

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

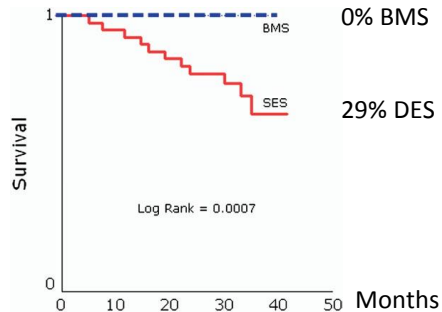
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BASKET-SAVAGE: Background

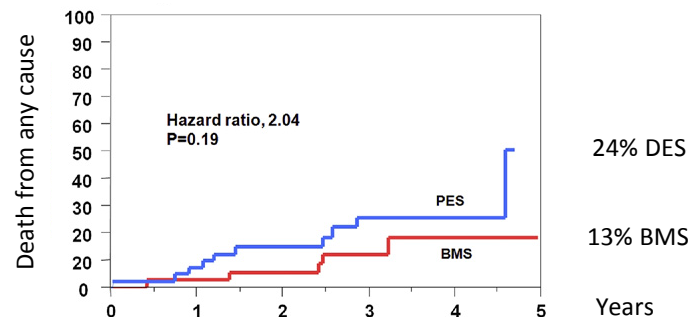
- Saphenous vein grafts (SVG): different pathophysiology than native coronary vessels
- Poor outcomes after SVG PCI due to peripheral embolization of friable material and high incidence of restenosis and atherosclerotic disease progression
- Proven efficacy and safety of DES in SVG PCI up to 1 year
-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

DELAYED RRISC
(n=75)



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

SOS
(n=80)



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



BASKET-SAVAGE: 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



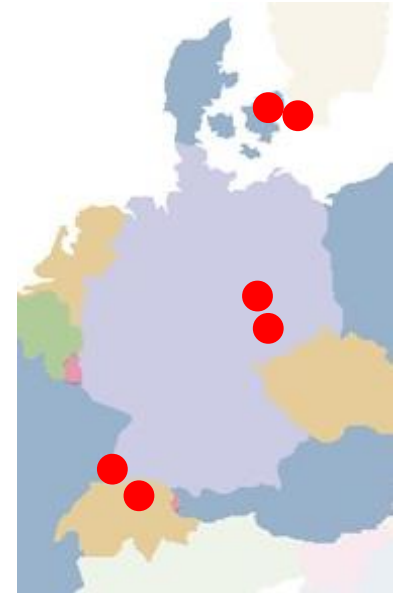
BASKET-SAVAGE: Trial Design

- 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)

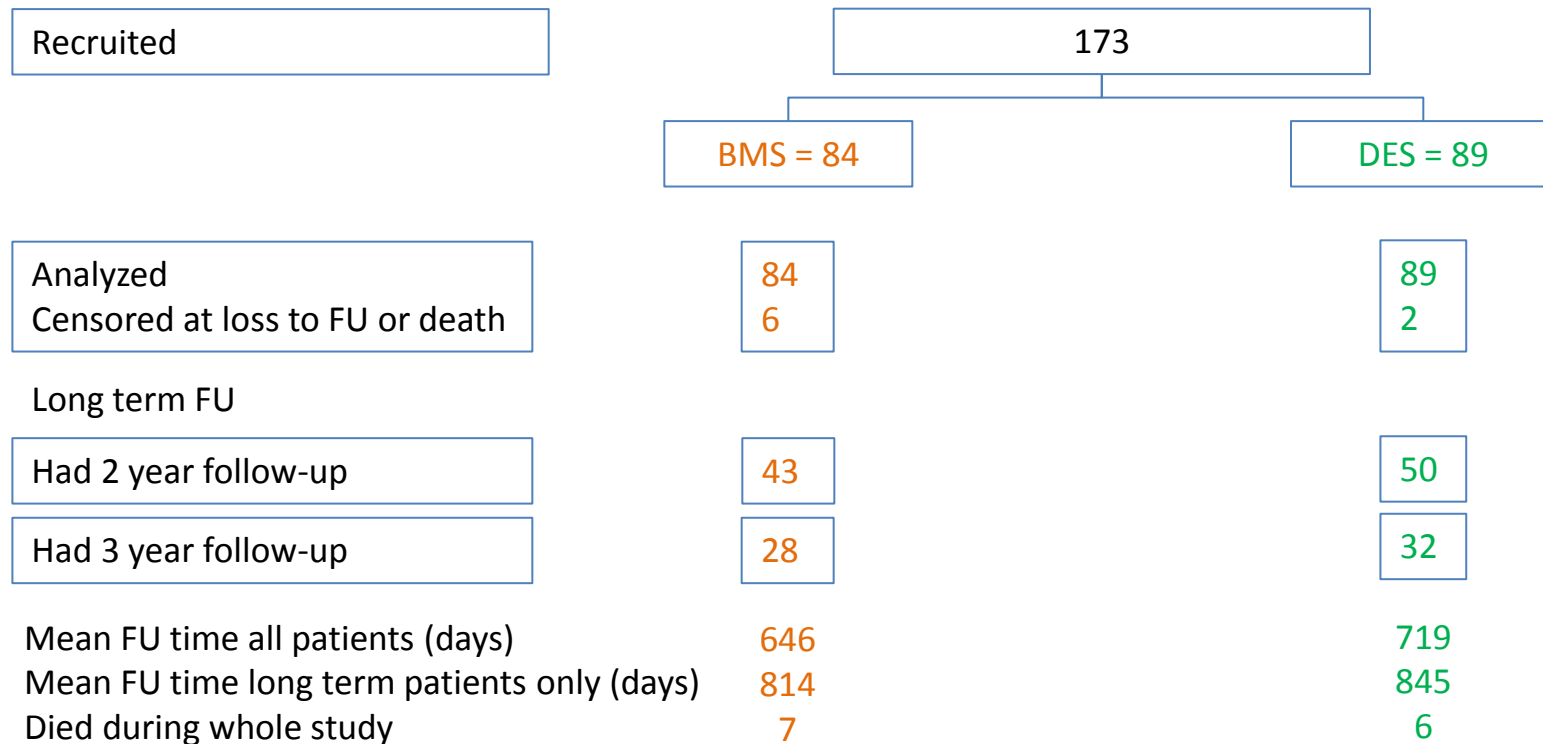


BASKET-SAVAGE: Participating Centers

Center	Country	PI
University Hospital Basel	Switzerland	R. Jeger
Triemli Hospital Zürich	Switzerland	F. Eberli
Heart Center Leipzig	Germany	S. Möbius-Winkler
Zentralklinik Bad Berka	Germany	A. Farah
Rigshospitalet Copenhagen	Denmark	T. Engstrøm
Gentofte Hospital Hellerup	Denmark	S. Galatius



BASKET-SAVAGE: Patient Flow Chart



BASKET-SAVAGE: Patient Demographics and History

	All	BMS	DES	p
Age (years)	71 ± 8	71 ± 9	71 ± 8	0.74
Sex (male, %)	90	89	90	1.00
Diabetes (%)	44	41	46	0.54
Hypertension (%)	90	89	91	0.80
Hypercholesterolemia (%)	86	87	85	0.83
ACS (%)	38	39	37	0.88
Chronic angina (%)	53	55	51	0.65
Silent Ischemia (%)	20	19	20	1.00
Prior MI (%)	63	60	66	0.52
Stroke (%)	7	5	8	0.54
PAOD (%)	18	20	16	0.55
Renal failure (%)	4	6	2	0.26

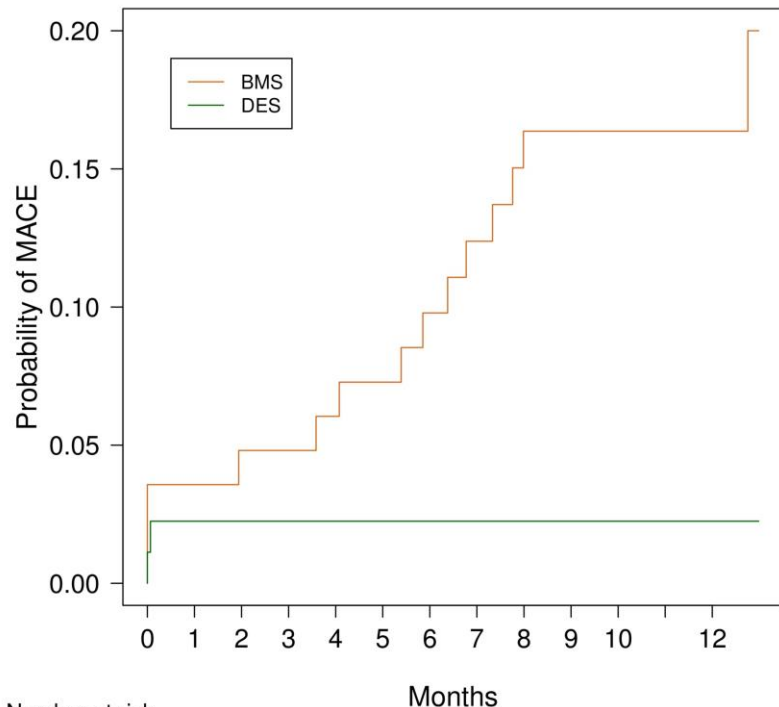


BASKET-SAVAGE: Angiography and PCI

	All	BMS	DES	p
Grafts per patient (n)	3 ± 1	3 ± 1	3 ± 1	0.50
Graft age (years)	13 ± 5	14 ± 6	12 ± 5	0.07
Target graft to... (%)				0.77
- LAD	16	17	15	
- LCX/RIM	47	50	45	
- RCA	37	33	40	
Stents per patient (n)	1.6 ± 1.0	1.5 ± 0.9	1.7 ± 1.1	0.39
Stent length per patient (mm)	31 ± 20	30 ± 20	31 ± 19	0.37
Resulting stent diameter (mm)	3.7 ± 0.6	3.7 ± 0.6	3.7 ± 0.6	0.61
Max. inflation pressure (atm)	16 ± 3	16 ± 3	16 ± 3	0.97
Filter wire (%)	66	63	69	0.52
Glycoprotein IIb/IIIa inhibitors (%)	74	72	76	0.60



BASKET-SAVAGE: MACE 12 Months (1° Endpoint)



BMS 17.9%

$p < 0.001$

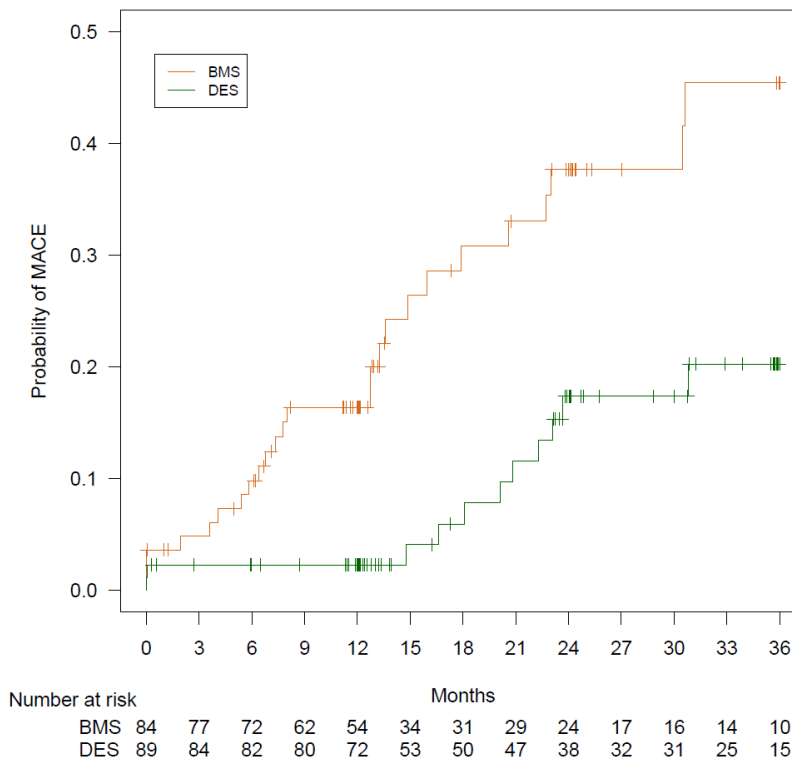
DES 2.3%

Number at risk

BMS	84	79	77	77	76	74	72	67	63	62	62	62	54
DES	89	85	85	84	84	84	82	81	81	80	80	80	72



BASKET-SAVAGE: MACE 3 Years (Long-Term FU)



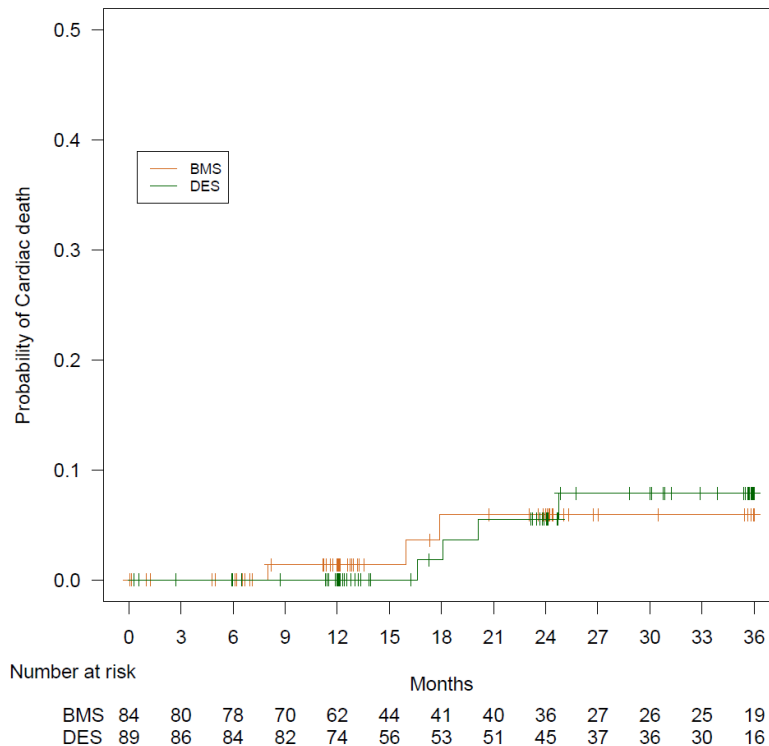
BMS 29.8%

p=0.0012

DES 12.4%



BASKET-SAVAGE: Cardiac Death (Long-Term FU)



DES 4.5%
p=0.95
BMS 3.6%



BASKET-SAVAGE: Results (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



BASKET-SAVAGE: Limitations

- Stents not available anymore in most countries of the world
 - Only product with very large sizes (>4 mm) at time of study design
- Early termination due to slow enrollment
 - Largest long-term SVG PCI outcome-trial with DES vs. BMS
 - Significance of endpoint results achieved
- Combination of distal protection devices and glycoprotein IIb/IIIa-inhibitors may have been important, but this specific contribution cannot be analysed separately



BASKET-SAVAGE: 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

