Structural Heart Disease Percutaneous Valvular Interventions: The current and next chapters…..

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ACC Chapter Guidelines for this Morning's Lecture

- Don't mention there is a beautiful resort right outside 18 holes of golf
- Do address the questions: When should we refer to Structural Cardiologist
  What's new in Structural Valve Disease
- Don't Give the Usual TAVR Talk

(which is really too bad because I have a pretty awesome Usual TAVR Talk)

Multiple Disclaimers

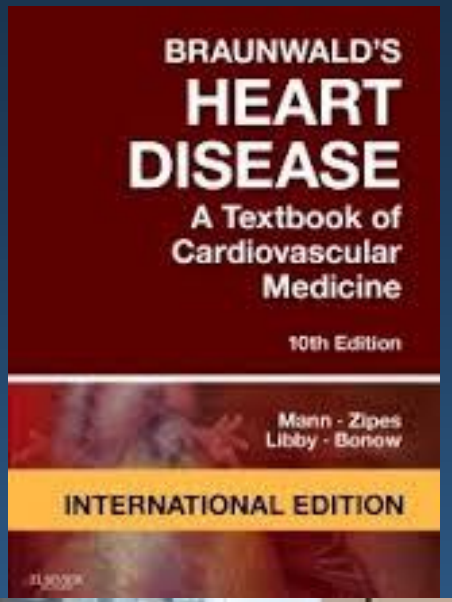
- Investigator/Proctor/Consultant for Boston Scientific Lotus Valve
- Investigator/Proctor for Edwards Laboratory Sapien Valve
- Investigator for Abbott MitraClip
- Investigator for Tendyne Mitral Prosthesis
- I too would like to be outside today

When to Refer to Structural Cardiologist?

- ….begs the question of WHAT is a Structural Cardiologist

1950's Only One Type of Cardiologist: Clinical Cardiologist

Clinical Cardiologist: Eugene Braunwald



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In Memorandum: Rolf Gunner, MD Jan 27, 1926 –March 18, 2017 Age 91

Consummate Clinical Cardiologist and Role Model

Navy Scholarship NU MD 1949
Bronze Star in Korea
Cook County Resident->Chief Cardiology
Loyola Medical Center 1986 Bronze Star
Post Retirement BraveHearts Veterans Program

Per Son Bill: Family Dog Unintentional Lipid Study Subject

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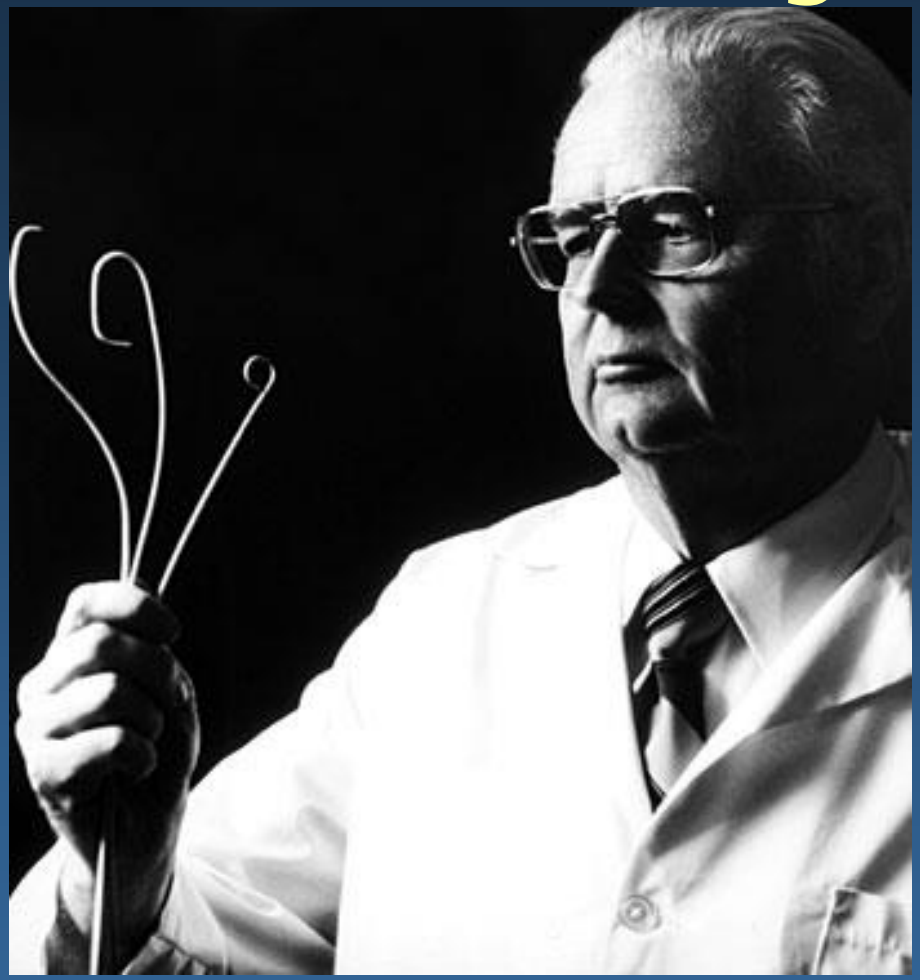
1960: Invasive Cardiologist

Invasive Radiologist



Melvin P Judkins, MD
Catheters engineered to go where intended if unthwarted by the operator

1970s: Cardiologist in Two Flavors

Non Invasive

Invasive

September 1977: Interventional Cardiologist

Andreas Gruntzig
Insightful, cool and dashing…

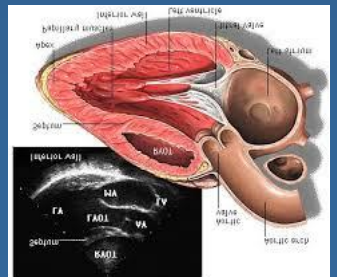
1980's Cardiologists: Five Subtypes

Clinical/Non Invasive

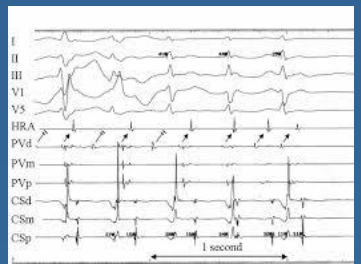
Invasive/Non Interventional

INVERVENTIONAL

Imagers (not Imaginers)



Electrophysiologists



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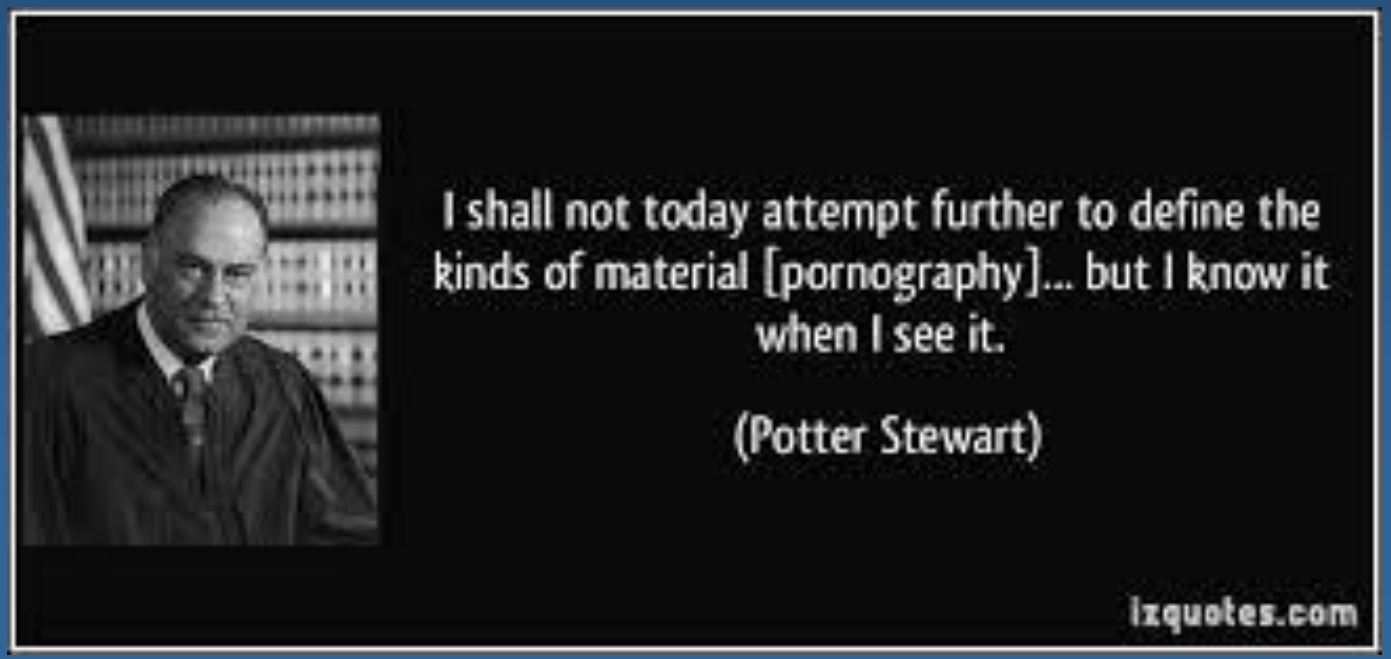
Current Decade: One More Cardiologic Discipline

What is Structural Heart Disease?

To many of us it is little like Supreme Court Justice Potter Stewart's 1960 definition of Pornography:

"I know it when I see it"



Defining Structural Heart Disease Outline of Structural Fellowship

Catheterization and Cardiovascular Interventions 76:E90–E105 (2010)

Core Curriculum

Interventional Fellowship in Structural and Congenital Heart Disease for Adults

Carlos E. Ruiz,[1*] MD, PhD, FACC, FSCAI, Ted E. Feldman,[2] MD, FACC, FSCAI, Ziyad M. Hijazi,[3] MD, FACC, FSCAI, David R. Holmes, Jr.,[4] MD, FACC, FSCAI, John G. Webb,[5] MD, FACC, FSCAI, E. Murat Tuzcu,[6] FACC, FSCAI, Howard Herrmann,[7] MD, FACC, FSCAI, and Gerard R. Martin,[8] MD, FACC

Training for structural and adult congenital heart disease interventions remains undeveloped. With the advent of recent percutaneous interventions for the treatment of structural and valvular heart disease, such as transcatheter aortic and pulmonary valve implantation, mitral valve repair, and the expansion of shunt closure procedures, there is a clear need to define the training requirements for this category of procedures. The training needs to be aligned with the goals and priorities of a basic or advanced level and be categorized into acquired and congenital. This document will define the training needs and knowledge base for the developing field of structural heart disease intervention.

Key words: core curriculum; structural heart disease; training

Confused by the term? Not alone….

EDITOR'S PAGE

Structural Heart Disease?

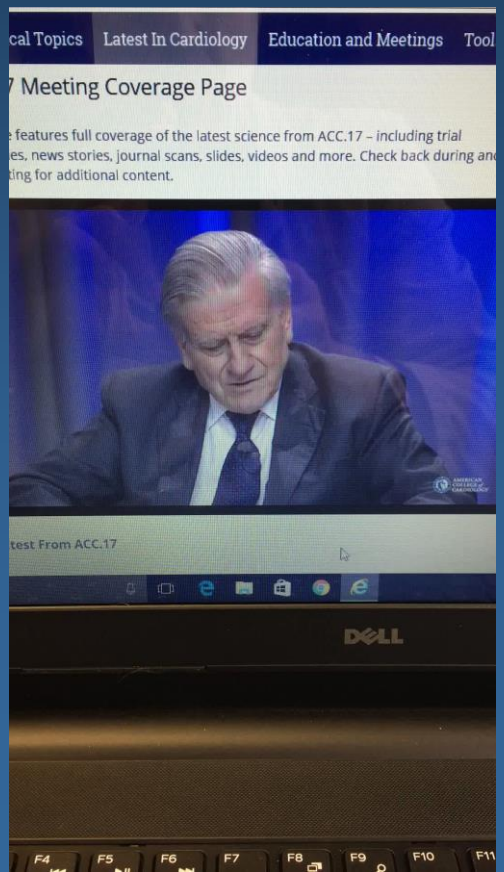
Anthony N. DeMaria, MD, MACC
Editor-in-Chief, Journal of the American College of Cardiology

Having gotten my frustration with the term "translational research" off my chest, I decided to address the other expression that I find confusing, that is, structural heart disease. This term is appearing with increasing frequency throughout cardiology. Patients are said to have structural heart disease, programs have been developed specifically to deal with the problem, individual cardiologists proclaim themselves to be experts in the area, and even *JACC* is complicit in having devoted an entire focus issue to the subject (1). All of this attention has been directed to the entity of structural heart disease despite the fact that it remains uncertain, at least to me, what exactly is meant by the name.

ACC 2017 Some Still Frustrated by Term Structural Cardiologists

Dr. Valentin Fuster:

“So called structuralists”



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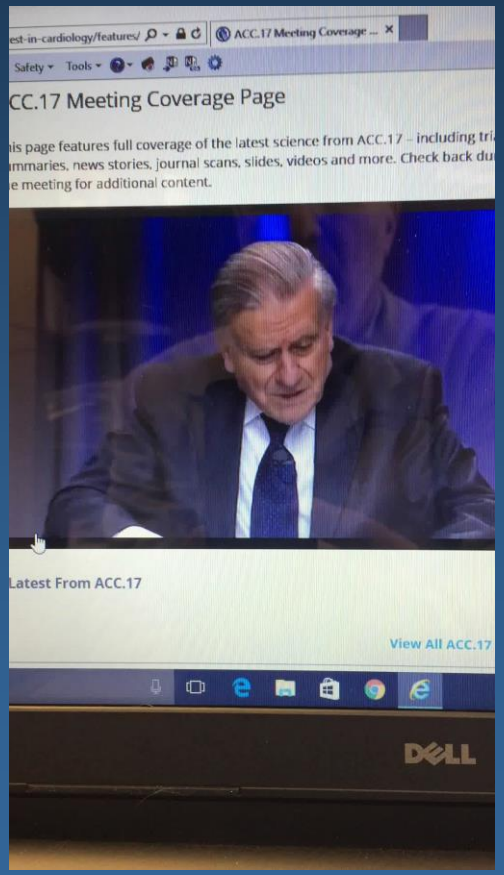
ACC 2017 Dr. Fuster Digs in Deeper



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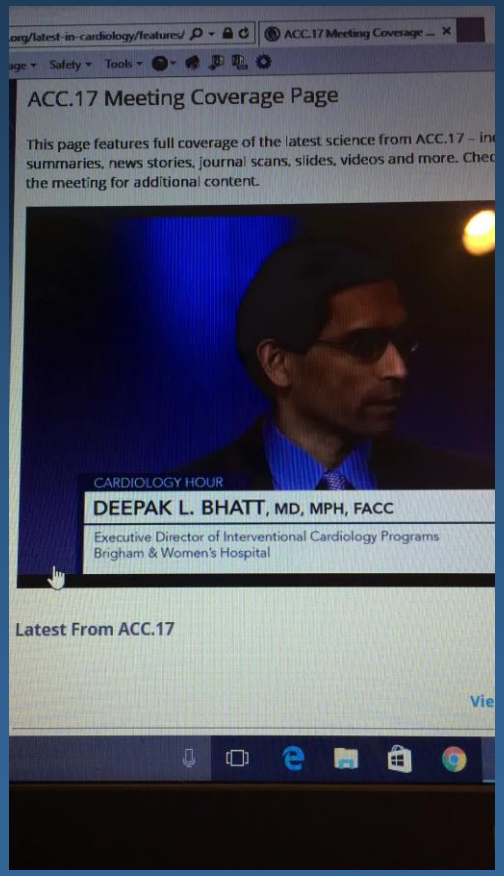
Deepak Clears the Air



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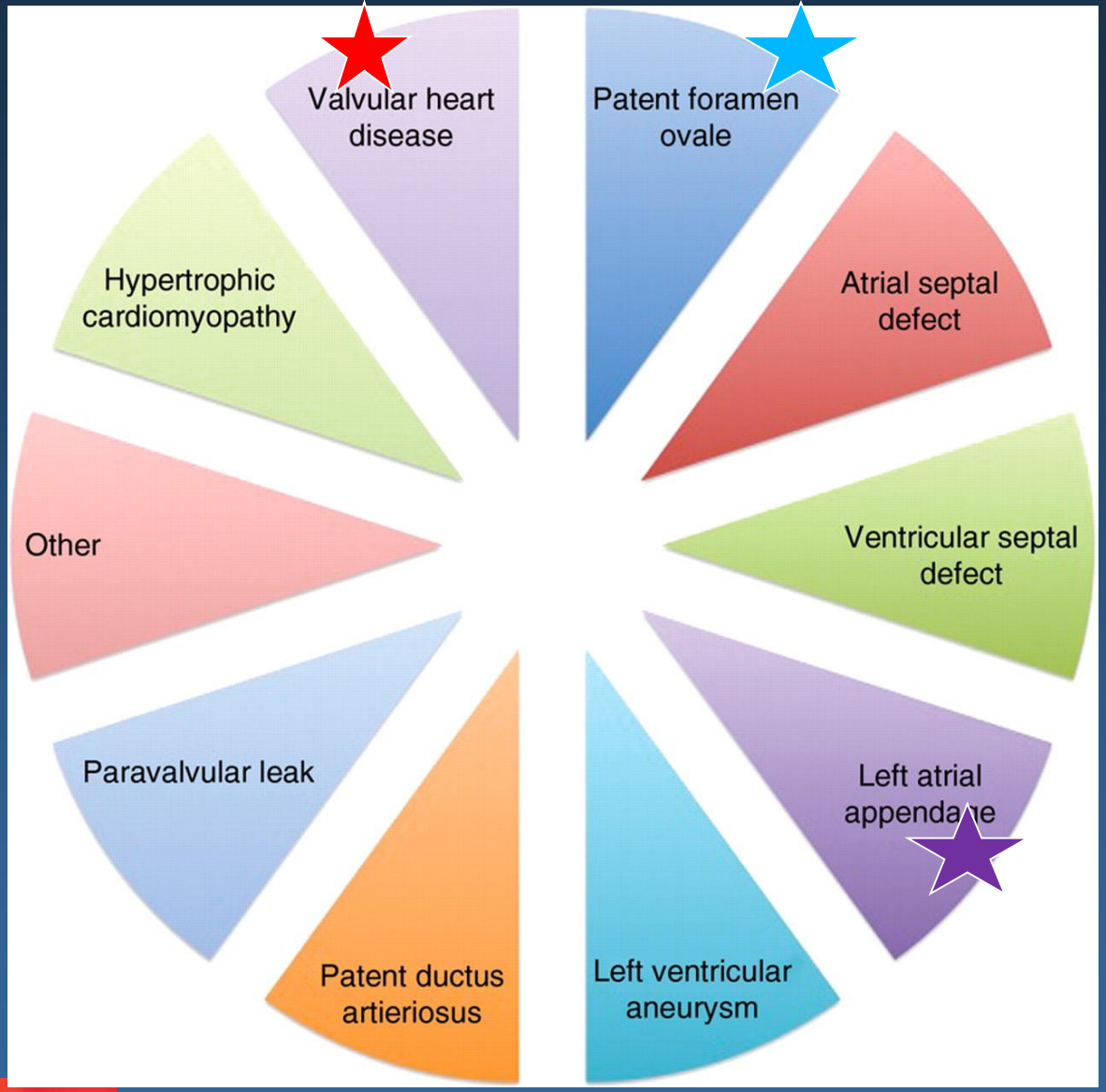
As I said above, it seems to me that what we are really talking about is noncoronary heart disease that is susceptible to percutaneous interventional therapy. Of course, such phraseology would not be well suited to describe the expertise of a highly trained physician or the special advantage of a focused and designated program. It may well be that I am making too much of the lack of precision of the term; the most important thing is that everyone understands what is meant when it is used

Anthony N. DeMaria, MD, MACC
Editor-in-Chief, Journal of the American College of Cardiology

Working definition: percutaneous non coronary interventions

In the end we are back to Chief Justice Potter's approach:
"We know it when we see it"

What is the spectrum of interventional structural heart disease?

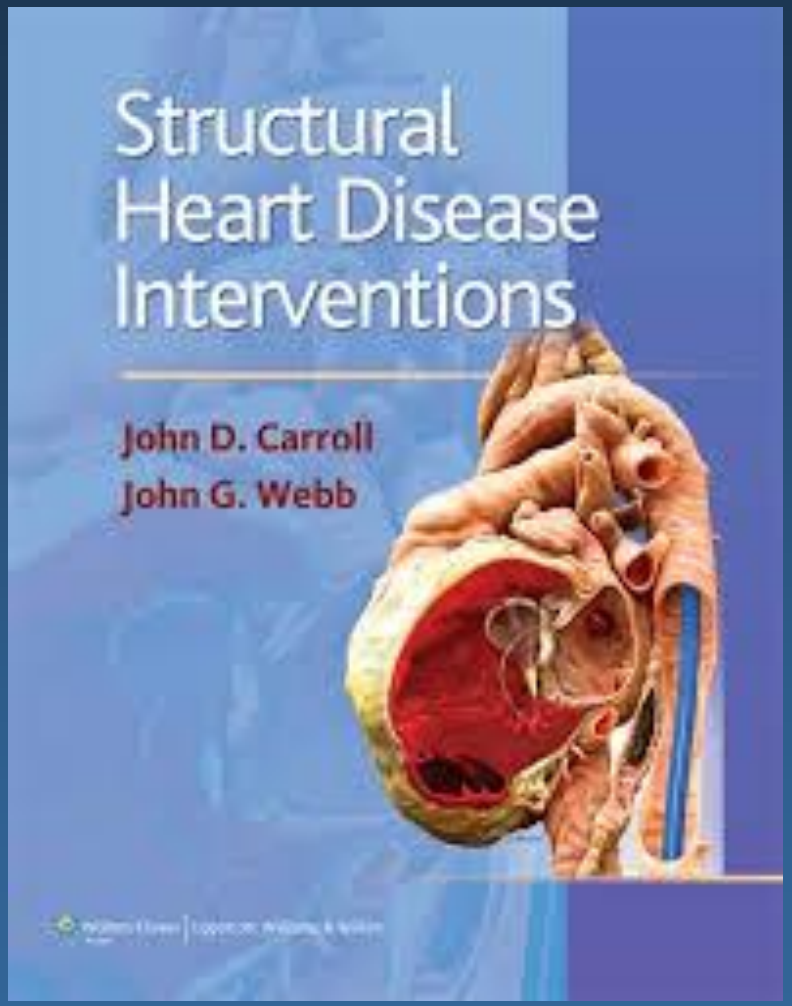


*most recent approvals

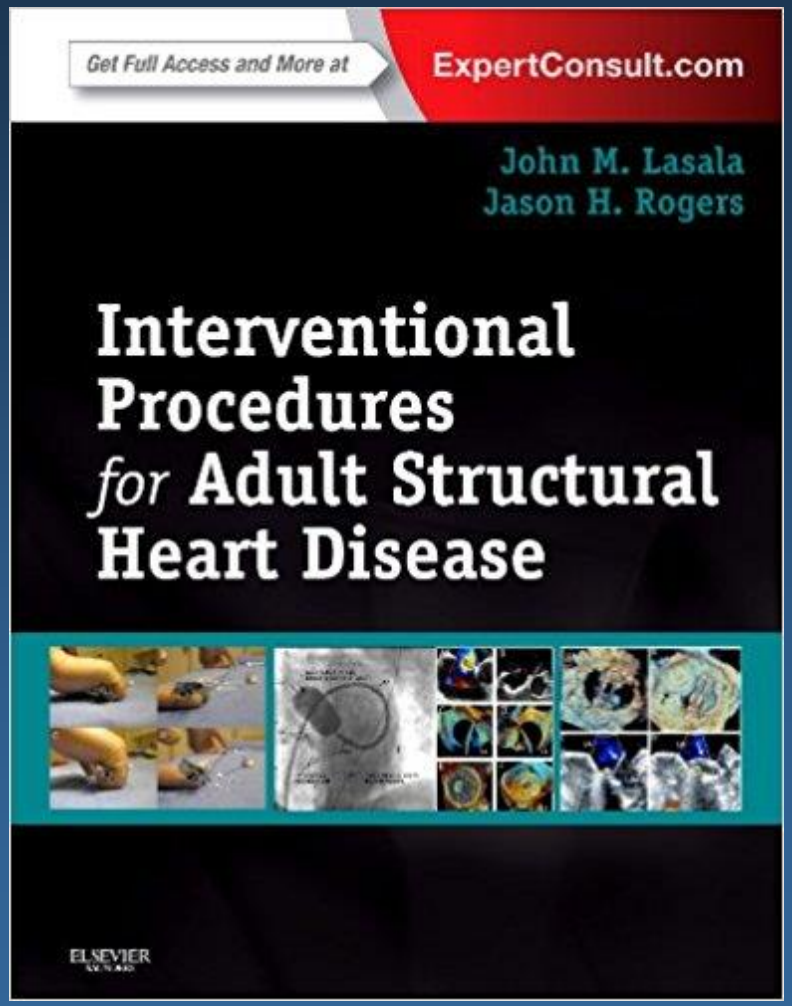
European Heart Journal Supplements

Steinberg D H et al. Eur Heart J Suppl 2010;12:E2-E9

Full Spectrum Structural Heart



Amazon $204



Amazon $128

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Most Recent Non Valvular FDA Approval: Percutaneous PFO Closure for Cryptogenic Stroke

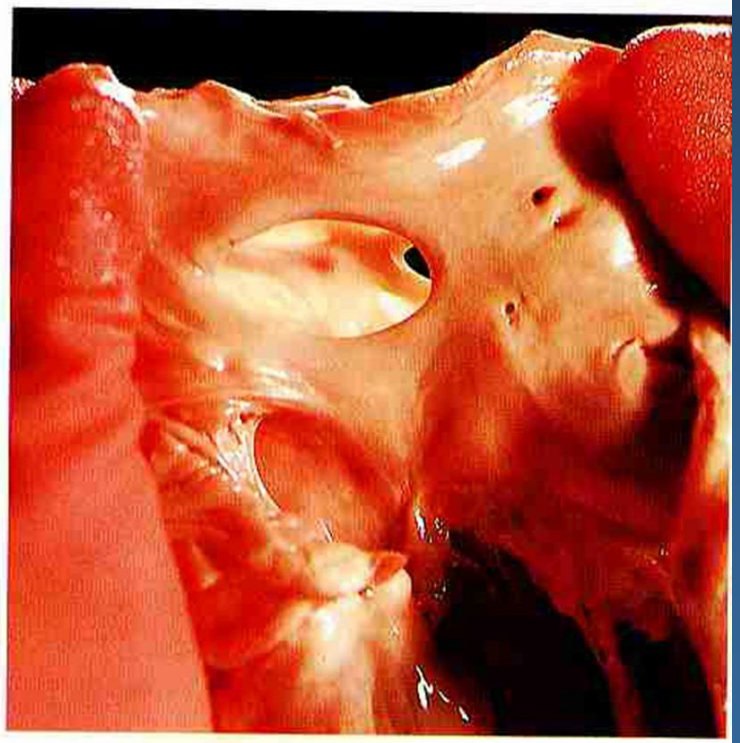

Fig. 6.69 Patent foramen ovale. Heart held against the light (viewed from the right ventricle).

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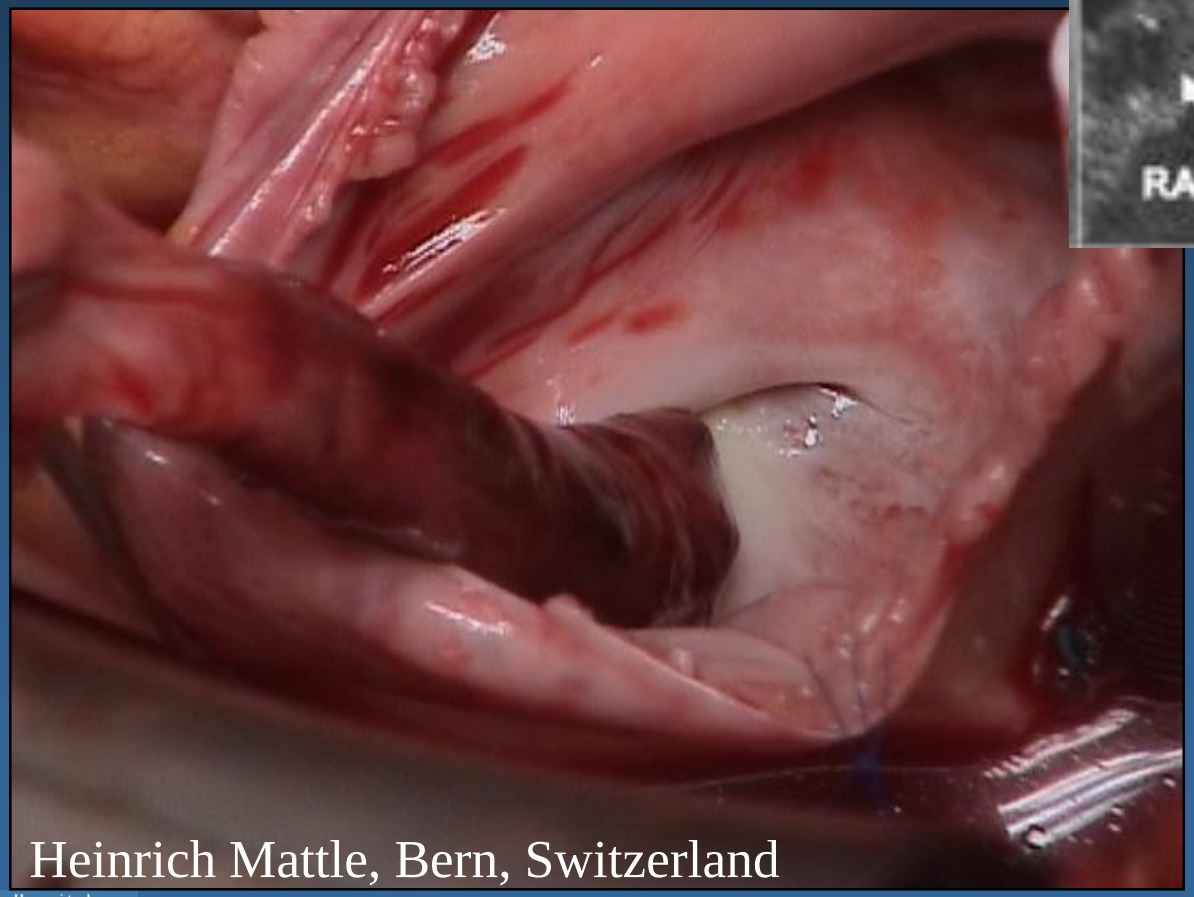
Potential Relationship PFO and Stroke is Not New

In 1877, Cohnheim performed a necropsy on a young woman who had died from a stroke. He hypothesized that a clot passing through the patent foramen ovale must have caused her demise. Thus, the first description in medical literature on paradoxical embolism appeared.

Cohnheim J. *Thrombose und Embolie: Vorlesungüber allgemeine Pathologie*. Berlin, Germany: Hirschwald; 1877:134.

PFO and Paradoxical Embolism

Clot caught in the act



Heinrich Mattle, Bern, Switzerland

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Provided by AGA Medical

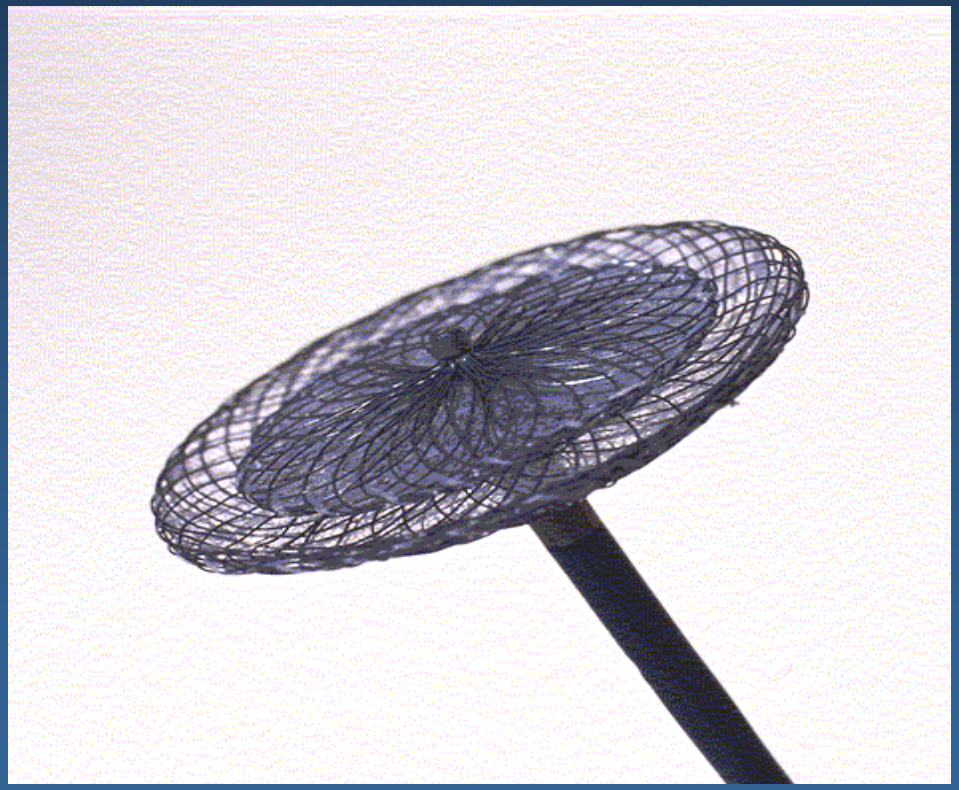
Humanitarian Device Exemption for PFO Devices

FDA restricted use to patient with PFO who failed therapy with a TIA/CVA despite "conventional" drug therapy defined separately as a therapeutic INR

- CardioSeal PFO (NMT)
  received HDE February 2000
- Amplatzer PFO (AGA)
  received HDE April 2002

AGA Medical Amplatzer PFO Device

- Self Expandable
- Nitinol wire .005”-.006”
- Internal polyester fabric
- Short connecting waist
- Sizes 18, 25, 35mm based on RA disc size
- RA disc larger than LA disc in 25 and 35 mm sizes
- CE Mark Approved
- Over 4000 world wide implants as of 2004



RESPECT Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Closure of Patent Foramen Ovale versus Medical Therapy after Cryptogenic Stroke

John D. Carroll, M.D., Jeffrey L. Saver, M.D., David E. Thaler, M.D., Ph.D., Richard W. Smalling, M.D., Ph.D., Scott Berry, Ph.D., Lee A. MacDonald, M.D., David S. Marks, M.D., and David L. Tirschwell, M.D., for the RESPECT Investigators*

N =980 (Aug 2003 to Dec 2011)
PFO and prior stroke
Randomized Antiplatelet or Coumadin v AGA Device

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NEJM May 2013

RESPECT Trial: AGA Medical

Intention to treat: did not make significance due to pre device implant strokes

In the as-treated cohort device versus medical therapy (5 events vs. 16 events; hazard ratio, 0.27; 95% CI, 0.10 to 0.75; P = 0.007).

CONCLUSIONS

In the primary intention-to-treat analysis, there was no significant benefit associated with closure of a patent foramen ovale in adults who had had a cryptogenic ischemic stroke. However, closure was superior to medical therapy alone in the prespecified per-protocol and as-treated analyses, with a low rate of associated risks. (Funded by St. Jude Medical; RESPECT ClinicalTrials.gov number, NCT00465270.)

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

For Immediate Release

October 28, 2016

FDA News Release

FDA approves new device for prevention of recurrent strokes in certain patients

The U.S. Food and Drug Administration today approved the Amplatzer PFO Occluder device. The PFO Occluder reduces the risk of a stroke in patients who previously had a stroke believed to be caused by a blood clot that passed through a small hole in the heart, called a patent foramen ovale (PFO), and then traveled to the brain.

"The Amplatzer PFO Occluder provides a non-surgical method for doctors to close a PFO," said Bram Zuckerman, M.D., director of the Division of Cardiovascular Devices in the FDA's Center for Devices and Radiological Health. "But as the device labeling clearly states, patients need to be evaluated carefully by a neurologist and cardiologist to rule out other known causes of stroke and help ensure that PFO closure with the device is likely to assist in reducing the risk of a recurrent stroke."

When to referred to Structural Cardiology

- PFO with Cryptogenic Stroke

- What's next:

  Insurance Company "buy in"

  (Wisconsin carriers more liberal than IL)

- Confirmation

  REDUCE Trial Gore Device/CNS Imaging

Valvular Interventions

Four Valves, Eleven Leaflets and 30 Minutes

- Aortic (well established therapy)
- Mitral (next frontier)
- Pulmonic (pediatricians)
- "The Forgotten Valve" Tricuspid

Calcified Aortic Stenosis

Primarily a disease of the elderly

Calcified Aortic Stenosis

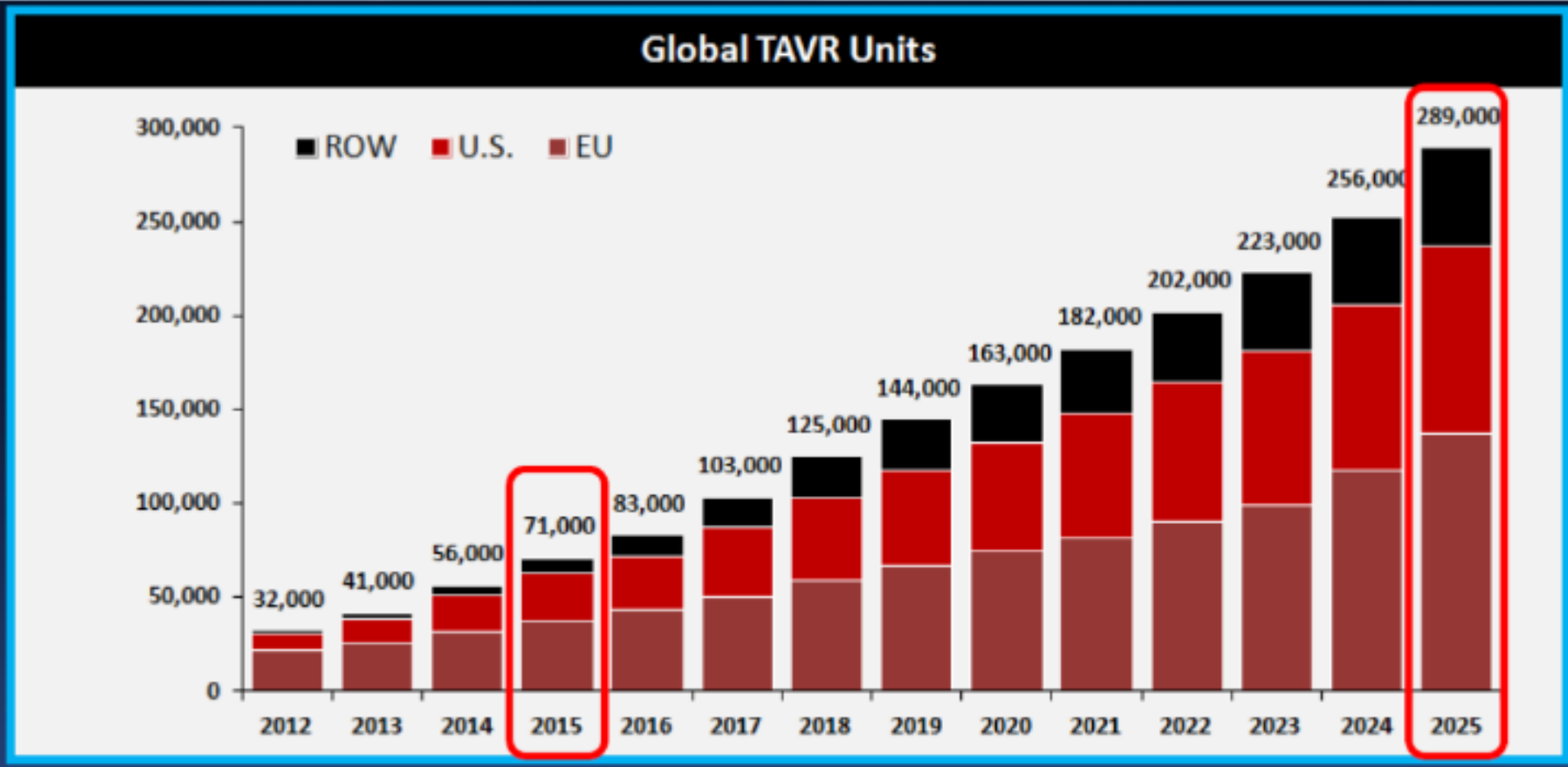
Primarily a disease of the elderly

Incidence is increasing

Aortic Stenosis: Increasing prevalence as Patients Live Longer and Celebrate more birthdays

- AHA: AS most common acquired valve disease in elderly patients affecting 3% of those over 75 years of age
- US Government: Number of Americans over the age of 85 will exceed 11 million in the next 20 years
- If we do the math….more than 3.3 million cases of AS in the US by 2036

TAVR: Projected 4 fold growth over 10 years



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

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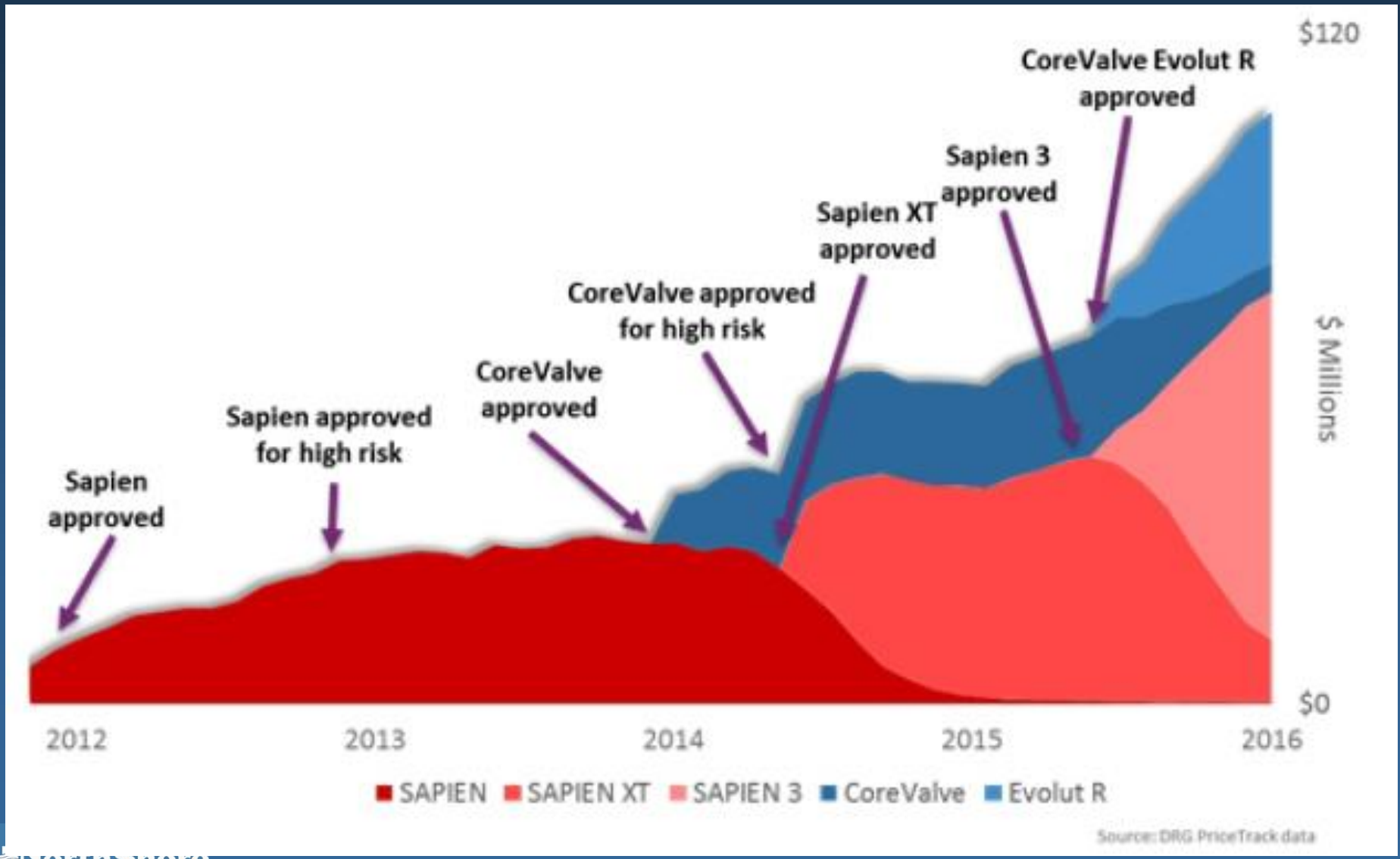
M Leon, TVT 2016

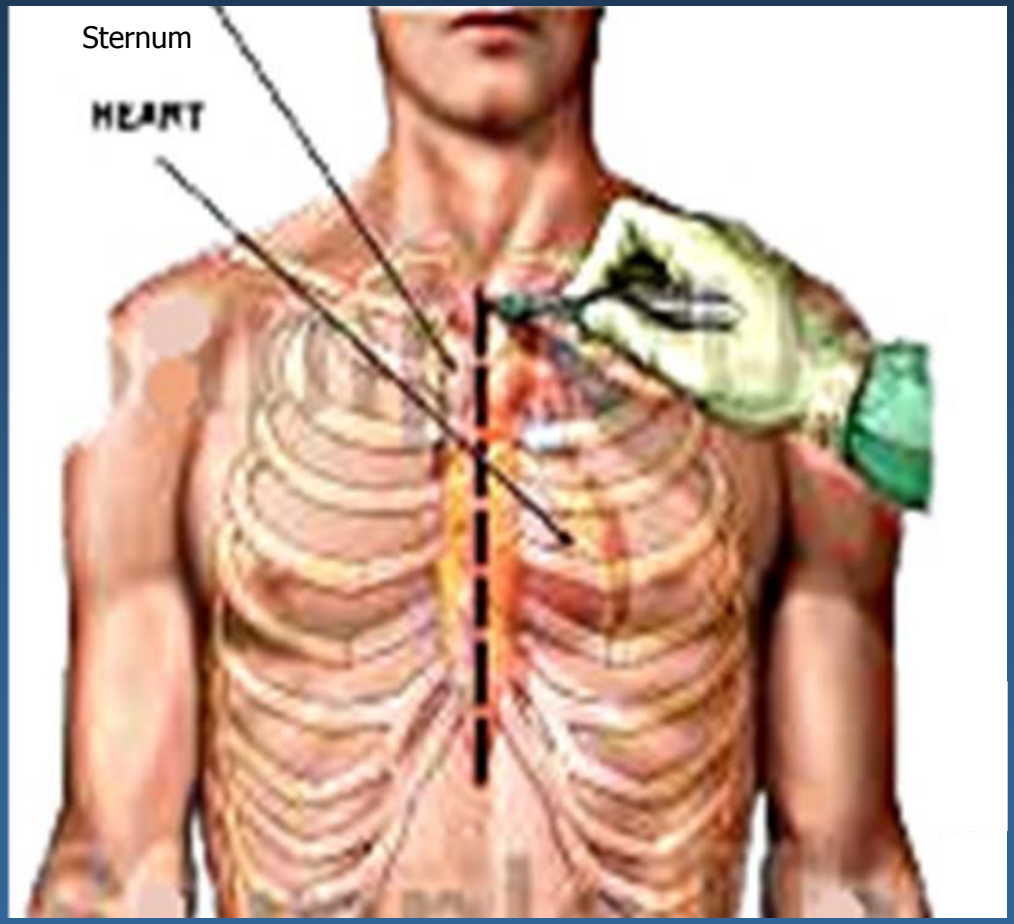
US TAVR Industry Growth $1.1 M



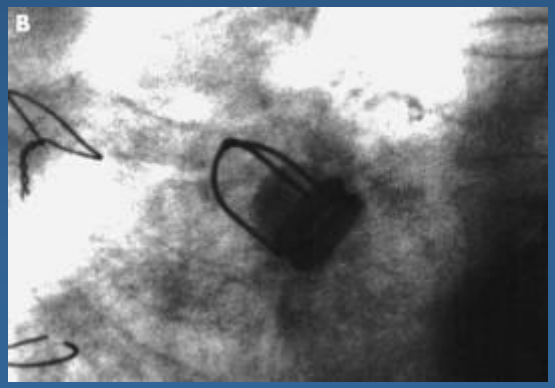
Aortic Stenosis is A Mechanical Problem

Requires a mechanical solution

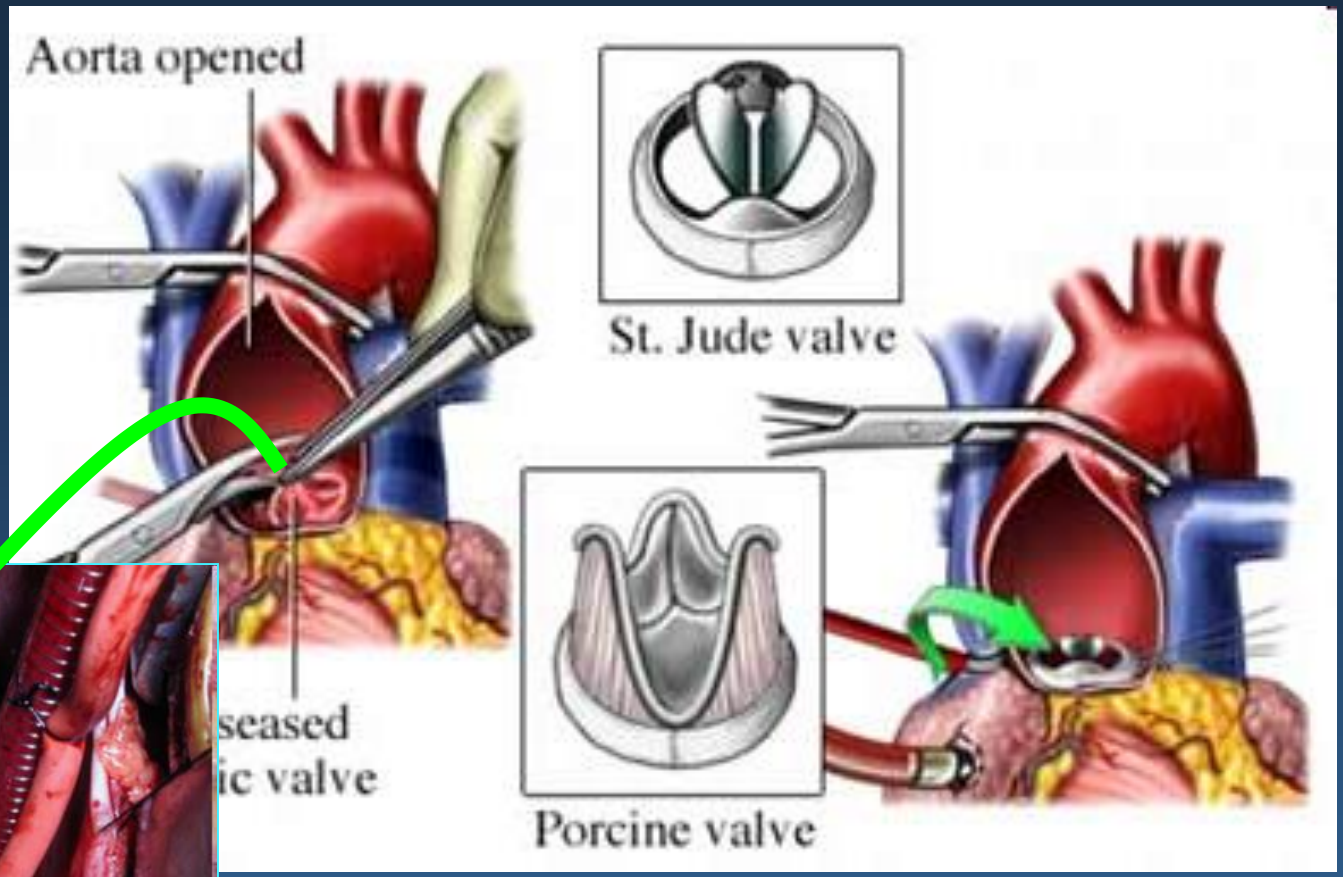
Mechanical Solution: Open Surgery

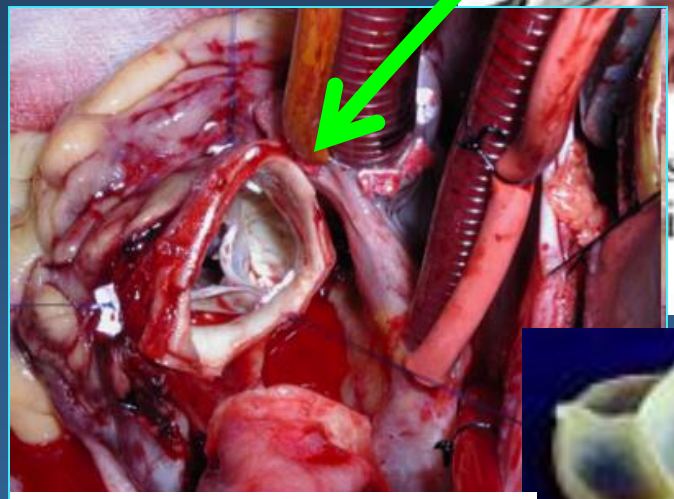


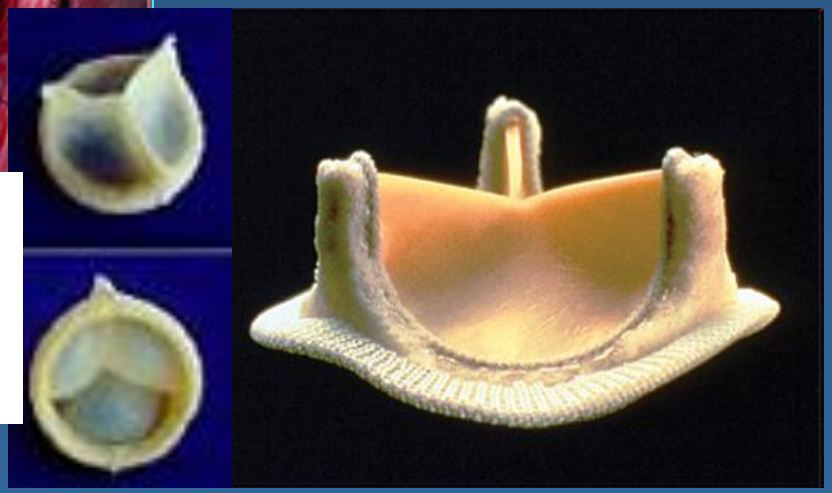
B Starr 1960



Multiple "Improved" Surgical Valves

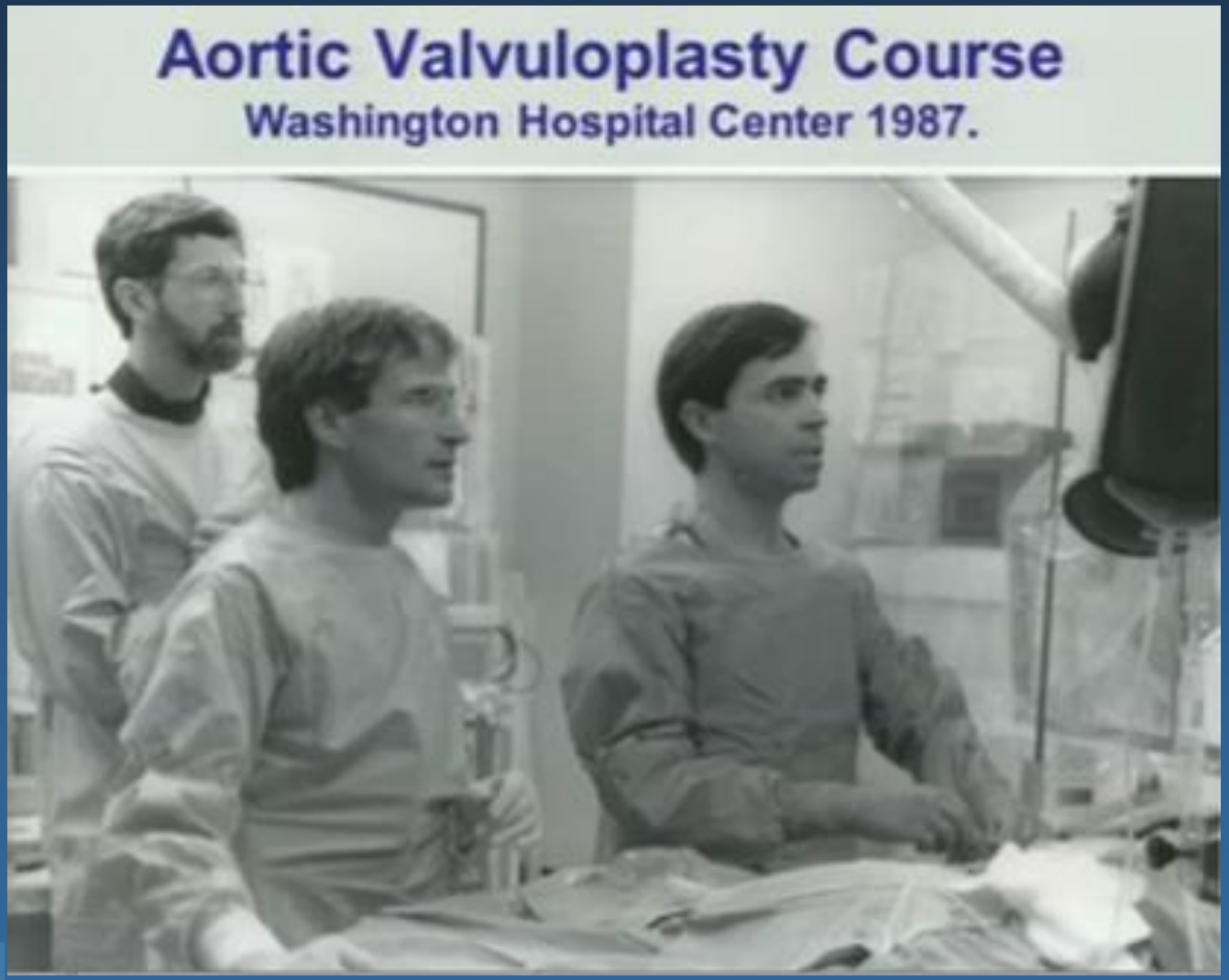




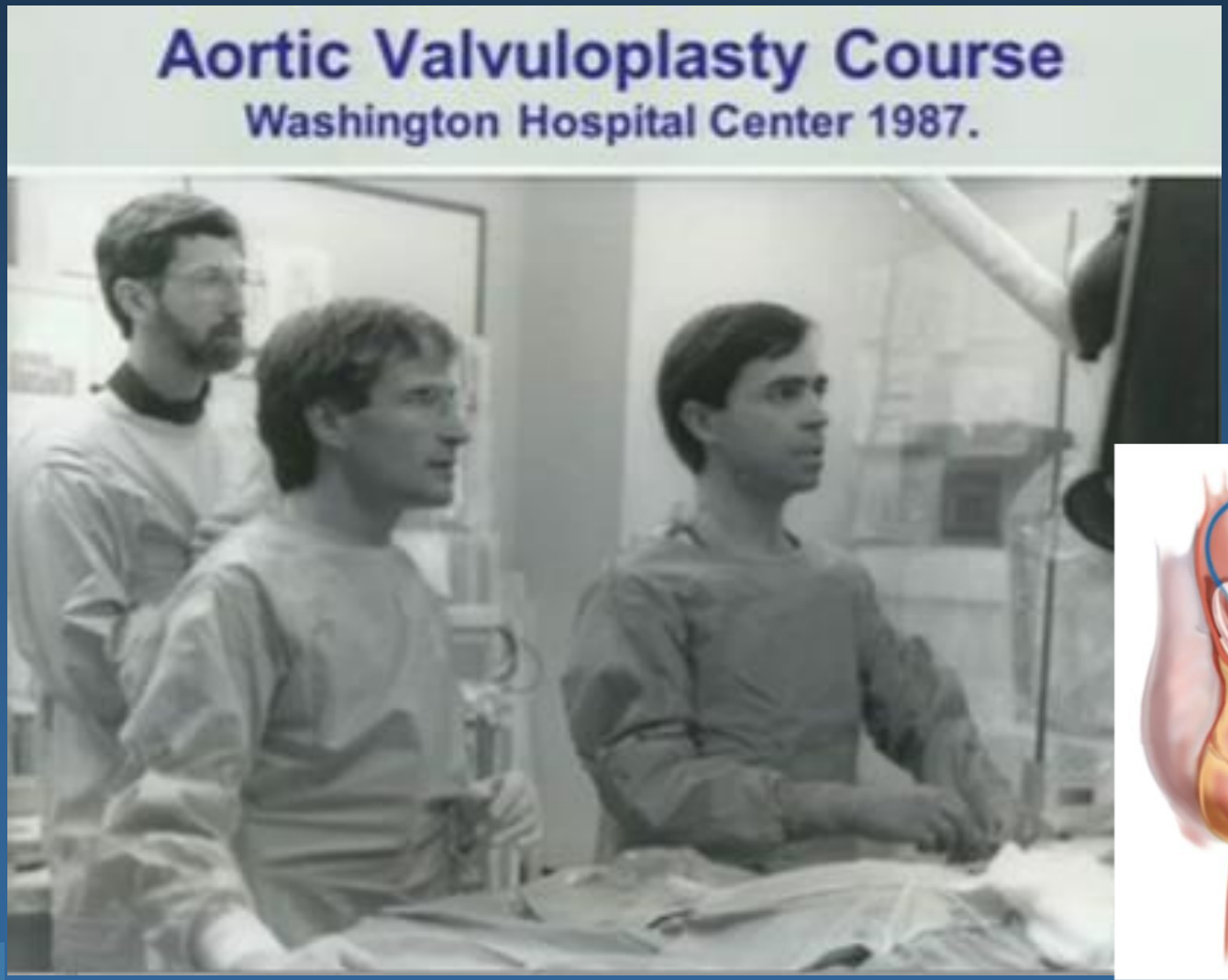


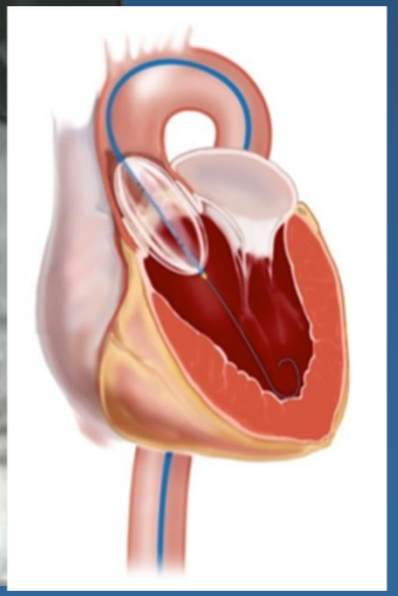
Onyx

The Search for Non Surgical Aortic Stenosis Therapy Begins: Balloon Aortic Dilatation



The Search for Non Surgical Aortic Stenosis Therapy Begins: Balloon Aortic Dilatation





BAV: Balloon Aortic Valvuloplasty

- A Cribier, MD 1985
- Limited improvement in valve area
- Limited durability due to restenosis with nearly 100% restenosis by 12 months
- Role stand alone therapy delegated historically to palliative therapy for elderly inoperable patients and occasionally as a bridge to surgical therapy

Non Surgical Solution: Transcatheter Aortic Valve Replacement TAVR

Fast Forward 16 years 1986 First BAV
First In Man 2002: Now A Revolution Still in Evolution

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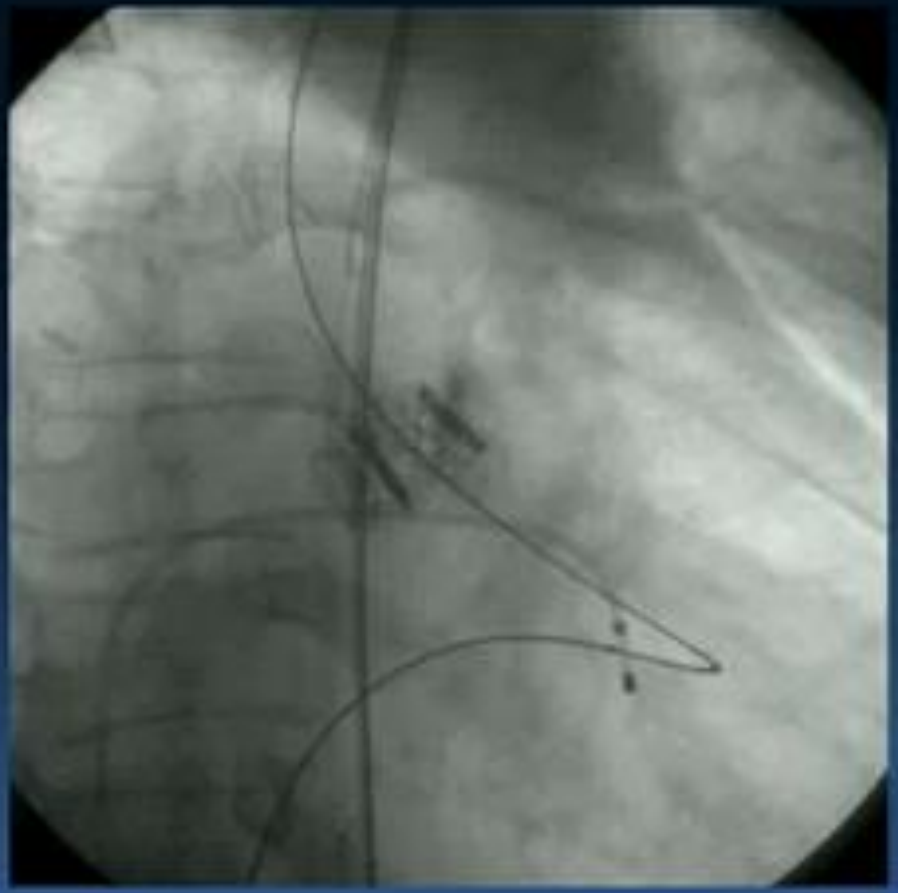
April 16, 2002, FIM-TAVI, Transseptal



Valve deployment

April 16, 2002, FIM-TAVI, Transseptal

15 min post-TAVI

Dr. Alain Cribier
First-in-Man PIONEER

April 16, 2002

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION
American Heart Association. Learn and Live.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Nov 2002

- Not hard to believe French celebration involved alcohol
- Remarkable that the first patient was only 67 year old

TAVR: From initial case in France to US Trials

Given demographics of AS and the politics of the FDA, TAVR has had its US roots as a therapy for Older Patients with High Surgical Risk

Original US TAVR studies "High Risk" patients for SAVR or "Inoperable" for SAVR

- Four Major Initial US Trials:

  PARTNER IB Inoperable

  ave age 83.1 STS 11.2

  PARTNER IA High Risk

  ave age 83.6 STS 11.8

  CoreValve US Extreme Risk

  ave age 83 STS 10.3

  CoreValve US High Risk

  ave age 83.2 STS 7.3

Original Four Major US TAVR studies "High Risk" or "Extreme Risk"mpatients all have similar favorable results

PARTNER IB 5 yr mortality:

TAVR better than meds

PARTNER IA 5 yr mortality:

TAVR not inferior to Surgery

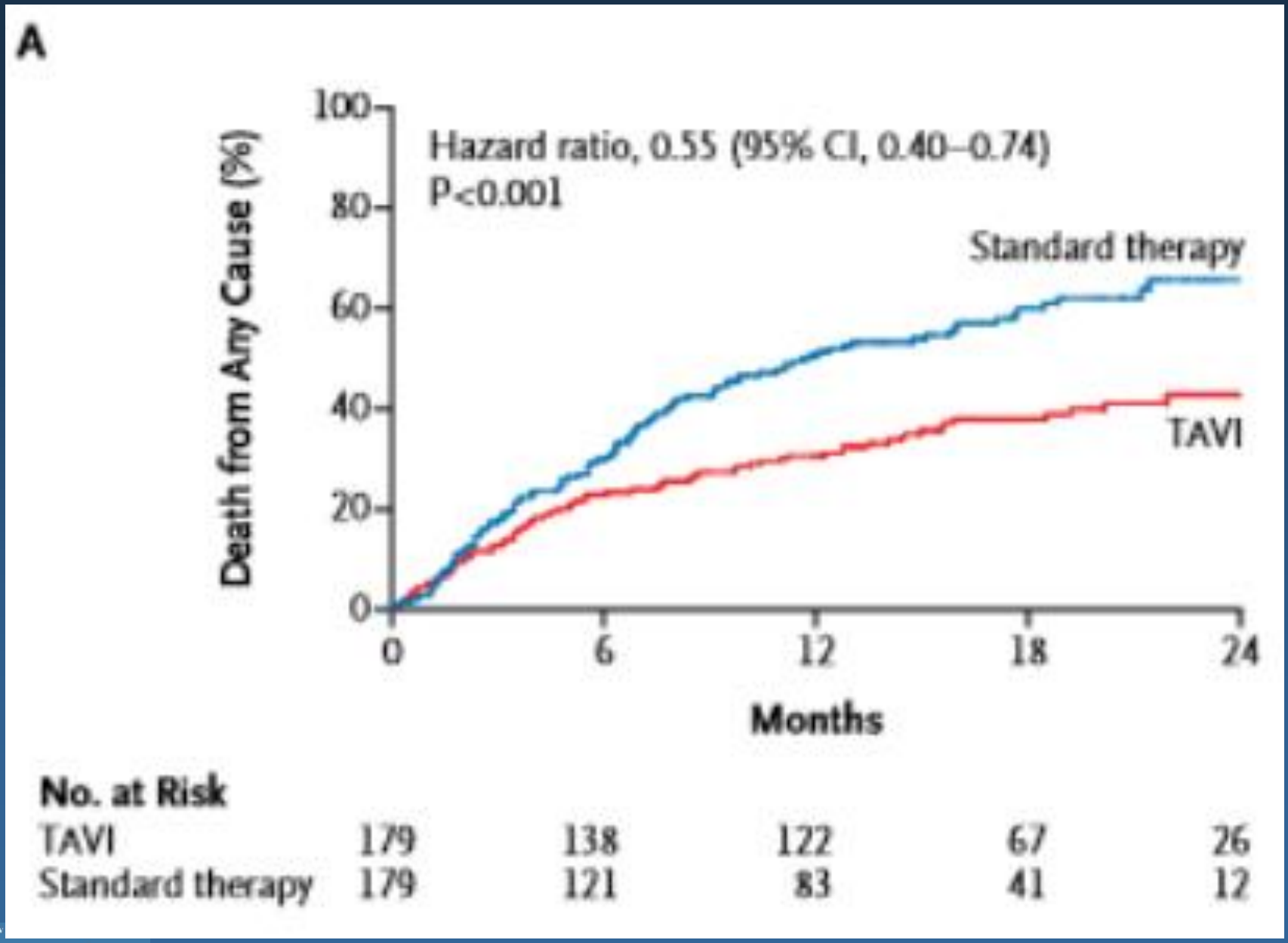
CoreValve US Extreme Risk:

TAVR better than Meds

CoreValve US High Risk:

TAVR better than Surgery

PARTNER 1B Inoperable one year outcomes



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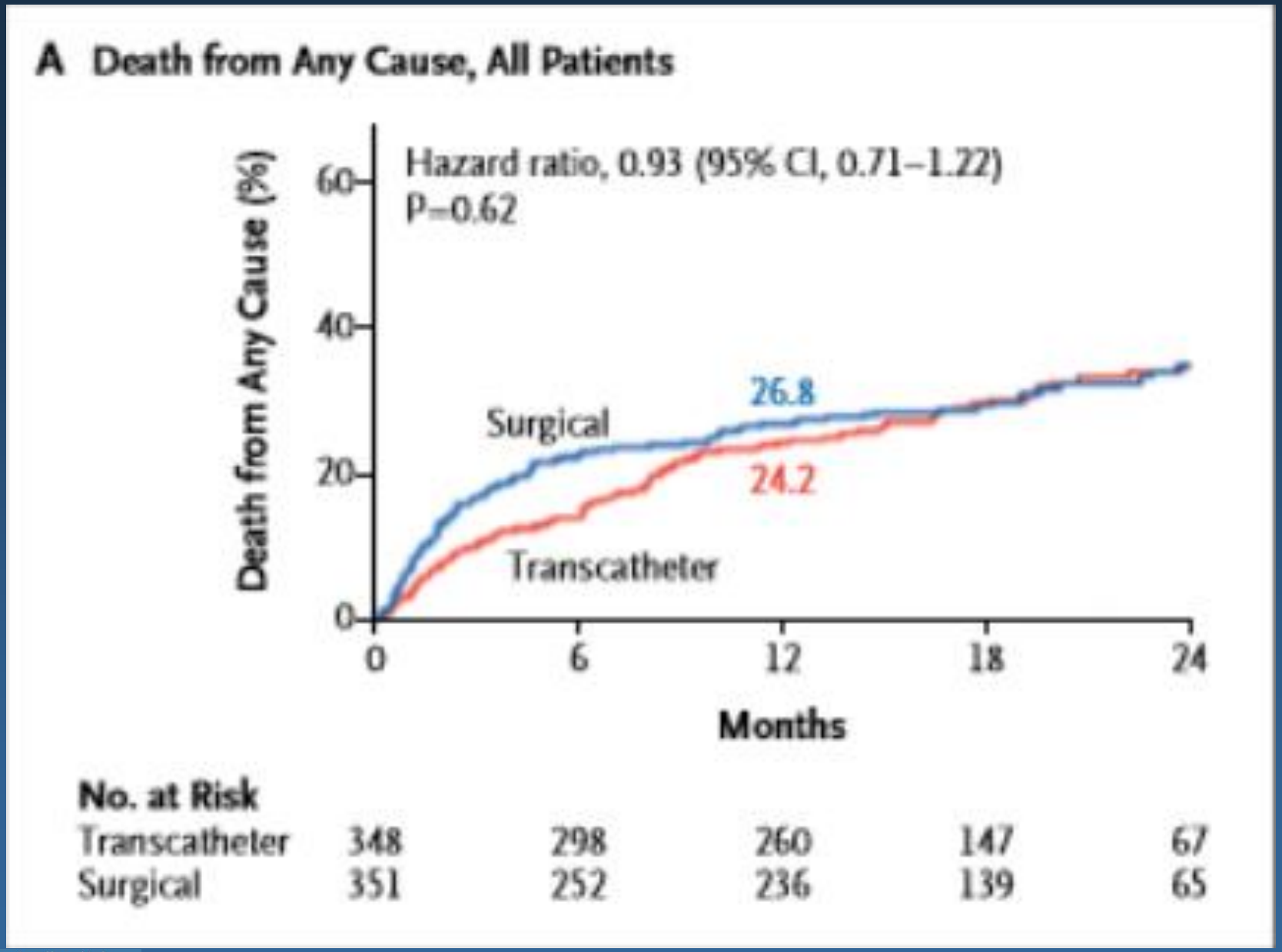
NEJM 2010

PARTNER 1A High Risk 2 yr outcomes



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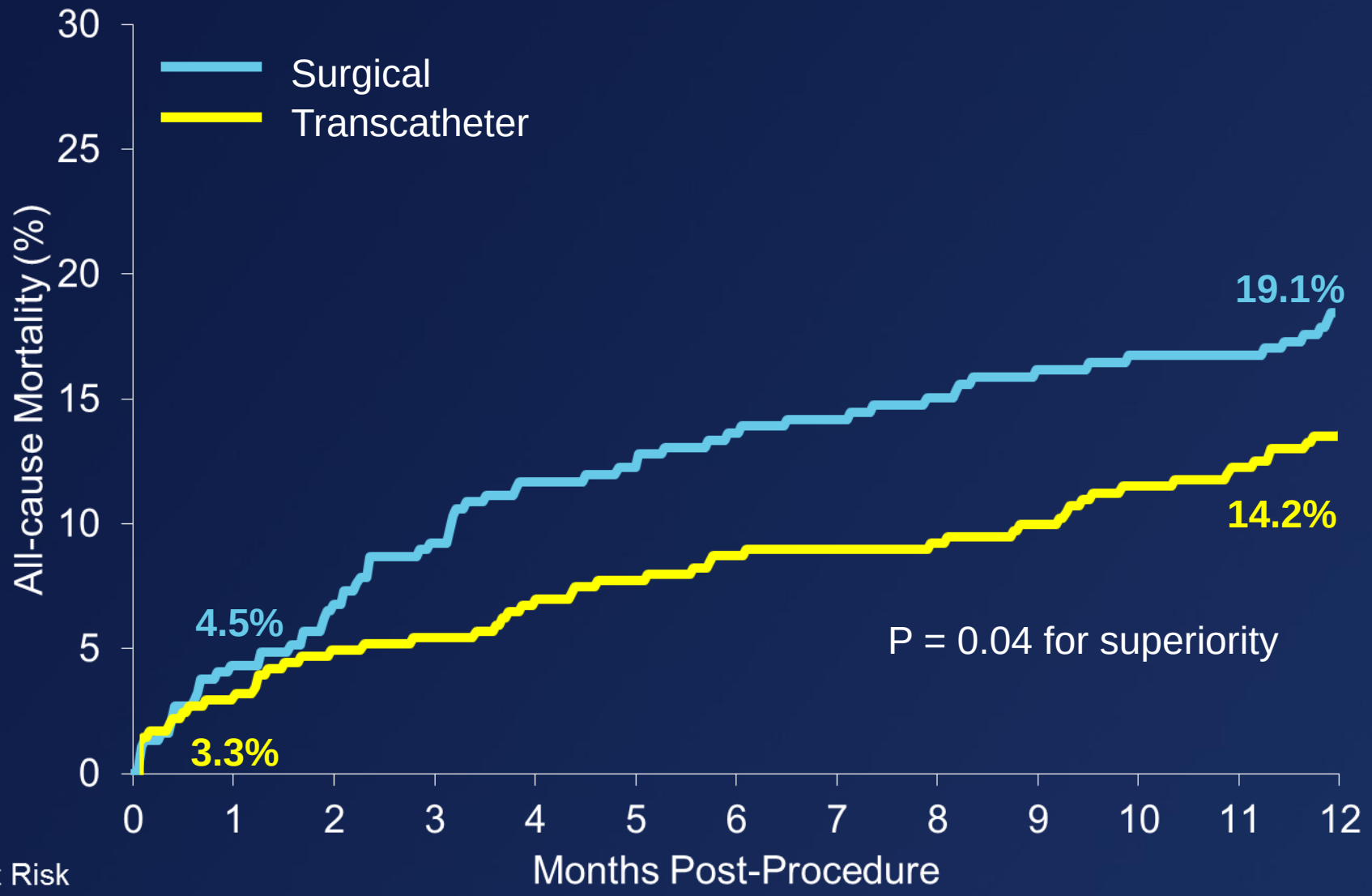
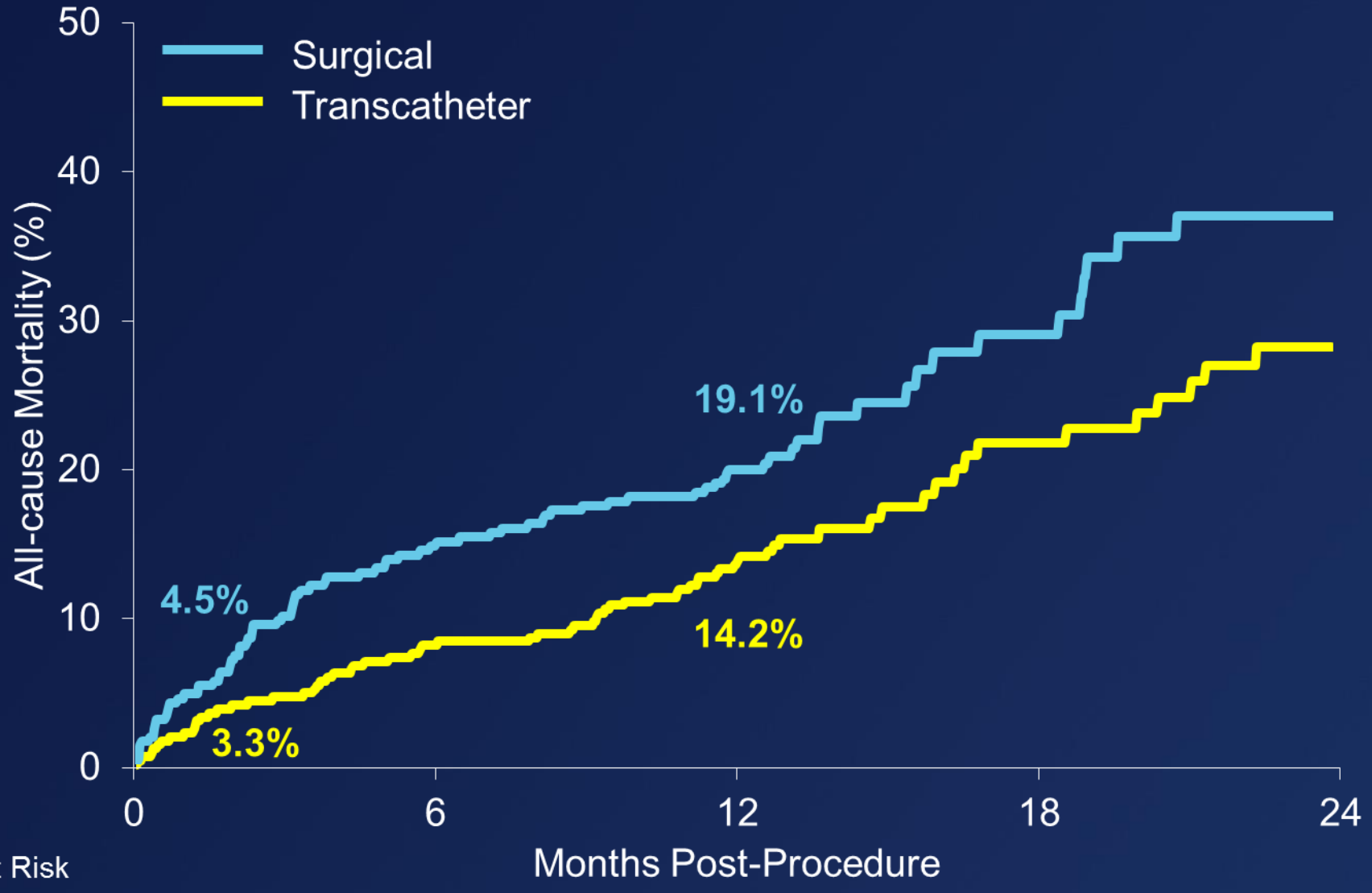
NEJM 2011

Primary Endpoint: 1 Year All-cause Mortality



No. at Risk					
Surgical	357	341	297	274
Transcatheter	390	377	353	329

2-Year All-cause Mortality: CoreValve High Risk



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

PARTNER1 High Risk and Inoperable Data: Outcomes in Nonagenarians

Outcomes in Nonagenarians Undergoing Transcatheter Aortic Valve Replacement in the PARTNER-I Trial

Vinod H. Thourani, MD, Hanna A. Jensen, MD, PhD, Vasilis Babaliaros, MD, Susheel K. Kodali, MD, Jeevanantham Rajeswaran, PhD, John Ehrlinger, PhD, Eugene H. Blackstone, MD, Rakesh M. Suri, MD, Creighton W. Don, MD, PhD, Gabriel Aldea, MD, Mathew R. Williams, MD, Raj Makkar, MD, Lars G. Svensson, MD, PhD, James M. McCabe, MD, Larry S. Dean, MD, Samir Kapadia, MD, David J. Cohen, MD, Augusto D. Pichard, MD, Wilson Y. Szeto, MD, Howard C. Herrmann, MD, Chandan Devireddy, MD, Bradley G. Leshnower, MD, Gorav Ailawadi, MD, Hersh S. Maniar, MD, Rebecca T. Hahn, MD, Martin B. Leon, MD, and Michael Mack, MD

- PARTNER 1 Cohort A (high Risk) or Cohort B (Inoperable) 2007 to 2012
- 537 Nonagenarians TAVR
- Transfemoral or Transapical TAVR

Ann Thorac Surg 2015;100:785–93

TAVR in Nonagenarians: Survival "Normalized"

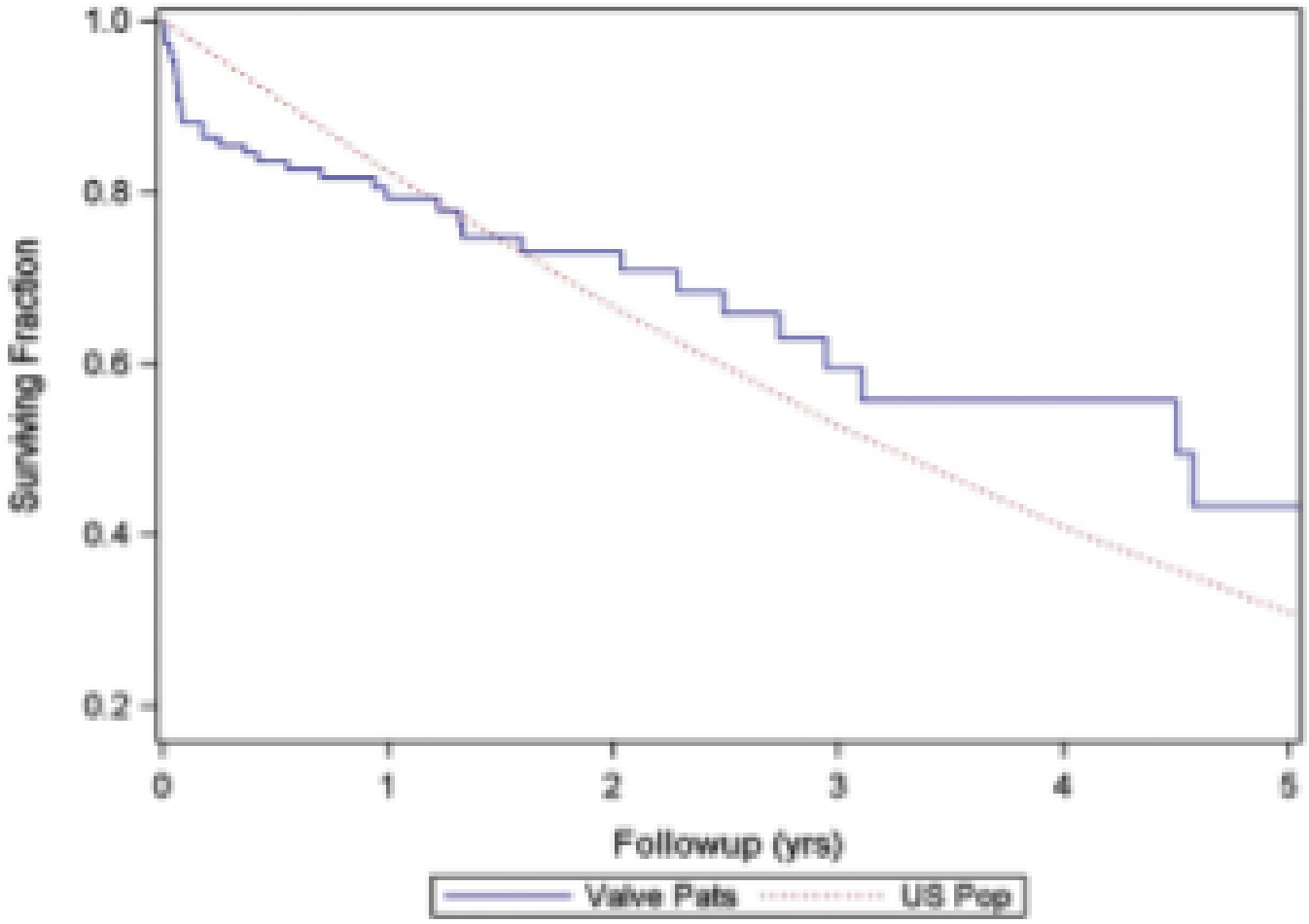


Fig 1. Long-term survival of study valve patients (blue line) compared with US actuarial survival from the Social Security Actuarial Life Table (red line).

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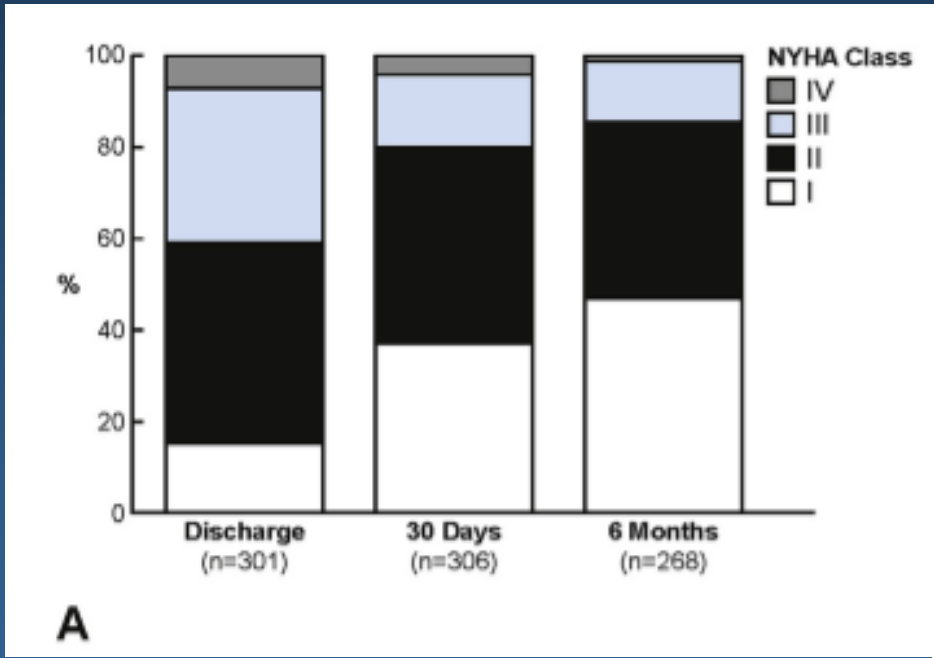
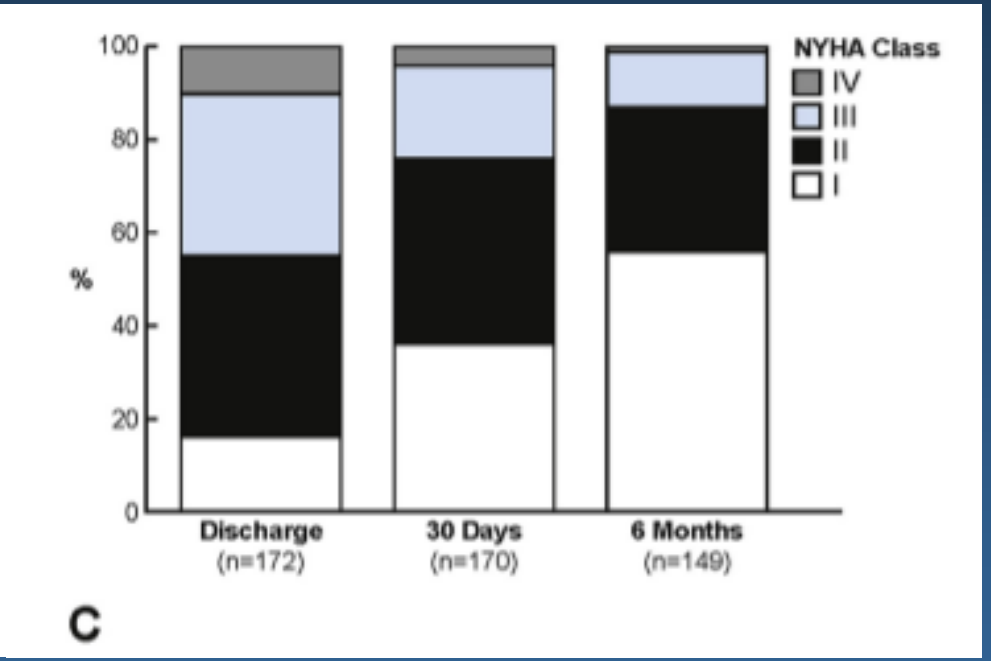
Ann Thorac Surg 2015;100:74–80

Functional Class post TAVR: Nonagenarians



Transfemoral



Transapical

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Ann Thorac Surg 2015;100:785–93

Quality of Live: Nonagenarians improved

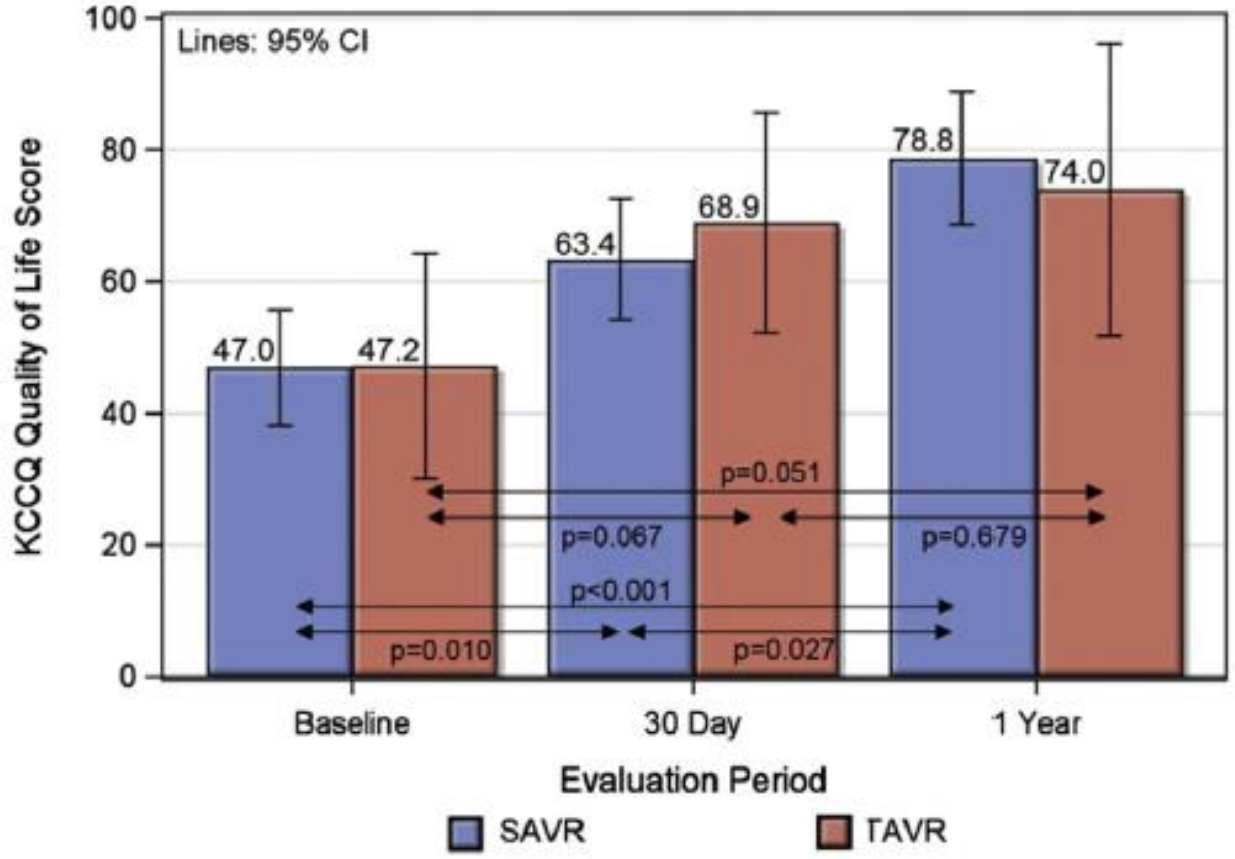
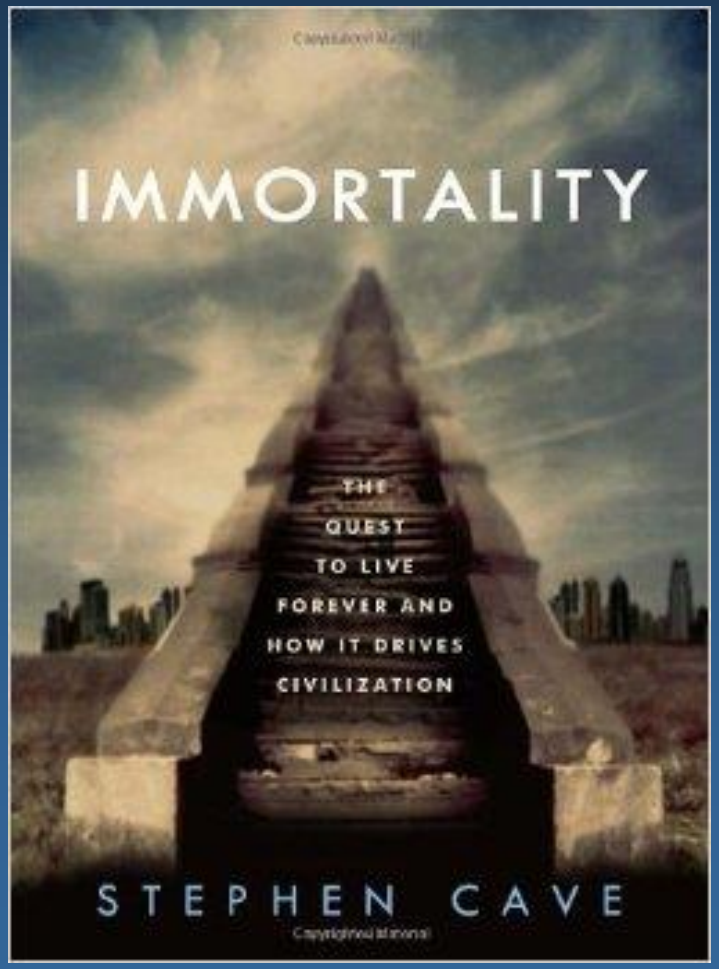


Fig 4. Kansas City Cardiomyopathy Questionnaire (KCCQ) quality of life scores by treatment method: surgical aortic valve replacement (SAVR [blue bars]) or transcatheter aortic valve replacement (TAVR [red bars]), with 95% confidence interval (CI) shown. Lines with arrowheads show comparison between the groups indicated.

Ann Thorac Surg 2015;100:74–80

No Trial: TAVR Grant Immortality



Extreme and High Risk TAVR
Solid Foundation

STS Calculator

- Basis for initial risk stratification for TAVR
- Based on historical SAVR data set
- Risk Stratification

  Extreme Risk > 10% STS mortality

  High Risk > 8% STS mortality

  Intermediate Risk 4 to 8% STS mortality

  Low Risk <4% STS mortality

Eyeball test: Subjective

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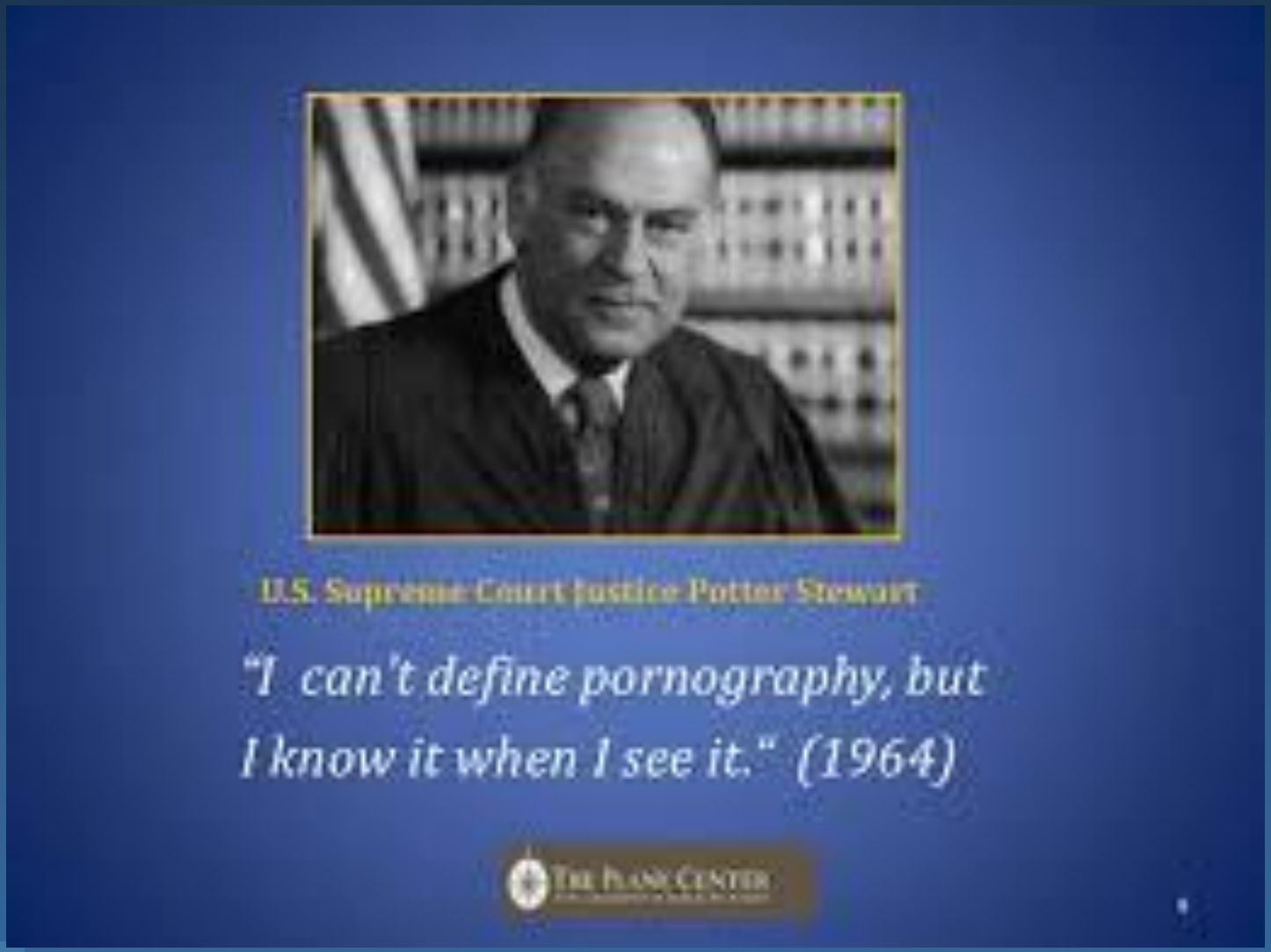
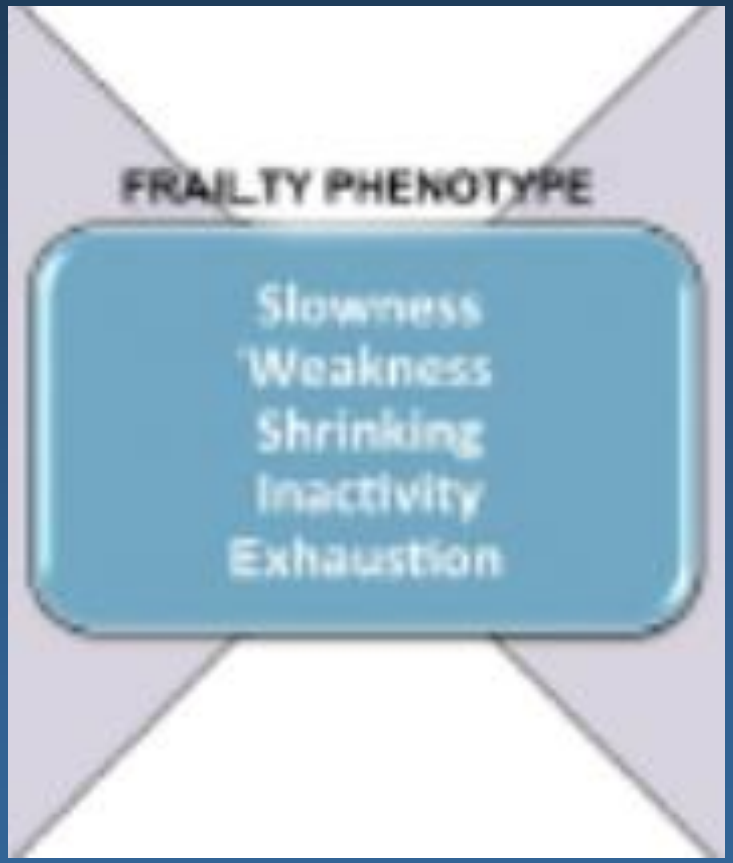
Google images

"I know it when I see it" Test



Objective Measurement of Phenotype of Frailty



Objective measures

- 5 meter walk test
- Grip Strength
- Albumin
- ADLs

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JACC 2014 White Paper on Frailty

Wal Test

Adjusted for height

- Greent et al. - 5 MWT; in m / s divided into quartiles:0-3 points

  Suendermann et al. - 4 MWT

- Afilalo et al.- 5 MWT, 3 times, averaged, permitted to use walking aids
  - Frailty = slow walkers >6s
- validated for CV patients
- Strong predictor of mortality

Pic. from www. SCIREproject.com

Dominant Hand Grip Strength

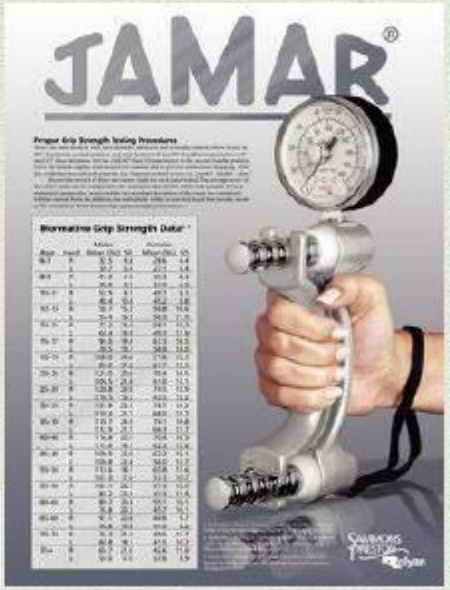
Adjusted for BMI and gender

The absolute values of grip strength measurements can be influenced by many aspects such as frequency of testing, body position, encouragement instruction, time of day and testing protocol

Green et al. Jamar dynamometer, quartiles stratified by gender, 0-3 points

Suendermann et al. was part of CAF

Low values = impaired QOL & > mortality



Katz Independent Index

- Feeding without assistance
- Bathing without assistance
- Dressing without assistance
- Transferring without assistance
- Toileting independently
- Urinary continence

2014 ACC/AHA Guidelines

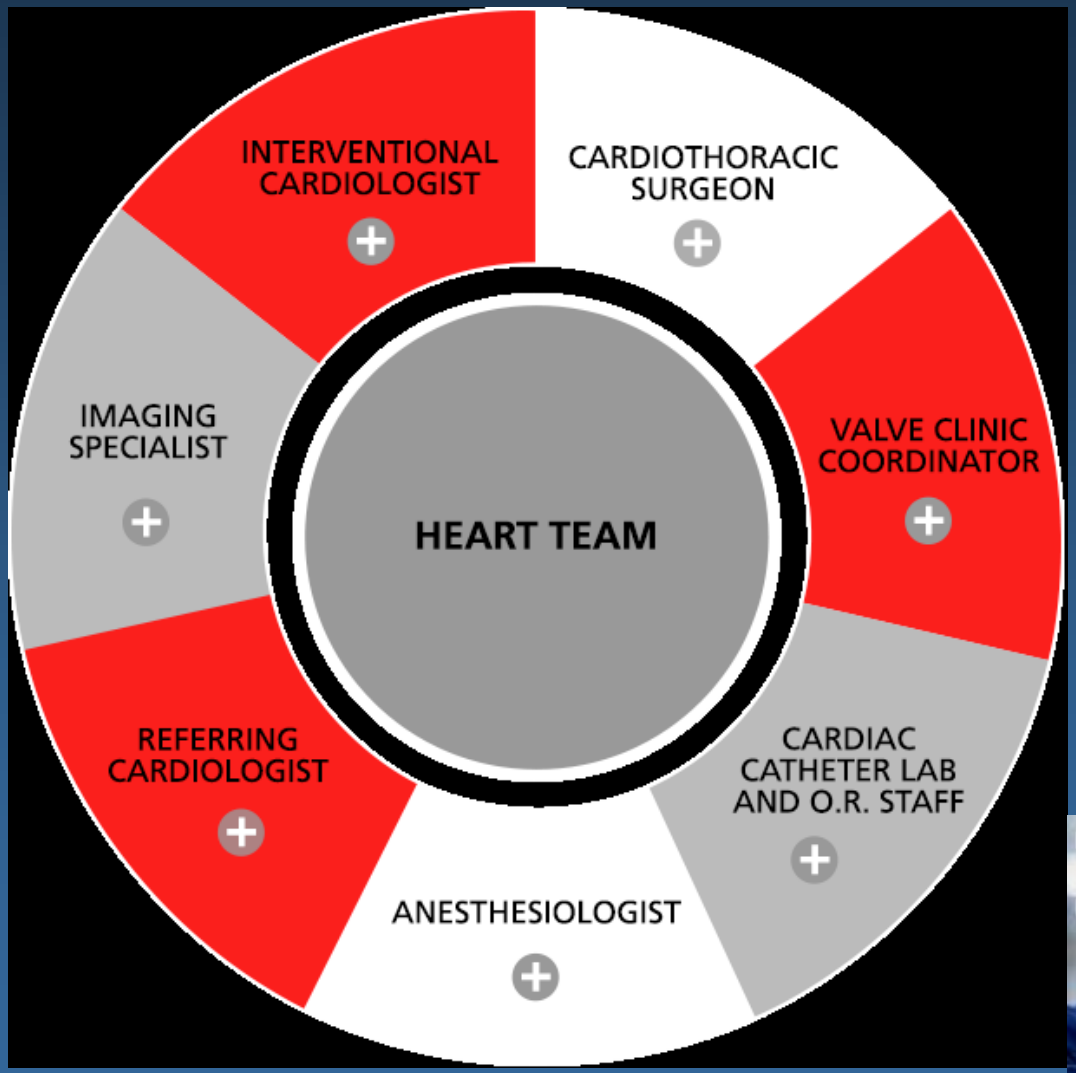
2.5. Evaluation of Surgical and Interventional Risk

See Table 5 for risk assessment combining STS risk estimate, frailty, major organ system dysfunction, and procedure-specific impediments.

Table 5. Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

	Low Risk (Must Meet ALL Criteria in This Column)	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)
STS PROM*	<4% **AND**	4% to 8% **OR**	>8% **OR**	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y **OR**
Frailty†	None **AND**	1 Index (mild) **OR**	≥2 Indices (moderate to severe) **OR**	
Major organ system compromise not to be improved postoperatively‡	None **AND**	1 Organ system **OR**	No more than 2 organ systems **OR**	≥3 Organ systems **OR**
Procedure-specific impediment§	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

Heart Team Assessment: Surgical Risk



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TAVR Intermediate Risk

The NEW ENGLAND JOURNAL of MEDICINE

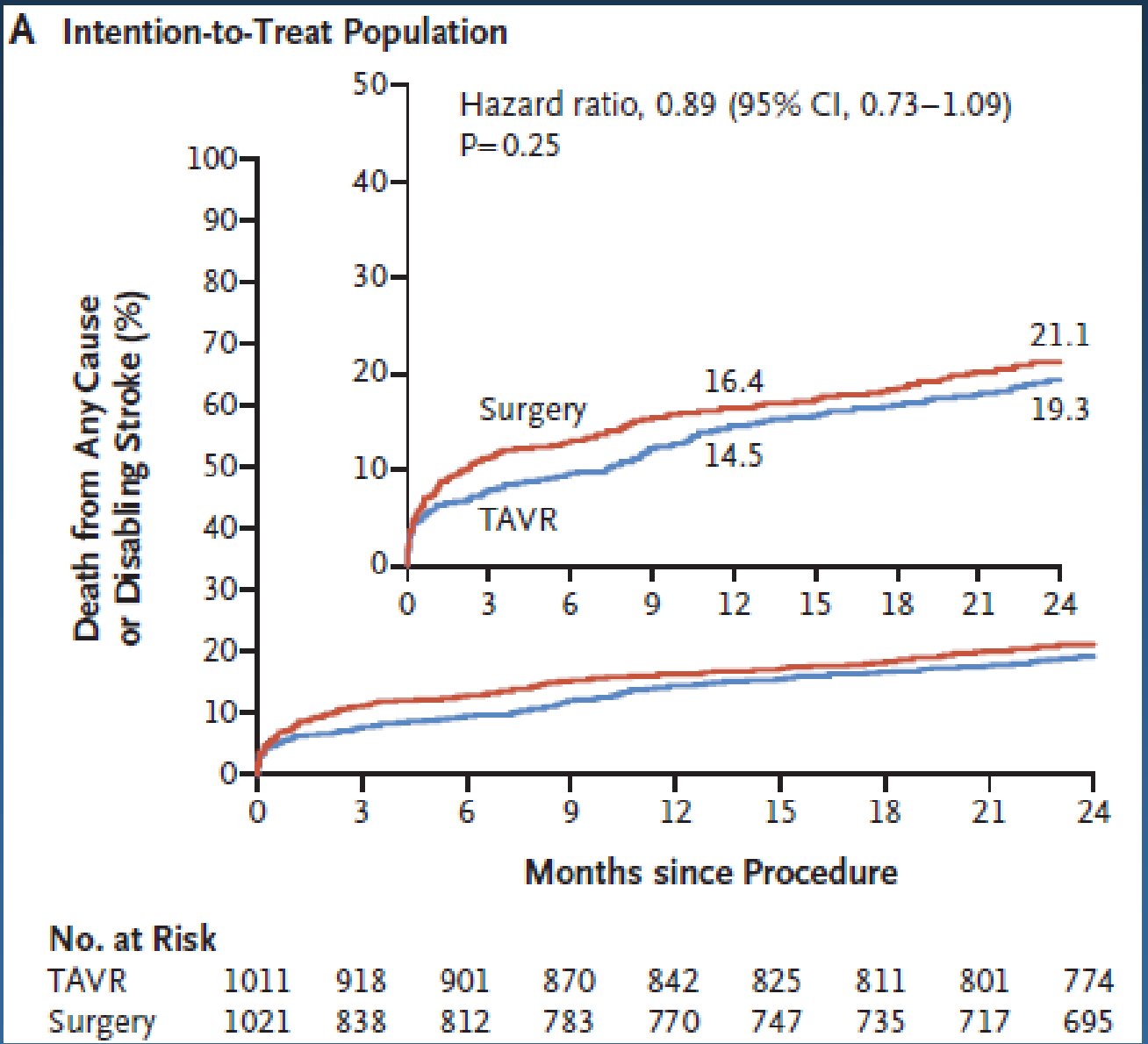
ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D.,

- 2032 patients (76% TF; 24% TA)
- Randomized Surgery v TAVR (Sapien)
- STS "4" to 8 mean 5.8

TAVR Intermediate Risk: TAVR not Inferior to SAVR Death/Disabling Stroke



TF resulted in larger AVA, less AF, less bleeding, less renal dysfunction, less vascular complications and less AI than SAVR

NEJM April 2016

FDA TAVR Approval: Intermediate Risk August 2016

FDA News Release

FDA approves expanded indication for two transcatheter heart valves for patients at intermediate risk for death or complications associated with open-heart surgery

August 18, 2016

The U.S. Food and Drug Administration today approved an expanded indication for the Sapien XT and Sapien 3 transcatheter heart valves for patients with aortic valve stenosis who are at intermediate risk for death or complications associated with open-heart surgery. These devices were previously approved only in patients at high or greater risk for death or complications during surgery.

SURTAVI
ACC 2017/NEJM

ORIGINAL ARTICLE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

Michael J. Reardon, M.D., Nicolas M. Van Mieghem, M.D., Ph.D., Jeffrey J. Popma, M.D., Neal S. Kleiman, M.D., Lars Søndergaard, M.D., Mubashir Mumtaz, M.D., David H. Adams, M.D., G. Michael Deeb, M.D., Brijeshwar Maini, M.D., Hemal Gada, M.D., Stanley Chetcuti, M.D., Thomas Gleason, M.D., John Heiser, M.D., Rüdiger Lange, M.D., Ph.D., William Merhi, D.O., Jae K. Oh, M.D., Peter S. Olsen, M.D., Nicolo Piazza, M.D., Ph.D., Mathew Williams, M.D., Stephan Windecker, M.D., Ph.D., Steven J. Yakubov, M.D., Eberhard Grube, M.D., Ph.D., Raj Makkar, M.D., Joon S. Lee, M.D., John Conte, M.D., Eric Vang, Ph.D., M.P.H., Hang Nguyen, B.S., Yanping Chang, M.S., Andrew S. Mugglin, Ph.D., Patrick W.J.C. Serruys, M.D., Ph.D., and Arie P. Kappetein, M.D., Ph.D., for the SURTAVI Investigators*

N Engl J Med 2017; 376:1321-1331 | April 6, 2017 | DOI: 10.1056/NEJMoa1700456

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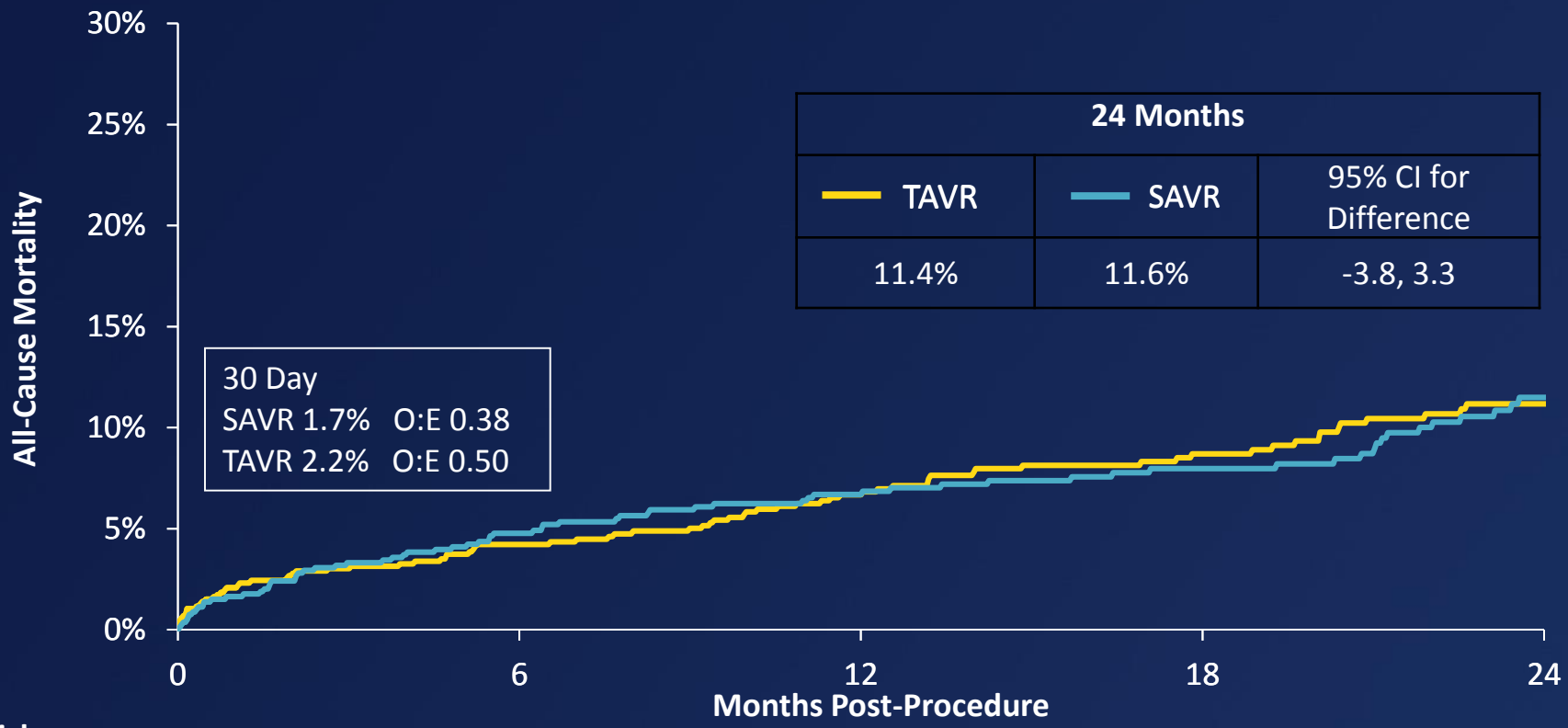
All-Cause Mortality

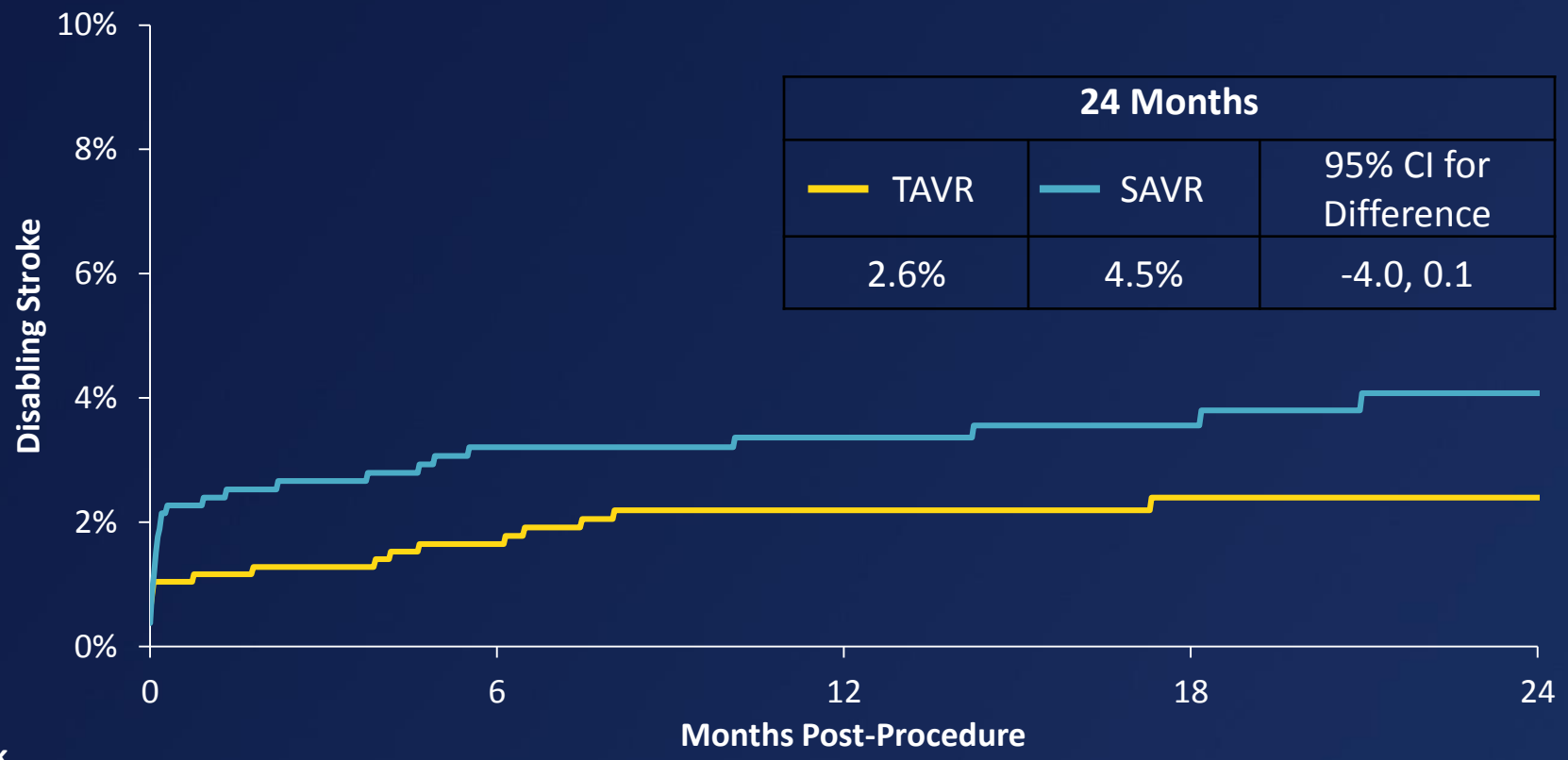


No. at Risk					
SAVR	796	690	569	414	249
TAVR	864	762	621	465	280

ACC 2017 NEJM March 2017

Disabling Stroke

CoreValve SURTAVI Trial



24 Months		
TAVR	SAVR	95% CI for Difference
2.6%	4.5%	-4.0, 0.1

No. at Risk					
SAVR	796	674	555	407	241
TAVR	864	755	612	456	272

ACC 2017 NEJM March 2017

30-Day Safety and Procedure-related Complications

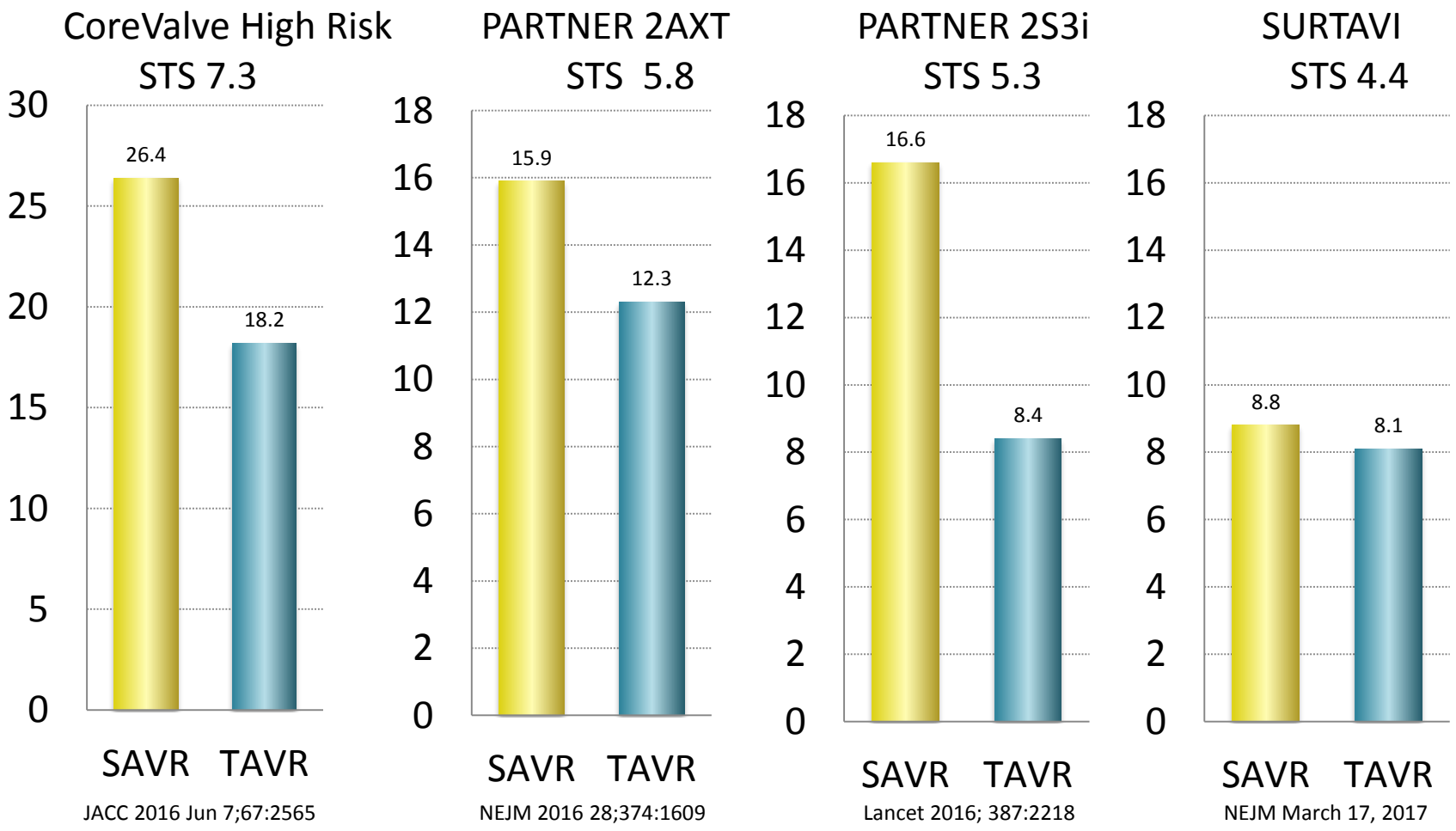
	TAVR (N=864)	SAVR (N=796)	95% CI for Difference
All-cause mortality or disabling stroke	2.8	3.9	-2.8, 0.7
All-cause mortality	2.2	1.7	-0.9, 1.8
Disabling stroke	1.2	2.5	-2.6, 0.1
All stroke	3.4	5.6	-4.2, -0.2
Overt life-threatening or major bleeding	12.2	9.3	-0.1, 5.9
Transfusion of PRBCs* - n (%)			
0 units	756 (87.5)	469 (58.9)	24.4, 32.5
2 – 4 units	48 (5.6)	136 (17.1)	-14.5, -8.5
≥ 4 units	31 (3.6)	101 (12.7)	-11.7, -6.5
Acute kidney injury, stage 2-3	1.7	4.4	-4.4, -1.0
Major vascular complication	6.0	1.1	3.2, 6.7
Cardiac perforation	1.7	0.9	-0.2, 2.0
Cardiogenic shock	1.1	3.8	-4.2, -1.1
Permanent pacemaker implant	25.9	6.6	15.9, 22.7
Atrial fibrillation	12.9	43.4	-34.7, -26.4

*Percentage rates, all others are Bayesian rates

ACC 2017 NEJM March 2017

TAVR Randomized Trials

Death & Stroke 12 Months



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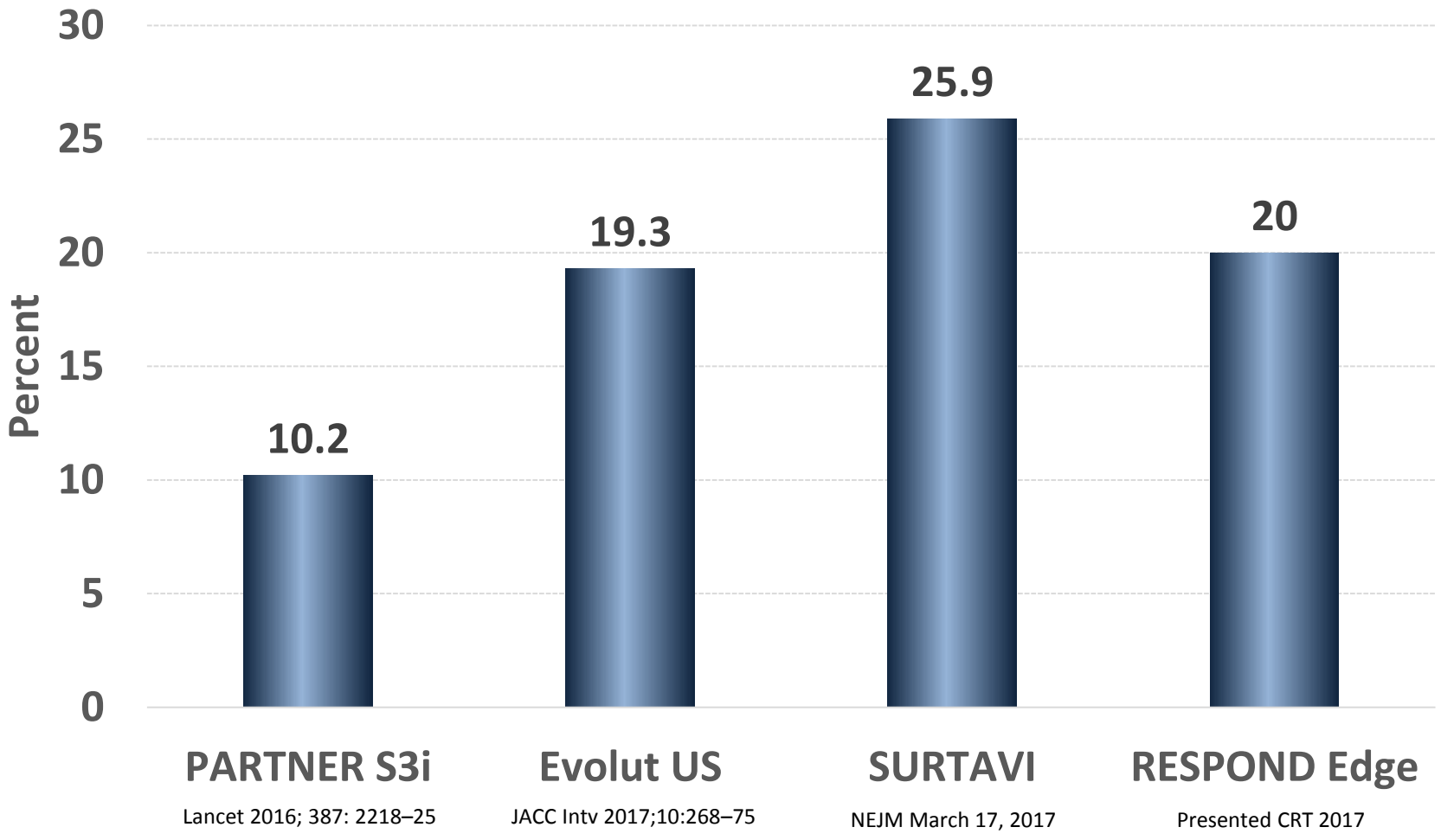
New Pacemaker Implant Rate 30 Days



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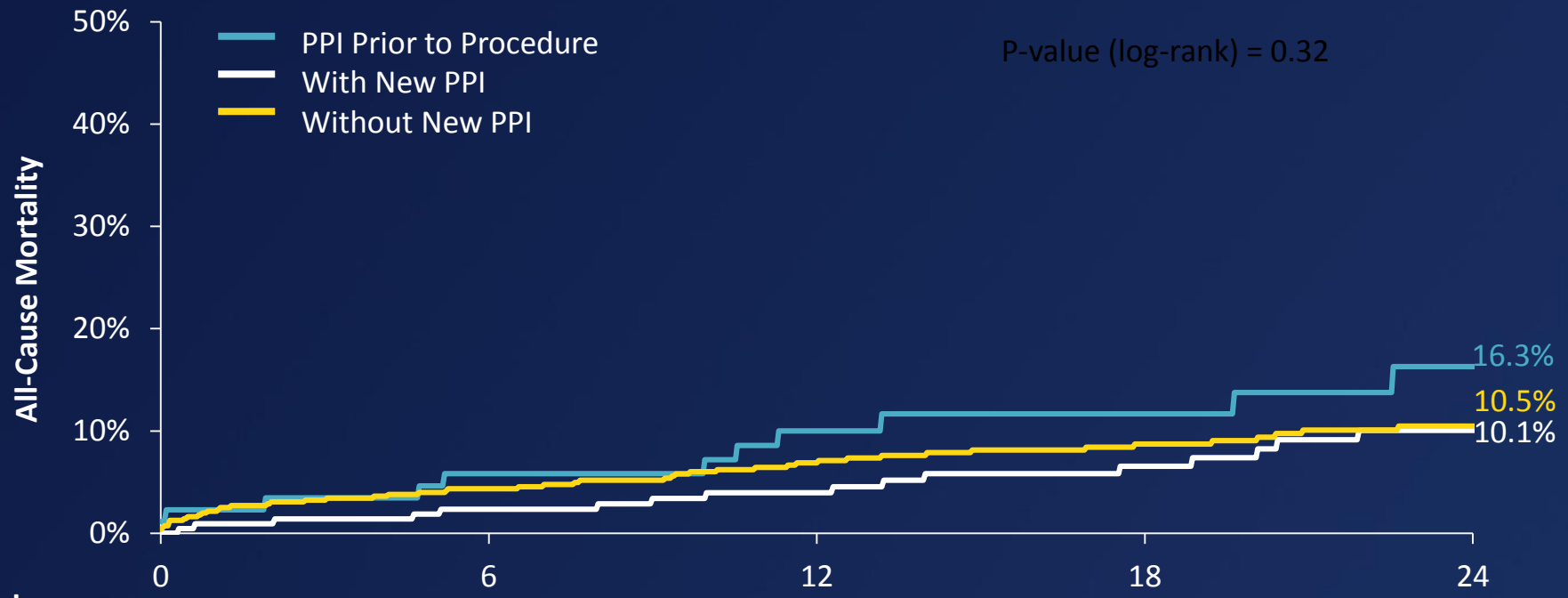
All-Cause Mortality by Pacemaker Implantation



No. at Risk					
PPI Prior	87	74	59	46	28
With New PPI	217	198	164	121	56
Without New PPI	559	491	400	300	197

Post TAVR Pacemakers Just because you have one at 30 days does not mean you are using it

Medtronic Micra

TAVR What's Now What's Next?

- Equivalency or better than meds in Extreme Risk
  STS >10
- Equivalency or better in High Risk
  STS 8 to 10
- Equivalency or better in Intermediate Risk
- STS 4 to 8 (CMS allowing down to 3)

Low Risk STS less than 4

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TAVR What's: Next – Low Risk

PARTNER 2 and SURTAVI CMS Reimbursed

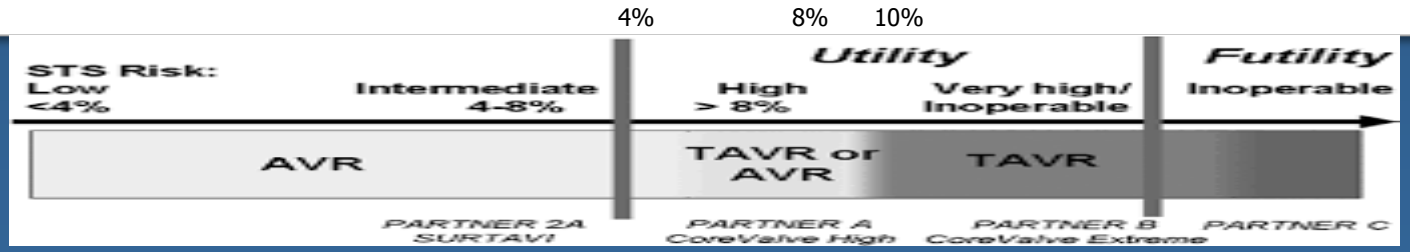
Intermediate Risk STS 3/4 to 8

PARTNER 3 Trial

Low Risk STS <4

CMS Reimbursed

High STS 8 to 10 & Extreme Risk STS>10



STS Mortality Risk for SAVR based on historical data base

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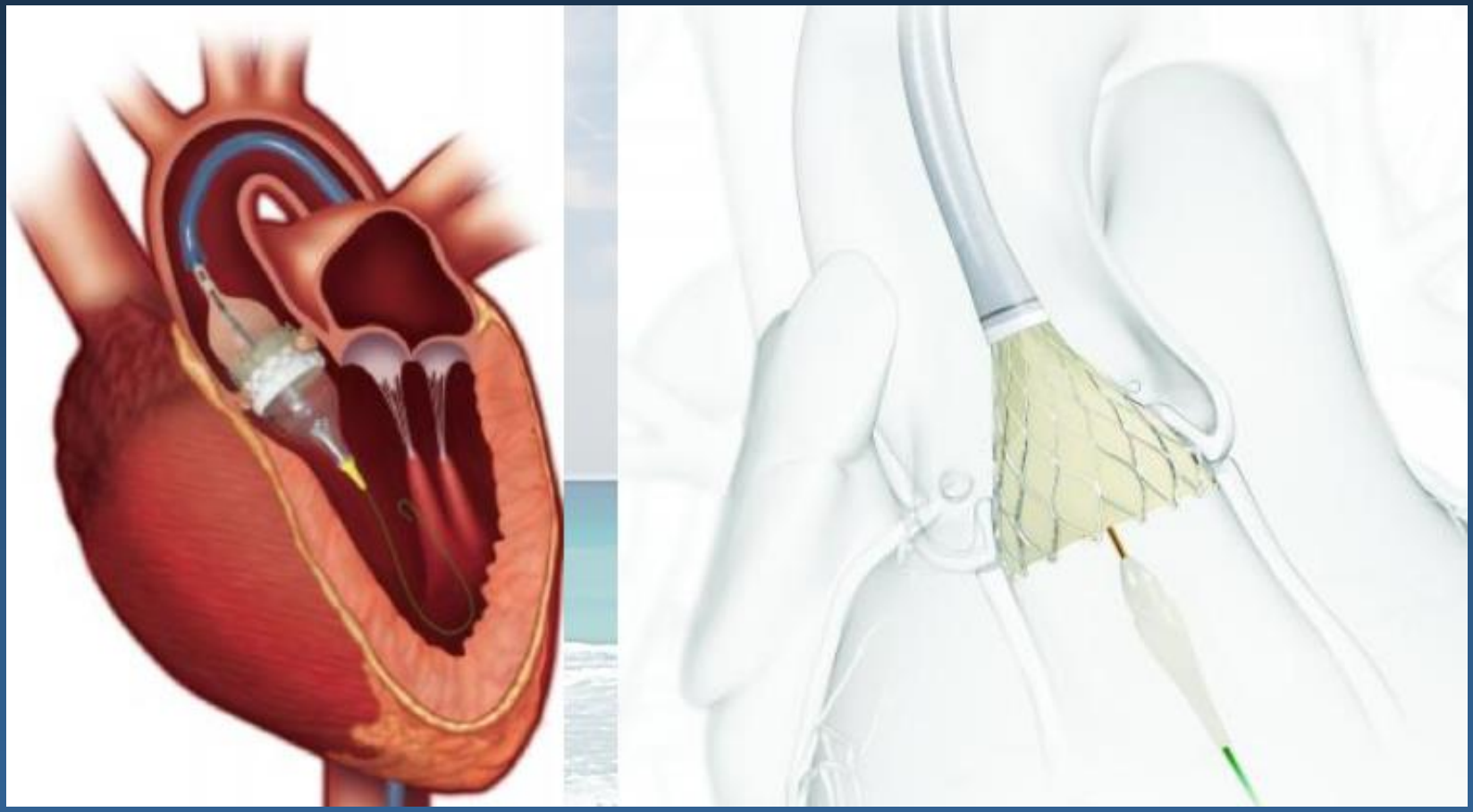
TAVR Low Risk Trials: STS <4



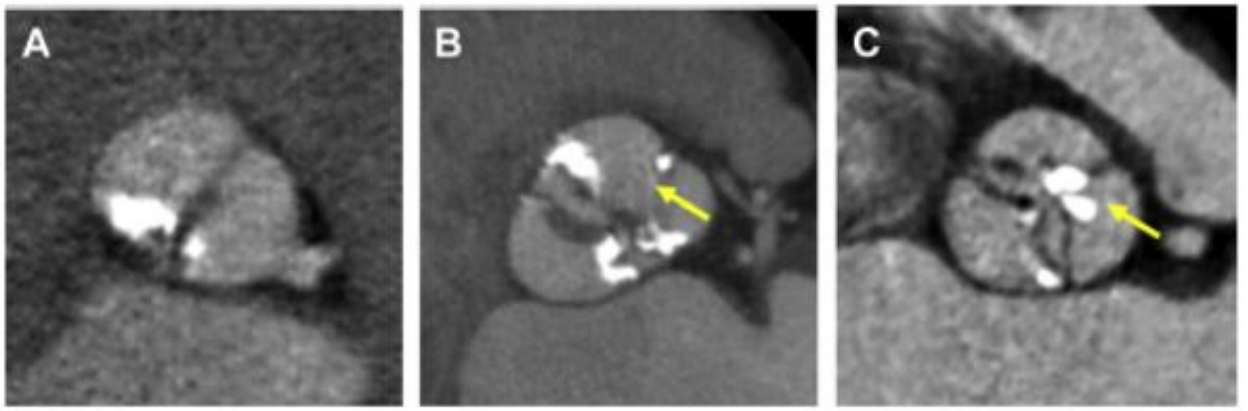
PARTNER III **NOTION**

Lower Risk, Younger patients: Bicuspid AO Valve

Bicuspid Aortic Valve Stenosis

Favorable Early Outcomes With a Next-Generation Transcatheter Heart Valve in a Multicenter Study

FIGURE 1 Bicuspid Types



(A) Sievers type 0 bicuspid valve with 2 symmetric cusps, but no raphe. **(B)** Sievers type 1 bicuspid valve with a partially imaged **(yellow a**

Historically trials excluded Bicuspids

PARTNER 3 Low Risk Bicuspid Study

REPRISE LOTUS Bicuspid Study

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 9, NO. 8, 2016

APRIL 25, 2016:817–24

Bicuspid S3 TAVR: 30 Day Clinical and Echo

TABLE 4 30-Day Clinical Events (N = 51)*

Mortality	2 (3.9)
Myocardial infarction	0 (0)
Stroke, total events	1 (1.9)
Disabling stroke	0 (0)
Nondisabling stroke	1 (1.9)
Bleeding, total events	14 (27.5)
Life-threatening	2 (3.9)
Major	3 (5.9)
Minor	9 (17.6)
Vascular complications, total events	7 (13.7)
Major	2 (3.9)
Minor	5 (9.8)
Acute kidney injury ≥2	1 (1.9)
New permanent pacemaker†	12 (23.5)

TABLE 3 30-Day Post-Procedural Echocardiographic Findings

	All Patients (N = 51)
Aortic valve mean gradient, mm Hg	11.2 ± 4.7
Aortic valve peak gradient, mm Hg	22.0 ± 8.2
Aortic valve area, cm^2	1.68 ± 0.32
Aortic regurgitation	
None/trivial	32 (62.8)
Mild	19 (37.2)
Moderate	0 (0)
Severe	0 (0)
Left ventricular ejection fraction <40, %	10 (19.6)
Mitral regurgitation ≥ moderate, %	1 (1.9)

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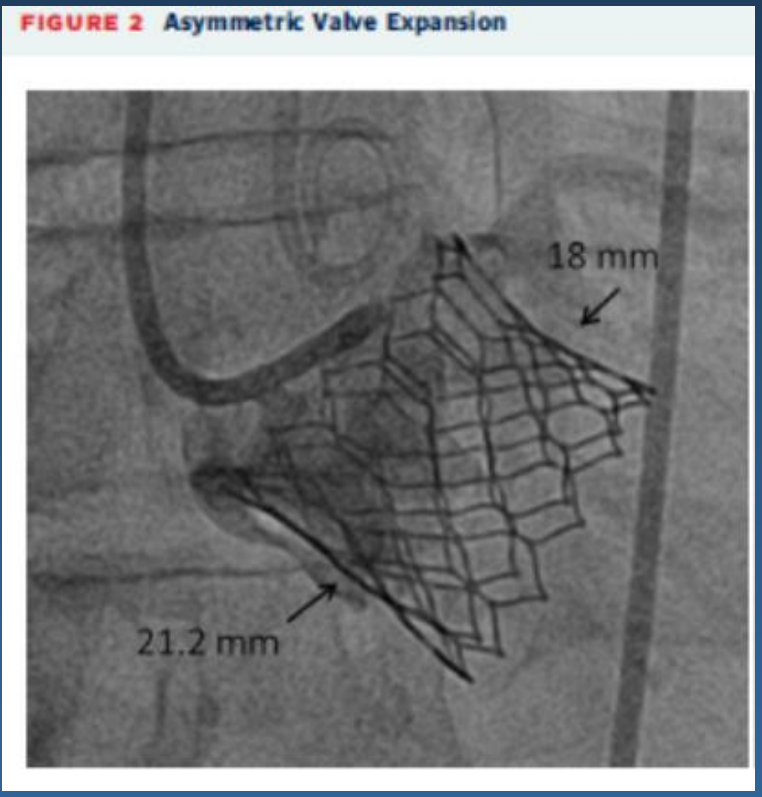
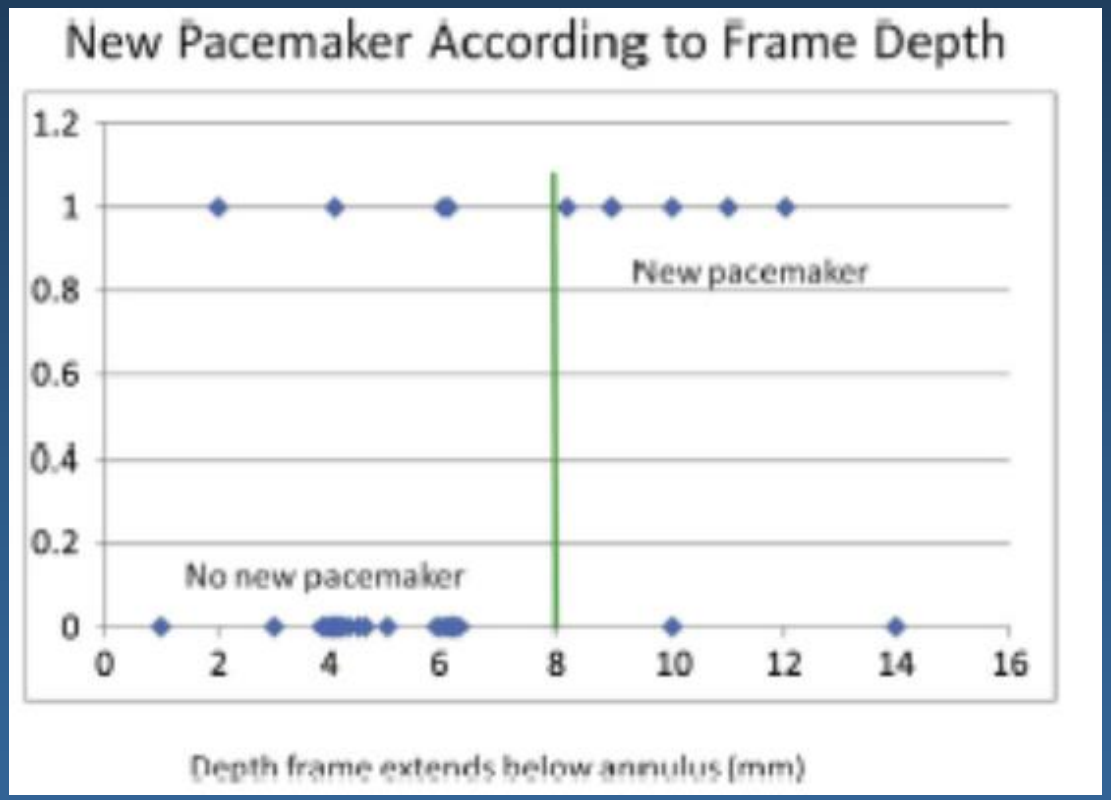
JACC Int April 2016

Bicuspid S3 TAVR: Pacemakers on Implant Depth





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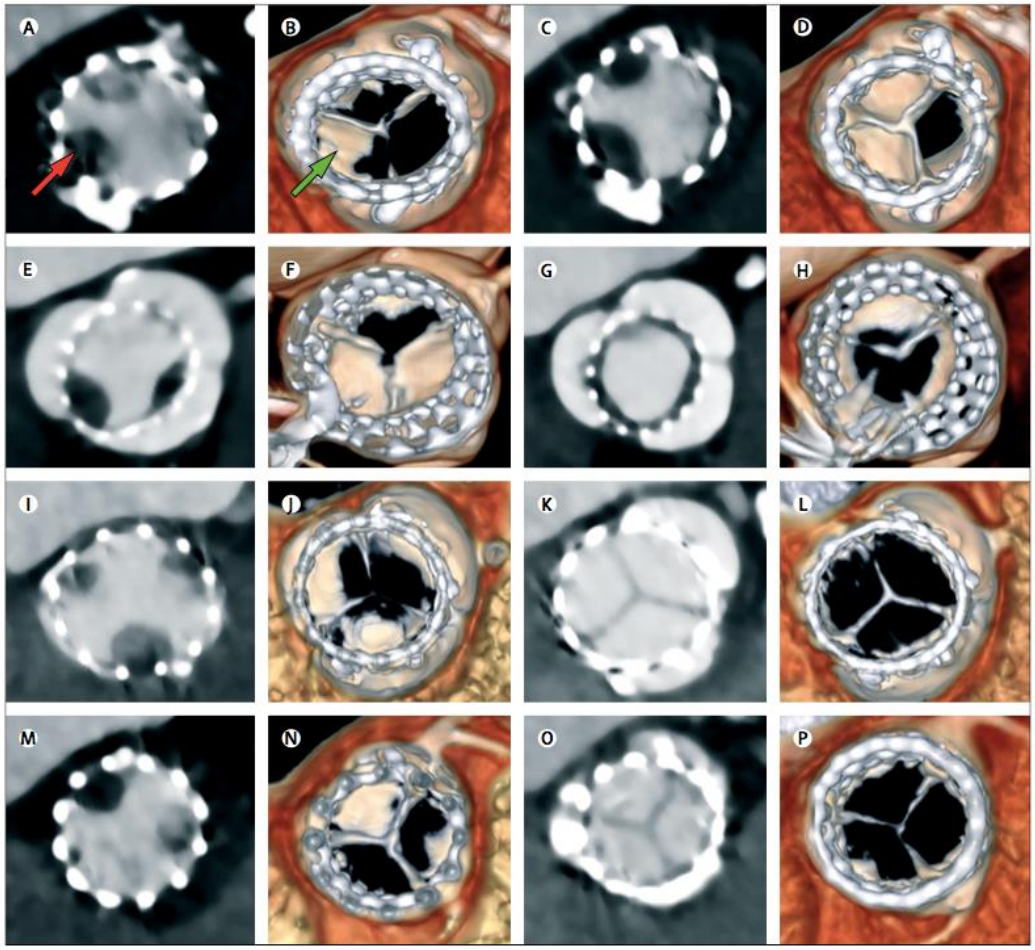
Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves



Effect of anticoagulation on hypoattenuating opacities and reduced leaflet motion
(A–D) Reduced leaflet motion at baseline on DAPT. Resolution of hypoattenuating opacities and restoration of normal leaflet motion with 3 months OAC with (E–H) warfarin, (I–L) rivaroxaban, and (M–P) apixaban. Red arrow= hypoattenuating opacities, green arrow= reduced leaflet motion.

LANCET March 19, 2017

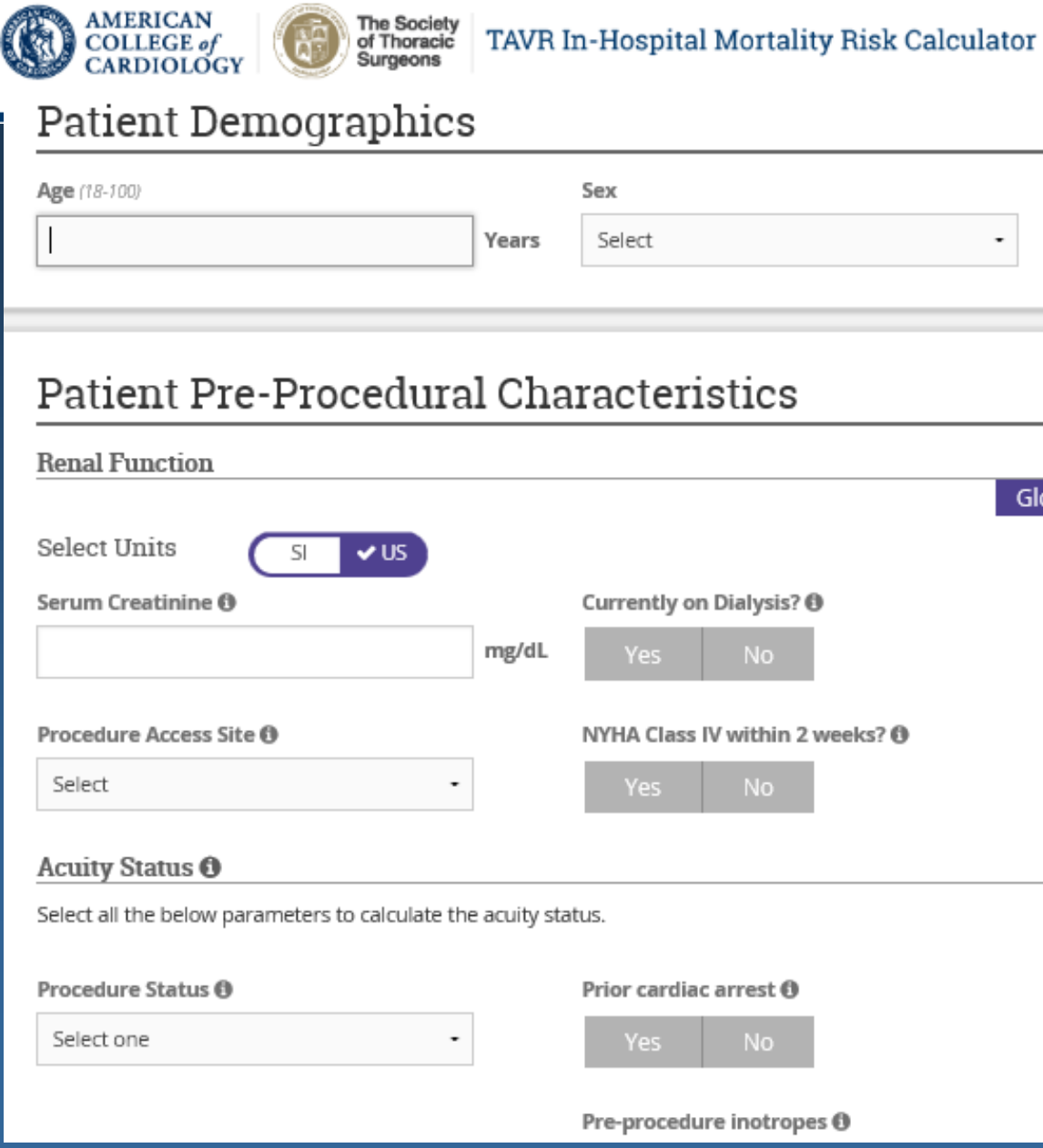
TAVR Summary

- P3i and SURTAVI have shown benefit in intermediate risk patients STS 3 to 8%
- Trials are now ongoing for "low risk" STS <3% patients
- TAVR "risk calculators" are now being developed and validated to augment STS and aid in discussions or TAVR Risk rather than Surgical Risk

TAVR Summary

- Approved as good or better than SAVR for Extreme Risk STS > 12, High Risk STS 8 to 10 and Intermediate Risk STS 3 or 4 to 8
- Investigational for Low Risk
- Controversial for Bicuspids and caution regarding concurrent AO aneurysm
- Refer them ALL to Structuralist/Heart Team –Commercial for High and Intermediate Risk, Trials for the others

TAVR Risk Calculator: Instead of Surgical Risk Calculator



96 year old retired MD

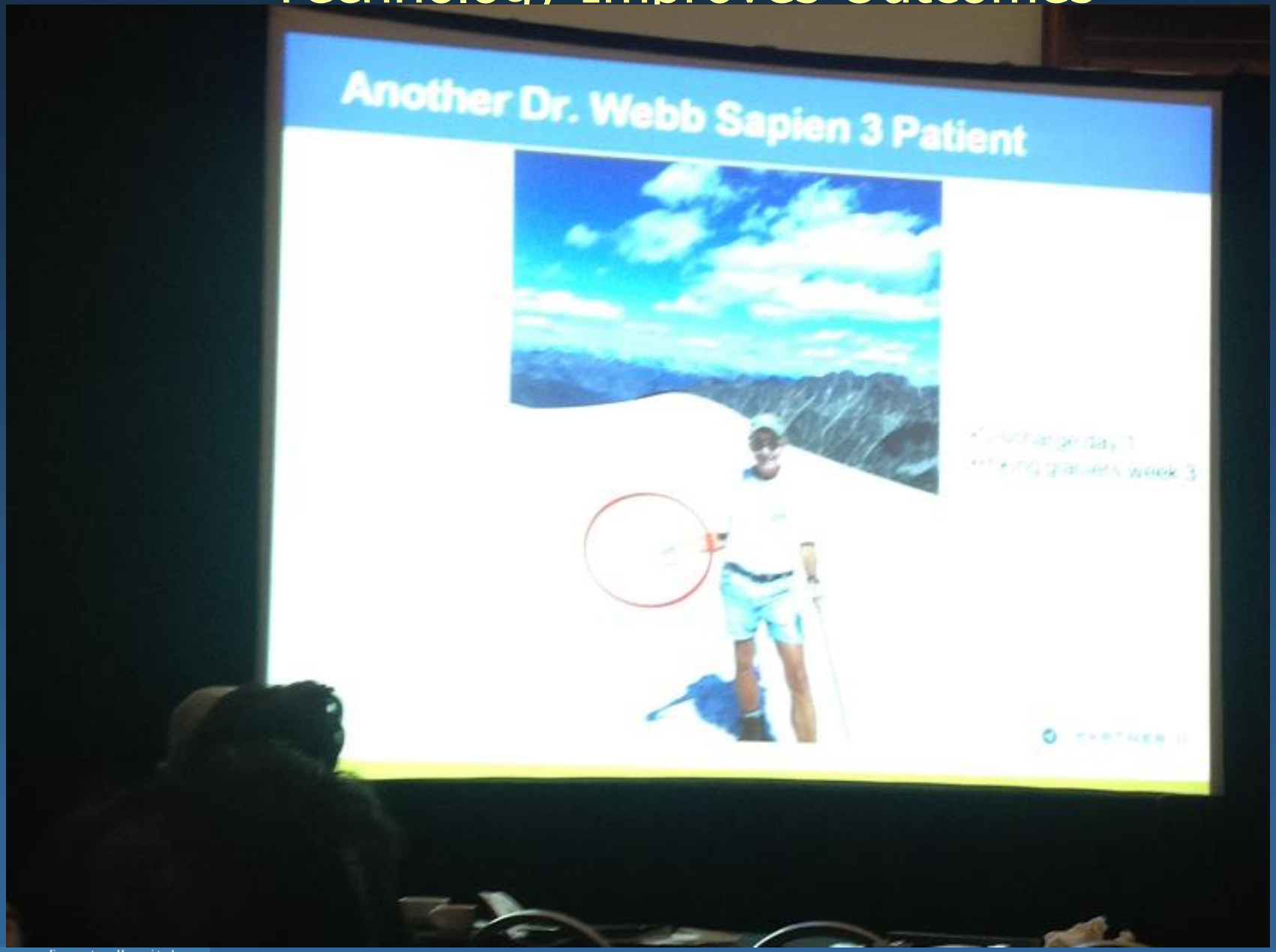
Evanston Hospital
NorthShore
University HealthSystem

6 hours post TF TAVR P1 Pt

98 year old U of I Dentist

Still practicing, 30 day TAVR F/U R3 Lotus Valve

Technology Improves Outcomes



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Shown at P2 Investigators Meeting-Discharged Day 1/Hiking Glaciers Week

Improvements in technology and technique improved outcomes in all age groups

- Lower profile devices/delivery systems
  - nominally at 14F
- Lower PVL rates
  - sealing skirts
- Lower pacemaker rates
  - improved implantation techniques
- Simplified implantations
  - conscious sedation
  - no Foleys
  - early ambulation

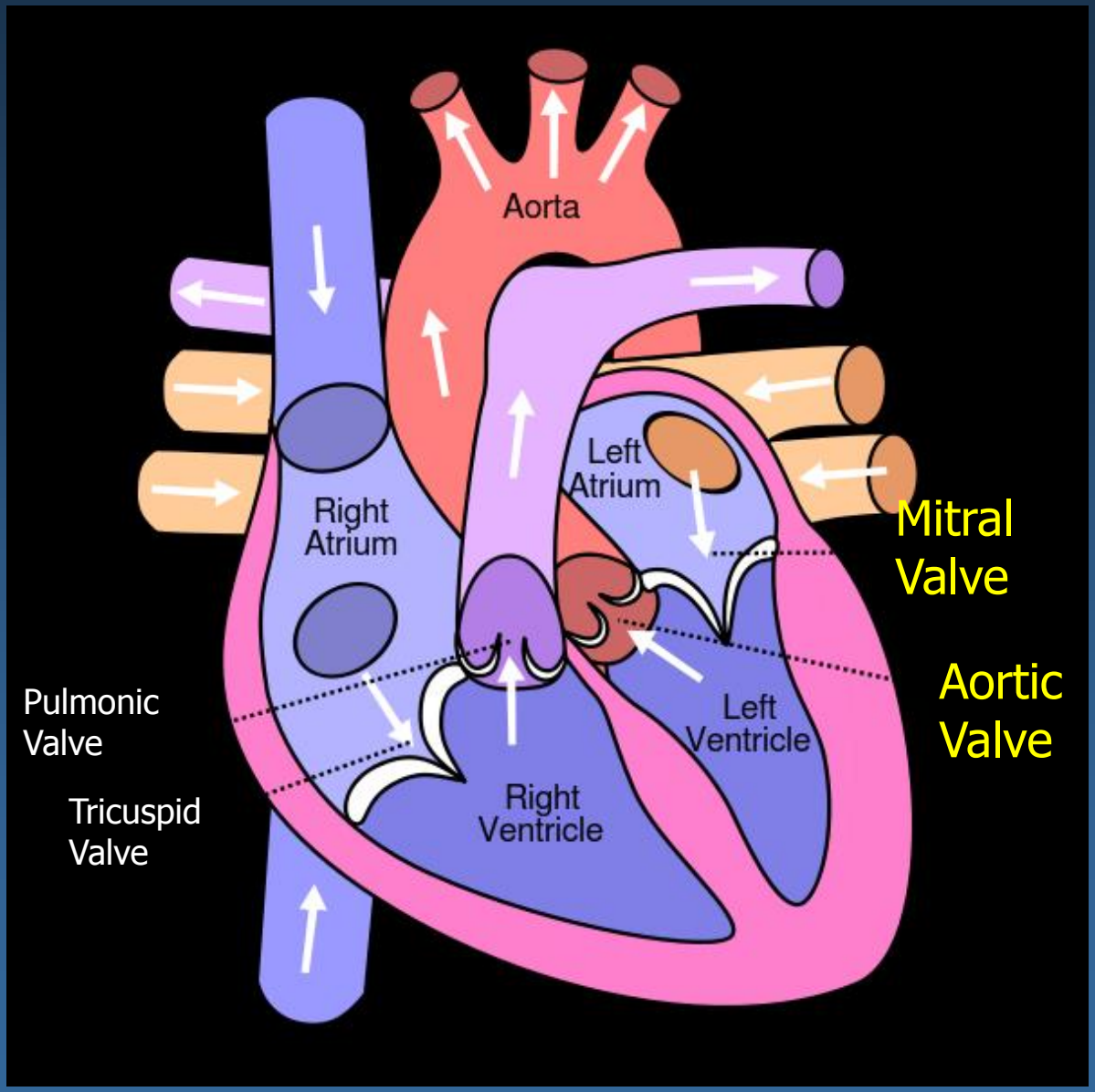
AS/TAVR When to Refer to Structural Cardiology?

- Dr. Feldman: "Just Refer them all"

- Extreme, High, Intermediate STS Risk get done commercially
- The rest (ie low risk) get randomized

Three Valves and Eight Leaflets and 10 Minutes yet to go….

Percutaneous Mitral Therapies



Mitral Valvuloplasty: Success

- Inoue 1984 first described dilating stenosed mitral valve using a specialized balloon

Mitral Balloon Valvuloplasy

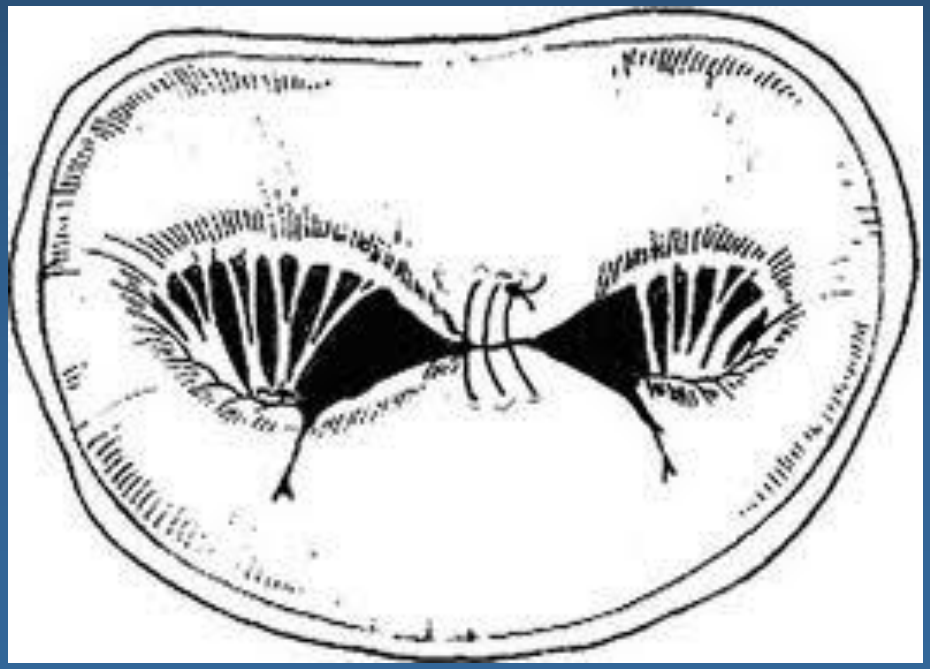
- Durable results
- ACC/AHA Guideline driven *first* choice therapy for stenosed mitral valves of suitable anatomy – ideally minimum calcium
- NorthShore has one of the World's "Zen Masters" of balloon mitral valvuloplasty: Dr. Feldman—initial Inoue investigator and one of the worlds most accomplished Inoue operators from who we all learn
- World wide most PTMC for rheumatic mitral stenosis and while endemic areas persist rheumatic mitral stenosis is relatively uncommon in the US
- MBV generally NOT applicable to the elderly and many due to calcification

Mitral Stenosis: Mitral Annular Calcification

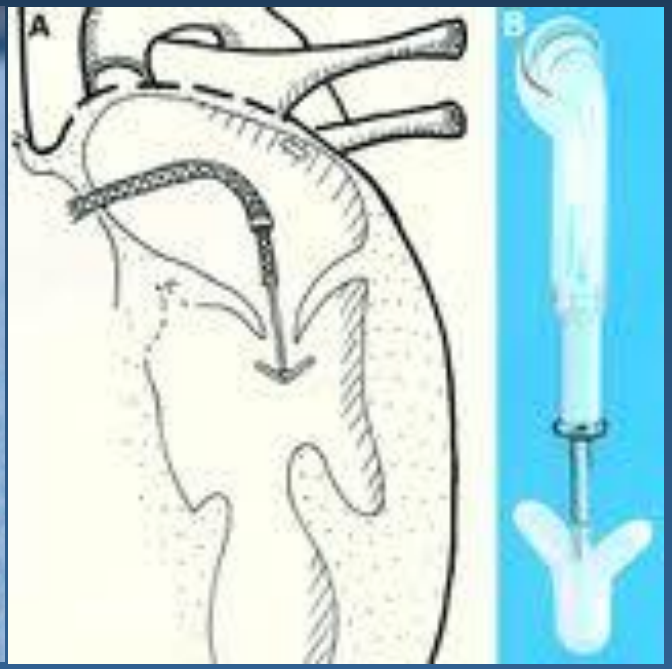
Mitral Regurgitation: Leaky Valve

Mitral Regurgitation

- Number of different surgical repairs and replacements
- One caught the attention of an interventional cardiologist (Fred St. Goar)—Alfieri Edge to Edge repair

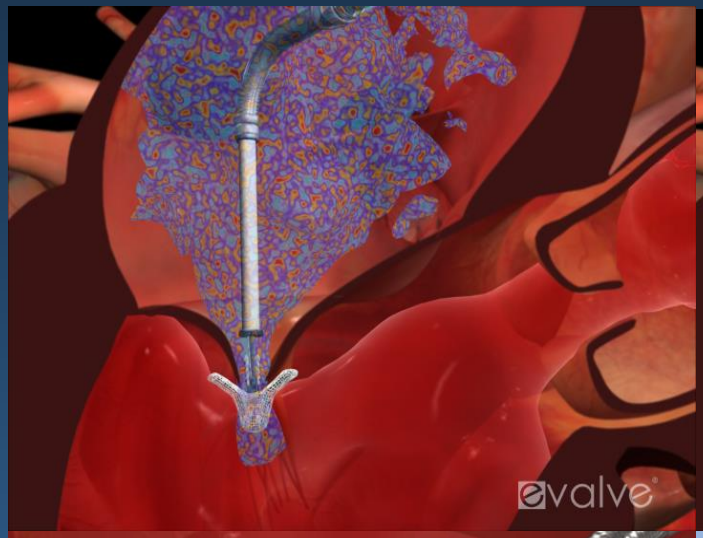


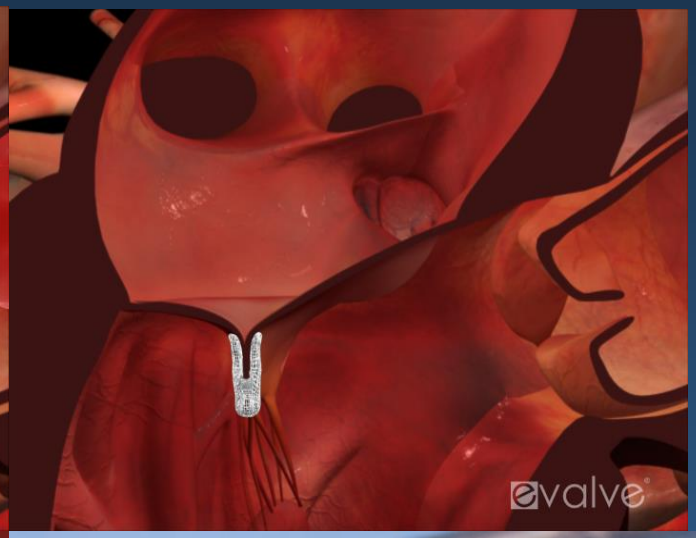
Transcatheter Mitral Clip Repair

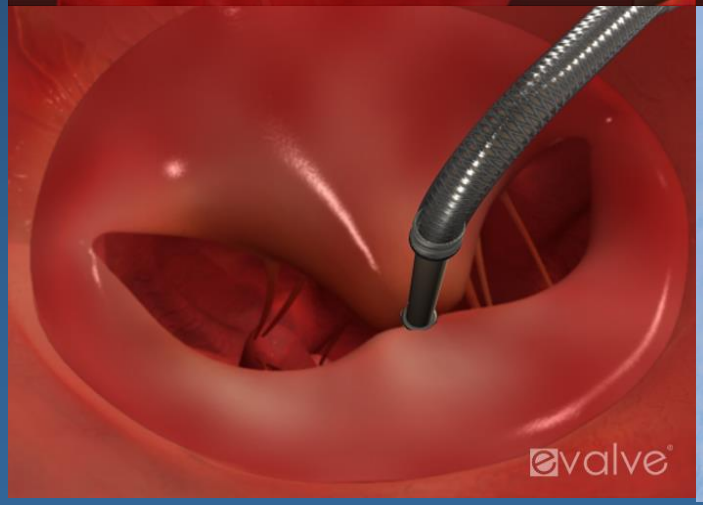


London Valve Sept 2016: 35,000 Patients Treated World Wide

Percutaneous Mitral Repair







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***Caution**: Investigational Device. Limited by Federal (US) Law to Investigational Use*

First US MitraClip: Evanston Hospital

EVEREST II: Mitral Clip v Surgery

- 279 Patients
- Average age Clip 65 y/o v Surgery 67 y/o
- Functional MR Clip 27% versus Surgery 25%
- Degenerative MR Clip 73% v Surgery 77%

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2011 VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

METHODS

We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+) mitral regurgitation in a 2:1 ratio to undergo either percutaneous repair or conventional surgery for repair or replacement of the mitral valve. The primary composite end point for efficacy was freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation at 12 months. The primary safety end point was a composite of major adverse events within 30 days

CONCLUSION

Compared to conventional surgery, the MitraClip procedure was associated with similar improvements in clinical outcomes with improved safety.

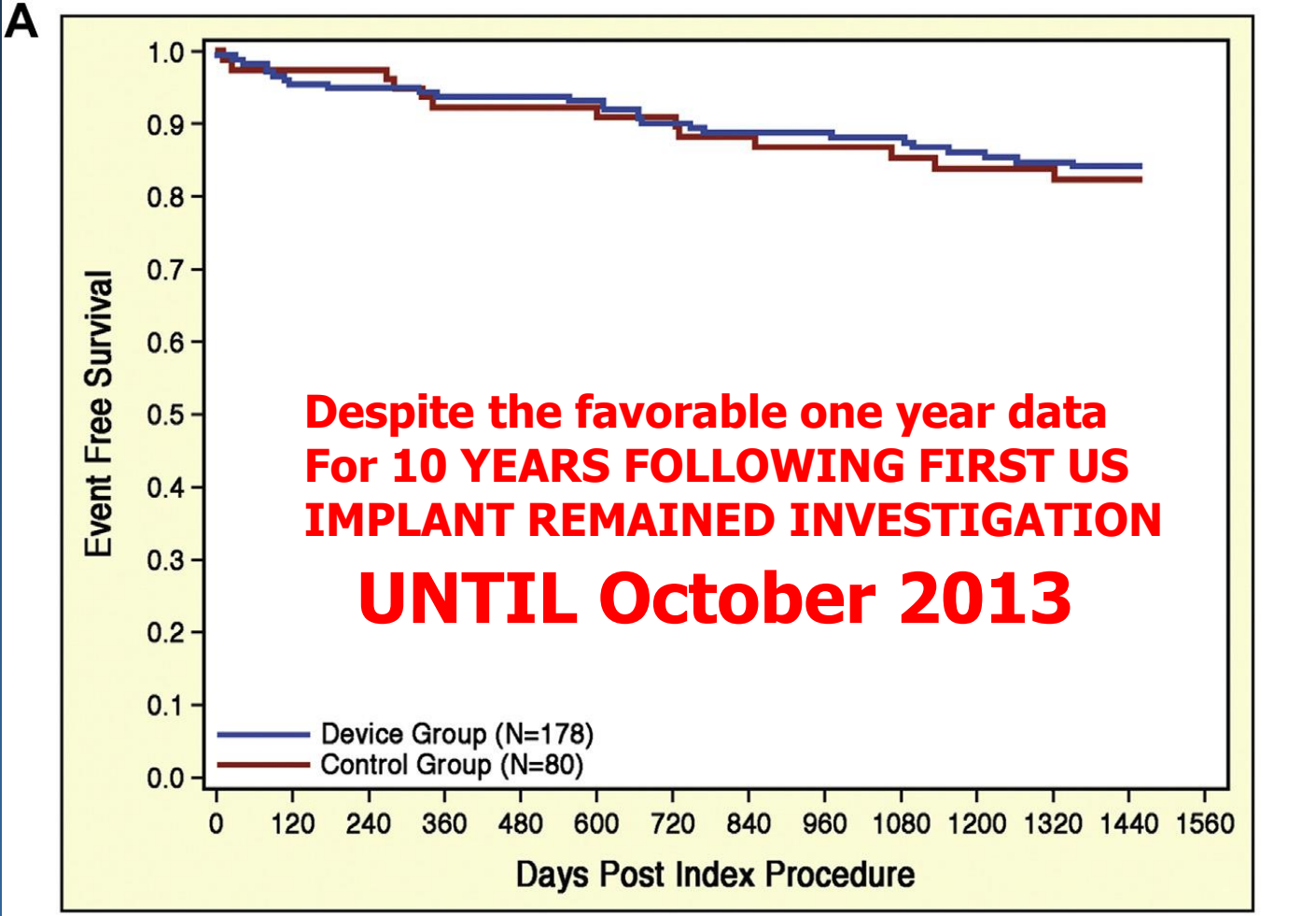
(P<0.001). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

NorthShore University HealthSystem Evanston Hospital

NEJM 2011

4 Year EVERST II: MitraClip v Surgery for Mitral Regurgitation



Feldman et al JACC 2013

Evanston Hospital
NorthShore
University HealthSystem

FDA Mitral Clip Approval: 10/25/13

Prohibitive Surgical Risk Degenerative MR

Abbott's First-In-Class MitraClip® Device Now Available for U.S. Patients

Treatment with Minimally Invasive Device Can Improve Quality of Life for Patients with Debilitating Mitral Valve Disease Who Are at Prohibitive Surgical Risk

ABBOTT PARK, Ill., October 25, 2013 – Abbott today announced that its first-in-class, catheter-based MitraClip® therapy has received U.S. Food and Drug Administration (FDA) approval and will launch immediately in the United States, providing physicians with a breakthrough treatment option for patients suffering from mitral regurgitation (MR). The MitraClip device has been approved for patients with significant symptomatic degenerative MR who are at prohibitive risk for mitral valve surgery. Degenerative MR is a type of MR caused by an anatomic defect of the mitral valve of the heart. Prohibitive risk is determined by the clinical judgment of a heart team due to the presence of one or more documented surgical risk factors.

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http://dx.doi.org/10.1016/j.jacc.2015.10.018

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

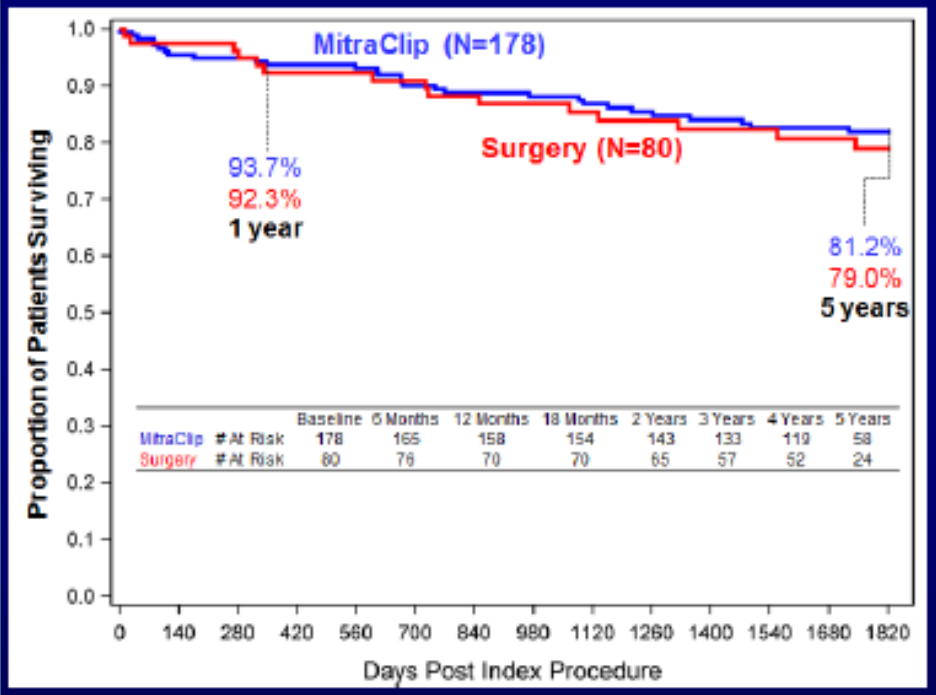
Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,§ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PhD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,††† Elyse Foster, MD,§§§ Andrew Wang, MD,‖‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,§### for the EVEREST II Investigators

Evanston Hospital NorthShore University HealthSystem

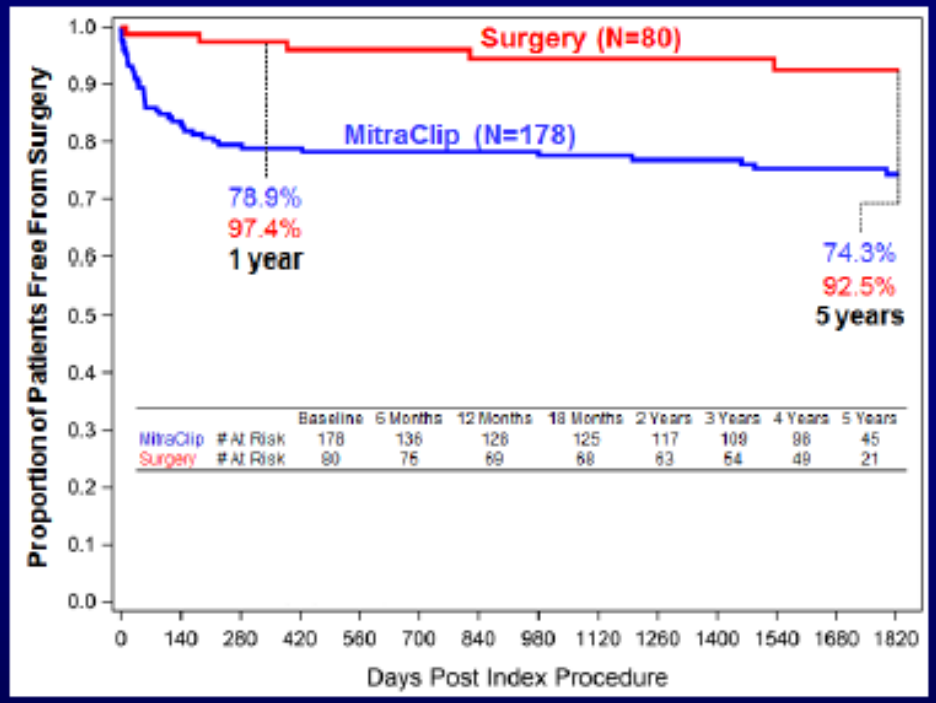
JACC 2015

Freedom From Mortality and MV Surgery/Re-operation 5 year follow up of EVEREST II trial

Kaplan-Meier Freedom From Mortality



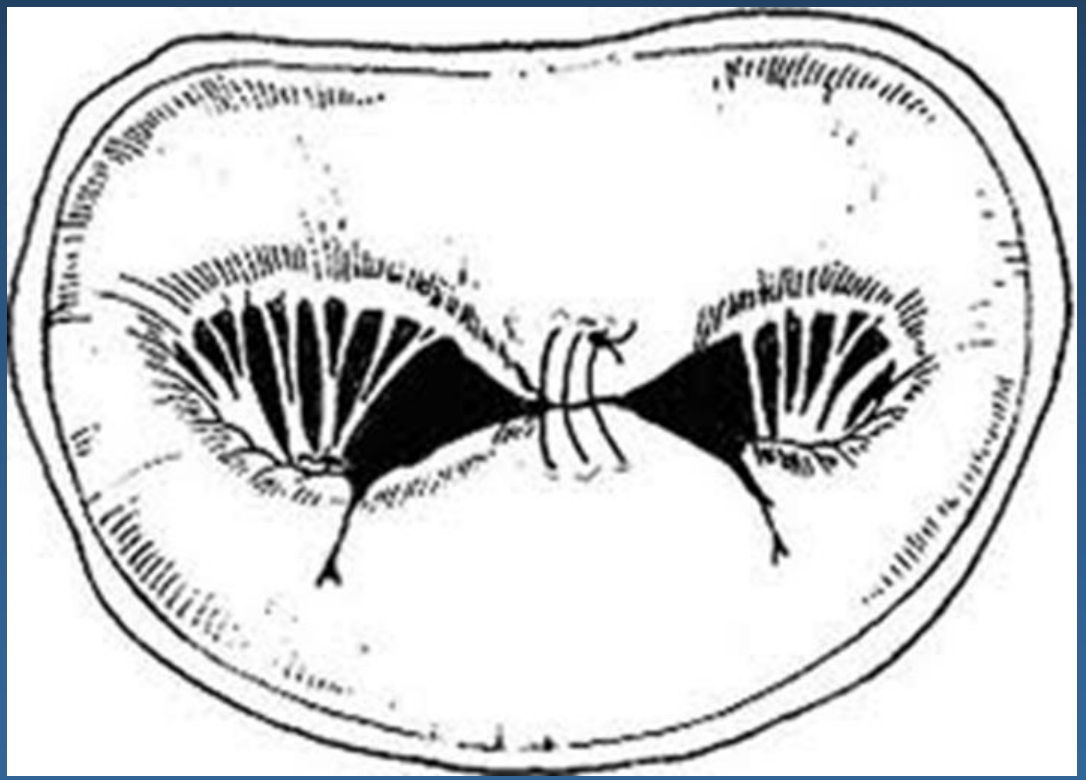
Kaplan-Meier Freedom From Mitral Valve Surgery/Re-operation



Feldman T, Kar S, Mauri L et al. J Am Coll Cardiol 2015

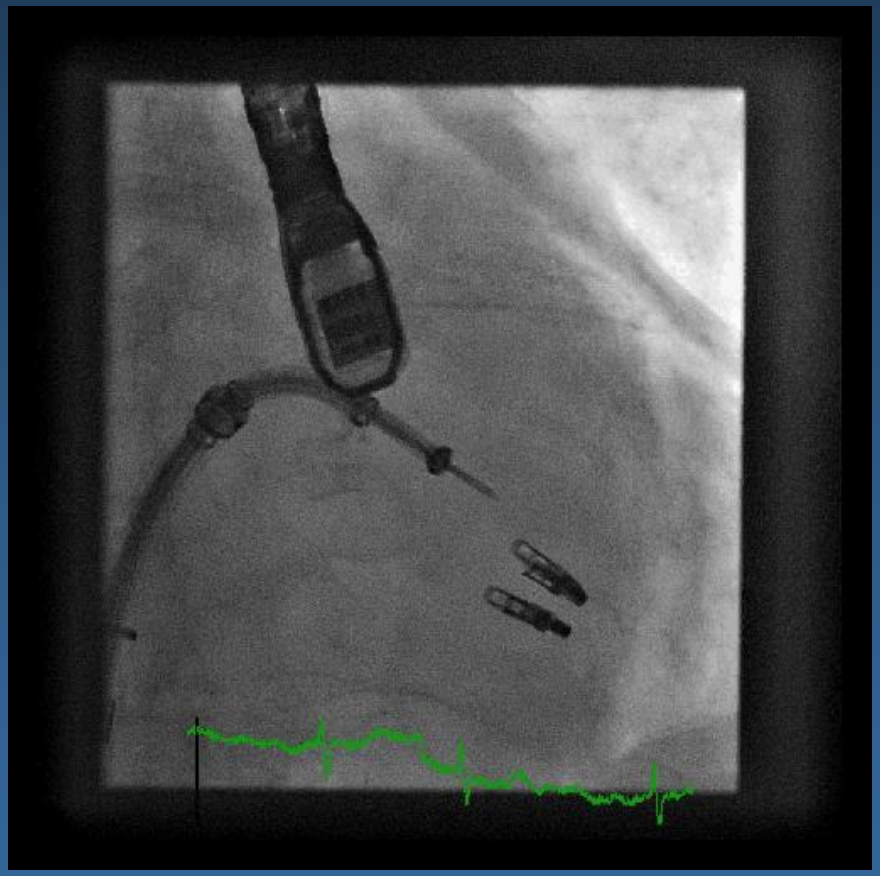
Evanston Hospital NorthShore University HealthSystem

Annuloplasty effect?
Edge to Edge repair
potential AP Tether that will limit progressive LV dilatation



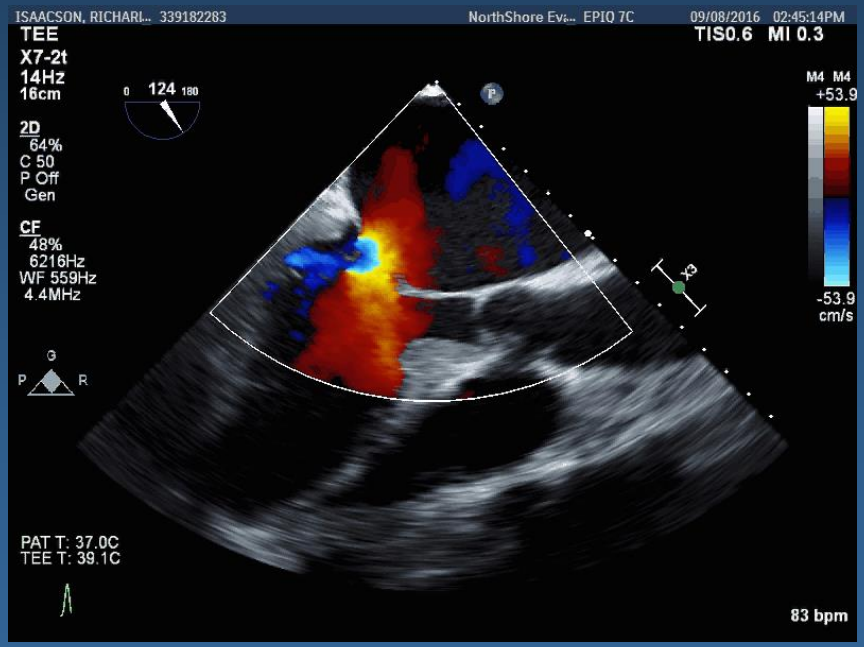
"Hypothesis: Psudo annuloplasty effect limiting annular dilatation"

95 year old: DMR

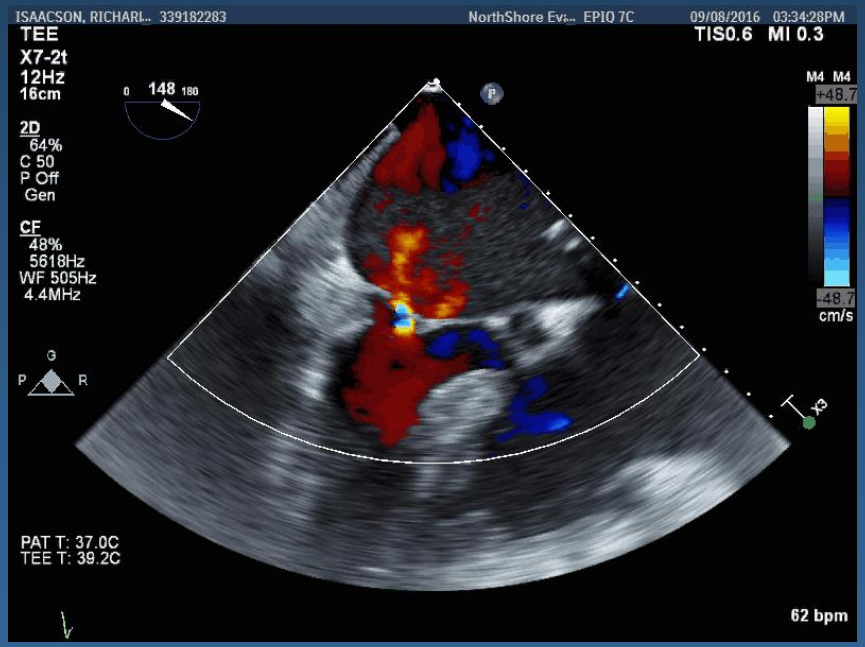


95 year old DMR: Two Clips

Pre



Post



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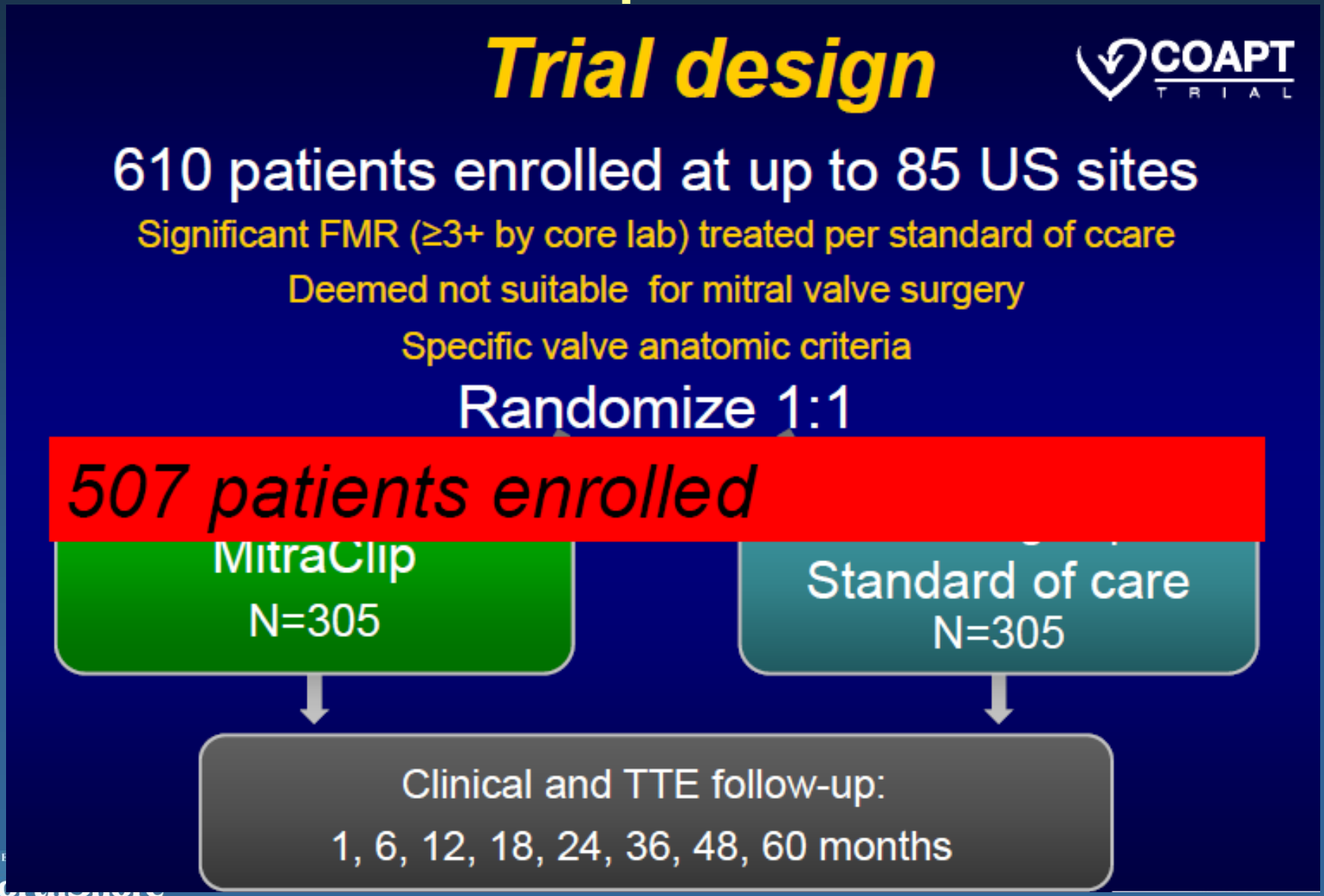
MitraClip: Clinical summary

- > 40,000 cases
- Effective in selected patients with functional or degenerative MR
- Only FDA approved transcatheter device*
- Ongoing clinical trials on FMR
- Safe
- Effective
- Evidence of durability

*FDA approval only for high risk DMR

MitraClip for FMR



When to refer for MitraClip transcatheter Mitral Repair?

- Severe mitral regurgitation
- High or prohibitive surgical risk
- DMR Commercial
- FMR Investigational

Ongoing NorthShore Mitral Regurgitation Research

- MitraClip for Prohibitive non Degenerative Mitral Regurgitation COAPT TRIAL
- Tendyne fisability trial
- MITRAL Trail Sapien in Mitral Position
- Anticipated oon Non Edge to Edge Mitral Repair via Coronary Sinus Trial with CARILLON Device and CardioBand

TMVR: Transcatheter Mitral Valve Replacement

Promising new technologies on the horizon…

What is being done today and a glimpse into the very near future

"Making Mitral Great Again"

Quote attributed to Danny Davir, MD
Political affiliation unknown

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NorthShore
University HealthSystem

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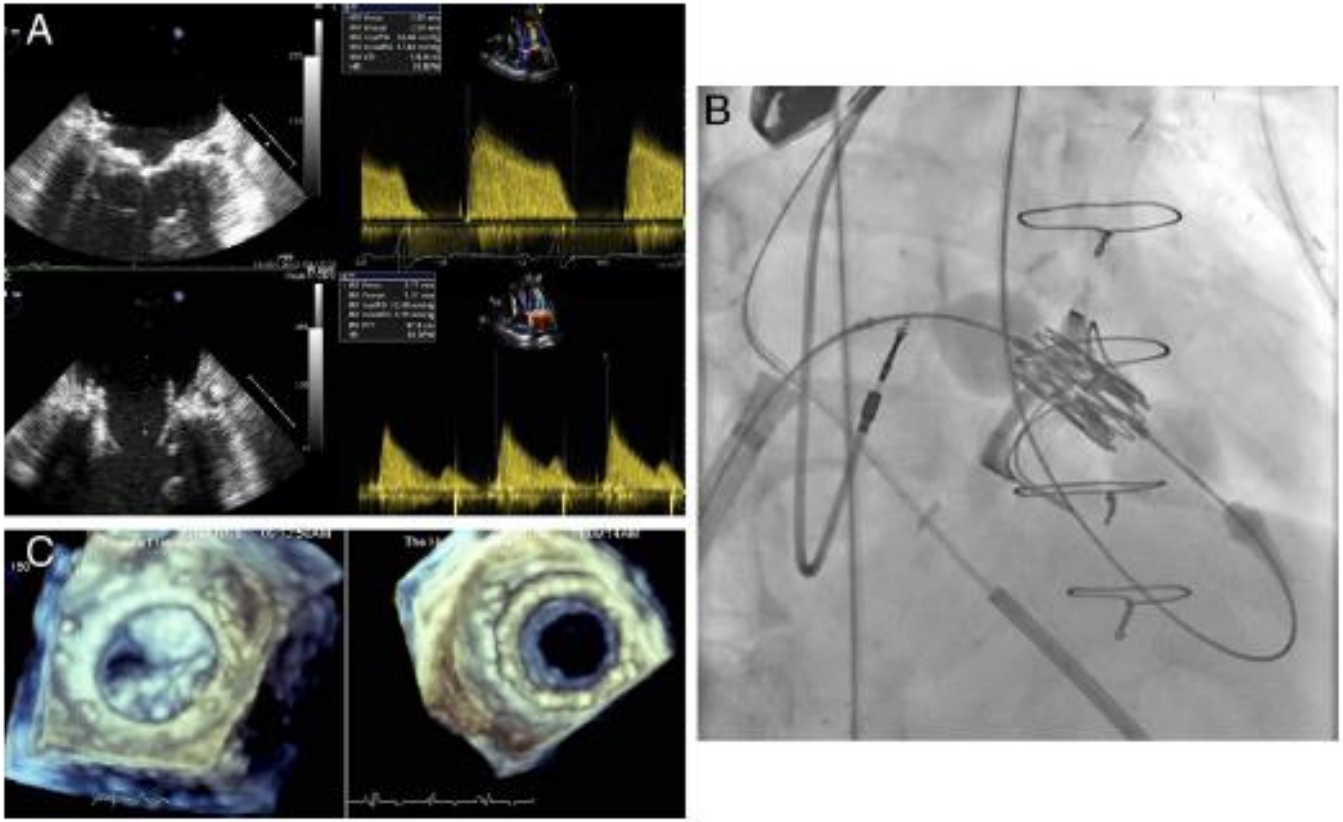
http://dx.doi.org/10.1016/j.jacc.2012.08.1033

IMAGES IN CARDIOLOGY

Percutaneous Transvenous Mitral Valve Implantation

A. B. Gopalamurugan, MD,* Antonios Pantazis, MD,* Silvia Schievano, PHD,†
Andrew M. Taylor, MD,† Michael J. Mullen, MD*
London, United Kingdom



From the *Heart Hospital, University College London

A 75-year-old-man with previous coronary artery bypass graft surgery and mitral valve replacement with a 27-mm St. Jude porcine valve was in New York Heart Associa-

Percutaneous Transvenous Transseptal Transcatheter Valve Implantation in Failed Bioprosthetic Mitral Valves, Ring Annuloplasty, and Severe Mitral Annular Calcification

Mackram F. Eleid, MD,[a] Allison K. Cabalka, MD,[a] Matthew R. Williams, MD,[b] Brian K. Whisenant, MD,[c] Oluseun O. Alli, MD,[d] Neil Fam, MD,[e] Peter M. Pollak, MD,[a] Firas Barrow, MD,[b] Joseph F. Malouf, MD,[a] Rick A. Nishimura, MD,[a] Lyle D. Joyce, MD, PHD,[a] Joseph A. Dearani, MD,[a] Charanjit S. Rihal, MD, MBA[a]

METHODS Percutaneous transfemoral antegrade transseptal implantation of Edwards SAPIEN prosthesis (Edwards Lifesciences, Irvine, California) was performed in 48 patients with degenerated mitral bioprosthesis (n = 33), previous ring annuloplasty (n = 9), and severe MAC (n = 6).

RESULTS The mean Society of Thoracic Surgeons risk score was 13.2 ± 7.4% with a mean age 76 ± 11 years. Acute procedural success was achieved in 42 of 48 patients (88%) in the overall group and 31 of 33 (94%) in the failed bioprosthetic mitral valve group and success rate of 11 of 15 (73%) in patients with failed annuloplasty rings and MAC. After successful procedure, no patients had > mild residual mitral prosthetic or periprosthetic regurgitation; mean transvalvular gradients were 6 ± 2.5 mm Hg. Thirty-day survival free of death and cardiovascular surgery was 85% in the overall group and 91% in the failed bioprosthetic mitral valve subgroup.

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JACC Intervention 2016

Transeptal Edwards S3 Valve in Valve for Mitral Prosthesis

- Based on favorable registry data Edwards Laboratories may go to FDA later this year for approval

"Sapien S3 TMVR"

- The MITRAL Trial (TMVR with S3 THV)
  - Valve in Mitral Valve
  - Valve in failed Mitral Valve Ring
  - Valve in MAC

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Dr. Guerrero: PI

MITRAL Trial Activity as of 3-30-17

Sites activated/IRB approval= 8/8
Patients presented= 82 (43/20/19)
Patients enrolled= 47 (13/16/18)
Patients treated= 42 (13/13/16)

Site	Presented (MAC/VinR/VinV)	Enrolled (MAC/VinR/VinV)	Implanted (MAC/VinR/VinV)
Henry Ford Hospital	10 (4/5/1)	8 (3/4/1)	8 (3/4/1)
Evanston Hospital	26 (12/9/5)	15 (3/7/5)	13 (3/5/5)
Mayo Clinic	14 (12/1/1)	5 (3/1/1)	5 (3/1/1)
Columbia	14 (8/1/5)	8 (3/1/4)	5 (3/0/2)
Mass General Hosp	7 (4/0/3)	4 (1/0/3)	4 (1/0/3)
Medstar	4 (0/1/3)	4 (0/1/3)	4 (0/1/3)
Piedmont	5 (2/2/1)	3 (0/2/1)	3 (0/2/1)
Cedars	2 (1/1/0)	0 (0/0/0)	0 (0/0/0)

The MITRAL Trial

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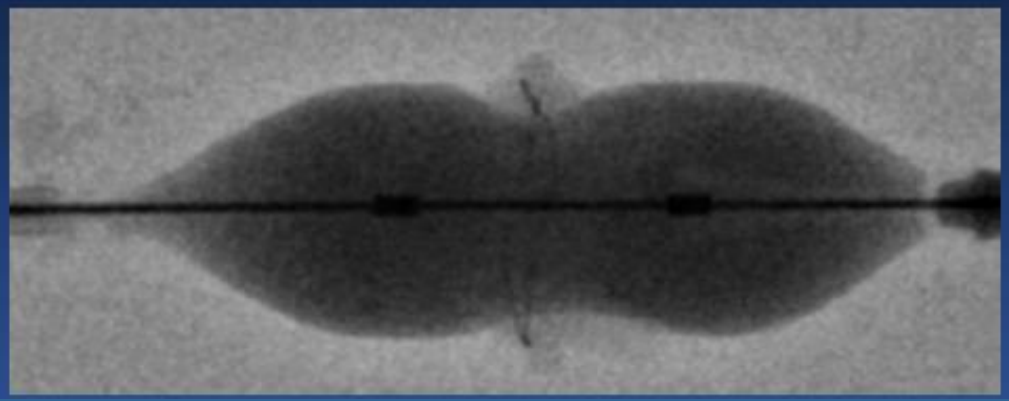
NorthShore
University HealthSystem

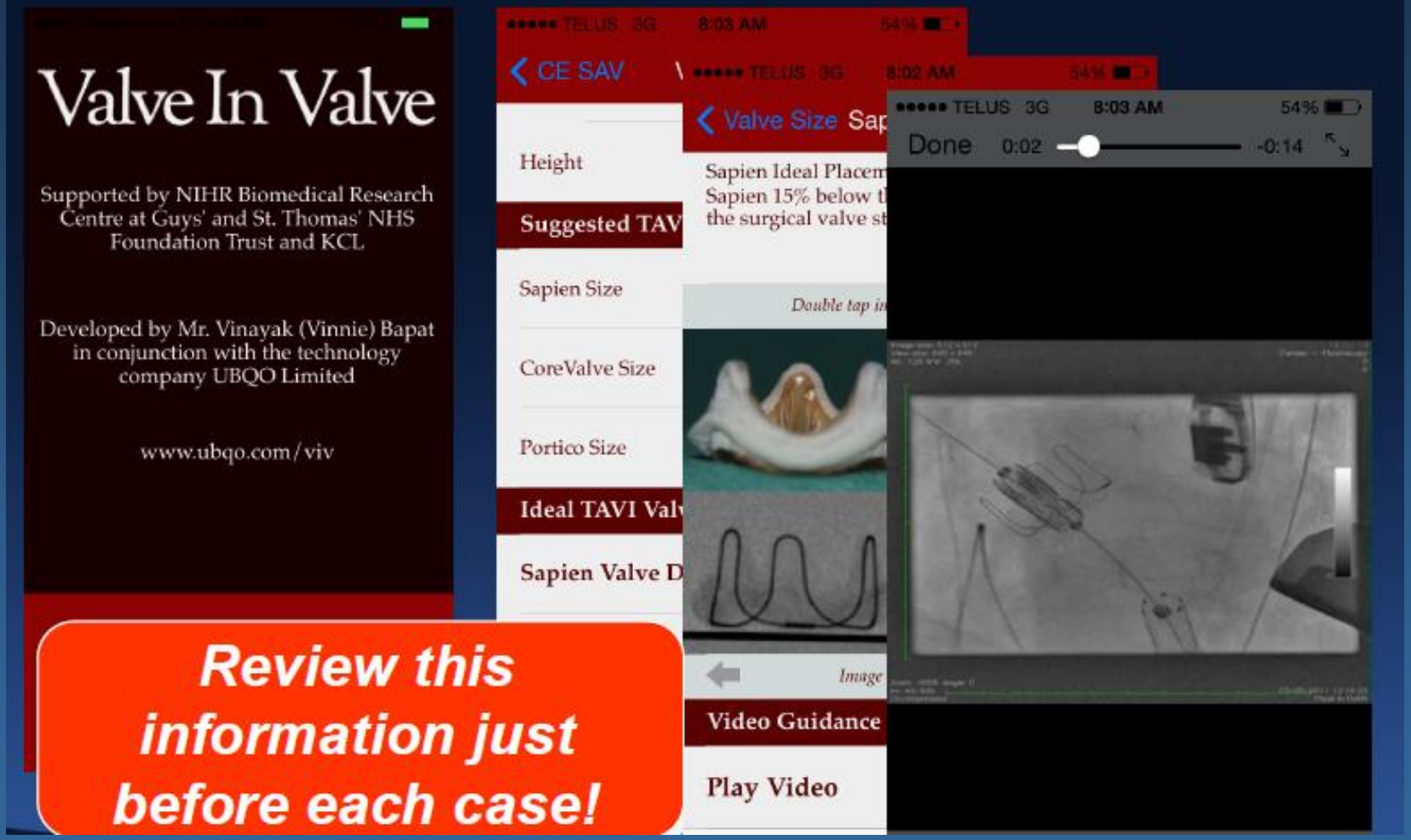
Correct Placement Requires Understanding of Valve Geometry

Biocor/ Epic– Thin wire at the level of sewing ring



- Narrowest Portion – Sewing Ring
- Identifying Sewing Ring Crucial
- Place Sapien 15% Below Sewing Ring

Valve in Valve App



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Mitral Valve in Ring: Complete ring can offer anchor

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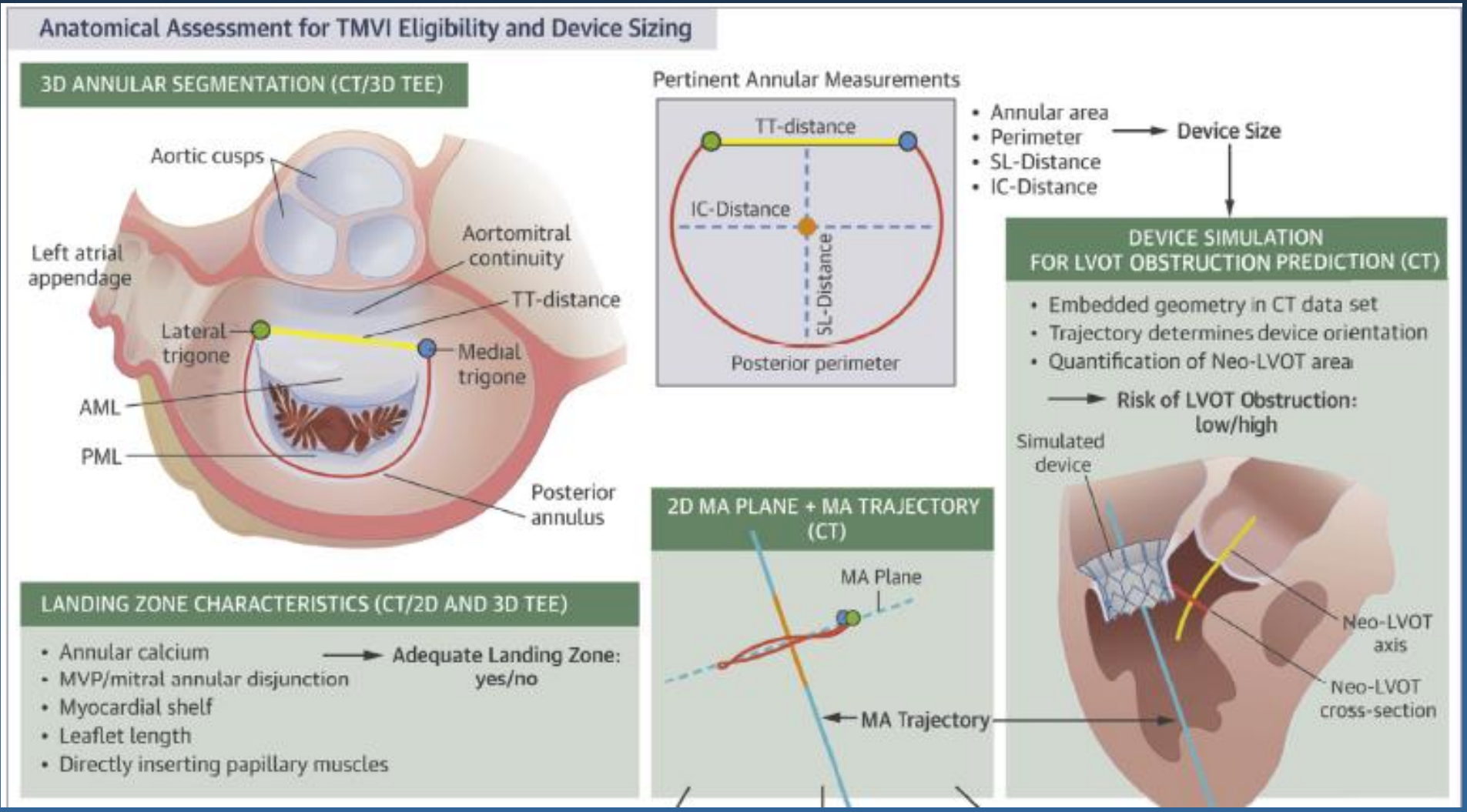
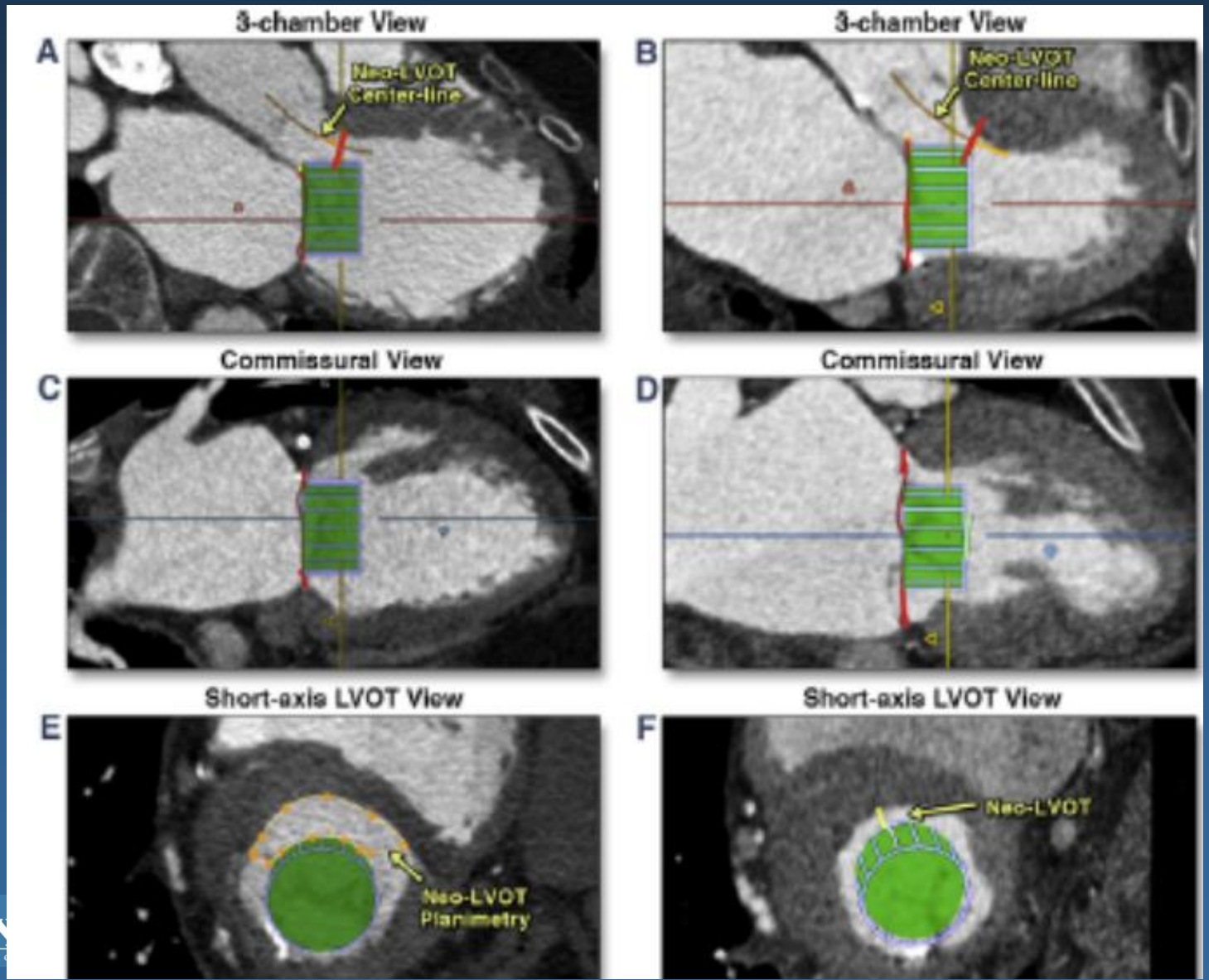
University HealthSystem

Mitral more complex than Aortic
3 D valve: D Shaped/Saddle shaped with sub annular structures
TMVR Issues: Anchoring and LVOT obstruction



Mitral Annular Calcification: Need enough to anchor
CT is the "Gold Standard"

If Anterior leaflet intact: Can be issues with LVOT obstruction (CT Modeling Neo LVOT)

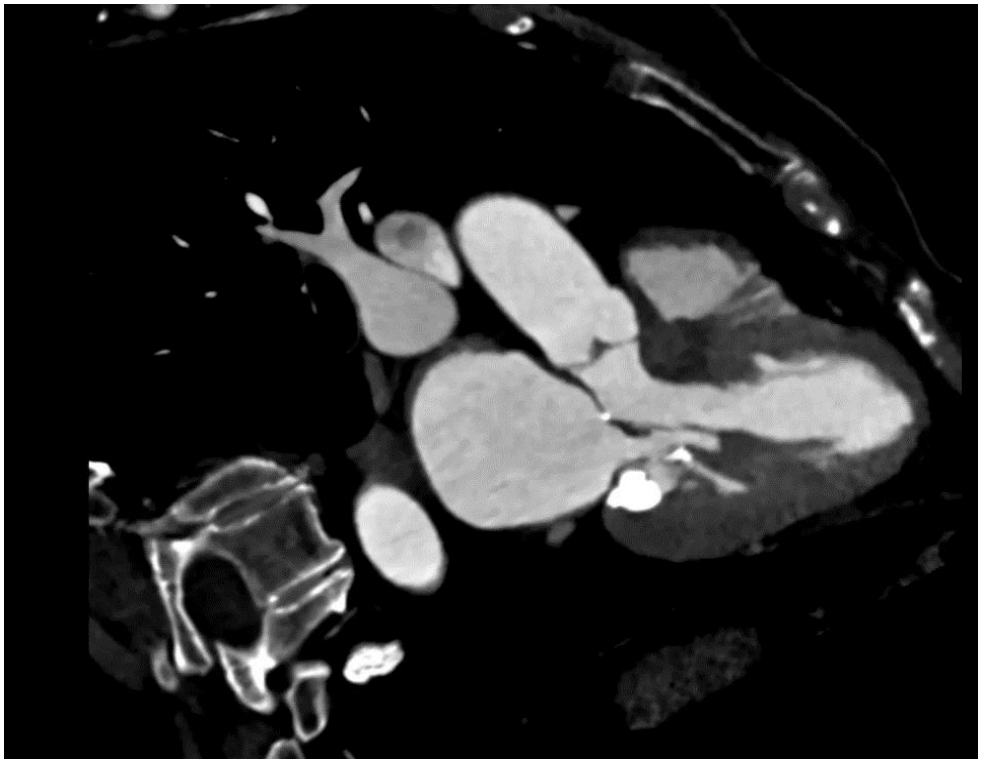


JACC Imaging 2015

Role of Alcohol Septal Ablation prior to TMVR

Pre-ablation

Post-ablation

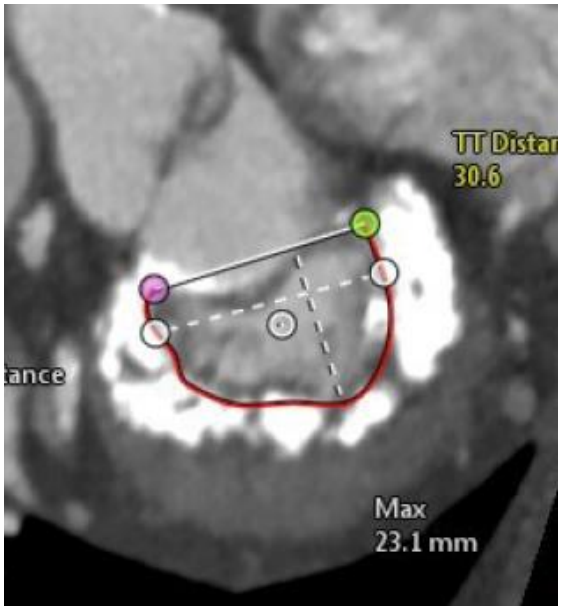


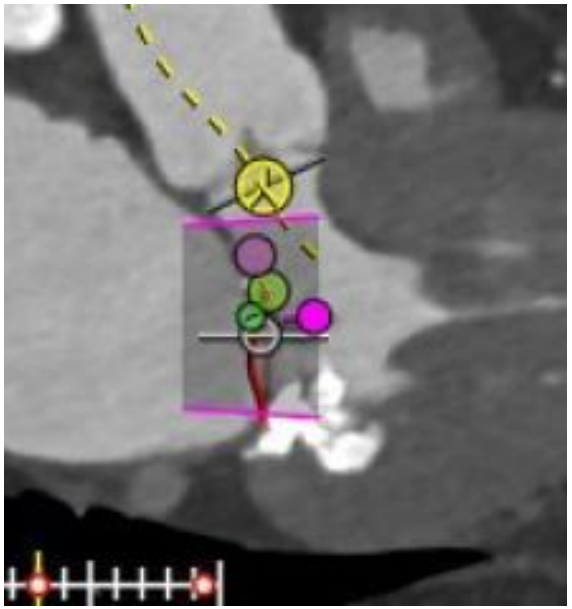
Courtesy of Dr. Dee Dee Wang

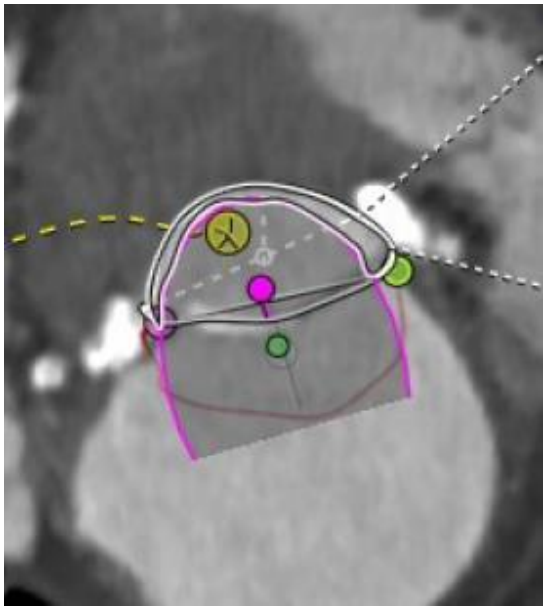
8 patients successfully treated with TMVR after alcohol ablation
(TMVR in MAC Registry and MITRAL Trial)

NorthShore University HealthSystem
Evanston Hospital

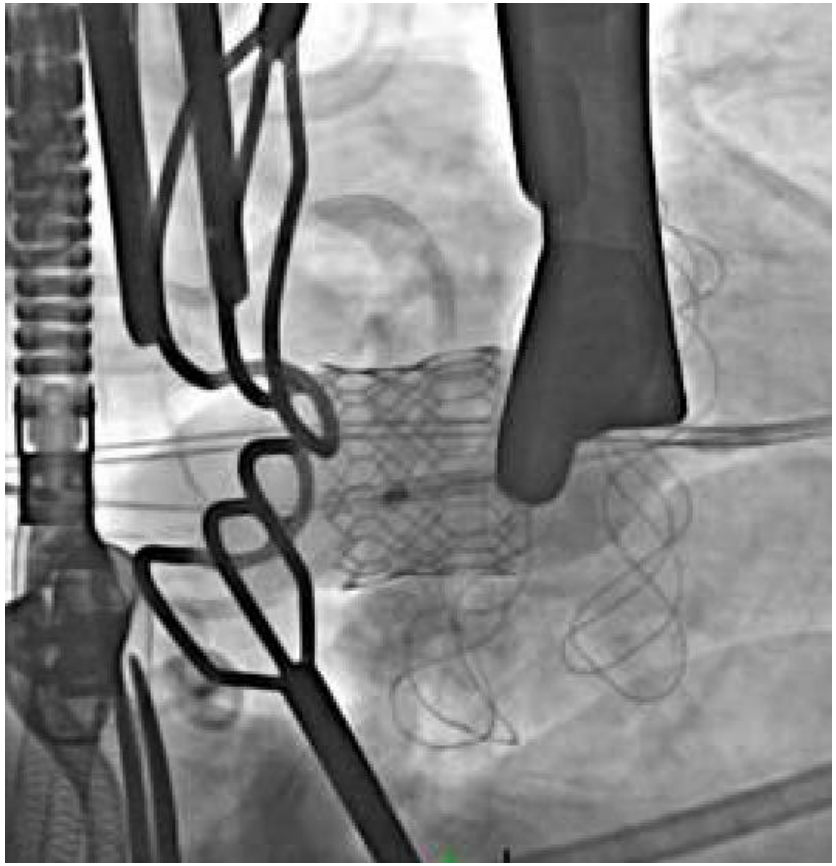
Role of Anterior Leaflet Resection prior to TMVR prevent LVOT obstruction

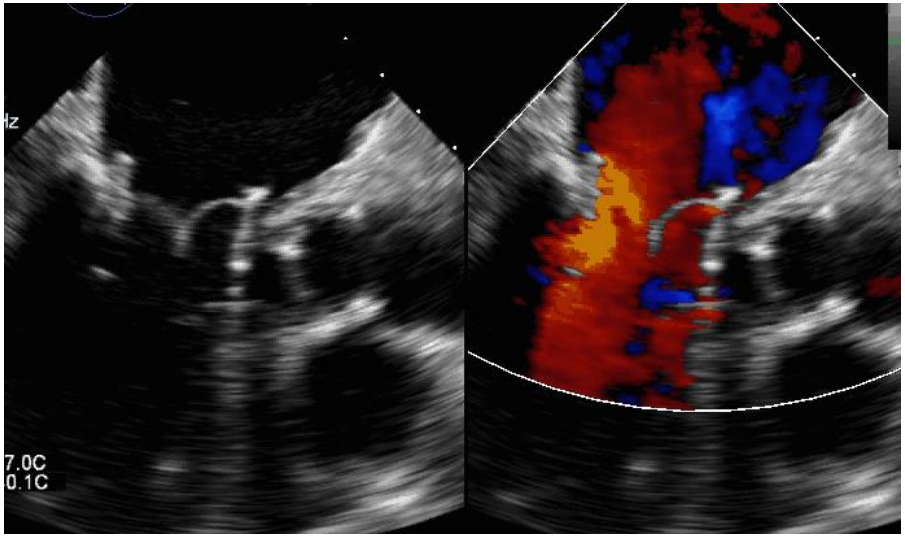


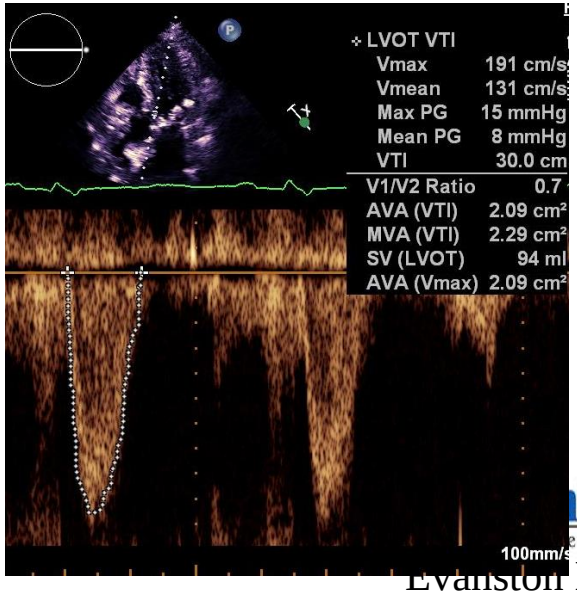




Role of Anterior Leaflet Resection prior to TMVR





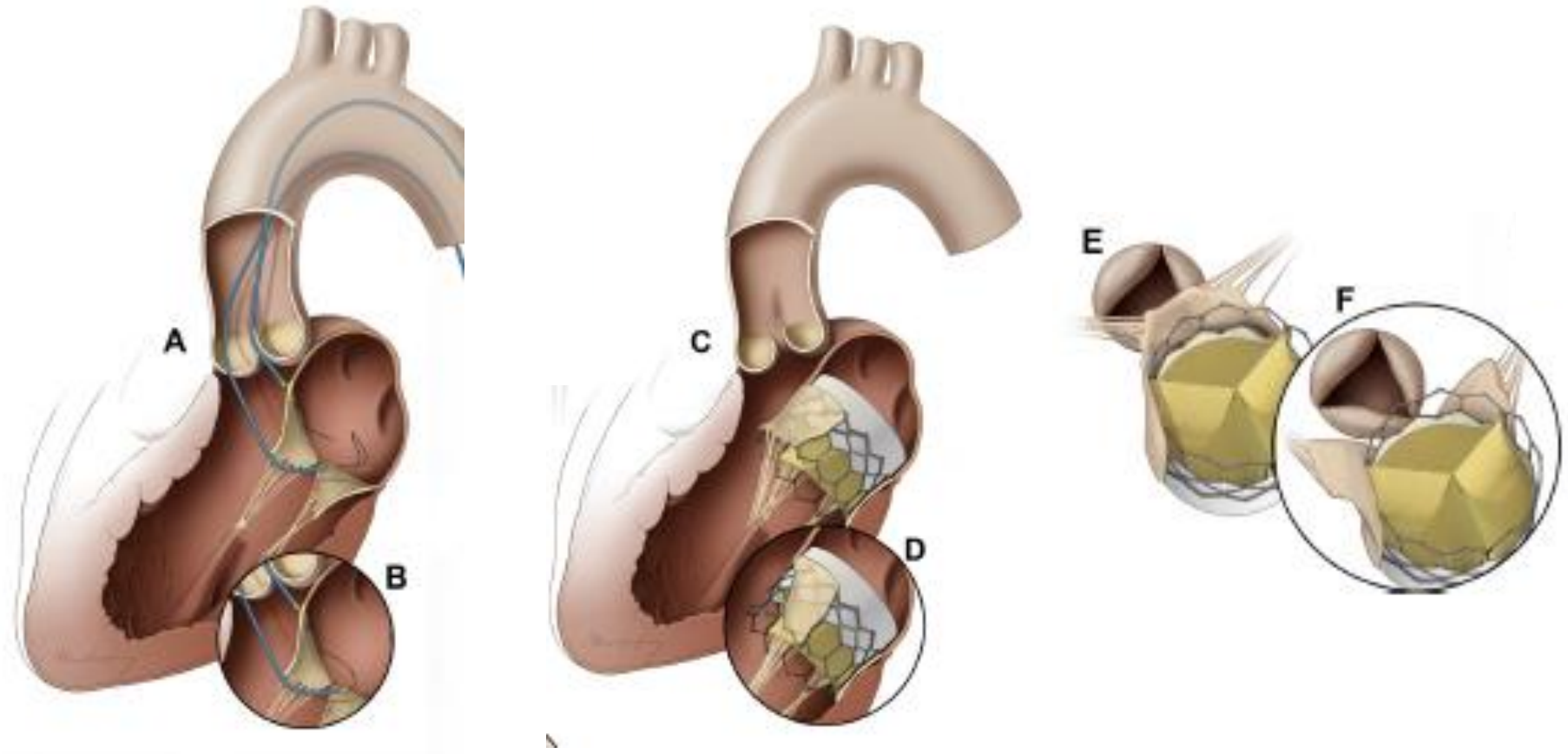


6-month follow 2-17-17
NYHA I
Mean MVG 4 mmHg
Mean LVOT gradient 5 mmHg

Percutaneous Anterior Leaflet Laceration prior to TMVR

LAMPOON

Laceration of the **A**nterior **M**itral leaflet to **P**revent LV**O**T **O**bstructio**N**



Khan et al, *JACC Intv 2016*;9:1835-43.

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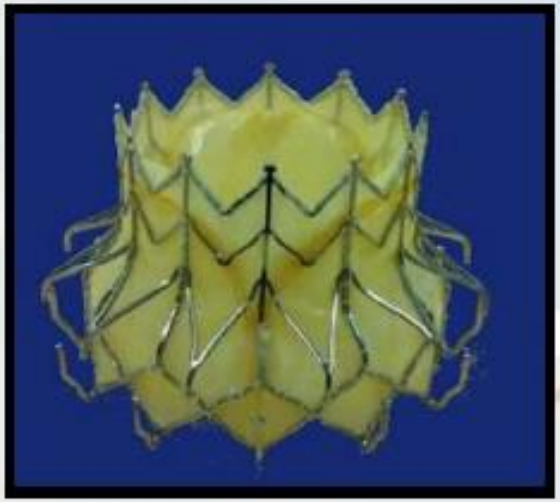
Evanston Hospital

TMVR Candidates

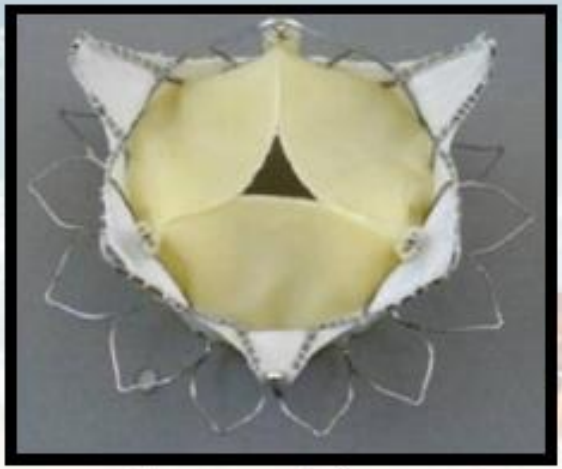
Tendyne

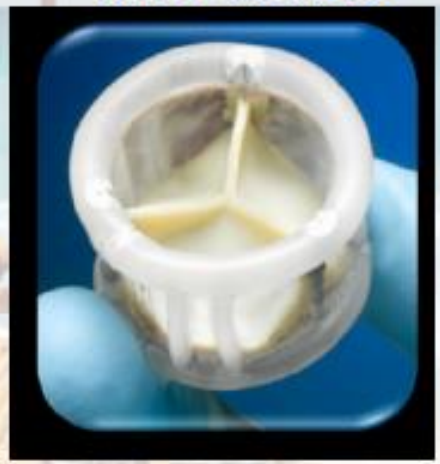


CardiAQ

Twelve Medtronic

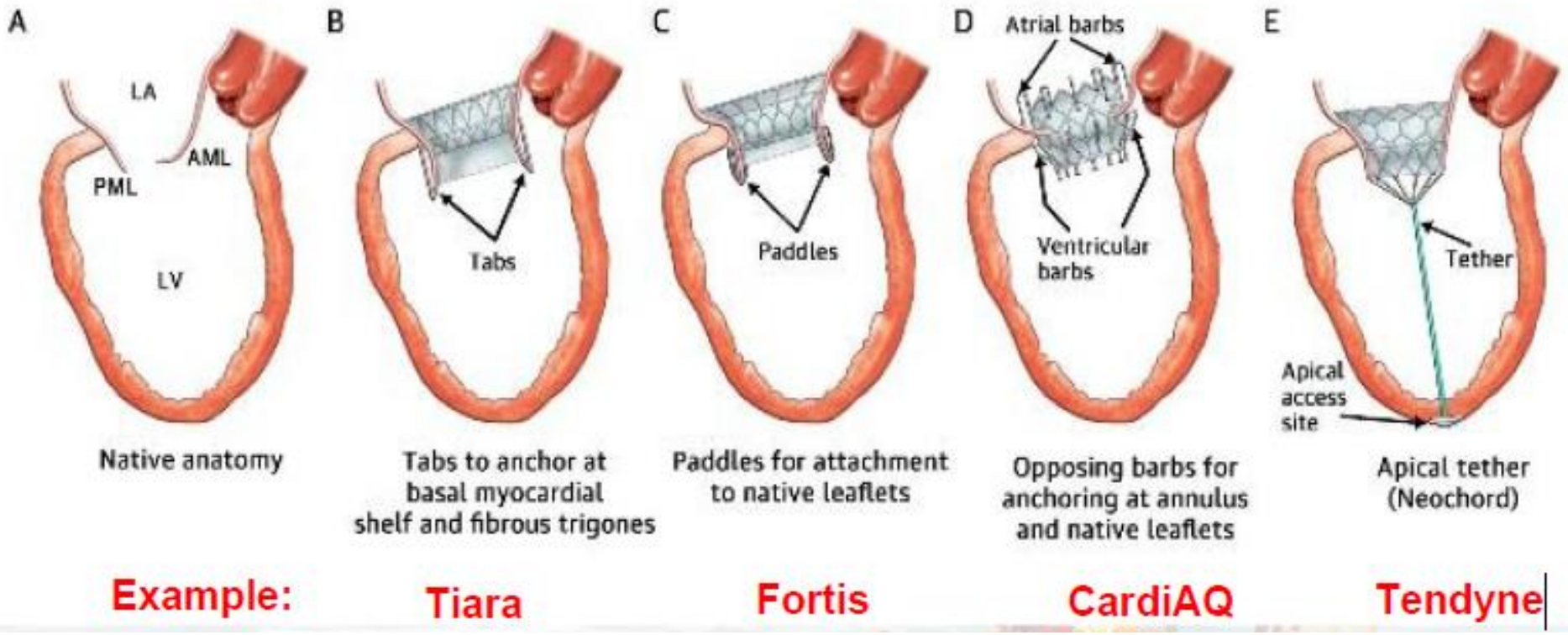
Edwards Mitral





Direct flow

Transcatheter Mitral Valve Implantation (TMVI/TMVR)



Blanke et al. JACC Imaging 2015

Tendyne Abbott Transapical Off Pump Mitral Valve Prosthesis

FIM Paraguay Feb 19 2013
57 year old male DMR
JACC Interventions 2014

Evanston Hospital
NorthShore
University HealthSystem

NorthShore Evanston Hospital First Case: January 2016

Tendyne TMVI Investigators

Global Feasibility Study (n=30)

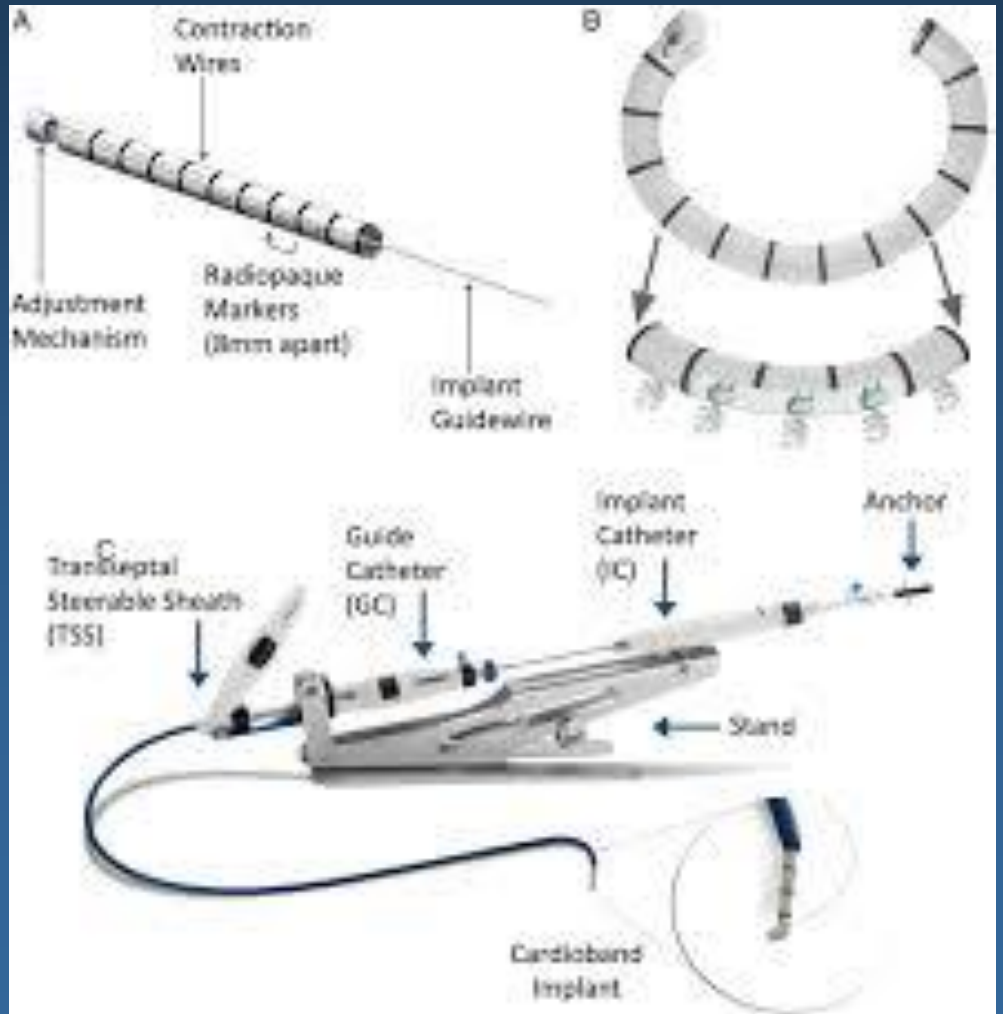
- St Vincent's Hospital, Sydney
- Abbott Northwestern, Minneapolis
- **Prince Charles Hosp, Brisbane**
- **Baylor Heart and Vascular, Dallas**
- **Oslo University Hospital, Oslo**
- **Evanston Hospital, Chicago**
- **Cleveland Clinic, Cleveland**
- **Medstar Hospital, Washington DC**

November 2014 – March 2016

Evanston Hospital
NorthShore
University HealthSystem

Percutaneous Annuloplasty: CardioBand

- ValTech (Israeli Company recently acquired by Edwards Life Sciences)—CE Mark in Europe



CE Mark n=50 at 6 centers

Evanston Hospital NorthShore University HealthSystem

CardioBand: Transcatheter Annuloplasty

CE Mark n=50
Current world experience 300

NorthShore Cath Lab 2016: CardioBand Model Implant

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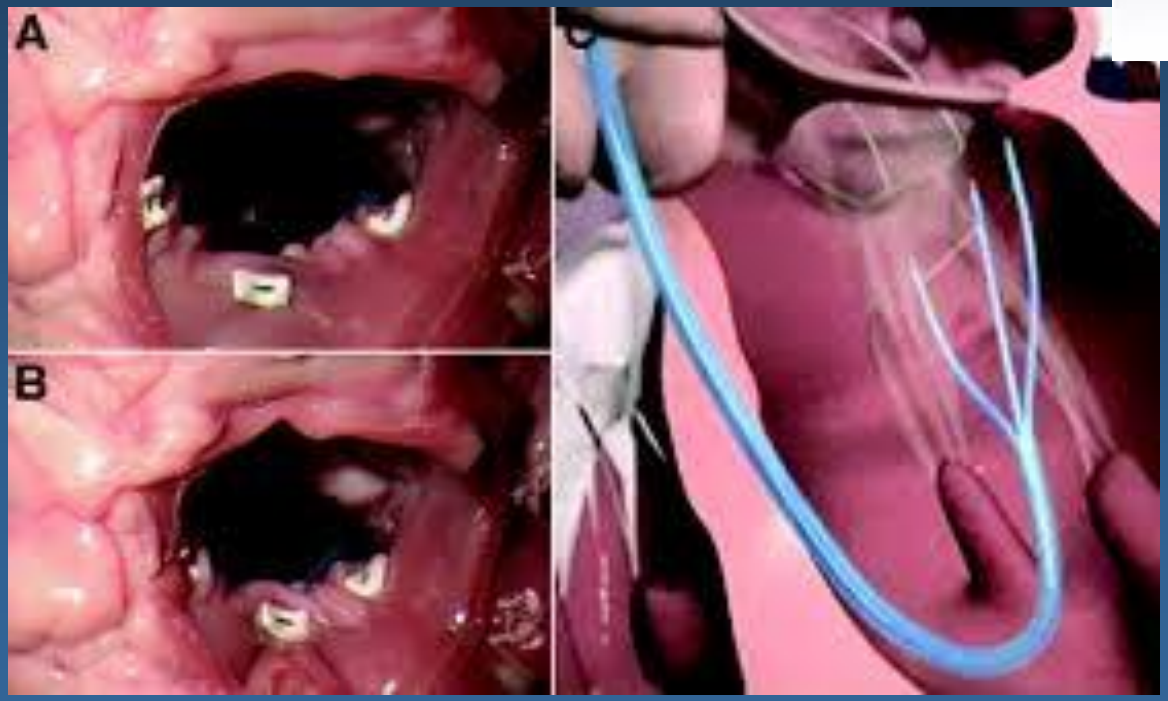
Mitralign: Transcatheter Suture Pleges

- CE Mark in Europe n=61



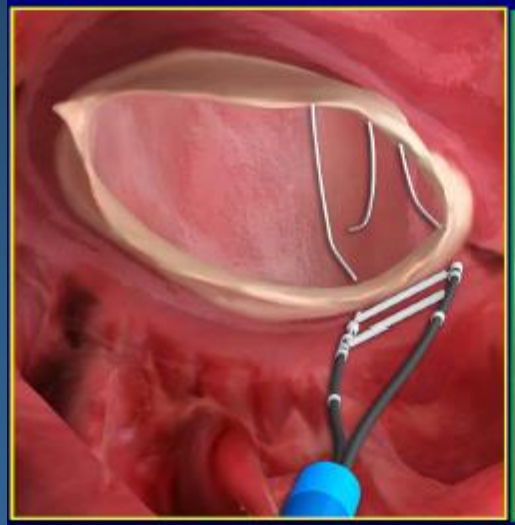
Mitralign Procedural Steps

3 Main Components

Wire Placement

Pledget Delivery

Plication & Lock



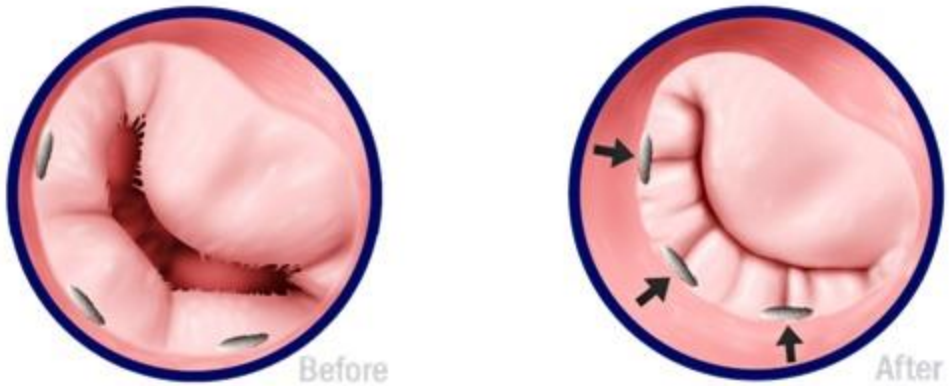
Investigational Device Only: Not Available in the EU or US

Cedars-Sinai Medical Center

Evanston Hospital
NorthShore
University HealthSystem

Mitralign Solution

Posterior plication reduces septal-lateral dimension



A relatively small (1 cm, 20%) plication of the posterior annulus can normalize the S-L dimension and reduce Ischemic MR

Tibayan et al. Pre-Clinical Evaluation *Ciculation.* 2003;108:II-128-133

Surgical MVR: Address Leaflets and Annulus

Cases of combined percutenaous therapy are beginning to surface to recreate the surgical experience of leaflet repair (Clip) and annuloplasty (Cardioband):

- Percutaneous Mitral Clip leaflet repair
- Percutaneous Annuloplasty

Emerging technologies for direct and indirect percutaneous mitral annuloplasty

Ted Feldman*, MD, FESC, FACC, MSCAI; Mayra Guerrero, MD, FACC, FSCAI; Michael H. Salinger, MD, FACC, FSCAI

NorthShore University HealthSystem, Evanston, IL, USA

- Circlage Annuloplasty (CS to RA loop via septal perforation)
- Millapede (LA side adjustable annuloplasty ring)
- Mitraspan (Annulus to Apex tether)
- Accucinch (LV side adjustable annuloplasty ring)
- Quantumcor (RF energy to annulus to promote fibrosis and retraction)

Evanston Hospital NorthShore University HealthSystem

EuroIntervention: 2016(12) Y1-8

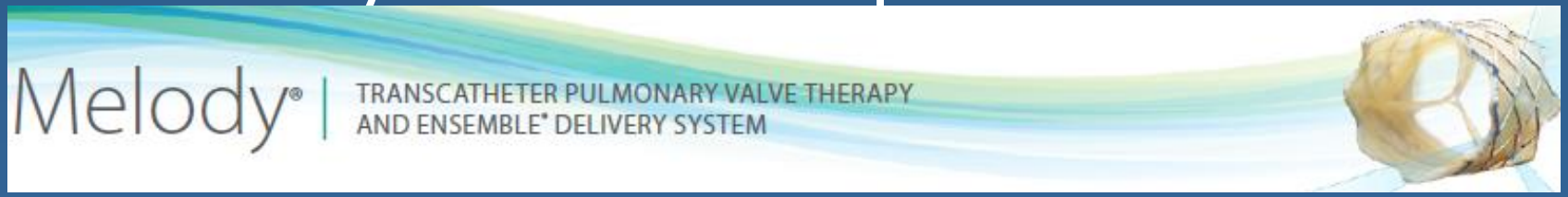
Pulmonic Valve

- BPV (balloon pulmonic valvuloplasty) for pulmonic stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
C, D	Severe PS	• Thickened, distorted, possibly calcified leaflets with systolic doming and/or reduced excursion • Other anatomic abnormalities may be present, such as narrowed RVOT	• V_{max} >4 m/s; peak instantaneous gradient >64 mm Hg	• RVH • Possible RV, RA enlargement • Poststenotic enlargement of main PA	• None or variable and dependent on severity of obstruction

- TPVR (transcatheter pulmonic valve replacement)

  Melody Valve and Sapien XT



Metronic Melody: 18 to 22 mm Bovine Jugular Vein

Tricuspid Disease:

- "The Forgotten Valve"

Surgeons:

Morbidity and Mortality of Tricuspid Regurgitation

Interventionalists:

Catching Up

Tricuspid: The Forgotten Valve

mitralign

FOR IMMEDIATE RELEASE

JACC Reports on First-In-Human Transcatheter Tricuspid Repair

Mitralign Transcatheter Annuloplasty System could present a non-surgical option for both mitral and tricuspid valve regurgitation

TEWKSBURY, MA – March 12, 2015 –A detailed reporting of the first successful case of a direct transcatheter tricuspid repair (TTVR) for severe TR has been reported by Prof. Dr. med. J. Schofer of the Medicare Center and Department for Percutaneous Interventions of Structural Heart Disease, Albertinen Heart Center, Hamburg in the current issue of the peer-reviewed Journal of the American College of Cardiology (JACC). The Mitralign System is currently being evaluated in clinical trials for an indication in functional mitral regurgitation. The device is not approved for sale or distribution in the EU or US.

TriAlign: Mitralign TVR 15 patients

Early Feasibility Study of a Transcatheter Tricuspid Valve Annuloplasty

SCOUT Trial 30-Day Results

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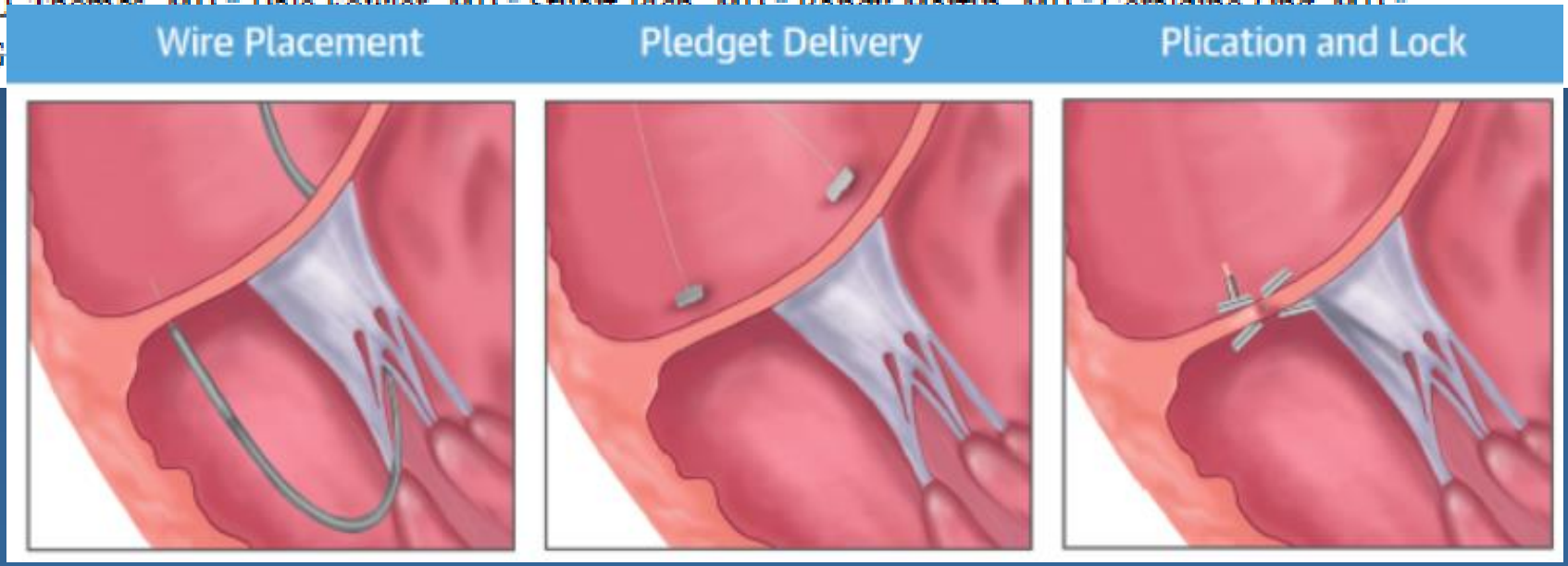
James D. Thomas, MD,[d] Dale Fowler, MD,[e] Stuart Rich, MD,[d] Randy Martin, MD,[c] Geraldine Ong, MD,[b]
Adam G



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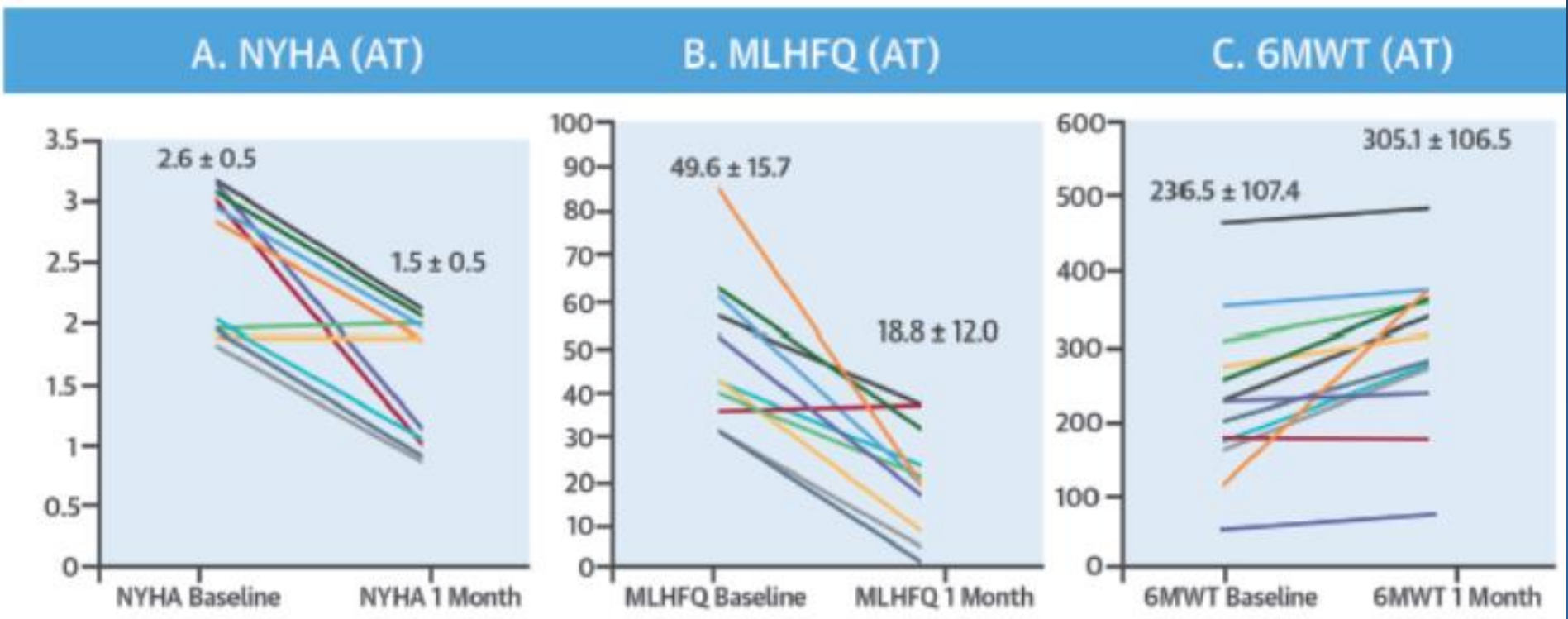
JACC Interventions April 2017

SCOT TriAlign TR Trial 30 Days

- 15 patients
- 12 Successful Plications



Hahn, R.T. et al. J Am Coll Cardiol. 2017;69(14):1795-806.

Tricuspid Regurgitation: MitraClip

Percutaneous Tricuspid Valve Regurgitation Repair With the MitraClip Device Using an Edge-to-Edge Bicuspidization Technique

Sameer Gafoor, MD[1,2]; O. Madalina Petrescu, MD[1]; Eric J. Lehr, MD, PhD[3]; Charles Puls, MD[4]; Ming Zhang, MD, PhD[1]; John L. Petersen II, MD[1]; John V. Olsen, MD[1]; Irina Penev, PA[1]; Mayank Agrawal, MD[1]; Rahul Sharma, MD[1]; Glenn Barnhart, MD[3]

J INVASIVE CARDIOL 2017;29(3):E30-E36.

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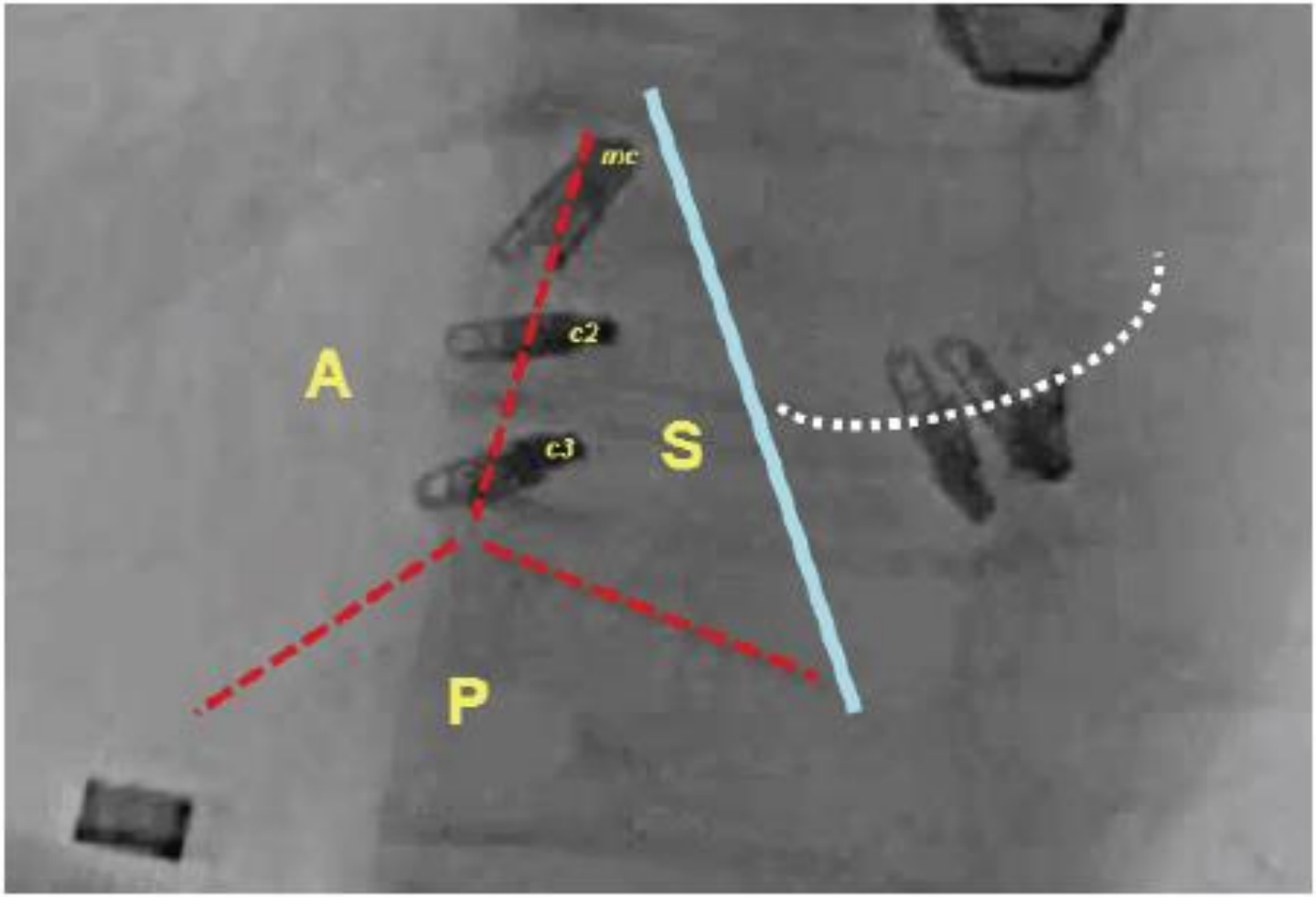
Bicuspidization Repair of Tricuspid With MitraClip



Percutaneous Tricuspid Repair

	Trialign	TriCinch	Cardioband	FORMA	TriClip	Millipede	TRAIPTA
							
Mechanism	Annuloplasty	Annuloplasty	Annuloplasty	Coaptation device	Leaflet plasty	Annuloplasty	Annuloplasty
Patients treated	± 50	±27	±19	±18	± 250	2 (surgical)	-
Ongoing Study	SCOUT II	PREVENT	TRI-REPAIR	SPACER	-	-	-

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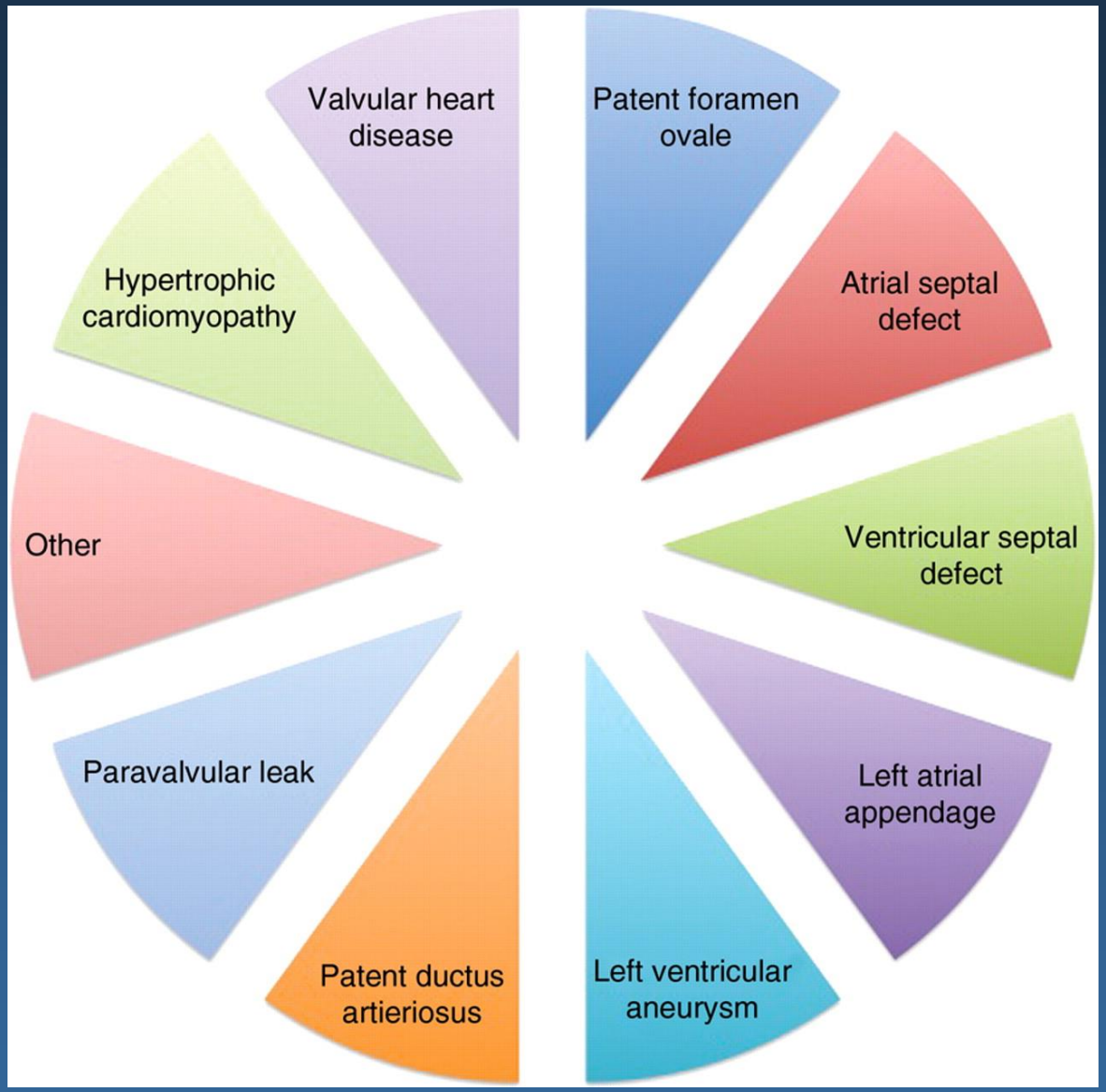
JACC April 2017

When to Refer to Structural Cardiology?

Always!



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Steinberg D H et al. Eur Heart J Suppl 2010;12:E2-E9