Heart valve replacement without surgery!

The rapid evolution of catheter treatment of heart valve problems

Neil Wimmer MD MSc FACC FSCAI

April 20, 2023

ChristianaCare

Our patient….

- 84 year old man.
- Lives with his son but remains active.
- Generally able to climb up stairs, but progressive limitation due to dyspnea.

- Prior medical history:
  - CAD s/p CABG
  - CKD with baseline creatinine 1.5
  - History of TIA
  - s/p endovascular AAA repair

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Our patient….

- Physical Exam:
  - BP 132/74 mm Hg, HR 68
  - Dampened, delayed carotid upstroke (parvus et tardus)
  - Late-peaking systolic ejection murmur (ii/vi)
  - Muffled aortic component of S2
- ECG: sinus rhythm with LVH with repolarization changes (strain pattern)

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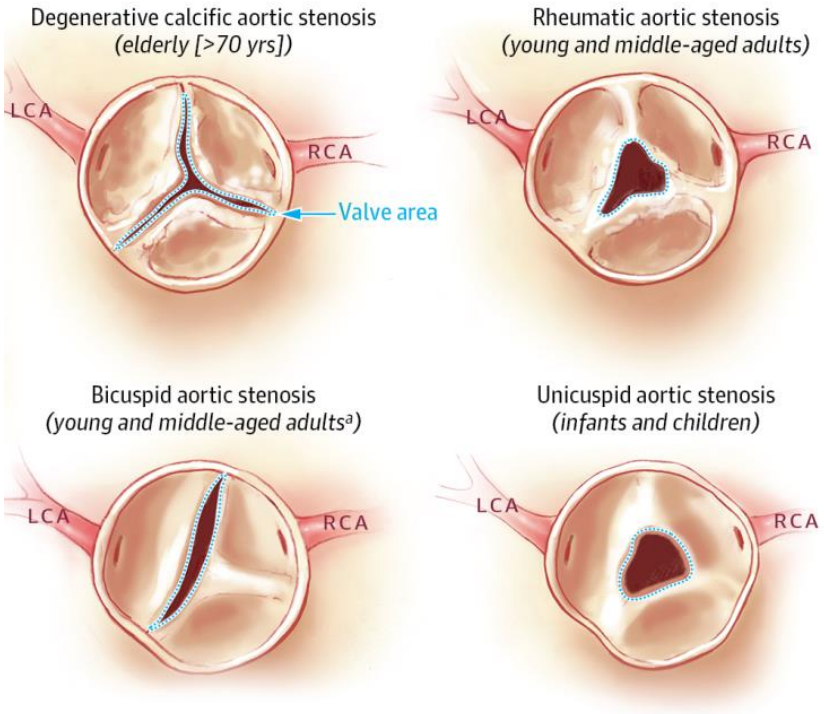
Aortic Valve Stenosis

Examples of types of aortic stenosis and age of presentation of aortic stenosis



JAMA Cardiol. 2016;1(5):623.
Image courtesy of Michael Davidson, MD

Our patient….

STS Adult Cardiac Surgery Database Version 2.9

RISK SCORES

Procedure: Isolated AVR

CALCULATE

Risk of Mortality:	4.529%
Renal Failure:	7.058%
Permanent Stroke:	2.030%
Prolonged Ventilation:	19.478%
DSW Infection:	0.337%
Reoperation:	4.434%
Morbidity or Mortality:	26.405%
Short Length of Stay:	12.754%
Long Length of Stay:	19.046%

PRINT CLEAR

an.
son but remains active.
to climb up stairs, but
nitation due to dyspnea.

history:
CABG
baseline creatinine 1.5
f TIA
vascular AAA repair

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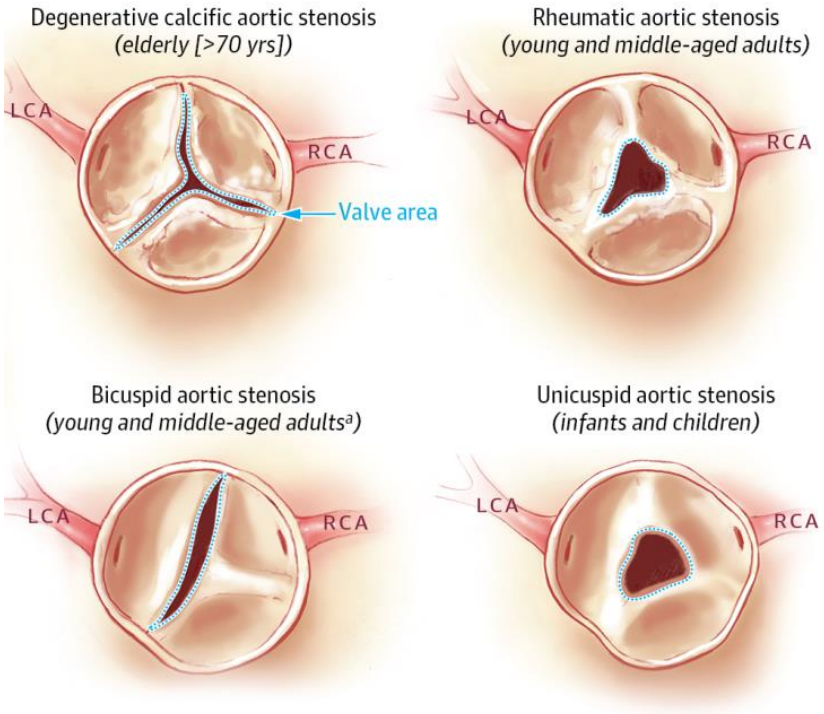
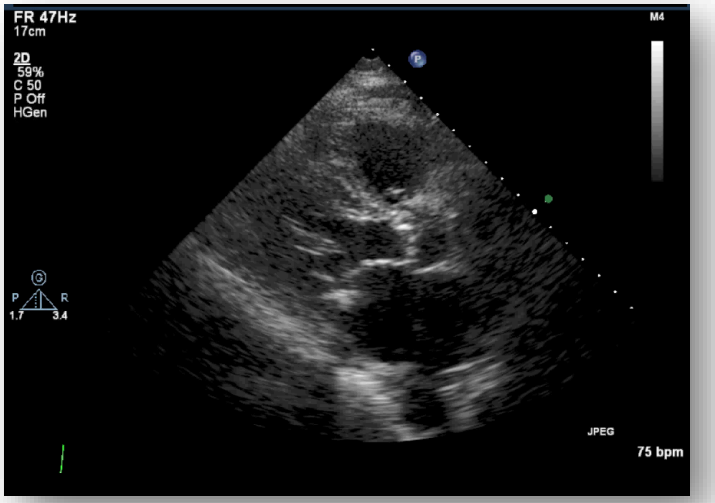
Aortic Valve Stenosis

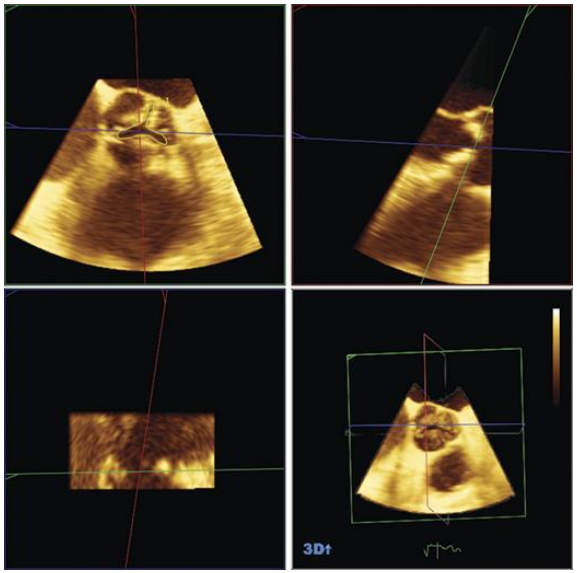
Examples of types of aortic stenosis and age of presentation of aortic stenosis



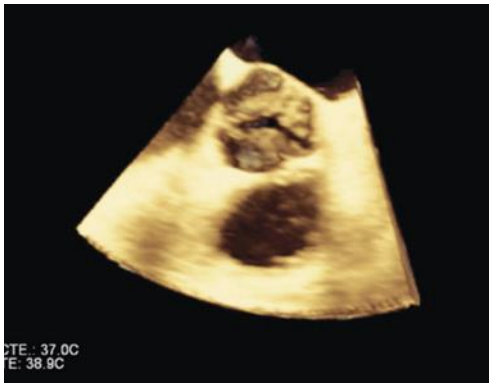
JAMA Cardiol. 2016;1(5):623.
Image courtesy of Michael Davidson, MD

Aortic Valve Stenosis: The diagnosis





- Any aortic stenosis: 14.2%
- Severe aortic stenosis: 3.4%



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J Am Coll Cardiol. 2013; 54(6).
Eur J Echocardiogr. 2009;11(1).

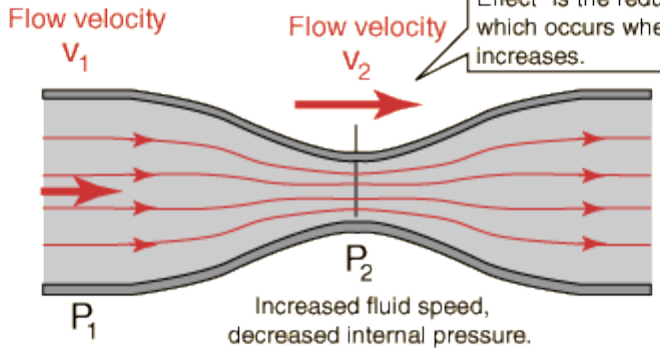
Aortic Valve Stenosis: The diagnosis

Energy per unit volume before = Energy per unit volume after

$$P_1 + \frac{1}{2}\rho v_1^2 + \rho g h_1 = P_2 + \frac{1}{2}\rho v_2^2 + \rho g h_2$$

Pressure Energy | Kinetic Energy per unit volume | Potential Energy per unit volume

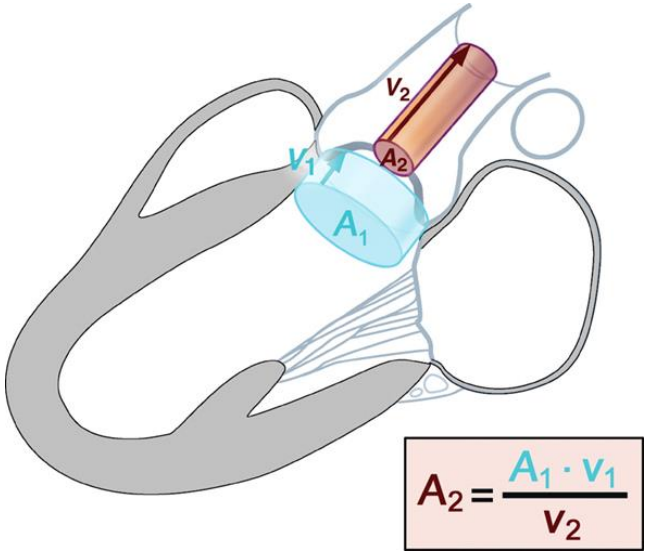
The often cited example of the Bernoulli Equation or "Bernoulli Effect" is the reduction in pressure which occurs when the fluid speed increases.



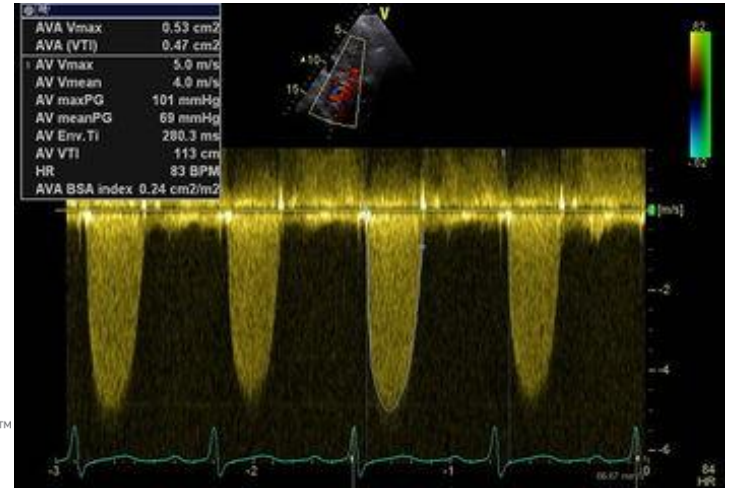
$A_2 < A_1$

$v_2 > v_1$

$P_2 < P_1$!



$$A_2 = \frac{A_1 \cdot v_1}{v_2}$$



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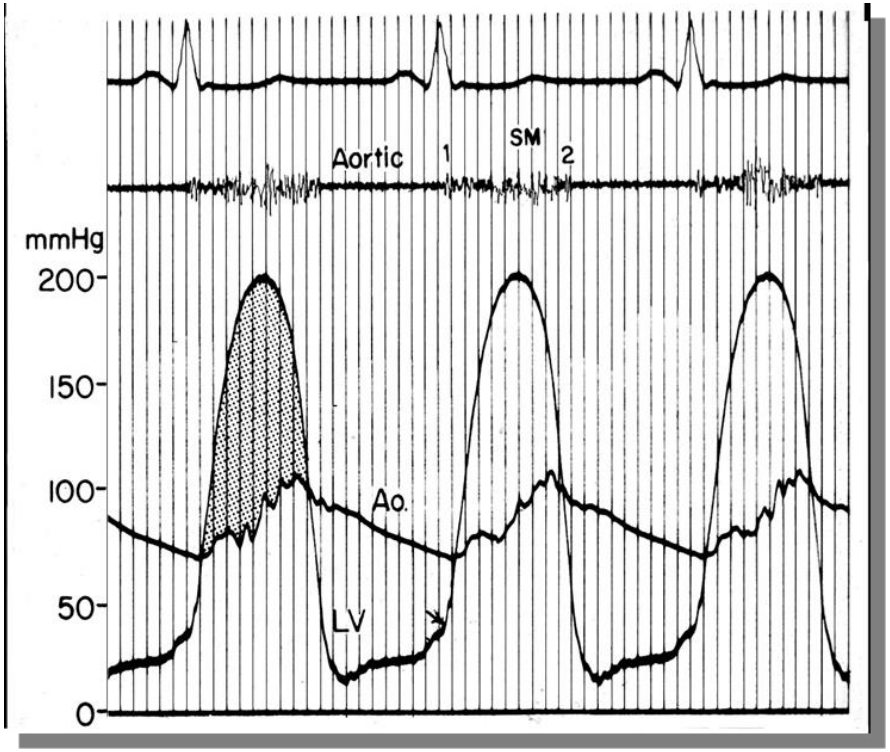
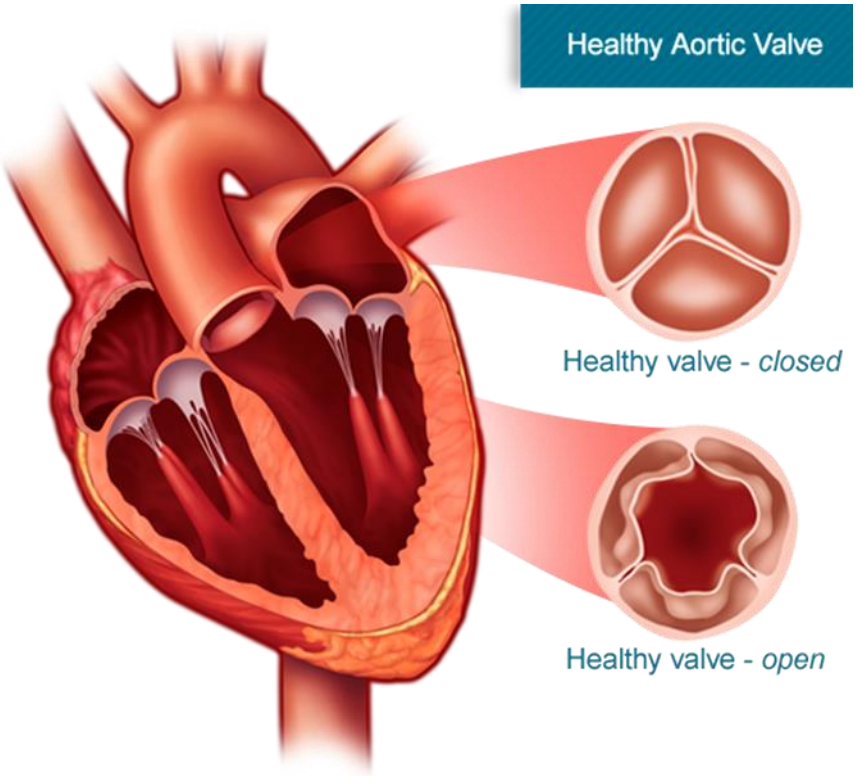
Eur J Echocardiogr. 2009;10(1):1-25.

Aortic Valve Stenosis: The diagnosis





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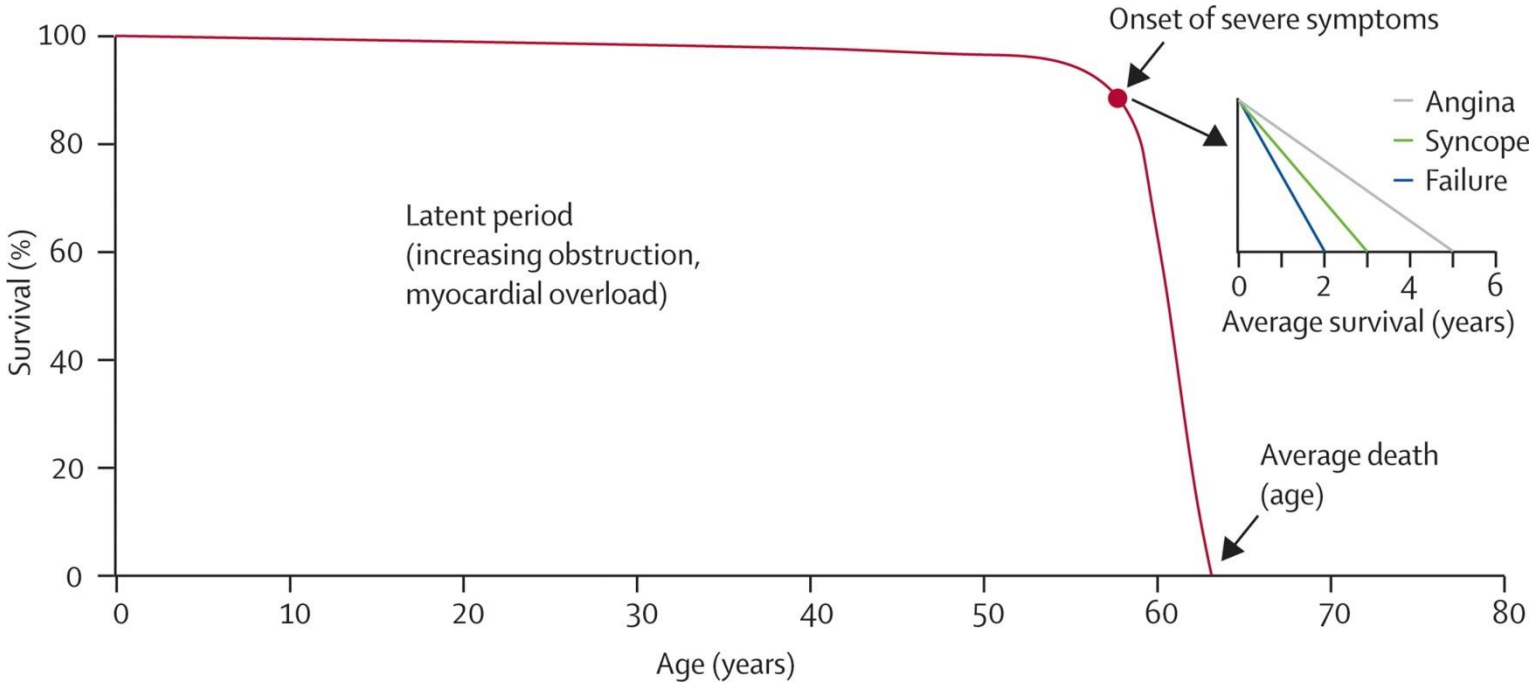
Aortic stenosis is deadly.



From Braunwald's Heart Disease, 10th ed.

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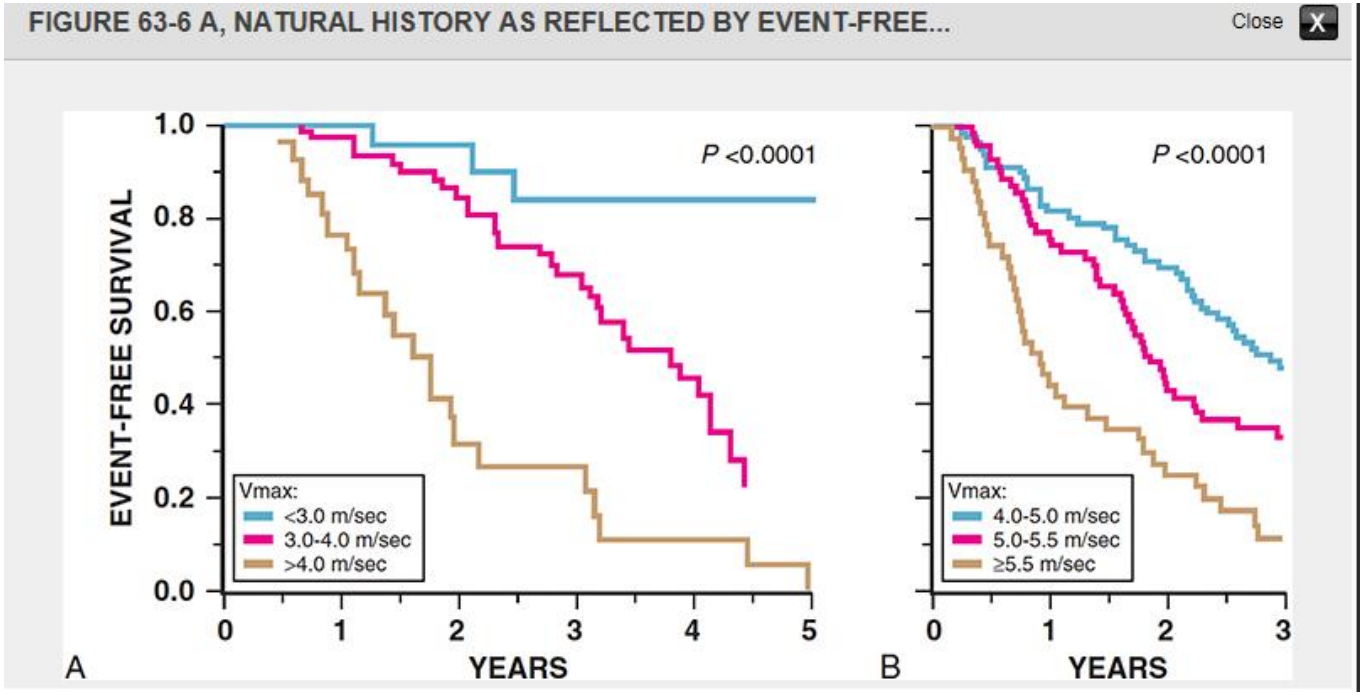
Aortic stenosis is deadly.



From Braunwald's Heart Disease, 10th ed.

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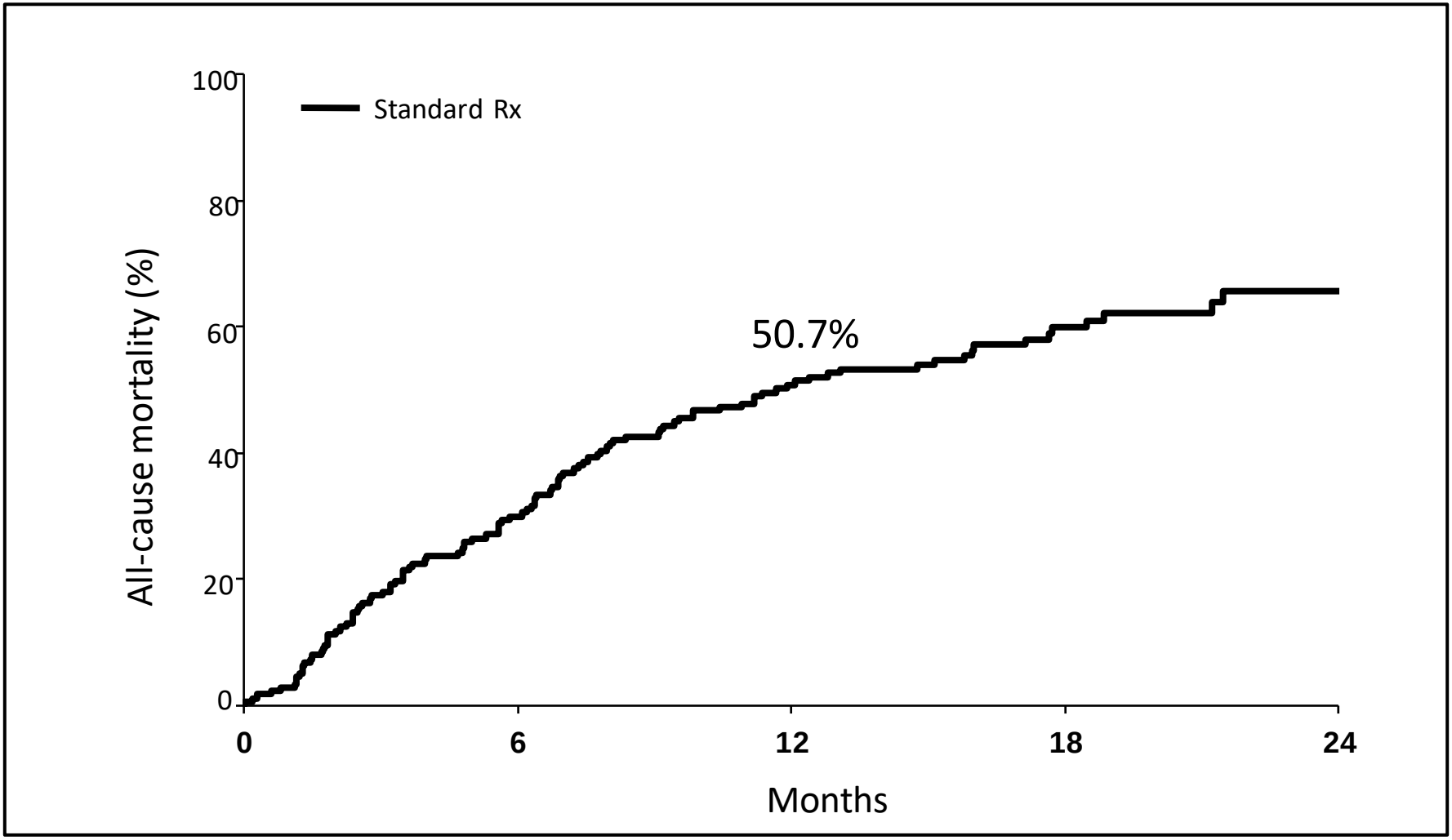
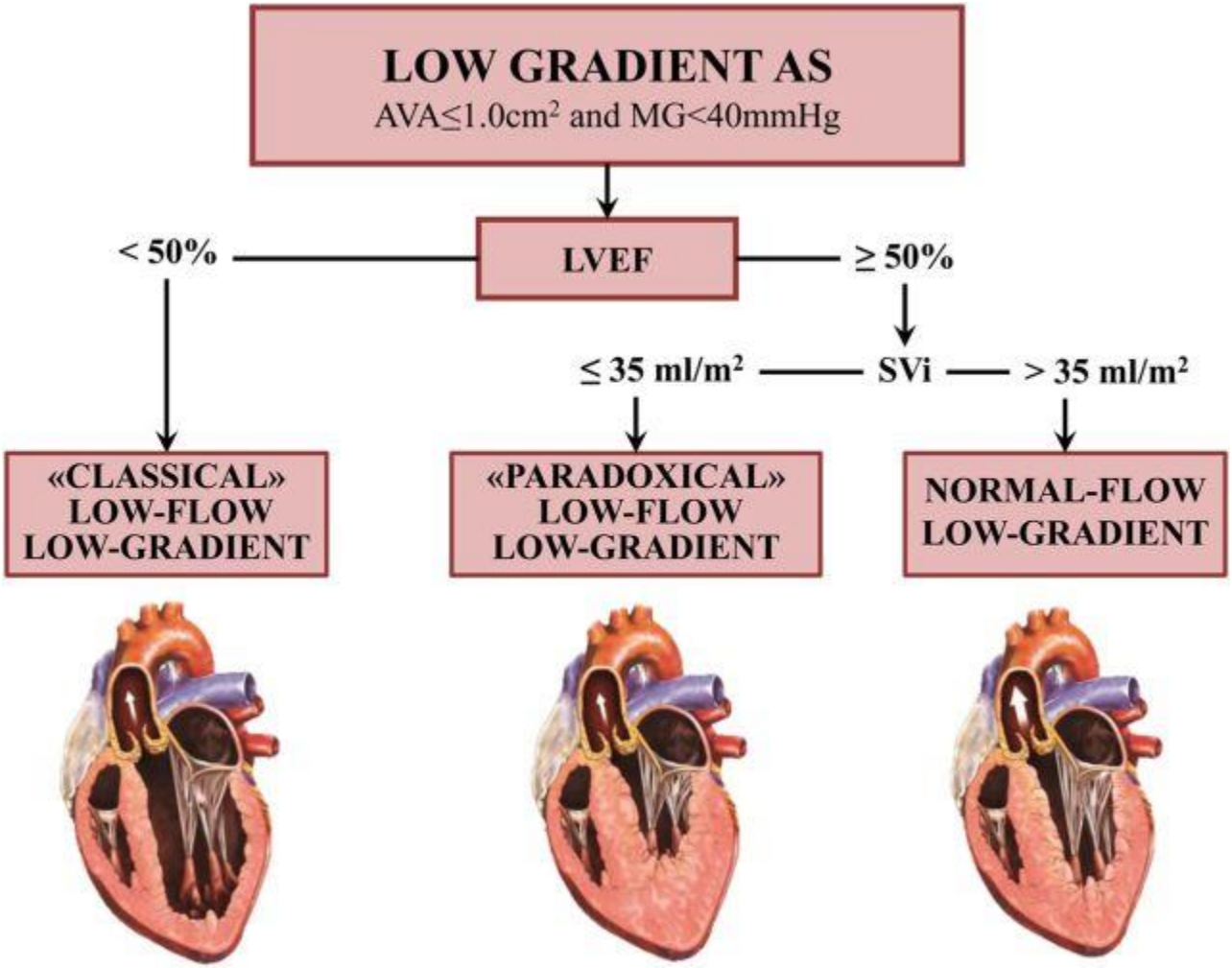
Mortality without valve replacement



Numbers at Risk					
Standard Rx	179	121	83	41	12

Leon MB, Smith CR, et al. *N Engl J Med* 2010

Low-flow, low gradient AS



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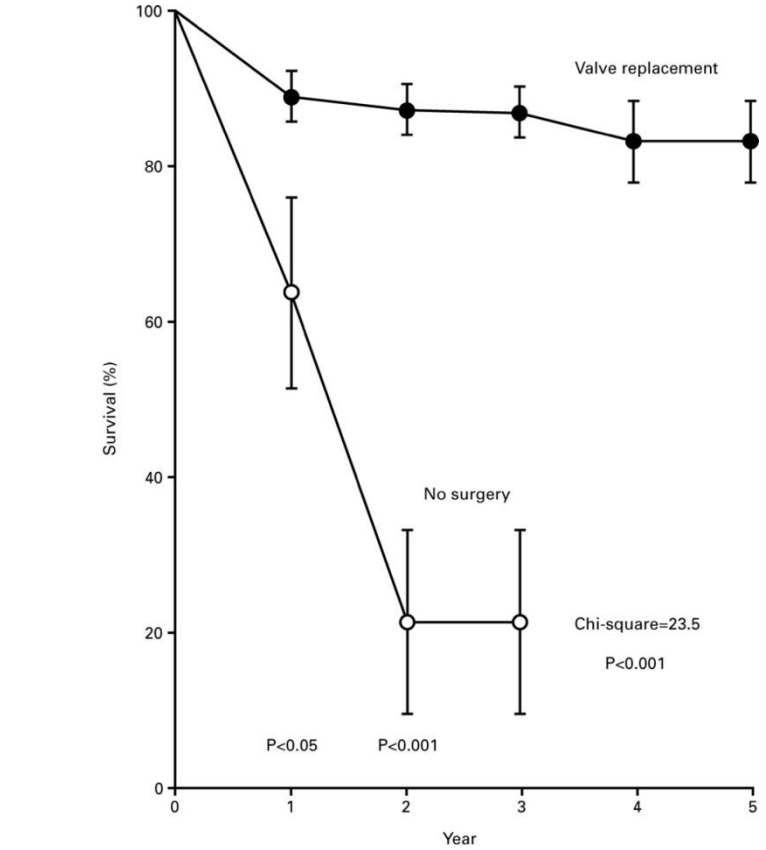
Clavel, Magne, Pibarot. European Heart Journal, 2016.

Surgical AVR - A Dramatic Intervention



NO. AT RISK

Valve replacement	125	87	51	35	9	0
No surgery	19	8	2	1	0	0

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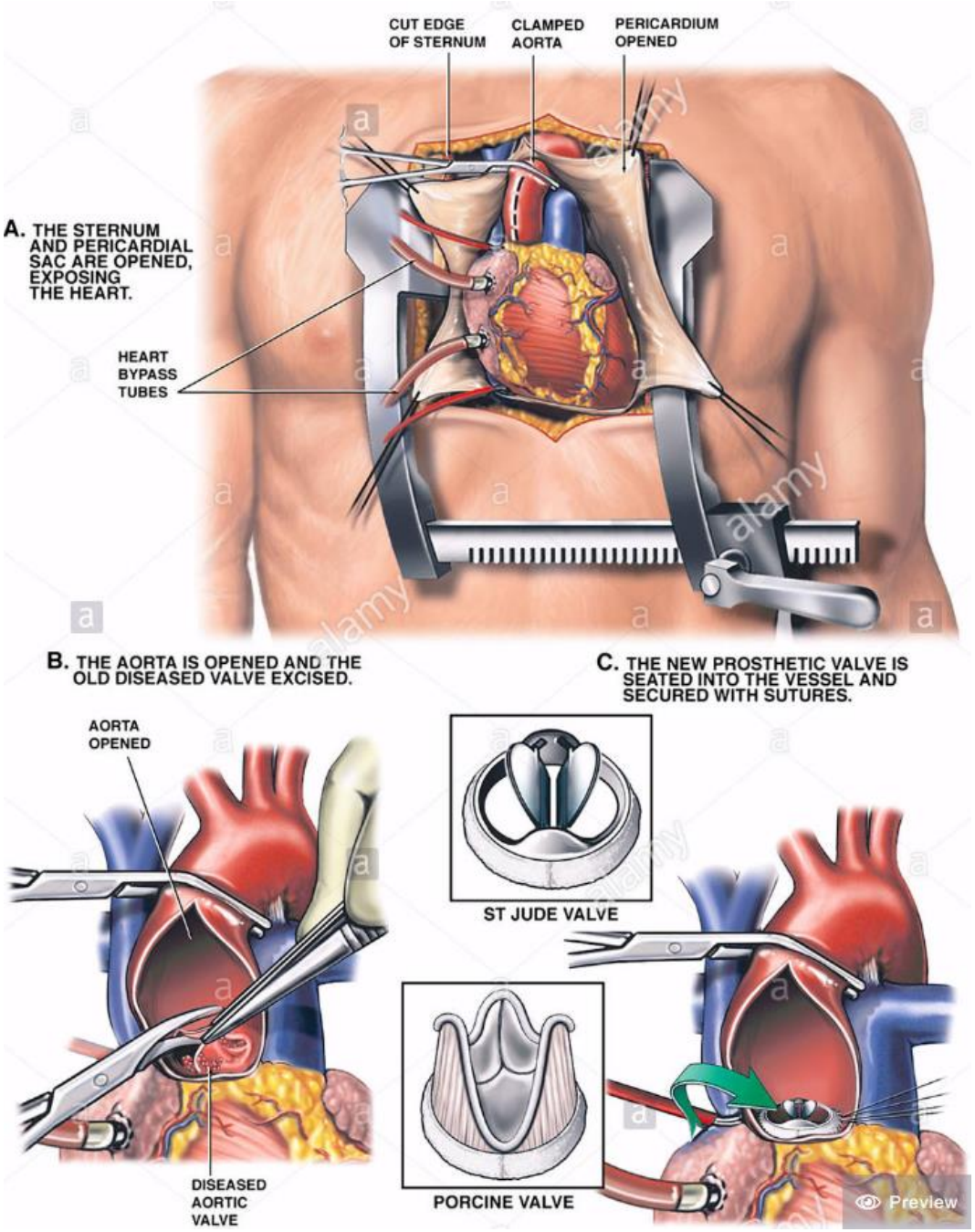
CUT EDGE OF STERNUM
CLAMPED AORTA
PERICARDIUM OPENED
A. THE STERNUM AND PERICARDIAL SAC ARE OPENED, EXPOSING THE HEART.
HEART BYPASS TUBES
B. THE AORTA IS OPENED AND THE OLD DISEASED VALVE EXCISED.
AORTA OPENED
DISEASED AORTIC VALVE
C. THE NEW PROSTHETIC VALVE IS SEATED INTO THE VESSEL AND SECURED WITH SUTURES.
ST JUDE VALVE
PORCINE VALVE
Preview

Surgical Aortic Valve Replacement

- More surgery being performed through 6-8 cm incisions

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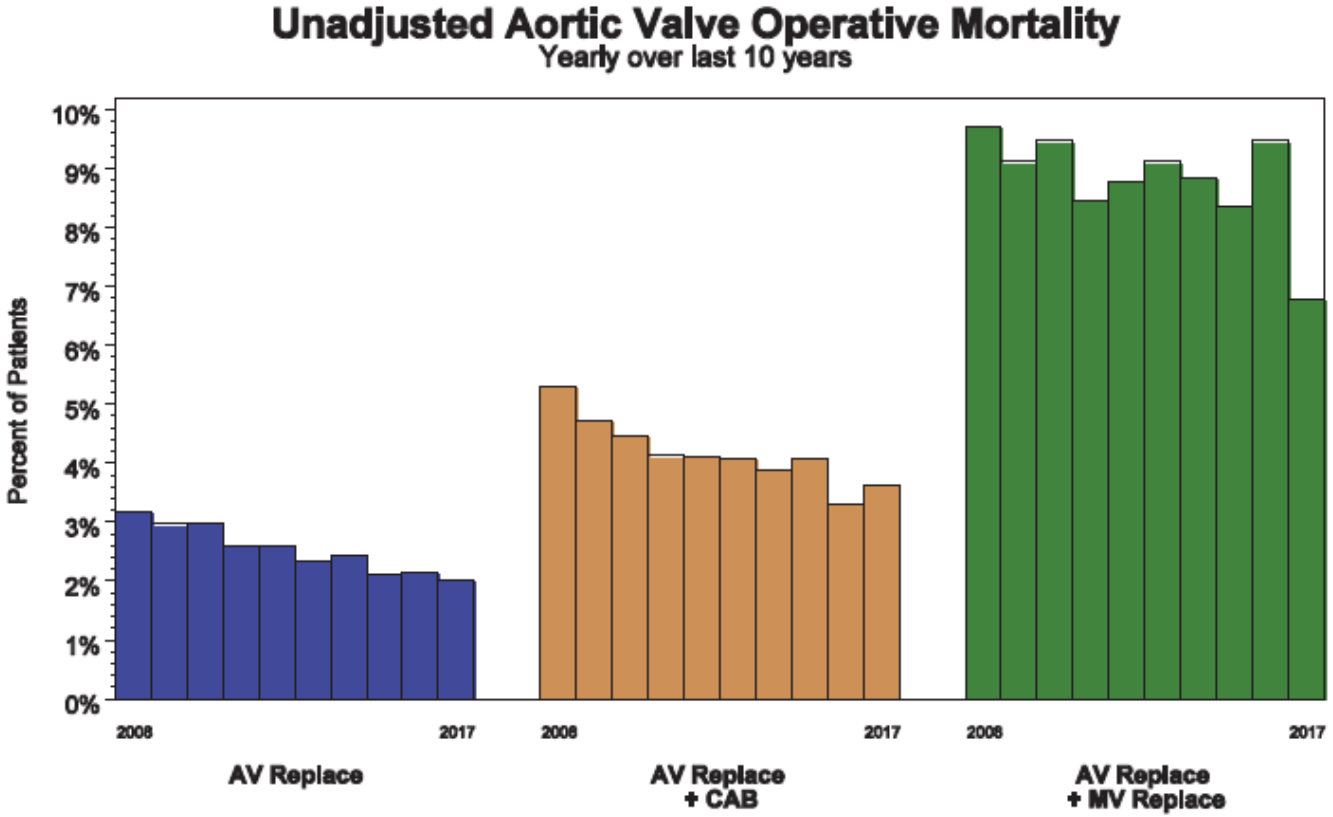
Surgical Aortic Valve Replacement



Society of Thoracic Surgery. 2017.

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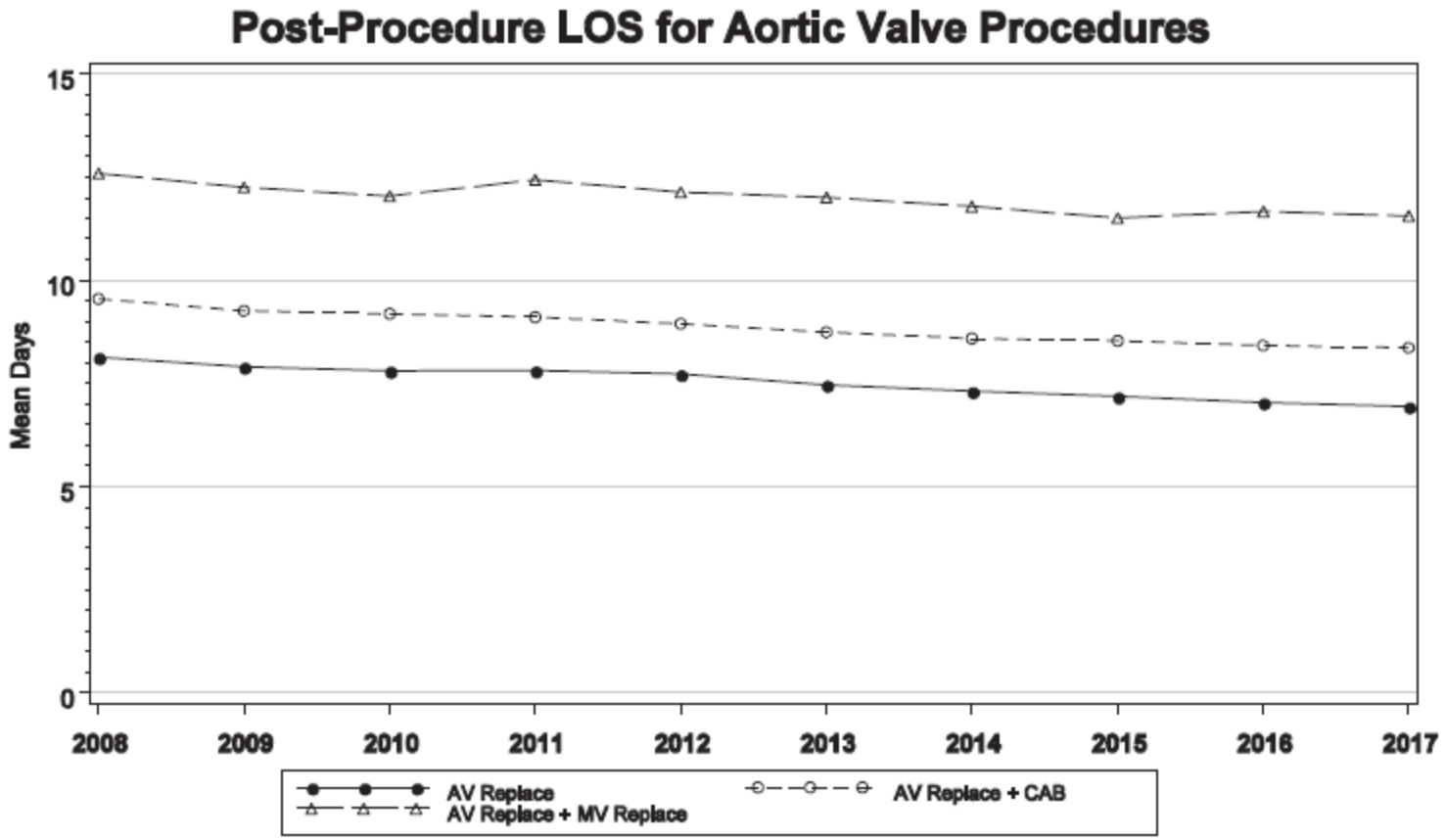
Surgical Aortic Valve Replacement



Society of Thoracic Surgery. 2017.

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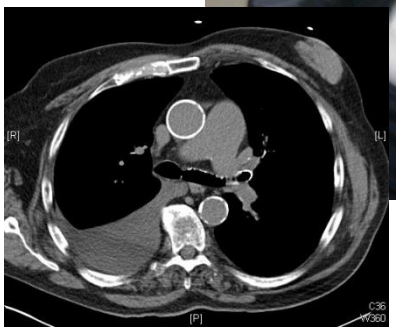
“Inoperability”



CHRISTIANA CARE HEALTH SYSTEM

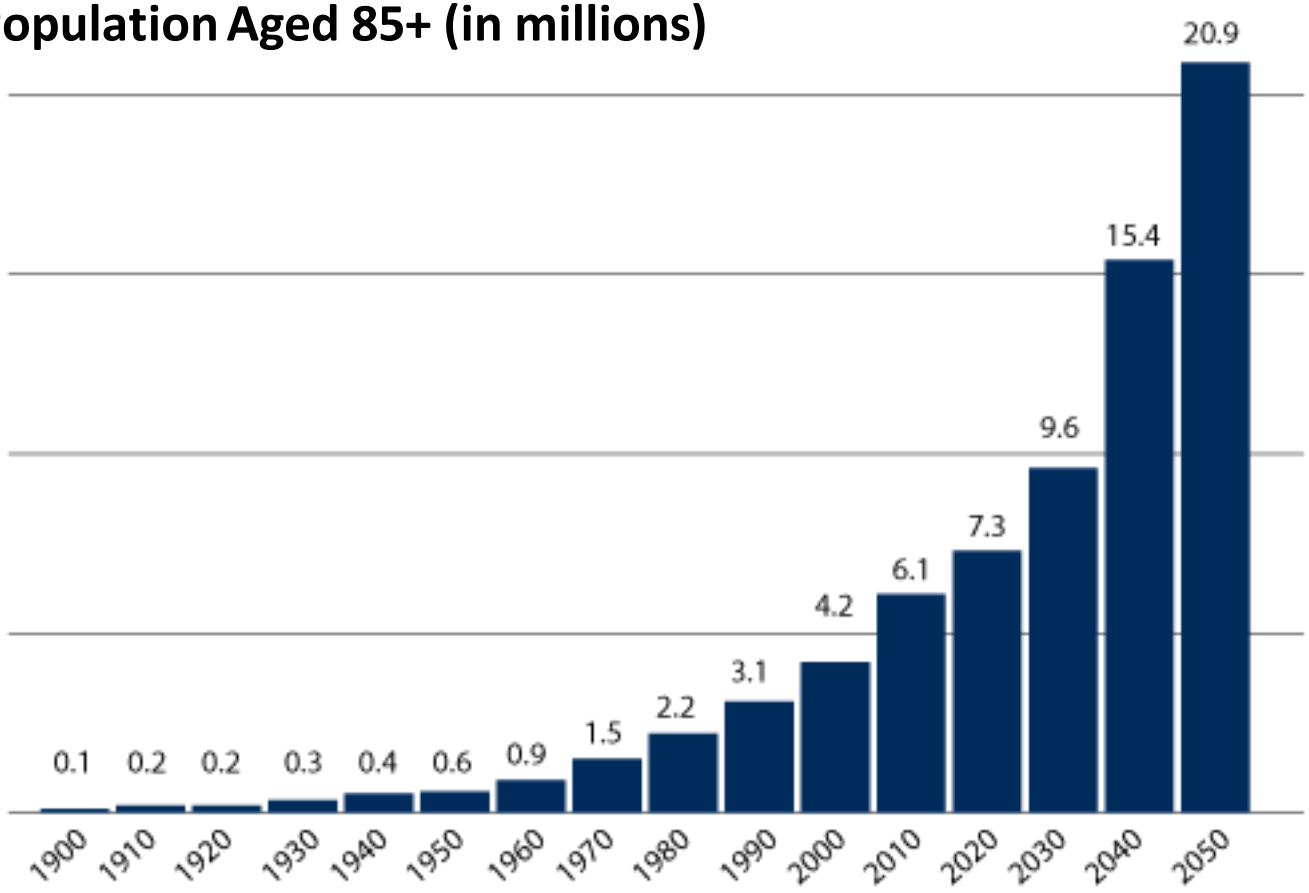
The standard discussion in the elderly.

Vs.

SEASONS
HOSPICE &
PALLIATIVE CARE

The U.S. Population is Aging Rapidly

U.S. Population Aged 85+ (in millions)



Sources of data: U.S. Census Bureau, "65+ in the United States: 2005," December 2005; U.S. Census Bureau, U.S. Interim Projections by Age, Sex, Race, and Hispanic Origin, 2004.

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In the pre-TAVR era, 50-60% of patients with severe AS did not undergo AVR.

Bach DS, et al. *Circ Cardiovasc Qual Outcomes*. 2009;2:533-539

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Aortic Stenosis is...

- Common
- Debilitating and deadly
- Readily treated….(sort of)….

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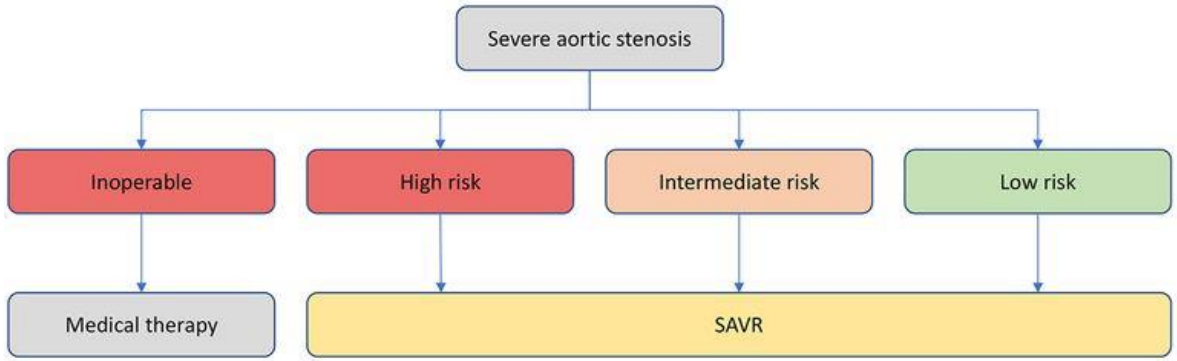
Evolution of our approach…

Before TAVR



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Rogers, Thourani, Waksman, JAHA. 2018.

Transcatheter aortic valve replacement (TAVR):

Disruptive technology

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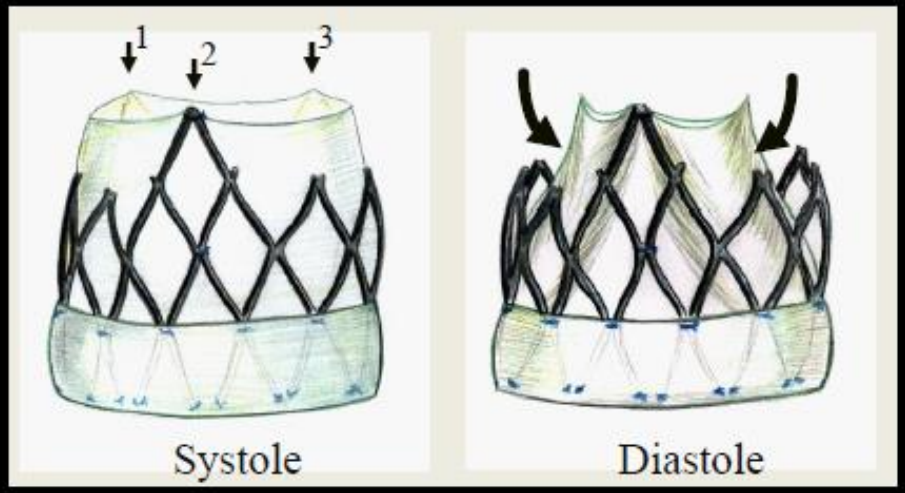
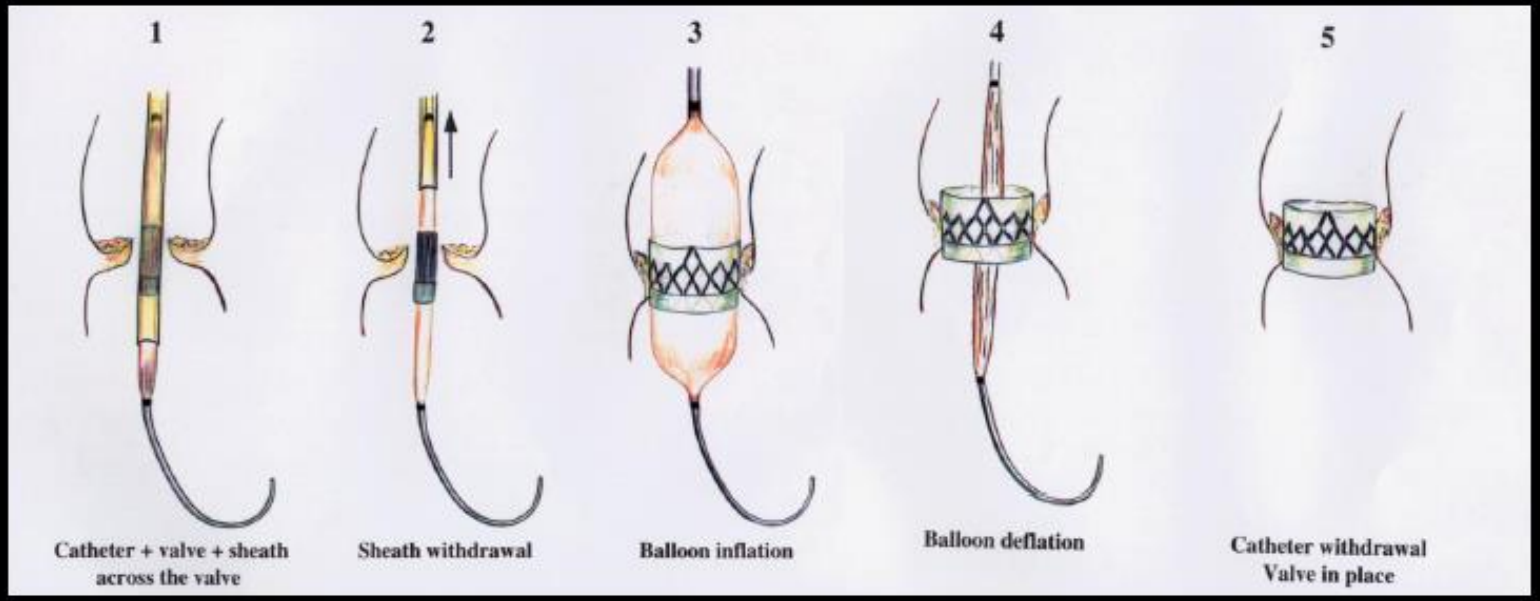
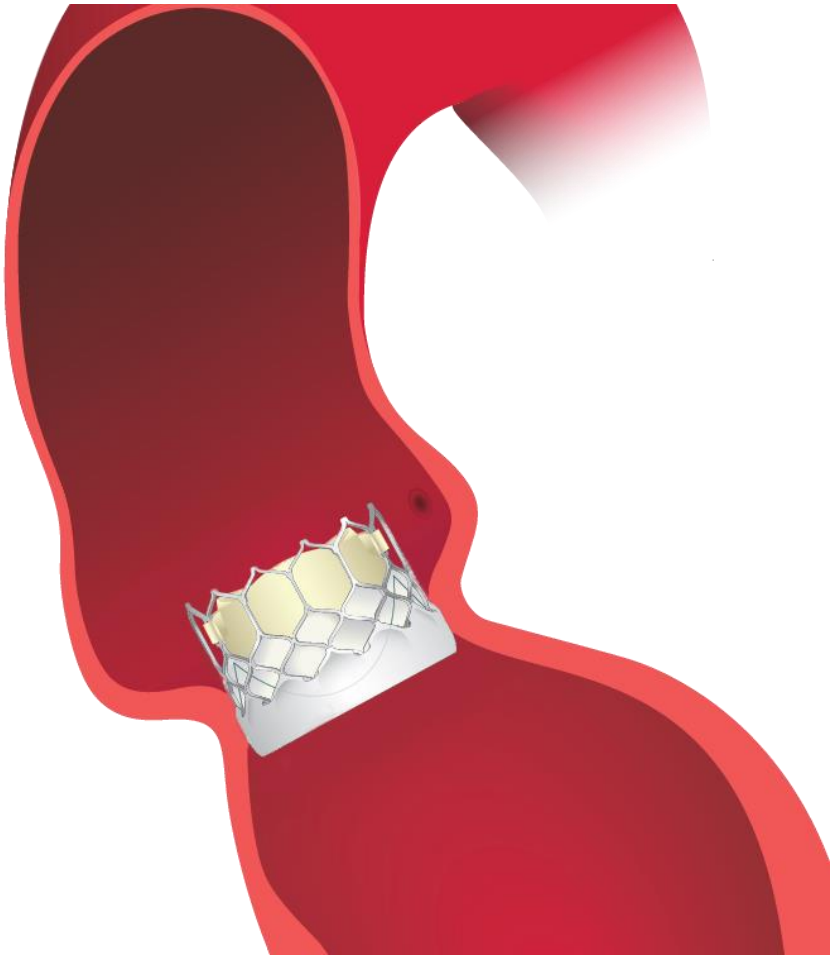
Alain Cribier Sketches (1990)







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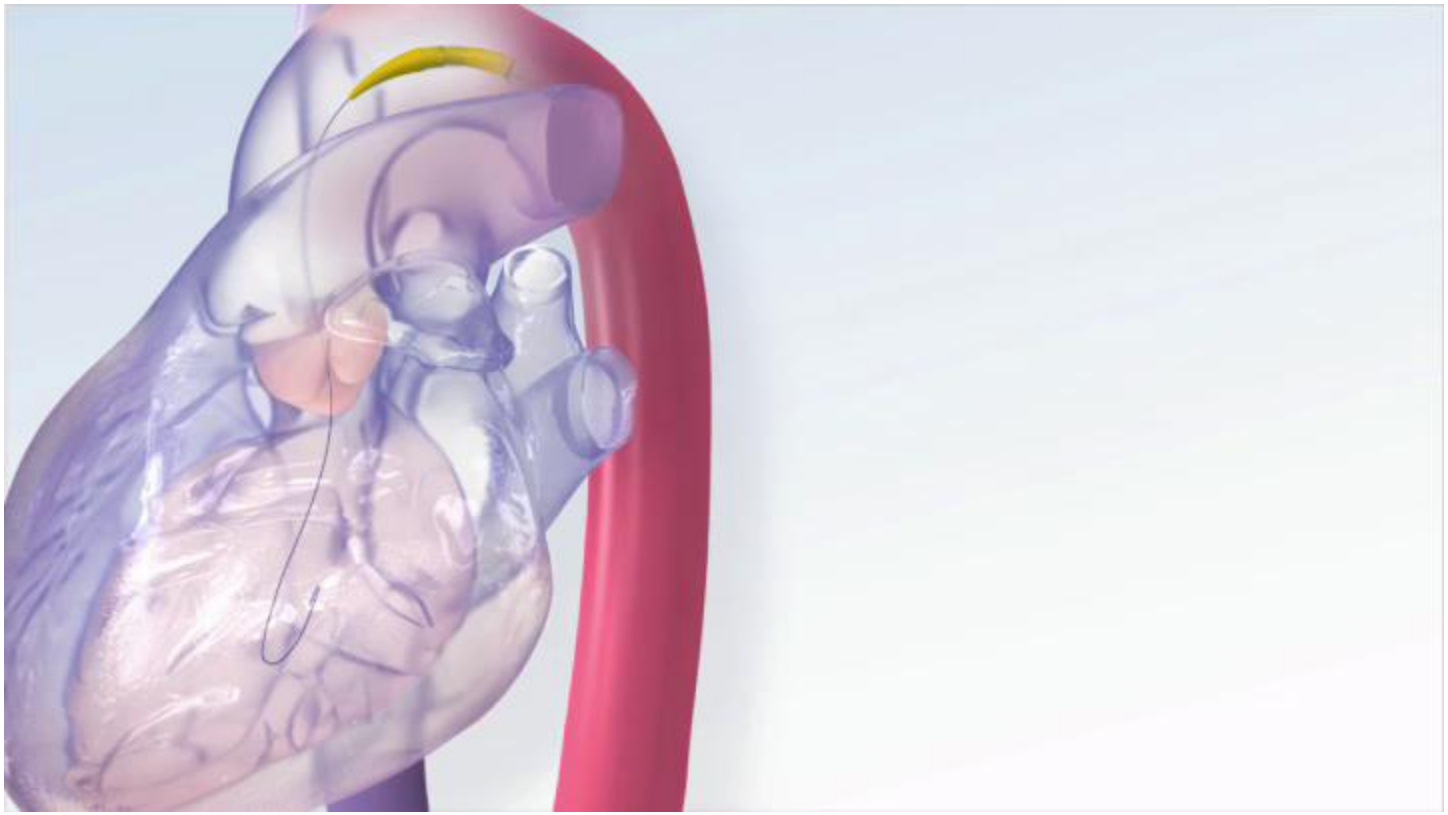
What does TAVR look like?



Animation from American Heart Association.

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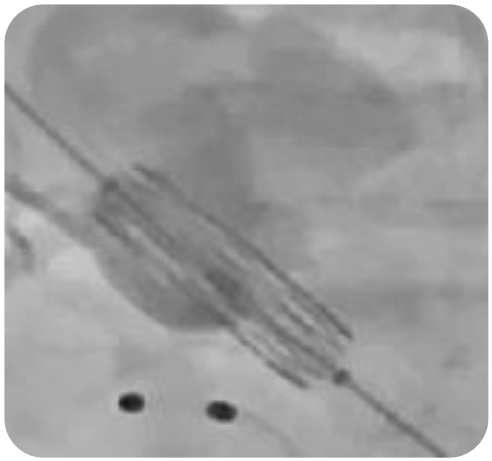
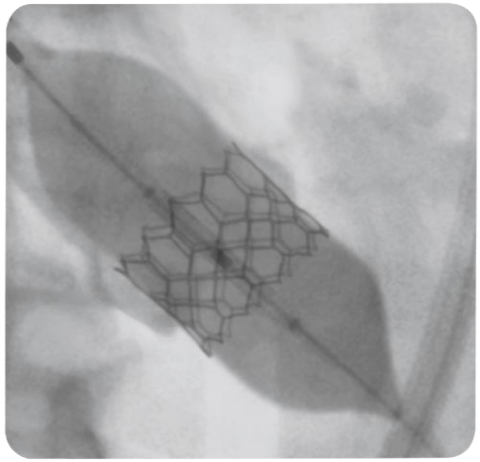
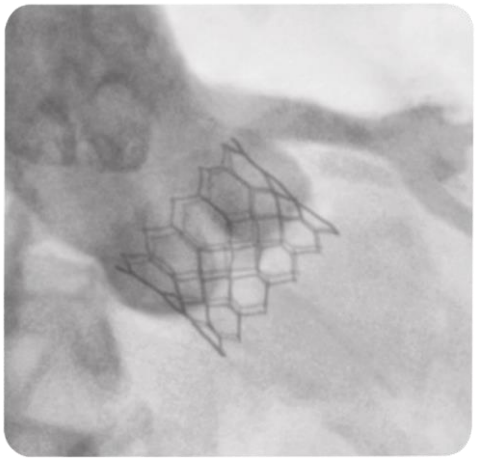
What does in look like in practice?

Initial Positioning	Deployment	Final Placement
		
Use Center Marker and fine positioning feature	Slow, controlled initial inflation using nominal volume	Precise placement

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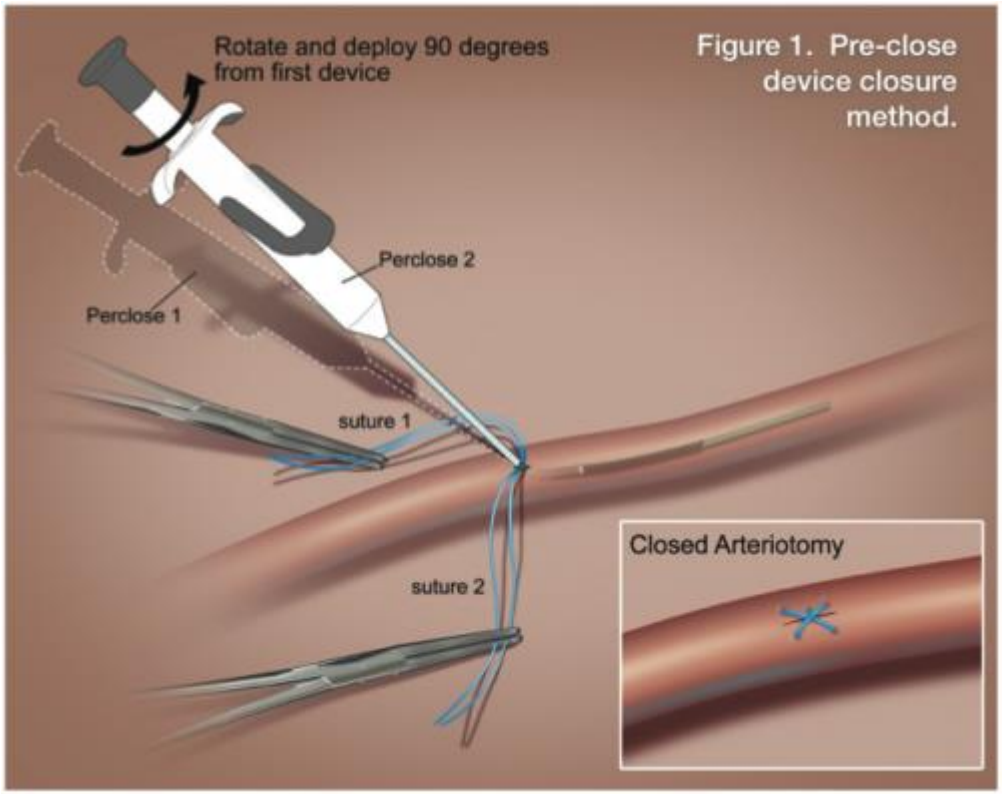
There was one other breakthrough…



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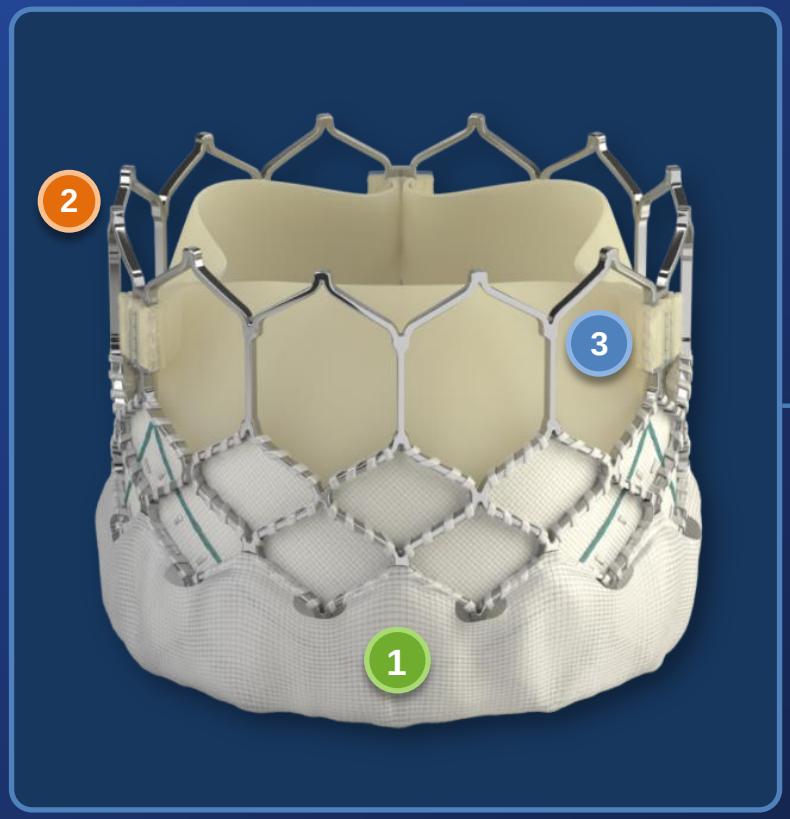
SAPIEN 3 Transcatheter Heart Valve



1 **Outer Sealing Skirt**

- Designed to minimize paravalvular (PV) leak

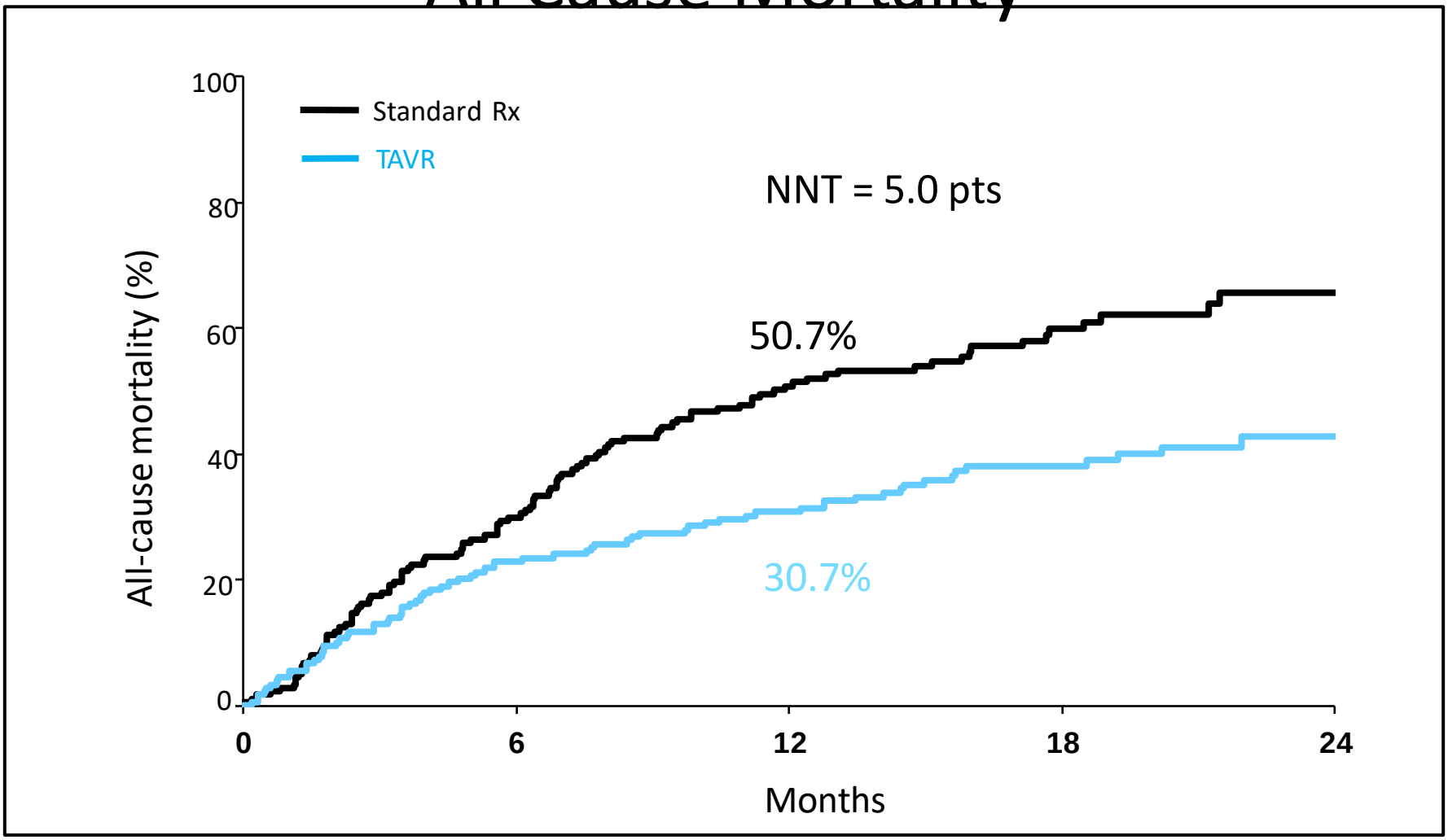
Frame Design

2

- Enhanced frame geometry for low delivery profile
- Cobalt-chromium

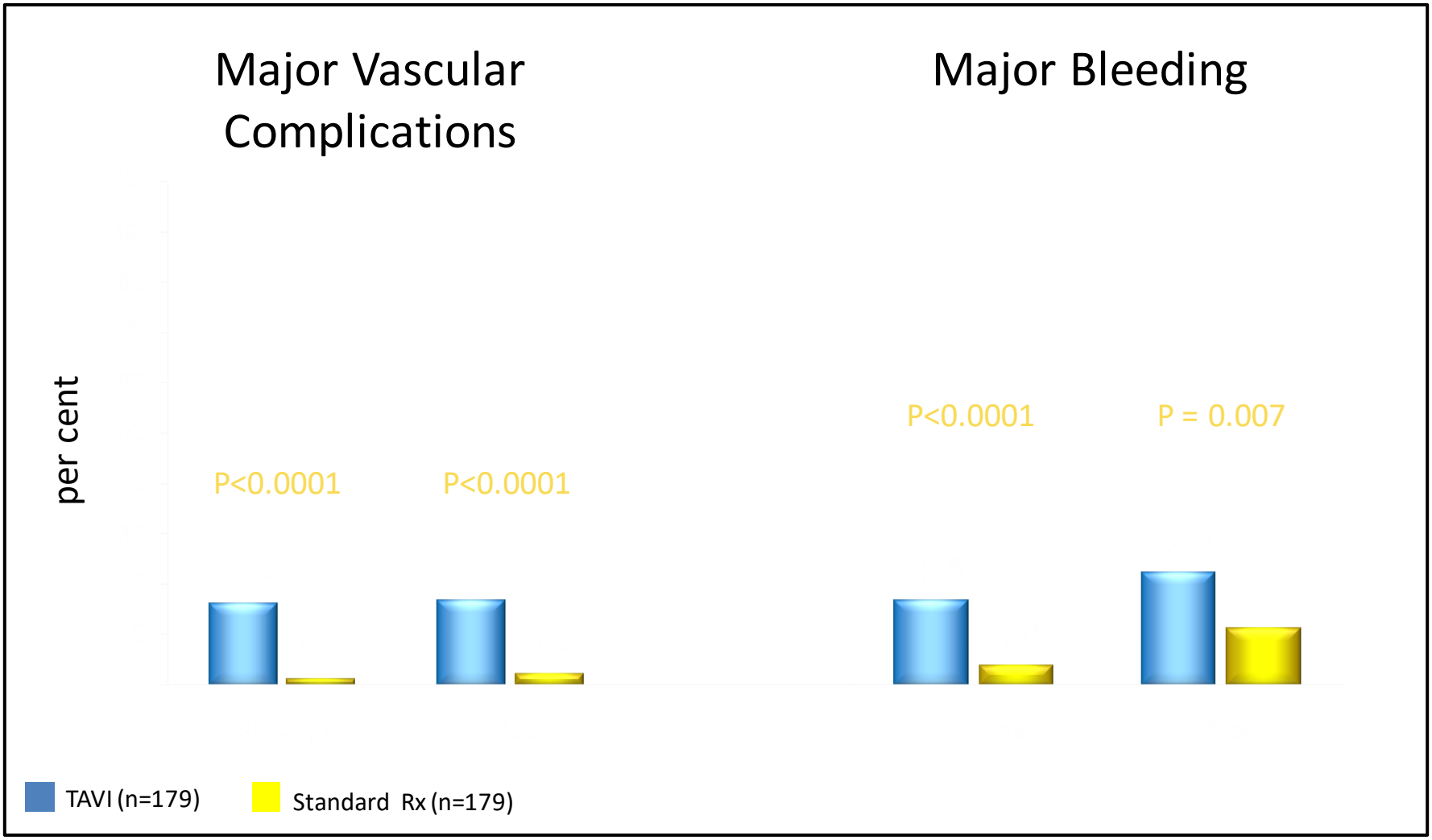
3 **Bovine Pericardial Tissue**

All Cause Mortality



Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

Clinical Outcomes at 30 Days and 1 Year



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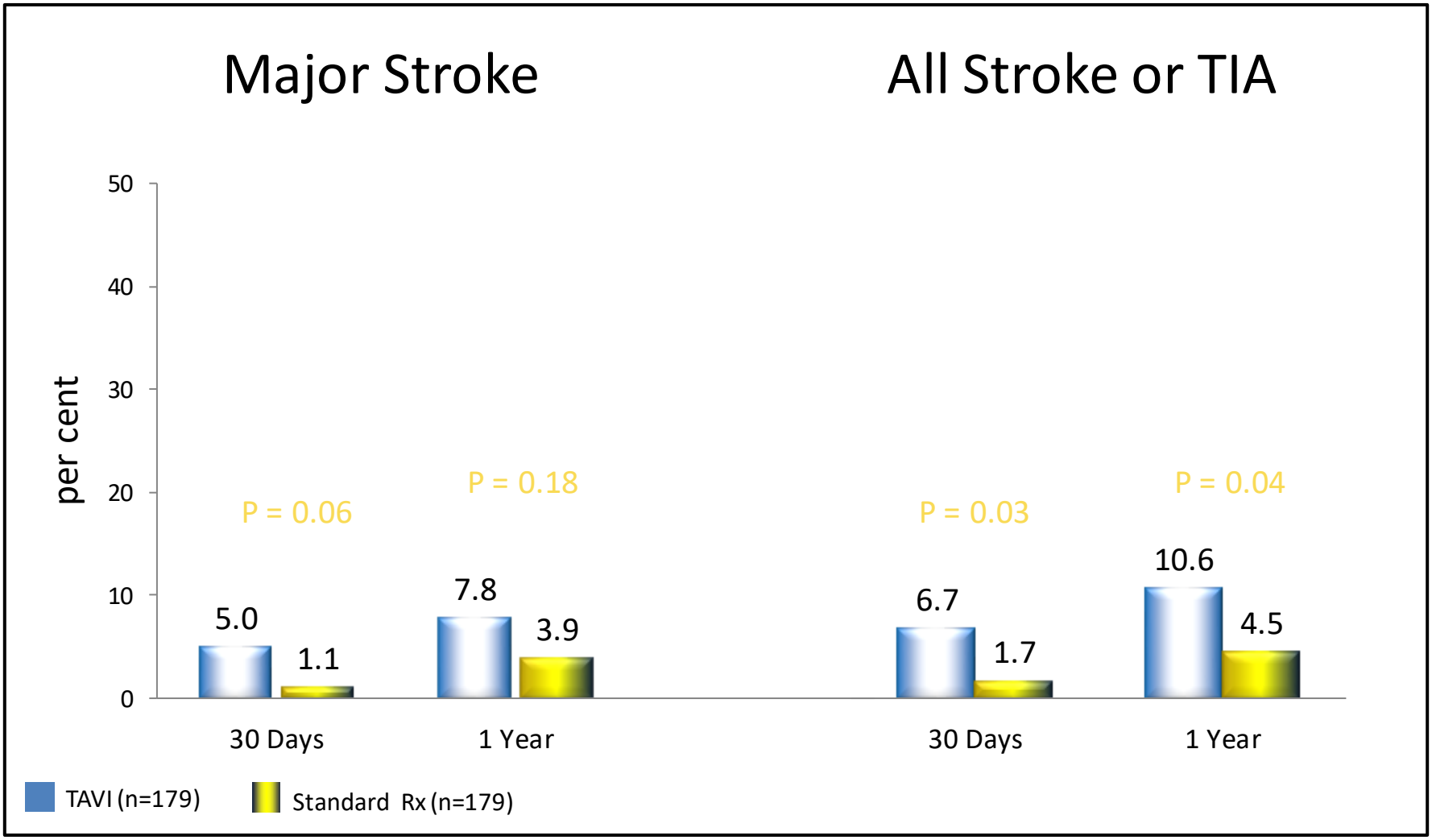
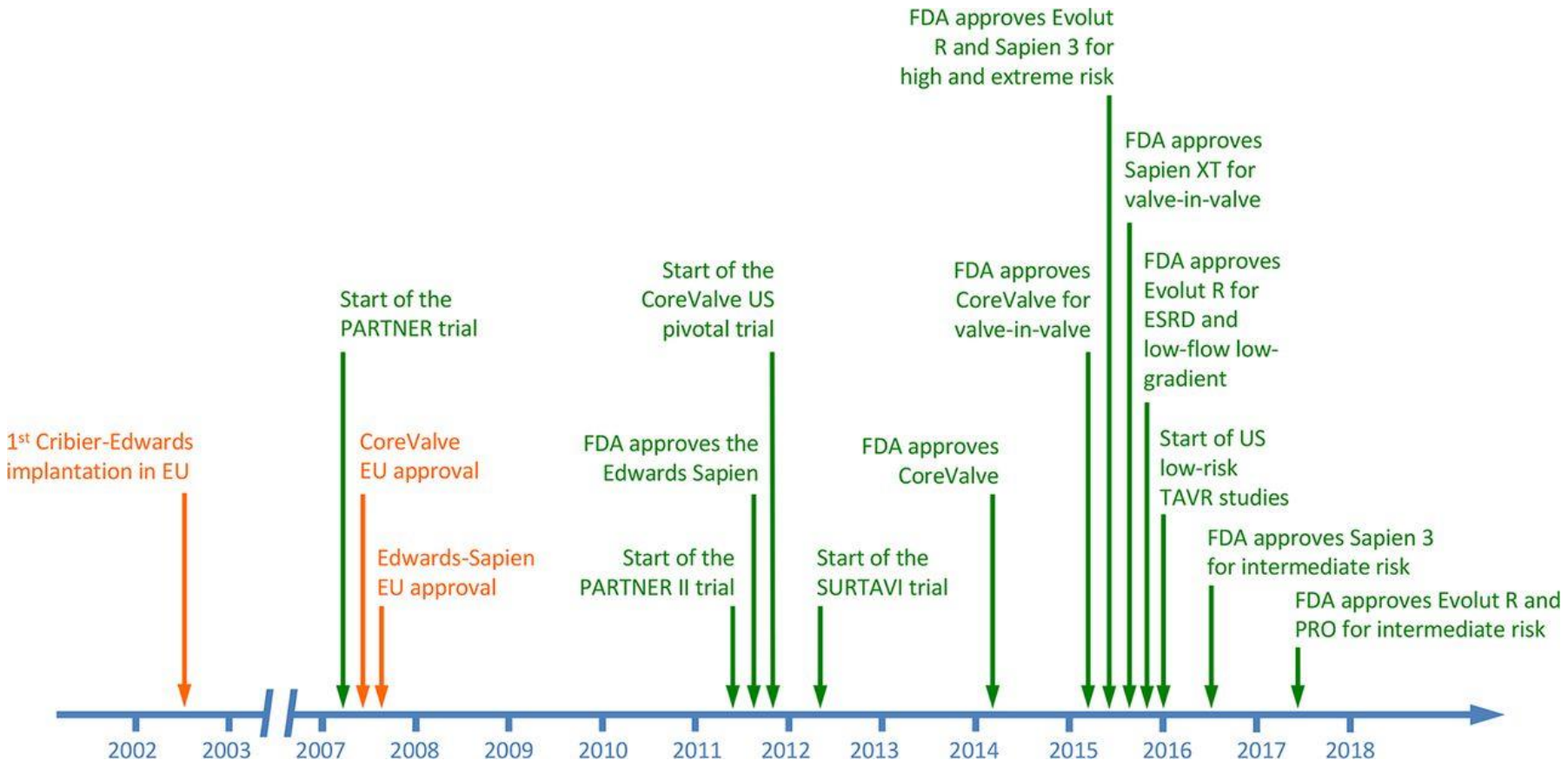


Timeline of TAVR adoption by regulators



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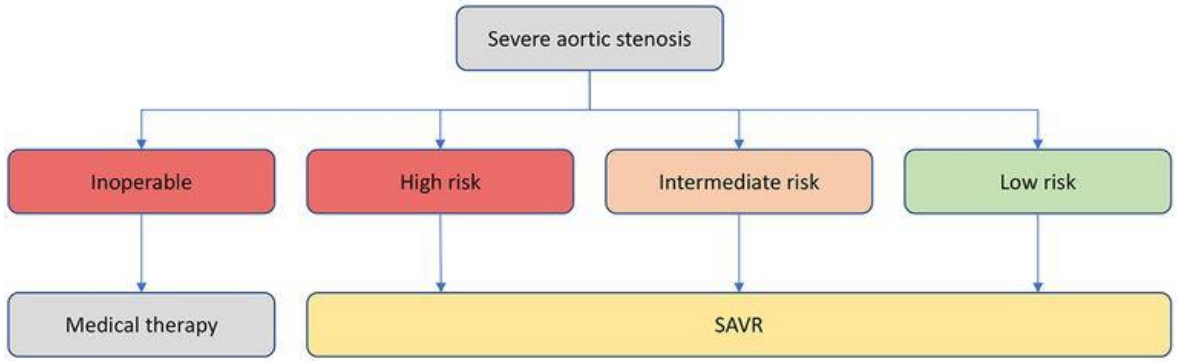
Rogers, Thourani, Waksman, JAHA. 2018.

Evolution of our approach…

Before TAVR



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Evolution of our approach…

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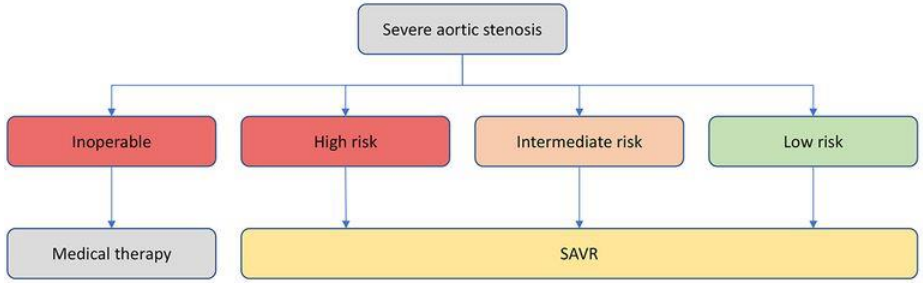
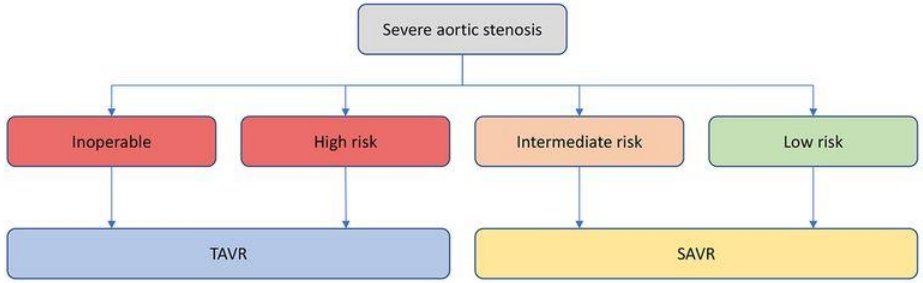


In 2011



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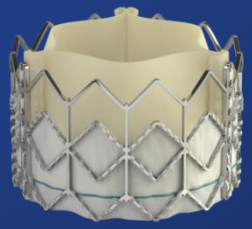
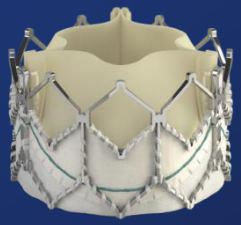
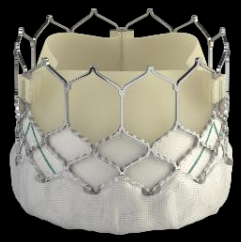
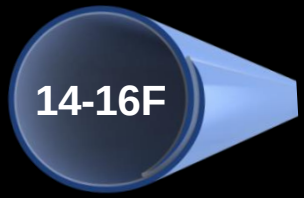
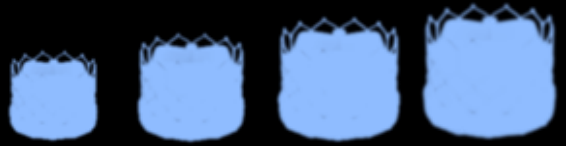
Rogers, Thourani, Waksman, JAHA. 2018.

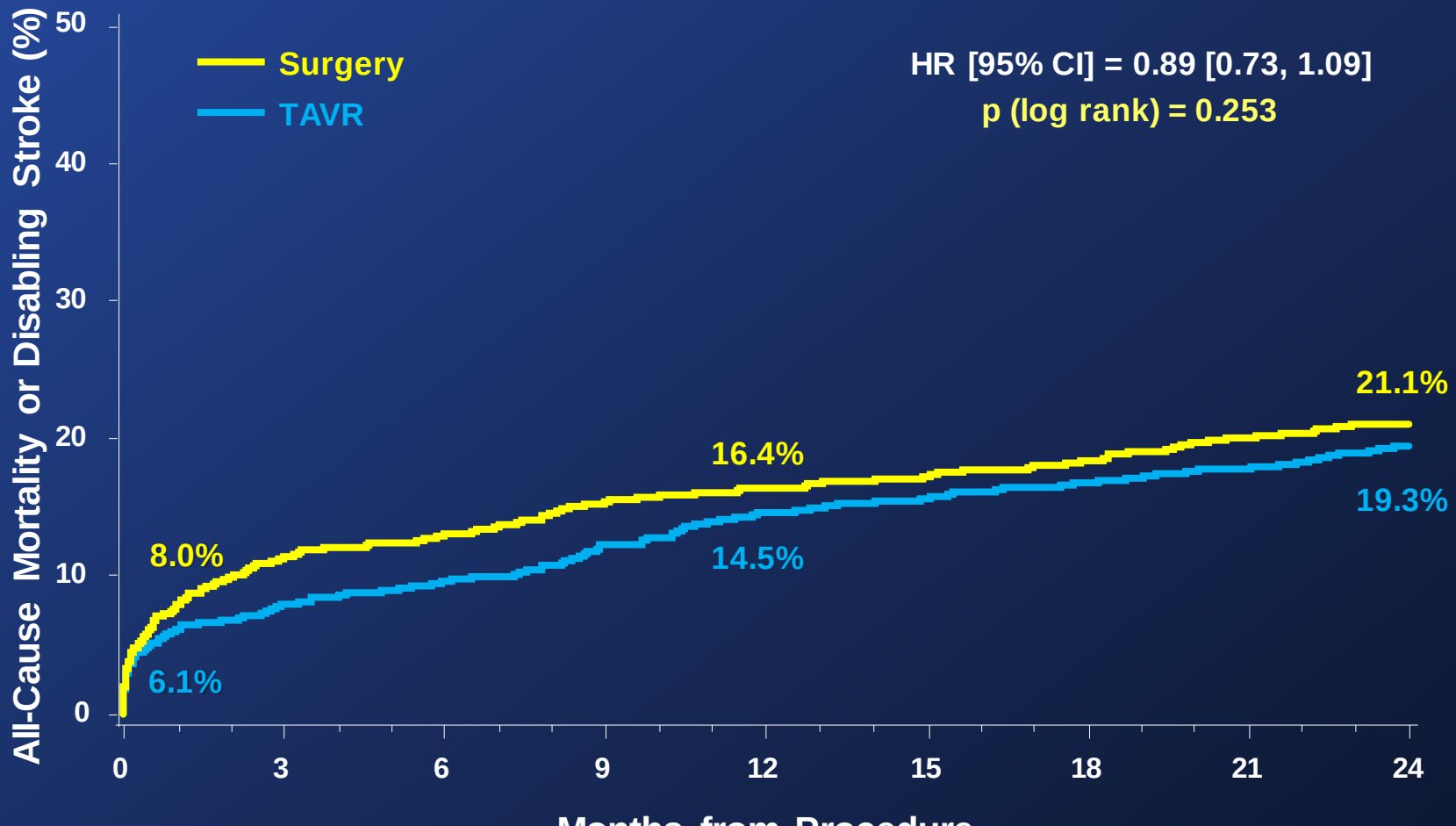
SAPIEN Platforms in PARTNER
Device Evolution

THE PARTNER II TRIAL

	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes	 23 mm, 26 mm	 23 mm, 26 mm, 29 mm	 20 mm, 23 mm, 26 mm, 29 mm

Primary Endpoint (ITT) with XT
All-Cause Mortality or Disabling Stroke

THE PARTNER II TRIAL

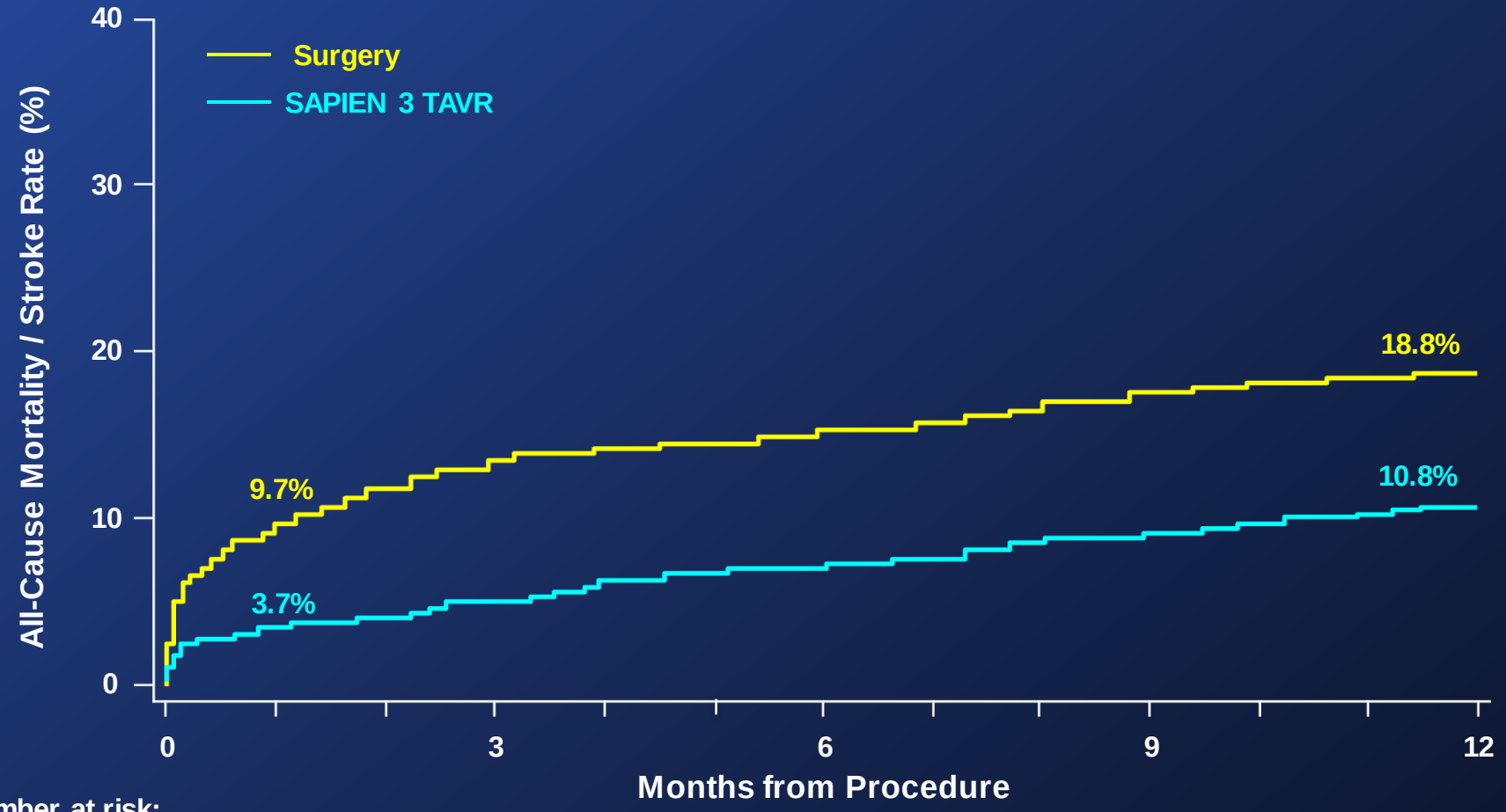


Number at risk:									
Surgery	1021	838	812	783	770	747	735	717	695
TAVR	1011	918	901	870	842	825	811	801	774

Unadjusted Time-to-Event Analysis –S3

All-Cause Mortality and All Stroke (AT)

THE PARTNER II TRIAL

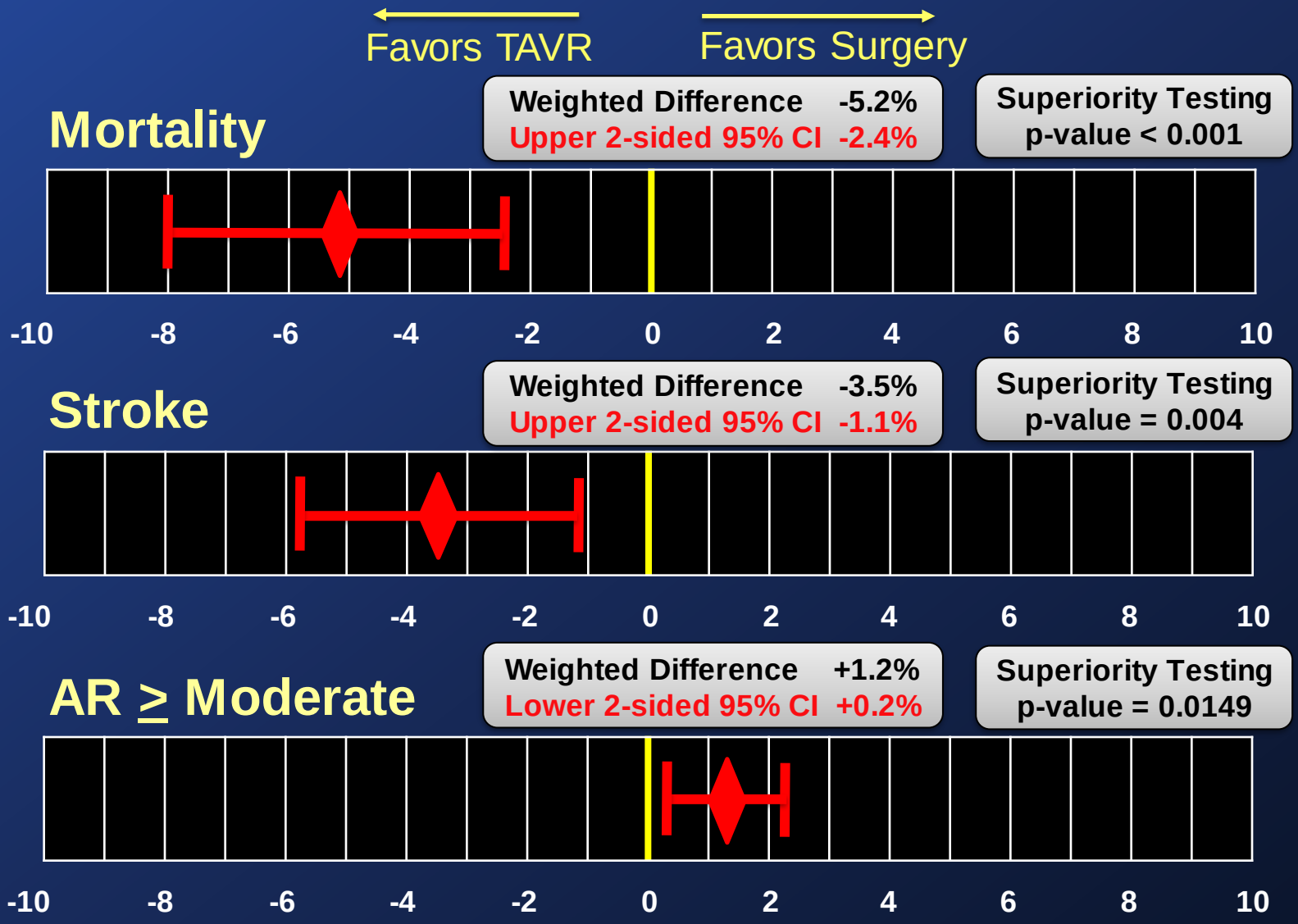


Number at risk:

P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

Superiority Analysis
Components of Primary Endpoint (VI)

THE PARTNER II TRIAL

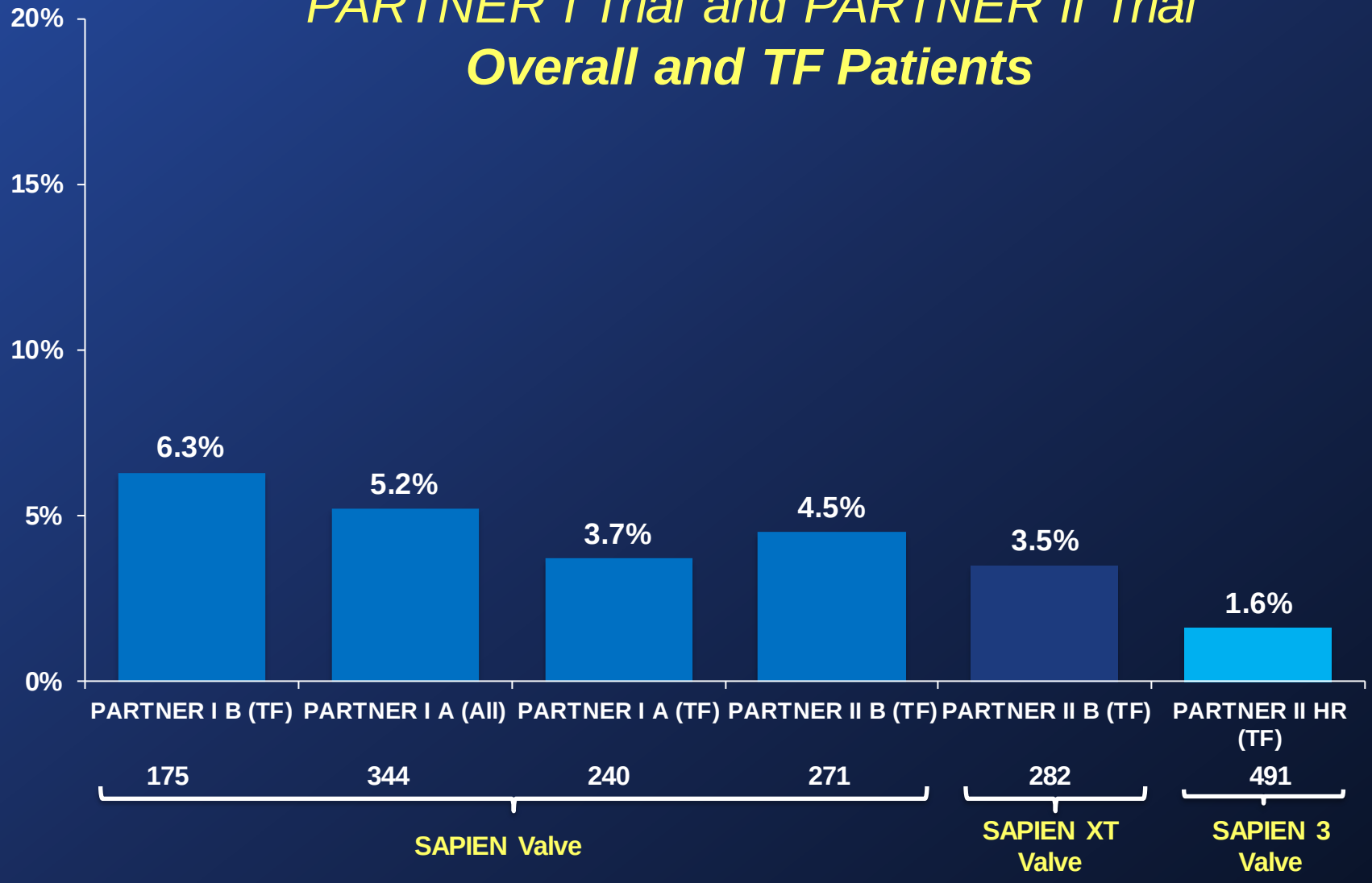


All-Cause Mortality at 30 Days
(As Treated Patients)

THE PARTNER II TRIAL

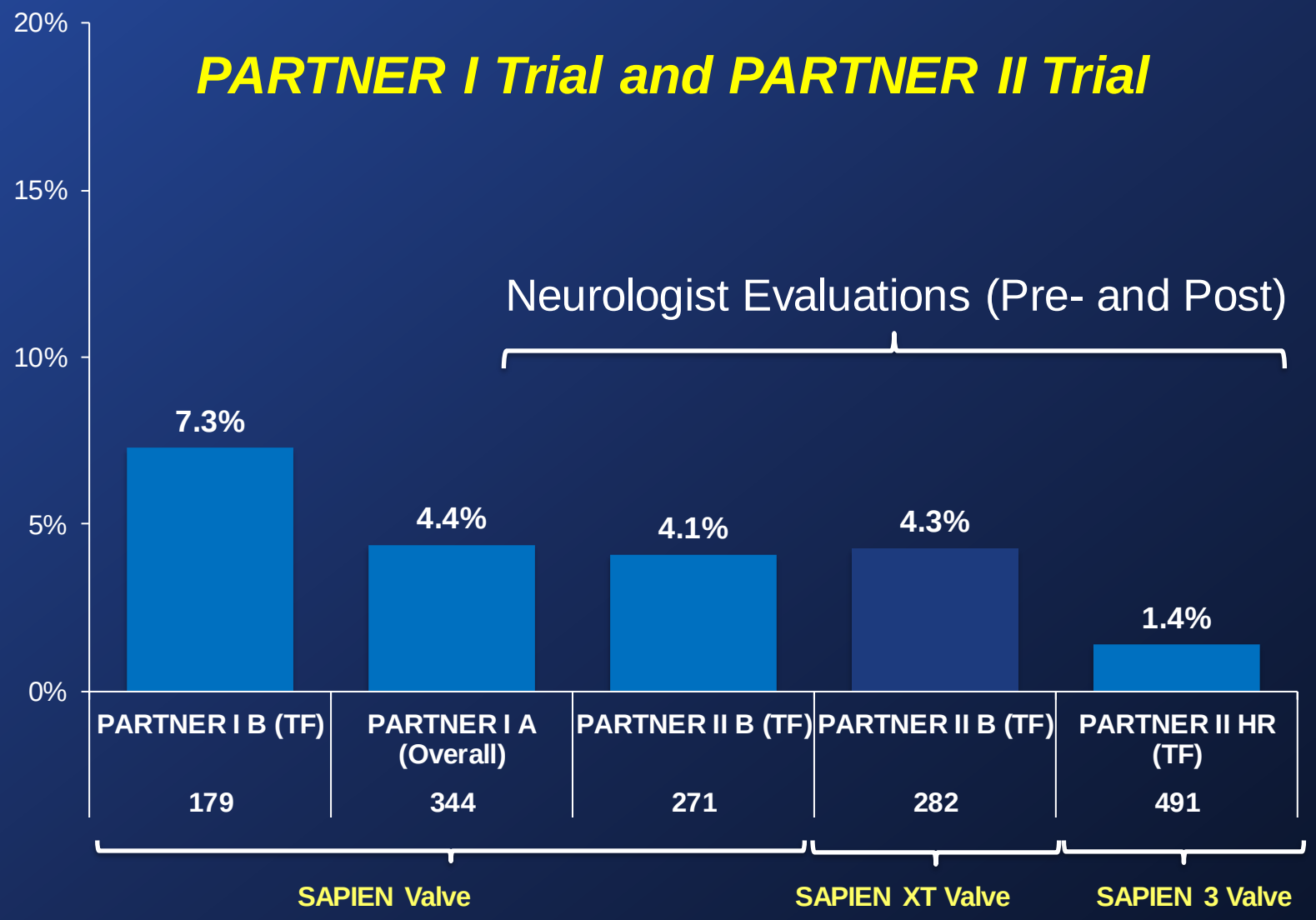
PARTNER I Trial and PARTNER II Trial

Overall and TF Patients



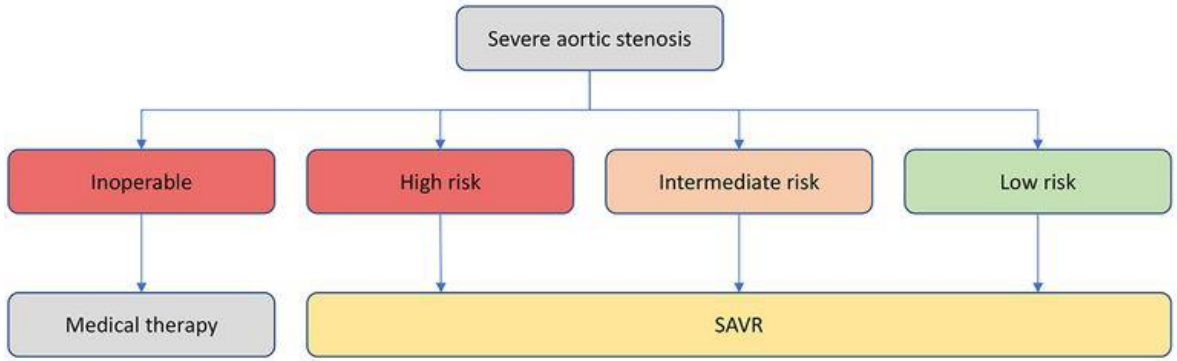
All Strokes at 30 Days

THE PARTNER II TRIAL



Evolution of our approach…

Before TAVR



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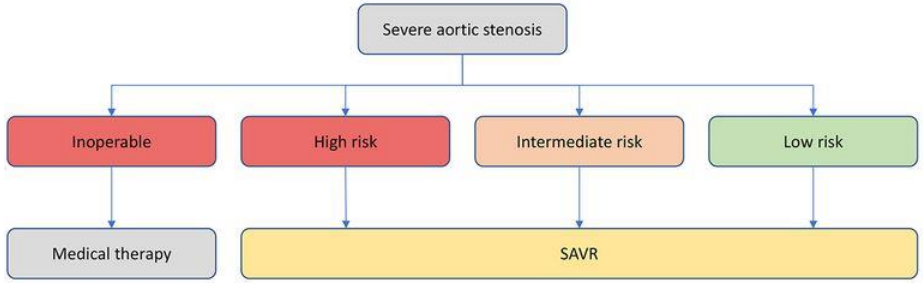
Rogers, Thourani, Waksman, JAHA. 2018.

Evolution of our approach…

Before TAVR



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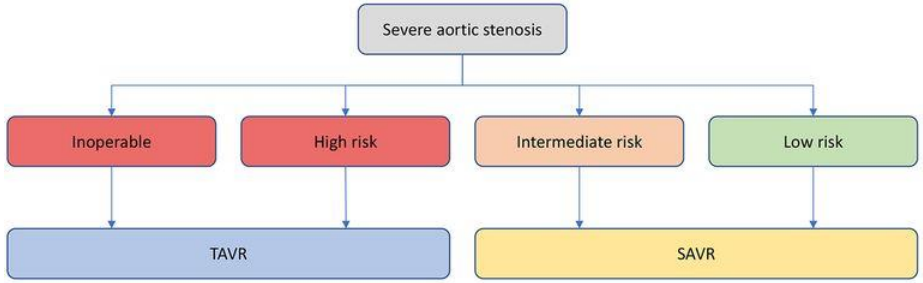

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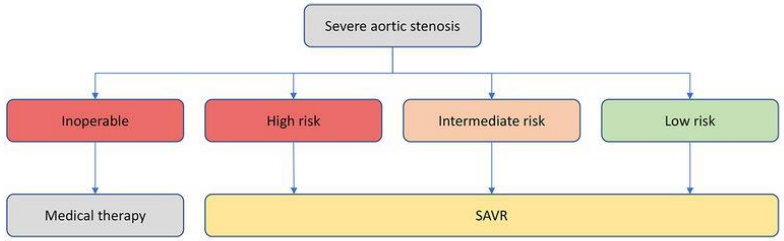
Rogers, Thourani, Waksman, JAHA. 2018.

Evolution of our approach…

Before TAVR



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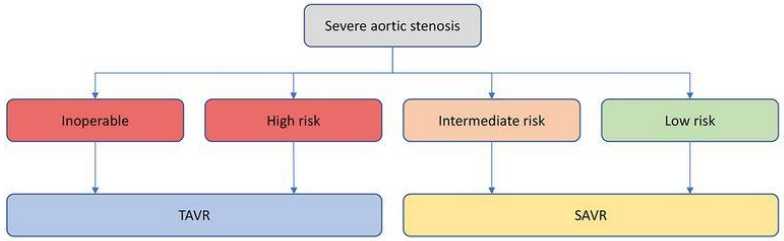

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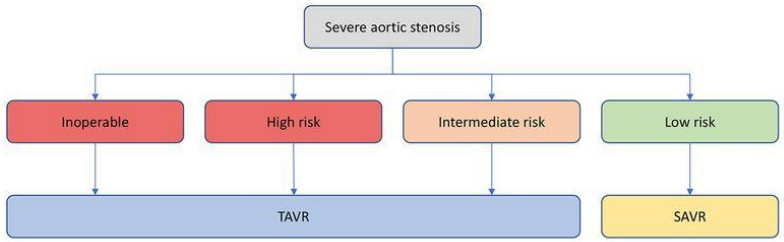

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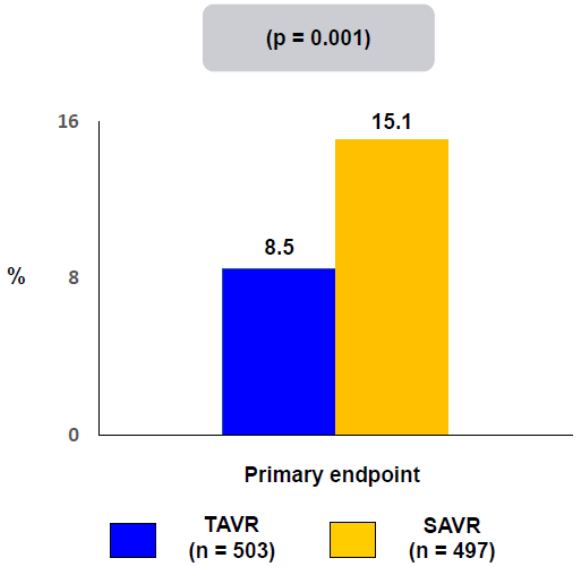
Rogers, Thourani, Waksman, JAHA. 2018.

TAVR in low risk patients (2019)

Trial Description: Low-risk patients with aortic stenosis were randomized to TAVR using the SAPIEN 3 valve versus SAVR.



RESULTS

- Primary outcome, all-cause mortality, stroke, or rehospitalization (related to the procedure, valve, or heart failure) at 1 year: 8.5% of the TAVR group vs. 15.1% of SAVR group ($p < 0.001$ for noninferiority, $p = 0.001$ for superiority)
- Stroke at 30 days: 0.6% for TAVR vs. 2.4% for SAVR ($p = 0.02$)
- Permanent pacemaker: 6.5% for TAVR vs. 4.0% for SAVR (p = NS)

CONCLUSIONS

- Among low-risk patients with aortic stenosis, TAVR was superior to SAVR at preventing death, stroke, or rehospitalization at 1 year
- TAVR was also associated with a lower incidence of stroke and a similar incidence of permanent pacemaker compared with SAVR

Mack MJ, et al. N Engl J Med 2019;Mar 17:[Epub]

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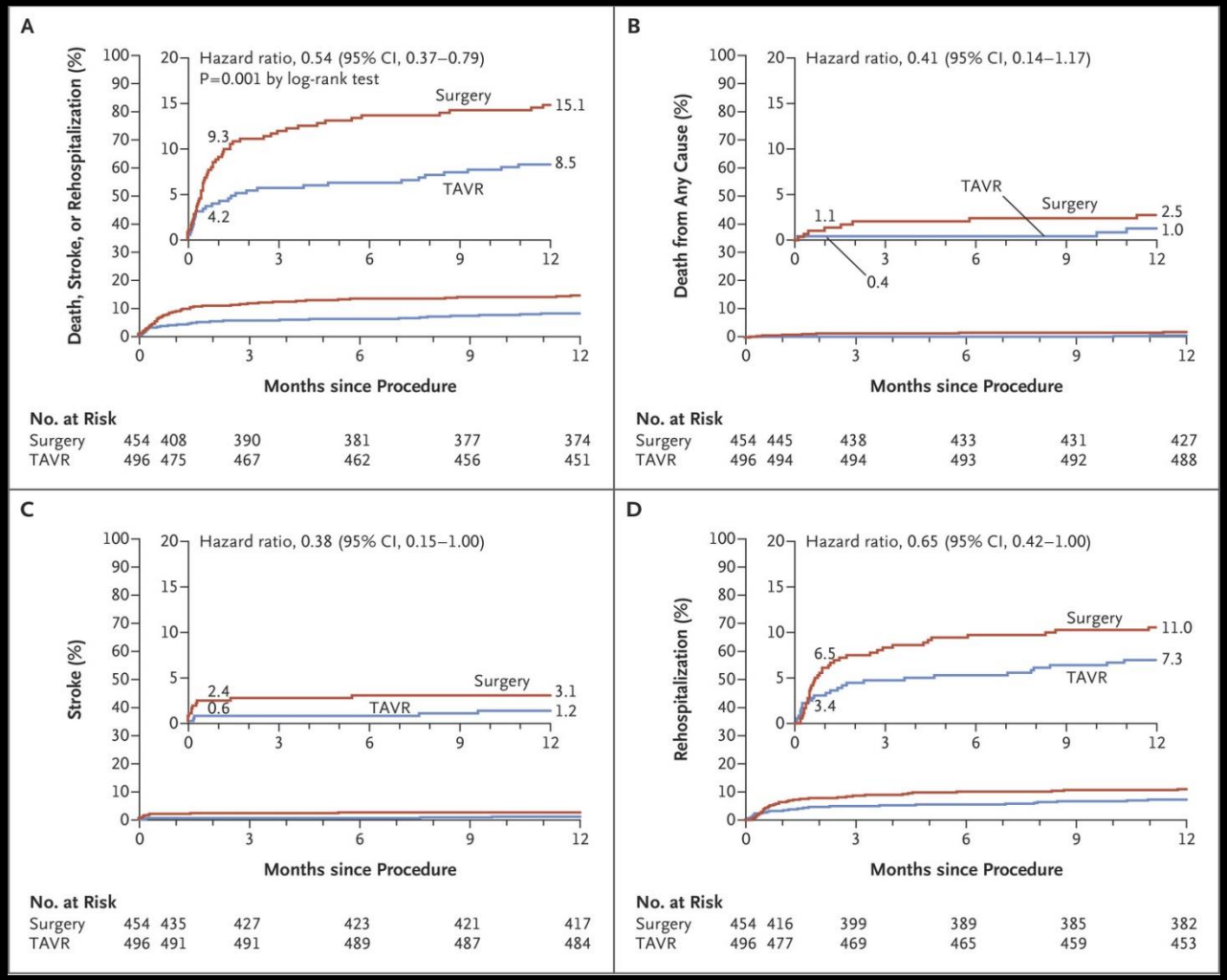
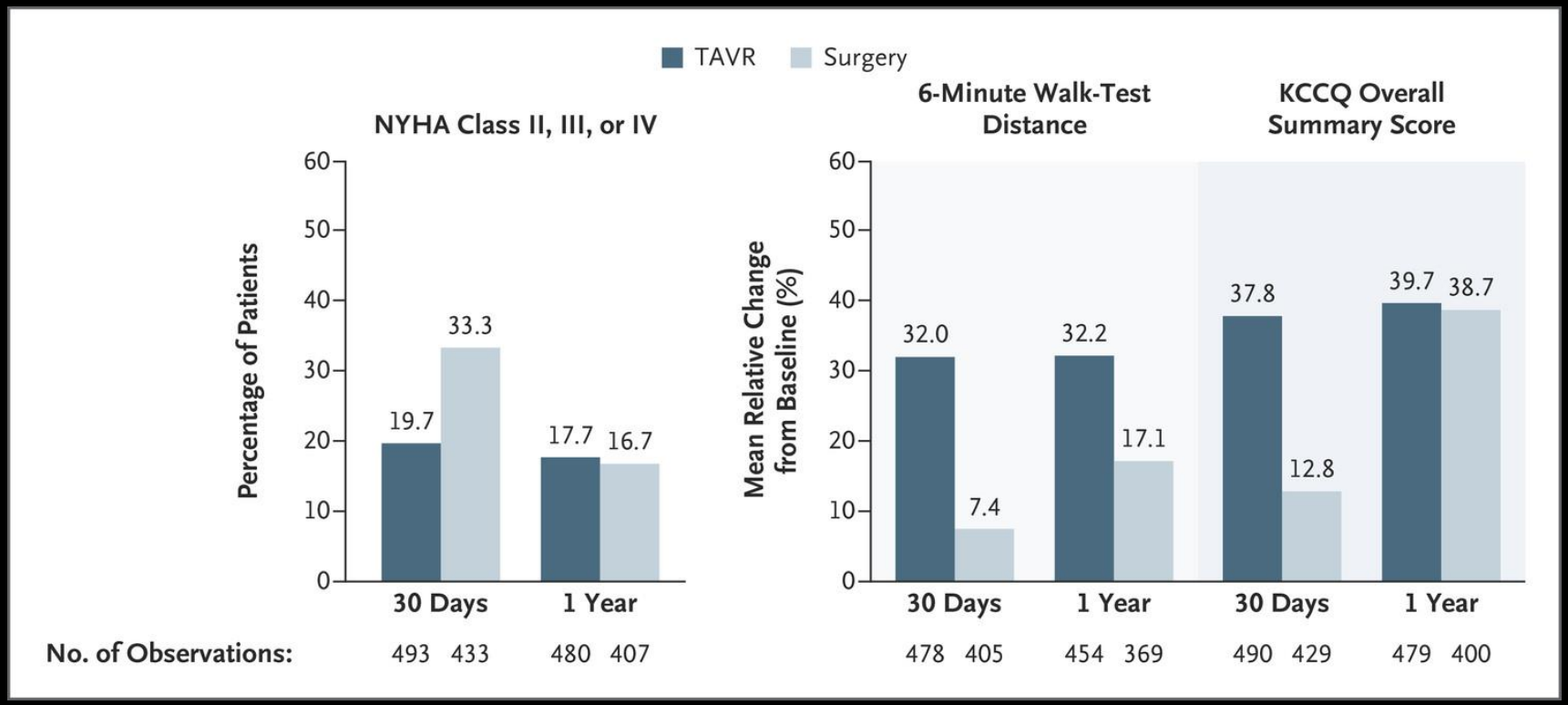
Important Endpoints in low-risk TAVR vs. SAVR



MJ Mack et al. N Engl J Med 2019;380:1695-1705.

The NEW ENGLAND JOURNAL of MEDICINE

Quality of Life in low-risk TAVR



MJ Mack et al. N Engl J Med 2019;380:1695-1705.

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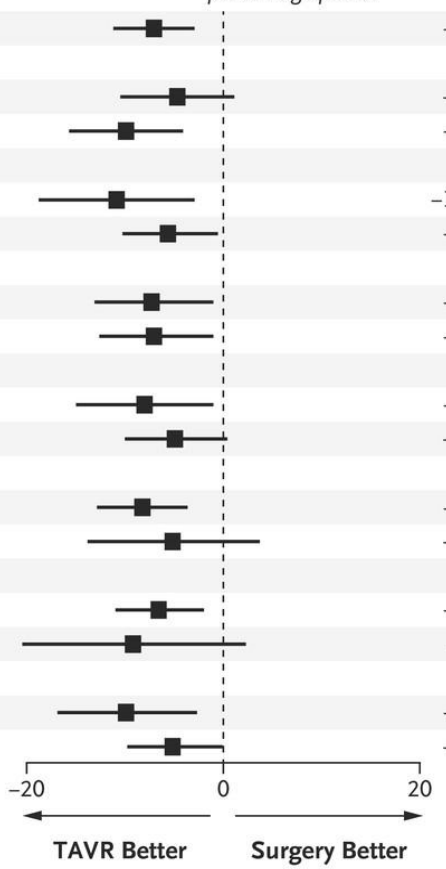
Low-risk TAVR subgroups

Subgroup	No. of Patients	TAVR	Surgery	Difference (95% CI)	P Value for Interaction
		no. of events/total no. (%)		*percentage points*	
Overall	950	42/496 (8.5)	68/454 (15.1)	−6.6 (−10.8 to −2.5)	
Age					0.21
≤74 yr	516	29/273 (10.6)	36/243 (14.9)	−4.3 (−10.1 to 1.5)	
>74 yr	434	13/223 (5.8)	32/211 (15.3)	−9.5 (−15.3 to −3.7)	
Sex					0.27
Female	292	13/161 (8.1)	24/131 (18.5)	−10.4 (−18.3 to −2.5)	
Male	658	29/335 (8.7)	44/323 (13.8)	−5.1 (−9.9 to −0.3)	
STS-PROM score					0.98
≤1.8	464	21/232 (9.1)	36/232 (15.7)	−6.7 (−12.6 to −0.7)	
>1.8	486	21/264 (8.0)	32/222 (14.5)	−6.5 (−12.2 to −0.8)	
Left ventricular ejection fraction					0.48
≤65	384	20/208 (9.6)	30/176 (17.2)	−7.6 (−14.5 to −0.7)	
>65	524	21/264 (8.0)	32/260 (12.4)	−4.4 (−9.6 to 0.7)	
NYHA class					0.54
I or II	687	23/341 (6.8)	50/346 (14.5)	−7.8 (−12.4 to −3.2)	
III or IV	263	19/155 (12.3)	18/108 (16.9)	−4.7 (−13.5 to 4.1)	
Atrial fibrillation					0.67
No	786	33/418 (7.9)	51/368 (14.0)	−6.1 (−10.5 to −1.7)	
Yes	163	9/78 (11.6)	17/85 (20.3)	−8.7 (−19.9 to 2.5)	
KCCQ overall summary score					0.27
≤70	407	23/219 (10.5)	37/188 (19.9)	−9.4 (−16.5 to −2.4)	
>70	536	18/275 (6.5)	29/261 (11.2)	−4.6 (−9.2 to 0.2)	



MJ Mack et al. N Engl J Med 2019;380:1695-1705.

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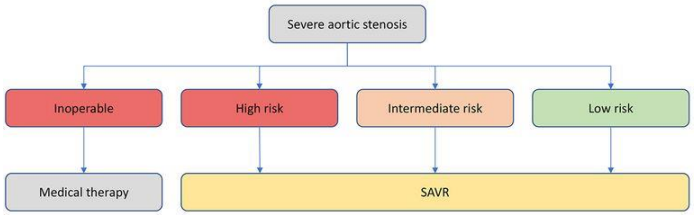
Evolution of our approach

Before TAVR



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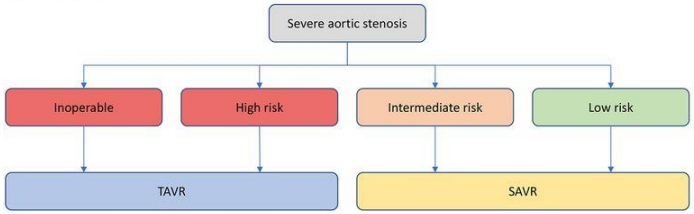

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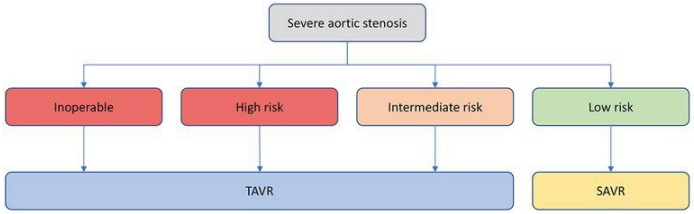
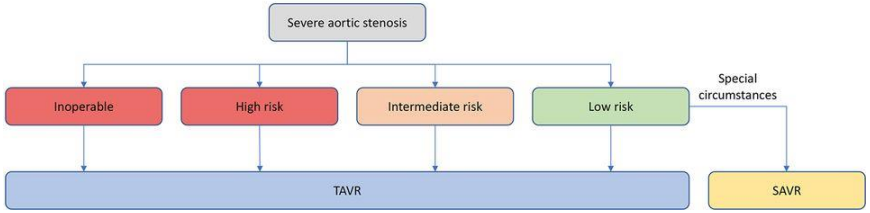
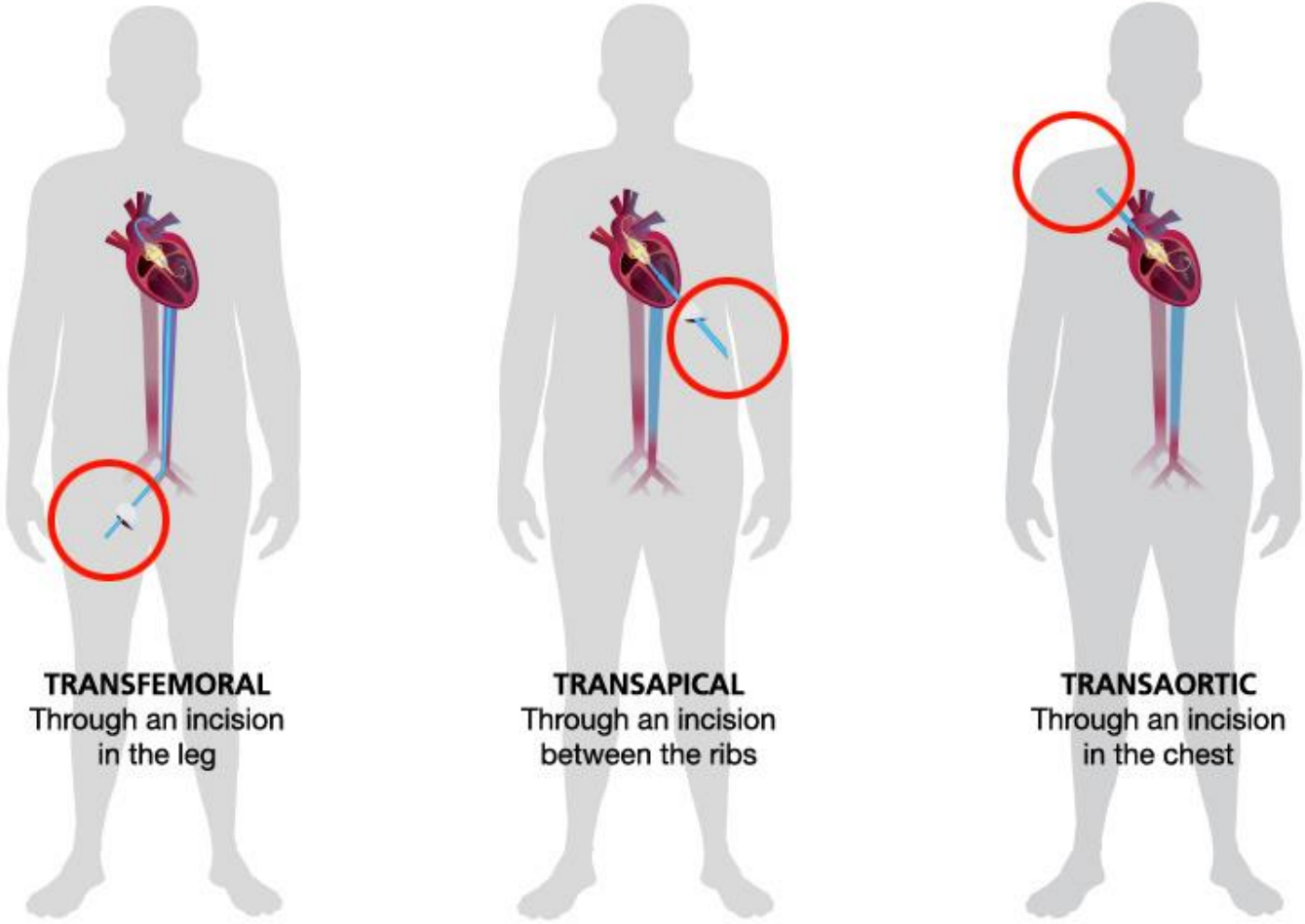


Now…



TAVR Access



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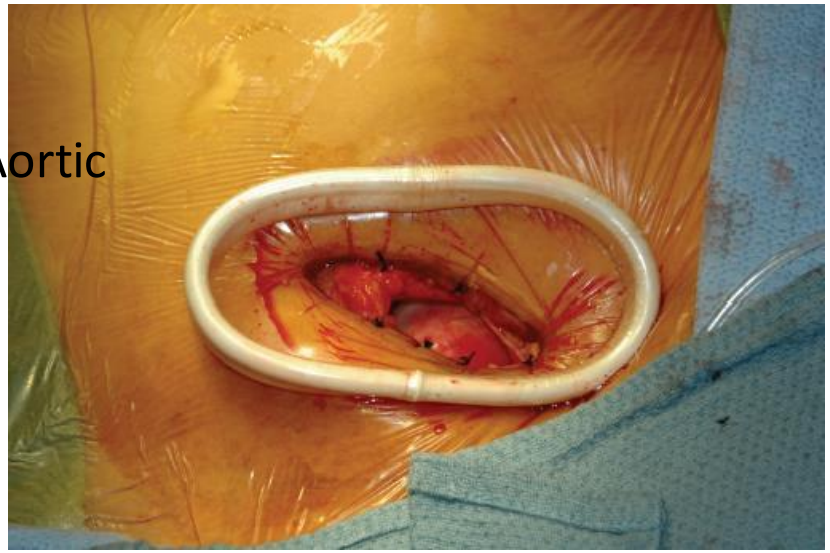
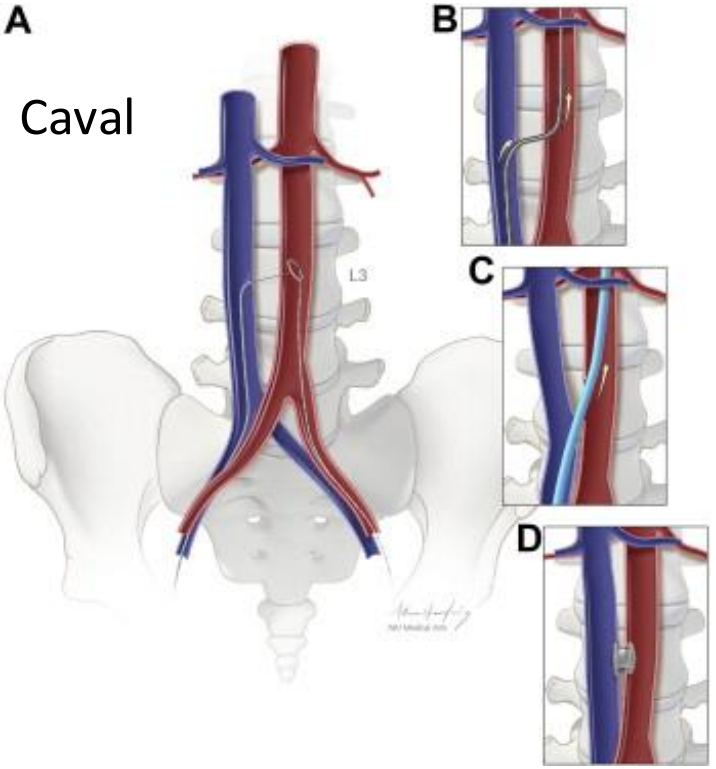
Alternative Approaches: You can be creative…

Aortic



Caval



Apical

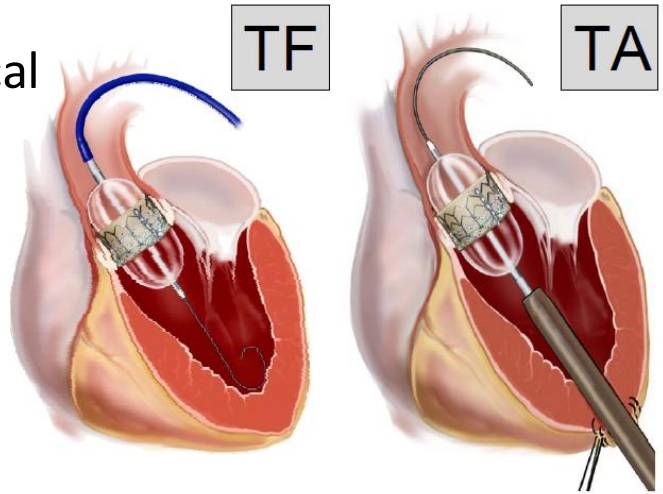
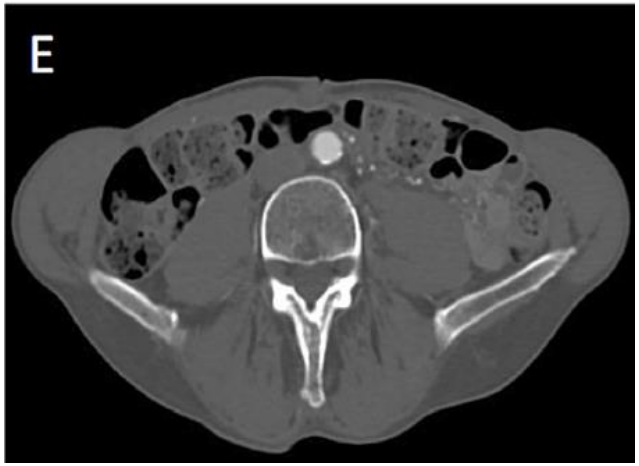
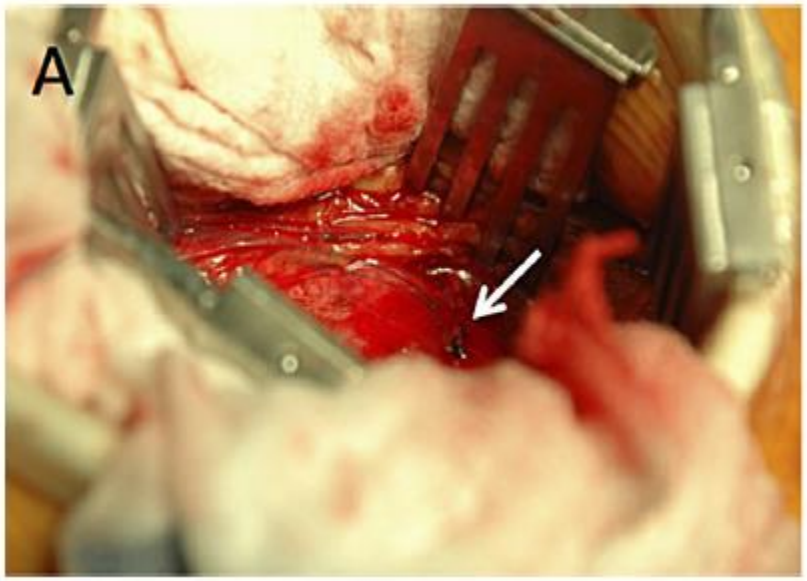
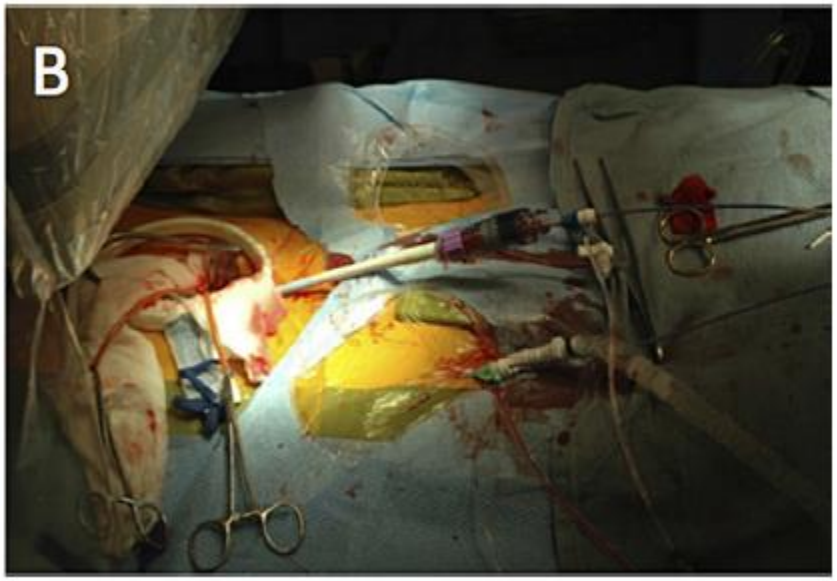


Photo courtesy of Michael Davidson, MD;
Schematics from AHA and Lederman et al. JACC. 2014.

Alternative approaches
You can be creative…

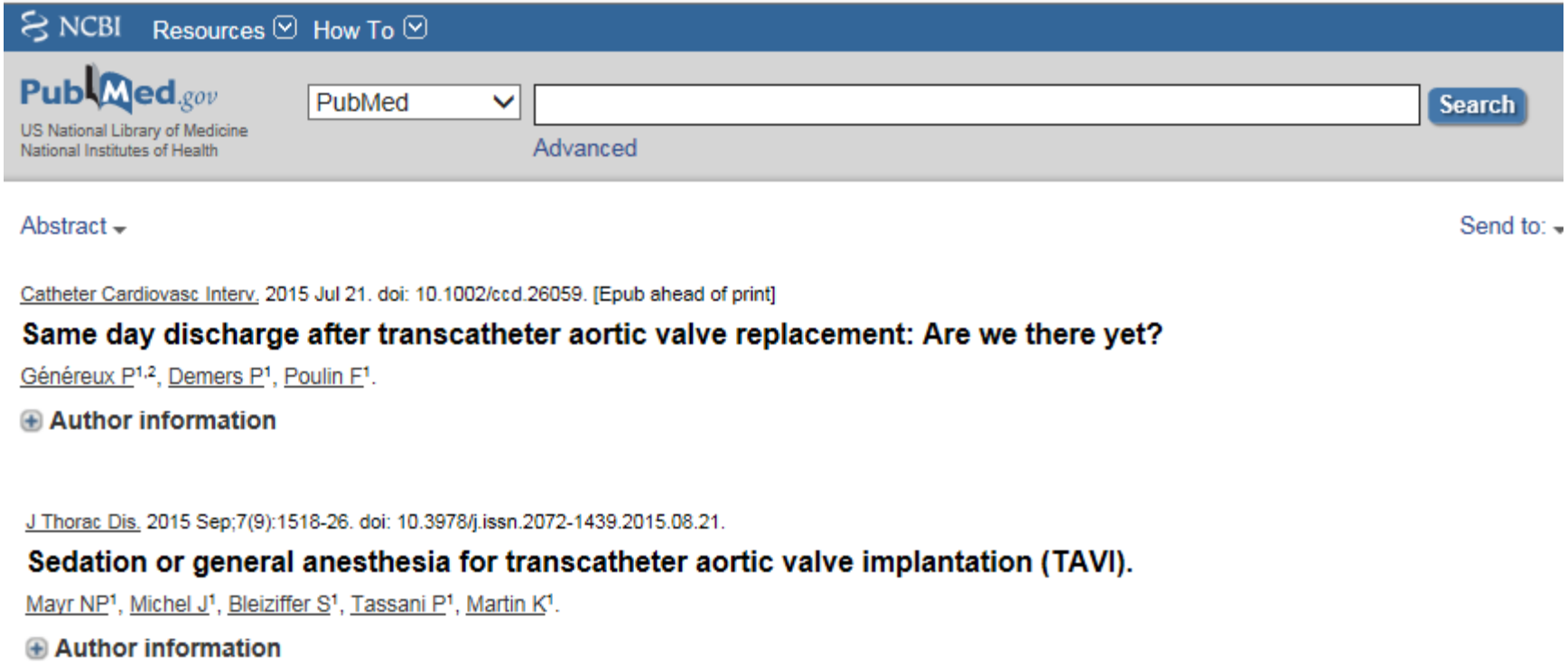






Zhan, Wimmer, Shah, Davidson. J Card Surg. 2015.

Procedural Developments and Continued Iterative Developments…



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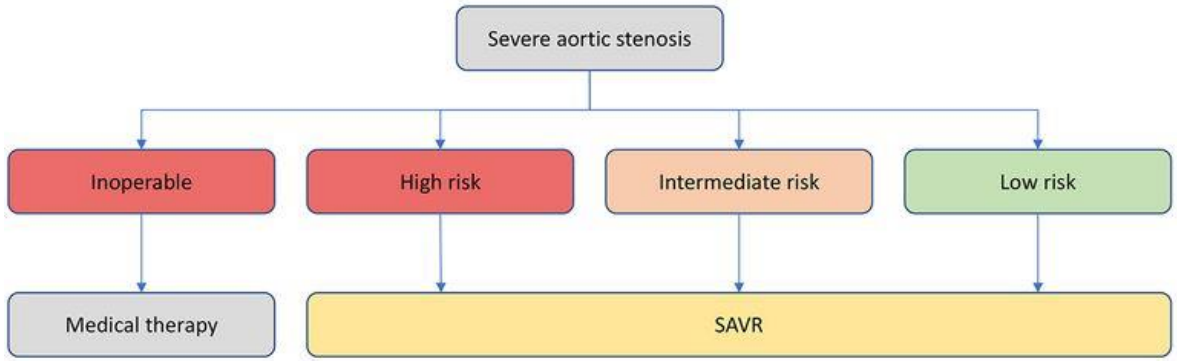
Evolution of our approach…

Before TAVR



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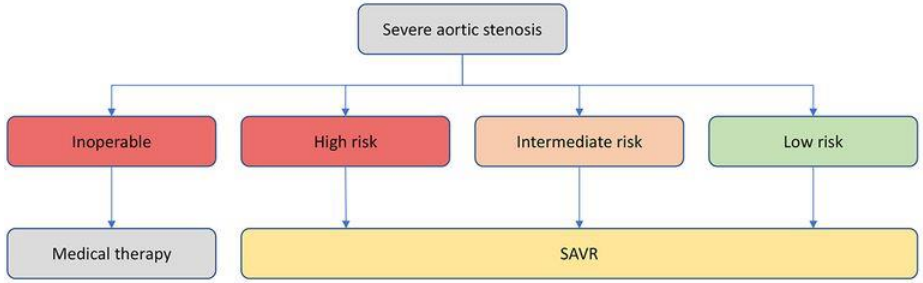
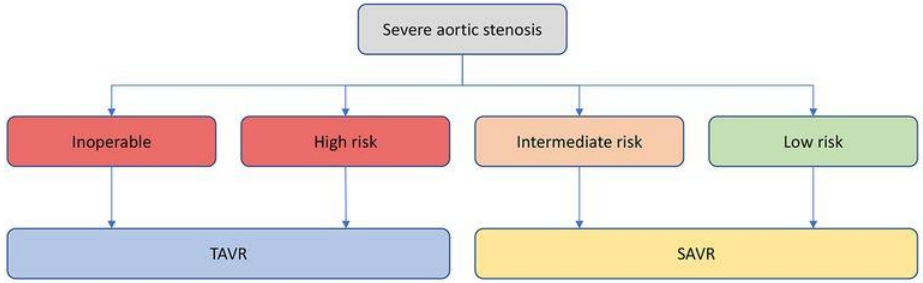
Rogers, Thourani, Waksman, JAHA. 2018.

Evolution of our approach…

Before TAVR



In 2011



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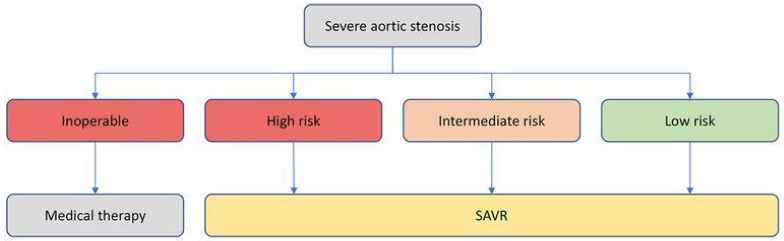
Evolution of our approach…

Before TAVR



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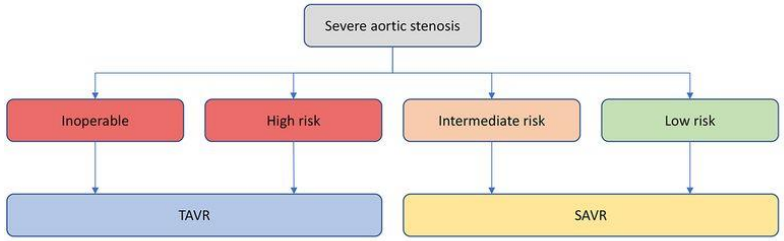

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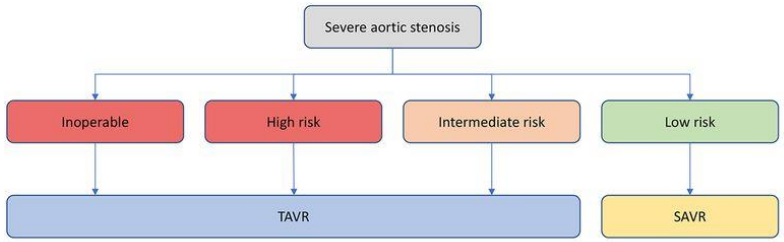

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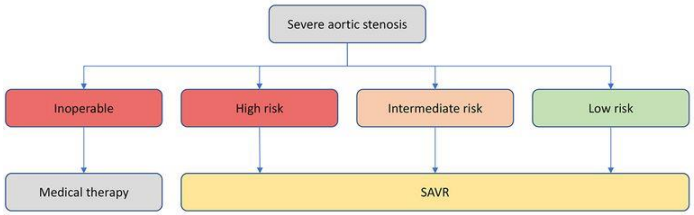
Evolution of our approach

Before TAVR



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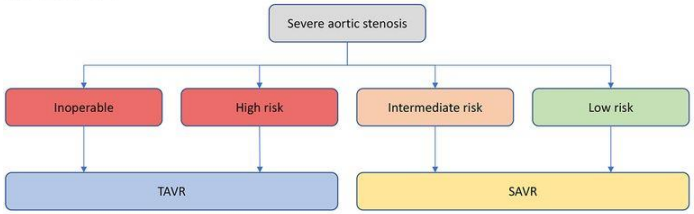

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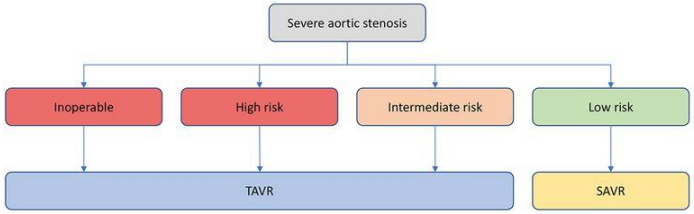

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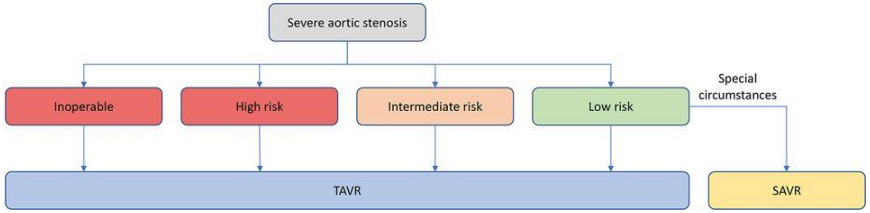

Evolution of our approach
When not to choose TAVR…

Indications
1. Young patient requiring a mechanical valve. ---Controversial: Young patient who wants a biologic valve but will outlive the prosthesis.
2. Bicuspid aortic stenosis with dilation of the ascending aorta
3. Very large aortic annulus
4. Patients ineligible for transfemoral access
5. Aortic stenosis with multivessel coronary artery disease

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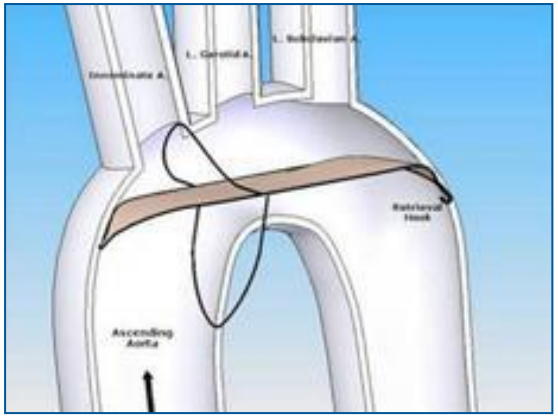
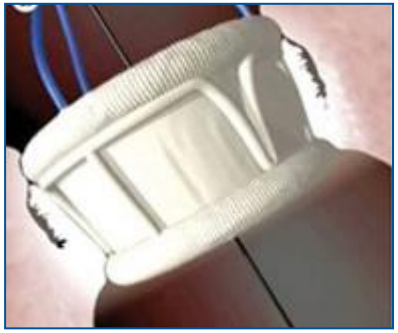
TAVR: Future Directions

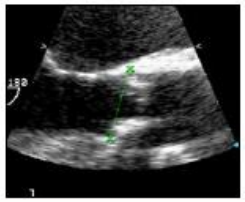
Current Limitations:

- Vascular Complications
  - Smaller devices (14 Fr)
  - Alternative access
- Stroke
  - Rates are improving
  - Embolic protection devices being studied
- Perivalvular Leak
  - Better sizing (MDCT)
  - Better "skirts"





Close cooperation of team specialists in valve disease



Radiologist

Anesthesiologist

Echocardiographist

Successful TAVI

Nurses
Technicians

Cardiac surgeon

Geriatrician

Cardiologist

Bottom line

- TAVR is FDA approved for the treatment of severe aortic stenosis across the risk spectrum!!!!

- Understanding the role of TAVR in younger patients will evolve over time.

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Questions?

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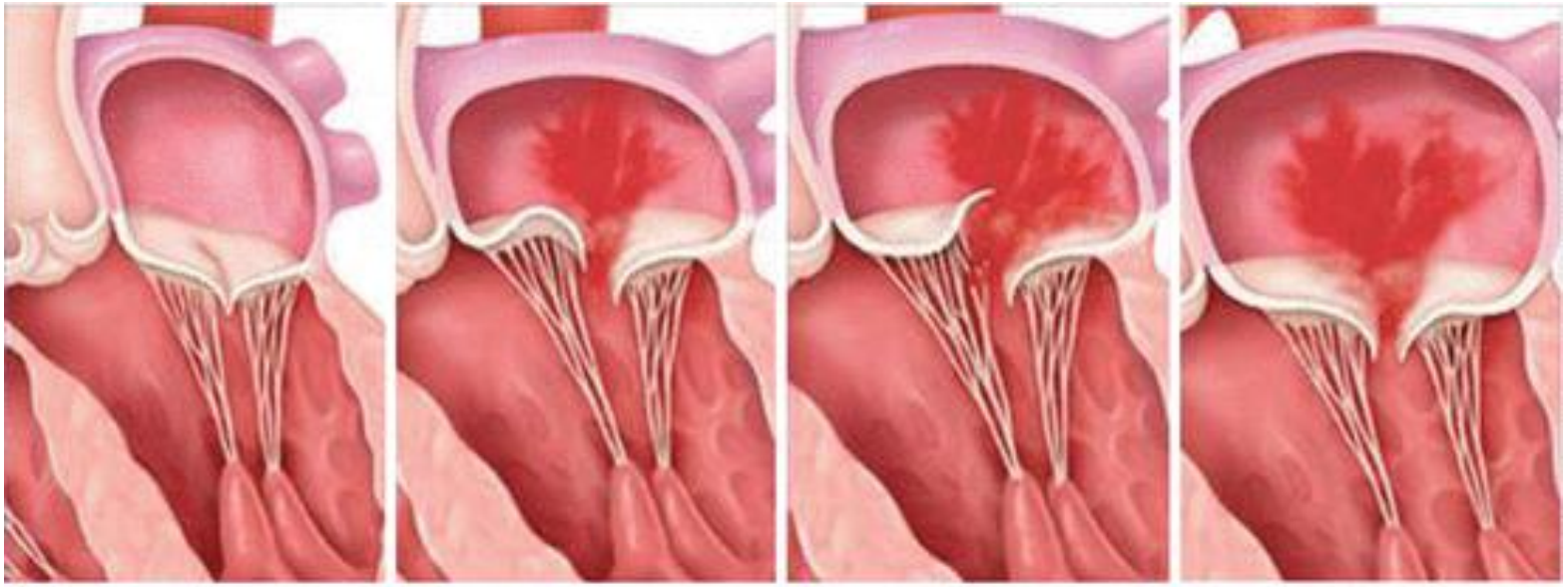
Switch gears…

Mitral Regurgitation…
a mixed bag of pathologies



Normal mitral valve

Degenerative MR caused by mitral valve prolapse

Degenerative MR caused by flail leaflet

Functional MR

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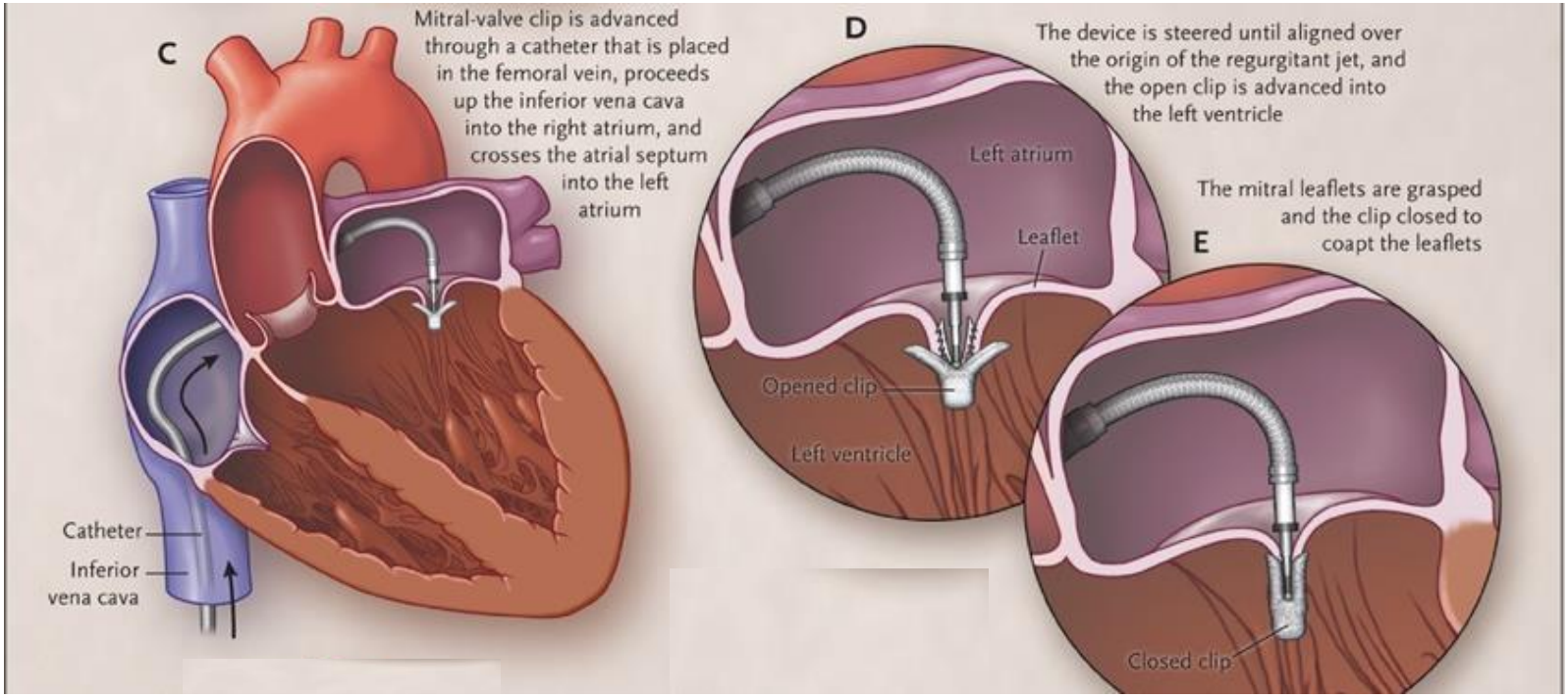
MitraClip schematic



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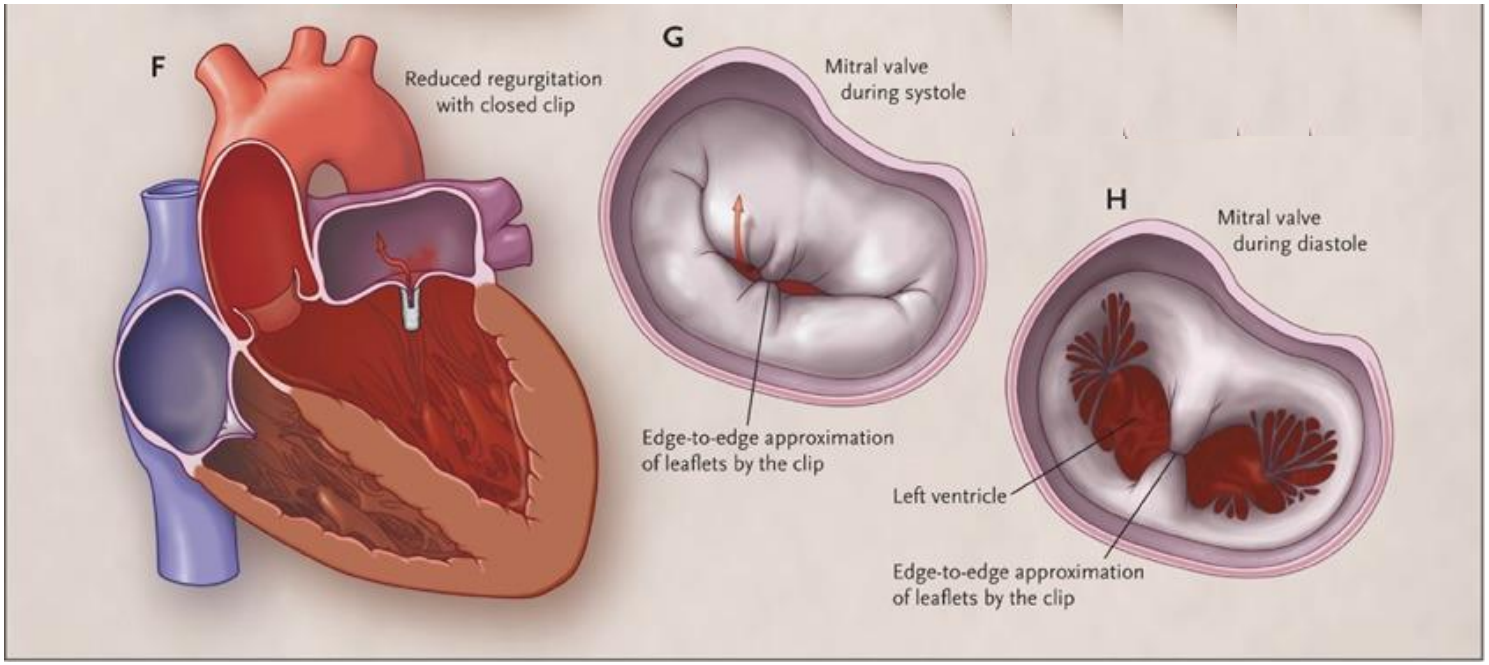
NEJM 2011.

MitraClip schematic



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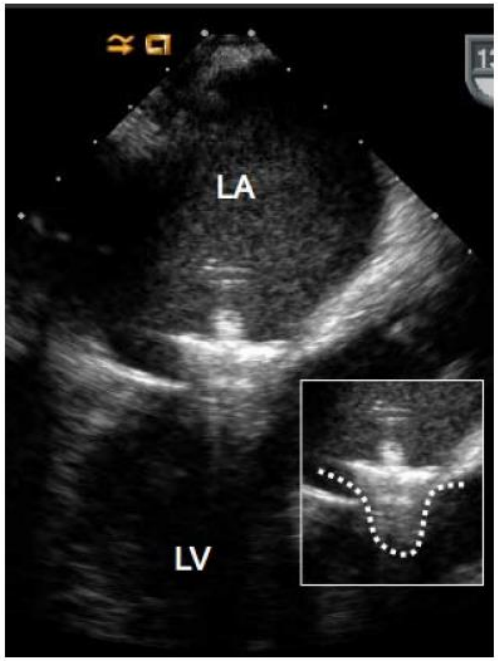
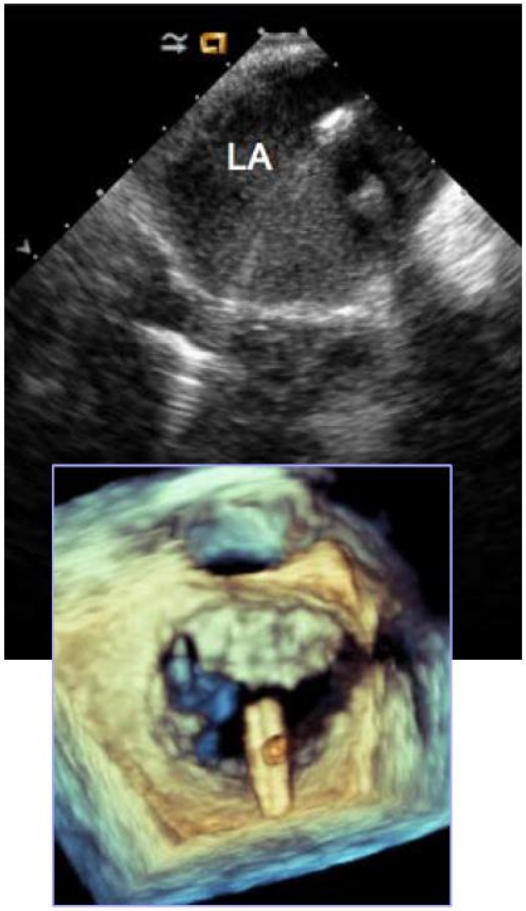
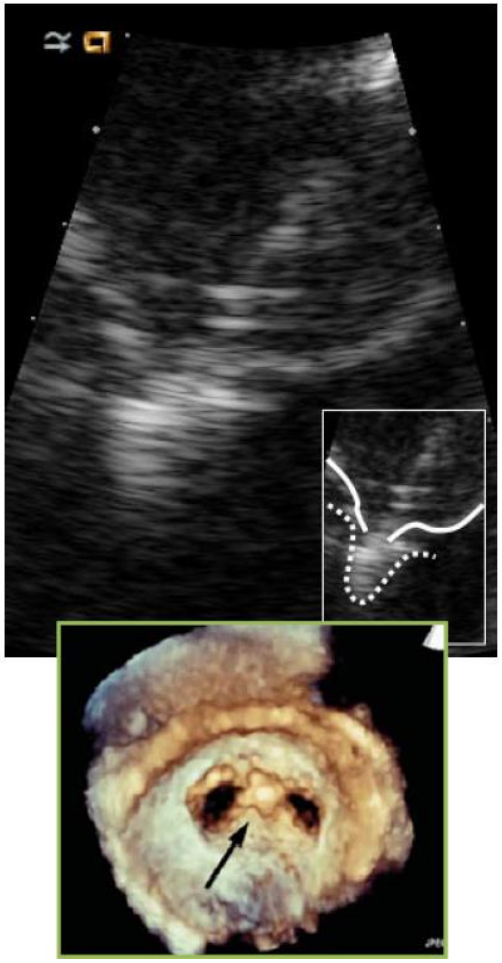
NEJM 2011.

Mitraclip in practice







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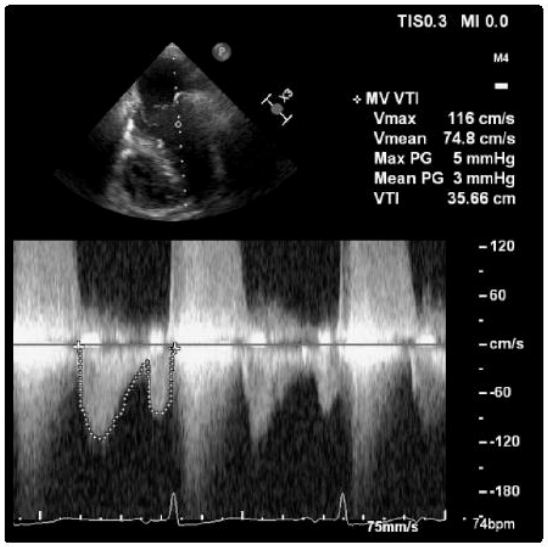
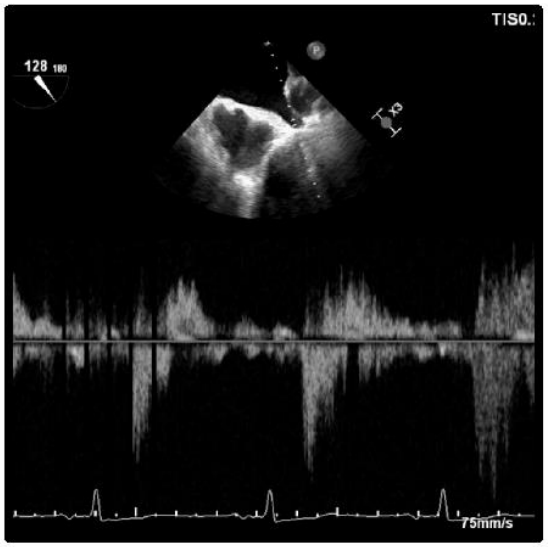
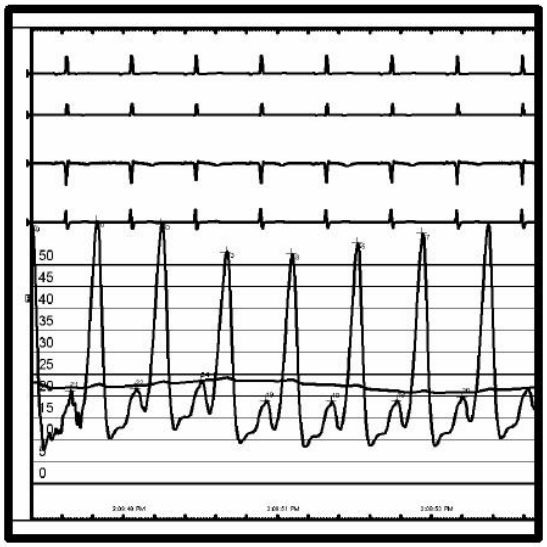
MitraClip hemodynamics (pre)



Mean TMG 3 mmHg



Reversed PV Flow



Mean LA 22 mmHg

LA V waves 60 mmHg

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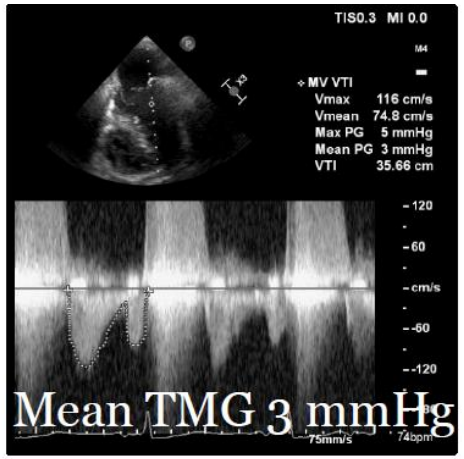
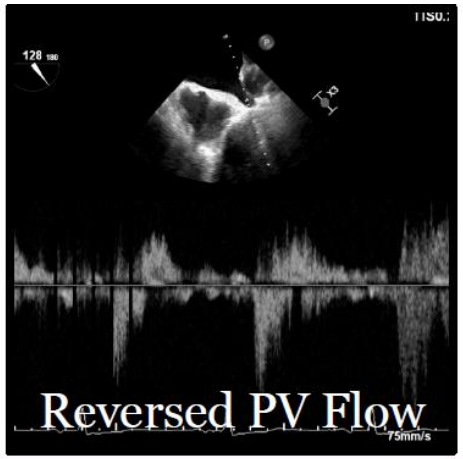
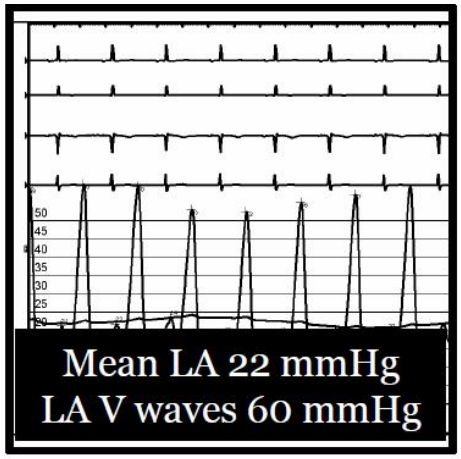
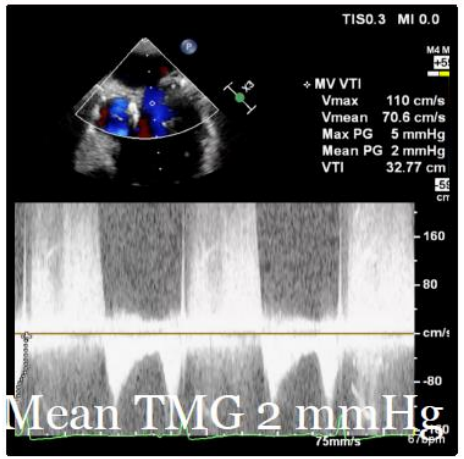
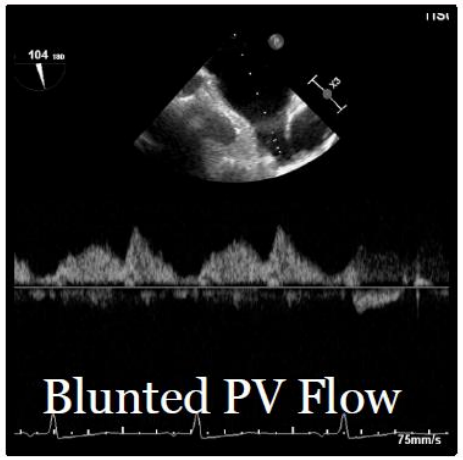
After first clip

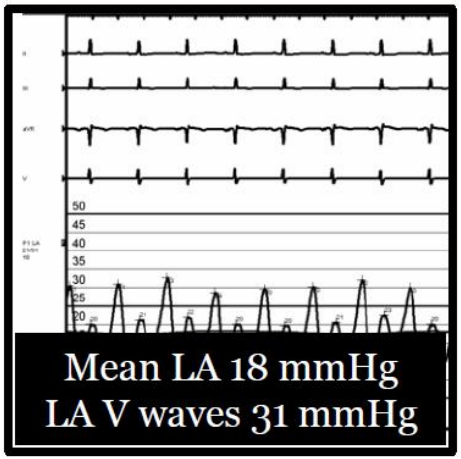












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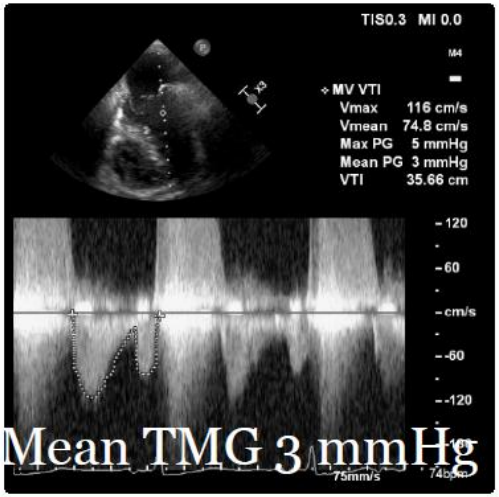
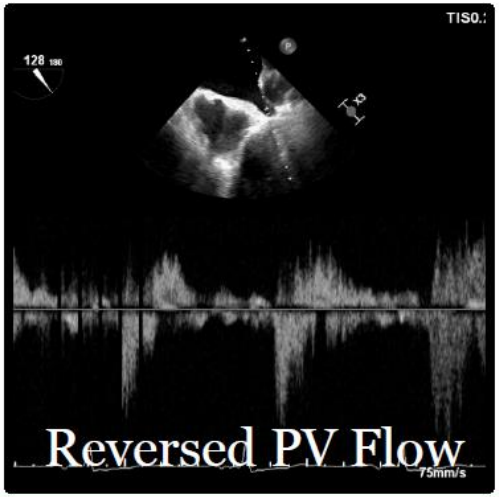
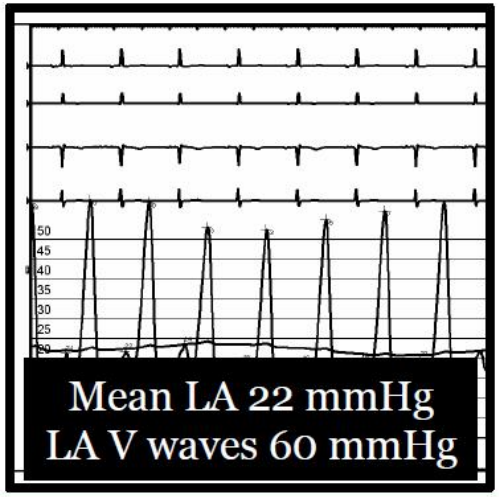
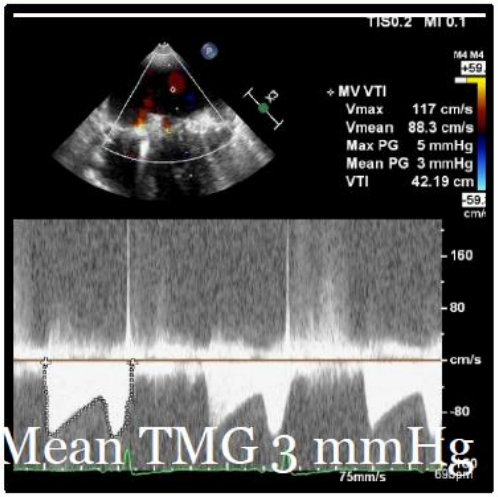
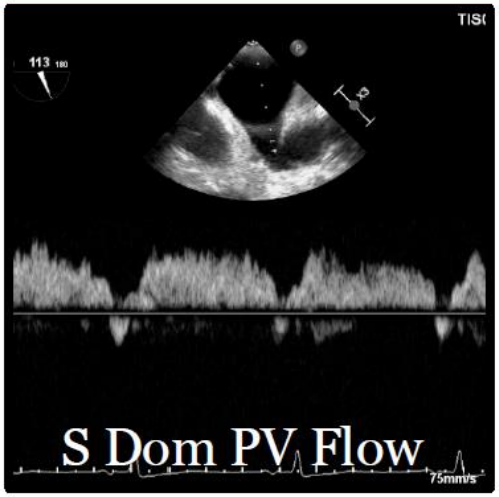
After second clip

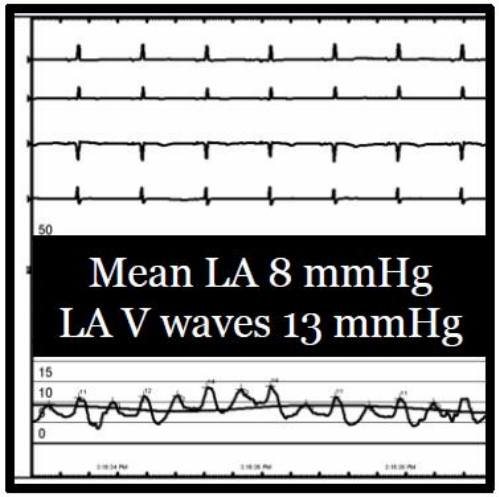












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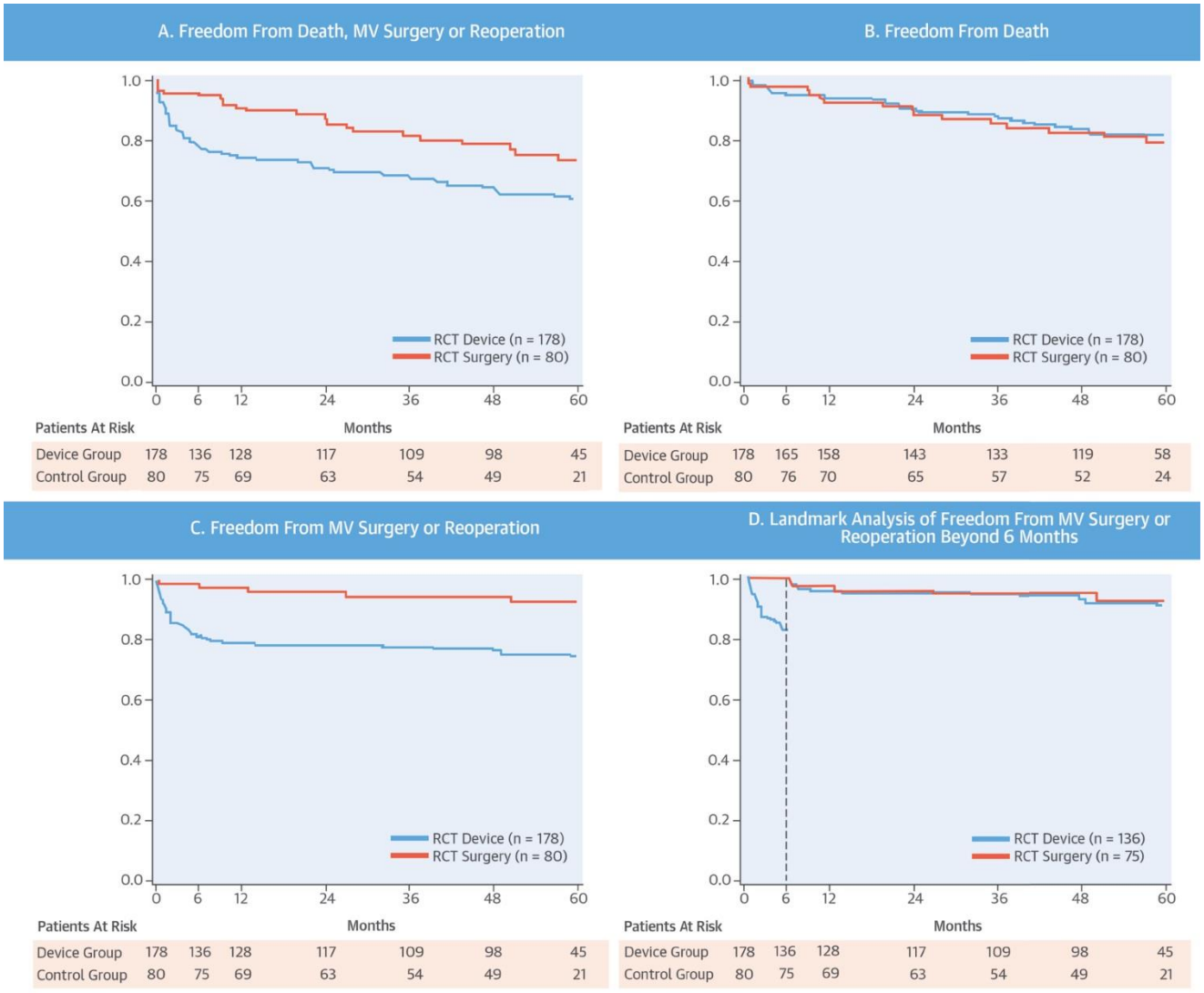
Everest II Final results (Degenerative)



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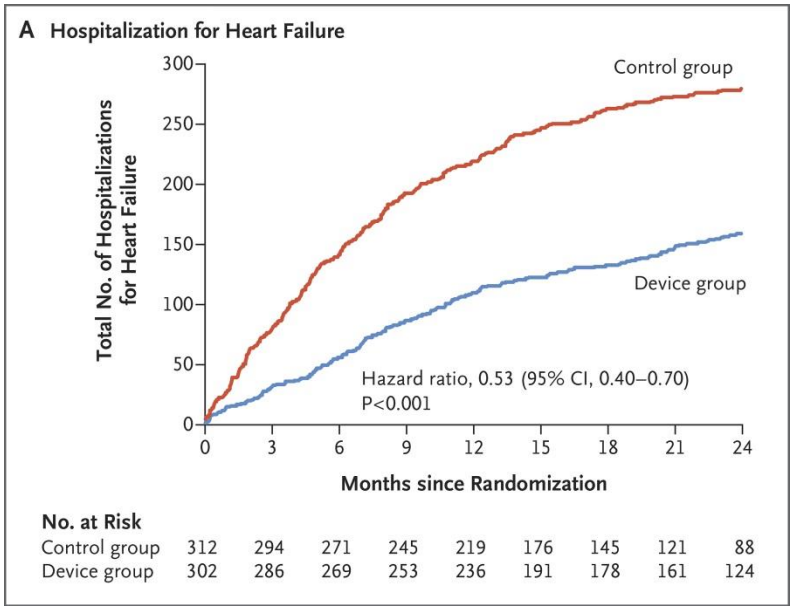
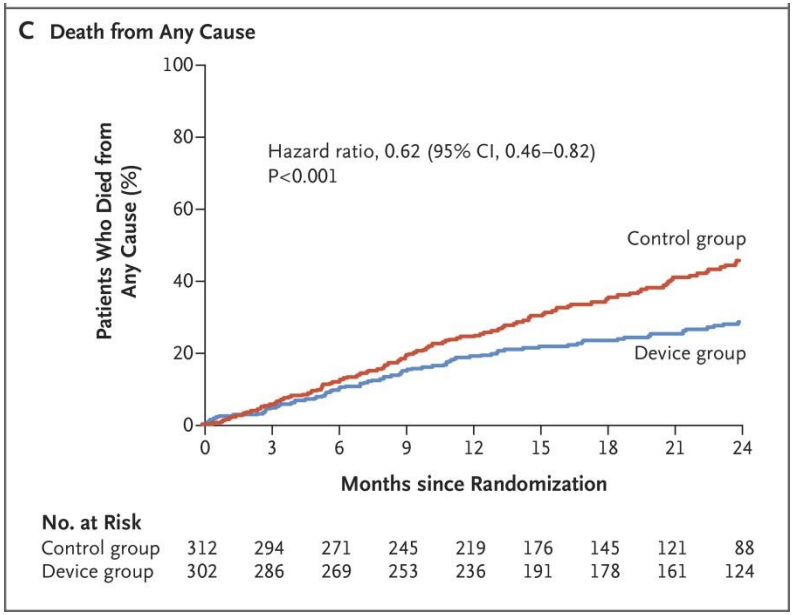
Feldman, T. et al. J Am Coll Cardiol. 2015; 66(25):2844-54.

COAPT trial in functional MR





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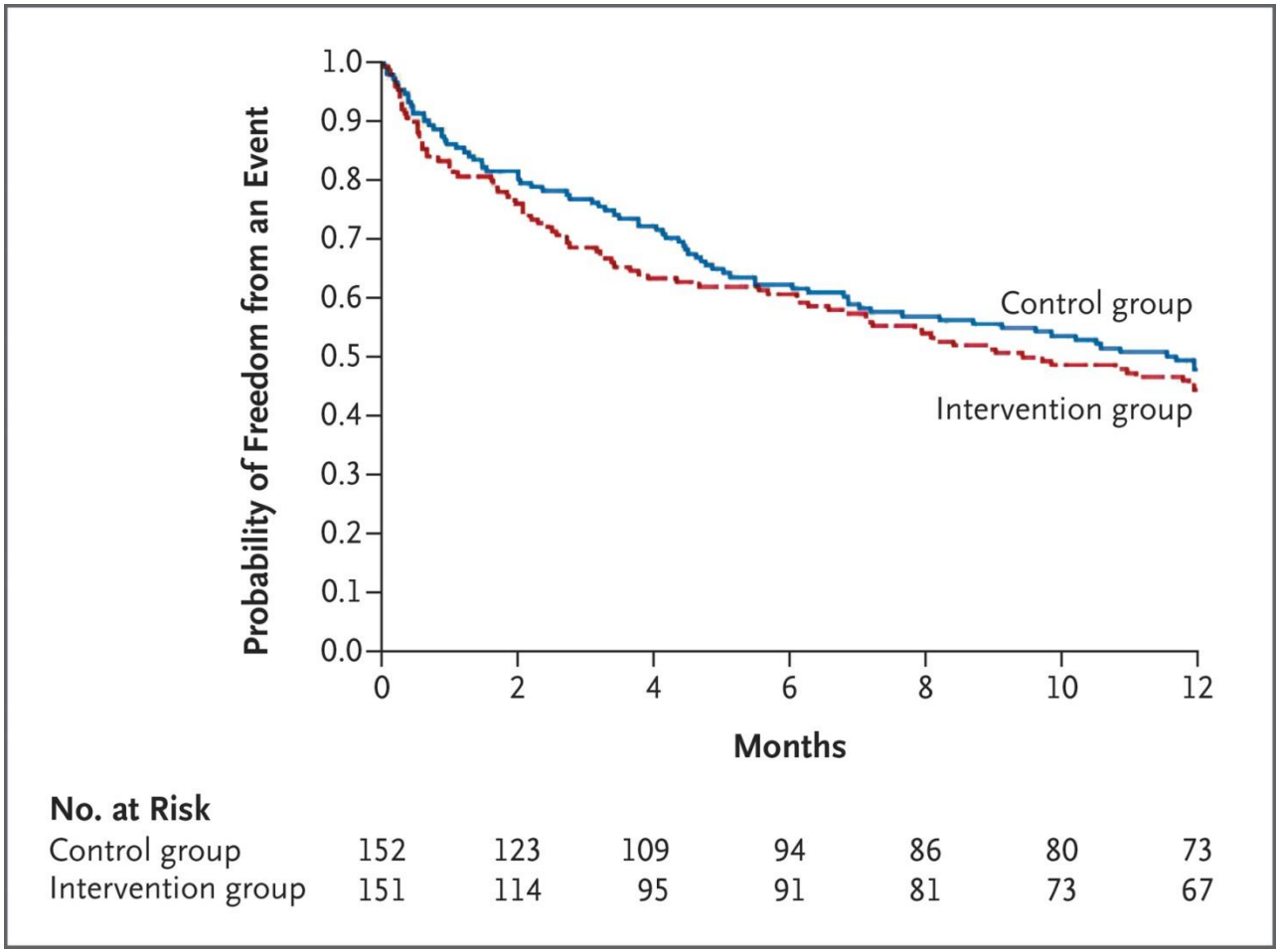
Stone. NEJM. 2018.

Mitra FR trial in functional MR



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Obadia. NEJM. 2018.

The evolution…

- Technologies to address valvular pathologies in less invasive ways continue to progress

- Exciting times are ahead!!!!

Thank you!

For further discussion or to refer a patient:

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Mary Kate Carroll
TAVR Clinical Practice Coordinator
302-733-7714
Mary.Carroll@christianacare.org

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Extra Slides

The Heart Team…an expanding concept

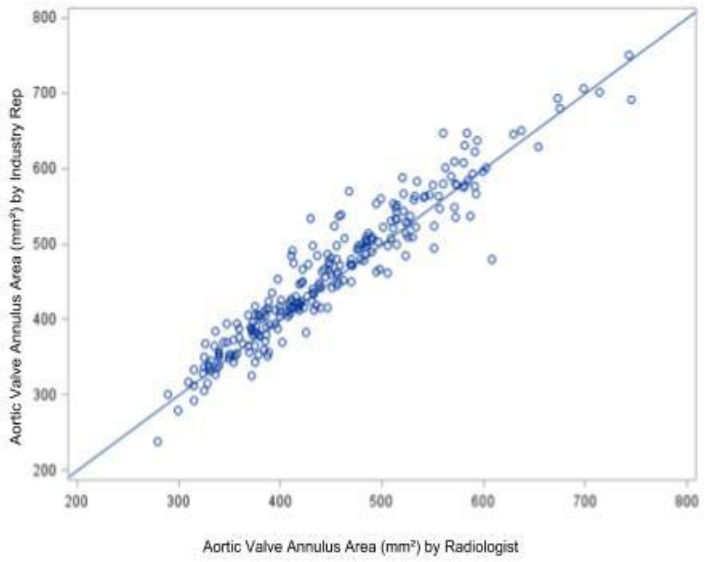


Figure 1A

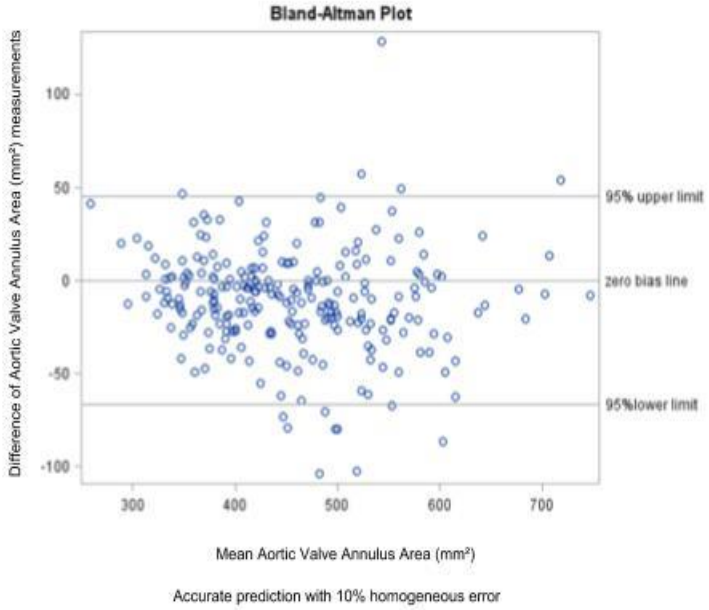


Figure 1B

Chawla, Zhang, Shah, Norton, Wimmer. Submitted. 2018.

Ongoing clinical trials in low risk patients

Name	Unique Identifier	Population	Study Design	Primary End Point	THV in TAVR Arm	Sample Size
LRT[23]	NCT02628899	No age restriction STS ≤3%	Feasibility study Prospective TAVR arm with historical SAVR controls	All-cause mortality at 30 d	Transfemoral SAPIEN 3 or Evolut R/PRO	200 TAVR in main arm Up to 100 TAVR in bicuspid arm
PARTNER 3[24]	NCT02675114	Age ≥65 y STS <4%	Noninferiority Randomized TAVR vs SAVR	All-cause mortality, all stroke, and rehospitalization at 1 y	Transfemoral SAPIEN 3	614 TAVR 614 SAVR
Medtronic TAVR in low risk patients[25]	NCT02701283	No age restriction STS <3%	Noninferiority Randomized TAVR vs SAVR	All-cause mortality or disabling stroke at 2 y	Transfemoral or subclavian Evolut R	625 TAVR 625 SAVR
NOTION 2[26]	NCT02825134	Age 18 to 75 y STS <4%	Noninferiority Randomized TAVR vs SAVR	Composite rate of all-cause mortality, myocardial infarction and stroke at 1 y	Transfemoral Any CE-approved THV	496 TAVR 496 SAVR

Rogers, Thourani, Waksman, JAHA. 2018.

The honest truth about many of our conversations in clinic.

Vs.

SEASONS
HOSPICE &
PALLIATIVE CARE

Severe Aortic Stenosis Decision Aid

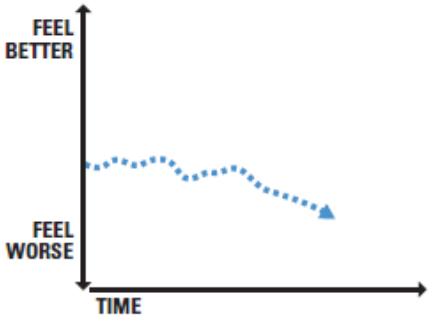
2 CHOICES | SYMPTOM MANAGEMENT / TAVR

What are my choices?	Will I feel better?

SYMPTOM MANAGEMENT
(Palliative Care)

- Valve is **not** changed
- Not Invasive

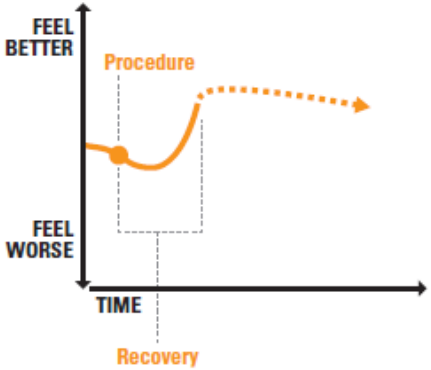
- Decision can be revisited over time



TAVR
Transcatheter Aortic Valve Replacement

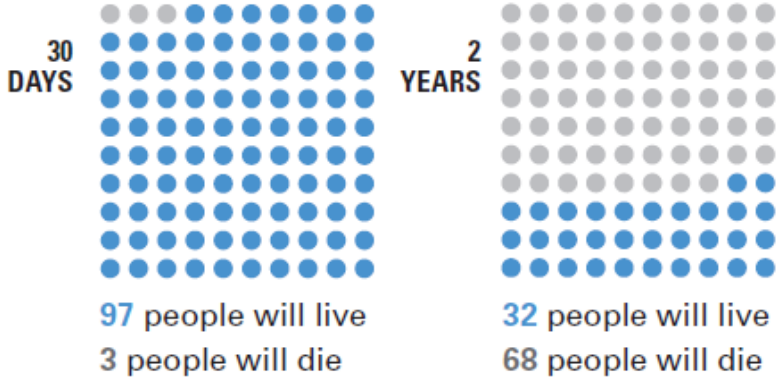
- Valve is changed
- Less Invasive

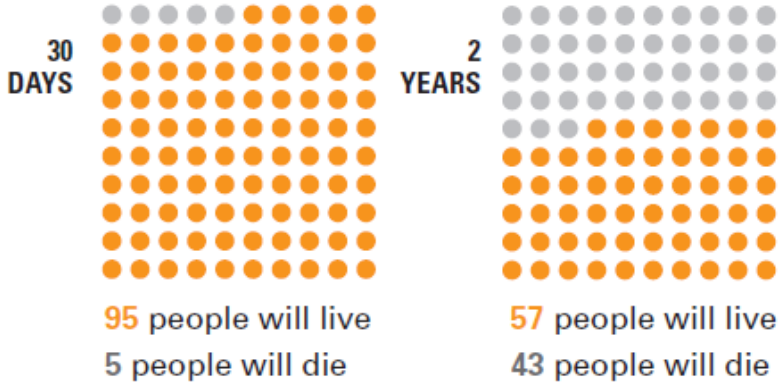
- New procedure, (FDA-approval in 2011)



Decision aides from ACC Championing Care Initiative (2014-2015).

Will it help me live longer?





What are the risks?

This choice may not include invasive procedures

2 out of 100 people will have a stroke or TIA within 30 days

5 out of 100 people will have a stroke or TIA within 1 year

7 out of 100 people will have a stroke or TIA within 30 days

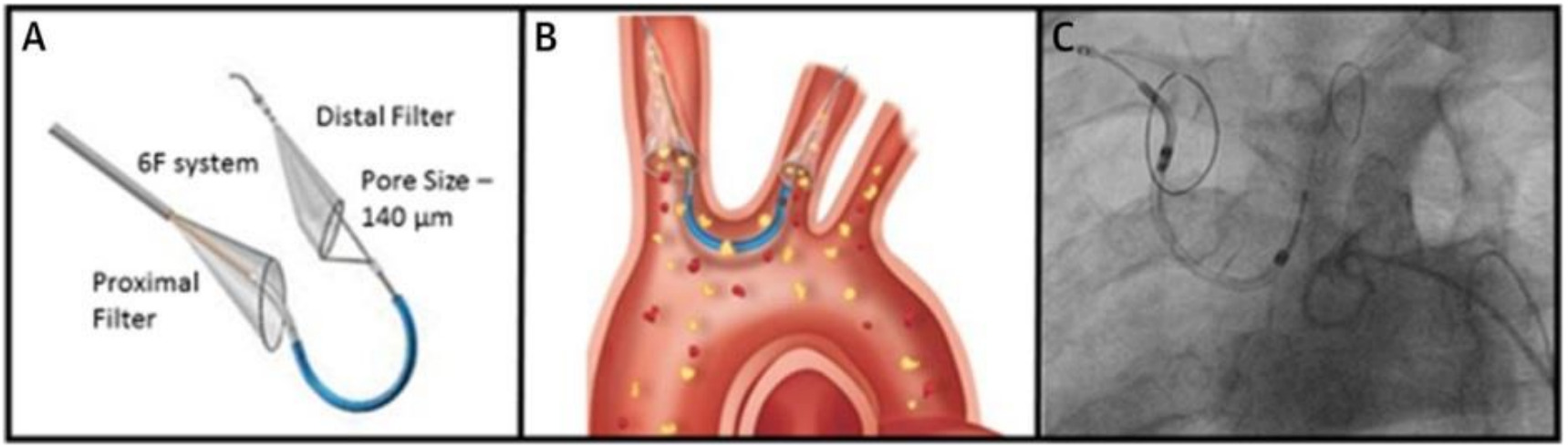
11 out of 100 people will have a stroke or TIA within 1 year

Other Possible Complications

- Major bleeding
- Kidney failure
- Pacemaker
- Damage to blood vessels

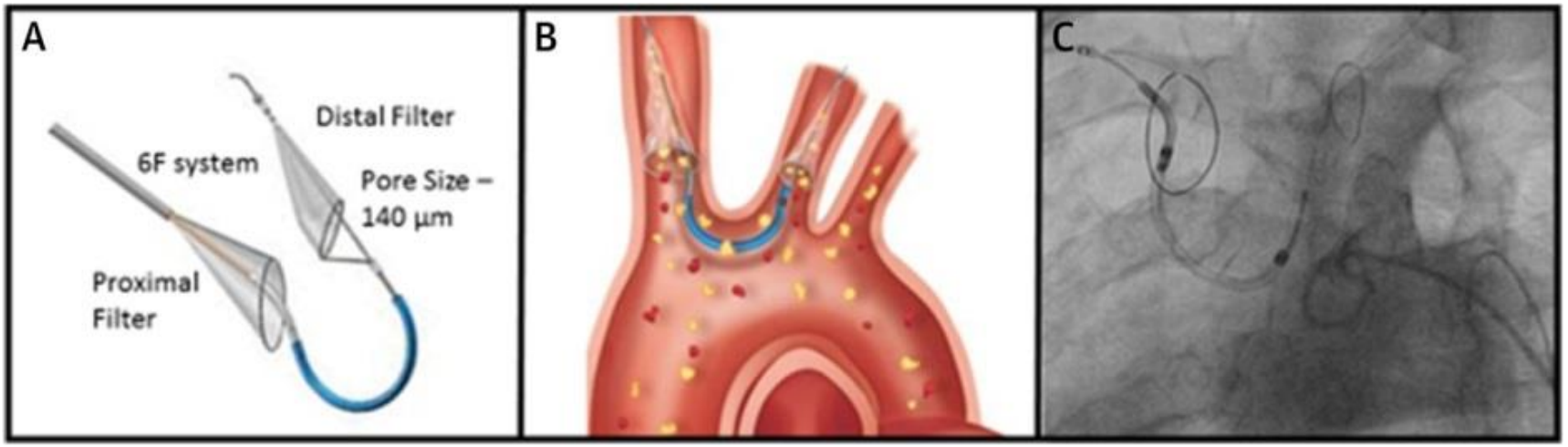
Decision aides from ACC Championing Care Initiative (2014-2015).

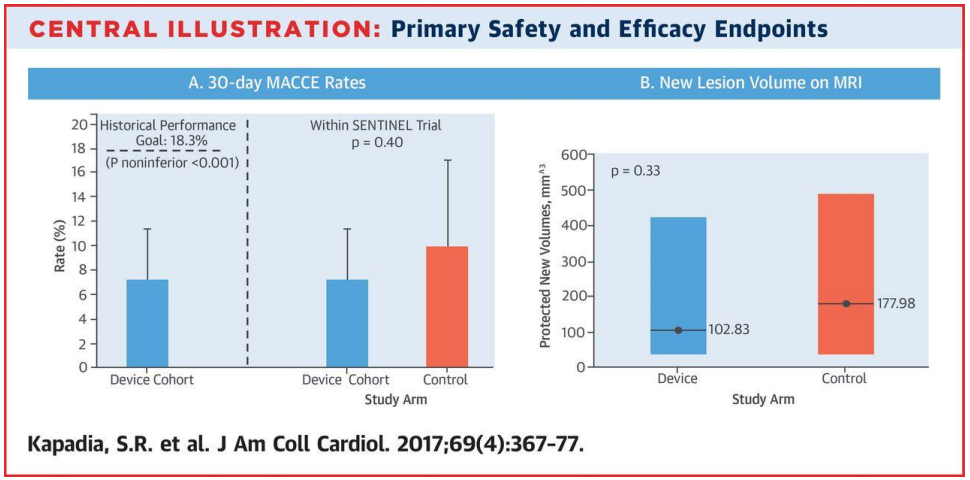
Embolic protection devices



Kapadia. J Am Coll Cardiol. 2017.

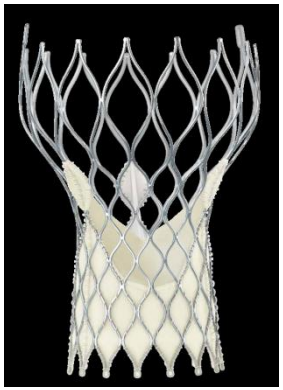
Embolic protection devices



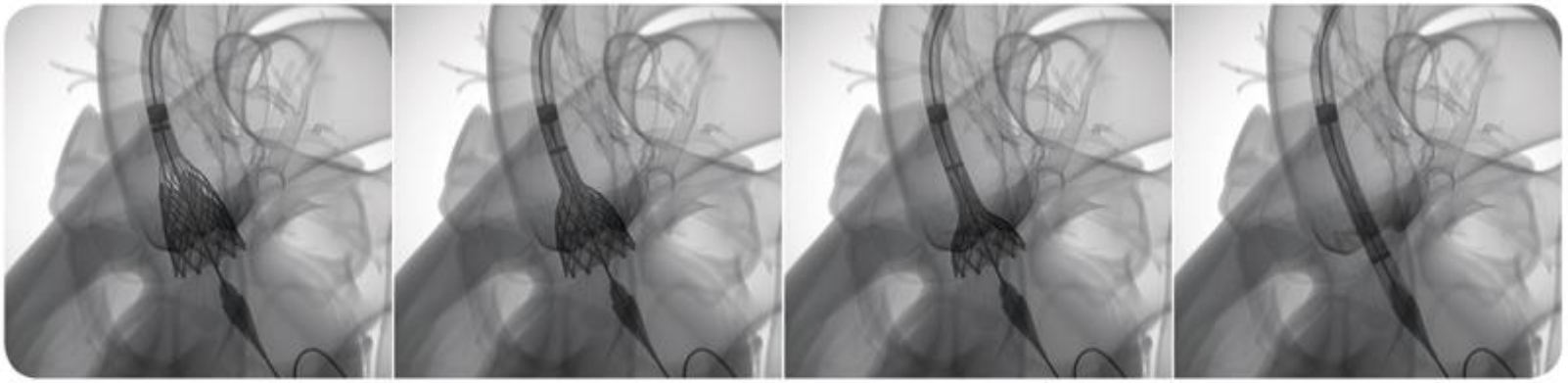


Kapadia. J Am Coll Cardiol. 2017.

There are options besides balloon expandable valves



Option to Fully Recapture and Reposition*



Valve positioned too deep

Recapture begins

Partially recaptured

Valve fully recaptured

CHOICE Trial: comparison of balloon expandable vs. self expandable

Table 4. Procedural Outcome

	No./Total No. (%)			
	Balloon-Expandable Valve (n = 121)	Self-expandable Valve (n = 120)	Relative Risk (95%CI)	*P* Value
Immediate procedural mortality	0 /121 (0)	0/120 (0)	-	-
Final aortic regurgitation				
Angiography[a]				
None/trace	75/121 (62.0)	42/120 (35.0)	1.77 (1.34-2.35)	
Mild	41/121 (33.9)	56/120 (46.7)	0.73 (0.53-0.99)	
Moderate	4/121 (3.3)	17/120 (14.1)	0.23 (0.08-0.67)	<.001
Severe	1/121 (0.8)	5/120 (4.2)	0.20 (0.02-1.67)	
Echocardiography[b]				
None/trace	88/121 (66.1)	59/120 (49.2)	1.48 (1.20-1.83)	
Mild	39/121 (32.2)	54/120 (45.0)	0.72 (0.52-0.99)	.005
Moderate	1/121 (0.8)	7/120 (5.8)	0.14 (0.02-1.13)	
Severe	1/121 (0.8)	0/120 (0)		
Aortic regurgitation index, mean (95% CI)[c]	29.0 (27.7-30.3)	27.3 (26.0-28.7)		.08
Coronary obstruction	2/121 (1.6)	0/120 (0.0)		.49
Annular rupture	0/121 (0)	0/120 (0)		
~~Left-to-right shunt~~	~~2/121 (1.6)~~	~~2/120 (1.7)~~	~~0.99 (0.14-6.93)~~	~~.99~~
Device success (primary endpoint)	116/121 (95.9)	93/120 (77.5)	1.24 (1.12-1.37)	<.001

[a] Assessed by angiography using the method of Sellers et al.[19] Aortic regurgitation was classified into the following grades: absent or trace, mild, moderate, and severe, the latter comprised grades 3 and 4 according to Sellers.

[b] Semiquantitatively assessed using echocardiography. For paravalvular regurgitation, grading was performed by estimating the proportion of the circumference of the valved stent occupied by the jet: less than 10% was graded as mild, 10% to 20% as moderate, and more than 20% as severe regurgitation.[20,21]

[c] Calculated as ([diastolic blood pressure –left ventricular end diastolic pressure]/systolic blood pressure) × 100 in 114 patients in self-expandable valve group and 116 in the balloon expandable valve group.

JAMA. 2014;311(15):1503-1514.

CHOICE Trial: comparison of balloon expandable vs. self expandable

Table 5. Thirty-Day Clinical Outcome

Variable	No./Total No. (%) Balloon-Expandable Valve (n = 121)	No./Total No. (%) Self-expandable Valve (n = 117)	Relative Risk (95% CI)	*P* Value
Death				
Any cause	5/121 (4.1)	6/117 (5.1)	0.81 (0.25-2.57)	.77
Cardiovascular causes	5/121 (4.1)	5/117 (4.3)	0.97 (0.29-3.25)	.99
Stroke	7/121 (5.8)	3/117 (2.6)	2.26 (0.60-8.52)	.33
Myocardial infarction	1/121 (0.8)	0/117 (0.0)		.99
Bleeding				
Life threatening	10/121 (8.3)	14/117 (12.0)	0.69 (0.32-1.49)	.35
Major	23/121 (19.0)	17/117 (14.5)	1.31 (0.74-2.32)	.36
Minor	11/121 (9.1)	9/117 (7.7)	1.18 (0.51-2.74)	.70
Major or minor	34/121 (28.1)	26/117 (22.2)	1.26 (0.81-1.97)	.30
Vascular complications				
All	17/121 (14.0)	15/117 (12.8)	1.10 (0.57-2.09)	.78
Major	12/121 (9.9)	13/117 (11.1)	0.89 (0.42-1.88)	.76
Minor	5/121 (4.1)	2/117 (1.7)	2.42 (0.48-12.21)	.28
Acute kidney injury	5/121 (4.1)	11/117 (9.4)	0.44 (0.16-1.23)	.13
Repeat procedure for valve-related dysfunction	1/121 (0.8)	2/117 (1.7)	0.48 (0.04-5.26)	.62
Combined safety end point[a]	22/121 (18.2)	27/117 (23.1)	0.79 (0.48-1.30)	.42
Major adverse cardiovascular and cerebrovascular events[b]	8/121 (6.6)	4/117 (3.4)	1.93 (0.60-6.25)	.38
Rehospitalization for heart failure	0/119 (0.0)	5/117 (4.3)		.02
NYHA class improvement	100/106 (94.3)	91/105 (86.7)	1.09 (1.00-1.19)	.06
Quality of life				
Score, mean (95% CI)	71.0 (68.2-73.9)	65.9 (62.4-69.5)		.02
Score change, median (IQR)	12.5 (0-20)	10 (0-20)		.19
New permanent pacemaker	19/110 (17.3)	38/101 (37.6)	0.46 (0.28-0.74)	.001

Abbreviations: IQR, interquartile range; NYHA, New York Heart Association.

[a] Defined as a composite of all-cause mortality, major stroke, life-threatening or disabling bleeding, acute kidney injury stage 3 including renal replacement therapy, periprocedural myocardial infarction, major vascular complications, and repeat procedure for valve-related dysfunction.

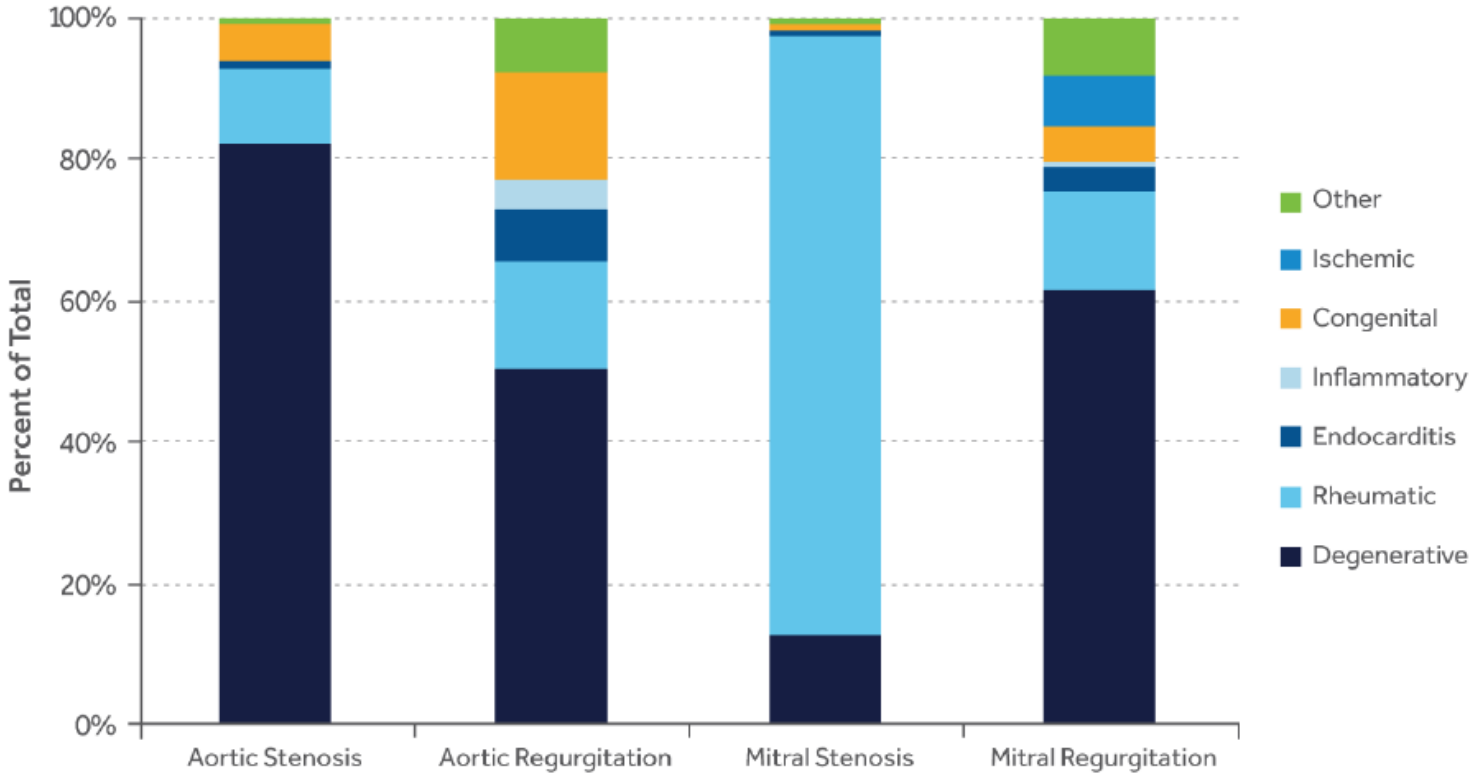
[b] Defined as a composite of myocardial infarction, cardiac or vascular surgery and stroke.

JAMA. 2014;311(15):1503-1514.

Other Outcomes of TAVR vs. SAVR in Intermediate risk patients

	PPM Implantation		Stroke		Moderate or Severe PVL		New Atrial Fibrillation	
	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR
PARTNER 2[12]	8.5%	6.9%	3.2%	4.3%	3.7%*	0.6%*	9.1%*	26.4%*
SURTAVI[14]	25.9%*	6.6%*	1.2%	2.5%	3.5%*	0.7%*	12.9%*	43.4*
NOTION[11]	34.1%*	1.6%*	1.4%	3.0%	15.3%*	1.8%*	16.9%*	57.8%*
SAPIEN 3 IR[13]	10.2%	7.3%	1.0%*	4.4%*	3.8%*	0.6%*	3.2%*	28.5%*

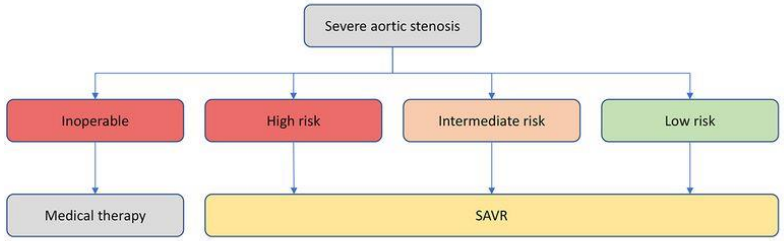
Etiology of Single Native Left-Sided Valve Disease



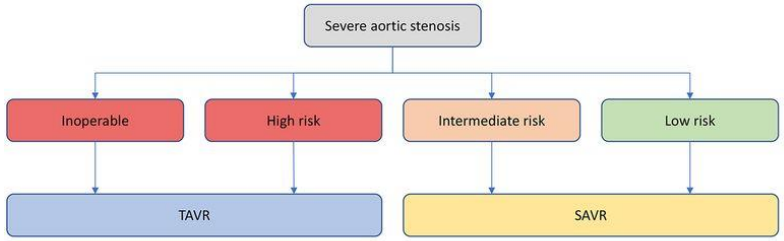
Iung B, Baron G, Butchart E, et al. *Eur Heart J*. 2003;24:1244-1253.

Evolution of our approach…

Before TAVR



In 2011



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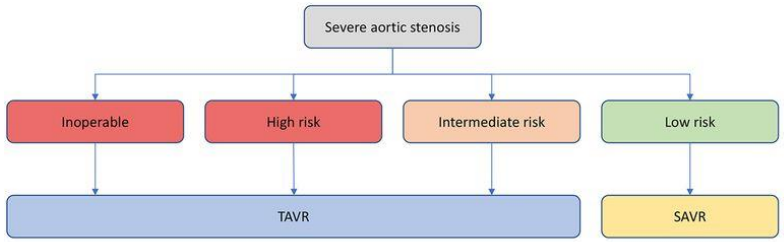
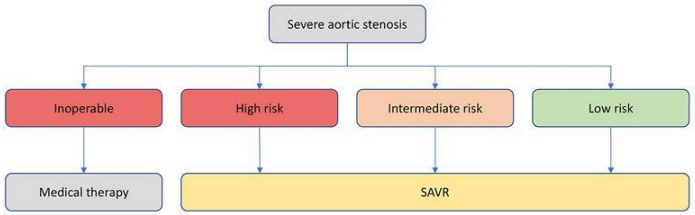


Rogers, Thourani, Waksman, JAHA. 2018.

Evolution of our approach

Before TAVR



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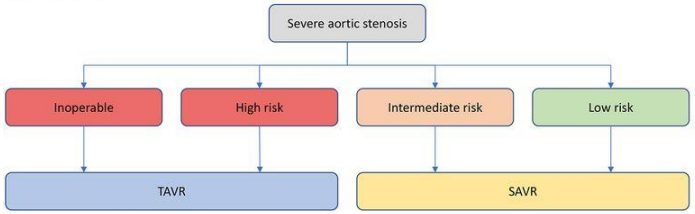

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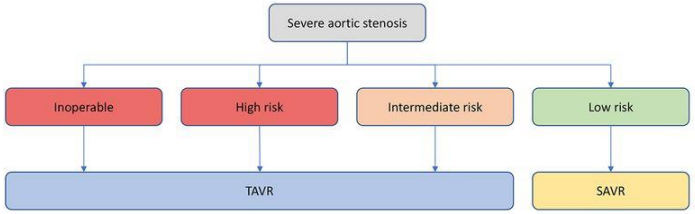
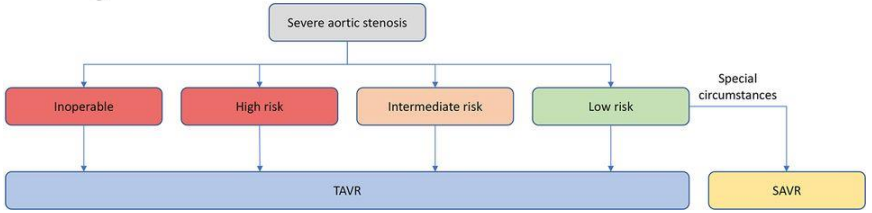


In the future…



Rogers, Thourani, Waksman, JAHA. 2018.

Outcomes of TAVR vs. SAVR in Intermediate risk patients

Type of Transcatheter Heart Valve	PARTNER 2[12] Edwards Sapien XT	SURTAVI[14] Medtronic CoreValve or Evolut R	NOTION[11] Medtronic CoreValve	SAPIEN 3 IR[13] Edwards Sapien 3
Time to end point	30 d	30 d	30 d	30 d
All-cause mortality	3.9%	2.2%	2.1%	1.1%
Disabling stroke	3.2%	1.2%	1.4%	1.0%
Paravalvular leak (≥ moderate)	3.7%	3.5%*	15.3%†	3.8%
Major vascular complications	7.9%	6.0%	5.6%*	6.1%
Major and life-threatening bleeding	10.4%	12.2%	11.3%*	4.6%
Acute kidney injury (stage 2 or 3)	1.3%	1.7%	0.7%*	0.5%
New permanent pacemaker implantation	8.5%	25.9%	34.1%	10.2%
Time to end point	2 y	2 y	2 y	1 y
All-cause mortality	16.7%	11.4%	8.0%	7.4%
Disabling stroke	6.2%	2.6%	3.6%	2.3%
Paravalvular leak (≥ moderate)	5.5%	5.7%	15.7%	1.5%
New permanent pacemaker implantation	11.8%	25.6%	41.3%	12.4%

	PPM Implantation		Stroke		Moderate or Severe PVL		New Atrial Fibrillation	
	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR
PARTNER 2[12]	8.5%	6.9%	3.2%	4.3%	3.7%*	0.6%*	9.1%*	26.4%*
SURTAVI[14]	25.9%*	6.6%*	1.2%	2.5%	3.5%*	0.7%*	12.9%*	43.4*
NOTION[11]	34.1%*	1.6%*	1.4%	3.0%	15.3%*	1.8%*	16.9%*	57.8%*
SAPIEN 3 IR[13]	10.2%	7.3%	1.0%*	4.4%*	3.8%*	0.6%*	3.2%*	28.5%*

Evolution of our approach
When not to choose TAVR…

Indications
1. Young patient requiring a mechanical valve
2. Bicuspid aortic stenosis with dilation of the ascending aorta
3. Very large aortic annulus
4. Patients ineligible for transfemoral access
5. Aortic stenosis with multivessel coronary artery disease

Rogers, Thourani, Waksman, JAHA. 2018.

Ongoing clinical trials in low risk patients

Name	Unique Identifier	Population	Study Design	Primary End Point	THV in TAVR Arm	Sample Size
LRT[23]	NCT02628899	No age restriction STS ≤3%	Feasibility study Prospective TAVR arm with historical SAVR controls	All-cause mortality at 30 d	Transfemoral SAPIEN 3 or Evolut R/PRO	200 TAVR in main arm Up to 100 TAVR in bicuspid arm
PARTNER 3[24]	NCT02675114	Age ≥65 y STS <4%	Noninferiority Randomized TAVR vs SAVR	All-cause mortality, all stroke, and rehospitalization at 1 y	Transfemoral SAPIEN 3	614 TAVR 614 SAVR
Medtronic TAVR in low risk patients[25]	NCT02701283	No age restriction STS <3%	Noninferiority Randomized TAVR vs SAVR	All-cause mortality or disabling stroke at 2 y	Transfemoral or subclavian Evolut R	625 TAVR 625 SAVR
NOTION 2[26]	NCT02825134	Age 18 to 75 y STS <4%	Noninferiority Randomized TAVR vs SAVR	Composite rate of all-cause mortality, myocardial infarction and stroke at 1 y	Transfemoral Any CE-approved THV	496 TAVR 496 SAVR

Rogers, Thourani, Waksman, JAHA. 2018.

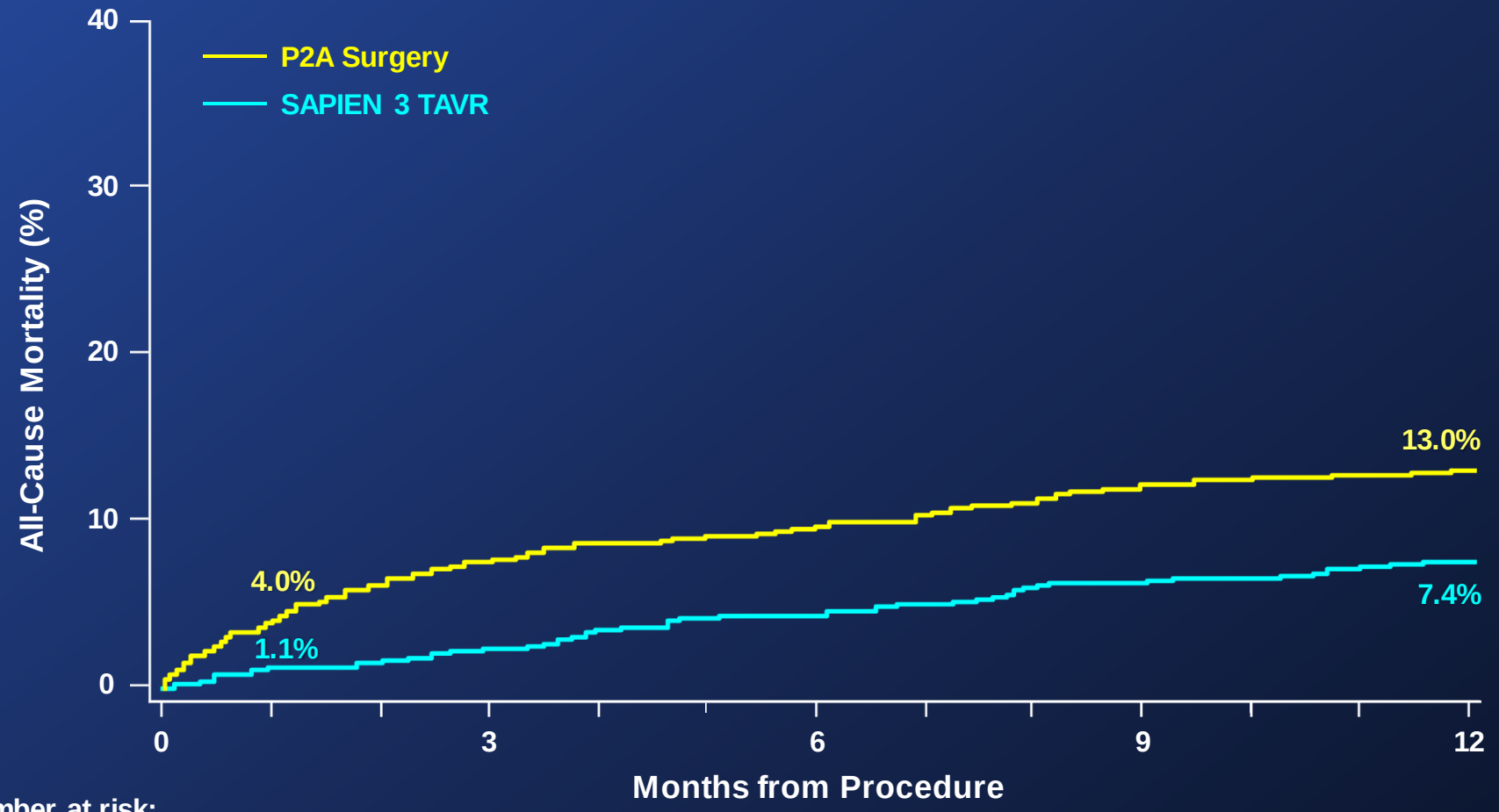
Other Unadjusted Clinical Outcomes
At 30 Days and 1 Year (AT)

THE PARTNER II TRIAL

Events (%)	30 Days		1 Year	
	TAVR (n = 1077)	Surgery (n = 944)	TAVR (n = 1077)	Surgery (n = 944)
Re-hospitalization	4.6	6.8	11.4	15.1
MI	0.3	1.9	1.8	3.1
Major Vascular Complication	6.1	5.4	---	---
AKI (Stage III)	0.5	3.3	---	---
Life-Threatening/Disabling Bleeding	4.6	46.7	---	---
New Atrial Fibrillation	5.0	28.3	5.9	29.2
New Permanent Pacemaker	10.2	7.3	12.4	9.4
Re-intervention	0.1	0.0	0.6	0.5
Endocarditis	0.2	0.0	0.8	0.7

Unadjusted Time-to-Event Analysis
All-Cause Mortality (AT)

THE PARTNER II TRIAL

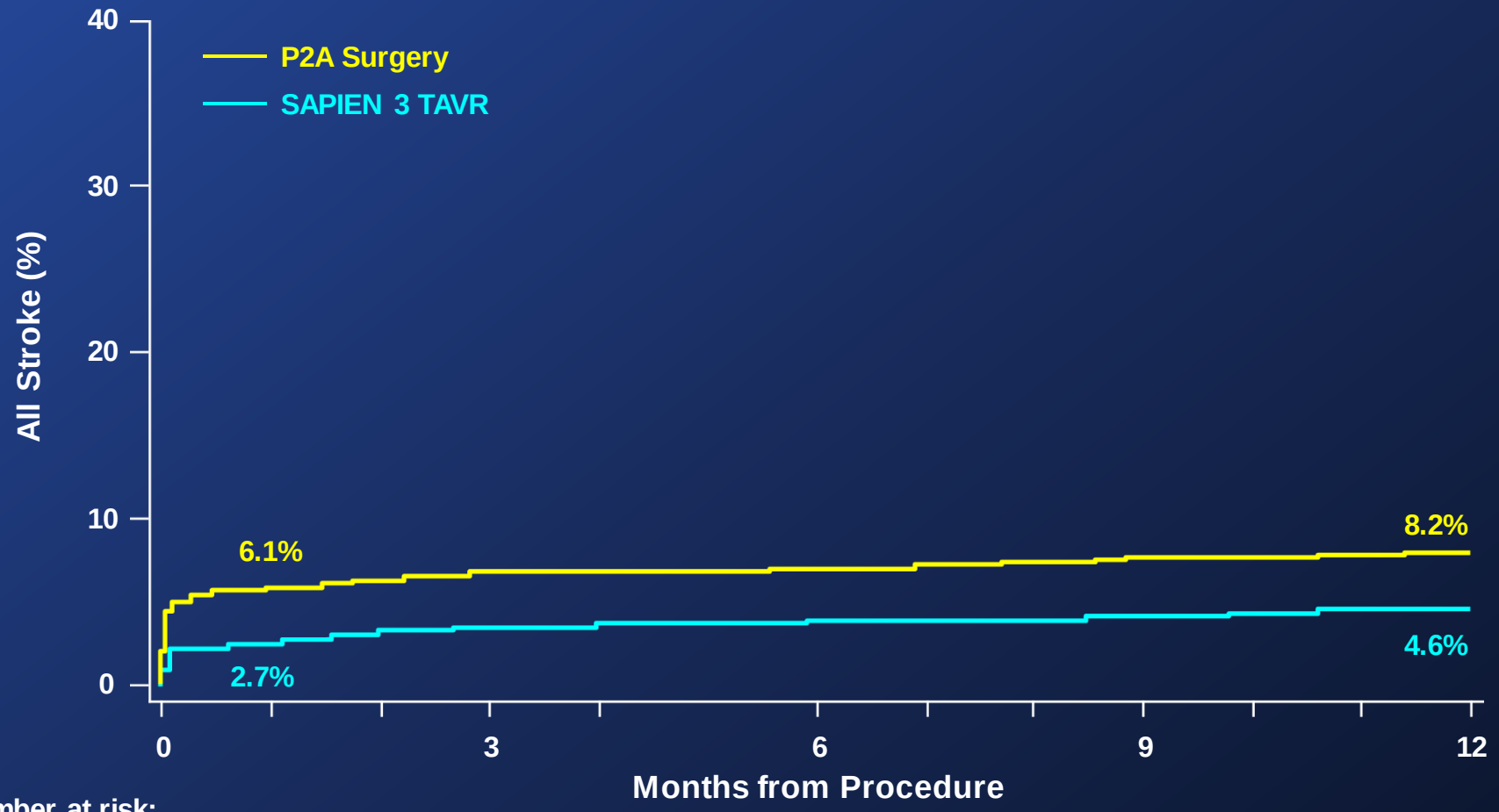


Number at risk:

P2A Surgery	944	859	836	808	795
S3 TAVR	1077	1043	1017	991	963

Unadjusted Time-to-Event Analysis
All Stroke (AT)

THE PARTNER II TRIAL



Number at risk:

P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

Partner Trial – High Risk Cohort

All-Cause Mortality at 30 Days and 1 Year
Patient Subgroups

THE PARTNER TRIAL

All-Cause Mortality at 30 Days

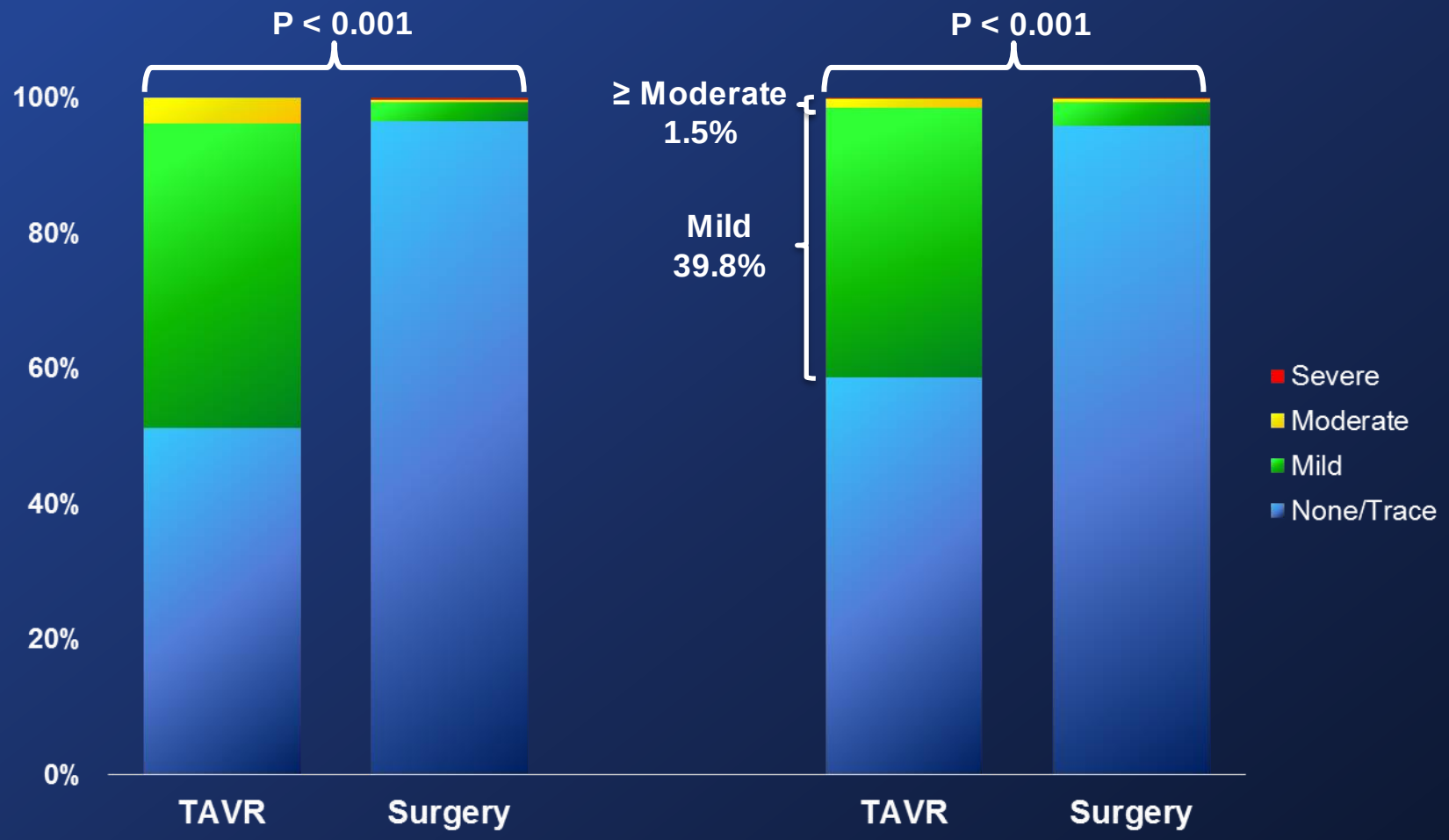
	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	*p*-value	TAVR	AVR	*p*-value	TAVR	AVR	*p*-value
ITT	12 (3.4)	22 (6.5)	0.07	8 (3.3)	15 (6.2)	0.13	4 (3.8)	7 (7.0)	0.32
AT	18 (5.2)	25 (8.0)	0.15	9 (3.7)	18 (8.2)	0.05	9 (8.7)	7 (7.6)	0.79

All-Cause Mortality at 1 Year

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	*p*-value	TAVR	AVR	*p*-value	TAVR	AVR	*p*-value
ITT	84 (24.2)	89 (26.8)	0.44	54 (22.2)	62 (26.4)	0.29	30 (29.0)	27 (27.9)	0.85
AT	81 (23.7)	78 (25.2)	0.64	51 (21.3)	55 (25.2)	0.33	30 (29.1)	23 (25.3)	0.55

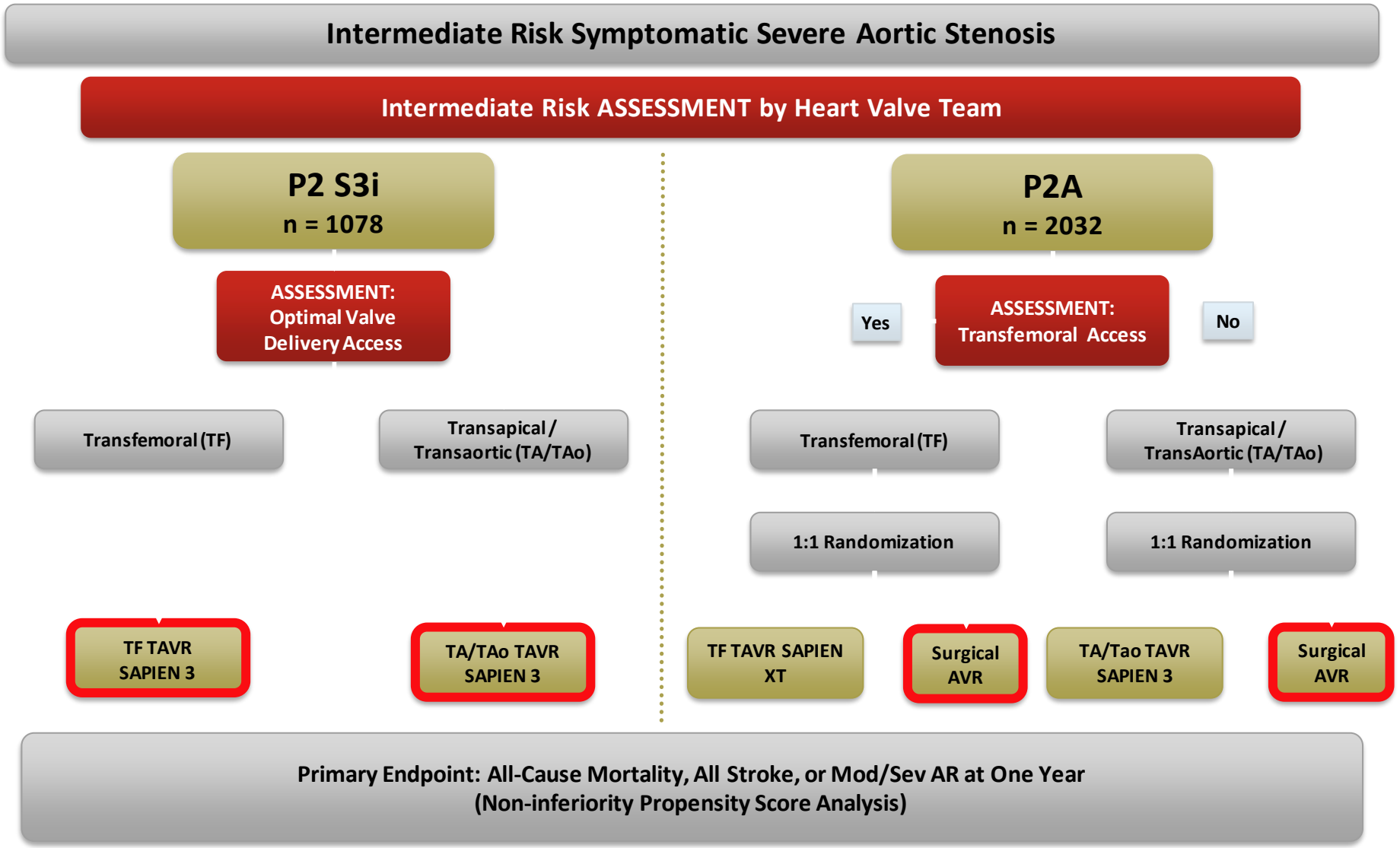
Paravalvular Regurgitation
3-Class Grading Scheme (VI)

THE PARTNER II TRIAL



No. of echos	30 Days	1 Year
P2A Surgery	755	610
S3i TAVR	992	875

The PARTNER 2A and S3i Trials



Challenges Addressed

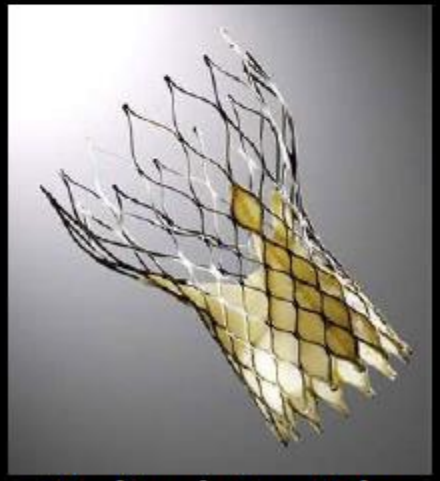
Edwards Sapien THV (1st generation) 22/24 Fr delivery system

Edwards Sapien 3

(14 Fr delivery system)

Medtronic Engager TA valve (Ventor Embracer)

St. Jude Medical Portico valve

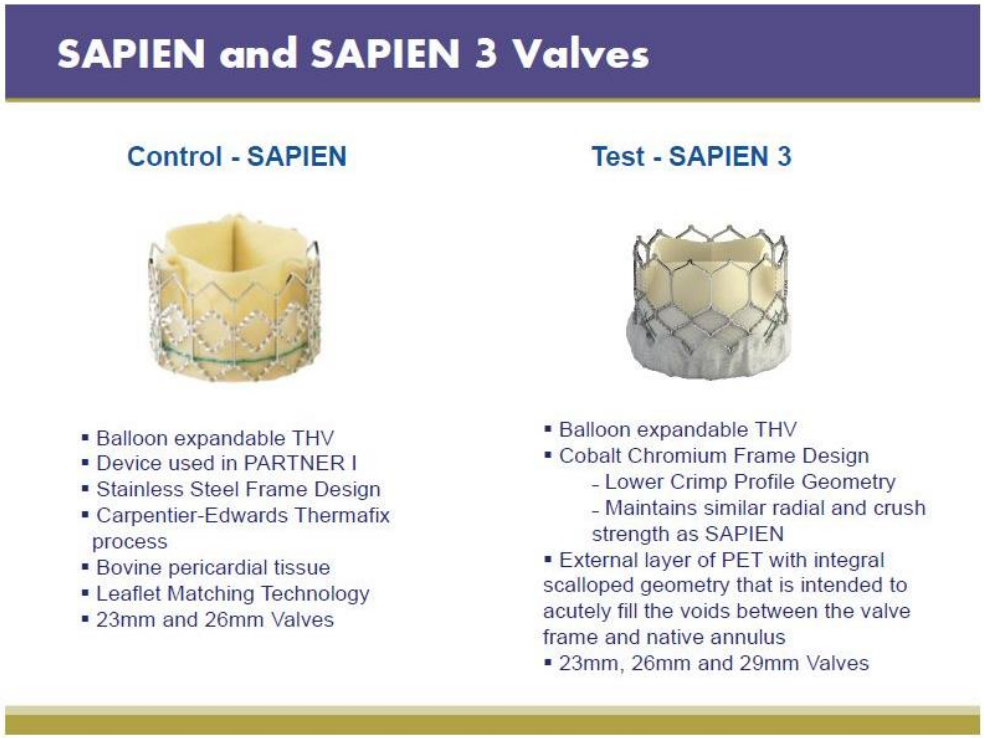


Medtronic CoreValve

Boston Scientific Lotus self-exp valve (Sadra Lotus)

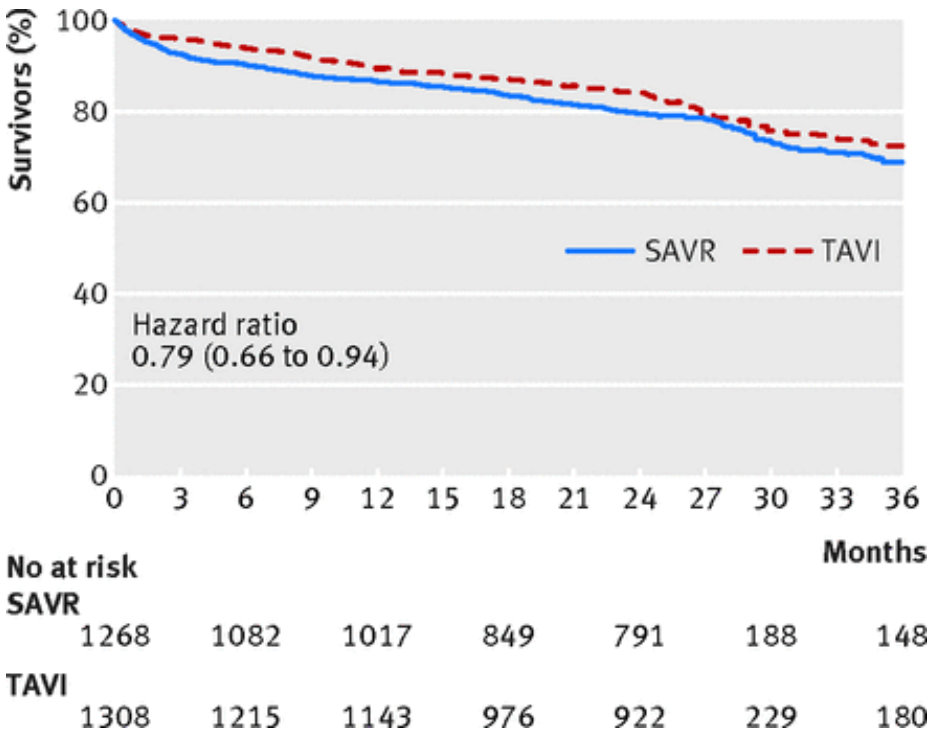
JenaValve

Iterative change and refinement of a technique



	20 mm	23 mm	26 mm	29 mm
Sheath size	14 Fr	14 Fr	14 Fr	16 Fr
Minimum vessel diameter	5.5 mm	5.5 mm	5.5 mm	6 mm

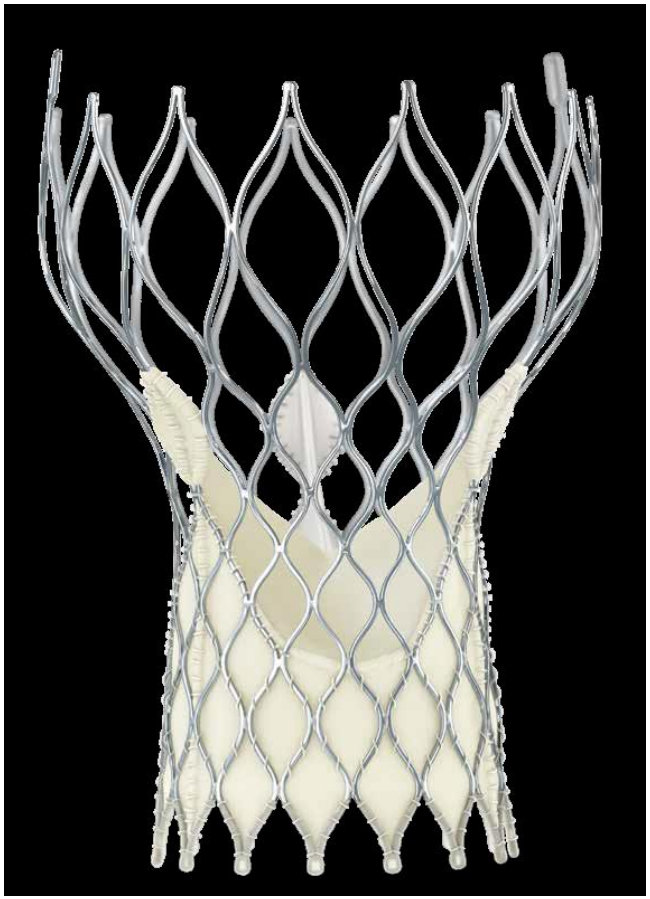
Intermediate risk meta-analysis



NOTION and PARTNER 2A provided data to 24 months, and US Pivotal provided data to 36 months

Siemieniuk et al. BMJ. 2016

There are options besides balloon expandable



CHOICE Trial: comparison of balloon expandable vs. self expandable

Table 5. Thirty-Day Clinical Outcome

Variable	No./Total No. (%)		Relative Risk (95% CI)	*P* Value
	Balloon-Expandable Valve (n = 121)	Self-expandable Valve (n = 117)		
Death				
Any cause	5/121 (4.1)	6/117 (5.1)	0.81 (0.25-2.57)	.77
Cardiovascular causes	5/121 (4.1)	5/117 (4.3)	0.97 (0.29-3.25)	.99
Stroke	7/121 (5.8)	3/117 (2.6)	2.26 (0.60-8.52)	.33
Myocardial infarction	1/121 (0.8)	0/117 (0.0)		.99
Bleeding				
Life threatening	10/121 (8.3)	14/117 (12.0)	0.69 (0.32-1.49)	.35
Major	23/121 (19.0)	17/117 (14.5)	1.31 (0.74-2.32)	.36
Minor	11/121 (9.1)	9/117 (7.7)	1.18 (0.51-2.74)	.70
Major or minor	34/121 (28.1)	26/117 (22.2)	1.26 (0.81-1.97)	.30
Vascular complications				
All	17/121 (14.0)	15/117 (12.8)	1.10 (0.57-2.09)	.78
Major	12/121 (9.9)	13/117 (11.1)	0.89 (0.42-1.88)	.76
Minor	5/121 (4.1)	2/117 (1.7)	2.42 (0.48-12.21)	.28
Acute kidney injury	5/121 (4.1)	11/117 (9.4)	0.44 (0.16-1.23)	.13
Repeat procedure for valve-related dysfunction	1/121 (0.8)	2/117 (1.7)	0.48 (0.04-5.26)	.62
Combined safety end point[a]	22/121 (18.2)	27/117 (23.1)	0.79 (0.48-1.30)	.42
Major adverse cardiovascular and cerebrovascular events[b]	8/121 (6.6)	4/117 (3.4)	1.93 (0.60-6.25)	.38
Rehospitalization for heart failure	0/119 (0.0)	5/117 (4.3)		.02
NYHA class improvement	100/106 (94.3)	91/105 (86.7)	1.09 (1.00-1.19)	.06
Quality of life				
Score, mean (95% CI)	71.0 (68.2-73.9)	65.9 (62.4-69.5)		.02
Score change, median (IQR)	12.5 (0-20)	10 (0-20)		.19
New permanent pacemaker	19/110 (17.3)	38/101 (37.6)	0.46 (0.28-0.74)	.001

Abbreviations: IQR, interquartile range; NYHA, New York Heart Association.

[a] Defined as a composite of all-cause mortality, major stroke, life-threatening or disabling bleeding, acute kidney injury stage 3 including renal replacement therapy, periprocedural myocardial infarction, major vascular complications, and repeat procedure for valve-related dysfunction.

[b] Defined as a composite of myocardial infarction, cardiac or vascular surgery and stroke.

JAMA. 2014;311(15):1503-1514.

When it comes to talking to elderly patients about this….

Severe Aortic Stenosis Decision Aid

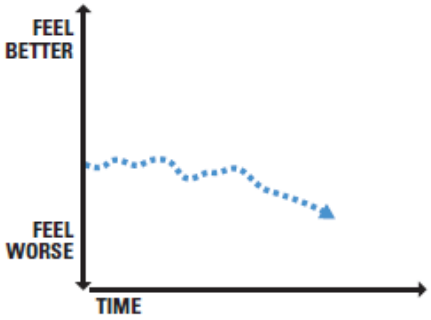
2 CHOICES | SYMPTOM MANAGEMENT / TAVR

What are my choices?	Will I feel better?

SYMPTOM MANAGEMENT
(Palliative Care)

- Valve is **not** changed
- Not Invasive

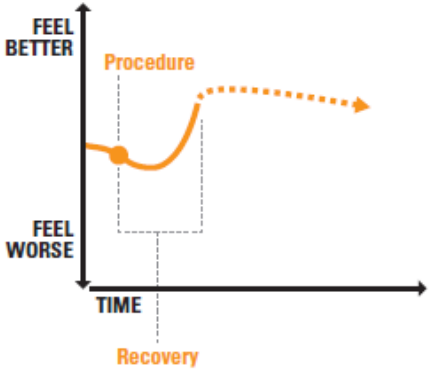
- Decision can be revisited over time



TAVR
Transcatheter Aortic Valve Replacement

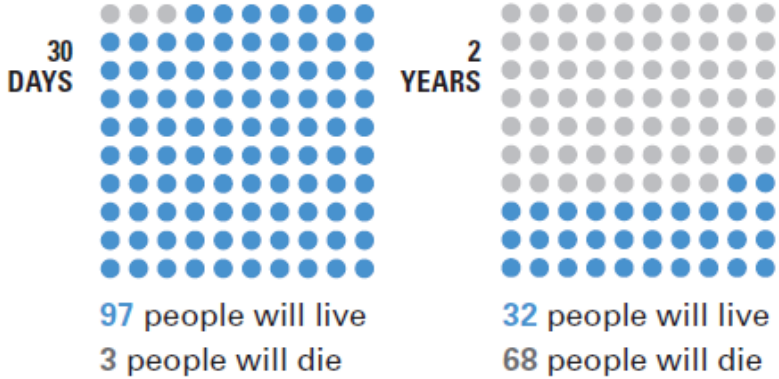
- Valve is changed
- Less Invasive

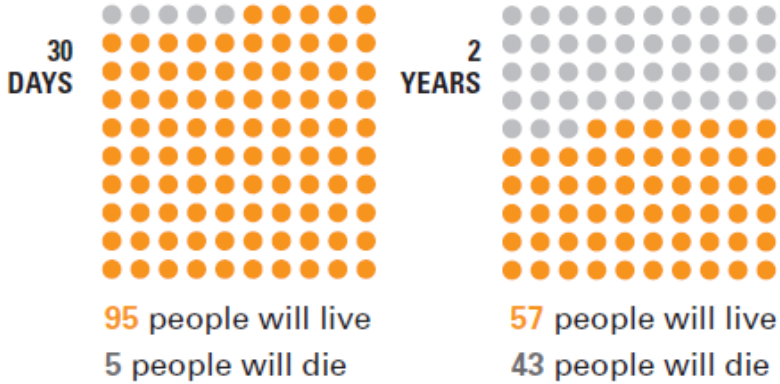
- New procedure, (FDA-approval in 2011)



Decision aides from ACC Championing Care Initiative (2014-2015).

Will it help me live longer?





What are the risks?

This choice may not include invasive procedures

2 out of 100 people will have a stroke or TIA within 30 days

5 out of 100 people will have a stroke or TIA within 1 year

7 out of 100 people will have a stroke or TIA within 30 days

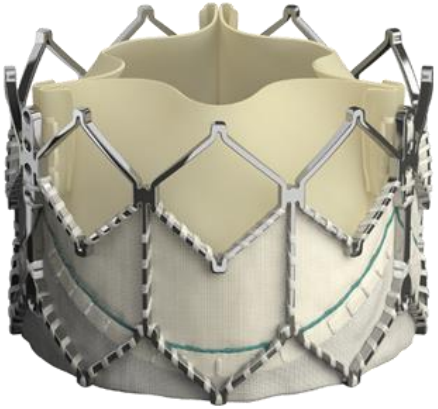
11 out of 100 people will have a stroke or TIA within 1 year

Other Possible Complications

- Major bleeding
- Kidney failure
- Pacemaker
- Damage to blood vessels

Decision aides from ACC Championing Care Initiative (2014-2015).

The honest truth about many of our conversations in clinic.



Vs.

SEASONS
HOSPICE &
PALLIATIVE CARE

Severe Aortic Stenosis Decision Aid

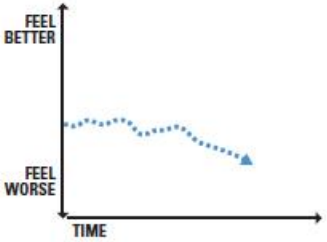
3 CHOICES | SYMPTOM MANAGEMENT / SAVR / TAVR

What are my choices?	Will I feel better?

SYMPTOM MANAGEMENT
(Palliative Care)

- Valve is **not** changed
- Not Invasive

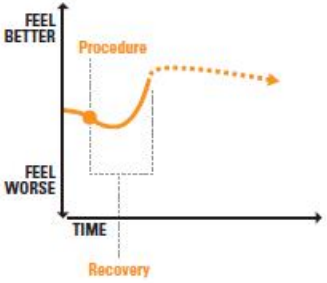
- Decision can be revisited over time



TAVR
Transcatheter Aortic Valve Replacement

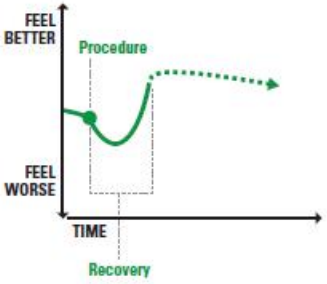
- Valve is changed
- Less Invasive

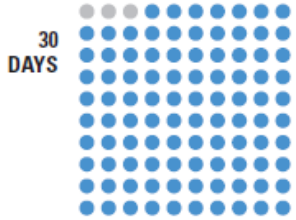
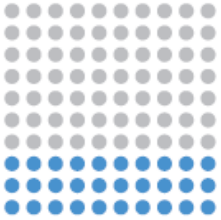
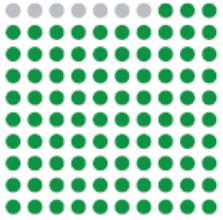
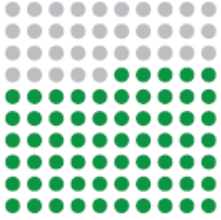
- New procedure, (FDA-approval in 2011)



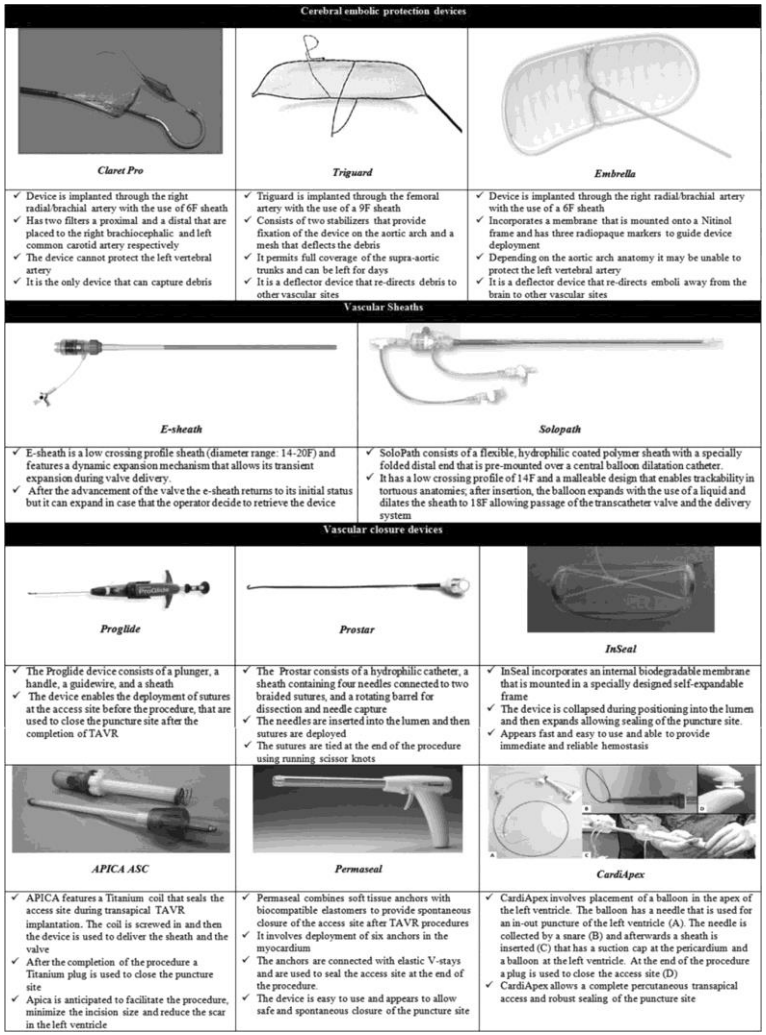
SAVR
Surgical Aortic Valve Replacement

- Valve is changed
- More Invasive



Will it help me live longer?	What are the risks?
 97 people will live 3 people will die  30 people will live 70 people will die	This choice may not include invasive procedures
 97 people will live 3 people will die  66 people will live 34 people will die	6 out of 100 people will have a stroke or TIA within 30 days 8 out of 100 people will have a stroke or TIA within 1 year Other Possible Complications • Major bleeding • Kidney failure • Pacemaker • Damage to blood vessels
 93 people will live 7 people will die  65 people will live 35 people will die	2 out of 100 people will have a stroke or TIA within 30 days 4 out of 100 people will have a stroke or TIA within 1 year Other Possible Complications • Major bleeding • Kidney failure • Pacemaker • Damage to blood vessels

Transcatheter aortic valve replacement (TAVR) enabling devices developed to facilitate the procedure and reduce the risk of complications.



Cerebral embolic protection devices

Claret Pro	*Triguard*	*Embrella*
✓ Device is implanted through the right radial/brachial artery with the use of 6F sheath ✓ Has two filters a proximal and a distal that are placed to the right brachiocephalic and left common carotid artery respectively ✓ The device cannot protect the left vertebral artery ✓ It is the only device that can capture debris	✓ Triguard is implanted through the femoral artery with the use of a 9F sheath ✓ Consists of two stabilizers that provide fixation of the device on the aortic arch and a mesh that deflects the debris ✓ It permits full coverage of the supra-aortic trunks and can be left for days ✓ It is a deflector device that re-directs debris to other vascular sites	✓ Device is implanted through the right radial/brachial artery with the use of a 6F sheath ✓ Incorporates a membrane that is mounted onto a Nitinol frame and has three radiopaque markers to guide device deployment ✓ Depending on the aortic arch anatomy it may be unable to protect the left vertebral artery ✓ It is a deflector device that re-directs emboli away from the brain to other vascular sites

Vascular Sheaths

E-sheath	*Solopath*
✓ E-sheath is a low crossing profile sheath (diameter range: 14-20F) and features a dynamic expansion mechanism that allows its transient expansion during valve delivery. ✓ After the advancement of the valve the e-sheath returns to its initial status but it can expand in case that the operator decide to retrieve the device	✓ SoloPath consists of a flexible, hydrophilic coated polymer sheath with a specially folded distal end that is pre-mounted over a central balloon dilatation catheter. ✓ It has a low crossing profile of 14F and a malleable design that enables trackability in tortuous anatomies; after insertion, the balloon expands with the use of a liquid and dilates the sheath to 18F allowing passage of the transcatheter valve and the delivery system

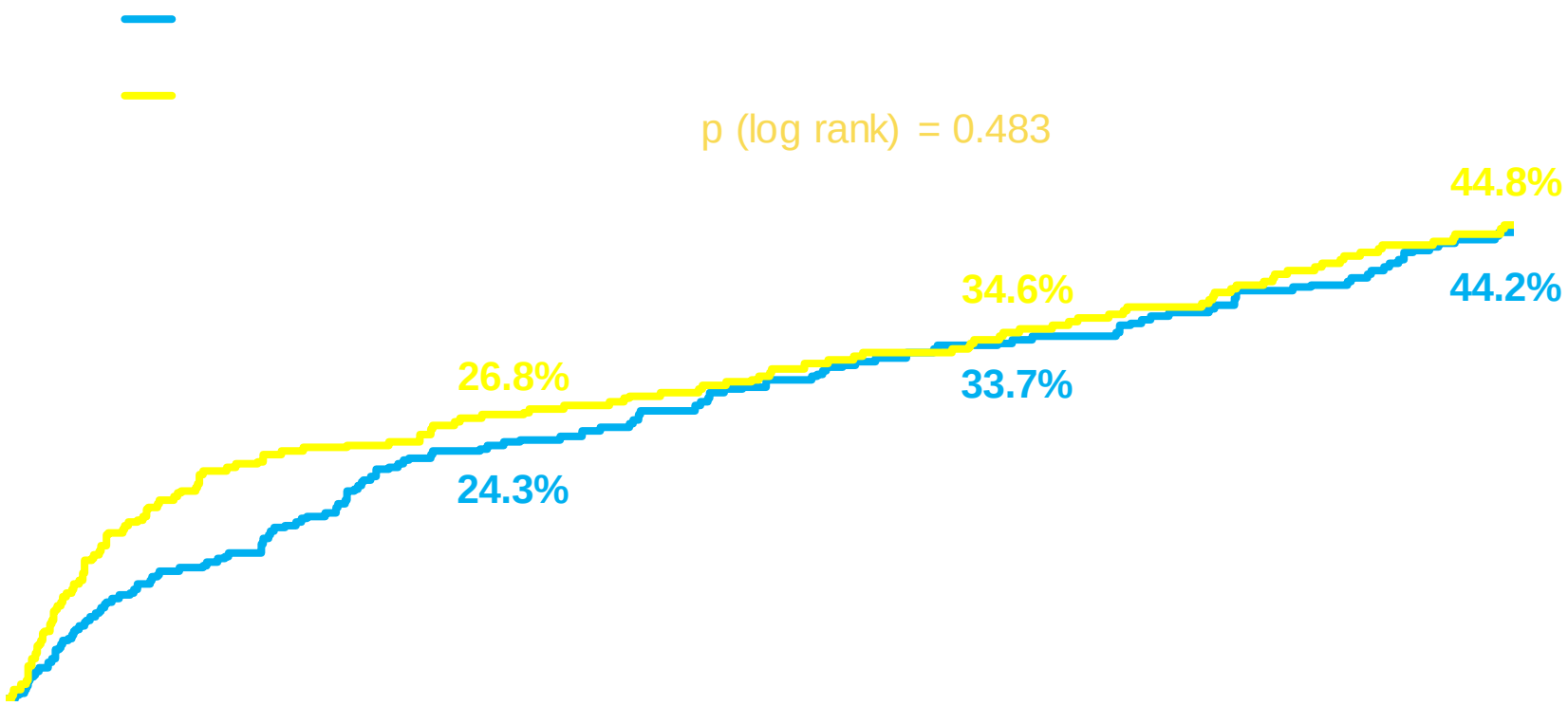
Vascular closure devices

Proglide	*Prostar*	*InSeal*
✓ The Proglide device consists of a plunger, a handle, a guidewire, and a sheath ✓ The device enables the deployment of sutures at the access site before the procedure, that are used to close the puncture site after the completion of TAVR	✓ The Prostar consists of a hydrophilic catheter, a sheath containing four needles connected to two braided sutures, and a rotating barrel for dissection and needle capture ✓ The needles are inserted into the lumen and then sutures are deployed ✓ The sutures are tied at the end of the procedure using running scissor knots	✓ InSeal incorporates an internal biodegradable membrane that is mounted in a specially designed self-expandable frame ✓ The device is collapsed during positioning into the lumen and then expands allowing sealing of the puncture site. ✓ Appears fast and easy to use and able to provide immediate and reliable hemostasis
APICA ASC	*Permaseal*	*CardiApex*
✓ APICA features a Titanium coil that seals the access site during transapical TAVR implantation. The coil is screwed in and then the device is used to deliver the sheath and the valve ✓ After the completion of the procedure a Titanium plug is used to close the puncture site ✓ Apica is anticipated to facilitate the procedure, minimize the incision size and reduce the scar in the left ventricle	✓ Permaseal combines soft tissue anchors with biocompatible elastomers to provide spontaneous closure of the access site after TAVR procedures ✓ It involves deployment of six anchors in the myocardium ✓ The anchors are connected with elastic V-stays and are used to seal the access site at the end of the procedure. ✓ The device is easy to use and appears to allow safe and spontaneous closure of the puncture site	✓ CardiApex involves placement of a balloon in the apex of the left ventricle. The balloon has a needle that is used for an in-out puncture of the left ventricle (A). The needle is collected by a snare (B) and afterwards a sheath is inserted (C) that has a suction cap at the pericardium and a balloon at the left ventricle. At the end of the procedure a plug is used to close the access site (D) ✓ CardiApex allows a complete percutaneous transapical access and robust sealing of the puncture site

Christos V. Bourantas, and Patrick W. Serruys Circulation Research. 2014;114:1037-1051

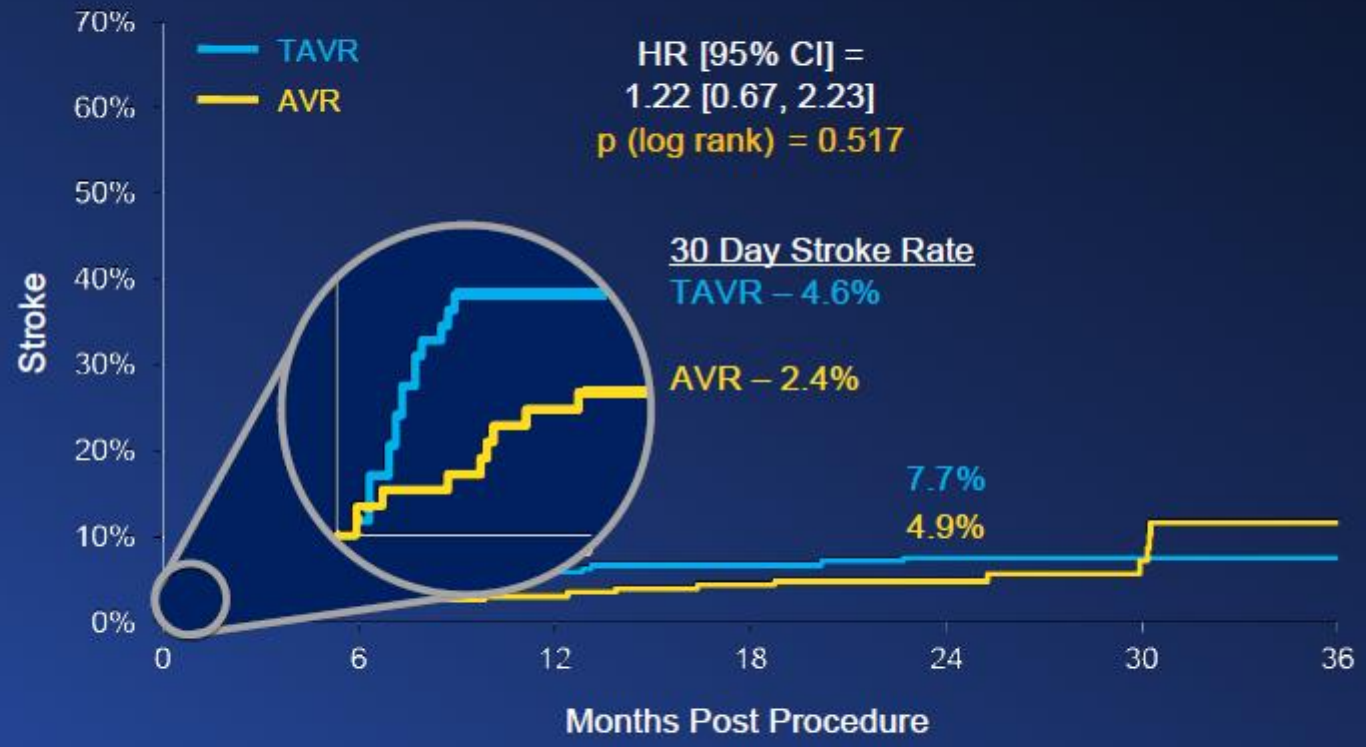
American Heart Association.

All-Cause Mortality (ITT)



TAVR	348	298	261	239	222	187	149
AVR	351	252	236	223	202	174	142

Strokes (ITT)

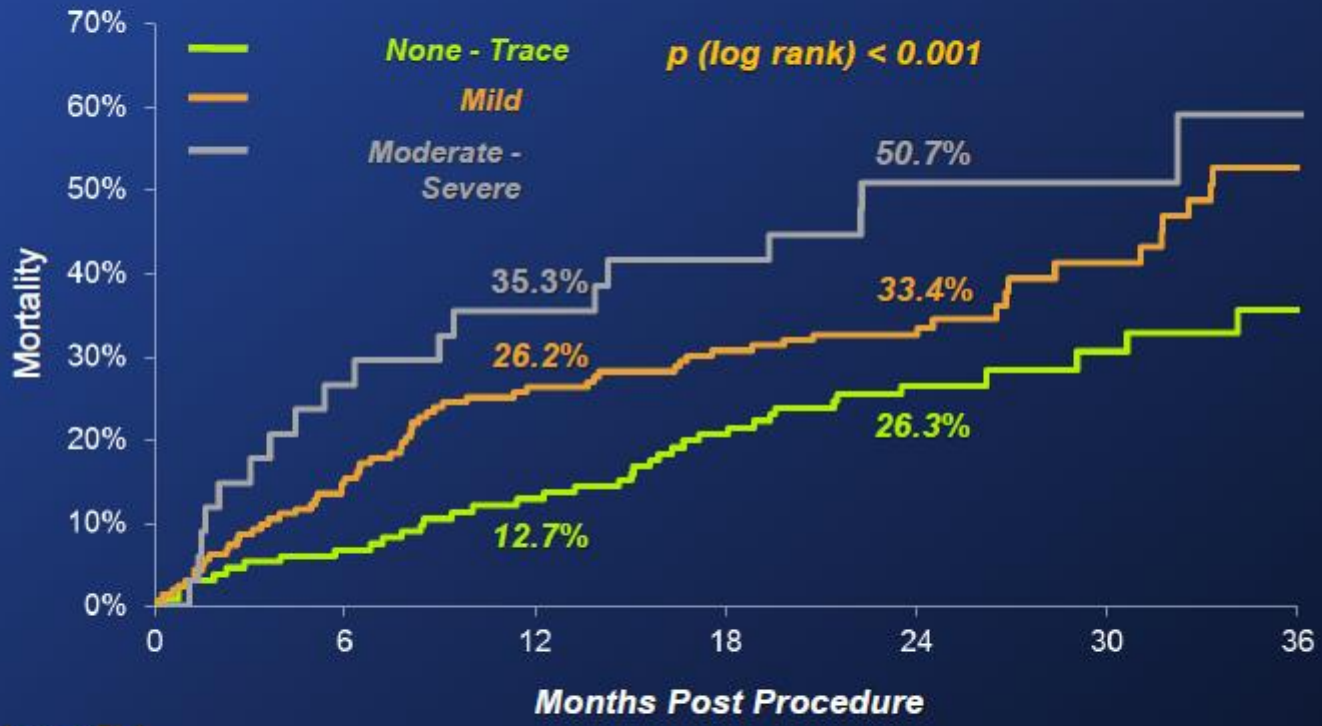


Numbers at Risk

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

Total AR and Mortality
TAVR Patients (AT)
High Risk Cohort

THE PARTNER TRIAL



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

FDA Label

Transapical

The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transapical delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction > 20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons operative risk score ≥ 8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement.

Transfemoral

The Edwards SAPIEN Transcatheter Heart Valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transfemoral delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to either be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or 2) be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons predicted operative risk score ≥8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement.

Partner Trial -Inoperable: 2-year results

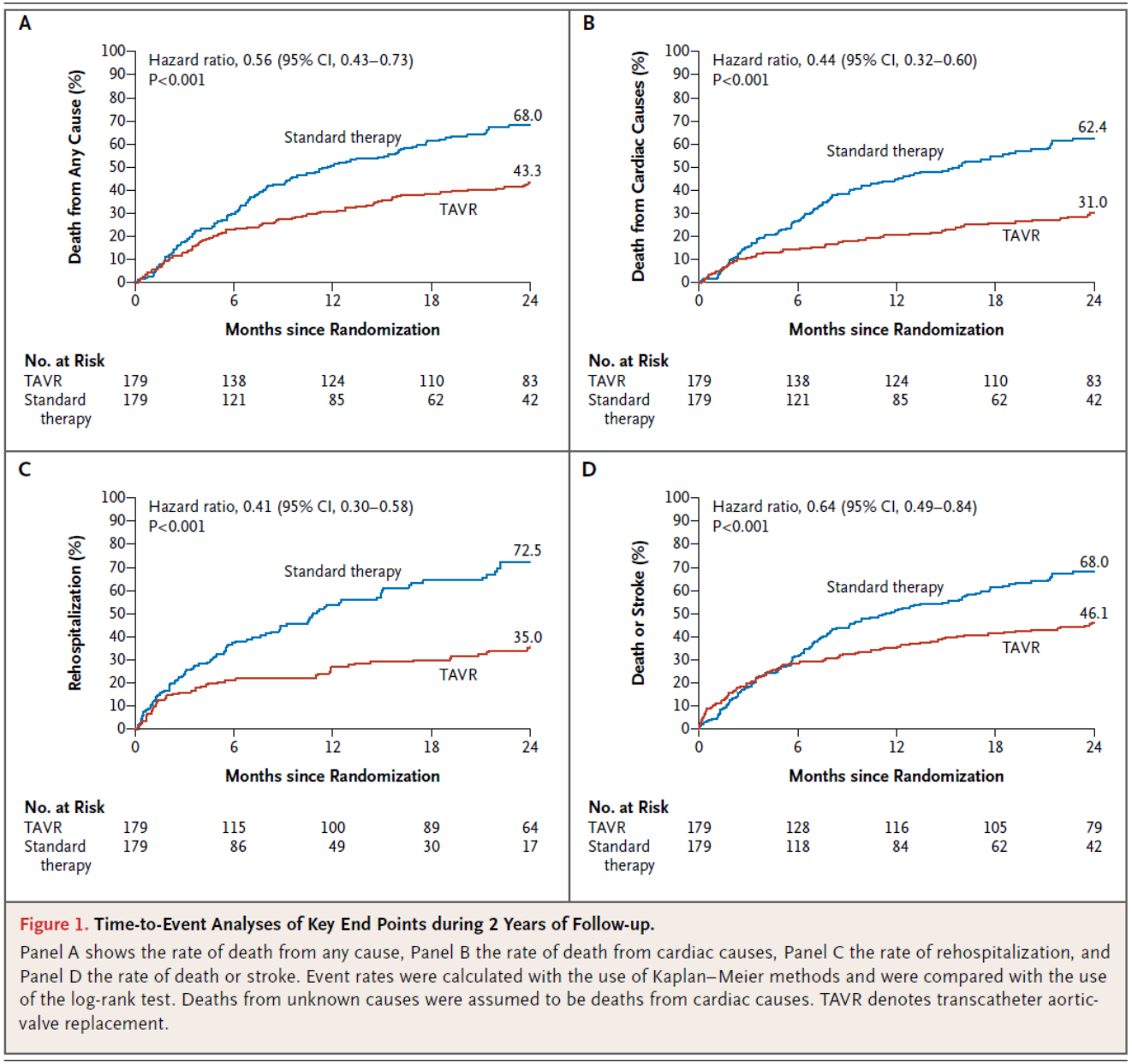
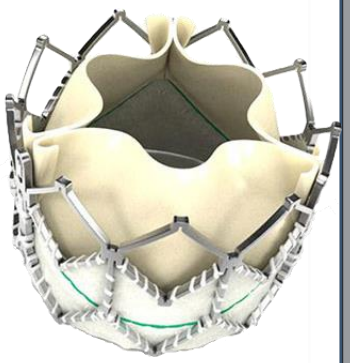


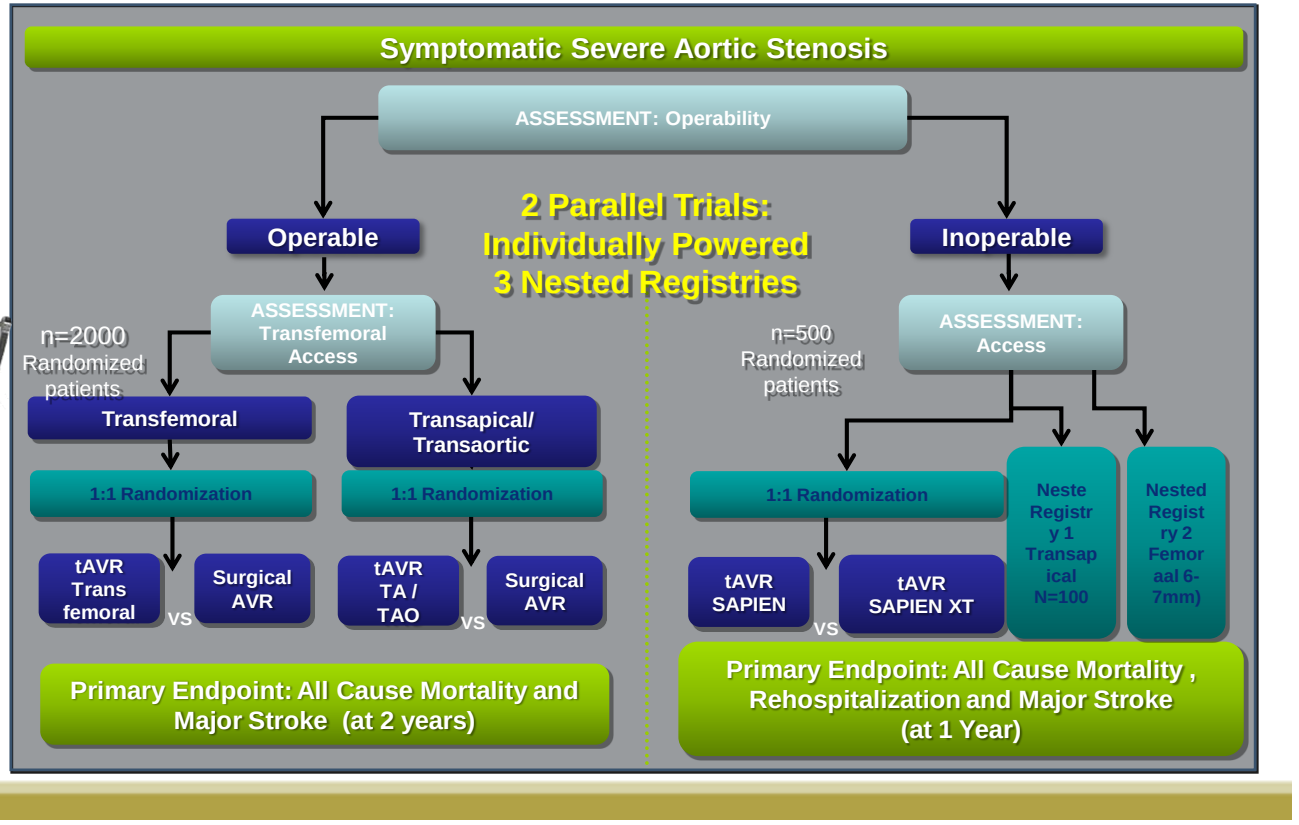
Figure 1. Time-to-Event Analyses of Key End Points during 2 Years of Follow-up.

Panel A shows the rate of death from any cause, Panel B the rate of death from cardiac causes, Panel C the rate of rehospitalization, and Panel D the rate of death or stroke. Event rates were calculated with the use of Kaplan–Meier methods and were compared with the use of the log-rank test. Deaths from unknown causes were assumed to be deaths from cardiac causes. TAVR denotes transcatheter aortic-valve replacement.

Leon MB, Smith CR, et al. *N Engl J Med* 2010

The PARTNER II Study Design



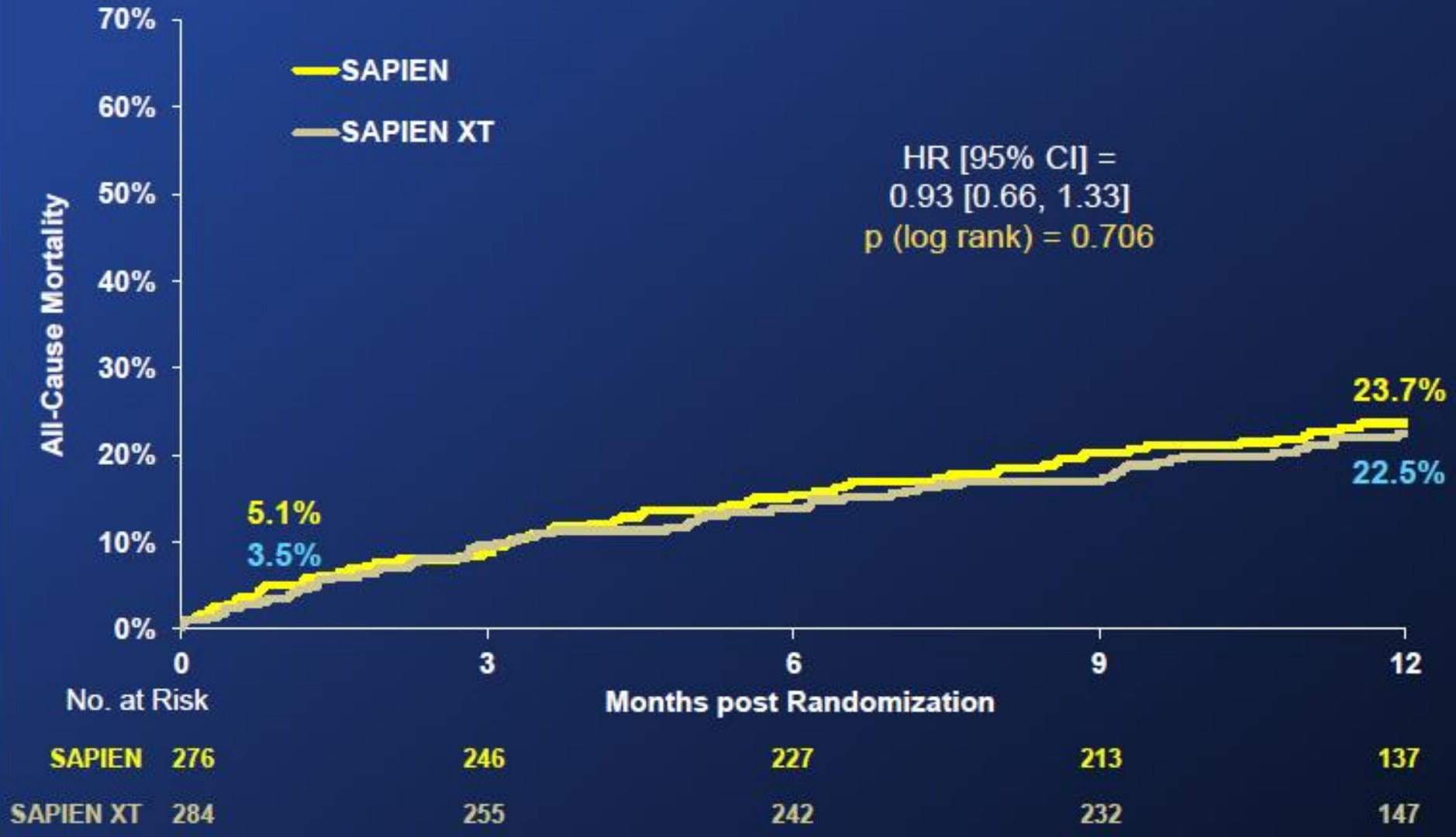


Nested Registry 3

- Transcatheter valve in surgical valve implantation (TV-SVI)
- n=100

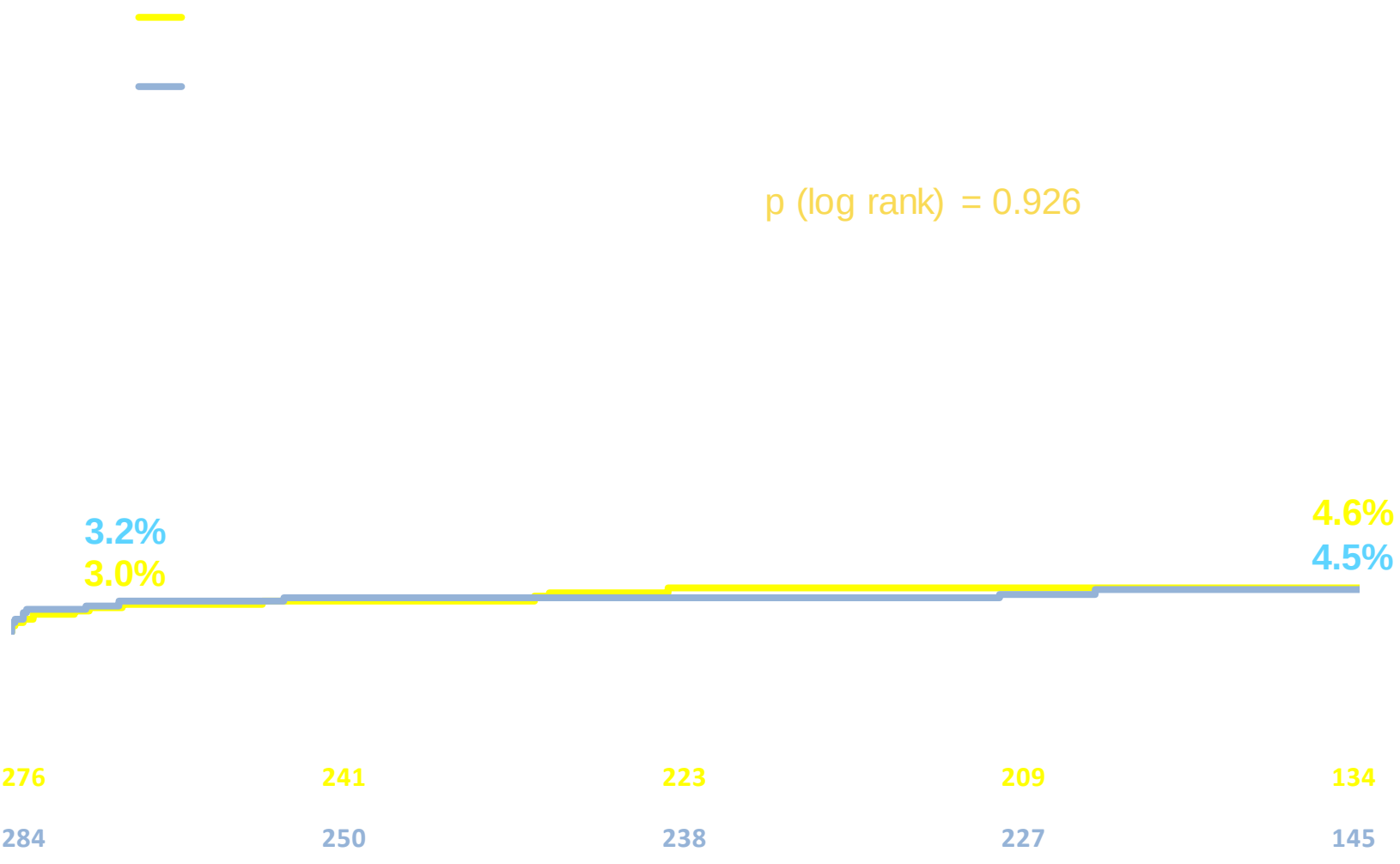
All-Cause Mortality (ITT)

THE PARTNER II TRIAL



No. at Risk					
SAPIEN	276	246	227	213	137
SAPIEN XT	284	255	242	232	147

Disabling Stroke (ITT)

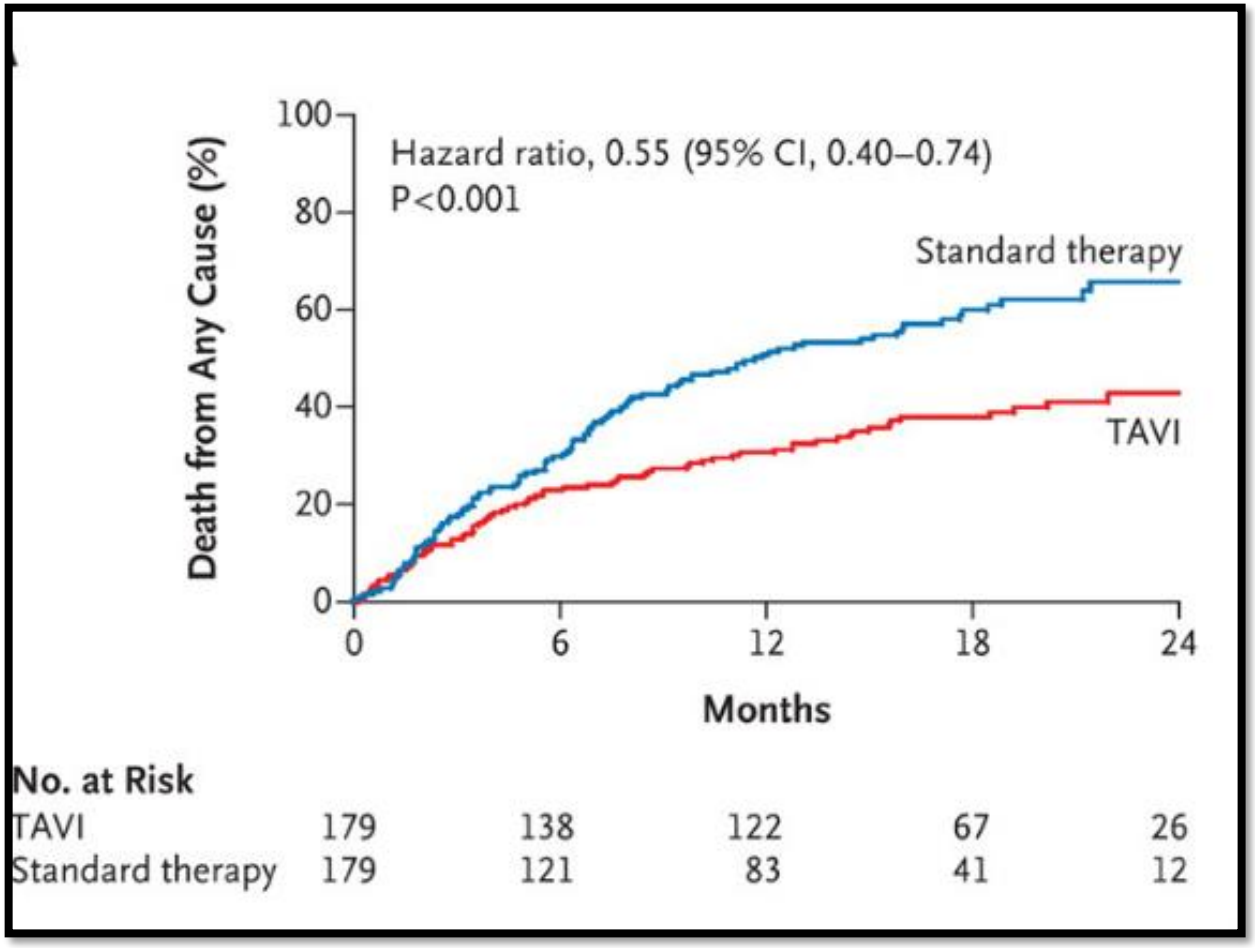


Vascular Complication Categories:
At 30 Days (AT)

THE PARTNER II TRIAL

	SAPIEN (n=271)		SAPIEN XT (n=282)		
Events	n	%	n	%	p-value
Perforation	13	4.8	2	0.4	0.003
Dissection	25	9.2	12	4.3	0.03
Hematoma	16	5.9	10	3.6	0.23

Half are dead at one year with medical rx



Leon MB, Smith CR, et al. *N Engl J Med* 2010

Controversies

- Surgical considerations
  - Are there advantages to mini-AVR?
  - Choice of valve:
    - Performance considerations
    - Durability
    - Anticoagulation
- What patients should get transcatheter AVR (TAVR)?

- What about “inoperable” patients?

When to Refer?

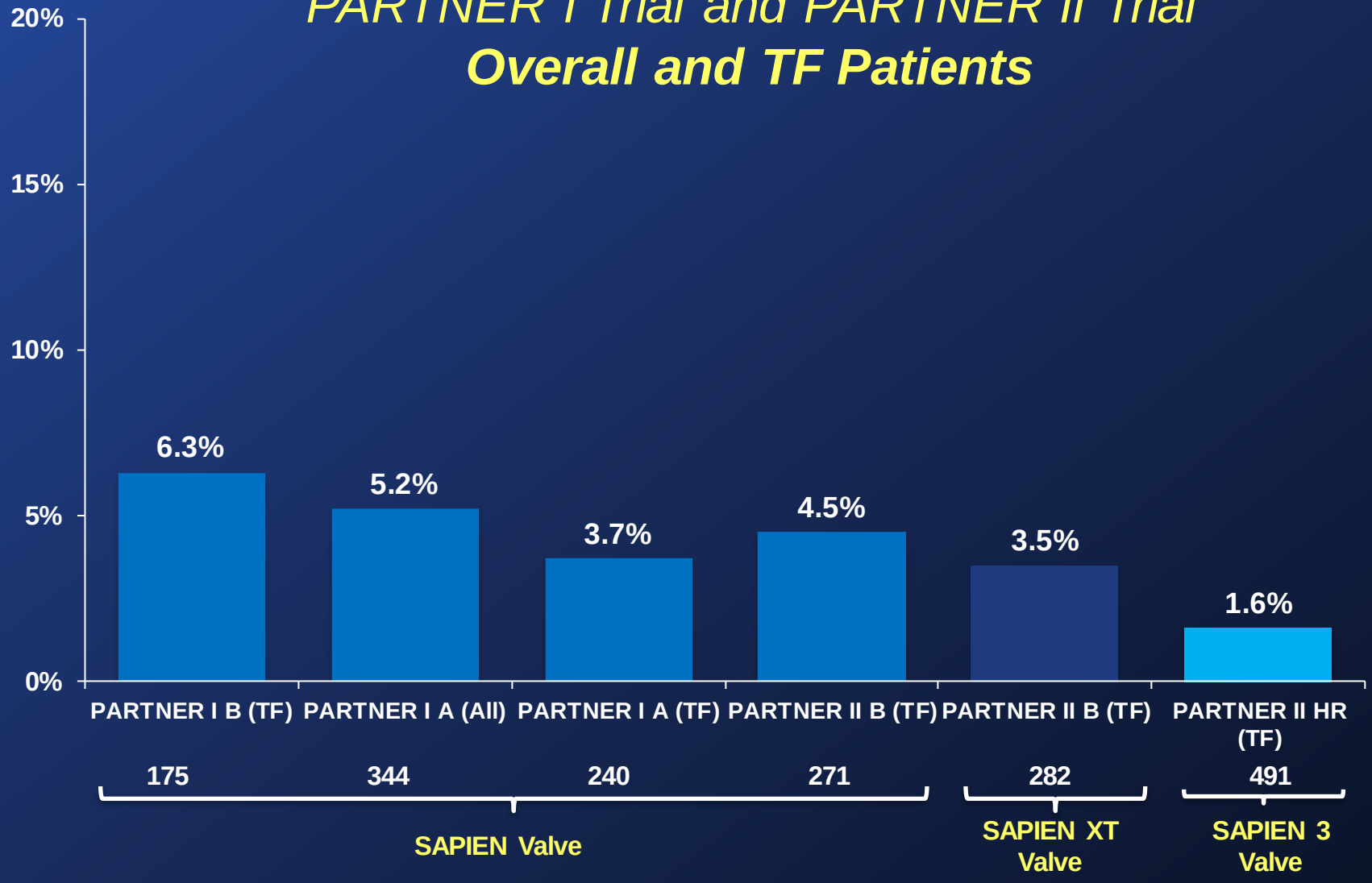
- Severe symptomatic AS
- Moderate or severe AS undergoing another cardiac operation
- Severe asymptomatic AS with
  - LV systolic dysfunction
  - Abnormal exercise response
  - High likelihood of rapid progression

All-Cause Mortality at 30 Days
(As Treated Patients)

THE PARTNER II TRIAL

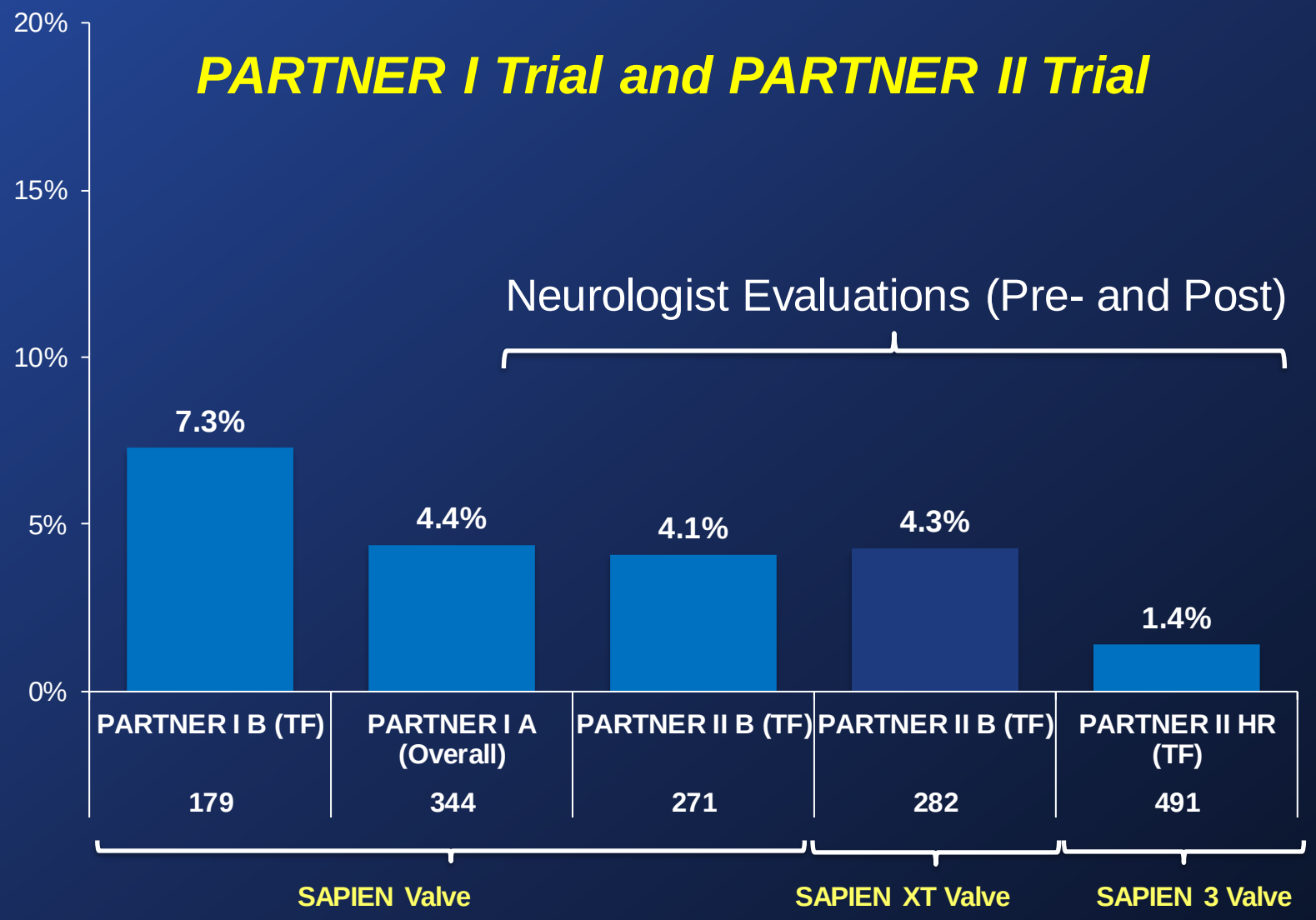
PARTNER I Trial and PARTNER II Trial

Overall and TF Patients



All Strokes at 30 Days

THE PARTNER II TRIAL



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At 30 Days (AT)

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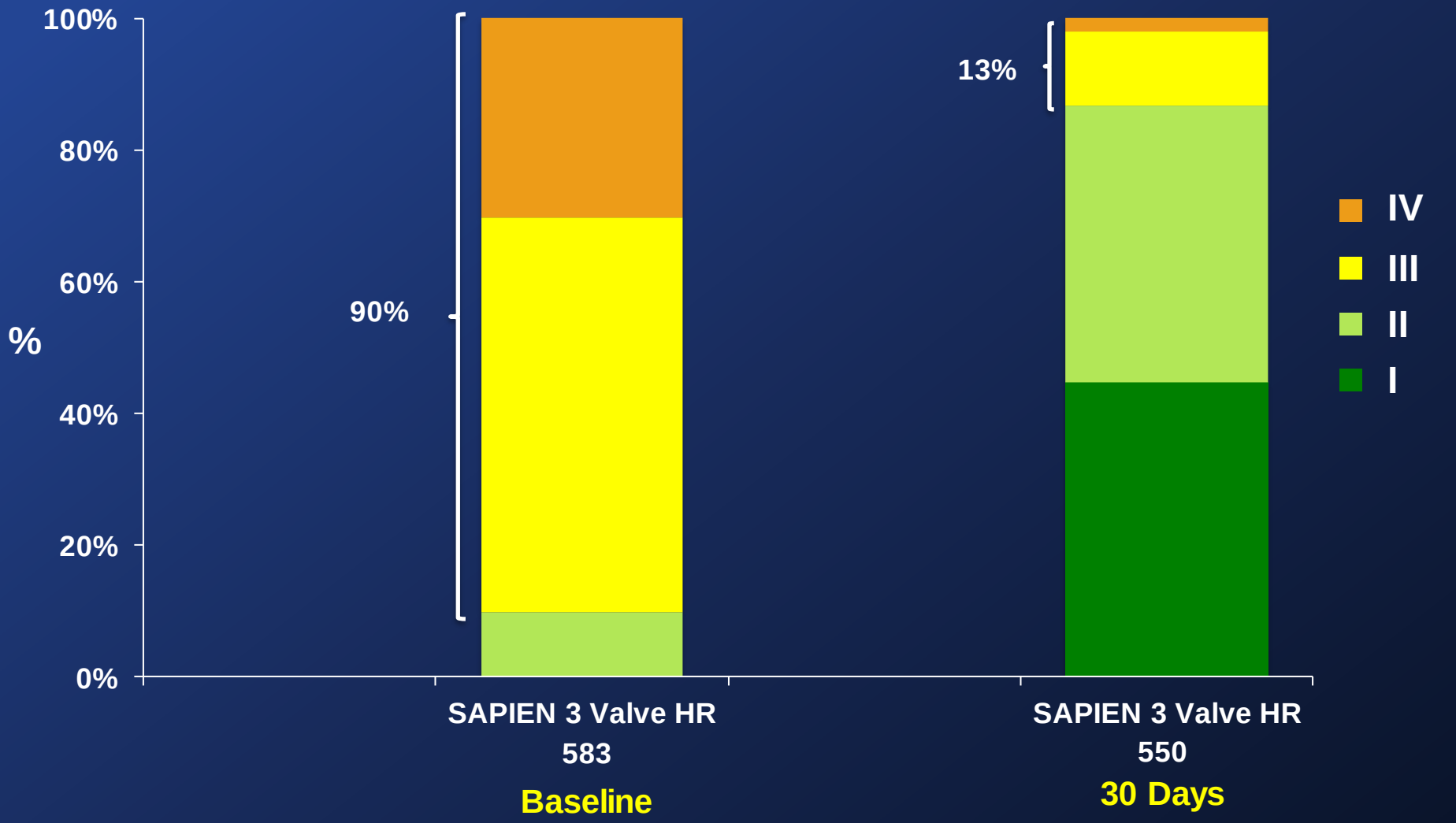
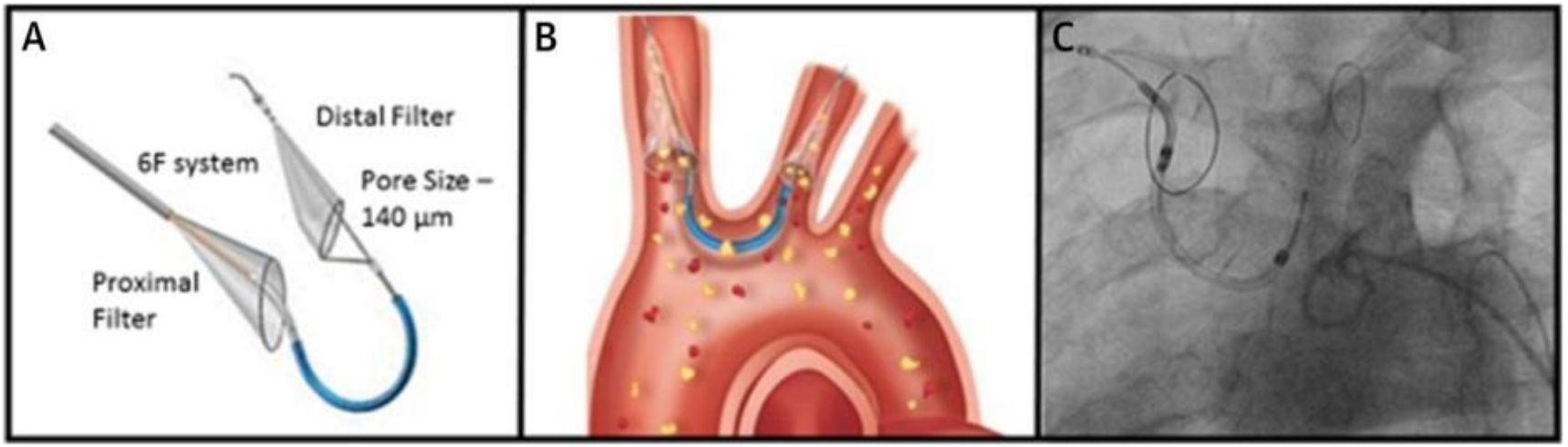
NYHA Functional Class
(As Treated Patients)

THE PARTNER II TRIAL



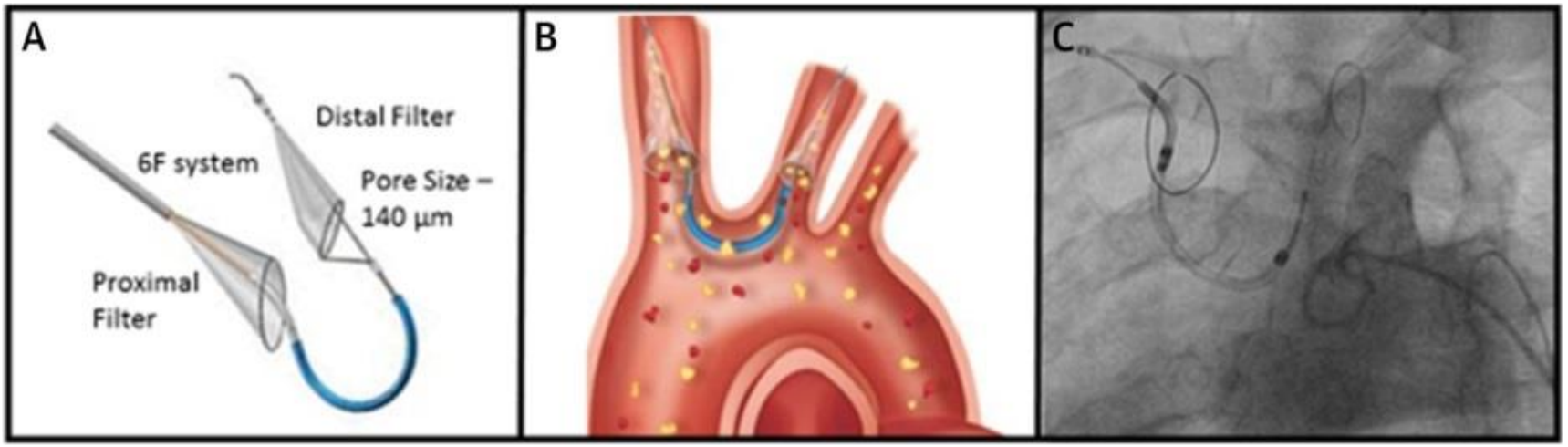
THE PARTNER II TRIAL

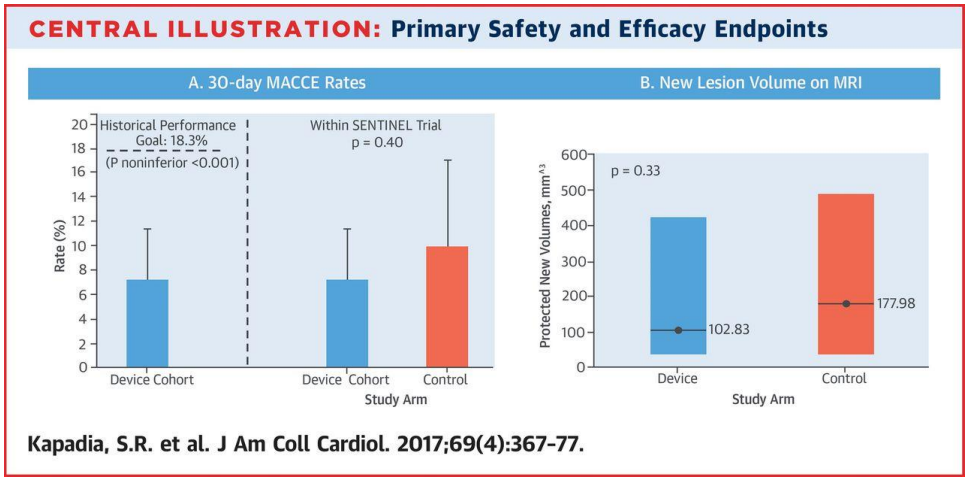
Embolic protection devices



Kapadia. J Am Coll Cardiol. 2017.

Embolic protection devices





Kapadia. J Am Coll Cardiol. 2017.

When it comes to talking to elderly patients about this….