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DI SCIENZE
CARDIOVASCOLARI



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Percutaneous Coronary Intervention Utilizing a New Endothelial Progenitor Cells Antibody-Coated Stent: A Prospective Single-Center Registry in High-Risk Patients

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GENOUS stent at CBM

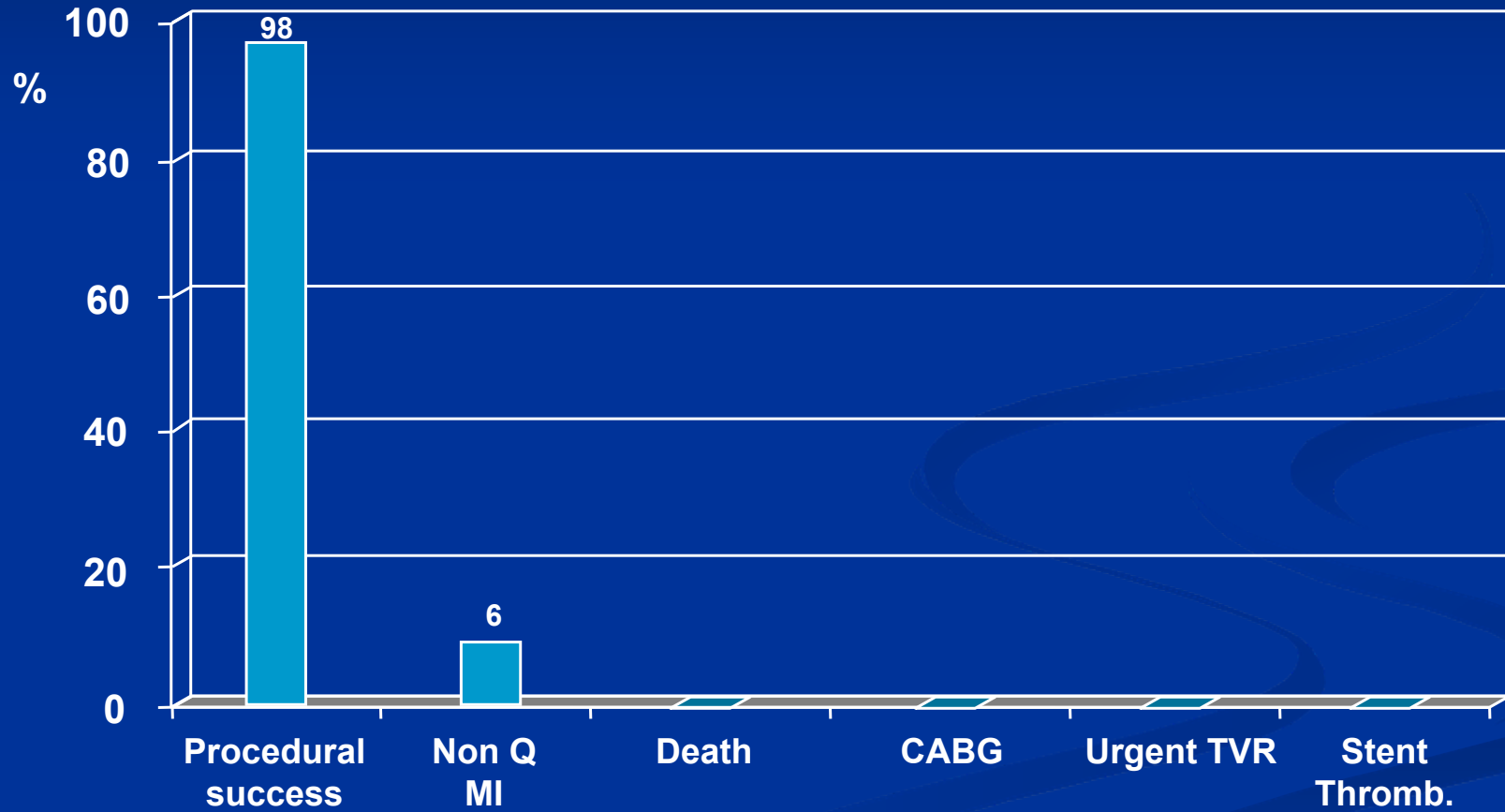
- **80 consecutive patients received 93 Genous Bio-engineered R stent™ in our Institution from November 2005 to March 2007**
- **All patients had at least 2 of the following features defining clinical and/or angiographic increased risk:**
 - **diabetes mellitus**
 - **Acute coronary syndromes (unstable angina, non ST-segment elevation acute myocardial infarction or ST-segment elevation acute myocardial infarction <1 month)**
 - **left ventricular dysfunction (left ventricular ejection fraction <40%)**
 - **multivessel intervention**
 - **B2/C coronary lesions**
- **All patients were receiving aspirin (100 mg/day), clopidogrel (600 mg loading dose >3 hours before the procedure), and HMG-CoA reductase inhibitors before procedure**

Demographic/Clinical features (n=80)	No (%)
Mean age (years)	66±10
Men	64 (80)
<u>Diabetes mellitus</u>	<u>26 (33)</u>
Hypertension	56 (70)
Hypercholesterolemia (> 200 mg/dl)	63 (79)
Cigarette smoking	47 (59)
Clinical pattern	
Stable angina	21 (26)
<u>Unstable angina/NSTEMI</u>	<u>23 (29)</u>
<u>Recent STEMI (< 1 month)</u>	<u>35 (44)</u>
Remote myocardial infarction	1 (1)
Left ventricular ejection fraction ≤ 40%	6 (8)
Previous coronary by-pass surgery	5 (6)
<u>Statin therapy</u>	<u>80 (100)</u>

Angiographic features	No. (%)
Treated coronary arteries	85
Patients with single-vessel disease	71 (89)
Patients with multi-vessel disease	9 (11)
Treated vessel	
Left anterior descending	46 (54)
Circumflex	13 (15)
Right	26 (31)
Lesion type B2/C	45 (56)
Patients with	
In-stent restenosis	7 (9)
Ostial lesions	4 (5)
Bifurcating lesions	3 (4)
Multivessel intervention	7 (9)
Use of long stents	14 (18)
Implantation of multiple stents	13 (16)
Glycoprotein IIb/IIIa (tirofiban) infusion	8 (10)

Procedural features	No. (%)
Total n° of stents	93
Stent / patient	1.16
<u>Mean stent length (mm)</u>	<u>20</u>
Range (mm)	18-23
Mean stent diameter (mm)	3.1
Range (mm)	2.75-3.5
Mean deployment pressure (atm)	13.6±1.3
Mean % stenosis pre-procedure (%)	80±15
Mean % stenosis after procedure (%)	2.2±2.5
MLD before procedure (mm)	0.8±0.4
MLD after procedure (mm)	3.3±0.5
Acute gain (mm)	2.5±0.6
Procedural success	79 (98)

Procedural and In-hospital results



FOLLOW UP RESULTS

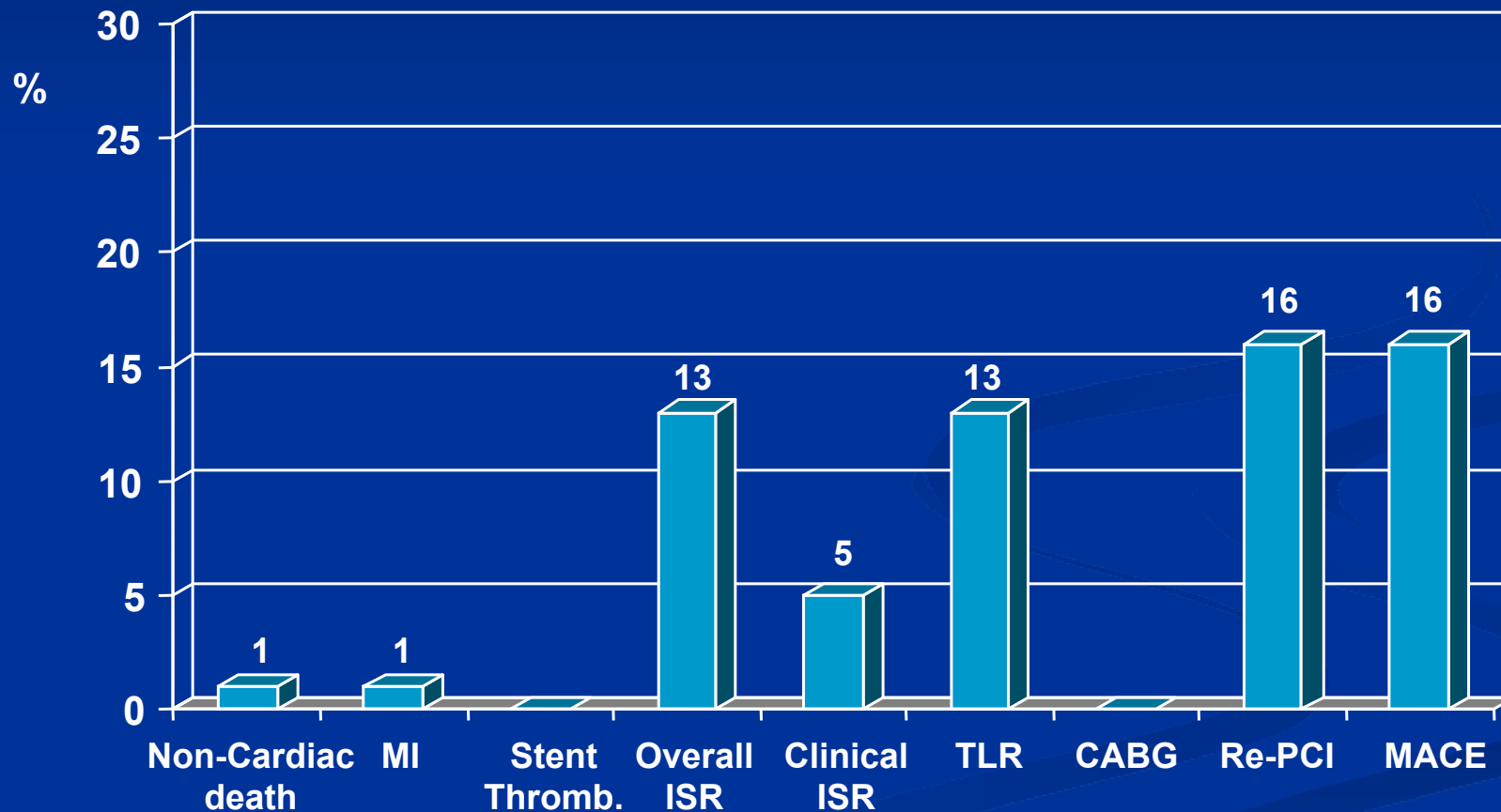
Clinical follow-up data	No. (%)
<u>Follow-up duration (mo)</u>	<u>14±4</u>
<u>Dual Antiplatelet Therapy Duration (mo)</u>	<u>2</u>
Death	
Cardiac	-
Non cardiac	1 (1)
Myocardial infarction	1 (1)
Stent thrombosis	-
In-stent restenosis	
Clinical	4 (5)
Overall	10 (13)
TLR	10 (13)
<u>Late loss (mm)</u>	<u>0.88±0.62</u>
Coronary by-pass surgery	-
Re-PCI*	13 (16)
Total MACE	13 (16)

* Target lesion revascularization + non target lesion revascularization

MACE: major adverse cardiac events; PCI: percutaneous coronary intervention; TLR: target lesion revascularization

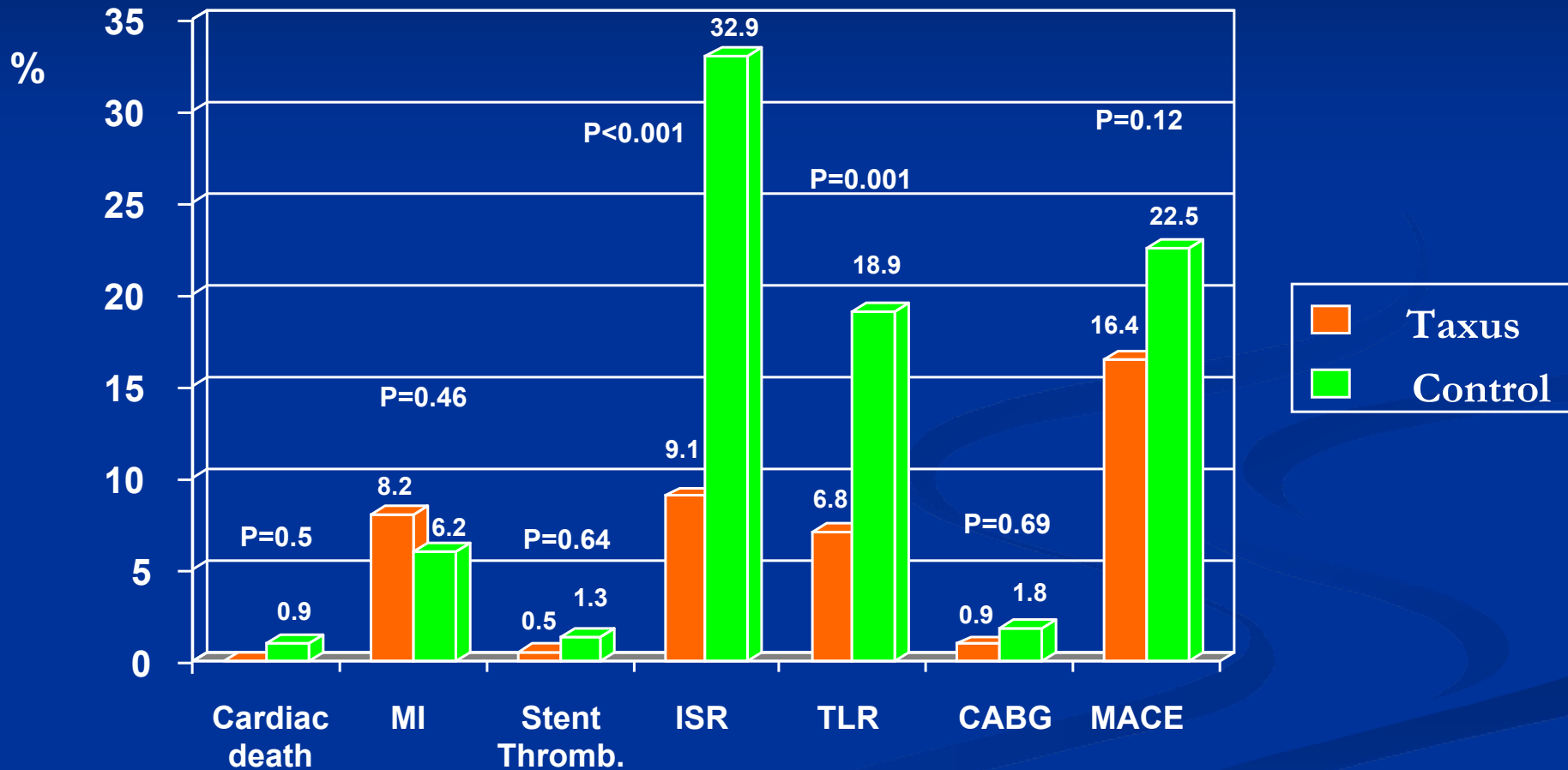
FOLLOW UP RESULTS

Mean 14±4 months

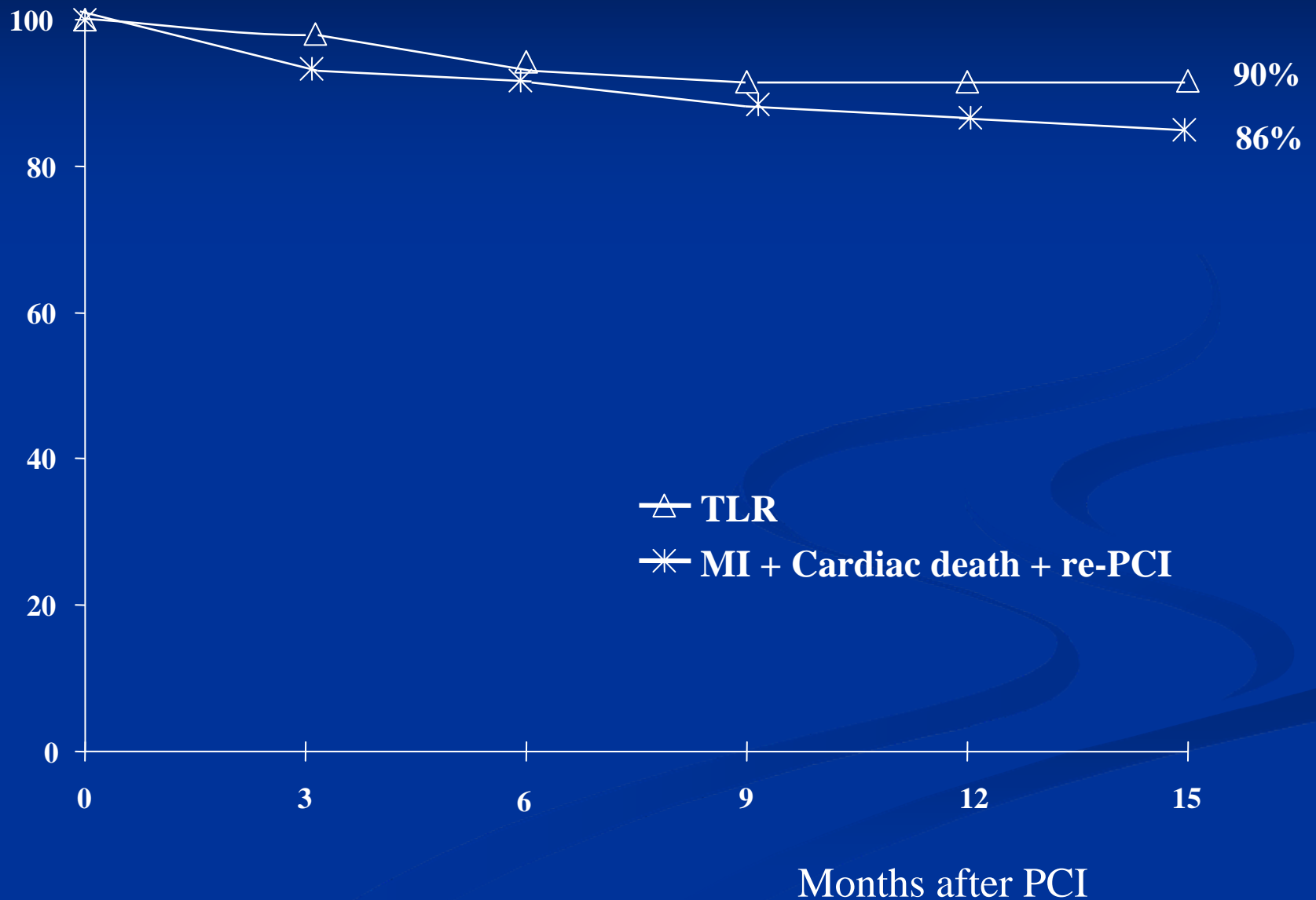


TAXUS VI trial

FOLLOW-UP RESULTS AT 9 MONTHS (N=446)



Actuarial event-free survival curves



CONCLUSIONS

- **Intracoronary stents coated with antibodies to surface antigens of EPCs in patients with angiographic or clinical high risk features is safe, without acute, subacute or late stent thrombosis at 14 months**
- **Such results may compare favourably to those reported for the currently available drug-eluting stents**
- **Double anti-platelet regimen given for only 2 months post procedure**