

NOBORI 2

Late Breaking Results

One Year Clinical Outcome

Prof. Ran Kornowski
On behalf of NOBORI Investigators



Disclosures

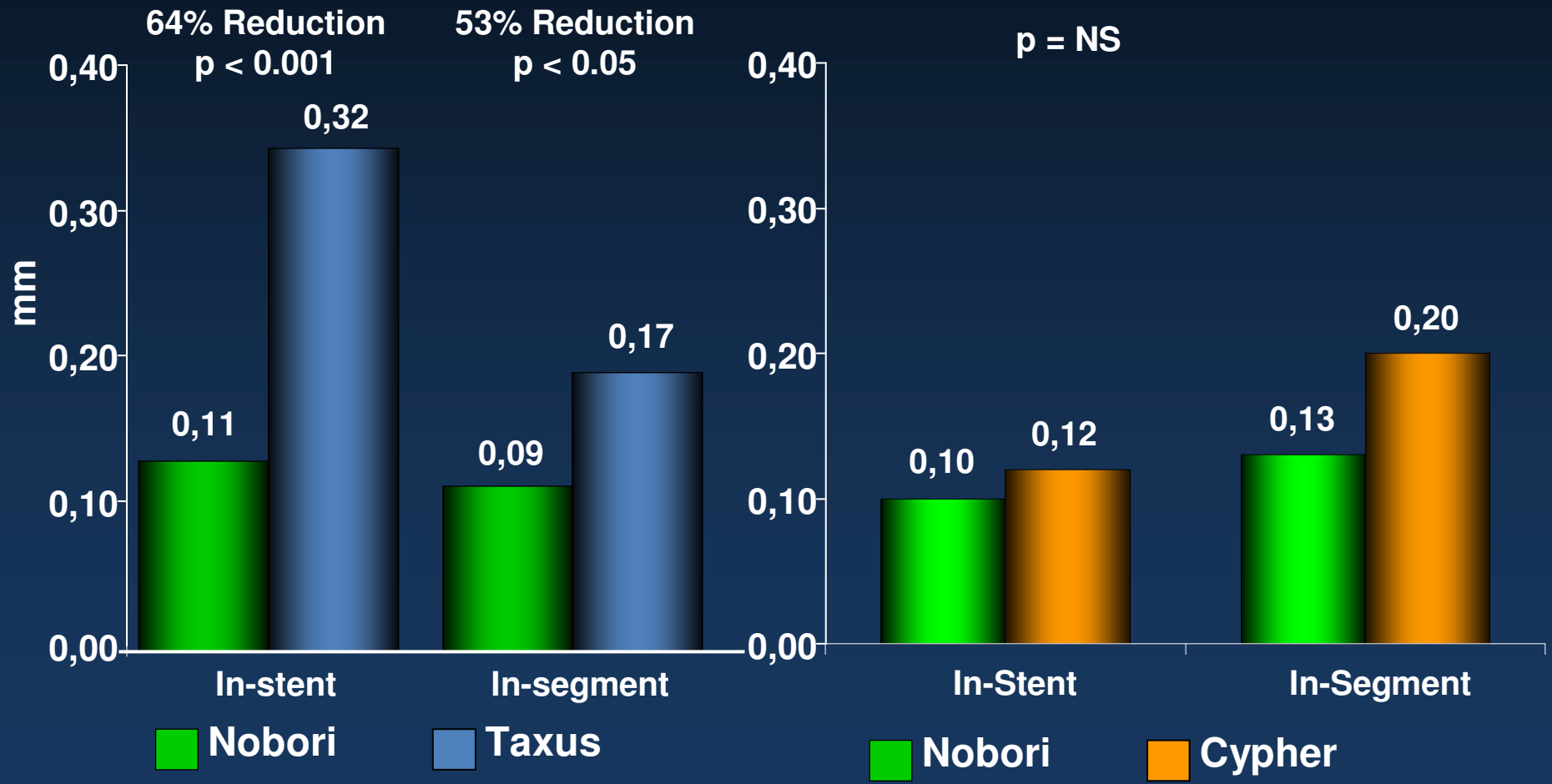
- **Ran Kornowski, MD**
 - **Nothing to disclose**



Late Loss in NOBORI trials at 9 Months

NOBORI 1 N=363 (2:1 randomization)

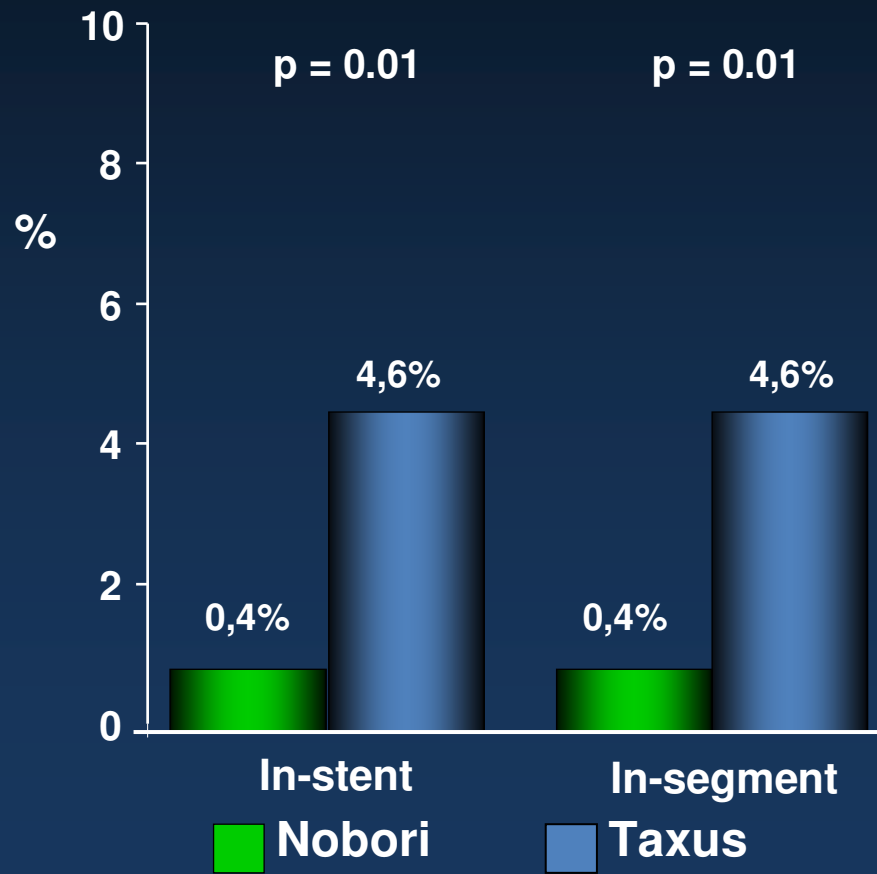
NOBORI CORE N=107 (1:1 randomization)



Binary Restenosis in NOBORI Trials at 9 Months

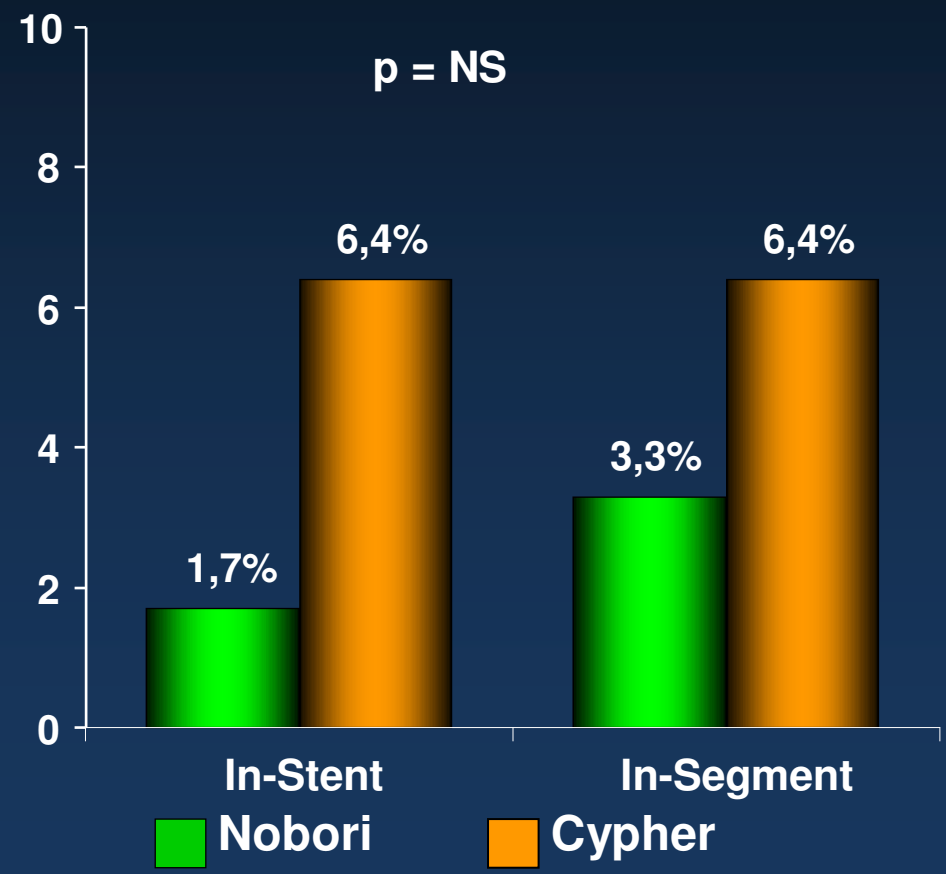
NOBORI 1

N=363 (2:1 randomization)

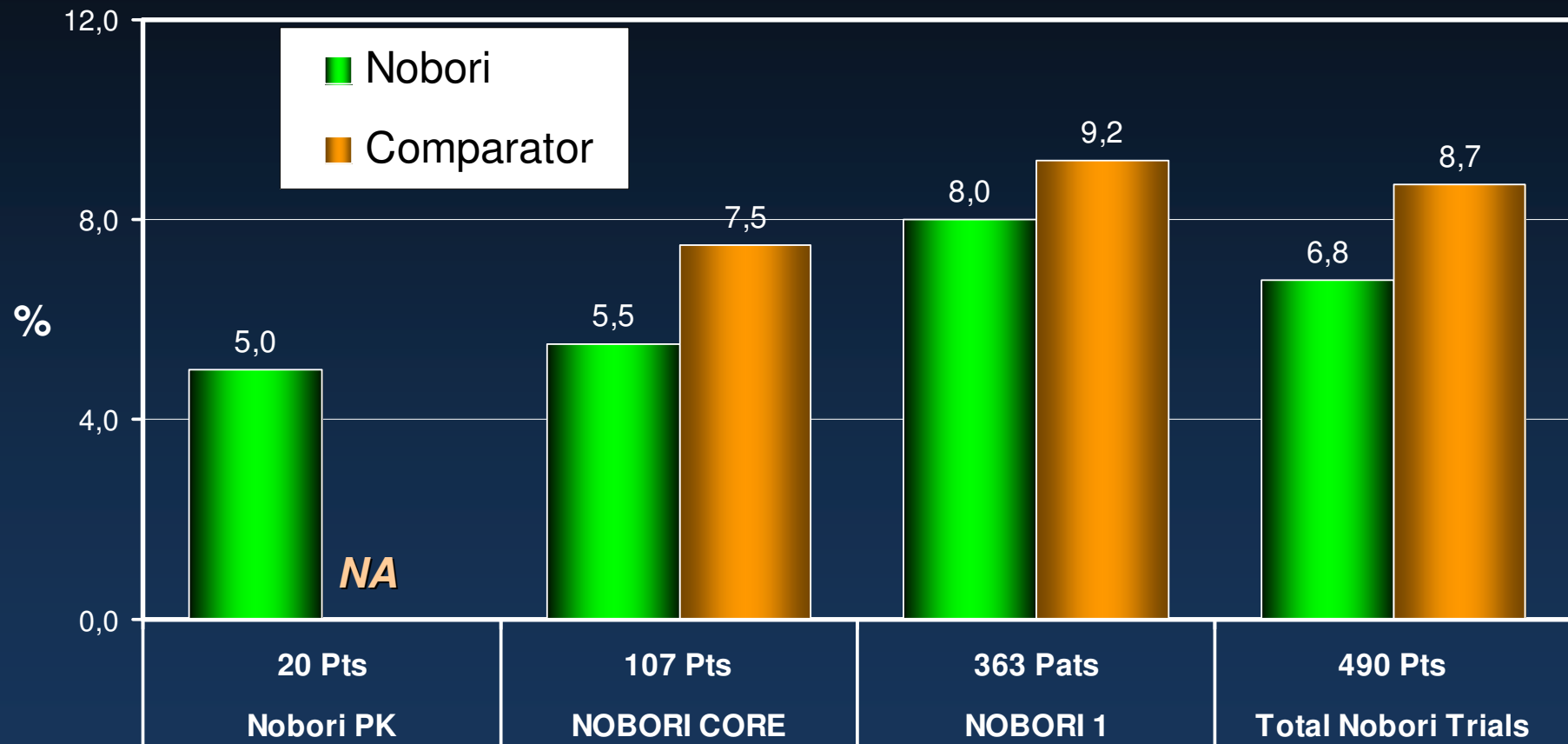


NOBORI CORE

N=107 (1:1 randomization)

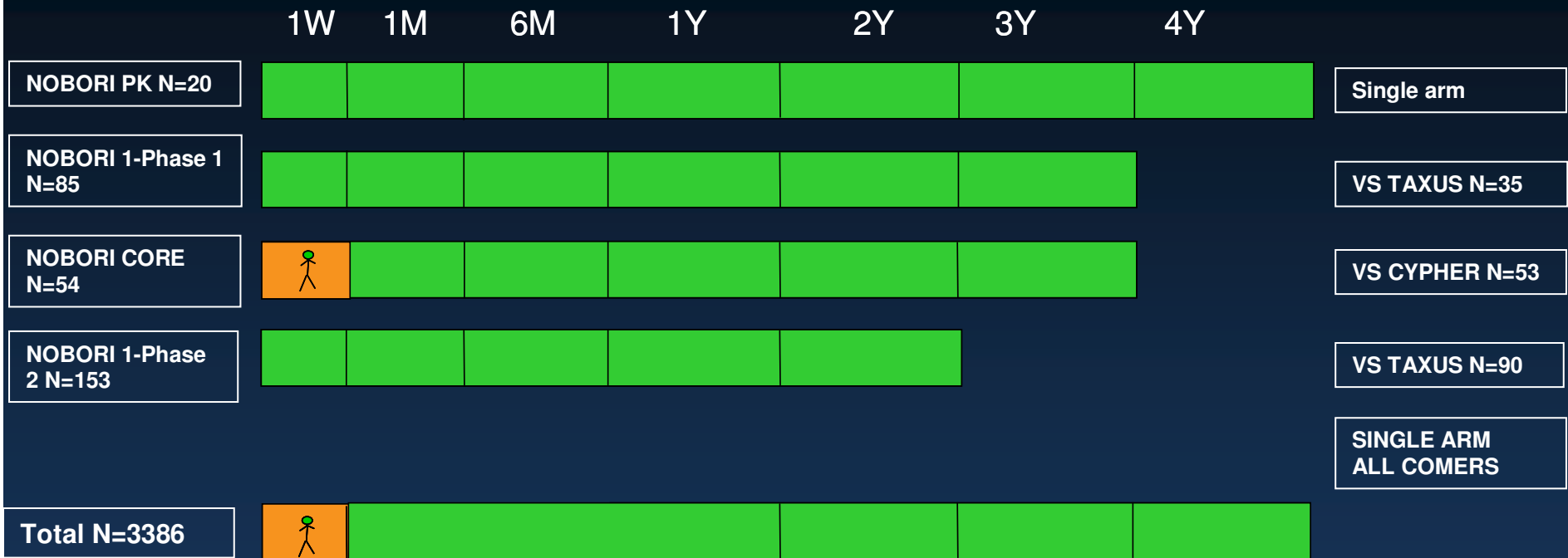


MACE Rate in NOBORI Trials at 2 Years



MACE = Cardiac Death, MI, Clinically Driven Target Vessel Revascularization

Nobori DES - Stent Thrombosis



	<1W	1W - 1M	1M - 6M	6M - 1Y	1Y - 2Y	2Y - 3Y	3Y - 4Y
N° (N° - ST)	315 (1)	315 (0)	315 (0)	315 (0)	315 (0)	159 (0)	20 (0)
ST NOBORI	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ST Comparator	1.1%	0.0%	0.0%	0.0%	0.6%	0.6%	NA



NOBORI 2

**A Prospective, Multi-center, Single Arm,
Observational study of the Nobori™ Drug Eluting
Stent System**

Eligibility Criteria

- ✓ **Patients (age \geq 18 years old) who are eligible for percutaneous coronary intervention using DES (and RVD matches available Nobori™ DES sizes).**
- ✓ **Patients have been informed of the nature of the study and agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee of the respective clinical site, wherever such requirement exist;**

NOBORI 2

Study Organization

- PI:

- Dr. G.B. Danzi

- Executive Operational Committee:

- B. Chevalier
- P. Urban
- W. Wijns
- M. Wiemer
- J. Goicolea
- A. Serra
- R. Kornowski

- Monitoring:

- 100% monitoring on-line, 30% on-site
- EMCD and independent monitors

- Study management: **EMCD-Terumo**

- Data management:

- Electronic data collection **KIKA Medical**

- Steering Committee:

- E. Stabile
- K. E. Hauptmann
- P. Kala
- J. Koolen
- R. Koning
- F. Fath-Ordoubadi
- D. Carrie

- CEC:

- C. Hanet
- G. Stankovic
- J. Vos
- M.A. Vogt

- Angiographic Corelab:

- **MCR – Milan**
- **CorExperts - Belgrade**

- Sponsor:

- **Terumo Europe**

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Study Endpoint

**Primary Endpoint:
Clinical Outcomes at 12 m Follow-up**



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- **First 1000 patients**
 - Extensive monitoring
 - Highest quality control standards
 - On Label versus Off Label groups analyzed
- **On-label group included patients with indications similar to pre-approval clinical trials and DES label**
- **Off-label group included all patients not fulfilling eligibility criteria for those trials and being outside the labeled indications**

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Baseline Patient Characteristics

	N=1000
Age (years \pm SD)	64 \pm 11
Male (%)	80.0
Previous MI (%)	30.0
Prior PCI/CABG (%)	36.0
Diabetes Mellitus (%)	29.6
Hyperlipidemia (%)	67.8
Hypertension (%)	64.3
Current smoker (%)	22.7

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Patient Characteristics according to indications

	On-Label N=320	Off-Label N=680	Total Population N=1000	P On vs Off
Age (years \pm SD)	64 \pm 11	64 \pm 11	64 \pm 11	0.72
Male (%)	74.4	82.2	80.0	0.01
Previous MI (%)	21.9	33.4	30.0	<0.001
Prior PCI/CABG (%)	32.5	37.5	36.0	0.14
Diabetes Mellitus (%)	31.6	28.7	29.6	0.37
Hyperlipidemia (%)	73.8	65.0	67.8	0.01
Hypertension (%)	66.3	63.4	64.3	0.35
Current smoker (%)	21.9	23.1	22.7	0.69

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Patient and lesion subgroups distribution

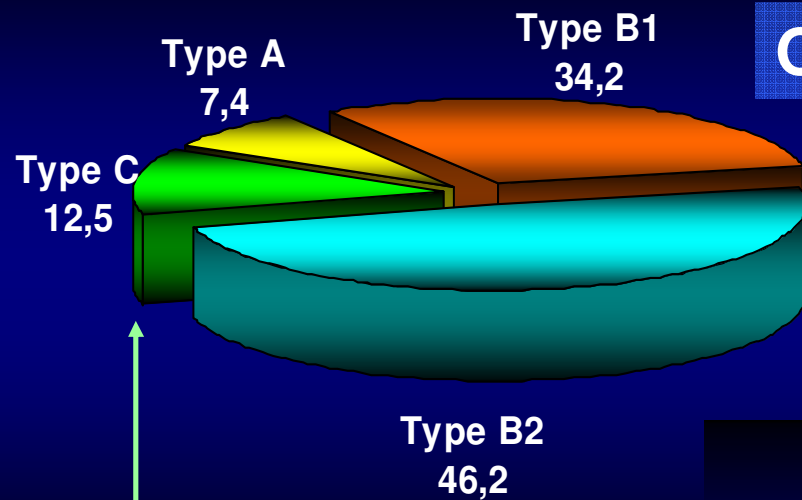
Subgroups %	On-Label N=320	Off-Label N=680	Total Population	P-value On vs Off
Small vessels (<2.5mm)	30.0	39.4	36.6	<0.001
Lesion Length	12.8 ± 5.9	16.0 ± 9.6	15.0 ± 8.7	<0.001
Long lesions (>20 mm)	33.4	51.9	46.0	<0.001
Acute/recent MI	0.0	36.6	24.9	<0.001
CTO lesions	0.0	4.2	2.9	<0.001
Bifurcation involvement	0.0	25.7	17.5	<0.001

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Procedural Characteristics

	On Label n=320	Off Label n=680	Total Population	P value
Lesions / patient (n ±SD)	1.14	1.60	1.46 ±0.68	<0.001
Stents / patient (n ±SD)	1.14	2.0	1.71 ±1.14	<0.001

Lesion Classification (%)



On Label



Off Label

43,3

Type A 3,0
Type B1 12,2

Type B2 42,3

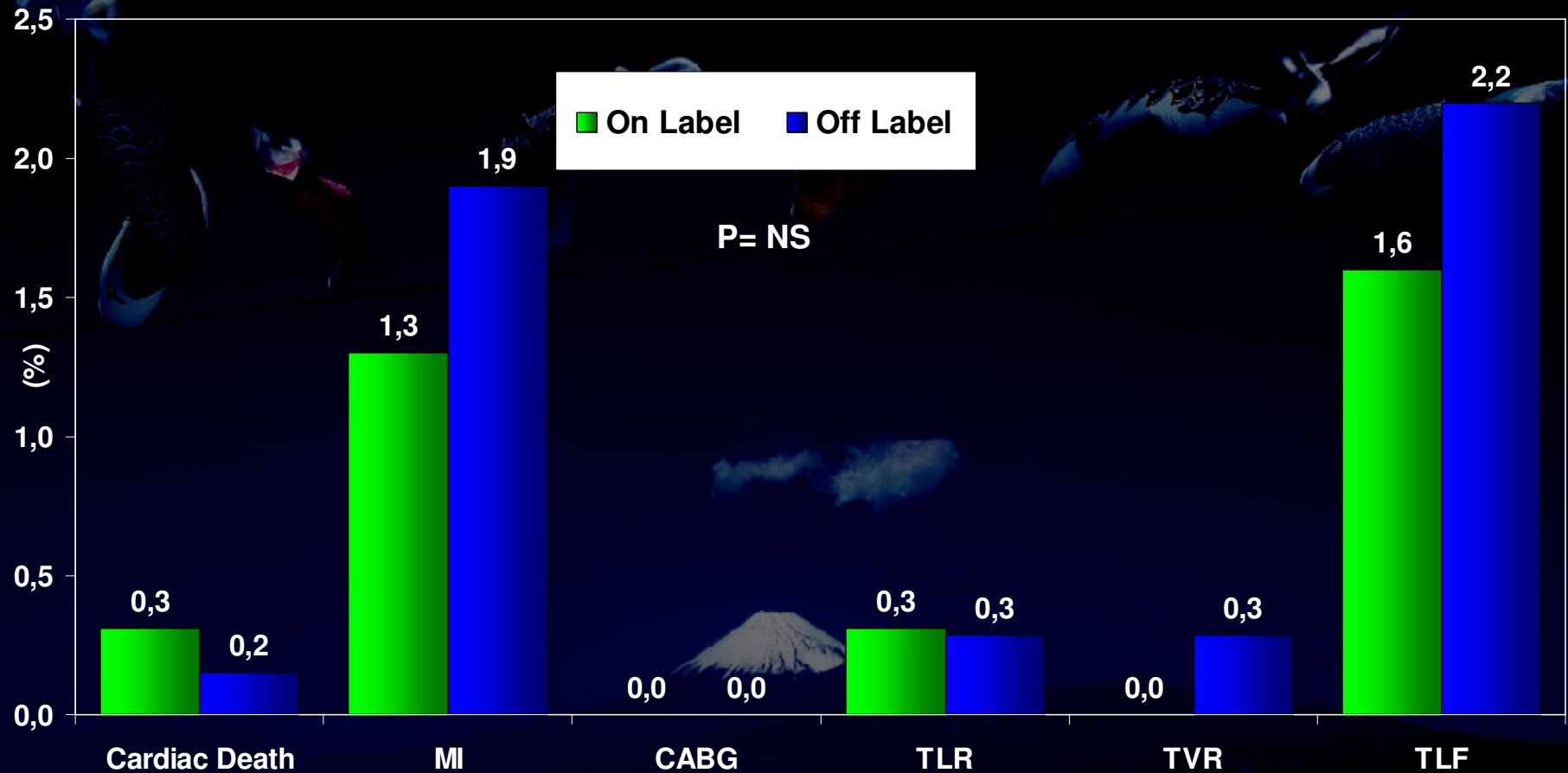
Type C 42,5

$P < 0.001$

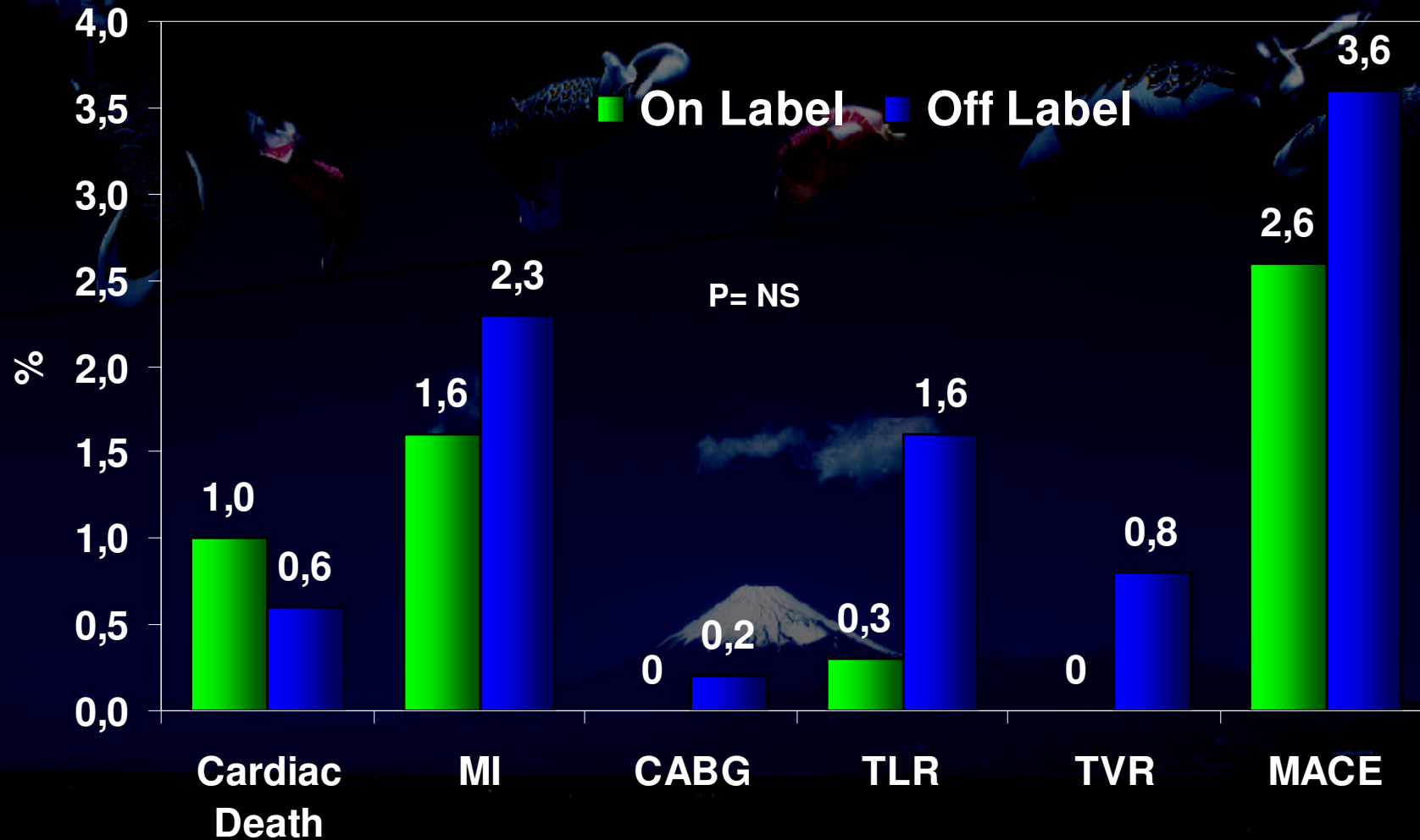


RESULTS

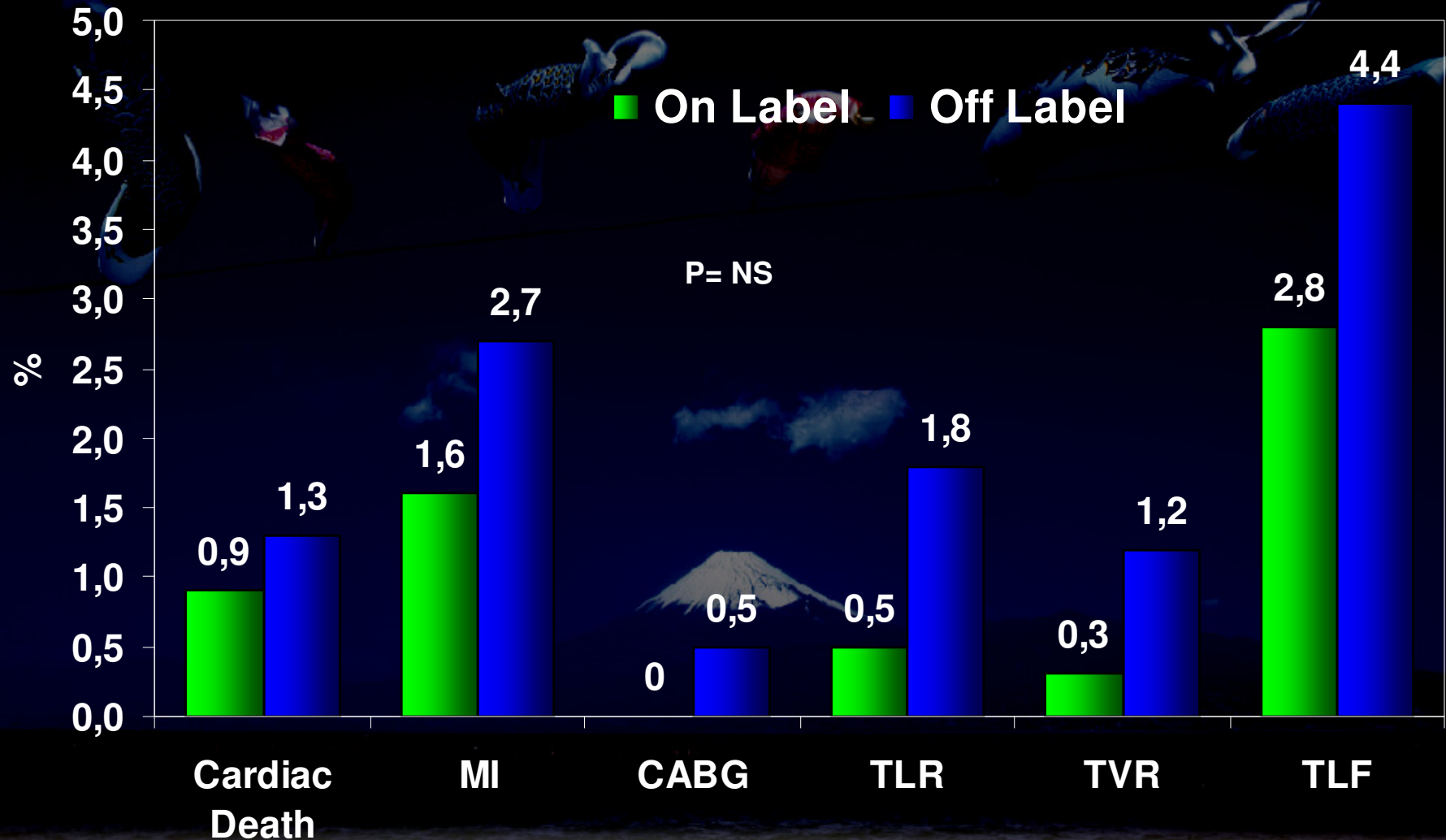
Adverse Events up to Discharge



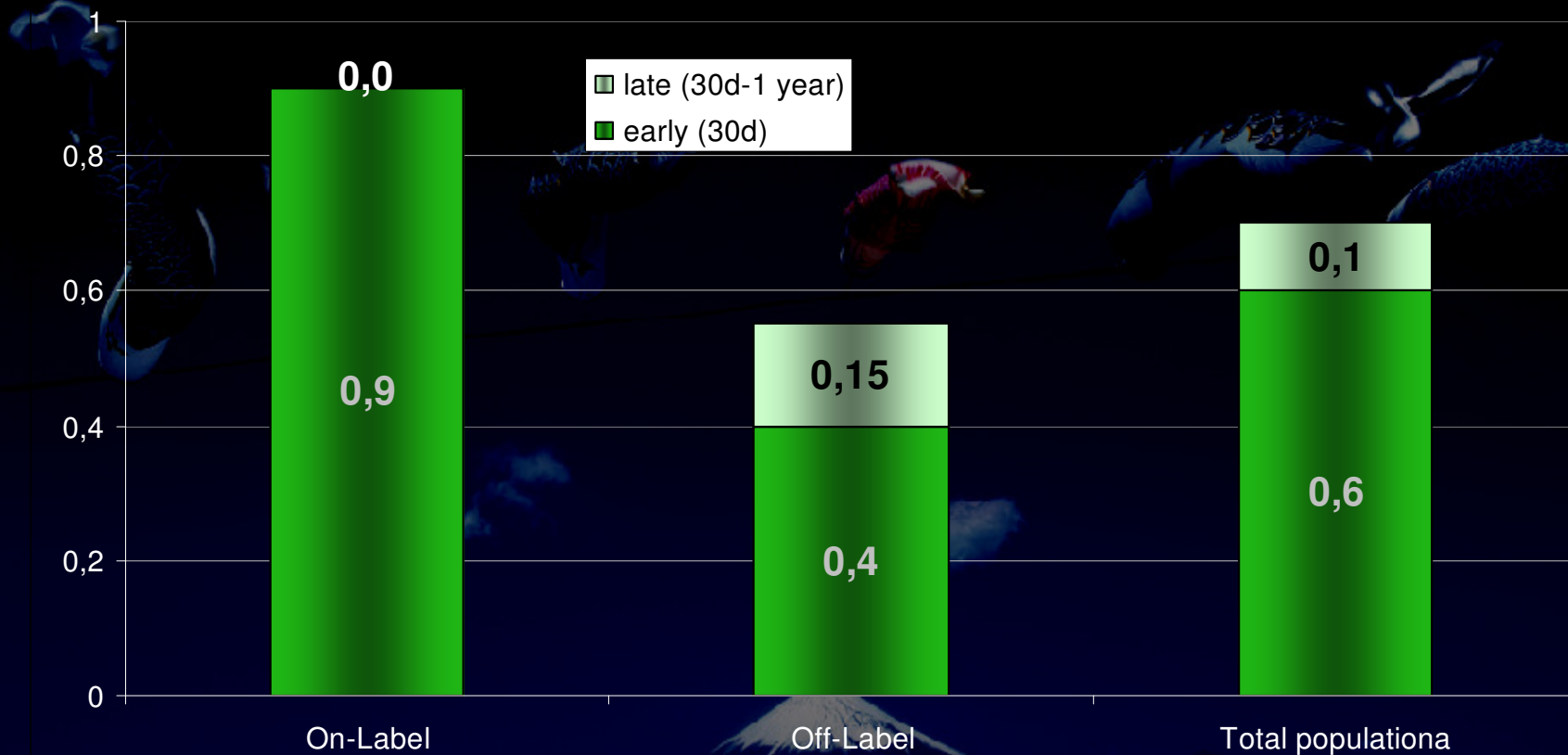
Clinical Outcomes at 6 m Follow-up



Primary Endpoint Clinical Outcomes at 12 m Follow-up



Stent Thrombosis



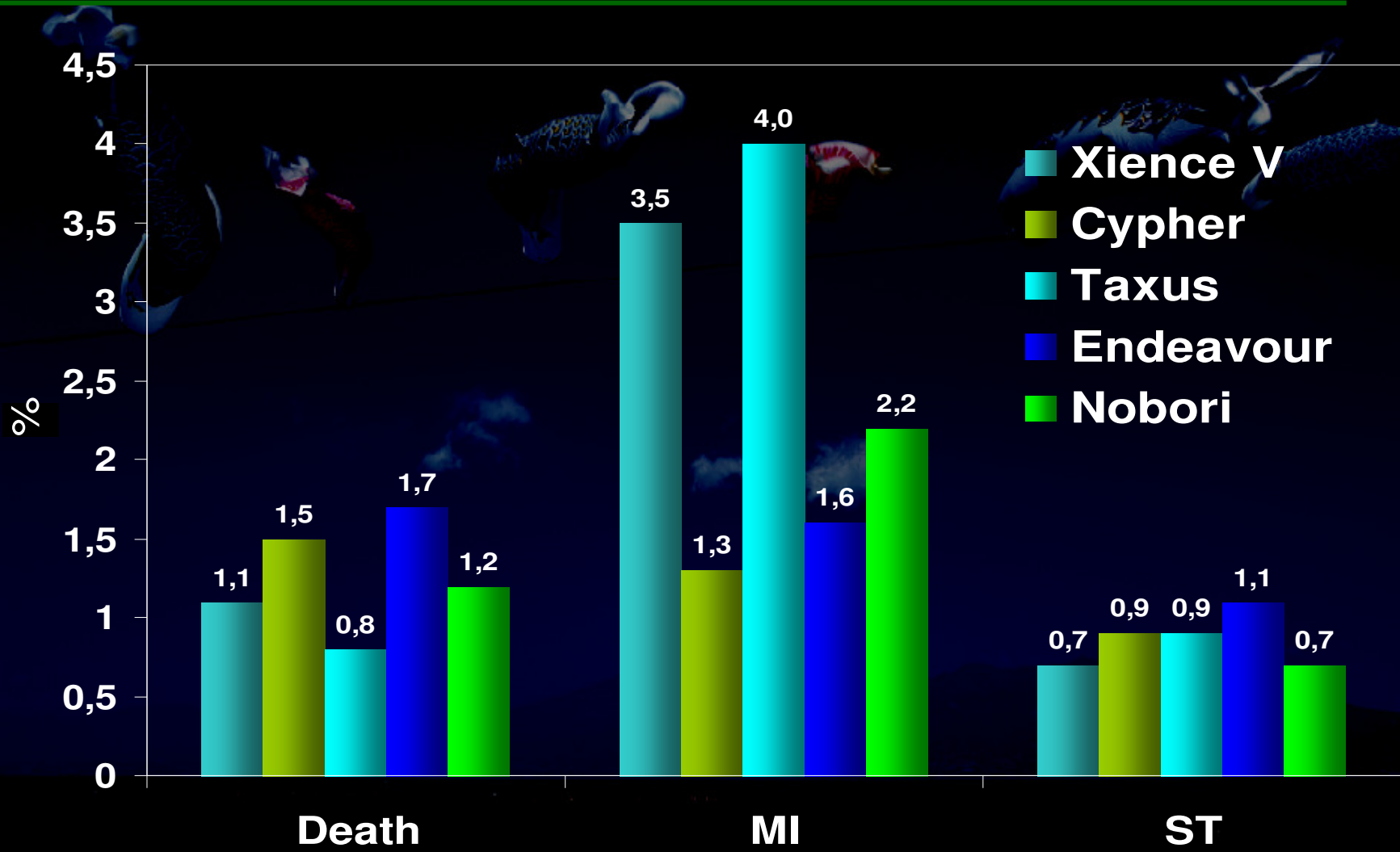
6 Months = 95% of patients at DAT
12 Months = 77% of patients at DAT

Late ST - One patients treated for AMI with stenosis in SVG – due to mistake of GP was off DAT one month after the procedure. ST at 3m.

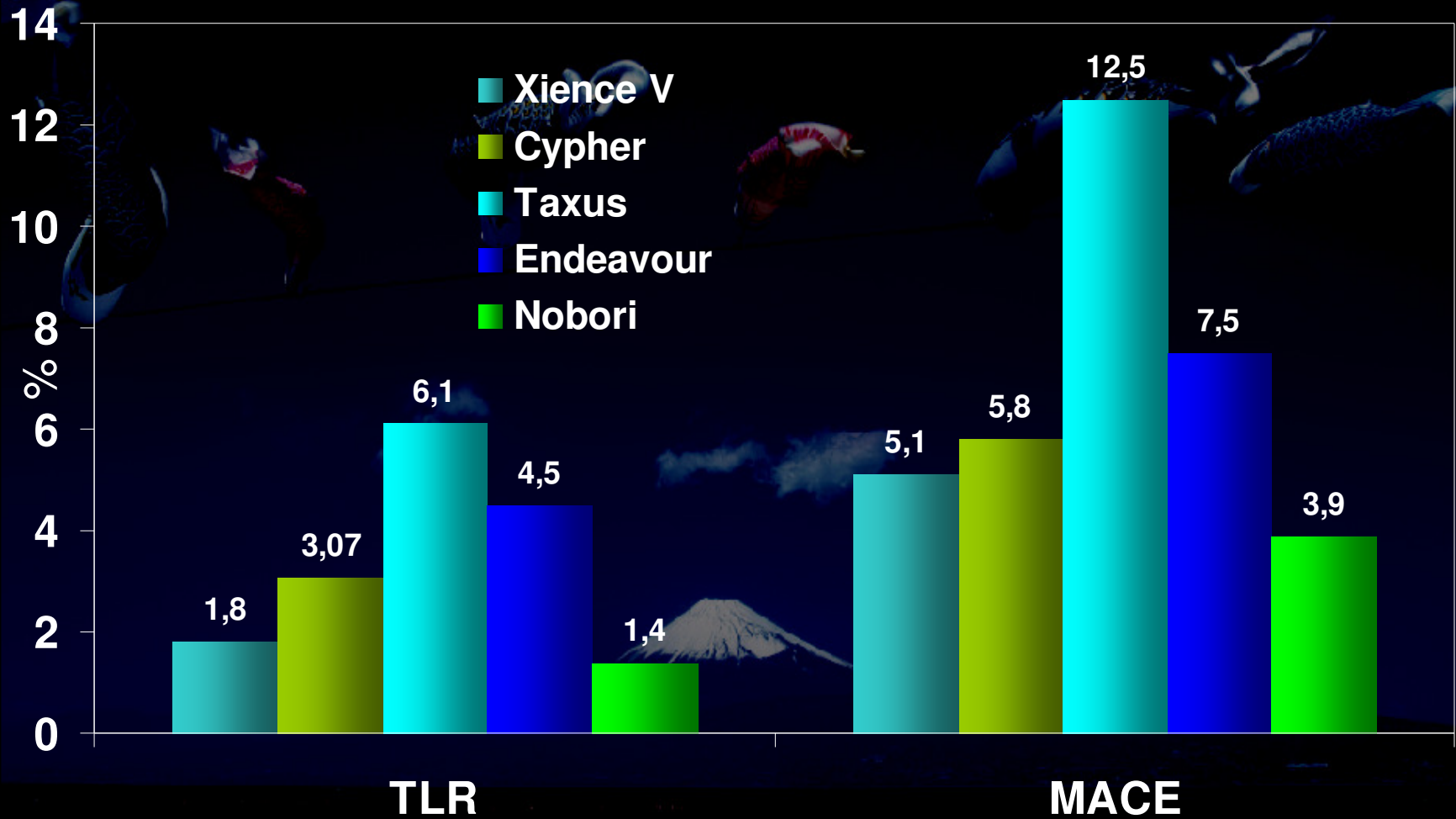
12 Months Clinical Outcomes Comparison with Similar Registries

Study	SPIRIT V	e-CYPHER	ATLAS	e-FIVE	NOBORI 2
Cardiac Death %	1.1	1.5	0.8	1.7	1.2
MI %	3.5	1.3	4.0	1.6	2.2
TLR %	1.8	3.1	6.1	4.5	1.4
CABG %	0.3	0.12	NA	4.9	0.4
TVR %	2.8	NA	9.2	NA	2.2
MACE %	5.1	5.8	12.5	7.5	3.9
ST %	0.7	0.9	0.9	1.1	0.7

Safety endpoints at 1 Year



Efficacy at 1 Year



Conclusions

Results of consecutive patients treated with Nobori stent in real life setting are very encouraging

Across subsets of challenging lesions and high-risk patient subgroups, excellent acute results and low rates of MACE have been observed

These results give further indication of potential benefit that Nobori, a DES with a biodegradable polymer and abluminal coating, could bring for treatment of patients with CAD

Further extensive Clinical program will help to fully explore the value of biodegradable polymer and abluminal coating