

Japan unprotected left main coronary artery disease PCI strategy on new generation stents (J-Lesson) registry

On behalf of the J-Lesson investigators

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Conflict statement

Speaker's name: Naoto Inoue

- **I have the following potential conflicts of interest to report:**
 - Consulting-Kaneka, Medicon, Japan Life Line
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest**

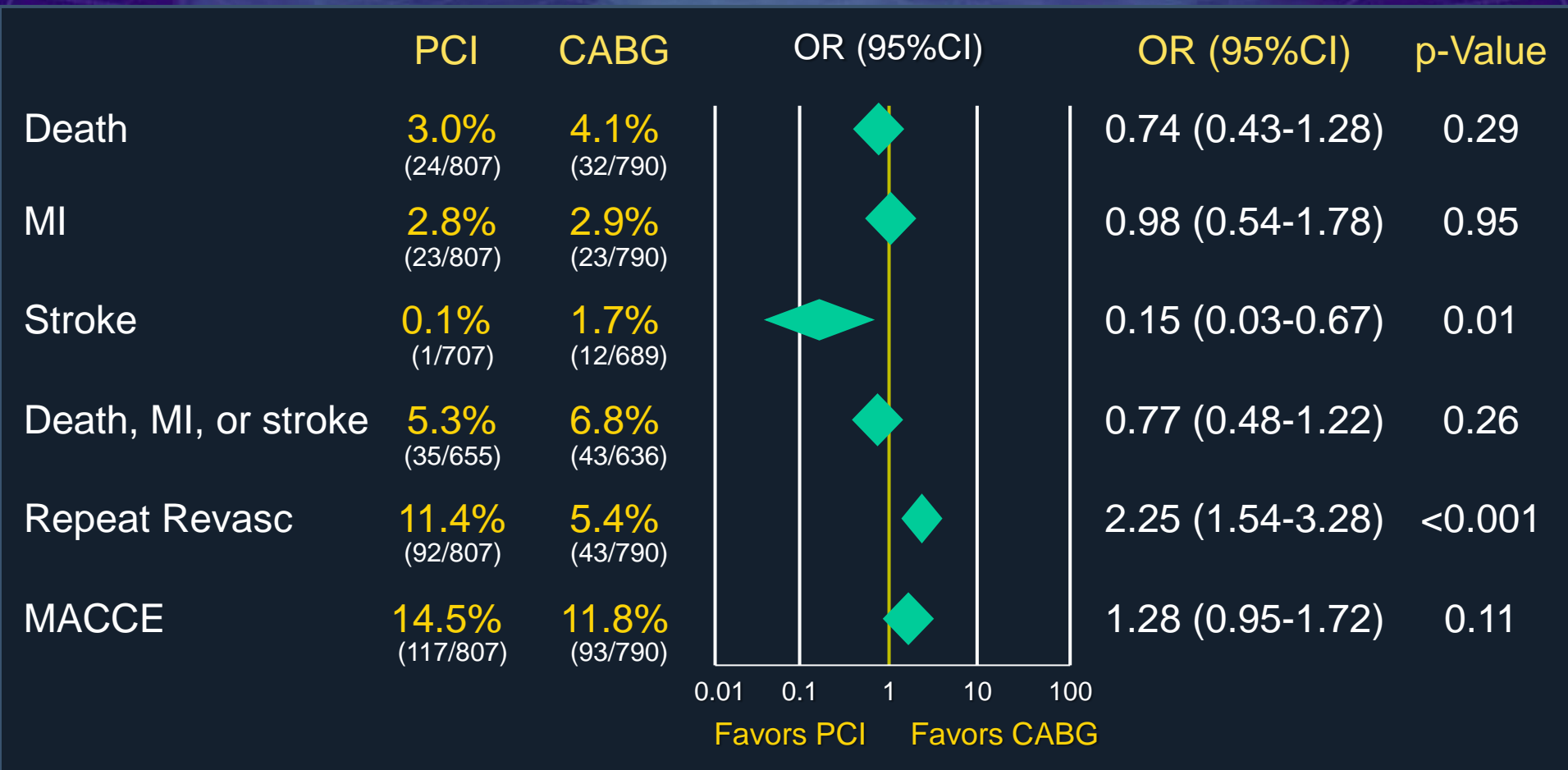
PCI (1st gen DES) vs. CABG for Left Main Ds. Meta-analysis of 4 RCTs, 1,611 Patients

Trial	LEMANS	SYNTAX LM	Boudriot et al.	PRECOMBAT
Year	2008	2009	2010	2011
N total	105	705	201	600
Age, mean years	61	65	68	62
Male	67%	74%	75%	77%
Diabetes	18%	25%	36%	32%
Distal LM involved	58%	61%	71%	65%
+0/1/2/3 VD, %	0/9/23/68	13/20/31/36	29/31/27/14	10/17/32/41
Syntax Score, mean	25	30	24	25
Log Euroscore, mean	3.4	3.9	2.5	2.7
LIMA-LAD	81%	97%	99%	94%

PCI (1st gen DES) vs. CABG for Left Main Ds.

Meta-analysis of 4 RCTs, 1,611 Patients

1-Year Outcomes



SYNTAX trial

De novo disease (n=1 800)

Limited Exclusion Criteria

- Previous interventions
- Acute MI with CPK > 2x
- Concomitant cardiac surgery

Left Main Disease
(isolated, +1, +2 or +3 vessels)

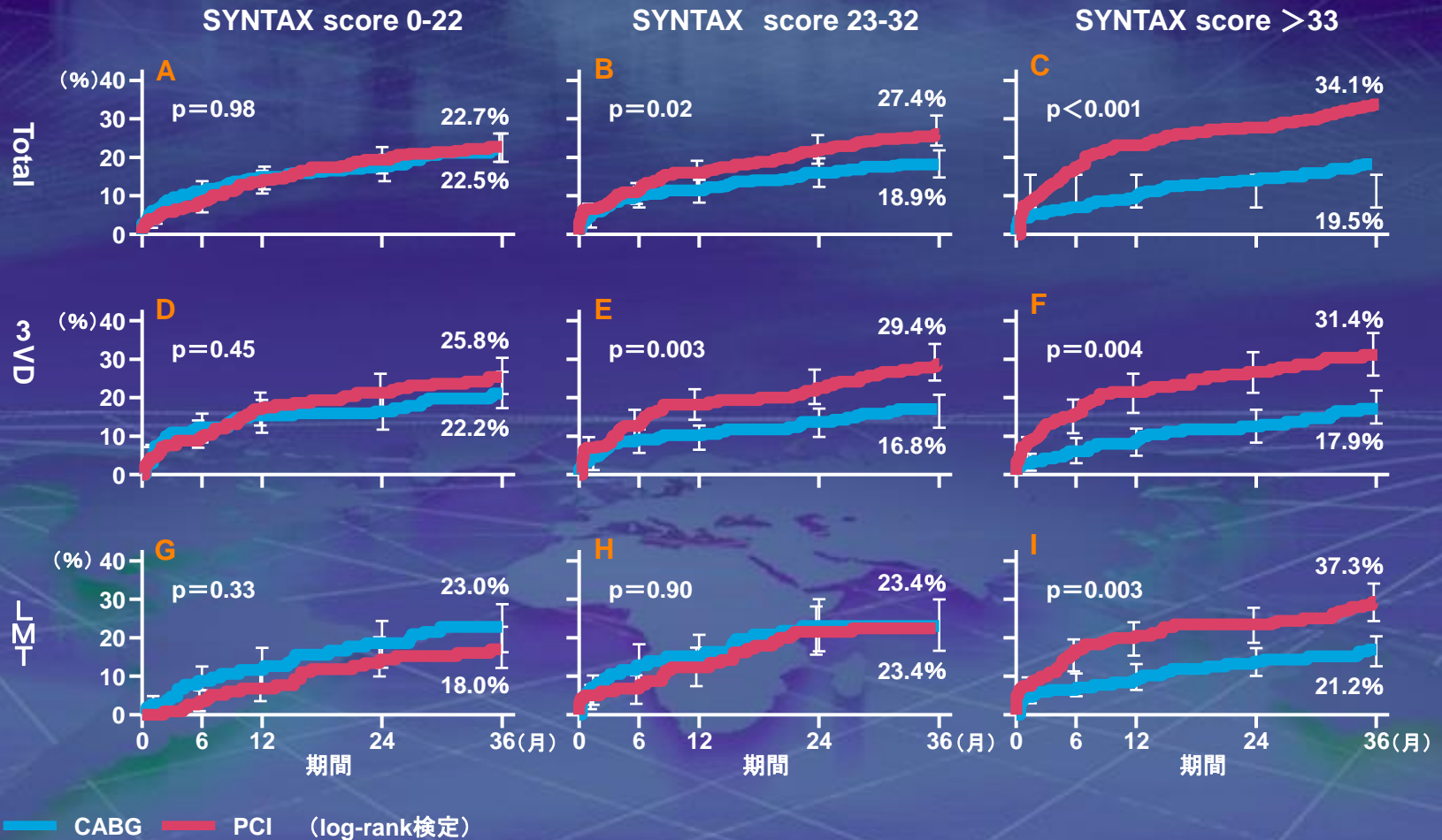
N=705

3 Vessel Disease
(revasc all 3 vascular territories)

N=1 095

Serruys PW et al. NEJM 2009;360:961-72

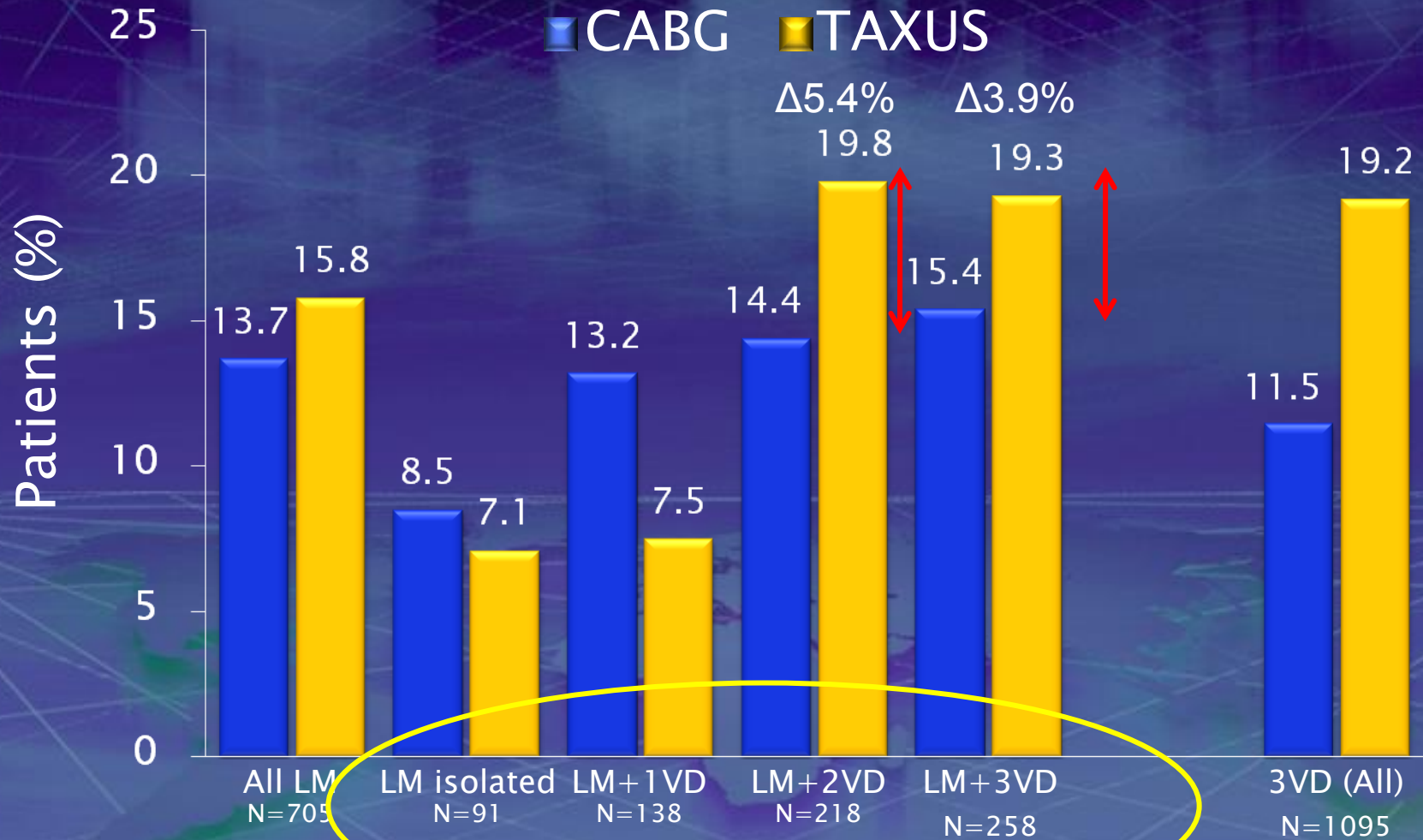
SYNTAX Trial 3-year follow up



Kappetein AP et al European Heart Journal 2011 ; 32 : 2125-2134

Left Main and Three Vessel Disease

Subgroup MACCE Rates at 12 Months



Comparisons for the LM and 3VD subgroups are observational only and hypothesis generating

J-LESSON

ESC 2014 Guideline

Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality

Recommendations according to extent of CAD	CABG		PCI		Ref ^c
	Class ^a	Level ^b	Class ^a	Level ^b	
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C	
One-vessel disease with proximal LAD stenosis.	I	A	I	A	107,108,160,161,178,179
Two-vessel disease with proximal LAD stenosis.	I	B	I	C	108,135,137
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score >32.	I	B	III	B	17
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B	17,157,175,176
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B	17,157,175,176
Three-vessel disease with a SYNTAX score >32.	I	A	III	B	17,157,175,176

CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease.

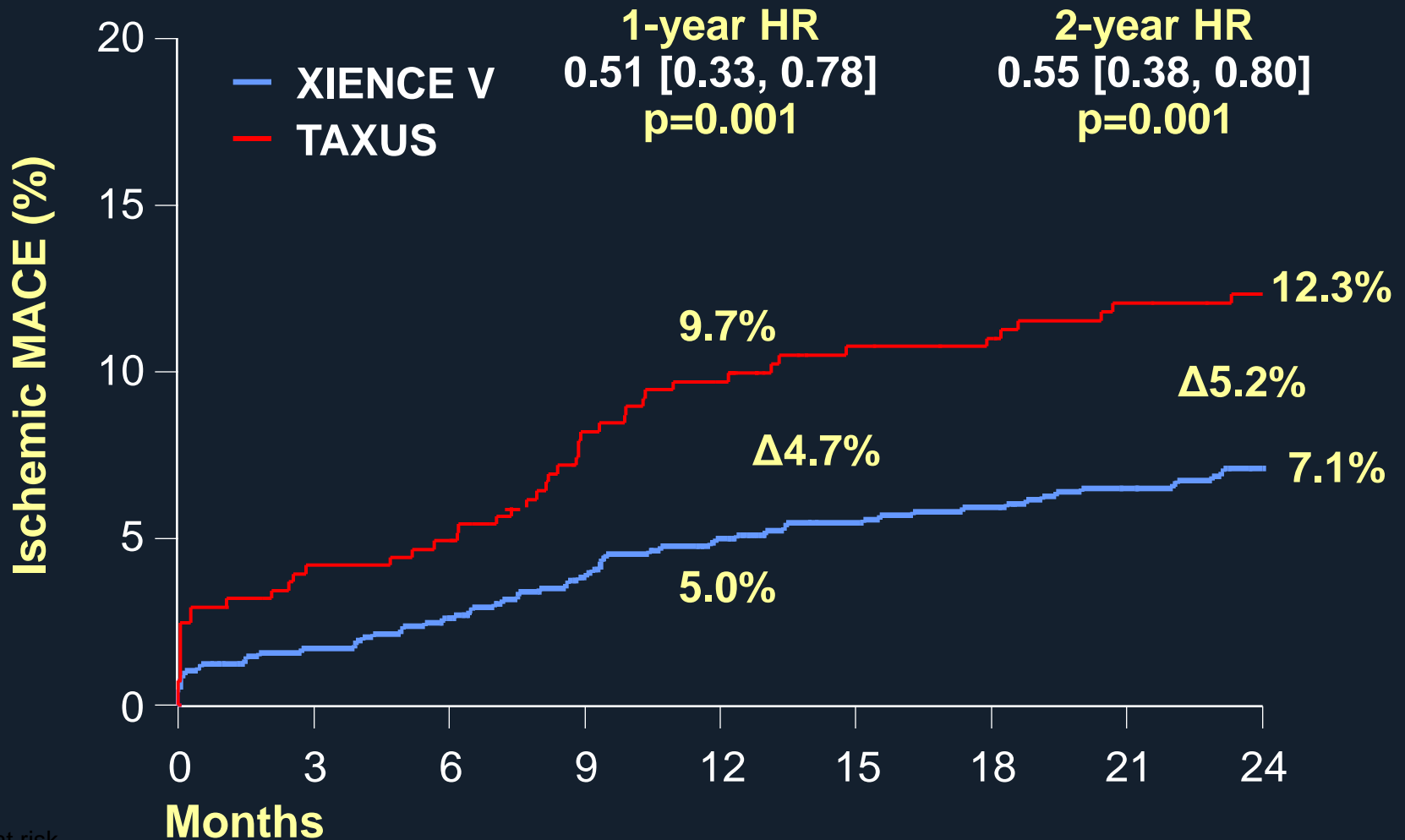
^aClass of recommendation.

^bLevel of evidence.

^cReferences.

The role of new generation stent for LMT disease

SPIRIT II + III: Ischemic MACE



Number at risk

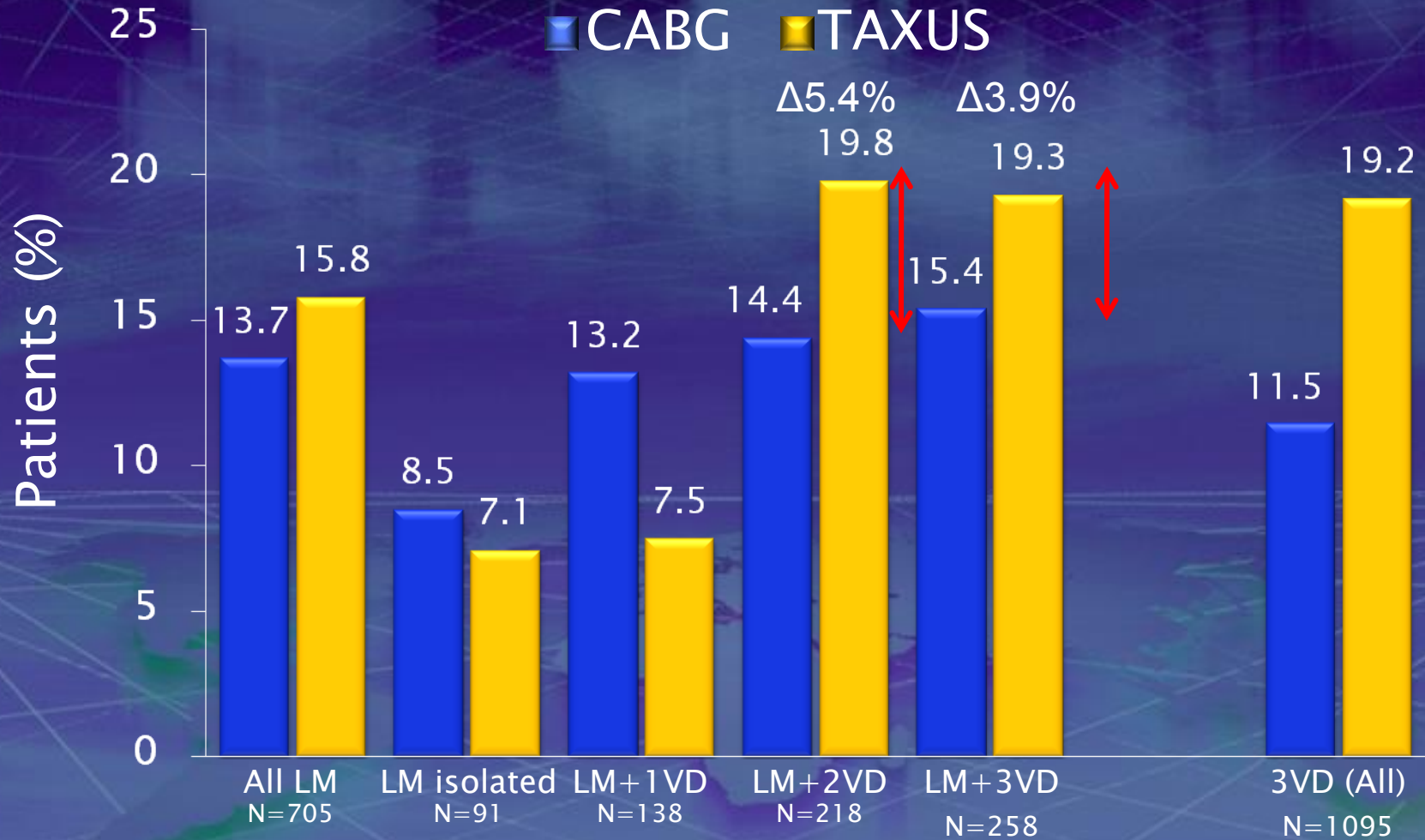
XIENCE V	892	871	859	841	827	804	800	790	783
TAXUS	409	386	381	363	354	340	335	332	329

MACE = Cardiac death, MI, or ischemic TLR

CVIT 2010 Global Discussion JCR 2015

Left Main and Three Vessel Disease

Subgroup MACCE Rates at 12 Months



Comparisons for the LM and 3VD subgroups are observational only and hypothesis generating

EXCEL: Study Design

4000 pts with left main disease

↓
SYNTAX score ≤ 32

Consensus agreement by heart team



Yes
(N=2500)

→ No

(N=1500)



PCI and CABG
registries
(limited in-hosp data)

R



PCI (Xience Prime)
(N=1250)

CABG
(N=1250)

Clinical follow-up: 30 days, 6 months, yearly through 5 years

J-LESSON

Japan Unprotected Left Main Coronary artery
Disease PCI Strategy On New Generation Stents

Study design

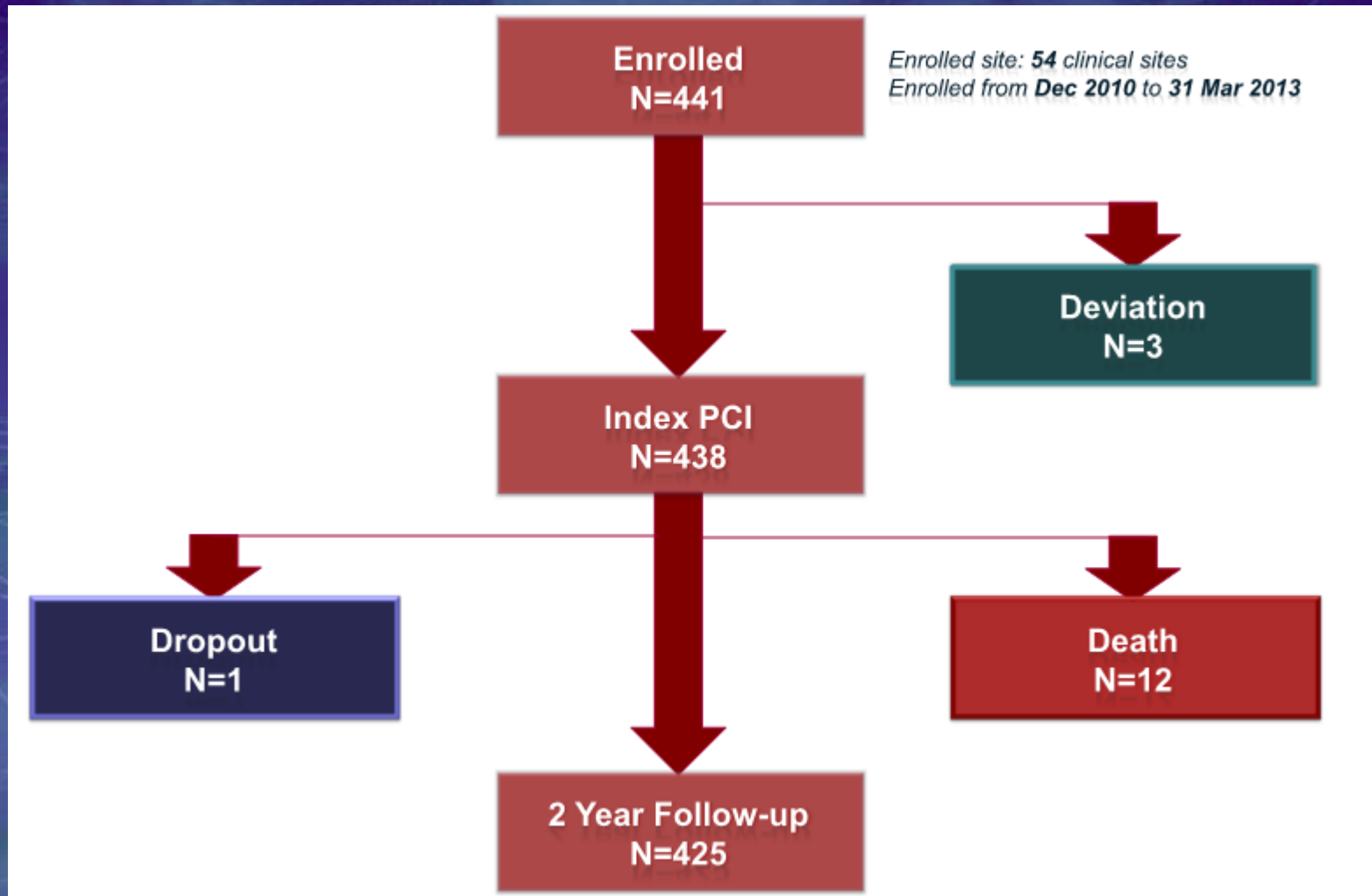
Multicenter Prospective Registry of PCI with a New Generation Everolimus-eluting Stent for Unprotected Left Main Coronary Artery Disease

- Evaluate the incidence of major adverse cardiac and cerebrovascular events (MACCE), target vessel failure (TVF), and stent thrombosis out to 3 years after the procedure in patients who underwent percutaneous coronary intervention (PCI) with everolimus-eluting stents for unprotected left main coronary artery (ULMCA) disease and lesions involving the ULMCA in Japan.

The difference in procedures in Japan and those in Western nations

- frequent introduction/use of IVUS at early clinical treatment would influence the treatment results.
- Follow up angiography is common and can be covered by insurance.

Two-year outcomes of Japan unprotected left main coronary artery disease PCI strategy on new generation stents (J-Lesson) registry



Patient's characteristics

	438 (%)
Age (>65 years)	363(82.9)
Male	336(76.7)
Clinical presentation	
SAP	227(51.8)
UAP	91(20.8)
Silent myocardial ischemia	95(21.7)
others	25(5.7)
DM	177(40.4)
Hyperlipidemia	335(75.5)
Hypertension	350(79.9)
Smoking	262(59.8)
Prior history of PCI	161(36.8)
Prior history of CABG	4(0.9)
Previous MI	79(18.0)
Cerebral vascular disease	9(8.9)
PAD	33(7.5)

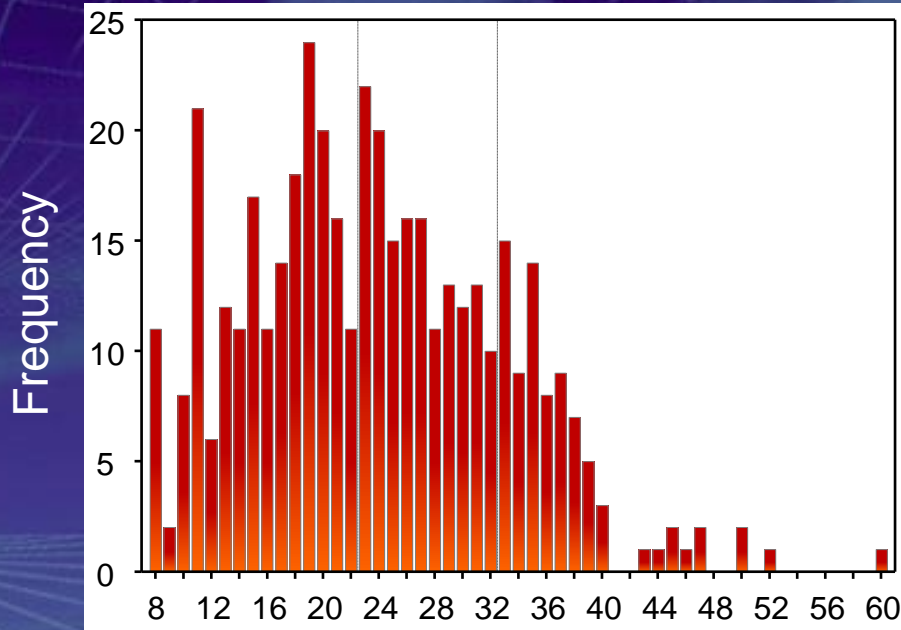
Lesion location of LMT and stenting

Case n=438 (%)		All (438)	
Ostial	50 (11.4)	Single cross over	390(89.0)
Body	16(3.7)	Culotte	20(4.6)
Bifurcation	372(84.9)	T-stenting	23(5.3)
		Crush stent	3(0.7)
		Kissing stent	2(0.5)
Bifurcation		Medina 1-1-1(75)	
(1.0.0)	60(16.1)	Single cross over	36(48.0)
(1.1.0)	194(52.2)	Culotte	18(24.0)
(0.1.0)	26(7.0)	T-stenting	17(22.7)
(1.0.1)	16(4.3)	Crush stent	2(2.7)
(0.1.1)	1(0.3)	Kissing stent	2(2.7)
(0.01)	0(0)		
(1.1.1)	75(20.2)		

Angiographic and procedural findings

	438 (%)
LMT only	220 (50.2)
LMCA at bifurcation	372 (84.9)
LMT+other vessel	218 (49.8)
+1 vessel	75 (40.0)
+2 vessels	39 (8.9)
+3 vessels	4 (0.9)
IVUS usage	
pre	421 (93.8)
post	427 (97.5)
Stent (min- max)	
No. of stent/lesion	1.3 (1.0-5.0)
stent length	29.3 (6.0-96.0)

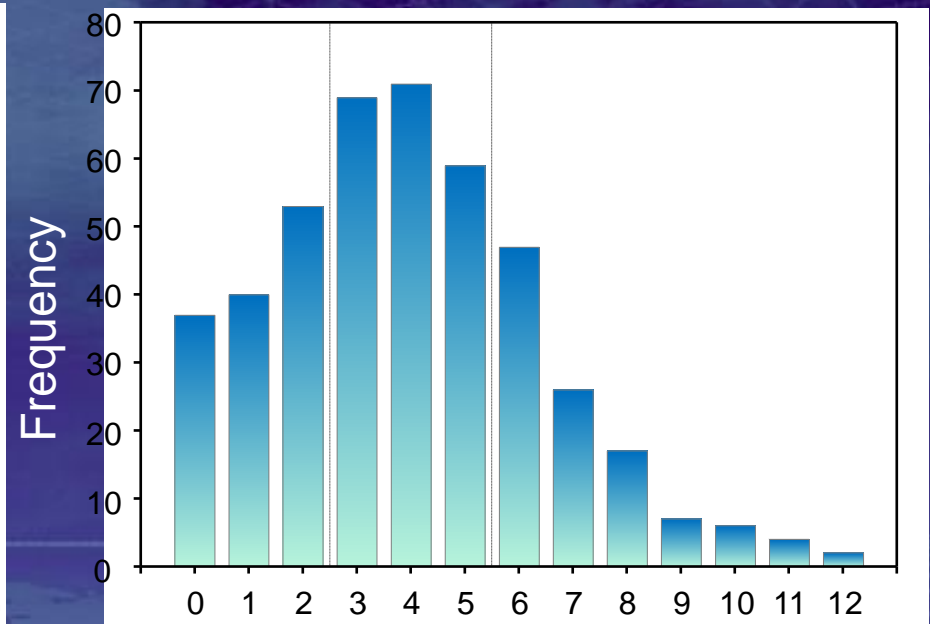
Distribution: EuroSCORE, and SYNTAX Score



Baseline SYNTAX Score

	n	%
SYNTAX Score ≤ 22	202	47.1
23-32	146	34.0
≥ 33	81	18.9

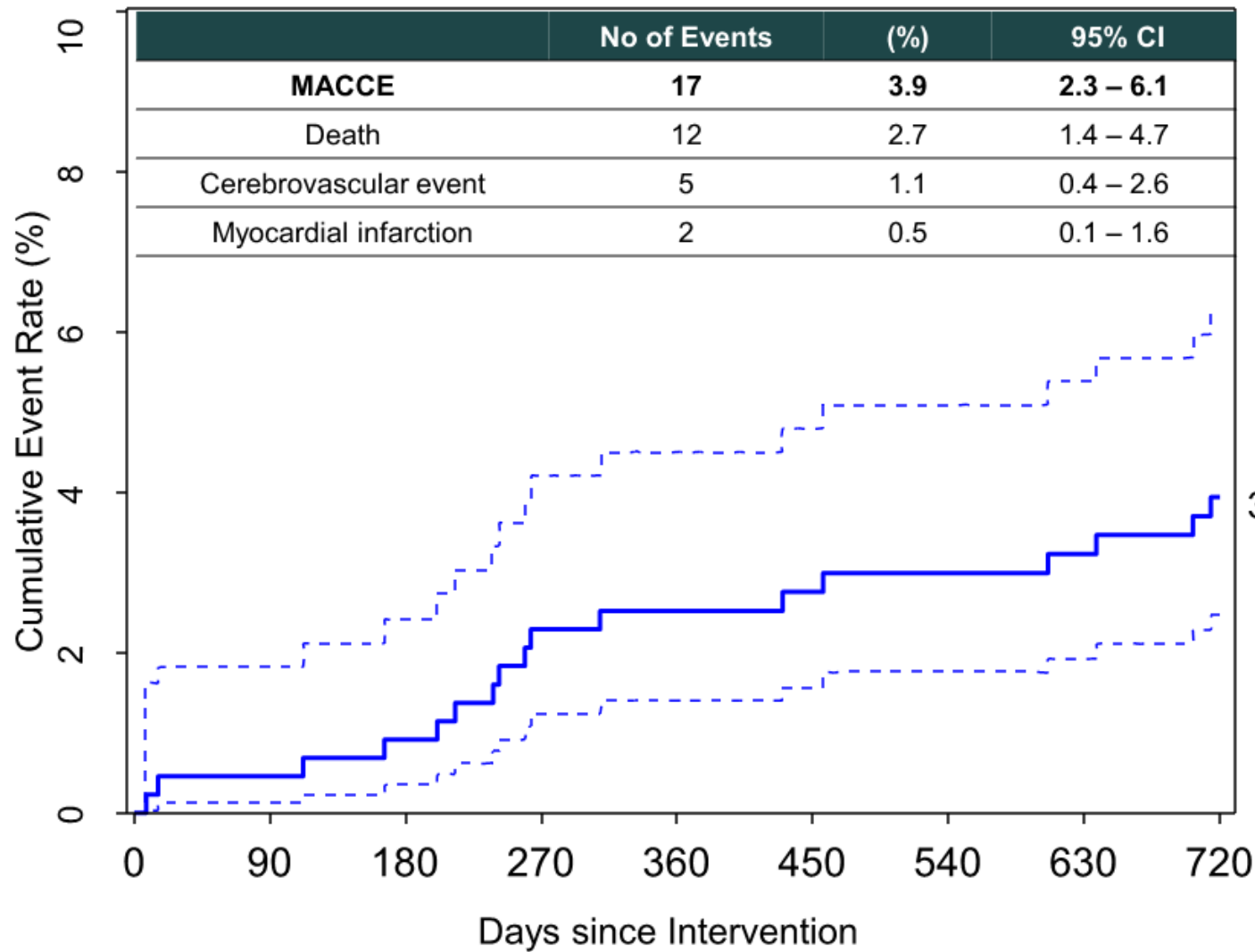
Mean \pm SD 23.8 \pm 9.1



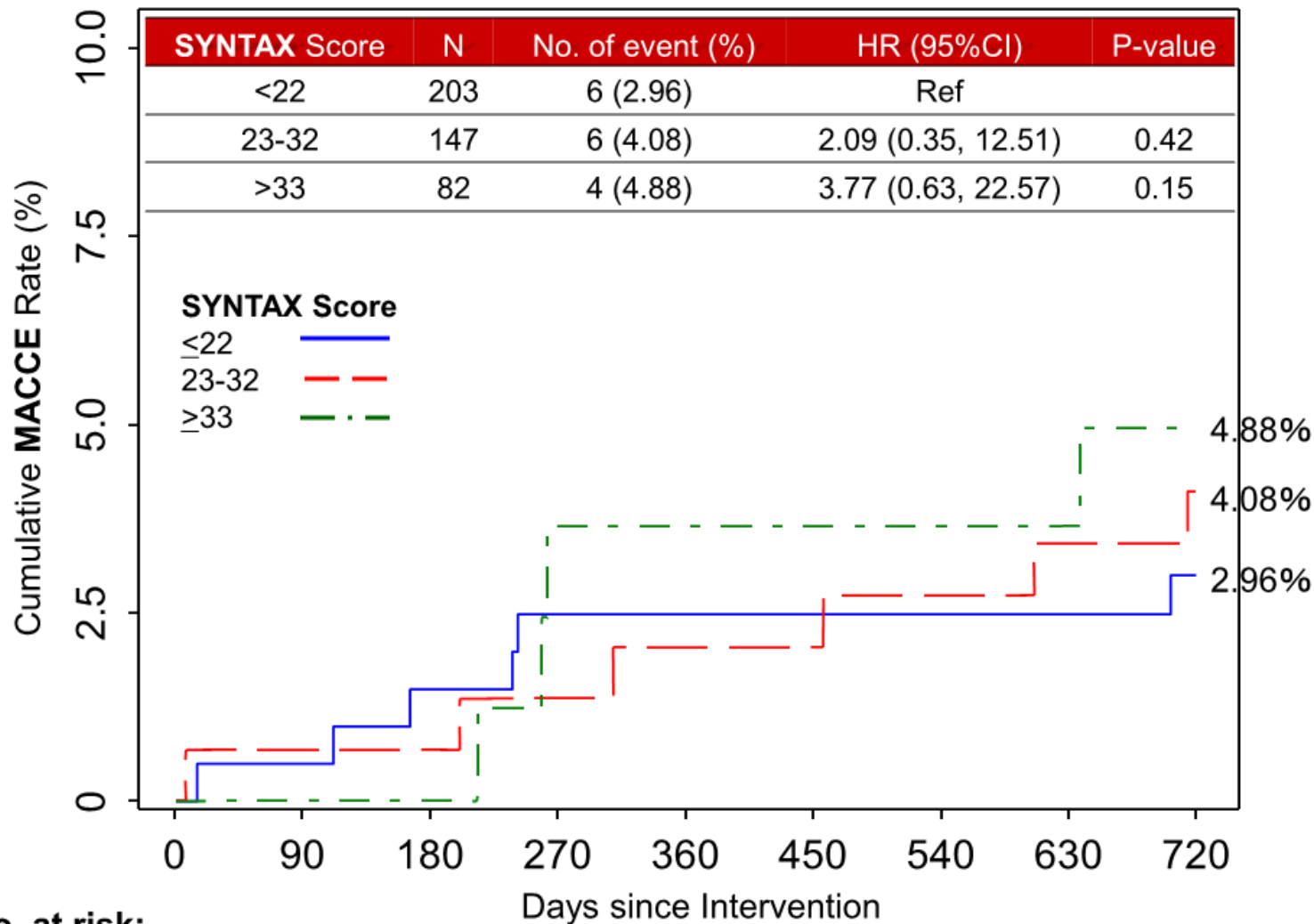
Baseline EuroSCORE

	n	%
EuroSCORE 0-2	130	29.7
3-5	199	45.4
≥ 6	109	24.9

Mean \pm SD 3.9 \pm 2.5



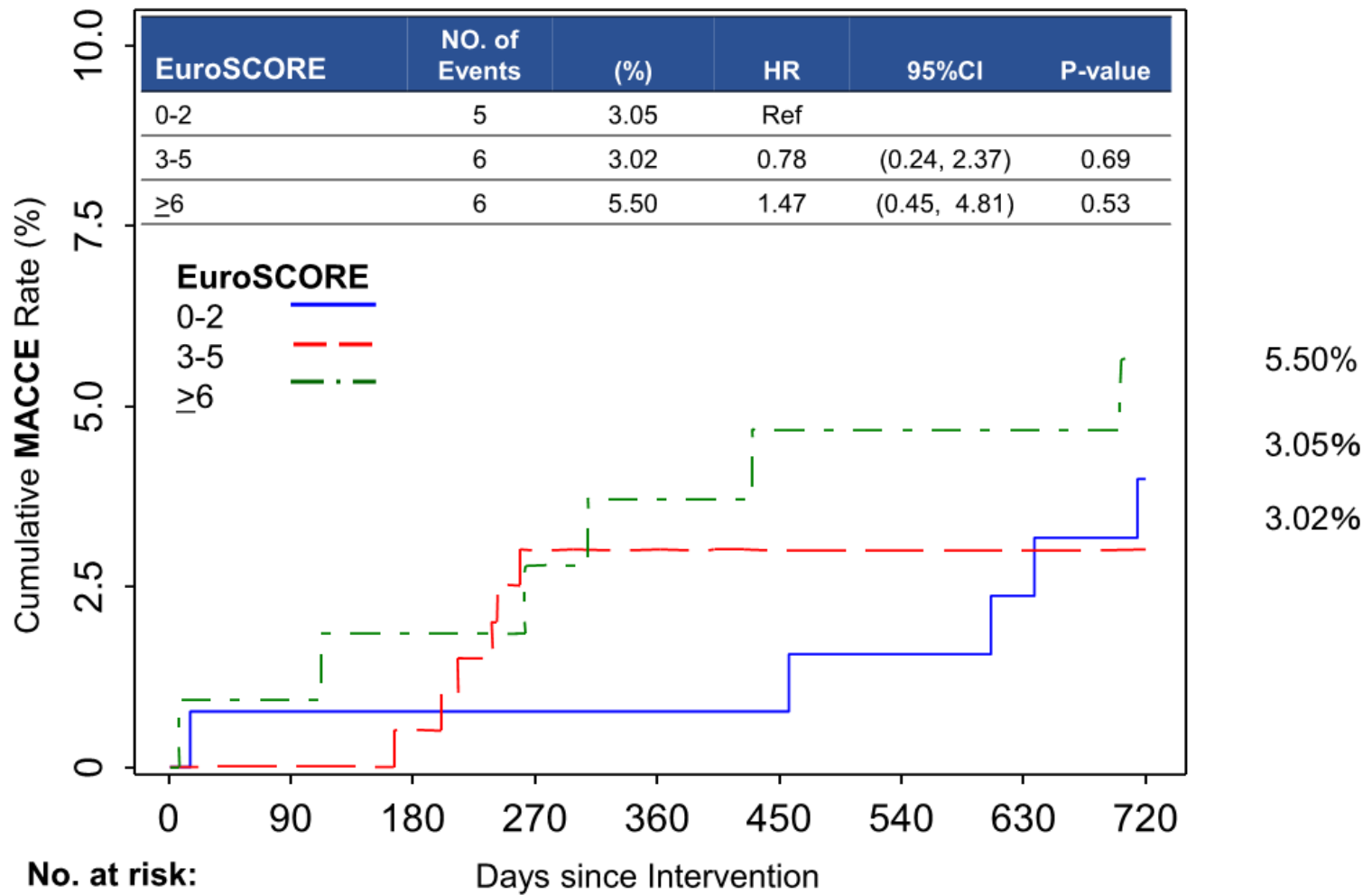
No. at risk: 438 436 434 427 420 413 411 409 405



No. at risk:

SYNTAX Score

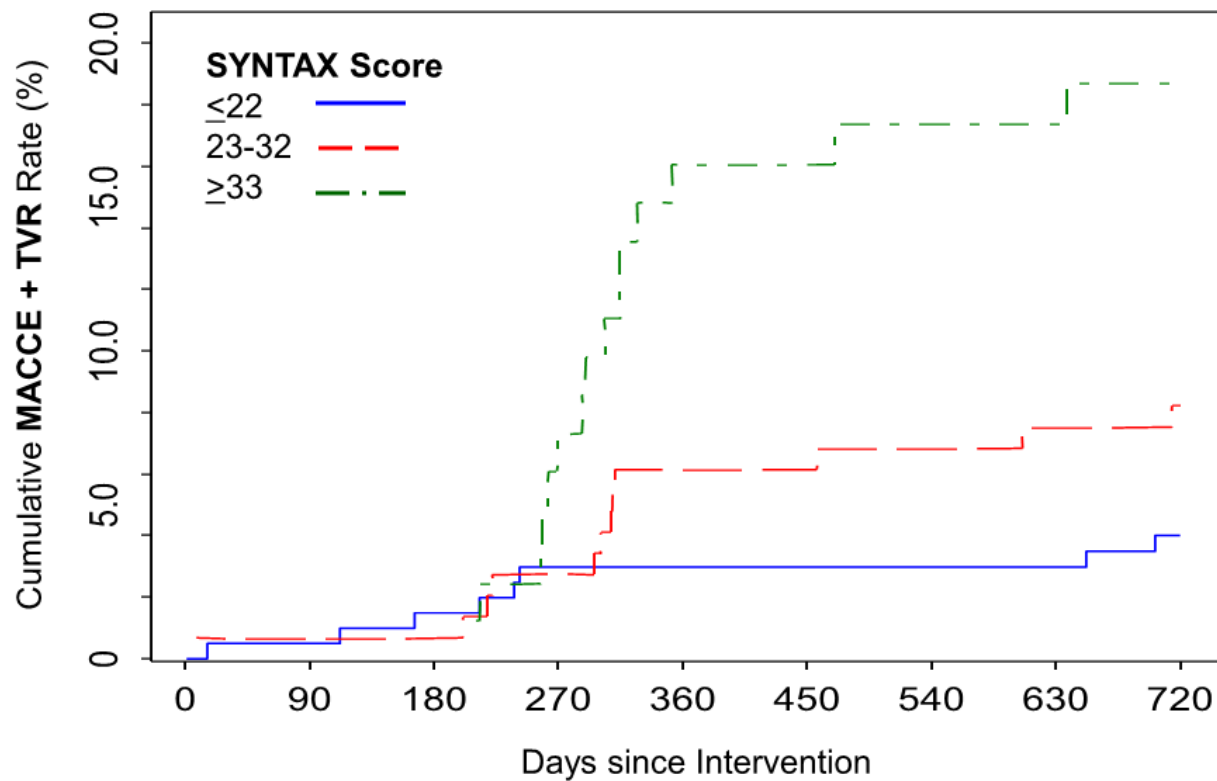
<22	203	202	200	197	195	193	191	191	189
23-32	147	147	147	146	144	143	143	141	140
>=33	82	82	82	81	78	75	75	74	74



No. at risk:
SYNTAX
Score

0-2	130	130	130	130	127	127	124	122	120
3-5	199	199	199	194	192	189	189	189	189
≥6	109	108	107	105	103	100	100	100	99

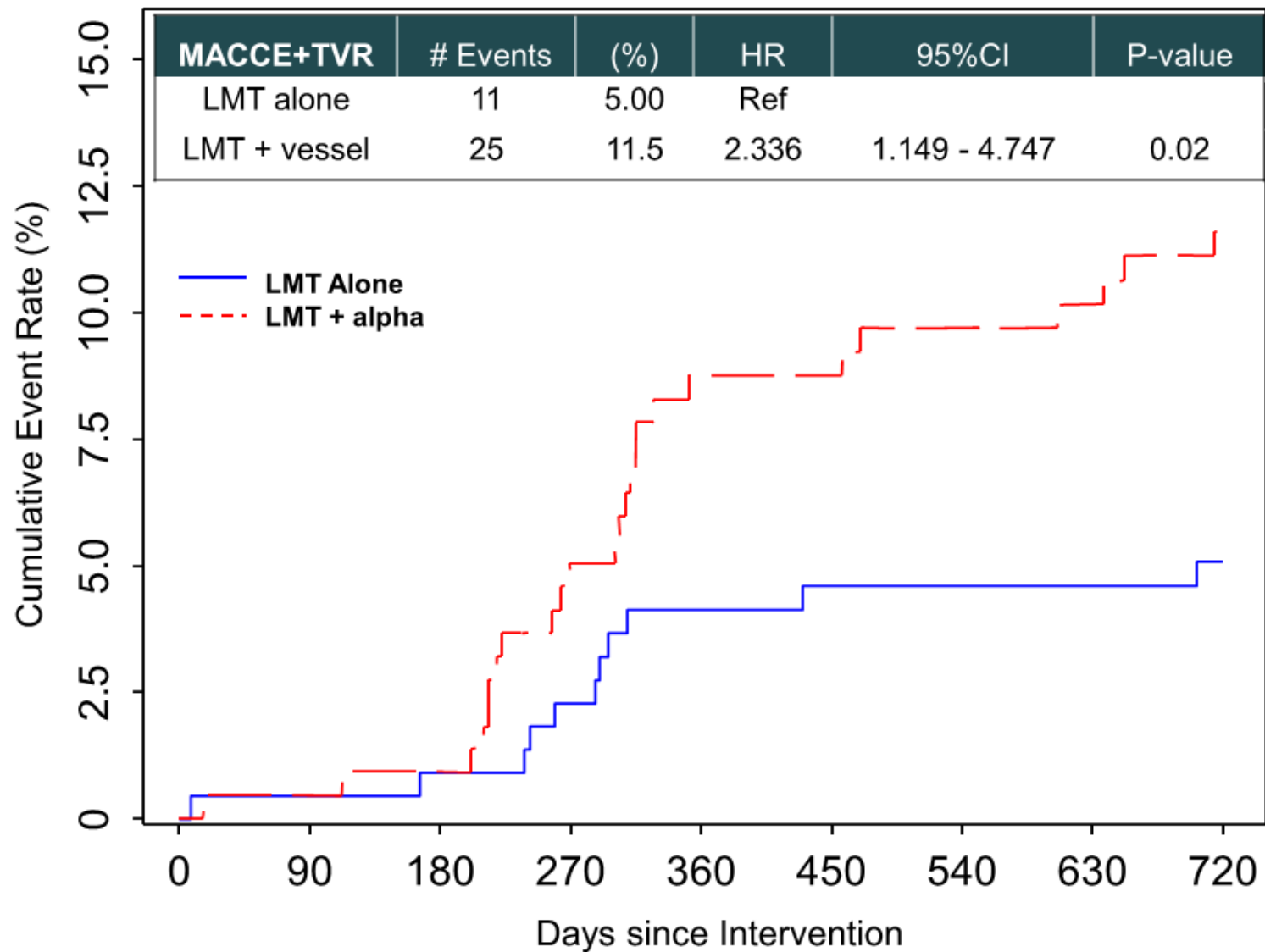
SYNTAX Score	NO. of Events	N	(%)	HR	95%CI	P-value
≤22	8	203	3.94	Ref		
23-32	12	147	8.16	2.08	0.85 – 5.09	0.11
≥33	15	82	18.29	4.97	2.11 – 11.73	0.0003



No. at risk:

SYNTAX Score

≤22	203	202	200	196	194	192	191	190	186
23-32	147	147	147	144	138	137	136	135	133
≥32	82	82	82	77	68	65	64	64	62



# at risk							
LMT alone	220	219	218	215	206	202	201
201	198						
LMT+alpha	218	218	217	207	198	195	193
191	187						

Conclusion in J-Lesson

- A total of 453 patients undergoing EES deployment for UPLMT was evaluated at 2year.
- More than 95% of patients were treated by IVUS guidance.
- Both SYNTAX score and Euro score did not affect on the incidence of MACCE.
- The incidence of future TVR was associated with SYNTAX score, but Euro score did not.
- Pts with LMT lesion alone has a lower risk of future TVR.
- This study confirmed that SYNTAX score is useful tool to discriminate the risk of TVR.

The background is a dark blue gradient with a faint, light blue grid pattern. A world map is visible, rendered in a lighter blue color, showing the continents. The text "Thank you!" is centered in a large, white, sans-serif font.

Thank you!