Safety and efficacy of biodegradable polymer DES in management of patients with acute STEMI -Final 3-year results of the MASTER study-

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Potential conflicts of interest

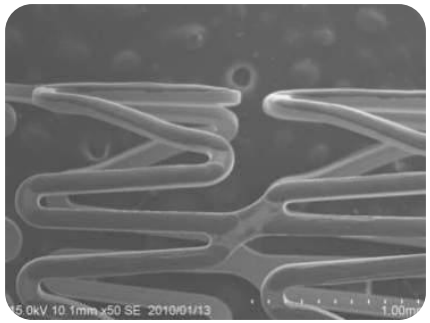
Goran Stankovic, MD

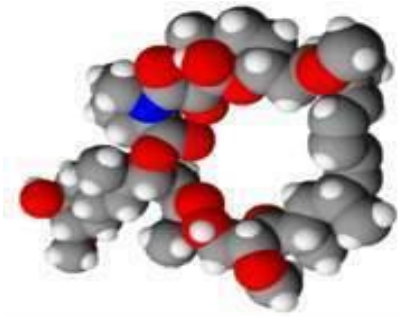
- **I do not have any potential conflict of interest**

MASTER – Aim

To evaluate the **safety and efficacy** of a novel sirolimus drug-eluting stent (**DES**) with **bioresorbable polymer** coating **(Ultimaster),** in patients with an acute ST-elevated myocardial infarction (**STEMI**) in comparison to its bare metal stent **(BMS)** platform (**Kaname)**.

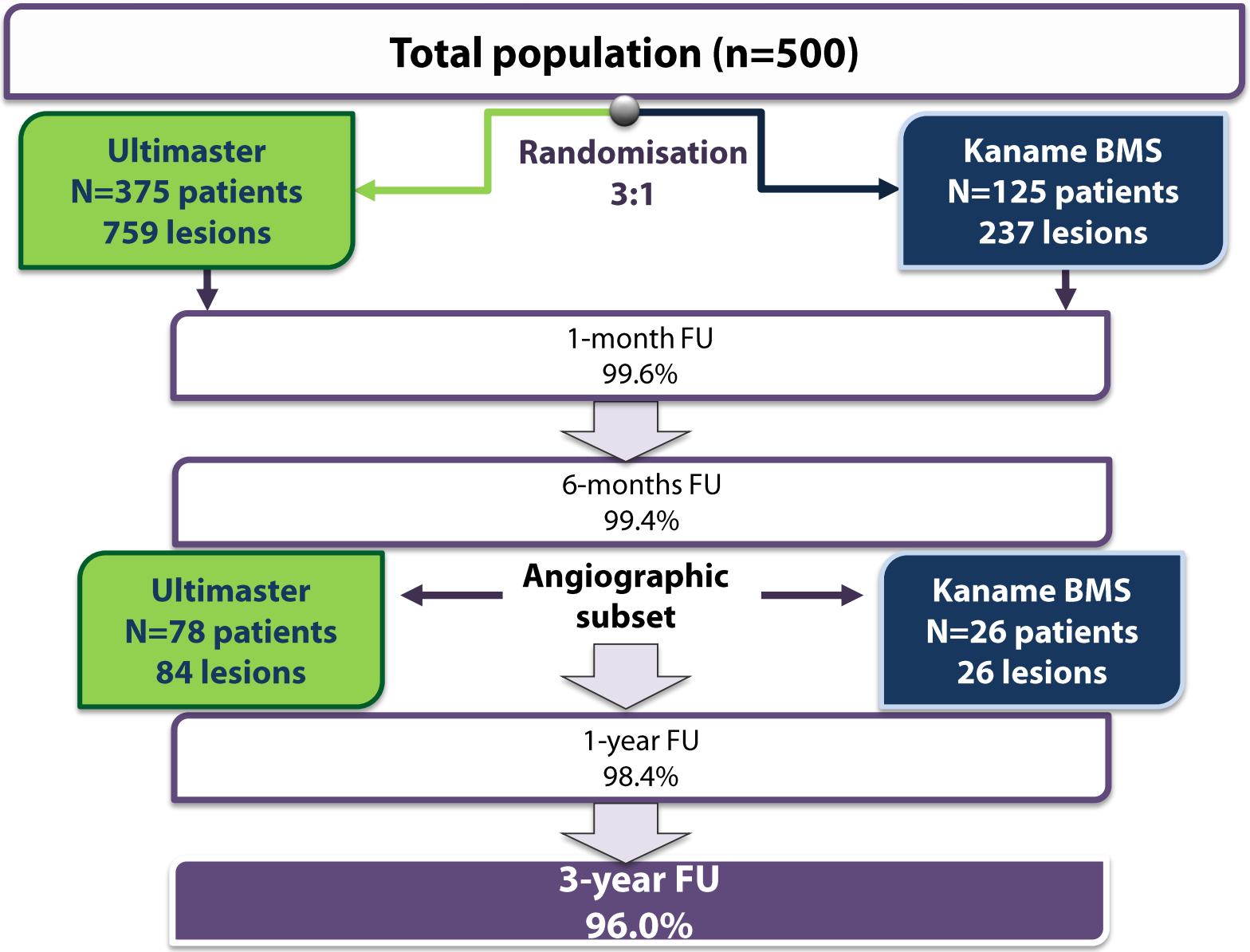
Ultimaster DES – study device





Platform	Stent material	***CoCr***（L605）
	Strut Thickness	***80μm***
	number of links	***2*** (all sizes)
Carrier	***Bioresorbable polymer***	PDLLA+PCL
	Coating	***Abluminal***
Drug	***Sirolimus***	3.9μg/mm stent
	Release profile	***3-4month***

MASTER - study design



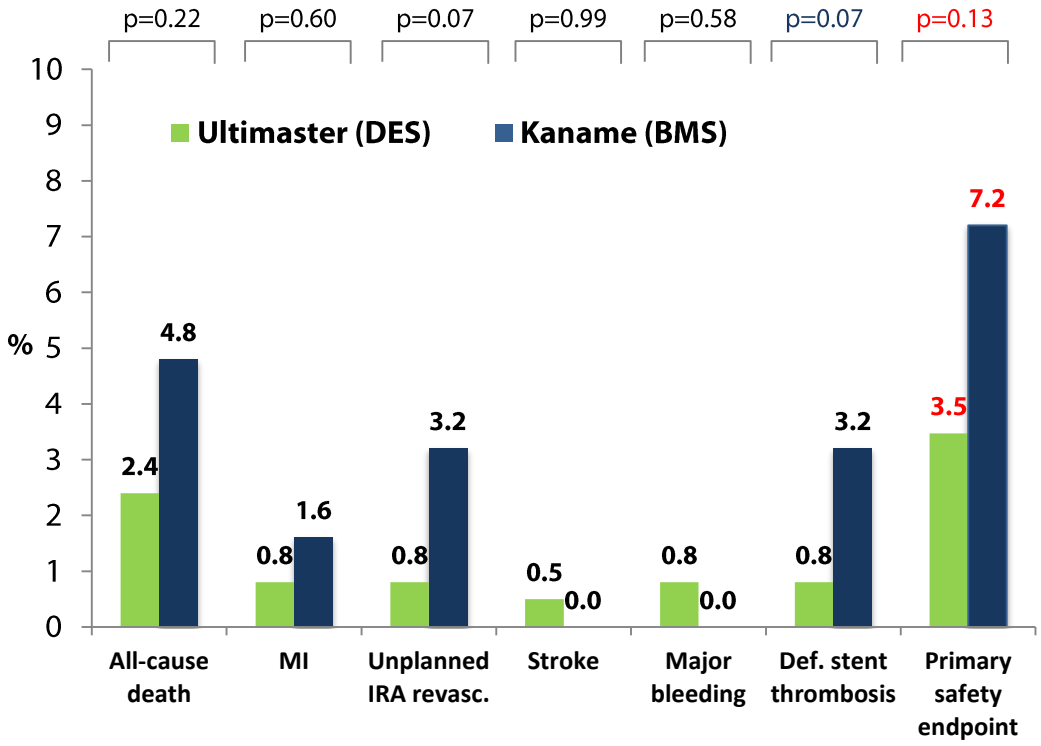
Baseline characteristics

	Ultimaster (DES) N=375	Kaname (BMS) N=125	p
Patient characteristics			
Age, years	60.2 ± 11.0	61.5 ± 11.0	0.23
Gender, male, %	81.1	80.0	0.79
Diabetes, %	15.5	12.8	0.56
Hypertension, %	53.6	51.2	0.68
Dyslipidemia, %	39.0	36.0	0.60
Current smoker, %	50.7	48.0	0.68
Family history of CAD, %	34.7	32.8	0.74
Pain to balloon time, min	294±223	263±213	0.20
Door to balloon time, min	74±86	70±123	0.76
Procedure and lesion characteristics			
Thrombectomy, %	35.5	37.6	0.69
Diameter stenosis pre-procedure (visual estimate), %	96.4±9.0	96.8±7.2	0.58
Number of stents implanted/patient, n	1.47±0.87	1.33±0.58	**0.04**
Total implanted stent length/patient, mm	29.7±17.2	26.1±11.9	**0.01**

Values represent mean ± SD or %

Primary safety and efficacy endpoint

Primary safety endpoint at 1 month:
Composite of all-cause death, recurrent MI, unplanned infarct-related artery (IRA) revascularization, stroke, definite stent thrombosis or major bleeding at 1 month



Primary efficacy endpoint at 6 months:
Late lumen loss (LL), mm

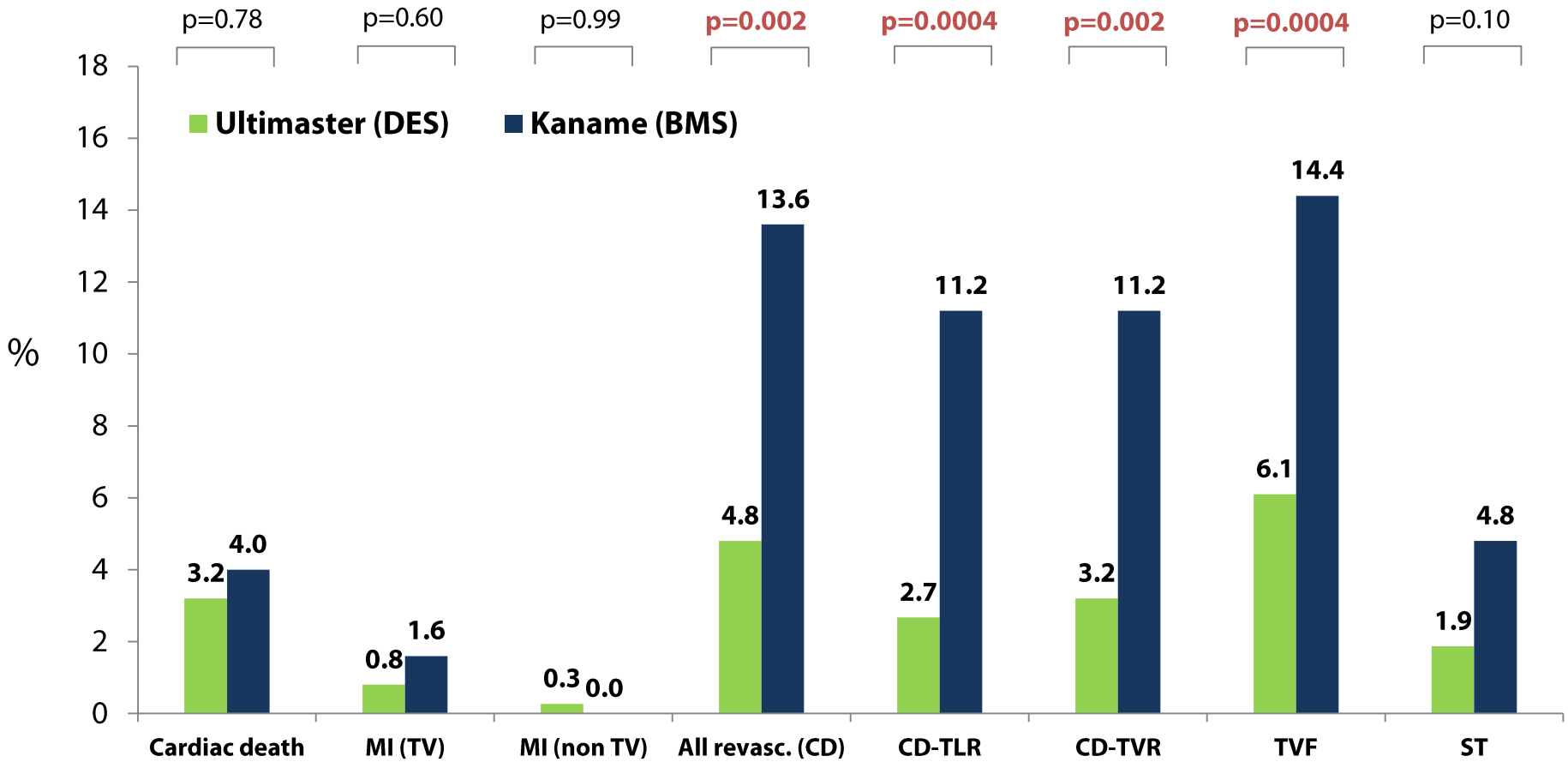
Late loss result:

Ultimaster:0.09±0.43 mm

BMS: 0.79±0.67 mm

Ultimaster is SUPERIOR; p=0.013

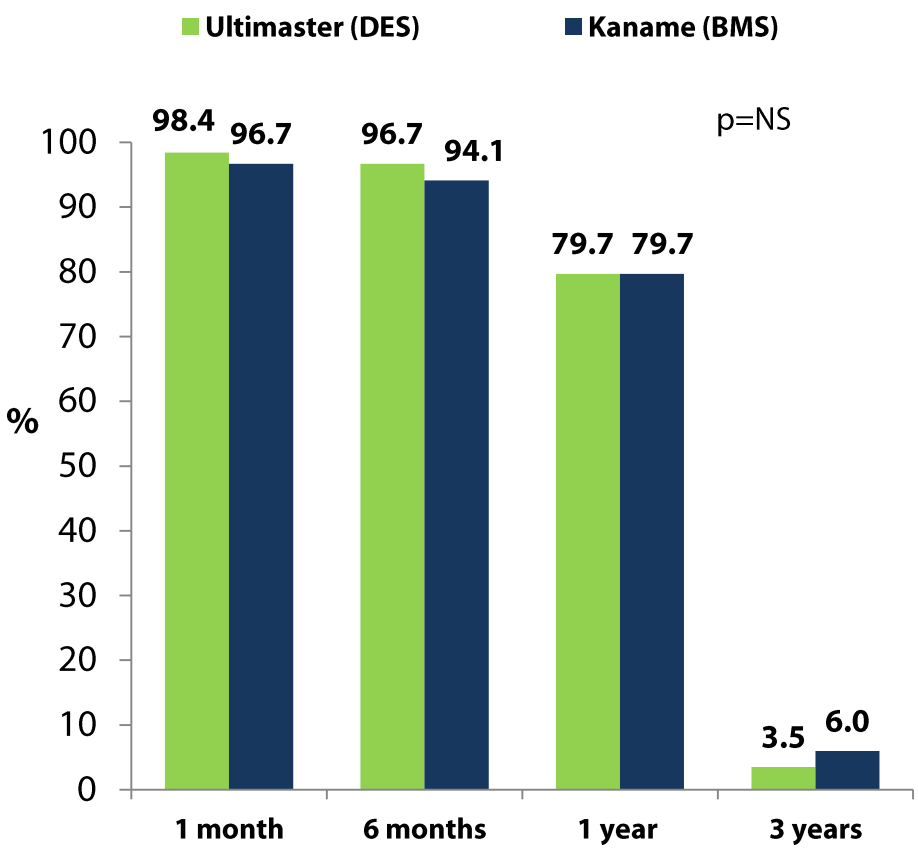
1-year clinical outcomes



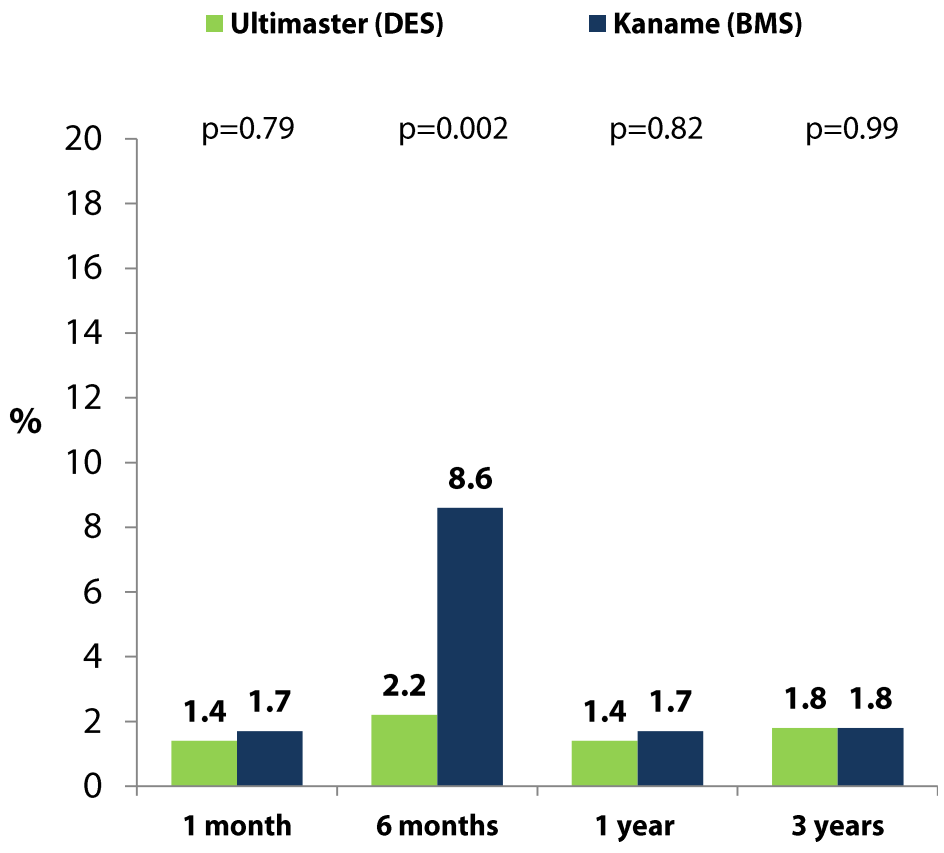
MI: myocardial infarction; **TV**: target-vessel; **CD**: clinically driven; **TLR**: target-lesion revascularization; **TVR**: target-vessel revascularization; **TVF** : target-vessel failure, a composite endpoint of cardiac death, TV-MI and CD-TVR; **ST**: definite or probable stent thrombosis

DAPT and angina status up to 3 year FU

Dual antiplatelet therapy (DAPT)

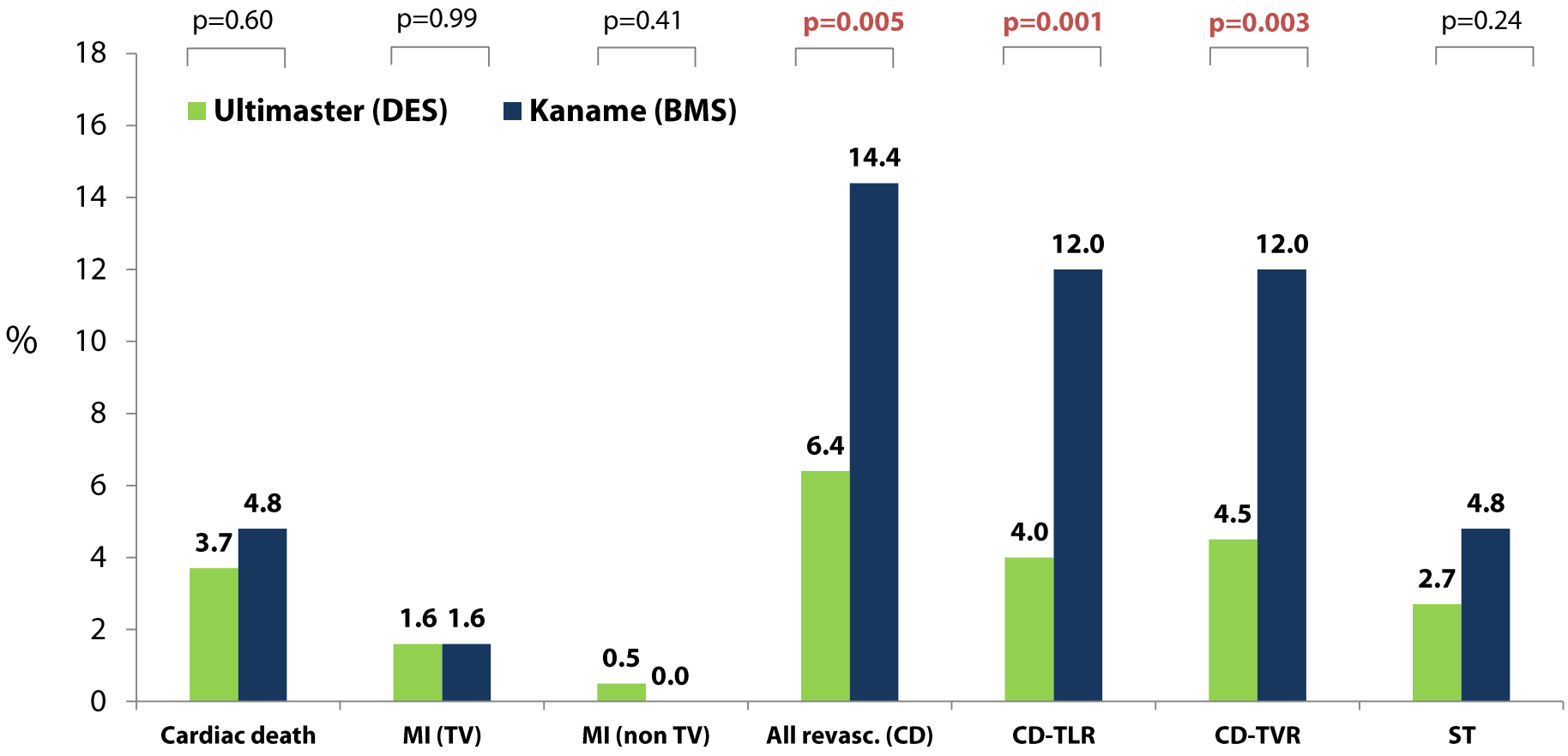


Anginal complaints



NS: not significant (p>0.05)

3-year clinical outcomes



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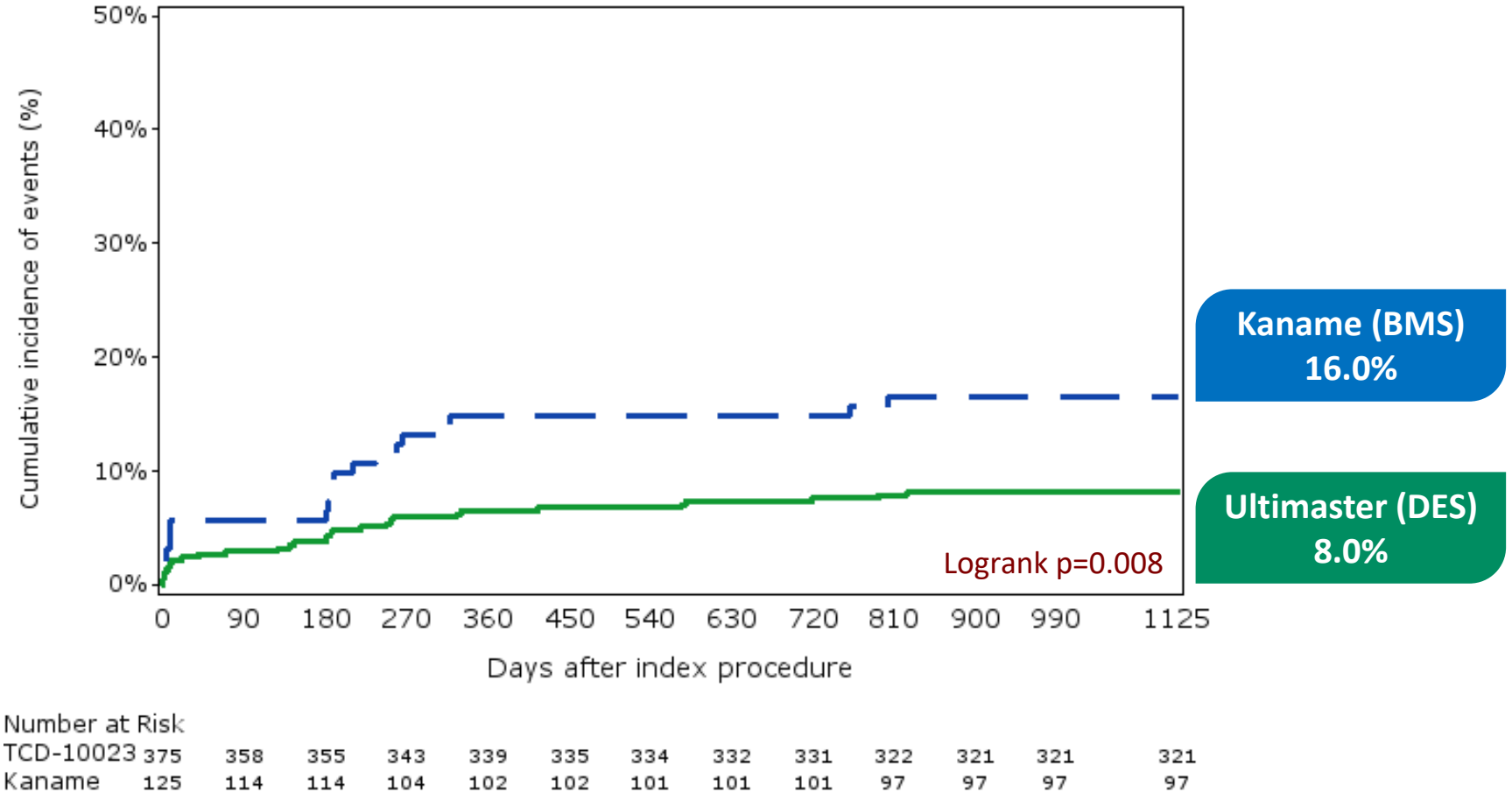
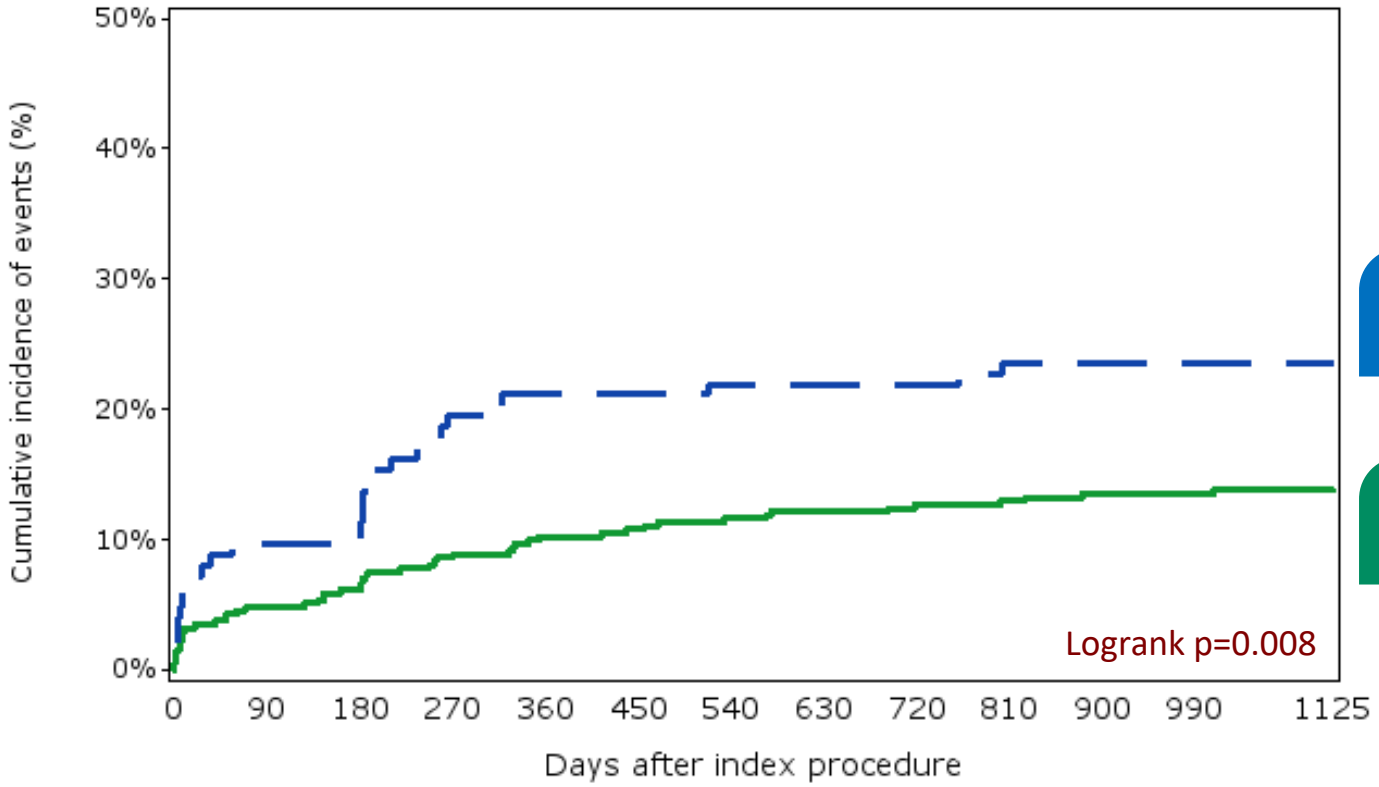
Target vessel failure at 3 year



TVF : target-vessel failure, a composite endpoint of cardiac death, target vessel MI and clinically driven target vessel revascularization

Patient-oriented composite endpoint at 3 year



Number at Risk

TCD-10023	375	354	349	336	330	326	323	321	319	313	311	311	310
Kaname	125	111	111	98	96	96	95	95	95	92	92	92	92

POCE: patient-oriented composite endpoint defined at any death, any MI and any coronary revascularization

Why is this important?

The **MASTER study** gives strong evidence of superiority of **Ultimaster DES** over **Kaname BMS as** treatment for **STEMI patients,** regarding **safety and efficacy,** with a lower rate of **target vessel failure** up until **3 year follow up**.

The essentials to remember

Why?

- In contemporary PCI procedures of STEMI patients, new generation DES are evermore frequently use.

What?

- Asses the performance of new generation DES with bioresorbable coating versus its BMS platform.

How?

- Performe randomized controlled trial (MASTER) to evaluate Ultimaster DES in comparison with Kaname BMS.

What are the results?

- Ultimaster is safe and efficient in STEMI patients in absolute terms and relative to Kaname BMS.

Why is this important?

- Favourable 3-years clinical outcomes assure the long-term safe use of Ultimaster DES in STEMI patients.