



E-Five Registry

12 month results from Latin America

Fausto Feres

Instituto Dante Pazzanese de Cardiologia

São Paulo- Brazil

E-Five Registry

Rationale for Registries

- Advantages:
 - Clinical outcomes from the real world versus RCTs necessary to determine device safety and efficacy
- Limitations:
 - Reduced monitoring versus RCTs
 - Lost to follow up
 - Potential under reporting
- The E-Five registry was designed to gain insight into clinical outcomes with the Endeavor DES in a real world patient population

E-Five Registry

Prospective, Multicenter Registry

PI: Chaim Lotan, Ian Meredith and Martin Rothman

Single and Multiple Coronary Artery Lesions
Stent Diameters: 2.25-4.0 mm
Stent Length: 8/9-30 mm

N = 8,000 patients
200 sites

Europe, Asia Pacific, Israel, New Zealand, Latin America

Clinical/MACE



Primary Endpoint: MACE at 12 months

Secondary Endpoints: MACE at 30 days and 6 mo, Stent thrombosis, procedure success rate; device success rate; lesion success rate

Drug Therapy: ASA and Clopidogrel ≥ 3 months

Zotarolimus Dose: 10 μg per mm stent length

*Limited number of centers.

E-Five Latin America Fausto et al SOLACI 2008

E-Five Registry

Design

- Definitions:
 - **MACE: Death, MI, emergent bypass, TLR**
 - Stent Thrombosis: cardiac death <30 days post procedure or angiographic/autopsy confirmation of thrombus
 - Additional adjudication using ARC definite/probable definition for ST
 - Myocardial Infarction: 2x ULN CK including CKMB (confirmation by enzymes)
- **2 year follow up in 2000 patients**

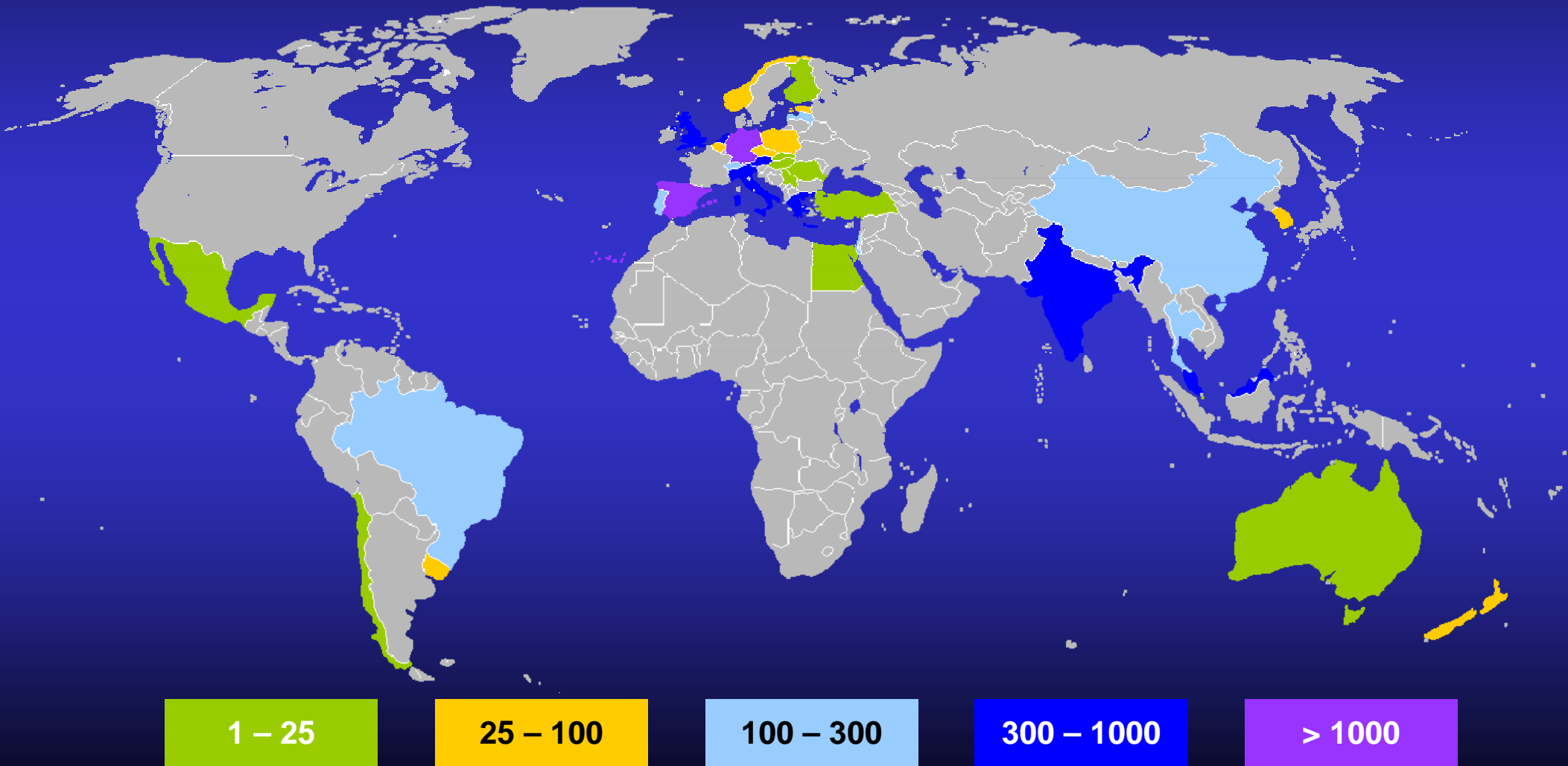
E-Five Registry

Data System and Quality Control

- Clinical Event Committee:
 - Cardialysis (Rotterdam, The Netherlands)
 - Independent adjudication of all reported MACE and Stent Thrombosis (protocol and ARC definite/probable) events
- Data Monitoring:
 - 10% monitoring aimed at detecting underreporting (CRO and Medtronic)
 - Random patient selection
- Electronic Data Collection

E-Five Enrollment

8314 patients enrolled



E-Five Latin America Fausto et al SOLACI 2008

E-Five Enrollment in Latin America

220 patients enrolled



E-Five Registry

Patient Demographics

Latin America
n = 220 Patients

Global E-5
n = 8314 Patients

Male (%)	70.0	76.7
Age (years)	63.3 ± 11.0	63.3 ± 11.1
Prior MI (%)	47.3	32.2
Non Q-wave MI	10.9	12.2
Q wave MI	37.3	21.3
Prior PCI (%)	26.8	25.3
Prior CABG (%)	10.0	7.5
Diabetes Mellitus (%)	34.7	32.7
Acute coronary syndrome (%)	50.1	55.7
Recent MI (%) <72hrs	7.3	21.8
Unstable Angina (%)	41.8	33.9

E-Five Registry

Procedure Characteristics

	Latin America n = 291 lesions	Global E-5 n = 10339 lesions
Total Stent Length (mm)	23.2 ± 9.9	23.5 ± 12.2
Lesion Length (mm)	17.3 ± 9.1	18.5 ± 10.6
Stent:Lesion Length	1.4 ± 0.4	1.4 ± 0.7
Long lesions (>20 mm)	36.1%	30.4%
Minimum Endeavor Stent Diameters implanted		
2.25 mm (%)	4.8	6.9
2.5 mm (%)	16.8	21.7
2.75 mm (%)	9.3	16.1
3.0 mm (%)	42.3	33.1
3.5 mm (%)	21.3	17.9
4.0 mm (%)	5.5	4.3

E-Five Registry

Complex Subsets

Latin America

n = 220 Patients

n = 291 Lesions

Global E-5

n = 8314 Patients

n = 10339 Lesions

Diabetics – % (n)	34.5 (76/220)	32.7 (2721/8314)
Insulin Dependent – % (n)	5.0 (11/220)	25.1 (682/2721)
Non Insulin Dependent – % (n)	95 (209/220)	74.9 (2039/2721)
Lesions ≥ 20mm – % (n)	36.1 (105/291)	38.8 (4006/10332)
RVD ≤ 2.75mm – % (n)	26.8 (78/291)	39.2 (4057/10339)
Unstable Angina – % (n)	41.8 (92/220)	33.9 (2820/8314)
Recent MI <72% – % (n)	7.3 (16/220)	21.8 (1813/8314)

Clinical Outcomes to 12 months per protocol

Latin America

n= 211

Global

n = 7832

Death (all) – % (n)	0.5 (1)	2.4 (191)
Cardiac	0.5 (1)	1.7 (135)
MI (all) – % (n)	0	1.6 (128)
Q Wave	0	0.4 (31)
Non Q wave	2(1%)	1.3 (98)
Death (cardiac) + MI (all) – % (n)	0.5 (1)	3.0 (238)
Stent Thrombosis – % (n)	0	1.0 (82)
0-30 days	0	0.8 (62)
31-365 days	0	0.3 (21)
TLR – % (n)	3.8 (8)	
TVR (non-TL) – % (n)	0.9 (2)	0.7 (52)
TVR – % (n)	4.7 (10)	4.9 (387)
MACE – % (n)	4.3 (9)	
TVF – % (n)	5.2 (11)	7.2 (565)

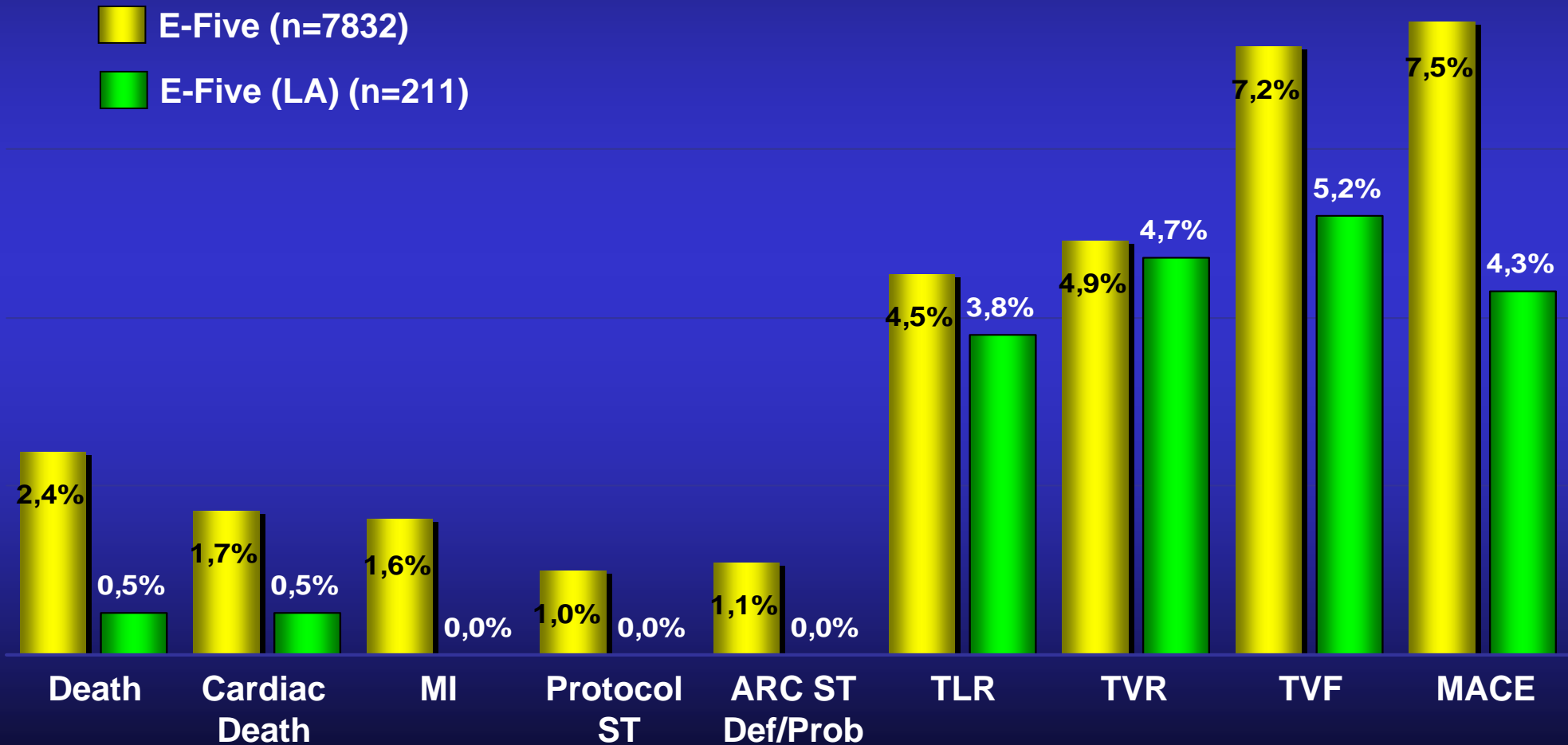
E-Five Registry

Clinical Outcomes to 12 months per protocol

	Latin America n= 211	Global n = 7832
Death (all) – % (n)	0.5 (1)	2.4 (191)
Cardiac	0.5 (1)	1.7 (135)
MI (all) – % (n)	0	1.6 (128)
Q Wave	0	0.4 (31)
Non Q wave	0	1.3 (98)
Death (cardiac) + MI (all) – % (n)	0.5 (1)	3.0 (238)
Stent Thrombosis – % (n)	0	1.0 (82)
0-30 days	0	0.8 (62)
31-365 days	0	0.3 (21)
TLR – % (n)	3.8 (8)	4.5 (349)
TVR (non-TL) – % (n)	0.9 (2)	0.7 (52)
TVR – % (n)	4.7 (10)	4.9 (387)
MACE – % (n)	4.3 (9)	7.5% (587)
TVF – % (n)	5.2 (11)	7.2 (565)

E-Five Registry

Clinical Outcomes out to 12 months



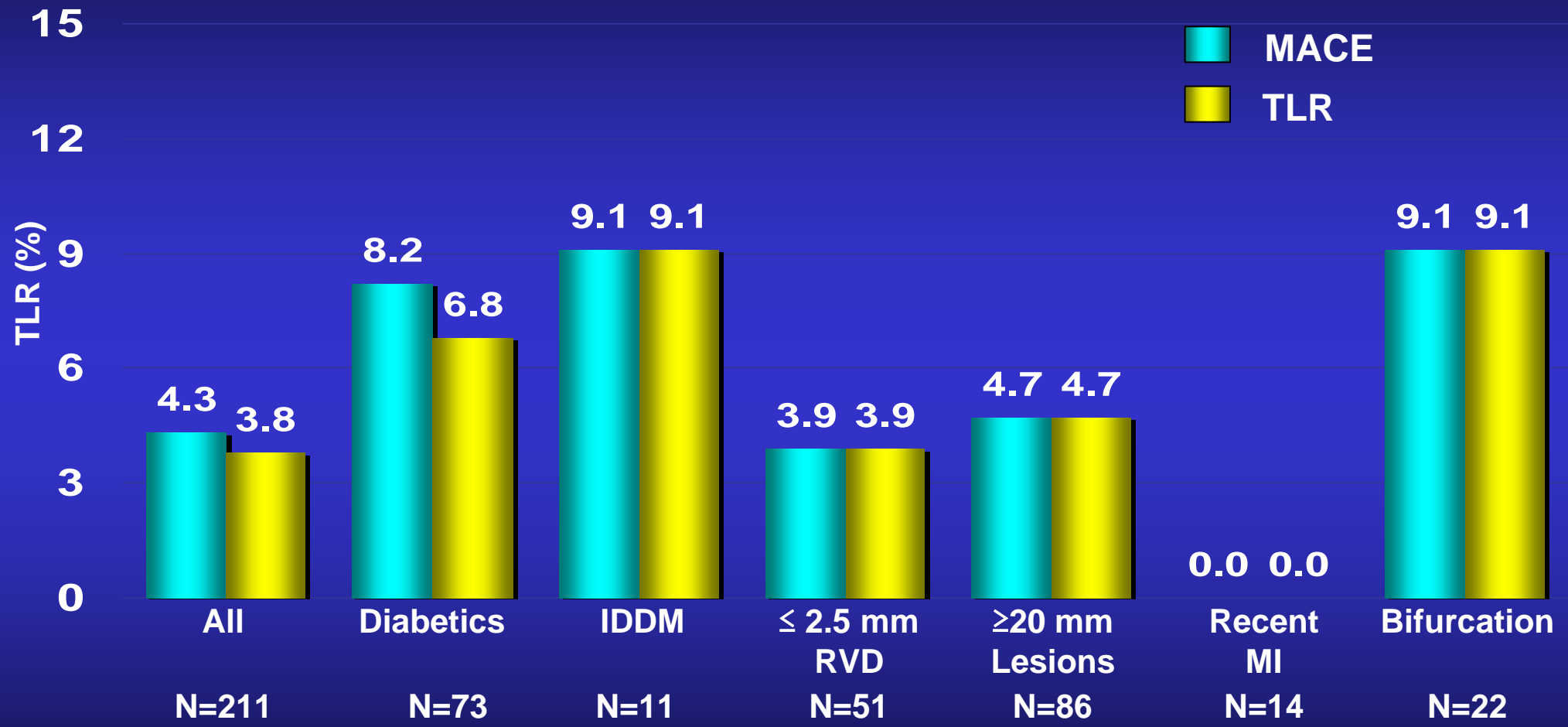
E-Five Registry

Dual Antiplatelet Therapy (DAPT) Usage

<i>Percent of patients on DAPT at:</i>	30 days	6 months	12 months
Latin American Patients	99.5%	44.9%	22.5%
All patients	97.9% (7824/7988)	85.3% (6736/7895)	61.4% (4759/7748)

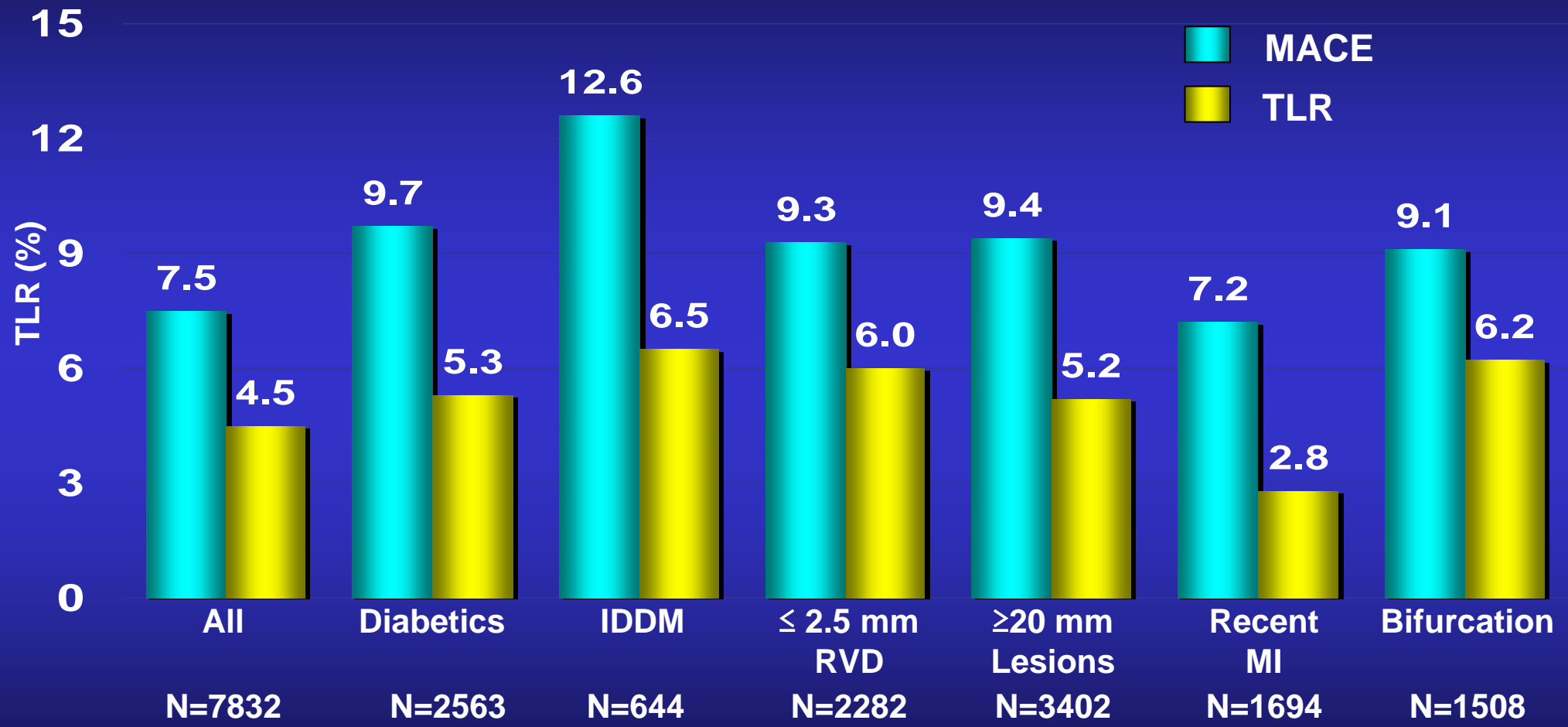
E-Five Latin America

MACE and TLR Across Subgroups at 12 Months



E-Five (Global

MACE and TLR Across Subgroups at 12 Months



E-Five Registry : *Summary*

- The clinical outcomes for patients enrolled in the E-Five Registry, **Global and Latin America** were low and consistent with the outcomes seen in the Endeavor Clinical Program
 - **MACE 7.5% and 4.3%**
 - **TLR 4.5% and 3.8%**
- These results were achieved despite almost 70% of the patients enrolled being considered complex including:
 - Diabetics
 - Recent Myocardial Infarction patients
 - Lesions ≥ 20 mm in length
- The 12 month follow up was excellent with 94.2% (n=7832) followed out to 12 months

E-Five Registry

Conclusion

- The Endeavor drug eluting stent was associated with a consistently low TLR rate regardless of lesion complexity and region of the world (Latin America and others)
- **These results were achieved in spite of low compliance with DAPT (45% at 6 months and 22% at 12 months)**
- In this complex patient and lesion cohort the cardiac death, MI and ST rates (protocol and ARC def/prob) were remarkably low and also consistent with the safety findings from the ENDEAVOR Clinical Program