HBR SMS BA9

BIOFREEDOM™

POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM

Powered by BA9™ BIOLIMUS A9™

Freedom to treat

LEADERS FREE

The Landmark trial evaluating BioFreedom in High Bleeding Risk (HBR) patients with 1 month DAPT

Polymer-free Drug-Coated Coronary Stents
in Patients at High Bleeding Risk

BIOSENSORS INTERNATIONAL™

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The Landmark trial evaluating BioFreedom in High Bleeding Risk (HBR) patients with 1 month DAPT

LEADERS FREE Trial Design

Prospective, double-blind randomized (1:1) trial
2466 High Bleeding Risk (HBR) PCI patients

BioFreedom™ DCS vs. **Gazelle™ BMS**

DAPT mandated for 1 month only, followed by long-term SAPT

Primary safety endpoint

Composite of cardiac death, MI, definite / probable stent thrombosis at 1 year (non-inferiority then superiority)

Primary efficacy endpoint

Clinically-driven TLR at 1 year (superiority)

A Significantly Sicker Population

Baseline Characteristics	DCS (%)	BMS (%)
Mean age	**75.7 + 9.4**	**75.7 + 9.3**
Female gender	29.8	30.9
BMI	27.5 ± 4.8	27.2 ± 4.6
Diabetes	**34.0**	**32.3**
NSTEMI presentation	22.4	23.2
STEMI presentation	4.7	4.0
Prior MI	19.6	21.4
Prior PCI	22.2	21.9
Prior CABG	9.4	10.1
Multivessel CAD	**62.9**	**61.6**
Congestive heart failure	**14.4**	**12.4**
Atrial fibrillation	**34.9**	**34.6**
Peripheral vascular disease	15.7	15.8
Chronic obstructive pulmonary disease	10.9	11.7

No significant differences in baseline characteristics between the groups

- Average age is 76 years (10 years older than typical all-comers trial population)
- 62% multivessel disease
- 35% atrial fibrillation
- 13% congestive heart failure
- 33% diabetes mellitus

Values reflect the mean of the aggregate population

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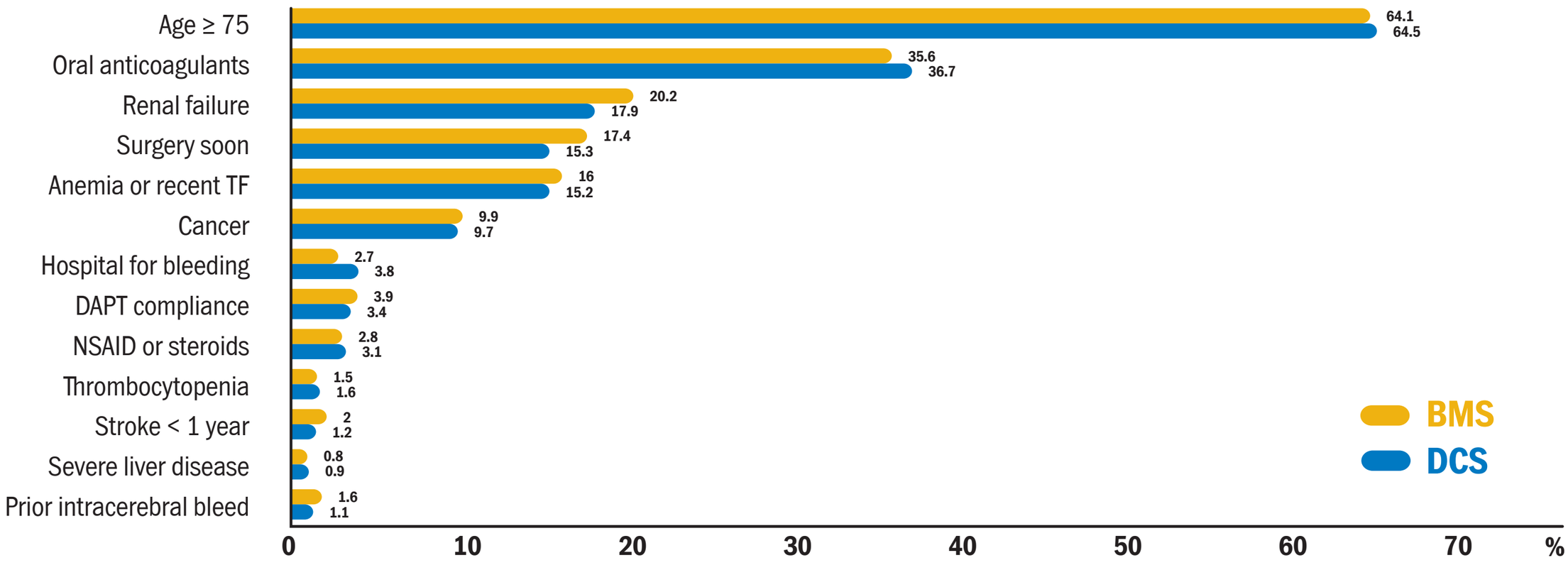
LEADERS FREE

Defining the HBR population

Neglected and Systematically Excluded from Stent Trials

On average, patients in LEADERS FREE had 1.7 inclusion criteria



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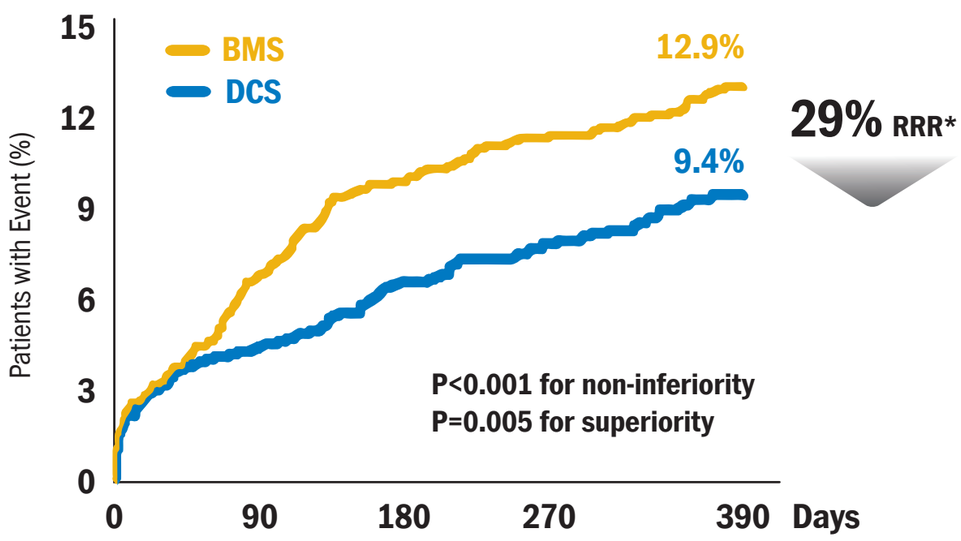
LEADERS FREE

Significantly Safer than BMS

29% Reduction in the Rate of the Composite of Cardiac Death, MI, ST

Primary Safety Endpoint (Composite of Cardiac Death, MI, ST)



Number at Risk

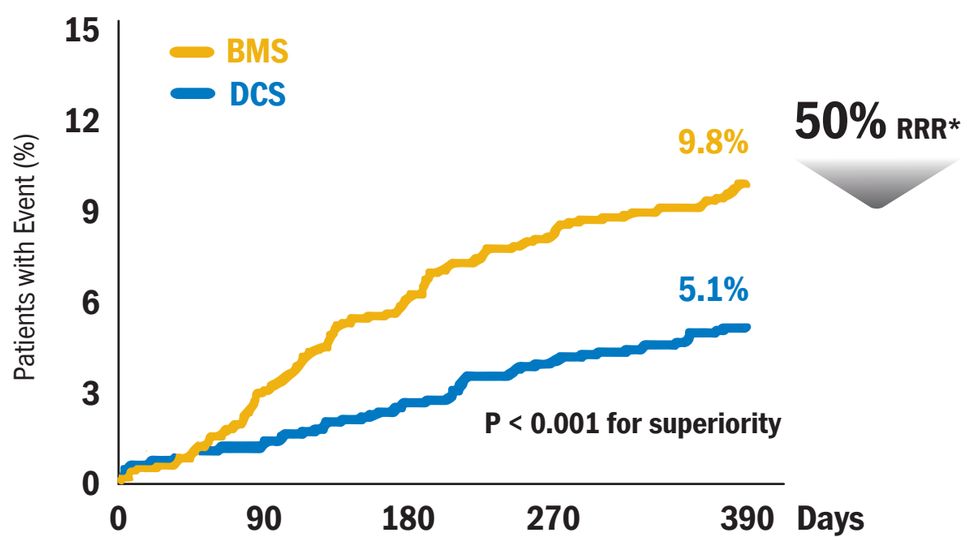
DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000

390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.71; 95% CI : 0.56 to 0.91; P = 0.005 for superiority
* Relative Risk Reduction

Significantly more Effective than BMS

50% Reduction in the Rate of Restenosis.

Primary Efficacy Endpoint (Clinically-Driven TLR)



Number at Risk

DCS	1221	1167	1130	1098	1053
BMS	1211	1131	1072	1034	984

390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.50; 95% CI : 0.37 to 0.69; P<0.001 for superiority
* Relative Risk Reduction

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POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM

Freedom to treat

BioFreedom is the only active stent with 1 month DAPT that has demonstrated superior outcomes to BMS

- ☑ **Significantly Safer than BMS**
- ☑ **Significantly more Effective than BMS**

With LEADERS FREE, BioFreedom becomes the **standard of care for High Bleeding Risk (HBR) patients**

Reference:
Urban et al. New England Journal of Medicine 2015; published ahead of print October 14. DOI: 10.1056/NEJMoa1503943

BioFreedom™ drug-coated stent and Gazelle™ coronary stent are CE Mark approved. Data on file at Biosensors International for any sustained claims in this brochure.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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