

Treatment of left main using DES with bioresorbable polymer

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on behalf of e-ULTIMASTER Investigators

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I do not have any potential conflict of interest to declare

- ◆ Treatment of Left Main disease remains a challenge. The decision on PCI or CABG and clinical outcomes in LM are influenced by LM disease pattern such as bifurcation involvement or overall coronary atherosclerotic burden (e.g: other diseased vessels).
- ◆ e-Ultimaster is a large, prospective, world-wide registry that enrolled all-comer patients treated with Ultimaster DES and followed up until 1 year after the procedure.
- ◆ This registry offers an opportunity to explore PCI treatment of LM patients in real life.

E-ULTIMASTER registry

4 continents, 50 countries, 376 sites

Study enrolment completed, follow-up ongoing
> 37,000 patients enrolled

Interim analysis
1-year follow-up
n=25,990 patients
n=840 treated in Left Main

**Patients treated only
in LM**
n=383

**Patients treated in LM
plus other vessels**
n=457

CLINICAL FOLLOW-UP



An independent Clinical Event Committee reviewed and adjudicated all endpoint-related serious adverse events

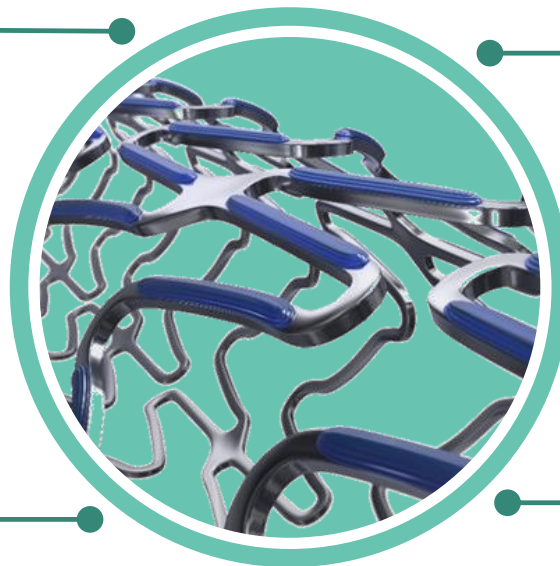
CoCr sirolimus-eluting stent

Innovative abluminal, bioresorbable drug coating applied in a **gradient** to **reduce the risk of polymer cracking** and delamination

Short-term polymer exposure mirrors biological response, promoting **rapid vascular repair** within 3–4 months

PCL added to PDLLA, **increasing the elasticity** of the innovative **bioresorbable polymer coating**

Flexible **80µm CoCr platform** for **optimal conformability**, to reduce mechanical stress on the vessel wall



BASELINE PATIENT CHARACTERISTICS

	LM only n=383	LM+ 1 or more vessels (LM+MV) n=457	P-value
Age, years	69.0±10.8	69.3±10.7	0.78
Gender, male %	72.9	75.1	0.48
Current smoking, %	14.4	17.0	0.33
Diabetes, %	34.5	32.4	0.56
Hypertension, %	74.9	71.0	0.21
Hypercholesterolemia,%	62.2	63.5	0.72
Renal impairment, %	16.7	13.8	0.25
Previous PCI, %	39.6	35.6	0.25
Previous CABG, %	22.3	18.7	0.22
ACS, %	38.9	44.9	0.09

BASELINE LESION/PROCEDURE CHARACTERISTICS

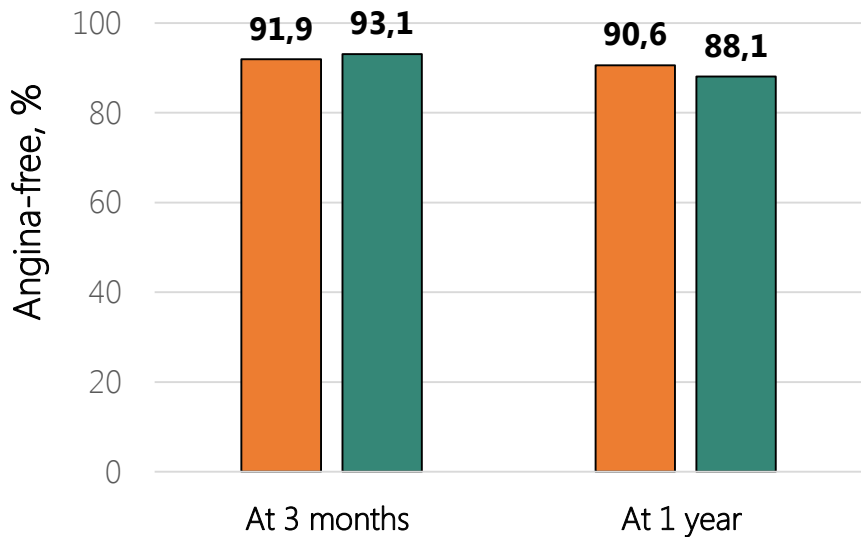
	LM only n=383	LM +1 or more vessels (LM+MV) - n=457	P-value
N° of vessels diseased per patient, mean±SD	1.6±0.8	2.4±0.6	<0.001
N° of vessels treated per patient, mean±SD	-	1.3±0.5*	-
Radial access, % per patient	68.2	67.4	0.82
Imaging - IVUS, % per patient	27.4	20.8	0.04
Imaging - OFDI, % per patient	11.5	7.3	0.07
Long lesions ≥ 25mm, % per patient	47.8	54.9	0.04
N° of stents implanted per patient, mean±SD	1.4±0.7	2.2±1.2	<0.001
Total length of implanted stents per patient, mm,	31.4±21.2	48.2±31.8	<0.001
Characteristics of left main lesion			
Calcified lesions, %	32.7	30.7	0.55
Bifurcation, %	52.5	44.7	0.03
Ostial lesions, %	27.5	29.6	0.54
Post-dilatation, %	72.2	68.7	0.29

*Number of vessels treated, except left main

Angina status

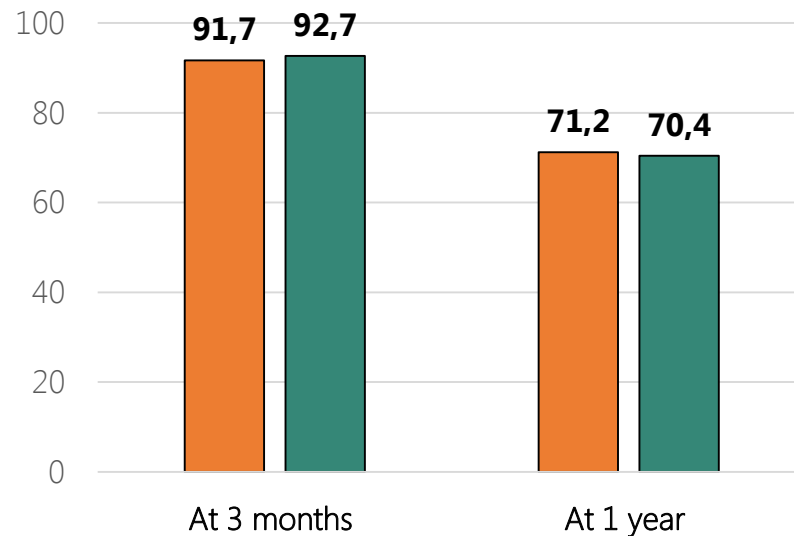
LM only LM+MV

P=NS for all

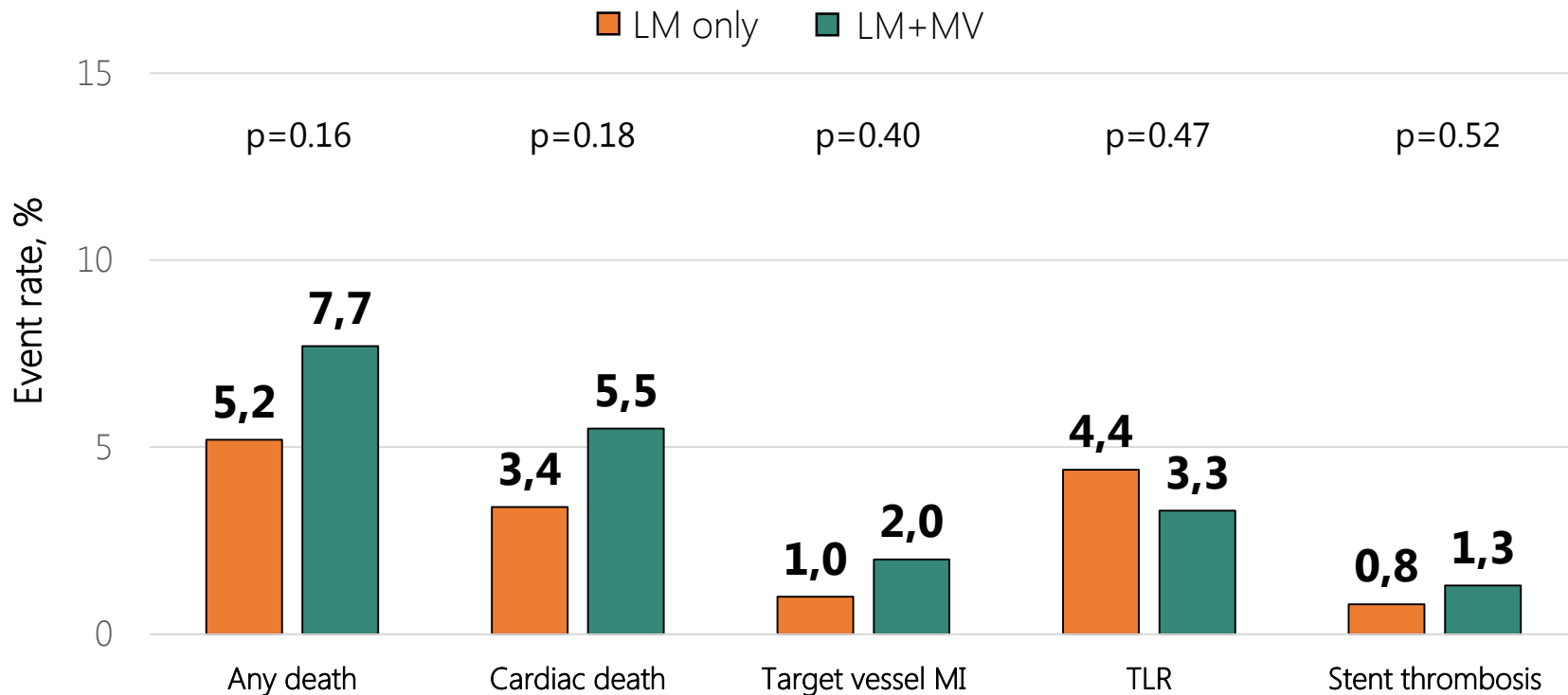


DAPT status

LM only LM+MV

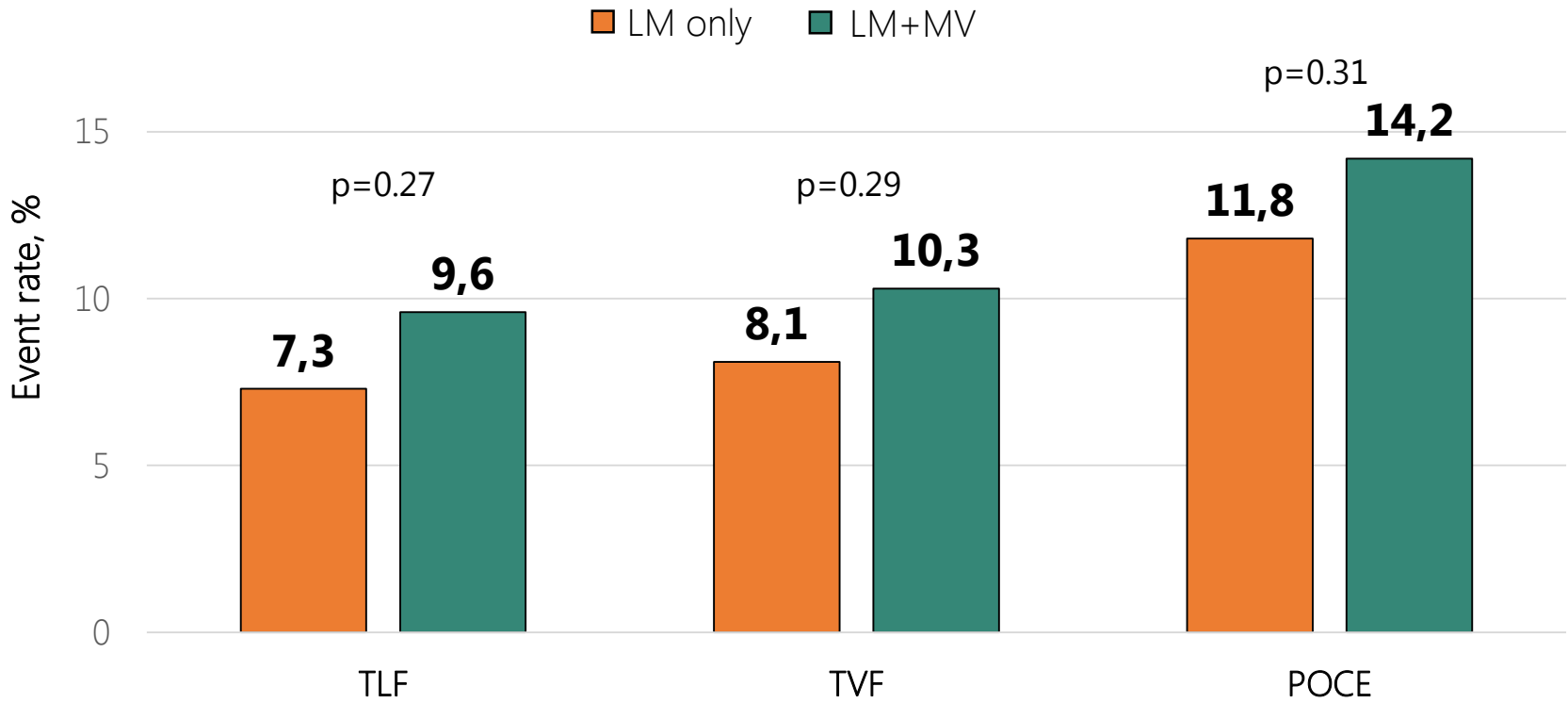


CLINICAL OUTCOMES AT 1 YEAR



MI: myocardial infarction; TLR: target lesion revascularization; TLF: target lesion failure (a composite of cardiac death, target-vessel MI or clinically-driven TLR); TVF, target vessel failure (composite of cardiac death, target-vessel MI or clinically-driven TVR); **Stent thrombosis**: Definite + probable stent thrombosis

CLINICAL OUTCOMES (COMPOSITE ENDPOINTS) AT 1 YEAR



POCE: patient-oriented composite endpoint (a composite of all-cause mortality, any MI or any coronary revascularization); TLF: target lesion failure (a composite of cardiac death, target-vessel MI or clinically-driven TLR); TVF: target vessel failure (composite of cardiac death, target-vessel MI or clinically-driven TVR)

Predictor: left main + 1 or more vessel diseased

	Adjusted* Odds ratio	95% confidence interval	P-value
Cardiac death/MI	2.08	1.05-4.11	0.03
TLF	1.31	0.81-2.12	0.28
MACE	1.25	0.79-1.98	0.34

***Adjusted for significant covariates selected by stepwise logistic regression**

MACE: major cardiac adverse events (cardiac death, any MI, clinically-driven TVR or emergent CABG); **MI:** myocardial infarction; **TLF:** target lesion failure (a composite of cardiac death, target-vessel MI or clinically-driven TLR);

	Adjusted odds ratio	95% confidence interval	p-value
At least 1 target vessel besides LM	1.31	0.81-2.12	0.28
Diabetes mellitus	1.83	1.14-2.95	0.01
Hypercholesterolemia	0.56	0.35-0.89	0.01
Renal failure	2.40	1.44-4.02	<0.001
Ostial lesion	1.50	0.93-2.41	0.09
Long lesions	0.47	0.29-0.78	0.003

Results based on stepwise logistic regression, with covariates considered for entering the model:

Age, gender, body mass index, diabetes, hypertension, hypercholesterolemia, smoking, previous MI, previous PCI, renal impairment, acute coronary syndrome, multi-vessel disease, N lesions identified, N lesions treated, vessel treated, N of stents implanted, length of stents implanted, in-stent restenosis, chronic total occlusion, bifurcation, long lesions, small vessels, calcification, AHA/ACC lesion classification, radial access

- ◆ In complex patients treated for left main coronary artery disease, with or without additional treated vessels, the Ultimaster DES showed good clinical outcomes at 1 year.
- ◆ This registry provides insights into PCI treatment of LM patients in daily clinical practice, and indicates the new generation thin strut sirolimus-eluting Ultimaster stent with bioresorbable polymer offers a good option for treating LM patients.