

Drug coated balloon supported Supera stent vs. Supera stent in intermediate and long-segment lesions of the superficial femoral artery: 2-year results of the RAPID trial

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On behalf of JPPM de Vries, DA Werson, B Fioole, D Vroegindeweyj , JA Vos, DAF van den Heuvel and the RAPID trial investigators.

Disclosure

Speaker name:

SW de Boer

I have the following potential conflicts of interest to report:

- An unrestricted grant was received from Cardionovum.

RAPID trial study design

DESIGN

Prospective, international, multi-centre RCT
160 patients, 1:1 randomisation
Investigator-initiated, unrestricted grant by Cardionovum

STUDY AIM

Investigate a DCB supported Supera stenting strategy vs Supera alone in challenging intermediate and long SFA lesions ($\geq 5\text{cm}$)

PRIMARY ENDPOINTS

Primary patency¹ at 24 months

INCLUSION CRITERIA

Rutherford 2-6
De novo SFA lesions $\geq 5\text{cm}$ (no restriction on length)

EXCLUSION CRITERIA

Contra-indication for anticoagulation
Severe renal failure (e-GFR $<30\text{ mL/min/1.73m}^2$)
Acute or acute on chronic limb ischemia

¹ defined as as the absence of binary restenosis (peak systolic velocity ratio (PSVR) ≥ 2.4 on duplex ultrasound (DUS) or $>50\%$ stenosis on digital subtraction angiography (DSA))

Legflow Paclitaxel-Coated balloon

LEGFLOW Characteristics

Paclitaxel $3.0\mu\text{g}/\text{mm}^2$

Excellent manoeuvrability

Highly stable coating matrix

Homogeneous drug transfer

High inflation pressures

4.0 mm – 10.0 mm balloon diameter

800 mm or 1350 mm catheter length



Baseline characteristics RAPID

		DCB + stent		POBA + stent		P	
Age (years)		67.6	(7.5)	67.0	(8.0)	0.626 ^c	
Sex	Male	52/80		50/80		0.869 ^b	
Rutherford categories						0.836 ^b	
	category 2	37/80		39/80			
	category 3	29/80		28/80			
	category 4	7/80		5/80			
	category 5	6/80		5/80			
	category 6	1/80		3/80			
ABI							
	Rest	0.59	(0.20)	0.61	(0.19)	0.480 ^c	
	After exercise	0.34	(0.18)	0.38	(0.19)	0.225 ^c	
Toe pressure							
	Dig 1	mmHg	59	(28.9)	64	(40.0)	0.513 ^c
	Dig 2	mmHg	61	(48.3)	96	(71.8)	0.245 ^c
SVS risk score	0-24	5,8	(3.2)	5.5	(3.0)	0.547 ^c	
Creatinine	μmol/l	80,9	(21,8)	82,7	(27,5)	0.649 ^c	
Risk factors							
	Diabetes	Yes	23/80		24/80		0.863 ^b
	Smoking, current or recent	Yes	40/80		39/80		1.000 ^b
	BMI	Kg/m ²	26.4	(4.9)	27.1	(4.3)	0.375 ^c

17% CLI

29% diabetes

Lesion characteristics

		DCB + stent	POBA + stent	P
TASC II Classification				0.747
A		8/80	10/80	
B		40/80	35/80	
C		15/80	20/80	
D		17/80	15/80	
Side	Right	44/80	45/80	0.873
Ostial SFA involvement	Yes	20/80 (25%)	20/80 (25%)	1.000
Occlusion	Yes	61 (76.3%)	56 (70.0%)	0.476
Length on angiogram	cm	15.8±7.4	15.8±7.6	0.996
Long lesions (≥15cm)	Yes	40/80	44/80	0.526
Severe calcification		31/80 (38.8%)	29/80 (36.3%)	0.984
Reference diameter	mm	5.1±0.7	5.2±0.8	0.624

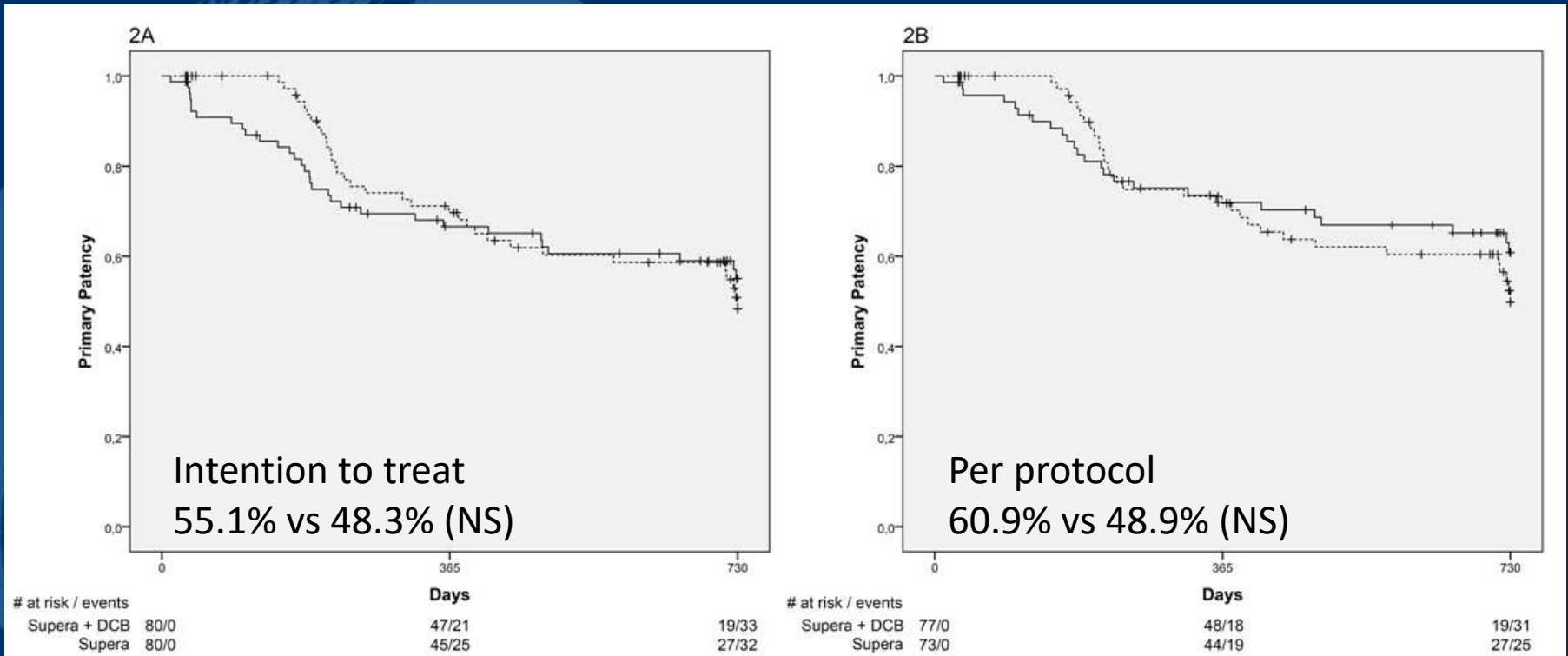
42% TASC C/D

>50% long

PACCS 3-4¹

¹Rocha-Singh KJ1, Zeller T, Jaff MR; Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. Catheter Cardiovasc Interv. 2014 May 1;83(6):E212-20. doi: 10.1002/ccd.25387. Epub 2014 Feb 10.

24 months Primary patency



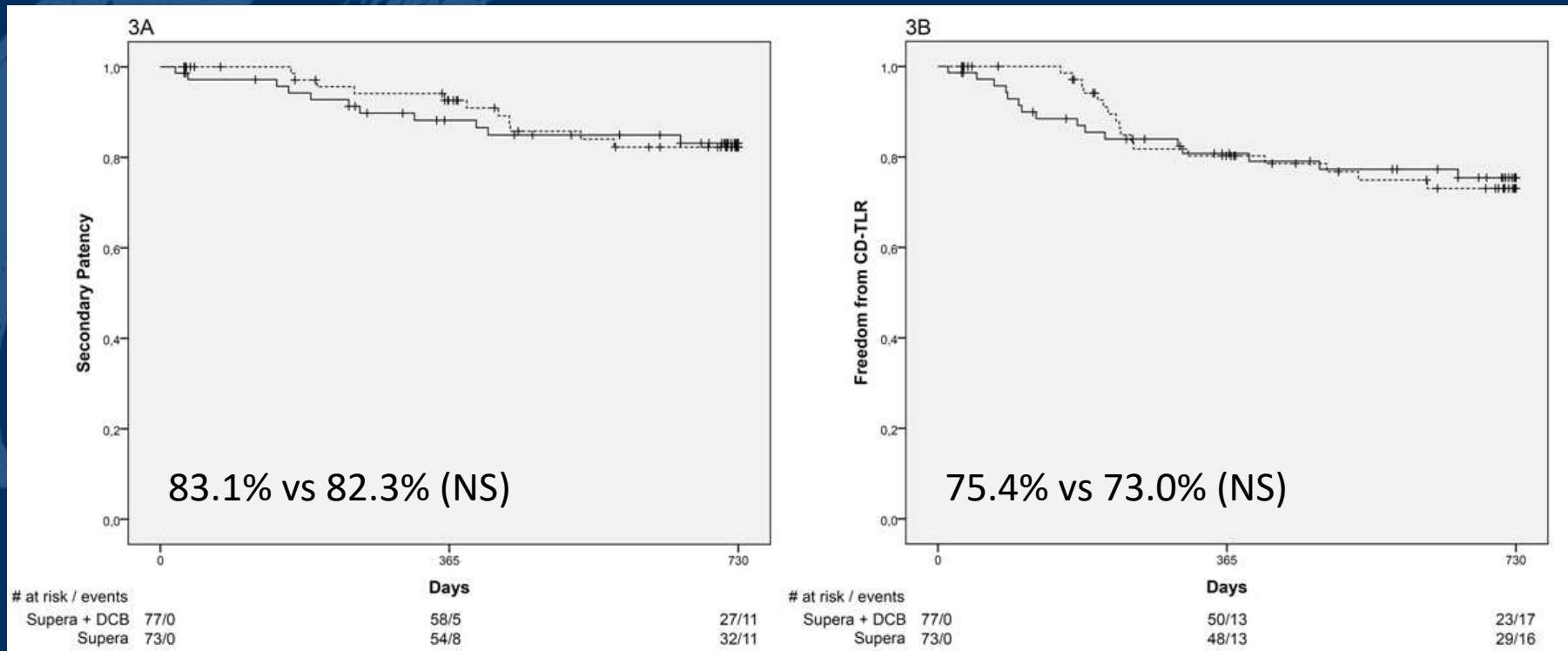
Key lesion characteristics

Lesion length 15.8cm

TASC C/D 42%

Occlusions >70%

24 months secondary patency / Freedom from CD-TLR



Safety outcome RAPID

- 7 deaths, which accounted for 8 events.
- Freedom from all-cause mortality at 24 months 92.8% [85.9% - 99.7%] VS 93.7% [87.6% - 99.8%] (NS).
- Freedom from MALE and periprocedural death at 24 months 68.5% [57.7% - 79.3%] vs 75.2% [64.8% - 85.6%] (NS).

Conclusions

- The 2-year results of a primary Supera stenting strategy are consistent with other trials reporting on treatment of intermediate and long SFA lesions.
- The Legflow DCB is safe to use in long SFA lesions.
- A DCB supported primary Supera-stenting strategy did not improve patency rates compared to a Supera-only strategy.

Big thank you to everybody who made the RAPID trial possible!



Thank you!



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