

***Drug Eluting Balloon DIOR:
From Concept to Clinical Application***

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NOTHING TO DISCLOSE

Unsolved Problems and Limitations with Drug Eluting Stents

- *DIABETES*
- *IN-STENT RESTENOSIS*
- *BIFURCATIONS*
- *SMALL VESSELS*
- *ST- ELEVATION MI*
- *NON RESPONSIVENESS TO CLOPIDOGREL OR UNABLE TO LONG TERM DUAL ANTIPLATELET THERAPY*

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Table 2. Unadjusted and adjusted predictors of mortality in patients with diabetes.

Cumulative risk of death	Un-adjusted relative risk		Adjusted relative risk	
	RR	95% CI	RR	95% CI
Severity of disease				
2-vessel disease vs. one-vessel disease	1.42	1.25-1.62	1.08	0.94-1.26
3-vessel disease vs. one-vessel disease	3.00	2.64-3.40	1.55	1.32-1.82
Left main disease vs. one-vessel disease	6.50	5.38-7.86	2.18	1.75-2.72
Medication at PCI:				
Glycoprotein 2B/3A inhibitor	0.98	0.88-1.09	0.90	0.80-1.02
Aspirin before PCI	0.78	0.68-0.90	0.86	0.74-1.002
Clopidogrel before PCI	0.75	0.68-0.83	0.84	0.74-0.95
Indication of PCI:				
non-ST-elevation ACS vs. stable CAD	1.57	1.35-1.82	1.31	1.12-1.54
ST-elevation MI vs. stable CAD	2.52	2.15-2.95	2.03	1.69-2.44
Complete revascularisation	0.42	0.37-0.46	0.81	0.71-0.93
Additional stents implanted	1.06	1.003-1.11	1.10	1.03-1.16
Use of BMS vs. no stent	0.65	0.56-0.75	0.66	0.55-0.79
Use of DES vs. no stent	0.56	0.47-0.66	0.65	0.52-0.80
Use of any DES vs. only BMS	0.86	0.77-0.96	0.98	0.86-1.12

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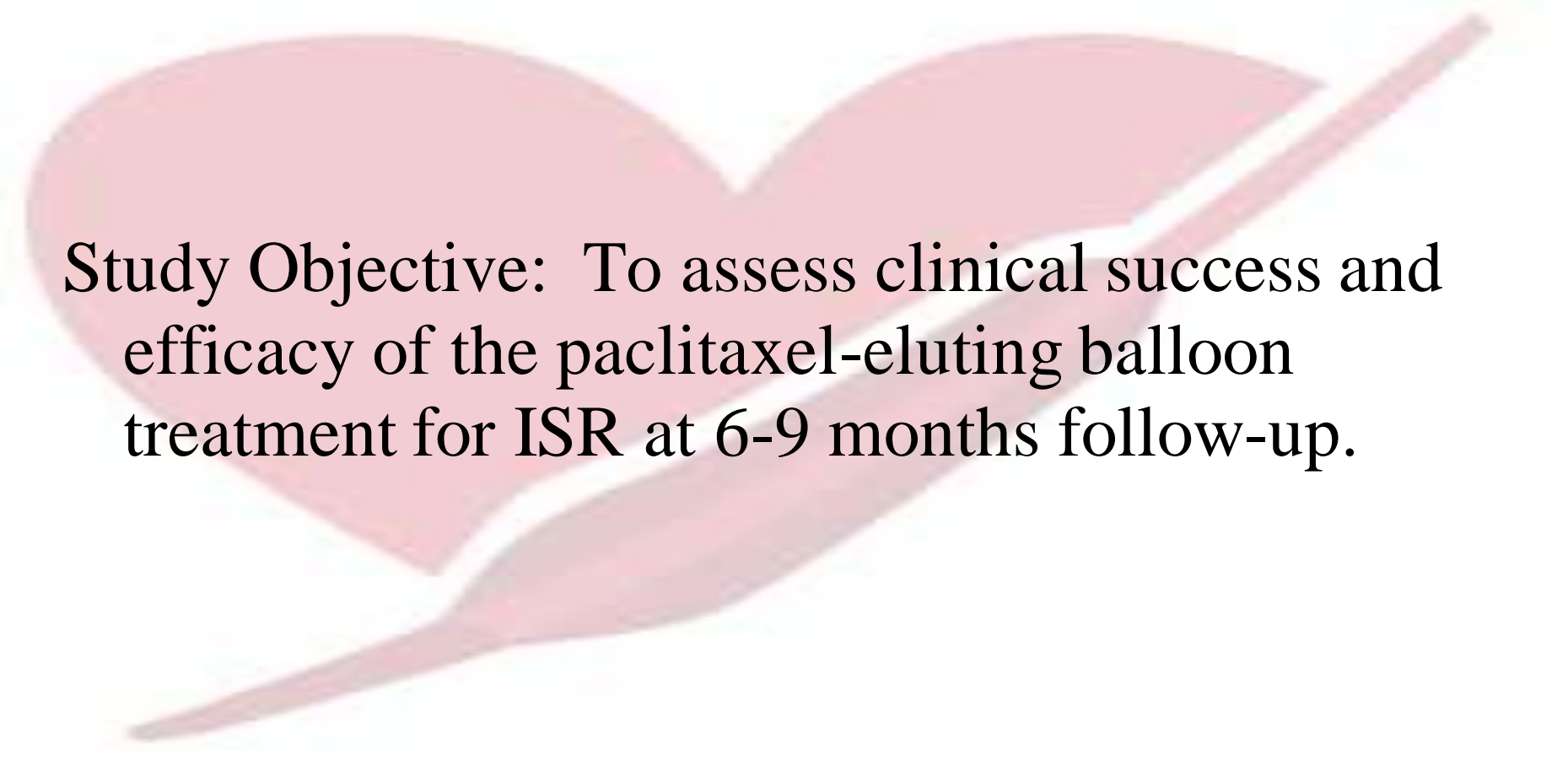
Table 2. In- and Out-of-Hospital Complications Out to 3 Years—All Patients

Nonhierarchical Complications to 1,080 Days	Vascular Brachytherapy (n = 125)	Sirolimus-Eluting Stent (n = 259)	All Patients (n = 384 Patients, n = 384 Lesions)	Difference (95% CI)	p Value
MACE (death, Q- or non-Q-wave MI, emergency CABG, TLR)	28.0% (35/125)	23.6% (61/259)	25.0% (96/384)	4.4% (−4.6% to 14.1%)	0.379
Death	2.4% (3/125)	3.9% (10/259)	3.4% (13/384)	−1.5% (−4.9% to 3.3%)	0.560
Cardiac	0.8% (1/125)	1.5% (4/259)	1.3% (5/384)	−0.7% (−3.2% to 3.0%)	1.000
Noncardiac	1.6% (2/125)	2.3% (6/259)	2.1% (8/384)	−0.7% (−3.6% to 3.5%)	1.000
MI (Q- or WHO non-Q-wave)	3.2% (4/125)	6.2% (16/259)	5.2% (20/384)	−3.0% (−7.1% to 2.3%)	0.327
All Q-wave MI	0.0% (0/125)	1.5% (4/259)	1.0% (4/384)	−1.5% (−3.9% to 1.6%)	0.309
TV Q-wave MI	0.0% (0/125)	1.5% (4/259)	1.0% (4/384)	−1.5% (−3.9% to 1.6%)	0.309
Non-TV Q-wave MI	0.0% (0/125)	0.0% (0/259)	0.0% (0/384)	0.0% (−1.5% to 3.0%)	—
All WHO non-Q-wave MI	3.2% (4/125)	4.7% (12/259)	4.2% (16/384)	−2.2% (−6.2% to 3.0%)	0.444
TV WHO non-Q-wave MI	3.2% (4/125)	3.1% (8/259)	3.2% (12/384)	−1.8% (−5.7% to 3.3%)	0.598
Non-TV WHO non-Q-wave MI	0.0% (0/125)	1.6% (4/259)	1.0% (4/384)	−0.4% (−2.2% to 2.6%)	1.000
All TV MI (Q- or WHO non-Q-wave MI)	3.2% (4/125)	3.1% (8/259)	4.2% (16/384)	−2.6% (−6.6% to 2.7%)	0.325
All non-TV MI (Q or WHO non-Q-wave MI)	0.0% (0/125)	0.4% (1/259)	0.3% (1/384)	−0.4% (−2.2% to 2.6%)	1.000

**ARC ST:
2.4% with VBT
4.2% with SES**

Protocol Review

Valentines Trial



Study Objective: To assess clinical success and efficacy of the paclitaxel-eluting balloon treatment for ISR at 6-9 months follow-up.

Protocol Review

Valentines Trial

Study Methodology:

Multi-center, international, short-term registry

300 patients recruited at up to 100 centers

Enrollment from 14Feb2010 – 23Feb2010

Elective PCI for treatment of ISR in native vessel

Patients treated with DEB, with or without adjunctive angioplasty

Followed for 12 months

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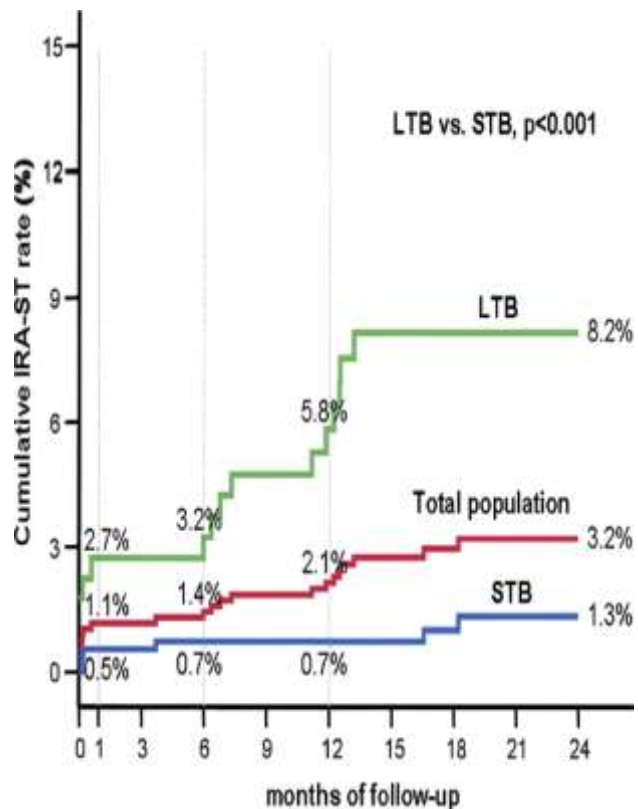
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- 1.- DEBIUT Randomized Bifurcation Study: P. Stella
- 2.- Spanish SMALL Vessels Study: A.Serra
- 3.- DIOR STEMI Randomized Study: P.Stella

DES Myths and Realities

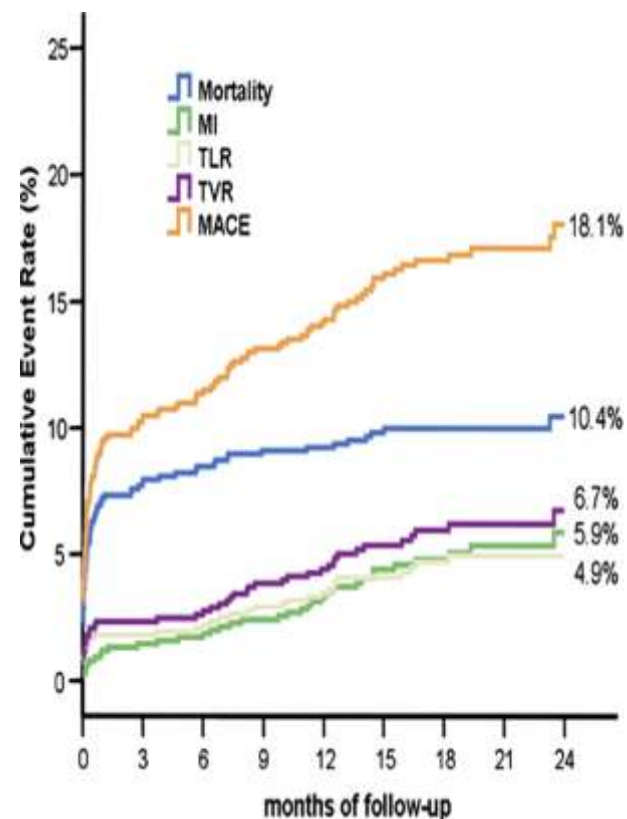
Infarct-Related Artery Stent Thrombosis



Sianos, G. et al. J Am Coll Cardiol 2007;50:573-583



Overall Clinical Outcomes



Sianos, G. et al. J Am Coll Cardiol 2007;50:573-583



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Six- month FU	Overall n=804	Resp. n=699	Non- Resp. n=105	p value
❖ Cardiac death	19 (2.4)	10 (1.4)	9 (8.6)	<0.001
❖ Cardiac death and stent thrombosis	28 (3.5)	19 (2.7)	11 (10.5)	<0.001
❖ Pts with ST-elevation AMI	n=217	n=199	n=18	
❖ Stent thrombosis	11 (5.1)	7 (3.5)	4 (22)	< 0.001