



# LEADERS FREE ACS 2 Year Clinical Evidence



CK Naber on behalf of the LEADERS FREE investigators

Christoph K. Naber is part of CERC  
and receives speaker honoraria from Biosensors

# Leaders Free ACS

In high bleeding risk patients, the *Leaders Free* trial demonstrated superiority of a BA9 polymer-free drug coated stent over BMS, associated with only one month DAPT, both in terms of safety and efficacy.

The prespecified *Leaders Free ACS* sub-study demonstrated that these results were consistent in patients with an acute coronary syndrome, suggesting, that a BMS should no longer be recommended to be used in this group of patients

Here we present for the first time the outcome of the *Leaders Free ACS* population after two years.

Urban et al. N Engl J Med 2015  
Naber et al. Eur Heart J 2016  
Garrot et al. JACC 2017

# Leaders Free ACS

Parameter	Gazelle (N=329)	Biofreedom (N=330)	Total (N=659)	p-value
Age (mean±SD)	76.5±9.0	76.9±10.0	76.7±9.5	n.s.
Female N(%)	110 (33.4)	122 (37.0)	232 (35.3)	n.s.
NSTEMI N(%)	281 (85.4)	273 (82.7)	554 (84.1)	n.s.
Diabetes N(%)	108 (32.8)	111 (33.8)	219 (33.3)	n.s.
Renal Impairment N(%)	81 (24.8)	66 (20.1)	147 (22.4)	n.s.
Previous Stroke N(%)	26 (7.9)	46 (14.1)	72 (11.0)	0.01
Previous MI N (%)	82 (24.9)	63 (19.1)	145 (22.0)	n.s.
Previous CABG N(%)	23 (7)	24 (7.3)	47 (7.1)	n.s.
Previous PCI N(%)	67 (20.4)	55 (16.7)	122 (18.5)	n.s.
Atrial Fibrillation N(%)	109 (33.1)	84 (25.5)	193 (29.3)	0.03

Naber et al. Eur Heart J 2016

# Leaders Free ACS

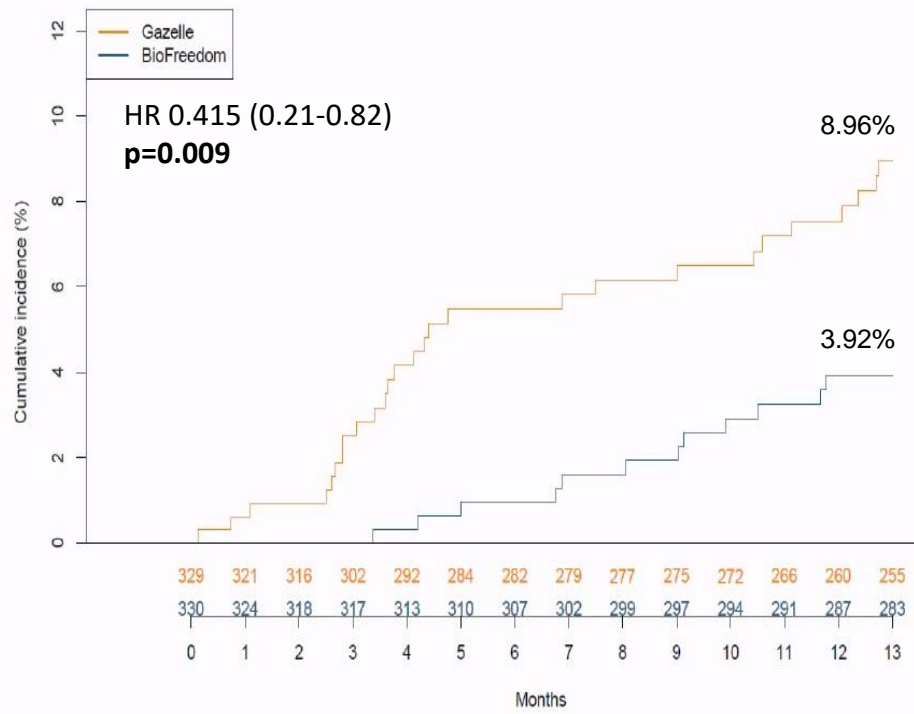
Parameter	Gazelle (N=329)	Biofreedom (N=330)	Total (N=659)	p-value
LL mm (mean±SD)	17.6±8.9	18.3±11.3	17.9±10.1	n.s.
LL ≥30 mm N(%)	40 (7.2)	33 (6.7)	73 (7.0)	n.s.
RVD mm (mean±SD)	3.0±0.5	3.0±0.5	3.0±0.5	n.s.
RVD ≤2.75 mm (mean±SD)	167 (30.0)	166 (33.9)	333 (31.8)	n.s.
ACC-Class B2&C* N(%)	266 (29.5)	244 (30.6)	500 (30.0)	n.s.
LAD N(%)	174 (52.9)	192 (58.2)	366 (55.5)	n.s.
Stent Length mm (mean±SD)	36.5±26.5	33.4±23.3	35.0±25.0	n.s.
Overlapping Stent N (%)	62 (18.9)	49 (14.8)	111 (16.9)	n.s.
Residual Stenosis % (mean±SD)	1.9±8.5	2.0±8.9	1.9±8.7	n.s.

Naber et al. Eur Heart J 2016

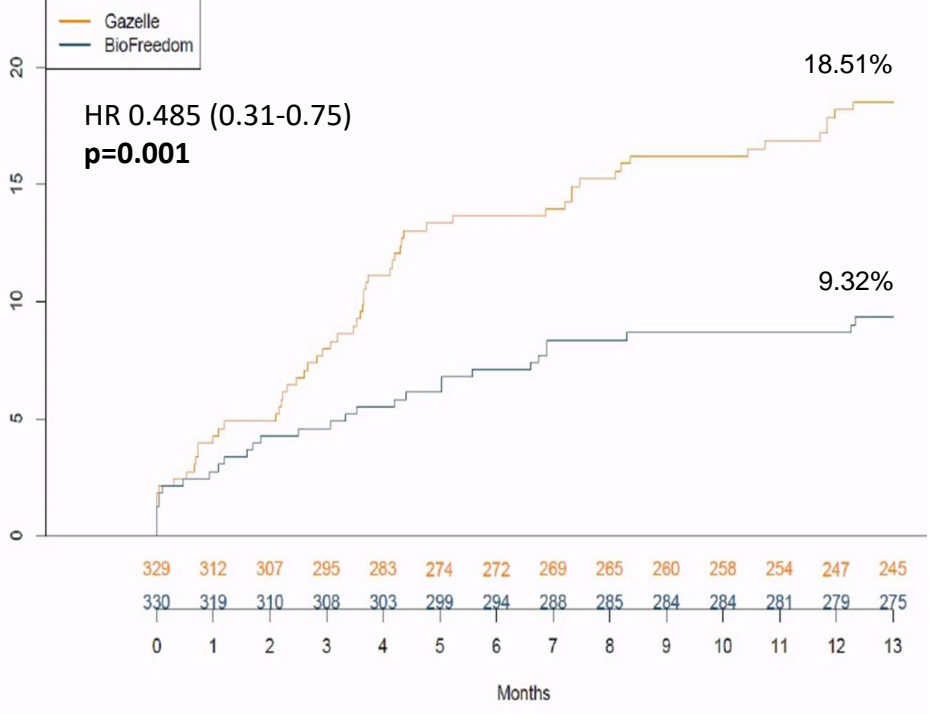


# Leaders Free ACS 12 Months

Clinically Driven TLR

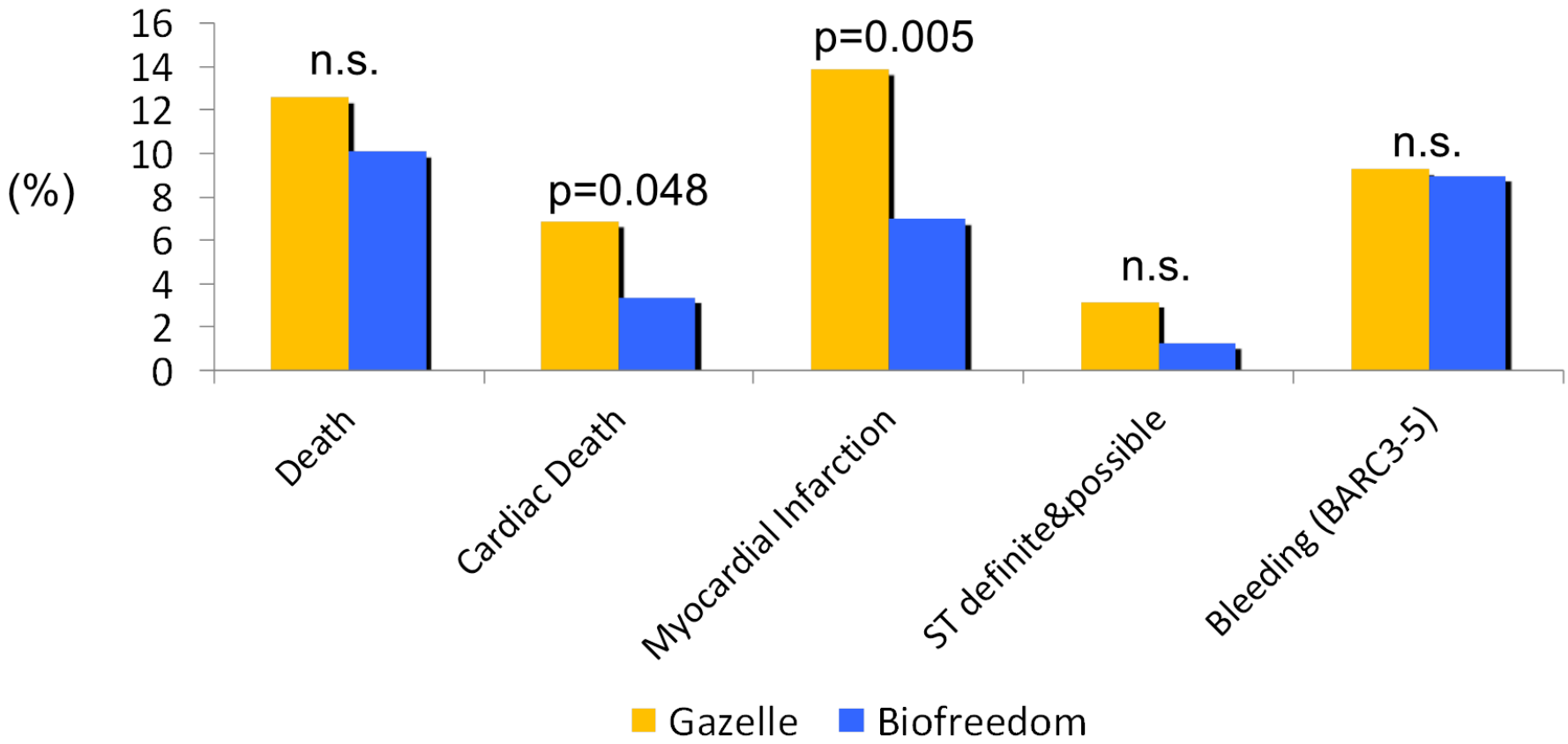


Primary Safety Endpoint



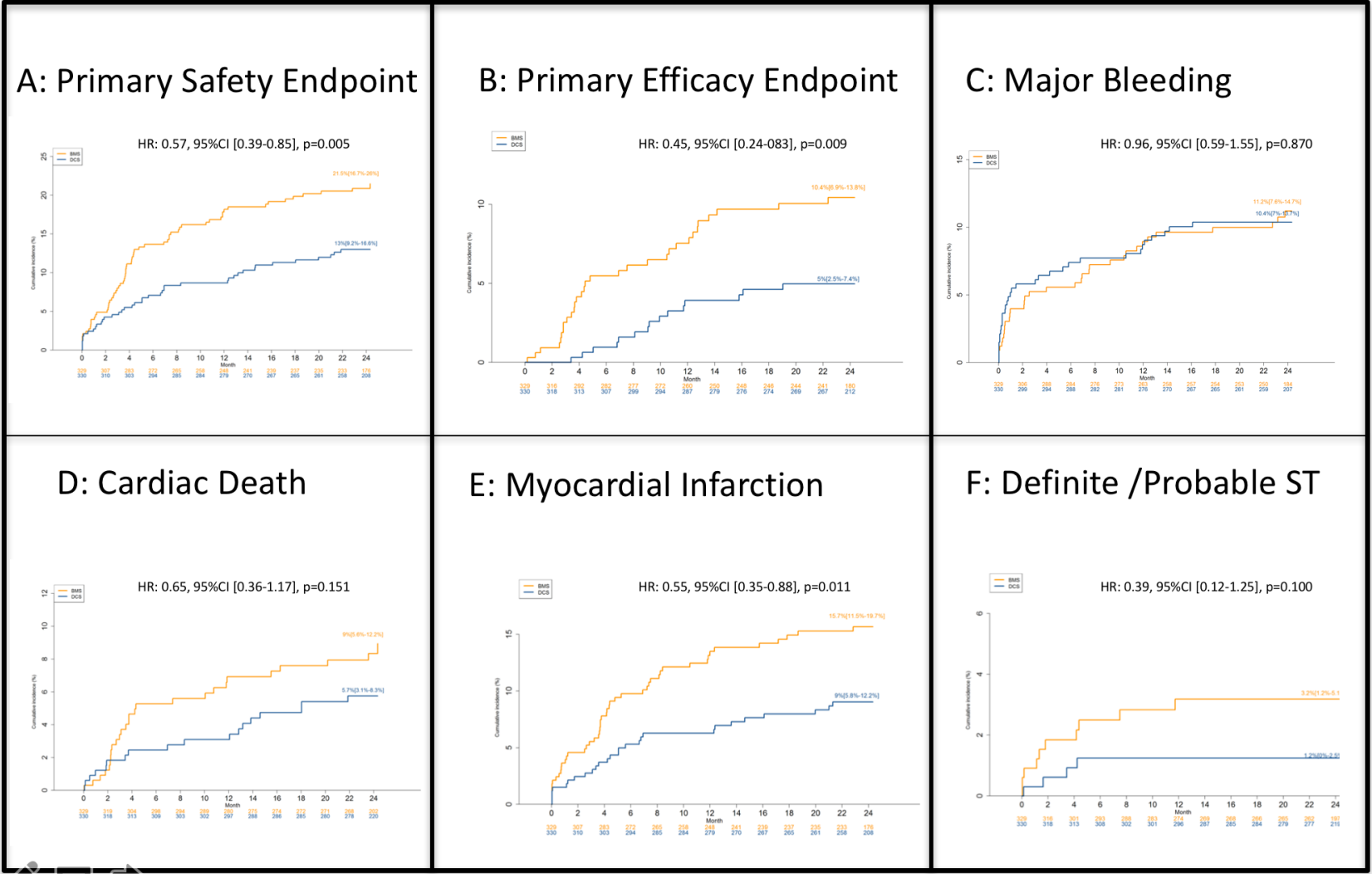
Naber et al. Eur Heart J 2016

# Leaders Free ACS 12 Months



Naber et al. Eur Heart J 2016

# Leaders Free ACS 2 Years



Jensen et al. EuroIntervention 2018



# Leaders Free ACS 2 Years

	1 Year			2 Year		
	Drug-coated stent (N=330)	Bare-metal stent (N=329)	P Value	Drug-coated stent (N=330)	Bare-metal stent (N=329)	P Value
<b>Primary safety endpoint: cardiac death, MI or stent thrombosis</b>	30 (9.3)	59 (18.5)	0.001	41 (13%)	67 (21.5%)	0.005
<b>Cardiac death</b>	11 (3.4)	22 (6.9)	0.049	18 (5.8%)	27 (8.9%)	0.151
<b>Myocardial infarction</b>	22 (6.9)	43 (13.8)	0.005	28 (9.0%)	48 (15.7%)	0.011
<b>Definite or probable stent thrombosis</b>	4 (1.2)	10 (3.1)	0.099	4 (1.2)	10 (3.1)	0.099
<b>Primary efficacy endpoint: clinically driven TLR</b>	12 (3.9)	27 (9.0)	0.009	16 (5.3%)	32 (10.7%)	0.010
<b>Bleeding</b>						
<b>BARC 1-5</b>	65 (20.2)	67 (21.3)	0.860	78 (24.7%)	73 (23.6%)	0.720
<b>BARC 2-5</b>	49 (15.2)	54 (17.2)	0.600	58 (18.3%)	60 (19.5%)	0.784
<b>BARC 3-5</b>	29 (9.0)	29 (9.2)	0.990	33 (10.4%)	34 (11.2%)	0.870

TLR: target lesion revascularization; BARC: bleeding according to Academic Research Consortium definition.

Jensen et al. EuroIntervention 2018

In high bleeding risk patients with an acute coronary syndrome the safety and efficacy benefits of the BA9-DCS over a BMS, both with only 1 month DAPT, persisted during 24 months of follow up.

These findings do further discourage the use of a BMS in these patients.

**PCR**