Future Trials in PCI

Exploring Unresolved Issues

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Presentation

- Ischemic Heart Failure: CABG vs. PCI
- PCI Guidance: QCA vs. Imaging
- Long Lesions: Stent vs. Scaffold Jacket

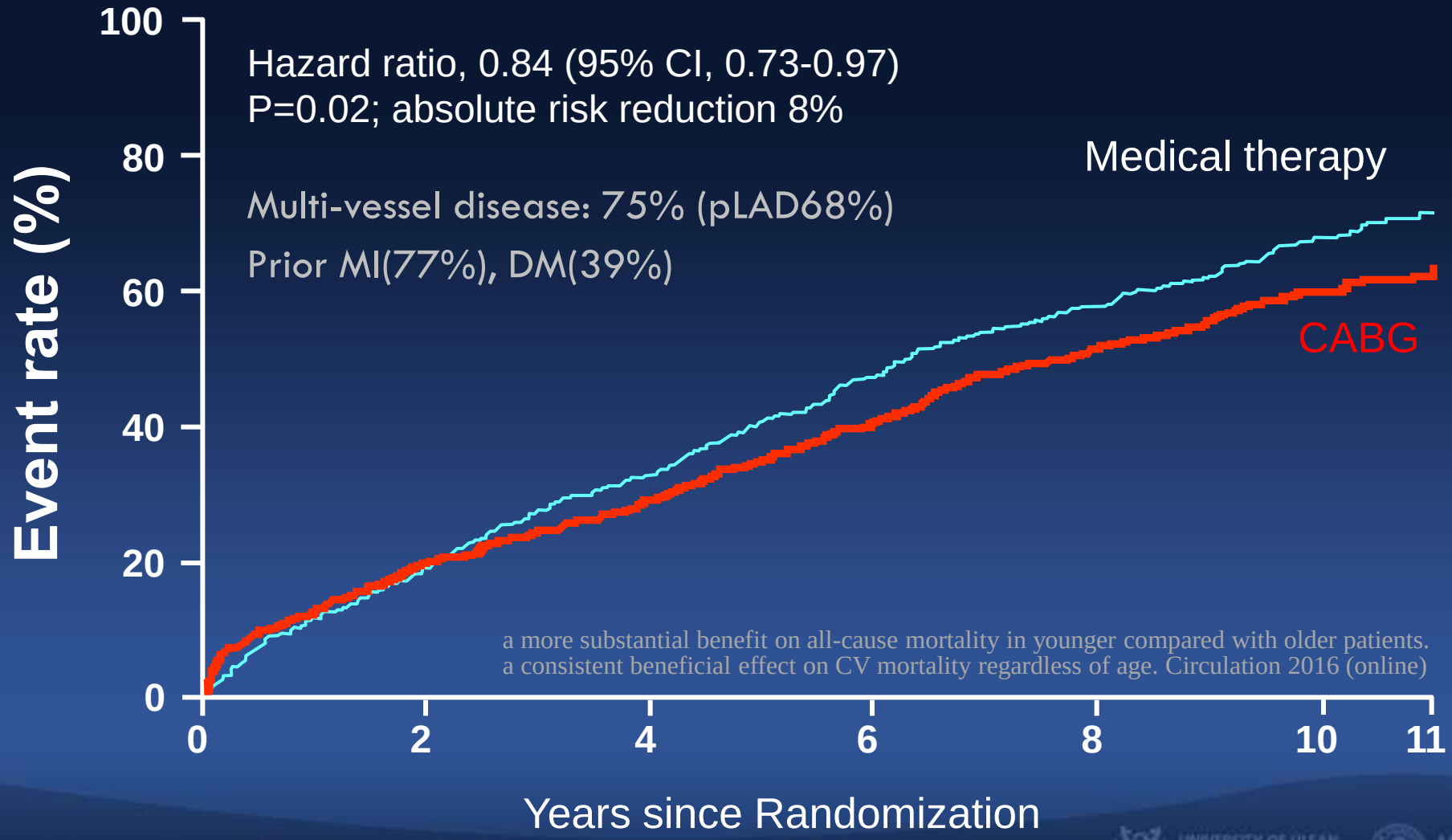
Revascularization in Severe LV Dysfunction (EF≤35%)

- 2011 ACC/AHA/SCAI Guideline
  - CABG for non-LM (IIbB)
  - PCI: insufficient data

- 2014 ESC/EACTS Guideline
  - CABG for LM (IC) or MVD (IB)
  - PCI if CABG not indicated (IIbC)

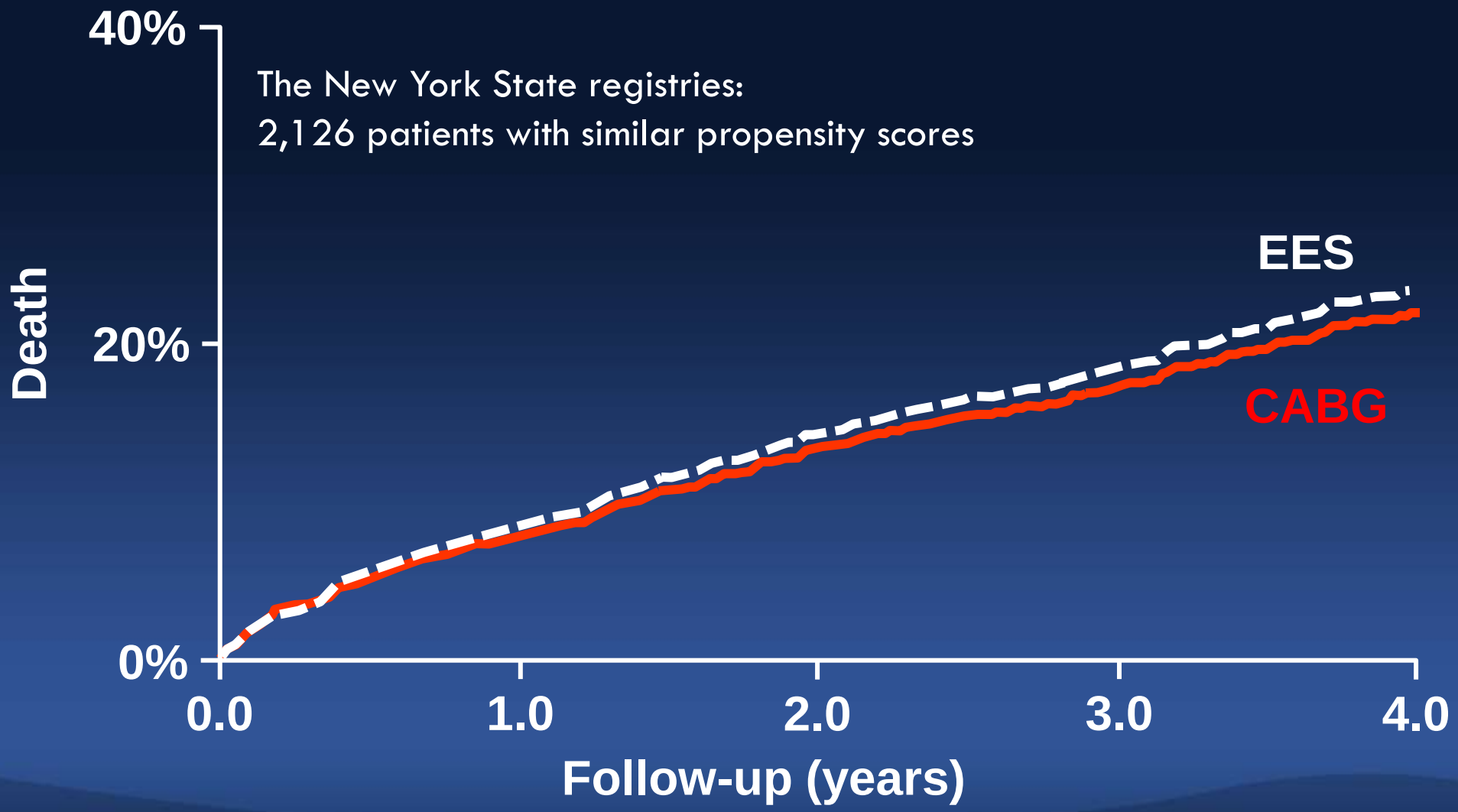
STICH Trial

LVEF <35% and graftable CAD, N=1212



a more substantial benefit on all-cause mortality in younger compared with older patients.
a consistent beneficial effect on CV mortality regardless of age. Circulation 2016 (online)

CABG versus DES for MVD and Severe LV Dysfunction



Circulation 2016;133:2132-2140

Summary

- Ischemic LV dysfunction with significant CAD
  - CABG remains the standard of care.
  - PCI is considered for poor surgical candidate.

- Future trials for ischemic severe LV dysfunction
  - CABG versus PCI with DES
    on top of optimal medical therapy

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The AVIO Trial: IVUS- vs. Angiography-Guided Stent Implantation in Complex Coronary Lesions

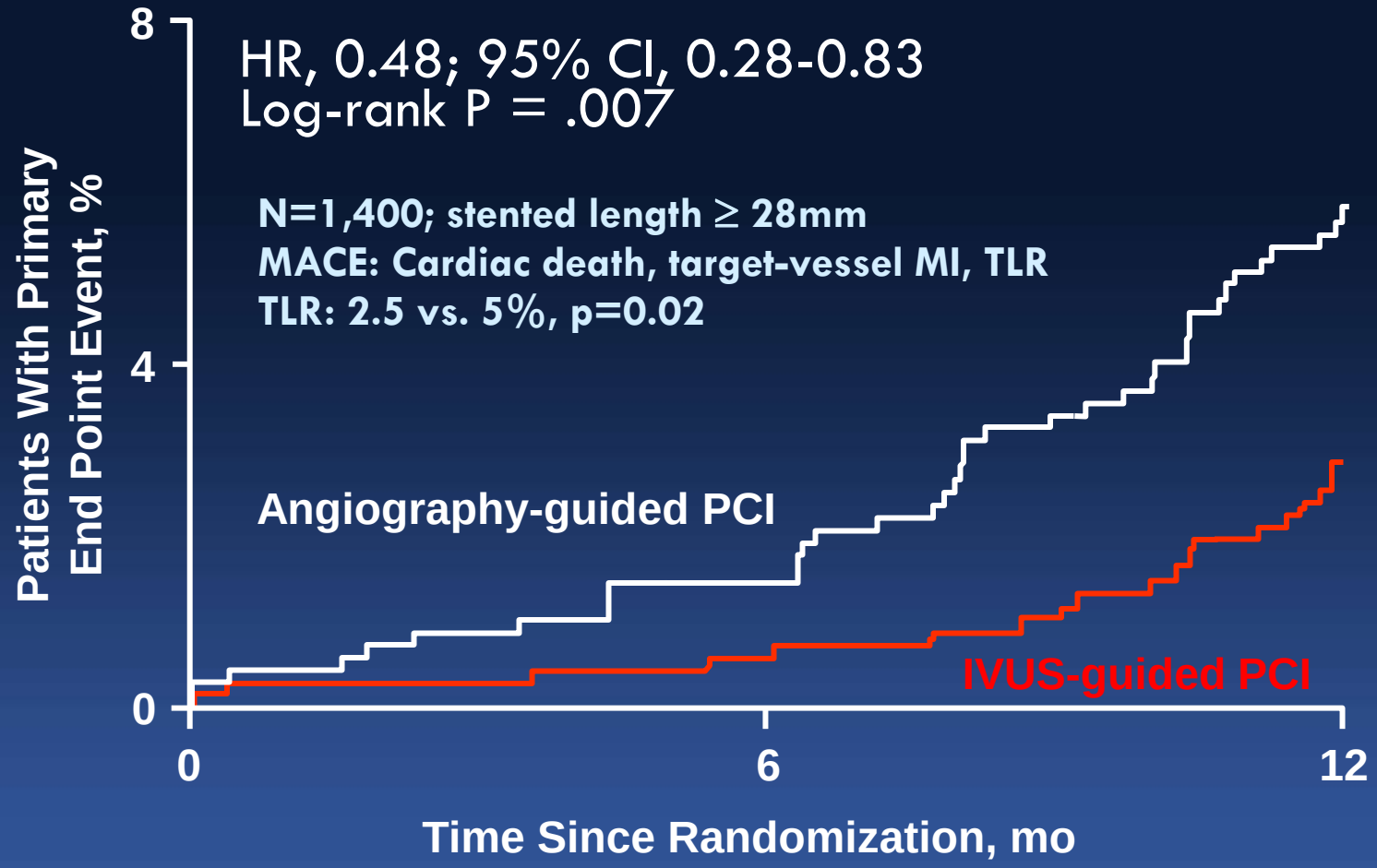
bifurcations, long lesions, CTO, or small vessels

	IVUS (n=142)	Angio (n=142)
30 d MACE		
Q wave MI	0 (0%)	0 (0%)
Non-Q wave MI	10 (7.0%)	10 (7.0%)
TLR	1 (0.7%)	0 (0%)
TVR	1 (0.7%)	0 (0%)
Cardiac death	0	1 (0.7%)
Cumulative at 24-month MACE		
MI	10 (7.0%)	12 (8.5%)
TLR	13 (9.2%)	17 (11.9%)
TVR	14 (7.8%)	22 (15.5%)
Cardiac death	0	2 (1.4%)

P value was NS for all comparisons.

Am Heart J 2013;165:65-72

IVUS-XPL Randomized Clinical Trial



Among patients requiring long coronary stent implantation, the use of IVUS-guided everolimus-eluting stent implantation, compared with angiography-guided stent implantation, resulted in a significantly lower rate of MACE

JAMA2015:314:2155-63

IVUS-XPL: What Makes the Difference?

Angiography-guided:
- stent size & length by visual estimation,
- post-dilation if residual DS ≥30% by visual estimation

IVUSU-guided: decisions according to IVUS findings

Differences in key parameters:
- adjunctive post-dilation: 76% vs. 57%, p<0.001
- final balloon size: 3.14 vs. 3.04mm, p<0.001
- final MLD: 2.64 vs. 2.56mm, p<0.001
- residual diameter stenosis: 12.79 vs. 13.74%, p=0.04

ILUMIEN III A Randomized Controlled Trial Comparing OCT Guided, IVUS-Guided and Angiography-Guided PCI

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	*P* OCT vs IVUS	*P* OCT vs Angio
Dissection, any	28%	40%	44%	0.04	0.006
Major	14%	26%	19%	0.009	0.25
Minor	14%	13%	25%	0.84	0.02

	OCT (n=140)	IVUS (n=135)	Angio (n=140)	*P* OCT vs IVUS	*P* OCT vs Angio
Malapposition, any	41%	38%	59%	0.62	0.002
Major	11%	21%	31%	0.02	<0.0001
Minor	31%	18%	28%	0.01	0.60

OCT: stent malapposition, minor edge dission, minor thrombi, minor plaque prolapse

Limitations of Previous Studies

The key determinant of the device failure is not imaging-guidance itself but suboptimal results.

Looking at angiography guidance:

- Smaller stent: Angiography guidance was based on visual estimation, often leading to choose undersized stents.
- Stent underexpansion: High pressure post-dilatation was not routinely used, leading to inadequate stent expansion.

QCA-Guided PCI

Careful Decision, Clean Outcome

- Design by angio (shoulder to shoulder)
  creating harmony with reference vessels
- Sizing by QCA (fine edge-tunning)
  distal RVD + ~10% of distal RVD
- Finish by 3D (dilate, dilate & one more dilate)
  minimal residual diameter stenosis <10% by QCA

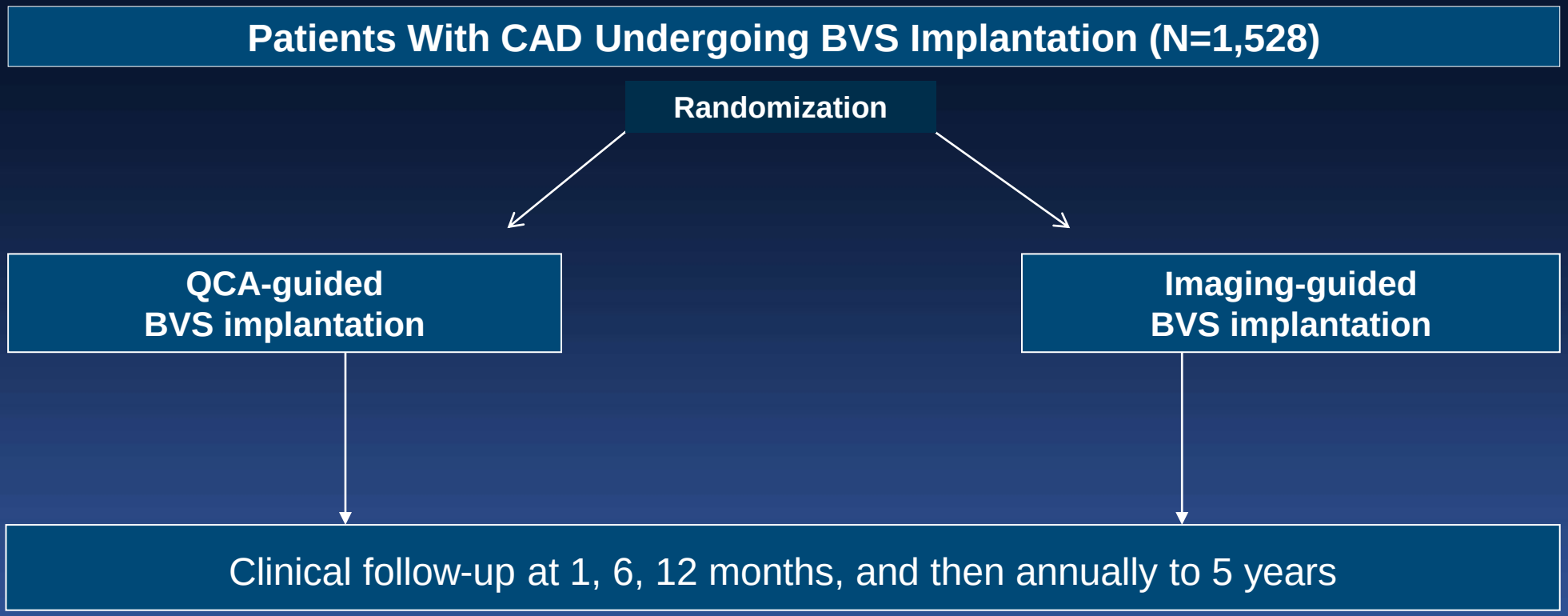
Why QCA Guidance?

IVUSplasty vs.
ANGIOplasty

IVUS guidance:
- a limited impact on PCI outcome
- no reimbursement of IVUS worldwide, except Japan
- absorb trials: absorb 3 (11.2%), absorb China (0.4%), absorb Japan (68.7%)

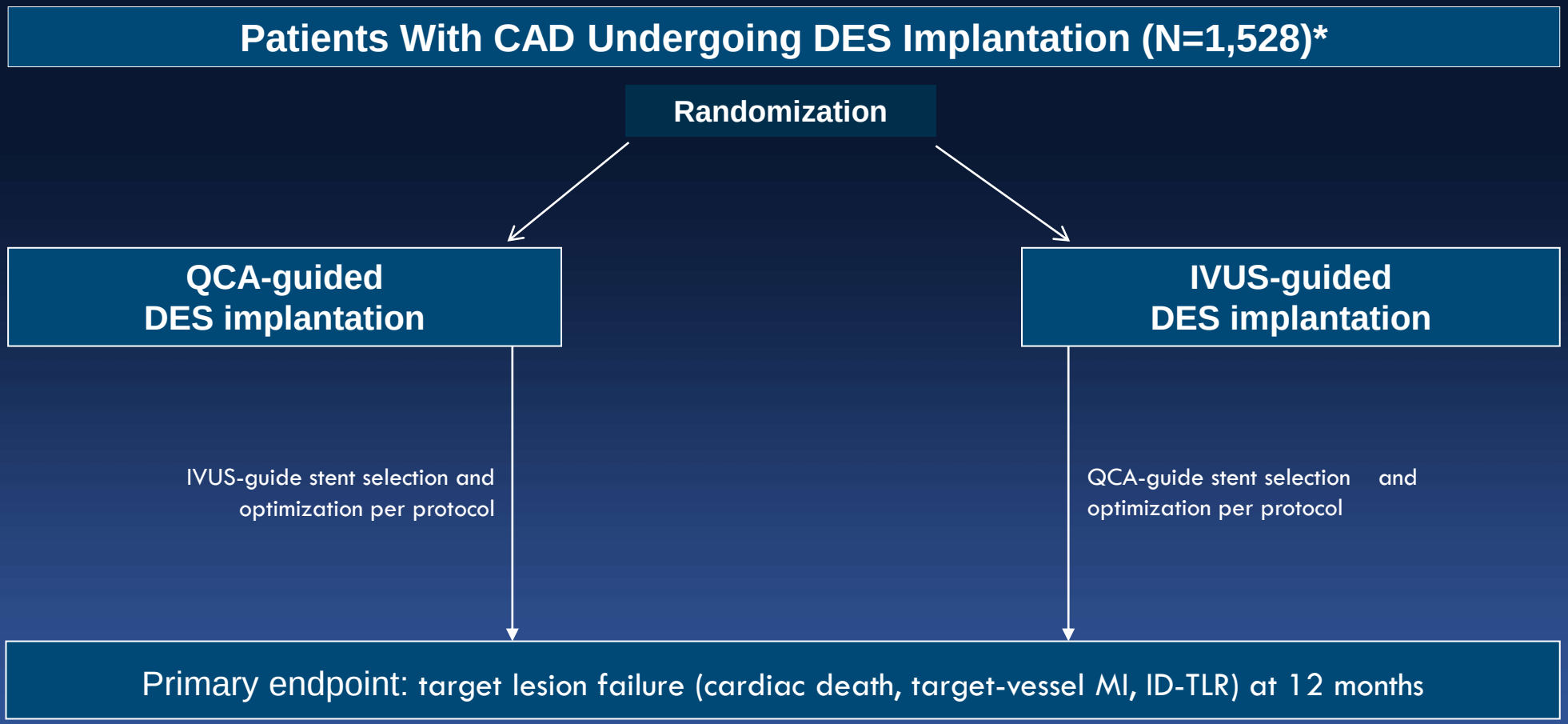
QCA guidance:
- available at every catheterization laboratory
- quick and easy without additional cost
- a reliable time-honored method

Quantitative Coronary Angiography versus Imaging *GUID*anc*E* for *B*ioresorbable *V*ascular *S*caffold Implantation: **GUIDE–BVS** trial



*Primary endpoint: target-lesion failure (cardiac death, TV-MI, or ID-TLR) at 1 year

Quantitative Coronary Angiography versus Intravascular Ultrasound *GUIDanc*E for *D*rug-*E*luting *S*tent Implantation: GUIDE–DES trial



*Drug-eluting stent (DES): everolimus-eluting stents (Xience, Synergy), zotarolimus-eluting stents (resolute Onyx)

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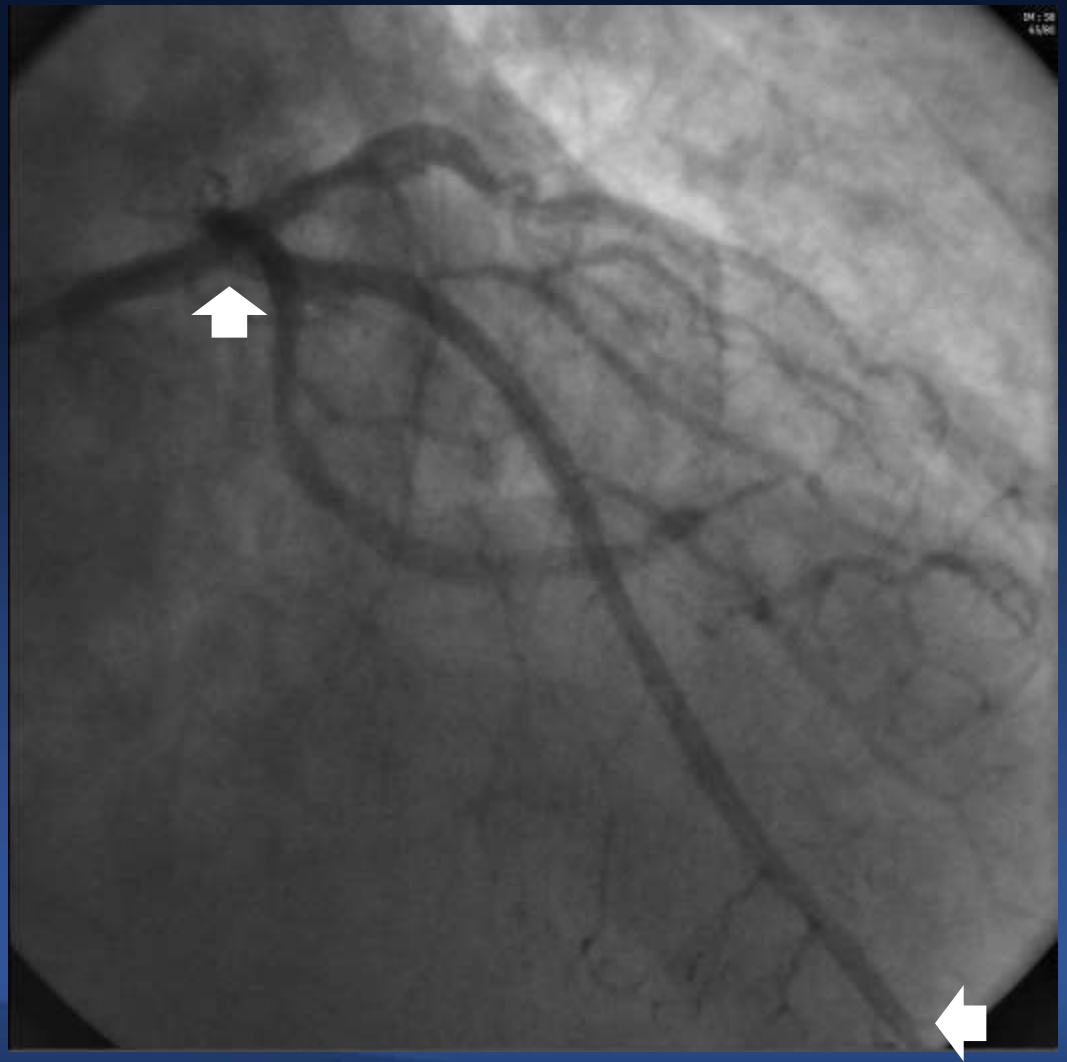
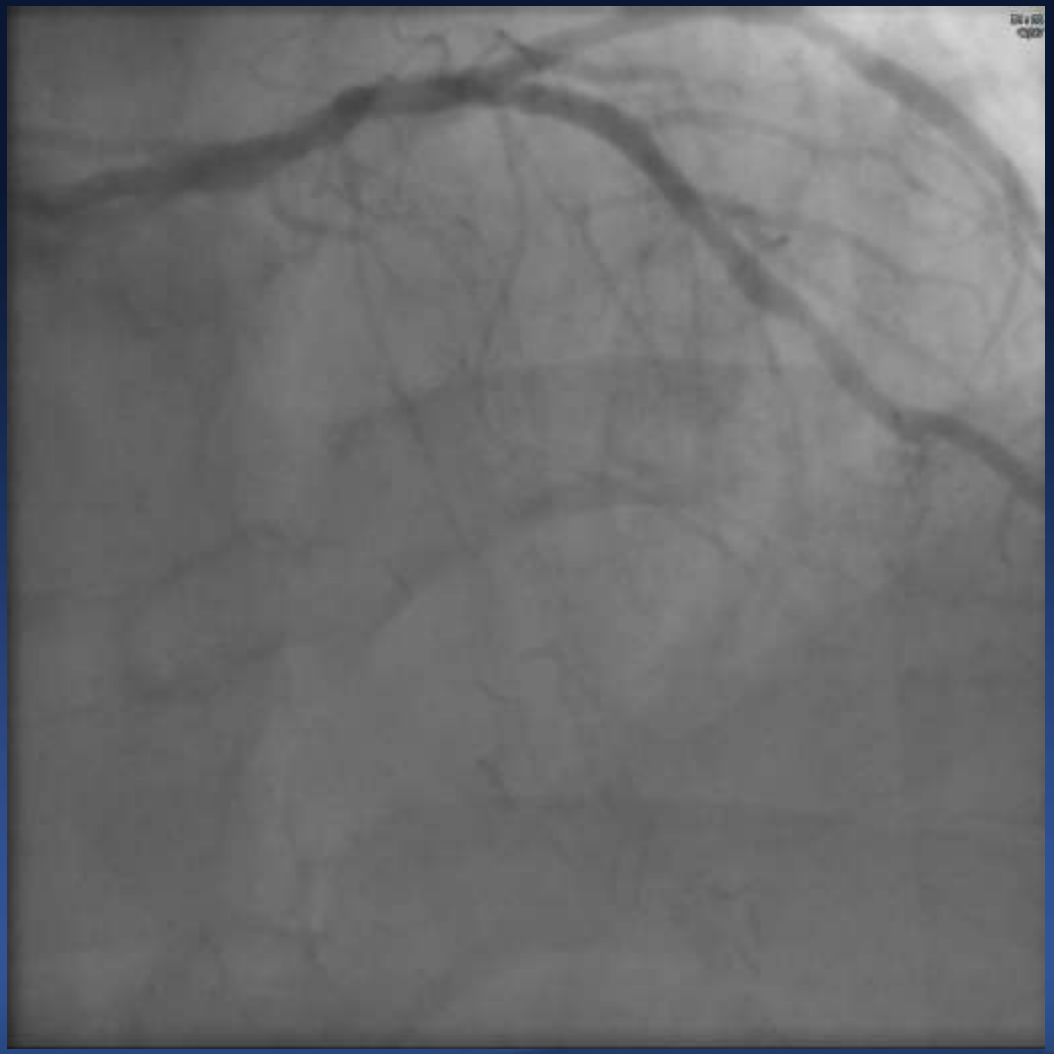
Full Metal Jacket Failure

A Definite "No Go"

M/64, stable angina



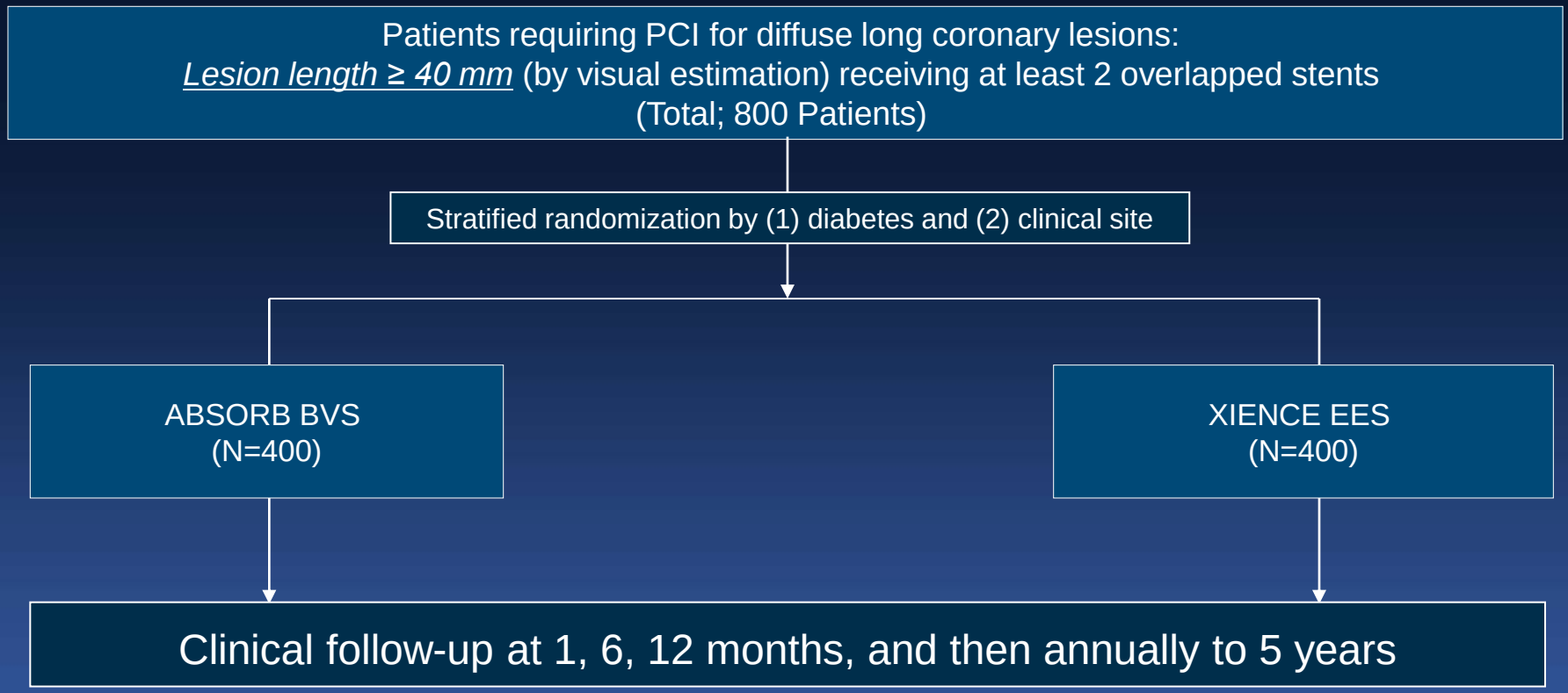
4 cyphers: stented length (~112mm)



9 years later: total occlusion

Everolimus-Eluting Bioresorbable Scaffolds versus Everolimus-Eluting Metallic Stents for Diffuse Long Coronary Artery Disease

ABSORB-LONG Trial



*Primary endpoint: target-lesion failure (cardiac death, TV-MI, or ID-TLR) at 1 year

Ideal BRS,
more than just resorption

1. User-friendly design (stronger & ductile)
2. Scaffold thrombosis minimized (thinner & round)
3. Appropriately gone, 6-12 months (a time of uncertainty)

…Chasing the Dream

BRSGo The Future is Near

…ready for the next Jump!

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