TMVR in MAC: How I do It Pearls & Pitfalls

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Conflict of Interest Disclosures

PI/ Steering Committee Roles

- Abbott-Co-PI SUMMIT Trial, Steering Committee- Repair MR Trial
- Edwards- Executive Steering Committee CLASP TR Trial, PI- MOMENTIS Trial
- NIH CTSN- Co-PI Concomitant Tricuspid During Mitral Surgery Trial, Steering Committee, Primary Trial
- Atricure- DSMB

Consultant Roles

- Medtronic
- Abbott
- Edwards
- Gore
- Admedus
- Atricure
- Johnson & Johnson
- Philips
- JenaValve
- Arthrex
- CryoLife

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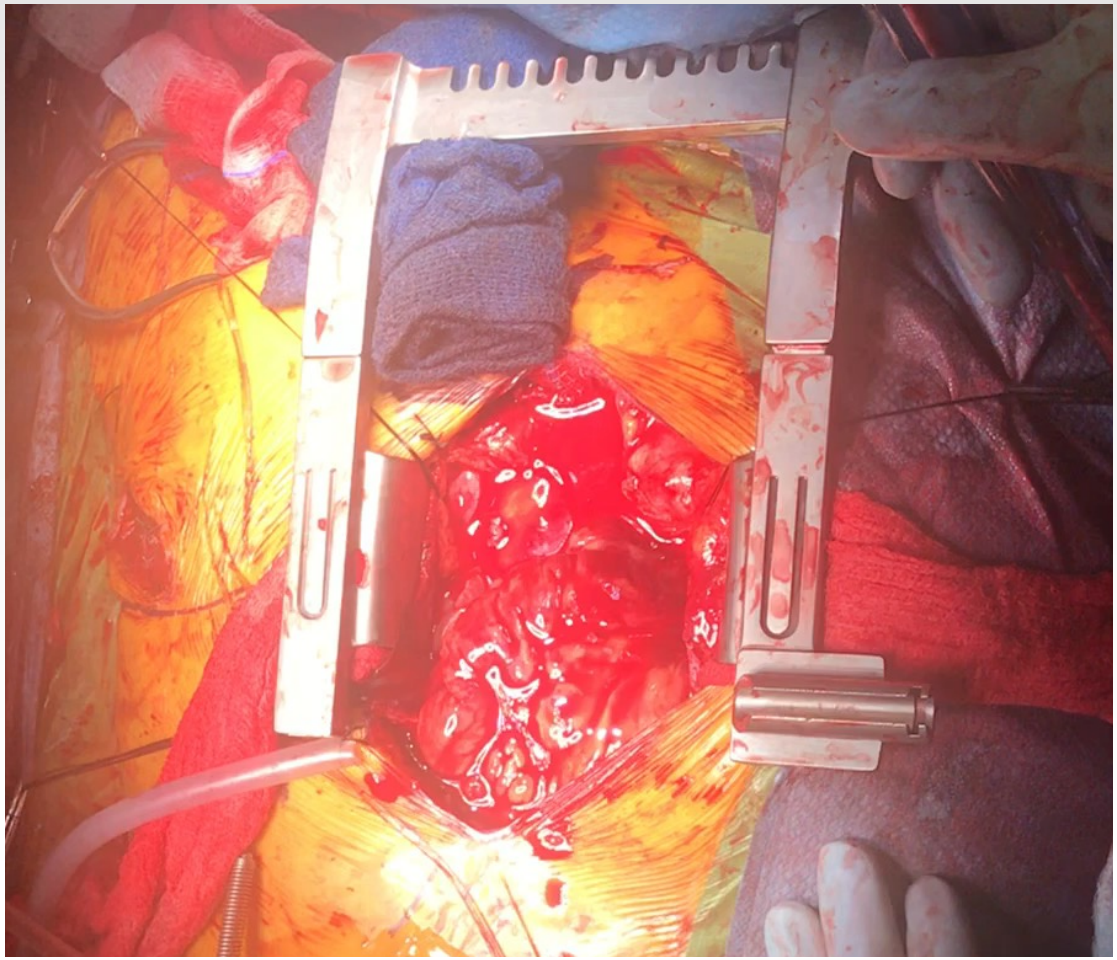
The MAC Epidemic

- Recognition of and referrals for MAC are increasing
- Highly variable pattern and severity
- MR: MAC can be incidental or cause of mitral disease
- MS: Severe MAC often the cause; can make MVR risky for AV groove disruption

Avoid This Complication!



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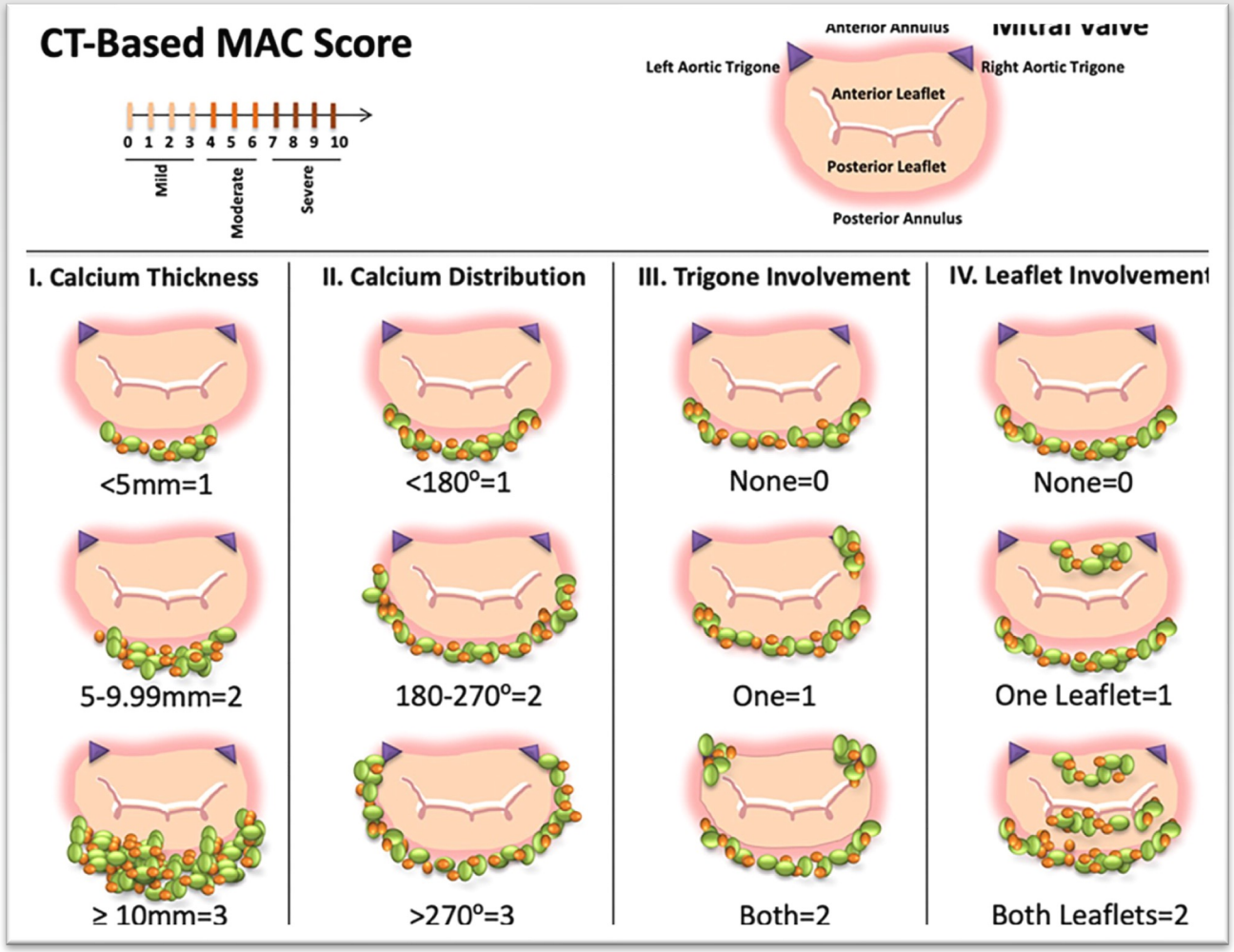
MAC Classification



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Diagnosis, Classification, and Management of Patients With MAC: Heart Valve Collaboratory Consensus Guidelines

Diagnosis and Classification

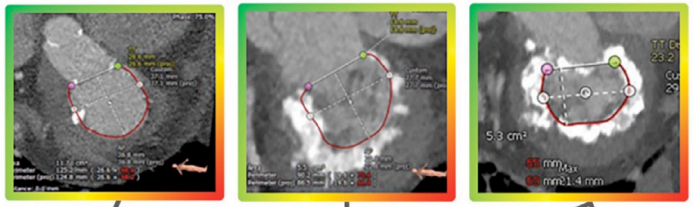
Diagnosis
- TEE
- MDCT

Classification and Anatomic Risk
- Annular Size
- MAC Score and Calcium Burden
- LVOT Obstruction Risk
- Sealing/PVL Risk

Adjunctive Therapies
- Septal Modification
- Leaflet Modification
- Surgical Myectomy

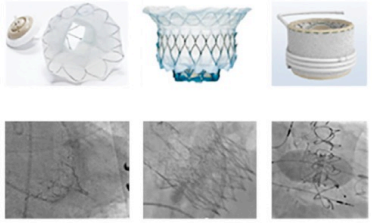
Treatment of Mitral Valve With MAC

Green MAC, Yellow MAC or Red MAC for Different Therapies

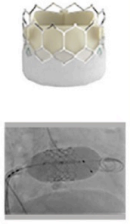


Surgical Replacement

TMVR in MAC



Transseptal or Transatrial ViMAC



- Surgical risk and risk of LVOT obstruction are important considerations in device choice.
- With acceptable anatomy, a 30-day mortality ≤10% can be achieved.
- Multiple clinical trials are available for patients with MAC, and results are forthcoming.

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Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease With Severe Mitral Annular Calcification

Results From the First Multicenter Global Registry

Mayra Guerrero, MD,[a] Danny Dvir, MD,[b] Dominique Himbert, MD,[c] Marina Urena, MD,[c] Mackram Eleid, MD,[d] Dee Dee Wang, MD,[e] Adam Greenbaum, MD,[e] Vaikom S. Mahadevan, MBBS, MD,[f] David Holzhey, MD, PhD,[g] Daniel O'Hair, MD,[h] Nicolas Dumonteil, MD,[i] Josep Rodés-Cabau, MD,[j] Nicolo Piazza, MD,[k] Jose H. Palma, MD, PhD,[l] Augustin DeLago, MD,[m] Enrico Ferrari, MD,[n] Adam Witkowski, MD, PhD,[o] Olaf Wendler, MD, PhD,[p] Ran Kornowski, MD,[q] Pedro Martinez-Clark, MD,[r] Daniel Ciaburri, MD,[s] Richard Shemin, MD,[t] Sami Alnasser, MD,[u] David McAllister, DO,[v] Martin Bena, MD,[w] Faraz Kerendi, MD,[x] Gregory Pavlides, MD,[y] Jose J. Sobrinho, MD,[z] Guilherme F. Attizzani, MD,[aa] Isaac George, MD,[bb] George Nickenig, MD,[cc] Amir-Ali Fassa, MD,[dd] Alain Cribier, MD,[ee] Vinnie Bapat, MD,[ff] Ted Feldman, MD,[a] Charanjit Rihal, MD,[d] Alec Vahanian, MD,[c] John Webb, MD,[b] William O'Neill, MD[e]

Outcomes Poor With Percutaneous Sapien in MAC

Length of stay, days	17.7 ± 18
30-day/procedural death*	19/64 (29.7)
Cardiovascular	8/64 (12.5)
LVOTO	2/64 (3.1)
LV perforation	2/64 (3.1)
Complete AV block	1/64 (1.56)
MI (air emboli due to pulmonary vein perforation)	1/64 (1.56)
Stroke	2/64 (3.1)

JACC Cardiovasc Interv. 2016 Jul 11;9(13):1361-71.

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Benefits and Risks of Surgical Balloon Expandable Valves in MAC

Benefits

- Minimize Suture placement
- Less Debridement, Less risk of Annular Rupture
- Can be Performed MIS

Risks

- Sizing Critically Important
- PVL
- LVOTO Risk

Case

Important Pearls

1. Mitral Protocol CT: Ensure native annulus not too large
   - MS preferred over MR
2. MAC must be 270- 360 degrees
   - Place conventional annular sutures in region of incomplete MAC
3. Remove Some of the Anterior Leaflet to Minimize LVOTO Risk
   - Should leave good rim for seal
4. Place at least 4 annular sutures, but as many as feasible
5. Sizing: Use valve sizer or balloon size
   - I prefer to balloon as little as possible

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Important Pearls

6. Perform myectomy directly through LA if needed
    - Use TEE to measure thickness
7. If MS, resect some papillary muscles to ensure good LV inflow
8. Circularize Landing zone with commissural closure/ “Felt Pillow”
    - Overlap felt in commissures to convert D to circular landing zone
9. Orient Valve by marking commisures with atrial suture
    - Perform before Crimping Valve
10. Land Valve at least 50% in Left Atrium
11. Be Gentle with Reballooning

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MIS SITRAL

Summary of study findings of balloon-expandable valve implantation in 51 patients with mitral valve disease complicated by mitral annular calcification (MAC)

BaylorScott&White THE HEART HOSPITAL PLANO
Joint ownership with physicians

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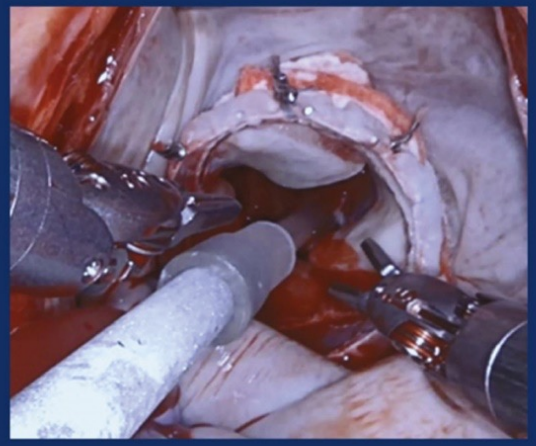
51 Patients
Mitral Valve Disease with MAC
Treated with Transatrial
Balloon-Expandable valve



Technical Success
94%

30-day Mortality
13.7%

1-year Mortality
33.3%

Implications
1. Transatrial BEV in MAC is feasible in select patients.
2. Next steps: improve patient selection and outcomes.

BEV, balloon-expandable valve; MAC, mitral annular calcification.

Smith & Ailawadi, JTCVS 2021

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Early outcomes following transatrial transcatheter mitral valve replacement in patients with severe mitral annular calcification

Michael I. Brener, MD MS,[a] Mohanad Hamandi, MD,[b] Estee Hong, MS,[c] Alejandro Pizano, MD,[d] Morgan T. Harloff, MD,[e] Evan F. Garner, MD,[f] Abdallah El Sabbagh, MD,[g] Ryan K. Kaple, MD,[h] Arnar Geirsson, MD,[i] David W. Deaton, MD,[j] Ashequl M. Islam, MD,[j] Ramesh Veeregandham, MD,[k] Vinayak Bapat, MD,[l] Omar K. Khalique, MD,[a] Yuming Ning, PhD,[c] Paul A. Kurlansky, MD,[c] Paul A. Grayburn, MD,[m] Tamim M. Nazif, MD,[a] Susheel K. Kodali, MD,[a] Martin B. Leon, MD,[a] Michael A. Borger, MD, PhD,[n] Raymond Lee, MD,[o] Keshav Kohli, MS,[p] Ajit P. Yoganathan, PhD,[p] Andrea Colli, MD, PhD,[q] Mayra E. Guerrero, MD,[g] James E. Davies, MD,[f] Kyle W. Eudailey, MD,[f] Tsuyoshi Kaneko, MD,[e] Tom C. Nguyen, MD,[f] H[illegible] Isaac George, MD[c]

JTCVS 2022

Early outcomes Following Transatrial Transcatheter Mitral Valve Replacement in Patients with Severe Mitral Annular Calcification

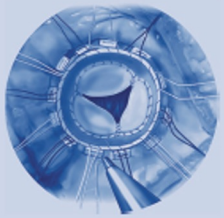
Methods

126 patients with severe MAC and MV dysfunction

Isolated MS 48.4%
Isolated MR 19.8%
Mixed MS/MR 31.7%

12 centers in US and Europe

Transatrial valve-in-MAC (ViMAC) performed with BEV via sternotomy (62.7%) or thoracotomy (37.3%)



Results

Technical success **94.4%**

5 Out of 118 patients had > mild paravalvular leak*

8 patients developed LV outflow tract obstruction

HR 2.31 (95% CI 1.07-4.99) for mortality at last follow-up (median = 89 days) in patients with significant MR vs. isolated MS

Implications

Transatrial ViMAC is a reasonable alternative to traditional surgical MVR in selected patients with MAC and MV dysfunction.

Further work required to compare different strategies that are less invasive than traditional MVR

Patients with significant, ≥ 3+ MR associated with MAC may benefit less from ViMAC than patients with isolated MS.

BEV = balloon expandable valve, HR = hazard ratio, LV = left ventricular, MAC = mitral annular calcification, MR = mitral regurgitation, MS = mitral stenosis, MV = mitral valve, MVR = mitral valve replacement

* Characterized on immediate post-operative echocardiograms

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	Overall cohort (n = 126)	Isolated MS (n = 61)	Isolated MR (n = 25)	Mixed disease (n = 40)	*P* value
Periprocedural outcomes					
Technical success, n (%)	119 (94.4)	60 (98.4)	20 (80.0)	39 (97.5)	.006
In-hospital mortality, n (%)	14 (11.1)	6 (9.8)	3 (12.0)	5 (13.2)	.87
Device embolization, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	.99
Valve thrombosis, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	.99
Repeat MV Surgery, n (%)	6 (4.8)	1 (1.6)	4 (16.0)	1 (2.5)	.03
Stroke, n (%)	3 (2.4)	3 (5.0)	0 (0.0)	0 (0.0)	.43
Myocardial infarction, n (%)	1 (0.8)	1 (1.6)	0 (0.0)	0 (0.0)	.99
Hemolytic anemia, n (%)	11 (8.7)	5 (8.2)	3 (12.0)	3 (7.5)	.71
Annular disruption, n (%)	3 (2.4)	2 (3.3)	0 (0.0)	1 (2.5)	.99
Coronary compression, n (%)	1 (0.8)	1 (1.6)	0 (0.0)	0 (0.0)	.99
Permanent pacemaker implantation, n (%)	20 (15.9)	12 (19.7)	1 (4.0)	7 (17.5)	.22
LV outflow tract obstruction, n (%)	8 (6.3)	6 (9.8)	1 (4.0)	1 (2.5)	.50
Paravalvular leak, n/total n (%)					.46
None	73 (61.9)	36 (59.0)	12 (60.0)	25 (67.6)	
Trace	28 (23.7)	18 (29.5)	5 (25.0)	5 (13.5)	
Mild	12 (10.2)	4 (6.6)	2 (10.0)	6 (16.2)	
Moderate	5 (4.2)	3 (4.9)	1 (5.0)	1 (2.7)	
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Major bleeding, n (%)	18 (14.3)	10 (16.4)	4 (16.0)	4 (10.0)	.74
Hemodialysis,* n (%)	10 (7.9)	4 (6.5)	2 (8.0)	4 (10.0)	.67

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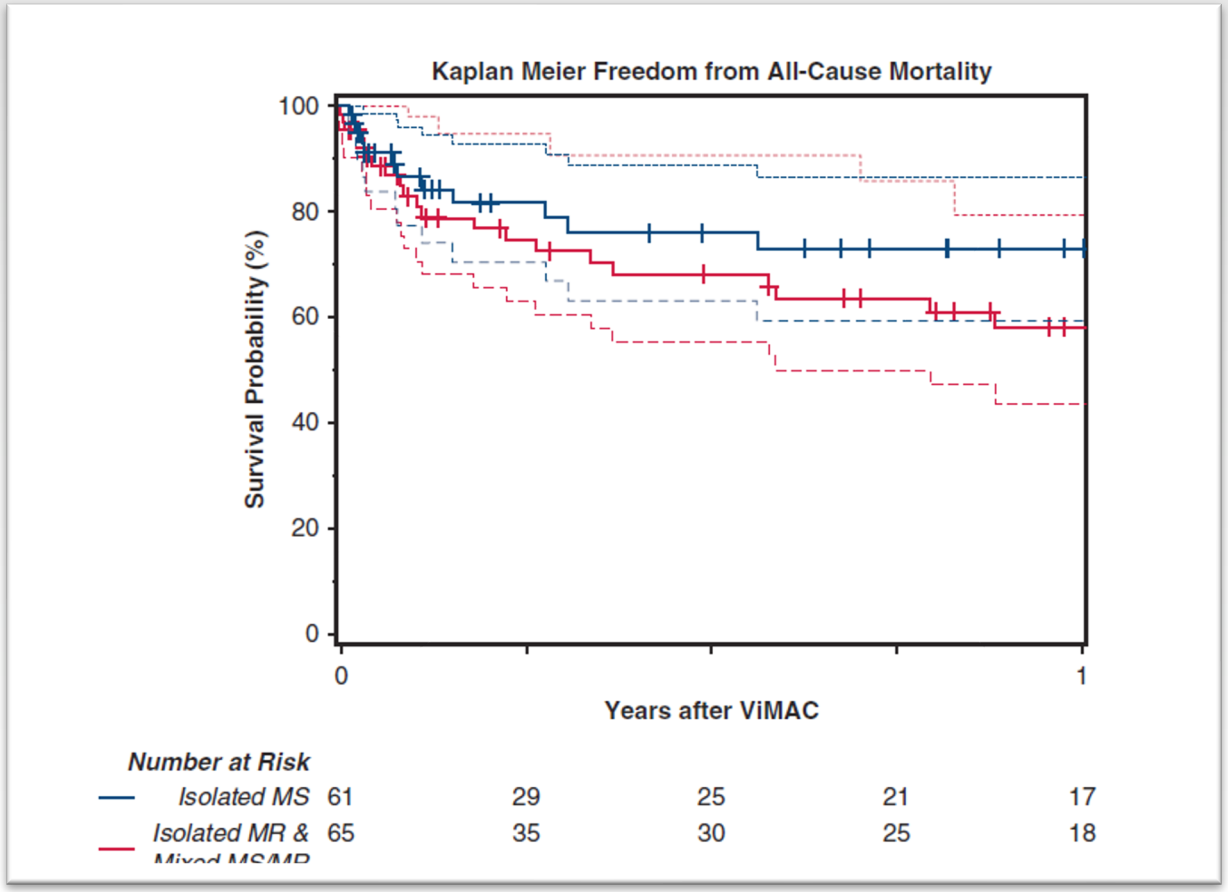
Patients With MR>3+ Do Worse



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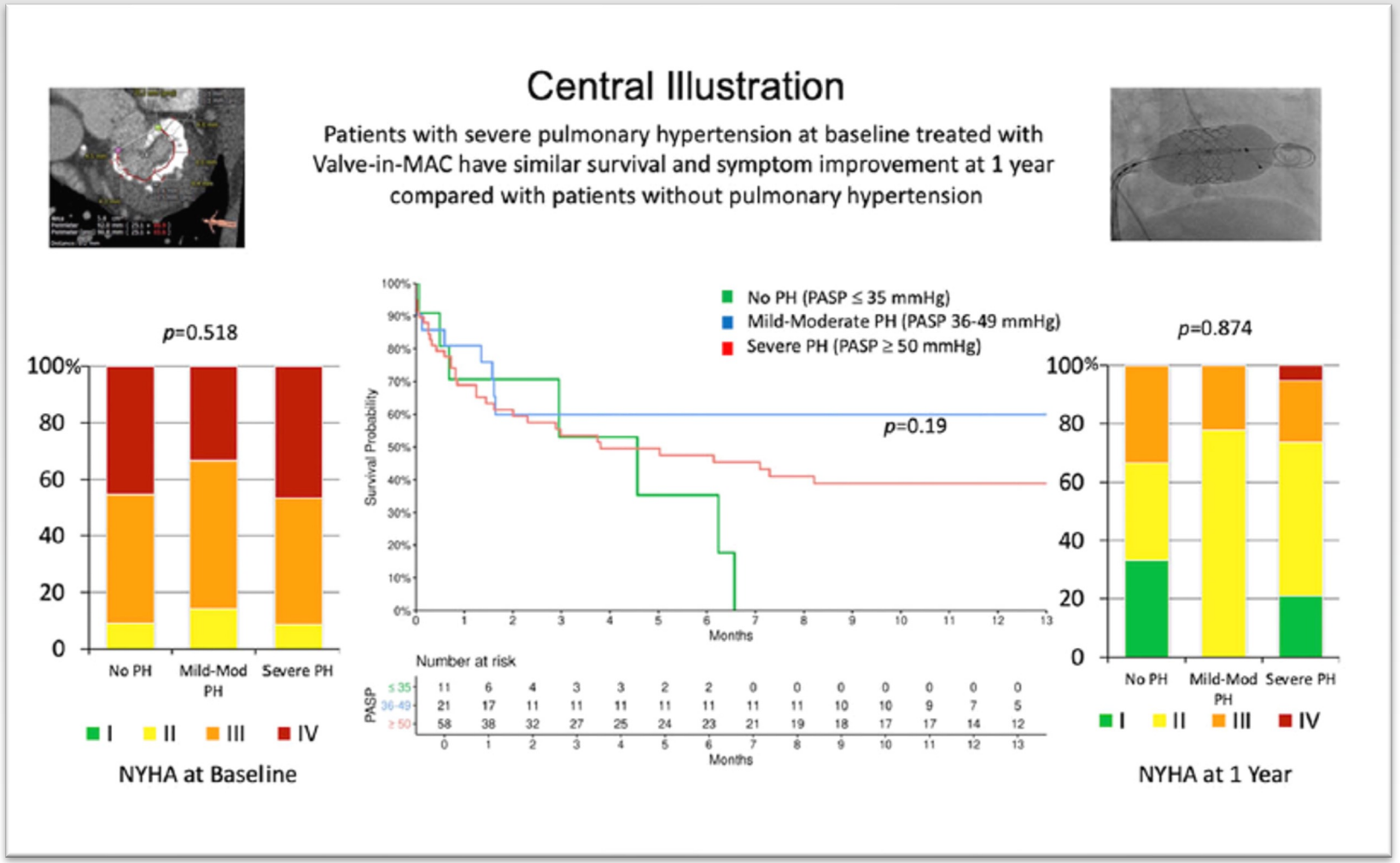
PASP >50mm Hg No Impact on Risk



Cagijas and Guerrero. CCI 2022

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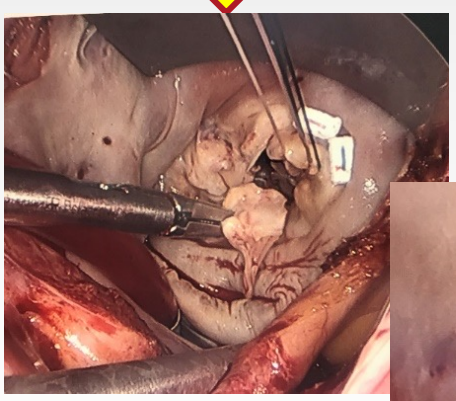
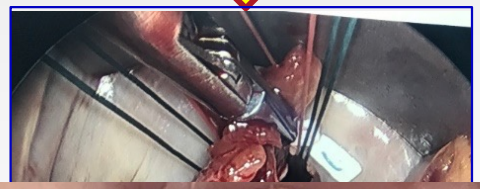
Few Key Steps

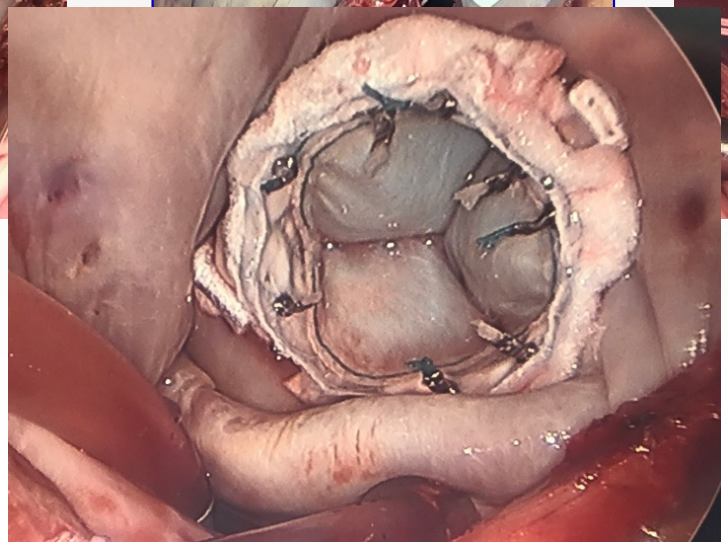
Remove A2

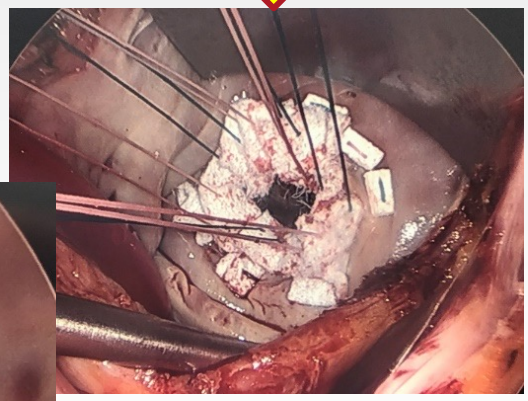
Septal Resection/ Pap Resection

Felt Pillow









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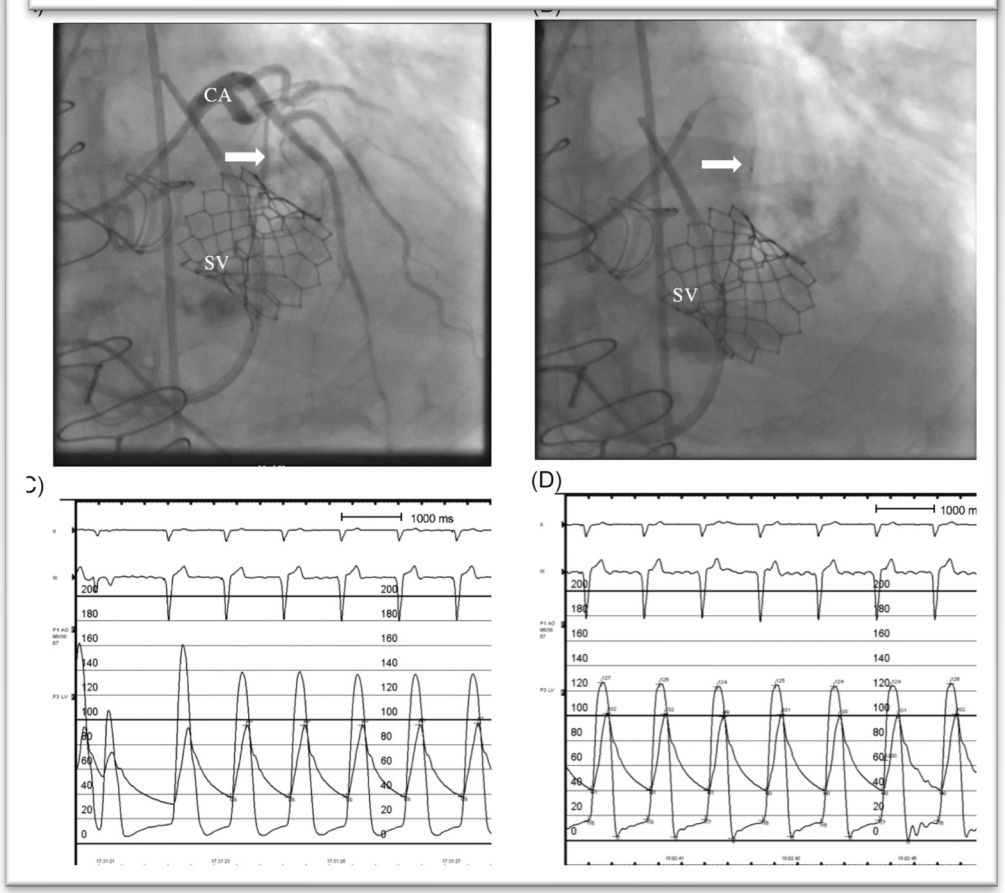
DOI: 10.1111/jocs.14236

CASE REPORT

JOURNAL OF CARDIAC SURGERY WILEY

Septal ablation acutely reduces outflow obstruction after transcatheter mitral valve replacement

Aamir Javaid BS | Zachary Tyerman MD | Jared P. Beller MD | Gorav Ailawadi MD



Pitfalls

1. Avoid patients with severe PH (PASP> 70mmHg)
2. Avoid patients too frail, still overall high mortality at 1 year
3. Too large Annuli can result in PVL
4. Evaluate LVOTO risk carefully, Resection of septum common
5. Avoid SITRAL in patients on Steroids

6. *Don’t advertise this procedure, MAC not for the weary!*

Conclusions

1. Severe MAC is a morbid condition due to diastolic dysfunction, pulmonary hypertension, comorbidities
2. Conventional Surgery has risks of annular rupture
3. Future TMVR devices are preferred, but many patients excluded anatomically
4. Balloon expandable Valve in MAC more inclusive, and MS preferred over pure MR
5. Biggest risks are PVL and LVOTO
6. Operative and 1 year mortality are still high due to diastolic dysfunction and frailty