

# **Sapien is better than Corevalve!**

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Associate Director, Cedars-Sinai Heart Institute

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Los Angeles

# Eberhard Grube: Pioneer in the field of TAVR



Eberhard Grube, MD

# Why is Sapien (Balloon Expandable) better?

- A trans-catheter heart valve for all valve locations
- Versatile with different routes of implantation
- World wide experience in over 20,000 patients with first implant > 10 yrs ago
- Most robust data with survival, QOL, comparison to surgery, cost-effectiveness
- Valve durability at 3-4 years in core lab adjudication
- Safer in some aspects (paravalvular AI, conduction system issues)

# Edwards-Cribier, Sapien, Sapien XT..



# Edwards SAPIEN vs SAPIEN XT Transcatheter Heart Valves



## NEW FRAME GEOMETRY

- Less metal content
- Lower crimp profile

## NEW FRAME MATERIAL

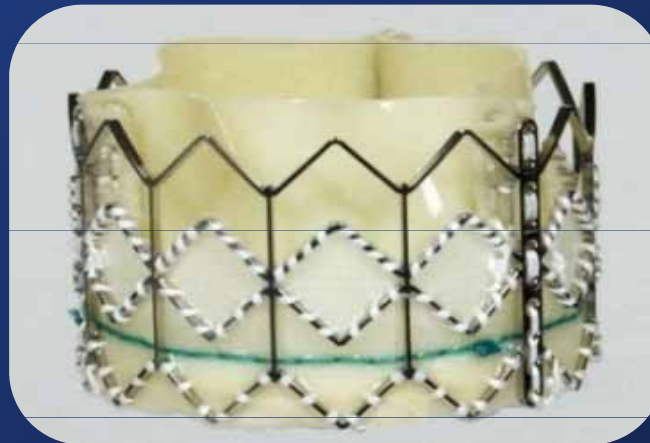
- Cobalt-chromium
- Greater tensile and yield strength

## NEW LEAFLET GEOMETRY

- Partially closed

### SAPIEN THV

Stainless Steel



### SAPIEN XT THV

Cobalt-chromium



RetroFlex 3

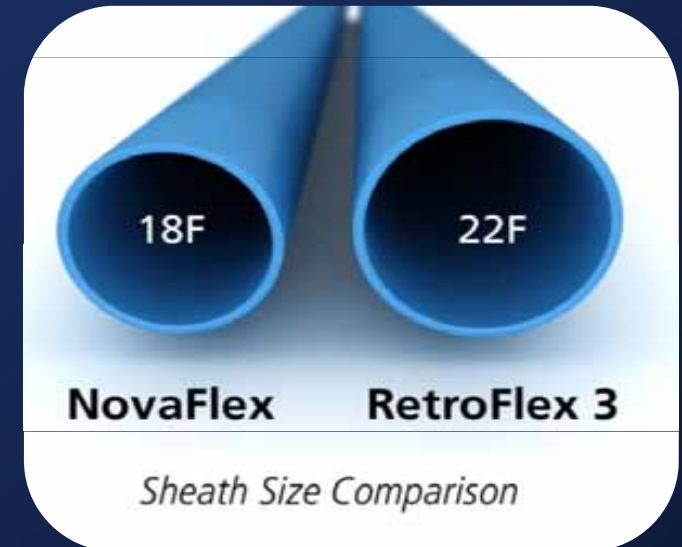


NovaFlex

# Sheath Size Comparison



Valve	Valve Size	Sheath ID	Sheath OD	Minimum Vessel Diameter
SAPIEN THV	23mm	22F	25F (8.4mm)	7.0mm
SAPIEN XT THV	23mm	18F	22F (7.2mm)	6.0mm
SAPIEN THV	26mm	24F	28F (9.2mm)	8.0mm
SAPIEN XT THV	26mm	19F	23F (7.5mm)	6.5mm

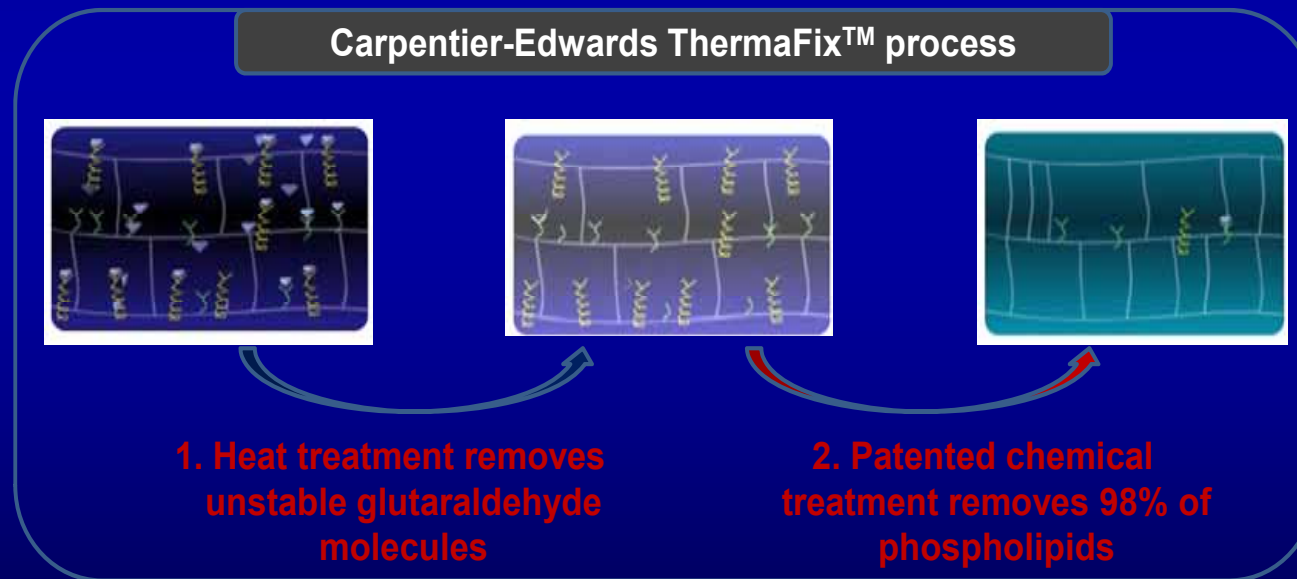


33% reduction in CSA

# Carpentier-Edwards ThermaFix Process\*

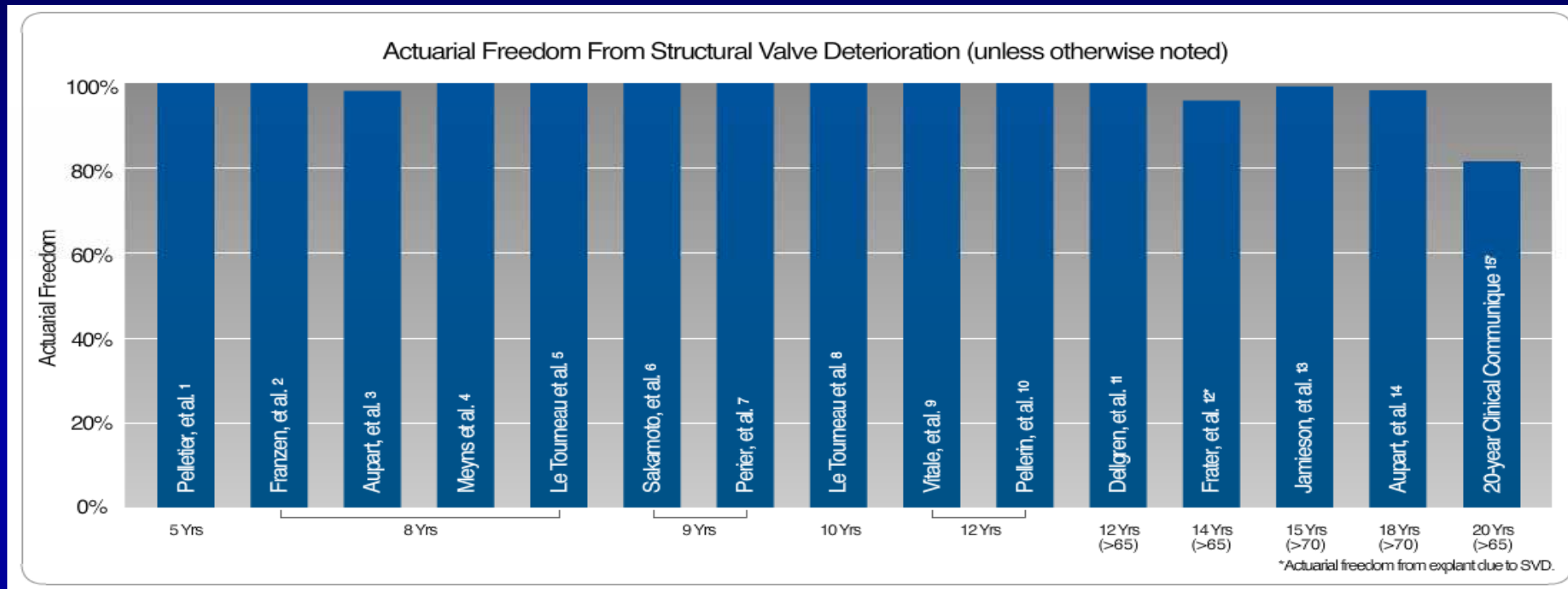
- There are two major Calcium binding sites that lead to calcification
  1. Unstable Glutaraldehyde molecules /
  2. Phospholipid molecules

ThermaFix is the only anti-calcification treatment that removes both Ca<sup>+</sup> binding sites



- The Edwards SAPIEN THV incorporates the same manufacturing processes used on premier Carpentier-Edwards PERIMOUNT Magna pericardial valves

# Surgically Implanted pericardial bioprostheses are very durable



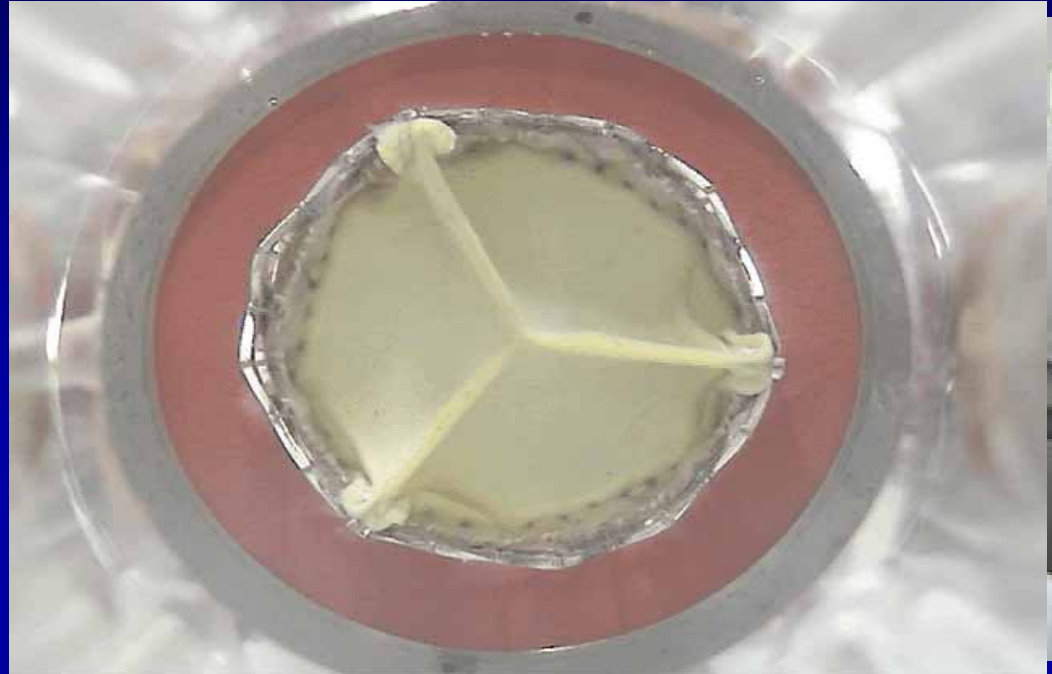
1. Pelletier, et al. Aortic Valve Replacement with the Carpentier-Edwards Pericardial Bioprosthesis: Clinical and Hemodynamic Results. *J Card Surg* 1988; Suppl. V.3.:405-412.
2. Franzen, et al. Aortic Valve Replacement with Pericardial Valves in Patients with Small Aortic Roots. Clinical Results in a Consecutive Series of Patients Receiving 19 and 21mm Prostheses. *Scand Cardiovasc J* 2001; 35:114-118.
3. Aupart M, et al. The influence of age on valve related events with Carpentier-Edwards pericardial valves. *J Cardiovasc Surg* 1995; 36:297-302
4. Meyns B, et al. Aortic and Mitral Valve Replacement With the Carpentier-Edwards Pericardial Bioprosthesis: Mid-Term Clinical Results. *J Heart Valve Dis* 1993; 2:66-70
5. Le Tourneau T, et al. Mid-Term Comparative Follow-Up After Aortic Valve Replacement with the Carpentier-Edwards and Pericarbon Pericardial Prostheses. *Circulation* 1999; 100[suppl II]:II-11-II-16
6. Sakamoto Y, et al. Carpentier-Edwards Pericardial Aortic Valve in Middle-aged Patients - Comparison with the St. Jude Medical Valve. *Jpn J Thorac Cardiovasc Surg* 2005; 53:465-469
7. Perier P, et al. Long-Term Evaluation of the Carpentier-Edwards Pericardial Valve in the Aortic Position. *J Card Surg* 1991; 6;4[suppl]:589-594
8. Le Tourneau T, et al. Ten-Year Echocardiographic and Clinical Follow-Up of Aortic Carpentier-Edwards Pericardial and Supraannular Prosthesis : A Case-Match Study. *Ann Thorac Surg* 2002; 74:2010-5
9. Vitale N, et al. Clinical and Hemodynamic Evaluation of Small Perimount Aortic Valves in Patients Aged 75 Years or Older. *Ann Thorac Surg* 2003; 75:35-40
10. Pellerin P, et al. Carpentier-Edwards Pericardial Bioprosthesis in Aortic Position: Long-Term Follow-up 1980 to 1994. *Ann Thorac Surg* 1995; 60:S292-6
11. Dellgren G, et al. Late hemodynamic and clinical outcomes of aortic valve replacement with the Carpentier-Edwards Perimount pericardial bioprosthesis. *J Thorac Cardiovasc Surg* 2002; 124:146-54
12. Frater R, et al. Long-Term Durability and Patient Functional Status of the Carpentier-Edwards® Perimount® Pericardial Bioprosthesis in the Aortic Position. *J Heart Valve Dis* 1998; 7:48-53
13. Jamieson WR, et al. 15-Year Comparison of Supra-Annular Porcine and PERIMOUNT Aortic Bioprostheses. *Asian Cardiovasc Thorac Ann* 2006; 14:200-205
14. Aupart M, et al. Perimount Pericardial Bioprosthesis for Aortic Calcified Stenosis: 18-Year Experience with 1,133 Patients. *J of Heart Valve Dis* 2006; 15:768-776
15. Carpentier-Edwards PERIMOUNT aortic pericardial bioprosthesis 20-year Results. Data on file at Edwards Lifesciences, 2003.



# Accelerated Wear Testing

- **200 Million Cycles Testing**

- Steady Backflow
- Steady Forward Flow
- Pulsatile Flow Pressure Drop
- Pulsatile Flow Regurgitation
- Flow Visualization



- **Irregular shape testing**

- Over-expansion
- Under-expansion
- Oval shape



## Transaortic Transcatheter Aortic Valve Implantation Using Edwards SAPIEN Valve: A Novel Approach

Vinayak Bapat,<sup>1,2\*</sup> FCRS, CTh, Muhammed Z. Khawaja,<sup>1,2</sup> MBBS, Rizwan Attia,<sup>1,2</sup> MBChB, Ashok Narayana,<sup>1,2</sup> MBBS, Karen Wilson,<sup>1,2</sup> BSc, Kirsty Macgillivray,<sup>1,2</sup> BSc, Christopher Young,<sup>1,2</sup> MD, Jane Hancock,<sup>1,2</sup> PhD, Simon Redwood,<sup>1,2</sup> MD, and Martyn Thomas,<sup>1,2</sup> MD

## Early Experience of Transaortic TAVI—The Future of Surgical TAVI?

Andrew Clarke, FRACP\*, Paul Wiemers, Karl K.C. Poon, FRACP, Constantine N. Aroney, FRACP, FCSANZ, Gregory Scalia, FRACP, Darryl Burstow, FRACP, FCSANZ, Darren L. Walters, MPhil, FRACP, FCSANZ and Peter Tesar, FRACP, FCSANZ

*The Prince Charles Hospital, Brisbane, Australia*

## Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation

“The Hamburg Sankt Georg Approach”

Ulrich Schäfer, MD,\* Yen Ho, MD,† Christian Frerker, MD,\* Dimitry Schewel, MD,\* Damian Sanchez-Quintana, MD,‡ Joachim Schofer, MD,§ Klaudija Bijuklic, MD,§ Felix Meincke, MD,\* Thomas Thielsen, MD,\* Felix Kreidel, MD,\* Karl-Heinz Kuck, MD\*

*Hamburg, Germany; London, United Kingdom; and Badajoz, Spain*



Vascular access in TAVI

Transseptal antegrade transcatheter aortic valve replacement for no-access option patients. A contemporary experience

## Outcomes After Transcatheter Aortic Valve Implantation With Both Edwards-SAPIEN and CoreValve Devices in a Single Center

The Milan Experience

Cosmo Godino, MD,\*† Francesco Maisano, MD,‡ Matteo Montorfano, MD,\* Azeem Latib, MD,\*† Alaide Chieffo, MD,\* Iassen Michev, MD,\*† Rasha Al-Lamee, MD,\*† Marta Bande, MD,\* Marco Mussardo, MD,\* Francesco Arioli, MD,\* Alfonso Iclasi, MD,\* Micaela Cioni, MD,‡ Maurizio Taramasso, MD,‡ Irina Arcendar, MD,‡ Antonio Grimaldi, MD,‡ Pietro Spagnolo, MD,§ Alberto Zangrillo, MD,|| Giovanni La Canna, MD,‡ Ottavio Alfieri, MD,‡ Antonio Colombo, MD\*†

*Milan, Italy*

Percutaneous Aortic Valve Implantation Retrograde From the Femoral Artery  
John G. Webb, Mann Chandavimol, Christopher R. Thompson, Donald R. Ricci, Ronald G. Carere, Brad I. Munt, Christopher E. Buller, Sanjeevan Pasupati and Samuel Lichtenstein

## Transcatheter Aortic Valve Implantation for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at Very High or Prohibitive Surgical Risk

Acute and Late Outcomes of the Multicenter Canadian Experience

Josep Rodés-Cabau, MD,\* John G. Webb, MD,† Anson Cheung, MD,‡ Jian Ye, MD,‡ Eric Dumont, MD,\* Christopher M. Feindel, MD,‡ Mark Osten, MD,‡ Madhu K. Natarajan, MD,§ James L. Velianou, MD,§ Giuseppe Martucci, MD,|| Benoit DeVarennes, MD,|| Robert Chisholm, MD,¶ Mark D. Peterson, MD,¶ Samuel V. Lichtenstein, MD,‡ Fabian Nietispach, MD,‡ Daniel Doyle, MD,\* Robert DeLarochellière, MD,\* Kevin Teoh, MD,§ Victor Chu, MD,§ Adrian Dancea, MD,|| Kevin Lachapelle, MD,|| Asim Cheema, MD,¶ David Latter, MD,¶ Eric Horlick, MD,‡

*Quebec City and Montreal, Quebec; Vancouver, British Columbia; and Toronto and Hamilton, Ontario, Canada*

## Transapical Transcatheter Aortic Valve Implantation in Humans: Initial Clinical Experience

Samuel V. Lichtenstein, Anson Cheung, Jian Ye, Christopher R. Thompson, Ronald G. Carere, Sanjeevan Pasupati and John G. Webb

## United States Feasibility Study of Transcatheter Insertion of a Stented Aortic Valve by the Left Ventricular Apex

Lars G. Svensson, MD, PhD, Todd Dewey, MD, Samir Kapadia, MD, Eric E. Roselli, MD, Alan Stewart, MD, Matt Williams, MD, William N. Anderson, PhD, David Brown, MD, Marty Leon, MD, Bruce Lytle, MD, Jeffrey Moses, MD, Michael Mack, MD, Murat Tuzcu, MD, and Craig Smith, MD

## Transapical Aortic Valve Implantation in 175 Consecutive Patients

Excellent Outcome in Very High-Risk Patients

Miralem Pasic, MD, PhD, Axel Unbehaun, MD, Stephan Dreysse, MD, Thorsten Drews, MD, Semih Buz, MD, Marian Kukucka, MD, Alexander Mladenow, MD, Tom Gromann, MD, Roland Hetzer, MD, PhD

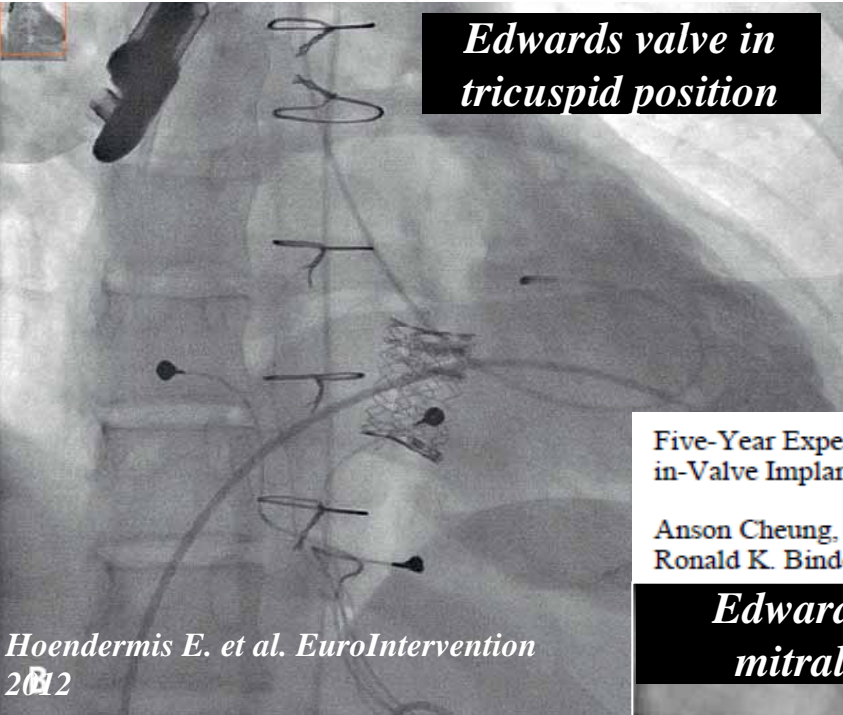
*Berlin, Germany*

## Transapical Minimally Invasive Aortic Valve Implantation: Multicenter Experience

Thomas Walther, Paul Simon, Todd Dewey, Gerhard Wimmer-Greinecker, Volkmar Falk, Marie T. Kasimir, Mirko Doss, Michael A. Borger, Gerhard Schuler, Dietmar Glogar, Wolfgang Fehske, Ernst Wolner, Friedrich W. Mohr and Michael Mack

**Percutaneous Edwards SAPIEN valve implantation in the tricuspid position: case report and review of literature**

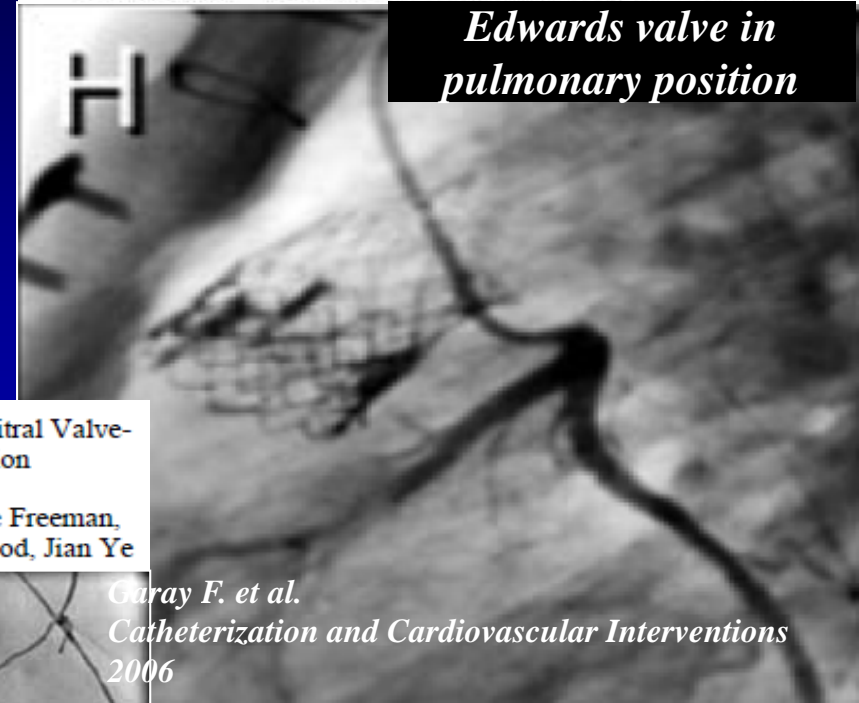
Elke S. Hoendermis<sup>1\*</sup>, MD, PhD; Yvonne L. Douglas<sup>1</sup>, MD, PhD; Ad F. M. van den Heuvel<sup>1</sup>, MD, PhD



**Edwards valve in tricuspid position**

**Percutaneous Replacement of Pulmonary Valve Using the Edwards-Cribier Percutaneous Heart Valve: First Report in a Human Patient**

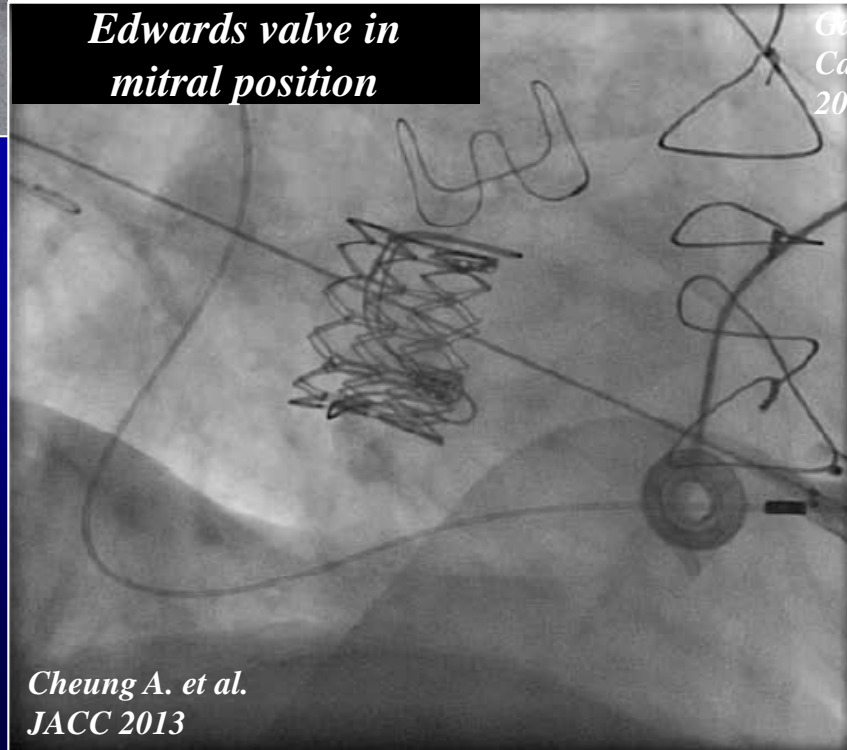
Francisco Garay,<sup>1,2</sup> MD, John Webb,<sup>3</sup> MD, and Ziyad M. Hijazi,<sup>1,2\*1</sup> MD, MPH, FSCAI



**Edwards valve in pulmonary position**

**Five-Year Experience with Transcatheter Transapical Mitral Valve-in-Valve Implantation for Bioprosthetic Valve Dysfunction**

Anson Cheung, John G. Webb, Marco Barbanti, Melanie Freeman, Ronald K. Binder, Christopher Thompson, David A. Wood, Jian Ye



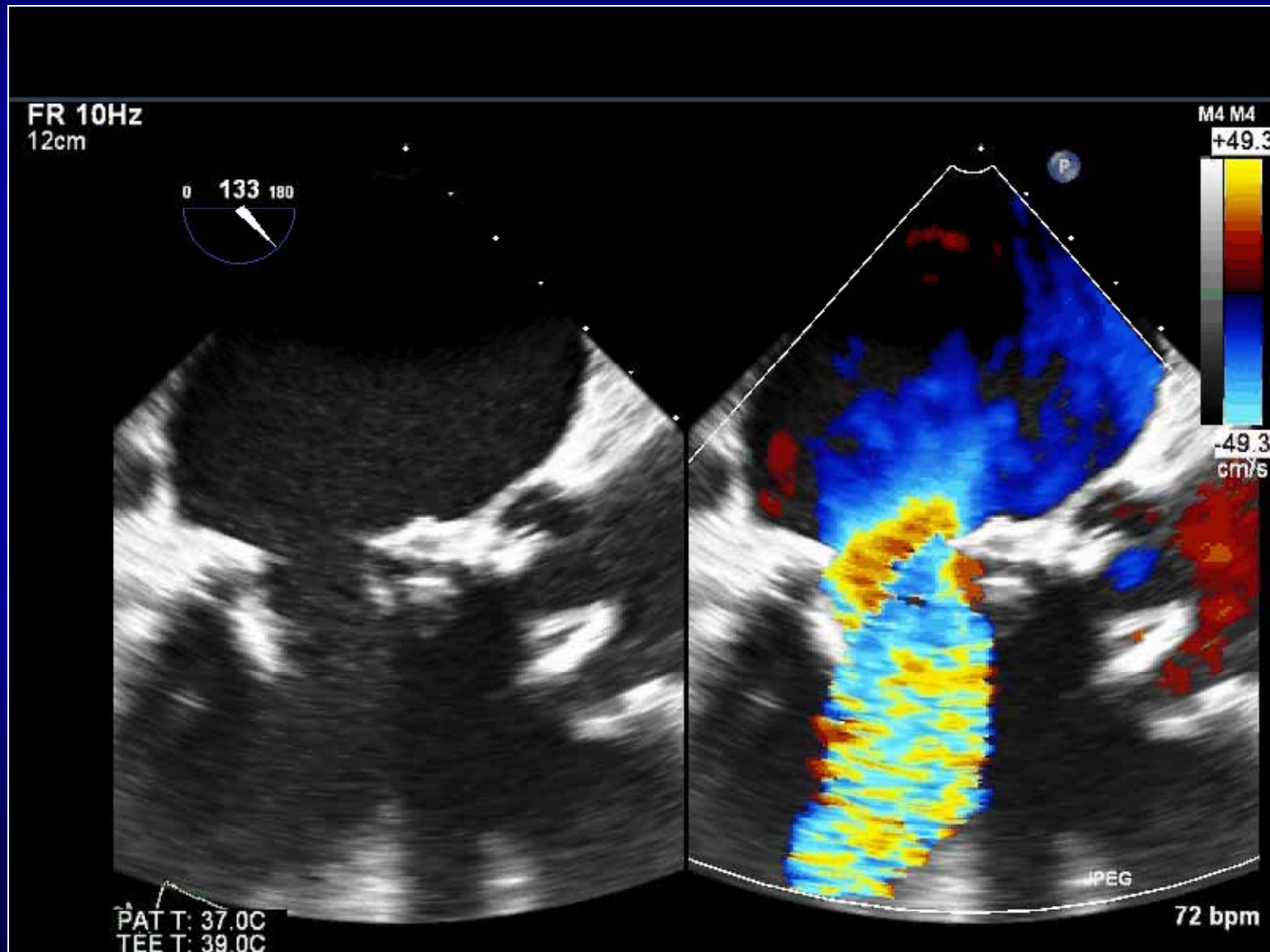
**Edwards valve in mitral position**

Garay F. et al.  
*Catheterization and Cardiovascular Interventions*  
2006

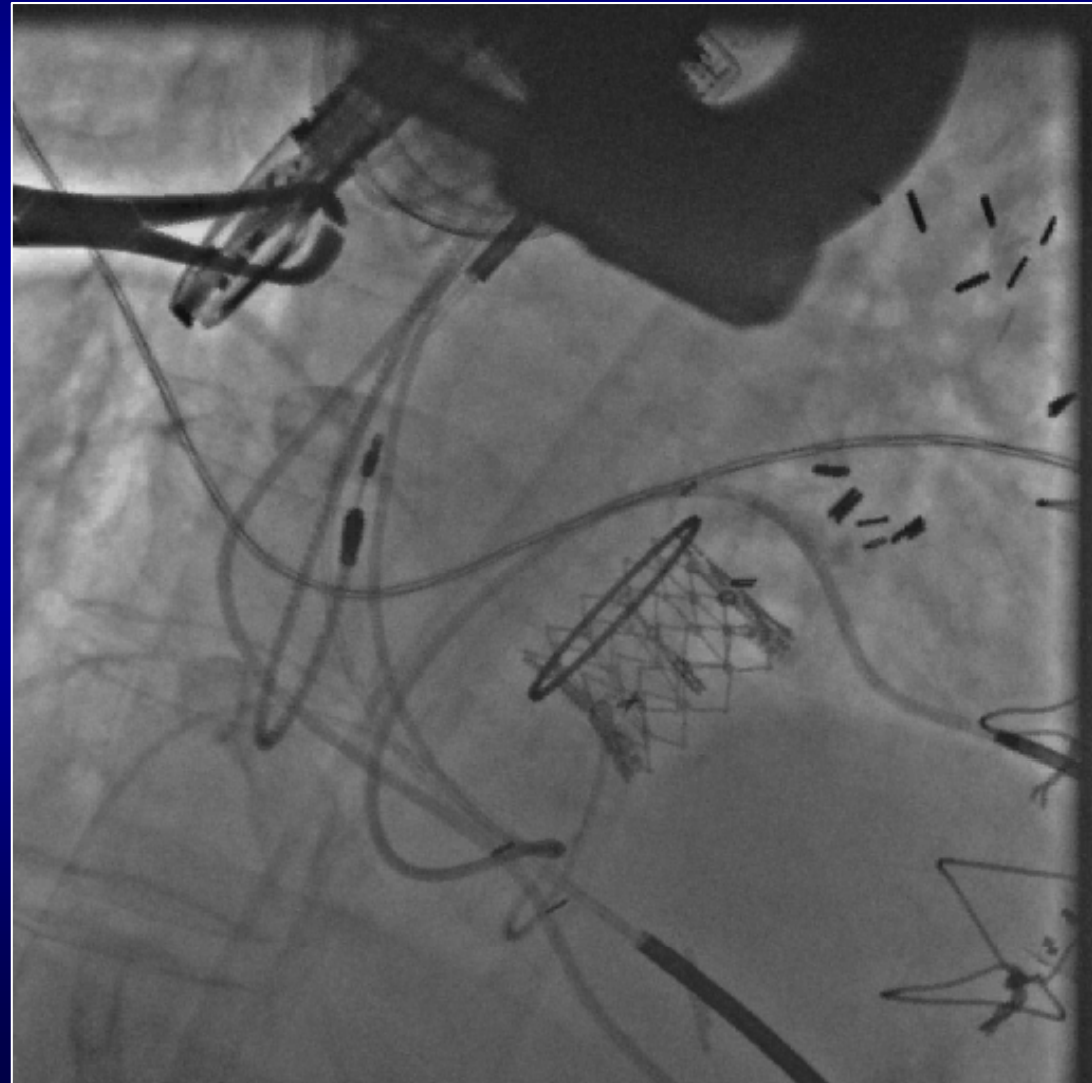
Cheung A. et al.  
*JACC* 2013

Hoendermis E. et al. *EuroIntervention*  
2012

# Flail Anterior Bioprosthetic Mitral Valve Leaflet with severe Mitral Regurgitation

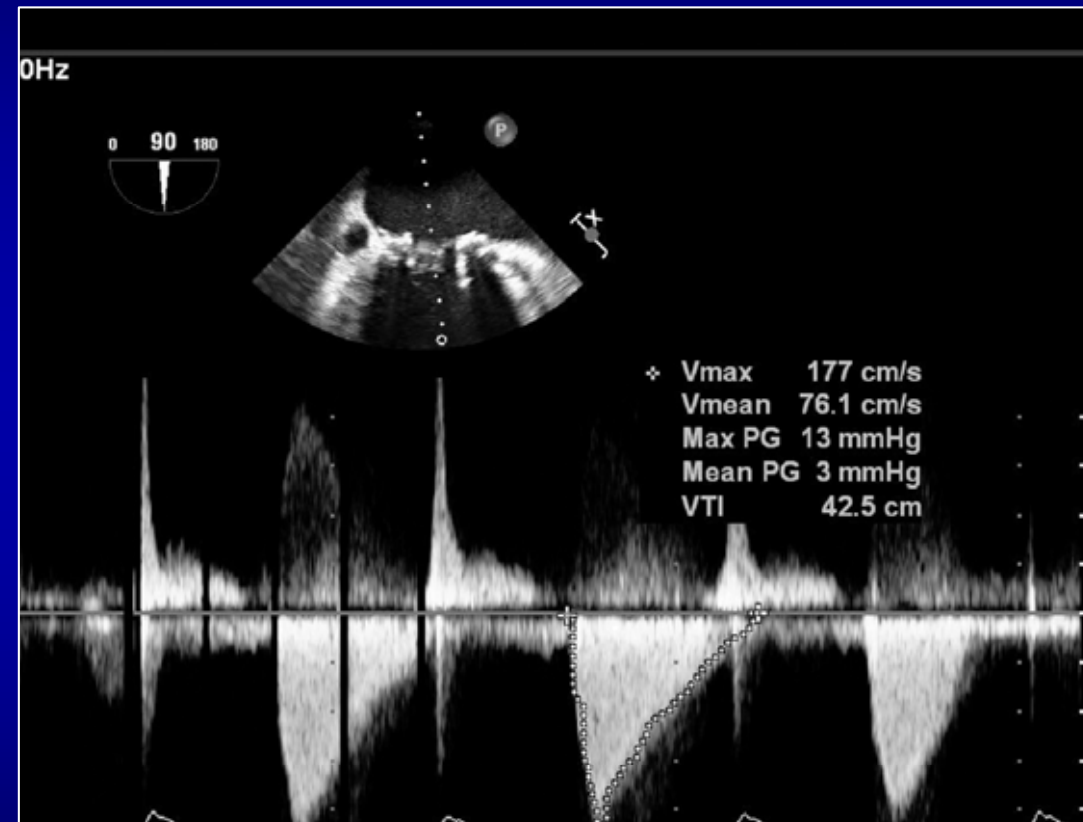
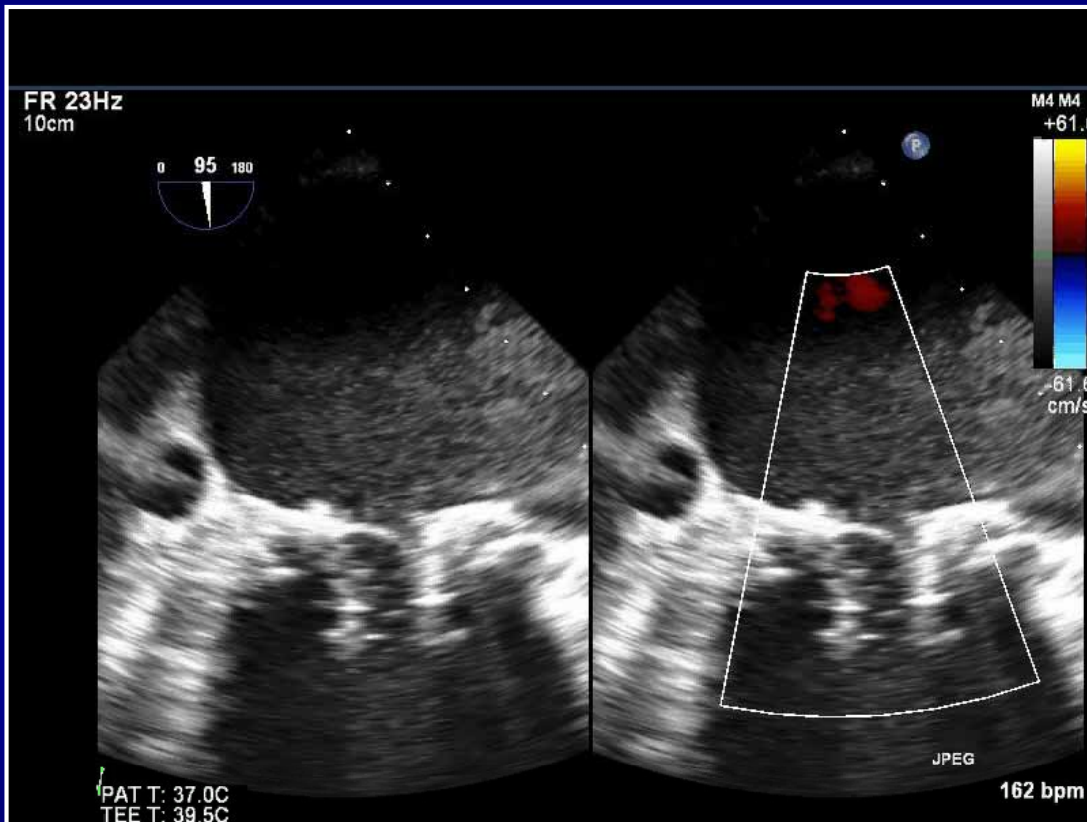


# Valve-in-valve implantation of 29-mm Sapien-XT valve by Transapical approach



# Final Result

## No significant MR or MS



*Patient discharged home 5 days later*  
*No peri-procedural or in-hospital complications*

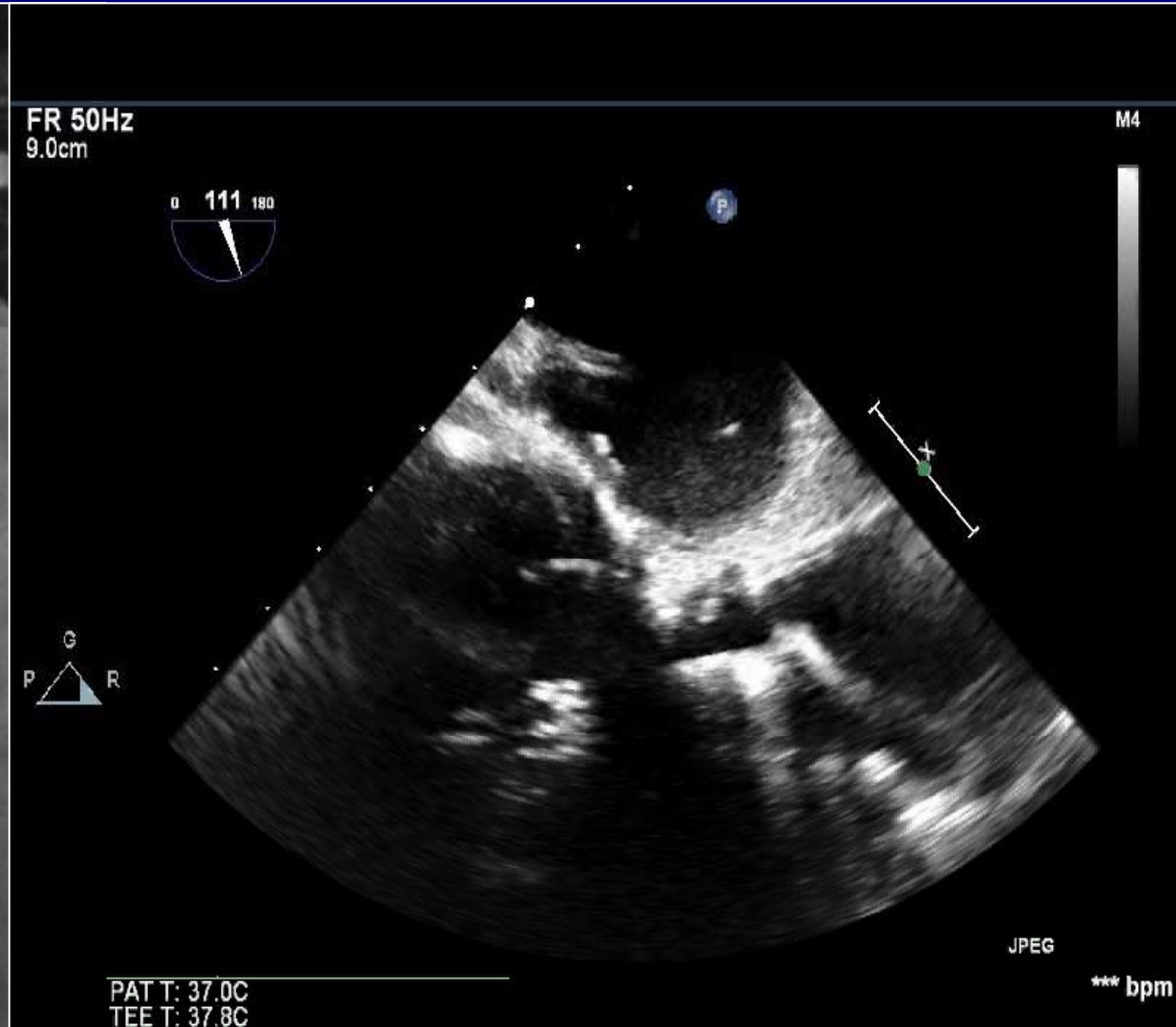
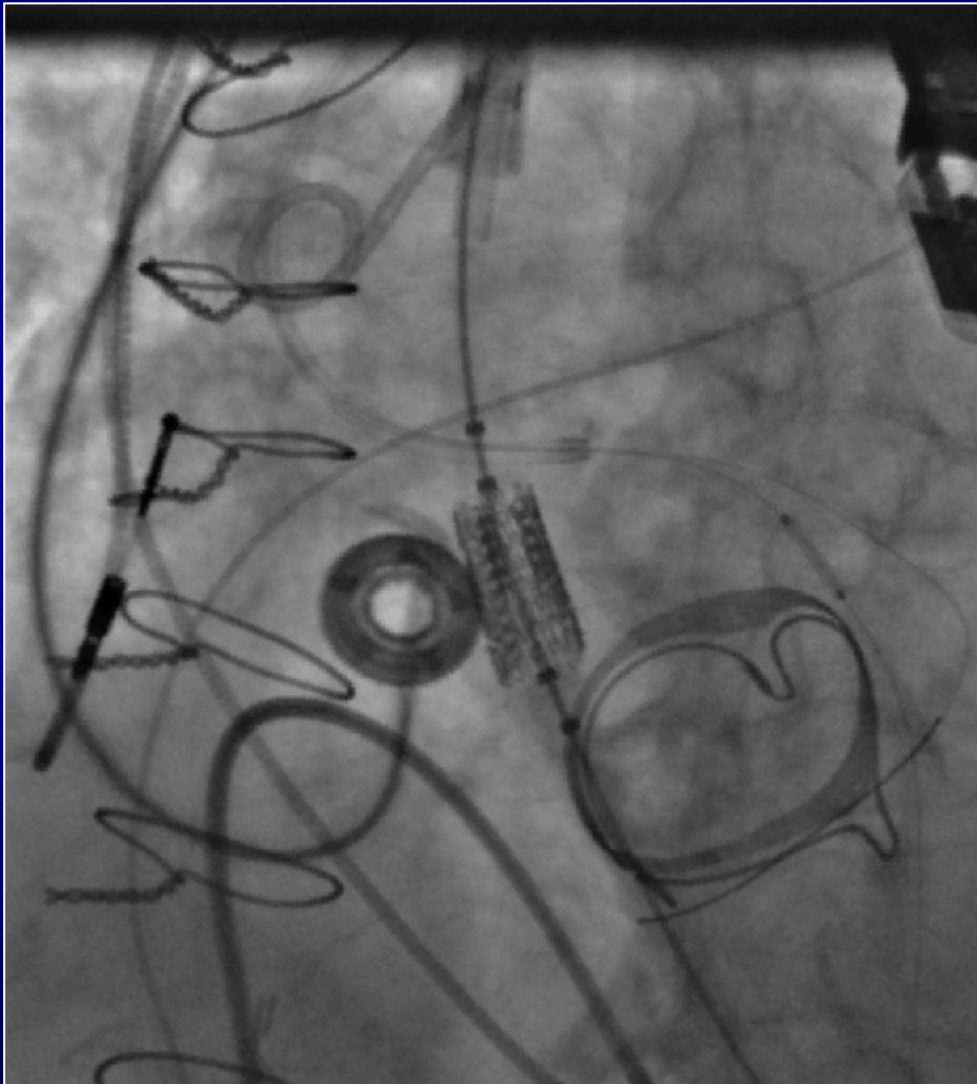
**79 y/o female undergoing transcatheter valve-in-valve implantation with Edwards-SAPIEN valve for degenerative failed 23-mm St. Jude Toronto SPV bioprosthetic aortic valve with significant AR**

PMH:

- Bioprosthetic 23-mm St. Jude Toronto SPV bioprosthetic aortic valve (20 years ago)
- Bioprosthetic 27-mm stented CE mitral bioprosthetic valve (5 years ago)
- Atrial fibrillation
- Hypertension
- Dyslipidemia
- Sick-sinus syndrome requiring permanent pacemaker.



# 23 mm Edwards-SAPIEN valve deployment by the transfemoral approach





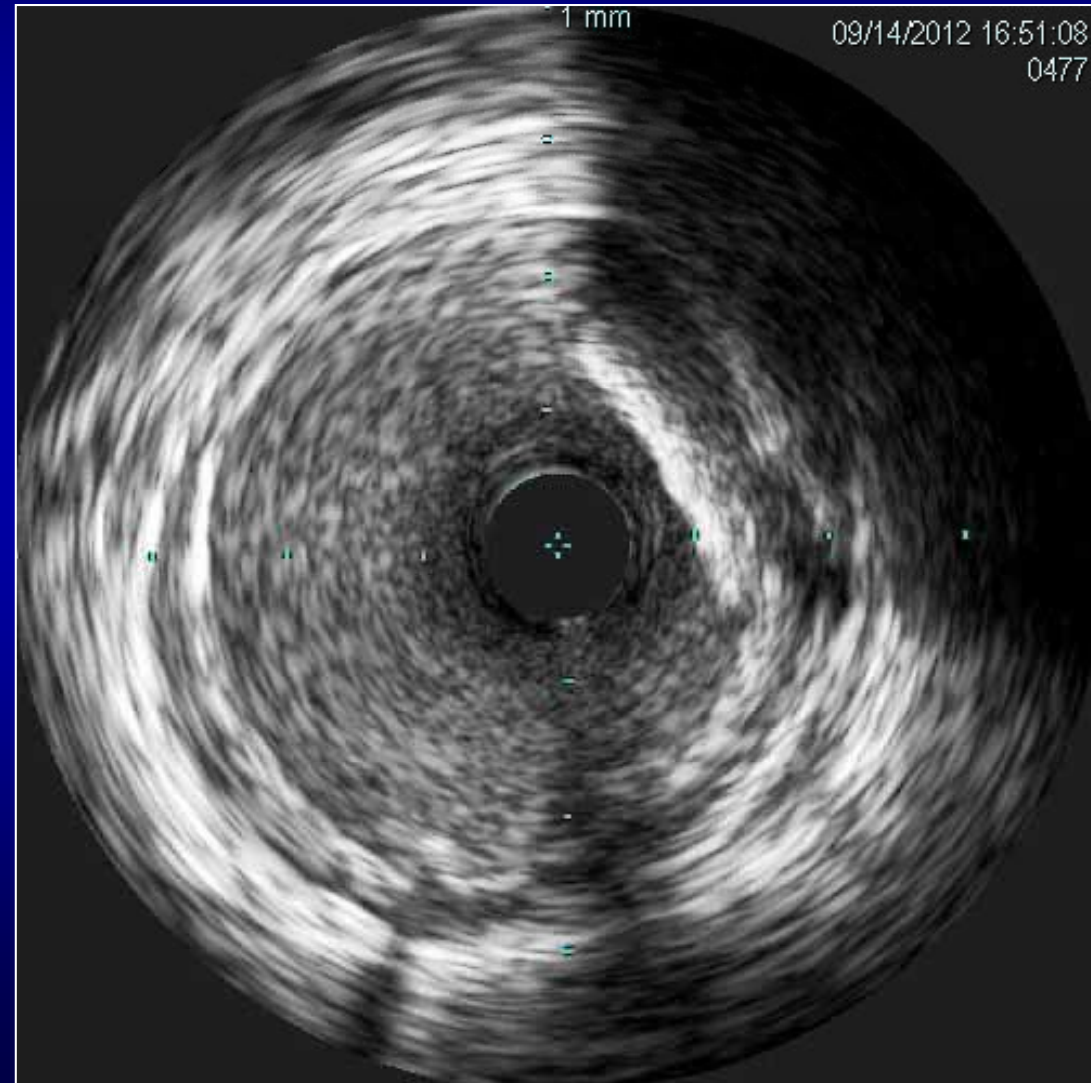
# Significant LM compromise due to the prosthetic valve



# Final result

s/p Xience 4.0 x 12 mm and Veriflex 4.0 x 12 mm stents to  
the LM

**No significant LM stenosis**



# Publications in NEJM



1-Year outcomes published on-line June 5, 2011  
@ NEJM.org and in print June 9, 2011

The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812

JUNE 9, 2011

## Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Morrow, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, M.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators\*

2-Year outcomes published on-line March 26, 2012  
@ NEJM.org and print May 3, 2012

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., 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\*



## Publications in NEJM

# The NEW ENGLAND JOURNAL of MEDICINE

## Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,  
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,  
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,  
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D.,  
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*

The NEW ENGLAND JOURNAL of MEDICINE

### ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Hasan Jilaihawi, M.D.,  
Samir Kapadia, M.D., Augusto D. Pichard, M.D., Pamela S. Douglas, M.D.,  
Vinod H. Thourani, M.D., Vasilis C. Babaliaros, M.D., John G. Webb, M.D.,  
Howard C. Herrmann, M.D., Joseph E. Bavaria, M.D., Susheel Kodali, M.D.,  
David L. Brown, M.D., Bruce Bowers, M.D., Todd M. Dewey, M.D.,  
Lars G. Svensson, M.D., Ph.D., Murat Tuzcu, M.D., Jeffrey W. Moses, M.D.,  
Matthew R. Williams, M.D., Robert J. Siegel, M.D., Jodi J. Akin, M.S.,  
William N. Anderson, Ph.D., Stuart Pocock, Ph.D., Craig R. Smith, M.D.,  
and Martin B. Leon, M.D., for the PARTNER Trial Investigators\*

# PARTNER Study Design



## Symptomatic Severe Aortic Stenosis

**ASSESSMENT: High-Risk AVR Candidate**  
3,105 Total Patients Screened

n = 699

**High-Risk**

**Total = 1,057 patients**

**2 Parallel Trials:  
Individually Powered**

**ASSESSMENT:  
Transfemoral  
Access**

**High-Risk TF**

**High-Risk TA**

1:1 Randomization

1:1 Randomization

**TF TAVR**

VS

**AVR**

**TA TAVR**

VS

**AVR**

**Primary Endpoint: All-Cause Mortality (1 yr)  
(Non-inferiority)**

**Inoperable**

n = 358

**ASSESSMENT:  
Transfemoral  
Access**

1:1 Randomization

**TF TAVR  
n = 179**

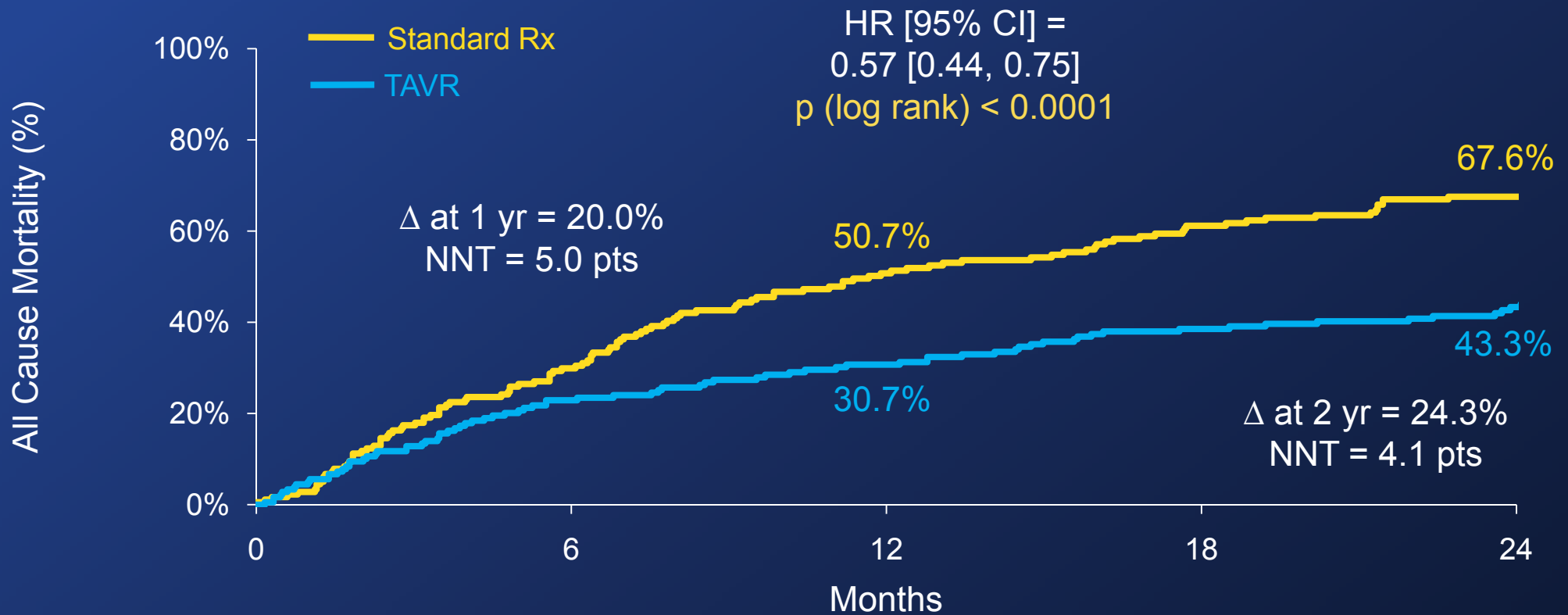
VS

**Standard  
Therapy  
n = 179**

**Primary Endpoint: All-Cause Mortality  
Over Length of Trial (Superiority)**

# All Cause Mortality (ITT)

## Crossover Patients Followed

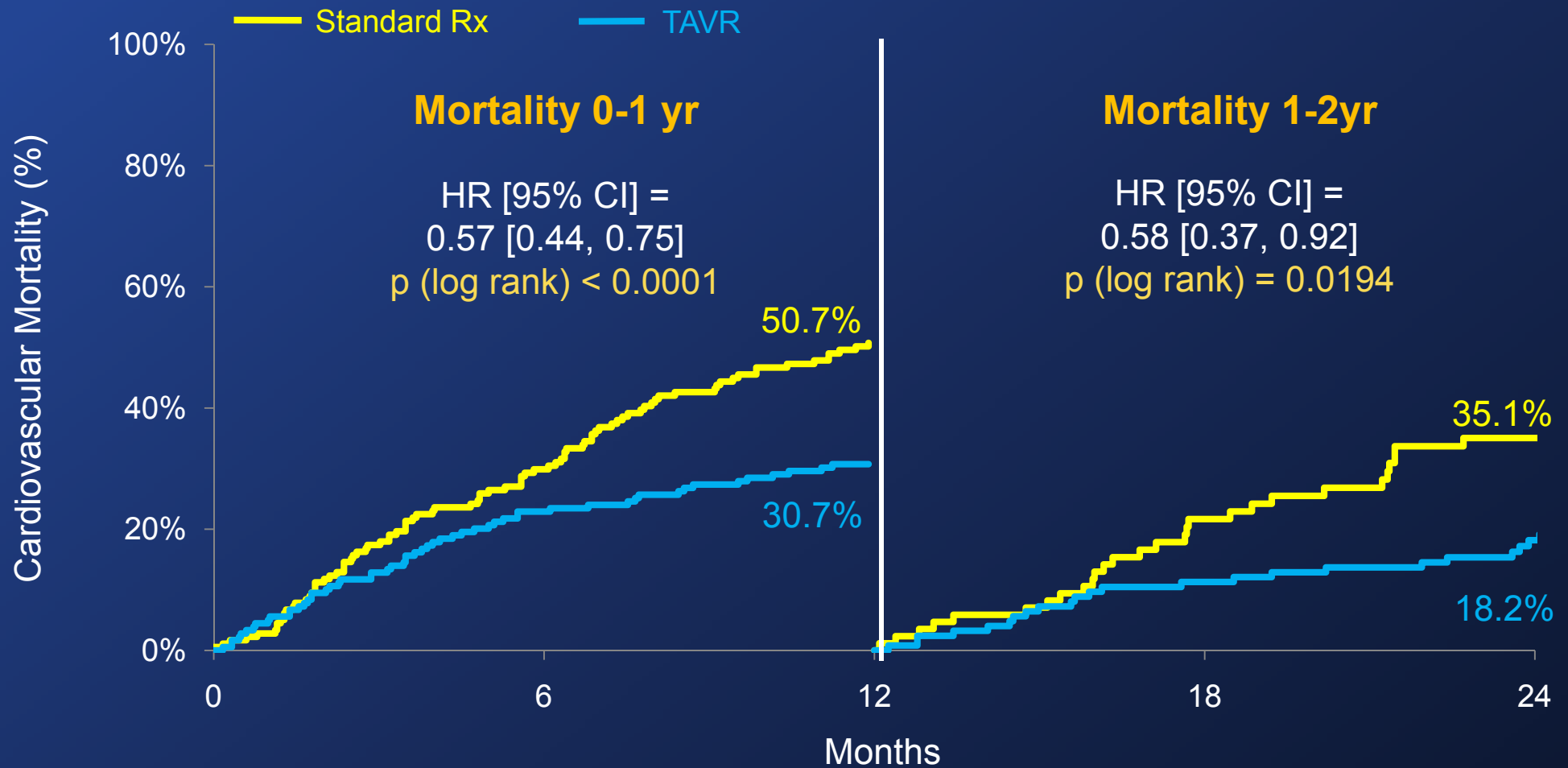


### Numbers at Risk

	0	6	12	18	24
TAVR	179	138	124	110	83
Standard Rx	179	121	85	67	51

# All Cause Mortality (ITT)

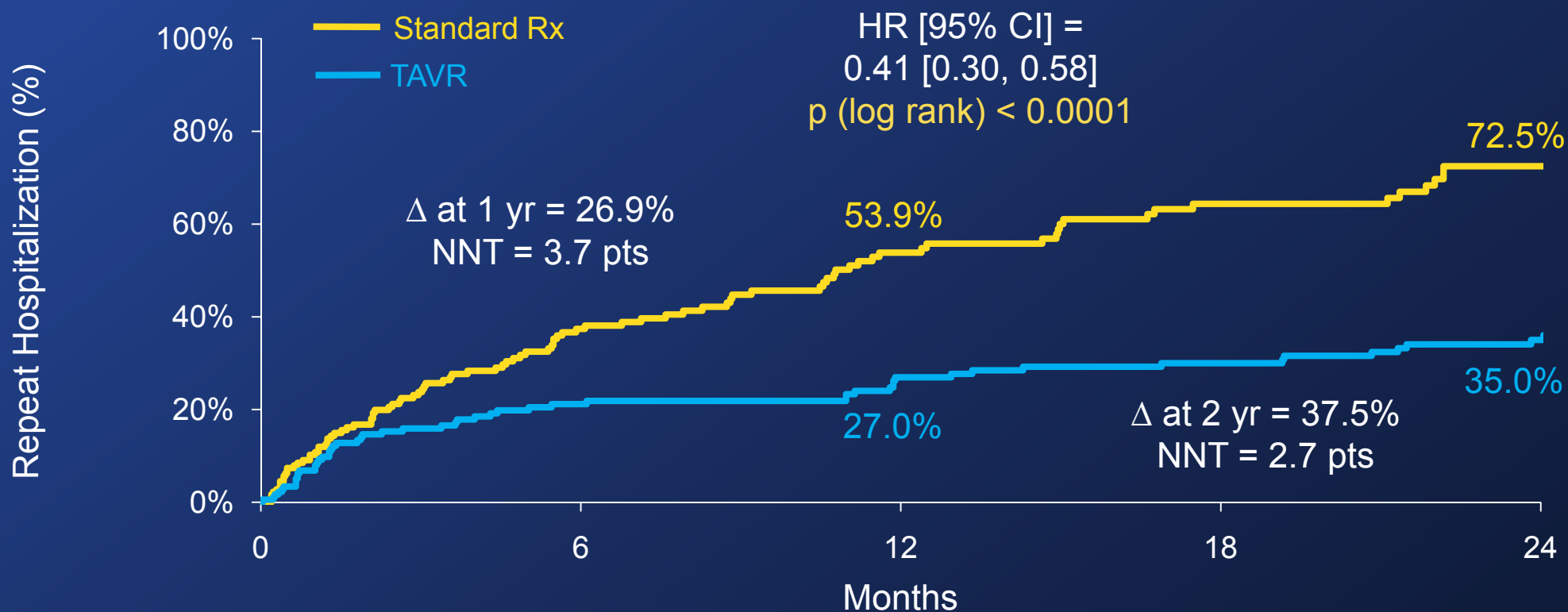
## Landmark Analysis



### Numbers at Risk

	0	6	12	18	24
TAVR	179	138	124	110	83
Standard Rx	179	121	85	62	42

# Repeat Hospitalization (ITT)



## Numbers at Risk

	0	6	12	18	24
TAVR	179	115	100	89	64
Standard Rx	179	86	49	30	17



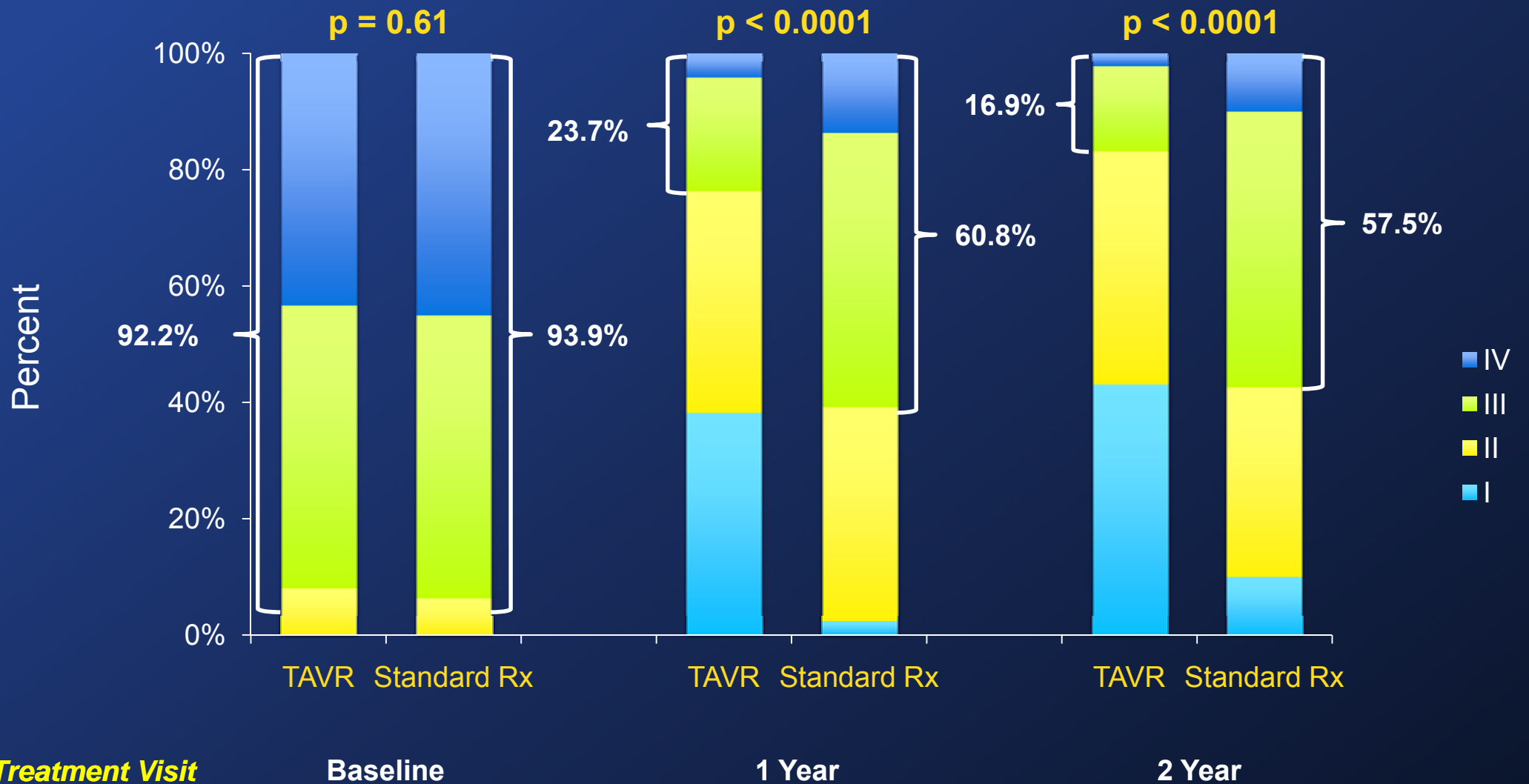
# Hospitalization Through 2 Years



	<i>TAVR</i>	<i>Standard Tx</i>	<i>p value</i>
<b>Repeat Hospitalizations (No.)</b>	78	151	<.0001
<b>Repeat Hospitalizations (%)</b>	35.0%	72.5%	<.0001
<b>Days Alive Out of Hospital Median [IQR]</b>	699 [201-720]	355 [116-712]	.0003

# NYHA Class Over Time

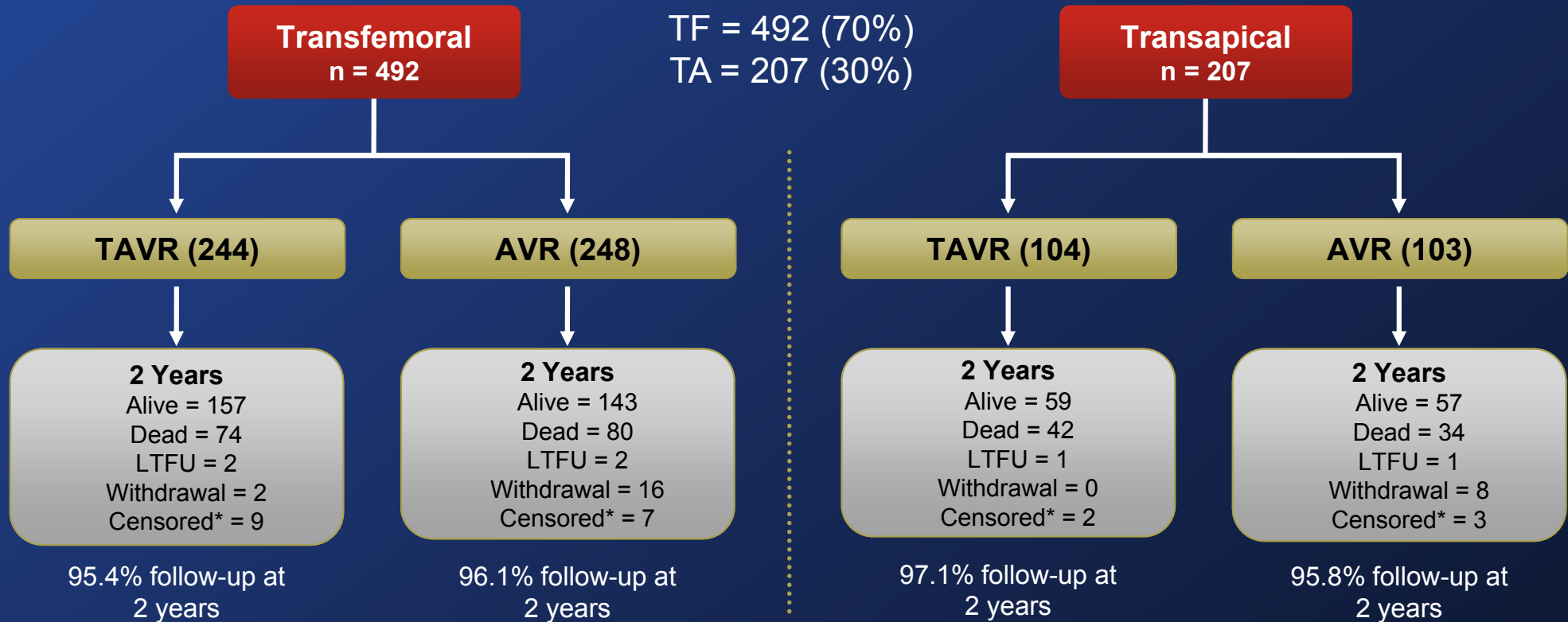
## Survivors



# Study Flow

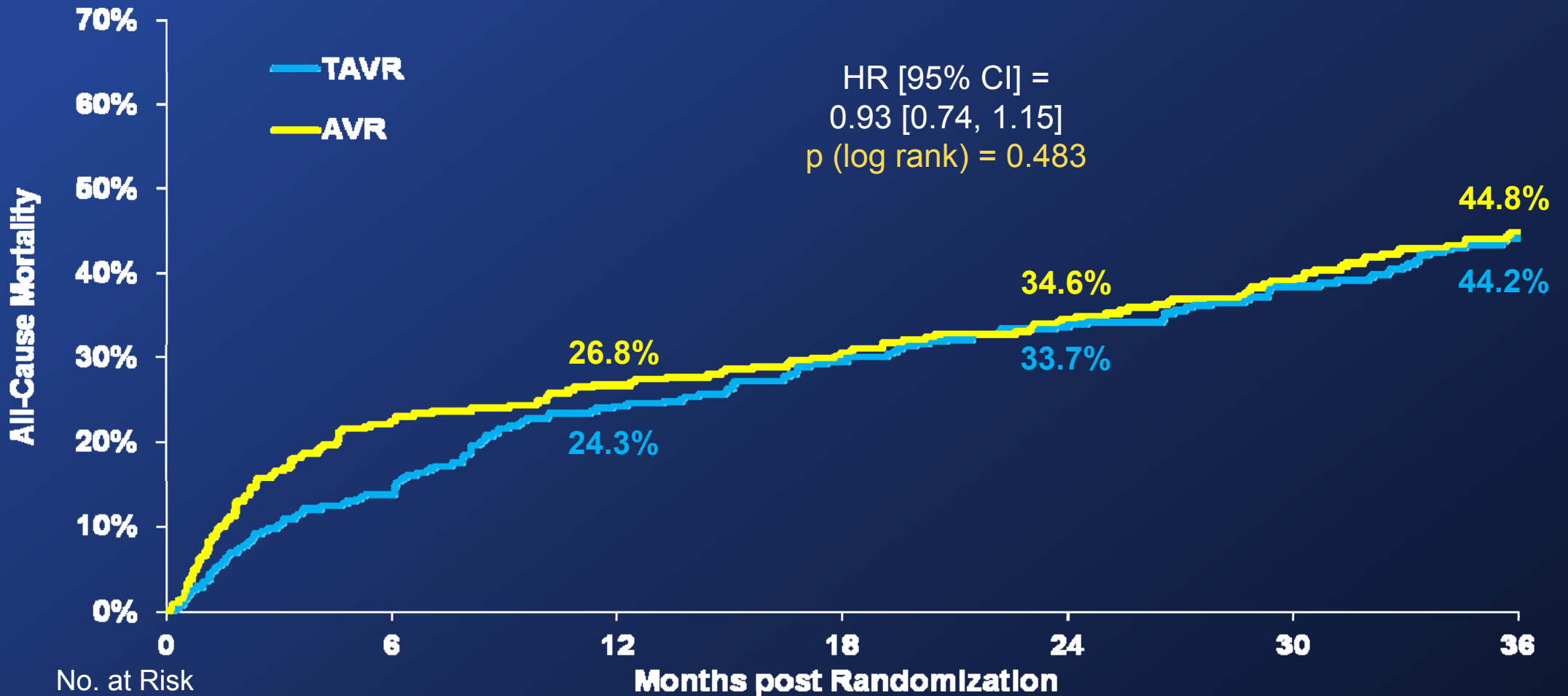


**Randomized = 699 patients**



\*Censored = Patient is alive at last contact but no information available within follow-up window

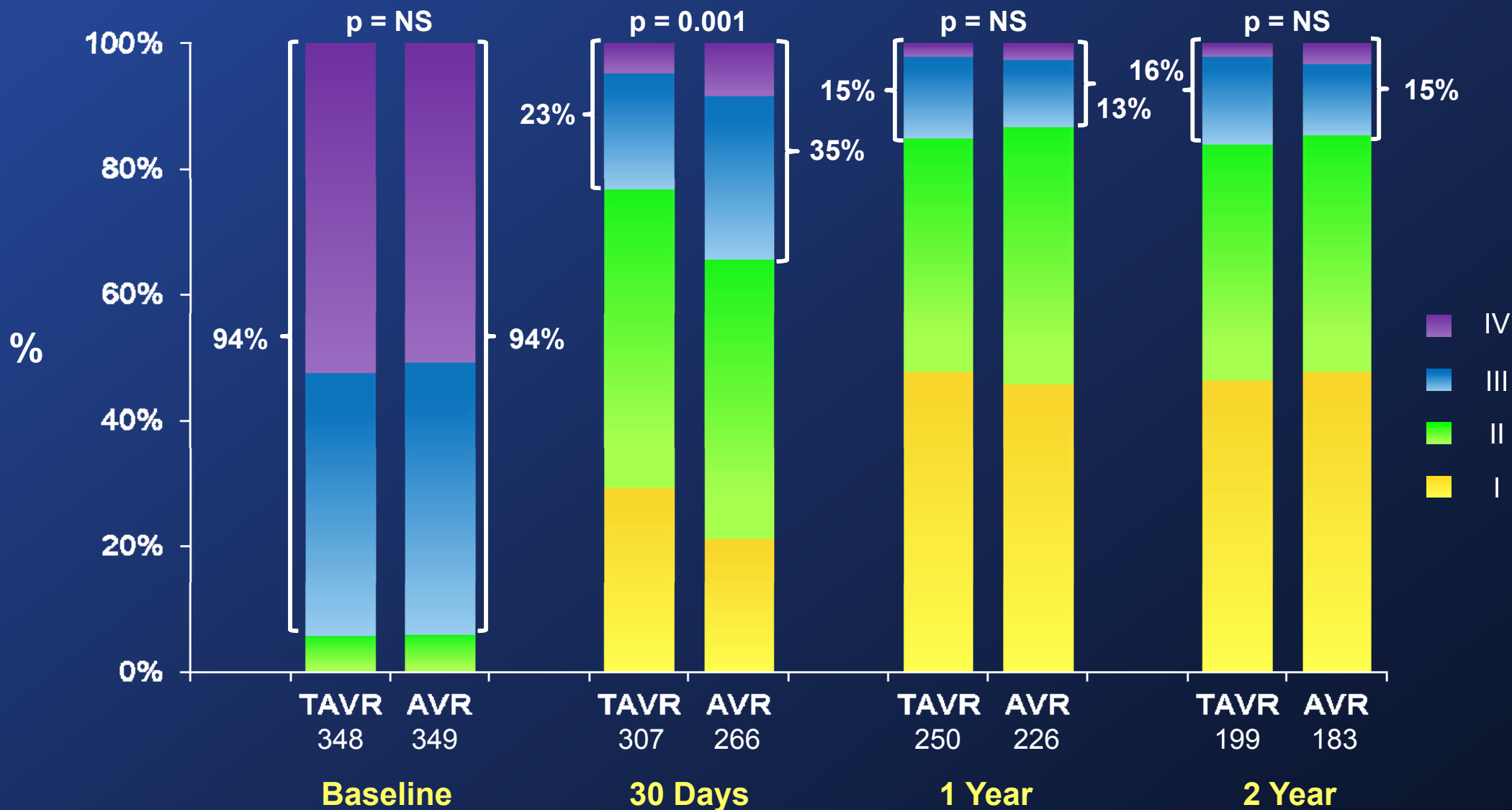
# All-Cause Mortality (ITT)



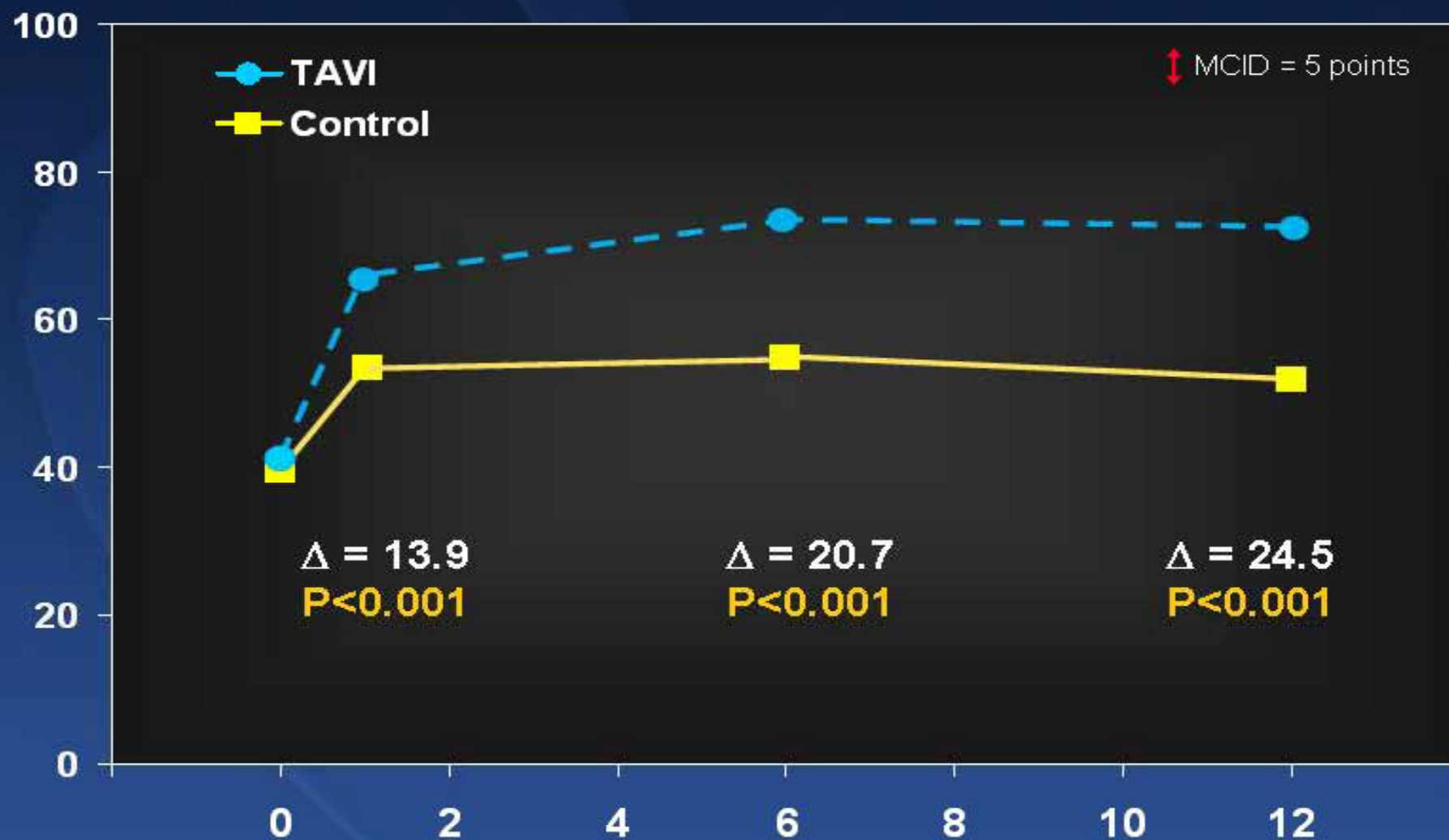
No. at Risk

	0	6	12	18	24	30	36
TAVR	348	298	261	239	222	187	149
AVR	351	252	236	223	202	174	142

# NYHA Class Survivors (ITT)



# Primary Endpoint: KCCQ Overall Summary

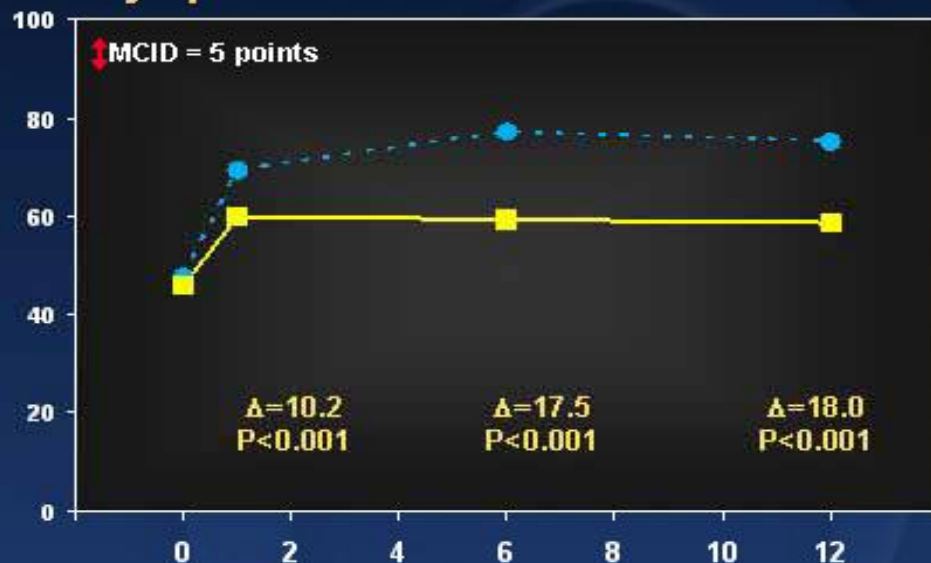


MCID = minimum clinically important difference

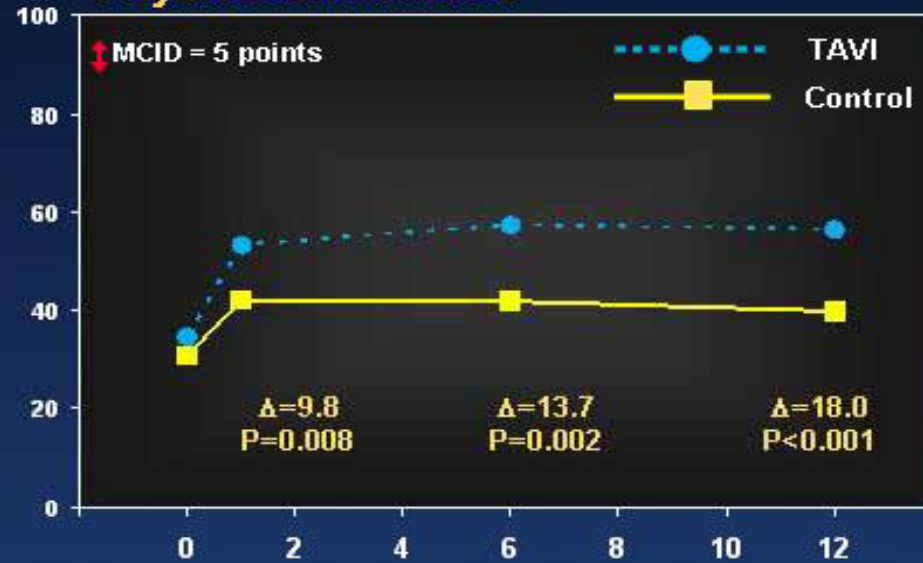
# KCCQ Subscales



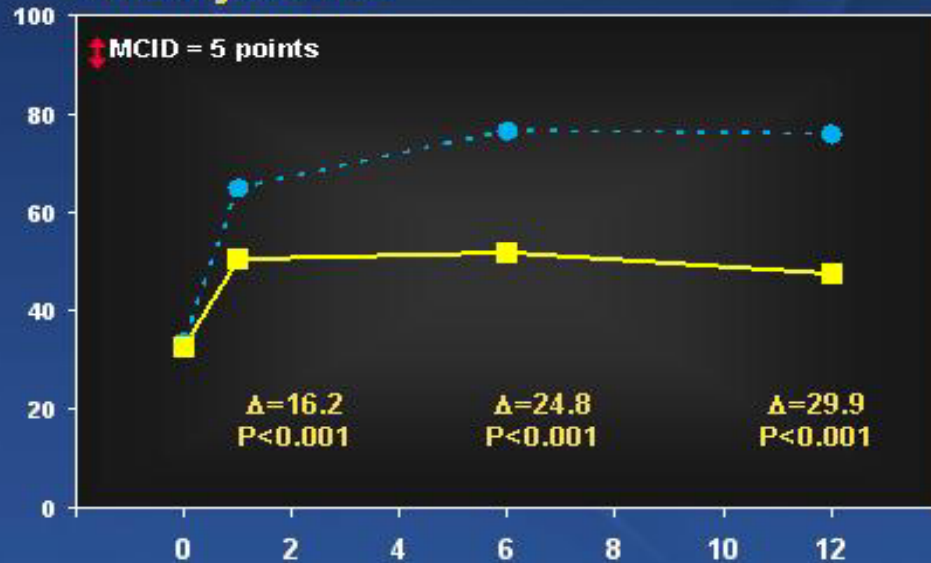
## Symptom Score



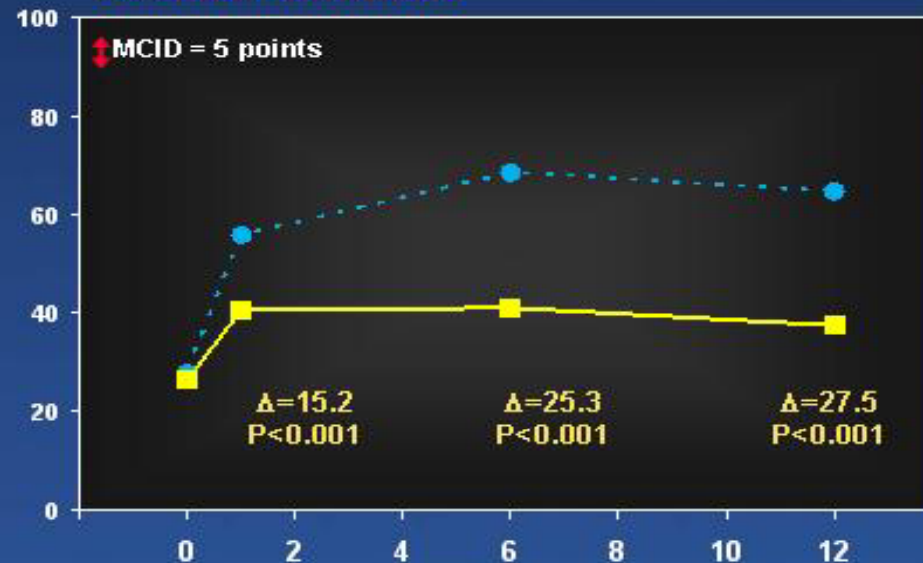
## Physical Limitations



## Quality of Life



## Social Limitations



MCID = minimum clinically important difference

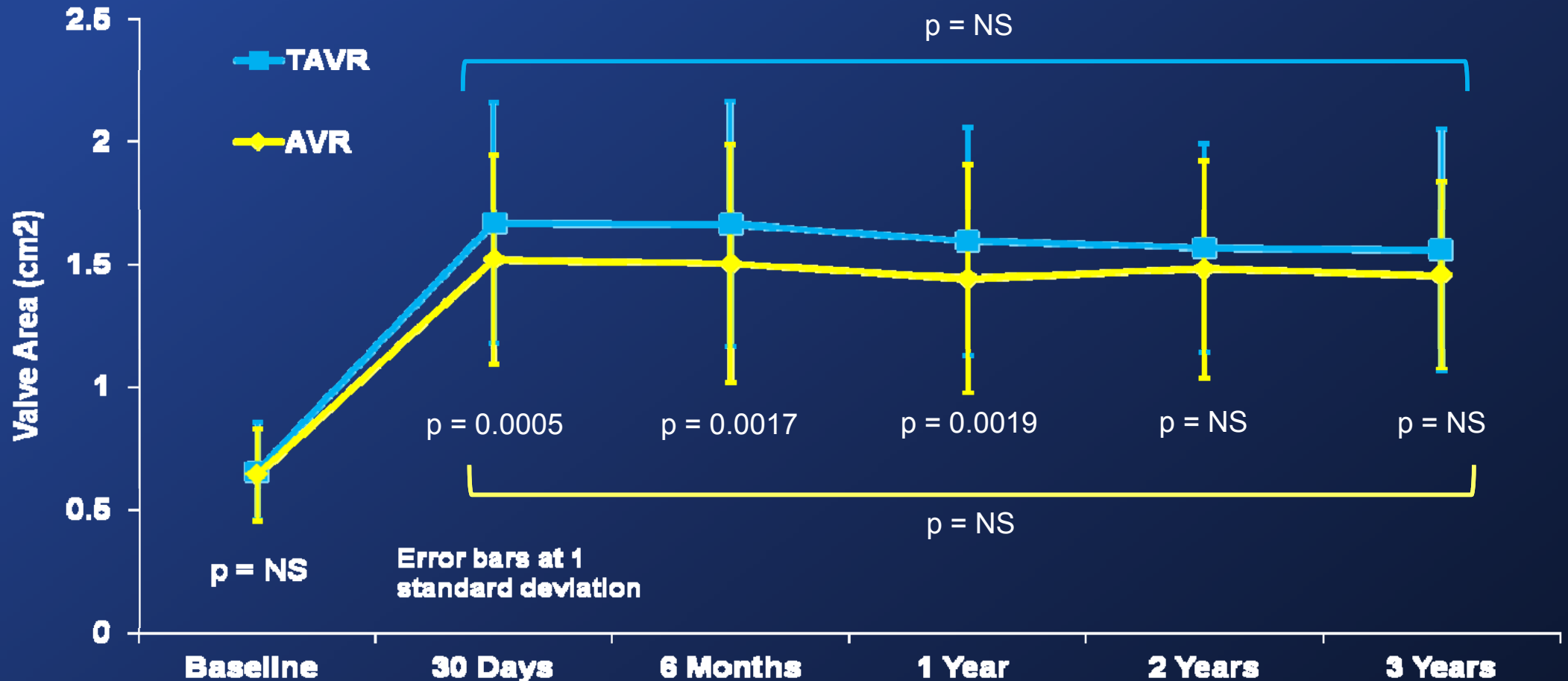
# Mean Gradient & Valve Area





# Echocardiographic Findings (AT)

## Aortic Valve Area

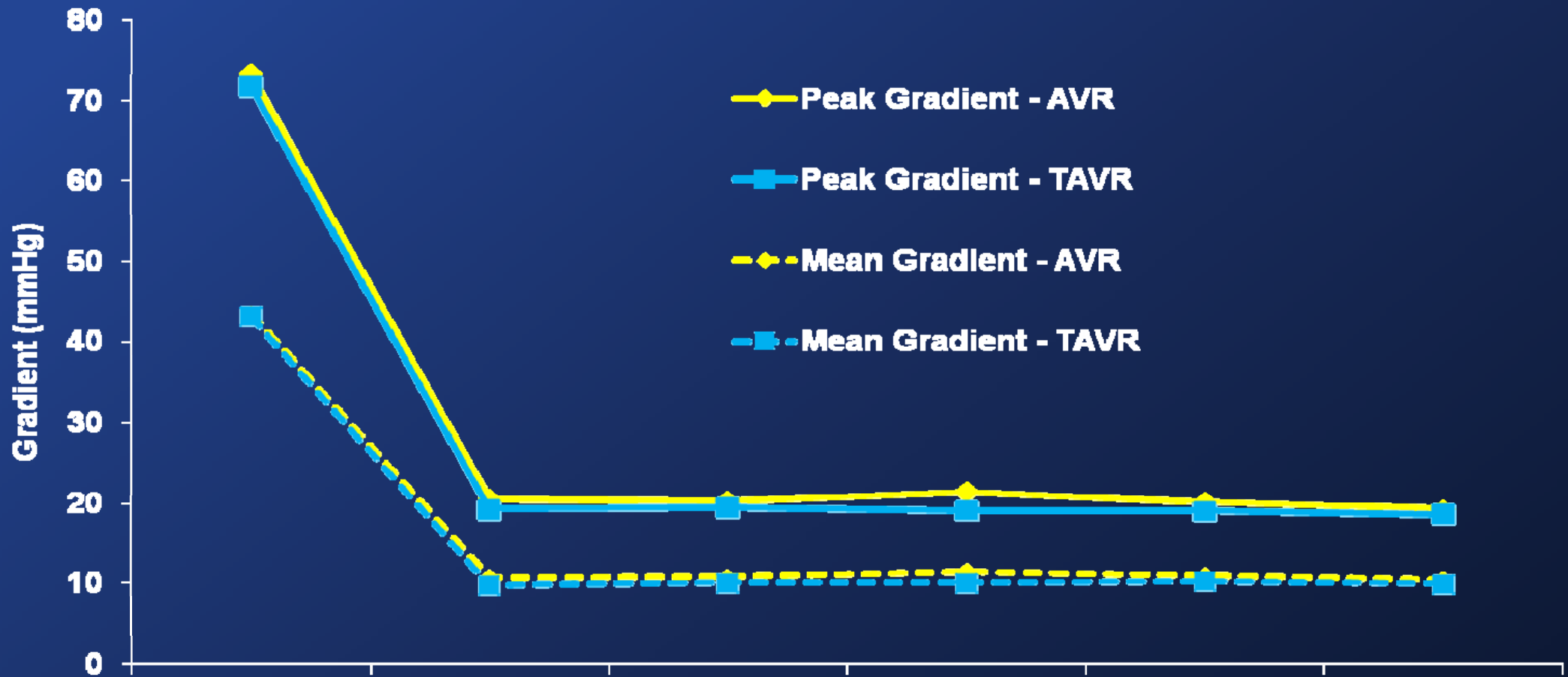


No. of Echos

TAVR	304	271	223	211	150	88
AVR	294	226	163	154	121	70

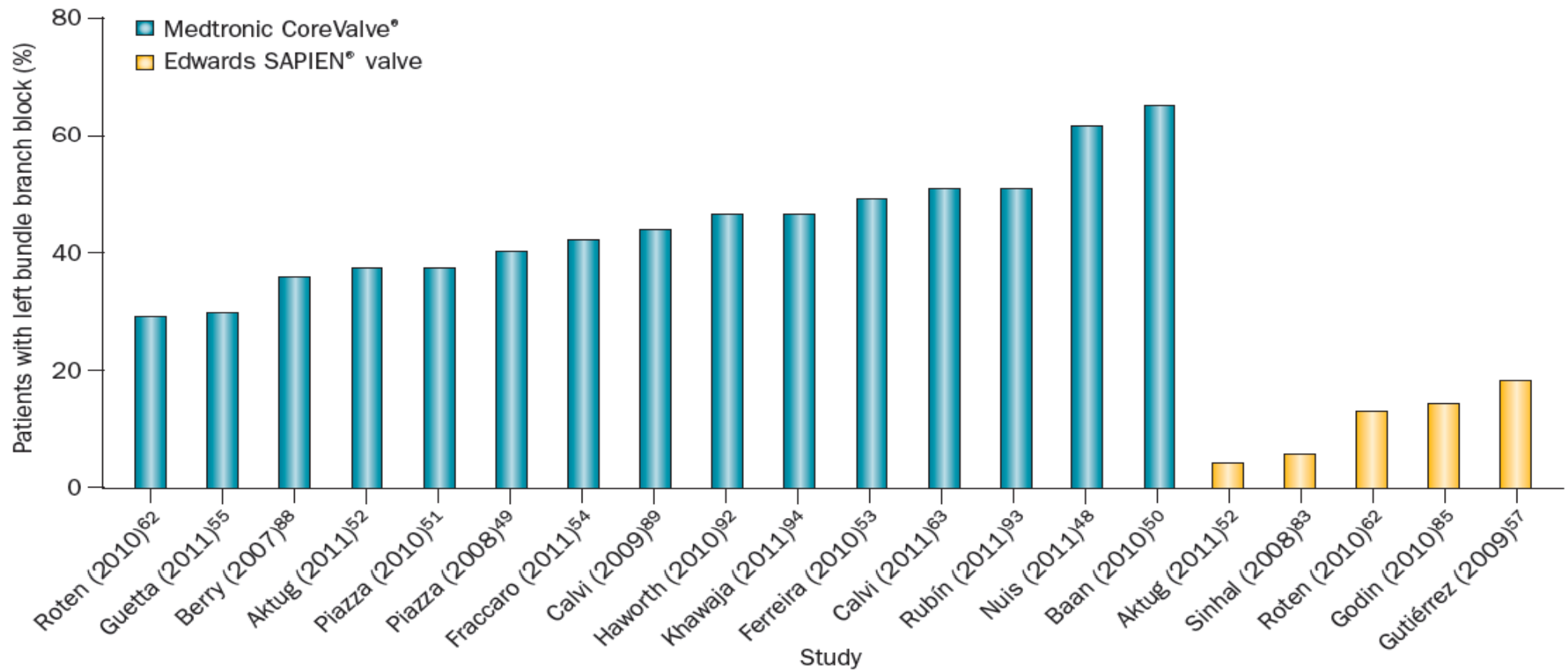
# Echocardiographic Findings (AT)

## Mean & Peak Gradients

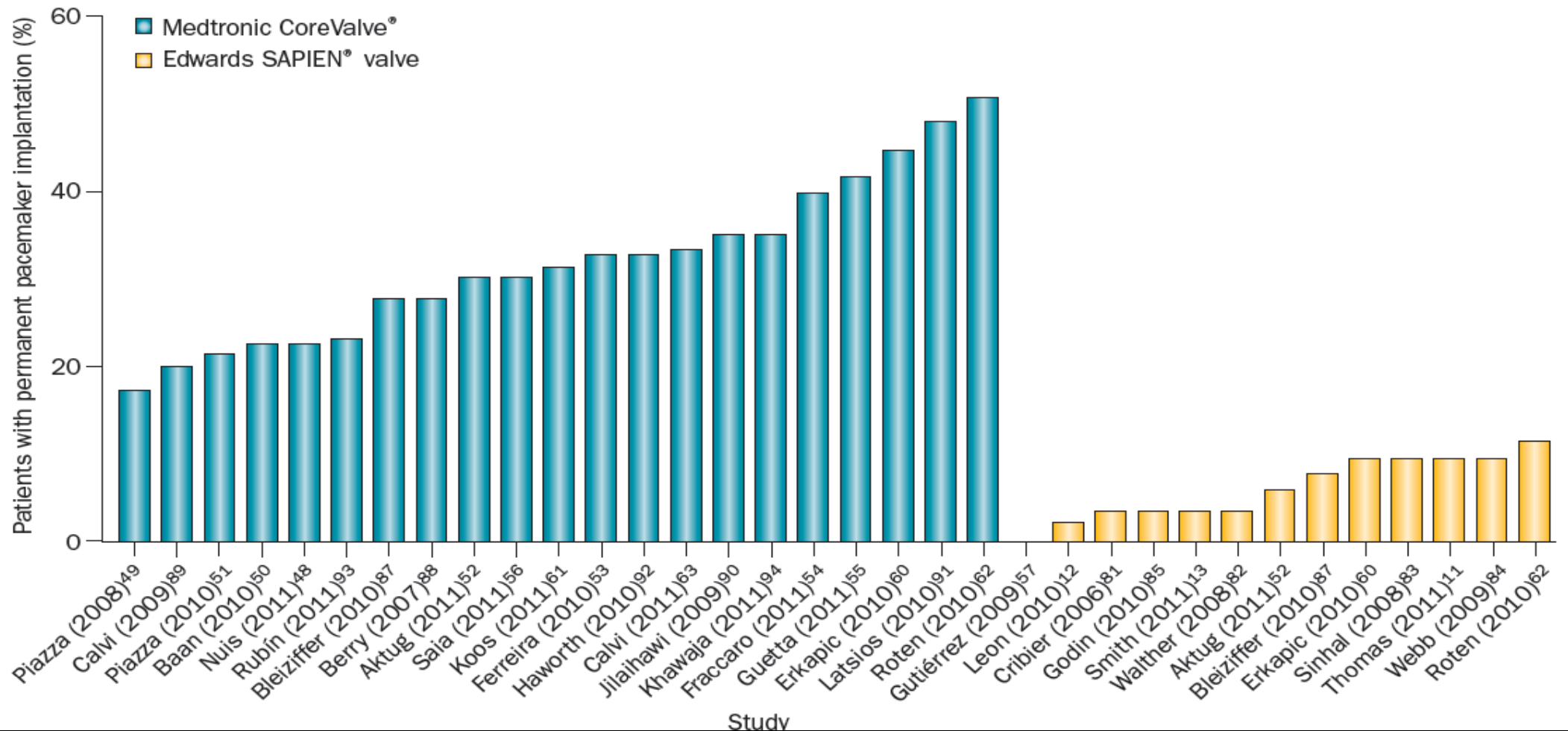


	Baseline	30 Days	6 Months	1 Year	2 Years	3 Years
No. of Echos						
TAVR	310	277	233	219	155	88
AVR	299	230	169	158	123	72

# Incidence of LBBB after TAVR with Medtronic CoreValve or Edwards-SAPIEN valve



# Incidence of Permanent Pacemaker Implantation after TAVR with Medtronic CoreValve or Edwards-SAPIEN valve



# Increased incidence of perivalvular AR with CoreValve?

Outcomes	All Patients (N= 3195)	Transfemoral Approach (N= 2361)	Transapical Approach (N= 567)	Subclavian Approach (N= 184)	P Value†	Edwards SAPIEN (N= 2107)	Medtronic CoreValve (N=1043)
Periprosthetic regurgitation at 30 days — no./total no. (%)					0.09		
Grade 0	724/1915 (37.8)	483/1418 (34.1)	173/334 (51.8)	37/112 (33.0)		515/1256 (41.0)	203/642 (31.6)
Grade 1	875/1915 (45.7)	671/1418 (47.3)	131/334 (39.2)	58/112 (51.8)		567/1256 (45.1)	301/642 (46.9)
Grade 2	301/1915 (15.7)	251/1418 (17.7)	30/334 (9.0)	15/112 (13.4)		169/1256 (13.5)	128/642 (19.9)
Grade 3	15/1915 (0.8)	13/1418 (0.9)	0	2/112 (1.8)		5/1256 (0.4)	10/642 (1.6)

# Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement

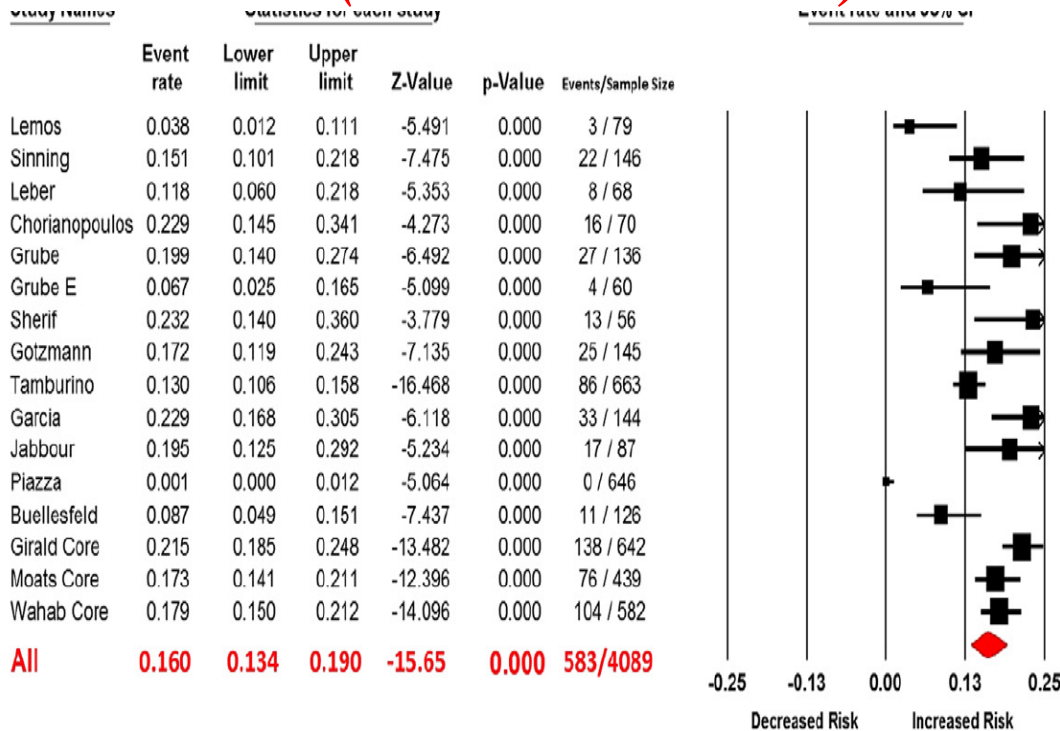
Meta-Analysis and Systematic Review of Literature

Meta-analysis of 45 studies  
12,926 patients

Moderate or severe AR is more common with CoreValve implantation

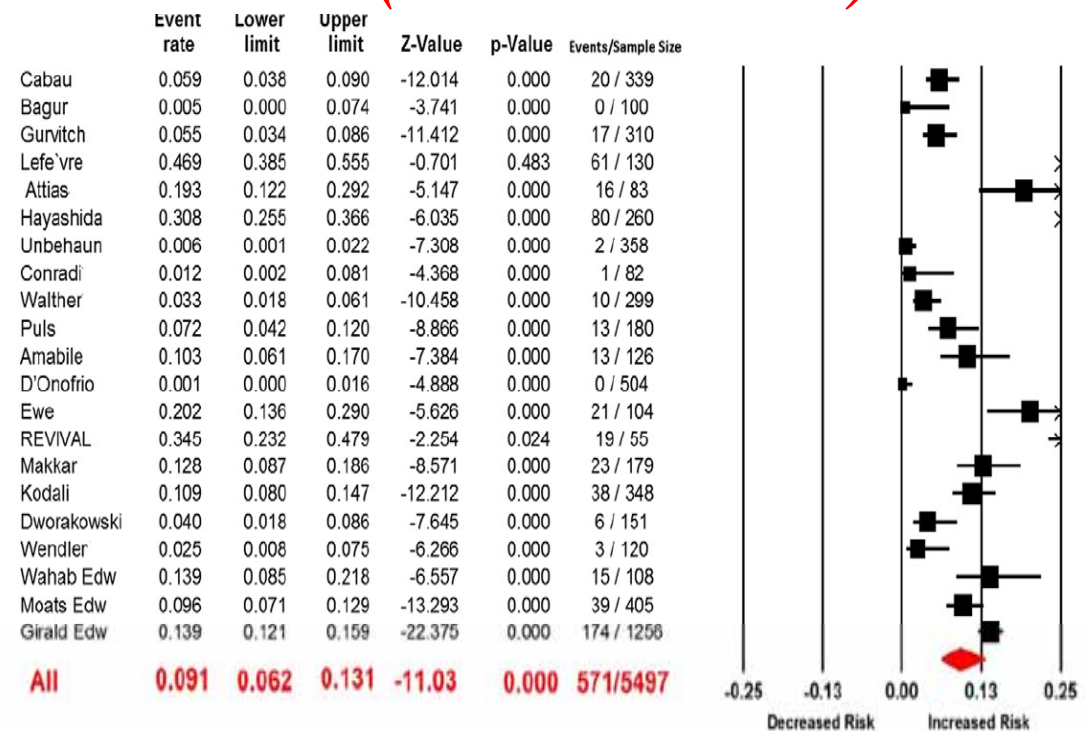
## Core Valve

**16% (95% CI 13.4-19.0)**



## Edwards Valve

**9.1% (95% CI 6.2-13.1)**



# Edwards SAPIEN vs SAPIEN XT Transcatheter Heart Valves



## NEW FRAME GEOMETRY

- Less metal content
- Lower crimp profile

## NEW FRAME MATERIAL

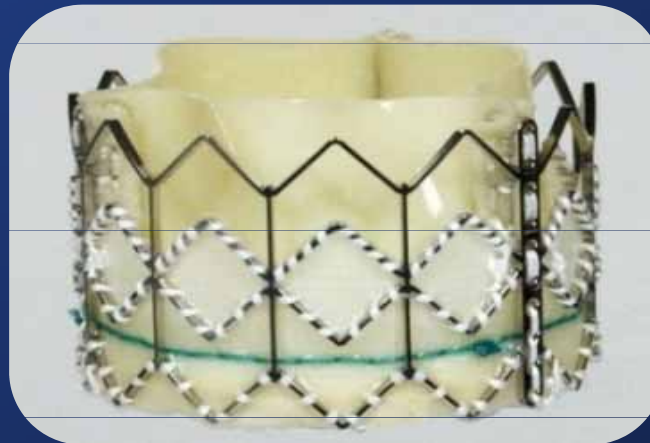
- Cobalt-chromium
- Greater tensile and yield strength

## NEW LEAFLET GEOMETRY

- Partially closed

## SAPIEN THV

Stainless Steel



## SAPIEN XT THV

Cobalt-chromium



RetroFlex 3



NovaFlex

# Procedural Factors (AT)



Events	SAPIEN (n=271)		SAPIEN XT (n=282)		p-value
	n		n		
Procedure time (mins)	271	109.6 ± 57.2	282	101.0 ± 43.2	0.18
Anesthesia time (mins)	266	212.0 ± 75.7	277	197.6 ± 60.8	0.02
≥ 2 valves implanted	10	3.7	3	1.1	0.05
Valve embolization	0	0	0	0	NA
Aborted procedure	8	3.0	2	0.7	0.06
Aortic rupture	2	0.7	1	0.4	0.62
Aortic dissection	1	0.4	1	0.4	0.99
IABP during procedure	6	2.2	1	0.4	0.06
Cardiopulmonary Bypass	5	1.8	5	1.8	0.99



# Vascular Complication Categories: At 30 Days (AT)



Events	SAPIEN (n=271)		SAPIEN XT (n=282)		p-value
	n	%	n	%	
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

# Where would I use Corevalve over Sapien ?

- Very calcified aortic root:less risk of root rupture
- Cases where the Sino-tubular junction is narrower than the annulus
- Very low LVEF where rapid pacing is a relative contraindication or increases the risk of the procedure
- Aortic regurgitation with little or no calcium
- When subclavian access is the best available choice in a given patient
- ? Select THV in aortic bioprosthetic valve:lower gradients



*Calcified Root  
& Asc Aorta*

cm

4

R

L



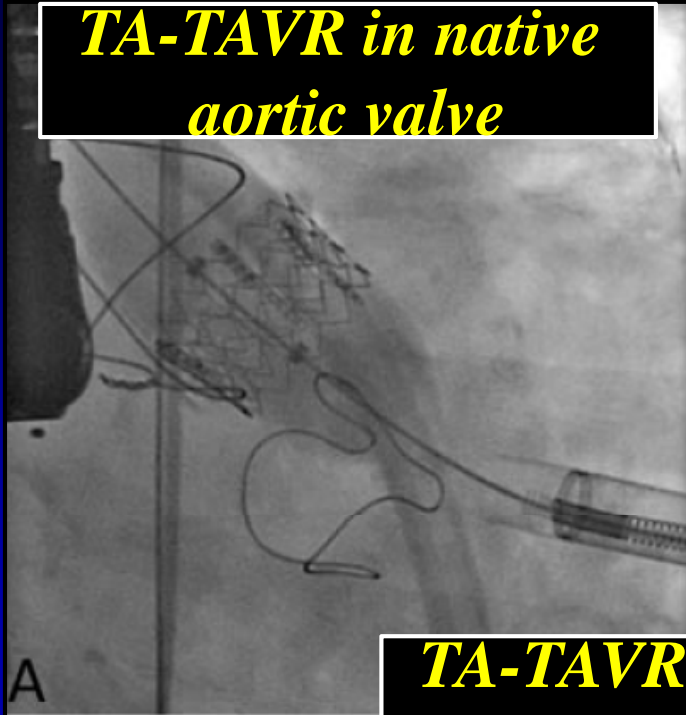
# Where would I use Corevalve preferentially over Sapien ?

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# Why is Sapien (Balloon Expandable) better?

- A trans-catheter heart valve for all native valves
- Versatile with different routes of implantation
- World wide experience in over 20,000 patients with first implant > 10 yrs ago
- Most robust data with survival, QOL, comparison to surgery, cost-effectiveness
- Valve durability at 3-4 years in core lab adjudication
- Safer in some aspects (paravalvular AI, conduction system issues)

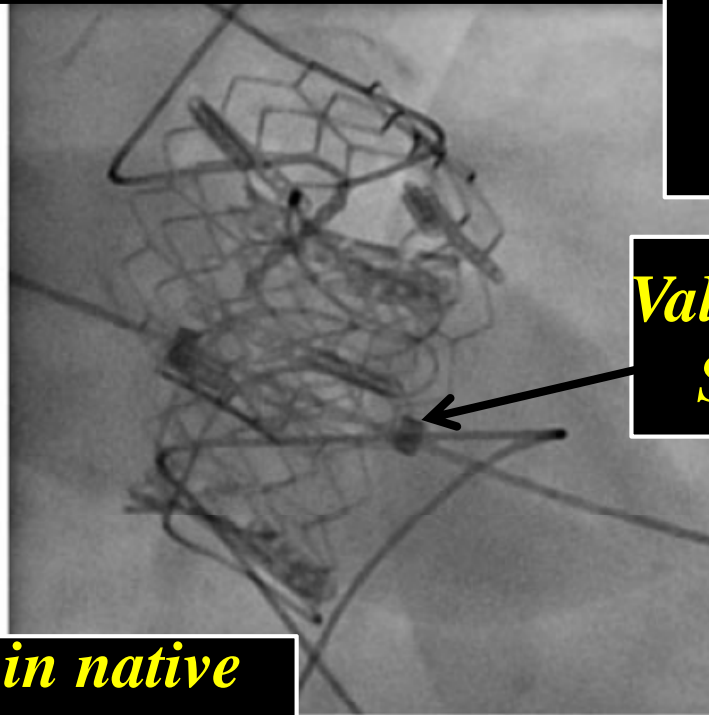
*TA-TAVR in native aortic valve*



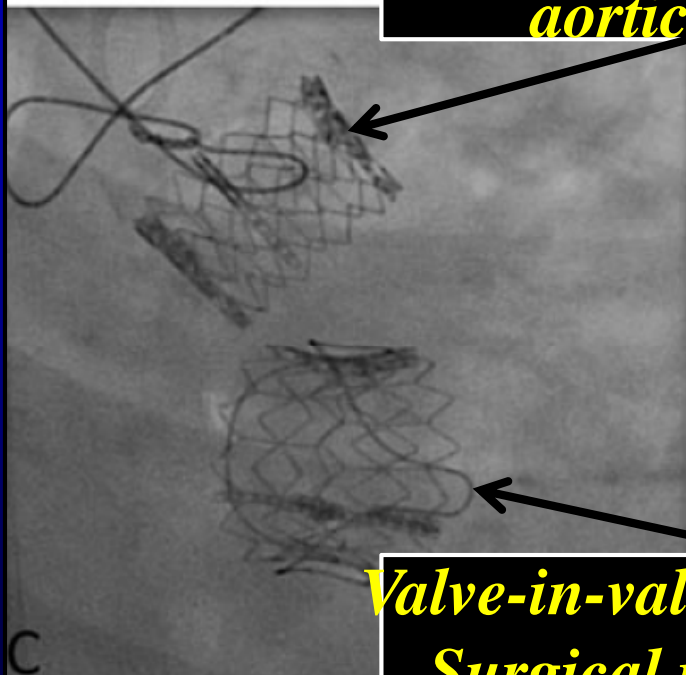
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*Anson Cheung and John Webb*

*Valve-in-valve implantation in Surgical mitral prosthesis*



*TA-TAVR in native aortic valve*



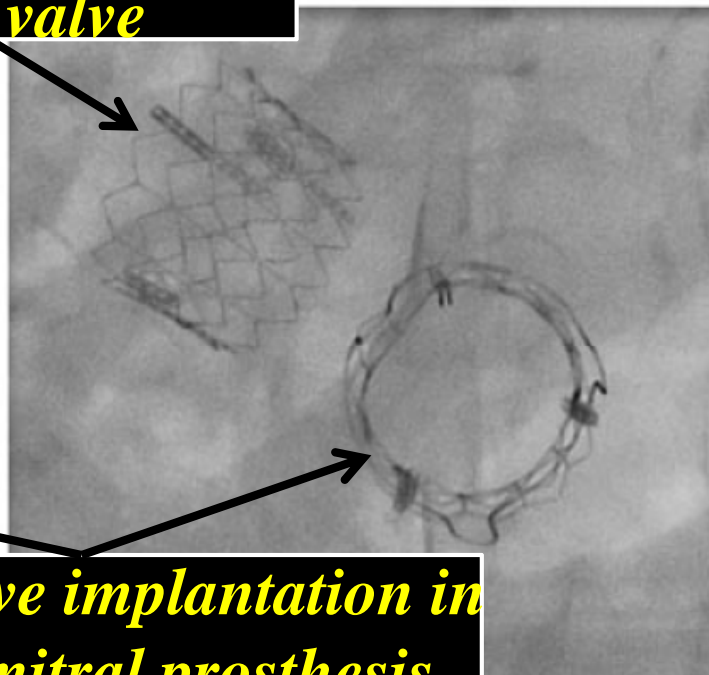
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*TAVR in native aortic valve*

*AND*

*Valve-in-valve of surgical mitral valve*

*Valve-in-valve implantation in Surgical mitral prosthesis*



# Is there high quality evidence to answer key questions:

- Is it versatile? YES
- Does it save lives? YES
- Does it improve quality of life? YES
- Is it as good as surgery? YES
- Does it have cost effectiveness data? YES
- Is there good valve durability data? YES
- Does it have FDA approval? YES



## **A note of humility/concession ...**

Lack of evidence of benefit does not equate with evidence of lack of benefit....