

# NOBORI 2 Trials

## One Year Clinical Outcomes

Dr G.B. Danzi

Ospedale Maggiore Policlinico  
Milano, Italy

# INTRODUCTION

**Pivotal DES trials enrolled restricted patient population, not truly representative of every day practice**

**The use of drug eluting stents (DES) in every day practice doesn't correspond to the patients treated in pivotal trials and the safety of DES use in complex patients is not fully established**

**Therefore, we initiated a large study to assess in a real life setting, the usage pattern and outcomes of patients treated with Nobori DES**



# NOBORI 2

## Trial Characteristics

- **Inclusion – All Patients eligible for PCI with DES**
- **Off-line baseline QCA analysis by independent Corelab**
- **Highest quality control standards (35% monitoring on-site; >90% on-line)**
- **Electronic CRF**
- **All events adjudicated by an independent CEC**
- **Independent statistical analysis and data management**

# NOBORI 2

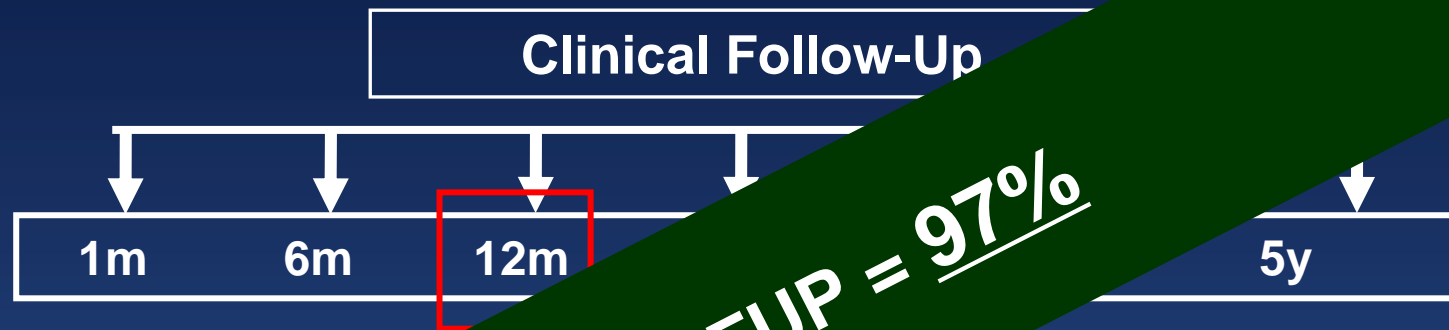
## Study Patient population

**3067 consecutive patients treated with new generation DES, Nobori in 125 centres in Europe, Asia and Africa are included.**

**Patients are automatically allocated to 2 analysis groups based on baseline lesions/patients characteristics :**

- **Simple - On-label group included patients with characteristics similar to patients enrolled in pivotal clinical trials**
- **Complex - Off-label group included all patients not fulfilling eligibility criteria for those trials**

# NOBORI 2 Study Design



**12 Months FUP = 97%**

Primary End Point: Failure at 12 months post-procedure

- 1. Myocardial infarction (Q-wave and non-Q-wave not clearly attributable to non-target vessel),
- 2. Clinically driven target lesion revascularization

# NOBORI 2 Study Study Organization

- **PI:**

**Dr. G.B. Danzi**

- **Executive Operational Committee:**

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

- **Monitoring**

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

- **Study management:** 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
- A. Vogt
- B. Rensing
- C. J. Royaards

- **Angiographic Corelab:**

- MCR – Milan
- CorExperts - Belgrade

- **Sponsor:** Terumo

# Complex lesions/patients

## Complex Lesions

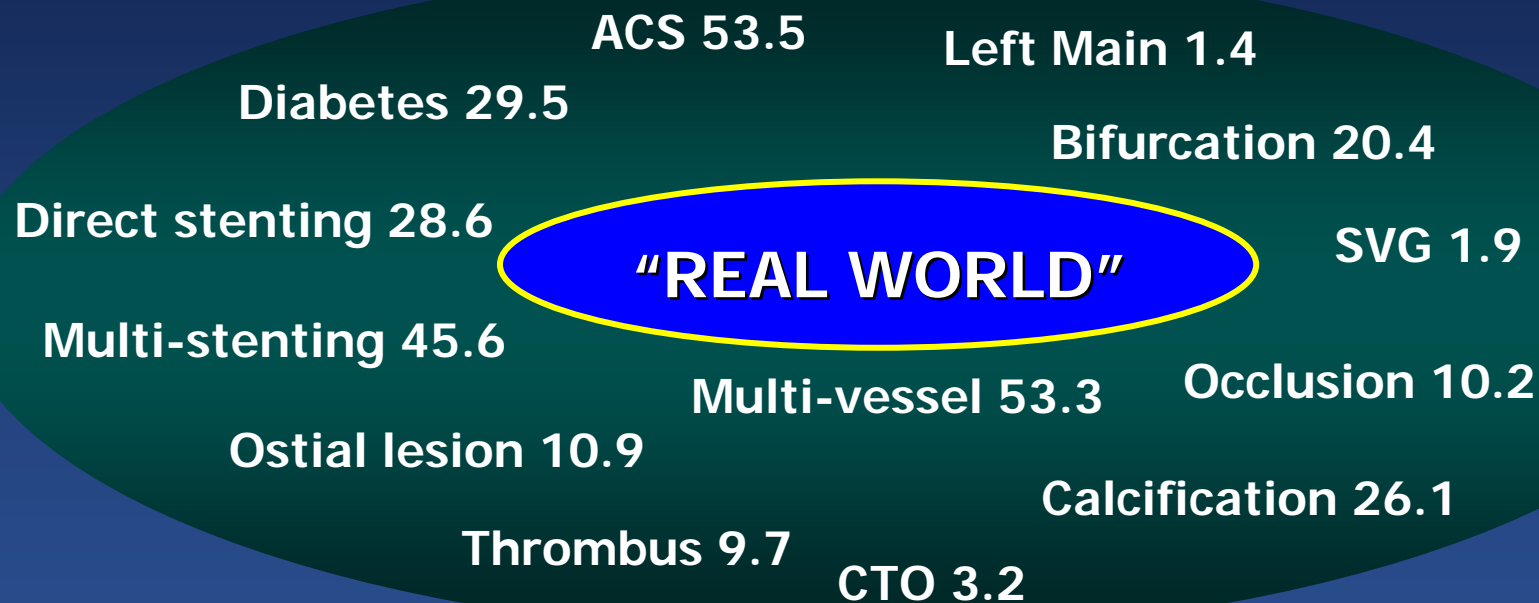
- B2/C classification
- Long Lesions (>20mm)
- Small vessels (<2.5mm)
- CTO
- Vein graft
- Bifurcation
- Left Main
- In-Stent Restenosis
- Thrombus containing

## Complex Patients

- Diabetes
- Renal dysfunction
- ACS
- Elderly >80 years
- Heart Failure (EF<30%)
- Multivessel Disease
- Multiple vessels treated



## NOBORI 2 Trial



Clinical Follow-Up up to 5 years

**Primary Endpoint: Target Lesion Failure at 12 months**  
Composite of Cardiac Death, MI Target vessel related and TLR

# NOBORI 2 Study Baseline Demographics

	Simple N=825	Complex N=2242	Total N=3067	P-value
Age (mean $\pm$ SD)	64.5 $\pm$ 10.5	64.3 $\pm$ 11.1	64.4 $\pm$ 11.0	0.77
%				
Female	26.1	21.6	22.0	0.001
Previous MI	25.3	36.1	33.2	<0.001
Prior PCI	29.7	33.0	32.1	0.09
Prior CABG	7.4	9.3	8.8	0.09
Diabetes Mellitus	29.1	29.6	29.5	0.82
Insulin-dependent	7.3	6.9	7.0	0.69
Hyperlipidemia	74.8	69.7	71.1	0.007
Hypertension	71.7	68.1	69.1	0.06
Current smoker	21.5	27.1	25.6	0.003
Charlson Comorbidity Score (mean $\pm$ SD)	2.8 $\pm$ 1.5	3.3 $\pm$ 1.8	3.2 $\pm$ 1.8	<0.001

# NOBORI 2 Study Clinical Presentation

	<b>Simple N=825</b>	<b>Complex N=2242</b>	<b>Total N=3067</b>	<b>P-value</b>
<b>%</b>				
<b>Silent ischemia</b>	<b>13.0</b>	<b>15.8</b>	<b>15.1</b>	<b>0.05</b>
<b>Stable angina</b>	<b>64.6</b>	<b>38.9</b>	<b>45.8</b>	<b>&lt;0.001</b>
<b>Unstable angina</b>	<b>22.4</b>	<b>45.3</b>	<b>39.1</b>	<b>&lt;0.001</b>
<b>Acute Coronary Syndrome</b>	<b>22.4</b>	<b>64.9</b>	<b>53.5</b>	<b>&lt;0.001</b>

# NOBORI 2 Study Procedural Characteristics

(mean±SD) per patient	Simple N=825	Complex N=2242	Total N=3067	P-value
# Vessels diseased	1.58±0.73	1.79±0.78	1.73±0.77	<0.001
# Lesion detected	1.68±0.95	2.15±1.16	2.02±1.13	<0.001
# Lesions treated	1.12±0.34	1.51±0.75	1.40±0.69	<0.001
# Stents implanted	1.35±0.71	1.87±1.17	1.73±1.09	<0.001
<b>Lesion Classification %</b>				
A	5.3	3.2	3.7	0.006
B1	30.8	21.7	23.6	<0.001
B2	39.0	42.7	41.9	0.06
C	24.9	32.4	30.8	<0.001

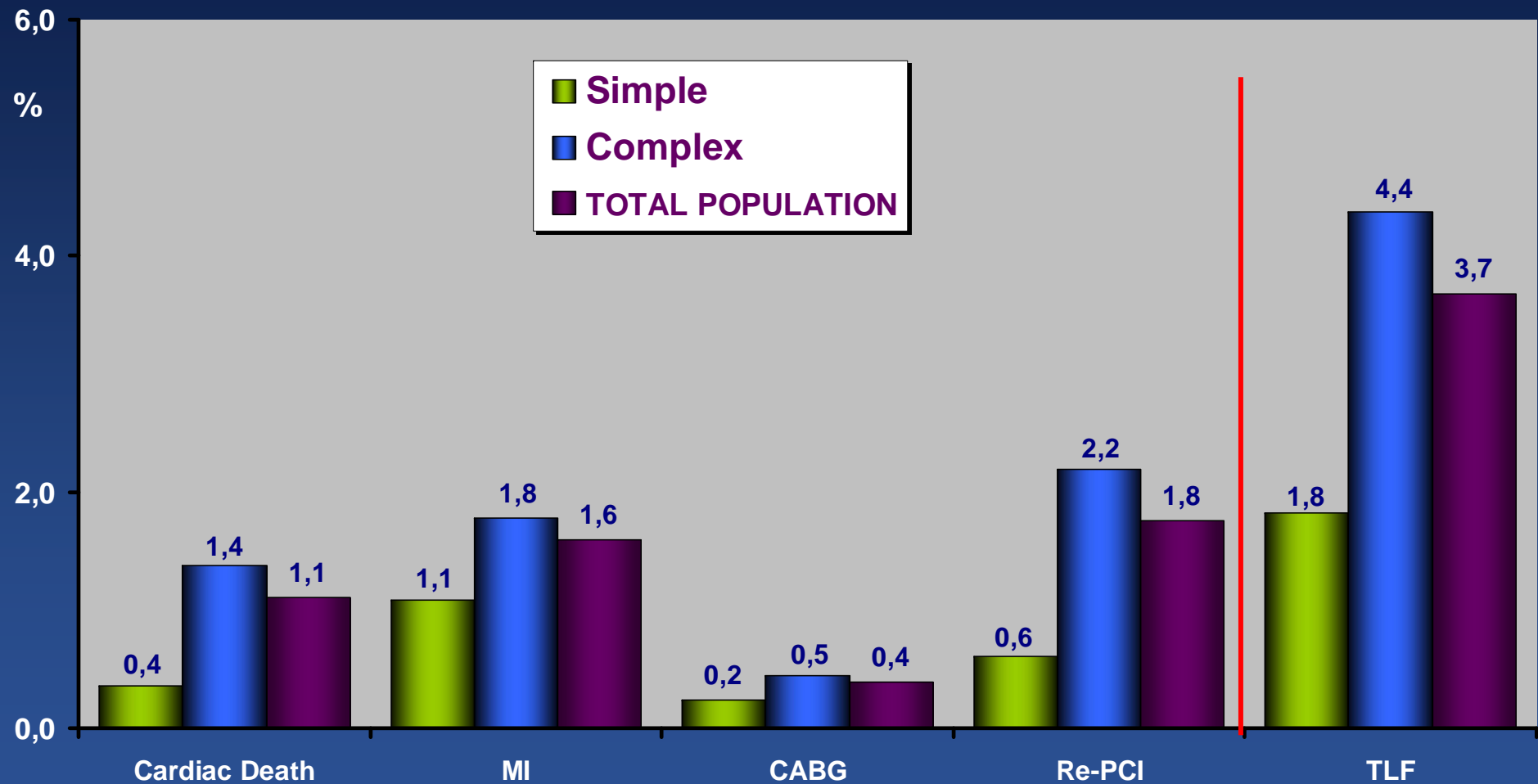
# NOBORI 2 Study Lesion Characteristics

<b>%</b>	<b>Simple</b>	<b>Complex</b>	<b>Total</b>	<b>P-value</b>
<b>Bifurcation</b>	<b>0.0</b>	<b>26.0</b>	<b>20.4</b>	<b>&lt;0.001</b>
<b>Ostial</b>	<b>6.7</b>	<b>12.1</b>	<b>10.9</b>	<b>&lt;0.001</b>
<b>Occlusion</b>	<b>4.7</b>	<b>11.8</b>	<b>10.2</b>	<b>&lt;0.001</b>
<b>Thrombus</b>	<b>0.0</b>	<b>12.3</b>	<b>9.7</b>	<b>&lt;0.001</b>
<b>Moderate/Severe Calcification</b>	<b>22.1</b>	<b>27.1</b>	<b>26.1</b>	<b>0.003</b>

# NOBORI 2 Study QCA Quantitative Data

<b>(mean±SD)</b>	<b>Simple</b>	<b>Complex</b>	<b>Total Population</b>	<b>P-value</b>
<b>RVD, mm</b>	<b>2.61±0.57</b>	<b>2.61±0.58</b>	<b>2.61±0.58</b>	<b>0.89</b>
<b>Lesion Length, mm</b>	<b>15.27±9.25</b>	<b>15.68±9.68</b>	<b>15.59±9.59</b>	<b>0.52</b>
<b>MLD pre, mm</b>	<b>0.91±0.48</b>	<b>0.81±0.50</b>	<b>0.83±0.50</b>	<b>&lt;0.001</b>
<b>MLD post, mm</b>	<b>2.52±0.46</b>	<b>2.50±0.47</b>	<b>2.51±0.47</b>	<b>0.23</b>
<b>DS – pre, %</b>	<b>65.4±16.2</b>	<b>68.9±17.8</b>	<b>68.2±17.5</b>	<b>&lt;0.001</b>
<b>DS – post, %</b>	<b>12.6±6.6</b>	<b>13.2±7.1</b>	<b>13.1±7.0</b>	<b>0.19</b>
<b>Acute gain, mm</b>	<b>1.62±0.54</b>	<b>1.69±0.59</b>	<b>1.68±0.58</b>	<b>0.003</b>

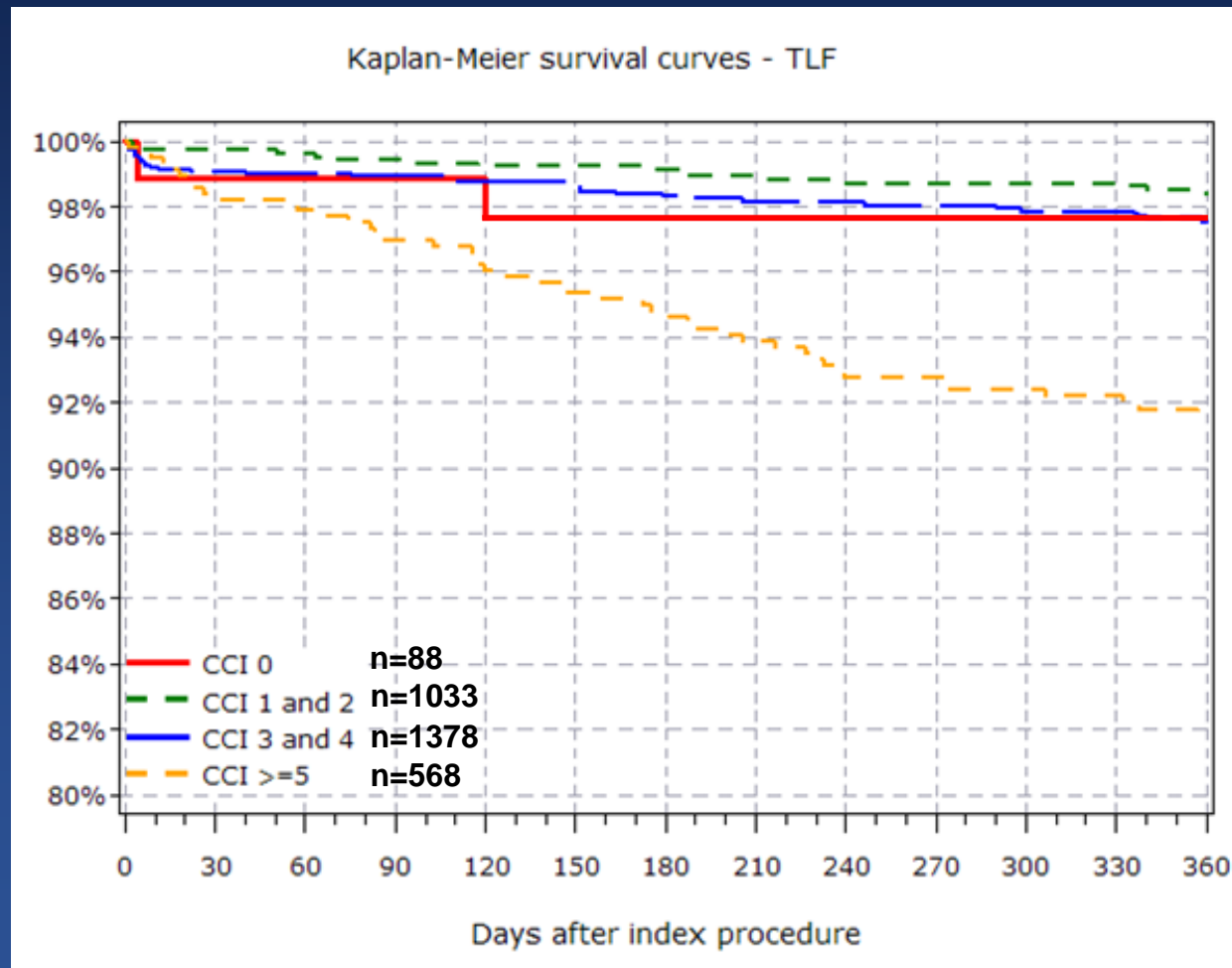
# NOBORI 2 Study 1 Year Clinical Outcomes



PRIMARY ENDPOINT TLF = Target Lesion Failure (Cardiac death, target vessel related MI and TLR)

# NOBORI 2

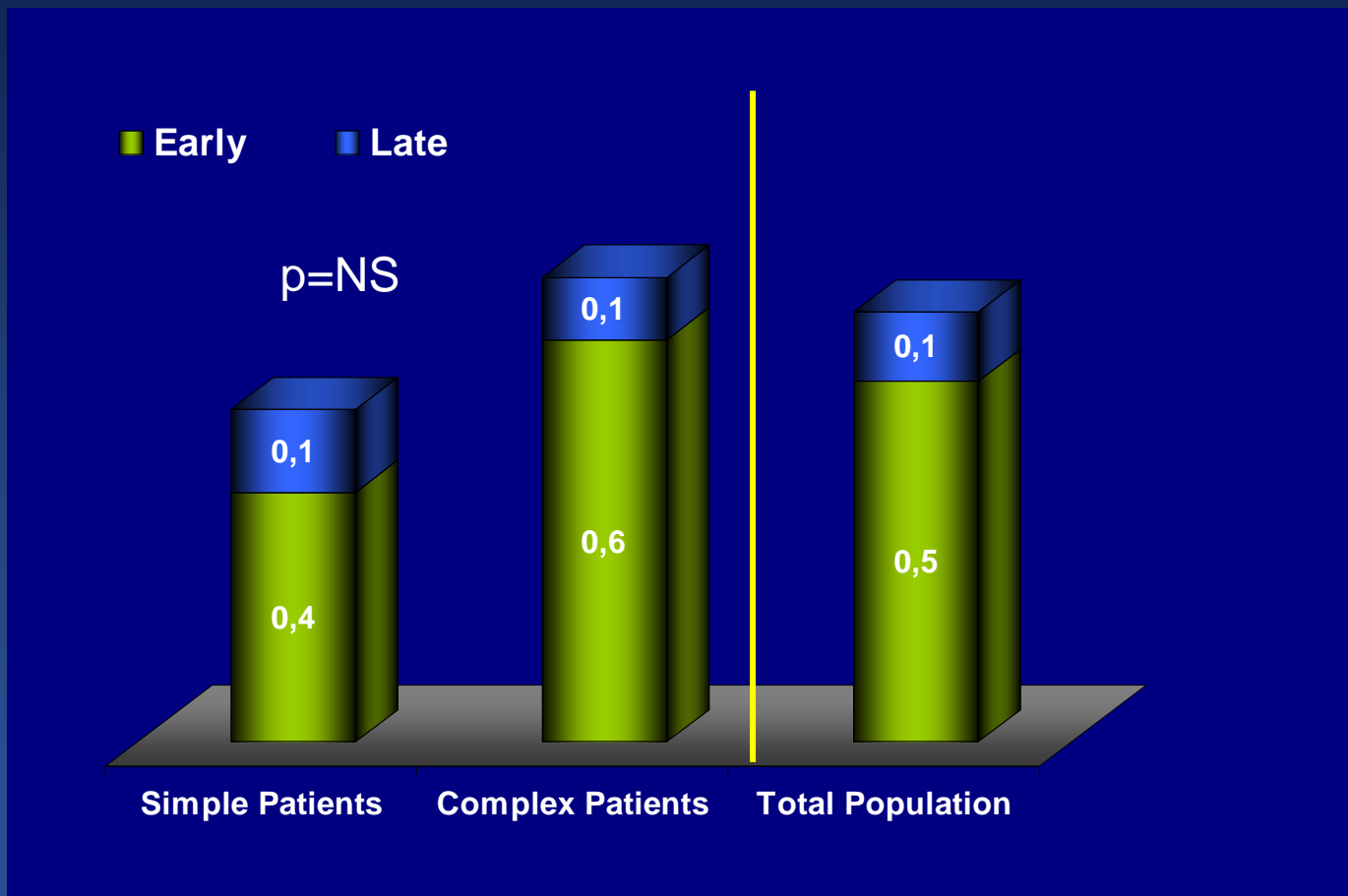
## Impact of Charlson Comorbidity Index at 1 Year TLF





# NOBORI 2 Study

## Stent Thrombosis at 1 Year

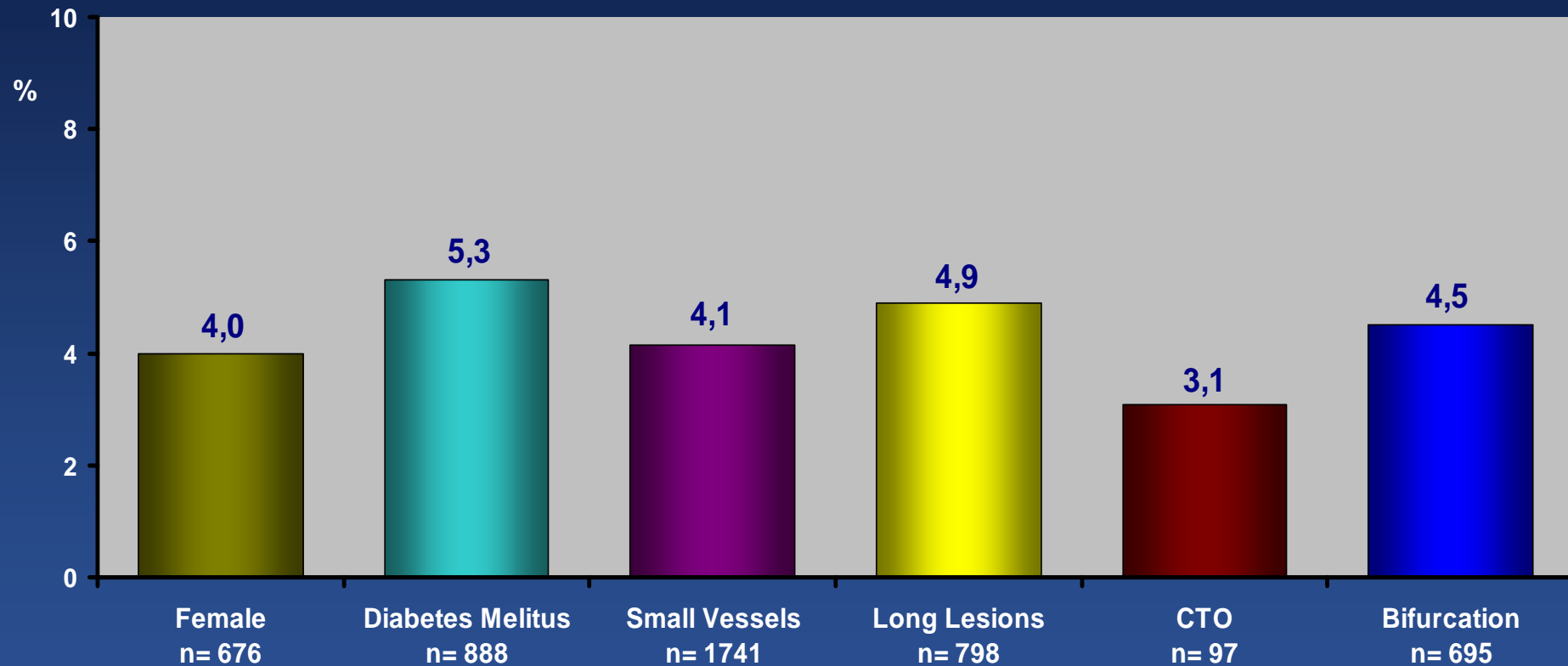


Early = acute +subacute

Definite and Probable ST, ARC definitions

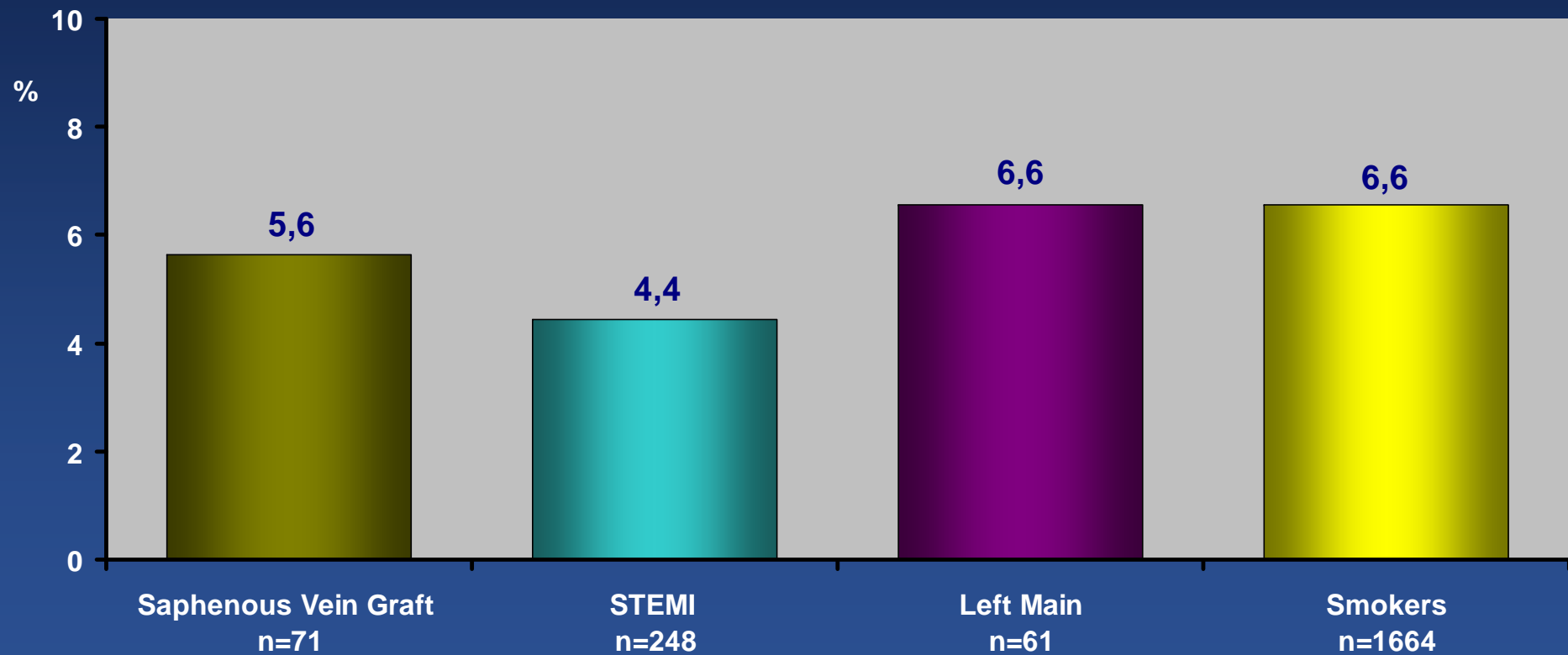
# NOBORI 2 Study

## 1 Year TLF in Patient/Lesion Subsets



TLF = Target Lesion Failure (Cardiac death, MI Target vessel related, TLR)

# NOBORI 2 Study 1 Year TLF in Patient/Lesion Subsets



TLF = Target Lesion Failure (Cardiac death, MI Target vessel related, TLR)

# ALL-COMMERS REGISTRIES

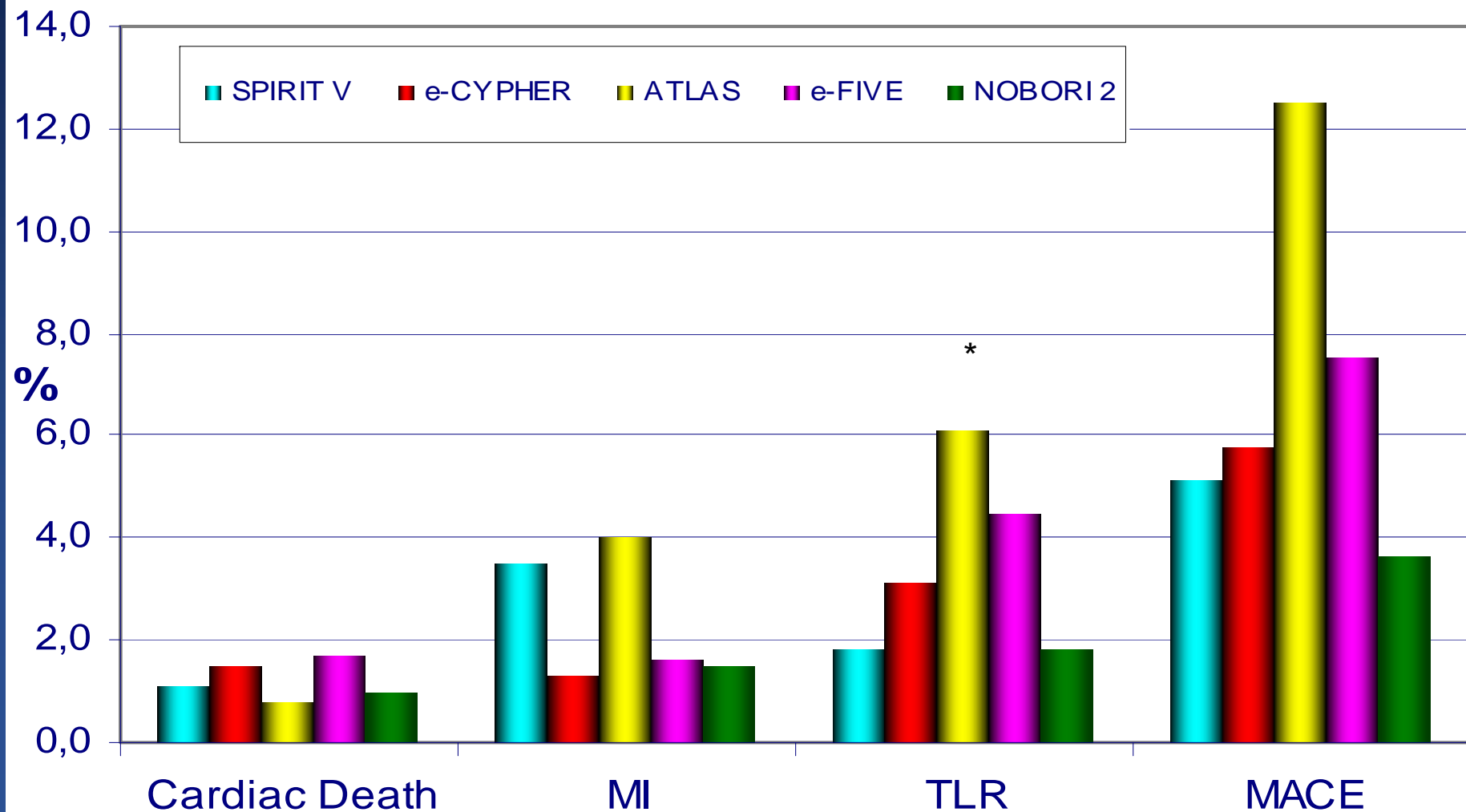
## (Enrolling Complex Patients/Lesions)

Study	SPIRIT V Xince V	e- CYPHER Cypher	ATLAS Taxus Liberte	e-FIVE Endeavor	NOBORI 2 Nobori	Overall
Age (yr)	63	62	62	63	64	62-64
Diabetes*	30	29	25	33	30	25-33
Bifurcation*	9.0	11	NA	18.9	21	9-21
Total occlusion*	0.0	9.0	NA	0.0	9.0	0-9.0
Left Main*	1.0	2.2	0.0	1.9	2.1	0-2.2
AMI*	0.0	7.2	0.0	14	19	0-19
B2/C Lesions*	82	85	75	60	72	60-85
MVD *	42	56	NA	10.9**	53	Up to 53

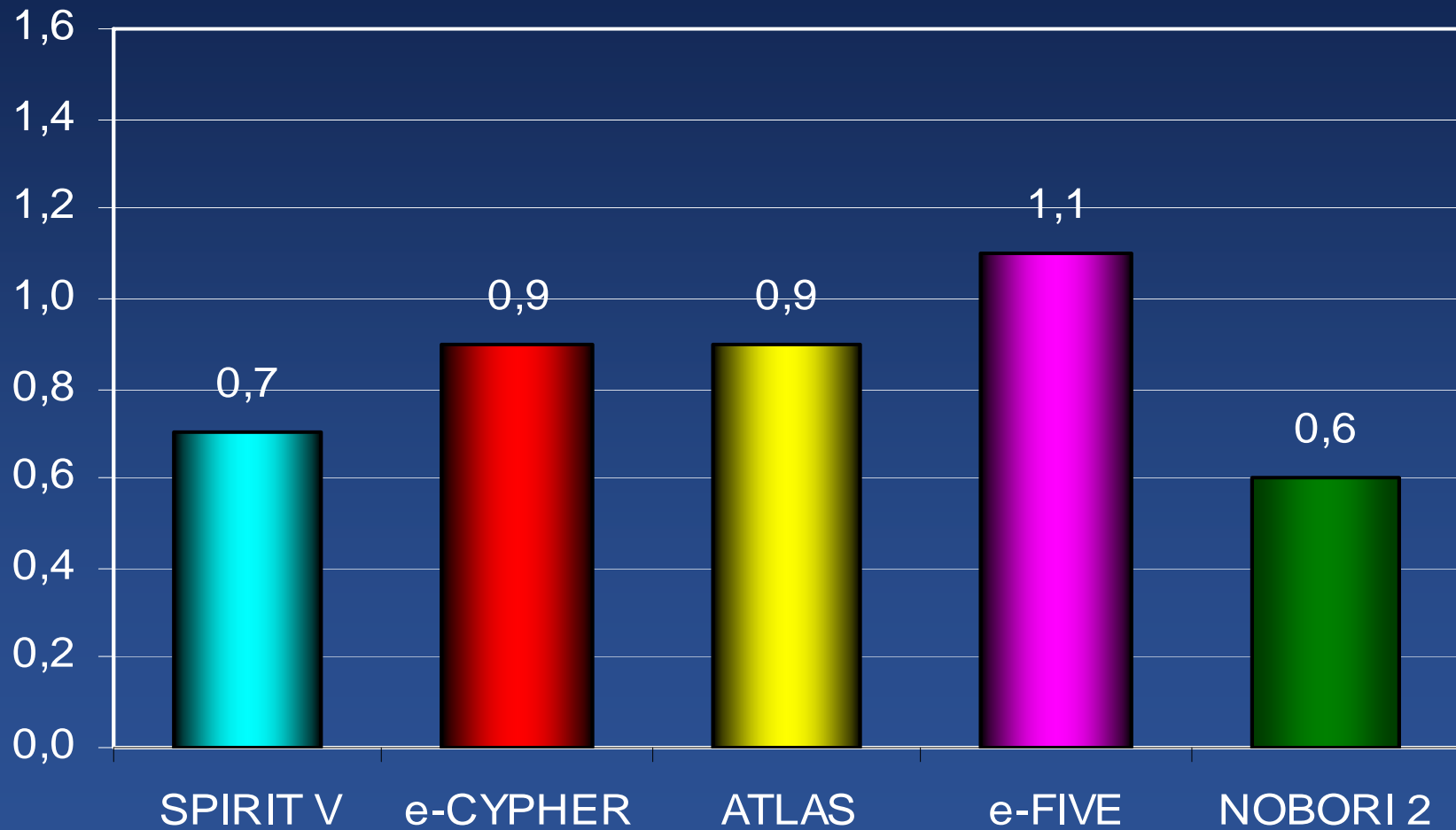
\* all values are in %

\*\* treated

# One year Clinical Outcome Registries Enrolling Complex Patients



# Stent Thrombosis at One Year Registries Enrolling Complex Patients



# Conclusions

- **Results of both simple and complex patients treated with Nobori stent in real life setting are very encouraging**
- **Nobori DES met expectations by offering excellent and consistent results in various geographic areas and patient subsets**
- **Particularly appealing are results in STEMI, Bifurcation, Small Vessels, Long Lesions and Diabetic Patients**
- **Further extensive studies and long term follow-up of ongoing studies is expected to give additional reassurance of Nobori performance**