

DELTA 2: A Prospective, Multicenter Registry Evaluating New Generation Drug-Eluting Stents in Patients with Obstructive Left Main Coronary Artery

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on behalf of the DELTA-2 Investigators

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Disclosure Statement of Financial Interest

I, Davide Capodanno, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Patients Enrollment in DELTA 2

From 19 Centers 7 Countries

Italy n= 1383

- San Raffaele Scientific Institute
- EMO-GVM Centro Cuore Columbus
- A.O. Ordine Mauriziano Umberto I
- Ferrarotto Hospital
- University of Catania
- University of Turin
- S. Giovanni Battista Hospital
- A.O.U San Luigi Gonzaga
- Infermi Hospital
- Humanitas Research Hospital

Latvia n= 719

- Latvian Centre of Cardiology
- Pauls Stradins Clinical University Hospital

France n= 601

- Institut Hospitalier Jacques Cartier
- Clinique Pasteur

US n= 463

- Mount-Sinai Medical Center

Netherlands n= 428

- Erasmus Medical Center Thorax center

Japan n= 382

- New Tokyo Hospital

Switzerland n= 10

- University Hospital of Zurich

DELTA 2

LM PCI with 2nd generation DES data
received from 19 centers (N=4635)

→ Protected N=468

→ Not 2nd DES N=142

- 1st DES N=77

- BMS N=43

- BVS N=22

→ No LM stenosis N=23

→ After the period N=11

→ Others N=5

**DELTA 2 enrollment
(N=3986)**

DELTA II: Endpoints

Primary Endpoint

- Incidence of death, MI, and CVA at follow-up

Secondary Endpoint

- Death (overall + cardiac)
- Death + MI
- MACCE (Death + MI + CVA + TVR)
- TVR

Same Endpoints/ Definitions as DELTA I

Statistical Analysis

- Individual patient data was pooled in a single pre-specified structured dataset and analyzed with a single-stage approach
- Event rates (with 95% CI) and absolute rate differences at follow-up were estimated with the Kaplan-Meier method as time-to-first event
- Predictors for endpoint events were estimated with multivariable Cox regression analysis
- In order to account for pre-treatment differences between the DELTA-2 PCI cohort and the historical DELTA-1 CABG cohort a propensity score was generated by means of a logistic regression model. Calibration of the logistic regression model was assessed with the Hosmer-Lemeshow test. Subsequently, Cox regression models stratified by quintiles of propensity score were performed to estimate differences between treatments
- The proportionality assumption of the Cox regression models was tested with the Schoenfeld residual method. If the proportionality assumption was violated, the exposure was modeled as a time-dependent covariate
- Multicollinearity across covariates in the multivariable model was assessed with the VIF, with $VIF > 10$ indicating significant multicollinearity
- A level of $p < 0.05$ was set as statistically significant. Analyses were performed with STATA and SPSS softwares

Baseline characteristics (1)

	N=3986
Age, y	69.6±10.9
Male	74.5%
Hypertension	78.2%
Dyslipidemia	72.7%
Diabetes	30.8%
Insulin	7.6%
Current smoking	15.8%
Smoker history (current + ex)	35.7%
Family history of CAD	28.7%
Chronic kidney disease	31.2%
Previous MI	28.2%
Previous CABG	8.3%
Previous PCI	41.5%
LVEF, %	53±11

Baseline characteristics (2)

	N=3986
<i>Clinical presentation</i>	
Stable angina/Silent ischemia	63.9%
Unstable angina	15.2%
NSTEMI	14.8%
STEMI	6.2%
Multivessel disease	74.3%
LAD/CX disease	87.7%
RCA disease	48.3%
SYNTAXscore	27.0 ± 10.6
<i>Lesion location</i>	
Ostial/shaft only	15.4%
Involving Distal-Bifurcation	84.6%
True bifurcation	39.8%

Procedural characteristics (1)

	N=3986
Elective	71.8%
Urgent/Emergent	28.2%
Radial access	39.3%
No of vessel treated	1.6±0.7
No of lesion treated	1.9±1.0
IVUS use	36.1%
IABP	6.7%

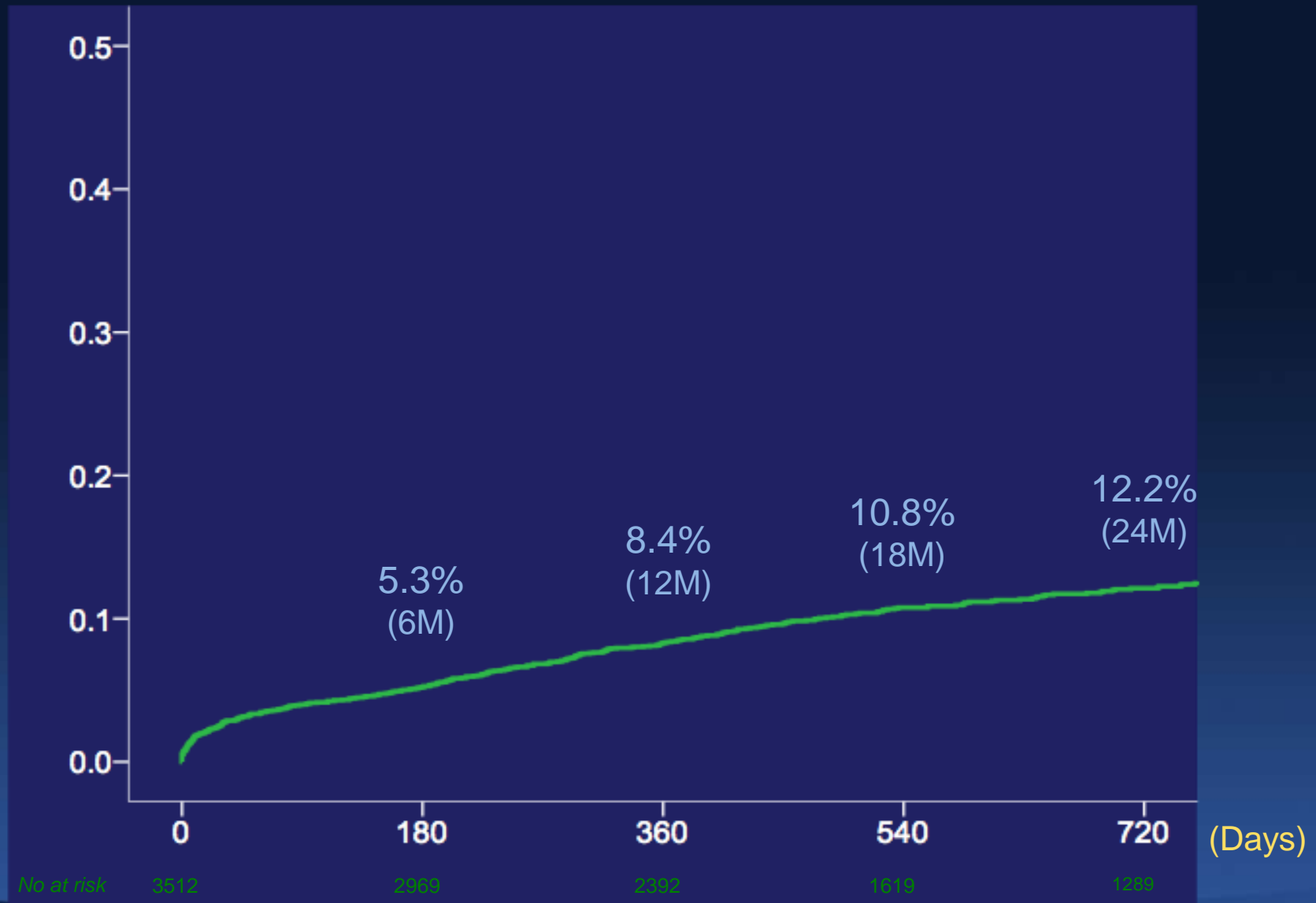
Procedural Characteristics (2)

	N=3986
Pre-dilatation	71.1%
Rotablator	6.1%
Post-dilatation	86.6%
Max balloon diameter	4.0±0.5 mm
Maximum pressure	18.5±4.7 atm
Kissing balloon inflation	48.2%
DES type	
EES	74.9%
ZES	9.1%
BES	13.1%
SES	2.9%
LM stent diameter	3.6±0.4 mm
Total stent length	27.1±19.6 mm
Bifurcation 2 stenting	20.4%

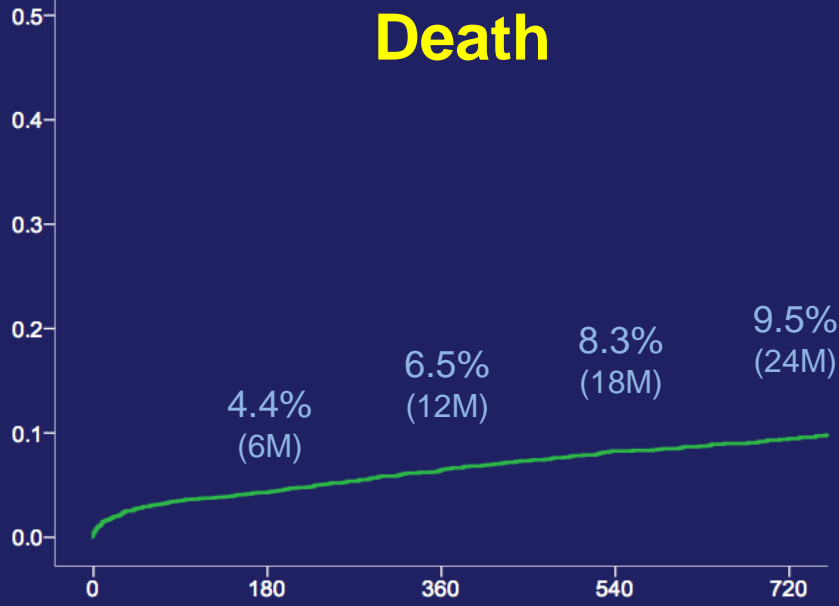
In-hospital Outcomes

	N=3986
All cause death	1.3% (53/3986)
Cardiac death	1.1% (43/3986)
Hospital MI	4.0% (158/3986)
TLR	0.3% (10/3986)
TVR	0.4% (15/3986)
CVA	0.2% (7/3986)
CABG	0.1% (2/3986)
Definite or Probable ST	0.4% (17/3986)
Definite ST	0.2% (9/3986)
Probable ST	0.2% (8/3986)

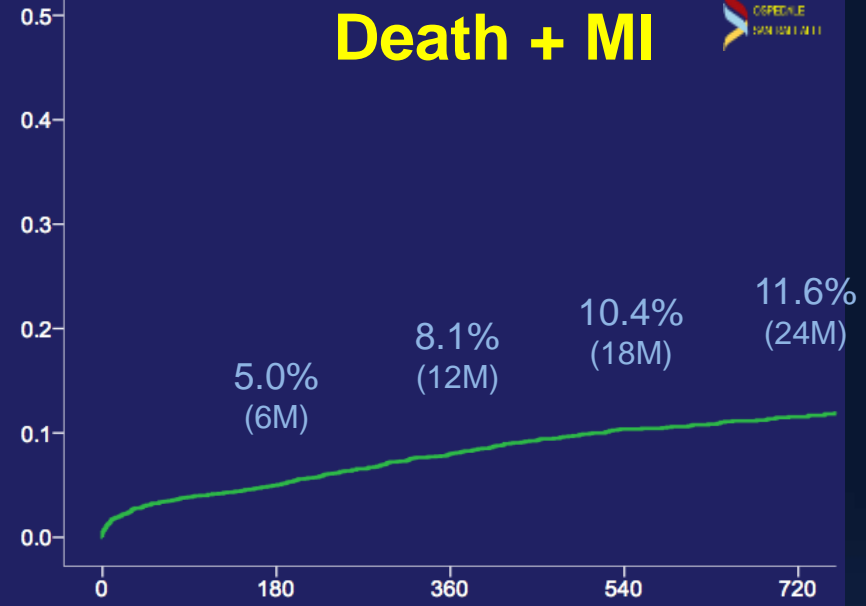
Primary Endpoint (Death + MI + CVA)



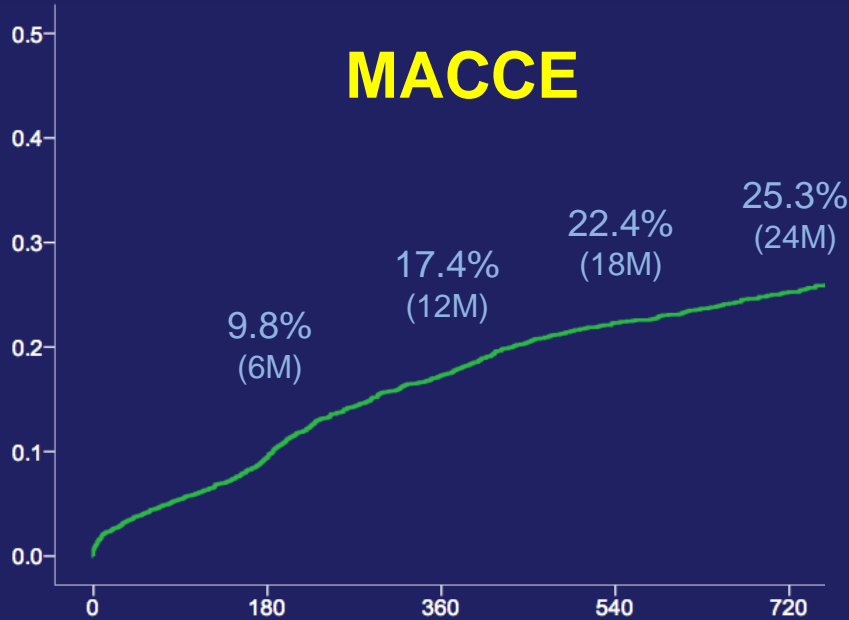
Death



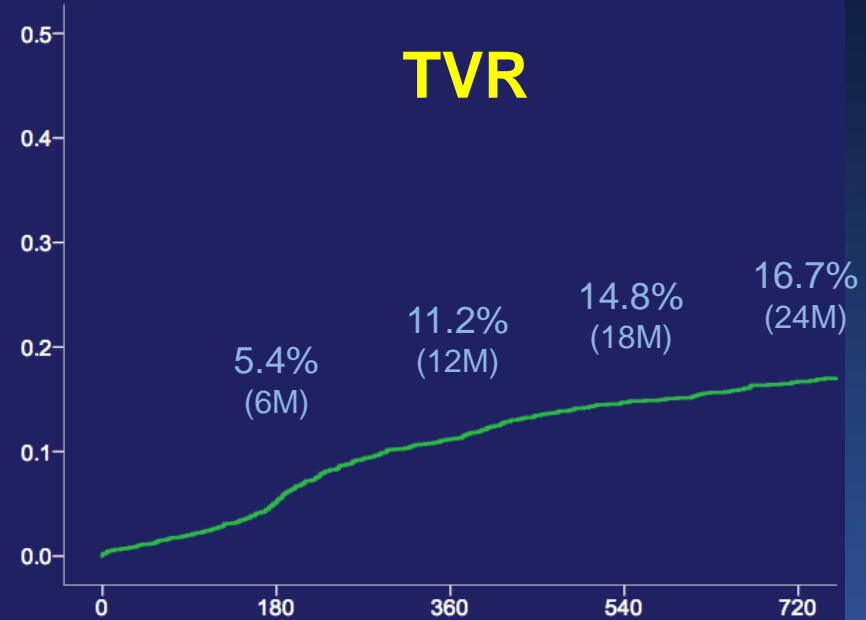
Death + MI



MACCE



TVR



MACCE at Follow-up

	6-months	12-months	18-months	24-months
Death/ MI/ CVA	180 (5.3%)	270 (8.4%)	321 (10.8%)	344 (12.2%)
MACCE	328 (9.8%)	557 (17.4%)	667 (22.4%)	715 (25.3%)
All cause death	149 (4.4%)	212 (6.5%)	248 (8.3%)	268 (9.5%)
Cardiac death	107 (3.1%)	145 (4.5%)	164 (5.4%)	170 (5.8%)
MI	33 (1.0%)	64 (2.1%)	80 (2.9%)	81 (3.0%)
TVR	174 (5.4%)	340 (11.2%)	413 (14.8%)	441 (16.7%)
TLR	99 (3.1%)	214 (7.2%)	252 (9.1%)	270 (10.3%)
CVA	14 (0.4%)	19 (0.6%)	22 (0.8%)	26 (1.0%)
Definite/ Probable ST	38 (1.1%)	47 (1.5%)	50 (1.6%)	50 (1.6%)
- Definite ST	17 (0.5%)	24 (0.8%)	27 (0.9%)	27 (0.9%)
- Probable ST	21 (0.6%)	23 (0.7%)	23 (0.7%)	23 (0.7%)

Median follow-up: 501 days

%, calculated by Kaplan-Meier Method

Multivariate Analysis for Death/MI/CVA

	HR	95%CI	p-value
Age, y	1.03	1.01-1.04	0.003
Dyslipidemia	0.70	0.51-0.96	0.024
Diabetes mellitus	1.51	1.12-2.02	0.006
CKD	1.58	1.16-2.15	0.004
LVEF	0.96	0.95-0.97	<0.001
Emergent/Urgent (vs. Elective)	1.83	1.33-2.52	<0.001
Femoral access (vs. Radial)	1.68	1.17-2.42	0.005
Requirement of Rotablator	1.73	1.02-2.94	0.041

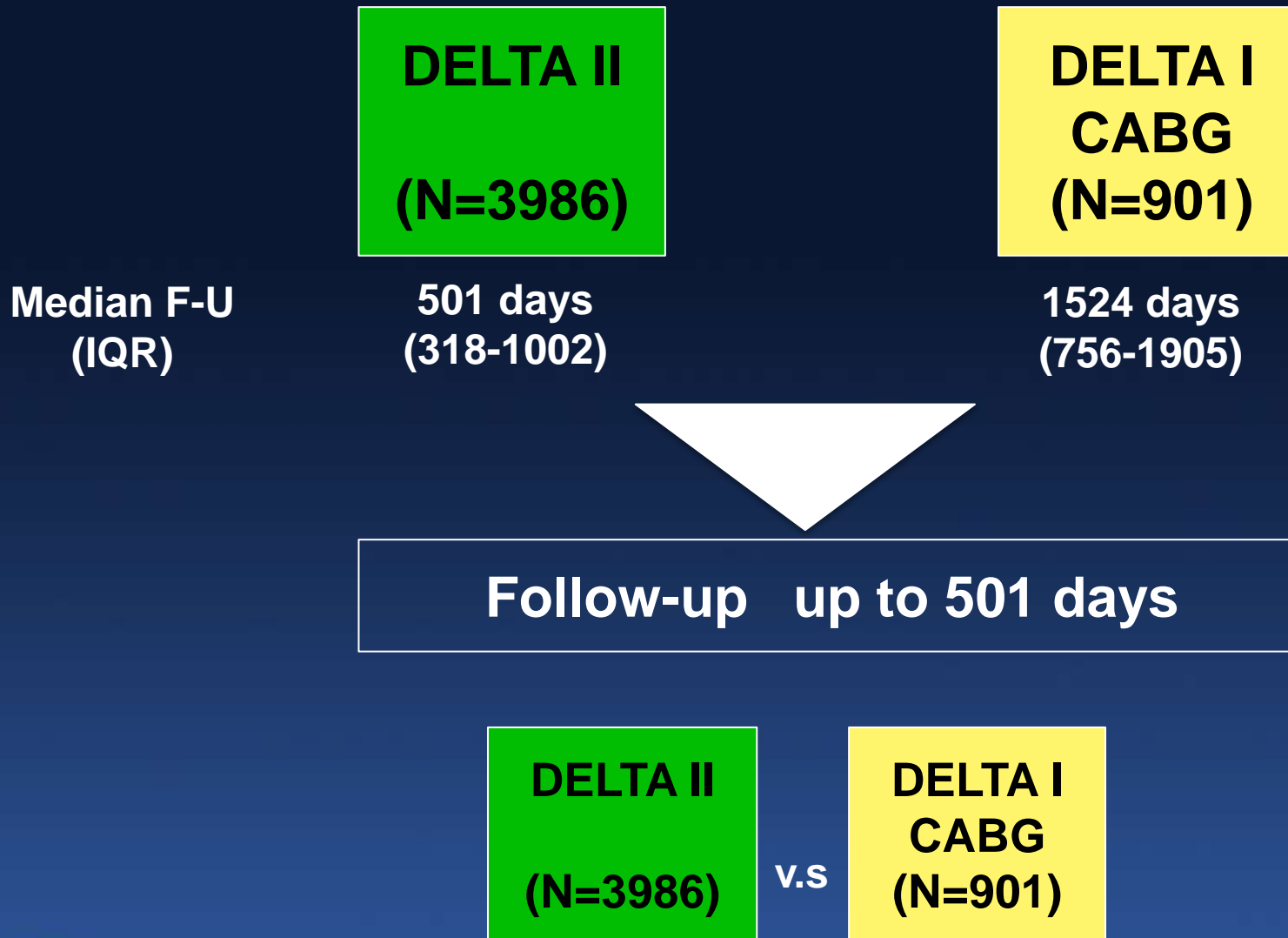
Multivariate Analysis for MACCE

	HR	95%CI	p-value
Diabetes Mellitus	1.72	1.43-2.07	<0.001
LVEF	0.98	0.97-0.99	<0.001
Multivessel disease	1.35	1.00-1.82	0.049
Emergent/Urgent (vs Elective)	1.34	1.07-1.67	0.012
Femoral access (vs radial)	1.27	1.02-1.58	0.03
IABP	1.87	1.34-2.60	<0.001
Pre-dilatation	0.82	0.67-0.99	0.044
Requirement of Rotablator	1.87	1.34-2.60	<0.001
LM stent diameter, mm	0.70	0.53-0.92	0.012
2 stenting	1.37	1.09-1.72	0.007

Multivariate Analysis for TVR

	HR	95%CI	p-value
Age, y	0.981	0.971-0.992	0.001
Diabetes Mellitus	1.839	1.477-2.289	<0.001
Requirement of Rotablator	1.899	1.256-2.873	0.002
LM stent diameter, mm	0.569	0.413-0.786	0.001
2 stenting	1.496	1.134-1.973	0.004

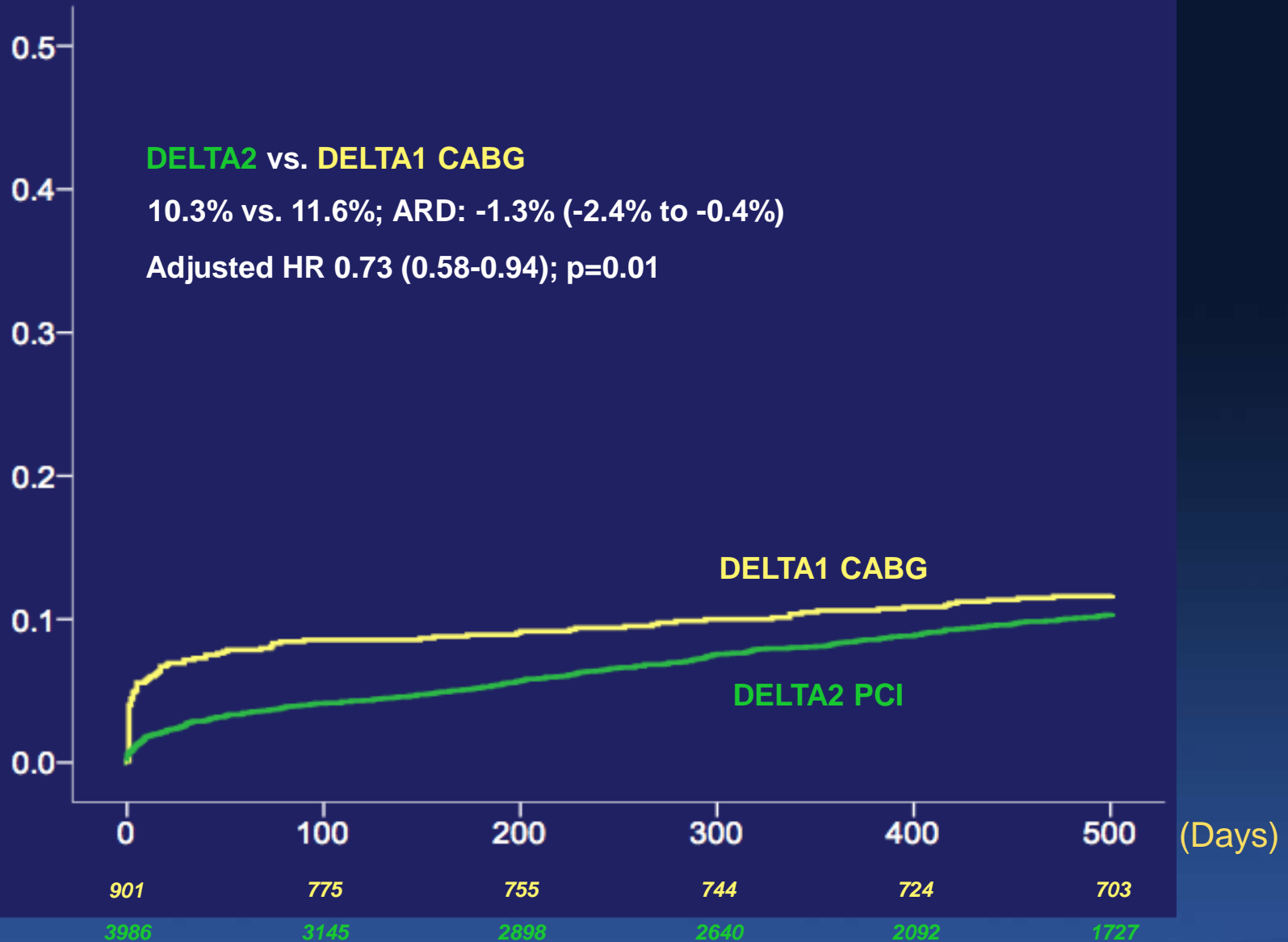
Comparison with DELTA1 CABG



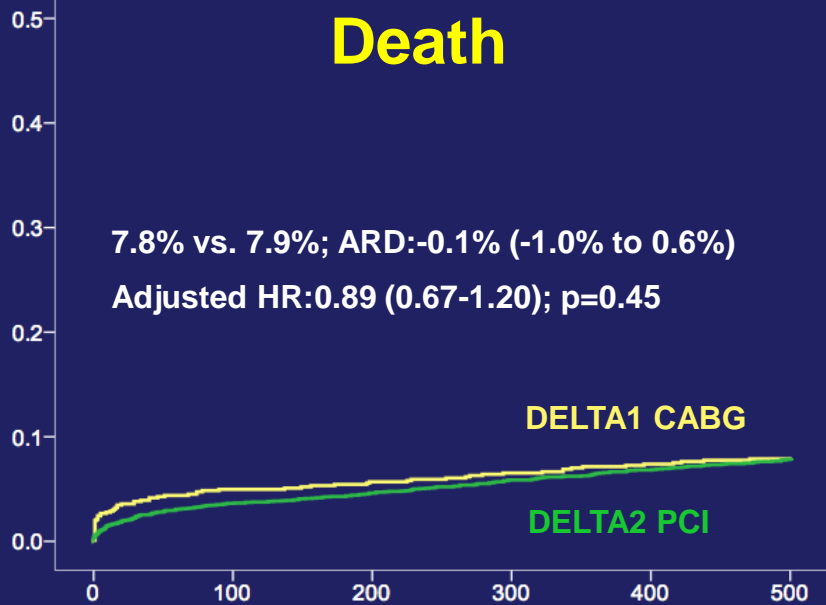
Baseline differences

	DELTA2	DELTA1 CABG	DELTA2 vs1CABG
	n=3986	n=901	Difference (95%CI)
Age, y	70±11	67±10	3.0 (2.2 to 3.7)
Male	75%	64%	10.9% (7.5% to 14.3%)
Hypertention	78%	68%	10.6% (7.3% to 13.9%)
Diabetes	31%	34%	-3.2% (-6.6% to 0.2%)
Previous CABG	8%	3%	5.7% (4.3% to 7.0%)
Previous PCI	42%	14%	27.7% (25.0% to 30.5%)
LVEF, %	53±11	53±12	0.0 (-0.8 to 0.9)
STEMI/NSTEMI	21%	12%	9.1% (6.6% to 11.6%)
Urgent/Emergent	28%	17%	10.7% (7.9% to 13.6%)
SYNTAX score	27±11	39±13	-10.7 (-11.8 to -9.5)

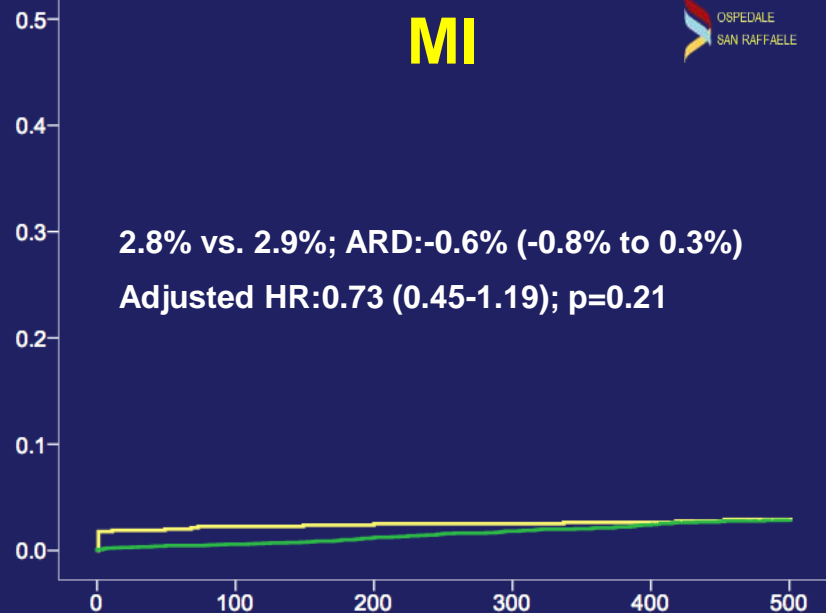
Primary Endpoint (Death+MI+CVA)



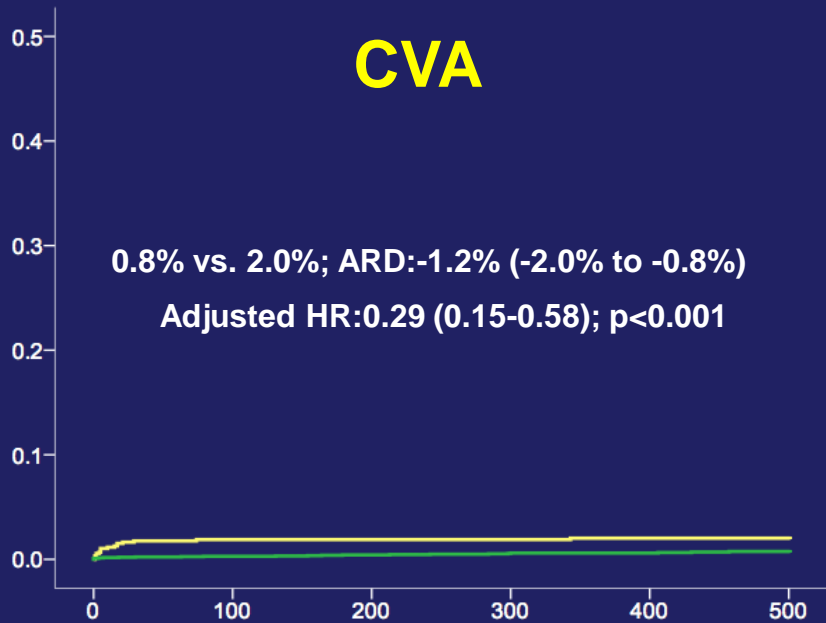
Death



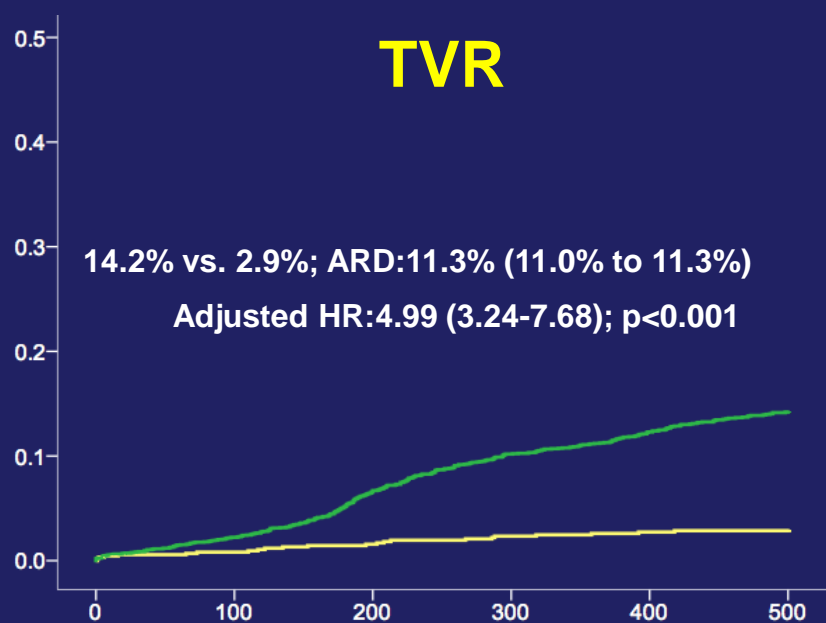
MI



CVA



TVR



Conclusions

- DELTA II registry showed that in a real world scenario (including STEMI, cardiogenic shock and ACS patients and patients that would have been excluded from RCT) PCI with second generation DES for unprotected LM disease has acceptable occurrence of MACCE at mid term clinical follow-up
- The comparison with the historical cohort of patients treated with CABG from DELTA 1 showed that the occurrence of death, MI and CVA is comparable. Indeed there is the advantage of PCI in CVA and CABG in TVR occurrence.