

Cardiology at the interface of primary and secondary care: Structural heart disease

This webinar will start soon.

Cardiology at the interface of primary and secondary care: Structural heart disease

Zoom webinar – Wednesday 8 July 2026

6.30-8pm

Acknowledgement of traditional owners

We acknowledge the Tasmanian Aboriginal people as the traditional owners and ongoing custodians of the land on which we are meeting today. We pay our respects to Elders past and present.

We would also like to acknowledge Aboriginal people who are joining us today.



Some housekeeping



Tonight's webinar is being recorded:
<https://learning.primaryhealthtas.com.au>



Please use the Zoom Q&A feature to ask questions



Please don't forget to register for your next webinar at:
<https://www.primaryhealthtas.com.au/for-health-professionals/events/>



Learning Outcomes



Identify and diagnose common and uncommon valvular heart disease presentations



Discuss the contemporary treatment of valvular heart disease



Discuss frailty and its impact on functional and mortality outcomes



Explore the role of the primary care physician in valvular heart disease and chronic disease management



Presenter

Dr Heath Adams

Cardiologist at the Royal Hobart
Hospital



Panellist

Dr Graeme Bleach

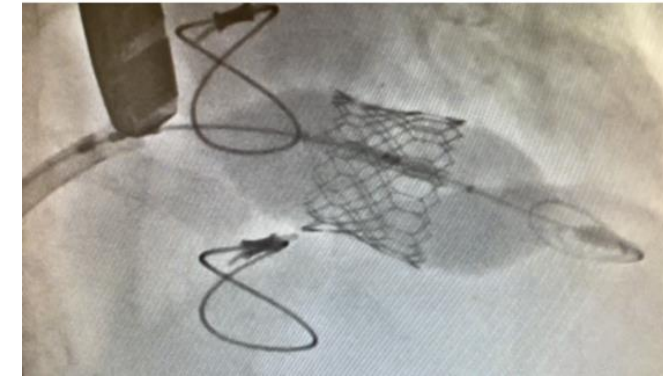
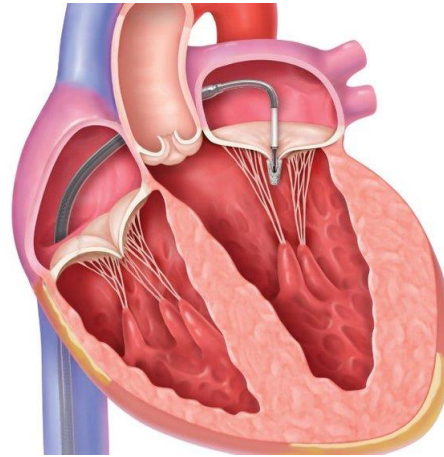
Lead Clinical Editor Tasmanian
HealthPathways
Primary Health Tasmania



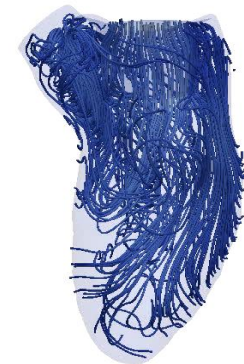
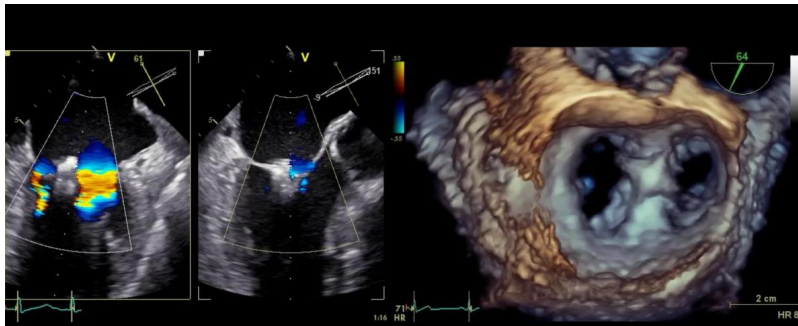
Panellist

Dr Paul MacIntyre

Statewide clinical lead for cardiac
services in Tasmania and
consultant cardiologist at the
Royal Hobart Hospital



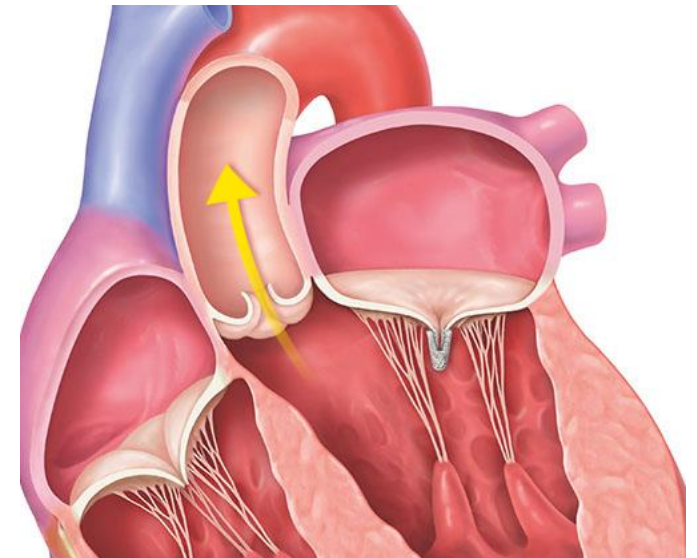
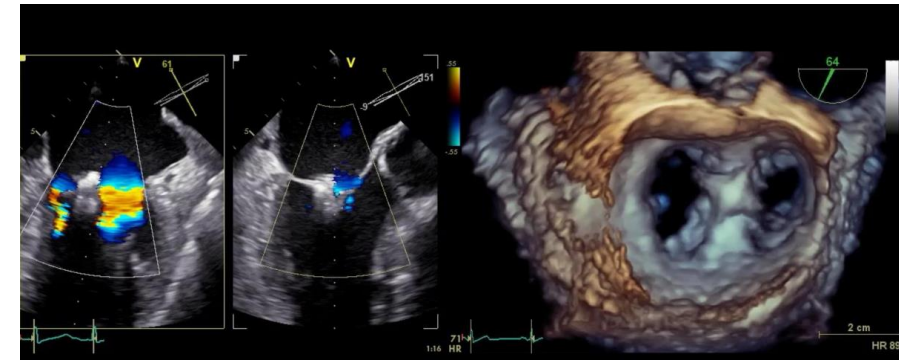
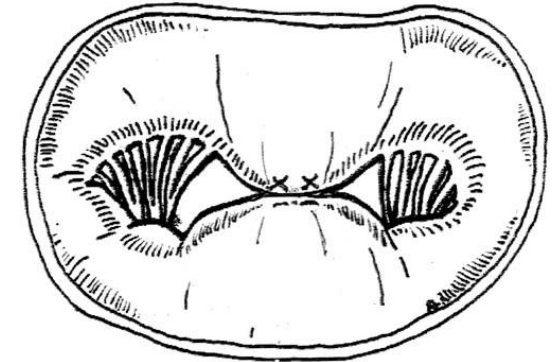
Structural Heart Interventions in Tasmania "The Rising Tide"



Dr Heath Adams
BMedSci, MBBS(Hons), DipUKMP, FRACP, FCSANZ
Interventional & Structural Cardiologist
Royal Hobart Hospital, HPH & Calvary LV
Adjunct Senior Researcher – Menzies Institute
Dr MG Ciezar Memorial Scholar
University of Tasmania
CSANZ Interventional Council Secretary

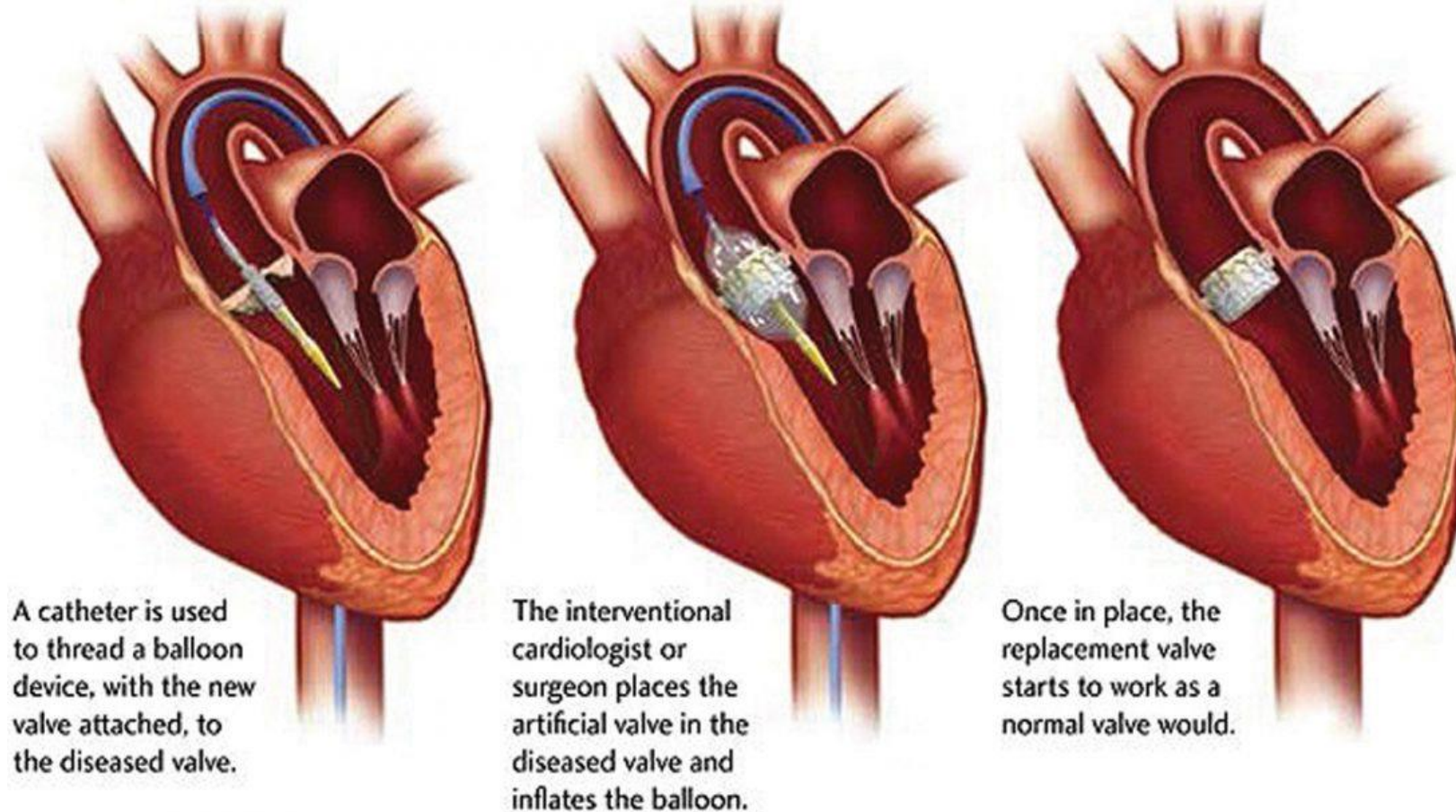
Structural Heart Interventions

- Aortic Valve Interventions
 - Transcatheter Aortic Valve Implantation (TAVI) for severe aortic stenosis
 - TAVI in SAVR (VIV TAVI) for degenerated surgical bio prosthesis
- Mitral Valve Interventions
 - Transcatheter Edge to Edge Repair (TEER) in severe mitral regurgitation (eg mitral clip)
 - Transcatheter Mitral Valve Implantation in MVR for degenerated surgical bioprosthesis (mitral VIV) or surgical rings (mitral VIR)
- PFO/ASD closure
- Paravalvular Leak Closure (mitral or aortic)
- Left atrial appendage closure



What is a TAVI/TAVR?

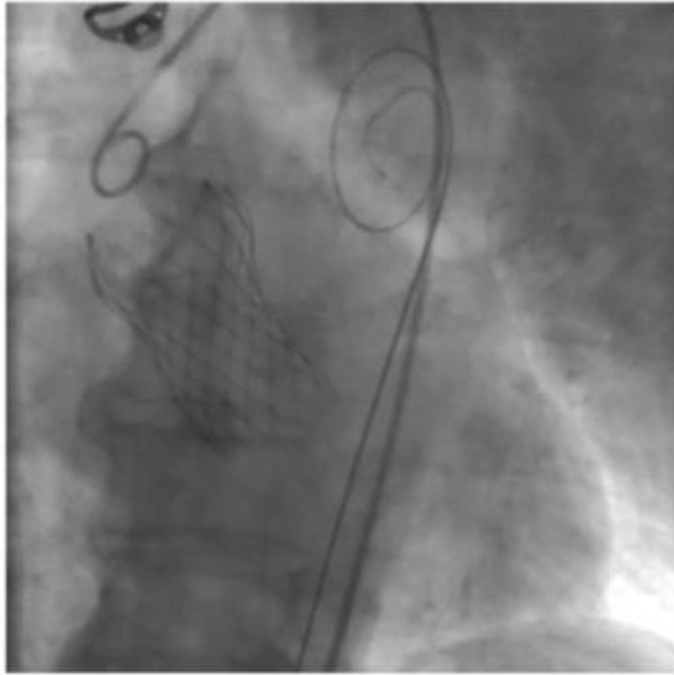
<https://www.youtube.com/watch?v=CxqpYlbmvP4>



What is a TAVI/TAVR?



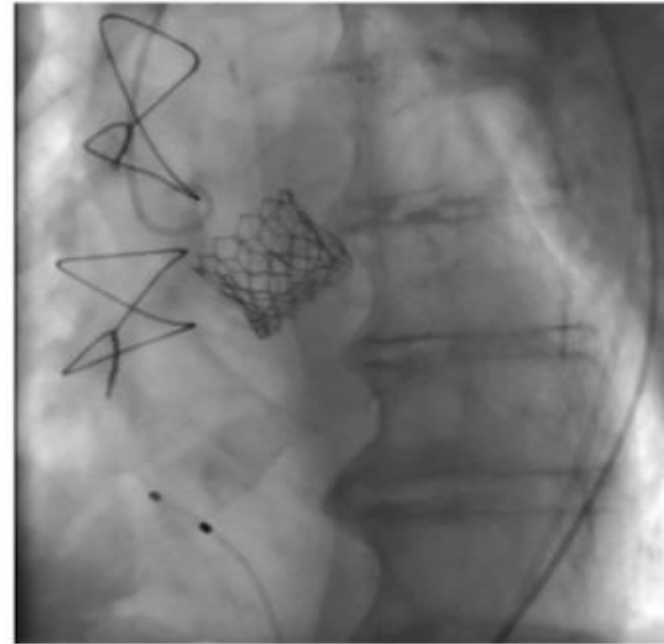
to thread a balloon device, with the new valve attached, to the diseased valve.

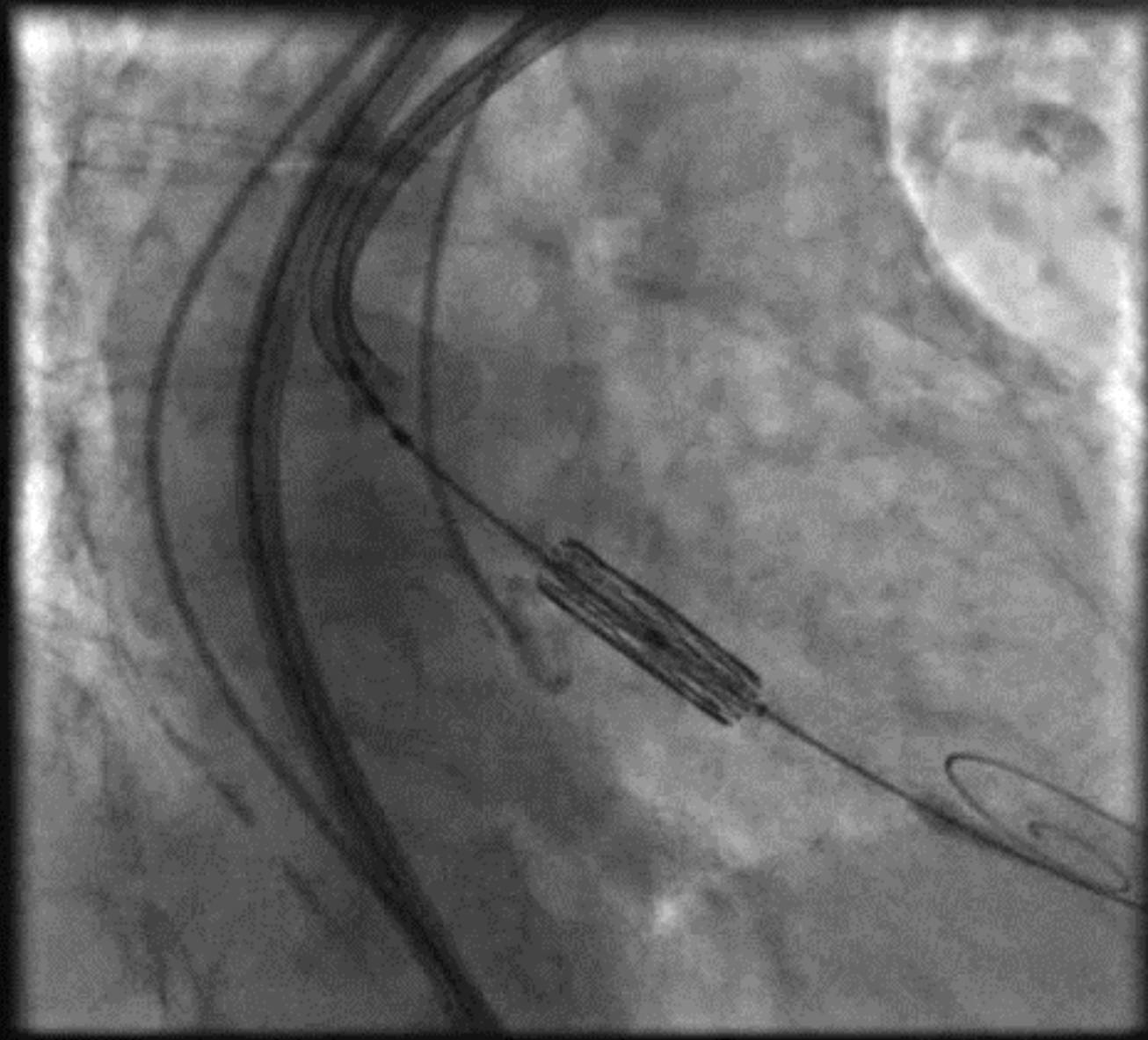


cardiologist or surgeon places the artificial valve in the diseased valve and inflates the balloon.

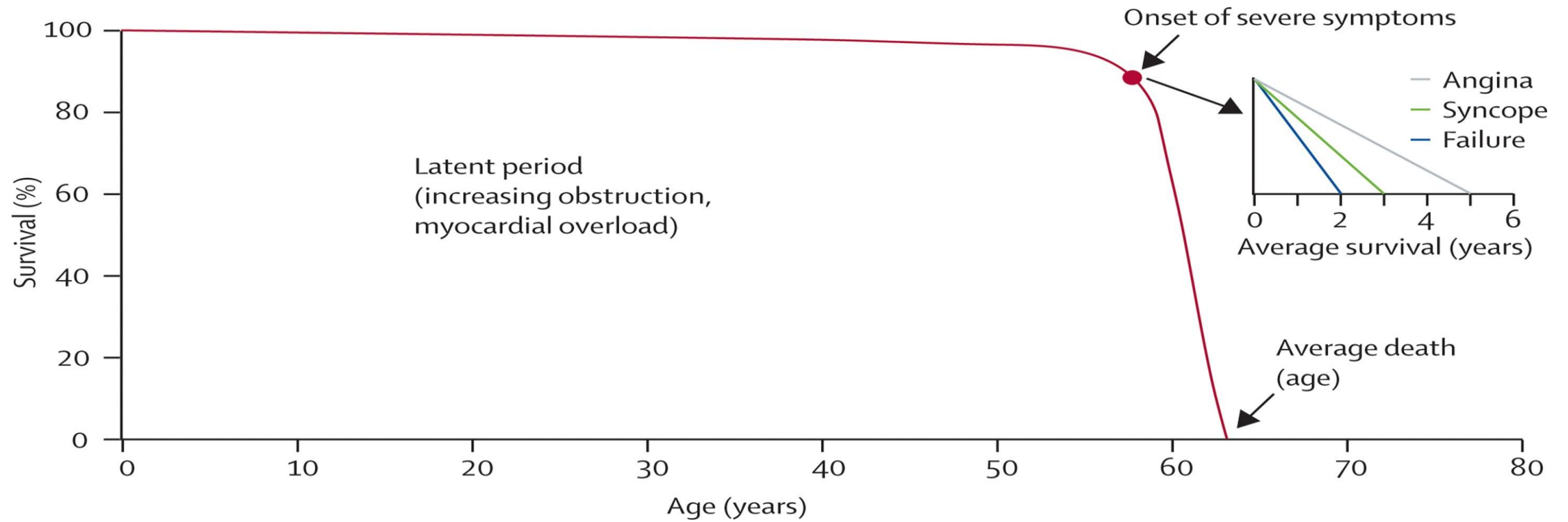


replacement valve starts to work as a normal valve would.

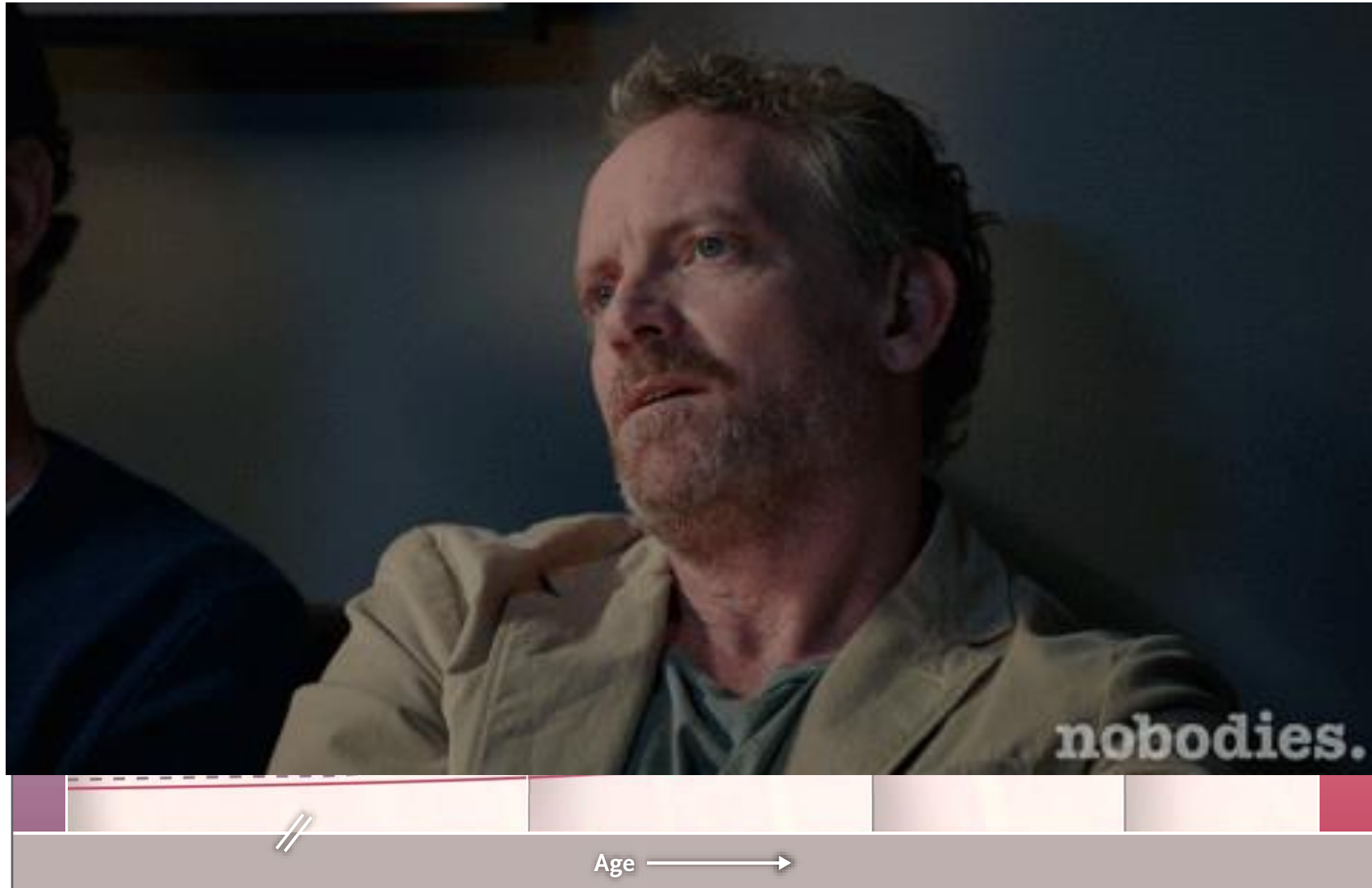




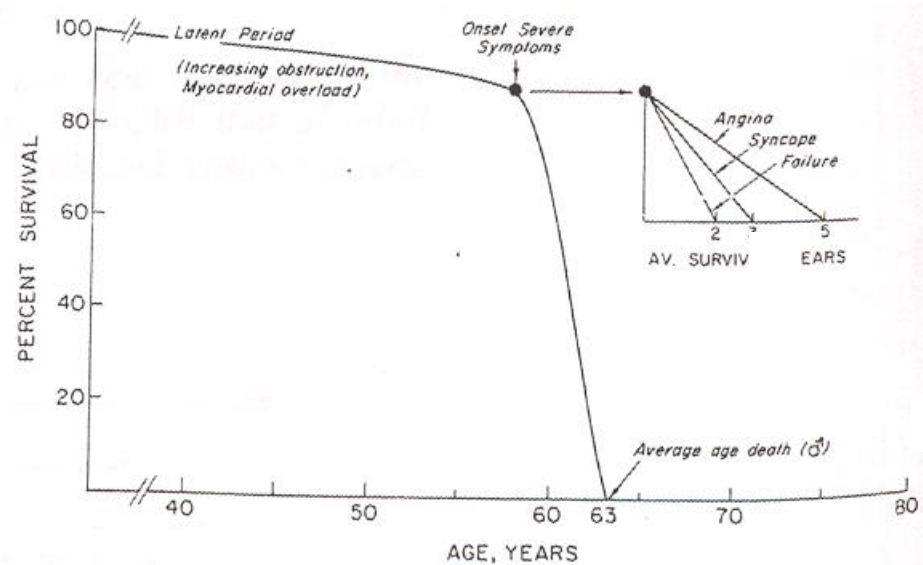
Severe aortic stenosis survival curve



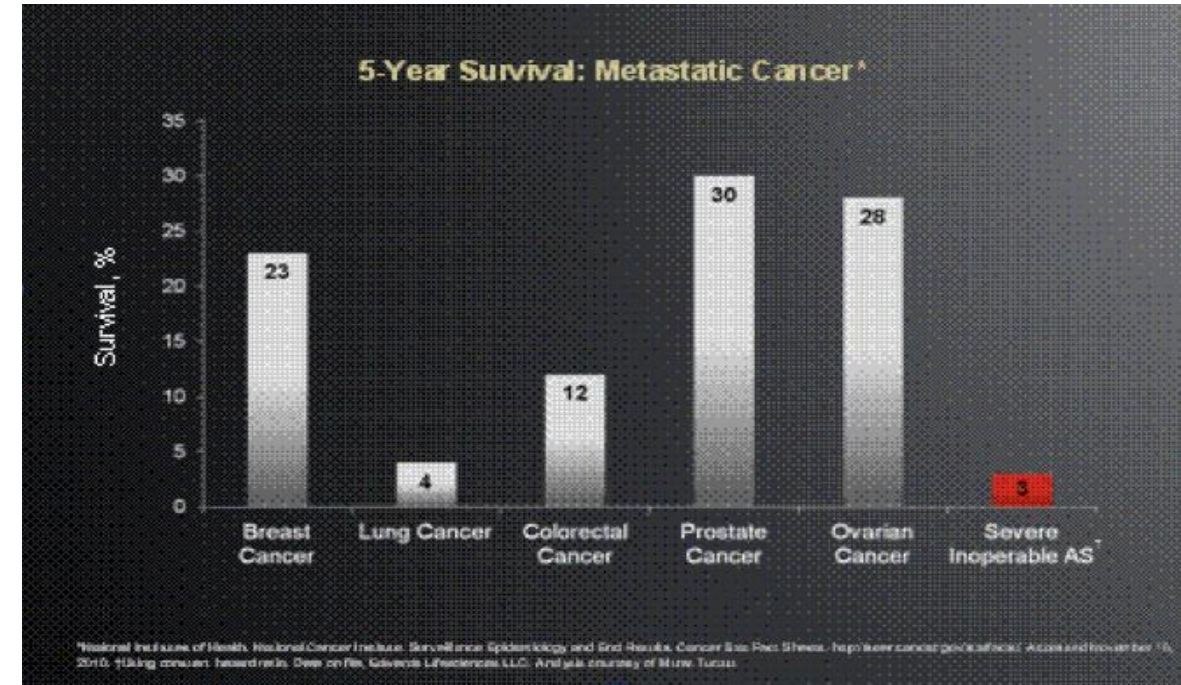
Pathophysiology of Aortic Stenosis



Natural History of Aortic Stenosis



A review of studies performed during 1913 to 1970 found that mean survival after onset of
→ heart failure ranged from 0.5 to 2.8 years
→ syncope ranged from 0.8 to 3.8 years
→ angina ranged from 2 to 4.7 years



The Malignant Valve

Prevalence of AS

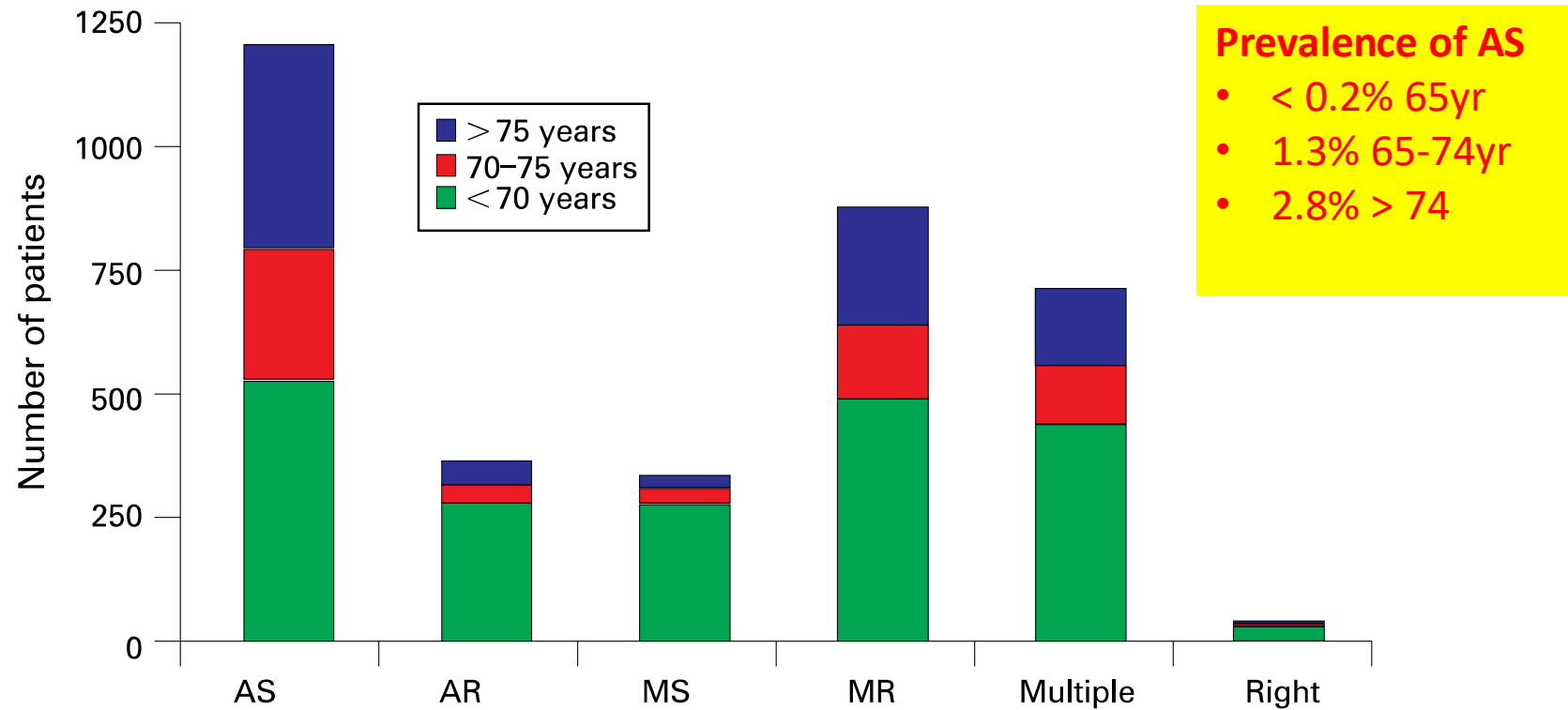


Figure 3 Age distribution according to the type of valvular heart disease in 3547 patients with native valve disease in the Euro Heart Survey.¹ AS, aortic stenosis; AR, aortic regurgitation; MS, mitral stenosis; MR, mitral regurgitation; Multiple, multiple valve disease; Right, right sided heart disease.

Early and late outcomes after isolated aortic valve replacement in octogenarians: an Australasian Society of Cardiac and Thoracic Surgeons Cardiac Surgery Database Study

Akshat Saxena^a, Chin-Leng Poh^b, Diem T. Dinh^b, Christopher M. Reid^b, Julian A. Smith^c, Gilbert C. Shardey^d
and Andrew E. Newcomb^{a,e,*}

Australian analysis demonstrated a mortality rate of 9% at 30 days in patients over 80 years of age

Predictors of death

- CKD
- Diabetes Mellitus
- NYHA class III/IV HF
- Stroke
- Extremes of BMI

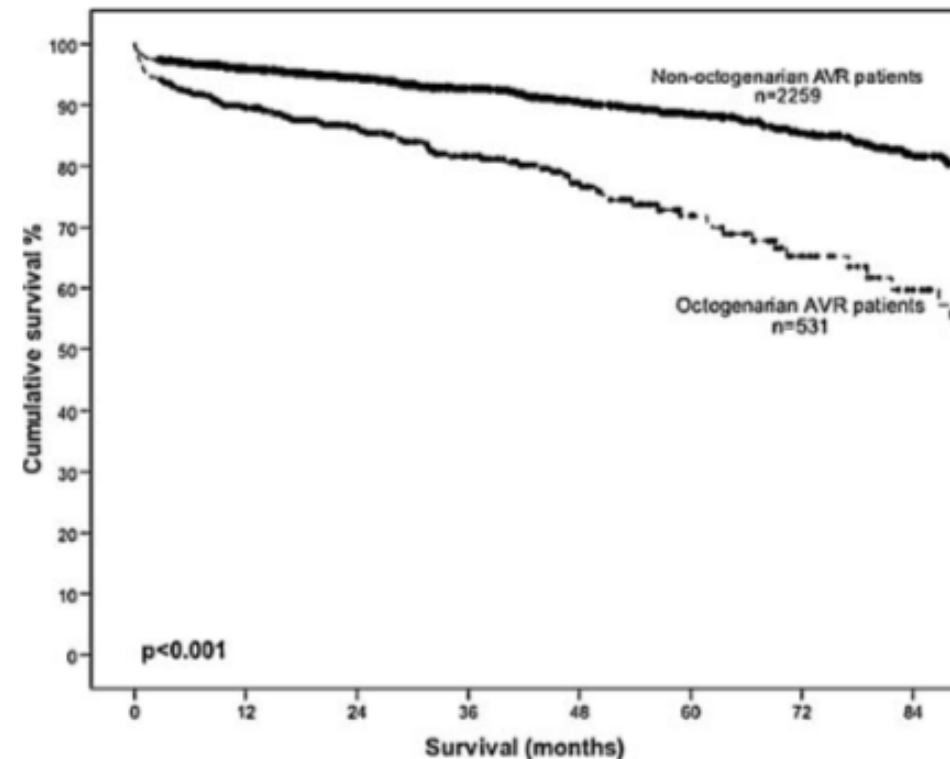


Figure 1: Overall survival in patients undergoing isolated AVR, stratified by age.

Diagnosis of severe AS (on TTE)

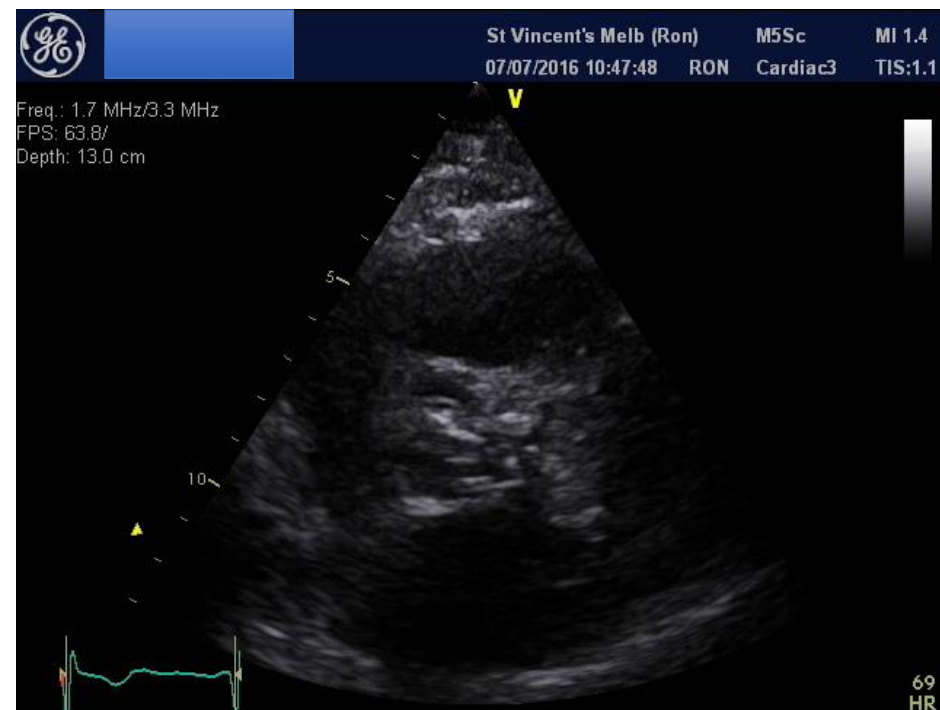
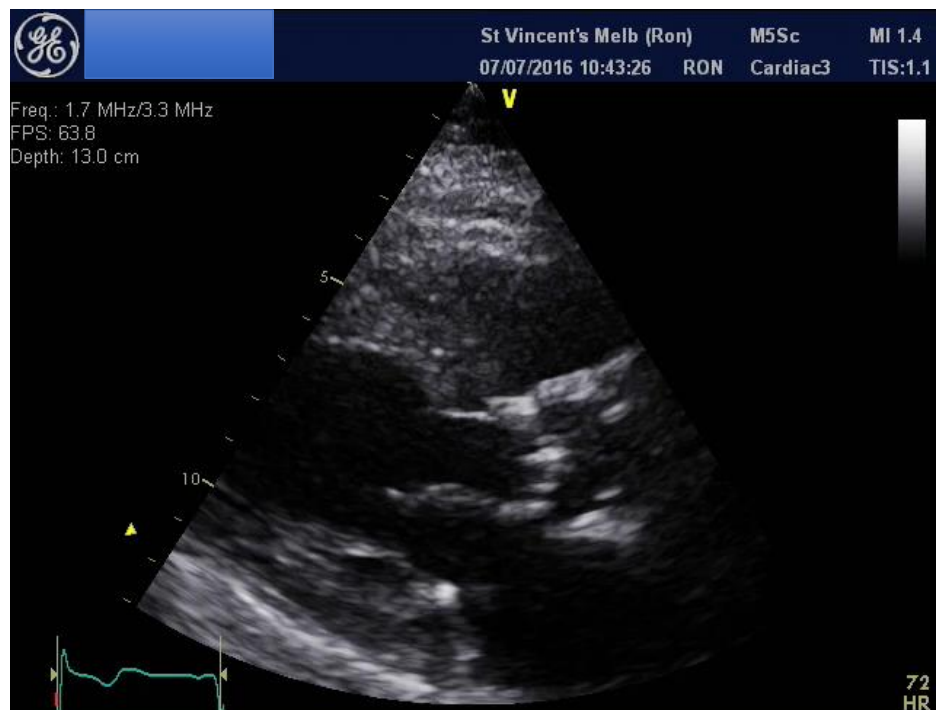
Table 3 Recommendations for grading of AS severity

	Aortic sclerosis	Mild	Moderate	Severe
Peak velocity (m/s)	≤ 2.5 m/s	2.6–2.9	3.0–4.0	≥ 4.0
Mean gradient (mmHg)	–	< 20	20–40	≥ 40
AVA (cm^2)	–	> 1.5	1.0–1.5	< 1.0
Indexed AVA (cm^2/m^2)	–	> 0.85	0.60–0.85	< 0.6
Velocity ratio	–	> 0.50	0.25–0.50	< 0.25

What's Normal?



Aortic Stenosis on Echo



Dr. Alain Cribier

First-in-Man PIONEER



Circulation American Heart Association
JOURNAL OF THE AMERICAN HEART ASSOCIATION
Learn and Live.

- Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
- First Human Case Description
- Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Conclusions – “Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.”

April 16, 2002

Where is the Bang for Buck in Cardiology?

METHODS	ARR	NNT
NSTEMI Invasive PCI (MACE)	1.3%	~76
PCSK9 vs Statin Alone (MACE)	1.6%	~62.5
Ticagrelor vs Clopidogrel (MACE)	1.9%	~50
STEMI vs Primary PCI vs lytics (MACE)	2.3%	~43.4
Beta-blocker in Heart Failure (Mortality/HF)	~12%	~8
Entresto vs ACE/ARB (death or HF hosp)	4.7%	~19.5
ICD (Ischaemic; mortality)	3%	33

ARR = Absolute risk reduction
NNT = Number needed to treat

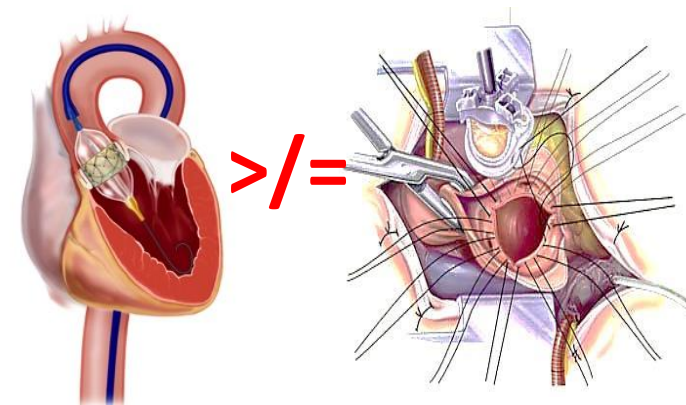
Evidence

- Inoperable
- High Risk
- Intermediate Risk
- Low Risk

CLINICAL EVIDENCE ACROSS RISK CATEGORIES



Low



Evidence: Inoperable patients severe AS

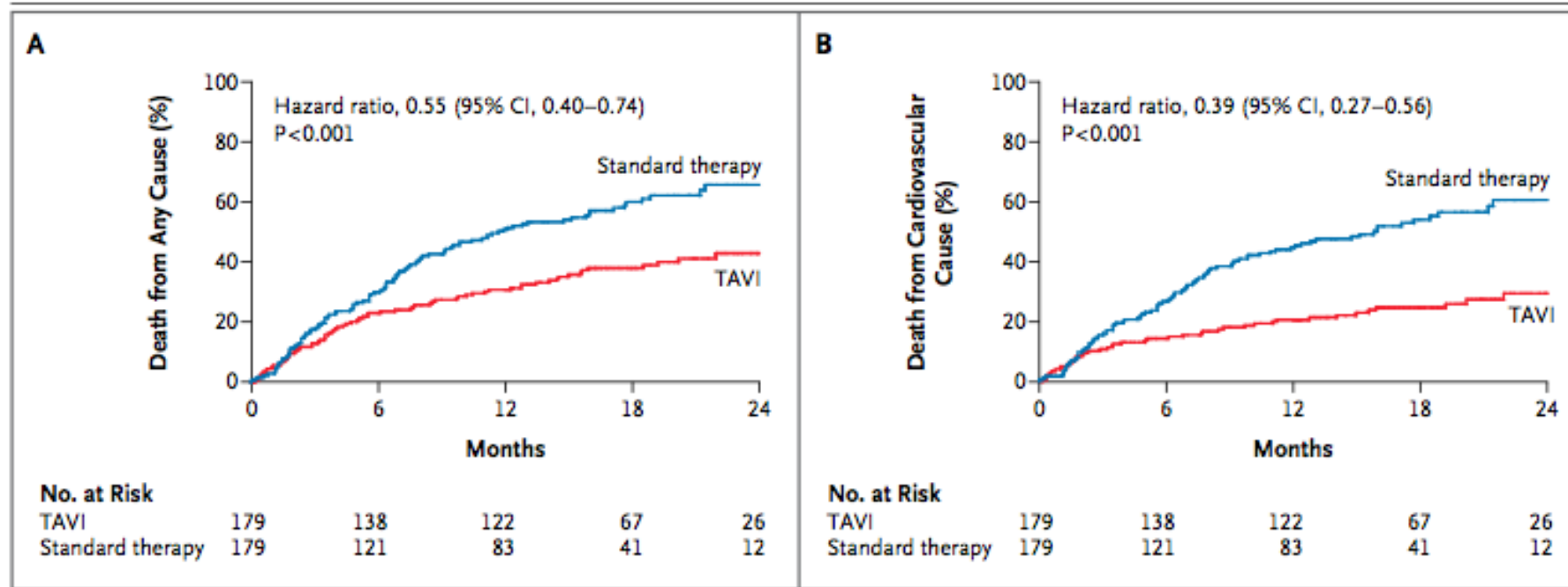


Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,

- 358 patients at 21 centres with severe aortic stenosis
- Patients were assessed by Cardiothoracic surgeons and deemed unfit for surgery
- Randomised to standard best medical therapy vs TAVI
- Primary end point was death from any cause at 1 year.

Evidence: Inoperable patients severe AS



At 1 year, death from any cause was 30.7% in the TAVI group vs 50.7% in the best medical therapy group (P<0.001)

ARR in death of 20%

Death from CV cause 19.6% in TAVI group vs 41.9% P<0.001 at 12 months

Evidence: High risk patients severe AS

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

795 patients underwent randomisation at 45 centres in the US.

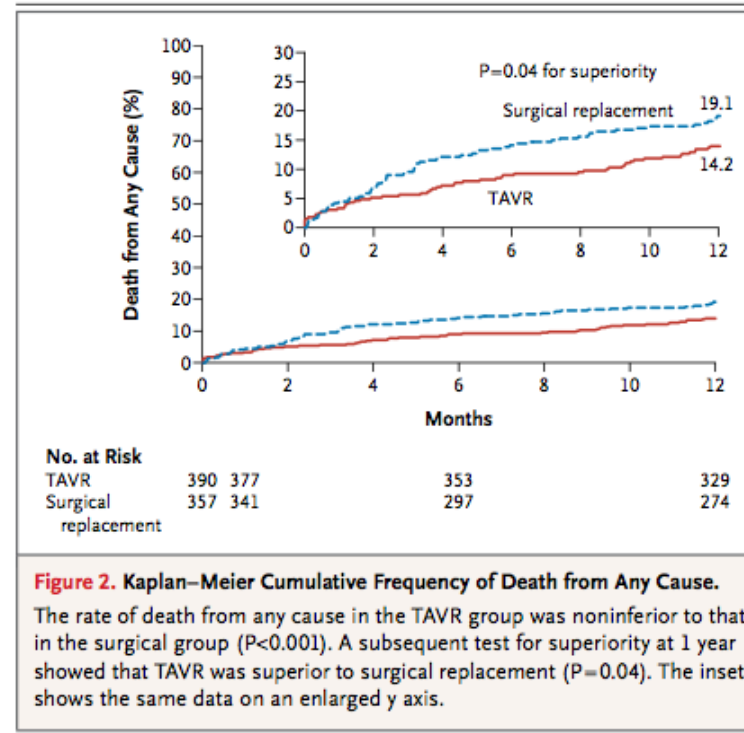
Patients randomised had severe AS who had been deemed at increased surgical risk as assessed by the heart team at each centre .

STS risk predictor of mortality and assessment of other co-morbidities was used to determine appropriate patients

Patients were randomised in 1:1 fashion to AVR vs TAVI

Primary end point was death from any cause at 12 months, analysed in both non-inferiority and superiority testing

Evidence: High risk patients TAVI vs SAVR



In the as treated analysis, the rate of death from any cause at 1 year was lower in the TAVI group 14.2% vs the surgical AVR group 19.1%. $P < 0.001$ for inferiority and $P = 0.04$ for superiority.

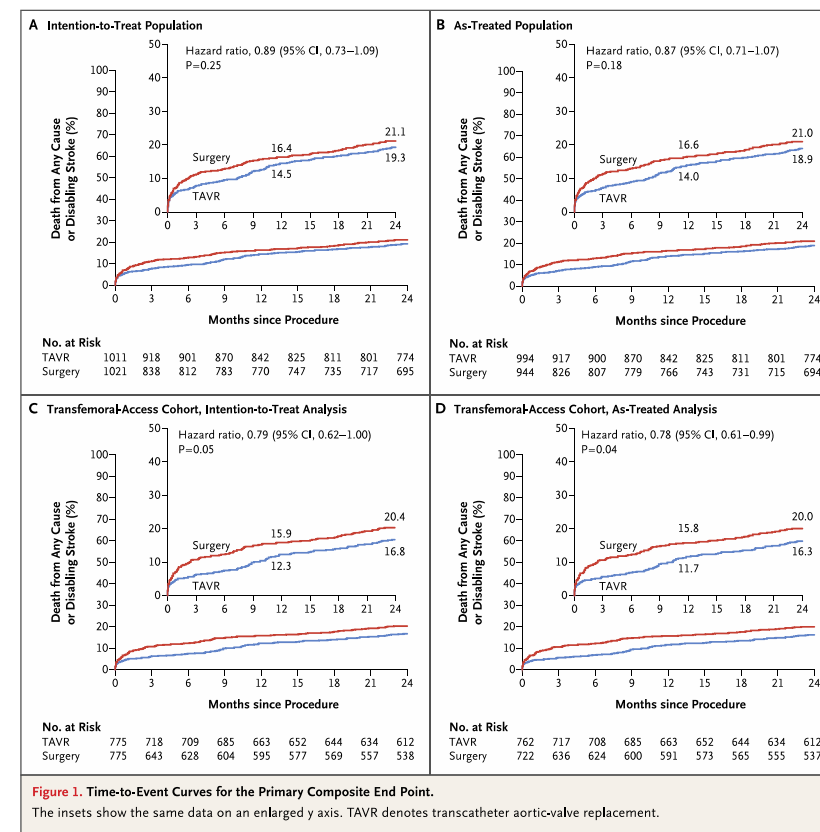
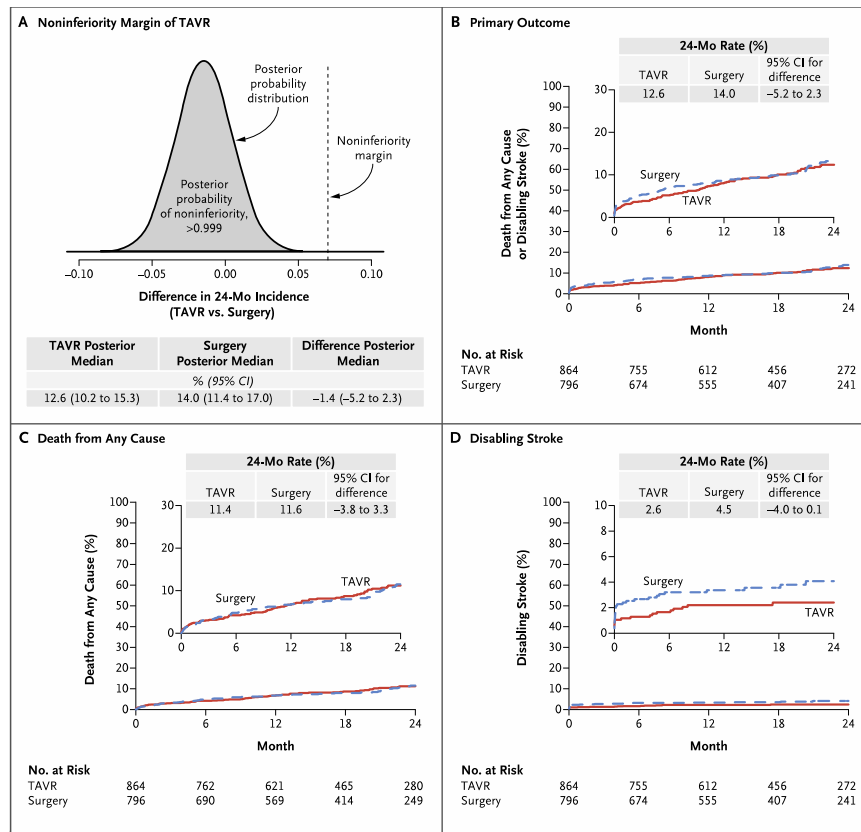
Absolute risk reduction of 4.9%, NNT = 20

Evidence: Intermediate risk patients TAVI vs SAVR

SURTAVI



PARTNER 2A



PARTNER 3 Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*



EVOLUT Low Risk Trial

The NEW ENGLAND JOURNAL of MEDICINE

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Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*



PARTNER 3 Trial

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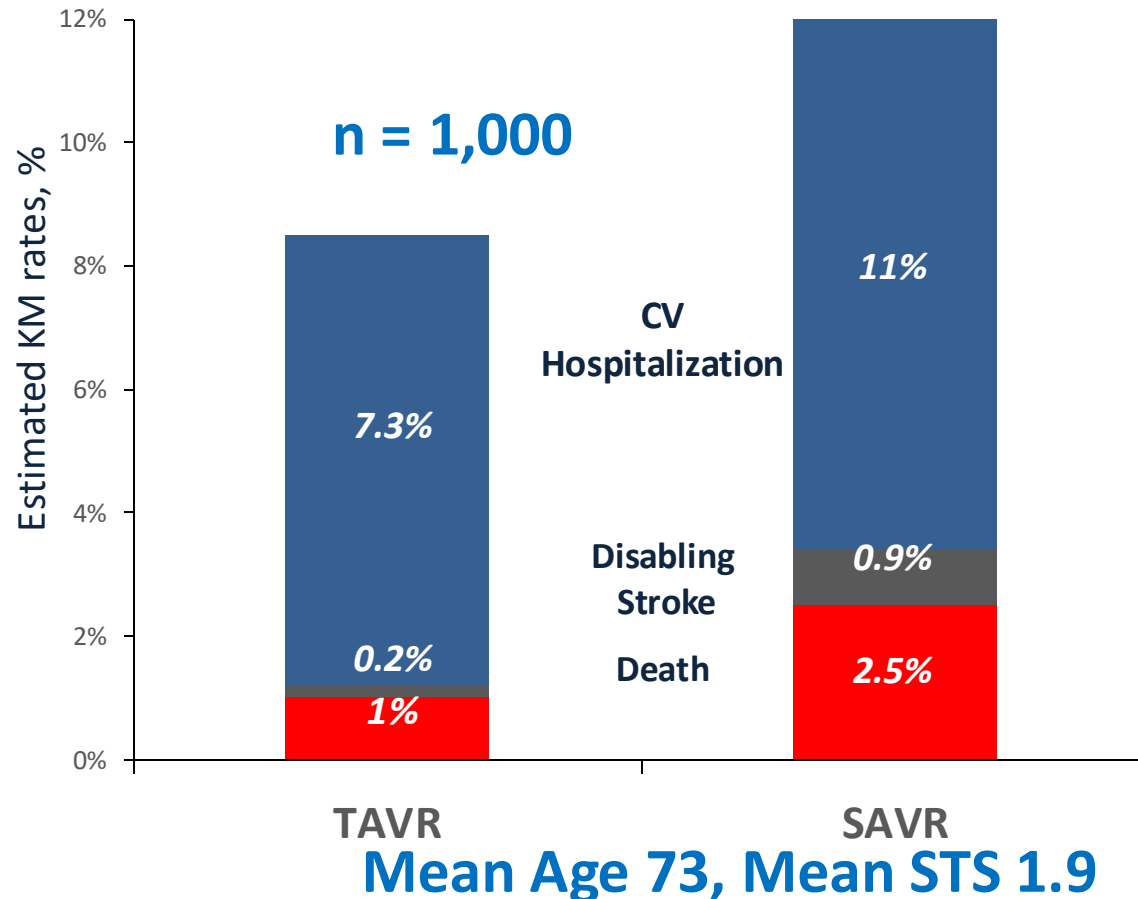


Clinical Implications

Death, Disabling Stroke and Re-Hospitalizations to 1 Year

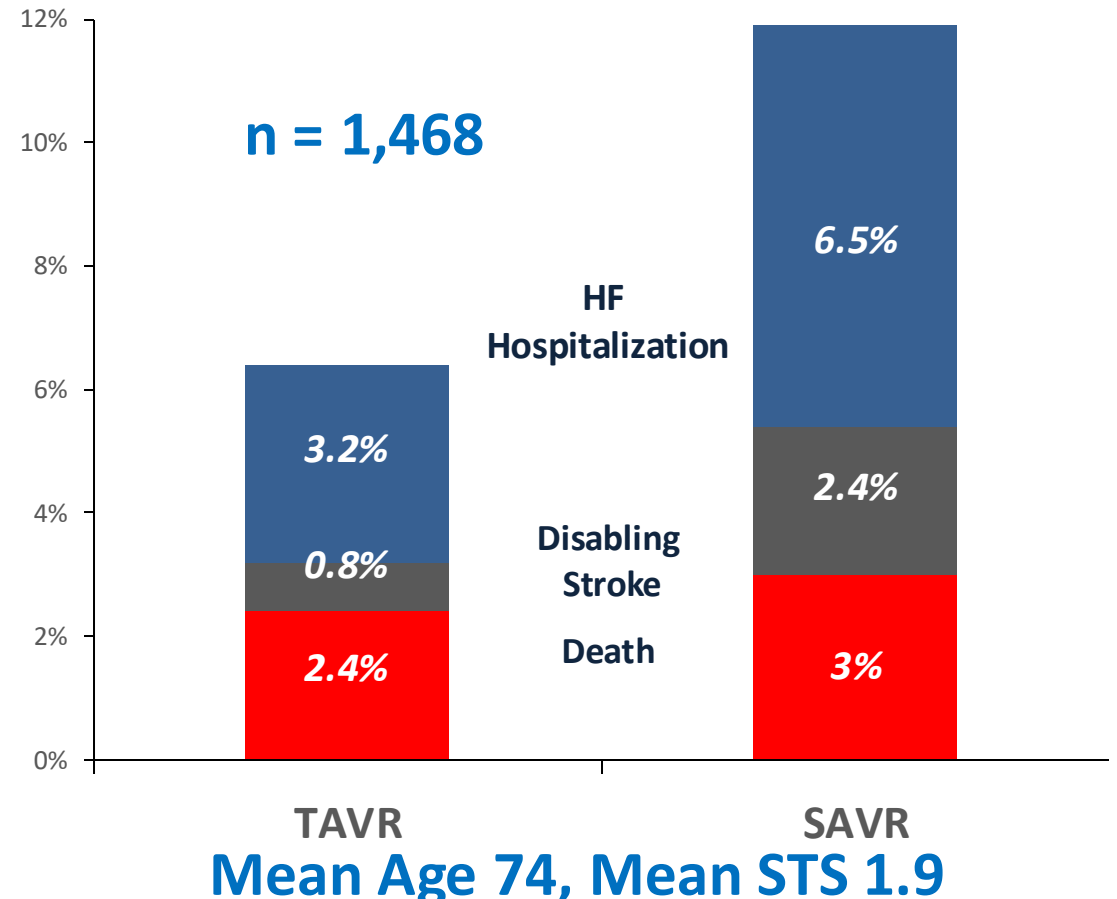
PARTNER 3 Trial

Mack MJ et al, N Engl J Med. 2019 May 2;380(18):1695-1705

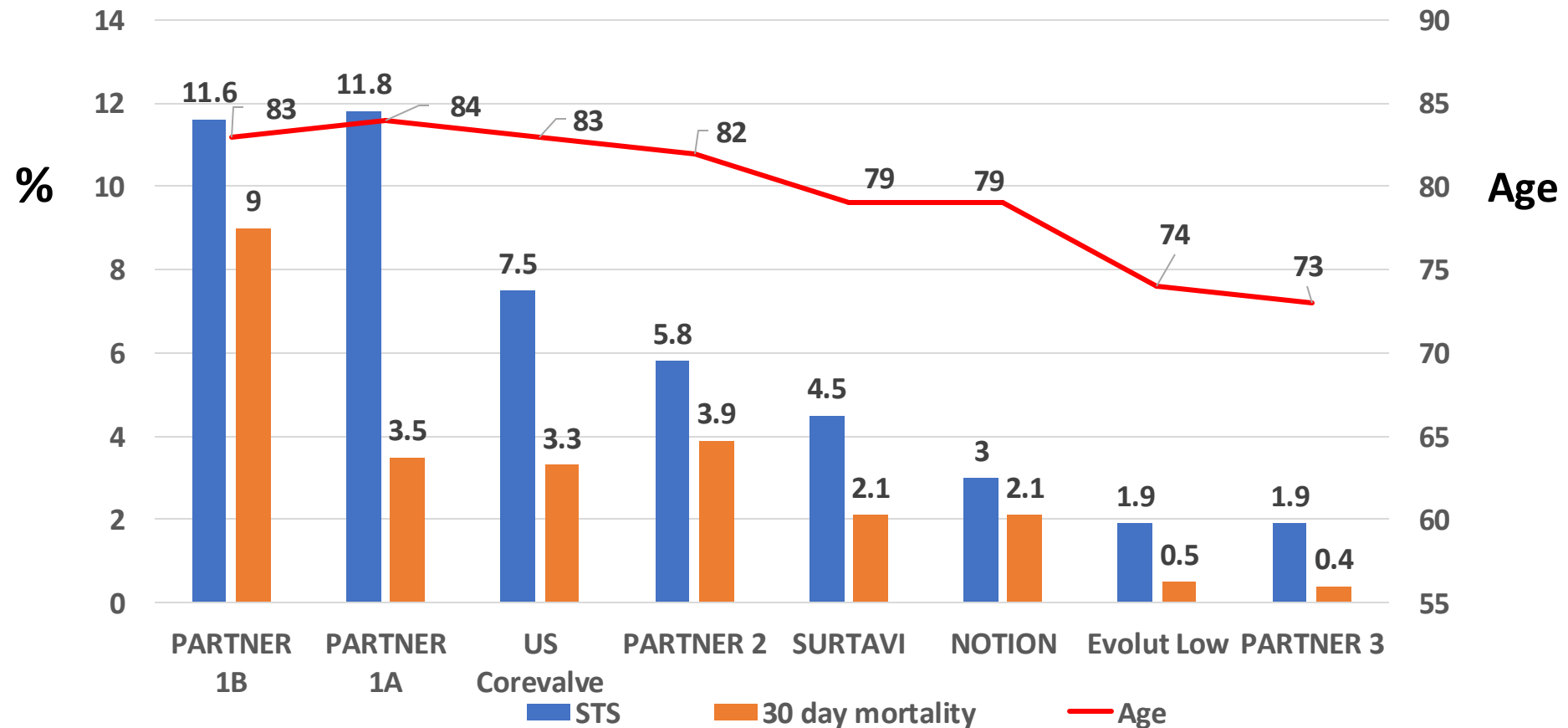


Evolut Low-Risk Trial

Popma JJ et al, N Engl J Med. 2019 May 2;380(18):1706-1715



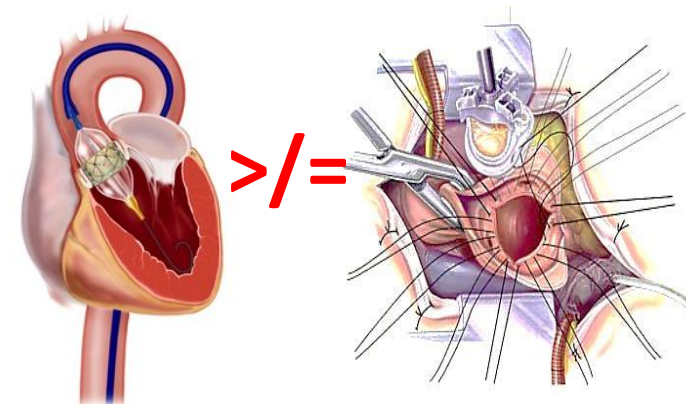
Evolving Risk Profile in TAVI Randomised Trials



CLINICAL EVIDENCE ACROSS RISK CATEGORIES



Low



The Low-Risk TAVI Trials for Severe Aortic Stenosis: Future Implications for Australian and New Zealand Heart Teams

Heath Adams, MBBS, FRACP^{a,b,c,*},
 Ross Roberts-Thomson, MBBS, FRACP^{a,d},
 Tiffany Patterson, MBBS, PhD, MRCP^{a,e},
 Bernard Prendergast, DM, FRCP, FESC^a,
 Simon Redwood, MD, FRCP, FACC^{a,e}

Table 1 Evidence TAVI from Major RCT's & Mortality Outcomes.

Name Publication Year	Number of patients	Comparison group	Surgical risk average (STS %)	Primary outcome	Mortality outcome TAVI at specified timepoint (%)	Mortality comparison group (%)	Mortality p-value 95% CI and/or HR	TAVI approach
PARTNER 1B trial 2010 [1]	358	Medical Management	11.6	All-cause mortality at 1 year	30.7	50.7	HR 0.55 (95% CI 0.40-0.74), p<0.001	TF
PARTNER 1A trial 2011 [2]	699	SAVR	11.7	All-cause mortality at 1 year	24.2	26.8	p=0.44	TF and TA
PARTNER 2 2016 [3]	2,032	SAVR	5.8	All-cause mortality + disabling stroke at 2 years	16.7	18.0	p=0.45	TF and TA
SURTAVI 2017 [4]	1,746	SAVR	4.5	All-cause mortality + disabling stroke at 2 years	11.4	11.6	(95% CI -3.8 to 3.3)	TF, TS and TAo
NOTION 2016 [5]	280	SAVR	3.0	All-cause mortality + disabling stroke at 1 year	4.9	7.5	p=0.38	TF and TS
PARTNER 3 2019 [6]	950	SAVR	1.9	All-cause mortality, disabling stroke or rehospitalisation at 1 year	1.0	2.5	HR 0.41 (95% CI 0.14-1.17)	TF
Evolut Low-risk Trial 2019 [7]	1,403	SAVR	1.9	All-cause mortality + disabling stroke at 2 years	4.5	4.5	(95% CI -3.2-3.2)	TF

Abbreviations: STS, Society of Thoracic Surgeons; TA, transapical; TAo, transaortic; TF, transfemoral; TS, transsubclavian; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve replacement; HR, heart rate; SURTAVI, Surgical Replacement and Transcatheter Aortic Valve Implantation; NOTION, Nordic Aortic Valve Intervention; PARTNER, Placement of AoRTic TraNscathetER Valve Trials.

TAVI vs the Rest

METHODS	ARR	NNT
NSTEMI Invasive PCI (MACE)	1.3%	~76
PCSK9 vs Statin Alone (MACE)	1.6%	~62.5
Ticagrelor vs Clopidogrel (MACE)	1.9%	~50
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Entresto vs ACE/ARB (death or HF hosp)	4.7%	~19.5
ICD (Ischaemic; mortality)	3%	33
TAVI vs best medical therapy (Mortality)	20%	5
TAVI vs SAVR (high risk pts)(Mortality)	4.9%	~20
TF TAVI vs SAVR intermediate risk (MACE)	3.6%	~27.7
TAVI vs SAVR low risk patients (Mortality)	2.5%	40

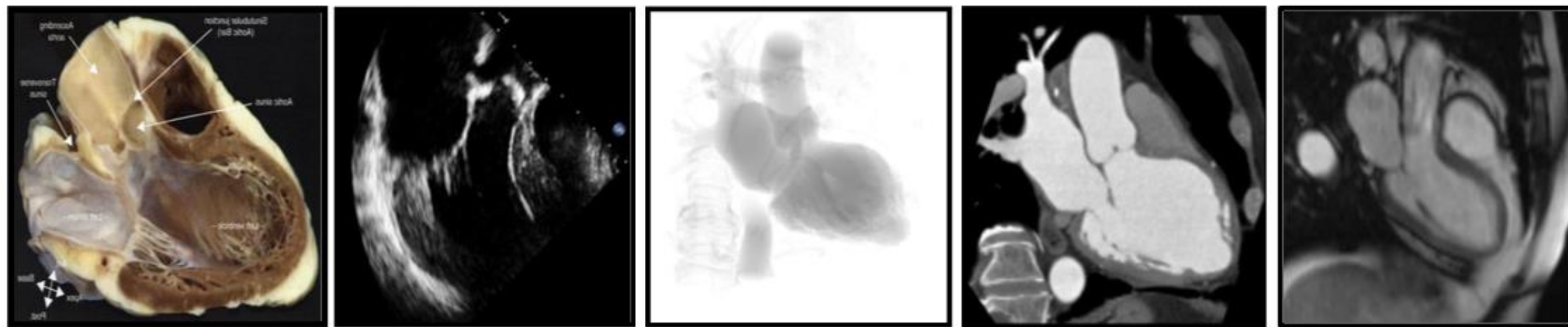
ARR = Absolute risk reduction
NNT = Number needed to treat

Drivers of Success

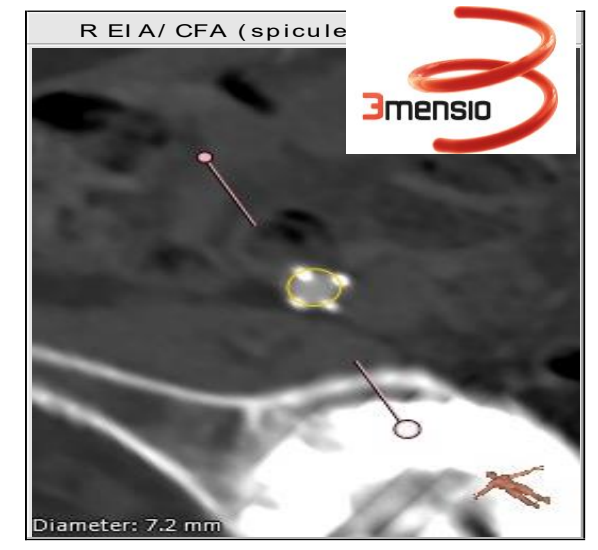
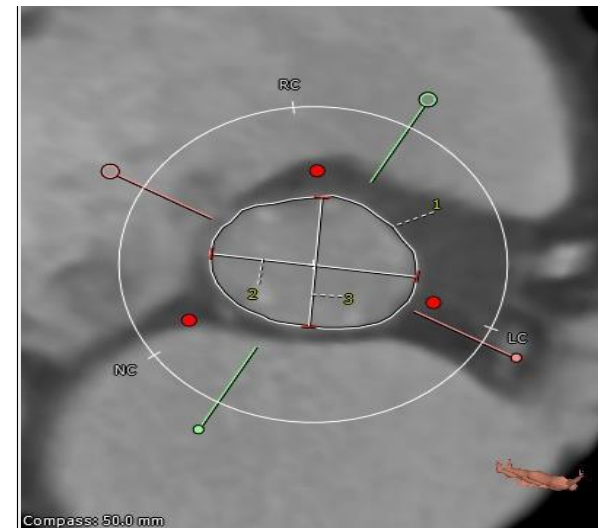
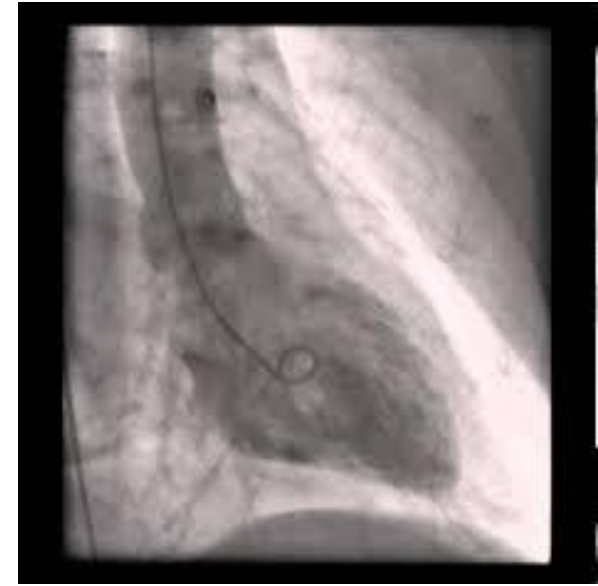
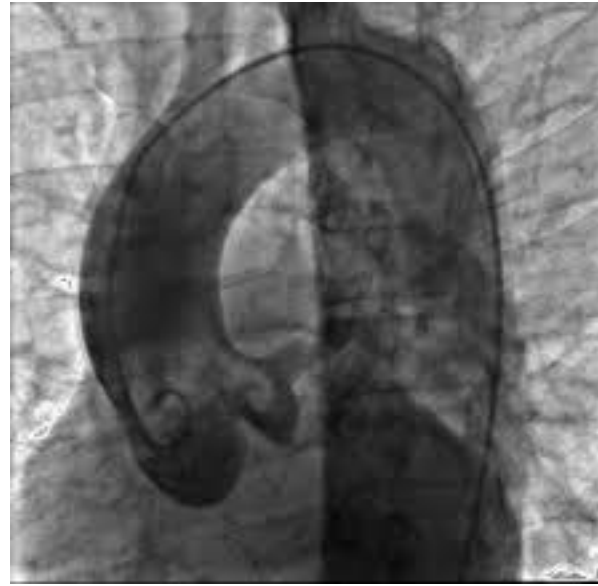
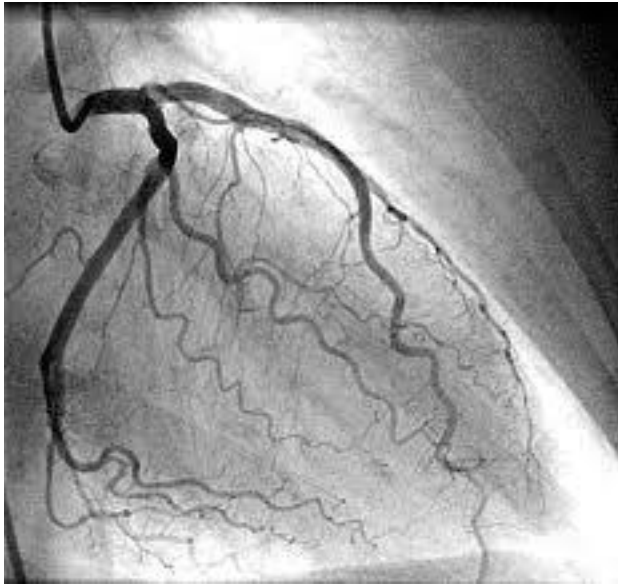
- Multi-disciplinary Heart Team
- Strong background in evidenced-based medicine
- Rapid improvements in device design
- Simplification of the procedure
- Reduction in complications

Prior Preparation Prevents Poor TAVI Performance

Multimodality Imaging



The TAVI Work Up



Conclusion

Conclusion: CT TAVI Shirley Walters

A 24.7, 481

P - 25.6, 80.3

L - 13.6 (15.6)

R - 18.2 (14)

Nil LVOT ca

Implant - 10/7, angle 54

Device: ER 29, 5326

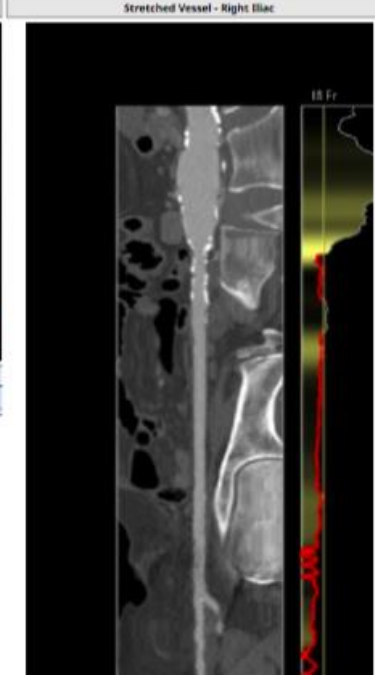
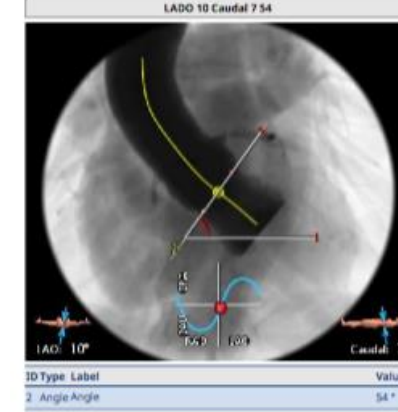
Vascular

Moderate burden of calcification, minimal tortuosity

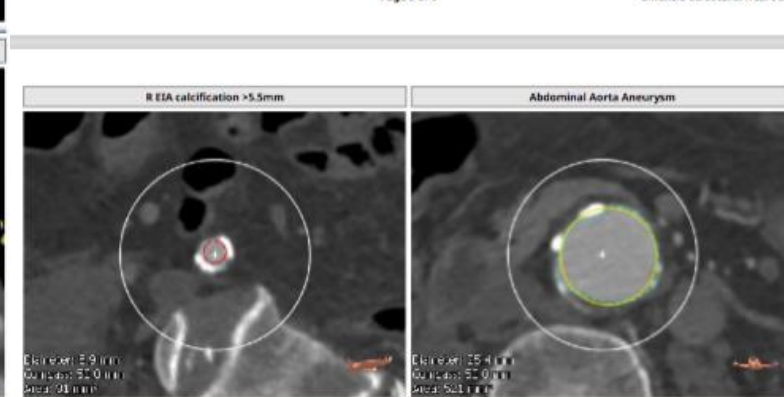
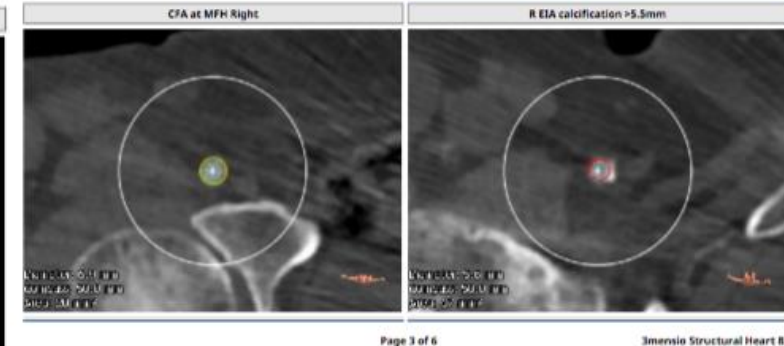
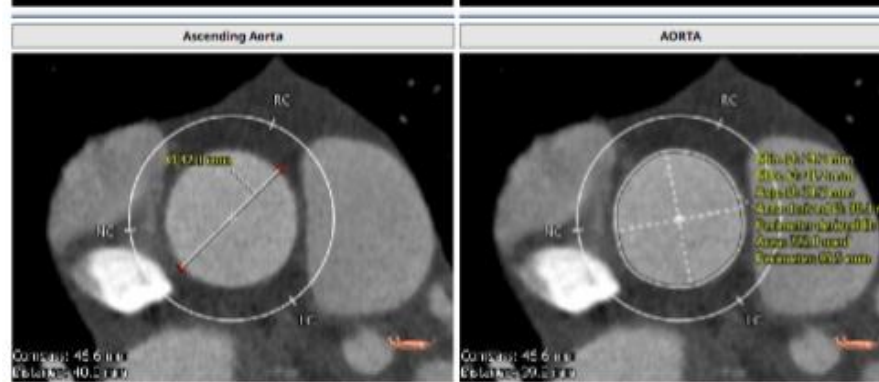
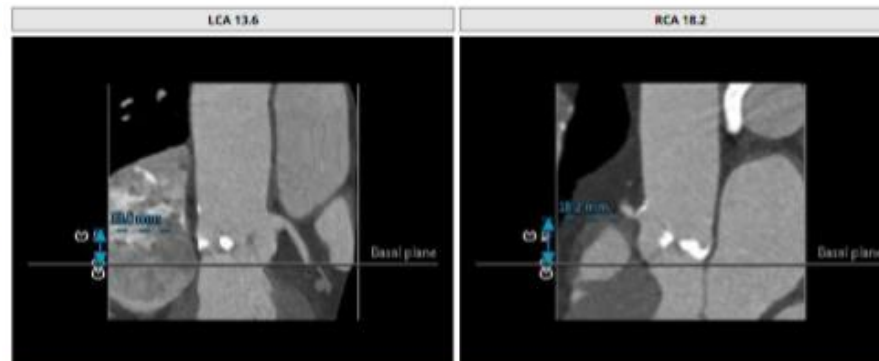
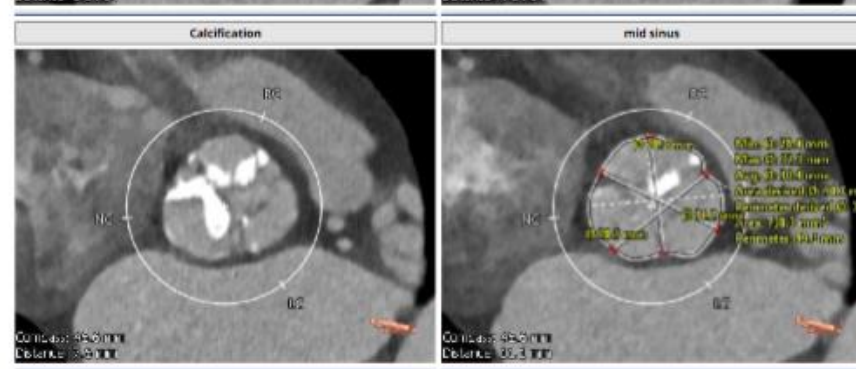
R - suitable calibre, low level of bifurcation

L - suitable calibre, low level of bifurcation, napkin ring at proximal external iliac

Plan: Right sided primary access



Screenshots





Preoperative



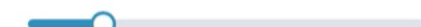
CRAN: 29°
LAO: 33°



Global Opacity



aorta_pre



calcs_pre

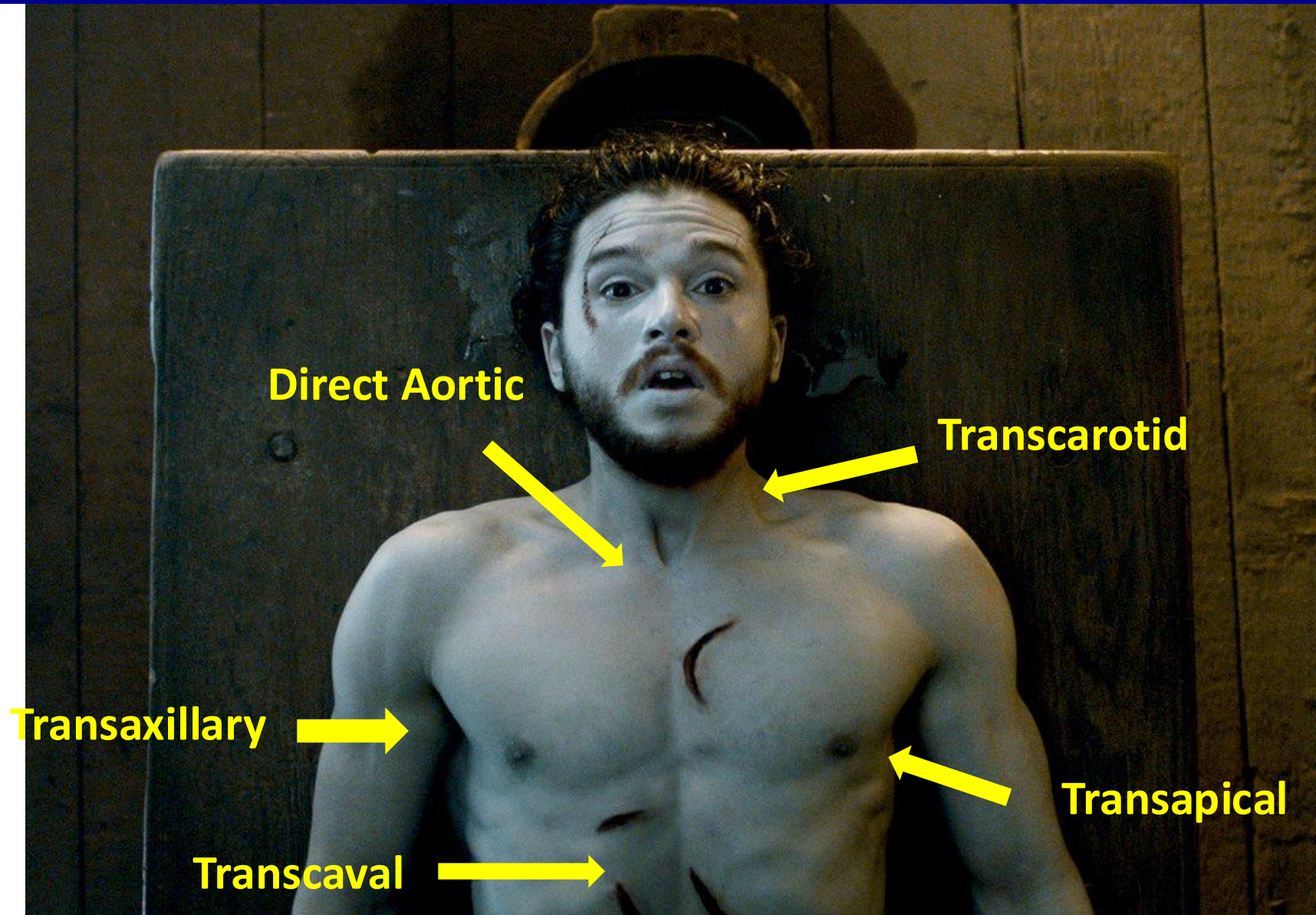


valve_pre



Reset

Alternative Access



MEDICAL IMAGING—ORIGINAL ARTICLE

Outcomes of incidental findings on multi-detector computed tomography for transcatheter aortic valve implantation assessment: A single-centre study and review of the literature

Francis J Ha,¹  Jodie Li Mei Tham,^{1,2} Sarang Paleri,¹ Christine Wright,¹ Kelvin K Yap,³ Heath SL Adams,^{1,4} Robert J Whitbourn^{1,2} and Sonny C Palmer^{1,2}

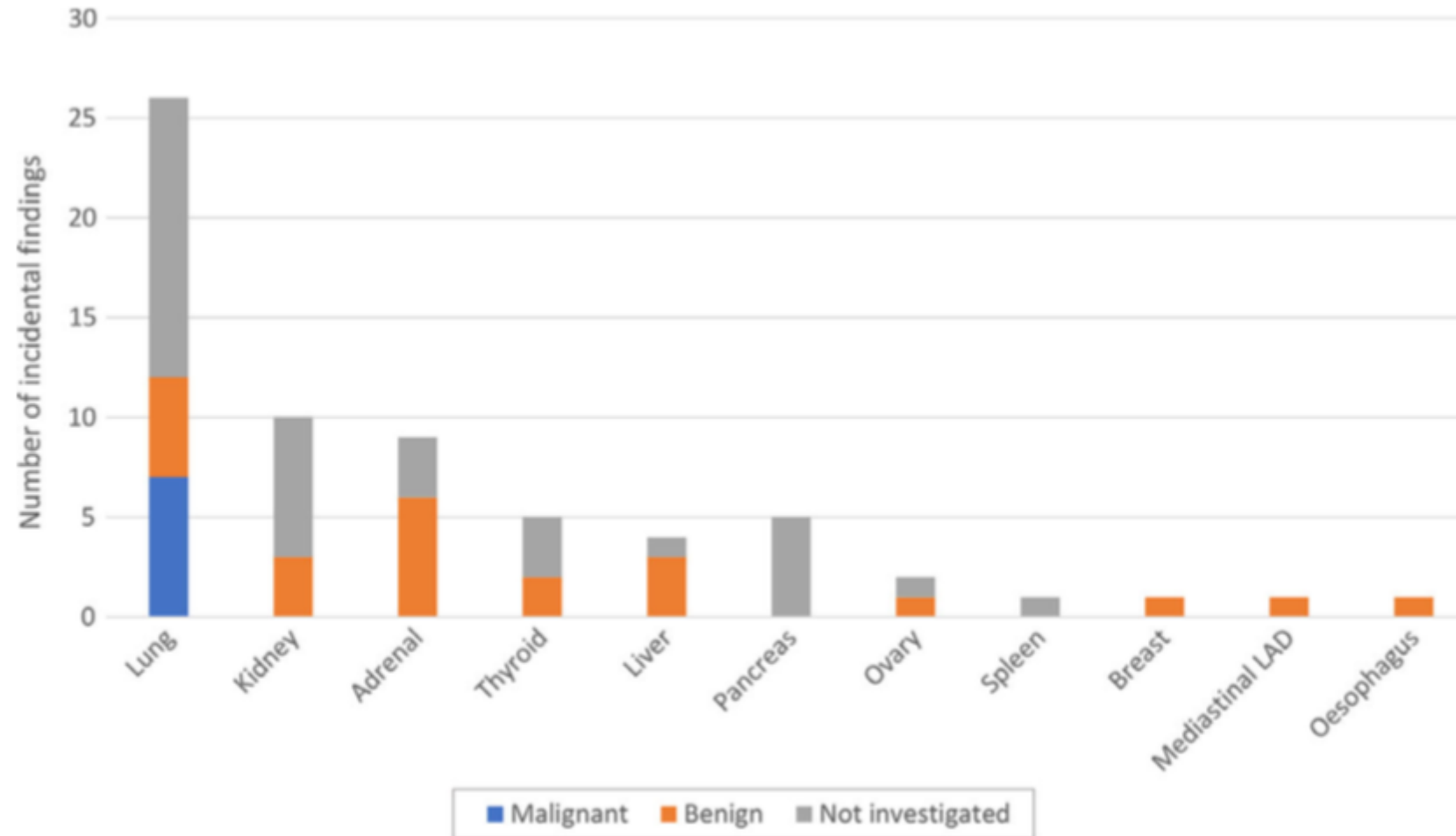


Fig. 1. Outcome of incidental findings of immediate and non-immediate clinical significance.

Outcomes of incidental findings on multi-detector computed tomography for transcatheter aortic valve implantation assessment: A single-centre study and review of the literature

Francis J Ha,¹  Jodie Li Mei Tham,^{1,2} Sarang Paleri,¹ Christine Wright,¹ Kelvin K Yap,³ Heath SL Adams,^{1,4} Robert J Whitbourn^{1,2} and Sonny C Palmer^{1,2}

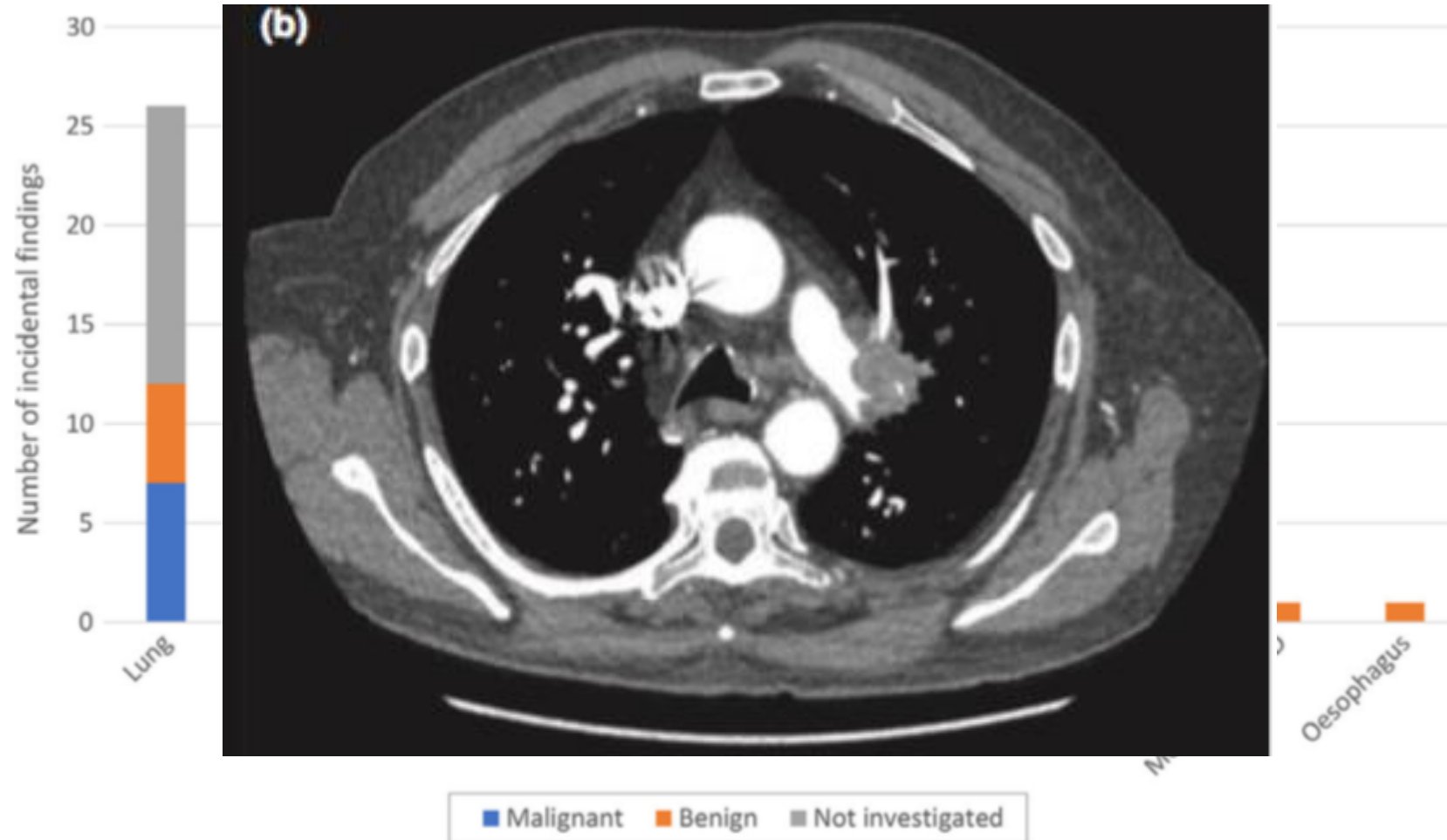
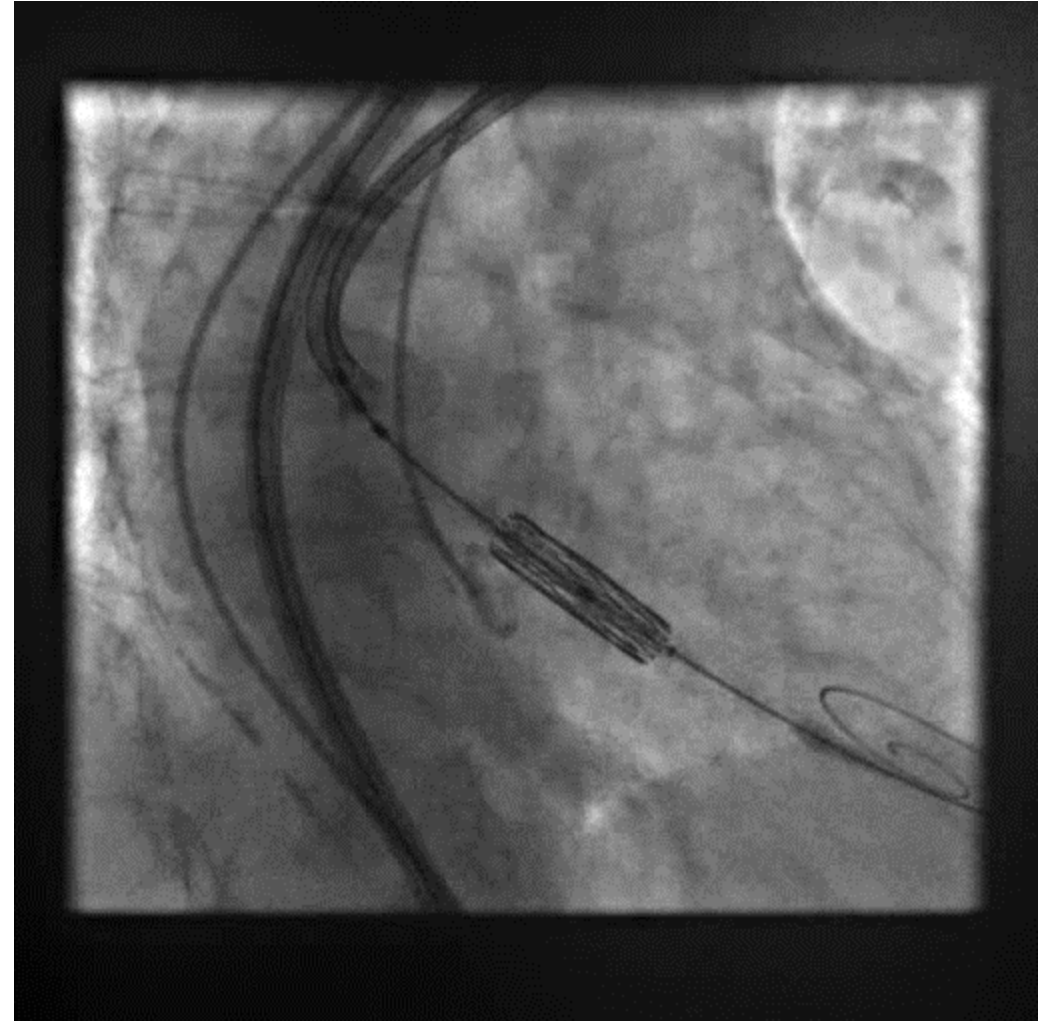


Fig. 1. Outcome of incidental findings of immediate and non-immediate clinical significance.

Streamlined TAVI (90% of cases)

- Local anaesthetic and light sedation
- One operator, one fellow, one nurse (6 people in the room)
- Bifemoral arterial access
 - one 6 F for pigtail,
 - one 14-16 F for valve delivery
- No need for balloon valvuloplasty
- Occasional cerebral protection
- One rapid pacing run to deliver valve
- Percutaneous closure



Streamlined TAVI (90% of cases)

- In hospital 1-2 days post procedure
- Mobilise evening of procedure after minimum 4 hours
- Average case time 45min skin to skin
- **No routine need for ICU**
- **No routine need for TOE**
- **No routine need for GA**
- A ward telemetry bed and regular groin observations in necessary

Intra Procedural Nursing Notes

SEE ANESTHETIC CHART

LEFT

6F - arterial
angioseal @ 1123

Angio-Seal™ VIP
REF 610132
LOT 06082554

Sedation Score	Tick	Time
0 = none (alert)		
S = Sleeping normally		
1 = Mild (occas. drowsy but easy to rouse)		
2 = Moderate (freq. drowsy but easy to rouse)		
3 = severe (somnolent, difficult to rouse)		

26 mm⁽⁺²⁾ valve ☒ 1118

RIGHT

8F - arterial → 14F esheath
X2 proglide inserted @ 1110

Edwards Lifesciences

REF 9600TFX26

Edwards SAPIEN 3 Transcatheter Heart Valve

2019-12-08

SN 5553835

Lot No. S-17M6403

Implant Date

Surgeon

Patient

(01)07612989037484
(17)191208(21)5553835

closed @ 1120

Runner Nurse's Signature: Rg

Time out of Lab: _____

* (R) femoral incision closed with vicryl 2-0 Self absorbable Suture *

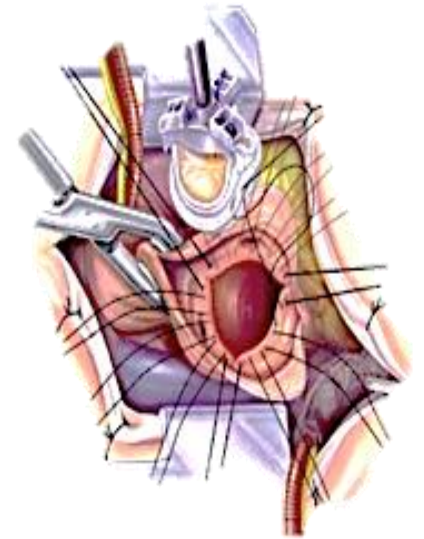
STROKE

MORTALITY

RE-HOSPITALIZATION



>



Resource Utilisation



**NYHA Class
II/III/IV**

% of Patients

SAVR

33%

TAVI

20%

P < 0.01

***PARTNER 3
Trial @ 30
Days***

N Engl J Med. 2019

**Six-Minute
Walk Distance**



% Change vs. baseline

P < 0.01

32%

TAVI

7%

SAVR

% Change
vs. baseline

P < 0.01

38%

TAVI

13%

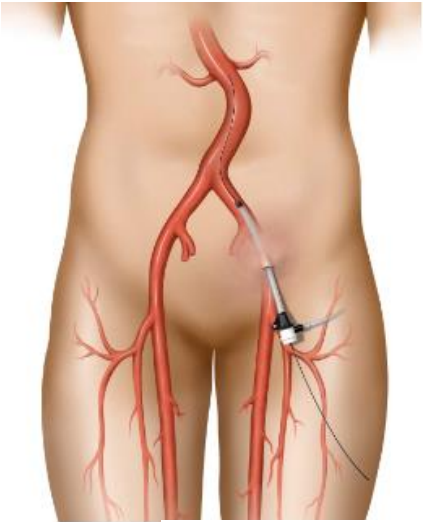
SAVR

**Quality
of life**

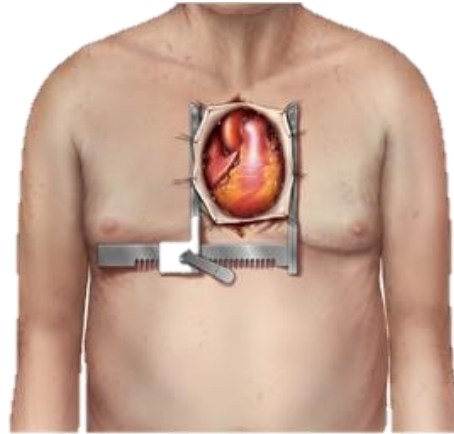


TAVI - IMPROVED RESOURCE UTILIZATION

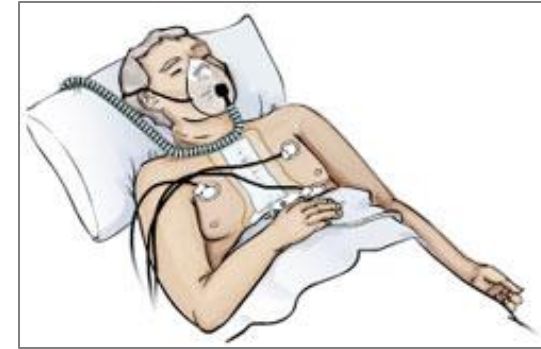
TRANSFEMORAL TAVI



SAVR

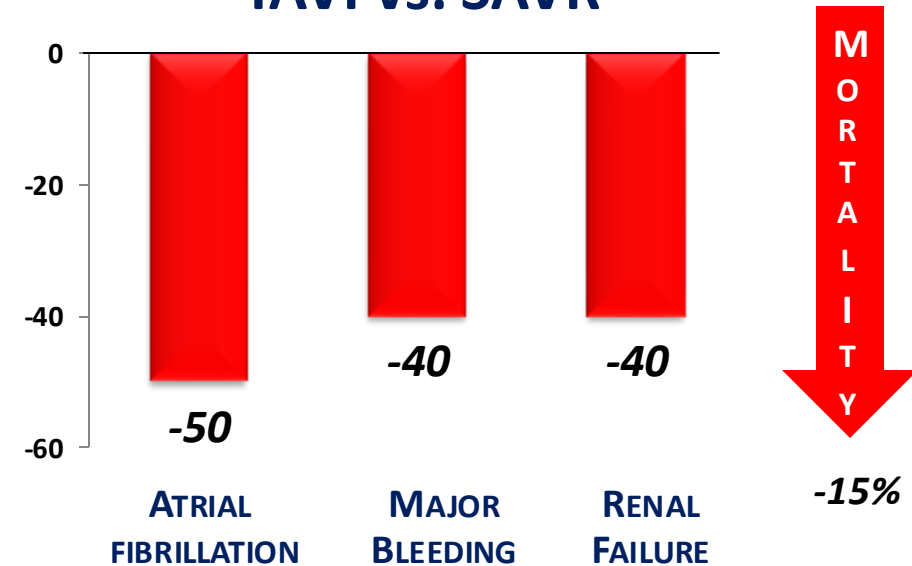


EARLY PERI-PROCEDURE



NO	OPEN THORACOTOMY	YES
NO	CARDIOPULMONARY BYPASS	YES
NO	OROTRACHEAL INTUBATION	YES
NO	GENERAL ANESTHESIA	YES
NO	PROLONGED VENTILATION	YES

TAVI vs. SAVR



TAVI - IMPROVED RESOURCE UTILIZATION



Procedure time

55%



ICU stay

50%



Total hospital stay

33%

PARTNER 2A

N Engl J Med.
2016;374:1609-20

SURTAVI

N Engl J Med.
2017;376:1321-1331

74%

33%

40%

Same Day Discharge!

Featured Case Reports

CCI 2016

Same Day Discharge after Transcatheter Aortic Valve Replacement: Are We There yet?

Philippe G n reux,^{1,2*} MD, Philippe Demers,¹ MD, and Fr d ric Poulin,¹ MD

Early discharge after transcatheter aortic valve replacement (TAVR) has been increasingly reported, and is now becoming routinely performed in experienced TAVR centers. However, to the best of our knowledge, no case has been described where a patient was safely discharged on the same the day of the procedure. This report will present the case of a patient who underwent a successful transfemoral TAVR and was safely discharged home the same day. Specific requirements and criteria are proposed to ensure the safety of this approach.   2015 Wiley Periodicals, Inc.

Key words: TAVR; TAVI; discharge

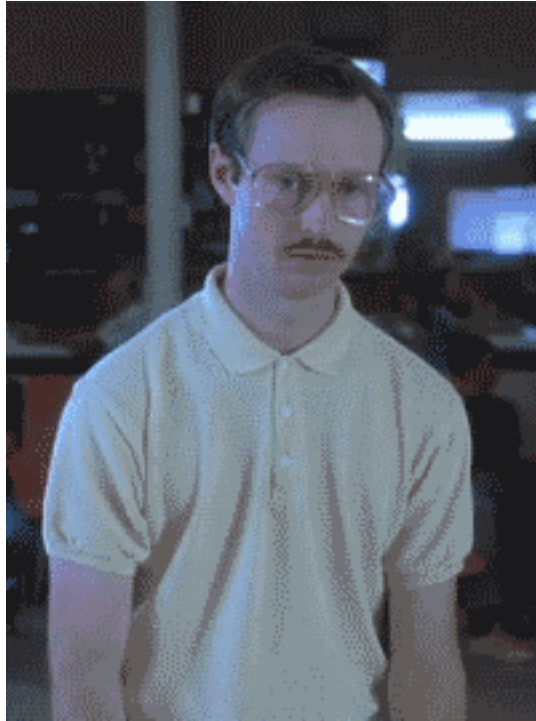
What is required to expand TAVI to moderate and low risk patients?

- **Outcomes** need to be equal or better than SAVR
 - Mortality
 - Stroke
- **Patient preference** for TAVI
 - Morbidity (including PPM), recovery time, patient experience
- **Valve durability** comparable to (*or better than*) surgery
- **Affordable**
 - Cheaper and/or more cost-effective

The favourable outcomes of TAVI are consistent across the entire risk spectrum suggesting that surgical risk estimation is no longer the basis to guide the choice between TAVI and SAVR

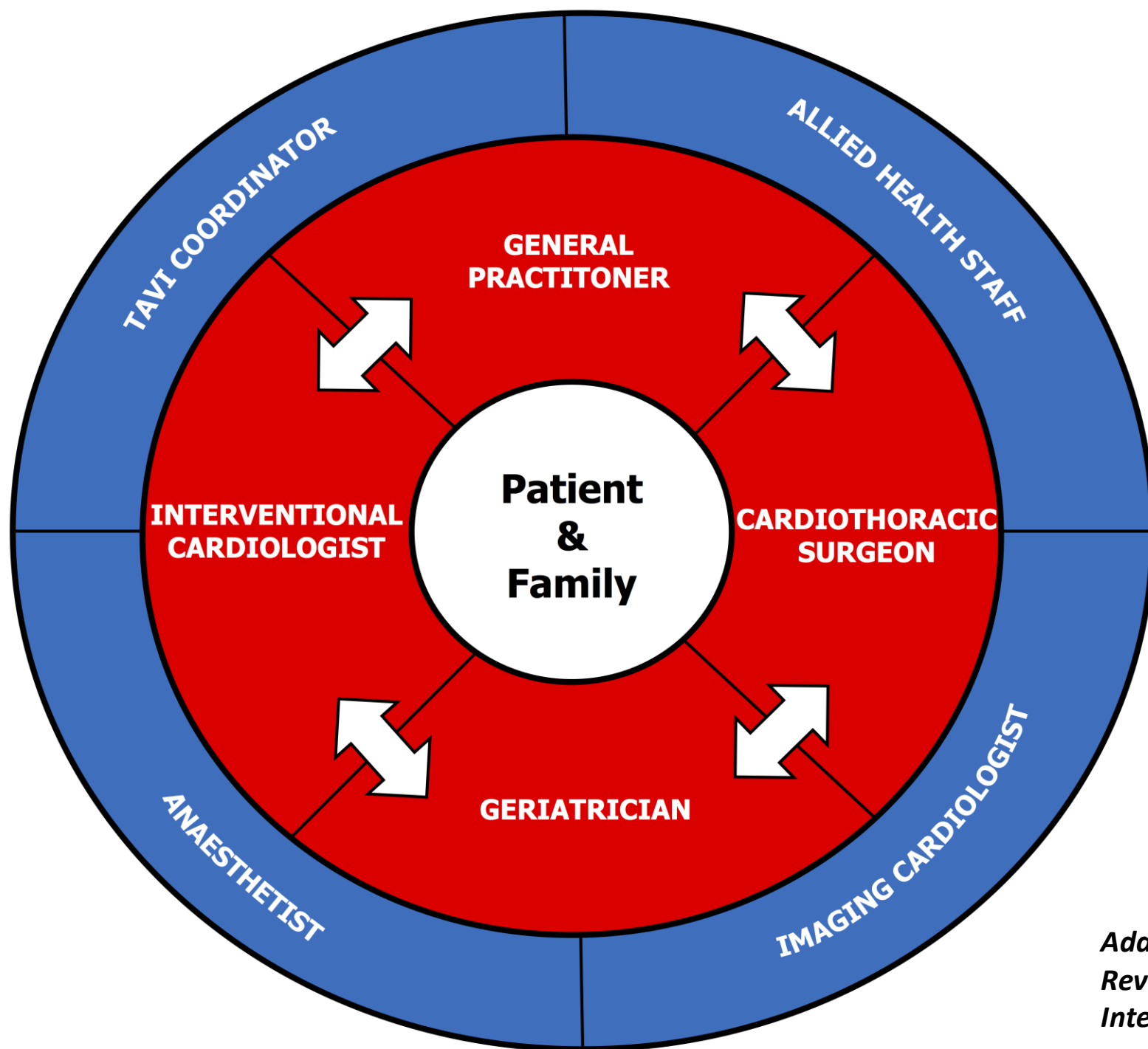
Everyone's a Winner?

Cardiologist



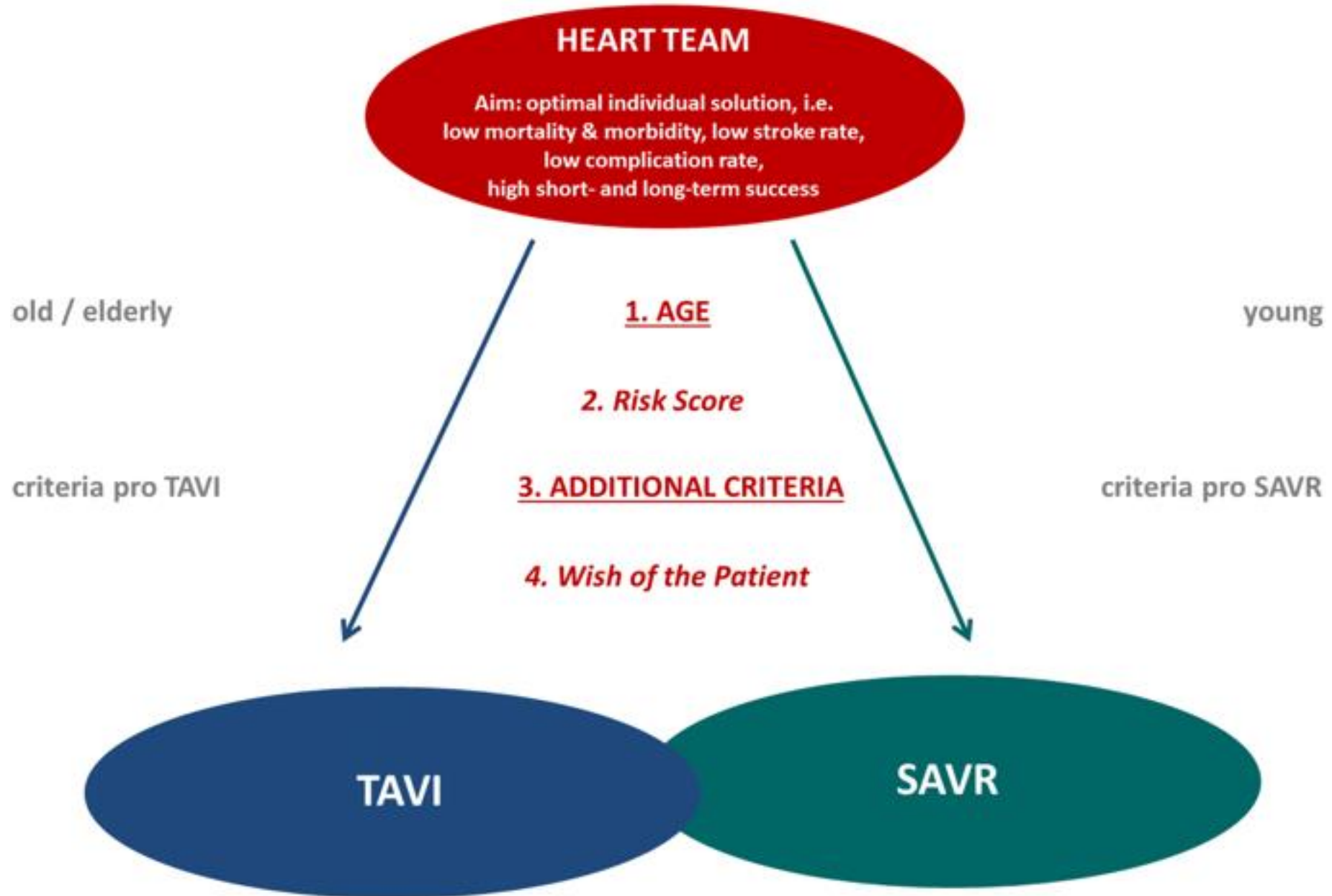
Cardiac Surgeon





*Adams H et al, A Contemporary
Review of Severe Aortic Stenosis,
Intern Med J, doi: 10.1111/imj.14071*

Choice of Treatment in Symptomatic Aortic Stenosis



Frailty

Physician's Guide

- Cognition
- Get up and go
- Gait speed
- Hand grip
- Weight loss
- Window watching
- Family support



The Results



BEFORE



AFTER

The Results – Being Realistic & Managing Expectations



BEFORE



AFTER

Frailty

Comprised of 6 components giving a total score of 7

- Mini-mental State Exam <27 (worth 2 points)
- Unable to perform basic ADLs (worth 1 point)
- Unable to perform instrumental ADLs (worth 1 point)
- Mini nutritional assessment (worth 1 point)
- Timed up and go test (worth 1 point)
- Pre clinical assessment “eye ball” test (worth 1 point)

If a person scores 3 or greater they are considered frail, with validated poorer outcomes with both TAVI or SAVR

Shoenberger et al, European Heart Journal 2013

Clinical Frailty Scale*



1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2 Well – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.



3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.



4 Vulnerable – While not dependent on others for daily help, often **symptoms limit activities**. A common complaint is being "slowed up", and/or being tired during the day.



5 Mildly Frail – These people often have more **evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6 Moderately Frail – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7 Severely Frail – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. Terminally Ill - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are not otherwise evidently frail.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005; 173:489-495.

Impact of Frailty Markers for Unplanned Hospital Readmission Following Transcatheter Aortic Valve Implantation

Mike Saji, MD; Ryosuke Higuchi, MD; Tetsuya Tobaru, MD, PhD; Nobuo Iguchi, MD; Shuichiro Takanashi, MD, PhD; Morimasa Takayama, MD, PhD; Mitsuaki Isobe, MD, PhD

Table 4. Predictors of Unplanned Readmission in Univariate and Multivariate Cox Regression Analyses

Parameters	HR	95% CI	P value	Adjusted HR	95% CI	P value
Age (every 10-year increase)	0.90	0.59–1.37	0.640			
Women	0.83	0.49–1.40	0.501			
Body mass index (<20 kg/m ² decrease)	1.05	0.74–1.48	0.766			
NYHA classification (every degree increase)	2.28	1.54–3.37	<0.001	2.28	1.08–2.44	0.019
STS score (every 4% increase)	1.72	1.35–2.19	<0.001	1.72	1.18–2.13	0.002
Diabetes mellitus	1.33	0.96–2.33	0.317			
Hypertension	1.19	0.63–2.24	0.577			
Dyslipidemia	0.64	0.38–1.06	0.080			
Previous myocardial infarction	0.79	0.24–2.56	0.706			
Previous bypass surgery	0.46	0.18–1.16	0.103			
Peripheral artery disease	1.39	0.79–2.45	0.248			
Previous stroke	0.84	0.36–1.97	0.700			
Previous pacemaker implantation	0.79	0.19–3.26	0.752			
Atrial fibrillation	1.87	1.10–3.18	0.019	2.49	1.41–4.40	0.002
COPD (moderate/severe)	4.79	2.39–9.59	<0.001	4.79	3.50–16.9	<0.001
Hemoglobin level (<11 g/dL)	1.98	1.19–3.31	0.009	1.98	1.14–3.28	0.014
eGFR (every 15 mL/min/1.73 m ² decrease)	1.33	0.99–1.79	0.057			
Albumin level (<3.5 g/dL)	2.32	1.40–3.84	0.001	2.32	1.17–3.55	0.012
Ejection fraction (every 10% decrease)	1.25	0.96–1.65	0.095			
Aortic valve area (every 0.1 cm ² increase)	1.07	0.98–1.47	0.648			
Mean pressure gradient (every 10-mmHg decrease)	0.97	0.82–1.15	0.781			
MR (every degree increase)	1.47	1.02–2.12	0.038	1.47		
Pulmonary artery pressure (>40 mmHg)	1.33	0.63–2.80	0.446			
Transfemoral approach	1.26	0.69–2.30	0.445			
SAPIEN XT vs. CoreValve vs. SAPIEN 3	0.95	0.63–1.44	0.822			

CI, confidence interval; HR, hazard ratio. Other abbreviations as in Table 1.

Clinical update

TAVI or No TAVI: identifying patients unlikely to benefit from transcatheter aortic valve implantation

Rishi Puri^{1,2,3}, Bernard Jung^{4,5}, David J. Cohen⁶, and Josep Rodés-Cabau^{1*}

Table 1 Medical comorbidities and factors predicting poorer outcomes post-transcatheter aortic valve implantation

Medical comorbidity	Factors specifically associated with futility
CLD	6MWT < 150 m ¹³ Oxygen-dependency ¹⁴
Advanced CKD	Atrial fibrillation ²¹ Dialysis dependence ²¹
Frailty	>2 frailty indices (Katz activities of daily living + mobility status) ³⁰
Cardiovascular conditions	LVEF < 30% Pre-capillary or combined PH ^b (mean PAP > 25 mmHg) ⁴⁴ Low trans-aortic gradient Impaired contractile reserve Low flow state (<35 mL/m ²) ⁴⁰ Organic severe MR

6MWT, 6-min walk test; LVEF, left ventricular ejection fraction; PH, pulmonary hypertension; PAP, pulmonary artery pressures; MR, mitral regurgitation.

^aTime taken to walk 5 m is >6 s.

Katz indices are: independence in feeding, bathing, dressing, transferring, toileting, urinary incontinence.

^bMeasured invasively. Combined PH defined as post-capillary PH (measured by LV end-diastolic pressure > 15 mmHg) with a diastolic pulmonary artery pressure ≥ 7 mmHg than LV end-diastolic pressure.

Table 3 Integrated approach for estimating transcatheter aortic valve implantation-specific risk and futility

Criteria	Low risk	Intermediate risk	High risk	Prohibitive risk
PARTNER TAVI score ^a , OR FRANCE 2 TAVI score	<25% risk of mortality or lack of QOL improvement at 6 months Risk score: 0 (30-day mortality risk < 5%)	25–50% risk of mortality or lack of QOL improvement at 6 months Risk score: 1–5 (30-day mortality risk 5–15%)	>50% risk of mortality or lack of QOL improvement at 6 months Risk score: 6–7 (30-day mortality risk 15–25%)	Risk score ≥ 8 (30-day mortality risk > 25%)
Frailty ^b	None	1 index	≥2 indices	≥4 indices
Specific major organ system compromise not to be improved post-TAVI ^c	None	1 organ system	2 organ systems	≥3 organ systems

^a<http://h-outcomes.com/tavi-risk-calculator/>.

^bFrailty based on Katz Index (independence in feeding, bathing, dressing, transferring, toileting, and urinary incontinence)³⁰ and independence in ambulation (walk 5 m in <6 s).

^cExamples of major organ system compromise:³⁴ Cardiac—severe LV systolic or diastolic dysfunction or RV dysfunction, and fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 < 50% or DLCO < 50% of predicted; CNS dysfunction (dementia, Alzheimer's disease, Parkinson's disease, and CVA with persistent physical limitation); GI dysfunction—Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin < 3.0; cancer—active malignancy; and liver—any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

Predictors of functional decline in elderly patients undergoing transcatheter aortic valve implantation (TAVI)

Andreas W. Schoenenberger^{1†}, Stefan Stortecky^{2†}, Stephanie Neumann¹,

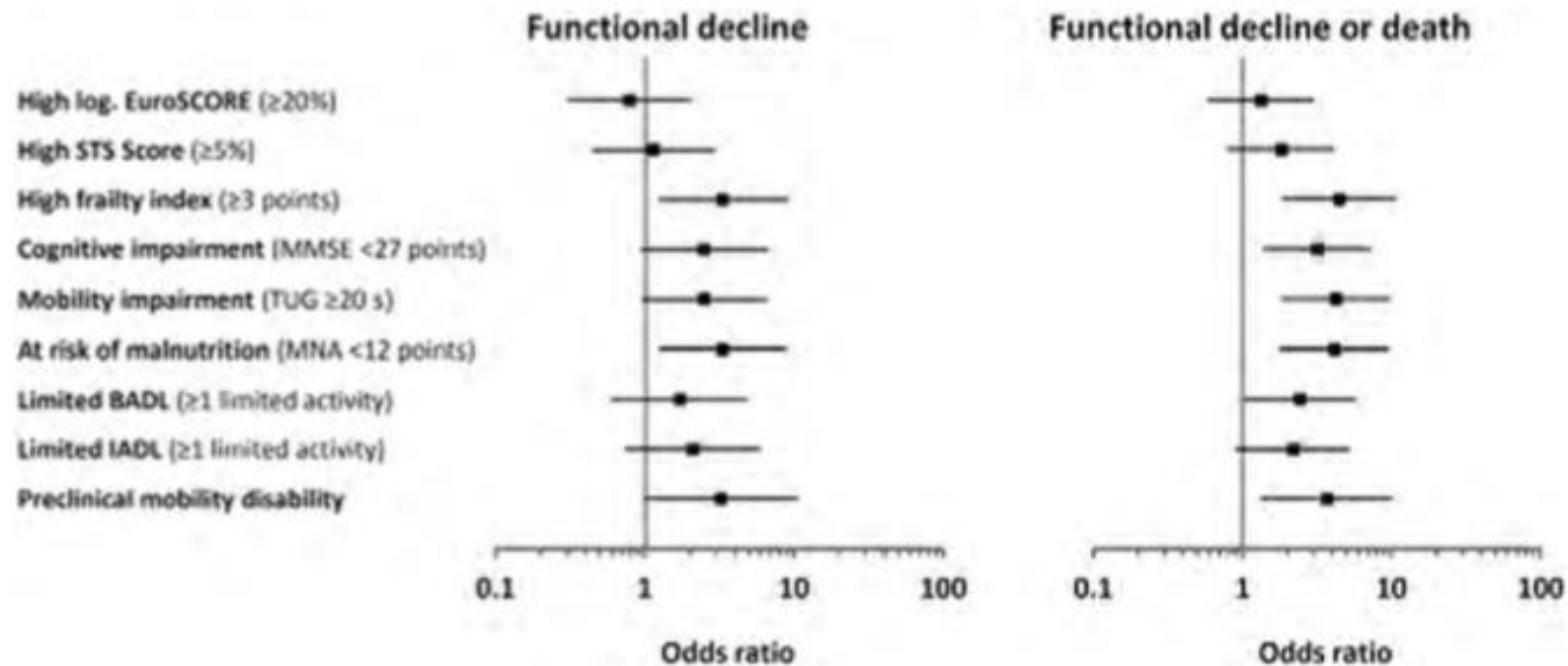
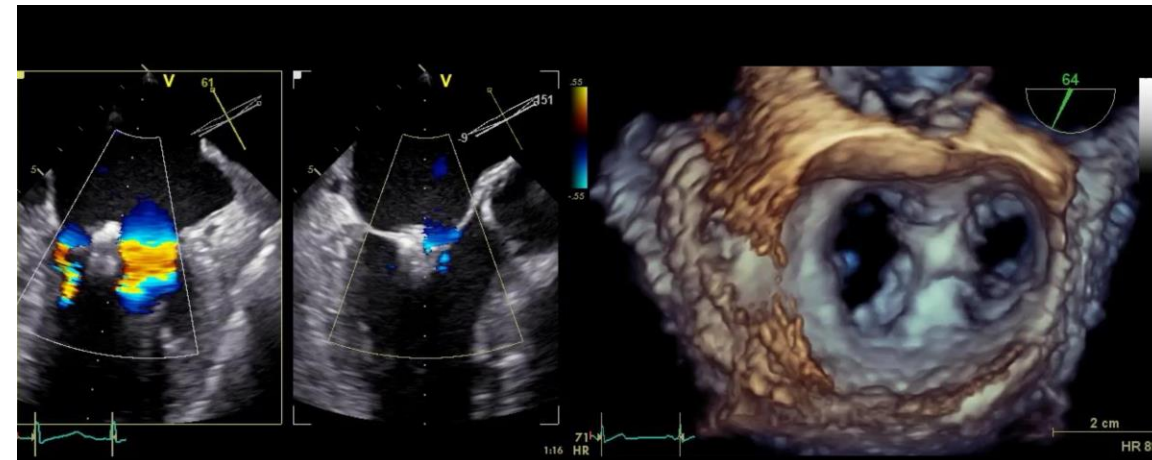
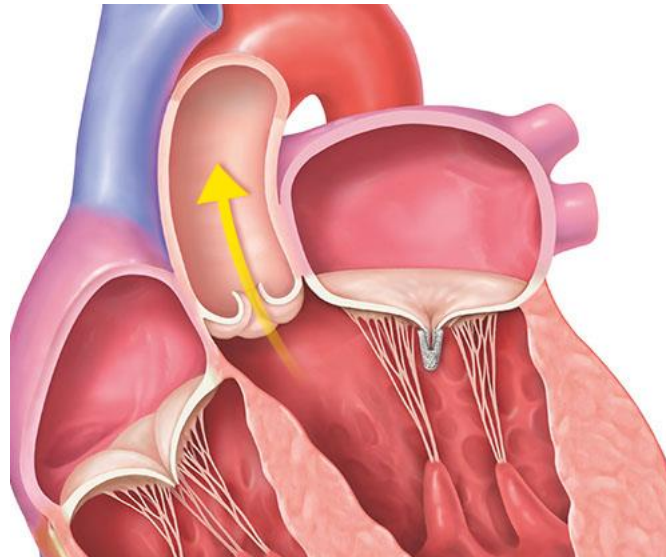
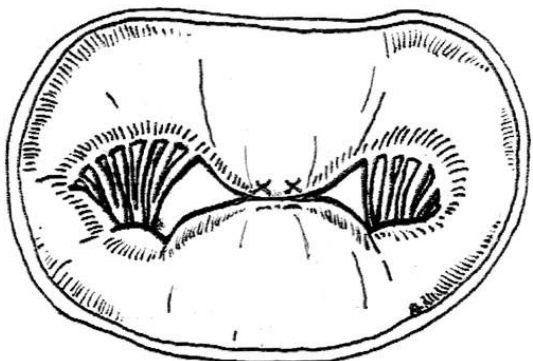
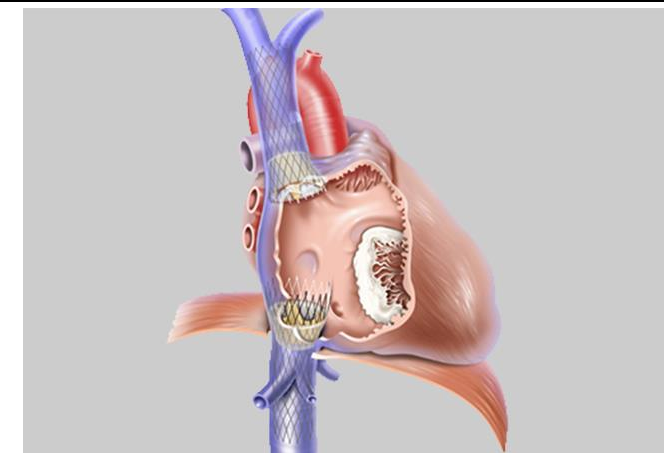


Figure 2 Odds ratios and 95% confidence intervals of univariable associations of dichotomized risk predictors with functional decline (defined as deterioration of the ability to perform basic activities of daily living) and functional decline or death in forest plots. BADL, basic activities of daily living; IADL, instrumental activities of daily living; MMSE, mini mental state exam; MNA, mini nutritional assessment; TUG, timed get up and go test.

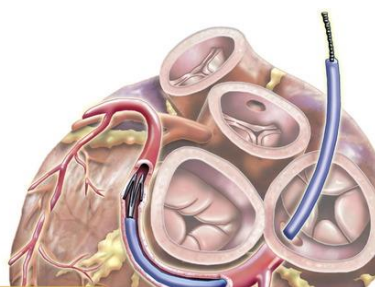
Questions?



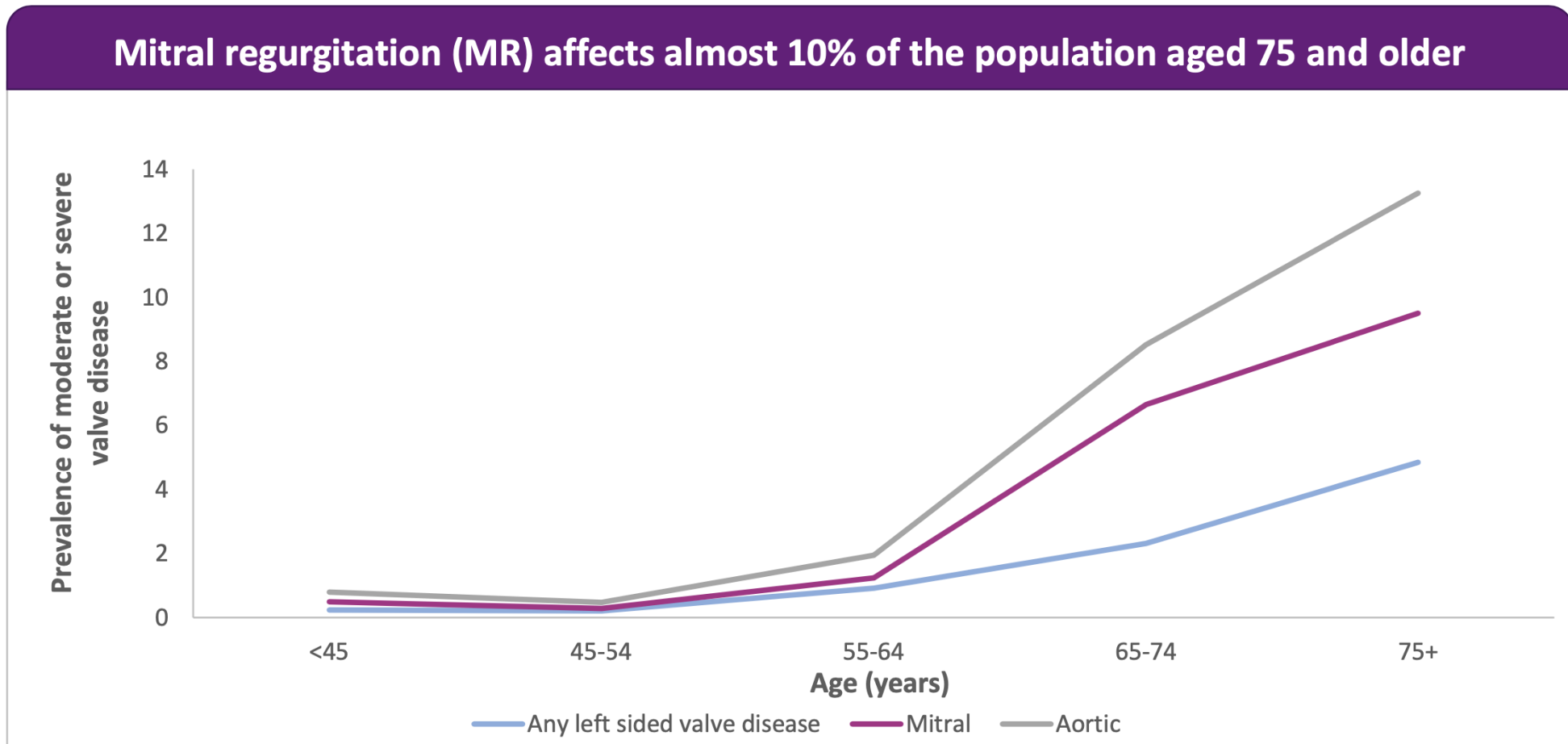
Mitral and Tricuspid Interventions (Addressing the Poor Cousins)



Dr Heath Adams
BMedSci, MBBS(Hons), DipUKMP, FRACP, FCSANZ
Interventional & Structural Cardiologist
Royal Hobart Hospital
Dr MG Ciezar Memorial Scholar
Senior Adjunct Researcher Menzies Institute
University of Tasmania



Incidence



Medical therapy for Severe MR vs Surgery

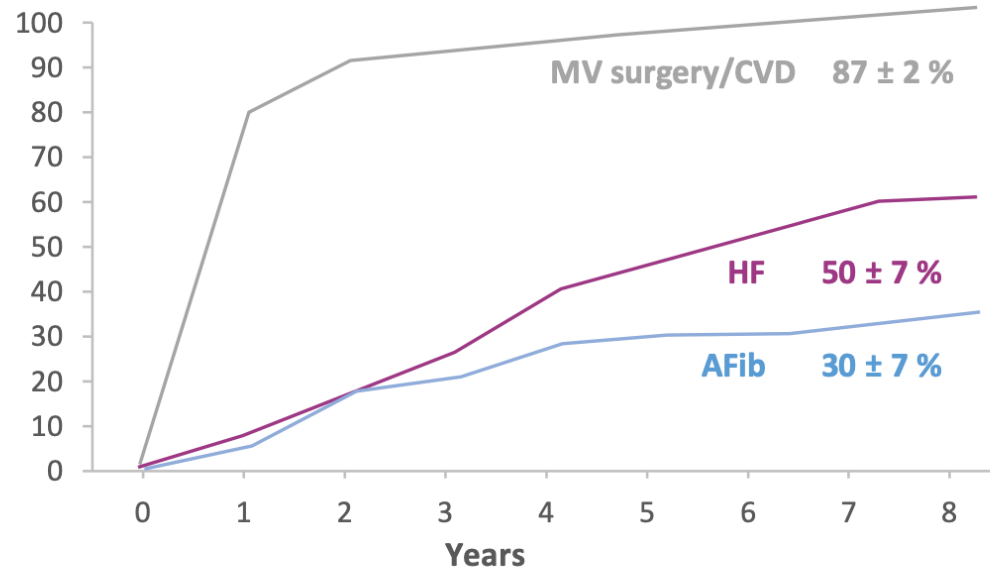
Primary MR

(Grigioni et al. JACC CV Imaging 2008;1:133-41)

MIDA Registry

Pts with nonsurgical management with severe MR due to flail leaflet (N =394)

Incidence (%)



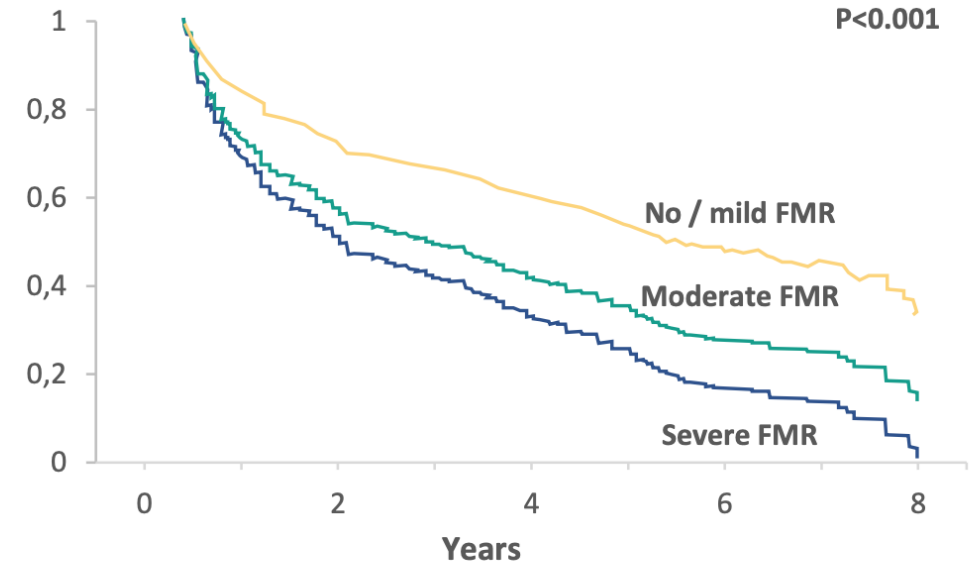
Patients at risk (n)	MV surgery/CVD	115	82	59	47	34	29	19	13
	HF	112	75	55	37	27	23	15	12
	Afib	97	68	47	36	28	24	16	11

Secondary MR

(Goliash G et al. EHJ 2018;39:39-46)

576 pts with HFrEF; 47% died during median 5-year FU; severe FMR in 21%, mod FMR in 32%

Survival



No / mild FMR	272	209	173	56	12
Moderate FMR	185	120	87	39	8
Severe FMR	119	61	42	22	3

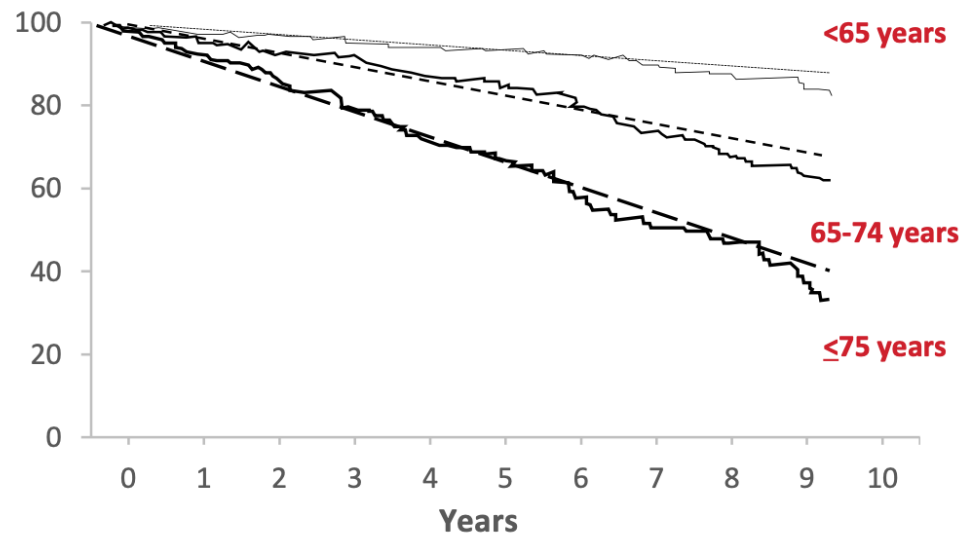
Surgery primary MR vs secondary MR

Primary MR

(Detaint et al Circulation. 2006;114:265-272)

Similar observed to expected survival ratios among elderly (≥ 75 y, n=284) and younger (65 to 74 y, n=504; and < 65 y, n=556) patients

Survival



Expected

Observed

< 65 yr

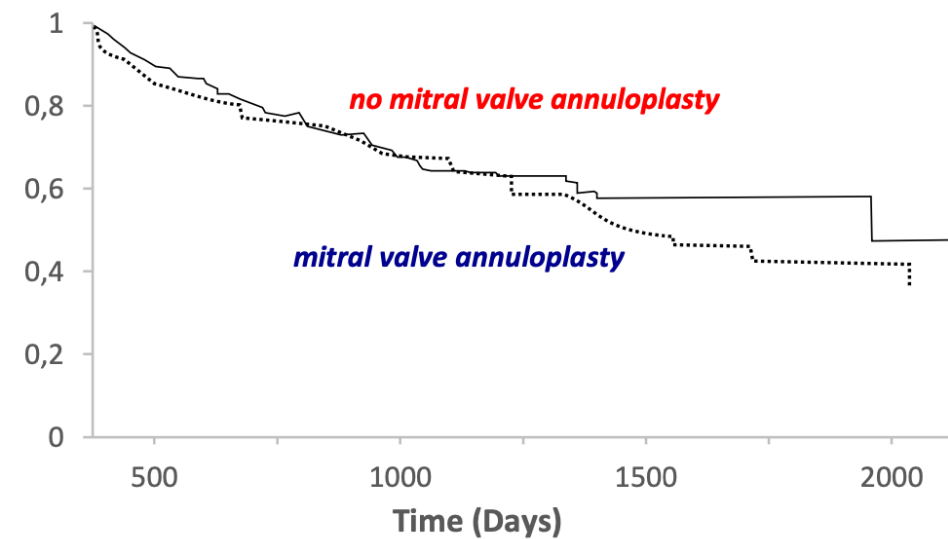
65-74 yr

≥ 75 yr

Secondary MR

(Wu AH et al. J Am Coll Cardiol 2005;45:381-387)

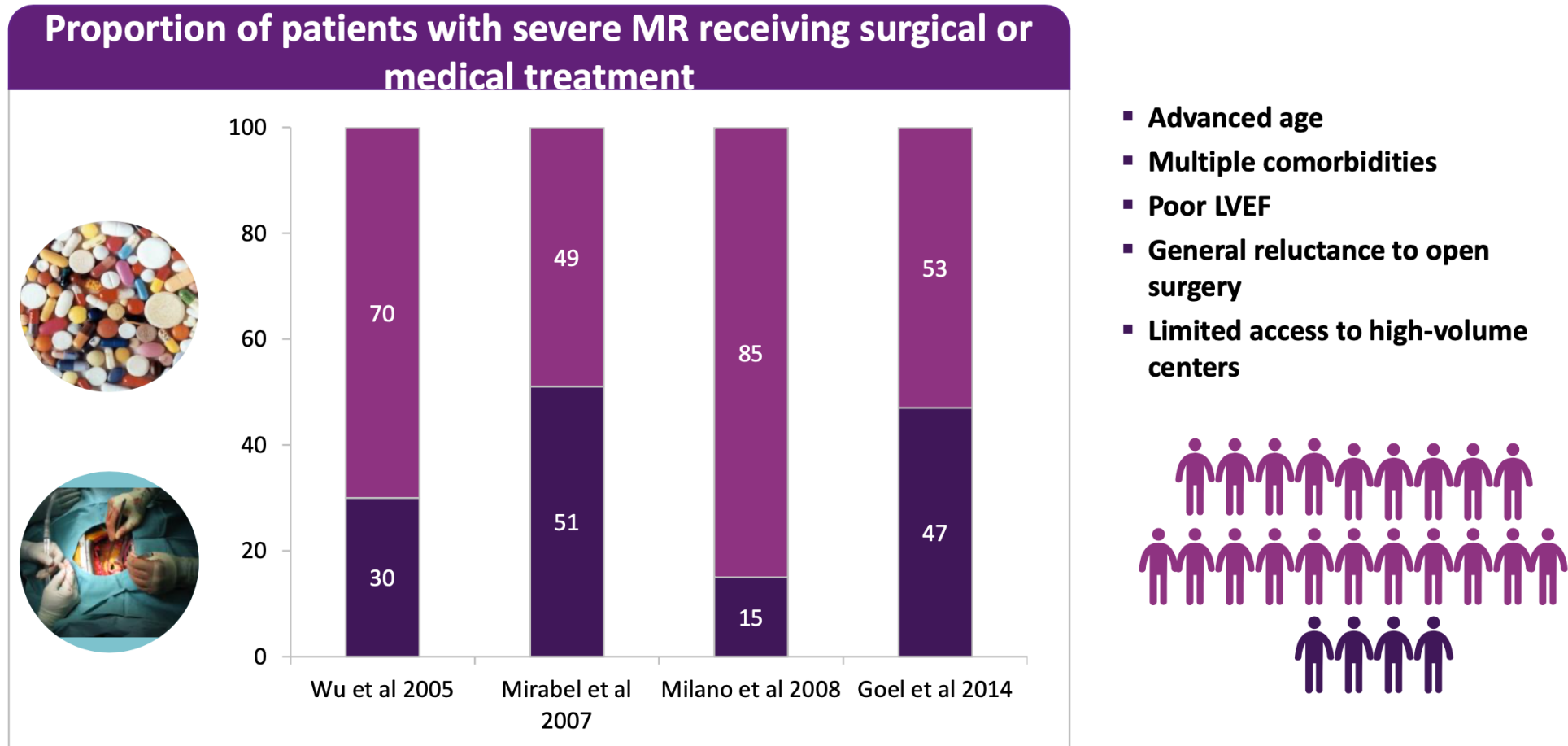
Event-free Survival

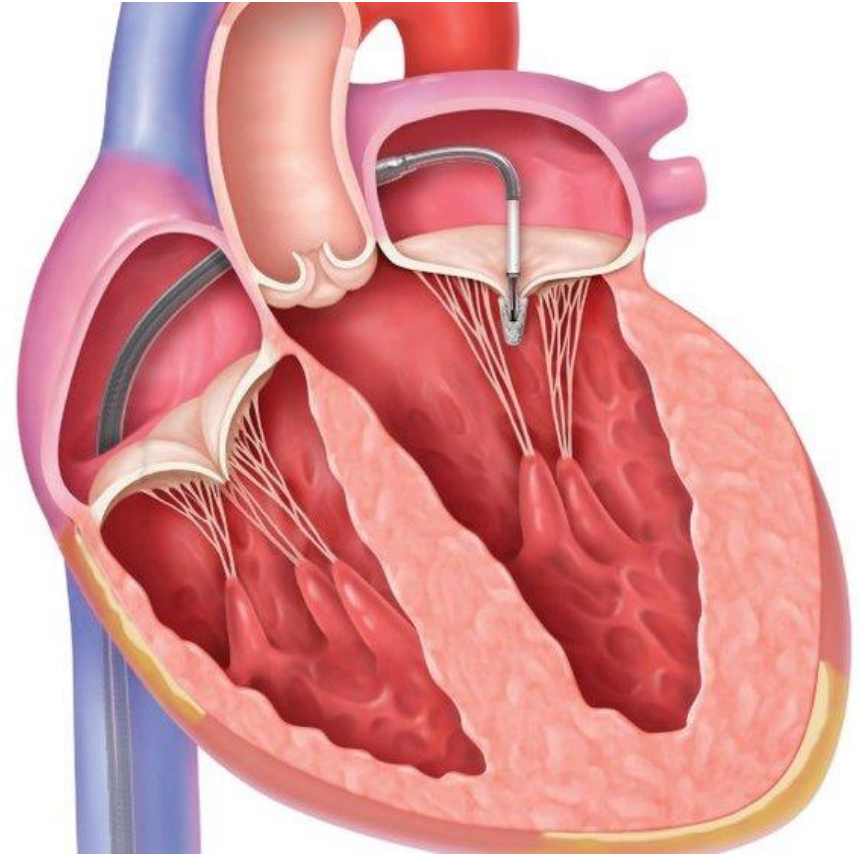
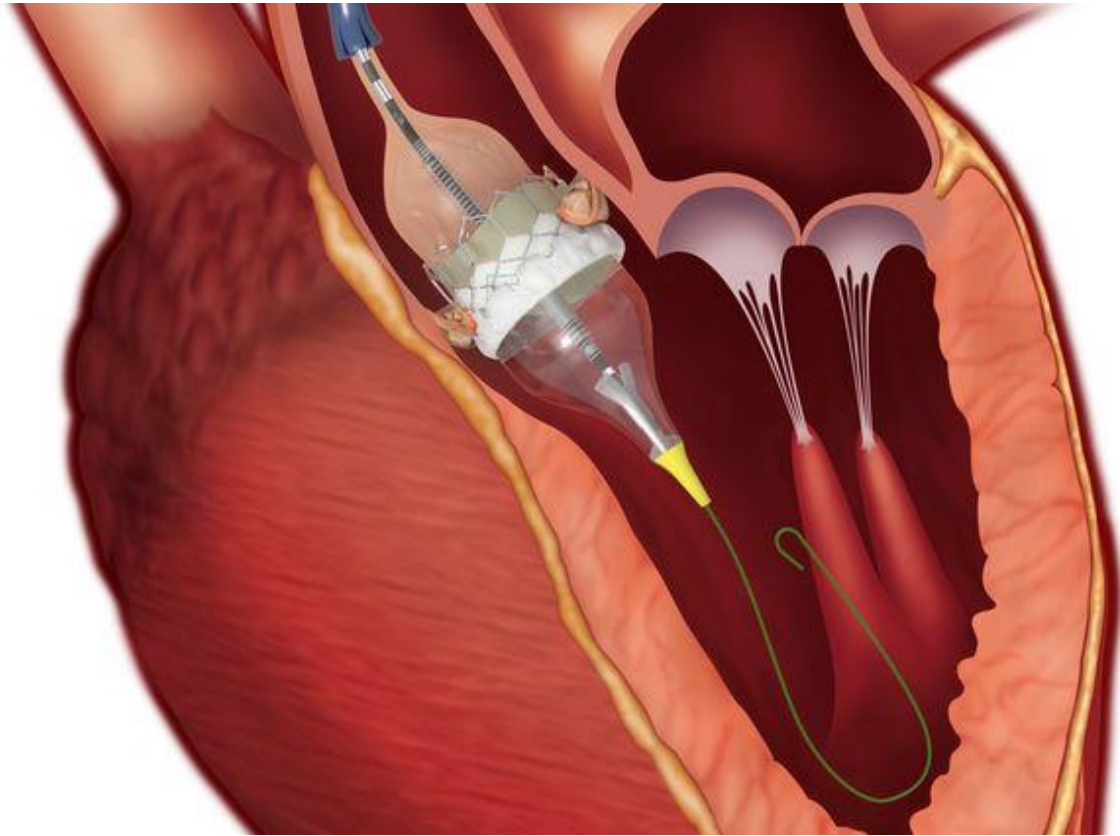


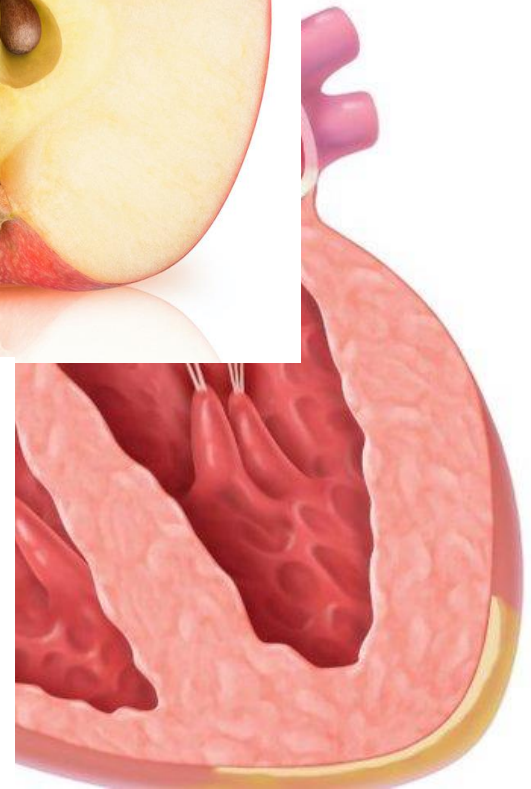
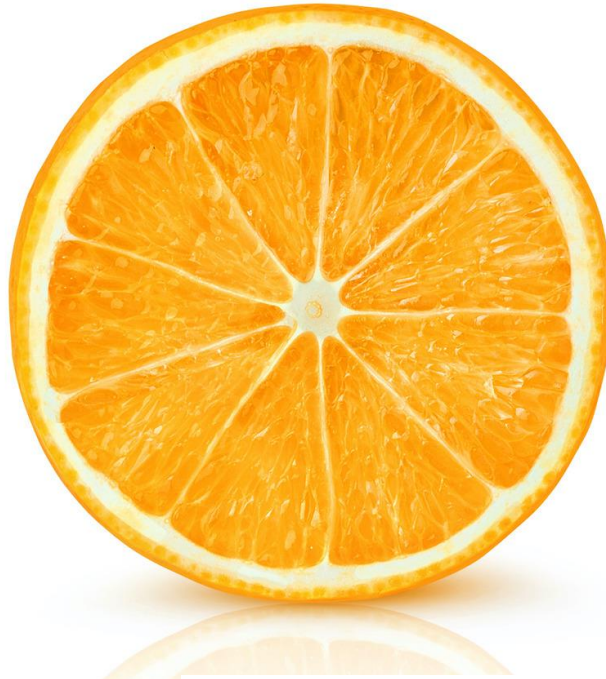
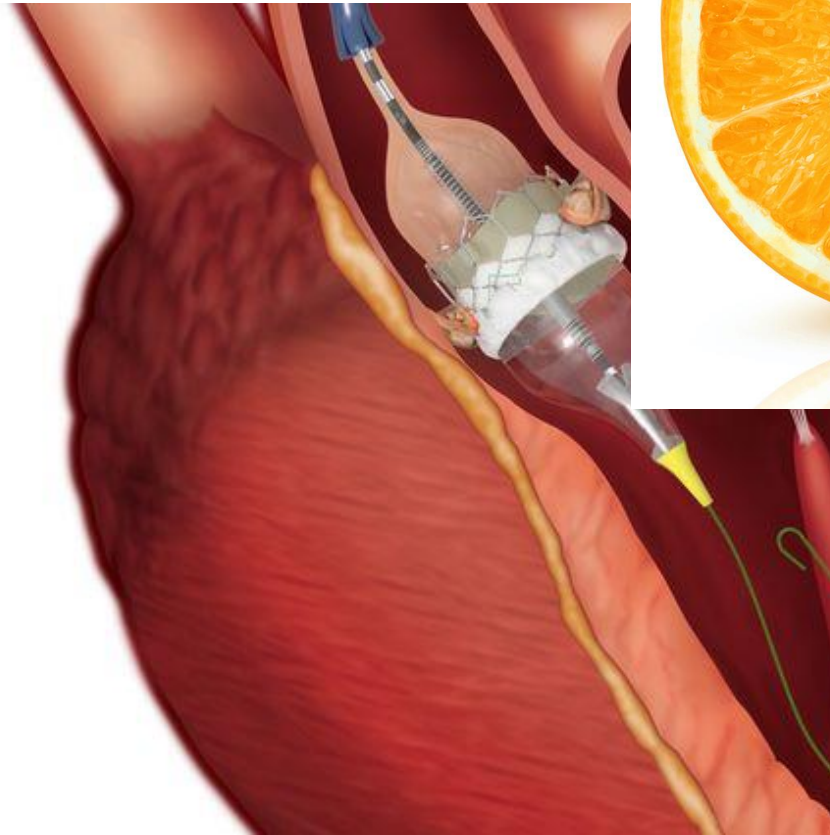
mitral valve annuloplasty

no mitral valve annuloplasty

Patient's not offered treatment



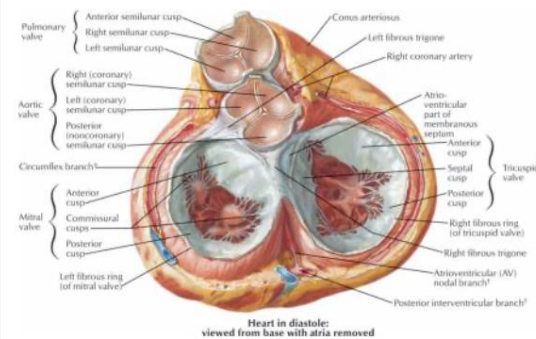




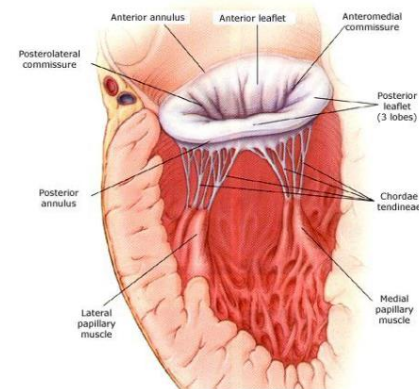
Why is mitral valve interventions not similar to aortic valve interventions?

Complex Anatomy

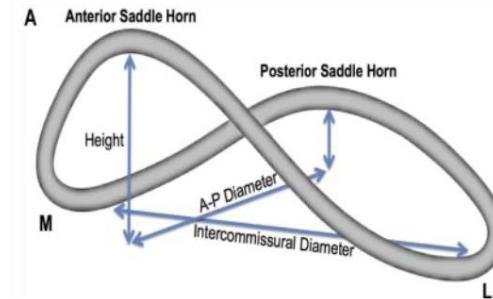
Anatomic relations with the aortic valve, conduction system, the circumflex artery, the coronary sinus



Frequently more than one component of the complex is affected in MR



The annulus is noncircular, saddle-shaped and highly dynamic



Frame Deformation ∨



Non-clinical case
not intended for medical use



∨ neo-LVOT Area

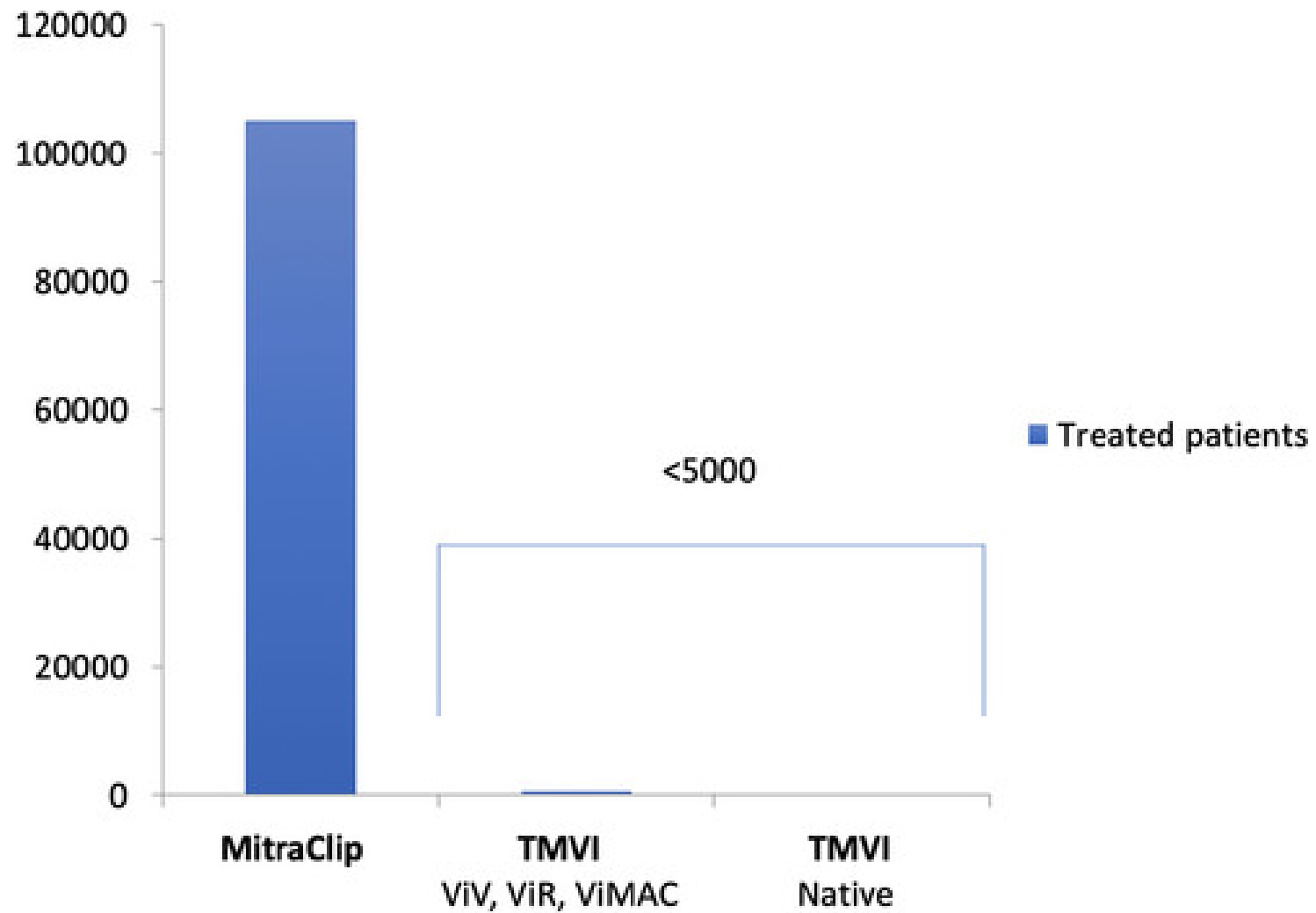
452.7mm²



CRAN: 0°
LAO: 0°

Mitral valve interventions

- Transcatheter edge to edge repair (TEER)
- Transcatheter mitral valve replacement – (TMVR)
 - Mitral valve in valve for degenerate surgical bioprosthesis
 - Mitral valve in ring
 - Mitral valve in mitral annular calcium
 - Mitral valve replacement – native mitral valve - trials in progress
- Percutaneous mitral balloon valvotomy – mitral stenosis patients
- Direct and indirect annuoplasty devices



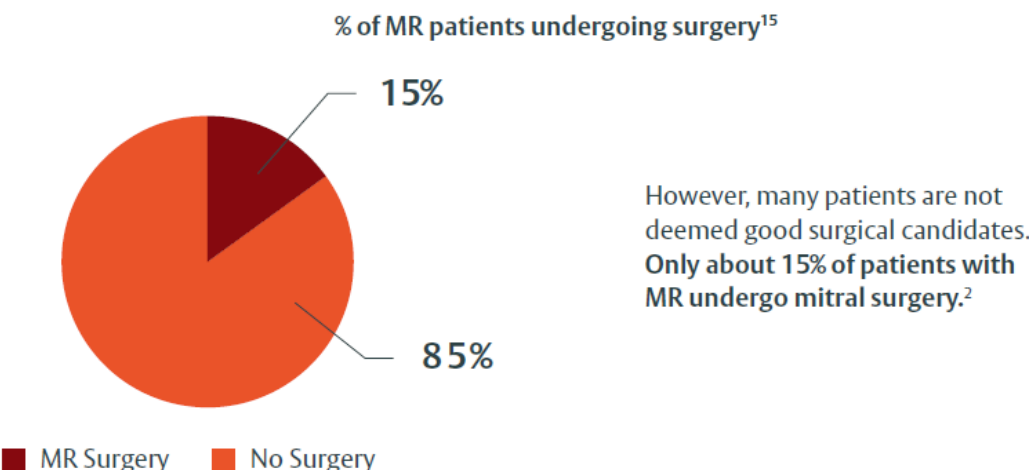
Treatment options for MR patients are limited

Treatment options for MR patients depend on the type of MR and patient condition

Degenerative mitral regurgitation (DMR)

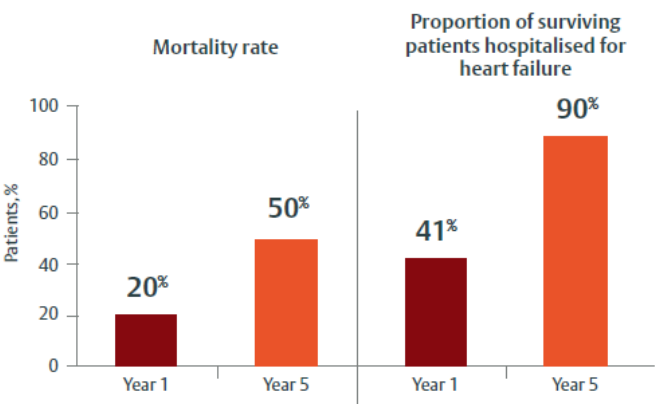
Treatment options include watchful waiting, mitral valve surgery, and transcatheter mitral valve repair.

Mitral valve surgery is invasive and traditionally performed through a full median sternotomy, which requires extracorporeal circulation.



Functional mitral regurgitation (FMR)

Treatment options include use of guideline-directed medical therapy (GDMT), cardiac resynchronisation therapy, mitral valve surgery, and transcatheter mitral valve repair. However, mitral valve surgery for FMR patients is not supported by current physician society guidelines since it does not prevent progression of disease.



Medically managed patients with severe MR have poor outcomes

The use of GDMT for the treatment of FMR is focused on symptom relief from LV dysfunction, but not the disease progression.¹⁵

Medically managed patients with severe secondary MR have poor outcomes with high rates of heart failure hospitalisation¹⁵

MR is common and increases with age

Mitral regurgitation is the most common clinically significant heart valve disease ^{5,6}



~2%
of the population
has MR

Up to 10% of people over 75 years old have MR and disease progression commonly leads to more severe, symptomatic MR.⁶

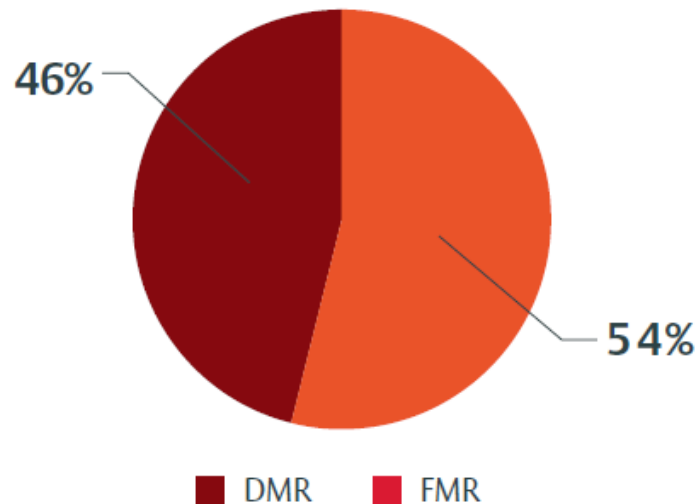


~200,000
of people in Australia

5000 people in
Tasmania!!!

In Australia, approximately 200,000 people have moderate or severe MR*

FMR / DMR



The prevalence of **degenerative or primary MR** is likely underestimated because these patients initially experience a prolonged asymptomatic period; primary MR of mild severity therefore may remain undetected.

Functional or secondary MR is highly prevalent in patients with left ventricular systolic dysfunction and heart failure. In a study of 1,331 patients with myocardial infarction, ischemic MR was observed in 50% of patients.⁹

Patients with MR have worse quality of life than others of similar age

SF-36 physical component scores



18%

lower than normal

population ≥ 75 years

(MR: 32.0 vs Normal: 39.99) ¹⁴

SF-36 mental component scores



8%

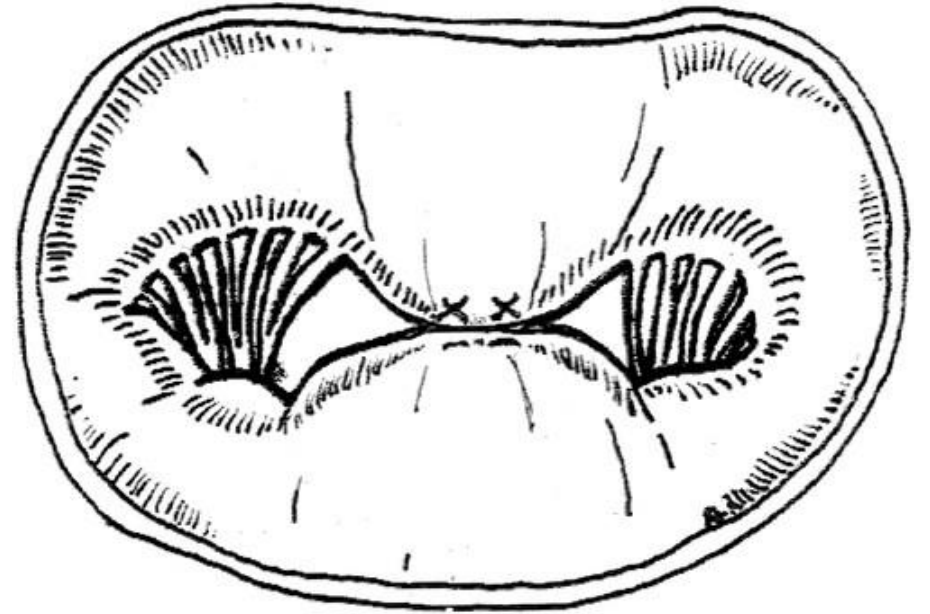
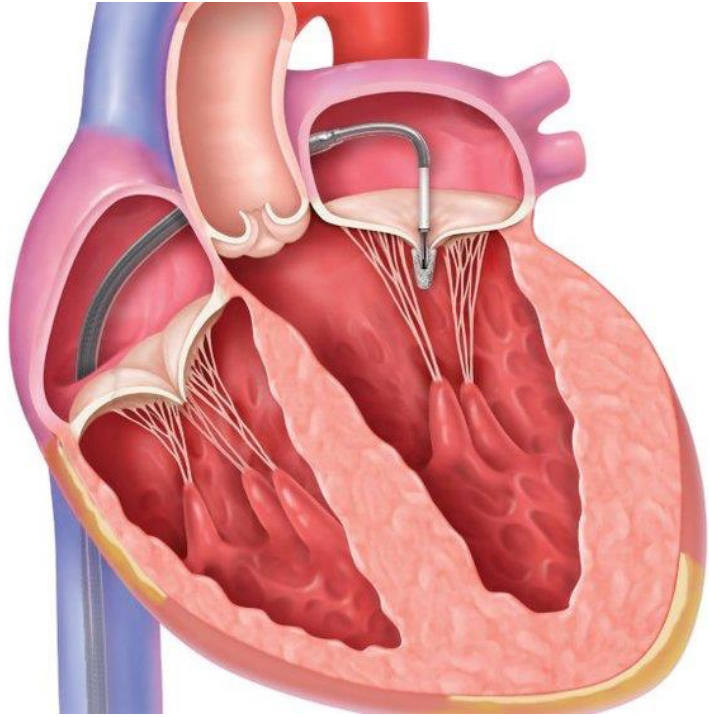
lower than normal

population ≥ 75 years

(MR: 46.1 vs Normal: 50.2) ¹⁴

MR has a significant impact on quality of life in patients with heart failure, quality of life is independently related to survival.¹⁴

In a study of TMVr, primary MR patients at baseline were found to have to have **SF-36 scores (physical and mental components) well below the norm** for age-adjusted US population, 75 years and older.¹⁴



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Percutaneous Repair or Surgery for Mitral Regurgitation

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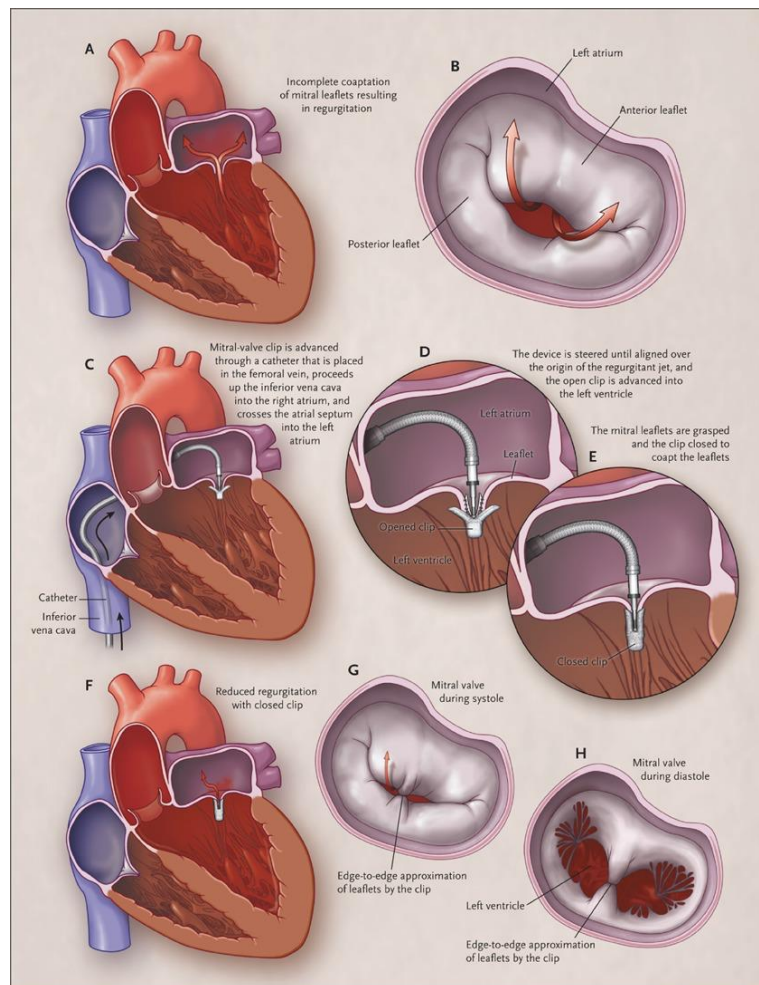


Table 2. Primary Efficacy End Point at 12 Months and Major Adverse Events at 30 Days in the Intention-to-Treat Population.*			
Event	Percutaneous Repair no. (%)	Surgery	P Value
Primary efficacy end point			
Freedom from death, from surgery for mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation†	100 (55)	65 (73)	0.007
Death	11 (6)	5 (6)	1.00
Surgery for mitral-valve dysfunction‡	37 (20)	2 (2)	<0.001
Grade 3+ or 4+ mitral regurgitation	38 (21)	18 (20)	1.00
Major adverse event at 30 days§			
Any major adverse event	27 (15)	45 (48)	<0.001¶
Any major adverse event excluding transfusion	9 (5)	9 (10)	0.23
Death	2 (1)	2 (2)	0.89
Myocardial infarction	0	0	NA
Reoperation for failed surgical repair or replacement	0	1 (1)	0.74
Urgent or emergency cardiovascular surgery for adverse event	4 (2)	4 (4)	0.57
Major stroke	2 (1)¶	2 (2)	0.89
Renal failure	1 (<1)	0	1.00
Deep wound infection	0	0	NA
Mechanical ventilation for >48 hr	0	4 (4)	0.02
Gastrointestinal complication requiring surgery	2 (1)	0	0.78
New onset of permanent atrial fibrillation	2 (1)	0	0.78
Septicemia	0	0	NA
Transfusion of ≥2 units of blood	24 (13)	42 (45)	<0.001

* The 12-month efficacy analysis included 181 patients in the percutaneous-repair group and 89 patients in the surgery group. The 30-day safety analysis included 180 patients in the percutaneous-repair group and 94 in the surgery group (for details, see Fig. 1). NA denotes not applicable.

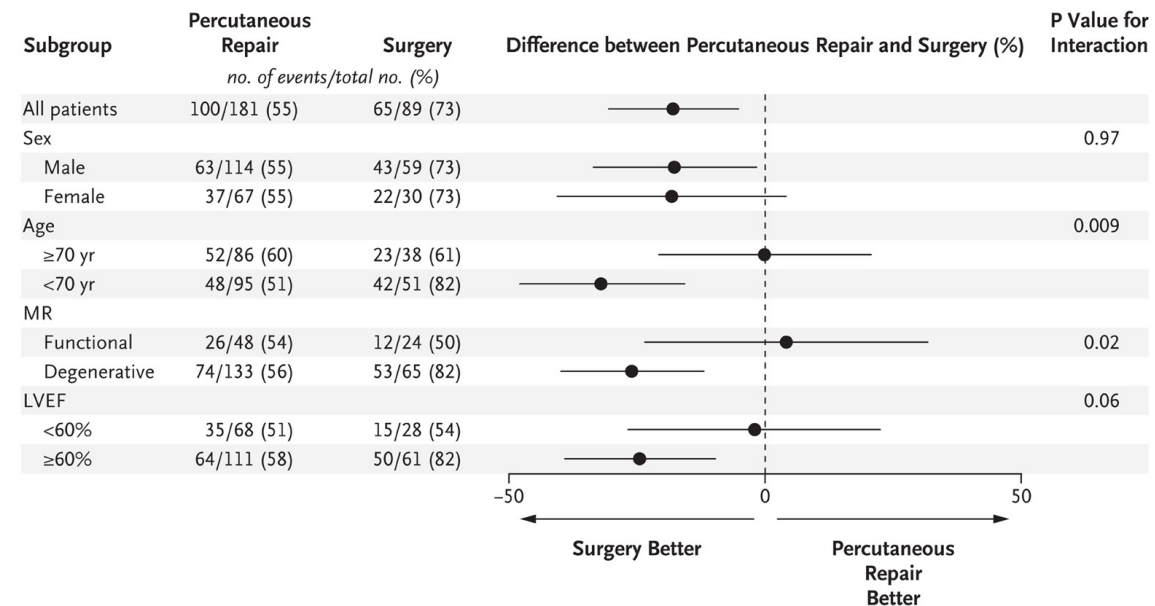
† Rates of the components of the composite primary end point do not total the rates of the composite because patients could have more than one event.

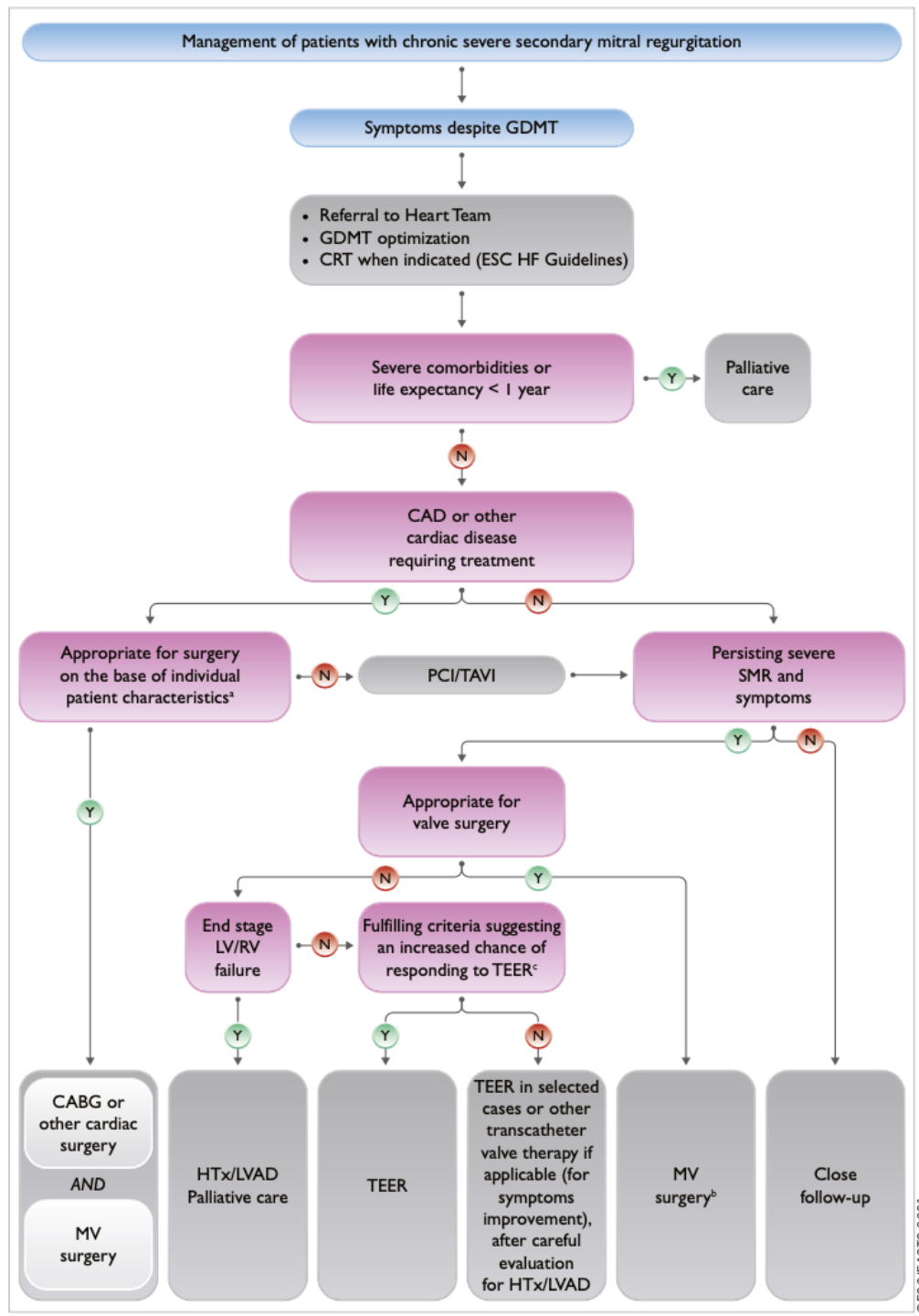
‡ This component is the rate of the first mitral-valve surgery in the percutaneous-repair group and the rate of reoperation for mitral-valve dysfunction in the surgery group.

§ Patients could have more than one adverse event at 30 days.

¶ This P value was calculated to test for the increased superiority of percutaneous repair, as compared with surgery, by a prespecified safety margin of ~2%.

| One stroke occurred in a patient who underwent randomization but was not treated.





Recommendations on indications for intervention in severe primary mitral regurgitation

Recommendations	Class ^a	Level ^b
Mitral valve repair is the recommended surgical technique when the results are expected to be durable. ²⁹³⁻²⁹⁶	I	B
Surgery is recommended in symptomatic patients who are operable and not high risk. ²⁹³⁻²⁹⁶	I	B
Surgery is recommended in asymptomatic patients with LV dysfunction (LVESD ≥ 40 mm and/or LVEF $\leq 60\%$). ^{277,286,292}	I	B
Surgery should be considered in asymptomatic patients with preserved LV function (LVESD < 40 mm and LVEF $> 60\%$) and AF secondary to mitral regurgitation or pulmonary hypertensionc (SPAP at rest > 50 mmHg). ^{285,289}	IIa	B
Surgical mitral valve repair should be considered in low-risk asymptomatic patients with LVEF $> 60\%$, LVESD < 40 mm and significant LA dilatation (volume index ≥ 60 mL/m ² or diameter ≥ 55 mm) when performed in a Heart Valve Centre and a durable repair is likely. ^{285,288}	IIa	B
TEER may be considered in symptomatic patients who fulfil the echocardiographic criteria of eligibility, are judged inoperable or at high surgical risk by the Heart Team and for whom the procedure is not considered futile. ²⁹⁹⁻³⁰²	IIb	B

Mitral edge to edge repair secondary MR

MITRA-FR compared to COAPT	MITRA-FR (304 pts at 37 centers)	COAPT (610 pts at 89 centers)
Technical implantation success	96%	98%
EROA (mean $\pm$ SD)	31 $\pm$ 10 mm ²	41 $\pm$ 15 mm ²
LVEDV (mean $\pm$ SD)	135 $\pm$ 35 mL/m ²	101 $\pm$ 34 mL/m ²
GDMT at baseline and FU	variable adjustment in each group per "real-world" practice	GDMT at baseline, few major changes during FU
Different primary endpoints	54.6%/51.3% p = NS at 12 months	151 of 283/92 of 160 at 24 months p < 0.001
Mortality at 1 year	~23% p = NS	28% compared to 22% p < 0.001
MR $\geq$ 2 at BS $\rightarrow$ 12 months $\rightarrow$ >24 months	8% $\rightarrow$ 17% $\rightarrow$?	7.4% $\rightarrow$ 5.3% $\rightarrow$ 0.9%

EROA – effective regurgitant orifice area; SD – standard deviation; BS – baseline; LVEDV – left ventricle end-diastolic volume; GDMT – guideline-directed medical therapy; FU – follow-up; NS – non-significant; COAPT – Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for Extremely High Surgical Risk Patients; MITRA-FR – Multicentre Randomized Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation.

Recommendations on indications for mitral valve intervention in chronic severe secondary mitral regurgitation^a

Recommendations	Class ^b	Level ^c
Valve surgery/intervention is recommended only in patients with severe SMR who remain symptomatic despite GDMT (including CRT if indicated) and has to be decided by a structured collaborative Heart Team. ^{247,323,336,337}	I	B
Patients with concomitant coronary artery or other cardiac disease requiring treatment		
Valve surgery is recommended in patients undergoing CABG or other cardiac surgery. ^{329,330,333}	I	B
In symptomatic patients, who are judged not appropriate for surgery by the Heart Team on the basis of their individual characteristics, ^d PCI (and/or TAVI) possibly followed by TEER (in case of persisting severe SMR) should be considered.	IIa	C
Patients without concomitant coronary artery or other cardiac disease requiring treatment		
TEER should be considered in selected symptomatic patients, not eligible for surgery and fulfilling criteria suggesting an increased chance of responding to the treatment. ^{337,338,356,357 e}	IIa	B
Valve surgery may be considered in symptomatic patients judged appropriate for surgery by the Heart Team.	IIb	C
In high-risk symptomatic patients not eligible for surgery and not fulfilling the criteria suggesting an increased chance of responding to TEER, the Heart Team may consider in selected cases a TEER procedure or other transcatheter valve therapy if applicable, after careful evaluation for ventricular assist device or heart transplant. ^e	IIb	C

Operator and Institutional Requirements for Transcatheter Mitral Valve Therapies in Australia: a CSANZ and ANZSCTS Position Statement

David W.M. Muller, MBBS, MD ^{a,*}, Aubrey Almeida, MBBS ^b, Anthony Camuglia, MBBS ^c, Darren Walters, MBBS, MPhil ^d, Jurgen Passage, MBBS ^e, Gregory M. Scalia, MBBS, M Med Sci ^f, Ravi Bhindi, MBBS, PhD ^g, Sidney Lo, MBBS ^h, Jayme Bennetts, MBBS ⁱ, Antony Walton, MBBS ^j, On behalf of Cardiac Society of Australia and New Zealand (CSANZ) and Australia and New Zealand Society of Cardiac and Thoracic Surgery (ANZSCTS)

Table 1 Key individual, institutional, and program requirements for TMVT accreditation of new operators and TMVT hospitals.

Operator	Institution	Program
≥300 career PCIs	≥1,000 caths/year and ≥300 PCIs/year	Multidisciplinary heart team with auditable meeting minutes
≥50 structural heart disease interventions AND ≥20 transseptal procedures	≥50 open heart surgical procedures/year including ≥30 mitral valve operations/year	TMVT co-ordinator and database manager
≥20 TMVT procedures during past 2 yrs	At least 2 on-site cardiac surgeons and appropriate operating room staff	TMVT database with facility to export data to TMVT National Registry
CT Surgeon: ≥20 MV surgeries/yr (50% repairs)	On-site vascular surgery with ≥30 endovascular procedures/year	
≥10 proctored device-specific TMVT cases	Anticipated annual TMVT volume ≥20 cases	
Anticipated annual TMVT volume ≥20 cases	Cath lab/hybrid lab with appropriate resources for TMVT Expertise in TMVT imaging including TTE, TOE and cardiac CT imaging Cardiac anaesthesia support Postoperative ICU/HDU/CCU support Electrophysiology/pacing support	

Abbreviations: CCU, coronary care unit; HDU, high dependency unit; ICU, intensive care unit; MV, mitral valve; PCI, percutaneous coronary intervention; TMVT, transcatheter mitral valve therapies; TOE, transoesophageal echocardiogram; TTE, transthoracic echocardiogram.

Summary – Simplistic/practical TEER screening approach

Better



Worse

Where

Single jet
Central

Multiple jets
Non-central

What

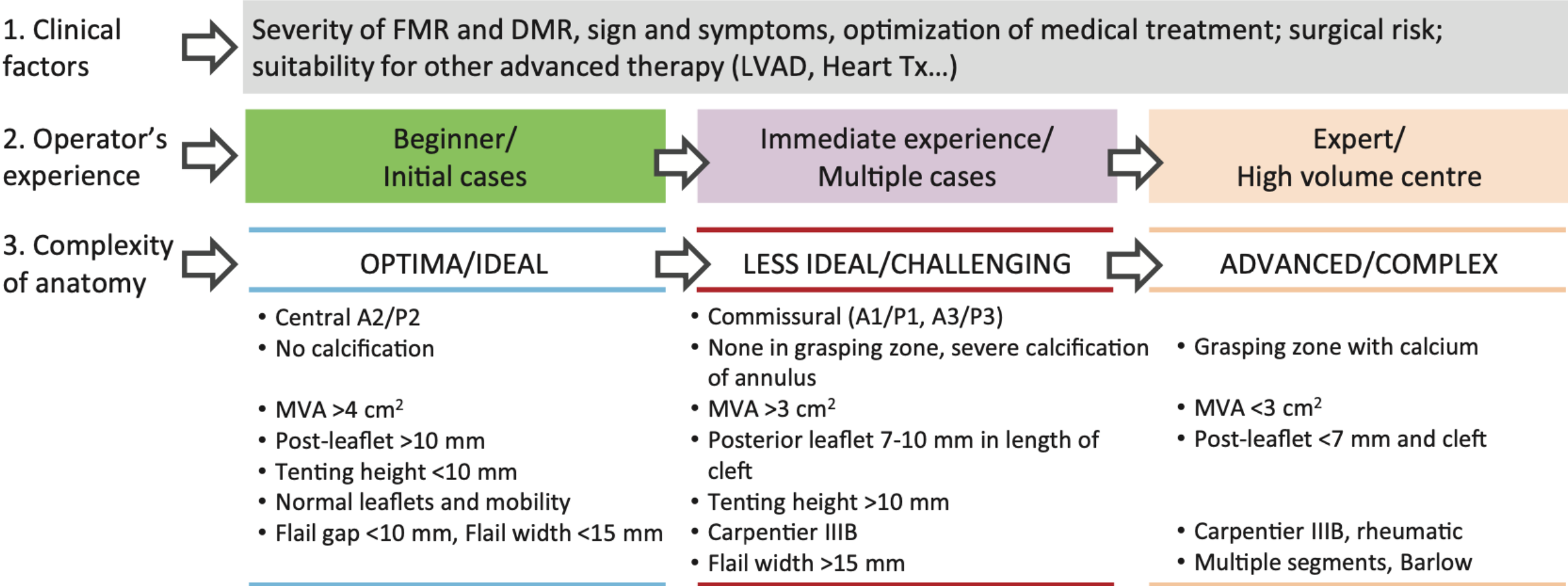
Long leaflets
No tethering
Focal prolapse/flail
No calcification
MVA >4cm²

Short free leaflet
Severe tethering
Extensive prolapse/flail
Calcification (especially edge)
MVA <4cm²

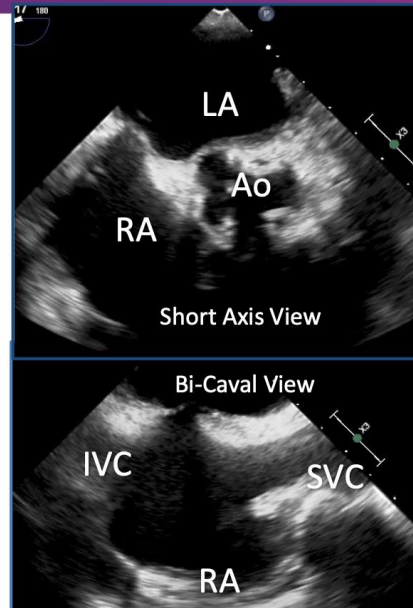
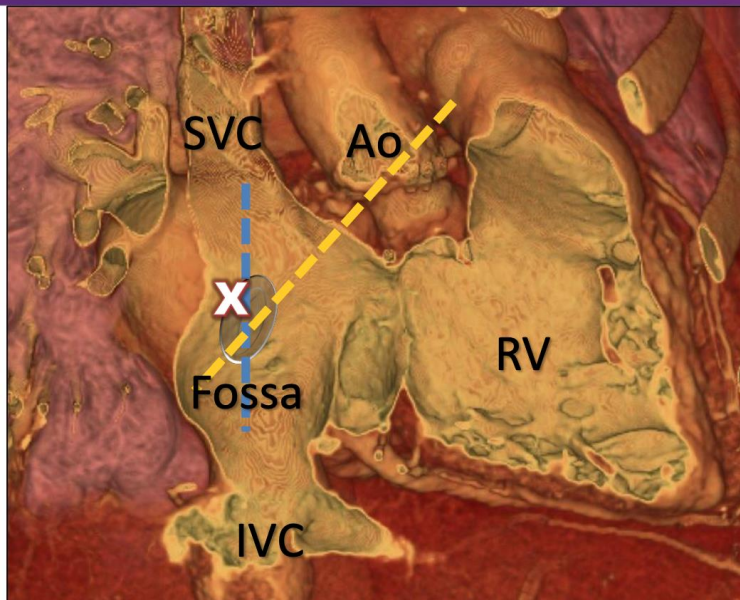
Fossa

Fossa height >4cm
Fossa directly above mitral

Fossa height <4cm
Fossa anteriorly displaced



TEE and Anatomy

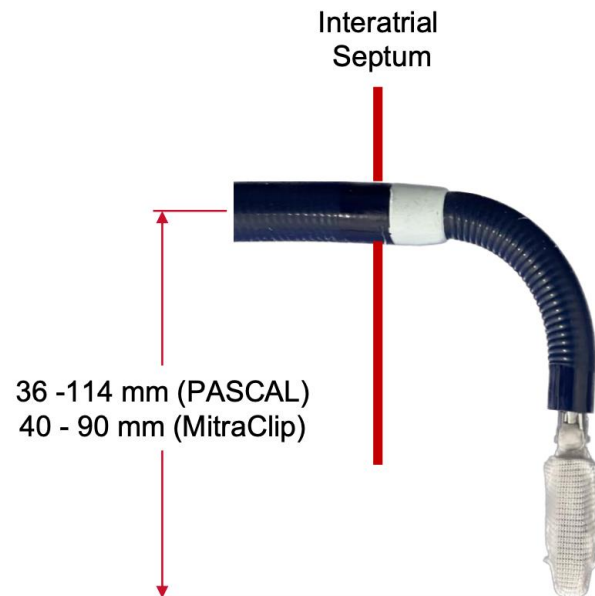


Transseptal puncture: equipment

- Transseptal kit
 - BRK XS needle + SL0 8,5F sheath + 0.032" wire (Abbott)
 - or similar kit (Mullins etc)
 - Special kit: Baylis NRG RF kit (Boston)
- TEE guidance
 - Bicaval view bi-plane
- Fluoro view AP

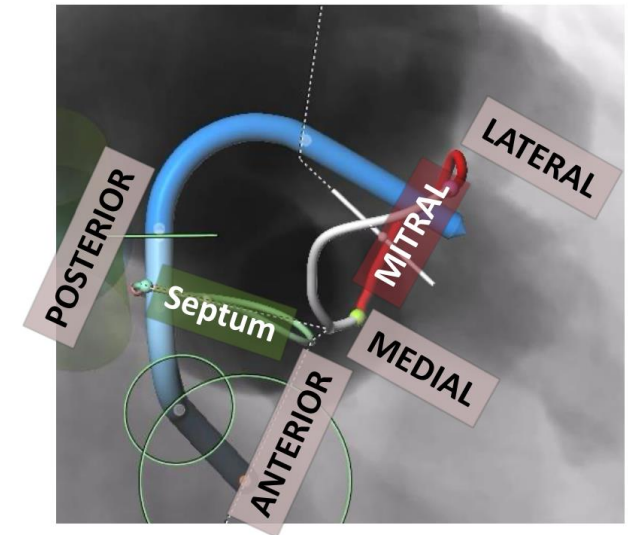
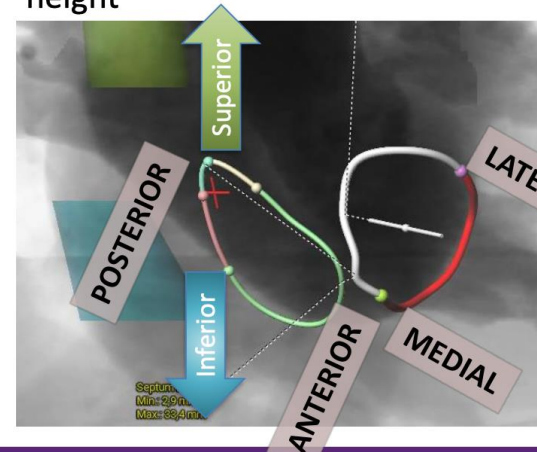


Why is 4 cm height needed?



Transseptal puncture: where

- Safe puncture ≥ 4 cm from mitral annulus
 - Less strict for lateral target or functional MR
- Posterior (most important), superior-mid height



The PASCAL transcatheter valve repair system is designed for effective MR reduction



PASCAL transcatheter valve repair system

The PASCAL system allows TMVr by using clasps, paddles, and a spacer. The clasps and paddles gently grasp leaflets to facilitate coaptation, while the spacer is intended to fill the regurgitant orifice area and prevent backflow, thereby reducing MR. ²

- **PASCAL repair system**

Independent and spontaneous leaflet capture

Broad paddles maximise leaflet coaptation

Central spacer fills the regurgitant orifice area without overt reduction

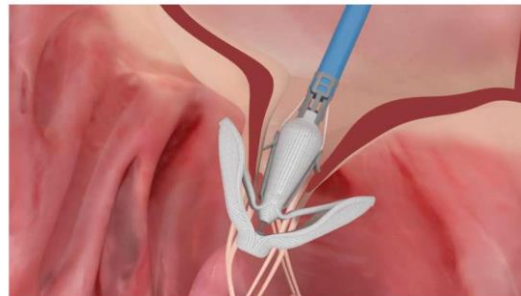
in orifice area, particularly for the second implant

- **A safe and effective treatment option for DMR, FMR and mixed aetiology**

Designed for
effective MR reduction¹

Enables optimised leaflet capture

Helps promote
procedural safety



Key Innovations

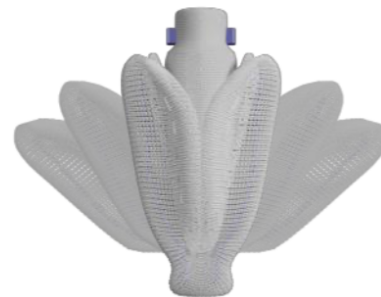
Optimised leaflet capture

- Empowering delivery system with direct manoeuvring in three planes
- Independent leaflet capture



Designed for effective MR reduction

- Broad paddles maximise leaflet coaptation
- Central spacer fills the regurgitant orifice area



Excellent safety profile

- Spacer and contoured paddles design reduce stress on leaflets
- Implant elongation helps promote safe subvalvular manoeuvring

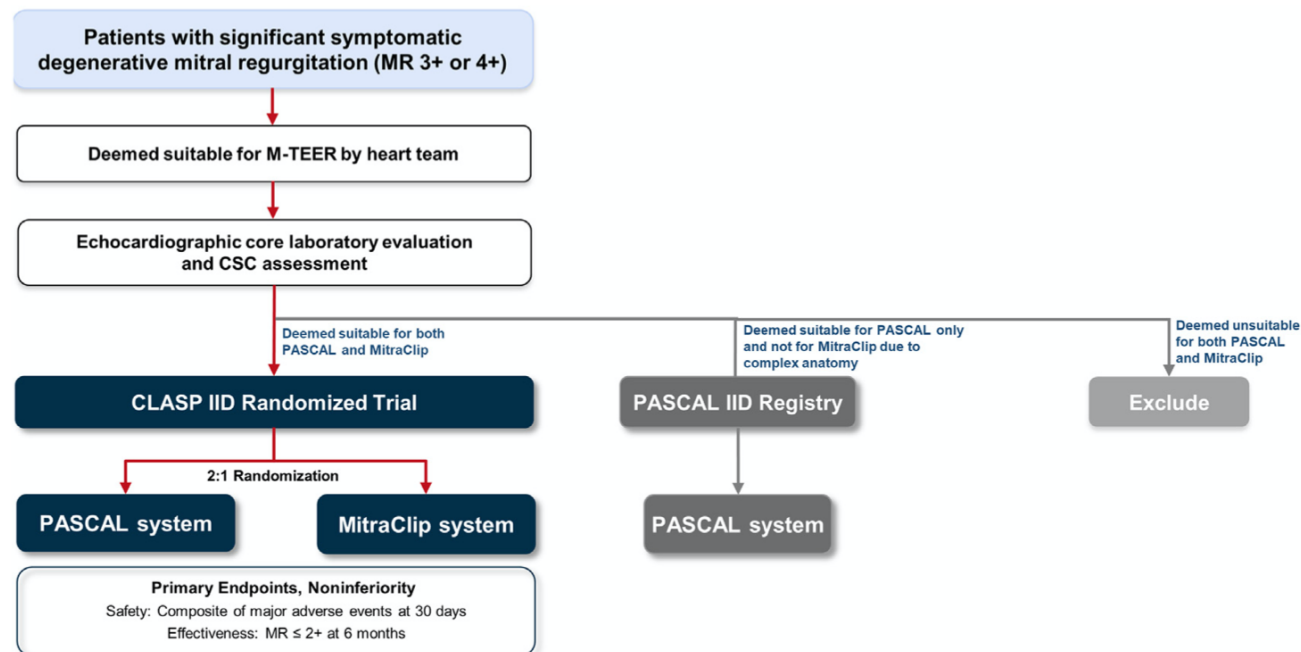


Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients



D. Scott Lim, MD,^a Robert L. Smith, MD,^b Linda D. Gillam, MD, MPH,^c Firas Zahr, MD,^d Scott Chadderdon, MD,^d Raj Makkar, MD,^e Ralph Stephan von Bardeleben, MD, PhD,^f Robert M. Kipperman, MD,^c Andrew N. Rassi, MD,^g Molly Szerlip, MD,^b Scott Goldman, MD,^h Ignacio Inglessis-Azuaje, MD,ⁱ Pradeep Yadav, MD,^j Philipp Lurz, MD, PhD,^k Charles J. Davidson, MD,^l Mubashir Mumtaz, MD,^m Hemal Gada, MD,^m Saibal Kar, MD,ⁿ Susheel K. Kodali, MD,^o Roger Laham, MD,^p William Hiesinger, MD,^q Neil P. Fam, MD,^r Mirjam Kessler, MD,^s William W. O'Neill, MD,^t Brian Whisenant, MD,^u Chad Kliger, MD,^v Samir Kapadia, MD,^w Volker Rudolph, MD,^x Joseph Choo, MD,^y James Hermiller, MD,^z Michael A. Morse, MD,^{aa} Niklas Schofer, MD,^{bb} Sameer Gafoor, MD,^{cc} Azeem Latib, MD,^{dd} Konstantinos Koulogiannis, MD,^c Leo Marcoff, MD,^c Jörg Hausleiter, MD,^{ee}
on behalf of CLASP IID Pivotal Trial Investigators

FIGURE 1 The CLASP IID Trial Design



Flowchart illustrating the trial design. CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial; CSC = central screening committee; MR = mitral regurgitation; M-TEER = mitral valve transcatheter edge-to-edge repair.

TABLE 1 Baseline Characteristics			
	PASCAL (n = 117)	MitraClip (n = 63)	P Value
Demographics			
Age, y	81.1 ± 6.9 (117)	81.2 ± 6.2 (63)	0.926
Male	78/117 (66.7)	43/63 (68.3)	0.869
Body mass index, kg/m ²	25.9 ± 5.4 (117)	26.2 ± 4.8 (63)	0.499
STS score for mitral valve repair, %	4.1 ± 2.8 (117)	3.6 ± 2.2 (63)	0.476
STS score for mitral valve replacement, %	5.7 ± 3.3 (117)	5.1 ± 2.6 (63)	0.437
EuroSCORE II, %	3.9 ± 2.9 (117)	4.1 ± 3.1 (63)	0.736
NYHA functional class III/IV	71/117 (60.7)	39/63 (61.9)	1.000
Medical history/comorbidities			
Atrial fibrillation	67/117 (57.3)	38/63 (60.3)	0.752
Cardiomyopathy	16/117 (13.7)	11/63 (17.5)	0.517
Coronary artery disease (≥50% stenosis)	46/117 (39.3)	25/63 (39.7)	1.000
Renal insufficiency ^a (eGFR < 60 ml/min)	35/117 (29.9)	24/63 (38.1)	0.318
Diabetes	19/117 (16.2)	15/63 (23.8)	0.235
Hypertension	98/117 (83.8)	57/63 (90.5)	0.263
Hyperlipidemia	87/117 (74.4)	39/63 (61.9)	0.090
Myocardial infarction	19/117 (16.2)	7/63 (11.1)	0.385
Peripheral arterial disease	3/117 (2.6)	2/63 (3.2)	1.000
Anemia (chronic, Hb ≤ 9 g/dL)	7/117 (6.0)	5/63 (7.9)	0.755
Stroke	9/117 (7.7)	1/63 (1.6)	0.169
TIA	10/117 (8.5)	3/63 (4.8)	0.547
COPD	20/117 (17.1)	12/63 (19.0)	0.838
Pacemaker/ICD	7/117 (6.0)	9/63 (14.3)	0.096
PCI	27/117 (23.1)	14/63 (22.2)	1.000
Coronary artery bypass graft	15/117 (12.8)	6/63 (9.5)	0.630
Gastrointestinal or esophageal bleeding	10/117 (8.5)	7/63 (11.1)	0.600
Pulmonary hypertension ^b	53/117 (45.3)	30/63 (47.6)	0.876
Home oxygen use	6/117 (5.1)	3/63 (4.8)	1.000
Hospitalizations for heart failure (≥1 in past 12 mo)	40/117 (34.2)	25/63 (39.7)	0.516
Aortic valve surgery/intervention	14/117 (12.0)	2/63 (3.2)	0.056
Tricuspid valve surgery/intervention	0/117 (0.0)	1/63 (1.6)	0.350

TABLE 1 Baseline Characteristics

	PASCAL (n = 117)	MitraClip (n = 63)	P Value
Echocardiographic measures			
Degenerative mitral regurgitation etiology	117/117 (100)	63/63 (100)	—
MR 3+ ^c	29/115 (25.2)	13/63 (20.6)	0.581
MR 4+ ^c	86/115 (74.8)	50/63 (79.4)	0.581
Effective regurgitant orifice area, cm ²	0.50 ± 0.15 (80)	0.50 ± 0.20 (49)	0.857
Left ventricular end-systolic dimension, mm	38.3 ± 7.7 (116)	39.8 ± 7.8 (62)	0.215
Left ventricular end-diastolic dimension, mm	57.1 ± 6.5 (117)	57.4 ± 6.5 (63)	0.889
Left ventricular end-systolic volume, mL	59.5 ± 28.8 (113)	63.7 ± 27.4 (63)	0.195
Left ventricular end-diastolic volume, mL	143.3 ± 48.6 (113)	149.9 ± 44.8 (63)	0.180
Left ventricular ejection fraction, %	59.6 ± 8.7 (117)	58.3 ± 9.0 (63)	0.346
Transmitral mean gradient, mm Hg	2.5 ± 1.1 (113)	2.4 ± 1.1 (59)	0.400
Pulmonary artery systolic pressure, mm Hg	42.3 ± 11.4 (99)	45.6 ± 14.6 (51)	0.225
TAPSE, mm	20.6 ± 5.4 (86)	21.0 ± 5.6 (47)	0.875
Left atrial volume, cm ³	116.3 ± 37.6 (116)	121.3 ± 45.8 (63)	0.859
TR 3+ ^d	3/116 (2.6)	3/63 (4.8)	0.426
Mitral valve area, cm ²	6.1 ± 1.4 (90)	6.0 ± 1.6 (50)	0.556

FIGURE 2 Patient Disposition and Flow for the CLASP IID Randomized Trial

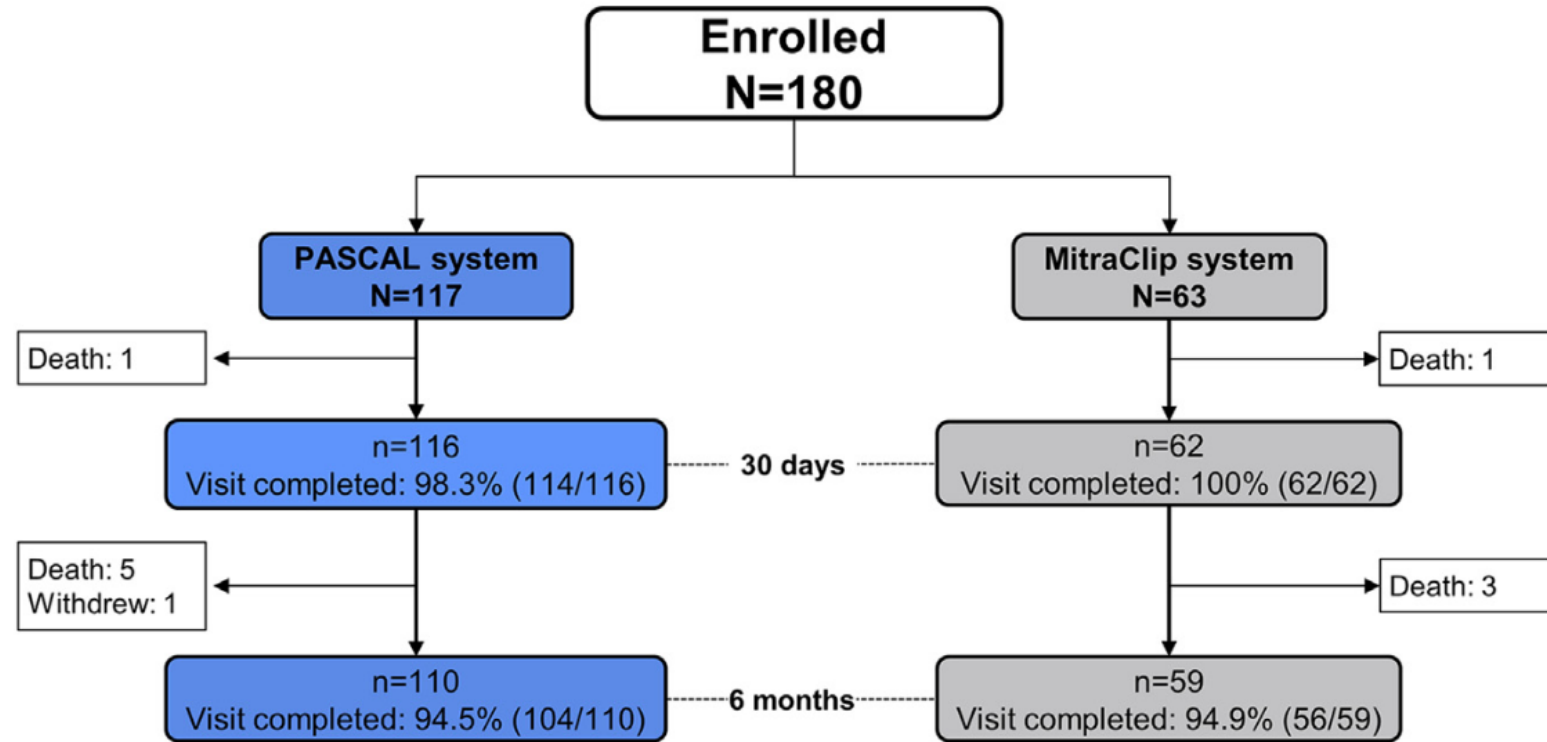
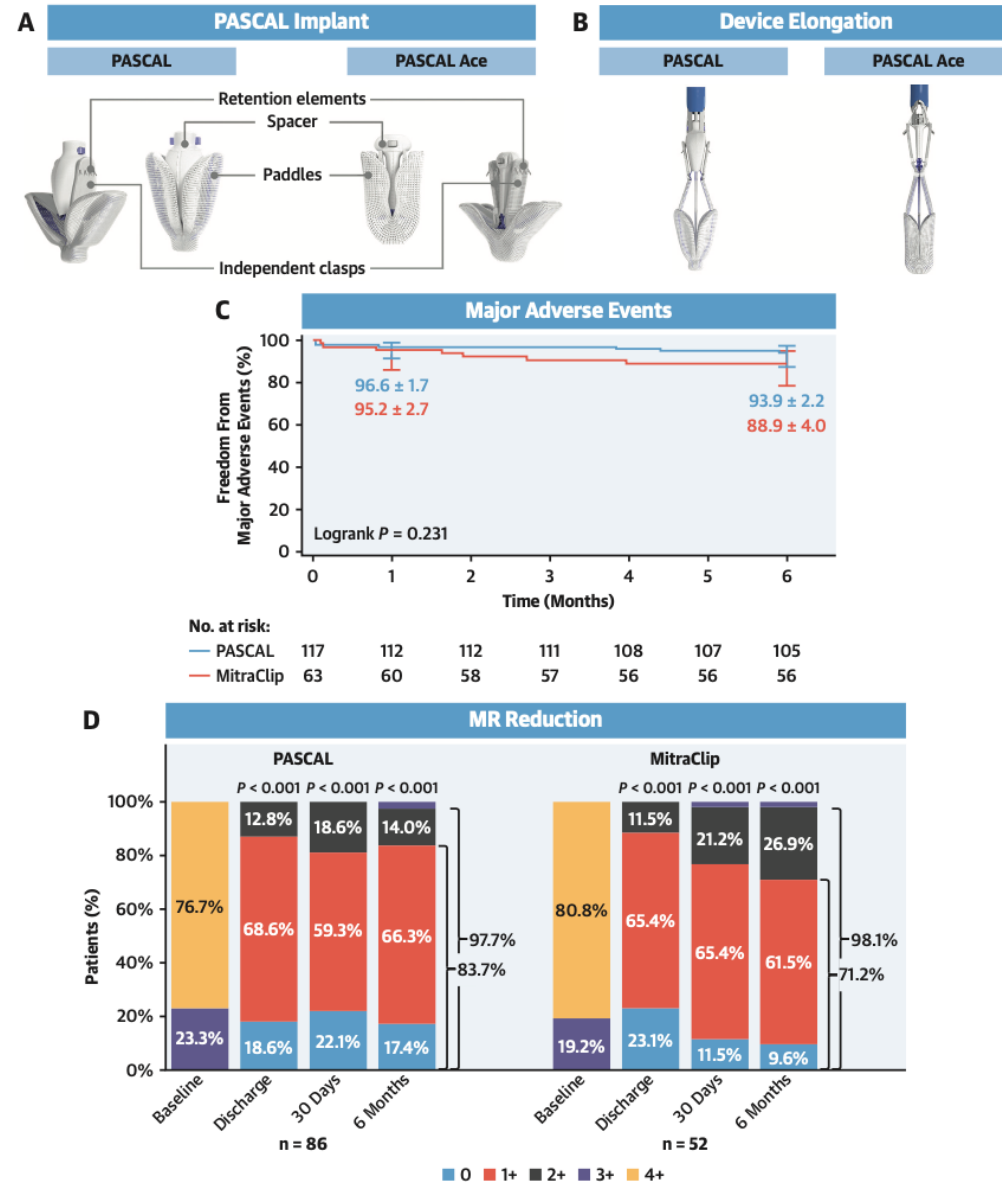


Illustration of patient enrollment, randomization, and follow-up, with visit windows of 30 ± 7 days and $6 \text{ months} \pm 30$ days. For follow-up visits affected by the COVID-19 pandemic, the visit windows were adjusted to $30 \text{ days} -7/+14$ days and $6 \text{ months} -30/+90$ days. CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial.

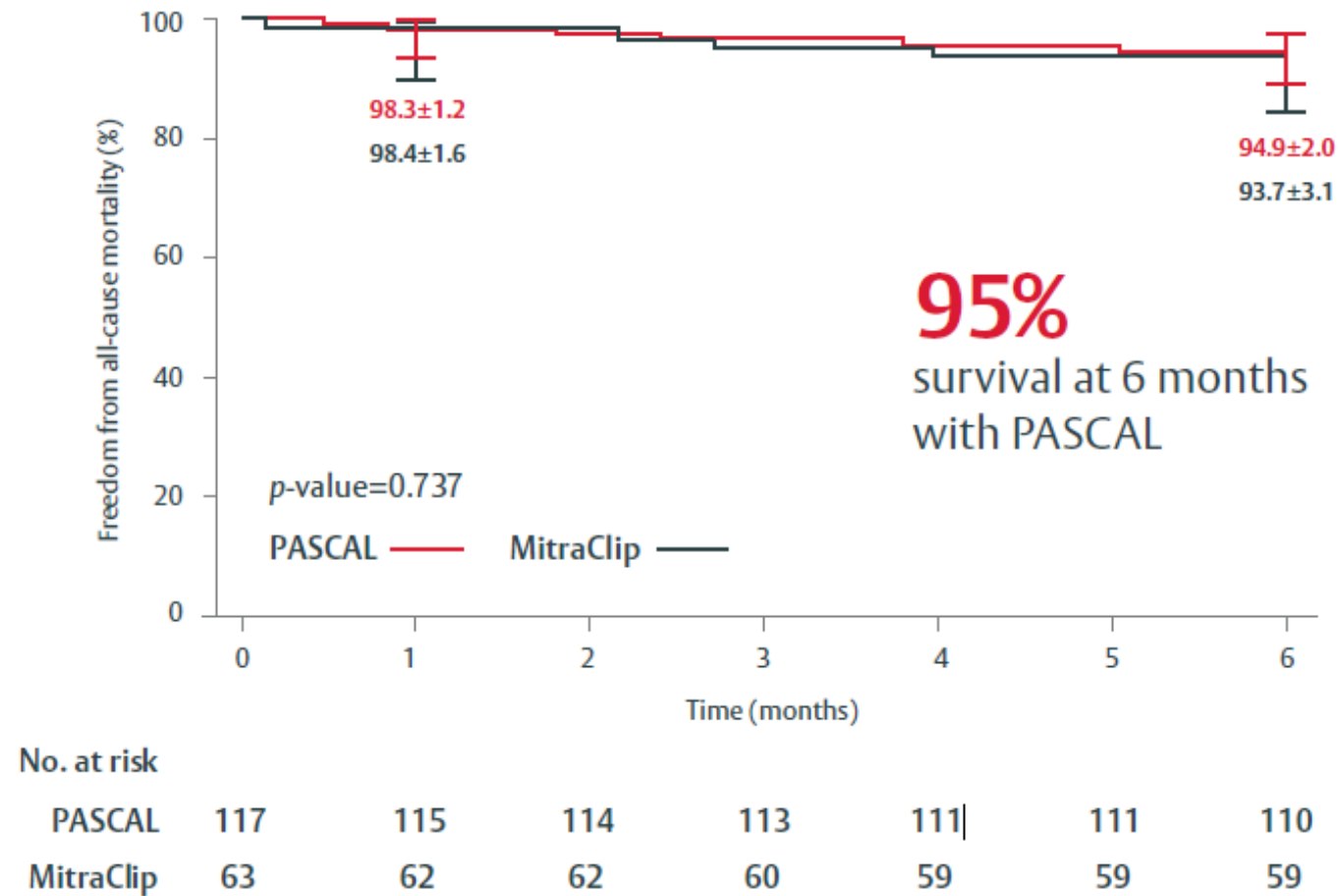


Lim DS, et al. J Am Coll Cardiol Interv. 2022;15(24):2523-2536.

(A) PASCAL implant design. (B) Elongation feature of the PASCAL implant. (C) Kaplan-Meier estimates for freedom from major adverse events (MAE) (Kaplan-Meier estimate ± SE). Error bars represent 95% CI. MAE include cardiovascular mortality, stroke, myocardial infarction, need for new renal replacement therapy, severe bleeding, and nonelective mitral valve reintervention (either percutaneous or surgical). (D) Mitral regurgitation severity assessed by echocardiography core laboratory using transthoracic echocardiography. The graph shows paired analysis, and P values were calculated using the Wilcoxon signed rank test. CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial.

Patient outcomes at 6 months

Survival



Kaplan-Meier analysis of estimated time to first event $\pm$ SE.

PASCAL clinical evidence

CLASP IID overview

The CLASP IID trial is the first randomised study to directly compare transcatheter edge-to-edge repair (TEER) outcomes between the PASCAL system and the MitraClip system for prohibitive surgical risk patients with significant symptomatic degenerative MR. The trial also included a Registry arm for patients who were non-randomisable in the CLASP IID trial.

The trial demonstrated safety and effectiveness of the PASCAL system and met non-inferiority endpoints. The PASCAL system demonstrated a high rate of implantation success with low complication rates at 30 days and a sustained MR reduction of $MR \leq 2+$ at 6 months. Patients also experienced significant improvements in functional status and quality of life. ²⁰

The CLASP IID trial demonstrates the PASCAL system is safe and effective for patients who have significant symptomatic DMR.

3%

major adverse event
rate* at 30 days

98%

of patients had sustained MR
reduction of $MR \leq 2+$ at 6 months

*Defined as the composite of cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding, and nonelective mitral valve reintervention.

Patient outcomes at 6 months

Clinically and statistically significant improvements

HIGH SURVIVAL RATE



95%
Survival

LOW RATE OF HF-RELATED REHOSPITALISATION



98%
Freedom from HF-related
rehospitalisation

SUSTAINED MR REDUCTION



98%*
of patients achieved
MR grade $\leq 2+$

84%*
of patients achieved
MR grade $\leq 1+$

SIGNIFICANT FUNCTIONAL IMPROVEMENTS IN NYHA CLASS AND KCCQ SCORE



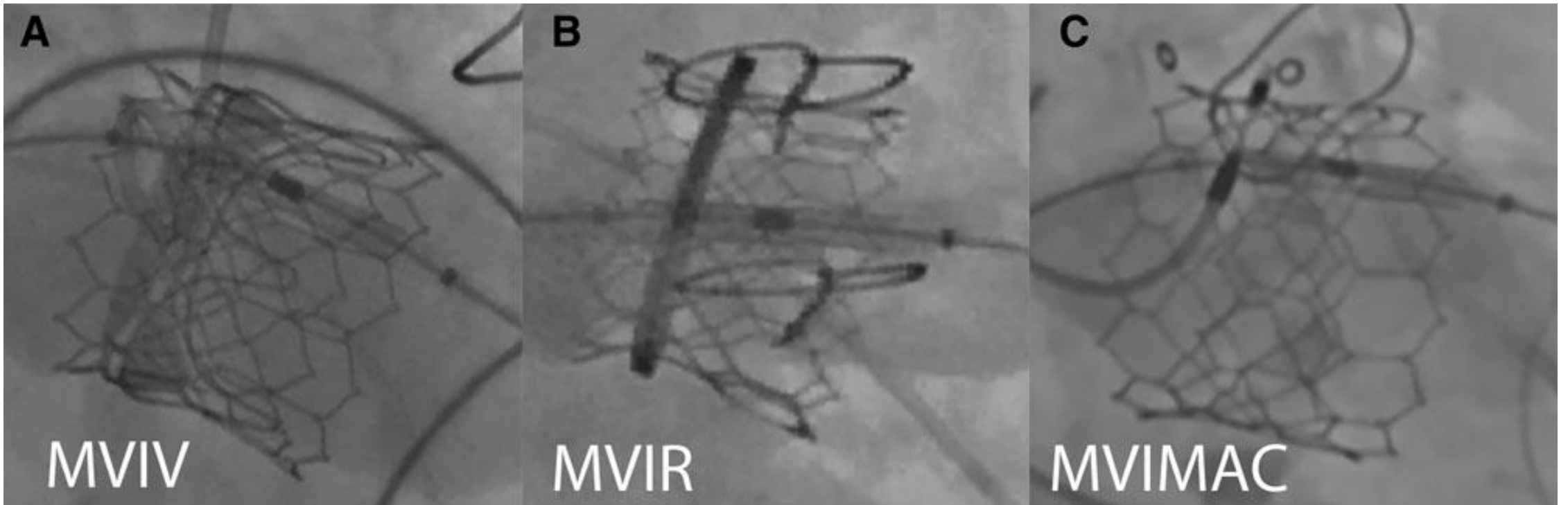
86%*
in NYHA class I/II and

17-point*
improvement in KCCQ score

KCCQ, Kansas City Cardiomyopathy Questionnaire.

* $P < .001$.

The good, the bad and the ugly



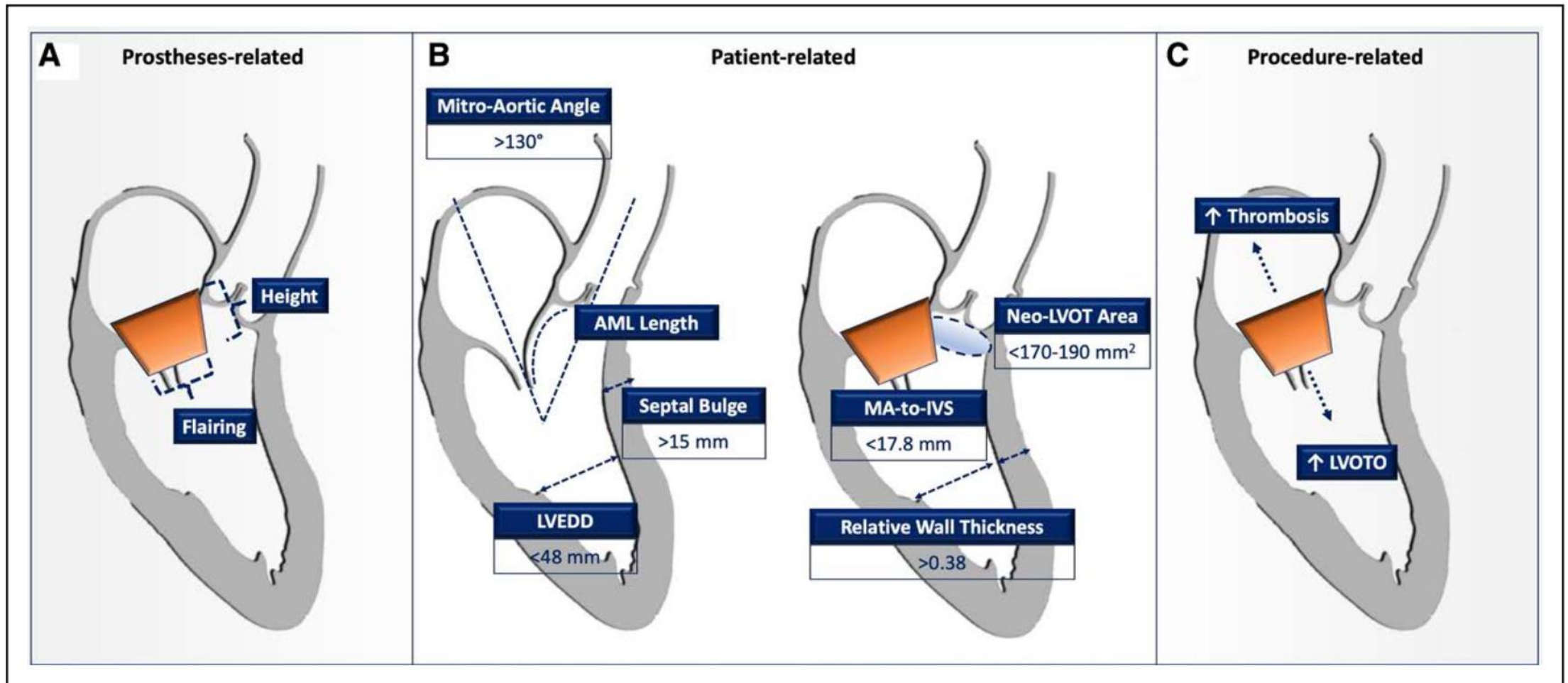


Figure 3. Left ventricle outflow tract obstruction (LVOTO) risk factors according to prostheses (A), patient (B), and procedure features (C).

Relative wall thickness: ratio between the posterior wall thickness and the left ventricle end-diastolic diameter (LVEDD). AML indicates anterior mitral leaflet; IVS, interventricular septum; LVOT, left ventricle outflow tract; and MA, mitral annulus.

A Challenging Case – severe MR with 2 prior sternotomies

70 years of age female from home and previously independent presents with acute pulmonary oedema and stage IV heart failure

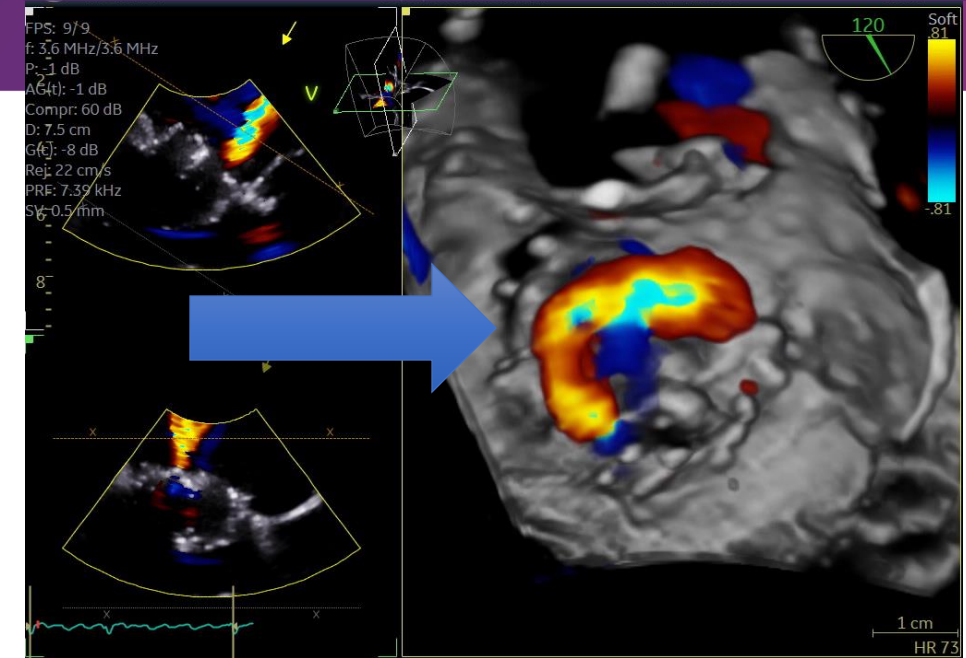
History

- Childhood rheumatic heart disease treated with surgical mitral valve replacement (33 mm St Jude Medical Epic porcine tissue valve) and aortic valve replacement (25mm St Jude Medical Epic porcine) in 2011.
- **2017:** survived a Type A aortic dissection treated with supracoronary ascending aortic graft in 2017. She was left with a chronic type B aortic dissection with a large false lumen (see arrow).
- The left kidney is atrophic as perfused from the false lumen, with chronic kidney disease stage IV with an eGFR 27.
- **2022 stroke:** MRI brain showing bilateral parietal cortical infarcts with good neurological recovery and normal function.
- Persistent atrial fibrillation



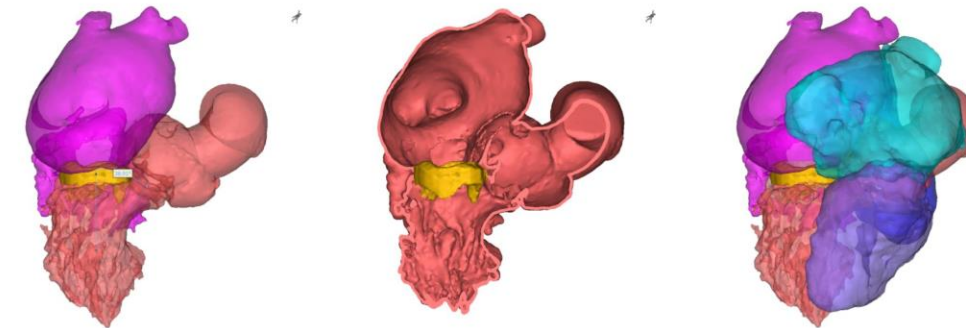
Investigations

- Coronary angiography: performed from right radial artery showed mild coronary disease
- 3D - Transoesophageal echocardiography: Anterolateral bioprosthetic 33 St Jude Medical mitral valve cusp prolapse, marked valve degeneration, and perforation with 2 jets of eccentric severe MR. Small LV cavity with normal LVEF. Aortic valve is functioning satisfactorily with mildly raised gradient mean 14mmHg.
- CT shows well seated mitral valve without frame degeneration



Key Anatomical Structures in 3D

Measurement	Value	Unit
Left ventricular volume	64.61	mL
Aorto-mitral angle	38.91	deg



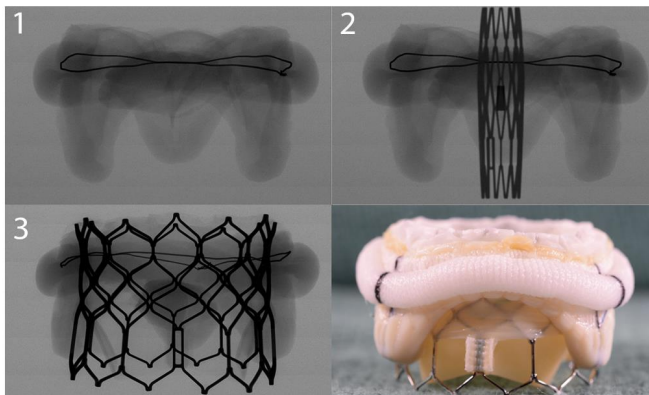
Heart Team Discussion

70 year old female with severe symptomatic MR through a degenerative 33 St Jude Medical Epic bioprosthesis in the mitral position who has had 2 prior sternotomies, stage IV chronic kidney disease and prior stroke

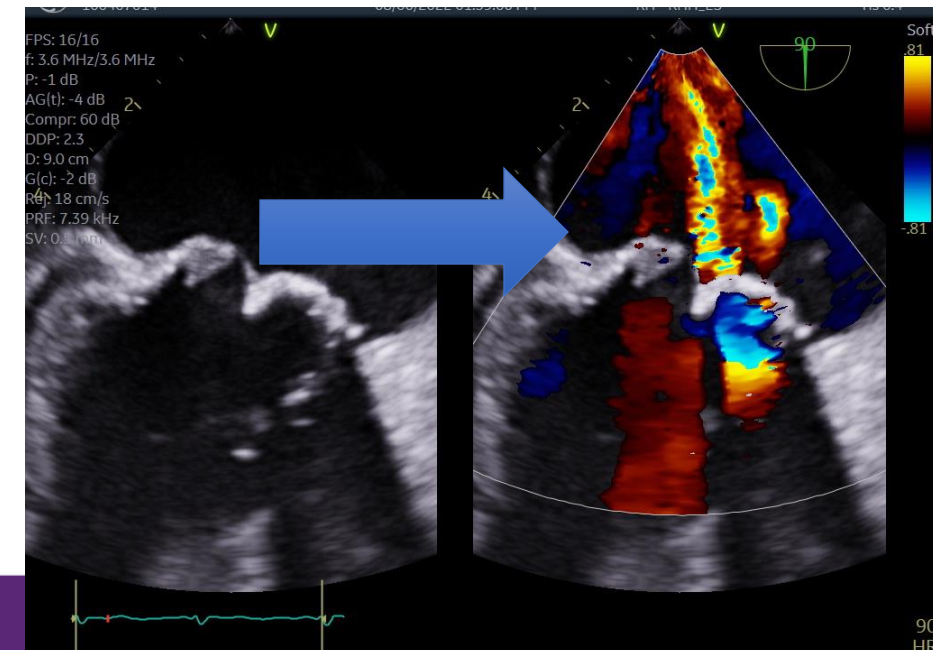
Risk score:

- Society Thoracic Surgeons score 48%
- Euroscore II 32%

Heart Team deemed the patient to be inoperable. For consideration of Mitral VIV THV placement with a 29mm Sapien 3 valve with cerebral protection (due to recent CVA) with limited option for bailout mechanical circulatory support due to residual type B aortic dissection...



LondonValves.com



CT of the mitral valve for procedural planning - low risk of LVOT obstruction

Executive Summary Plan 30-70

Landing Zone Measurements	Value	Unit
Perimeter (projected)	73.59	mm
Area (projected)	426.33	mm ²
Largest diameter (projected)	24.77	mm
Smallest diameter (projected)	21.5	mm

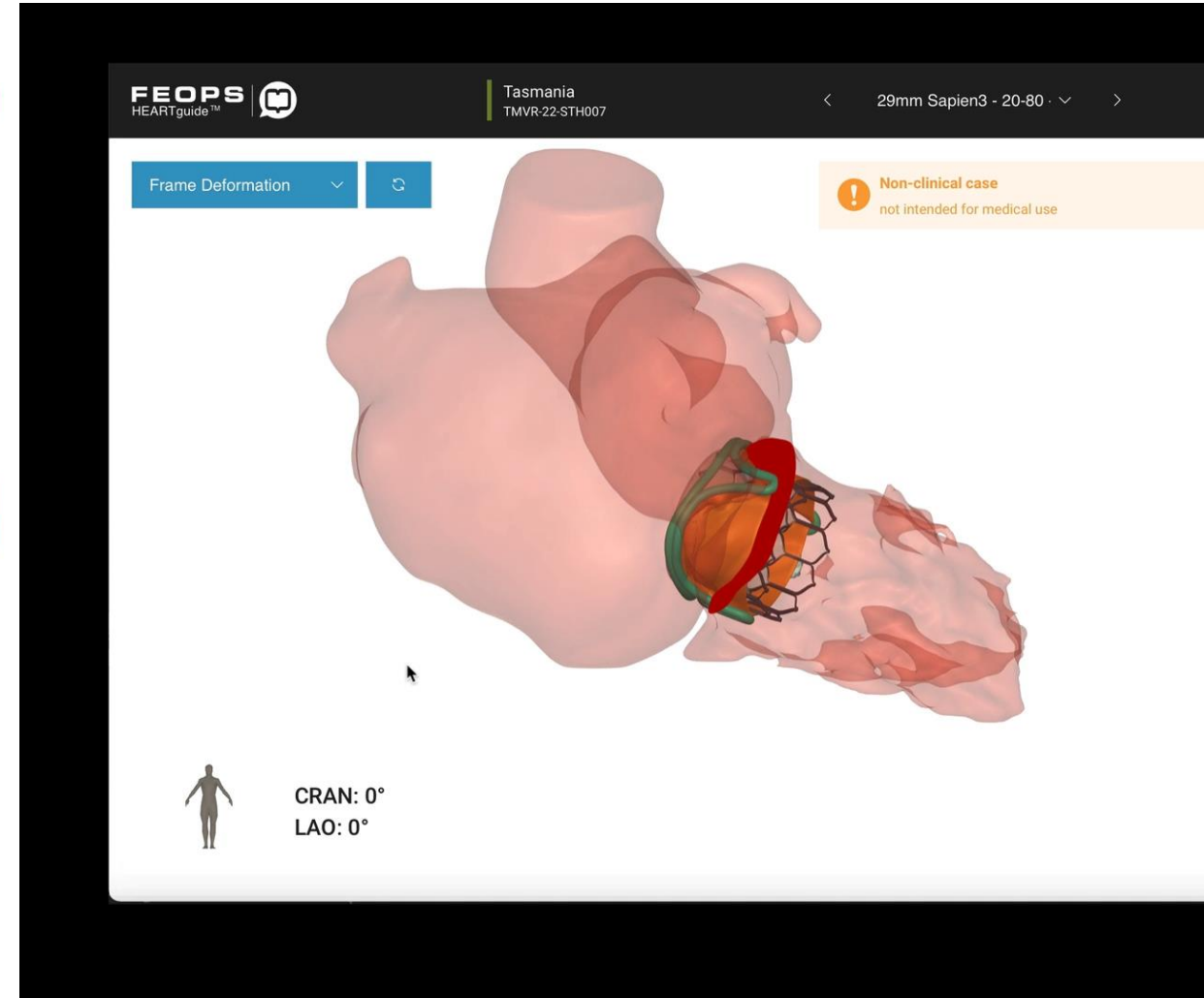
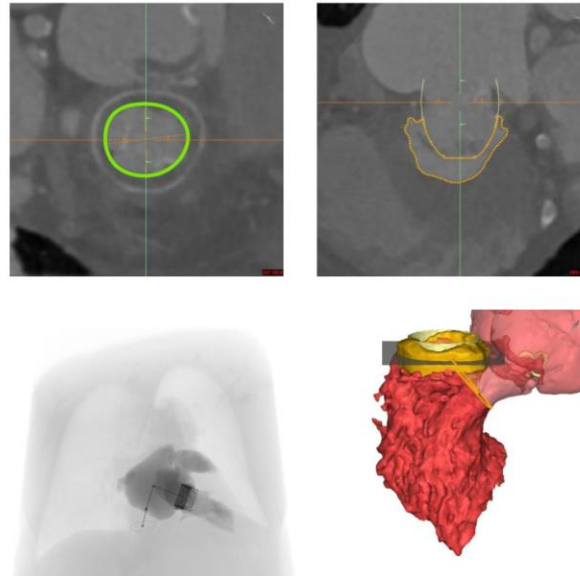
Device Name	Size	Position (LA/LV)
Cylinder S3	29x22.5	30/70

NeoLVOT Measurements	Value	Unit
Automatic NeoLVOT area	347.12	mm ²
Area blocked	57	%

Perpendicular to device	Predicted C-Arm Angle	Unit
RAO	12.31	deg
CRAN	24.22	deg

60% Diastole

materialise

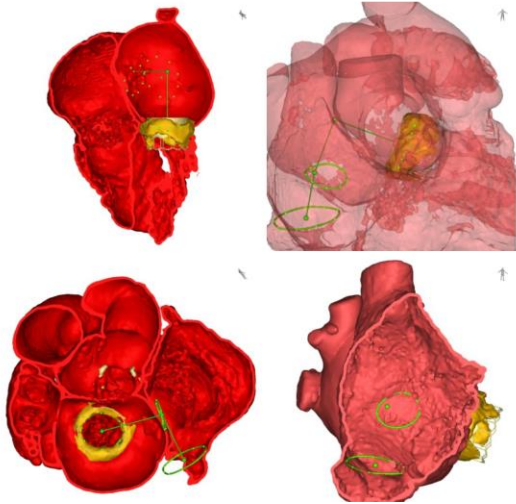


Procedure – Transfemoral mitral valve-in-valve implantation with an Edwards Sapien 3 29mm valve with cerebral protection and precise 30% atrial / 70% ventricular deployment and trans-septal puncture with atrial septostomy, Agilis catheter used to railroad 2 x XS Safari Wires safely to LV over pigtails for extra support

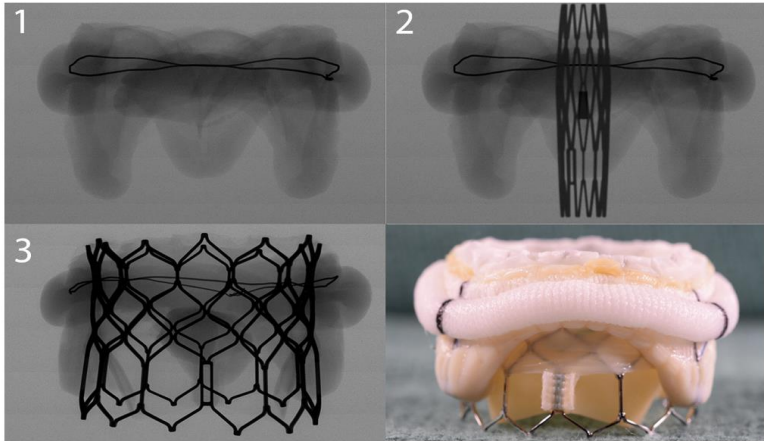
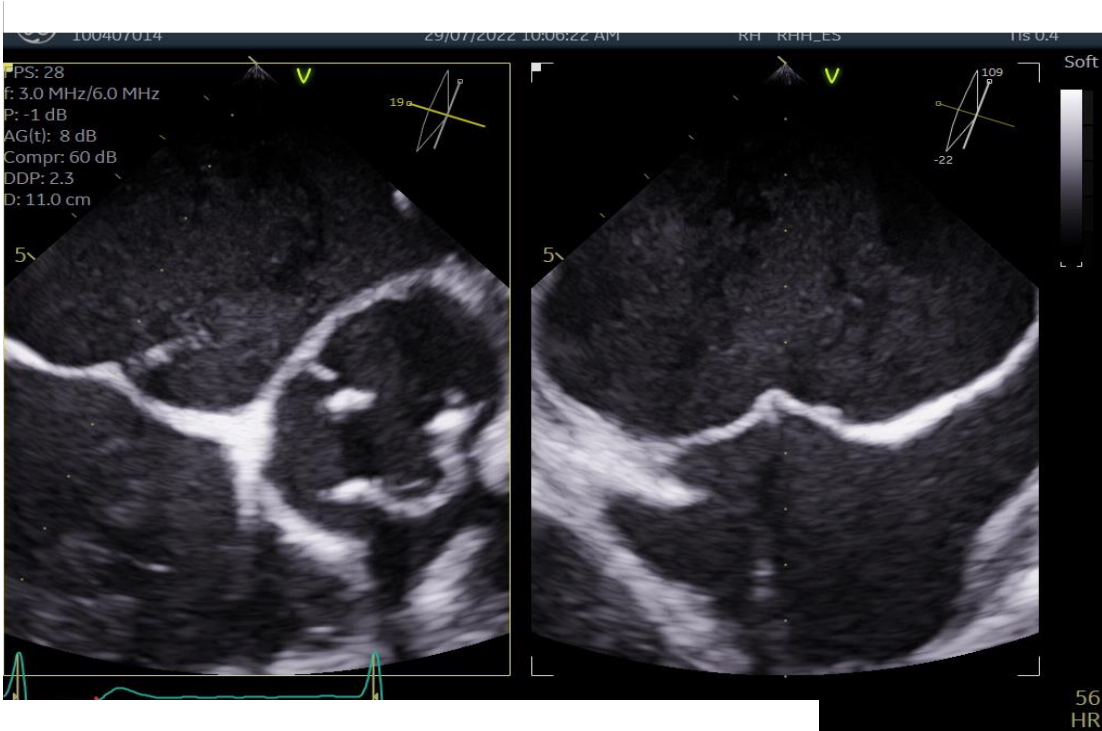
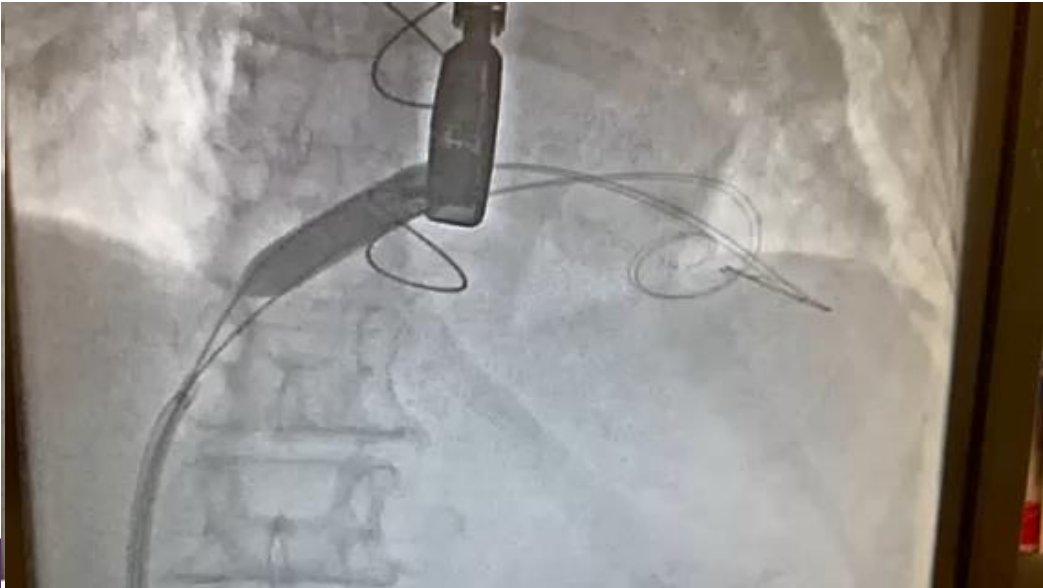
Transseptal Delivery

Septal crossing

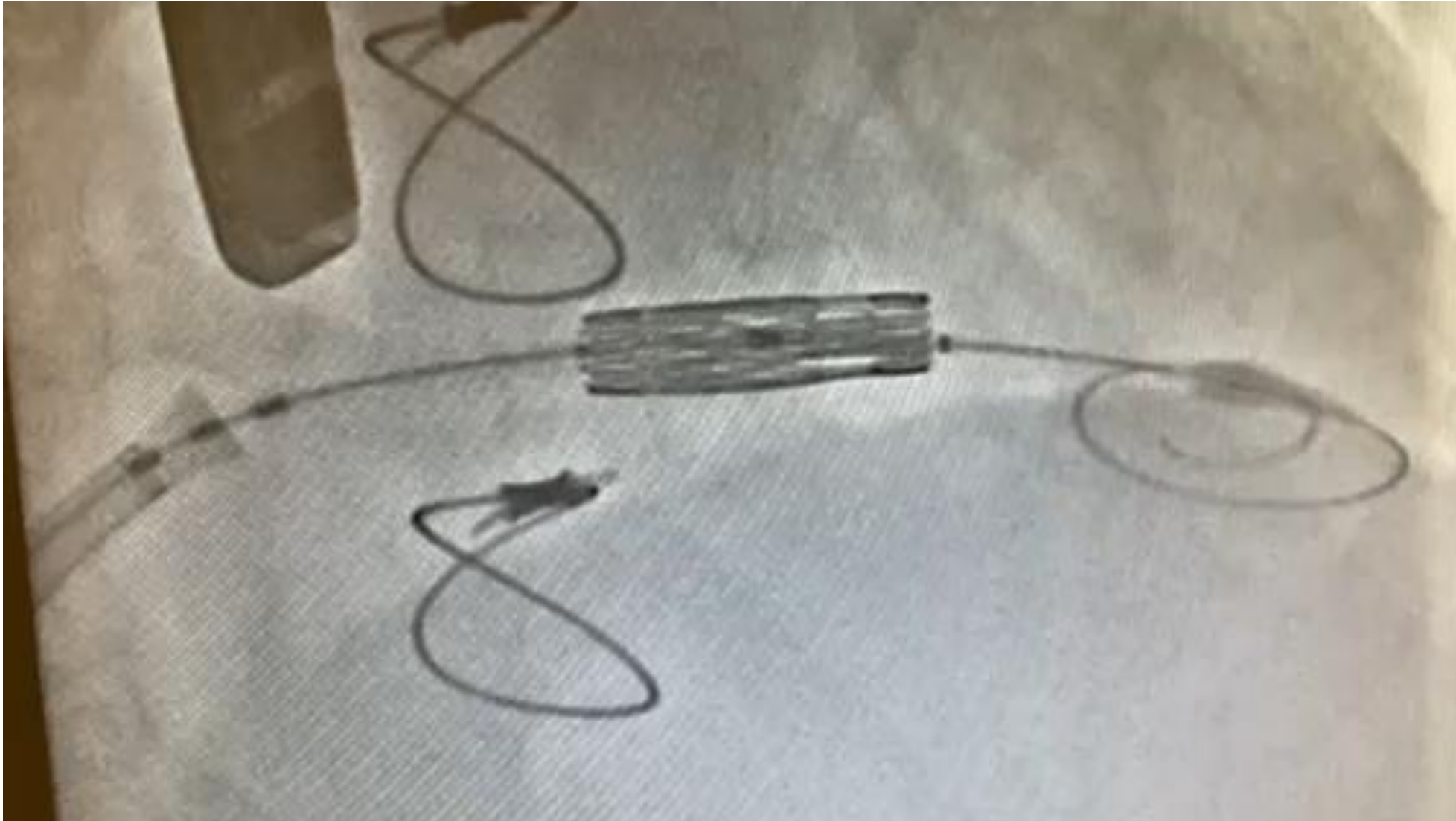
Measurement	Value	Unit
Angle IVC – fossa ovalis	91.24	deg
Angle at fossa ovalis	141.31	deg
Crossing depth into LA	37.17	mm
Angle fossa ovalis – device	90	deg
Mitral height	41.44	mm



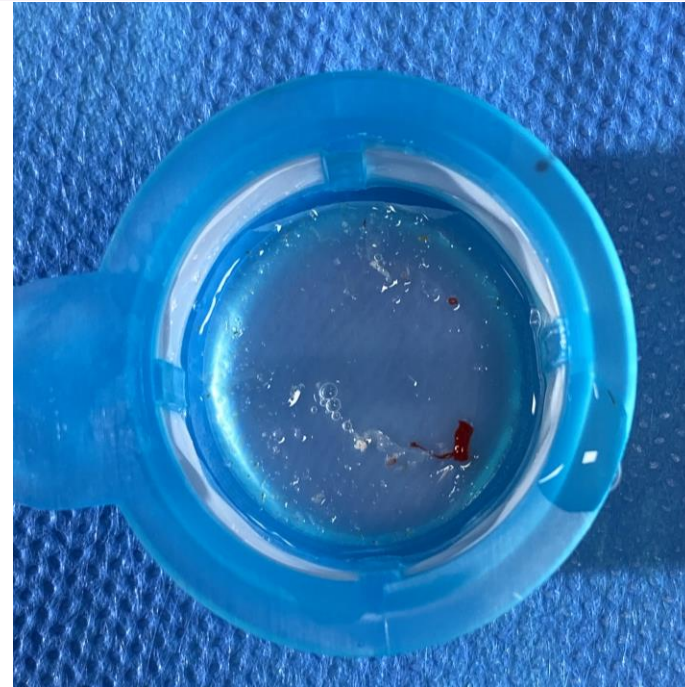
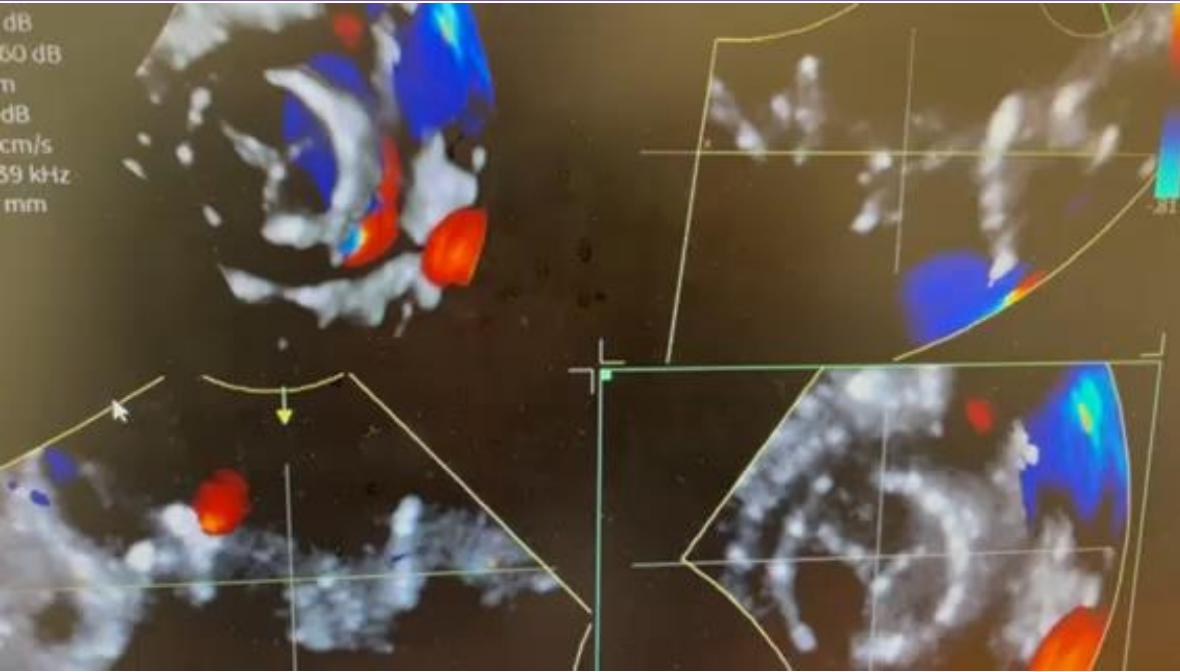
Delivery



Successful delivery of Sapien 3 29mm valve (nominal deployment) with no residual mitral regurgitation
30% Atrial / 70% Ventricular – minimal radiopaque markings



No residual mitral regurgitation, LVOT gradient 16mmHg at end of case,
Sentinel removed with minor clot noted in the LCA filter



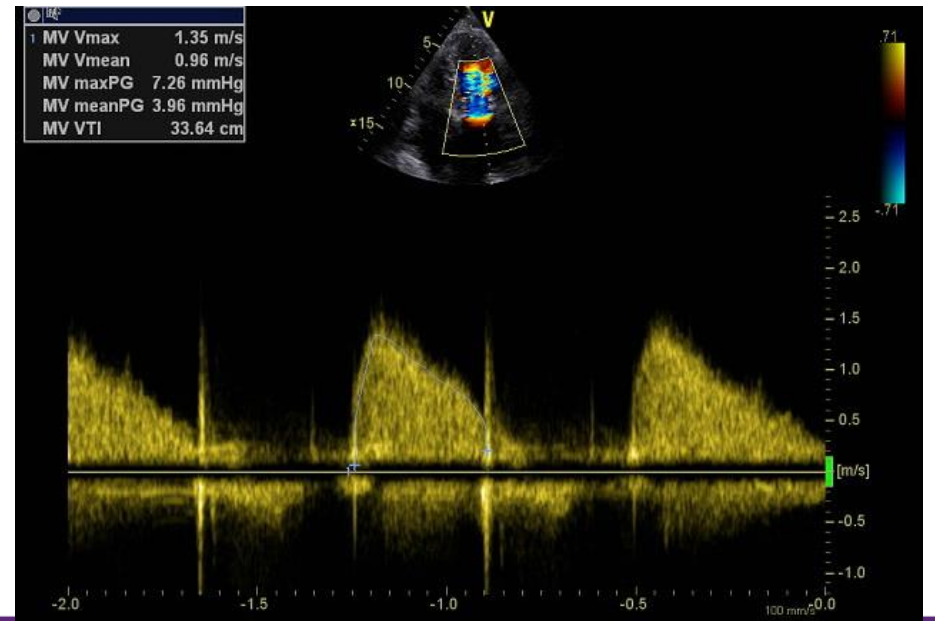
Progress and Conclusion

Progress

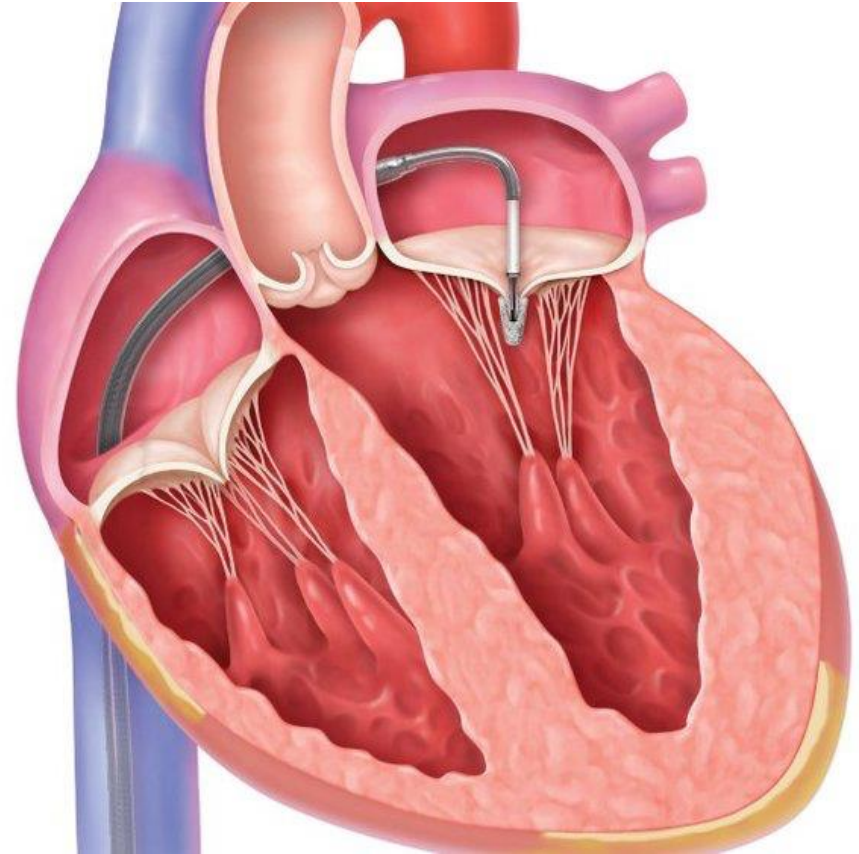
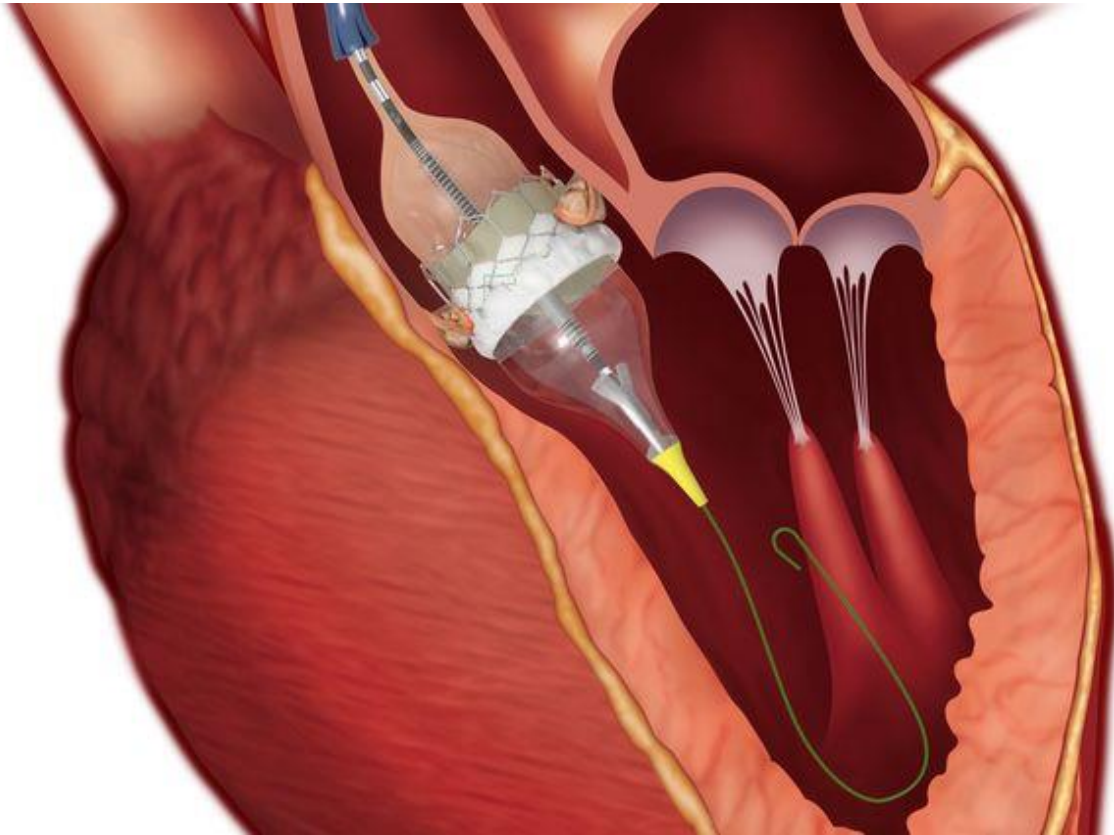
- Extubated on table, less SOB objectively day 1.
- Recovered well and discharged day 2.
- NYHA class I and at home at 30 day follow up.
- Back to playing lawn bowls

Conclusion

- Transcatheter mitral valve in valve remains a viable option for degenerated bioprosthesis.
- This case highlights the consistent challenge for TMVR procedural planning: to perform all the required anatomical measurements adequately and also assess the risk of obstruction of the left ventricular outflow tract and potential paravalvular leak.
- Cerebral protection can be considered for mitral interventions in high risk patients.



What about TMVR in the native mitral valve?





	Tendyne (Abbott) N=100	Tiara (Neovasc) N=79	Intrepid (Medtronic) N=50	Evoque (Edwards) N=15	Sapien M3 (Edwards) N=15	Highlife (Highlife SAS) N=15	Cardiovalve (Valtech) N=5
Frame	Nitinol double frame SE	Nitinol SE	Nitinol double frame SE	Nitinol SE	Cobalt-chromium BE	Nitinol SE	Nitinol SE
Leaflets	3 porcine	3 bovine	3 bovine	3 bovine	3 bovine	3 bovine	3 bovine
Anchoring mechanism	Apical tether	Leaflet engagement	Small cleats + Radial force	Annulus clamping	Nitinol dock system	External anchor	Leaflet grasping
Approach	Transapical	Transapical	Transapical	Transfemoral	Transfemoral	Transapical	Transfemoral
Delivery system, Fr	36	32-36	35	30	20	39	28
FMR aetiology, %	89	62	72	27	/	73	100
Technical success, %	97	93	98	93	87	73	100
30-day mortality, %	6	13	14	7	3	20	60
1-year mortality, %	26	/	/	/	/	20	60

Figure 2. Transcatheter mitral valve implantation in native mitral valve.

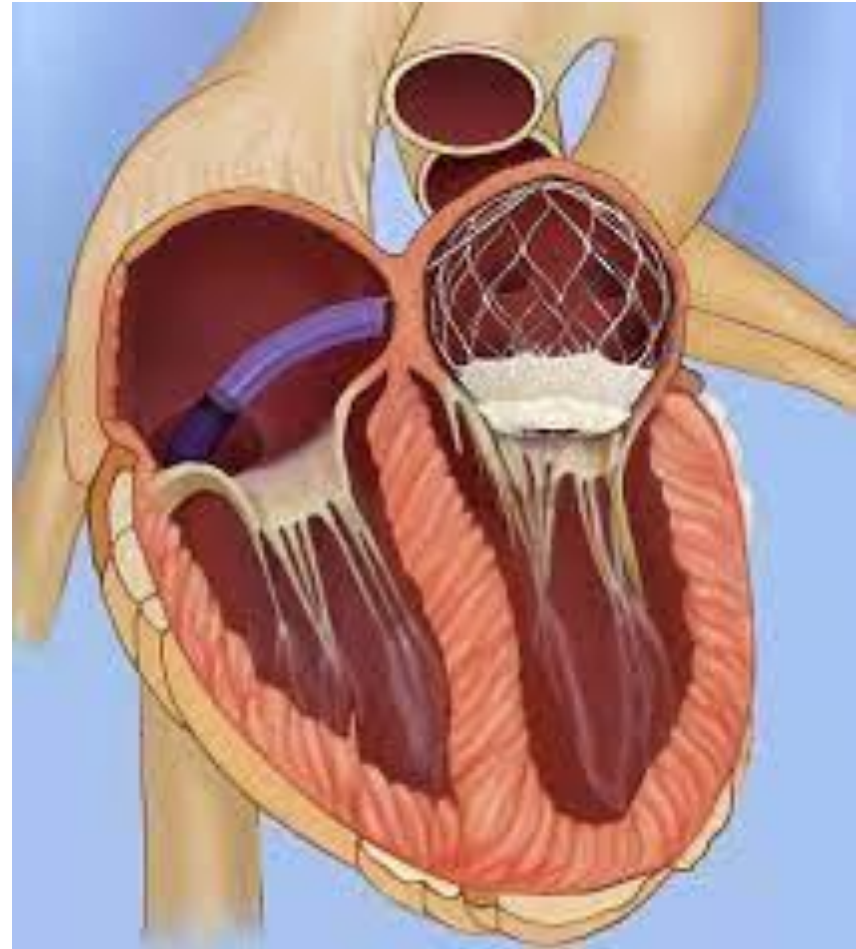
BE indicates balloon-expandable; FMR, functional mitral regurgitation; Fr, French; and SE, self-expandable.

M3 – Encircle Trial

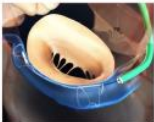
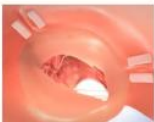
- **The SAPIEN M3 dock:**
- Nitinol dock designed to encircle native mitral leaflets to provide an anchor for the SAPIEN M3 valve
- **The SAPIEN M3 valve:**
- Specifically engineered to respect the native mitral anatomy
- Leverages 29 mm SAPIEN 3 valve tissue and frame
- Includes full-frame PET skirt
- <https://www.youtube.com/watch?v=LF8YYUDCyvU>

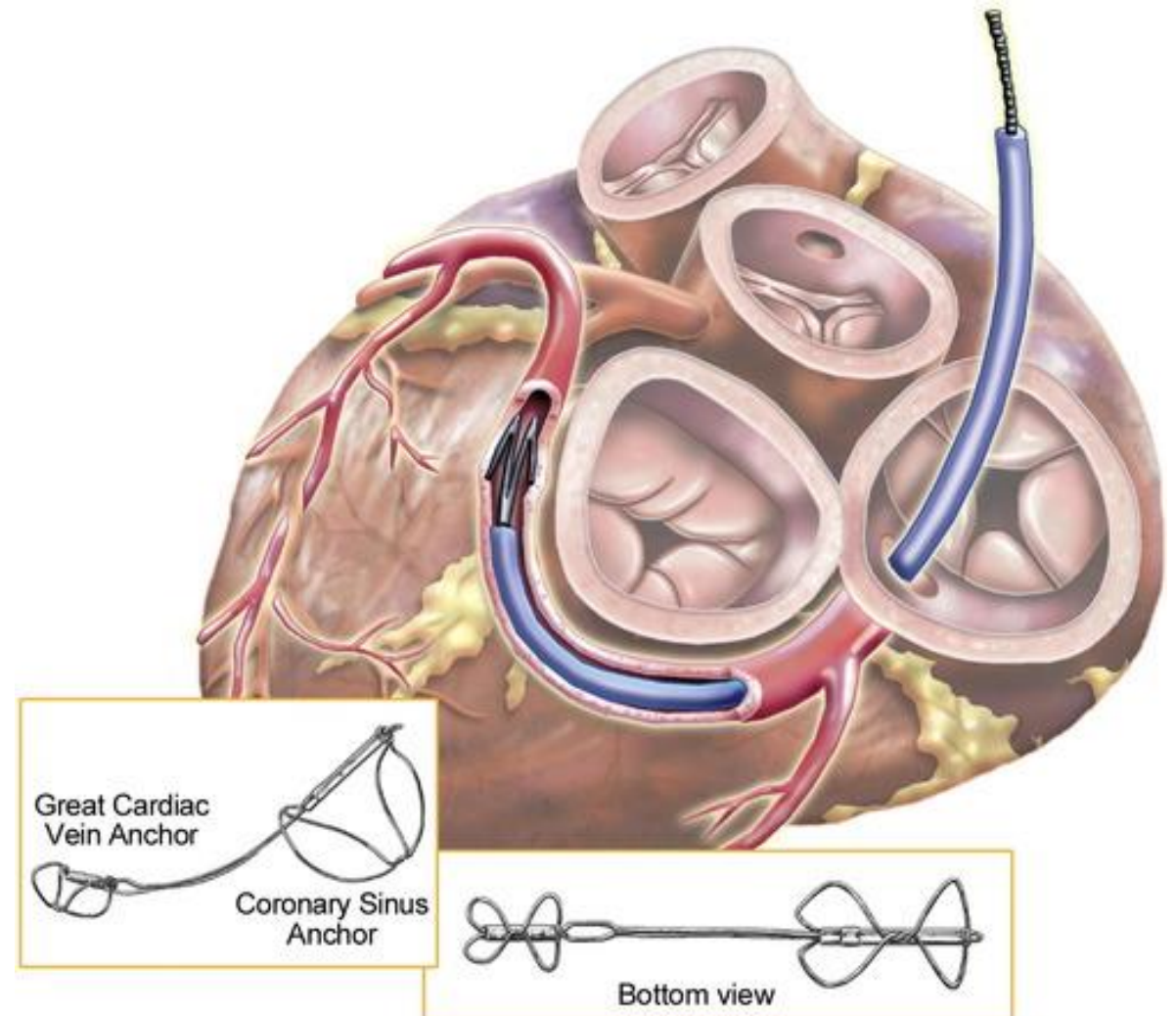


Alta Valve – trans-septal, recapturable, self expanding, low risk of LVOTO

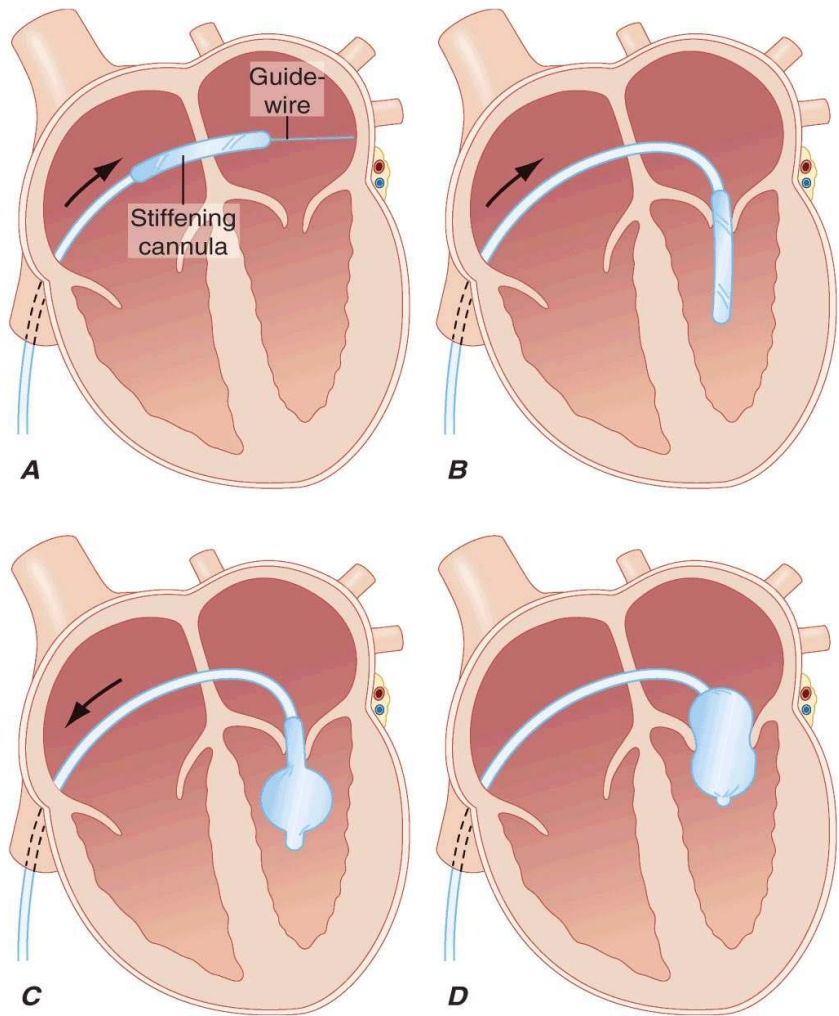


Annuloplasty

Device	Name	Technique
	PASCAL (Edwards Lifesciences, Irvine, CA, USA)	Edge-to-Edge Leaflet Repair
	Carillon (Cardiac Dimensions, Kirkland, WA, USA)	Indirect Annuloplasty
	Cardioband (Edwards Lifesciences, Irvine, CA, USA)	Direct Annuloplasty
	Amend (Valcare Medical, Israel)	Direct Annuloplasty
	IRIS (Millipede, Inc., Santa Rosa, CA, USA)	Direct Annuloplasty
	Mitralign (Mitralign, Inc., Tewksbury, MA, USA)	Direct Annuloplasty
	NeoChord (NeoChord, Inc., St. Louis Park, MN, USA)	Chordal Repair
	HARPOON (Edwards Lifesciences, Irvine, CA, USA)	Chordal Repair



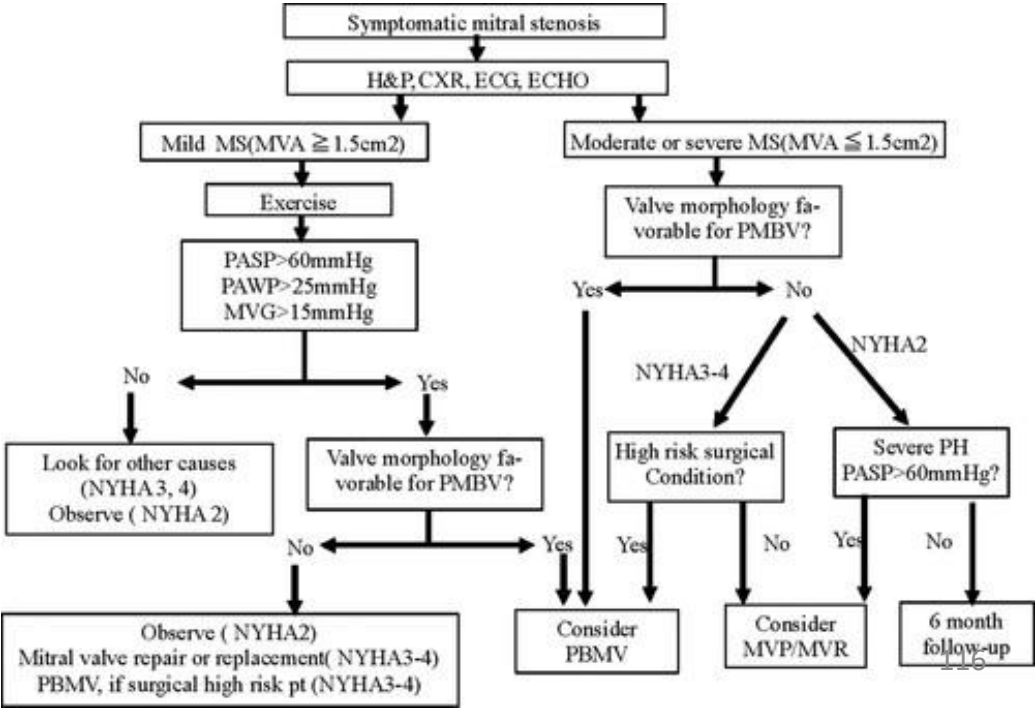
PMBV <8 Wilkins score



Mitral valve stenosis - Wilkins score

Assessment of mitral valve anatomy according to the Wilkins score[5]				
Grade	Mobility	Thickening	Calcification	Subvalvular Thickening
1	Highly mobile valve with only leaflet tips restricted	Leaflets near normal in thickness (4-5 mm)	A single area of increased echo brightness	Minimal thickening just below the mitral leaflets
2	Leaflet mid and base portions have normal mobility	Midleaflets normal, considerable thickening of margins (5-8 mm)	Scattered areas of brightness confined to leaflet margins	Thickening of chordal structures extending to one-third of the chordal length
3	Valve continues to move forward in diastole, mainly from the base	Thickening extending through the entire leaflet (5-8mm)	Brightness extending into the mid-portions of the leaflets	Thickening extended to distal third of the chords
4	No or minimal forward movement of the leaflets in diastole	Considerable thickening of all leaflet tissue (>8-10mm)	Extensive brightness throughout much of the leaflet tissue	Extensive thickening and shortening of all chordal structures extending down to the papillary muscles

• The total score is the sum of the four items and ranges between 4 and 16.



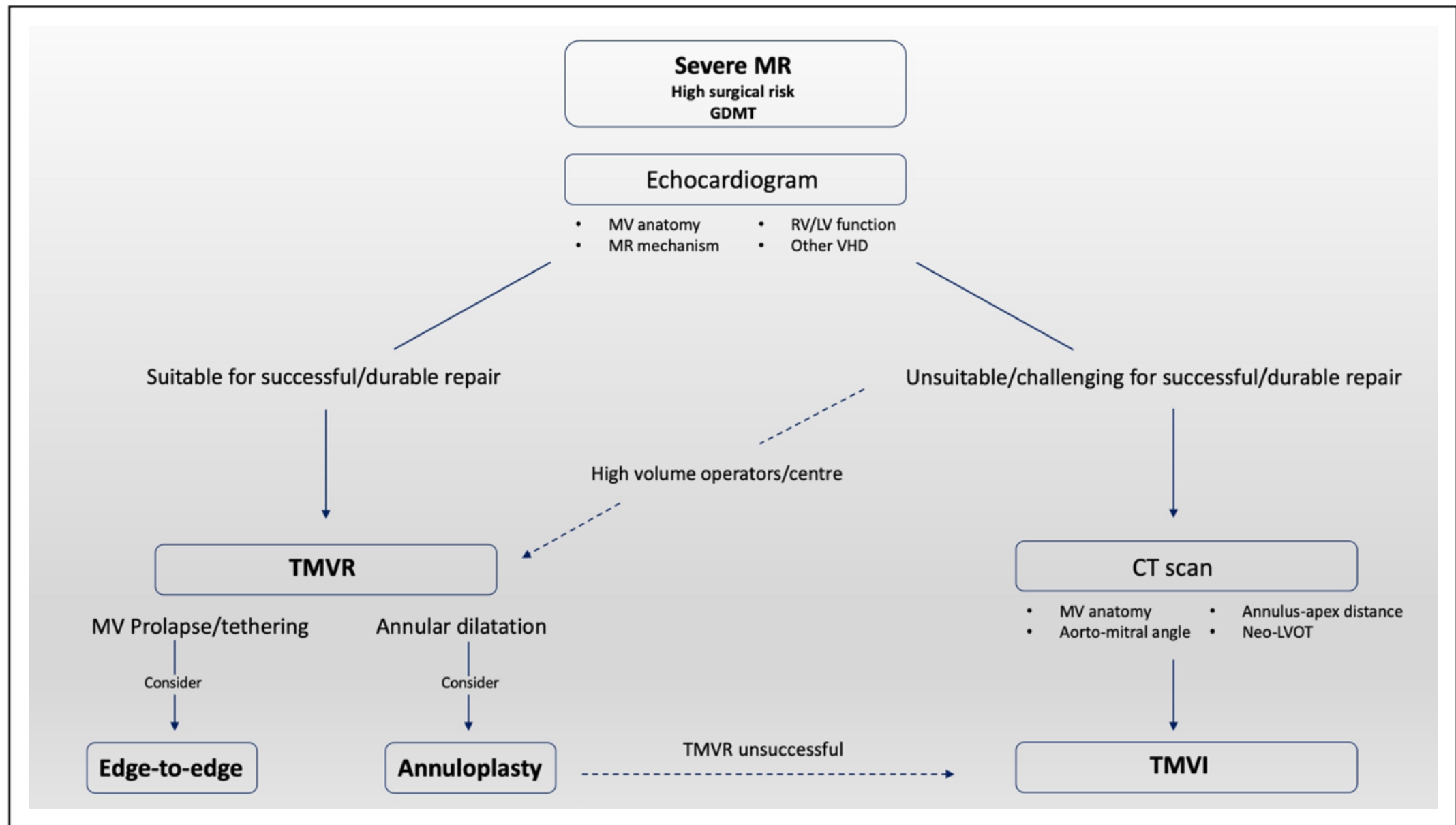
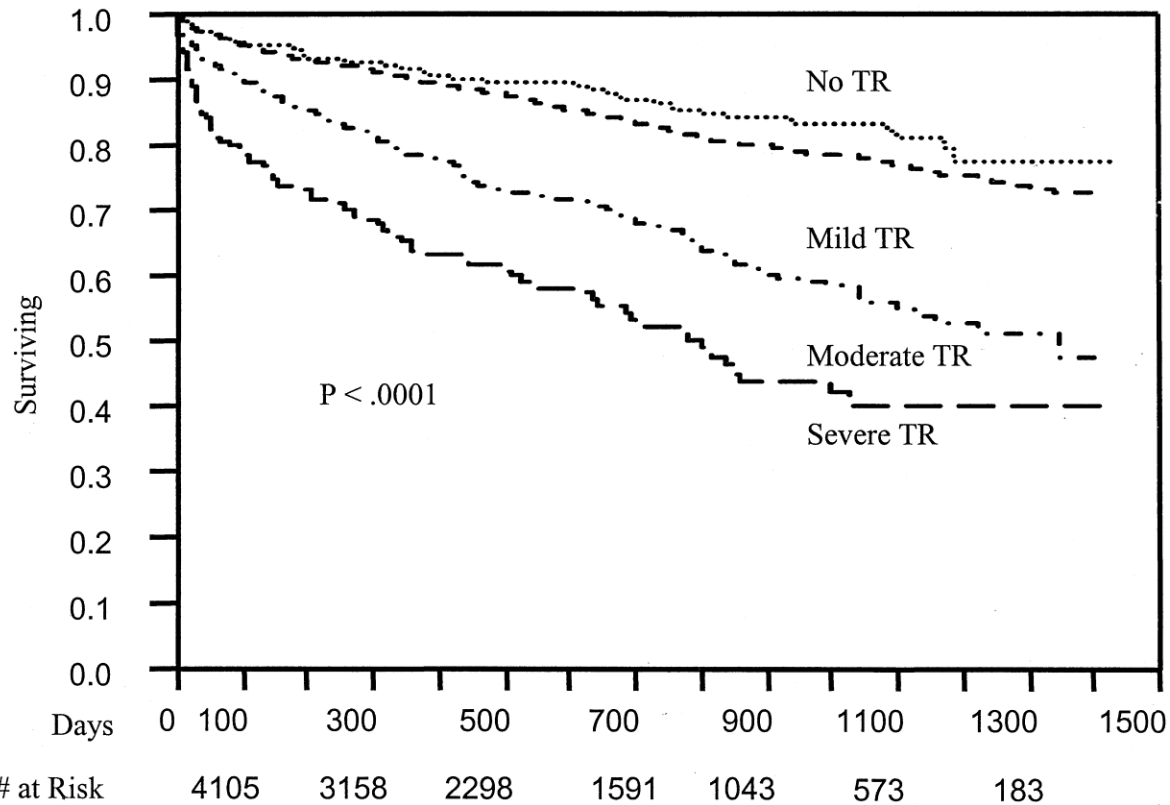
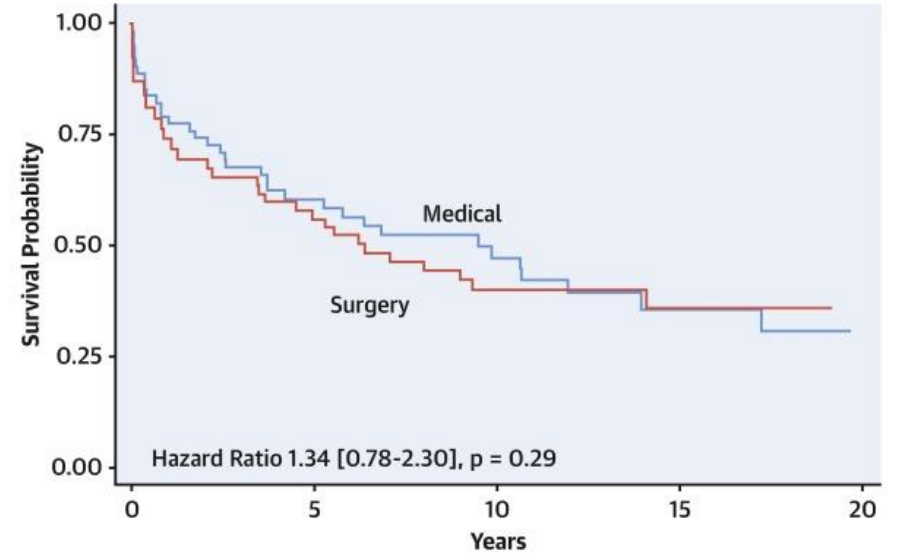


Figure 5. Proposed decisional algorithm for transcatheter therapies correcting mitral regurgitation (MR) in native mitral valve (MV). CT indicates computed tomography; GDMT, guideline-directed medical therapy; LV, left ventricle; LVOT, left ventricle outflow tract; RV, right ventricle; TMVI, transcatheter mitral valve implantation; TMVR, transcatheter mitral valve repair; and VHD, valvular heart disease.

Severe Tricuspid Regurgitation



CENTRAL ILLUSTRATION: Surgery Versus Medical Therapy for Severe Tricuspid Regurgitation



Axtell, A.L. et al. J Am Coll Cardiol. 2019;74(6):715-25.

Tricuspid options

Annuplasty

Edge-to-edge
plasty

Transcatheter
heart valve

Trialign



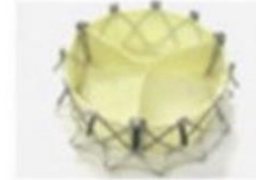
TriCinch



MitraClip



NaviGate



Cardioband



Millipede



PASCAL



TricValve

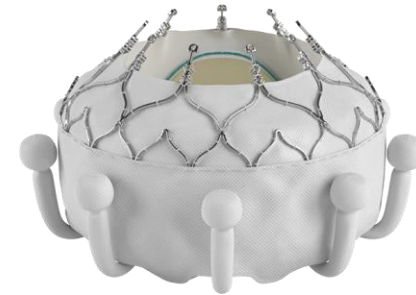


Table 1 Transcatheter tricuspid valve device technical characteristics⁶²

Device	Technique	Access	Sheath (Fr)	Procedural success	Study
TriCinch	Annuloplasty	TF	24	75%	PREVENT
Trialign	Annuloplasty	TJ	14	93%	SCOUT I
Cardioband	Annuloplasty	TF	24	100%	TRI-REPAIR
TRAIPTA	Annuloplasty	TF	14	100%	Early feasibility studies
FORMA	Coaptation device	Axillary vein	20–24	89%	SPACER Trial
TriClip	Tricuspid edge to edge techniques	TF	24	100%	Triluminate
PASCAL	Tricuspid edge to edge techniques	TF	22	92%	Early feasibility studies warranted
Millipede System	Annuloplasty	S/TF		100%	FIH Study
PASTA device	Tricuspid edge to edge techniques	TJ/TA	8–12	90%	Early feasibility studies warranted
CAVI–TricValve	caval valve implantation	TF	27	100%	TRICAVAL

Table 3 Baseline characteristics and procedural outcomes of transcatheter tricuspid regurgitation studies according to each device⁶⁴

	TriClip Nickenig <i>et al</i> (n=85)	PASCAL Fam <i>et al</i> (n=28)	FORMA Kodali <i>et al</i> (n=29)	CAVI Dreger <i>et al</i> (n=14)	Trialign Hahn <i>et al</i> (n=15)	Cardioband Nickenig <i>et al</i> (n=30)	TriCinch Denti (n=24)
Age, years	77.8±7.9	78±6	76±8	77 (68.2–82.0)	74±7	75±6.6	74±8
Female sex	66%	15 (54)	19 (66)	86%	13 (87)	22 (73)	20 (83)
Atrial fibrillation	92%	26 (93)	24 (83)	na	10 (67)	28 (93)	n/a
NYHA III–IV	75%	28 (100)	25 (86)	86%	10 (67)	25 (83)	14 (58)
Transtricuspid CIED	14%	1 (3)	n/a	na	0 (0)	4 (13)	n/a
EuroSCORE II, %	8.7±10.7 (80)	6.2±5.2	8.4 5.3	14.6±11.6	n/a	4.1±2.8	5.5
Echocardiography							
LVEF, %	59.39±8.09 (73)	59±6	57±12	56.4±6.4	60±12	57±11	n/a
TAPSE, mm	1.44±0.31 (79)	16±3	14±0.4	16.1±5.2	16±4	n/a	n/a
Vena contracta width, mm	17.3 0.07	11.4±5	16±0.5	na	13±3	12.6±4.5	n/a
EROA, cm ²	0.65 0.03	1.3±2.4	2.2±1.5	1.23±0.6	0.7±0.5	0.79±0.5	n/a
Procedural and 30-day outcomes							
Procedural success	na	24 (86)	27 (93)	100%	15 (100)	30 (100)	18 (81)
Procedural death	na	0 (0)	2 (7)	0	0 (0)	0 (0)	n/a
Need for cardiac surgery	na	0 (0)	3 (10)	29%	0 (0)	0 (0)	n/a
30-day TR grade >moderate	na	4/26 (15)	n/a	na	n/a	5 (24)	
Follow-up							
Follow-up time, months	1 year	30 days	30 days	3	12 m	6	6
Mortality	7.1 (6/84)	2 (7)	2 (7)	8 (57%)	2 (13)	3 (10)	0 (0)
TR grade>moderate	na	4/26 (15)	2 (7)	na	n/a	5 (28)	(75)
NYHA I–II	83%	23/26 (88)	18/25 (72)	na	5/10 (50)	22 (88)	n/a

LVEF, left ventricular ejection fraction; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

TEER for tricuspids

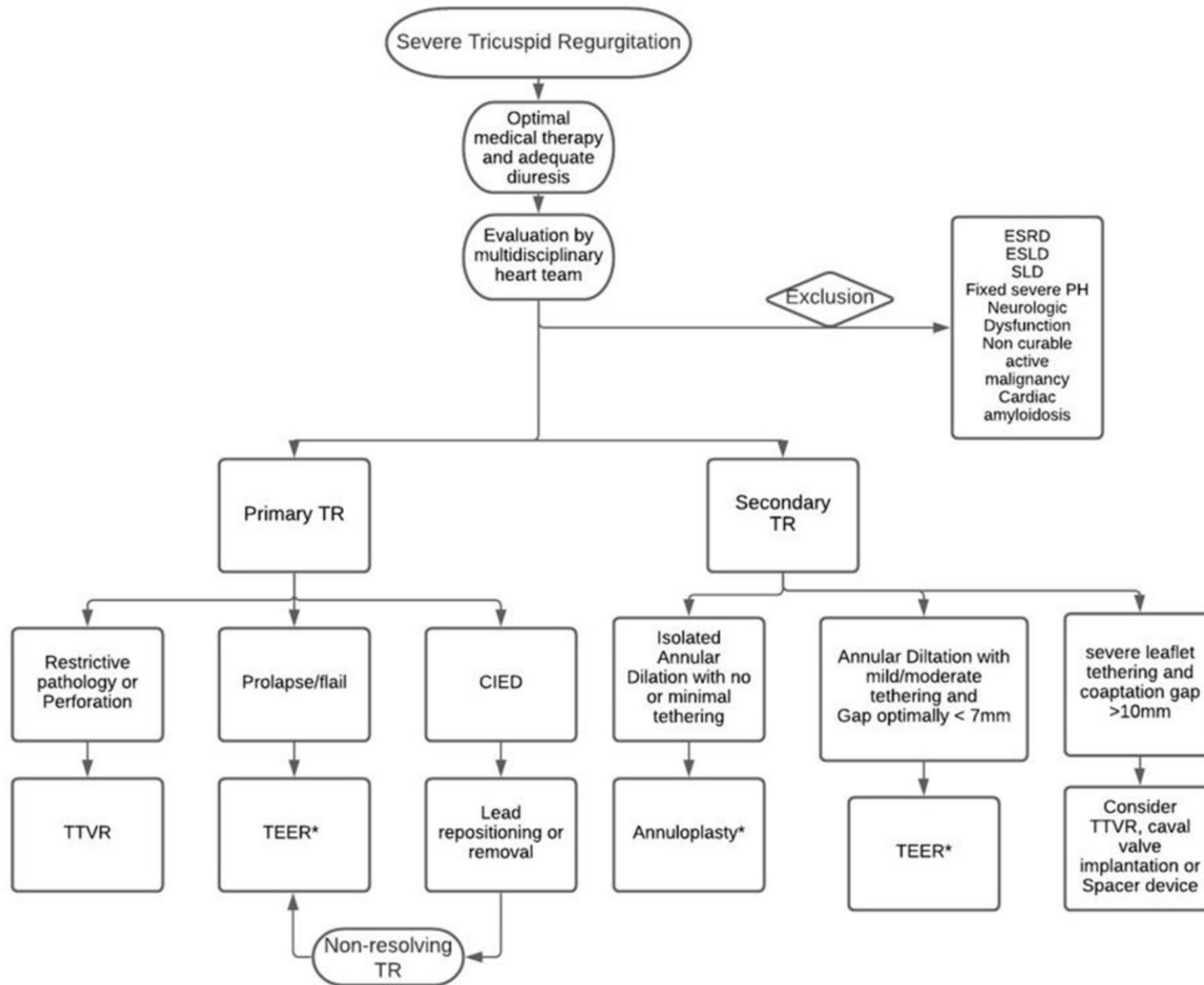
Table 2 Ideal and complicating factors for transcatheter tricuspid valve interventions^{28 63}

Approach	Ideal factors	Complicating factors
Edge to edge repair	▶ Coaptation defect < 7 mm ▶ Adequate leaflet mobility ▶ Anteroseptal jet ▶ Confined leaflet prolapse or flail leaflet ▶ RV lead without primary leaflet obstruction	▶ Gap > 8.5 mm ▶ Thick/short leaflets ▶ Leaflet perforation ▶ Difficult echocardiographic visualisation ▶ CIED RV lead leaflet impingement ▶ Anteroposterior jet location ▶ Severe leaflet tethering

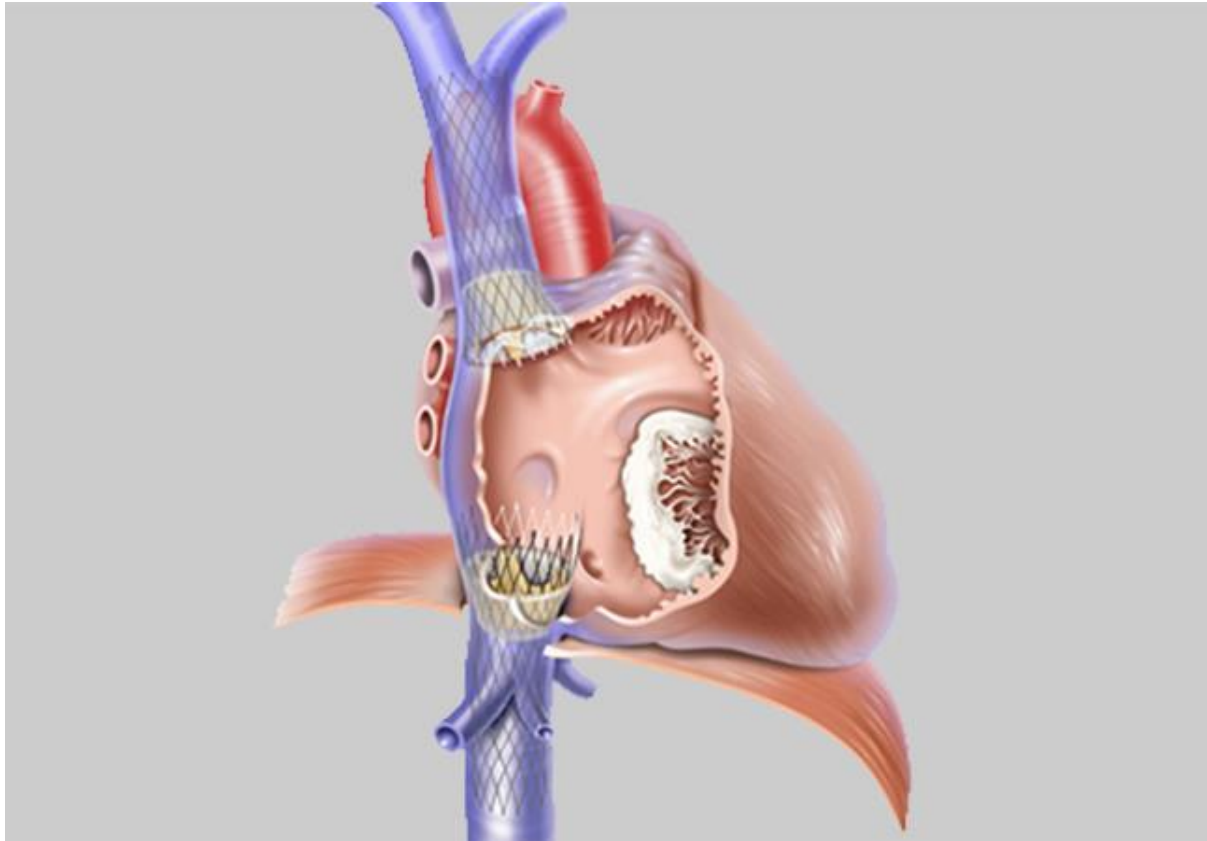
Transcatheter Repair for Patients with Tricuspid Regurgitation

Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D., Peter Tadros, M.D., Matthew J. Price, M.D., Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M.D., Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., et al., for the TRILUMINATE Pivotal Investigators*

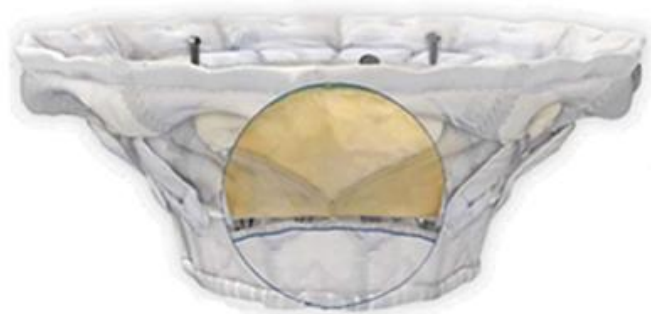
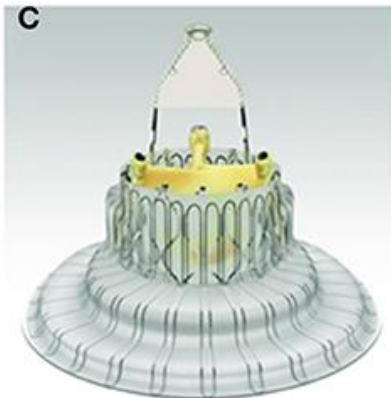
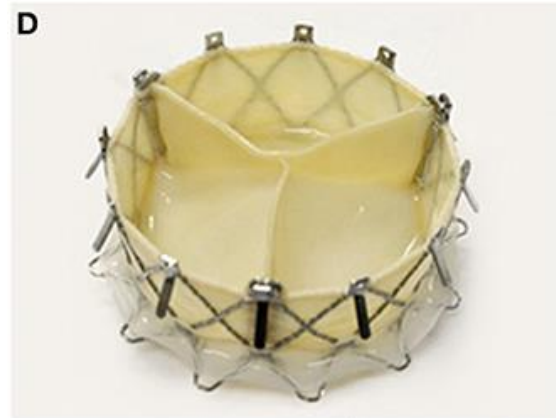
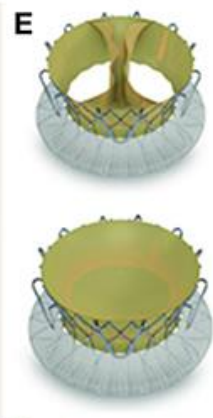
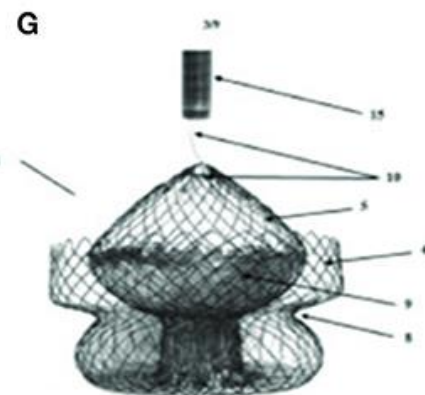
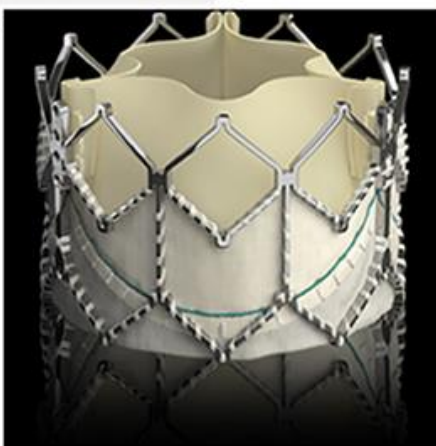
- TEER vs medical therapy
- A total of 350 patients were enrolled; 175 were assigned to each group.
- The mean age of the patients was 78 years, and 54.9% were women.
- The results for the primary end point favored the TEER group (win ratio, 1.48; 95% confidence interval, 1.06 to 2.13; $P=0.02$).
- The incidence of death or tricuspid-valve surgery and the rate of hospitalization for heart failure did not appear to differ between the groups.
- The KCCQ quality-of-life score changed by a mean ($\pm$ SD) of 12.3 ± 1.8 points in the TEER group, as compared with 0.6 ± 1.8 points in the control group ($P<0.001$).
- At 30 days, 87.0% of the patients in the TEER group and 4.8% of those in the control group had tricuspid regurgitation of no greater than moderate severity ($P<0.001$).
- TEER was found to be safe; 98.3% of the patients who underwent the procedure were free from major adverse events at 30 days.



Tric Valve – TRICUS-EURO CE study



- 35 pts (mean age 76 ± 6.8 years, 83% women) were treated using the TricValve system. NYHA functional class III or IV.
- At 30 days, procedural success was 94%, with no procedural deaths or conversions to surgery.
- A significant increase in QOL at 6 months follow-up was observed (baseline and 6-month Kansas City Cardiomyopathy Questionnaire scores 42.01 ± 22.3 and 59.7 ± 23.6 , respectively; $P = 0.004$), correlating with a significant improvement in NYHA functional class, with 79.4% of patients noted to be in functional class I or II at 6 months ($P = 0.0006$).
- The rates of 6-month all-cause mortality and heart failure hospitalization were 8.5% and 20%, respectively.

A**B****C****D****E****F****G****H****I****J**

Left Atrial Appendage Closure

Review of the Evidence, Procedure and Complications

Abbott

AMULET

Boston
Scientific

WATCHMAN
FLX

Dr Heath Adams

BMedSci MBBS (Hons), DipUKMP, GDipClinLShip, FRACP FCSANZ

Interventional Cardiologist, Royal Hobart Hospital

Clinical Lead for TAVI

VMO, Hobart Heart Centre & Calvary Hospitals

Adjunct Senior Researcher, Menzies Research Institute, University of Tasmania

Do we sometimes Rob Peter to pay Paul?



CHADS-VASC Score

Risk factors		
C	Congestive Heart Failure	+1 point
H	Hypertension	+1 point
A₂	Age ≥75	+2 point
D	Diabetes	+1 point
S₂	Stroke/TIA History	+2 point
V	Vascular Disease	+1 point
A	Age 65-74	+1 point
S	Sex (Female)	+1 point

Stroke risk per year	
SCORE	% RATE PER YEAR
0	0%
1	1.3%
2	2.2%
3	3.2%
4	4.0%
5	6.7%
6	9.8%
7	9.6%
8	6.7%
9	15.2%

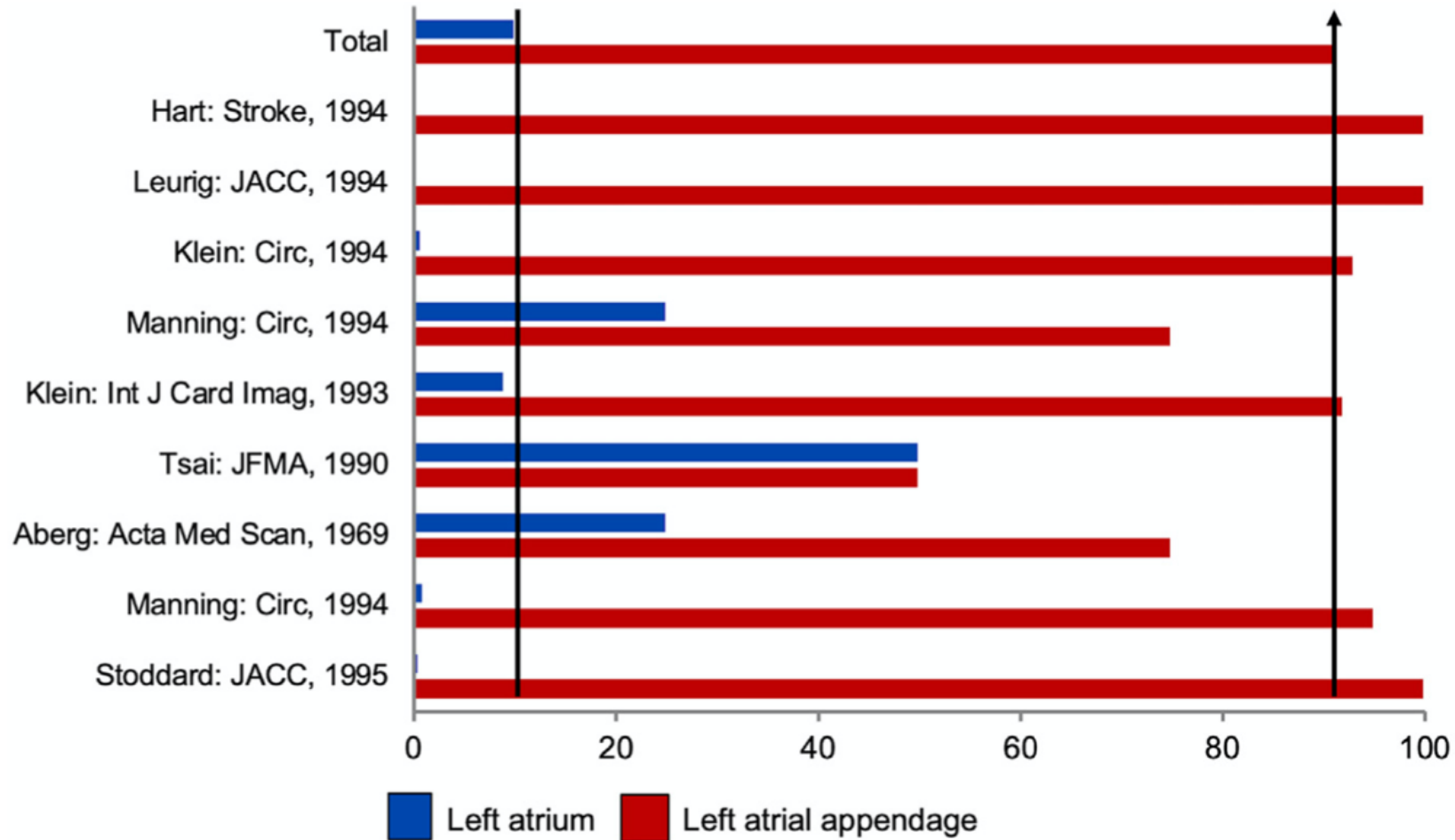
HAS-BLED Score

ESC and Canadian Guidelines

Clinical characteristics comprising the HAS-BLED Bleeding Risk Score

Letter	Clinical characteristic*	Points	HAS-BLED score (total points)	Bleeds per 100 patient-years [†]
H	Hypertension (ie uncontrolled blood pressure)	1	0	1.13
A	Abnormal renal and liver function (1 point each)	1 or 2	1	1.02
S	Stroke	1	2	1.88
B	Bleeding tendency or predisposition	1	3	3.74
L	Labile INRs (for patients taking warfarin)	1	4	8.70
E	Elderly (age greater than 65 years)	1	5 to 9	Insufficient data
D	Drugs (concomittant aspirin or NSAIDs) or alcohol abuse (1 point each)	1 or 2		
		Maximum 9 points		

FIGURE 1 The Left Atrial Appendage as a Nidus for Thrombus Formation in Patients With Atrial Fibrillation



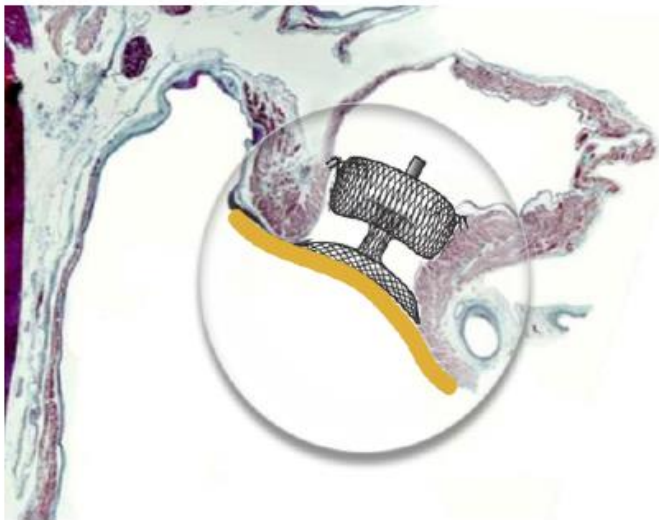
91% in LAA



LAA = left atrial appendage.

Abbott AMULET

Left Atrial Appendage Occlusion Device

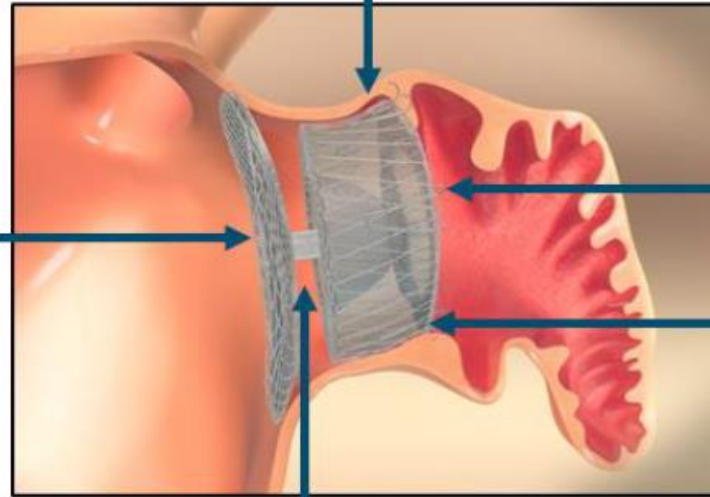


Disc

- Designed to **completely seal** the LAA at the orifice

Lobe

- Positioned **inside** the LAA neck
- Designed **to conform** to different sizes and shapes of LAA anatomy



Stabilizing Wires

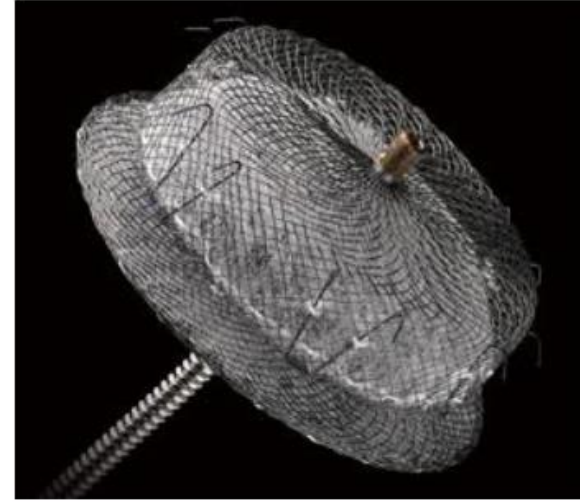
- **Engage** with the wall of the LAA
- **Help** hold the device in place

Waist

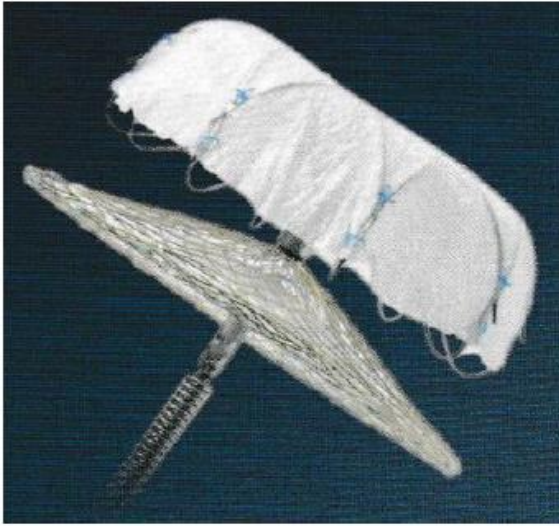
- **Maintains tension** between lobe and disc
- **Flexible connection** allows device to self-orient



**Boston
Scientific**
WATCHMAN



Abbott
AMULET



**Lifetech
Scientific**
LAmbre



**Boston
Scientific**
**WATCHMAN
FLX**

Protect AF Trial

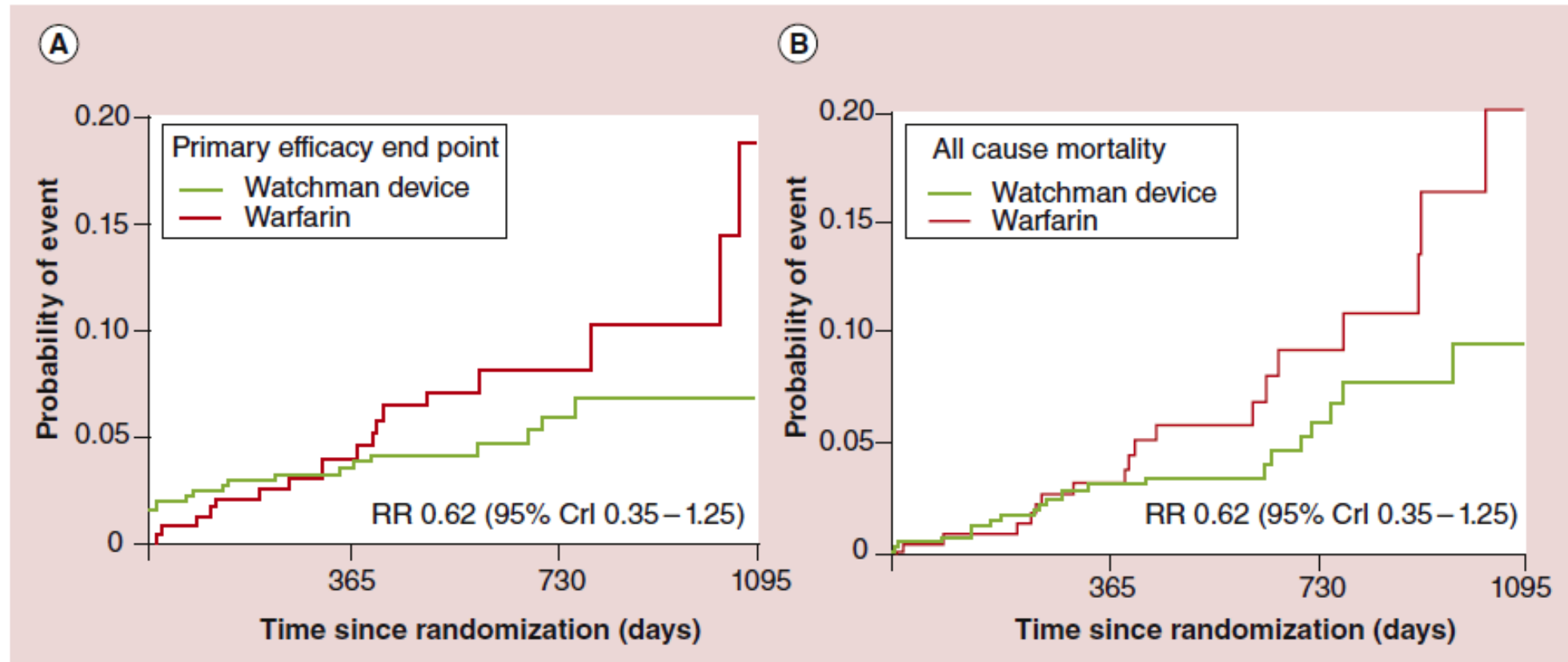
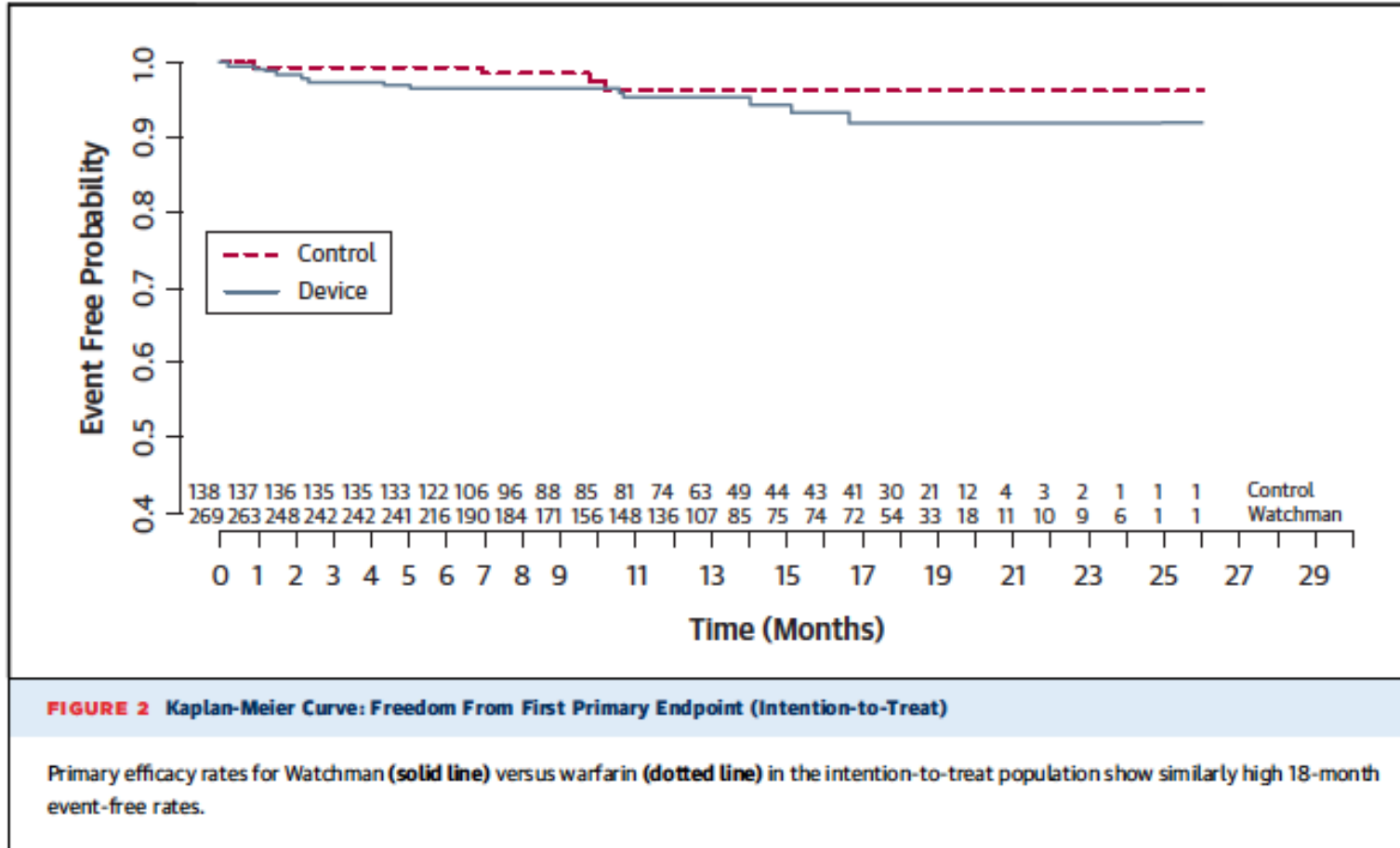


Figure 3. Protect AF Trial 1065 patient year analysis. (A) Primary efficacy end point was defined as a composite of stroke, systemic embolism, and CV death; **(B)** All-cause mortality. Reproduced with permission from [20].

PREVAIL TRIAL



PREVAIL TRIAL

TABLE 5 Safety Coprimary Endpoint Results and Events by Type
(Intention-to-Treat): Device Group Only

	% (n/N)	95% CrI
Safety primary endpoint results	2.2% (6/269)	2.652%
	No. of Events	% of Subjects
Safety events by type		
Device embolization	2	0.7
Arteriovenous fistula	1	0.4
Cardiac perforation	1	0.4
Pericardial effusion with cardiac tamponade	1	0.4
Major bleed requiring transfusion	1	0.4
Abbreviation as in Table 2.		

PRAGUE 17 Trial

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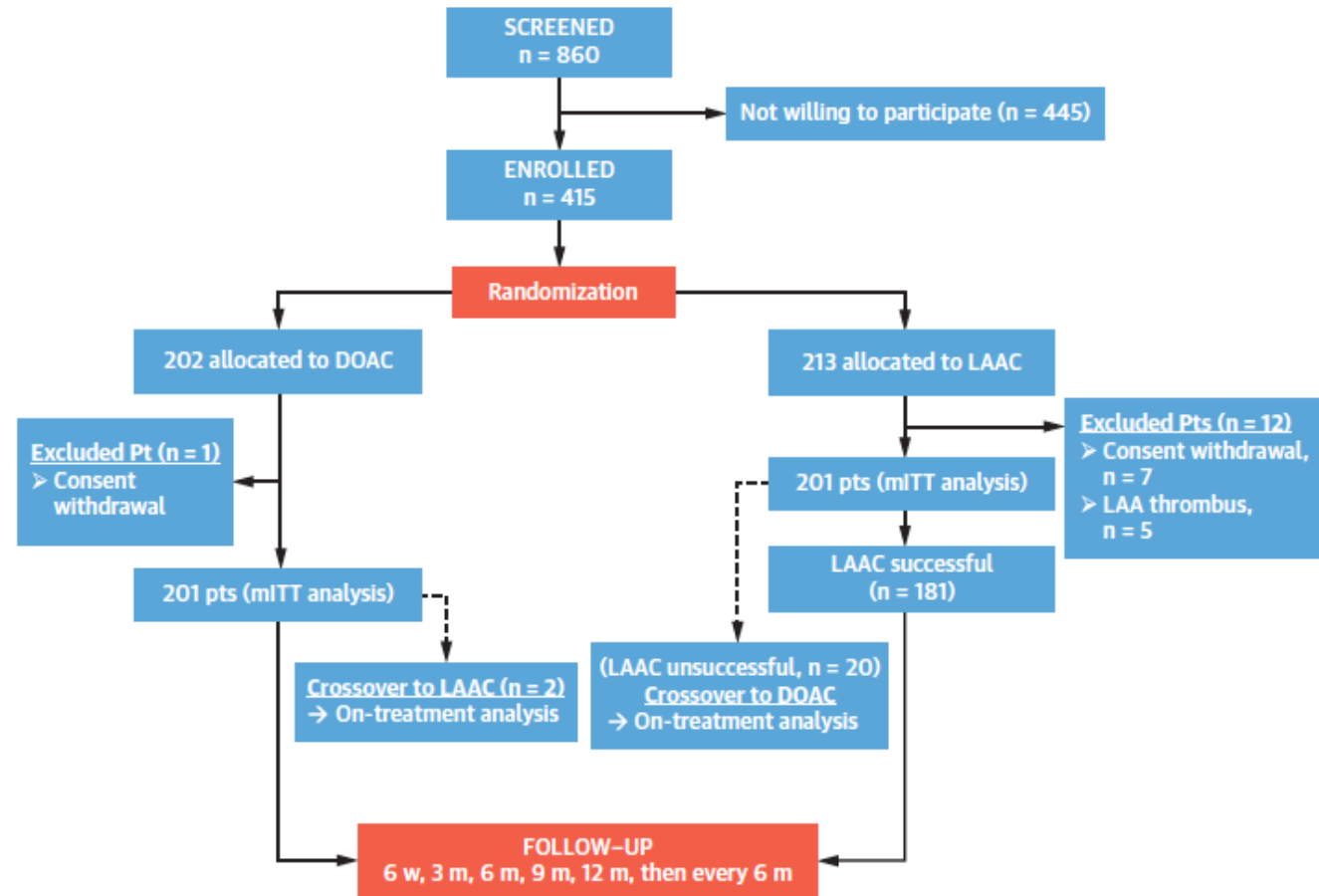
Left Atrial Appendage Closure Versus Direct Oral Anticoagulants in High-Risk Patients With Atrial Fibrillation



Pavel Osmancik, MD, PhD,^a Dalibor Herman, MD, PhD,^a Petr Neuzil, MD, CSc,^b Pavel Hala, MD,^b Milos Taborsky, MD, CSc,^c Petr Kala, MD, PhD,^d Martin Poloczek, MD,^d Josef Stasek, MD, PhD,^e Ludek Haman, MD, PhD,^e Marian Branny, MD, PhD,^f Jan Chovancik, MD,^f Pavel Cervinka, MD, PhD,^g Jiri Holy, MD,^g Tomas Kovarnik, MD, PhD,^h David Zemanek, MD, PhD,^h Stepan Havranek, MD, PhD,^h Vlastimil Vancura, MD, PhD,ⁱ Jan Opatrny, MD,ⁱ Petr Peichl, MD, PhD,^j Petr Tousek, MD, PhD,^a Veronika Lekesova, MD,^b Jiri Jarkovsky, RNDr, PhD,^k Martina Novackova, MGR,^k Klara Benesova, MGR,^k Petr Widimsky, MD, DrSc,^{a,*} Vivek Y. Reddy, MD,^{b,l,*}
on behalf of the PRAGUE-17 Trial Investigators

PRAGUE 17 Trial

FIGURE 1 Patient CONSORT Diagram



Flow diagram of the progress through the study (enrollment, allocation, exclusion or withdrawal, and follow-up). CONSORT = Consolidated Standards of Reporting Trials; DOAC = direct oral anticoagulant; LAAC = left atrial appendage closure; m = months; mITT = modified intention-to-treat; Pt = patient; Pts = patients; w = weeks.

TABLE 1 Baseline Characteristics and Risk Factors of Participants

	DOAC (n = 201)	LAAC (n = 201)	Missing Values
Demographics			
Age, yrs	73.2 ± 7.2	73.4 ± 6.7	—
<75	122 (60.7)	116 (57.7)	—
>75	79 (39.3)	85 (42.3)	—
Male	130 (64.7)	134 (66.7)	—
Weight, kg	88.1 ± 16.2	86.9 ± 17.6	—
Clinical history			
AF type			
Paroxysmal	67 (33.3)	53 (26.4)	—
Persistent	46 (22.9)	47 (23.4)	—
Long-standing persistent	16 (8.0)	18 (9.0)	—
Permanent	72 (35.8)	83 (41.3)	—
CHA ₂ DS ₂ -VASc	4.7 ± 1.5	4.7 ± 1.5	—
CHA ₂ DS ₂ -VASc ≤3	50 (24.9)	48 (23.9)	—
CHA ₂ DS ₂ -VASc = 4	40 (19.9)	47 (23.4)	—
CHA ₂ DS ₂ -VASc = 5	57 (28.4)	50 (24.9)	—
CHA ₂ DS ₂ -VASc ≥6	54 (26.9)	56 (27.9)	—
HAS-BLED	3.0 ± 0.9	3.1 ± 0.9	—
Heart failure	90 (44.8)	88 (43.8)	—
Hypertension	186 (92.5)	186 (92.5)	—
Diabetes mellitus	90 (44.8)	73 (36.3)	—
History of cardioembolic event	69 (34.3)	73 (36.3)	—
Of which stroke	63 (91.3)	66 (90.4)	—
History of MI	39 (19.4)	30 (14.9)	—
Randomized at experienced centers	140 (69.7)	141 (70.1)	—
Prior antithrombotic treatment			
Warfarin	104 (51.7)	85 (42.3)	—
DOACs	55 (27.4)	66 (32.8)	—
If no OAC, new AF appearance	30 (71.4)	38 (76)	—
Aspirin	32 (15.9)	39 (19.4)	—
Clopidogrel	11 (5.5)	17 (8.5)	—
Dual antiplatelet treatment	6 (3.0)	7 (3.5)	—
Other (low-dose LMWH, none)	19 (9.5)	24 (11.9)	—

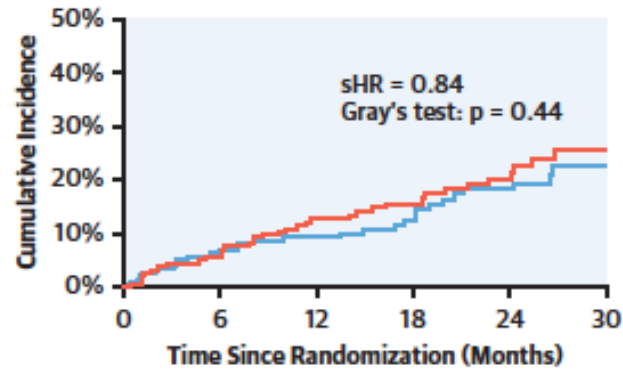
TABLE 2 Procedural Characteristics of the LAAC Group (N = 181)

Procedure duration, min	60 (45–85)
Fluoroscopy, min	11 (6–16)
Device type	
Amulet	111 (61.3)
Watchman	65 (35.9)
Watchman-FLX	5 (2.8)
Procedures requiring >1 device	17 (9.4)
Size of the final device	
Amulet	25.5 ± 4.1
Watchman	27.3 ± 3.8
Watchman-FLX	26.4 ± 1.3
Leak on the device by TEE or ICE imaging	7 (3.9)
Qualitative assessment of device position*	
Optimal	172 (95.0)
Suboptimal	7 (3.9)
Poor	2 (1.1)
Temporary thrombus during procedure†	2 (1.1)
Ultrasound navigation	
TEE	92 (50.8)
ICE	74 (40.9)
TEE + ICE	15 (8.3)
Sedation	
General anesthesia	55 (30.4)
Deep analgesedation	28 (15.5)
Mild analgesedation	98 (54.1)
Mild pericardial effusion (post-procedural)‡	4 (2.2)
Antithrombotic treatment at discharge	
Aspirin	149 (82.3)
Clopidogrel	149 (82.3)
DOAC	20 (11.1)
Warfarin	9 (5.0)
LMWH	9 (5.0)

Values are median (interquartile range) or (%). *n = 181. †n = 181. ‡n = 181.

PRAGUE 17 Trial

FIGURE 2 Primary Endpoint



No. at Risk*

— LAAC 201 (0) 178 (1) 144 (3) 107 (6) 74 (6) 41 (7)
— DOAC 201 (0) 181 (0) 136 (1) 102 (2) 67 (4) 32 (4)

	Primary Endpoint – CIF (95% CI)				
	6M	12M	18M	24M	30M
LAAC	7.0% (3.5% to 10.6%)	9.4% (5.2% to 13.5%)	12.3% (7.4% to 17.2%)	18.4% (12.0% to 24.7%)	22.5% (14.9% to 30.2%)
DOAC	5.5% (2.3% to 8.6%)	12.7% (7.9% to 17.5%)	15.6% (10.2% to 21.0%)	20.1% (13.7% to 26.5%)	25.6% (17.6% to 33.6%)

Cumulative incidence function for the primary endpoint in the presence of competing risk (noncardiovascular death) in the mITT population. *Number of patients who are free of an event is supplemented (in parentheses) by number of patients with competing risk up to given time. CI = confidence interval; CIF = cumulative incidence function; sHR = subdistribution hazard ratio; other abbreviations as in Figure 1.

TABLE 3 Incidence of Composite Primary Endpoint and its Components in the Presence of Competing Risk (Noncardiovascular Death for Primary Endpoint and Cardiovascular Death, All-Cause Death for Other Endpoints) in the Intention-to-Treat Populations

	DOAC (n = 201)			LAAC (n = 201)			Subdistribution Hazard Ratio (95% CI)	p Value	p Value for Noninferiority
	No. of Patients With Event	No. Events	Event Rate/Yr	No. of Patients With Event	No. Events	Event Rate/Yr			
Primary endpoint	41	47	13.42	35	38	10.99	0.84 (0.53–1.31)	0.44	0.004
Cardiovascular death	15	15	4.28	11	11	3.18	0.75 (0.34–1.62)		
All stroke/TIA	9	9	2.57	9	9	2.60	1.00 (0.40–2.51)		
Ischemic stroke/TIA	8	8	2.28	9	9	2.60	1.13 (0.44–2.93)		
Systemic embolism	1	1	0.29	0	0	0.00	—		
Procedure/device related complications	—	—	—	9	9	2.60	—		
ISTH major/nonmajor bleeding	22	26	7.42	18	19	5.50	0.81 (0.44–1.52)		
ISTH major/nonmajor bleeding not related to device	22	26	7.42	12	13	3.76	0.53 (0.26–1.06)		

CI — confidence interval; ISTH — International Society on Thrombosis and Hemostasis; TIA — transient ischemic attack; other abbreviations as in Table 1.

TABLE 4 LAAC Device- or Procedure-Related Complications

	Early (≤7 Days) Occurrence	Late (>7 Days) Occurrence	Total
Pericardial effusion	0	2*	2
Device embolization	1†	0	1
Device-related death	0	1‡	1
Procedure-related death	1‡	0	1
Vascular complications	2§	0	2
Other complications	0	2	2
Total	4	5	9

*Late pericardial effusions occurred at 89 and 194 days after implantation with the Amulet device. One was treated with pericardiocentesis and the other conservatively; both patients had good outcomes. †Acute device embolization during the procedure, requiring surgical removal. ‡See details in the Supplemental Appendix. §Includes 1 femoral pseudoaneurysm and 1 large groin hematoma, both treated with vascular surgery. ||One device malposition at the left inferior pulmonary vein, with successful removal and reimplantation. One large device-related thrombus was diagnosed by TEE imaging 113 days after implantation. The thrombus was considered potentially malignant (although no embolic event had occurred), so surgical removal was successfully performed.

LAAC — left atrial appendage closure.

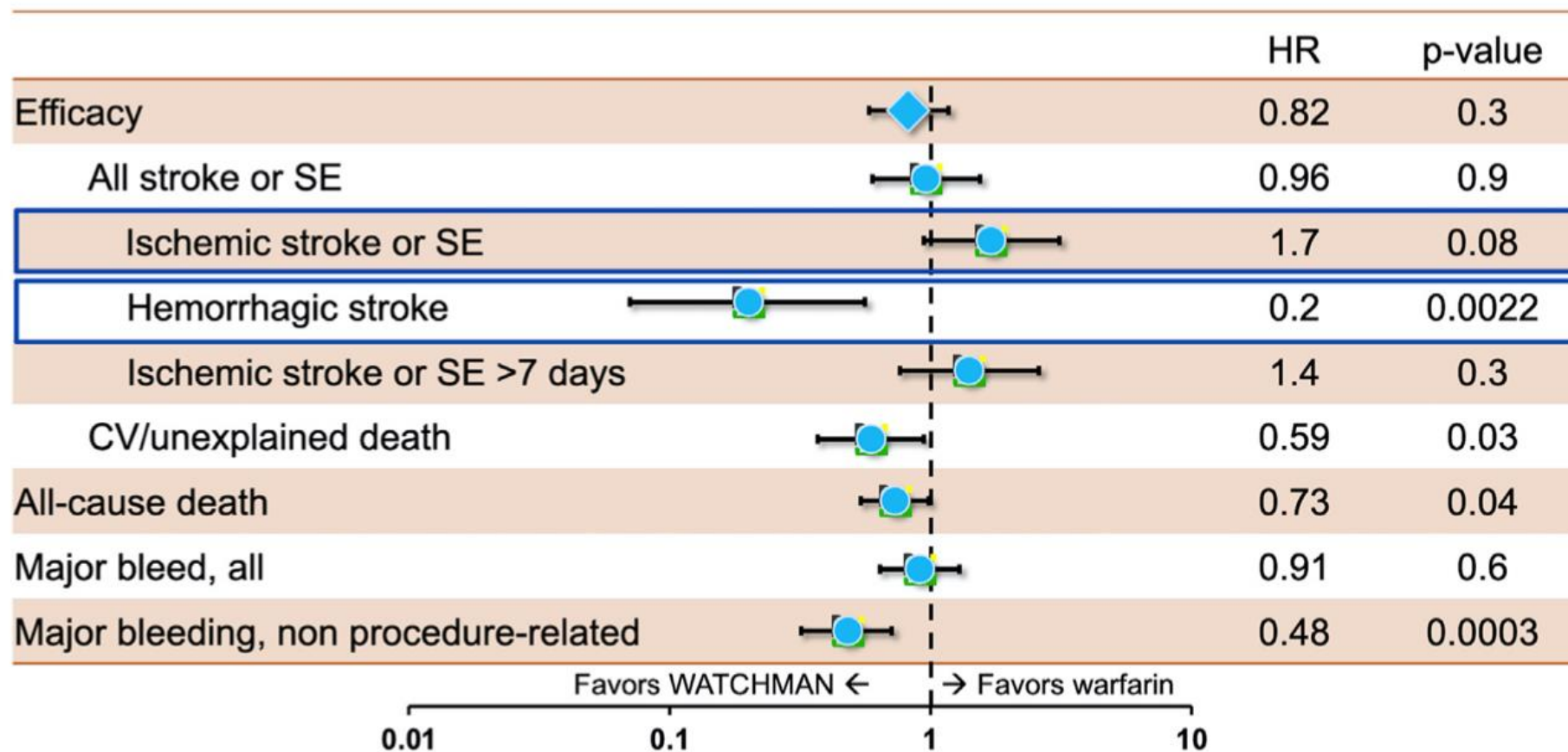
TABLE 1 Key Findings of the LAAO Randomized Clinical Trials

Trial	Design	Patients	Key Findings
PROTECT AF (19683639)	Noninferiority Watchman vs warfarin	Device (n = 463) Control (n = 244)	- The primary efficacy endpoint (stroke, SE, and CV/unexplained death) event rate was 3.0 per 100 patient-years (95% CrI: 1.9-4.5) in the device group and 4.9 per 100 patient-years (2.8-7.1) in the control group (RR: 0.62, 95% CrI: 0.35-1.25) - Primary safety events were more frequent in the intervention group (7.4 per 100 patient-years, 95% CrI: 5.5-9.7 vs 4.4 per 100 patient-years, 95% CrI: 2.5-6.7; RR: 1.69, 1.01-3.19)
PREVAIL (24998121)	Noninferiority Watchman vs warfarin	Device (n = 269) Control (n = 138)	- First coprimary efficacy endpoint (stroke, SE, and CV/unexplained death) event rate at 18 mo was 0.064 in the device group vs 0.063 in the control group (RR 1.07 [95% CrI: 0.57-1.89])^a - Second coprimary efficacy endpoint (stroke or SE >7 d after randomization) was 0.025 vs 0.020 (risk difference 0.005 [95% CrI: -0.019 to 0.027]) - Adverse events lower than PROTECT AF (4.2% vs 8.7%; <i>P</i> = 0.004)
PRAGUE-17 (32586585)	Noninferiority LAAO device vs DOAC	Device (n = 201) Control (n = 201)	- The annualized rate of the primary composite outcome (stroke, TIA, SE, CV death, major or nonmajor clinically relevant bleeding, or procedure-/device-related complications) was 10.99% with LAAO and 13.42% with DOAC (sHR: 0.84; 95% CI: 0.53-1.31; <i>P</i> = 0.44; <i>P</i> = 0.004 for noninferiority) - Major LAAO-related complications occurred in 9 (4.5%) patients

^aDid not achieve the prespecified criteria noninferiority (upper boundary of 95% CrI ≥ 1.75).

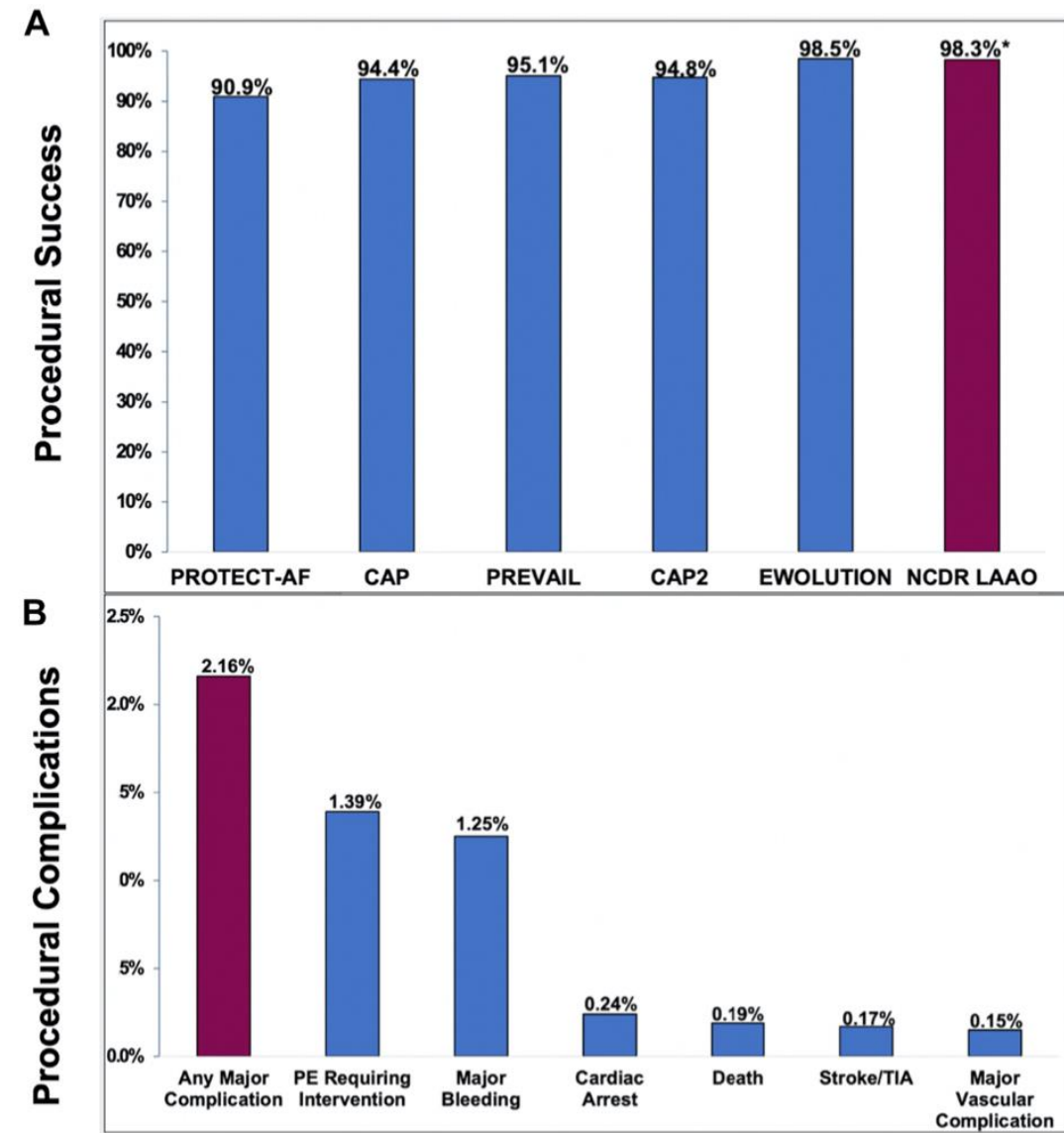
CrI = credible interval; CV = cardiovascular; DOAC = direct oral anticoagulant; LAAO = left atrial appendage occlusion; PREVAIL = Evaluation of the WATCHMAN Left Atrial Appendage (LAA) Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy); PRAGUE = Left Atrial Appendage Closure vs. Novel Anticoagulation Agents in Atrial Fibrillation; PROTECT AF = WATCHMAN Left Atrial Appendage System for Embolic PROTECTION in Patients With Atrial Fibrillation; RR = rate ratio; SE = systemic embolization; sHR = subdistribution hazard ratio; TIA = transient ischemic attack.

FIGURE 2 Patient-Level Meta-analysis Illustrating 5-Year Pooled Outcomes of PROTECT AF and PREVAIL Trials



CV = cardiovascular; HR = hazard ratio; PREVAIL = Evaluation of the WATCHMAN Left Atrial Appendage (LAA) Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy); PROTECT AF = WATCHMAN Left Atrial Appendage System for Embolic PROTECTION in Patients With Atrial Fibrillation; SE = systemic embolization.

FIGURE 3 Procedural Outcomes in the NCDR LAAO Registry



(A) Procedural success in LAAO Registry compared with the early LAAO trials and their nested registries. **(B)** Procedural complications in the LAAO Registry. CAP = continuous access to PROTECT AF registry; EWOLUTION = Registry on WATCHMAN Outcomes in Real-Life Utilization); PE = pericardial effusion; TIA = transient ischemic attack.

LAAO guidelines recommendations



- Consensus statements/guidelines from ACC/HRS/SCAI + EHRA/EAPCI – and, most recently, from the ESC (AF guidelines, august 2016) provide *some* guidance on the use of LAAO in selected patients:

LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause).	IIb	B
--	-----	---

TABLE 2 Current U.S. and European Guidelines on the Use of Percutaneous LAAO Devices

Society, Year	COR	LOE	Recommendation
AHA/ACC/HRS, 2019	IIb	B-NR	Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (Clinical trial data and FDA approval of the Watchman device necessitated this recommendation.)
ESC/EACTS, 2020	IIb	B	LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (eg, intracranial bleeding without a reversible cause)

ACC = American college of cardiology; AF = atrial fibrillation; AHA = American heart association; COR = class of recommendation; EACTS = European Association for Cardio-Thoracic Surgery; ESC = European Society of Cardiology; FDA = Food and Drug Administration; HRS = Heart Rhythm Society; LAA = left atrial appendage; LOE = level of evidence.

TABLE 3 Overview of Current and Planned Randomized Trials on Percutaneous LAAO

Study Name/Sponsor	Trial Size	Trial Objective	Intervention	Control	Primary Outcome Measures	Follow-Up
CHAMPION-AF (NCT04394546) Boston Scientific	3,000	Assess the role of LAAO in NVAF patients who are eligible for long-term DOAC	LAAO with Watchman/FLX	DOAC	Composite of ischemic stroke or SE; Composite of ischemic stroke, SE, or CV death (NI); nonprocedural major bleeding (S)	3 y
CATALYST (NCT04226547) Abbott	2,650	Assess the role of LAAO in NVAF patients who are eligible for long-term DOAC	LAAO with Amulet	DOAC	Composite of ischemic stroke or SE; Composite of ischemic stroke, SE, or CV death (NI); nonprocedural major bleeding (S)	3 y
OCCLUSION-AF (NCT03642509) Aarhus University	750	Assess the role of LAAO in NVAF patients who are eligible for long-term DOAC	LAAO with Amulet or Watchman	DOAC	Composite of stroke, SE, major bleeding, and all-cause mortality	5 y
CLOSURE-AF (NCT03463317) Charite University	1,512	Assess the role of LAAO in NVAF patients with high bleeding risk or contraindication to OAC	CE-mark/approved LAAO device	DOAC or VKA	Composite of stroke, SE, major bleeding (BARC type 3-5), CV, or unexplained death	2 y
STROKECLOSE (NCT02830152) Nordic Universities	750	Assess the role of LAAO in NVAF patients with an ICH within 12 mo	LAAO with Amulet	Medical therapy	Composite of stroke, SE, major bleeding, and all-cause mortality	5 y
CLEARANCE (NCT04298723) Jena University	550	Assess the role of LAAO in NVAF patients with a history of ICH	LAAO with Watchman FLX	Medical therapy	Composite of stroke, SE, BARC type 2-5 bleeding, and CV or unexplained death	2 y
COMPARE-LAAO (NCT04676880) R&D Cardiologie	609	Assess the role of LAAO in NVAF patients with contraindication for OAC	LAAO with Watchman FLX or Amulet	Antiplatelets or no therapy	Time to first occurrence of stroke; Time to first occurrence of the stroke, TIA, or SE; Procedural complications	5 y
OPTION (NCT03795298) Boston Scientific	1,600	Assess the role of LAAO in NVAF patients undergoing catheter ablation for AF	LAAO with Watchman/FLX	DOAC	Composite of stroke, death, or SE (NI); nonprocedural major bleeding (S)	3 y
WATCH-TAVR (NCT03173534) Boston Scientific	350	Assess the role of LAAO in NVAF patients undergoing TAVR	TAVR + LAAO with Watchman	TAVR + medical therapy	All-cause mortality, stroke, and bleeding	1 y
CONFORM ^a (NCT05147792) Conformal Medical	1,400	Assess the performance of the CLAAS device (head-to-head device trial)	LAAO with CLASS device	LAAO with Watchman FLX or Amulet	Procedure-related complications, all-cause death, major bleeding (12 mo); ischemic stroke or SE (18 mo)	1.5 y
WAVECREST2 ^a (NCT03302494) Coherex Medical	1,550	Assess the performance of the WaveCrest device (head-to-head device trial)	LAAO with WaveCrest	LAAO with Watchman	Procedure-related complications (45 d), all-cause death; major bleeding; ischemic stroke or SE (24 mo)	2 y

^aActive, not yet recruiting.

BARC = Bleeding Academic Research Consortium; CE = Conformite Europeenne; CLAAS = Conformal; CV = cardiovascular; DOAC = direct oral anticoagulant; ICH = intracranial hemorrhage; LAAO = left atrial appendage occlusion; NI = noninferiority; NVAF = nonvalvular atrial fibrillation; OAC = oral anticoagulation; S = superiority; SE = systemic embolization; TAVR = transcatheter aortic valve replacement; TIA = transient ischemic attack; VKA = vitamin-K antagonist.

LAAO contraindications

- **AF with low risk of stroke, e.g. CHA2DS2-VASc ≤ 1**
- **Valvular heart disease, e.g. mitral stenosis**
- **Other indications for long-term OAC: VTE, mechanical prosthetic valve, thrombi in left atrium or ventricle.**
- **Contraindications for transseptal puncture, e.g. thrombus/tumour/infection, (atrial septum closure device).**

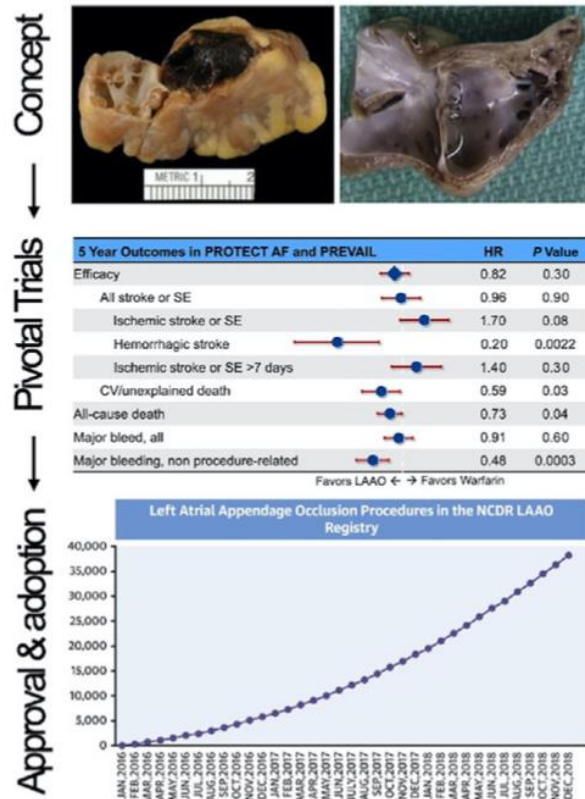
MBS Guidelines

Transcatheter occlusion of left atrial appendage, and cardiac catheterisation performed by the same practitioner, for stroke prevention in a patient who has non-valvular atrial fibrillation and a contraindication to life-long oral anticoagulation therapy, and is at increased risk of thromboembolism demonstrated by:

- (a) a prior stroke (whether of an ischaemic or unknown type), transient ischaemic attack or non-central nervous system systemic embolism; or
- (b) at least 2 of the following risk factors:
 - (i) an age of 65 years or more;
 - (ii) hypertension;
 - (iii) diabetes mellitus;
 - (iv) heart failure or left ventricular ejection fraction of 35% or less (or both);
 - (v) vascular disease (prior myocardial infarction, peripheral artery disease or aortic plaque)

CENTRAL ILLUSTRATION Current Advances and Remaining Challenges With LAAO

Evolution of LAAO



Remaining Challenge With LAAO

Efficacy Data



Current Status

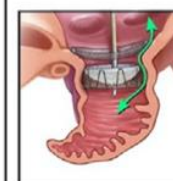
Limited clinical trial data

Future Directions

More RCTs ongoing

↑ Large registry analyses

Device Leak



Current Status

Leaks → more events

Future Directions

Newer devices & improved techniques

Device-Related Thrombus



Current Status

2%-4% DRT rate

Future Directions

Prediction tools

Mitigation strategies

Procedural Optimization



Current Status

TEE, GA, ↑ SDD

Future Directions

CTA, ICE

Performance metrics

Alkhouli M, et al. JACC Adv. 2022;1(5):100136.

CCT = cardiac computed tomography; DRT = device related thrombus; GA = general anesthesia; ICE = intracardiac echo; LAAO = left atrial appendage occlusion; RCT = randomized controlled trial; SDD = same day discharge; TEE = transesophageal echo.

FIGURE 4 Predictors of DRT in the LAAO Literature

Published Predictors of DRT

Clinical Characteristics
Anatomy/Function/Blood

Age, prior stroke or TIA, coagulopathy, permanent AF, low LVEF, renal failure, vascular disease

Procedural Factors
Device/Implant/Leaks

LAA diameter, implant depth, procedural complications (effusion)

Post-Procedure Tx
OAC/APT

? Antiplatelets therapy only

AF = atrial fibrillation; APT = antiplatelet therapy; DRT = device-related thrombus; LAA = left atrial appendage; LVEF = left ventricular ejection fraction; OAC = oral anticoagulation; TIA = transient ischemic attack.

FIGURE 7 Mechanism of Peri-Device Leak After Left Atrial Appendage Occlusion With the Watchman Device

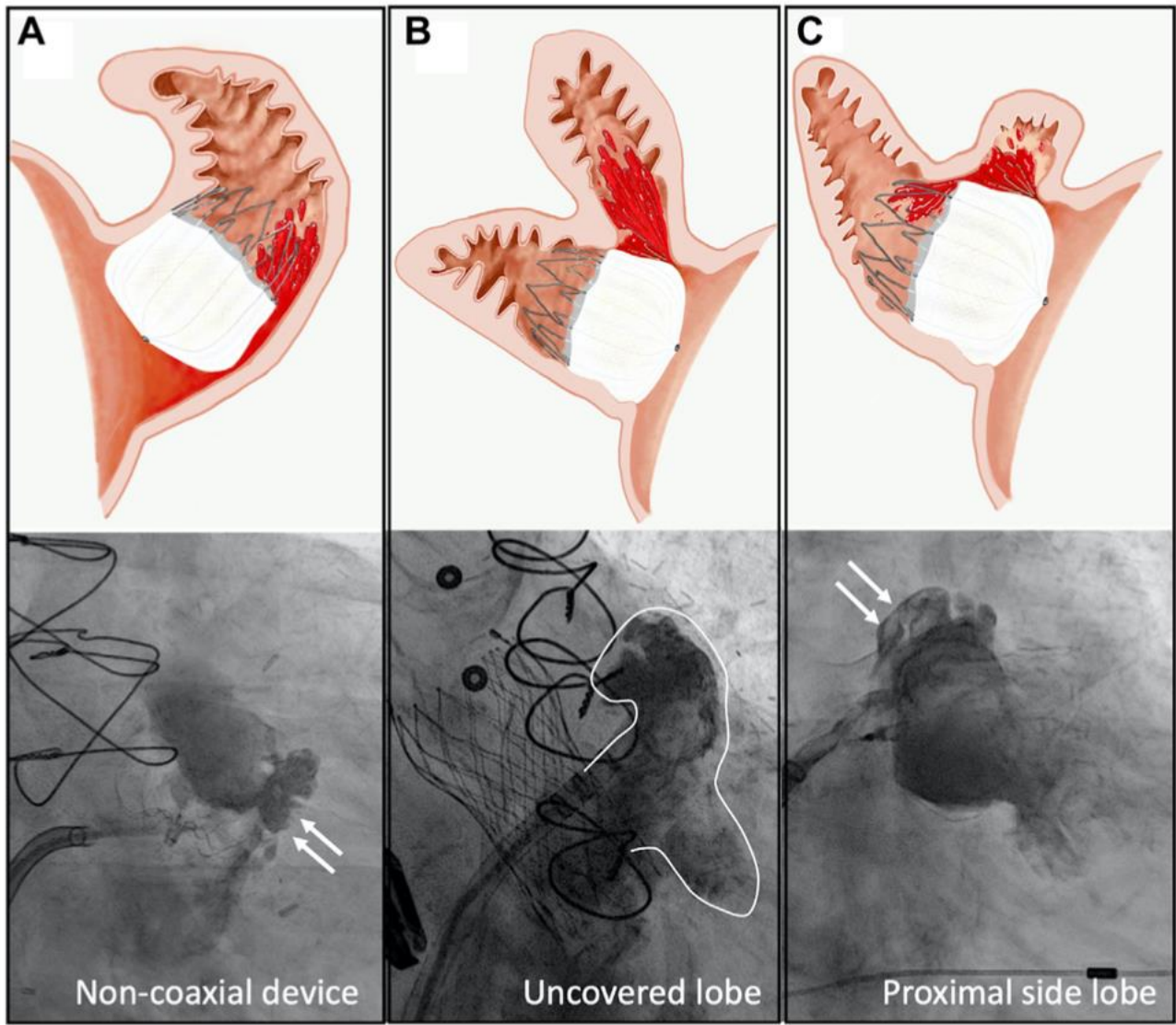
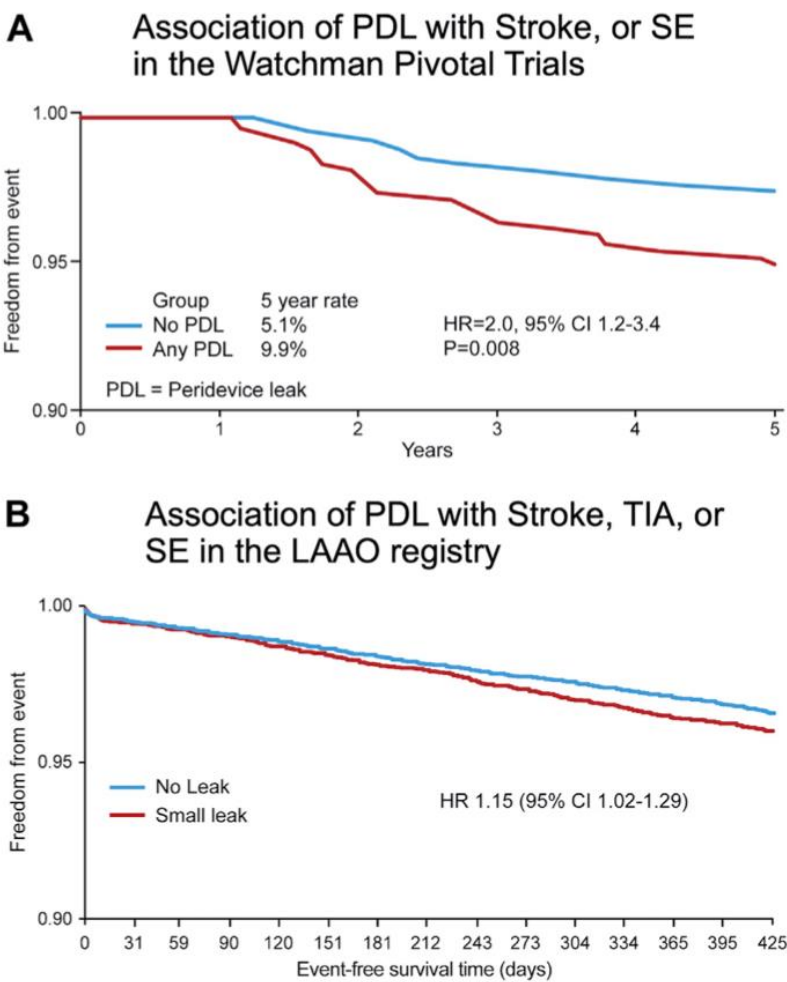


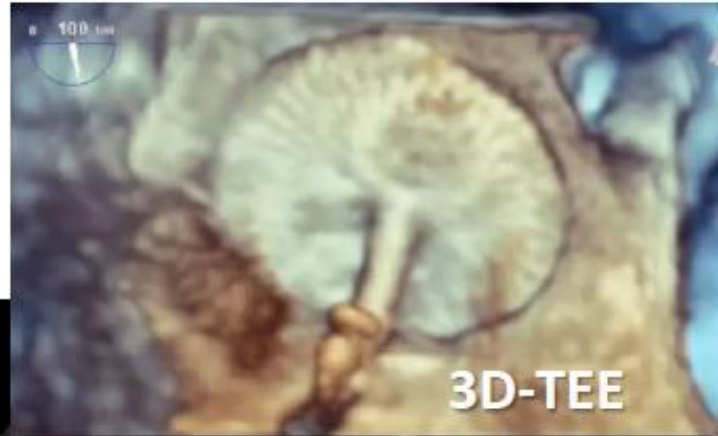
Illustration of the different mechanisms of peri-device leaks. **(A)** Point to the non-coaxial device (**white arrows**). **(B)** Uncovered lobe. **(C)** Point to the proximal side lobe (**white arrows**).

FIGURE 8 Clinical Impact of Peri-Device Leak After Left Atrial Appendage Occlusion With the Watchman Device

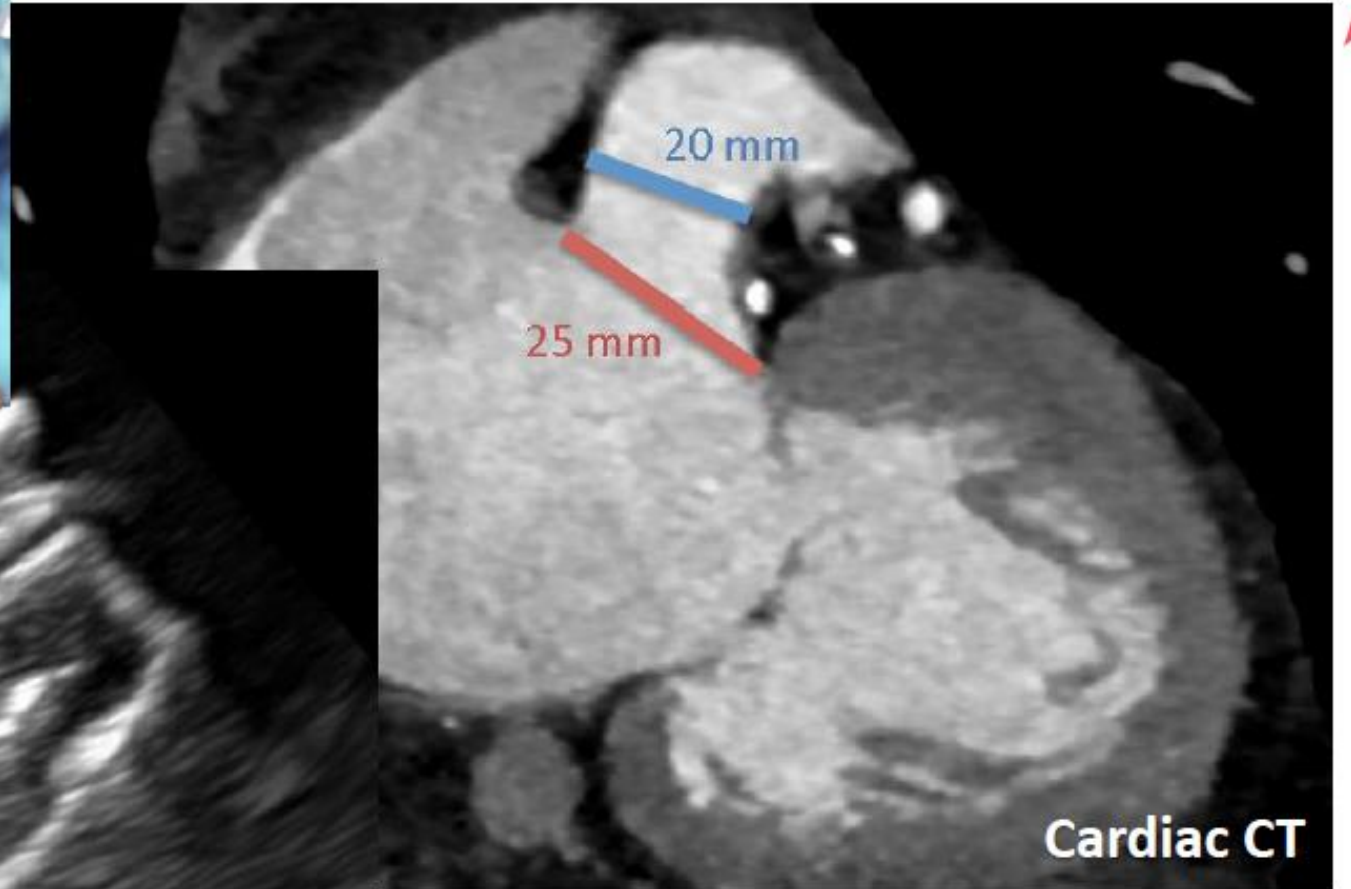


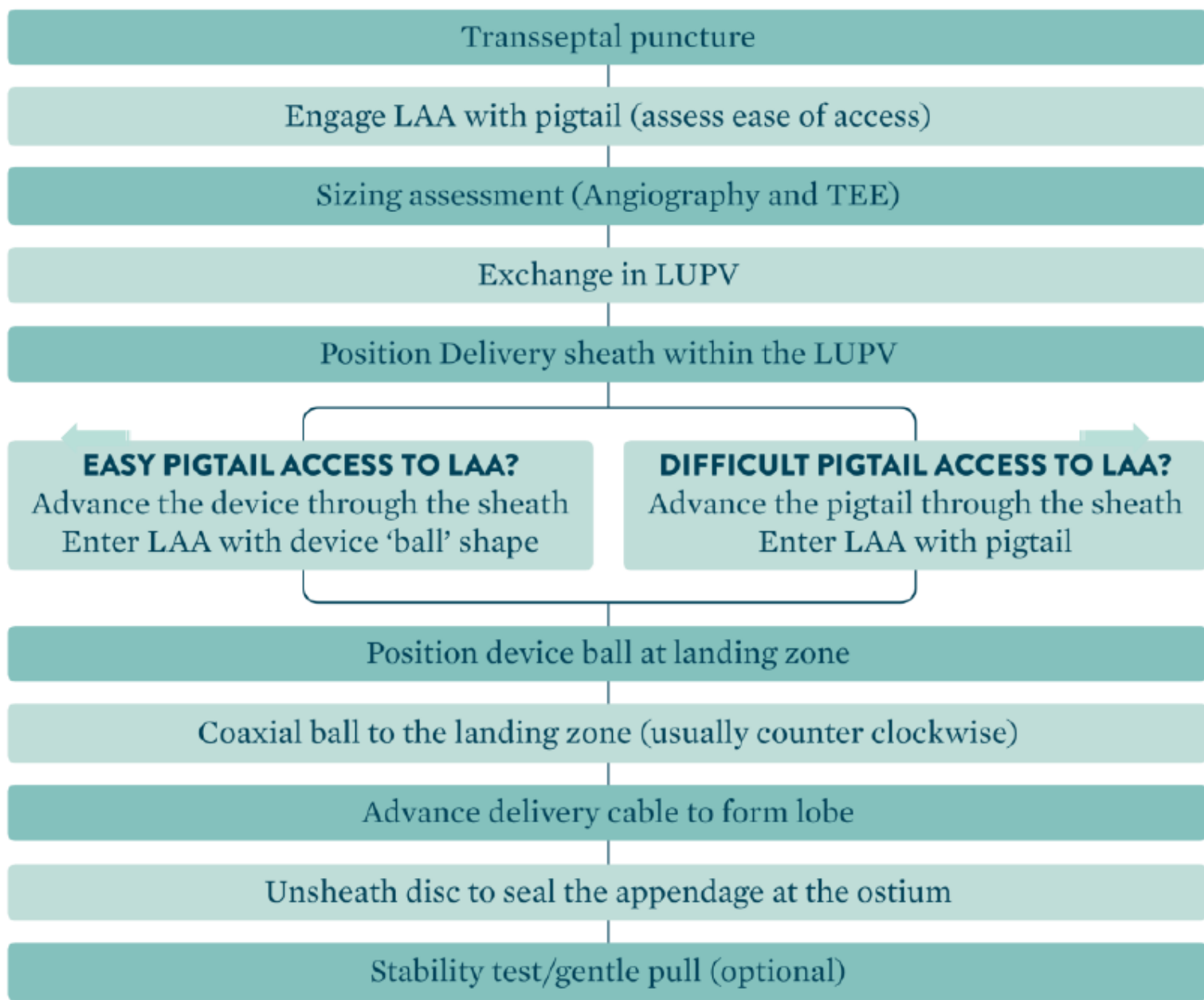
(A) Data from the Pivotal Trial (PROTECT AF, PREVAIL, and CAP-1). **(B)** Data from the NCDR LAAO Registry. CI = confidence interval; HR = hazard ratio; LAAO = left atrial appendage occlusion; PDL = peridevice leak; PREVAIL = Evaluation of the WATCHMAN Left Atrial Appendage (LAA) Closure Device in Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy; PROTECT AF = WATCHMAN Left Atrial Appendage System for Embolic PROTECTION in Patients With Atrial Fibrillation; SE = systemic embolization; TIA = transient ischemic attack.

Imaging: cardiac CT, TEE, intra-cardiac echo

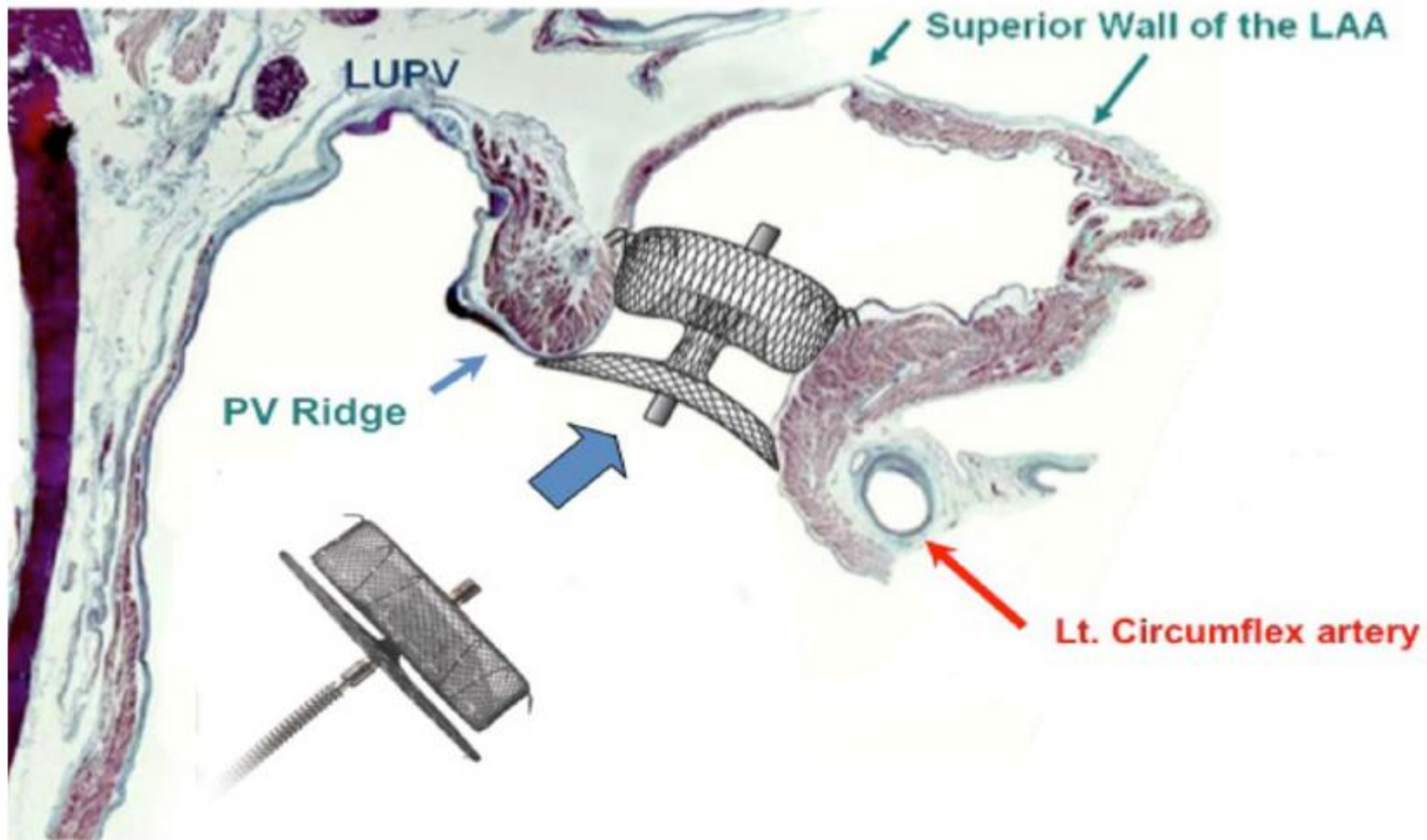


Intra-Cardiac Echo (ICE)

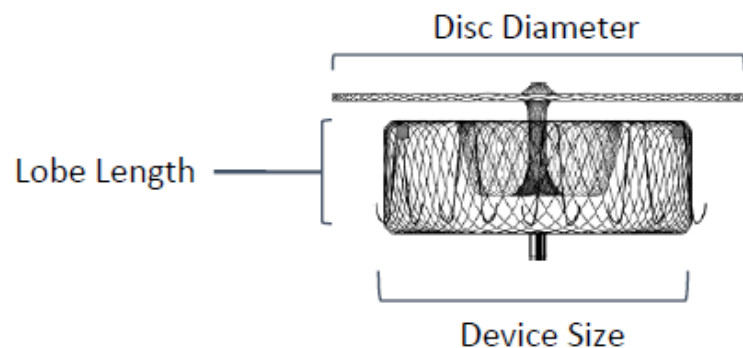




LAAO technique: sizing

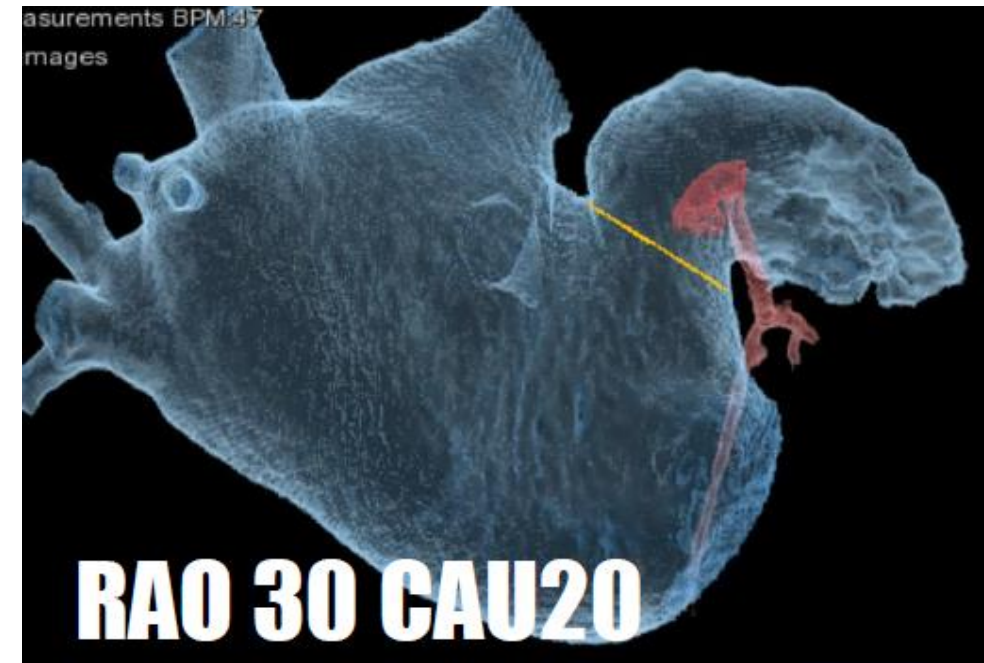
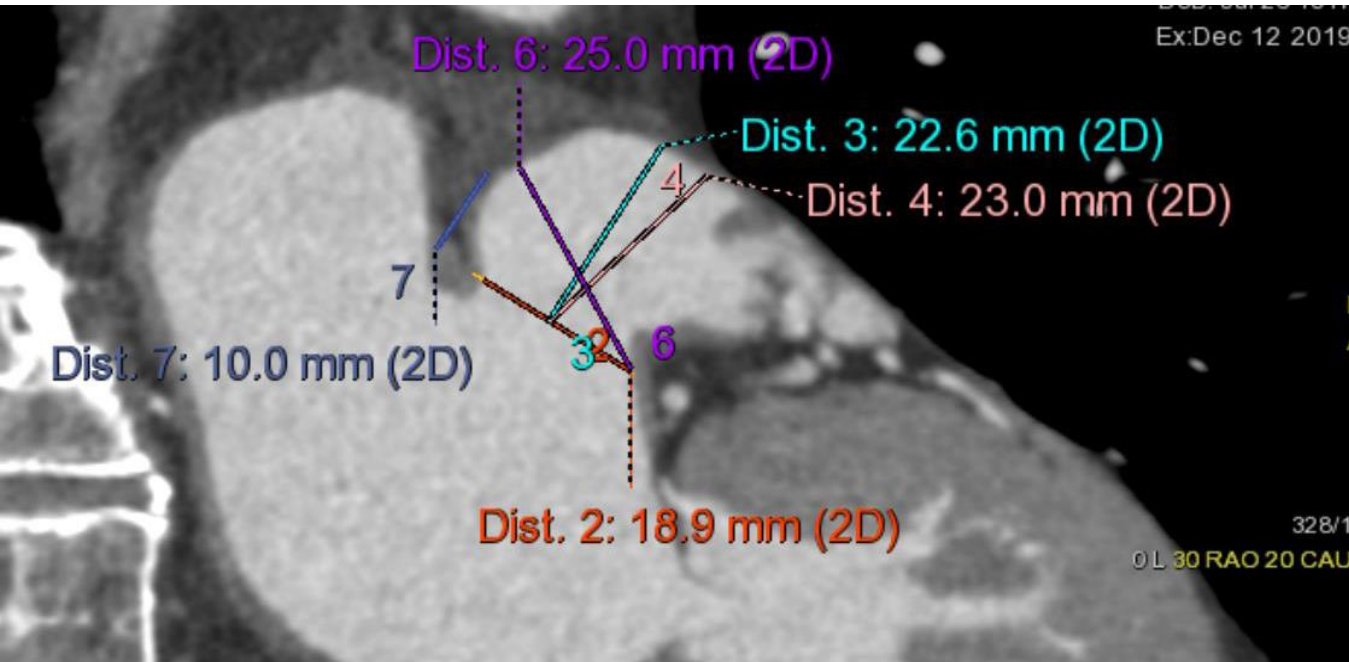


Maximum Landing Zone Width (mm)	Amulet™ Device Size	Lobe Length (mm)	Minimum LAA Depth (mm)	Disc Diameter (mm)	Sheath Diameter
11.0-13.0	16	7.5	≥ 10	22	12 F <i>or</i> 14 F (with adaptor)
13.0-15.0	18	7.5	≥ 10	24	
15.0-17.0	20	7.5	≥ 10	26	
17.0-19.0	22	7.5	≥ 10	28	
19.0-22.0	25	10	≥ 12	32	
22.0-25.0	28	10	≥ 12	35	14 F
25.0-28.0	31	10	≥ 12	38	
28.0-31.0	34	10	≥ 12	41	



Device Size Selection - Amulet

CT Pre Procedural Analysis



Overall structure
Re-construction
Re-measurement
Decide fluoroscopic angle

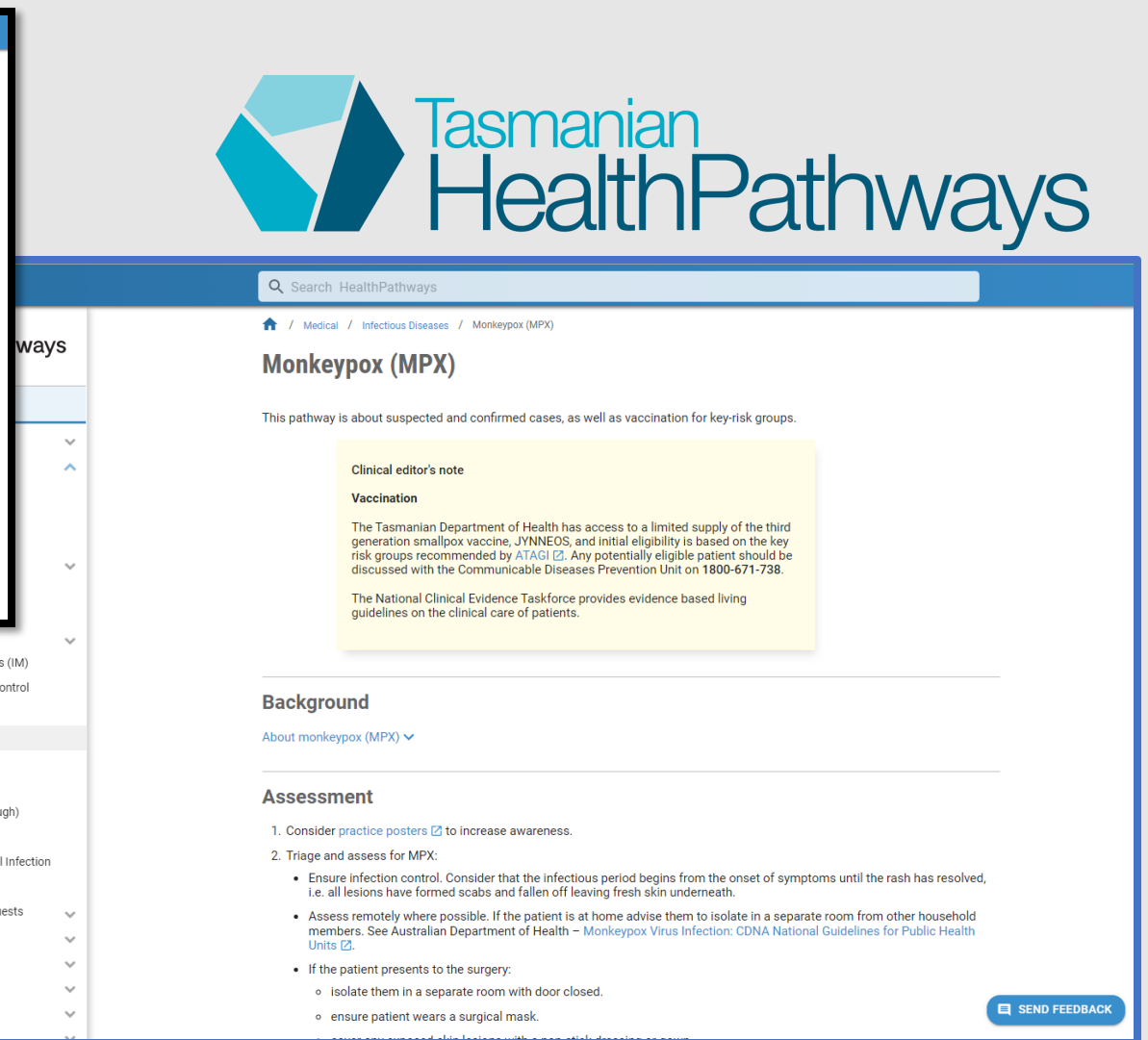




Tasmanian HealthPathways is a web-based information portal developed by Primary Health Tasmania. It is designed to help primary care clinicians plan local patient care through primary, community and secondary healthcare systems.



tasmania.communityhealthpathways.org



To gain access to HealthPathways, please email
healthpathways@primaryhealthtas.com.au



HEALTHPATHWAYS

CPD Events

Tuesday 12 May 2026 – Online and in person, 6.30pm to 8pm (in person registration from 6pm)
Multidisciplinary Care in Diabetes: The Cycle of Care and Beyond

Wednesday 20 May 2026 – 6.30pm to 8pm
Dementia Care for GPs: Behaviour Support, Services and Psychotropics

View more events...

Latest News

4 May
Diphtheria outbreak in northern Australia
Primary Health Tasmania has issued a *Primary Care Alert* for local health providers regarding a diphtheria outbreak in northern Australia. Read more [here](#).

9 March
PRECISE Genomics in Primary Care portal now live
The [PRECISE Genomics in Primary Care Portal](#) helps GPs quickly identify genetic red flags and make appropriate referrals. It offers concise fact sheets, e-learning, and practical guidance to embed genomics in everyday practice.

30 January
Infant formula recall: Sanulac Nutritionals Australia
Public Health Services at the Tasmanian Department of Health advises that Food Standards Australia New Zealand (FSANZ) have issued a food recall for 2 batches of infant formula produced by Sanulac Nutritionals Australia Pty Ltd. [Read more...](#)

22 December

Pathway Updates

Updated – 14 May
Pruritus (Itch)

Updated – 8 May
Shoulder Pain

NEW – 8 May
Acute Shoulder Trauma

Updated – 8 May
Shoulder Dislocation and Chronic Instability

Updated – 8 May
Fibroids

VIEW MORE UPDATES...



- ONLINE LEARNING HUB
- PRIMARY HEALTH TASMANIA
- RACGP RED BOOK
- FINDHELPTAS
- MBS ONLINE
- NPS MEDICINEWISE
- PBS
- TASMANIAN HEALTH DIRECTORY
- PRIMARY HEALTH TASMANIA EVENTS

About HealthPathways

- What is HealthPathways?
- How do I use HealthPathways?
- How do I send feedback on a pathway?

CPD Hours for HealthPathways Use by Specialist General Practitioners

About Continuing Professional Development (CPD)

The aim of the continuing professional development (CPD) requirements of the [Medical Board of Australia](#) is to support quality, lifelong learning for doctors that is relevant, effective, and evidence-based.

The 3 core elements of CPD are:

1. [CPD homes](#) – for quality assurance
2. [Professional development plans](#) – for purpose
3. [Different types of CPD](#) – for value

Using HealthPathways for CPD

HealthPathways is a source of contemporary and practical clinical information, localised to the geographical region of the medical practitioner. Application of knowledge contained within pathways to the individual patient provides an opportunity for reflection upon current understanding of the patient's clinical condition, and how it may be improved. This reflective learning can be self-reported as a CPD activity.

- Clinicians with an [individual HealthPathways account](#) can access a [CPD Reporting](#) tool to help log their HealthPathways CPD activity.

CPD reporting

Allows clinicians to:

- view an automatic log of time spent in HealthPathways (this log is private and secure).
- select specific logs relevant to their personal CPD, and add reflections and learning notes.
- generate and export a PDF report for easy submission to CPD Homes.

To access CPD Reporting, clinicians need to be logged into their [individual HealthPathways account](#), and then click in the secondary pane on the [right-hand side of the HealthPathways site](#).

- Clinicians without an individual HealthPathways account can still self-report time spent in HealthPathways as a reflective activity. To help reporting, reflective learning templates have been developed for both colleges:

ABOUT THIS PAGE

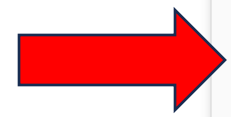
Page information

Topic ID: 1361051

CPD REPORTING

Add learning notes

Create a CPD report



Search results for **valve**

95 results found

[Heart Valve Disease](#)

[Asymptomatic Heart Valve Disease - Follow-up](#)

[Prosthetic Heart Valves - Follow-up](#)

See also Infective Endocarditis Prophylaxis.

[Postoperative Care of Cardiac Patients](#)

[Heart Murmurs in Adults](#)

This pathway is about new presentations of heart murmurs. See also: [Asymptomatic Heart Valve Disease - Follow Up](#) | [Prosthetic Heart Valves - Follow Up](#)

[Infective Endocarditis Prophylaxis](#)

[Warfarin Over-anticoagulation](#)

This pathway is about warfarin-associated bleeding and elevated INR without bleeding. See also: [Warfarin – Starting and Monitoring](#)

[Antithrombotics in Surgery or Other Procedures](#)

[Warfarin - Starting and Monitoring](#)

See also: [Warfarin Over-anticoagulation](#) | [Direct Oral Anti-coagulants \(DOACs\)](#)

[Cardiac Catheterisation Complications](#)

This pathway is about managing the most common complications that can occur after cardiac catheterisation.



Chest Pain



Presyncope and Syncope

Heart Failure



Heart Murmurs in Adults

Heart Valve Disease

Hyperlipidaemia and Familial
Hypercholesterolaemia

Infective Endocarditis Prophylaxis

Long QT Syndrome

Palpitations

Postoperative Care of Cardiac
Patients

Cardiology Requests



Dermatology



Diabetes



Diving and Hyperbaric Medicine

Heart Murmurs in Adults

1. Take a history:

- Ask about [symptoms suggesting an underlying cardiac abnormality](#) ▼.
- Check for [risk factors for structural heart disease](#) ▼.
- Consider [murmur in hyperdynamic states \(high cardiac output\)](#) ▼ (e.g., fever, pregnancy, anaemia, hyperthyroidism).

2. Examine the patient:

- Check [vital signs](#) ▼, height and weight, and calculate [BMI](#) ▼.
- Perform a thorough [cardiovascular examination](#) ▼.
- Consider features to distinguish benign murmurs from [pathological murmurs](#) ▼.
- Consider [significant causes of murmurs](#) ▼.

3. Investigation:

- If patient with soft [grade 1 to 2 mid-systolic murmur](#) ▼, asymptomatic, and with normal physical examination, consider [12-lead ECG](#) ▼. Look for left ventricular hypertrophy (LVH), right ventricular hypertrophy (RVH), arrhythmia.
- Chest X-ray is rarely helpful unless other indications exist.
- Arrange [echocardiogram](#) in all patients with:
 - diastolic or continuous murmur.
 - [high grade mid-systolic \(> grade 3\)](#) ▼, pansystolic, or late systolic murmurs.
 - radiation to neck or back, clicks, or extra heart sounds present.
 - any murmur with symptoms or clinical findings suggestive of heart disease.
 - any murmur with abnormal ECG or chest X-ray.
- Consider baseline FBE, C+Es/LFT, thyroid stimulating hormone (TSH), and lipids, and complete a [cardiovascular assessment](#).

Heart Murmurs in Adults

- Consider features to distinguish benign murmurs from [pathological murmurs](#) ^.

Pathological murmurs

A pathological murmur is more likely if:

- pansystolic, diastolic, or continuous.
- high grade (> 3/6).
- harsh sounding.
- high amplitude.
- widespread and/or radiating.
- abnormal pulses.
- associated click, abnormal S2, added heart sound (e.g., thrill, click).
- the patient has signs or symptoms of heart disease.

- Consider [significant causes of murmurs](#) ^.

Significant causes of murmur

Murmur source	Murmur features	Associated finding
Aortic stenosis	- Harsh late-peaking crescendo-decrescendo systolic murmur - Heard best at right 2nd intercostal space (ICS)	- Abnormal carotid upstroke - Diminished and delayed pulse (pulsus parvus (weak) and

Chest Pain 

Presyncope and Syncope

Heart Failure 

Heart Murmurs in Adults

Heart Valve Disease 

Asymptomatic Heart Valve Disease
- Follow-up

Prosthetic Heart Valves - Follow-up

Hyperlipidaemia and Familial
Hypercholesterolaemia

Infective Endocarditis Prophylaxis

Long QT Syndrome

Palpitations 

Postoperative Care of Cardiac
Patients

Cardiology Requests 

Prosthetic Heart Valves - Follow-up

1. Ask about [symptoms indicating complications with heart valves](#) .
2. If mechanical valves, ask about anticoagulation.
3. Examination – check:
 - heart rhythm and blood pressure.
 - for [signs of complications](#) .
4. Consider the most common complications with prosthetic valves:
 - [Thrombus](#) 
 - [Endocarditis](#)  – always consider if unexplained fever or raised CRP in patient with prosthetic valve.
 - [Valve dysfunction](#) 
 - Rhythm disturbance – commonly [atrial fibrillation](#), especially in mitral valve replacement, or AV nodal block in aortic valve replacement.
5. Arrange investigations:
 - If suspicion of rhythm disturbance, perform an ECG. If assistance with interpretation is required, seek cardiology advice and [transmit the image](#) .
 - If haemodynamically stable and suspect subacute endocarditis, arrange [specific investigations](#) .
 - If taking warfarin, check INR.
 - If new symptoms suggestive of valve dysfunction, arrange [echocardiography](#).
6. If suspect subacute endocarditis, apply [Duke Criteria for Infective Endocarditis](#) .

Management

Some final words

- After the webinar ends, your browser will open a link to an evaluation survey.
- Statements of attendance will be emailed to participants.
- For event queries, please contact events@primaryhealthtas.com.au

Evaluation survey - Cardiology
Series: Structural heart disease



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