Does DCB technology have an important role in de novo lesions? If not today, tomorrow?

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Potential disclosures

Speaker's name: Bernardo Cortese

☑ *I have the following potential conflicts of interest to report (last 2 years):*

Consultant: Aachen Resonance, Abbott Vascular, Astra Zeneca, Kardia, Innova, Stentys, Daiiki-Sankyo.

Honorarium: Hexacath, Amgen

Institutional grant/research support: AB Medica, St Jude

Question n° 1
Does DCB technology have an important role in de novo lesions?

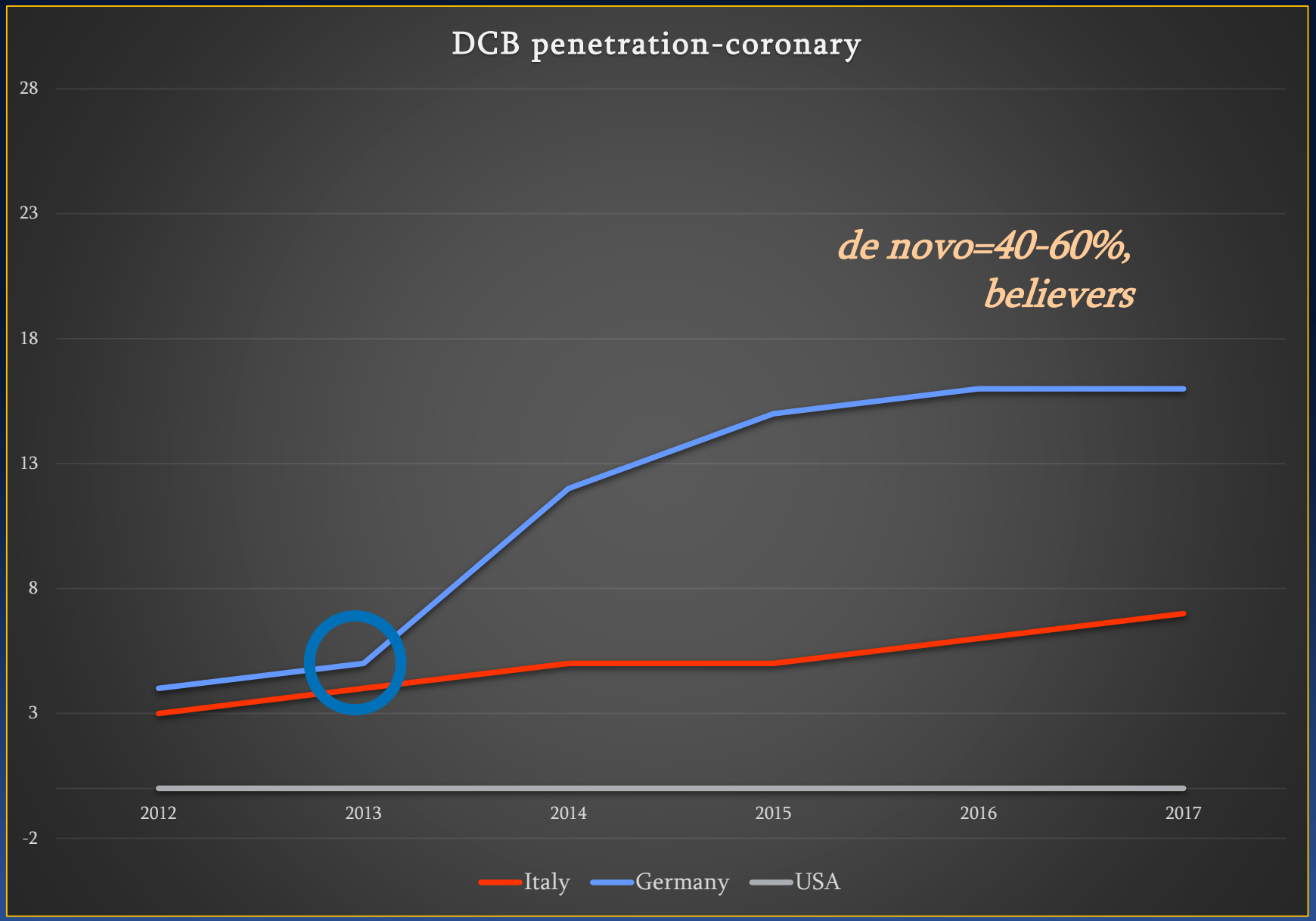
Answer: NO.

point 1: low penetration

point 2: some devices do not work

point 3: no large clinical trials

point 4: small, focused studies


DCB penetration-coronary
28
23
18
13
8
3
-2
2012
2013
2014
2015
2016
2017
de novo=40-60%,
believers
Italy
Germany
USA

Question n° 1
Does DCB technology have an important role in de novo lesions?

Answer: NO.

point 1: low penetration

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point 4: small, focused studies

DCB: the LLL dispersion

DCB: NO class effect!!!

B Cortese, modified from TCT 2013

Question n° 1
Does DCB technology have an important role in de novo lesions?

Answer: NO.

point 1: low penetration

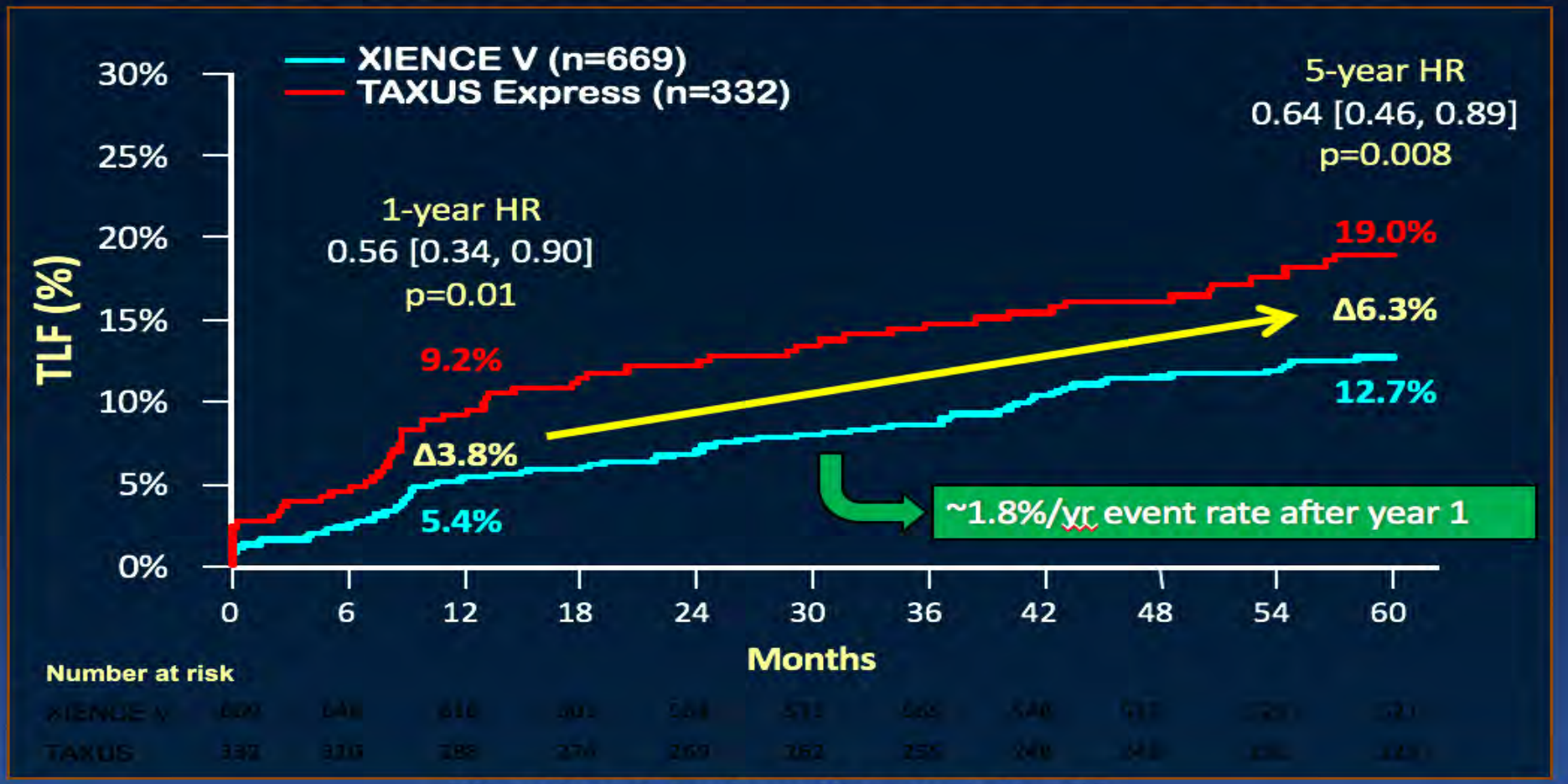
point 2: no class effect-some devices do not work

point 3: no large clinical trials

point 4: small, focused studies

EES: 100000 pts enrolled in clinical trials
BVS: 30000 pts enrolled in clinical trials

SPIRIT III: Target Lesion Failure @5 years



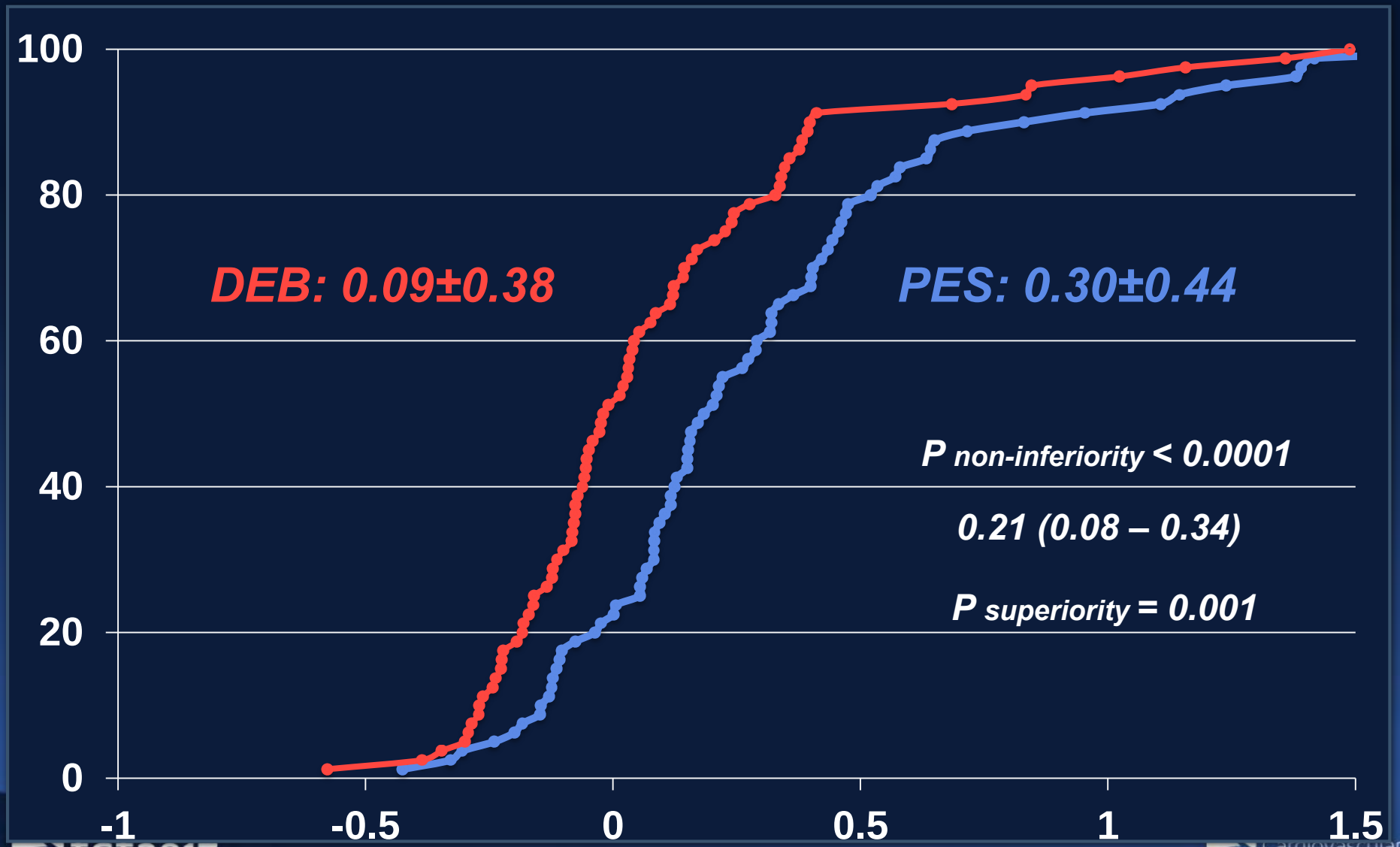
TLF = cardiac death, target vessel MI, or ischemic-driven TLR

Gada H et al. J Am Coll Cardiol Intv 2013;6:1263–6.

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian

In.Pact-BELLO study-LLL

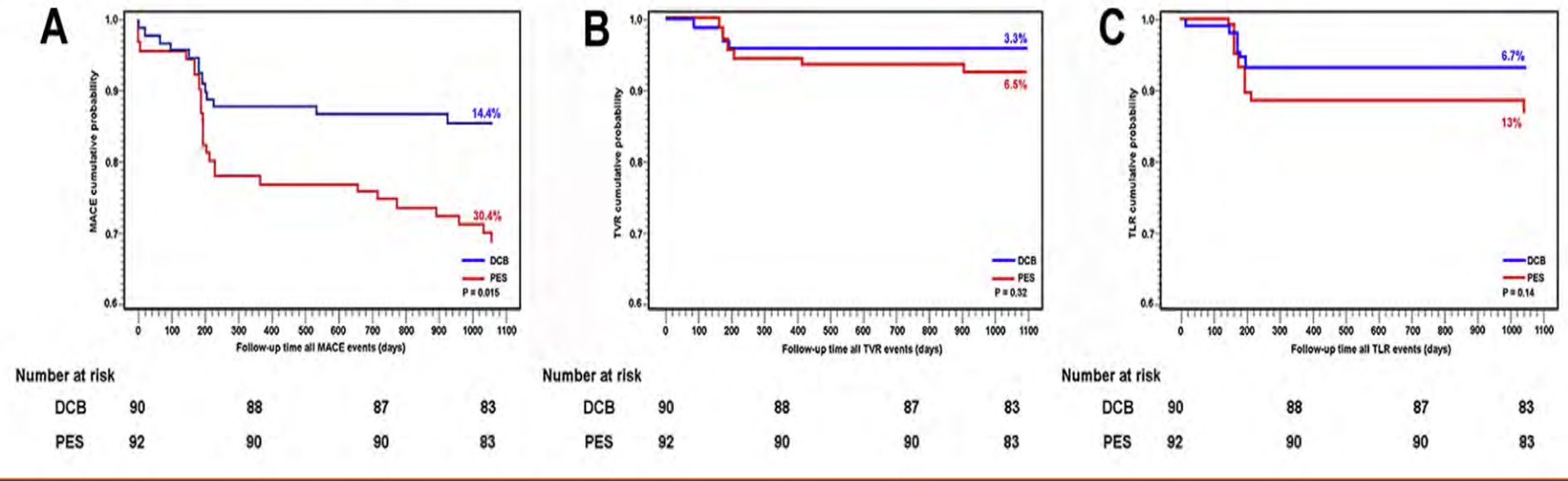


A Colombo, JIM 2012

In.Pact-BELLO study-3y

MACE

FIGURE 1 3-Year Outcomes Following DCB Treatment for De Novo Coronary Disease in Small Vessels in Comparison With PES Treatment



Number at risk				
DCB	90	88	87	83
PES	92	90	90	83

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A Latib, JACC Int '15

Coronary dissection healing with DCB

July 2012-July 2014: DCB in native coronary vessels

156 patients

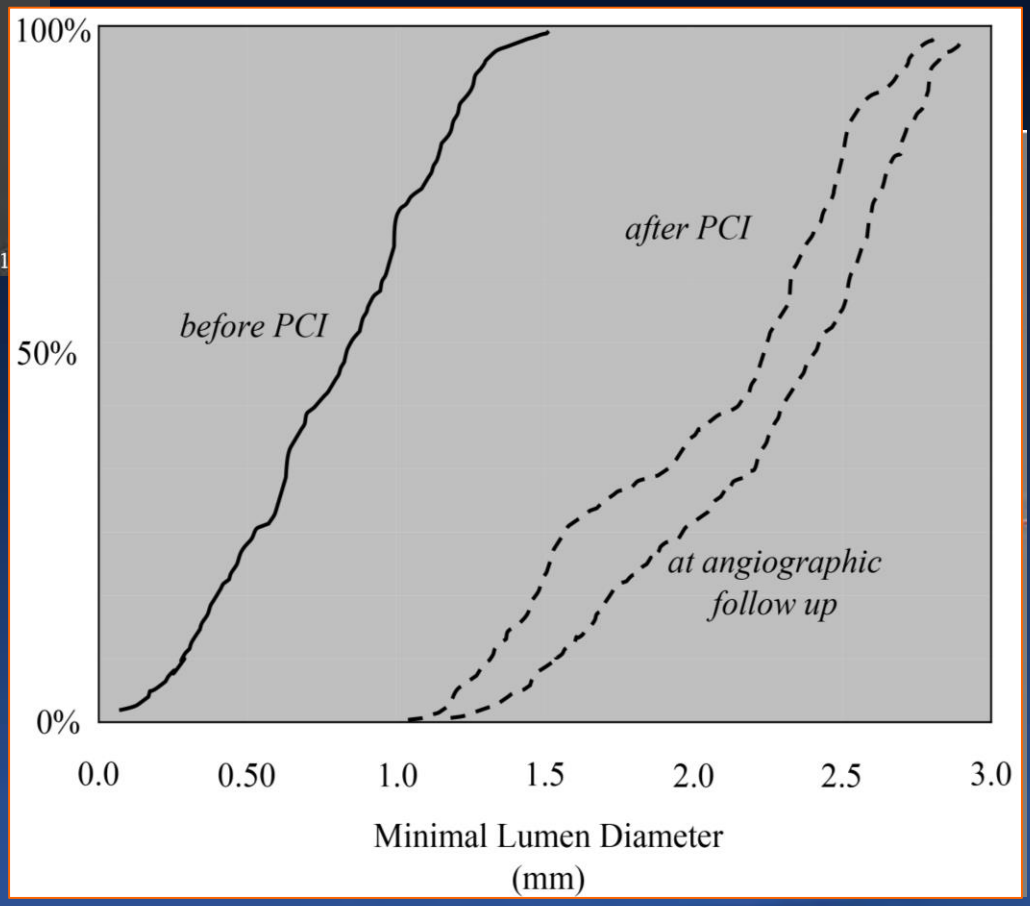
52 with dissection

48 left with A-C dissection

4 stents

6-month angio follow up

B Cortese, JACC Int 201



B Cortese, JACC Int 2015

Elutax SV: DCB-RISE registry

Clinical End-points at the longest available Follow-up (n=544)

follow up, months (SD)		13.3 (7.0)	
	ISR (n=282)	de-novo (n=262)	p
TLR, n (%)	32 (10%)	7 (3.2%)	0.006
Target-vessel MI, n (%)	4 (1.2%)	0	0.14
Stroke, n (%)	1 (0.3%)	1 (0.4%)	1
All-cause death	5 (1.5%)	6 (2.7%)	0.36
Cardiac death	3 (0.9%)	0	0.27
DOCE	34 (12%)	7 (3.2%)	0.001

Question n° 2
Will DCB technology have an important role tomorrow?

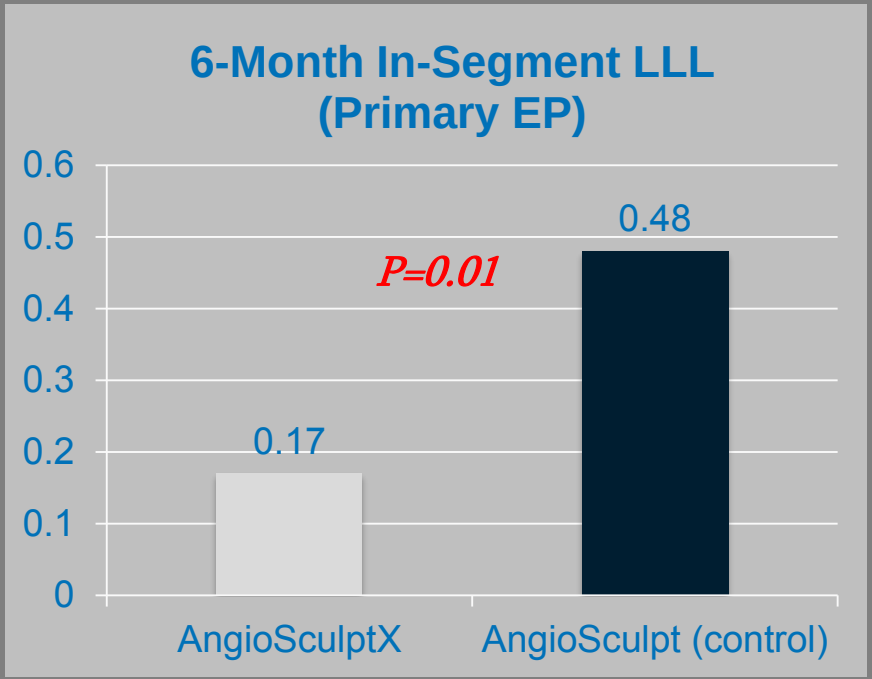
Answer: I am optimistic.

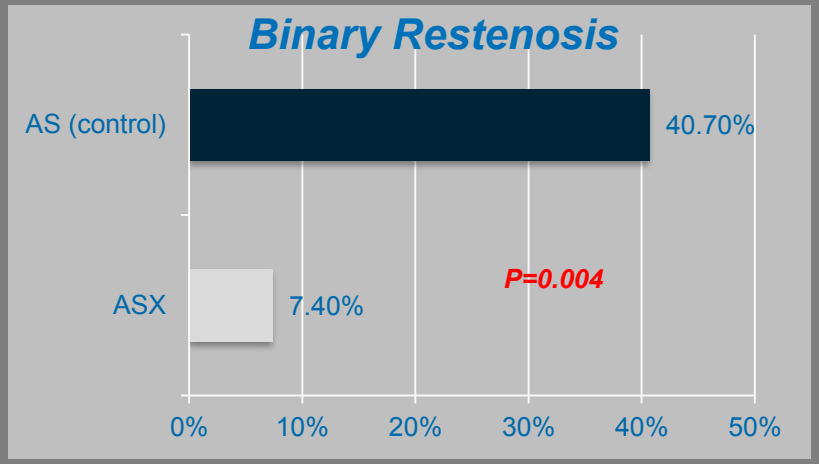
point 1: new technologies

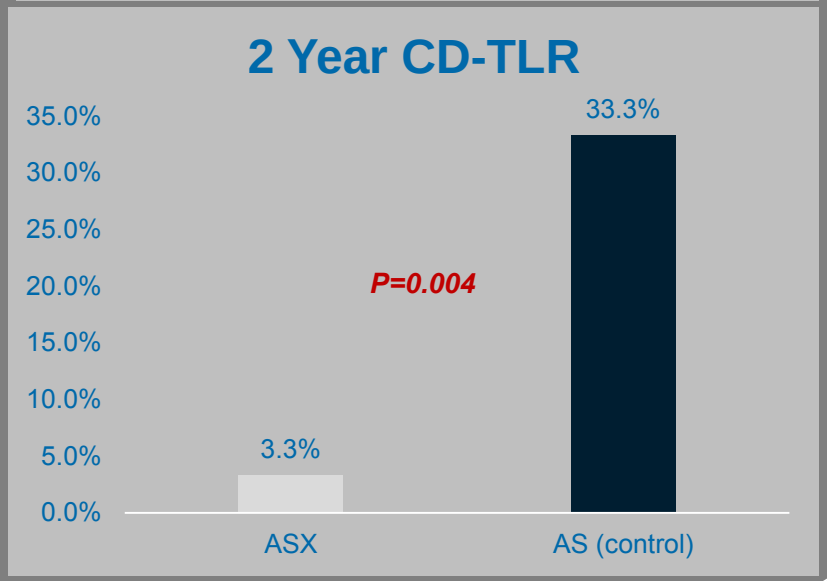
point 2: a more "mature" predisposition to clinical trials

Angiosculpt X-PATENT-C Trial

BMS restenosis

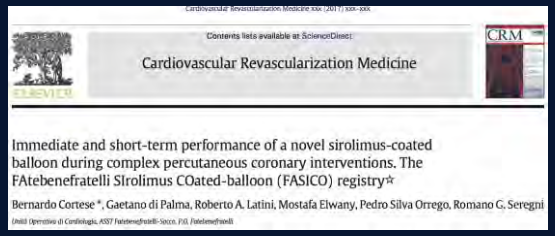






Scheller B, Cath Cardiovasc Interv. 2016

Magic Touch-FASICO registry


Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Immediate and short-term performance of a novel sirolimus-coated balloon during complex percutaneous coronary interventions. The FAtebenefratelli SIrolimus COated-balloon (FASICO) registry☆

Bernardo Cortese *, Gaetano di Palma, Roberto A. Latini, Mostafa Elwany, Pedro Silva Orrego, Romano G. Seregni

n=32, lesions=34	
Age, mean [SD]	68.56 [±9,45]
Male gender, %	11
Diabete mellitus, %	38
ACS, %	32
ISR, %	47
ISR and failure of PCB	*31*
Moderate/severe calcifications	*32*
Multivessel disease	*50*

SCB length, mean, mm (SD)	21.02 (4.7)
SCB diameter, mean, mm (SD)	2.6 (0.52)
Inflation time, mean, sec (SD)	50 (16.7)
Inflation pressure, mean, atm. (SD)	11.6 (4.73)
Minimal lumen diameter pre, mean, mm (SD)	0.39 (0.08)
Minimal lumen diameter post, mean, mm (SD)	2.20 (0.44)
Hybrid approach SCB + DES on the same vessel, n (%)	9 (26.5)
Hybrid approach SCB + stent on another vessel (same procedure), n (%)	5 (14.7)
TnI peak after PCI, average value, μg/l (SD)	40 (21.6)
Angiographic success, %	100
Procedural success, %	100

Clinical follow up (average: 6.9 ± 1.7 months).

DAPT ongoing, n [%]	10 [31.6]
All-cause death, n [%]	0
Cardiac death, n [%]	0
Target lesion revascularization, n [%]	3 [9.4]
MI, n [%]	0
MACE, n [%]	3 [9.4]

B Cortese, CV Revasc Med '17

FASICO *natives*

- *21 consecutive native vessels treated with SCB*
- *6 months angiographic follow up (available in 15 pts today)*
- *Single-centre*
- *Primary endpoint LLL*

RVD, mean SD	2.46 ± 0.4
High calcium burden	38%
Stenosis pre, mean (%) SD	78 ± 10
Lesion length	24.5±7
MLD pre, mean SD	0.65 ± 0.3
MLD post, mean SD	2.04 ± 0.4
Acute gain mean, SD	1.25 ± 0.6
Final stenosis, mean (%) SD	14 ± 16

Months, mean SD	6 ± 2
MLD, mean SD	1.93 ± 0.7
LLL, mean SD	0.12 ± 0.3
Stenosis (%) SD	19 ± 23
Binary restenosis, n (%)	1 (6.7)

B Cortese & group, unpublished data

The EASTBOURNE Registry

thE All-comers Sirolimus-coaTed BallOon eURopeaN rEgistry

Inclusion criteria: any type of coronary lesions, including native vessel disease and in-stent restenosis.

- *Prospective, multicenter, spontaneous clinical registry*
- *Consecutive enrollment*
- *real world, all comers patients*
- *1000 patients at ca. 30 european/asian sites.*
- *Chairmen: B. Cortese, A. Colombo*

VIRTUE balloon- SABRE study

FIM, prosp. 9 European centres

ISR (DES or BMS)

50 pts

Primary endpoints:

- *TLF at 30 days*
- *LLL at 6 months*

TABLE 4 Angiographic Results at 6 Months

	ITT (n = 47)	PP (n = 36)	PP Group vs. Exclusion Group p Value
RVD, mm*	2.52 ± 0.38	2.52 ± 0.32	0.927
MLD, mm	1.75 ± 0.54	1.96 ± 0.32	0.0007
Diameter stenosis, %	30.27 ± 19.88	22.27 ± 9.44	0.0481
Change diameter stenosis, %	12.67 ± 20.64	5.22 ± 11.38	0.0020
LLL, mm†	0.31 ± 0.52	0.12 ± 0.33	0.0005
Binary restenosis‡	9 (19.1)	1 (2.8)	<0.0001

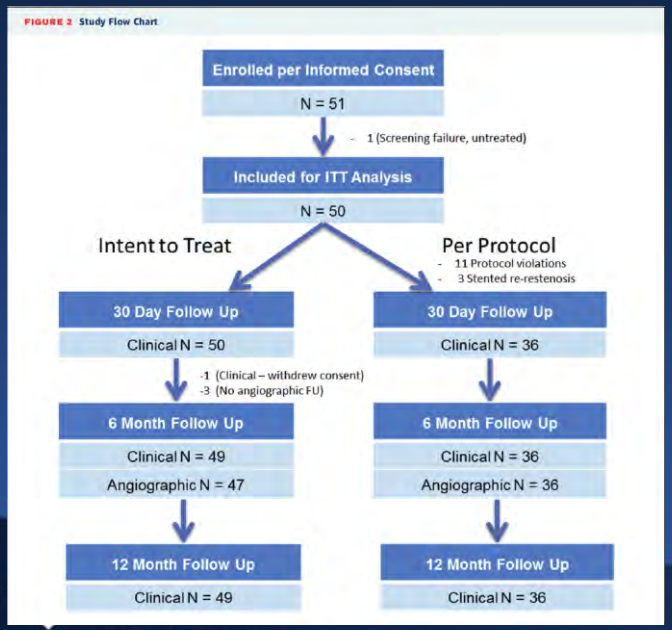


TABLE 3 Clinical Safety Outcomes

	ITT Analysis				PP Analysis	
	In Hospital (n = 50)	30 Days (n = 50)	6 Months (n = 49)	12 Months (n = 49)	6 Months (n = 36)	12 Months (n = 36)
Cardiac death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
MI*	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)
CABG	0 (0)	0 (0)	1 (2)	1 (2)	0 (0)	0 (0)
TLR†	0 (0)	0 (0)	4 (8.2)	6 (12.2)	1 (2.8)	1 (2.8)
TLF	0 (0)	0 (0)‡	4 (8.2)	6 (12.2)	1 (2.8)	1 (2.8)
MACE§	0 (0)	0 (0)	5 (10.2)	7 (14.3)	1 (2.8)	1 (2.8)

Verheye, JACC Int '17

Cardiovascular Research Foundation

Does DCB technology have an important role in de novo lesions?
If not today, tomorrow?

TODAY they are not the playmakers, in coronary arena

TOMORROW they can:

- *new devices*
- *ad hoc, powered studies (but forget about the numbers of SPIRIT, ABSORB, …)*