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New Lessons from Delta Registries

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Disclosure Statement of Financial Interest



I, Alaide Chieffo 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.

DELTA Registry



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Drug-Eluting Stent for Left Main Coronary Artery Disease

The DELTA Registry: A Multicenter Registry Evaluating Percutaneous Coronary Intervention Versus Coronary Artery Bypass Grafting for Left Main Treatment

Results In total 2,775 patients were included: 1,874 were treated with PCI versus 901 with CABG. At 1,295 (interquartile range: 928 to 1,713) days, there were no differences, at the adjusted analysis, in the primary composite endpoint of death, cerebrovascular accidents, and myocardial infarction (MI) (adjusted hazard ratio [HR]: 1.11; 95% confidence interval [CI]: 0.85 to 1.42; $p = 0.47$), mortality (adjusted HR: 1.16; 95% CI: 0.87 to 1.55; $p = 0.32$), or composite endpoint of death and MI (adjusted HR: 1.25; 95% CI: 0.95 to 1.64; $p = 0.11$). An advantage of CABG over PCI was observed in the composite secondary endpoint of MACCE (adjusted HR: 1.64; 95% CI: 1.33 to 2.03; $p < 0.0001$), driven exclusively by the higher incidence of target vessel revascularization with PCI.

Conclusions In our multinational all-comers registry, no difference was observed in the occurrence of death, cerebrovascular accidents, and MI between PCI and CABG. An advantage of CABG over PCI was observed in the incidence of MACCE, driven by the higher incidence of target vessel revascularization with PCI. (J Am Coll Cardiol Intv 2012;5:718–27) © 2012 by the American College of Cardiology Foundation

Chieffo A. JACC Cardiovasc Interv. 2012

Propensity Score Matched Groups

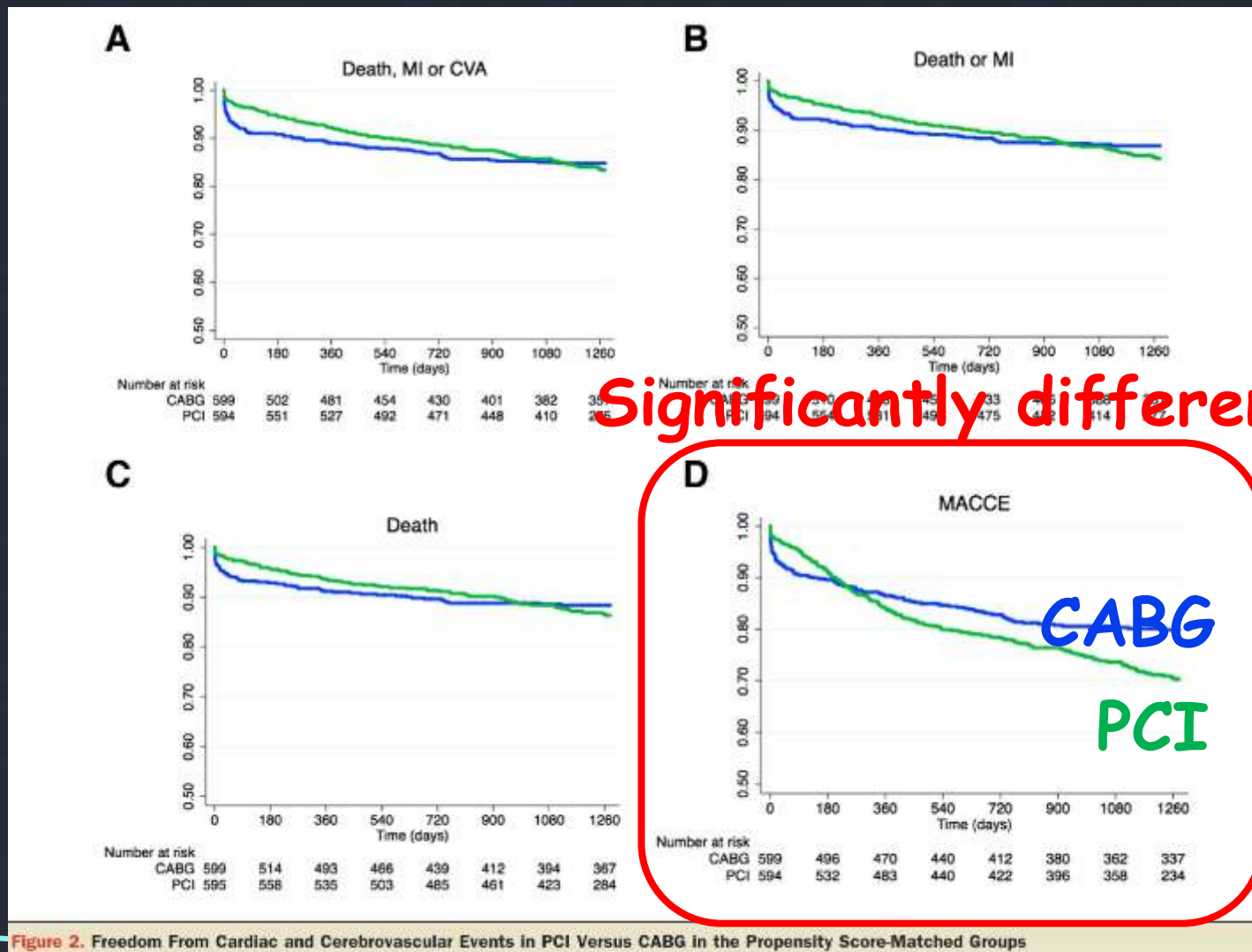


Figure 2. Freedom From Cardiac and Cerebrovascular Events in PCI Versus CABG in the Propensity Score-Matched Groups

Chieffo A. JACC Cardiovasc Interv. 2012

PCI for Ostial/Midshaft

versus

Distal Bifurcation in ULMCA lesions

JACC Cardiovasc Interv 2013 Dec;6(12):1242-9

Study Population Flowchart

DELTA Registry (N = 2775)

Patients treated with CABG were excluded (N = 901)

Patients treated with PCI (N = 1874)

Ostial/midshaft lesion (N = 744)

Distal bifurcation lesion (N = 1130)

Patients treated with bifurcation stenting were excluded (N = 262)

Ostial/midshaft ULMCA PCI group (N = 482)

Distal ULMCA PCI group (N = 1130)

Study population (N = 1612)

Baseline Clinical Characteristics

	Ostial/midshaft ULMCA PCI (N = 482)	Distal ULMCA PCI (N = 1130)	P value
Male	352 (73.0)	851 (75.3)	0.335
Age, yrs	64.3 ± 11.3	66.3 ± 11.3	0.003
Family history of CAD	149 (30.9)	341 (30.2)	0.769
Hypertension	307 (63.7)	719 (63.6)	0.980
Dyslipidemia	284 (58.9)	715 (63.3)	0.099
Smokers	231 (47.9)	513 (45.4)	0.351
Diabetes	127 (26.3)	322 (28.5)	0.379
Chronic kidney disease	40 (8.3)	59 (5.2)	0.018
Clinical presentation			
Unstable angina	166 (34.4)	387 (34.2)	0.941
NSTEMI	54 (11.2)	141 (12.5)	0.472
STEMI	18 (3.7)	32 (2.8)	0.339
Previous PCI	130 (27.0)	283 (25.0)	0.417
LVEF, %	53.9 ± 12.3	53.6 ± 11.4	0.581
EuroSCORE	4.5 ± 3.4	5.0 ± 3.6	0.042

Lesion and Procedural Characteristics 1

	Ostial/midshaft ULMCA PCI (N = 482)	Distal ULMCA PCI (N = 1130)	P value
Multivessel disease	338 (70.1)	962 (85.1)	<0.001
RCA disease	164 (34.0)	431 (38.1)	0.124
SYNTAX score	26.1 ± 12.3	29.7 ± 14.3	<0.001
True bifurcation	0	624 (55.2)	
Pre-dilatation	177 (36.7)	536 (47.4)	<0.001
Post-dilatation	207 (42.9)	533 (47.1)	0.119
Atherectomy	3 (0.6)	21 (1.9)	0.112
Rotablator	5 (1.0)	20 (1.8)	0.276
Cutting balloon	69 (14.3)	81 (7.3)	<0.001
IABP	15 (3.1)	102 (9.0)	<0.001
IVUS	161 (33.4)	381 (33.7)	0.622

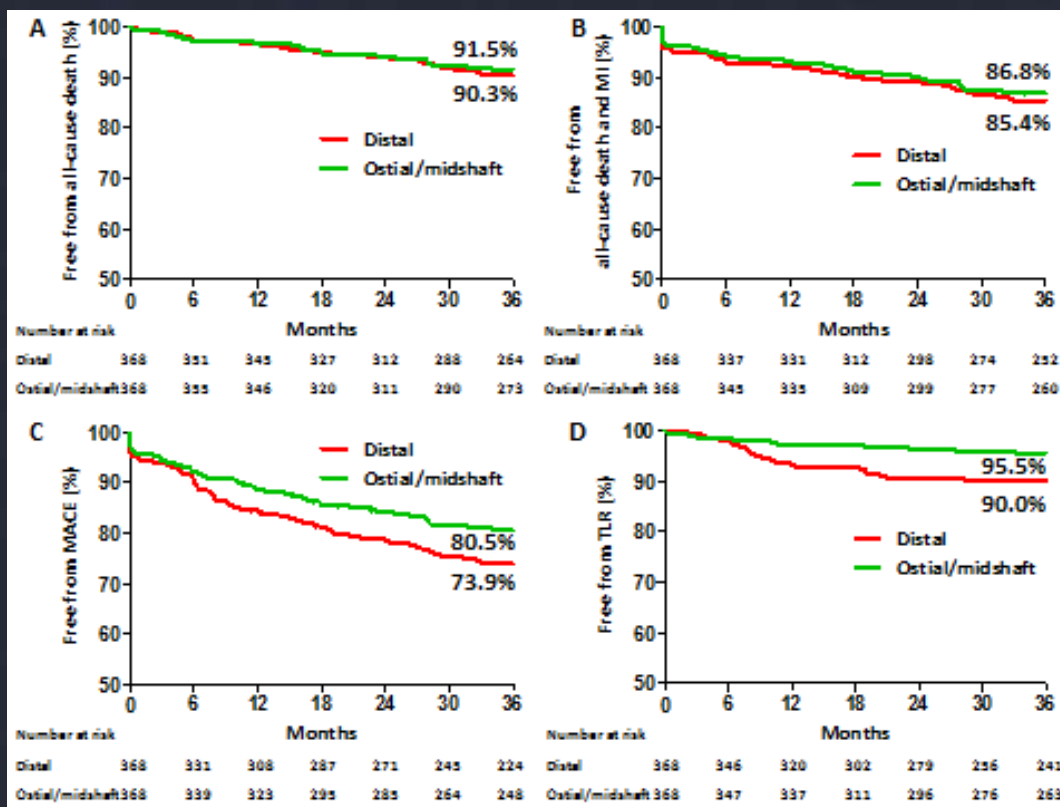
Lesion and Procedural Characteristics 2

	Ostial/midshaft ULMCA PCI (N = 482)	Distal ULMCA PCI (N = 1130)	P value
DES type			0.100
SES	281 (58.3)	599 (53.0)	
PES	199 (41.3)	515 (45.6)	
ZES/EES	2 (0.4)	16 (1.4)	
Stent diameter, mm	3.51 ± 0.36	3.33 ± 0.36	<0.001
Total stent length, mm	15.9 ± 13.5	24.8 ± 18.8	<0.001
Number of stents per lesion	1.09 ± 0.34	1.41 ± 0.61	<0.001
Post-dilatation	207 (42.9)	533 (47.1)	0.123
Maximum balloon diameter, mm	3.88 ± 0.58	3.59 ± 0.54	<0.001
Maximum pressure, atm	16.7 ± 3.6	15.8 ± 4.2	0.002
Final kissing balloon inflation	0	677 (59.9)	

Study Endpoints (Distal vs Ostial/Midshaft)

		P value	HR	95% CI
MACE	Unadjusted	<0.001	1.57	1.28-1.98
	PS adjusted	0.001	1.48	1.16-1.89
All-cause death	Unadjusted	0.074	1.31	0.97-1.77
	PS adjusted	0.057	1.45	0.99-2.14
Death/MI	Unadjusted	0.018	1.36	1.05-1.74
	PS adjusted	0.050	1.37	1.00-1.86
TVR	Unadjusted	<0.001	1.97	1.44-2.68
	PS adjusted	0.003	1.68	1.19-2.38
TLR	Unadjusted	<0.001	2.29	1.53-3.41
	PS adjusted	0.002	2.00	1.29-3.10

Propensity score matched groups (368 pairs)



		P value	HR	95% CI
MACE	PS matched	0.006	1.48	1.12-1.95
All-cause death	PS matched	0.230	1.32	0.84-2.08
Death/MI	PS matched	0.188	1.28	0.89-1.84
TVR	PS matched	0.003	1.82	1.23-2.69
TLR	PS matched	0.001	2.32	1.41-3.82

PCI Versus CABG for Ostial/midshaft Lesions in ULMCA

JACC Cardiovasc Interv 2014 Apr;7(4):354-61

Study Population Flowchart

DELTA Registry (N = 2775)

Patients with distal bifurcation lesion were excluded (N = 1657)

Patients with ostial/midshaft lesion (N = 1118)

Treated with PCI
(N = 744)

Treated with CABG
(N = 374)

Patients treated with bifurcation stenting were excluded (N = 262)

PCI group (N = 482)

CABG group (N = 374)

Study population (N = 856)

Baseline Clinical Characteristics

	PCI (N = 482)	CABG (N = 374)	P value
Male	352 (73.0)	231 (61.8)	<0.001
Age, yrs	64.3 ± 11.3	66.8 ± 10.0	0.001
Family history of CAD	149 (30.9)	96 (25.7)	0.092
Hypertension	307 (63.7)	264 (70.6)	0.034
Dyslipidemia	284 (58.9)	240 (64.2)	0.106
Smokers	231 (47.9)	169 (45.2)	0.426
Diabetes	127 (26.3)	138 (36.9)	0.001
IDDM	25 (5.2)	24 (6.4)	
Chronic kidney disease	40 (8.3)	17 (4.5)	0.029
Clinical presentation			
Stable angina/silent ischemia	244 (50.6)	121 (32.4)	<0.001
Unstable angina	166 (34.4)	197 (52.7)	<0.001
NSTEMI	54 (11.2)	55 (14.7)	0.127
STEMI	18 (3.7)	1 (0.2)	0.001
Previous PCI	130 (27.0)	56 (15.0)	<0.001
LVEF, %	53.9 ± 12.3	53.5 ± 12.0	0.565
EuroSCORE	4.5 ± 3.4	5.2 ± 2.6	0.003

Lesion and Procedural Characteristics

	PCI (N = 482)	CABG (N = 374)	P value
Multivessel disease	338 (70.1)	338 (90.4)	<0.001
RCA disease	164 (34.0)	221 (59.1)	<0.001
SYNTAX score	26.1 ± 12.3	35.5 ± 13.1	<0.001
IABP	15 (3.1)	15 (4.0)	0.478
IVUS	161 (33.4)		
Vessels treated	1.17 ± 0.78	2.29 ± 0.98	<0.001
PCI for LAD or LCx	243 (50.4)		
PCI for RCA	67 (13.9)		
DES type			
SES	281 (58.3)		
PES	199 (41.3)		
ZES/EES	2 (0.4)		
Mean stent diameter, mm	3.51 ± 0.36		
Mean stent length, mm	15.9 ± 13.5		
Max balloon diameter, mm	3.88 ± 0.58		
Max pressure, atm	16.7 ± 3.6		
Mean arterial graft		1.9 ± 1.1	
Mean venous graft		1.6 ± 1.2	

First generation DES

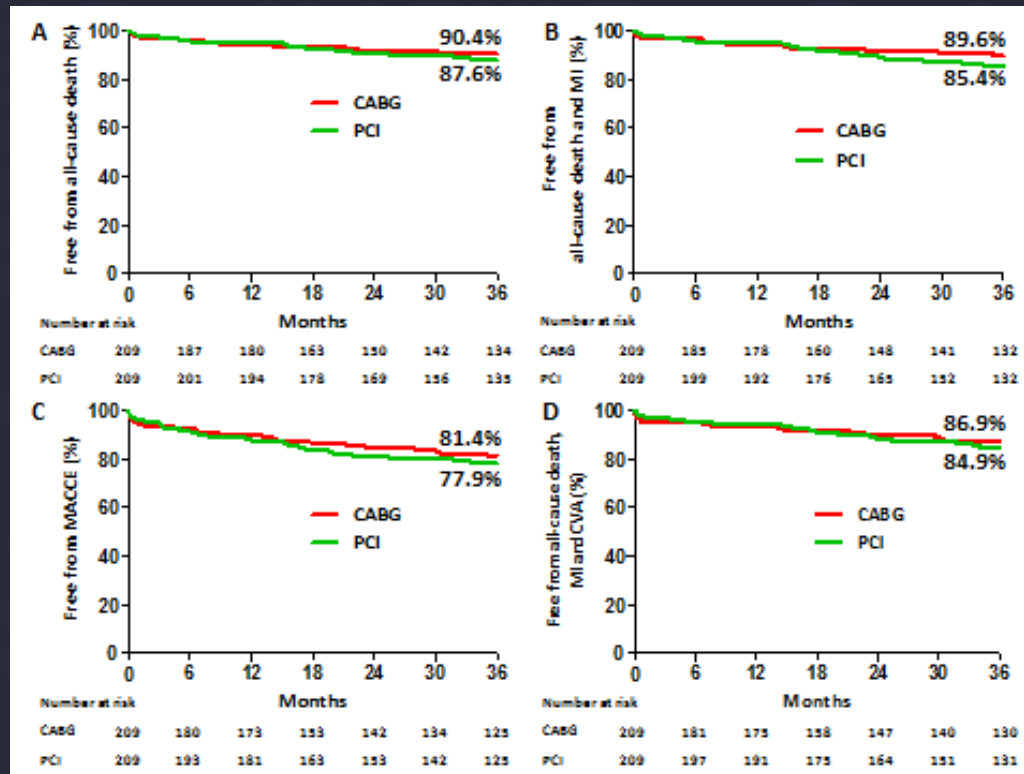
Study Endpoints (PCI vs CABG)

		P value	HR	95% CI
Death/MI/CVA	Unadjusted	0.793	1.05	0.75-1.46
	PS adjusted	0.372	1.21	0.79-1.86
MACCE	Unadjusted	0.059	1.33	0.99-1.78
	PS adjusted	0.113	1.34	0.93-1.93
All-cause death	Unadjusted	0.307	1.24	0.82-1.88
	PS adjusted	0.255	1.35	0.80-2.27
Death/MI	Unadjusted	0.623	1.09	0.76-1.57
	PS adjusted	0.235	1.33	0.83-2.12
TVR	Unadjusted	0.009	2.15	1.21-3.80
	PS adjusted	0.039	1.94	1.03-3.64
TLR	Unadjusted	0.057	2.03	0.98-4.21
	PS adjusted	0.090	2.00	0.90-4.45

Predictors of the primary endpoint on Cox multivariable analysis

	HR	95% CI	P value
PCI vs. CABG	0.986	0.638-1.523	0.948
Age	1.034	1.007-1.062	0.014
EuroSCORE	1.085	1.004-1.173	0.039
Female gender	0.809	0.507-1.303	0.389
Diabetes	1.206	0.772-1.884	0.411
LVEF	0.988	0.970-1.007	0.204
Multivessel disease	1.004	0.549-1.836	0.991
AMI	0.906	0.507-1.620	0.739

Propensity score matched groups (209 pairs)



		P value	HR	95% CI
Death/MI/CVA	PS matched	0.350	1.25	0.78-2.01
MACCE	PS matched	0.104	1.40	0.93-2.10
All-cause death	PS matched	0.348	1.31	0.74-2.32
Death/MI	PS matched	0.220	1.38	0.82-2.31
TVR	PS matched	0.060	1.97	0.97-4.00
TLR	PS matched	0.073	2.23	0.93-5.37

Insights from the W- DELTA
(Women- Drug Eluting stent for
LefT main coronary Artery
disease) Registry

Am J Cardiol 2014 Apr 15;113(8):1348-55

Baseline Clinical Characteristics Overall Population

	PCI (n=489)		CABG (n=328)		P Value
	N	%	N	%	
Age	67.4±12.6		67.9±11.6		0.562
Hypertension	359	73.4	240	72.9	0.111
Diabetes	161	32.9	101	30.7	0.504
NSTEMI	66	13.5	34	10.4	0.181
STEMI	10	2.0	2	0.6	0.094
CKD	28	5.7	9	2.7	0.044
EuroSCORE	5.6±4.0		5.4±2.6		0.395
SYNTAX Score	26.8±13.0		37.1±12.8		<0.001
LVEF	54.8±12.2		54.5±11.0		0.731

Baseline Characteristics Propensity Matched Population

PCI (n=175)

CABG (n=175)

	N	%	N	%	P Value
Age	67.1±12.0		67.5±10.3		0.736
Hypertension	120	68.6	125	71.0	0.617
Diabetes	50	28.6	55	31.3	0.584
Prev PCI	35	20.0	31	17.6	0.567
Multivessel Disease	160	91.4	162	92.0	0.834
RCA Disease	104	59.4	104	59.4	1.000
EuroSCORE	5.1±2.5		5.6±4.2		0.270
LVEF	55.2±11.9		54.3±11.0		0.445

In Hospital Events

Propensity Matched Population

PCI (n=175)

CABG (n=175)

	N	%	N	%	OR (95% CI)	P Value
All Cause Death	3	1.7	4	2.3	0.750 (0.165-3.401)	0.709
Cardiac Death	3	1.7	3	1.7	1.006 (0.200-5.053)	0.994
MI	12	6.9	24	13.6	0.466 (0.225-0.965)	0.040
TLR	0	0	0	0		
TVR	0	0	0	0		
Stroke	1	0.6	3	1.7	0.367 (0.038-3.568)	0.388
MACCE	15	8.6	29	16.5	0.057 (0.007-0.497)	0.009

Long Term Events

Propensity Matched Population

PCI (n=175)

CABG (n=175)

	N	%	N	%	OR (95% CI)	P Value
All Cause Death	20	11.4	15	8.5	0.722 (0.357-1.461)	0.365
Cardiac Death	10	5.7	11	6.3	1.100 (0.455-2.660)	0.832
MI	8	4.6	3	1.7	0.362 (0.094-1.388)	0.138
TLR	18	10.3	5	2.8	0.255 (0.092-0.703)	0.008
TVR	32	18.3	7	4.0	0.185 (0.079-0.432)	<0.001
Stroke	5	2.9	6	3.4	1.200 (0.359-4.007)	0.767
MACCE	52	29.7	27	15.3	0.429 (0.254-0.723)	0.001

Median 1,148 (IQR 545-1,543) days

DELTA Registry 2