Presented by the Department of Anesthesiology
and Division of Cardiac Surgery
Peter Munk Cardiac Centre
Toronto General Hospital
University Health Network

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@drephrem

PERCUTANEOUS OPTIONS FOR THE MITRAL VALVE

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No disclosures




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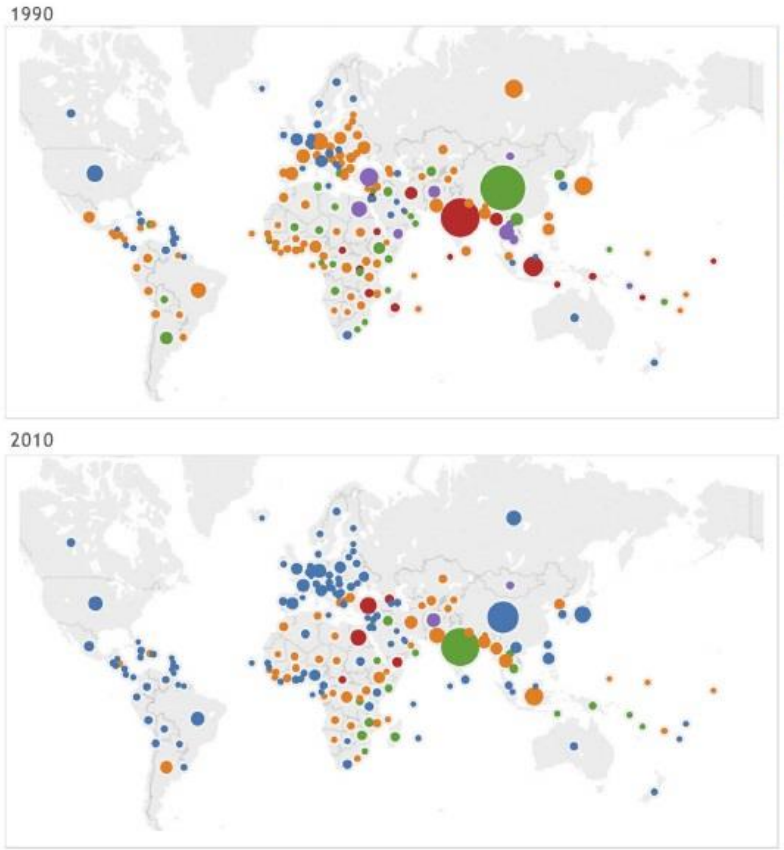
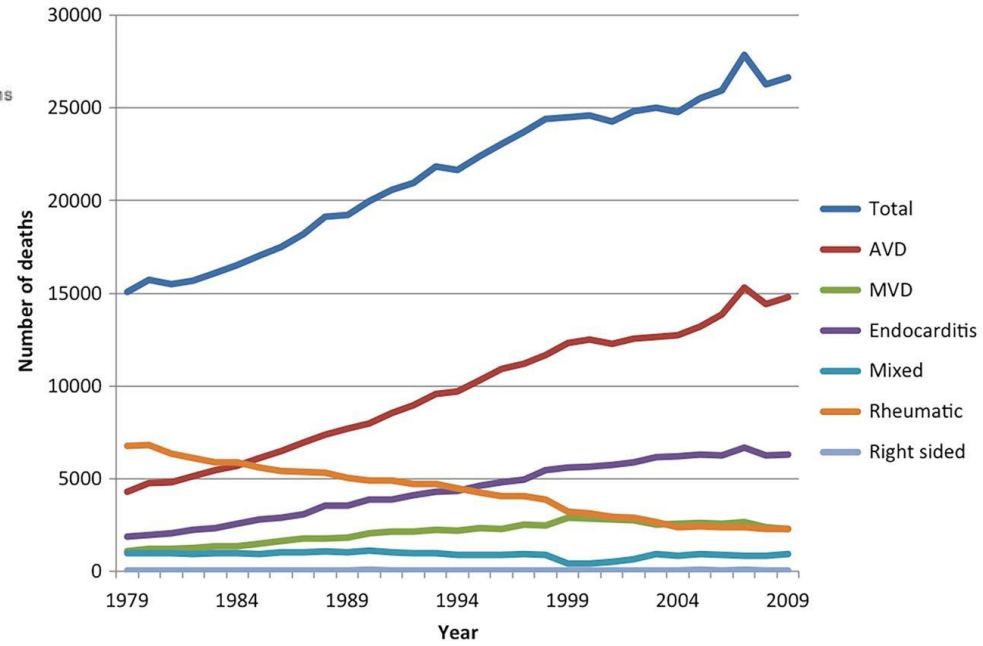
Outline

- Epidemiology of MV disease
- Established percutaneous interventions
  - Native MV
  - Artificial MV
- Prospects/future directions in interventions
- Current and prospective milestones for peri-procedural echocardiography

Epidemiology of MV disease





Coffey S, et al. Heart 2016;102:75–85. doi:10.1136/heartjnl-2014-307020

ESTABLISHED PERCUTANEOUS INTERVENTIONS

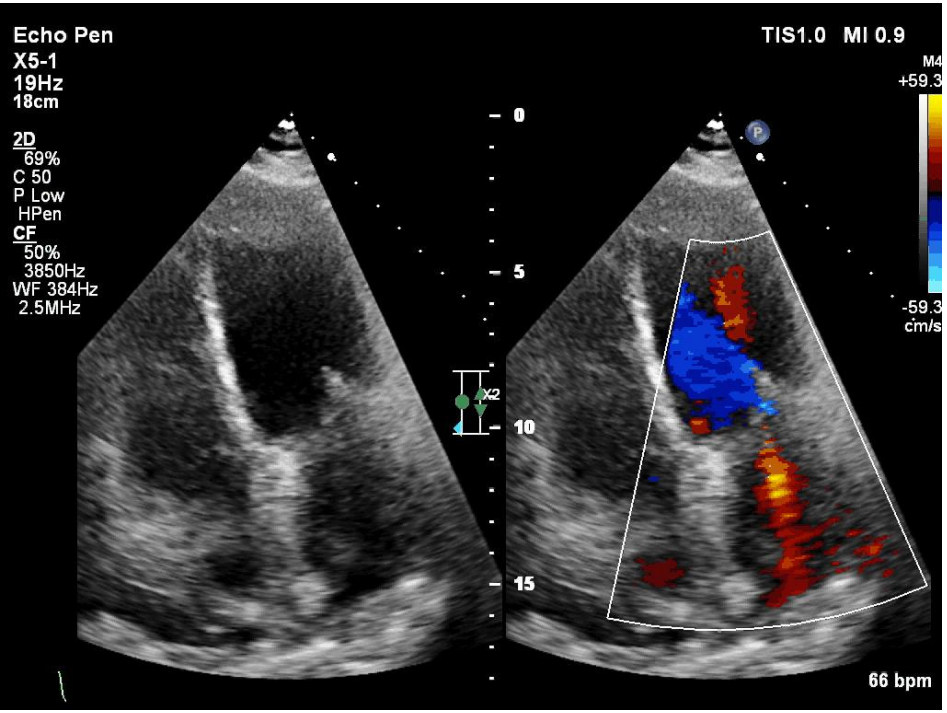
Native MV

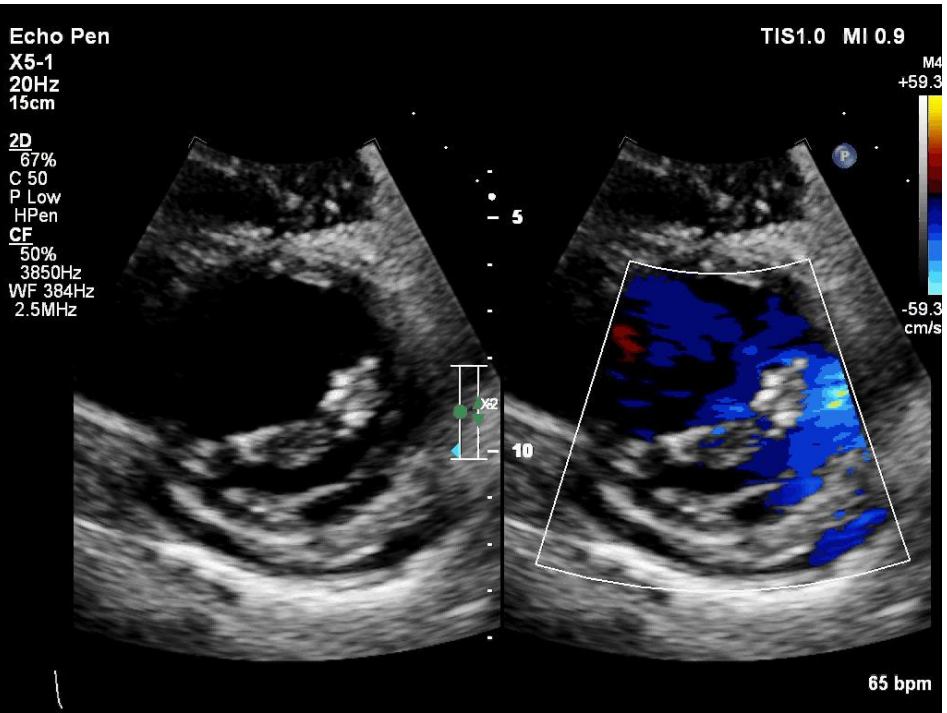
PBMV

- Severe MS (MVA <1.5 cm2), favorable morphology and no contraindications (e.g. LA thrombus or significant MR) (Class I)
- Asymptomatic patients with MVA <1.5 cm2, pHTN (PASP>50 mm Hg at rest or >60 mm Hg with exercise), and favorable morphology (Class I)
- Calcific MS + high risk for surgical commissurotomy IF NYHA FC III-IV and severe MS (MVA <1.5 cm2) (Class IIa)
- Consider if lower risk for surgical commissurotomy (Class IIb)
- NYHA FC II-IV with MVA >1.5 cm2 and pHTN (Class IIb)
- Asymptomatic with MVA<1.5 cm2 & new A fib (Class IIb)

Nishimura et al. J Am Coll Cardiol. 2017 Jul 11;70(2):252-289. doi: 10.1016/j.jacc.2017.03.011.

PBMV


Echo Pen
X5-1
19Hz
18cm
2D
69%
C 50
P Low
HPen
CF
50%
3850Hz
WF 384Hz
2.5MHz
TIS1.0 MI 0.9
M4
+59.3
-59.3
cm/s
66 bpm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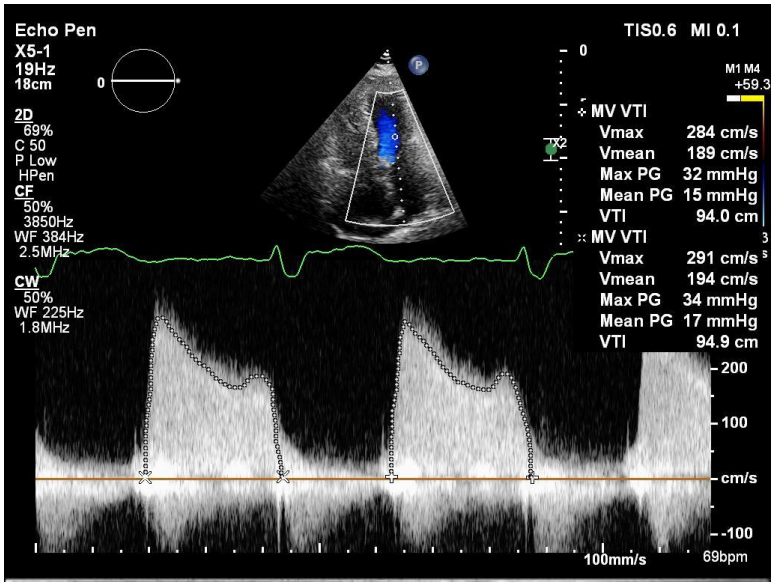
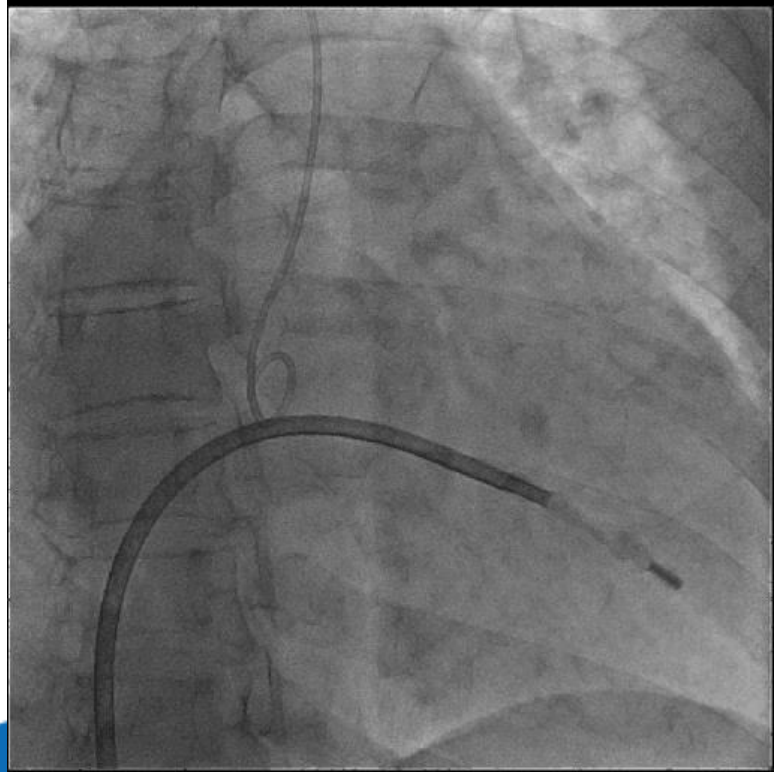
20Hz
15cm
2D
67%
C 50
P Low
HPen
CF
50%
3850Hz
WF 384Hz
2.5MHz
TIS1.0 MI 0.9
M4
+59.3
-59.3
cm/s
65 bpm


Echo Pen
X5-1
19Hz
18cm
2D
69%
C 50
P Low
HPen
CF
50%
3850Hz
WF 384Hz
2.5MHz
CW
50%
WF 225Hz
1.8MHz
TIS0.6 MI 0.1
M1 M4
+59.3
MV VTI
Vmax 284 cm/s
Vmean 189 cm/s
Max PG 32 mmHg
Mean PG 15 mmHg
VTI 94.0 cm
MV VTI
Vmax 291 cm/s
Vmean 194 cm/s
Max PG 34 mmHg
Mean PG 17 mmHg
VTI 94.9 cm
200
100
cm/s
-100
100mm/s
69bpm



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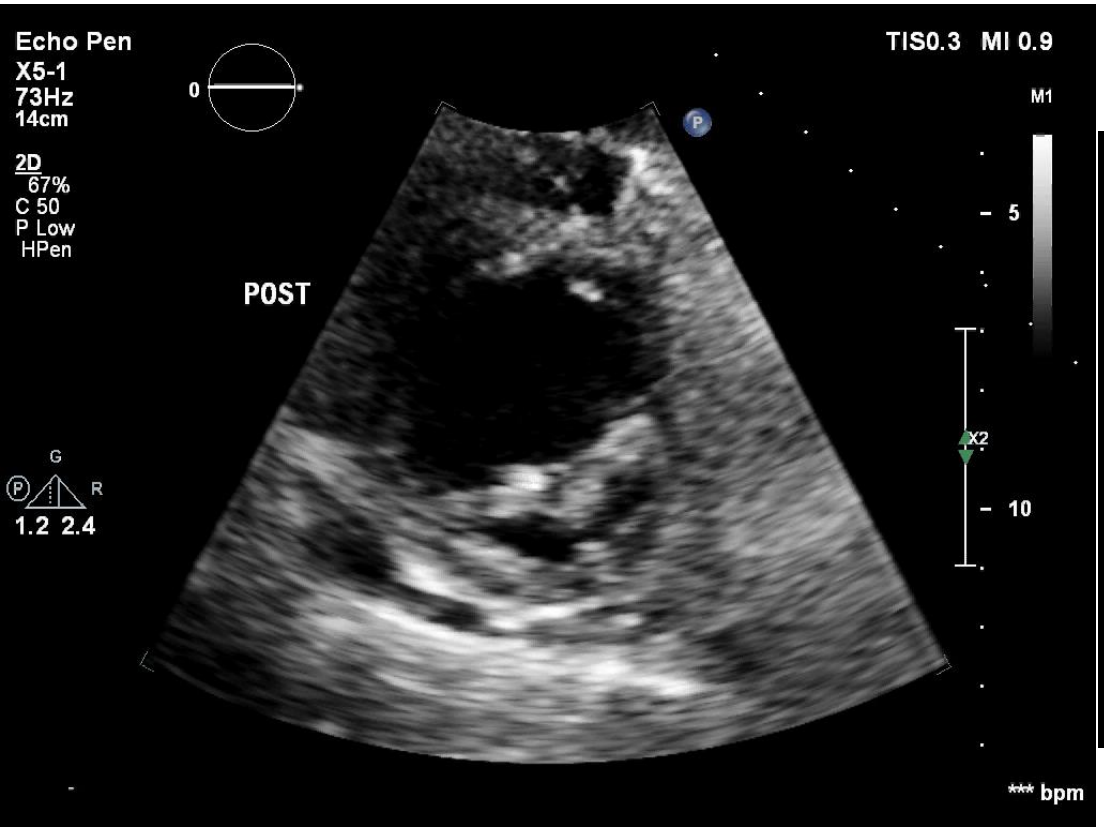

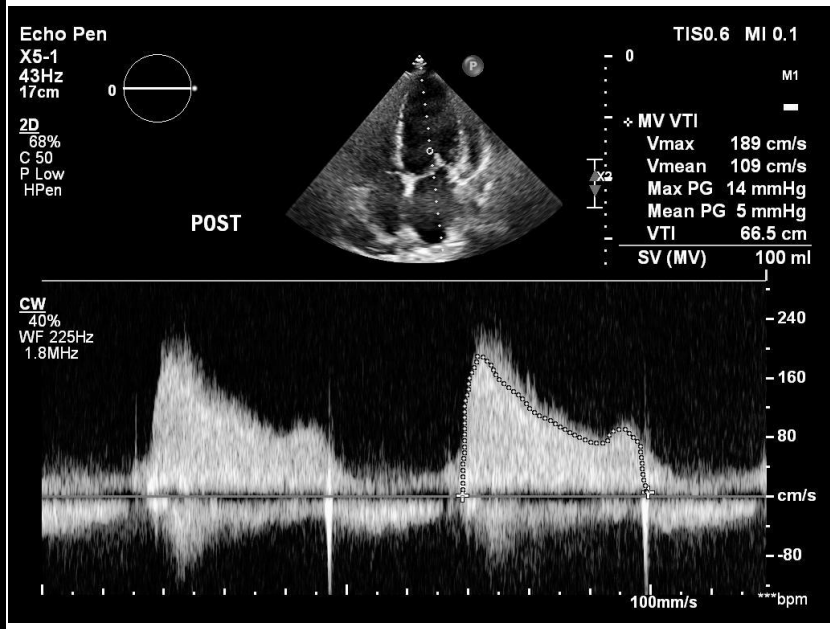

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Table 2. Primary Efficacy End Point at 12 Months and Major Adverse Events at 30 Days in the Intention-to-Treat Population.*

Event	Percutaneous Repair	Surgery	P Value
	no. (%)		
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.

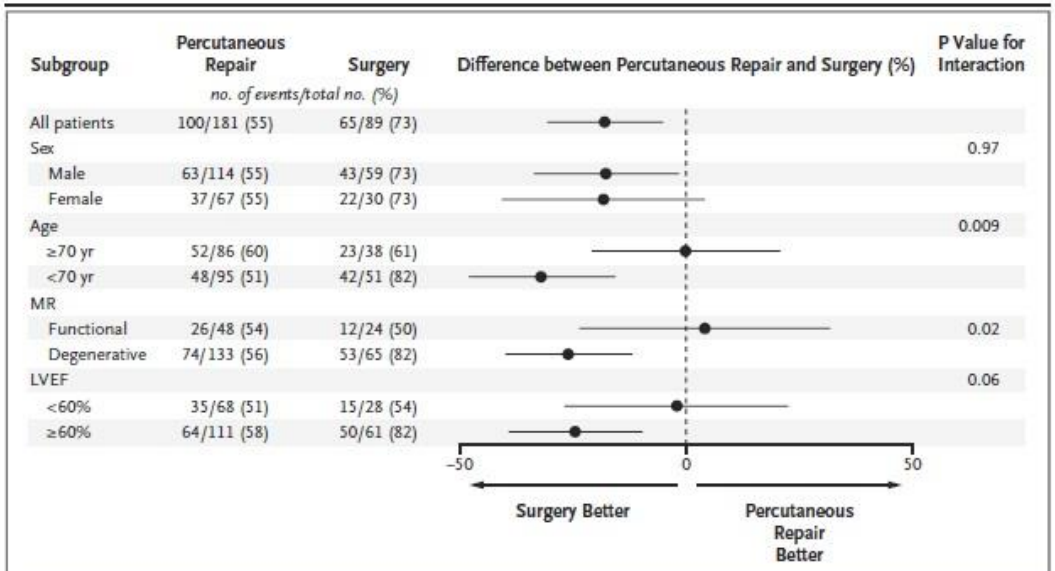

Figure 3. Subgroup Analyses for the Primary End Point at 12 Months.

Shown are the difference in rates of the primary efficacy end point (freedom from death, from mitral-valve surgery, and from grade 3+ or 4+ mitral regurgitation) between patients in the percutaneous-repair group and those in the surgery group for all randomized patients and those in four post hoc subgroups. In the subgroup for the comparison of the left ventricular ejection fraction (LVEF), data were missing for two patients, including one patient who had mitral regurgitation of more than grade 2+. The horizontal lines indicate 95% confidence intervals.

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Feldman T, et al. N Engl J Med. 2011 Apr 14;364(15):1395-406. doi: 10.1056/NEJMoa1009355.

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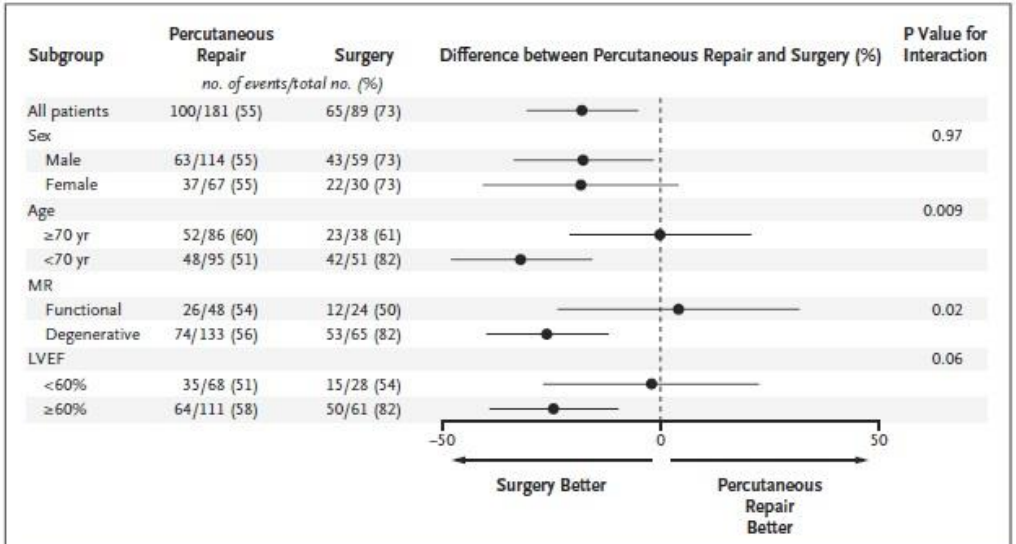

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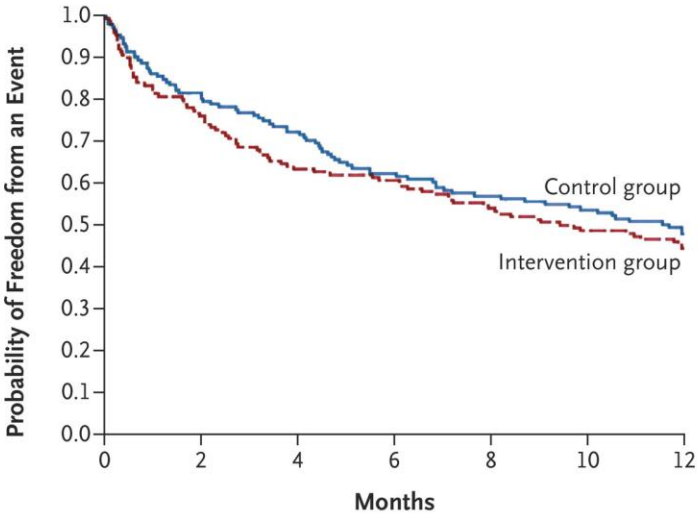

No. at Risk

Control group	152	123	109	94	86	80	73
Intervention group	151	114	95	91	81	73	67

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J Obadia et al. N Engl J Med 2018. DOI: 10.1056/NEJMoa1805374

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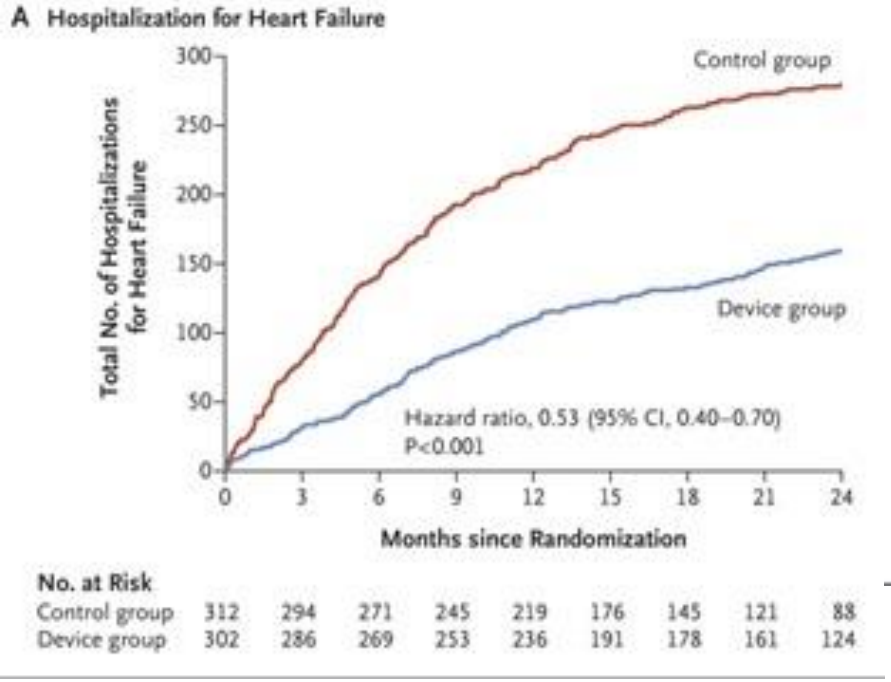

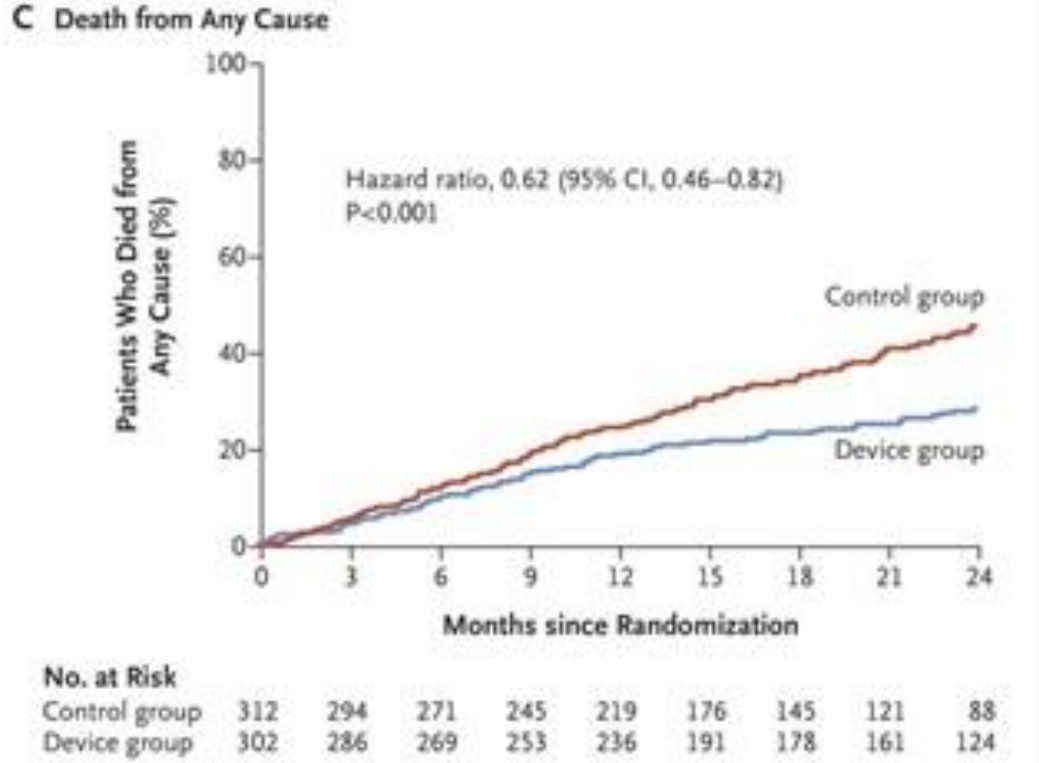

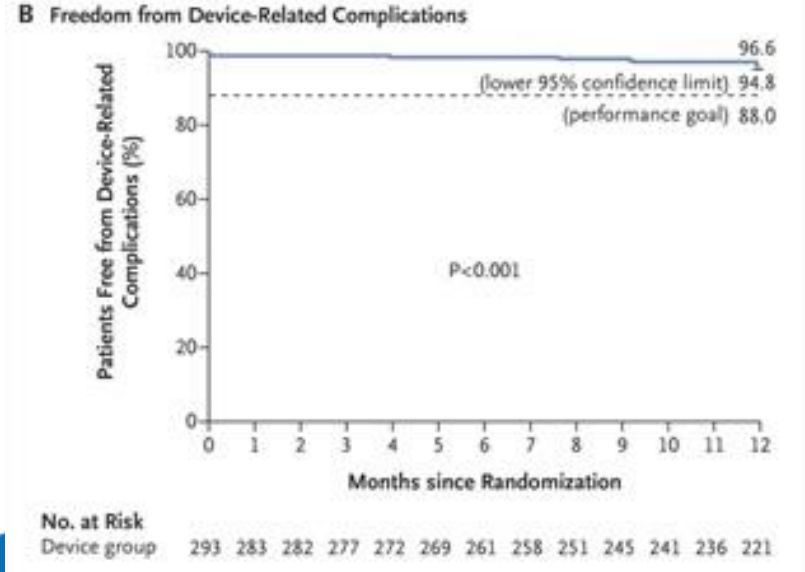

GW Stone et al. N Engl J Med 2018. DOI: 10.1056/NEJMoa1806640

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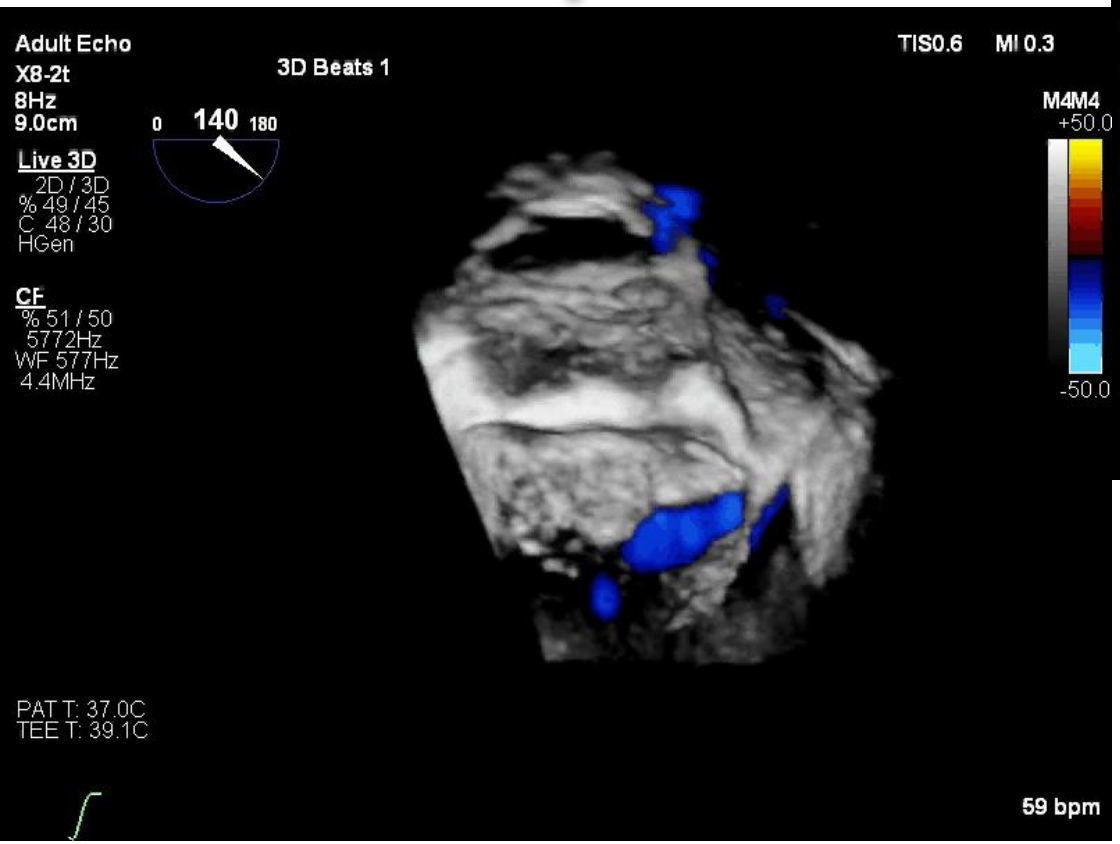
Why are the COAPT Results so Different from MITRA-FR?

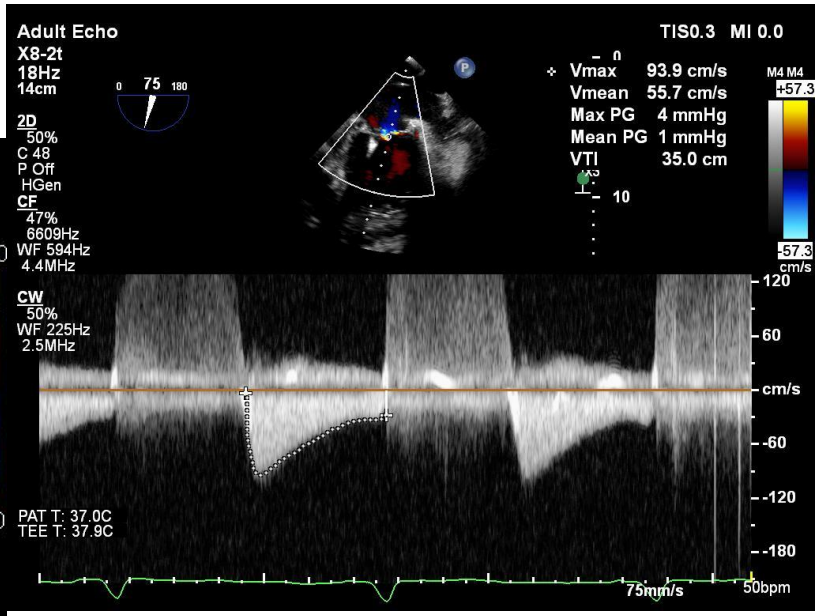
Possible Reasons

	MITRA-FR (n=304)	COAPT (n=614)
Severe MR entry criteria	Severe FMR by EU guidelines: EROA >20 mm^2 or RV >30 mL/beat	Severe FMR by US guidelines: EROA >30 mm^2 or RV >45 mL/beat
EROA (mean ± SD)	31 ± 10 mm^2	41 ± 15 mm^2
LVEDV (mean ± SD)	135 ± 35 mL/m^2	101 ± 34 mL/m^2
GDMT at baseline and FU	Receiving HF meds at baseline – allowed variable adjustment in each group during follow-up per "real-world" practice	CEC confirmed pts were failing maximally-tolerated GDMT at baseline – few major changes during follow-up
Acute results: No clip / ≥3+ MR	9% / 9%	5% / 5%
Procedural complications*	14.6%	8.5%
12-mo MitraClip ≥3+ MR	17%	5%

*MITRA-FR defn: device implant failure, transf or vasc compl req surg, ASD, card shock, cardiac embolism/stroke, tamponade, urg card surg

MitraClip





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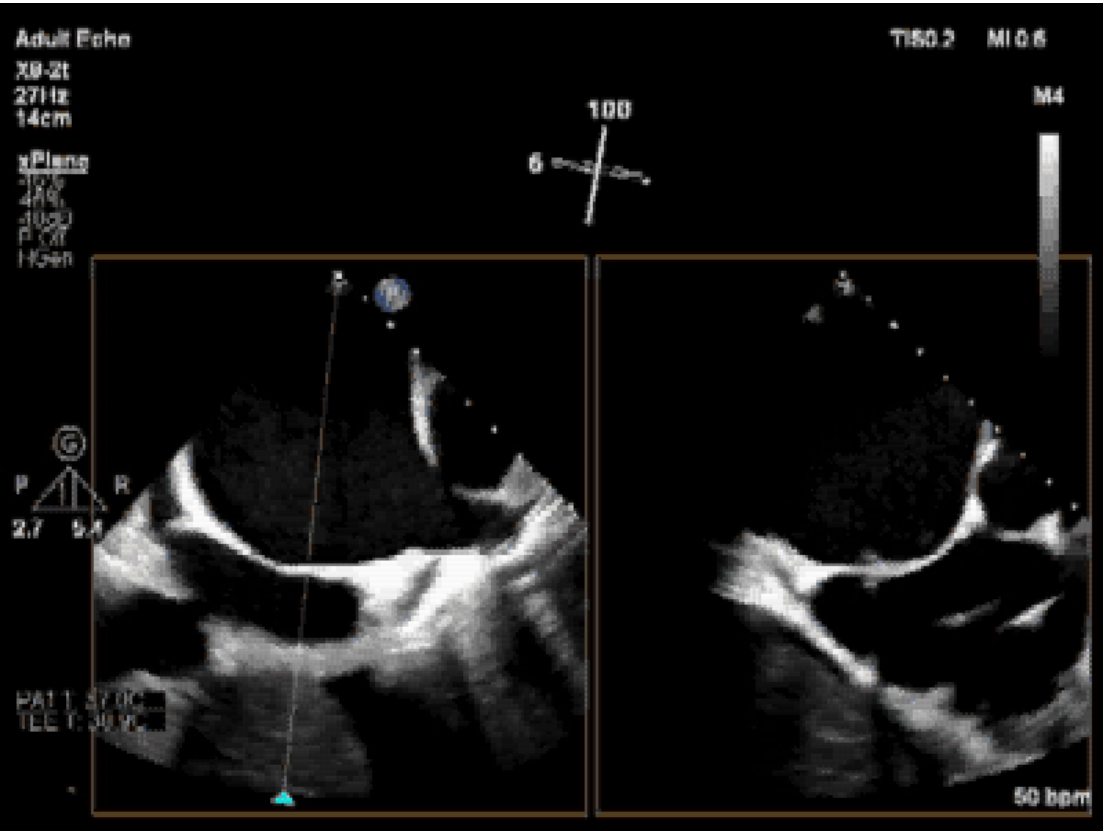

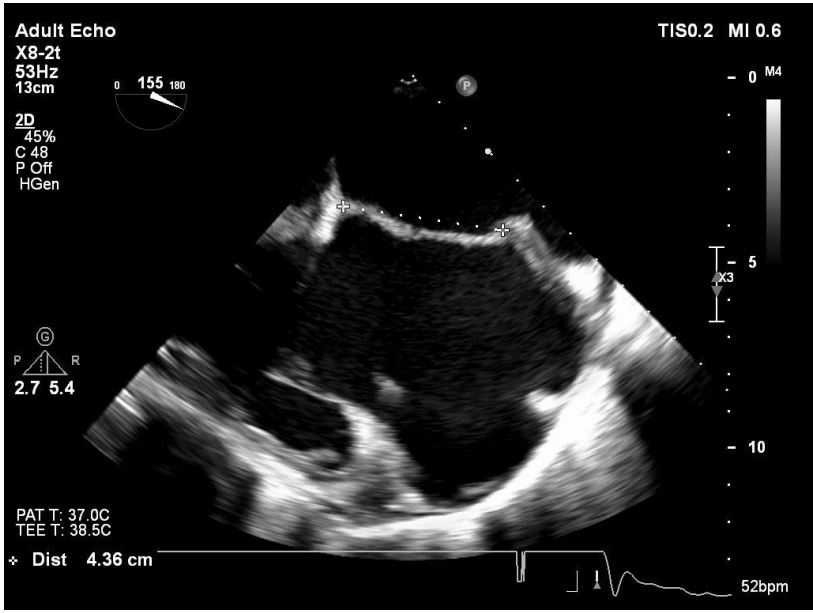

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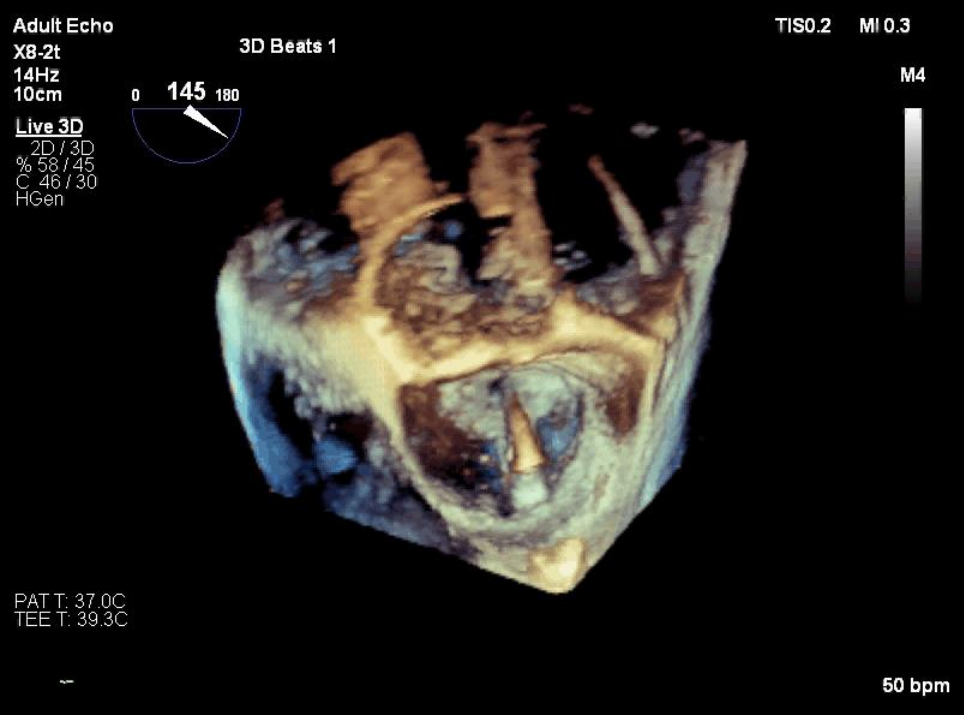
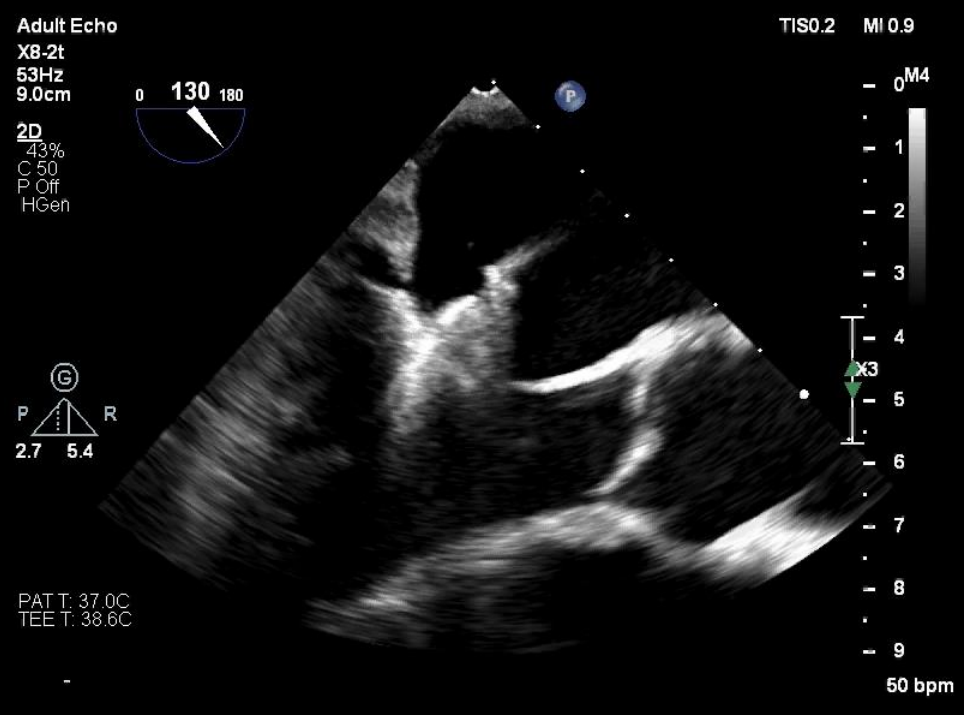

Adult Echo
X8-2t
14Hz
10cm
Live 3D
2D / 3D
% 58 / 45
C 46 / 30
HGen
3D Beats 1
TIS0.2 MI 0.3
M4
0 145 180
PAT T: 37.0C
TEE T: 39.3C
50 bpm


Adult Echo
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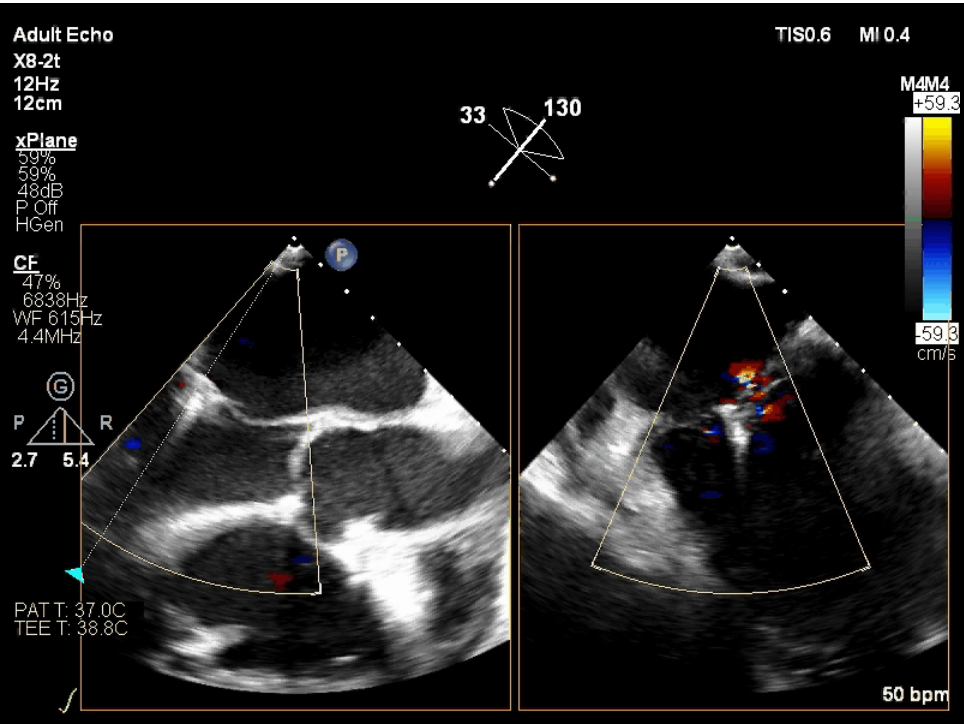
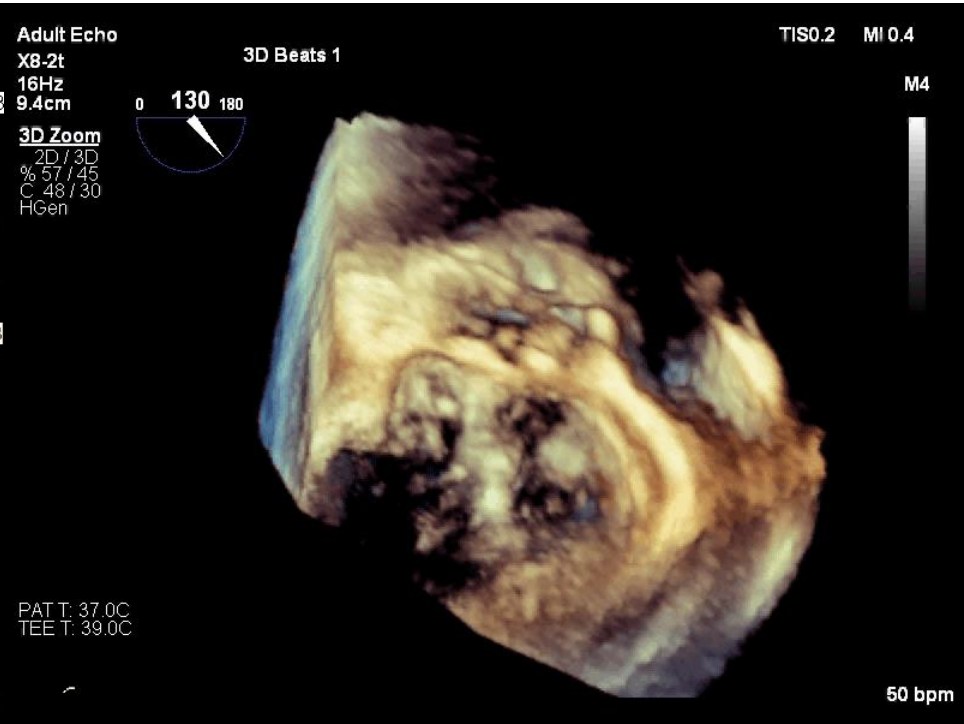
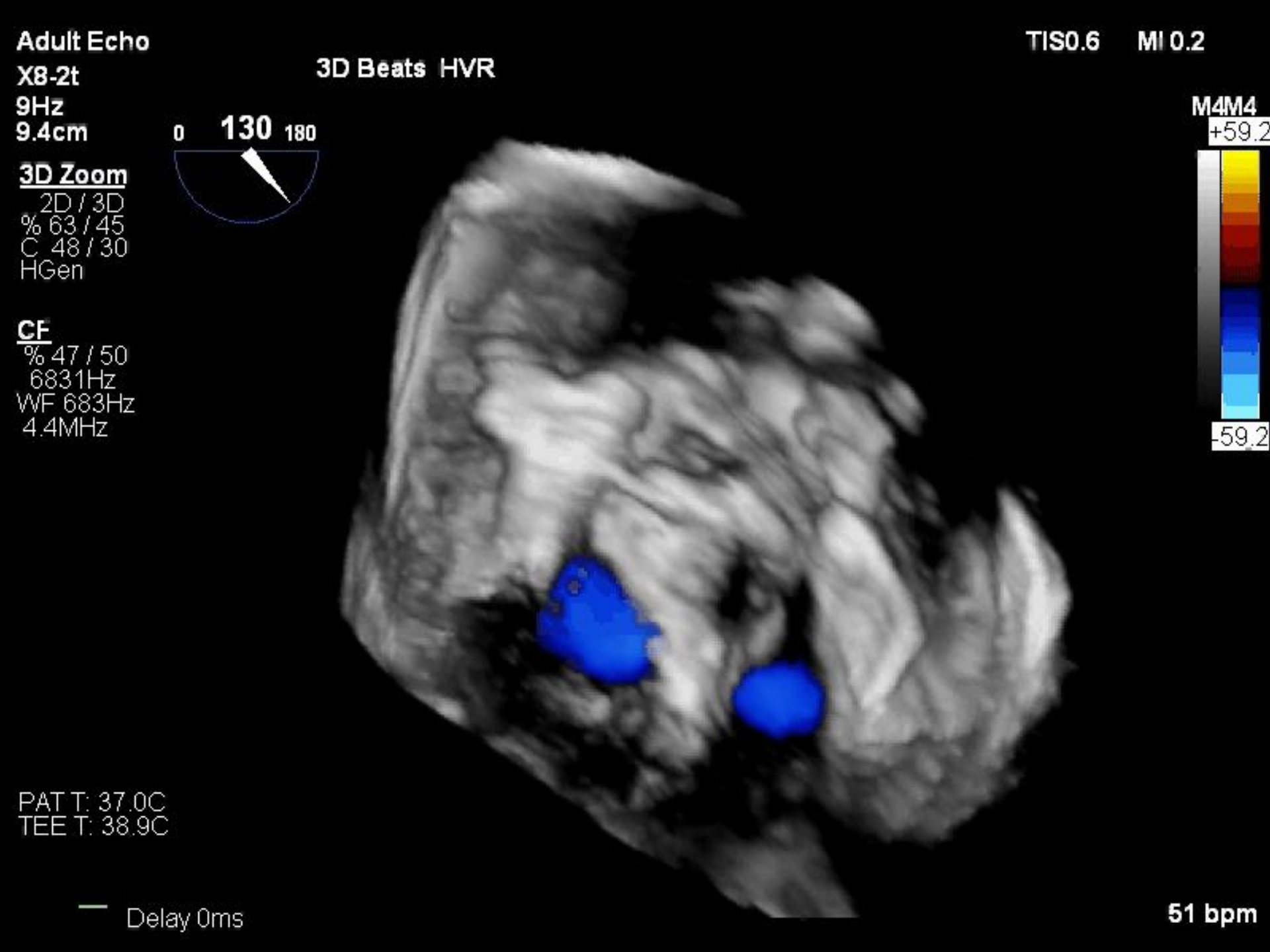
53Hz
9.0cm
2D
43%
C 50
P Off
HGen
TIS0.2 MI 0.9
M4
0 130 180
P R
2.7 5.4
X3
PAT T: 37.0C
TEE T: 38.6C
50 bpm


Adult Echo
X8-2t
12Hz
12cm
xPlane
59%
59%
48dB
P Off
HGen
CF
47%
6838Hz
WF 615Hz
4.4MHz
33 130
M4M4
+59.3
-59.3
cm/s
P R
2.7 5.4
TIS0.6 MI 0.4
PAT T: 37.0C
TEE T: 38.8C
50 bpm

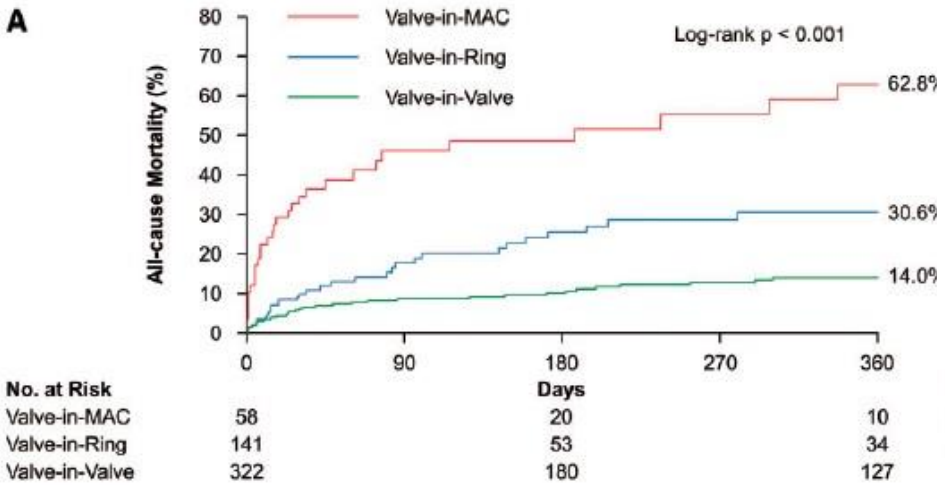

Adult Echo
X8-2t
16Hz
9.4cm
3D Zoom
2D / 3D
% 57 / 45
C 48 / 30
HGen
3D Beats 1
TIS0.2 MI 0.4
M4
0 130 180
PAT T: 37.0C
TEE T: 39.0C
50 bpm

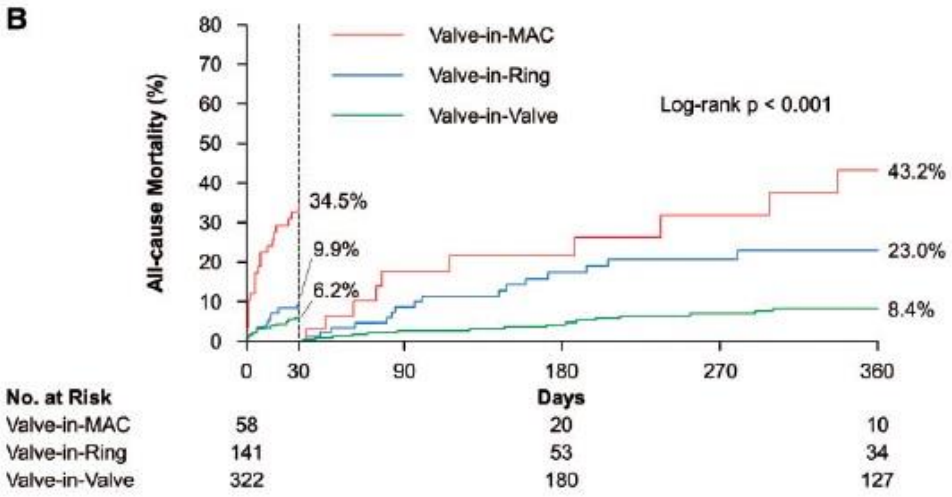

Adult Echo
X8-2t
9Hz
9.4cm
3D Beats HVR
TIS0.6 MI 0.2
0 130 180
3D Zoom
2D / 3D
% 63 / 45
C 48 / 30
HGen
CF
% 47 / 50
6831Hz
WF 683Hz
4.4MHz
M4M4
+59.2
-59.2
PAT T: 37.0C
TEE T: 38.9C
Delay 0ms
51 bpm

ESTABLISHED PERCUTANEOUS INTERVENTIONS

Artificial MV

Valve in Valve





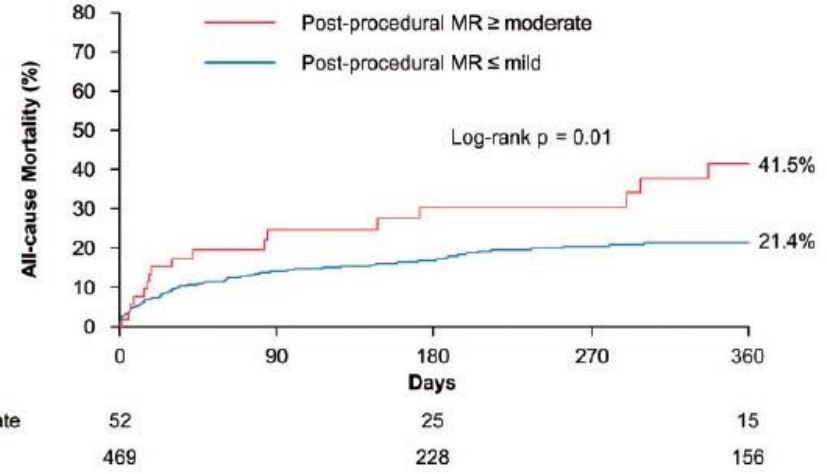


Table 4 Predictors of all-cause mortality

	Univariate model		Multivariate model	
	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value
Age	1.02 (1.00–1.04)	0.015		
Female	1.09 (0.75–1.58)	0.65		
NYHA functional Class IV	1.29 (0.63–2.67)	0.48		
STS score	1.04 (1.02–1.06)	0.001	1.02 (1.01–1.06)	0.006
Peripheral vascular disease	1.39 (0.83–2.32)	0.21		
Previous cerebrovascular accident	1.07 (0.66–1.76)	0.78		
Chronic pulmonary disease	1.80 (1.25–2.61)	0.002	1.54 (1.06–2.24)	0.025
Predominant mitral regurgitation at baseline	1.26 (0.88–1.81)	0.22		
LVEF per increase of 10%	0.92 (0.80–1.05)	0.21		
Prior CABG	0.99 (0.67–1.45)	0.95		
Prior myocardial infarction	1.02 (0.62–1.69)	0.93		
Transseptal access	1.12 (0.76–1.65)	0.58		
Pre-procedural mitral valve status				
Failed annuloplasty rings vs. degenerated bioprostheses	1.96 (1.27–3.02)	0.003	1.99 (1.27–3.12)	0.003
Severe MAC vs. degenerated bioprostheses	5.85 (3.68–9.29)	<0.001	5.29 (3.29–8.51)	<0.001
Need for second valve implantation	1.21 (0.56–2.59)	0.63		
LVOT obstruction	2.87 (1.66–4.96)	<0.001		
Post-procedural mitral regurgitation moderate or greater	2.00 (1.25–3.21)	0.004	1.72 (1.06–2.81)	0.029
Mean gradient 10 mmHg or more at post-procedure	1.30 (0.71–2.35)	0.40		

CABG, coronary artery bypass graft surgery; CI, confidence interval; HR, hazard ratio; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MAC, mitral annular calcification; NYHA, New York Heart Association; STS, society of thoracic surgeons.

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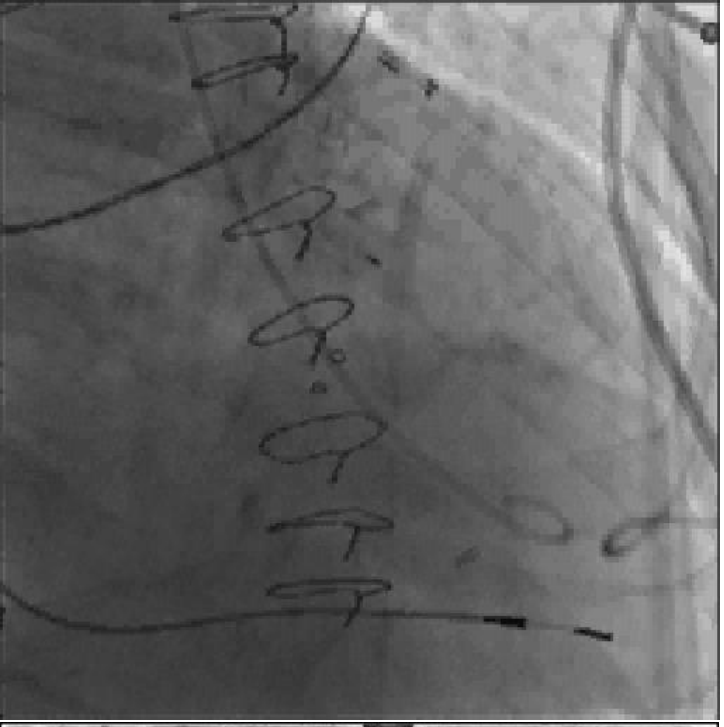
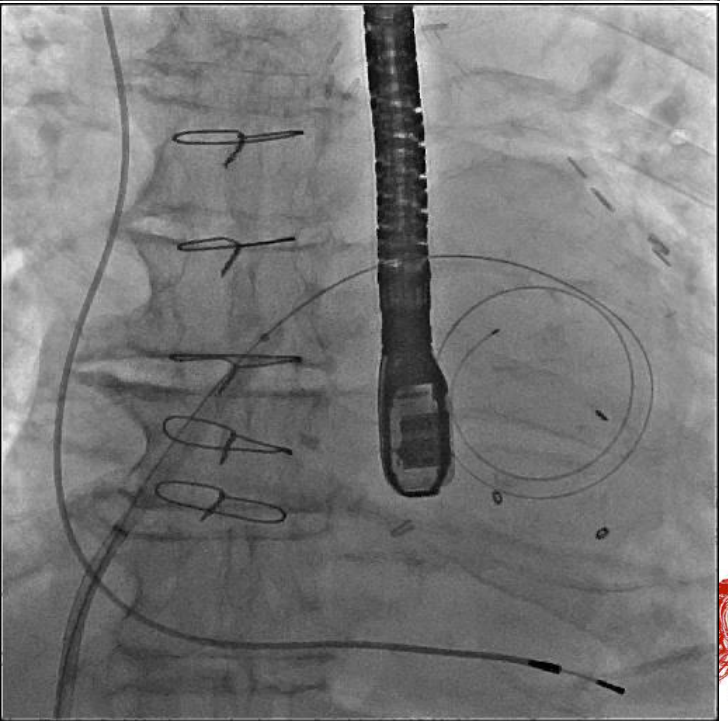
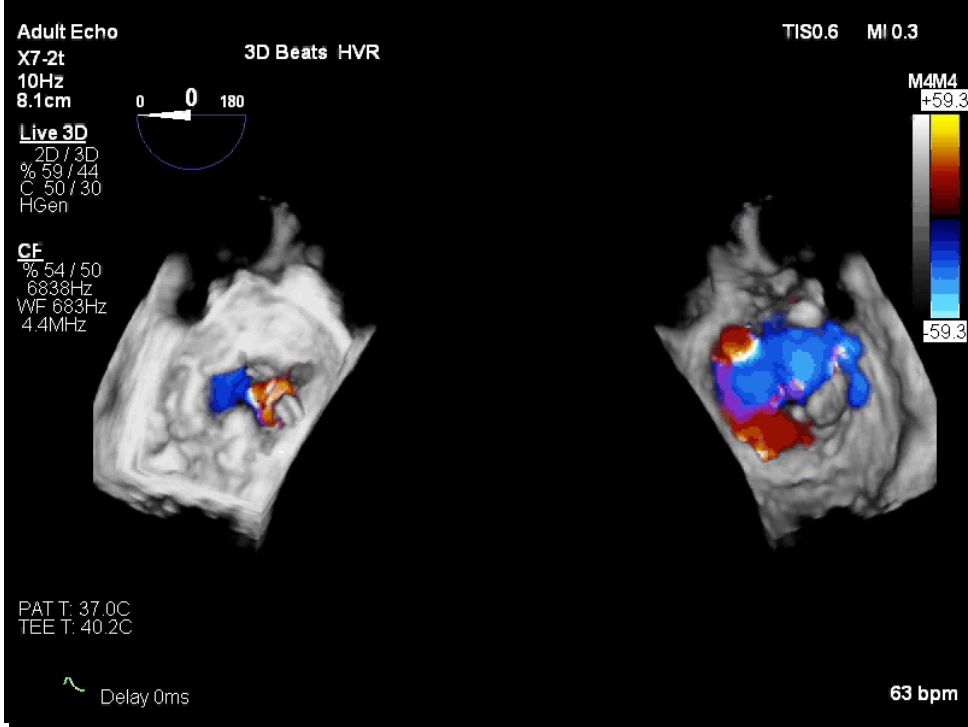
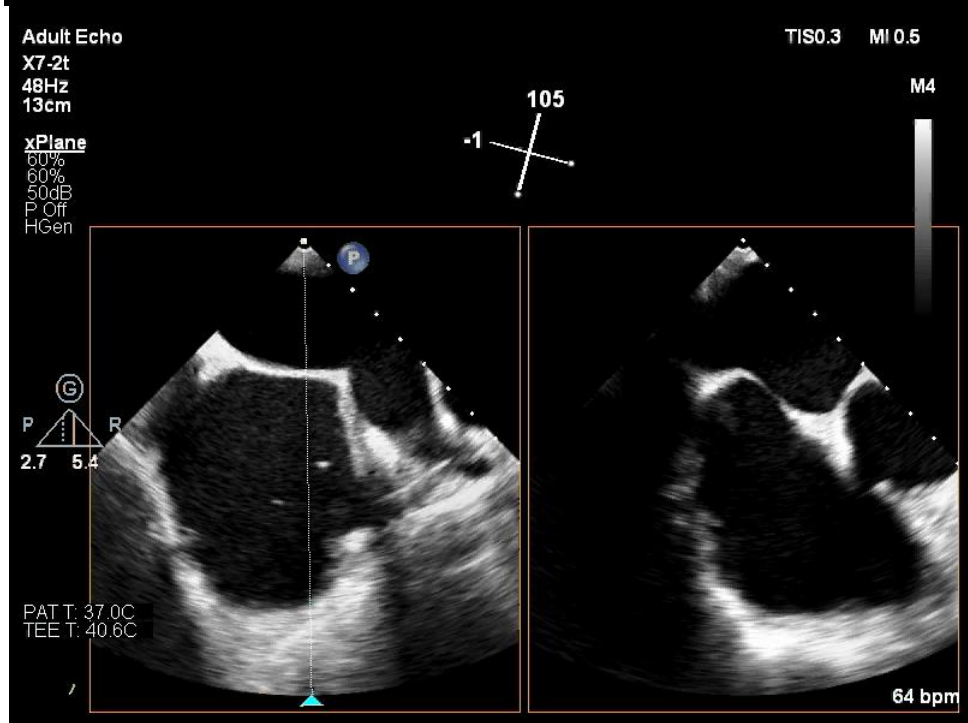
Yoon SH et al. Eur Heart J. 2018 Oct 23. doi: 10.1093/eurheartj/ehy590.
Guerrero M et al. Circulation. 2018;136:A23085









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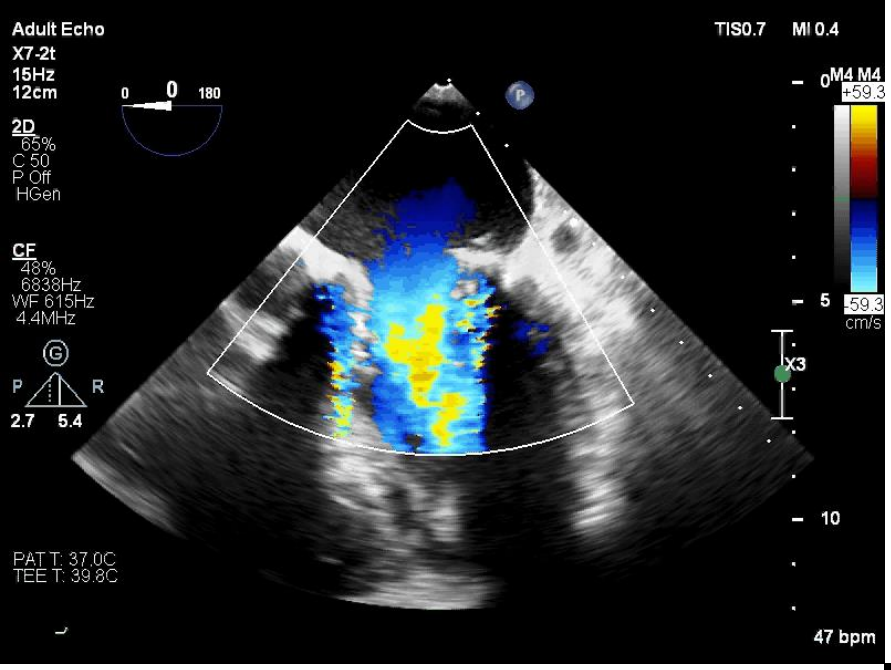

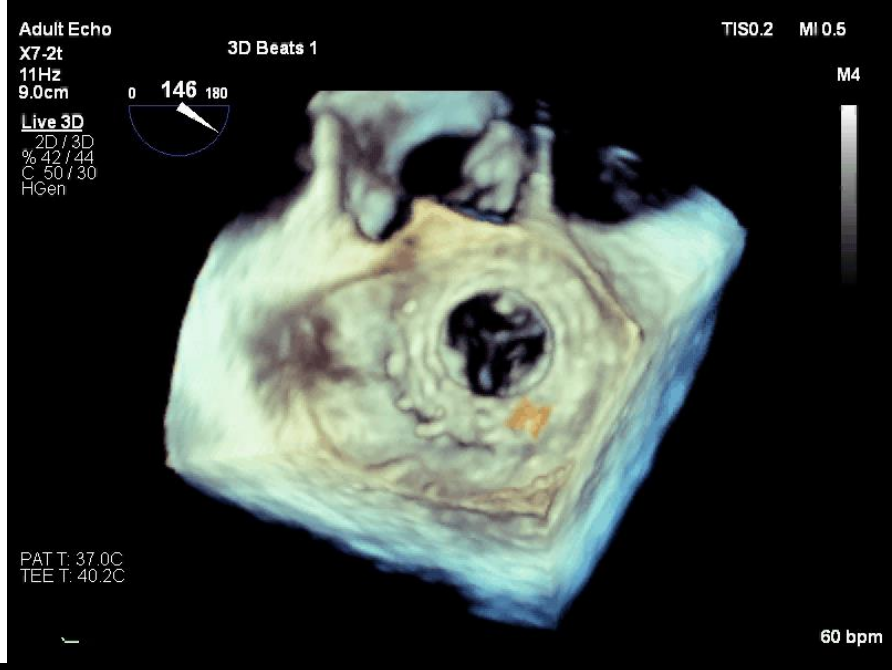

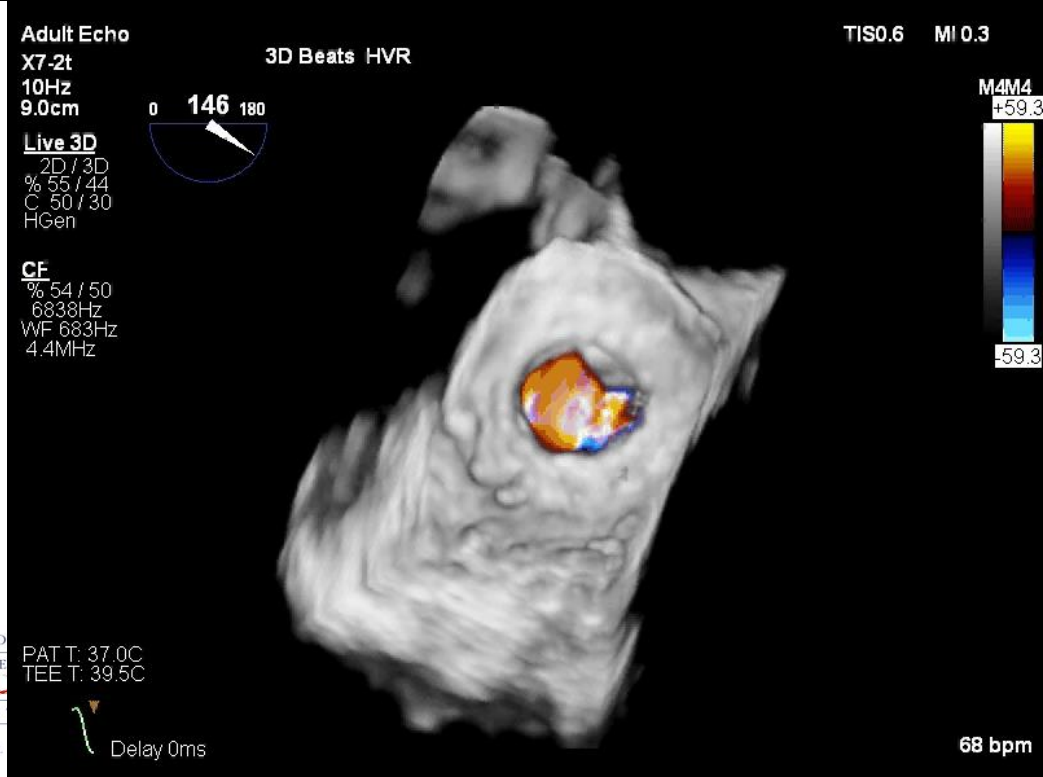

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Paravalvular leak closure

- 141 defects,115 patients, 78% MV
  - 93% CHF, 37% hemolytic anemia
  - Technical success rate 89%
  - 72% of survivors free of severe symptoms or need for surgery at 3-yr follow-up

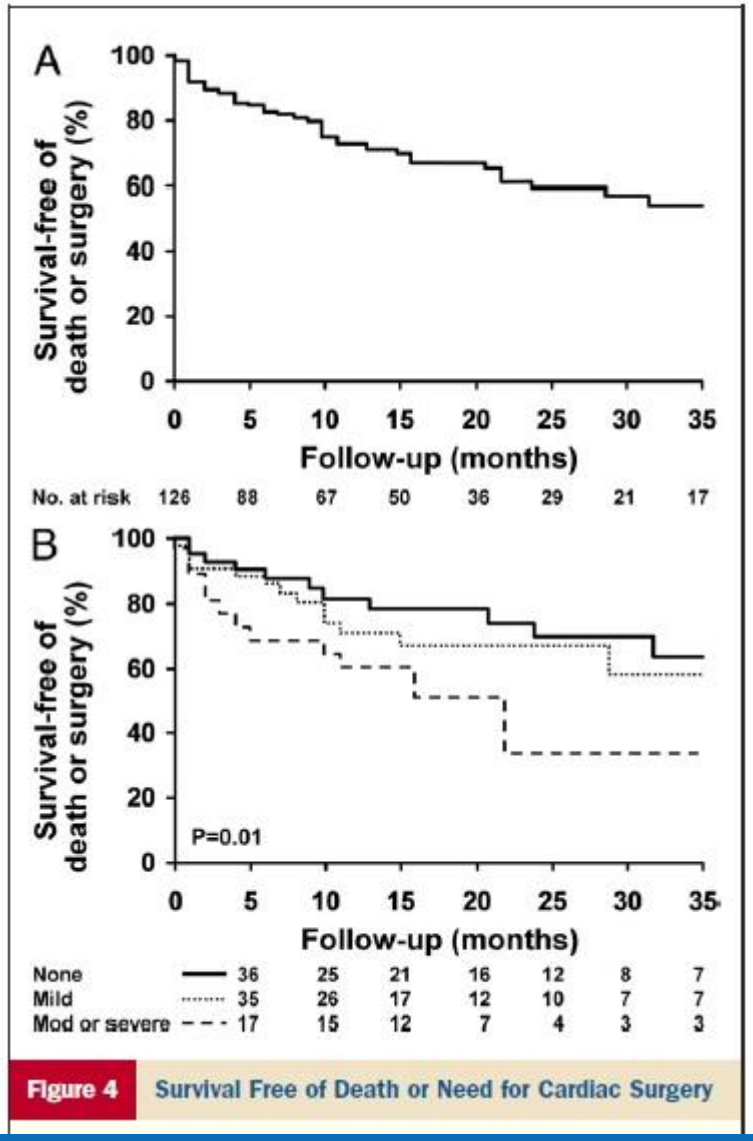
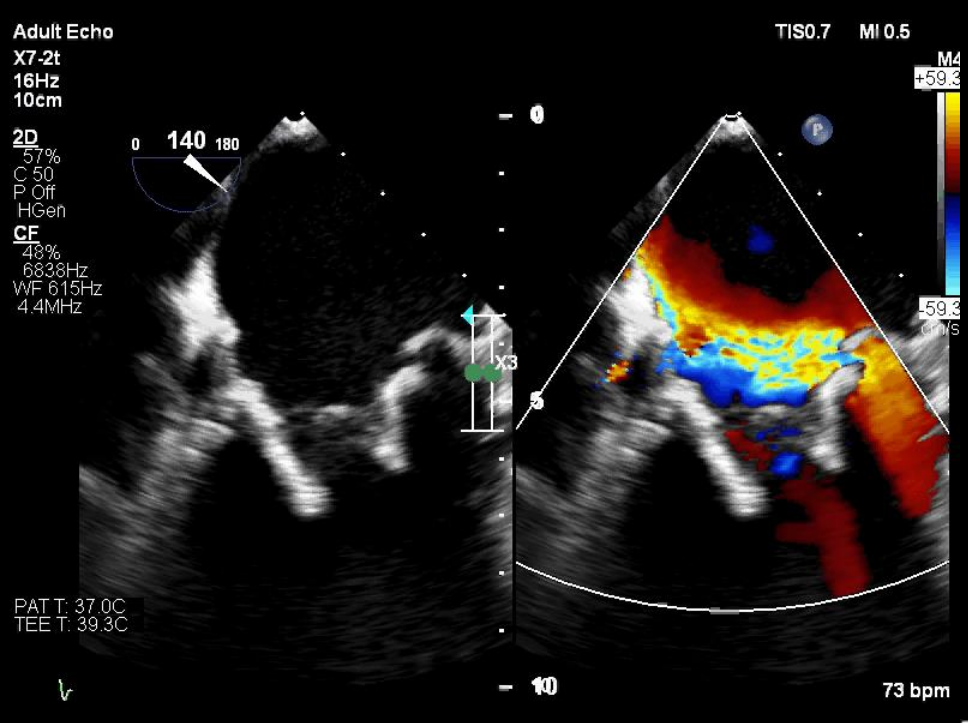
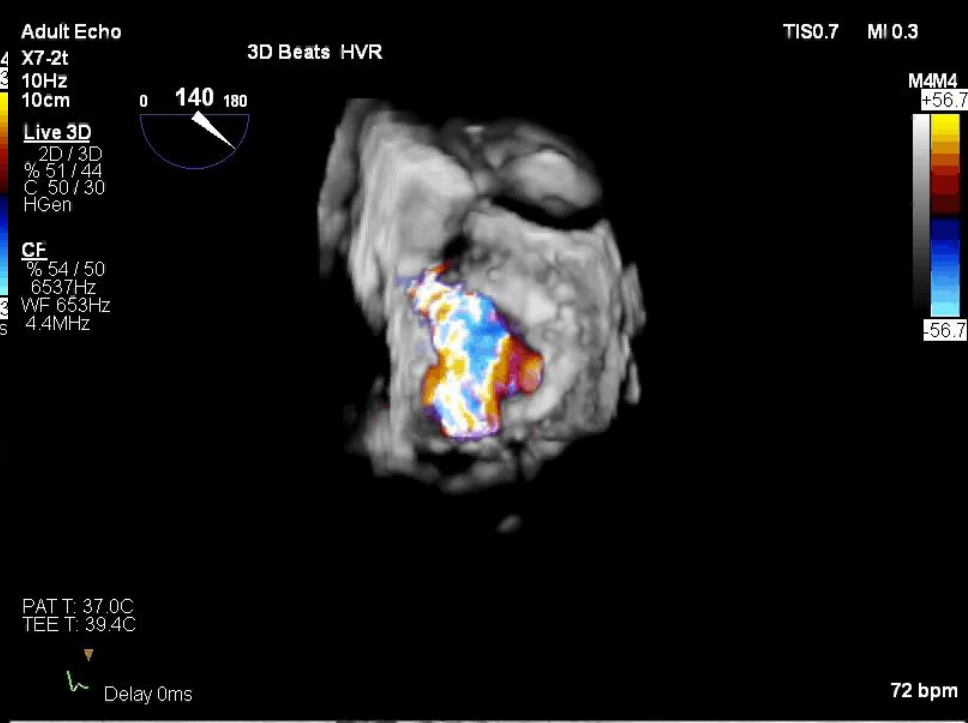
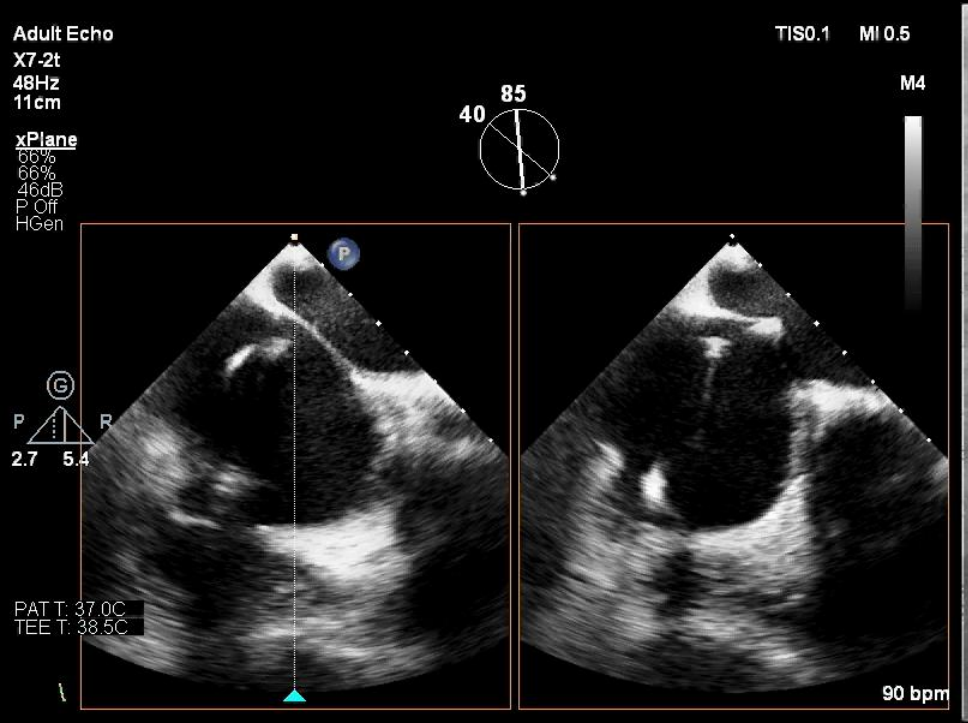


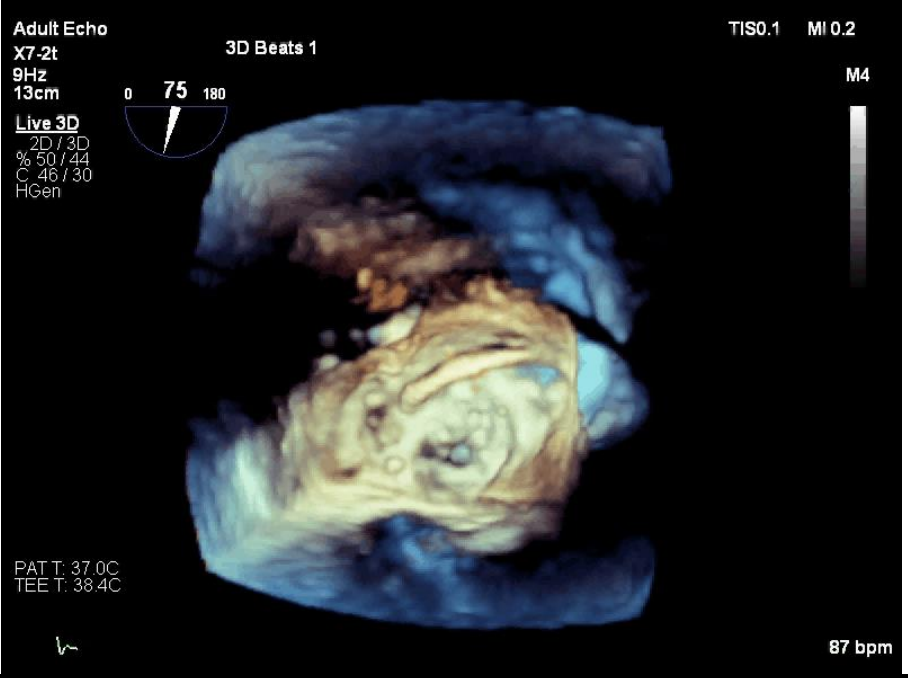
Figure 4 Survival Free of Death or Need for Cardiac Surgery

Rihal CS et al. JACC Cardiovasc Interv. 2012 Feb;5(2):121-30.

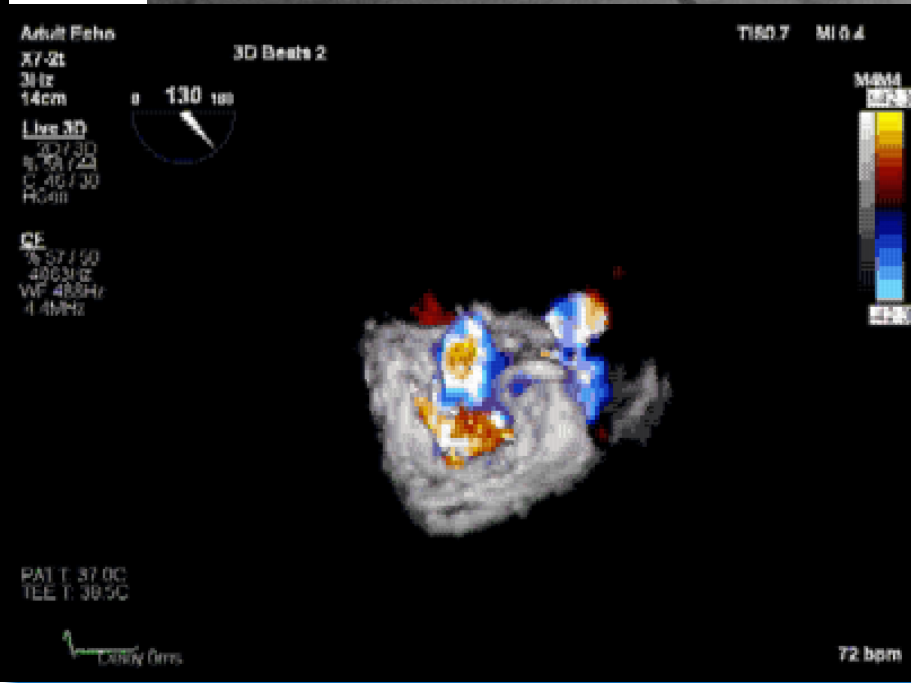

Adult Echo
X7-2t
16Hz
10cm
2D
57%
C 50
P Off
HGen
CF
48%
6838Hz
WF 615Hz
4.4MHz
TIS0.7 MI 0.5
M4
PAT T: 37.0C
TEE T: 39.3C
73 bpm

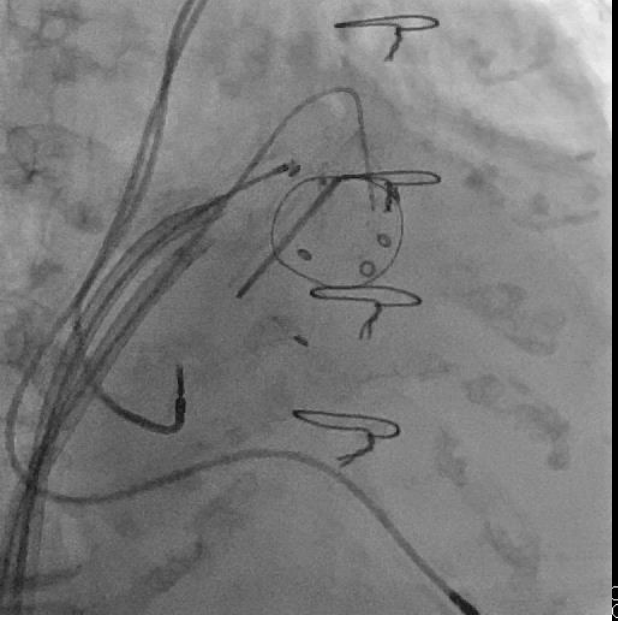

Adult Echo
X7-2t
10Hz
10cm
Live 3D
2D / 3D
% 51 / 44
C 50 / 30
HGen
CF
% 54 / 50
6537Hz
WF 653Hz
4.4MHz
3D Beats HVR
TIS0.7 MI 0.3
M4M4
+56.7
-56.7
PAT T: 37.0C
TEE T: 39.4C
Delay 0ms
72 bpm


Adult Echo
X7-2t
48Hz
11cm
xPlane
66%
66%
46dB
P Off
HGen
TIS0.1 MI 0.5
M4
PAT T: 37.0C
TEE T: 38.5C
90 bpm

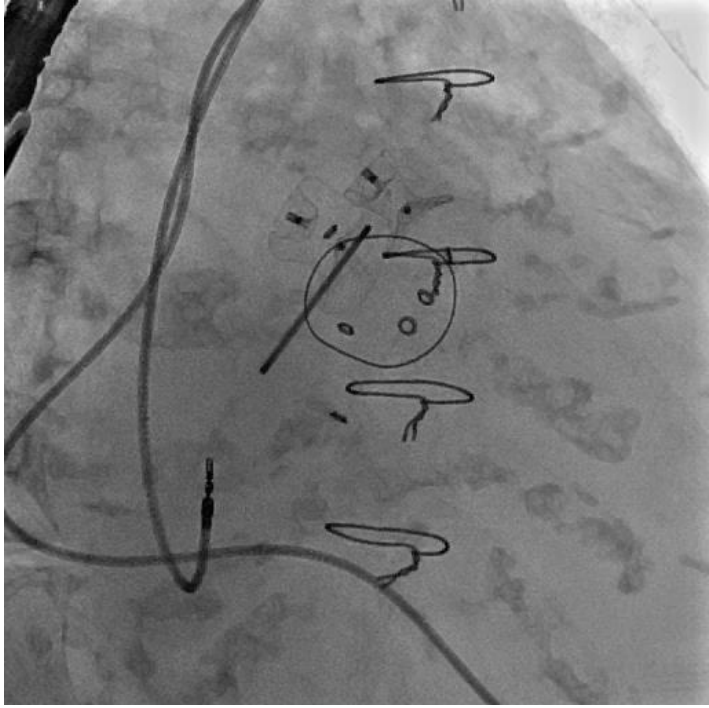

Adult Echo
X7-2t
9Hz
13cm
3D Beats 1
TIS0.1 MI 0.2
M4
0 75 180
Live 3D
2D / 3D
% 50 / 44
C 46 / 30
HGen
PAT T: 37.0C
TEE T: 38.4C
87 bpm

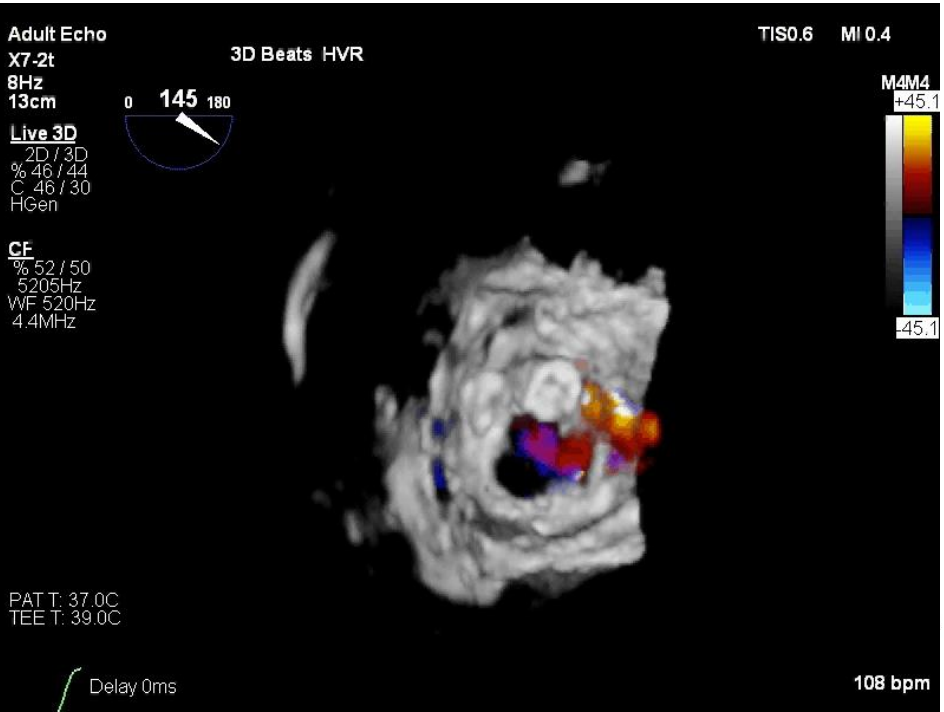

Adult Echo
X7-2t
11Hz
14cm
3D Beats 1
TIS0.0 MI 0.1
M4
0 130 180
Live 3D
2D / 3D
% 53 / 44
C 46 / 30
HGen
PAT T: 37.0C
TEE T: 38.3C
74 bpm

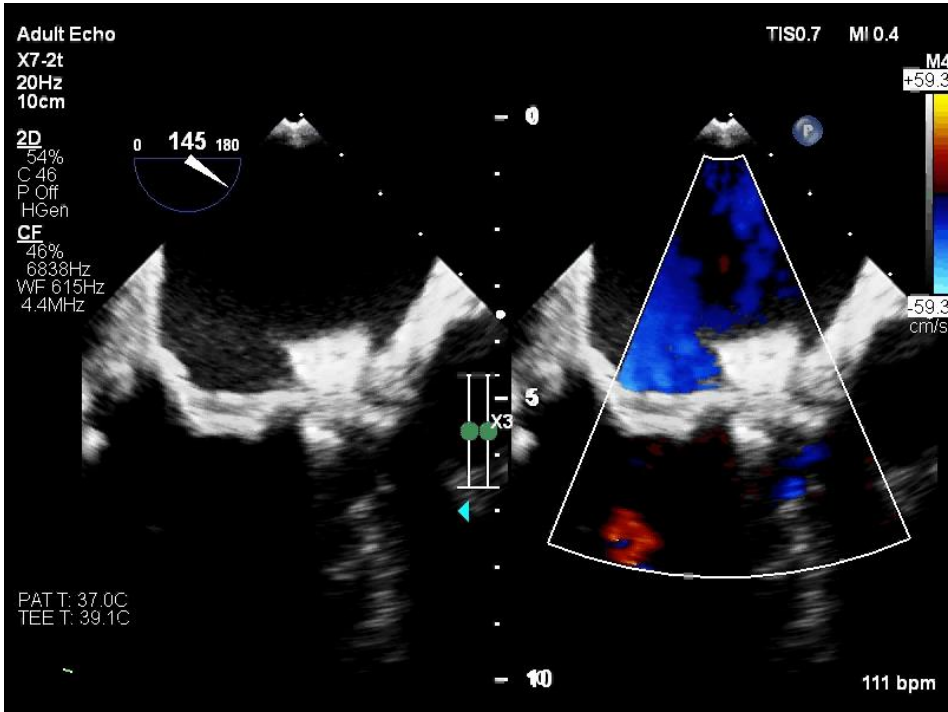

Adult Echo
X7-2t
3D Beats 2
TIS0.7 MI 0.4
MMM
0 130 180
Live 3D
CE
PAT T: 37.0C
TEE T: 38.5C
72 bpm




3D Beats 1
0
145
180




Adult Echo
X7-2t
8Hz
13cm
Live 3D
2D / 3D
% 46 / 44
C 46 / 30
HGen
CF
% 52 / 50
5205Hz
WF 520Hz
4.4MHz
3D Beats HVR
TIS0.6
MI 0.4
0
145
180
M4M4
+45.1
-45.1
PAT T: 37.0C
TEE T: 39.0C
Delay 0ms
108 bpm


Adult Echo
X7-2t
20Hz
10cm
2D
54%
C 46
P Off
HGen
CF
46%
6838Hz
WF 615Hz
4.4MHz
TIS0.7
MI 0.4
0
145
180
M4
+59.3
-59.3
cm/s
0
5
10
X3
PAT T: 37.0C
TEE T: 39.1C
111 bpm

PROSPECTS/FUTURE DIRECTIONS IN INTERVENTIONS

Valve in valve

Edwards SAPIEN 3 Transcatheter Heart Valve

Valve-in-Valve Positioning

Aortic Positioning

Surgical Valve Features	SAPIEN 3 Valve Positioning Considerations
Visible stent frame 	Align the base of the **central marker 3-5 mm above the base** of the surgical valve stent frame 
Visible outflow markers only 	Align the outflow of the **crimped SAPIEN 3 valve 2 mm above** the surgical valve outflow markers 
No visible radiopaque markers 	Align the **base of the central marker** with the annular plane 
Final SAPIEN 3 valve implant depth should be targeted **no more than 20% (ventricular)** for optimal valve function	

Final aortic position provided for reference purposes only 

Mitral Positioning

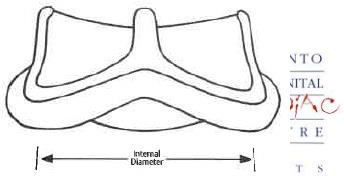
Surgical Valve Features	SAPIEN 3 Valve Positioning Considerations
Visible stent frame 	Align the base of the **central marker 3-5 mm below the base** (towards ventricle) of the surgical valve stent frame 
Visible outflow markers only 	Align the outflow of the **crimped SAPIEN 3 valve 2 mm below** (towards ventricle) the surgical valve outflow markers 
No visible radiopaque markers 	Align the **base of the central marker** with the annular plane 
Final SAPIEN 3 valve implant depth should be targeted **no more than 20% (atrial)** for optimal valve function	

Edwards SAPIEN 3 Transcatheter Heart Valve

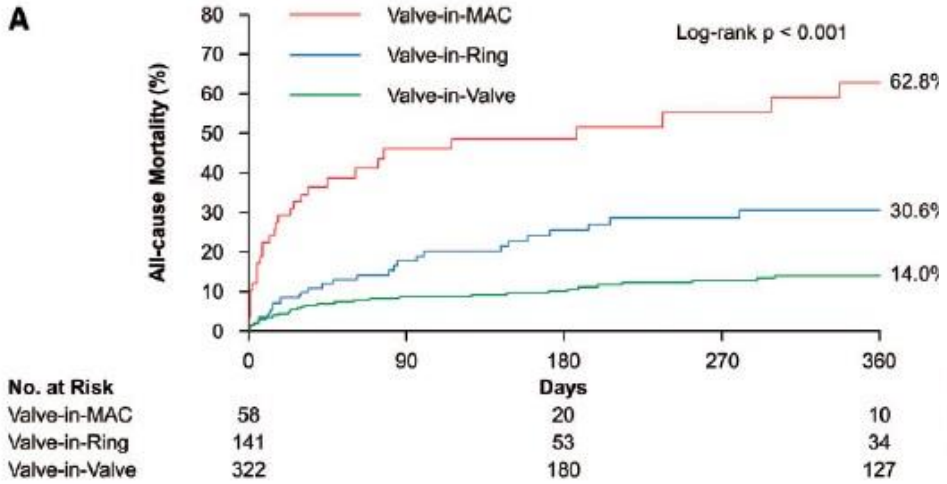
Valve-in-Valve Sizing

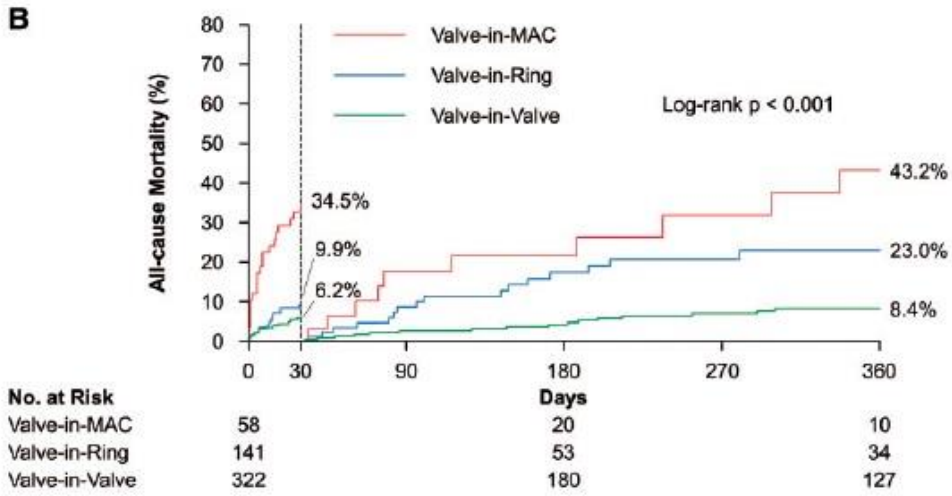
- In general, **measured internal diameters** may be smaller than the manufacturer's internal diameter and labeled valve size due to various mechanisms of surgical valve failure (e.g., calcification or pannus).[1]
- Sizing considerations for stented and stentless may differ. Overall assessment and actual internal dimensions of the pre-existing surgical valve are critical.
- Use of CT, MRI, and/or TEE is suggested to confirm actual internal dimensions.

Surgical Valve True ID*	SAPIEN 3 Transcatheter Heart Valve Size
16.5-19 mm	**20 mm**
18.5-22 mm	**23 mm**
22-25 mm	**26 mm**
25-28.5 mm	**29 mm**



Valve in ring





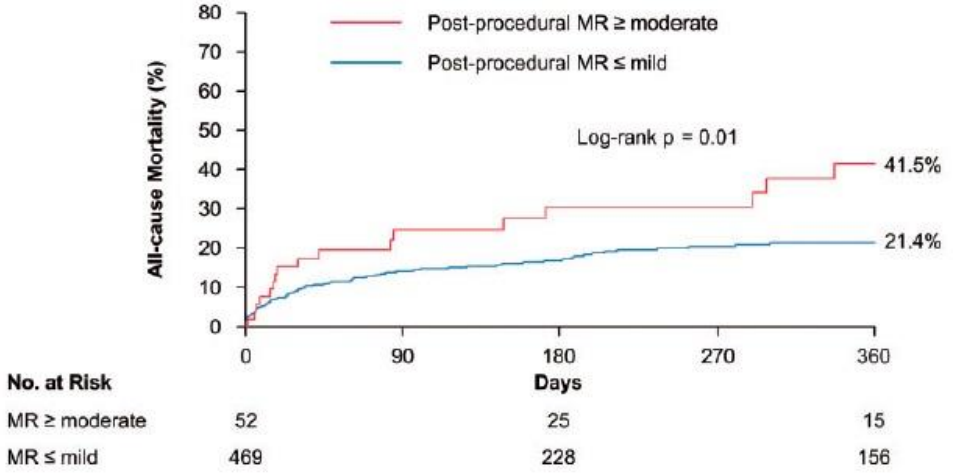


Table 4 Predictors of all-cause mortality

	Univariate model		Multivariate model	
	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value
Age	1.02 (1.00–1.04)	0.015		
Female	1.09 (0.75–1.58)	0.65		
NYHA functional Class IV	1.29 (0.63–2.67)	0.48		
STS score	1.04 (1.02–1.06)	0.001	1.02 (1.01–1.06)	0.006
Peripheral vascular disease	1.39 (0.83–2.32)	0.21		
Previous cerebrovascular accident	1.07 (0.66–1.76)	0.78		
Chronic pulmonary disease	1.80 (1.25–2.61)	0.002	1.54 (1.06–2.24)	0.025
Predominant mitral regurgitation at baseline	1.26 (0.88–1.81)	0.22		
LVEF per increase of 10%	0.92 (0.80–1.05)	0.21		
Prior CABG	0.99 (0.67–1.45)	0.95		
Prior myocardial infarction	1.02 (0.62–1.69)	0.93		
Transseptal access	1.12 (0.76–1.65)	0.58		
Pre-procedural mitral valve status				
Failed annuloplasty rings vs. degenerated bioprostheses	1.96 (1.27–3.02)	0.003	1.99 (1.27–3.12)	0.003
Severe MAC vs. degenerated bioprostheses	5.85 (3.68–9.29)	<0.001	5.29 (3.29–8.51)	<0.001
Need for second valve implantation	1.21 (0.56–2.59)	0.63		
LVOT obstruction	2.87 (1.66–4.96)	<0.001		
Post-procedural mitral regurgitation moderate or greater	2.00 (1.25–3.21)	0.004	1.72 (1.06–2.81)	0.029
Mean gradient 10 mmHg or more at post-procedure	1.30 (0.71–2.35)	0.40		

CABG, coronary artery bypass graft surgery; CI, confidence interval; HR, hazard ratio; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; MAC, mitral annular calcification; NYHA, New York Heart Association; STS, society of thoracic surgeons.

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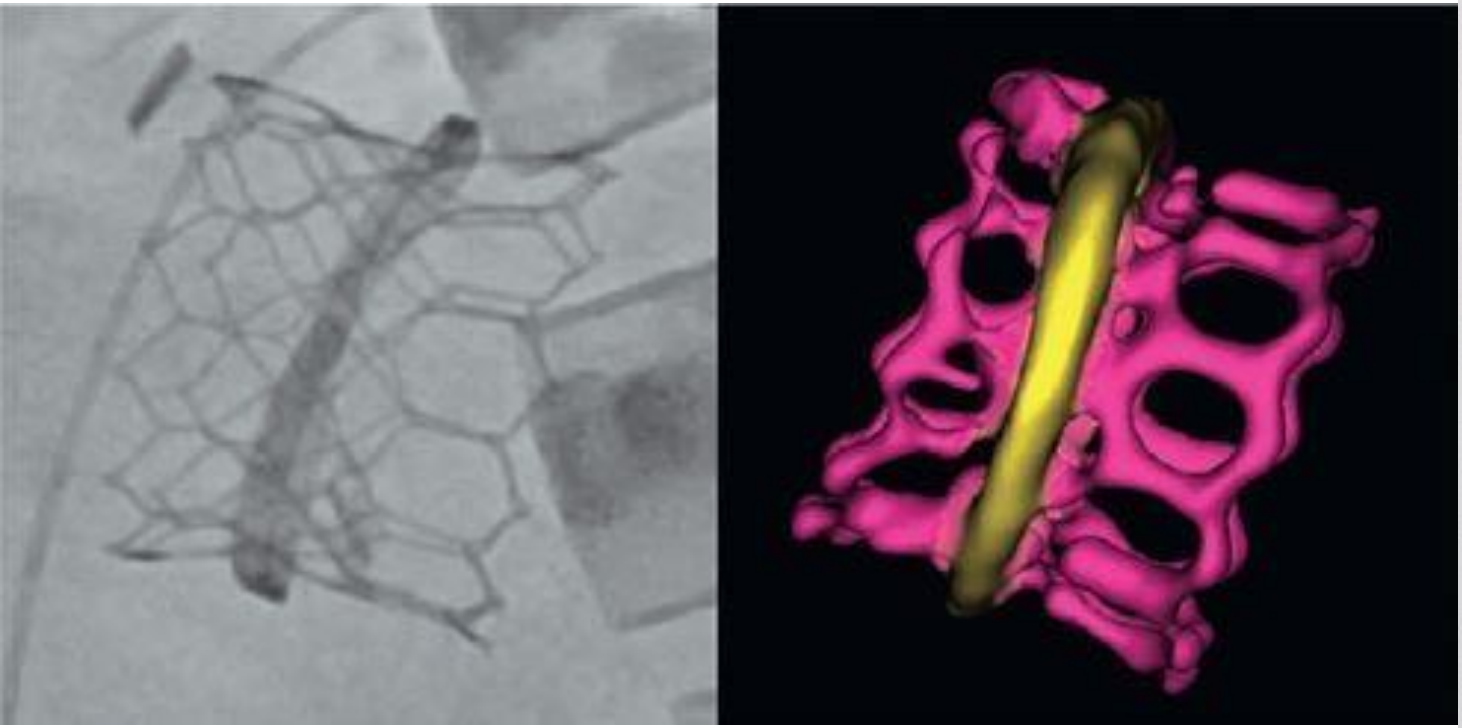
Yoon SH et al. Eur Heart J. 2018 Oct 23. doi: 10.1093/eurheartj/ehy590.
Guerrero M et al. Circulation. 2018;136:A23085

Valve in ring

- MITRAL-ViR arm
  - 30 patients, all transseptal access
    - Technical success 70%
      - Second valve in 6 patients with good outcomes
    - 2 in-hospital deaths
  - Procedural success at 30 days 62%
  - 7 ASA to increase likelihood of procedural success

Guerrero M et al. Abstract presentation at TCT 2017

Valve in ring



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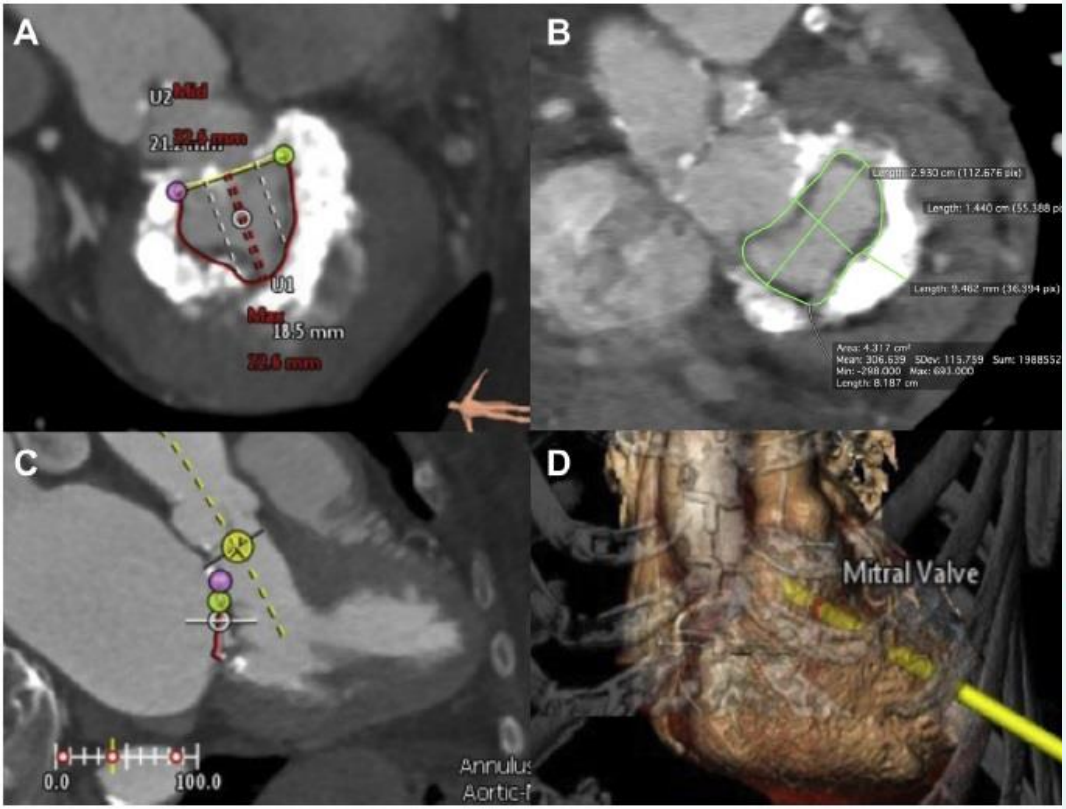
Valve in MAC



WHAT IS KNOWN? Patients with severe MAC have very high surgical risk for standard MV surgery. There is currently an unmet clinical need for many patients who are not treated due to their high surgical risk. There is limited data from few isolated reports of successful TMVR with balloon-expandable aortic THVs in patients with MAC who are not candidates for standard surgery.

WHAT IS NEW? This is the largest multicenter report to date of patients with severe MAC undergoing TMVR. We found that TMVR is feasible in patients with severe MAC who are not candidates for standard MV surgery but is associated with significant adverse events.

WHAT IS NEXT? Further studies are needed to refine the screening process to improve outcomes. The MITRAL trial is prospectively evaluating the safety and feasibility of this procedure and may provide further insights to improve the technical success, patient selection, and overall clinical outcomes.

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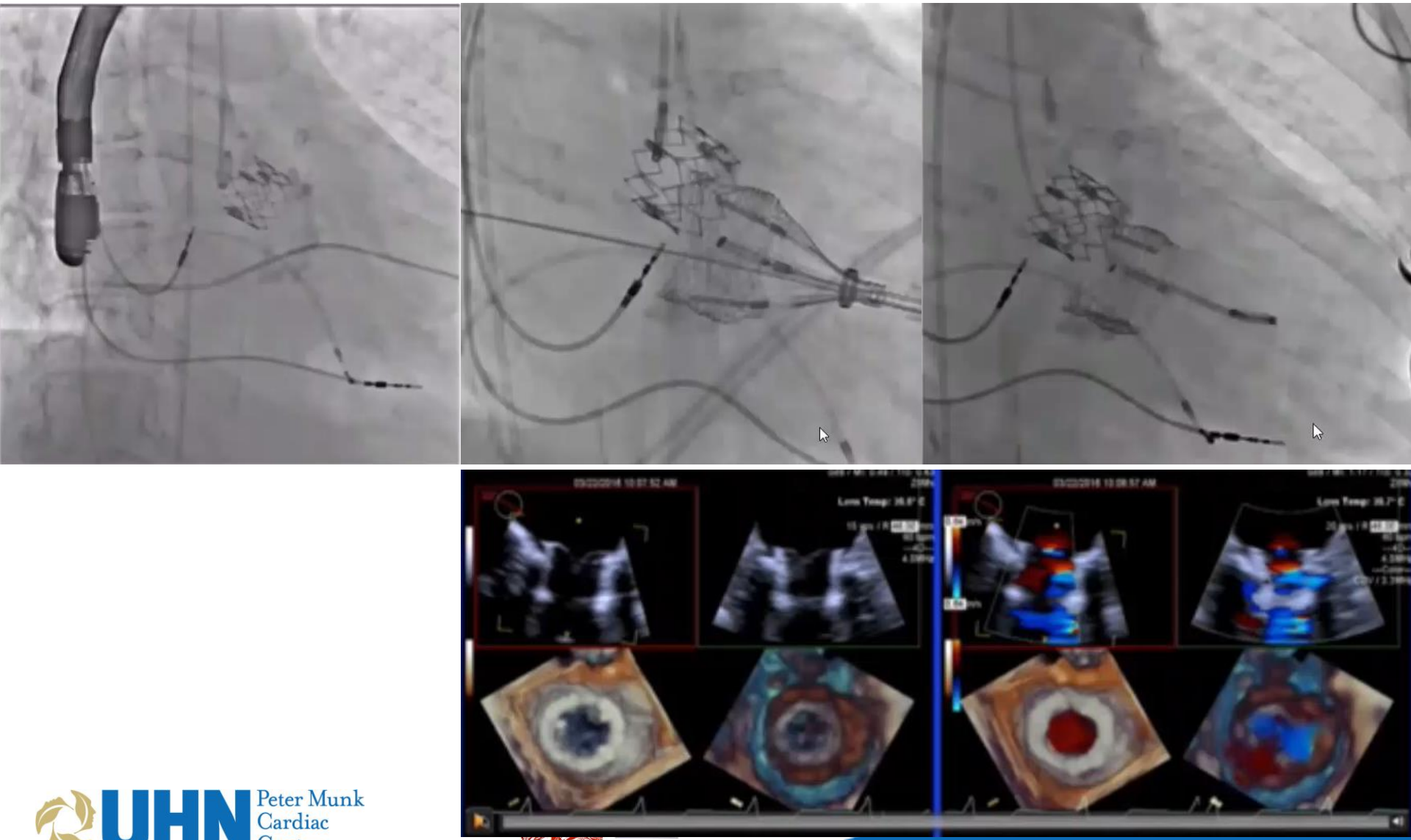
Guerrero M et al. JACC Cardiovasc Interv. 2016 Jul 11;9(13):1361-71. doi: 10.1016/j.jcin.2016.04.022.

Valve in MAC



LAMPOON

New devices

Ruiz CE et al. J Am Coll Cardiol. 2015 Jul 14;66(2):169-83. doi: 10.1016/j.jacc.2015.05.034.

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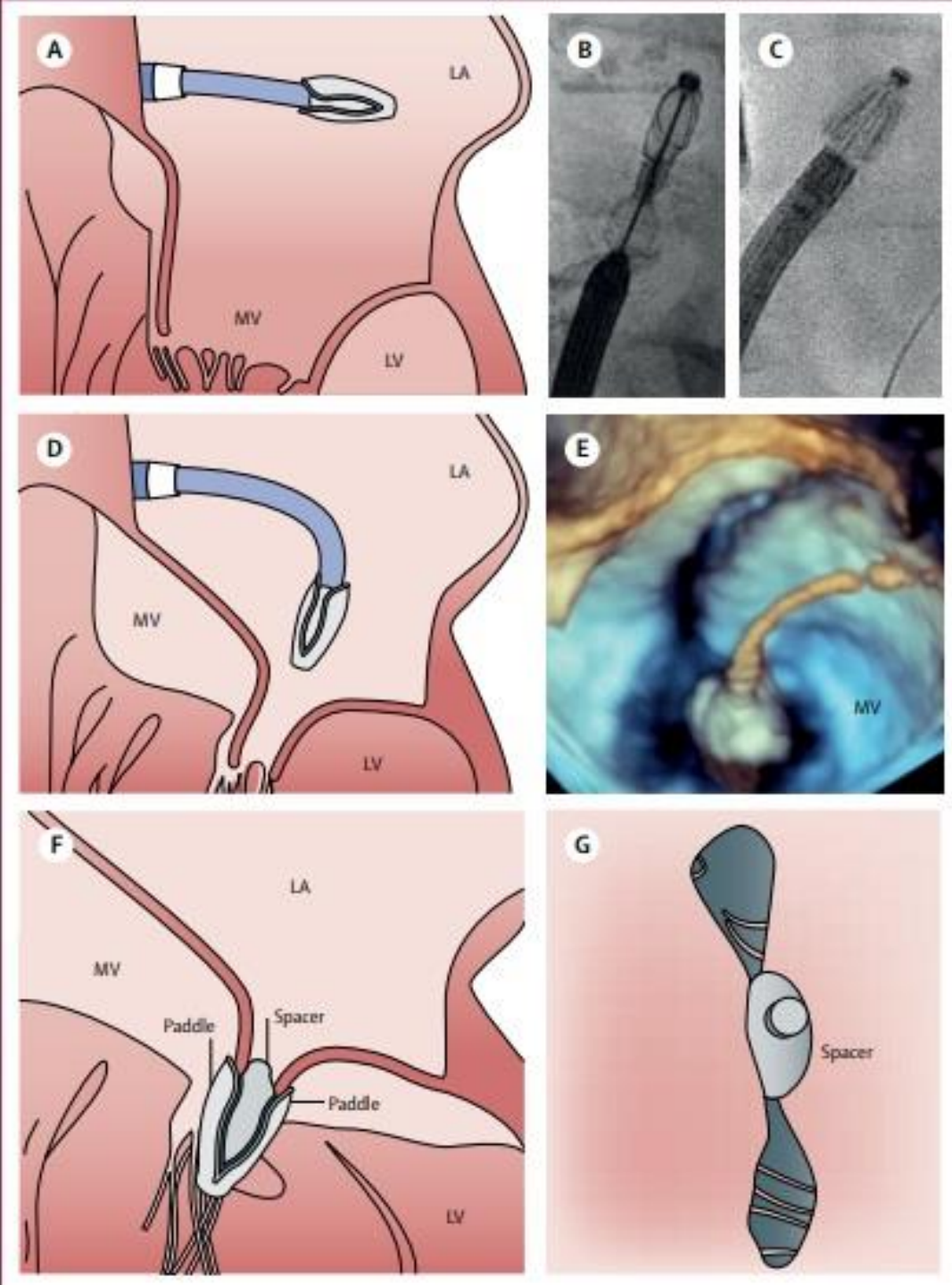
PASCAL



Praz F et al. Lancet. 2017 Aug 19;390(10096):773-780. doi: 10.1016/S0140-6736(17)31600-8.

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Tendyne

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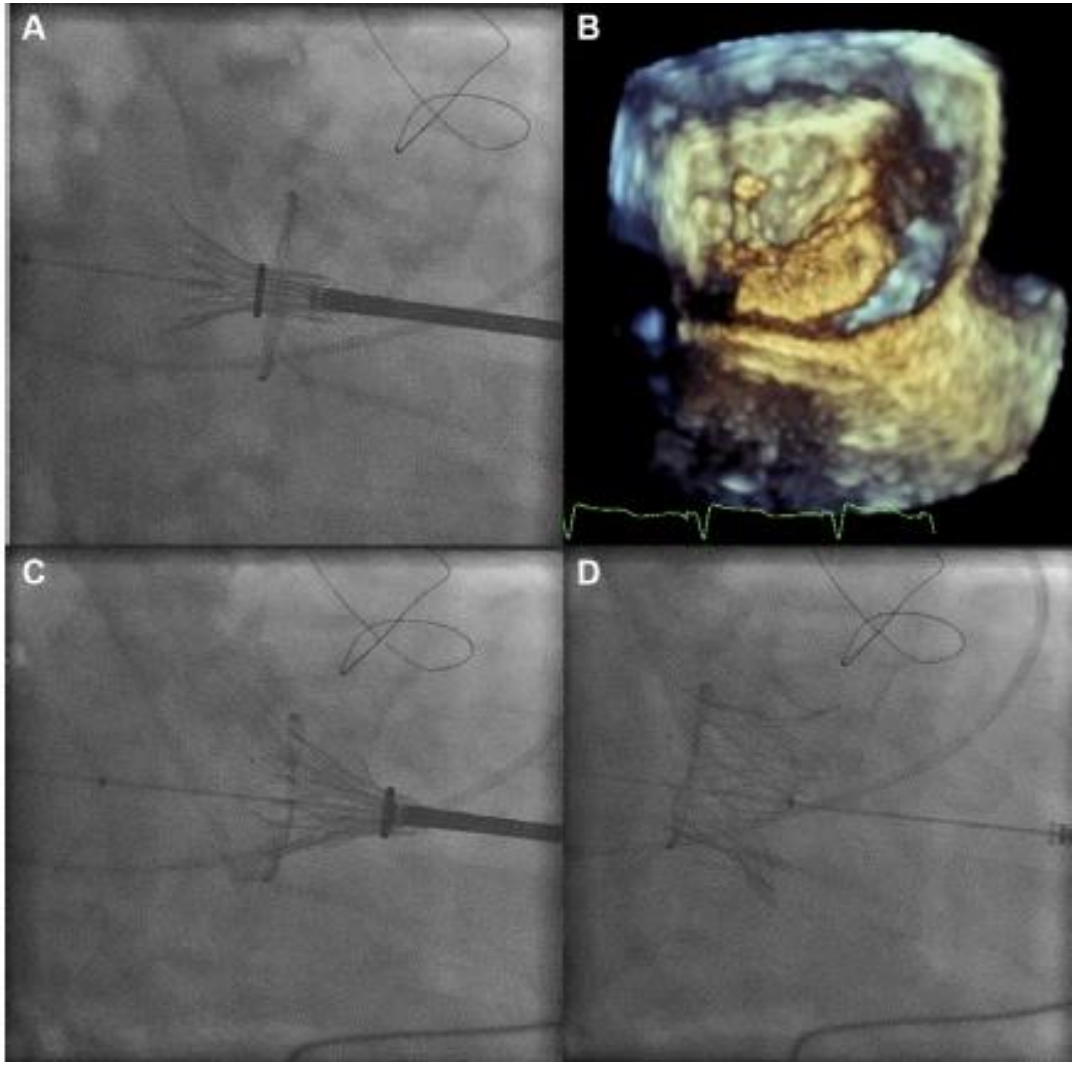
Duncan A et al. EuroIntervention. 2017 Oct 13;13(9):e1047-e1057. doi: 10.4244/EIJ-D-17-00154.

TIARA



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Cheung A et al. JACC Cardiovasc Interv. 2017 Oct 9;10(19):2012-2014. doi: 10.1016/j.jcin.2017.08.019.

Therapies for mitral regurgitation with...

...native valves

- Edge-to-edge repair: Mitraclip, Pascal
- Annuloplasty rings: Carillon (Direct); Mitralign, Accucinch device and Cardioband (Indirect)
- Chordal implants: NeoChord and V-Chordal
- Transcatheter mitral valve replacement (TMVR): CardiAQ mitral valve, Fortis mitral valve, TIARA mitral valve and Tendyne mitral valve

...mechanical prosthetic valves

- No approved options for repair or replacement

...biological prosthetic valves

- ViV off-label TAVR for prosthesis
- Valve-in-ring (ViR) off-label TAVR for annuloplasty

...paravalvular leaks (PVL)

- Off-label Amplatzer vascular plugs

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Ruiz CE et al. J Am Coll Cardiol. 2015 Jul 14;66(2):169-83. doi: 10.1016/j.jacc.2015.05.034.

CURRENT AND PROSPECTIVE MILESTONES FOR PERI-PROCEDURAL ECHOCARDIOGRAPHY

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CURRENT

- Mastery of procedure-specific TEE requirements
- Mastery of modified angles and/or axes to accommodate for atypical anatomy
- Comfort with 3D TEE

TEE Mitral Valve Anatomy Assessment

Members Present: EH MO Moz MB VR MMc PB MM WT AC JD NB KS Abbott

Date of Review: **Date of TEE:**

Patient Name: **MRN:** **IP** **Elective**

ECHO Image Quality: **Excellent** **Good** **Suboptimal**

MR Pathology: **Degenerative** **Functional**

MVA > 4cm2 ☐
Septal Height > 4 cm ☐

Presence Flail leaflet ☐
Flail Width < 15mm (> is ineligible) ☐
Flail Gap < 10mm (> is ineligible - consider XTR device) ☐

Location Dominant Jet (A2P2 or other location- Carpentier Classification) _____

Commissural Prolapse Involving Dominant Jet ☐
Presence Secondary Jet ☐
Location: _____

Posterior Leaflet length > 0.7cm (< is difficult grasp) ☐

Presence of MAC ☐
Presence of Leaflet Calcification in grasping area ☐
Presence of Mitral CLI ☐

FMR Pathology:

Malcoaption Gap <2-3 mm (>difficult grasp) ☐
EORA > 30mm2 ☐
LVEF is 20-50% ☐
LVEDV < 120 ml/m2 ☐
Regurgitant Volume >45ml/m2 ☐
No excessive LV dilation (No benefit dilated LV and decreased MR) ☐
Guideline Directed Medical therapy (GDMT) ☐
Best Tolerated GDMT and still symptomatic ☐
CRT implant ☐

Status: Green Yellow Orange Red Black

Summary:

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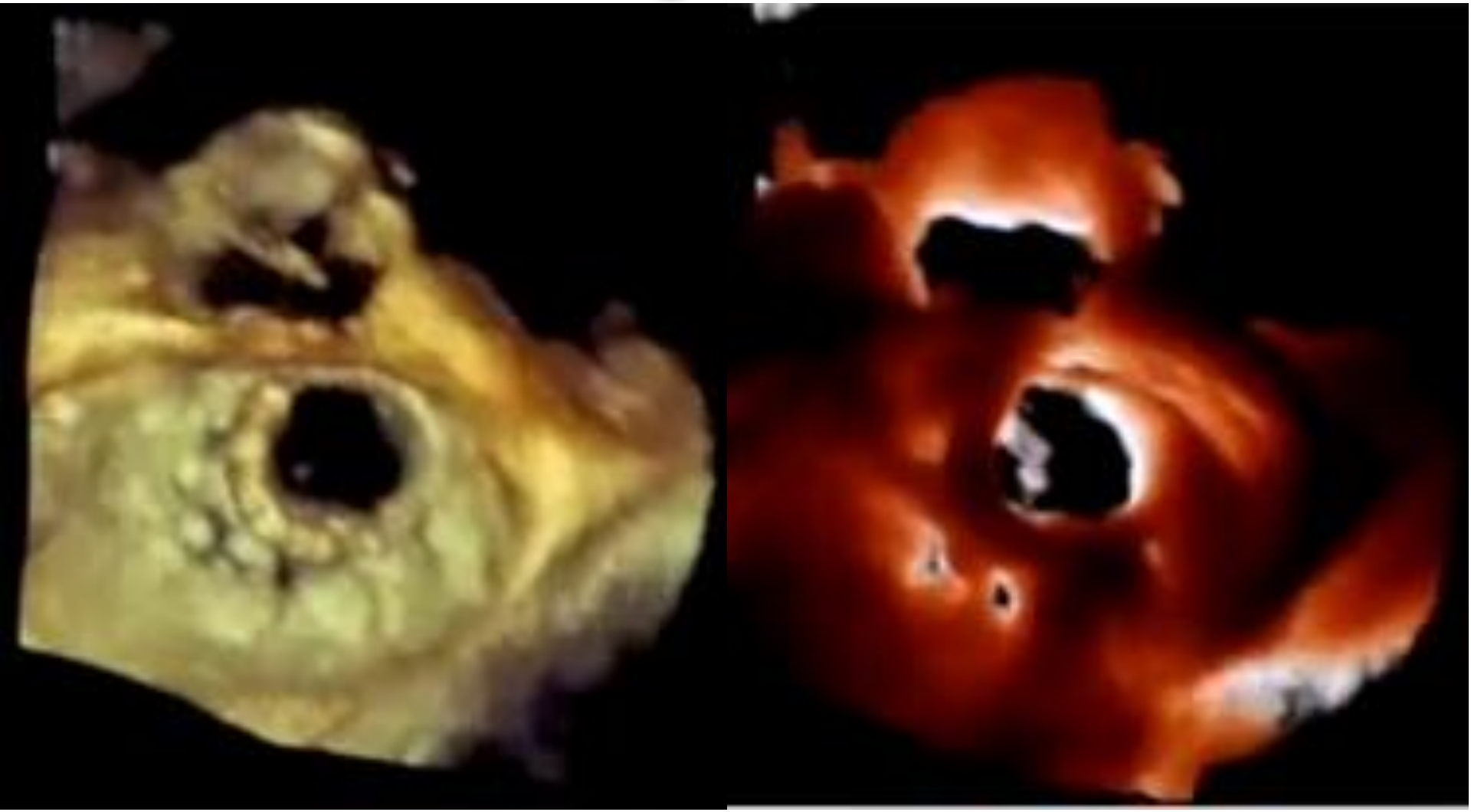
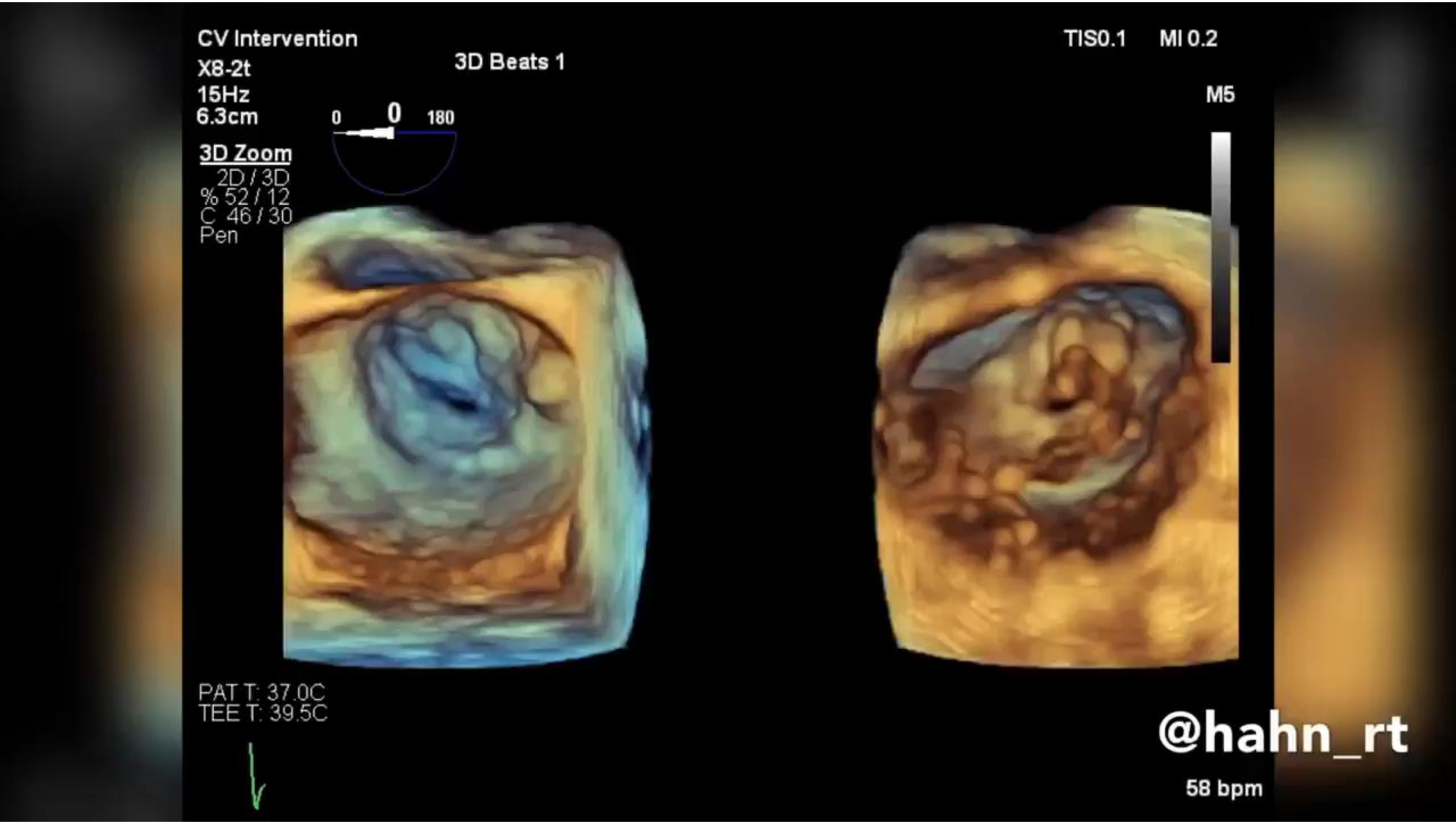
Going forward



Illumination or pseudo-colorization



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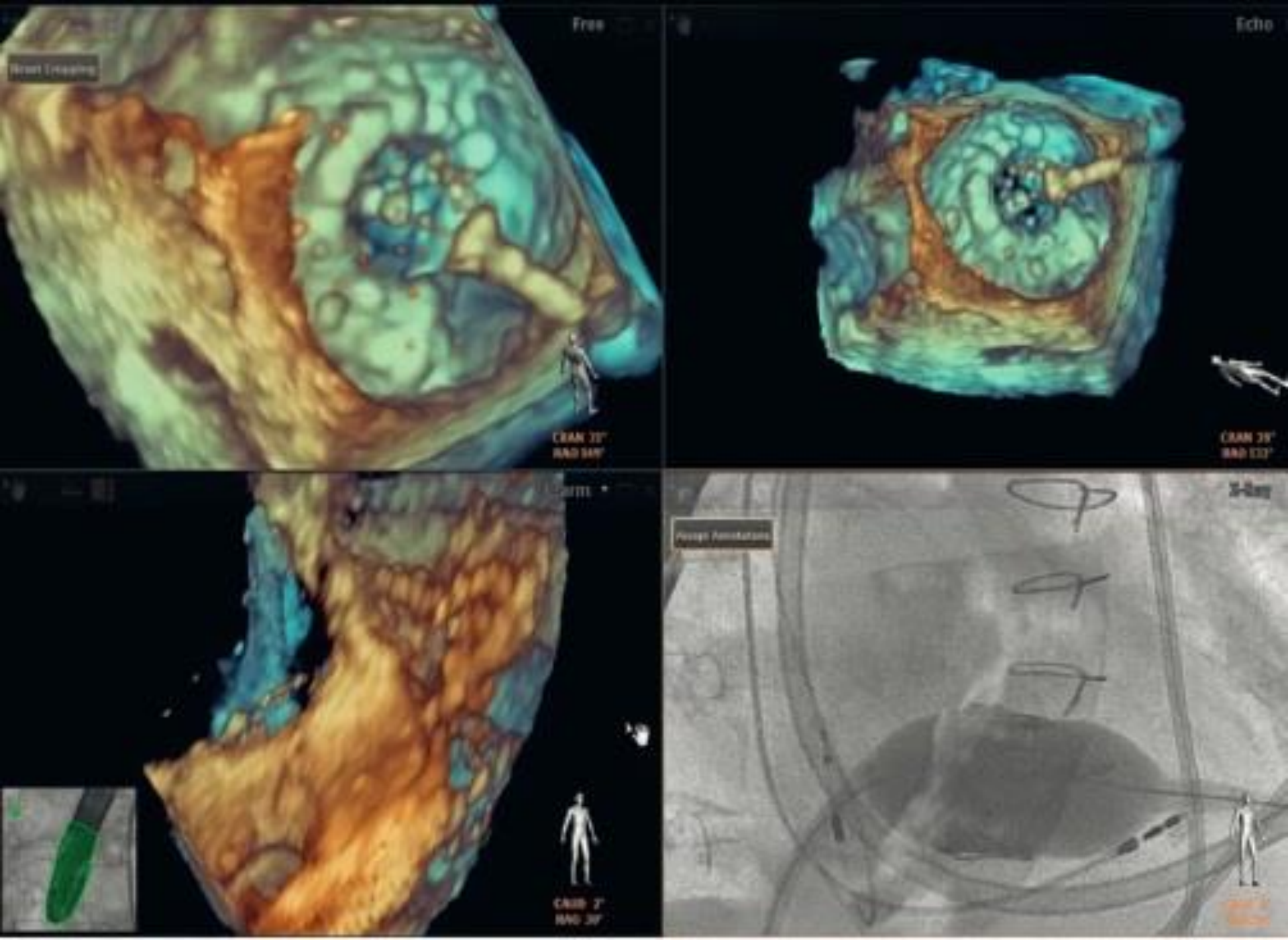
FUSION IMAGING

Ruiz CE et al. J Am Coll Cardiol. 2015 Jul 14;66(2):169-83. doi: 10.1016/j.jacc.2015.05.034.



Ruiz CE et al. J Am Coll Cardiol. 2015 Jul 14;66(2):169-83. doi: 10.1016/j.jacc.2015.05.034.

Thank you for your attention

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