

Updates in Structural Heart Disease

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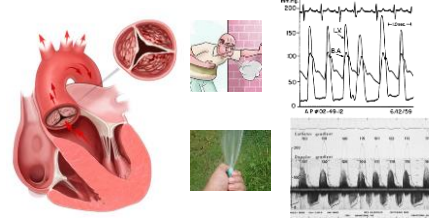
Advancing Cardiovascular Care through Hospital Collaboration



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Aortic Stenosis

In every patient the presence of aortic stenosis was confirmed by the demonstration of a systolic pressure gradient between the left ventricle and brachial artery at the time of left heart catheterization*

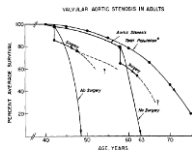


Morrow et al. 1963, Ann Surgery; Brockenbrough et al. 1961, Circulation; Currie 1985

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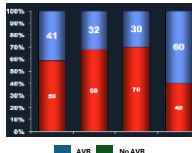
Aortic Stenosis: Background

Severe Symptomatic Aortic Stenosis:
50% 2-year Mortality



* Ross and Braunwald 1958, Circulation

Severe Symptomatic Aortic Stenosis:
Percent Treated



* Bourmeil et al. Heart 1999;82:143-148
* Jung et al. European Heart Journal 2002;23:1327-1343
* Pothof et al. Circulation 2005
* Chakraborty et al. J Heart Valve Dis 2006;15:310-321

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TAVR Candidacy

Dr Henning Rud Anderson

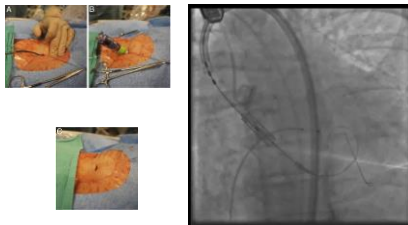


Dr Alan Cribier



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Transcatheter Aortic Valve Replacement



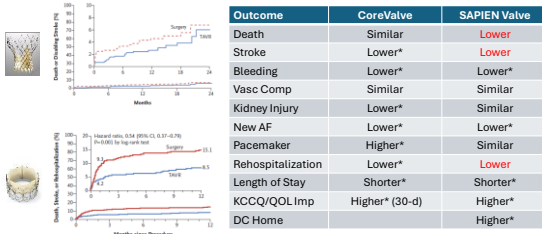
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TAVR for Severe Symptomatic Aortic Stenosis

	LOW	INTERMED	HIGH	INOPERABLE
	< 70 yo, no comorbidities	80 years old, 1-2 comorbidities	80 years old Prior sternotomy	
SAVEN	PARADOX III	PARADOX III	PARADOX III	PARADOX III
CORE	NOT Low Risk	SAVEN	PARADOX III	PARADOX III
SAVR				

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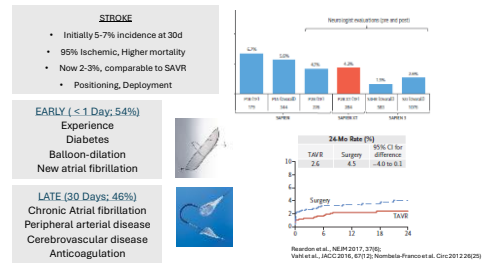
Low Risk TAVR Trials, Reported March 2019



Mack et al, 2019 NEJM; Popma et al., 2019 NEJM

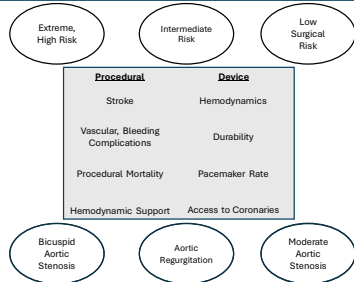
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Fewer Procedural Complications



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Evolving Populations, Considerations

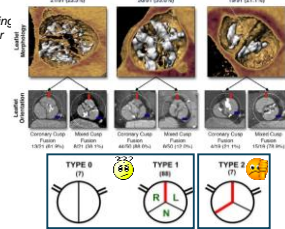


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Emerging Populations for TAVR: Bicuspid Valve Disease

Balloon-expandable (BE) and self-expanding (SE) valves are approved in US and EU for all surgical risk strata regardless of valve anatomy.

- ~ 25% patients referred for AVR
- Associated aortopathy
- "Commissural Splitting"
- Classification Systems
- Raphe vs Commissures
- Cusp Fusion



Alkhalil et al, 2016, JACC Cardiovasc Imaging
Yoon et al, 2017, JACC
Vincent et al, 2021, Circulation

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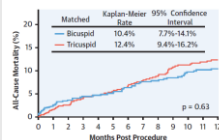
Emerging Populations for TAVR: Bicuspid Valve Disease

At least 40 observational trials of TAVR in Bicuspid valve disease that include nearly 13,000 patients

STS/ACC TVT Registry TAVR in bicuspid and tricuspid valve, n = 929 propensity matched pair

Similar 1-year survival

- Comparable stroke rates
- Change in NYHA class similar
- KCCQ/QOL improvement similar
- ≥ Moderate AI more frequent
- Higher rate of AV reintervention



Forest et al, 2020

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Emerging Populations for TAVR: Aortic Insufficiency

Case reports and small case series in patients with severe AI that were not surgical candidates

Using valves designed for AS, there was higher mortality, device embolization and need for a 2nd valve, and a greater rate of PVL than in those patients treated for AS

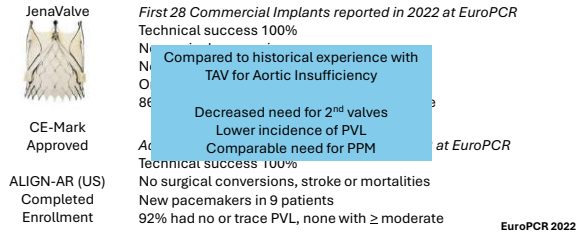


Anchors that do not require calcium to secure
Permit commissural alignment

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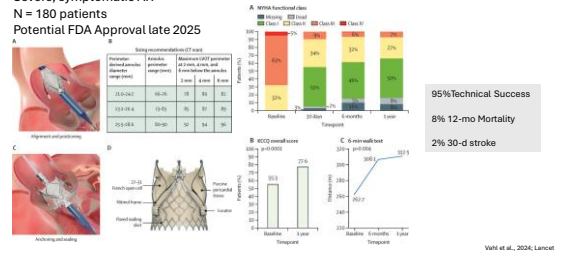
Emerging Populations for TAVR: Aortic Insufficiency



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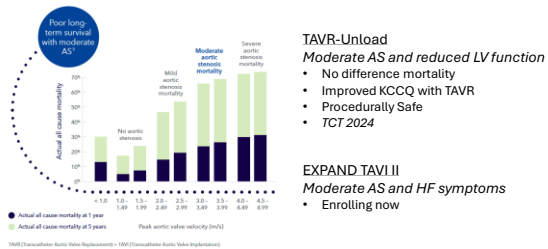
ALIGN-AR Trial: TAVR for Aortic Insufficiency

High or prohibitive risk surgical candidates
Severe, symptomatic AR
N = 180 patients
Potential FDA Approval late 2025



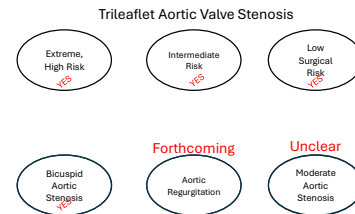
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TAVR for Moderate AS



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TAVR Commercially Available



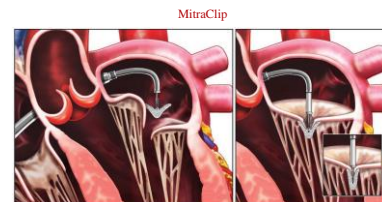
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Strategies for Atrioventricular Valves



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Mitral Transcatheter Edge-to-Edge Repair (TEER) for Mitral Regurgitation



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MitraClip and Delivery Device Fluoroscopy



COAPT Trial

Key Inclusion/Exclusion Criteria

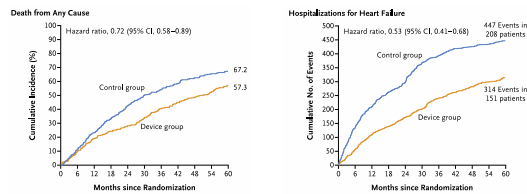
- Symptomatic (NYHA class II-IV) with at least moderate-to-severe ($\geq 3+$) mitral regurgitation with LVEF $\geq 20\%$ and $\leq 50\%$.
- Surgery will not be offered as a treatment option.
- LV end systolic dimension ≤ 70 mm.
- Mitral valve orifice area ≥ 4.0 cm².
- Optimally treated for coronary artery disease and heart failure including CRT if qualify.
- No evidence of moderate or severe right ventricular dysfunction.
- Pulmonary artery systolic pressure ≤ 70 mmHg.
- Do not require continuous oxygen therapy or chronic oral steroid use for chronic obstructive pulmonary disease (COPD).

Stone GW, et al. N Engl J Med. 2018;379:2307-18.

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COAPT Trial 5 – Year Outcomes



Stone GW, et al. N Engl J Med. 2023;388:2037-48.

COAPT Trial

Powered Secondary Endpoints

- | | |
|-----------------------------------------------------------------------------------------------|--------|
| 1. MR grade $\leq 2+$ at 12 months | <0.001 |
| 2. All-cause mortality at 12 months | <0.001 |
| 3. Death and all heart failure hospitalization through 24 months | <0.001 |
| 4. Change in quality-of-life (KCCQ) from baseline to 12 months | <0.001 |
| 5. Change in 6 minute walk distance from baseline to 12 months | <0.001 |
| 6. All-cause hospitalizations through 24 months | <0.05 |
| 7. NYHA class I or II at 12 months | <0.001 |
| 8. Change in LVEDV from baseline to 12 months | <0.005 |
| 9. All-cause mortality at 24 months | <0.001 |
| 10. Death, stroke, MI, or non-elective CV surgery for device-related complications at 30 days | <0.001 |

Stone GW, et al. N Engl J Med. 2018;379:2307-18.

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Intrepid® Transcatheter Mitral Valve Replacement (TMVR) APOLLO Clinical Trial

TEER	TMVR
Limitations <ul style="list-style-type: none"> Residual mitral regurgitation Not suitable for severe MAC Not suitable for degenerative hypoplasia or previous mitral valvulopathy with ring Contrast results with secondary mitral regurgitation No application for mitral stenosis 	Potential advantages <ul style="list-style-type: none"> Complete MR reduction Supportive results with severe MAC Supportive results in patients with valve-to-valve and valve-in-ring Minimally investigated with secondary mitral regurgitation Potential application for mitral stenosis

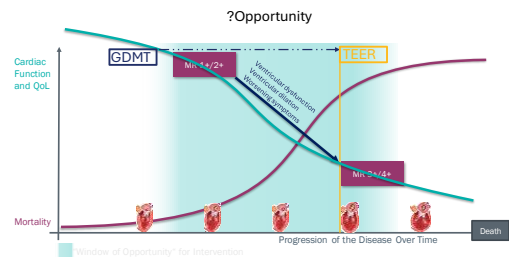
MAC, mitral annular calcification; MR, mitral regurgitation; TEER, transcatheter edge-to-edge repair; TMVR, transcatheter mitral valve replacement.



Quentin et al., 2023 / Clin Med

- Moderate-to-severe ($3+$) or severe ($4+$) symptomatic mitral regurgitation.
- Moderate ($2+$) symptomatic mitral regurgitation combined with mitral stenosis plus mitral annular calcification.
- Have to be unsuitable for treatment with approved transcatheter repair or surgical mitral valve intervention.

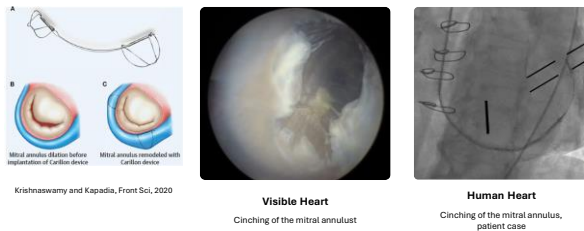
Time Gap exists between Cardiomyopathy and MR



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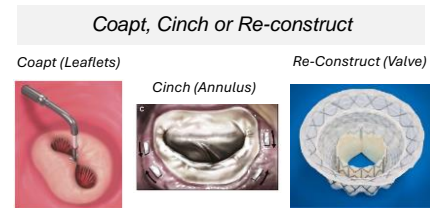
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EMPOWER Trial: Carillon device for annular reduction



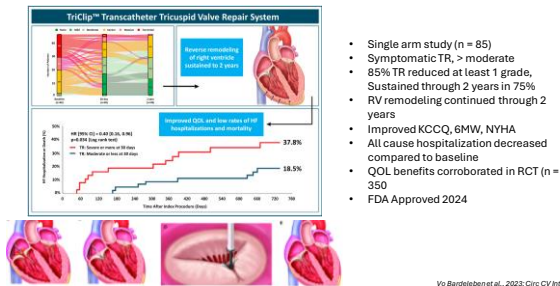
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Strategies for Atrioventricular Valves



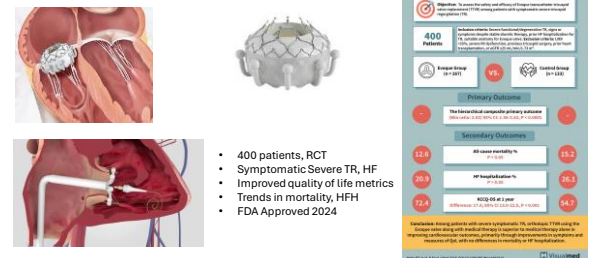
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TRILUMINATE: Tricuspid Valve Edge to Edge Repair



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TRISCEND II: Tricuspid Valve Replacement



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Update in Structural Heart Disease

Aortic Valve Disease

- Commercial TAVR for aortic stenosis, multiple other valves in clinical trials
- Clinical trials for aortic insufficiency, JenaValve anticipated approval 2025

Mitral Valve Disease

- Clips are approved (MitraClip, Pascal)
- Multiple trials for replacement (e.g. APOLLO)
- Multiple trials for annuloplasty strategies (Corcinch, Carillon)

Tricuspid Valve Disease

- Clip is approved (TriClip); other trials forthcoming
- Valve replacement approved (Evoque); other trials forthcoming
- Multiple trials for annuloplasty strategies (Corcinch, Carillon)

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Update in Structural Heart Disease

Percutaneous therapies have been developed for most valvular heart diseases.

They have comparable, and often superior safety profiles to traditional surgery.

Efficacy is comparable to the surgical approach in aortic stenosis, and superior to surgery in functional mitral regurgitation.

Forthcoming trials will determine efficacy of annuloplasty devices and perhaps combined approaches.

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Thank You

Advancing Cardiovascular Care through Hospital Collaboration

