The evolution, current status and future development of percutaneous therapies for valvular heart disease

Ted Feldman, M.D., MSCAI FACC FESC

Evanston Hospital

2017 Carl J. Wiggers Memorial Lecture

April 19th, 2017

Cleveland, Ohio

NorthShore University HealthSystem
Evanston Hospital

Ted Feldman MD, *MSCAI FACC FESC*

Disclosure Information

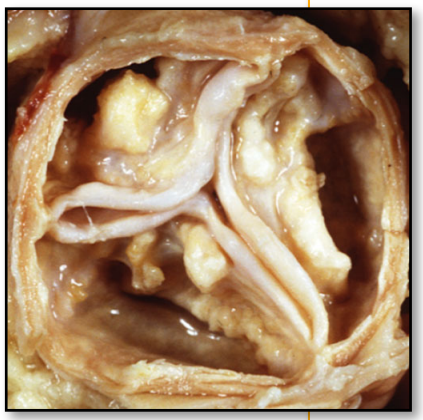
The following relationships exist:

Grant support: Abbott, BSC, Cardiokinetics, Corvia, Edwards, WL Gore
Consultant: Abbott, BSC, Edwards, WL Gore
Stock Options: Mitralign

Off label use of products and investigational devices will be discussed in this presentation

Aortic Stenosis

By JOHN ROSS, JR., M.D. AND EUGENE BRAUNWALD, M.D.



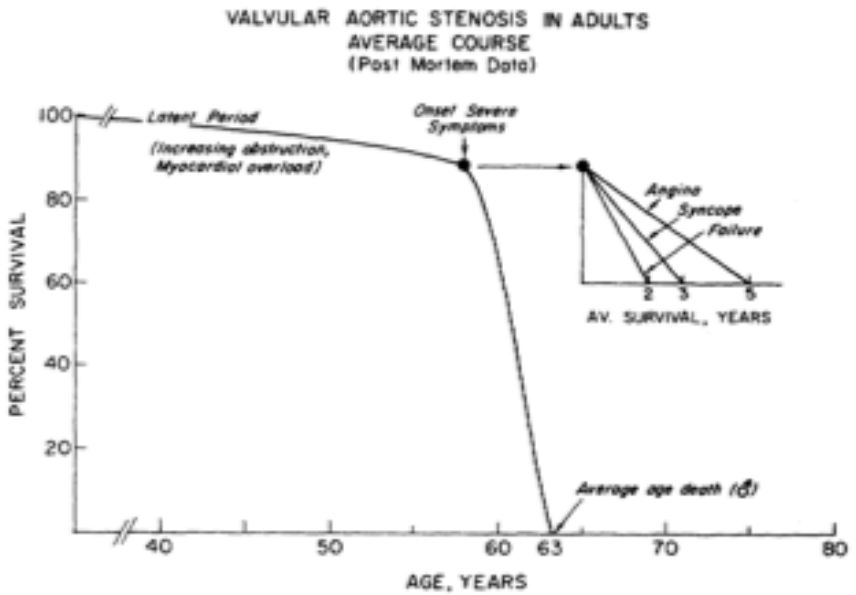
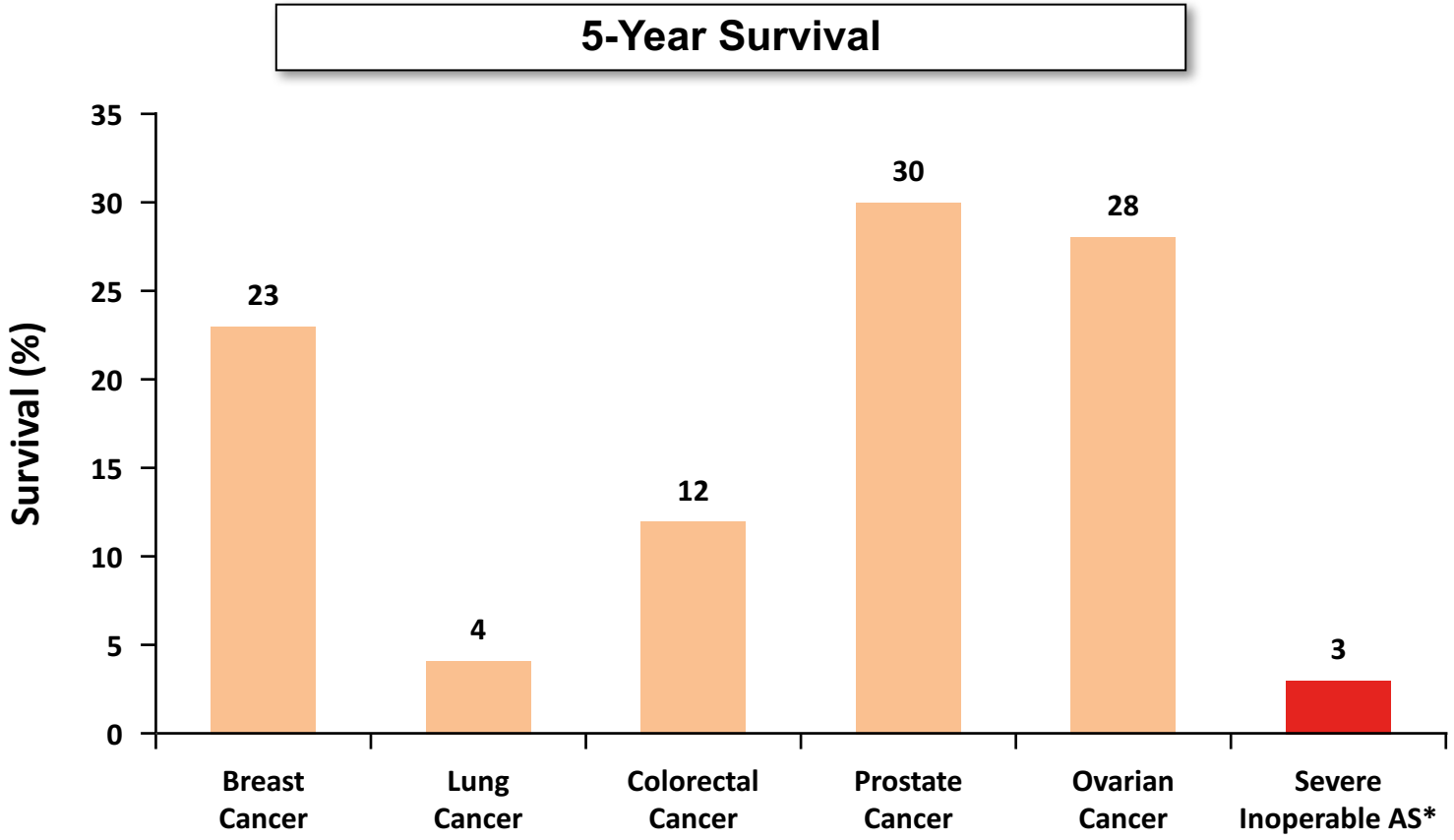


Figure 1

Average course of valvular aortic stenosis in adults. Data assembled from postmortem studies.

Supplement V to Circulation, Vols. XXXVII and XXXVIII, July 1968

Symptomatic AS Is a Malignant Disease



- 5-year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer, and severe inoperable AS is reported here

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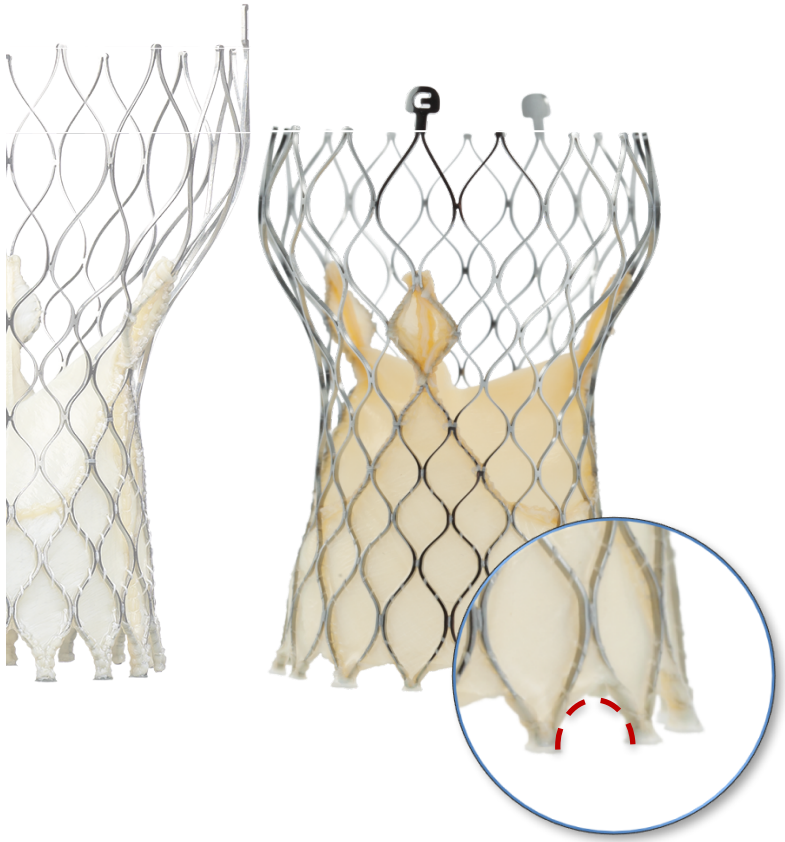
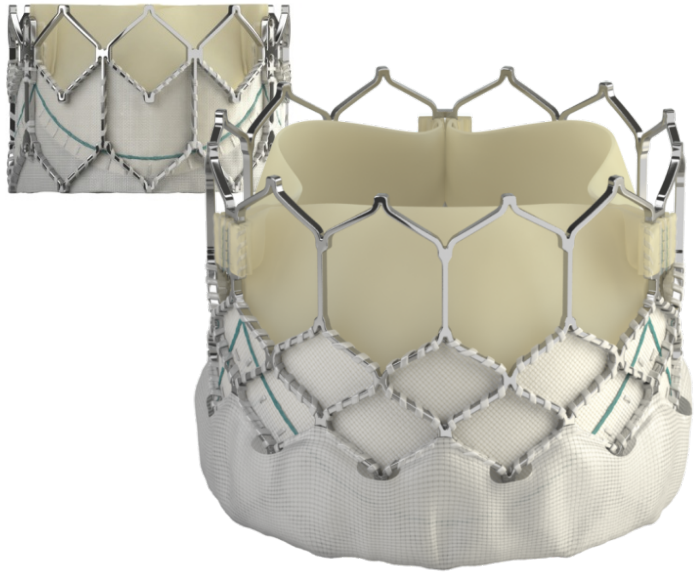
Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic.

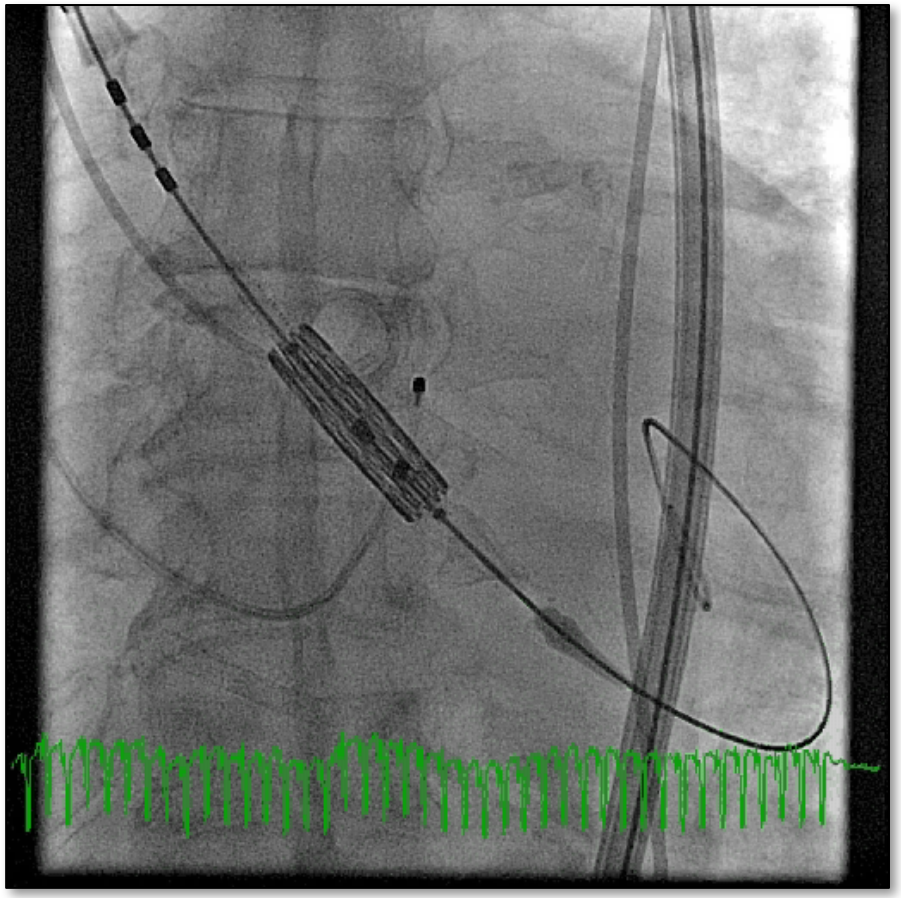
Approved in the US

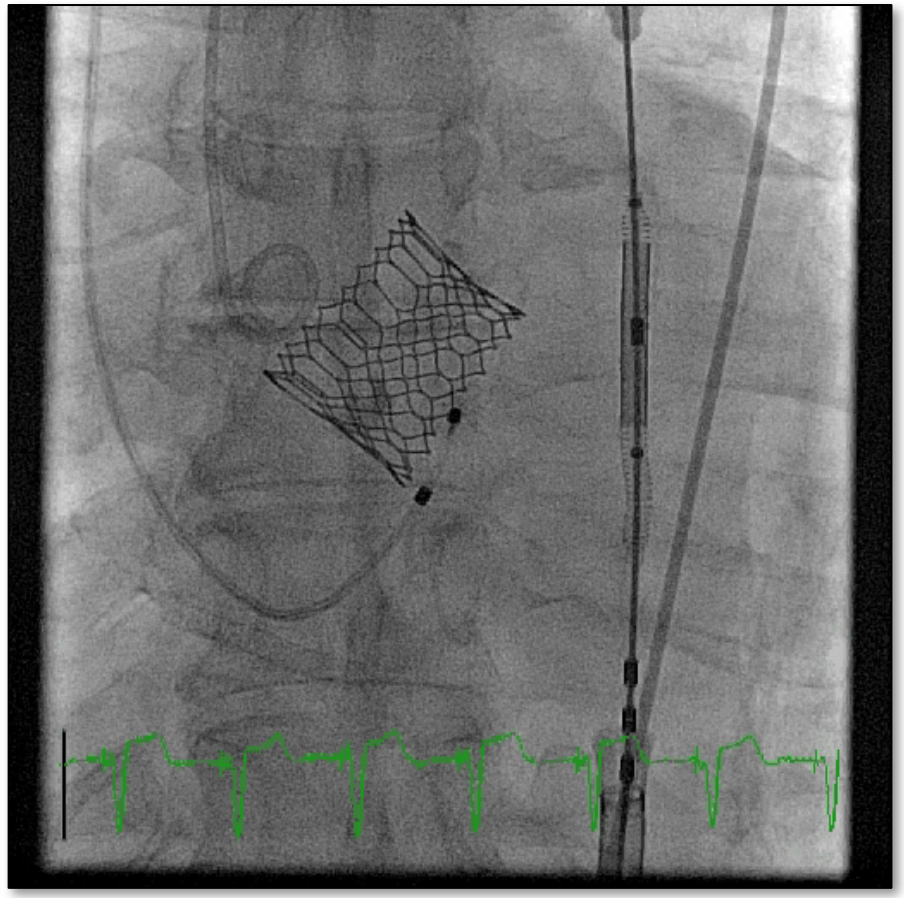
Medtronic CoreValve Evolut R

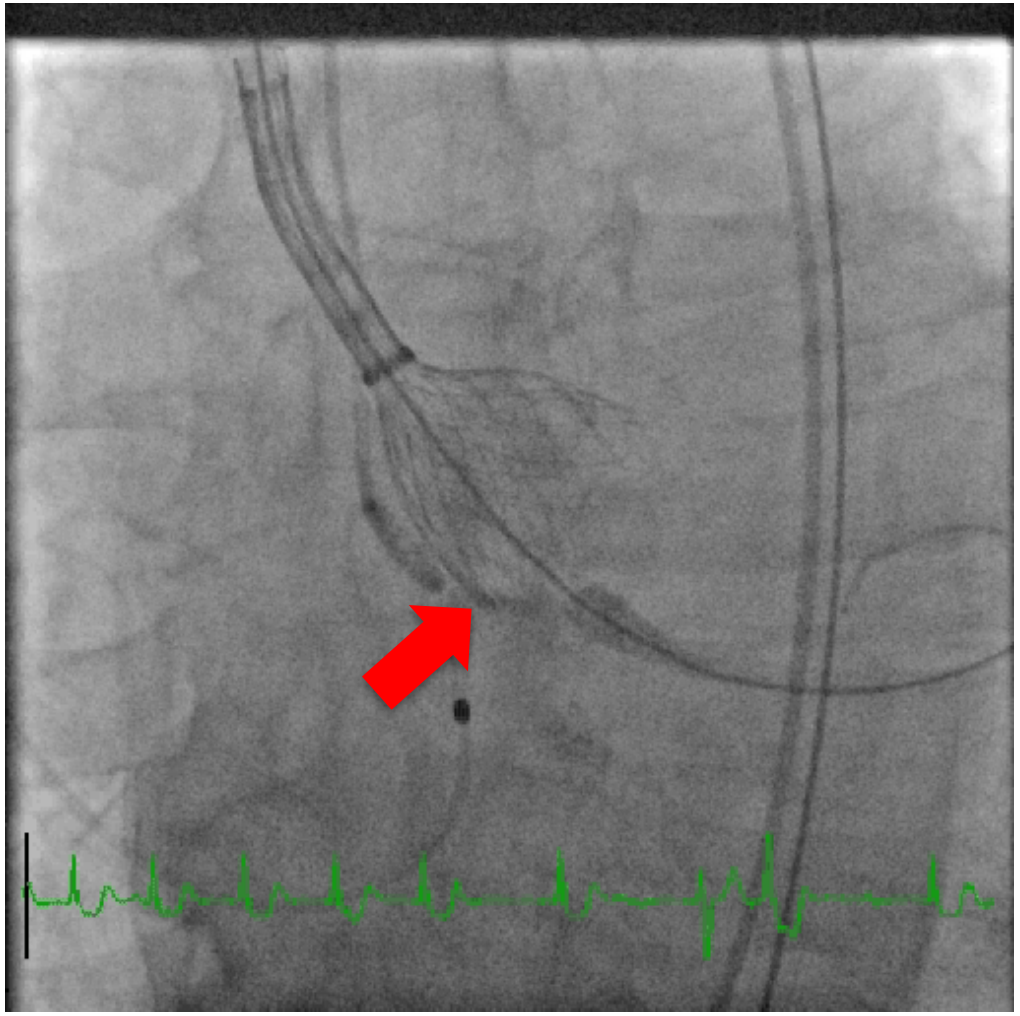


Edwards Lifesciences S3

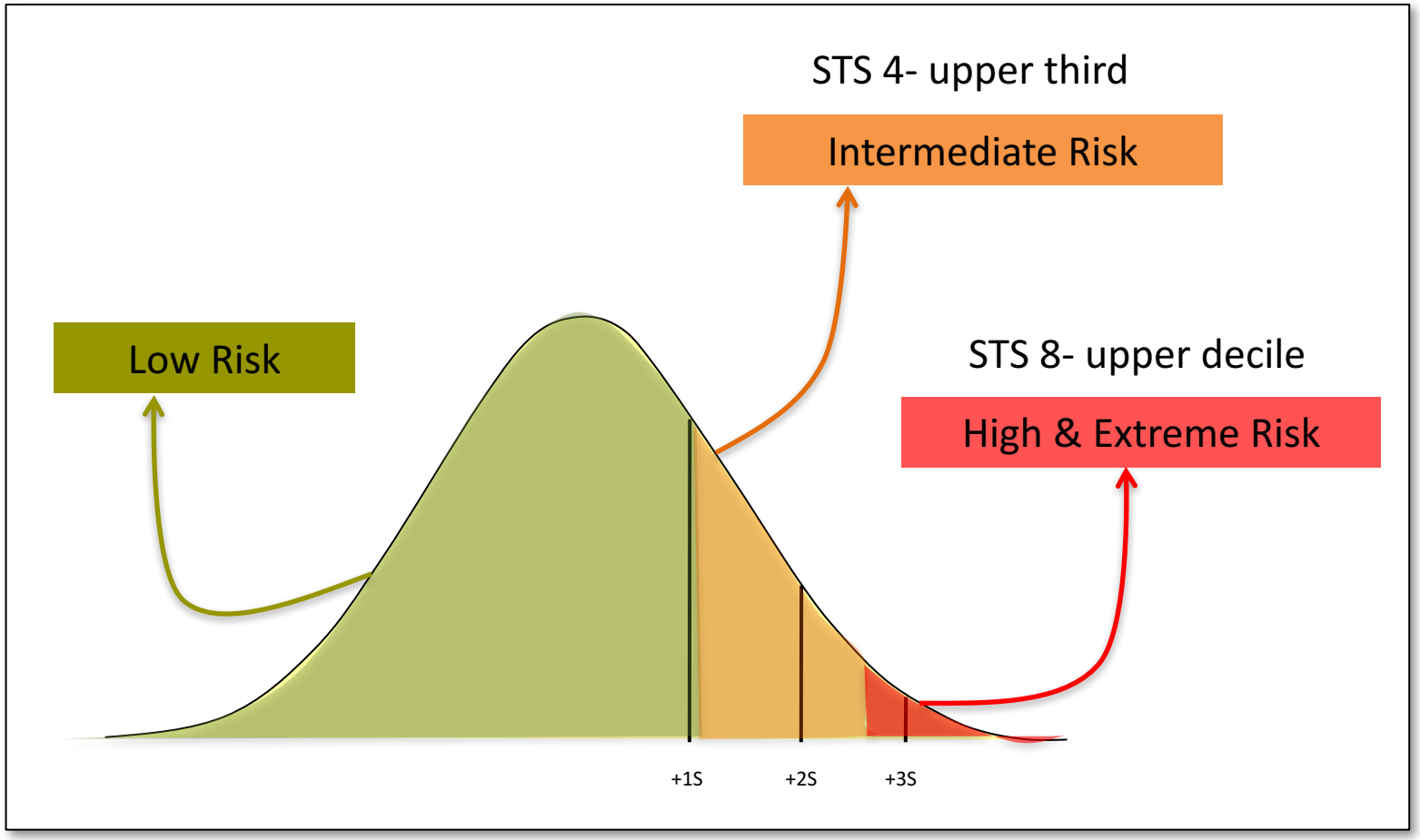








STS Risk Distribution



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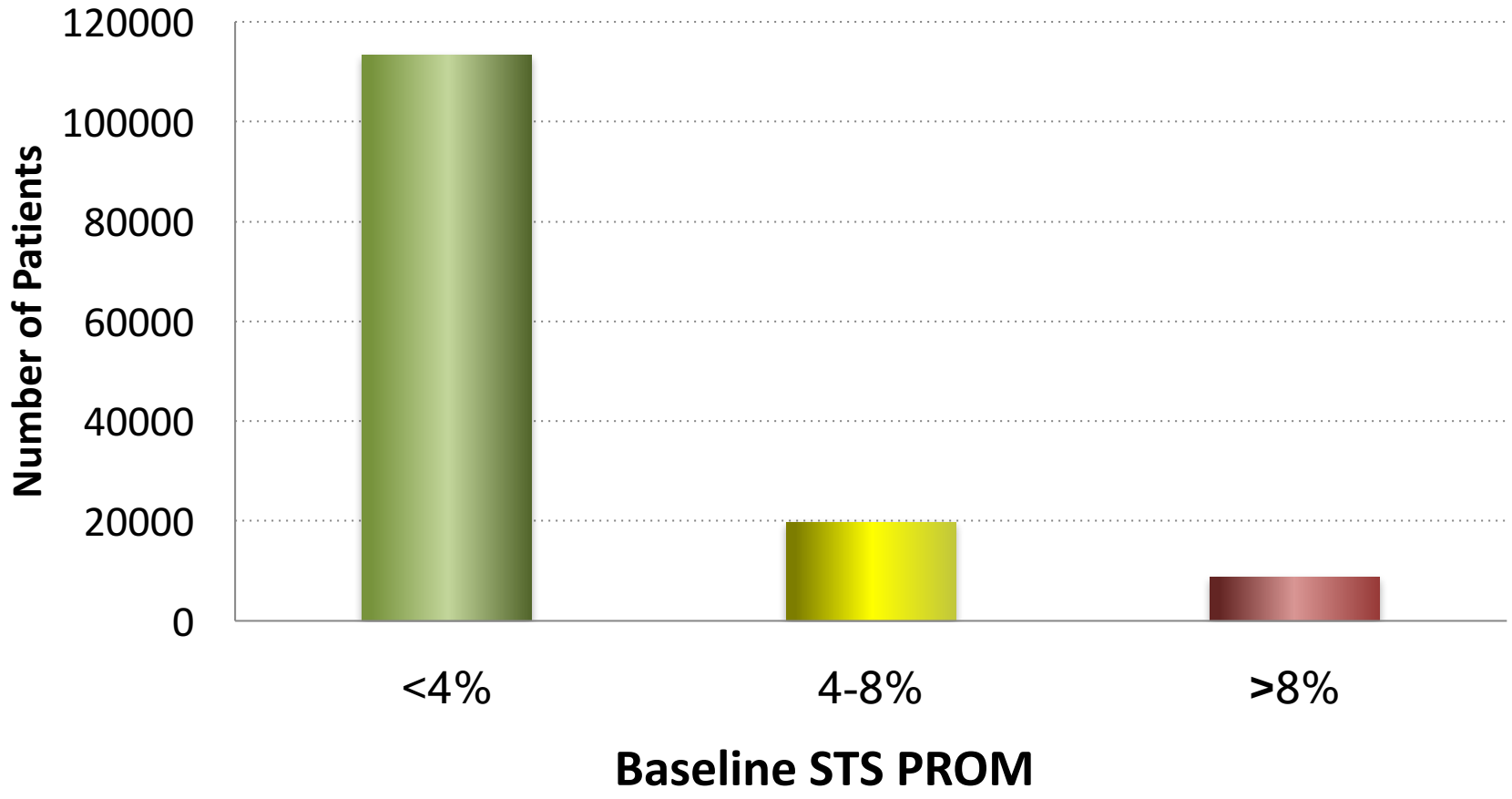
Contemporary Real-World Outcomes of Surgical AVR in 141,905 Low-Risk, Intermediate-Risk, & High-Risk Patients- 2002 to 2010



Mean Age	65	77	77
Median STS	1.46%	5.24%	11.2%
Operative Mortality	1.4%	5.1%	11.9%

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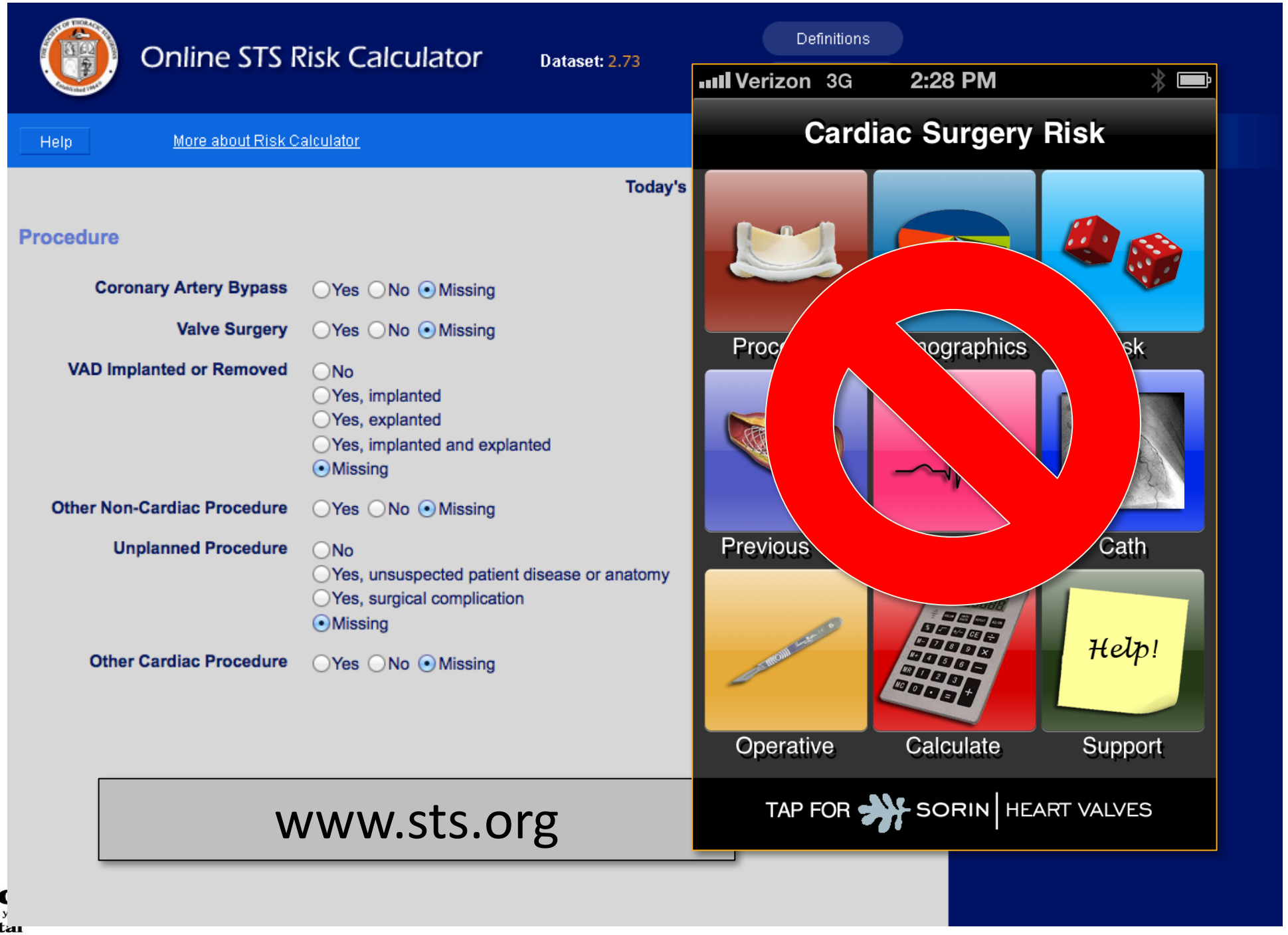
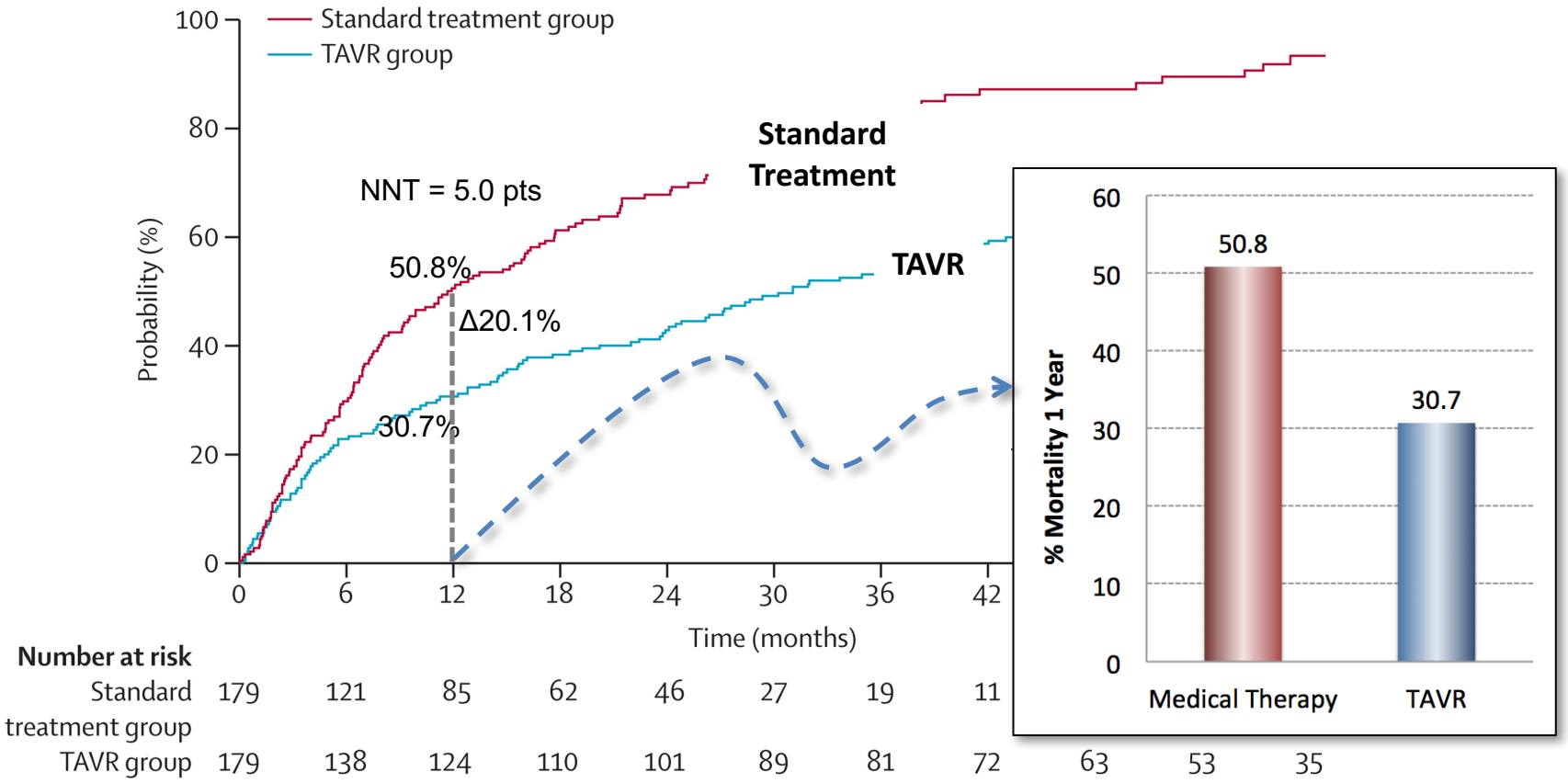
Ann Thorac Surg 2015;99:55–61


Online STS Risk Calculator
Dataset: 2.73
Definitions
Help
More about Risk Calculator
Today's
Procedure
Coronary Artery Bypass
Yes No Missing
Valve Surgery
Yes No Missing
VAD Implanted or Removed
No
Yes, implanted
Yes, explanted
Yes, implanted and explanted
Missing
Other Non-Cardiac Procedure
Yes No Missing
Unplanned Procedure
No
Yes, unsuspected patient disease or anatomy
Yes, surgical complication
Missing
Other Cardiac Procedure
Yes No Missing
www.sts.org
Verizon 3G 2:28 PM
Cardiac Surgery Risk
Previous
Cath
Operative
Calculate
Support
Help!
TAP FOR SORIN | HEART VALVES

5-year outcomes of TAVR compared with standard treatment for patients with inoperable aortic stenosis

PARTNER 1B



All-cause mortality for the intention-to-treat population

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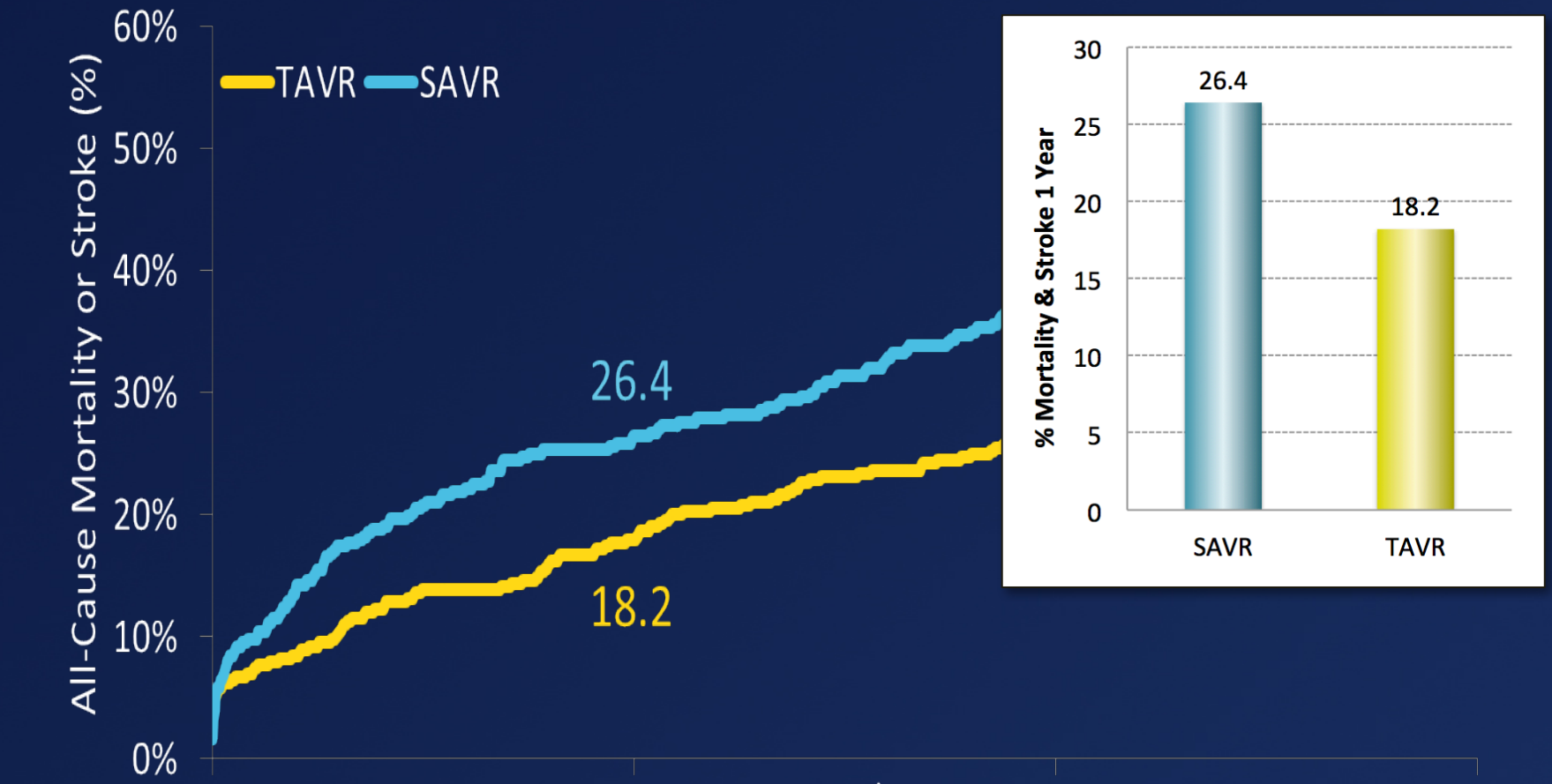
Kapadia S: The Lancet 2015 DOI: 10.1016/S0140-6736(15)60290-2

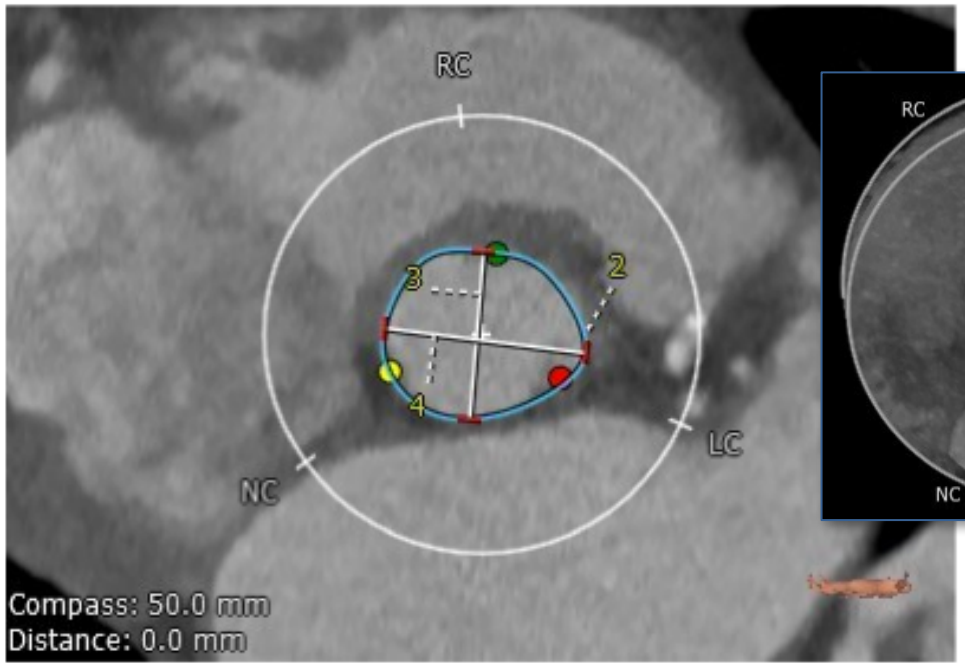
All-Cause Mortality or Stroke

High Risk Cohort

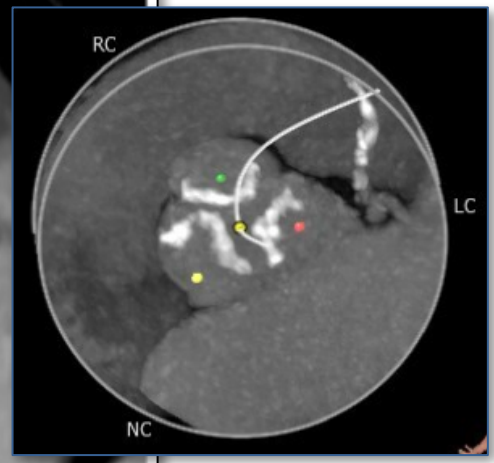


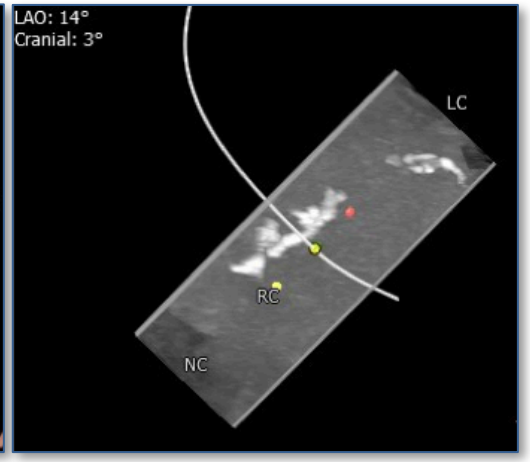
J Am Coll Cardiol. 2016 Jun 7;67(22):2565-74

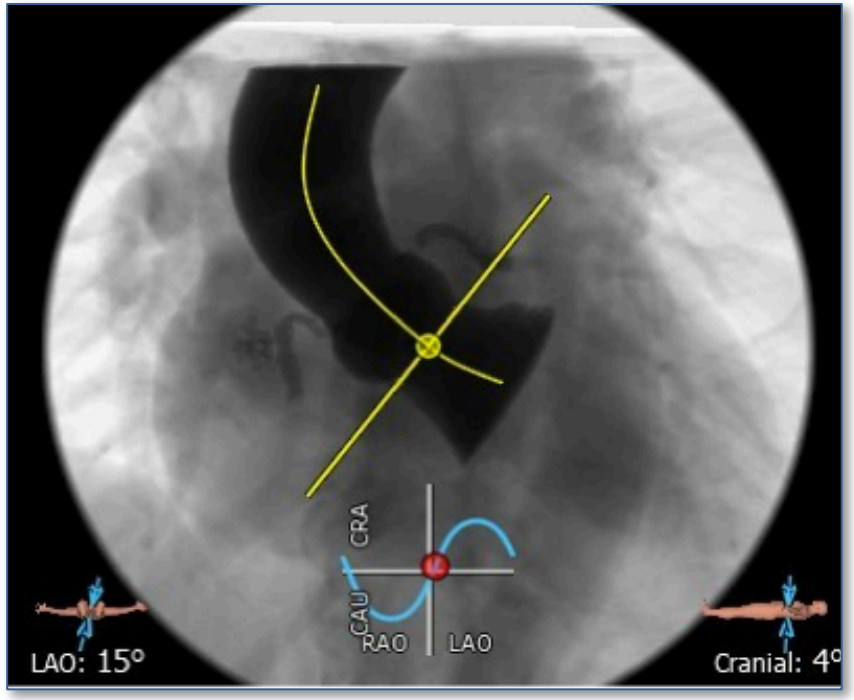
Annulus



ID	Type	Label	Value
2	MasterSplineAtCurve	Area derived Ø	21.3 mm
		Perimeter derived Ø	21.6 mm
		Area	357.0 mm²
		Perimeter	67.8 mm
3	Diameter	Diameter	19.3 mm
4	Diameter	Diameter	23.4 mm







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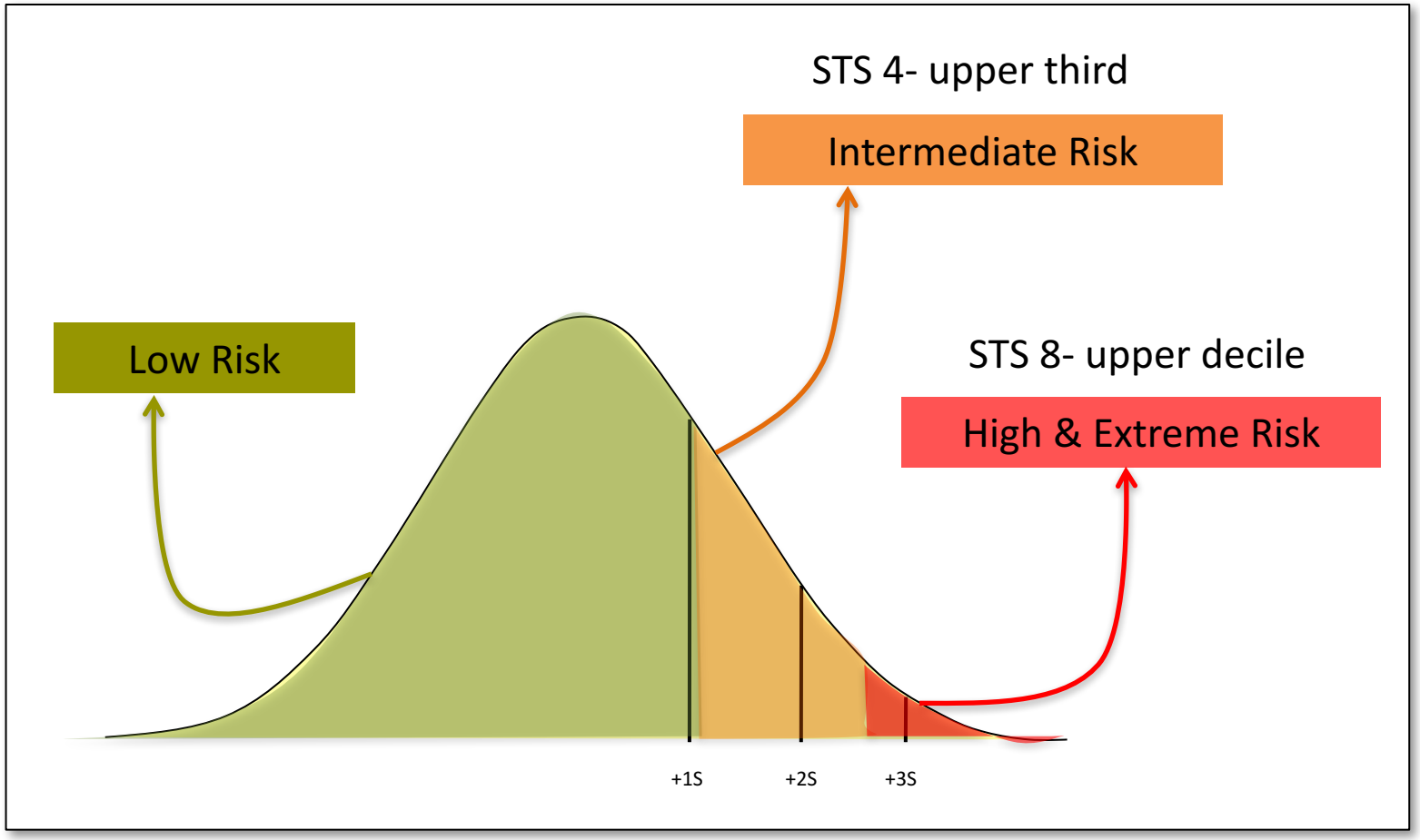
STS Risk Distribution



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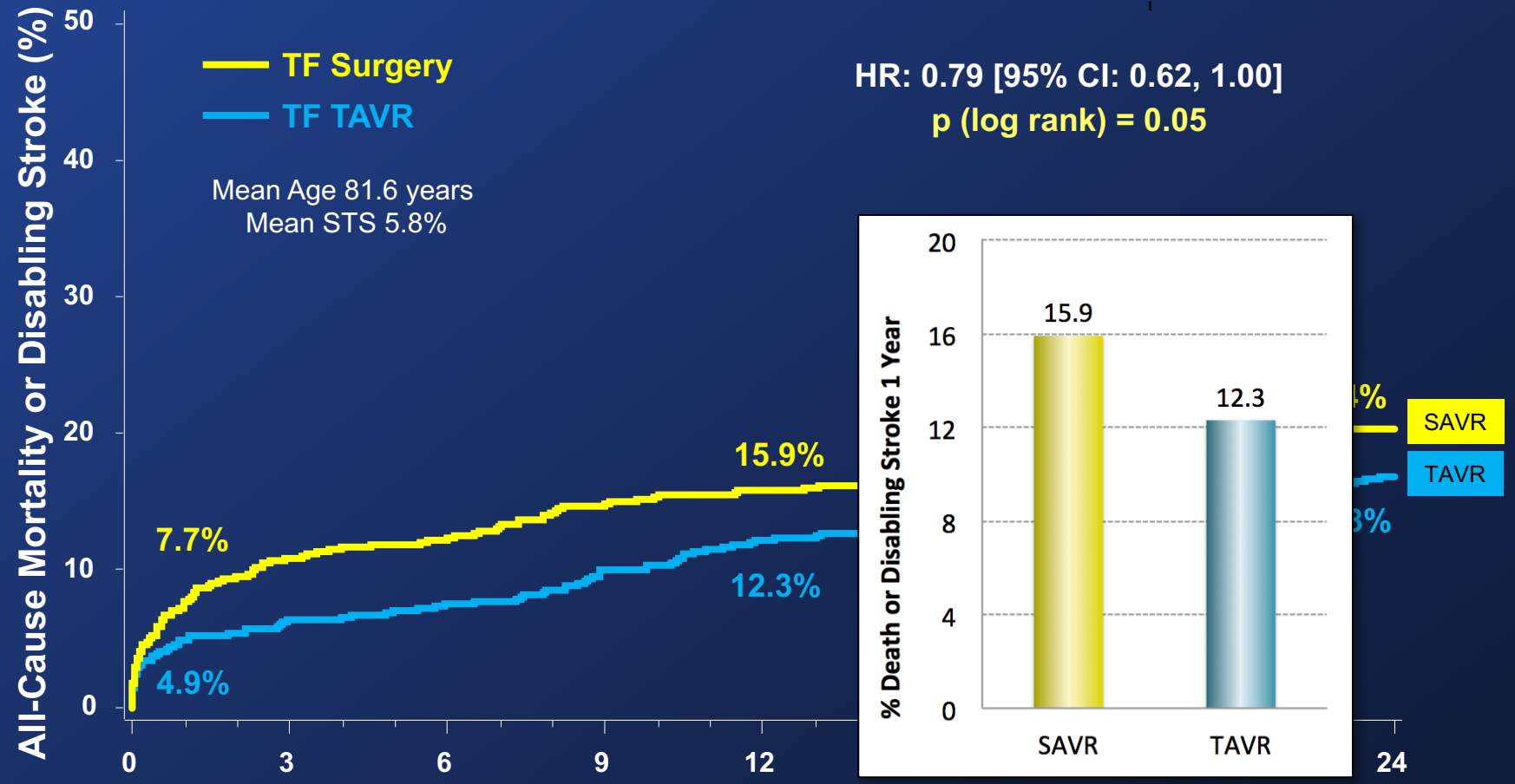
TF Primary Endpoint (ITT)
All-cause Mortality or Disabling Stroke

THE PARTNER II AXT TRIAL



Number at risk:									
TF Surgery	775	643	628	604	595	577	569	557	538
TF TAVR	775	718	709	685	663	652	644	634	612

N Engl J Med. 2016 Apr 28;374(17):1609-20

TAVR vs surgical valve replacement in intermediate-risk patients

Complications

	30 days					
	TAVR			SAVR		
	Events (n)	Cumulative KM estimates	Numbers at risk	Events (n)	Cumulative KM estimates	Numbers at risk
Death						
From any cause	12	1·1%			4·0%	902
Cardiac death	10	0·9%	1063	29	3·1%	902
Non-cardiac death	2	0·2%	1063	9	1·0%	902
Neurological events						
Transient ischaemic attack	4	0·4%	1059	4	0·4%	898
Any stroke	29	2·7%			6·1%	852
Disabling stroke	11	1·0%	1053	41	4·4%	868
Non-disabling stroke	18	1·7%	1045	16	1·7%	886
Death from any cause or disabling stroke	22	2·0%	1053	75	8·0%	868
Rehospitalisation	49	4·6%	1017	62	6·8%	845
Myocardial infarction	3	0·3%	1060	18	1·9%	889
Life-threatening or disabling bleeding	50	4·6%	1018	440	46·7%	493
Major vascular complication	66	6·1%	1000	51	5·4%	860
Acute kidney injury (stage 3)	5	0·5%	1058	31	3·3%	879
New atrial fibrillation	54	5·0%			28·3%	649
New permanent pacemaker	109	10·2%			7·3%	836
Endocarditis	2	0·2%	1061	0	0·0%	902
Aortic valve re-intervention	1	0·1%	1062	0	0·0%	902

Lancet 2016; 387: 2218–25

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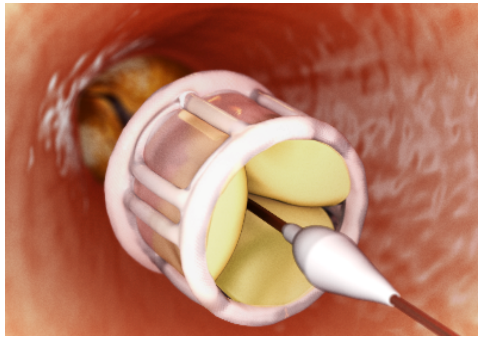
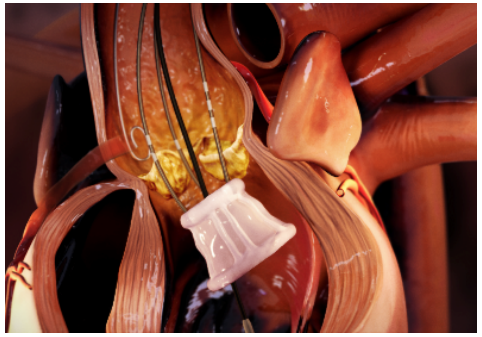
Next Gen TAVR US Trials

LOTUS

Direct Flow



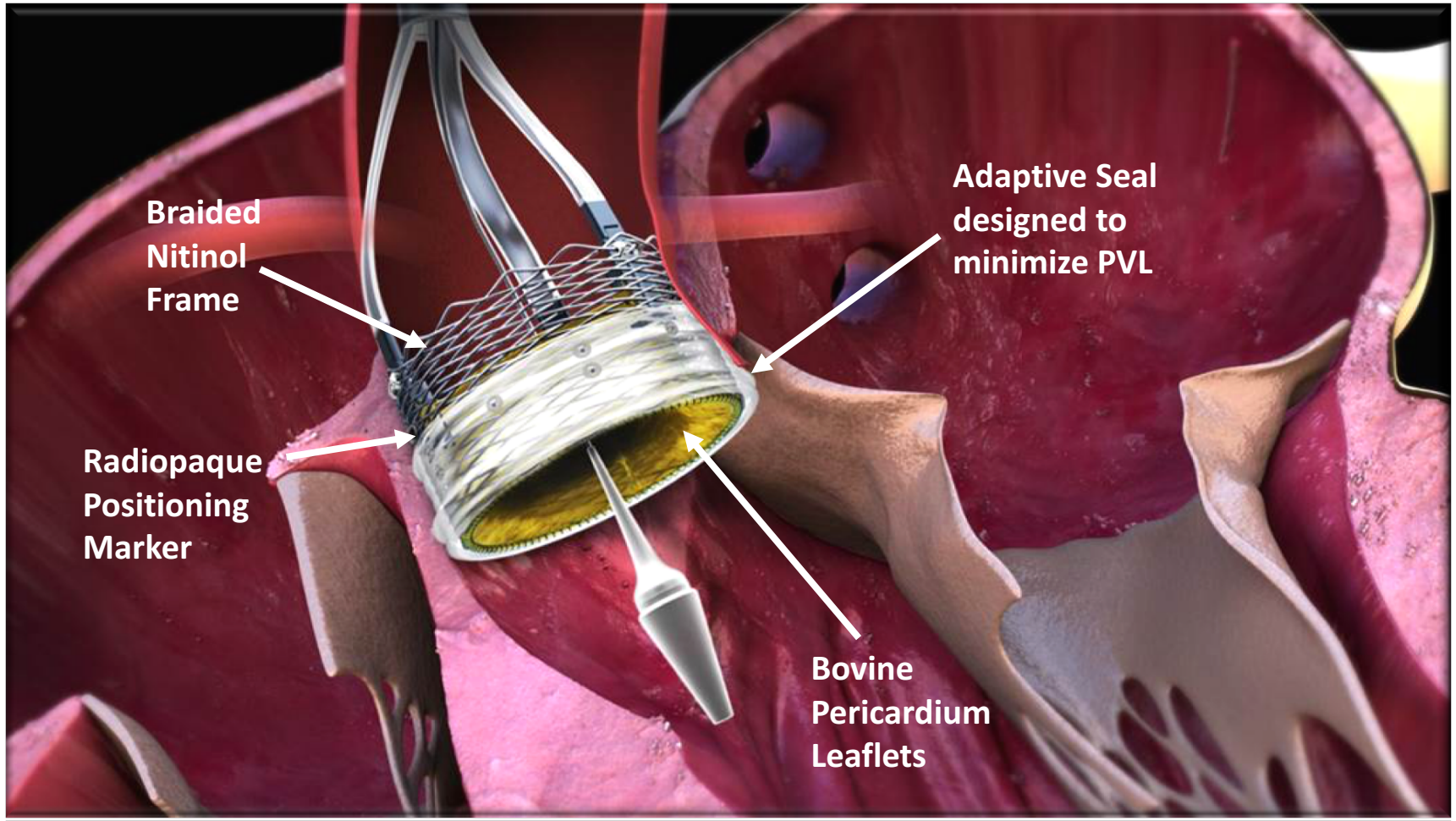


Portico

Fully retrievable, no PVL, early function	Fully retrievable, no PVL, early function	Fully retrievable, early function
CE Study n=250, CE approved 10/2013	CE Study n=100, CE approved 1/2013	CE Study n=102, CE approved 9/2015
EU post market n=1000	EU post market n=500	EU Study n=220
US IDE n=912	US Feasibility n=30, US IDE n=648	US IDE n=912
Enrollment completed	Enrollment ongoing	Enrollment ongoing

Lotus Valve System

Fully repositionable & retrievable



- Controlled mechanical expansion for precise placement
- Early valve function enables hemodynamic stability

CAUTION: Lotus is an investigational device and restricted under federal law to investigational use only. Not available for sale.

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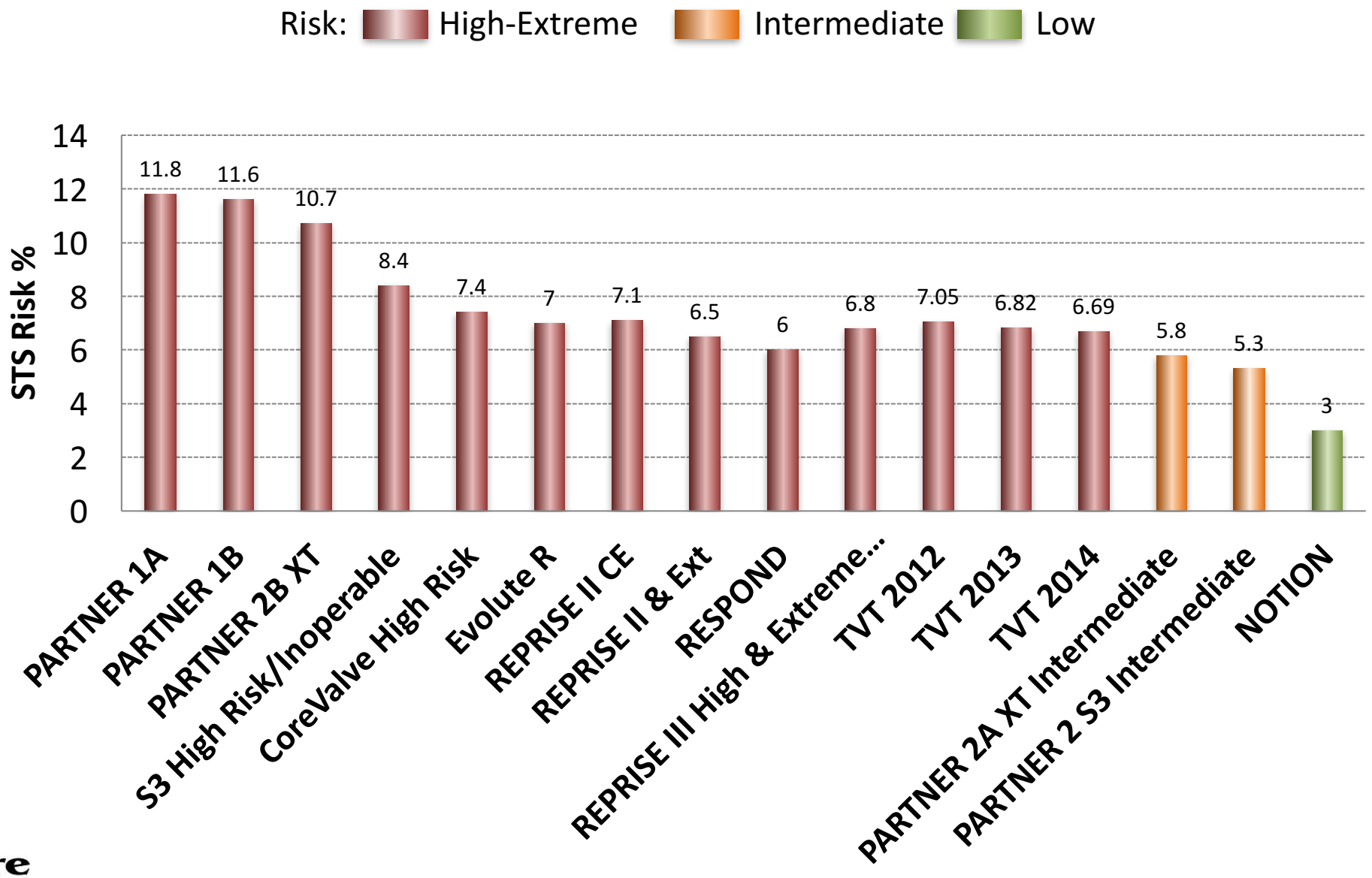
Spectrum of Trial Risk



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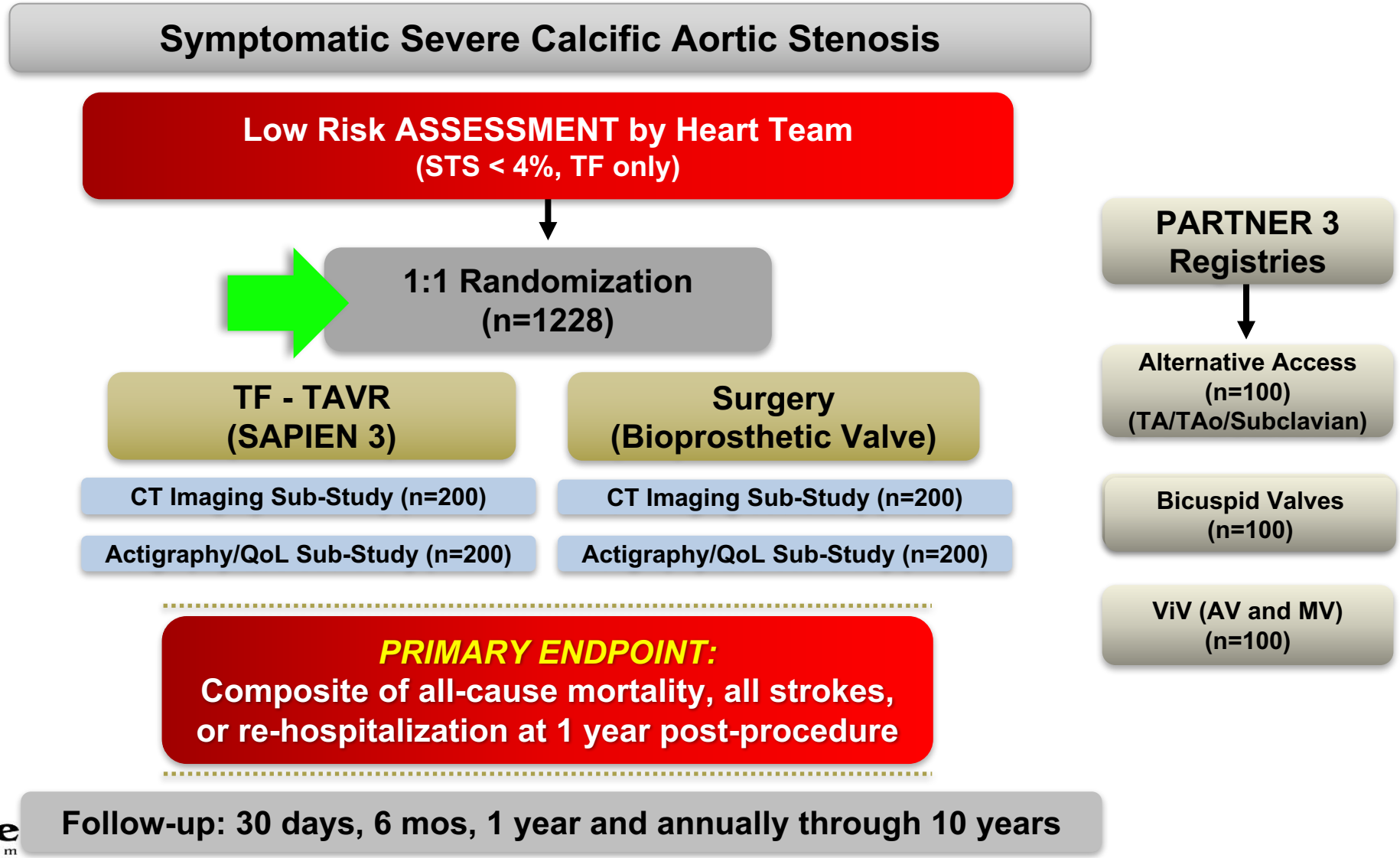
The PARTNER 3 Trial

Study Design



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Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

2016 euro PCR

First look at long-term durability of transcatheter heart valves:

Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul's Hospital, Vancouver, Canada.

On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb

EAPCI EUROPEAN SOCIETY OF CARDIOLOGY EACTS

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University HealthSy
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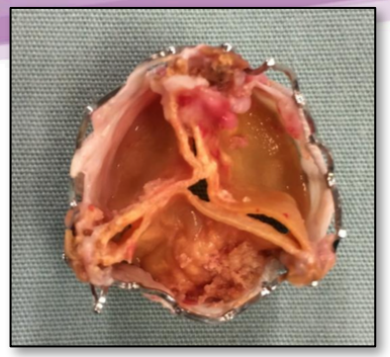
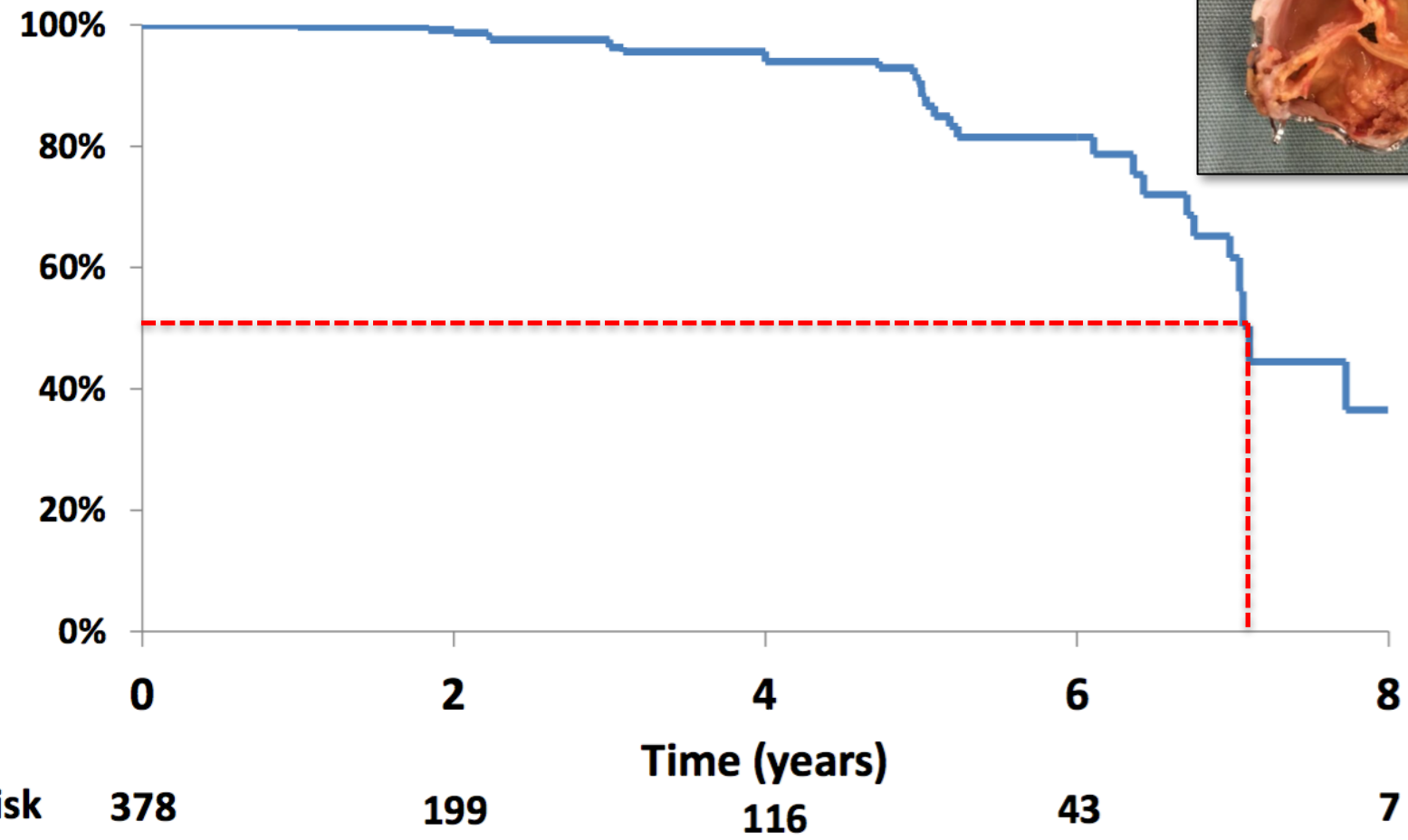
Freedom from THV degeneration

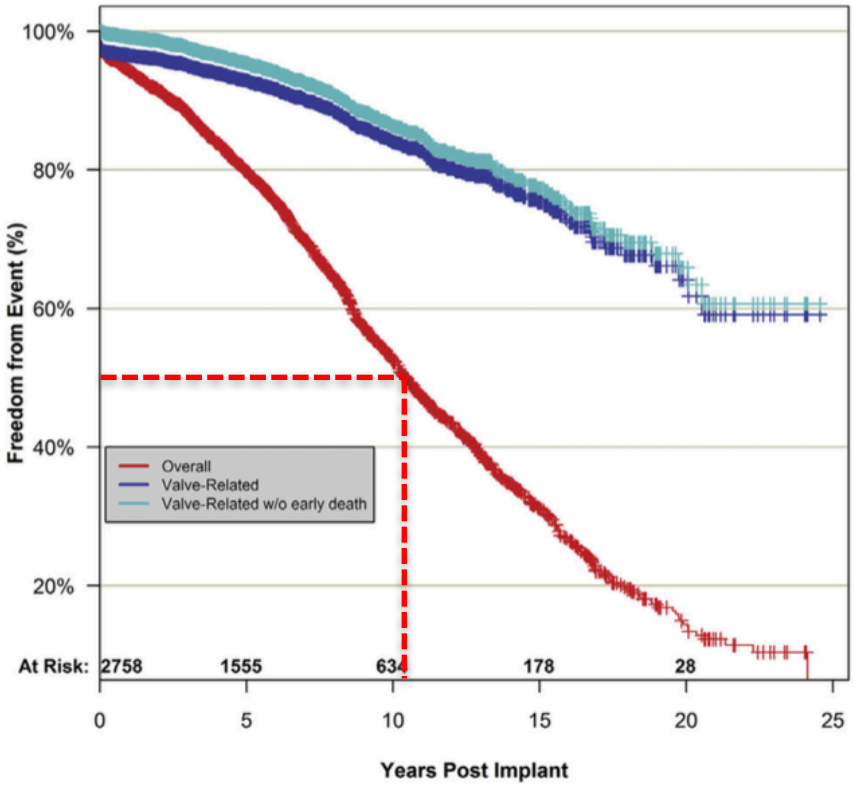




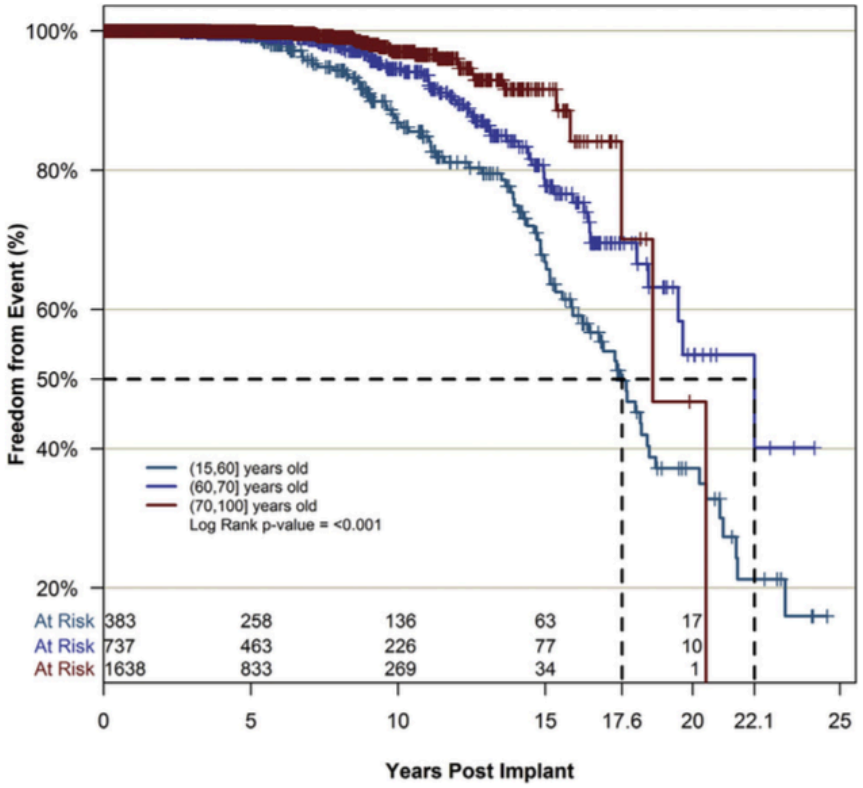
THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position



Overall and valve-related survival



Freedom from structural valve deterioration

Structural Valve Deterioration

- severe AS mean transvalvular gradient > 40 mm Hg
- or severe AR effective regurgitant orifice area > 0.30 cm2, vena contracta > 0.6 cm

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Bourguignon T: Ann Thorac Surg 2015;99:831–7

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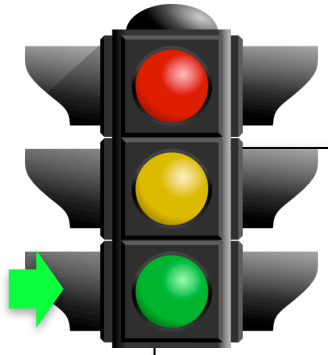

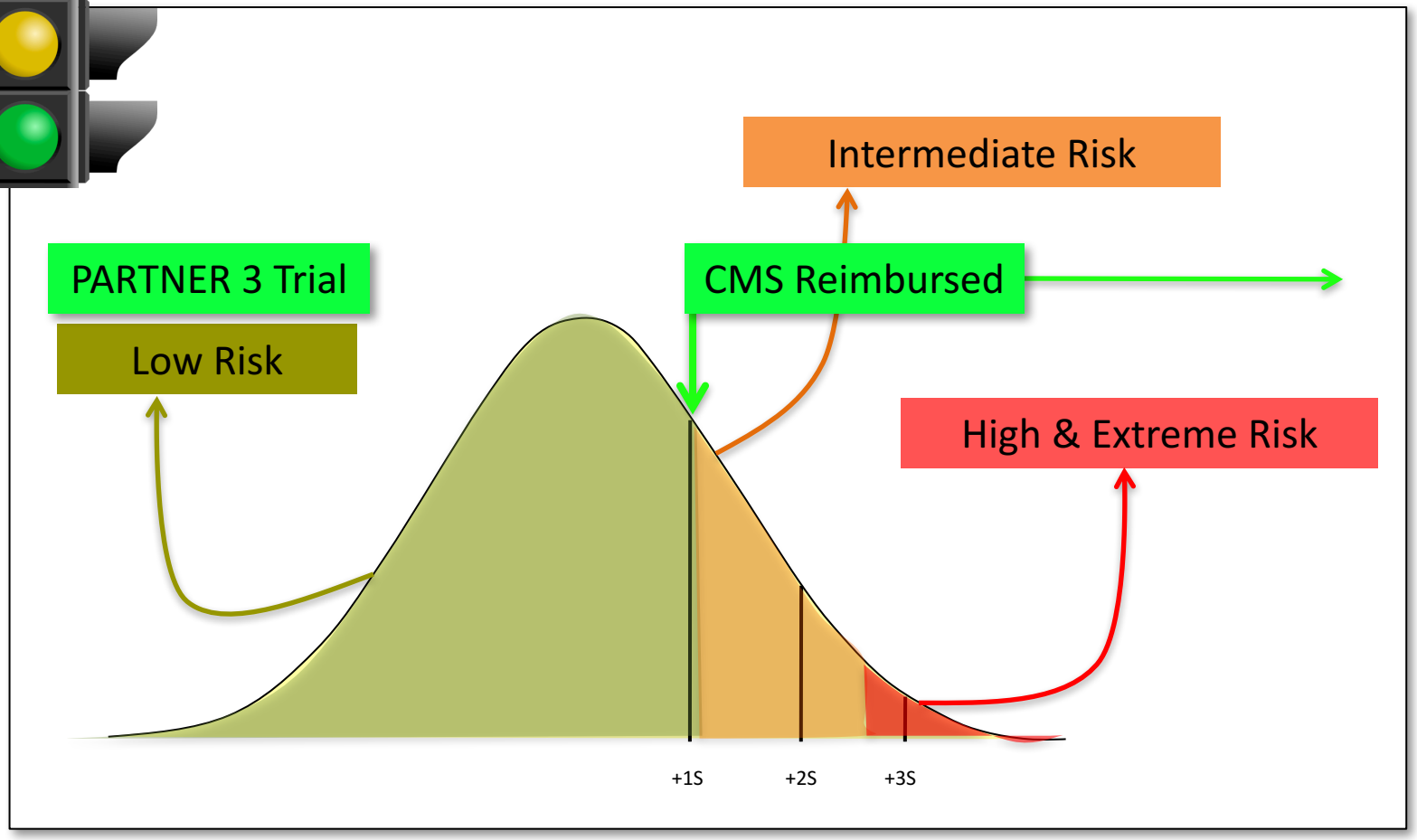

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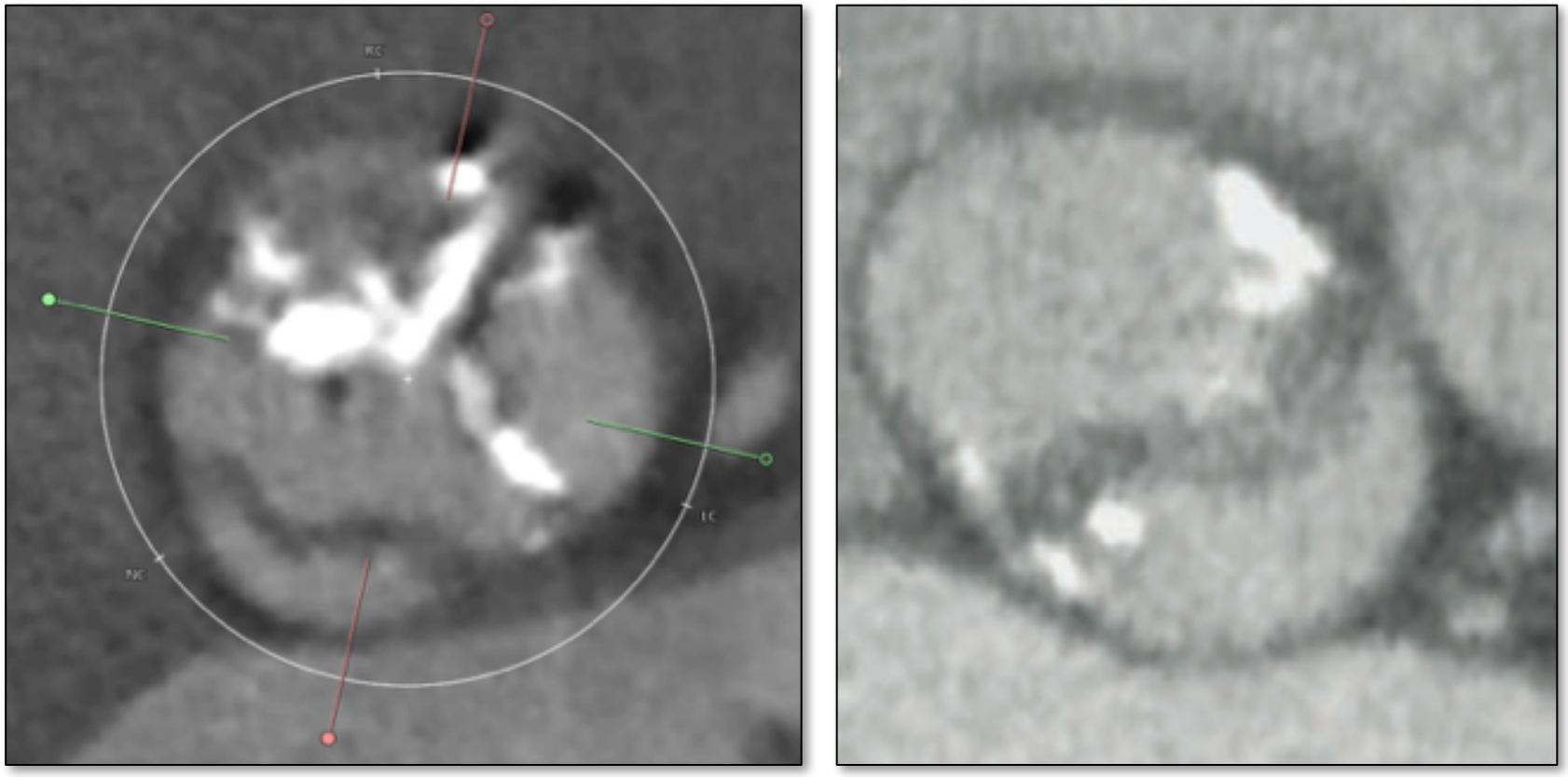
Bicuspid Aortic Valve Excluded



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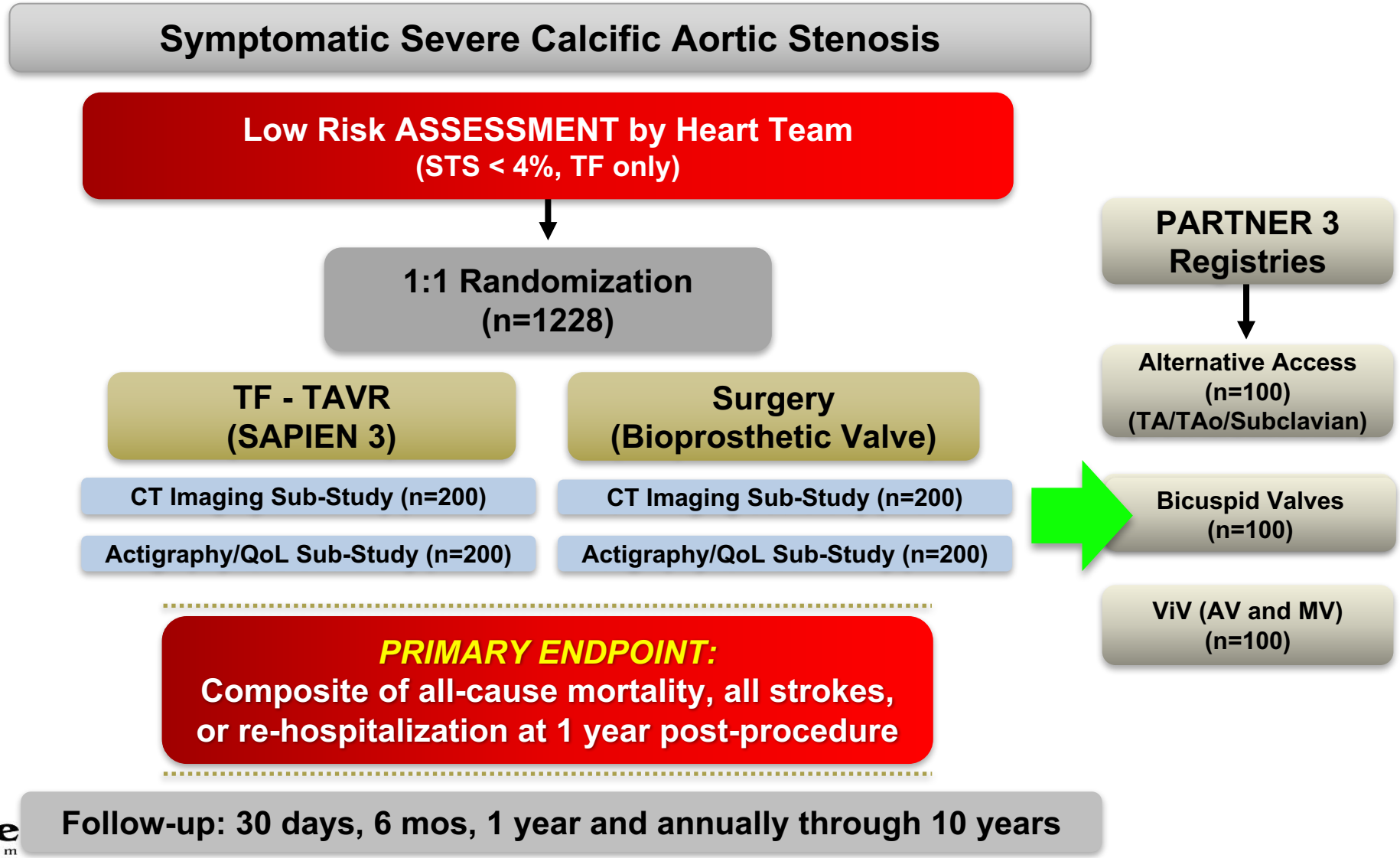

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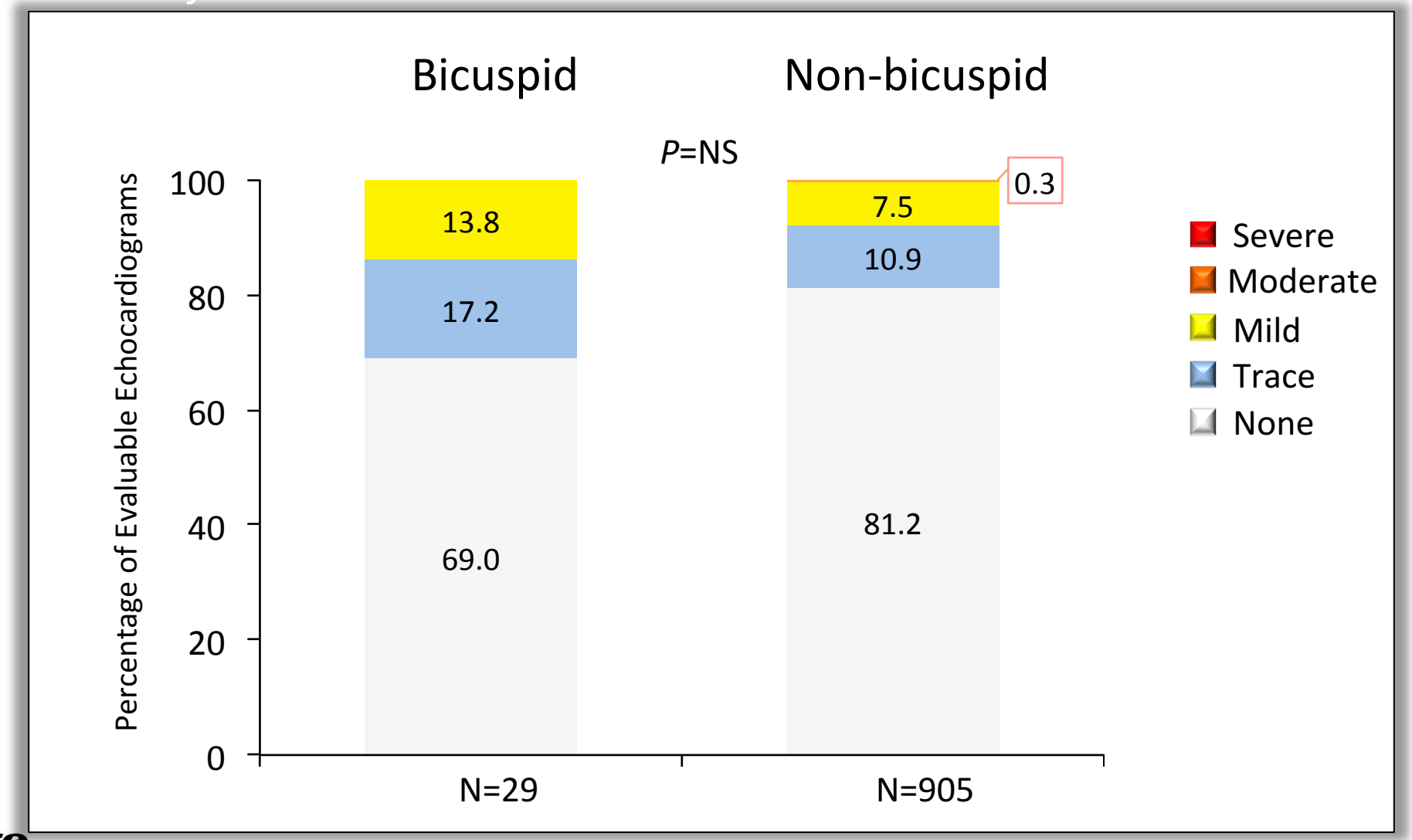
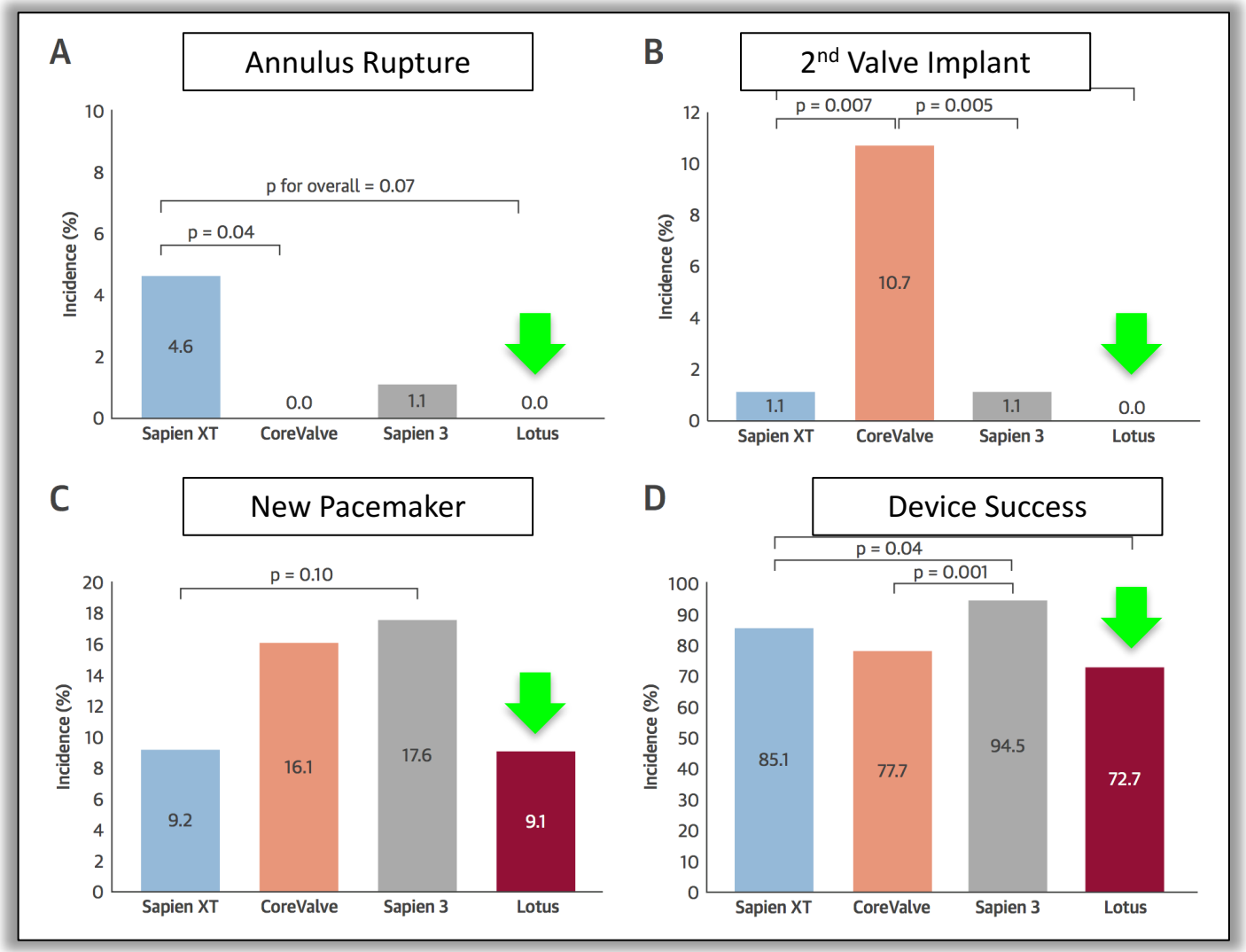
RESPOND Bicuspid Analysis: PVL at Discharge

As-treated population (N=996)



Presented by Blackman, PCR 2016.

TAVR With Early vs New-Generation Devices in Bicuspid Aortic Valve Stenosis



J Am Coll Cardiol 2016;68:1195–205

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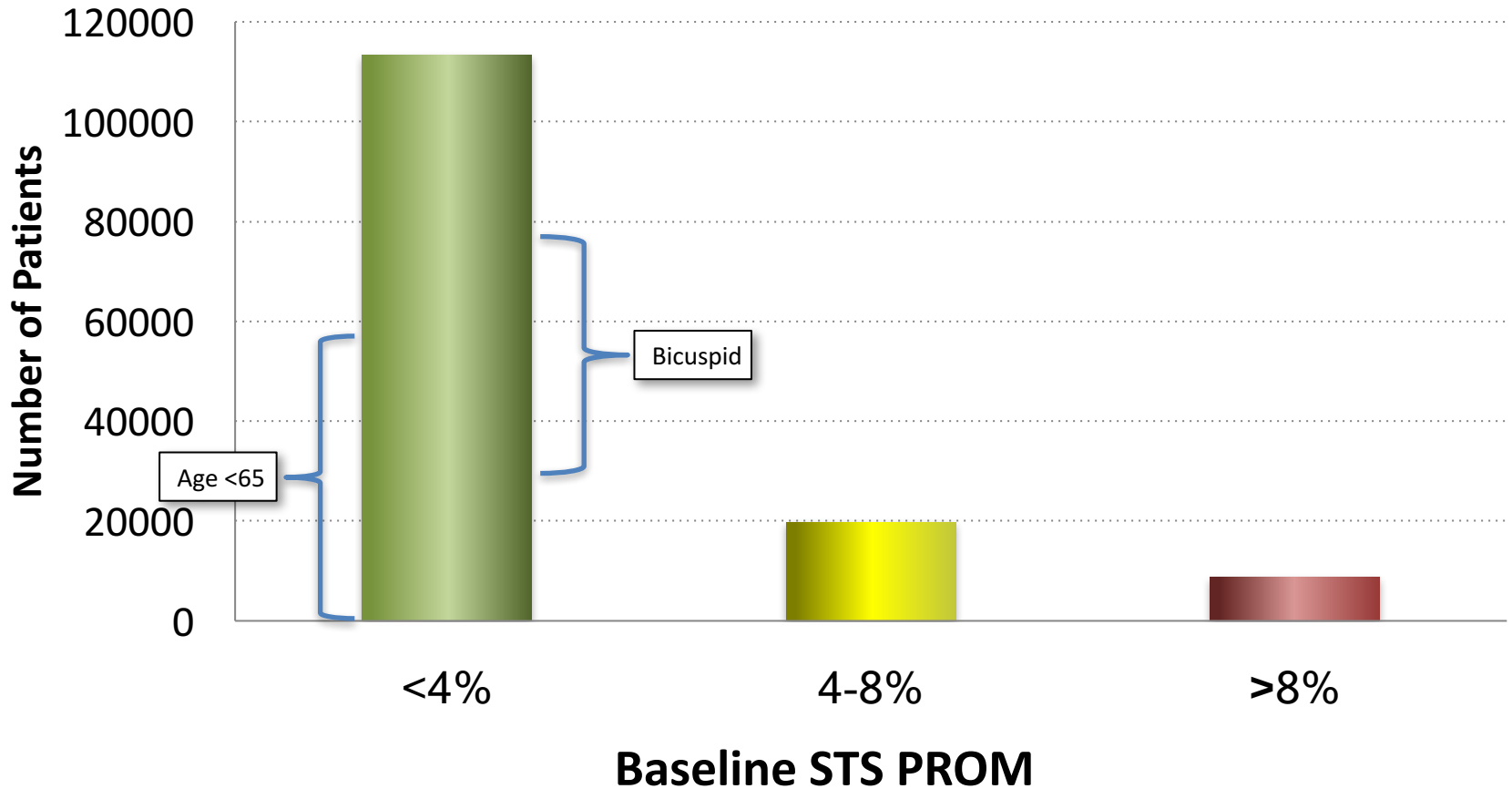

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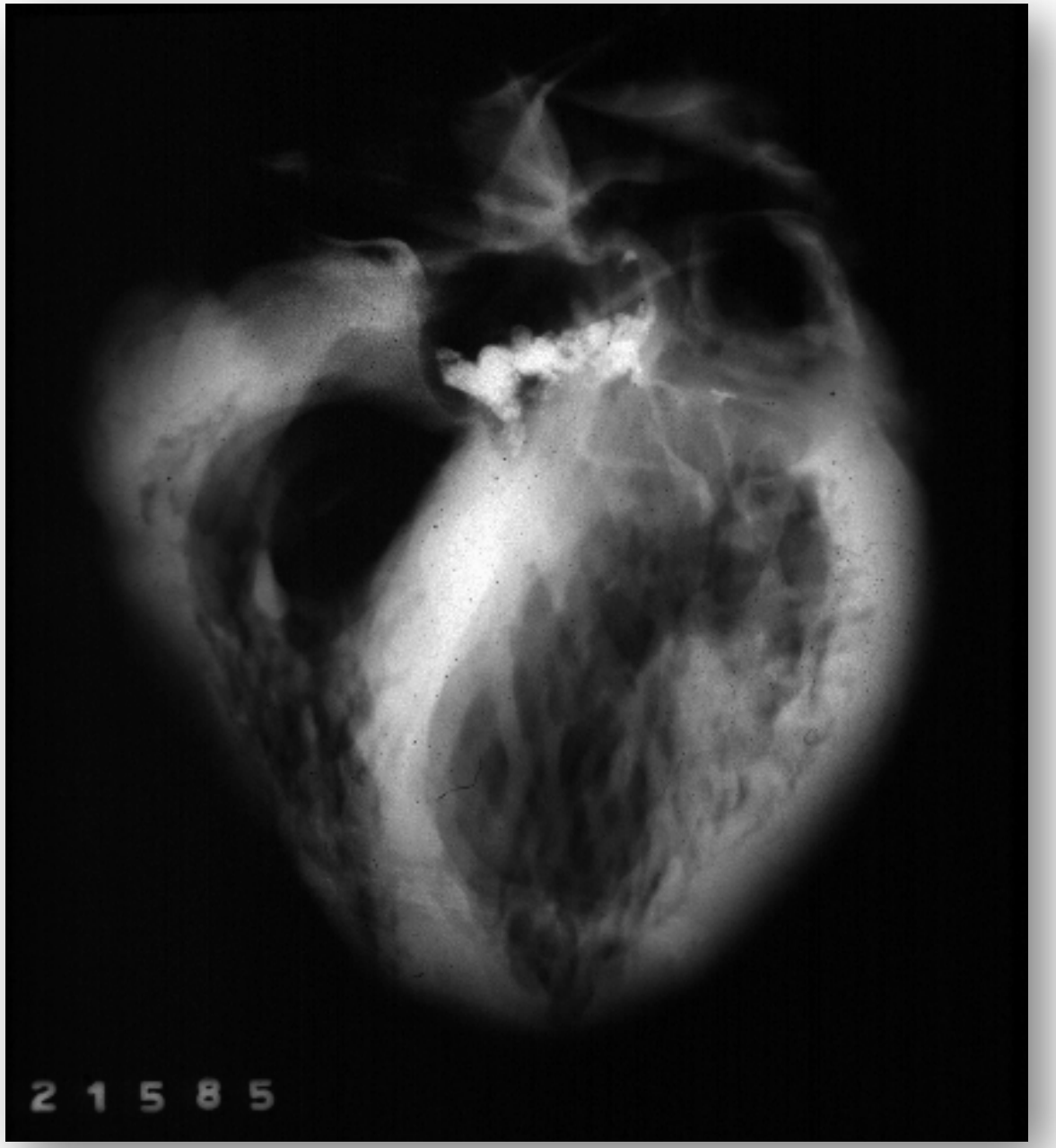
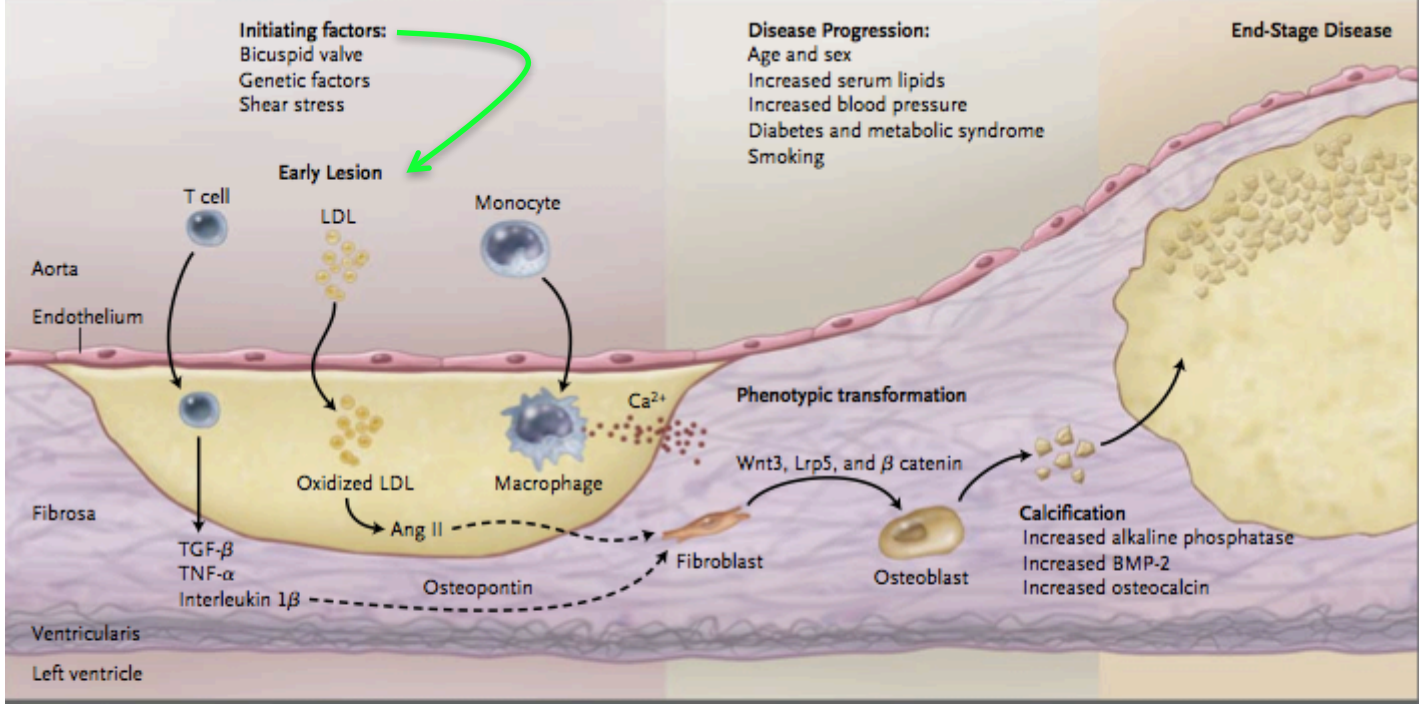
Ann Thorac Surg 2015;99:55–61

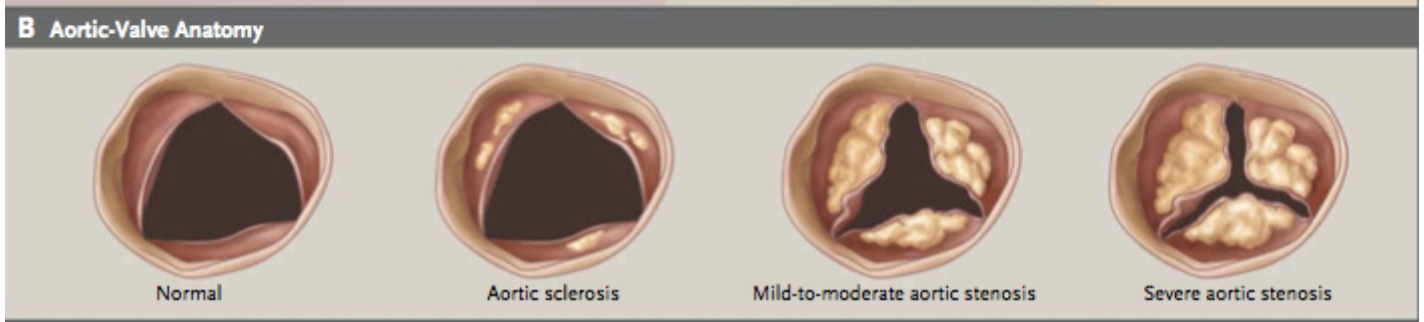
Calcific Aortic Stenosis

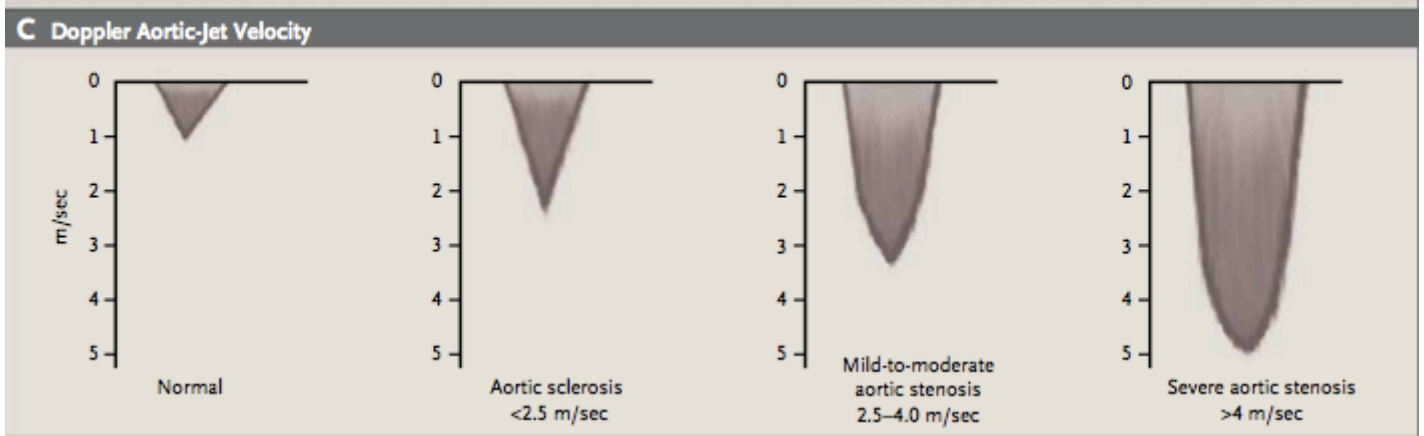


Calcific Aortic Stenosis

Otto, NEJM 359;13, 2008







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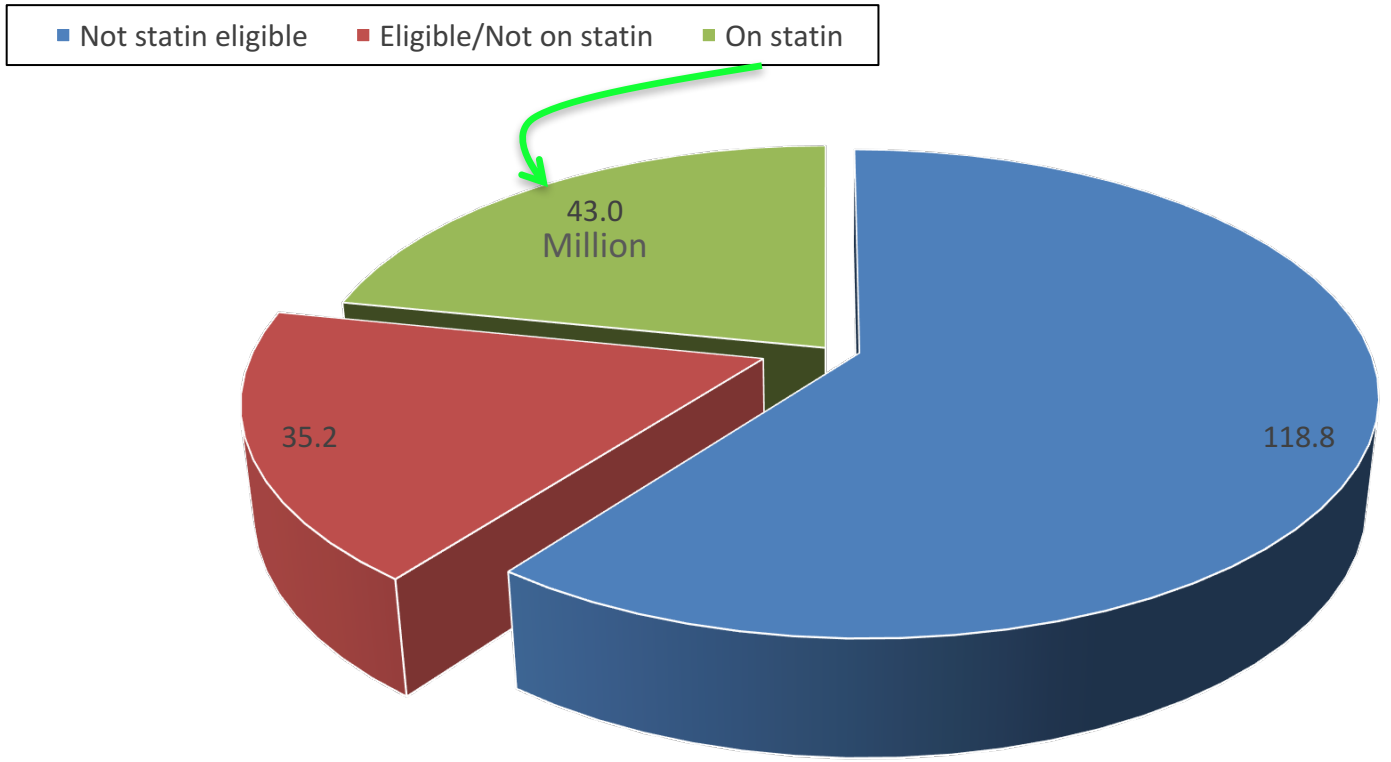
CDC Morbidity and Mortality Weekly Report (MMWR) December 4, 2015 / 64(47);1305-11

Prevalence of Cholesterol Treatment Eligibility and Medication Use Among Adults Age ≥21

United States, 2005–2012



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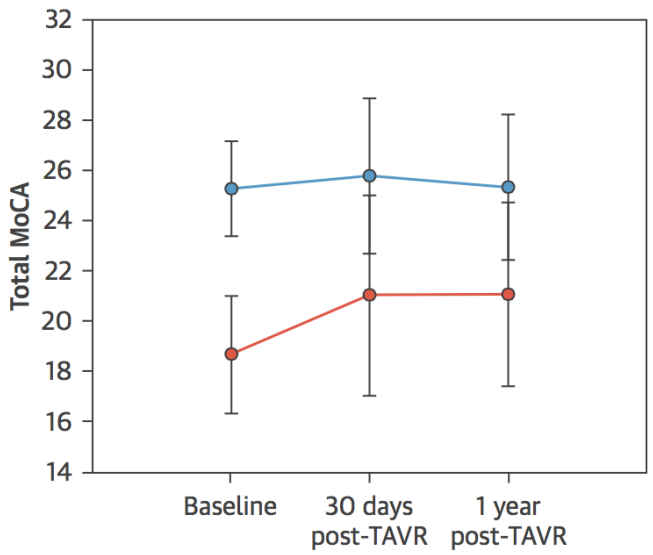
Serial Changes in Cognitive Function Following TAVR

Can TAVR make me smarter?

METHODS Fifty-one patients (median age 80.0 [interquartile range:
TAVR and prospective assessment of cognitive function using the Mo
short-term (30 days), and 1 year post-TAVR. Processing speed and exe
with the digit-symbol substitution test (DSST), Trail Making Tests (TMT
Cognitive decline (CD) was determined by changes in mean scores and
index (RCI).

RESULTS The baseline mean total MoCA score was 22.71 ± 3.84. Twe
impaired using a cutoff of <23 of 30 points. Mean total MoCA score i
stable at 1 year (p = 0.022). On the basis of the RCI of total MoCA sc
CD, which persisted at 1 year in 1 patient (2.0%). Four patients (7.8%
increasing to 15% among those with baseline cognitive impairment. N
the mean DSST, TMT, and verbal fluency test scores. On the basis of t
reduction in performance of at least 1 test at 30 days that persisted a

FIGURE 1 Evolution of Mean Total MoCA Score Over Time According to Baseline Score



Blue line = patients with baseline MoCA >23; **orange line** = patients with baseline MoCA <23. MoCA = Montréal Cognitive Assessment.

CONCLUSIONS: TAVR was associated with global improvement in cognitive status, more pronounced among those with cognitive impairment pre-TAVR. However, early decline in some complex cognitive functions was observed in one-quarter of TAVR recipients, persisting at 1 year in 10% of patients.

J Am Coll Cardiol 2016;68:2129–41

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Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	??
High Surgical Risk	Commercial MitraClip	COAPT

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

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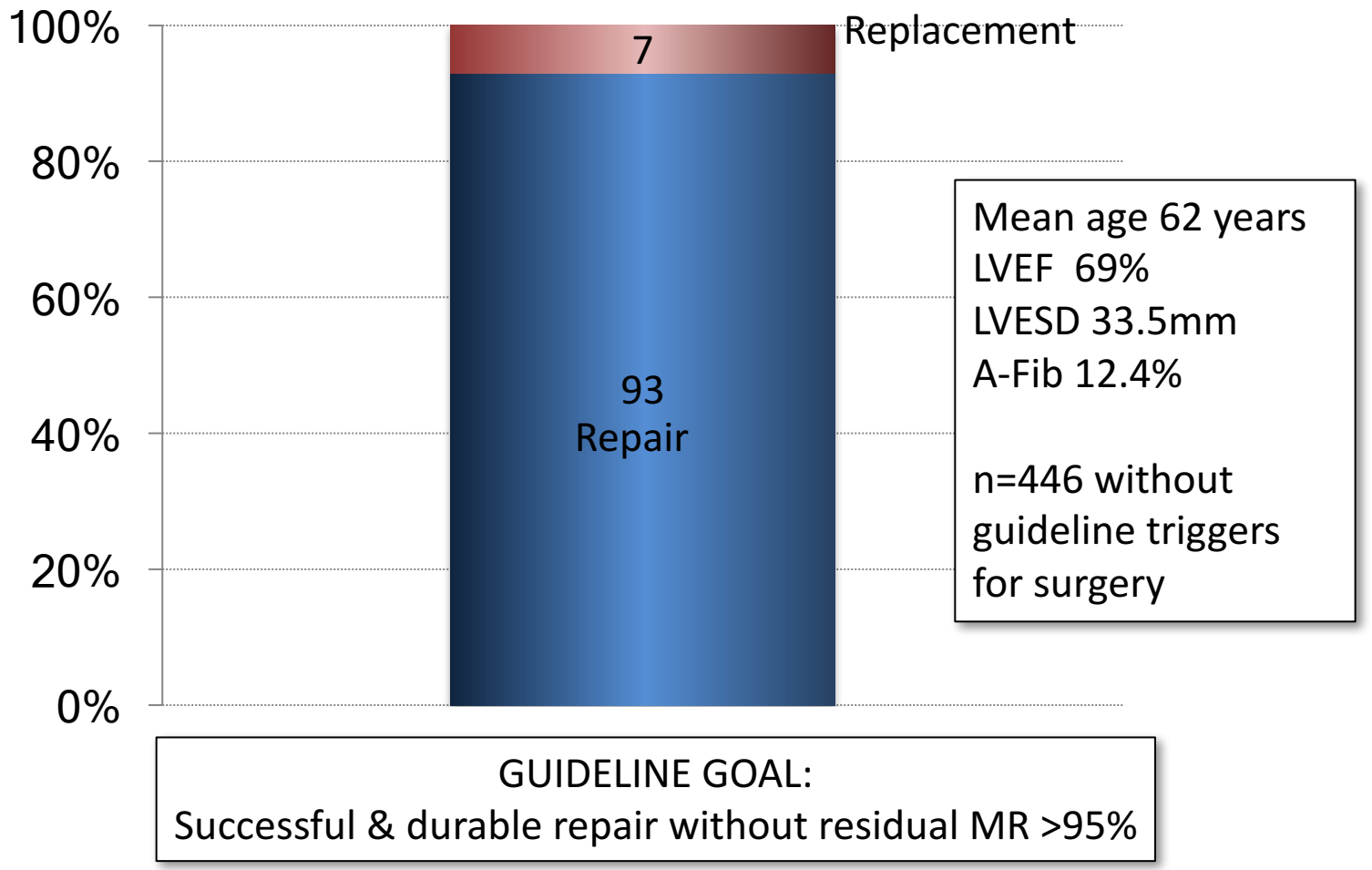
rventions,

Table 17. Summary of Recommendations for Chronic *Primary* MR

Recommendations	COR	LOE
MV surgery is recommended for symptomatic patients with chronic severe primary MR (stage D) and LVEF >30%	I	B
MV surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30%–60% and/or LVESD ≥40 mm, stage C2)	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished	I	B
Concomitant MV repair or replacement is indicated in patients with chronic severe primary MR undergoing cardiac surgery for other indications	I	B
MV repair is reasonable in asymptomatic patients with chronic severe primary MR (stage C1) with preserved LV function (LVEF >60% and LVESD <40 mm) in whom the likelihood of a successful and durable repair without residual MR is >95% with an expected mortality rate of <1% when performed at a Heart Valve Center of Excellence	IIa	B
MV repair is reasonable for asymptomatic patients with chronic severe nonrheumatic primary MR (stage C1) and preserved LV function in whom there is a high likelihood of a successful and durable repair with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure >50 mm Hg)	IIa	B
Concomitant MV repair is reasonable in patients with chronic moderate primary MR (stage B) undergoing cardiac surgery for other indications	IIa	C
MV surgery may be considered in symptomatic patients with chronic severe primary MR and LVEF ≤30% (stage D)	IIb	C
MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B
MVR should not be performed for treatment of isolated severe primary MR limited to less than one half of the posterior leaflet unless MV repair has been attempted and was unsuccessful	III: Harm	B

JACC Vol. 63, No. 22, 2014 June 10, 2014:e57–185

Early Surgery vs Watchful Waiting for MR Due to Flail Mitral Leaflets



n=446 surgery
6 tertiary centers from France, Italy, Belgium, and the United States
Suri RM JAMA. 2013;310(6):609-616. doi:10.1001/jama.2013.8643

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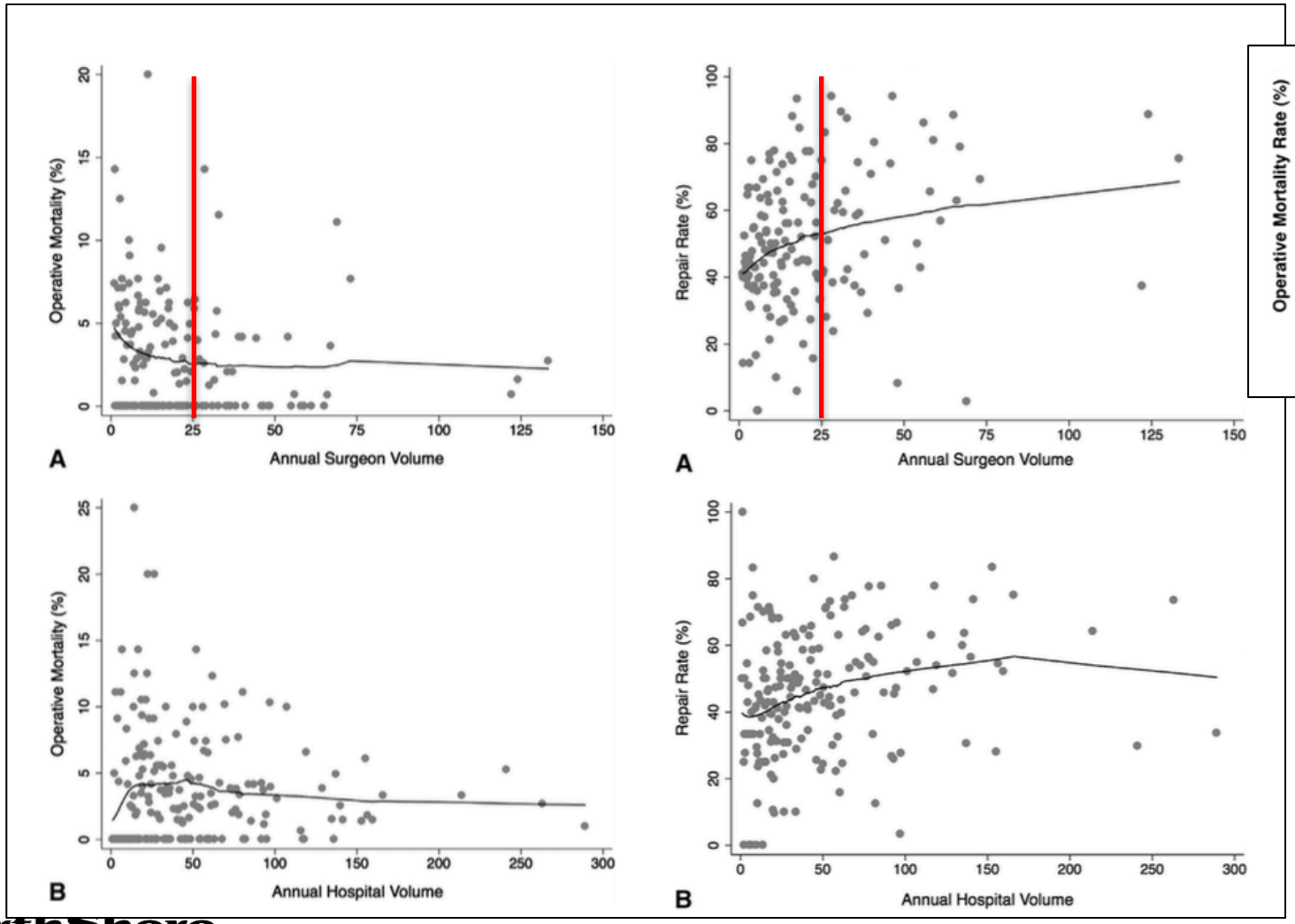
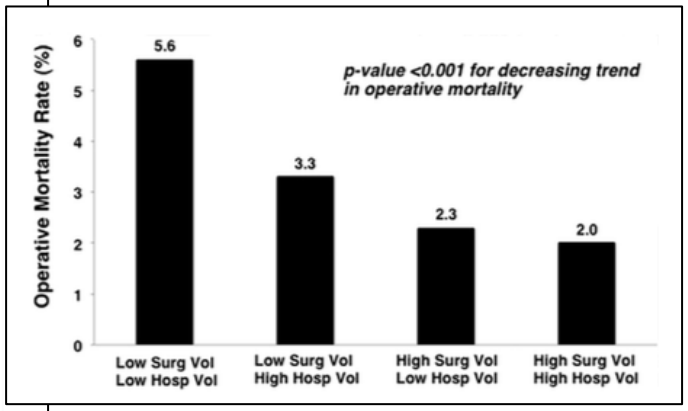
Operative outcomes in mitral valve surgery:

Combined effect of surgeon and hospital volume in a population-based analysis - isolated mitral valve surgery for MR 2003-2008





The effect of hospital volume on operative outcomes of mitral valve surgery was largely driven by the individual surgeon volumes within that hospital.

Nationwide Inpatient Sample
n=50,152 eligible patients
J Thorac Cardiovasc Surg 2013;146:638-46

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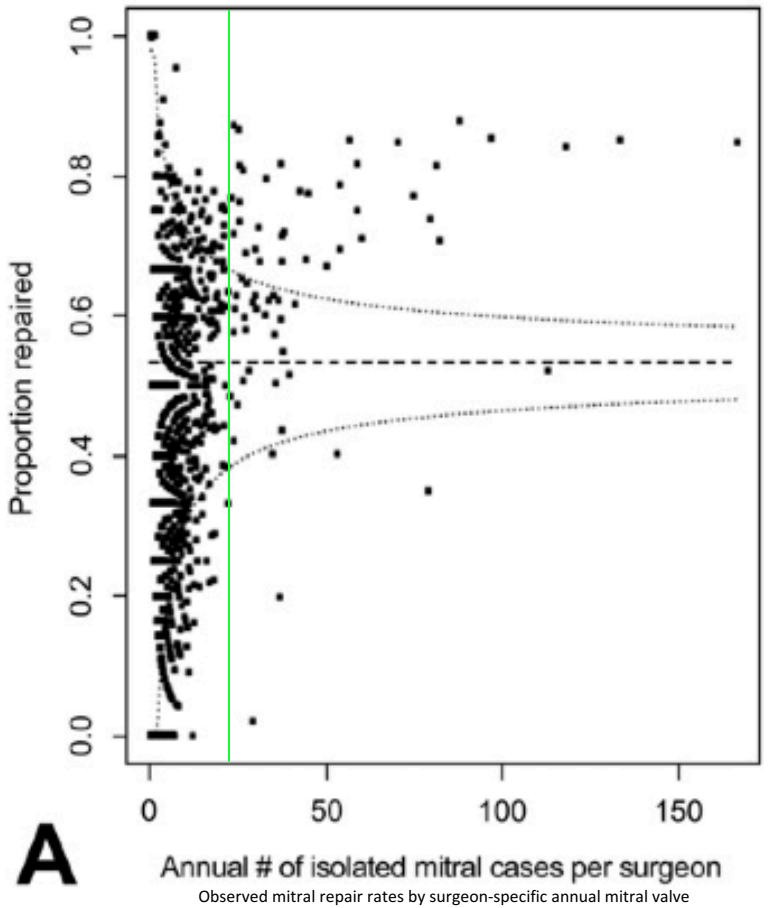
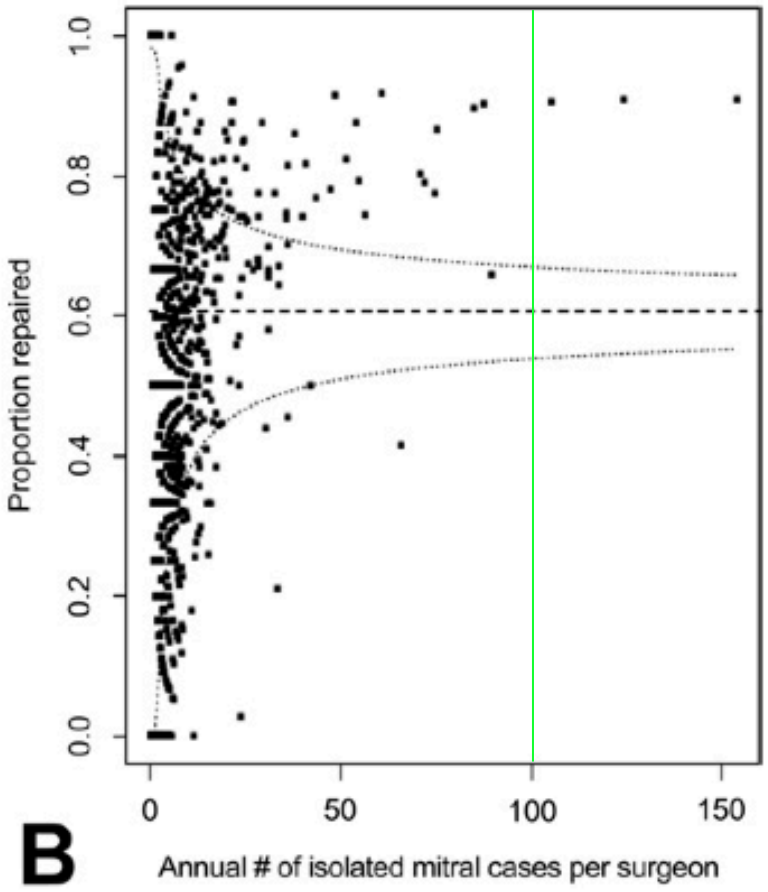
Predictors of Mitral Valve Repair: Clinical and Surgeon Factors



Observed mitral repair rates by surgeon-specific annual mitral valve repair volume



Surgeon-specific mitral valve repair volume without mitral stenosis cases

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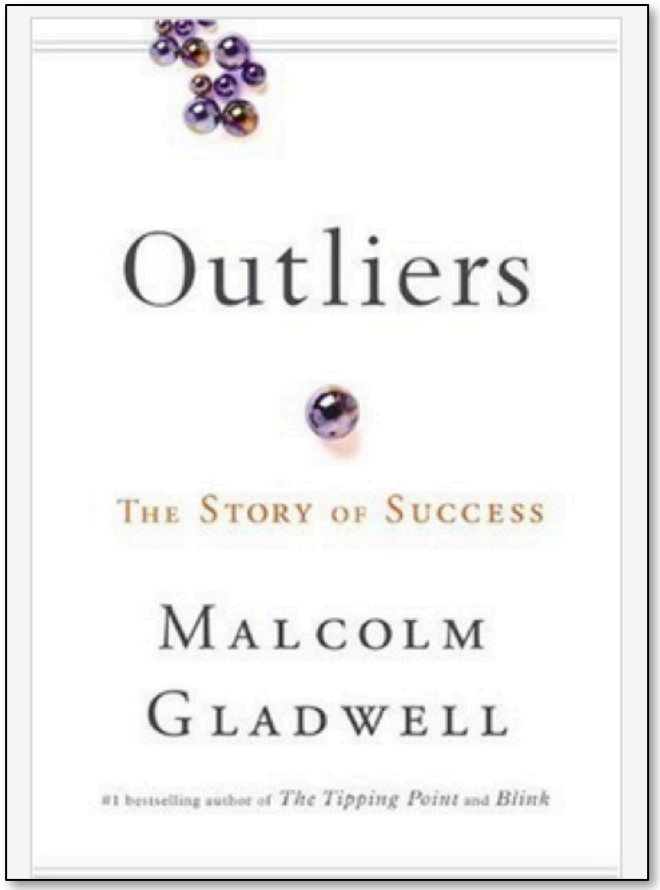
Ann Thorac Surg 2010;90:1904–12

Gladwell "10,000-Hour Rule"



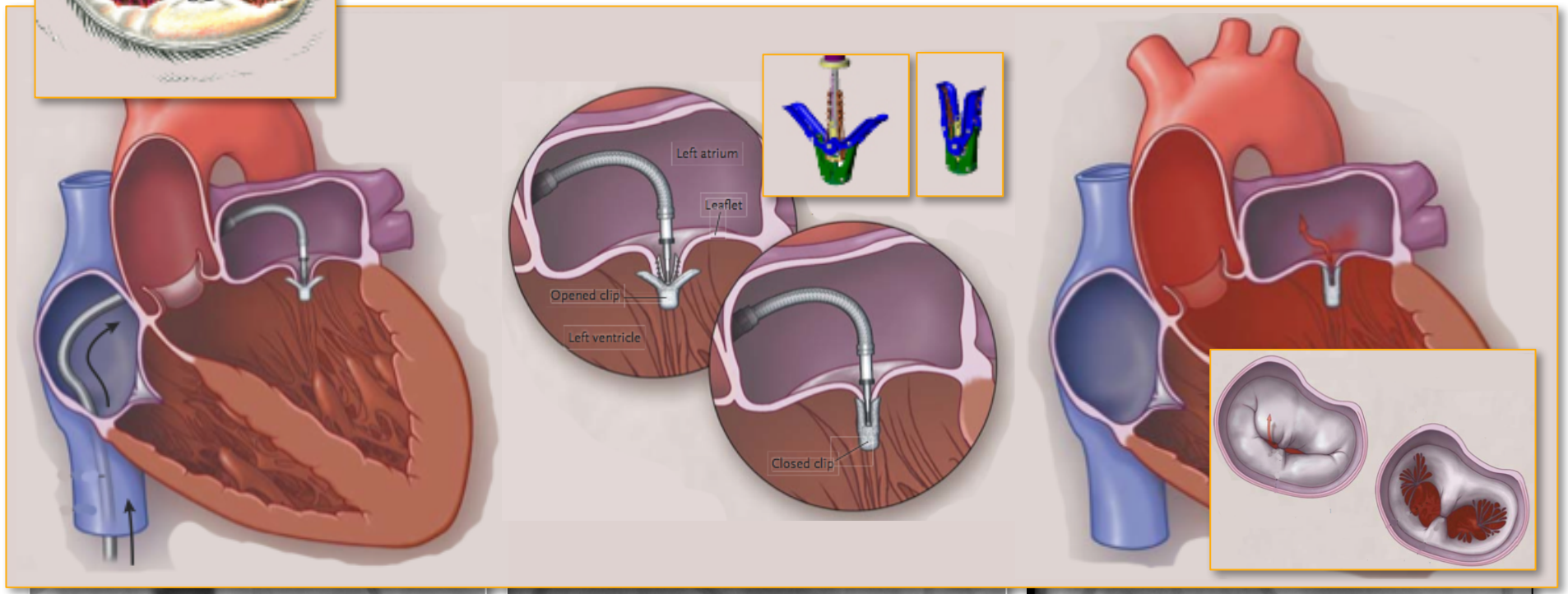
The key to achieving world class expertise in any skill is, to a large extent, a matter of practicing the correct way, for a total of around 10,000 hours.

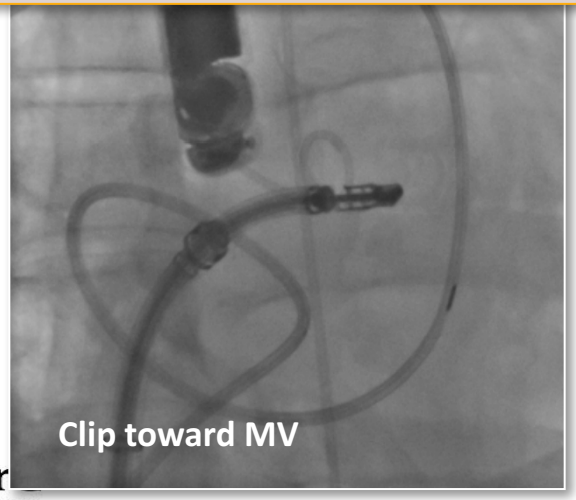
Therapy for MR

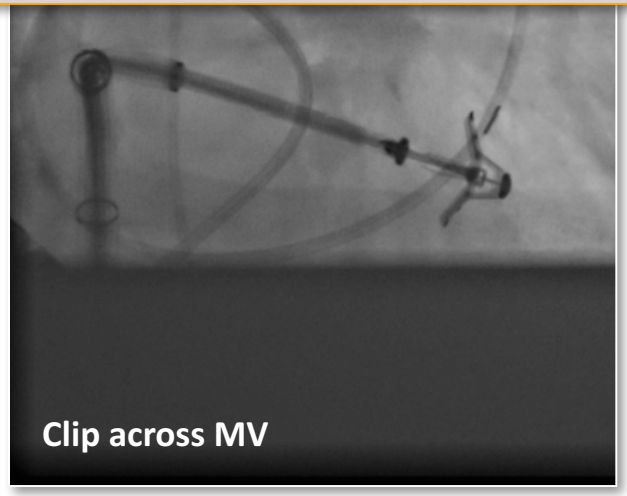
	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	??
High Surgical Risk	Commercial MitraClip	COAPT

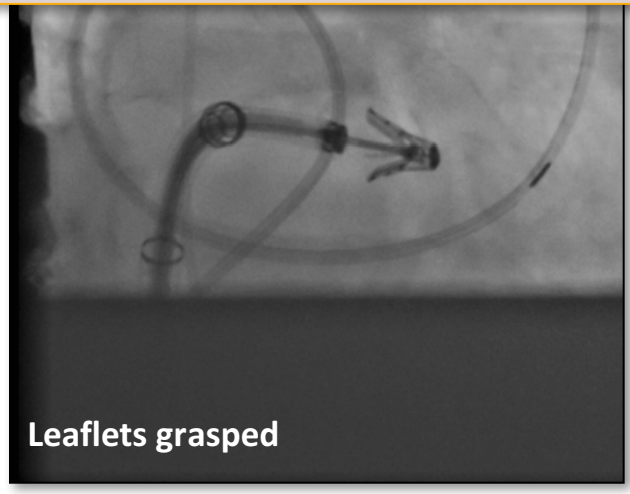
Catheter-Based Mitral Valve Repair

MitraClip System









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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*

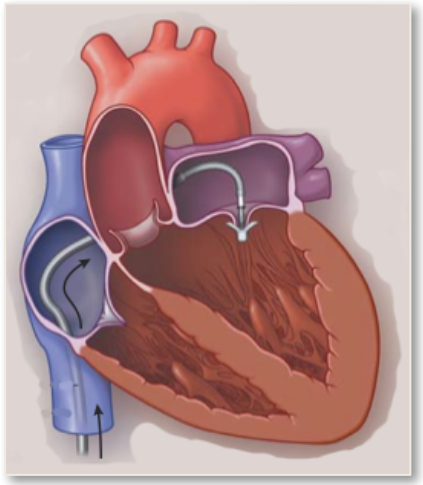
BACKGROUND

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

of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($P<0.001$). 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

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)



CONCLUSIONS

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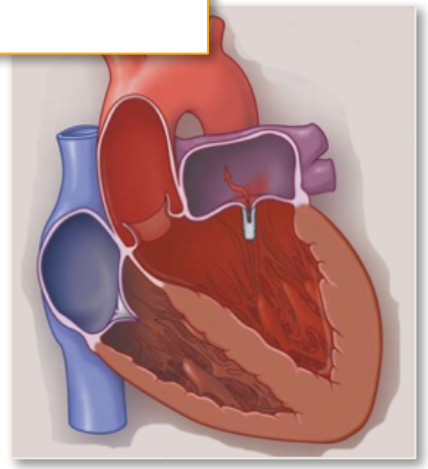

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Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

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

ABSTRACT

BACKGROUND In the second Endovascular Valve Edge-to-Edge Repair Study trial, treatment of mitral regurgitation (MR) with a novel percutaneous device showed superior safety compared with surgery, but less effective reduction in MR at 1 year.

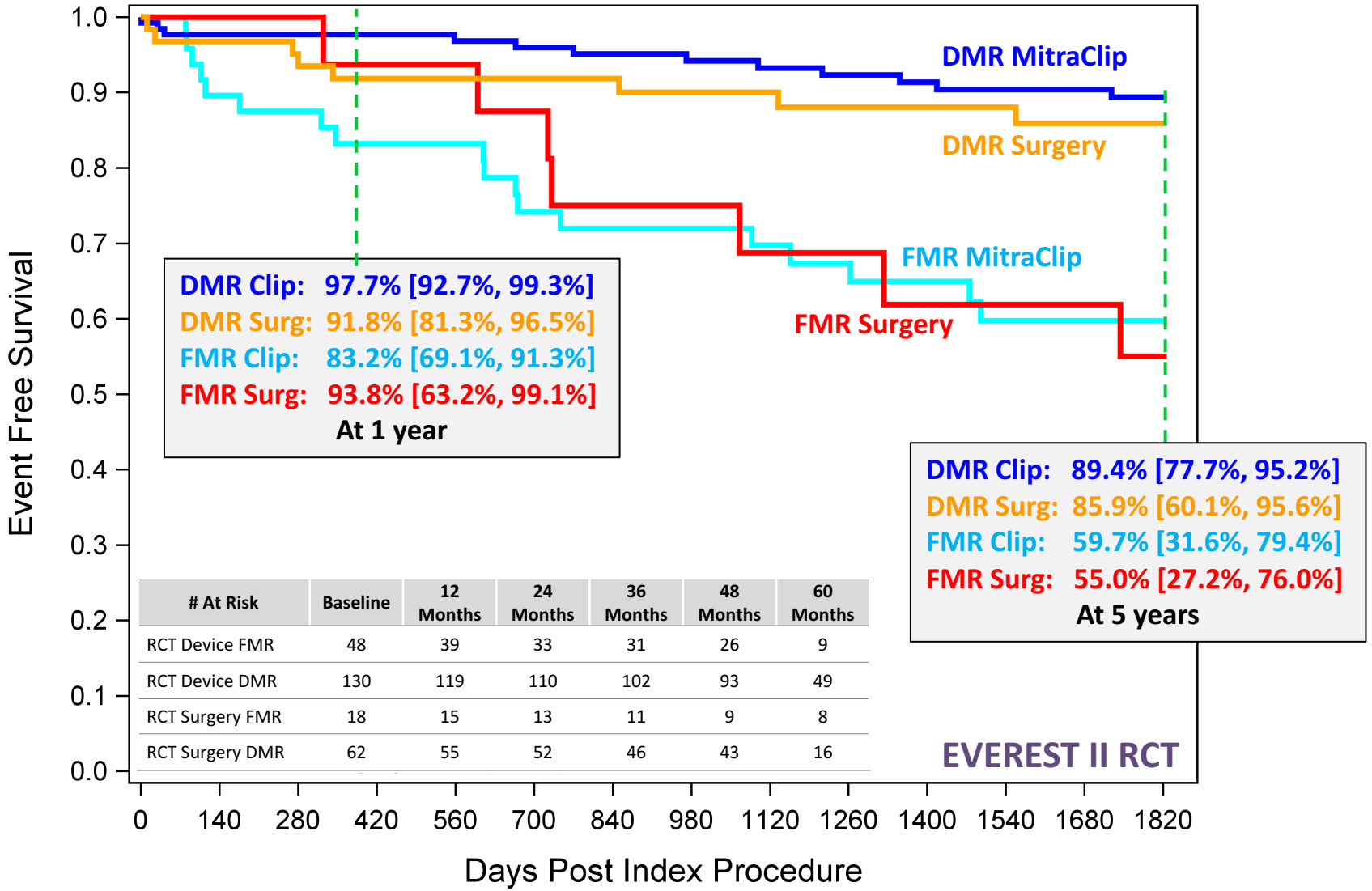
OBJECTIVES This study sought to evaluate the final 5-year clinical outcomes and durability of percutaneous mitral valve (MV) repair with the MitraClip device compared with conventional MV surgery.

METHODS Patients with grade 3+ or 4+ MR were randomly assigned to percutaneous repair with the device or conventional MV surgery in a 2:1 ratio (178:80). Patients prospectively consented to 5 years of follow-up.

RESULTS At 5 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the as-treated population was 44.2% versus 64.3% in the percutaneous repair and surgical groups, respectively ($p = 0.01$). The difference was driven by increased rates of 3+ to 4+ MR (12.3% vs. 1.8%; $p = 0.02$) and surgery (27.9% vs. 8.9%; $p = 0.003$) with percutaneous repair. After percutaneous repair, 78% of surgeries occurred within the first 6 months. Beyond 6 months, rates of surgery and moderate-to-severe MR were comparable between groups. Five-year mortality rates were 20.8% and 26.8% ($p = 0.4$) for percutaneous repair and surgery, respectively. In multivariable analysis, treatment strategy was not associated with survival.

CONCLUSIONS Patients treated with percutaneous repair more commonly required surgery for residual MR during the first year after treatment, but between 1- and 5-year follow-up, comparably low rates of surgery for MV dysfunction with either percutaneous or surgical therapy endorse the durability of MR reduction with both repair techniques. (EVEREST II Pivotal Study High Risk Registry; NCT00209274). (J Am Coll Cardiol 2015;66:2844–54)

Freedom From Mortality & Reintervention



# At Risk	Baseline	12 Months	24 Months	36 Months	48 Months	60 Months
RCT Device FMR	48	39	33	31	26	9
RCT Device DMR	130	119	110	102	93	49
RCT Surgery FMR	18	15	13	11	9	8
RCT Surgery DMR	62	55	52	46	43	16

Kaplan-Meier estimate

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http://dx.doi.org/10.1016/j.jacc.2013.12.062

Percutaneous Mitral Valve Repair for Mitral Regurgitation in High-Risk Patients

Results of the EVEREST II Study

Donald
Ramon
Michae

RESULTS In the studies, 327 of 351 patients completed 12 months of follow-up. Patients were elderly (76 ± 11 years of age), with 70% having functional MR and 60% having prior cardiac surgery. The mitral valve device reduced MR to ≤2+ in 86% of patients at discharge ($n = 325$; $p < 0.0001$). Major adverse events at 30 days included death in 4.8%, myocardial infarction in 1.1%, and stroke in 2.6%. At 12 months, MR was ≤2+ in 84% of patients ($n = 225$; $p < 0.0001$). From baseline to 12 months, left ventricular (LV) end-diastolic volume improved from 161 ± 56 ml to 143 ± 53 ml ($n = 203$; $p < 0.0001$) and LV end-systolic volume improved from 87 ± 47 ml to 79 ± 44 ml ($n = 202$; $p < 0.0001$). New York Heart Association functional class improved from 82% in class III/IV at baseline to 83% in class I/II at 12 months ($n = 234$; $p < 0.0001$). The 36-item Short Form Health Survey physical and mental quality-of-life scores improved from baseline to 12 months ($n = 191$; $p < 0.0001$). Annual hospitalization rate for heart failure fell from 0.79% pre-procedure

The percutaneous mitral valve device significantly reduced MR, improved clinical symptoms, and decreased LV dimensions at 12 months in this high-surgical-risk cohort.

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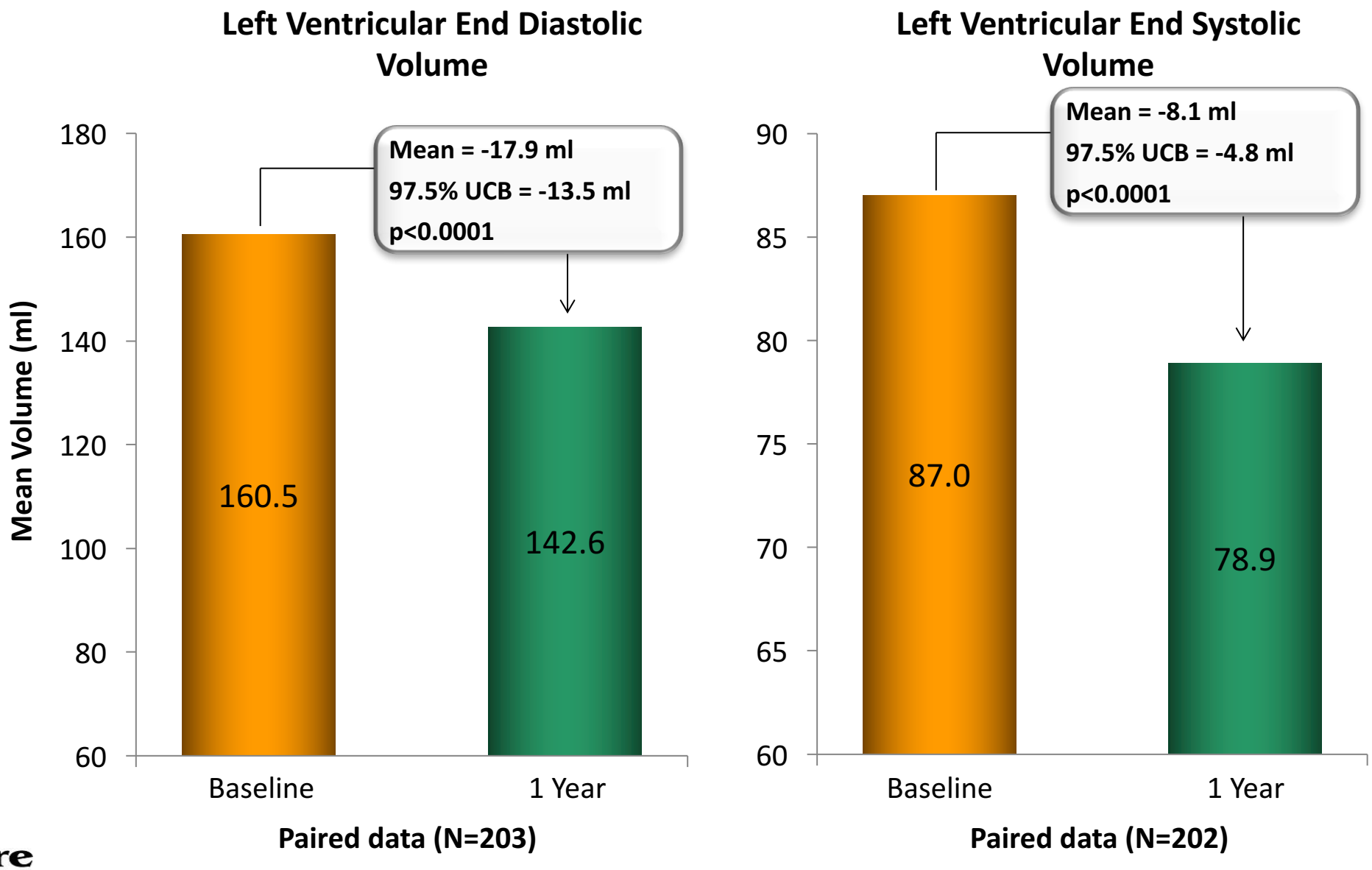
Left Ventricular Volumes



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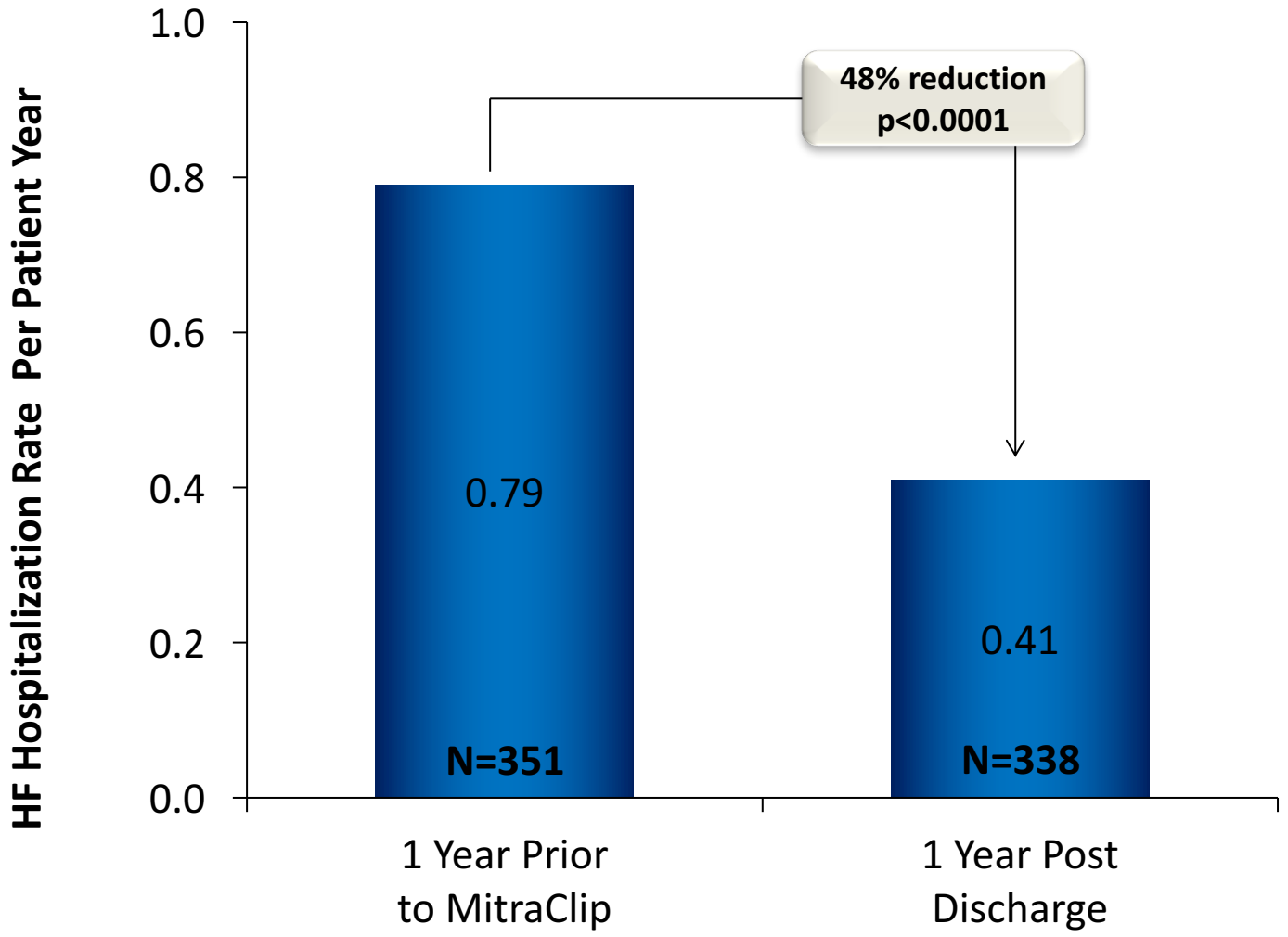
Hospitalizations for Heart Failure



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All treated

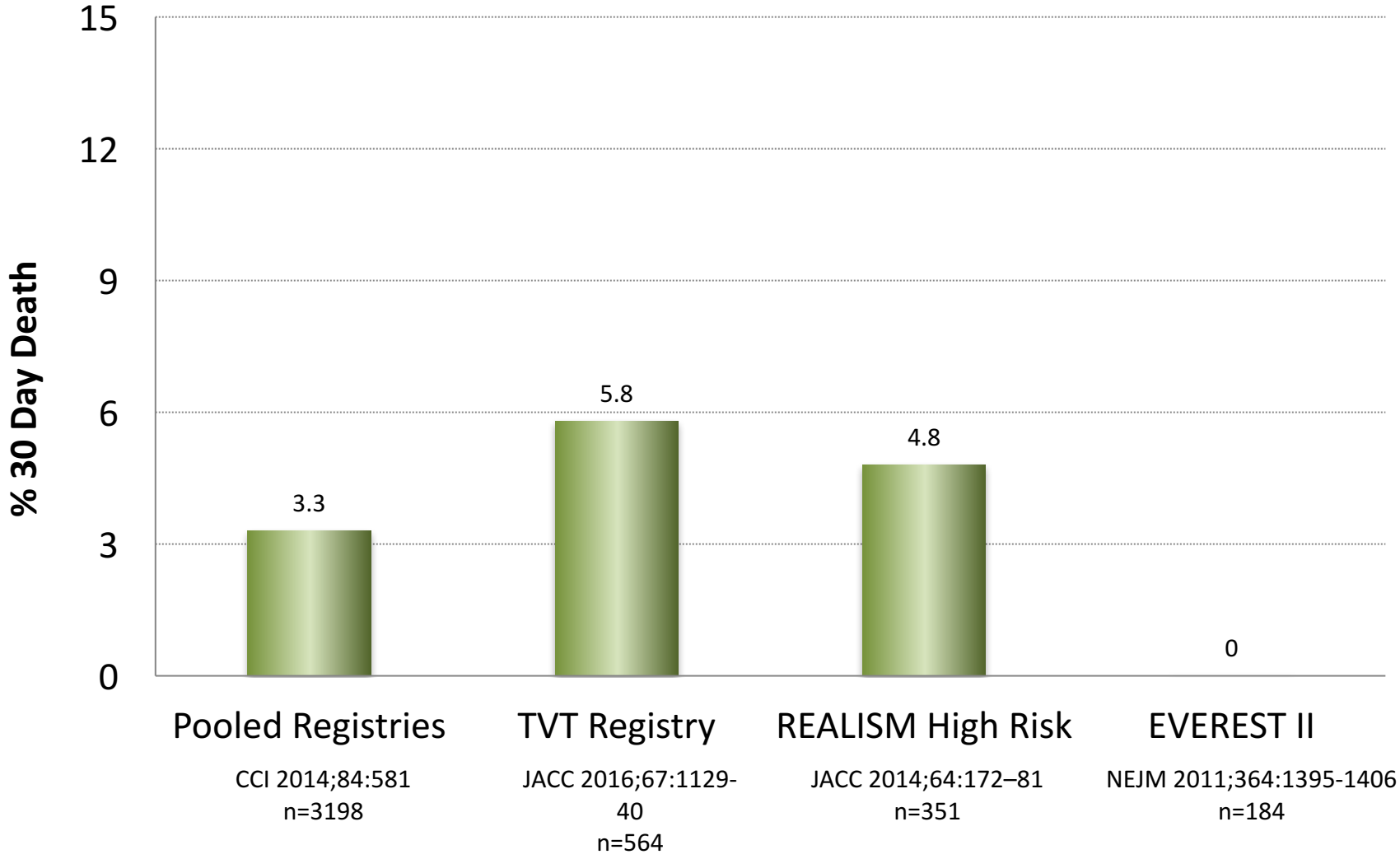
Registries

Prospective-Multicenter

Study	n
REALISM US Continued Access	899
REALISM Compassionate/Emergency Use	66
ACCESS Europe Phase I	567
ACCESS Europe Phase II	286
German Transcatheter Mitral Valve Interventions (TRAMI)	1002
GRASP-It	304
MitraSwiss registry nationwide	265
Sentinel Registry EURObservational Research Programme ESC	628
MitraClip Asia-Pacific Registry (MARS)	145
ANZ MitraClip Registry	45

MitraClip

30 Day Mortality



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Evanston Hospital

Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation After Transcatheter Mitral Valve Repair

D. Scott Lim, MD,* Matthew R. Reynolds, MD, MSc,†‡ Ted Feldman, MD,§ Saibal Kar, MD,‖
Howar
Paul G

METHODS A prohibitive-risk DMR cohort was identified by a multidisciplinary heart team that retrospectively evaluated high-risk DMR patients enrolled in the EVEREST (Endovascular Valve Edge-to-Edge Repair Study) II studies.

RESULTS A total of 141 high-risk DMR patients were consecutively enrolled; 127 of these patients were retrospectively identified as meeting the definition of *prohibitive risk* and had 1-year follow-up (median: 1.47 years) available. Patients were elderly (mean age: 82.4 years), severely symptomatic (87% New York Heart Association class III/IV), and at prohibitive surgical risk (STS score: 13.2 ± 7.3%). TMVR (MitraClip) was successfully performed in 95.3%; hospital stay was 2.9 ± 3.1 days. Major adverse events at 30 days included death in 6.3%, myocardial infarction in 0.8%, and stroke in 2.4%. Through 1 year, there were a total of 30 deaths (23.6%), with no survival difference between patients discharged with MR ≤1+ or MR 2+. At 1 year, the majority of surviving patients (82.9%) remained MR ≤2+ at 1 year, and 86.9% were in New York Heart Association functional class I or II. Left ventricular

TMVR in prohibitive surgical risk patients is associated with safety and good clinical outcomes, including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year.

including decreases in rehospitalization, functional improvements, and favorable ventricular remodeling, at 1 year. (Real World Expanded Multi-center Study of the MitraClip System [REALISM]; NCT01931956)

J Am Coll Cardiol 2014;64:182–92

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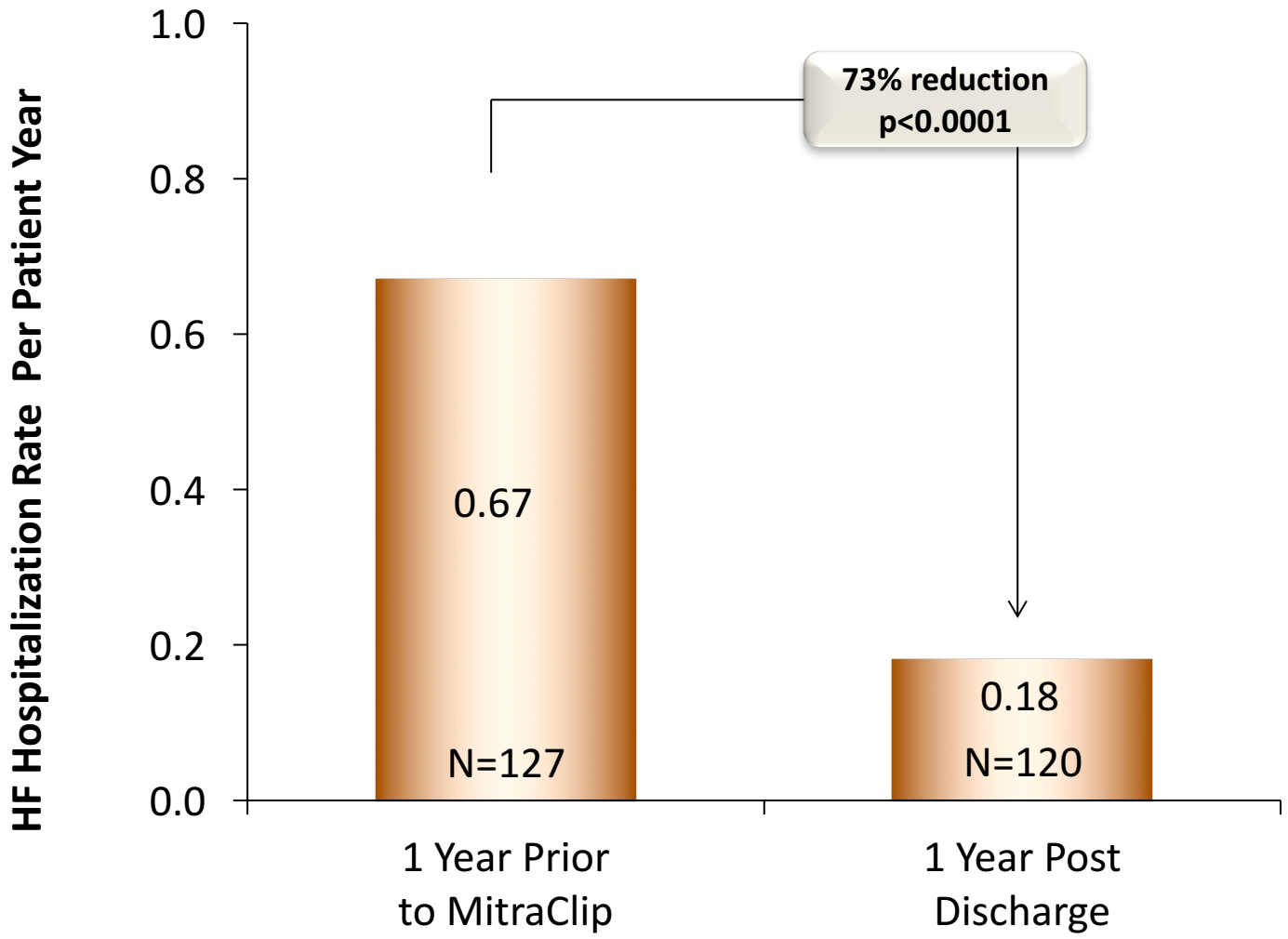
Baseline Demographics and Comorbidities

Characteristic	Prohibitive Risk DMR N = 127
Age (mean ± SD)	82 ± 9 years
Patients over 75 years of age	84%
Male Gender	55%
Coronary Artery Disease	73%
Prior Myocardial Infarction	24%
Previous Cardiovascular Surgery	48%
Atrial Fibrillation History	71%
Prior Stroke	10%
Diabetes	30%
Moderate to Severe Renal Disease	28%
Chronic Obstructive Pulmonary Disease	32%
STS Mortality Risk (mean ± SD) [v2.73, replacement]	13.2 ± 7.3%
SF-36 QoL Physical Component Score (mean ± SD)	32.0 ± 8.7
SF-36 QoL Mental Component Score (mean ± SD)	46.1 ± 12.5

Post-Procedural and Discharge Results

Post-Procedural and Discharge Results	**Prohibitive Risk DMR N = 127**
Post-Procedural (mean ± SD)	
ICU/CCU duration	1.4 ± 1.8 days
Length of hospital stay	2.9 ± 3.1 days
Discharge MR, (%)	
MR ≤ 2+ at Discharge	82%
MR ≤ 1+ at Discharge	54%
Discharged home, (%)	87%

Hospitalizations for Heart Failure



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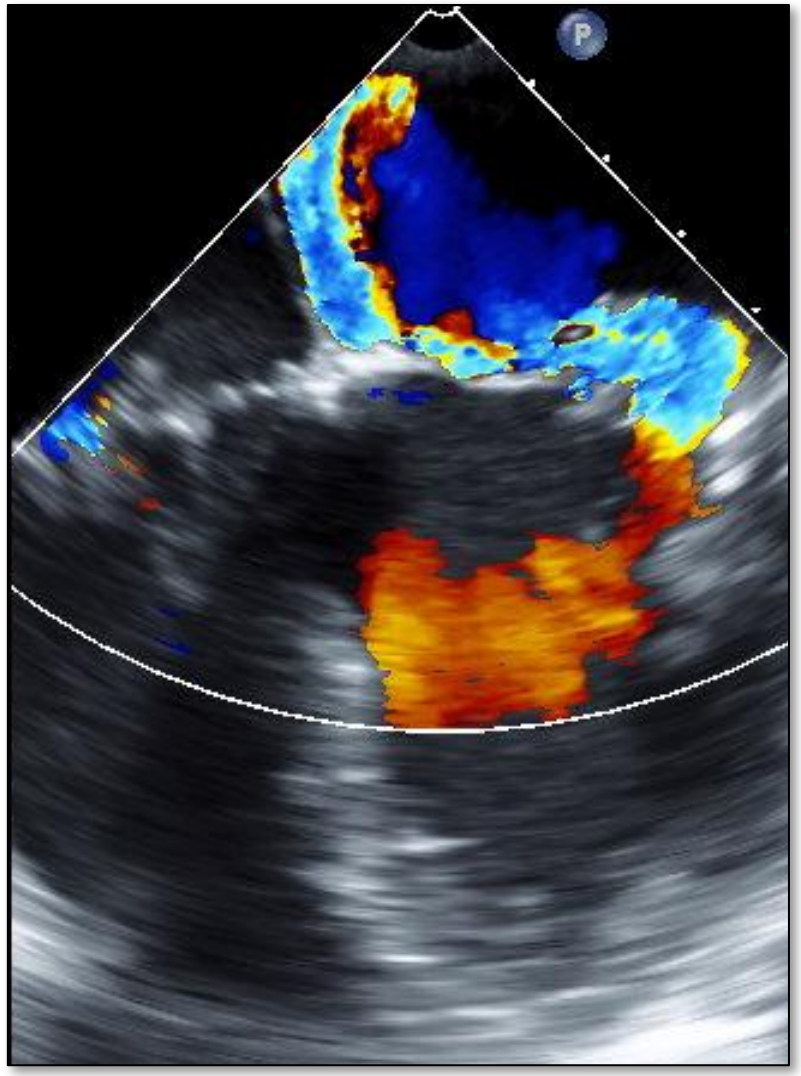
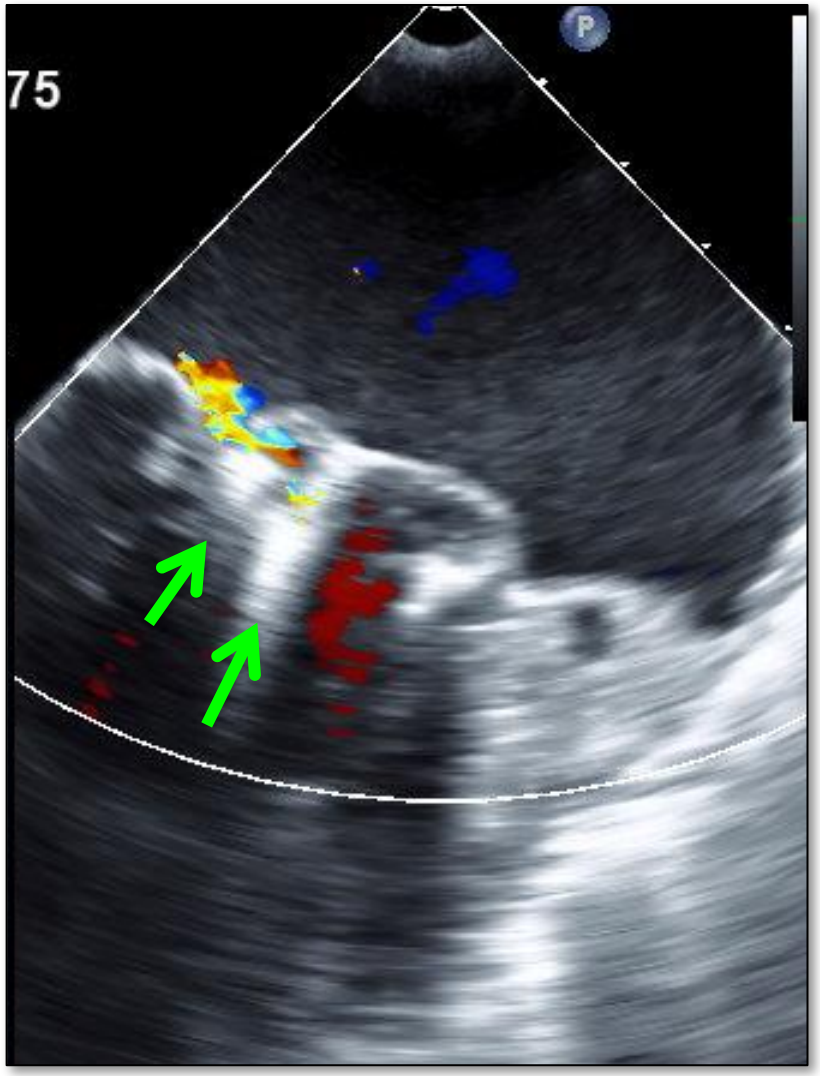
J Am Coll Cardiol 2014;64:182–92

DMR Case Example

- 87M
- Multiple hospitalizations for CHF
- EF 70-75%
- NYHA Class III
- PASP 50mmHg
- STS
  - Repair 7.5%
  - Replace 11%

Pre vs Post 2 Clips





Surgical & Interventional Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Surgical Mitral Repair	
High Surgical Risk	Commercial MitraClip	International Practice- 3 CE Devices

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PRACTICE GUIDELINE

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association
on Practice Guidelines

Isolated surgery for secondary MR

Recommendations for Chronic Severe Secondary MR

Recommendations	COR	LOE	References
MV surgery is reasonable for patients with chronic severe secondary MR (stages C and D) who are undergoing CABG or AVR	IIa	C	N/A
MV surgery may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe secondary MR (stage D)	IIb	B	(439,448–458) 2001-2012
MV repair may be considered for patients with chronic moderate secondary MR (stage B) who are undergoing other cardiac surgery	IIb	C	N/A

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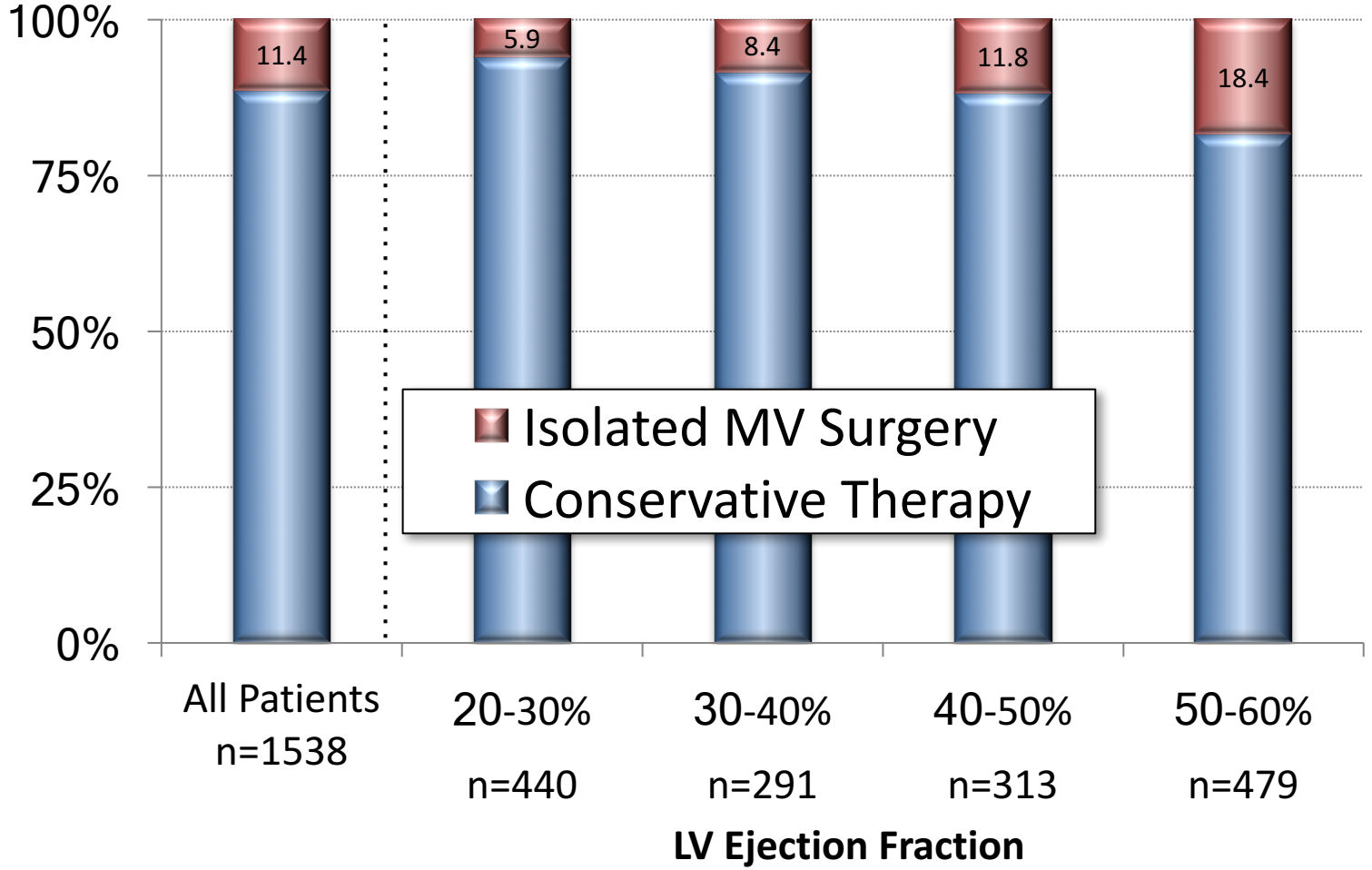
Treatment of isolated FMR

Duke Databank: 1,538 pts with echocardiographic 3+ - 4+ FMR and LVEF ≥20% between 2000 and 2010 **not** undergoing CABG



Velazquez EJ, Samad Z, Al-Khalidi HR, Sangli C, Grayburn PA, Massaro JM, Stevens SR, Feldman TE, Krucoff MW. The MitraClip and Survival in Patients with Mitral Regurgitation at High Risk for Surgery: A Propensity-Matched Comparison. Am Heart J. 2015 Nov;170(5):1050-1059.e3.

A Multicenter, Randomized, Controlled Study to Assess Mitral vAlve reconsTrucTion for advancEd Insufficiency of Functional or iscHemic ORigiN (MATTERHORN)

- **MitraClip vs Reconstructive mitral valve surgery**
- Estimated Enrollment: 210
- Composite of death, rehospitalisation for heart failure, reintervention, assist device implantation and stroke (whatever is first) 12 months post intervention
- Inclusion Criteria:
  - Clinically significant mitral regurgitation of primarily functional pathology
  - Left Ventricular Ejection Fraction (LVEF) ≥20% and ≤45% determined by echocardiography
  - High surgical risk as determined by Heart Team consensus Documented New York Heart Association Class III or Class IV heart failure, despite optimal standard of care therapy

NCT02371512
https://clinicaltrials.gov/ct2/show/NCT02371512?titles=MATTERHORN&rank=1

Open questions in Interventional Therapy for MR

	Degenerative	**Functional**
Low Surgical Risk	Matterhorn	??
High Surgical Risk	US Approval	COAPT Mitra-France RESHAPE-HF 2 EVOLVE-HF Mitra-CRT

Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk

COAPT TRIAL

>615 patients enrolled at 100 US sites

Significant FMR ≥3+ core lab; EF<50%; CHF hospitalization or BNP>300

High risk for mitral valve surgery- Local Heart Team

Specific valve anatomic criteria

Randomize 1:1

MitraClip

Control group Standard of care

Safety: Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

Effectiveness: Recurrent heart failure hospitalizations

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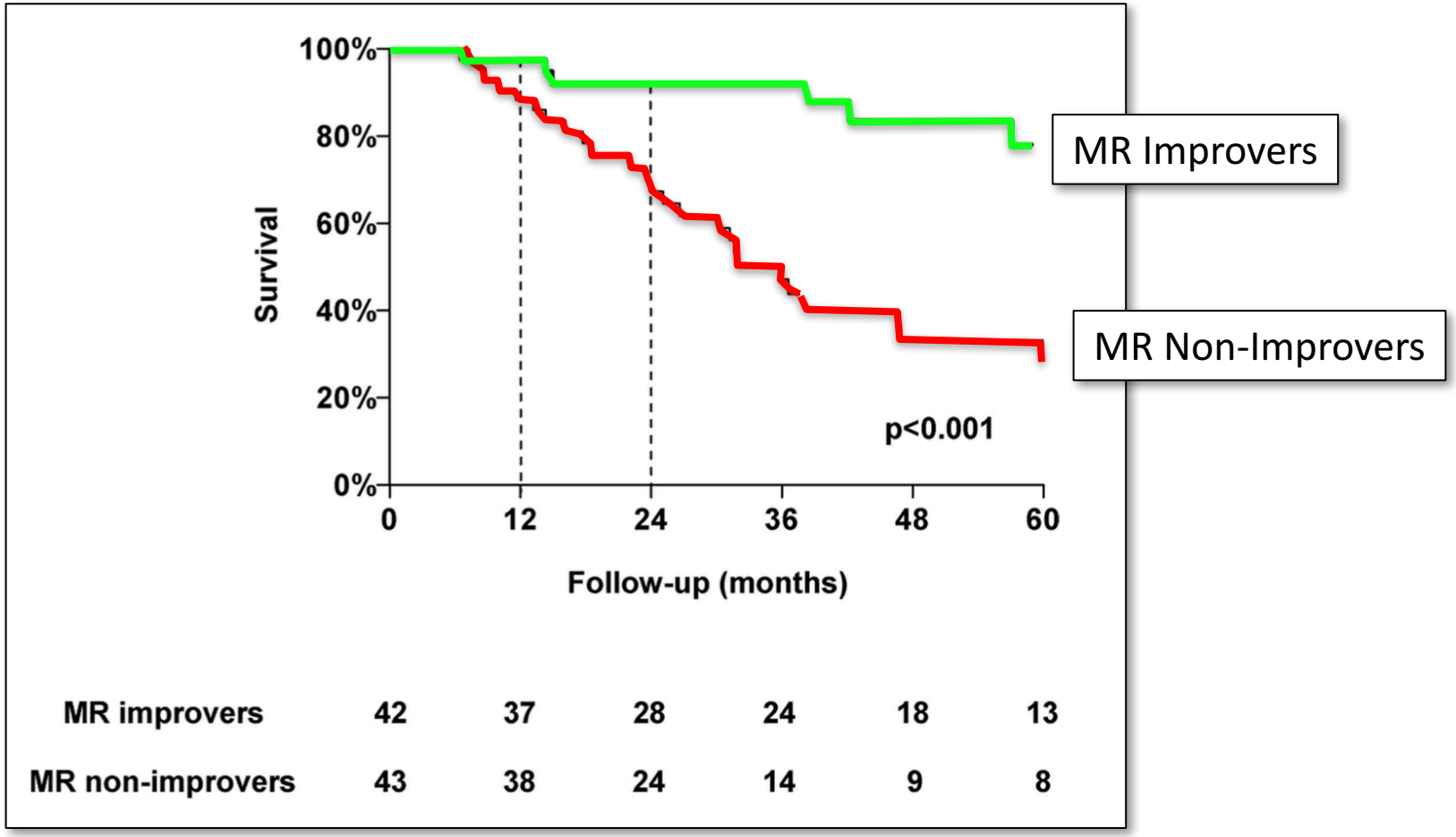
CRT in Moderate-Severe Functional MR and High Operative Risk



van Bommel RJ, Marsan NA, Delgado V, Borleffs CJ, van Rijnsoever EP, Schalij MJ, Bax JJ. Circulation. 2011;124:912-919

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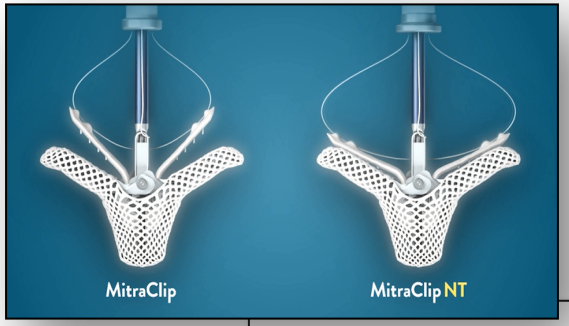
Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary MR (MITRA-FR)

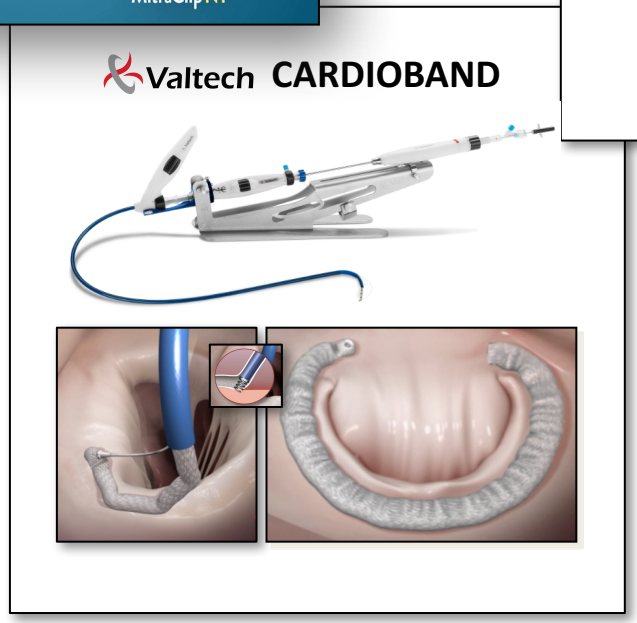
- **MitraClip vs optimal therapy alone**
- Estimated Enrollment: 288 at 22 sites- >290 enrolled as of Jan 2017
- Primary Outcome Measures: All-cause mortality and unplanned hospitalizations for heart failure 1 year
- Inclusion Criteria
  - Age > 18 years old
  - Severe secondary mitral regurgitation confirmed by the Echocardiography Core Laboratory Characterized by a regurgitation volume > 30 mL/beat or a regurgitant orifice area > 20 mm2
  - New York heart Association Class≥ II.
  - Left ventricular ejection fraction between 15% and 40%
  - Minimum of 1 hospitalization for heart failure within 12 months preceding randomization
  - Assessed by the investigator to be on optimal standard of care therapy for heart failure
  - Assessed by the heart team to be not eligible to a mitral surgery intervention

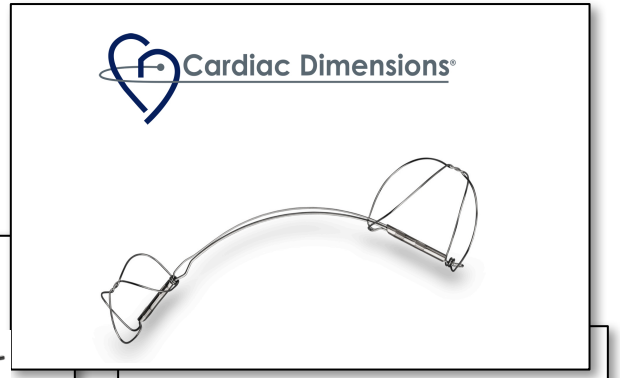
Profs. Obadia and Vahanian
NCT01920698
https://clinicaltrials.gov/ct2/show/NCT01920698?intr=Mitraclip&cntry1=EU%3AFR&rank=1

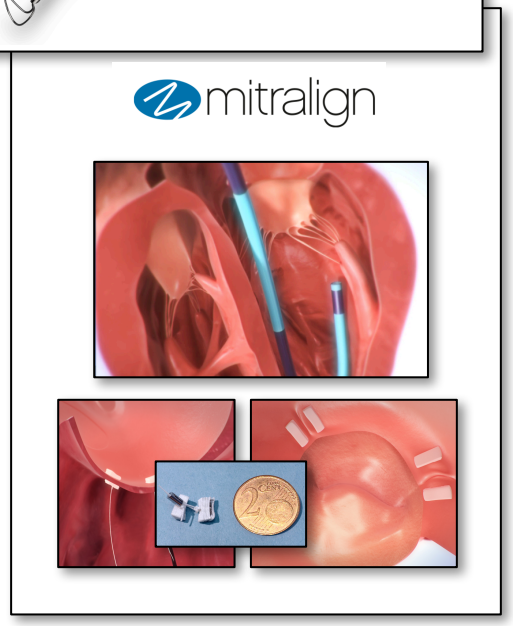
Percutaneous Mitral Repair

Approved or In Commercial Use









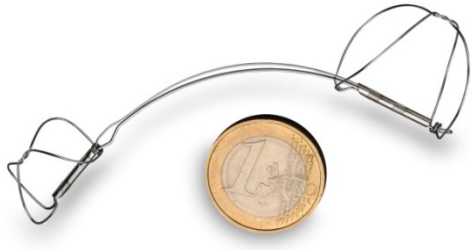
Mitral Repair Trials: Primary Endpoints

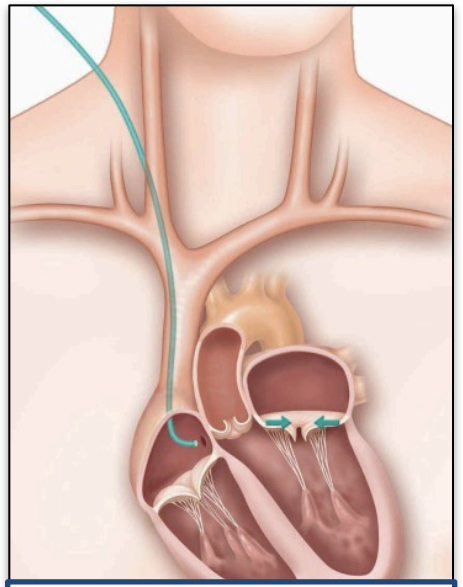
TRIAL	FU	Primary Endpoint
CRDIOBAND REPAIR Registry	1 month	Reduction in severity of MR
CARILLON REDUCE FMR	1 year	Change in regurgitant volume
CARILLON US IDE	1 year	Composite mortality, HFH, 6MWT and Regurgitant Volume
COAPT	1 year	Recurrent heart failure hospitalizations
MITRA-FR	1 year	All-cause mortality and unplanned heart failure hospitalizations
MATTERHORN	1 year	Composite death, heart failure rehospitalisation, reintervention, assist device implant & stroke
RESHAPE HF 2	1 year	Composite recurrent heart failure hospitalizations and cardiovascular death
EVOLVE-HF	6 months	6MWT
MITRA-CRT	1 year	Free from stroke, device embolization, emergent surgery/pericardiocentesis or procedural mortality, 6MWT, no readmissions for HF, transplant or mortality

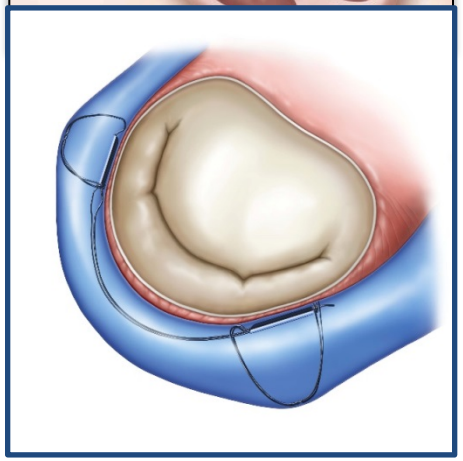
Cardiac Dimensions Carillion

Indirect annuloplasty with nitinol device anchored into the coronary sinus to reduce annulus dimensions
Transjugular approach

- 700 pts treated for commercial use
- 113 pts implanted in prospective trials
- FMR
- Safe (Death @30d 0% device related)
- Results @12 mo
  - 1 grade of MR reduction
  - 1 NYHA Class improvement (from III to II)
- indirect CS approach
- annular reduction around 15-20%







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TITAN and TITAN II Safety Data

	MAE Incidence (intention to treat)			
	TITAN[1]		TITAN II[2]	
	30-day Rate	Device Related	30-day Rate	Device Related
Death	1.9%	0.0%	2.8%	0.0%
MI	0.0%	0.0%	0.0%	0.0%
Cardiac Perforation	0.0%	0.0%	0.0%	0.0%
Device Embolism	0.0%	0.0%	0.0%	0.0%
Surgery or PCI related to the device	0.0%	0.0%	0.0%	0.0%
MAE Rate	1.9%	0.0%	2.8%	0.0%

[1]TITAN death associated with contrast-induced renal failure in non-implanted patient (n=53 intention-to-treat)

Zero device-related Major Adverse Events (MAE)

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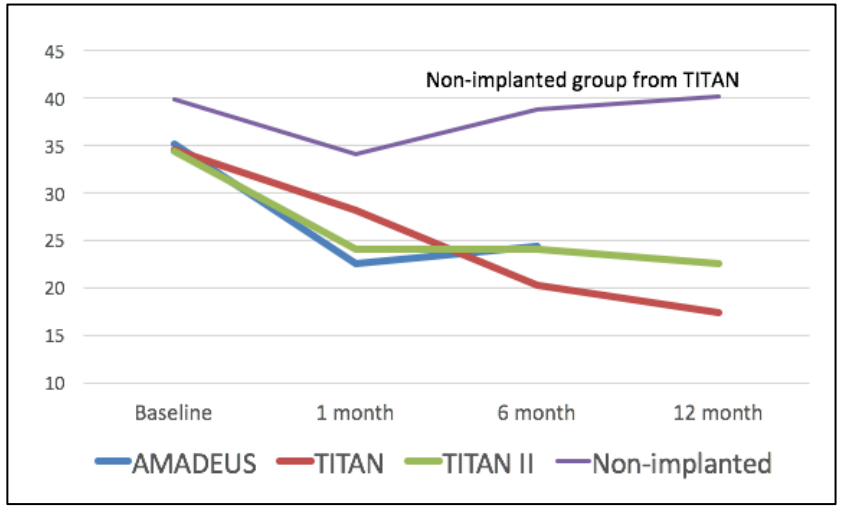
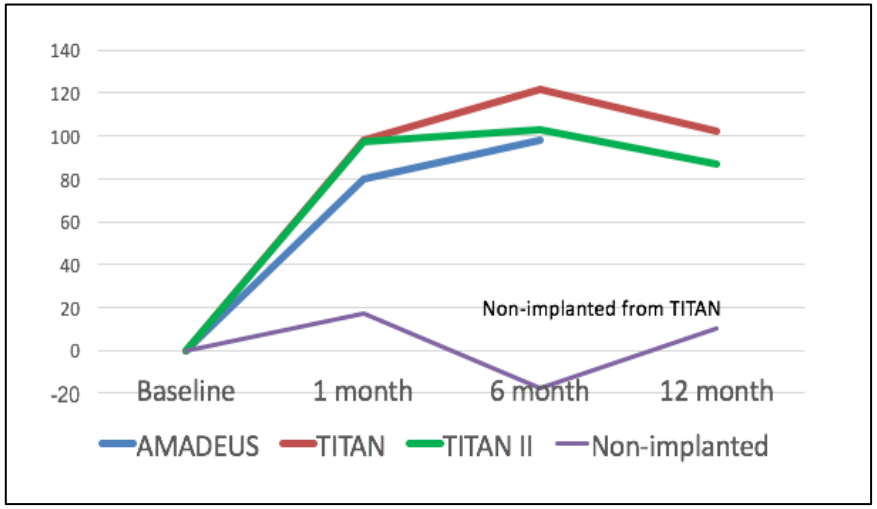
1. Siminiak, T., et al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. EU J of HF, 2012.

Carillon Clinical Trials

Regurgitant volume



6 minute walk test



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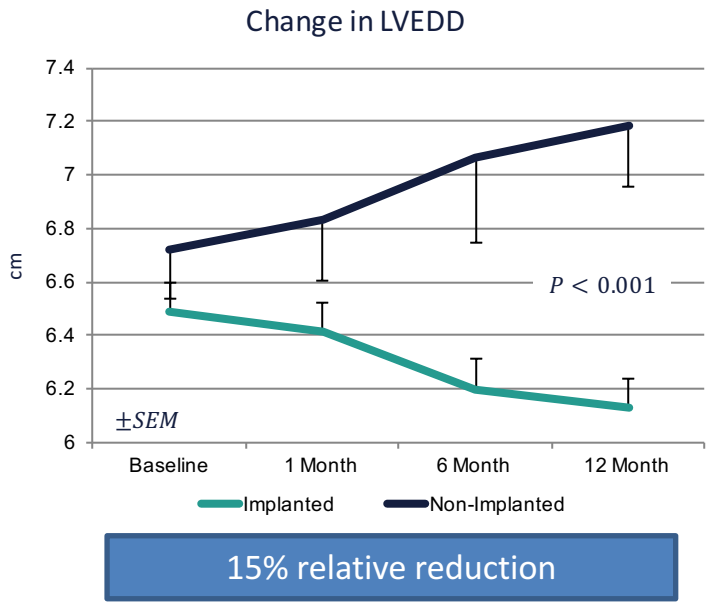
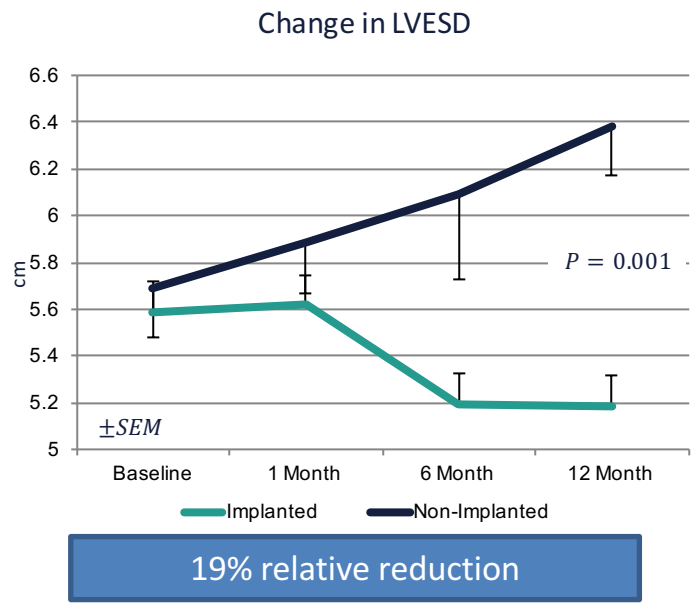
Results from TITAN & TITAN II: Reverse Remodeling



15% relative reduction



19% relative reduction

Results analyzed by Core Lab
Relative reduction stated at 12-months as a comparison between implanted and non-implanted cohorts

1. Siminiak, T., et al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. EU J of HF, 2012.
2. Lipiecki, J. et al. Coronary sinus-based percutaneous annuloplasty as treatment for functional mitral regurgitation: the TITAN II trial. Open Heart, 2016

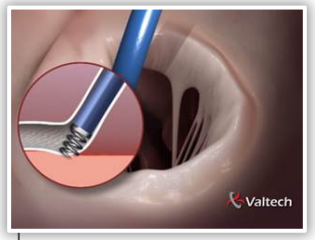
CARILLON Mitral Contour System for Reducing FMR (REDUCE FMR)

- Blinded, sham controlled trial
  - Coronary Sinus Quantitative Venography is done to ensure adequate size for device – patients randomized after venography
  - Device implantation takes only ~10 minutes after randomization, allowing for effective blinding
- 3:1 randomization ≈180 patients
- Primary Endpoint: Regurgitant Volume at 1 year
- Randomization estimated to be completed in summer (60% enrolled)
- Europe, Australia and New Zealand

Carillon Pivotal FDA IDE Trial

- 400 patient trial in 50 sites in US, Canada, Europe and Australia
- Blinded, sham-controlled
- 2:1 randomization
- Co-Primary Efficacy Endpoints
  - 1st Primary endpoint: Hierarchical Endpoint
    - Death, Heart Failure, 6 minute walk-test at 12 months
  - 2nd Co-Primary Efficacy Endpoint
    - Reduction in Regurgitant Volume at 12 months in treatment group compared to control group

Cardioband procedure: Major Steps



Pre-Procedure Planning

1 Transseptal Puncture

2 System Insertion

3 Implant Deployment

4 Implant Size Adjustment

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Study Demographics (N=61)

Variable	No. (%) or Mean
Age (years)	72 ± 6
Gender	Male 44 (72%) Female 17 (28%)
Euroscore II (%)	7
Baseline NYHA Class of III or IV	53 (86%)
Ischemic **Non Ischemic**	36 (59%) 25 (31%)
LVEDD (mm) Avg±SD	60 ± 6
EF (%) Avg±SD	33 ± 11
Prev CABG **COPD** **Moderate to Severe Renal Failure** **Severe Pulmonary Hypertension** **Afib**	19 (31%) 13 (21%) 46 (75%) 15 (24%) 46 (75%)

Reported Major Safety Events at 30 Days

30 Day Events*	Patients Experiencing Event, # (%) All Patients N=61
Death	2 (3.3%)
Hemorrhagic Stroke**	1 (1.7%)
Need for elective Mitral Operation**	1 (1.7%)
Myocardial Infarction	2 (3.2%)
Major Bleeding Complications	2 (3.3%)
Renal Failure	4 (6.6%)
Respiratory Failure	0 (0%)
Cardiac Tamponade	1 (1.7%)

* VARC Guidelines (European Heart Journal, 2012, 33:2403-2414)
** Part of the Death case
One additional death case per ITT - compassionate

Study Outcomes: ITT Cohort

- **Implant rate** **98.4%** (60/61)
- **Device success** **85.2%** (52/61)
  (@ Discharge)

  Device failures (n=9):
  - Death (unrelated to device) n=2
  - No cinching n=2
  - Anchor detachment n=5

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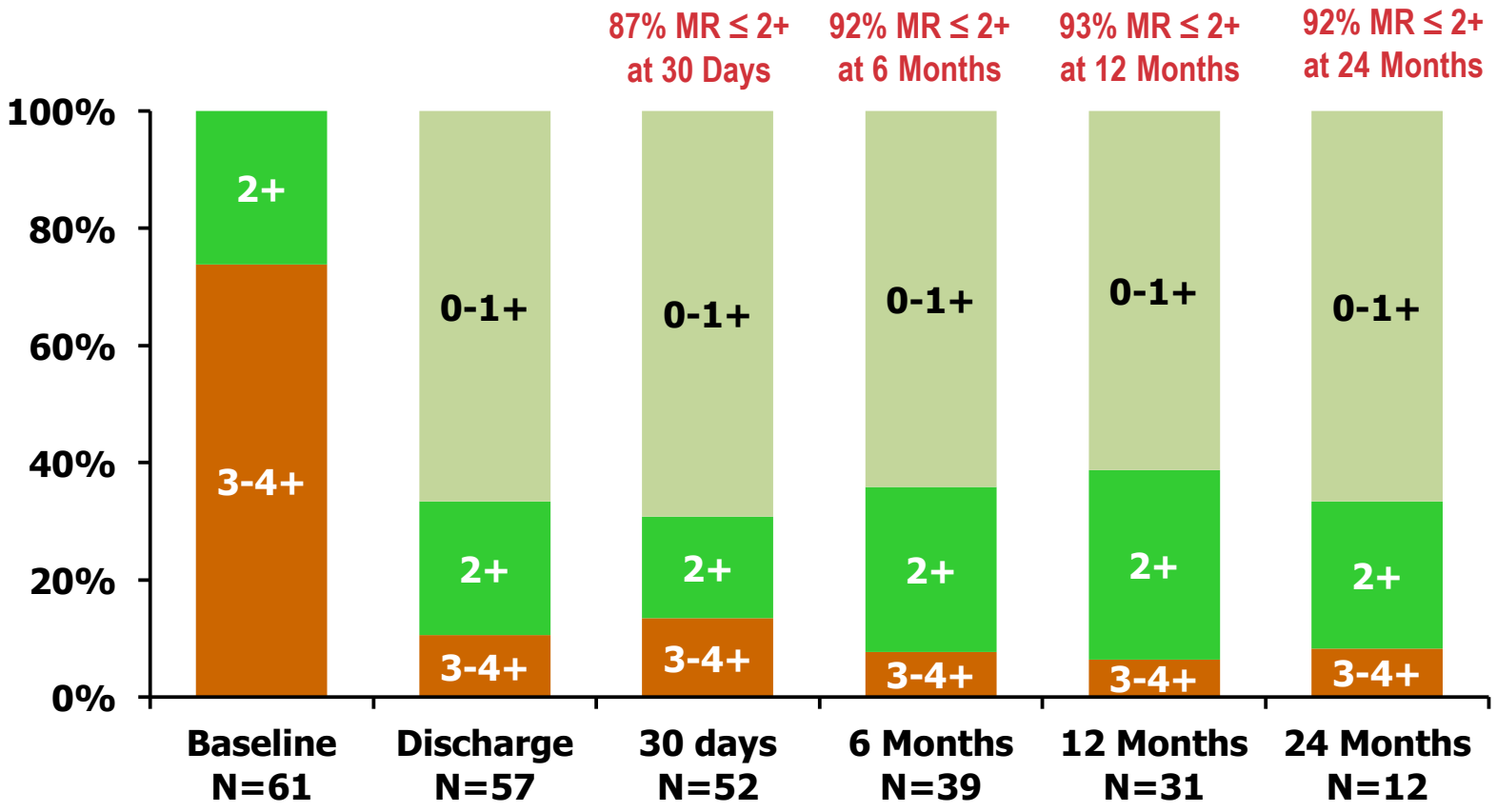
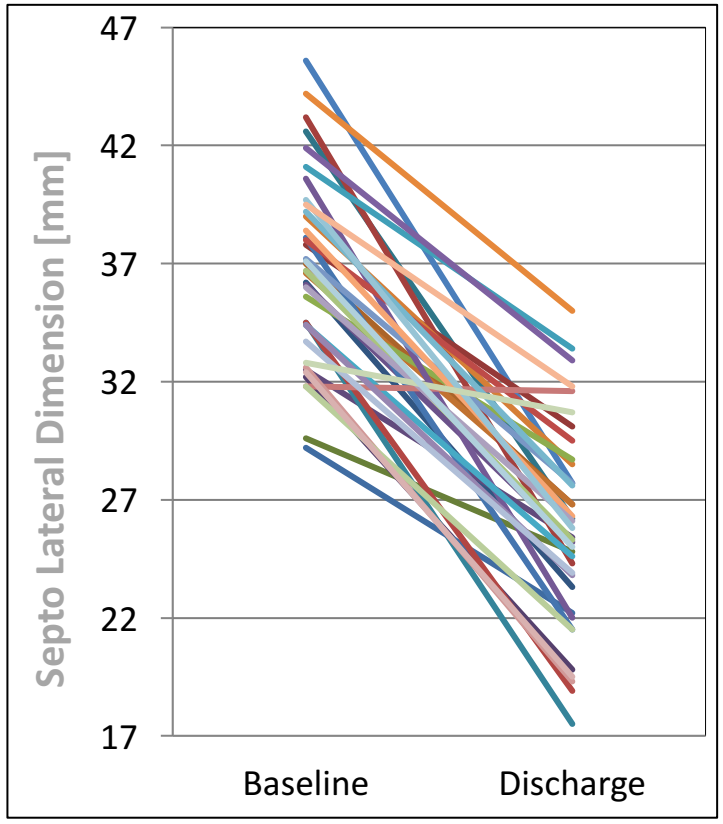
92% patients with MR≤2+ At 24 Months By Core Lab*

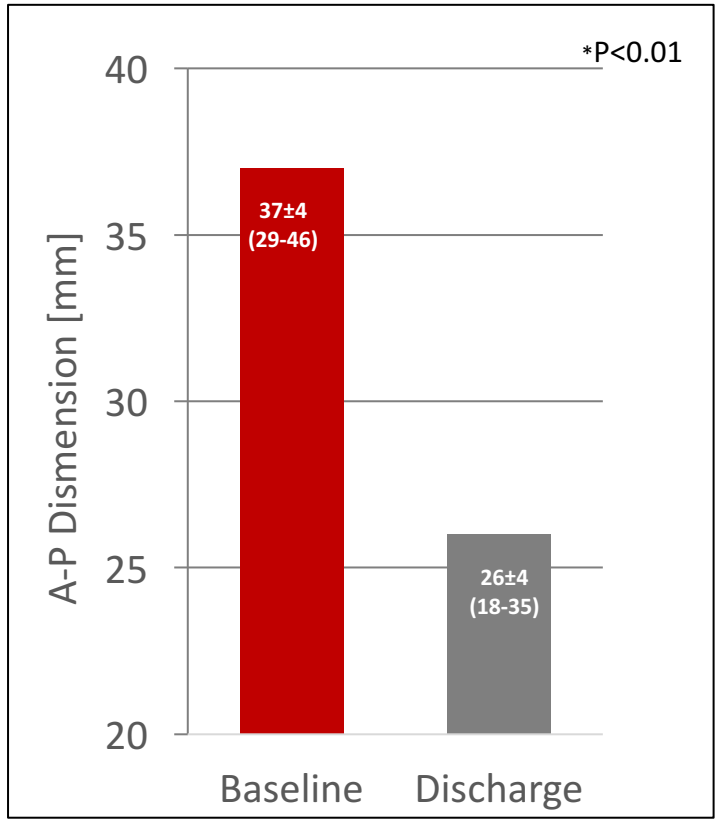


*Dr. Paul Grayburn – Baylor University

Annular Reconstruction by Significant Reduction in Septo Lateral (A-P) Dimension

30% average reduction in A-P





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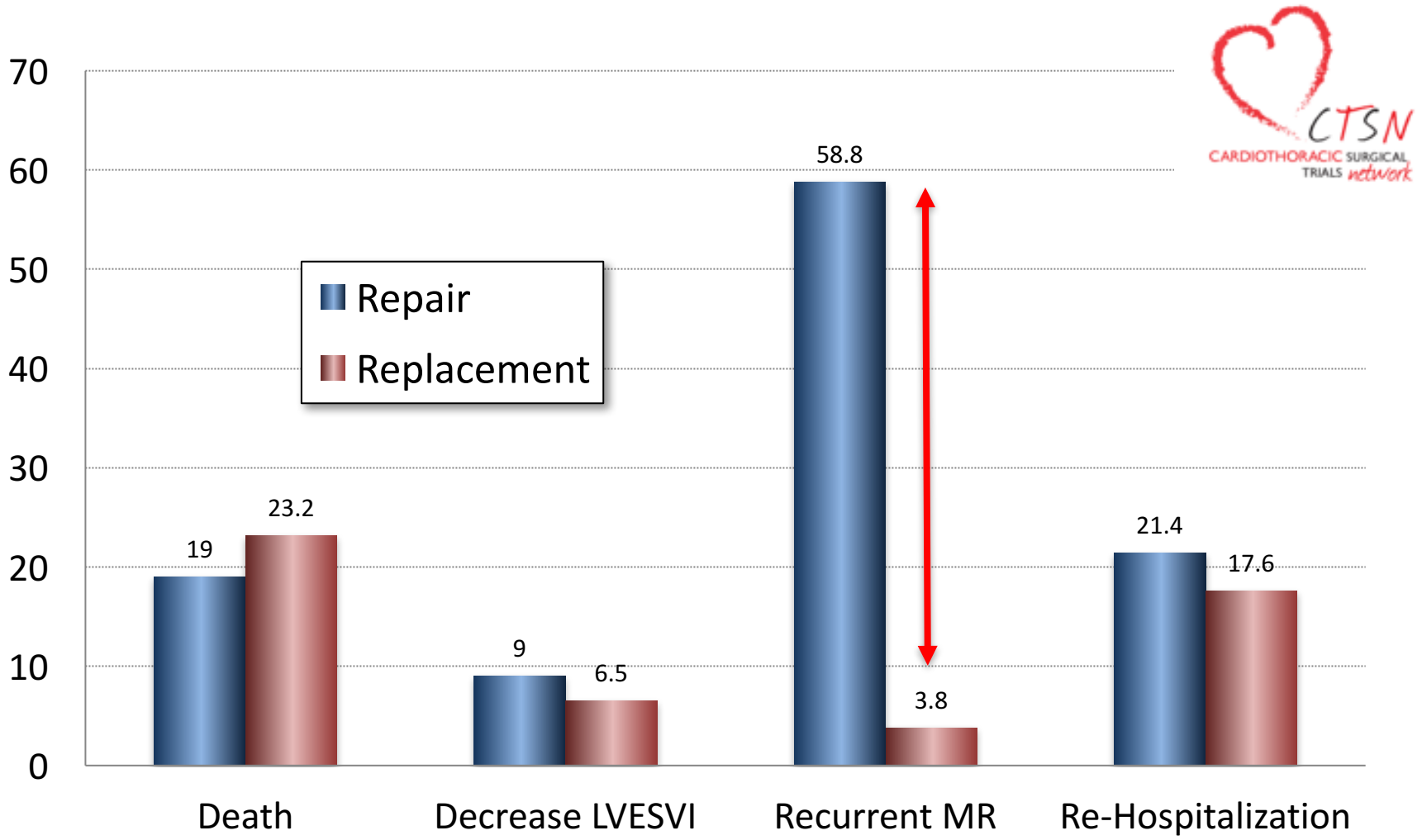
Two-Year Outcomes of Surgical Treatment of Severe Ischemic MR



CTSN CARDIOTHORACIC SURGICAL TRIALS network

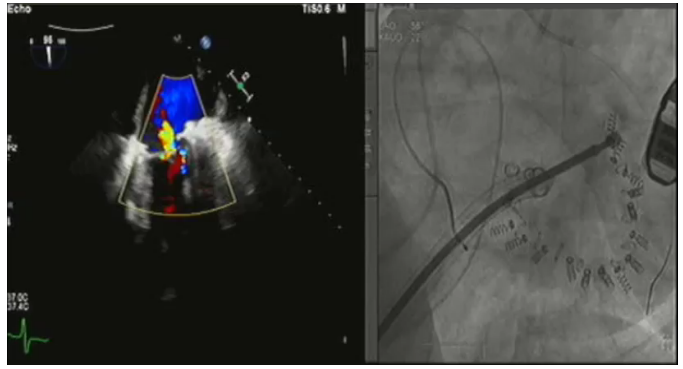
NorthShore University HealthSystem Evanston Hospital

n=251

Goldstein D et al. N Engl J Med 2016;374:344-353

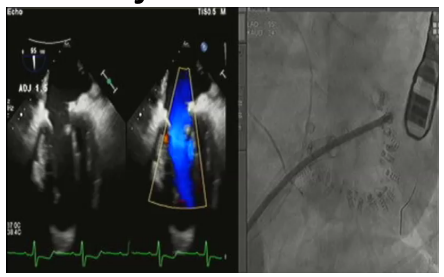
Real time monitoring of MR reduction

Pre Adjustment

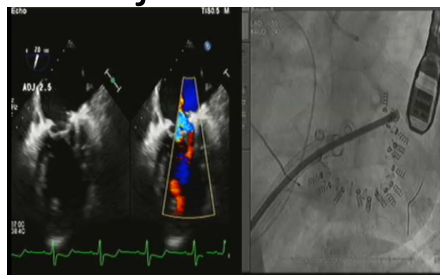


Valtech

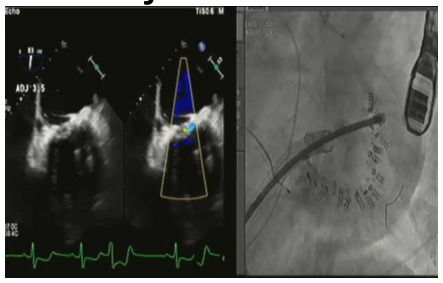
Adjustment 1



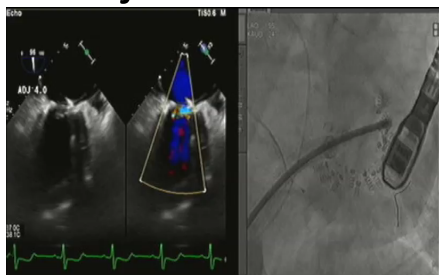
Adjustment 2



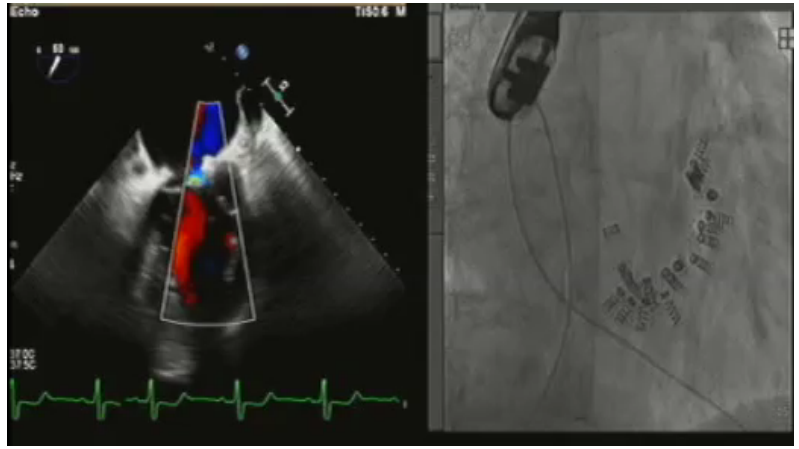
Adjustment 3



Adjustment 4



Post procedure



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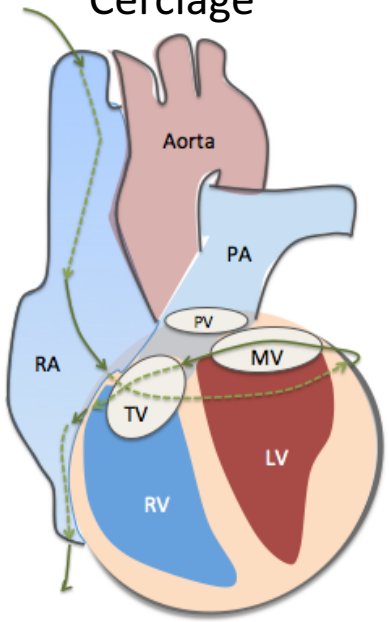
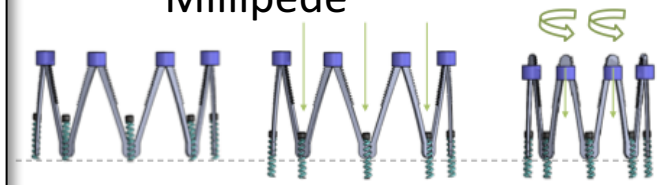
Cerclage

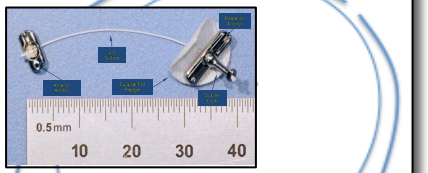


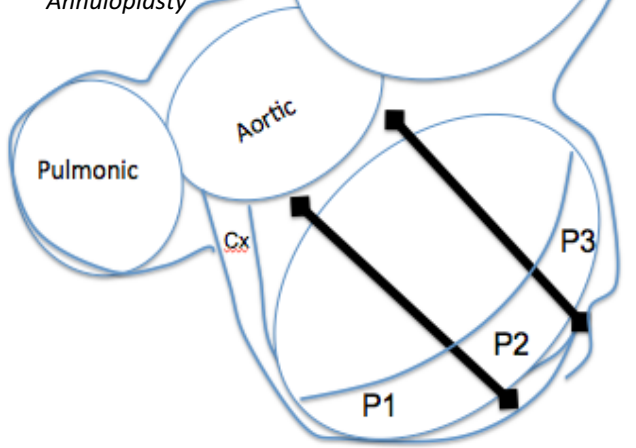
Millipede



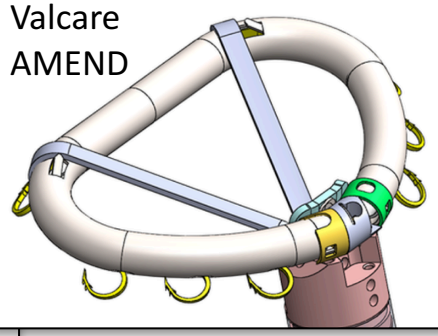
TASRA

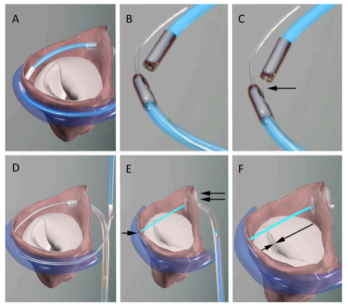
Trans-Apical Segmental Reduction Annuloplasty





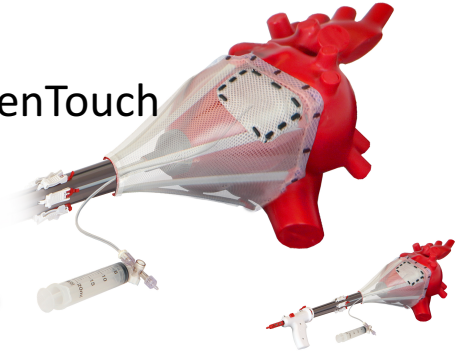
Valcare AMEND

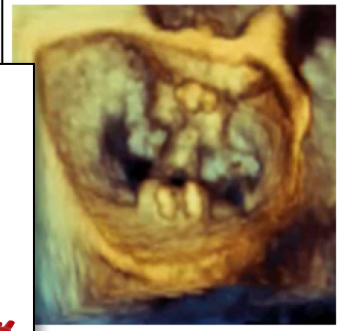




Arto

VenTouch





Mitral Bridge

MR reduction +
LV remodeling

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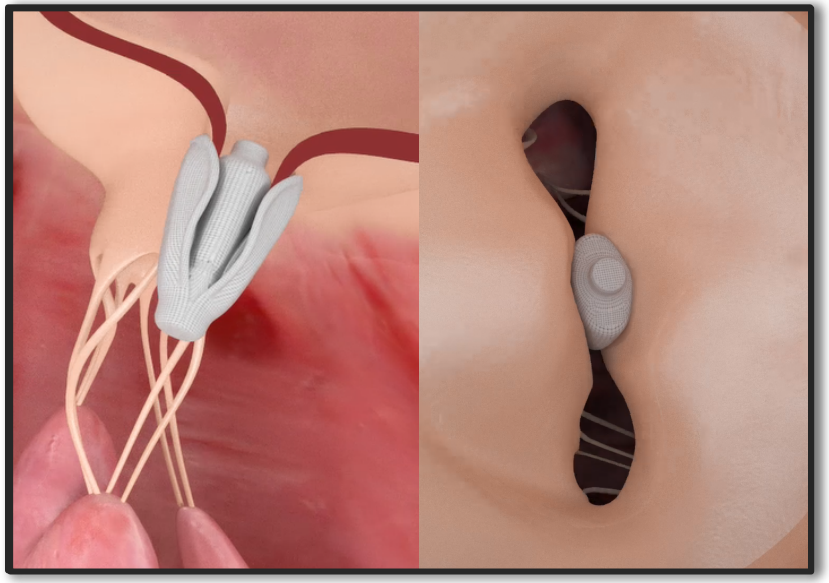
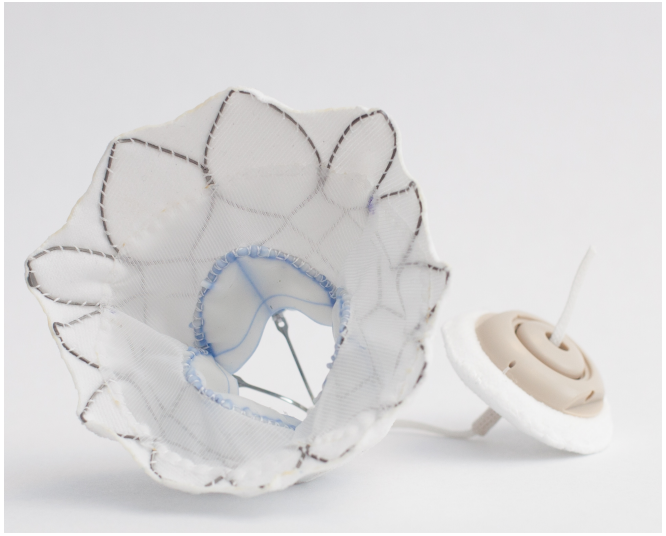
Edwards PASCAL Repair System

- Spacer is clasped between both Mitral Valve leaflets
- Independent leaflet clasping
- Simple “Commander-like” delivery system
- Conventional transfemoral/transseptal approach

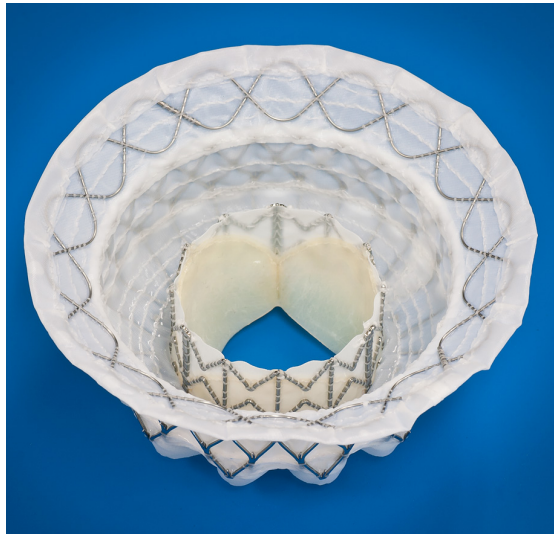


TMVR



Tendyne-Abbott

CardiAQ-Edwards



TWELVE-Medtronic

BARRON'S TAKE

Edwards Lifesciences Wisely Acquires CardiAQ

Analysts cheer Edwards' $400 million acquisition of heart device maker CardiAQ. Expect more gains.

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By TERESA RIVAS
July 13, 2015

A savvy deal landed Edwards Lifesciences two analyst up
should expect more good news.

Early Monday, RBC Capital Markets and Northland Capita
on Edwards Lifesciences Corp. (ticker: EW) to Outperfor
Edwards' acquisition, announced Friday, of privately-held
Edwards is paying $350 million, and up to an additional $
are met, for the early-stage company that is developing a
implantation (TMVI) system.

Medtronic to buy Twelve for $408M+, joining Abbott and Edwards on the transcatheter mitral valve bandwagon

August 25, 2015 | By Varun Saxena

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21

The run on independent transcatheter mitral valve replacement companies is now resembling a stampede thanks to Medtronic's ($MDT) decision to purchase Twelve, a portfolio company of medical device incubator The Foundry, for up to $458 million.

valve replacements has generated
aims to extend the minimally invasive,
replacement of the mitral valve.

gned for patients with mitral valve
rgery is not recommended, analogous to
o frail for open heart surgery. Mitral valve
hen the mitral valve doesn't close
d when the heart contracts.

Abbott Completes Acquisition of Tendyne Holdings, Inc.

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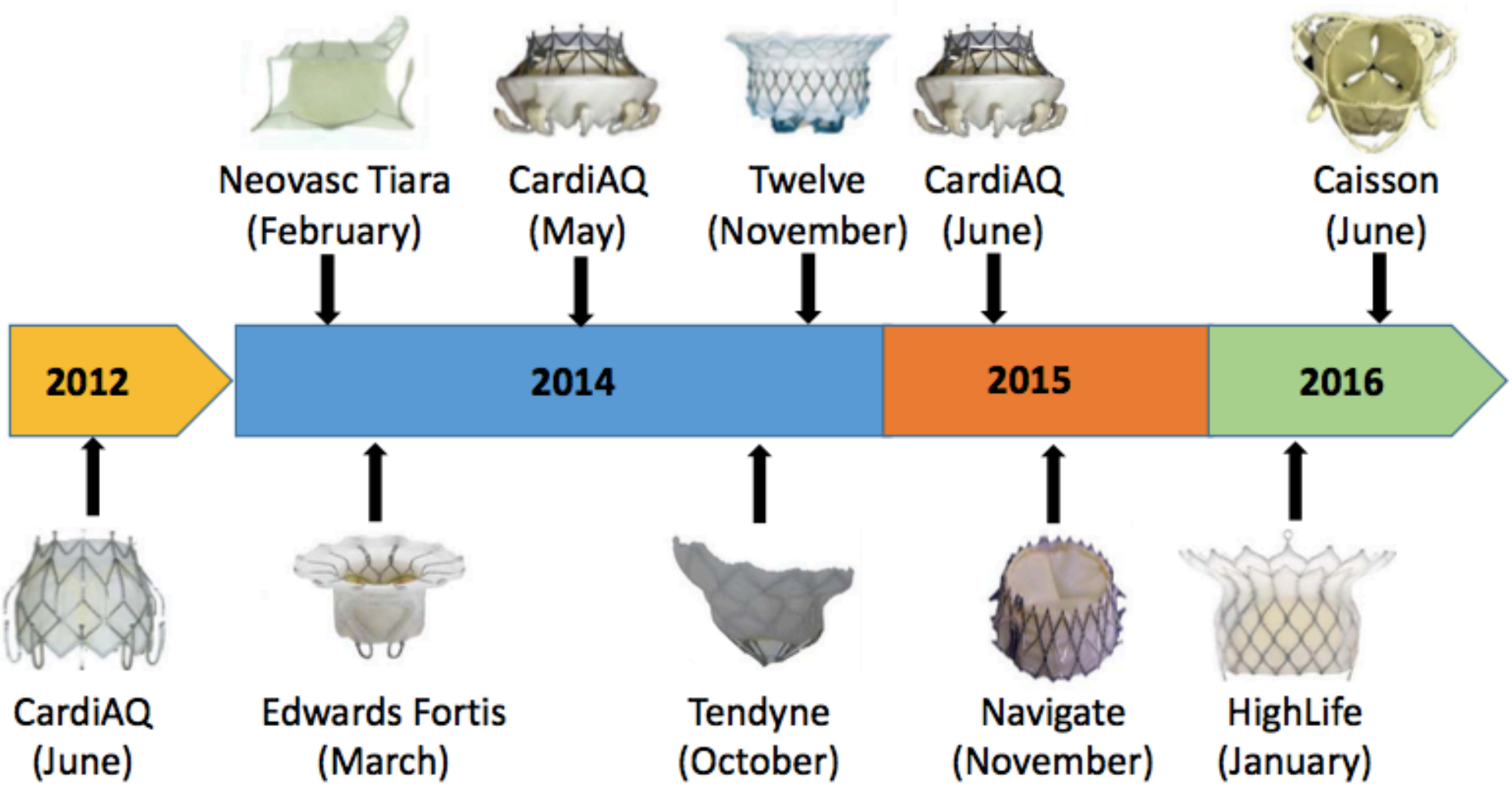
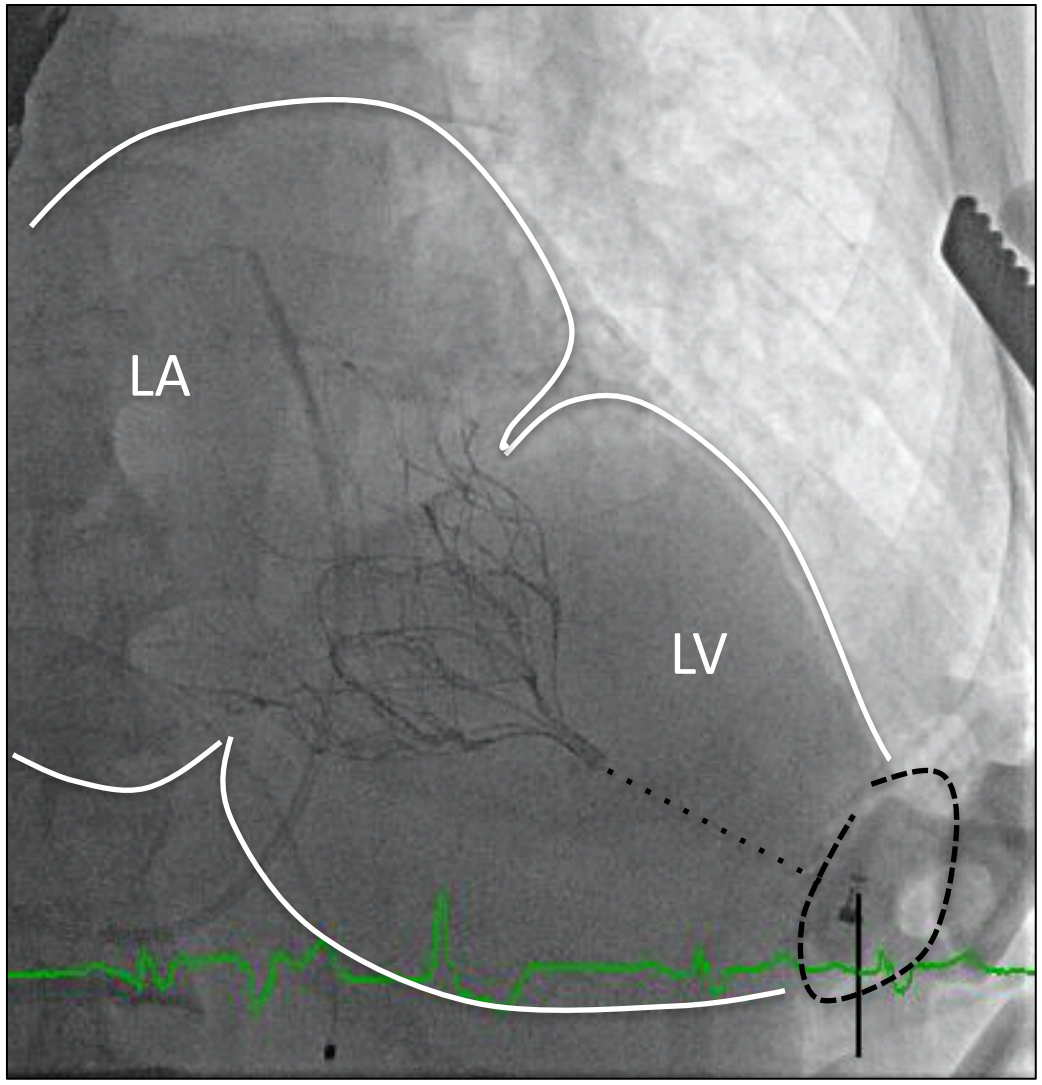
ABBOTT PARK, Ill., Sept. 2, 2015 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that it has completed its acquisition of Tendyne Holdings, Inc., a private medical device company focused on developing minimally invasive mitral valve replacement therapies. Abbott acquired the equity of Tendyne that it did not already own for $225 million upfront, resulting in a total transaction value of $250 million, plus potential future payments tied to regulatory milestones.

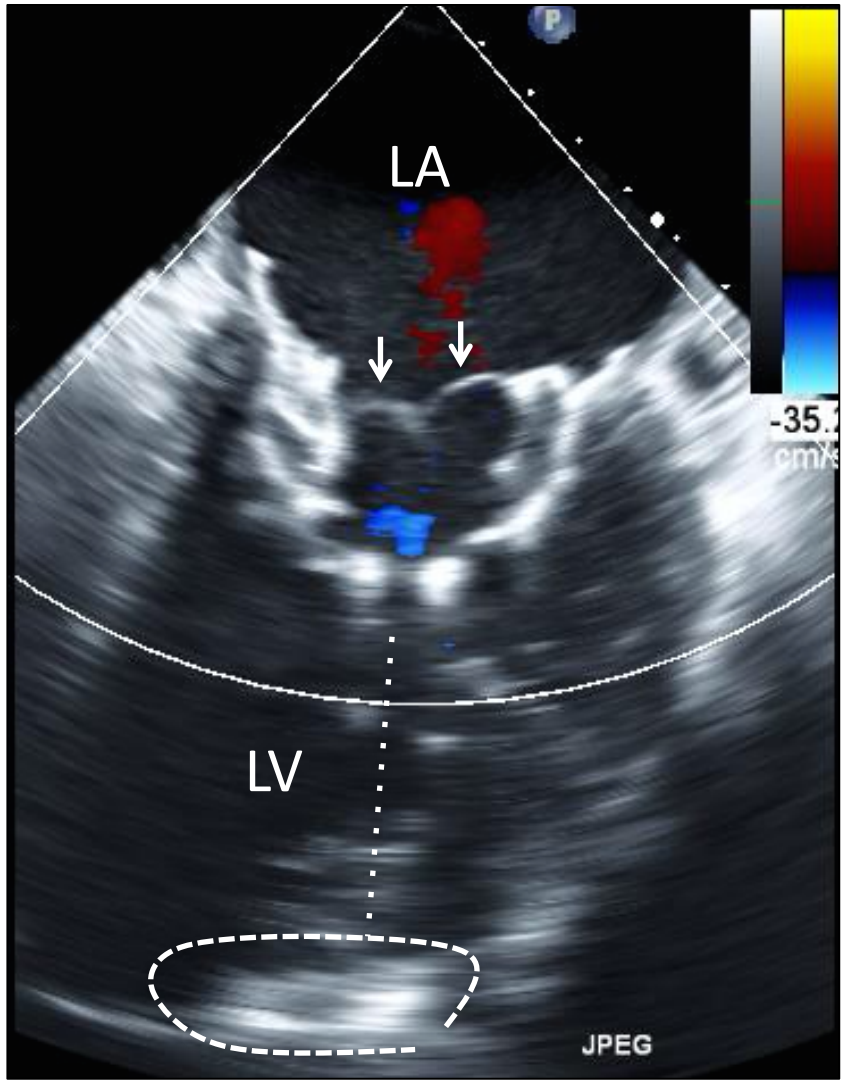
"The Tendyne acquisition broadens Abbott's foundation as a leader in treatments for mitral valve disease, which is highly complex and requires multiple treatment options," said John M. Capek, Ph.D., executive vice president, Ventures, Abbott. "Our goal is to provide effective, less invasive valve treatment technologies to treat people based on their specific anatomy and health situation."

Tendyne's Bioprosthetic Mitral Valve System is designed to be implanted in a beating heart, without the need for open heart surgery, which would be a new treatment option for mitral valve replacement. It is an investigational device and not currently available for sale. The U.S. Food and Drug Administration has given approval for a feasibility clinical trial to provide data about the device's safety and effectiveness. The trial has begun enrolling patients, and there are plans to begin enrollment next year in a clinical trial to support CE Mark in Europe.

TMVR 1st In Human Timeline

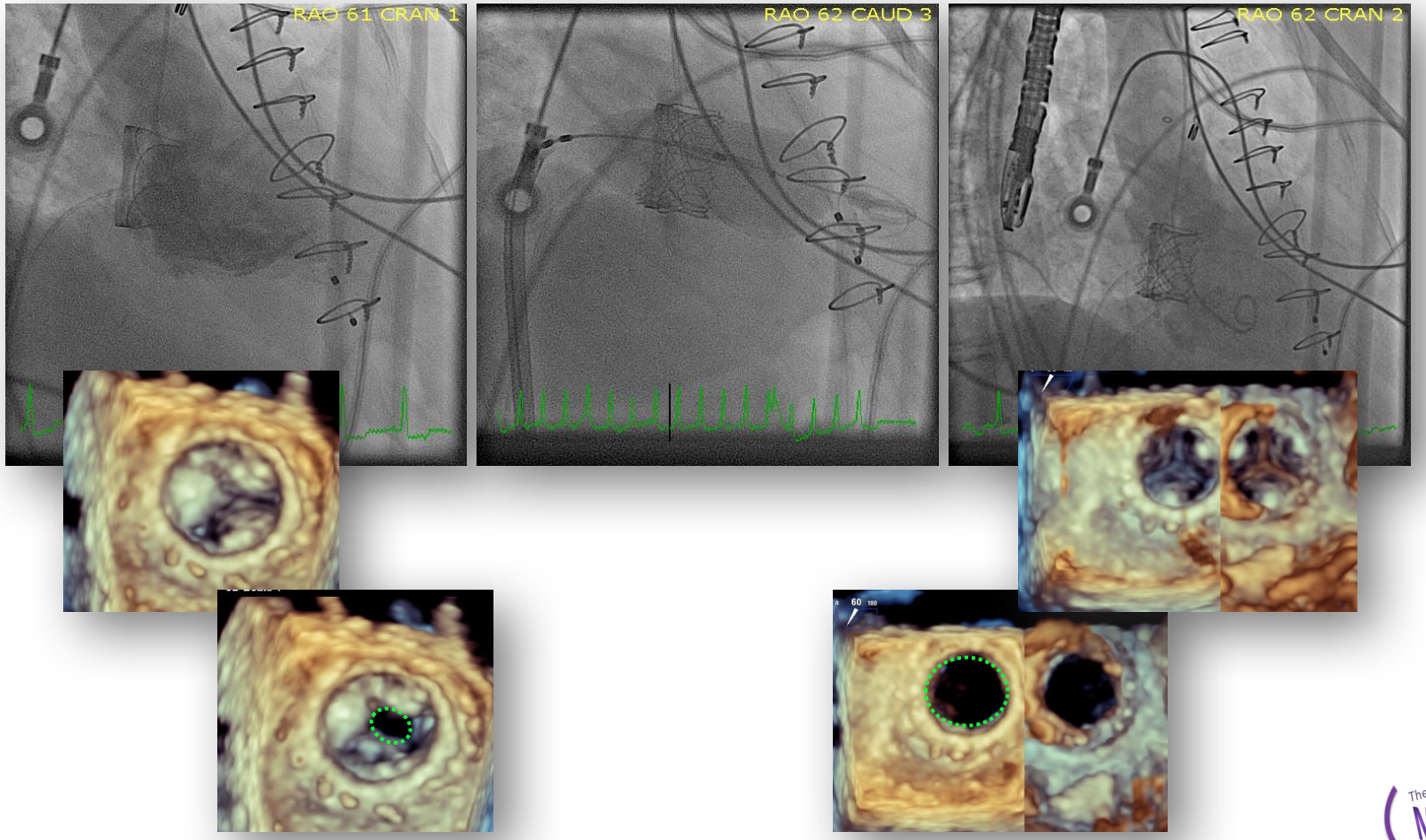



LA
LV


LA
LV
JPEG

TAVR=TMVR?

SAPIEN in Perimount



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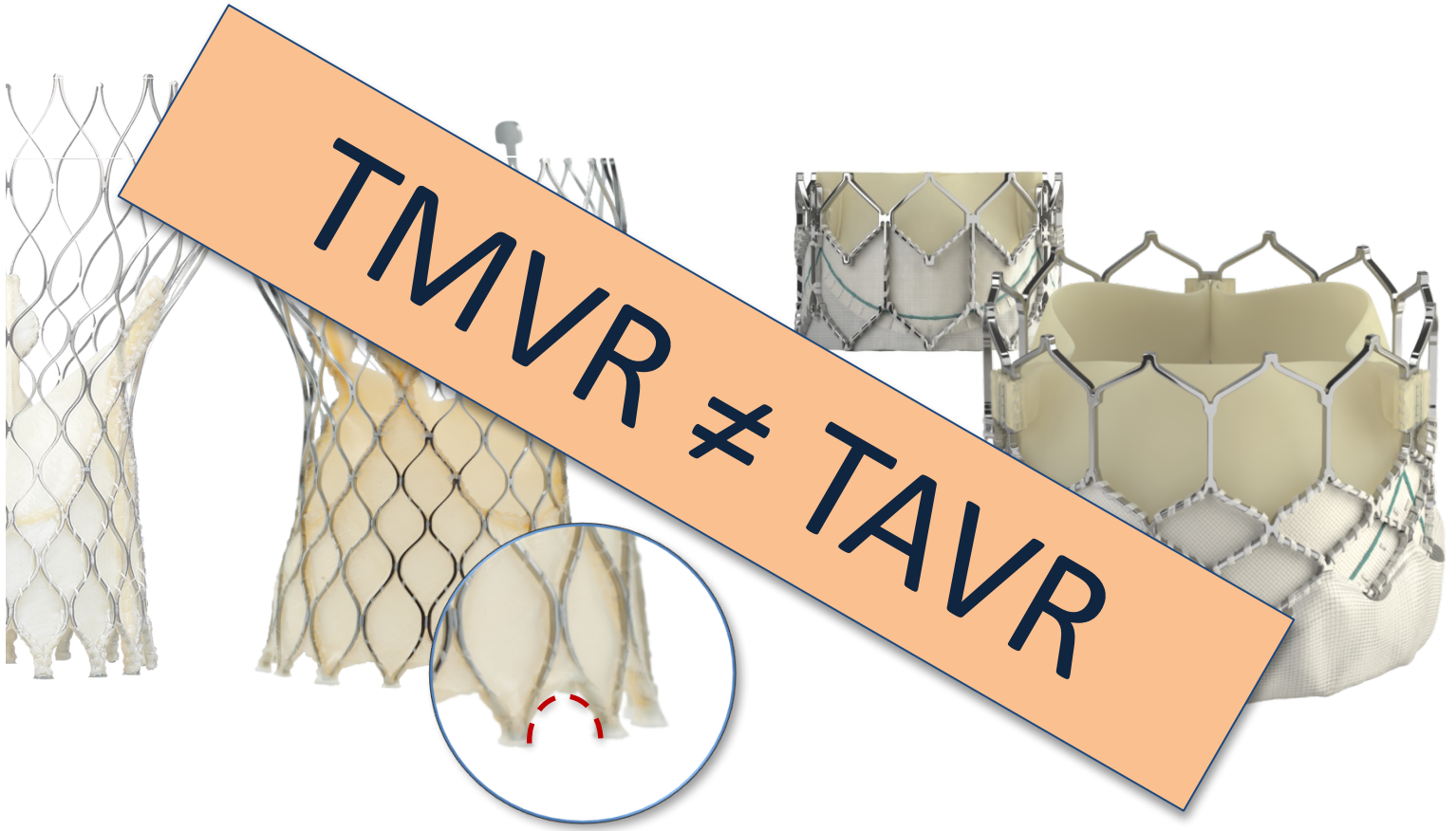
The MITRAL Trial

Approved in the US

Medtronic CoreValve
Evolut R

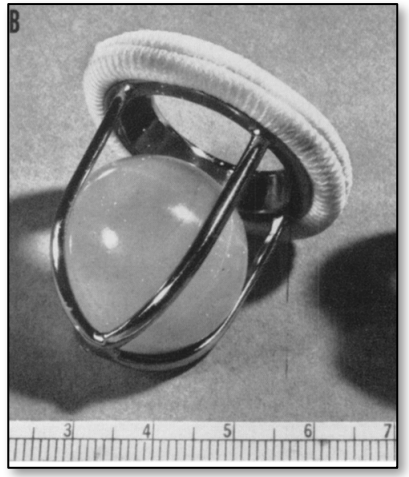
Edwards Lifesciences
S3

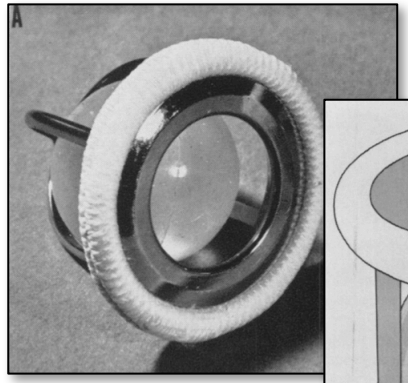


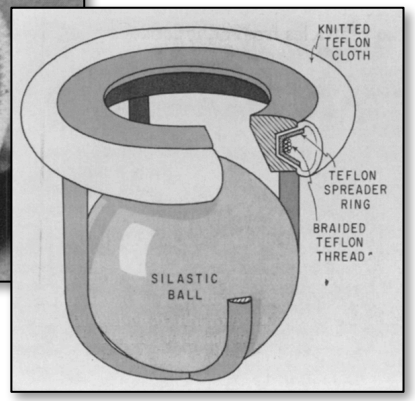
Mitral Replacement: *

Clinical Experience with a Ball-Valve Prosthesis

ALBERT STARR, M.D., M. LOWELL EDWARDS, B.S.





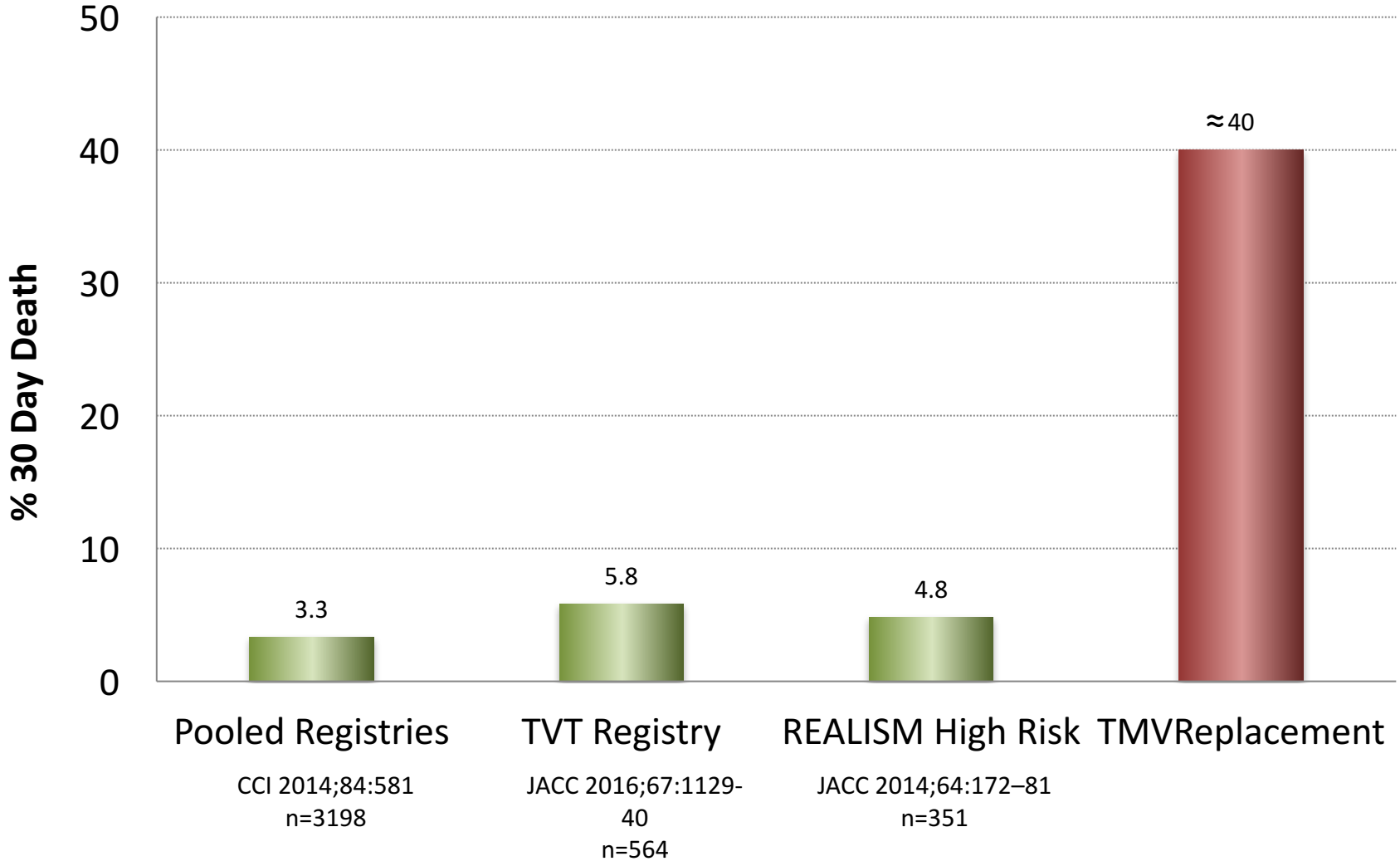


Problems of fixation, function and thrombotic occlusion of the prosthesis have prevented long-term survival in most instances.

Starr A, Edwards L: Ann Surg 1961 154;726-40

Mitral Repair vs Repalcement

30 Day Mortality



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TAVR Patient Summary

Name:)

Demographics Ref By: Berger, Ronald G. MD

Ref Date:	8/8/2016	Age: 89, Male		DOB: 4/8/1927	
PCP:	Block, Robert S. MD		Team MD:	Ted Feldman MD	
Status:	Active		Pathway:	Trial	
Height:					
Access:	Transfemoral - Left, Lotus 25mm, Edwards S3 26mm			EKG:	,
STS:	5.7%				

Consult 1		Consult 2	
Date:	9/2/2016	Date:	9/1/2016
Surgeon:	Paul Pearson, MD	Surgeon:	Hyde Russell, MD
Eval:	high risk	Eval:	High risk

History HTN: Yes HL: Yes Mitral R.: Yes

CAD			Afib/Aflut	Yes	Paroxysmal		Date	7/5/2016
CHF	Yes		Pacemaker	No			Status	Cleared
Diabetes			PAD				Comment	
IS			Renal				**Frailty**	
GI	Yes	Barret's esophagus Ulcerative colitis	Creatinine	1.6, 6/3/2016	GFR: 8/17/2016, 38		Grip	+ Walk +
Comment:	Retired Pediatric Cardiologist Anemia ITP Spinal stenosis Contrast allergy						Albumin	3.1 ADL 6/6

Lab Result

CATH Date	BAV	EF %	AnnS	MG mm Hg	LM	Comment
8/16/2016						No sign CAD, large caliber iliac vessels

TEE Date	Rvw	EF %	AnnS	Clot	AVA cm2	MG mm Hg	Vmax m/sec	VAI cm2/m2	AI	MR	TR	Comment
8/16/2016		70	2.7	no	0.4	53	5.1		Trivial	Mild	Mild/Mod	

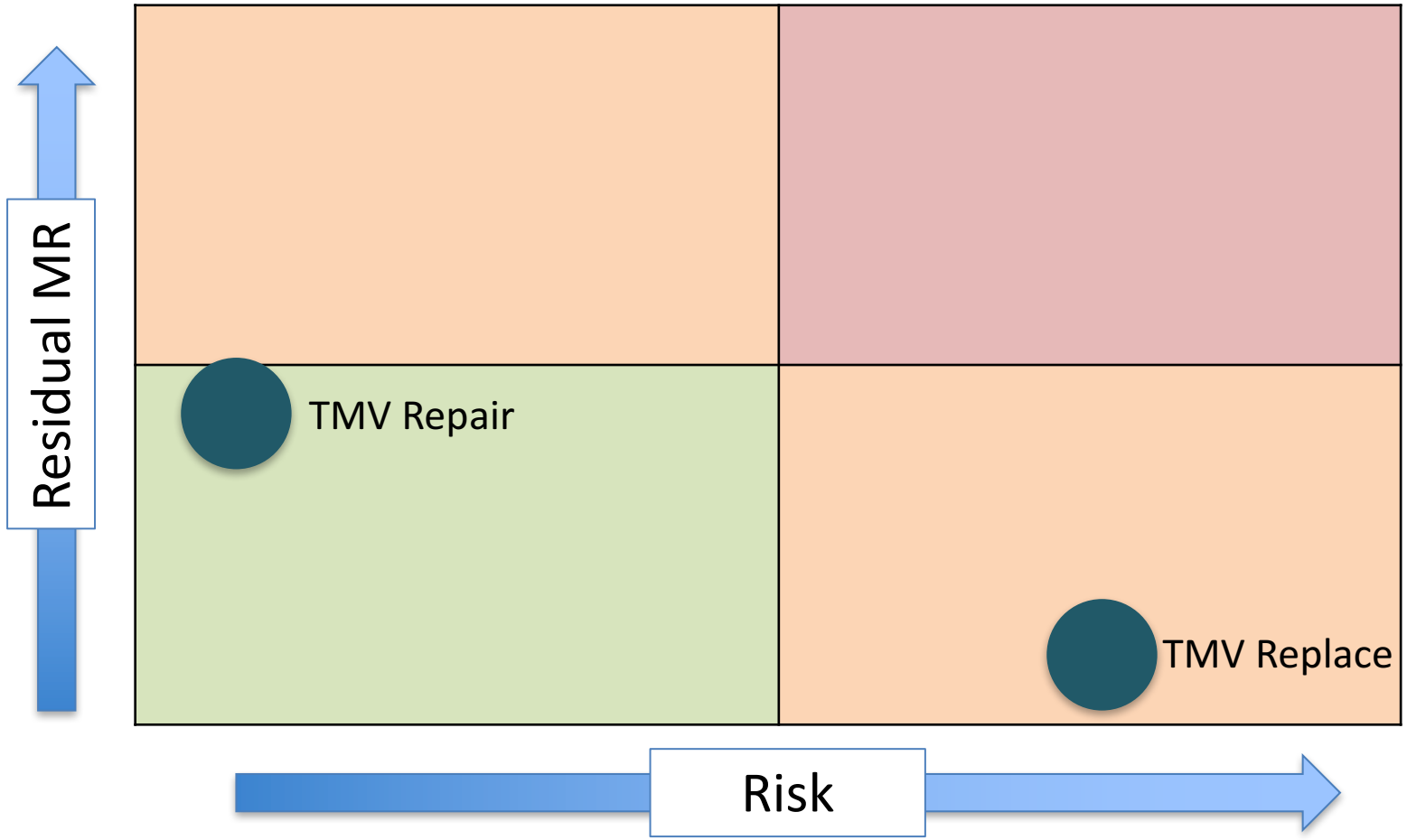
TTE Date	Rvw	EF %	AnnS	Clot	AVA cm2	MG mm Hg	Vmax m/sec	VAI cm2/m2	AI	MR	TR	Comment
8/4/2016		70			0.55	56	5.3	0.29	Trace			

CTA Date	Rvw	Aneur	AnnS	Findings	Comment
9/1/2016					

PFT Date	FEV1 % pred
8/24/2016	144

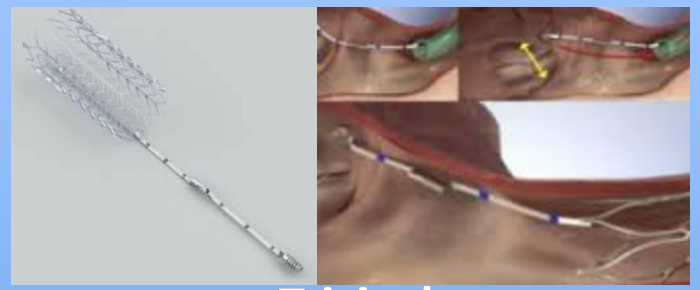
Status

8/8/2016 JS TEF rec cath
8/23/2016 JS Patient req
9/14/2016 JS reprisle con
9/15/2016 RS Pt conside

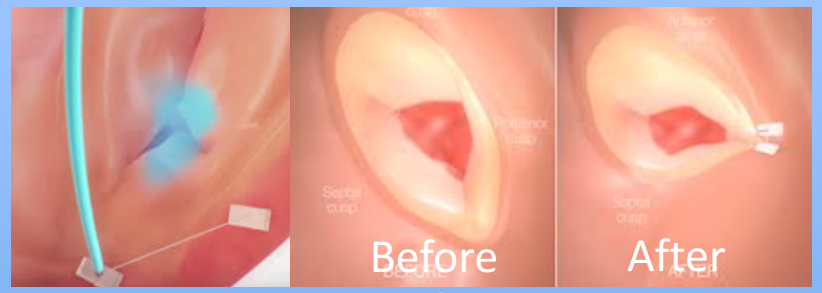

Residual MR
TMV Repair
TMV Replace
Risk

TRICUSPID

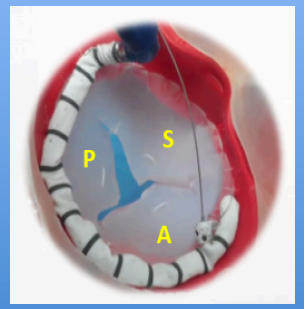
Annular modification



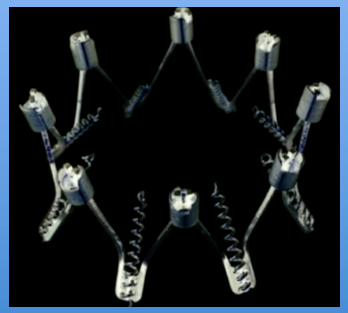
Tricinch



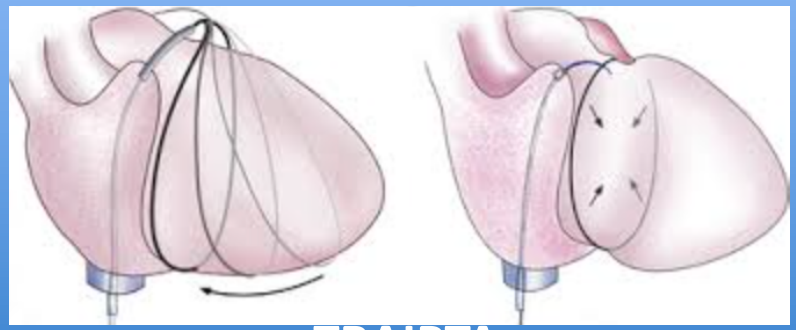
Trialign



Cardioband

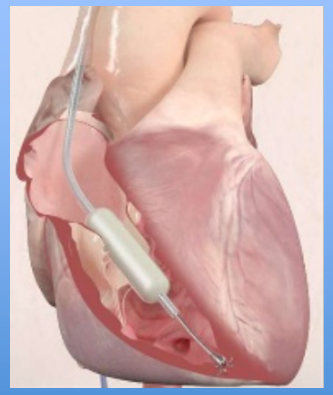


Millipede



TRAIPTA

Leaflet apposition

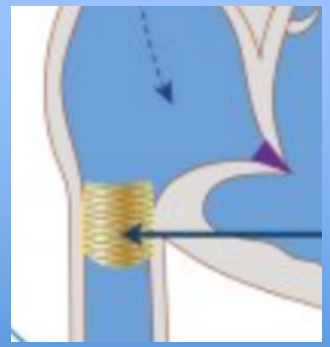


Forma Device

MitraClip

Caval Valve Implantation

TricValve



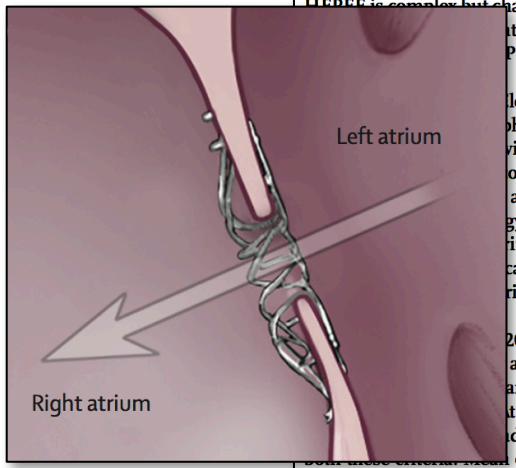
Sapien Valve implanted in the inferior cava vein

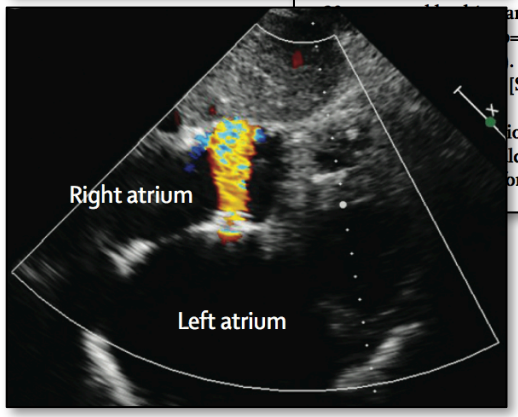
A transcatheter intracardiac shunt device for heart failure with preserved ejection fraction (REDUCE LAP-HF): a multicentre, open-label, single-arm, phase 1 trial

*Gerd Hasenfuß, Chris Hayward, Dan Burkhoff, Frank E Silvestry, Scott McKenzie, Finn Gustafsson, Filip Malek, Jan Van der Heyden, Irene Lang, Mark C Petrie, John G F Cleland, Martin Leon, David M Kaye, on behalf of the REDUCE LAP-HF study investigators**

Summary

Background Heart failure with preserved ejection fraction (HFPEF) is a common, globally recognised, form of heart failure for which no treatment has yet been shown to improve symptoms or prognosis. The pathophysiology of HFPEF is complex but characterised by increased left atrial pressure, especially during exertion, which might be a key tionale for the present study was that a mechanical approach to reducing left atrial pressure PEF.





Advances in Clinical Trials

Transcatheter Interatrial Shunt Device for the Treatment of Heart Failure

Rationale and Design of the Randomized Trial to REDUCE Elevated Left Atrial Pressure in Heart Failure (REDUCE LAP-HF I)

Ted Feldman, MD; Jan Komtebedde, DVM; Daniel Burkhoff, MD, PhD; Joseph Massaro, PhD; Mathew S. Maurer, MD; Martin B. Leon, MD; David Kaye, MD; Frank E. Silvestry, MD; John G.F. Cleland, MD; Dalane Kitzman, MD; Spencer H. Kubo, MD; Dirk J. Van Veldhuisen, MD; Franz Kleber, MD; Jean-Noël Trochu, MD, PhD; Angelo Auricchio, MD, PhD; Finn Gustafsson, MD, PhD; Gerd Hasenfuβ, MD; Piotr Ponikowski, MD; Gerasimos Filippatos, MD; Laura Mauri, MD, MSc; Sanjiv J. Shah, MD

Abstract—Heart failure with preserved ejection fraction (HFpEF), a major public health problem with high morbidity and mortality rates, remains difficult to manage because of a lack of effective treatment options. Although HFpEF is a heterogeneous clinical syndrome, elevated left atrial pressure—either at rest or with exertion—is a common factor among all forms of HFpEF and one of the primary reasons for dyspnea and exercise intolerance in these patients. On the basis of clinical experience with congenital interatrial shunts in mitral stenosis, it has been hypothesized that the creation of a left-to-right interatrial shunt to decompress the left atrium (without compromising left ventricular filling or forward cardiac output) is a rational, nonpharmacological strategy for alleviating symptoms in patients with HFpEF. A novel transcatheter interatrial shunt device has been developed and evaluated in patients with HFpEF in single-arm, nonblinded clinical trials. These studies have demonstrated the safety and potential efficacy of the device. However, a randomized, placebo-controlled evaluation of the device is required to further evaluate its safety and efficacy in patients with HFpEF. In this article, we give the rationale for a therapeutic transcatheter interatrial shunt device in HFpEF, and we describe the design of REDUCE Elevated Left Atrial Pressure in Heart Failure (REDUCE LAP-HF I), the first randomized controlled trial of a device-based therapy to reduce left atrial pressure in HFpEF.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT02600234.

(*Circ Heart Fail*. 2016;9:e003025. DOI: 10.1161/CIRCHEARTFAILURE.116.003025.)

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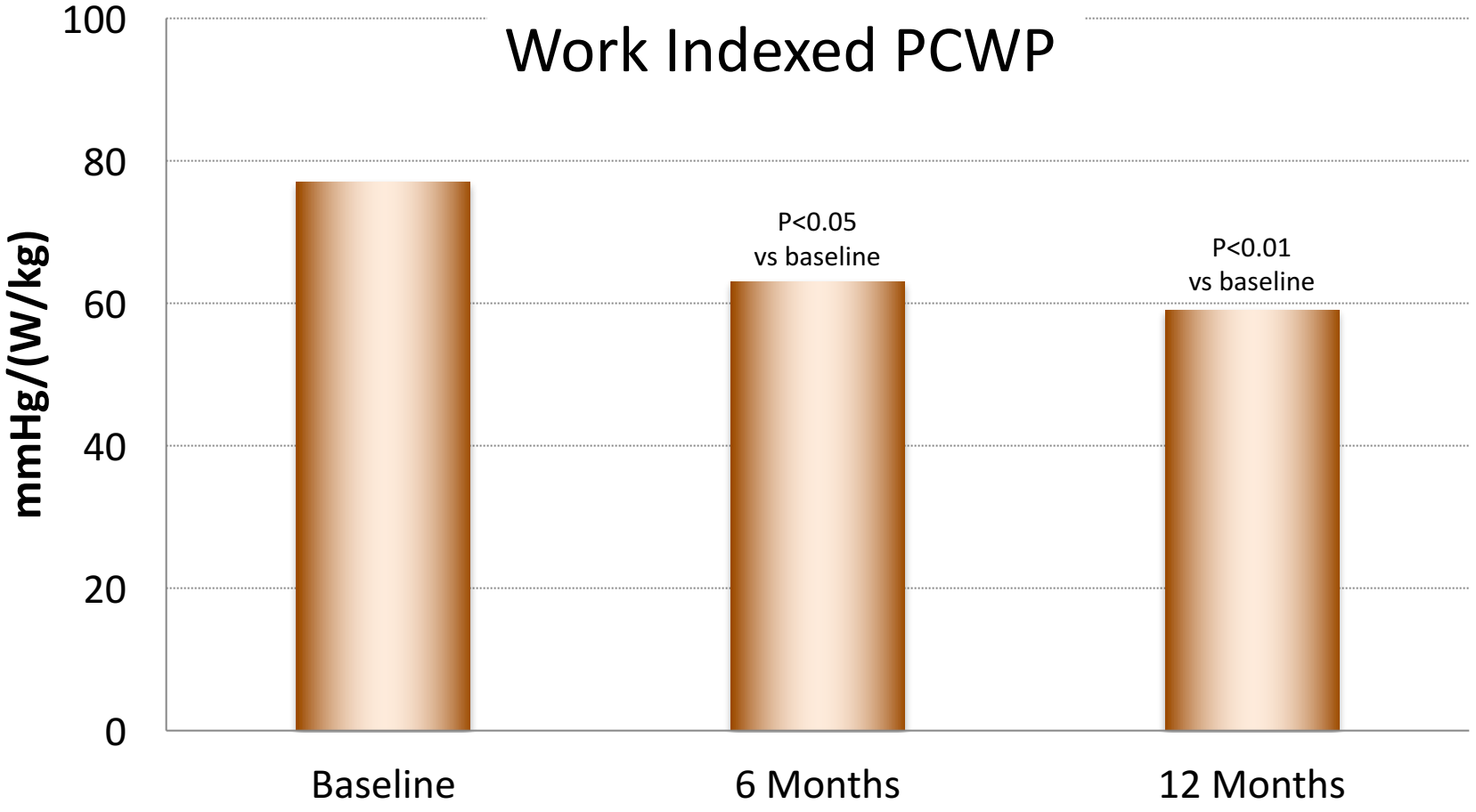
One-Year Outcomes After Interatrial Shunt Device for the Management of HFpEF



Circ Heart Fail. 2016;9:e003662. DOI: 10.1161/CIRCHEARTFAILURE.116.003662

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