

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

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**TCT**

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# Disclosure Statement of Financial Interest

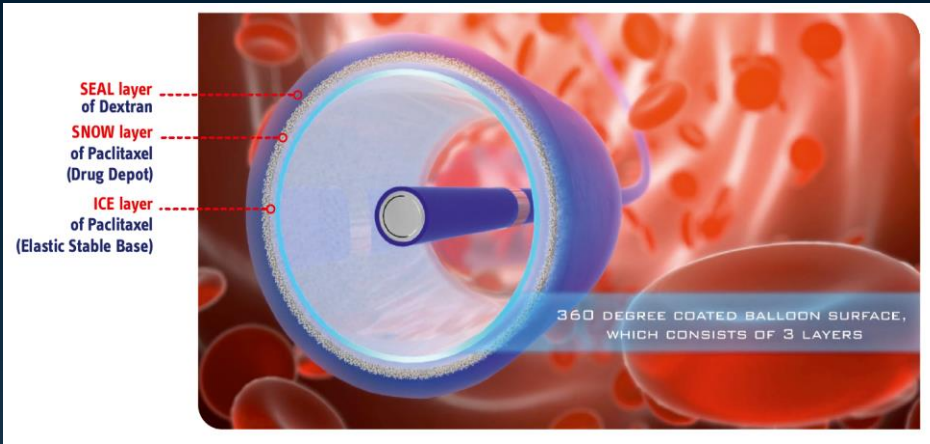
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## *Background of PICCOLETO II*

- 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*



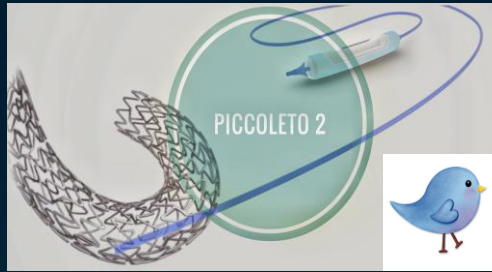
- *SEAL layer made of DEXTRAN, a hydrogel with hydrophilic features, to obtain a longer drug absorption in time*
- *drug deployed on inflated balloon*
- *lower dose PTX (2.2 micrg/mm<sup>2</sup>)*
- *higher PTX persistance at 30 days (5-8% of the drug)*

# 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)	<i>de novo</i> (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

# PICCOLETO II-PIs and participating Centers



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

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*Independent clinical Ev. Comm.*

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

*Clinicaltrials.gov: NCT 03899818*

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

170 screened and not enrolled

patients with de novo lesions in SVD  
(diameter  $\leq 2.75$  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

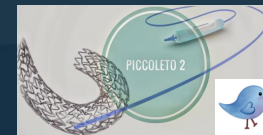
108 6-mo. clinical fup

102

36-mo. clinical fup

101

36-mo. clinical fup



# *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



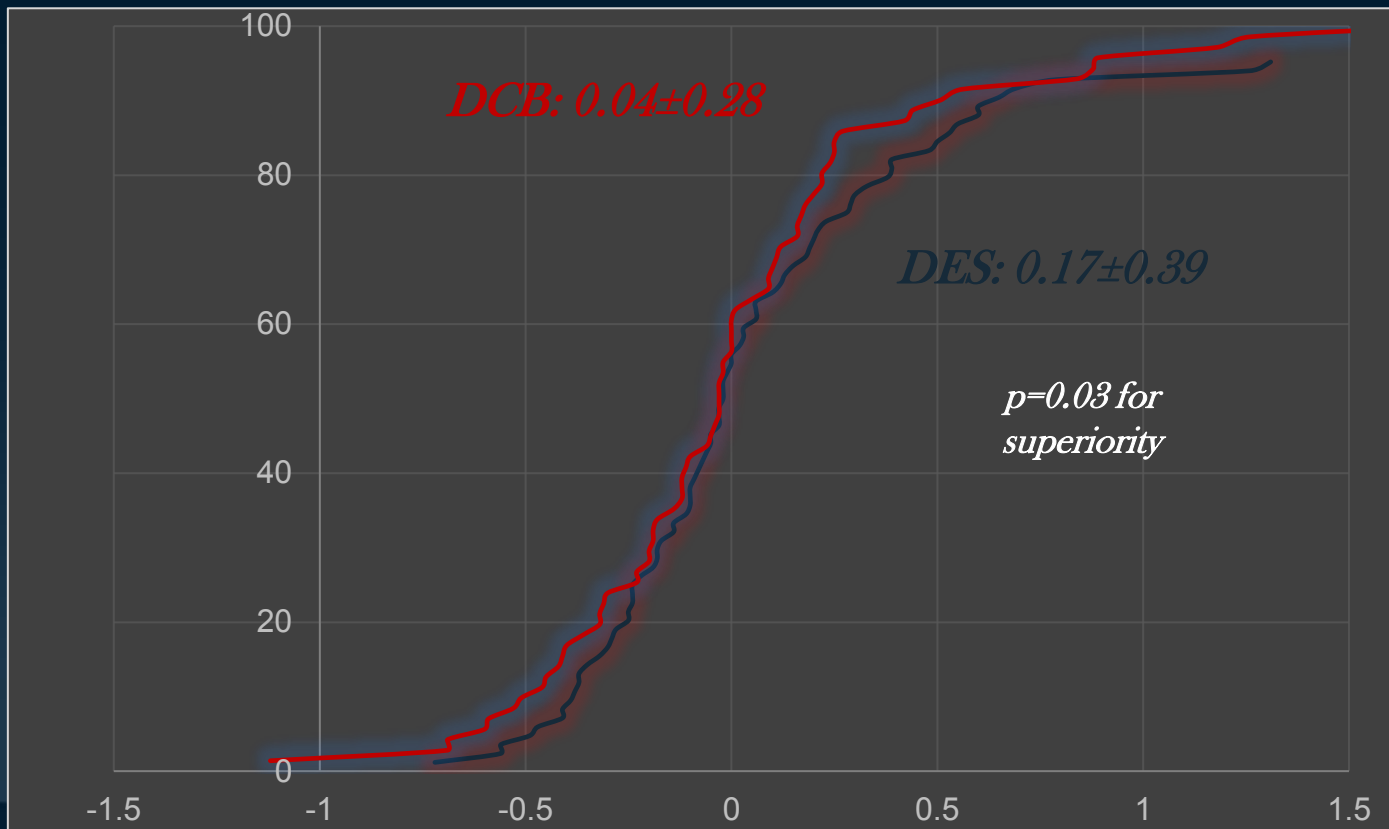
## Baseline clinical characteristics

	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*

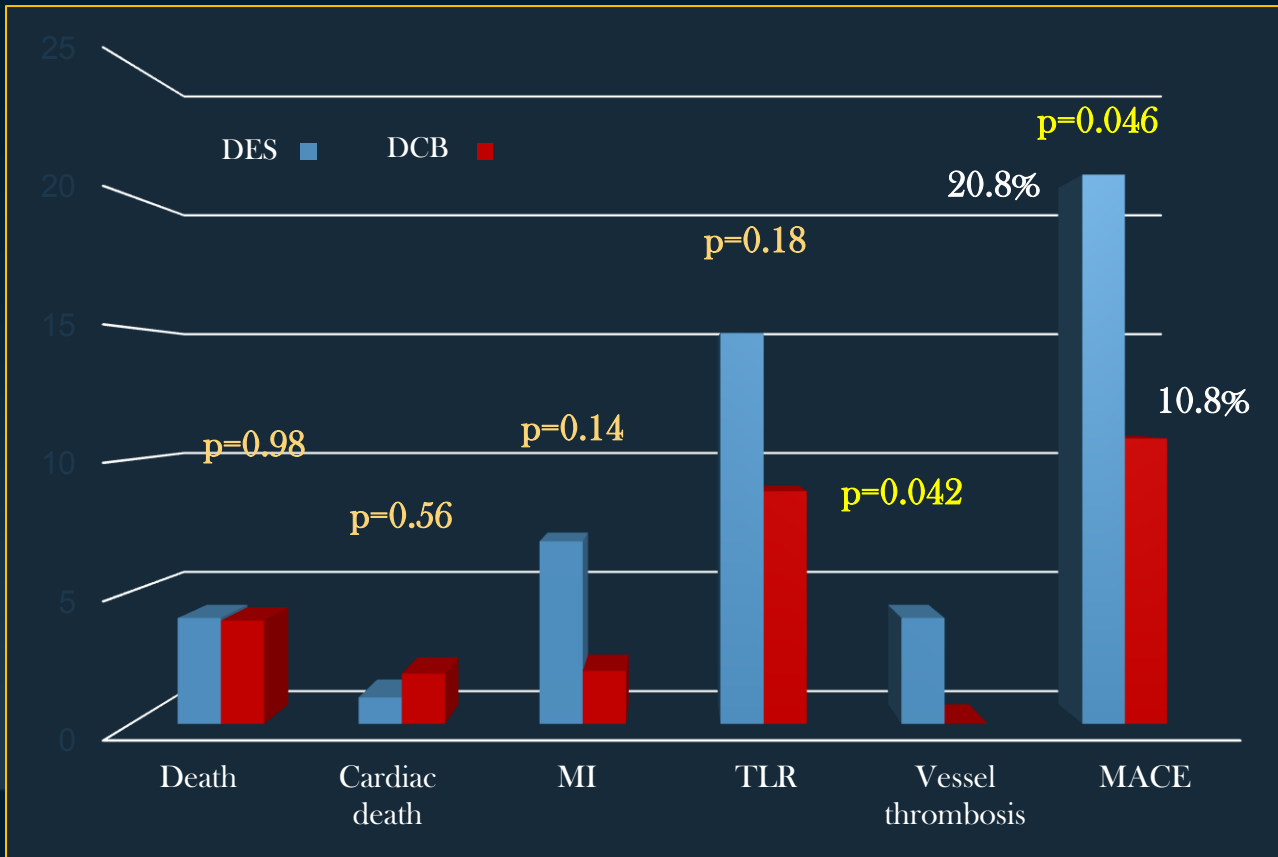
	<b>DES</b>	<b>DCB</b>	<b>p</b>
Number of patients and lesions	114	118	
 Predilatation, n (%)	78 (69)	99 (84)	0.007
Postdilatation, n (%)	66 (59.4)	4 (3.3)	0.001
Number of devices used (mean), n	1.12	1.03	0.04
Length of device used (mean), mm (SD)	18.3 (6.9)	21.8 (8.2)	0.04
Mean inflation pressure, atm (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)*



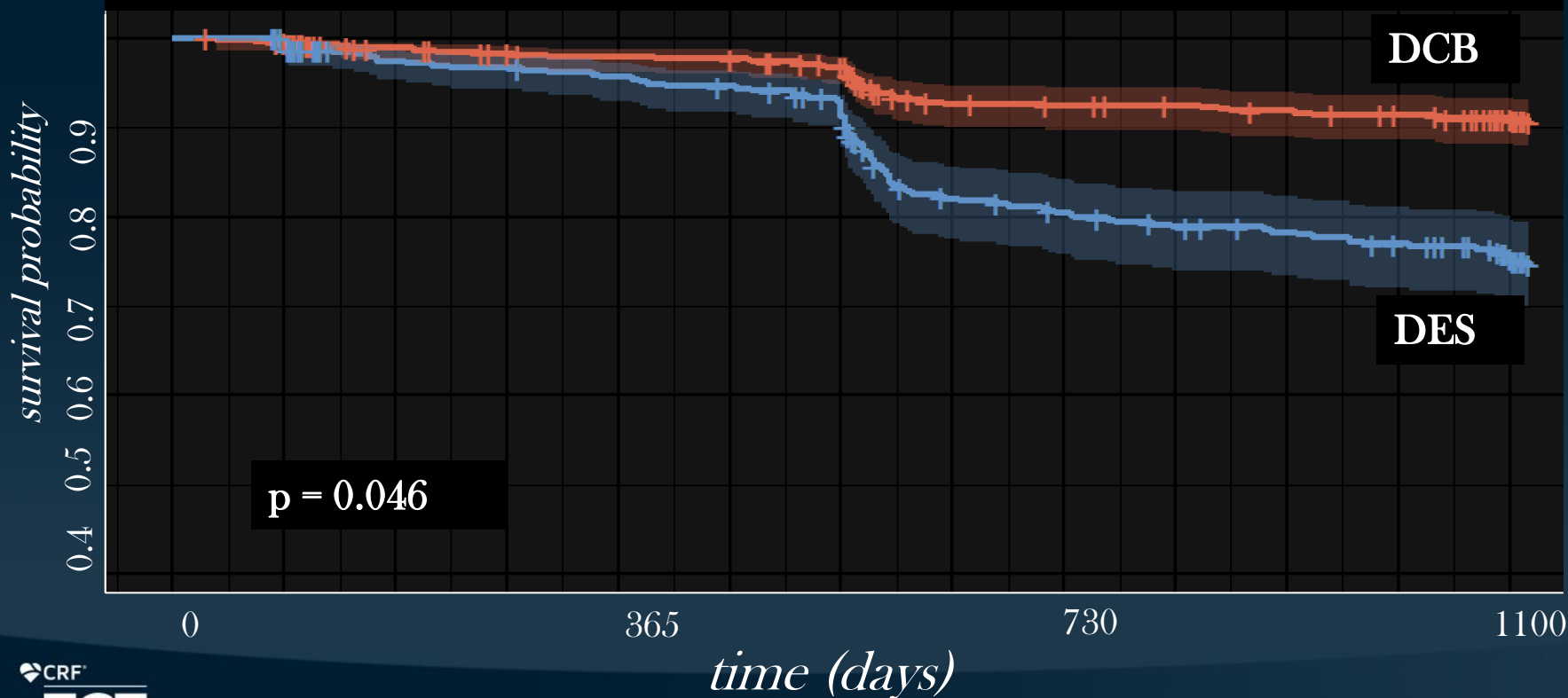
# 3y. clinical outcome

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

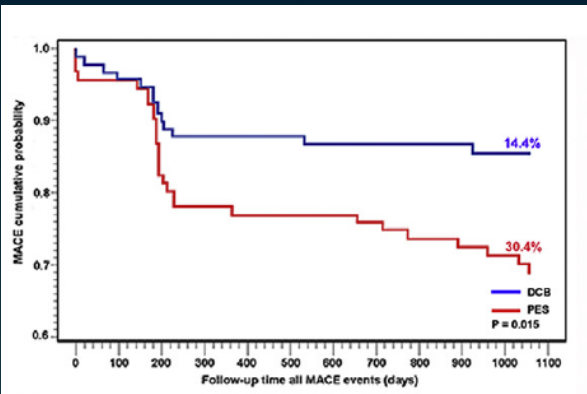


# Kaplan Meier curves of freedom from MACE at 3 year

## KM curves - MACEDesc

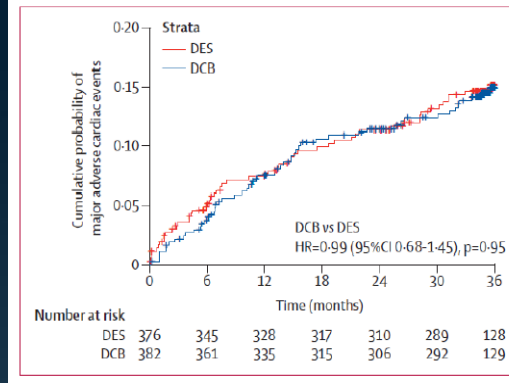


# is it too much to expect better clinical outcome by DCB vs. DES on the long term?



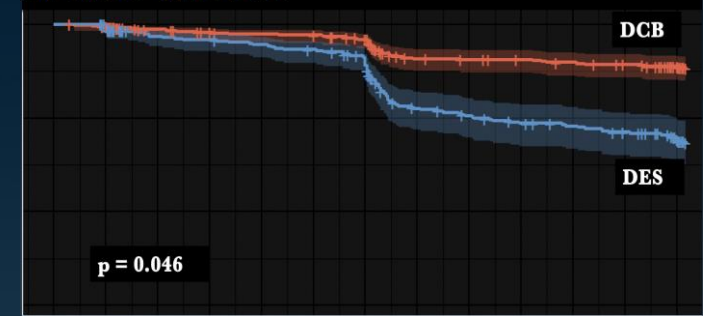
BELLO 3y. JACC Int '15

36-month Follow-Up:



BS II 3y. Lancet '20

KM curves - MACEDesc



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 ought 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.*