

10 Years of Transcatheter solutions for MAC

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Disclosures

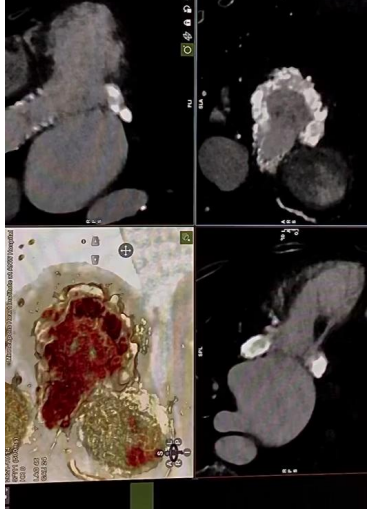
- Consultant / Honorarium / Grants
 - Edwards Lifesciences
 - Medtronic Inc
 - Boston Scientific
 - Abbott
 - 4C
- Founder
 - V2Vmedtech

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MAC remains a technical challenge for mitral valve surgery

- Severe Mitral annular calcification
 - Suture placement can be difficult – PV leak
 - Inadequate Valve size
 - AV disruption
 - Stroke
 - PPM

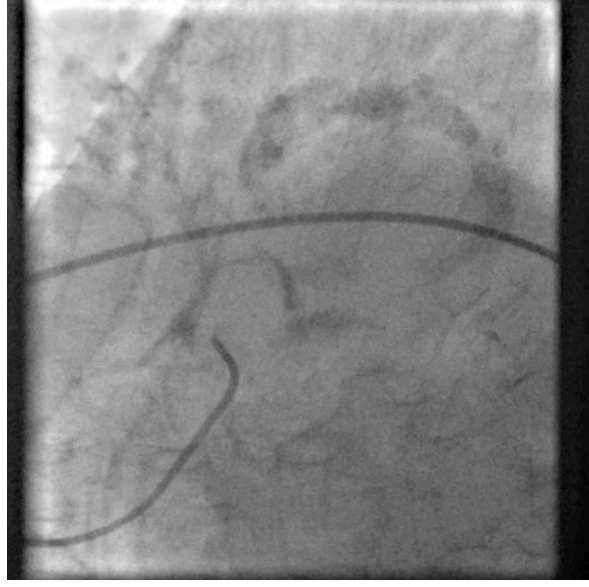


Placement of Transcatheter Valves in MAC is an attractive option

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TEER FEASIBLE IN MINORITY



Mixed disease
Small MV area
Tethered leaflets
Leaflets prone to tear

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TRANSCATHETER VALVES
for MAC



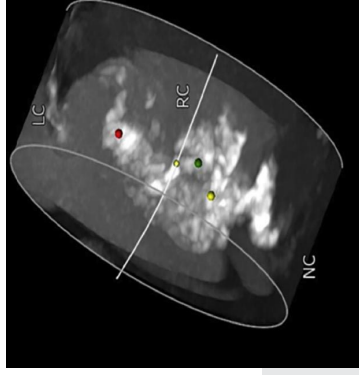
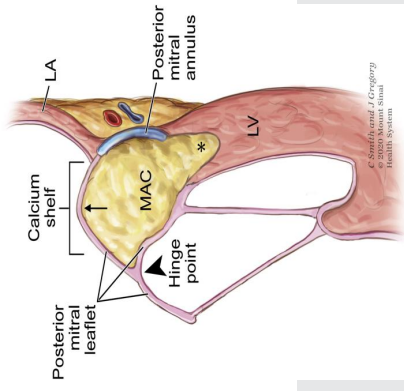
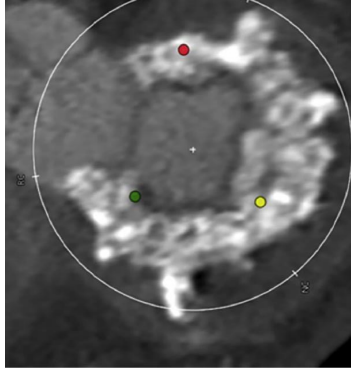
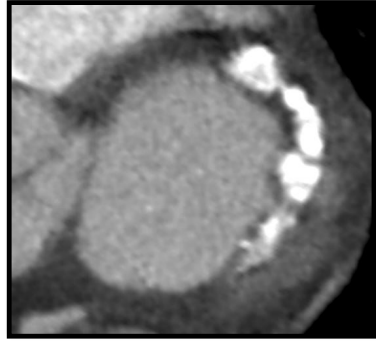
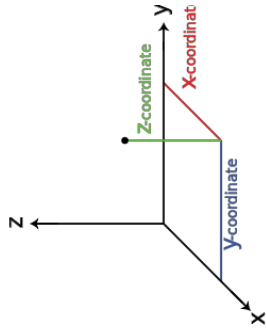
TAVR DEVICES

TMVR DEVICES

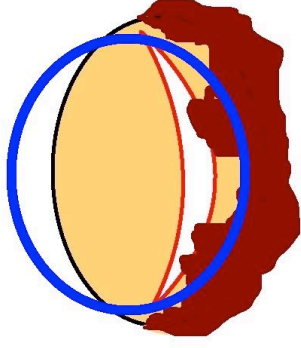
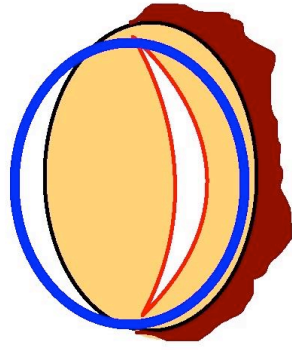
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MAC is 3-Dimensional



MAC contours and issues



Calcification can also involve leaflets and subvalvular structures

Calcification Pattern: Anchoring, effect on circularity

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First Case reported

Circulation

AHA Journals Journal Information All Issues Subjects Features Resources

Home > Circulation > Vol. 128, No. 6 > First in Human Transapical Implantation of an Inverted Transcatheter Aortic Va...

FREE ACCESS
RESEARCH ARTICLE

PDF/EPUB

First in Human Transapical Implantation of an Inverted Transcatheter Aortic Valve Prosthesis to Treat Native Mitral Valve Stenosis

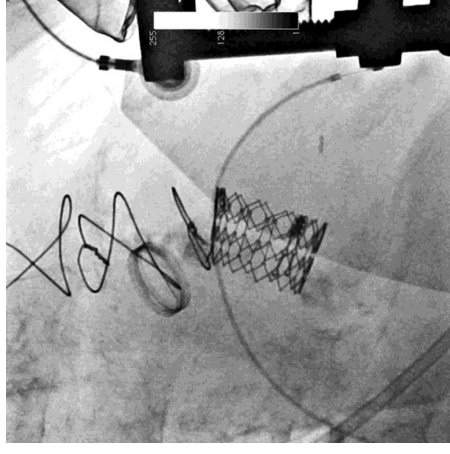
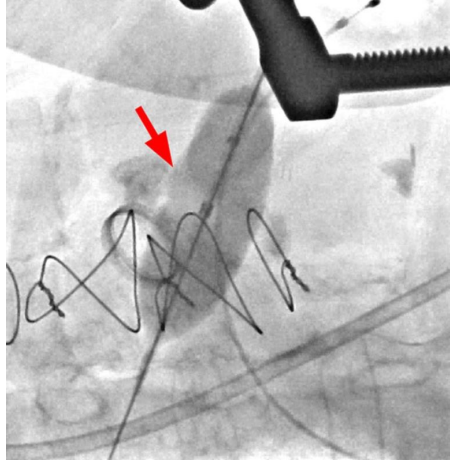
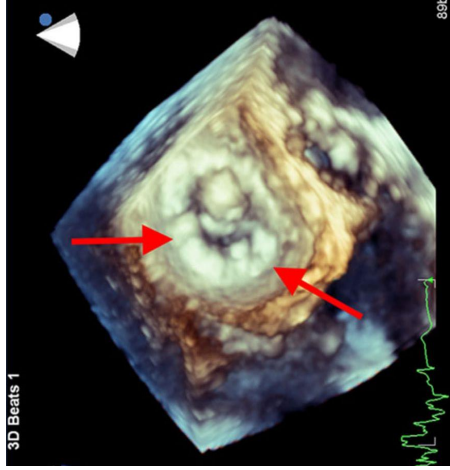
Ragheb Hasan, Vaikom S. Mahadevan, Heiko Schneider and Bernard Clarke

Originally published 6 Aug 2013 | <https://doi.org/10.1161/CIRCULATIONAHA.113.001466> | Circulation. 2013;128:e74–e76

Tools Share

Jump to

Trans-Apical Implant of 29 Sapien XT



First Surgical Direct Implants

Transcatheter valve used in a bailout technique during complicated open mitral valve surgery

P Astarci, D Glineur, L De Kerchove, G El Khoury
Interactive cardiovascular and thoracic surgery, 2013 • academic.oup.com

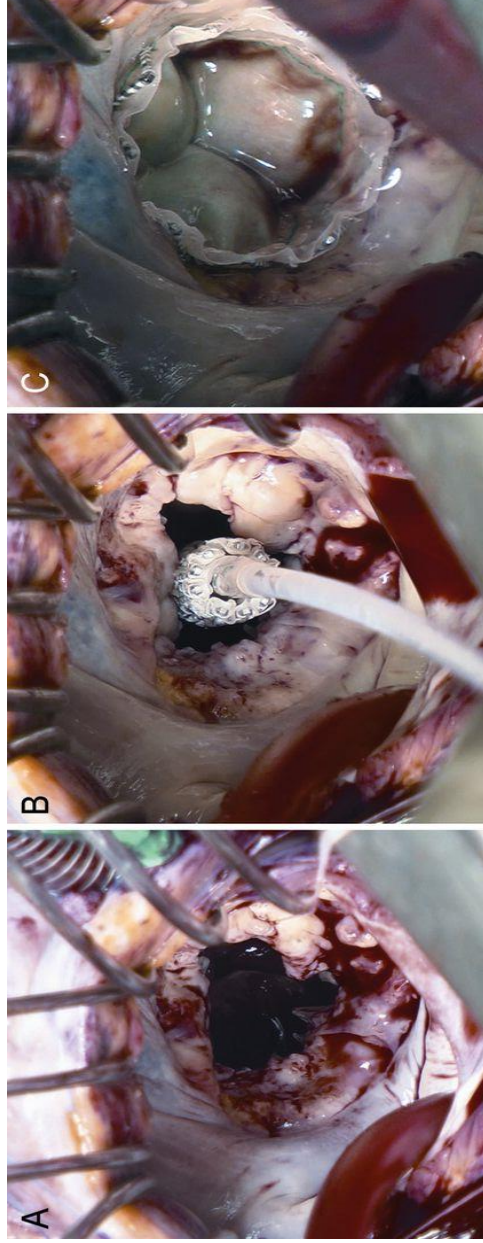
Abstract

Here, we describe the case of a 62-year old woman who required aortic and mitral valve replacement plus coronary artery bypass grafting. Transoesophageal echocardiogram revealed stenosis of the aortic valve (Ao valve area, 0.9 cm²; PG, 45 mmHg; MG, 25 mmHg) and a diseased calcified mitral valve with stenosis and regurgitation (mitral valve area, 1.1 cm²; MG, 10 mmHg; RV, 25 ml; ERO, 12 mm²). The mitral annulus calcifications were very deep into the left atrium and the left ventricle muscle, around the full annulus circumference. We decided to avoid complete deep mitral annulus decalcification. The left atrium was surgically exposed, and we deployed a 26-mm Edwards SAPIEN XT endovale through the left atriotomy. To prevent paravalvular leakage, we then used a pericardial patch to close the gap between the endovale and the calcified mitral annulus. The postoperative echocardiogram showed perfect anchoring of the endovale in the mitral annulus without any paravalvular leakage.

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Figure 1: (A) Intraoperative view of the heavily calcified mitral annulus. (B) Positioning of the Edwards SAPIEN valve ...

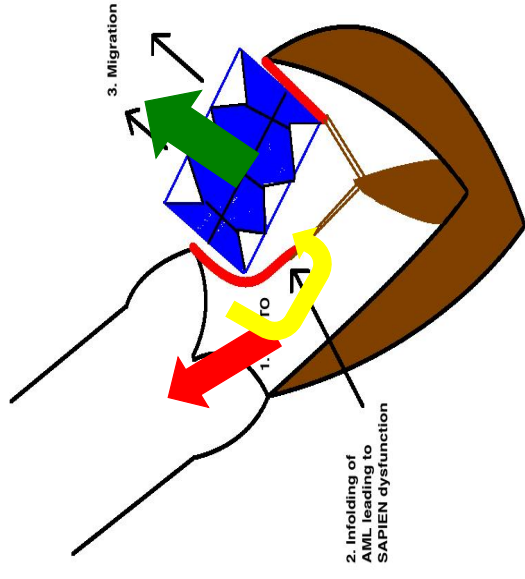


Interact CardioVasc Thorac Surg, Volume 17, Issue 4, October 2013, Pages 745–747, <https://doi.org/10.1093/icvts/ivt249>

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Problems encountered

- LVOT Obstruction
- Embolisation
- Leaflet in folding



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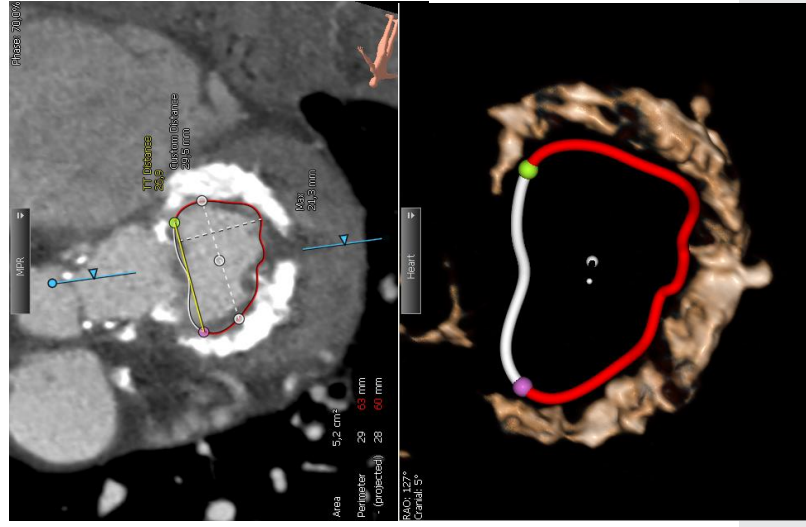
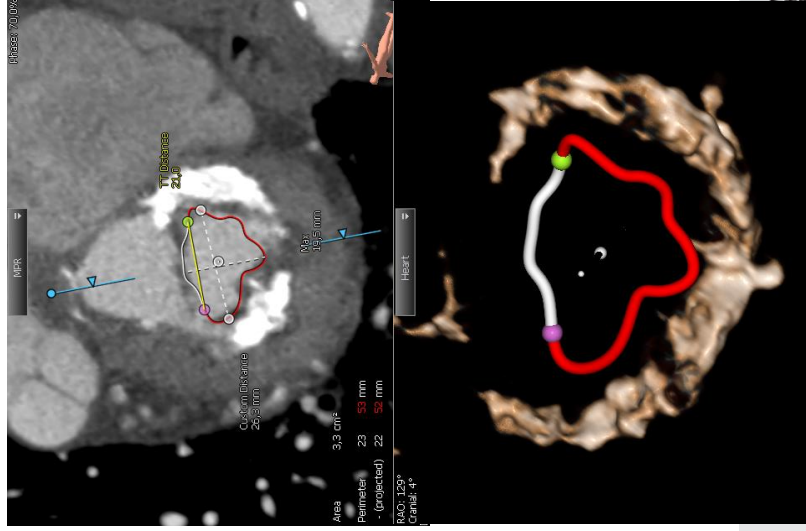
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Sizing/Suitability

- Which modality? CT has emerged into a successful modality for planning
- What are we measuring?
- How does it translate in to result?

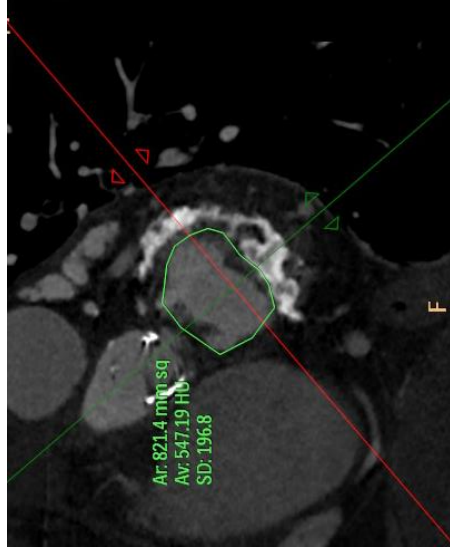
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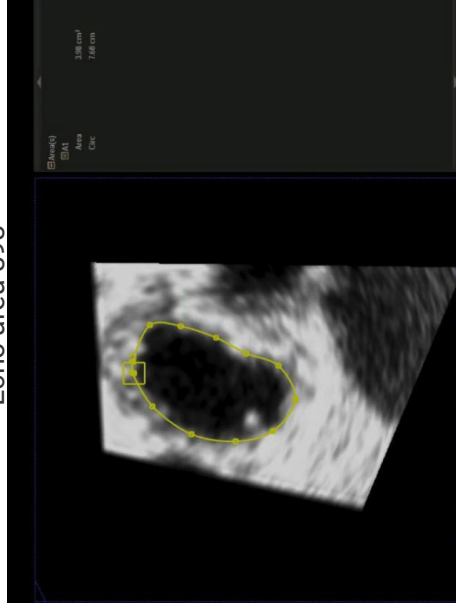


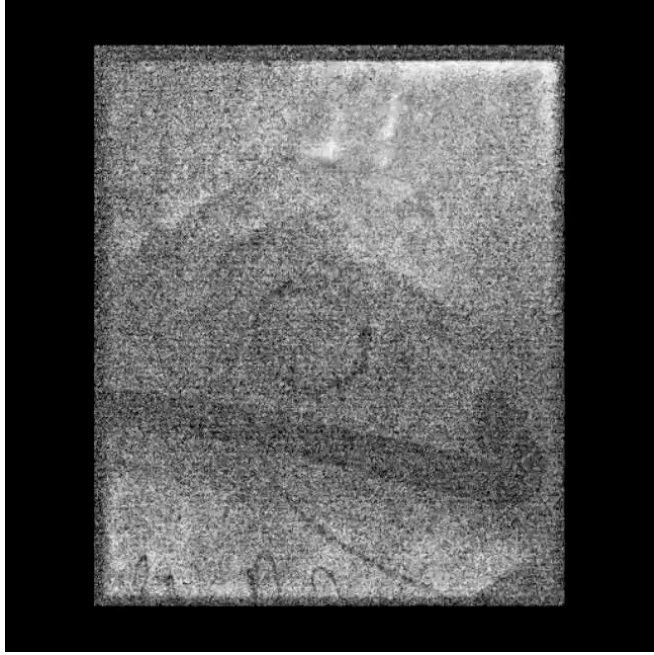
Is this the correct way to measure it?

CT area 547



Echo area 398





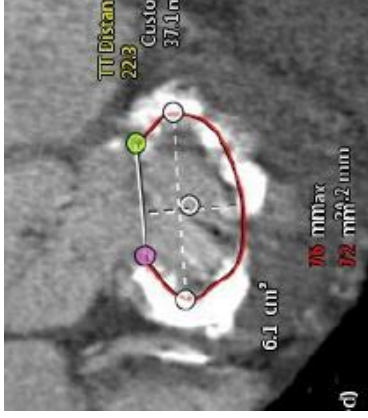
**Observe the GAP between
the Device and the MAC**

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TAV-in-MAC: Annulus Sizing

(Manual, 3Mensio, Circle CV Imaging)

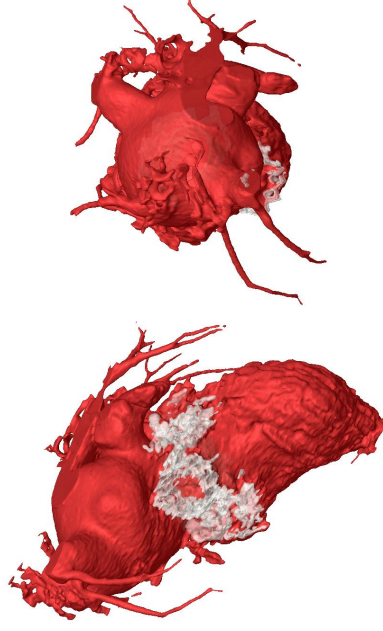
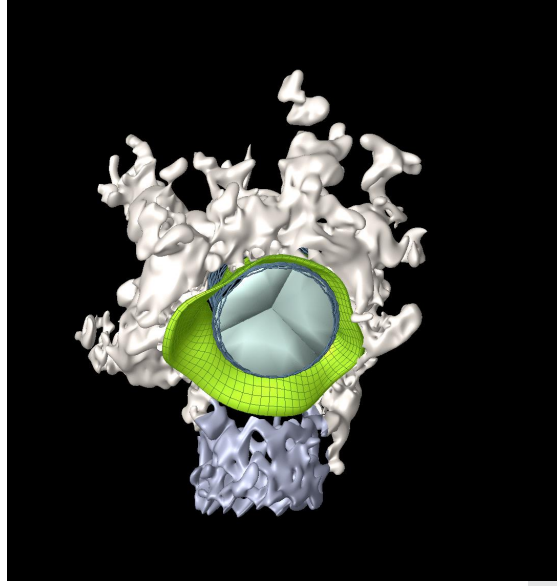


- Measure both systole and diastole
- D-Shape method more reproducible and conservative
- Chose THV based on area and oversize aggressively if feasible
- Goal is to end with flare in LV
- Aim for final position of 80/20 LV/LA

Use of Recapturable Devices

Lotus in MAC : CT planning

Post-op 4D MSCT: 1 year

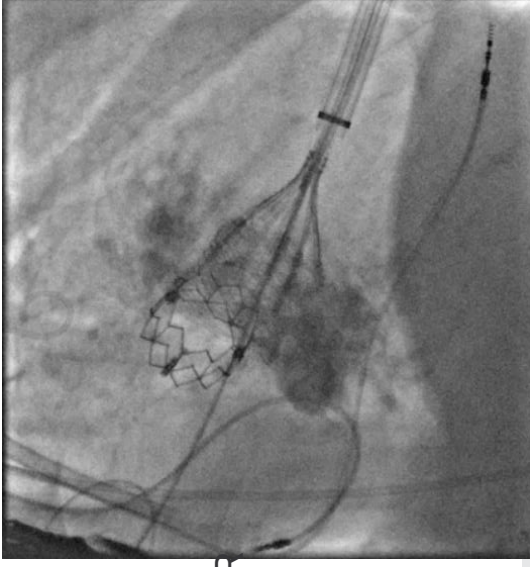


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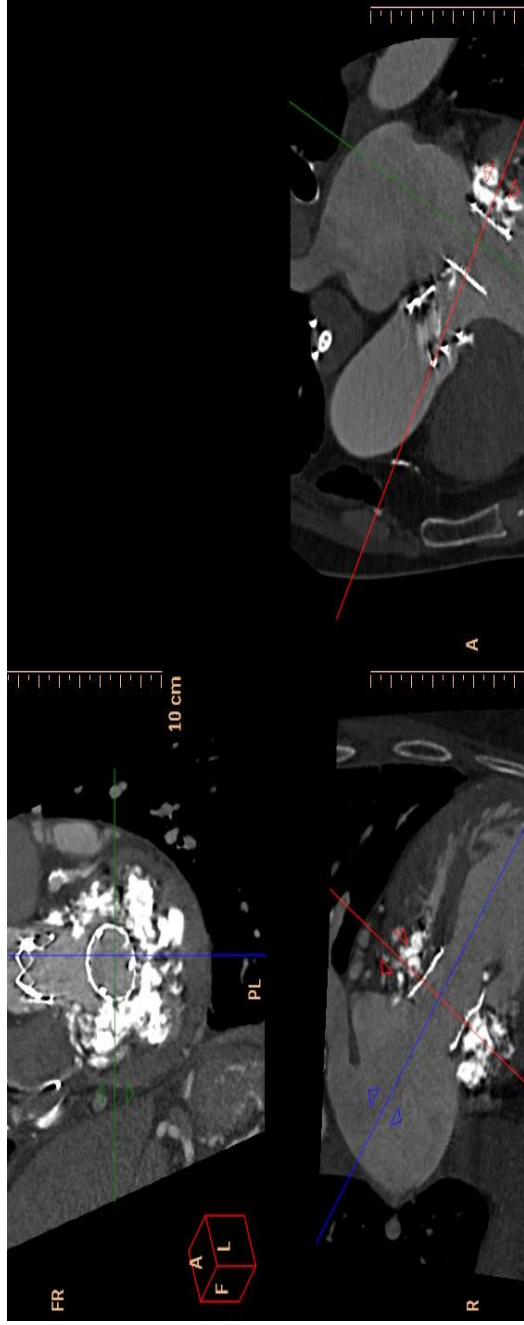
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Patient 2

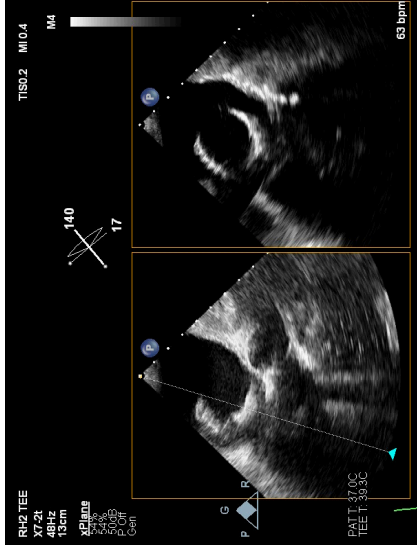
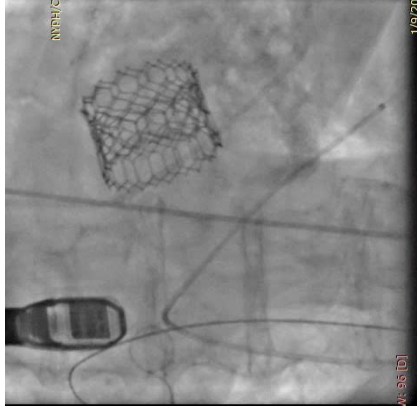
78 year old
TAVR: 1 year ago
Presented with persistent MR
Heavy MAC

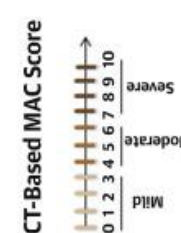
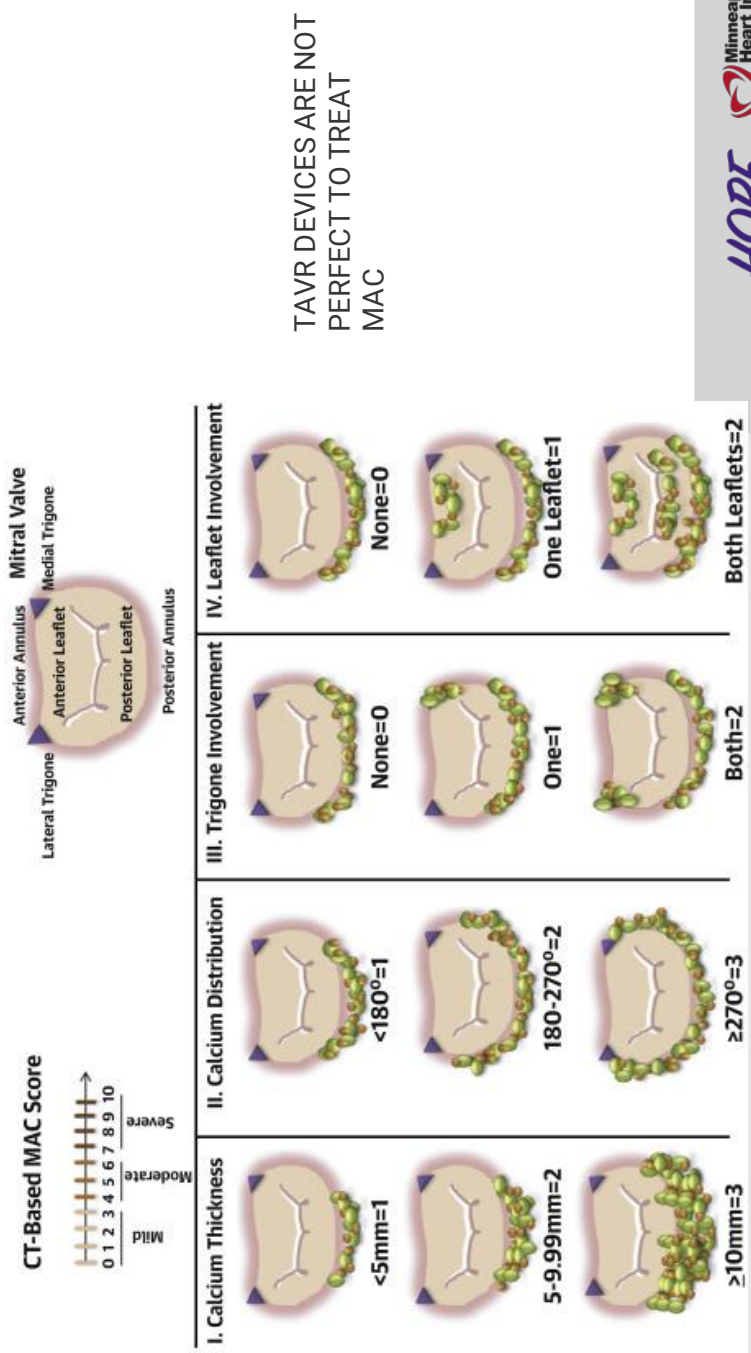


Follow up



Valve Embolization





I. Calcium Thickness	II. Calcium Distribution	III. Trigone Involvement	IV. Leaflet Involvement
<5mm=1	<180°=1	None=0	None=0
5-9.99mm=2	180-270°=2	One=1	One Leaflet=1
>10mm=3	≥270°=3	Both=2	Both Leaflets=2

TAVR DEVICES ARE NOT PERFECT TO TREAT MAC

LVOTO

Is a possibility after Mitral

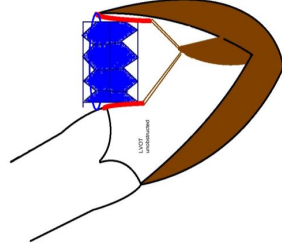
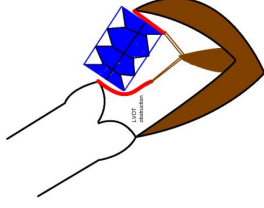
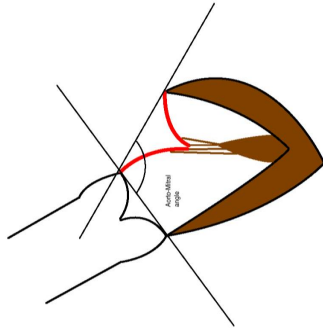
1. VIV
2. VIR
3. MAC
4. TMVR

Risk with MAC is highest

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LVOTO Etiology



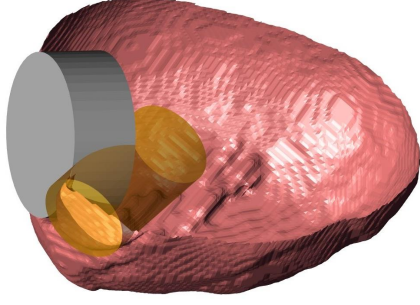
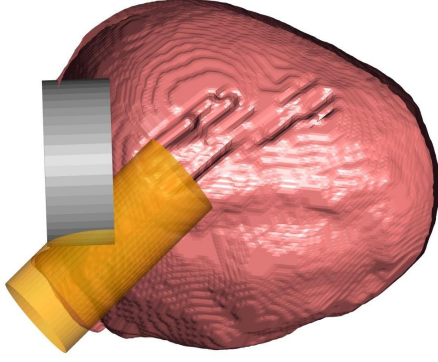
Less Chance if
AMA angle is obtuse

Greater Chance if
AMA angle is less obtuse

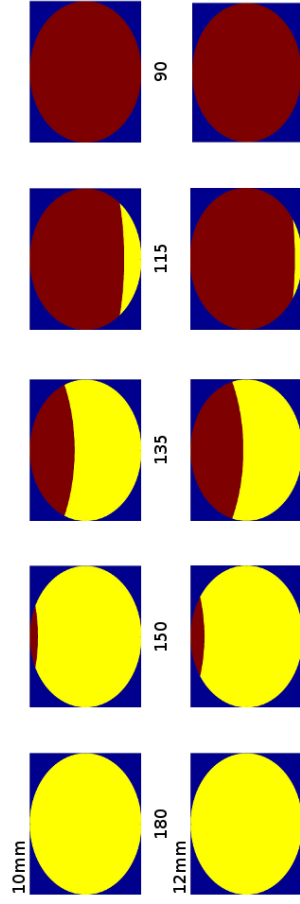
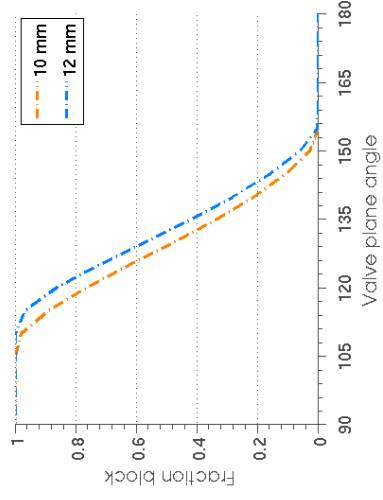
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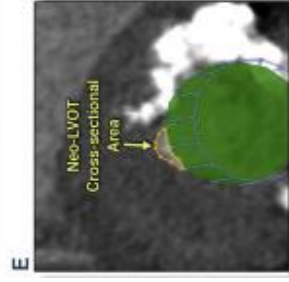
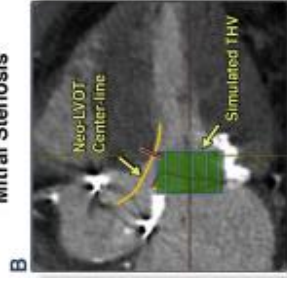
Can we predict it?



Fraction of Aorta blocked by 10mm and 12 mm valve as a function of valve plane angle



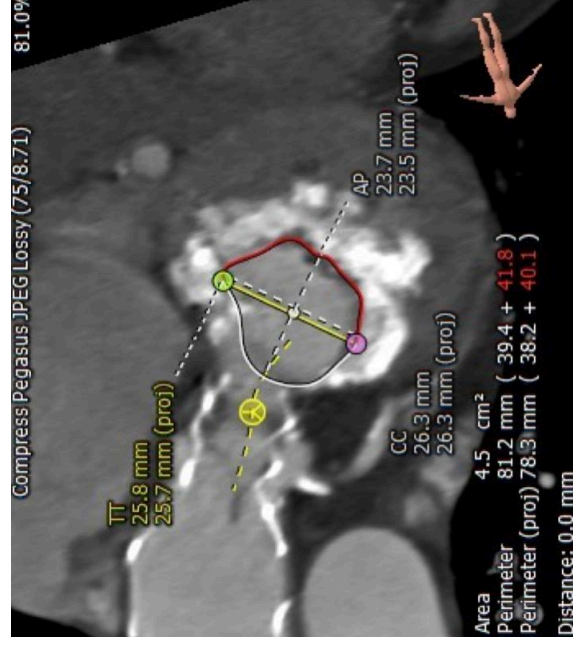
THV in Calcific Mitral Stenosis



1. Important to understand that for each device the Neo-LVOT cut off may be different
2. Balloon expandable valves – flare can increase the risk
3. Nitinol based devices – may conform and have less risk?
4. D-shape device may have reduced risk

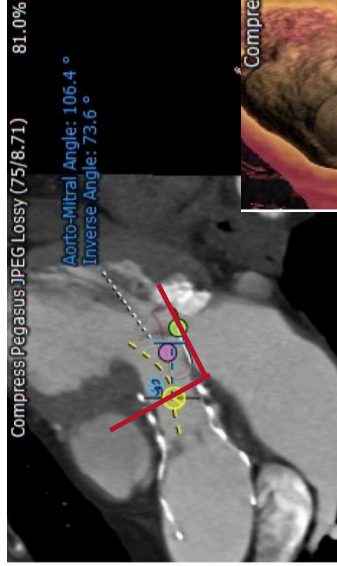
Case Example

- 80-year old female patient
- TAVI done 3 years ago
- MR now severe
- High risk for surgery

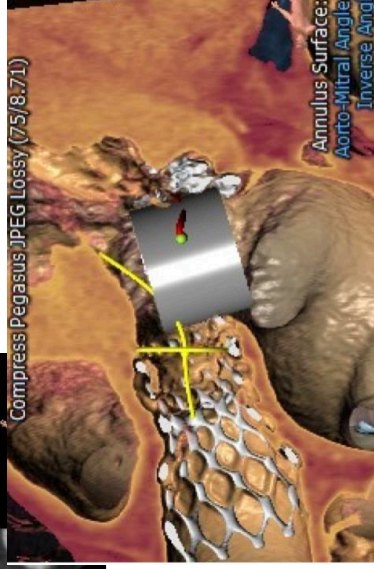


AP- 23.5
CC- 25.8
Area - 450

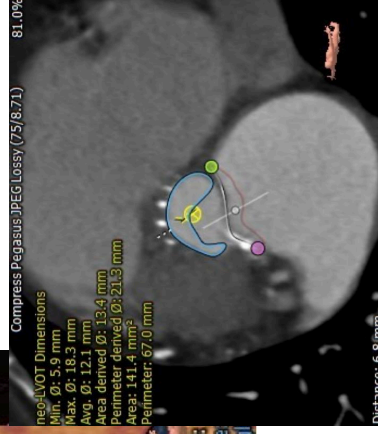
Looks suitable



AMA angle – 106 !

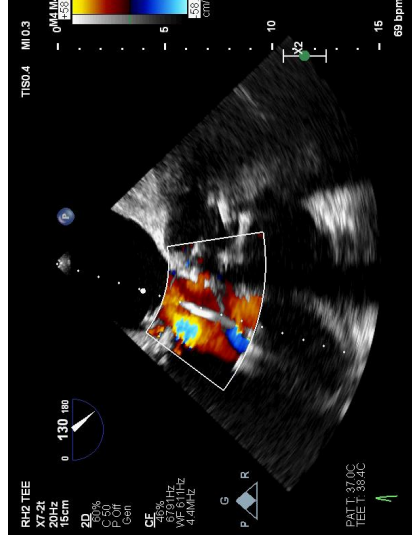


Simulated 26 S3



Neo LVOT
1.3-1.4

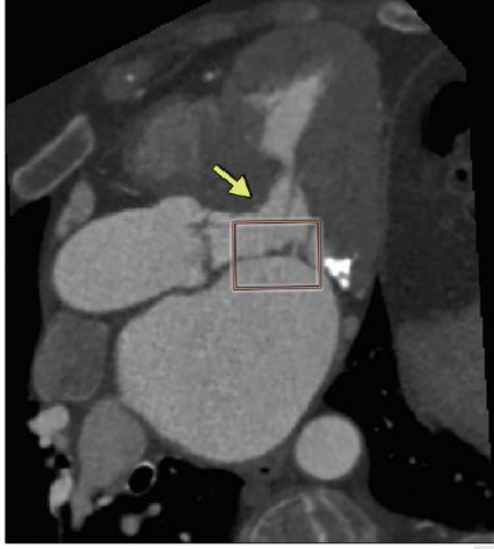
LVOT Obstruction



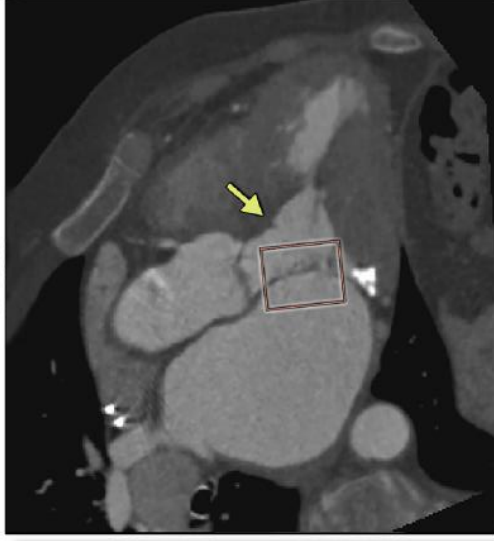
Severe LVOT obstruction with peak velocity in early systole up to 4.8m/s

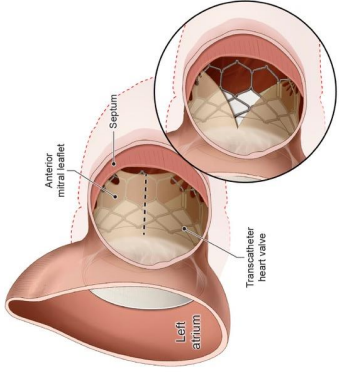
Alcohol Septal ablation

Pre



Post





LAMPOON

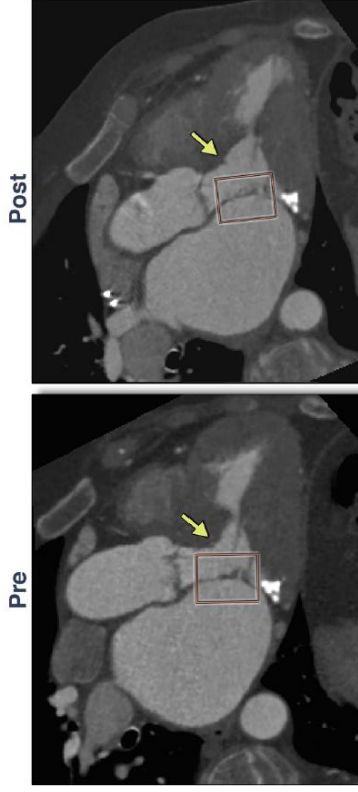
- Most TMVR devices are fully covered
- Need leaflets in some for anchoring

Newer Open cell designs may help

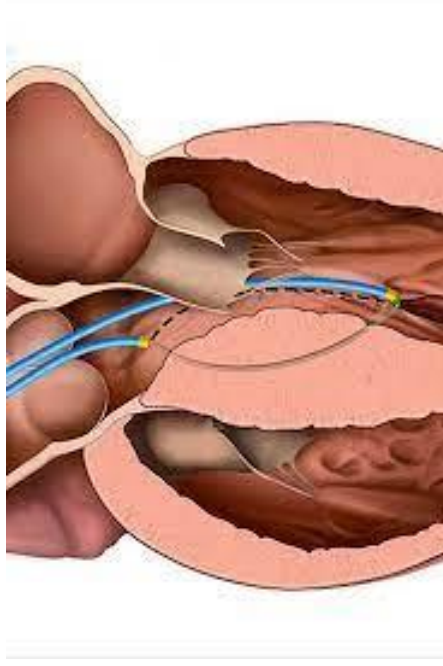
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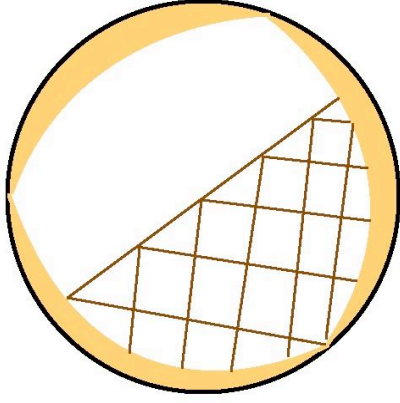
Alcohol Septal ablation



SEASAME



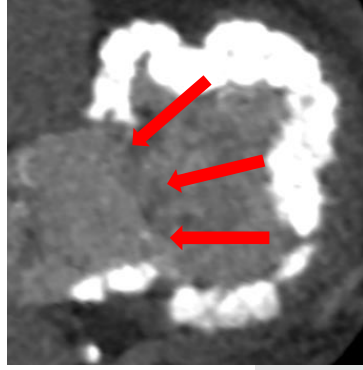
Open Surgery



LVOTO

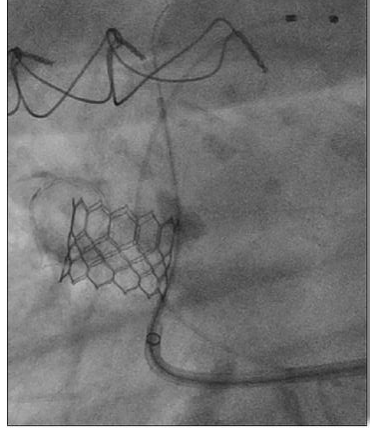
Risk with MAC is highest

- Small ventricle
- Thickened leaflets
- Posterior MAC will push the device more anteriorly



Paravalvular regurgitation

- Device closure



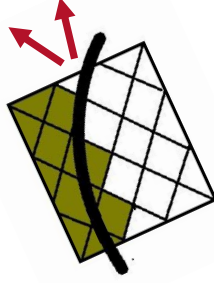
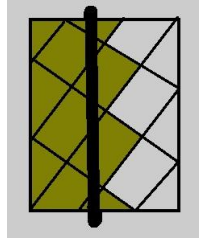
Post TMVR – impossible to close with plugs

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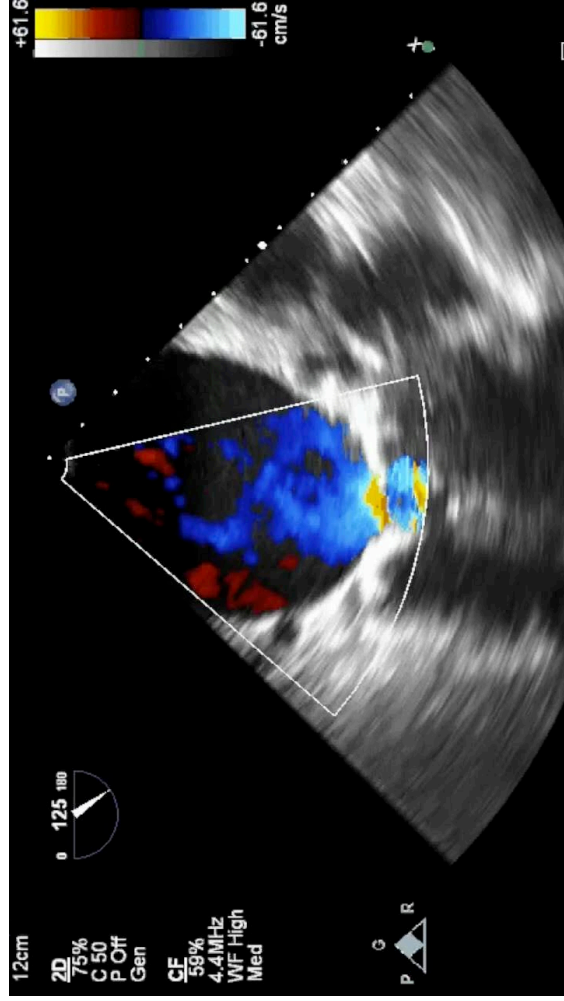
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Valve Positioning and leakage

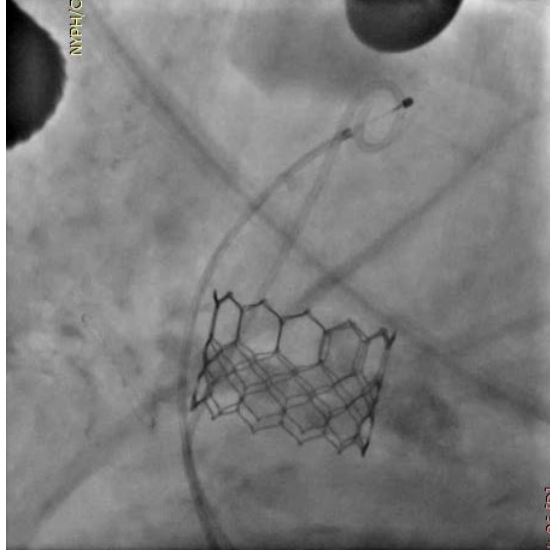
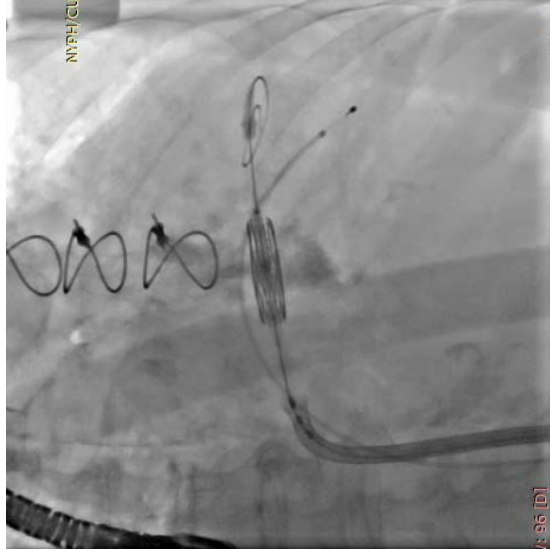
- Valve positioning – especially Trans-septal approach is critical
- Be prepared for a second valve!



AS and MAC with MR



Trans-septal approach



Learnings from TAVR device use

- Outcomes were poor specially with TA approach
- Comorbidities play important role
- LVOTO risk is higher
- Pathology is variable

MR or MS

Distribution of calcification: Annulus / leaflet/ both

Risk of leak

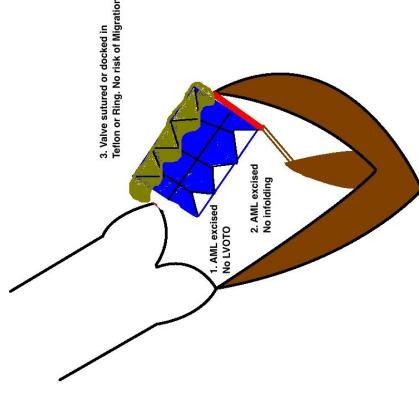
Risk of embolisation

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During Open surgery

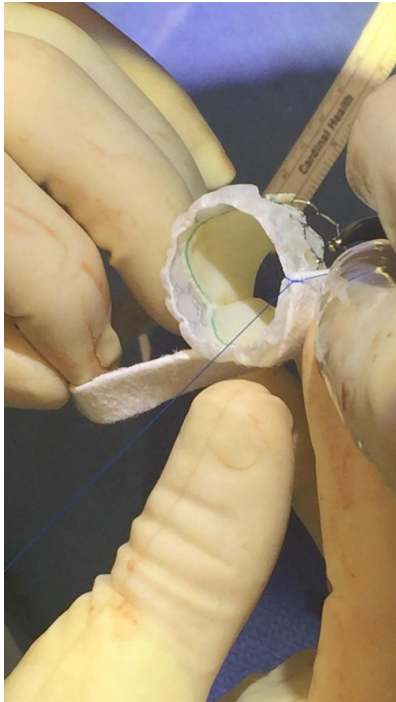
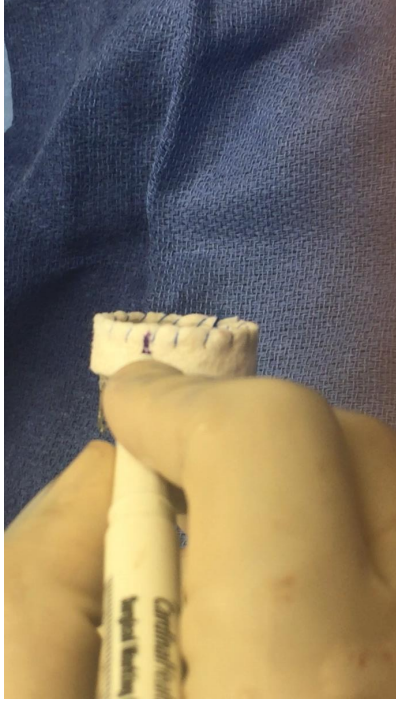
- Excise AML
- Size with balloon
- Use Certitude system
- Mark Commissures
- Flex the system
- 20% inflation-stop-adjust-proceed
- Watch the atrial portion as it foreshortens

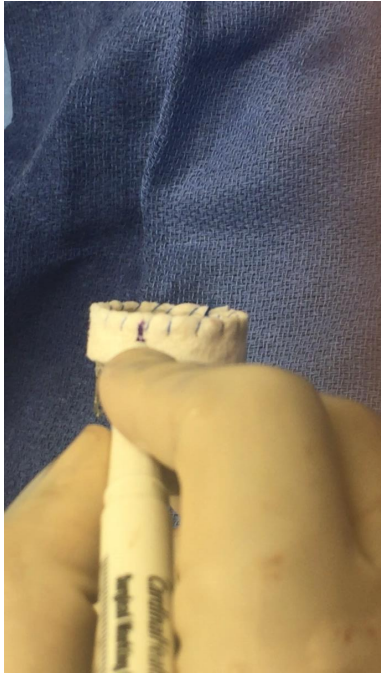


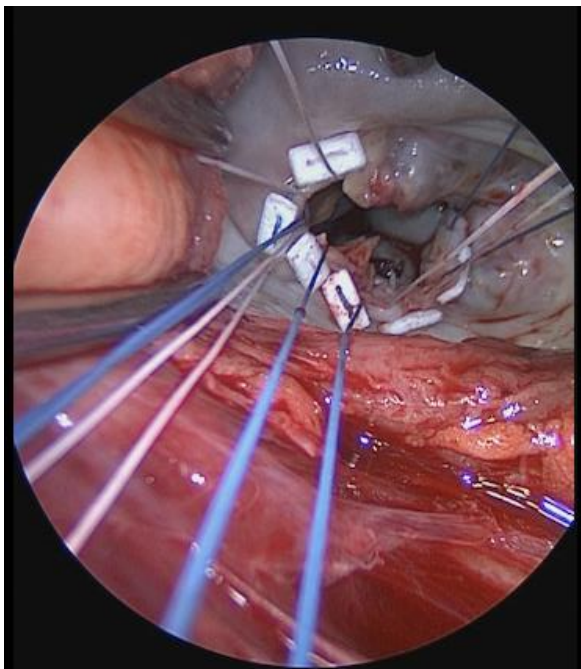
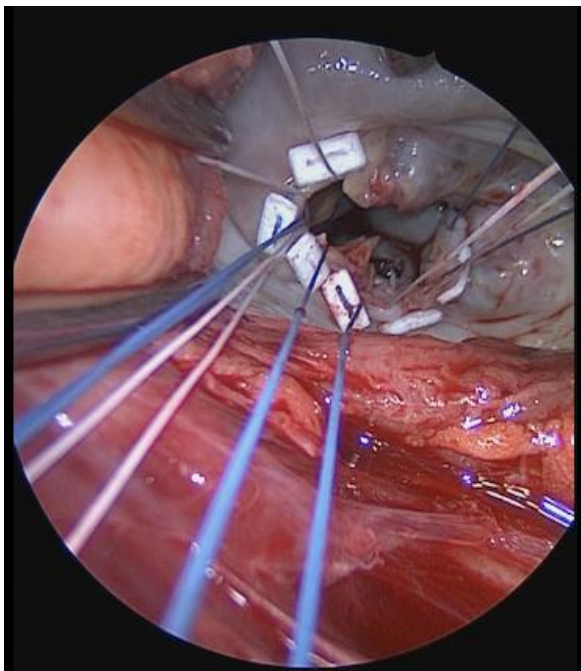
Reported results
have been encouraging
But at present in USA
It is **OVERUSED**

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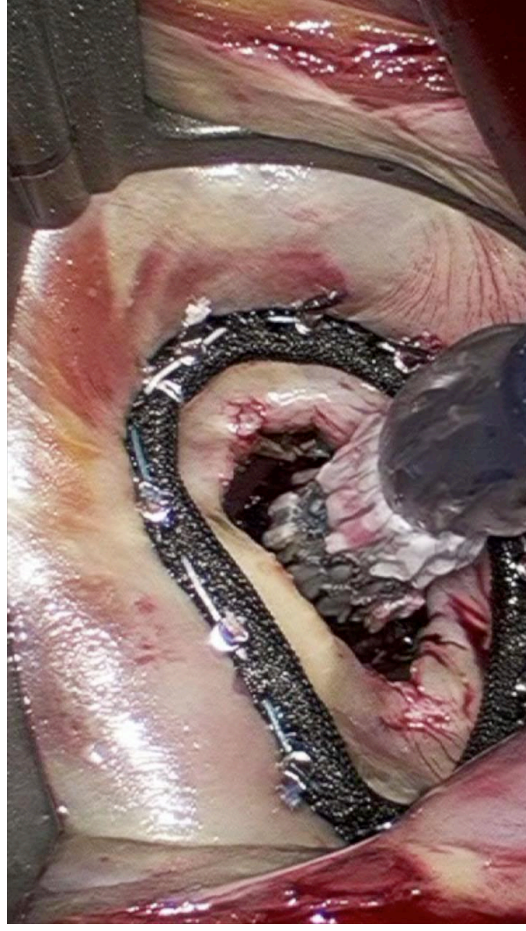




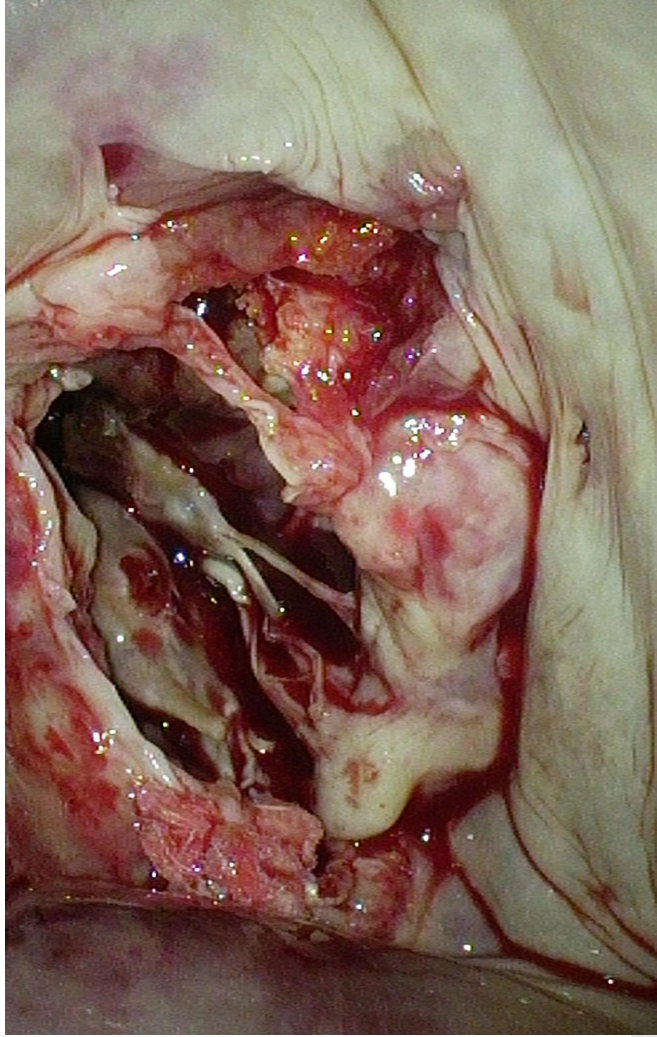
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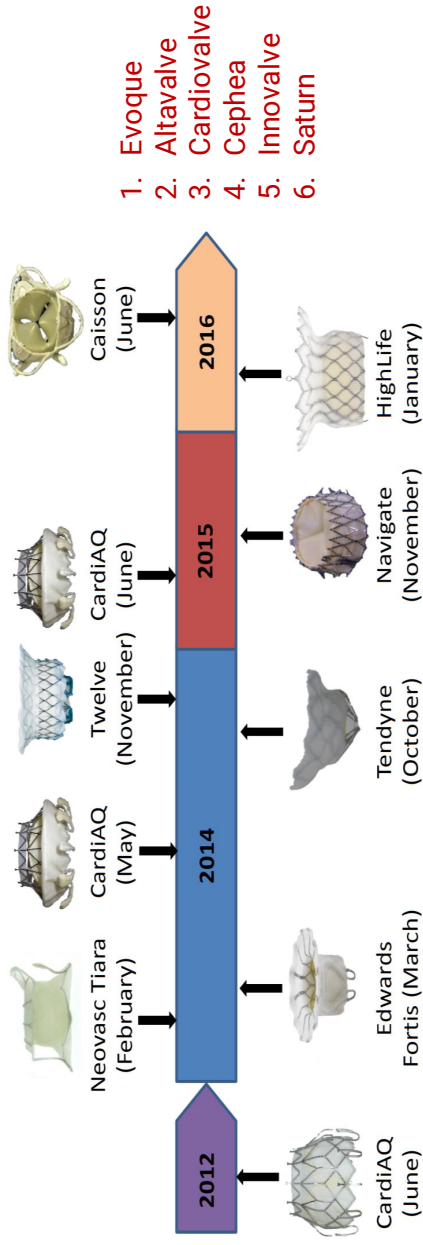
Option



Oversizing



TMVR timeline



1. Evoque
2. Altavalle
3. Cardiovalve
4. Cephea
5. Innovalve
6. Saturn

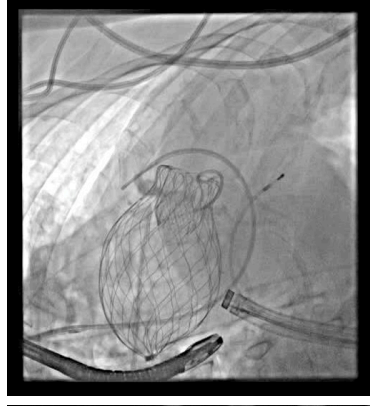
TMVR DEVICES

- Early focus on FMR
- MAC exclusion criteria for all EFS trials

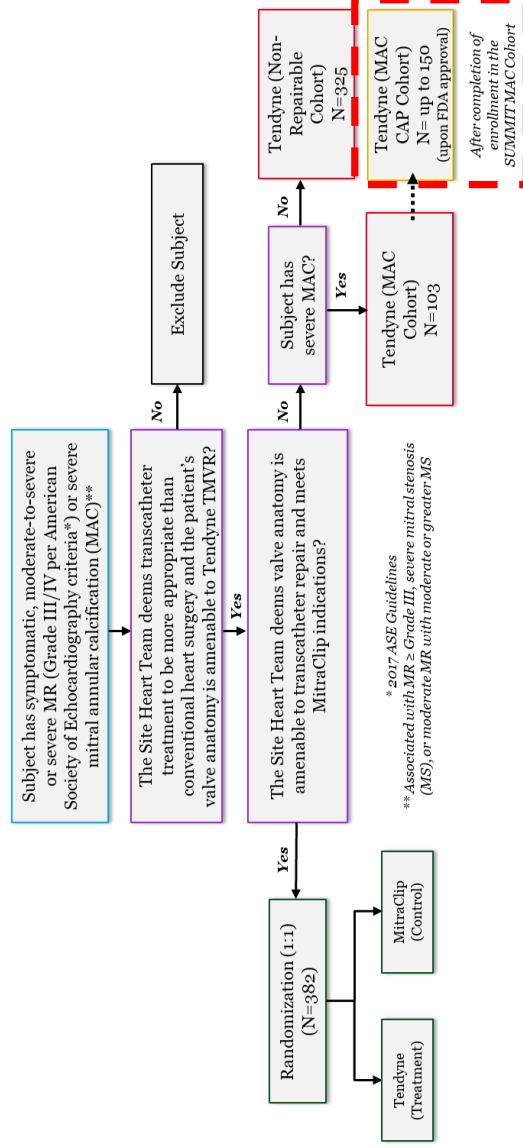


- **Worry about anchoring**
- **Size incompatibility**

TMVR devices in MAC have done very well



SUMMIT Trial Design



August 2022

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Tendyne



Tendyne Device

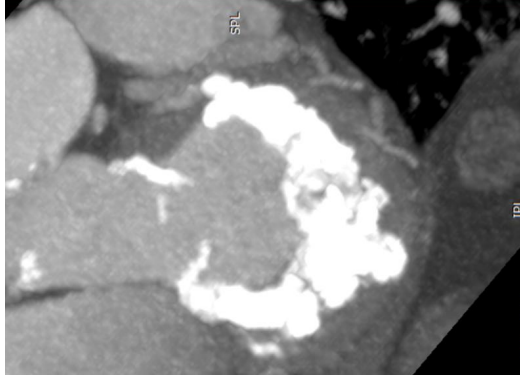
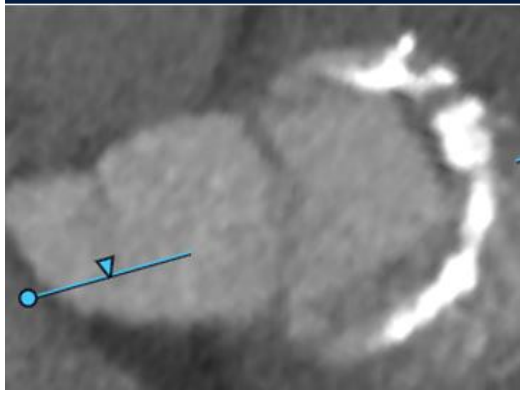
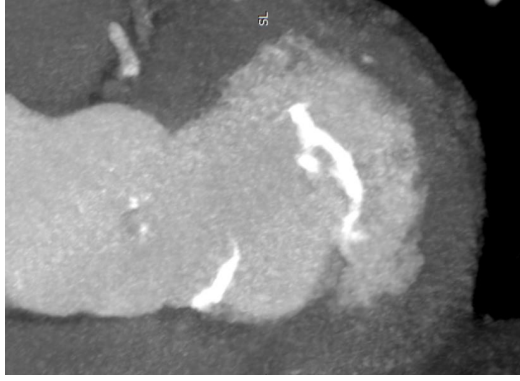
- D-Shaped
- Self-Expanding Nitinol Frame
- Porcine Pericardial Tri-Leaflet Valve
- Left Ventricular Tether to Apex
- Multiple sizes

Intra-annular fixation

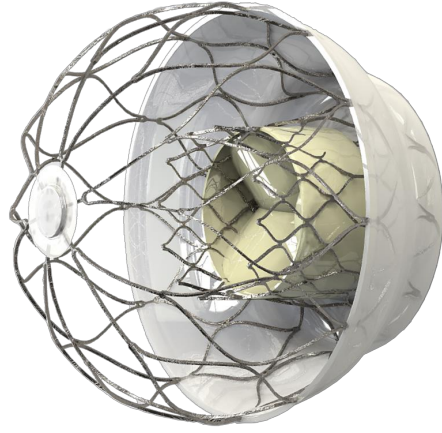
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Word of Caution: All MACs not SEVERE



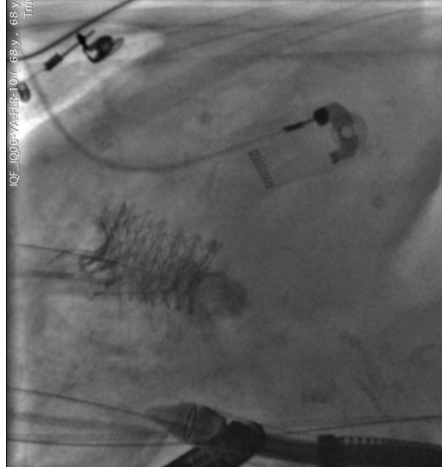
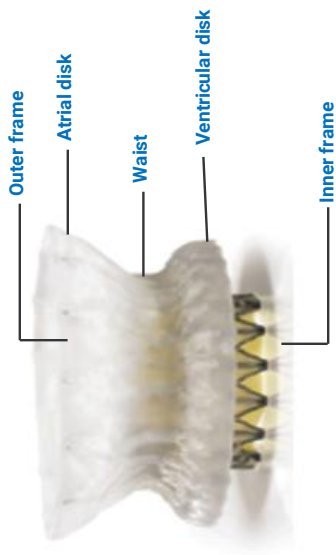
Alta Valve and MAC: lowest risk of LVOTO?



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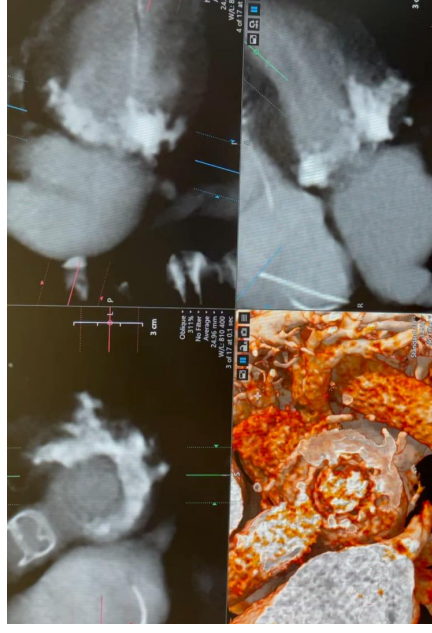
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Cephea: lower profile



Surgery

- Surgery is also evolving in this group of patients and use of CT helps us in planning
 - Sizing
 - Technical issues



Final Thoughts

- TAVR in MAC is a viable option in **select group** of patients
- Outcomes improving after careful selection and TS approach
- Increasing experience with Dedicated TMVR devices
- LVOTO is a big issue
- Surgery is a good option in low and intermediate risk patients

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