Heart Valves: What can go Wrong and the Latest Approaches to Making them Right Again

December 6, 2022

Sammy Elmariah, MD, MPH, FACC, FAHA, FSCAI
Chief, Interventional Cardiology
Medical Director, Cardiac Catheterization Laboratory
Co-Director, Heart Valve Program, UCSF
Associate Professor of Medicine, UCSF

UCSF Health
Heart & Vascular Center

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Anatomy of the Heart

Heart Pro III

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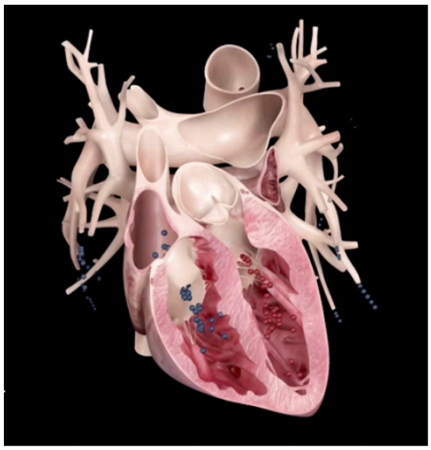
Valvular heart disease

- All valves can become leaky (regurgitant) or narrow (stenotic)
- Valvular heart disease becomes more prevalent with age
- >13% of adults over 75 years old
- Most common types:
  - Aortic stenosis
  - Mitral regurgitation
  - Mitral stenosis
  - Tricuspid regurgitation



Heart Pro III

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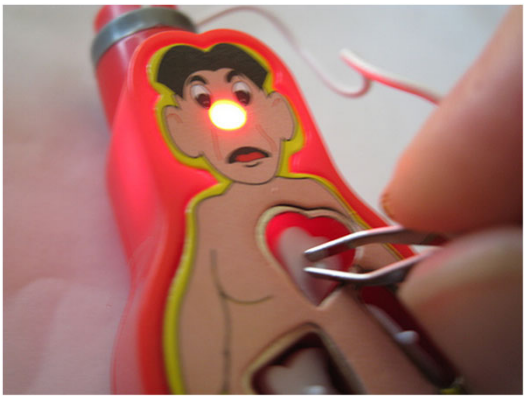
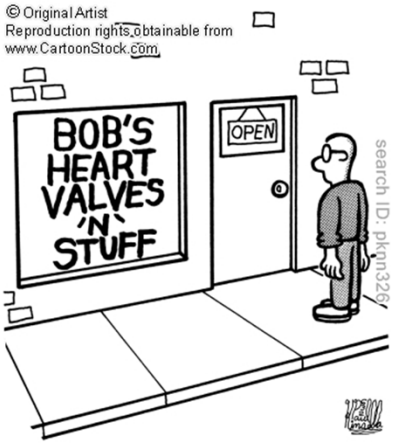
Treatment of valvular heart disease
Cardiac surgery



Gold standard for valvular heart disease



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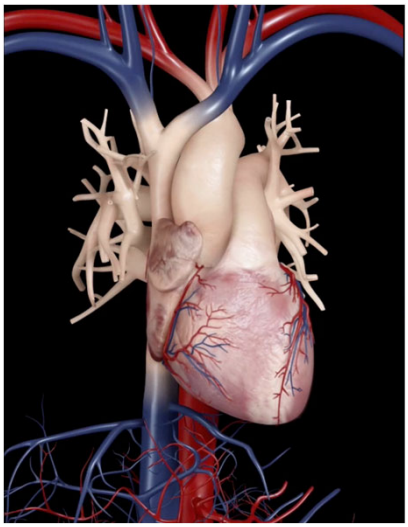
Interventional cardiology & cardiac catheterization



Heart Pro III

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Aortic Stenosis

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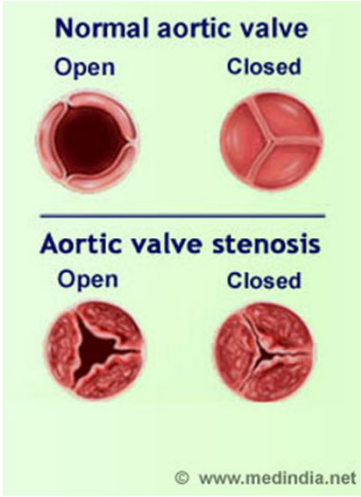
Valvular heart disease: Aortic stenosis

Aortic stenosis

- Valve becomes calcified and rigid
- Poor valve opening places increased demand on the heart
- Symptoms
  - Angina, chest pain or tightness
  - Shortness of breath
  - Passing out or dizziness with activity
- Once symptoms develop, average survival is only 2 to 3 years unless valve is replaced



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Valvular heart disease: Aortic stenosis

HIGH RISK FOR SURGICAL AVR

- Advanced age (>80)
- Redo cardiac surgery
  - especially prior CABG
- Heart dysfunction
- Atherosclerotic aorta
- Cerebrovascular disease
- Peripheral artery disease
- Chronic kidney disease
- Chronic lung disease
- Diabetes

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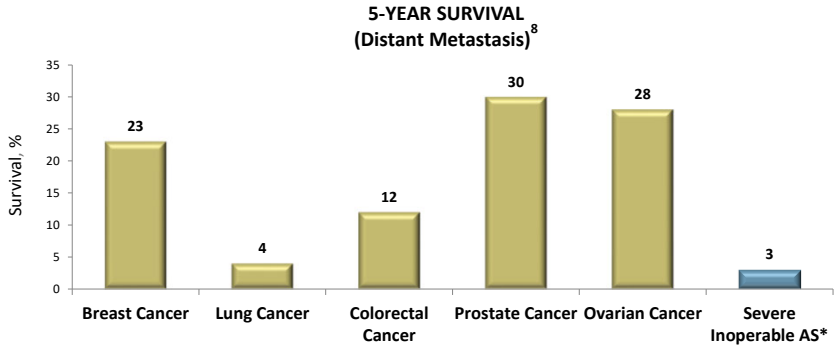
Prognosis of inoperable severe AS



5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic
National Institutes of Health. http://seer.cancer.gov/statfacts/. Accessed Nov. 2010.

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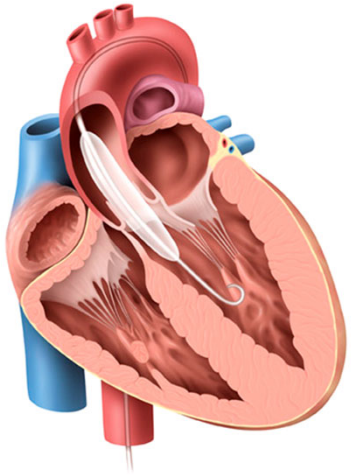
Valvular heart disease: Aortic stenosis

Percutaneous balloon aortic valvuloplasty



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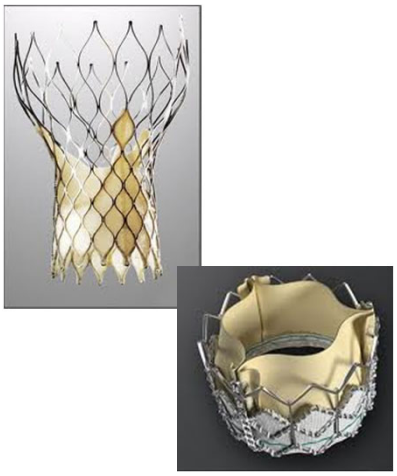
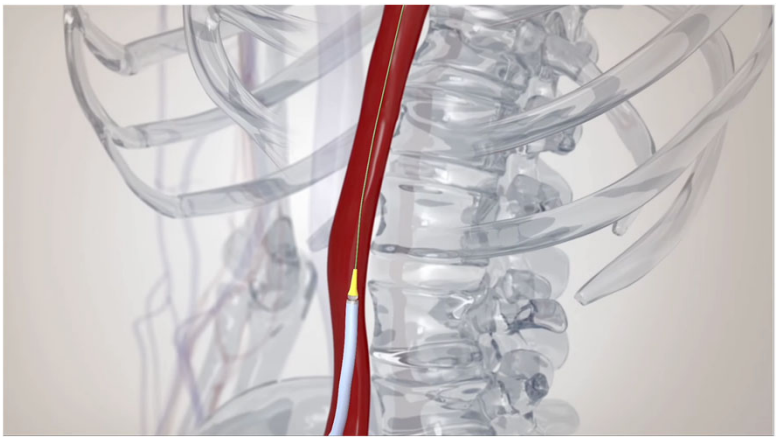
Transcatheter aortic valve replacement (implantation)





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Comparative advantages/disadvantages

TAVI	SAVR
BENEFITS: • Helps you live longer • Helps you feel better • Less invasive procedure • Shorter recovery time	**BENEFITS:** • Helps you live longer • Helps you feel better • Over 50 years of experience with procedure • Can address other heart problems like blocked heart arteries or problems with other valves
Almost **98 out of 100** patients are still living within two years and more than **2 in 100** patients will die.	Almost **97 in 100** patients are still living within two years and just over **3 in 100** patients will die.
98% live 2% die	97% live 3% die
RISKS:	**RISKS:**
More than **2 in 100** patients suffer from a **stroke** in two years.	More than **3 in 100** patients suffer from a **stroke** in two years.
2.4%	3.6%
Nearly **8 in 100** patients suffer from **major bleeding**	Nearly **26 in 100** patients suffer from **major bleeding**
7.9%	25.9%
Almost **8 in 100** need a **pacemaker** within 30 days	**4 in 100** need a **pacemaker** within 30 days
6.6%	4.1%

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Considerations:

- Young age / longevity
- Anatomic constraints
- Other heart problems (blocked arteries, valve disease, etc.)
- Other health problems

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Shared Decision-Making

"All patients are different, and there may be certain features about your heart which affect what your doctor thinks about your treatment."

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Bioprosthetic valve failure

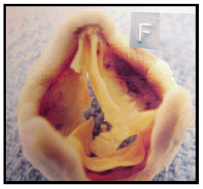
Pannus

Thrombus

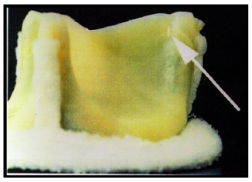
Calcification

- Surgical valve durability ~ 15 years
- Transcatheter valve durability ?? ~10 years

Wear & Tear (int.)



Wear & Tear (ext.)



Endocarditis

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Dvir D, et al. TCT 2015

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Valve-in-valve TAVR
A tool when biologic prosthetic valves fail

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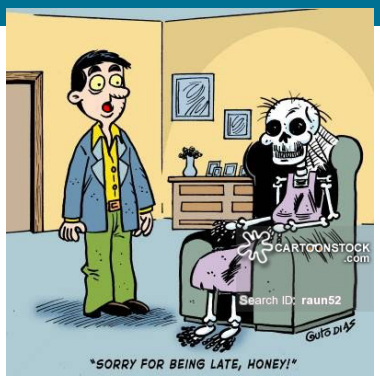
Aortic Stenosis
Challenges

- Patients presenting with severe AS today are older than previously experienced.
- In the current era, challenges arise when waiting for symptoms.
  - More comorbid conditions
  - Reduced physical activity renders assessment of symptoms unreliable
  - Insidious symptom onset leads to gradual reduction in activity
  - Symptoms often underreported and underestimated



Late recognition of "symptomatic" severe AS

16 Pibarot P and Dumesnil JG. Cardiac Valvular Medicine. 1st ed. 2012.

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Aortic Stenosis

Unmet clinical needs

Sensitive and low-cost methods to optimize the timing and outcomes of aortic valve replacement

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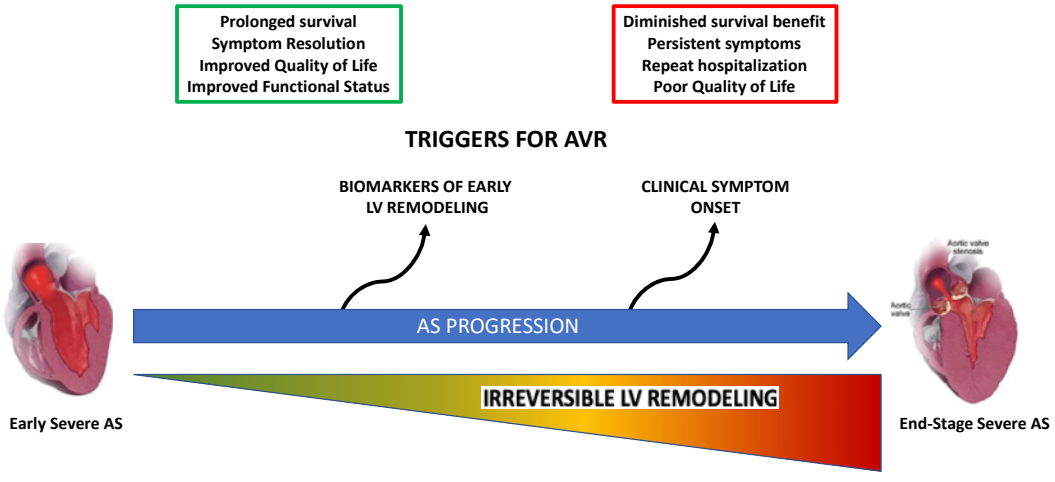
A Stitch in Time:

Biomarker-Guided Timing of Aortic Valve Replacement for Severe Aortic Stenosis?



Window of opportunity for superior outcome from AVR?

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Januzzi JL Jr, Elmariah S. *JACC Cardiovasc Interv*. 2018 Nov 12;11(21):2182-2184.

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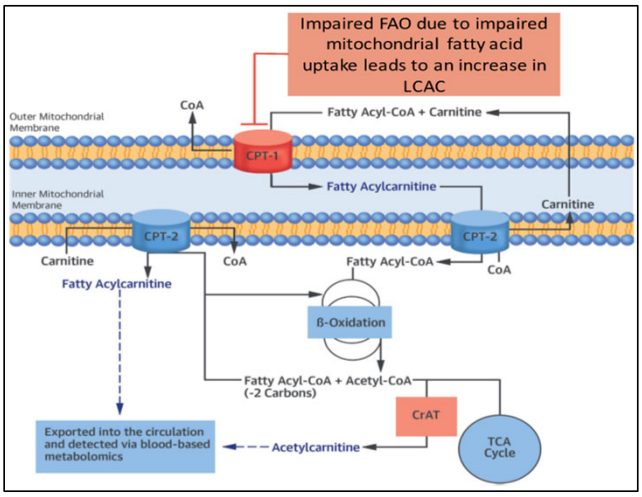
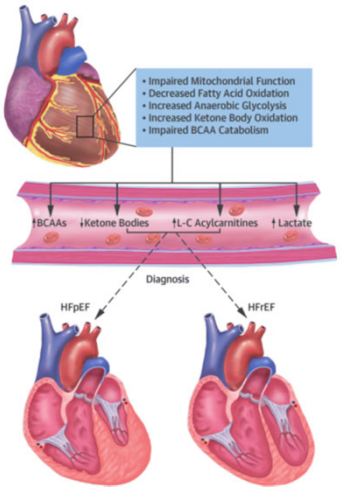
Acylcarnitines reflect fatty acid oxidation.





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Ussher J, Elmariah S, et al. J Am Coll Cardiol. 2016; 68:2850–70.

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Mitral Regurgitation

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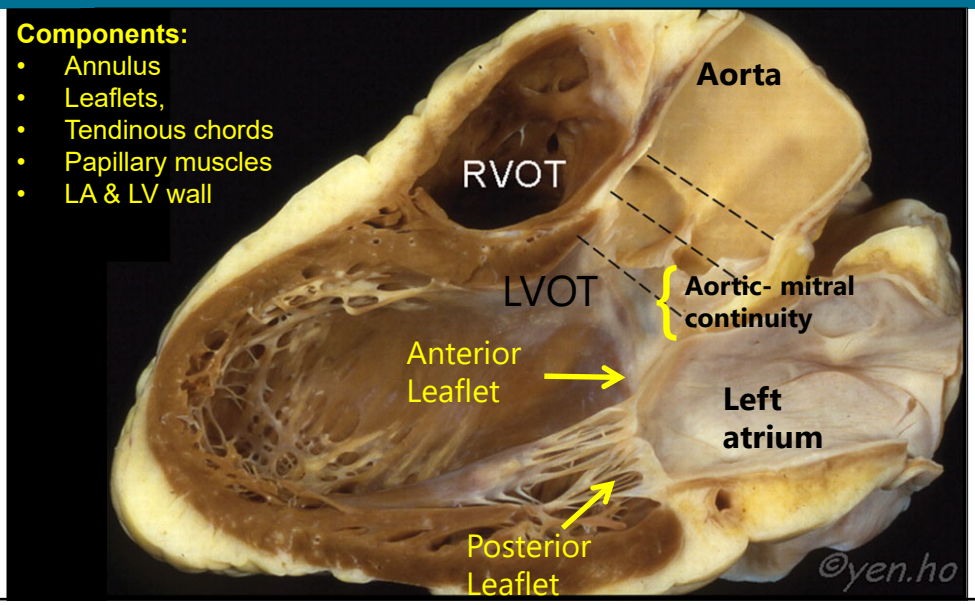
Mitral Valve Anatomy



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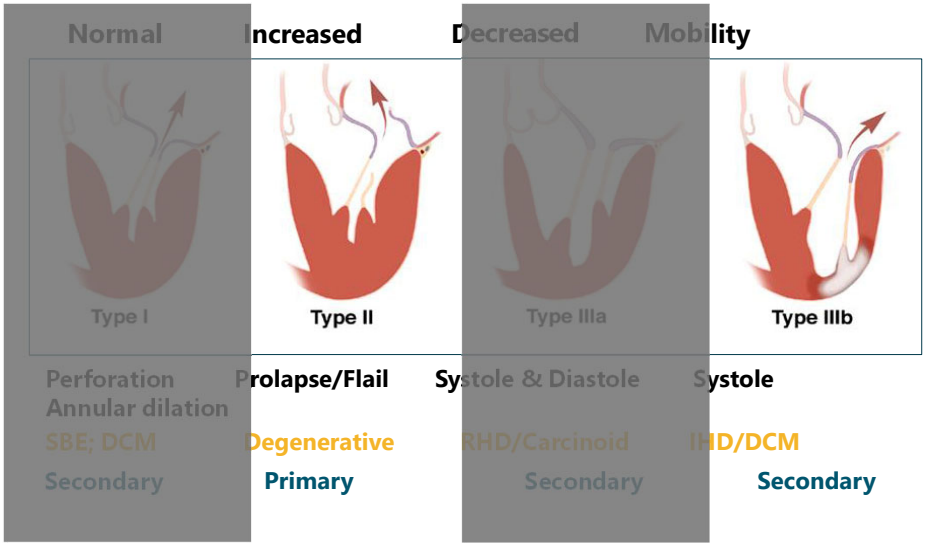
Carpentier MV Classification- Leaflet Mobility



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Valvular heart disease: Mitral regurgitation

- 1.7% of the U.S adult population has MR
- Most common form of valvular heart disease
- Symptoms
  - Shortness of breath
  - Palpitations / atrial fibrillation
  - Swollen feet or ankles
- Leads to weakening of the heart

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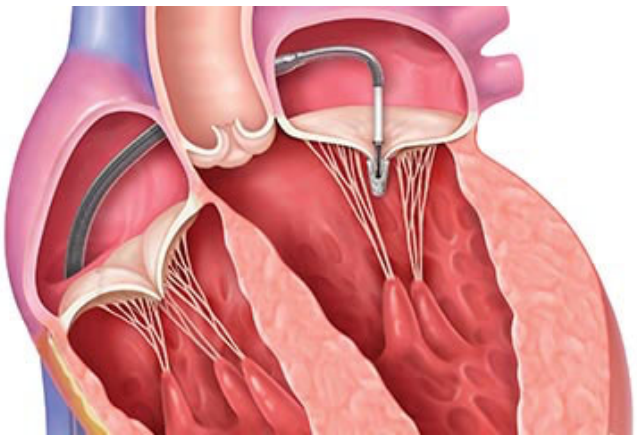
Transcatheter edge-to-edge repair



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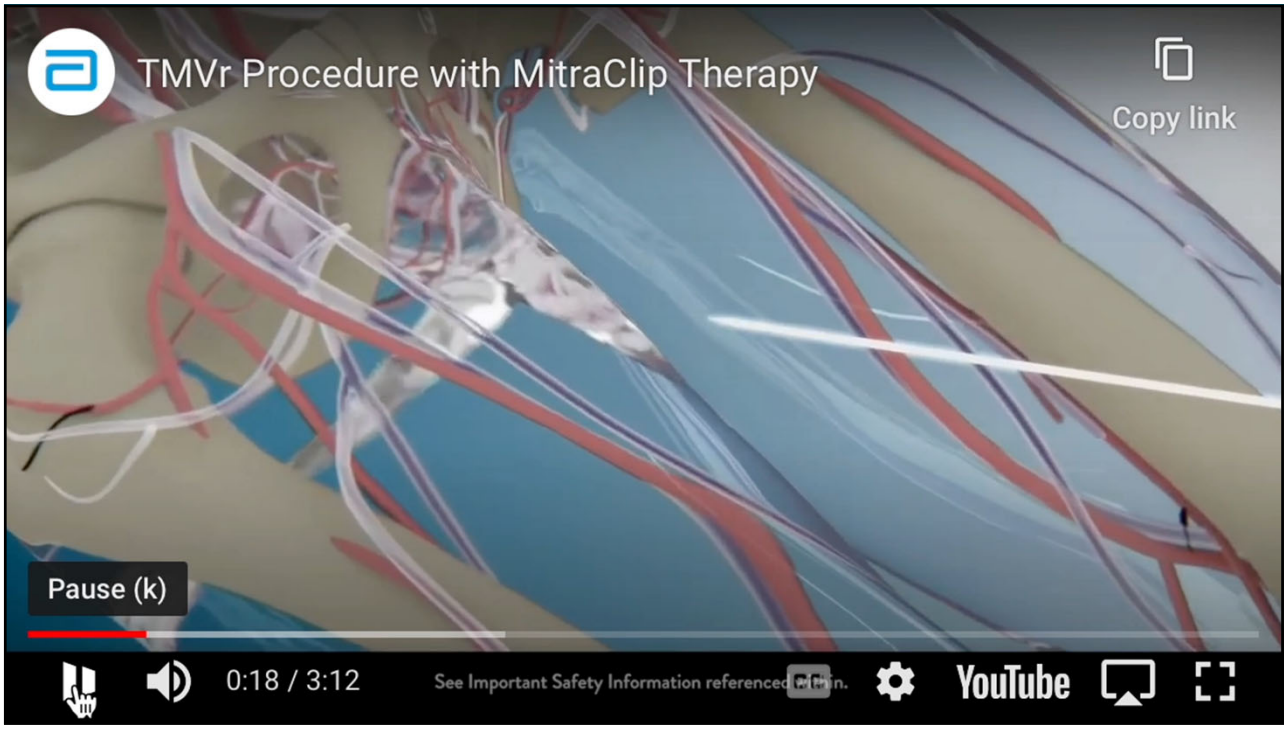

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Transcatheter edge-to-edge repair
Clinical Results

- Procedure is approved for subset of patients with mitral regurgitation (MR):
  - Patients with primary (leaflet problem) MR that are at high-risk for surgery
  - Patients with secondary (muscle problem) MR that have symptoms despite maximal medical therapy
- Ongoing clinical trials are evaluating use of transcatheter procedures in a broader patient population

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Transcatheter mitral valve replacement

Multiple devices remain under investigation

Partida R, Elmariah S. Currently Treat Options Cardiovasc Med. 2017;19(5)32

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Mitral Stenosis

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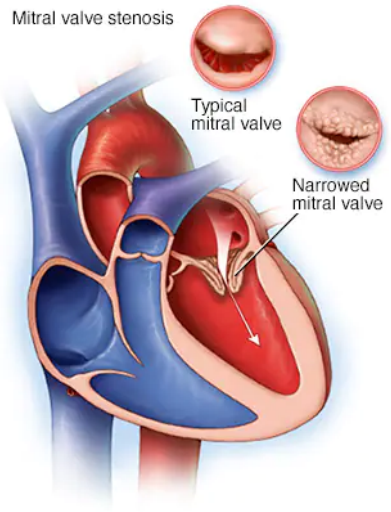
Valvular heart disease: Mitral stenosis

- Primarily caused by rheumatic fever
- Due to untreated strep throat or scarlet fever (infections caused streptococcus pyogenes or group A strep)
- In the U.S., present in 1 in 100,000 people
- In India, present in 100-150 in 100,000 people
- Symptoms
  - Shortness of breath
  - Palpitations
  - Stroke
  - Swollen feet or ankles



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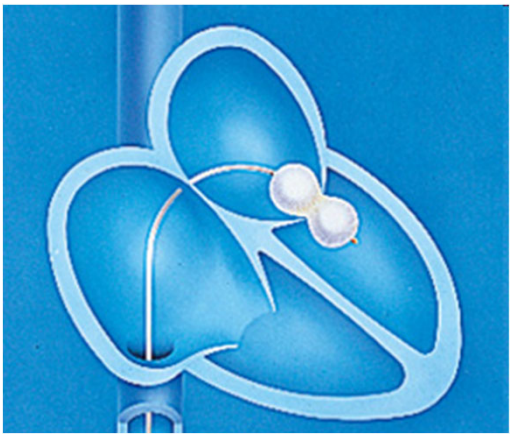
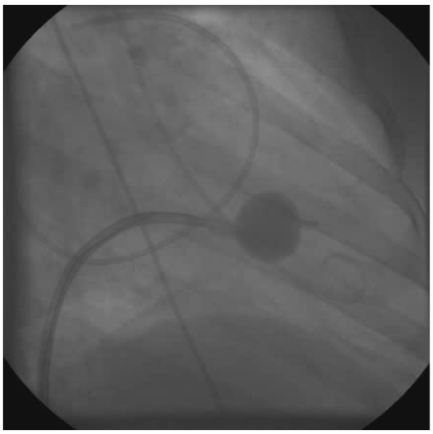
Percutaneous balloon mitral valvuloplasty





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Tricuspid Regurgitation

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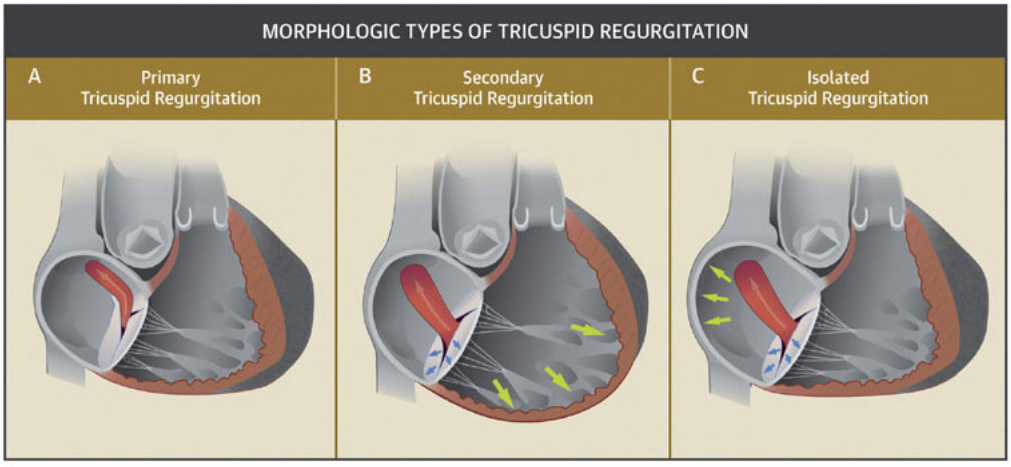
Tricuspid valve
The forgotten valve



Prihadi, E.A. et al. J Am Coll Cardiol Img. 2019;12(3):491-9.

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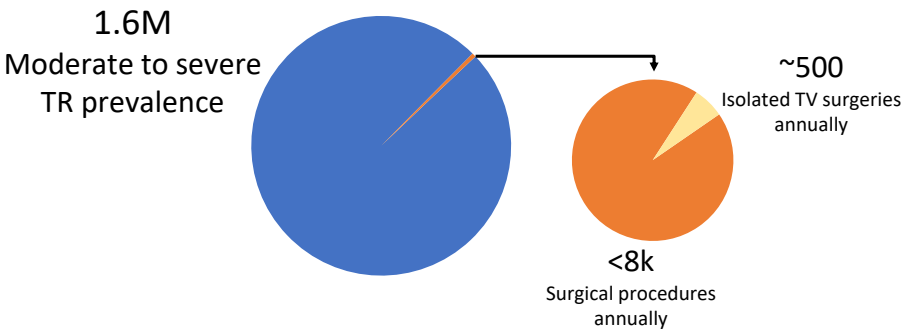
Tricuspid regurgitation
Common yet rarely treated!

- >Mild TR is present in 14.8% of men and 19.1% of women



Singh J *et al. Am J Cardiol* 1999;83:897-902.
Stuge O, Liddicoat J. *J Thorac Cardiovasc Surg.* 2006;132:1258-61.
Zack CJ, *et al. J Am Coll Cardiol.* 2017;70:2953-60.

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Tricuspid Regurgitation
Clinical Manifestations

- Fatigue and decreased functional capacity
- Peripheral edema and ascites
- Dyspnea
- End-organ injury: cardiorenal, congestive hepatopathy
- Protein malnutrition and cachexia
- RV Failure
- Mortality

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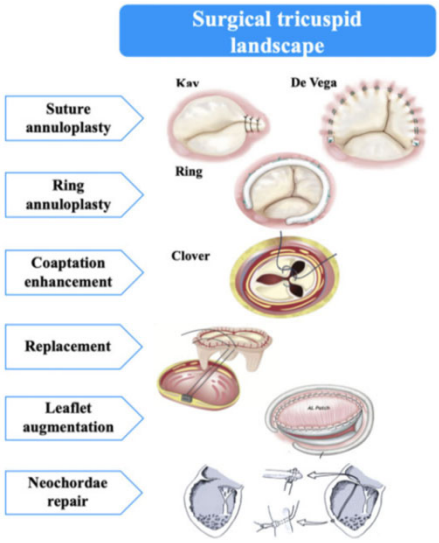
Treatment Options for Severe TR
Surgical & Transcatheter



Chang et al. *Eur Heart J.* 2020;41:1932-40.

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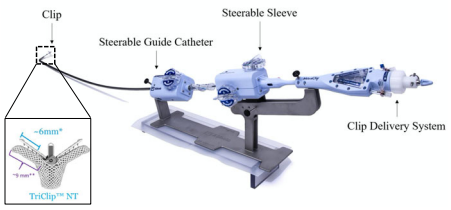
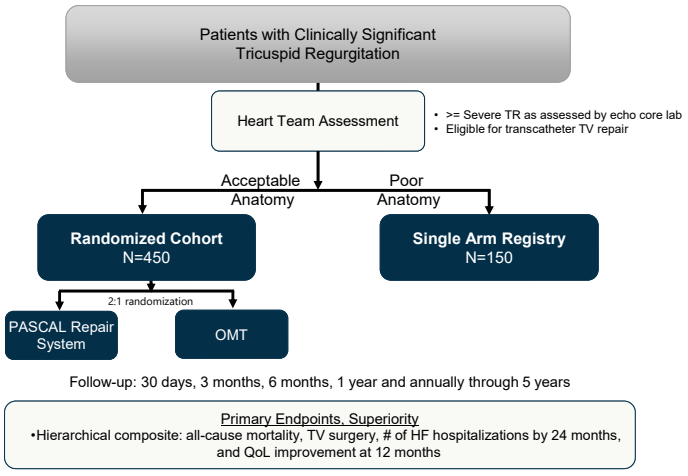
Transcatheter Tricuspid Valve Edge-to-Edge Repair

TRILUMINATE Pivotal Trial



CLASP II TR Trial



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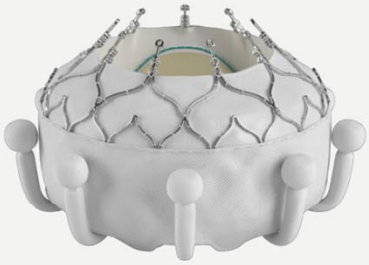
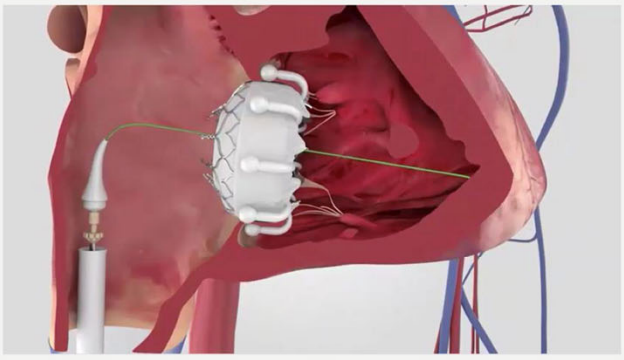
Transcatheter Tricuspid Valve Replacement

THE TRISCEND STUDY

Unique valve design engages leaflets, chords, and annulus to achieve secure placement





Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (52, 48, 44 mm)

28F transfemoral delivery system compatible with all valve sizes

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Promising early results

Early results have been promising and suggest that tricuspid valve intervention may:

- Reduce heart failure symptoms
- Improve quality of life
- Improve functional capacity
- Prolong life

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Conclusions

- Novel interventions are expanding our ability to treat valvular heart disease via minimally invasive means associated with rapid recovery
- Transcatheter interventions for valvular heart disease are rapidly evolving with several ongoing clinical trials available to patients at UCSF
- Transcatheter interventions complement surgical therapies to allow for the comprehensive management of valvular heart disease

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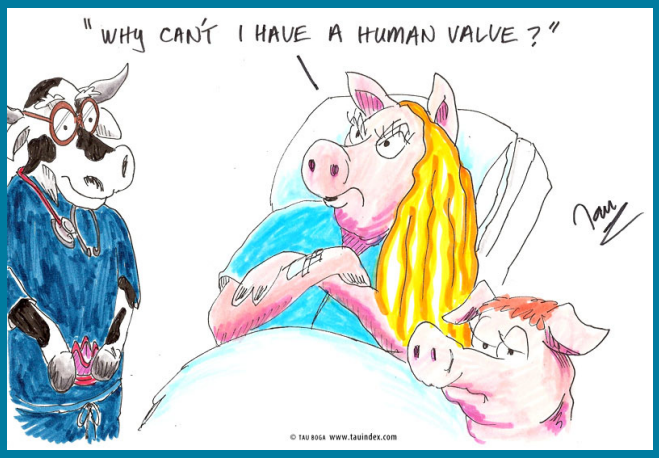

Thank you!

Sammy.Elmariah@ucsf.edu

@SammyElmariahMD

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