Update on Invasive Cardiology

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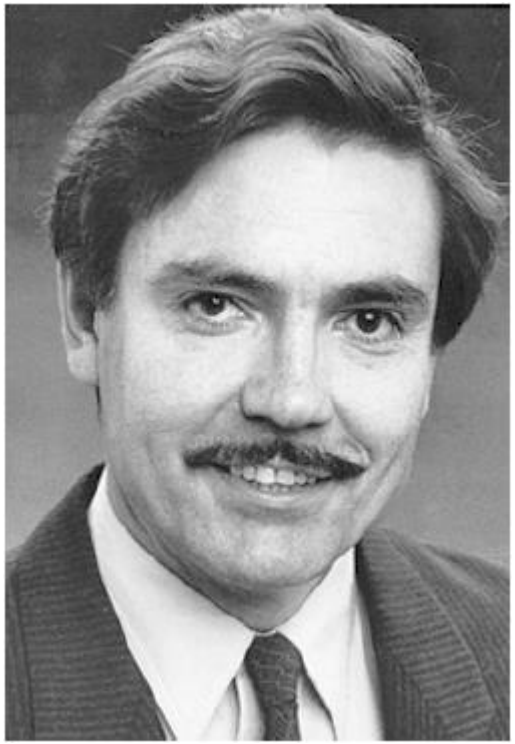
System Medical Director

Structural Heart Disease and Intervention

Virginia Mason Franciscan Health™

Objectives

1. Invasive CAD management
2. Update on valvular intervention (aortic, mitral and tricuspid valves)
3. Invasive therapy for advanced heart failure
4. Atrial appendage occlusion



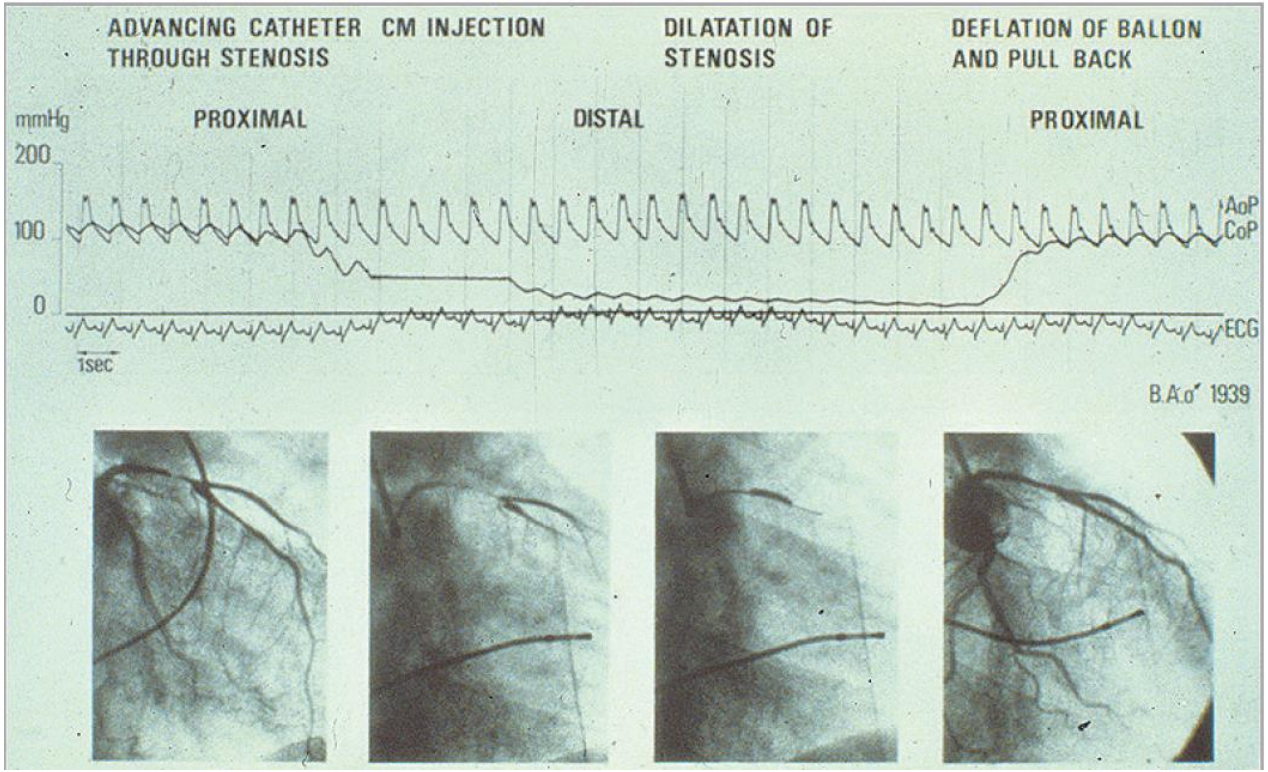
Andreas Roland Grüntzig was born in Dresden, Germany, ten weeks before the outbreak of the Second World War on 25 June 1939

Initially they developed a double lumen balloon catheter, which allowed balloon inflation through one lumen and perfusion of the occluded artery through the other.

The double lumen catheter was ultimately used for the first time to treat an iliac artery stenosis on 23 January 1975.

The first dilatation of a coronary artery was performed through collaboration with Richard Myler in San Francisco on 9 May 1977.

State of the art: 40 years of percutaneous cardiac intervention



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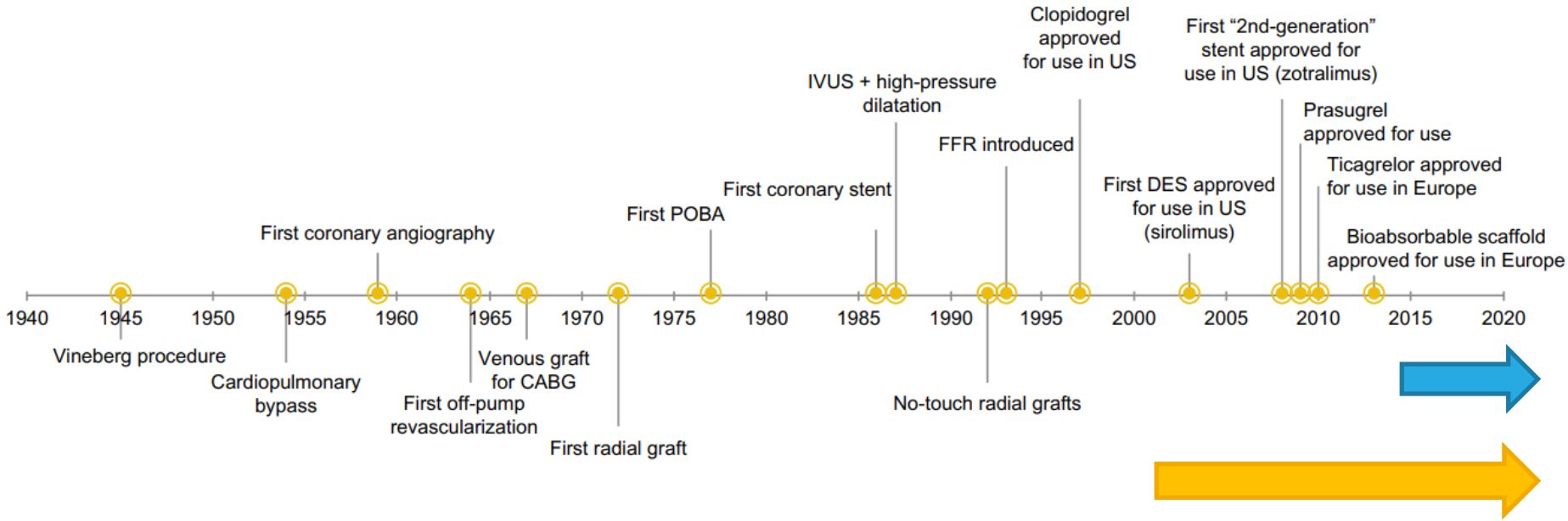

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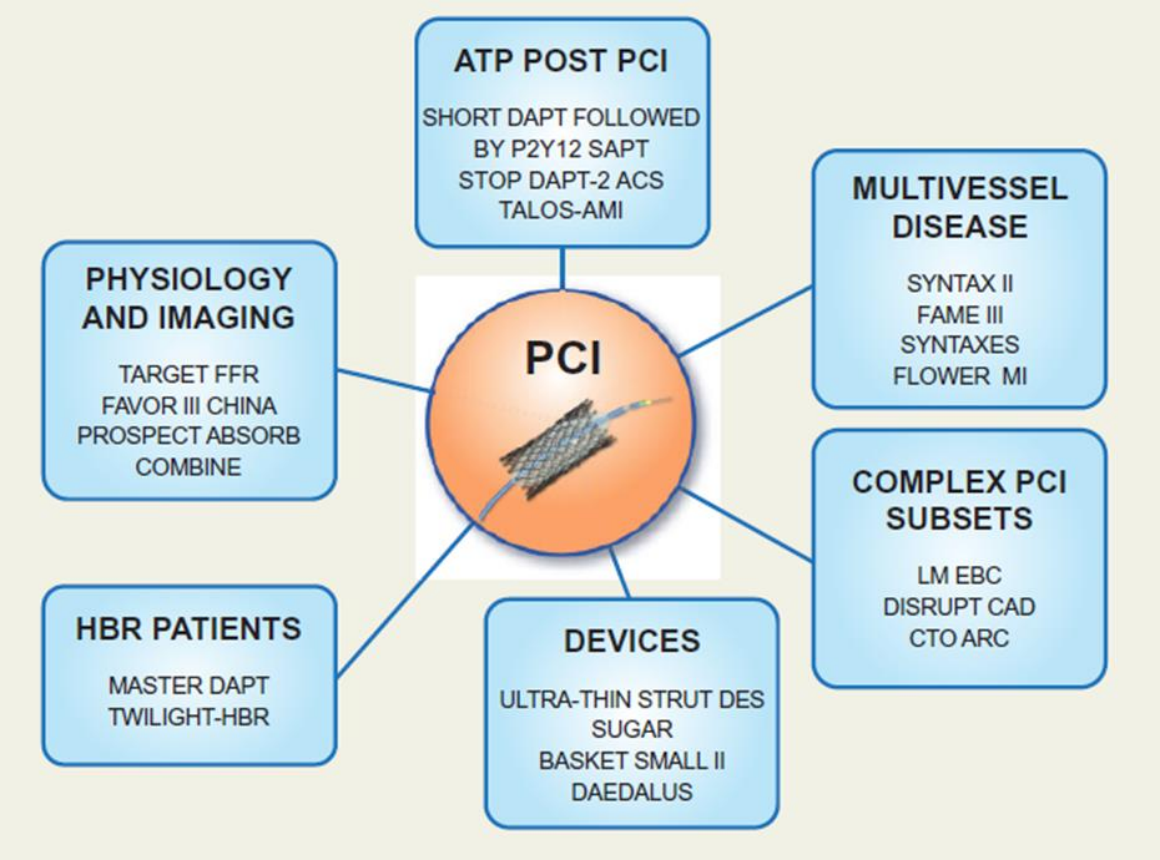
Research Reports in Clinical Cardiology 2015:6 57–71



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2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

2021 ESC/EACTS Guidelines for the management of valvular heart disease

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

2020 ESC Guidelines for the management of adult congenital heart disease

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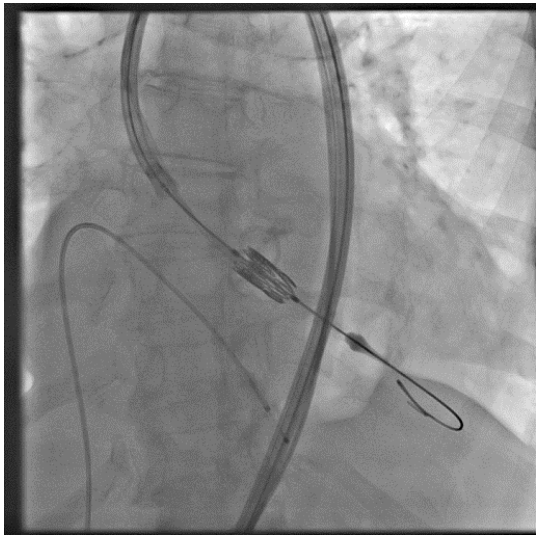
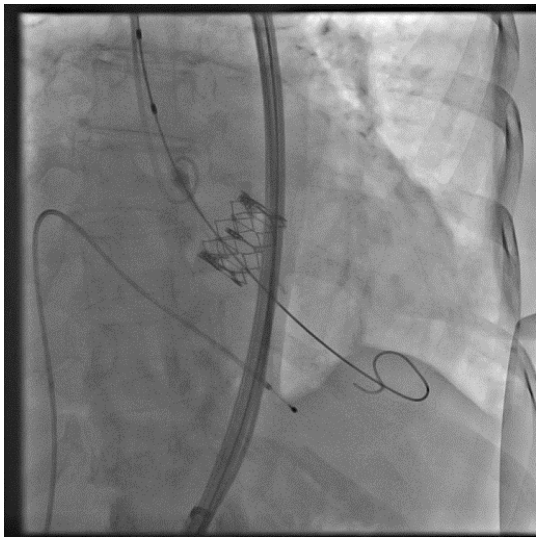

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Stage: A, B, C, D

Target: Aortic, Mitral, Tricuspid Valve

Risk stratification: STS score, EURO score, Frailty…..

Outcome: TVT registry

Age and Durability……..

Multivalvular abnormalities

Destination VS Bridging therapy

With/without CAD

Expanded Indications

Heart team approach

Shared decision making process

Clinical trials on AV, MV, TV and PV

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STS National Database

STS Public Reporting

STS/ACC TVT Registry

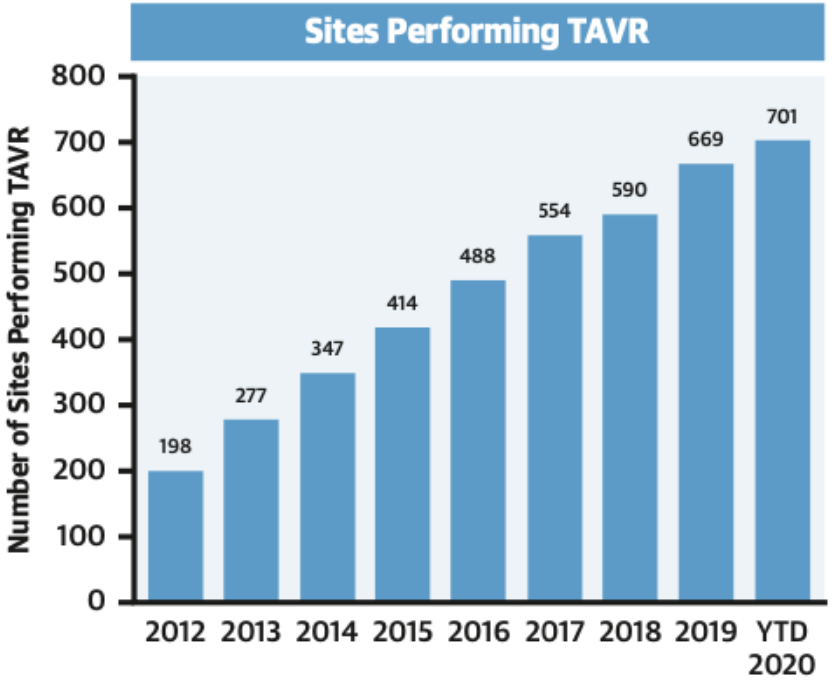
STS/ACC TVT Registry Public Reporting

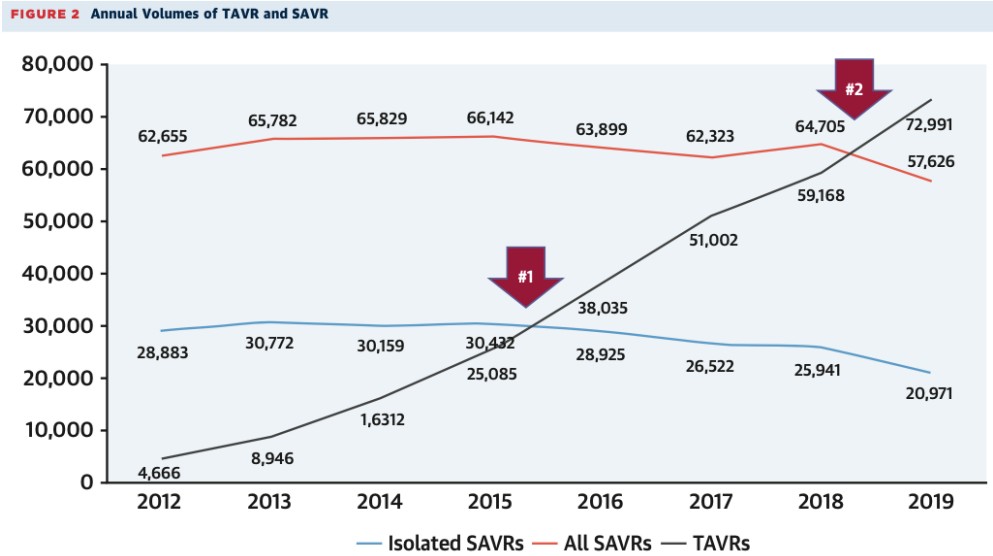
STS/ACC TVT Registry

STS/ACC TVT Registry™

The STS/ACC TVT Registry, created through a collaboration between STS and the American College of Cardiology (ACC), monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients. Employing state-of-the-art heart valve technology, transcatheter heart valve procedures provide new treatment options for patients who are not eligible for conventional heart valve replacement or repair surgery.

The TVT Registry has been approved by the Centers for Medicare & Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage decisions for transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve repair (TMVR).





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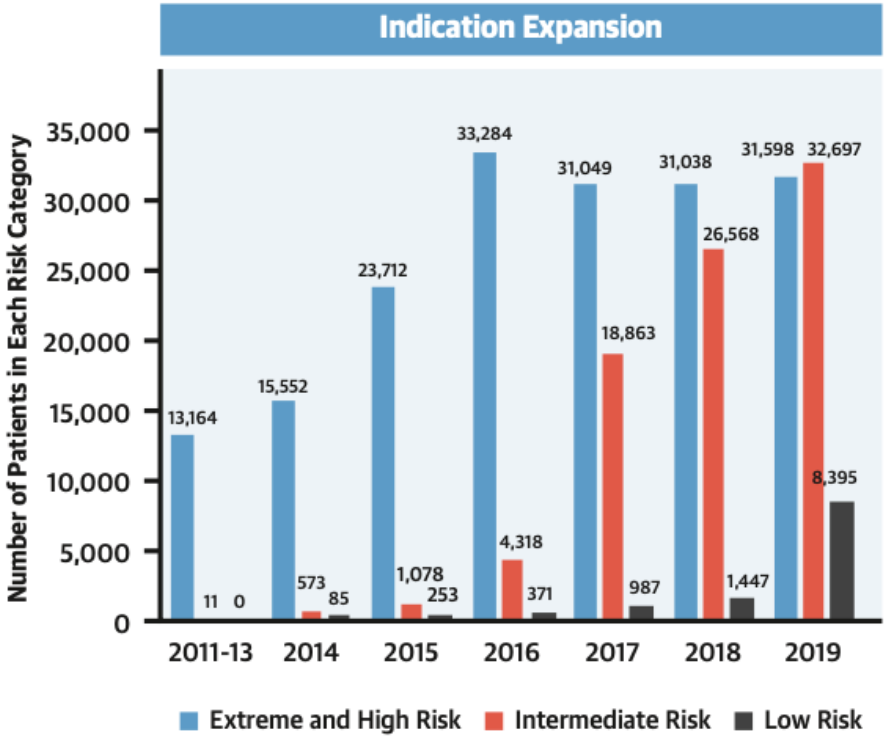

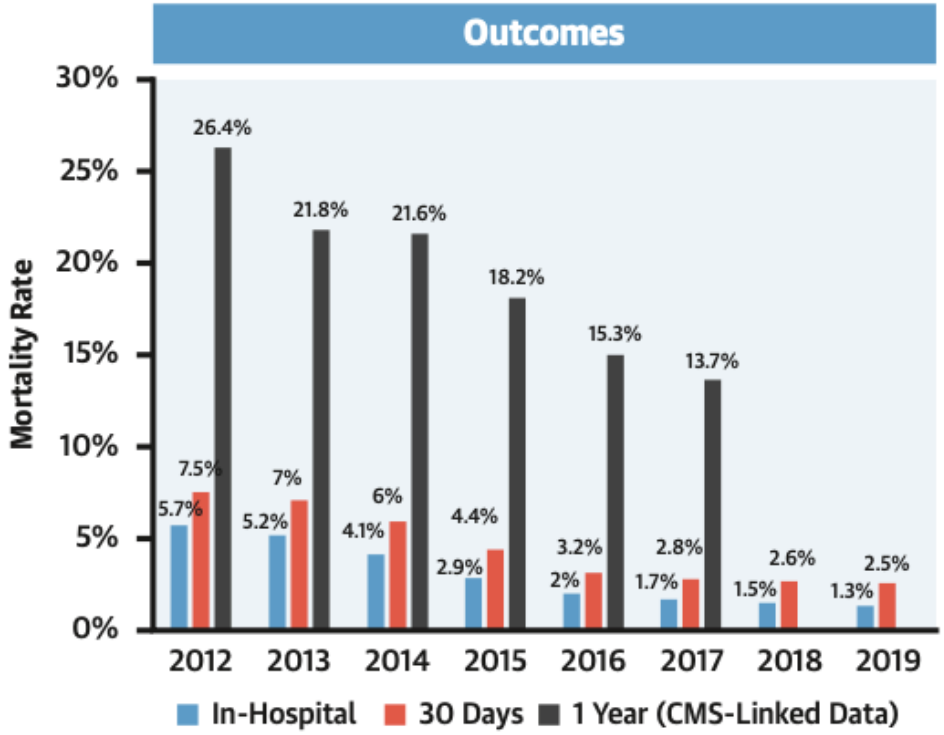

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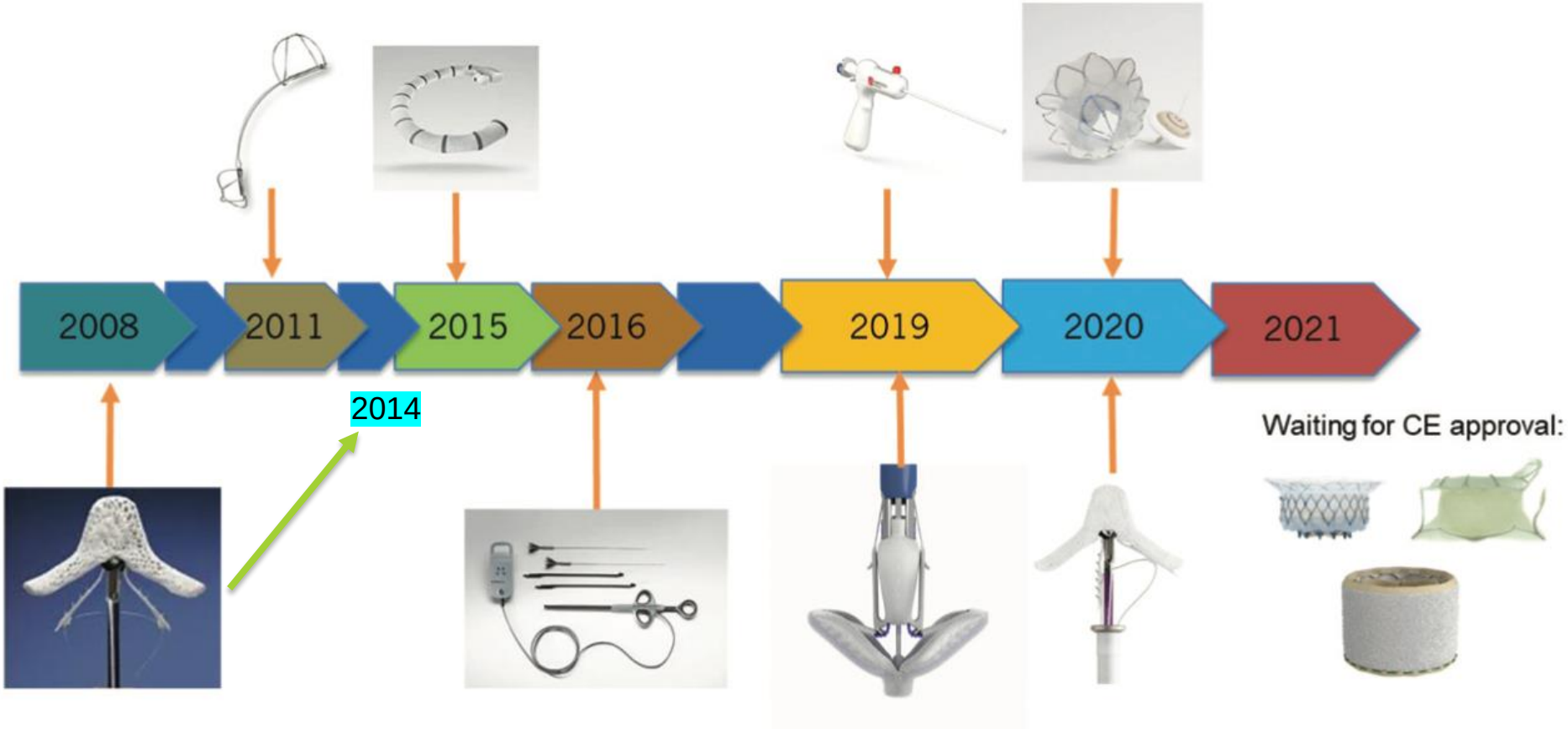
Evidence for TAVR demonstrated:

- ➢Lower Stroke
- ➢Lower Mortality
- ➢Less Atrial Fibrillation
- ➢Quicker Recovery
- ➢Better Hemodynamics
- ➢No Scar

Perspectives on Transcatheter Mitral Therapy



Transcatheter Edge to Edge Repair (TEER)

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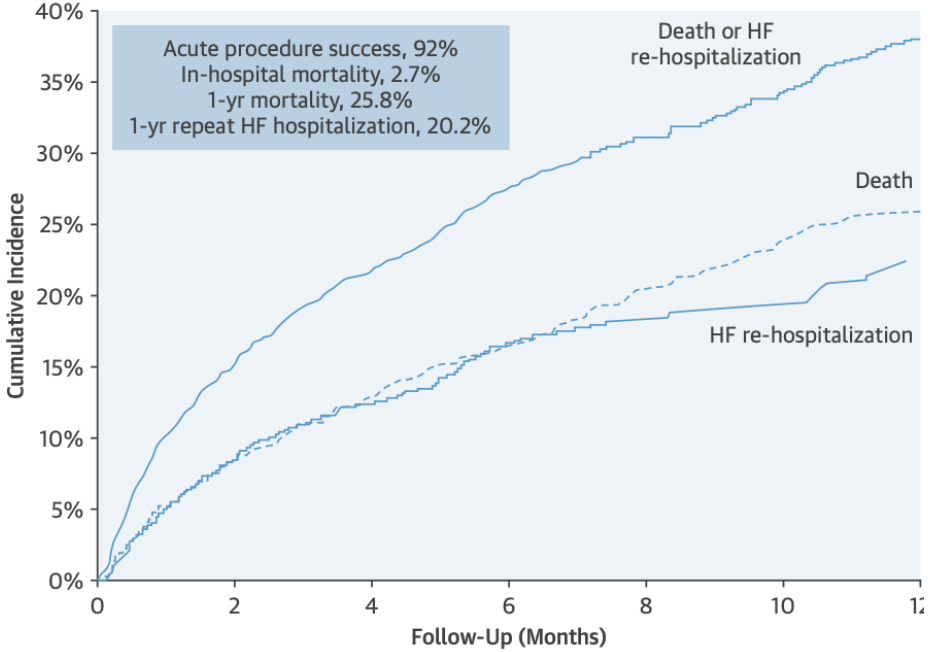
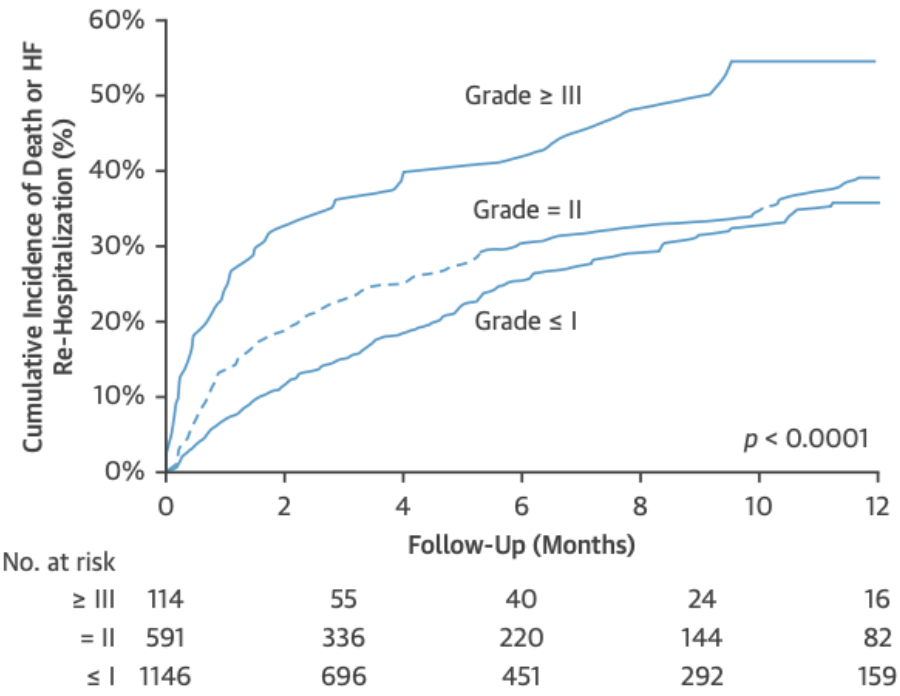
Outcomes With Transcatheter Mitral Valve Repair in the United States

An STS/ACC TVT Registry Report





Sorajja, P. et al. J Am Coll Cardiol. 2017;70(19):2315–27.

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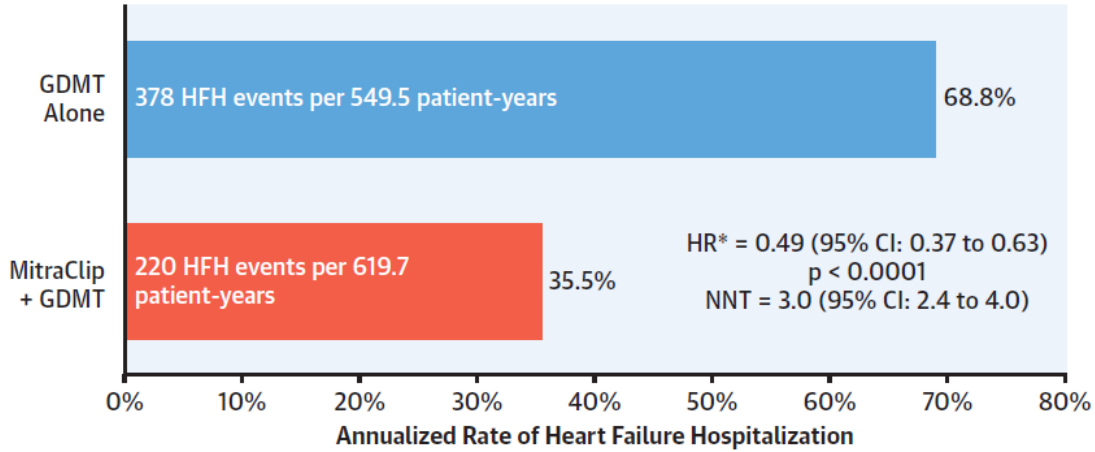

TABLE 2 Device-Related Complications in the Safety Analysis Population

	Through 30 Days	Through 12 Months	Through 24 Months	Through 36 Months
Overall rate	4 (1.4)	9 (3.3)	13 (5.2)	18 (8.7)
Device-related complications	4 (1.4)	4 (1.4)	4 (1.4)	4 (1.4)
Single leaflet device attachment	2 (0.7)	2 (0.7)	2 (0.7)	2 (0.7)
Device embolization	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
Endocarditis requiring surgery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mitral stenosis requiring surgery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Any device-related complication requiring nonelective cardiovascular surgery	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
Progressive heart failure	0 (0.0)	5 (2.0)	9 (3.8)	14 (7.4)
Left ventricular assist device implant	0 (0.0)	3 (1.2)	6 (2.6)	10 (5.4)
Heart transplantation	0 (0.0)	2 (0.8)	3 (1.3)	5 (2.6)

Values are n (%). The safety population (n = 293) consisted of those patients in whom a MitraClip procedure was attempted. Therefore, the left ventricular assist device and heart transplantation rates here vary slightly from those in Table 3, which were analyzed in the intention-to-treat population.

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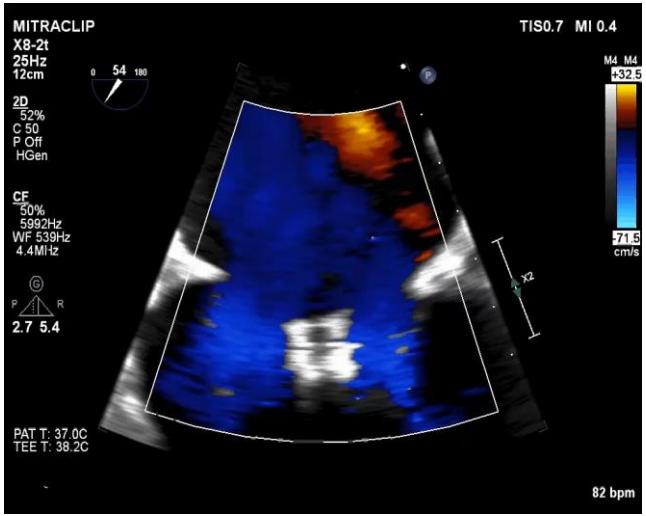

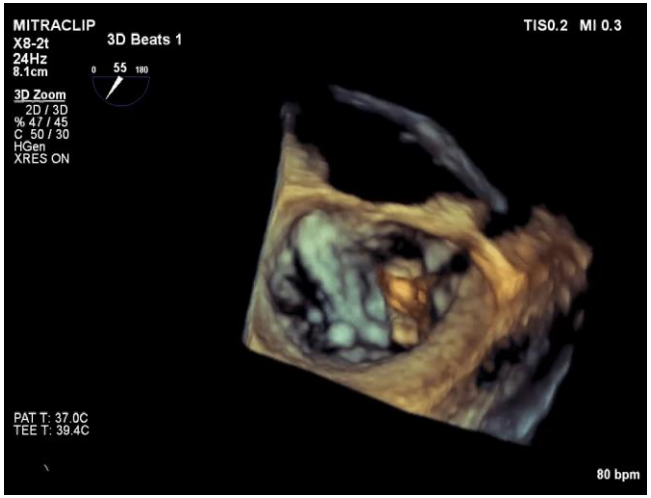

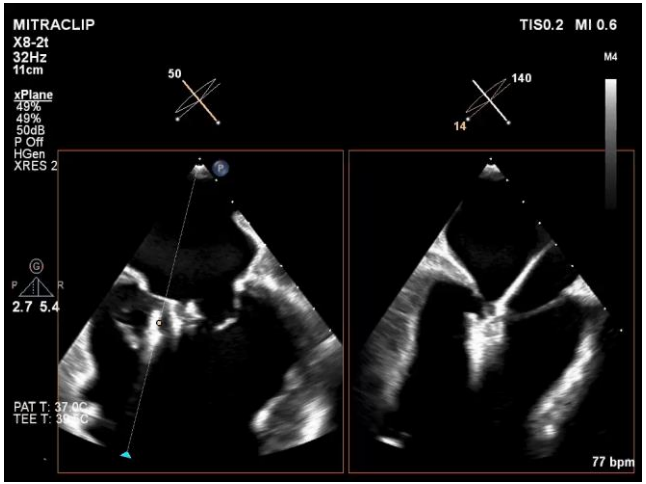

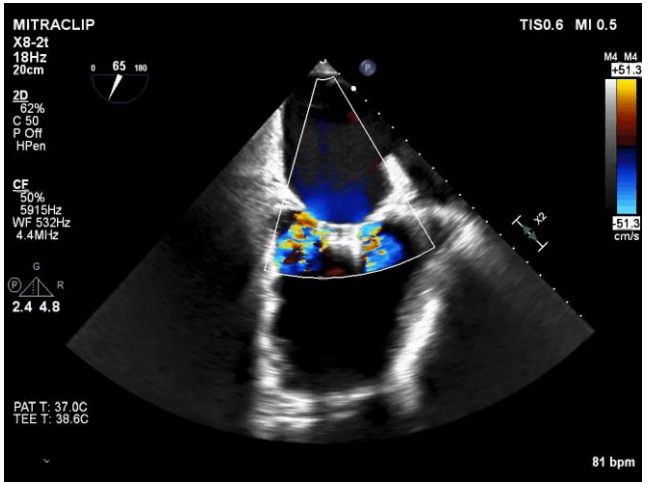

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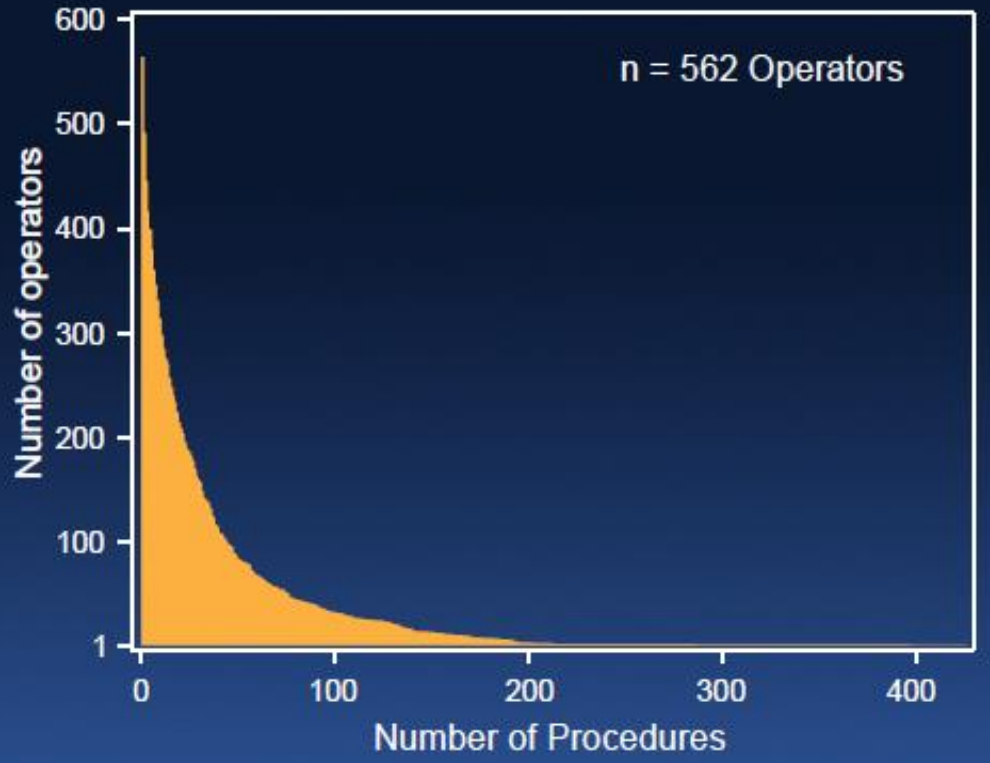
Results: Mitraclip Volume



- **14,923 cases performed by 562 operators at 290 sites between 2013 and 2018**
- **230 operators with case experience between 26-50**
- **116 operators with case experience > 50**

Mitral Valve Surgery for MR

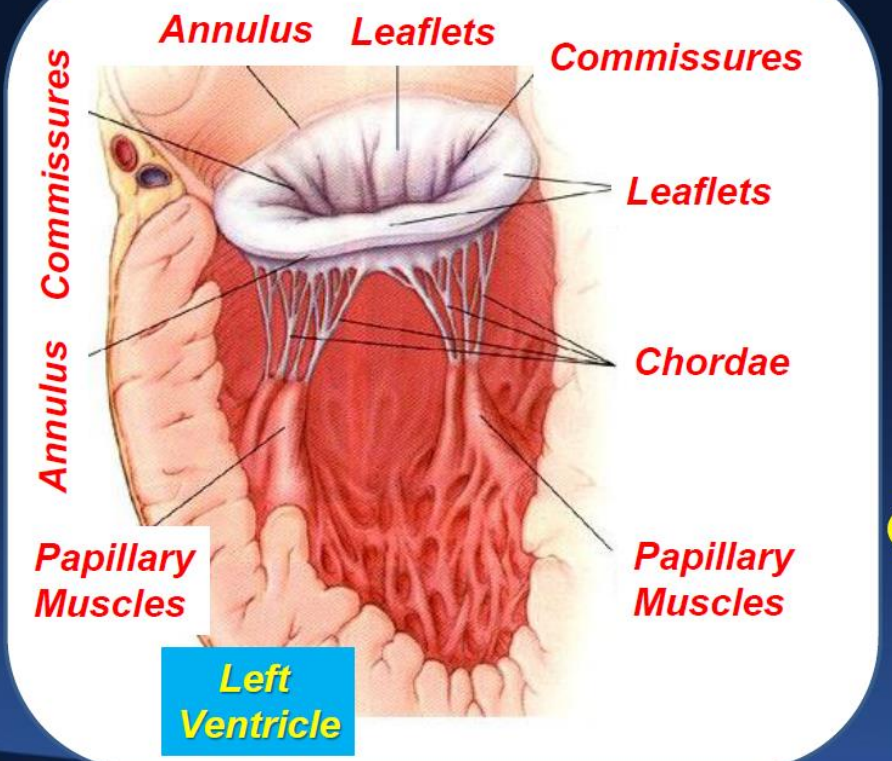
There is no GOOD transcatheter MR repair!

A Replacement

is better than

A BAD Repair!

Mitral Interventions



TARGETS

1. Leaflets
2. Annulus
3. Chordae
4. Left ventricle
5. Multiple sites

TMVR

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TMVR Devices

Tendyne (Abbott)

M3 (Edwards)

Intrepid (Medtronic)

Tiara (Neovasc)

Cephea (Abbott)

EVOQUE (Edwards)

Highlife

AltaValve

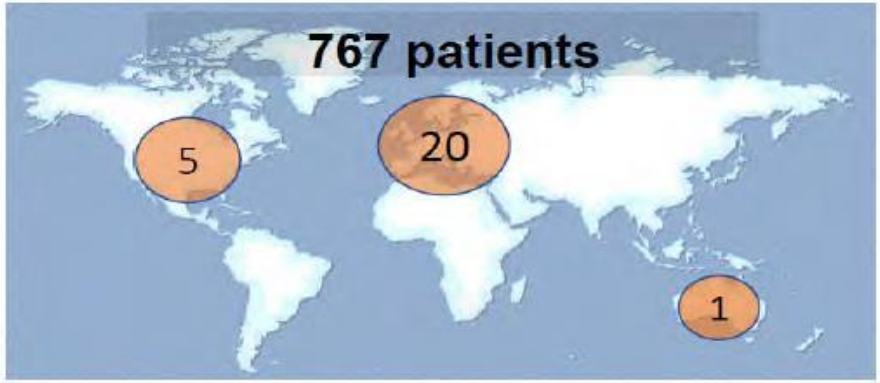
CHOICE-MI

The CHoice of OptImal transCatheter trEatment for Mitral Insufficiency Registry

- investigator-initiated
- multicentre
- international
- retrospective
- device-independent
- 05/2014 – 03/2021

CHOICE-MI inclusion criteria:

- significant MR
- unsuitable for standard therapy
  - high risk for surgery
  - suboptimal TEER anatomy
- screening for TMVI



Baseline characteristics (clinical, echo, CT)

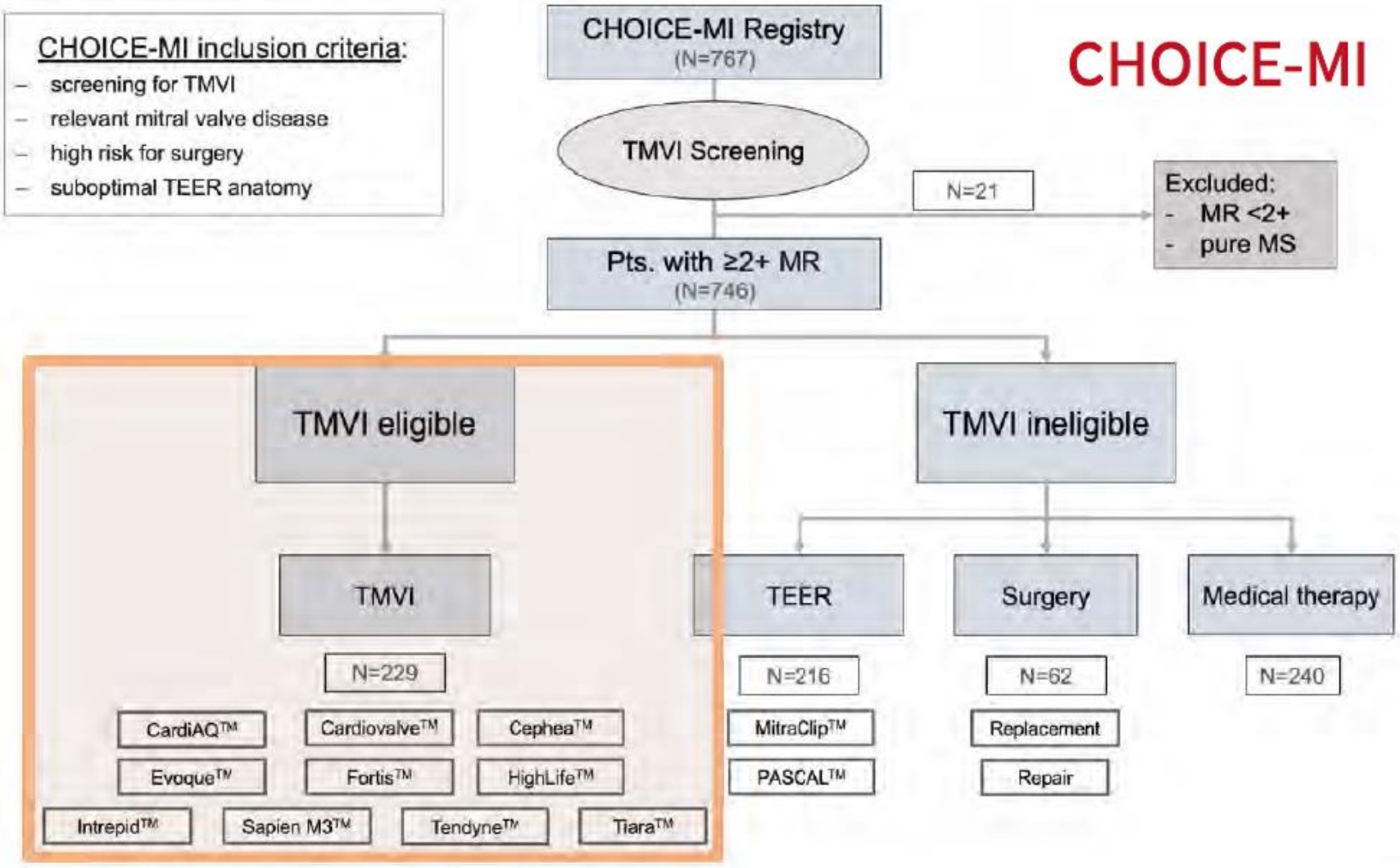
PMR	SMR	Mixed PMR/SMR	MAC

MVARC criteria

Clinical / echo outcome at 30-days and 1-year

Primary composite outcome: 1-year all-cause mortality or heart failure hospitalisation

CHOICE-MI

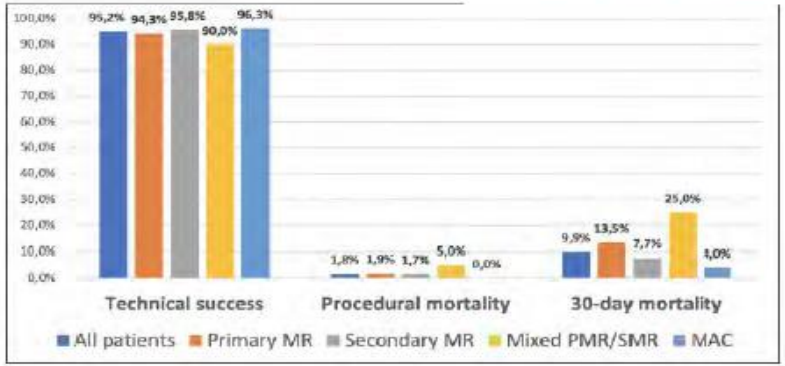

CHOICE-MI inclusion criteria:
– screening for TMVI
– relevant mitral valve disease
– high risk for surgery
– suboptimal TEER anatomy
CHOICE-MI Registry
(N=767)
TMVI Screening
N=21
Excluded:
- MR <2+
- pure MS
Pts. with ≥2+ MR
(N=746)
TMVI eligible
TMVI ineligible
TMVI
TEER
Surgery
Medical therapy
N=229
N=216
N=62
N=240
CardiAQ™
Cardiovalve™
Cephea™
Evoque™
Fortis™
HighLife™
Intrepid™
Sapien M3™
Tendyne™
Tiara™
MitraClip™
PASCAL™
Replacement
Repair

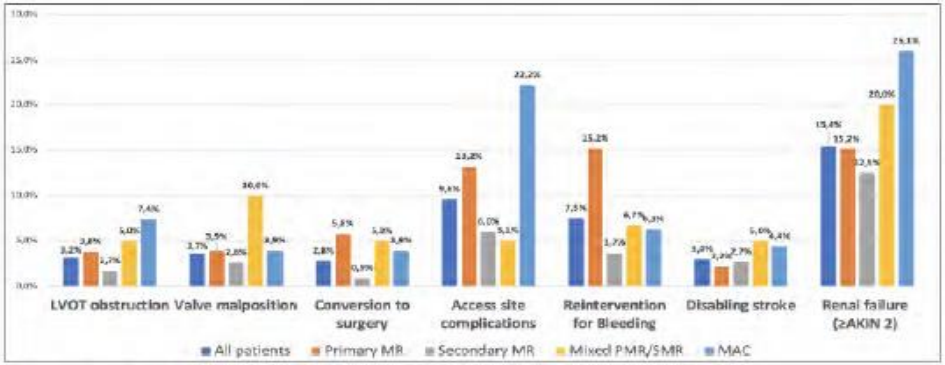
CHOICE-MI

TA-TMVI 89.2%, TS-TMVI 10.8%

MVARC 30-day outcomes

Technical success 95.2%
Procedural mortality 1.8%
30-day mortality 9.9%





LVOT obstruction 3.2%
Valve malposition 3.7%
Conversion to surgery 2.8%
Access site complications 9.6%
Reintervention for bleeding 7.5%
Disabling stroke 3.1%
AKI 15.4%

Median follow-up time 1.94 (1.53-2.11) years

Primary composite endpoint of **1-year** all-cause mortality or HF hospitalization **39.2%**
[no difference primary MR (44.1%), secondary MR (39.1%), mixed MR (20.0%) (p=0.68)]

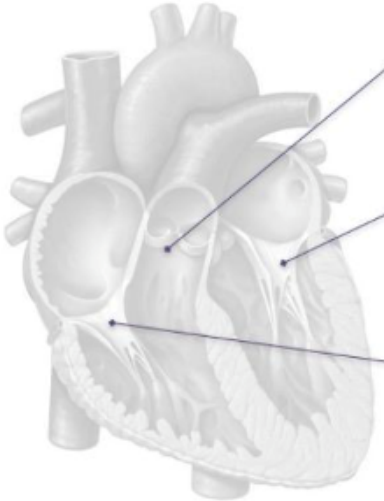
TR: Community Prevalence

≥65 years, n=2500
Screening for undiagnosed VHD
51% had newly diagnosed VHD
2X ↑ Low socioeconomic status, 3x ↑ in AF

21,020 TTEs, 1990-2000
N=417 with ≥ mod TR
0.55% age/sex-adjusted US prevalence

OxVALVE

Moderate/Severe Heart Valve Disease

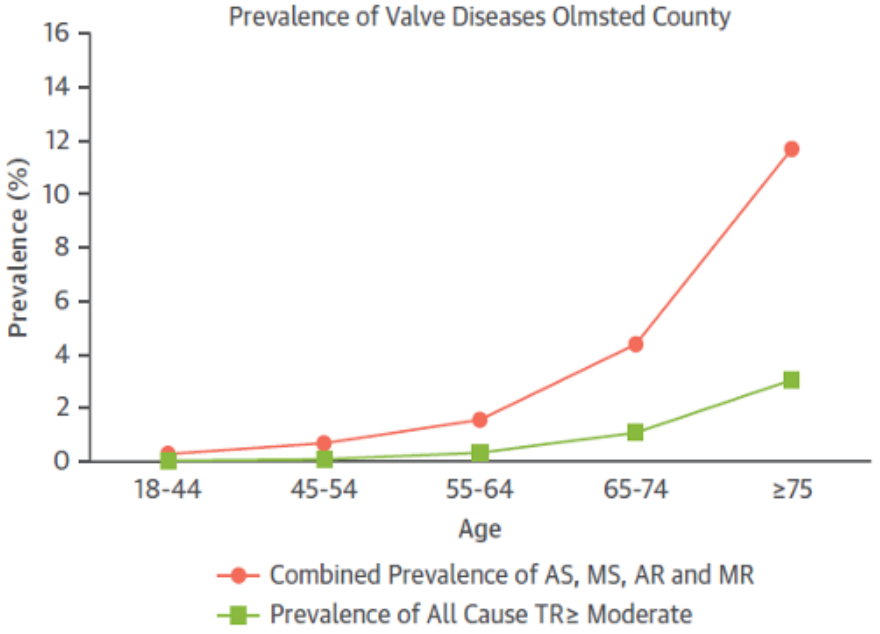


Aortic Stenosis
Prevalence: 1.9% (TBC)
Newly diagnosed: 0.7% (TBC)

Mitral Regurgitation
Prevalence: 3.5%
Newly diagnosed: 2.4%

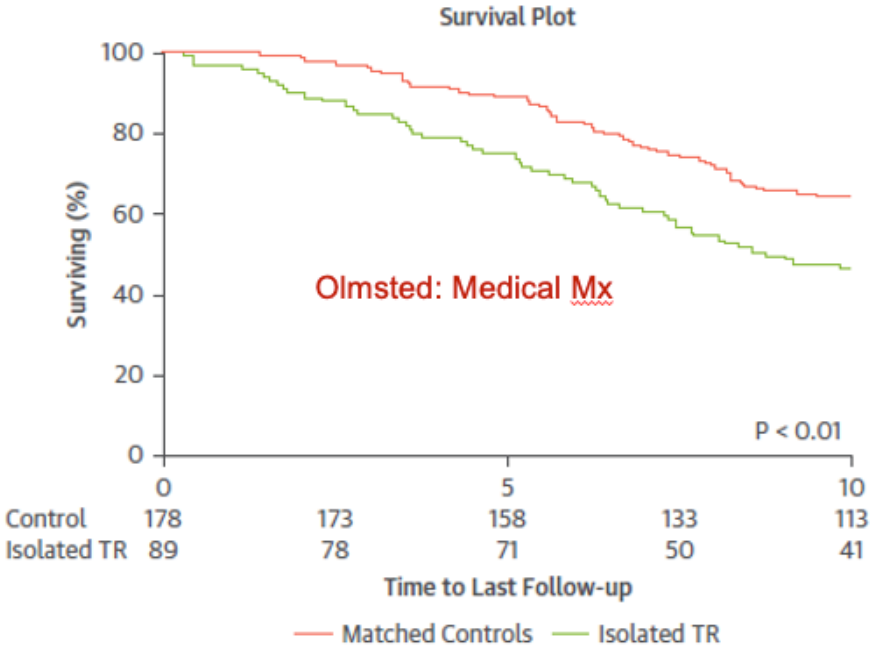
Tricuspid Regurgitation
Prevalence: 2.6%
Newly diagnosed: 1.7%

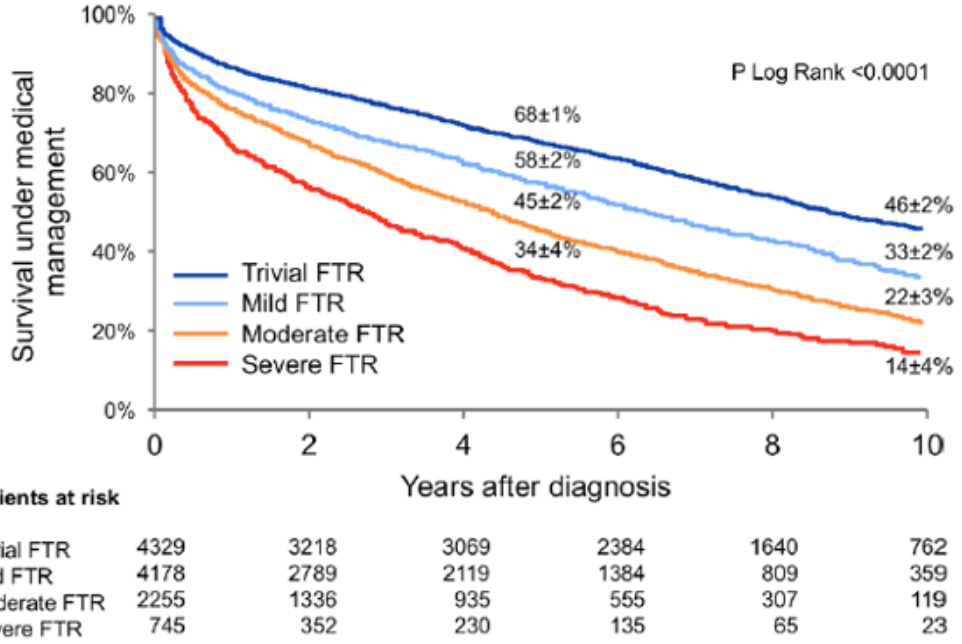
By 2050, projected doubling in incidence of VHD



D'Arcy J et al. Eur Heart J 2016; Topilsky Y et al. JACC CV Img 2019

Isolated TR: Prognosis

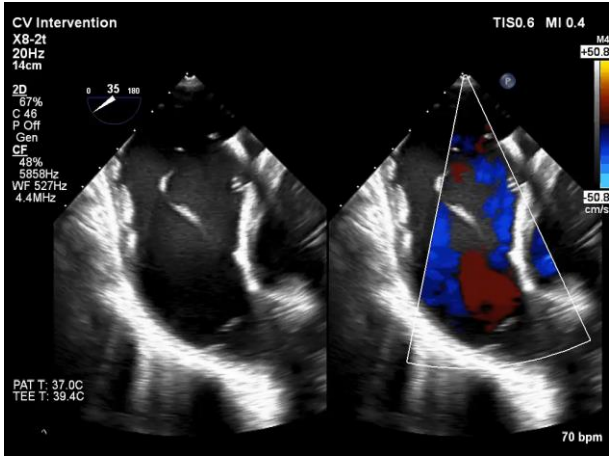


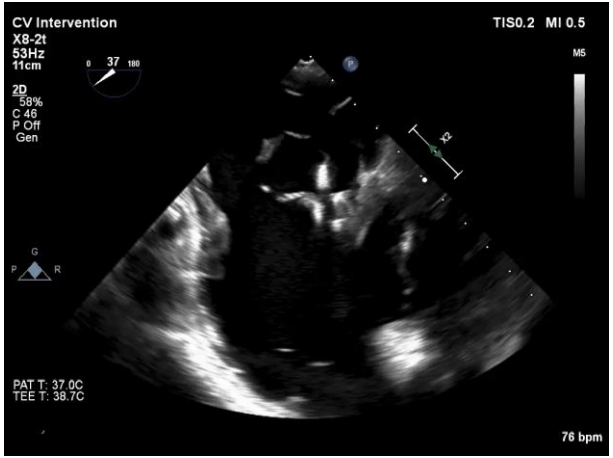


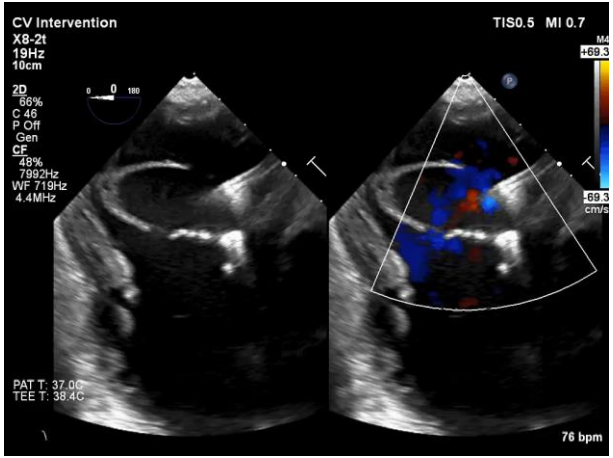
LVEF ≥50%, PASP <50 mmHg, no pacer/ICD wire, no prior valve surgery, no other VHD >mild, no congenital/pericardial disease

Mayo Clinic 2003-2011: HFrEF population μ LVEF 36%
N=13026; 32% TR mild, 17% TR mod, 6% TR severe

Topilsky Y et al. JACC CV Img 2019; Benfari G et al. Circulation 2019







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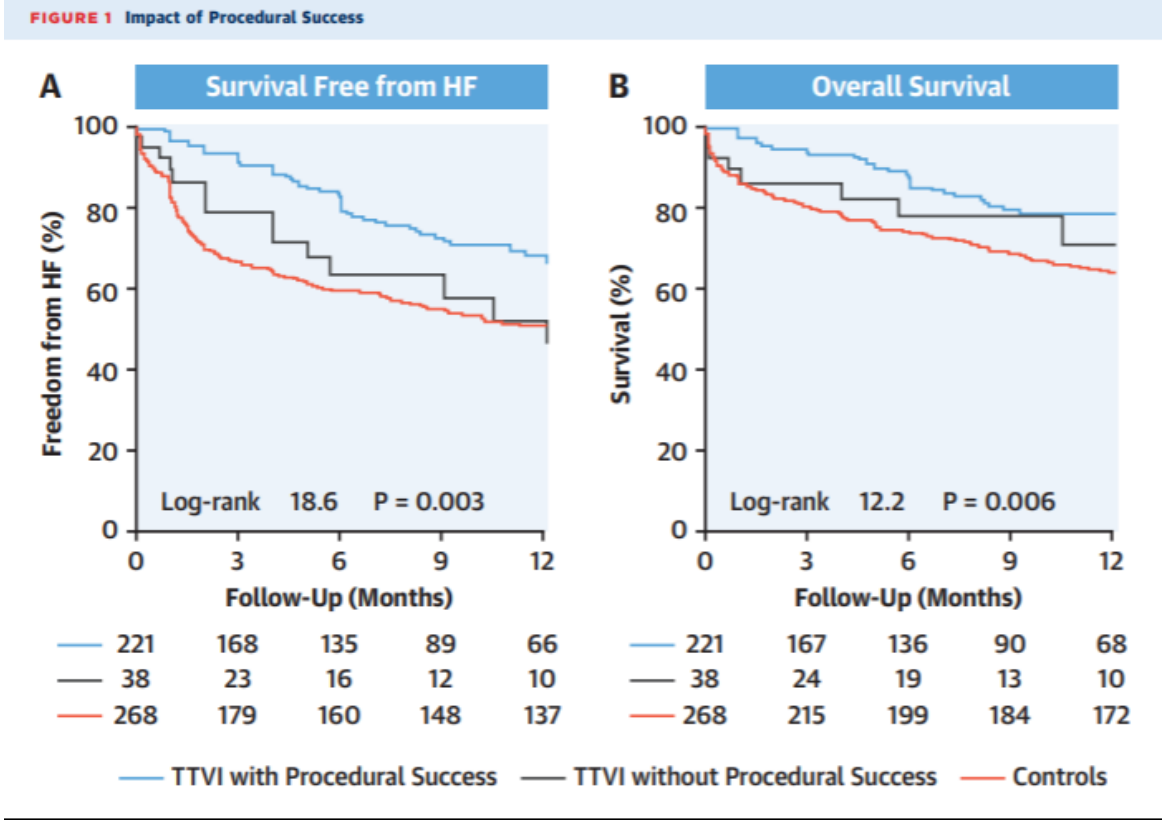
Transcatheter Versus Medical Treatment of Patients With Symptomatic Severe Tricuspid Regurgitation



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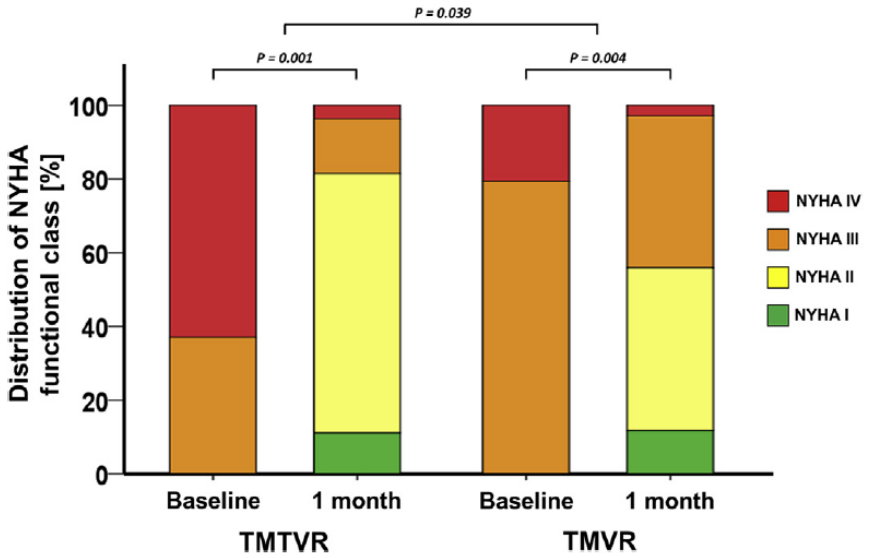
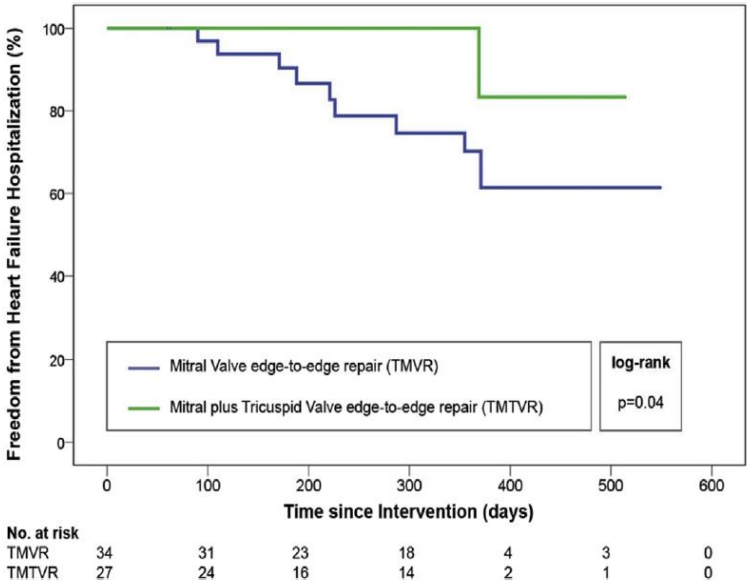
Combined Mitral and Tricuspid Versus Isolated Mitral Valve Transcatheter Edge-to-Edge Repair in Patients With Symptomatic Valve Regurgitation at High Surgical Risk

Effect of TMTVR and TMVR on NYHA Functional Class



Rates of Heart Failure Hospitalization in Patients With TMTVR and TMVR



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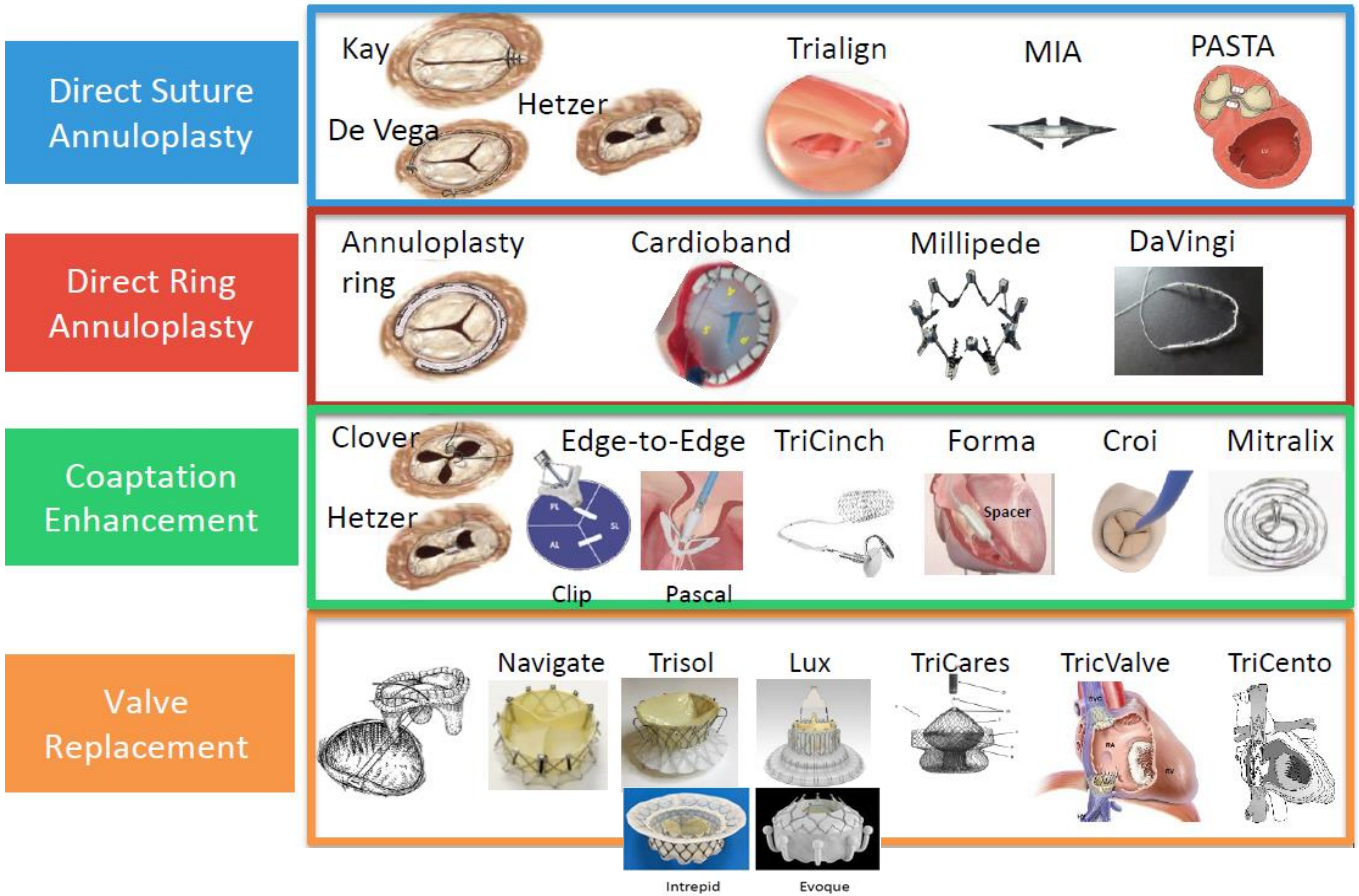
Treatment Landscape for TR

Transcatheter Tricuspid Landscape

Secondary TR Anatomical Approach

- Leaflets
- Commissures
- Annulus



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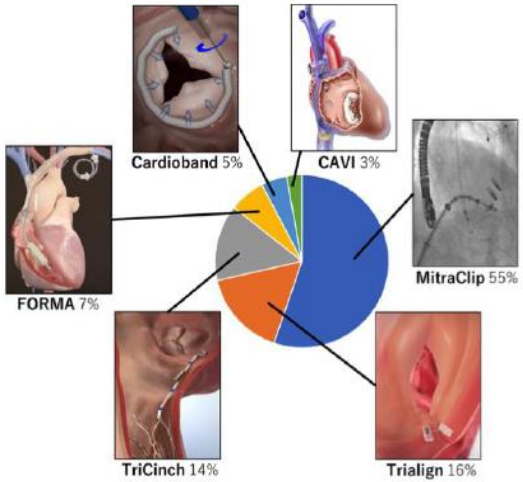
Increase of transcatheter procedures. Leaflet therapies (edge-to-edge) most commonly being used

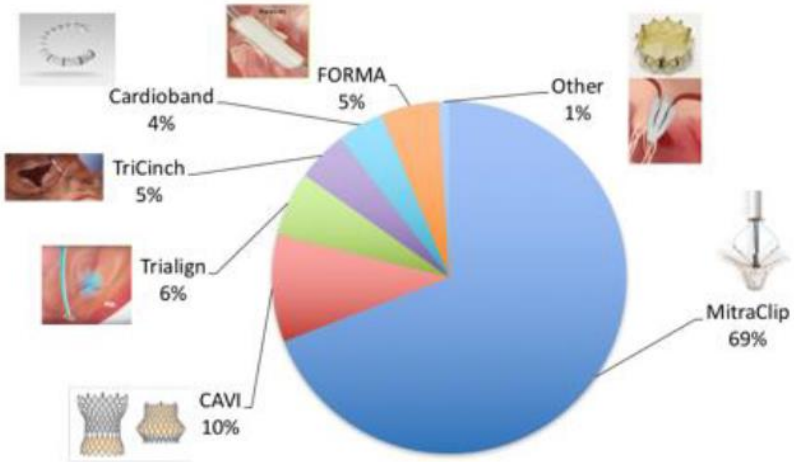
TriValve Registry

January 2014 – December 2016
N = 106



Taramasso et al. J Am Coll Cardiol Intv 2017;10:1982–90

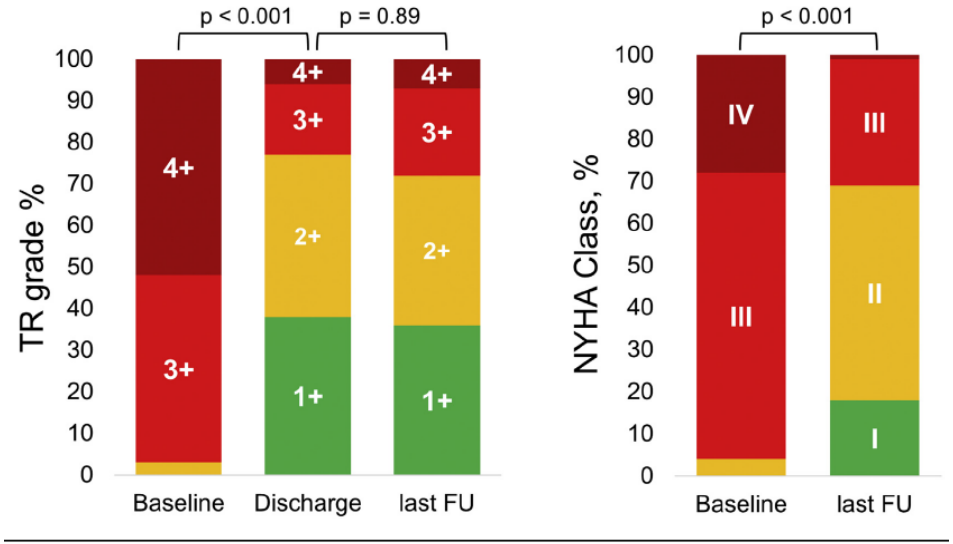
January 2014 – May 2018
N = 304



Taramasso et al. J Am Coll Cardiol Intv 2018

1-Year Outcomes After Edge-to-Edge Valve Repair for Symptomatic Tricuspid Regurgitation: Results From the TriValve Registry

FIGURE 1 Tricuspid Regurgitation and New York Heart Association Class Over Time



(Left) Stacked diagram of tricuspid regurgitation (TR) grading at different points of time. There was a significant reduction in TR between baseline and post-procedure ($p < 0.001$) but no difference between post-procedure and last follow-up (FU) ($p = 0.89$). **(Right)** Stacked diagram of New York Heart Association (NYHA) functional class at baseline and at follow-up showing significant improvement ($p < 0.001$). There was down-grading of at least 1 NYHA functional class in 72% of cases.

TABLE 5 Outcomes at Last Follow-Up (N = 249)

Follow-up time, days	290 (141-392)
Estimated mortality at 1 yr*	20.3 (14.6-25.8)
Estimated combined mortality and unplanned rehospitalization for heart failure at 1 yr*	34.7 (27.3-41.0)
Tricuspid surgery	7 (2.8)
NYHA functional class (n = 175/212)	
I	31 (17.7)
II	90 (51.4)
III	52 (29.7)
IV	2 (1.1)
Decrease of ≥1 NYHA functional class (n = 175/212)	130 (72.0)
Peripheral edema (n = 169/212)	45 (26.6)
Ascites (n = 179/212)	37 (20.7)
TR severity, grade (n = 167/212)	
1+, mild	61 (36.5)
2+, moderate	60 (35.9)
3+, severe	35 (21.0)
4+, massive	11 (6.6)
TAPSE, cm (n = 140/212)	15.9 ± 4.3
LVEF, % (n = 157/212)	49.6 ± 14.1
Systolic pulmonary artery pressure, mm Hg (n = 141/212)	39.3 ± 14.8

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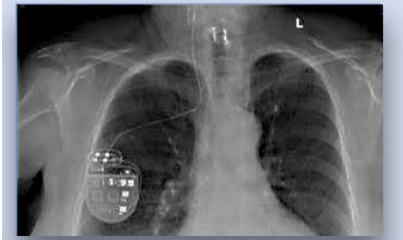
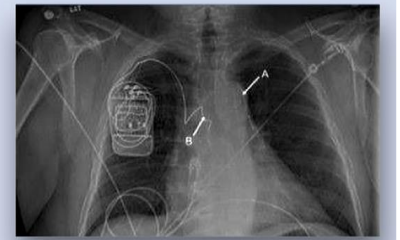
Novel Devices in Heart Failure

Baroreceptor Activation Therapy	Interatrial Shunt Device	Phrenic Nerve Stimulation
		
Physiologic target	**Physiologic target**	**Physiologic target**
Parasympathetic activation to quiet persistent sympathetic activation	Shunting of blood volume from left to right heart to relieve left atrial pressure	Phrenic nerve activation to reduce sleep disordered breathing
Target population	**Target population**	**Target population**
Heart failure with reduced ejection fraction on optimal medical therapy	Heart failure (with or without LVEF) with elevated left atrial pressures	Central sleep apnea which is highly correlated with heart failure

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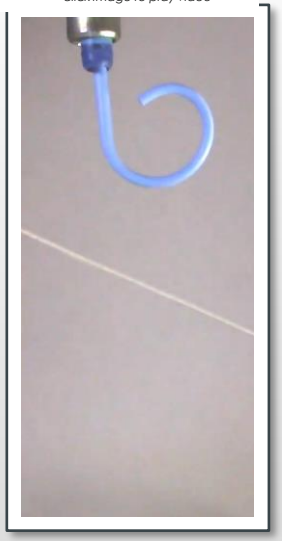
J Am Coll Cardiol HF 2020;8:251–64

Safely Advance and Maneuver

Fully rounded ball designed to safely advance and maneuver within the LAA

Design Differentiator

click image to play video



click image to play video

PINNACLE FLX Safety Outcome

Zero
Pericardial Effusions
Requiring open cardiac surgery through 24 months[1]

Bench test results may not necessarily be indicative of clinical performance.

[1]PINNACLE FLX 24 Month Results, Late Breaking Clinical Trial Presentation, Dr. Saibal Kar, TVT 2021,

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PINNACLE FLX Trial Results

PINNACLE FLX Trial met primary safety and efficacy endpoints and demonstrated high procedural success and DOAC discontinuation at 45-day follow-up[1]

0.5%	100%	98.8%	96.2%
Event Rate	LAA Closure	Procedural Success	DOAC Discontinued
Met Primary Safety Endpoint	Met Primary Efficacy Endpoint	Procedural Success	DOAC Discontinuation at 45-Day Follow-up

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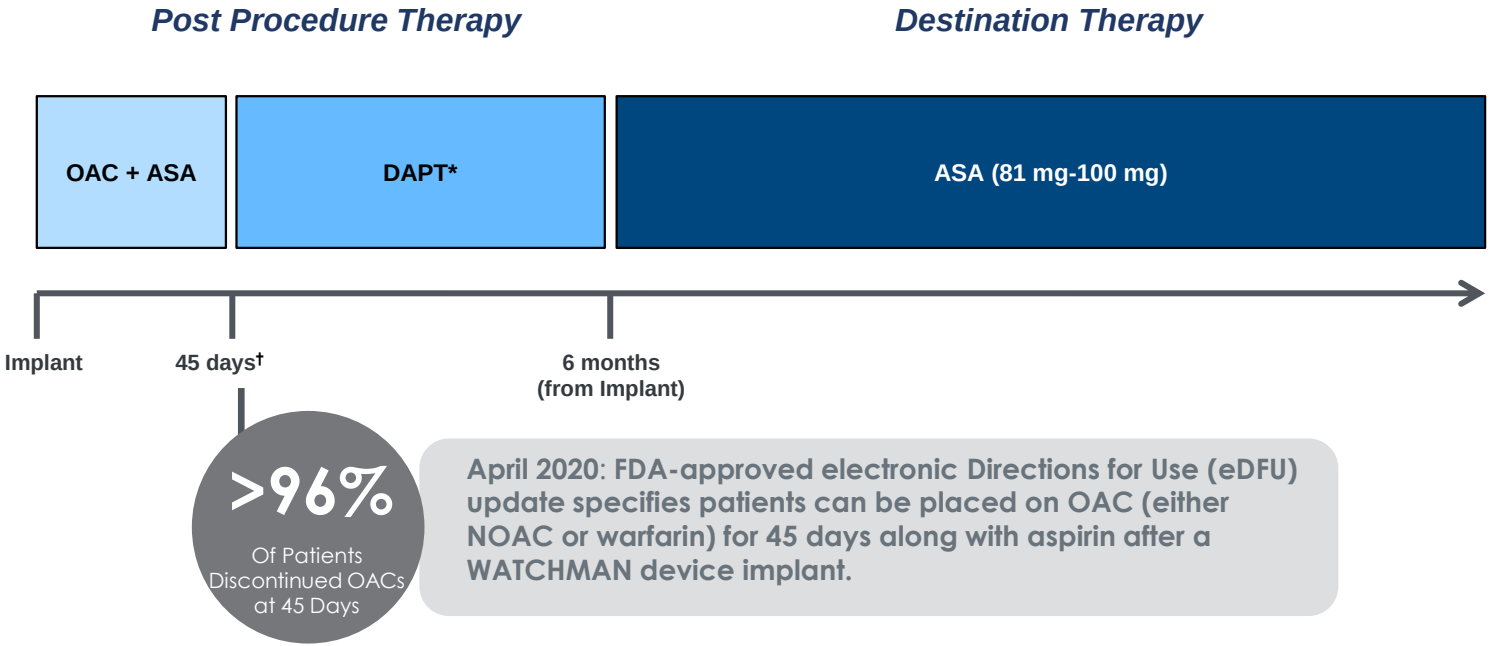
Post-Implant Drug Regimen



* Any P2Y12 inhibitor and ASA

† At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak < 5mm), skipping the P2Y12 inhibitor + ASA pharmacotherapy

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WATCHMAN Therapy Candidates

What type of LAAC candidates are you referring today?

CHA2DS2-VASc of ≥ 2 (or CHA2DS2-VASc of ≥ 3 for Medicare patients)

Drug Interactions	Bleeder	Future Bleeder	Non-Compliant	Lifestyle
Not suitable for long-term warfarin use due to other medical treatment needs	History of major and/or non-major bleeding	No prior bleeds but high-risk / include fall risk	Tolerant, but not taking OAC	Patient prefers device over OAC Appropriate rationale to seek a non-pharmacologic alternative to warfarin.

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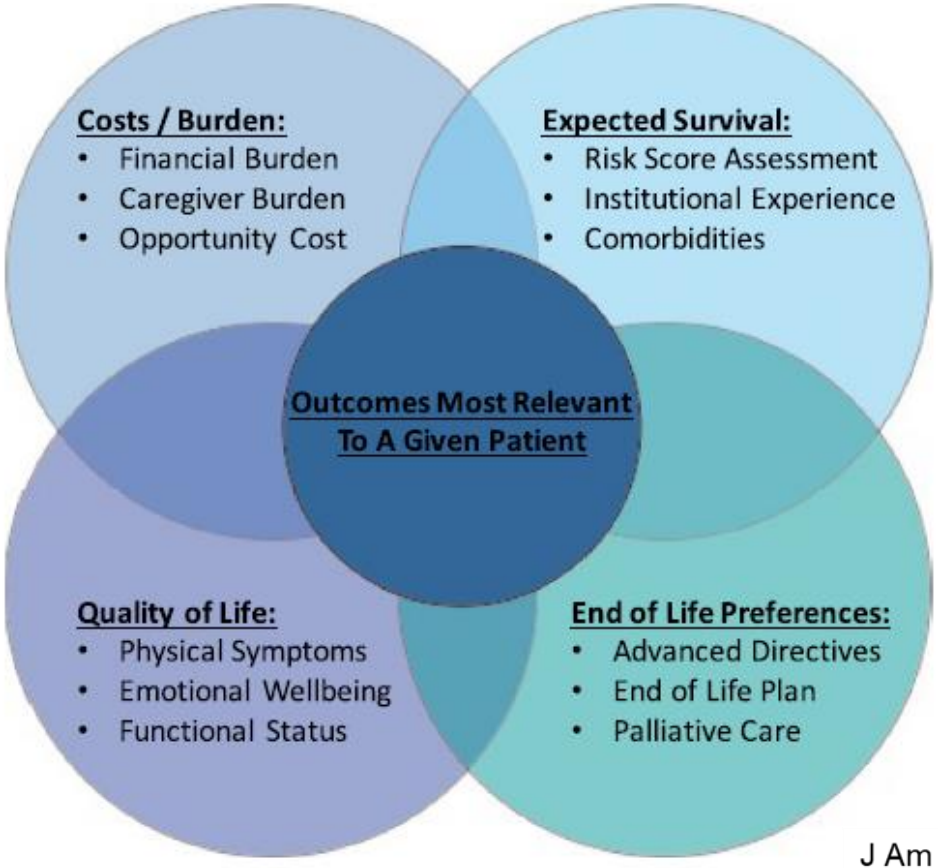
Personalized Approach to Addressing Patient Goals



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J Am Coll Cardiol HF 2020;8:523–36

Conclusion

1. CAD intervention: mature, precision, selection

2. Transcatheter aortic valve intervention: mature

3. Mitral valve intervention: evolving new devices and indications

4.Tricuspid valve intervention: understanding the pathology and development of new therapy

5. Heart failure: GDMT, new concept, LV mechanical remodel, VAD

6. Appendage occlusion: mature, community acceptance

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