Transcatheter Mitral Valve Interventions: Clinical Indications

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Conflicts of interest:

-Consultant for Medtronic

-Consultant for Cephea

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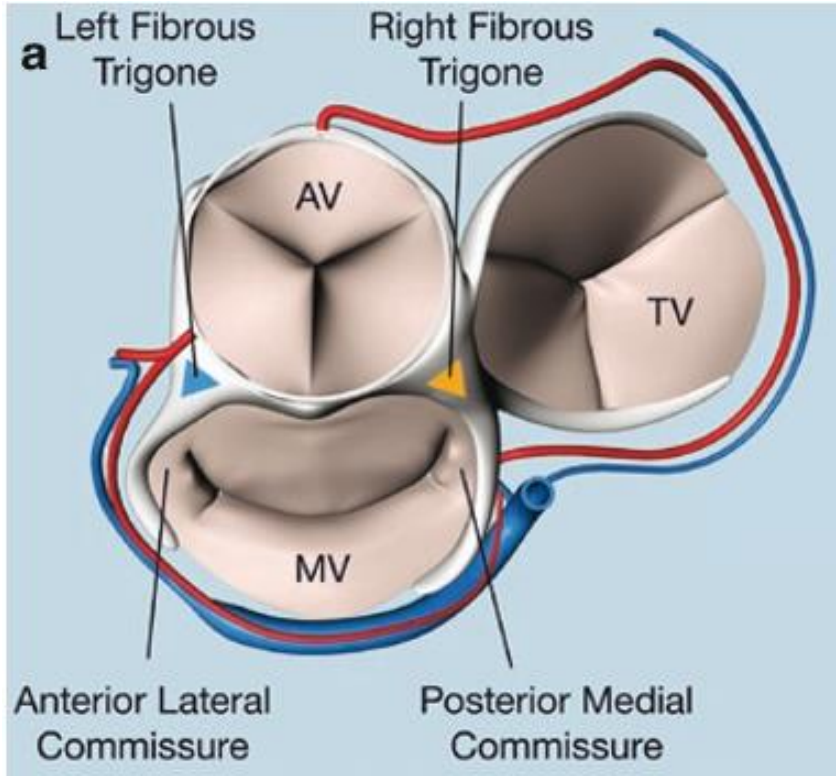
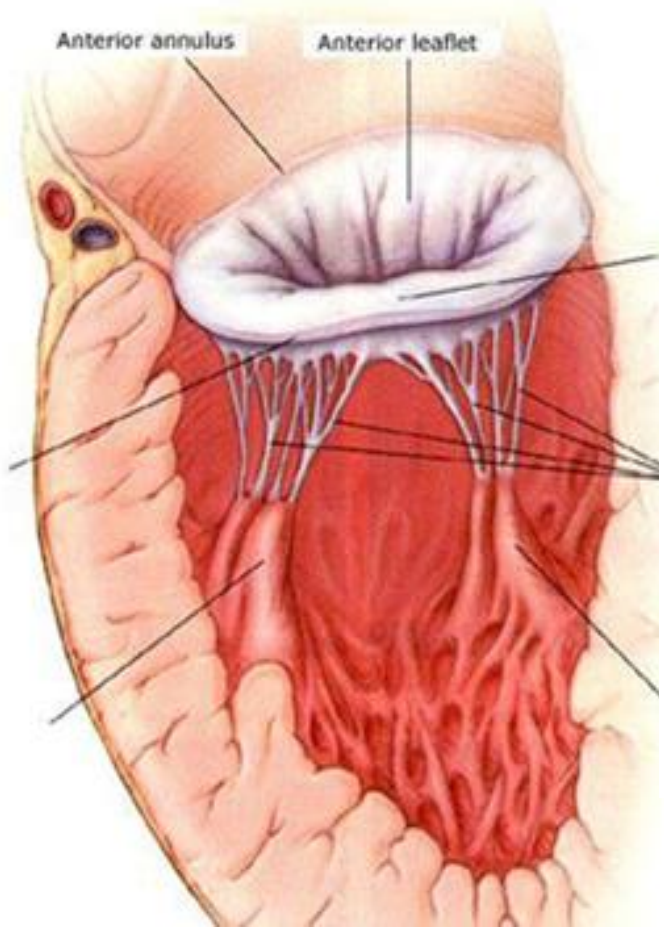
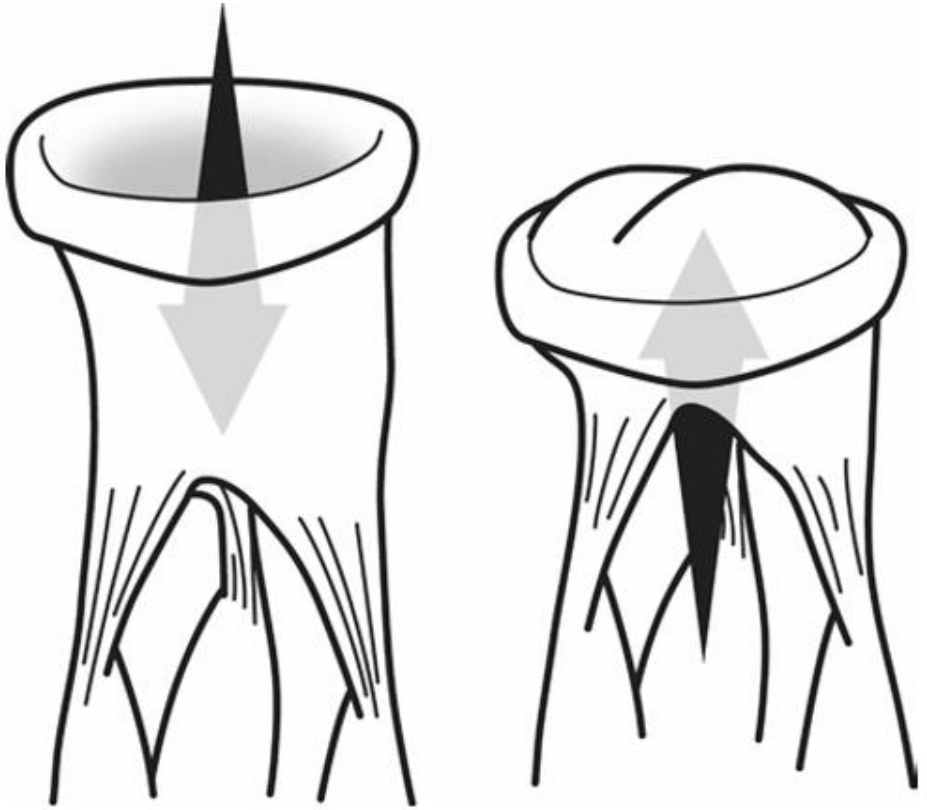
Anatomy of the mitral valve

A complex and dynamic valve







Mitral valve disease

Stenosis

Rheumatic disease

Leaflets thickening
Comsissures fusion,
Chordae retraction
Calcifications

Extrinsic compression

Mitral annular calcifications

Regurgitation

Primary

Abnormal structure of the leaflets/ chordae

- Inflammatory disease
- Congenital

Secondary

LV disease

- Ischemic
- Dilated Cardiomyopathy

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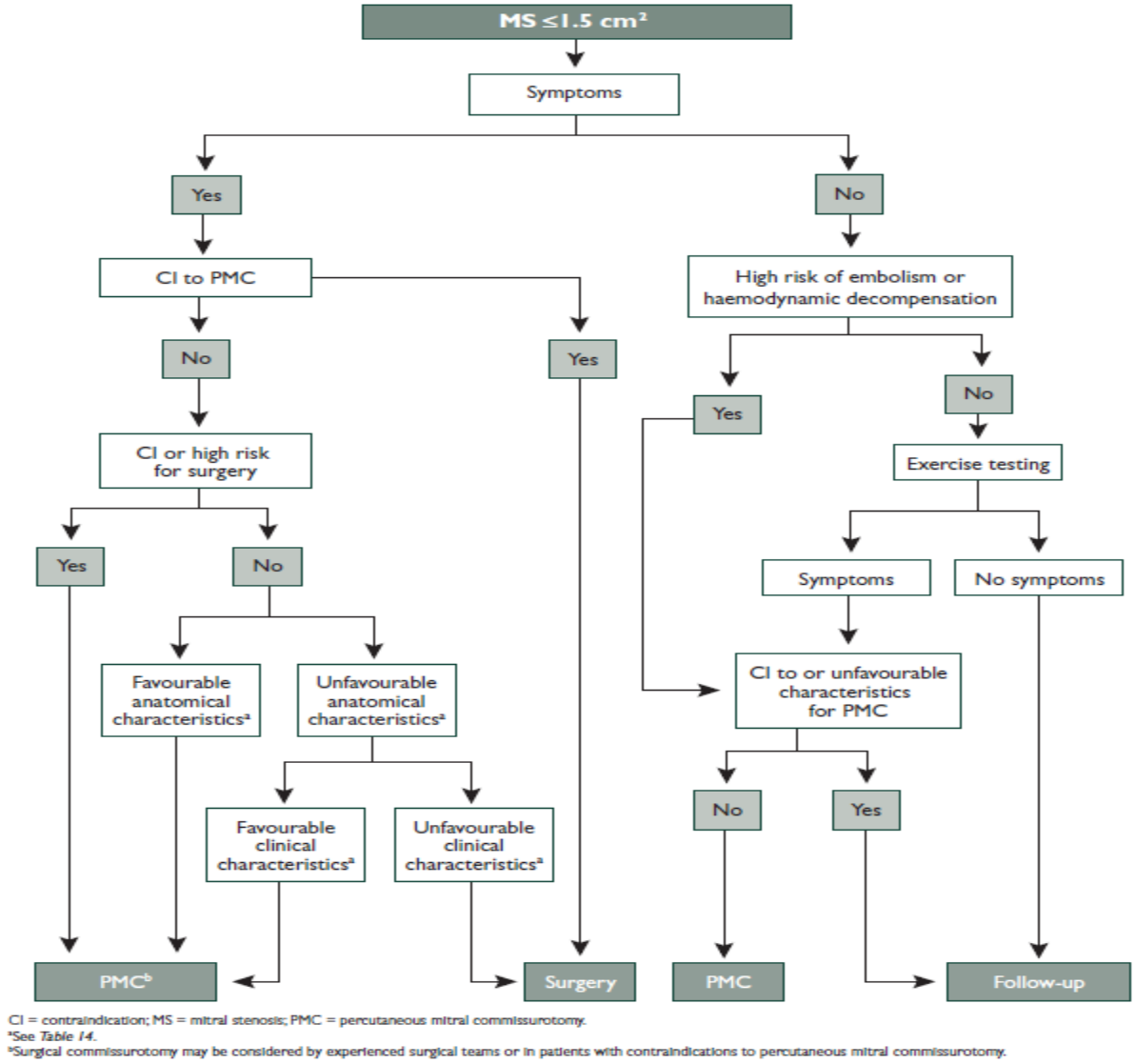
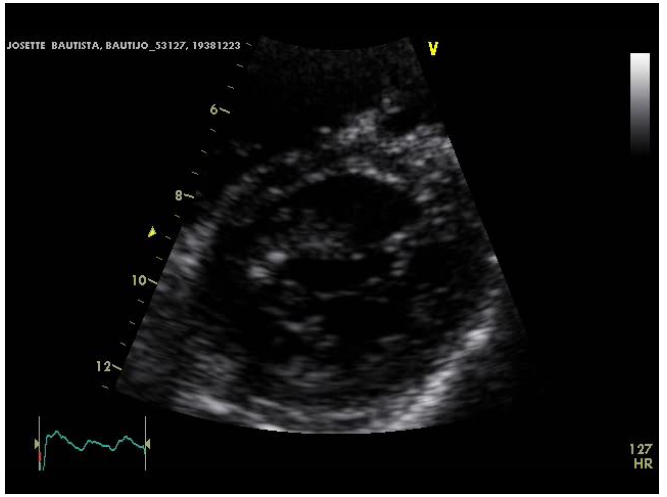
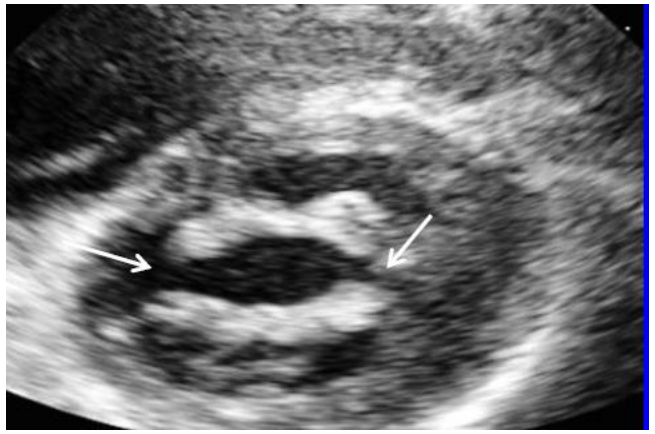
Mitral stenosis

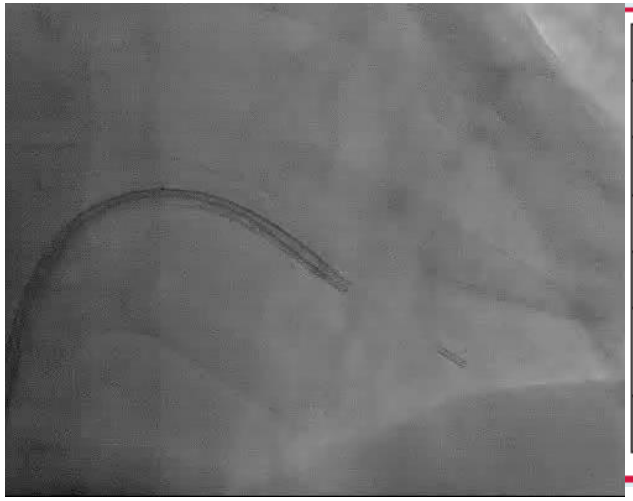
Percutaneous mitral commissurotomy



CI = contraindication; MS = mitral stenosis; PMC = percutaneous mitral commissurotomy.
[a]See *Table 14*.
[b]Surgical commissurotomy may be considered by experienced surgical teams or in patients with contraindications to percutaneous mitral commissurotomy.



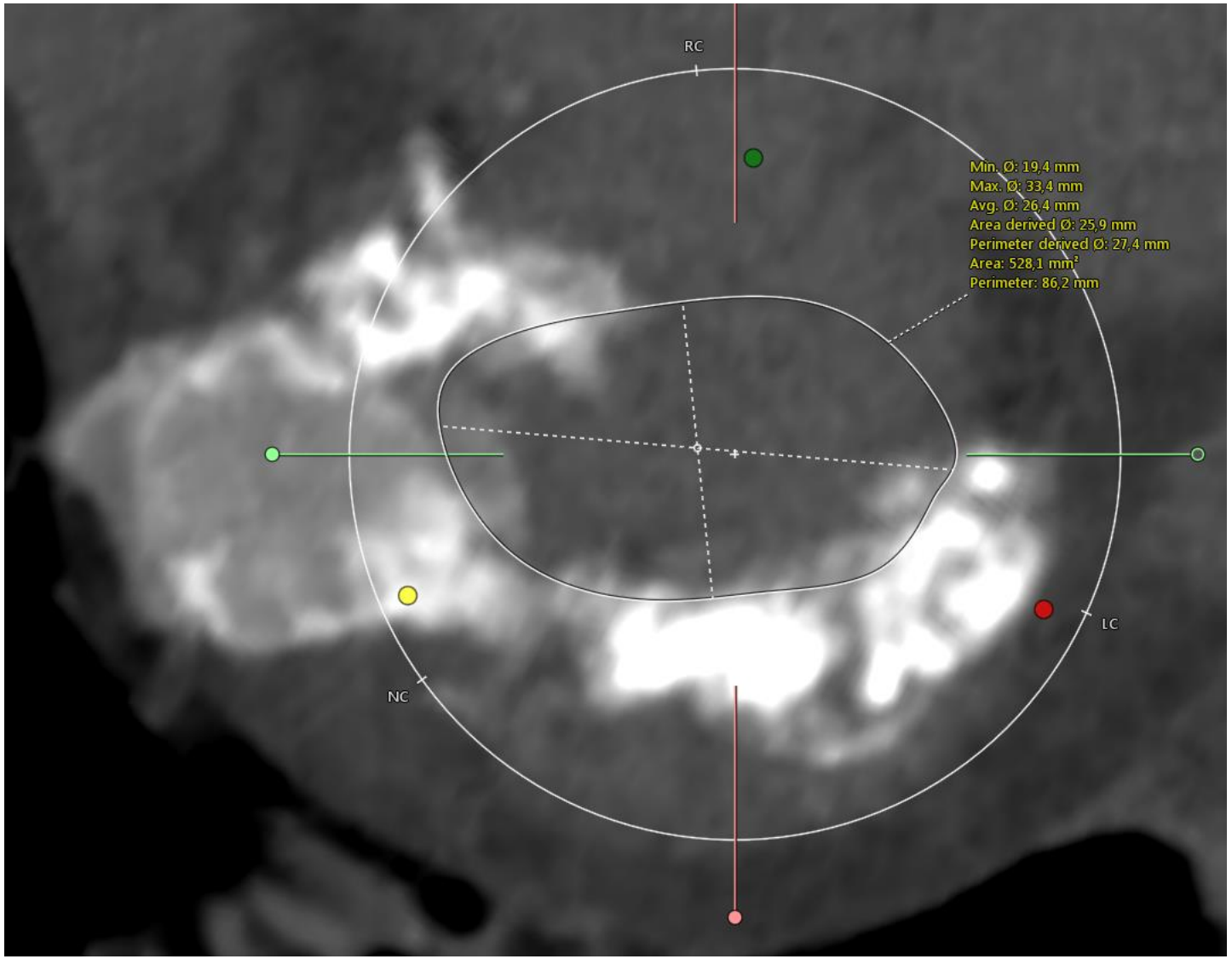


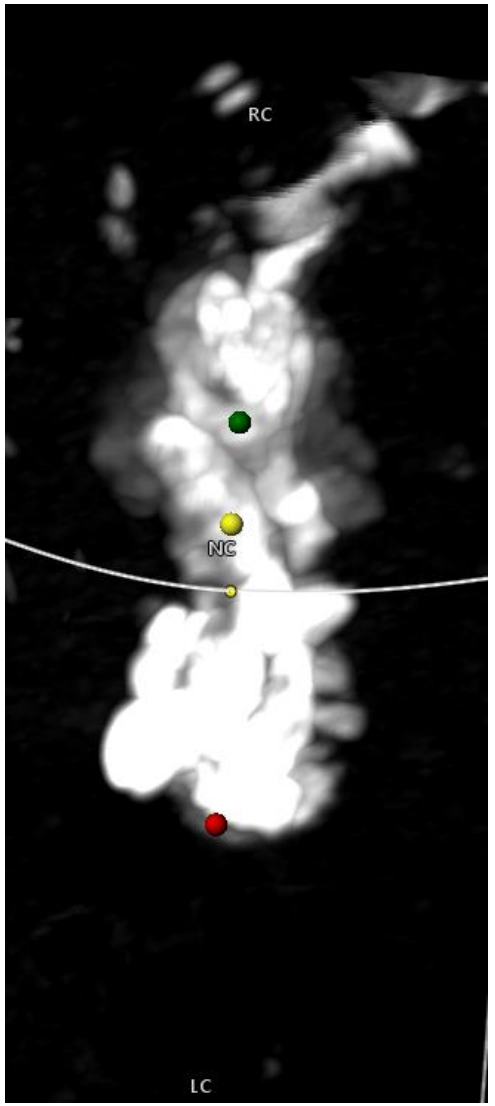


- Mitral valve area >1.5 cm²
- Left atrial thrombus
- More than mild mitral regurgitation
- Severe or bicommissural calcification
- Absence of commissural fusion
- Severe concomitant aortic valve disease, or severe combined tricuspid stenosis and regurgitation
- Concomitant coronary artery disease requiring bypass surgery

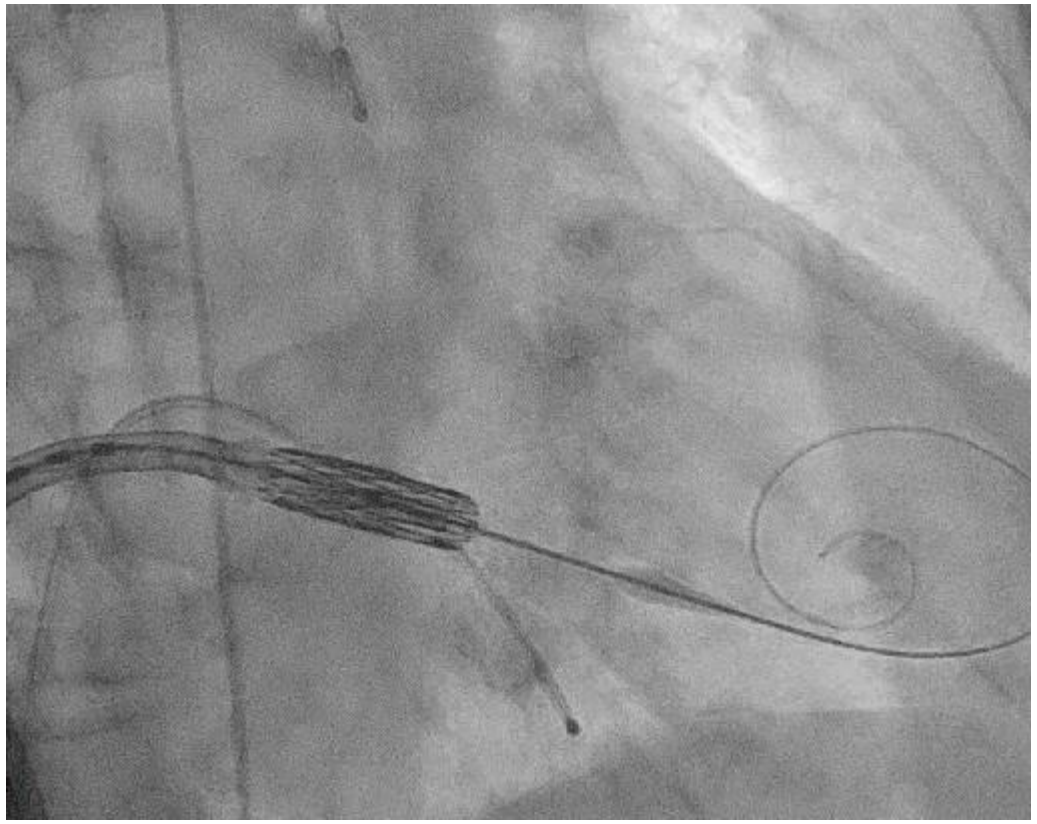
Contra-indications

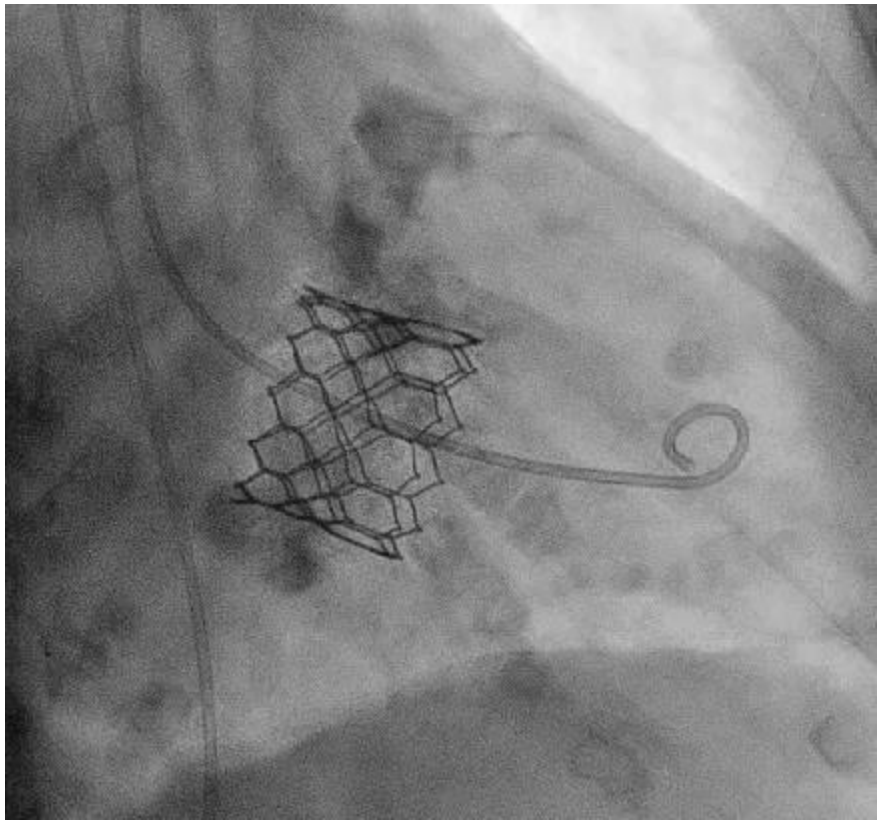
Percutaneous treatment of MAC





Percutaneous treatment of MAC





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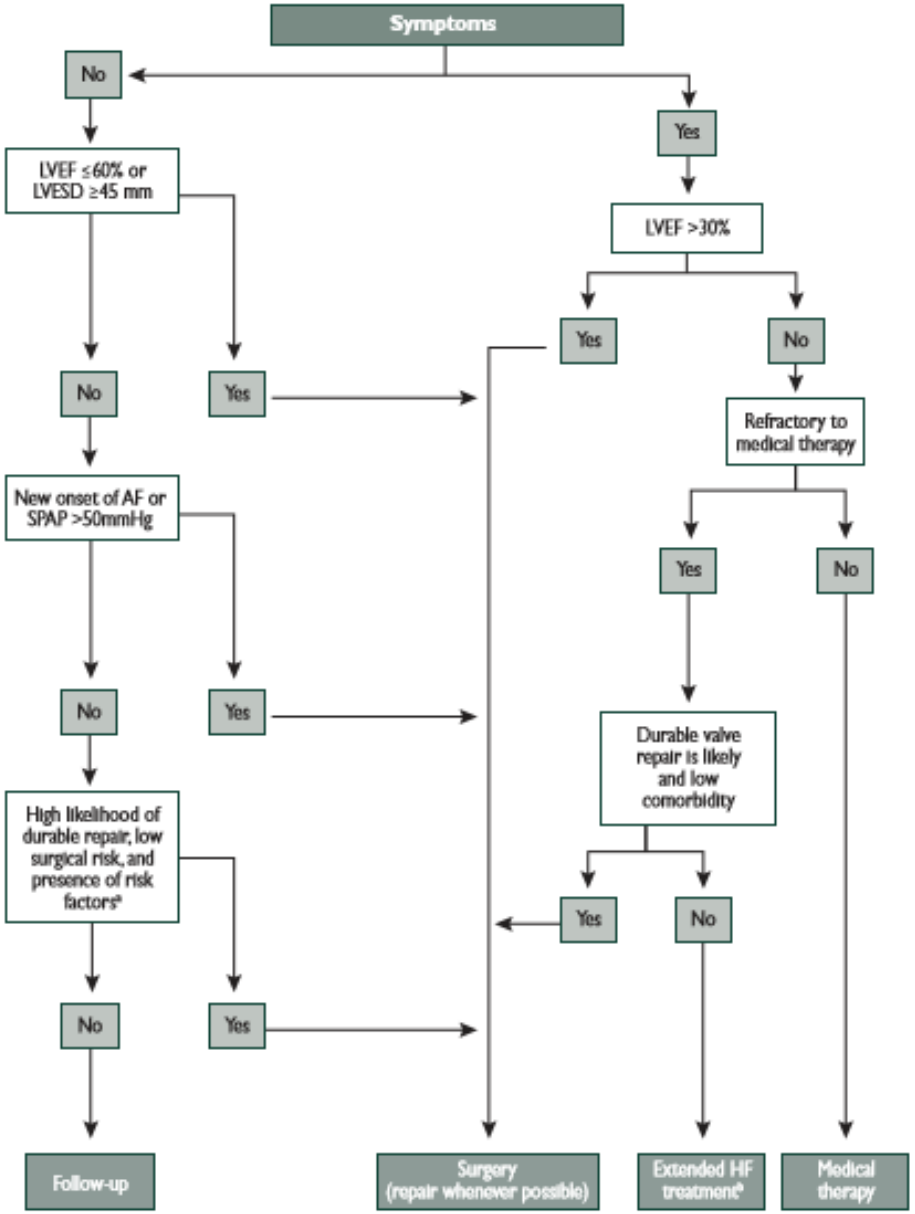
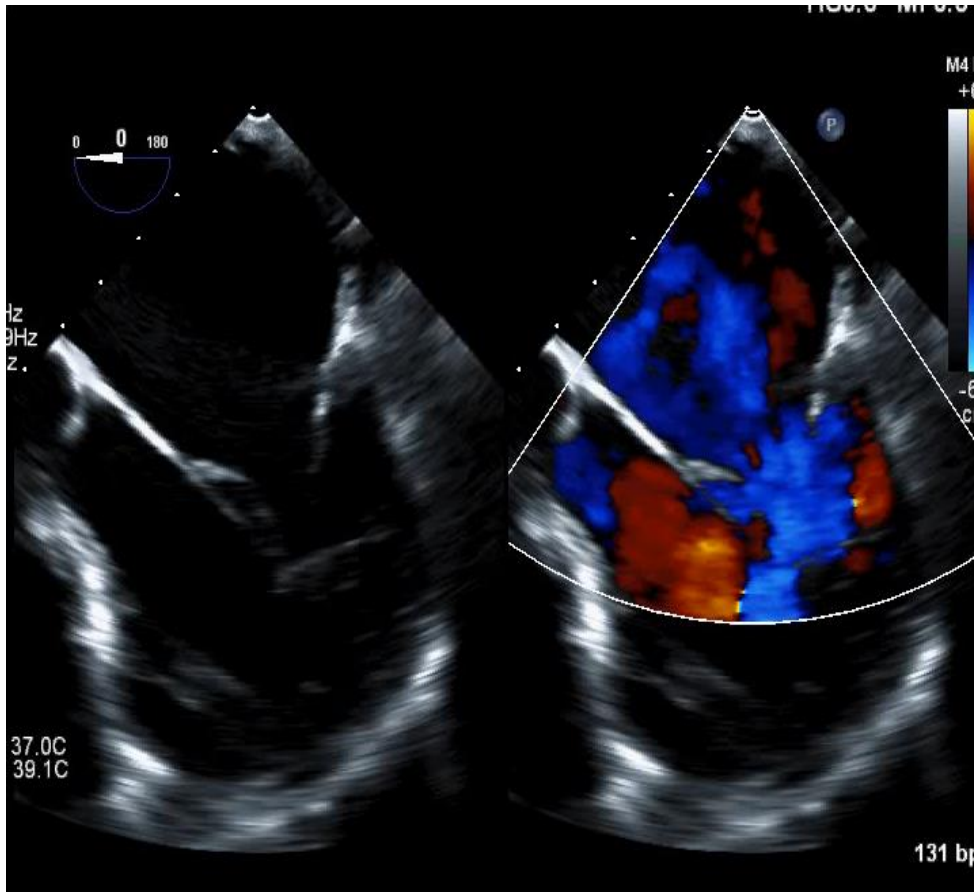
Mitral regurgitation

ESC/EACTS guidelines





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Percutaneous mitral repair

Transcatheter mitral valve repair: portfolio

Edge-to-Edge	Direct Annuloplasty	Chordal repair	Coaptation Enhancement
•Cardica •Mitraclip •Mitraclamp •SAT Mitral Clip •St. Jude leaflet plication	• Cardiac Implants • Millipede • Mitralign • Mitraspan • TAU-PNU CSTV • PolyCor MIATM • Transmural cerclage system • Valcare AMEND	• Babic chords • CoreMedic • Harpoon Medical • Neochord DS1000 • Valtech V-chordal	• Cardiac Dimensions • Cardiosolutions mitralspacer • Coramaze • GDS Accucinch • Mitralix MISTRAL • MVRX Arto • Mitral Butterfly Vienna university • Bioventrix • Mardil BACE

Courtesy of N. Piazza

Transcatheter mitral valve repair: CE mark Evolution

MitraClip Evalve
(Abbott)

Enhanced CARILLON®
Mitral Contour System
Cardiac Dimensions
(September)

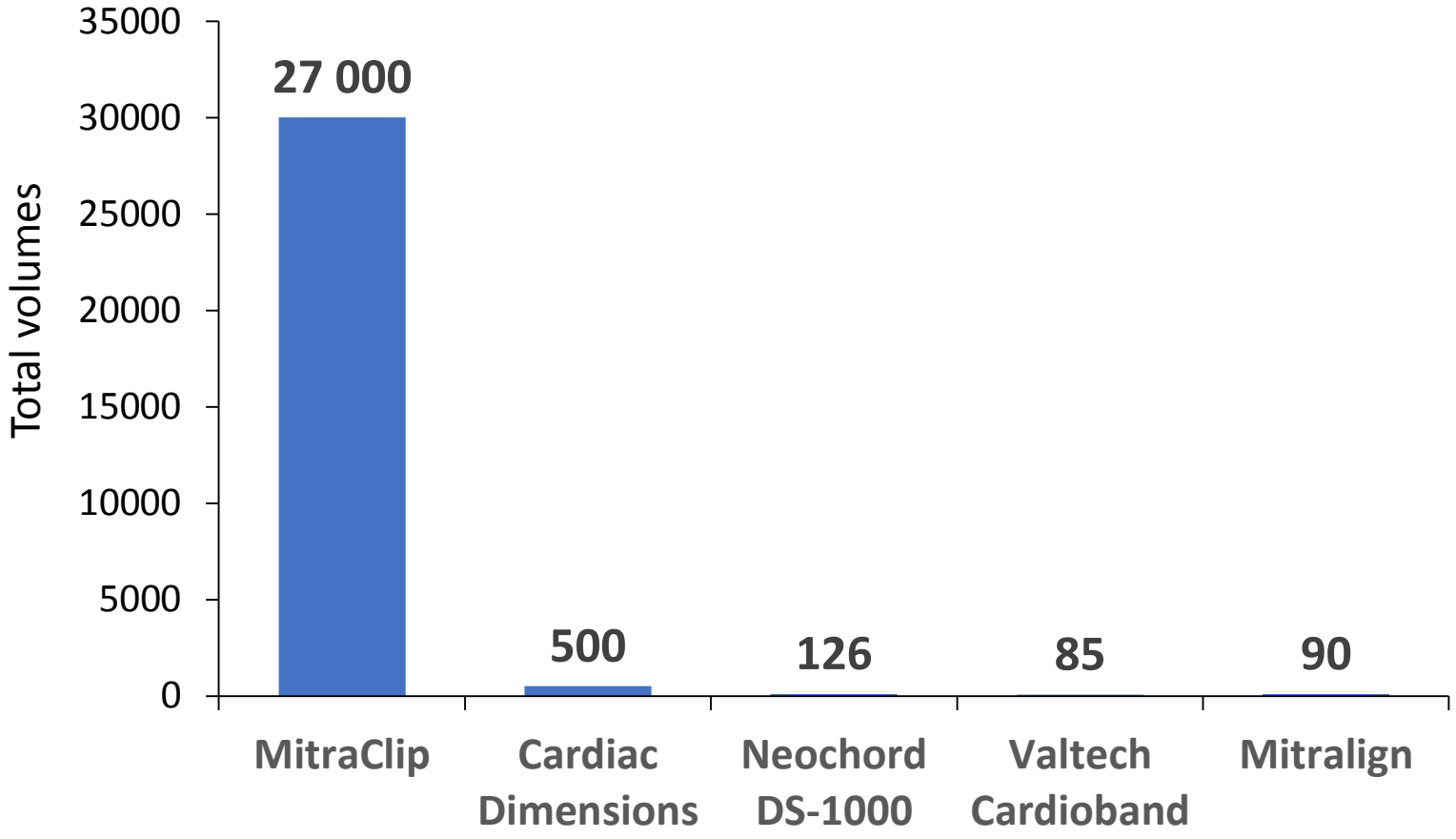
CardioBand Valtech
(September)

2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016

CARILLON® Mitral Contour
Cardiac Dimensions
(February)

Neochord
(January)

Mitralign
(February)


35000
30000
25000
20000
15000
10000
5000
0
Total volumes
27 000
500
126
85
90
MitraClip
Cardiac Dimensions
Neochord DS-1000
Valtech Cardioband
Mitralign

MitraClip

Ideal for Mitralclip treatment
Severe mitral regurgitation
and
Optimal valve morphology
and
SMR with LV-EF <30 %
or
PMR (with operation-indication following guidelines)
and
A high operative risk or other risk-constellations

MitraClip

Unsuitable valve morphology
Perforated mitral valve leaflet or cleft
Severe calcification in the grip-zone
Haemodynamically significant mitral stenosis (valve opening area $<3\ cm^2$, MPG ≥ 5 mmHg)
Mobile length of the posterior leaflet <7 mm
Rheumatic leaflet thickening and restriction in systole and diastole(Carpentier IIIA)
Barlow's syndrome with multisegment flail leaflets

Percutaneous mitral replacement

Transcatheter mitral valve replacement

Braile Biomedica

Braile Biomedica

CardiAQ 1st G

CardiAQ Edwards

Cephea

Direct Flow Medical

Twelve Medtronic

M-Valve

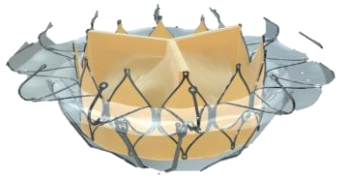
Edwards Fortis

HighLife

Navigate

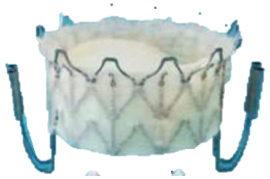
Neovasc Tiara

PermaValve MID



Sinomed

Tendyne Abbott



SATURN TMVR

Valtech CardioValve

Daidalos sutureless clamp

Others: Caisson, MitraHeal, Mitrassist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo

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TMVR: Enrolled populations

	CardiAQ (n=9)	Tendyne (n=11)	Edwards FORTIS (n=13)	Twelve (n=12)	Neovasc (n=11)
Age (years)	80	75	71	75	39-89
Males (%)	67	100	77	67	N/A
Secondary MR (%)	100	N/A	93	75	73
Prior cardiac Sx (%)	78	32	N/A	42	55
LVEF (%)	42	40	34	43	34

30 day mortality has ranged between 0-40%
largely influenced by patient selection

Tendyne: Baseline Characteristics

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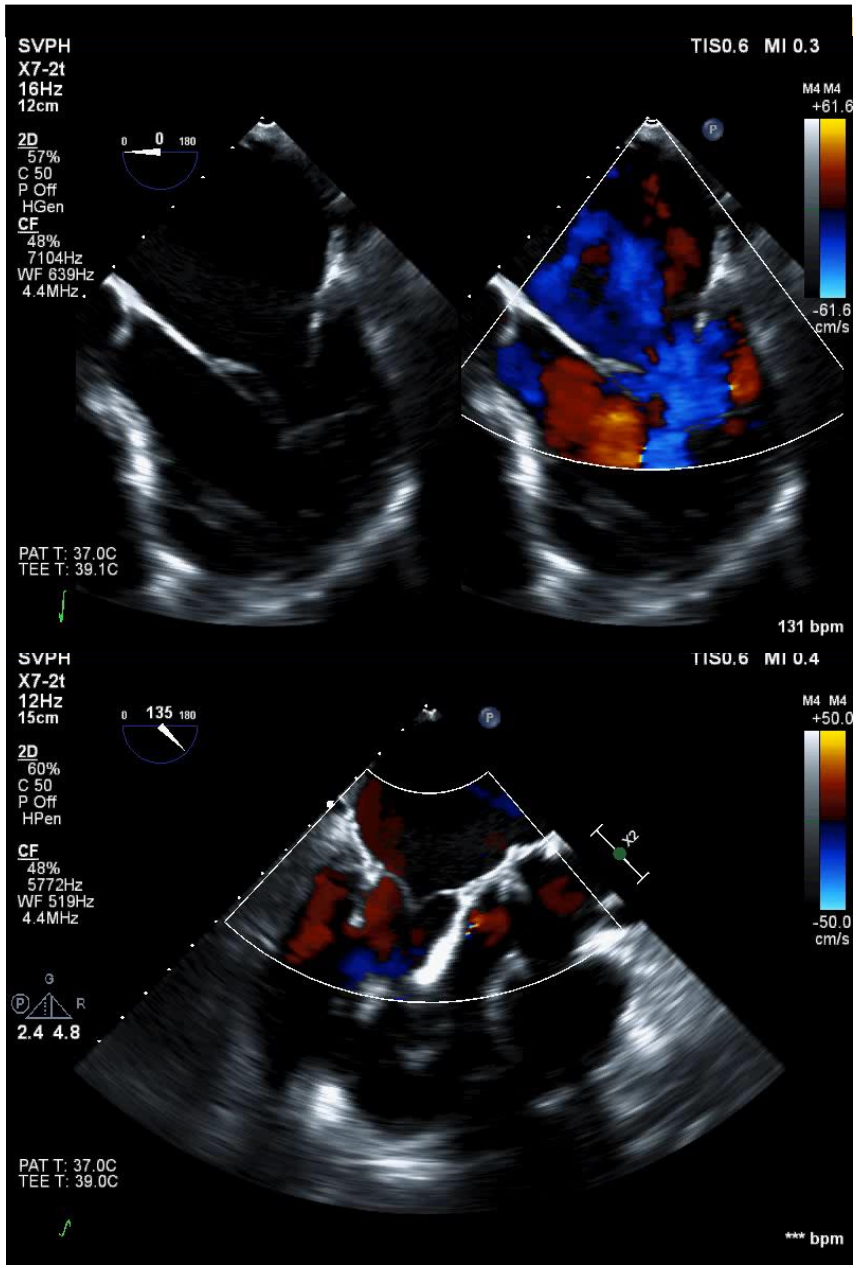
Pt.	Age	Sex	Valve Etiology	PreOp MR	PreOp NYHA	PreOp EF	PreOp STS
1	68	F	FMR	4+	III/IV	35%	7%
2	76	M	DMR	4+	IV	51%	9%
3	87	M	DMR	4+	III	47%	7%
4	76	M	FMR	4+	II	24%	7%
5	74	F	DMR	4+	III/IV	61%	8%
6	73	M	FMR	4+	IV	40%	2%
7	77	M	FMR	4+	IV	35%	8%
8	76	M	FMR	4+	III	30%	4%
9	82	M	FMR	4+	III	44%	10%
10	73	M	FMR	4+	III	35%	16%

Highlights:

- ✓ **Mix of FMR / DMR Etiologies**
- ✓ **All Patients MR 4+**
- ✓ **High Risk Patients Not Suitable for Conventional Surgery**
- ✓ **Initial Learnings:**
  - ✓ **Atrial Deployment (Patients 1-2) Resulted in PVL**
  - ✓ **Intra-Annular Deployment Resulted in No PVL**
- ✓ **Tendyne TMVR can be Safely and Atraumatically Retrieved**

Tendyne: Pre and Post Echo

- 73 yr old M, anterior MI 1997, LVEF 40%, moderate MR
- Severe FMR/CCF, biventricular PPM 09/14
- Severe cardiac, renal and hepatic failure 12/14; LVEF <30%, PA >75mmHg.
- 3mth follow-up: no MR, NYHA I, LVEF 45%



Slide courtesy of Dr. David Muller, St. Vincent's Hospital, Sydney Australia

Twelve TMVR Pilot Study

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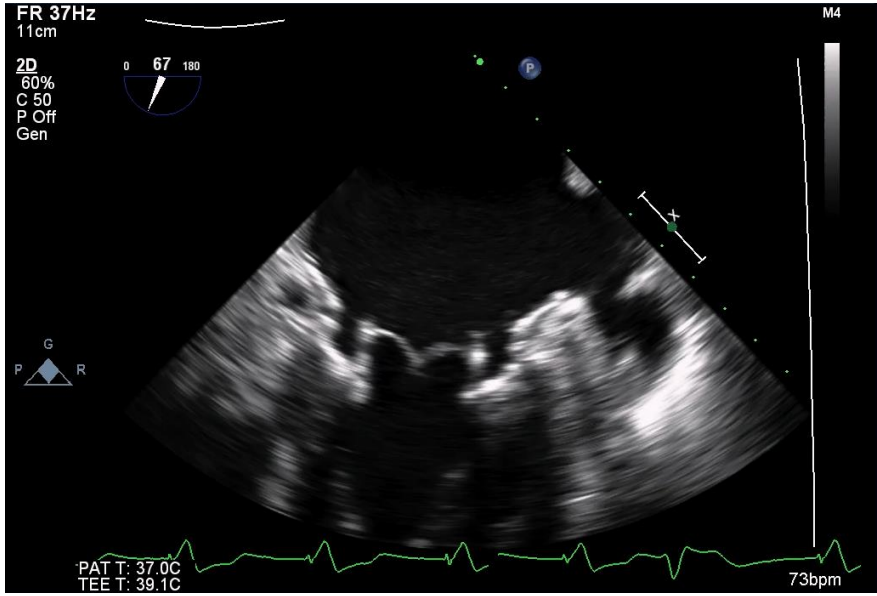
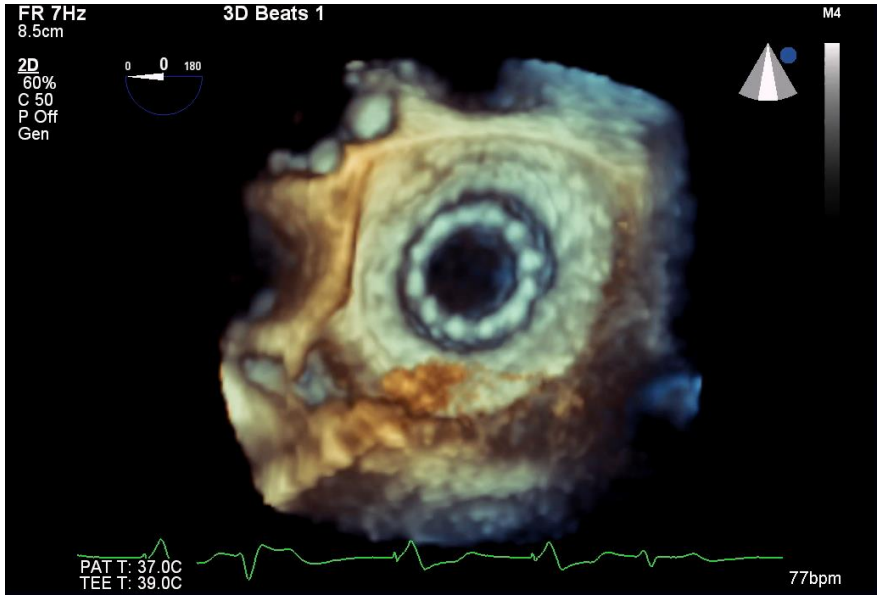
- Key Inclusion Criteria
  1. Severe MR (MR Grade 3-4+)
  2. Symptomatic MR (NYHA Class II-IV)
  3. Trans-apical access deemed feasible by the treating physician
  4. Native mitral valve geometry and size compatible with the Twelve TMVR
  5. No or minimal mitral valve calcification
- Key Exclusion Criteria
  1. **Left ventricular ejection fraction (LVEF) < 20**
  2. Evidence of intracardiac mass, thrombus, or vegetation
  3. **Pulmonary hypertension (PAP > 70mmHg)**
  4. **Hypertrophic Obstructive Cardiomyopathy (HOCM)**
  5. Prior valve surgery or need for other valve surgery
  6. Prior stroke within 30 days
  7. Need for coronary revascularization
  8. History of, or active, endocarditis
  9. Renal insufficiency (Creatinine > 2.5 mg/dL)





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CONCLUSION

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Mitral valve disease remains complex

Several percutaneous interventions can be discussed

Inoperable or high-risk patients (Heart Team)

The optimal patient population needs to be defined for TMVR

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Thank You