

Structural Intervention in Heart failure

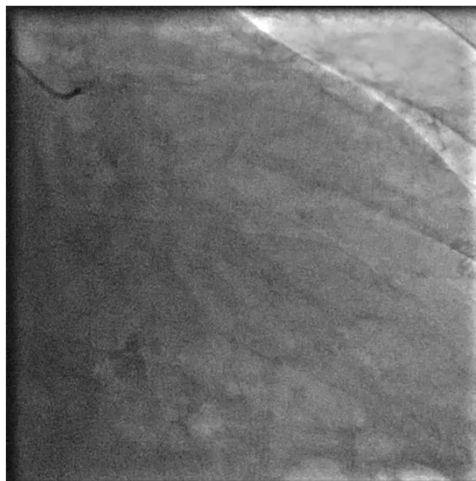
Ankush Lahoti, MD
Structural and Interventional Cardiology
TTUHSC, Lubbock

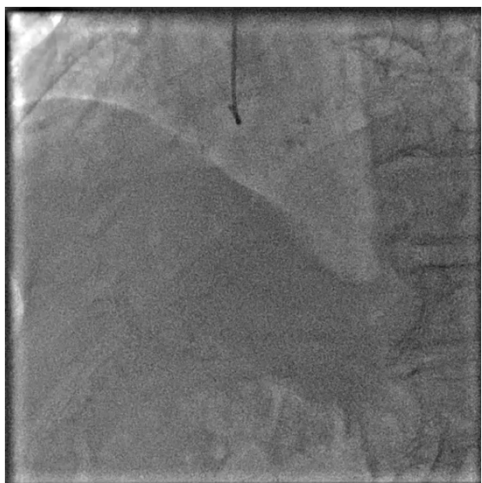
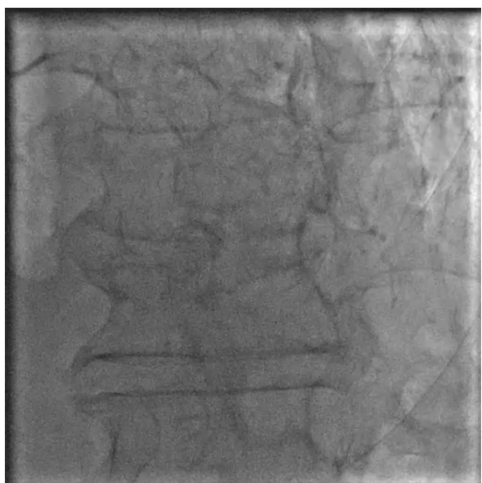
Topics

- TAVR
- Trans catheter edge to edge repair

Case

- 78 year old gentleman with past medical history of paroxysmal atrial fibrillation on warfarin, HTN presented to hospital with complaints of shortness of breath on exertion, lower extremity edema.
- On further evaluation patient was found to be anemic and echocardiogram performed showed severe aortic stenosis with LVEF of 30-35% (unknown baseline LVEF).
- Anemia was corrected and patient was referred for LHC and RHC which confirmed severe Aortic stenosis with multivessel CAD





TAVR

- Transcatheter aortic valve replacement has been commercially performed in US since 2012
- Initially was approved for prohibitive risk and with further trials TAVR is now also performed in appropriate patient with low risk
- Lets dive into the stages and guidelines

Table 13. Stages of Valvular Aortic Stenosis



Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	<ul style="list-style-type: none"> • BAV (or other congenital valve anomaly) • Aortic valve sclerosis 	Aortic $V_{max} < 2$ m/s with normal leaflet motion	None	None
B	Progressive AS	<ul style="list-style-type: none"> • Mild to moderate leaflet calcification/fibrosis of a bicuspid or trileaflet valve with some reduction in systolic motion 	<ul style="list-style-type: none"> • Mild AS: aortic V_{max} 2.0–2.9 m/s or mean P < 20 mm Hg • Moderate AS: aortic V_{max} 3.0–3.9 m/s or mean P 20– 	<ul style="list-style-type: none"> • Early LV diastolic dysfunction may be present • Normal LVEF 	None

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Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
C: Asymptomatic Severe AS					
C1	Asymptomatic severe AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	<ul style="list-style-type: none"> Aortic $V_{max} \geq 4$ m/s or mean P ≥ 40 mm Hg AVA typically is ≤ 1.0 cm² (or AVAi 0.6 cm²/m²) but not required to define severe AS Very severe AS is an aortic $V_{max} \geq 5$ m/s or mean P ≥ 60 mm Hg 	<ul style="list-style-type: none"> LV diastolic dysfunction Mild LV hypertrophy Normal LVEF 	<ul style="list-style-type: none"> None Exercise testing is reasonable to confirm symptom status
C2	Asymptomatic	Severe leaflet	<ul style="list-style-type: none"> Aortic $V_{max} > 4$ 	LVEF $< 50\%$	None

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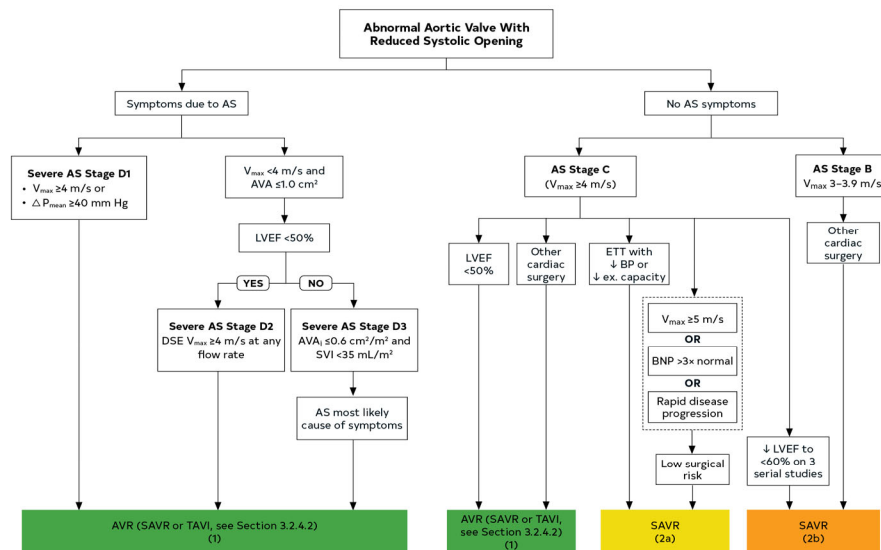
Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
D: Symptomatic severe AS					
D1	Symptomatic severe high-gradient AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	<ul style="list-style-type: none"> Aortic $V_{max} \geq 4$ m/s or mean P ≥ 40 mm Hg AVA typically ≤ 1.0 cm² (or AVAi ≤ 0.6 cm²/m²) but may be larger with mixed AS/AR 	<ul style="list-style-type: none"> LV diastolic dysfunction LV hypertrophy Pulmonary hypertension may be present 	<ul style="list-style-type: none"> Exertional dyspnea, decreased exercise tolerance, or HF Exertional angina Exertional syncope or presyncope
D2	Symptomatic severe low-flow, low-gradient	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	<ul style="list-style-type: none"> AVA ≤ 1.0 cm² with resting aortic $V_{max} < 4$ m/s or mean P < 40 mm Hg Dobutamine stress echocardiography shows AVA < 1.0 	<ul style="list-style-type: none"> LV diastolic dysfunction LV hypertrophy LVEF 	<ul style="list-style-type: none"> HF Angina Syncope or presyncope

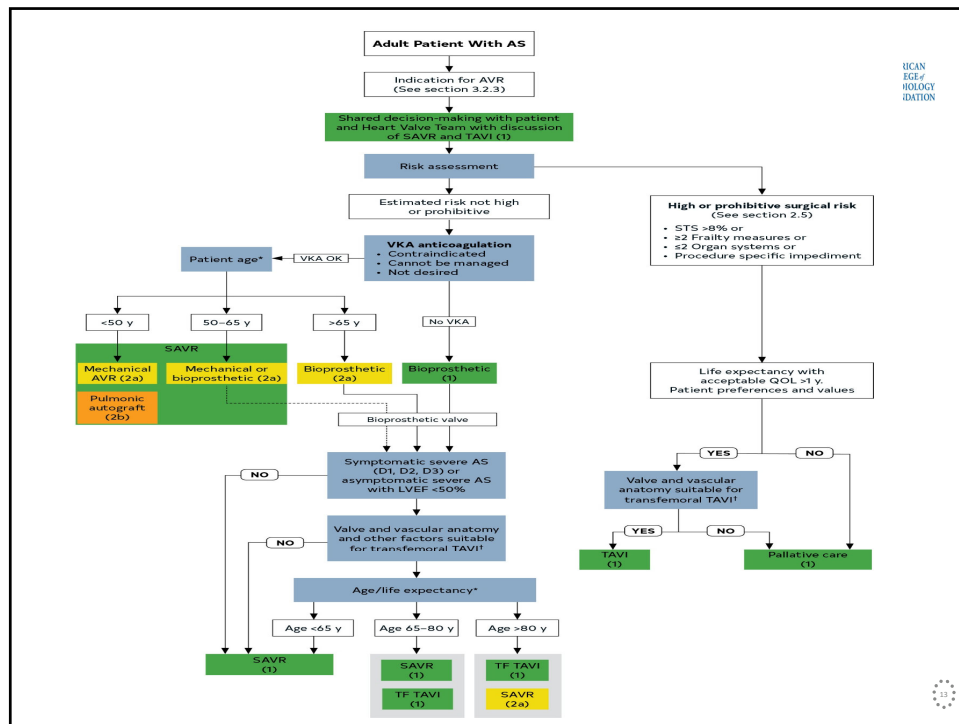
Table 13. Stages of Valvular Aortic Stenosis



Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
D: Symptomatic severe AS					
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	<ul style="list-style-type: none"> AVA $\leq 1.0 \text{ cm}^2$ (indexed AVA $\leq 0.6 \text{ cm}^2/\text{m}^2$) with an aortic $V_{\text{max}} < 4 \text{ m/s}$ or mean P $< 40 \text{ mm Hg}$ AND Stroke volume index $< 35 \text{ mL/m}^2$ Measured when patient is normotensive (systolic blood 	<ul style="list-style-type: none"> Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF $\geq 50\%$ 	<ul style="list-style-type: none"> HF Angina Syncope or presyncope

Timing of Intervention for AS





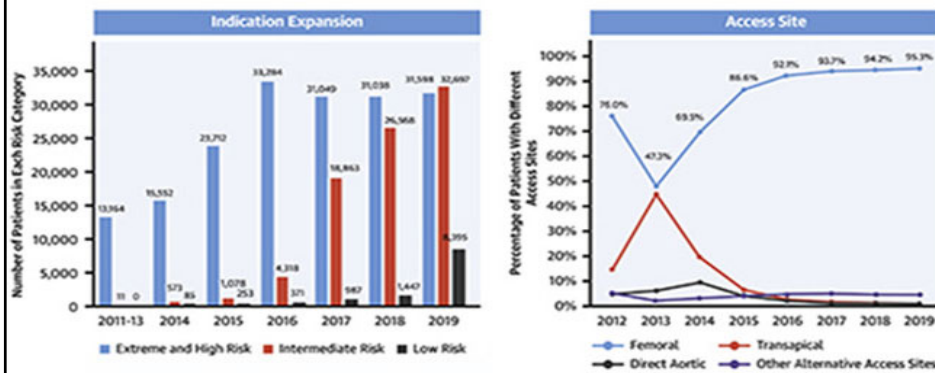
	Favors SAVR	Favors TAVI	Favors Palliation
Age/life expectancy*	<ul style="list-style-type: none"> Younger age/longer life expectancy 	<ul style="list-style-type: none"> Older age/fewer expected remaining years of life 	<ul style="list-style-type: none"> Limited life expectancy
Valve anatomy	<ul style="list-style-type: none"> BAV Subaortic (LV outflow tract) calcification Rheumatic valve disease Small or large aortic annulus† 	<ul style="list-style-type: none"> Calcific AS of a trileaflet valve 	
Prosthetic valve preference	<ul style="list-style-type: none"> Mechanical or surgical bioprosthetic valve preferred Concern for patient–prosthesis mismatch (annular enlargement might be considered) 	<ul style="list-style-type: none"> Bioprosthetic valve preferred Favorable ratio of life expectancy to valve durability TAVI provides larger valve area than same size SAVR 	
Concurrent cardiac conditions	<ul style="list-style-type: none"> Aortic dilation‡ Severe primary MR Severe CAD requiring bypass grafting Septal hypertrophy requiring myectomy AF 	<ul style="list-style-type: none"> Severe calcification of the ascending aorta (“porcelain” aorta) 	<ul style="list-style-type: none"> Irreversible severe LV systolic dysfunction Severe MR attributable to annular calcification

	Favors SAVR	Favors TAVI	Favors Palliation
Noncardiac conditions		<ul style="list-style-type: none"> Severe lung, liver, or renal disease Mobility issues (high procedural risk with sternotomy) 	<ul style="list-style-type: none"> Symptoms likely attributable to noncardiac conditions Severe dementia Moderate to severe involvement of ≥ 2 other organ systems
Frailty	<ul style="list-style-type: none"> Not frail or few frailty measures 	<ul style="list-style-type: none"> Frailty likely to improve after TAVI 	<ul style="list-style-type: none"> Severe frailty unlikely to improve after TAVI
Estimated procedural or surgical risk of SAVR or TAVI	<ul style="list-style-type: none"> SAVR risk low TAVI risk high 	<ul style="list-style-type: none"> TAVI risk low to medium SAVR risk high to prohibitive 	<ul style="list-style-type: none"> Prohibitive SAVR risk ($>15\%$) or post-TAVI life expectancy <1 y
Procedure-specific impediments	<ul style="list-style-type: none"> Valve anatomy, annular size, or low coronary ostial height precludes TAVI Vascular access does not allow transfemoral TAVI 	<ul style="list-style-type: none"> Previous cardiac surgery with at-risk coronary grafts Previous chest irradiation 	<ul style="list-style-type: none"> Valve anatomy, annular size, or coronary ostial height precludes TAVI Vascular access does not allow transfemoral TAVI

	Favors SAVR	Favors TAVI	Favors Palliation
Goals of Care and patient preferences and values	<ul style="list-style-type: none"> Less uncertainty about valve durability Avoid repeat intervention Lower risk of permanent pacemaker Life prolongation Symptom relief Improved long-term exercise capacity and QOL Avoid vascular complications Accepts longer hospital stay, pain in recovery period 	<ul style="list-style-type: none"> Accepts uncertainty about valve durability and possible repeat intervention Higher risk of permanent pacemaker Life prolongation Symptom relief Improved exercise capacity and QOL Prefers shorter hospital stay, less postprocedural pain 	<ul style="list-style-type: none"> Life prolongation not an important goal Avoid futile or unnecessary diagnostic or therapeutic procedures Avoid procedural stroke risk Avoid possibility of cardiac pacemaker

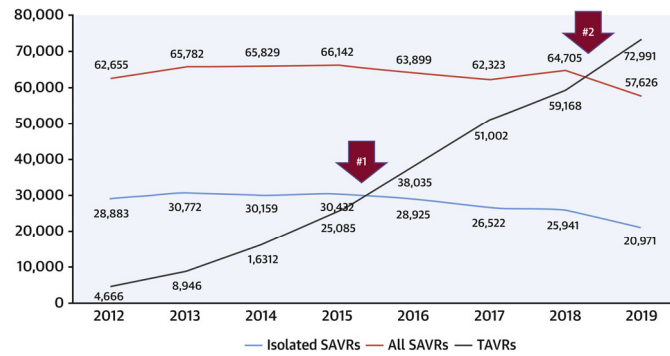


Carroll J, Mack M, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2020 Nov, 76 (21) 2492–2516.



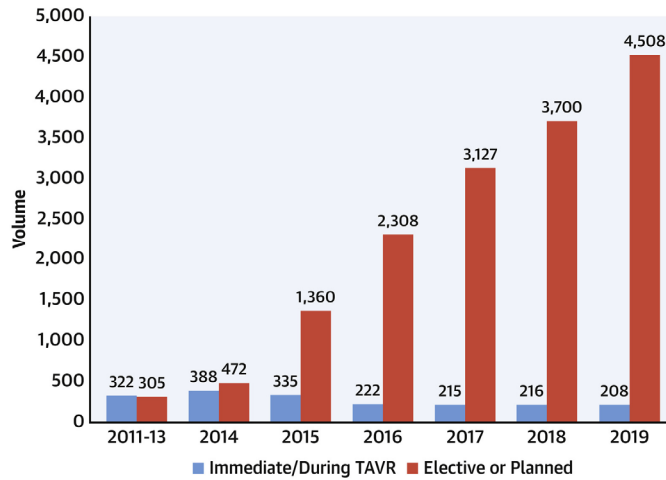
Carroll J, Mack M, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2020 Nov, 76 (21) 2492–2516.

Annual volume of TAVR and SAVR



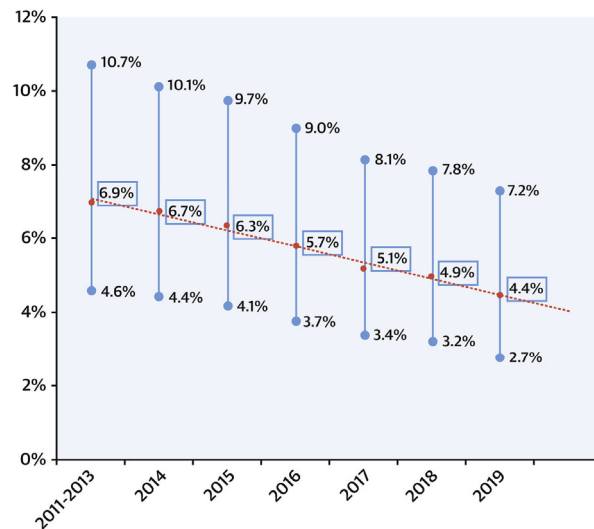
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Valve in valve TAVR implants



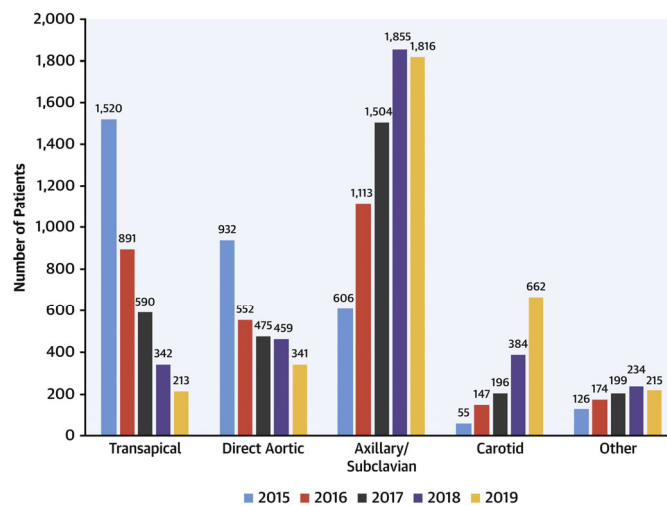
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Risk profile of patients

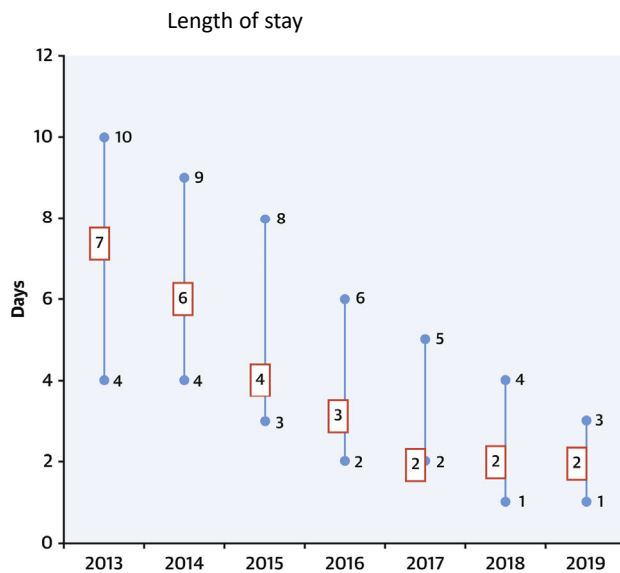


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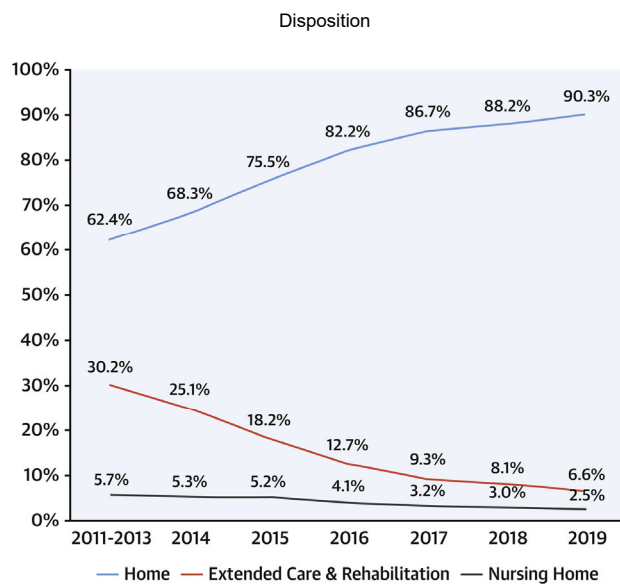
Forms of Alternate Access



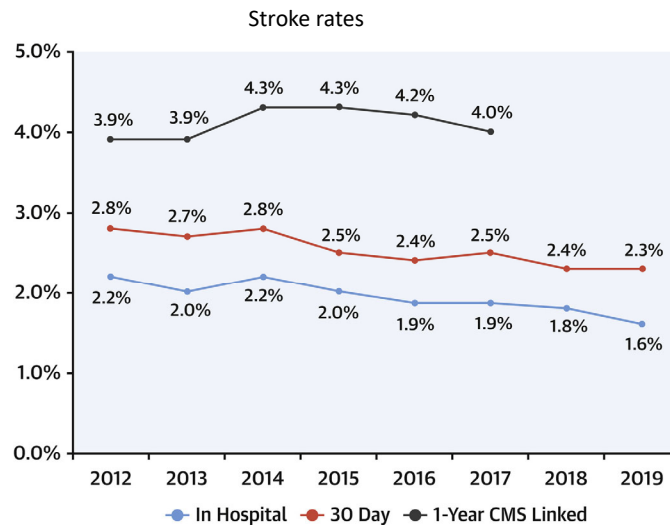
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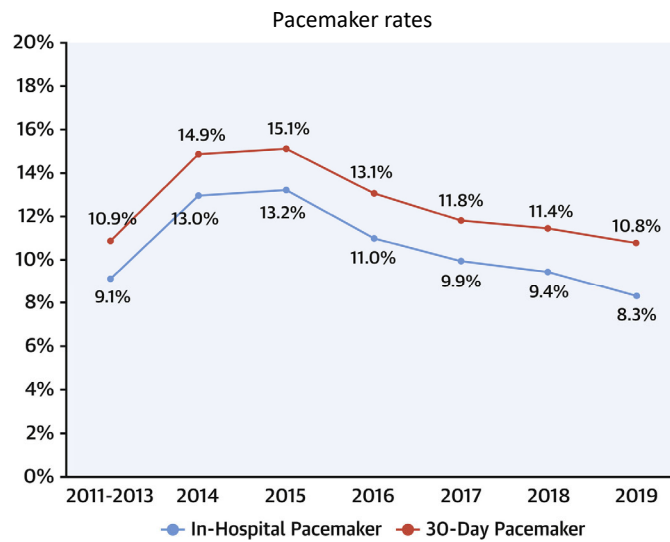
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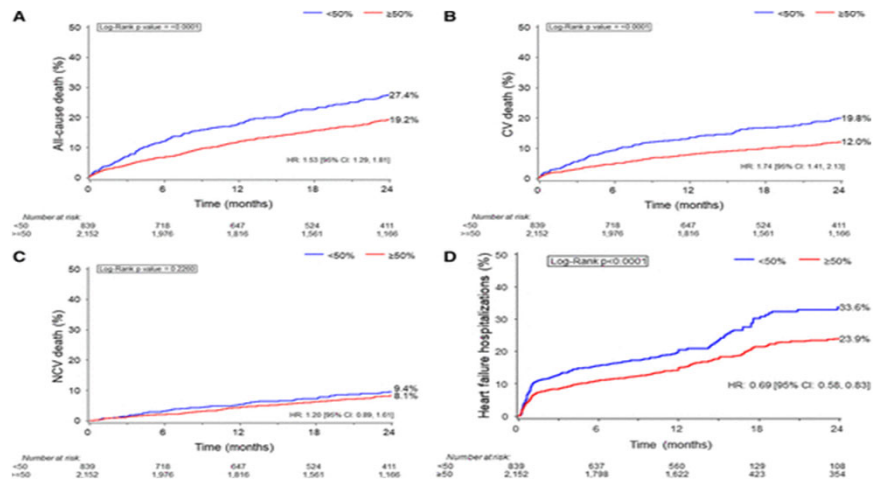
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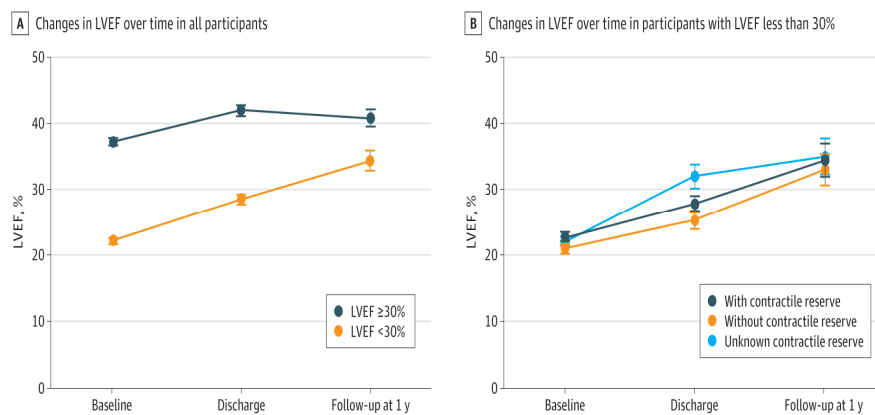
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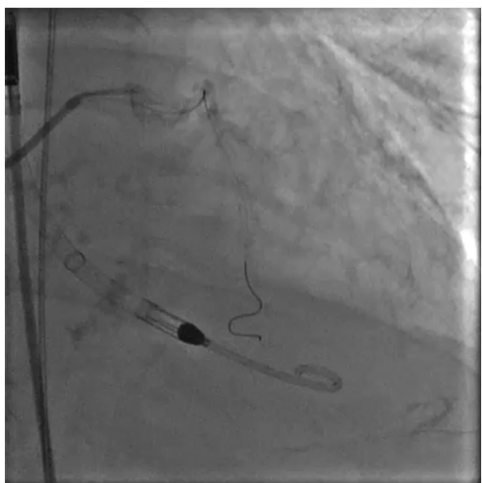
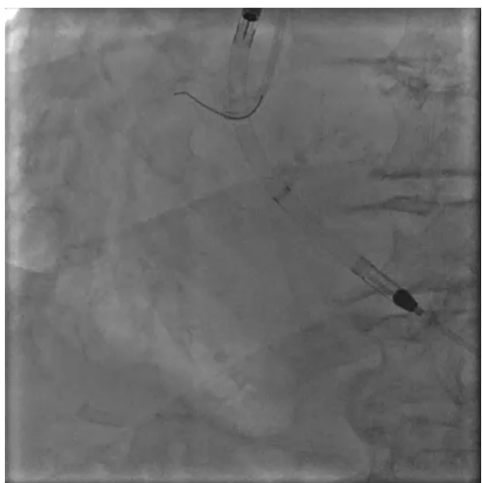
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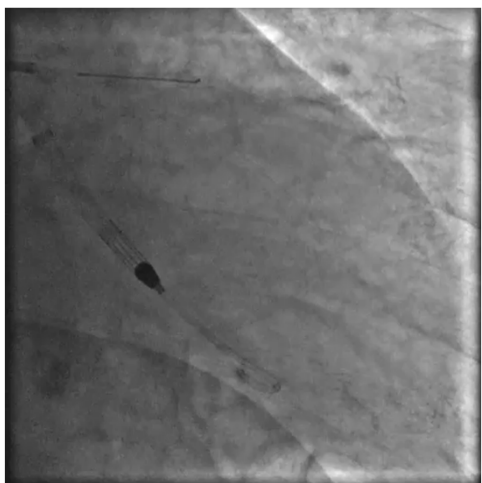
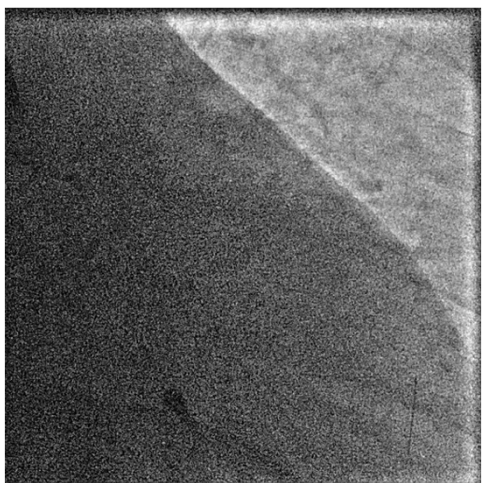


Ariel Furer. Circulation: Heart Failure. Effect of Baseline Left Ventricular Ejection Fraction on 2-Year Outcomes After Transcatheter Aortic Valve Replacement, Volume: 12, Issue: 8, DOI: (10.1161/CIRCHEARTFAILURE.118.005809)



Outcomes From Transcatheter Aortic Valve Replacement in Patients With Low-Flow, Low-Gradient Aortic Stenosis and Left Ventricular Ejection Fraction Less Than 30%: A Substudy From the TOPAS-TAVI Registry







Transcatheter edge to edge repair

Mitral Regurgitation

Primary



- Structural abnormality
- Leaflets
 - Subvalvular apparatus
 - Chordae and papillary muscles

Secondary



- Structurally normal valve
- Incomplete coaptation
 - LV failure (ischemic or not)
 - Annular dilatation related to A Fib



The COAPT Trial

Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation

A parallel-controlled, open-label, multicenter trial in 614 patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remained symptomatic despite maximally-tolerated GDMT

Randomize 1:1*

MitraClip + GDMT
N=312

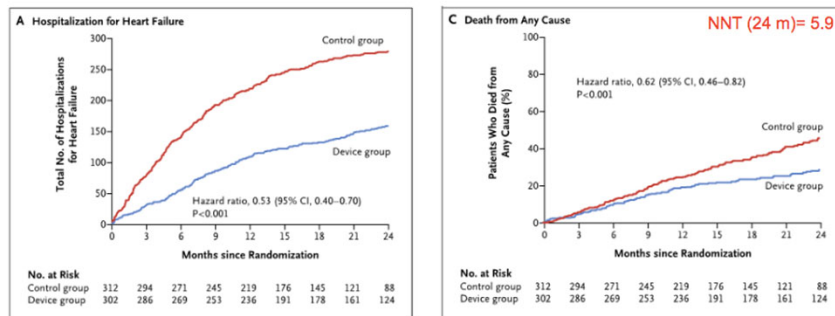
GDMT alone
N=302

Follow-up at 30d, 6mo, 1y, 18mo, 2y, 3y, 4y, 5y

Stone et al NEJM 2018 379: 2307-2318 , presented at TCT 2018

COAPT Trial

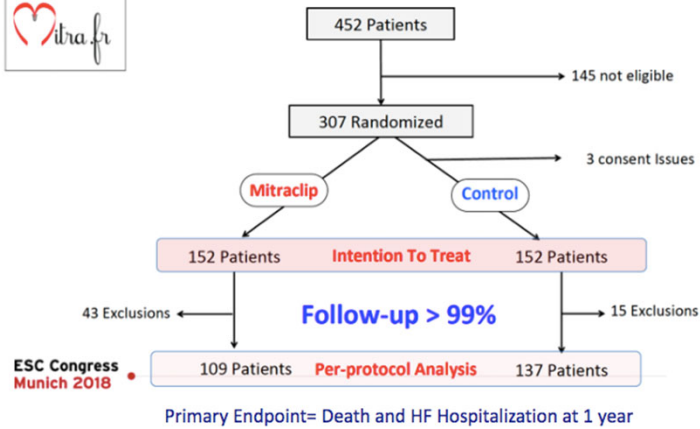
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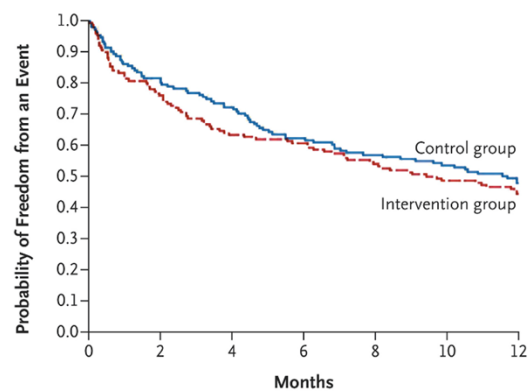
MITRA-FR Trial



Obadia et al at esc 2018

Primary outcome

All cause death or unplanned hospitalization for heart failure hospitalization at 12 mon



No. at Risk							
Control group	152	123	109	94	86	80	73
Intervention group	151	114	95	91	81	73	67

Obadia et al NEJM 2018 aug 27

COAPT vs. MITRA-FR: MR, LV Volumes and Function

	COAPT (n=614)	MITRA-FR (n=304)
EROA, mm ² (mean ± SD)	41 ± 15	31 ± 10
- <30 mm ²	14% (80/591)	52% (157/301)
- 30 – 40 mm ²	46% (270/591)	32% (95/301)
- >40 mm ²	41% (241/591)	16% (49/301)
LVEF, % (mean ± SD)	31 ± 9	33 ± 7
LVEDV, mL/m ² (mean ± SD)	101 ± 34	135 ± 35

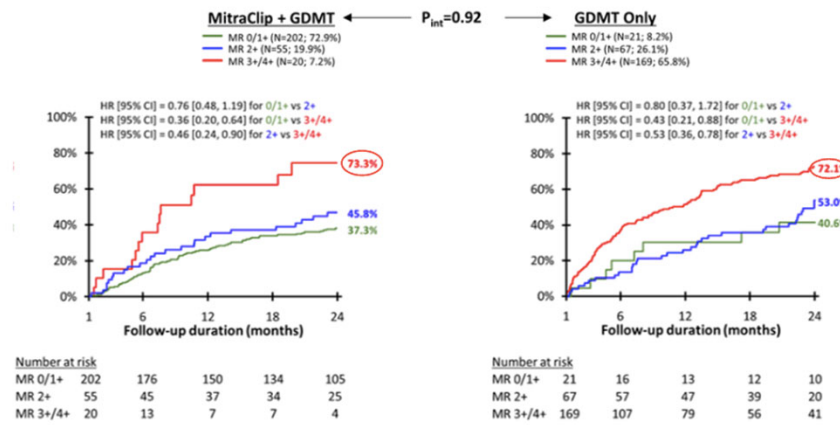
Obadia JF et al. NEJM. 2018 Aug 27. doi: 10.1056/NEJMoa1805374; Stone GW et al. NEJM. 2018 Sept 23.

Stone et al at TCT

Difference between COAPT and mitra FR

	COAPT	Mitral FR
EROA mm2	41+- 15	31+- 10
LVEDV ml/m2	101+- 34	135+- 35
Residual MR Acute MR >3+	5%	9%
At 12 months Residual MR>3+	5%	17%

All-cause Mortality or HFH according to severity of residual MR



Kar et al Circulation aug 2021

COR	LOE	Recommendations
2a	B-R	<p>1. In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), transcatheter edge-to-edge mitral valve repair (TEER) is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD ≤70 mm, and pulmonary artery systolic pressure ≤70 mm Hg.</p>

Otto et al JACC 2021

