Disclosures for W Wijns, MD, PhD

- Consulting Fees: on my behalf go to the Cardiovascular Research Center Aalst
- Contracted Research between the Cardiovascular Research Center Aalst and several pharmaceutical and device companies
- Ownership Interest: Cardiovascular Research Center Aalst is co-founder of Cardio³BioSciences (cell-based regeneration cardiovascular therapies)
- Chairman of PCR /EuroPCR, the annual Course of EAPCI

Publication On-line

THE LANCET

Stent thrombosis and major clinical events at 3 years after zotarolimus-eluting or sirolimus-eluting coronary stent implantation: a randomised multicentre open-label controlled trial

Edoardo Camenzind, William Wijns, Laura Mauri, Volkhard Kurowski, Keyur Parikh, Runlin Gao, Christoph Bode, John P Greenwood, Eric Boersma, Pascal Vranckx, Eugene McFadden, Patrick W Serruys, William W O'Neil, Brenda Jorissen, Frank Van Leeuwen, Ph Gabriel Steg*, for the PROTECT Steering Committee and Investigators†*

Study Design
Largest RCT & First Trial Powered for Comparing ST with DES
Initialization Committee: E. Camenzind, G. Steg and W. Wijns

Real-world patients
Single and multiple coronary artery lesions. No limitations on number of lesions/vessels

Endeavor ZES
n = 4400

N = 8800
1:1 Randomization
196 sites world wide
in 5 continents

Cypher SES
n = 4400

Clinical endpoints

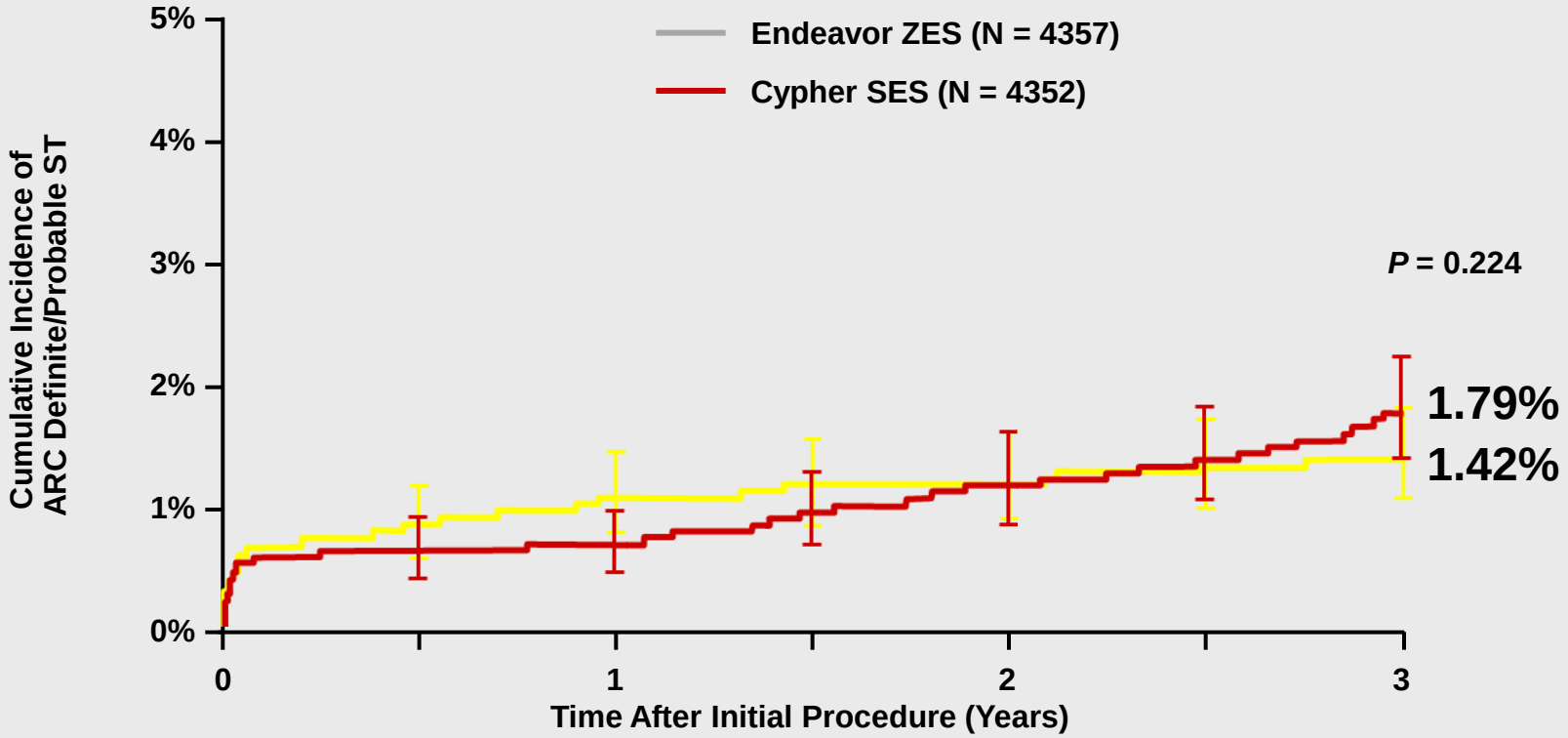
30d | 6mo | 12mo | 18mo | 24mo | 30mo | **3yr** | 4yr | 5yr

<u>Primary Endpoint:</u> Composite of ARC Definite / Probable Stent Thrombosis at 3yrs
<u>Principle Secondary Endpoints:</u>

- **Total Death/Large MI**
- **Total Death/Non-Fatal MI**
- **Cardiac Death/Large MI**
- **Cardiac Death/Non-Fatal MI at 3 yrs**

Camenzind E, et al. *Am Heart J*. 2009;158:902-9

Primary Endpoint
Definite/Probable Stent Thrombosis to 3 Yrs



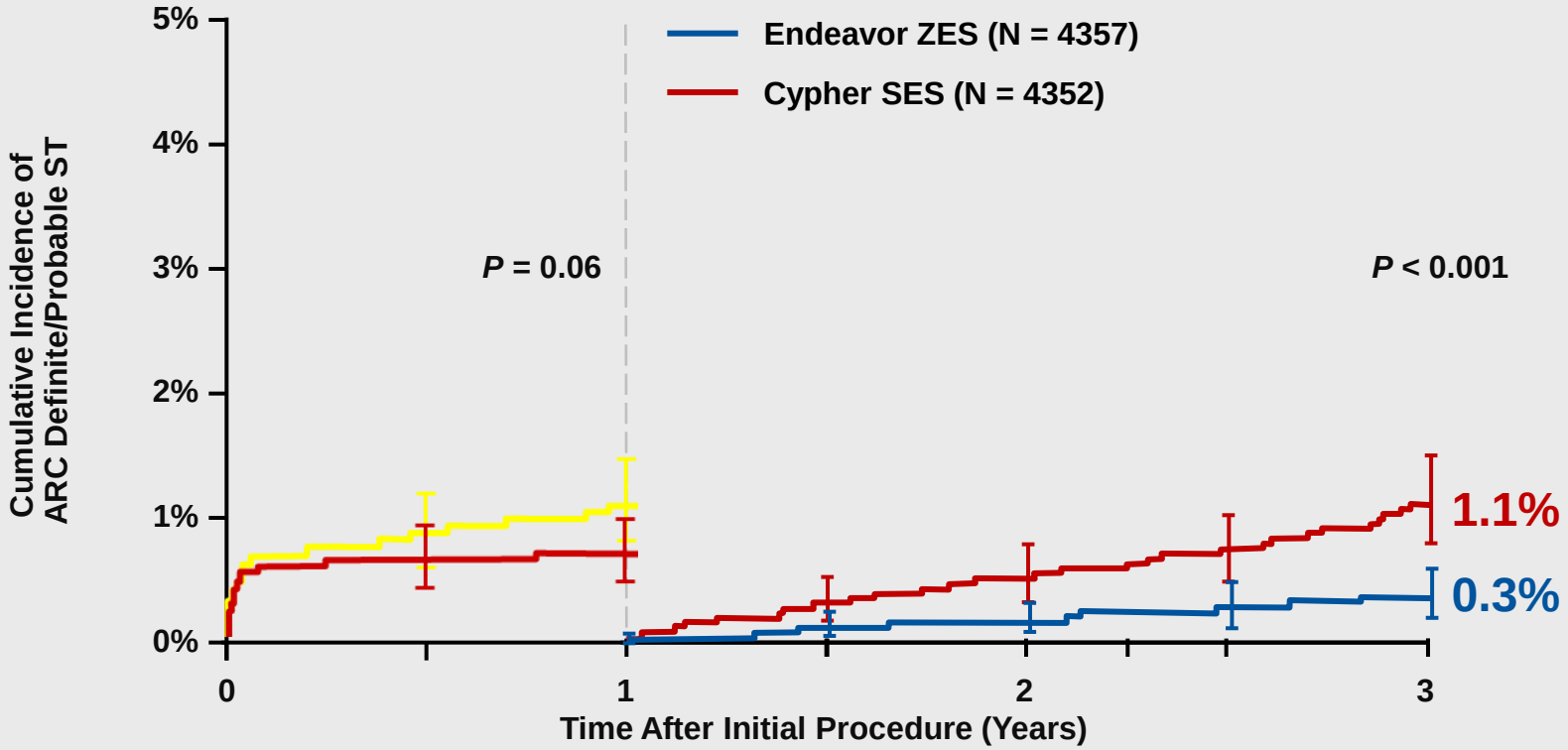
Patients at Risk				
E-ZES	4357	4347	4222	4119
SES	4352	4344	4211	4100

Other Endpoints at 3 Years

%	Endeavor ZES N = 4357	Cypher SES N = 4352	P-value
Total death and large non-fatal MI	5.3	6.0	0.16
Total death and non-fatal MI	7.7	8.4	0.25
Cardiac death and large non-fatal MI	3.7	4.1	0.33
Cardiac death and non-fatal MI	6.2	6.6	0.45
Stroke	1.5	1.4	0.81
Bleeding (TIMI major/ minor/ minimal)	4.7	4.4	0.38
Major	1.8	1.6	0.51
TLR	5.6	3.5	<0.0001
TVR	8.2	7.1	0.03
MACE (death, MI, TLR, emergent CABG)	12.3	10.8	0.02
MACCE (death, MI, TLR, eCABG, Stroke)	13.5	11.8	0.02

All values based on Kaplan-Meier estimates

Definite/Probable Stent Thrombosis Before and After 1 Year



Patients at Risk				
E-ZES	4357	4347	4222	4119
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Conclusions

- PROTECT trial is the largest prospective randomized head to head DES trial ever presented and demonstrates that:
  - There is no difference in definite or probable ST rates at 3 years between Endeavor ZES and Cypher SES
  - Other clinical safety and efficacy endpoints are also low and sustained out to 3 years
- Time analysis suggests that a difference in ST between groups is emerging over time, emphasizing the importance of continued follow-up
- Large pragmatic trials such as PROTECT are essential to determine differential outcomes between DES and to capture the impact of improved procedural and clinical practice on ST rates over time