TCT@ACCi2-2014 Highlights

Neal S. Kleiman, MD

April 24, 2014

HOUSTON Methodist
DEBAKEY HEART & VASCULAR CENTER

Note

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- Most of the data slides I will present are drawn directly from the original presentations.
- Credit for slide production should be given to the original presenters.
- I like studies that disrupt existing dogma.

NEXT Trial of the Nobori Biolimus-Eluting Stent

Masahiro Natsuahi, MD

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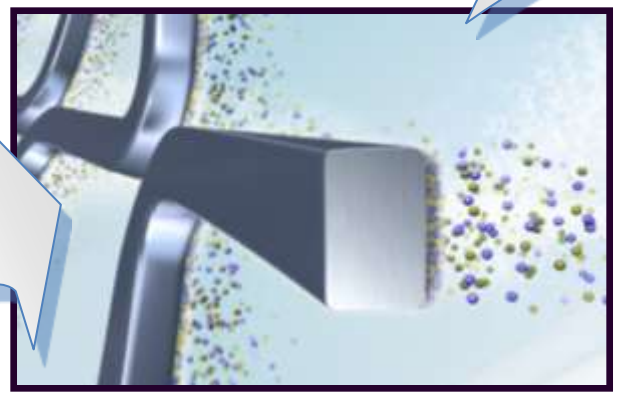
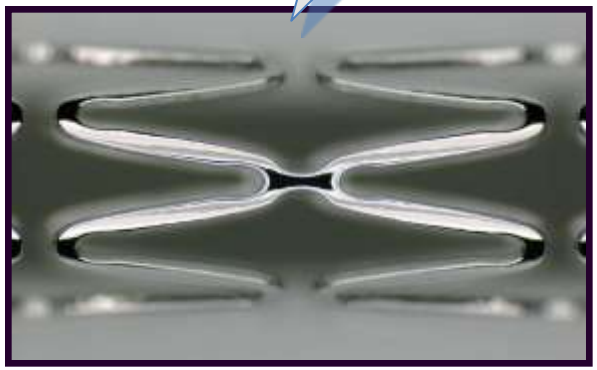
PLA Biodegradable Polymer

- Abluminal coating
- Controlled biodegradability
- Precise drug release kinetics
- Simultaneous release of drug and polymer degradation



Biolimus A9™

- Anti-proliferative, anti-inflammatory properties
- Highly lipophilic with optimal local tissue uptake



BMS Platform

- Stainless steel alloy stent
- Wide cell opening with optimal side branch access
- Innovative delivery system with hydrophilic M-coating

Study Design

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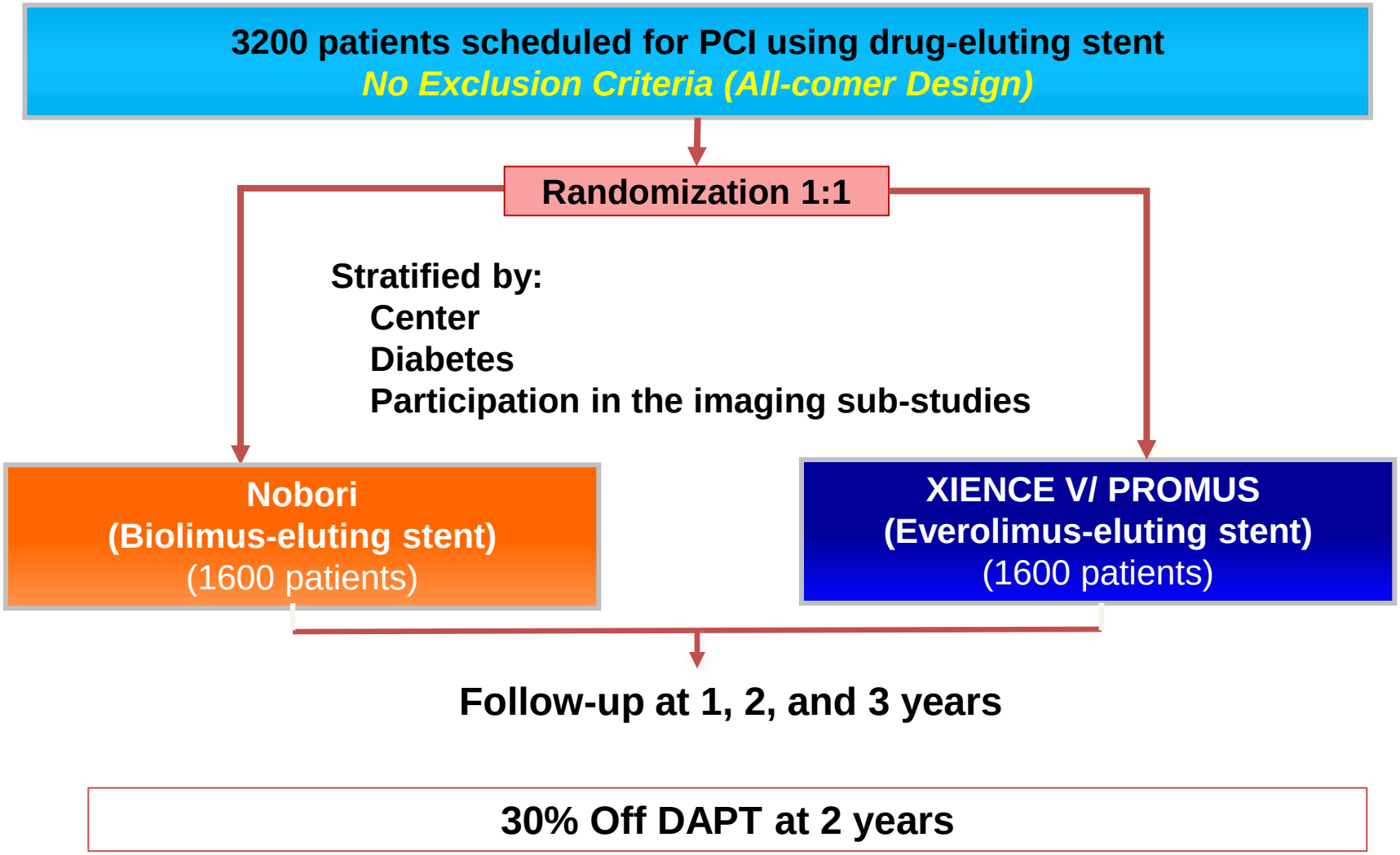

30% Off DAPT at 2 years

Non-inferiority Assessment for the Primary Safety Endpoint

Death or Myocardial Infarction

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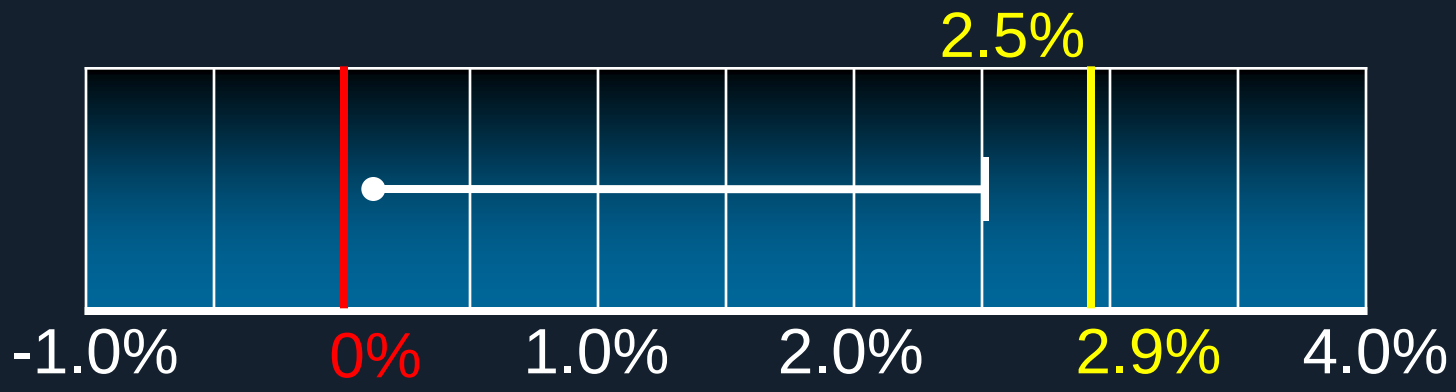
BP-BES 7.83% vs. DP-EES 7.69%

$P_{non\text{-}inferiority} = 0.003$

Difference: 0.14%

Upper one-sided 99.4% CI: 2.5%



No Δ in Stent thrombosis or TLR

ZEUS Trial

Marco Valgimigli, MD

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- **Zotarolimus-eluting Endeavor sprint stent in Uncertain DES candidates (ZEUS)**
- DES reduce the risk of target vessel failure.
- First generation stents have raised concerns about higher frequency of stent thrombosis.
- Prolonged DAPT has been recommended.
- **ZEUS was designed to disentangle the effects of DES vs BMS from those of long-term vs short term DAPT.**

Zotarolimus-eluting Endeavor Sprint

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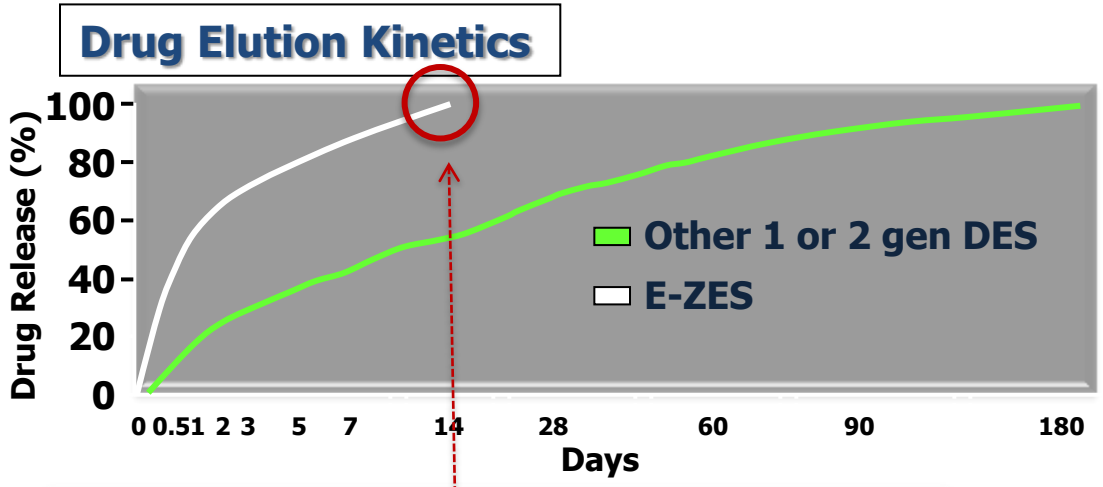
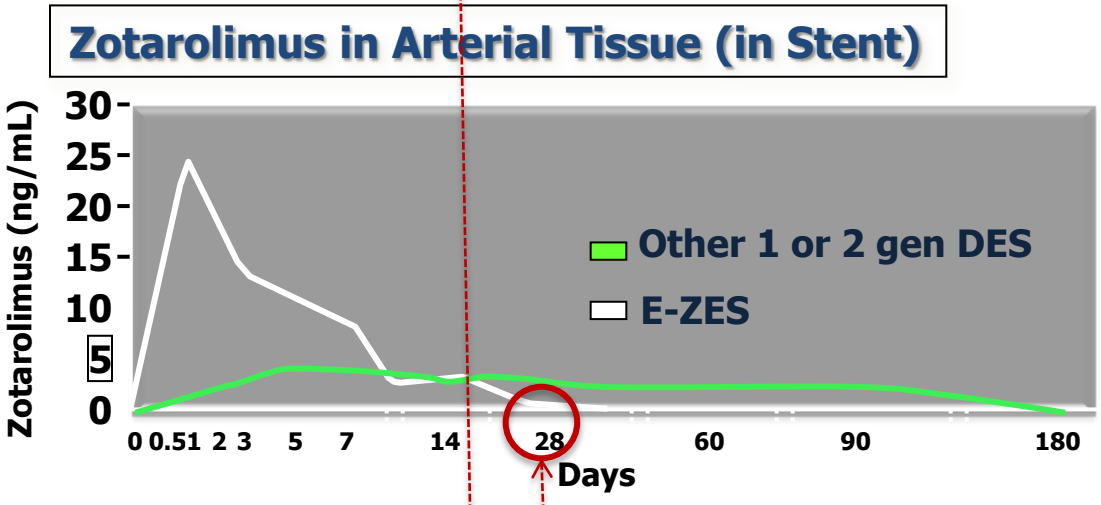


ZES (PC-Coating)
100% Eluted at 14 days



No detectable drug in arterial tissue beyond 28 days

EuroInterv.2007;3:50-53

Drug gets in and out quickly.

Study Design

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Urgent or emergent coronary stenting in pts fulfilling ≥1 of the below:

High Bleeding Risk
- Need for OACs
- Previous Relevant Bleeding
- Age > 80 y/o
- Bleeding diathesis
- Known Anemia (Hb<10 gr/dl)
- Need for CCS or NSAID

High Thrombotic Risk
- Intolerance to ASA
- Intolerance to any $P2Y_{12}$
- Planned surgery w/in 1 year
- Cancer-life expectancy >1 Y
- Pro-thrombotic diathesis

Low Restenosis Risk
- Planned stent ≥3.0 mm, apart from LMCA and SVG intervention or for ISR lesions

N=1,606

Endeavor Sprint Zotarolimus-eluting Stent

Thin-strut Bare Metal Stent

Primary Endpoint: Death, Myocardial Infarction or Target Vessel Revascularization at 12 months

Am Heart J. 2013 Nov;166(5):831-8

Study Design

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Urgent or emergent coronary stenting in pts fulfilling ≥1 of the below:

High Bleeding Risk
- Need for OACs
- Previous Relevant Bleeding
- Age > 80 y/o
- Bleeding diathesis
- Known Anemia (Hb<10 gr/dl)
- Need for CCS or NSAID

DAPT: *30 days*

High Thrombotic Risk
- Intolerance to ASA
- Intolerance to any $P2Y_{12}$
- Planned surgery w/in 1 year
- Cancer-life expectancy >1 Y
- Pro-thrombotic diathesis

DAPT: *None if* ASA/$P2Y_{12}$i intol. *Up to surgery* if planned *≥ 6 mos* in others

Low Restenosis Risk
- Planned stent ≥3.0 mm, apart from LMCA and SVG intervention or for ISR lesions

DAPT: Stable CAD *30 days* ACS ≥ *6 mos*

62.5% of patients off DAPT within 2 months

Am Heart J. 2013 Nov;166(5):831-8

Study Population

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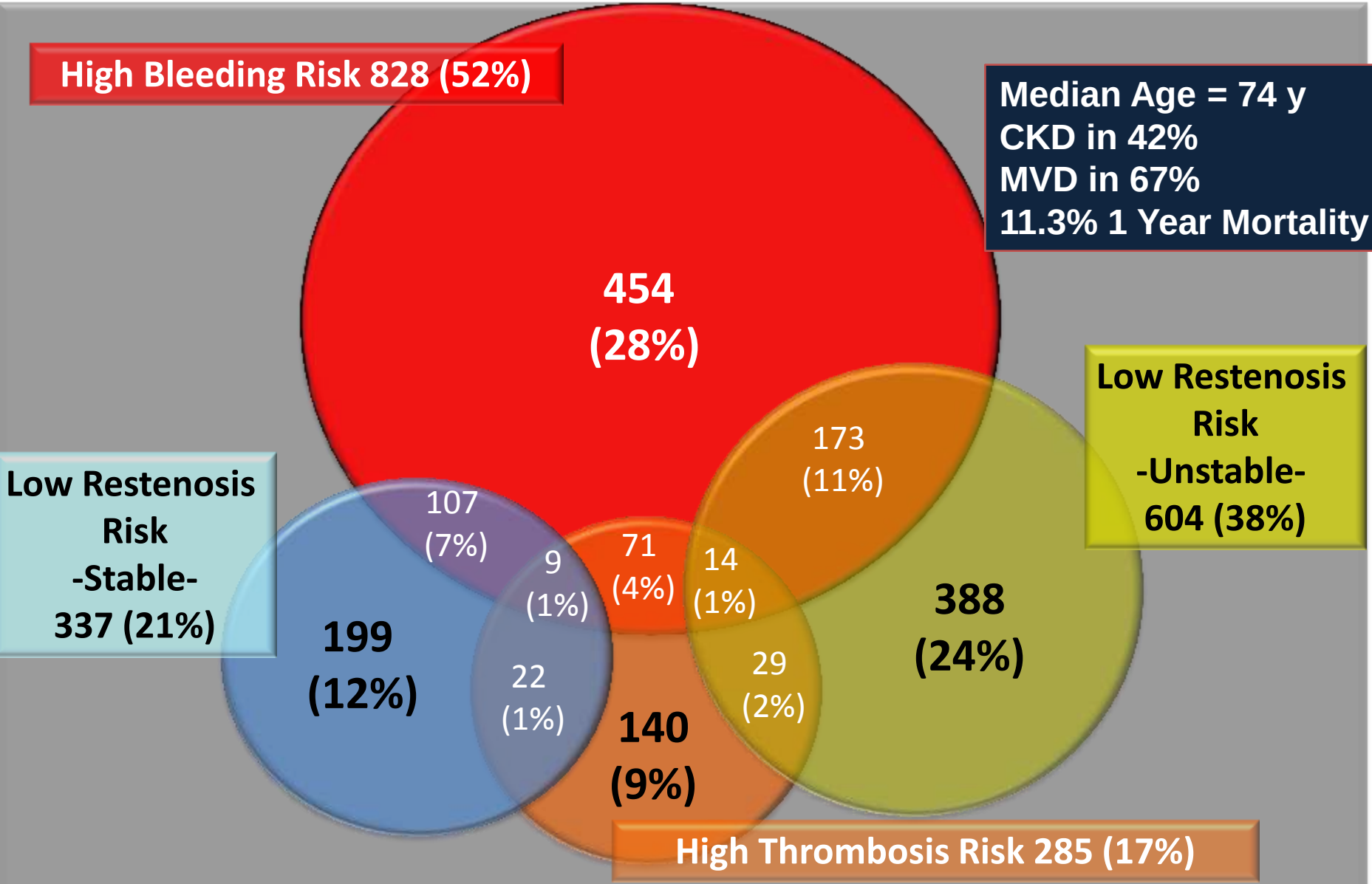

Major Adverse Cardiovascular Events (Primary Endpoint)

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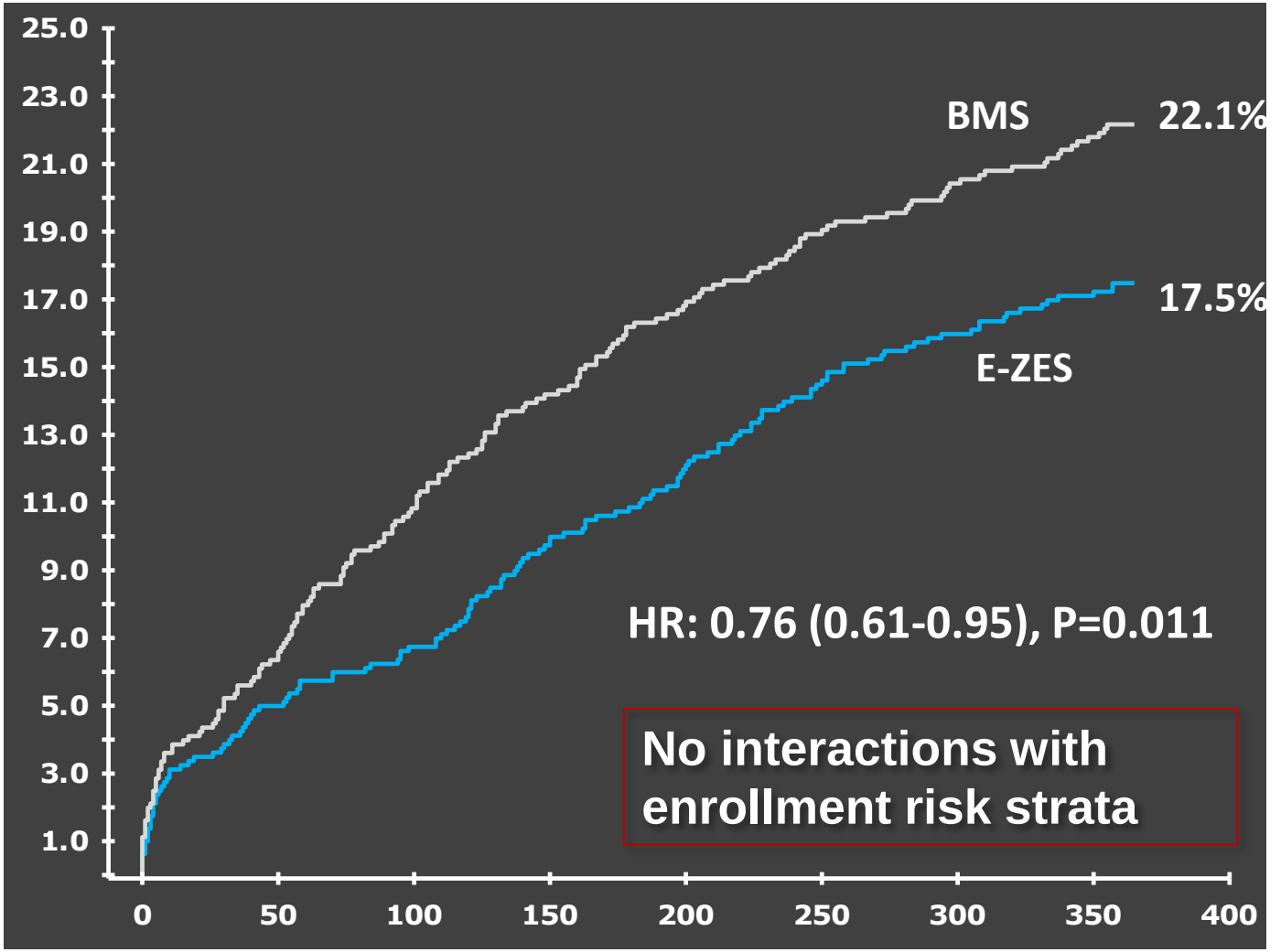

No. at Risk								
BMS	804	752	716	689	668	651	639	628
E-ZES	802	761	747	723	705	685	673	664

Definite or Probable Stent Thrombosis

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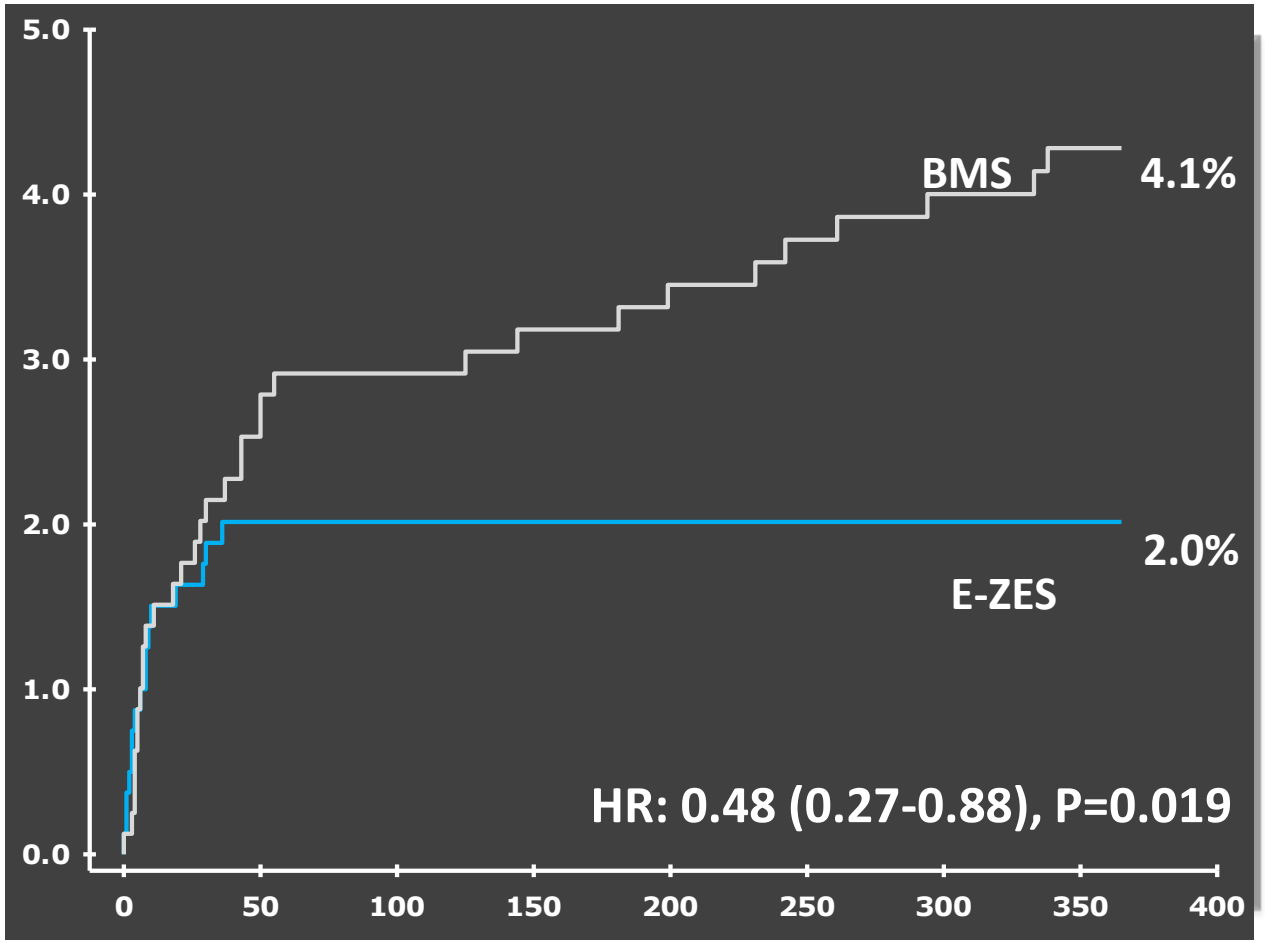

No. at Risk								
BMS	804	763	739	723	712	701	692	685
E-ZES	802	767	758	741	733	721	713	708

Bleeding events in the two groups

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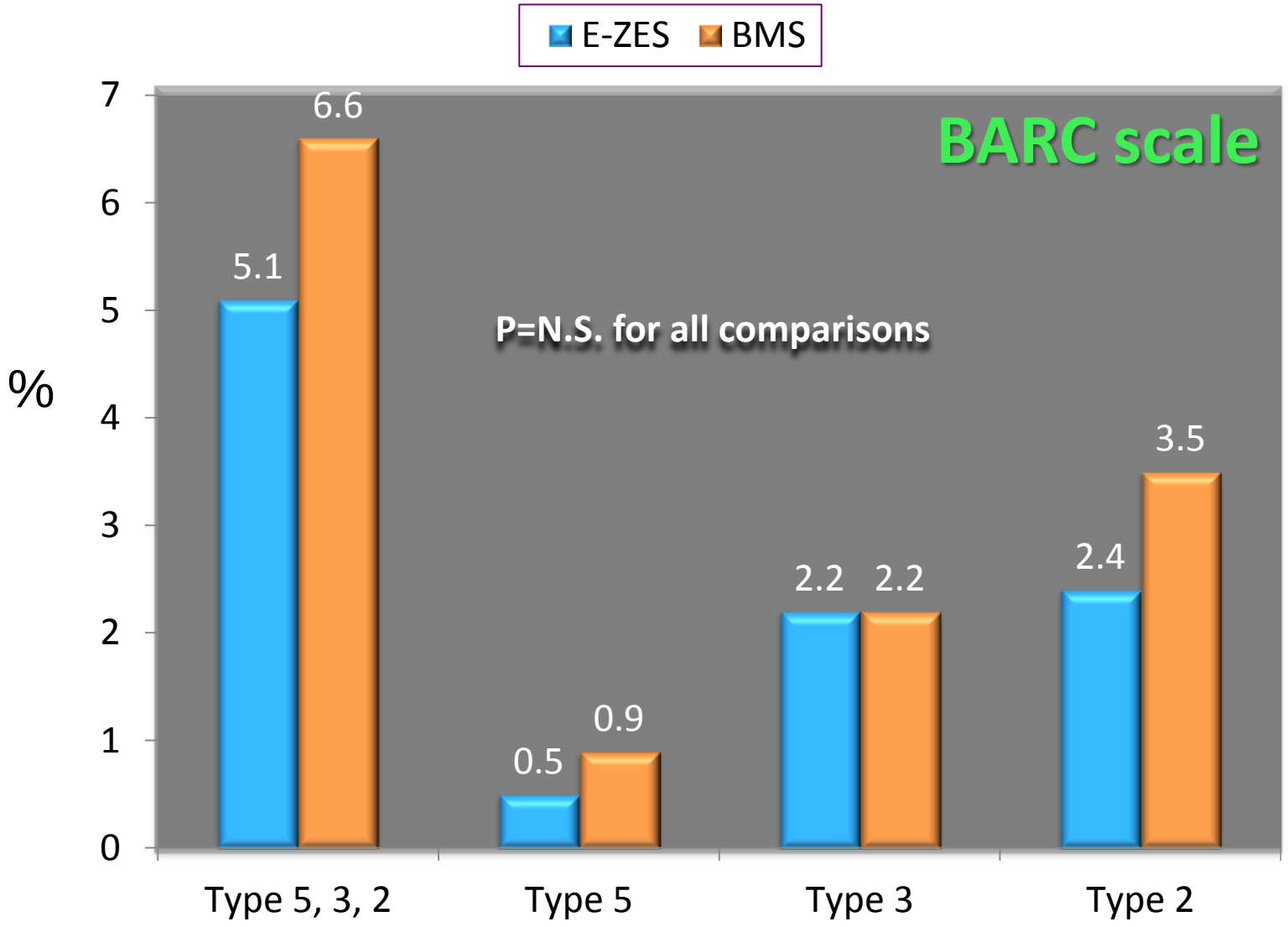

HEAT PPCI

Adeel Shahzad, MD

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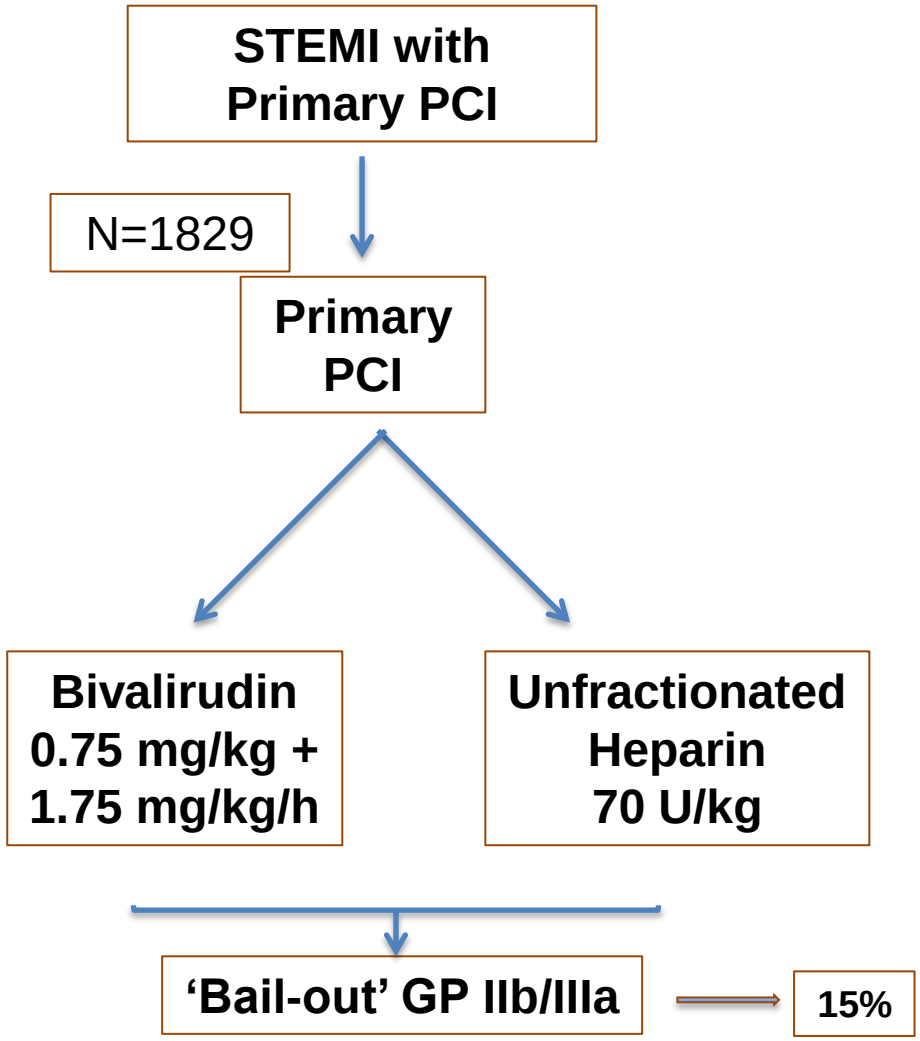

	Bivalirudin	Heparin	RR
1 EP (Death/Stroke / RE-MI/TLR)	8.7%	5.7%	1.52 (1.1 - 2.1) P=0.01
Death	5.1%	4.3%	
uTLR	2.7%	0.7%	
Stent Thrombosis (ARC d + p)	3.4%	0.9%	3.91 (1.6-9.5) P=0.01
Bleeding	3.5%	3.1%	1.15 (0.7 – 1.9)

89 % Pras. or Ticag.

81 % Radial

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HEAT PPCI: Major Issues for Discussion

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- Approval given by UK regulatory authorities
- Informed consent obtained several days after randomization. Can informed consent be obtained in the setting of an acute STEMI?
- "All comers" → 99% of patients with STEMI
- Unexpectedly high rate of acute (<24 hours) stent thrombosis in bivalirudin-treated patients.
- Unlike HORIZONS AMI, there was no late catch-up of stent thrombosis → Effect of prasugrel/ticagrelor?

BRAVE 4 Trial

Gert Richart, MD

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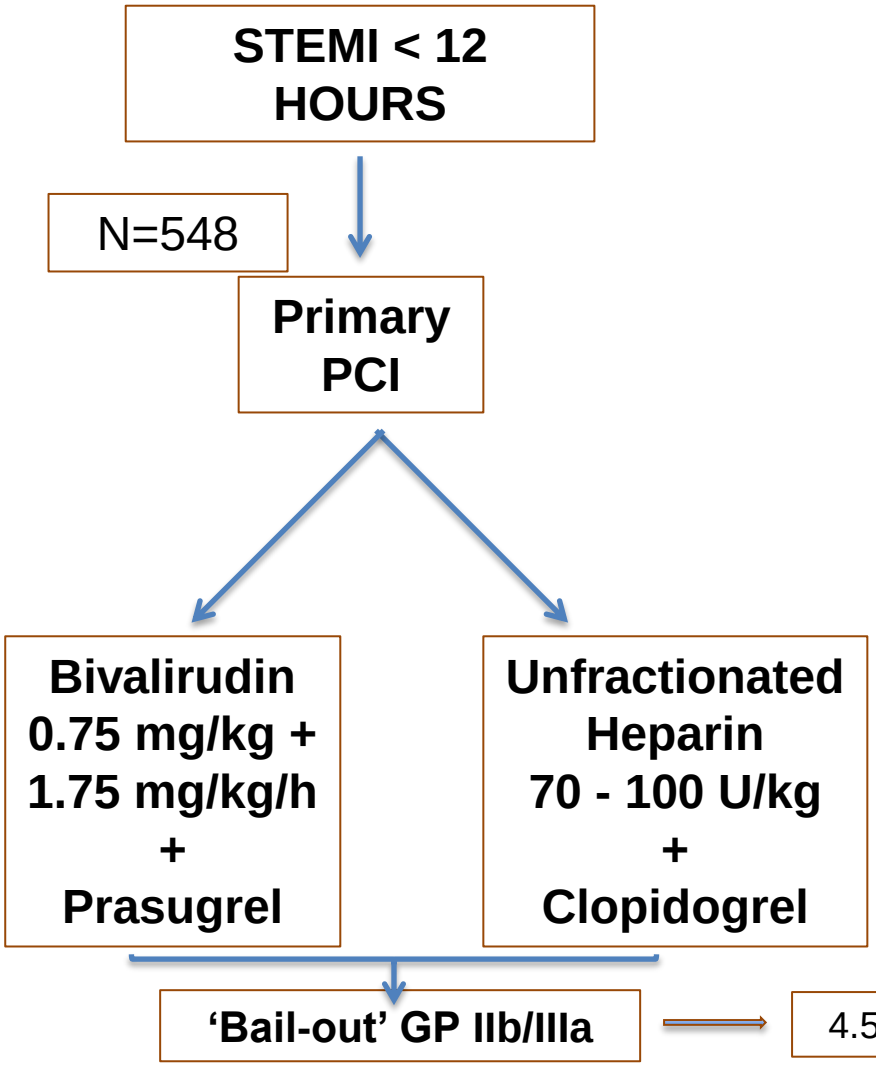

	Bival-irudin	Heparin	P
1 EP (Death/Stroke /uTLR/Stent Thrombosis/ Major Bleeding	15.6%	14.5%	0.68
1 EP (Death/Stroke /uTLR/Stent Thrombosis	4.8%	5.5%	0.89
Death	2.6%	2.5%	0.85
Non-CABG Bleeding	14.2%	12%	0.54

95 % Prasugrel

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NAPLES III Trial

Carlo Briguori, MD

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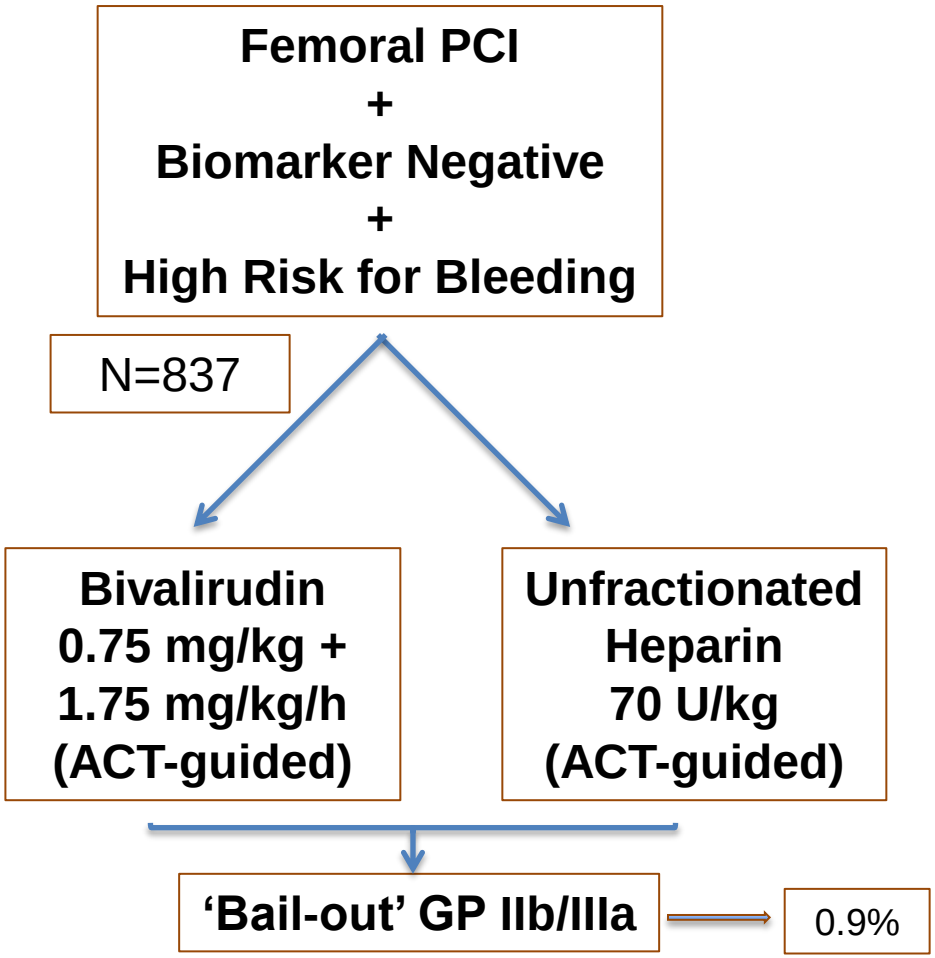

	Bivalirudin	Heparin	RR
1 EP (REPLACE 2 Major Bleeding)	3.3%	2.6%	1.28 (0.58) P=0.54
Transfusion > 2U	0.9%	0.9%	
Major + Minor Bleeding	8.1%	9.1%	0.88 (0.55-1.44) P=0.63
Death	2..4%	1.4%	P=0.31
Stent Thrombosis	0.5%	0.5%	P=0.99

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Bivalirudin vs Heparin

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- Three trials of bivalirudin vs heparin challenge conventional dogma.
- Limitations include number of patients enrolled, number of centers involved, degree of clinical rigor compared with the large multicenter trials.
- Made the point that clinical assumptions need to be revisited every few decades as drug, devices, and practices change.

EVEREST II 5 Year Follow-up

Ted Feldman, MD

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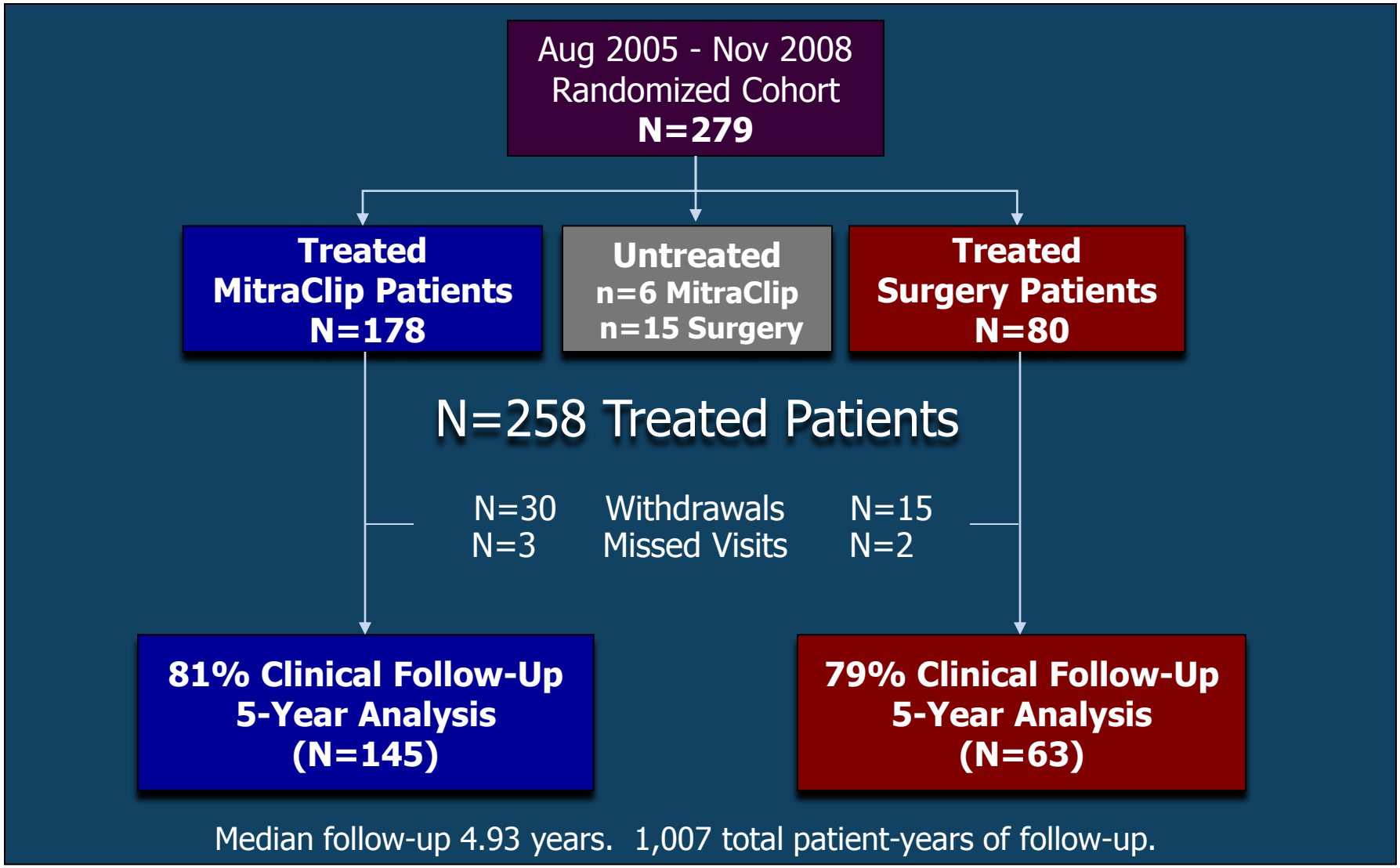

Median follow-up 4.93 years. 1,007 total patient-years of follow-up.

Kaplan-Meier Freedom From MV Surgery in MitraClip Group or Re-operation in Surgery Group

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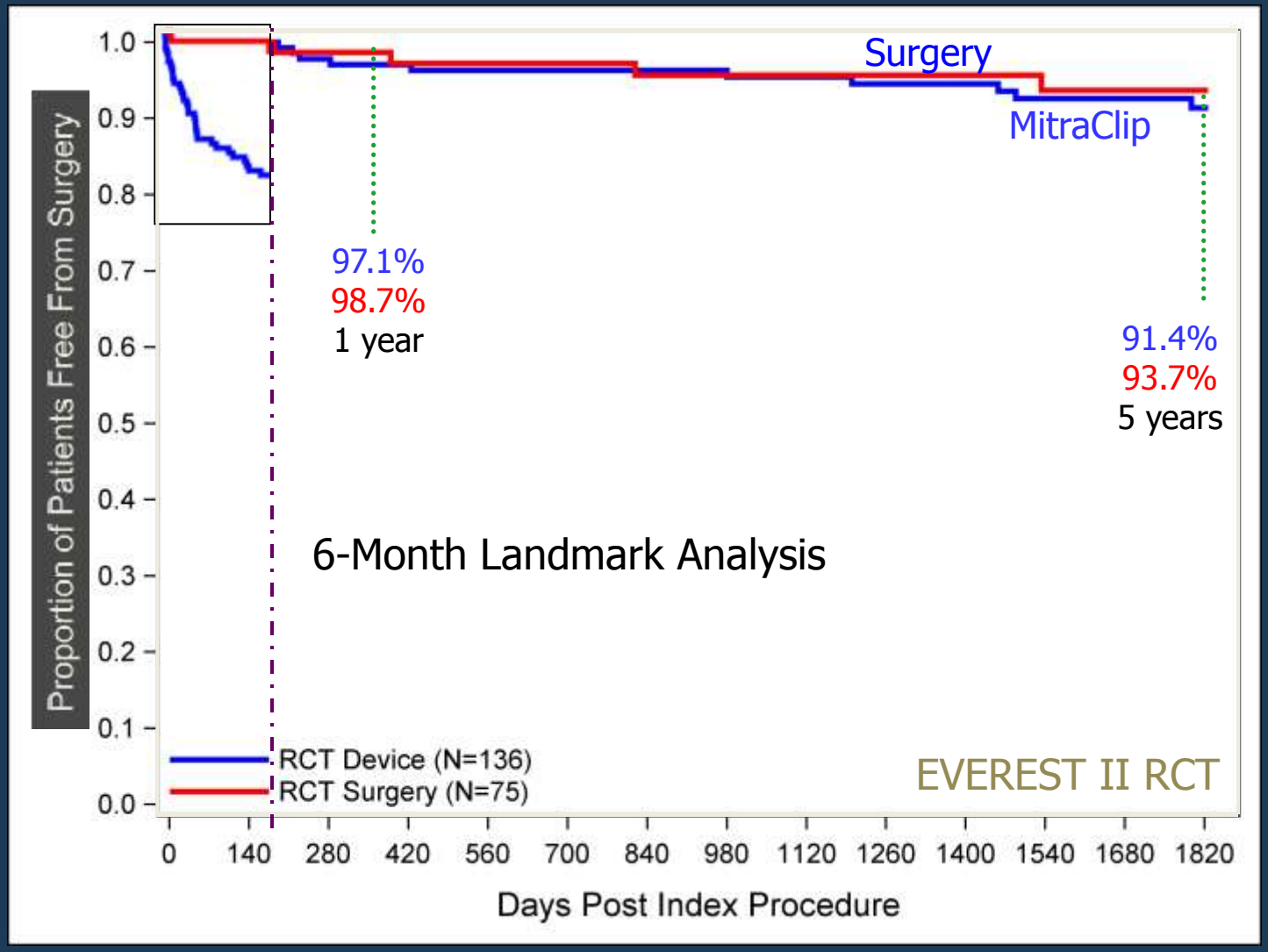

Mitral Regurgitation Grade

EVEREST II RCT All Treated Patients (N=258)

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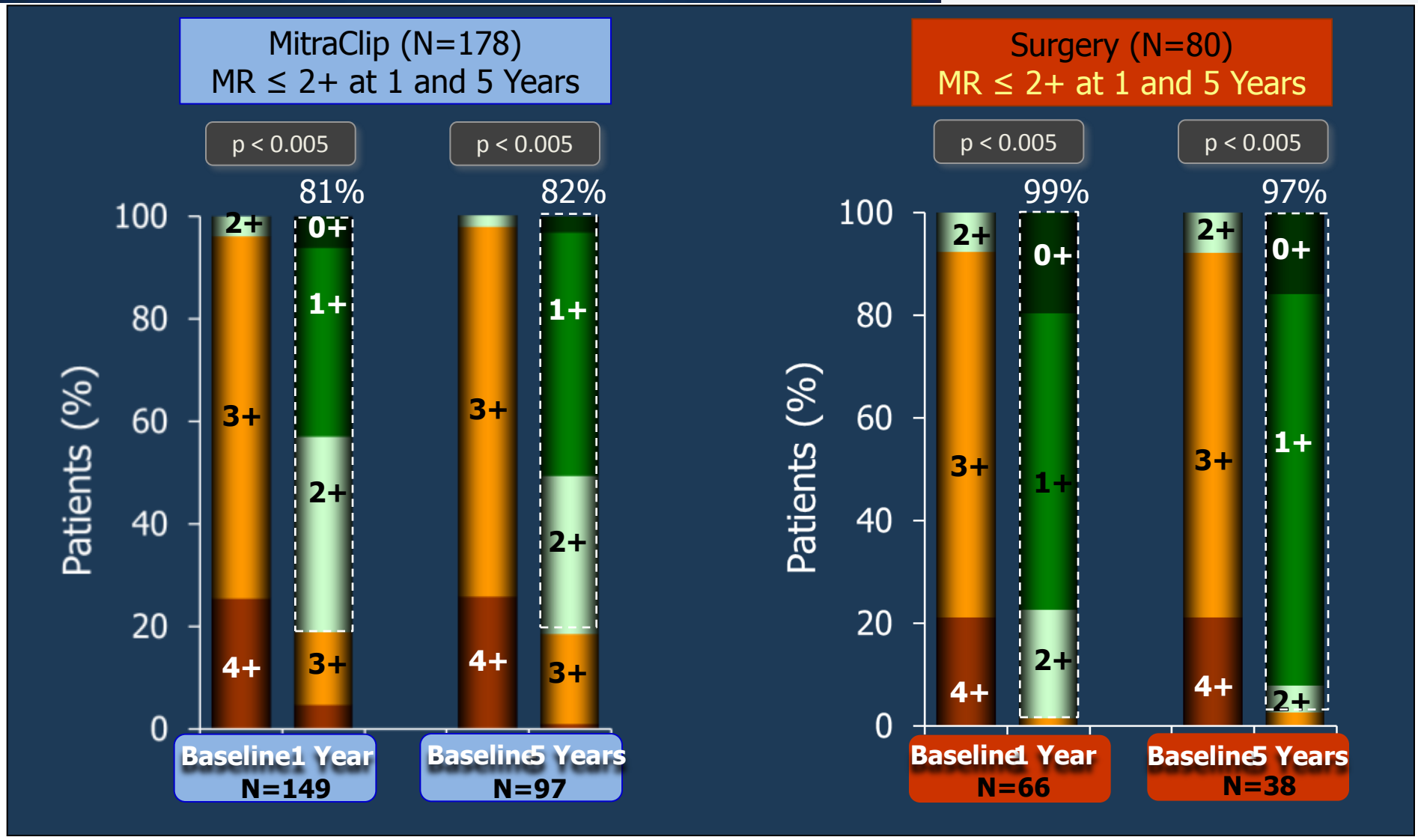

NYHA Functional Class

EVEREST II RCT All Treated Patients (N=258)

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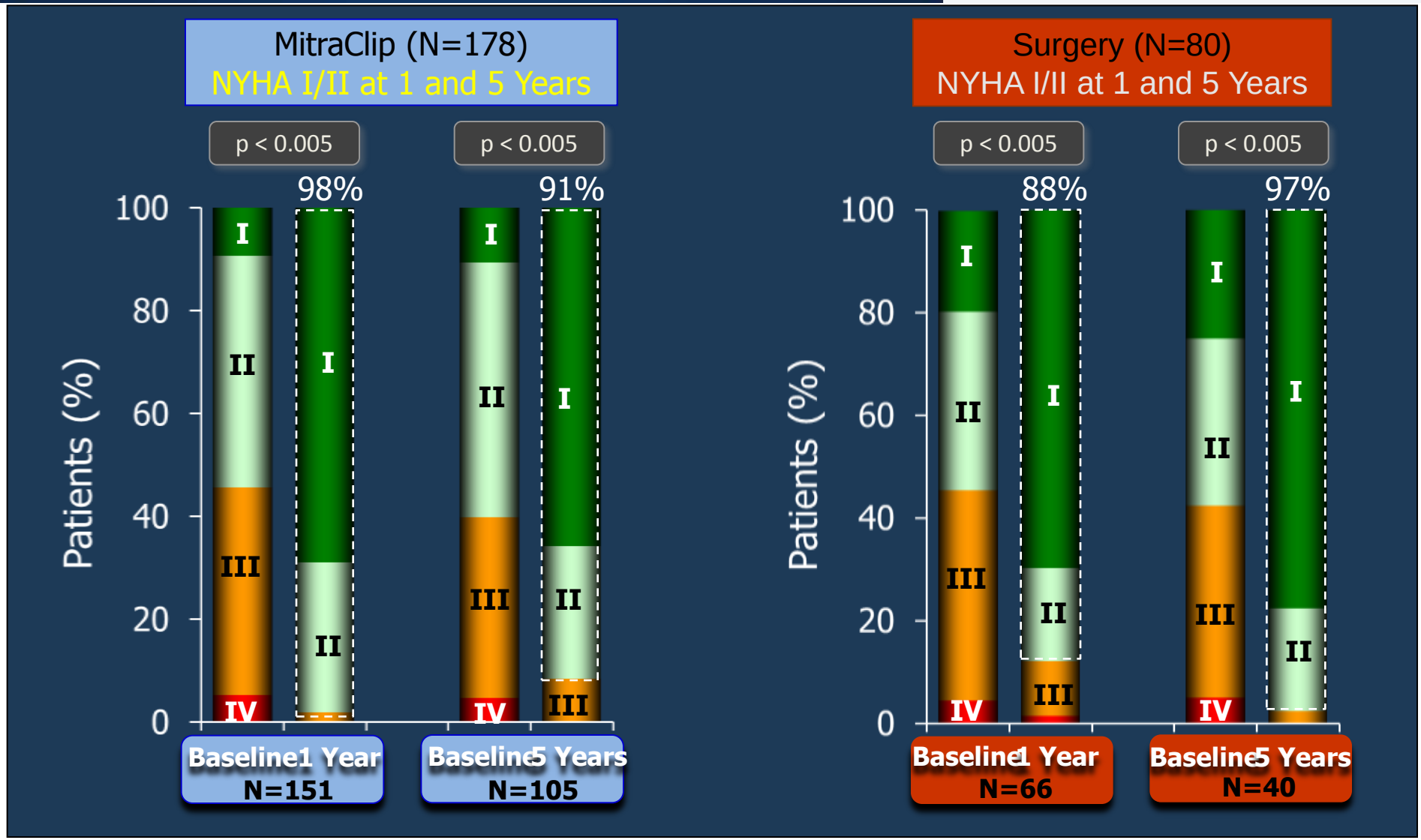

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