



e-HEALING Registry

Post Marketing Registry of the
Genous Bio-engineered R stent

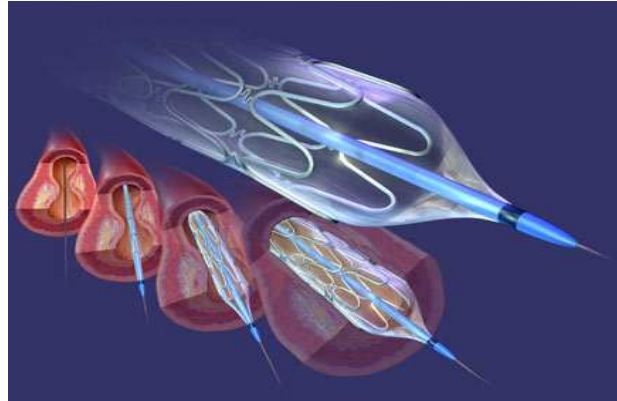
Final Results of the 1-Year Follow-Up

Kui-Hian Sim, R.J. de Winter, P. Damman, S. Silber, M. Grisold,
E.E. Ribeiro, H. Suryapranata, J. Wojcik
and all e-HEALING investigators

- **Research & Advisory Board** with AstraZenica, Bayer, B Braun, Boehringer Ingelheim, Boston Scientific Corporation, Bristol Myer Squibbs, Biosensor, Eli Lilly, GSK, GE Healthcare, JNJ Cordis , JNJ Janssen-Cilag, MSD, Medtronic, Novartis, OrbusNeich, Pfizer, Philips Medical, Roche Medical, Roche Diagnostic, Sanofi Aventis, Schering-Plough, Siemens, Servier, Terumo

Concept of the EPC-capturing Stent

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Stent placement in percutaneous coronary angioplasty causes tissue injury due to **plaque and endothelial disruption**



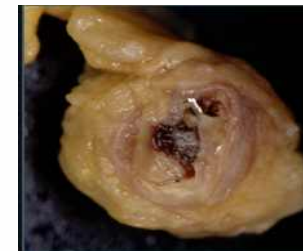
Smooth muscle cell proliferation



Instant Restenosis



Thrombus formation

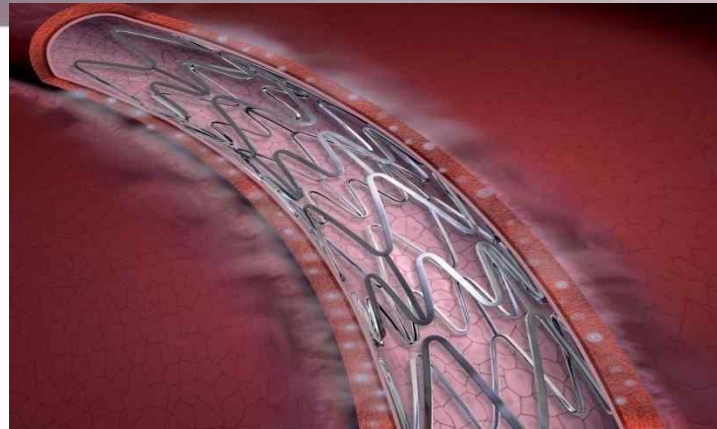


Stent thrombosis



Concept of the EPC-capturing Stent

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Drug eluting stent delivers anti-proliferative medication



inhibits

Smooth muscle cell proliferation

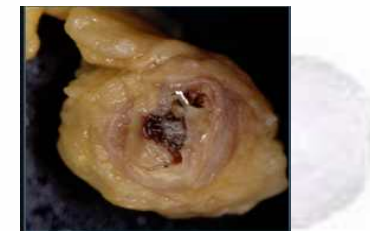


Instent Restenosis



delays endothelial healing

Thrombus formation



Stent thrombosis

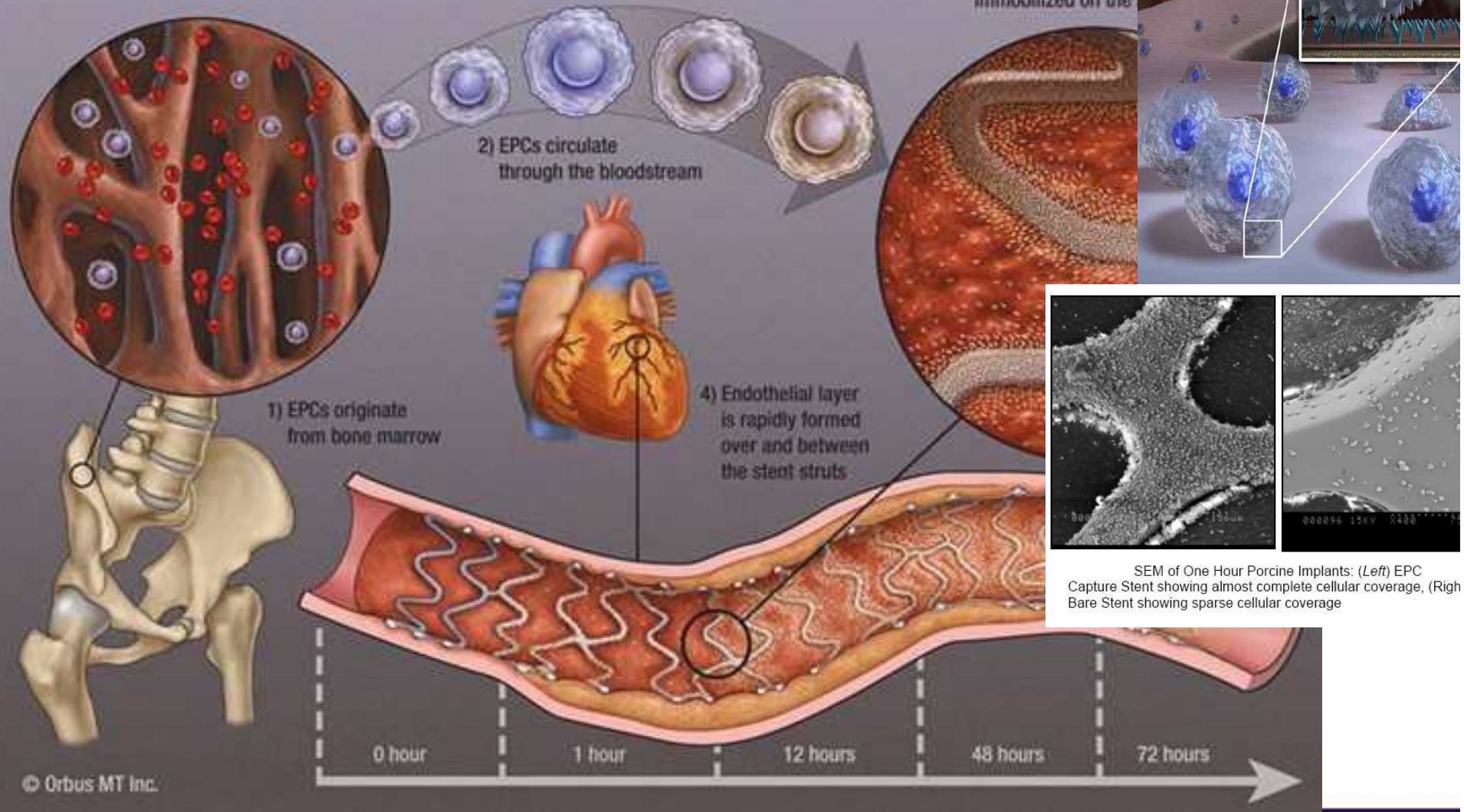
- Longer duration of dual antiplatelet therapy
- Bleeding complications and cost



Concept of the EPC-capturing Stent

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GENOUS: the Role of Endothelial Progenitor Cells (EPCs)



Overview

- Principal Investigators: R.J. de Winter, S. Silber
- Multi-center (144 sites), worldwide, prospective registry of patients treated with a Genous Bio-engineered R stent in accordance with the Instructions for Use
- Patients with de novo lesions in native coronary arteries
- Recommendation of at least two weeks statin treatment prior to the procedure and one month clopidogrel post-procedure
- Follow-up: 1, 6, and 12 month clinical follow-up
- Primary outcome: Target Vessel Failure at 12 months

Registry Management

- On site electronic data capture via the internet with built in consistency checks (KIKA)
- Comprehensive data management / monitoring plan (Cardialysis)
- Independent adjudication of site reported MACE and stent thrombosis (Drs. Bassand, Herrman, Philipp, Radke, Ronner, Tilsted)
- Independent global steering committee (Drs. Silber, de Winter, Grisold, Ribeiro, Suryapranata, Wojcik, Sim)

Status – 4939 patients received ≥ 1 Genous stent between October 2005 and November 2007

Objectives

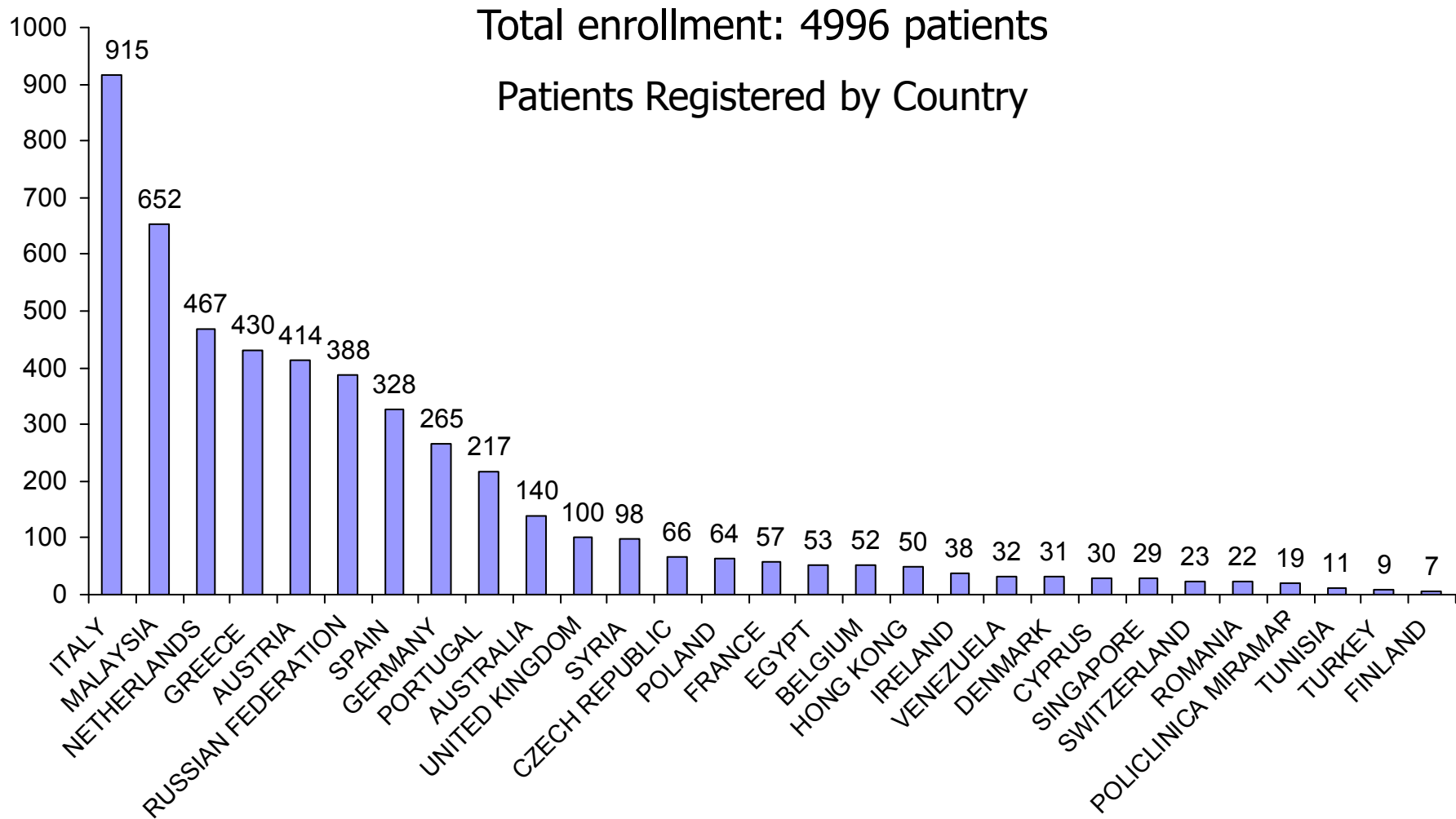
- Collect post marketing data on patients:
 - receiving at least one Genous Bio-engineered R stent
 - "On Label" indication (according to the Instructions for Use)
 - receiving at least two weeks of statin therapy at the time of stenting and with recommended one month of DAPT post stenting
- Assess clinical outcomes and safety of these patients out to 12 months post-procedure
- Identify any potential unanticipated adverse device-related effects that may not have been noted prior to market approval
- Collect data on procedural practices and demographic characteristics and determine how these variables affect clinical outcomes



144 SITES

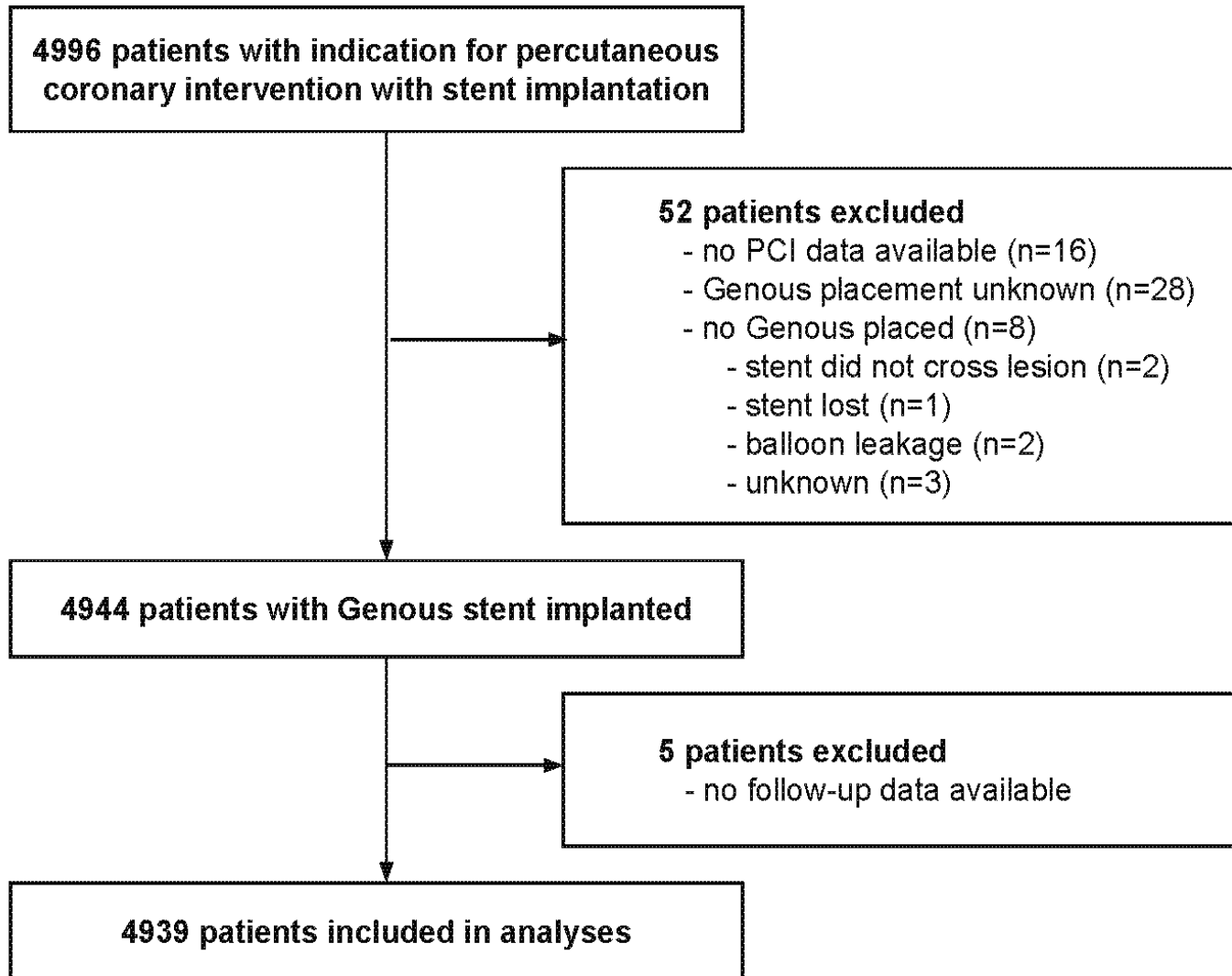


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e-HEALING - Method

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Patient Demographics

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Age	63 years
Males	78.9%
Diabetics	25.0%
Hypertension	68.4%
Hypercholesterolemia	74.5%
Current Smokers	24.9%
Family History of MI	28.1%
Previous MI	36.8%
Previous PCI	19.2%
Previous CABG	6.2%
Previous Stroke	6.0%



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Ischemic Status at screening

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Unstable angina	42.3%
Stable angina	43.3%
Silent ischemia	14.4%



e-HEALING Indications for PCI

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Non STEMI (ongoing instability)	5.9%
Unstable angina (ongoing instability)	20.1%
Post STEMI (stabilized)	8.1%
Post Non STEMI (stabilized)	5.2%
Post unstable angina (stabilized)	6.1%
Elective PCI (stable angina &/or documented ischemia)	46.4%
Others/Unknown	8.4%

e-HEALING Lesion Characteristics

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De novo	97.7%
Restenotic	2.3%

Lesion Classification	
Type A	15.3%
Type B1	35.4%
Type B2	29.8%
Type C	19.5%

Lesion Length (mm)	
Mean ± Std Dev	16.5 ± 8.6

Reference Vessel (mm)	
Mean ± Std Dev	3.0 ± 0.4

u1

Number of stents/patient	1.3
Number of lesions/patient	1.3



Slide 15

u1

6433 Genous stent placed/4939 patients
ursula, 2010-04-15

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Individual Outcomes at 12 Months, KM estimates

N=4939	
Cardiac Death	1.7 %
MI	1.9 %
Q-wave	0.4 %
Non Q-wave	1.6 %
TLR (Clinically Driven)	5.7 %
PCI	5.2 %
CABG	0.6 %
Main composite outcome (TVF)*	8.4%
Composite cardiac death, MI, TLR	7.9 %
Acute stent thrombosis**	0.2 %
Sub-acute stent thrombosis**	0.7 %
Late stent thrombosis**	0.2 %

All events adjudicated by CEC

*TVF: composite of death or MI attributable to target vessel, or TVR

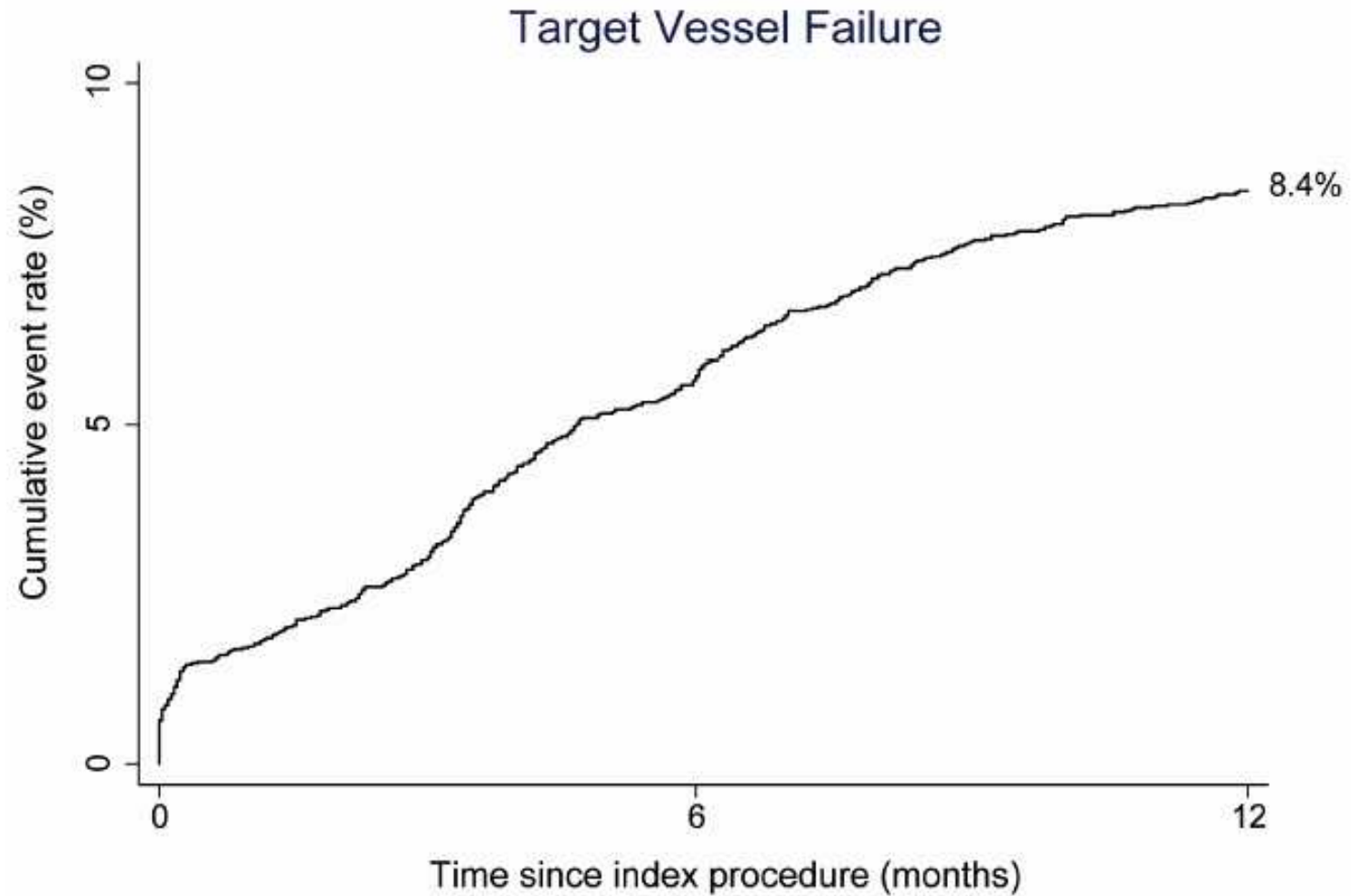
** : ARC, definite or probable



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12 Months composite Outcome

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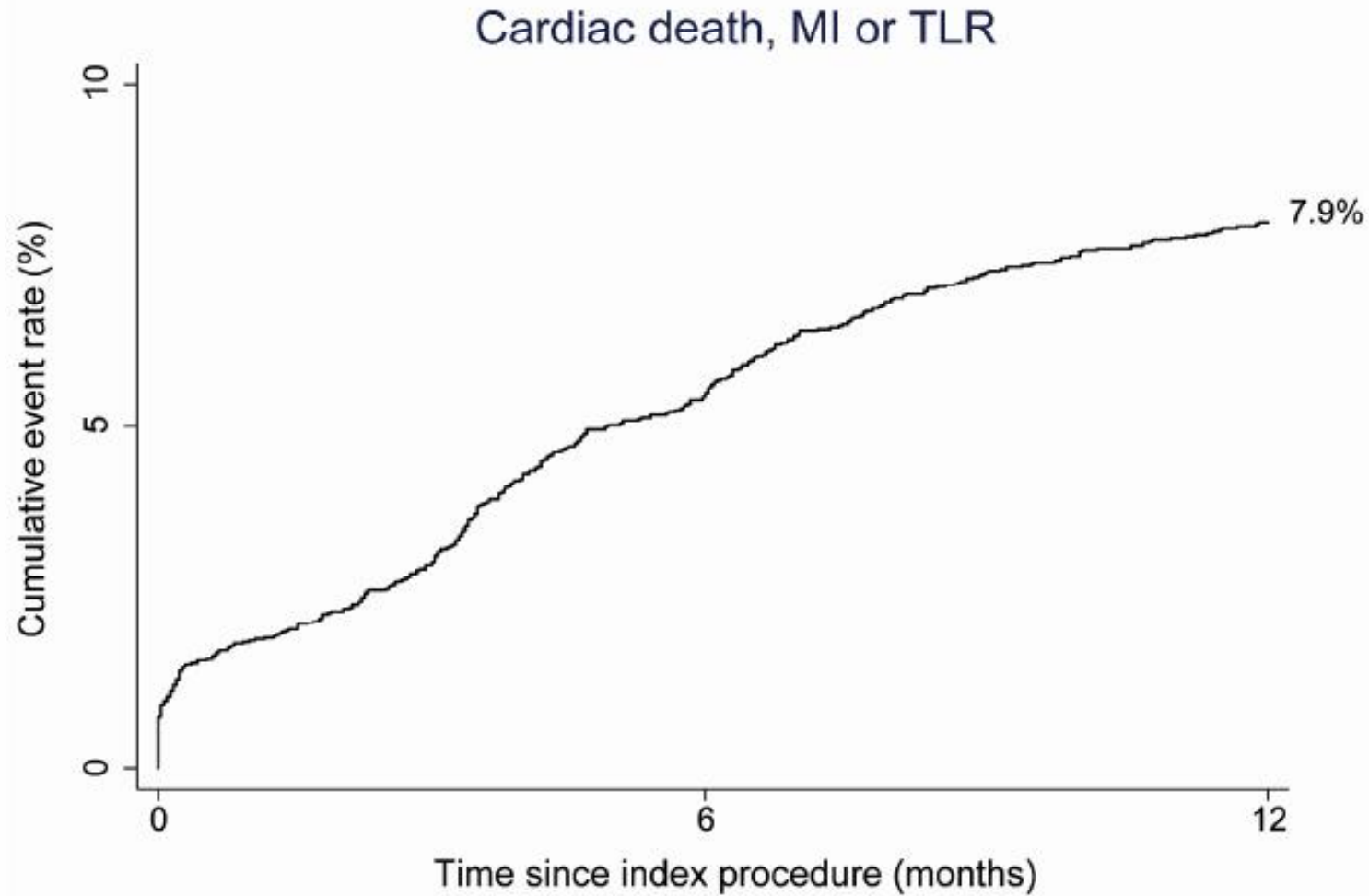


All events adjudicated by CEC

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12 Months composite Outcome

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All events adjudicated by CEC

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Clinical Events in Diabetes at 12 Months (n= 1243)

	30 days	6 months	12 months
Cardiac Death	0.8 %	2.0 %	2.9 %
MI	0.8 %	1.4 %	1.4 %
Q-wave	0.2 %	0.2 %	0.2 %
Non Q-wave	0.6 %	1.2 %	1.2 %
TLR (Clinically Driven)	0.2 %	3.1 %	4.6 %
PCI	0.2 %	2.7 %	4.1 %
CABG	0.0 %	0.4 %	0.5 %
Primary outcome	1.8 %	6.5 %	8.9 %

Acute stent thrombosis	0.2 %
Sub-acute stent thrombosis	0.2 %
Late stent thrombosis	0.7 %

All events adjudicated by CEC

Worst MACE per patient = cardiac death, MI, CABG, and clinically driven TLR



Comparison of GENOUS EPC Capture Stent with DES (E-Healing Registry)



	Genous (E-Healing)	Cypher (LEADERS)	Taxus (SYNTAX)
Inclusion Criteria	All comers	All comers	All comers
Number of Patients	4939	850	903
Follow up Duration	12 months	9 months	12 months
Cardiac Death	1.7%	2.5%	4.3%
MI	1.9%	4.6%	4.8%
Clinical Driven TLR	5.7%	4.9%	13.7%
MACE	7.9%	10.5%	17.2%
Stent Thrombosis	1.1%	2.2%	3.4%
Dual Antiplatelet Therapy	4 weeks	12 months	12 months



e-HEALING 12 months outcome

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Study strengths:

- Registry
 - All comers
 - Multicenter, international, prospective
 - Electronic robust data capture
 - No angiographic follow up
 - Event adjudication

Study limitations:

- Registry
 - Randomized studies are ongoing



e-HEALING Conclusion

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Coronary stenting with the Genous stent results in:

- Excellent clinical outcomes
 - composite primary endpoint 7.7% in a worldwide, all comers population.
- Low incidence of repeat revascularization
 - The TLR rate in diabetics was similar to the overall e-HEALING population and the 1.2% increase in the primary endpoint was driven by the increase in mortality.
- Low incidence of stent thrombosis
 - 1.2% stent thrombosis rate at 12 months (1 month recommendation of DAPT).
- the e-HEALING Registry demonstrate that the Genous Bio-engineered R stent is safe and effective.

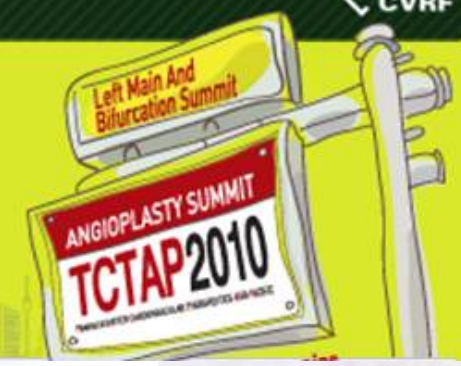


15TH April 28-30, 2010, Seoul, Korea
The Convention Center,
Sheraton Grande Walkerhill Hotel



ANGIOPLASTY SUMMIT
TCTAP 2010
LEFT MAIN & BIFURCATION SUMMIT

*“Celebrating 15 Years of
Evolution to Revolution...”*



♥ Ta & G'day