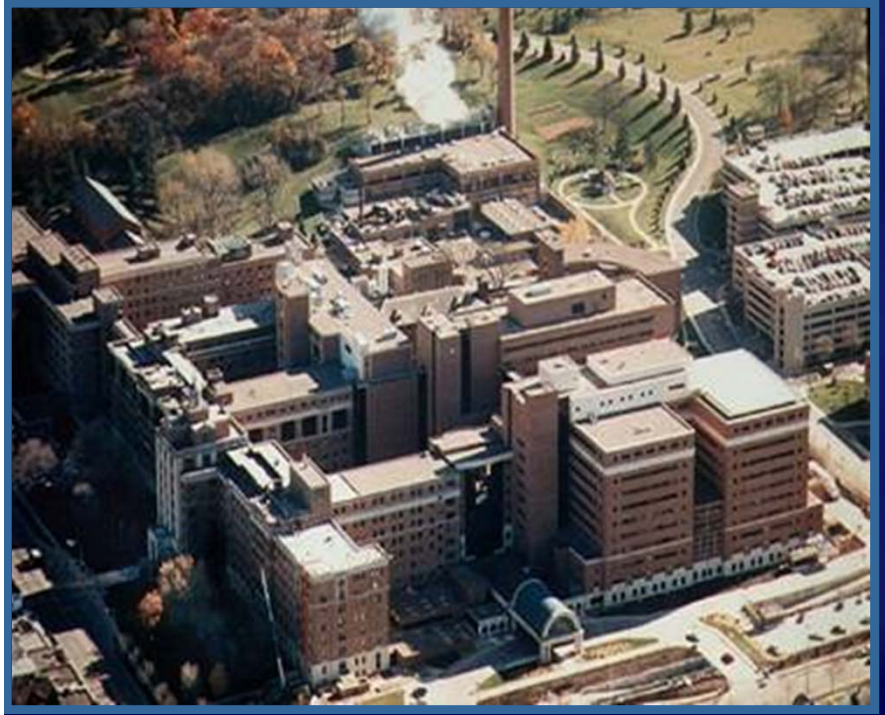


Transcatheter Aortic Valve Replacement

Charanjit S. Rihal MD MBA
Professor of Medicine
Chair, Division of Cardiovascular Diseases

Mayo Clinic and Foundation
Rochester, MN, USA

DISCLOSURES

Research: Edwards Lifesciences
Personal: None

Learning Objectives

1. Identify candidates for transcutaneous valve placement
2. Understand novel alternatives for management of aortic stenosis
3. Review the latest randomized clinical data

Outline

1. What is the role of TAVR for inoperable patients with AS?
2. How does TAVR compare with AVR for high-risk AS?
3. What is the risk of stroke?
4. Does paravalvular leak matter?
5. Is TAVR cost effective?

HES 75M

Symptoms

- NYHA 3-4
- CCS 2

Comorbidities

- Prior CABG
- Sternal rewiring
- TIA / stroke
- s/p right CEA
- HTN, lipids
- Sleep apnea
- Duodenal ulcer

HES 75M

Echo

- EF 65%
- Gradient 68 mm Hg
- Vmax 4.7
- Valve area 0.68 cm2 (normal > 3)
- Annulus 23 mm

Cath

- Internal thoracic artery graft patent
- 2 saphenous vein grafts patent

More about Risk Calculator | New | Print

Today's Date 11/24/2008

edure

Coronary Artery Bypass (•) Yes ( ) No ( ) Missing

Ventricular Assist Device ( ) Yes (•) No ( ) Missing

Valve Surgery (•) Yes ( ) No ( ) Missing

Aortic
- ( ) No
- (•) Replacement
- ( ) Repair/Reconstruction
- ( ) Root Reconstruction with Valve Conduit
- ( ) Replacement + aortic graft conduit (not a valve conduit)
- ( ) Root Reconstruction with Valve Sparing
- ( ) Resuspension Aortic Valve with replacement of ascending Aorta
- ( ) Resuspension Aortic Valve without replacement of ascending Aorta
- ( ) Resection Sub-Aortic Stenosis
- ( ) Missing

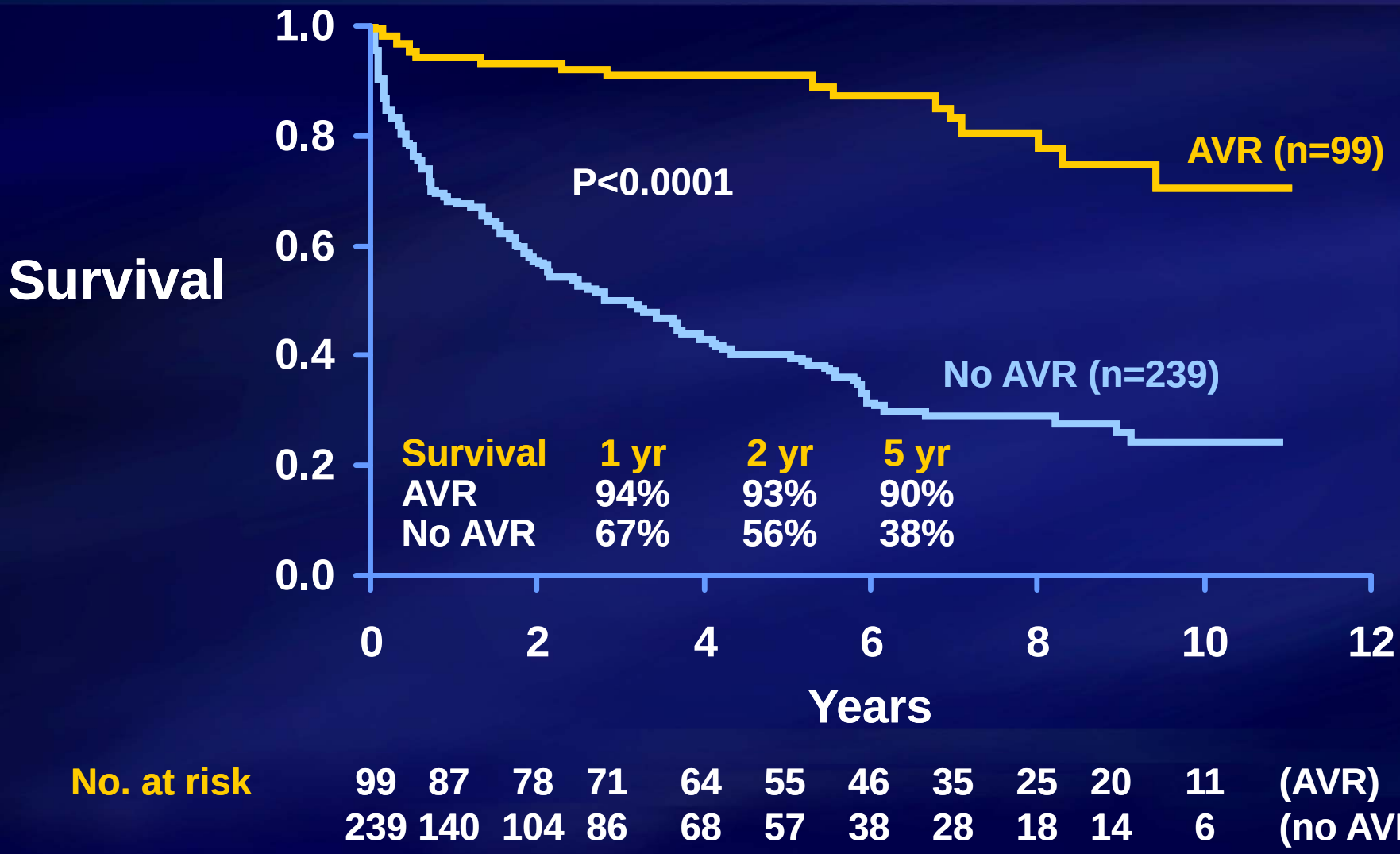
Mitral
- (•) No
- ( ) Annuloplasty Only
- ( ) Replacement
- ( ) Reconstruction with Annuloplasty
- ( ) Reconstruction without Annuloplasty
- ( ) Missing

Tricuspid
- (•) No
- ( ) Annuloplasty Only
- ( ) Replacement
- ( ) Reconstruction with Annuloplasty

Calculations

Procedure Name	AVRepl+CABG
Risk of Mortality	12.3%
Morbidity or Mortality	57.9%
Long Length of Stay	31.5%
Short Length of Stay	7.2%
Permanent Stroke	5.9%
Prolonged Ventilation	46.7%
DSW Infection	0.8%
Renal Failure	22.1%
Reoperation	22.1%

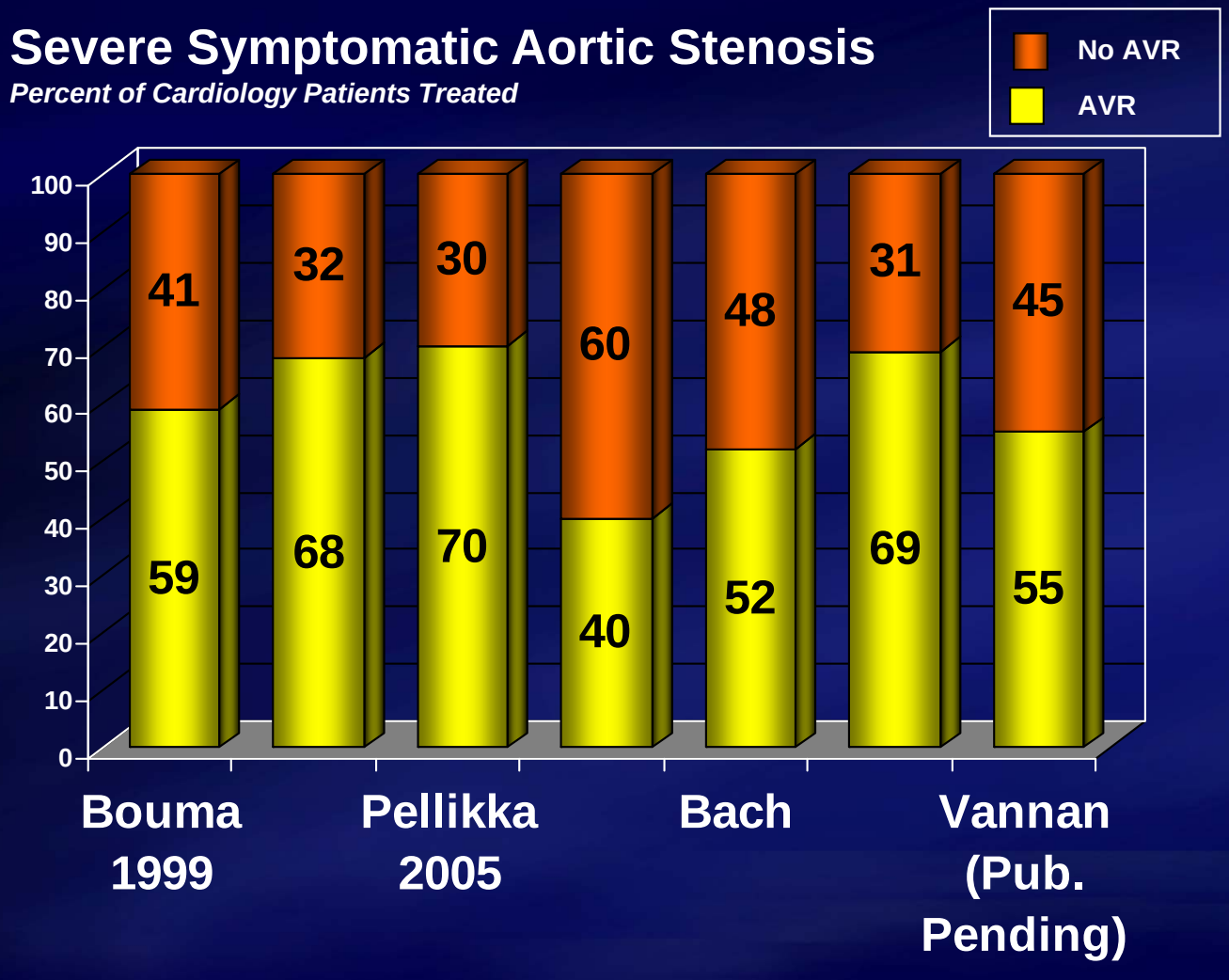
Severe Aortic Stenosis (Asymptomatic) with and without surgery



MAYO CLINIC

Pai et al: Ann Thorac Surg 82:2116, 2006

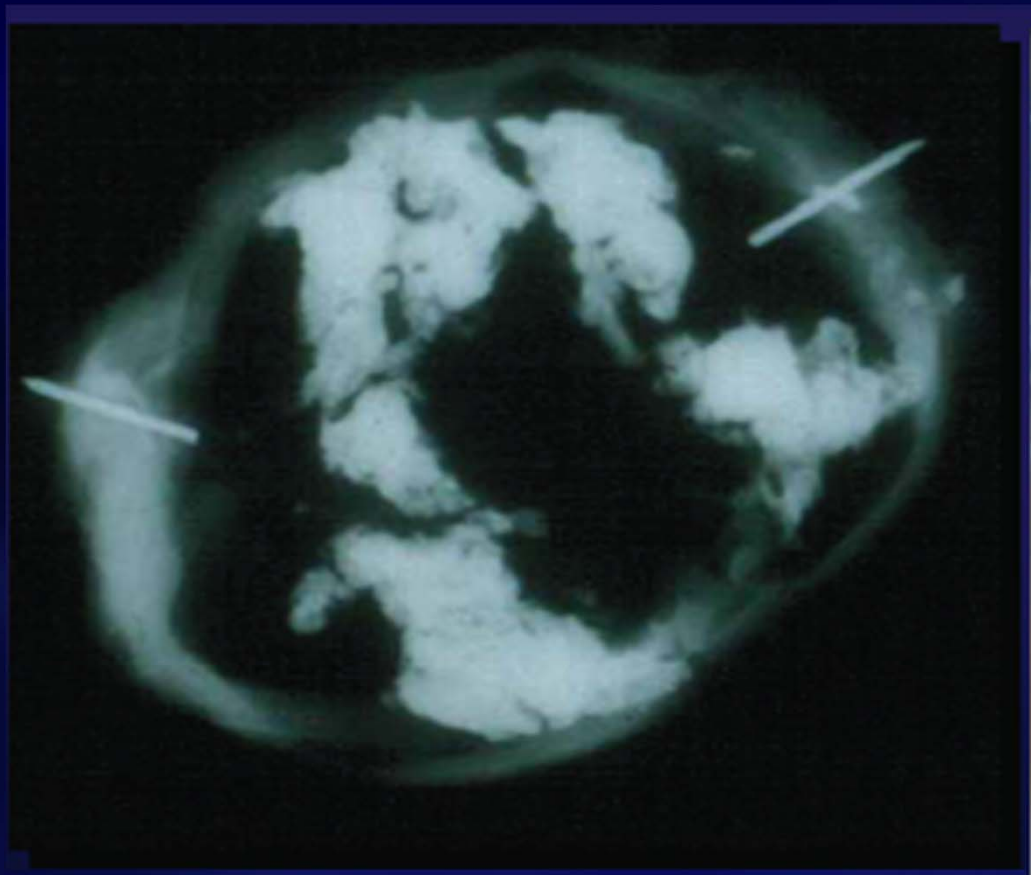
At least 30-40% of Patients Go Untreated

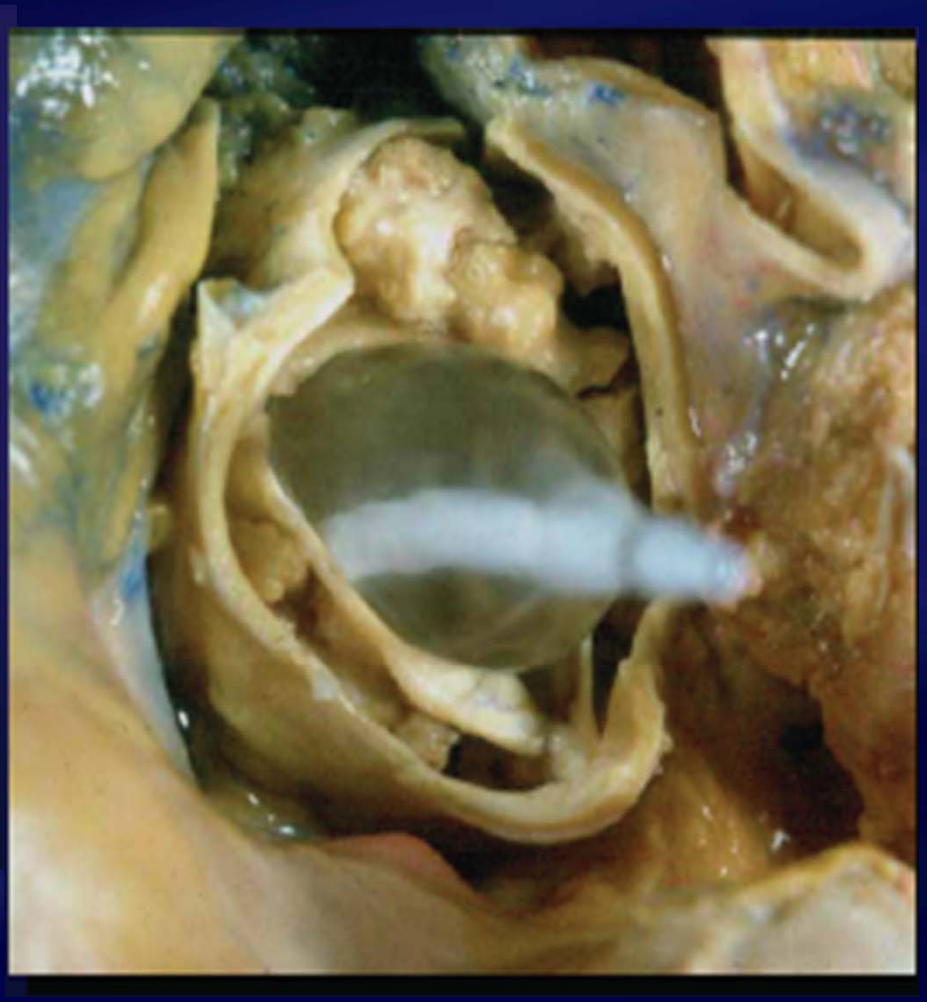


Under-treatment especially prevalent among patients managed by *Primary Care* physicians

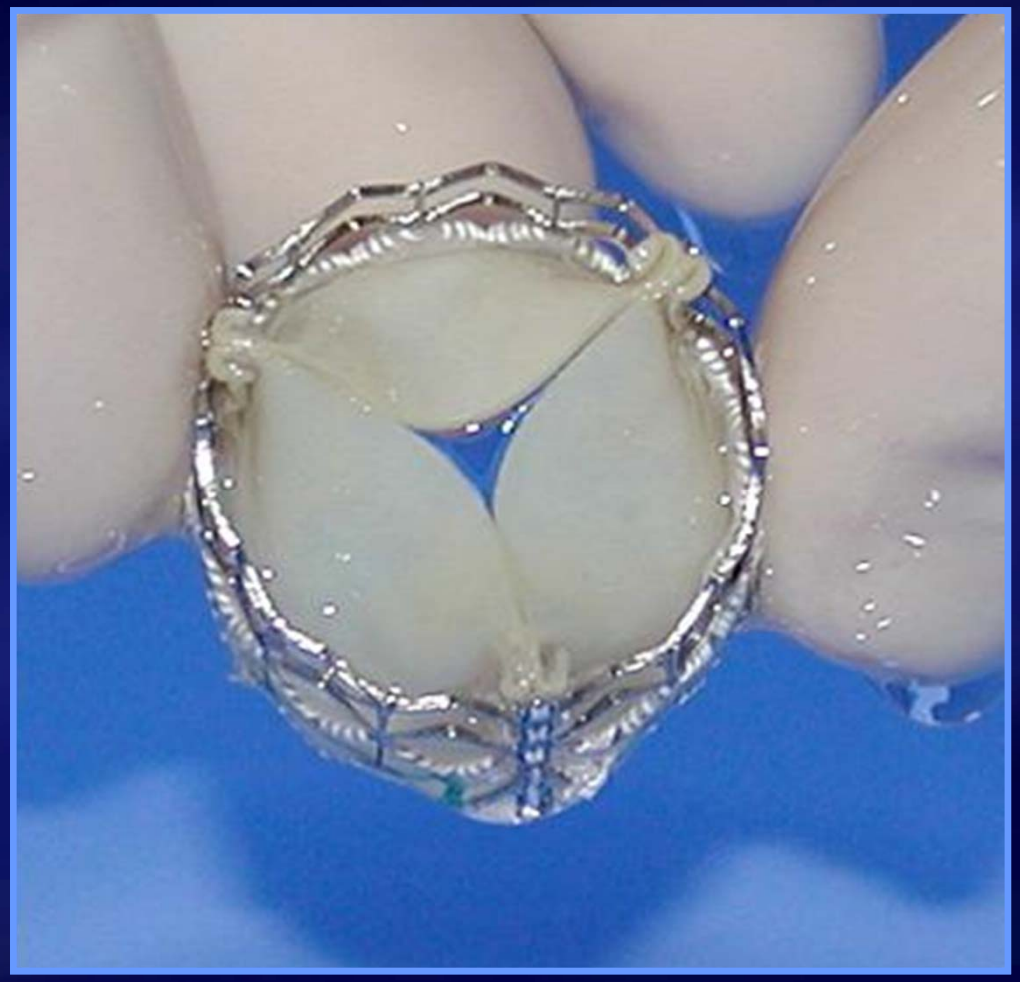
1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis2006;15:312-321

Aortic Valvuloplasty does not work

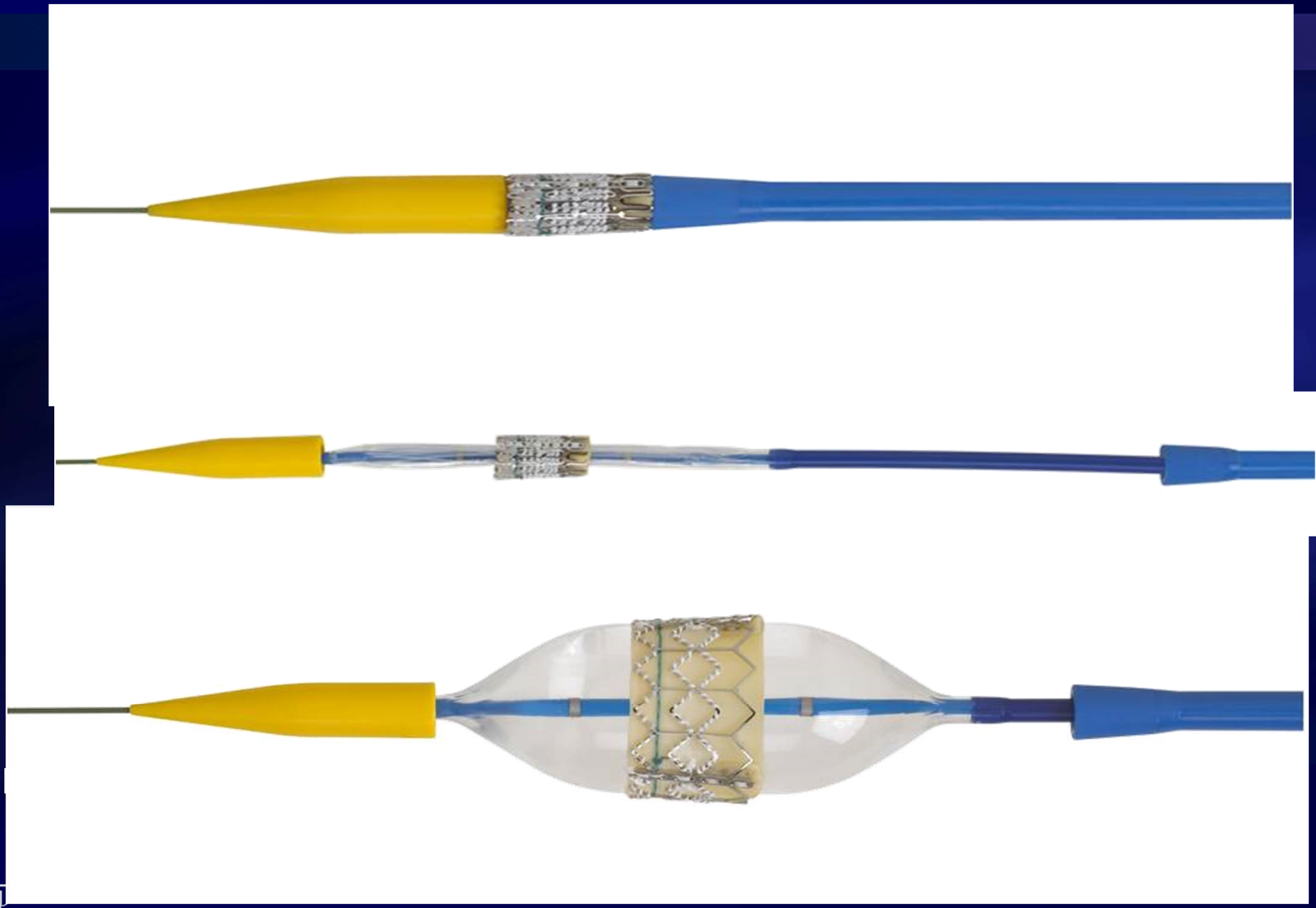




Transcutaneous Aortic Valve Prosthesis



Delivery System



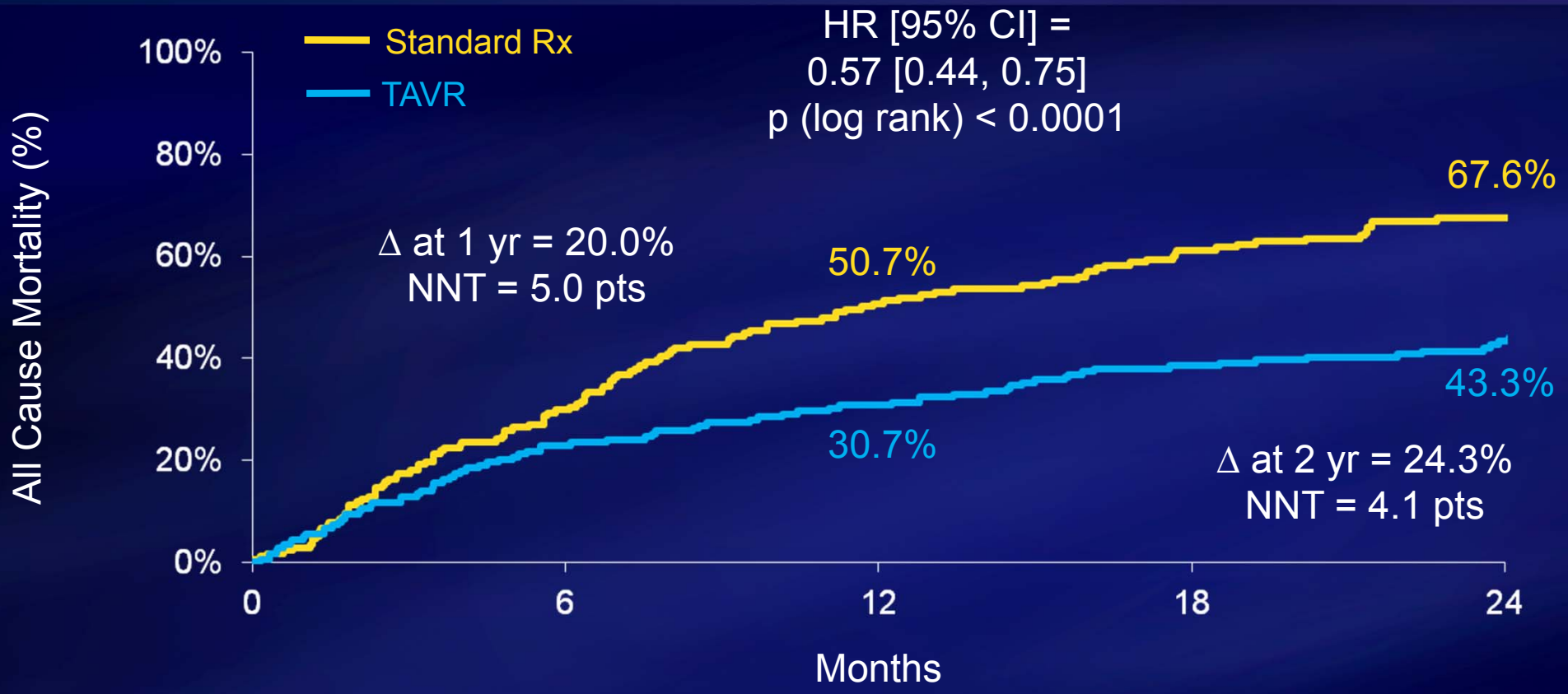
Patient Characteristics (1)

Characteristic	TAVR n = 179	Standard Rx n = 179	p value
Age – yr	***83.1 ± 8.6***	***83.2 ± 8.3***	***0.95***
Male sex (%)	***45.8***	***46.9***	***0.92***
STS Score	***11.2 ± 5.8***	***12.1 ± 6.1***	***0.14***
NYHA			
I or II (%)	***7.8***	***6.1***	***0.68***
III or IV (%)	***92.2***	***93.9***	***0.68***
CAD (%)	***67.6***	***74.3***	***0.20***
Prior MI (%)	***18.6***	***26.4***	***0.10***
Prior CABG (%)	***37.4***	***45.6***	***0.17***
Prior PCI (%)	***30.5***	***24.8***	***0.31***
Prior BAV (%)	***16.2***	***24.4***	***0.09***
CVD (%)	***27.4***	***27.5***	***1.00***

Patient Characteristics (2)

Characteristic	TAVR n = 179	Standard Rx n = 179	p value
PVD (%)	***30.3***	***25.1***	***0.29***
COPD			
Any (%)	***41.3***	***52.5***	***0.04***
O_2 dependent (%)	***21.2***	***25.7***	***0.38***
Creatinine > 2 mg/dL (%)	***5.6***	***9.6***	***0.23***
Atrial fibrillation (%)	***32.9***	***48.8***	***0.04***
Perm. pacemaker (%)	***22.9***	***19.5***	***0.49***
Pulmonary HTN (%)	***42.4***	***43.8***	***0.90***
Frailty (%)	***18.1***	***28.0***	***0.09***
Porcelain aorta (%)	***19.0***	***11.2***	***0.05***
Chest wall radiation (%)	***8.9***	***8.4***	***1.00***
Chest wall deformity (%)	***8.4***	***5.0***	***0.29***
Liver disease (%)	***3.4***	***3.4***	***1.00***

All Cause Mortality (ITT)



Numbers at Risk

TAVR	*179*	*138*	*124*	*110*	*83*
Standard Rx	*179*	*121*	*85*	*67*	*51*

Assessment of Treatment Effect Size

Lives saved/1,000 pt treated

β-blockers post MI	6
ASA for MI	24
SK for MI	25
Accel t-PA	10
ACEi post MI	5
ACEi + low LVEF	57

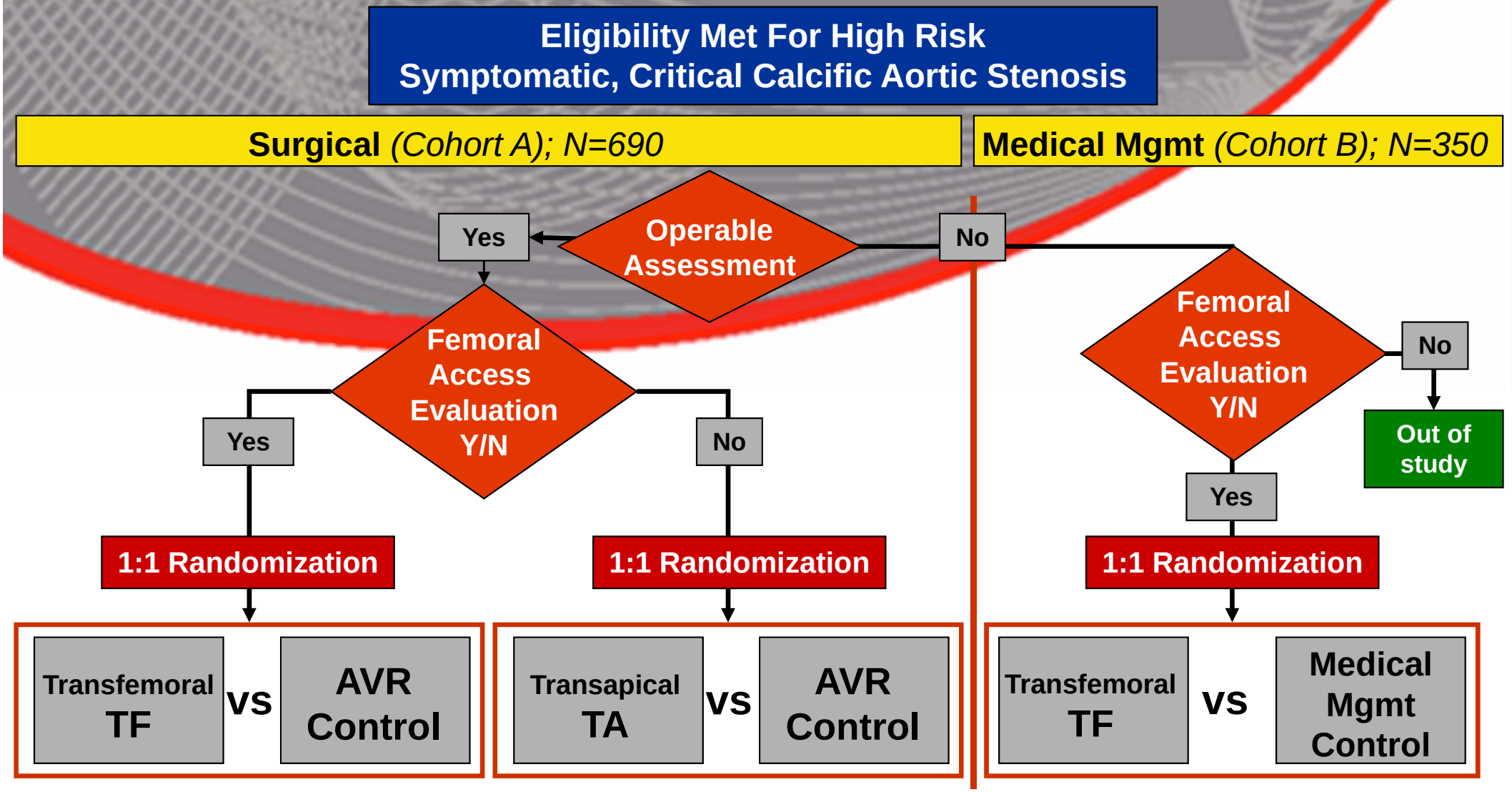
Mean Gradient & Valve Area

Error bars = ± 1 Std Dev

Outline

1. What is the role of TAVR for inoperable patients with AS?
2. How does TAVR compare with AVR for high-risk AS?
3. What is the risk of stroke?
4. Does paravalvular leak matter?
5. Is TAVR cost effective?

PARTNER Trial 2.0:
One Valve, Two delivery systems, TF & TA



Sub-group analyses:

- TA vs. control
- TF vs. control
- TF and TA vs. control (combined)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Ph.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

ABSTRACT

BACKGROUND

The Placement of Aortic Transcatheter Valves (PARTNER) trial showed that among high-risk patients with aortic stenosis, the 1-year survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical replacement. However, longer-term follow-up is necessary to determine whether TAVR has prolonged benefits.

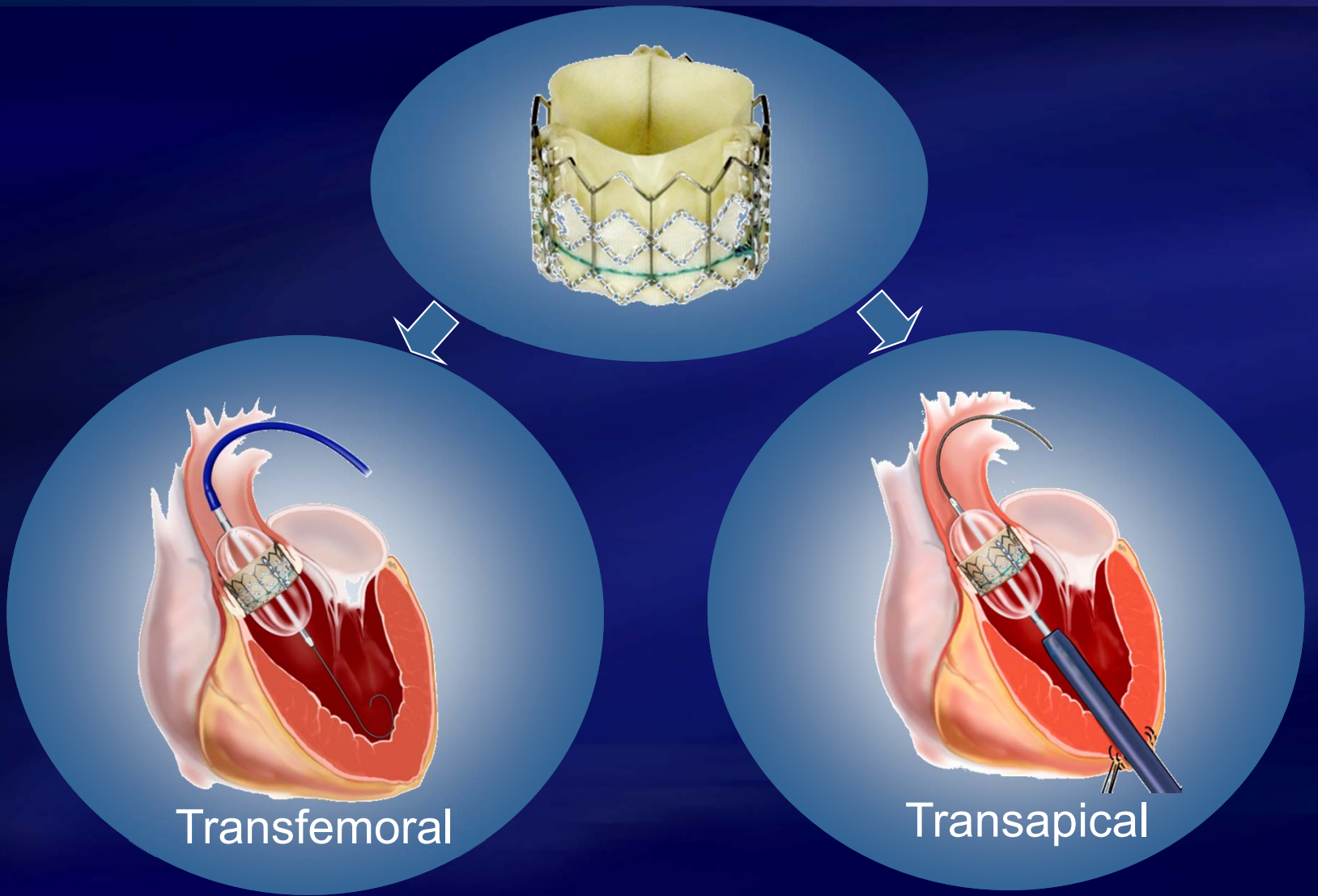
METHODS

At 25 centers, we randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either surgical aortic-valve replacement or TAVR. All patients were followed for at least 2 years, with assessment of clinical outcomes and echocardiographic evaluation.

RESULTS

From Columbia University Medical Center and New York Presbyterian Hospital (S.K.K., M.R.W., C.R.S., R.T.H., M.B.L.) and Lenox Hill Hospital (G.P.F.) — both in New York; Cleveland Clinic Foundation, Cleveland (L.G.S.); University of British Columbia and St. Paul's Hospital, Vancouver, Canada (J.G.W.); Cedars–Sinai Medical Center, Los Angeles (R.R.M.); Medical City Dallas, Dallas (T.M.D.); Emory University School of Medicine, Atlanta (V.H.T.); Washington Hospital Center, Washington, DC (A.D.P.); Stanford University Medical School, Palo Alto (M.F.), Scripps Clinic, La Jolla (P.S.T.), and Edwards Lifesciences, Irvine (J.J.A., W.N.A.) — all in California; Hospital of the University of Pennsylvania, Philadelphia (W.Y.S.); University of Virginia, Charlottesville (S.L.); Mayo Clinic, Rochester, MN (K.L.G.); Northwestern University, Chi-

TAVR
Transfemoral and Transapical

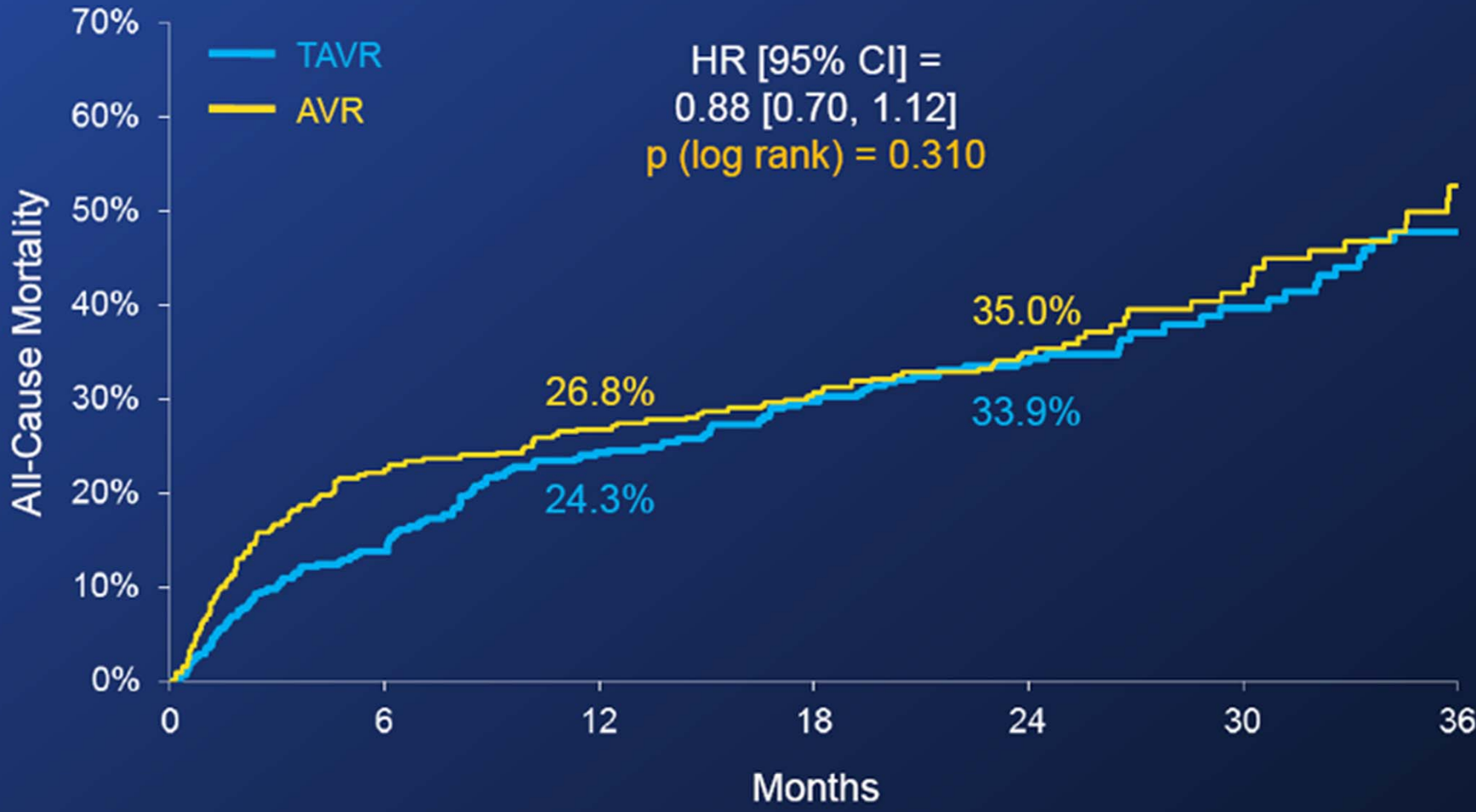


Patient Characteristics (1)

THE PARTNER TRIAL

Characteristic	*TAVR (N = 348)*	*AVR (N = 351)*	*p-value*
Age (yr)	83.6 ± 6.8	84.5 ± 6.4	0.07
Male sex - %	57.8	56.7	0.82
STS Score	11.8 ± 3.3	11.7 ± 3.5	0.61
Logistic EuroSCORE	29.3 ± 16.5	29.2 ± 15.6	0.93
NYHA			
II - %	5.7	6.0	
III or IV - %	94.3	94.0	0.79
CAD - %	74.9	76.9	0.59
Previous MI - %	26.8	30.0	0.40
Prior CV Intervention - %	72.1	71.6	0.93
Prior CABG - %	42.6	44.2	0.70
Prior PCI - %	34.0	32.5	0.68
Prior BAV - %	13.4	10.2	0.24
Cerebrovascular disease - %	29.3	27.4	0.60

All-Cause Mortality (ITT)

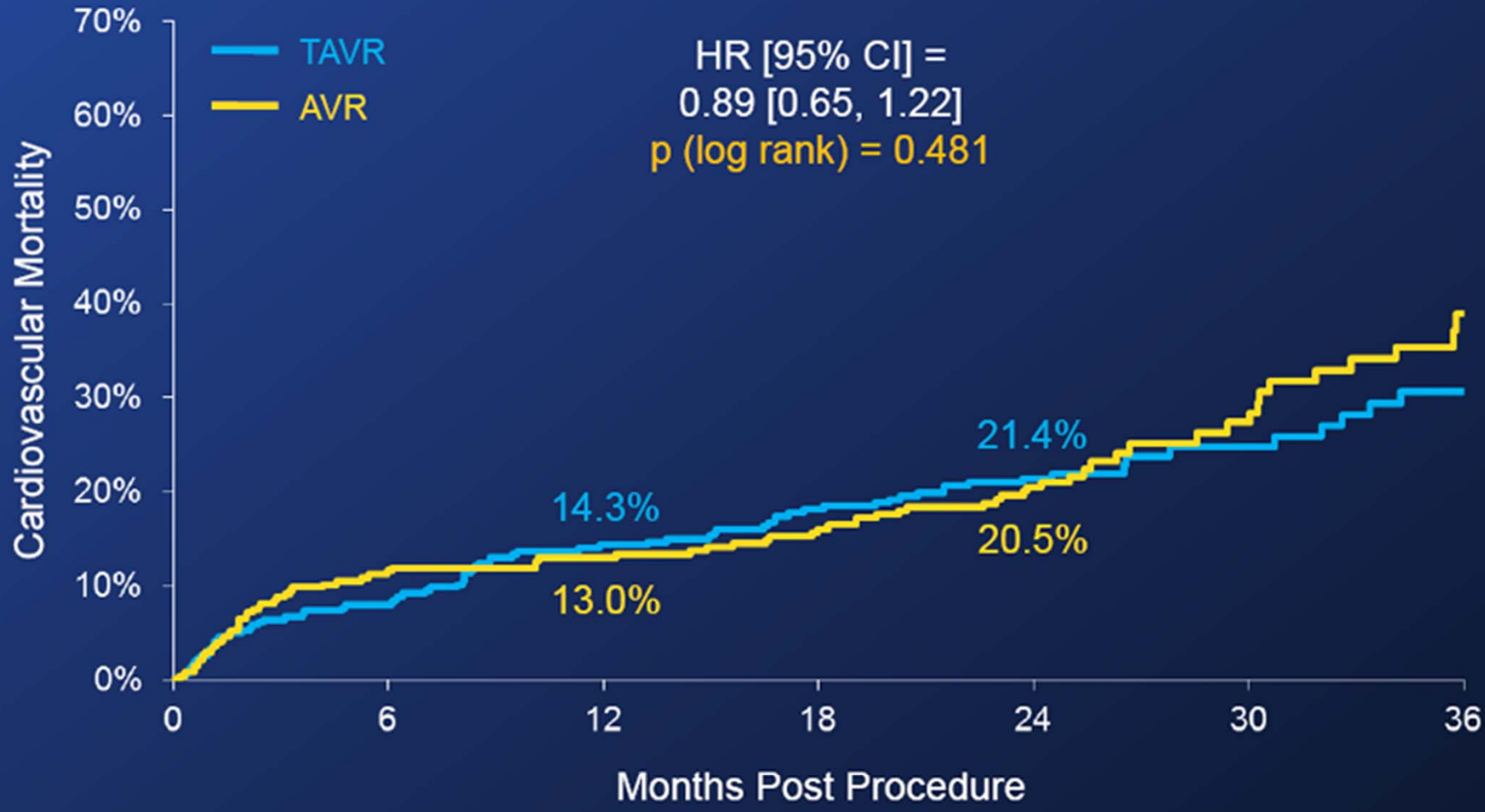


Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

Cardiovascular Mortality (ITT)

THE PARTNER TRIAL



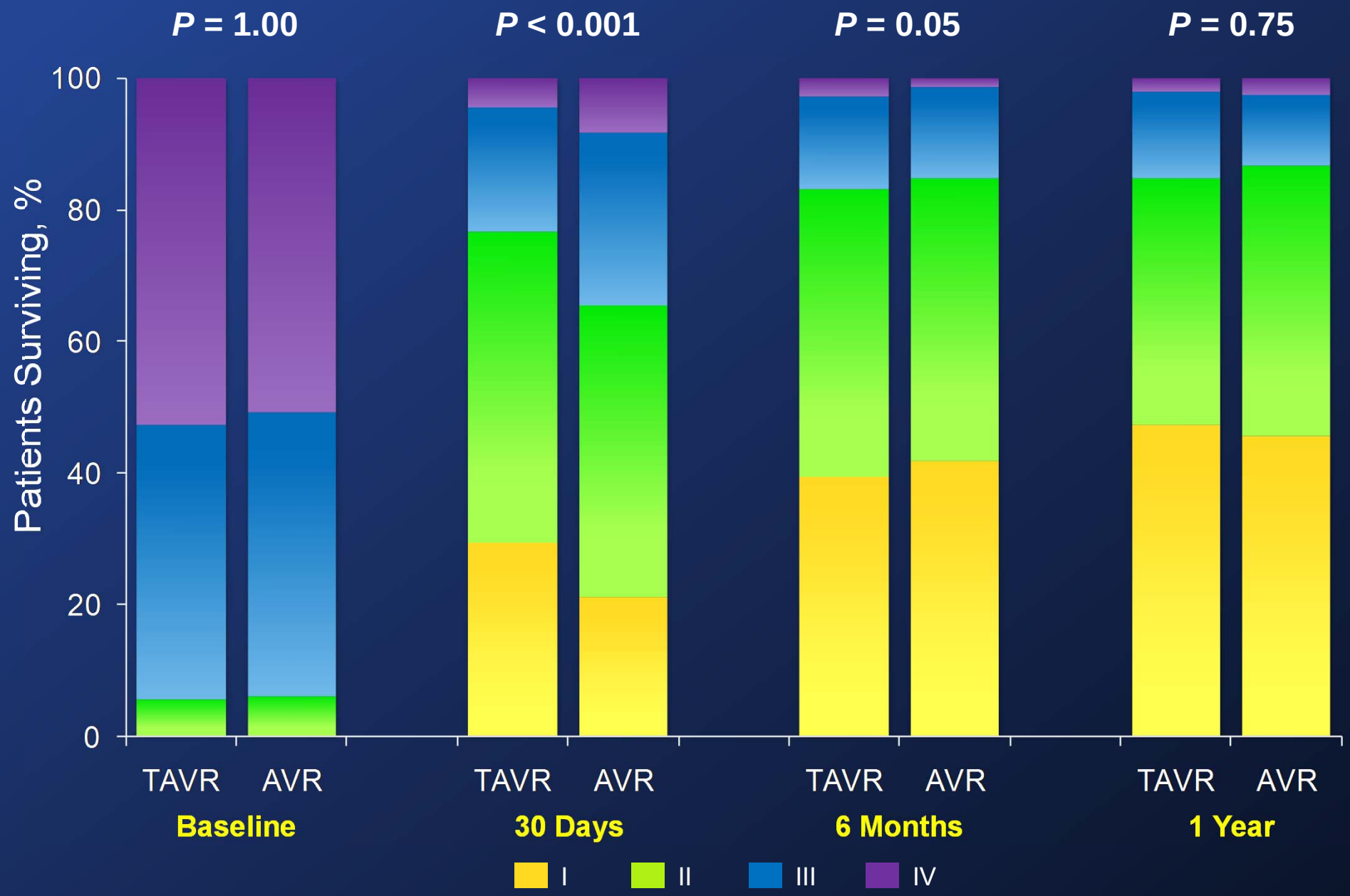
Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

Surgical AVR Outcomes

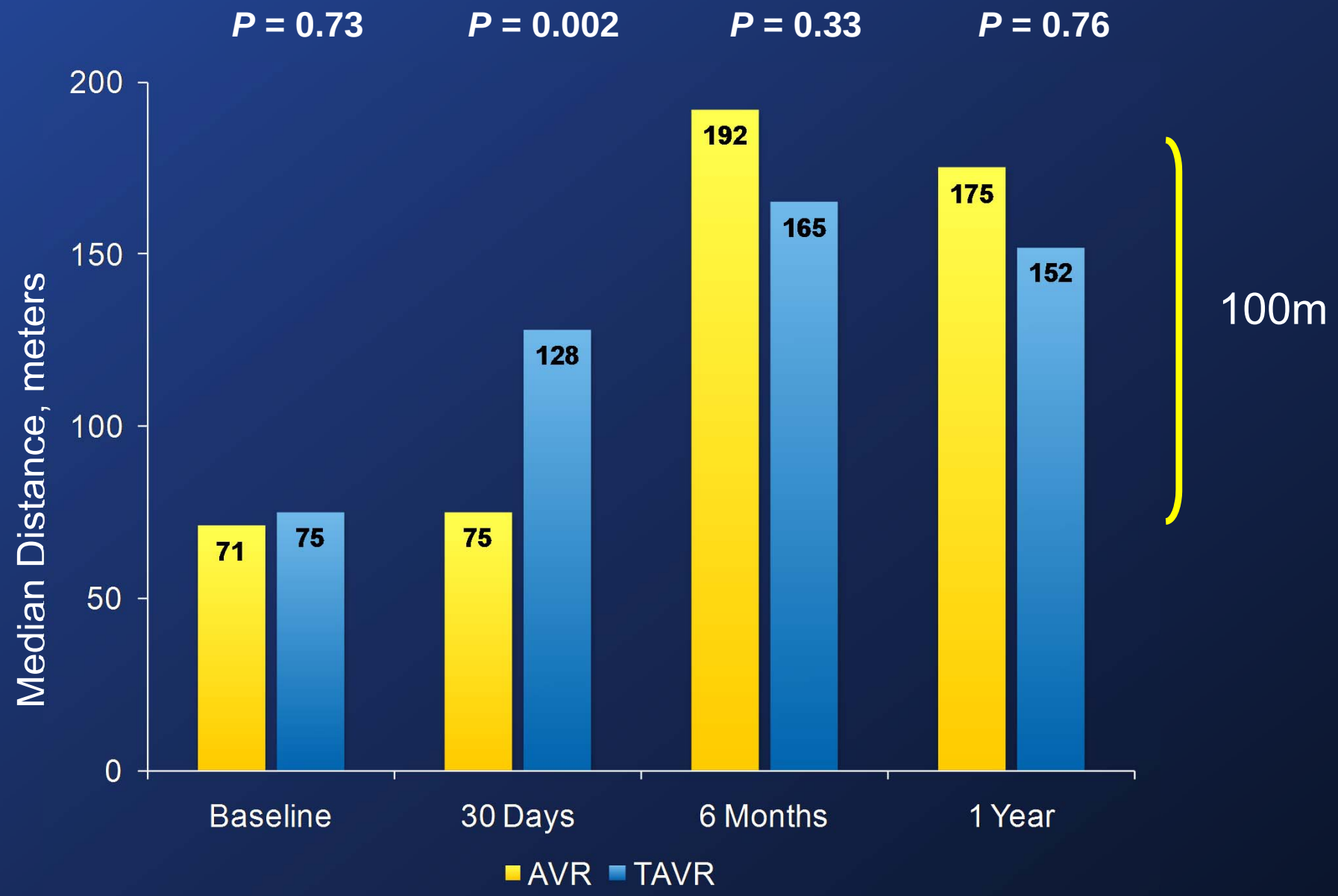
- Using an established predictive risk model (STS), the expected (“E”) 30-day mortality after AVR was 11.8%.
- The observed (“O”) 30-day mortality in the as-treated AVR control group was 8.0%.
- O:E = 0.68 indicates better than predicted surgical outcomes in the control AVR patients.
- There were no significant site or surgeon differences.

NYHA Functional Class



Six-Minute Walk Test
All Patients (N=699)

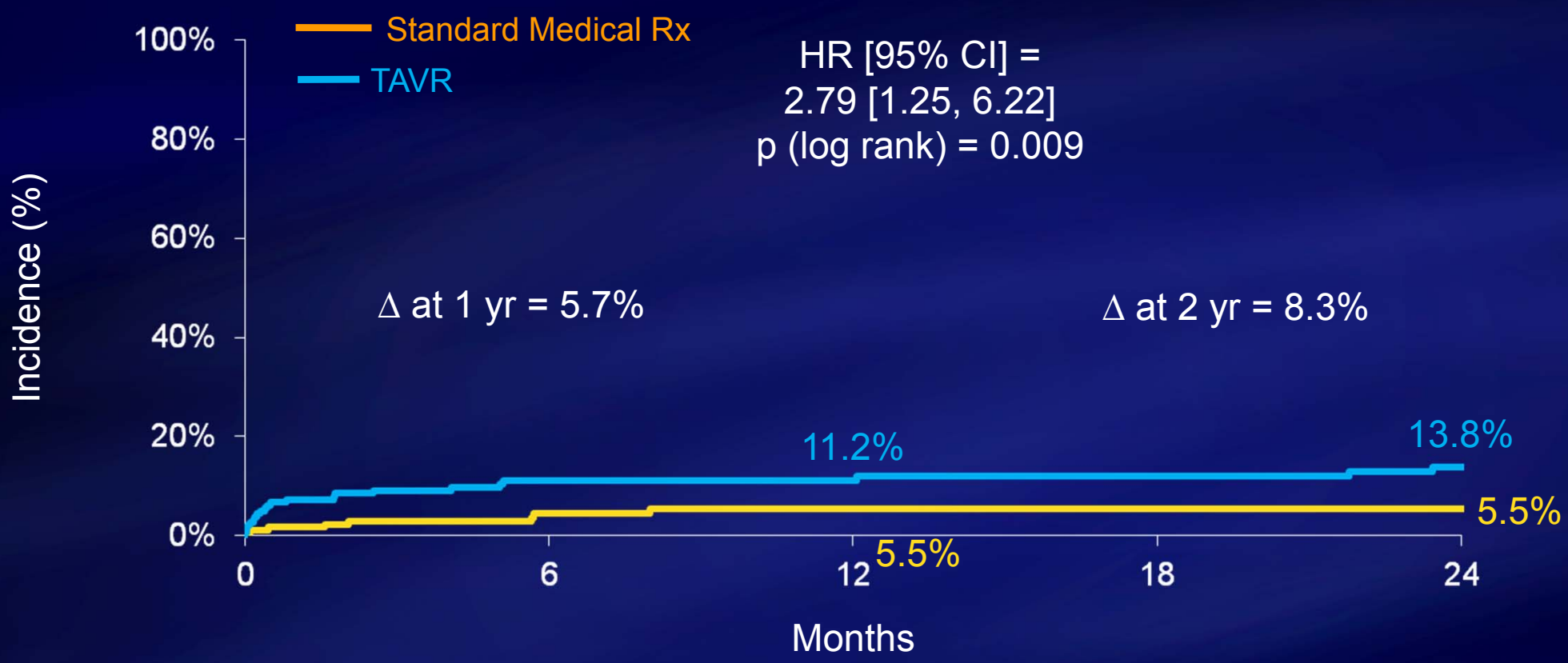
THE PARTNER TRIAL



Outline

1. What is the role of TAVR for inoperable patients with AS?
2. How does TAVR compare with AVR for high-risk AS?
3. What is the risk of stroke?
4. Does paravalvular leak matter?
5. Is TAVR cost effective?

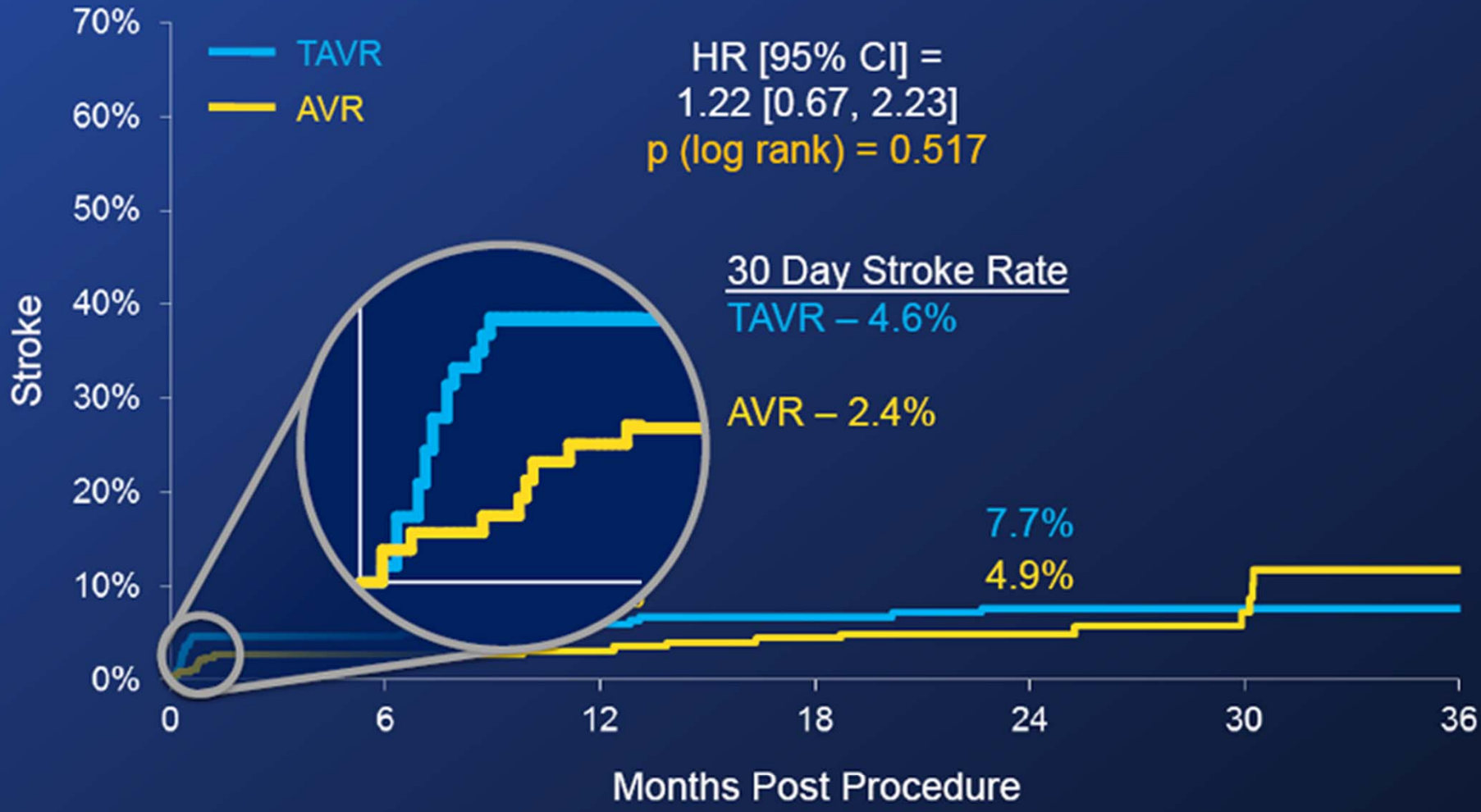
Inoperable patients: All Strokes



Numbers at Risk

TAVR	*179*	*128*	*116*	*105*	*79*
Standard Rx	*179*	*118*	*84*	*62*	*42*

Strokes (ITT) AVR vs TAVR patients



Numbers at Risk

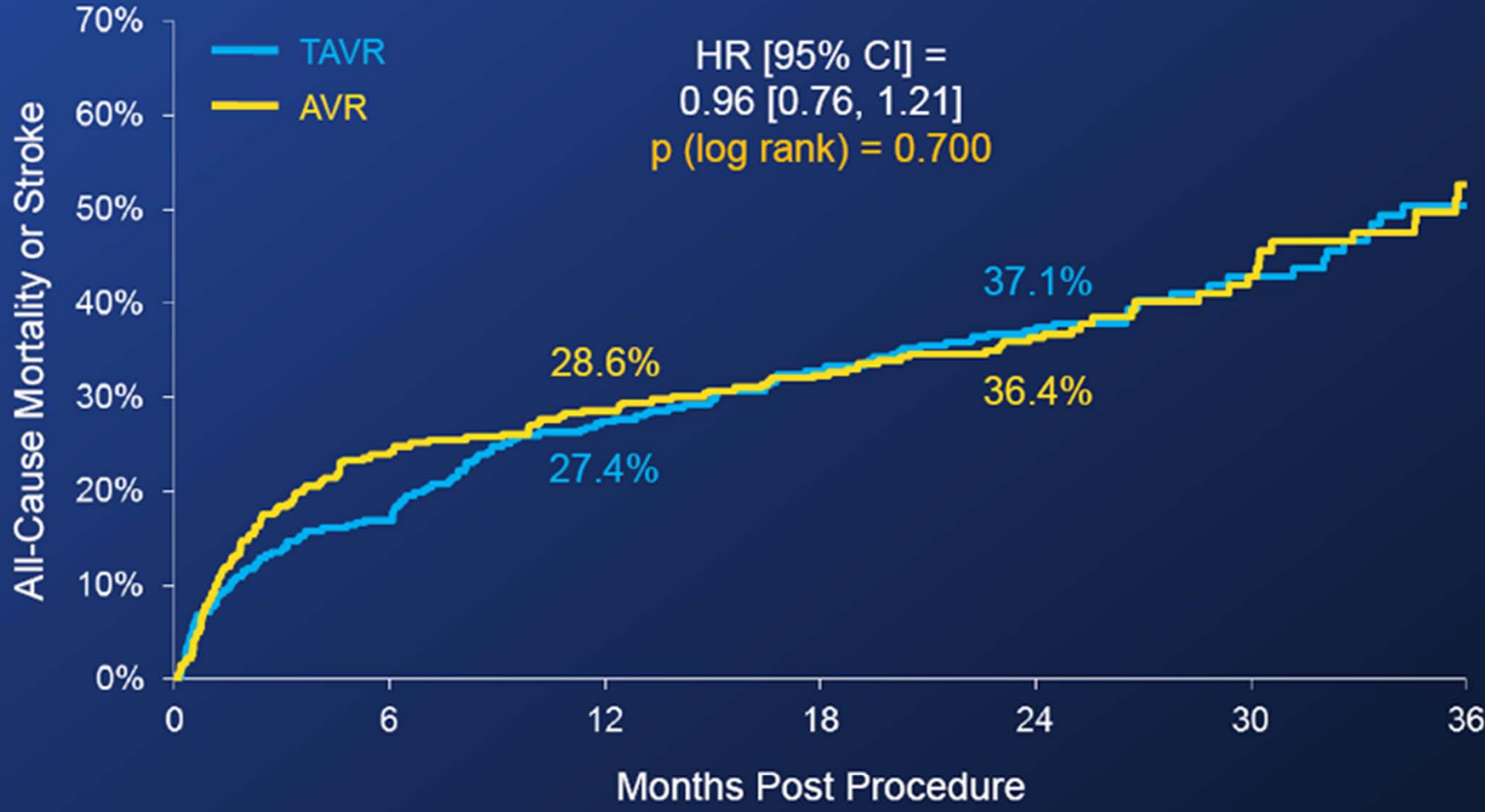
TAVR	348	287	249	224	162	65	28
AVR	351	246	230	211	160	62	31

What is most important from the patient's standpoint?

- Being alive and free of stroke with improved quality of life.

All-Cause Mortality or Strokes (ITT)

THE PARTNER TRIAL



Numbers at Risk

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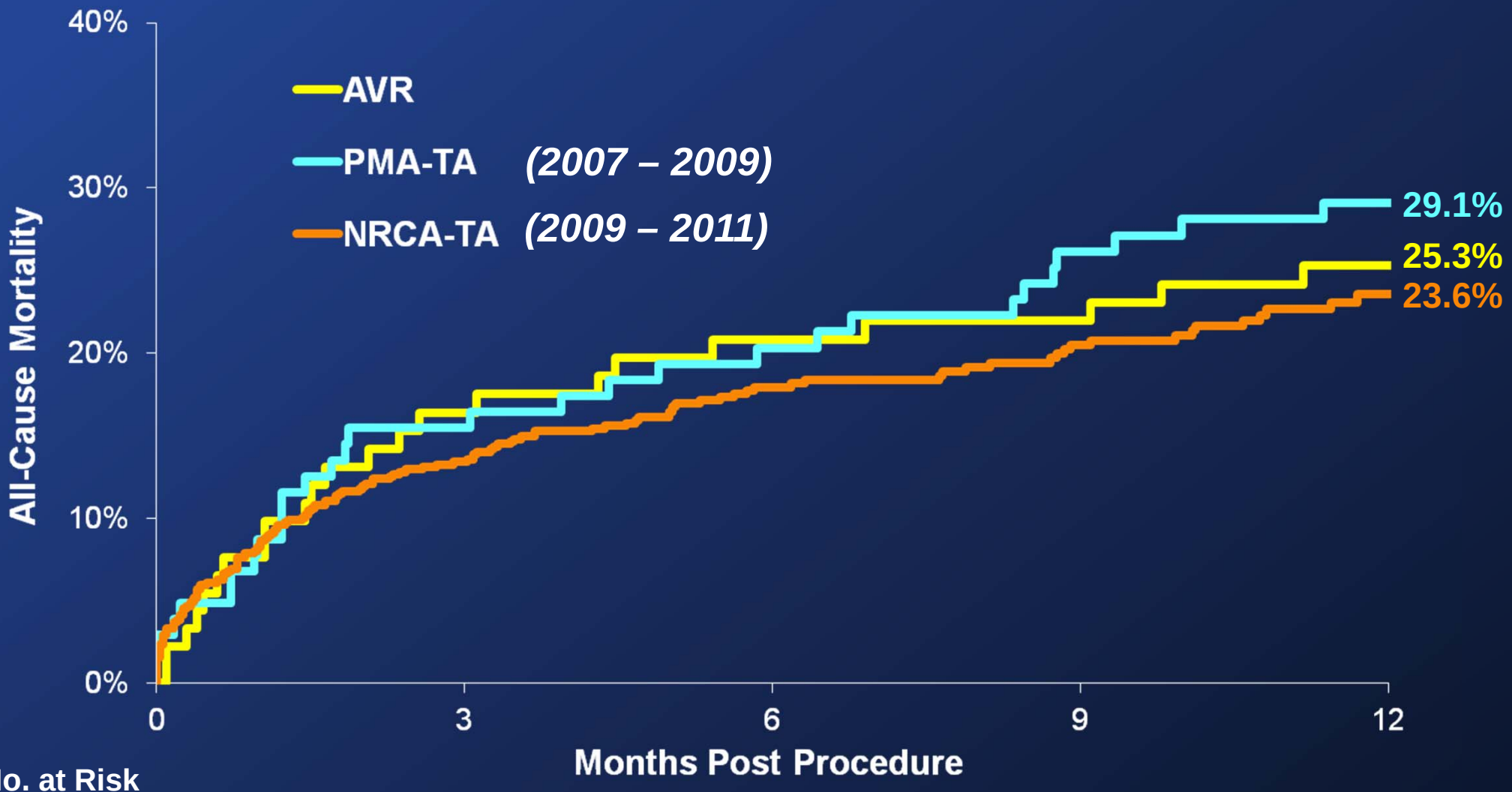
AVR	351	246	230	211	160	62	31

All-Cause Mortality (AT)



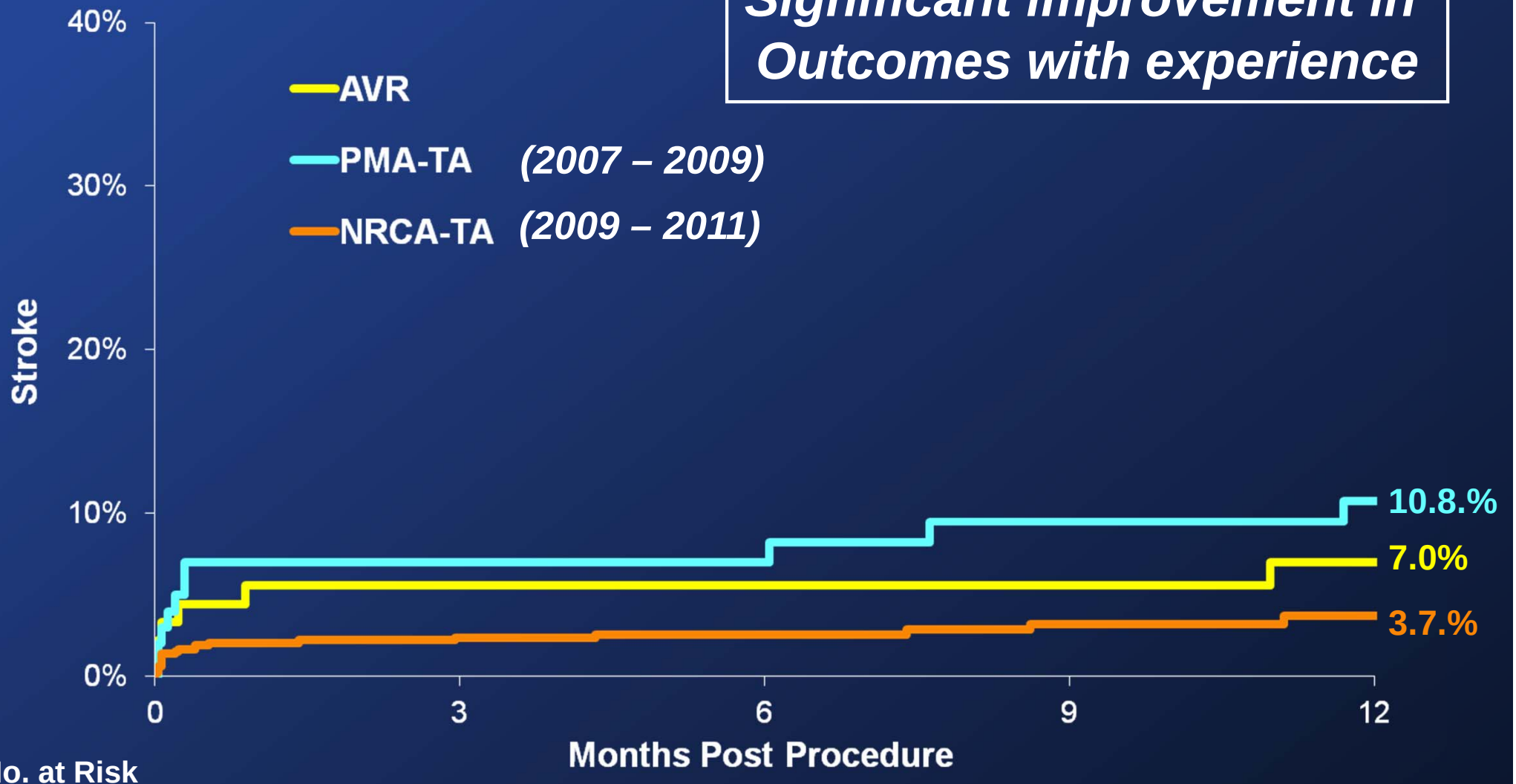
No. at Risk

AVR	92	76	71	70	67
PMA-TA	104	87	82	76	73
NRCA-TA	822	571	370	297	126

Stroke (AT)

THE PARTNER TRIAL

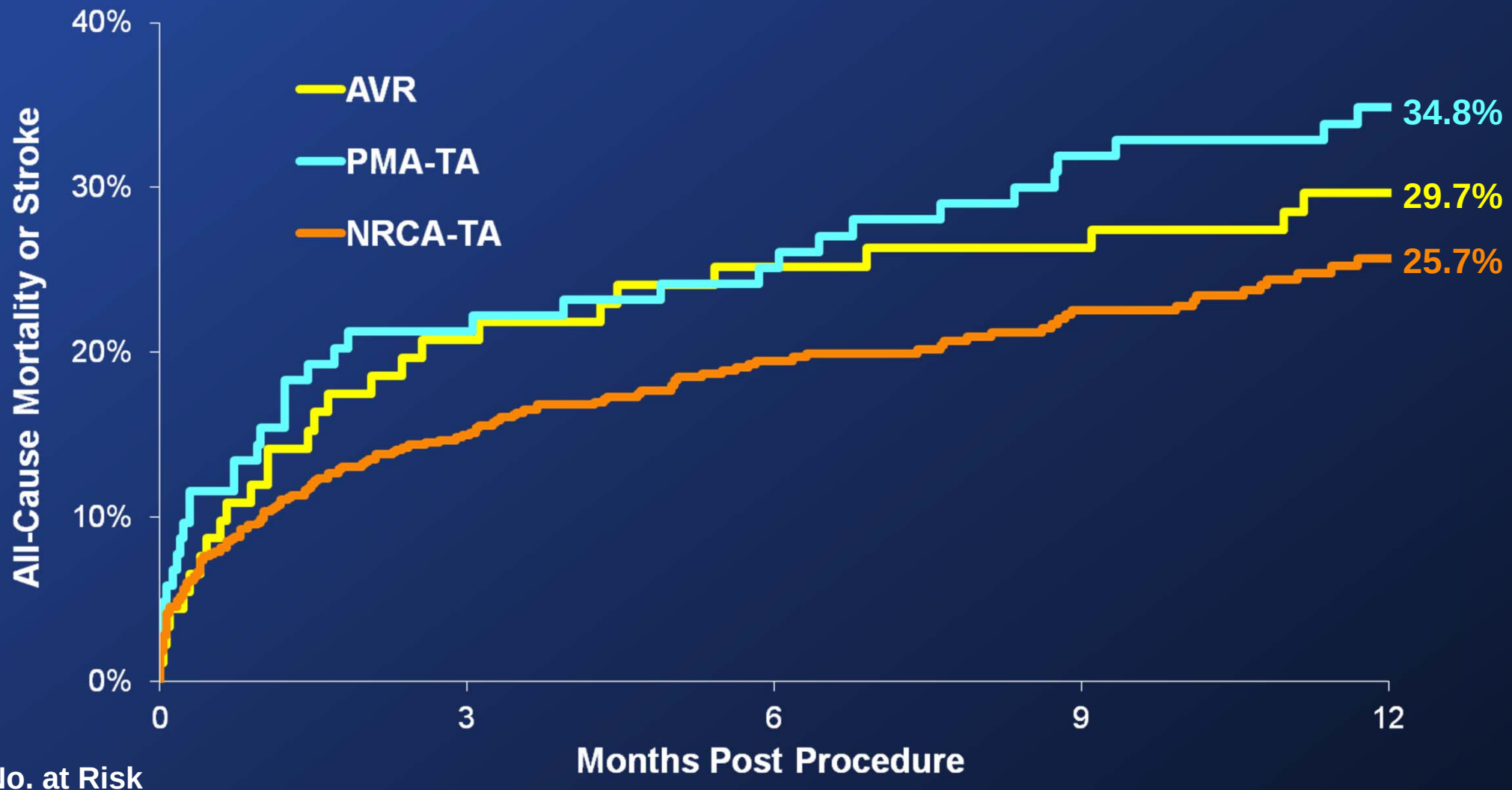
Significant improvement in Outcomes with experience



No. at Risk

AVR	92	72	67	66	63
PMA-TA	104	81	77	70	67
NRCA-TA	822	563	365	291	123

All-Cause Mortality or Stroke (AT)



No. at Risk

AVR	92	72	67	66	63
PMA-TA	104	81	77	70	67
NRCA-TA	822	563	365	291	123

A percutaneous aortic device for cerebral embolic protection during cardiovascular intervention

Jeffrey P. Carpenter, MD,[a] Judith T. Carpenter, MD,[a] Armando Tellez, MD,[b] John G. Webb, MD,[c] Geng Hua Yi, MD,[b] and Juan F. Granada, MD,[b] *Camden, NJ; Orangeburg, NY; and Vancouver, British Columbia, Canada*

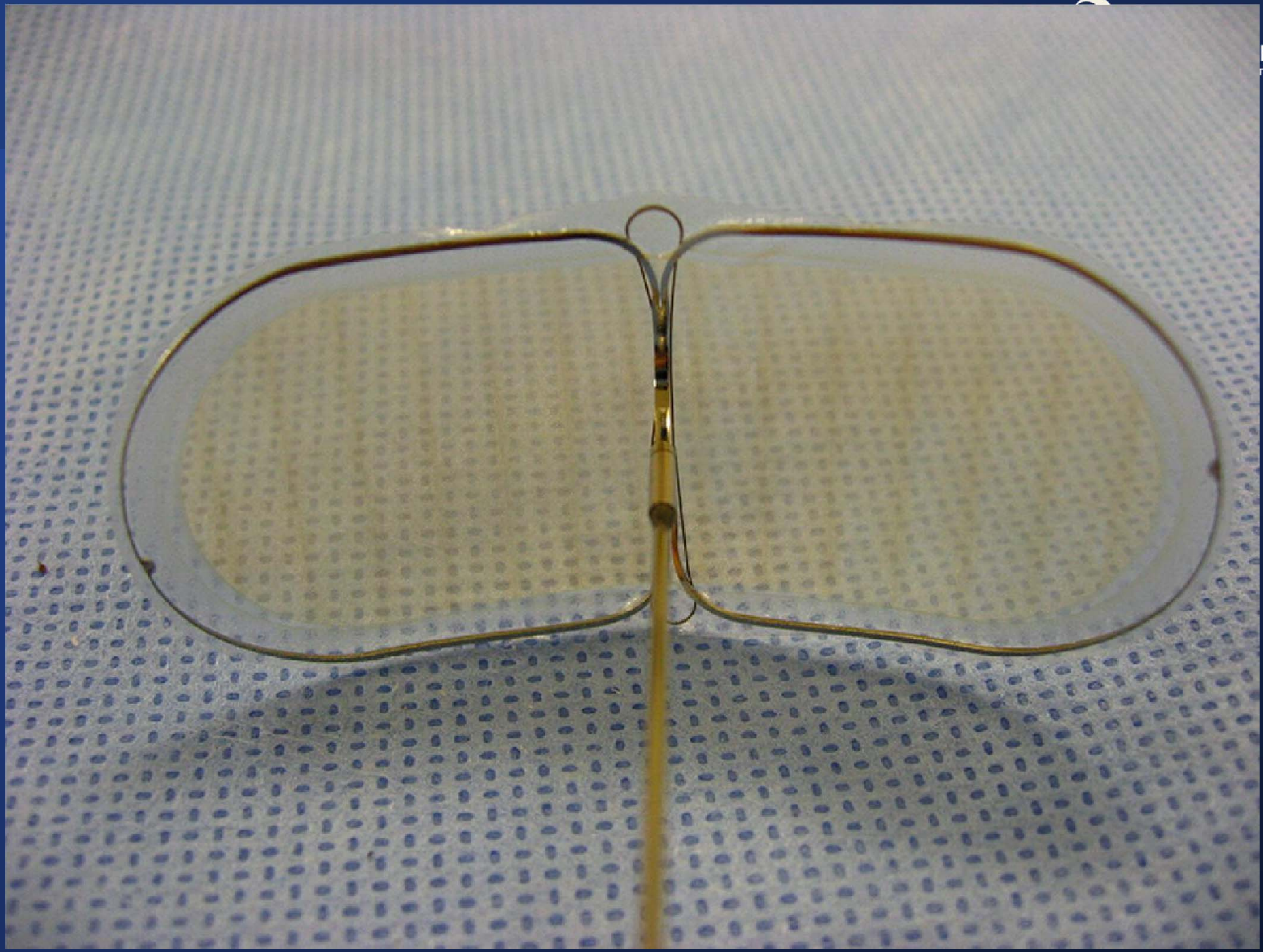
Background: Embolic stroke is a major cause of morbidity in aortic and cardiac interventional procedures. Although cerebral embolic protection devices have been developed for carotid interventions and for open heart surgery, a percutaneous device for cerebral embolic protection during aortic and cardiac interventions would be desirable.

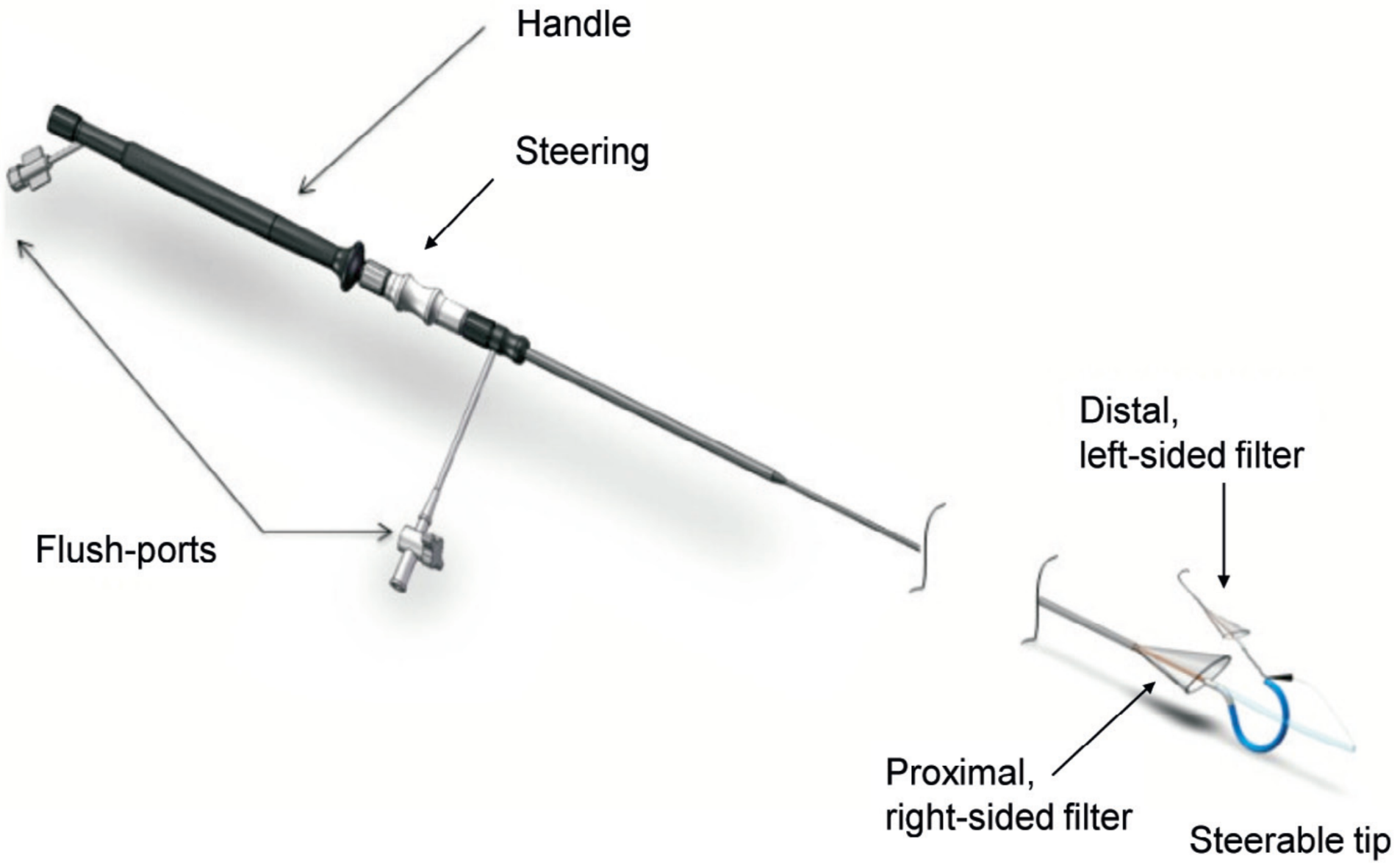
Methods: The Embrella Embolic Deflector (Embrella Cardiovascular Inc, Wayne, Pa) is a percutaneously placed embolic protection device, inserted by a 6F access in the pig's right forelimb, and deployed in the aorta, covering the brachiocephalic vessel origins. The device functions by deflecting embolic debris downstream in the aortic circulation. A swine model (n = 3) was developed for testing the deployment, retrieval, and efficacy of the device using a carotid filtration circuit for collection of emboli. Human atheromatous material was prepared as embolization particles with diameters between 150 and 600 μm. Deflection efficiency of the device was calculated by comparing numbers of embolic particles in the carotid circulation during protected and unprotected injections.

Results: The device was reliably deployed, positioned, and retrieved (n = 24). There was no significant drop in blood pressure across the membrane of the device to suggest reduction of cerebral blood flow. The device did not become occluded by embolic debris despite an embolic load many times that encountered in the clinical situation. Particles entering the carotid circulation after aortic injection of emboli were reduced from 19% of total (unprotected) to 1.3% (protected, $P < .0001$), with 98.7% of all injected particles being deflected downstream. There was no evidence of arterial injury related to the device found at necropsy.

Conclusion: The Embrella Embolic Deflector performs safely and reliably in the swine model of human atheroembolism. It effectively deflects almost all emboli downstream, away from the carotid circulation. The deflector shows promise as an aortic embolic protection device and merits further investigation. (J Vasc Surg 2011;54:174-81.)

Clinical Relevance: Embolic stroke plagues cardiovascular interventions involving manipulation of the heart and proximal aorta. An embolic protection device for use during these interventions which can be percutaneously placed is desirable in order to reduce the cerebrovascular risk of these interventions.




Handle
Steering
Flush-ports
Distal,
left-sided filter
Proximal,
right-sided filter
Steerable tip

Outline

1. What is the role of TAVR for inoperable patients with AS?
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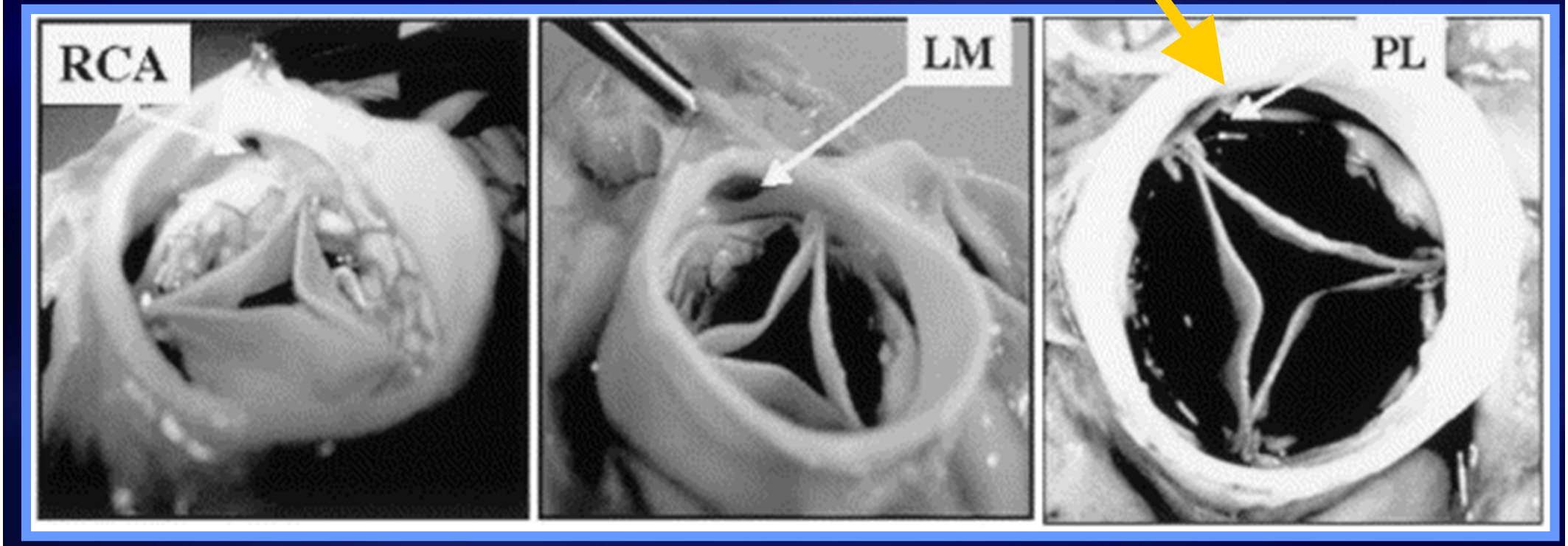
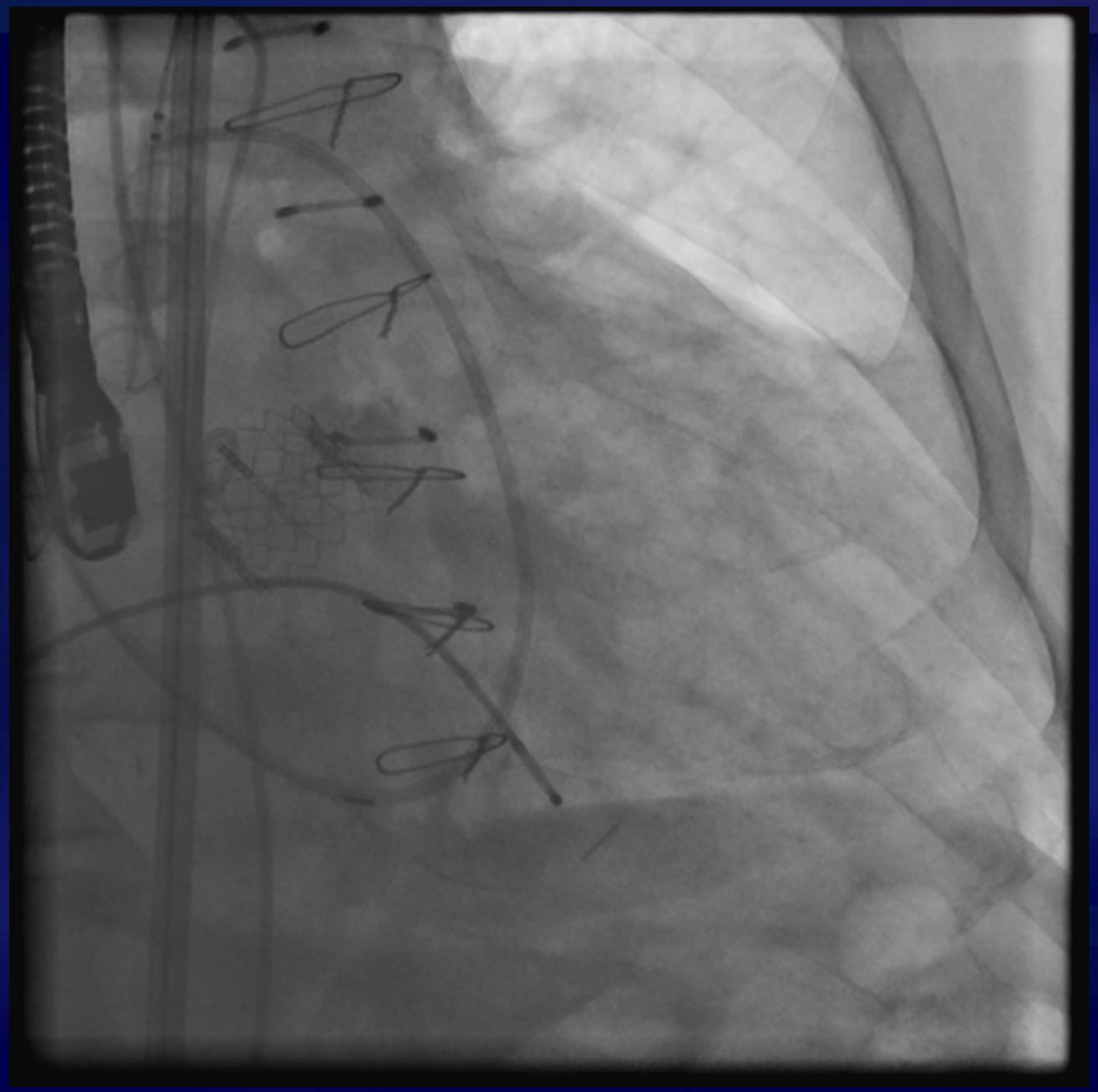
3. What is the risk of stroke?
4. Does paravalvular leak matter?
5. Is TAVR cost effective?

Paravalvular Leak

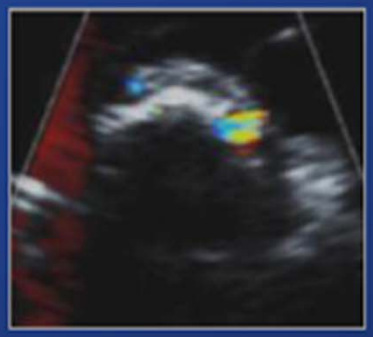


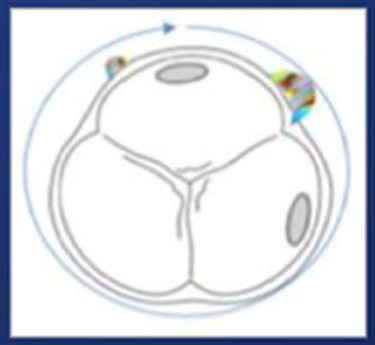
Cribier et al: JACC 2004

Typical Paravalvular Leak

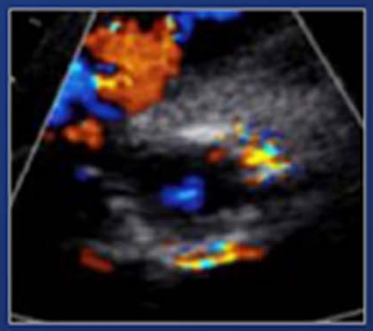


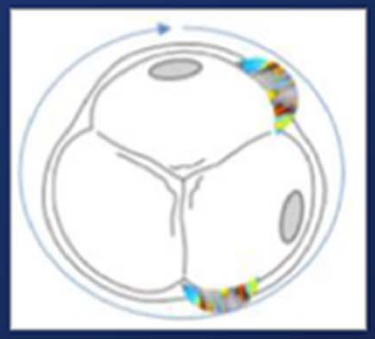
PARTNER Grading Criteria for Paravalvular AR



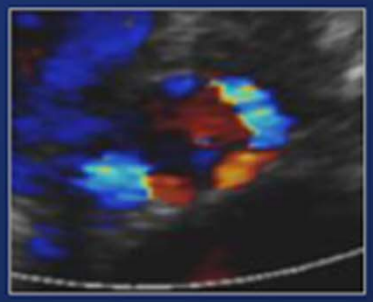


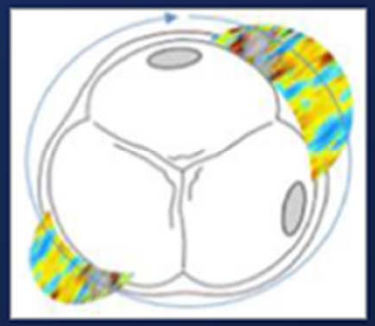
Circumference = 6″
AR = 0.1+0.35 = 0.45″
Ratio = 8%
Severity = Mild (< 10%)





Circumference = 6″
AR = 0.5+0.5 = 1.0″
Ratio = 17%
Severity = Moderate (10 – 20%)
(Trans AR also present)



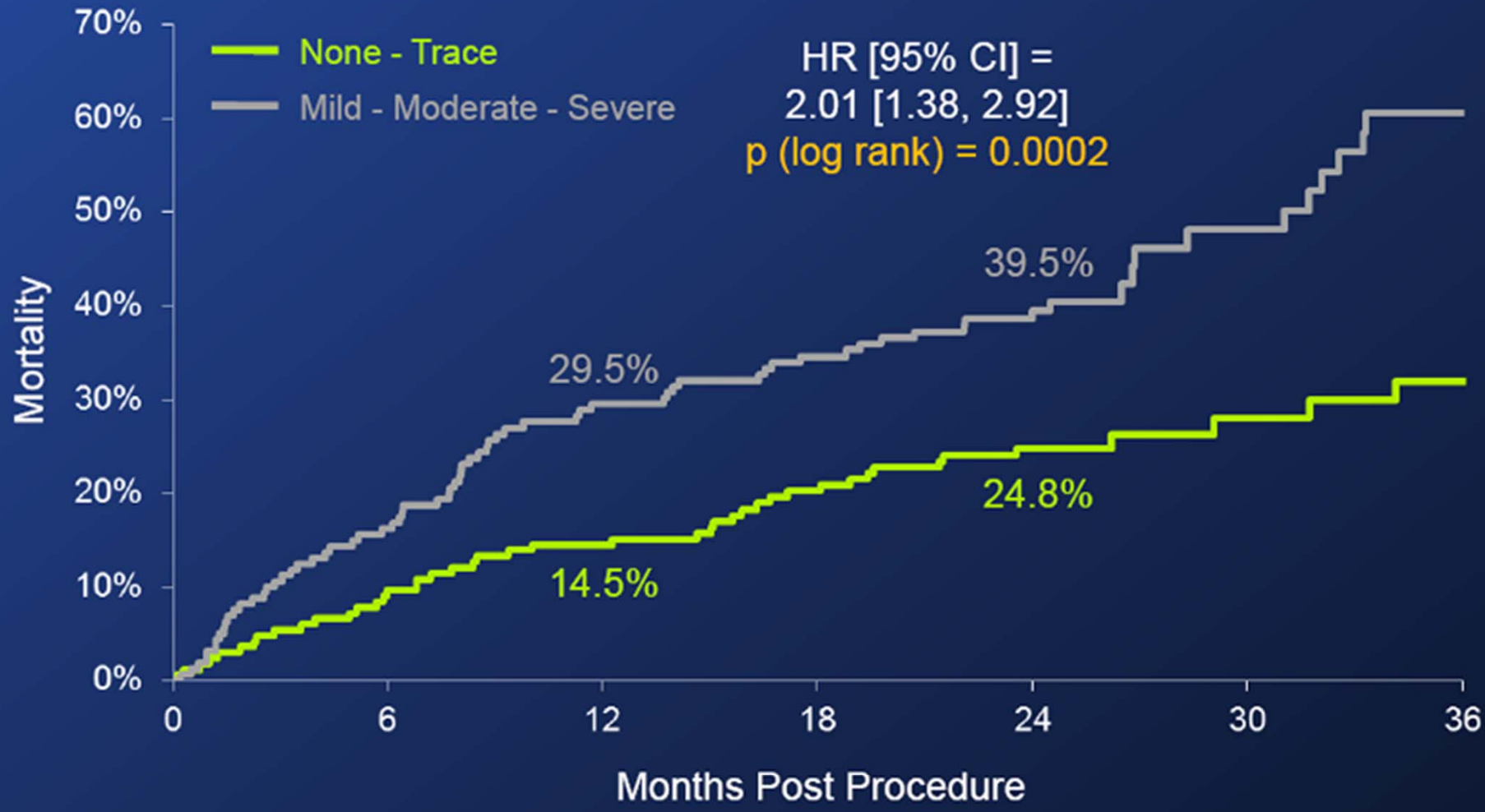


Circumference = 6″
AR = 0.6+1.1 = 1.7″
Ratio = 28%
Severity = Severe (> 20%)

Images courtesy of Pamela Douglas, MD, FASE

Paravalvular AR and Mortality
TAVR Patients (AT)

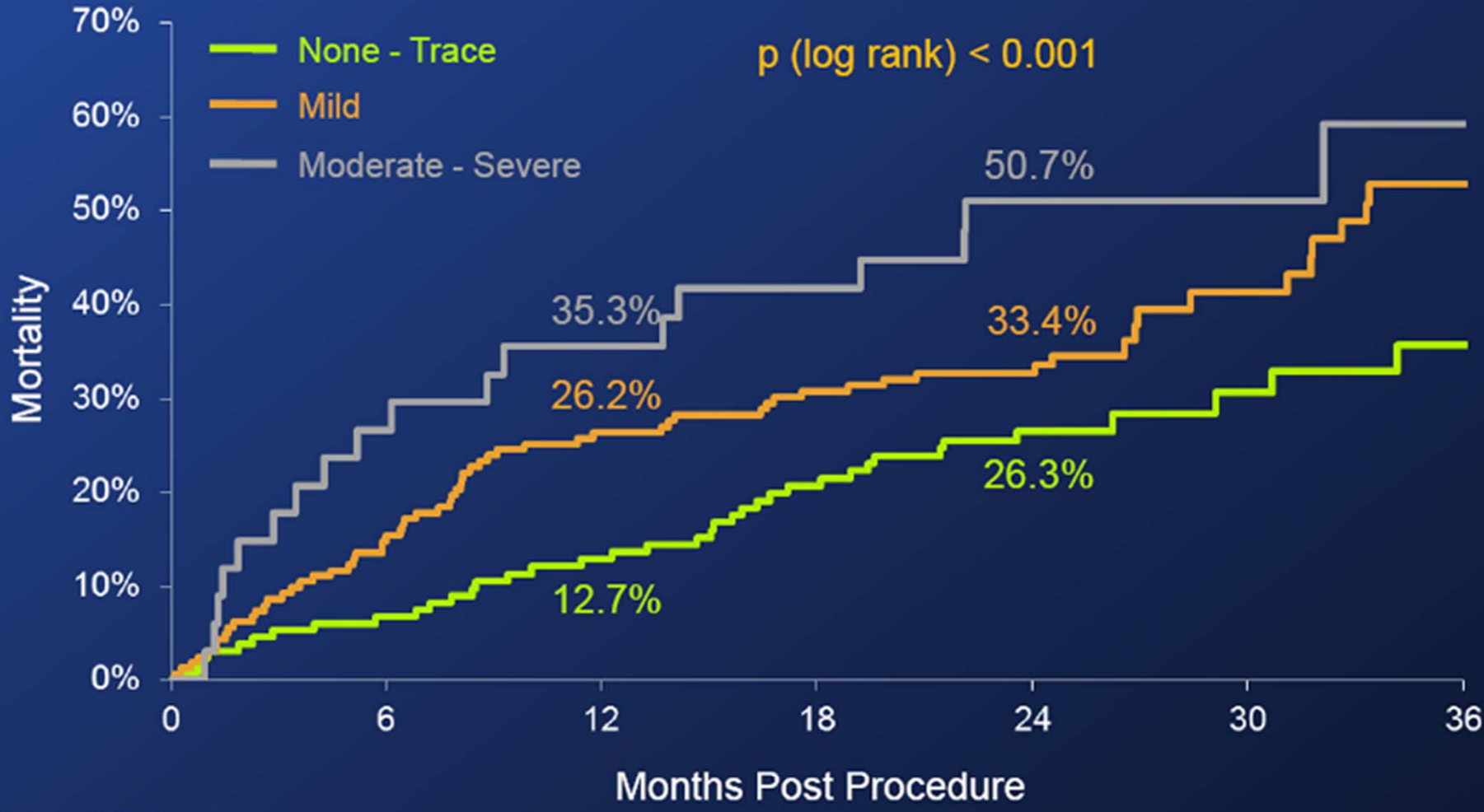
THE PARTNER TRIAL



Numbers at Risk

None-Tr	167	149	140	126	87	41	16
Mild-Mod-Sev	160	134	112	101	64	26	12

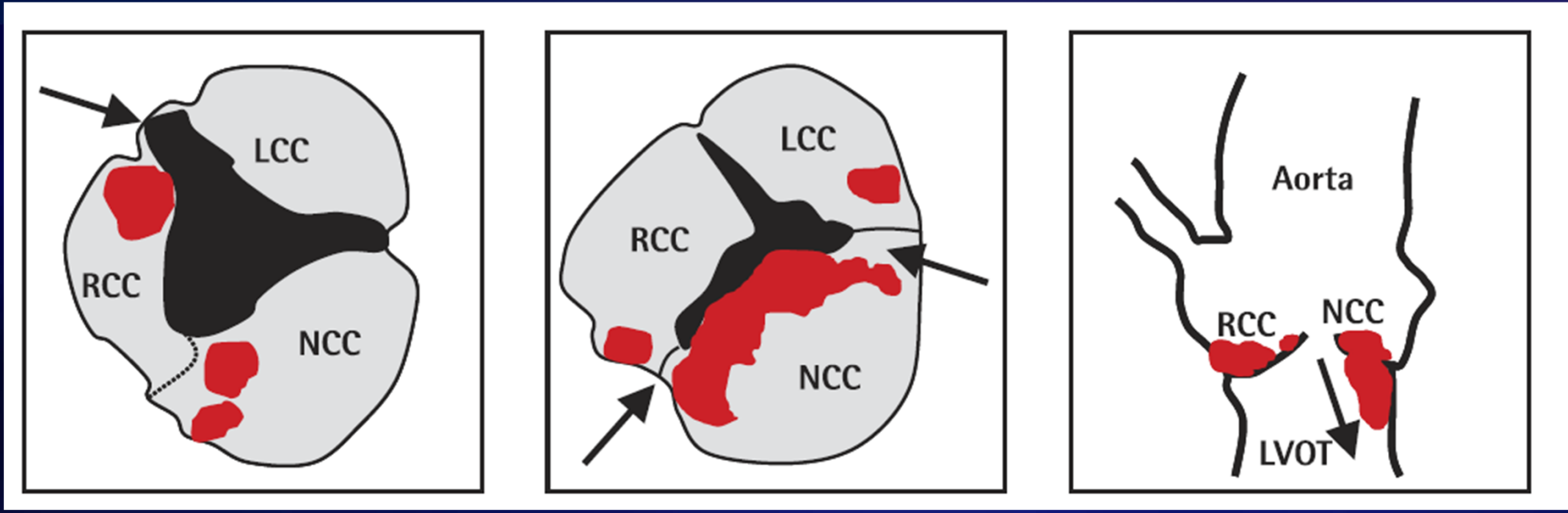
Total AR and Mortality
TAVR Patients (AT)



Numbers at Risk

None-Tr	135	125	115	101	68	31	11
Mild	165	139	121	111	71	33	16
Mod-Sev	34	25	22	19	15	6	2

Asymmetric Calcification



Primary risk factor for post TAVI perileak

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ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.10.857

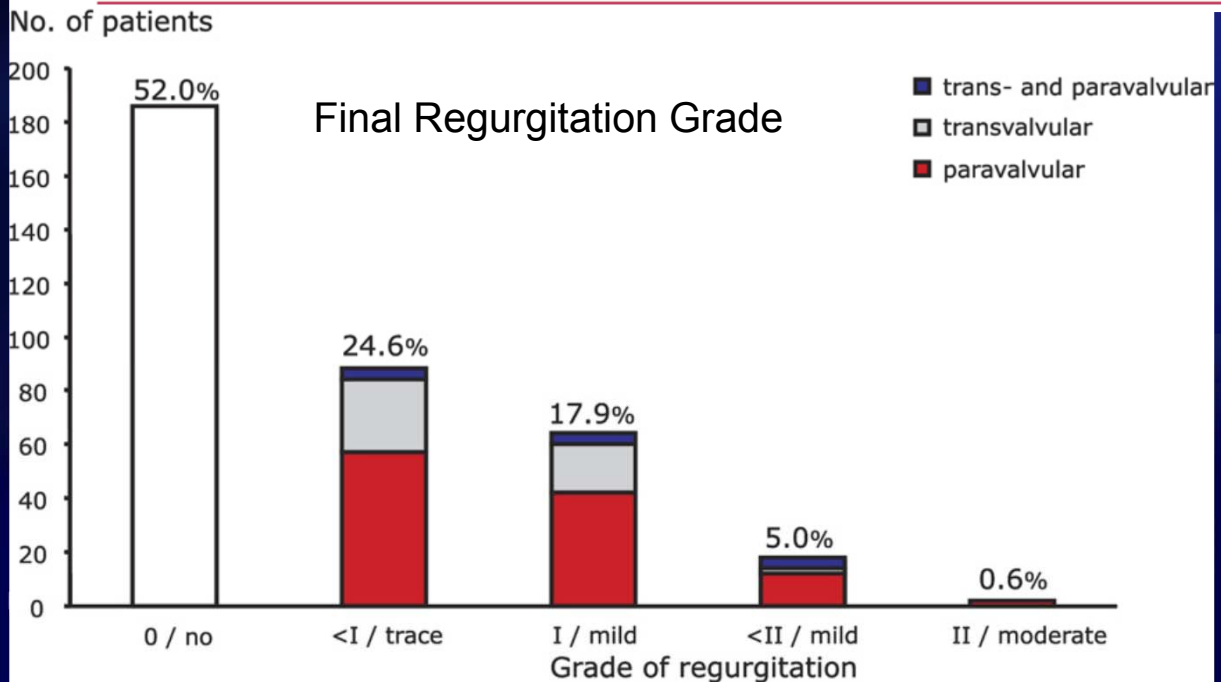
CLINICAL RESEARCH Interventional Cardiology

Transapical Aortic Valve Implantation

Incidence and Predictors of Paravalvular Leakage and Transvalvular Regurgitation in a Series of 358 Patients

Axel Unbehaun, MD, Miralem Pasic, MD, PHD, Stephan Dreysse, MD, Thorsten Drews, MD, Marian Kukucka, MD, Alexander Mladenow, MD, Ekaterina Ivanitskaja-Kühn, MD, Roland Hetzer, MD, PHD, Semih Buz, MD

Berlin, Germany

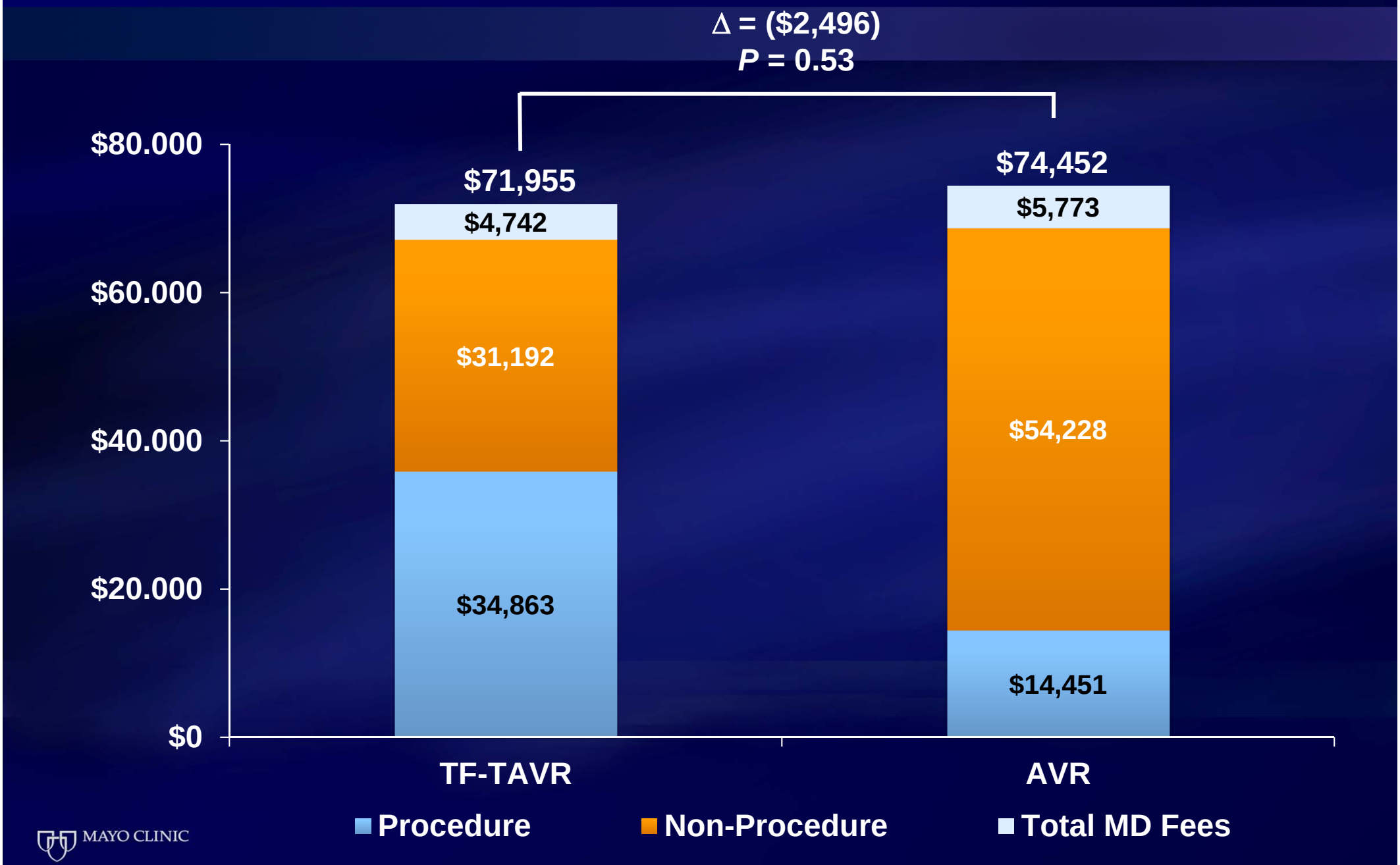


N = 258
Redilation 5%
Second valve 4%

Outline

1. What is the role of TAVR for inoperable patients with AS?
2. How does TAVR compare with AVR for high-risk AS?
3. What is the risk of stroke?
4. Does paravalvular leak matter?
5. Is TAVR cost effective?

TF vs AVR Index Admission Costs



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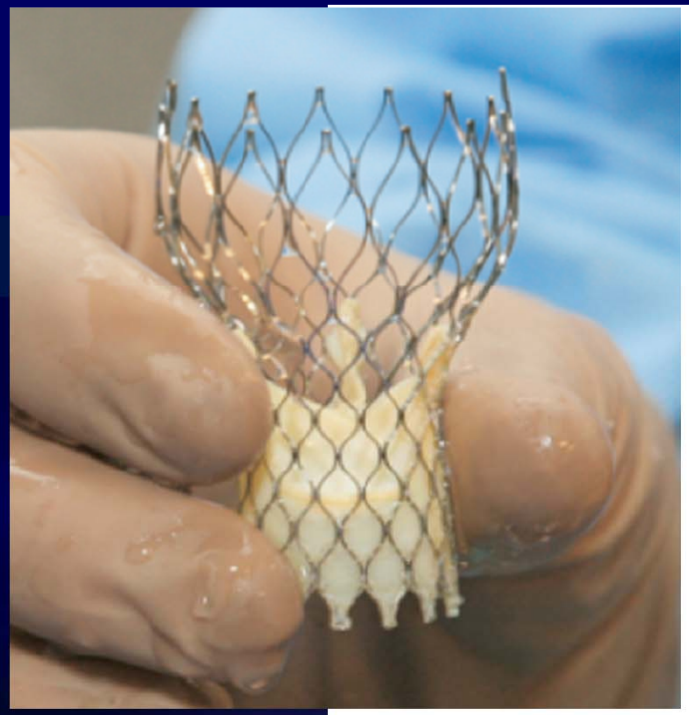


The NEW ENGLAND JOURNAL of MEDICINE

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*

From Mount Sinai Medical Center, New York (D.H.A.), and St. Francis Hospital, Roslyn (N.R., G.P.) — both in New York; Beth Israel Deaconess Medical Center, Boston (J.J.P.); Houston Methodist DeBakey Heart and Vascular Center (M.J.R., N.S.K.), and Texas Heart Institute at St. Luke's Medical Center (J.S.C.) — both in Houston; Riverside Methodist Hospital, Columbus, OH (S.J.Y.); University of Michigan Medical Center, Ann Arbor (G.M.D., S. Chetcuti), and Spectrum Health Hospitals, Grand Rapids (J.H., W.M.) — both in Michigan; University of Pittsburgh Medical Center, Pittsburgh (T.G.G.); Palo Alto Veterans Affairs Medical Center, Palo Alto, CA (M.B.); St. Vincent Medical Center, Indianapolis (J.H.); University of Kansas Hospital, Kansas City (G.Z., P.T.); Duke University Medical Center, Durham, NC (G.C.H., J.K.H.); Johns Hopkins Hospital, Baltimore (J.C.); Pinnacle Health, Harrisburg, PA (B.M., M.M.); and Medtronic, Minneapolis (S. Chenoweth), and Mayo Clinical Foundation, Rochester (J.K.O.) — both in

ABSTRACT

BACKGROUND

We compared transcatheter aortic-valve replacement (TAVR), using a self-expanding transcatheter aortic-valve bioprosthesis, with surgical aortic-valve replacement in patients with severe aortic stenosis and an increased risk of death during surgery.

METHODS

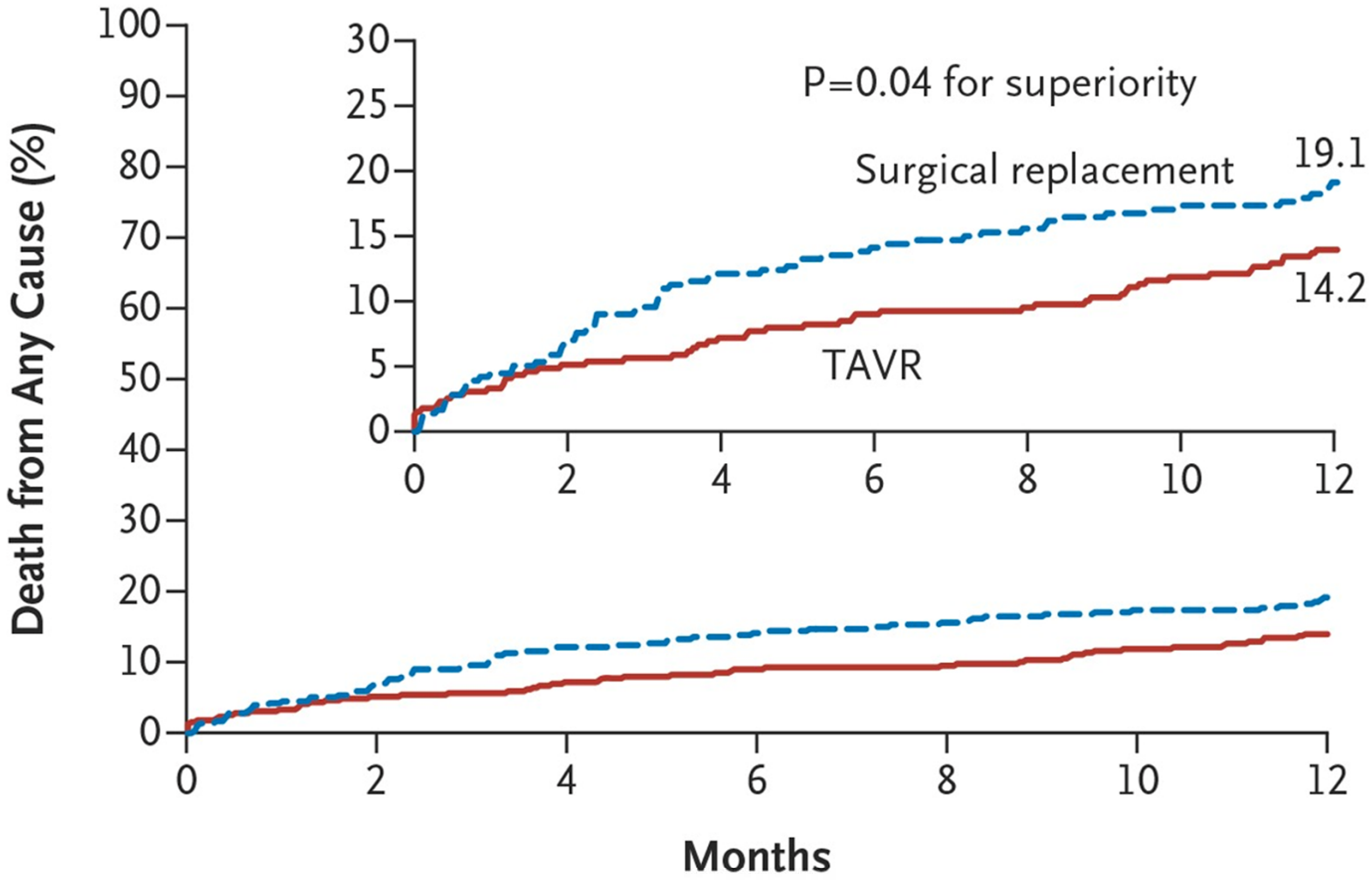
We recruited patients with severe aortic stenosis who were at increased surgical risk as determined by the heart team at each study center. Risk assessment included the Society of Thoracic Surgeons Predictor Risk of Mortality estimate and consideration of other key risk factors. Eligible patients were randomly assigned in a 1:1 ratio to TAVR with the self-expanding transcatheter valve (TAVR group) or to surgical aortic-valve replacement (surgical group). The primary end point was the rate of death from any cause at 1 year, evaluated with the use of both noninferiority and superiority testing.

RESULTS

A total of 795 patients underwent randomization at 45 centers in the United States. In the as-treated analysis, the rate of death from any cause at 1 year was significantly lower in the TAVR group than in the surgical group (14.2% vs. 19.1%), with an absolute reduction in risk of 4.9 percentage points (upper boundary of the 95% confidence interval, −0.4; P<0.001 for noninferiority; P = 0.04 for superiority). The

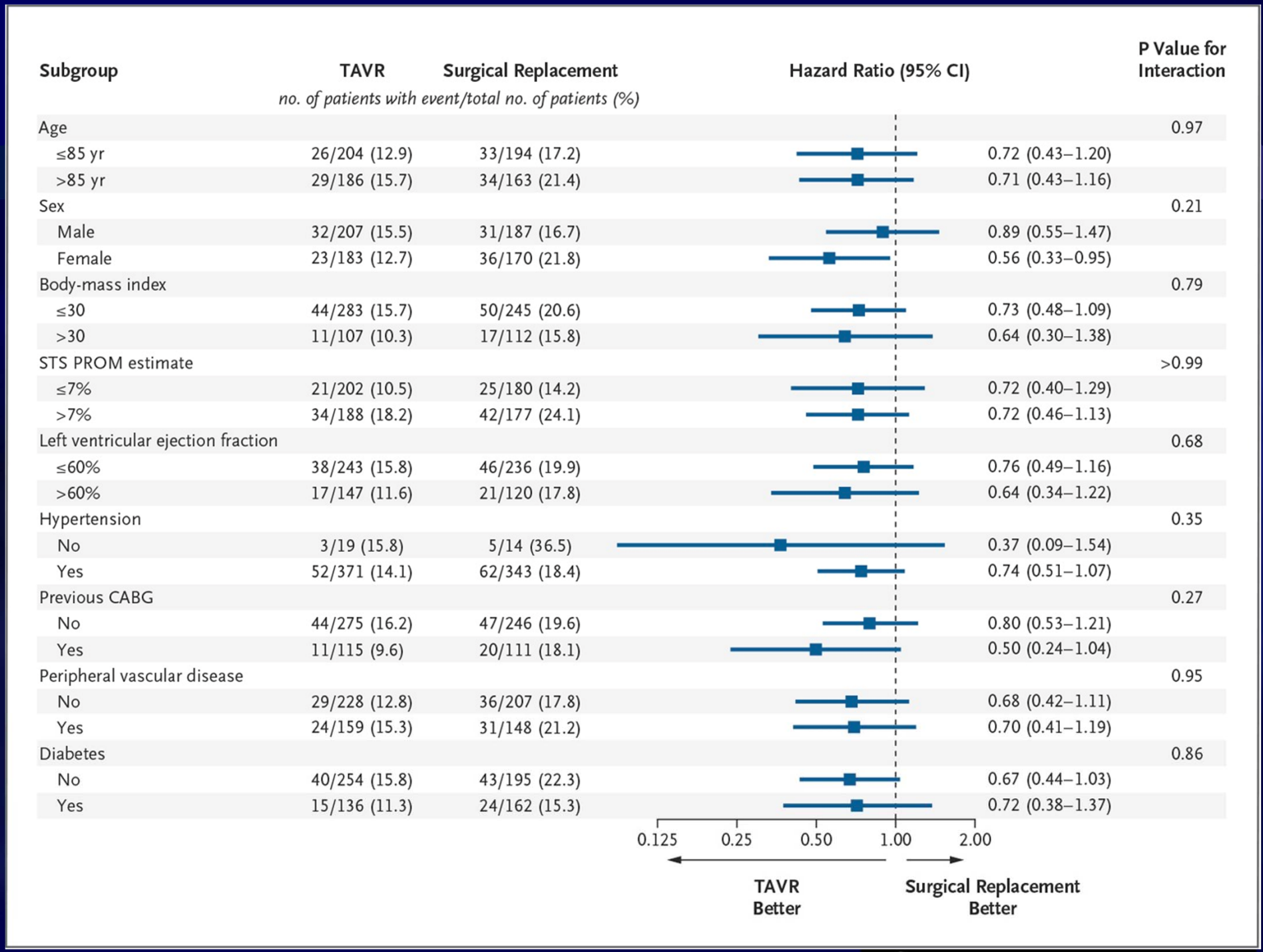
Summary

- Transcatheter aortic-valve replacement with a new self-expanding prosthesis was compared with surgical aortic-valve replacement in patients with aortic stenosis who were at high surgical risk.
- The rate of death from any cause at 1 year was lower in the TAVR group.



No. at Risk

TAVR	390	377	353	329
Surgical replacement	357	341	297	274


Subgroup
TAVR
Surgical Replacement
no. of patients with event/total no. of patients (%)
Hazard Ratio (95% CI)
P Value for Interaction
Age 0.97
≤85 yr 26/204 (12.9) 33/194 (17.2) 0.72 (0.43–1.20)
>85 yr 29/186 (15.7) 34/163 (21.4) 0.71 (0.43–1.16)
Sex 0.21
Male 32/207 (15.5) 31/187 (16.7) 0.89 (0.55–1.47)
Female 23/183 (12.7) 36/170 (21.8) 0.56 (0.33–0.95)
Body-mass index 0.79
≤30 44/283 (15.7) 50/245 (20.6) 0.73 (0.48–1.09)
>30 11/107 (10.3) 17/112 (15.8) 0.64 (0.30–1.38)
STS PROM estimate >0.99
≤7% 21/202 (10.5) 25/180 (14.2) 0.72 (0.40–1.29)
>7% 34/188 (18.2) 42/177 (24.1) 0.72 (0.46–1.13)
Left ventricular ejection fraction 0.68
≤60% 38/243 (15.8) 46/236 (19.9) 0.76 (0.49–1.16)
>60% 17/147 (11.6) 21/120 (17.8) 0.64 (0.34–1.22)
Hypertension 0.35
No 3/19 (15.8) 5/14 (36.5) 0.37 (0.09–1.54)
Yes 52/371 (14.1) 62/343 (18.4) 0.74 (0.51–1.07)
Previous CABG 0.27
No 44/275 (16.2) 47/246 (19.6) 0.80 (0.53–1.21)
Yes 11/115 (9.6) 20/111 (18.1) 0.50 (0.24–1.04)
Peripheral vascular disease 0.95
No 29/228 (12.8) 36/207 (17.8) 0.68 (0.42–1.11)
Yes 24/159 (15.3) 31/148 (21.2) 0.70 (0.41–1.19)
Diabetes 0.86
No 40/254 (15.8) 43/195 (22.3) 0.67 (0.44–1.03)
Yes 15/136 (11.3) 24/162 (15.3) 0.72 (0.38–1.37)
0.125
0.25
0.50
1.00
2.00
TAVR Better
Surgical Replacement Better

Original Investigation

Comparison of Balloon-Expandable vs Self-expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement
The CHOICE Randomized Clinical Trial

Mohamed Abdel-Wahab, MD; Julinda Mehilli, MD; Christian Frerker, MD; Franz-Josef Neumann, MD; Thomas Kurz, MD; Ralph Tölg, MD; Dirk Zachow, MD; Elena Guerra, MD; Steffen Massberg, MD; Ulrich Schäfer, MD; Mohamed El-Mawardy, MD; Gert Richardt, MD; for the CHOICE investigators

IMPORTANCE Transcatheter aortic valve replacement (TAVR) is an effective treatment option for high-risk patients with severe aortic stenosis. Different from surgery, transcatheter deployment of valves requires either a balloon-expandable or self-expandable system. A randomized comparison of these 2 systems has not been performed.

OBJECTIVE To determine whether the balloon-expandable device is associated with a better success rate than the self-expandable device.

DESIGN, SETTING, AND PATIENTS The CHOICE study was an investigator-initiated trial in high-risk patients with severe aortic stenosis and an anatomy suitable for the transfemoral TAVR procedure. One hundred twenty-one patients were randomly assigned to receive a balloon-expandable valve (Edwards Sapien XT) and 120 were assigned to receive a self-expandable valve (Medtronic CoreValve). Patients were enrolled between March 2012 and December 2013 at 5 centers in Germany.

INTERVENTIONS Transfemoral TAVR with a balloon-expandable or self-expandable device.

MAIN OUTCOMES AND MEASURES The primary end point was device success, which is a composite end point including successful vascular access and deployment of the device and retrieval of the delivery system, correct position of the device, intended performance of the heart valve without moderate or severe regurgitation, and only 1 valve implanted in the proper anatomical location. Secondary end points included cardiovascular mortality, bleeding and vascular complications, postprocedural pacemaker placement, and a combined safety end point at 30 days, including all-cause mortality, major stroke, and other serious complications.

RESULTS Device success occurred in 116 of 121 patients (95.9%) in the balloon-expandable valve group and 93 of 120 patients (77.5%) in the self-expandable valve group (relative risk [RR], 1.24, 95% CI, 1.12-1.37, $P < .001$). This was attributed to a significantly lower frequency of residual more-than-mild aortic regurgitation (4.1% vs 18.3%; RR, 0.23; 95% CI, 0.09-0.58; $P < .001$) and the less frequent need for implanting more than 1 valve (0.8% vs 5.8%, $P = .03$) in the balloon-expandable valve group. Cardiovascular mortality at 30 days was 4.1% in the

Editorial page 1500

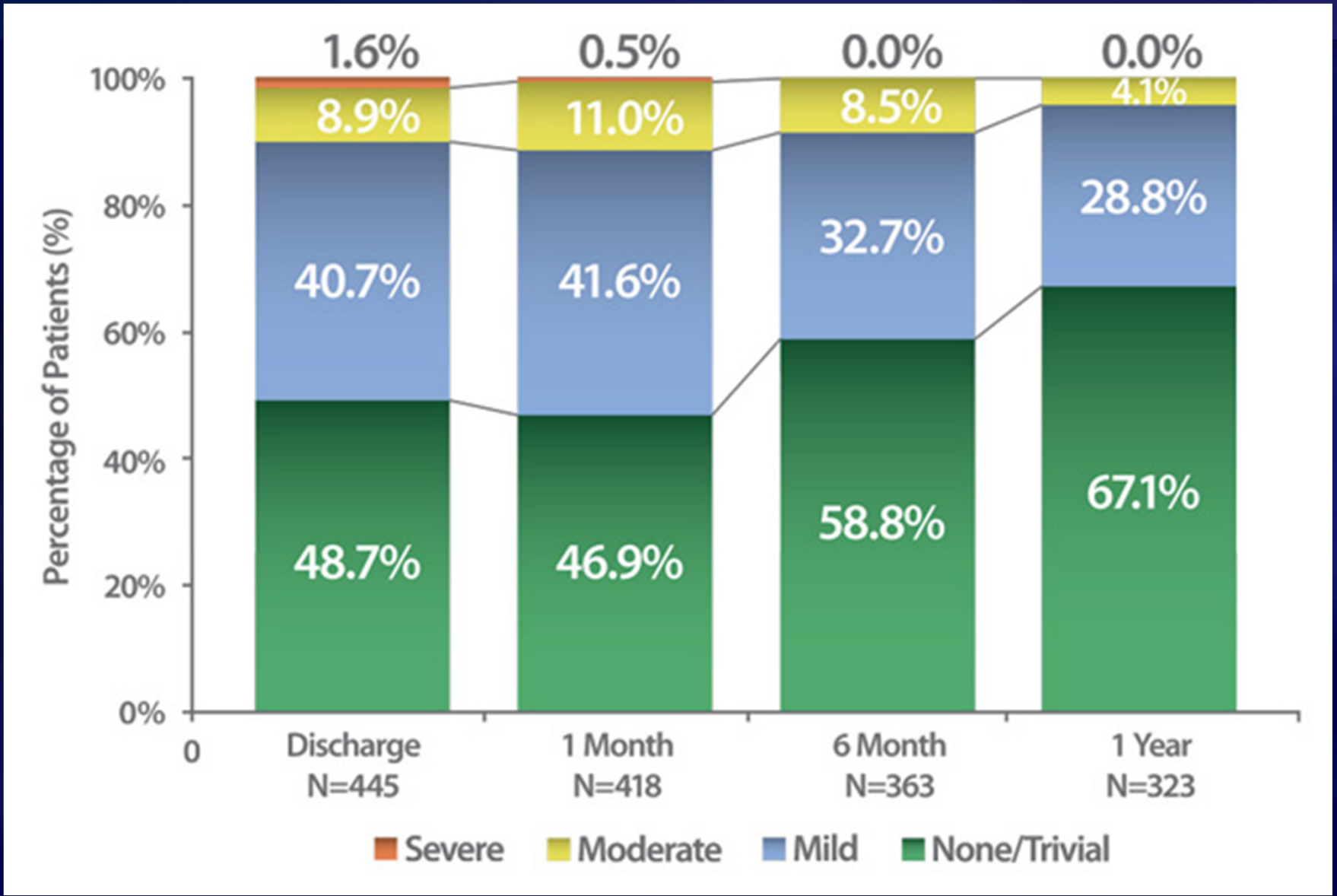
Author Audio Interview at jama.com

Supplemental content at jama.com

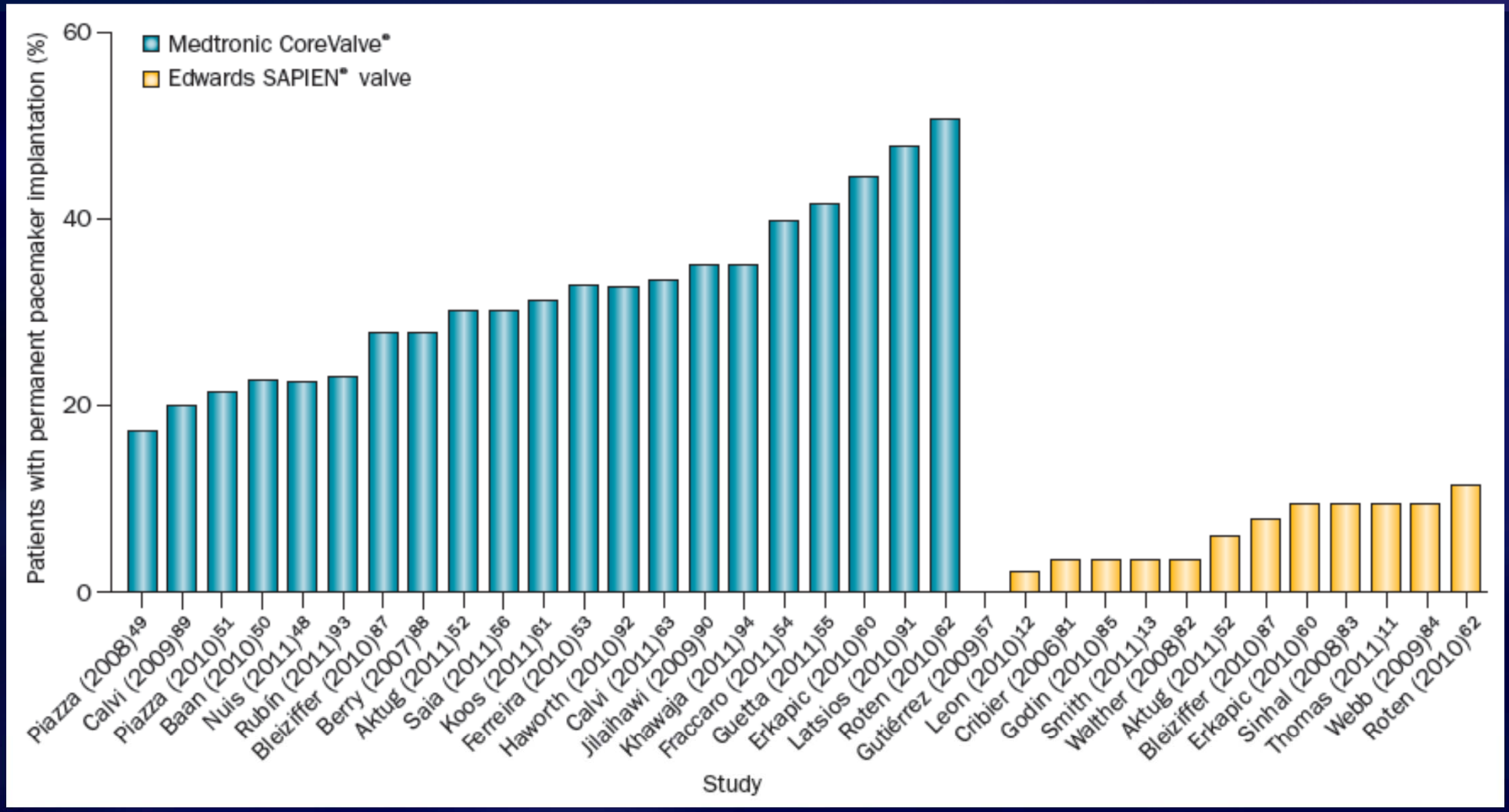
30 Day Outcomes

	Balloon Expandable	Self Expanding	p
Device Success	95.9%	77.5%	<0.001
> Mild AR	4.1%	18.3%	<0.001
CV Mortality	4.1%	4.3%	
New PPM	17.3%	37.6%	0.01

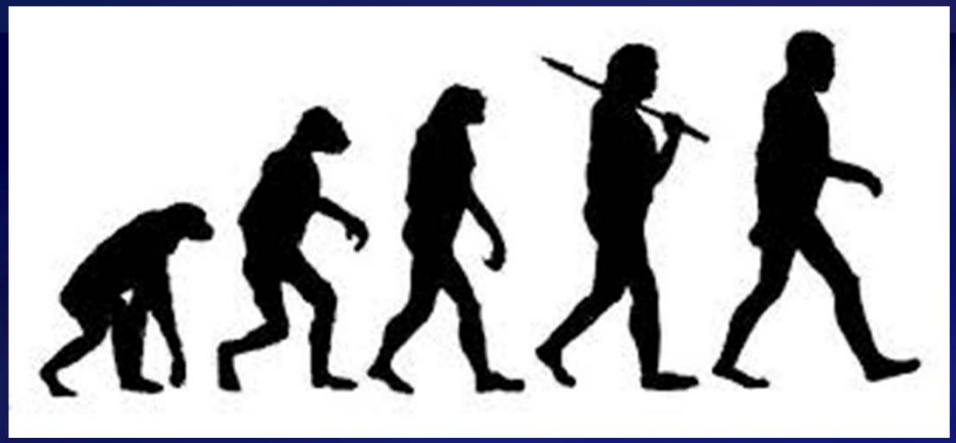
CoreValve – Less Paravalvular Leak

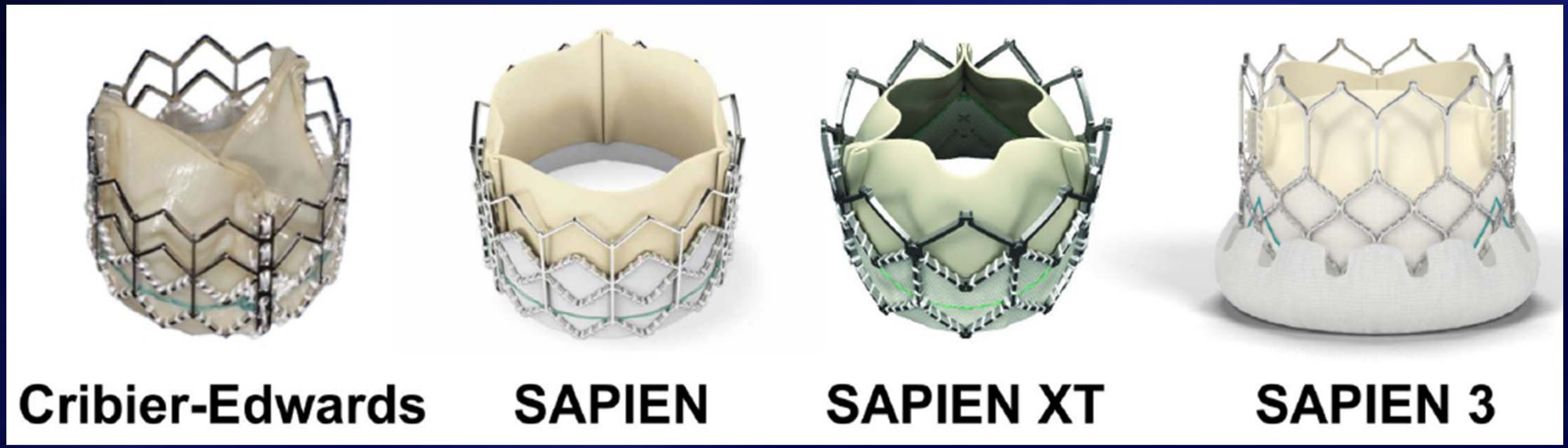


CoreValve – More Permanent Pacemakers

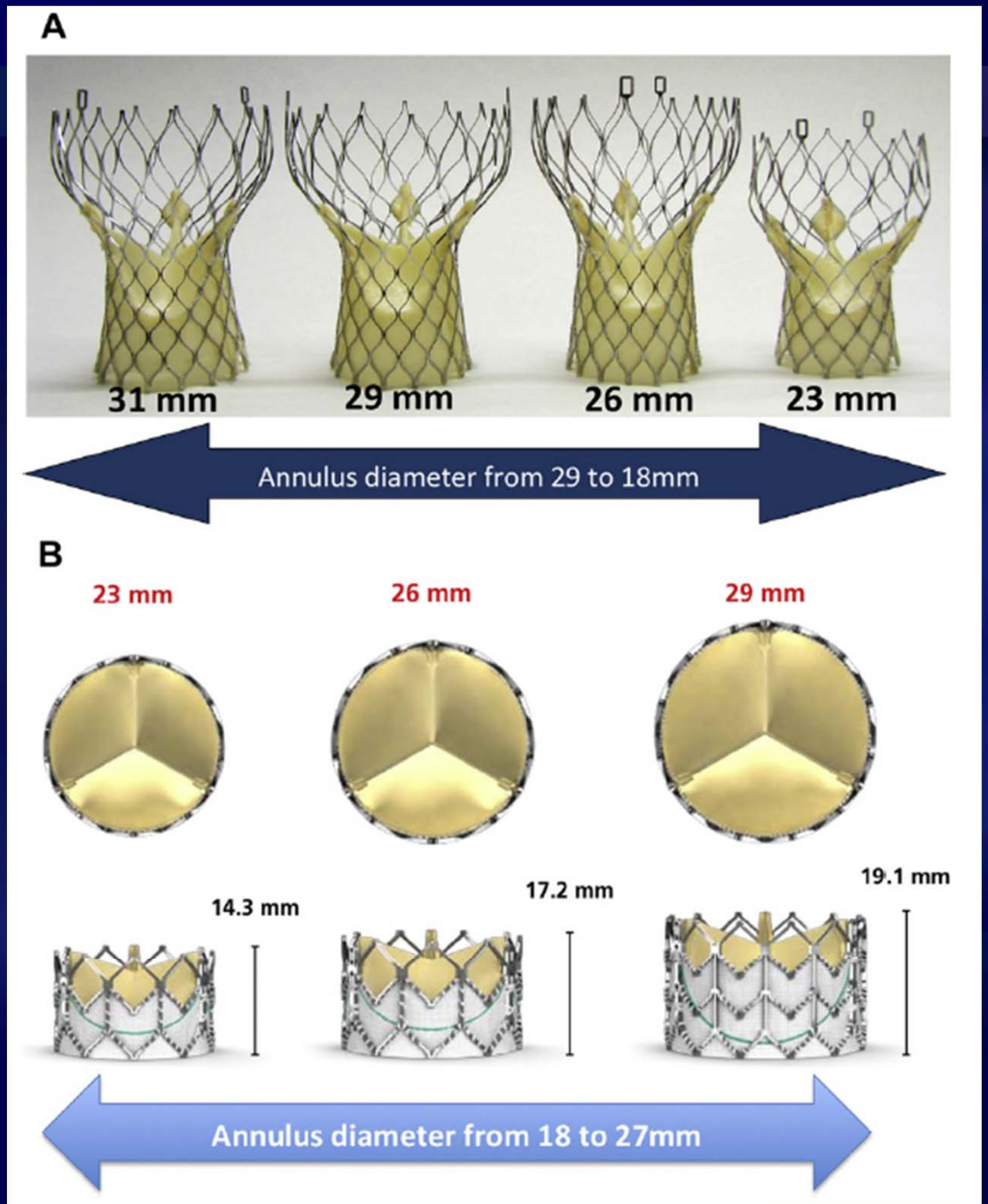


TAVR Today – An Evolution



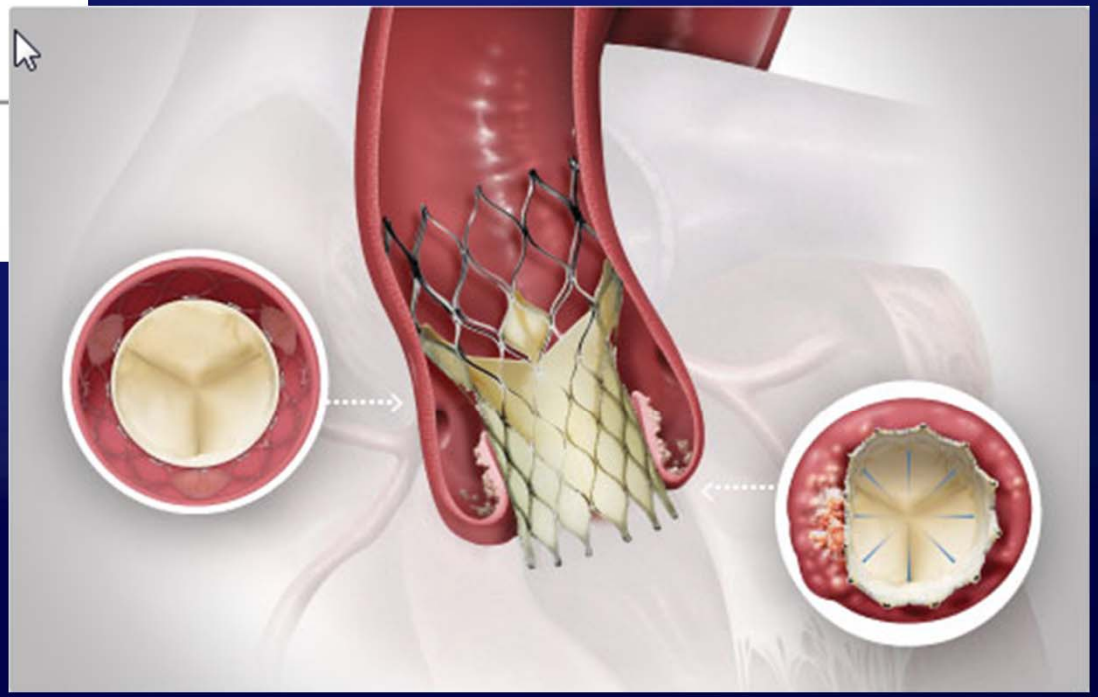


TAVR Tomorrow – More Choices



CoreValve® Evolut™

The *Next* Step



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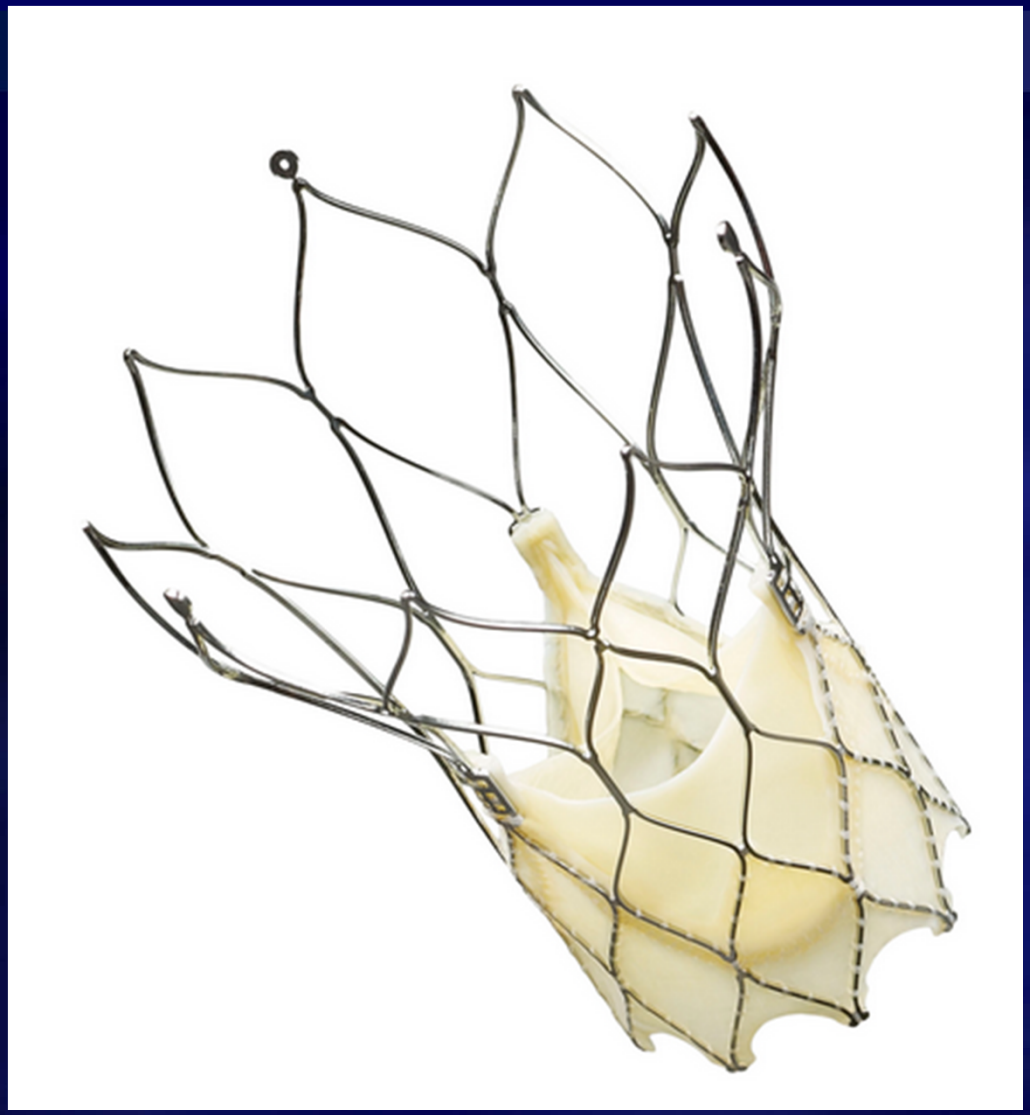
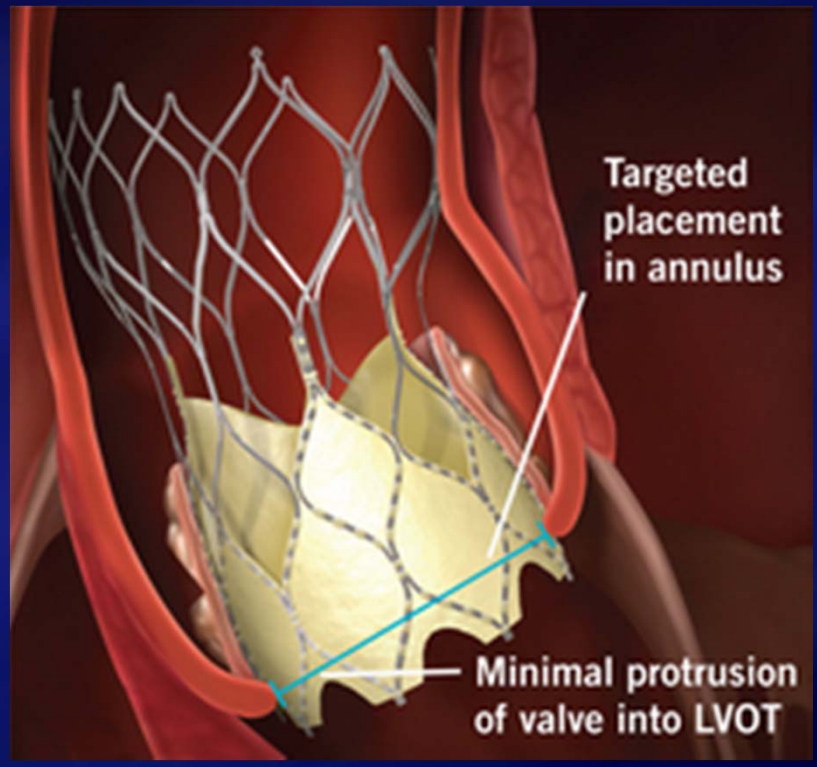
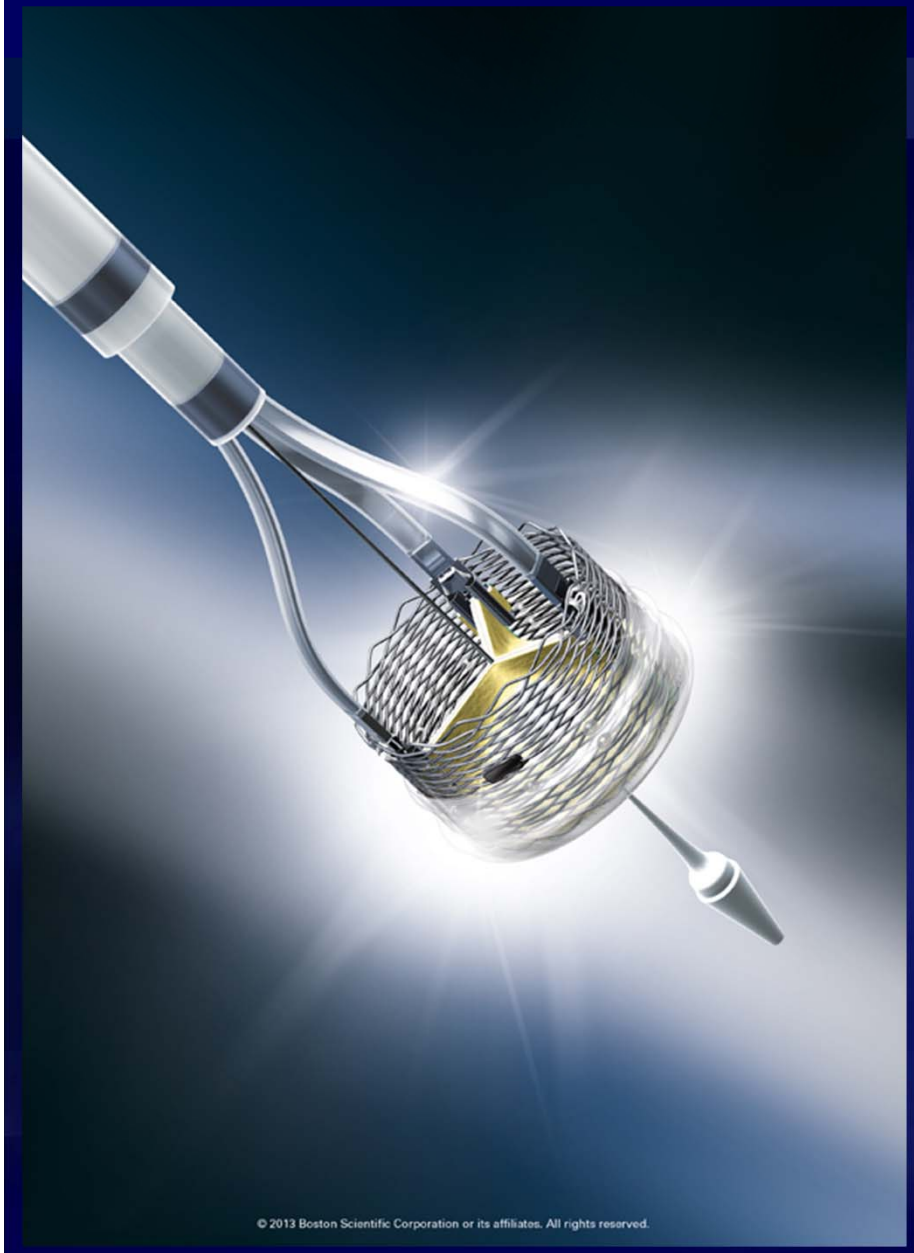
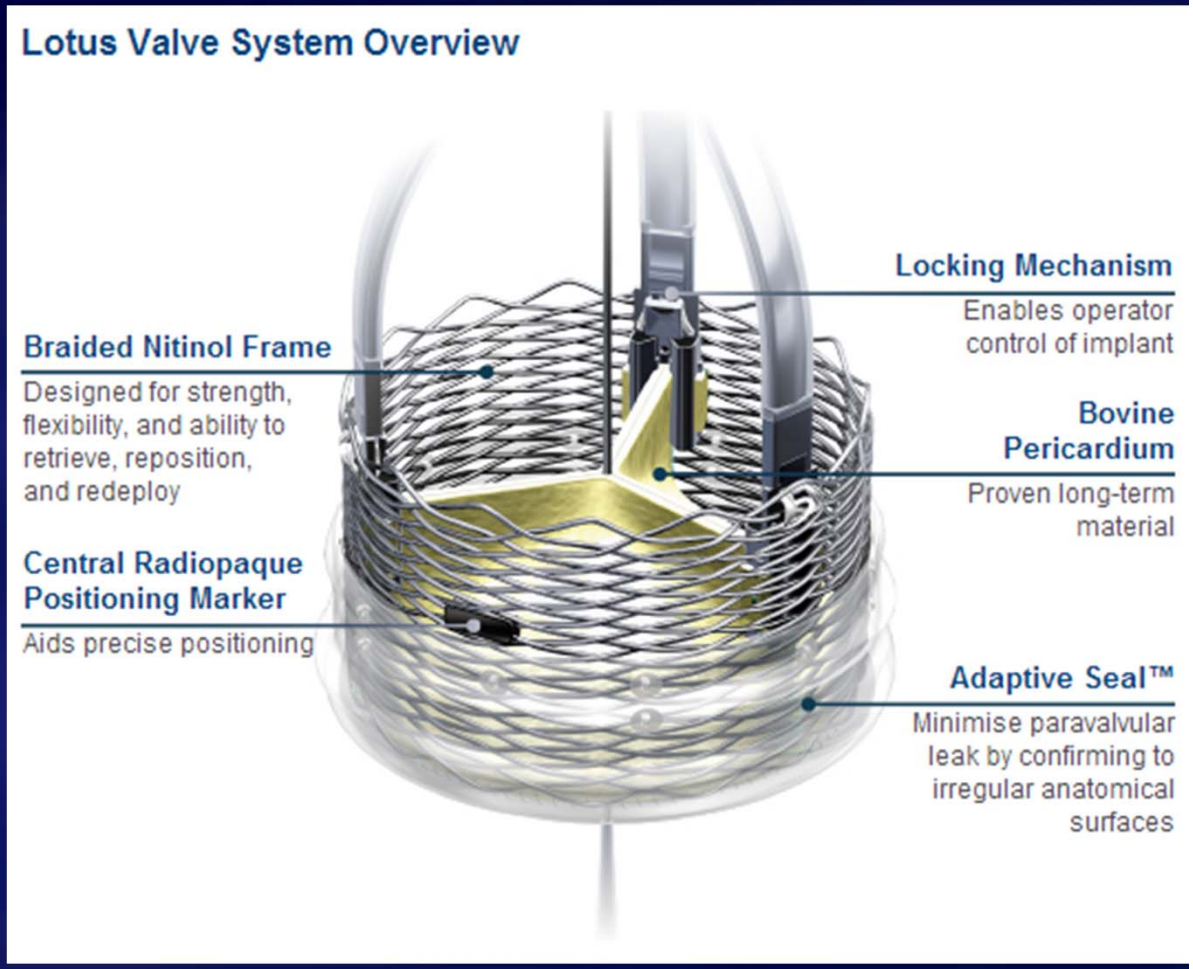
St. Jude Medical - PORTICO





BSC Lotus Valve – The REPRISE Trials

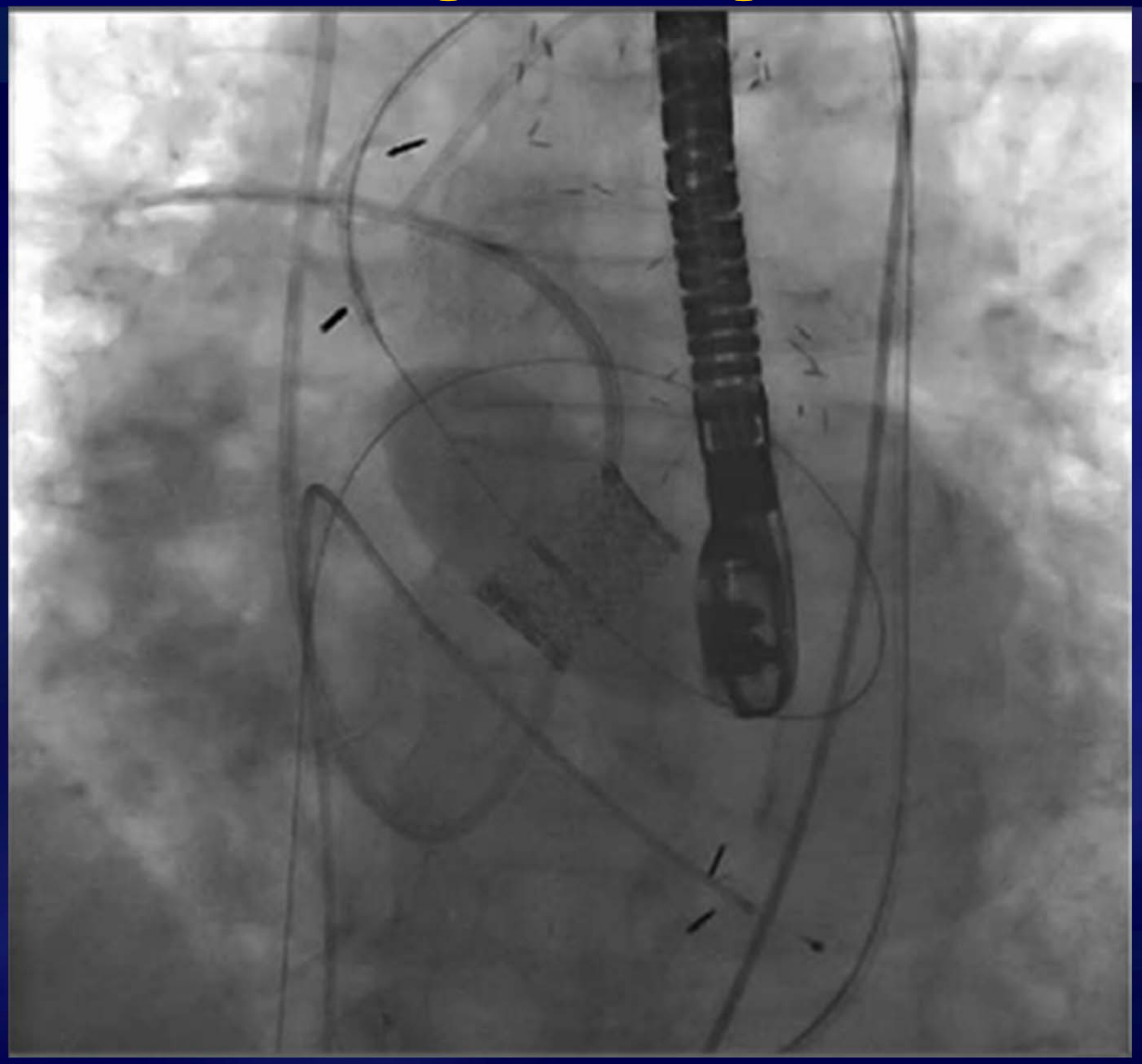




The Direct Flow Medical Valve

- CE Mark - Jan 2013
- Completed SALUS
  US Phase 1 – Jan 2014
- Planning US Pivotal Trial to begin 2014

The Future: A Return to the beginning?



Trans-Venous Trans-septal TAVR

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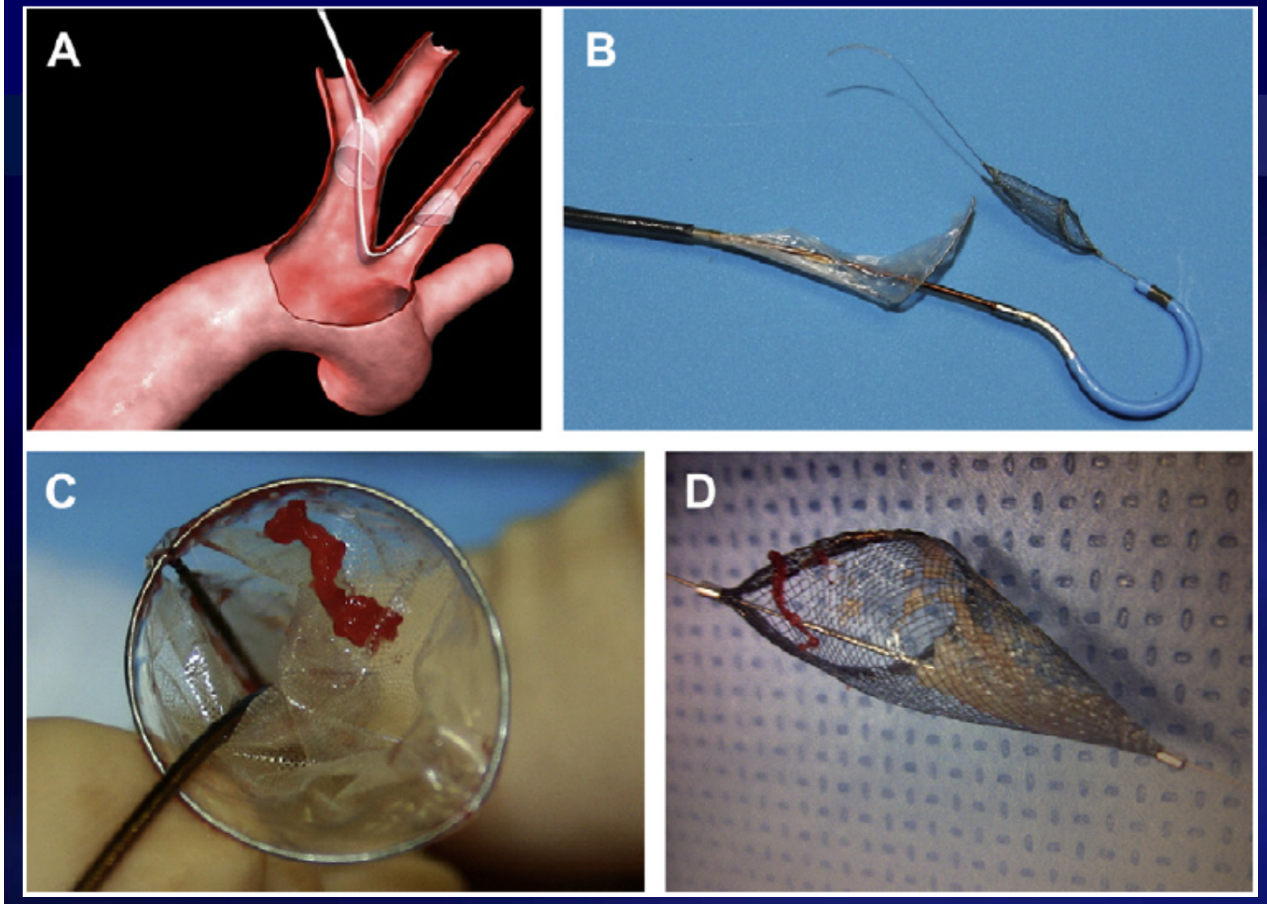
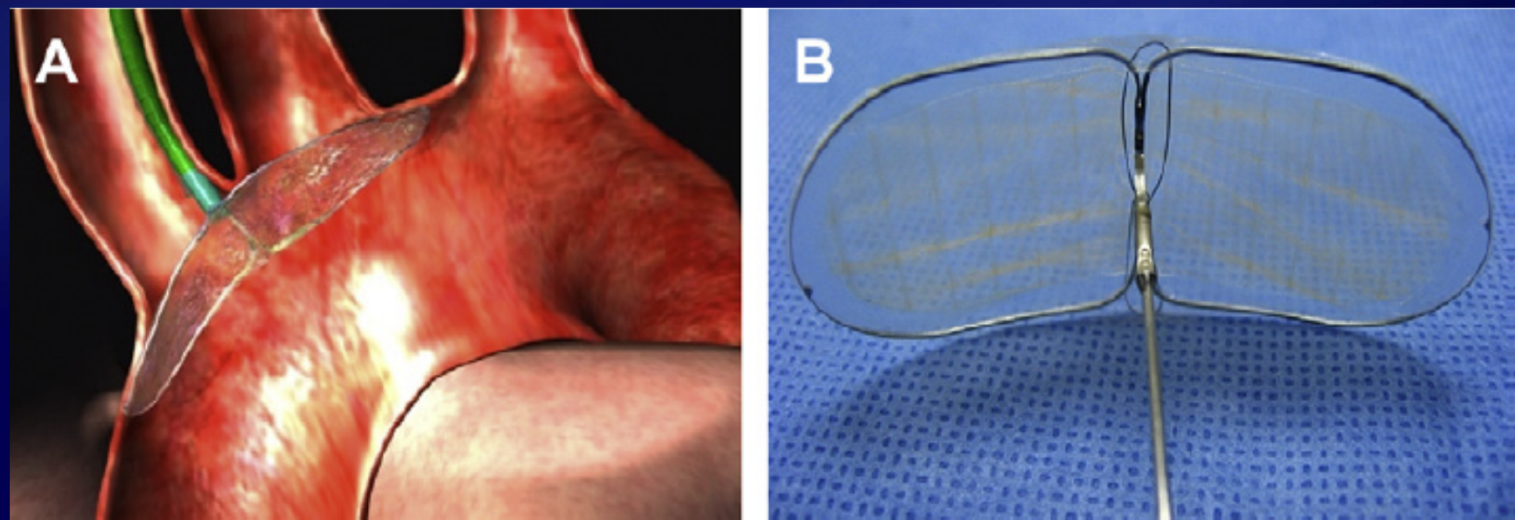
O'Neill CCI 2013

The Future – Embolic Protection



Claret Tandem Device

Embrella Edwards



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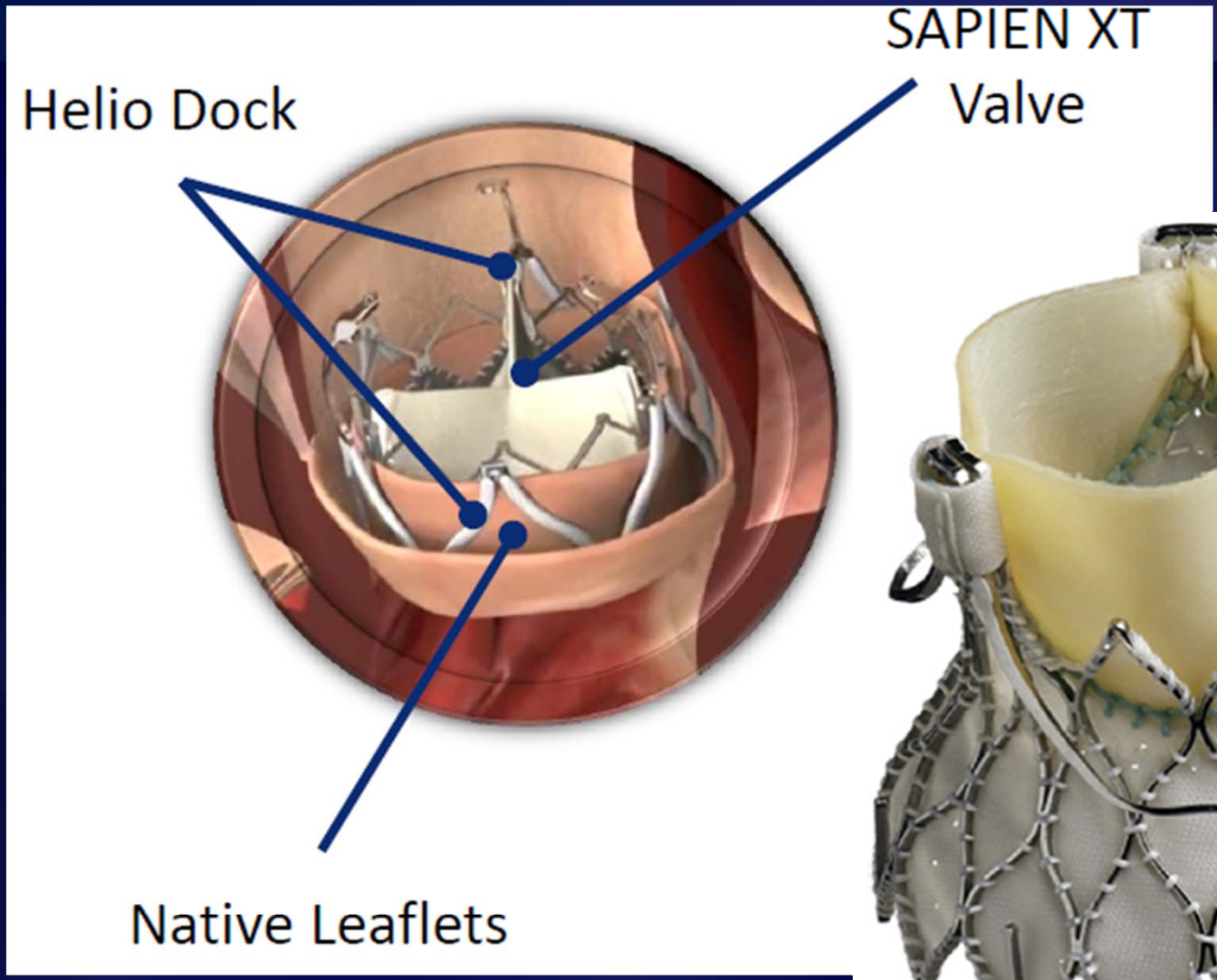
The Future – Aortic Insufficiency



Conclusions

1. TAVR is superior to medical therapy for inoperable patients with AS

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2. TAVR compares favorably with AVR for high-risk AS

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4. Paravalvular leak is related to calcification and predicts outcomes

Conclusions

1. TAVR is superior to medical therapy for inoperable patients with AS
2. TAVR compares favorably with AVR for high-risk AS
3. There is a risk of stroke with both TAVR and AVR
4. Paravalvular leak is related to calcification and predicts outcomes
5. Transfemoral TAVR is cost effective

Which of the following are candidates for TAVI?

- An 82-year-old man with prior CABG, prior TIAs, moderate COPD, and a creatinine of 1.8.
- A 50-year-old man with prior mantle irradiation, severe AS, and a heavily calcified aorta.
- A 55-year-old woman with a bicuspid aortic valve and severe AS.
- A 40-year-old man with Marfan's syndrome and severe AR who refuses surgery.

A) All of the above.
B) None of the above.
C) Some of the above.

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The STS score is:

1. A system of grading the severity of aortic stenosis
2. A way of quantitating surgical risk
3. Usually higher than the Euroscore
4. A NASCAR ranking system

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rihal@mayo.edu

Thank You