3-Year Outcome of paclitaxel DCB vs. DES for Native Vessel Disease Treatment: Final Follow Up of the Randomized PICCOLETO II Trial

Bernardo Cortese, MD FESC
Milano, Italy
www.bernardocortese.com

DCB INTERNATIONAL ACADEMY

Fondazione Ricerca e Innovazione Cardiovascolare

Disclosure Statement of Financial Interest

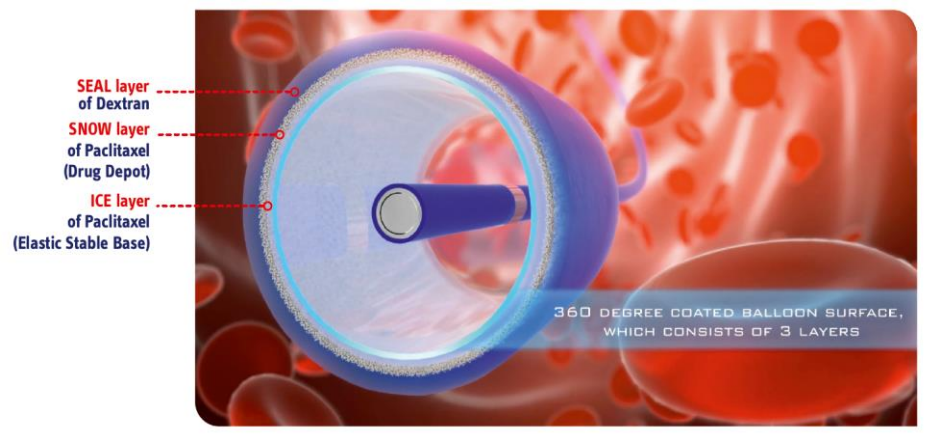
I, [insert name] DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Faculty disclosure information can be found on the app

Background of PICCOLETO II

- Higher rates of adverse events with DES in some settings: SVD, diffuse disease, complex lesions.
- New generation DCB were born in order to improve drug deliverability and tissue retention in the vessel wall, and to reduce drug dispersion/embolization.
- This study sought to evaluate the angiographic efficacy and clinical performance of Elutax SV DCB as compared to EES in a SVD setting.

Elutax SV/Emperor DCB



- *SEAL layer made of DEXTRAN, a hydrogel with hydrophilic features, to obtain a longer drug absorption in time*
- *drug deployed on inflated balloon*
- *lower dose PTX (2.2 micrg/mm2)*
- *higher PTX persistance at 30 days (5-8% of the drug)*

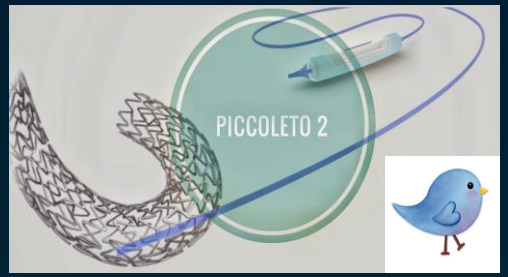
Elutax SV: DCB-RISE registry

Table 4 Clinical endpoints at the longest available follow-up

	n = 507		
	13.3 (7.4)		
Average duration of follow-up, months (SD)	ISR (n = 269)	*de novo* (n = 238)	*P*
TLR, n (%)	24 (9%)	6 (2.6%)	0.006
TLR managed with CABG, n (%)	3 (1%)	1 (0.4%)	0.64
TLR managed with PCI, n (%)	21 (7.8%)	5 (2.1%)	0.003
Target-vessel MI, n (%)	3 (1.1%)	0	0.14
Stroke, n (%)	1 (0.3%)	1 (0.4%)	1
All-cause death	6 (2.2%)	6 (2.5%)	0.36
Cardiac death	3 (1.1%)	0	0.27
DOCE	30 (11%)	6 (2.6%)	0.001

B. Cortese, J CV Med 2018

PICCOLETO II-PIs and participating Centers



GISE
Società Italiana di Cardiologia Interventistica

academic, multicenter, multinational, open-label, prospective randomized clinical trial

Steering Comm.: B. Cortese, G. Di Palma, F. Alfonso

Independent clinical Ev. Comm.

Independent Core lab.: Cardiovasc. Inst., University of Ferrara

Clinicaltrials.gov: NCT 03899818

Bernardo Cortese MD, Chairman and PI
- Milano, Italy

Fernando Alfonso MD,
- Hospital de la Princesa, Madrid, Spain

Gaetano Di Palma MD,
- Milano, Italy

Marcos Garcia Guimaraes MD,
- Hospital de la Princesa, Madrid, Spain

Davide Piraino MD,
- Univ. of Palermo, Italy

Pedro Silva Orrego MD,
- Fatebenefratelli Hospital, Milano, Italy

Dario Pellegrini MD,
- Univ. of Milano Bicocca, Italy; Radbound UMC, Nijmgen, The Netherlands

Gianluca Campo MD,
- Cardiovascular Institute, Univ. of Ferrara, Italy

Dario Buccheri MD,
- San Giovanni di Dio Hosp., Agrigento, Italy

Andrea Erriquez MD,
- Cardiovascular Institute, Univ. of Ferrara, Italy

Fernando Rivero MD,
- Hospital de la Princesa, Madrid, Spain

Giulia Zambelli MD,
- Az. Osp. Policlinico Giaccone, Palermo, Italy

CRF TCT

Multicenter, investigator-driven, open-label, prospective RCT

170 screened and not enrolled

patients with de novo lesions in SVD (diameter ≤2.75 mm)

January 2015-May 2018

232 enrolled
centralized blocks RANDOMIZATION 1:1 (prior to GW)

5 lost
8 refused

118 Elutax SV DCB

114 Xience EES

3 lost
7 refused

105 with angio

104 with angio

Primary endpoint
(6 months)
Core lab

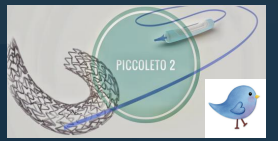
112 6-mo. clinical fup

108 6-mo. clinical fup

102
36-mo. clinical fup

101
36-mo. clinical fup

B. Cortese, JACC Int '20



Study endpoints

Primary endpoint

In-lesion late lumen loss at 6-months (core lab)

Secondary endpoints

- minimal lumen diameter (MLD)
- % diameter stenosis
- binary restenosis
- MACE (cardiac death, non-fatal MI, TLR) thru 3 years
- the single components

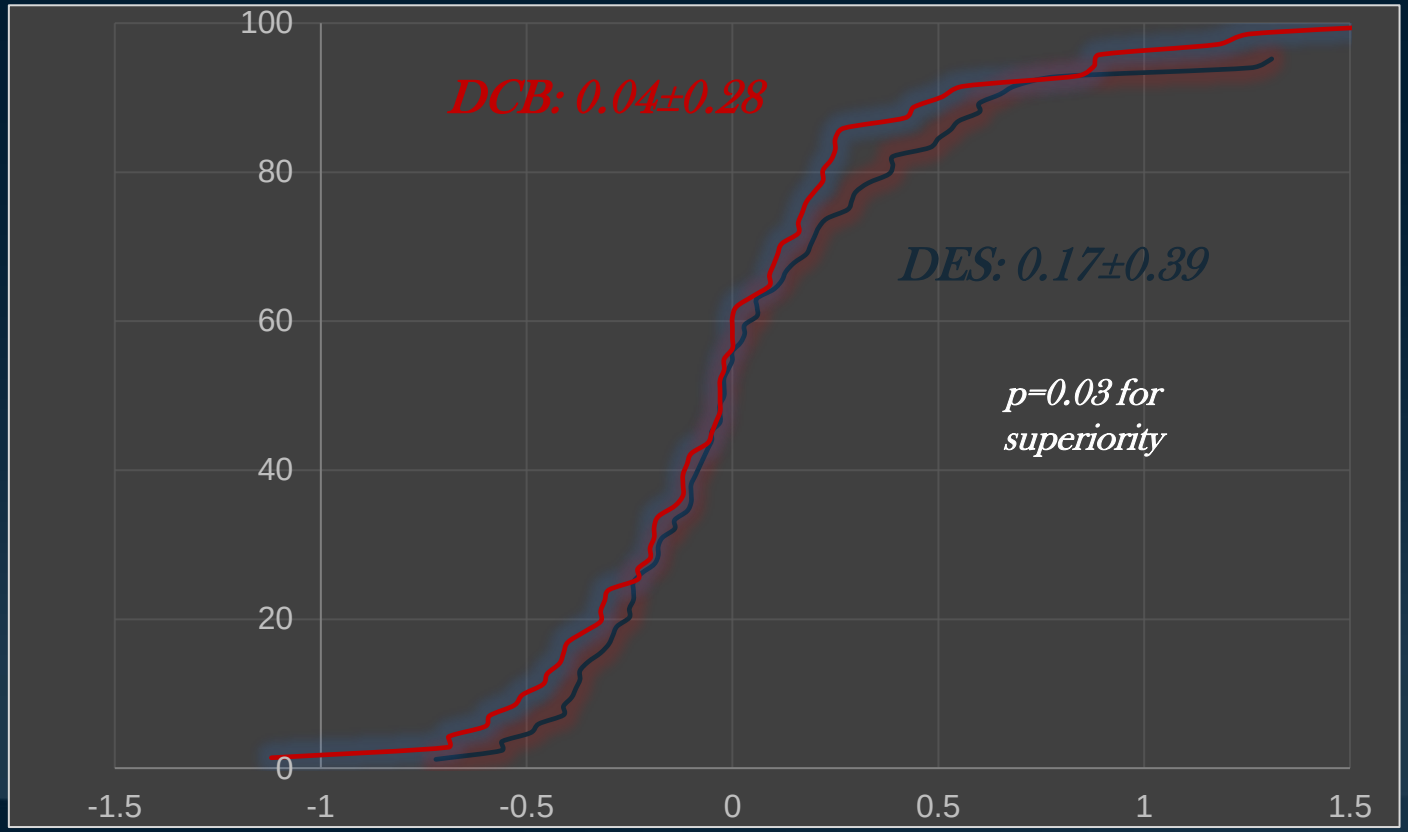
Baseline clinical characteristics

	DES	DCB	p
Number of patients	114	118	
Male, n (%)	87 (76.9)	83 (70.3)	0.25
Age, years, median (IQR)	66 (15.75)	64 (16)	0.32
Hypertension, n (%)	76 (67.2)	77 (65.2)	0.74
Diabetes, n (%)	40 (35.4)	45 (38)	0.65
Insulin depend. diabetes, n (%)	15 (13.3)	21 (17.8)	0.66
Smoke, n (%)	19 (16.7)	23 (19.5)	0.84
Dyslipidemia, n (%)	63 (55)	72 (61)	0.66
Renal failure, n (%)	12 (10.6)	4 (3.3)	*0.03*
Previous MI, n (%)	34 (30)	45 (38)	0.19
Previous CABG, n (%)	4 (3.5)	4 (3.3)	0.95
Previous PCI, n (%)	60 (53)	59 (50)	0.33
LVEF, Median (IQR)	58 (7)	58 (10)	0.89

Baseline procedural characteristics

	DES	DCB	p
Number of patients and lesions	114	118	
Predilatation, n (%)	78 (69)	99 (84)	0.007
Postdilatation, n (%)	66 (59.4)	4 (3.3)	0.001
Number of devices used (mean), n	1.12	1.03	0.04
Length of device used (mean), mm (SD)	18.3 (6.9)	21.8 (8.2)	0.04
Mean inflation pressure, atm (SD)	13.7 (2.5)	11.4 (3.3)	0.07
Mean duration of inflation, sec (SD)	21.4 (11.8)	49.2 (14.5)	0.003
Bailout stenting, n (%)	-	8 (6.8)	-
Angiographic success, n (%)	113 (99.1)	116 (98.3)	0.88
Procedural success, n (%)	112 (98.2)	116 (98.3)	0.92

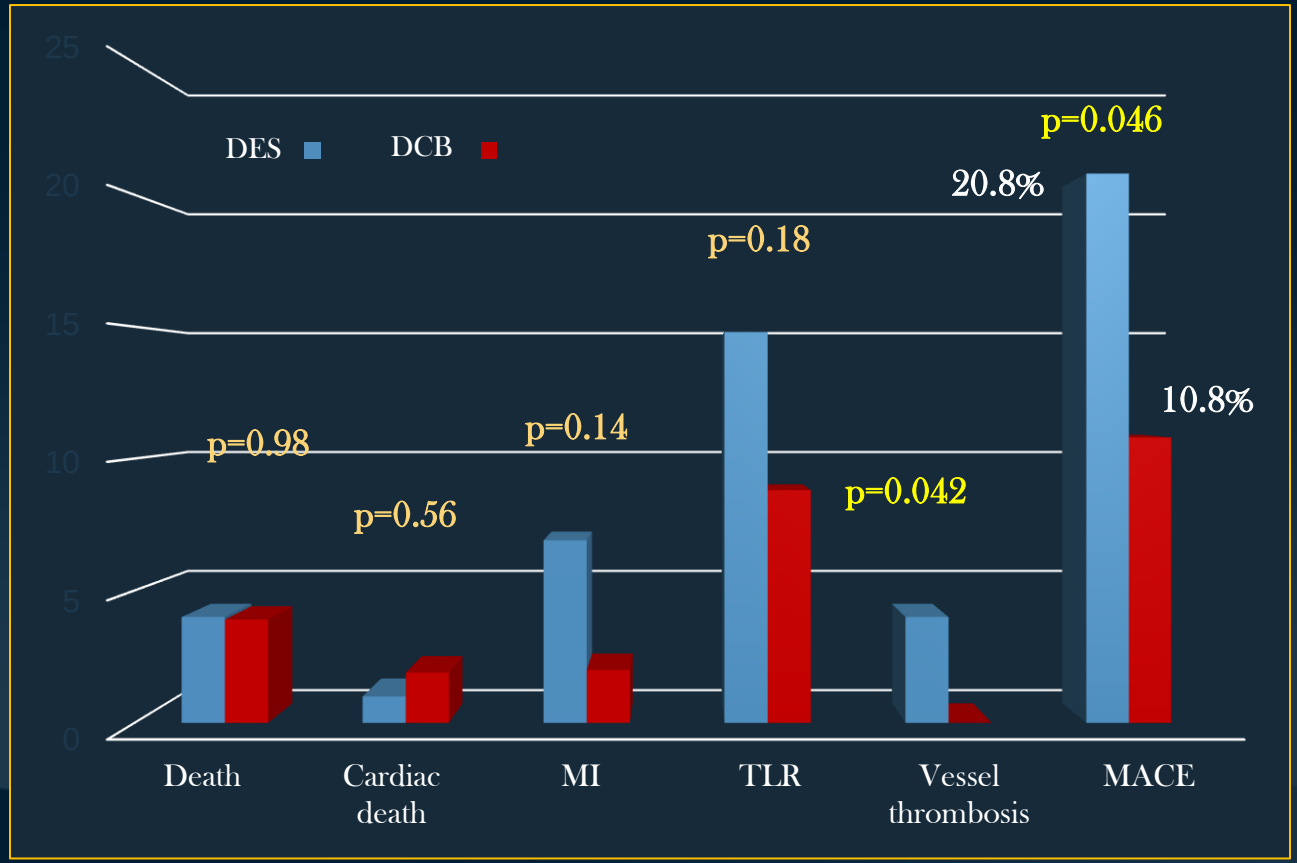
In-lesion LLL (primary study endpoint)



B. Cortese, JACC Int '20

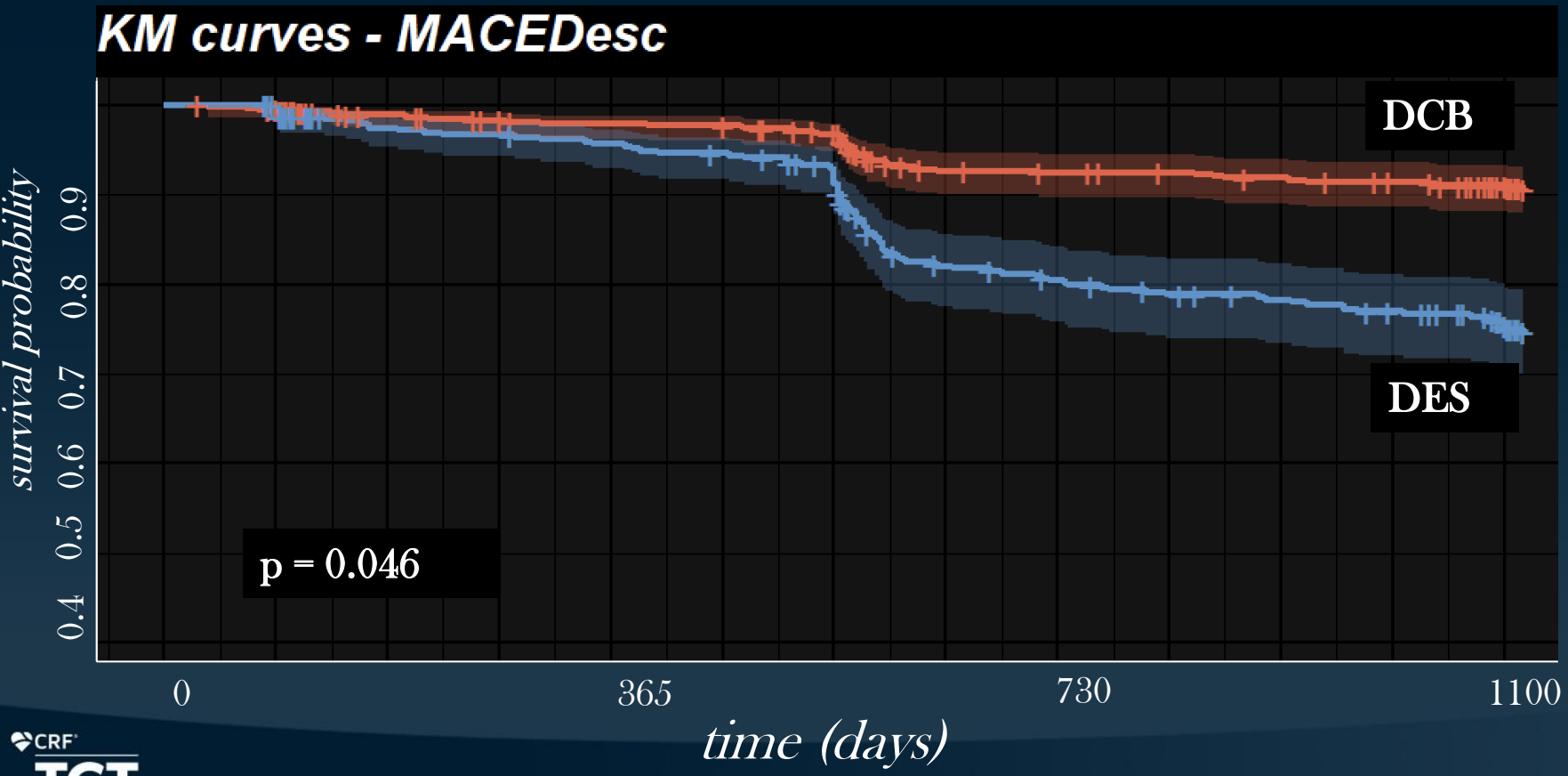
3y. clinical outcome

(median 1101, interquartile range: 1055 to 1146 days)



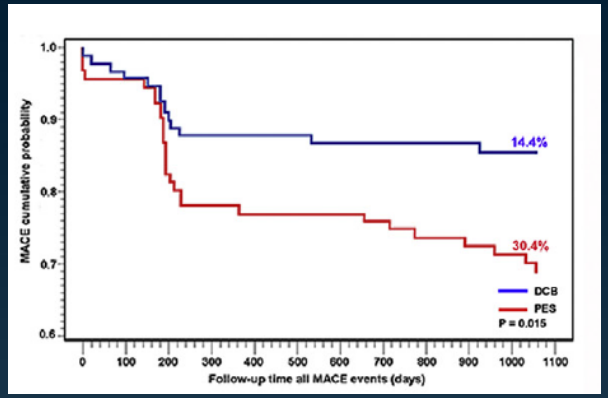
CRF TCT

Kaplan Meier curves of freedom from MACE at 3 year

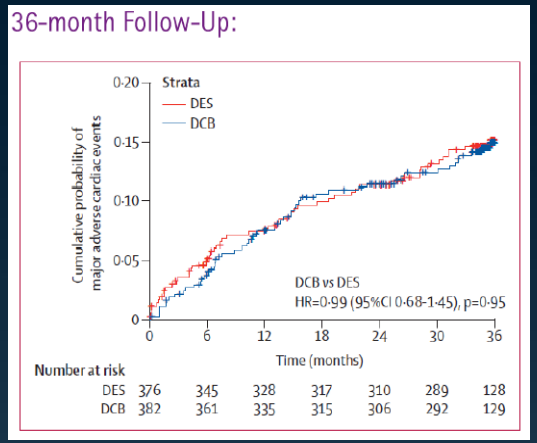


CRF TCT

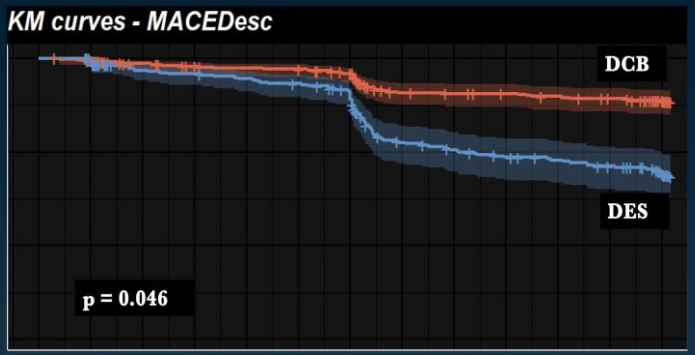
is it too much to expect better clinical outcome by DCB vs. DES on the long term?



BELLO 3y. JACC Int '15



BS II 3y. Lancet '20



PICCOLETO II 3y. TCT '22

PICCOLETO II-current limitations

- *PII is a relatively small study, not powered for hard clinical endpoints*
- *only DCB-expert centers, it is possible that the outcome can be slightly different with less-experienced operators*
- *these results cannot be perceived for all available DCB (a class effect does not exist).*

conclusions

- *PICCOLETO II study ougth to compare Elutax SV DCB vs EES in the small vessel disease setting, and superiority was obtained as regards LLL (primary EP).*
- *the final 3-year follow up shows a significant reduction in abrupt vessel closure and MACE in the DCB arm.*
- *adequately powered studies are needed, to understand if this sign of improved outcome with latest generation paclitaxel DCB is confirmed, and the curve of the events remains flat.*