2019 euro PCR

Revascularisation with paclitaxel-coated balloon angioplasty versus drug-eluting stenting in acute myocardial infarction: a prospective, randomised controlled trial

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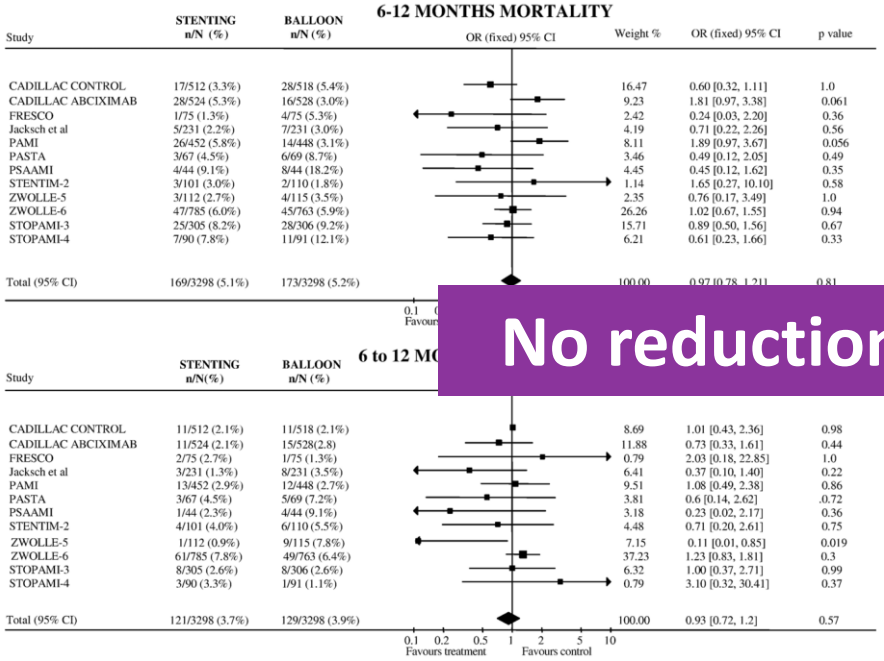
Potential conflicts of interest

Speaker's name : Nicola S. Vos

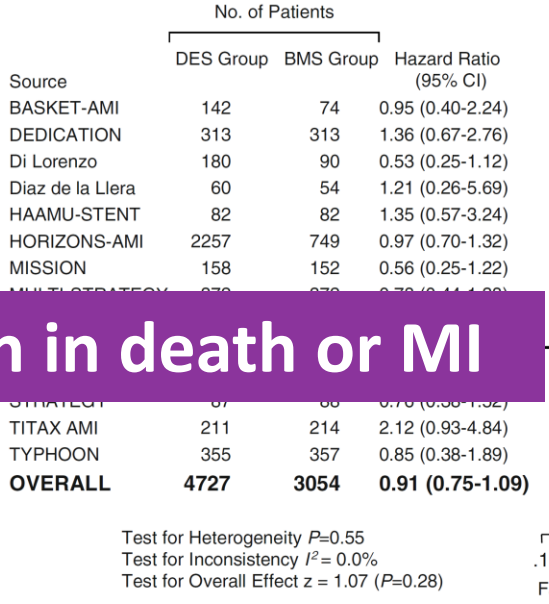
- ☑ I do not have any potential conflict of interest to declare

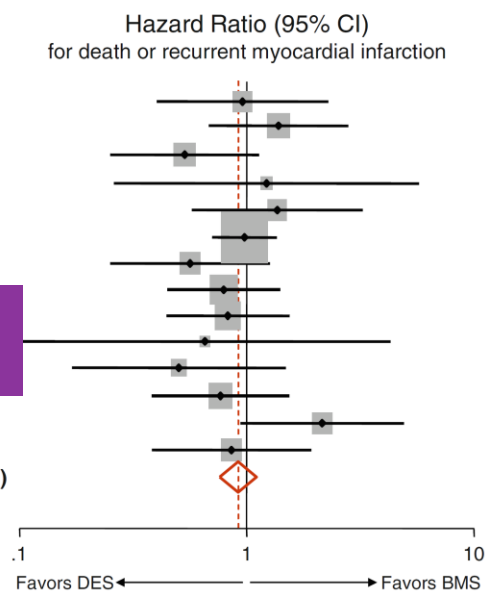
Background - 1

BMS vs POBA



DES vs BMS

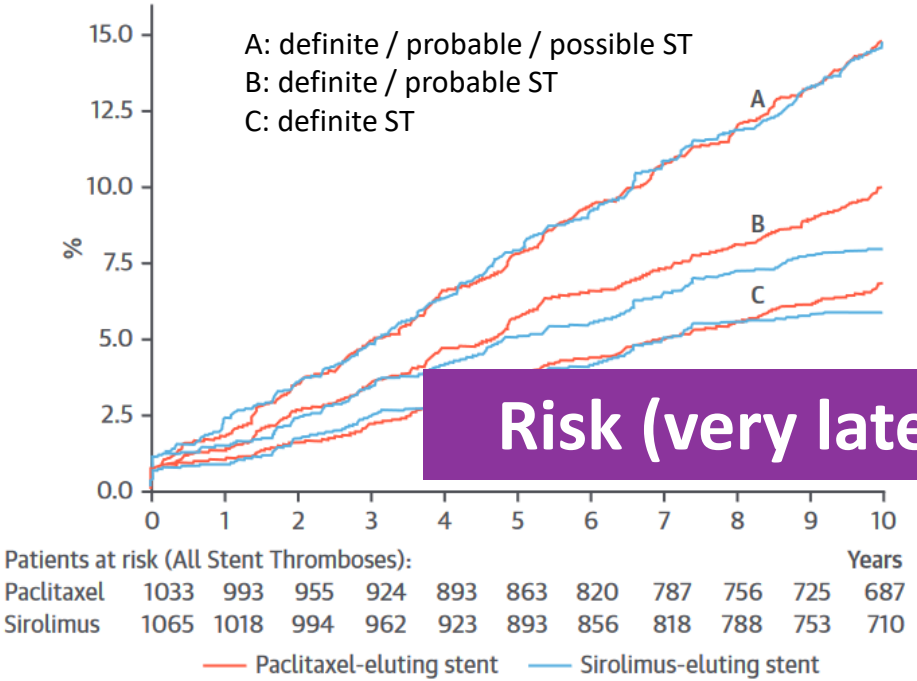


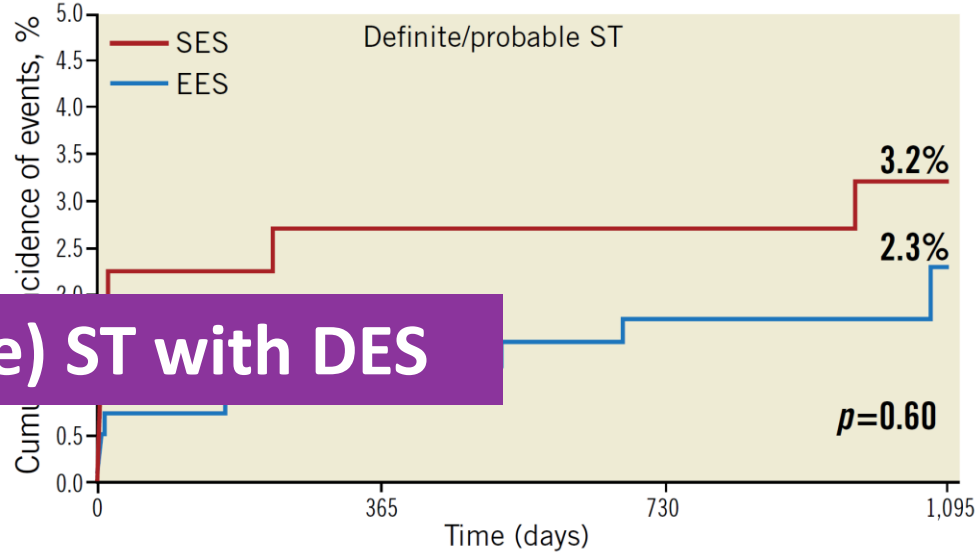


No reduction in death or MI

De Luca et al, Int J Cardiol 2008; Dibra et al, Clin Res Cardiol 2010

Background - 2





Risk (very late) ST with DES

Galloe et al, J Am Coll Cardiol 2017; Hofma et al, EuroIntervention 2015

Hypothesis and study design - 1

- DCB ‘only’ strategy:
  - No potential short- and long-term disadvantages stent implantation
  - Reduction probability of restenosis observed in POBA era

- Paclitaxel-eluting balloon versus DES in primary PCI
  - DCB: Pantera Lux (Biotronik)
  - DES: Orsiro (Biotronik) or Xience (Abbott)

- Efficacy:
  - Primary end point: fractional flow reserve at 9-months follow-up
    - Margin of noninferiority ≤ 0.05
  - Secondary end points:
    - Late luminal loss (QCA) at 9-months follow-up
    - MACE (cardiac death, recurrent MI, TLR)
- Safety:
  - Stent thrombosis / major bleeding (BARC)

Study design - 2

STEMI eligible for PPCI

Exclusion criteria:
- age < 18 year or > 75 year
- history of MI
- stent implantation (< 1month)
- contraindications DAPT / anticoagulation therapy
- cardiogenic shock / intubation

Inclusion criteria (cath lab):
- de novo culprit lesion
- native coronary artery
- absence of severe calcification
- diameter ≥2.5mm and ≤4.0mm

and

- residual stenosis ≤50% *after* optimal lesion preparation (by visual assessment)

Randomisation (1:1):
- DCB*
- DES

*** Bail-out stenting in case of:**
- Residual stenosis >50% (by visual assessment)
- Coronary dissection ≥ type C

Index hospitalisation:
- TTE / ECG / laboratory

Follow-up

At 9 months: day clinic
- laboratory
- TTE
- control coronary angiography
  - FFR / iFR target lesion
  - QCA target lesion

Long-term: by telephone
- 2 year
- 3 year
- 4 year
- 5 year

Results - 1

Procedural characteristics

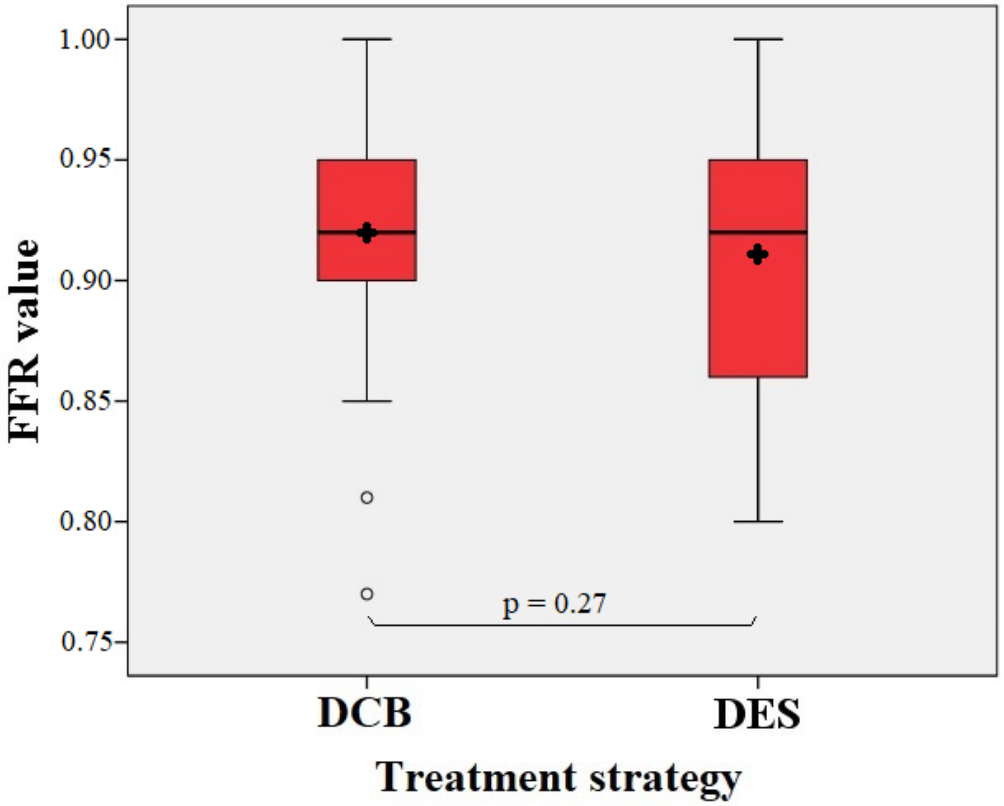
	DCB (n = 60)	DES (n = 60)	p Value
DAPT loading dose	60 (100)	60 (100)	1.00
P2Y12 inhibitor			0.70
Prasugrel	4 (7)	3 (5)	
Ticagrelor	56 (93)	57 (95)	
Radial approach	59 (98)	60 (100)	0.32
Amount of diseased vessels			0.91
1-VD	44 (73)	42 (70)	
2-VD	12 (20)	14 (23)	
3-VD	4 (6.7)	4 (6.7)	
Infarct-related artery			0.50
RCA	29 (48)	28 (47)	
LAD	19 (32)	24 (40)	
RCx	12 (20)	8 (13)	
TIMI flow grade pre-procedure			0.53
0	30 (50)	30 (50)	
1	5 (8)	3 (5)	
2	6 (10)	11 (18)	
3	19 (32)	16 (27)	
Thrombosuction performed	47 (78)	50 (83)	0.49
Predilatation performed	60 (100)	57 (95)	0.08
Pressure predilatation, atm	13.2 ± 3.0	12.6 ± 2.5	0.28
DCB		–	–
Only	49 (82)		
Additional stenting	11 (18)		
DCB		–	–
Average pressure, atm	10.2 ± 2.7		
Inflation time, s	64 ± 15		
Postdilatation performed	11 (18)	15 (25)	0.14
Pressure postdilatation, atm	12.6 ± 2.8	15.1 ± 5.2	0.24
TIMI flow grade post-procedure			
0	0 (0)	0 (0)	0.32
1	0 (0)	0 (0)	
2	1 (2)	0 (0)	
3	59 (98)	60 (100)	
Time to first medical contact, min	60 (26-120)	60 (30-120)	0.54
Time to balloon, min	125 (90-210)	128 (90-210)	0.90
ST-segment resolution (90-120 min), %			0.20
<30	3 (5)	0 (0)	
30-70	16 (27)	15 (25)	
>70	41 (68)	45 (75)	

Results - 2

Primary end point

FFR at 9-months FU

DCB (n=35)	DES (n=38)	P value
0.92 ± 0.05	0.91 ± 0.06	0.27



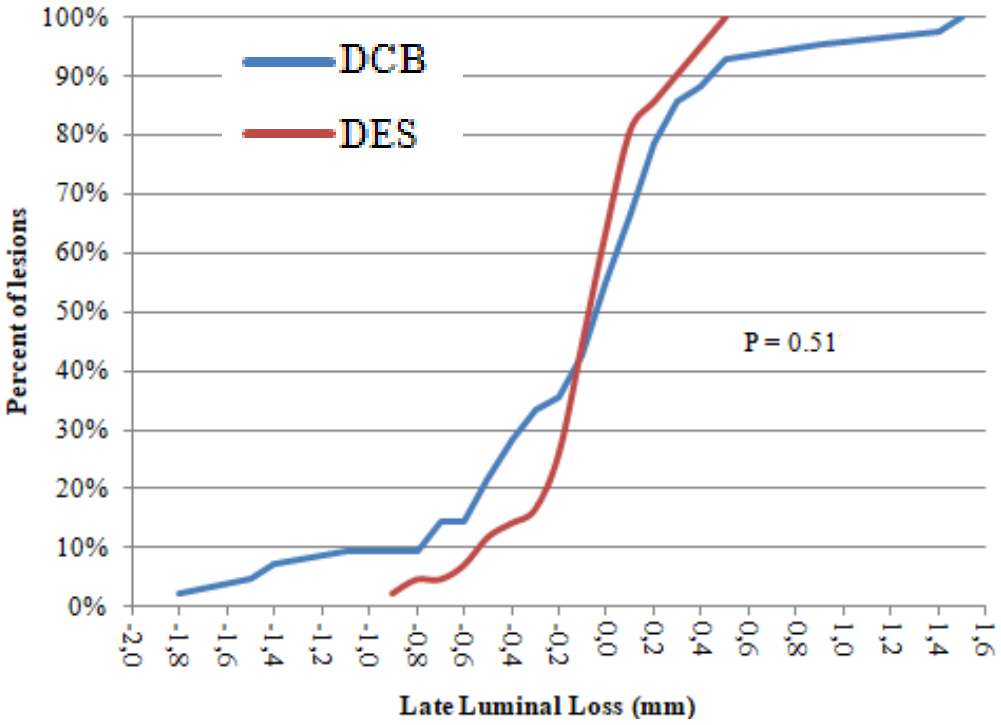
Results - 3

Secondary end points at 9-months FU

	DCB (n=42)	DES (n=42)	P value
LLL (mm)	0.05 [-0.40 – 0.20]	0.00 [-0.16 – 0.10]	0.51

MACE	DCB	DES	P value
MACE			1.00*
Cardiac death	0/60	0/60	
Recurrent MI	0/58	0/54	
TLR	2/58	1/54	

*Fisher exact



Conclusion

- DCB strategy in STEMI: efficient, safe and feasible
  - Despite a small risk of coronary dissections requiring bail-out stenting
  - Results up to 9-months follow-up
- ‘Truly leaving nothing behind’ without compromising results
- Further investigation: patient and lesion characteristics who may benefit a DCB strategy the most
- Clinical follow-up will evaluate prognostic value of FFR as physiologic end point in these patients

The essentials to remember

- *Why?*
  - Despite major improvements in primary PCI, still potential disadvantages of DES
- *What?*
  - DCB strategy in primary PCI; 'truly leaving nothing behind'
- *How?*
  - DCB vs 3th generation DES
  - Primary end point: FFR at 9-months FU
- *What are the results?*
  - DCB noninferior to DES regarding FFR at 9-months FU
  - No significant differences in LLL and MACE up to 9-months FU
- *Why is this important?*
  - DCB could be a valuable alternative strategy in selected patients or lesions in STEMI
  - Long-term FU and further investigation is needed

Thank you for your attention

JACC Cardiovascular Interventions

Paclitaxel-Coated Balloon Angioplasty Versus Drug-Eluting Stent in Acute Myocardial Infarction

The REVELATION Randomized Trial

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