

Biodegradable polymer SES vs permanent polymer EES in patients with coronary artery disease

5-year outcomes from ISAR-TEST 4

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Potential conflicts of interest

Speaker's name: Robert A. Byrne MB BCh PhD FESC

☒ **I have the following potential conflicts of interest to report:**

Consultant:

Employment in industry:

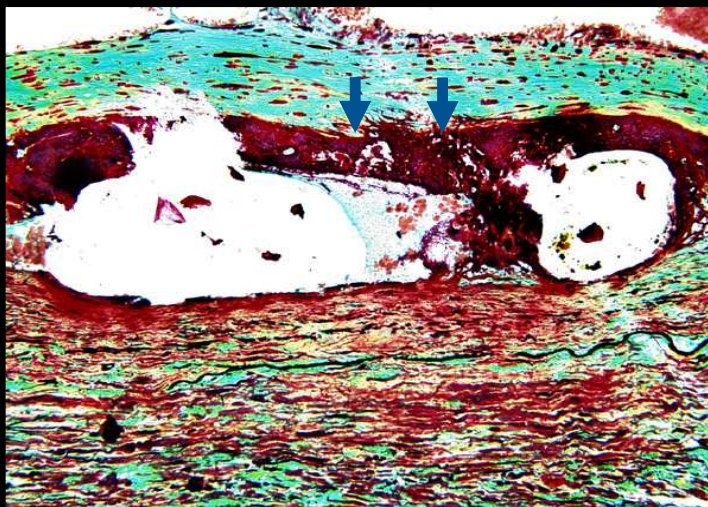
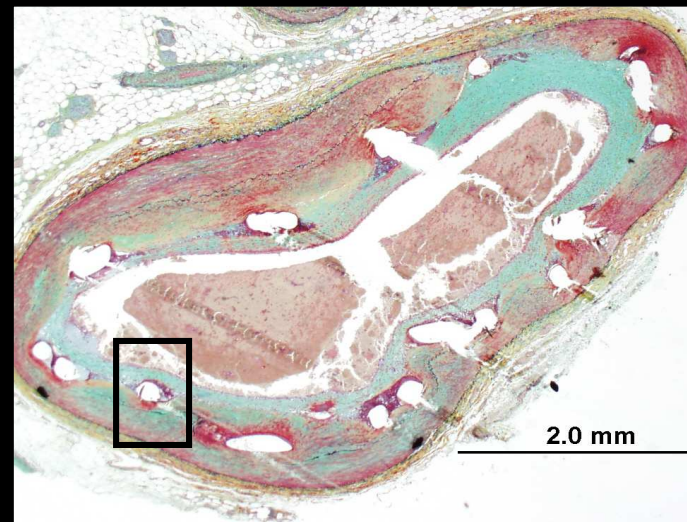
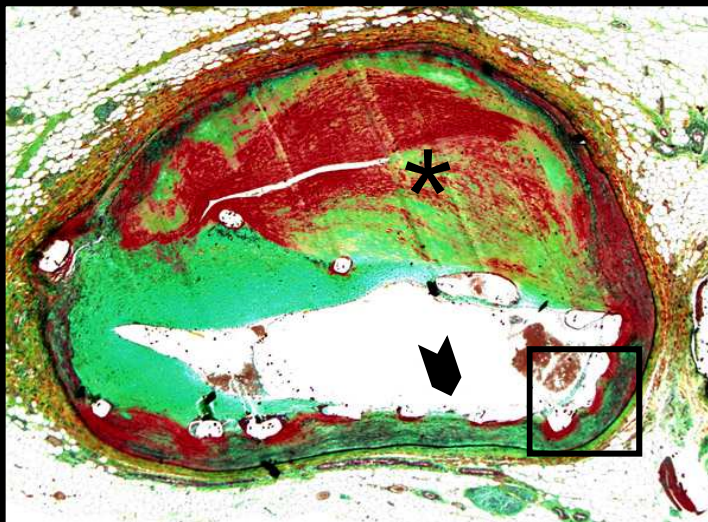
Honorarium: B. Braun, Biotronik

Institutional grant/research support:

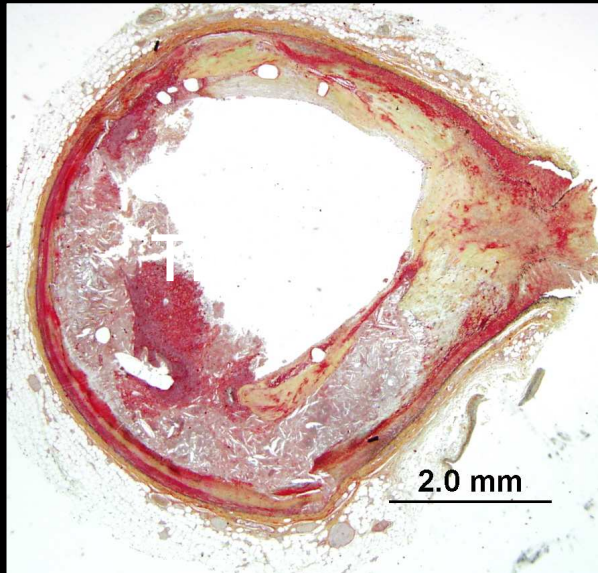
Owner of a healthcare company:

Stockholder of a healthcare company:

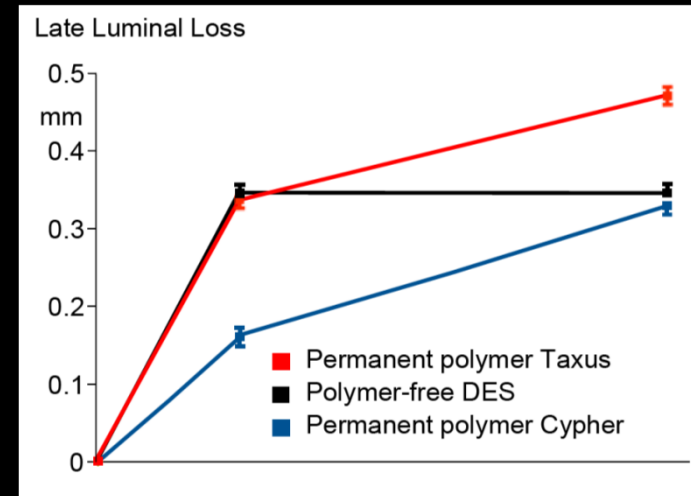
Delayed Arterial Healing After DES



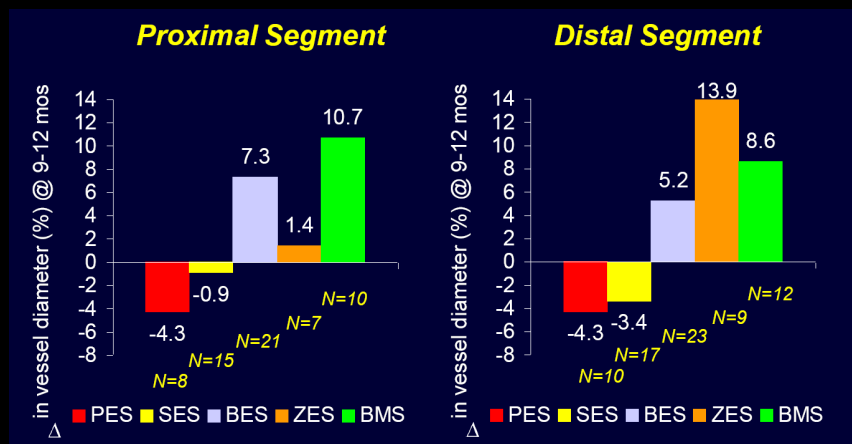
Delayed Arterial Healing Spectrum



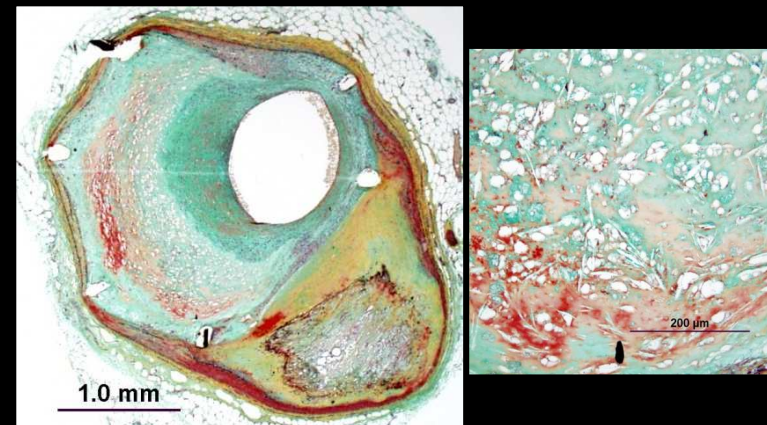
Late Stent Thrombosis



Late Luminal Creep

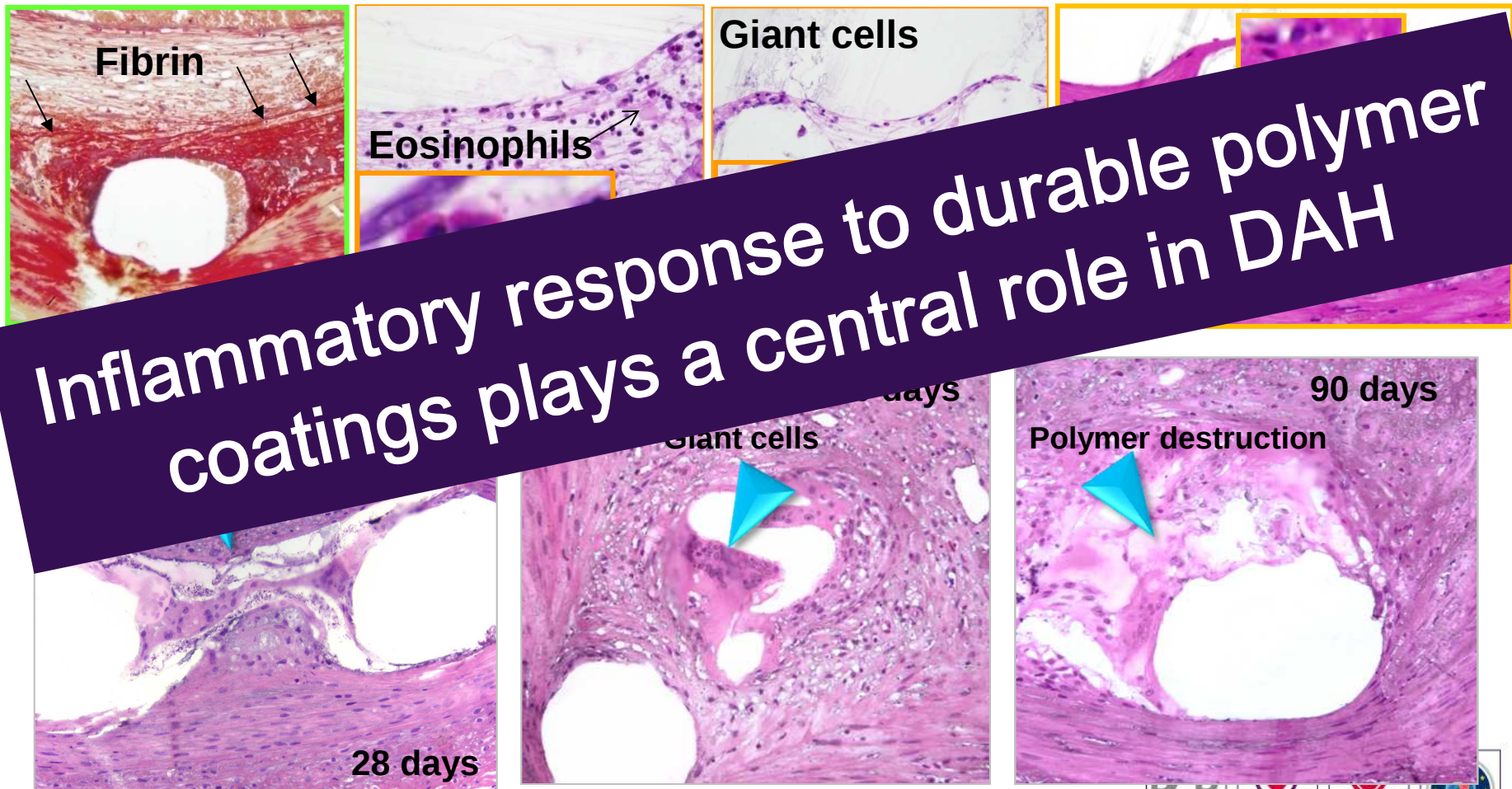


Vasomotor Dysfunction



De novo In-stent Atherosclerosis

Durable Polymer Associated Inflammation

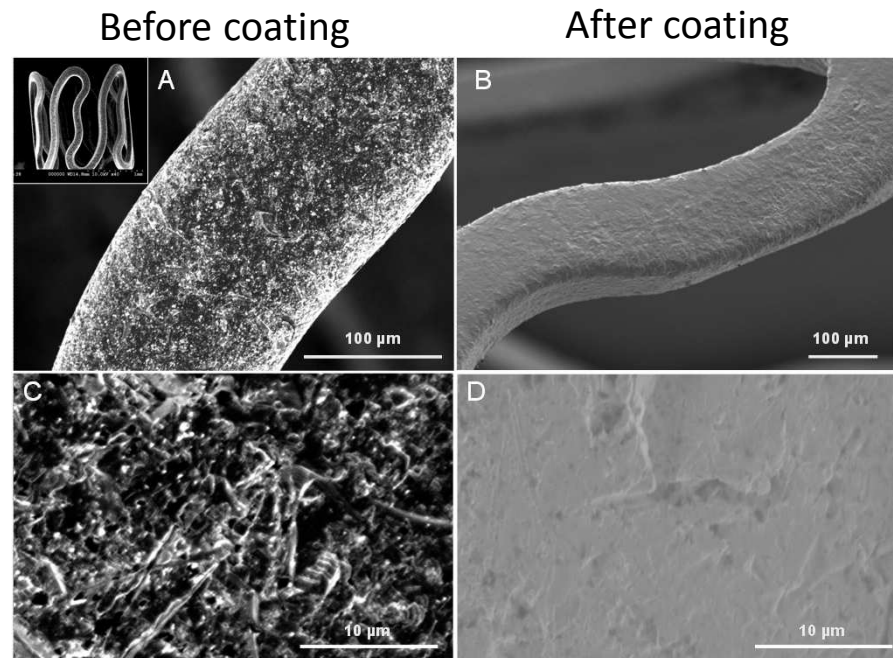


ISAR-TEST Stent Programme

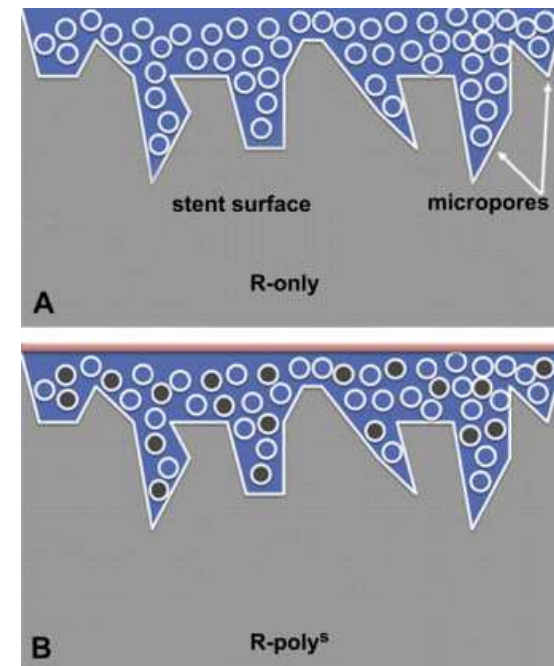
Aim: to develop a high efficacy, high performance workhorse DES without resort to durable polymer coatings

Yukon Choice PC

A combination of microporous stent surface, reduced quantity of PDLLA biodegradable polymer and sirolimus



Wessely et al, ATVB 2005



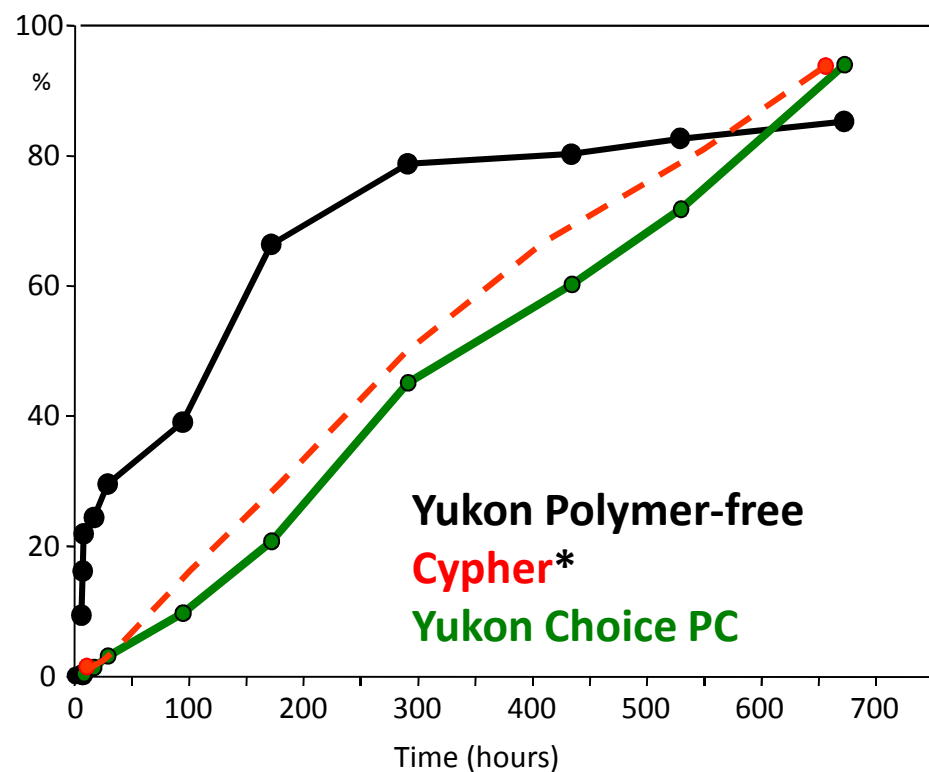
Steigerwald et al, Biomaterials 2009

- Micropores act like drug reservoirs that use Van-der-Waals forces to control the release-kinetics of the drug
- The microporous surface enables a minimum load of PDLLA biodegradable polymer (<1/4th of the polymer load in other DES) which is degraded in 60 days



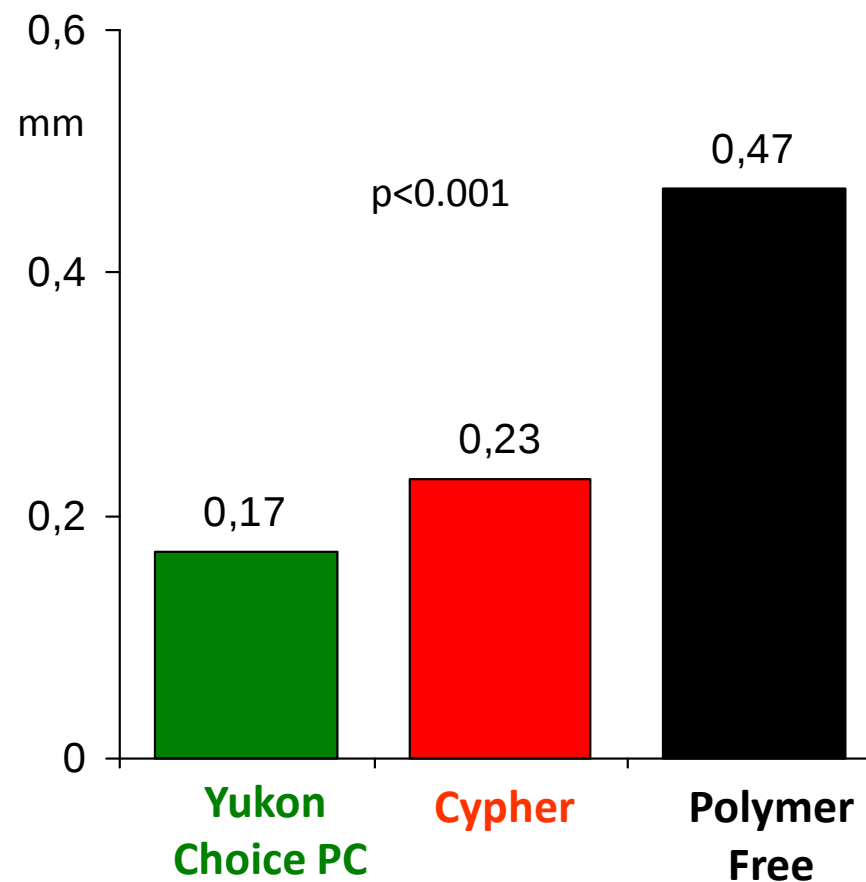
Release Kinetics and Antirestenotic Efficacy ISAR-TEST 3

(A) Drug release kinetics



*approximated

(B) Late luminal loss at 6-8 months



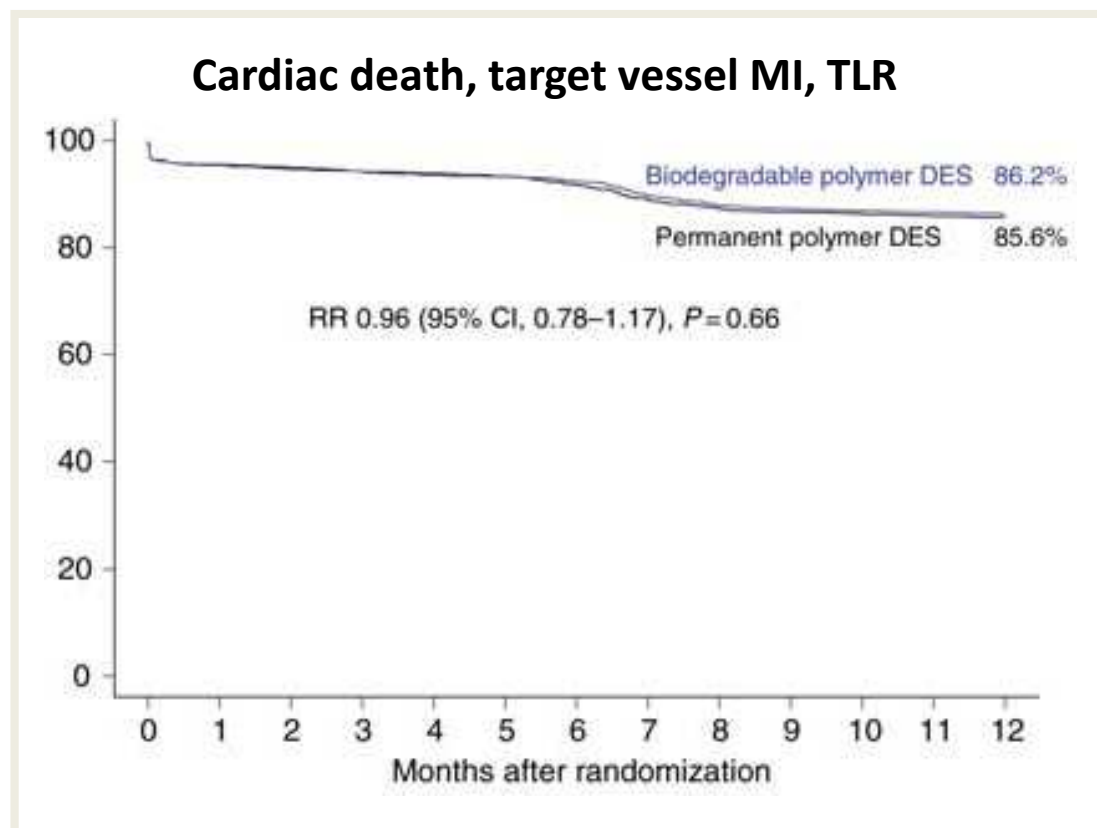
Mehilli et al. EHJ 2008; Byrne et al. Heart 2009

ISAR-TEST 4

2603 pts

Yukon Choice PC
(BP Sirolimus)

Cypher or Xience
(PP Siro-/everolimus)

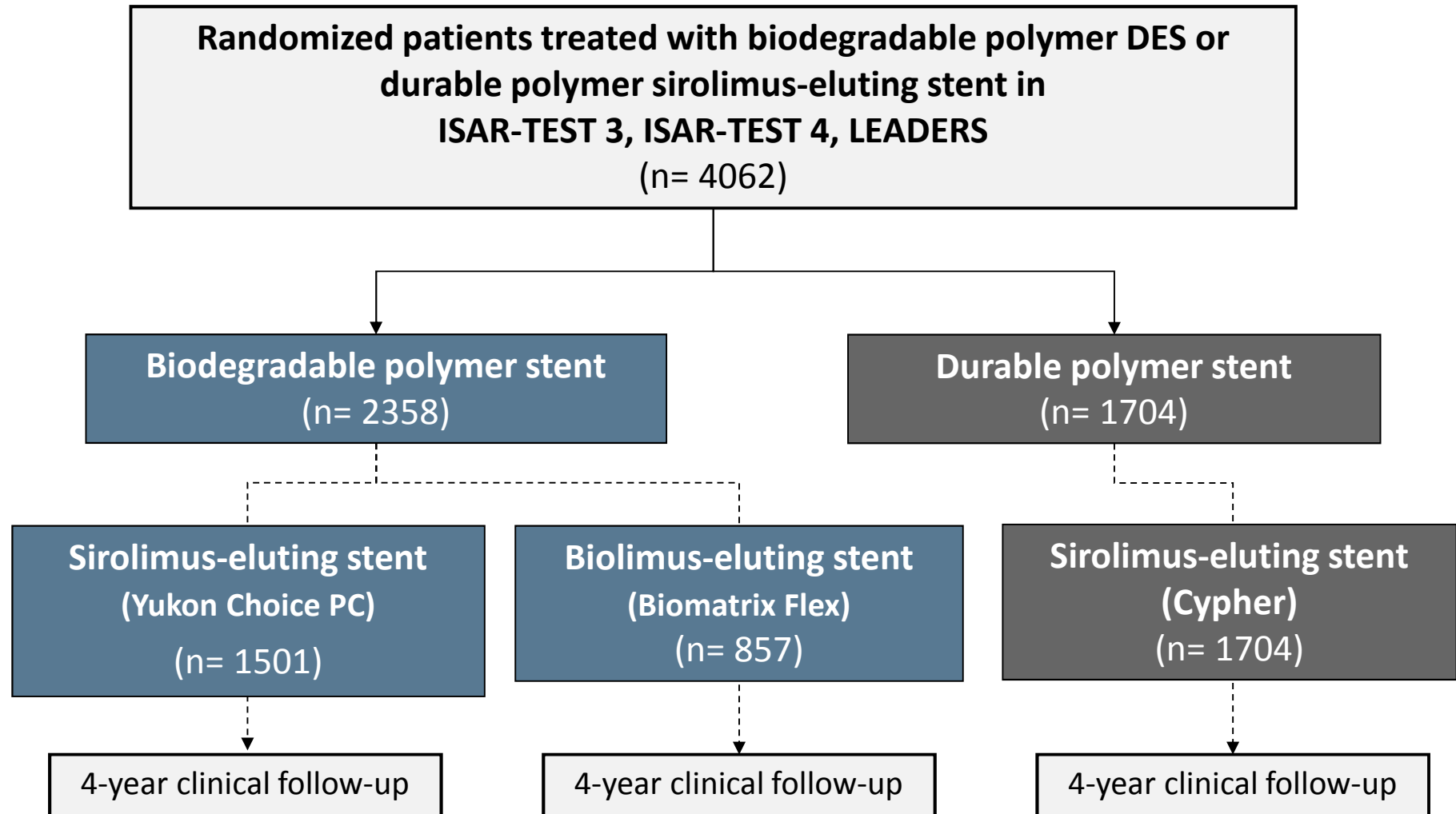


Byrne et al., EHJ 2009

But...

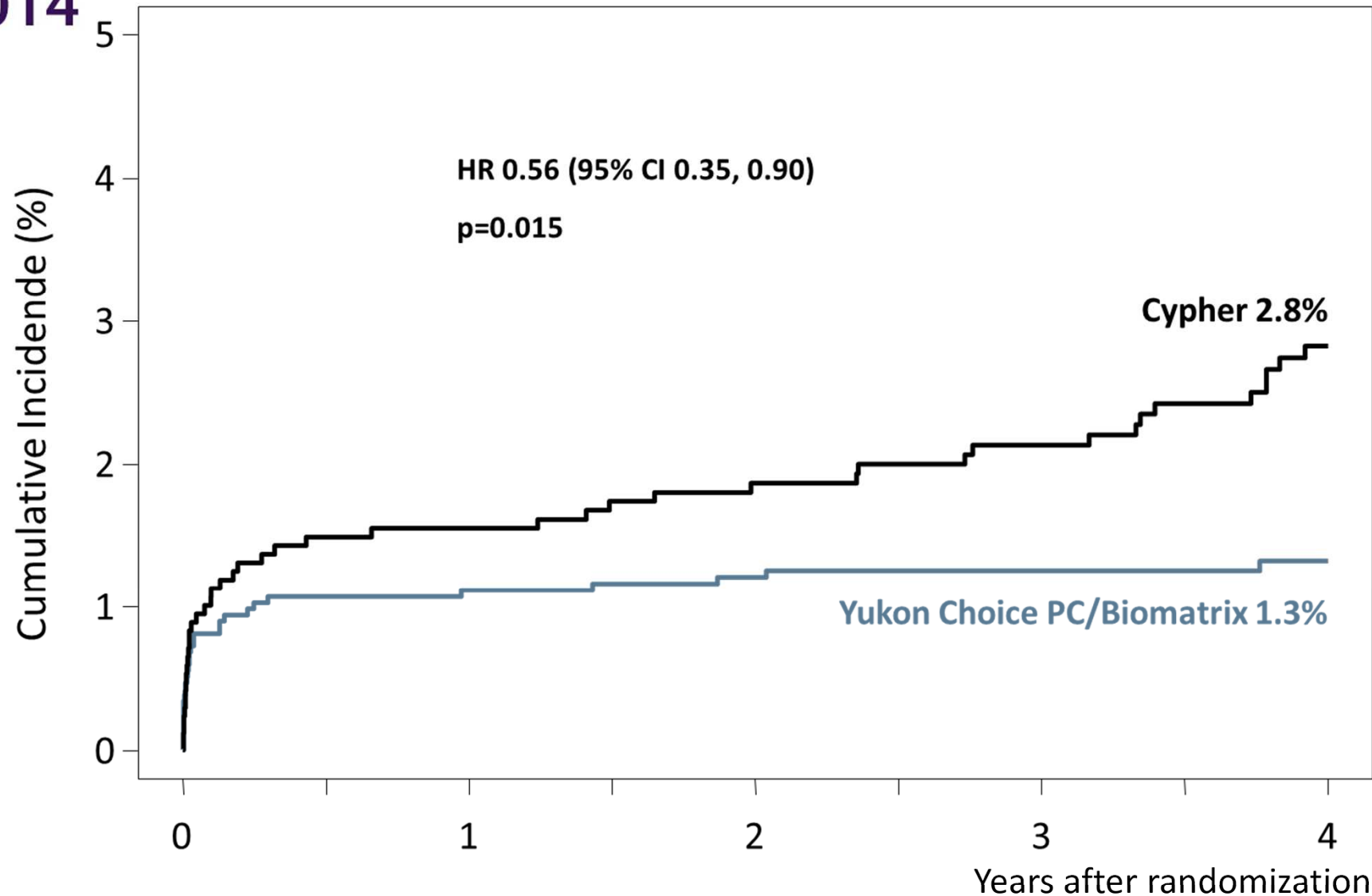
**...the hypothesized clinical
advantage of BP-DES is expected
to accrue with time**

ACC Featured Clinical Study 2012



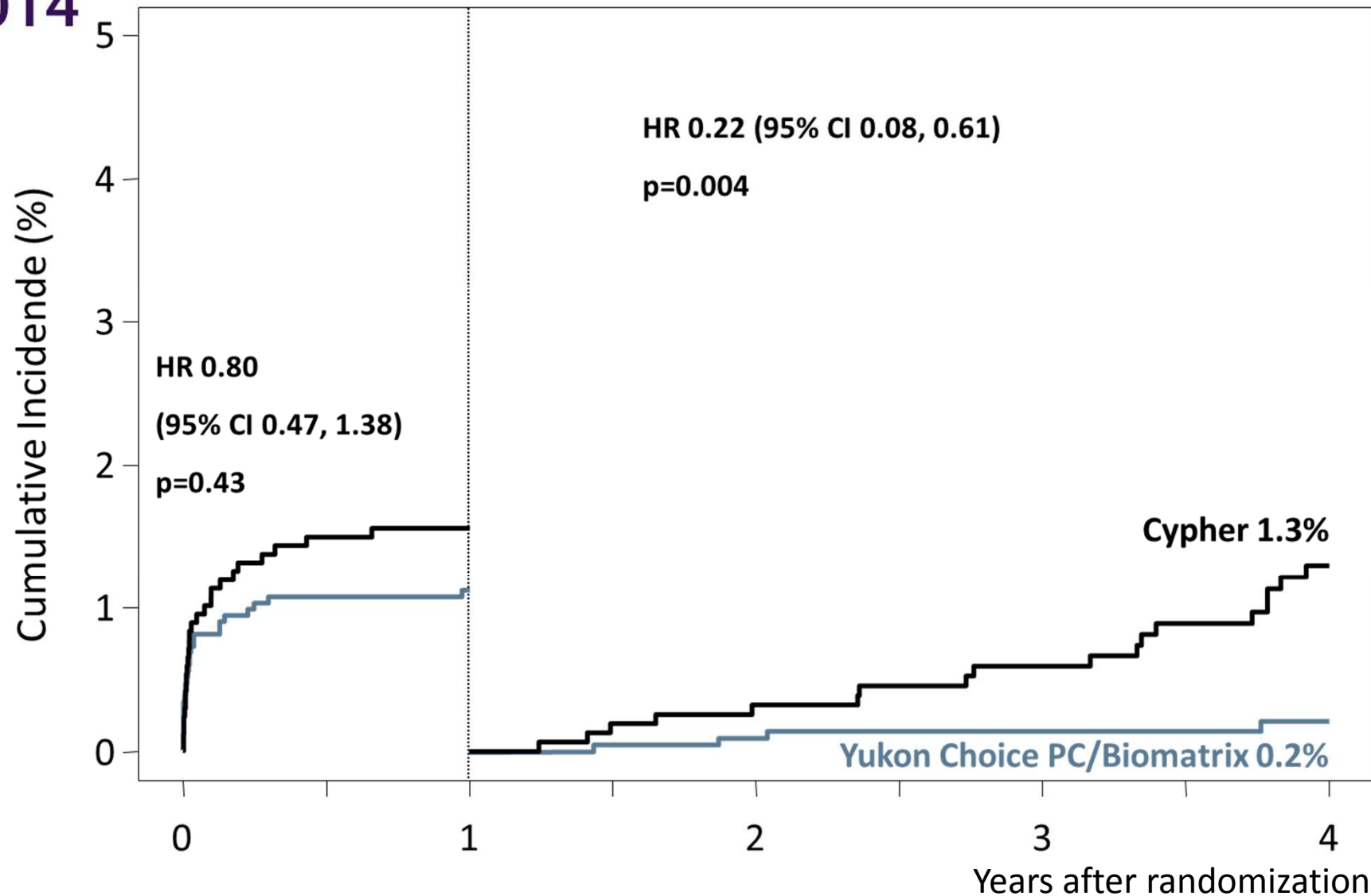
Stefanini, Byrne et al. Eur Heart J 2012

BP-DES vs. PP-DES Definite Stent Thrombosis



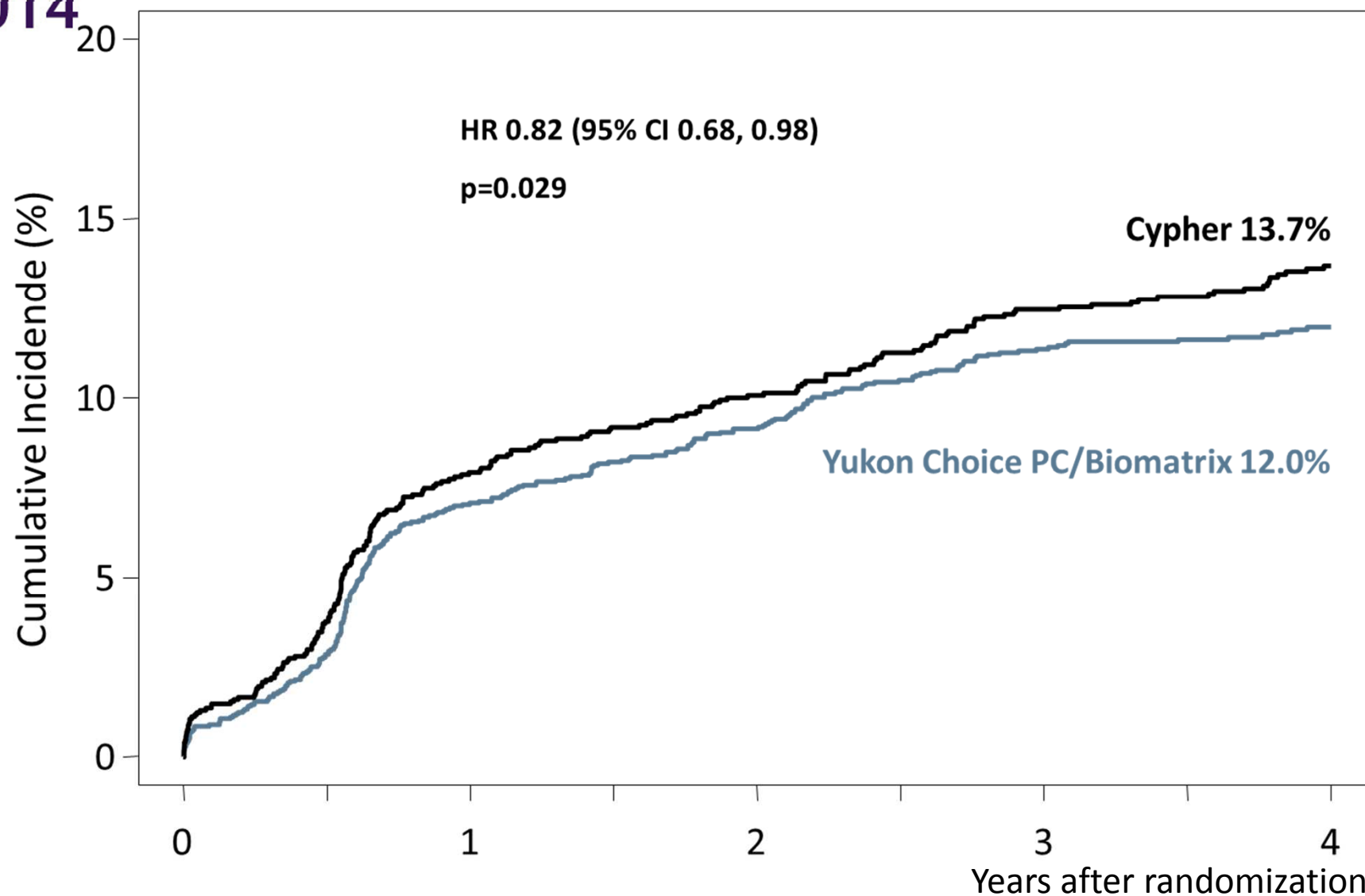
Stefanini, Byrne et al. Eur Heart J 2012

BP-DES vs. PP-DES Definite Stent Thrombosis



Stefanini, Byrne et al. Eur Heart J 2012

BP-DES vs. PP-DES Target Lesion Revascularization



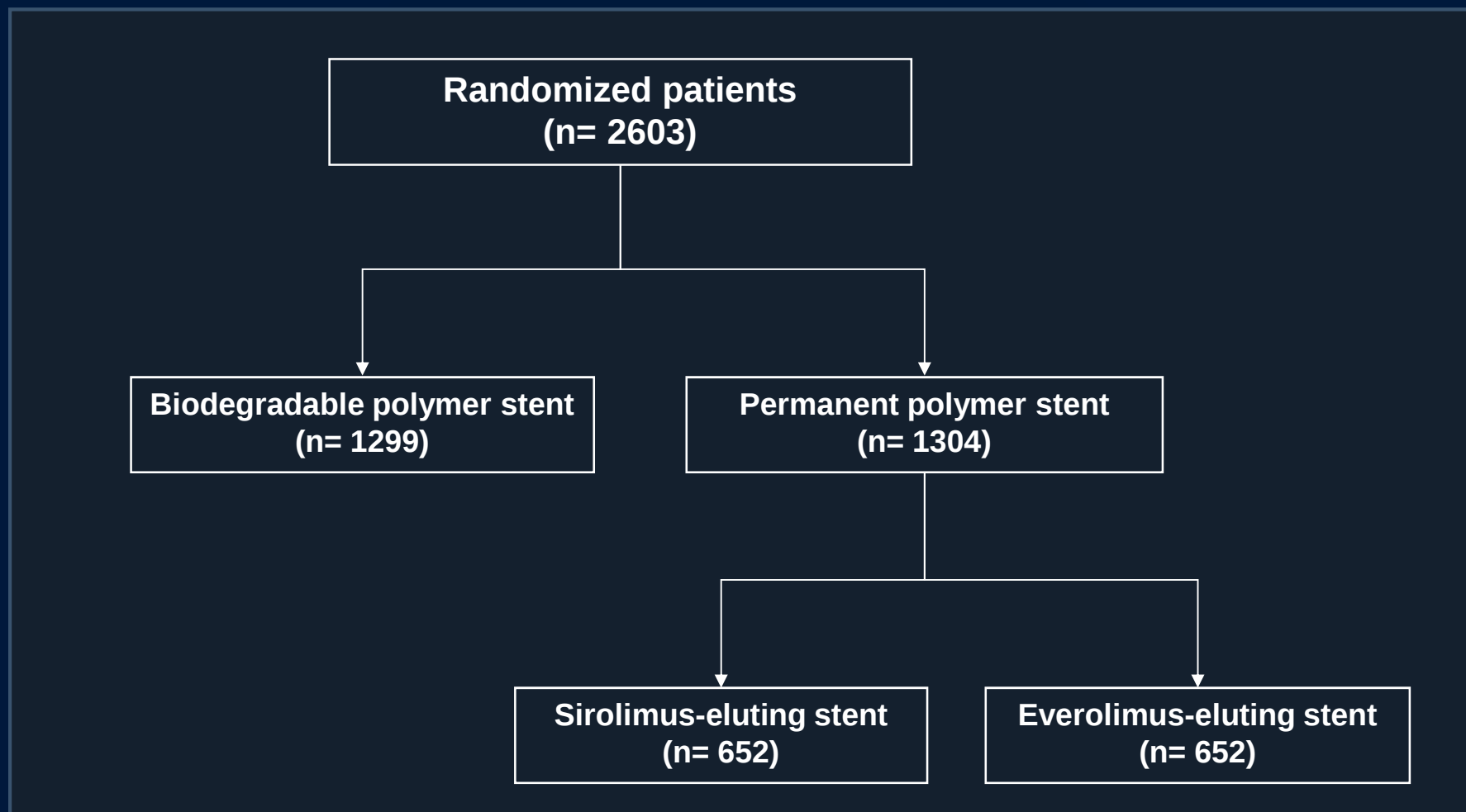
Stefanini, Byrne et al. Eur Heart J 2012

But...

...the first generation sirolimus-eluting Cypher stent is no longer the comparator of choice

ISAR-TEST 4: Final 5-Year Data

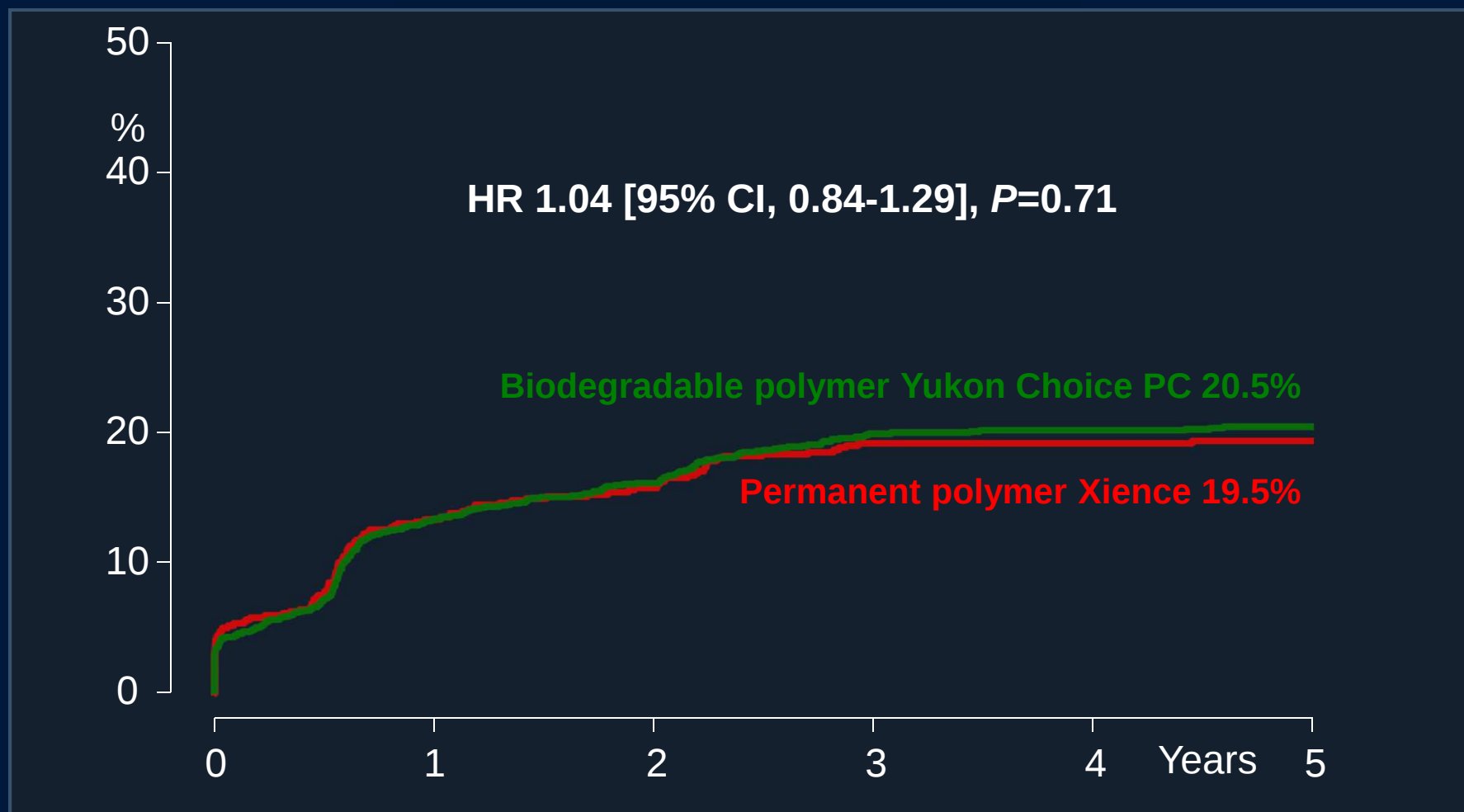
Study Design



Kufner et al. under review

ISAR-TEST 4: Final 5-Year Data

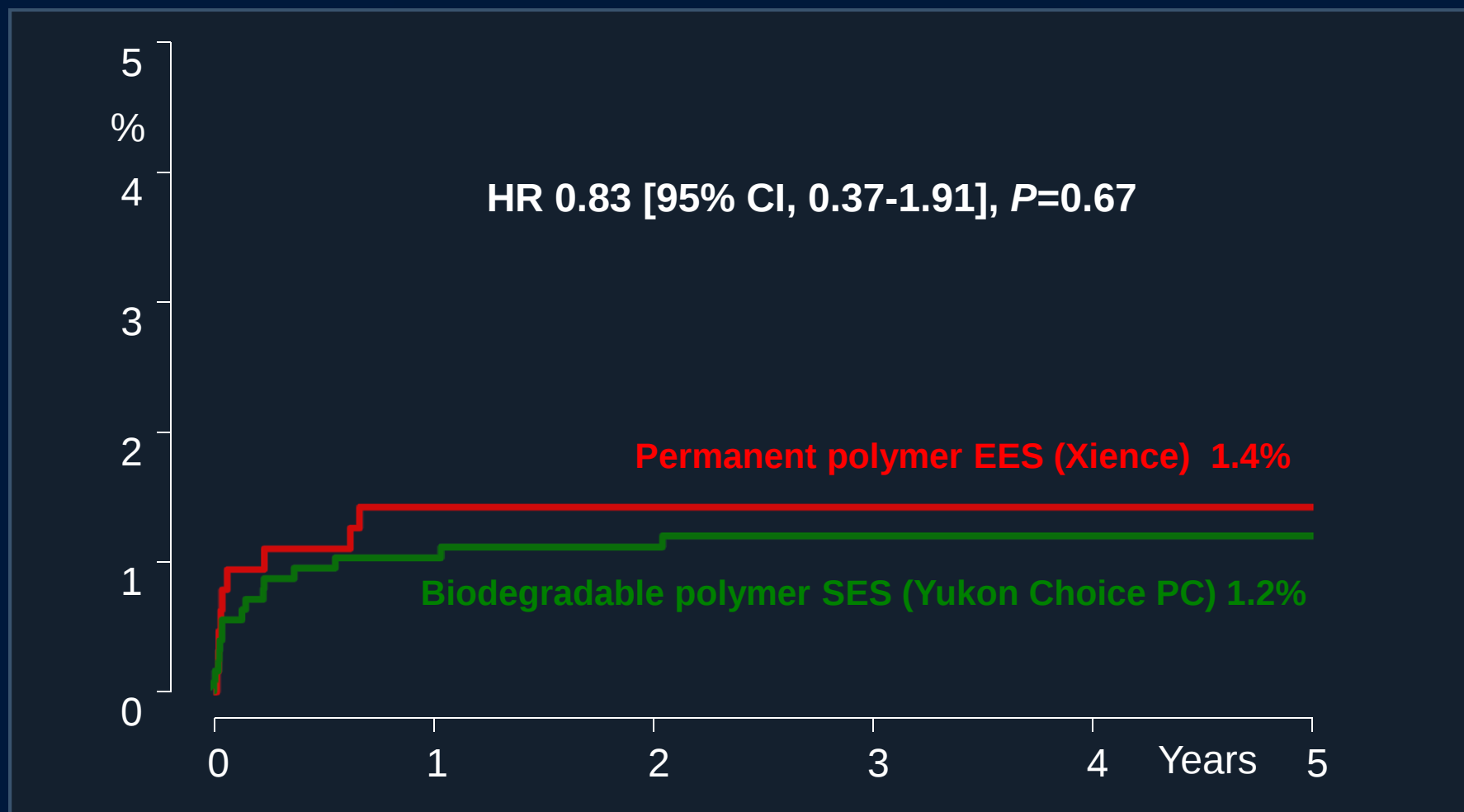
Cardiac death/target vessel MI/TLR



Kufner et al. under review

ISAR-TEST 4: Final 5-Year Data

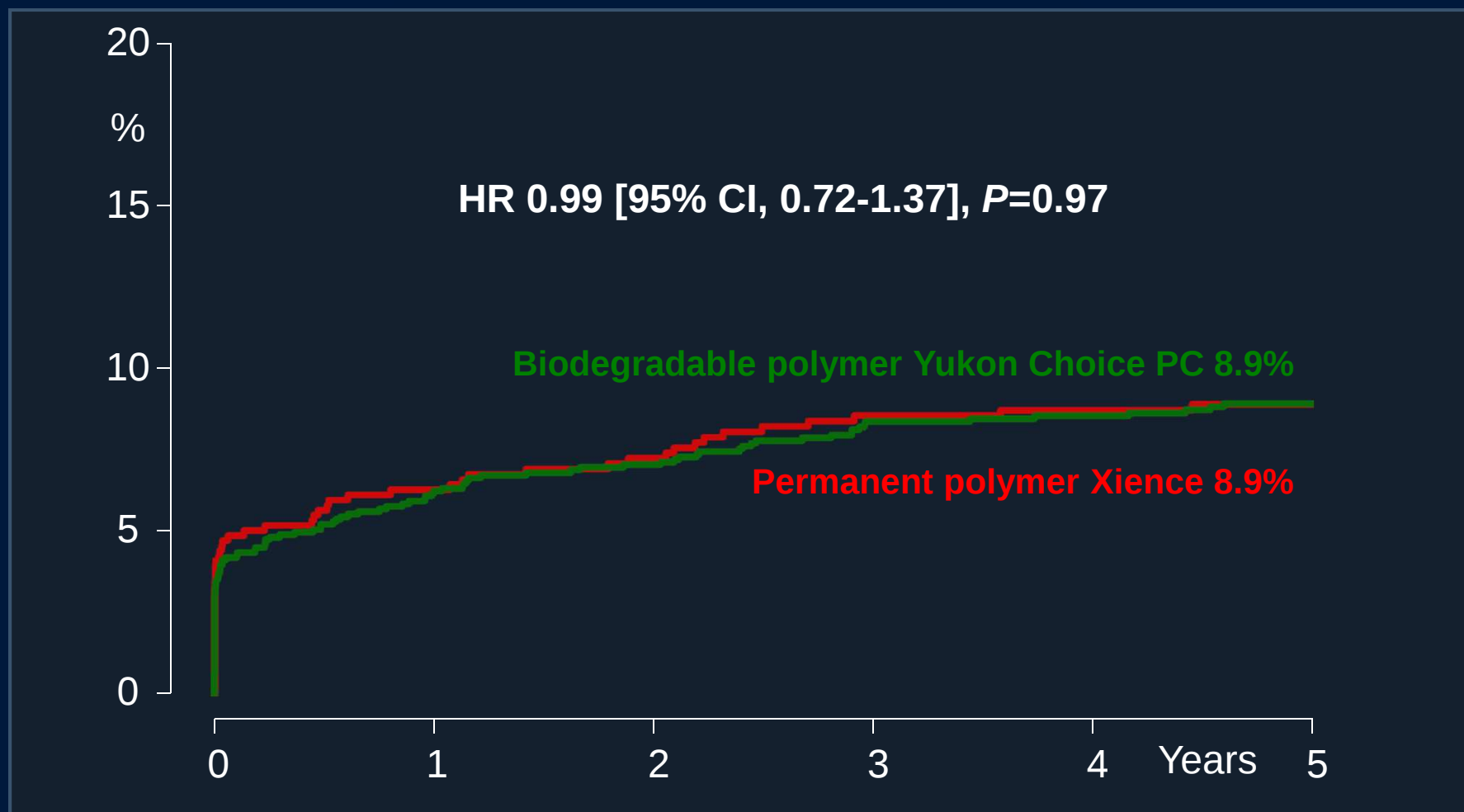
Definite/probable stent thrombosis



Kufner et al. under review

ISAR-TEST 4: Final 5-Year Data

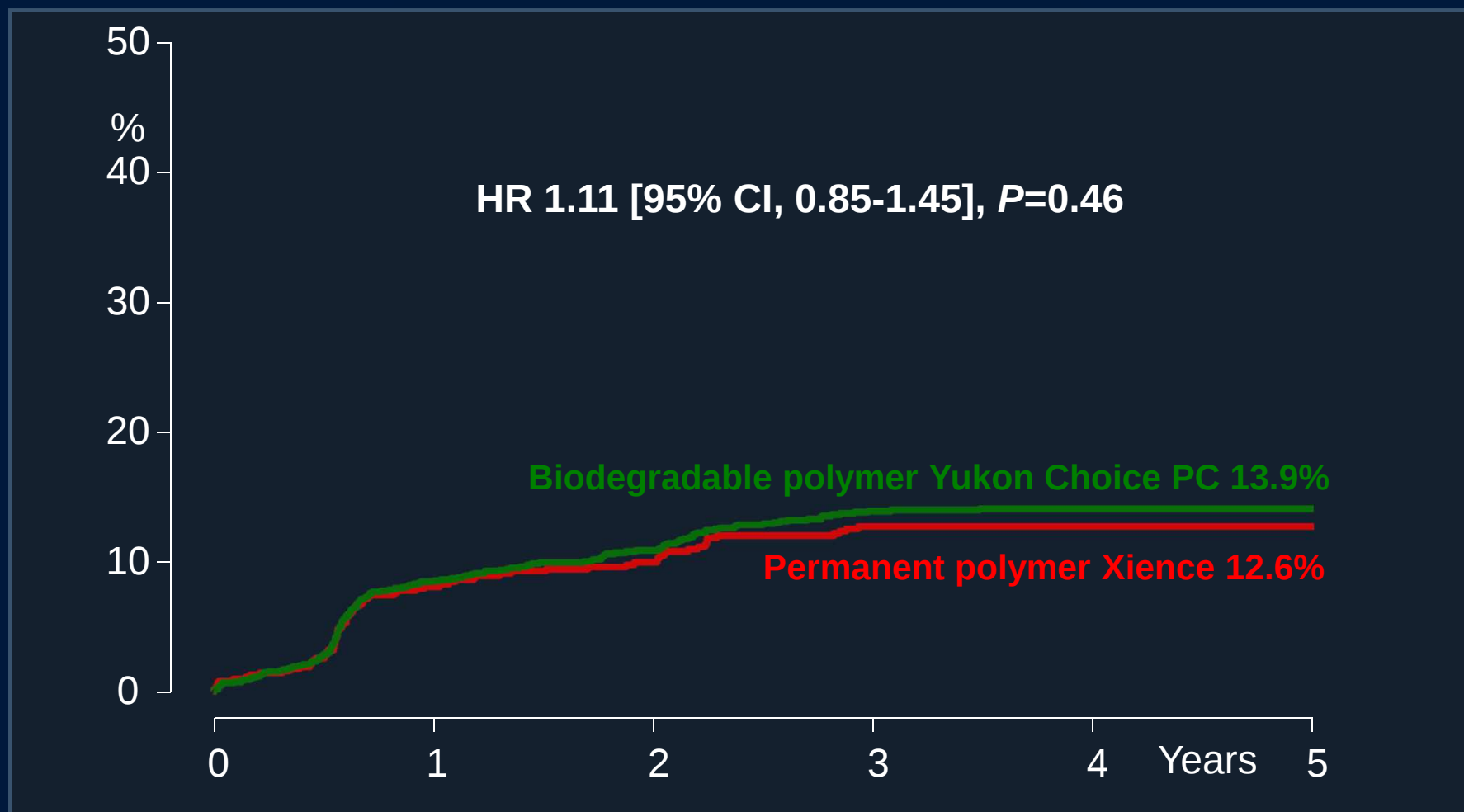
Cardiac death/target vessel MI



Kufner et al. under review

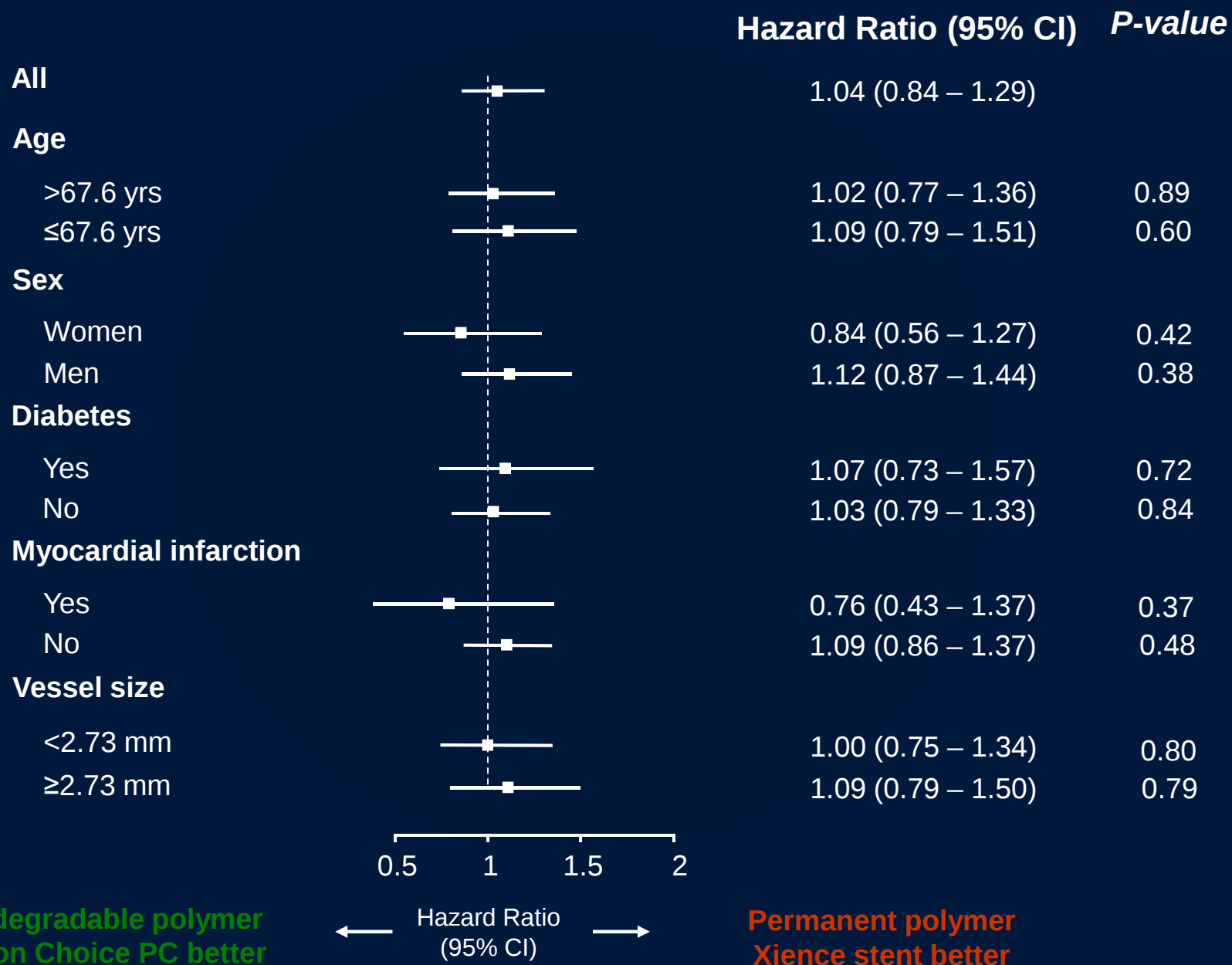
ISAR-TEST 4: Final 5-Year Data

Target lesion revascularization



Kufner et al. under review

ISAR-TEST 4: Final 5-Year Data



Biodegradable polymer SES vs permanent polymer EES in patients with coronary disease

Final 5-year outcomes from ISAR-TEST 4

- In the ISAR-TEST 4 we demonstrated non-inferiority of a microporous thin-strut biodegradable polymer Yukon Choice PC SES versus permanent polymer Cypher SES and Xience EES at 12-months
- Pooled 4-year data with ISAR-TEST 3 and LEADERS showed superior clinical outcomes in comparison with permanent polymer Cypher SES
- Final 5-year follow-up data demonstrates comparable clinical outcomes between biodegradable polymer Yukon Choice PC SES and the permanent polymer Xience EES in terms of overall target lesion failure, stent thrombosis and target lesion revascularization

Thank you for your attention



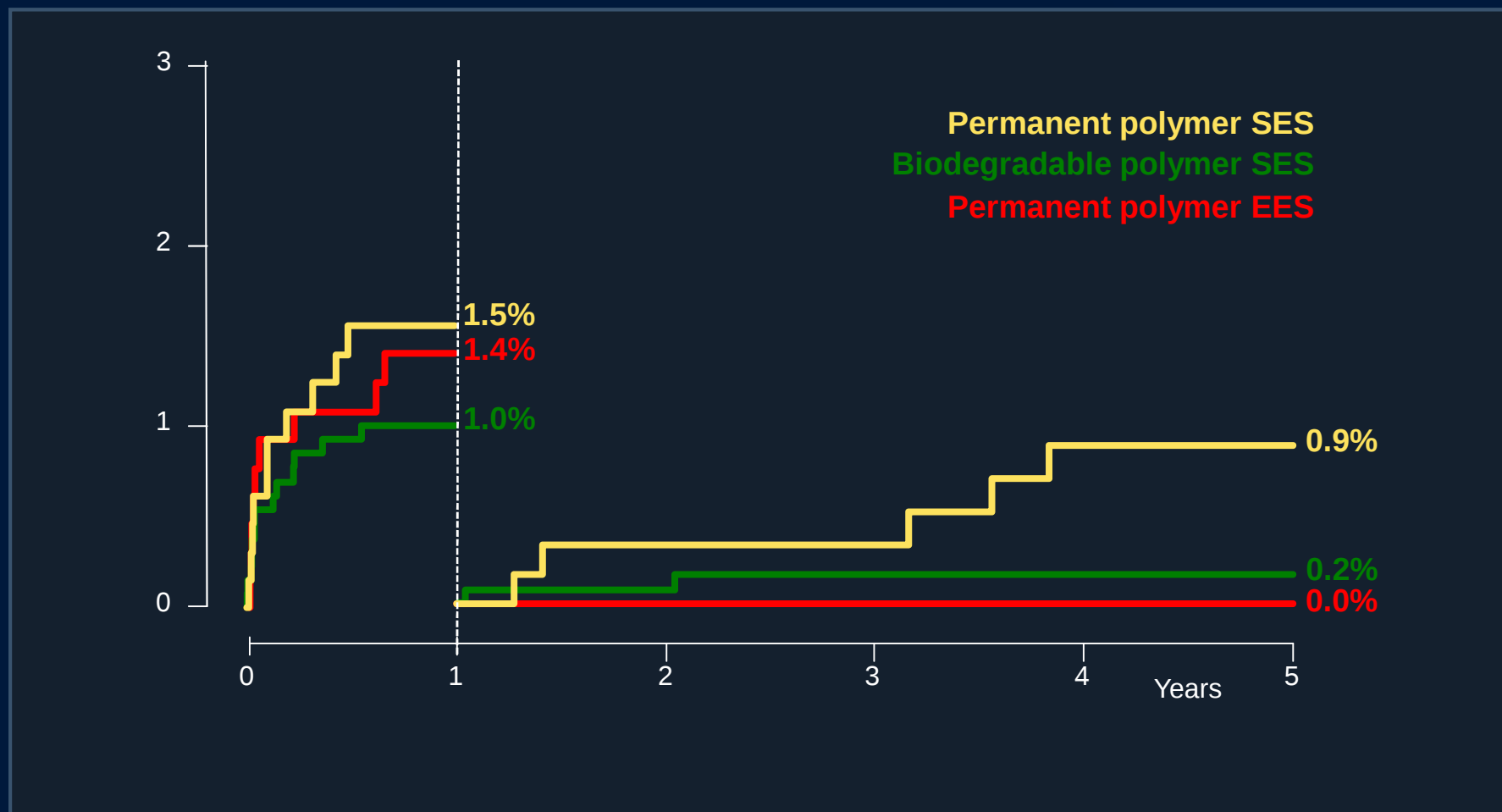
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ISAR-TEST 4: Final 5-Year Data

Stent thrombosis



Kufner et al. under review