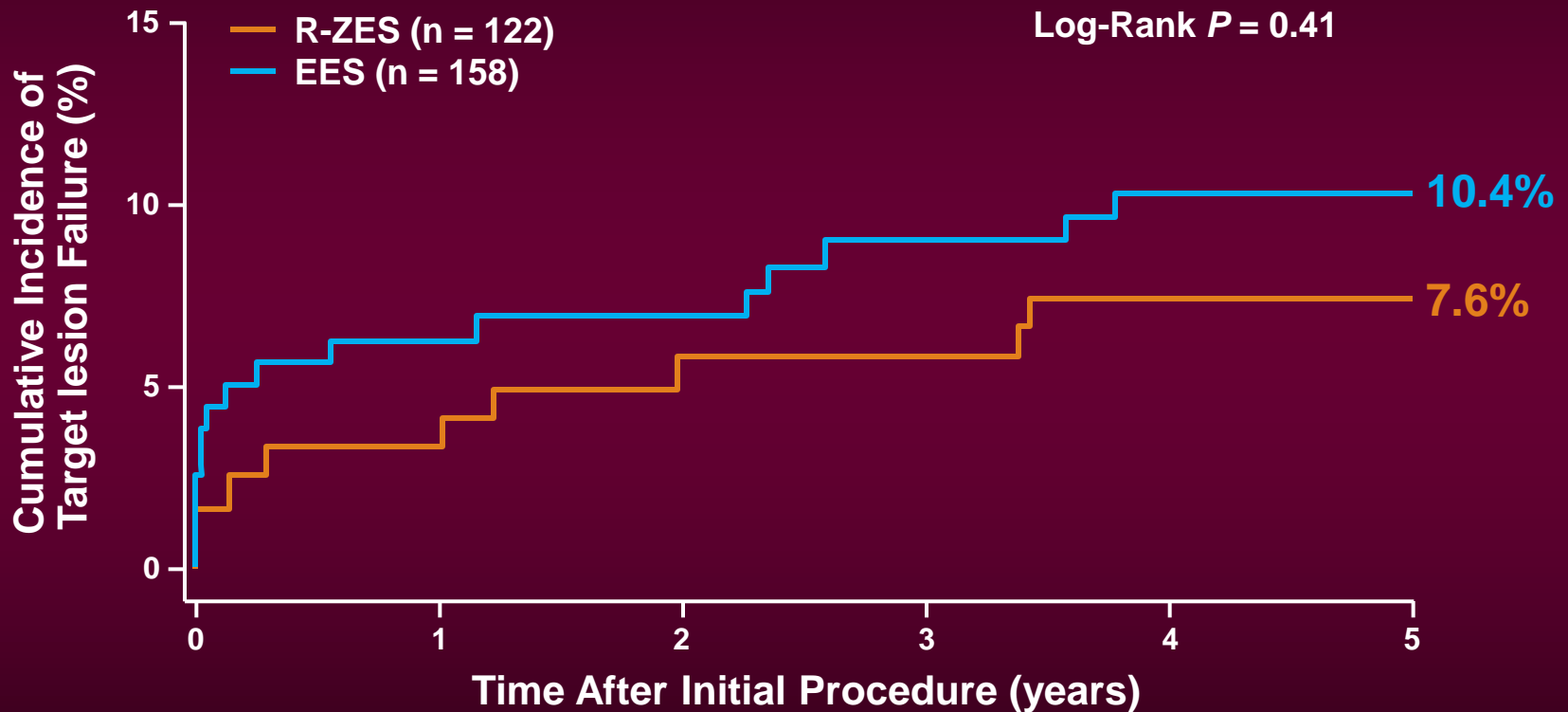


%	R-ZES N = 122 pts, 161 lesions	EES N = 158 pts, 231 lesions	P value
Age (yr)	59.7 ± 11.5	61.1 ± 11.2	0.29
Men	77.9	82.4	0.37
Diabetes mellitus	9.0	11.3	0.56
Prior MI	8.2	14.6	0.13
Prior PCI	5.7	8.2	0.49
≥1 Bifurcation	13.1	13.9	0.86
≥1 Total occlusion	52.5	51.6	0.91
Lesions treated per patient	1.3 ± 0.6	1.5 ± 0.9	0.10
Lesion length (mm)	11.3 ± 5.8	12.8 ± 7.3	0.10
No. of stents per patient	1.7 ± 1.1	2.1 ± 1.3	0.03
Stent length per patient (mm)	32.7 ± 19.8	39.5 ± 26.7	0.02



RESOLUTE All Comers: STEMI Subgroup

Target Lesion Failure to 5 Years



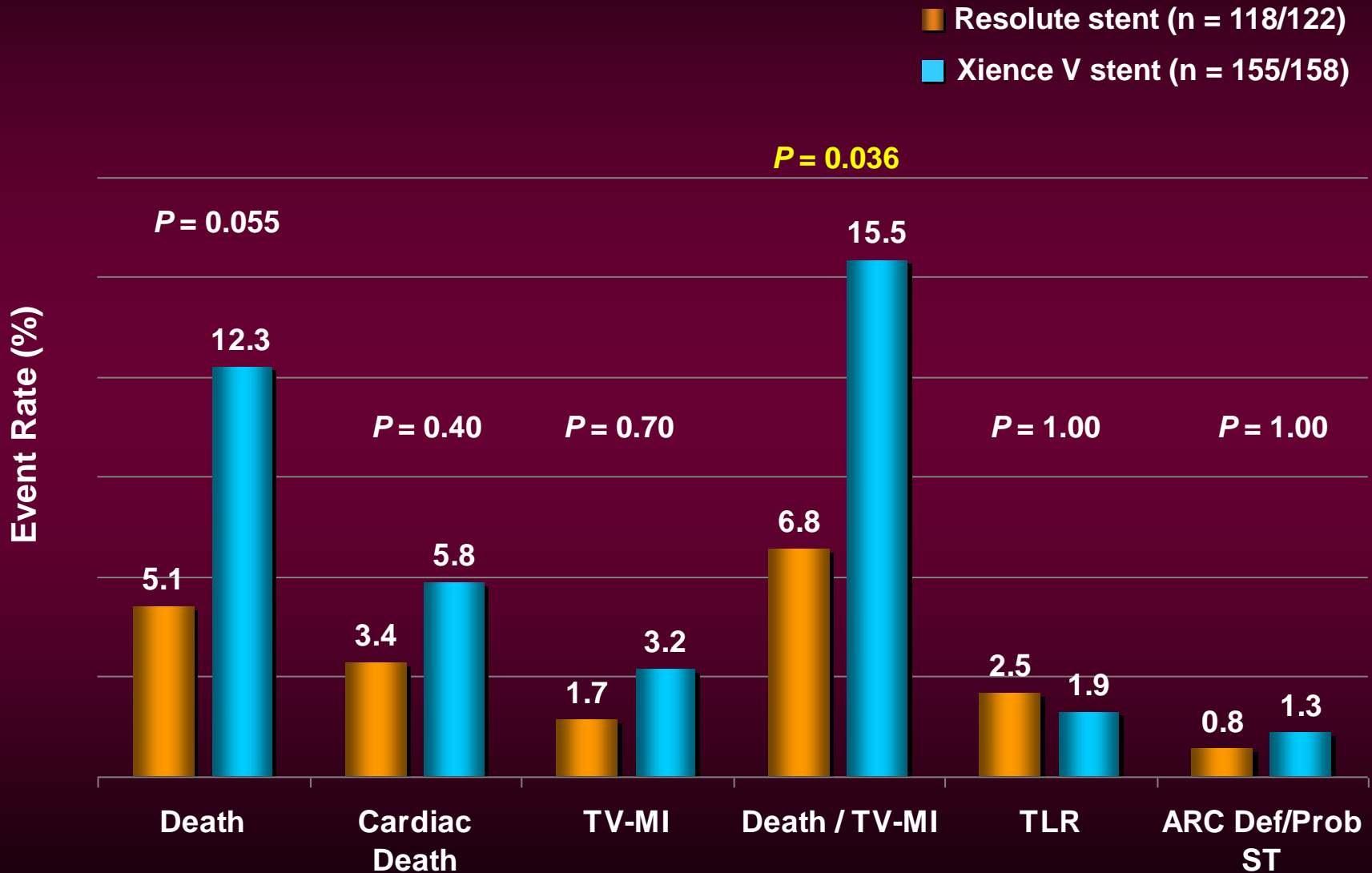
No. at risk

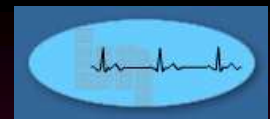
R-ZES	122	120	116	111	110	106
EES	158	156	144	141	135	131

RESOLUTE All Comers: STEMI Subgroup



Clinical Outcomes to 5 Year





SUMMARY of Safety Outcomes From The RESOLUTE Global Clinical Program

Similar clinical outcomes in:

Small vessels & very small vessels

Small vessels, diabetics vs non-diabetic
(higher outcomes in IDDM)

Multivessel vs single vessel PCI

Primary PCI Resolute vs Xience V stents