Drug-Eluting vs. Bare Metal Stents in Saphenous Vein Grafts: The Prospective Randomized BASKET-SAVAGE Trial

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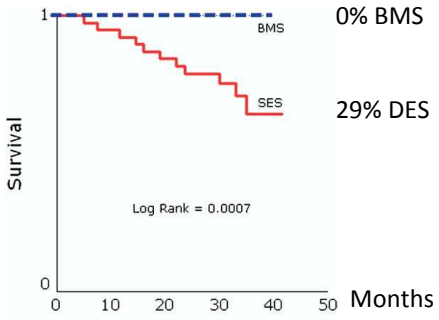
Background

- **Saphenous vein grafts (SVG): different pathophysiology than native coronary vessels**
- **Poor outcomes after SVG PCI due to peripheral embolization of friable material and high incidence of restenosis and atherosclerotic disease progression**
- **Proven efficacy and safety of DES in SVG PCI up to 1 year**
- **Increased mortality in existing long-term data of DES in SVG PCI >1 year**

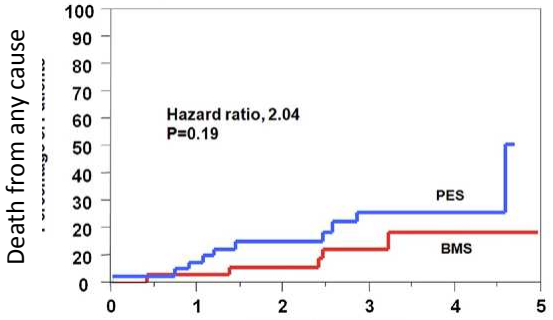
DELAYED RRISC
(n=75)



0% BMS

29% DES

SOS
(n=80)



24% DES

13% BMS

Vermeersch P et al, J Am Coll Cardiol 2007;50:261–7

Brilakis ES et al, JACC Cardiovasc Interv. 2011;4:176-82

Declaration of Interest

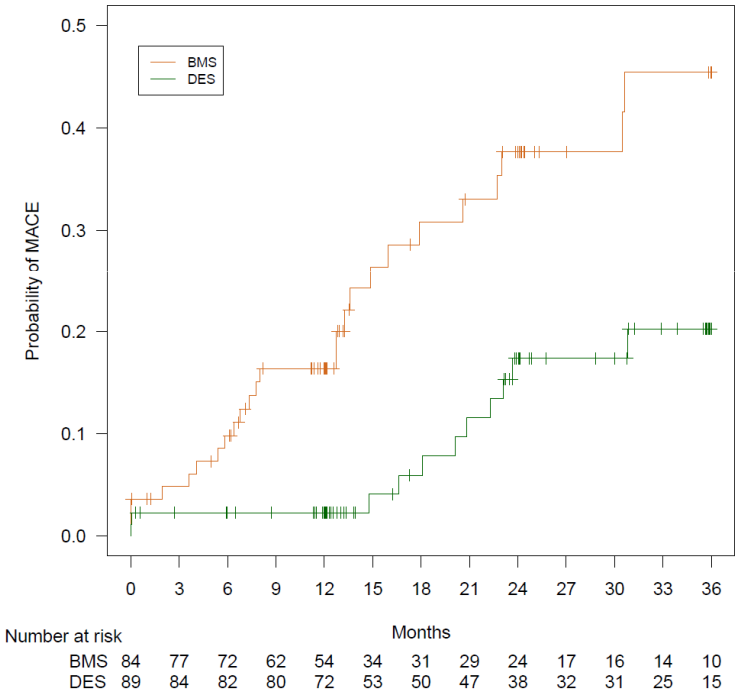
- **None**

Purpose and key points about methods

- **Aim: To assess the efficacy and safety of DES vs. BMS in SVG PCI**
  - Combination with distal protection devices and glycoprotein IIb/IIIa inhibitors
  - Large number of patients
  - Short- and long-term follow-up
- **Prospective multicenter RCT**
  - Patients with SVG lesions and an indication for PCI
  - Randomization 1:1 to DES (TAXUS Liberté) vs. BMS (Liberté)
  - Strongly recommended: Use of glycoprotein IIb/IIIa-inhibitors and distal protection devices (filter wire)
  - Sample size: 240 patients (two-sided α-level = 0.05, power = 80%)
- **Early termination of the study due to slow enrollment**
- **1° endpoint: MACE (cardiac death, non-fatal MI, and TVR) @ 12 months**
- **2° endpoints: Definitive/probable stent thrombosis, major bleeding, long-term follow-up (24, 36, 60 months)**

Results

MACE Long-Term Follow Up



Summary

	1 Year			Long-Term		
	BMS	DES	p	BMS	DES	p
MACE	17.9	2.3	<0.001	29.8	12.4	0.0012
Cardiac Death	1.2	0	0.41	3.6	4.5	0.95
Non-fatal MI	11.9	2.3	0.025	15.5	6.7	0.081
TVR	11.9	0	<0.001	19.1	4.5	<0.001
Major Bleeding	2.4	2.3	0.91	2.4	2.3	0.91
Stent Thrombosis	4.8	0	0.09	7.1	5.6	0.64
Non-cardiac Death	3.6	1.1	0.40	4.8	2.3	0.51

Conclusions

- **Confirmed efficacy and safety of DES vs. BMS in SVG PCI up to 1 year**
  - Significant reduction of MACE, MI, and TVR rates
  - Results comparable to native vessel PCI when DES combined with distal protection devices and glycoprotein IIb/IIIa inhibitors
- **Persistent efficacy and safety of DES vs. BMS in SVG PCI up to 3 years**
  - No increased late mortality risk