Latest Treatments for Heart Valve Problems

Emerging Structural Heart Procedures

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Background

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- Historically, a number of cardiac conditions could only be treated with open heart surgery.
- Given the increasing age of our population, in addition to the multiple co-morbid issues involved, the risk of complications of operating on this population has also gone up.
- Medical technology has made leaps and bounds in the last decade in regard to treating CV disorders.

Background

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- Thirty years ago: use of coronary balloons (PTCA), followed by stents revolutionized acute coronary syndromes, i.e., "heart attacks."
- Pacemakers implanted w/o open heart surgery changed the dynamic of heart rhythm disorders.
- The one major area that was not successfully addressed: structural heart, i.e., valves, appendage.
- Major changes in the last decade…

Structural Heart Revolution

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- Revolution, not just evolution!
- We now have the capability to address serious internal cardiac issues with minimally invasive techniques.
- Results, with certain procedures, have now shown to be equivalent *if not better* with certain conditions than surgical standard of care.
- And this movement only seems to be gaining strength with newer technologies entering the cardiac arena every year.

Mitral Regurgitation

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- Affects thousands of Americans
- Vastly undertreated
- Basically means the mitral valve has become “leaky”- blood spills backwards into the lungs rather than going forward into the left ventricle as a result of weak or “degenerated” mitral leaflets.
- Results in progressive shortness of breath, fatigue, and eventual heart failure

Mitral Regurgitation Etiologies

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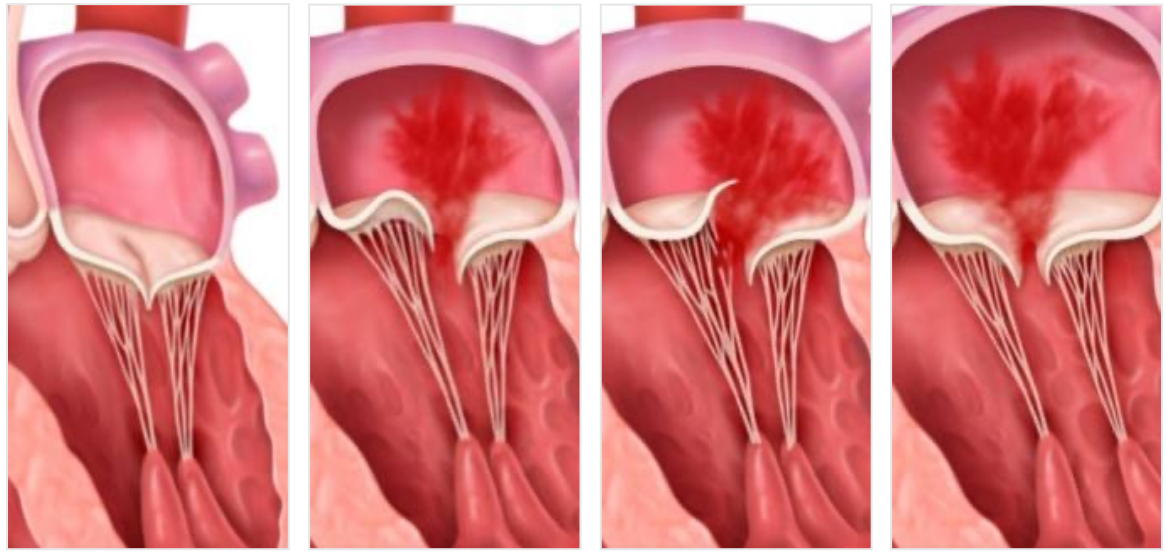
Causes

- Degenerative MR (also known as primary or organic MR) is usually due to an anatomic abnormality of the mitral valve itself, including the leaflets, and/or the subvalvular apparatus, such as the chordae or papillary muscles.

- Functional MR (also known as secondary MR) is the result of left ventricular dilation, which can be secondary to ischemic heart disease. Left ventricular dysfunction leads to annular dilation and incomplete coaptation of the mitral valve resulting in MR.



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

Moderate or Severe Valvular Disease is Common and Increases With Age

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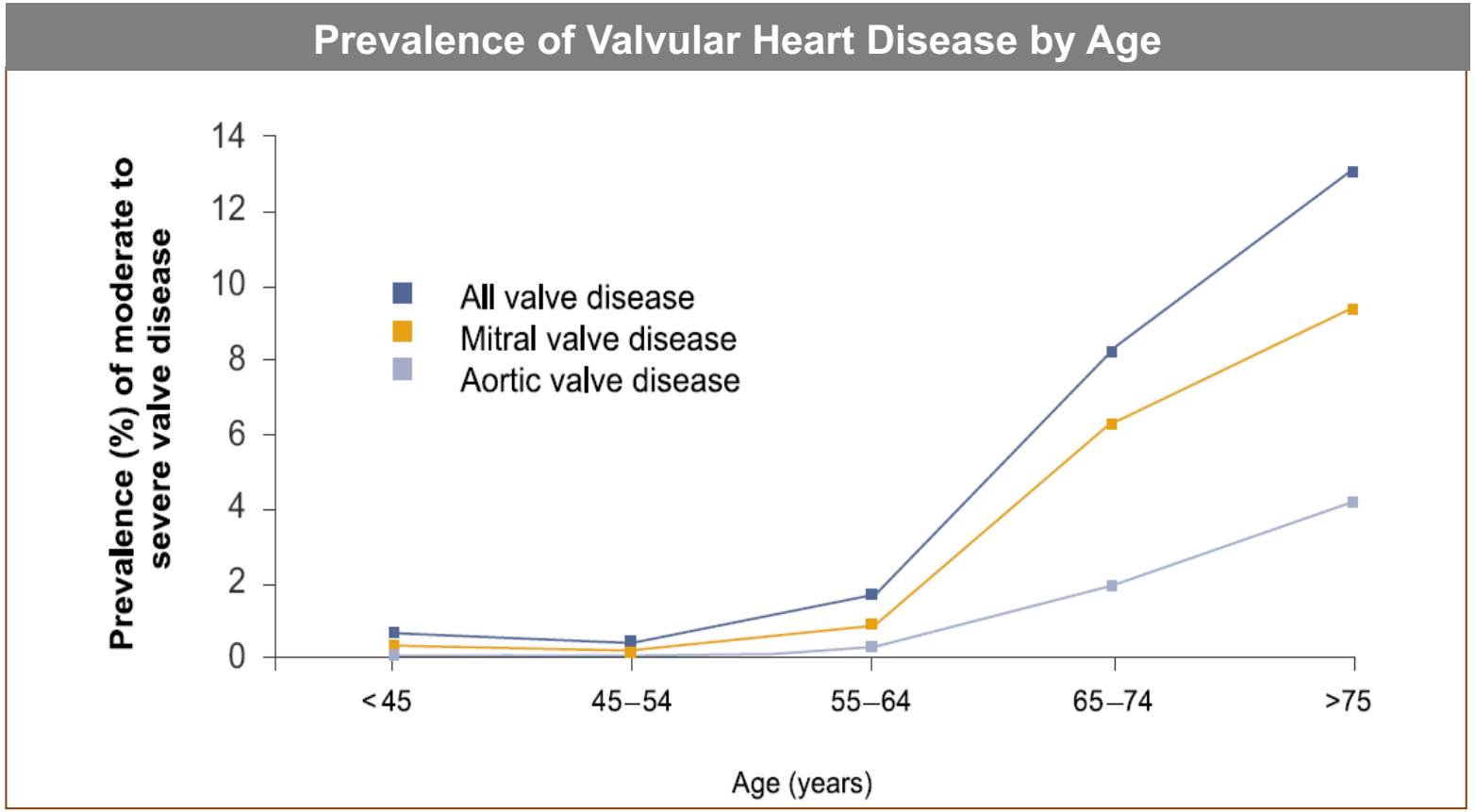
Mitral regurgitation is the most common type of heart valve insufficiency in the US[1,2]

Prevalence increases with increasing age, from 0.5% for 18-44 year olds rising to 9.3% for ≥75 year olds (p<.0001)



1. Heart Disease and Stroke Statistics 2010 Update: A Report From the American Heart Association. *Circulation.* 2010;121:e46-e215.
2. Nkomo et al. Burden of Valvular Heart Diseases: A Population-based Study, Lancet, 2006; 368: 1005-11.

MR Progresses to Heart Failure

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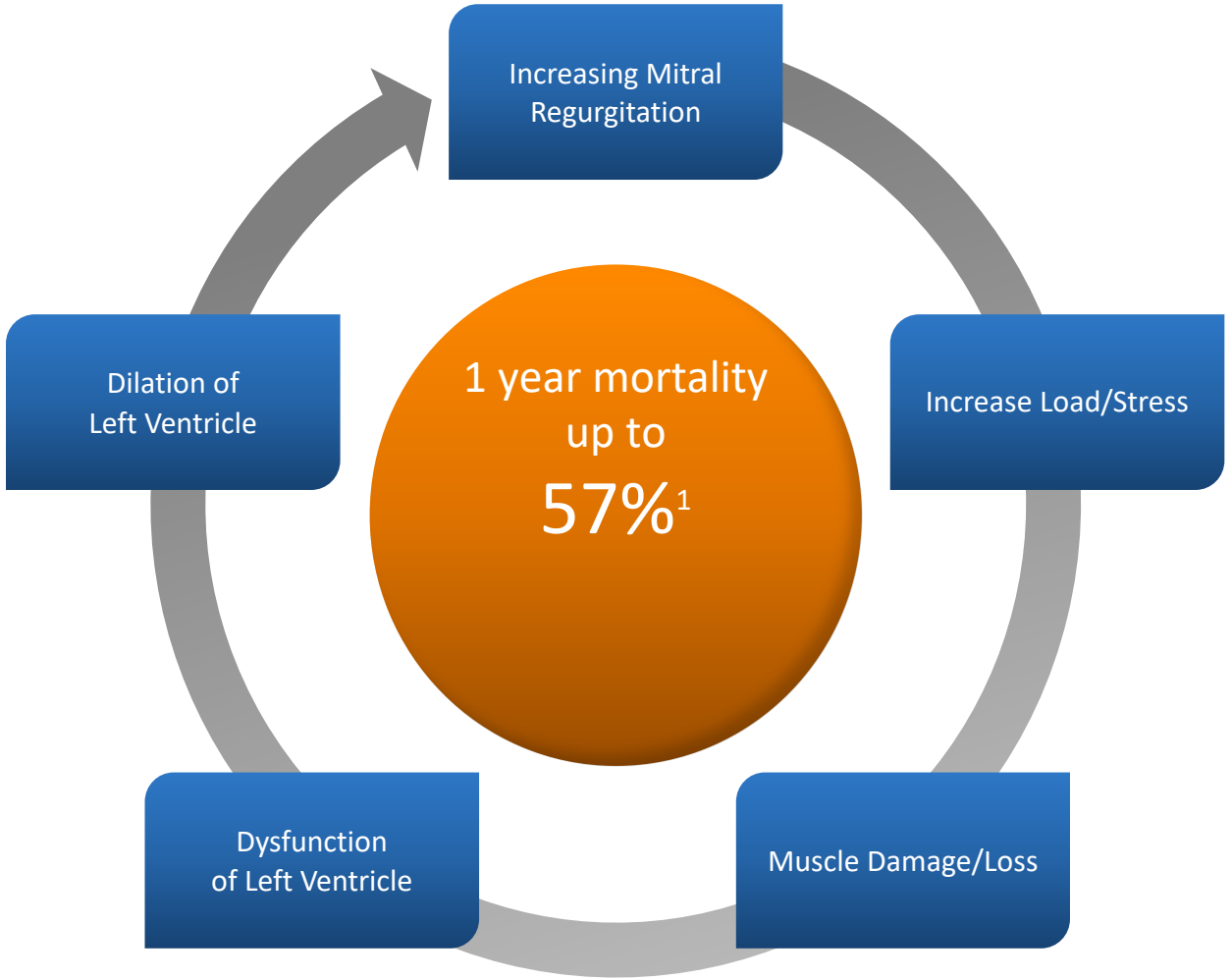

MR initiates a cascade of events progressing to heart failure, then death, if untreated.[2,3]

[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
[2] Grigioni F, et al. Outcomes in mitral regurgitation due to flail leaflets a multicenter European study. JACC Cardiovasc Imaging. 2008 Mar;1(2):133-41
[3] Enriquez-Sarano M, et al. Quantitative determinants of the outcome of asymptomatic mitral regurgitation. N Engl J Med. 2005 Mar 3;352(9):875-83

Treatment

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- Historically, only medical therapy, followed by surgery (if possible) were mainstays of treatment.
- Medical therapy, though effective in many cases, cannot reverse degenerative disease.
- Surgery is the gold-standard (and still is).
- However, surgery can be high-risk in this population, and needs to be done by a surgeon with the skill/experience to perform a MV replacement/repair.

MitraClip System
First-in-class, Leading Technology

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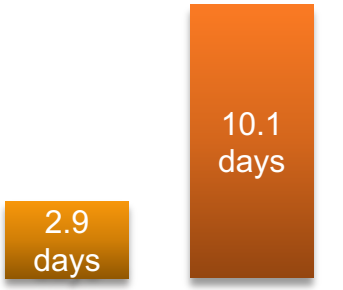
The MitraClip System performs percutaneous mitral valve repair by creating a vertical line of coaptation, forming a double-orifice valve. [1,2]

- Beating heart procedure—no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize MR reduction
- Designed to preserve surgical options
- Femoral venous access
- Low hospital length of stay

1. MitraClip Clip Delivery System Summary of Safety and Effectiveness Data (SSED)
2. MitraClip Clip Delivery System Instructions for Use.

Successful Outcomes for Patients and Centers

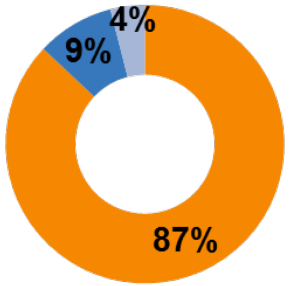
Post-procedure Impact of MitraClip Therapy



EII Prohibitive Risk DMR MitraClip (N=127)

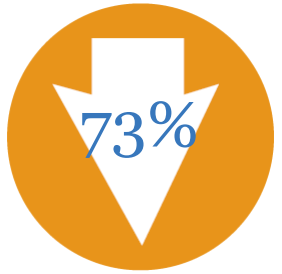
Partner B TAVR (N=175)

Low Hospital Length of Stay vs. TAVR[1,2]



87% of MitraClip patients discharged to home[3]

Majority of MitraClip patients discharged to home with or without home health care (9% to nursing home/skilled nursing facility, 4% died prior to discharge)



73% reduction in hospitalization rate[4]

HF hospitalization rates per patients decreased from 0.67 (1 year prior to MitraClip therapy) to 0.18 (1 year post discharge)

[1] MitraClip Clip Delivery System Summary of Safety and Effectiveness Data (SSED)
[2] Reynolds et al. Circulation. 2012;125:1102-1109.
[3] Data on file at Abbott Vascular.
[4] MitraClip Clip Delivery System Instructions for Use.

See important safety information referenced within.

MitraClip Video

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Follow this link to watch video: https://www.youtube.com/watch?v=FVSzWP77nNo

Aortic Stenosis

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- Aortic stenosis (AS) can be seen earlier in life as a congenital issue, i.e., bicuspid valve, but is more often seen as a calcific, age-related issue.
- Calcific aortic stenosis - a very real problem in the U.S.
- Results in closure of the aortic valve, which causes progressive angina, syncope, light-headedness, and eventual heart failure/death.

Prevalence of Aortic Stenosis

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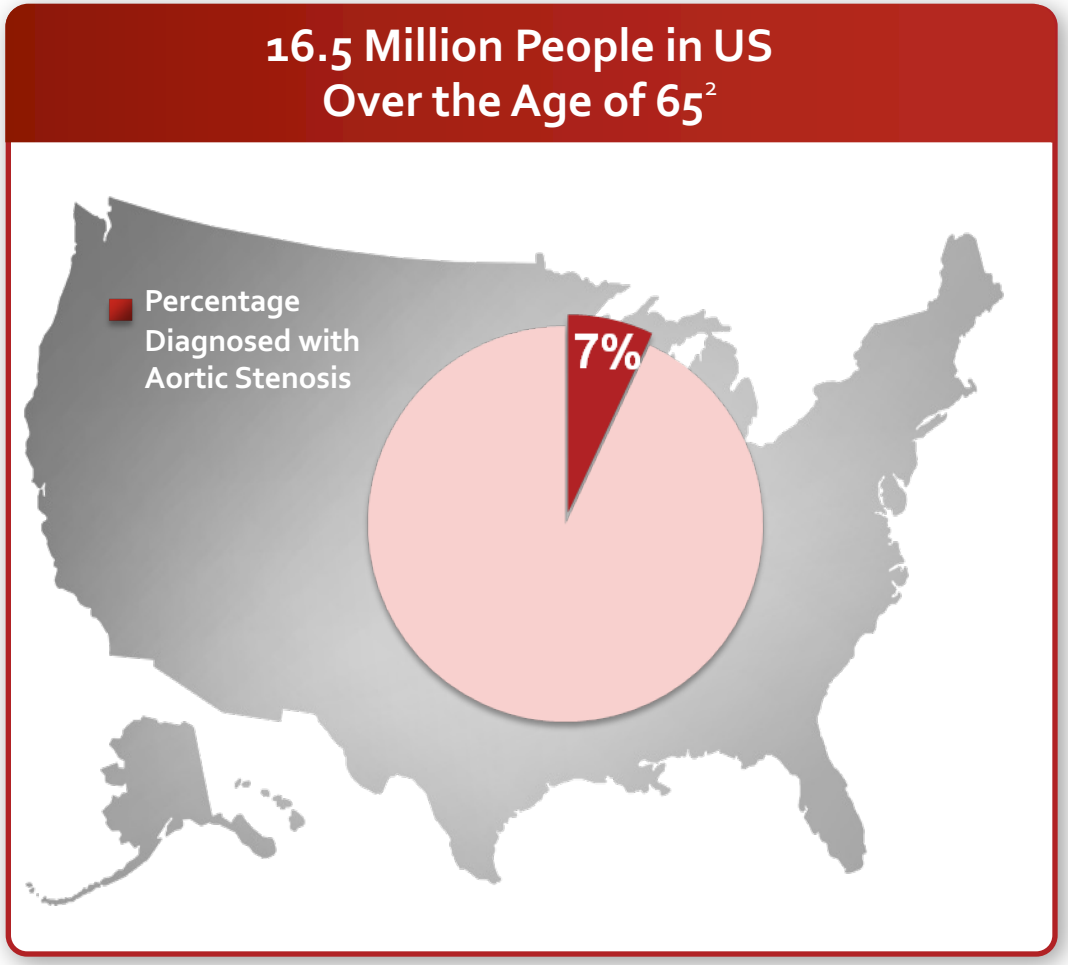
- Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65.[1]

- It is more likely to affect men than women; 80% of adults with symptomatic aortic stenosis are male.[3]



Aortic Stenosis Demographics

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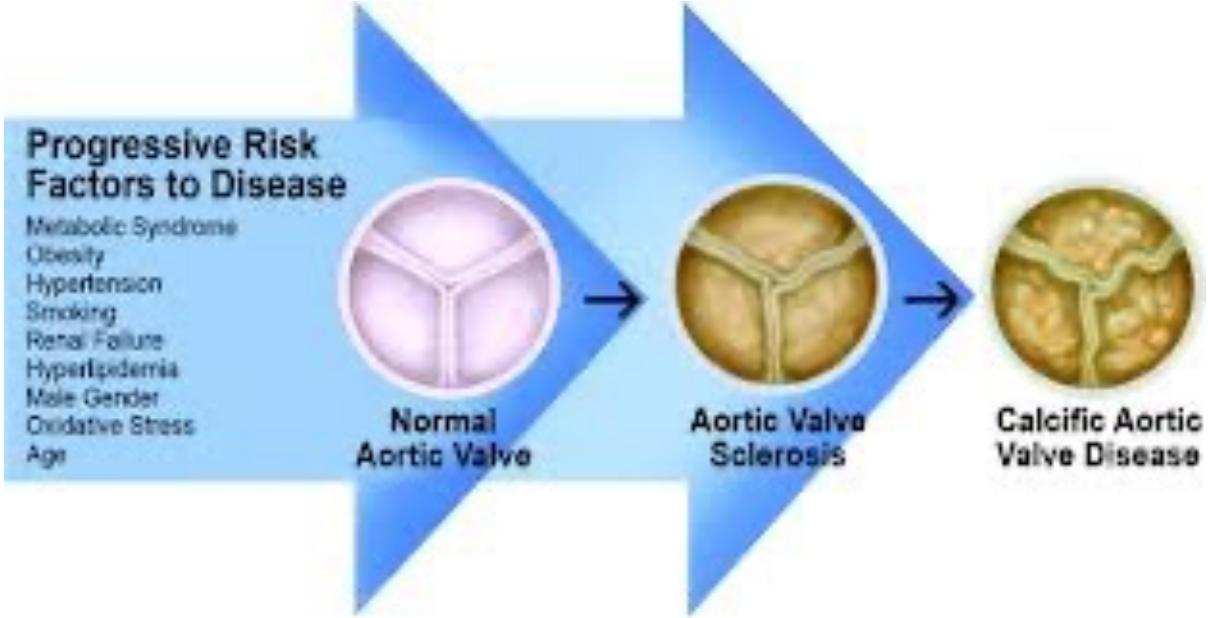
- Aortic stenosis — 2% US population > 65 yrs old
- Aortic sclerosis — 29% US population > 65 yrs old
- Aortic sclerosis — 50% greater risk of mortality and myocardial infarction
- Aortic sclerosis progresses to aortic stenosis in 9% over 5 years



What Causes Aortic Stenosis in Adults?

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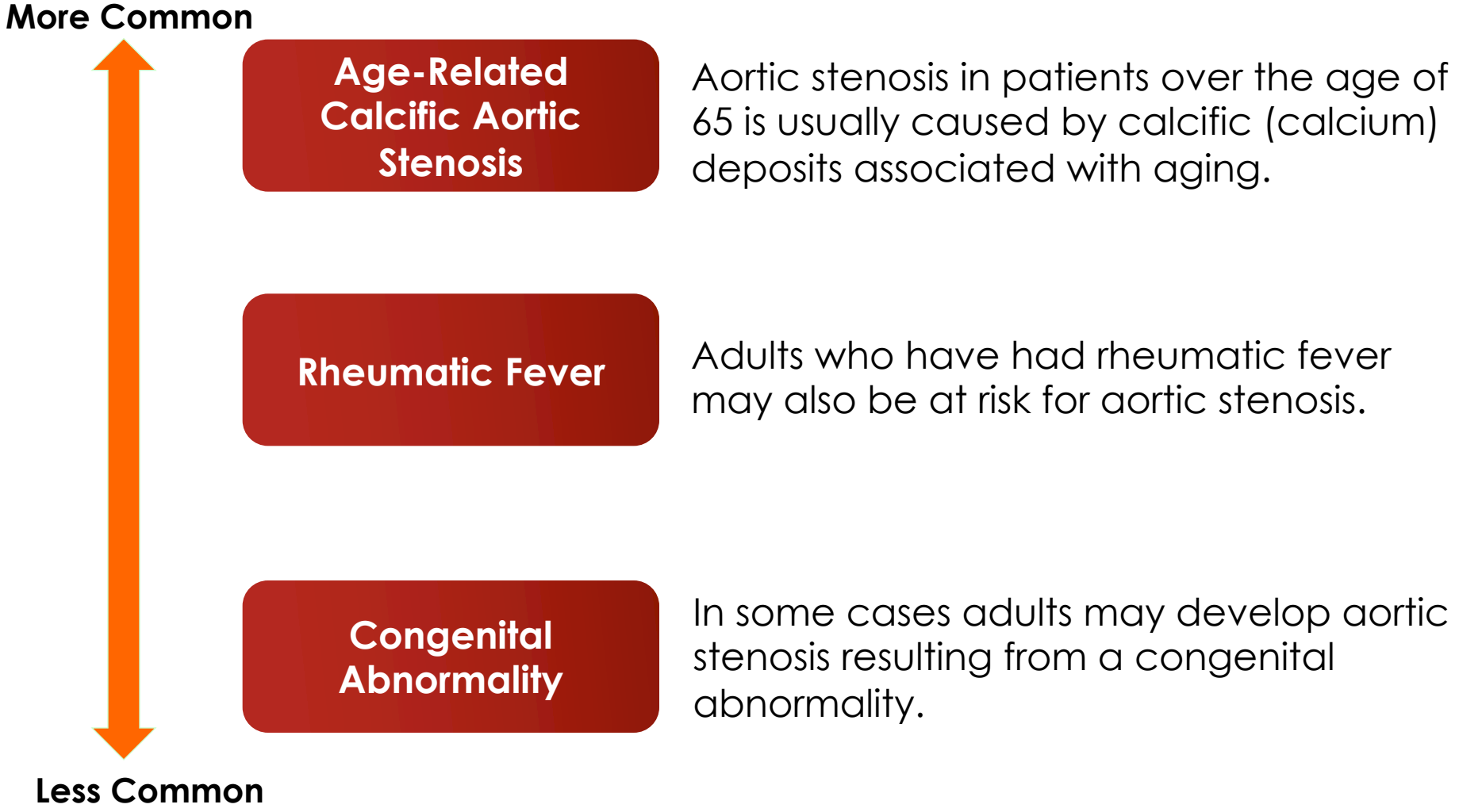

Major Risk Factors

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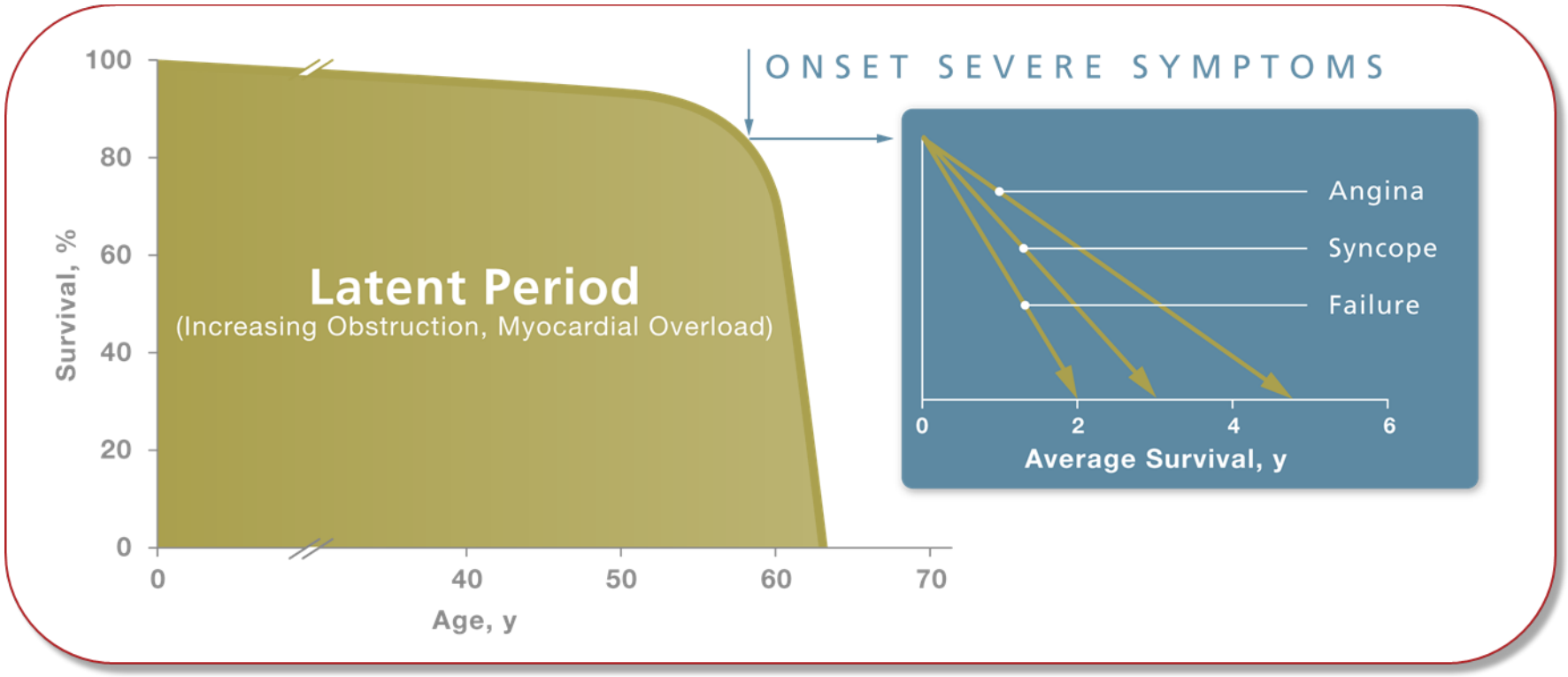
Independent clinical factors associated with degenerative aortic valve disease include the following: [4]

- Increasing age
- Male gender
- Hypertension
- Smoking
- Elevated lipoprotein A
- Elevated LDL cholesterol

Aortic Stenosis is Life Threatening and Progresses Rapidly



- Survival after onset of symptoms is 50% at 2 years and 20% at 5 years. [1]
- Surgical intervention for severe aortic stenosis should be performed promptly once even minor symptoms occur. [1]

Sobering Perspective

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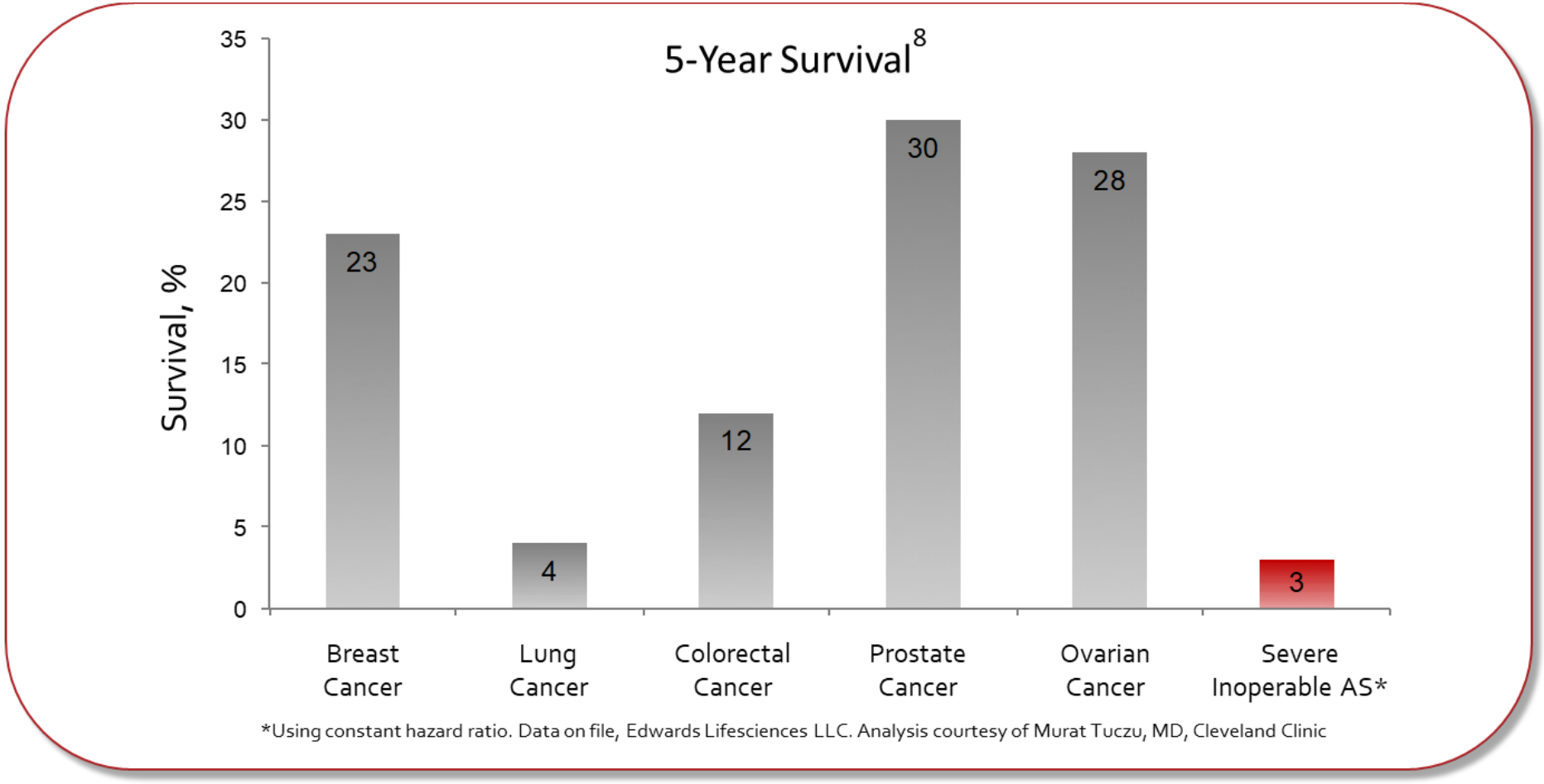

5-year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis.

Aortic Valve Replacement Greatly Improves Survival

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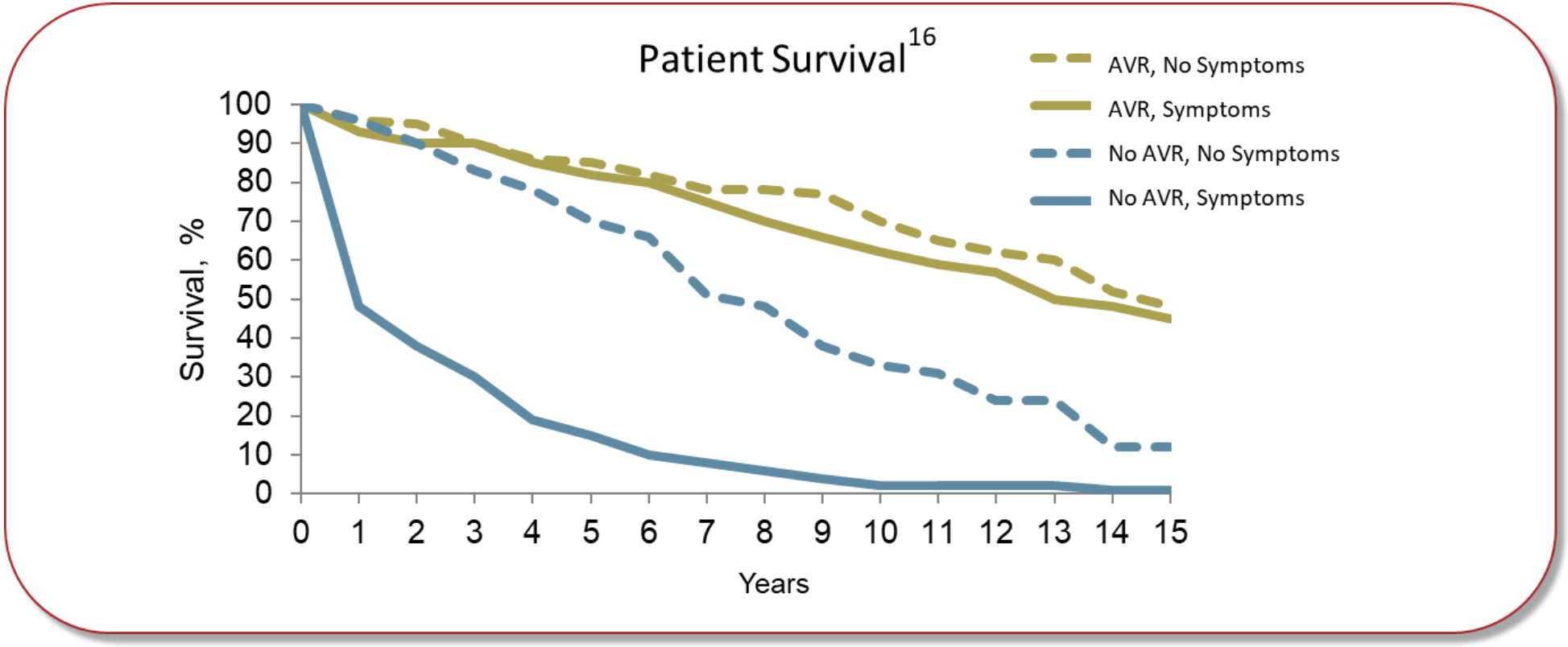
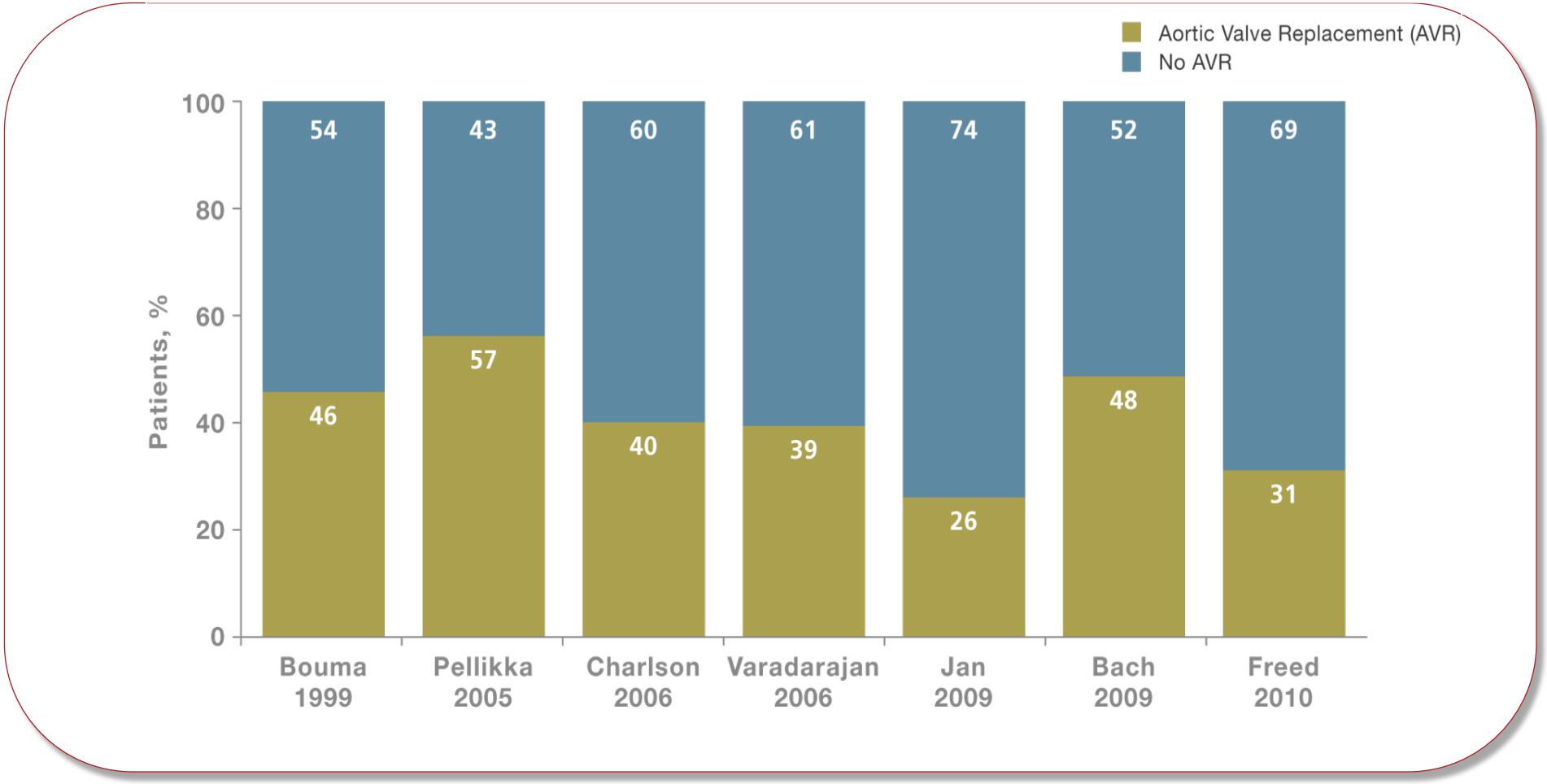


- Study data demonstrate that early and late outcomes were similarly good in both symptomatic and asymptomatic patients.
- It is important to note that among asymptomatic patients with SAS, omission of surgical treatment was the most important risk factor for late mortality.

Low Percentage of Aortic Valve Surgery



- Studies show at least 40% of patients with severe AS are not treated with an AVR9-15.

Aortic Valve Replacement

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- Open heart surgery becomes riskier with the older population.
- The need for long hospital stays, rehab, and treatment of co-morbid issues are major factors.
- The last ten years has seen a revolution in AS therapy.
- TAVR has become a viable technology in the treatment of AS.

What is TAVR-Transcatheter Aortic Valve Replacement?

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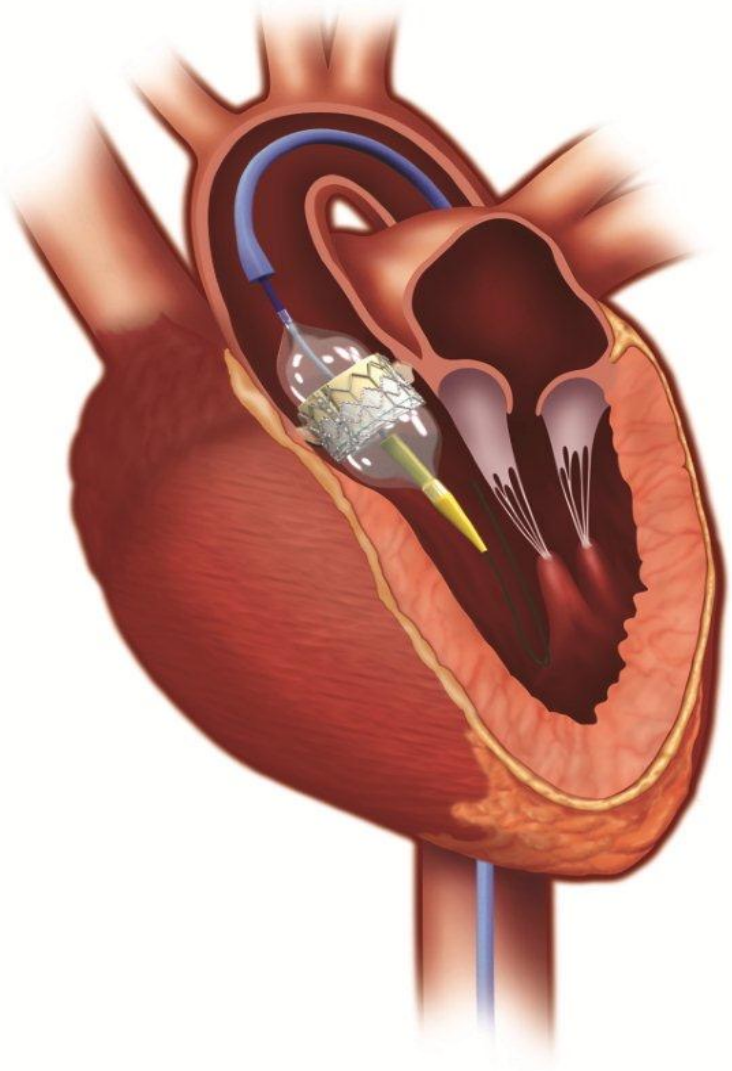
- An aortic valve replacement as an alternative to traditional thoracotomy.

- Less invasive than traditional thoracotomy for patients considered too high risk for traditional surgery.



Three TAVR Options

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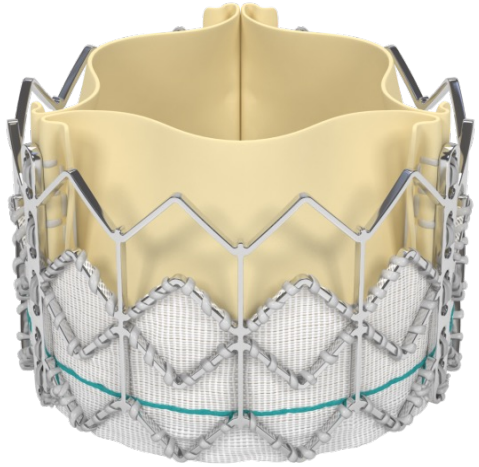
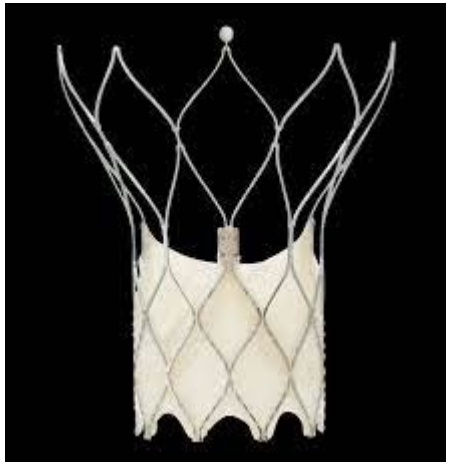
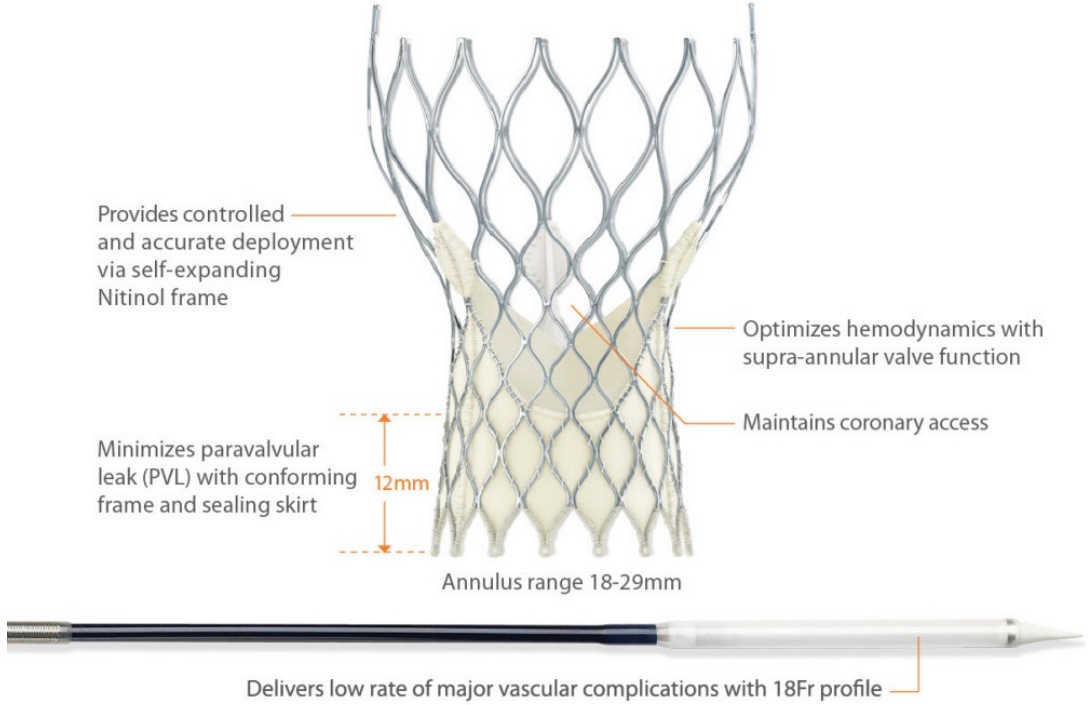
- Edwards Sapien Valve
- Stainless Steel Frame





- Medtronic CoreValve
- Nitinol Frame-self expanding



Abbott Portico TAVR: only for high-risk/inoperable

Medtronic Corevalve

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- Excellent results from multiple studies for both approved valves.
- Corevalve: Recent studies have shown *better* results in high-risk patients receiving a trans-femoral Corevalve as opposed to open heart surgery.
- The question of long-term durability is still being examined.
- TAVR now approved for low-risk, and intermediate-risk populations, not just high-risk.
- Low-risk trials recently revealed TAVR can be utilized in this population as well. FDA/CMS approval is pending.

TAVR Video

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https://www.medtronic.com/us-en/patients/treatments-therapies/transcatheter-aortic-valve-replacement.html

Summary

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- Heart valve disease is growing in the U.S. population.
- We need alternatives to standard surgical therapy for patients who are at higher risk for complications.
- Both TAVR and Mitraclip represent the forefront of these therapies…but they are certainly not the last!!

Thank You!!

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Emerging Structural Heart Procedures

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