Structural Heart Disease Transcatheter Aortic Valve Replacement (TAVR) Part Two an Update

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I HAVE NO DISCLOSURES

Learning Objectives

- To update the new indications for TAVR in low risk patients and discuss other aortic valve disease where TAVR might be indicated
- To discuss the status of mitral valve repair with the Mitraclip, indications and evaluation
- To discuss the role of palliative care in the advanced heart failure patient

Extending the Boundaries of TAVR: Future Directions

The TAVR train has left the station for multiple new stops

TAVR Extensions in 7 Minutes

- Low Risk
- Bicuspid Valves
- Asymptomatic AS
- Moderate AS in CHF
- Autologous Valves

The PARTNER 3 Trial
Study Design

Symptomatic Severe Calcific Aortic Stenosis

Low Risk ASSESSMENT by Heart Team
(STS < 4%, TF only)

1:1 Randomization
(n=1,228)

TF - TAVR (SAPIEN 3)	Surgery (Bioprosthetic Valve)
CT Imaging Sub-Study (n=200)	CT Imaging Sub-Study (n=200)
Actigraphy/QoL Sub-Study	Actigraphy/QoL Sub-Study

PRIMARY ENDPOINT:
Composite of all-cause mortality, all strokes, or re-hospitalization at 1 year post-procedure

Follow-up: 30 days, 6 mos, 1 year and annually through 10 years

PARTNER 3 Registries

- Alternative Access (n=100) (TA/TAo/Subclavian)
- Bicuspid Valves (n=50)
- SAVR orTAVR ViV (n=100/25)
- Mitral ViV or ViR (n=50/50)

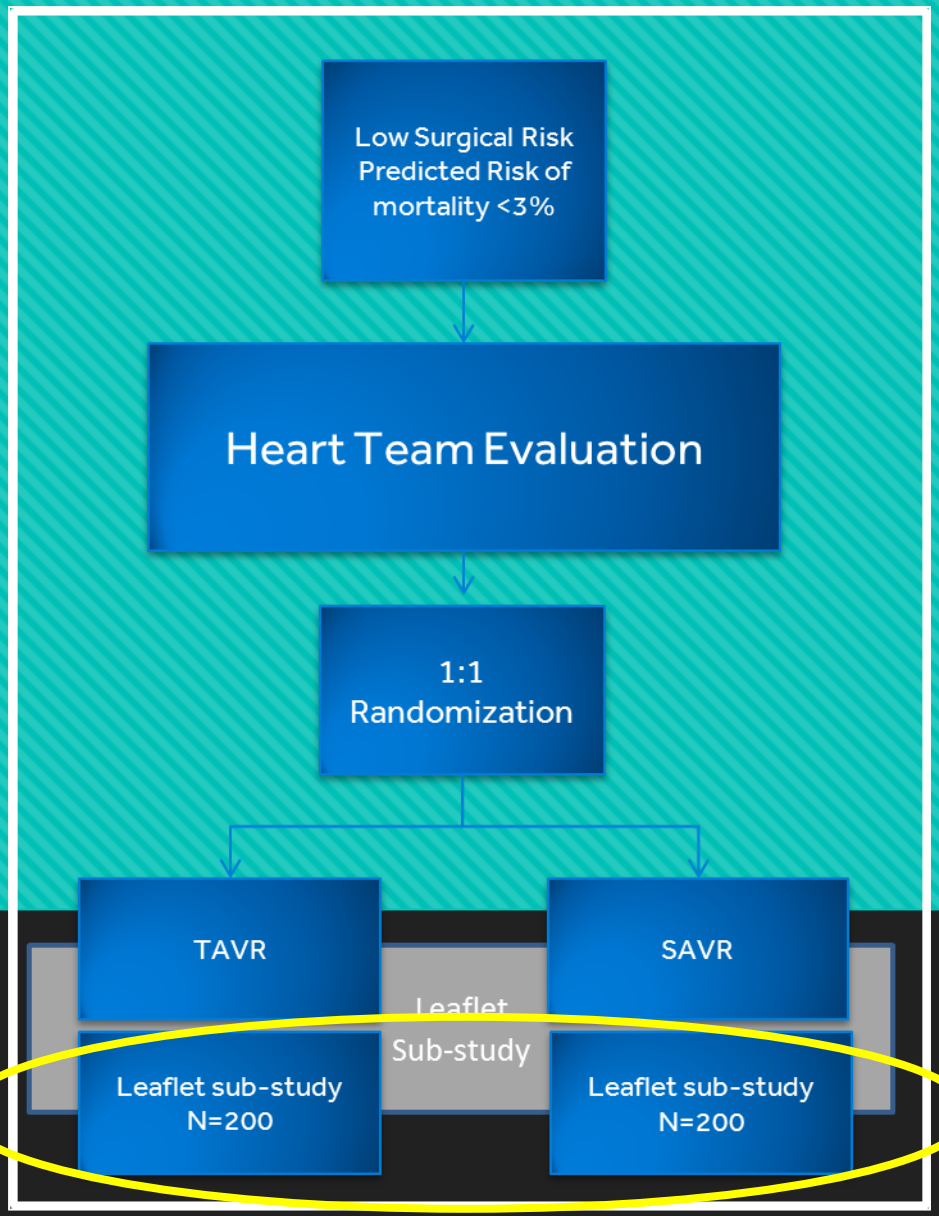
TAVR in Low-Risk Patients

- ***TAVR is now the dominant therapy in inoperable and high-risk AS patients; recent data shows clear benefits in intermediate-risk patients as well!***
- ***As complications continue to decline and the procedure is further simplified, there are clear secondary benefits associated with TAVR –*** reduced ICU and hospital LOS, more rapid QOL recovery, lower frequency of AKI, bleeding, and post-operative AF, and improved valve hemodynamics.
- ***TAVR should now be introduced to low-risk AS patients in thoughtful randomized clinical trials!***

MEDTRONIC TAVR RCT IN LOW RISK PATIENTS

TRIAL DESIGN & LEAFLET SUB-STUDY

- **Patient Population: Low Risk Cohort**
  - Determined by Heart Team to be low surgical risk
- **Primary Endpoint:**
  - Safety: Death, all stroke, life-threatening bleeding, major vascular complications, or AKI at 30 days
  - Efficacy: Death or major stroke at 2 years
- **Sample Size: ~1200 Subjects**
- **Follow-up Evaluations:**
  - 30-days, 6-month , 18-month, and 1 thru 5 years
- **Number of Sites: Up to 80 sites**



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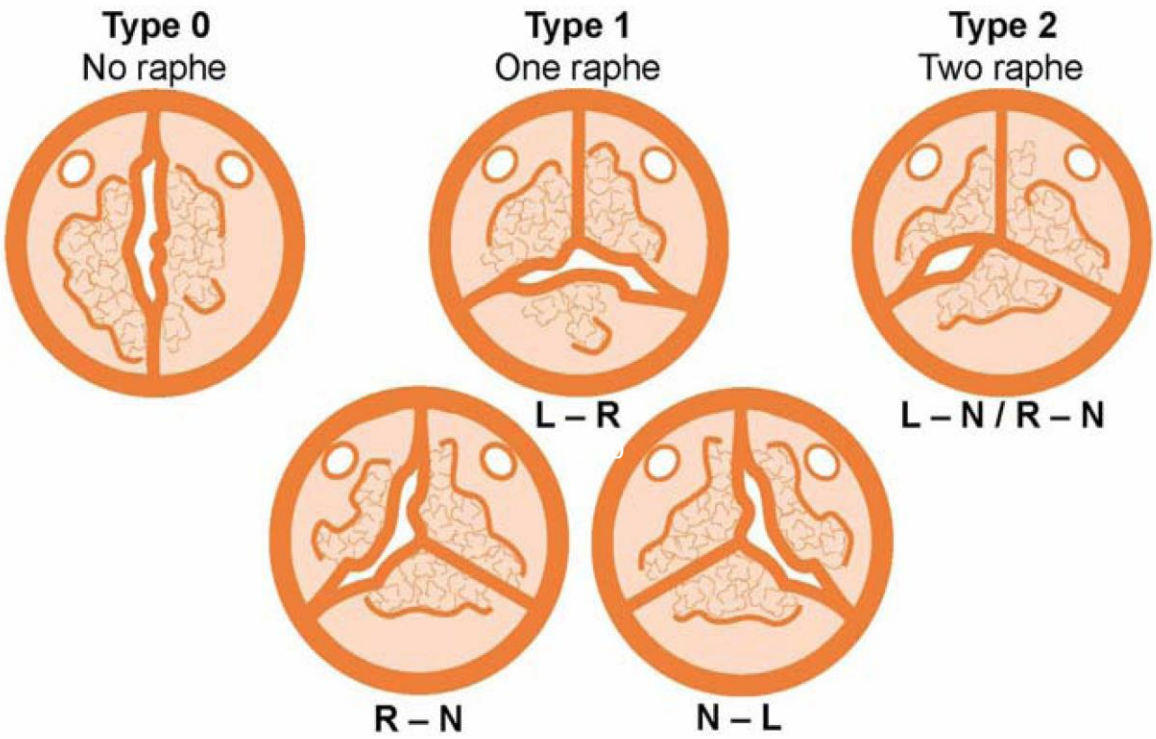
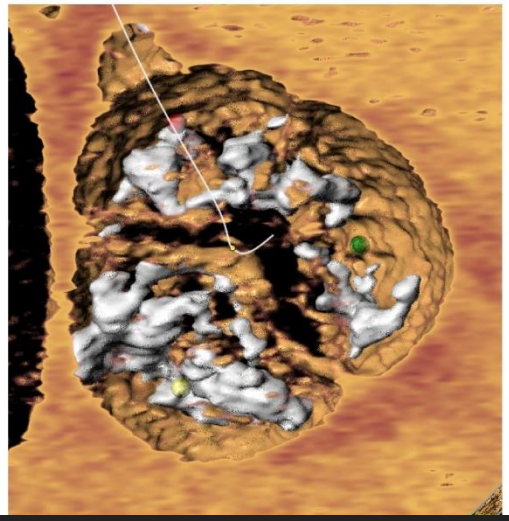
Classification of Bicuspid Valves

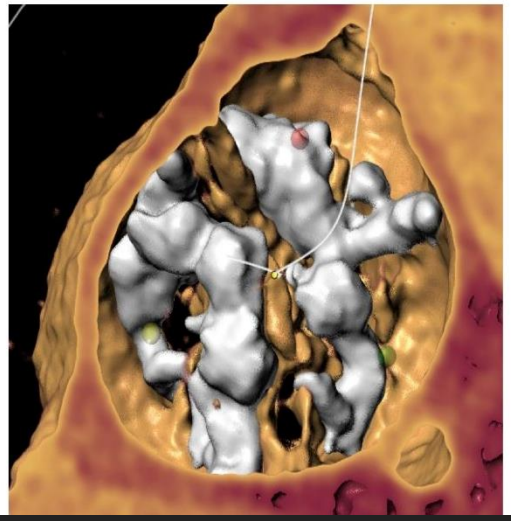


A simplified anatomical classification for TAVI

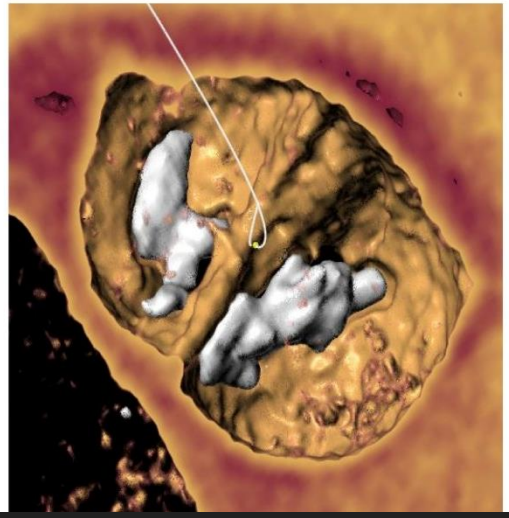
Tricommissural
21/91 (23.3%)



Bicommissural raphe-type
50/91 (55.6%)

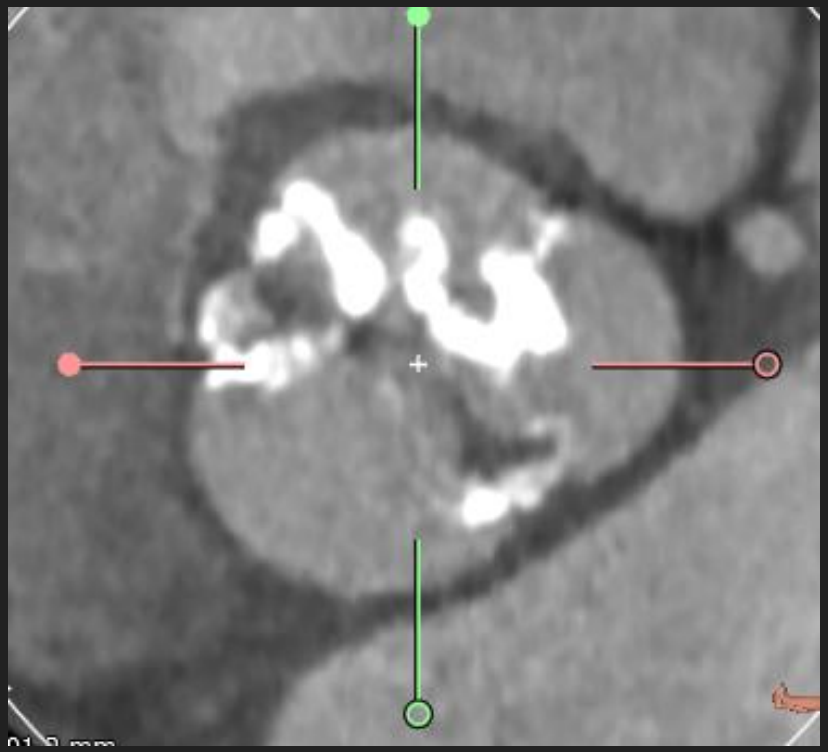


Bicommissural non raphe-type
19/91 (21.1%)

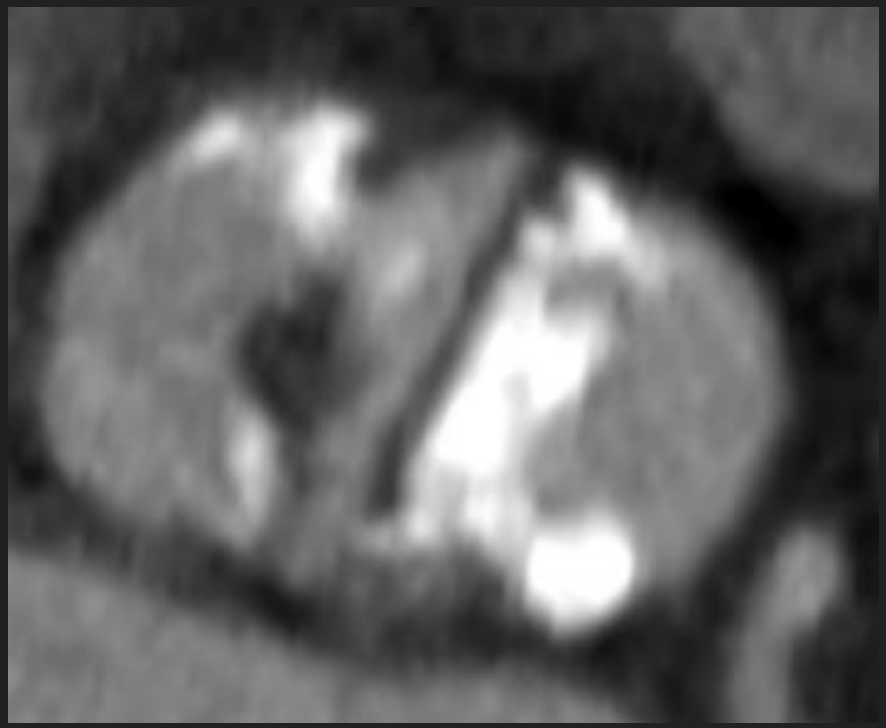


Hasan Jilaihawi , JACC Imaging

Type I: L-R

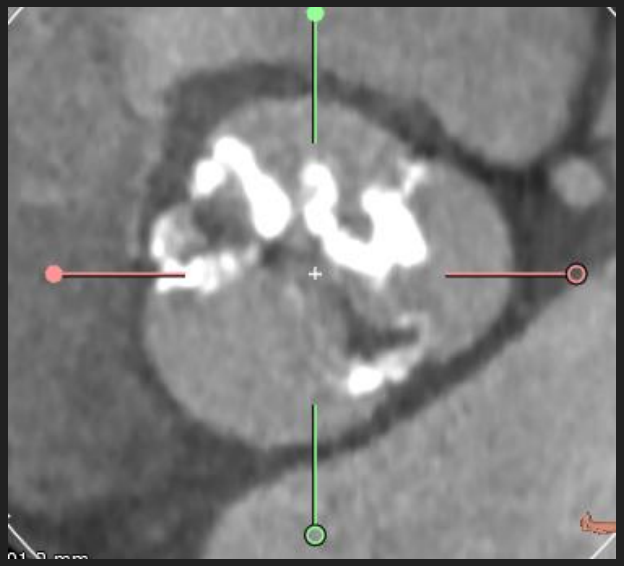


Type 0



Why Bicuspids Are Problematic for TAVR

- Bulky Eccentric Calcification
  - Incomplete valve expansion
  - Paravalvar leak
  - Annulus rupture
  - Higher PPM Rate
- Abnormal/lower coronary orifices
- Ascending Aortopathy- 25%
  - Needs Treatment
- Ovality of annulus
  - Risk of paravalvar leak
  - Long-term durability of the TAVI valve?

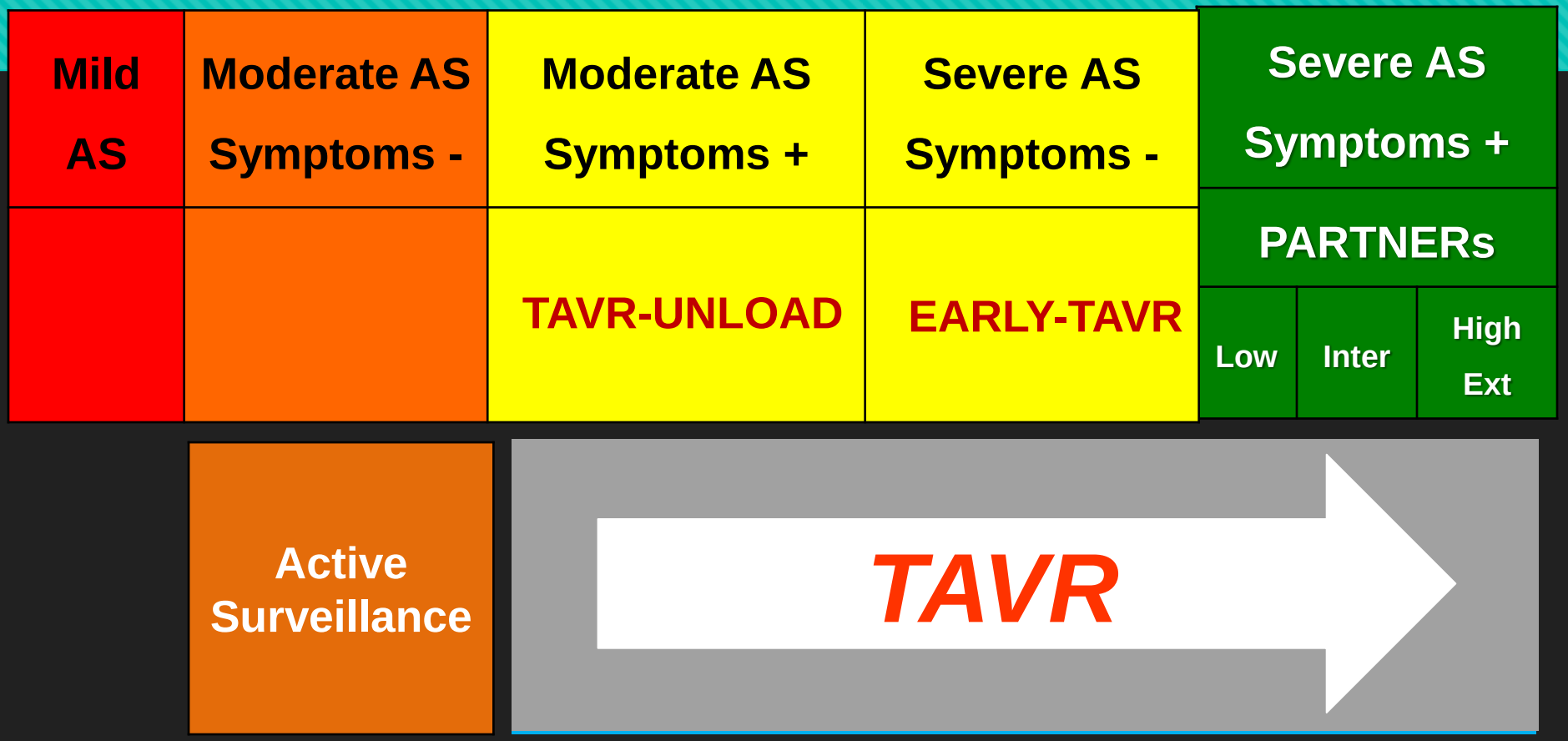


- For these reasons bicuspid valves had been excluded from all randomized trials
- Relative contraindication for TAVI according to guidelines
  - Risk of rupture/dissection

TAVR Extensions in 7 Minutes

- Low Risk
- Bicuspid Valves
- Asymptomatic AS
- Moderate AS in CHF
- Autologous Valves

Aortic Stenosis Redefined:
Functional Classification



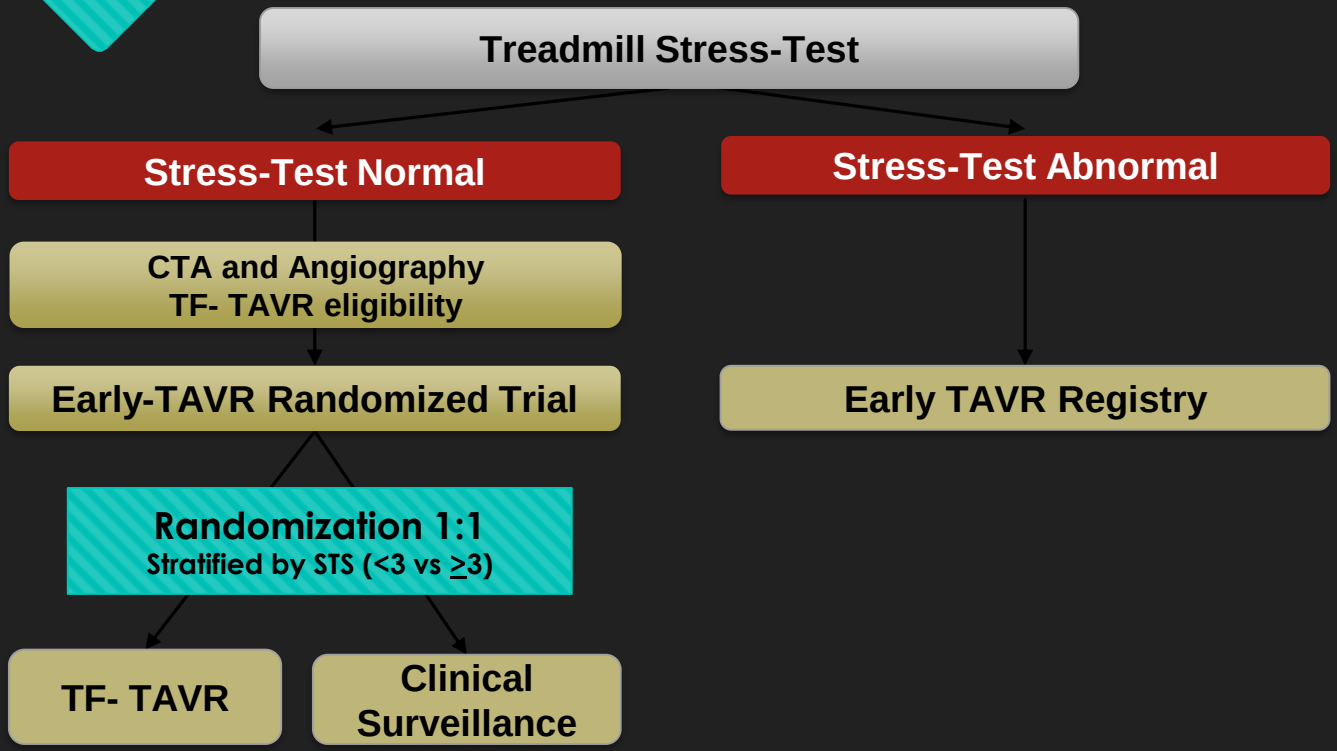
Courtesy of P. Généreux TVT 2016

EARLY TAVR Trial

Study Flow

Asymptomatic Severe AS and 2D-TTE (PV ≥4m/s or AVA ≤1 cm^2)

Exclusion if patient is symptomatic, EF<50%, concomitant surgical indications, bicuspid valve, or STS >8



Primary Endpoint (superiority): 2-year composite of all-cause mortality, all strokes, and repeat hospitalizations (CV)

TAVR Extensions in 7 Minutes

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- Autologous Valves

TAVR UNLOAD Trial

Study Design

(600 patients, 1:1 Randomized)

TAVR UNLOAD Trial

International
Multicenter
Randomized

Heart Failure
LVEF < 50%
NYHA ≥ 2
Optimal HF therapy (OHFT)
Moderate AS

R

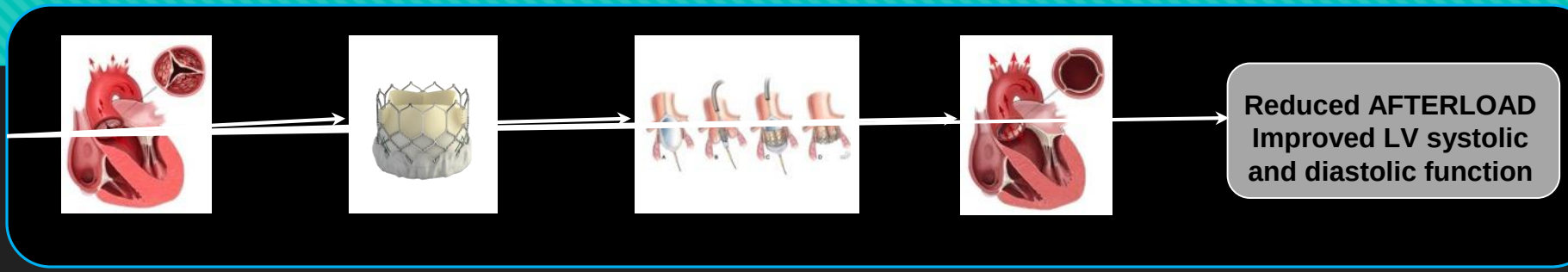
TAVR + OHFT

OHFT Alone

Follow-up:
1 month
6 months
1 year

Clinical endpoints
Symptoms
Echo
QoL

Primary Endpoint
Hierarchical occurrence of:
- **All-cause death**
- **Disabling stroke**
- **Hospitalizations for HF, aortic valve disease**
- **Change in KCCQ**



Reduced AFTERLOAD
Improved LV systolic and diastolic function

TAVR Extensions in 7 Minutes

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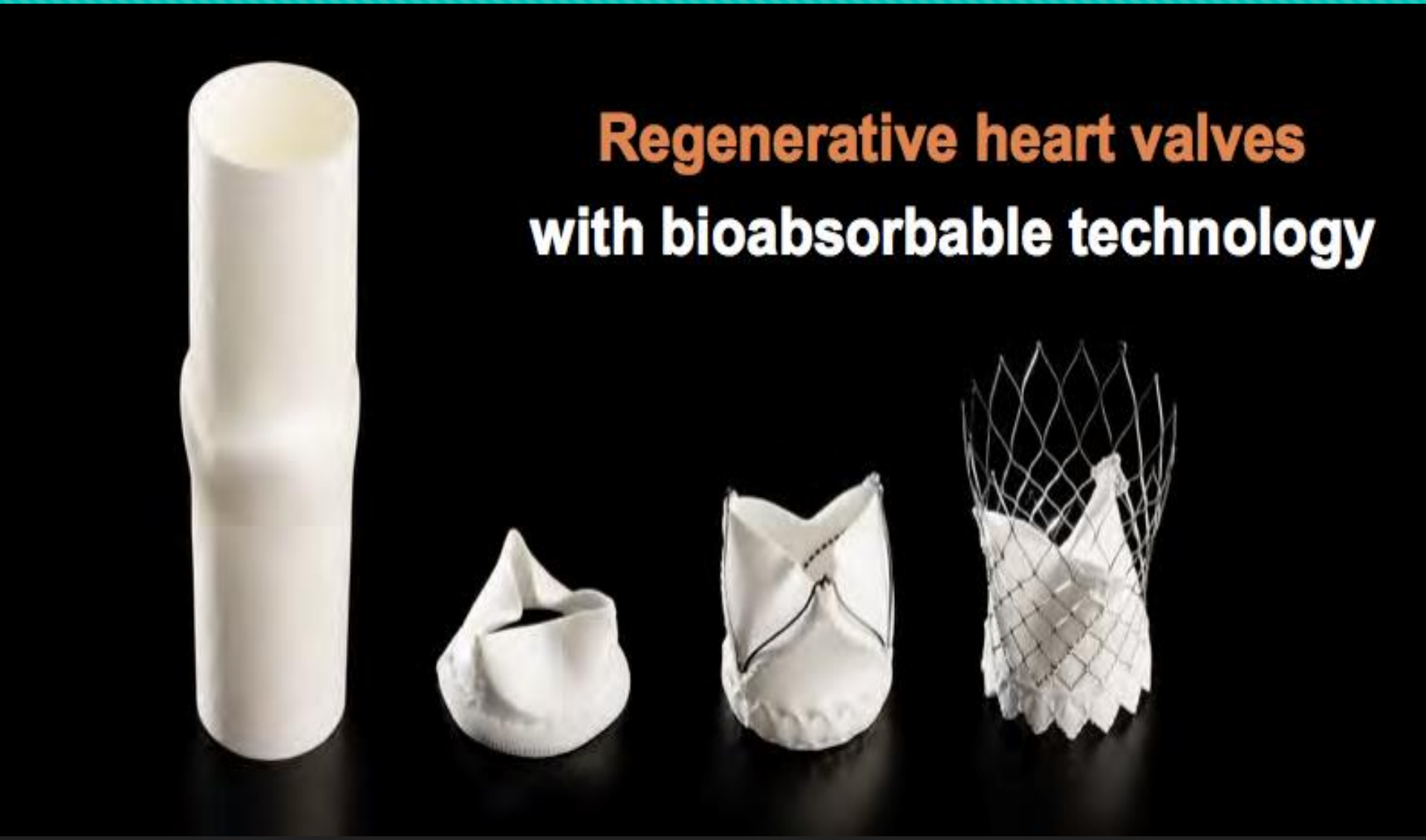
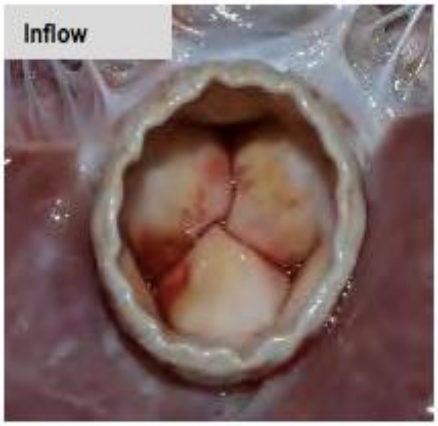
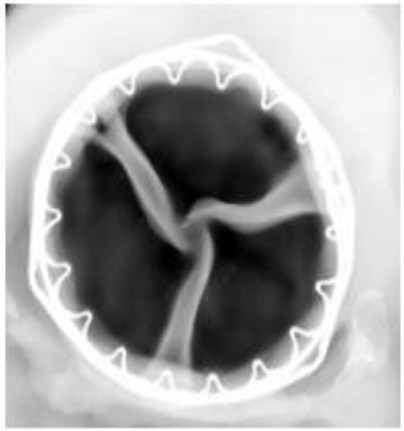
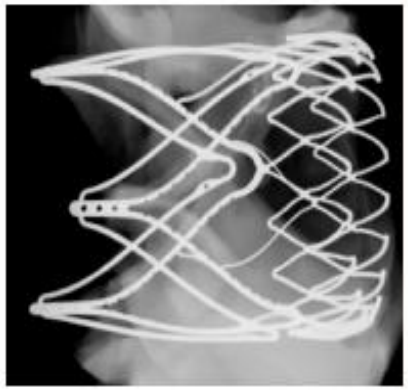
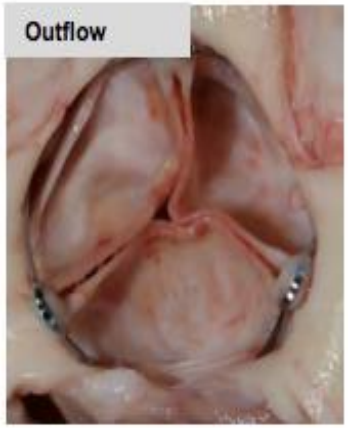

Regenerative heart valves
with bioabsorbable technology

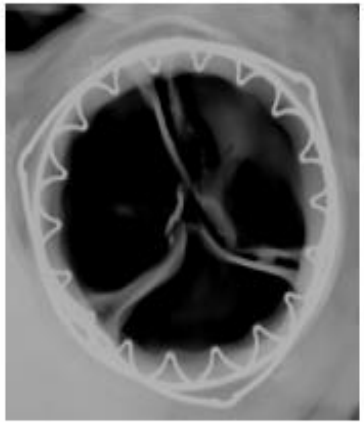


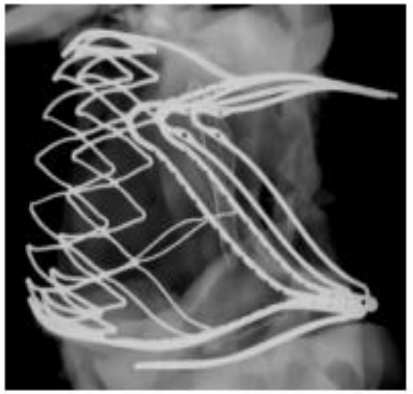




3 months

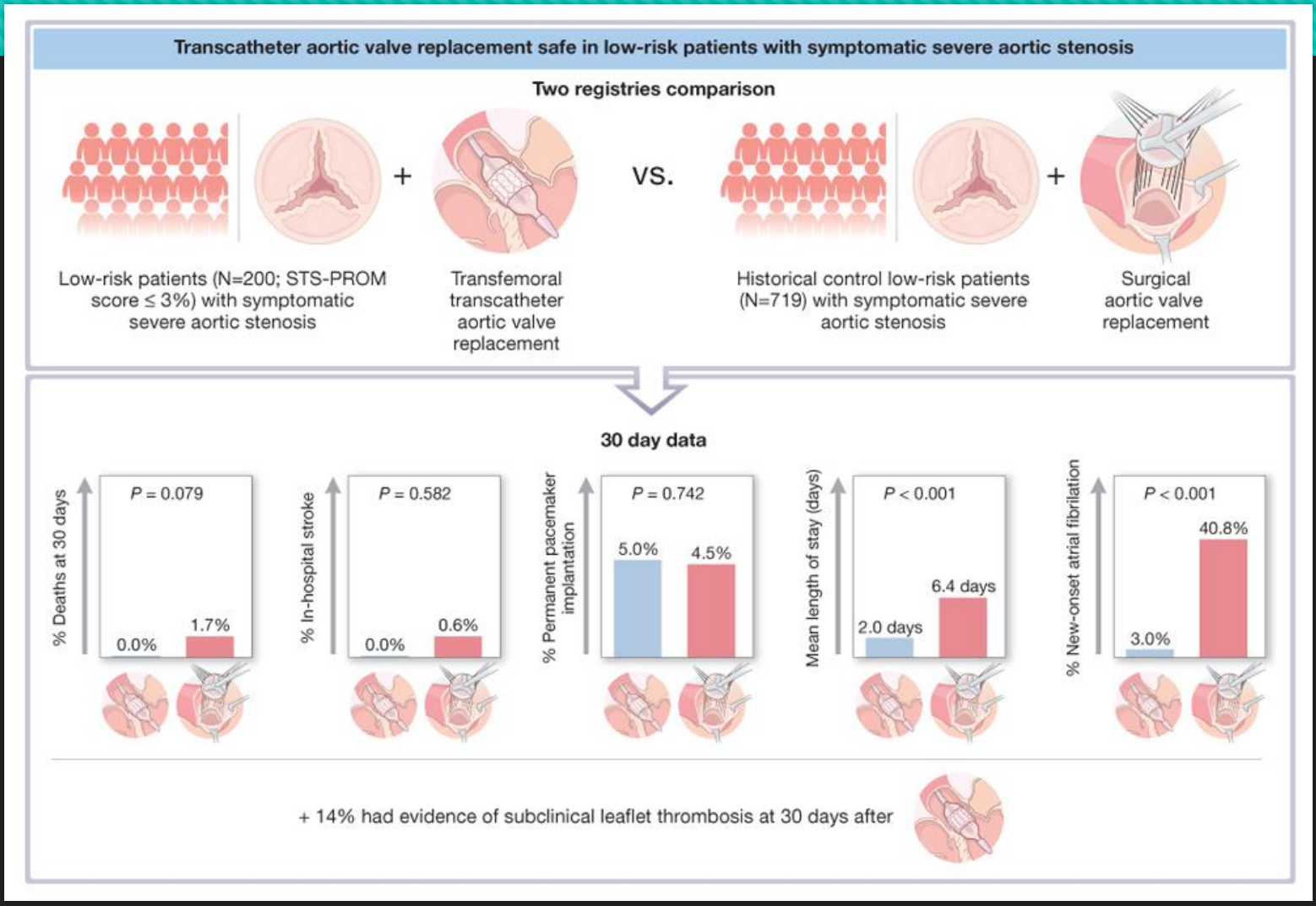






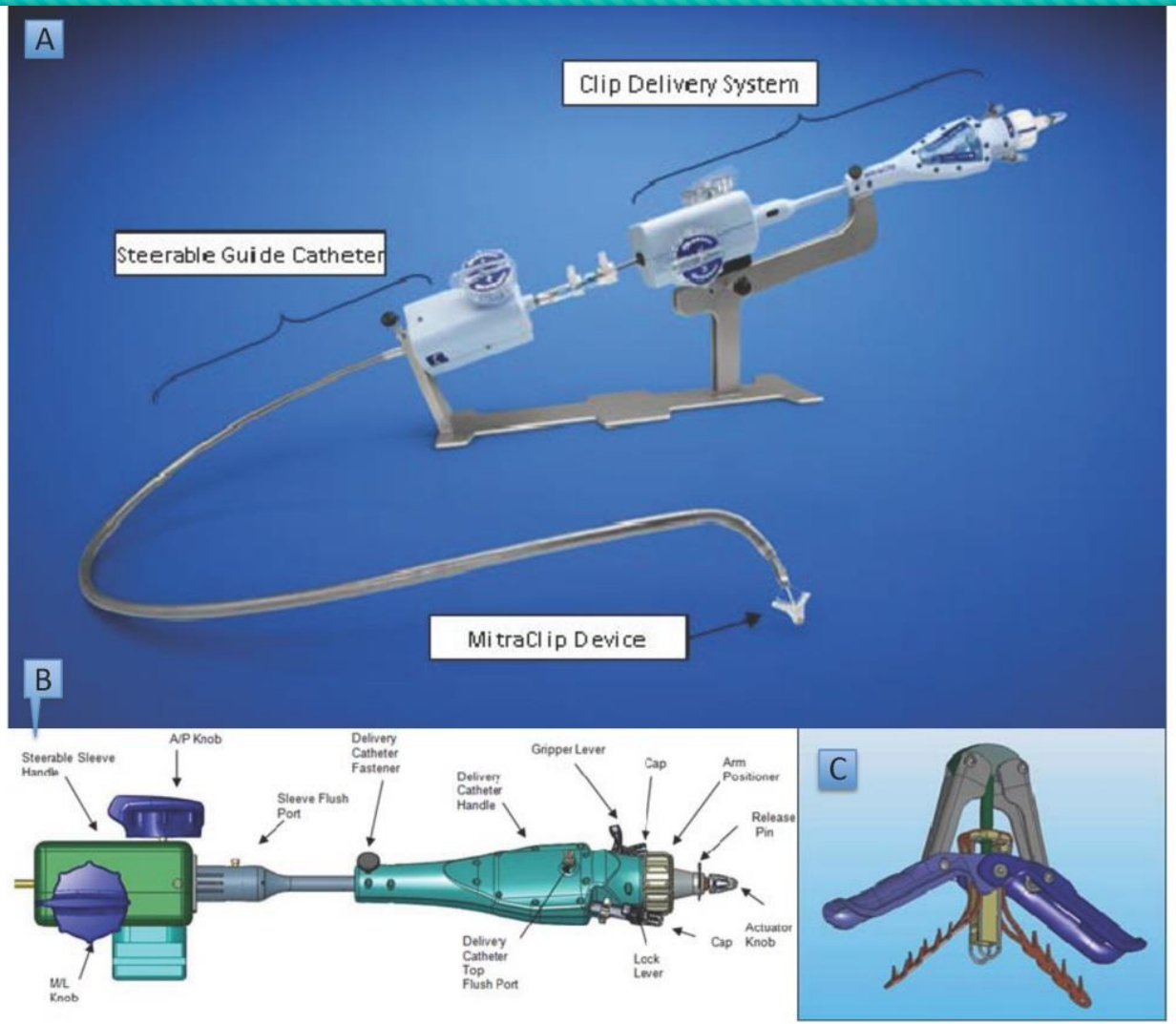
6 months

TAVR in Low risk patients

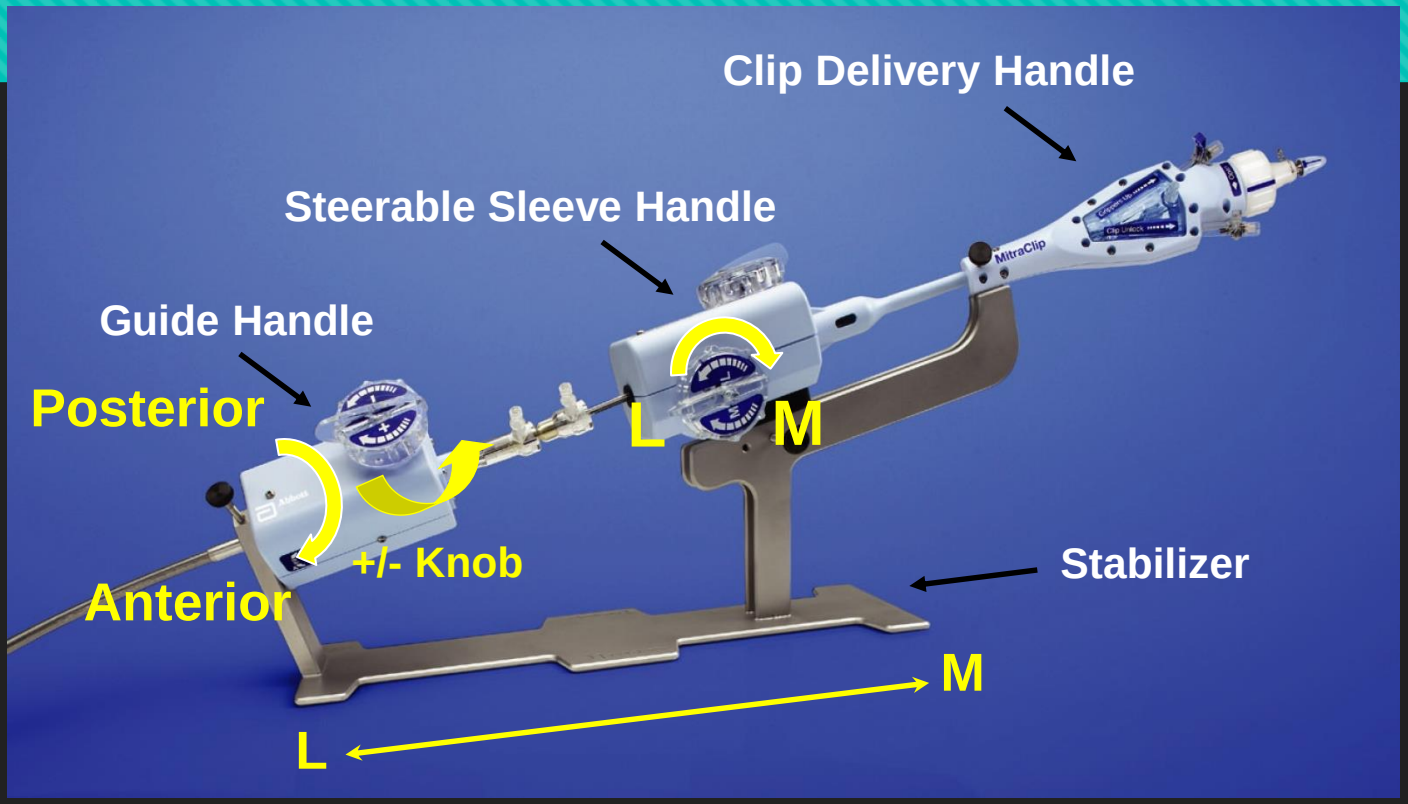


So where are we on Mitral valve treatment???

MitraClip Device

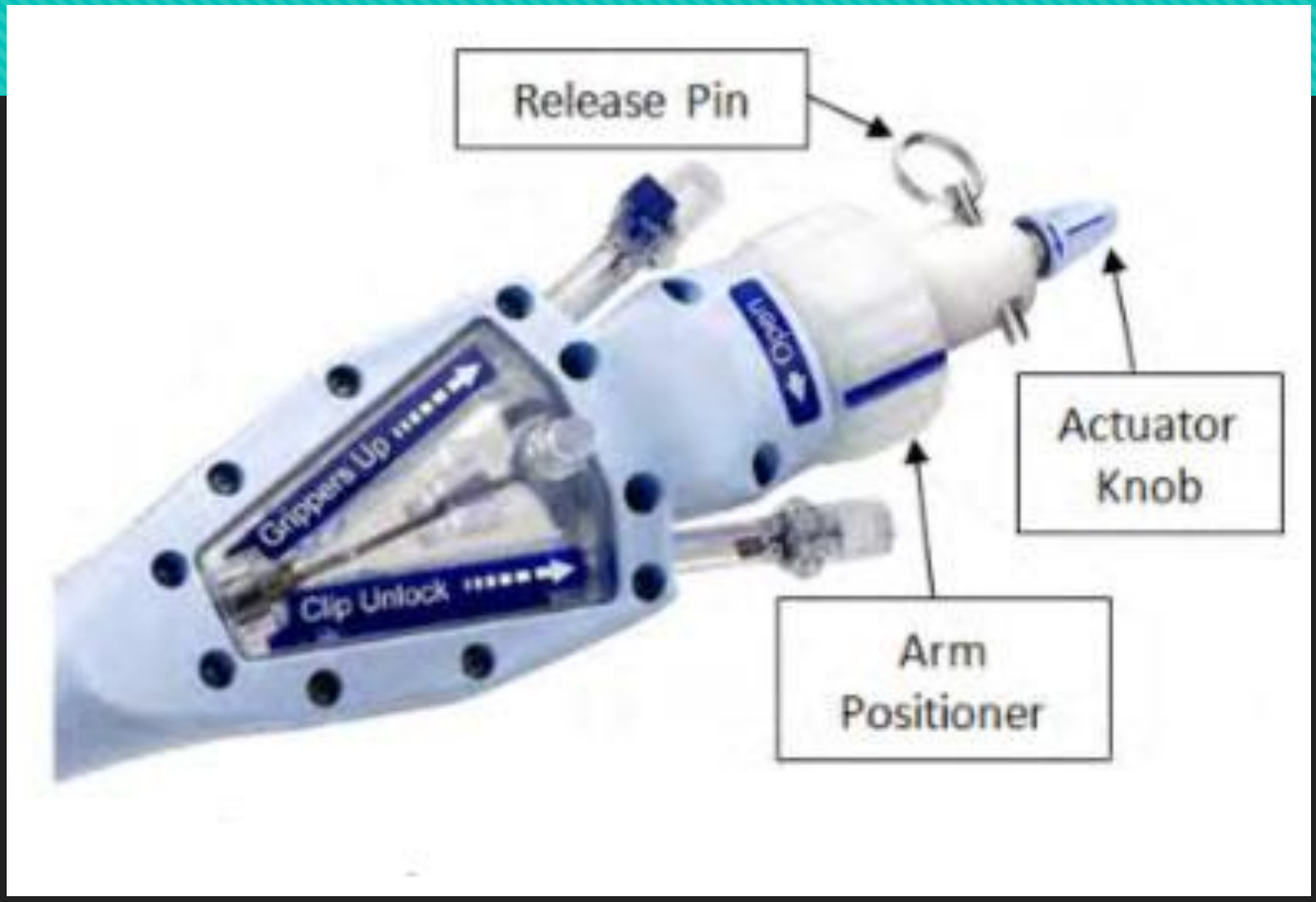

A
Clip Delivery System
Steerable Guide Catheter
MitraClip Device
B
Steerable Sleeve Handle
A/P Knob
Sleeve Flush Port
Delivery Catheter Fastener
Delivery Catheter Handle
Gripper Lever
Cap
Arm Positioner
Release Pin
Actuator Knob
Cap
Lock Lever
Delivery Catheter Top Flush Port
M/L Knob
C

MitraClip NT System Steering

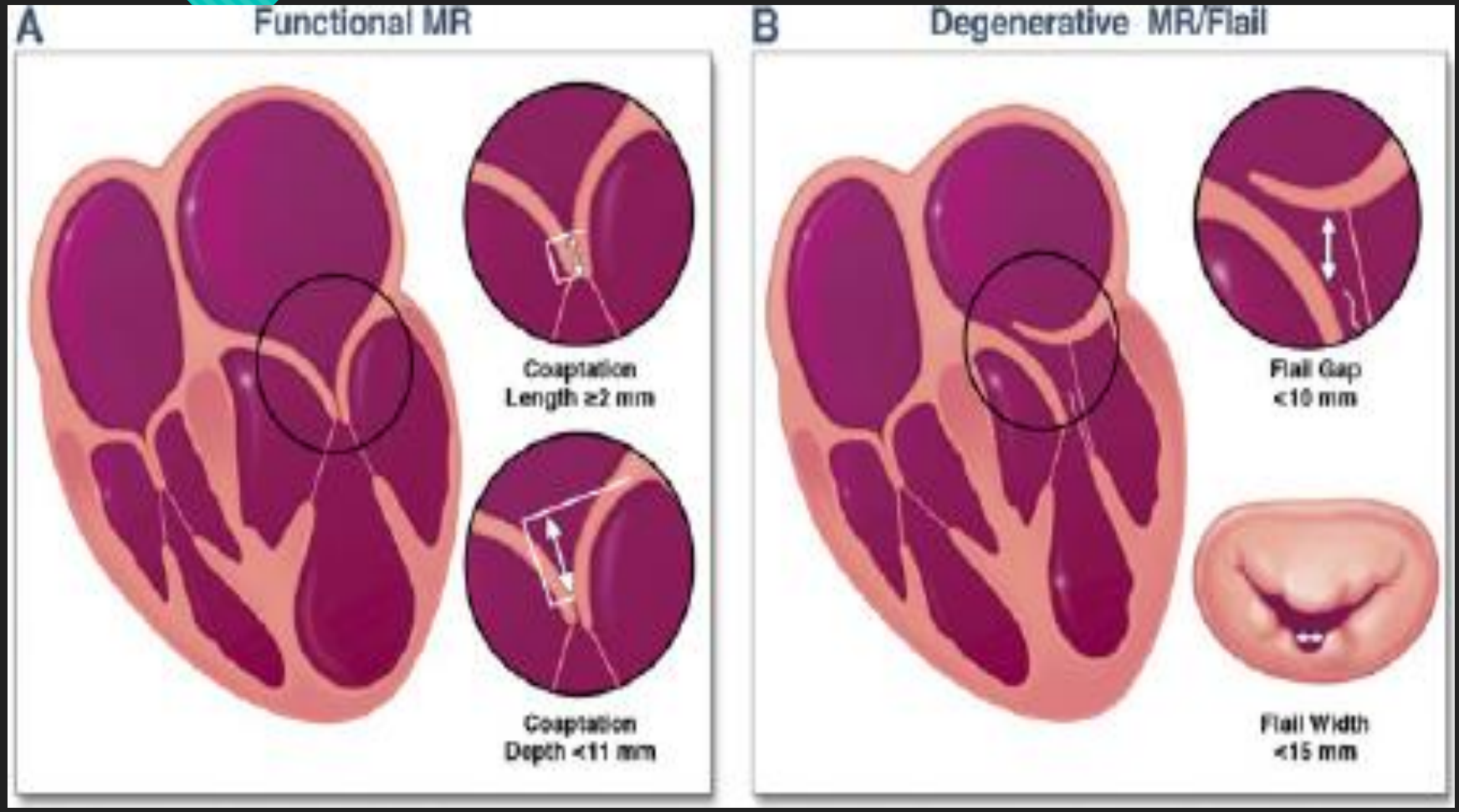


- Guide Handle – Anterior/Posterior, +/- Knob
- Sleeve Handle – Medial/Lateral, Anterior/Posterior Knobs
- Clip Delivery Handle – Clip Positioning, Grasping and Deployment
- Stabilizer – Medial/Lateral

MitraClip: Clip Delivery Handle



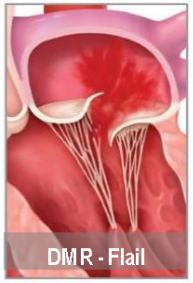
Anatomic Eligibility Criteria for MitraClip



MitraClip Indications for Use

INDICATION FOR USE:
Prohibitive Risk Primary MR (DMR)

The MitraClip® Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to **primary abnormality of the mitral apparatus** [degenerative MR] in patients who have been determined to be at **prohibitive risk for mitral valve surgery** by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.



MitraClip Indications for Use

2014 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease

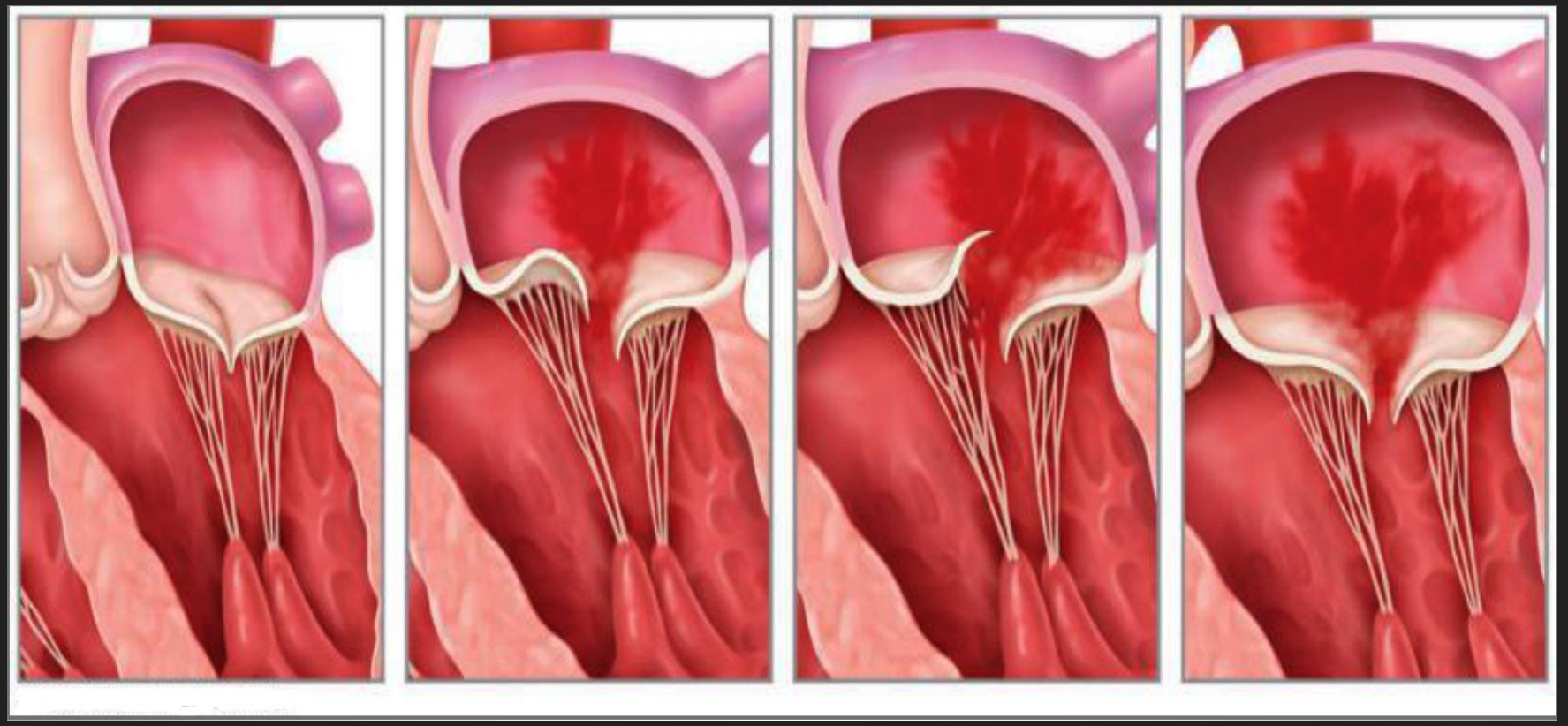
"Class IIb

3. **Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for HF (426). *(Level of Evidence: B)***

An RCT of percutaneous mitral valve repair using the MitraClip device versus surgical mitral repair was conducted in the United States. The clip was found to be safe but less effective than surgical repair because residual MR was more prevalent in the percutaneous group. However, the clip did reduce severity of MR, improved symptoms, and led to reverse LV remodeling. Percutaneous mitral valve repair should only be considered for patients with chronic primary MR who remain severely symptomatic with NYHA class III to IV HF symptoms despite optimal GDMT for HF and who are considered inoperable."[1]

[1]Source: Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP III, Guyton RA, O'Gara PT, Ruiz CE, Skubas NJ, Sorajja P, Sundt TM III, Thomas JD, 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease, *Journal of the American College of Cardiology* (2014), doi: 10.1016/j.jacc.2014.02.536.

Etiology of Mitral Regurgitation (MR)



Normal

Degenerative MR
- Prolapse

Degenerative MR
- Flail

Functional MR
Ischemic vs.
non-ischemic

- Due to dilated LV, mitral annulus or regional disruption of LV, MV apparatus

Types of Mitral Regurgitation

Causes

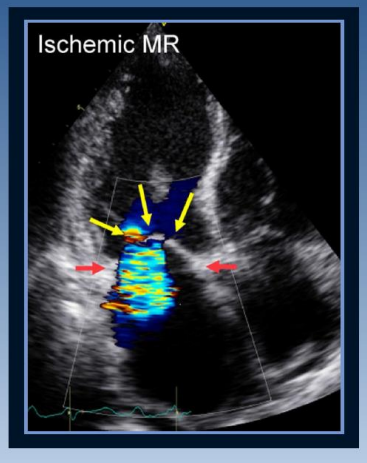
- Degenerative MR
  - Also known as primary or organic MR
  - Usually caused by an anatomic defect of one or more structures comprising the mitral valve apparatus—the annulus, the leaflets, the chordae tendineae, and the papillary muscles
- Functional MR
  - Also known as secondary MR
  - Results from left ventricular (LV) dysfunction and dilation, which causes otherwise normal valve components to fail and results in MR

Normal Mitral Valve | Degenerative MR: Prolapse | Degenerative MR: Flail | Functional MR

Secondary Mitral Regurgitation / Functional MR

Secondary Mitral Regurgitation

A Ventricular Problem



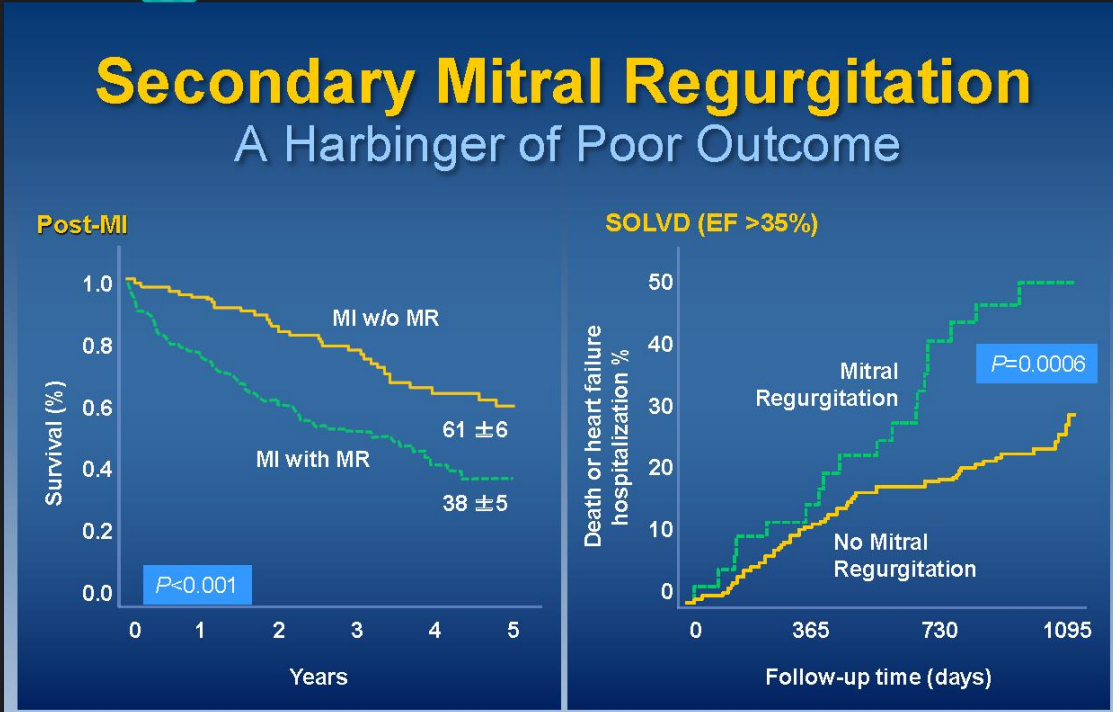
Regional or Global Dysfunction

- Papillary muscle displacement
- Annular flattening
- Leaflet tethering

Pathophysiology of MR

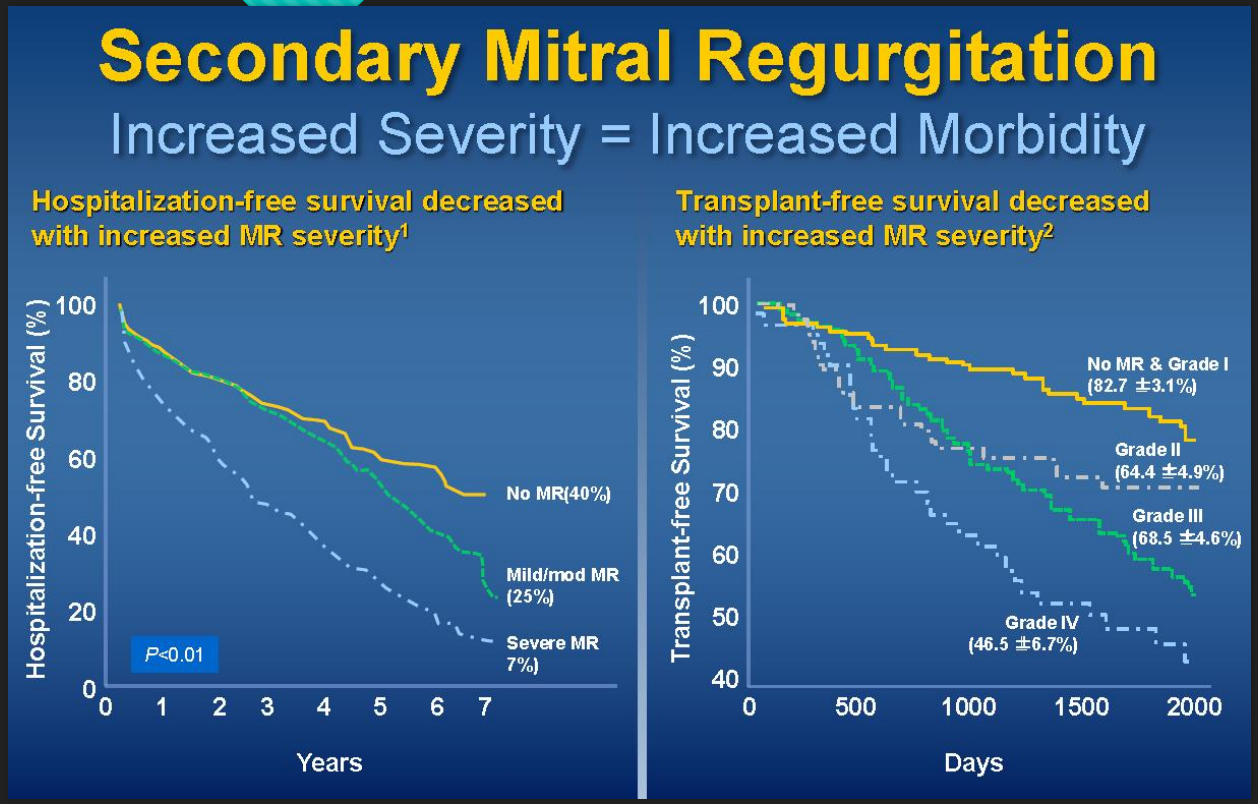
[1] Cioffi G, et al. Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. European Journal of Heart Failure 2005 Dec;7(7):1112-7.

Functional MR leads to Poor Outcomes…



Grigioni F, et al. Circulation 2001; 103: 1759-64.
Basket JF, et al. Can J Cardiol 2007; 23: 797-800.

Functional MR leads to Poor Outcomes…



1. Rossi A, et al. "Independent prognostic value of functional mitral regurgitation in patients with heart failure: a quantitative analysis of 1256 patients with ischemic and non-ischemic dilated cardiomyopathy." *Heart* 2011; 97 (20): 1675-80.
2. Bursi F, et al. "Prognostic implications of functional mitral regurgitation according to the severity of the underlying chronic heart failure: a long term outcome study." *Eur J Heart Fail* 2010; 12(4): 382-8.

General Principles of Therapy for MR Etiology

Primary MR

No Medical Therapy
(Diuretics palliative)

Surgery for symptoms or LV dysfunction
(Repair > Replacement)

Consider prophylactic repair for low risk with long term survival

Secondary MR

Medical Therapy first
(BB,ACE/ARB, Aldactone, Diuretics)

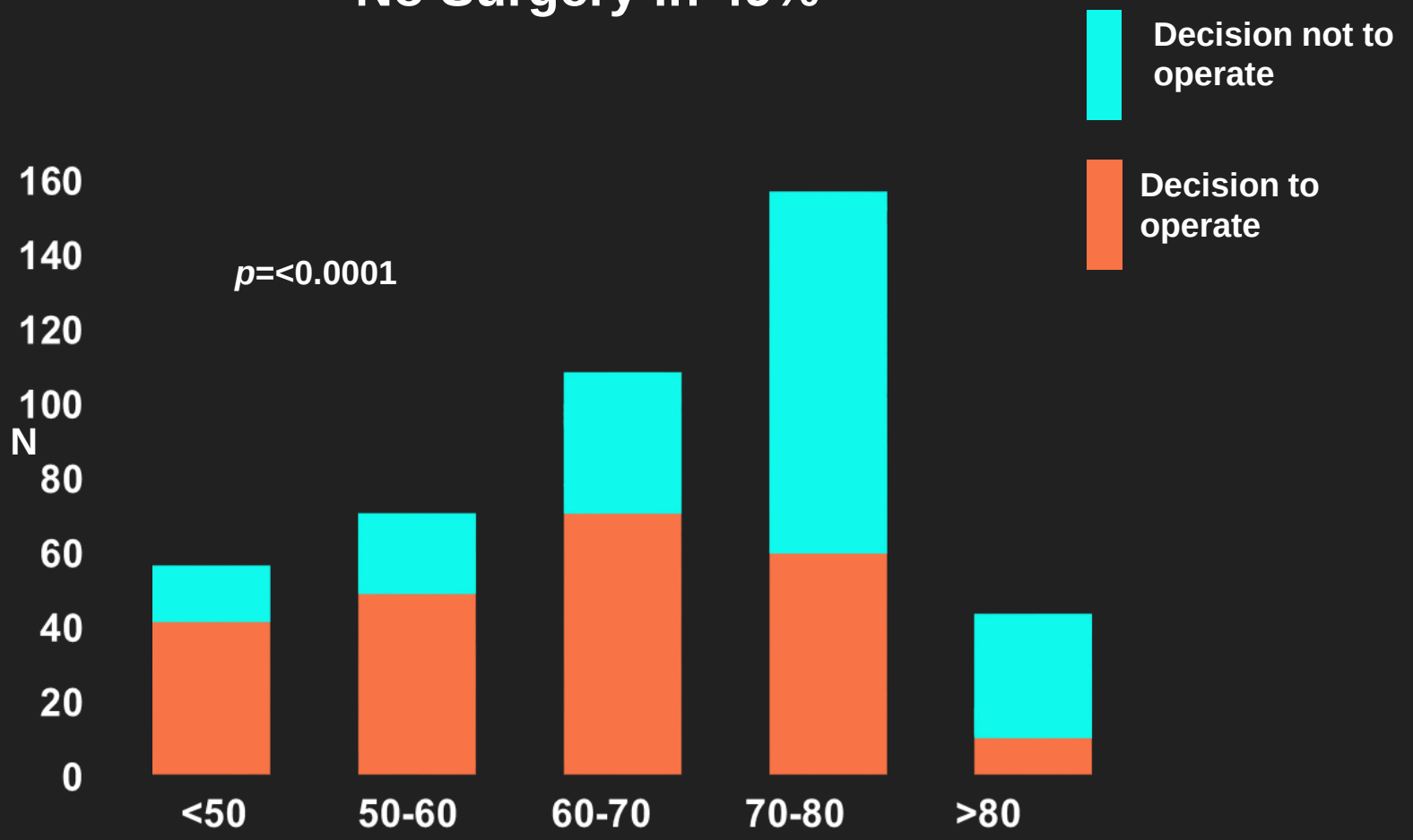
CRT

Surgery only in highly selected pts with CHF
(Class 3/4 symptomatic and acceptable surgical risk)

Not All Patients Are Good Surgical Candidates

396 Patients in Europe with Symptomatic Severe MR (53% degenerative)

No Surgery in 49%

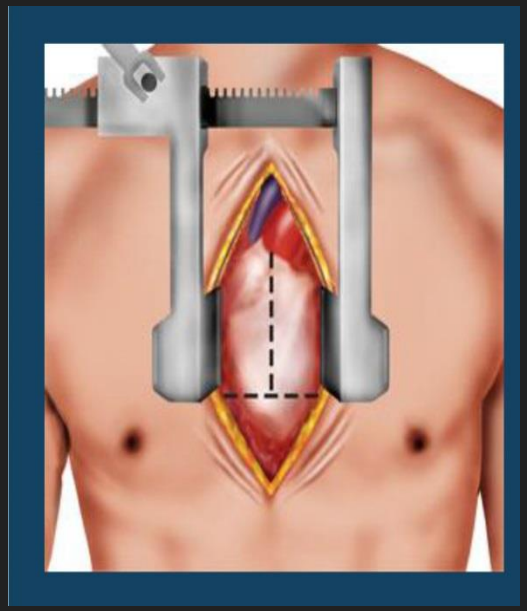


Mirabel et al., E Heart J 2007;28:1358

EVEREST II Randomized Clinical Trial

Surgical and Percutaneous Therapy for Mitral Regurgitation

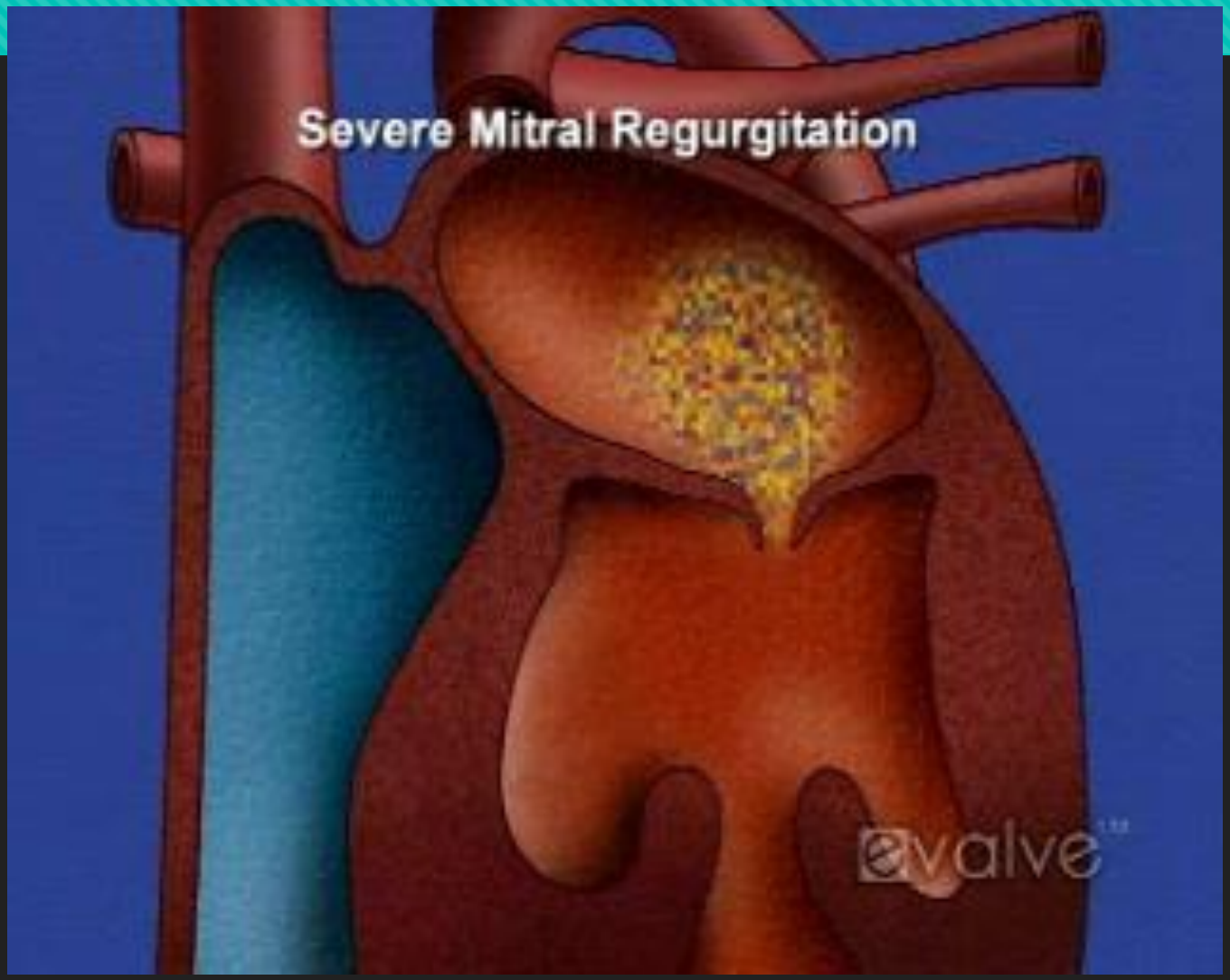
Mitral Valve Surgery
Repair/Replacement



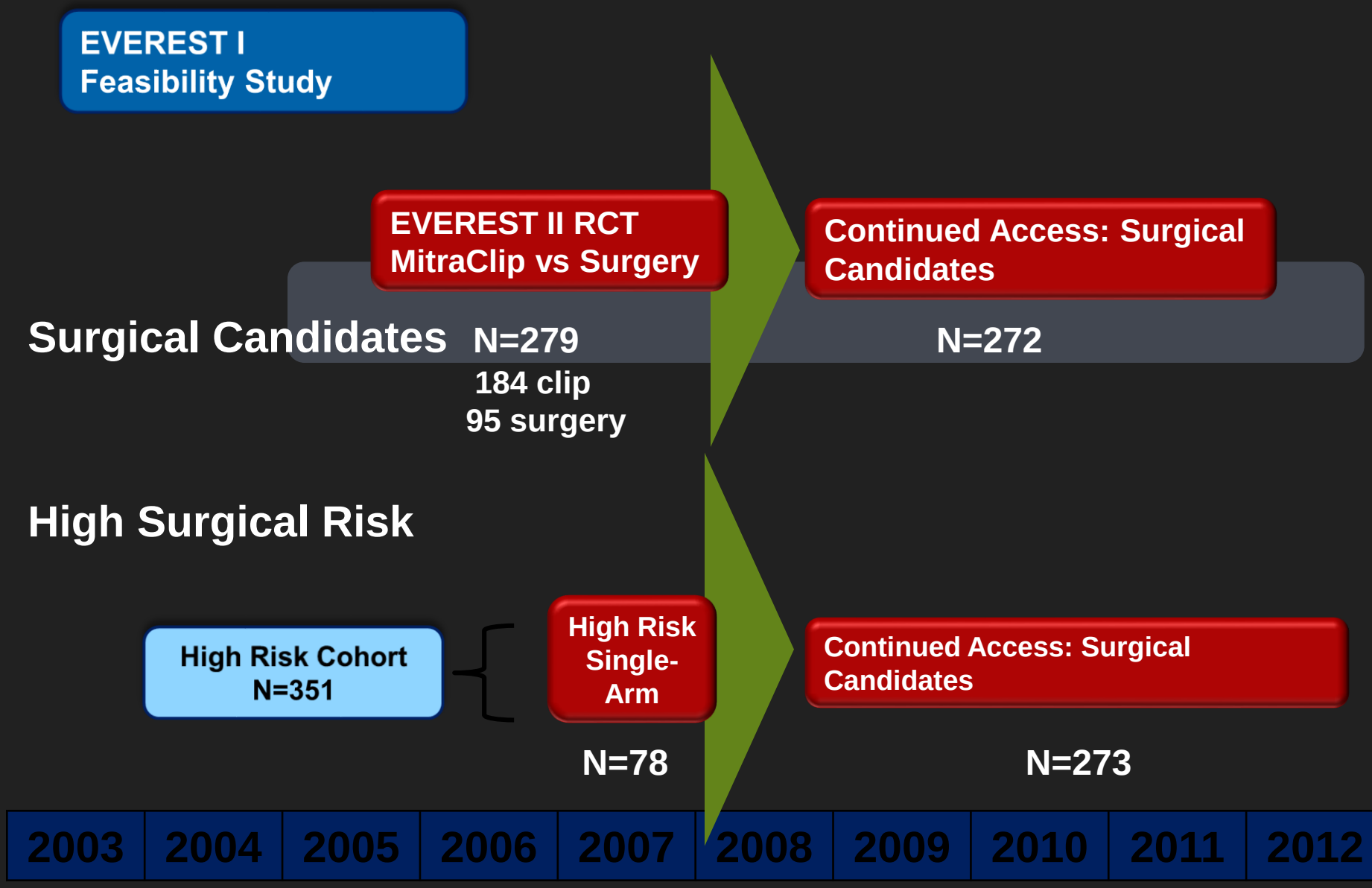
or

Catheter Based Mitral Valve Repair
MitraClip System

MitraClip Deployment Technique

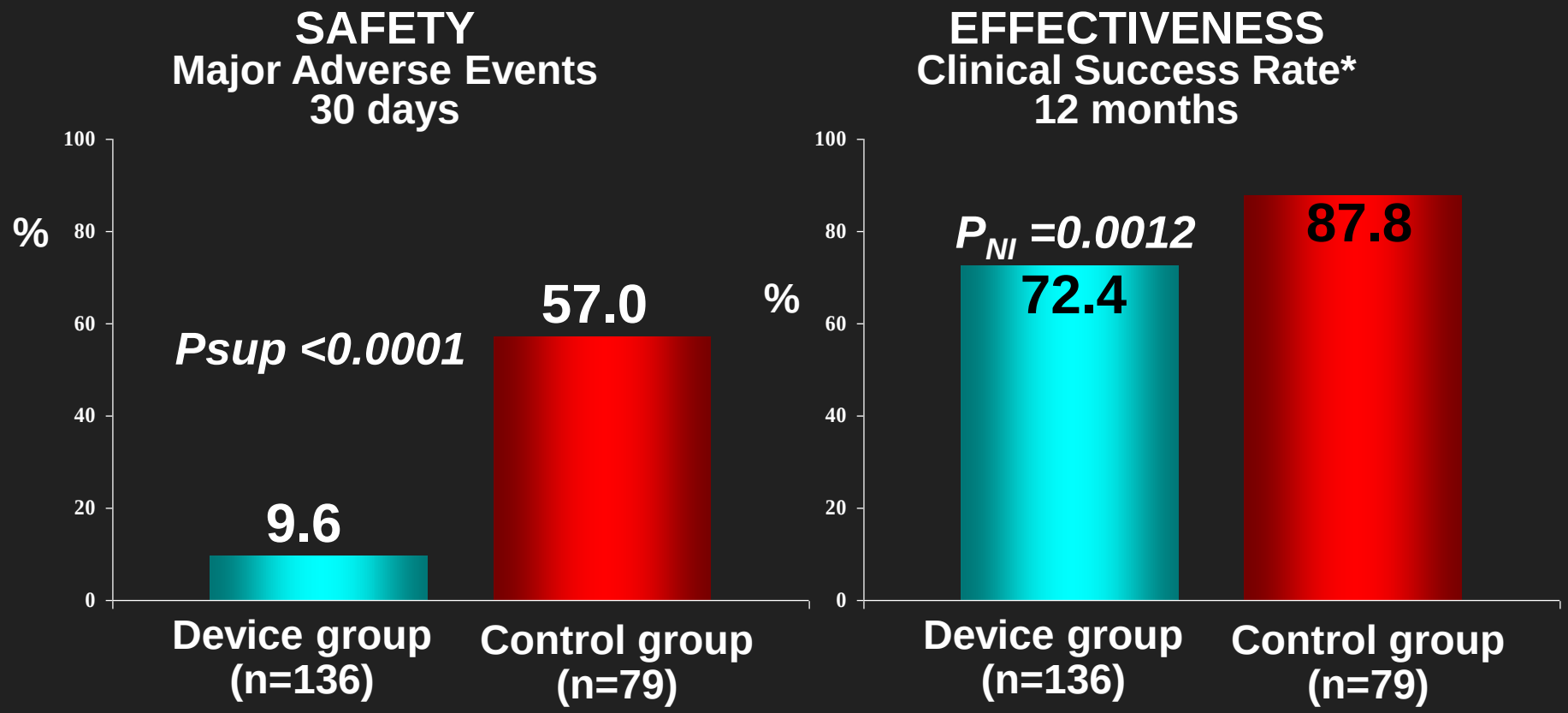


MitraClip System: US Clinical Trial Experience



EVEREST II (Endovascular Valve Edge-to-Edge Repair) Study

Primary Endpoints Per Protocol Cohort



*Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction, MR >2+ at 12 Month

Feldman T et al, ACC 2010

The NEW ENGLAND JOURNAL of MEDICINE

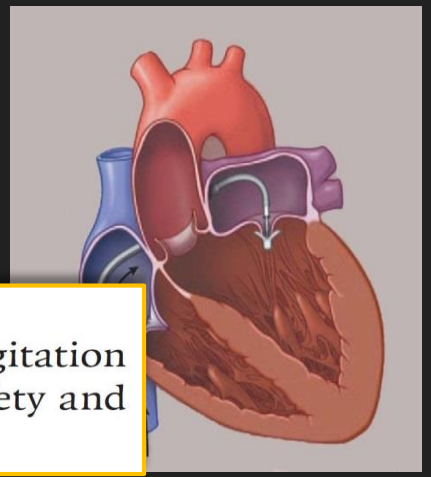
ESTABLISHED IN 1812 APRIL 14, 2011 VOL. 364 NO. 15

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald D. 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.,

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.

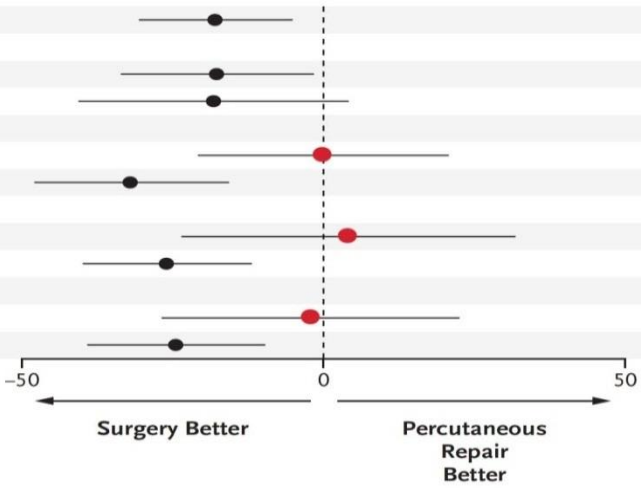


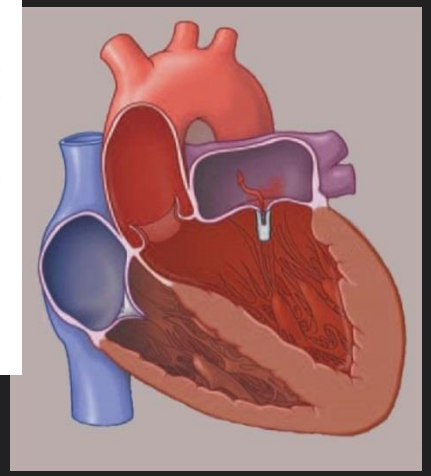
edges of the mitral leaflets at the origin of the regurgitant jet.

METHODS

We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+)

Subgroup	Percutaneous Repair	Surgery
	no. of events/total no. (%)	
All patients	100/181 (55)	65/89 (73)
Sex		
Male	63/114 (55)	43/59 (73)
Female	37/67 (55)	22/30 (73)
Age		
≥70 yr	52/86 (60)	23/38 (61)
<70 yr	48/95 (51)	42/51 (82)
MR		
Functional	26/48 (54)	12/24 (50)
Degenerative	74/133 (56)	53/65 (82)
LVEF		
<60%	35/68 (51)	15/28 (54)
≥60%	64/111 (58)	50/61 (82)



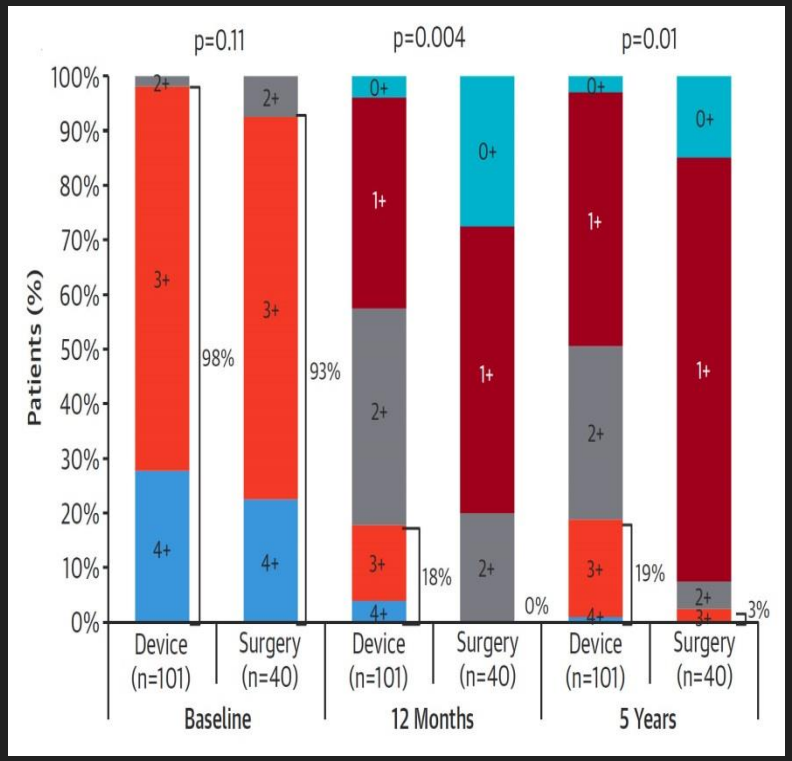


than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)

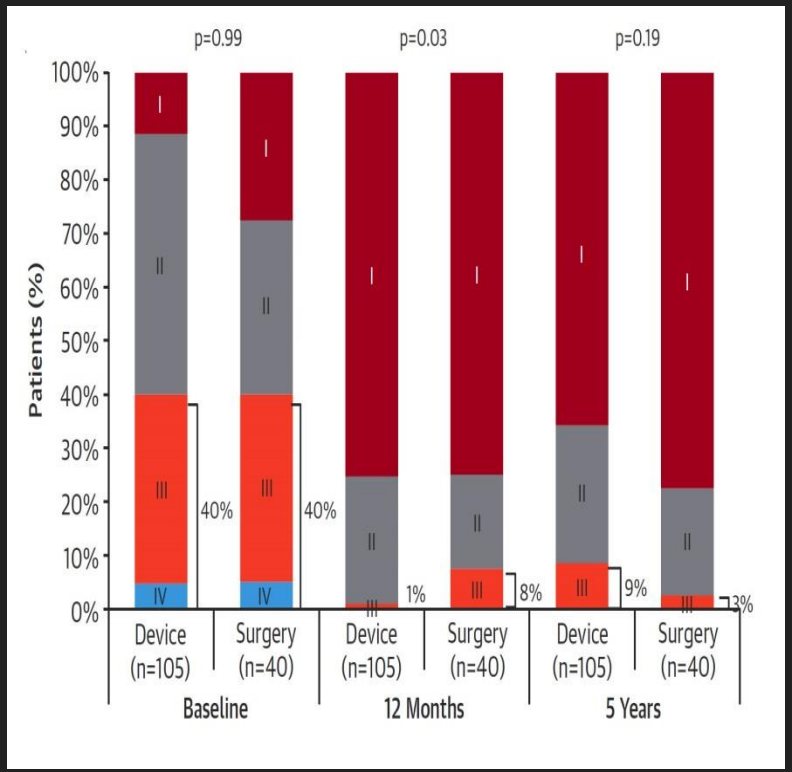
Feldman et al. NEJM 2011:364;678

EVEREST II Trial: Severity of MR and Heart Failure Symptoms Post-Treatment

Echocardiographic Severity of MR



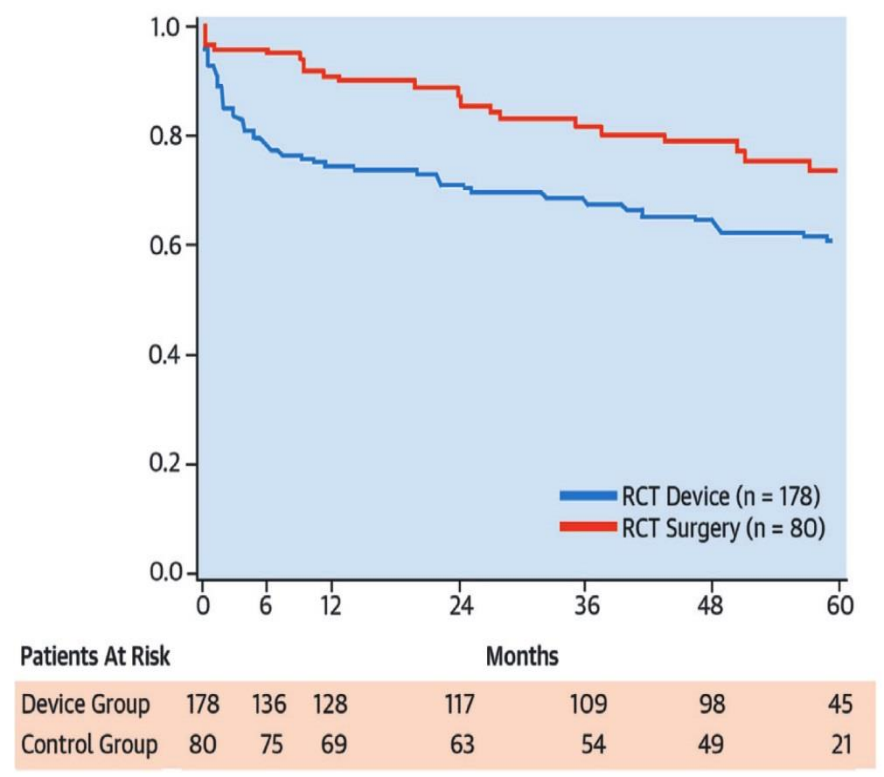
NYHA Functional Class



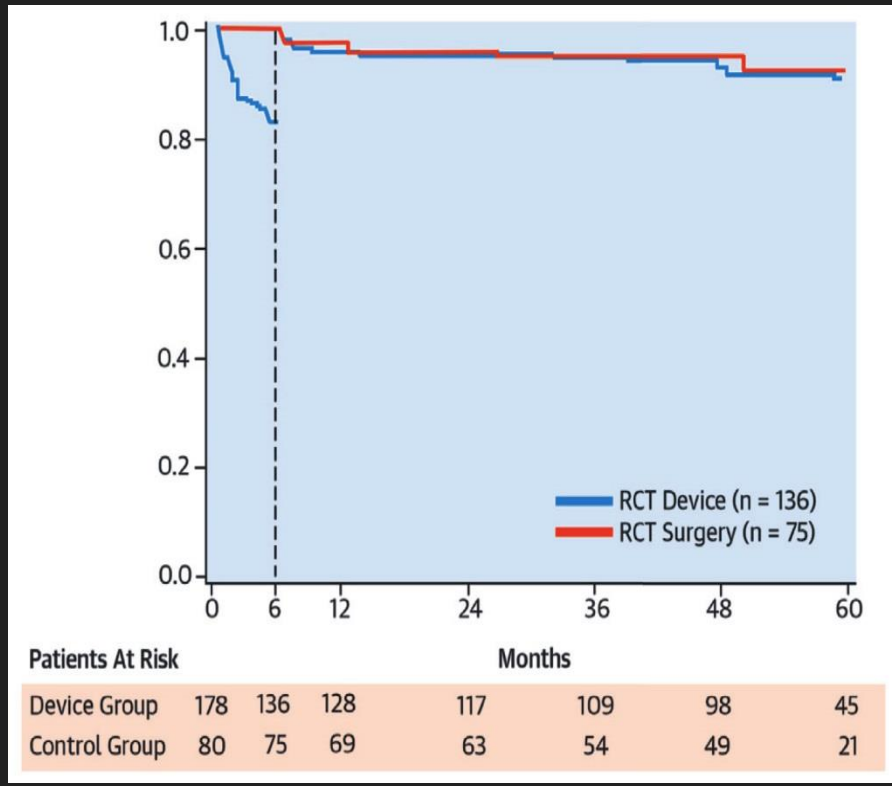
Feldman et al., J Am Coll Cardiol 2015;66:2844

EVEREST II Trial: 5-Year Clinical Outcomes – Percutaneous Repair and Surgery for Mitral Regurgitation

Freedom from Death, MV Surgery or Reoperation



Landmark Analysis of Freedom from Death, MV Surgery or Reoperation Beyond 6 Months



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

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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%)

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

CONCLUSIONS 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. (Real World Expanded Multi-center Study of the MitraClip System [REALISM]; NCT01931956)

Worldwide Experience Using the MitraClip

Study	Population	N
EVEREST I (Feasibility)	Feasibility patients	55
EVEREST II (Pivotal)	Pre-randomized patients	60
EVEREST II (Pivotal)	Non-randomized patients (High risk Study)	78
EVEREST II (Pivotal)	Randomized patients (2:1 Clip to Surgery)	184 Clip 95 Surgery
REALISM (Contd Access)	Non-randomized patients	899
Compassionate/ Use	Non-randomized patients	66
ACCESS Europe Phase I	Non-randomized patients	567
ACCESS Europe Phase II	Non-randomized patients	286
Commercial Use	Commercial patients	>40,000
Total		>41,000

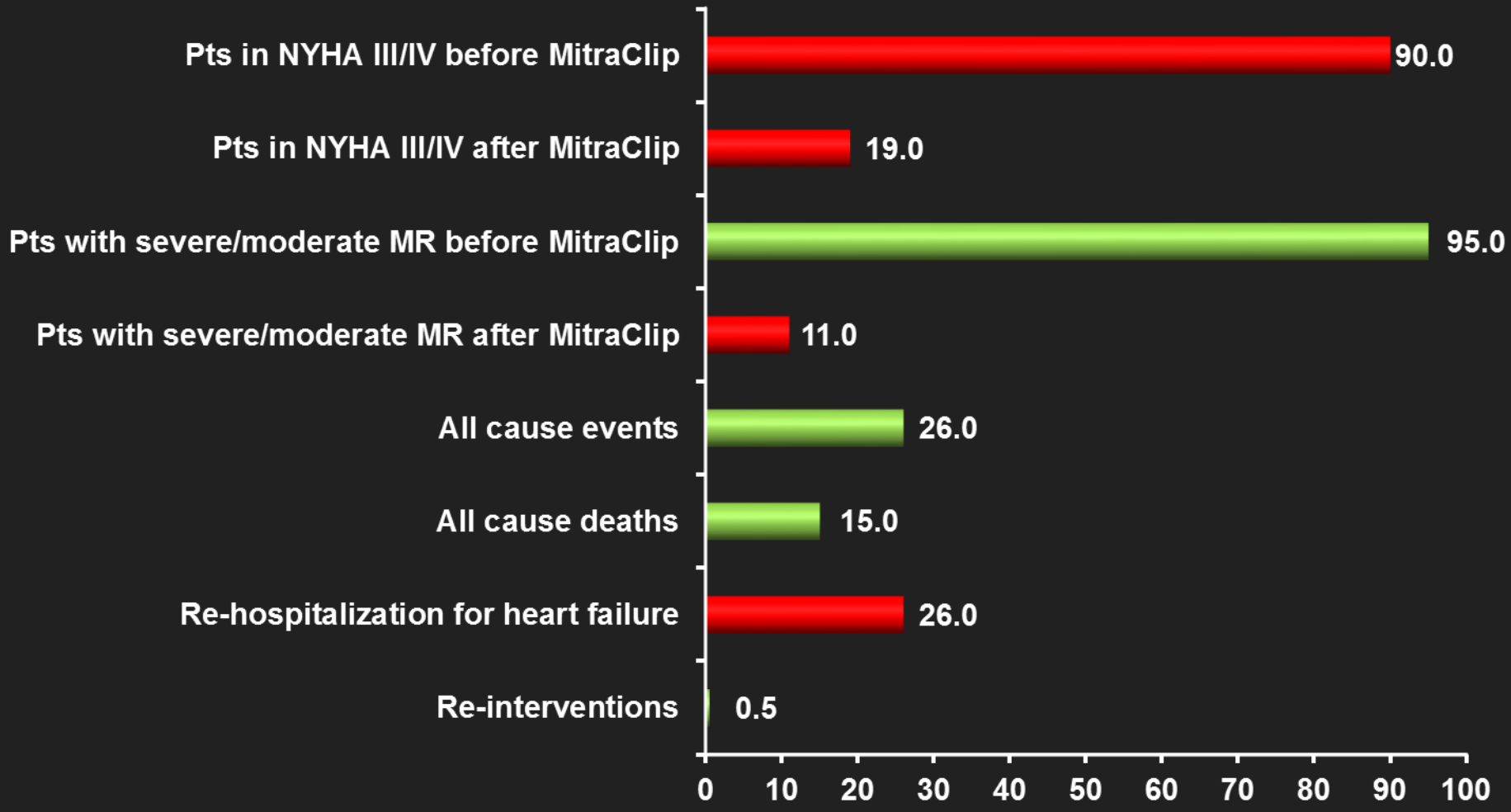
The American Journal of Cardiology

Meta-Analysis of the Usefulness of Mitraclip in Patients With Functional Mitral Regurgitation

Fabrizio D'ascenzo, MD[a], Claudio Moretti, MD[a], Walter Grosso Marra, MD[a], Antonio Montefusco, MD[a], Pierluigi Omede, MD[a], Salma Taha, MD[a,b,*], Davide Castagno, MD[a], Oliver Gaemperli, MD[c], Maurizio Taramasso, MD[d], Simone Frea, MD[a], Stefano Pidello, MD[e], Volker Rudolph, MD[f], Olaf Franzen, MD[g], Daniel Braun, MD[h], Cristina Giannini, MD[i], Huseyin Ince, MD[j], Leor Perl, MD[k], Giuseppe Zoccai, MD[l], Sebastiano Marra, MD[a], Maurizio D'Amico, MD[a], Francesco Maisano, MD[m], Mauro Rinaldi, MD[a], and Fiorenzo Gaita, MD[a]

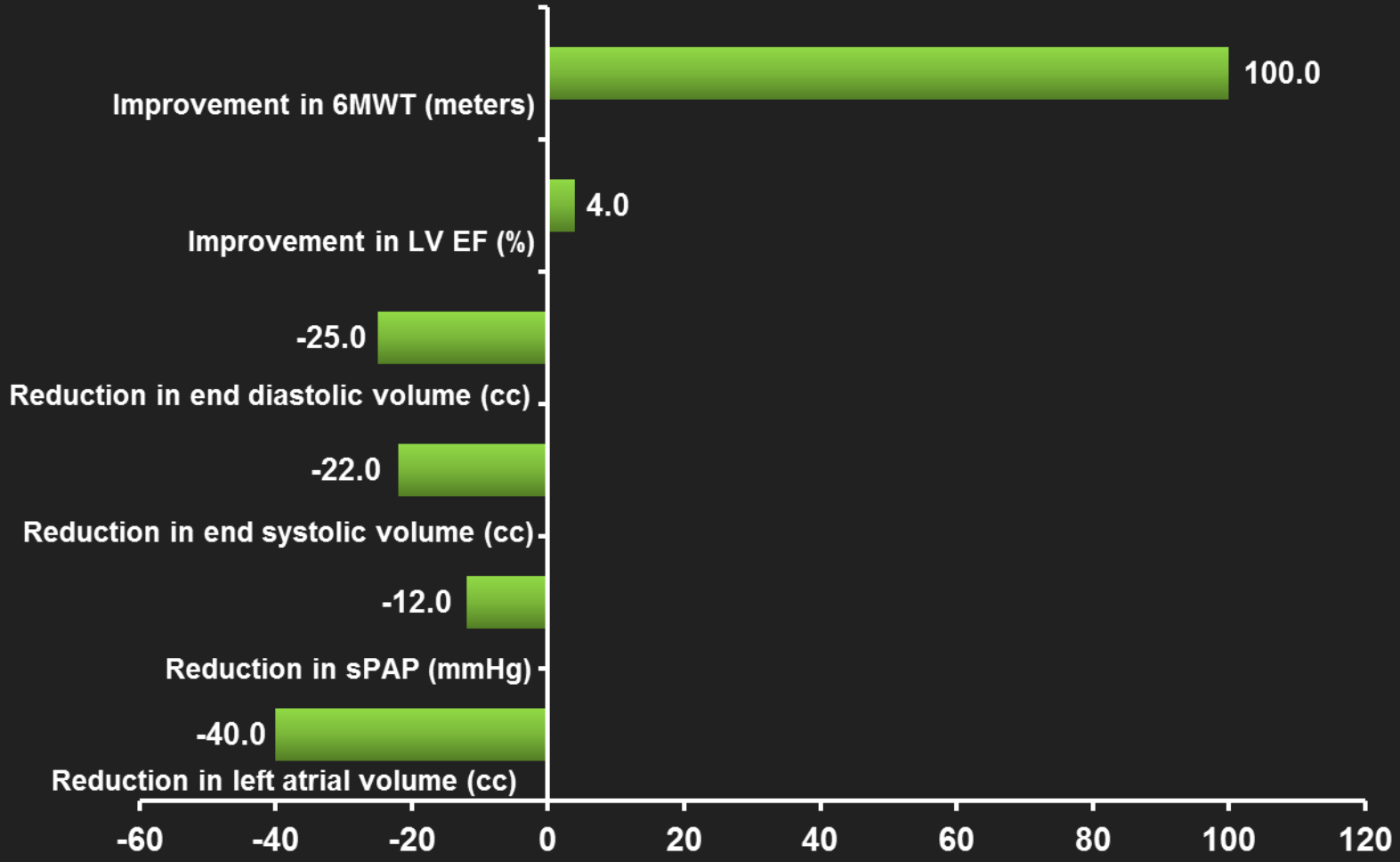
(Am J Cardiol 2015;116:325–331)

Adverse Clinical Events at Follow-Up of 9 Months

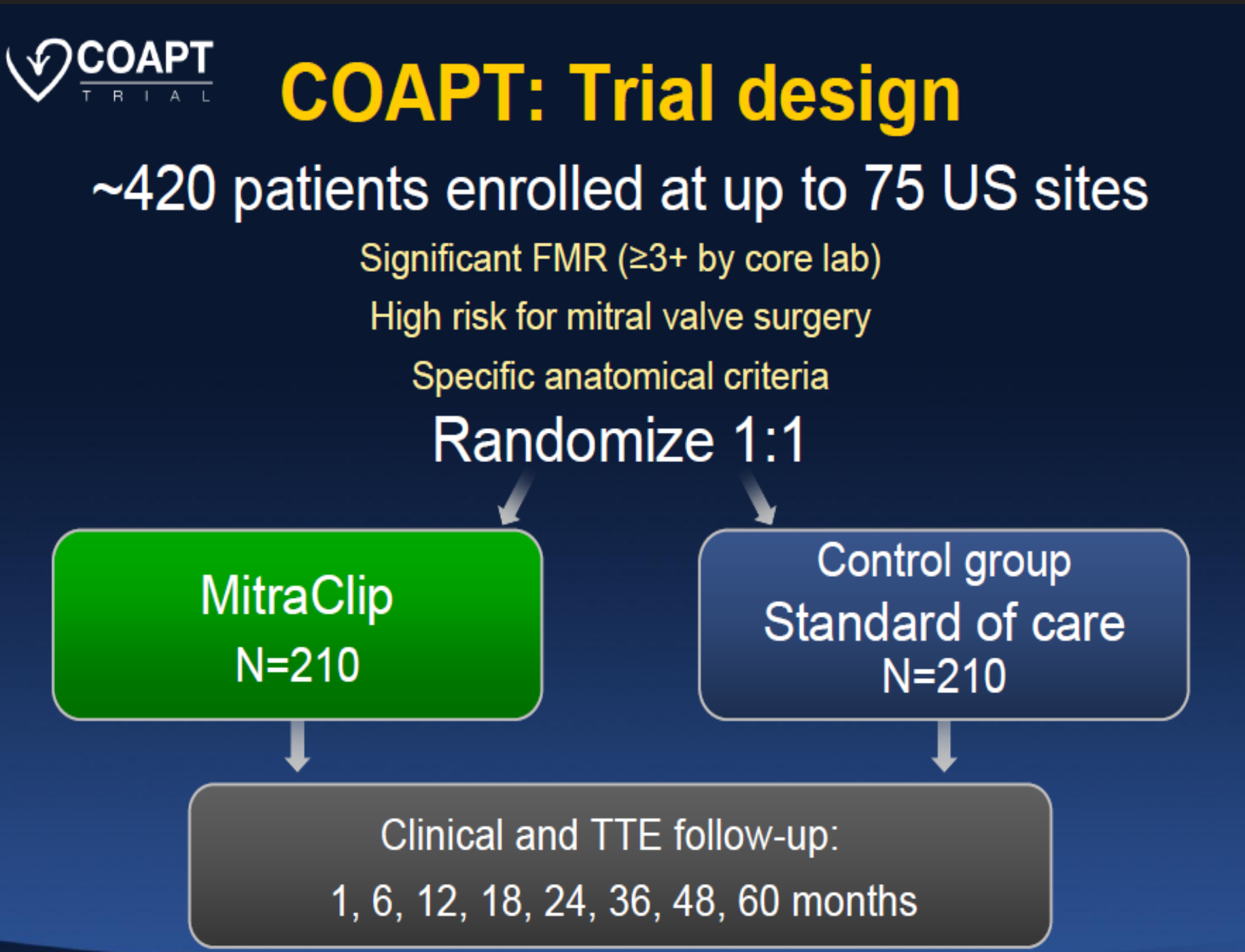


D'ascenzo et al., Am J Cardiol 2015;116:325

Change of Functional and Echocardiographic Data at Follow-Up



D'ascenzo et al., Am J Cardiol 2015;116:325


COAPT
TRIAL
COAPT: Trial design
~420 patients enrolled at up to 75 US sites
Significant FMR (≥3+ by core lab)
High risk for mitral valve surgery
Specific anatomical criteria
Randomize 1:1
MitraClip
N=210
Control group
Standard of care
N=210
Clinical and TTE follow-up:
1, 6, 12, 18, 24, 36, 48, 60 months

COAPT Trial: Primary Endpoints

- Primary Effectiveness (min 1-year follow-up all pts)
  - Recurrent heart failure hospitalizations
    - Superiority hypothesis (Andersen-Gill)

- Primary Safety (1 year)
  - Composite of all-cause death, stroke, worsening kidney function, or LVAD or cardiac transplant
    - Non-inferiority hypothesis

MitraClip Procedure Indications

- **FDA Approval**
  - MitraClip is approved for patients with symptomatic primary MR that are poor surgical candidates as designated by the Heart Team
- **ACC/AHA Guidelines**
  - MitraClip may be considered for prohibitive risk patients with primary MR and severe symptoms (Class IIb)

Evidence base Therapy for MR

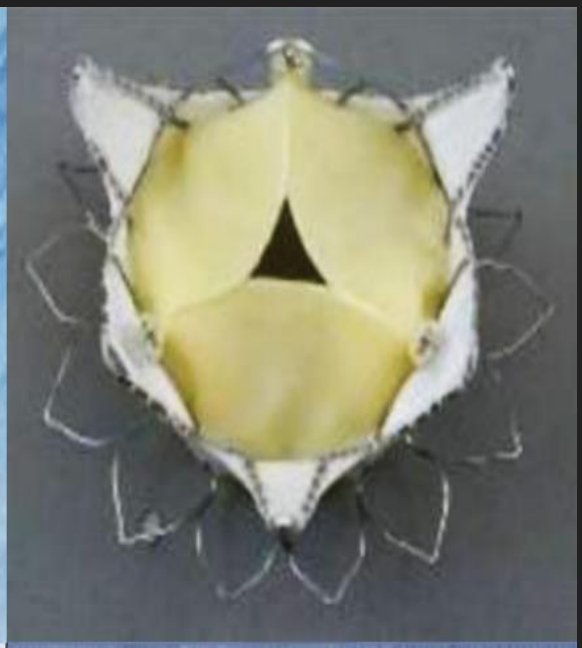
	Degenerative	Functional
Low Surgical Risk	✓ Surgical MVR	? Surgical MVR ??
High Surgical Risk	✓ Surgical MVR ✓ Commercial MitraClip-registry	MitraClip ✓ Global Practice-registries ✓ COAPT/ Reshape trials

Transcatheter Mitral Valve Replacement (TMVR)

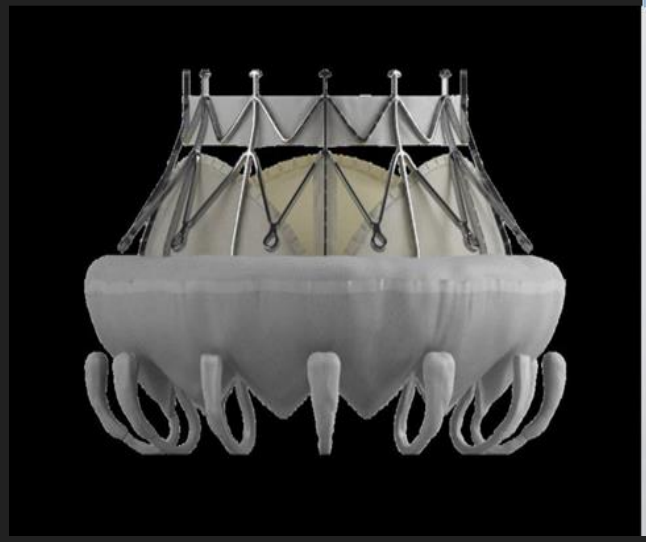
- TS and TA access approaches
- All self-expanding
- All in the FIM or Phase 1 trials

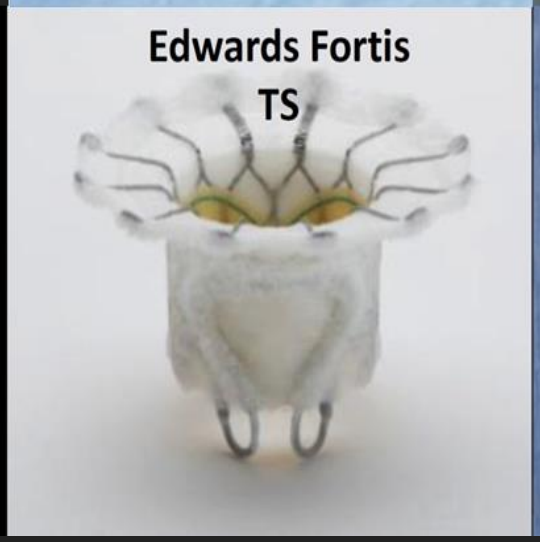
Abbott Tendyne
TA

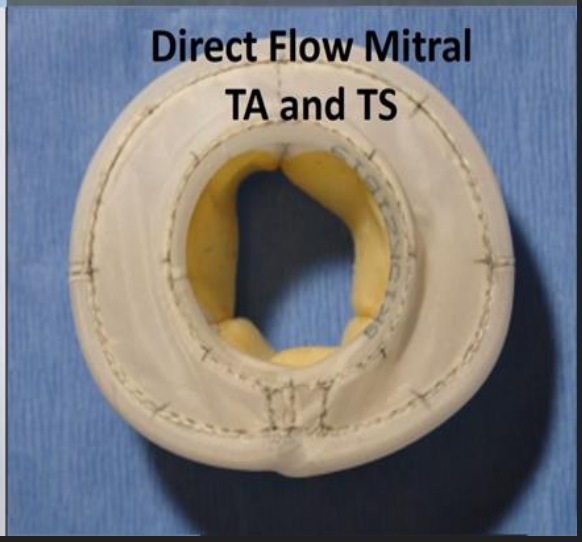
Neovasc Tiara
TA



Edwards CardiAQ
TA and TS







Take Home Messages for MitraClip Percutaneous Approaches for Ischemic/Functional MR in 2017+

- MitraClip therapy is now FDA approved for symptomatic patients with severe MR of degenerative etiology (DMR) who are poor surgical candidates
- For patients with symptomatic FMR in high surgical risk pts MitraClip is available through COAPT randomized trial
- MitraClip implantation registry studies in FMR have shown acceptable results in high surgical risk pts; to reduce LV cavity size, MR volume, CHF class and re-hospitalization

With all the advances in heart failure and valvular heart disease what is the role of palliative care??

The burden of heart failure

NUMBER of PATIENTS

21 MILLION adults worldwide are living with heart failure

This number is expected to rise.[1,2]

ECONOMIC BURDEN

In 2012, the overall worldwide cost of heart failure was nearly **$108 BILLION.**[6]

MORTALITY

50% of heart failure patients die within 5 years from diagnosis.[5]

REHOSPITALISATION

Heart failure is the **NUMBER 1** cause of hospitalisation for patients aged >65 years.[4]

COMORBIDITIES: The vast majority of HF patients has 3 or more comorbidities [3]

1. Mozaffarian D et al. Circulation. 2015;131(4):e29-e322.
2. Mosterd A et al. Heart. 2007;93(9):1137-1146.
3. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf
4. Cowie MR et al. Oxford PharmaGenesis; 2014. http://www.oxfordhealthpolicyforum.org/AHFreport. Accessed February 18, 2015.
5. Fauci AS et al. Harrison's Principles of Internal Medicine. 17th ed. New York: McGraw-Hill; 2008.
6. Cook C et al. *Int J Cardiol*. 2014;171(3):368-376.

NYHA CLASS

Class I: Symptoms with more than ordinary activity

Class II: Symptoms with ordinary activity

Class III: Symptoms with minimal activity

- Class IIIa: No Dyspnea at rest
- Class IIIb: Recent Dyspnea at rest

Class IV: Symptoms at rest

AHA CLASS – ACC/AHA

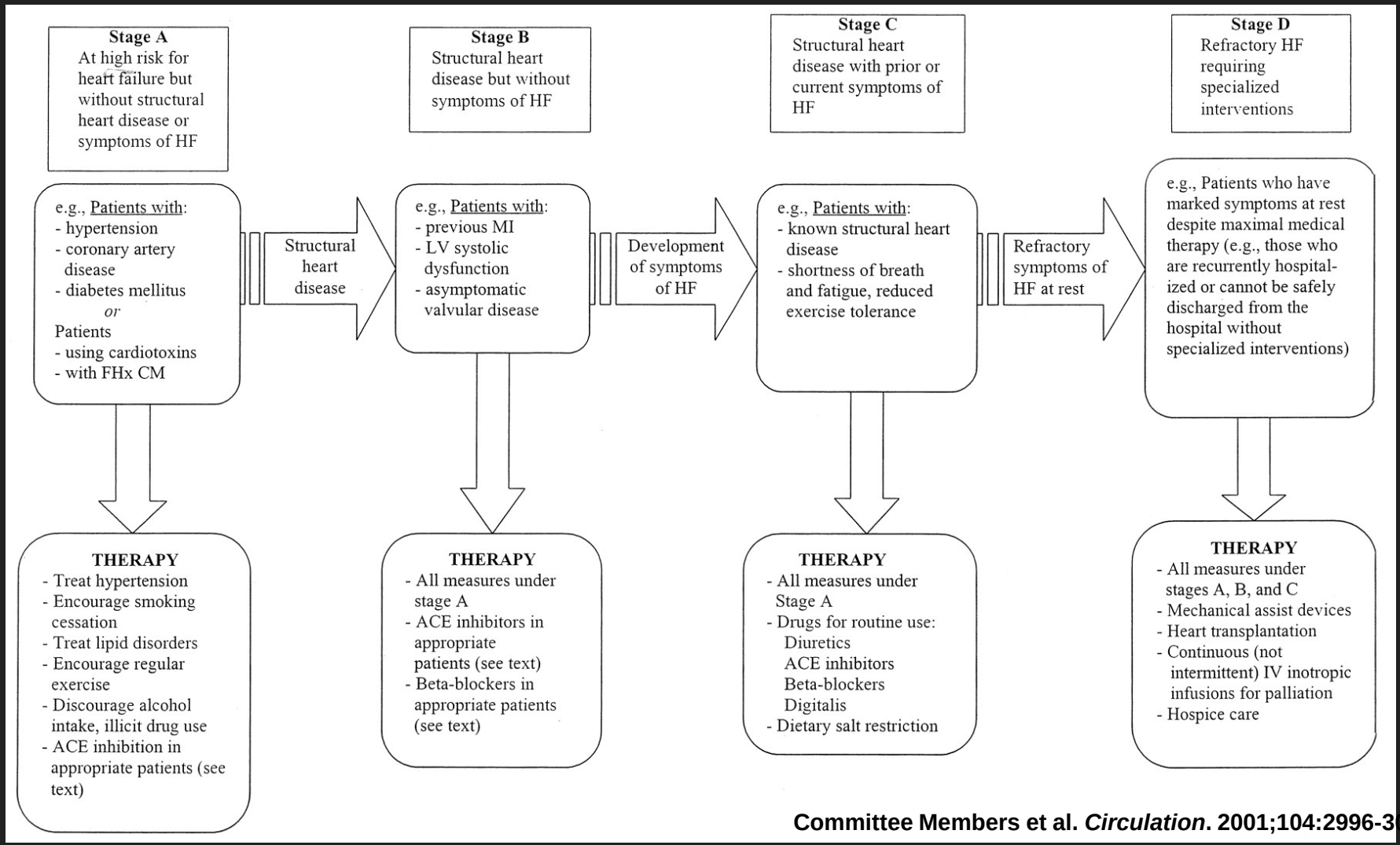
A - Risk factor or predisposition (no structural disease)

B - Structural disease, no symptoms

C - Disease and symptoms at any time

D - Disease and requires advanced treatment (ICD, LVAD)

Figure 1. Stages in the evolution of HF and recommended therapy by stage.



Committee Members et al. *Circulation*. 2001;104:2996-3007

New Categories:

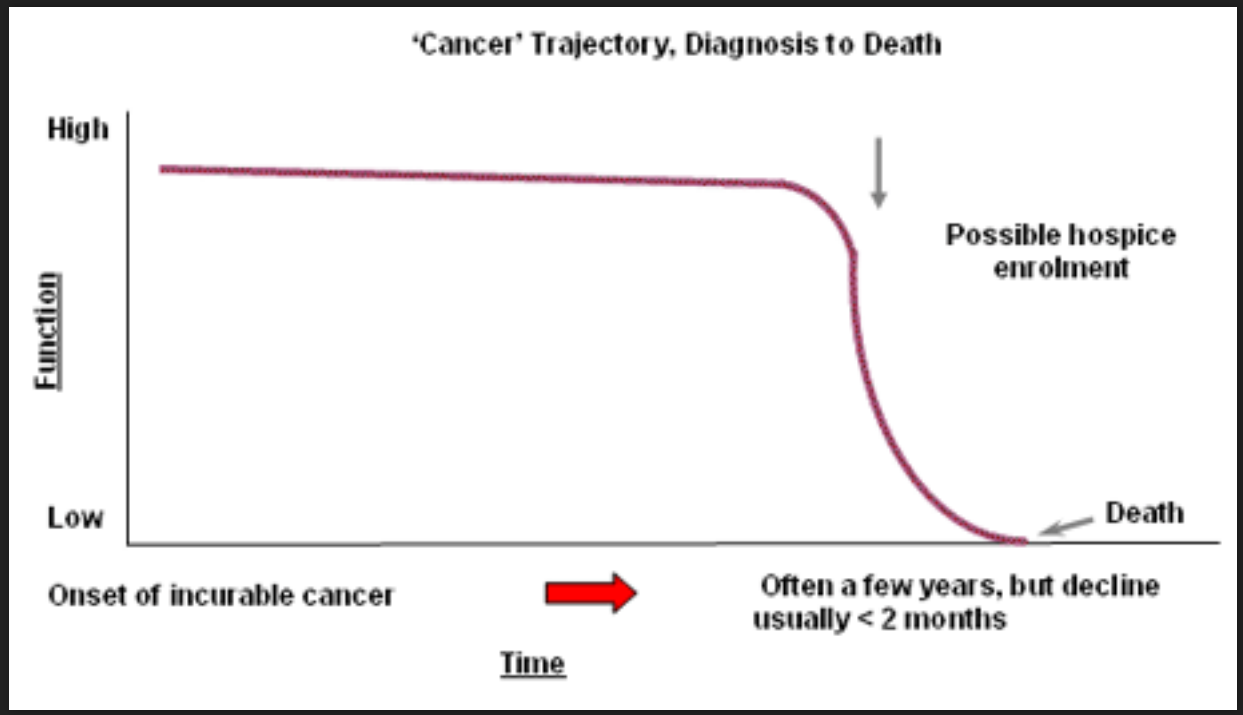
HFrEF

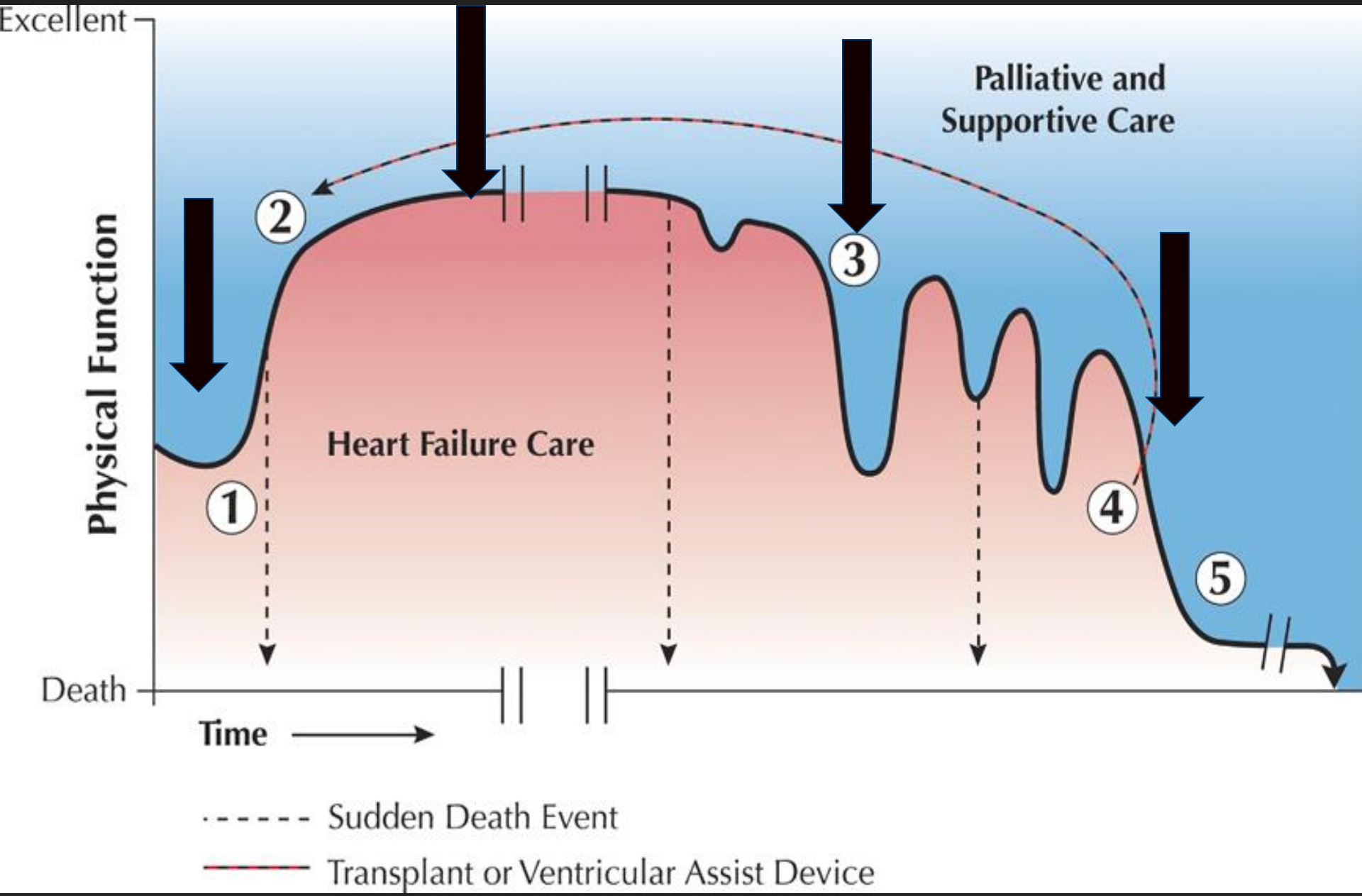
- EF < 50%

HFpEF

- EF normal
- Challenging
- Similar morbidity and mortality
- Older age, women, HTN

Trajectory: Oncology



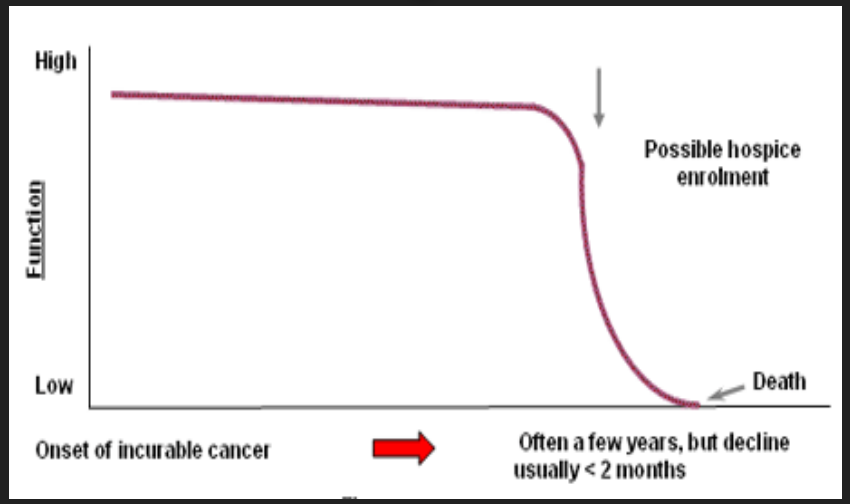


Goodlin, SJ Am Coll Cardiol 2009;54:386–96

A Tale of Two Illnesses

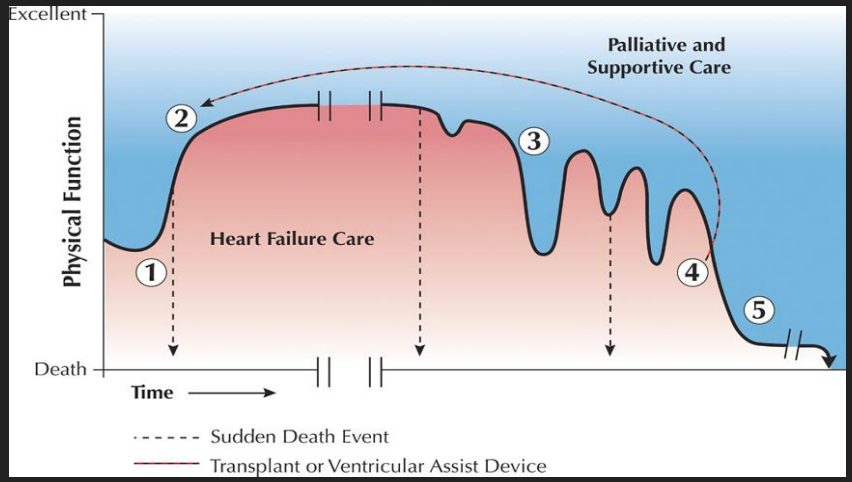
Cancer

- Chemotherapy
- Often a transition point
- Public awareness that cancer can cause death
- Investigations "show" progression
- Understanding variable



Heart Failure

- HF medications continue
- No transition points
- Little awareness of prognosis in HF
- Imaging "hidden"
- Poor patient/family understanding



Symptom Prevalence

(Solano, Gomes and Higginson. JPSM. Jan 2006)

Heart Failure	Cancer
Breathlessness 60-88%	Breathlessness 10-70%
Fatigue 69-82%	Fatigue 32-90%
Pain 41-77%	Pain 35-96%
Anxiety / Depression 9-49%	Anxiety / Depression 3-79%
Insomnia 36-48%	Insomnia 36-48%
Nausea 17-48%	Nausea 6-68%
Constipation 38-42%	
Anorexia 21-41%	Anorexia 30-92%

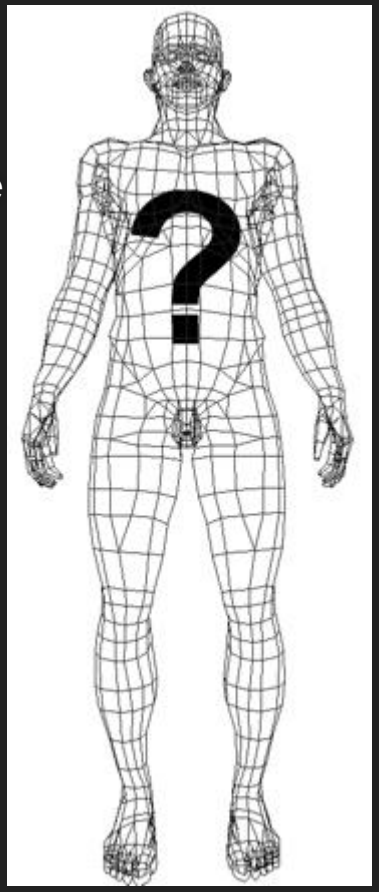
St Joseph's Hospice

Prognostication:

Prognostication underlies the infrastructure in palliative

But, in HF – prognostication

defies us!



More than 100 variables have been associated with mortality and re- hospitalization in heart failure

- General
  - Age, diabetes, sex, weight (BMI), etiology of HF, comorbidities (COPD, cirrhosis)
- Laboratory markers
  - Na, creatinine (and eGFR), urea, BUN,
  - Hgb, % lymphocytes,
  - uric acid
  - Low HDL
  - Insulin resistanc
- Urine
  - Abluminuria
  - NGAL - neutrop lipocalin
- Biomarkers
  - BNP, NT pro BNI
  - GDF-15 (growth
  - cortisol, TNF, ET, N
  - adrenomedullin,
  - protein apoptosis
- Medication
  - Intolerance to ACEI, diuretic dose
- FC IV
  - Especially if sustained > 90 days
  - 6 minute walk

WHAT SHOULD YOU DO ?????

- Cardiopulmonary markers
  - Peak VO2, % predicted, VE/VCO2, AT, workload, systolic BP < 130, HR recovery
- Clinical Exam markers
  - BP (admission and discharge), heart rate, JVP, +S3, cachexia
  - Depression
  - ep apnea
  - e (LV, LA, RA), sphericity,
  - ons
- Hemodynamic markers
  - PA pressures, CO, CI, MVO2
- Endomyocardial biopsies
  - Microarrays transcriptomic biomarkers
- Marital status

Consistent Predictors

Increasing age

Lower ejection fraction

Higher NYHA class

Hyponatremia

Elevated and rising BUN

Repeated admissions to hospital

From Selby, D. 2008

Another way to think about it:

Significant cardiac dysfunction with:

- Marked dyspnea and fatigue
- End organ hypo-perfusion at rest
- Symptoms with minimal exertion
- Maximal medical therapy

AHA Stage D – refractory symptoms

Goodlin et al, Journal of Cardiac Failure Vol. 10 No. 3 2004

Hunt SA et al JACC 2001;38:2101–13.

Take home points

- Advanced heart failure techniques such as TAVR and Mitraclip are often considered in patients with severe heart failure and other comorbidities which effect outcomes and improvement on an individual basis
- Palliative care and advanced care discussions are integral to treating these patients

Questions??