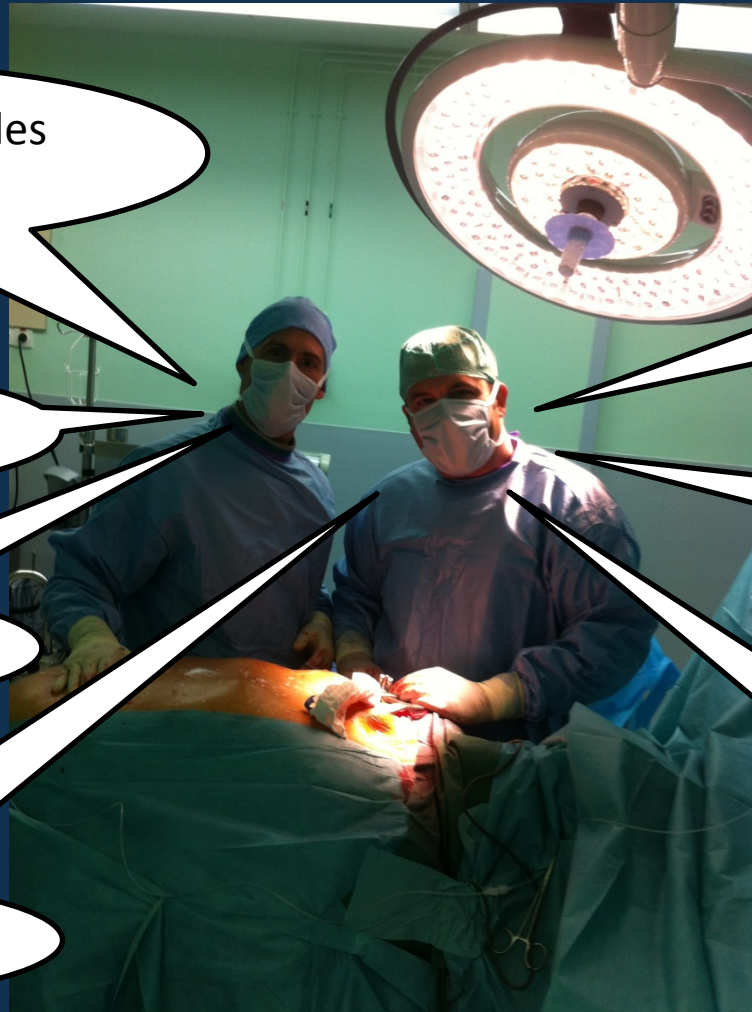


Prise en charge du patient valvulaire :

Que nous apprennent les dernières
données cliniques ?

Eric Maupas, Hôpital Privé Franciscaines, Nîmes
GCS Languedoc Roussillon CHU Montpellier

Des réponses pour alimenter le « café du commerce » - Heart Team...



Ca marche le truc des
cardiologues ?

Il y a des fuites avec
ce truc !!!

Ils ont plus d'AVC !

Il est gros le
tuyau !!!!

Laisse tomber,
c'est que pour
les graves!!!

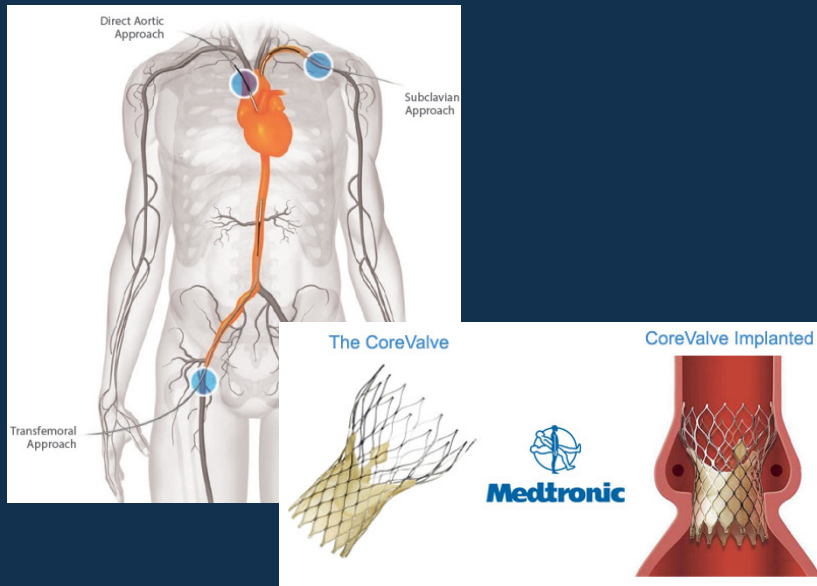
Ils sont capables
d'y arriver ces
tordus...

Si ca fait mieux,
on devient
cardiologue...

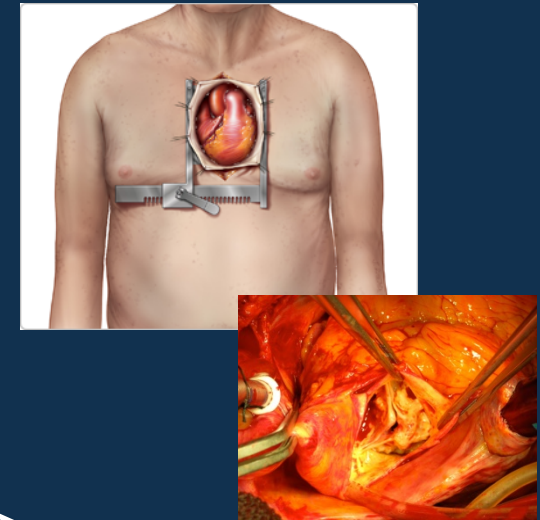
Que retenir des données cliniques

- Résultats cliniques: mortalité, AVC
- Résultats échographiques : fuites aortiques →
 - grade
 - évolution dans le temps
 - retentissement clinique ?
- Quelles conséquences pour la pratique quotidienne:
Sizing CT +++

TAVI



SAVR



CoreValve US Pivotal Trial
Extreme Risk Iliofemoral
Study Results

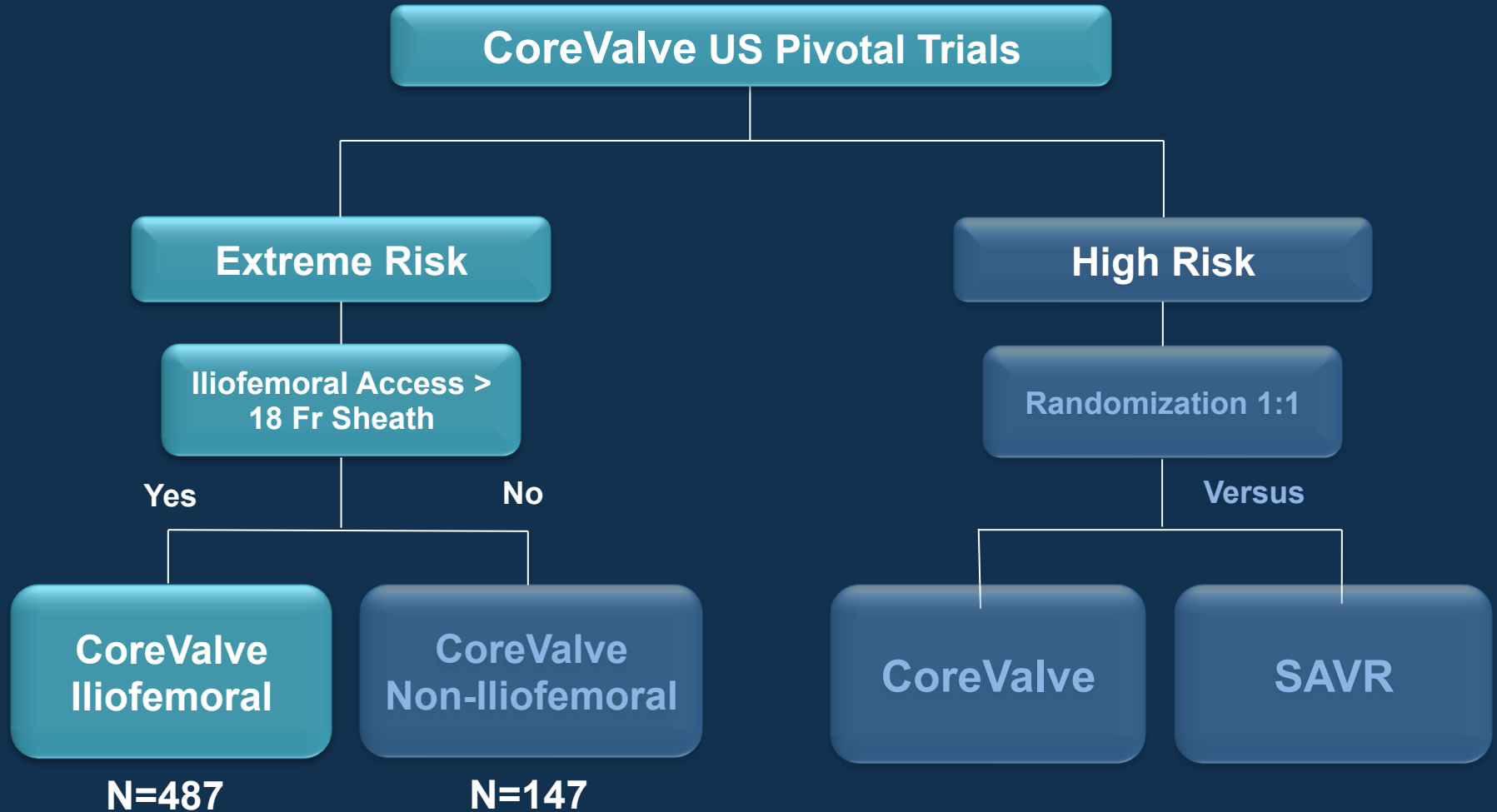
CoreValve US Pivotal Trial
High Risk
Study Results

SurTAVI Trial
Intermediate Risk
Study (recruiting)

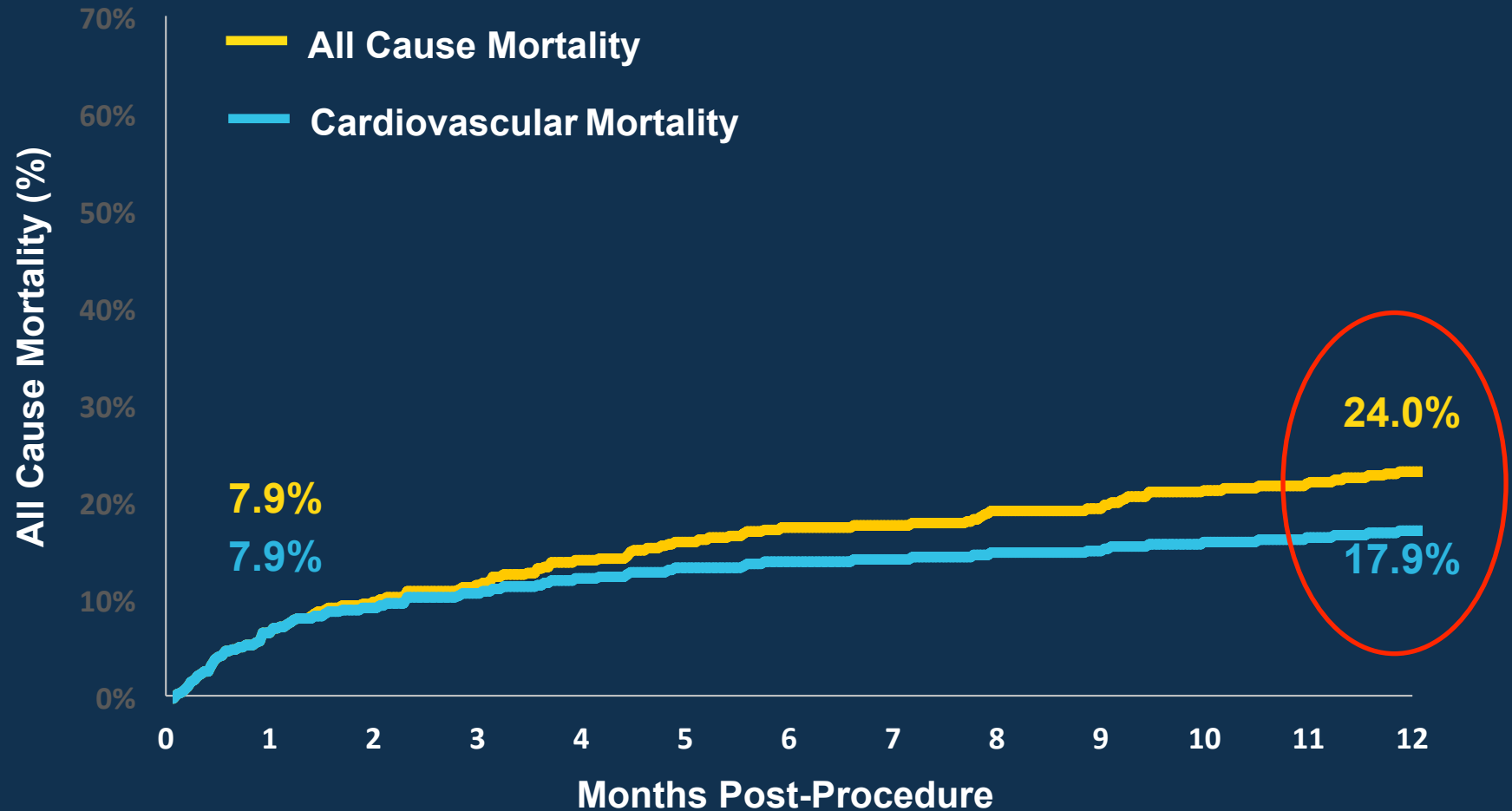


Pivotal Trial Design

CoreValve US Pivotal Trials



High Survival - 1 Year Mortality



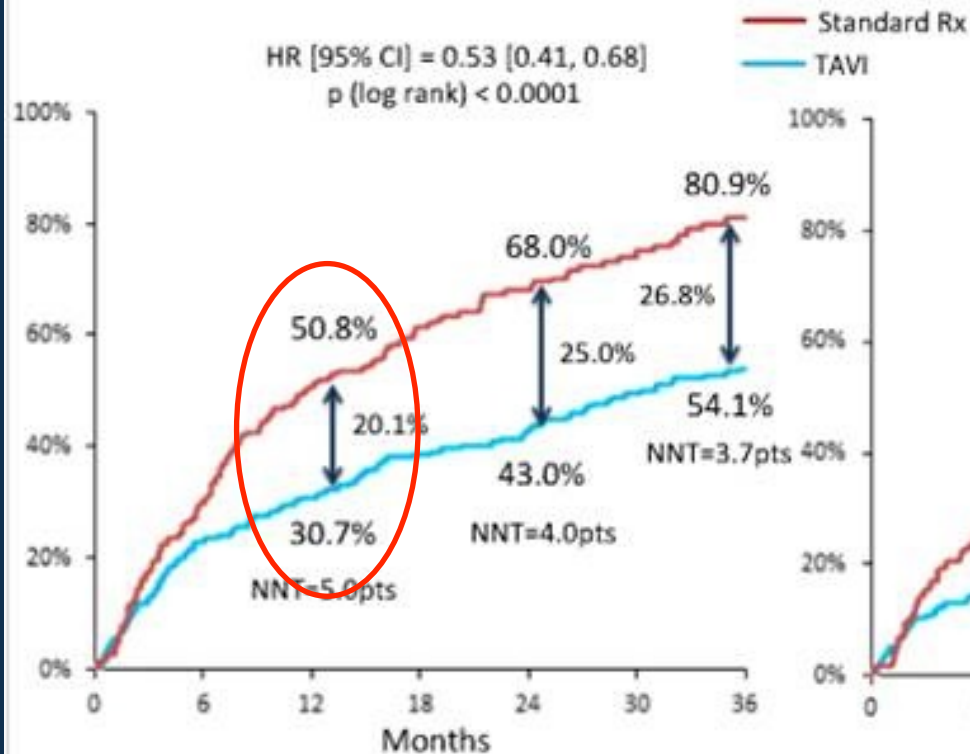
TAVI vs. Medical Treatment

In inoperable Patients – 3 Year F/U

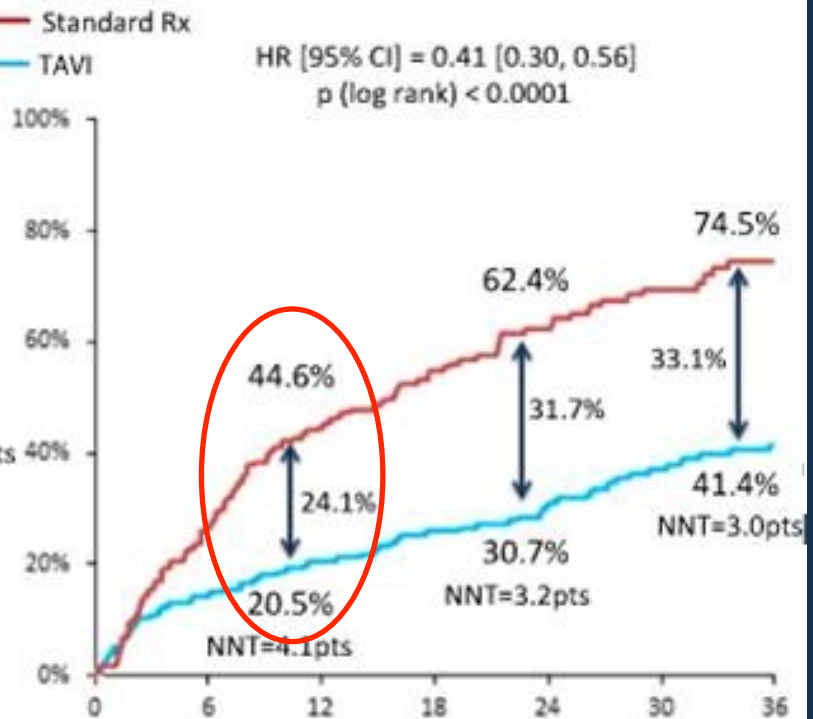
Partner B

Leon MB et al. NEJM 2010; Presented at TCT 2012, Miami

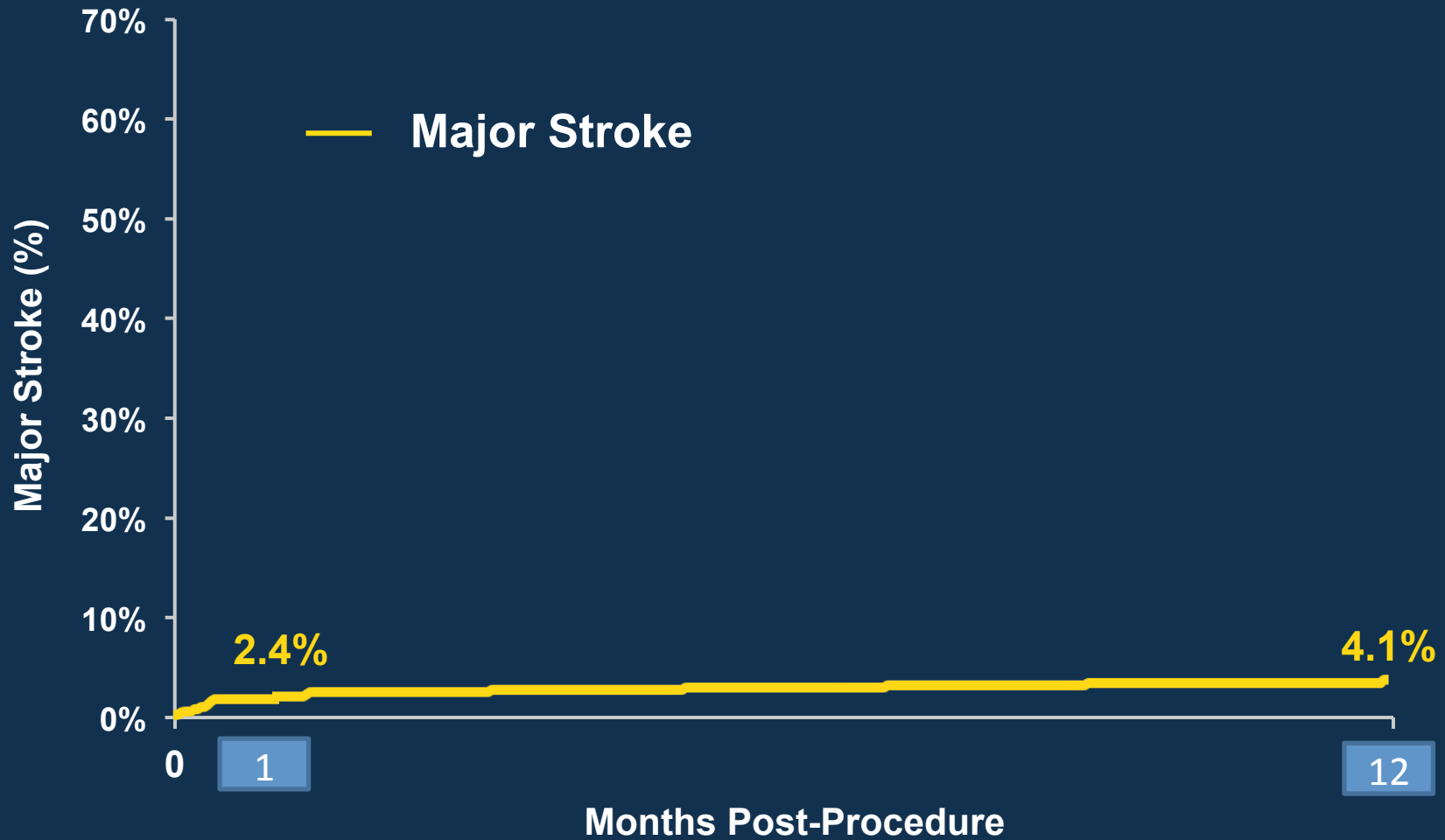
All – Cause Death



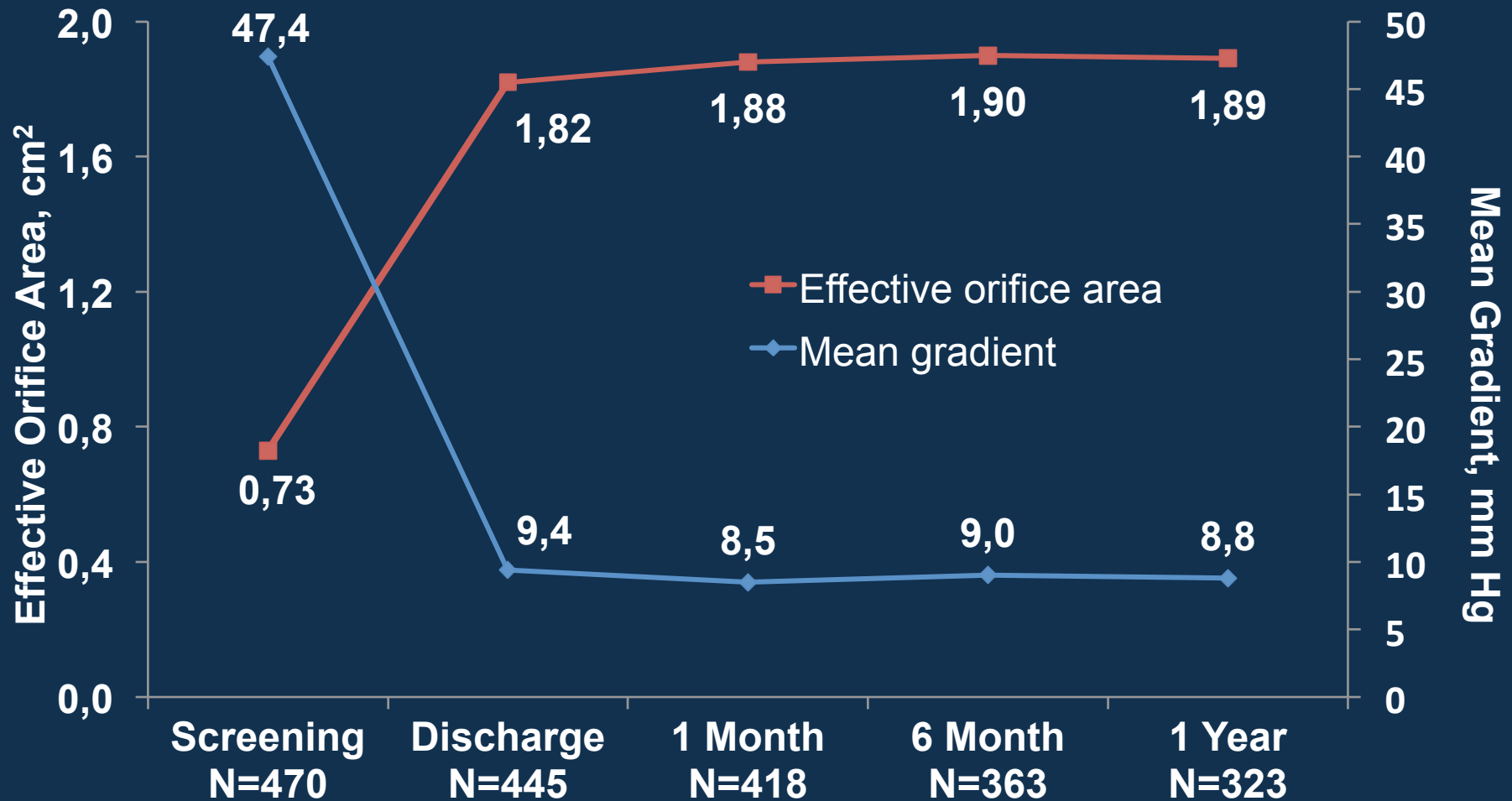
Cardiac Death



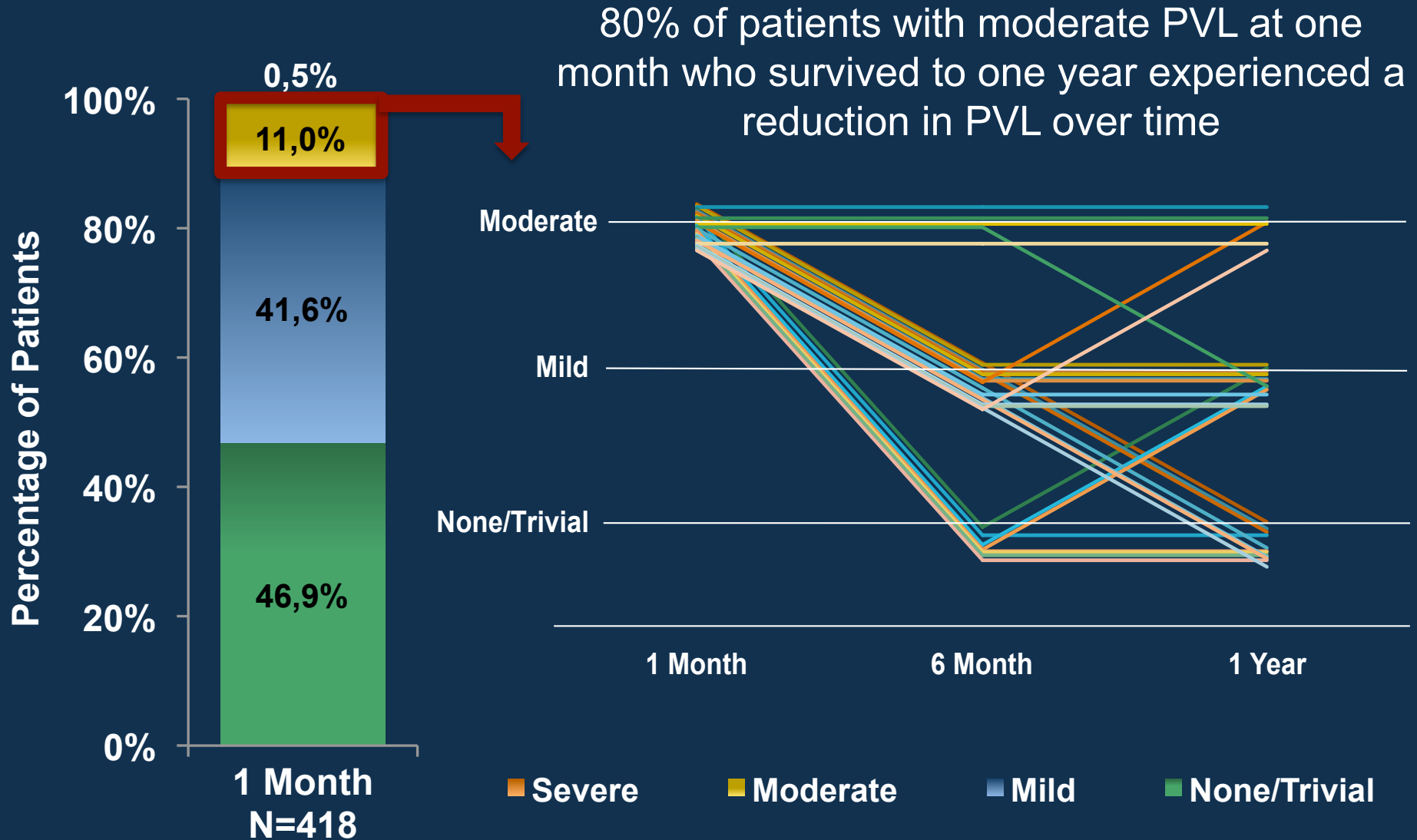
Low and Stable Stroke Rate



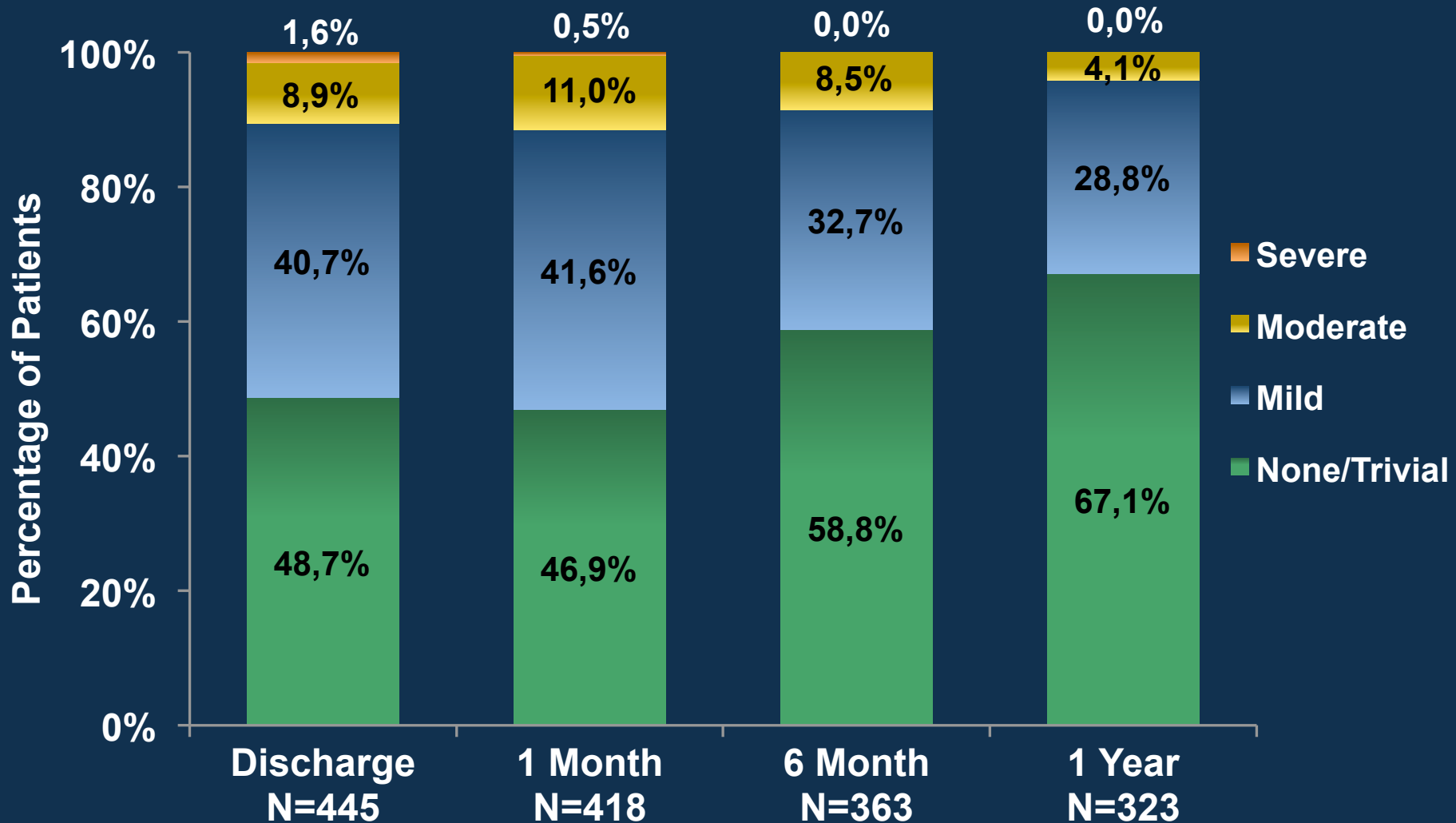
Echocardiographic Findings



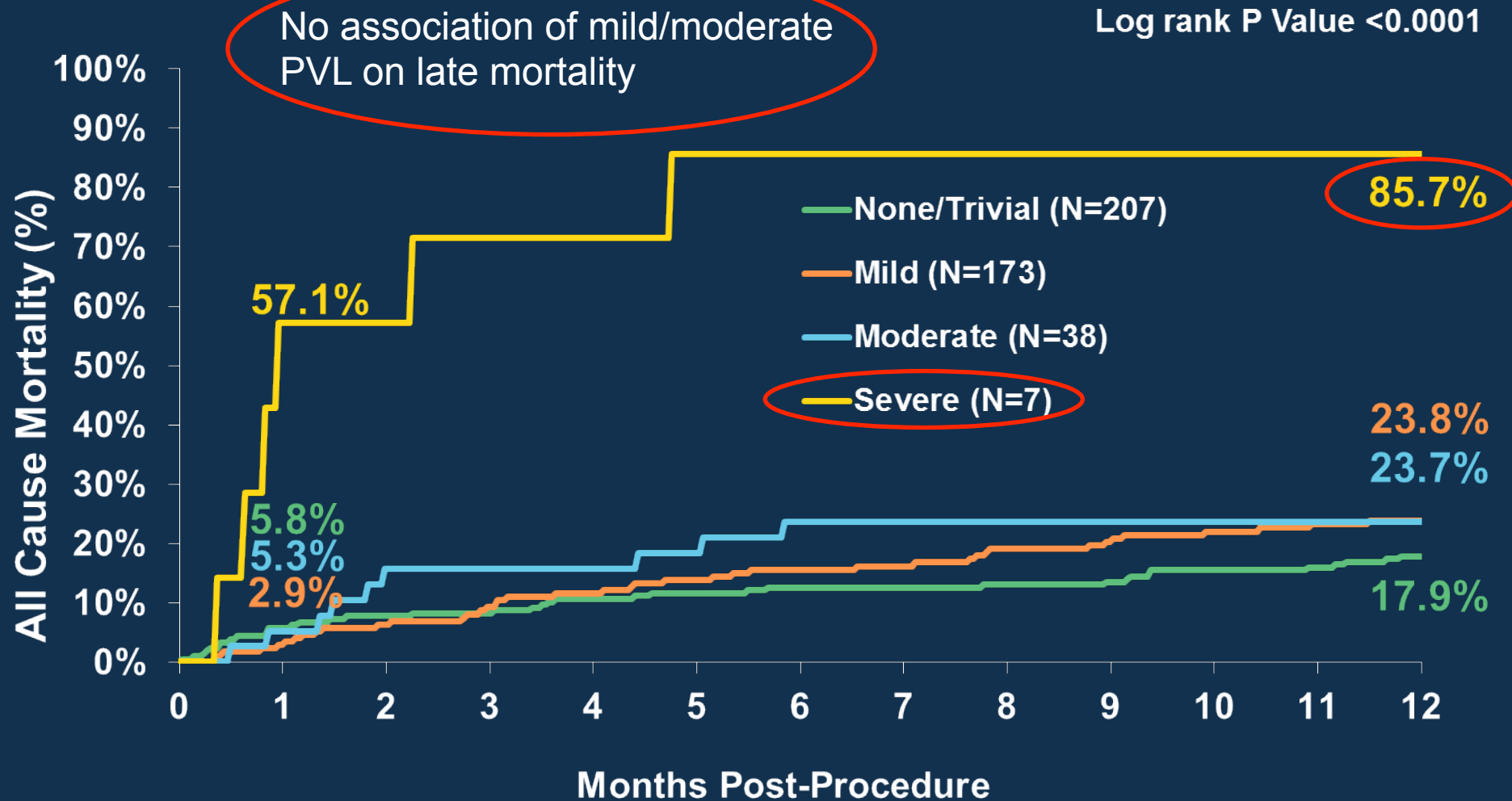
Paravalvular Regurgitation



Paravalvular Regurgitation

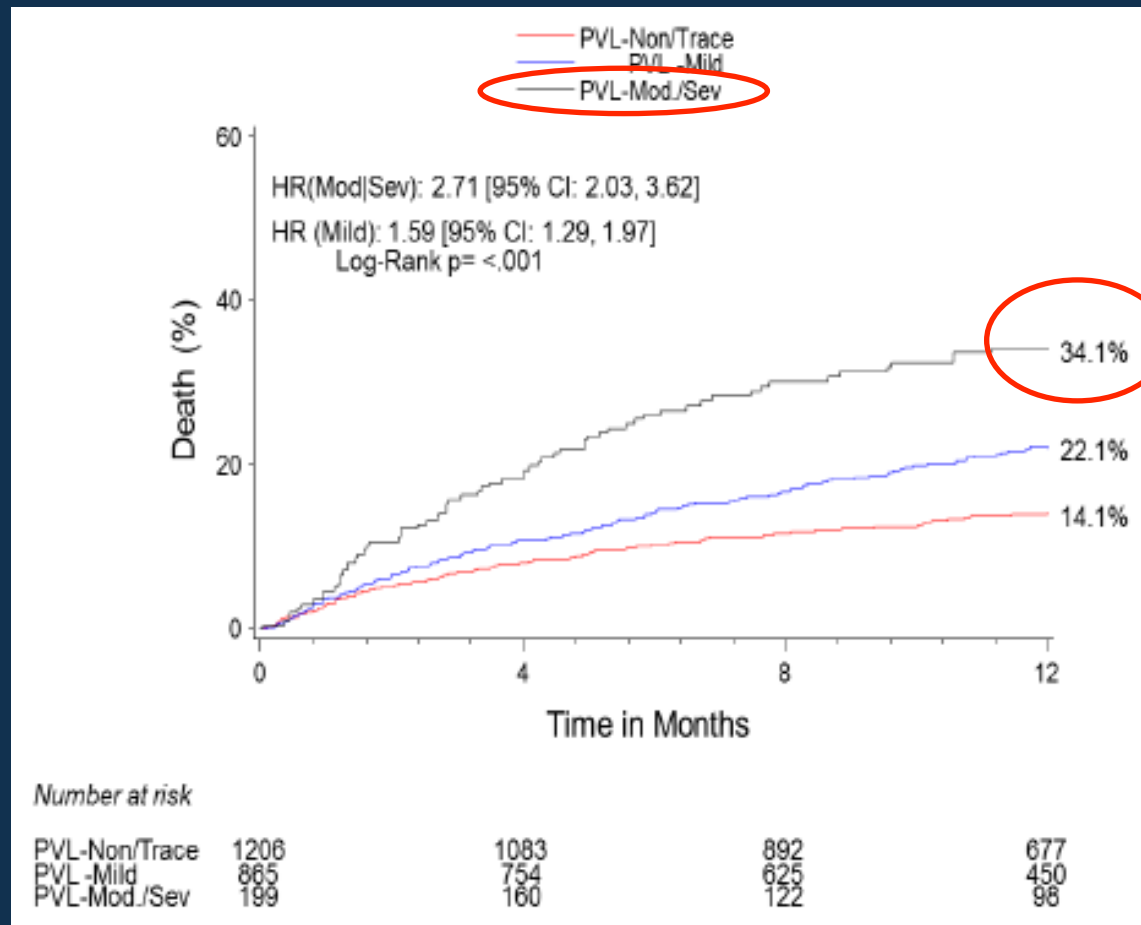
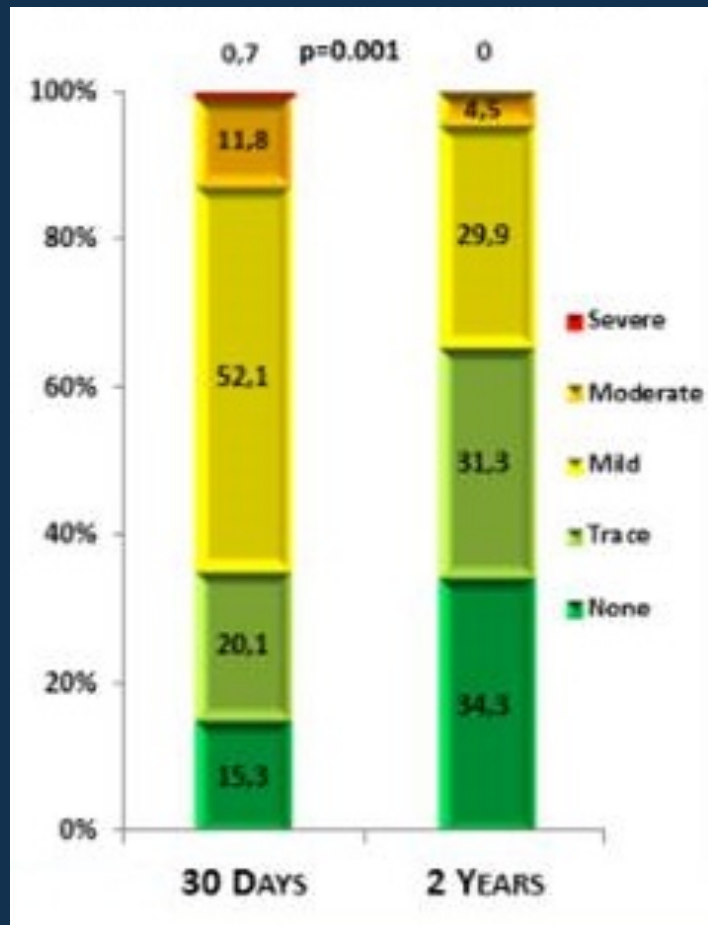


Impact of PVL on Late Mortality



Impact of PVL on Late Mortality

Partner B



Impact of PVL on Late Mortality

Transcatheter Aortic Valve Implantation With the Edwards SAPIEN Versus the Medtronic CoreValve Revalving System Devices

A Multicenter Collaborative Study: The PRAGMATIC Plus Initiative
(Pooled-Rotterdam-Milano-Toulouse In Collaboration)

Alaïde Chieffo, MD,* Gill Louise Buchanan, MBChB,* Nicolas M. Van Mieghem, MD,†
Didier Tchetché, MD,‡ Nicolas Dumonteil, MD,§ Azeem Latib, MD,*
Robert M. A. van der Boon, MSc,† Olivier Vahdat, MD,‡ Bertrand Marcheix, MD, PhD,§
Bruno Farah, MD,‡ Patrick W. Serruys, MD, PhD,† Jean Fajadet, MD,‡ Didier Carrié, MD, PhD,§
Peter P. T. de Jaegere, MD, PhD,† Antonio Colombo, MD*

Registry of Transcatheter Aortic-Valve Implantation in High-Risk Patients

Martine Gilard, M.D., Ph.D., Hélène Eltchaninoff, M.D., Bernard Lung, M.D.,
Patrick Donzeau-Gouge, M.D., Ph.D., Karine Chevreul, M.D., Jean Fajadet, M.D.,
Pascal Leprince, M.D., Alain Leguerrier, M.D., Michel Lievre, Ph.D., Alain Prat, M.D.,
Emmanuel Teiger, M.D., Thierry Lefevre, M.D., Dominique Himbert, M.D.,
Didier Tchetché, M.D., Didier Carrié, M.D., Bernard Albat, M.D., Alain Cribier, M.D.,
Gilles Rioufol, M.D., Ph.D., Arnaud Sudre, M.D., Didier Blanchard, M.D.,
Frederic Collet, M.D., Pierre Dos Santos, M.D., Nicolas Meneveau, M.D., Ph.D.,
Ashok Tirouvanziam, M.D., Christophe Caussin, M.D., Philippe Guyon, M.D.,
Jacques Bosch, M.D., Herve Le Breton, M.D., Frederic Collart, M.D.,
Remi Houel, M.D., Stephane Delpine, M.D., Geraud Souteyrand, M.D.,
Xavier Favereau, M.D., Patrick Ohlmann, M.D., Vincent Doisy, M.D.,
Gilles Grollier, M.D., Antoine Gommeaux, M.D., Jean-Philippe Claudel, M.D.,
Francois Bourlon, M.D., Bernard Bertrand, M.D., Eric Van Belle, M.D., Ph.D.,
and Marc Laskar, M.D., for the FRANCE 2 Investigators*

Major limitations:
No central independent
Echo Core Laboratory

CoreValve US Pivotal Trial High Risk Results

ACC-2014

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D.,
Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D.,
Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D.,
Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O.,
George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D.,
George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D.,
John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D.,
Sharla Chenoweth, M.S., and Jae K. Oh, M.D.,
for the U.S. CoreValve Clinical Investigators*

Pivotal Trial Design

CoreValve US Pivotal Trial

Extreme Risk

**Iliofemoral Access >
18 Fr Sheath**

**CoreValve
Iliofemoral**

**CoreValve
Non-
Iliofemoral**

High Risk

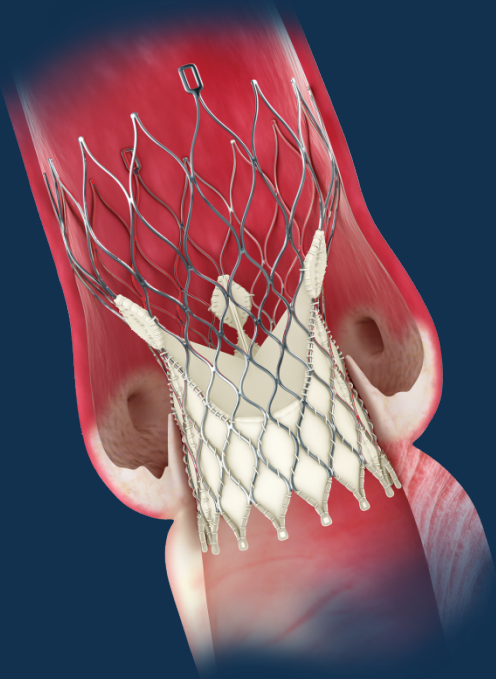
Randomization* 1:1

**CoreValve
(any route)**

SAVR

Compare the safety and effectiveness of TAVR with the CoreValve prosthesis to surgical valve replacement in symptomatic patients with severe aortic stenosis at increased surgical risk

Study Device and Access Routes



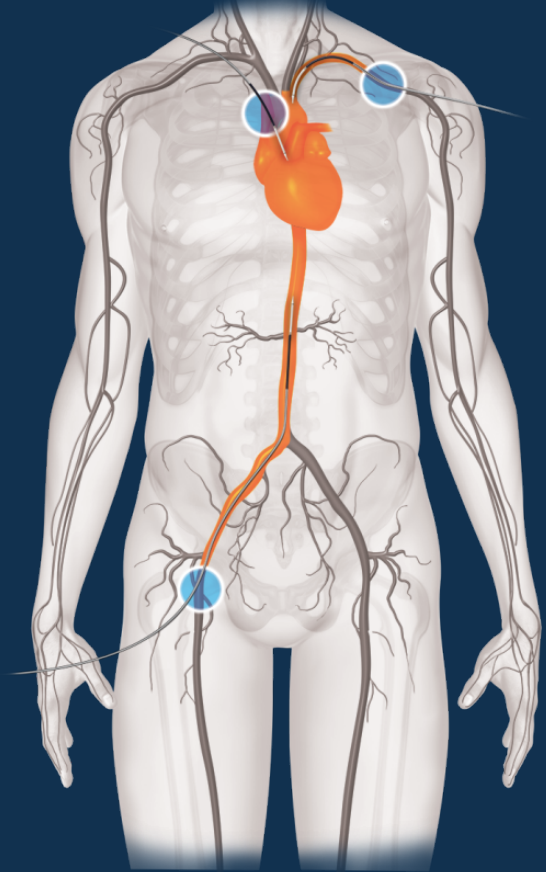
4 valve sizes
(18-29 mm annular range)



SIZING CT ++++



18Fr delivery system



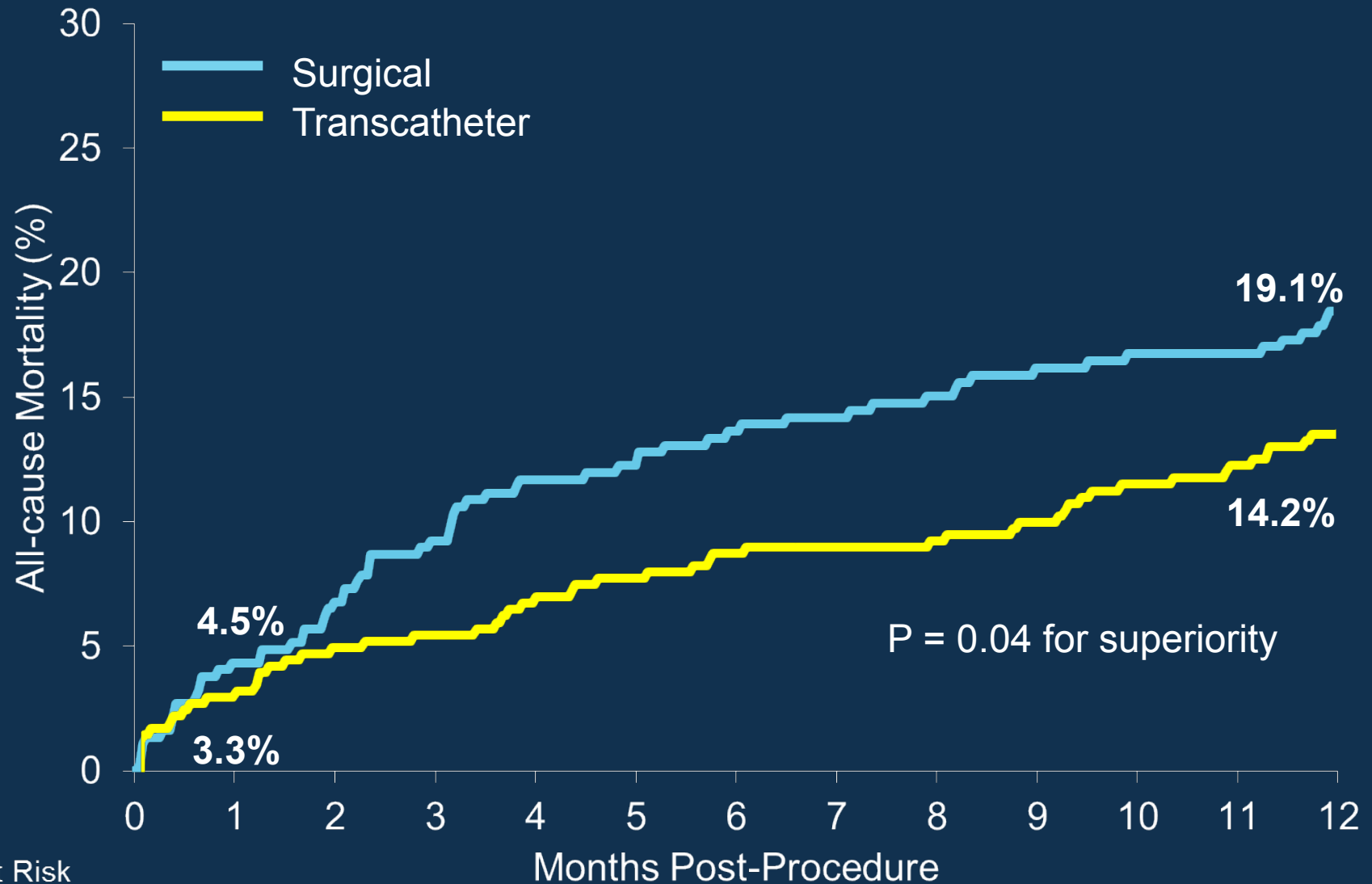
Transfemoral
Subclavian
Direct Aortic

Baseline Demographics

Characteristic	TAVR N=390	SAVR N=357
Age, years	83.1 ± 7.1	83.2 ± 6.4
Men, %	53.1	52.4
STS Predicted Risk of Mortality, %	7.3 ± 3.0	7.5 ± 3.4
Logistic EuroSCORE, %	17.7 ± 13.1	18.6 ± 13.0
NYHA Class III/IV, %	85.6	86.8
Prior Coronary-artery Bypass Surgery	29.5	31.1
Diabetes Mellitus, %	34.9*	45.4*
Insulin Requiring Diabetes, %	11.0	13.2
Prior Stroke, %	12.6	14.0
Modified Rankin 0 or 1, %	74.5	87.2
Modified Rankin > 1, %	25.5	12.8
STS Severe Chronic Lung Disease, %	13.3	9.0

*P < 0.01

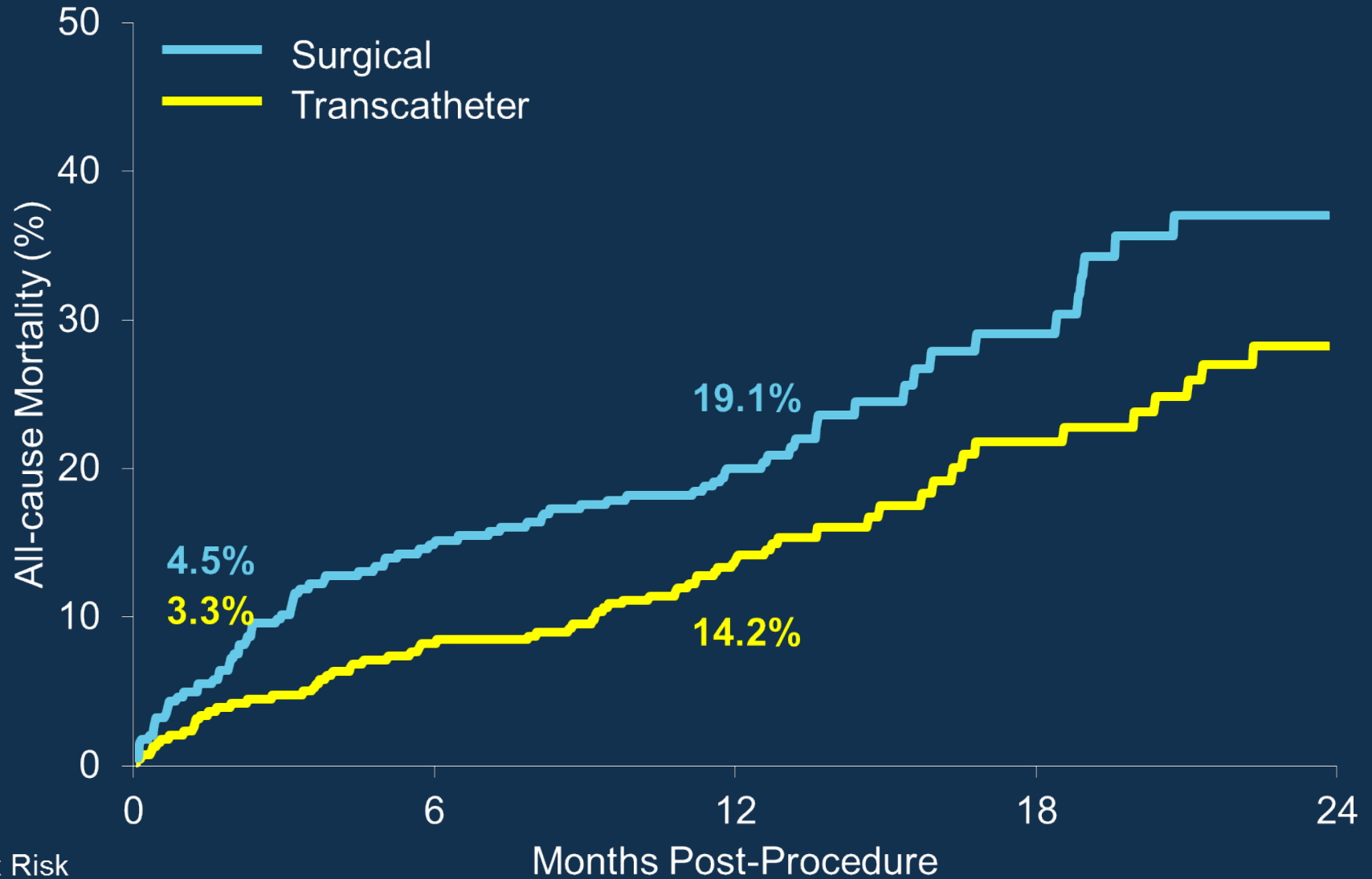
Primary Endpoint: 1 Year All-cause Mortality



No. at Risk

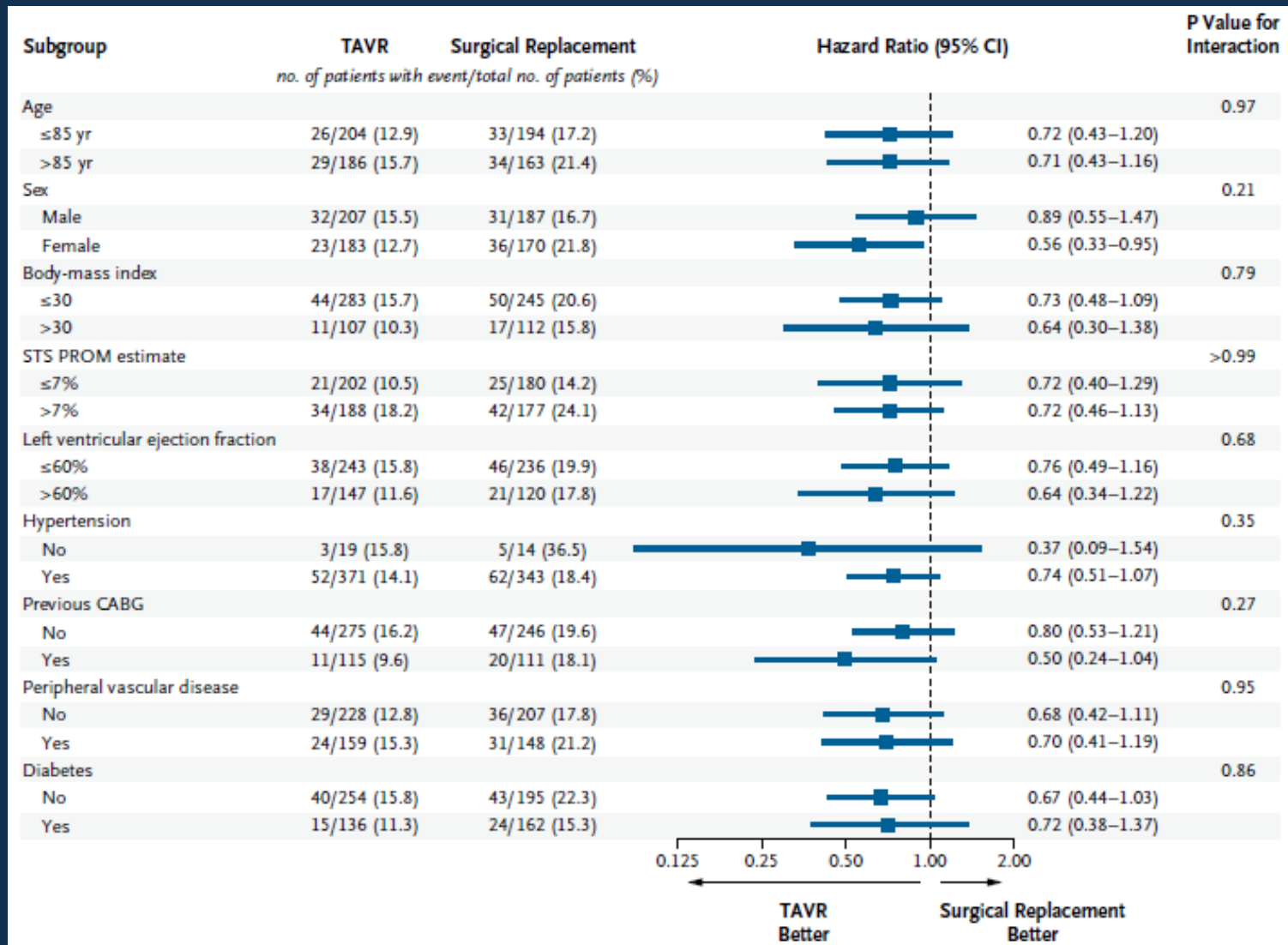
Surgical	357	341	297	274
Transcatheter	390	377	353	329

2-Year All-cause Mortality

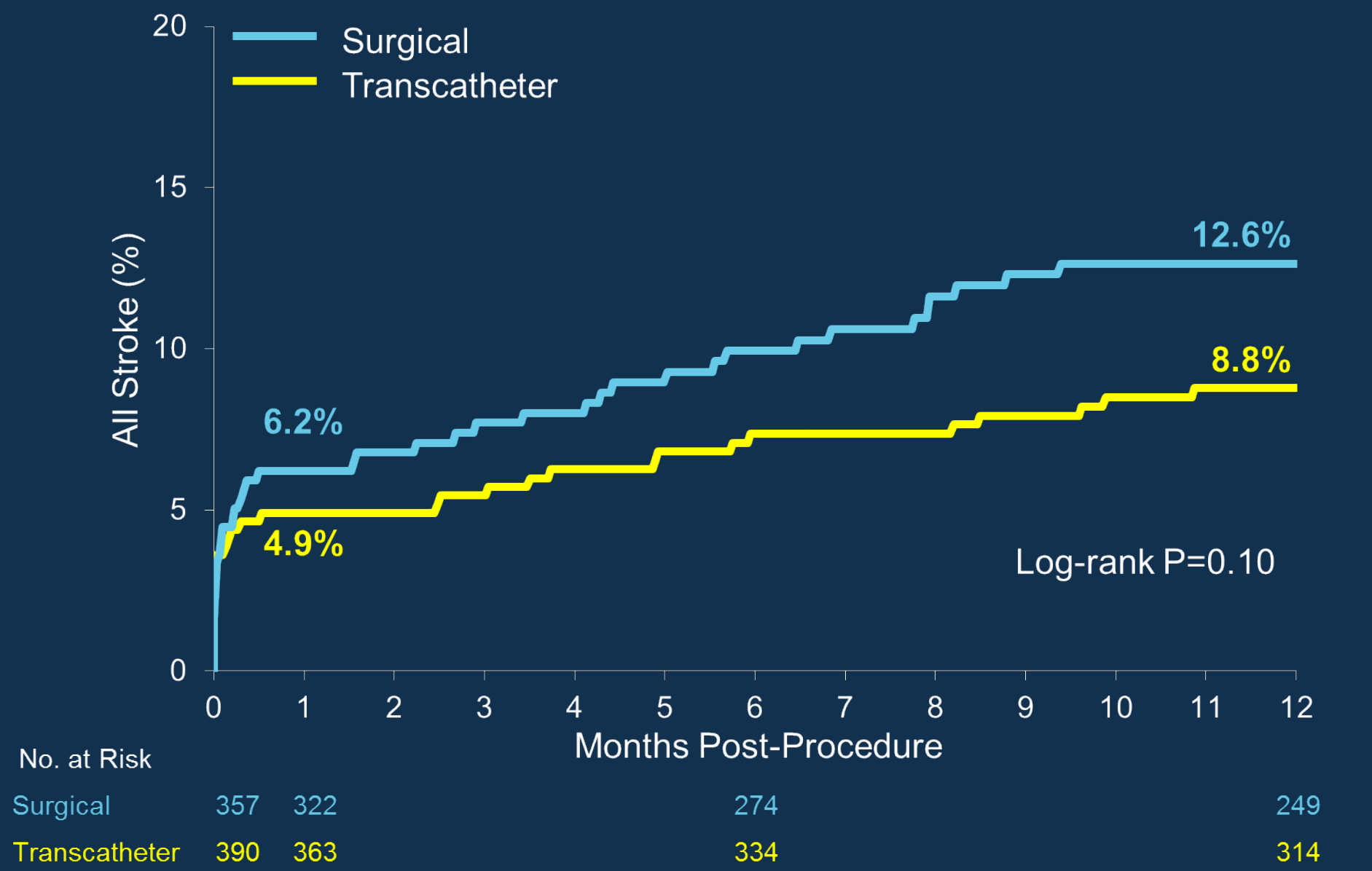


No. at Risk				
Surgical	357	341	274	28
Transcatheter	390	377	329	38

Subgroup Analysis for 1 Year Mortality



All Stroke

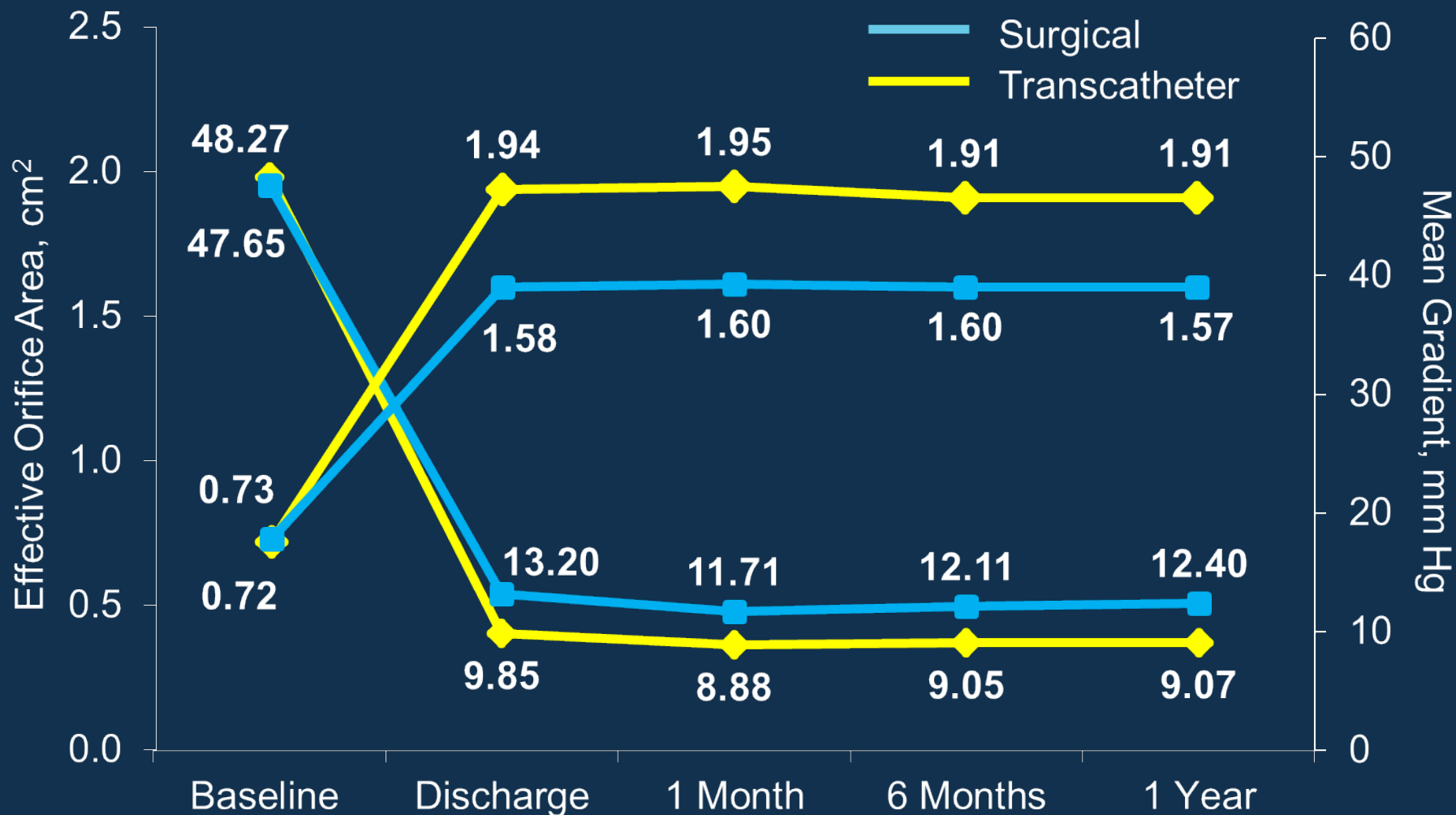


Other Endpoints

Events*	1 Month			1 Year		
	TAVR	SAVR	P Value	TAVR	SAVR	P Value
Vascular complications (major), %	5.9	1.7	0.003	6.2	2.0	0.004
Pacemaker implant, %	19.8	7.1	<0.001	22.3	11.3	<0.001
Bleeding (life threatening or disabling), %	13.6	35.0	<0.001	16.6	38.4	<0.001
New onset or worsening atrial fibrillation, %	11.7	30.5	<0.001	15.9	32.7	<0.001
Acute kidney injury, %	6.0	15.1	<0.001	6.0	15.1	<0.001

* Percentages reported are Kaplan-Meier estimates and log-rank P values

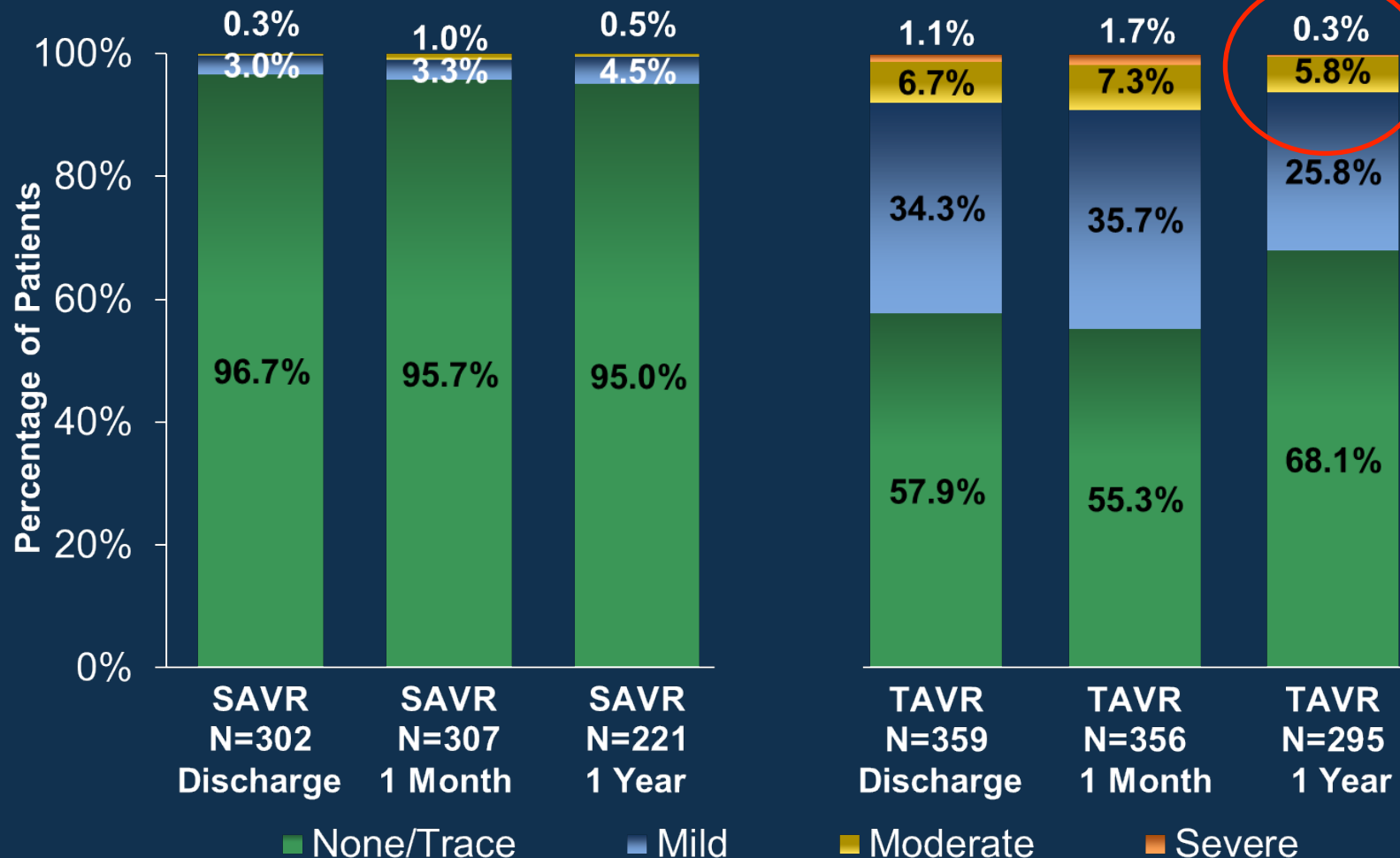
Echocardiographic Findings



Post implant, there were significant differences ($P < 0.001$) between TAVR and SAVR at each time point for both EOA and mean gradient.

Paravalvular Regurgitation

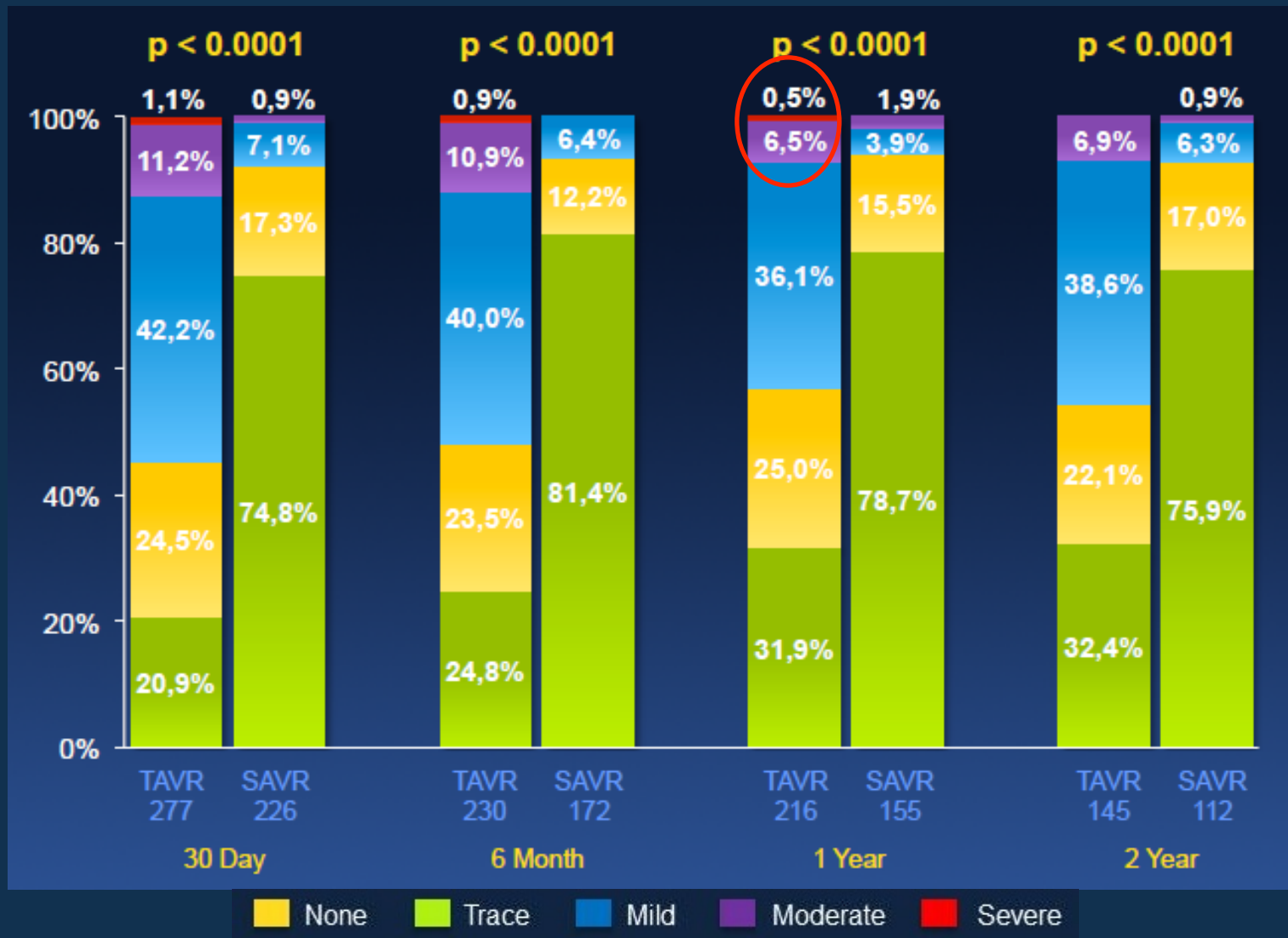
An independent echocardiographic core laboratory
reviewed all echocardiograms



There was significantly lower PVL with SAVR over TAVR at each time point ($P < 0.001$)

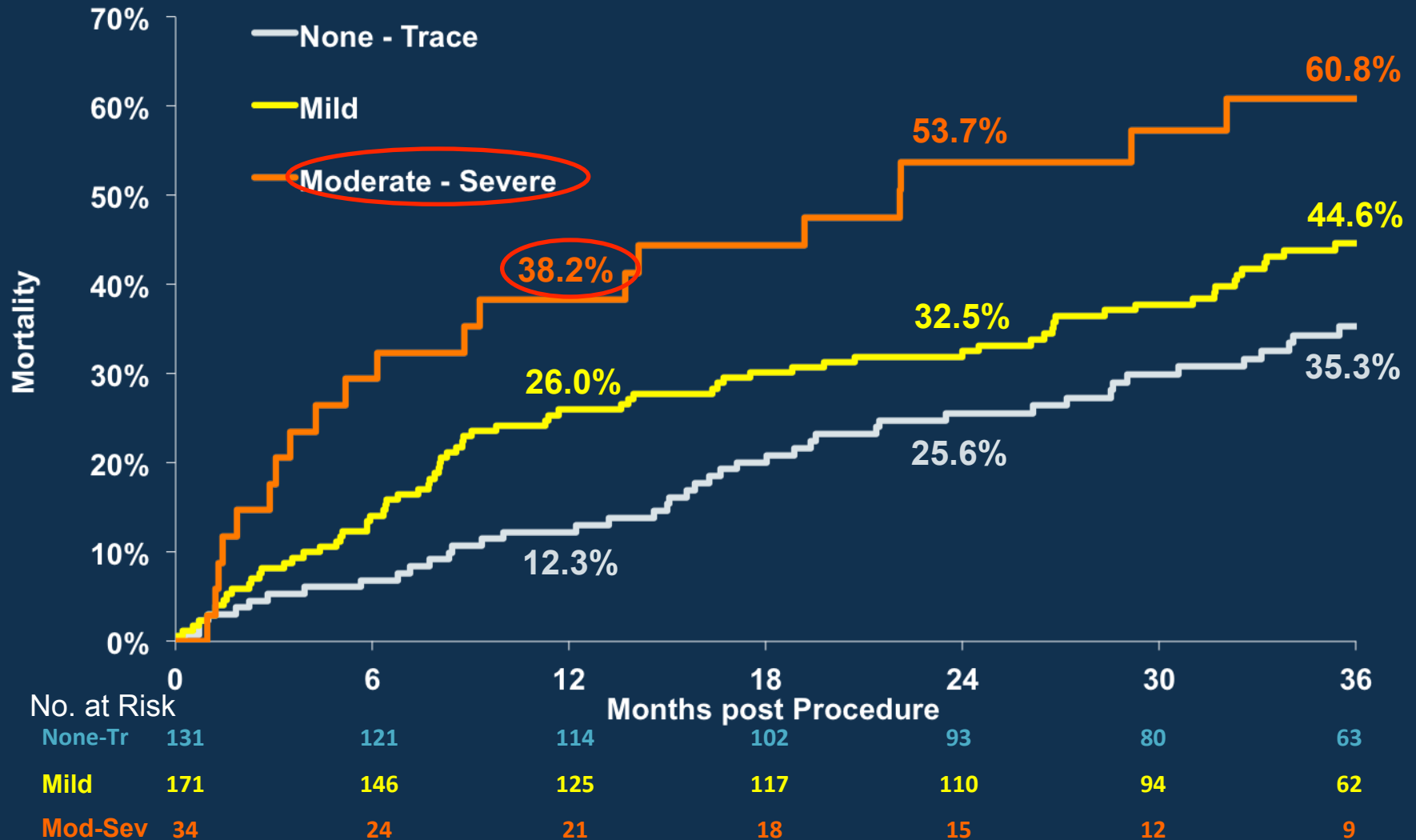
Paravalvular Regurgitation

Partner A



Impact of Total AR on Mortality

Partner A



Conclusions

- **High Survival** : At one year, CoreValve TAVI significantly outperforms surgical valve replacement
- **Low and Stable Stroke Rate**
- **Low rate of moderate/severe aortic regurgitation that improved over time**: These outcomes may be attributable to the use of CT assessment of aortic annular diameter for valve-size selection before enrollment, higher placement of the valve within the aortic annulus, and sustained expansion of the nitinol frame