NYU Langone Health

RUSK REHABILITATION

Rehabilitation Management of Transcatheter Heart Procedures

Disclosures

- None

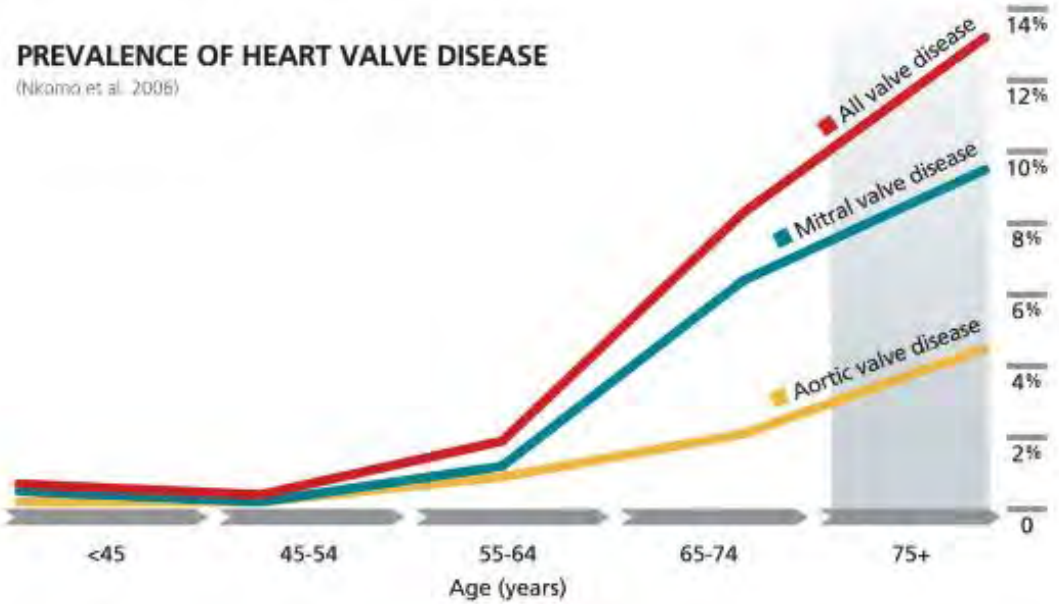
NYU Langone Health

Objectives

- Discuss Current State of Transcatheter Procedures
- Review Evidence and Future Studies
- Describe Rehabilitative Management across the Continuum of Care

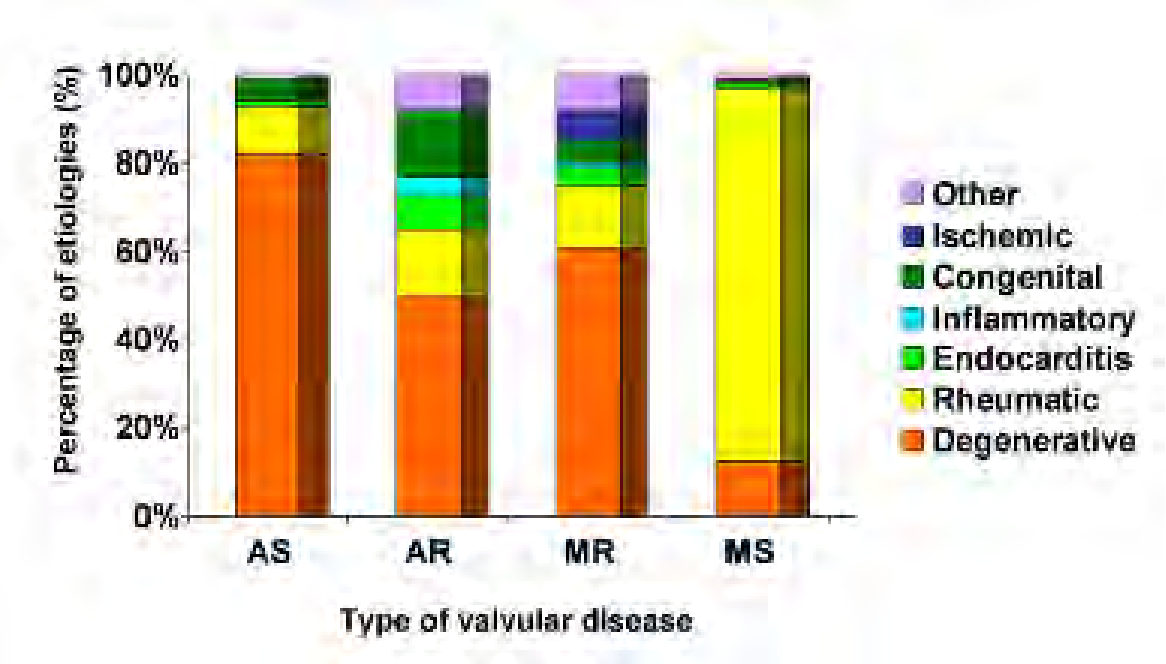
NYU Langone Health

Heart Valve Disease Incidence



NYU Langone Health

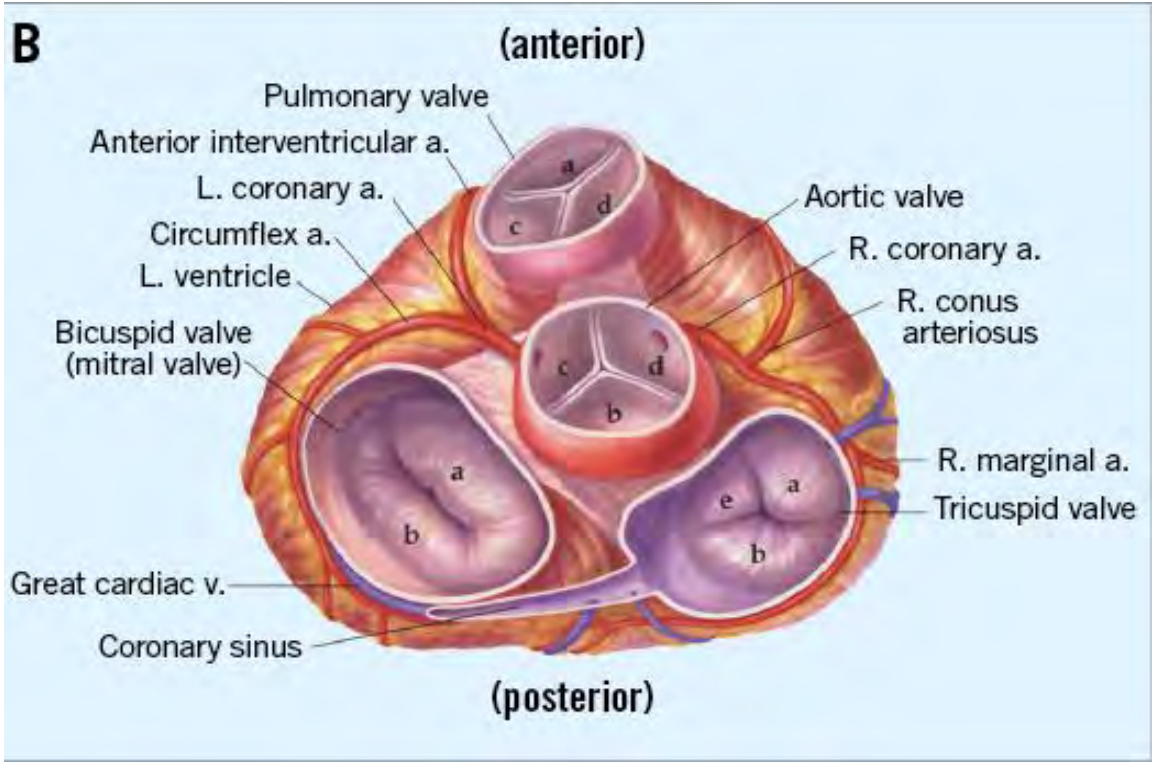
Heart Valve Disease Incidence



Canadian Journal of Cardiology 30 (2014) 962-970

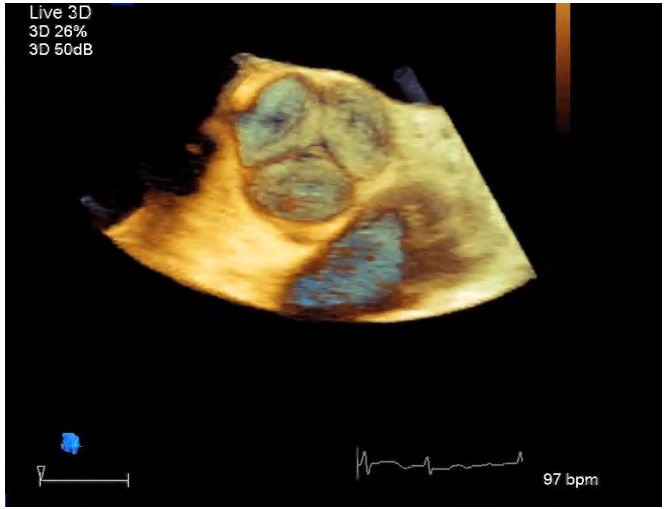
NYU Langone Health

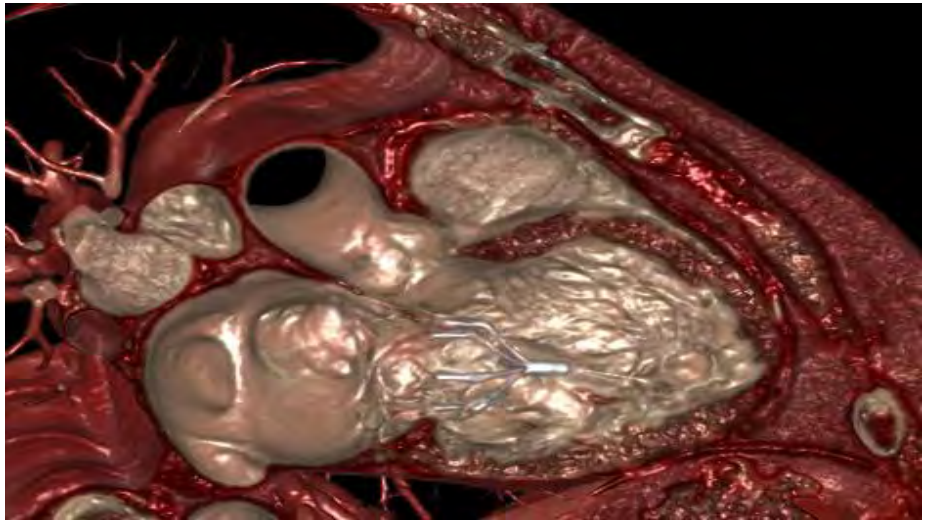
Valve Anatomy

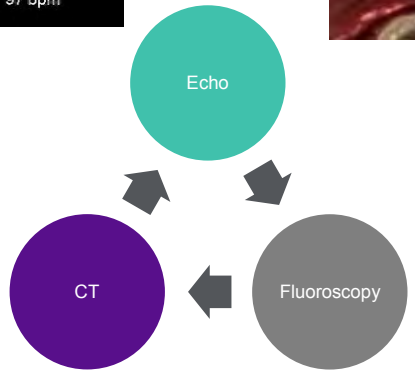


NYU Langone Health

Advances in Technology, Technique, and Imaging





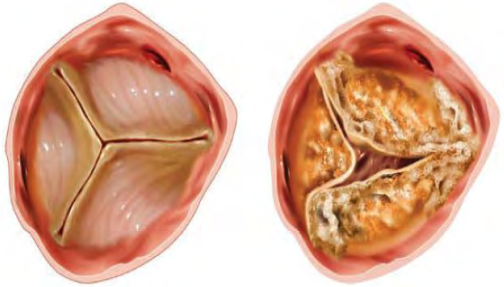


NYU Langone Health

Projected Growth

NYU Langone Health

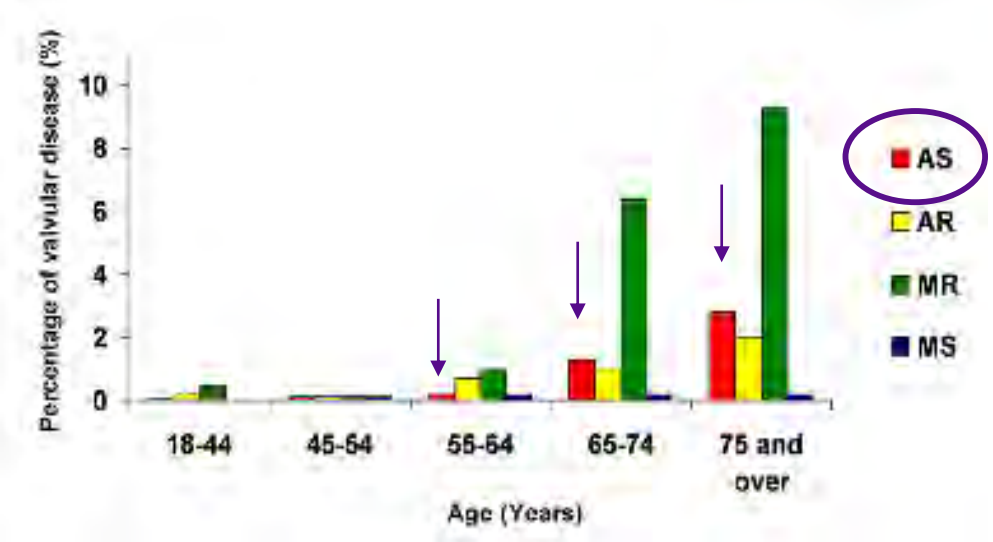
Aortic Stenosis (AS)



Normal Valve | Stenotic Valve

Congenital Abnormality	Rheumatic Fever	Infection	Age-Related Calcific Aortic Stenosis
less common →			more common
In some cases adults may develop aortic stenosis resulting from a congenital abnormality.	Adults who have had rheumatic fever may also be at risk for aortic stenosis.	Aortic stenosis can be caused by various infections.	Aortic stenosis in patients over the age of 65 is usually caused by calcific (calcium) deposits associated with aging.

Aortic Valve Disease Incidence

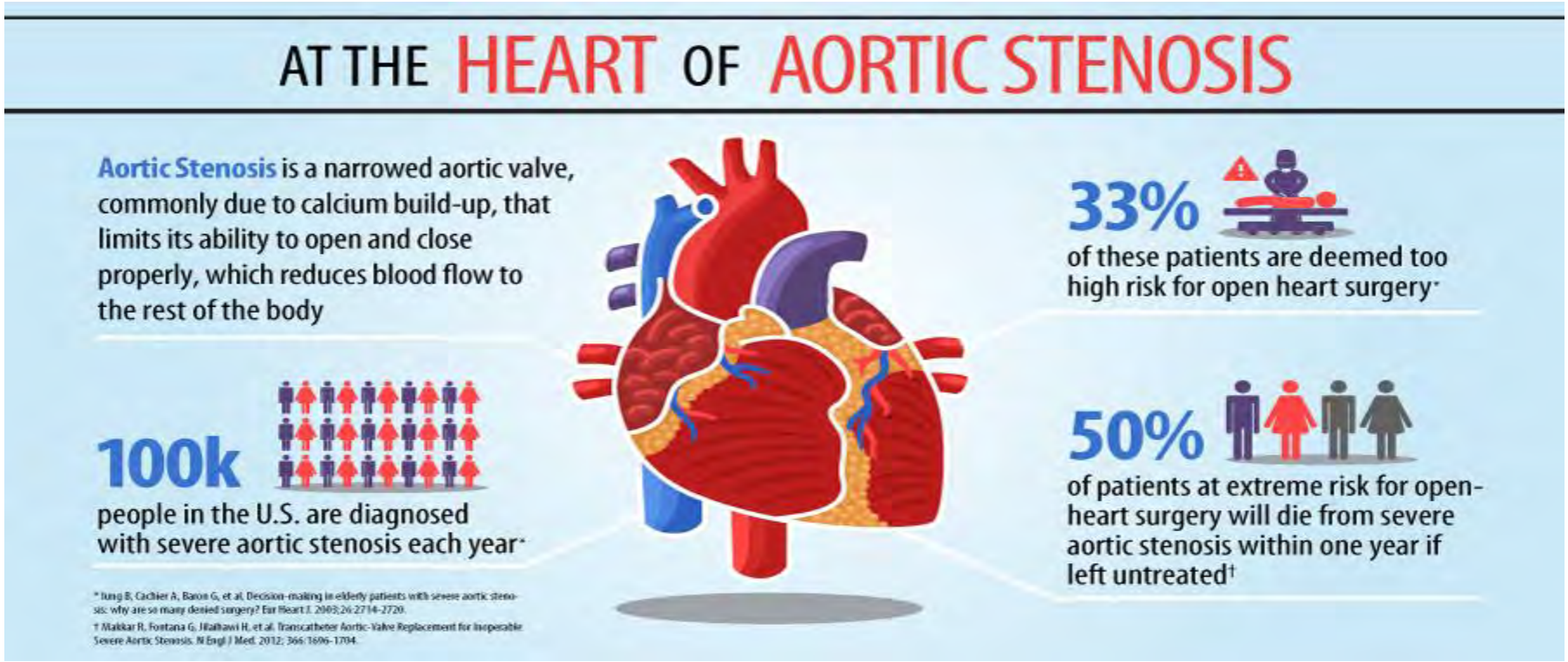


- ≤0.2% before 65 years of age
- 1.3% between 65 and 74 years
- 2.8% after 75 years

Canadian Journal of Cardiology 30 (2014) 962-970

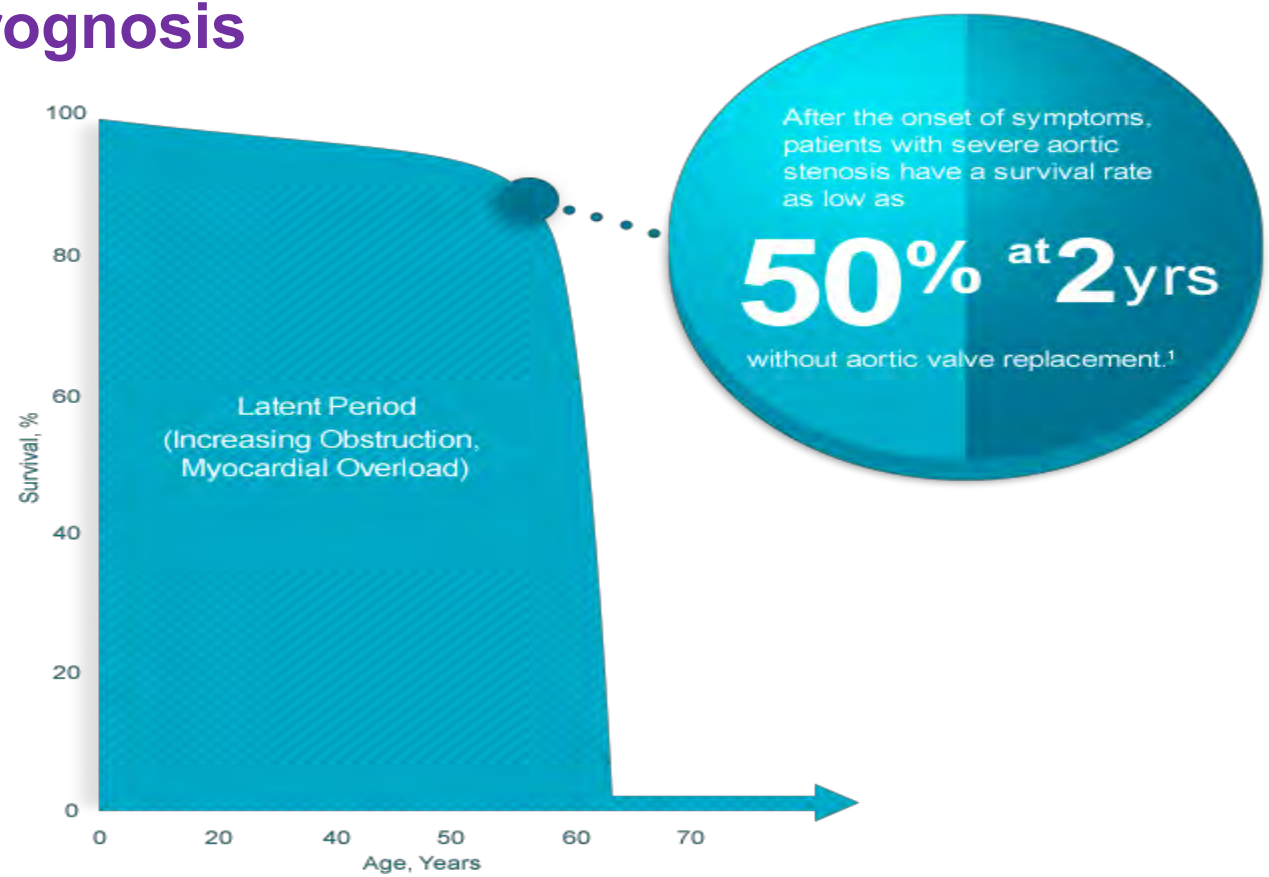
NYU Langone Health

Epidemiology



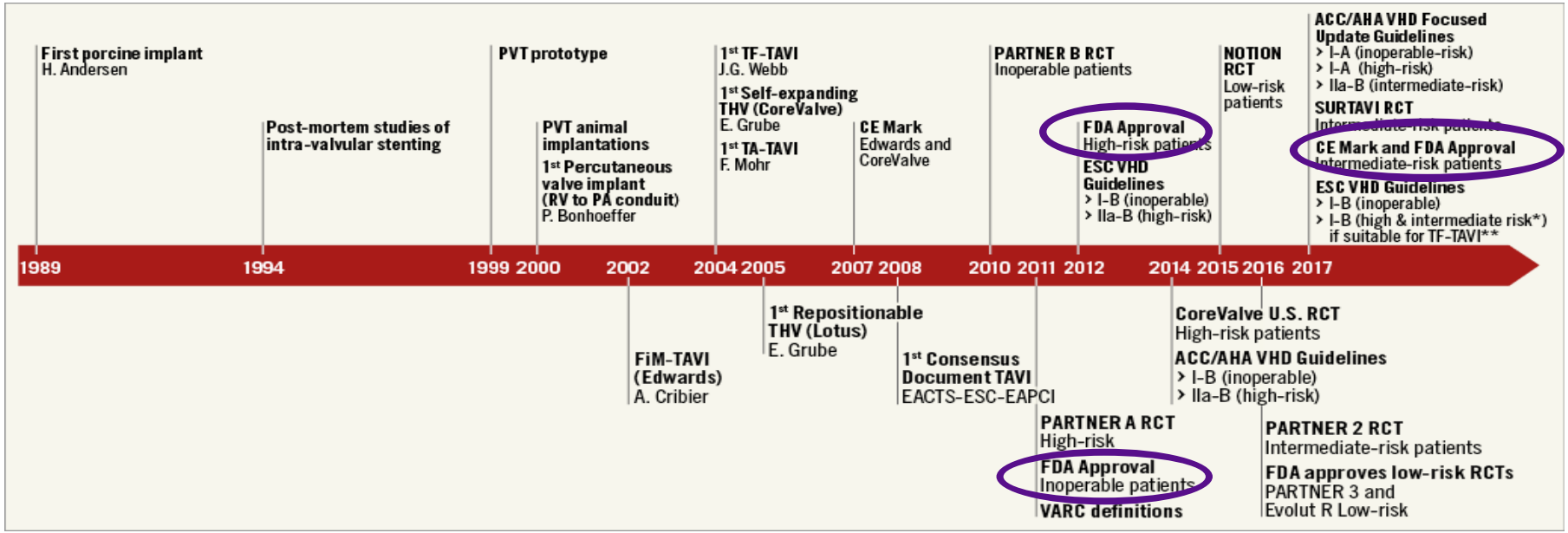
NYU Langone Health

Prognosis



NYU Langone Health

Evidence: Timeline of TAVR Evolution



2016 EuroIntervention

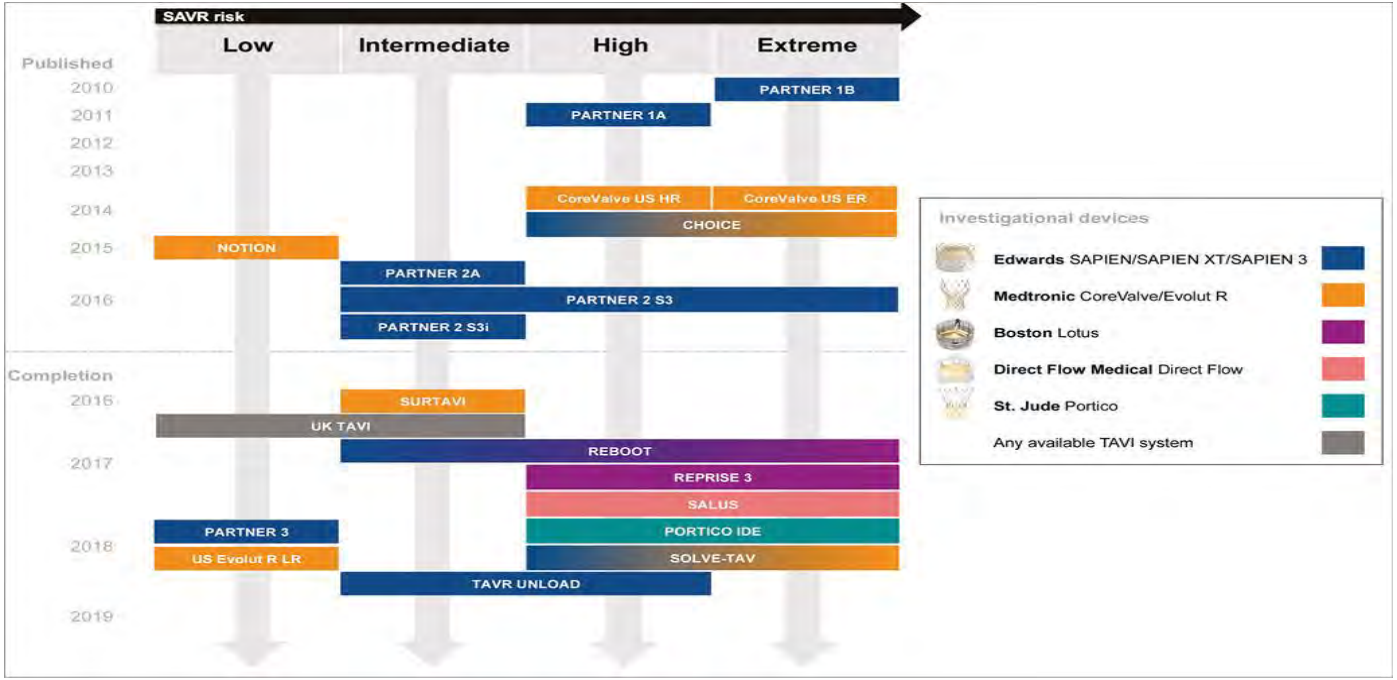
NYU Langone Health

Literature

- Partner A&B, II
- Corevalve, SurTavi

NYU Langone Health

TAVI Trials: Impact on Clinical Practice



2016 EuroIntervention

NYU Langone Health

SAVR vs TAVR: Current Guidelines

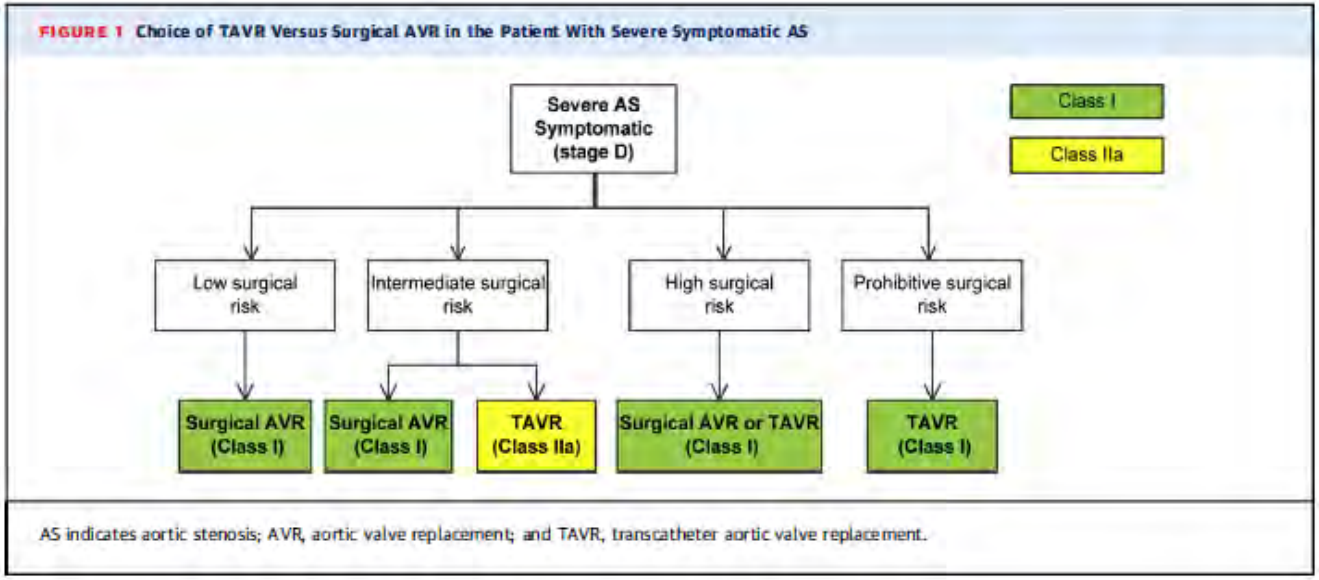
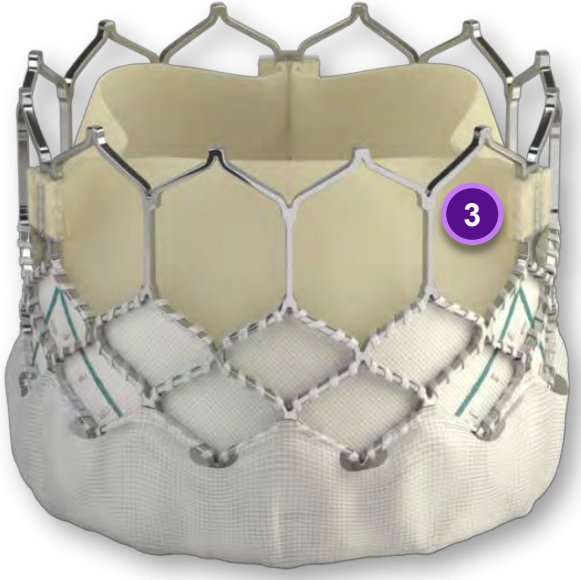


Figure 1. American Heart Association/American College of Cardiology guidelines recommendations for TAVR versus surgical aortic valve replacement in severe AS. Adapted from Nishimura RA et al[2] and reprinted with permission from the *Journal of the American College of Cardiology*; Publisher: Elsevier. Abbreviations: AS, aortic stenosis; AVR, aortic valve replacement; TAVR, transcatheter aortic valve replacement.

NYU Langone Health

TAVR: Valve Systems

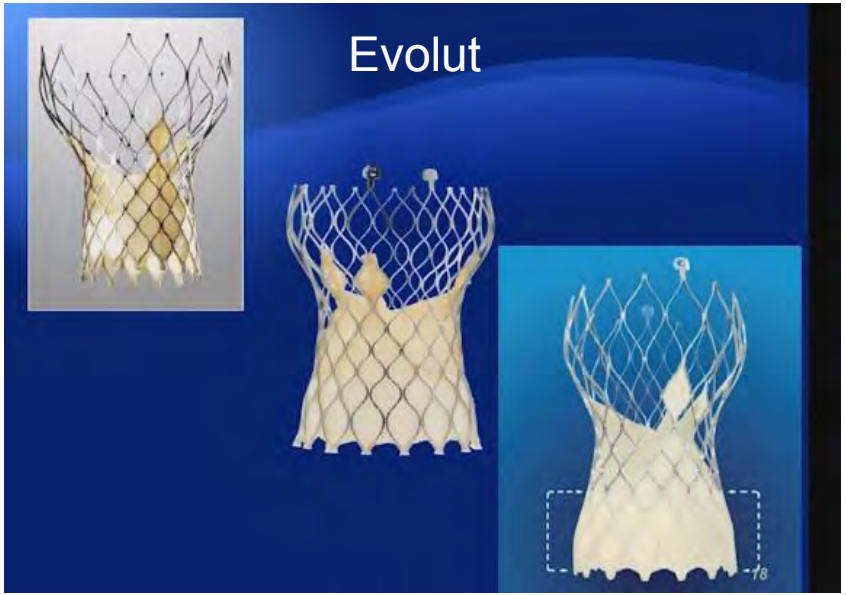
Sapien 3 Valve



Evolut Pro Valve

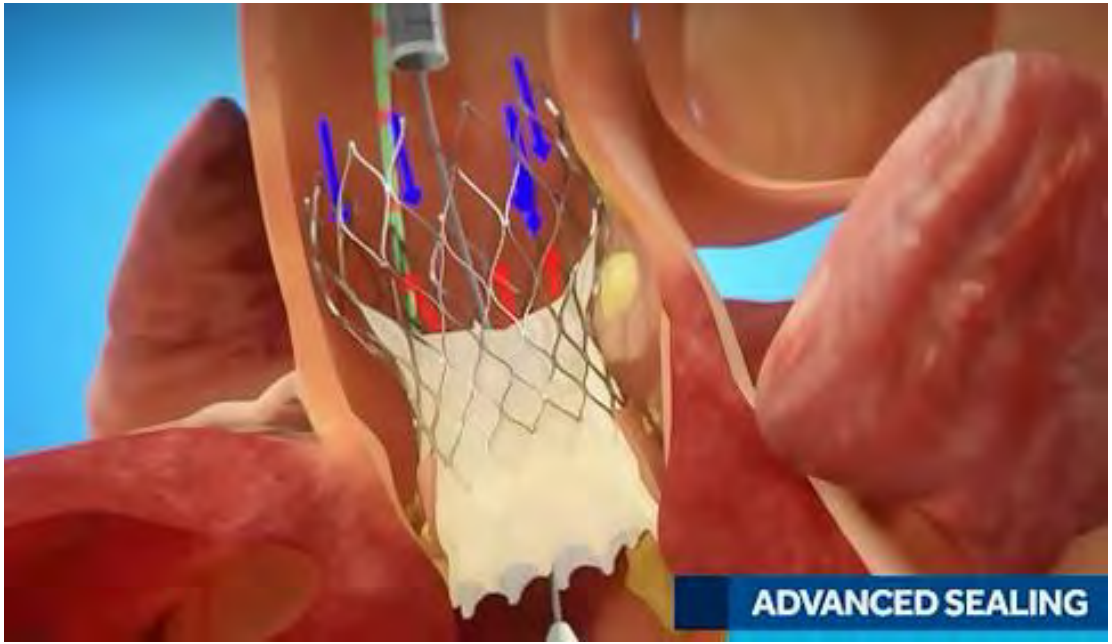
NYU Langone Health

Device Evolution



NYU Langone Health

TAVR: Evolut Pro



NYU Langone Health

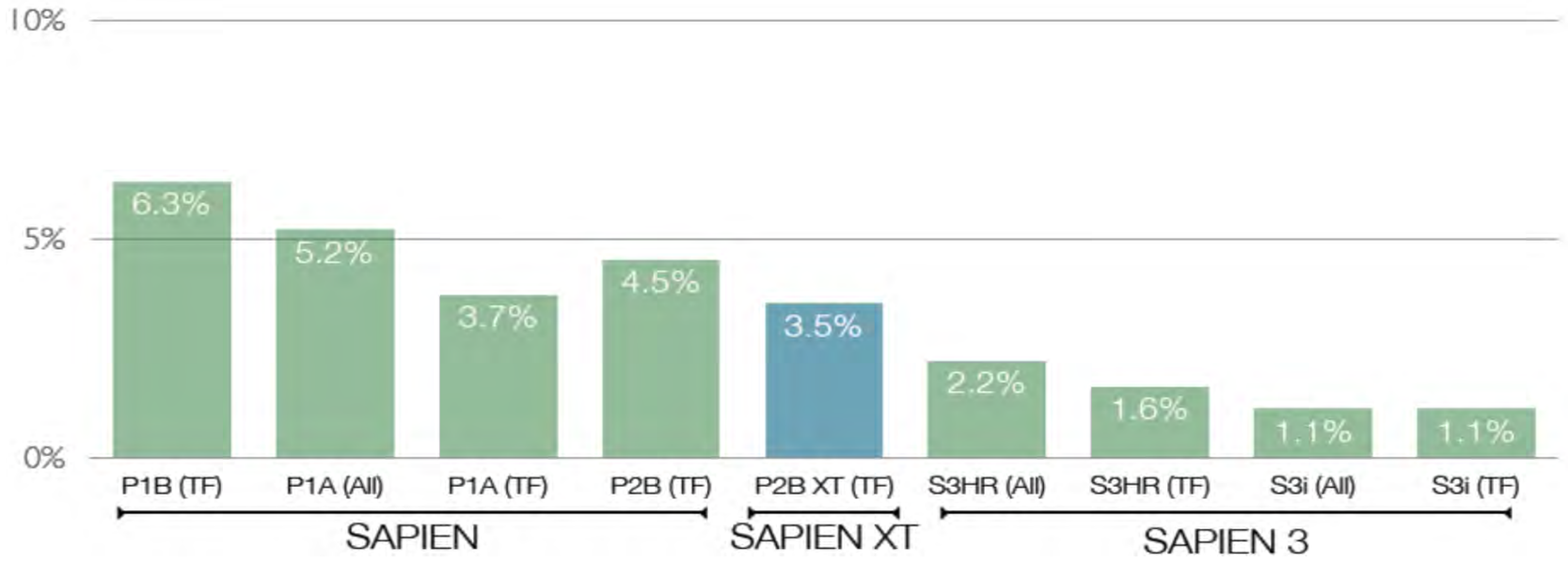
TAVR: Sapien 3

Initial Positioning	Deployment	Final Placement
		
Positioning	Inflation	*Placement*

NYU Langone Health

Mortality Rates

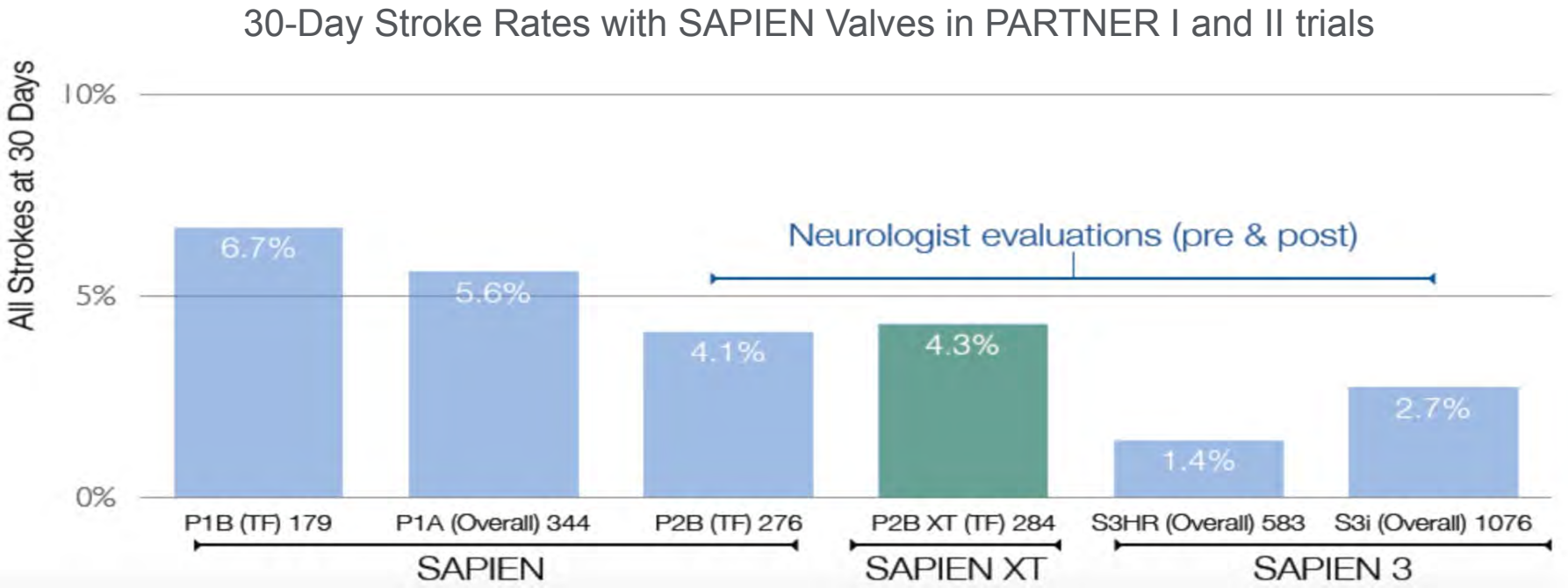
30-Day Mortality Rates with SAPIEN Valves in PARTNER I and II trials



Vahl et al. JACC 2016

NYU Langone Health

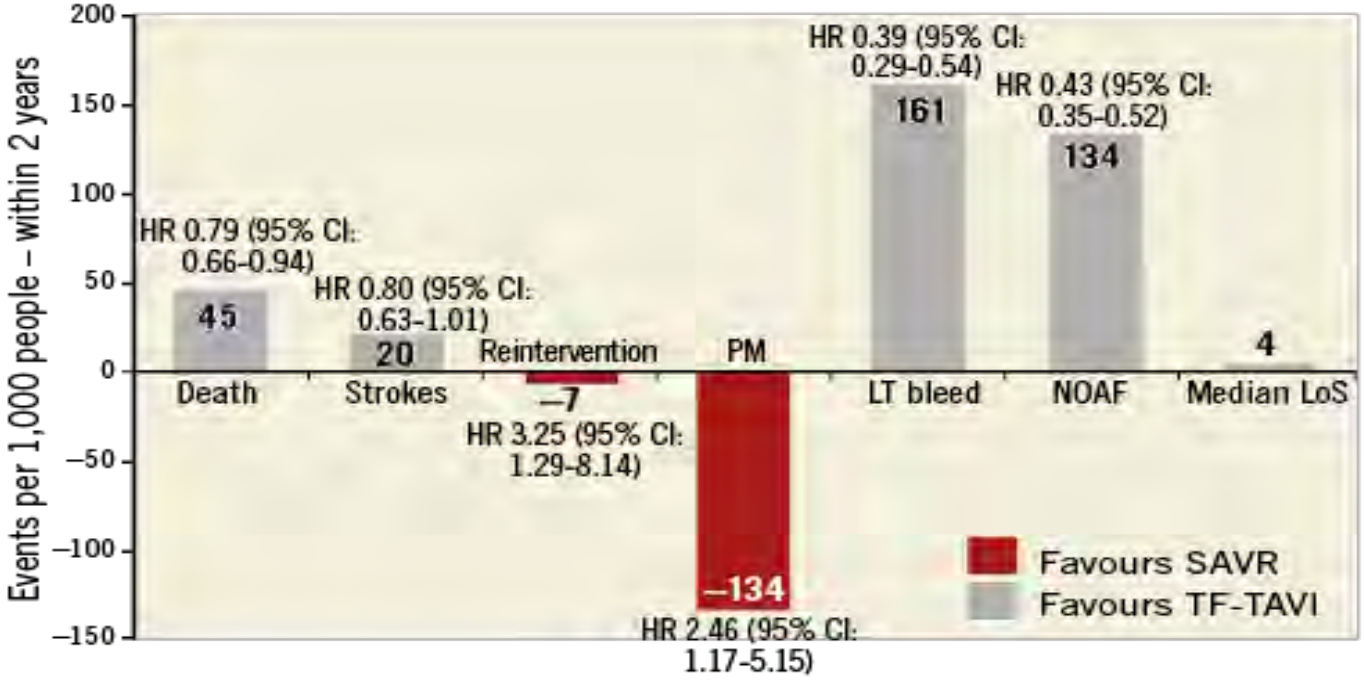
Stroke Rates



Vahl et al. JACC 2016

NYU Langone Health

TAVR vs SAVR

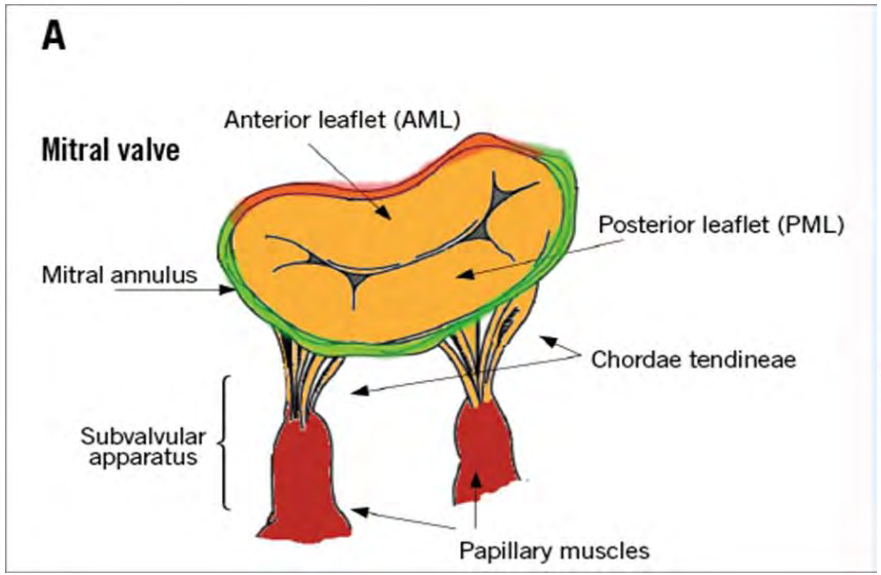


Comparison of major clinical outcomes between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR).

Siemieniuk RA et al. BMJ 2016

NYU Langone Health

Mitral Valve Anatomy



Normal AORTIC valve in adult humans is roughly the size of a **US nickel or dime.**

2-4 cm²

Normal MITRAL valve area in adult humans is roughly the size of a **US quarter.**

4-6 cm²

Normal TRICUSPID valve in adult humans is roughly the size of a **US half-dollar coin.**

6-8 cm²

NYU Langone Health

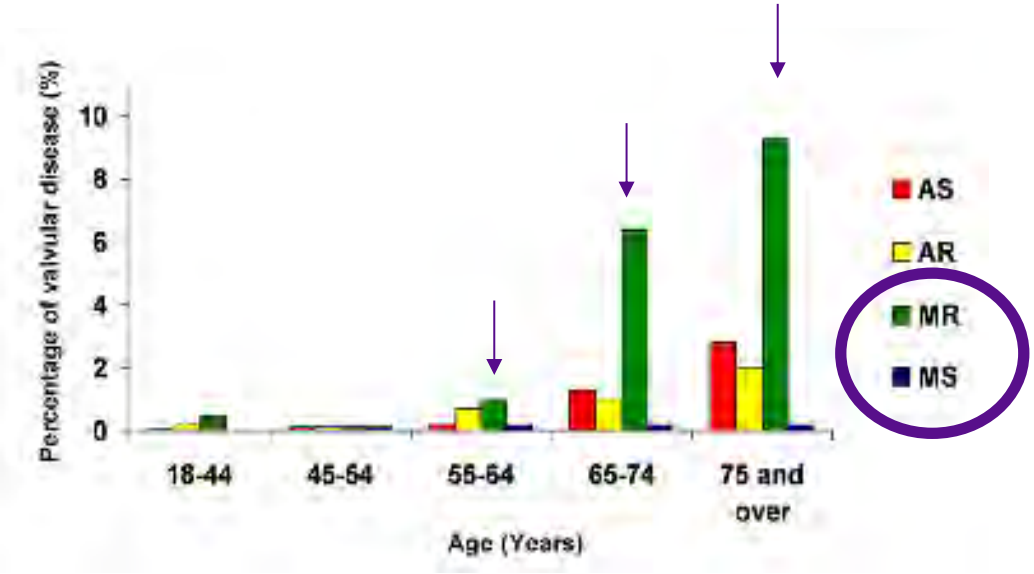
Mitral Valve Disease

Mitral Stenosis	Acute Mitral Regurgitation	Chronic Mitral Regurgitation

•Rheumatic - Majority
•Congenital
•Prosthetic valve stenosis
•Mitral Annular Calcification
•Left Atrial Myxoma
	•Infective endocarditis
	•Ischemic Heart disease
	•Mitral valve prolapse
	•Chordal rupture
	•Papillary muscle rupture
	•Chest trauma
		•Ischemic Heart disease
		  •Papillary ms dysfunction
		  •Inferior & posterior MI
		•Mitral Valve prolapse
		•Infective endocarditis
		•Rheumatic
		•Prosthetic
		•Mitral annular calcification
		•Cardiomyopathy
		  •LV dilatation

NYU Langone Health

Mitral Valve Disease Incidence



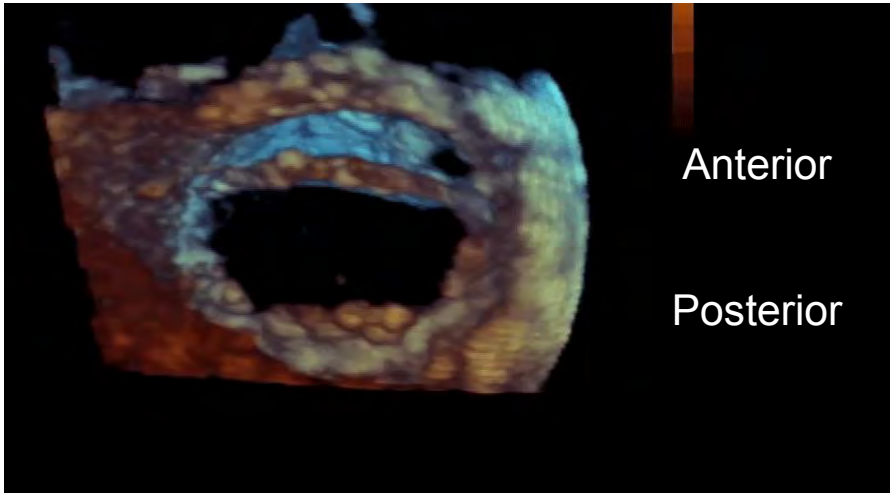
- MR most common
- MS rare with estimates of 0.1%
- Increased risk with normal aging

Canadian Journal of Cardiology 30 (2014) 962-970

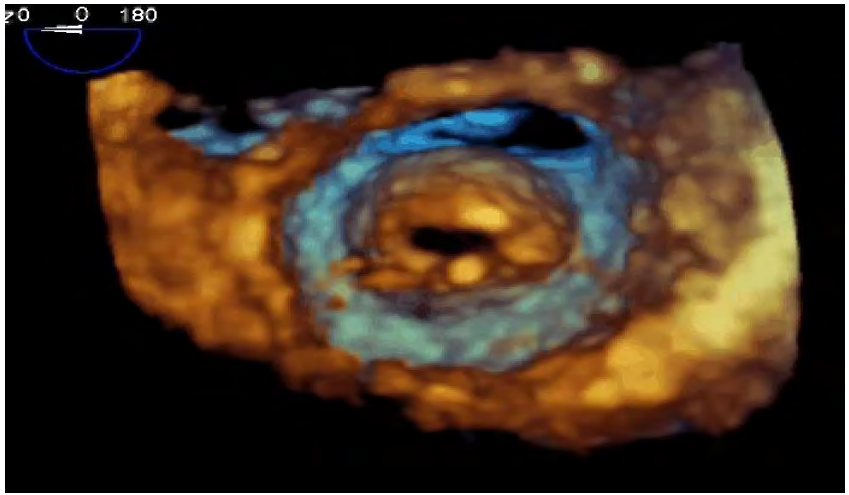
NYU Langone Health

Normal Mitral Valve vs. Rheumatic Mitral Stenosis

Mitral valve seen from **left ventricular** perspective



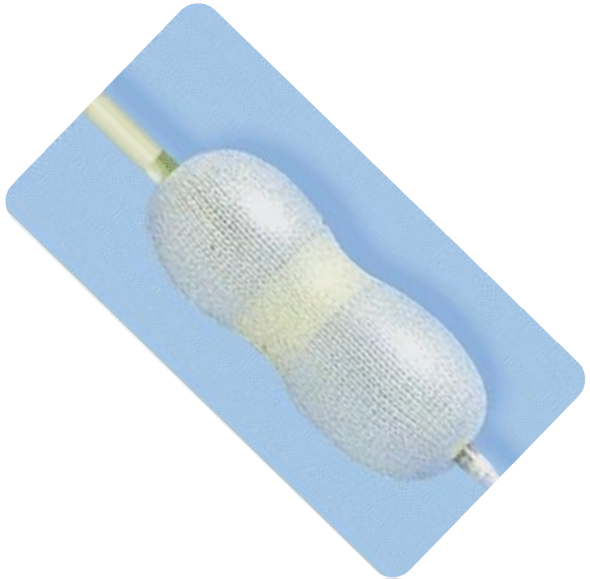
Normal mitral valve



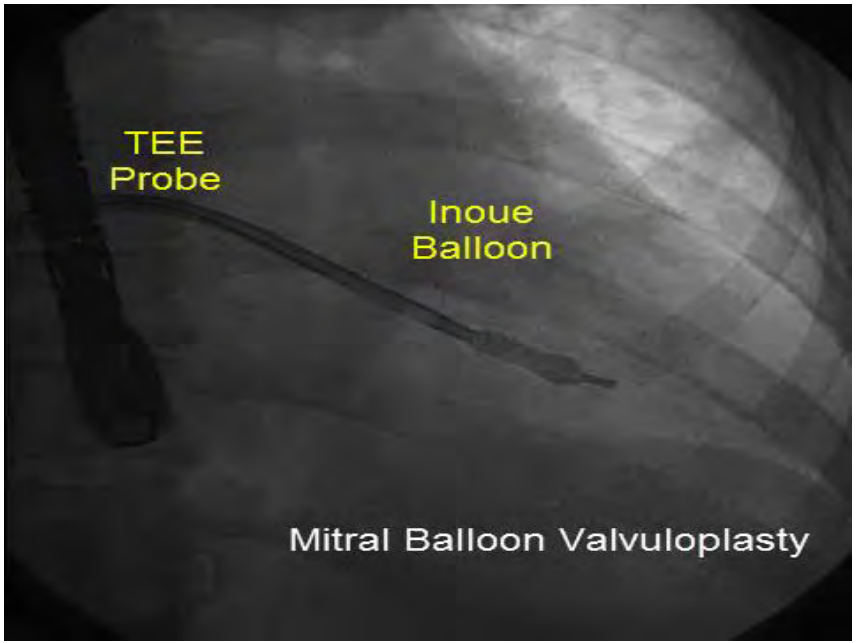
Severe mitral stenosis

NYU Langone Health

Percutaneous Mitral Balloon Valvuloplasty



The balloon is reinforced with a nylon micromesh. Its shape changes in 3 stages, depending on the extent of inflation



Fluoroscopic guidance of PMBV

NYU Langone Health

Mitral Regurgitation Incidence

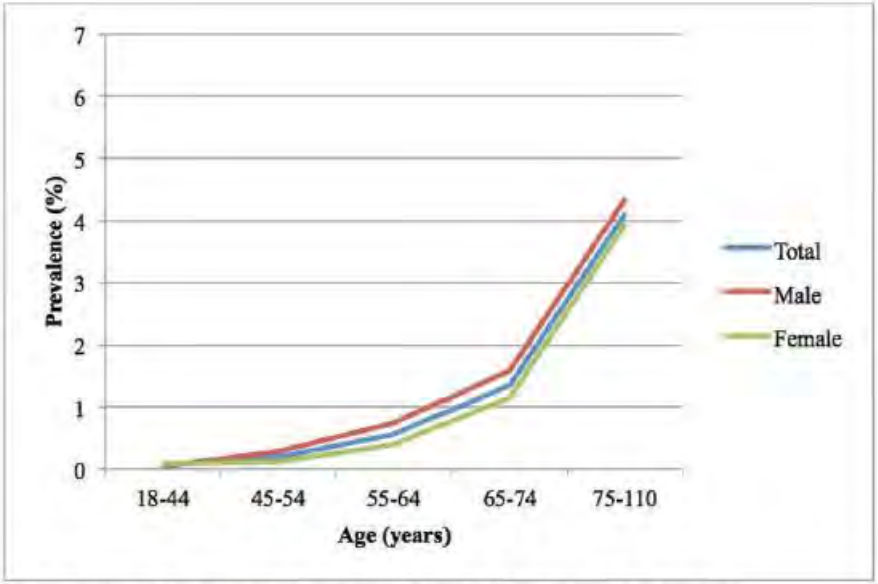
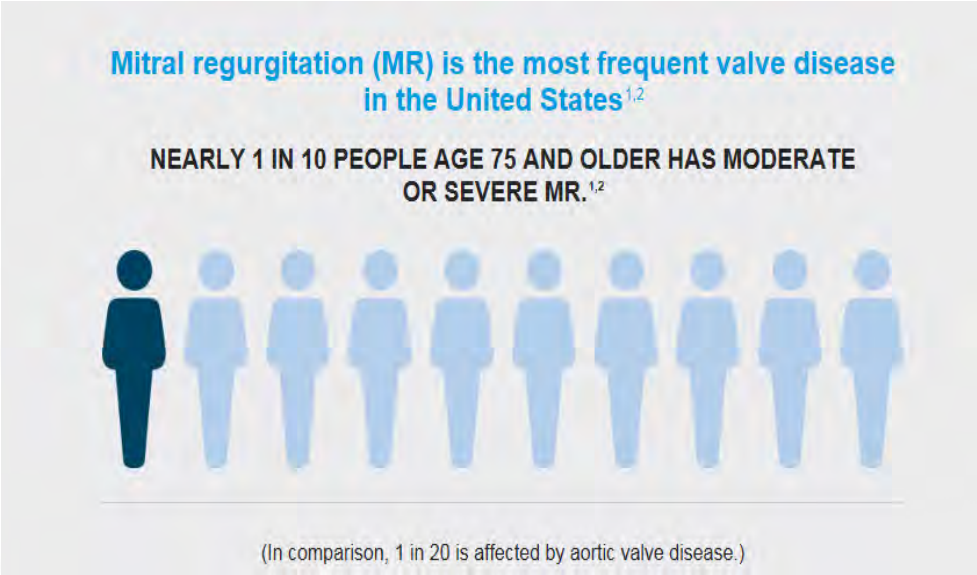


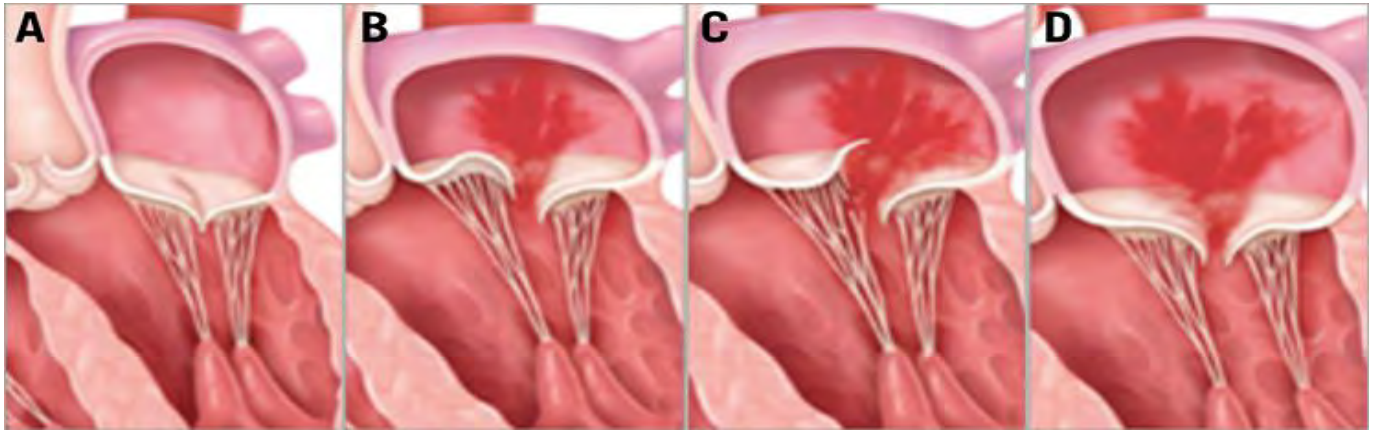
Figure: Prevalence of isolated moderate to severe MR according to age and sex

JACC April 5, 2016 Volume 67, Issue 13



NYU Langone Health

Mechanism of Mitral Regurgitation



Types of mitral regurgitation. A) Normal mitral valve. B) Degenerative MR caused by mitral leaflet prolapse. C) Degenerative MR caused by flail leaflet. D) Functional MR caused by dilated ventricle and tethering of the mitral leaflets.

NYU Langone Health

Transcatheter Mitral Valve Repair Technologies

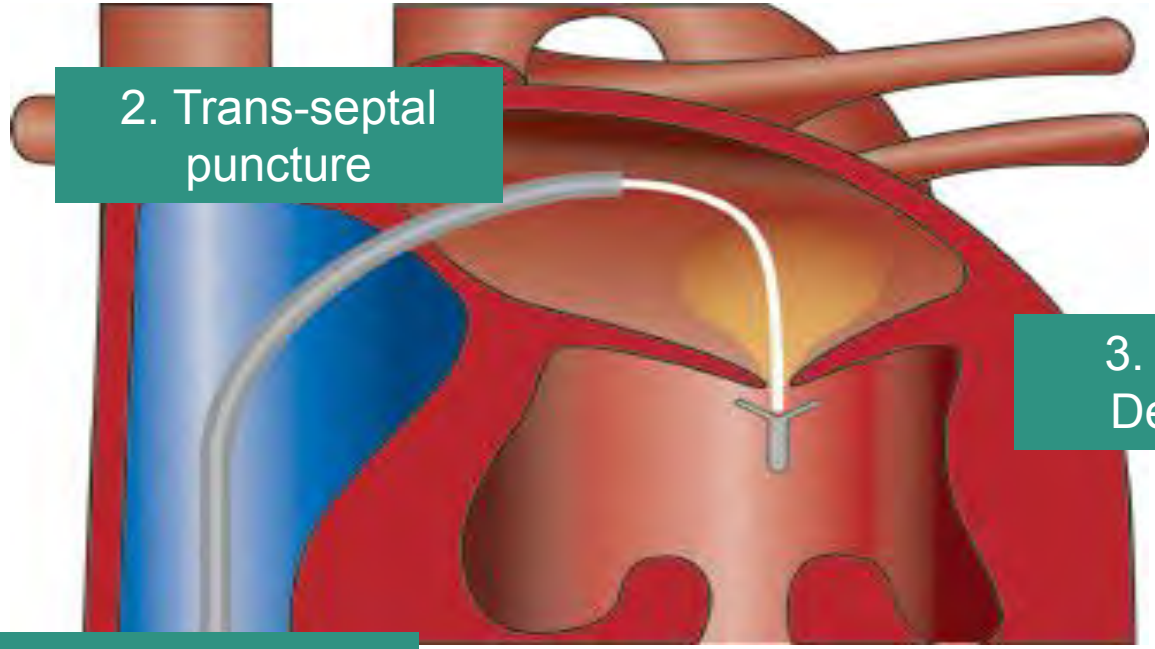
Company	Abbott	NeoChord	Cardiac Dimensions	Valtech Cardio	Mitralign
Name	**MitraClip**	**DS1000**	**Carillon***	**Cardioband**	**Bident**
					
Description	Edge-to-edge technique	Implantation through TA access	Coronary sinus cinching	Transcatheter surgical-like annuloplasty	Plication device
Strengths	Versatility (DMR and FMR)	Solid surgical background	Simplicity	Solid surgical background	Simpler than other direct annuloplasty
Weaknesses	Lack of annuloplasty	TA access	Limited efficacy, unpredictable results	Complexity, advanced imaging	Limited efficacy
MR aetiology	DMR and FMR	DMR	FMR	FMR	FMR
Status	About 40,000 patients worldwide	About 300 patients	About 500 patients	About 100 patients	About 100 patients

DMR: degenerative mitral regurgitation; FMR: functional mitral regurgitation. * Carillon® Mitral Contour System®; Cardiac Dimensions Inc., Kirkland, WA, USA

EuroIntervention 2016;12:Y97-Y101

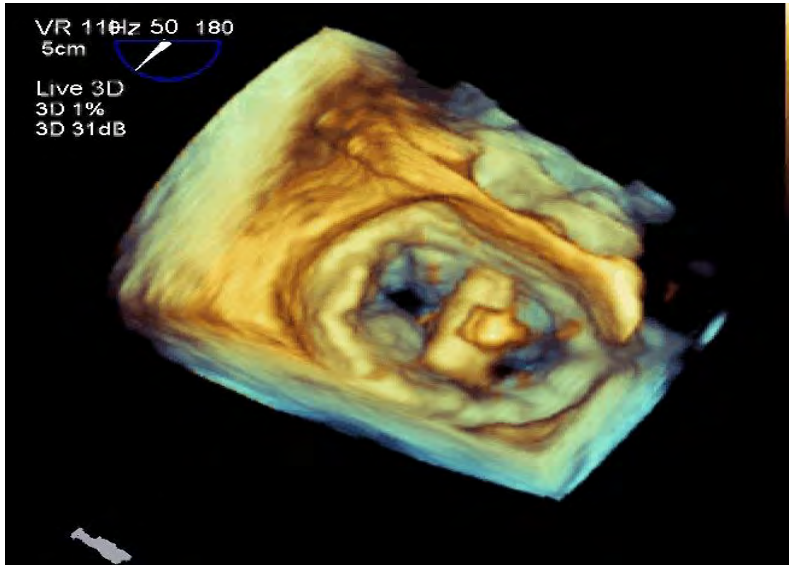
NYU Langone Health

3D TEE Guidance of Mitral Clip Procedure

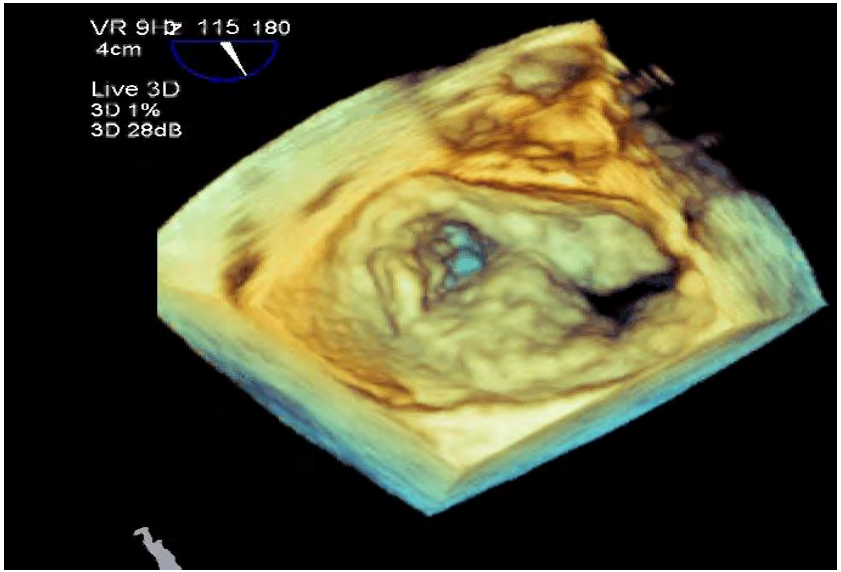


NYU Langone Health

CLIP POSITION



Clip being positioned:
note flail segment



Clip released:
no more flail segment

NYU Langone Health

Transcatheter Mitral Valve Replacement (TMVR)

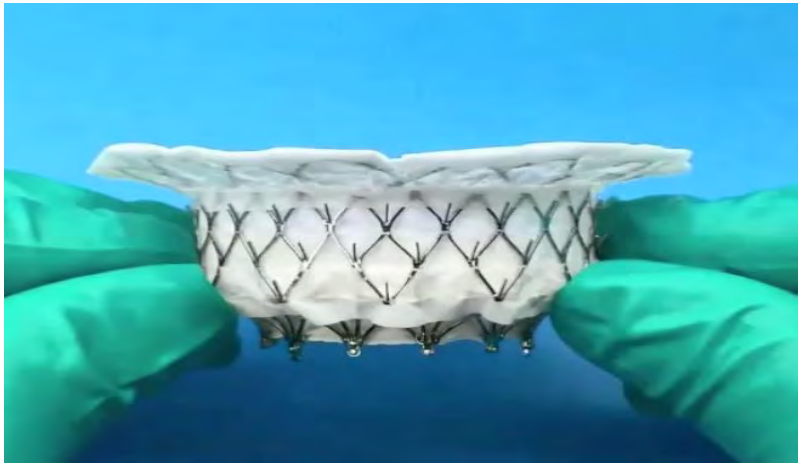
Company	Abbott	Edwards	Edwards	Medtronic	Neovasc
Name	Tendyne	CardiAQ	Fortis	Twelve	Tiara
					
Patients treated	31	12	23	15	15
First implant	October 2014	June 2012	February 2014	September 2014	January 2014
Functional aetiology	86%	64%	100%	73%	54%
Successful deployment	21/23 (91%)	9/11 (82%)	10/13 (77%)	14/15 (93%)	9/11 (82%)
30-day mortality	1/23 (4%)	5/11 (45%)	5/13 (38%)	2/15 (13%)	3/11 (27%)
MR grade 0 at follow-up	19/19 (100%)	na	8/9 (89%)	13/14 (93%)	na

MR: mitral regurgitation; na: not available (adapted from Meredith I. Transcatheter Mitral Valve Implantation: Early Clinical Outcomes. EuroPCR 2016).

EuroIntervention 2016;12:Y97-Y101

NYU Langone Health

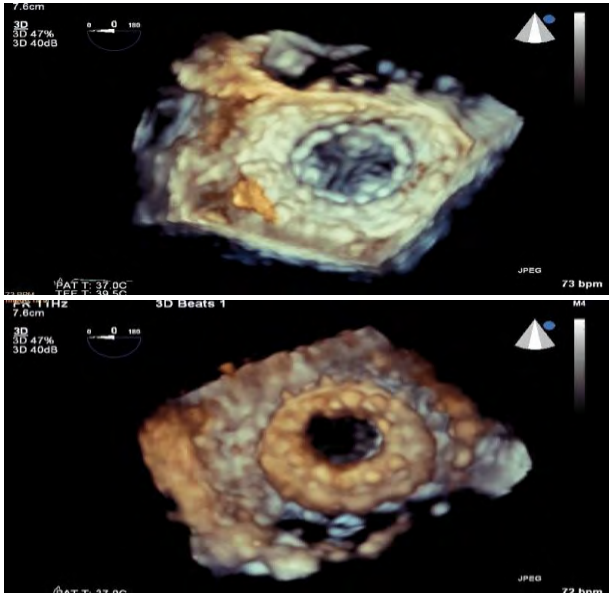
INTREPID – TMVR System

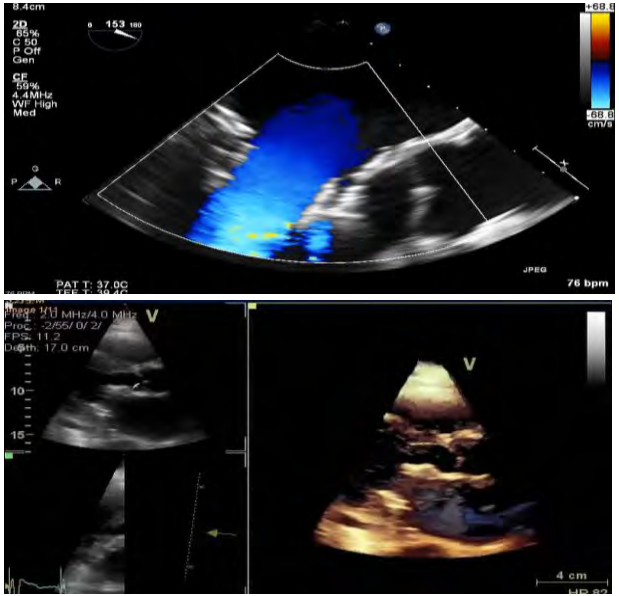


- Conformable Outer Stent engages annulus and leaflets providing fixation and sealing while isolating the inner stent from the dynamic anatomy
- Circular Inner Stent houses a tricuspid bovine pericardium valve
- Flexible Brim

NYU Langone Health

Intrepid Transapical Valve Program





CAISSON Transcatheter MVR

ANCHOR

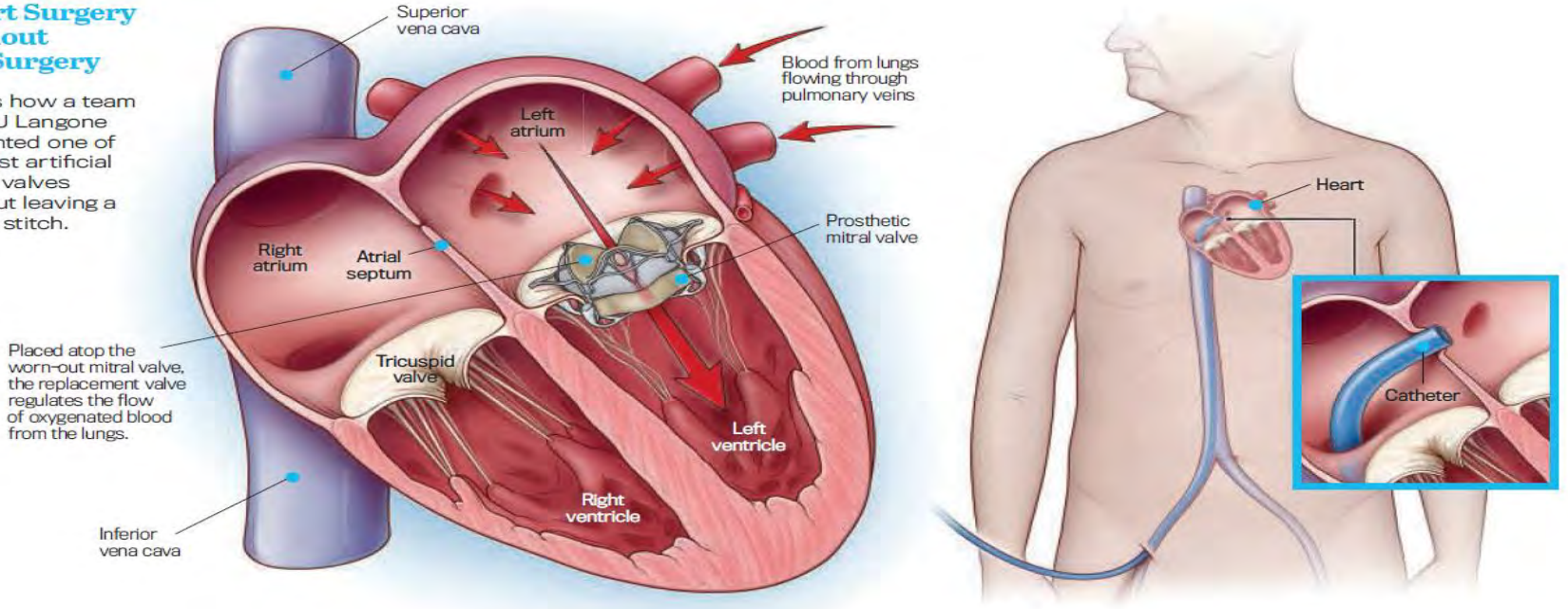
VALVE

VALVE IN ANCHOR

NYU Langone Health

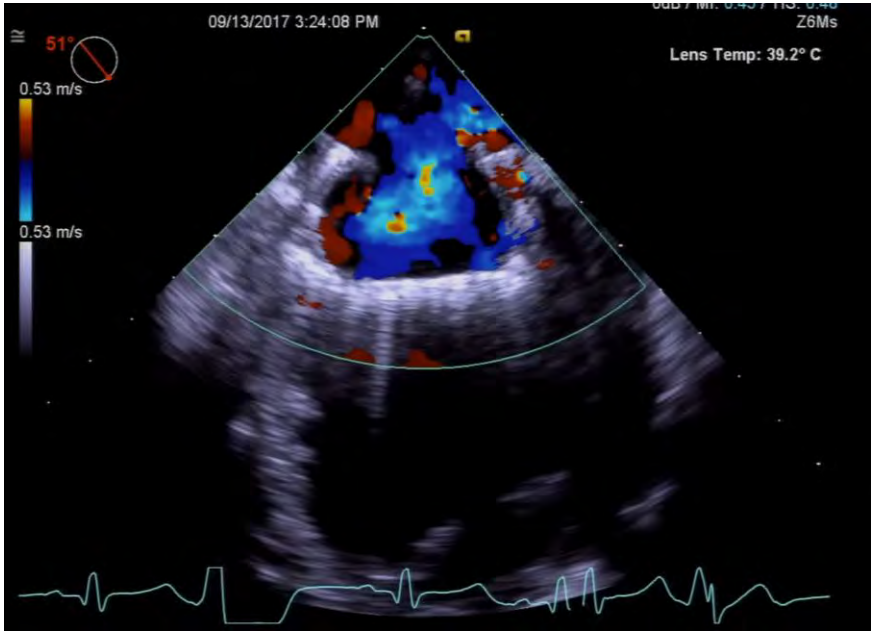
Heart Surgery without the Surgery

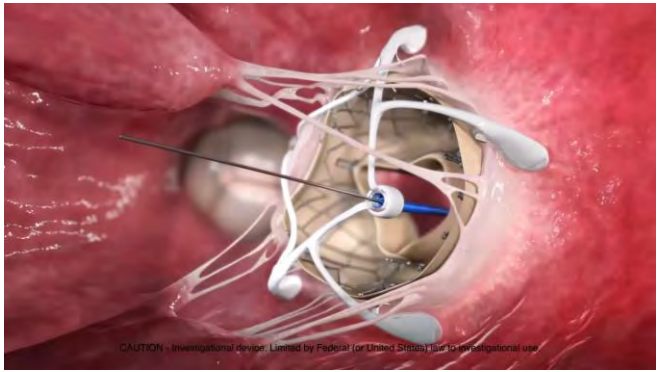
Here's how a team at NYU Langone implanted one of the first artificial mitral valves without leaving a single stitch.

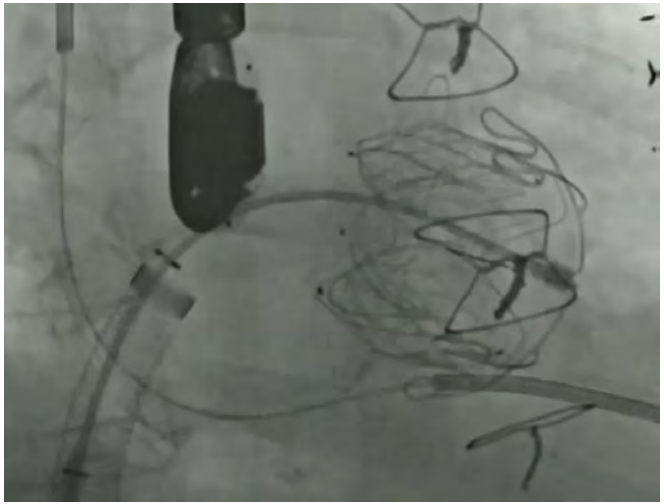


NYU Langone Health

Final Deployment







NYU Langone Health
NYU Langone MEDICAL CENTER

Rehabilitative Management Across the Continuum

Phase I: Acute Hospital

Home Care/TeleRehabiltation

Subacute Rehabilitation

Inpatient Rehabilitation

Phase II & III: Outpatient Rehabilitation

Community

NYU Langone Health

Rehabilitation Considerations

Where does your patient fit…

- Inoperable, High Risk, Intermediate, Low Risk???
- Society of Thoracic Surgeons (STS) score:
  - Low Risk
  - Intermediate Risk
  - High Risk
- Comorbid Conditions
- Frailty Score
- How long have they been monitoring (Degree of deconditioning)
- Functional Status

STS Risk Score:
Procedure: AV Replacement
Risk of Mortality: 7.444%
Morbidity or Mortality: 31.567%
Long Length of Stay: 18.976%
Short Length of Stay: 9.57%
Permanent Stroke: 3.832%
Prolonged Ventilation: 22.66%
DSW Infection: 0.146%
Renal Failure: 12.799%
Reoperation: 10.821%

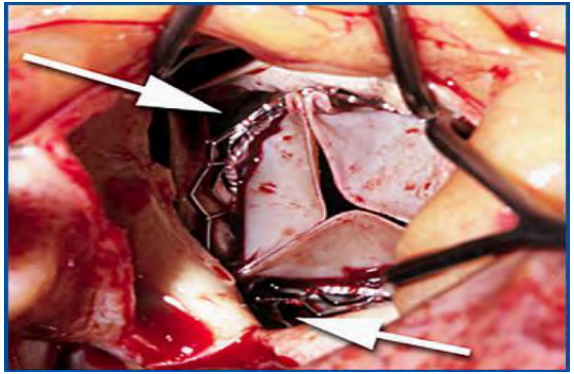
Katz Index of Independence In Activities of daily Living: media
5 meter walk speed:media
6 minute walk: media
Grip test: media
Living situation: alone
Caregiver: none
Greater than 2 Falls in the last six months: No
Has the patient been hospitalized over the last year: No
If yes how many times: n/a
NYHA II
CCS no angina

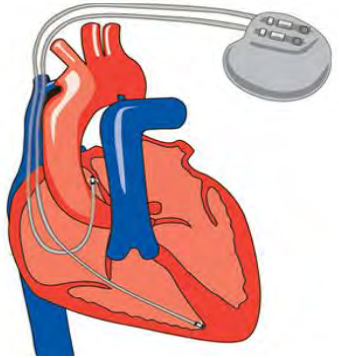
NYU Langone Health

Rehabilitation Considerations

Major Complications

- Bleeding
- Stroke
- Arrhythmia: AF, High Degree AV Blocks, BBB, PPM
- Paravalvular Leak (PVL)
- Thrombosis

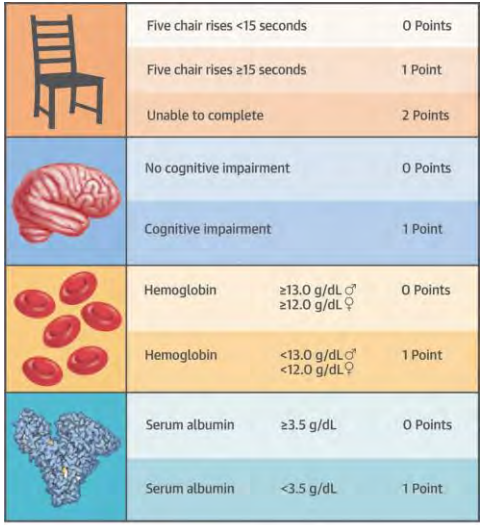




NYU Langone Health

Outcomes

- Frailty Tests
  - Grip strength
  - Essential Frailty Tool
  - Katz Index, Barthel Index
  - Timed Up and Go (TUG)
- Functional Testing
  - 5 meter walk speed
  - 6 minute walk test (6MWT)
  - Exercise Tolerance Test (ETT)
  - Cardiopulmonary Exercise Test (CPET)
- Questionnaires
  - KCCQ



EFT Score	1-Year Mortality TAVR	SAVR
0-1	6%	3%
2	15%	7%
3	28%	16%
4	30%	38%
5	65%	50%

EFT Points: _____

Frailty in Older Adults Undergoing Aortic Valve Replacement. JACC 2017

NYU Langone Health

Signs and Symptoms

- Subjective: SOB, fatigue, palpitations, Incisional discomfort, Dizzy/lightheaded
- Observation:
  - Edema, Increased RR, JVD
- Examination:
  - Resting Vitals: HR, BP, Spo2
  - Auscultation: rales
  - ECG: Irregular heart beat (palpitations)
  - Incisional location

Assess hemodynamics with self care, transfers, ambulation

Decreased exercise tolerance and work capacity

NYU Langone Health

Acute: Post-op Rehab Guidelines

- Patient will be on bed rest for 3.0 hours post-op
- Therapist evaluates patient 3.0 hours post-op, once hemostasis achieved at catheter access sites and patient's HR and BP stable
- OOB/Ambulation as tolerated with vital signs monitored with each new position change (supine >semifowlers >long sitting > sitting EOB >standing >walking)
- Therapist to make mobility recommendations
  - Activity order based on therapist recommendations
  - Nursing/PCT to follow therapy recommendations
    - Therapy continue to make recommendations daily as patient progresses

Acute: Post-op Therapy Guidelines

- Plan of Care (LOS 2 days)
  - PT Provided (Monday-Sunday)
    - POD #0: 1x
    - POD # 1-2: 1x/discharged
  - OT (Monday-Friday, Weekends for Evals only, follow up sessions as need to ensure safe discharge)
    - POD # 1-2: 1x daily

Acute: Post-op Therapy Guidelines

- **Precautions**
  - Patients who are in complete heart block or have an extremely slow rhythm (<50bpm) and are TVP dependent should remain on bedrest. Some TVP dependent patients may be allowed OOB to chair for meals (case by case basis)
  - If patient cleared for OOB/ambulation with TVP, activity order must be present stating ‘patient cleared for OOB/ambulation with TVP’
  - Avoid shoulder ROM to side where TVP present
  - Ensure TVP stabilized with two anchors prior to mobilizing patient - consult NP/PA/RN to reinforce TVP
  - Once TVP removed, continue to carefully monitor VS response to activity

Phase II CR Literature

Transcatheter Aortic Valve Replacement: Optimizing Outcomes for Health Recovery.

Table 3

Benefits and Adverse Events of Cardiac Rehabilitation After Transcatheter Aortic Valve Replacement[a]

	Reference Number
Benefits	
Improved 6-min walk distance	41, 42, 45, 47, 48
Improved peak oxygen uptake	46, 48
Improved muscular strength, rowing, pull down, and leg press	46
Improved Barthel Index	42, 45,47
Improved quality of life	46
Adverse events	
No major complications were directly associated with the exercise training	42, 47, 49

[a]Barthel index is a validated scale (0 = total dependence; 100 = total independence) of independence in activities of daily living.[42,49]

References @ JCRP 2018, 38:1-7

NYU Langone Health

Phase II Systematic Review

- started cardiac rehabilitation early after TAVR (mean: 26 d)
- improvement in 6-min walk distance from 186 m to 257 m (odds ratio = 0.69; 95% CI, 0.47-0.91; *P* < .001).
- significant increase (3.7 mL/min/kg) in peak oxygen uptake on a cardiopulmonary exercise test, improved muscular strength, better quality of life, and reduced symptom burden.
- safe and is associated with marked improvements in exercise capacity, functional independence, and frailty parameters, and should be encouraged in all patients.

Cardiac rehabilitation programme after transcatheter aortic valve implantation versus surgical aortic valve replacement: systematic review and meta-analysis . *Eur J Prev Cardiol* . 2017 ; 24 (7): 688-697 .

Outpatient: Rehabilitation Management

Considerations

- Know your patient (comorbidities, STS, Frailty, etc.)
- Emphasis on Function Assessment
  - History of Falls, Balance, Transfers, Gait
- Cardiac Rehabilitation Session
  - Safety, choice the right modalities
- Monitor vitals closely
  - Establish baseline; HR, BP, ECG.
  - Determine if appropriate response to Activity
- Post-discharge recommendations:
  - Ensure post program plan is established

NYU Langone Health

Outpatient:

Exercise Presc

- Driven by Out
  - Frequency:
  - Intensity: TI
  - Type: TM, R
  - Time: 60 m
- Home Exercis
- Patient and F

	Pre-Rehab	Post-Rehab
Date:	01/24/2018	07/12/2018
Place:	ACC 16	ACC 16
Protocol:	naughton	naughton
Duration:	2:01	11:01
MET Level:	1.7	6.3
Rest HR:	90	70
Max HR:	111	130
Rest BP:	180/100	144/68
Max ex BP:	190/100	138/80
RPP:	21090	17940
ST Changes:	none	BLA, likely no significant changes
Symptoms:	Max HR achieved	Max HR achieved
Comments:	negative	Likely negative maximal EST for ischemia.

Stress Test Percentage Improvement: 270%

Exercise Prescription:
THR: 90-100
THR Changes: none
Starting MET Level: 1
RPE: 12 - 13
Predicted DC MET Goal: 3

Exercise Class Progress:
Avg. Starting MET: 3.5
Avg. Recent MET: 4.5
%Improvement: 29%

Percent of DC MET Goal Achieved:
Predicted MET: 3
Actual Met: 4.5
%Achieved: 150%

Exit Ex. Prescriptions:
THR: 110-120
RPE: 11-14

NYU Langone Health

Conclusion

- Percutaneous valve repair/replacement is a rapidly evolving field
- Numerous research trials evaluating new devices and lower risk patients
- Cardiac Rehab - need more supportive evidence
  - Standardize approach: Outcomes, Scales, Questionnaires
- Rehabilitation is safe and effective
  - Exercise Capacity: Improved 6MWT distance, Peak VO_2, MET Level
  - Improved Muscle Strength
  - Functional Independence
  - Frailty: Improved tests (Barthel, Katz, etc.)
  - Improved QOL
- Use rehabilitation evidence to help guide medical care

NYU Langone Health

Resources

- Transcatheter Aortic Valve Replacement: Optimizing Outcomes for Health Recovery. JCRP 2018, 38:1-7
- Cardiac rehabilitation program after transcatheter aortic valve implantation versus surgical aortic valve replacement: Systematic review and meta-analysis. European Journal of Preventive Cardiology 2017, 24:688-697.
- Functional Status and Quality of Life After Transcatheter Aortic Valve Replacement: A Systematic Review. Ann Intern Med 2014, 160:243-254.
- Exercise training improves exercise capacity and quality of life after transcatheter aortic valve implantation: A randomized pilot trial. Am Heart J 2016, 182:44-53.
- Predictors and Association With Clinical Outcomes of the Changes in Exercise Capacity After Trans Cather Aortic Valve Replacement. Circulation 2017, 136:632-643.
- TMVR: Continuing the Paradigm Shift in Valvular Heart Disease Therapy. JACC 2015, 66:9 1020-1022
- Transcatheter Mitral Valve Replacement Clears the First Hurdle. JACC 2017, 69:4 392-394.

NYU Langone Health